CARDIAC RHYTHM MANAGEMENT

# Product Performance Report

## 2021 Second Edition

Abbott

# Letter from Abbott

As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, Abbott continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose health and well-being depend on their performance. From product design through patient follow-up, Abbott employees are dedicated to product quality and patient safety.

In keeping with this commitment, we publish the Product Performance Report (PPR) semi-annually to ensure that the healthcare community and the patients it serves are informed about the performance of our cardiac devices, which include implantable cardiac monitors (ICMs), implantable cardioverter defibrillators (ICDs), implantable pacemakers, and implantable pacing and defibrillation leads. Abbott recognizes that such performance data must be transparent and consistent.

In order to meet these goals we continue our commitment to the reporting methods described in the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", which set standards for lead performance reporting and specifically addressed the reporting of active registry performance data. Determined to provide the highest level of transparency, Abbott goes beyond the AdvaMed recommendations by identifying the root cause of each ICM, ICD, and pacemaker malfunction and providing subcategories of lead malfunctions.

Continuing within this edition of the PPR and consistent with previously published editions, Abbott reports on expanded data from actively monitored studies. Post-Approval Studies are standard practice for Abbott, providing a rich source of actively collected and continuously monitored reliability and performance data for cardiac rhythm management products. This PPR features product performance data from several Abbott post-approval studies and encompasses more than 62,000 implants from multiple product families, including leads, ICDs and pacemakers, making it the most comprehensive actively monitored product performance dataset in the industry.

As we continually strive to provide unbiased and reliable information on the performance of our products, Abbott is pleased to release the second edition of the 2021 Product Performance Report containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,

**Robert Blunt**
Divisional Vice President, Quality

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## Serving Our Mission

Abbott is advancing the treatment of heart and vascular disease through breakthrough medical technologies, allowing people to restore their health and get on with their lives. We focus on improving treatment options for coronary artery disease, cardiac rhythm management, atrial fibrillation, heart failure, structural heart and peripheral artery disease. We are here for the people we serve in their pursuit of healthy lives. This has been the way of Abbott for more than a century—passionately and thoughtfully translating science into lasting contributions to health.

Toward this mission, we maintain a rigorous approach to ensuring the quality of our products. The key elements of this effort include:

- Compliance with U.S. and international quality system standards, such as the U.S. FDA Quality Systems Regulation (21 CFR Part 820) and ISO 13485 (an international standard for the Quality Management System for medical devices)
- Thorough evaluation of product design, including extensive design verification and validation, as well as product qualification testing
- Rigorous control of the design and manufacturing processes
- Inspection and qualification of externally supplied components and materials
- Timely analysis of returned products, including extensive malfunction investigation
- Extensive internal auditing
- Post market surveillance
- Continuous improvement programs
- Ensuring the highest ethical standards

We continue to be committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Abbott Representative or Abbott Technical Services at 1-800-722-3774. Thank you for your input and continued support, allowing Abbott to positively impact the lives of thousands of patients every year.

# What's New in This Report

### UPDATE ON FORTIFY™, FORTIFY ASSURA™, QUADRA ASSURA™, QUADRA ASSURA MP™, UNIFY™, UNIFY ASSURA™ AND UNIFY QUADRA™ ICD PREMATURE BATTERY DEPLETION ADVISORY

In order to provide our physician customers and patients the most up-to-date information, Abbott has included an update on the Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ ICD premature battery depletion advisory (October 2016) in the Focus on Clinical Performance section (see pages 299-301). This section includes an overview on the analysis of products returned to Abbott. Additionally, for advisory models with at least 500 active devices in service, Abbott provides a separate product performance data page per model number.

### UPDATE ON RIATA™ LEAD PERFORMANCE

Since 2011, Abbott continues to include an update on Riata lead performance in the Focus on Clinical Performance section (see pages 302-305). This section provides the latest Riata lead externalized conductor rates from passive complaint and returns handling, and describes in considerable detail the rates of other types of Riata insulation abrasion failure mechanisms that Abbott has identified from returns analysis.

### UPDATE ON DURATA™ LEAD PERFORMANCE

Durata lead performance continues to meet expectations by all measures. Our confidence in the Durata lead performance is based on combined data from three prospective, actively monitored registries that include approximately 11,000 Optim™ insulated defibrillation leads. Additionally, this section provides details on the very low rate of abrasion failures that have been identified on Optim insulated defibrillation leads. A statistical analysis of this registry data performed by PHRI, and independent, third-party has been published in December 2021 as a manuscript in the *Heart Rhythm O² Journal* (heartrhythmopen.com).

### UPDATE ON OPTIM™ LEAD INSULATION

The Abbott Optim lead insulation combines the best characteristics of two established lead insulation materials, polyurethane and silicone. This novel insulation technology imparts lubricity, strength, and abrasion resistance while still maintaining flexibility and biostability. This Product Performance Report provides an up-to-date statistical assessment of the long-term durability of Optim lead insulation on Abbott defibrillation leads (see pages 307-308).

# Customer Reported Performance Data

Product performance data derived from customer-initiated complaints and returned products is referred to as Customer Reported Performance Data. While Abbott strongly encourages the submission of any relevant complaints and product returns; this data is not proactively solicited or regularly monitored like data from the Post-Approval studies. Underreporting of events within customer reported performance data is recognized throughout our industry. Abbott is constantly improving the accuracy and utility of the data within this Product Performance Report.

## SUMMARY INFORMATION

The Customer Reported Performance Data page for each model or model group includes a table of model-specific information. Several terms from this table that are relevant to performance data calculations are defined below:

**Registered U.S. Implants -** The total number of U.S. implanted devices for which patient and device information has been provided to Abbott. This total includes devices which have been explanted or are otherwise out of service.

**Estimated Active U.S. Implants -** The total number of U.S. registered implants that have not been identified to Abbott as explanted or otherwise out of service. An adjustment is made to account for the underreporting of patient mortality. Abbott performed an analysis of the data gathered from multiple clinical studies including some Abbott sponsored studies to determine the mortality rate within the pacemaker and ICD patient population and has factored this into the estimation of the number of active U.S. implants.

**Estimated Longevity -** The estimated number of years in which a device is expected to reach its Elective Replacement Indicator (ERI), as stated in the product literature. The estimate is based on battery life approximations and empirical battery performance distributions. It is strongly affected by many factors such as programmed parameters, percentage of time paced, internal impedance, etc. For example, the 9.2 year estimated longevity of an Accent™ DR model PM2110 pacemaker is based on the mean longevity (or 50%) value in the product literature corresponding to pacing at 60 ppm, 2.5V dual-chamber output at 0.4 ms pulse width, 500 ohm lead impedance, 100% DDD pacing, and Stored EGMs On. Actual performance can vary considerably, depending on the actual programmed settings and operations.

**Normal Battery Depletion -** The condition where a returned device met its electrical specification and reached its elective replacement indicator voltage (1) with an implant duration meeting or exceeding the nominal predicted longevity at default shipped settings, or (2) with an implant duration exceeding 75% of its estimated longevity, based on longevity calculations using information from device usage and the actual device settings. The quantity of normal battery depletions reported is determined directly from laboratory analysis and does not represent any adjustment to account for underreporting.

## SURVIVAL CALCULATION GENERAL METHODS

For ICDs, pacemakers, ICMs, and leads, we compile cumulative survival data based on the actuarial (or life-table) method of survival analysis, consistent with ISO 5841-2:2014(E) "Reporting of Clinical Performance of Populations of Pulse Generators and Leads" and the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads". Product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report, and a minimum sample size for each reported time period of 200 devices. "Survival" refers to the proper function of the device, not the survival of the patient, and is intended to illustrate the calculated probability of device survival at a given point in time. A survival probability of 99% at five years, for example, indicates that at five years after implant, the system has a 1% risk of incurring a malfunction and/or normal battery depletion. All domestically implanted devices within each model family are included in the calculations.

With the large size of the U.S. data pool, and the same products are generally used both in the U.S. and internationally, we consider the data in this report to accurately represent each device's performance, regardless of where in the world it was implanted.

The ISO 5841-2:2014(E) "Reporting of Clinical Performance of Populations of Pulse Generators and Leads" was revised in August 2014. The revision clarified survivor definitions and reporting methods, further standardizing product performance reporting across the cardiac rhythm management implantable device and lead manufacturers.

This revision of the ISO standard specifically excludes lead malfunctions confirmed through returned product analysis which were received with no accompanying complaint from the survival probability calculations. However, to provide the highest level of transparency, Abbott continues to include malfunctions not associated with a complaint in the survival probability calculations and in the tabular display of laboratory-confirmed malfunctions.

## ICD, PACEMAKER, AND ICM SURVIVAL ANALYSIS

The data used for the analysis of ICDs, pacemakers, and ICMs includes up-to-date device registration information and the laboratory analysis of all domestically implanted devices returned to Abbott. The analysis measures device performance to specification, and does not reflect medical complications, such as infection, erosion, muscle stimulation or inhibition, or units implanted for fewer than 24 hours.

In accordance with ISO 5841-2:2014(E), the survival calculations for ICDs, pacemakers, and ICMs are adjusted to reduce the bias caused by underreporting of malfunctions and normal battery depletions. Abbott compared the malfunctions and normal battery depletion rates calculated from our actively monitored populations to the rates calculated from our passively monitored populations and have adjusted the survival calculations accordingly.

Survival data are presented in a single table and graph. The survival data is separated into "Including Normal Battery Depletion" and "Excluding Normal Battery Depletion" categories. The "Including Normal Battery Depletion" data reflects the frequency of device removal due to normal battery depletion and malfunction of any type. The "Excluding Normal Battery Depletion" category reflects the frequency of device removal due to malfunctions only.

## ICD, PACEMAKER, AND ICM MALFUNCTION REPORTING

The quantity and rate of malfunctions recorded for each ICD, pacemaker, and ICM model are presented in a tabular format on both the Customer Reported Performance Data and Actively Monitored Study Data pages. The root cause of all laboratory-confirmed malfunctions is classified into one of eight categories: Electrical Component, Electrical Interconnect, Battery, High Voltage Capacitor (ICDs and CRT-Ds only), Software/Firmware, Mechanical, Possible Early Battery Depletion, or Other. Note that in the rare cases where multiple malfunctions are identified in a single device, a single malfunction category will be selected with priority given in the order of the list above. Consistent with previous performance reports, ICD and Pacemaker malfunctions are further classified as with or without compromised therapy.

ISO 5841-2 (E) was revised in August 2014. This version of the standard (ISO 5841-2:2014 (E)) modified the definitions of device malfunctions with compromised therapy and device malfunctions without compromised therapy from the previous version of the standard (ISO 5841-2:2000 (E)). In Product Performance Reports (PPRs) published prior to July 2021, Abbott used the definitions of these terms included in ISO 5841-2:2000 (E). Beginning with the July 2021 PPR, Abbott is using the revised definitions in ISO 5841-2:2014 (E) to classify device malfunctions. Abbott maintains its commitment to provide the highest level of transparency in reporting.

### Malfunction Definitions

**Malfunction** - failure of a device to meet its performance specifications or otherwise perform as intended.

**Malfunction with Compromised Therapy** - device malfunction causing compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service.

**Malfunction without Compromised Therapy** - Pulse generator malfunction that did not compromise pacing or defibrillation therapy while implanted and in service.

Note: Therapy is not compromised as long as the critical patient-protective pacing and defibrillation therapies are available. This includes changes in device settings that occur as intended by the design and do not result in loss of critical patient protective therapies but are the reported reasons for explant. Examples include (but are not limited to): reversion to a designed ”safe mode”, ”backup mode”, ”power-on reset” or other manufacturerspecific terminology, error-affecting diagnostic functions, telemetry function, data storage, malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

### Malfunction Root Cause Category Definitions

**Electrical Component** - Findings linked to electrical components such as integrated circuits, resistors, low voltage capacitors, diodes, etc. Does not include high voltage capacitors or batteries as those are separately listed.

**Electrical Interconnect** - Findings linked to the connections between electrical components such as wires, solder joints, wire bonds, feedthroughs, etc.

**Battery** - Findings linked to the battery and its components.

**High Voltage Capacitor** - Findings linked to the high voltage capacitor and its components.

**Software/Firmware** - Findings linked to software or firmware function.

**Mechanical** - Findings linked to mechanical components such as headers, setscrews, fluid seals, internal supports, the hermetic case, etc.

**Possible Early Battery Depletion** - Findings where the actual reported implant time is less than 75% of the expected longevity calculated using the available device setting information and no root cause was able to be identified. Additionally, in the absence of a specific root cause finding, returned devices with insufficient device setting information to determine conclusively if battery depletion was normal or premature are conservatively classified as Possible Early Battery Depletion malfunctions.

**Other** - Findings linked to other components such as packaging and accessories, and findings where analysis is inconclusive, as well as other complications not included above.

## LEADS SURVIVAL ANALYSIS

Implanted cardiac leads are subjected to constant, complex flexural and torsional forces, interactions with other leads and/or the pulse generator device, plus other forces associated with cardiac contractions, patient physical activity, posture, and anatomy. Therefore, the functional lifetime of cardiac leads is limited and cannot be predicted with a high degree of confidence. Understanding these limitations, survival estimates are provided for all leads included in this report.

The data used for the survival analysis of leads includes up-to-date lead registration information, chronic complications (>30 days) reported by the field, and the laboratory analysis of all domestically implanted leads returned to Abbott. Complaints reported within 30 days of implant (acute observations), are considered to be related to factors other than lead malfunction, such as patient specific characteristics or implant technique, and are therefore excluded from the survival calculations, consistent with industry practice. If there is laboratory data that determines the lead to have exhibited a malfunction, and the lead is known to have been implanted for more than 24 hours, the lead is counted as a non-survivor. If a lead is the subject of a complaint report, and was implanted for more than 30 days (chronic complication), then the lead is counted as a non-survivor. These criteria are also followed for partial lead returns. This method for non-returned complications is used to ensure a conservative failure estimate for lead performance. Chronic complications commonly associated with non-returned leads and partial lead returns include, but are not limited to, reports of sensing, pacing, and capture anomalies, perforation, and dislodgement.

## LEADS OBSERVATION AND COMPLICATION REPORTING

Reporting for recently released lead models provides detail on specific chronic complications (more than 30 days implant), as well as acute observations (post implant to 30 days), that are reported to Abbott as complaints. Each complication and observation is categorized into one of the eleven categories below, irrespective of whether the lead has been returned for analysis. The quantity and rate of each complication and observation type is provided in a tabular format on the Customer Reported Performance Data page. Note that in the rare cases where multiple complaints are identified for a single lead, a single category will be selected with priority given in the order of the list below.

**Cardiac Perforation -** Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance (high thresholds), chest pain, or tamponade.

**Conductor Fracture -** A mechanical break within a lead conductor (includes connectors, coils, cables and/or electrodes) observed visually, electrically, or radiographically.

**Lead Dislodgement -** Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance.

**Failure to Capture -** Intermittent or complete failure to achieve cardiac stimulation (atrial or ventricular) at programmed output delivered outside of the cardiac refractory period. A sudden and significant increase in the pacing threshold value (elevated thresholds compared to previous measured value) at which 2:1 safety margin can no longer be achieved.

**Oversensing -** Misinterpretation of cardiac or non-cardiac events as cardiac depolarization, e.g. T-waves, skeletal muscle potentials, and extracardiac electromagnetic interference (EMI).

**Failure to Sense (undersensing) -** Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals (atrial or ventricular) during non-refractory periods at programmed sensitivity settings.

**Insulation Breach -** A disruption or break in lead insulation observed visually, electrically, or radiographically.

**Abnormal Pacing Impedance -** Pacing impedance is typically considered abnormal if a measurement is < 200 Ω or > 2000 Ω (based on lead model and measurement range of the device).

**Abnormal Defibrillation Impedance -** Defibrillation impedance is typically considered abnormal if a measurement is < 20 Ω or > 200 Ω (based on lead model and measurement range of the device).

**Extracardiac Stimulation -** Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle.

**Other -** Specific proprietary lead mechanical attributes such as lead incorporated sensors, connectors or seal rings which affect a lead's ability to perform as designed or remain in service, as well as other complications not included above.

## LEADS MALFUNCTION REPORTING

As a supplement to the survival estimates, the categorization of lead malfunctions emphasizes the root cause of malfunction rather than a functional longevity prediction. In accordance with AdvaMed guidelines, laboratory analysis results of returned leads are categorized into one of the following five categories of malfunctions. The quantity and rate of each malfunction type is provided in a tabular format on the Customer Reported Performance Data and the Actively Monitored Study Data pages. Note that in the rare cases where multiple malfunctions are identified in a single lead, a single malfunction category will be selected with priority given in the order of the list below. The definition for each malfunction type is provided below:

**Conductor Fracture -** Conductor break with complete or intermittent loss of continuity that could interrupt current flow. This type of malfunction includes any conductor fracture such as those associated with flex-fatigue or clavicular crush damage.

In an effort to further increase customer understanding of Abbott defibrillation and left-heart lead performance, subcategories of conductor fracture are also provided. The definitions of these subcategories are provided below:

**Clavicular Crush -** Conductor fracture due to strong compression and bending at the approximation of the first rib and clavicle.

**In the Pocket -** Conductor fracture not within the vascular or cardiac systems, typically within the subcutaneous pocket or associated with the suture sleeve, excluding the mechanism of clavicular crush.

**Intravascular -** Conductor fracture within the vascular or cardiac systems.

**Insulation Breach -** Any lead insulation breach, such as: 1) proximal abrasion associated with lead-to-lead or lead-to-can contact in the pocket, 2) mid-lead insulation damage caused by clavicular crush or insulation wear in the region of vein insertion, 3) distal abrasion due to lead-to-lead interactions or contact with anatomic structures, and 4) externalized conductors in the distal region.

Subcategories of insulation breach for defibrillation and left-heart leads are also provided. The definitions of these subcategories are provided below:

**Lead-to-Can Contact -** Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) combined with repetitive skeletal movement caused abrasion that resulted in a full thickness outer insulation breach.

**Lead-to-Lead Contact -** Repetitive contact between two leads caused abrasion that resulted in a full thickness outer insulation breach.

**Clavicular Crush -** Damage due to strong compression between the first rib and clavicle resulted in a full thickness outer insulation breach.

**Externalized Conductors -** Abrasion resulted in an outer insulation breach within the vascular or cardiac systems allowing the normally contained conductors to become visible outside the lead body. Externalized conductors were described in our December 2010 and November 2011 communications regarding insulation abrasion failures on silicone Riata™ and Riata™ ST lead families (summary on pages 327-328) and in our April 2012 communication regarding insulation abrasion failures on QuickSite™ and QuickFlex™ lead families. Additional information regarding externalized conductors on Riata™ and Riata™ ST leads can be found at https://www.cardiovascular.abbott/us/en/hcp/product-advisories/riata.html.

**Other (Insulation Breach) -** Insulation breaches that resulted from a failure mode not represented by the other four categories. This includes a variety of failure modes, such as damage at the suture sleeve and contact with patient anatomy. Also includes insulation breaches for which analysis was unable to isolate a specific cause.

**Crimps, Welds and Bonds -** Any interruption in the conductor or lead body associated with a point of connection.

**Other -** Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, and seal rings, as well as other analysis results not included in the alternate categories.

**Extrinsic Factors -** The lead was implanted greater than 30 days, removed from service with an associated complaint and returned for analysis, however analysis was inconclusive because (1) only portions of the lead were available, or (2) the returned lead was damaged by the explantation process, or (3) lab analysis could not determine an out of specification condition (typically with complaints such as dislodgements, perforations, or failure to capture).

# Actively Monitored Study Data

## SUMMARY INFORMATION

Since 2007 the Product Performance Report has included data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). This comprehensive study provided monitored performance data on pacemakers, ICDs, and leads. With product-specific, post-market registries being standard practice, Abbott continues to complement the SCORE registry with data from the SJ4 Post-Approval Study, the QuickFlex™ µ Lead Post-Approval Study, the Quadripolar CRT-D Post-Approval Study, and the OPTIMUM registry. These actively monitored study data now represent >62,000 implanted devices, and continues to be a very powerful source of product performance information which complements the data collected from Customer Reported Performance Data. Actively monitored study data is not susceptible to underreporting and provides the most accurate understanding of product performance. The many sites participating in these actively monitored studies are individually providing data on the performance of Abbott cardiac rhythm management products using common definitions and criteria. In addition, each of these sites is regularly audited by Abbott personnel to ensure comprehensive reporting.

| | STUDY DESCRIPTION | STUDY INITIATED | # SITES | # PATIENTS | PRODUCT TYPES/FAMILIES |
|---|---|---|---|---|---|
| SCORE (ST. JUDE MEDICAL PRODUCT LONGEVITY AND PERFORMANCE REGISTRY) | Prospective, actively monitored, multicenter registry to evaluate the long-term performance of Abbott market-released cardiac rhythm management products. | September 2007 | 80 | 11,247 | Pacemakers, ICDs, CRT-Ds, Leads (all types) |
| SJ4 POST-APPROVAL STUDY | Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the Abbott SJ4/DF4 connector and SJ4/DF4 defibrillation leads. | June 2009 | 58 | 1,701 | ICDs, CRT-Ds, Leads (all types) |
| QUICKFLEX™ µ POST-APPROVAL STUDY | Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the Abbott QuickFlex™ µ 1258T left ventricular leads. | September 2010 | 76 | 1,930 | CRT-Ds, Leads (all types) |
| QUADRIPOLAR CRT-D POST-APPROVAL STUDY | Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the Abbott Quadripolar CRT-D system. | February 2012 | 71 | 1,970 | Unify Quadra™ and Quadra Assura™ CRT-Ds, Leads (all types) |
| OPTIMUM REGISTRY | Prospective, actively monitored, multicenter registry to evaluate the long-term performance of market-released Abbott leads with Optim™ insulation material. | August 2006 | 241 | 14,120 | Leads (any model with Optim™ Insulation) |

The models included in the actively monitored data set are listed below:

## ICDS

Current™ + DR (Model CD2211-36)
Current™ + DR (Model CD2211-36Q)
Current™ + VR (Model CD1211-36Q)
Current™ DR RF (Model 2207-36)
Current™ VR RF (Model 1207-36)
Fortify™ DR (Model CD2231-40)
Fortify™ DR (Model CD2231-40Q)
Fortify™ VR (Model CD1231-40Q)
Promote™ + CRT-D (Model CD3211-36)
Promote™ + CRT-D (Model CD3211-36Q)
Promote™ RF CRT-D (Model 3207-36)
Quadra Assura™ CRT-D (Model CD3265-40)
Quadra Assura™ CRT-D (Model CD3265-40Q)
Quadra Assura™ CRT-D (Model CD3365-40Q)
Quadra Assura MP™ CRT-D (Model CD3369-40Q)
Unify Assura™ CRT-D (Model CD3357-40C)
Unify Assura™ CRT-D (Model CD3357-40Q)
Unify Quadra™ CRT-D (Model CD3249-40)
Unify Quadra™ CRT-D (Model CD3249-40Q)
Unify™ CRT-D (Model CD3231-40)
Unify™ CRT-D (Model CD3231-40Q)

## DEFIBRILLATION LEADS

Durata™ (Model 7122)
Durata™ (Models 7120/7121)
Durata™ DF4 (Model 7122Q)
Durata™ DF4 (Models 7120Q/7121Q)
Durata™ DF4 (Models 7170Q/7171Q)
Riata™ (Models 1580/1581)
Riata™ ST (Models 7000/7001)
Riata™ ST Optim™ (Models 7020/7021)
Riata™ ST Optim™ (Models 7070/7071)

## CRT LEADS

Quartet™ (Model 1458Q)
QuickFlex™ (Model 1156T)
QuickFlex™ XL (Model 1158T)
QuickFlex™ µ (Model 1258T)
QuickSite™ (Model 1056T)
QuickSite™ XL (Model 1058T)

## PACEMAKERS

Accent™ DR (Model PM2110)
Accent™ DR RF (Model PM2210)
Accent™ SR RF (Model PM1210)
Anthem™ RF CRT-P (Model PM3210)
Identity ADx™ XL DR (Model 5386)
Victory™ XL DR (Model 5816)
Zephyr™ DR (Model 5820)
Zephyr™ XL DR (Model 5826)
Zephyr™ XL SR (Model 5626)

## PACING LEADS

IsoFlex™ Optim™ (Model 1944)
IsoFlex™ Optim™ (Model 1948)
IsoFlex™ S (Model 1646)
OptiSense™ (Model 1699)
OptiSense™ (Model 1999)
Tendril™ (Model 1782)
Tendril™ (Model 1788)
Tendril™ SDX (Model 1688)
Tendril™ ST Optim™ (Model 1882)
Tendril™ ST Optim™ (Model 1888)
Tendril™ STS (Model 2088)

## QUALIFYING COMPLICATIONS

When abnormal performance is suspected of an actively monitored study device, the related clinical event and any resulting clinical action is reported to Abbott. A Qualifying Complication is defined to have occurred if the report identifies one of the following Clinical Events that resulted in one of the following Clinical Actions. Any Clinical Event without a related Clinical Action is not considered a Qualifying Complication.

### QUALIFYING CLINICAL EVENTS

Abnormal Defibrillation Impedance
Abnormal Pacing Impedance
Cardiac Perforation
Conductor Fracture
Extracardiac Stimulation
Failure to Capture
Failure to Sense
Inappropriate Shock
Insulation Breach
Lead Dislodgement
Loss of Telemetry
Oversensing
Pericardial Effusion
Premature Battery Depletion
Skin Erosion

### QUALIFYING CLINICAL ACTION

Generator Pacing Mode Changed
Lead Electrically Abandoned/Capped
Lead/Generator Explanted
Lead/Generator Replaced
Lead Polarity Changed
Lead Surgically Abandoned/Capped
Lead Surgically Repositioned

## SURVIVAL CALCULATION METHODS

Survival calculations for actively monitored studies are made in a manner consistent with the ISO 5841-2:2014(E) method used for Customer Reported Performance Data. A minimum of 100 devices are required to have been enrolled, with the latest interval to be reported having a minimum of 50 devices which have been followed for at least six months. Any device with a Qualifying Complication is defined as a non-survivor. Consistent with industry practice, Qualifying Complications for leads are included in the survival calculations for events with an implant duration greater than 30 days. For pacemakers and ICDs, Qualifying Complications are included in the survival calculations for events with an implant duration more than 24 hours. Medical complications unrelated to device performance are not considered as Qualified Complications. Devices included in the actively monitored studies are excluded from the Customer Reported Performance Data. Certain devices and leads, including any which transferred from Customer Reported Performance Data into Actively Monitored Study Data are subsequently excluded from the Customer Reported Performance Data and subject to these Survival Calculation methods. Actively monitored study performance data includes both advisory and non-advisory devices.

## MALFUNCTION REPORTING

The Actively Monitored Study Data page contains a table of all device malfunctions. The type, quantity, and rate of all laboratory-confirmed malfunctions are listed using the same categories reported in Customer Reported Performance Data. The malfunction data is not utilized in the actively monitored study survival calculations, but does provide important supplementary information about product performance and reliability.

## Medical Advisory Board Review

Abbott has an established and independent Medical Advisory Board (MAB) focused on cardiac rhythm management systems, including pulse generators and leads. One of the important tasks assigned to the MAB is the review of the performance data contained in this report prior to its release and publication on a semi-annual basis. MAB members and their location of practice include:

Dr. Anne Curtis, Buffalo, New York
Dr. Roger Freedman, Salt Lake City, Utah
Dr. Christoph Geller, Bad Berka, Germany
Dr. Thomas Mattioni, Paradise Valley, Arizona
Dr. Raymond Schaerf, Burbank, California
Dr. Bruce Wilkoff, Cleveland, Ohio

## Returning Devices to Abbott

To maintain the continued accuracy of our performance reporting, Abbott strongly encourages physicians to notify our Patient Records department (800-550-1648) each time a device is removed from service for any reason. Additionally, all explanted products are requested to be returned to Abbott for laboratory evaluation whether or not a malfunction is suspected. To facilitate the return of explanted devices, Abbott offers a no-cost Returned Products Kit comprised of a postage paid explant box with a shipping address label, a removed device information form, a biohazard bag, and biohazard labels to seal the explant box. This kit, #N0004, can be ordered free of charge by contacting Abbott Customer Service (800-681-9293).

## Contact Us

The Abbott team is always ready to respond to questions, comments or suggestions as well as receive product performance feedback. You can reach us by phone at 651-756-2000, on the web at www.abbott.com, or by contacting your local Abbott representative.

# Cardiac Resynchronization Therapy (CRT) ICDs

# Cardiac Resynchronization Therapy (CRT) ICDs

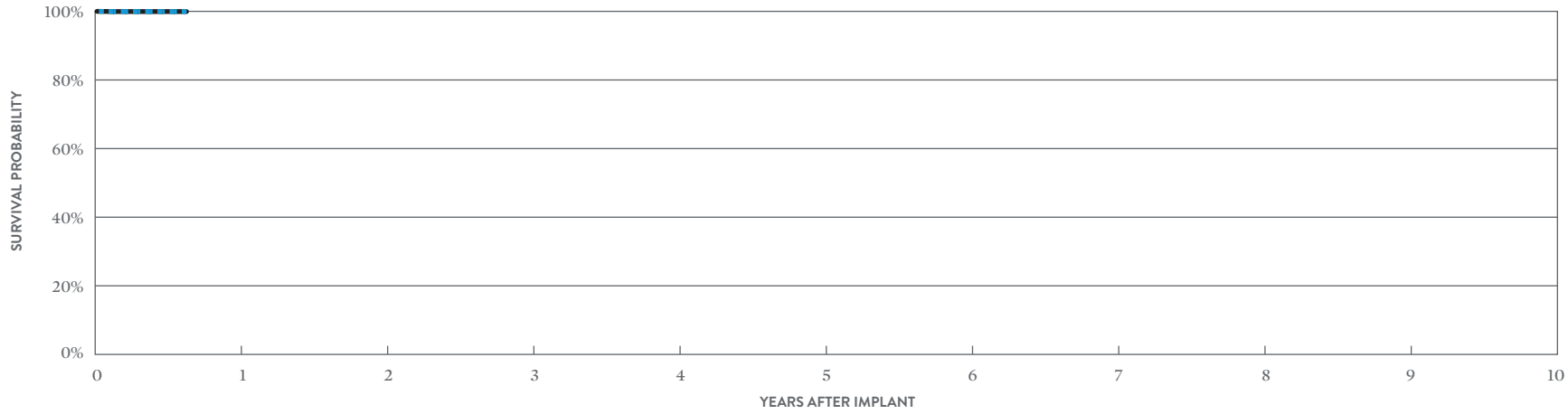
**CUSTOMER REPORTED PERFORMANCE DATA**

## Gallant™ HF CRT-D

### MODEL CDHFA500Q*

| | |
|---|---|
| US Regulatory Approval | July 2020 |
| Registered US Implants | 4,352 |
| Estimated Active US Implants | 4,169 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 0 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.02% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **1** | **0.02%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | AT 8 MONTHS |
|---|---|
| SURVIVAL PROBABILITY | 99.94% |
| ± 1 STANDARD ERROR | 0.05% |
| SAMPLE SIZE | 360 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | AT 8 MONTHS |
|---|---|
| SURVIVAL PROBABILITY | 99.94% |
| ± 1 STANDARD ERROR | 0.05% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

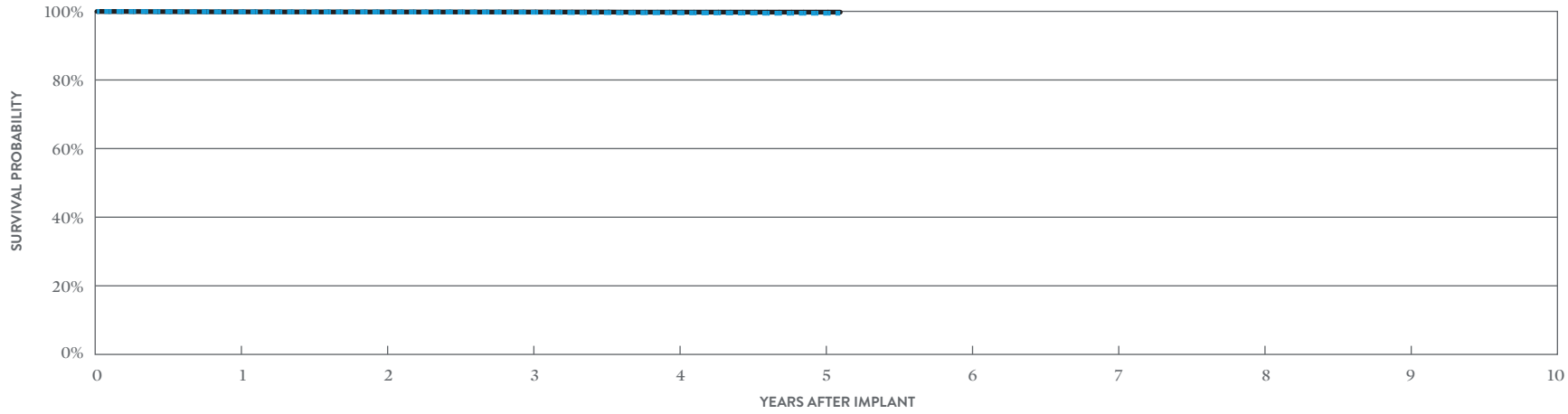
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura MP™ CRT-D

### MODEL CD3369-40Q*

| | |
|---|---|
| US Regulatory Approval | February 2016 |
| Registered US Implants | 68,769 |
| Estimated Active US Implants | 52,021 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 22 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 7 | 0.01% | 9 | 0.01% |
| Electrical Interconnect | 8 | 0.01% | 1 | <0.01% |
| Battery | 0 | 0.00% | 1 | <0.01% |
| High Voltage Capacitor | 0 | 0.00% | 2 | <0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 1 | <0.01% | 5 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 2 | <0.01% |
| Other | 4 | <0.01% | 6 | <0.01% |
| **Total** | **20** | **0.03%** | **26** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 62 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.82% | 99.75% | 99.61% | 99.47% | 99.47% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.02% | 0.04% | 0.06% | 0.06% |
| SAMPLE SIZE | 60,000 | 43,580 | 29,450 | 17,460 | 6,530 | 520 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 62 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.86% | 99.83% | 99.81% | 99.77% | 99.77% | 99.77% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

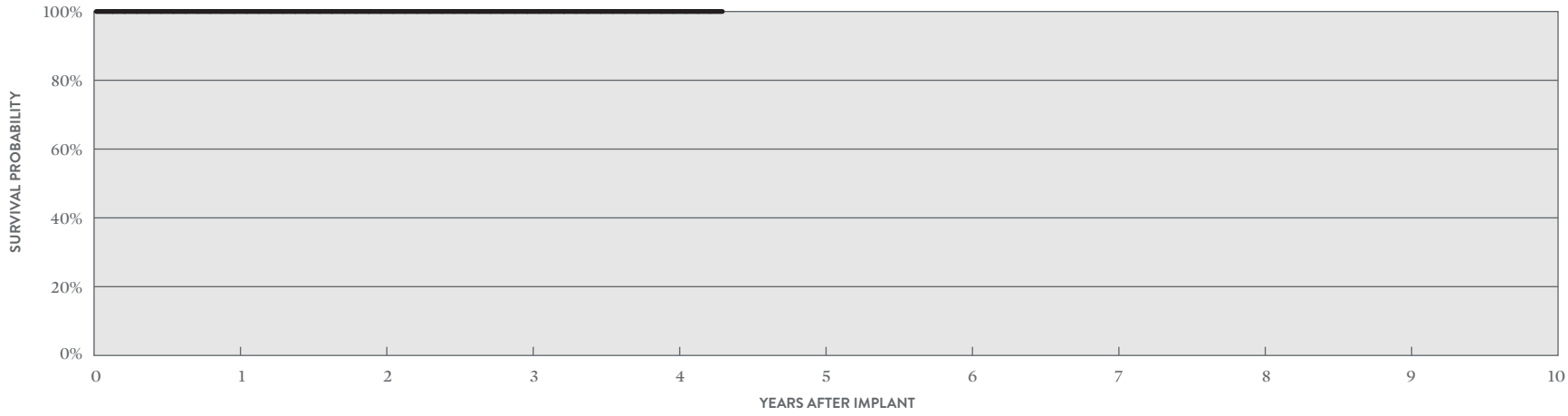
## Quadra Assura MP™ CRT-D

### MODEL CD3369-40Q*

| | |
|---|---|
| US Regulatory Approval | February 2016 |
| Number of Devices Enrolled in Study | 117 |
| Active Devices Enrolled in Study | 88 |
| Cumulative Months of Follow-up | 4,541 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS |
|---|
| None Reported |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | 4 | AT 52 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 110 | 90 | 80 | 70 | 50 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

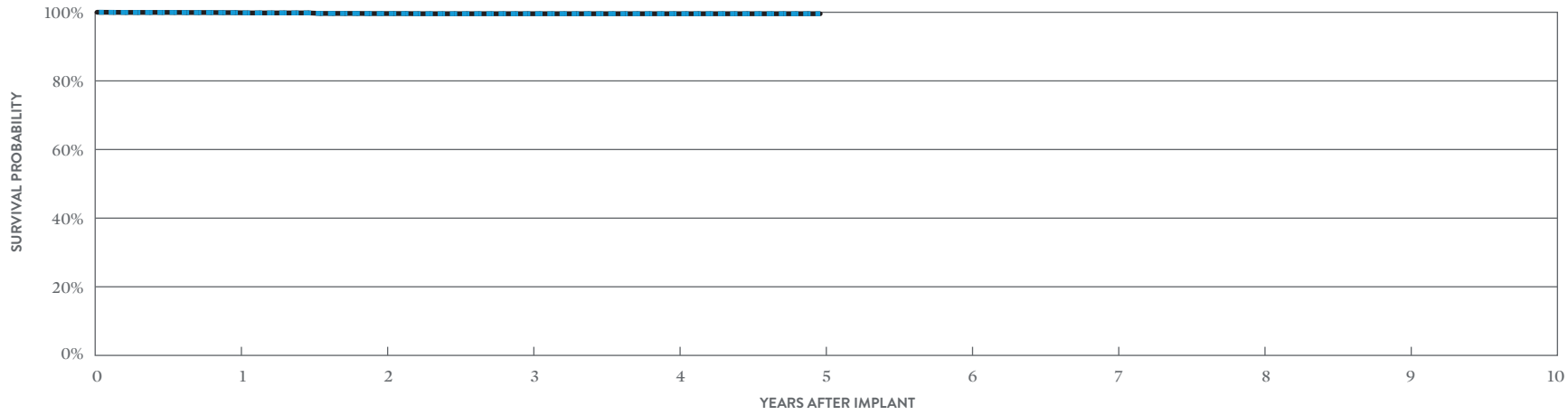
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura MP™ CRT-D

### MODEL CD3369-40C*

| | |
|---|---|
| US Regulatory Approval | February 2016 |
| Registered US Implants | 8,461 |
| Estimated Active US Implants | 6,243 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 1 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.02% | 0 | 0.00% |
| Electrical Interconnect | 2 | 0.02% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 1 | 0.01% | 1 | 0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.01% |
| Other | 0 | 0.00% | 3 | 0.04% |
| **Total** | **5** | **0.06%** | **6** | **0.07%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.86% | 99.59% | 99.48% | 99.48% | 99.25% |
| ± 1 STANDARD ERROR | 0.04% | 0.08% | 0.09% | 0.10% | 0.19% |
| SAMPLE SIZE | 7,340 | 5,410 | 3,890 | 2,490 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.62% | 99.57% | 99.57% | 99.57% |
| ± 1 STANDARD ERROR | 0.04% | 0.08% | 0.09% | 0.09% | 0.09% |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

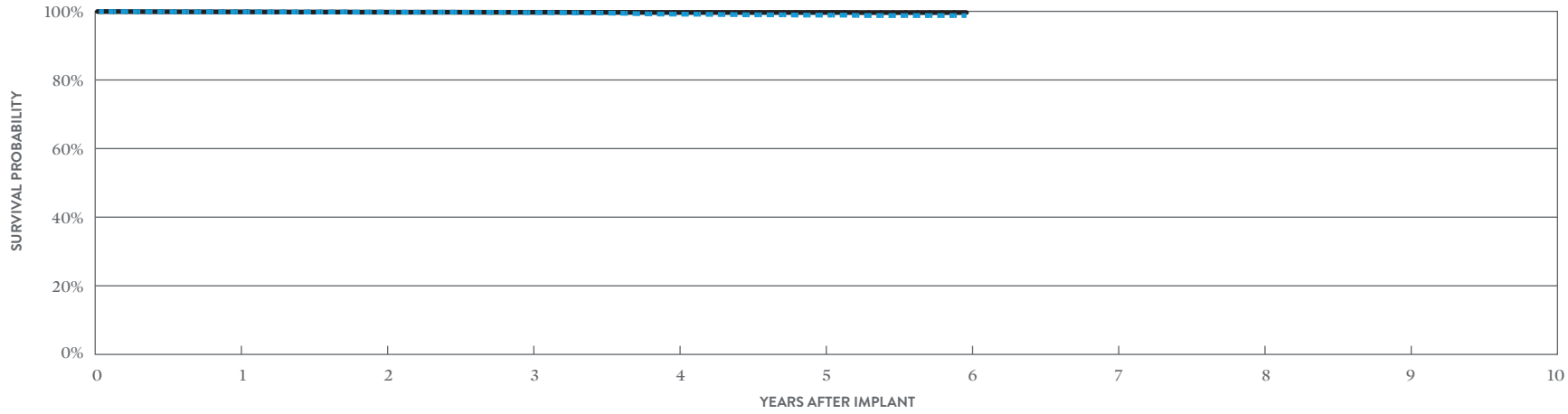
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3365-40Q* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 16,495 |
| Estimated Active US Implants | 10,453 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 34 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.02% | 4 | 0.02% |
| Electrical Interconnect | 6 | 0.04% | 0 | 0.00% |
| Battery | 2 | 0.01% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 2 | 0.01% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 8 | 0.05% |
| Possible Early Battery Depletion | 2 | 0.01% | 6 | 0.04% |
| Other | 2 | 0.01% | 6 | 0.04% |
| **Total** | **18** | **0.11%** | **24** | **0.15%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.77% | 99.65% | 99.19% | 98.90% | 98.78% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.08% | 0.10% | 0.11% |
| SAMPLE SIZE | 15,400 | 13,570 | 12,180 | 10,780 | 8,620 | 270 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.77% | 99.72% | 99.68% | 99.68% | 99.65% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.04% | 0.05% | 0.05% | 0.05% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

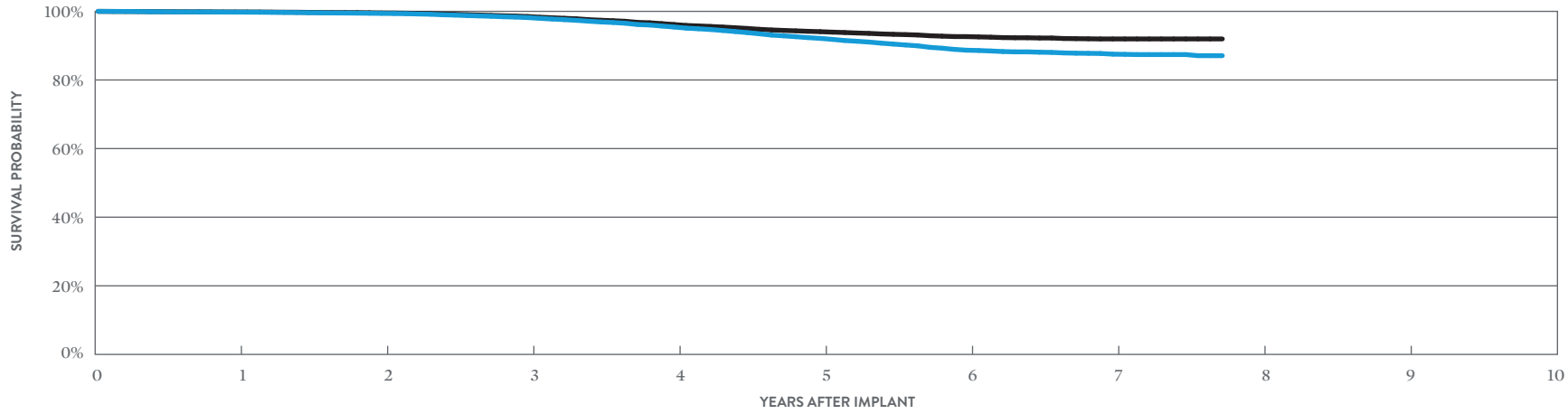
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3365-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 24,081 |
| Estimated Active US Implants | 10,647 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 254 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.02% | 14 | 0.06% |
| Electrical Interconnect | 10 | 0.04% | 0 | 0.00% |
| Battery | 3 | 0.01% | 17 | 0.07% |
| High Voltage Capacitor | 1 | <0.01% | 0 | 0.00% |
| Software/Firmware | 1 | <0.01% | 3 | 0.01% |
| Mechanical | 0 | 0.00% | 2 | <0.01% |
| Possible Early Battery Depletion | 42 | 0.17% | 377 | 1.57% |
| Other | 6 | 0.02% | 7 | 0.03% |
| **Total** | **69** | **0.29%** | **420** | **1.74%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 93 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.78% | 99.40% | 98.18% | 95.43% | 92.12% | 88.68% | 87.52% | 87.08% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.09% | 0.15% | 0.21% | 0.25% | 0.28% | 0.36% |
| SAMPLE SIZE | 22,650 | 19,990 | 17,610 | 15,710 | 14,230 | 12,170 | 7,070 | 270 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 93 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.54% | 98.50% | 96.16% | 94.08% | 92.64% | 91.96% | 91.96% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.09% | 0.14% | 0.18% | 0.21% | 0.23% | 0.23% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

**ACTIVELY MONITORED STUDY DATA**

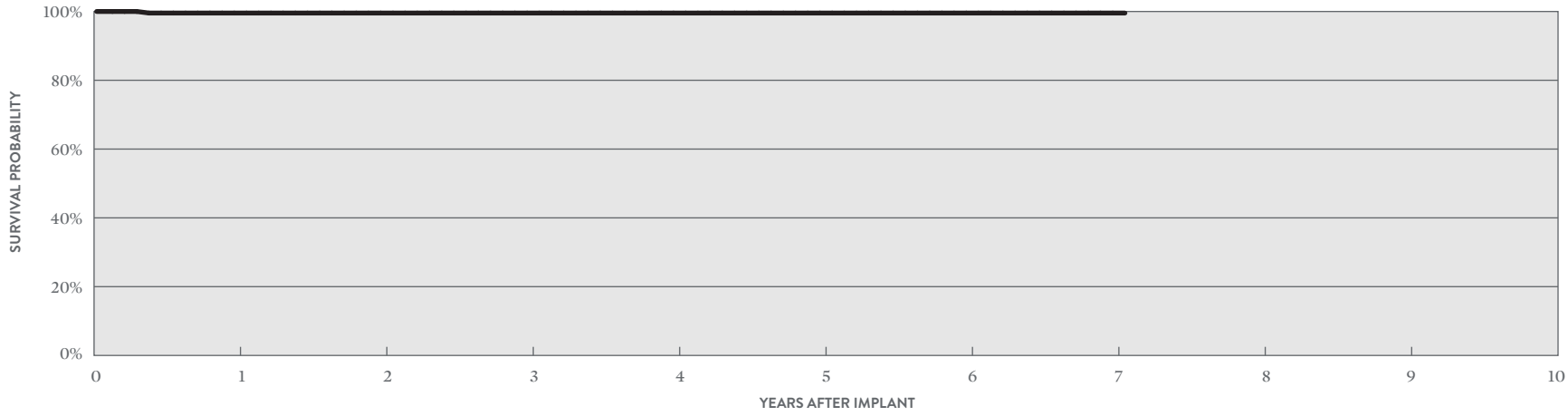
## Quadra Assura™ CRT-D

### MODEL CD3365-40Q*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Number of Devices Enrolled in Study | 235 |
| Active Devices Enrolled in Study | 109 |
| Cumulative Months of Follow-up | 11,290 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Skin Erosion | 1 | 0.43% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 2 | 0.85% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **2** | **0.85%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.55% | 99.55% | 99.55% | 99.55% | 99.55% | 99.55% | 99.55% | 99.55% |
| ± 1 STANDARD ERROR | 0.44% | 0.44% | 0.44% | 0.44% | 0.44% | 0.44% | 0.44% | 0.44% |
| SAMPLE SIZE | 220 | 190 | 160 | 130 | 100 | 70 | 60 | 50 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

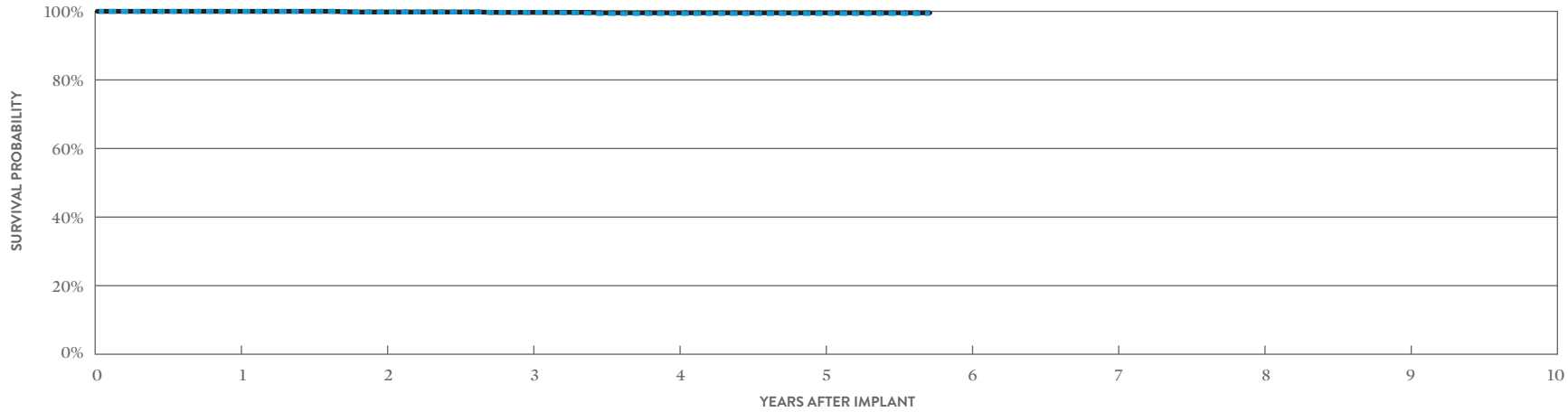
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3365-40C* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 2,648 |
| Estimated Active US Implants | 1,668 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 2 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.04% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 2 | 0.08% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.04% | 0 | 0.00% |
| **Total** | **3** | **0.11%** | **1** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 69 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.81% | 99.70% | 99.35% | 99.35% | 99.35% |
| ± 1 STANDARD ERROR | 0.00% | 0.10% | 0.12% | 0.19% | 0.19% | 0.19% |
| SAMPLE SIZE | 2,460 | 2,150 | 1,910 | 1,640 | 1,160 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 69 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.81% | 99.70% | 99.58% | 99.58% | 99.58% |
| ± 1 STANDARD ERROR | 0.00% | 0.10% | 0.12% | 0.15% | 0.15% | 0.15% |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

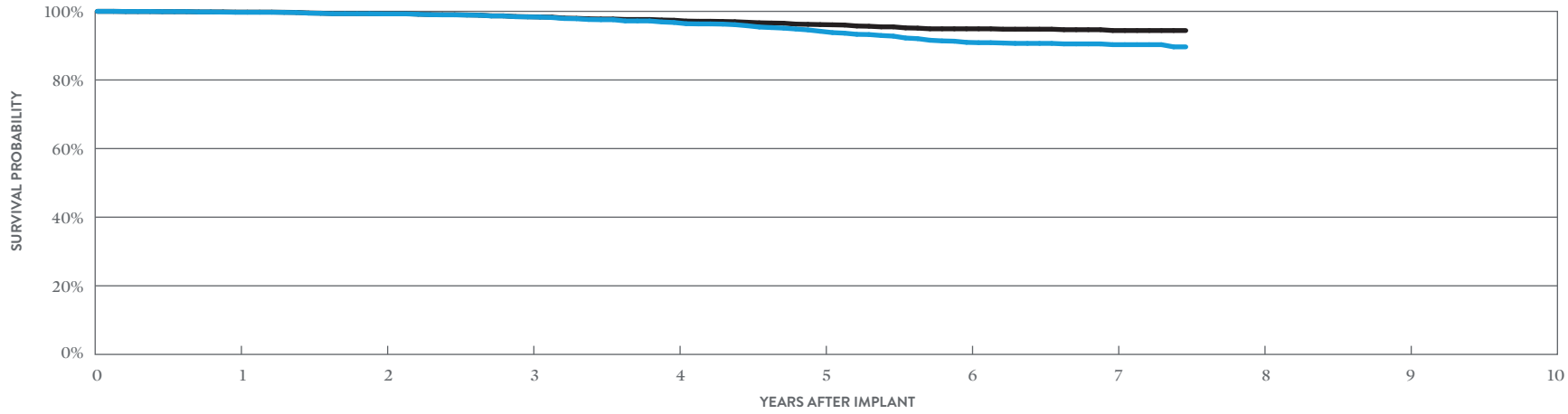
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3365-40C* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 5,626 |
| Estimated Active US Implants | 2,392 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 50 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.11% | 2 | 0.04% |
| Electrical Interconnect | 2 | 0.04% | 0 | 0.00% |
| Battery | 1 | 0.02% | 1 | 0.02% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.02% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 8 | 0.14% | 51 | 0.91% |
| Other | 3 | 0.05% | 2 | 0.04% |
| **Total** | **20** | **0.36%** | **57** | **1.01%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 90 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.74% | 99.27% | 98.39% | 96.76% | 94.20% | 90.96% | 90.29% | 89.65% |
| ± 1 STANDARD ERROR | 0.06% | 0.12% | 0.19% | 0.28% | 0.38% | 0.50% | 0.53% | 0.71% |
| SAMPLE SIZE | 5,220 | 4,480 | 3,860 | 3,390 | 3,050 | 2,480 | 1,410 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 90 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.78% | 99.31% | 98.43% | 97.41% | 96.14% | 94.91% | 94.41% | 94.41% |
| ± 1 STANDARD ERROR | 0.06% | 0.12% | 0.19% | 0.25% | 0.32% | 0.38% | 0.40% | 0.44% |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

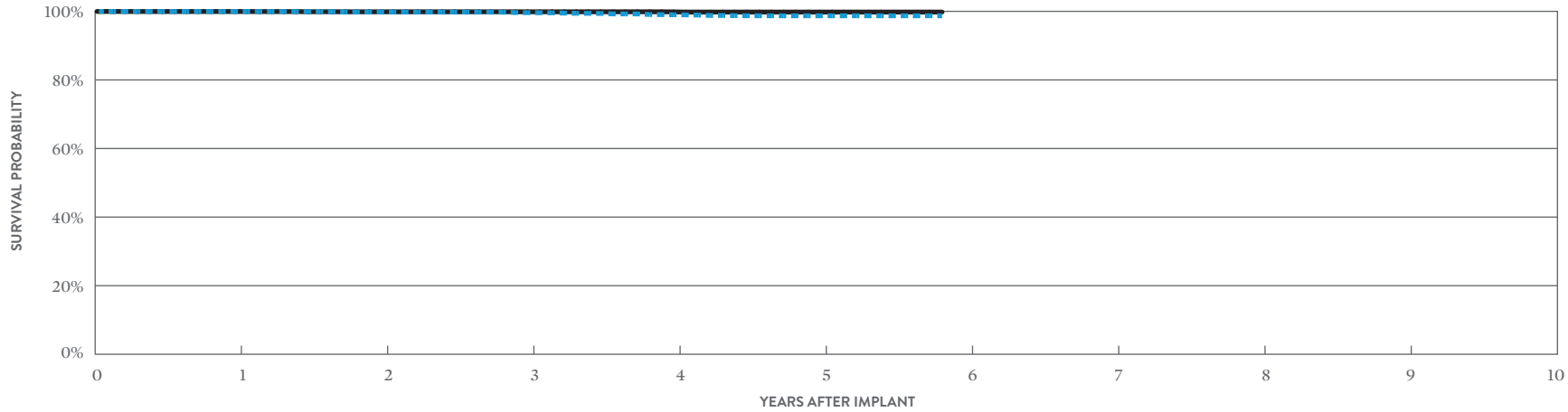
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3357-40Q* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 17,225 |
| Estimated Active US Implants | 12,098 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 30 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 5 | 0.03% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 1 | <0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | <0.01% | 2 | 0.01% |
| **Total** | **2** | **0.01%** | **8** | **0.05%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 70 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.82% | 99.61% | 99.00% | 98.70% | 98.70% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.06% | 0.11% | 0.14% | 0.14% |
| SAMPLE SIZE | 15,510 | 12,310 | 9,270 | 6,350 | 3,310 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 70 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.87% | 99.87% | 99.84% | 99.79% | 99.79% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.05% | 0.05% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

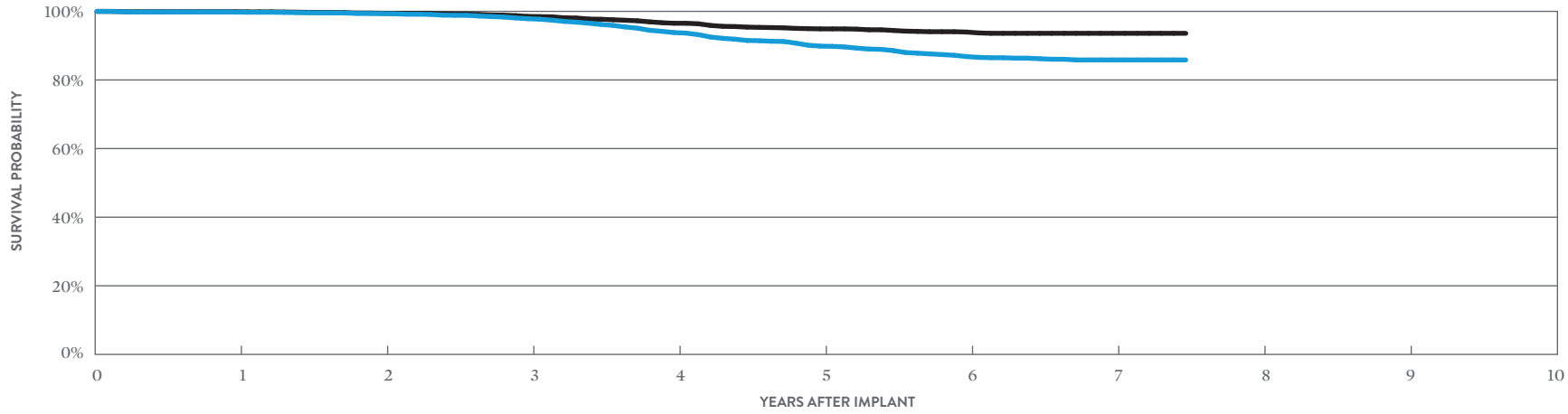
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3357-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 5,340 |
| Estimated Active US Implants | 2,178 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 94 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | 0.02% | 2 | 0.04% |
| Electrical Interconnect | 2 | 0.04% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 2 | 0.04% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 10 | 0.19% | 66 | 1.24% |
| Other | 0 | 0.00% | 3 | 0.06% |
| **Total** | **15** | **0.28%** | **71** | **1.33%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 90 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.78% | 99.34% | 97.85% | 93.81% | 89.86% | 86.82% | 85.84% | 85.84% |
| ± 1 STANDARD ERROR | 0.06% | 0.12% | 0.22% | 0.39% | 0.51% | 0.59% | 0.65% | 0.65% |
| SAMPLE SIZE | 4,980 | 4,310 | 3,730 | 3,270 | 2,880 | 2,280 | 1,220 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 90 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.46% | 98.53% | 96.53% | 94.89% | 93.97% | 93.60% | 93.60% |
| ± 1 STANDARD ERROR | 0.04% | 0.11% | 0.18% | 0.30% | 0.38% | 0.42% | 0.44% | 0.44% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

## Unify Assura™ CRT-D

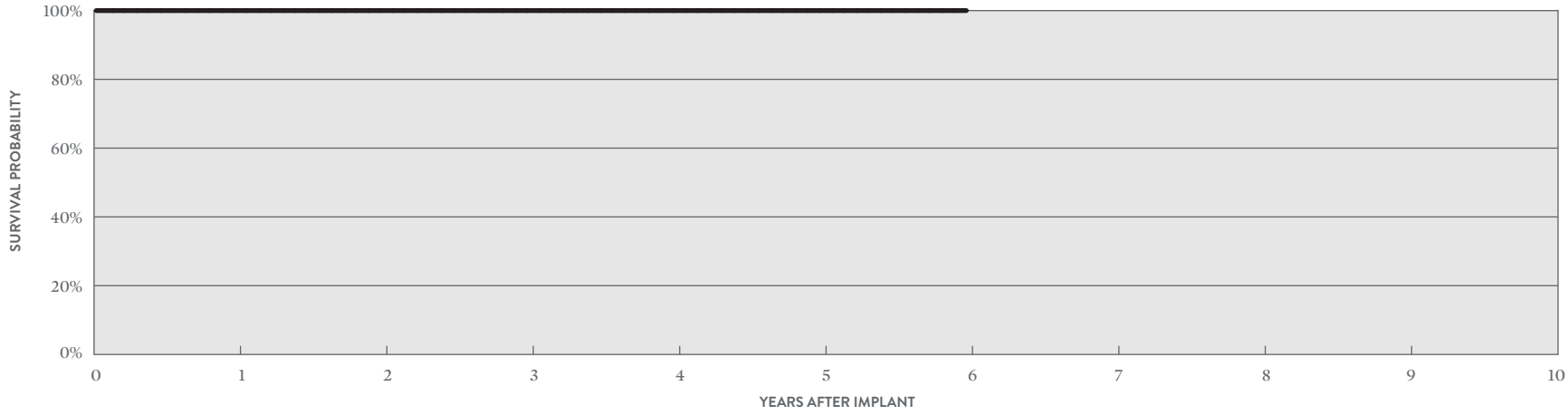
### MODEL CD3357-40Q*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Number of Devices Enrolled in Study | 269 |
| Active Devices Enrolled in Study | 158 |
| Cumulative Months of Follow-up | 12,138 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 2 | 0.74% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **2** | **0.74%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 250 | 220 | 180 | 160 | 120 | 50 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

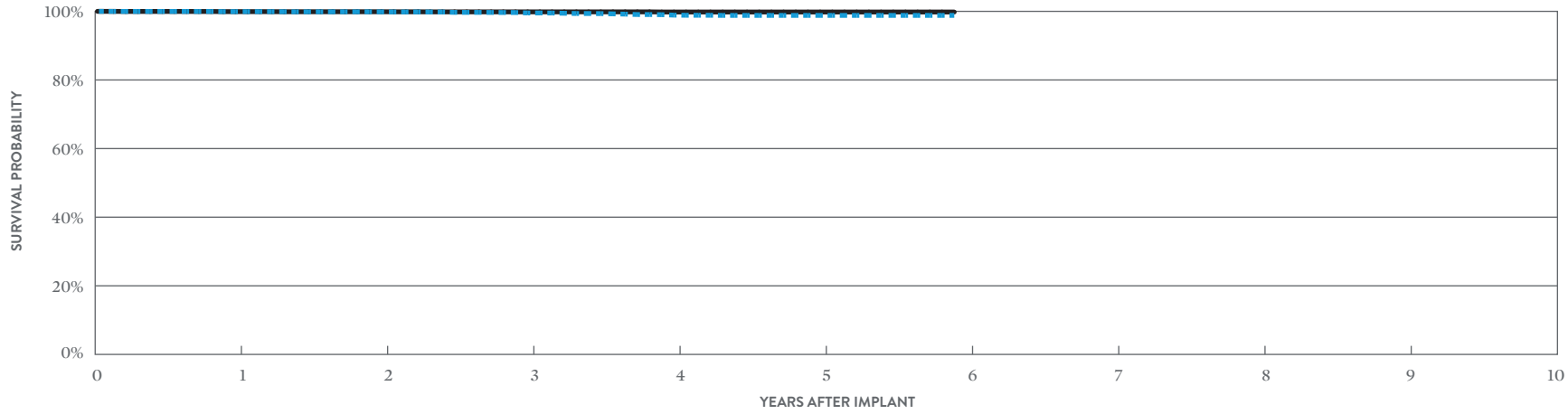
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3357-40C* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 16,082 |
| Estimated Active US Implants | 11,021 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 30 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | <0.01% |
| Electrical Interconnect | 2 | 0.01% | 1 | <0.01% |
| Battery | 0 | 0.00% | 1 | <0.01% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 0 | 0.00% | 3 | 0.02% |
| **Total** | **2** | **0.01%** | **8** | **0.05%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.85% | 99.53% | 98.90% | 98.82% | 98.82% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.06% | 0.11% | 0.13% | 0.13% |
| SAMPLE SIZE | 14,460 | 11,580 | 9,120 | 6,820 | 3,960 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.89% | 99.85% | 99.81% | 99.81% | 99.81% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.04% | 0.04% | 0.04% |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

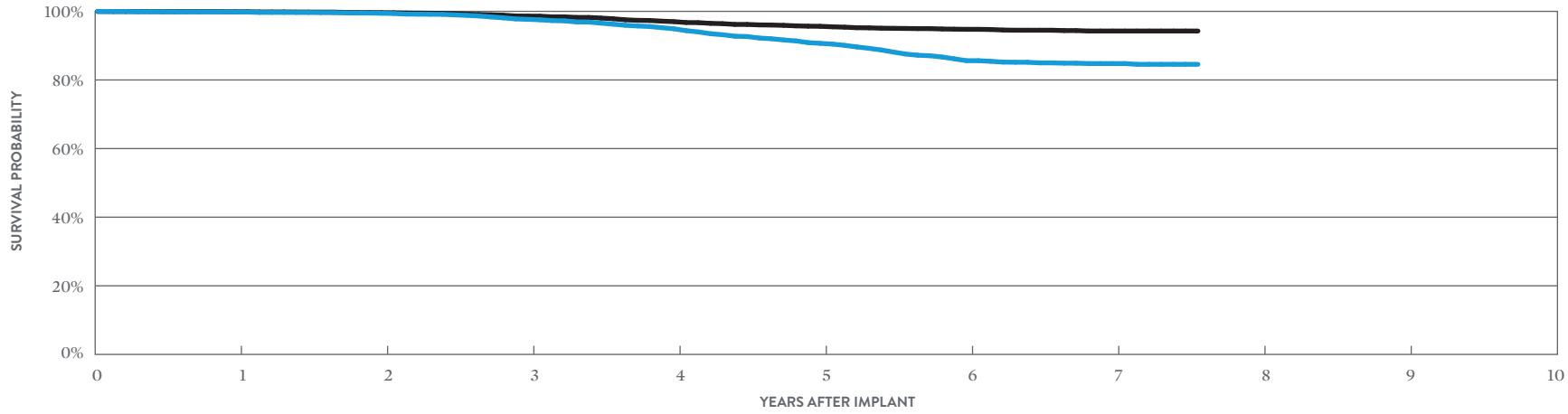
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3357-40C* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 9,588 |
| Estimated Active US Implants | 4,013 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 214 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.02% | 3 | 0.03% |
| Electrical Interconnect | 2 | 0.02% | 1 | 0.01% |
| Battery | 0 | 0.00% | 5 | 0.05% |
| High Voltage Capacitor | 1 | 0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.02% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 18 | 0.19% | 97 | 1.01% |
| Other | 1 | 0.01% | 3 | 0.03% |
| **Total** | **24** | **0.25%** | **112** | **1.17%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.44% | 97.67% | 94.91% | 90.67% | 85.62% | 84.78% | 84.56% |
| ± 1 STANDARD ERROR | 0.04% | 0.08% | 0.18% | 0.26% | 0.37% | 0.46% | 0.49% | 0.51% |
| SAMPLE SIZE | 8,970 | 7,810 | 6,770 | 5,960 | 5,320 | 4,430 | 2,440 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.62% | 98.62% | 97.00% | 95.64% | 94.76% | 94.27% | 94.27% |
| ± 1 STANDARD ERROR | 0.03% | 0.07% | 0.14% | 0.21% | 0.26% | 0.29% | 0.32% | 0.32% |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

**ACTIVELY MONITORED STUDY DATA**

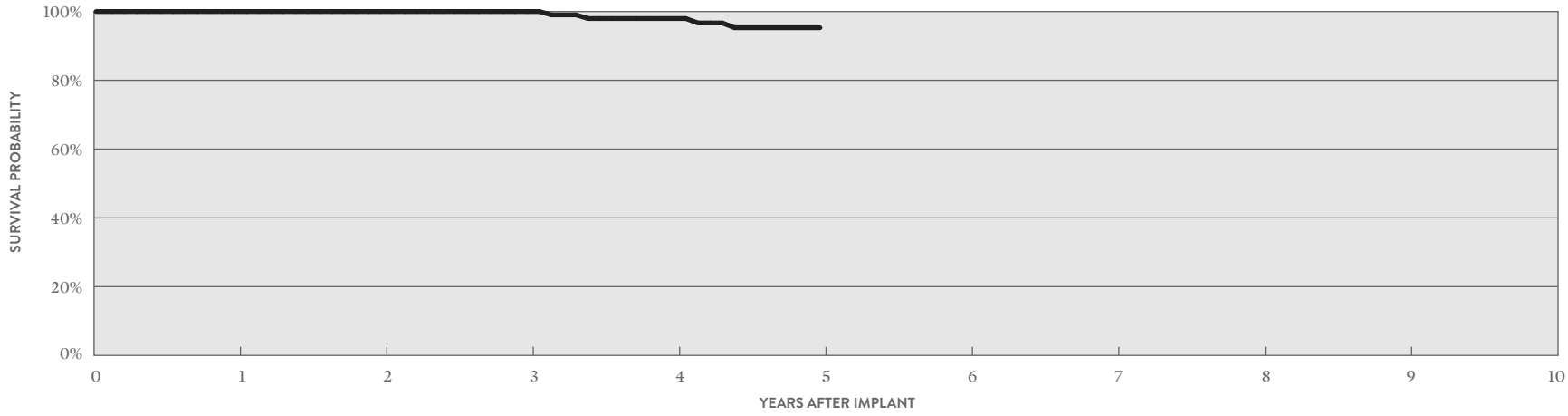
## Unify Assura™ CRT-D

### MODEL CD3357-40C*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Number of Devices Enrolled in Study | 232 |
| Active Devices Enrolled in Study | 82 |
| Cumulative Months of Follow-up | 8,427 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 4 | 1.72% |
| Skin Erosion | 1 | 0.43% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 4 | 1.72% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **4** | **1.72%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 97.96% | 95.29% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 1.43% | 2.33% |
| SAMPLE SIZE | 210 | 170 | 120 | 90 | 50 |

**Parylene coating.*

# Cardiac Resynchronization Therapy (CRT) ICDs

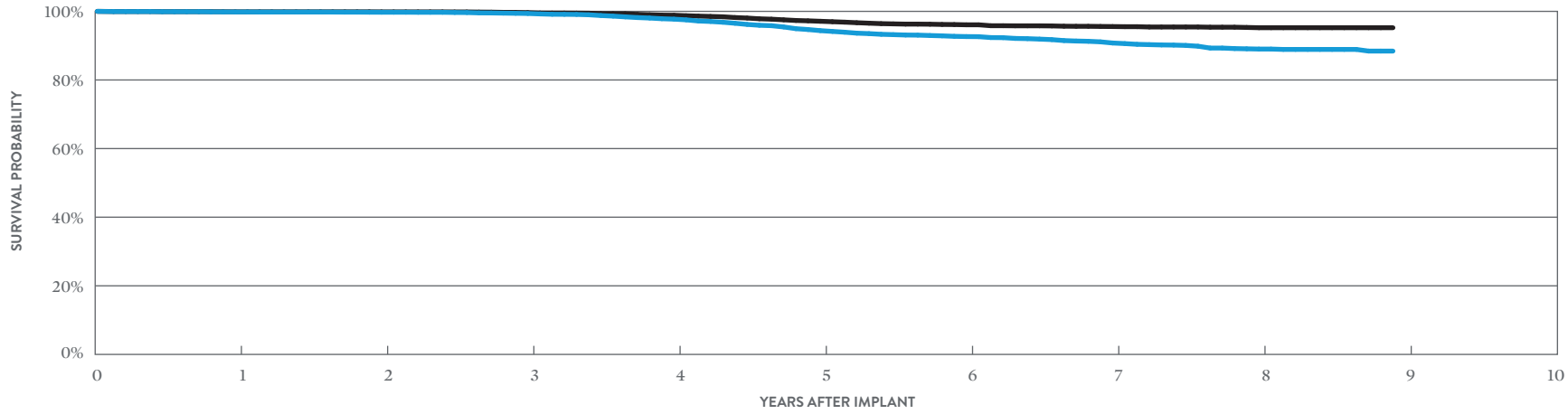
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3265-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 13,540 |
| Estimated Active US Implants | 4,155 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 180 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.01% | 6 | 0.04% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 1 | <0.01% | 7 | 0.05% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 1 | <0.01% | 2 | 0.01% |
| Mechanical | 0 | 0.00% | 2 | 0.01% |
| Possible Early Battery Depletion | 24 | 0.18% | 104 | 0.77% |
| Other | 1 | <0.01% | 1 | <0.01% |
| **Total** | **30** | **0.22%** | **122** | **0.90%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.74% | 99.38% | 97.73% | 94.38% | 92.65% | 90.77% | 89.01% | 88.42% |
| ± 1 STANDARD ERROR | 0.04% | 0.04% | 0.07% | 0.15% | 0.24% | 0.28% | 0.32% | 0.37% | 0.51% |
| SAMPLE SIZE | 12,740 | 11,330 | 10,170 | 9,020 | 7,930 | 7,020 | 5,980 | 3,770 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.85% | 99.64% | 98.87% | 97.11% | 96.08% | 95.57% | 95.23% | 95.23% |
| ± 1 STANDARD ERROR | 0.03% | 0.03% | 0.05% | 0.11% | 0.18% | 0.21% | 0.23% | 0.24% | 0.25% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

**ACTIVELY MONITORED STUDY DATA**

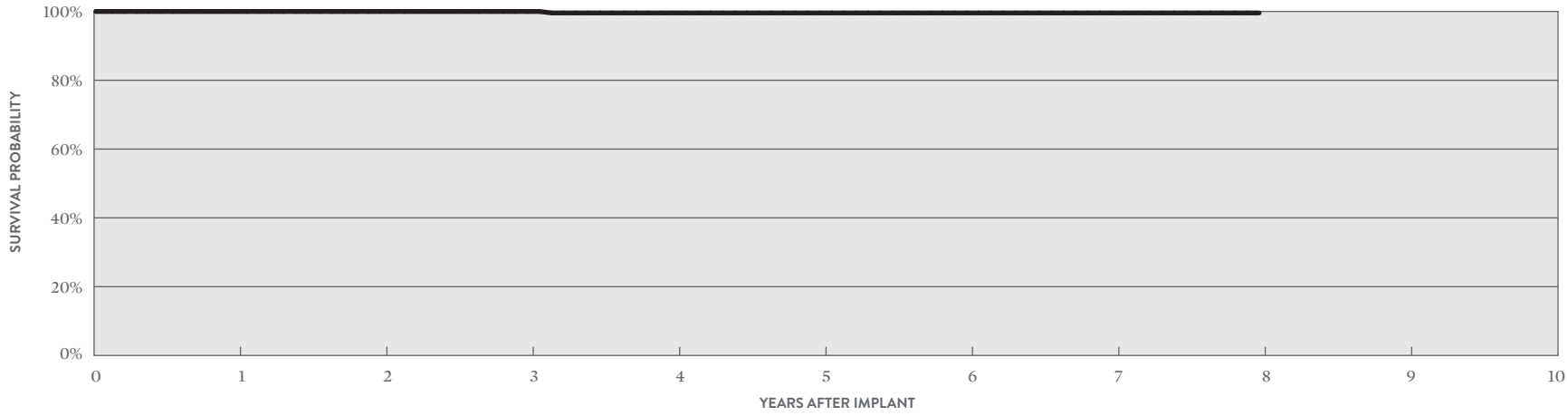
## Quadra Assura™ CRT-D

### MODEL CD3265-40Q*

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Number of Devices Enrolled in Study | 421 |
| Active Devices Enrolled in Study | 143 |
| Cumulative Months of Follow-up | 20,772 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 1 | 0.24% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 1 | 0.24% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.24% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **0.24%** | **1** | **0.24%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 7 | 6 | 8 |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 99.58% | 99.58% | 99.58% | 99.58% | 99.58% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.42% | 0.42% | 0.42% | 0.42% | 0.42% |
| SAMPLE SIZE | 390 | 330 | 270 | 210 | 160 | 140 | 140 | 60 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

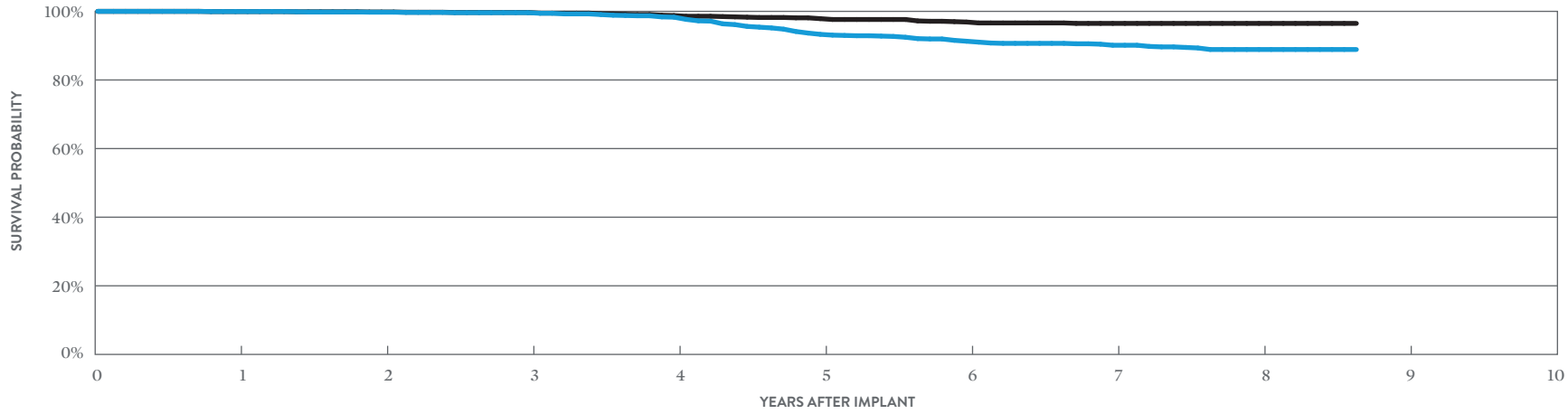
**CUSTOMER REPORTED PERFORMANCE DATA**

## Quadra Assura™ CRT-D

### MODEL CD3265-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 3,926 |
| Estimated Active US Implants | 1,234 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 63 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 1 | 0.03% | 0 | 0.00% |
| Battery | 0 | 0.00% | 2 | 0.05% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.03% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 5 | 0.13% | 17 | 0.43% |
| Other | 7 | 0.18% | 2 | 0.05% |
| **Total** | **13** | **0.33%** | **22** | **0.56%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 104 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.76% | 99.62% | 98.30% | 93.30% | 91.29% | 90.12% | 88.88% | 88.88% |
| ± 1 STANDARD ERROR | 0.04% | 0.09% | 0.11% | 0.24% | 0.50% | 0.58% | 0.63% | 0.70% | 0.70% |
| SAMPLE SIZE | 3,660 | 3,250 | 2,920 | 2,550 | 2,190 | 1,900 | 1,610 | 1,070 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 104 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.82% | 99.68% | 98.78% | 97.87% | 96.89% | 96.49% | 96.49% | 96.49% |
| ± 1 STANDARD ERROR | 0.04% | 0.07% | 0.10% | 0.20% | 0.27% | 0.36% | 0.39% | 0.39% | 0.39% |

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

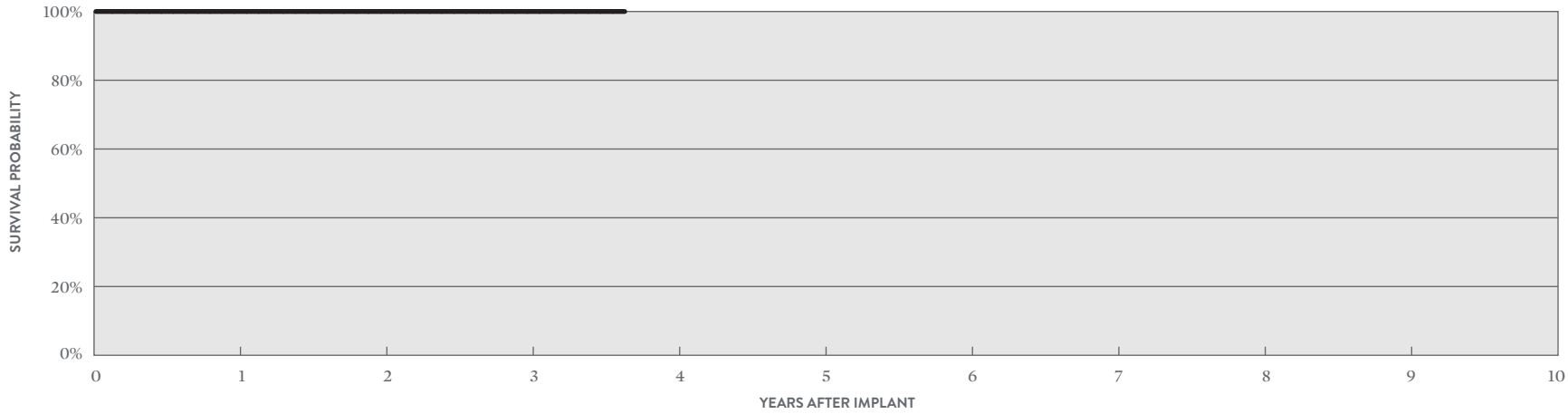
## Quadra Assura™ CRT-D

### MODEL CD3265-40

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Number of Devices Enrolled in Study | 100 |
| Active Devices Enrolled in Study | 37 |
| Cumulative Months of Follow-up | 5,234 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 1 | 1.00% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | 1.00% | 1 | 1.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **1.00%** | **1** | **1.00%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | AT 44 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 100 | 80 | 60 | 50 |

# Cardiac Resynchronization Therapy (CRT) ICDs

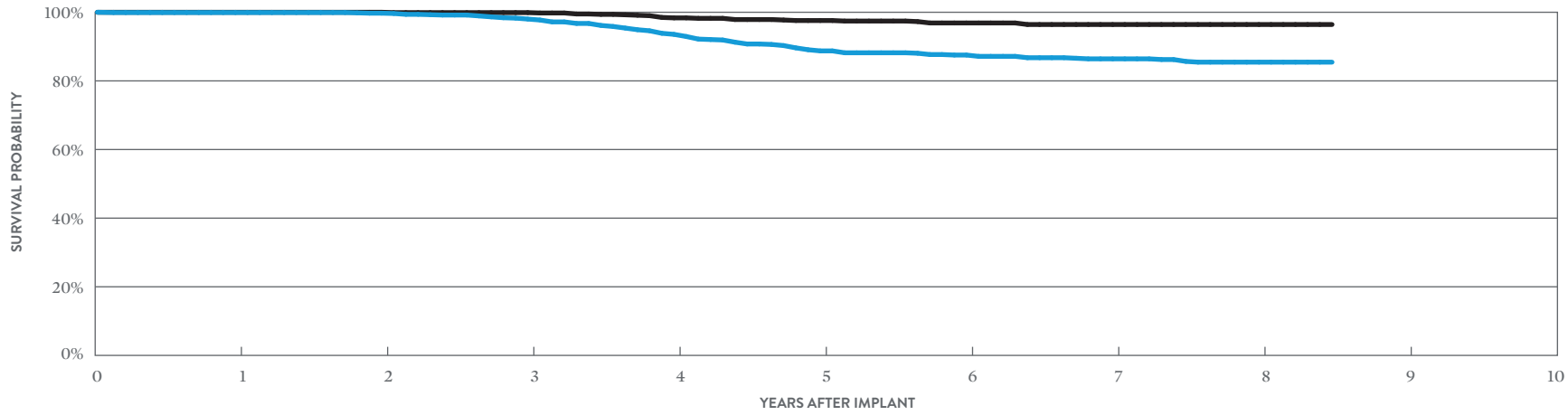
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3257-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 2,716 |
| Estimated Active US Implants | 825 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 71 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 2 | 0.07% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 1 | 0.04% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.04% |
| Possible Early Battery Depletion | 5 | 0.18% | 12 | 0.44% |
| Other | 2 | 0.07% | 0 | 0.00% |
| **Total** | **8** | **0.29%** | **15** | **0.55%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 102 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.73% | 98.02% | 93.56% | 88.74% | 87.53% | 86.42% | 85.46% | 85.46% |
| ± 1 STANDARD ERROR | 0.05% | 0.11% | 0.29% | 0.57% | 0.77% | 0.82% | 0.86% | 0.91% | 0.91% |
| SAMPLE SIZE | 2,520 | 2,190 | 1,930 | 1,650 | 1,410 | 1,240 | 1,060 | 720 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 102 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 99.90% | 98.36% | 97.59% | 96.88% | 96.43% | 96.43% | 96.43% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.07% | 0.30% | 0.39% | 0.45% | 0.49% | 0.49% | 0.49% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

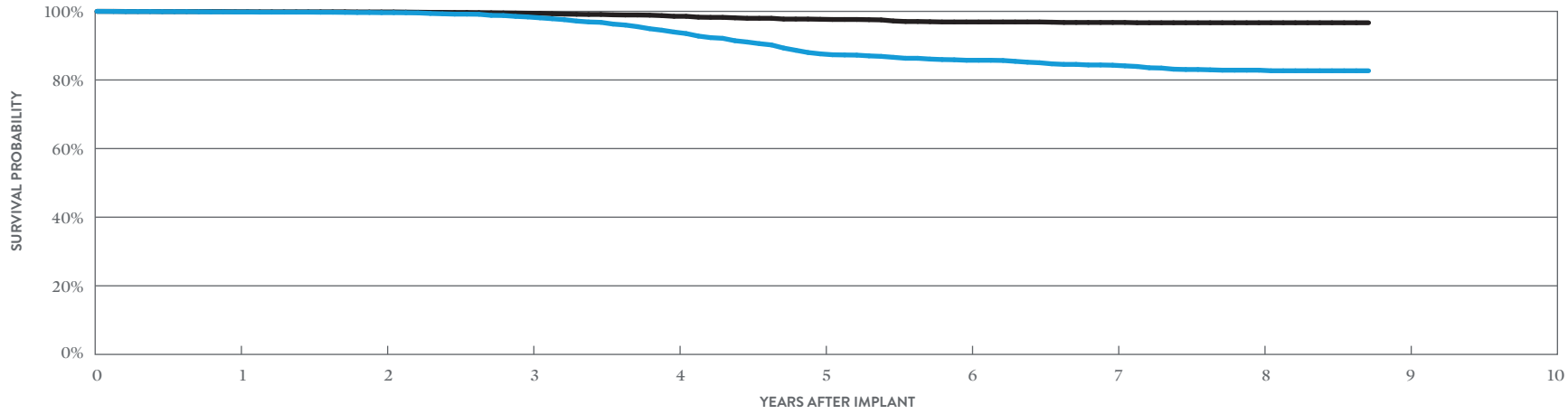
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Assura™ CRT-D

### MODEL CD3257-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 6,744 |
| Estimated Active US Implants | 1,989 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 216 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.09% | 3 | 0.04% |
| Electrical Interconnect | 1 | 0.01% | 0 | 0.00% |
| Battery | 1 | 0.01% | 1 | 0.01% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 4 | 0.06% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 10 | 0.15% | 29 | 0.43% |
| Other | 1 | 0.01% | 1 | 0.01% |
| **Total** | **19** | **0.28%** | **38** | **0.56%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.62% | 98.37% | 93.97% | 87.61% | 85.74% | 84.30% | 82.85% | 82.68% |
| ± 1 STANDARD ERROR | 0.05% | 0.08% | 0.17% | 0.34% | 0.50% | 0.55% | 0.58% | 0.62% | 0.63% |
| SAMPLE SIZE | 6,320 | 5,550 | 4,900 | 4,220 | 3,600 | 3,110 | 2,620 | 1,720 | 270 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.83% | 99.46% | 98.56% | 97.69% | 96.91% | 96.76% | 96.68% | 96.68% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.10% | 0.16% | 0.23% | 0.28% | 0.29% | 0.29% | 0.29% |

# Cardiac Resynchronization Therapy (CRT) ICDs

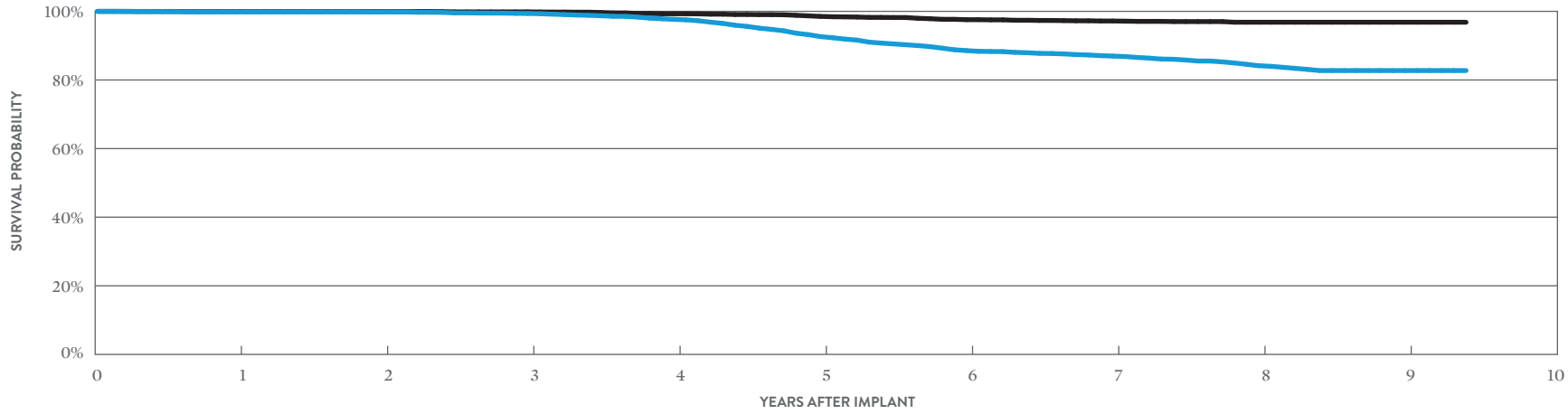
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Quadra™ CRT-D

### MODEL CD3249-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Registered US Implants | 8,948 |
| Estimated Active US Implants | 2,231 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 270 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.04% | 3 | 0.03% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.01% | 1 | 0.01% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 16 | 0.18% | 36 | 0.40% |
| Other | 3 | 0.03% | 0 | 0.00% |
| **Total** | **24** | **0.27%** | **41** | **0.46%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 113 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.84% | 99.38% | 97.66% | 92.65% | 88.56% | 86.96% | 84.15% | 82.74% | 82.74% |
| ± 1 STANDARD ERROR | 0.04% | 0.04% | 0.09% | 0.18% | 0.33% | 0.43% | 0.46% | 0.52% | 0.57% | 0.57% |
| SAMPLE SIZE | 8,410 | 7,500 | 6,780 | 6,120 | 5,330 | 4,540 | 3,820 | 2,950 | 1,770 | 340 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 113 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.95% | 99.85% | 99.29% | 98.53% | 97.57% | 97.19% | 96.83% | 96.83% | 96.83% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.05% | 0.11% | 0.15% | 0.21% | 0.23% | 0.26% | 0.26% | 0.26% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

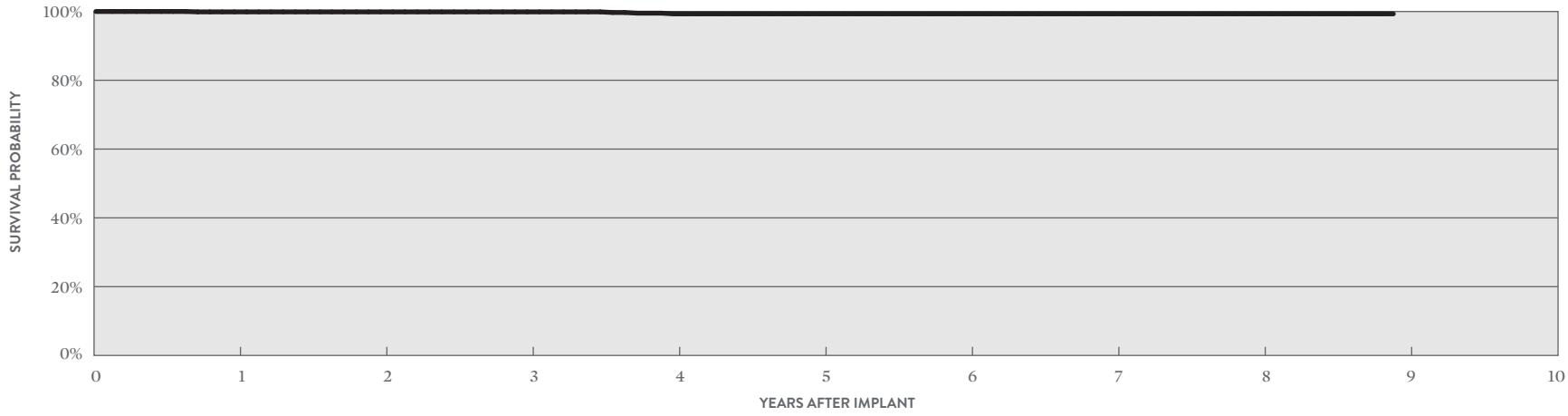
## Unify Quadra™ CRT-D

### MODEL CD3249-40Q*

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Number of Devices Enrolled in Study | 989 |
| Active Devices Enrolled in Study | 366 |
| Cumulative Months of Follow-up | 54,992 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 3 | 0.30% |
| Skin Erosion | 1 | 0.10% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | 0.10% | 3 | 0.30% |
| Other | 1 | 0.10% | 1 | 0.10% |
| **Total** | **2** | **0.20%** | **4** | **0.40%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.89% | 99.89% | 99.31% | 99.31% | 99.31% | 99.31% | 99.31% | 99.31% |
| ± 1 STANDARD ERROR | 0.11% | 0.11% | 0.11% | 0.29% | 0.35% | 0.35% | 0.35% | 0.35% | 0.35% |
| SAMPLE SIZE | 920 | 780 | 660 | 550 | 430 | 380 | 370 | 350 | 70 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

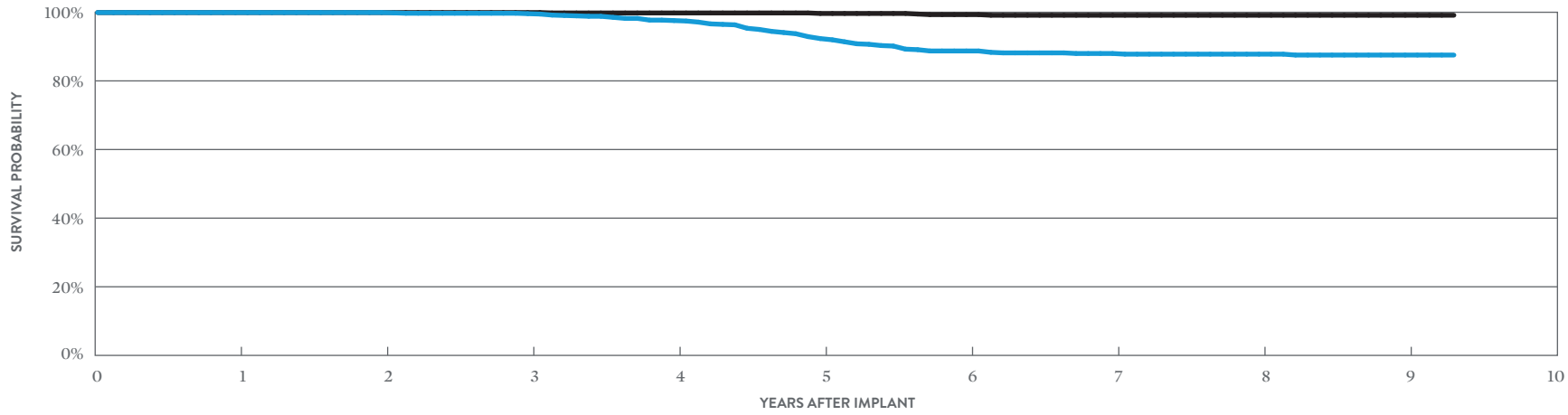
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify Quadra™ CRT-D

### MODEL CD3249-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Registered US Implants | 2,523 |
| Estimated Active US Implants | 668 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 69 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.04% |
| Possible Early Battery Depletion | 0 | 0.00% | 4 | 0.16% |
| Other | 1 | 0.04% | 0 | 0.00% |
| **Total** | **1** | **0.04%** | **5** | **0.20%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 112 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.92% | 99.59% | 97.58% | 92.33% | 88.72% | 87.98% | 87.79% | 87.53% | 87.53% |
| ± 1 STANDARD ERROR | 0.06% | 0.06% | 0.12% | 0.36% | 0.66% | 0.83% | 0.86% | 0.87% | 0.88% | 0.88% |
| SAMPLE SIZE | 2,360 | 2,060 | 1,820 | 1,620 | 1,410 | 1,210 | 1,030 | 840 | 560 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 112 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.92% | 99.92% | 99.80% | 99.65% | 99.31% | 99.13% | 99.13% | 99.13% | 99.13% |
| ± 1 STANDARD ERROR | 0.06% | 0.06% | 0.06% | 0.10% | 0.10% | 0.22% | 0.26% | 0.26% | 0.26% | 0.26% |

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

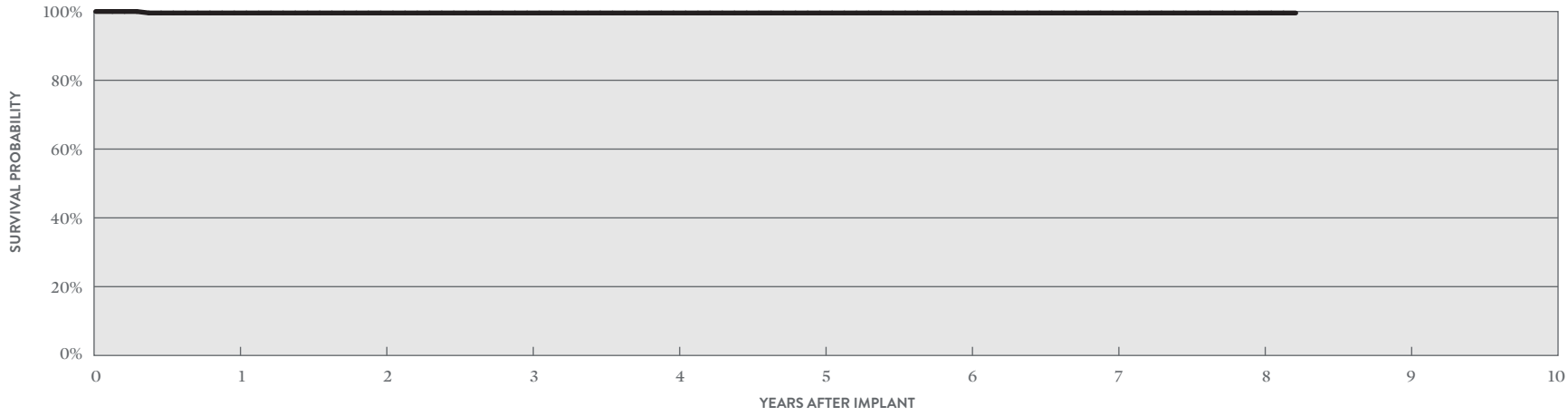
## Unify Quadra™ CRT-D

### MODEL CD3249-40

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Number of Devices Enrolled in Study | 245 |
| Active Devices Enrolled in Study | 65 |
| Cumulative Months of Follow-up | 12,082 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Skin Erosion | 1 | 0.41% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | 4 | 5 | 7 | 6 | 8 | AT 99 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% |
| ± 1 STANDARD ERROR | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% |
| SAMPLE SIZE | 230 | 190 | 160 | 130 | 90 | 70 | 70 | 60 | 50 |

# Cardiac Resynchronization Therapy (CRT) ICDs

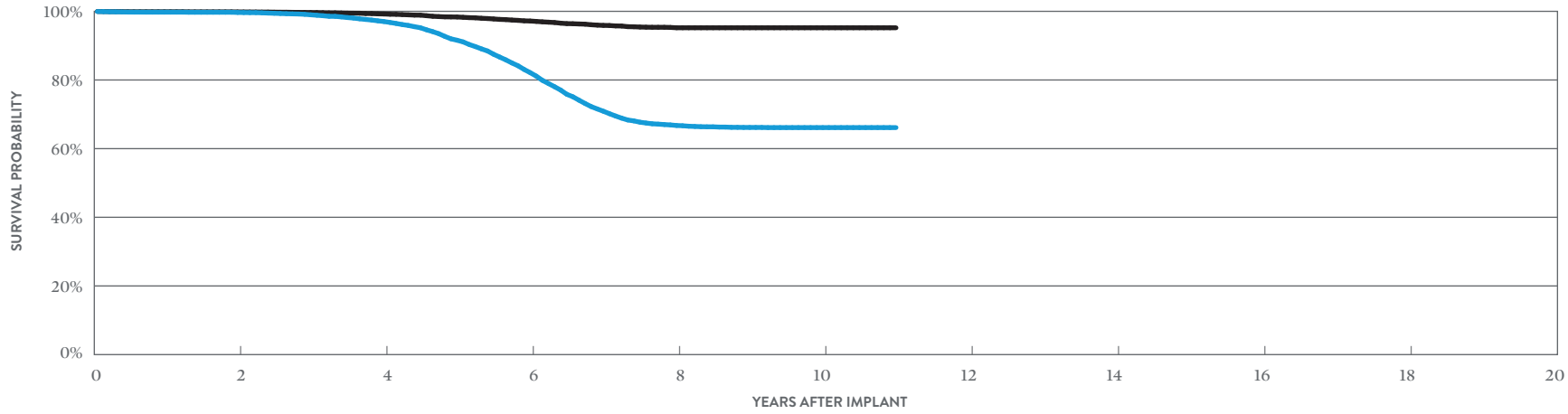
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify™ CRT-D

### MODEL CD3231-40Q (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 19,028 |
| Estimated Active US Implants | 3,886 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 1,217 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.01% | 5 | 0.03% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 14 | 0.07% | 9 | 0.05% |
| High Voltage Capacitor | 16 | 0.08% | 6 | 0.03% |
| Software/Firmware | 0 | 0.00% | 2 | 0.01% |
| Mechanical | 1 | <0.01% | 2 | 0.01% |
| Possible Early Battery Depletion | 56 | 0.29% | 58 | 0.30% |
| Other | 8 | 0.04% | 6 | 0.03% |
| **Total** | **98** | **0.52%** | **88** | **0.46%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.67% | 97.03% | 82.13% | 66.74% | 66.13% | 66.13% |
| ± 1 STANDARD ERROR | 0.04% | 0.14% | 0.36% | 0.47% | 0.48% | 0.48% |
| SAMPLE SIZE | 15,610 | 12,460 | 9,220 | 5,720 | 3,030 | 320 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.22% | 97.18% | 95.21% | 95.21% | 95.21% |
| ± 1 STANDARD ERROR | 0.03% | 0.07% | 0.16% | 0.22% | 0.23% | 0.23% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

**ACTIVELY MONITORED STUDY DATA**

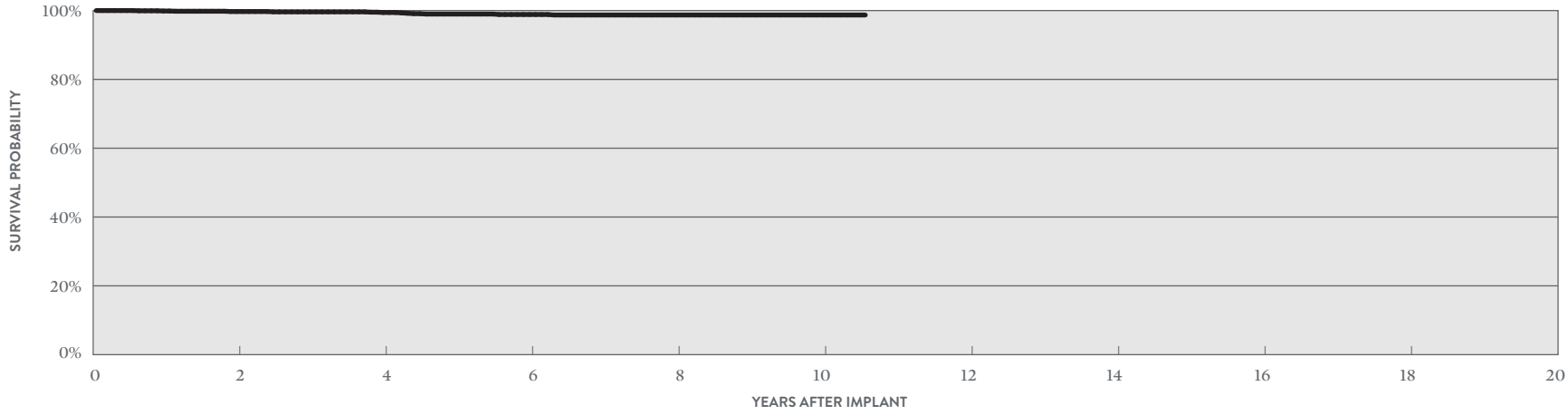
## Unify™ CRT-D

### MODEL CD3231-40Q

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 1,680 |
| Active Devices Enrolled in Study | 651 |
| Cumulative Months of Follow-up | 110,964 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 2 | 0.12% |
| Premature Battery Depletion | 10 | 0.60% |
| Skin Erosion | 1 | 0.06% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.06% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.06% | 1 | 0.06% |
| High Voltage Capacitor | 1 | 0.06% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.06% |
| Possible Early Battery Depletion | 12 | 0.71% | 4 | 0.24% |
| Other | 2 | 0.12% | 0 | 0.00% |
| **Total** | **16** | **0.95%** | **7** | **0.42%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 127 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.72% | 99.43% | 98.85% | 98.71% | 98.71% | 98.71% |
| ± 1 STANDARD ERROR | 0.14% | 0.19% | 0.34% | 0.37% | 0.37% | 0.37% |
| SAMPLE SIZE | 1,360 | 1,020 | 750 | 670 | 450 | 60 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

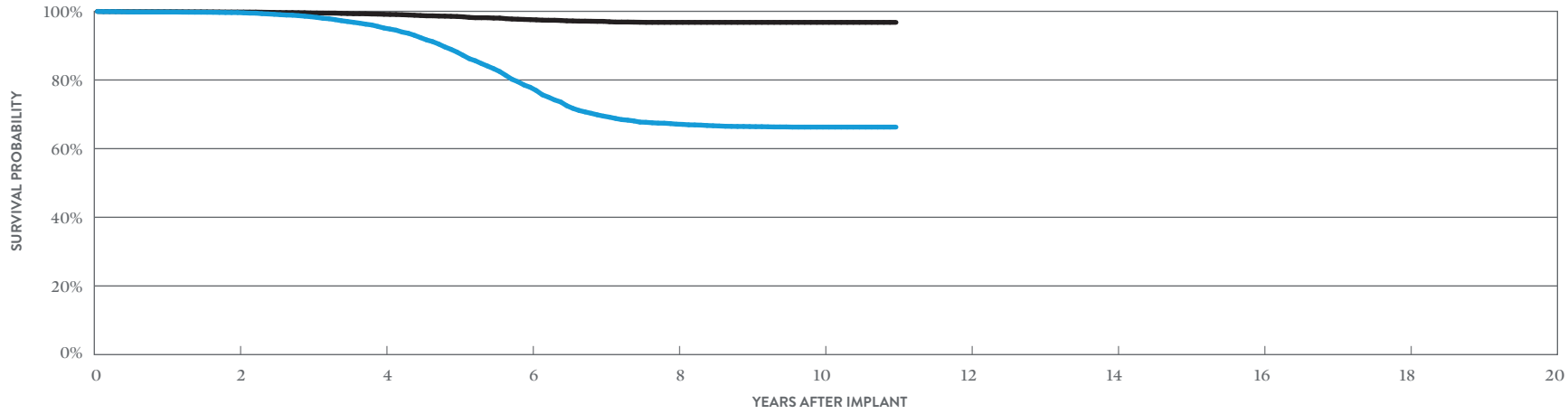
**CUSTOMER REPORTED PERFORMANCE DATA**

## Unify™ CRT-D

### MODEL CD3231-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 20,500 |
| Estimated Active US Implants | 4,579 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 1,363 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 10 | 0.05% | 5 | 0.02% |
| Electrical Interconnect | 3 | 0.01% | 0 | 0.00% |
| Battery | 9 | 0.04% | 3 | 0.01% |
| High Voltage Capacitor | 7 | 0.03% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | <0.01% |
| Mechanical | 1 | <0.01% | 1 | <0.01% |
| Possible Early Battery Depletion | 32 | 0.16% | 44 | 0.21% |
| Other | 11 | 0.05% | 11 | 0.05% |
| **Total** | **73** | **0.36%** | **66** | **0.32%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.64% | 95.14% | 77.88% | 67.13% | 66.28% | 66.28% |
| ± 1 STANDARD ERROR | 0.04% | 0.17% | 0.38% | 0.45% | 0.46% | 0.46% |
| SAMPLE SIZE | 16,600 | 12,870 | 9,100 | 5,940 | 3,000 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.80% | 99.14% | 97.58% | 96.79% | 96.79% | 96.79% |
| ± 1 STANDARD ERROR | 0.03% | 0.07% | 0.14% | 0.18% | 0.18% | 0.18% |

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

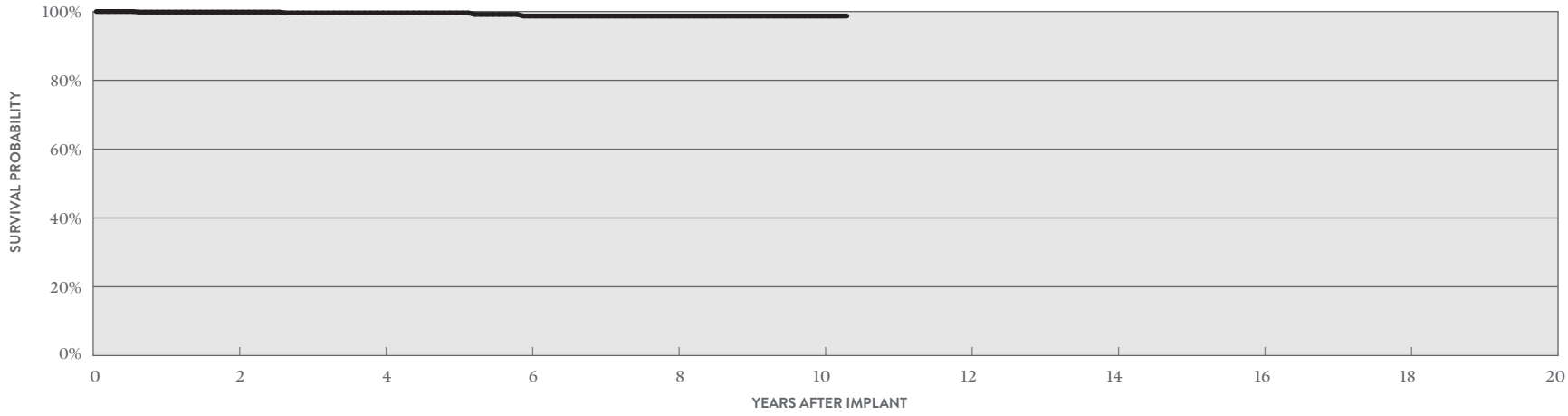
## Unify™ CRT-D

### MODEL CD3231-40

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 689 |
| Active Devices Enrolled in Study | 165 |
| Cumulative Months of Follow-up | 36,841 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 3 | 0.44% |
| Skin Erosion | 1 | 0.15% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | 0.15% | 0 | 0.00% |
| Electrical Interconnect | 1 | 0.15% | 0 | 0.00% |
| Battery | 1 | 0.15% | 2 | 0.29% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.15% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | 0.15% | 2 | 0.29% |
| Other | 0 | 0.00% | 1 | 0.15% |
| **Total** | **4** | **0.58%** | **6** | **0.87%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 124 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.59% | 98.69% | 98.69% | 98.69% | 98.69% |
| ± 1 STANDARD ERROR | 0.16% | 0.29% | 0.70% | 0.70% | 0.70% | 0.70% |
| SAMPLE SIZE | 510 | 350 | 220 | 180 | 120 | 50 |

# Cardiac Resynchronization Therapy (CRT) ICDs

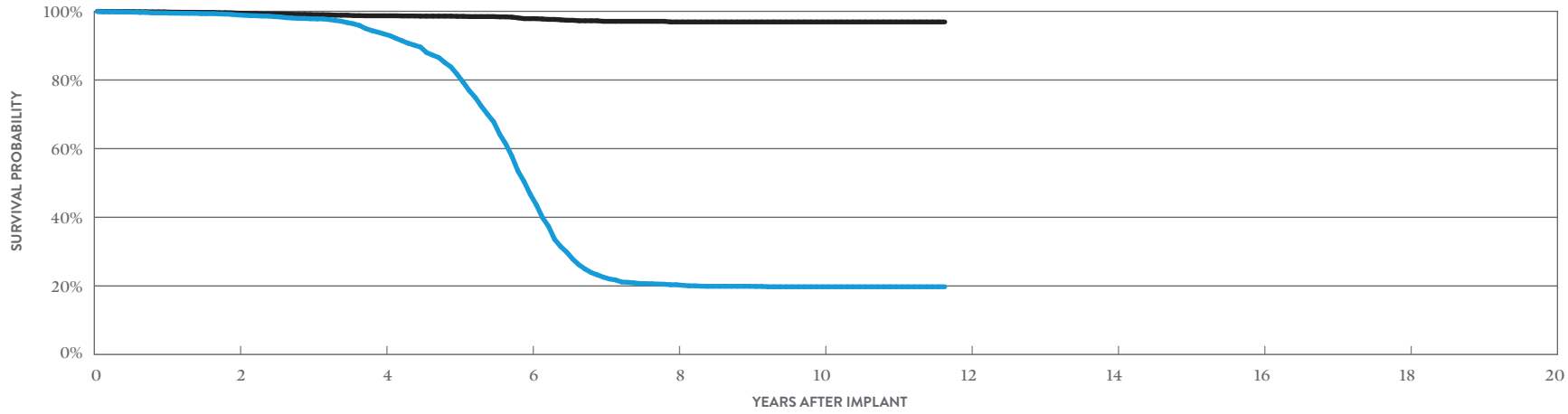
**CUSTOMER REPORTED PERFORMANCE DATA**

## Promote™ + CRT-D

### MODEL CD3211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 6,903 |
| Estimated Active US Implants | 910 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 1,325 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.06% | 3 | 0.04% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 9 | 0.13% | 5 | 0.07% |
| High Voltage Capacitor | 1 | 0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 11 | 0.16% |
| Mechanical | 1 | 0.01% | 0 | 0.00% |
| Possible Early Battery Depletion | 2 | 0.03% | 0 | 0.00% |
| Other | 5 | 0.07% | 6 | 0.09% |
| **Total** | **22** | **0.32%** | **25** | **0.36%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 140 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.95% | 93.42% | 46.73% | 20.35% | 19.76% | 19.76% |
| ± 1 STANDARD ERROR | 0.12% | 0.35% | 0.79% | 0.60% | 0.59% | 0.59% |
| SAMPLE SIZE | 5,490 | 4,250 | 2,600 | 1,130 | 940 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 140 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.46% | 98.70% | 97.87% | 96.91% | 96.91% | 96.91% |
| ± 1 STANDARD ERROR | 0.09% | 0.16% | 0.24% | 0.35% | 0.35% | 0.35% |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

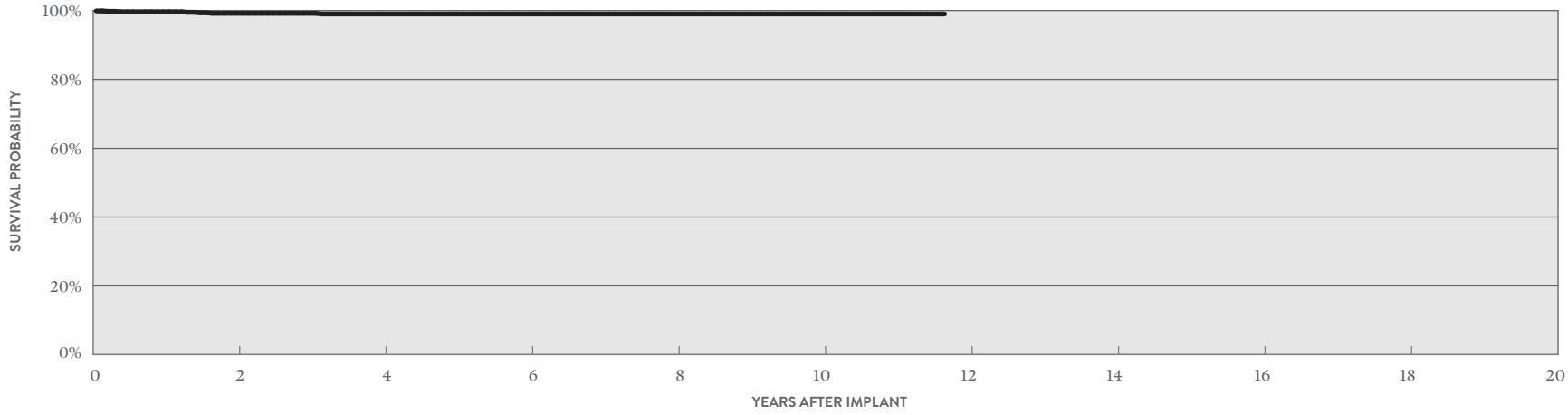
## Promote™ + CRT-D

### MODEL CD3211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Number of Devices Enrolled in Study | 856 |
| Active Devices Enrolled in Study | 207 |
| Cumulative Months of Follow-up | 52,414 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 3 | 0.35% |
| Premature Battery Depletion | 2 | 0.23% |
| Skin Erosion | 2 | 0.23% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | 0.12% | 1 | 0.12% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.12% | 1 | 0.12% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.12% |
| Possible Early Battery Depletion | 2 | 0.23% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **4** | **0.47%** | **3** | **0.35%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 140 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.19% | 99.00% | 99.00% | 99.00% | 99.00% | 99.00% |
| ± 1 STANDARD ERROR | 0.33% | 0.38% | 0.38% | 0.38% | 0.38% | 0.38% |
| SAMPLE SIZE | 680 | 480 | 300 | 240 | 210 | 70 |

**DF4-LLHH connector type.*

# Cardiac Resynchronization Therapy (CRT) ICDs

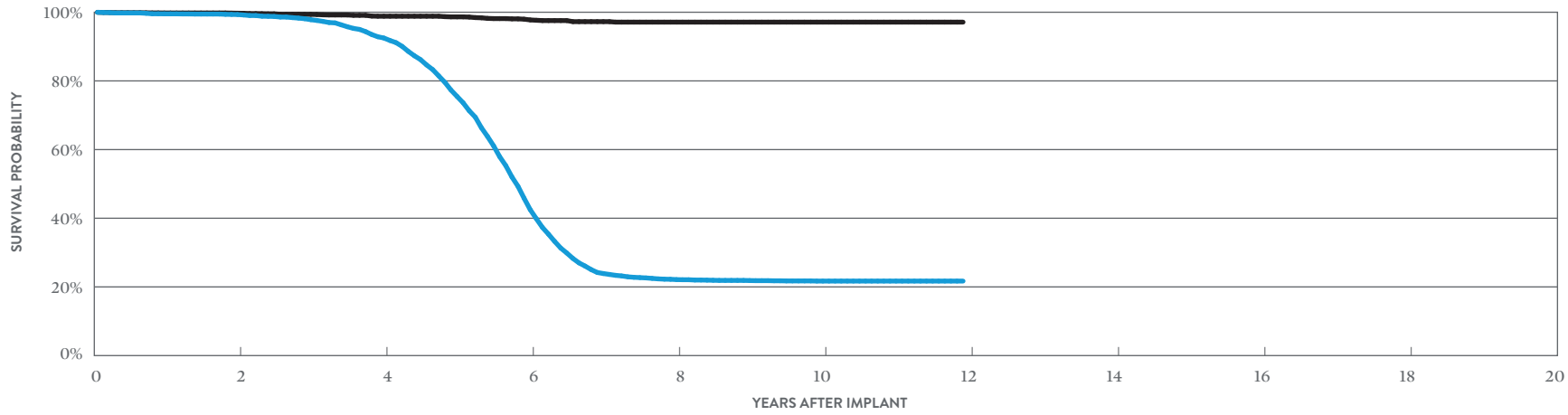
**CUSTOMER REPORTED PERFORMANCE DATA**

## Promote™ + CRT-D

### MODEL CD3211-36

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 8,646 |
| Estimated Active US Implants | 1,090 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 1,485 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.03% | 3 | 0.03% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 11 | 0.13% | 3 | 0.03% |
| High Voltage Capacitor | 2 | 0.02% | 0 | 0.00% |
| Software/Firmware | 1 | 0.01% | 11 | 0.13% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 5 | 0.06% | 1 | 0.01% |
| Other | 5 | 0.06% | 3 | 0.03% |
| **Total** | **27** | **0.31%** | **22** | **0.25%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.33% | 92.49% | 42.50% | 22.13% | 21.70% | 21.70% |
| ± 1 STANDARD ERROR | 0.09% | 0.35% | 0.73% | 0.58% | 0.58% | 0.58% |
| SAMPLE SIZE | 6,710 | 4,930 | 2,790 | 1,320 | 1,100 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.72% | 98.84% | 97.76% | 97.12% | 97.12% | 97.12% |
| ± 1 STANDARD ERROR | 0.06% | 0.14% | 0.22% | 0.31% | 0.31% | 0.31% |

# Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

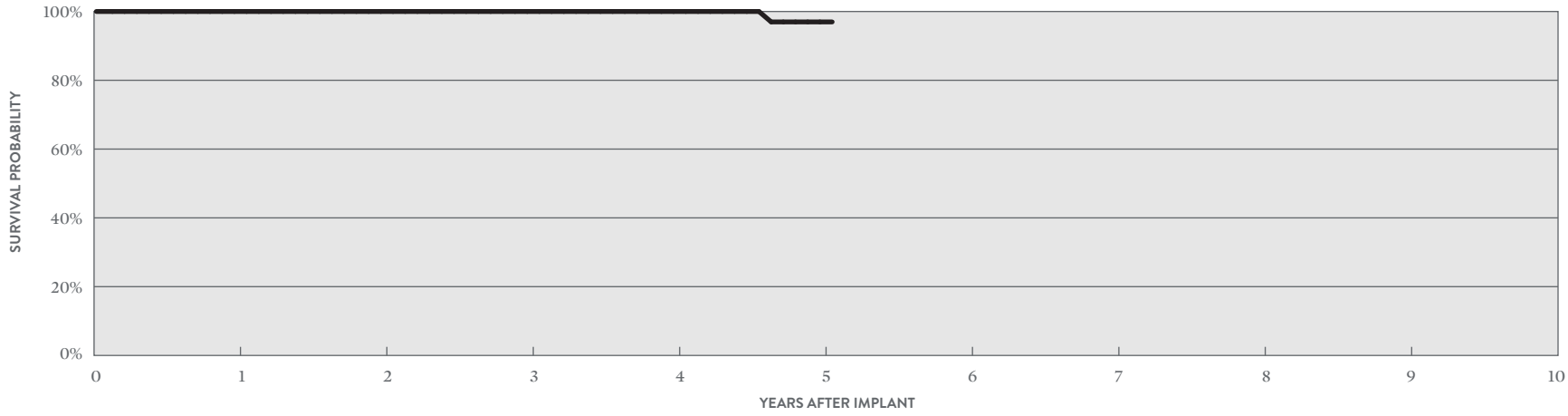
## Promote™ + CRT-D

### MODEL CD3211-36

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Number of Devices Enrolled in Study | 223 |
| Active Devices Enrolled in Study | 11 |
| Cumulative Months of Follow-up | 9,558 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Skin Erosion | 2 | 0.90% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 3 | 1.35% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **3** | **1.35%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 61 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 96.97% | 96.97% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 2.11% | 2.11% |
| SAMPLE SIZE | 210 | 170 | 130 | 100 | 70 | 50 |

# Cardiac Resynchronization Therapy (CRT) ICDs

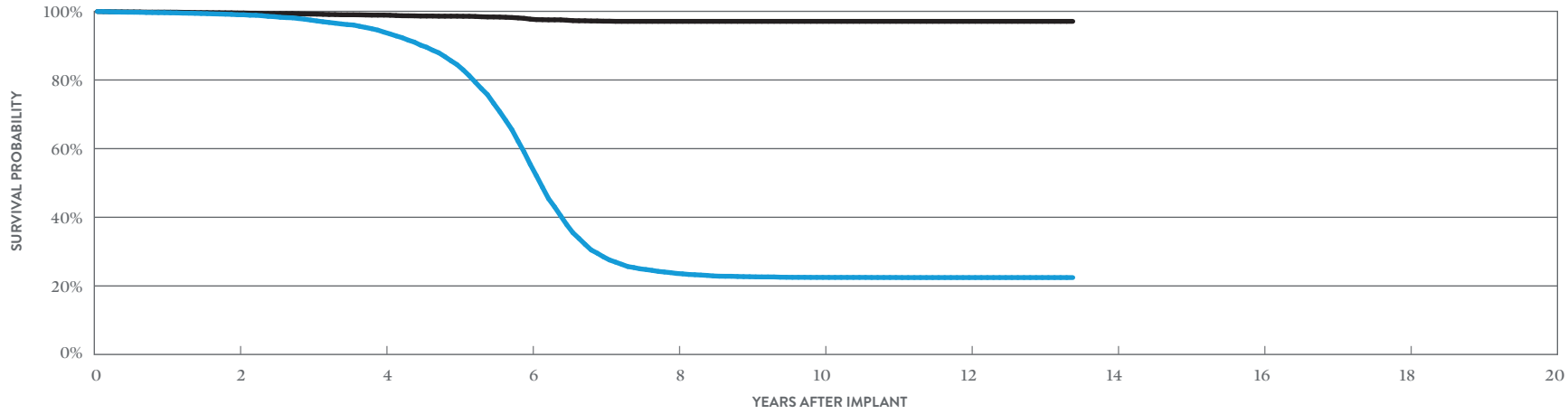
**CUSTOMER REPORTED PERFORMANCE DATA**

## Promote™ RF CRT-D

### MODEL 3207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 24,006 |
| Estimated Active US Implants | 2,288 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 3,420 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.02% | 6 | 0.02% |
| Electrical Interconnect | 5 | 0.02% | 3 | 0.01% |
| Battery | 19 | 0.08% | 9 | 0.04% |
| High Voltage Capacitor | 5 | 0.02% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 15 | 0.06% |
| Mechanical | 3 | 0.01% | 10 | 0.04% |
| Possible Early Battery Depletion | 10 | 0.04% | 6 | 0.02% |
| Other | 17 | 0.07% | 17 | 0.07% |
| **Total** | **63** | **0.26%** | **67** | **0.28%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.00% | 93.95% | 55.45% | 23.64% | 22.49% | 22.44% | 22.44% |
| ± 1 STANDARD ERROR | 0.07% | 0.19% | 0.47% | 0.40% | 0.39% | 0.39% | 0.39% |
| SAMPLE SIZE | 18,470 | 13,360 | 7,770 | 3,110 | 2,610 | 2,060 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.51% | 98.90% | 97.73% | 97.08% | 97.08% | 97.08% | 97.08% |
| ± 1 STANDARD ERROR | 0.05% | 0.08% | 0.13% | 0.19% | 0.19% | 0.19% | 0.19% |

# Cardiac Resynchronization Therapy (CRT) ICDs

**ACTIVELY MONITORED STUDY DATA**

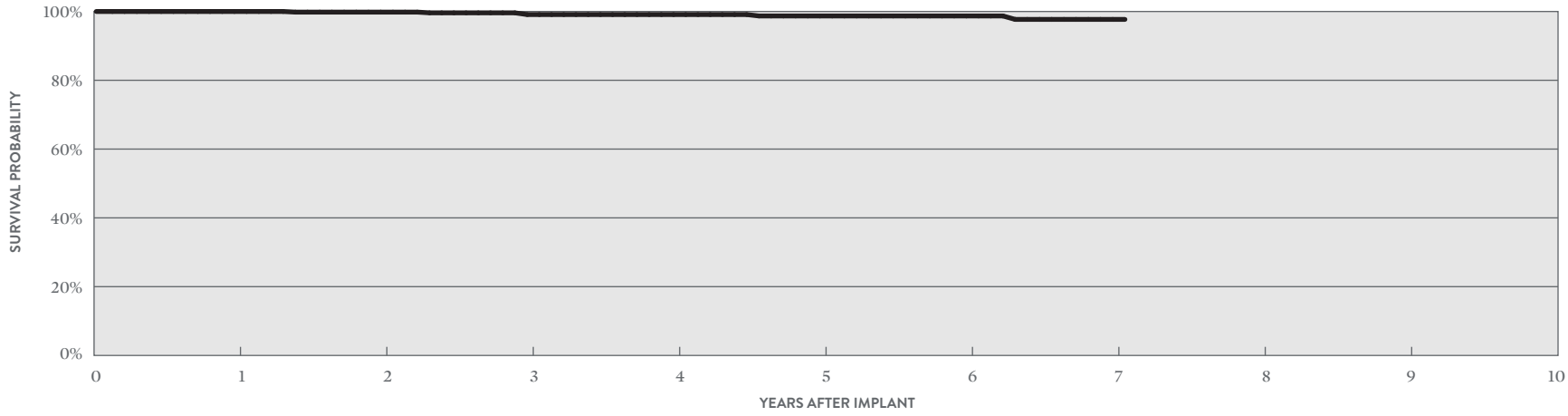
## Promote™ RF CRT-D

### MODEL 3207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Number of Devices Enrolled in Study | 672 |
| Active Devices Enrolled in Study | 18 |
| Cumulative Months of Follow-up | 30,581 |
| Estimated Longevity | (see table on page 53) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 1 | 0.15% |
| Premature Battery Depletion | 4 | 0.60% |
| Skin Erosion | 2 | 0.30% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.15% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 1 | 0.15% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.15% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.15% |
| Other | 2 | 0.30% | 1 | 0.15% |
| **Total** | **2** | **0.30%** | **5** | **0.74%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.82% | 99.11% | 99.11% | 98.70% | 98.70% | 97.70% | 97.70% |
| ± 1 STANDARD ERROR | 0.00% | 0.18% | 0.28% | 0.45% | 0.61% | 0.61% | 1.16% | 1.16% |
| SAMPLE SIZE | 630 | 540 | 450 | 340 | 240 | 160 | 90 | 60 |

# Cardiac Resynchronization Therapy (CRT) ICDs

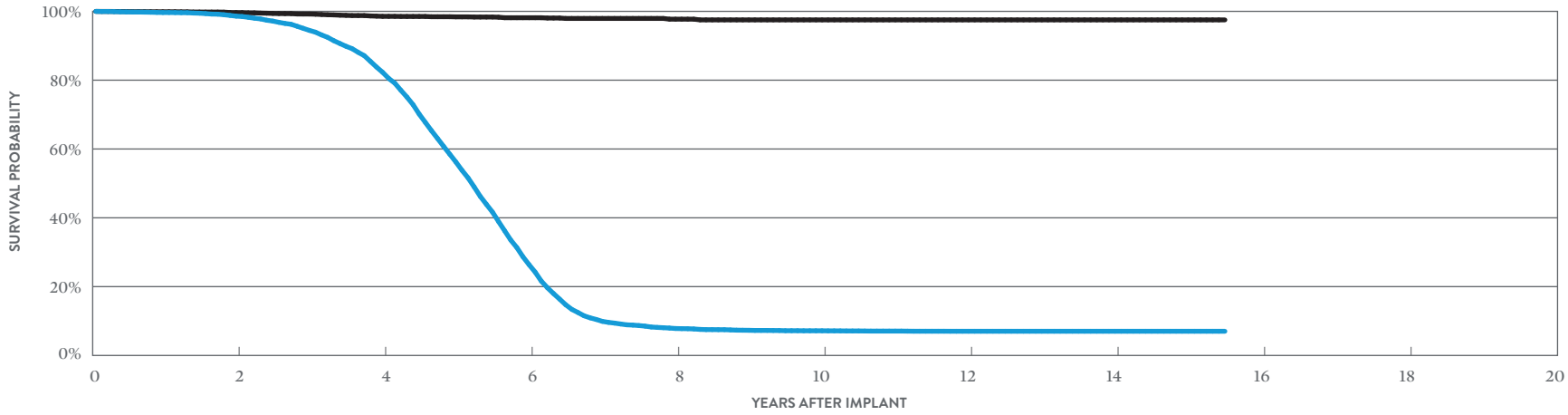
**CUSTOMER REPORTED PERFORMANCE DATA**

## Atlas™ + HF CRT-D

### MODEL V-343

| | |
|---|---|
| US Regulatory Approval | November 2004 |
| Registered US Implants | 18,776 |
| Estimated Active US Implants | 691 |
| Estimated Longevity | (see table on page 53) |
| Normal Battery Depletion | 3,494 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 316, 317) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.02% | 1 | <0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 40 | 0.21% | 4 | 0.02% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 7 | 0.04% | 11 | 0.06% |
| Other | 10 | 0.05% | 4 | 0.02% |
| **Total** | **60** | **0.32%** | **22** | **0.12%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 186 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.61% | 82.29% | 26.37% | 7.83% | 7.17% | 7.03% | 7.03% | 7.03% |
| ± 1 STANDARD ERROR | 0.09% | 0.35% | 0.48% | 0.27% | 0.25% | 0.25% | 0.25% | 0.25% |
| SAMPLE SIZE | 14,520 | 9,380 | 3,700 | 1,050 | 810 | 750 | 650 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 186 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.66% | 98.55% | 98.15% | 97.73% | 97.52% | 97.52% | 97.52% | 97.52% |
| ± 1 STANDARD ERROR | 0.05% | 0.11% | 0.15% | 0.23% | 0.28% | 0.28% | 0.28% | 0.28% |

## BATTERY LONGEVITY SUMMARY

# Cardiac Resynchronization Therapy (CRT) ICDs

## Cardiac Resynchronization Therapy (CRT) ICDs

Battery Longevity (years)

| MODELS | FAMILY | NO PACING | 25% PACING | 50% PACING | 100% PACING |
|---|---|---|---|---|---|
| CDHFA500Q | Gallant™ HF CRT-D*** | 10.6 | 9.5 | 8.7 | 7.4 |
| CD3369-40Q | Quadra Assura MP™ CRT-D* | 9.5 | 9.9 | 8.9 | 7.4 |
| CD3369-40C | Quadra Assura MP™ CRT-D* | 8.7 | 9.9 | 8.9 | 7.4 |
| CD3365-40Q | Quadra Assura™ CRT-D* | 7.4 | 9.9 | 8.9 | 7.4 |
| CD3365-40C | Quadra Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3357-40Q | Unify Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3357-40C | Unify Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3265-40Q | Quadra Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3265-40 | Quadra Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3257-40Q | Unify Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3257-40 | Unify Assura™ CRT-D* | 11.1 | 9.9 | 8.9 | 7.4 |
| CD3249-40Q | Unify Quadra™ CRT-D* | 10.2 | 9.0 | 8.1 | 6.7 |
| CD3249-40 | Unify Quadra™ CRT-D* | 10.2 | 9.0 | 8.1 | 6.7 |
| CD3231-40Q | Unify™ CRT-D* | 10.1 | 9.0 | 8.1 | 6.7 |
| CD3231-40 | Unify™ CRT-D* | 10.1 | 9.0 | 8.1 | 6.7 |
| CD3211-36Q | Promote™ + CRT-D** | 8.2 | 7.2 | 6.5 | 5.4 |
| CD3211-36 | Promote™ + CRT-D** | 8.2 | 7.2 | 6.5 | 5.4 |
| 3207-36 | Promote™ RF CRT-D** | 8.2 | 7.2 | 6.5 | 5.4 |
| V-343 | Atlas™ + HF CRT-D** | 7.9 | 7.1 | 6.4 | 5.4 |

*Pacing parameters: DDD-BiV, RV 2.5V, LV 2.5V, A 2.5V, 0.5 ms, 60 ppm, 500 ohms*

**Battery voltage range: 3.20-2.59. Three maximum charges per year.*

***Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.*

****Capacitor maintenance interval: 1 charge per every 9 months.*

SUMMARY INFORMATION

# Cardiac Resynchronization Therapy (CRT) ICDs

# Cardiac Resynchronization Therapy (CRT) ICDs

## Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CDHFA500Q | Gallant™ HF CRT-D* | | | | | | | | | | |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 99.85% | 99.82% | 99.75% | 99.61% | 99.47% | | | | | |
| CD3369-40C | Quadra Assura MP™ CRT-D | 99.86% | 99.59% | 99.48% | 99.48% | 99.25% | | | | | |
| CD3365-40Q | Quadra Assura™ CRT-D | 99.85% | 99.77% | 99.65% | 99.19% | 98.90% | 98.78% | | | | |
| CD3365-40Q | Quadra Assura™ CRT-D† | 99.78% | 99.40% | 98.18% | 95.43% | 92.12% | 88.68% | 87.52% | | | |
| CD3365-40C | Quadra Assura™ CRT-D | 100.00% | 99.81% | 99.70% | 99.35% | 99.35% | | | | | |
| CD3365-40C | Quadra Assura™ CRT-D† | 99.74% | 99.27% | 98.39% | 96.76% | 94.20% | 90.96% | 90.29% | | | |
| CD3357-40Q | Unify Assura™ CRT-D | 99.95% | 99.82% | 99.61% | 99.00% | 98.70% | | | | | |
| CD3357-40Q | Unify Assura™ CRT-D† | 99.78% | 99.34% | 97.85% | 93.81% | 89.86% | 86.82% | 85.84% | | | |
| CD3357-40C | Unify Assura™ CRT-D | 99.92% | 99.85% | 99.53% | 98.90% | 98.82% | | | | | |
| CD3357-40C | Unify Assura™ CRT-D† | 99.81% | 99.44% | 97.67% | 94.91% | 90.67% | 85.62% | 84.78% | | | |
| CD3265-40Q | Quadra Assura™ CRT-D† | 99.83% | 99.74% | 99.38% | 97.73% | 94.38% | 92.65% | 90.77% | 89.01% | | |
| CD3265-40 | Quadra Assura™ CRT-D† | 99.94% | 99.76% | 99.62% | 98.30% | 93.30% | 91.29% | 90.12% | 88.88% | | |
| CD3257-40Q | Unify Assura™ CRT-D† | 99.92% | 99.73% | 98.02% | 93.56% | 88.74% | 87.53% | 86.42% | 85.46% | | |
| CD3257-40 | Unify Assura™ CRT-D† | 99.81% | 99.62% | 98.37% | 93.97% | 87.61% | 85.74% | 84.30% | 82.85% | | |
| CD3249-40Q | Unify Quadra™ CRT-D† | 99.87% | 99.84% | 99.38% | 97.66% | 92.65% | 88.56% | 86.96% | 84.15% | 82.74% | |
| CD3249-40 | Unify Quadra™ CRT-D† | 99.92% | 99.92% | 99.59% | 97.58% | 92.33% | 88.72% | 87.98% | 87.79% | 87.53% | |
| CD3231-40Q | Unify™ CRT-D† | 99.76% | 99.67% | 98.99% | 97.03% | 91.58% | 82.13% | 70.89% | 66.74% | 66.17% | 66.13% |
| CD3231-40 | Unify™ CRT-D† | 99.79% | 99.64% | 98.43% | 95.14% | 88.12% | 77.88% | 69.48% | 67.13% | 66.43% | 66.28% |
| CD3211-36Q | Promote™ + CRT-D | 99.54% | 98.95% | 97.83% | 93.42% | 81.68% | 46.73% | 22.56% | 20.35% | 19.90% | 19.76% |
| CD3211-36 | Promote™ + CRT-D | 99.53% | 99.33% | 97.83% | 92.49% | 75.48% | 42.50% | 23.89% | 22.13% | 21.85% | 21.70% |
| 3207-36 | Promote™ RF CRT-D | 99.61% | 99.00% | 97.45% | 93.95% | 84.47% | 55.45% | 28.49% | 23.64% | 22.69% | 22.49% |
| V-343 | Atlas™ + HF CRT-D | 99.66% | 98.61% | 94.47% | 82.29% | 56.24% | 26.37% | 9.91% | 7.83% | 7.31% | 7.17% |

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

*†Premature battery depletion advisory population.*

## Cardiac Resynchronization Therapy (CRT) ICDs

# Survival Probability Summary

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CDHFA500Q | Gallant™ HF CRT-D* | | | | | | | | | | |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 99.86% | 99.83% | 99.81% | 99.77% | 99.77% | | | | | |
| CD3369-40C | Quadra Assura MP™ CRT-D | 99.89% | 99.62% | 99.57% | 99.57% | 99.57% | | | | | |
| CD3365-40Q | Quadra Assura™ CRT-D | 99.85% | 99.77% | 99.72% | 99.68% | 99.68% | 99.65% | | | | |
| CD3365-40Q | Quadra Assura™ CRT-D† | 99.83% | 99.54% | 98.50% | 96.16% | 94.08% | 92.64% | 91.96% | | | |
| CD3365-40C | Quadra Assura™ CRT-D | 100.00% | 99.81% | 99.70% | 99.58% | 99.58% | | | | | |
| CD3365-40C | Quadra Assura™ CRT-D† | 99.78% | 99.31% | 98.43% | 97.41% | 96.14% | 94.91% | 94.41% | | | |
| CD3357-40Q | Unify Assura™ CRT-D | 99.95% | 99.87% | 99.87% | 99.84% | 99.79% | | | | | |
| CD3357-40Q | Unify Assura™ CRT-D† | 99.90% | 99.46% | 98.53% | 96.53% | 94.89% | 93.97% | 93.60% | | | |
| CD3357-40C | Unify Assura™ CRT-D | 99.92% | 99.89% | 99.85% | 99.81% | 99.81% | | | | | |
| CD3357-40C | Unify Assura™ CRT-D† | 99.89% | 99.62% | 98.62% | 97.00% | 95.64% | 94.76% | 94.27% | | | |
| CD3265-40Q | Quadra Assura™ CRT-D† | 99.87% | 99.85% | 99.64% | 98.87% | 97.11% | 96.08% | 95.57% | 95.23% | | |
| CD3265-40 | Quadra Assura™ CRT-D† | 99.94% | 99.82% | 99.68% | 98.78% | 97.87% | 96.89% | 96.49% | 96.49% | | |
| CD3257-40Q | Unify Assura™ CRT-D† | 100.00% | 100.00% | 99.90% | 98.36% | 97.59% | 96.88% | 96.43% | 96.43% | | |
| CD3257-40 | Unify Assura™ CRT-D† | 99.90% | 99.83% | 99.46% | 98.56% | 97.69% | 96.91% | 96.76% | 96.68% | | |
| CD3249-40Q | Unify Quadra™ CRT-D† | 99.95% | 99.95% | 99.85% | 99.29% | 98.53% | 97.57% | 97.19% | 96.83% | 96.83% | |
| CD3249-40 | Unify Quadra™ CRT-D† | 99.92% | 99.92% | 99.92% | 99.80% | 99.65% | 99.31% | 99.13% | 99.13% | 99.13% | |
| CD3231-40Q | Unify™ CRT-D† | 99.88% | 99.83% | 99.66% | 99.22% | 98.35% | 97.18% | 95.90% | 95.21% | 95.21% | 95.21% |
| CD3231-40 | Unify™ CRT-D† | 99.88% | 99.80% | 99.52% | 99.14% | 98.50% | 97.58% | 97.08% | 96.79% | 96.79% | 96.79% |
| CD3211-36Q | Promote™ + CRT-D | 99.84% | 99.46% | 99.07% | 98.70% | 98.54% | 97.87% | 97.09% | 96.91% | 96.91% | 96.91% |
| CD3211-36 | Promote™ + CRT-D | 99.79% | 99.72% | 99.37% | 98.84% | 98.65% | 97.76% | 97.26% | 97.12% | 97.12% | 97.12% |
| 3207-36 | Promote™ RF CRT-D | 99.77% | 99.51% | 99.20% | 98.90% | 98.59% | 97.73% | 97.13% | 97.08% | 97.08% | 97.08% |
| V-343 | Atlas™ + HF CRT-D | 99.88% | 99.66% | 99.22% | 98.55% | 98.40% | 98.15% | 97.94% | 97.73% | 97.52% | 97.52% |

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

*†Premature battery depletion advisory population.*

# Cardiac Resynchronization Therapy (CRT) ICDs

## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDHFA500Q | Gallant™ HF CRT-D | 4,352 | 0.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 68,769 | 2.20% | 7 | 0.01% | 8 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 4 | <0.01% | **20** | **0.03%** |
| CD3369-40C | Quadra Assura MP™ CRT-D | 8,461 | 2.80% | 2 | 0.02% | 2 | 0.02% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **5** | **0.06%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 16,495 | 4.10% | 2 | 0.01% | 3 | 0.02% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | **9** | **0.05%** |
| CD3365-40Q | Quadra Assura™ CRT-D† | 24,081 | 16.10% | 6 | 0.02% | 10 | 0.04% | 3 | 0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 42 | 0.17% | 6 | 0.02% | **69** | **0.29%** |
| CD3365-40C | Quadra Assura™ CRT-D | 2,648 | 5.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.08% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | **3** | **0.11%** |
| CD3365-40C | Quadra Assura™ CRT-D† | 5,626 | 19.80% | 6 | 0.11% | 2 | 0.04% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 8 | 0.14% | 3 | 0.05% | **20** | **0.36%** |
| CD3357-40Q | Unify Assura™ CRT-D | 17,255 | 3.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | **2** | **0.01%** |
| CD3357-40Q | Unify Assura™ CRT-D† | 5,340 | 19.60% | 1 | 0.02% | 2 | 0.04% | 0 | 0.00% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 10 | 0.19% | 0 | 0.00% | **15** | **0.28%** |
| CD3357-40C | Unify Assura™ CRT-D | 16,082 | 4.10% | 0 | 0.00% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **0.01%** |
| CD3357-40C | Unify Assura™ CRT-D† | 9,588 | 20.20% | 2 | 0.02% | 2 | 0.02% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 18 | 0.19% | 1 | 0.01% | **24** | **0.25%** |
| CD3265-40Q | Quadra Assura™ CRT-D† | 13,540 | 15.20% | 2 | 0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 24 | 0.18% | 1 | <0.01% | **30** | **0.22%** |
| CD3265-40 | Quadra Assura™ CRT-D† | 3,926 | 17.90% | 0 | 0.00% | 1 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 5 | 0.13% | 7 | 0.18% | **13** | **0.33%** |
| CD3257-40Q | Unify Assura™ CRT-D† | 2,716 | 20.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 5 | 0.18% | 2 | 0.07% | **8** | **0.29%** |
| CD3257-40 | Unify Assura™ CRT-D† | 6,744 | 18.80% | 6 | 0.09% | 1 | 0.01% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 10 | 0.15% | 1 | 0.01% | **19** | **0.28%** |
| CD3249-40Q | Unify Quadra™ CRT-D† | 8,948 | 16.10% | 4 | 0.04% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 16 | 0.18% | 3 | 0.03% | **24** | **0.27%** |
| CD3249-40 | Unify Quadra™ CRT-D† | 2,523 | 17.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | **1** | **0.04%** |
| CD3231-40Q | Unify™ CRT-D† | 19,028 | 19.50% | 2 | 0.01% | 1 | <0.01% | 14 | 0.07% | 16 | 0.08% | 0 | 0.00% | 1 | <0.01% | 56 | 0.29% | 8 | 0.04% | **98** | **0.52%** |
| CD3231-40 | Unify™ CRT-D† | 20,500 | 20.50% | 10 | 0.05% | 3 | 0.01% | 9 | 0.04% | 7 | 0.03% | 0 | 0.00% | 1 | <0.01% | 32 | 0.16% | 11 | 0.05% | **73** | **0.36%** |
| CD3211-36Q | Promote™ + CRT-D | 6,903 | 28.10% | 4 | 0.06% | 0 | 0.00% | 9 | 0.13% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 2 | 0.03% | 5 | 0.07% | **22** | **0.32%** |
| CD3211-36 | Promote™ + CRT-D | 8,646 | 28.20% | 3 | 0.03% | 0 | 0.00% | 11 | 0.13% | 2 | 0.02% | 1 | 0.01% | 0 | 0.00% | 5 | 0.06% | 5 | 0.06% | **27** | **0.31%** |
| 3207-36 | Promote™ RF CRT-D | 24,006 | 27.20% | 4 | 0.02% | 5 | 0.02% | 19 | 0.08% | 5 | 0.02% | 0 | 0.00% | 3 | 0.01% | 10 | 0.04% | 17 | 0.07% | **63** | **0.26%** |
| V-343 | Atlas™ + HF CRT-D | 18,776 | 25.30% | 3 | 0.02% | 0 | 0.00% | 40 | 0.21% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.04% | 10 | 0.05% | **60** | **0.32%** |

*Definitions of malfunction categories can be found on* *pages 5-6.*
*†Premature battery depletion advisory population.*

# Cardiac Resynchronization Therapy (CRT) ICDs

## US Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDHFA500Q | Gallant™ HF CRT-D | 4,352 | 0.40% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.02%** |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 68,769 | 2.20% | 9 | 0.01% | 1 | <0.01% | 1 | <0.01% | 2 | <0.01% | 0 | 0.00% | 5 | <0.01% | 2 | <0.01% | 6 | <0.01% | **26** | **0.04%** |
| CD3369-40C | Quadra Assura MP™ CRT-D | 8,461 | 2.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 3 | 0.04% | **6** | **0.07%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 16,495 | 4.10% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 3 | 0.02% | 4 | 0.02% | **13** | **0.08%** |
| CD3365-40Q | Quadra Assura™ CRT-D† | 24,081 | 16.10% | 14 | 0.06% | 0 | 0.00% | 17 | 0.07% | 0 | 0.00% | 3 | 0.01% | 2 | <0.01% | 377 | 1.57% | 7 | 0.03% | **420** | **1.74%** |
| CD3365-40C | Quadra Assura™ CRT-D | 2,648 | 5.30% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.04%** |
| CD3365-40C | Quadra Assura™ CRT-D† | 5,626 | 19.80% | 2 | 0.04% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 51 | 0.91% | 2 | 0.04% | **57** | **1.01%** |
| CD3357-40Q | Unify Assura™ CRT-D | 17,255 | 3.40% | 5 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 2 | 0.01% | **8** | **0.05%** |
| CD3357-40Q | Unify Assura™ CRT-D† | 5,340 | 19.60% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 66 | 1.24% | 3 | 0.06% | **71** | **1.33%** |
| CD3357-40C | Unify Assura™ CRT-D | 16,082 | 4.10% | 1 | <0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 3 | 0.02% | **8** | **0.05%** |
| CD3357-40C | Unify Assura™ CRT-D† | 9,588 | 20.20% | 3 | 0.03% | 1 | 0.01% | 5 | 0.05% | 0 | 0.00% | 2 | 0.02% | 1 | 0.01% | 97 | 1.01% | 3 | 0.03% | **112** | **1.17%** |
| CD3265-40Q | Quadra Assura™ CRT-D† | 13,540 | 15.20% | 6 | 0.04% | 0 | 0.00% | 7 | 0.05% | 0 | 0.00% | 2 | 0.01% | 2 | 0.01% | 104 | 0.77% | 1 | <0.01% | **122** | **0.90%** |
| CD3265-40 | Quadra Assura™ CRT-D† | 3,926 | 17.90% | 0 | 0.00% | 0 | 0.00% | 2 | 0.05% | 0 | 0.00% | 1 | 0.03% | 0 | 0.00% | 17 | 0.43% | 2 | 0.05% | **22** | **0.56%** |
| CD3257-40Q | Unify Assura™ CRT-D† | 2,716 | 20.30% | 0 | 0.00% | 0 | 0.00% | 2 | 0.07% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 12 | 0.44% | 0 | 0.00% | **15** | **0.55%** |
| CD3257-40 | Unify Assura™ CRT-D† | 6,744 | 18.80% | 3 | 0.04% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 4 | 0.06% | 0 | 0.00% | 29 | 0.43% | 1 | 0.01% | **38** | **0.56%** |
| CD3249-40Q | Unify Quadra™ CRT-D† | 8,948 | 16.10% | 3 | 0.03% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 36 | 0.40% | 0 | 0.00% | **41** | **0.46%** |
| CD3249-40 | Unify Quadra™ CRT-D† | 2,523 | 17.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 4 | 0.16% | 0 | 0.00% | **5** | **0.20%** |
| CD3231-40Q | Unify™ CRT-D† | 19,028 | 19.50% | 5 | 0.03% | 0 | 0.00% | 9 | 0.05% | 6 | 0.03% | 2 | 0.01% | 2 | 0.01% | 58 | 0.30% | 6 | 0.03% | **88** | **0.46%** |
| CD3231-40 | Unify™ CRT-D† | 20,500 | 20.50% | 5 | 0.02% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 44 | 0.21% | 11 | 0.05% | **66** | **0.32%** |
| CD3211-36Q | Promote™ + CRT-D | 6,903 | 28.10% | 3 | 0.04% | 0 | 0.00% | 5 | 0.07% | 0 | 0.00% | 11 | 0.16% | 0 | 0.00% | 0 | 0.00% | 6 | 0.09% | **25** | **0.36%** |
| CD3211-36 | Promote™ + CRT-D | 8,646 | 28.20% | 3 | 0.03% | 0 | 0.00% | 3 | 0.03% | 0 | 0.00% | 11 | 0.13% | 1 | 0.01% | 1 | 0.01% | 3 | 0.03% | **22** | **0.25%** |
| 3207-36 | Promote™ RF CRT-D | 24,006 | 27.20% | 6 | 0.02% | 3 | 0.01% | 9 | 0.04% | 1 | <0.01% | 15 | 0.06% | 10 | 0.04% | 6 | 0.02% | 17 | 0.07% | **67** | **0.28%** |
| V-343 | Atlas™ + HF CRT-D | 18,776 | 25.30% | 1 | <0.01% | 0 | 0.00% | 4 | 0.02% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 11 | 0.06% | 4 | 0.02% | **22** | **0.12%** |

*Definitions of malfunction categories can be found on pages 5-6.*
*†Premature battery depletion advisory population.*

## Cardiac Resynchronization Therapy (CRT) ICDs

Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDHFA500Q | Gallant™ HF CRT-D | 7,734 | 0.54% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 69,568 | 2.34% | 7 | 0.01% | 8 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 4 | <0.01% | **20** | **0.03%** |
| CD3369-40C | Quadra Assura MP™ CRT-D | 8,593 | 3.24% | 2 | 0.02% | 2 | 0.02% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **5** | **0.06%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 40,859 | 11.54% | 8 | 0.02% | 13 | 0.03% | 4 | <0.01% | 1 | <0.01% | 2 | <0.01% | 0 | 0.00% | 43 | 0.11% | 7 | 0.02% | **78** | **0.19%** |
| CD3365-40C | Quadra Assura™ CRT-D | 8,326 | 15.93% | 6 | 0.07% | 2 | 0.02% | 1 | 0.01% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 8 | 0.10% | 4 | 0.05% | **23** | **0.28%** |
| CD3357-40Q | Unify Assura™ CRT-D | 23,124 | 7.67% | 1 | <0.01% | 2 | <0.01% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | 10 | 0.04% | 1 | <0.01% | **17** | **0.07%** |
| CD3357-40C | Unify Assura™ CRT-D | 26,150 | 10.57% | 2 | <0.01% | 4 | 0.02% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 18 | 0.07% | 1 | <0.01% | **26** | **0.10%** |
| CD3265-40Q | Quadra Assura™ CRT-D | 13,955 | 15.76% | 2 | 0.01% | 2 | 0.01% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 24 | 0.17% | 1 | <0.01% | **31** | **0.22%** |
| CD3265-40 | Quadra Assura™ CRT-D | 4,046 | 18.59% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 6 | 0.15% | 7 | 0.17% | **14** | **0.35%** |
| CD3257-40Q | Unify Assura™ CRT-D | 2,727 | 21.12% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 5 | 0.18% | 2 | 0.07% | **8** | **0.29%** |
| CD3257-40 | Unify Assura™ CRT-D | 6,723 | 19.37% | 6 | 0.09% | 1 | 0.01% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 10 | 0.15% | 1 | 0.01% | **19** | **0.28%** |
| CD3249-40Q | Unify Quadra™ CRT-D | 11,373 | 14.60% | 5 | 0.04% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 17 | 0.15% | 4 | 0.04% | **27** | **0.24%** |
| CD3249-40 | Unify Quadra™ CRT-D | 4,695 | 11.76% | 3 | 0.06% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.02% | 1 | 0.02% | **7** | **0.15%** |
| CD3231-40Q | Unify™ CRT-D | 20,973 | 19.95% | 3 | 0.01% | 1 | <0.01% | 15 | 0.07% | 17 | 0.08% | 0 | 0.00% | 1 | <0.01% | 68 | 0.32% | 10 | 0.05% | **115** | **0.55%** |
| CD3231-40 | Unify™ CRT-D | 23,767 | 18.87% | 11 | 0.05% | 4 | 0.02% | 10 | 0.04% | 7 | 0.03% | 0 | 0.00% | 1 | <0.01% | 34 | 0.14% | 11 | 0.05% | **78** | **0.33%** |
| CD3211-36Q | Promote™ + CRT-D | 16,097 | 14.85% | 15 | 0.09% | 0 | 0.00% | 14 | 0.09% | 8 | 0.05% | 1 | <0.01% | 2 | 0.01% | 8 | 0.05% | 6 | 0.04% | **54** | **0.34%** |
| CD3211-36 | Promote™ + CRT-D | 21,011 | 12.82% | 14 | 0.07% | 2 | <0.01% | 15 | 0.07% | 6 | 0.03% | 1 | <0.01% | 0 | 0.00% | 9 | 0.04% | 14 | 0.07% | **61** | **0.29%** |
| 3207-36 | Promote™ RF CRT-D | 25,838 | 27.05% | 5 | 0.02% | 5 | 0.02% | 22 | 0.09% | 5 | 0.02% | 0 | 0.00% | 3 | 0.01% | 10 | 0.04% | 20 | 0.08% | **70** | **0.27%** |
| V-343 | Atlas™ + HF CRT-D | 19,292 | 25.07% | 3 | 0.02% | 0 | 0.00% | 41 | 0.21% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.04% | 10 | 0.05% | **61** | **0.32%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Cardiac Resynchronization Therapy (CRT) ICDs

## Worldwide Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDHFA500Q | Gallant™ HF CRT-D | 7,734 | 0.54% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.01%** |
| CD3369-40Q | Quadra Assura MP™ CRT-D | 69,568 | 2.34% | 9 | 0.01% | 1 | <0.01% | 1 | <0.01% | 2 | <0.01% | 0 | 0.00% | 5 | <0.01% | 2 | <0.01% | 6 | <0.01% | **26** | **0.04%** |
| CD3369-40C | Quadra Assura MP™ CRT-D | 8,593 | 3.24% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 3 | 0.03% | **6** | **0.07%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 40,859 | 11.54% | 16 | 0.04% | 0 | 0.00% | 17 | 0.04% | 0 | 0.00% | 3 | <0.01% | 6 | 0.01% | 383 | 0.94% | 11 | 0.03% | **436** | **1.07%** |
| CD3365-40C | Quadra Assura™ CRT-D | 8,326 | 15.93% | 3 | 0.04% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 51 | 0.61% | 2 | 0.02% | **58** | **0.70%** |
| CD3357-40Q | Unify Assura™ CRT-D | 23,124 | 7.67% | 7 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 69 | 0.30% | 5 | 0.02% | **83** | **0.36%** |
| CD3357-40C | Unify Assura™ CRT-D | 26,150 | 10.57% | 4 | 0.02% | 2 | <0.01% | 6 | 0.02% | 0 | 0.00% | 2 | <0.01% | 2 | <0.01% | 102 | 0.39% | 6 | 0.02% | **124** | **0.47%** |
| CD3265-40Q | Quadra Assura™ CRT-D | 13,955 | 15.76% | 6 | 0.04% | 0 | 0.00% | 7 | 0.05% | 0 | 0.00% | 2 | 0.01% | 3 | 0.02% | 105 | 0.75% | 1 | <0.01% | **124** | **0.89%** |
| CD3265-40 | Quadra Assura™ CRT-D | 4,046 | 18.59% | 0 | 0.00% | 0 | 0.00% | 2 | 0.05% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 18 | 0.44% | 2 | 0.05% | **23** | **0.57%** |
| CD3257-40Q | Unify Assura™ CRT-D | 2,727 | 21.12% | 0 | 0.00% | 0 | 0.00% | 2 | 0.07% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 12 | 0.44% | 0 | 0.00% | **15** | **0.55%** |
| CD3257-40 | Unify Assura™ CRT-D | 6,723 | 19.37% | 3 | 0.04% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 4 | 0.06% | 0 | 0.00% | 29 | 0.43% | 1 | 0.01% | **38** | **0.57%** |
| CD3249-40Q | Unify Quadra™ CRT-D | 11,373 | 14.60% | 3 | 0.03% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 41 | 0.36% | 4 | 0.04% | **50** | **0.44%** |
| CD3249-40 | Unify Quadra™ CRT-D | 4,695 | 11.76% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.02% | 5 | 0.11% | 0 | 0.00% | **7** | **0.15%** |
| CD3231-40Q | Unify™ CRT-D | 20,973 | 19.95% | 6 | 0.03% | 0 | 0.00% | 10 | 0.05% | 6 | 0.03% | 2 | <0.01% | 3 | 0.01% | 62 | 0.30% | 6 | 0.03% | **95** | **0.45%** |
| CD3231-40 | Unify™ CRT-D | 23,767 | 18.87% | 7 | 0.03% | 0 | 0.00% | 5 | 0.02% | 0 | 0.00% | 3 | 0.01% | 1 | <0.01% | 49 | 0.21% | 12 | 0.05% | **77** | **0.32%** |
| CD3211-36Q | Promote™ + CRT-D | 16,097 | 14.85% | 6 | 0.04% | 0 | 0.00% | 7 | 0.04% | 0 | 0.00% | 16 | 0.10% | 2 | 0.01% | 4 | 0.02% | 9 | 0.06% | **44** | **0.27%** |
| CD3211-36 | Promote™ + CRT-D | 21,011 | 12.82% | 7 | 0.03% | 0 | 0.00% | 4 | 0.02% | 0 | 0.00% | 19 | 0.09% | 2 | <0.01% | 2 | <0.01% | 9 | 0.04% | **43** | **0.20%** |
| 3207-36 | Promote™ RF CRT-D | 25,838 | 27.05% | 7 | 0.03% | 3 | 0.01% | 10 | 0.04% | 1 | <0.01% | 17 | 0.07% | 10 | 0.04% | 7 | 0.03% | 18 | 0.07% | **73** | **0.28%** |
| V-343 | Atlas™ + HF CRT-D | 19,292 | 25.07% | 1 | <0.01% | 0 | 0.00% | 4 | 0.02% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 11 | 0.06% | 4 | 0.02% | **22** | **0.11%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Cardiac Resynchronization Therapy (CRT) ICDs

Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | INAPPROPRIATE SHOCK | | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD3369-40Q | 117 | 88 | 4,541 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3365-40Q | 235 | 109 | 11,290 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.43% | **1** | **0.43%** |
| CD3357-40Q | 269 | 158 | 12,138 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3357-40C | 232 | 82 | 8,427 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 1.72% | 1 | 0.43% | **5** | **2.16%** |
| CD3265-40Q | 421 | 143 | 20,772 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.24% | 0 | 0.00% | **1** | **0.24%** |
| CD3265-40 | 100 | 37 | 5,234 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 1.00% | 0 | 0.00% | **1** | **1.00%** |
| CD3249-40Q | 989 | 366 | 54,992 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.30% | 1 | 0.10% | **4** | **0.40%** |
| CD3249-40 | 245 | 65 | 12,082 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.41% | **1** | **0.41%** |
| CD3231-40Q | 1,680 | 651 | 110,964 | 2 | 0.12% | 0 | 0.00% | 0 | 0.00% | 10 | 0.60% | 1 | 0.06% | **13** | **0.77%** |
| CD3231-40 | 689 | 165 | 36,841 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.44% | 1 | 0.15% | **4** | **0.58%** |
| CD3211-36Q | 856 | 207 | 52,414 | 3 | 0.35% | 0 | 0.00% | 0 | 0.00% | 2 | 0.23% | 2 | 0.23% | **7** | **0.82%** |
| CD3211-36 | 222 | 11 | 9,558 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.90% | **2** | **0.90%** |
| 3207-36 | 672 | 18 | 30,581 | 1 | 0.15% | 0 | 0.00% | 0 | 0.00% | 4 | 0.60% | 2 | 0.30% | **7** | **1.04%** |

*A list of of complications can be found on page 12.*

# Cardiac Resynchronization Therapy (CRT) ICDs

## Actively Monitored Study Data Summary

### MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD3369-40Q | Quadra Assura™ CRT-D | 117 | 2.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 235 | 17.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3357-40Q | Unify Assura™ CRT-D | 269 | 16.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3357-40C | Unify Assura™ CRT-D | 232 | 17.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3265-40Q | Quadra Assura™ CRT-D | 421 | 21.10% | 0 | 0.00% | 1 | 0.24% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.24%** |
| CD3265-40 | Quadra Assura™ CRT-D | 100 | 17.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 1.00% | 0 | 0.00% | **1** | **1.00%** |
| CD3249-40Q | Unify Quadra™ CRT-D | 989 | 17.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.10% | 1 | 0.10% | **2** | **0.20%** |
| CD3249-40 | Unify Quadra™ CRT-D | 245 | 24.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3231-40Q | Unify™ CRT-D | 1,680 | 21.90% | 0 | 0.00% | 0 | 0.00% | 1 | 0.06% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 12 | 0.71% | 2 | 0.12% | **16** | **0.95%** |
| CD3231-40 | Unify™ CRT-D | 689 | 24.10% | 1 | 0.15% | 1 | 0.15% | 1 | 0.15% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.15% | 0 | 0.00% | **4** | **0.58%** |
| CD3211-36Q | Promote™ + CRT-D | 856 | 32.80% | 1 | 0.12% | 0 | 0.00% | 1 | 0.12% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.23% | 0 | 0.00% | **4** | **0.47%** |
| CD3211-36 | Promote™ + CRT-D | 222 | 28.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 3207-36 | Promote™ RF CRT-D | 672 | 35.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.30% | **2** | **0.30%** |

### MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD3369-40Q | Quadra Assura™ CRT-D | 117 | 2.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3365-40Q | Quadra Assura™ CRT-D | 235 | 17.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.85% | 0 | 0.00% | **2** | **0.85%** |
| CD3357-40Q | Unify Assura™ CRT-D | 269 | 16.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.74% | 0 | 0.00% | **2** | **0.74%** |
| CD3357-40C | Unify Assura™ CRT-D | 232 | 17.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 1.72% | 0 | 0.00% | **4** | **1.72%** |
| CD3265-40Q | Quadra Assura™ CRT-D | 421 | 21.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.24% | 0 | 0.00% | **1** | **0.24%** |
| CD3265-40 | Quadra Assura™ CRT-D | 100 | 17.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 1.00% | 0 | 0.00% | **1** | **1.00%** |
| CD3249-40Q | Unify Quadra™ CRT-D | 989 | 17.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.30% | 1 | 0.10% | **4** | **0.40%** |
| CD3249-40 | Unify Quadra™ CRT-D | 245 | 24.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD3231-40Q | Unify™ CRT-D | 1,680 | 21.90% | 1 | 0.06% | 0 | 0.00% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 1 | 0.06% | 4 | 0.24% | 0 | 0.00% | **7** | **0.42%** |
| CD3231-40 | Unify™ CRT-D | 689 | 24.10% | 0 | 0.00% | 0 | 0.00% | 2 | 0.29% | 0 | 0.00% | 1 | 0.15% | 0 | 0.00% | 2 | 0.29% | 1 | 0.15% | **6** | **0.87%** |
| CD3211-36Q | Promote™ + CRT-D | 856 | 32.80% | 1 | 0.12% | 0 | 0.00% | 1 | 0.12% | 0 | 0.00% | 0 | 0.00% | 1 | 0.12% | 0 | 0.00% | 0 | 0.00% | **3** | **0.35%** |
| CD3211-36 | Promote™ + CRT-D | 222 | 28.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 1.35% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **1.35%** |
| 3207-36 | Promote™ RF CRT-D | 672 | 35.60% | 1 | 0.15% | 0 | 0.00% | 1 | 0.15% | 0 | 0.00% | 1 | 0.15% | 0 | 0.00% | 1 | 0.15% | 1 | 0.15% | **5** | **0.74%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Cardiac Resynchronization Therapy (CRT) Pacemakers

# Cardiac Resynchronization Therapy (CRT) Pacemakers

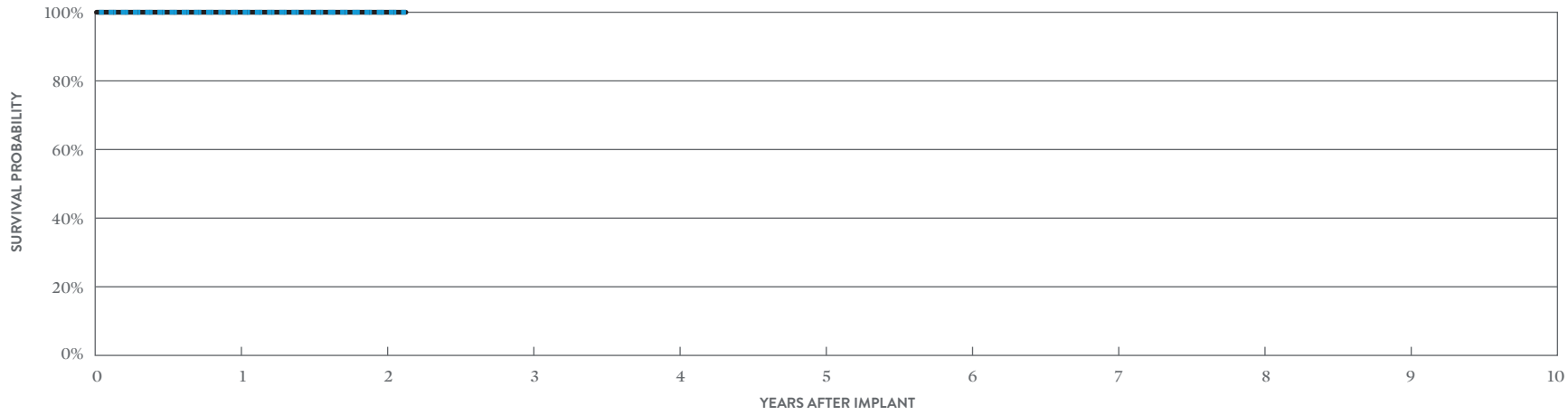
**CUSTOMER REPORTED PERFORMANCE DATA**

## Allure Quadra MP™ CRT-P

### MODEL PM3562

| | |
|---|---|
| US Regulatory Approval | January 2019 |
| Registered US Implants | 14,873 |
| Estimated Active US Implants | 13,214 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 0 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | AT 26 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 10,860 | 3,810 | 410 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | AT 26 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

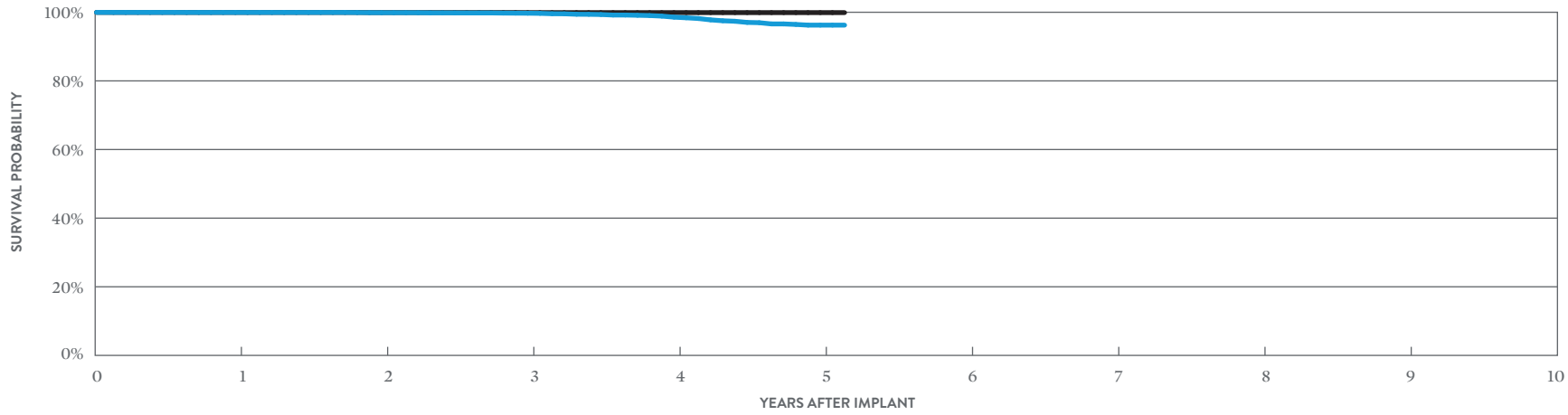
**CUSTOMER REPORTED PERFORMANCE DATA**

## Allure Quadra MP™ CRT-P

### MODEL PM3262

| | |
|---|---|
| US Regulatory Approval | February 2016 |
| Registered US Implants | 19,957 |
| Estimated Active US Implants | 13,993 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 77 |
| Number of US Advisories (see pg. 321) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | <0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 3 | 0.02% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 1 | <0.01% |
| **Total** | **3** | **0.02%** | **4** | **0.02%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 62 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.88% | 99.72% | 98.57% | 96.25% | 96.25% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.04% | 0.11% | 0.32% | 0.32% |
| SAMPLE SIZE | 18,880 | 16,820 | 13,210 | 8,080 | 3,030 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 62 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.92% | 99.90% | 99.90% | 99.90% | 99.90% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

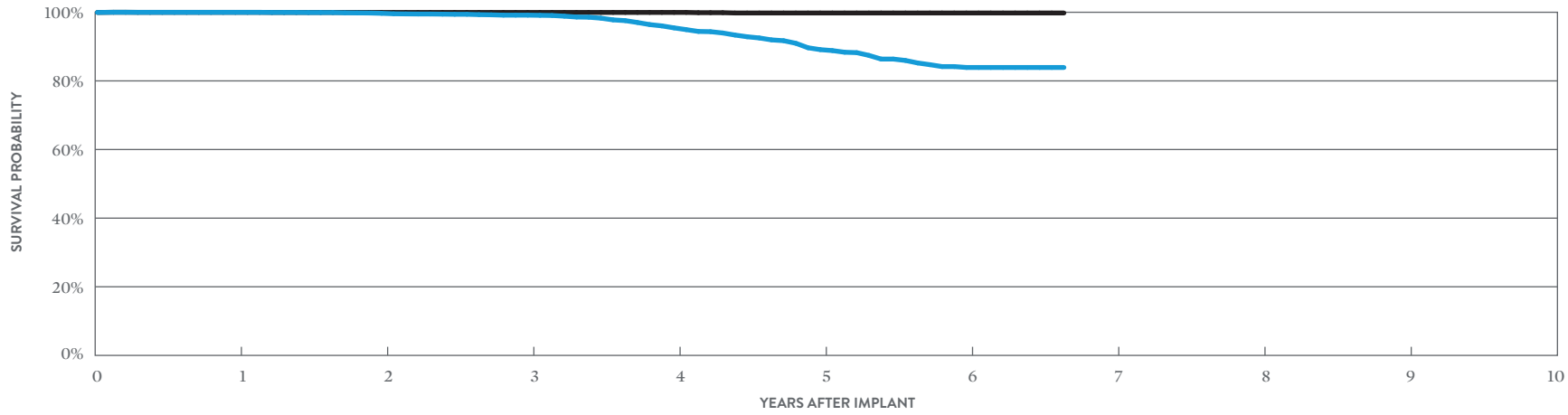
**CUSTOMER REPORTED PERFORMANCE DATA**

## Allure™ RF CRT-P

### MODEL PM3222

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 10,269 |
| Estimated Active US Implants | 6,689 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 153 |
| Number of US Advisories (see pg. 321) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 3 | 0.03% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **<0.01%** | **3** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 80 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.69% | 99.16% | 95.45% | 89.11% | 83.91% | 83.91% |
| ± 1 STANDARD ERROR | 0.02% | 0.06% | 0.12% | 0.32% | 0.59% | 0.84% | 0.86% |
| SAMPLE SIZE | 8,980 | 6,770 | 5,060 | 3,570 | 2,250 | 1,110 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 80 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.95% | 99.95% | 99.95% | 99.79% | 99.79% | 99.79% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.02% | 0.02% | 0.08% | 0.08% | 0.08% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

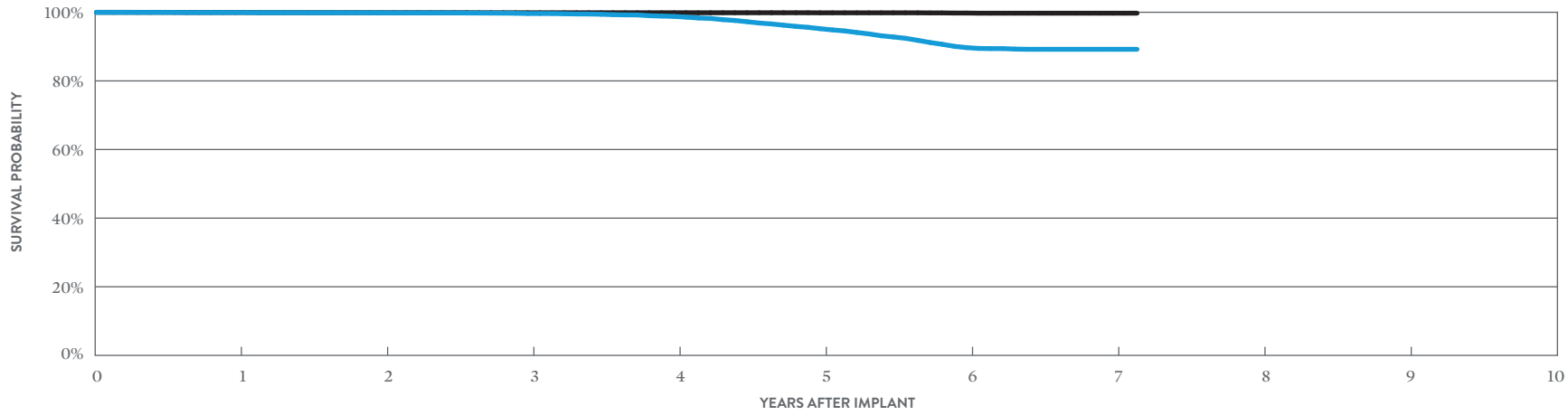
**CUSTOMER REPORTED PERFORMANCE DATA**

## Allure Quadra™ RF CRT-P

### MODEL PM3242

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 18,329 |
| Estimated Active US Implants | 9,912 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 387 |
| Number of US Advisories (see pg. 321) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 2 | 0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 1 | <0.01% | 11 | 0.06% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **<0.01%** | **13** | **0.07%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 86 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.83% | 99.63% | 98.79% | 95.21% | 89.70% | 89.21% | 89.21% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.09% | 0.19% | 0.32% | 0.34% | 0.34% |
| SAMPLE SIZE | 17,150 | 15,240 | 13,820 | 12,470 | 10,780 | 7,210 | 2,580 | 300 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 86 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.88% | 99.86% | 99.86% | 99.84% | 99.77% | 99.73% | 99.73% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.05% | 0.06% | 0.06% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

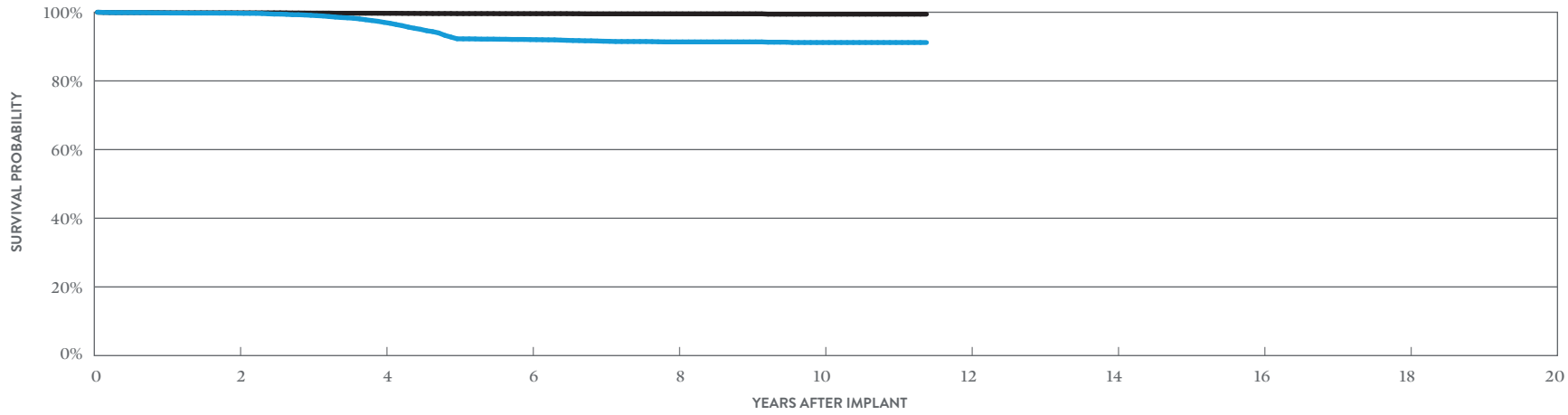
**CUSTOMER REPORTED PERFORMANCE DATA**

## Anthem™ RF CRT-P

### MODEL PM3210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 20,448 |
| Estimated Active US Implants | 5,792 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 388 |
| Number of US Advisories (see pgs. 321, 323) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.01% | 3 | 0.01% |
| Electrical Interconnect | 3 | 0.01% | 1 | <0.01% |
| Battery | 0 | 0.00% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 7 | 0.03% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | <0.01% | 3 | 0.01% |
| Other | 0 | 0.00% | 9 | 0.04% |
| **Total** | **7** | **0.03%** | **24** | **0.12%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 137 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.71% | 97.06% | 92.03% | 91.36% | 91.18% | 91.18% |
| ± 1 STANDARD ERROR | 0.04% | 0.14% | 0.25% | 0.26% | 0.28% | 0.28% |
| SAMPLE SIZE | 16,140 | 12,640 | 9,680 | 5,880 | 1,950 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 137 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.69% | 99.58% | 99.53% | 99.44% | 99.44% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.06% | 0.09% | 0.09% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

ACTIVELY MONITORED STUDY DATA

## Anthem™ RF CRT-P

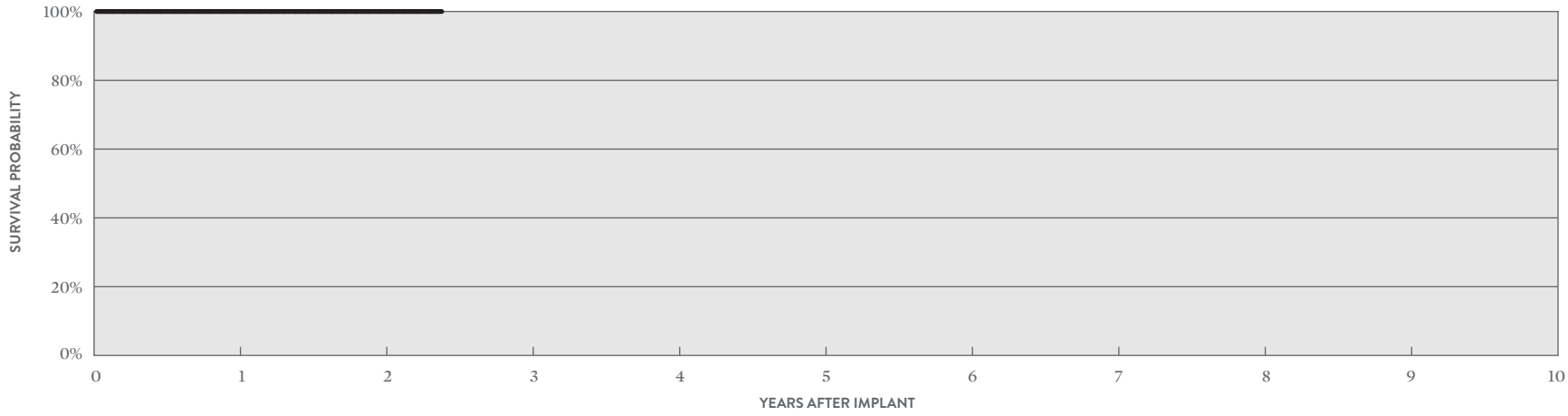
### MODEL PM3210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Number of Devices Enrolled in Study | 202 |
| Active Devices Enrolled in Study | 12 |
| Cumulative Months of Follow-up | 5,604 |
| Estimated Longevity | 8 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | AT 29 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 170 | 110 | 50 |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

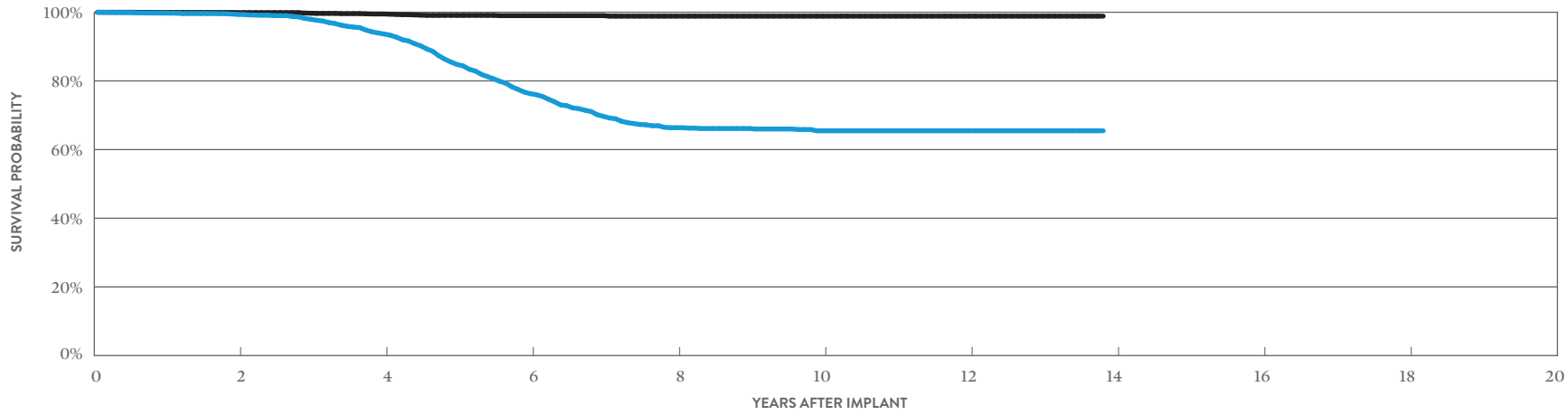
**CUSTOMER REPORTED PERFORMANCE DATA**

## Frontier™ II CRT-P

### MODEL 5586

| | |
|---|---|
| US Regulatory Approval | August 2004 |
| Registered US Implants | 6,911 |
| Estimated Active US Implants | 774 |
| Estimated Longevity | 6.5 Years |
| Normal Battery Depletion | 381 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 7 | 0.10% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 7 | 0.10% |
| Other | 1 | 0.01% | 3 | 0.04% |
| **Total** | **1** | **0.01%** | **17** | **0.25%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 166 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.37% | 93.68% | 76.28% | 66.37% | 65.47% | 65.47% | 65.47% |
| ± 1 STANDARD ERROR | 0.10% | 0.38% | 0.76% | 0.92% | 0.94% | 0.94% | 0.94% |
| SAMPLE SIZE | 5,050 | 3,530 | 2,230 | 1,300 | 920 | 730 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 166 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.49% | 99.00% | 98.86% | 98.86% | 98.86% | 98.86% |
| ± 1 STANDARD ERROR | 0.03% | 0.11% | 0.17% | 0.20% | 0.20% | 0.20% | 0.20% |

SUMMARY INFORMATION

# Cardiac Resynchronization Therapy (CRT) Pacemakers

# Cardiac Resynchronization Therapy (CRT) Pacemakers

## Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM3562 | Allure Quadra MP™ CRT-P | 100.00% | 100.00% | | | | | | | | |
| PM3262 | Allure Quadra MP™ CRT-P | 99.95% | 99.88% | 99.72% | 98.57% | 96.25% | | | | | |
| PM3222 | Allure™ RF CRT-P | 99.98% | 99.69% | 99.16% | 95.45% | 89.11% | 83.91% | | | | |
| PM3242 | Allure Quadra™ RF CRT-P | 99.92% | 99.83% | 99.63% | 98.79% | 95.21% | 89.70% | 89.21% | | | |
| PM3210 | Anthem™ RF CRT-P | 99.81% | 99.71% | 99.11% | 97.06% | 92.26% | 92.03% | 91.56% | 91.36% | 91.36% | 91.18% |
| 5586 | Frontier™ II CRT-P | 99.76% | 99.37% | 97.95% | 93.68% | 84.77% | 76.28% | 69.68% | 66.37% | 66.13% | 65.47% |

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM3562 | Allure Quadra MP™ CRT-P | 100.00% | 100.00% | | | | | | | | |
| PM3262 | Allure Quadra MP™ CRT-P | 99.95% | 99.92% | 99.90% | 99.90% | 99.90% | | | | | |
| PM3222 | Allure™ RF CRT-P | 99.98% | 99.95% | 99.95% | 99.95% | 99.79% | 99.79% | | | | |
| PM3242 | Allure Quadra™ RF CRT-P | 99.94% | 99.88% | 99.86% | 99.86% | 99.84% | 99.77% | 99.73% | | | |
| PM3210 | Anthem™ RF CRT-P | 99.87% | 99.83% | 99.75% | 99.69% | 99.60% | 99.58% | 99.53% | 99.53% | 99.53% | 99.44% |
| 5586 | Frontier™ II CRT-P | 99.93% | 99.89% | 99.71% | 99.49% | 99.09% | 99.00% | 99.00% | 98.86% | 98.86% | 98.86% |

# Cardiac Resynchronization Therapy (CRT) Pacemakers

## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3562 | Allure Quadra MP™ CRT-P | 14,873 | 1.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM3262 | Allure Quadra MP™ CRT-P | 19,957 | 4.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.02% | 0 | 0.00% | 0 | 0.00% | **3** | **0.02%** |
| PM3222 | Allure™ RF CRT-P | 10,269 | 6.10% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| PM3242 | Allure Quadra™ RF CRT-P | 18,329 | 8.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| PM3210 | Anthem™ RF CRT-P | 20,448 | 18.90% | 3 | 0.01% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | **7** | **0.03%** |
| 5586 | Frontier™ II CRT-P | 6,911 | 19.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | **1** | **0.01%** |

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3562 | Allure Quadra MP™ CRT-P | 14,873 | 1.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM3262 | Allure Quadra MP™ CRT-P | 19,957 | 4.60% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | **4** | **0.02%** |
| PM3222 | Allure™ RF CRT-P | 10,269 | 6.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.03% | 0 | 0.00% | 0 | 0.00% | **3** | **0.03%** |
| PM3242 | Allure Quadra™ RF CRT-P | 18,329 | 8.60% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 11 | 0.06% | 0 | 0.00% | 0 | 0.00% | **13** | **0.07%** |
| PM3210 | Anthem™ RF CRT-P | 20,448 | 18.90% | 3 | 0.01% | 1 | <0.01% | 1 | <0.01% | 7 | 0.03% | 0 | 0.00% | 3 | 0.01% | 9 | 0.04% | **24** | **0.12%** |
| 5586 | Frontier™ II CRT-P | 6,911 | 19.60% | 7 | 0.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.10% | 3 | 0.04% | **17** | **0.25%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Cardiac Resynchronization Therapy (CRT) Pacemakers

## Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3562 | Allure Quadra MP™ CRT-P | 36,676 | 0.64% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM3262 | Allure Quadra MP™ CRT-P | 35,637 | 2.56% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.01% | 1 | <0.01% | 0 | 0.00% | **4** | **0.01%** |
| PM3222 | Allure™ RF CRT-P | 32,833 | 1.98% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **0.01%** |
| PM3242 | Allure Quadra™ RF CRT-P | 36,857 | 4.39% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | **2** | **0.01%** |
| PM3210 | Anthem™ RF CRT-P | 21,093 | 18.14% | 3 | 0.01% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | **7** | **0.03%** |

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3562 | Allure Quadra MP™ CRT-P | 36,676 | 0.64% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | **4** | **0.01%** |
| PM3262 | Allure Quadra MP™ CRT-P | 35,637 | 2.56% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | **3** | **0.01%** |
| PM3222 | Allure™ RF CRT-P | 32,833 | 1.98% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | **3** | **0.01%** |
| PM3242 | Allure Quadra™ RF CRT-P | 36,857 | 4.39% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 14 | 0.04% | 1 | <0.01% | 1 | <0.01% | **19** | **0.05%** |
| PM3210 | Anthem™ RF CRT-P | 21,093 | 18.14% | 3 | 0.01% | 1 | <0.01% | 1 | <0.01% | 7 | 0.03% | 0 | 0.00% | 3 | 0.01% | 9 | 0.04% | **24** | **0.11%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Cardiac Resynchronization Therapy (CRT) Pacemakers

Actively Monitored Study Data Summary

## QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3210 | 202 | 12 | 5,604 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

## MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3210 | Anthem™ RF | 202 | 30.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

## MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM3210 | Anthem™ RF | 202 | 30.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*A list of of complications can be found on page 12.*
*Definitions of malfunction categories can be found on pages 5-6.*

# Left-Heart Leads

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

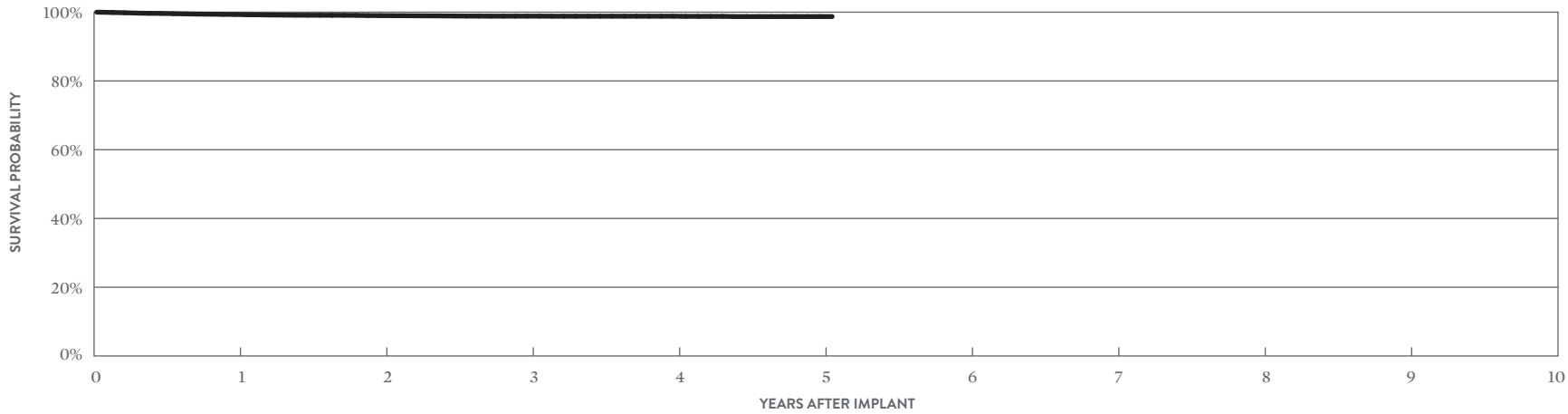
## Quartet™

### MODEL 1458QL

| | |
|---|---|
| US Regulatory Approval | October 2015 |
| Registered US Implants | 14,845 |
| Estimated Active US Implants | 11,177 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Quadpolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 1 | <0.01% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 28 | 0.19% | 94 | 0.63% |
| Failure to Capture | 17 | 0.11% | 29 | 0.20% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 2 | 0.01% | 0 | 0.00% |
| Abnormal Pacing Impedance | 5 | 0.03% | 10 | 0.07% |
| Extracardiac Stimulation | 27 | 0.18% | 29 | 0.20% |
| Other | 6 | 0.04% | 5 | 0.03% |
| **Total** | **86** | **0.58%** | **167** | **1.12%** |
| **Total Returned for Analysis** | **21** | | **51** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 48 | 0.32% |
| **Total** | **48** | **0.32%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | AT 61 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.34% | 99.00% | 98.84% | 98.82% | 98.72% | 98.72% |
| ± 1 STANDARD ERROR | 0.07% | 0.09% | 0.11% | 0.11% | 0.13% | 0.13% |
| SAMPLE SIZE | 12,750 | 9,070 | 6,160 | 3,690 | 1,400 | 240 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

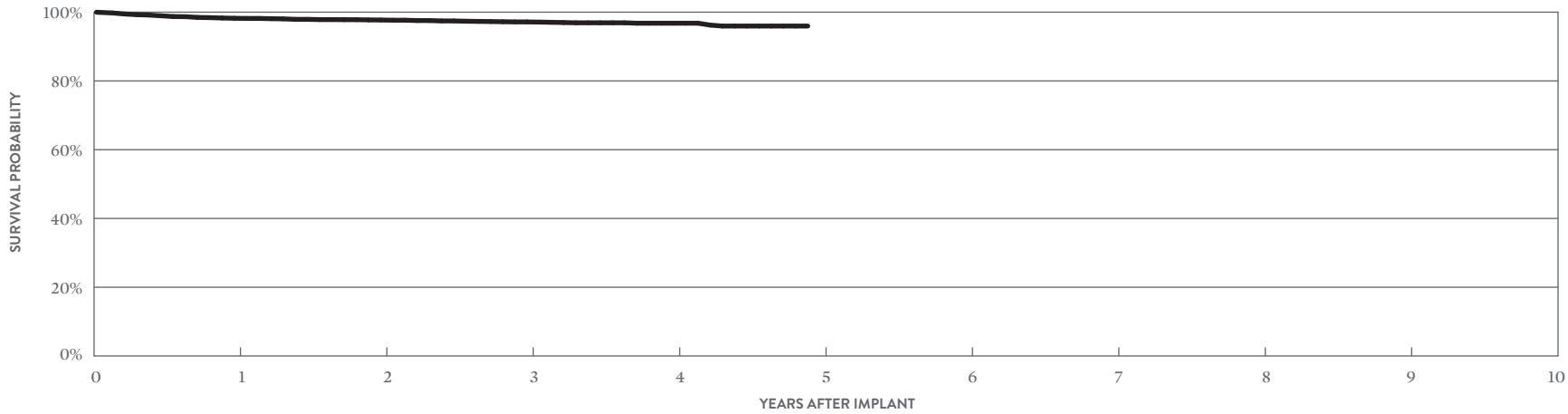
## Quartet™

### MODEL 1457Q

| | |
|---|---|
| US Regulatory Approval | March 2017 |
| Registered US Implants | 7,878 |
| Estimated Active US Implants | 5,850 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Quadpolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 1 | 0.01% | 0 | 0.00% |
| Lead Dislodgement | 38 | 0.48% | 120 | 1.52% |
| Failure to Capture | 9 | 0.11% | 33 | 0.42% |
| Oversensing | 1 | 0.01% | 2 | 0.03% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 2 | 0.03% |
| Abnormal Pacing Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 15 | 0.19% | 12 | 0.15% |
| Other | 7 | 0.09% | 5 | 0.06% |
| **Total** | **71** | **0.90%** | **174** | **2.21%** |
| **Total Returned for Analysis** | **19** | | **70** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 76 | 0.96% |
| **Total** | **76** | **0.96%** |




| YEAR | 1 | 2 | 3 | 4 | AT 59 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.22% | 97.72% | 97.17% | 96.79% | 95.96% |
| ± 1 STANDARD ERROR | 0.16% | 0.20% | 0.25% | 0.30% | 0.57% |
| SAMPLE SIZE | 6,420 | 4,070 | 2,440 | 1,100 | 200 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

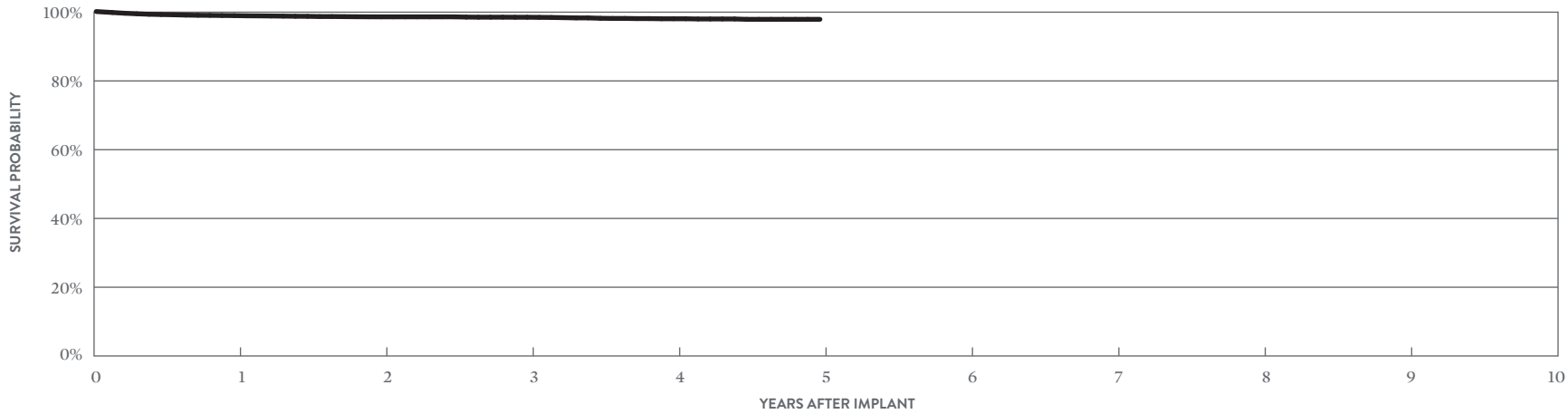
## Quartet™

### MODEL 1456Q

| | |
|---|---|
| US Regulatory Approval | October 2015 |
| Registered US Implants | 11,311 |
| Estimated Active US Implants | 8,507 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Quadpolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 2 | 0.02% | 1 | <0.01% |
| Conductor Fracture | 2 | 0.02% | 1 | <0.01% |
| Lead Dislodgement | 34 | 0.30% | 106 | 0.94% |
| Failure to Capture | 12 | 0.11% | 33 | 0.29% |
| Oversensing | 1 | <0.01% | 0 | 0.00% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 1 | <0.01% | 0 | 0.00% |
| Abnormal Pacing Impedance | 4 | 0.04% | 1 | <0.01% |
| Extracardiac Stimulation | 13 | 0.11% | 17 | 0.15% |
| Other | 6 | 0.05% | 2 | 0.02% |
| **Total** | **75** | **0.66%** | **161** | **1.42%** |
| **Total Returned for Analysis** | **20** | | **83** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 2 | 0.02% |
| Lead-to-Can Contact | 2 | 0.02% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 4 | 0.04% |
| Extrinsic Factors | 81 | 0.72% |
| **Total** | **87** | **0.77%** |




| YEAR | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.00% | 98.64% | 98.52% | 98.08% | 97.92% |
| ± 1 STANDARD ERROR | 0.10% | 0.12% | 0.13% | 0.19% | 0.22% |
| SAMPLE SIZE | 9,580 | 6,710 | 4,520 | 2,620 | 280 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

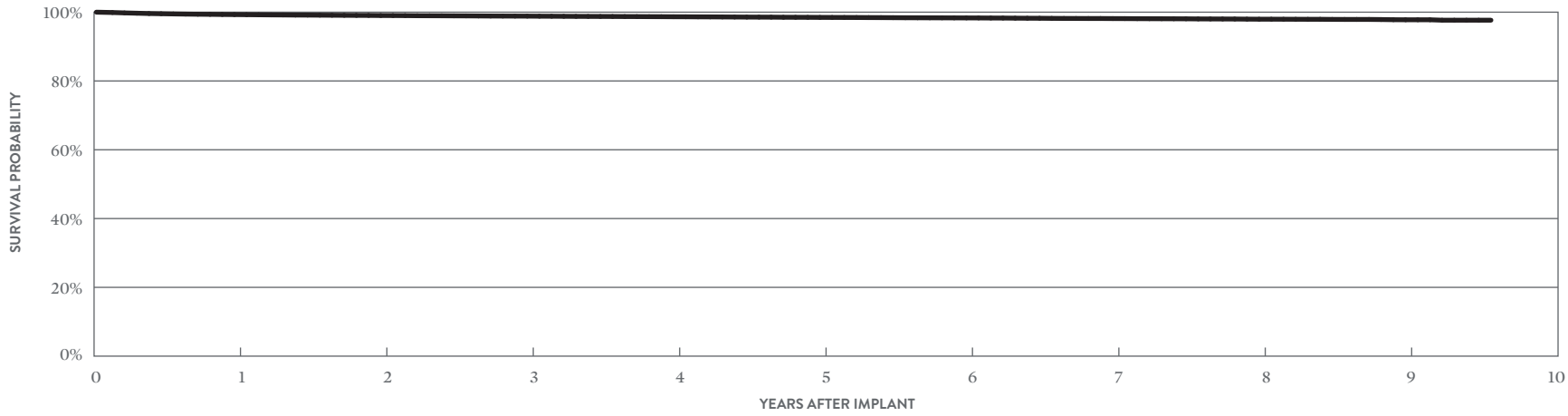
## Quartet™

### MODEL 1458Q

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Registered US Implants | 168,864 |
| Estimated Active US Implants | 99,079 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Quadpolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 6 | <0.01% | 5 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 36 | 0.02% |
| Lead Dislodgement | 286 | 0.17% | 1252 | 0.74% |
| Failure to Capture | 126 | 0.07% | 627 | 0.37% |
| Oversensing | 4 | <0.01% | 26 | 0.02% |
| Failure to Sense | 0 | 0.00% | 2 | <0.01% |
| Insulation Breach | 1 | <0.01% | 15 | <0.01% |
| Abnormal Pacing Impedance | 6 | <0.01% | 136 | 0.08% |
| Extracardiac Stimulation | 117 | 0.07% | 228 | 0.14% |
| Other | 122 | 0.07% | 65 | 0.04% |
| **Total** | **668** | **0.40%** | **2392** | **1.42%** |
| **Total Returned for Analysis** | **242** | | **868** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 10 | <0.01% |
| Clavicular Crush | 1 | <0.01% |
| In the Pocket | 3 | <0.01% |
| Intravascular | 6 | <0.01% |
| Insulation Breach | 8 | <0.01% |
| Lead-to-Can Contact | 3 | <0.01% |
| Lead-to-Lead Contact | 3 | <0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 2 | <0.01% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 15 | <0.01% |
| Extrinsic Factors | 828 | 0.49% |
| **Total** | **862** | **0.51%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 115 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.30% | 99.03% | 98.85% | 98.67% | 98.48% | 98.33% | 98.14% | 97.96% | 97.79% | 97.67% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.04% | 0.04% | 0.05% | 0.06% | 0.08% | 0.11% |
| SAMPLE SIZE | 152,060 | 124,410 | 104,310 | 86,610 | 69,500 | 50,490 | 31,130 | 16,450 | 6,970 | 260 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## ACTIVELY MONITORED STUDY DATA

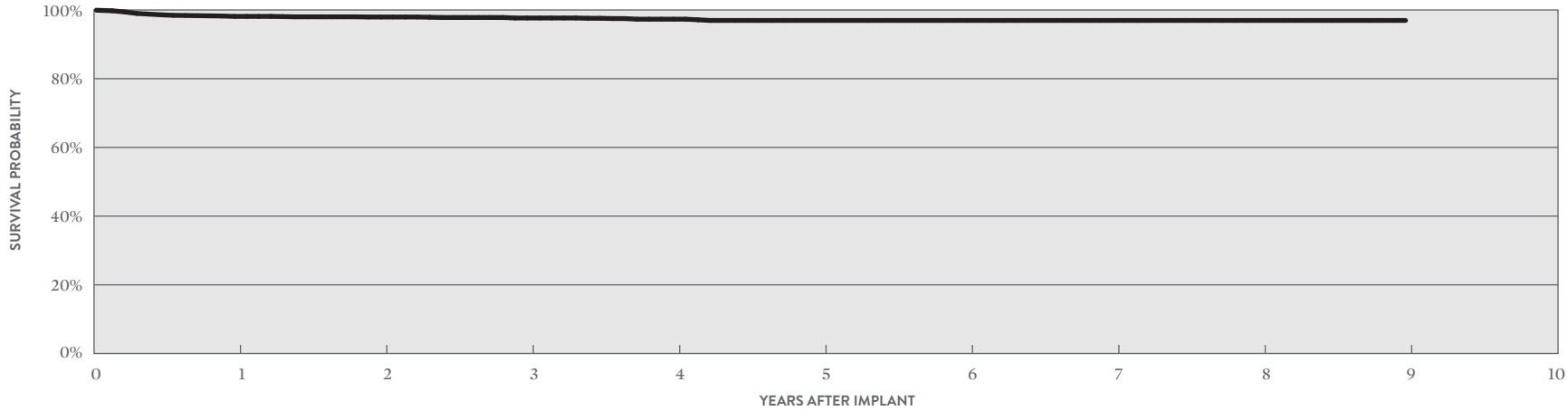
## Quartet™

### MODEL 1458Q

| | |
|---|---|
| US Regulatory Approval | November 2011 |
| Number of Devices Enrolled in Study | 2,158 |
| Active Devices Enrolled in Study | 892 |
| Cumulative Months of Follow-up | 116,980 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Quadpolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.05% |
| Extracardiac Stimulation | 3 | 0.14% |
| Failure to Capture | 9 | 0.42% |
| Insulation Breach | 1 | 0.05% |
| Lead Dislodgement | 38 | 1.76% |
| Oversensing | 1 | 0.05% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 22 | 1.02% |
| **Total** | **22** | **1.02%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.13% | 97.95% | 97.66% | 97.32% | 96.95% | 96.95% | 96.95% | 96.95% | 96.95% |
| ± 1 STANDARD ERROR | 0.29% | 0.32% | 0.35% | 0.39% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% |
| SAMPLE SIZE | 1,990 | 1,670 | 1,390 | 1,180 | 980 | 870 | 820 | 670 | 60 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

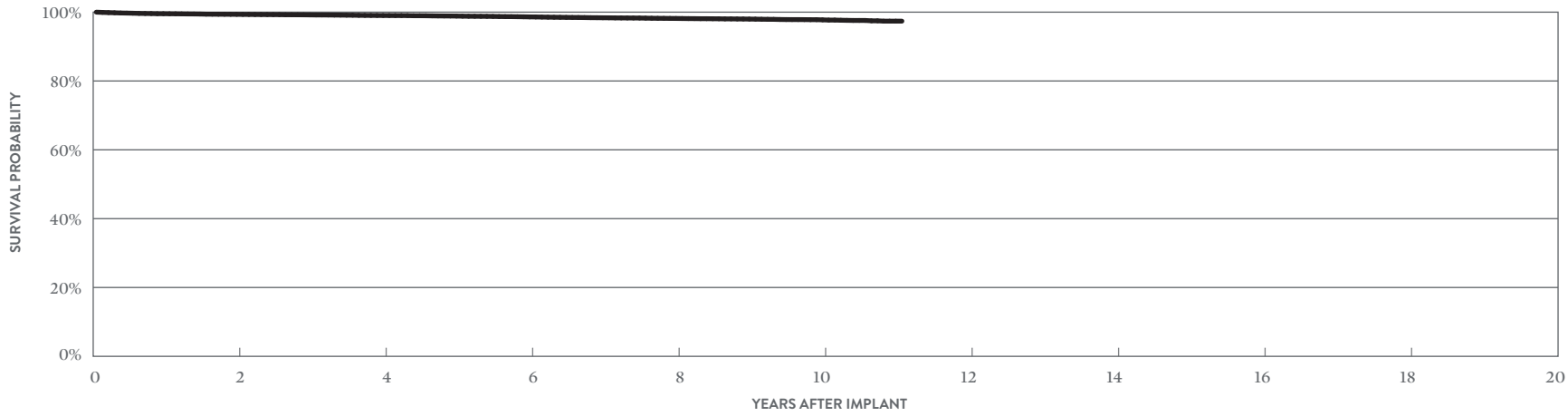
## QuickFlex™ µ

### MODEL 1258T

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 48,304 |
| Estimated Active US Implants | 21,539 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 1 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 44 | 0.09% |
| Lead Dislodgement | 49 | 0.10% | 238 | 0.49% |
| Failure to Capture | 20 | 0.04% | 261 | 0.54% |
| Oversensing | 0 | 0.00% | 28 | 0.06% |
| Failure to Sense | 1 | <0.01% | 3 | <0.01% |
| Insulation Breach | 0 | 0.00% | 16 | 0.03% |
| Abnormal Pacing Impedance | 5 | 0.01% | 76 | 0.16% |
| Extracardiac Stimulation | 21 | 0.04% | 82 | 0.17% |
| Other | 16 | 0.03% | 17 | 0.04% |
| **Total** | **112** | **0.23%** | **766** | **1.59%** |
| **Total Returned for Analysis** | **62** | | **227** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 9 | 0.02% |
| Clavicular Crush | 2 | <0.01% |
| In the Pocket | 3 | <0.01% |
| Intravascular | 4 | <0.01% |
| Insulation Breach | 6 | 0.01% |
| Lead-to-Can Contact | 1 | <0.01% |
| Lead-to-Lead Contact | 4 | <0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | <0.01% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 237 | 0.49% |
| **Total** | **253** | **0.52%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 133 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.36% | 99.03% | 98.62% | 98.17% | 97.76% | 97.39% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.06% | 0.08% | 0.10% | 0.17% |
| SAMPLE SIZE | 38,610 | 31,020 | 24,950 | 17,440 | 7,720 | 330 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## ACTIVELY MONITORED STUDY DATA

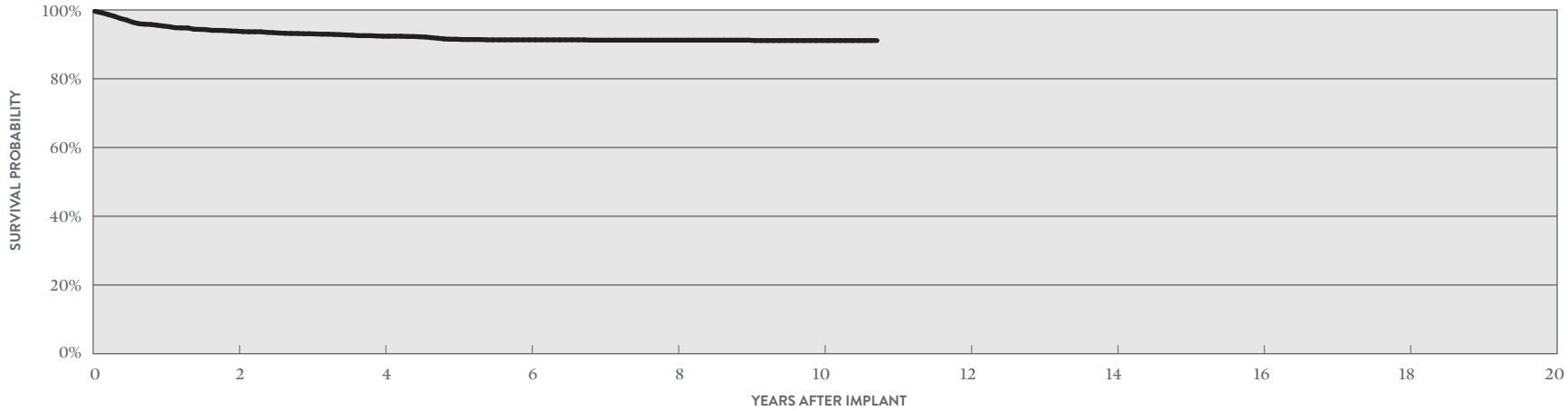
## QuickFlex™ µ

### MODEL 1258T

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 2,375 |
| Active Devices Enrolled in Study | 939 |
| Cumulative Months of Follow-up | 145,536 |
| Insulation | Optim™* |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 7 | 0.29% |
| Conductor Fracture | 3 | 0.13% |
| Extracardiac Stimulation | 56 | 2.36% |
| Failure to Capture | 49 | 2.06% |
| Insulation Breach | 1 | 0.04% |
| Lead Dislodgement | 52 | 2.19% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.04% |
| Clavicular Crush | 1 | 0.04% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 41 | 1.73% |
| **Total** | **42** | **1.77%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 129 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 93.83% | 92.36% | 91.30% | 91.21% | 91.10% | 91.10% |
| ± 1 STANDARD ERROR | 0.52% | 0.60% | 0.67% | 0.67% | 0.68% | 0.68% |
| SAMPLE SIZE | 1,760 | 1,280 | 970 | 900 | 610 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

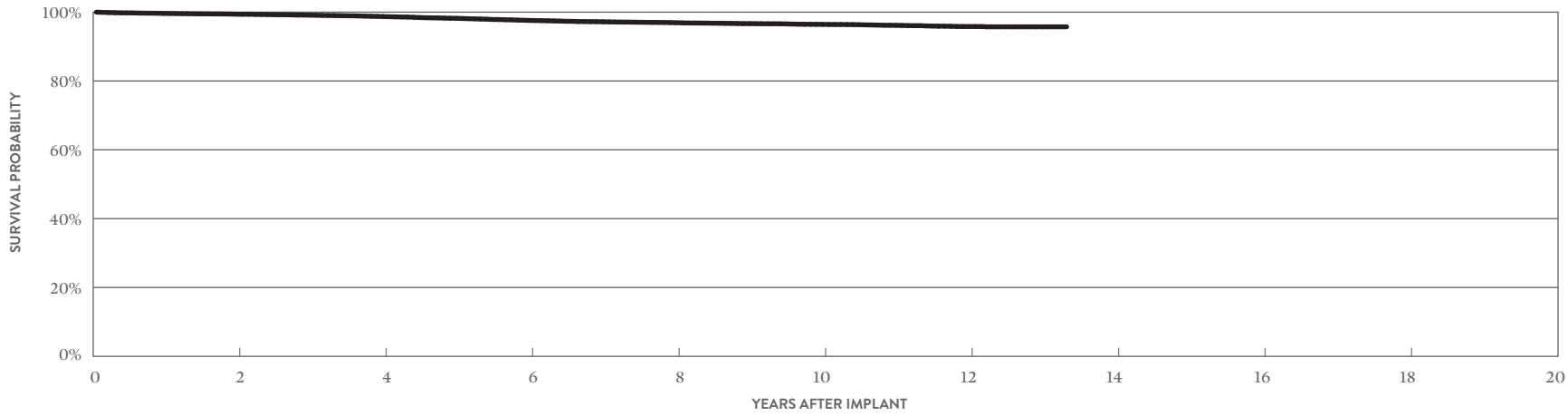
## QuickFlex™

### MODEL 1156T

| | |
|---|---|
| US Regulatory Approval | July 2007 |
| Registered US Implants | 27,671 |
| Estimated Active US Implants | 8,882 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 325) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 1 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 9 | 0.03% |
| Lead Dislodgement | 11 | 0.04% | 146 | 0.53% |
| Failure to Capture | 5 | 0.02% | 240 | 0.87% |
| Oversensing | 0 | 0.00% | 20 | 0.07% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 51 | 0.18% |
| Abnormal Pacing Impedance | 1 | <0.01% | 69 | 0.25% |
| Extracardiac Stimulation | 14 | 0.05% | 93 | 0.34% |
| Other | 9 | 0.03% | 9 | 0.03% |
| **Total** | **40** | **0.14%** | **638** | **2.31%** |
| **Total Returned for Analysis** | **14** | | **171** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 7 | 0.03% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 7 | 0.03% |
| Insulation Breach | 92 | 0.33% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 4 | 0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 14 | 0.05% |
| Other | 74 | 0.27% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 133 | 0.48% |
| **Total** | **232** | **0.84%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.41% | 98.72% | 97.60% | 96.93% | 96.44% | 95.82% | 95.74% |
| ± 1 STANDARD ERROR | 0.05% | 0.08% | 0.12% | 0.14% | 0.15% | 0.18% | 0.19% |
| SAMPLE SIZE | 21,390 | 16,770 | 13,550 | 11,400 | 9,550 | 4,910 | 300 |

# Left-Heart Leads

## ACTIVELY MONITORED STUDY DATA

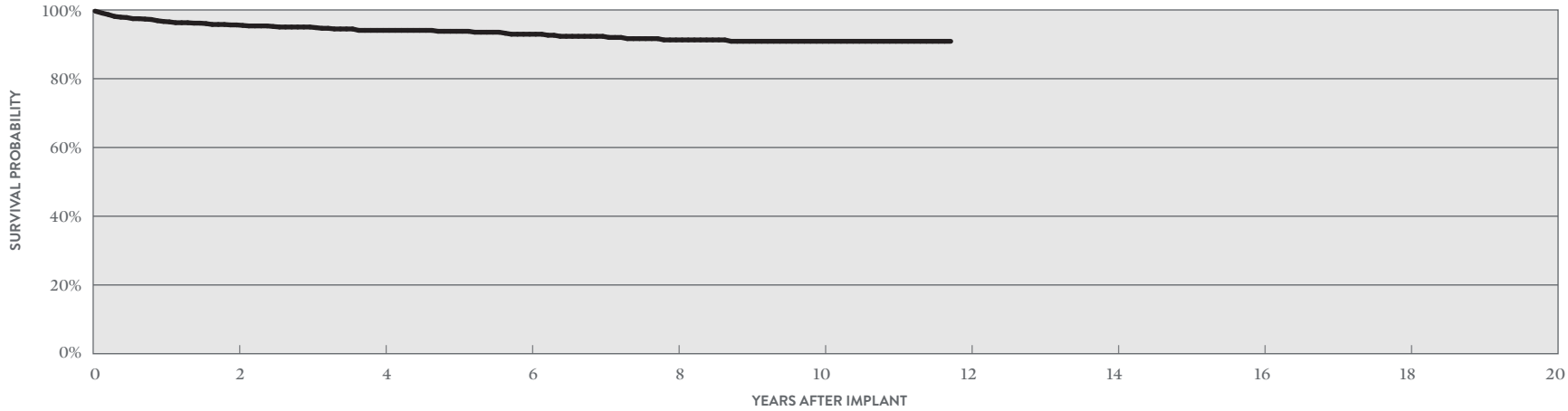
## QuickFlex™

### MODEL 1156T

| | |
|---|---|
| US Regulatory Approval | July 2007 |
| Number of Devices Enrolled in Study | 987 |
| Active Devices Enrolled in Study | 195 |
| Cumulative Months of Follow-up | 55,640 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.10% |
| Extracardiac Stimulation | 18 | 1.82% |
| Failure to Capture | 10 | 1.01% |
| Insulation Breach | 1 | 0.10% |
| Lead Dislodgement | 28 | 2.84% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 3 | 0.30% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 3 | 0.30% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 20 | 2.03% |
| **Total** | **23** | **2.33%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 95.64% | 94.06% | 92.94% | 91.28% | 90.88% | 90.88% |
| ± 1 STANDARD ERROR | 0.69% | 0.86% | 1.01% | 1.24% | 1.30% | 1.30% |
| SAMPLE SIZE | 750 | 470 | 330 | 260 | 200 | 50 |

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

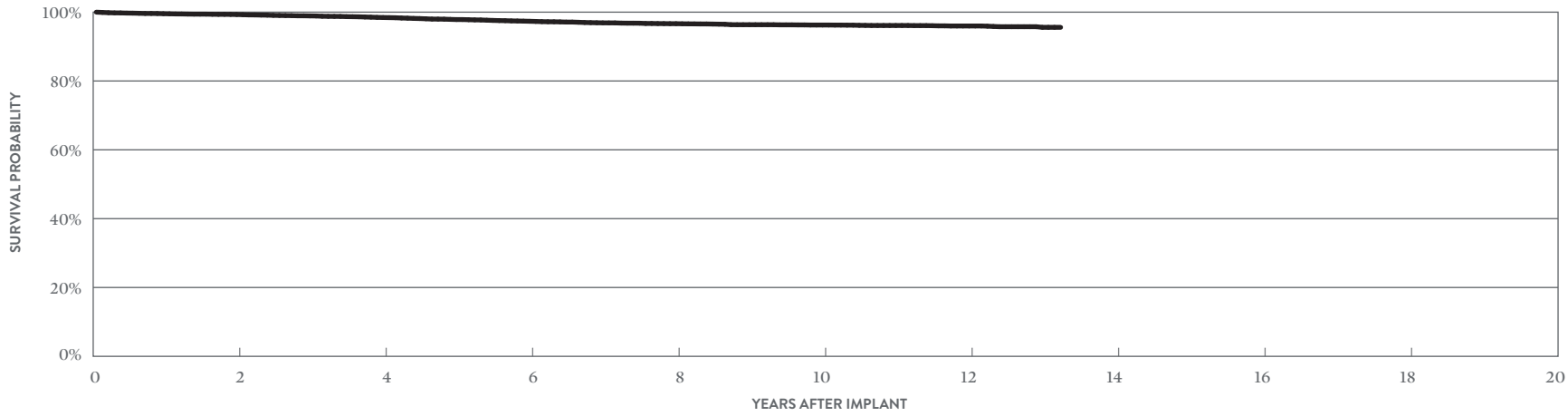
## QuickFlex™ XL

### MODEL 1158T

| | |
|---|---|
| US Regulatory Approval | July 2007 |
| Registered US Implants | 15,341 |
| Estimated Active US Implants | 5,091 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 325) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 1 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 5 | 0.03% |
| Lead Dislodgement | 9 | 0.06% | 101 | 0.66% |
| Failure to Capture | 2 | 0.01% | 152 | 0.99% |
| Oversensing | 0 | 0.00% | 3 | 0.02% |
| Failure to Sense | 0 | 0.00% | 1 | <0.01% |
| Insulation Breach | 0 | 0.00% | 35 | 0.23% |
| Abnormal Pacing Impedance | 2 | 0.01% | 28 | 0.18% |
| Extracardiac Stimulation | 6 | 0.04% | 35 | 0.23% |
| Other | 6 | 0.04% | 10 | 0.07% |
| **Total** | **25** | **0.16%** | **371** | **2.42%** |
| **Total Returned for Analysis** | **13** | | **125** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 5 | 0.03% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 1 | <0.01% |
| Intravascular | 4 | 0.03% |
| Insulation Breach | 59 | 0.38% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 2 | 0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 8 | 0.05% |
| Other | 49 | 0.32% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 90 | 0.59% |
| **Total** | **155** | **1.01%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 159 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.31% | 98.44% | 97.35% | 96.65% | 96.26% | 95.98% | 95.59% |
| ± 1 STANDARD ERROR | 0.07% | 0.12% | 0.16% | 0.19% | 0.21% | 0.22% | 0.31% |
| SAMPLE SIZE | 11,890 | 9,390 | 7,640 | 6,460 | 5,350 | 2,740 | 300 |

# Left-Heart Leads

## ACTIVELY MONITORED STUDY DATA

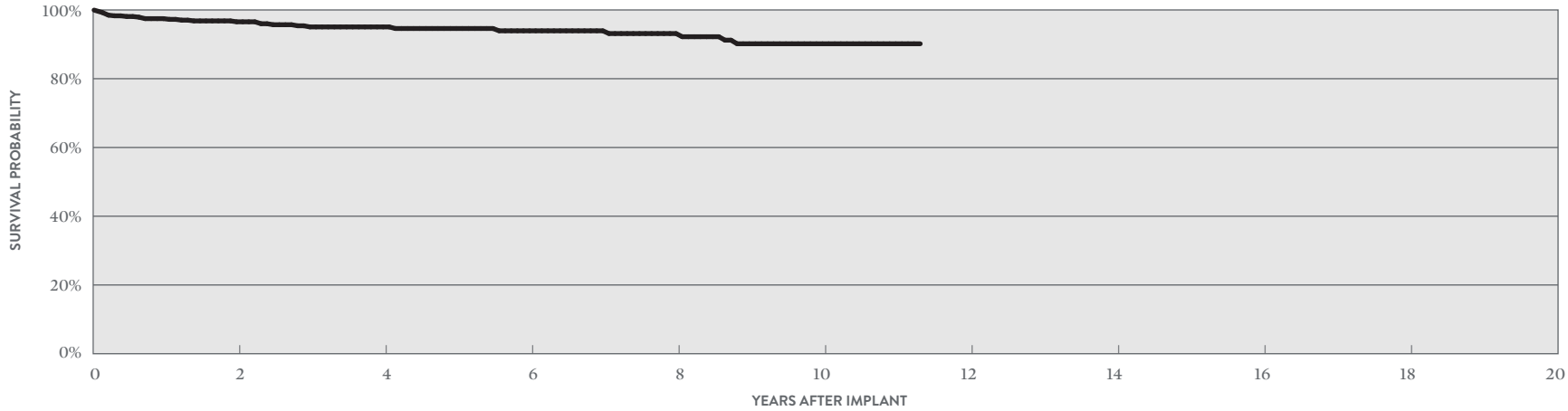
## QuickFlex™ XL

### MODEL 1158T

| | |
|---|---|
| US Regulatory Approval | July 2007 |
| Number of Devices Enrolled in Study | 553 |
| Active Devices Enrolled in Study | 74 |
| Cumulative Months of Follow-up | 27,732 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Extracardiac Stimulation | 9 | 1.63% |
| Failure to Capture | 10 | 1.81% |
| Insulation Breach | 1 | 0.18% |
| Lead Dislodgement | 7 | 1.27% |
| Skin Erosion | 1 | 0.18% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 1 | 0.18% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 1 | 0.18% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 7 | 1.27% |
| **Total** | **8** | **1.45%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 136 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 96.55% | 95.06% | 93.93% | 93.13% | 90.16% | 90.16% |
| ± 1 STANDARD ERROR | 0.79% | 1.05% | 1.31% | 1.53% | 2.24% | 2.24% |
| SAMPLE SIZE | 410 | 250 | 150 | 110 | 80 | 50 |

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

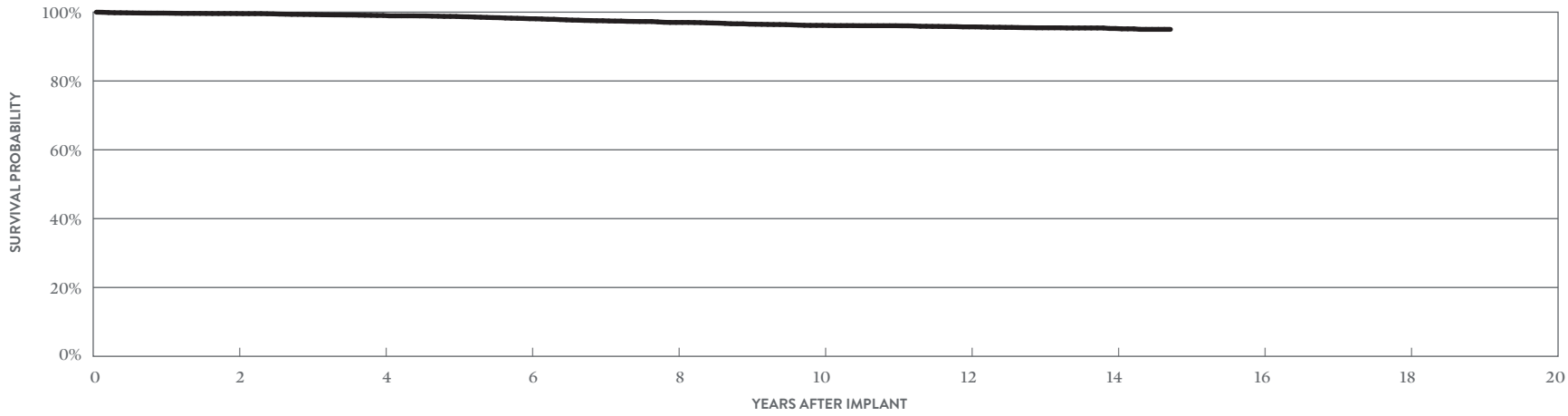
## QuickSite™ XL

### MODEL 1058T

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 9,995 |
| Estimated Active US Implants | 2,636 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 325) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 1 | 0.01% |
| Conductor Fracture | 0 | 0.00% | 8 | 0.08% |
| Lead Dislodgement | 10 | 0.10% | 35 | 0.35% |
| Failure to Capture | 3 | 0.03% | 95 | 0.95% |
| Oversensing | 1 | 0.01% | 4 | 0.04% |
| Failure to Sense | 0 | 0.00% | 2 | 0.02% |
| Insulation Breach | 0 | 0.00% | 32 | 0.32% |
| Abnormal Pacing Impedance | 2 | 0.02% | 21 | 0.21% |
| Extracardiac Stimulation | 9 | 0.09% | 25 | 0.25% |
| Other | 1 | 0.01% | 5 | 0.05% |
| **Total** | **26** | **0.26%** | **228** | **2.29%** |
| **Total Returned for Analysis** | **11** | | **39** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 2 | 0.02% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 2 | 0.02% |
| Insulation Breach | 26 | 0.26% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 1 | 0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 6 | 0.06% |
| Other | 19 | 0.19% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | 0.01% |
| Extrinsic Factors | 31 | 0.31% |
| **Total** | **60** | **0.60%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 177 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.59% | 99.04% | 98.09% | 97.01% | 96.15% | 95.72% | 95.25% | 95.00% |
| ± 1 STANDARD ERROR | 0.07% | 0.12% | 0.18% | 0.24% | 0.29% | 0.31% | 0.35% | 0.39% |
| SAMPLE SIZE | 7,690 | 5,800 | 4,500 | 3,660 | 3,180 | 2,790 | 1,660 | 210 |

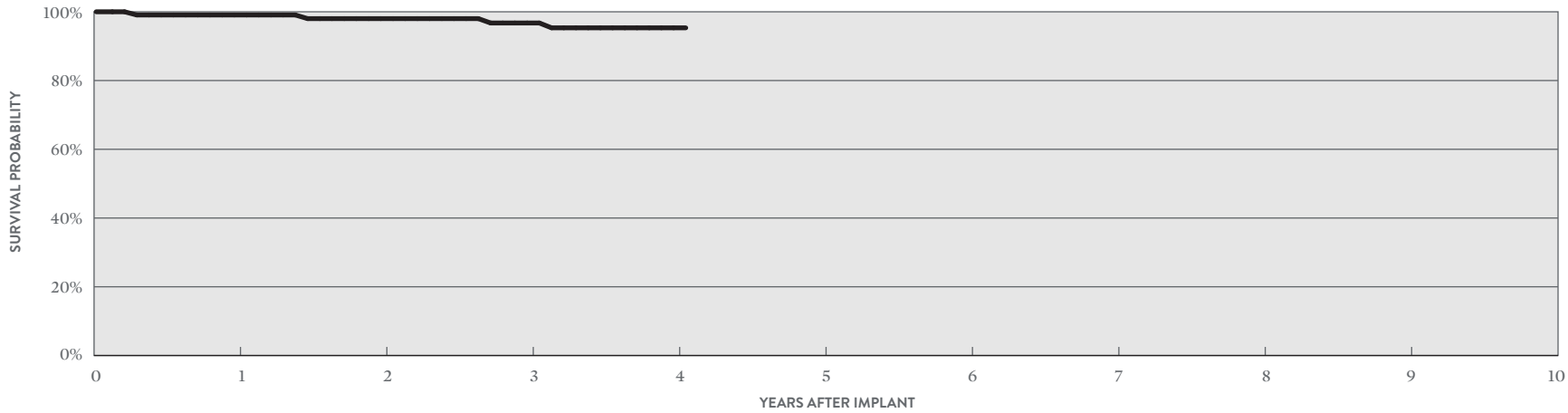
# QuickSite™ XL

## MODEL 1058T

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Number of Devices Enrolled in Study | 111 |
| Active Devices Enrolled in Study | 10 |
| Cumulative Months of Follow-up | 5,870 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Failure to Capture | 4 | 3.60% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **0** | **0.00%** |




| YEAR | 1 | 2 | 3 | 4 | AT 49 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.07% | 98.01% | 96.74% | 95.33% | 95.33% |
| ± 1 STANDARD ERROR | 0.92% | 1.39% | 1.87% | 2.31% | 2.31% |
| SAMPLE SIZE | 100 | 90 | 80 | 60 | 50 |

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

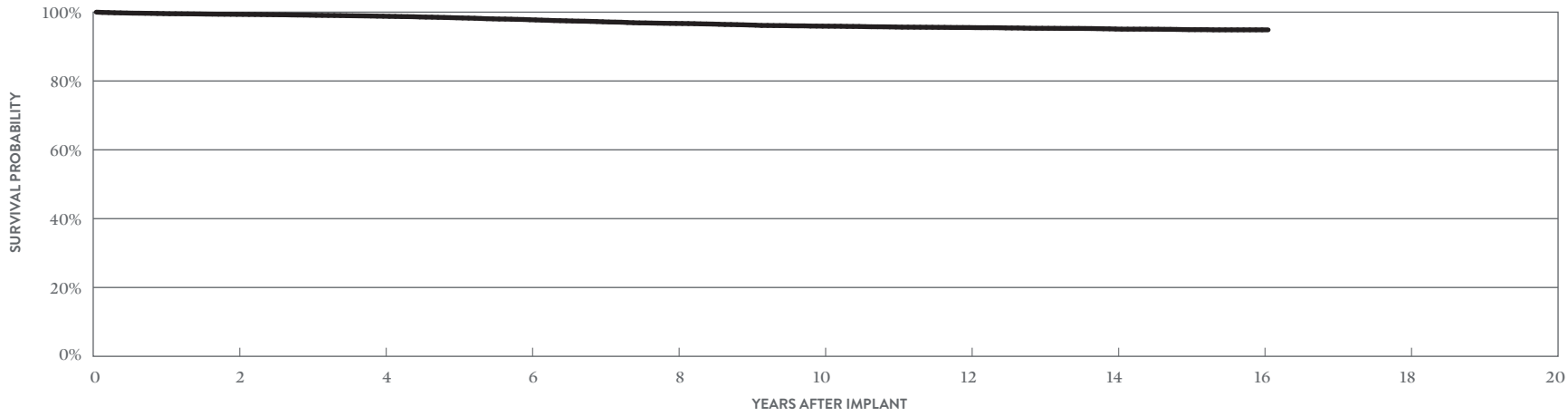
## QuickSite™

### MODEL 1056T

| | |
|---|---|
| US Regulatory Approval | April 2005 |
| Registered US Implants | 32,340 |
| Estimated Active US Implants | 7,687 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 325) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 13 | 0.04% |
| Lead Dislodgement | 32 | 0.10% | 174 | 0.54% |
| Failure to Capture | 15 | 0.05% | 294 | 0.91% |
| Oversensing | 2 | <0.01% | 26 | 0.08% |
| Failure to Sense | 0 | 0.00% | 2 | <0.01% |
| Insulation Breach | 1 | <0.01% | 111 | 0.34% |
| Abnormal Pacing Impedance | 3 | <0.01% | 66 | 0.20% |
| Extracardiac Stimulation | 22 | 0.07% | 107 | 0.33% |
| Other | 9 | 0.03% | 29 | 0.09% |
| **Total** | **84** | **0.26%** | **822** | **2.54%** |
| **Total Returned for Analysis** | **28** | | **212** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 6 | 0.02% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 2 | <0.01% |
| Intravascular | 4 | 0.01% |
| Insulation Breach | 92 | 0.28% |
| Lead-to-Can Contact | 1 | <0.01% |
| Lead-to-Lead Contact | 11 | 0.03% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 31 | 0.10% |
| Other | 49 | 0.15% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 162 | 0.50% |
| **Total** | **261** | **0.81%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 193 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.36% | 98.82% | 97.79% | 96.72% | 95.93% | 95.53% | 95.10% | 94.86% | 94.86% |
| ± 1 STANDARD ERROR | 0.05% | 0.07% | 0.10% | 0.14% | 0.16% | 0.18% | 0.19% | 0.21% | 0.21% |
| SAMPLE SIZE | 25,130 | 18,930 | 14,260 | 11,410 | 9,630 | 8,320 | 6,050 | 1,480 | 300 |

# Left-Heart Leads

## ACTIVELY MONITORED STUDY DATA

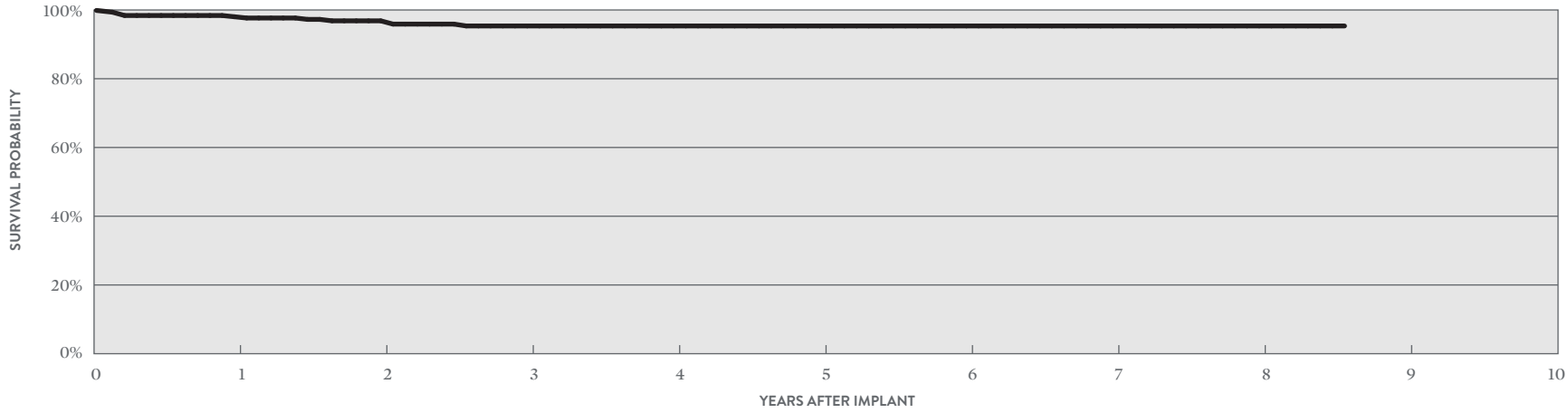
## QuickSite™

### MODEL 1056T

| | |
|---|---|
| US Regulatory Approval | April 2005 |
| Number of Devices Enrolled in Study | 319 |
| Active Devices Enrolled in Study | 35 |
| Cumulative Months of Follow-up | 15,754 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.31% |
| Extracardiac Stimulation | 2 | 0.63% |
| Failure to Capture | 4 | 1.25% |
| Lead Dislodgement | 5 | 1.57% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 1 | 0.31% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.31% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 4 | 1.25% |
| **Total** | **5** | **1.57%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 103 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.03% | 96.84% | 95.35% | 95.35% | 95.35% | 95.35% | 95.35% | 95.35% | 95.35% |
| ± 1 STANDARD ERROR | 0.71% | 1.04% | 1.34% | 1.34% | 1.34% | 1.34% | 1.34% | 1.34% | 1.34% |
| SAMPLE SIZE | 290 | 240 | 180 | 140 | 110 | 90 | 70 | 60 | 50 |

# Left-Heart Leads

## CUSTOMER REPORTED PERFORMANCE DATA

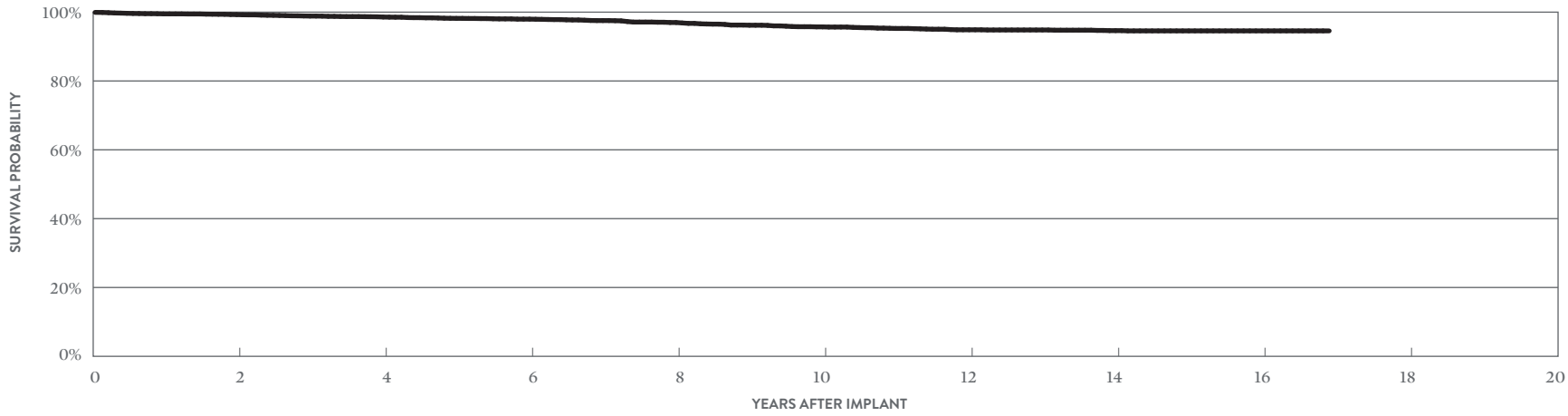
## QuickSite™

### MODEL 1056K

| | |
|---|---|
| US Regulatory Approval | June 2004 |
| Registered US Implants | 7,874 |
| Estimated Active US Implants | 1,558 |
| Insulation | Polyurethane/Silicone |
| Type and/or Fixation | S-Curve |
| Polarity | Unipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 7 | 0.09% |
| Lead Dislodgement | 10 | 0.13% | 36 | 0.46% |
| Failure to Capture | 3 | 0.04% | 73 | 0.93% |
| Oversensing | 0 | 0.00% | 2 | 0.03% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 6 | 0.08% |
| Abnormal Pacing Impedance | 0 | 0.00% | 8 | 0.10% |
| Extracardiac Stimulation | 10 | 0.13% | 32 | 0.41% |
| Other | 2 | 0.03% | 11 | 0.14% |
| **Total** | **25** | **0.32%** | **175** | **2.22%** |
| **Total Returned for Analysis** | **13** | | **51** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.04% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 3 | 0.04% |
| Insulation Breach | 3 | 0.04% |
| Lead-to-Can Contact | 2 | 0.03% |
| Lead-to-Lead Contact | 1 | 0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 53 | 0.67% |
| **Total** | **59** | **0.75%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 203 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.28% | 98.58% | 97.97% | 96.99% | 95.72% | 94.87% | 94.63% | 94.56% | 94.56% |
| ± 1 STANDARD ERROR | 0.10% | 0.15% | 0.20% | 0.28% | 0.36% | 0.42% | 0.43% | 0.44% | 0.44% |
| SAMPLE SIZE | 6,100 | 4,490 | 3,240 | 2,440 | 2,000 | 1,740 | 1,520 | 1,200 | 280 |

## SUMMARY INFORMATION

# Left-Heart Leads

## Left-Heart Leads

# Survival Probability Summary

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1458QL | Quartet™ | 99.34% | 99.00% | 98.84% | 98.82% | 98.72% | | | | | |
| 1457Q | QuickFlex™ µ | 98.22% | 97.72% | 97.17% | 96.79% | | | | | | |
| 1456Q | QuickFlex™ µ | 99.00% | 98.64% | 98.52% | 98.08% | 97.92% | | | | | |
| 1458Q | Quartet™ | 99.30% | 99.03% | 98.85% | 98.67% | 98.48% | 98.33% | 98.14% | 97.96% | 97.79% | |
| 1258T | QuickFlex™ µ | 99.55% | 99.36% | 99.20% | 99.03% | 98.86% | 98.62% | 98.37% | 98.17% | 97.99% | 97.76% |
| 1156T | QuickFlex™ | 99.63% | 99.41% | 99.13% | 98.72% | 98.21% | 97.60% | 97.20% | 96.93% | 96.67% | 96.44% |
| 1158T | QuickFlex™ XL | 99.55% | 99.31% | 98.91% | 98.44% | 97.85% | 97.35% | 96.89% | 96.65% | 96.35% | 96.26% |
| 1058T | QuickSite™ XL | 99.72% | 99.59% | 99.32% | 99.04% | 98.75% | 98.09% | 97.51% | 97.01% | 96.52% | 96.15% |
| 1056T | QuickSite™ | 99.58% | 99.36% | 99.13% | 98.82% | 98.36% | 97.79% | 97.20% | 96.72% | 96.27% | 95.93% |
| 1056K | QuickSite™ | 99.50% | 99.28% | 98.86% | 98.58% | 98.19% | 97.97% | 97.55% | 96.99% | 96.20% | 95.72% |

## Left-Heart Leads

# Acute Observation Summary

### POST IMPLANT ≤30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| 1458QL | Oct-15 | 14,845 | 11,177 | 1 | <0.01% | 0 | 0.00% | 28 | 0.19% | 17 | 0.11% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 5 | 0.03% | 27 | 0.18% | 6 | 0.04% | **86** | **0.58%** | **21** |
| 1457Q | Oct-15 | 7,878 | 5,850 | 0 | 0.00% | 1 | 0.01% | 38 | 0.48% | 9 | 0.11% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 15 | 0.19% | 7 | 0.09% | **71** | **0.90%** | **19** |
| 1456Q | Oct-15 | 11,311 | 8,507 | 2 | 0.02% | 2 | 0.02% | 34 | 0.30% | 12 | 0.11% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 4 | 0.04% | 13 | 0.11% | 6 | 0.05% | **75** | **0.66%** | **20** |
| 1458Q | Nov-11 | 168,864 | 99,079 | 6 | <0.01% | 0 | 0.00% | 286 | 0.17% | 126 | 0.07% | 4 | <0.01% | 0 | 0.00% | 1 | <0.01% | 6 | <0.01% | 117 | 0.07% | 122 | 0.07% | **668** | **0.40%** | **242** |
| 1258T | May-10 | 48,304 | 21,539 | 0 | 0.00% | 0 | 0.00% | 49 | 0.10% | 20 | 0.04% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 5 | 0.01% | 21 | 0.04% | 16 | 0.03% | **112** | **0.23%** | **62** |
| 1156T | Jul-07 | 27,671 | 8,882 | 0 | 0.00% | 0 | 0.00% | 11 | 0.04% | 5 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 14 | 0.05% | 9 | 0.03% | **40** | **0.14%** | **14** |
| 1158T | Jul-07 | 15,341 | 5,091 | 0 | 0.00% | 0 | 0.00% | 9 | 0.06% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 6 | 0.04% | 6 | 0.04% | **25** | **0.16%** | **13** |
| 1058T | Feb-06 | 9,955 | 2,636 | 0 | 0.00% | 0 | 0.00% | 10 | 0.10% | 3 | 0.03% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 9 | 0.09% | 1 | 0.01% | **26** | **0.26%** | **11** |
| 1056T | Apr-05 | 32,340 | 7,687 | 0 | 0.00% | 0 | 0.00% | 32 | 0.10% | 15 | 0.05% | 2 | <0.01% | 0 | 0.00% | 1 | <0.01% | 3 | <0.01% | 22 | 0.07% | 9 | 0.03% | **84** | **0.26%** | **28** |
| 1056K | Jun-04 | 7,874 | 1,558 | 0 | 0.00% | 0 | 0.00% | 10 | 0.13% | 3 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 10 | 0.13% | 2 | 0.03% | **25** | **0.32%** | **13** |

# Chronic Complication Summary

### >30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| 1458QL | Oct-15 | 14,845 | 11,177 | 0 | 0.00% | 0 | 0.00% | 94 | 0.63% | 29 | 0.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 10 | 0.07% | 29 | 0.20% | 5 | 0.03% | **167** | **1.12%** | **51** |
| 1457Q | Oct-15 | 7,878 | 5,850 | 0 | 0.00% | 0 | 0.00% | 120 | 1.52% | 33 | 0.42% | 2 | 0.03% | 0 | 0.00% | 2 | 0.03% | 0 | 0.00% | 12 | 0.15% | 5 | 0.06% | **174** | **2.21%** | **70** |
| 1456Q | Oct-15 | 11,311 | 8,507 | 1 | <0.01% | 1 | <0.01% | 106 | 0.94% | 33 | 0.29% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 17 | 0.15% | 2 | 0.02% | **161** | **1.42%** | **83** |
| 1458Q | Nov-11 | 168,864 | 99,079 | 5 | <0.01% | 36 | 0.02% | 1252 | 0.74% | 627 | 0.37% | 26 | 0.02% | 2 | <0.01% | 15 | <0.01% | 136 | 0.08% | 228 | 0.14% | 65 | 0.04% | **2392** | **1.42%** | **868** |
| 1258T | May-10 | 48,304 | 21,539 | 1 | <0.01% | 44 | 0.09% | 238 | 0.49% | 261 | 0.54% | 28 | 0.06% | 3 | <0.01% | 16 | 0.03% | 76 | 0.16% | 82 | 0.17% | 17 | 0.04% | **766** | **1.59%** | **227** |
| 1156T | Jul-07 | 27,671 | 8,882 | 1 | <0.01% | 9 | 0.03% | 146 | 0.53% | 240 | 0.87% | 20 | 0.07% | 0 | 0.00% | 51 | 0.18% | 69 | 0.25% | 93 | 0.34% | 9 | 0.03% | **638** | **2.31%** | **171** |
| 1158T | Jul-07 | 15,341 | 5,091 | 1 | <0.01% | 5 | 0.03% | 101 | 0.66% | 152 | 0.99% | 3 | 0.02% | 1 | <0.01% | 35 | 0.23% | 28 | 0.18% | 35 | 0.23% | 10 | 0.07% | **371** | **2.42%** | **125** |
| 1058T | Feb-06 | 9,955 | 2,636 | 1 | 0.01% | 8 | 0.08% | 35 | 0.35% | 95 | 0.95% | 4 | 0.04% | 2 | 0.02% | 32 | 0.32% | 21 | 0.21% | 25 | 0.25% | 5 | 0.05% | **228** | **2.29%** | **39** |
| 1056T | Apr-05 | 32,340 | 7,687 | 0 | 0.00% | 13 | 0.04% | 174 | 0.54% | 294 | 0.91% | 26 | 0.08% | 2 | <0.01% | 111 | 0.34% | 66 | 0.20% | 107 | 0.33% | 29 | 0.09% | **822** | **2.54%** | **212** |
| 1056K | Jun-04 | 7,874 | 1,558 | 0 | 0.00% | 7 | 0.09% | 36 | 0.46% | 73 | 0.93% | 2 | 0.03% | 0 | 0.00% | 6 | 0.08% | 8 | 0.10% | 32 | 0.41% | 11 | 0.14% | **175** | **2.22%** | **51** |

*Definitions of observations and complications can be found on page 7.*

## Left-Heart Leads

# US Malfunction Summary

| MODELS | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 1458QL | 14,845 | 5.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 48 | 0.32% | **48** | **0.32%** |
| 1457Q | 7,878 | 6.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 76 | 0.96% | **76** | **0.96%** |
| 1456Q | 11,311 | 9.00% | 0 | 0.00% | 2 | 0.02% | 0 | 0.00% | 4 | 0.04% | 81 | 0.72% | **87** | **0.77%** |
| 1458Q | 168,864 | 7.10% | 10 | <0.01% | 8 | <0.01% | 0 | 0.00% | 15 | <0.01% | 828 | 0.49% | **861** | **0.51%** |
| 1258T | 48,304 | 12.40% | 9 | 0.02% | 6 | 0.01% | 0 | 0.00% | 1 | <0.01% | 237 | 0.49% | **253** | **0.52%** |
| 1156T | 27,671 | 9.70% | 7 | 0.03% | 92 | 0.33% | 0 | 0.00% | 0 | 0.00% | 133 | 0.48% | **232** | **0.84%** |
| 1158T | 15,341 | 10.90% | 5 | 0.03% | 59 | 0.38% | 1 | <0.01% | 0 | 0.00% | 90 | 0.59% | **155** | **1.01%** |
| 1058T | 9,955 | 10.50% | 2 | 0.02% | 26 | 0.26% | 0 | 0.00% | 1 | 0.01% | 31 | 0.31% | **60** | **0.60%** |
| 1056T | 32,340 | 10.10% | 6 | 0.02% | 92 | 0.28% | 0 | 0.00% | 1 | <0.01% | 162 | 0.50% | **261** | **0.81%** |
| 1056K | 7,874 | 15.70% | 3 | 0.04% | 3 | 0.04% | 0 | 0.00% | 0 | 0.00% | 53 | 0.67% | **59** | **0.75%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Left-Heart Leads

### Worldwide Malfunction Summary

| MODELS | WORLWIDE SALES | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 1458QL | 31,259 | 2.42% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 59 | 0.19% | **60** | **0.19%** |
| 1457Q | 22,058 | 2.44% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 92 | 0.42% | **92** | **0.42%** |
| 1456Q | 32,131 | 3.15% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 6 | 0.02% | 103 | 0.32% | **112** | **0.35%** |
| 1458Q | 368,614 | 3.56% | 31 | 0.01% | 15 | <0.01% | 0 | 0.00% | 30 | 0.01% | 1213 | 0.33% | **1289** | **0.35%** |
| 1258T | 183,956 | 3.92% | 51 | 0.03% | 12 | 0.01% | 0 | 0.00% | 5 | <0.01% | 424 | 0.23% | **492** | **0.27%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Left-Heart Leads

# Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | ABNORMAL PACING IMPEDANCE | | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | EXTRACARDIAC STIMULATION | | FAILURE TO CAPTURE | | FAILURE TO SENSE | | INSULATION BREACH | | LEAD DISLODGEMENT | | OVERSENSING | | PERICARDIAL EFFUSION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 1458Q | 2,158 | 892 | 116,980 | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 3 | 0.14% | 9 | 0.42% | 0 | 0.00% | 1 | 0.05% | 38 | 1.76% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | **53** | **2.46%** |
| 1258T | 2,375 | 939 | 145,536 | 7 | 0.29% | 0 | 0.00% | 3 | 0.13% | 56 | 2.36% | 49 | 2.06% | 0 | 0.00% | 1 | 0.04% | 52 | 2.19% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **168** | **7.07%** |
| 1156T | 987 | 195 | 55,640 | 1 | 0.10% | 0 | 0.00% | 0 | 0.00% | 18 | 1.82% | 10 | 1.01% | 0 | 0.00% | 1 | 0.10% | 28 | 2.84% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **58** | **5.88%** |
| 1158T | 553 | 74 | 27,732 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 9 | 1.63% | 10 | 1.81% | 0 | 0.00% | 1 | 0.18% | 7 | 1.27% | 0 | 0.00% | 0 | 0.00% | 1 | 0.18% | **28** | **5.06%** |
| 1058T | 111 | 10 | 5,870 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 3.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **3.60%** |
| 1056T | 319 | 35 | 15,754 | 1 | 0.31% | 0 | 0.00% | 0 | 0.00% | 2 | 0.63% | 4 | 1.25% | 0 | 0.00% | 0 | 0.00% | 5 | 1.57% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **12** | **3.76%** |

### MALFUNCTIONS

| MODELS | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 1458Q | 2,158 | 6.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 22 | 1.02% | **22** | **1.02%** |
| 1258T | 2,375 | 7.00% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 41 | 1.73% | **42** | **1.77%** |
| 1156T | 987 | 9.40% | 0 | 0.00% | 3 | 0.30% | 0 | 0.00% | 0 | 0.00% | 20 | 2.03% | **23** | **2.33%** |
| 1158T | 553 | 6.00% | 0 | 0.00% | 1 | 0.18% | 0 | 0.00% | 0 | 0.00% | 7 | 1.27% | **8** | **1.45%** |
| 1058T | 111 | 6.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 1056T | 319 | 8.20% | 0 | 0.00% | 1 | 0.31% | 0 | 0.00% | 0 | 0.00% | 4 | 1.25% | **5** | **1.57%** |

*A list of complications can be found on page 12.*
*Definitions of malfunction categories can be found on pages 8-9.*

## DUAL-CHAMBER

# Implantable Cardioverter Defibrillator (ICD) Devices

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

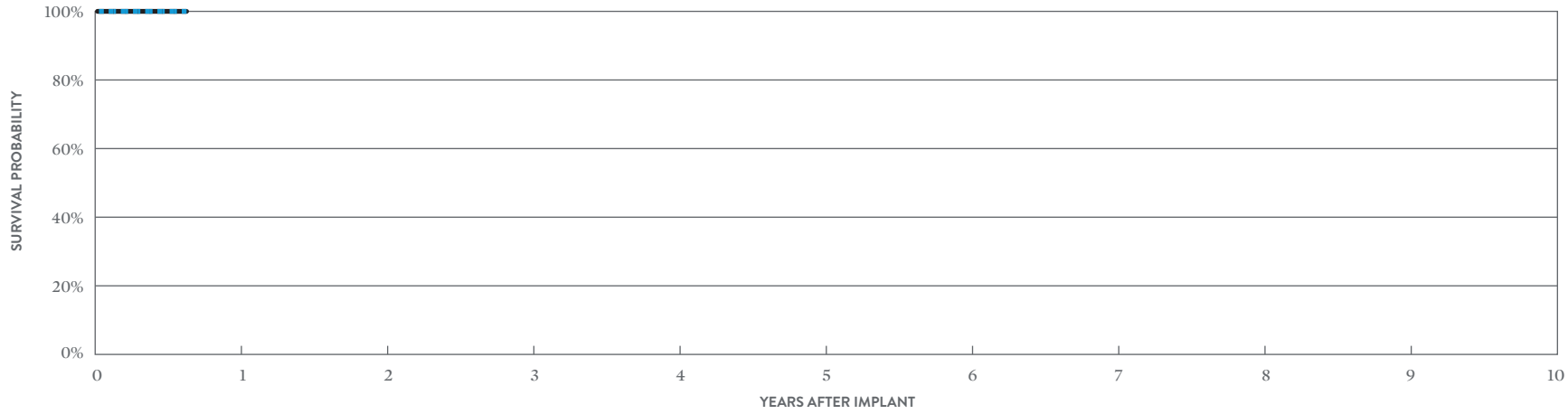
**CUSTOMER REPORTED PERFORMANCE DATA**

## Gallant™ DR

### MODEL CDDRA500Q*

| | |
|---|---|
| US Regulatory Approval | June 2020 |
| Registered US Implants | 3,534 |
| Estimated Active US Implants | 3,404 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 0 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | AT 8 MONTHS |
|---|---|
| SURVIVAL PROBABILITY | 100.00% |
| ± 1 STANDARD ERROR | 0.00% |
| SAMPLE SIZE | 290 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | AT 8 MONTHS |
|---|---|
| SURVIVAL PROBABILITY | 100.00% |
| ± 1 STANDARD ERROR | 0.00% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

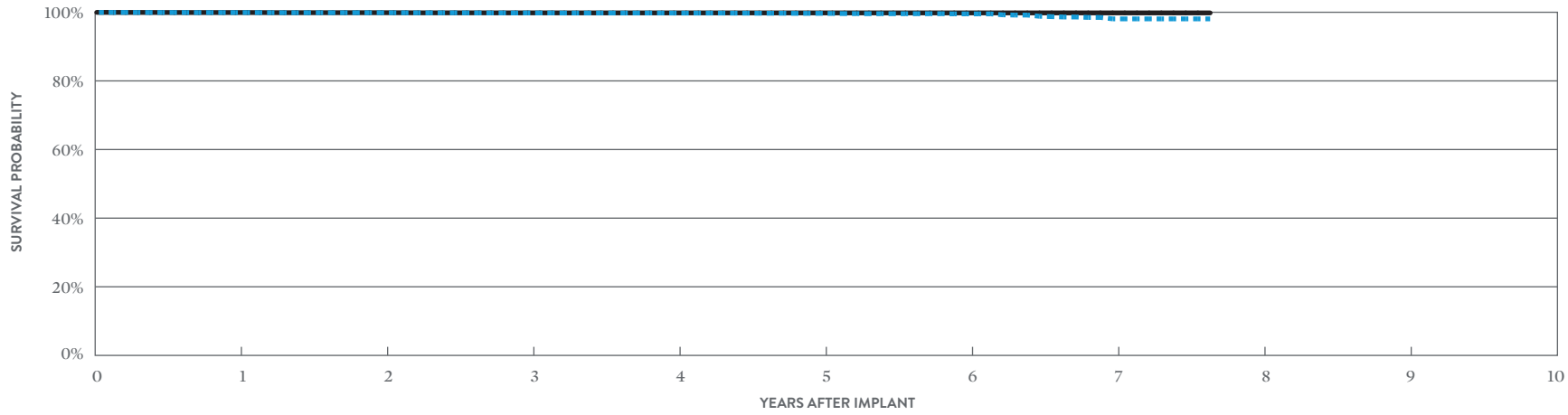
## CUSTOMER REPORTED PERFORMANCE DATA

## Ellipse™ DR

### MODEL CD2411-36Q*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 31,040 |
| Estimated Active US Implants | 20,439 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 23 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 310, 311, 313) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 4 | 0.01% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 2 | <0.01% | 1 | <0.01% |
| Software/Firmware | 1 | <0.01% | 0 | 0.00% |
| Mechanical | 1 | <0.01% | 3 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 2 | <0.01% | 2 | <0.01% |
| **Total** | **9** | **0.03%** | **11** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.91% | 99.87% | 99.80% | 99.76% | 99.68% | 99.53% | 98.08% | 98.08% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.03% | 0.03% | 0.05% | 0.07% | 0.23% | 0.29% |
| SAMPLE SIZE | 27,470 | 21,240 | 16,260 | 11,580 | 7,710 | 4,830 | 2,290 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.88% | 99.83% | 99.82% | 99.82% | 99.82% | 99.82% | 99.82% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

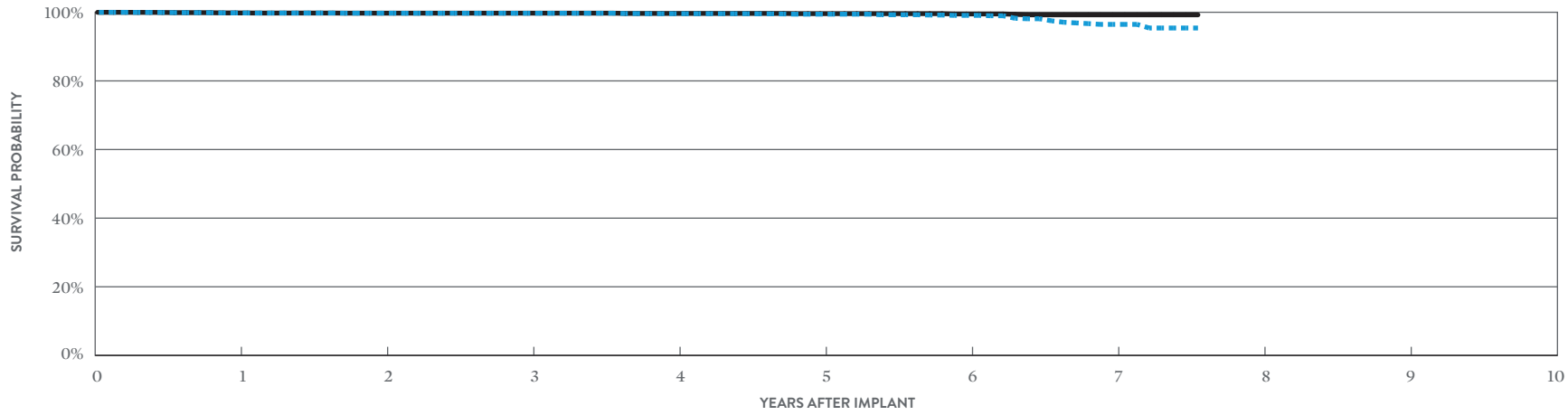
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ DR

### MODEL CD2411-36C*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 10,737 |
| Estimated Active US Implants | 6,410 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 22 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 310, 311, 313) | Four |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.03% | 2 | 0.02% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 7 | 0.07% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 3 | 0.03% |
| **Total** | **10** | **0.09%** | **7** | **0.07%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.74% | 99.72% | 99.59% | 99.44% | 99.09% | 96.47% | 95.41% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.06% | 0.07% | 0.09% | 0.15% | 0.47% | 0.66% |
| SAMPLE SIZE | 9,850 | 8,340 | 7,140 | 5,880 | 4,310 | 2,720 | 1,360 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.74% | 99.74% | 99.66% | 99.60% | 99.51% | 99.25% | 99.25% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.05% | 0.07% | 0.08% | 0.10% | 0.16% | 0.16% |

**Parylene coating.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

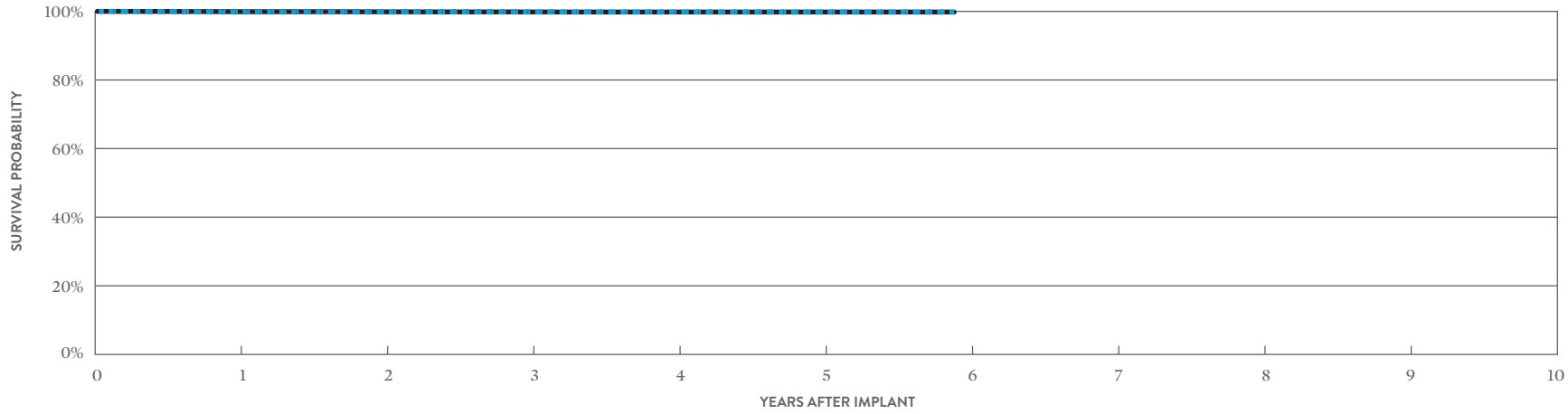
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2357-40Q* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 38,644 |
| Estimated Active US Implants | 27,648 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 6 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | <0.01% | 5 | 0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | <0.01% | 2 | <0.01% |
| High Voltage Capacitor | 3 | <0.01% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 2 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 5 | 0.01% | 0 | 0.00% |
| **Total** | **12** | **0.03%** | **11** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.88% | 99.82% | 99.79% | 99.76% | 99.73% | 99.73% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.03% | 0.03% | 0.04% | 0.04% |
| SAMPLE SIZE | 33,630 | 24,460 | 17,150 | 11,330 | 5,960 | 330 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.86% | 99.82% | 99.81% | 99.81% | 99.81% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.02% | 0.03% | 0.03% | 0.03% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

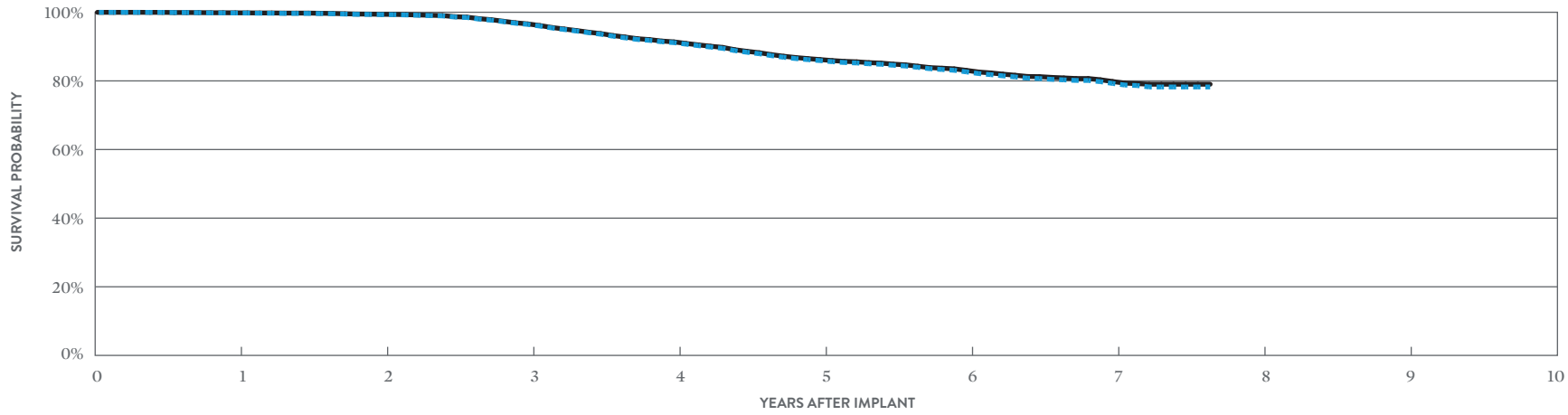
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2357-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 12,263 |
| Estimated Active US Implants | 5,646 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 19 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.02% | 8 | 0.07% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 12 | 0.10% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 71 | 0.58% | 515 | 4.20% |
| Other | 1 | <0.01% | 5 | 0.04% |
| **Total** | **76** | **0.62%** | **541** | **4.41%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.79% | 99.32% | 96.46% | 91.15% | 85.91% | 82.62% | 79.26% | 78.23% |
| ± 1 STANDARD ERROR | 0.04% | 0.08% | 0.18% | 0.30% | 0.37% | 0.41% | 0.48% | 0.57% |
| SAMPLE SIZE | 11,530 | 10,200 | 9,040 | 8,040 | 7,170 | 5,910 | 3,260 | 270 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.40% | 96.61% | 91.37% | 86.21% | 83.06% | 79.82% | 79.03% |
| ± 1 STANDARD ERROR | 0.04% | 0.07% | 0.18% | 0.30% | 0.37% | 0.41% | 0.48% | 0.55% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

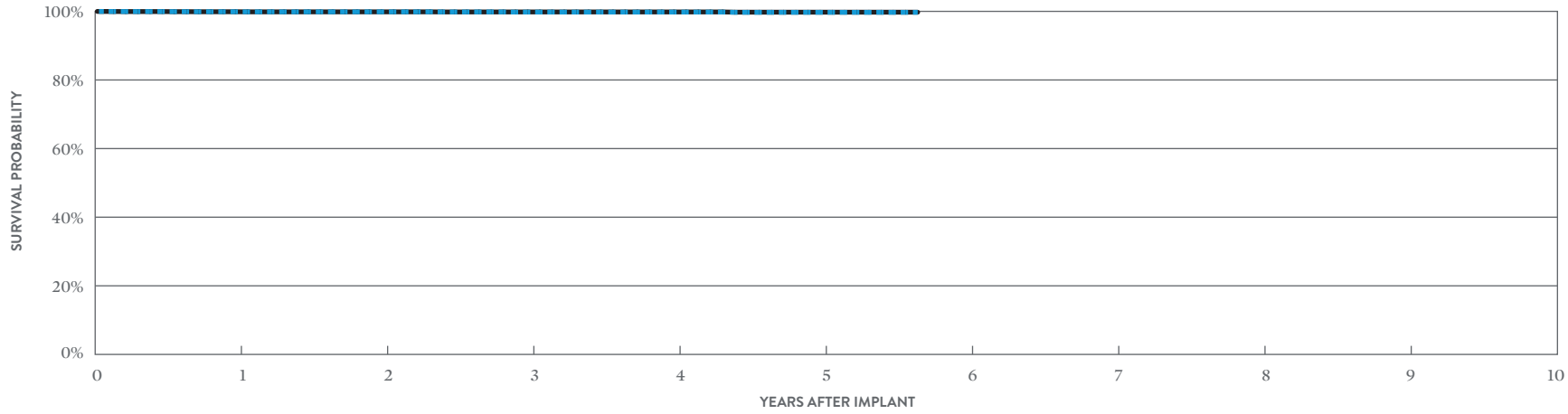
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2357-40C* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 9,916 |
| Estimated Active US Implants | 6,851 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 1 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.02% | 2 | 0.02% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 1 | 0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.01% |
| Mechanical | 0 | 0.00% | 2 | 0.02% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **3** | **0.03%** | **5** | **0.05%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.86% | 99.79% | 99.79% | 99.72% | 99.72% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.05% | 0.07% | 0.07% |
| SAMPLE SIZE | 8,860 | 7,130 | 5,850 | 4,480 | 2,440 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.86% | 99.83% | 99.83% | 99.76% | 99.76% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.05% | 0.07% | 0.07% |

**Parylene coating.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

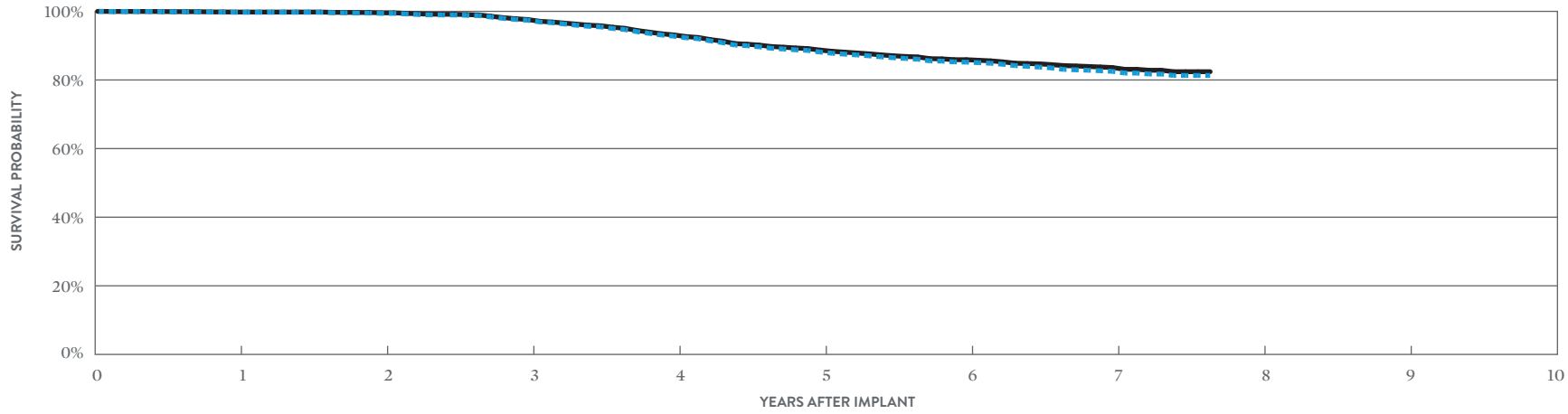
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2357-40C* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 6,956 |
| Estimated Active US Implants | 3,167 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 18 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.04% | 2 | 0.03% |
| Electrical Interconnect | 2 | 0.03% | 1 | 0.01% |
| Battery | 1 | 0.01% | 5 | 0.07% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 31 | 0.45% | 234 | 3.36% |
| Other | 2 | 0.03% | 1 | 0.01% |
| **Total** | **39** | **0.56%** | **243** | **3.49%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.72% | 99.41% | 97.41% | 92.77% | 88.13% | 85.20% | 82.51% | 81.32% |
| ± 1 STANDARD ERROR | 0.06% | 0.09% | 0.21% | 0.36% | 0.46% | 0.53% | 0.62% | 0.74% |
| SAMPLE SIZE | 6,540 | 5,780 | 5,120 | 4,540 | 4,010 | 3,210 | 1,790 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.80% | 99.58% | 97.61% | 93.12% | 88.71% | 85.91% | 83.61% | 82.41% |
| ± 1 STANDARD ERROR | 0.05% | 0.07% | 0.20% | 0.35% | 0.45% | 0.52% | 0.60% | 0.73% |

**Parylene coating.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

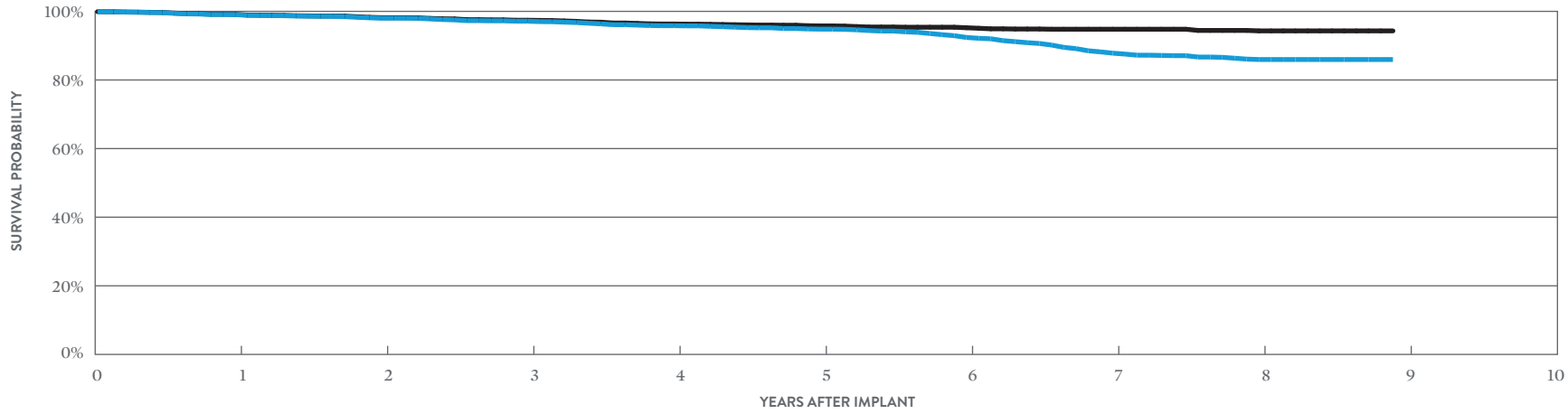
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ DR

### MODEL CD2311-36Q*

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 5,898 |
| Estimated Active US Implants | 2,170 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 109 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 311, 313) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.05% | 5 | 0.08% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 1 | 0.02% |
| High Voltage Capacitor | 65 | 1.10% | 14 | 0.24% |
| Software/Firmware | 1 | 0.02% | 0 | 0.00% |
| Mechanical | 2 | 0.03% | 3 | 0.05% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 5 | 0.08% | 2 | 0.03% |
| **Total** | **76** | **1.29%** | **25** | **0.42%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.04% | 98.01% | 97.13% | 95.82% | 94.81% | 92.39% | 87.81% | 85.96% | 85.96% |
| ± 1 STANDARD ERROR | 0.13% | 0.19% | 0.24% | 0.29% | 0.33% | 0.40% | 0.53% | 0.59% | 0.59% |
| SAMPLE SIZE | 5,530 | 4,910 | 4,440 | 4,050 | 3,690 | 3,340 | 2,950 | 2,060 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.13% | 98.16% | 97.41% | 96.31% | 95.76% | 95.22% | 94.79% | 94.31% | 94.31% |
| ± 1 STANDARD ERROR | 0.12% | 0.18% | 0.23% | 0.28% | 0.30% | 0.31% | 0.34% | 0.36% | 0.37% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

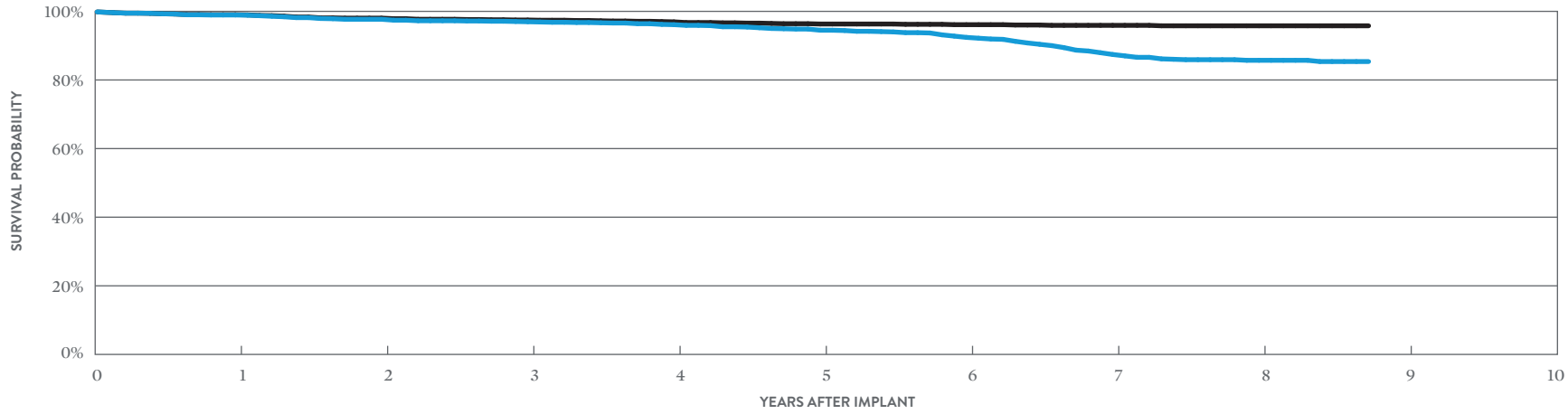
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ DR

### MODEL CD2311-36

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 3,747 |
| Estimated Active US Implants | 1,399 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 86 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 311, 313) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | 0.13% | 5 | 0.13% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 22 | 0.59% | 9 | 0.24% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 4 | 0.11% | 3 | 0.08% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 5 | 0.13% | 1 | 0.03% |
| **Total** | **36** | **0.96%** | **18** | **0.48%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.94% | 97.69% | 96.97% | 96.12% | 94.50% | 92.41% | 87.43% | 85.73% | 85.37% |
| ± 1 STANDARD ERROR | 0.17% | 0.26% | 0.30% | 0.34% | 0.41% | 0.50% | 0.67% | 0.74% | 0.78% |
| SAMPLE SIZE | 3,530 | 3,130 | 2,800 | 2,530 | 2,300 | 2,090 | 1,860 | 1,270 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.03% | 98.03% | 97.48% | 96.94% | 96.31% | 96.12% | 95.92% | 95.79% | 95.79% |
| ± 1 STANDARD ERROR | 0.16% | 0.24% | 0.27% | 0.30% | 0.34% | 0.36% | 0.37% | 0.38% | 0.38% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

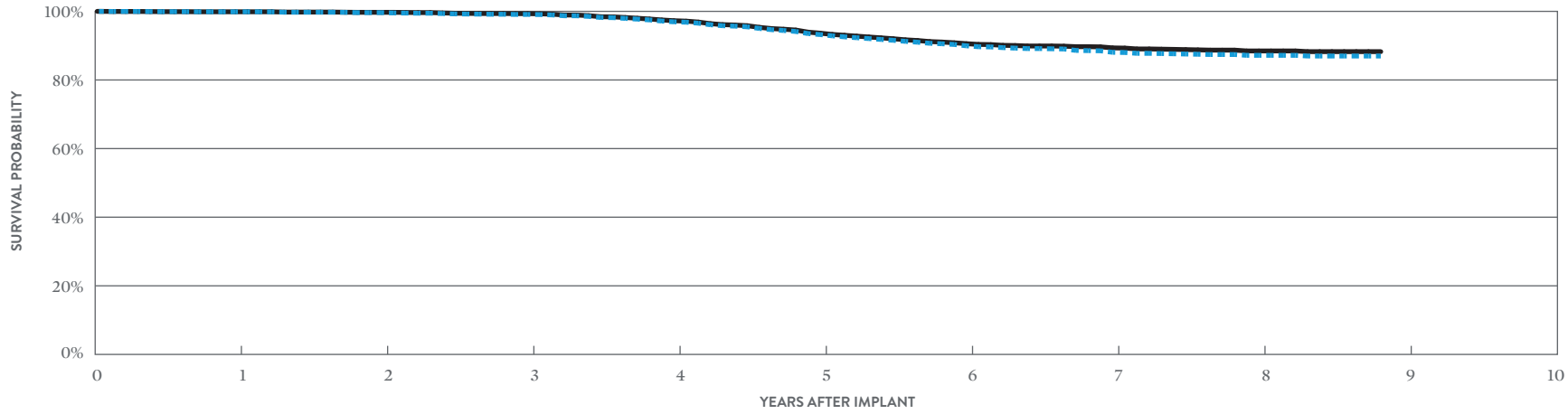
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2257-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 6,798 |
| Estimated Active US Implants | 2,723 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 23 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | 0.07% | 3 | 0.04% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.01% | 2 | 0.03% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.01% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 26 | 0.38% | 151 | 2.22% |
| Other | 3 | 0.04% | 1 | 0.01% |
| **Total** | **35** | **0.51%** | **159** | **2.34%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 106 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.88% | 99.63% | 99.10% | 96.94% | 93.23% | 89.95% | 88.06% | 87.18% | 86.98% |
| ± 1 STANDARD ERROR | 0.04% | 0.08% | 0.13% | 0.24% | 0.37% | 0.45% | 0.50% | 0.53% | 0.55% |
| SAMPLE SIZE | 6,400 | 5,670 | 5,070 | 4,530 | 4,040 | 3,600 | 3,200 | 2,270 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 106 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.88% | 99.72% | 99.33% | 97.27% | 93.64% | 90.58% | 89.35% | 88.46% | 88.26% |
| ± 1 STANDARD ERROR | 0.04% | 0.07% | 0.11% | 0.23% | 0.36% | 0.44% | 0.47% | 0.51% | 0.53% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

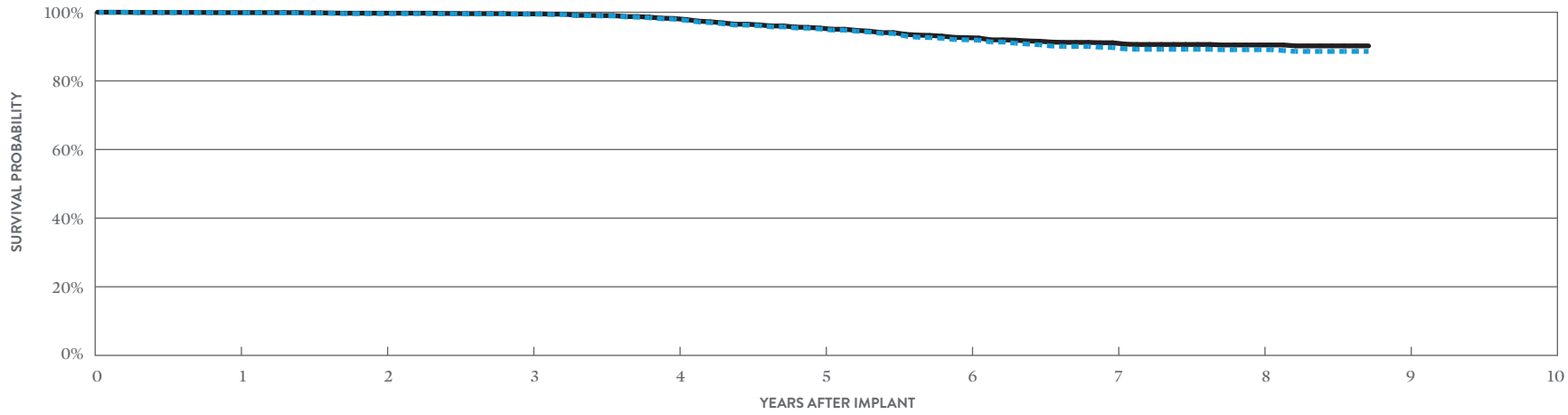
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ DR

### MODEL CD2257-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 4,235 |
| Estimated Active US Implants | 1,638 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 14 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.05% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.02% | 4 | 0.09% |
| High Voltage Capacitor | 1 | 0.02% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.02% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 12 | 0.28% | 73 | 1.72% |
| Other | 0 | 0.00% | 3 | 0.07% |
| **Total** | **16** | **0.38%** | **81** | **1.91%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.62% | 99.43% | 98.01% | 95.13% | 91.97% | 89.71% | 89.08% | 88.58% |
| ± 1 STANDARD ERROR | 0.06% | 0.10% | 0.13% | 0.25% | 0.41% | 0.54% | 0.61% | 0.64% | 0.68% |
| SAMPLE SIZE | 3,970 | 3,520 | 3,140 | 2,760 | 2,440 | 2,190 | 1,940 | 1,380 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.73% | 99.53% | 98.19% | 95.38% | 92.59% | 91.12% | 90.47% | 90.20% |
| ± 1 STANDARD ERROR | 0.05% | 0.09% | 0.12% | 0.24% | 0.40% | 0.52% | 0.58% | 0.60% | 0.63% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

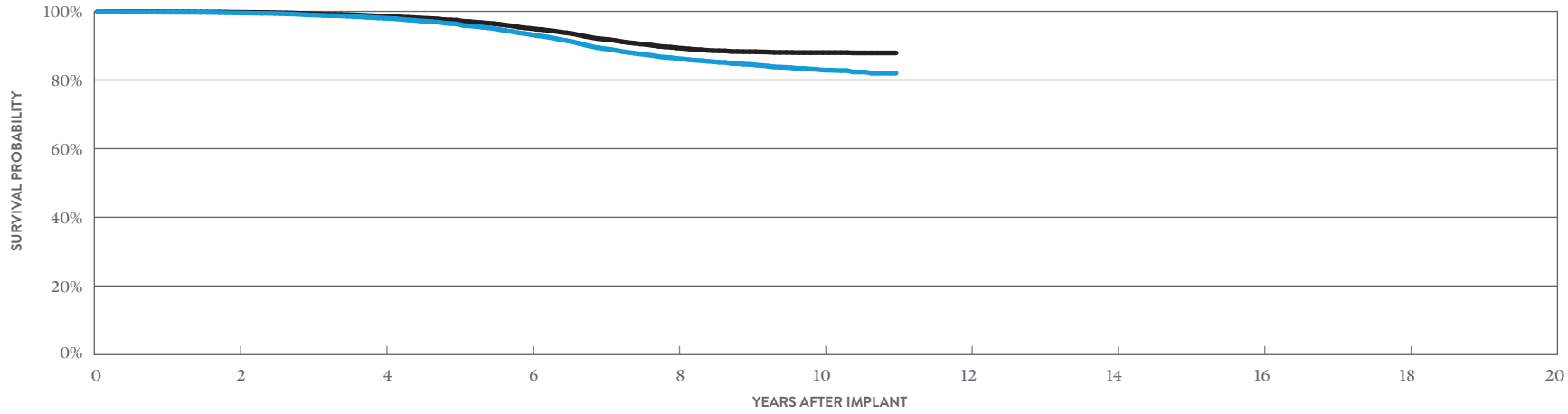
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify™ DR

### MODEL CD2231-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 26,876 |
| Estimated Active US Implants | 7,455 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 281 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 10 | 0.04% | 9 | 0.03% |
| Electrical Interconnect | 3 | 0.01% | 2 | <0.01% |
| Battery | 28 | 0.10% | 54 | 0.20% |
| High Voltage Capacitor | 5 | 0.02% | 2 | <0.01% |
| Software/Firmware | 1 | <0.01% | 2 | <0.01% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 164 | 0.61% | 386 | 1.44% |
| Other | 16 | 0.06% | 13 | 0.05% |
| **Total** | **227** | **0.84%** | **468** | **1.74%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.54% | 98.02% | 93.27% | 86.28% | 82.91% | 81.98% |
| ± 1 STANDARD ERROR | 0.04% | 0.10% | 0.19% | 0.28% | 0.33% | 0.39% |
| SAMPLE SIZE | 22,300 | 18,200 | 14,570 | 11,460 | 5,730 | 340 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.76% | 98.62% | 95.03% | 89.37% | 87.98% | 87.89% |
| ± 1 STANDARD ERROR | 0.03% | 0.08% | 0.17% | 0.25% | 0.28% | 0.28% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

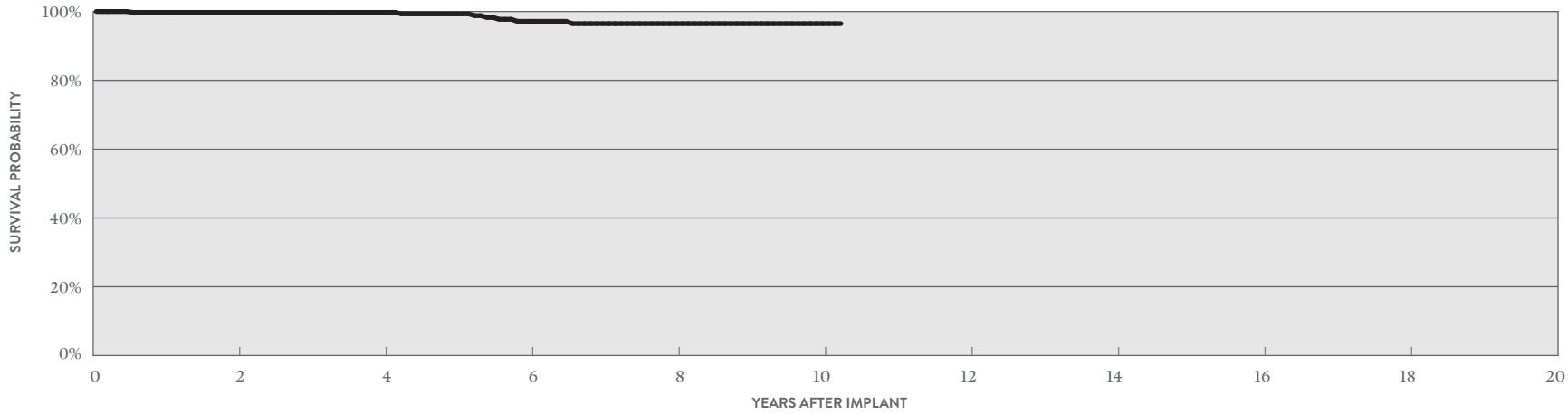
## Fortify™ DR

### MODEL CD2231-40Q*

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 390 |
| Active Devices Enrolled in Study | 94 |
| Cumulative Months of Follow-up | 25,850 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 7 | 1.79% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.26% | 1 | 0.26% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 2 | 0.51% | 7 | 1.79% |
| Other | 1 | 0.26% | 0 | 0.00% |
| **Total** | **4** | **1.03%** | **8** | **2.05%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 123 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.74% | 99.74% | 97.14% | 96.47% | 96.47% | 96.47% |
| ± 1 STANDARD ERROR | 0.26% | 0.26% | 1.18% | 1.35% | 1.35% | 1.35% |
| SAMPLE SIZE | 340 | 260 | 180 | 130 | 80 | 60 |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

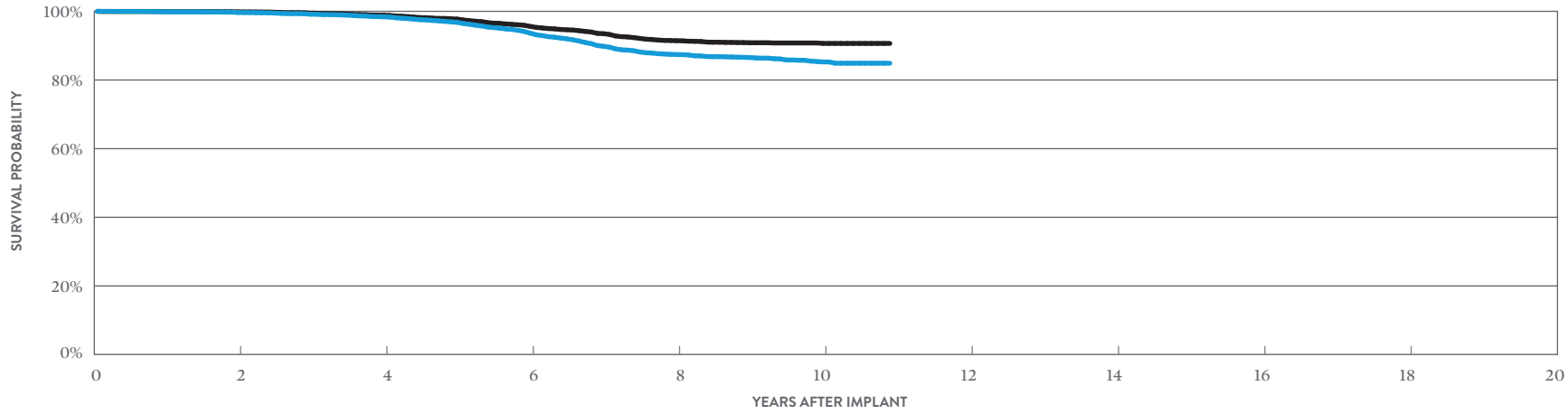
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify™ DR

### MODEL CD2231-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 12,092 |
| Estimated Active US Implants | 3,342 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 131 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 8 | 0.07% | 3 | 0.02% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 5 | 0.04% | 9 | 0.07% |
| High Voltage Capacitor | 8 | 0.07% | 2 | 0.02% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 59 | 0.49% | 127 | 1.05% |
| Other | 5 | 0.04% | 5 | 0.04% |
| **Total** | **86** | **0.71%** | **148** | **1.22%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 131 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.66% | 98.39% | 93.65% | 87.42% | 85.26% | 84.88% |
| ± 1 STANDARD ERROR | 0.05% | 0.13% | 0.28% | 0.42% | 0.48% | 0.51% |
| SAMPLE SIZE | 9,910 | 7,880 | 6,190 | 4,800 | 2,330 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 131 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.86% | 98.87% | 95.61% | 91.45% | 90.65% | 90.65% |
| ± 1 STANDARD ERROR | 0.03% | 0.11% | 0.23% | 0.36% | 0.38% | 0.39% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

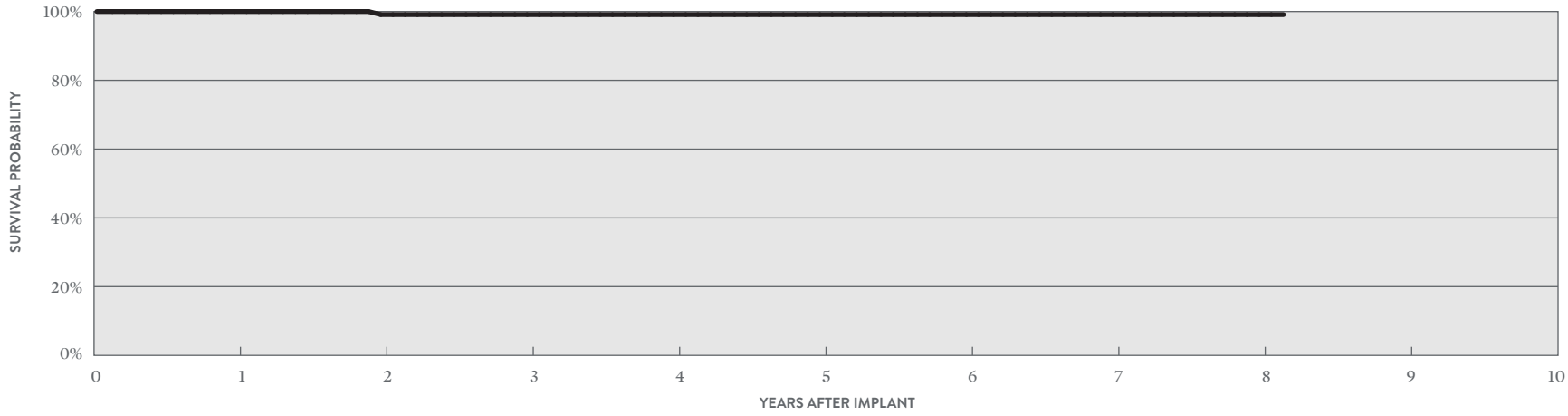
## Fortify™ DR

### MODEL CD2231-40

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 177 |
| Active Devices Enrolled in Study | 45 |
| Cumulative Months of Follow-up | 9,741 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 2 | 1.13% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | 0.56% | 3 | 1.69% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **0.56%** | **3** | **1.69%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 98 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.10% | 99.10% | 99.10% | 99.10% | 99.10% | 99.10% | 99.10% | 99.09% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.90% | 0.90% | 0.90% | 0.90% | 0.90% | 0.90% | 0.90% |
| SAMPLE SIZE | 160 | 130 | 100 | 90 | 70 | 60 | 60 | 50 | 50 |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

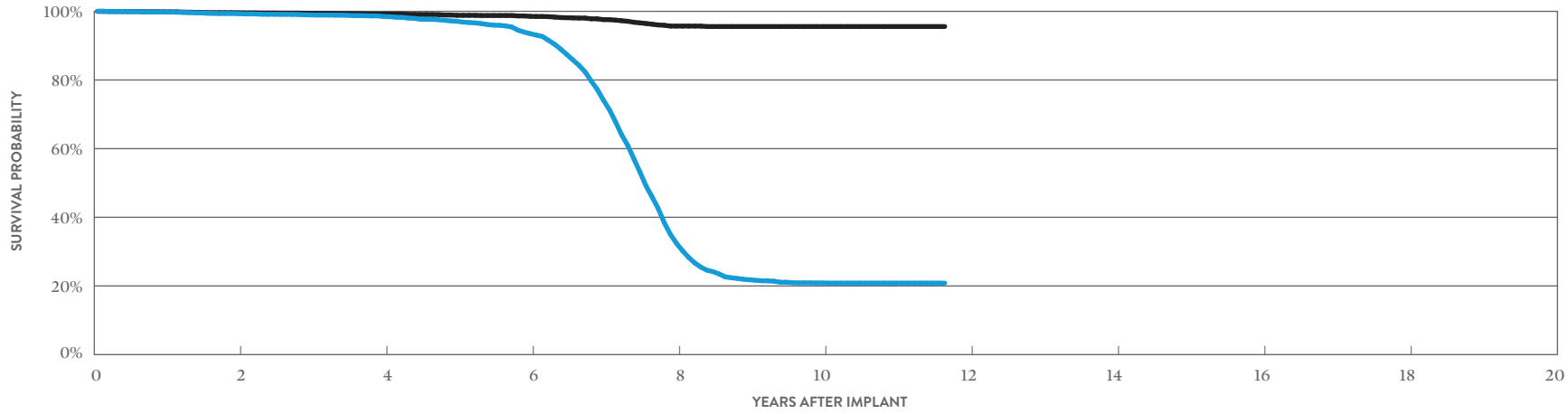
**CUSTOMER REPORTED PERFORMANCE DATA**

## Current™ + DR

### MODEL CD2211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 8,148 |
| Estimated Active US Implants | 1,122 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 1,467 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.07% | 6 | 0.07% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 6 | 0.07% | 8 | 0.10% |
| High Voltage Capacitor | 3 | 0.04% | 0 | 0.00% |
| Software/Firmware | 1 | 0.01% | 23 | 0.28% |
| Mechanical | 0 | 0.00% | 2 | 0.02% |
| Possible Early Battery Depletion | 4 | 0.05% | 3 | 0.04% |
| Other | 5 | 0.06% | 5 | 0.06% |
| **Total** | **25** | **0.31%** | **47** | **0.58%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 140 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.33% | 98.48% | 93.49% | 32.41% | 20.87% | 20.83% |
| ± 1 STANDARD ERROR | 0.10% | 0.14% | 0.34% | 0.69% | 0.56% | 0.56% |
| SAMPLE SIZE | 6,610 | 5,330 | 4,340 | 2,560 | 1,240 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 140 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.58% | 99.22% | 98.54% | 95.70% | 95.57% | 95.57% |
| ± 1 STANDARD ERROR | 0.07% | 0.11% | 0.16% | 0.35% | 0.36% | 0.36% |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

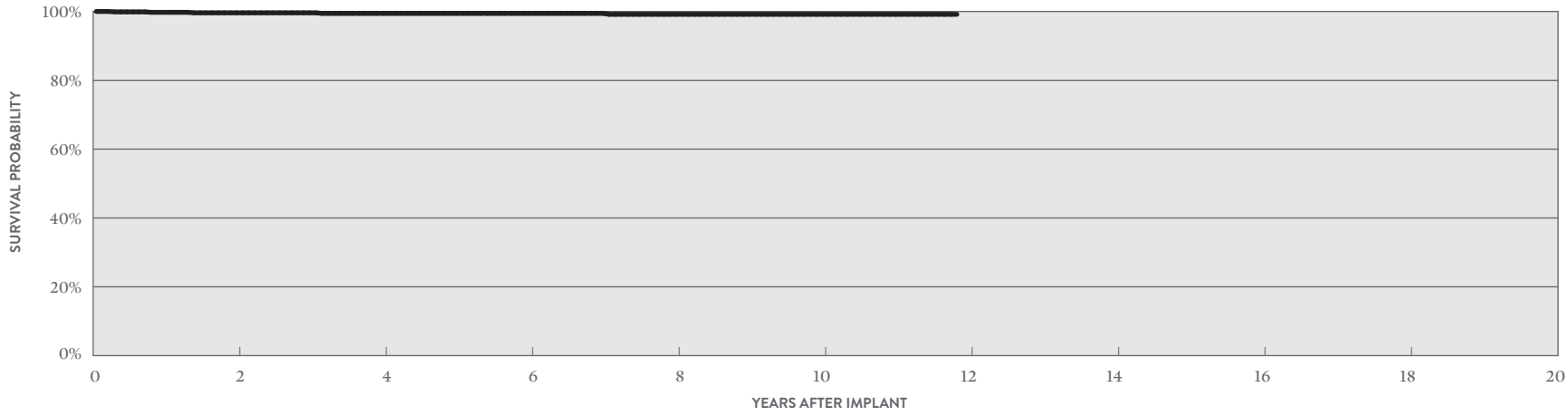
## Current™ + DR

### MODEL CD2211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Number of Devices Enrolled in Study | 835 |
| Active Devices Enrolled in Study | 301 |
| Cumulative Months of Follow-up | 65,161 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 4 | 0.48% |
| Skin Erosion | 1 | 0.12% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.12% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.12% | 2 | 0.24% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.24% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.12% |
| Other | 1 | 0.12% | 2 | 0.24% |
| **Total** | **2** | **0.24%** | **8** | **0.96%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 142 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.61% | 99.44% | 99.44% | 99.17% | 99.17% | 99.17% |
| ± 1 STANDARD ERROR | 0.23% | 0.28% | 0.28% | 0.39% | 0.39% | 0.39% |
| SAMPLE SIZE | 710 | 570 | 440 | 350 | 310 | 50 |

**DF4-LLHH connector type.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

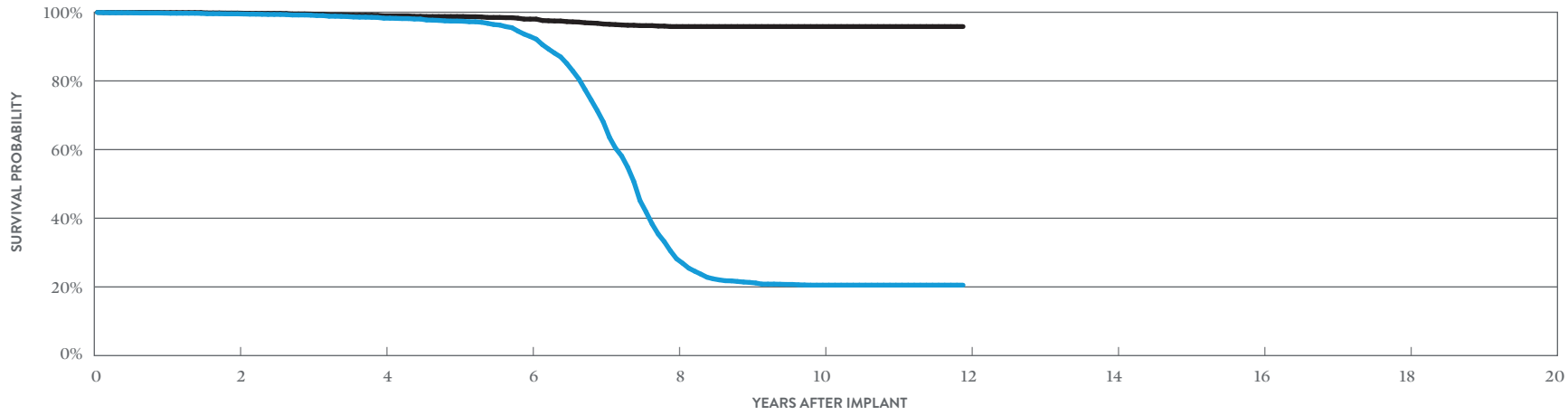
## CUSTOMER REPORTED PERFORMANCE DATA

## Current™ + DR

### MODEL CD2211-36

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 6,271 |
| Estimated Active US Implants | 907 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 1,101 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.05% | 1 | 0.02% |
| Electrical Interconnect | 2 | 0.03% | 0 | 0.00% |
| Battery | 8 | 0.13% | 4 | 0.06% |
| High Voltage Capacitor | 1 | 0.02% | 0 | 0.00% |
| Software/Firmware | 1 | 0.02% | 16 | 0.26% |
| Mechanical | 0 | 0.00% | 1 | 0.02% |
| Possible Early Battery Depletion | 9 | 0.14% | 4 | 0.06% |
| Other | 6 | 0.10% | 2 | 0.03% |
| **Total** | **30** | **0.48%** | **28** | **0.45%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.53% | 98.26% | 92.93% | 28.20% | 20.52% | 20.52% |
| ± 1 STANDARD ERROR | 0.09% | 0.18% | 0.41% | 0.76% | 0.64% | 0.64% |
| SAMPLE SIZE | 5,050 | 4,010 | 3,170 | 1,780 | 930 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.76% | 98.94% | 98.00% | 95.83% | 95.83% | 95.83% |
| ± 1 STANDARD ERROR | 0.07% | 0.14% | 0.23% | 0.38% | 0.38% | 0.38% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

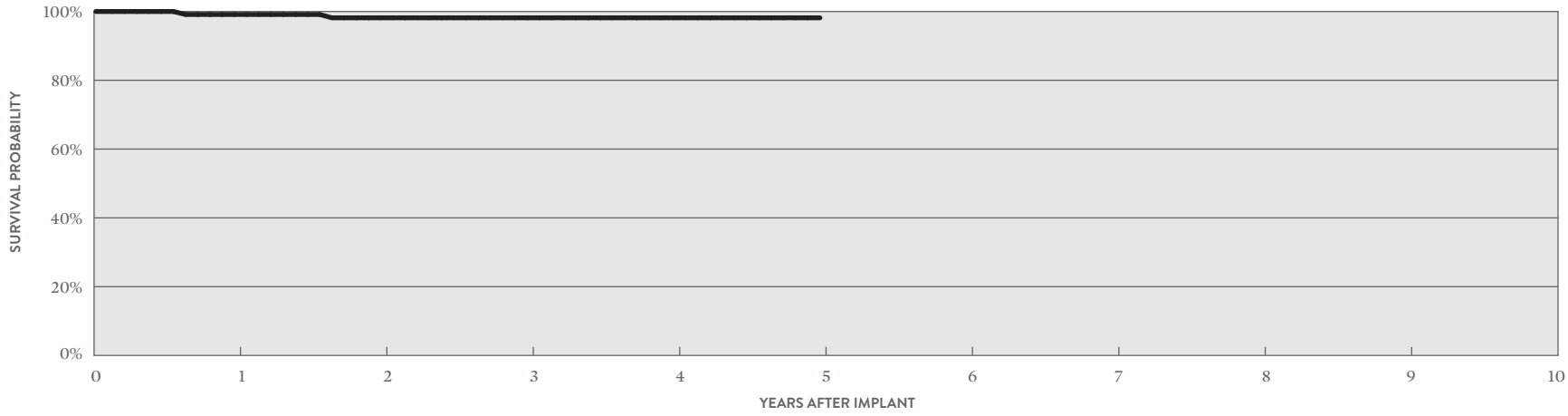
## Current™ + DR

### MODEL CD2211-36

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Number of Devices Enrolled in Study | 122 |
| Active Devices Enrolled in Study | 12 |
| Cumulative Months of Follow-up | 6,509 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 1 | 0.82% |
| Premature Battery Depletion | 1 | 0.82% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 1.64% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.82% | 1 | 0.82% |
| **Total** | **1** | **0.82%** | **3** | **2.46%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.13% | 98.16% | 98.16% | 98.16% | 98.16% |
| ± 1 STANDARD ERROR | 0.87% | 1.29% | 1.29% | 1.29% | 1.29% |
| SAMPLE SIZE | 120 | 100 | 80 | 60 | 50 |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

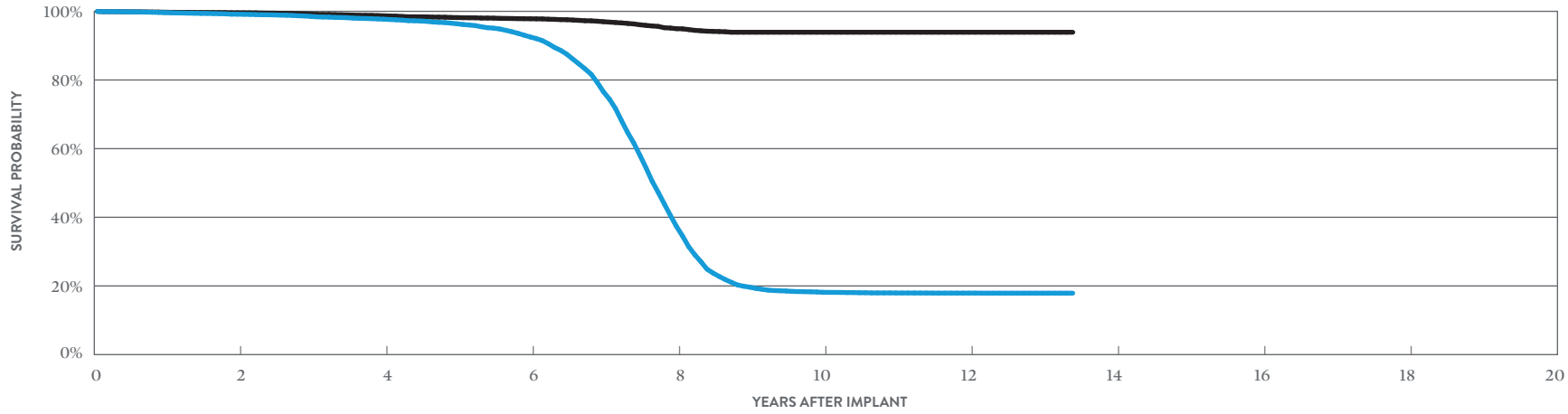
**CUSTOMER REPORTED PERFORMANCE DATA**

## Current™ DR RF

### MODEL 2207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 22,390 |
| Estimated Active US Implants | 2,385 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 3,697 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 11 | 0.05% | 12 | 0.05% |
| Electrical Interconnect | 6 | 0.03% | 2 | <0.01% |
| Battery | 21 | 0.09% | 9 | 0.04% |
| High Voltage Capacitor | 1 | <0.01% | 0 | 0.00% |
| Software/Firmware | 4 | 0.02% | 48 | 0.21% |
| Mechanical | 1 | <0.01% | 23 | 0.10% |
| Possible Early Battery Depletion | 40 | 0.18% | 21 | 0.09% |
| Other | 35 | 0.16% | 6 | 0.03% |
| **Total** | **119** | **0.53%** | **121** | **0.54%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.16% | 97.71% | 92.53% | 37.32% | 18.15% | 17.92% | 17.90% |
| ± 1 STANDARD ERROR | 0.07% | 0.12% | 0.22% | 0.46% | 0.34% | 0.33% | 0.33% |
| SAMPLE SIZE | 17,930 | 13,960 | 11,010 | 6,460 | 2,960 | 2,260 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.59% | 98.70% | 97.83% | 94.94% | 93.91% | 93.91% | 93.91% |
| ± 1 STANDARD ERROR | 0.05% | 0.09% | 0.12% | 0.22% | 0.28% | 0.28% | 0.28% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

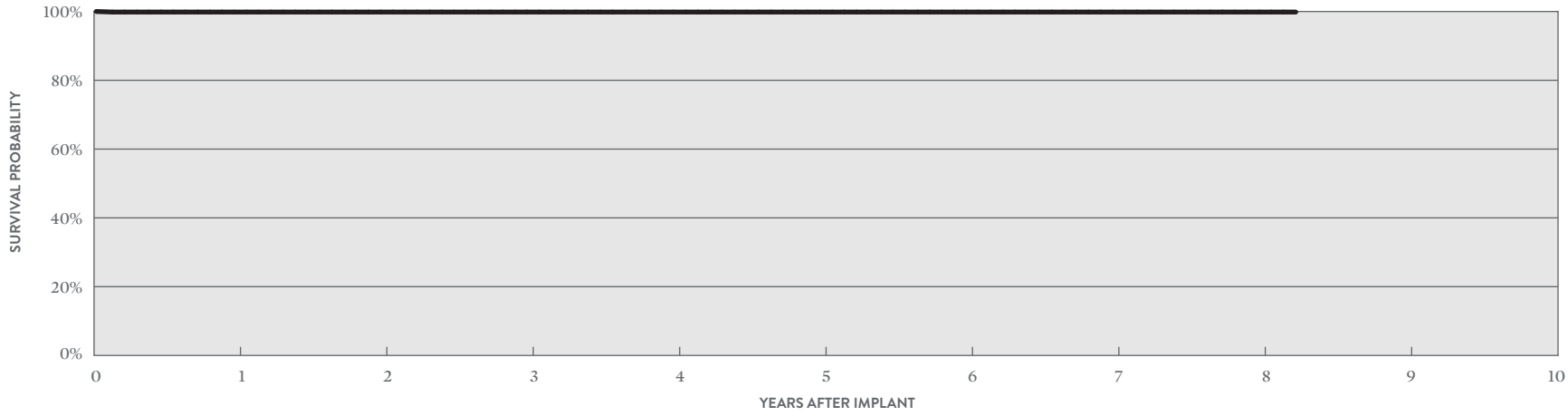
## Current™ DR RF

### MODEL 2207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Number of Devices Enrolled in Study | 631 |
| Active Devices Enrolled in Study | 32 |
| Cumulative Months of Follow-up | 33,421 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 1 | 0.16% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.32% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 1 | 0.16% | 1 | 0.16% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **0.16%** | **3** | **0.48%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 99 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% |
| ± 1 STANDARD ERROR | 0.16% | 0.16% | 0.16% | 0.16% | 0.16% | 0.16% | 0.16% | 0.16% | 0.16% |
| SAMPLE SIZE | 600 | 520 | 420 | 340 | 270 | 220 | 170 | 100 | 50 |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

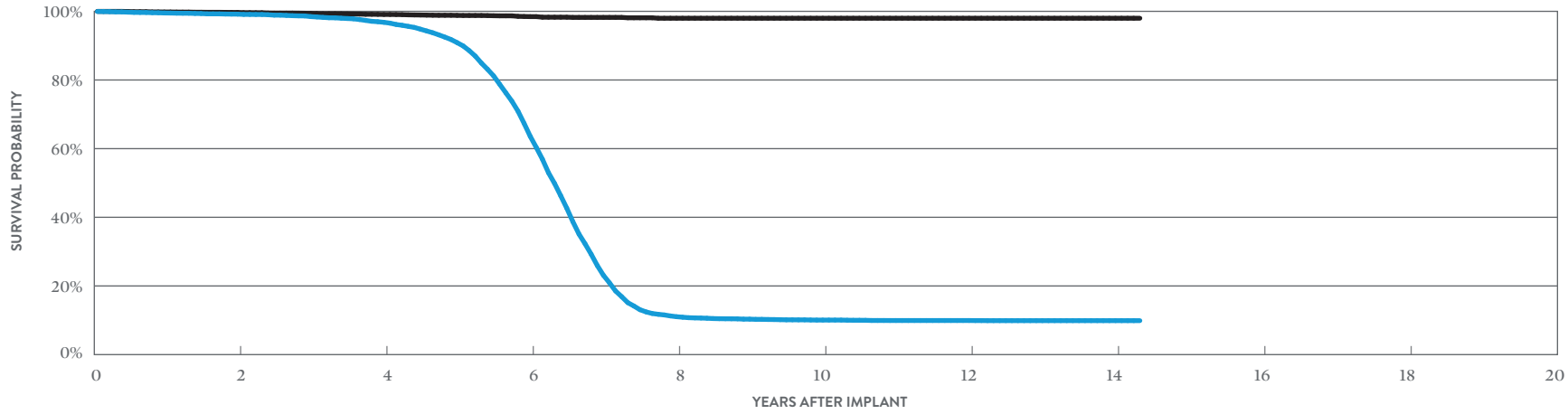
## CUSTOMER REPORTED PERFORMANCE DATA

## Atlas™ II + DR

### MODEL V-268

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 14,713 |
| Estimated Active US Implants | 1,030 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 2,967 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 316) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.04% | 4 | 0.03% |
| Electrical Interconnect | 4 | 0.03% | 0 | 0.00% |
| Battery | 9 | 0.06% | 3 | 0.02% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 19 | 0.13% | 6 | 0.04% |
| Other | 9 | 0.06% | 5 | 0.03% |
| **Total** | **47** | **0.32%** | **19** | **0.13%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 172 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.18% | 96.80% | 63.60% | 11.04% | 10.06% | 9.93% | 9.89% | 9.89% |
| ± 1 STANDARD ERROR | 0.08% | 0.17% | 0.54% | 0.32% | 0.30% | 0.30% | 0.30% | 0.30% |
| SAMPLE SIZE | 11,680 | 8,730 | 5,770 | 1,890 | 1,270 | 1,080 | 530 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 172 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.68% | 99.09% | 98.46% | 97.99% | 97.99% | 97.99% | 97.99% | 97.99% |
| ± 1 STANDARD ERROR | 0.05% | 0.09% | 0.13% | 0.19% | 0.19% | 0.19% | 0.19% | 0.19% |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

## Atlas™ II + DR

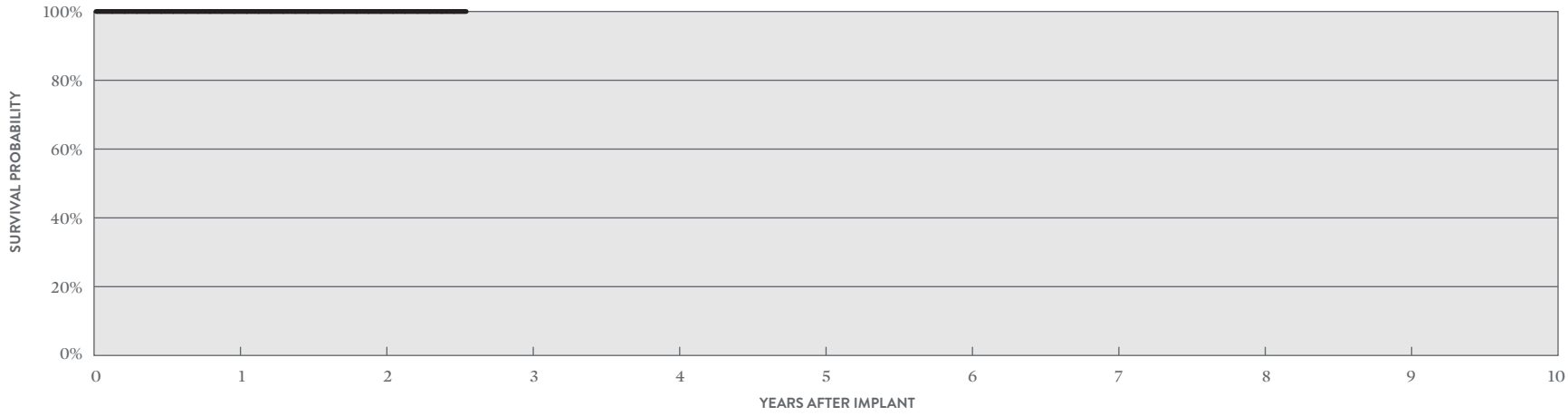
### MODEL V-268

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Number of Devices Enrolled in Study | 101 |
| Active Devices Enrolled in Study | 1 |
| Cumulative Months of Follow-up | 3,816 |
| Estimated Longevity | (see table on page 125) |
| Max. Delivered Energy | 36 joules |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 2 | 1.98% | 0 | 0.00% |
| **Total** | **2** | **1.98%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | AT 31 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 100 | 80 | 50 |

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

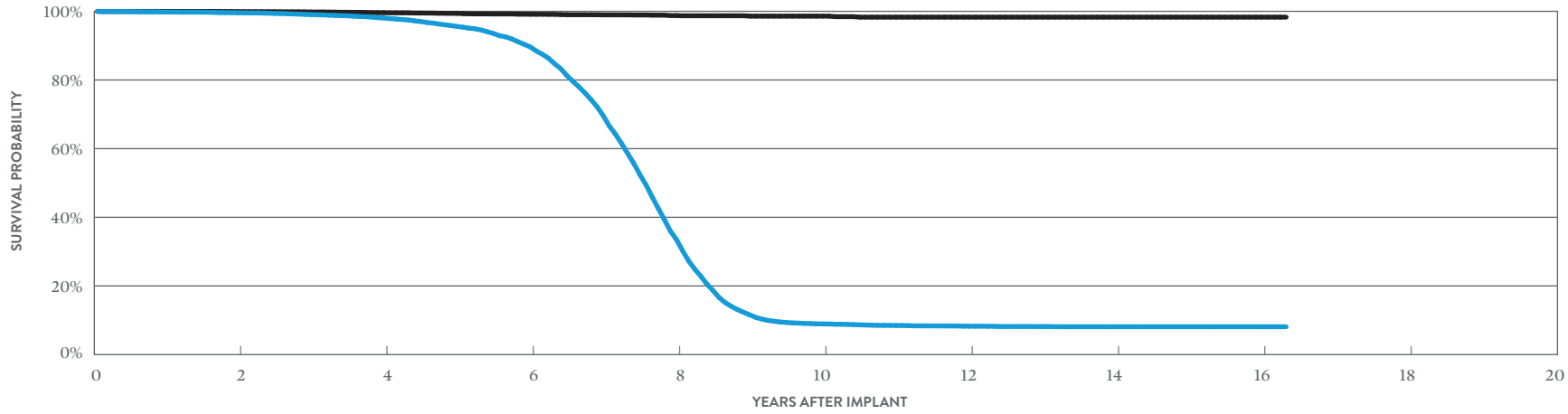
**CUSTOMER REPORTED PERFORMANCE DATA**

## Atlas™ + DR

### MODEL V-243

| | |
|---|---|
| US Regulatory Approval | October 2003 |
| Registered US Implants | 21,082 |
| Estimated Active US Implants | 1,039 |
| Estimated Longevity | (see table on page 125) |
| Normal Battery Depletion | 3,711 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 316, 317, 318) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | 0.02% | 3 | 0.01% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 12 | 0.06% | 4 | 0.02% |
| High Voltage Capacitor | 1 | <0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 4 | 0.02% |
| Possible Early Battery Depletion | 6 | 0.03% | 4 | 0.02% |
| Other | 17 | 0.08% | 2 | <0.01% |
| **Total** | **42** | **0.20%** | **17** | **0.08%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.57% | 98.06% | 89.63% | 33.49% | 8.93% | 8.27% | 8.12% | 8.12% | 8.12% |
| ± 1 STANDARD ERROR | 0.05% | 0.11% | 0.29% | 0.50% | 0.26% | 0.25% | 0.24% | 0.24% | 0.24% |
| SAMPLE SIZE | 16,890 | 12,750 | 9,090 | 4,860 | 1,580 | 1,240 | 1,050 | 440 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.62% | 99.15% | 98.76% | 98.60% | 98.31% | 98.31% | 98.31% | 98.31% |
| ± 1 STANDARD ERROR | 0.02% | 0.05% | 0.08% | 0.12% | 0.15% | 0.21% | 0.21% | 0.21% | 0.21% |

## BATTERY LONGEVITY SUMMARY

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Battery Longevity (years)

| MODELS | FAMILY | NO PACING | 25% PACING | 50% PACING | 100% PACING |
|---|---|---|---|---|---|
| CDDRA500Q | Gallant™ DR† | 10.6 | 9.9 | 9.3 | 8.2 |
| CD2411-36Q | Ellipse™ DR* | 10.4 | 9.6 | 8.9 | 7.7 |
| CD2411-36C | Ellipse™ DR* | 10.4 | 9.6 | 8.9 | 7.7 |
| CD2357-40Q | Fortify Assura™ DR** | 11.1 | 10.2 | 9.5 | 8.3 |
| CD2357-40C | Fortify Assura™ DR** | 11.1 | 10.2 | 9.5 | 8.3 |
| CD2311-36Q | Ellipse™ DR* | 10.4 | 9.6 | 8.9 | 7.7 |
| CD2311-36 | Ellipse™ DR* | 10.4 | 9.6 | 8.9 | 7.7 |
| CD2257-40Q | Fortify Assura™ DR** | 11.1 | 10.2 | 9.5 | 8.3 |
| CD2257-40 | Fortify Assura™ DR** | 11.1 | 10.2 | 9.5 | 8.3 |
| CD2231-40Q | Fortify™ DR** | 10.1 | 9.3 | 8.6 | 7.5 |
| CD2231-40 | Fortify™ DR** | 10.1 | 9.3 | 8.6 | 7.5 |
| CD2211-36Q | Current™ + DR*** | 8.2 | 7.5 | 7.0 | 6.1 |
| CD2211-36 | Current™ + DR*** | 8.2 | 7.5 | 7.0 | 6.1 |
| 2207-36 | Current™ DR RF*** | 8.2 | 7.5 | 7.0 | 6.1 |
| V-268 | Atlas™ II + DR*** | 8.2 | 7.5 | 7.0 | 6.1 |
| V-243 | Atlas™ + DR*** | 7.9 | 7.3 | 6.9 | 6.1 |

*Pacing parameters: DDD, 2.5V, 0.5 ms, 60 ppm, 500 ohms*

** Battery voltage range 3.20-2.59. Two maximum charges per year.*

*** Battery voltage range 3.20-2.59. Three maximum charges per year.*

**** Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.*

*†Capacitor maintenance interval: 1 charge per every 9 months*

SUMMARY INFORMATION

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CDDRA500Q | Gallant™ DR* | | | | | | | | | | |
| CD2411-36Q | Ellipse™ DR | 99.91% | 99.87% | 99.80% | 99.76% | 99.68% | 99.53% | 98.08% | | | |
| CD2411-36C | Ellipse™ DR | 99.81% | 99.74% | 99.72% | 99.59% | 99.44% | 99.09% | 96.47% | | | |
| CD2357-40Q | Fortify Assura™ DR | 99.88% | 99.82% | 99.79% | 99.76% | 99.73% | | | | | |
| CD2357-40Q | Fortify Assura™ DR† | 99.79% | 99.32% | 96.46% | 91.15% | 85.91% | 82.62% | 79.26% | | | |
| CD2357-40C | Fortify Assura™ DR | 99.89% | 99.86% | 99.79% | 99.79% | 99.72% | | | | | |
| CD2357-40C | Fortify Assura™ DR† | 99.72% | 99.41% | 97.41% | 92.77% | 88.13% | 85.20% | 82.51% | | | |
| CD2311-36Q | Ellipse™ DR | 99.04% | 98.01% | 97.13% | 95.82% | 94.81% | 92.39% | 87.81% | 85.96% | | |
| CD2311-36 | Ellipse™ DR | 98.94% | 97.69% | 96.97% | 96.12% | 94.50% | 92.41% | 87.43% | 85.73% | | |
| CD2257-40Q | Fortify Assura™ DR† | 99.88% | 99.63% | 99.10% | 96.94% | 93.23% | 89.95% | 88.06% | 87.18% | | |
| CD2257-40 | Fortify Assura™ DR† | 99.85% | 99.62% | 99.43% | 98.01% | 95.13% | 91.97% | 89.71% | 89.08% | | |
| CD2231-40Q | Fortify™ DR† | 99.75% | 99.54% | 98.95% | 98.02% | 96.33% | 93.27% | 89.17% | 86.28% | 84.55% | 82.91% |
| CD2231-40 | Fortify™ DR† | 99.88% | 99.66% | 99.16% | 98.39% | 96.79% | 93.65% | 89.82% | 87.42% | 86.55% | 85.26% |
| CD2211-36Q | Current™ + DR | 99.78% | 99.33% | 98.95% | 98.48% | 97.11% | 93.49% | 74.15% | 32.41% | 21.80% | 20.87% |
| CD2211-36 | Current™ + DR | 99.75% | 99.53% | 99.15% | 98.26% | 97.43% | 92.93% | 68.01% | 28.20% | 21.31% | 20.52% |
| 2207-36 | Current™ DR RF | 99.64% | 99.16% | 98.52% | 97.71% | 96.36% | 92.53% | 76.58% | 37.32% | 19.64% | 18.15% |
| V-268 | Atlas™ II + DR | 99.52% | 99.18% | 98.47% | 96.80% | 90.89% | 63.60% | 23.12% | 11.04% | 10.33% | 10.06% |
| V-243 | Atlas™ + DR | 99.79% | 99.57% | 99.05% | 98.06% | 95.59% | 89.63% | 69.51% | 33.49% | 11.57% | 8.93% |

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

*†Premature battery depletion advisory population.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Survival Probability Summary

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CDDRA500Q | Gallant™ DR* | | | | | | | | | | |
| CD2411-36Q | Ellipse™ DR | 99.92% | 99.88% | 99.83% | 99.82% | 99.82% | 99.82% | 99.82% | | | |
| CD2411-36C | Ellipse™ DR | 99.81% | 99.74% | 99.74% | 99.66% | 99.60% | 99.51% | 99.25% | | | |
| CD2357-40Q | Fortify Assura™ DR | 99.90% | 99.86% | 99.82% | 99.81% | 99.81% | | | | | |
| CD2357-40Q | Fortify Assura™ DR† | 99.84% | 99.40% | 96.61% | 91.37% | 86.21% | 83.06% | 79.82% | | | |
| CD2357-40C | Fortify Assura™ DR | 99.89% | 99.86% | 99.83% | 99.83% | 99.76% | | | | | |
| CD2357-40C | Fortify Assura™ DR† | 99.80% | 99.58% | 97.61% | 93.12% | 88.71% | 85.91% | 83.61% | | | |
| CD2311-36Q | Ellipse™ DR | 99.13% | 98.16% | 97.41% | 96.31% | 95.76% | 95.22% | 94.79% | 94.31% | | |
| CD2311-36 | Ellipse™ DR | 99.03% | 98.03% | 97.48% | 96.94% | 96.31% | 96.12% | 95.92% | 95.79% | | |
| CD2257-40Q | Fortify Assura™ DR† | 99.88% | 99.72% | 99.33% | 97.27% | 93.64% | 90.58% | 89.35% | 88.46% | | |
| CD2257-40 | Fortify Assura™ DR† | 99.90% | 99.73% | 99.53% | 98.19% | 95.38% | 92.59% | 91.12% | 90.47% | | |
| CD2231-40Q | Fortify™ DR† | 99.87% | 99.76% | 99.31% | 98.62% | 97.43% | 95.03% | 91.91% | 89.37% | 88.26% | 87.98% |
| CD2231-40 | Fortify™ DR† | 99.95% | 99.86% | 99.48% | 98.87% | 97.75% | 95.61% | 93.49% | 91.45% | 90.85% | 90.65% |
| CD2211-36Q | Current™ + DR | 99.85% | 99.58% | 99.41% | 99.22% | 98.83% | 98.54% | 97.58% | 95.70% | 95.57% | 95.57% |
| CD2211-36 | Current™ + DR | 99.90% | 99.76% | 99.47% | 98.94% | 98.75% | 98.00% | 96.57% | 95.83% | 95.83% | 95.83% |
| 2207-36 | Current™ DR RF | 99.75% | 99.59% | 99.21% | 98.70% | 98.18% | 97.83% | 96.98% | 94.94% | 93.91% | 93.91% |
| V-268 | Atlas™ II + DR | 99.81% | 99.68% | 99.40% | 99.09% | 98.82% | 98.46% | 98.23% | 97.99% | 97.99% | 97.99% |
| V-243 | Atlas™ + DR | 99.97% | 99.90% | 99.80% | 99.62% | 99.41% | 99.15% | 98.97% | 98.76% | 98.60% | 98.60% |

**No survival probability is stated at one year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data. Please refer to the individual graphs for data up to one year.*

*†Premature battery depletion advisory population.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDDRA500Q | Gallant™ DR | 3,534 | 0.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD2411-36Q | Ellipse™ DR | 31,040 | 4.10% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | **9** | **0.03%** |
| CD2411-36C | Ellipse™ DR | 10,737 | 6.30% | 3 | 0.03% | 0 | 0.00% | 0 | 0.00% | 7 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **10** | **0.09%** |
| CD2357-40Q | Fortify Assura™ DR | 38,644 | 3.50% | 3 | <0.01% | 0 | 0.00% | 1 | <0.01% | 3 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 5 | 0.01% | **12** | **0.03%** |
| CD2357-40Q | Fortify Assura™ DR† | 12,263 | 16.80% | 3 | 0.02% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 71 | 0.58% | 1 | <0.01% | **76** | **0.62%** |
| CD2357-40C | Fortify Assura™ DR | 9,916 | 4.60% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **0.03%** |
| CD2357-40C | Fortify Assura™ DR† | 6,956 | 18.20% | 3 | 0.04% | 2 | 0.03% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 31 | 0.45% | 2 | 0.03% | **39** | **0.56%** |
| CD2311-36Q | Ellipse™ DR | 5,898 | 11.90% | 3 | 0.05% | 0 | 0.00% | 0 | 0.00% | 65 | 1.10% | 1 | 0.02% | 2 | 0.03% | 0 | 0.00% | 5 | 0.08% | **76** | **1.29%** |
| CD2311-36 | Ellipse™ DR | 3,747 | 13.10% | 5 | 0.13% | 0 | 0.00% | 0 | 0.00% | 22 | 0.59% | 0 | 0.00% | 4 | 0.11% | 0 | 0.00% | 5 | 0.13% | **36** | **0.96%** |
| CD2257-40Q | Fortify Assura™ DR† | 6,798 | 16.10% | 5 | 0.07% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 26 | 0.38% | 3 | 0.04% | **35** | **0.51%** |
| CD2257-40 | Fortify Assura™ DR† | 4,235 | 18.30% | 2 | 0.05% | 0 | 0.00% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 12 | 0.28% | 0 | 0.00% | **16** | **0.38%** |
| CD2231-40Q | Fortify™ DR† | 26,876 | 15.60% | 10 | 0.04% | 3 | 0.01% | 28 | 0.10% | 5 | 0.02% | 1 | <0.01% | 0 | 0.00% | 164 | 0.61% | 16 | 0.06% | **227** | **0.84%** |
| CD2231-40 | Fortify™ DR† | 12,092 | 17.60% | 8 | 0.07% | 1 | <0.01% | 5 | 0.04% | 8 | 0.07% | 0 | 0.00% | 0 | 0.00% | 59 | 0.49% | 5 | 0.04% | **86** | **0.71%** |
| CD2211-36Q | Current™ + DR | 8,148 | 28.70% | 6 | 0.07% | 0 | 0.00% | 6 | 0.07% | 3 | 0.04% | 1 | 0.01% | 0 | 0.00% | 4 | 0.05% | 5 | 0.06% | **25** | **0.31%** |
| CD2211-36 | Current™ + DR | 6,271 | 29.70% | 3 | 0.05% | 2 | 0.03% | 8 | 0.13% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 9 | 0.14% | 6 | 0.10% | **30** | **0.48%** |
| 2207-36 | Current™ DR RF | 22,390 | 28.80% | 11 | 0.05% | 6 | 0.03% | 21 | 0.09% | 1 | <0.01% | 4 | 0.02% | 1 | <0.01% | 40 | 0.18% | 35 | 0.16% | **119** | **0.53%** |
| V-268 | Atlas™ II + DR | 14,713 | 29.90% | 6 | 0.04% | 4 | 0.03% | 9 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 19 | 0.13% | 9 | 0.06% | **47** | **0.32%** |
| V-243 | Atlas™ + DR | 21,082 | 27.40% | 5 | 0.02% | 1 | <0.01% | 12 | 0.06% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 6 | 0.03% | 17 | 0.08% | **42** | **0.20%** |

*Definitions of malfunction categories can be found on pages 5-6.*
*†Premature battery depletion advisory population.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## US Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDDRA500Q | Gallant™ DR | 3,534 | 0.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD2411-36Q | Ellipse™ DR | 31,040 | 4.10% | 4 | 0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 3 | <0.01% | 1 | <0.01% | 2 | <0.01% | **11** | **0.04%** |
| CD2411-36C | Ellipse™ DR | 10,737 | 6.30% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 3 | 0.03% | **7** | **0.07%** |
| CD2357-40Q | Fortify Assura™ DR | 38,644 | 3.50% | 5 | 0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | **11** | **0.03%** |
| CD2357-40Q | Fortify Assura™ DR† | 12,263 | 16.80% | 8 | 0.07% | 0 | 0.00% | 12 | 0.10% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 515 | 4.20% | 5 | 0.04% | **541** | **4.41%** |
| CD2357-40C | Fortify Assura™ DR | 9,916 | 4.60% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | **5** | **0.05%** |
| CD2357-40C | Fortify Assura™ DR† | 6,956 | 18.20% | 2 | 0.03% | 1 | 0.01% | 5 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 234 | 3.36% | 1 | 0.01% | **243** | **3.49%** |
| CD2311-36Q | Ellipse™ DR | 5,898 | 11.90% | 5 | 0.08% | 0 | 0.00% | 1 | 0.02% | 14 | 0.24% | 0 | 0.00% | 3 | 0.05% | 0 | 0.00% | 2 | 0.03% | **25** | **0.42%** |
| CD2311-36 | Ellipse™ DR | 3,747 | 13.10% | 5 | 0.13% | 0 | 0.00% | 0 | 0.00% | 9 | 0.24% | 0 | 0.00% | 3 | 0.08% | 0 | 0.00% | 1 | 0.03% | **18** | **0.48%** |
| CD2257-40Q | Fortify Assura™ DR† | 6,798 | 16.10% | 3 | 0.04% | 0 | 0.00% | 2 | 0.03% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 151 | 2.22% | 1 | 0.01% | **159** | **2.34%** |
| CD2257-40 | Fortify Assura™ DR† | 4,235 | 18.30% | 0 | 0.00% | 0 | 0.00% | 4 | 0.09% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 73 | 1.72% | 3 | 0.07% | **81** | **1.91%** |
| CD2231-40Q | Fortify™ DR† | 26,876 | 15.60% | 9 | 0.03% | 2 | <0.01% | 54 | 0.20% | 2 | <0.01% | 2 | <0.01% | 0 | 0.00% | 386 | 1.44% | 13 | 0.05% | **468** | **1.74%** |
| CD2231-40 | Fortify™ DR† | 12,092 | 17.60% | 3 | 0.02% | 0 | 0.00% | 9 | 0.07% | 2 | 0.02% | 1 | <0.01% | 1 | <0.01% | 127 | 1.05% | 5 | 0.04% | **148** | **1.22%** |
| CD2211-36Q | Current™ + DR | 8,148 | 28.70% | 6 | 0.07% | 0 | 0.00% | 8 | 0.10% | 0 | 0.00% | 23 | 0.28% | 2 | 0.02% | 3 | 0.04% | 5 | 0.06% | **47** | **0.58%** |
| CD2211-36 | Current™ + DR | 6,271 | 29.70% | 1 | 0.02% | 0 | 0.00% | 4 | 0.06% | 0 | 0.00% | 16 | 0.26% | 1 | 0.02% | 4 | 0.06% | 2 | 0.03% | **28** | **0.45%** |
| 2207-36 | Current™ DR RF | 22,390 | 28.80% | 12 | 0.05% | 2 | <0.01% | 9 | 0.04% | 0 | 0.00% | 48 | 0.21% | 23 | 0.10% | 21 | 0.09% | 6 | 0.03% | **121** | **0.54%** |
| V-268 | Atlas™ II + DR | 14,713 | 29.90% | 4 | 0.03% | 0 | 0.00% | 3 | 0.02% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 6 | 0.04% | 5 | 0.03% | **19** | **0.13%** |
| V-243 | Atlas™ + DR | 21,082 | 27.40% | 3 | 0.01% | 0 | 0.00% | 4 | 0.02% | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 4 | 0.02% | 2 | <0.01% | **17** | **0.08%** |

*Definitions of malfunction categories can be found on* *pages 5-6.*
*†Premature battery depletion advisory population.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices
## Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDDRA500Q | Gallant™ DR | 6,046 | 0.63% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD2411-36Q | Ellipse™ DR | 31,541 | 4.29% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | **9** | **0.03%** |
| CD2411-36C | Ellipse™ DR | 10,856 | 6.78% | 3 | 0.03% | 0 | 0.00% | 0 | 0.00% | 7 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **10** | **0.09%** |
| CD2357-40Q | Fortify Assura™ DR | 51,218 | 6.83% | 6 | 0.01% | 1 | <0.01% | 1 | <0.01% | 3 | <0.01% | 0 | 0.00% | 0 | 0.00% | 71 | 0.14% | 6 | 0.01% | **88** | **0.17%** |
| CD2357-40C | Fortify Assura™ DR | 17,030 | 10.62% | 5 | 0.03% | 2 | 0.01% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 31 | 0.18% | 2 | 0.01% | **42** | **0.25%** |
| CD2311-36Q | Ellipse™ DR | 5,885 | 13.39% | 3 | 0.05% | 0 | 0.00% | 0 | 0.00% | 65 | 1.10% | 1 | 0.02% | 2 | 0.03% | 0 | 0.00% | 5 | 0.08% | **76** | **1.29%** |
| CD2311-36 | Ellipse™ DR | 3,749 | 13.98% | 5 | 0.13% | 0 | 0.00% | 0 | 0.00% | 22 | 0.59% | 0 | 0.00% | 4 | 0.11% | 0 | 0.00% | 5 | 0.13% | **36** | **0.96%** |
| CD2257-40Q | Fortify Assura™ DR | 6,780 | 16.46% | 5 | 0.07% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 26 | 0.38% | 3 | 0.04% | **35** | **0.52%** |
| CD2257-40 | Fortify Assura™ DR | 4,234 | 18.82% | 2 | 0.05% | 0 | 0.00% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 12 | 0.28% | 0 | 0.00% | **16** | **0.38%** |
| CD2231-40Q | Fortify™ DR | 28,757 | 15.38% | 11 | 0.04% | 3 | 0.01% | 29 | 0.10% | 5 | 0.02% | 1 | <0.01% | 0 | 0.00% | 172 | 0.60% | 17 | 0.06% | **238** | **0.83%** |
| CD2231-40 | Fortify™ DR | 16,173 | 14.20% | 8 | 0.05% | 2 | 0.01% | 5 | 0.03% | 8 | 0.05% | 0 | 0.00% | 0 | 0.00% | 62 | 0.38% | 6 | 0.04% | **91** | **0.56%** |
| CD2211-36Q | Current™ + DR | 15,224 | 18.15% | 9 | 0.06% | 1 | <0.01% | 8 | 0.05% | 8 | 0.05% | 1 | <0.01% | 0 | 0.00% | 8 | 0.05% | 16 | 0.11% | **51** | **0.33%** |
| CD2211-36 | Current™ + DR | 13,483 | 15.07% | 8 | 0.06% | 5 | 0.04% | 11 | 0.08% | 4 | 0.03% | 1 | <0.01% | 0 | 0.00% | 12 | 0.09% | 10 | 0.07% | **51** | **0.38%** |
| 2207-36 | Current™ DR RF | 33,051 | 23.19% | 18 | 0.05% | 11 | 0.03% | 30 | 0.09% | 12 | 0.04% | 5 | 0.02% | 2 | <0.01% | 60 | 0.18% | 47 | 0.14% | **185** | **0.56%** |
| V-268 | Atlas™ II + DR | 25,779 | 19.57% | 15 | 0.06% | 5 | 0.02% | 19 | 0.07% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 32 | 0.12% | 20 | 0.08% | **92** | **0.36%** |
| V-243 | Atlas™ + DR | 34,105 | 19.12% | 5 | 0.01% | 3 | <0.01% | 25 | 0.07% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 14 | 0.04% | 30 | 0.09% | **78** | **0.23%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Worldwide Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CDDRA500Q | Gallant™ DR | 6,046 | 0.63% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD2411-36Q | Ellipse™ DR | 31,541 | 4.29% | 4 | 0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 3 | <0.01% | 1 | <0.01% | 2 | <0.01% | **11** | **0.03%** |
| CD2411-36C | Ellipse™ DR | 10,856 | 6.78% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 3 | 0.03% | **7** | **0.06%** |
| CD2357-40Q | Fortify Assura™ DR | 51,218 | 6.83% | 13 | 0.03% | 0 | 0.00% | 14 | 0.03% | 1 | <0.01% | 0 | 0.00% | 3 | <0.01% | 516 | 1.01% | 5 | <0.01% | **552** | **1.08%** |
| CD2357-40C | Fortify Assura™ DR | 17,030 | 10.62% | 4 | 0.02% | 1 | <0.01% | 5 | 0.03% | 0 | 0.00% | 1 | <0.01% | 2 | 0.01% | 234 | 1.37% | 2 | 0.01% | **249** | **1.46%** |
| CD2311-36Q | Ellipse™ DR | 5,885 | 13.39% | 5 | 0.08% | 0 | 0.00% | 1 | 0.02% | 14 | 0.24% | 0 | 0.00% | 3 | 0.05% | 0 | 0.00% | 2 | 0.03% | **25** | **0.42%** |
| CD2311-36 | Ellipse™ DR | 3,749 | 13.98% | 5 | 0.13% | 0 | 0.00% | 0 | 0.00% | 9 | 0.24% | 0 | 0.00% | 3 | 0.08% | 0 | 0.00% | 1 | 0.03% | **18** | **0.48%** |
| CD2257-40Q | Fortify Assura™ DR | 6,780 | 16.46% | 3 | 0.04% | 0 | 0.00% | 2 | 0.03% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 151 | 2.23% | 1 | 0.01% | **159** | **2.35%** |
| CD2257-40 | Fortify Assura™ DR | 4,234 | 18.82% | 0 | 0.00% | 0 | 0.00% | 4 | 0.09% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 73 | 1.72% | 3 | 0.07% | **81** | **1.91%** |
| CD2231-40Q | Fortify™ DR | 28,757 | 15.38% | 11 | 0.04% | 2 | <0.01% | 56 | 0.19% | 2 | <0.01% | 2 | <0.01% | 0 | 0.00% | 412 | 1.43% | 13 | 0.05% | **498** | **1.73%** |
| CD2231-40 | Fortify™ DR | 16,173 | 14.20% | 3 | 0.02% | 0 | 0.00% | 9 | 0.06% | 2 | 0.01% | 1 | <0.01% | 2 | 0.01% | 145 | 0.90% | 5 | 0.03% | **167** | **1.03%** |
| CD2211-36Q | Current™ + DR | 15,224 | 18.15% | 12 | 0.08% | 0 | 0.00% | 11 | 0.07% | 2 | 0.01% | 27 | 0.18% | 3 | 0.02% | 8 | 0.05% | 9 | 0.06% | **72** | **0.47%** |
| CD2211-36 | Current™ + DR | 13,483 | 15.07% | 1 | <0.01% | 1 | <0.01% | 4 | 0.03% | 1 | <0.01% | 20 | 0.15% | 2 | 0.01% | 5 | 0.04% | 6 | 0.04% | **40** | **0.30%** |
| 2207-36 | Current™ DR RF | 33,051 | 23.19% | 20 | 0.06% | 5 | 0.02% | 15 | 0.05% | 4 | 0.01% | 109 | 0.33% | 36 | 0.11% | 29 | 0.09% | 12 | 0.04% | **230** | **0.70%** |
| V-268 | Atlas™ II + DR | 25,779 | 19.57% | 7 | 0.03% | 0 | 0.00% | 8 | 0.03% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 9 | 0.03% | 6 | 0.02% | **32** | **0.12%** |
| V-243 | Atlas™ + DR | 34,105 | 19.12% | 6 | 0.02% | 0 | 0.00% | 6 | 0.02% | 0 | 0.00% | 0 | 0.00% | 8 | 0.02% | 6 | 0.02% | 4 | 0.01% | **30** | **0.09%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | INAPPROPRIATE SHOCK | | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD2231-40Q | 390 | 94 | 25,850 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 1.79% | 0 | 0.00% | **7** | **1.79%** |
| CD2231-40 | 177 | 45 | 9,741 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 1.13% | 0 | 0.00% | **2** | **1.13%** |
| CD2211-36Q | 835 | 301 | 65,161 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.48% | 1 | 0.12% | **5** | **0.60%** |
| CD2211-36 | 122 | 12 | 6,509 | 1 | 0.82% | 0 | 0.00% | 0 | 0.00% | 1 | 0.82% | 0 | 0.00% | **2** | **1.64%** |
| 2207-36 | 631 | 32 | 33,421 | 1 | 0.16% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.16%** |
| V-268 | 101 | 1 | 3,816 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*A list of of complications can be found on page 12.*

# Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Actively Monitored Study Data Summary

## MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD2231-40Q | Fortify™ DR | 390 | 21.50% | 0 | 0.00% | 0 | 0.00% | 1 | 0.26% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.51% | 1 | 0.26% | **4** | **1.03%** |
| CD2231-40 | Fortify™ DR | 177 | 19.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.56% | 0 | 0.00% | **1** | **0.56%** |
| CD2211-36Q | Current™ + DR | 835 | 35.90% | 0 | 0.00% | 0 | 0.00% | 1 | 0.12% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.12% | **2** | **0.24%** |
| CD2211-36 | Current™ + DR | 122 | 36.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.82% | **1** | **0.82%** |
| 2207-36 | Current™ DR RF | 631 | 38.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.16% | 0 | 0.00% | **1** | **0.16%** |
| V-268 | Atlas™ II + DR | 101 | 33.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 1.98% | **2** | **1.98%** |

## MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD2231-40Q | Fortify™ DR | 390 | 21.50% | 0 | 0.00% | 0 | 0.00% | 1 | 0.26% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 1.79% | 0 | 0.00% | **8** | **2.05%** |
| CD2231-40 | Fortify™ DR | 177 | 19.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 1.69% | 0 | 0.00% | **3** | **1.69%** |
| CD2211-36Q | Current™ + DR | 835 | 35.90% | 1 | 0.12% | 0 | 0.00% | 2 | 0.24% | 0 | 0.00% | 2 | 0.24% | 0 | 0.00% | 1 | 0.12% | 2 | 0.24% | **8** | **0.96%** |
| CD2211-36 | Current™ + DR | 122 | 36.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 1.64% | 0 | 0.00% | 0 | 0.00% | 1 | 0.82% | **3** | **2.46%** |
| 2207-36 | Current™ DR RF | 631 | 38.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.32% | 0 | 0.00% | 1 | 0.16% | 0 | 0.00% | **3** | **0.48%** |
| V-268 | Atlas™ II + DR | 101 | 33.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## SINGLE-CHAMBER

# Implantable Cardioverter Defibrillator (ICD) Devices

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

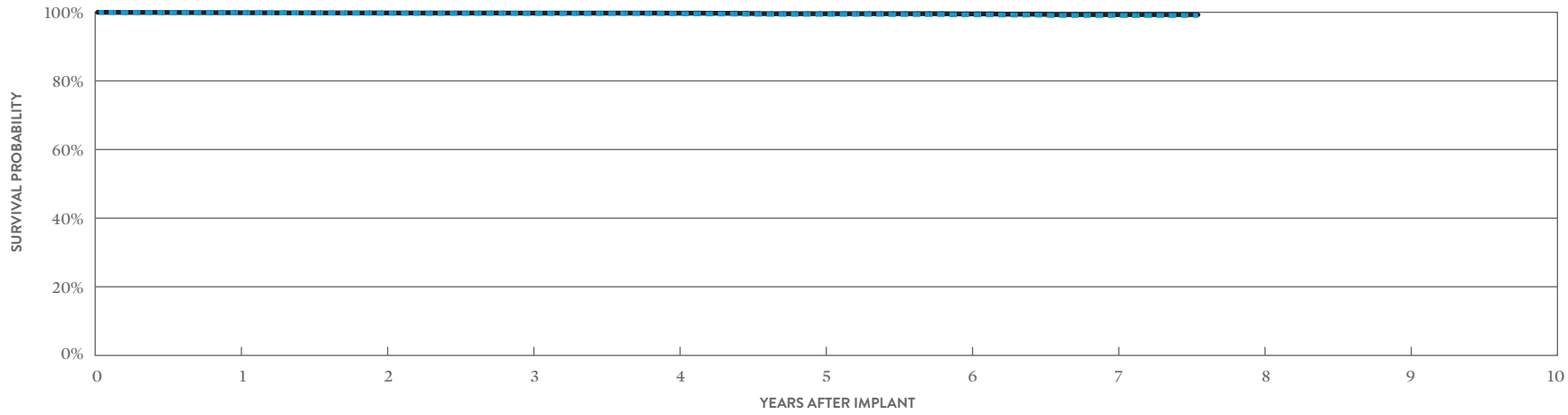
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ VR

### MODEL CD1411-36Q*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 22,667 |
| Estimated Active US Implants | 14,512 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 12 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 310, 311, 313) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | 0.02% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 10 | 0.04% | 4 | 0.02% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 3 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 2 | <0.01% |
| Other | 2 | <0.01% | 2 | <0.01% |
| **Total** | **17** | **0.07%** | **12** | **0.05%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.67% | 99.62% | 99.60% | 99.38% | 99.26% | 99.06% | 99.06% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.05% | 0.05% | 0.08% | 0.10% | 0.14% | 0.14% |
| SAMPLE SIZE | 20,400 | 16,320 | 12,680 | 9,200 | 6,340 | 3,960 | 1,830 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 91 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.81% | 99.76% | 99.74% | 99.58% | 99.52% | 99.31% | 99.31% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.04% | 0.06% | 0.08% | 0.13% | 0.13% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

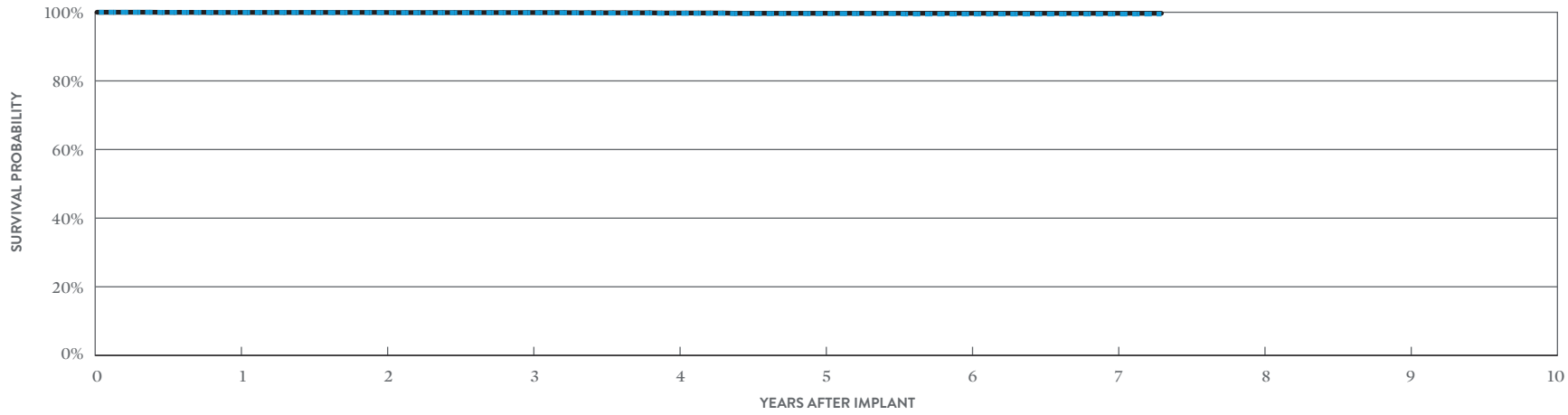
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ VR

### MODEL CD1411-36C*

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 6,953 |
| Estimated Active US Implants | 4,156 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 3 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 310, 311, 313) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 2 | 0.03% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 1 | 0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 2 | 0.03% |
| **Total** | **0** | **0.00%** | **6** | **0.09%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 88 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.90% | 99.86% | 99.69% | 99.61% | 99.49% | 99.49% | 99.49% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.09% | 0.10% | 0.13% | 0.13% | 0.13% |
| SAMPLE SIZE | 6,460 | 5,550 | 4,620 | 3,540 | 2,540 | 1,650 | 770 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 88 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.94% | 99.90% | 99.78% | 99.70% | 99.70% | 99.70% | 99.70% |
| ± 1 STANDARD ERROR | 0.03% | 0.03% | 0.04% | 0.07% | 0.09% | 0.09% | 0.09% | 0.09% |

**Parylene coating.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

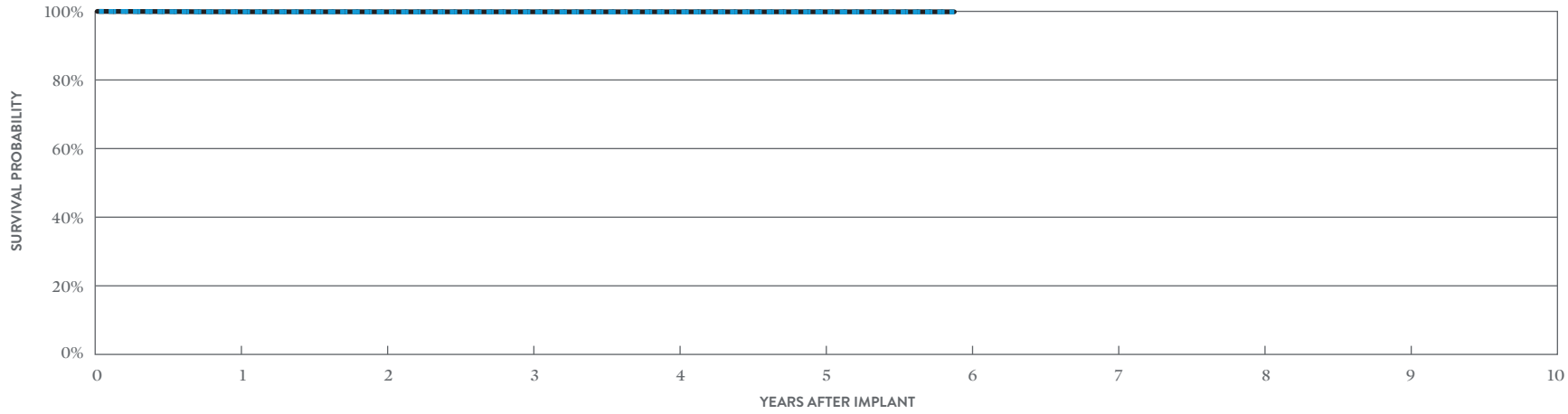
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1357-40Q* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 23,884 |
| Estimated Active US Implants | 16,671 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 4 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 1 | <0.01% |
| Electrical Interconnect | 2 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 3 | 0.01% | 2 | <0.01% |
| **Total** | **7** | **0.03%** | **5** | **0.02%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.82% | 99.82% | 99.82% | 99.82% | 99.82% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% |
| SAMPLE SIZE | 21,270 | 16,350 | 11,920 | 8,050 | 4,560 | 290 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 71 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.87% | 99.87% | 99.87% | 99.87% | 99.87% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

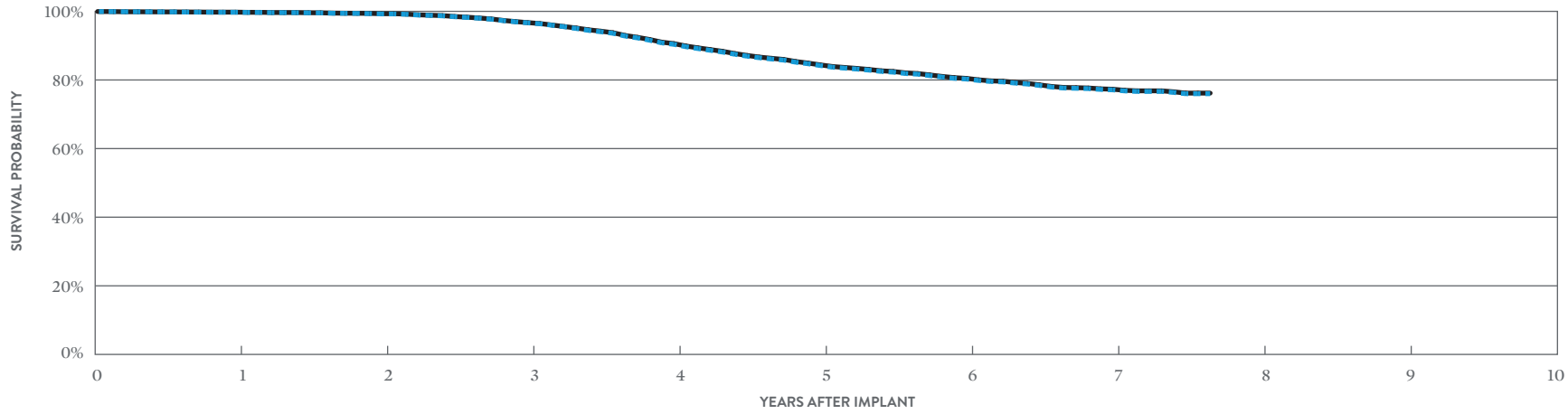
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1357-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 10,214 |
| Estimated Active US Implants | 4,717 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 6 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | 0.05% | 8 | 0.08% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 4 | 0.04% |
| High Voltage Capacitor | 2 | 0.02% | 0 | 0.00% |
| Software/Firmware | 1 | <0.01% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 65 | 0.64% | 508 | 4.97% |
| Other | 4 | 0.04% | 4 | 0.04% |
| **Total** | **78** | **0.76%** | **524** | **5.13%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.74% | 99.25% | 96.65% | 90.38% | 84.21% | 80.27% | 77.12% | 75.99% |
| ± 1 STANDARD ERROR | 0.05% | 0.09% | 0.19% | 0.34% | 0.42% | 0.48% | 0.54% | 0.66% |
| SAMPLE SIZE | 9,600 | 8,520 | 7,610 | 6,780 | 6,030 | 4,990 | 2,810 | 270 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 92 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.77% | 99.31% | 96.72% | 90.59% | 84.40% | 80.46% | 77.30% | 76.17% |
| ± 1 STANDARD ERROR | 0.05% | 0.08% | 0.19% | 0.33% | 0.42% | 0.47% | 0.54% | 0.66% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

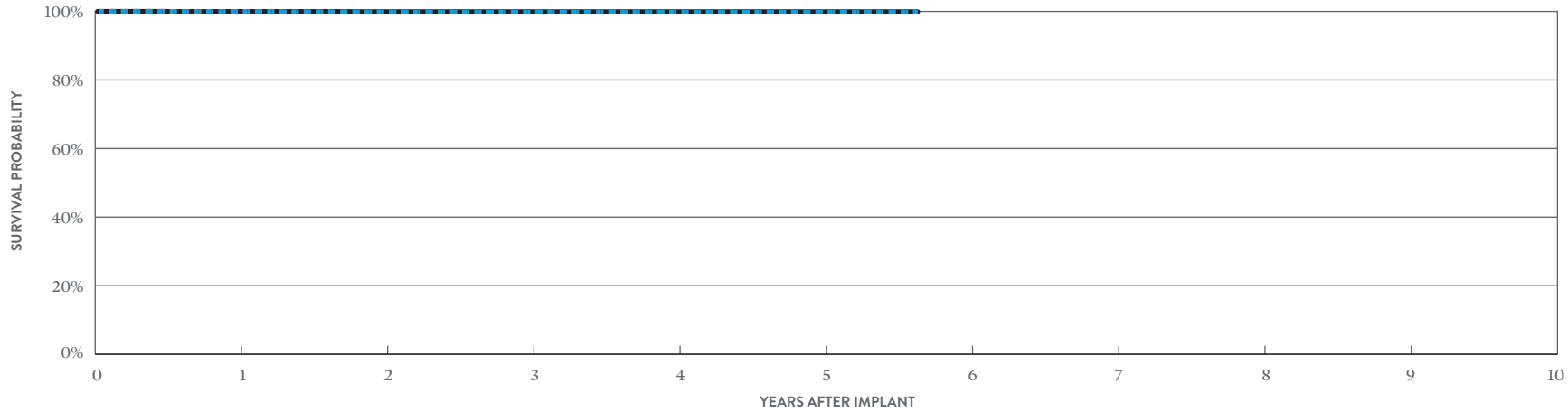
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1357-40C* (NON-BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 5,410 |
| Estimated Active US Implants | 3,643 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 1 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.02% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.02% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **2** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.86% | 99.86% | 99.86% | 99.86% | 99.86% |
| ± 1 STANDARD ERROR | 0.03% | 0.06% | 0.06% | 0.06% | 0.06% | 0.06% |
| SAMPLE SIZE | 4,980 | 4,190 | 3,360 | 2,280 | 1,170 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | 99.91% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.05% | 0.05% | 0.05% | 0.05% |

**Parylene coating.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

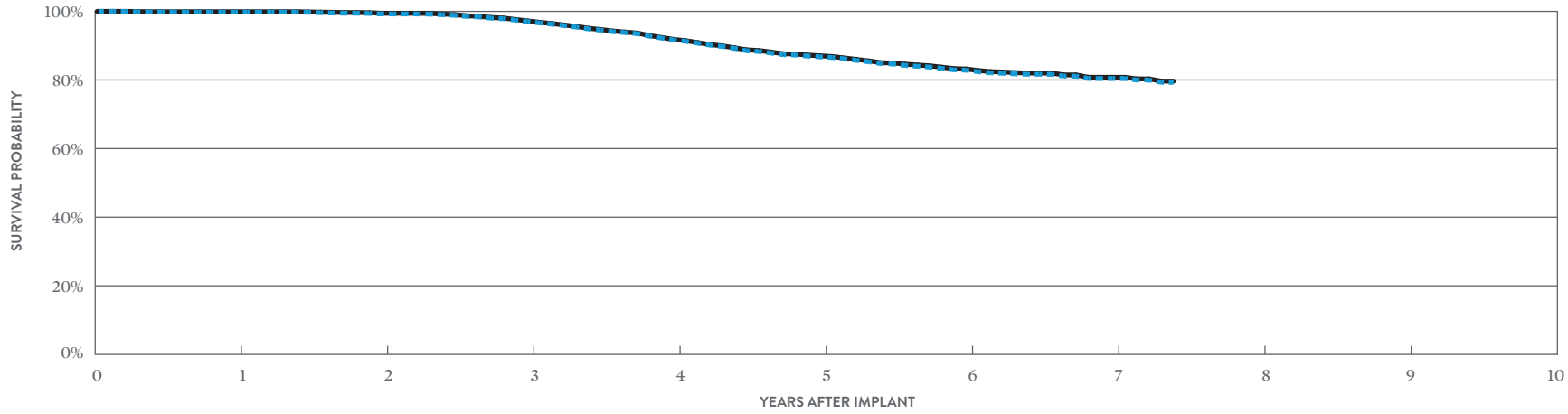
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1357-40C* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Registered US Implants | 4,131 |
| Estimated Active US Implants | 1,850 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 5 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.07% | 1 | 0.02% |
| Electrical Interconnect | 1 | 0.02% | 0 | 0.00% |
| Battery | 0 | 0.00% | 4 | 0.10% |
| High Voltage Capacitor | 1 | 0.02% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.02% |
| Mechanical | 1 | 0.02% | 0 | 0.00% |
| Possible Early Battery Depletion | 9 | 0.22% | 171 | 4.14% |
| Other | 0 | 0.00% | 2 | 0.05% |
| **Total** | **15** | **0.36%** | **179** | **4.33%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 89 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.80% | 99.25% | 97.03% | 91.64% | 86.75% | 82.84% | 80.43% | 79.31% |
| ± 1 STANDARD ERROR | 0.07% | 0.13% | 0.28% | 0.50% | 0.64% | 0.74% | 0.86% | 1.02% |
| SAMPLE SIZE | 3,880 | 3,410 | 3,000 | 2,630 | 2,280 | 1,810 | 970 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 89 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.44% | 97.22% | 91.82% | 87.03% | 83.19% | 80.77% | 79.65% |
| ± 1 STANDARD ERROR | 0.05% | 0.11% | 0.27% | 0.50% | 0.64% | 0.73% | 0.86% | 1.02% |

**Parylene coating.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

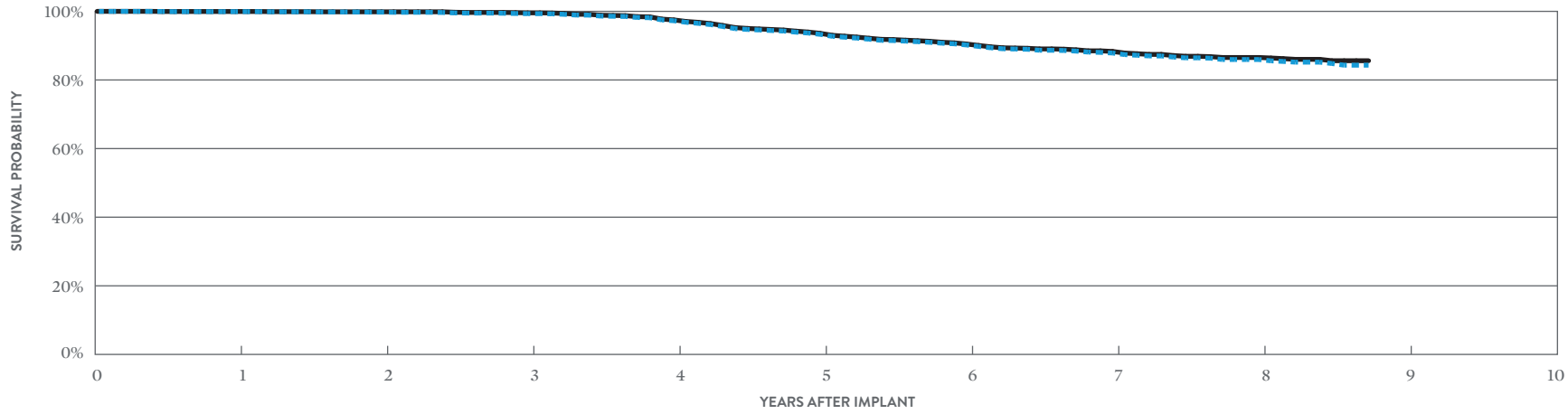
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1257-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 5,079 |
| Estimated Active US Implants | 2,140 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 11 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | 0.02% | 2 | 0.04% |
| Electrical Interconnect | 1 | 0.02% | 0 | 0.00% |
| Battery | 0 | 0.00% | 3 | 0.06% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 20 | 0.39% | 142 | 2.80% |
| Other | 1 | 0.02% | 0 | 0.00% |
| **Total** | **23** | **0.45%** | **147** | **2.89%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.77% | 99.33% | 97.26% | 93.30% | 90.20% | 87.85% | 85.96% | 84.31% |
| ± 1 STANDARD ERROR | 0.04% | 0.07% | 0.12% | 0.26% | 0.42% | 0.51% | 0.58% | 0.64% | 0.80% |
| SAMPLE SIZE | 4,780 | 4,260 | 3,830 | 3,420 | 3,070 | 2,760 | 2,460 | 1,760 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 105 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.87% | 99.57% | 97.50% | 93.59% | 90.48% | 88.31% | 86.55% | 85.61% |
| ± 1 STANDARD ERROR | 0.03% | 0.06% | 0.10% | 0.25% | 0.41% | 0.51% | 0.57% | 0.63% | 0.72% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

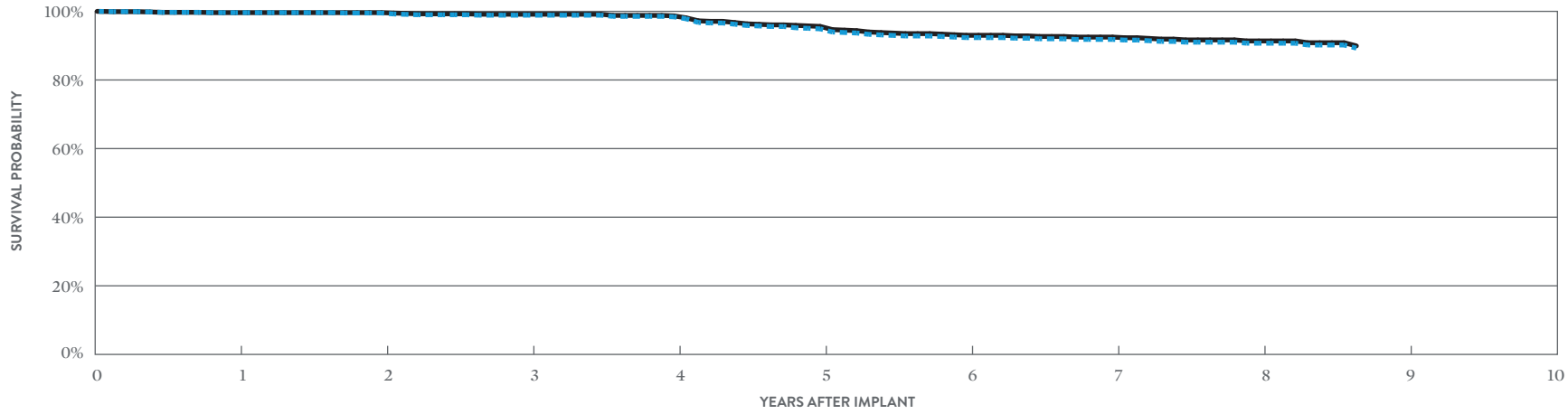
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify Assura™ VR

### MODEL CD1257-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 2,294 |
| Estimated Active US Implants | 958 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 4 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | 0.04% | 0 | 0.00% |
| Electrical Interconnect | 2 | 0.09% | 0 | 0.00% |
| Battery | 1 | 0.04% | 2 | 0.09% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 7 | 0.31% | 38 | 1.66% |
| Other | 2 | 0.09% | 1 | 0.04% |
| **Total** | **13** | **0.57%** | **41** | **1.79%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 104 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.63% | 99.52% | 98.88% | 98.40% | 94.90% | 92.34% | 91.82% | 90.71% | 89.27% |
| ± 1 STANDARD ERROR | 0.13% | 0.15% | 0.24% | 0.29% | 0.57% | 0.70% | 0.74% | 0.81% | 0.89% |
| SAMPLE SIZE | 2,140 | 1,880 | 1,660 | 1,470 | 1,310 | 1,190 | 1,060 | 760 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 104 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.63% | 99.63% | 99.16% | 98.68% | 95.61% | 93.02% | 92.50% | 91.38% | 89.93% |
| ± 1 STANDARD ERROR | 0.13% | 0.13% | 0.21% | 0.26% | 0.53% | 0.68% | 0.72% | 0.79% | 0.87% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

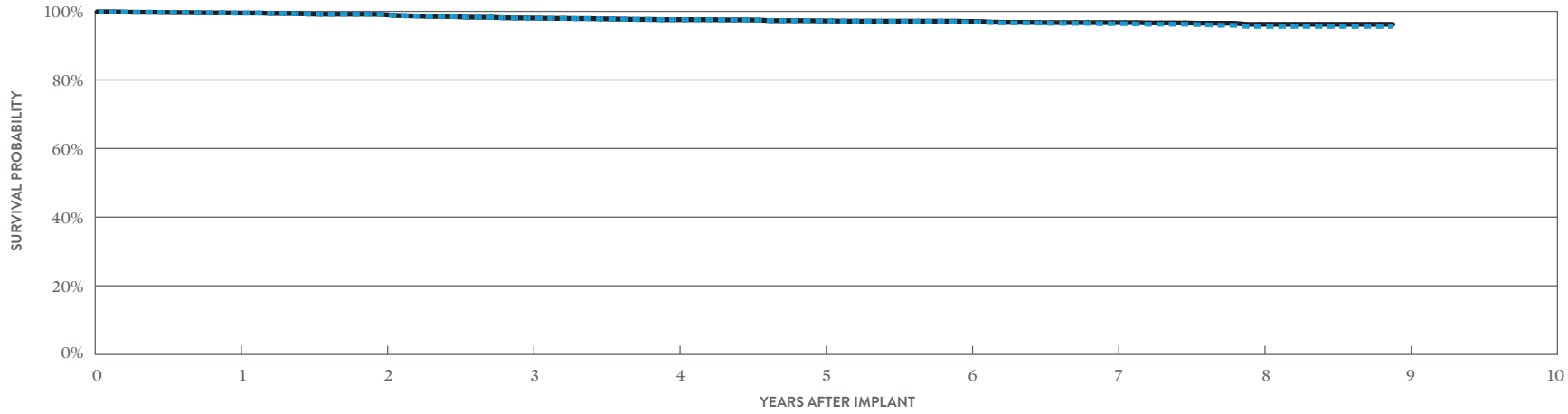
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ VR

### MODEL CD1311-36Q*

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 4,742 |
| Estimated Active US Implants | 2,070 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 7 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 311, 313) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | 0.04% | 2 | 0.04% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 38 | 0.80% | 8 | 0.17% |
| Software/Firmware | 1 | 0.02% | 0 | 0.00% |
| Mechanical | 1 | 0.02% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.02% | 3 | 0.06% |
| **Total** | **43** | **0.91%** | **13** | **0.27%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.51% | 99.11% | 98.08% | 97.59% | 97.23% | 96.94% | 96.43% | 95.62% | 95.62% |
| ± 1 STANDARD ERROR | 0.10% | 0.14% | 0.22% | 0.25% | 0.27% | 0.28% | 0.32% | 0.38% | 0.38% |
| SAMPLE SIZE | 4,460 | 3,980 | 3,580 | 3,230 | 2,950 | 2,700 | 2,450 | 1,820 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 107 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.51% | 99.11% | 98.08% | 97.59% | 97.23% | 97.08% | 96.74% | 96.23% | 96.23% |
| ± 1 STANDARD ERROR | 0.10% | 0.14% | 0.22% | 0.25% | 0.27% | 0.28% | 0.30% | 0.35% | 0.35% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

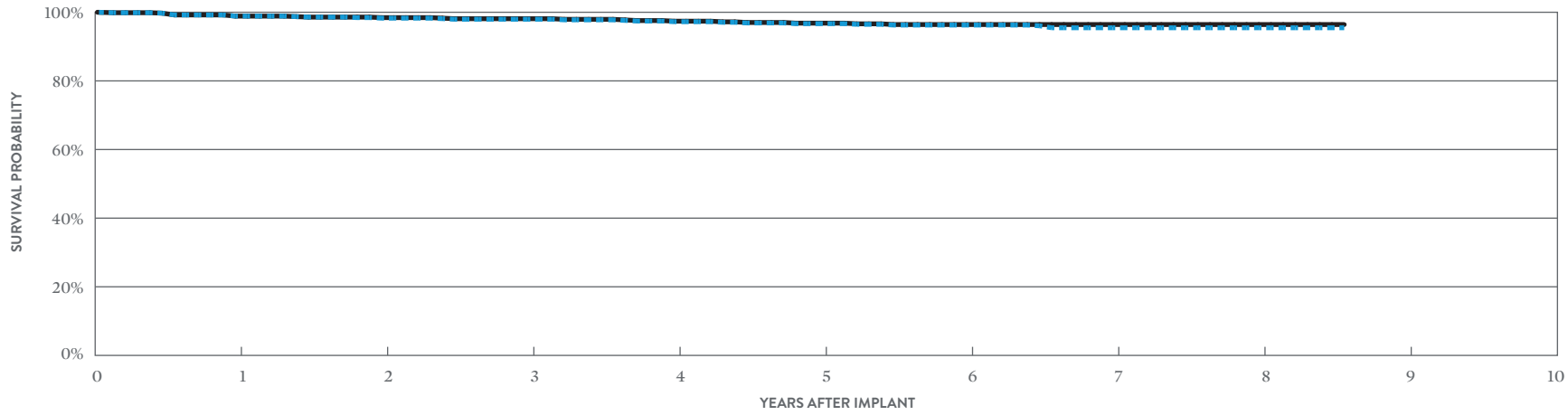
**CUSTOMER REPORTED PERFORMANCE DATA**

## Ellipse™ VR

### MODEL CD1311-36

| | |
|---|---|
| US Regulatory Approval | May 2012 |
| Registered US Implants | 1,620 |
| Estimated Active US Implants | 721 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 4 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 311, 313) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.25% | 1 | 0.06% |
| Electrical Interconnect | 1 | 0.06% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 8 | 0.49% | 2 | 0.12% |
| Software/Firmware | 0 | 0.00% | 1 | 0.06% |
| Mechanical | 2 | 0.12% | 1 | 0.06% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.06% | 0 | 0.00% |
| **Total** | **16** | **0.99%** | **5** | **0.31%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 103 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.88% | 98.29% | 97.97% | 97.25% | 96.68% | 96.27% | 95.48% | 95.48% | 95.48% |
| ± 1 STANDARD ERROR | 0.22% | 0.32% | 0.37% | 0.43% | 0.50% | 0.54% | 0.61% | 0.61% | 0.61% |
| SAMPLE SIZE | 1,530 | 1,360 | 1,220 | 1,110 | 1,020 | 930 | 850 | 620 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 103 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.88% | 98.44% | 98.12% | 97.40% | 96.83% | 96.42% | 96.42% | 96.42% | 96.42% |
| ± 1 STANDARD ERROR | 0.22% | 0.31% | 0.36% | 0.42% | 0.49% | 0.53% | 0.53% | 0.53% | 0.53% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

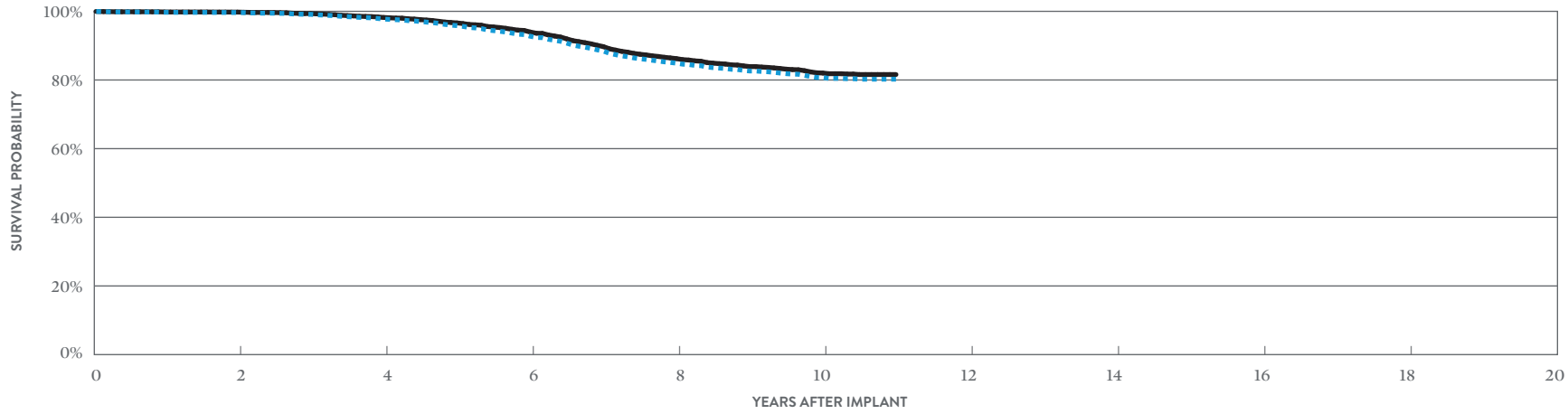
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify™ VR

### MODEL CD1231-40Q* (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 16,184 |
| Estimated Active US Implants | 5,547 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 60 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 7 | 0.04% | 8 | 0.05% |
| Electrical Interconnect | 2 | 0.01% | 0 | 0.00% |
| Battery | 18 | 0.11% | 46 | 0.28% |
| High Voltage Capacitor | 1 | <0.01% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 129 | 0.80% | 367 | 2.27% |
| Other | 9 | 0.06% | 6 | 0.04% |
| **Total** | **166** | **1.03%** | **429** | **2.65%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.66% | 97.75% | 92.75% | 84.90% | 80.67% | 80.24% |
| ± 1 STANDARD ERROR | 0.05% | 0.13% | 0.25% | 0.38% | 0.45% | 0.48% |
| SAMPLE SIZE | 13,330 | 10,800 | 8,670 | 6,910 | 3,620 | 280 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 132 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.78% | 98.21% | 93.97% | 86.22% | 82.02% | 81.59% |
| ± 1 STANDARD ERROR | 0.04% | 0.12% | 0.23% | 0.37% | 0.45% | 0.47% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

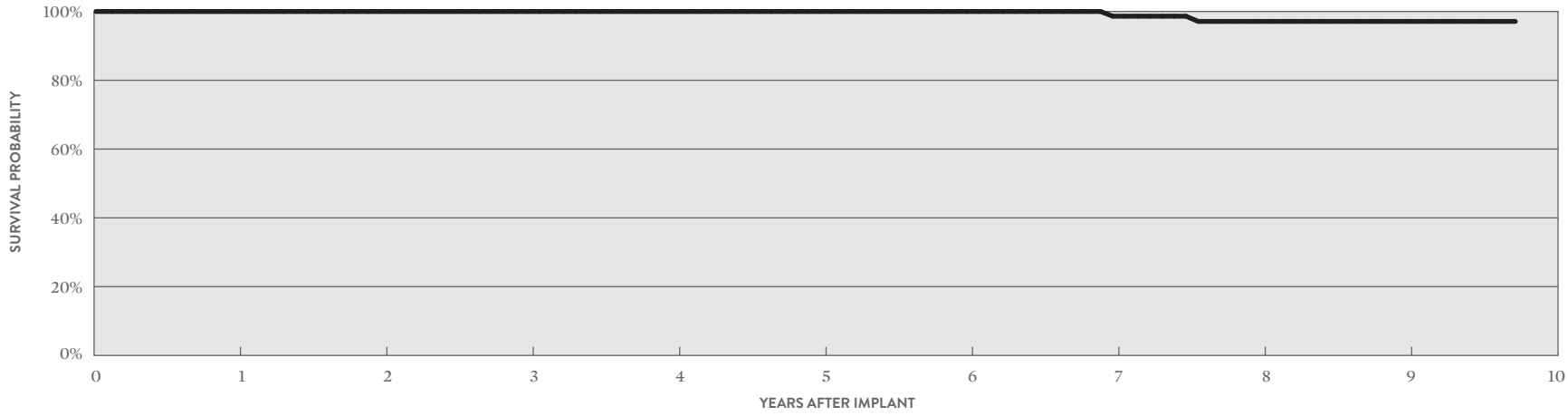
## Fortify™ VR

### MODEL CD1231-40Q*

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Number of Devices Enrolled in Study | 160 |
| Active Devices Enrolled in Study | 52 |
| Cumulative Months of Follow-up | 11,995 |
| Estimated Longevity | (see table on page 157) |
| Max. Delivered Energy | 40 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 2 | 1.25% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 1 | 0.63% |
| High Voltage Capacitor | 1 | 0.63% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 2 | 1.25% | 8 | 5.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **3** | **1.88%** | **9** | **5.63%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 117 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 98.63% | 97.12% | 97.12% | 97.12% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 2.01% | 2.01% | 2.01% |
| SAMPLE SIZE | 160 | 150 | 130 | 110 | 100 | 90 | 80 | 70 | 60 | 50 |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

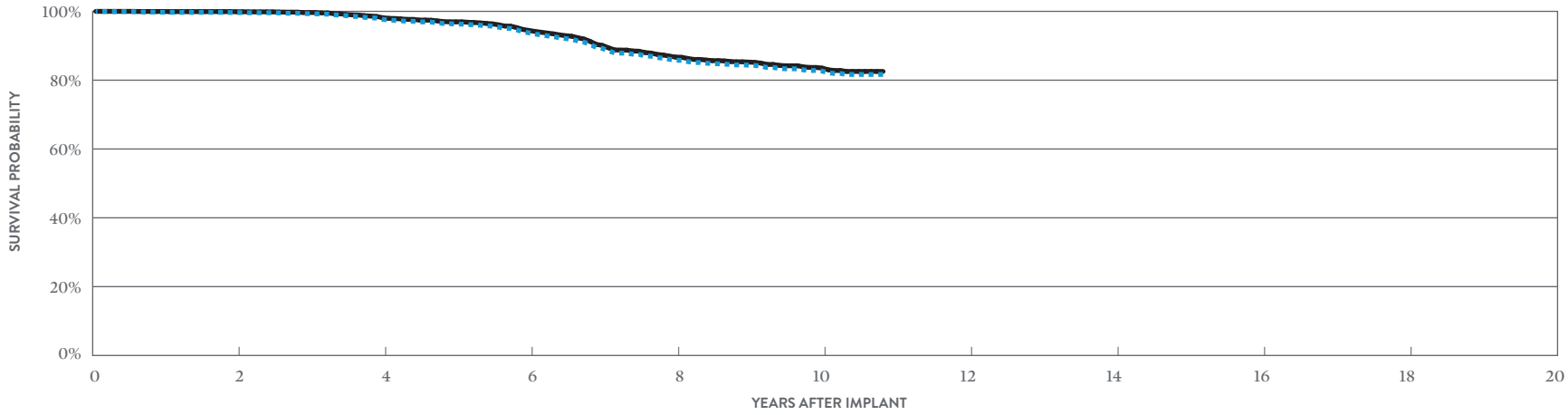
**CUSTOMER REPORTED PERFORMANCE DATA**

## Fortify™ VR

### MODEL CD1231-40 (BATTERY ADVISORY POPULATION)

| | |
|---|---|
| US Regulatory Approval | May 2010 |
| Registered US Implants | 6,781 |
| Estimated Active US Implants | 2,201 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 19 |
| Max. Delivered Energy | 40 joules |
| Number of US Advisories (see pgs. 311, 312) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.04% | 6 | 0.09% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 4 | 0.06% | 12 | 0.18% |
| High Voltage Capacitor | 10 | 0.15% | 3 | 0.04% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 43 | 0.63% | 129 | 1.90% |
| Other | 6 | 0.09% | 6 | 0.09% |
| **Total** | **66** | **0.97%** | **157** | **2.32%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 130 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.63% | 97.68% | 93.74% | 85.81% | 82.65% | 81.67% |
| ± 1 STANDARD ERROR | 0.07% | 0.20% | 0.37% | 0.58% | 0.67% | 0.75% |
| SAMPLE SIZE | 5,520 | 4,360 | 3,470 | 2,750 | 1,480 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 130 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 98.16% | 94.45% | 86.71% | 83.52% | 82.54% |
| ± 1 STANDARD ERROR | 0.03% | 0.18% | 0.36% | 0.57% | 0.67% | 0.75% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

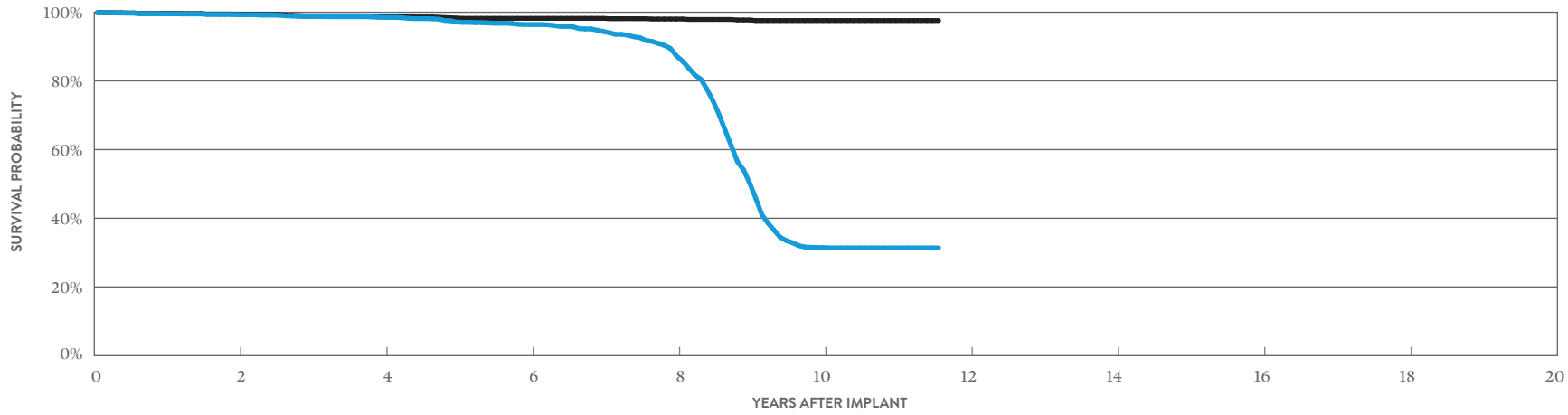
## CUSTOMER REPORTED PERFORMANCE DATA

## Current™ + VR

### MODEL CD1211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 4,432 |
| Estimated Active US Implants | 739 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 583 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.09% | 3 | 0.07% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 5 | 0.11% | 3 | 0.07% |
| High Voltage Capacitor | 1 | 0.02% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.05% |
| Mechanical | 0 | 0.00% | 1 | 0.02% |
| Possible Early Battery Depletion | 6 | 0.14% | 1 | 0.02% |
| Other | 3 | 0.07% | 2 | 0.05% |
| **Total** | **19** | **0.43%** | **12** | **0.27%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 139 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.29% | 98.48% | 96.42% | 87.26% | 31.46% | 31.37% |
| ± 1 STANDARD ERROR | 0.13% | 0.20% | 0.35% | 0.64% | 0.98% | 0.98% |
| SAMPLE SIZE | 3,600 | 2,880 | 2,330 | 1,910 | 940 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 139 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.41% | 98.87% | 98.22% | 98.02% | 97.58% | 97.58% |
| ± 1 STANDARD ERROR | 0.12% | 0.18% | 0.24% | 0.26% | 0.31% | 0.31% |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

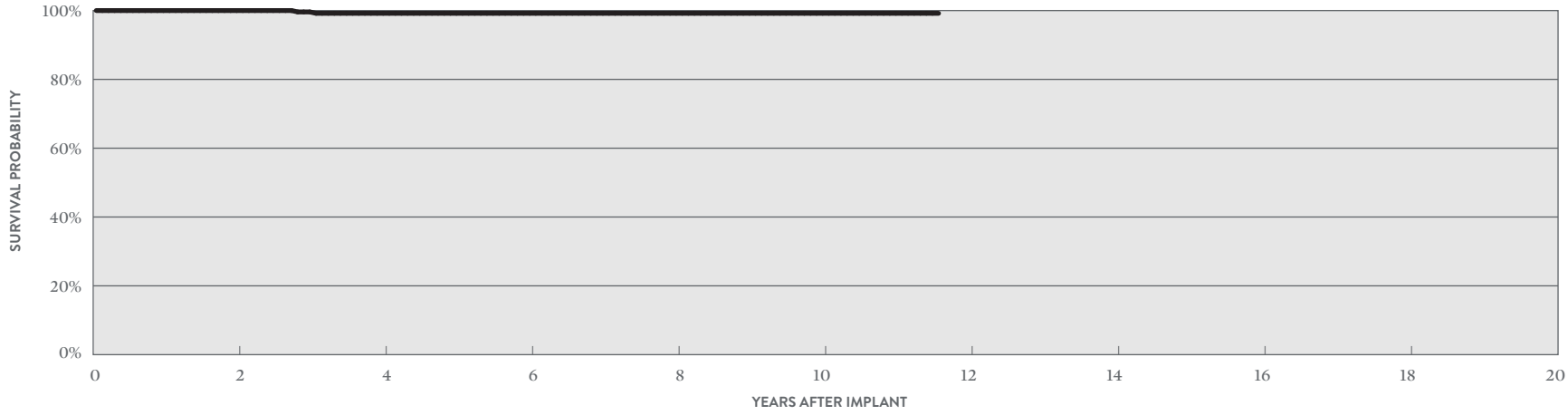
## Current™ + VR

### MODEL CD1211-36Q*

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Number of Devices Enrolled in Study | 363 |
| Active Devices Enrolled in Study | 140 |
| Cumulative Months of Follow-up | 28,133 |
| Estimated Longevity | (see table on page 157) |
| Max. Delivered Energy | 36 joules |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Inappropriate Shock | 1 | 0.28% |
| Premature Battery Depletion | 1 | 0.28% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 1 | 0.28% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | 0.28% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.28% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **0.28%** | **2** | **0.55%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 139 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.20% | 99.20% | 99.20% | 99.20% | 99.20% |
| ± 1 STANDARD ERROR | 0.00% | 0.56% | 0.56% | 0.56% | 0.56% | 0.56% |
| SAMPLE SIZE | 310 | 230 | 180 | 160 | 140 | 60 |

**DF4-LLHH connector type.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

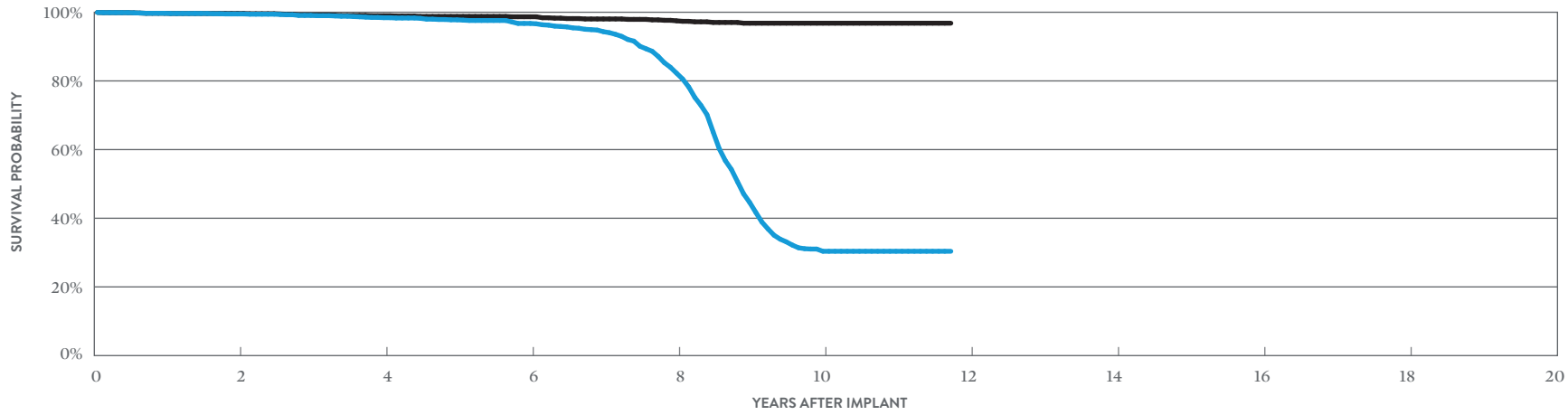
**CUSTOMER REPORTED PERFORMANCE DATA**

## Current™ + VR

### MODEL CD1211-36

| | |
|---|---|
| US Regulatory Approval | February 2009 |
| Registered US Implants | 3,640 |
| Estimated Active US Implants | 616 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 466 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | 0.08% | 3 | 0.08% |
| Electrical Interconnect | 2 | 0.05% | 0 | 0.00% |
| Battery | 5 | 0.14% | 0 | 0.00% |
| High Voltage Capacitor | 2 | 0.05% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 5 | 0.14% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 5 | 0.14% | 2 | 0.05% |
| Other | 2 | 0.05% | 1 | 0.03% |
| **Total** | **19** | **0.52%** | **11** | **0.30%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.50% | 98.41% | 96.74% | 82.26% | 30.38% | 30.38% |
| ± 1 STANDARD ERROR | 0.13% | 0.24% | 0.37% | 0.88% | 1.10% | 1.09% |
| SAMPLE SIZE | 2,930 | 2,350 | 1,870 | 1,480 | 690 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.64% | 98.97% | 98.68% | 97.50% | 96.81% | 96.81% |
| ± 1 STANDARD ERROR | 0.10% | 0.19% | 0.23% | 0.33% | 0.43% | 0.43% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

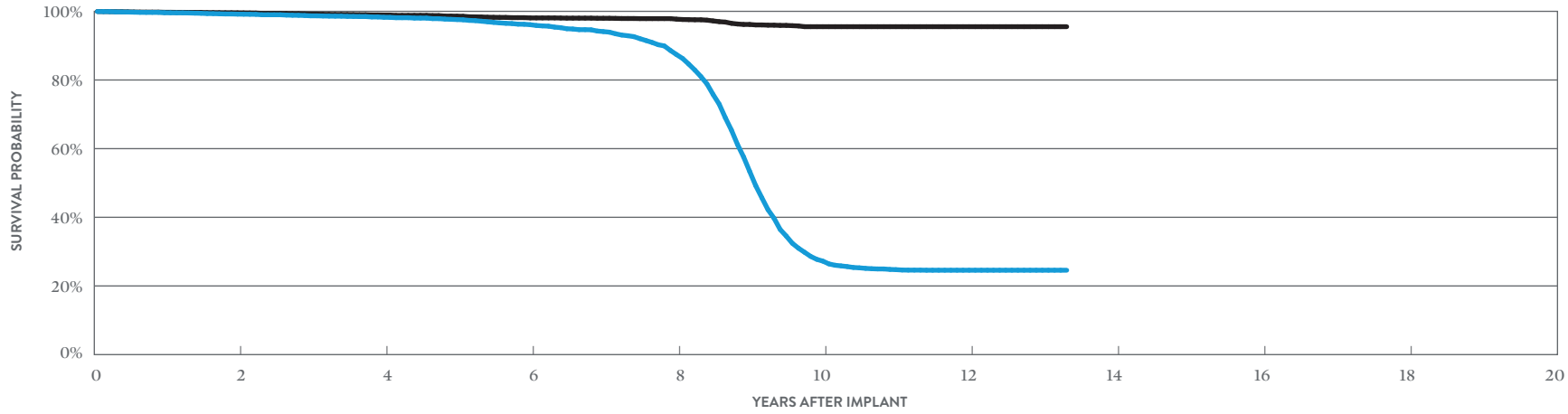
**CUSTOMER REPORTED PERFORMANCE DATA**

## Current™ VR RF

### MODEL 1207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 13,293 |
| Estimated Active US Implants | 1,703 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 1,822 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 311) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 6 | 0.05% | 10 | 0.08% |
| Electrical Interconnect | 10 | 0.08% | 0 | 0.00% |
| Battery | 10 | 0.08% | 5 | 0.04% |
| High Voltage Capacitor | 1 | <0.01% | 1 | <0.01% |
| Software/Firmware | 1 | <0.01% | 18 | 0.14% |
| Mechanical | 0 | 0.00% | 7 | 0.05% |
| Possible Early Battery Depletion | 14 | 0.11% | 18 | 0.14% |
| Other | 9 | 0.07% | 9 | 0.07% |
| **Total** | **51** | **0.38%** | **68** | **0.51%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.18% | 98.26% | 96.11% | 87.40% | 27.23% | 24.58% | 24.58% |
| ± 1 STANDARD ERROR | 0.08% | 0.13% | 0.21% | 0.40% | 0.55% | 0.52% | 0.52% |
| SAMPLE SIZE | 10,610 | 8,360 | 6,690 | 5,330 | 2,760 | 1,550 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.57% | 98.92% | 98.08% | 97.72% | 95.53% | 95.53% | 95.53% |
| ± 1 STANDARD ERROR | 0.06% | 0.10% | 0.15% | 0.16% | 0.29% | 0.29% | 0.29% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

**ACTIVELY MONITORED STUDY DATA**

## Current™ VR RF

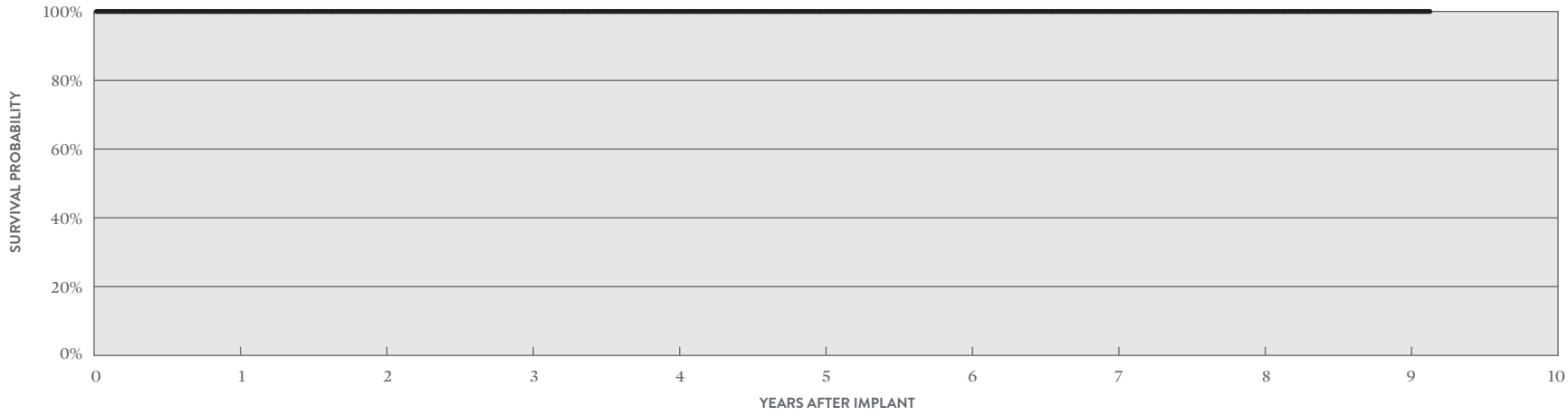
### MODEL 1207-36

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Number of Devices Enrolled in Study | 395 |
| Active Devices Enrolled in Study | 14 |
| Cumulative Months of Follow-up | 22,031 |
| Estimated Longevity | (see table on page 157) |
| Max. Delivered Energy | 36 joules |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.25% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| High Voltage Capacitor | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **1** | **0.25%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | AT 110 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 380 | 340 | 280 | 210 | 160 | 140 | 120 | 90 | 70 | 50 |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

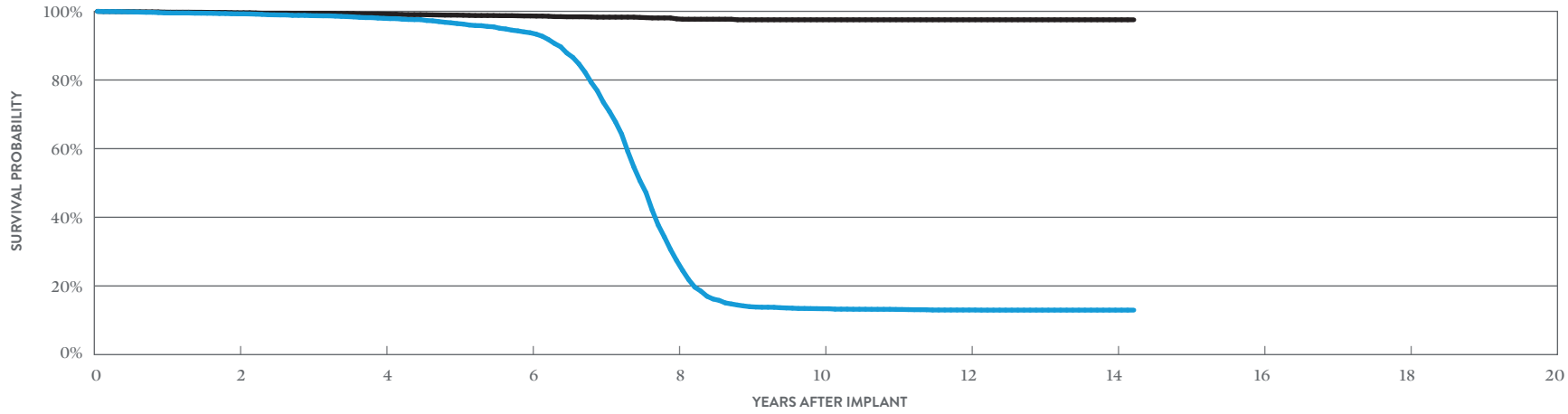
**CUSTOMER REPORTED PERFORMANCE DATA**

## Atlas™ II VR

### MODEL V-168

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 10,605 |
| Estimated Active US Implants | 902 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 1,863 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pg. 316) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | 0.04% | 3 | 0.03% |
| Electrical Interconnect | 2 | 0.02% | 0 | 0.00% |
| Battery | 10 | 0.09% | 2 | 0.02% |
| High Voltage Capacitor | 1 | <0.01% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 1 | <0.01% | 4 | 0.04% |
| Possible Early Battery Depletion | 10 | 0.09% | 5 | 0.05% |
| Other | 10 | 0.09% | 5 | 0.05% |
| **Total** | **38** | **0.36%** | **19** | **0.18%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 171 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.27% | 97.96% | 93.76% | 27.44% | 13.36% | 12.99% | 12.96% | 12.96% |
| ± 1 STANDARD ERROR | 0.09% | 0.16% | 0.31% | 0.64% | 0.43% | 0.42% | 0.42% | 0.42% |
| SAMPLE SIZE | 8,500 | 6,410 | 4,900 | 2,650 | 1,120 | 960 | 470 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 171 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.59% | 99.20% | 98.66% | 97.81% | 97.54% | 97.54% | 97.54% | 97.54% |
| ± 1 STANDARD ERROR | 0.06% | 0.10% | 0.14% | 0.19% | 0.26% | 0.26% | 0.26% | 0.26% |

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

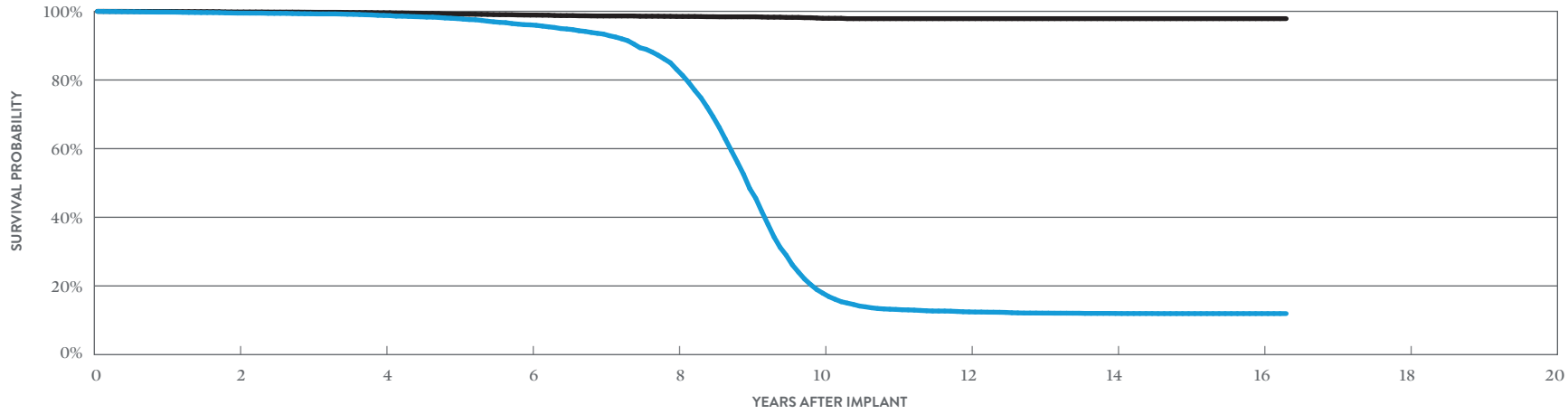
**CUSTOMER REPORTED PERFORMANCE DATA**

## Atlas™ + VR

### MODEL V-193

| | |
|---|---|
| US Regulatory Approval | October 2003 |
| Registered US Implants | 20,794 |
| Estimated Active US Implants | 1,354 |
| Estimated Longevity | (see table on page 157) |
| Normal Battery Depletion | 2,994 |
| Max. Delivered Energy | 36 joules |
| Number of US Advisories (see pgs. 316, 317, 318) | Three |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 2 | <0.01% |
| Electrical Interconnect | 5 | 0.02% | 1 | <0.01% |
| Battery | 9 | 0.04% | 2 | <0.01% |
| High Voltage Capacitor | 2 | <0.01% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 5 | 0.02% |
| Possible Early Battery Depletion | 26 | 0.13% | 5 | 0.02% |
| Other | 13 | 0.06% | 7 | 0.03% |
| **Total** | **57** | **0.27%** | **24** | **0.12%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.49% | 98.80% | 96.06% | 83.11% | 17.89% | 12.44% | 11.99% | 11.95% | 11.95% |
| ± 1 STANDARD ERROR | 0.05% | 0.09% | 0.18% | 0.39% | 0.41% | 0.33% | 0.32% | 0.32% | 0.32% |
| SAMPLE SIZE | 16,720 | 12,610 | 9,330 | 6,780 | 3,070 | 1,600 | 1,320 | 550 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.59% | 98.91% | 98.51% | 97.97% | 97.87% | 97.87% | 97.87% | 97.87% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.10% | 0.12% | 0.17% | 0.19% | 0.19% | 0.19% | 0.19% |

## BATTERY LONGEVITY SUMMARY

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Battery Longevity (years)

| MODELS | FAMILY | NO PACING | 25% PACING | 50% PACING | 100% PACING |
|---|---|---|---|---|---|
| CD1411-36Q | Ellipse™ VR* | 11.1 | 10.6 | 10.1 | 9.4 |
| CD1411-36C | Ellipse™ VR* | 11.1 | 10.6 | 10.1 | 9.4 |
| CD1357-40Q | Fortify Assura™ VR** | 11.7 | 11.3 | 10.8 | 10.1 |
| CD1357-40C | Fortify Assura™ VR** | 11.7 | 11.3 | 10.8 | 10.1 |
| CD1257-40Q | Fortify Assura™ VR** | 11.7 | 11.3 | 10.8 | 10.1 |
| CD1257-40 | Fortify Assura™ VR** | 11.7 | 11.3 | 10.8 | 10.1 |
| CD1311-36Q | Ellipse™ VR* | 11.1 | 10.6 | 10.1 | 9.4 |
| CD1311-36 | Ellipse™ VR* | 11.1 | 10.6 | 10.1 | 9.4 |
| CD1231-40Q | Fortify™ VR** | 10.8 | 10.3 | 9.9 | 9.1 |
| CD1231-40 | Fortify™ VR** | 10.8 | 10.3 | 9.9 | 9.1 |
| CD1211-36Q | Current™ + VR*** | 8.4 | 8.0 | 7.6 | 7.0 |
| CD1211-36 | Current™ + VR*** | 8.4 | 8.0 | 7.6 | 7.0 |
| 1207-36 | Current™ VR RF*** | 8.4 | 8.0 | 7.6 | 7.0 |
| V-168 | Atlas™ II VR*** | 8.4 | 8.0 | 7.6 | 7.0 |
| V-193 | Atlas™ + VR*** | 8.6 | 8.2 | 7.9 | 7.3 |

*Pacing parameters: VVI, 2.5V, 0.5 ms, 60 ppm, 500 ohms*

** Battery voltage range 3.20-2.59. Two maximum charges per year.*

*** Battery voltage range 3.20-2.59. Three maximum charges per year.*

**** Battery voltage range: 3.20-2.45. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.*

SUMMARY INFORMATION

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CD1411-36Q | Ellipse™ VR | 99.85% | 99.67% | 99.62% | 99.60% | 99.38% | 99.26% | 99.06% | | | |
| CD1411-36C | Ellipse™ VR | 99.94% | 99.90% | 99.86% | 99.69% | 99.61% | 99.49% | 99.49% | | | |
| CD1357-40Q | Fortify Assura™ VR | 99.87% | 99.82% | 99.82% | 99.82% | 99.82% | | | | | |
| CD1357-40Q | Fortify Assura™ VR† | 99.74% | 99.25% | 96.65% | 90.38% | 84.21% | 80.27% | 77.12% | | | |
| CD1357-40C | Fortify Assura™ VR | 99.96% | 99.86% | 99.86% | 99.86% | 99.86% | | | | | |
| CD1357-40C | Fortify Assura™ VR† | 99.80% | 99.25% | 97.03% | 91.64% | 86.75% | 82.84% | 80.43% | | | |
| CD1257-40Q | Fortify Assura™ VR† | 99.92% | 99.77% | 99.33% | 97.26% | 93.30% | 90.20% | 87.85% | 85.96% | | |
| CD1257-40 | Fortify Assura™ VR† | 99.63% | 99.52% | 98.88% | 98.40% | 94.90% | 92.34% | 91.82% | 90.71% | | |
| CD1311-36Q | Ellipse™ VR | 99.51% | 99.11% | 98.08% | 97.59% | 97.23% | 96.94% | 96.43% | 95.62% | | |
| CD1311-36 | Ellipse™ VR | 98.88% | 98.29% | 97.97% | 97.25% | 96.68% | 96.27% | 95.48% | 95.48% | | |
| CD1231-40Q | Fortify™ VR† | 99.73% | 99.66% | 99.12% | 97.75% | 95.83% | 92.75% | 88.42% | 84.90% | 82.62% | 80.67% |
| CD1231-40 | Fortify™ VR† | 99.74% | 99.63% | 99.34% | 97.68% | 96.29% | 93.74% | 89.23% | 85.81% | 84.36% | 82.65% |
| CD1211-36Q | Current™ + VR | 99.54% | 99.29% | 98.76% | 98.48% | 97.13% | 96.42% | 94.40% | 87.26% | 50.23% | 31.46% |
| CD1211-36 | Current™ + VR | 99.70% | 99.50% | 99.08% | 98.41% | 97.79% | 96.74% | 94.34% | 82.26% | 44.59% | 30.38% |
| 1207-36 | Current™ VR RF | 99.60% | 99.18% | 98.69% | 98.26% | 97.60% | 96.11% | 94.10% | 87.40% | 53.35% | 27.23% |
| V-168 | Atlas™ II VR | 99.54% | 99.27% | 98.74% | 97.96% | 96.44% | 93.76% | 73.51% | 27.44% | 13.96% | 13.36% |
| V-193 | Atlas™ + VR | 99.78% | 99.49% | 99.29% | 98.80% | 97.89% | 96.06% | 93.38% | 83.11% | 48.40% | 17.89% |

*†Premature battery depletion advisory population.*

## Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Survival Probability Summary

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CD1411-36Q | Ellipse™ VR | 99.87% | 99.81% | 99.76% | 99.74% | 99.58% | 99.52% | 99.31% | | | |
| CD1411-36C | Ellipse™ VR | 99.94% | 99.94% | 99.90% | 99.78% | 99.70% | 99.70% | 99.70% | | | |
| CD1357-40Q | Fortify Assura™ VR | 99.89% | 99.87% | 99.87% | 99.87% | 99.87% | | | | | |
| CD1357-40Q | Fortify Assura™ VR† | 99.77% | 99.31% | 96.72% | 90.59% | 84.40% | 80.46% | 77.30% | | | |
| CD1357-40C | Fortify Assura™ VR | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | | | | | |
| CD1357-40C | Fortify Assura™ VR† | 99.90% | 99.44% | 97.22% | 91.82% | 87.03% | 83.19% | 80.77% | | | |
| CD1257-40Q | Fortify Assura™ VR† | 99.96% | 99.87% | 99.57% | 97.50% | 93.59% | 90.48% | 88.31% | 86.55% | | |
| CD1257-40 | Fortify Assura™ VR† | 99.63% | 99.63% | 99.16% | 98.68% | 95.61% | 93.02% | 92.50% | 91.38% | | |
| CD1311-36Q | Ellipse™ VR | 99.51% | 99.11% | 98.08% | 97.59% | 97.23% | 97.08% | 96.74% | 96.23% | | |
| CD1311-36 | Ellipse™ VR | 98.88% | 98.44% | 98.12% | 97.40% | 96.83% | 96.42% | 96.42% | 96.42% | | |
| CD1231-40Q | Fortify™ VR† | 99.82% | 99.78% | 99.35% | 98.21% | 96.63% | 93.97% | 89.72% | 86.22% | 83.90% | 82.02% |
| CD1231-40 | Fortify™ VR† | 99.97% | 99.89% | 99.67% | 98.16% | 96.96% | 94.45% | 90.11% | 86.71% | 85.25% | 83.52% |
| CD1211-36Q | Current™ + VR | 99.66% | 99.41% | 98.94% | 98.87% | 98.30% | 98.22% | 98.22% | 98.02% | 97.75% | 97.58% |
| CD1211-36 | Current™ + VR | 99.70% | 99.64% | 99.22% | 98.97% | 98.78% | 98.68% | 98.04% | 97.50% | 96.81% | 96.81% |
| 1207-36 | Current™ VR RF | 99.73% | 99.57% | 99.19% | 98.92% | 98.59% | 98.08% | 97.98% | 97.72% | 96.18% | 95.53% |
| V-168 | Atlas™ II VR | 99.77% | 99.59% | 99.44% | 99.20% | 98.90% | 98.66% | 98.31% | 97.81% | 97.54% | 97.54% |
| V-193 | Atlas™ + VR | 99.95% | 99.81% | 99.74% | 99.59% | 99.17% | 98.91% | 98.65% | 98.51% | 98.41% | 97.97% |

*†Premature battery depletion advisory population.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1411-36Q | Ellipse™ VR | 22,667 | 4.20% | 5 | 0.02% | 0 | 0.00% | 0 | 0.00% | 10 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | **17** | **0.07%** |
| CD1411-36C | Ellipse™ VR | 6,953 | 5.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD1357-40Q | Fortify Assura™ VR | 23,884 | 3.60% | 2 | <0.01% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.01% | **7** | **0.03%** |
| CD1357-40Q | Fortify Assura™ VR† | 10,214 | 15.40% | 5 | 0.05% | 1 | <0.01% | 0 | 0.00% | 2 | 0.02% | 1 | <0.01% | 0 | 0.00% | 65 | 0.64% | 4 | 0.04% | **78** | **0.76%** |
| CD1357-40C | Fortify Assura™ VR | 5,410 | 5.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD1357-40C | Fortify Assura™ VR† | 4,131 | 17.50% | 3 | 0.07% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | 9 | 0.22% | 0 | 0.00% | **15** | **0.36%** |
| CD1257-40Q | Fortify Assura™ VR† | 5,079 | 14.30% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 20 | 0.39% | 1 | 0.02% | **23** | **0.45%** |
| CD1257-40 | Fortify Assura™ VR† | 2,294 | 16.30% | 1 | 0.04% | 2 | 0.09% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.31% | 2 | 0.09% | **13** | **0.57%** |
| CD1311-36Q | Ellipse™ VR | 4,742 | 9.40% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 38 | 0.80% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | **43** | **0.91%** |
| CD1311-36 | Ellipse™ VR | 1,620 | 12.20% | 4 | 0.25% | 1 | 0.06% | 0 | 0.00% | 8 | 0.49% | 0 | 0.00% | 2 | 0.12% | 0 | 0.00% | 1 | 0.06% | **16** | **0.99%** |
| CD1231-40Q | Fortify™ VR† | 16,184 | 15.60% | 7 | 0.04% | 2 | 0.01% | 18 | 0.11% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 129 | 0.80% | 9 | 0.06% | **166** | **1.03%** |
| CD1231-40 | Fortify™ VR† | 6,781 | 16.80% | 3 | 0.04% | 0 | 0.00% | 4 | 0.06% | 10 | 0.15% | 0 | 0.00% | 0 | 0.00% | 43 | 0.63% | 6 | 0.09% | **66** | **0.97%** |
| CD1211-36Q | Current™ + VR | 4,432 | 24.50% | 4 | 0.09% | 0 | 0.00% | 5 | 0.11% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 6 | 0.14% | 3 | 0.07% | **19** | **0.43%** |
| CD1211-36 | Current™ + VR | 3,640 | 23.90% | 3 | 0.08% | 2 | 0.05% | 5 | 0.14% | 2 | 0.05% | 0 | 0.00% | 0 | 0.00% | 5 | 0.14% | 2 | 0.05% | **19** | **0.52%** |
| 1207-36 | Current™ VR RF | 13,293 | 26.20% | 6 | 0.05% | 10 | 0.08% | 10 | 0.08% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 14 | 0.11% | 9 | 0.07% | **51** | **0.38%** |
| V-168 | Atlas™ II VR | 10,605 | 28.10% | 4 | 0.04% | 2 | 0.02% | 10 | 0.09% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 10 | 0.09% | 10 | 0.09% | **38** | **0.36%** |
| V-193 | Atlas™ + VR | 20,794 | 25.70% | 2 | <0.01% | 5 | 0.02% | 9 | 0.04% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 26 | 0.13% | 13 | 0.06% | **57** | **0.27%** |

*Definitions of malfunction categories can be found on* *pages 5-6.*
*†Premature battery depletion advisory population.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## US Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1411-36Q | Ellipse™ VR | 22,667 | 4.20% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 1 | <0.01% | 3 | 0.01% | 2 | <0.01% | 2 | <0.01% | **12** | **0.05%** |
| CD1411-36C | Ellipse™ VR | 6,953 | 5.80% | 2 | 0.03% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 2 | 0.03% | **6** | **0.09%** |
| CD1357-40Q | Fortify Assura™ VR | 23,884 | 3.60% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | **5** | **0.02%** |
| CD1357-40Q | Fortify Assura™ VR† | 10,214 | 15.40% | 8 | 0.08% | 0 | 0.00% | 4 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 508 | 4.97% | 4 | 0.04% | **524** | **5.13%** |
| CD1357-40C | Fortify Assura™ VR | 5,410 | 5.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | **2** | **0.04%** |
| CD1357-40C | Fortify Assura™ VR† | 4,131 | 17.50% | 1 | 0.02% | 0 | 0.00% | 4 | 0.10% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 171 | 4.14% | 2 | 0.05% | **179** | **4.33%** |
| CD1257-40Q | Fortify Assura™ VR† | 5,079 | 14.30% | 2 | 0.04% | 0 | 0.00% | 3 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 142 | 2.80% | 0 | 0.00% | **147** | **2.89%** |
| CD1257-40 | Fortify Assura™ VR† | 2,294 | 16.30% | 0 | 0.00% | 0 | 0.00% | 2 | 0.09% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 38 | 1.66% | 1 | 0.04% | **41** | **1.79%** |
| CD1311-36Q | Ellipse™ VR | 4,742 | 9.40% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 8 | 0.17% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.06% | **13** | **0.27%** |
| CD1311-36 | Ellipse™ VR | 1,620 | 12.20% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 2 | 0.12% | 1 | 0.06% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | **5** | **0.31%** |
| CD1231-40Q | Fortify™ VR† | 16,184 | 15.60% | 8 | 0.05% | 0 | 0.00% | 46 | 0.28% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 367 | 2.27% | 6 | 0.04% | **429** | **2.65%** |
| CD1231-40 | Fortify™ VR† | 6,781 | 16.80% | 6 | 0.09% | 0 | 0.00% | 12 | 0.18% | 3 | 0.04% | 0 | 0.00% | 1 | 0.01% | 129 | 1.90% | 6 | 0.09% | **157** | **2.32%** |
| CD1211-36Q | Current™ + VR | 4,432 | 24.50% | 3 | 0.07% | 0 | 0.00% | 3 | 0.07% | 0 | 0.00% | 2 | 0.05% | 1 | 0.02% | 1 | 0.02% | 2 | 0.05% | **12** | **0.27%** |
| CD1211-36 | Current™ + VR | 3,640 | 23.90% | 3 | 0.08% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 5 | 0.14% | 0 | 0.00% | 2 | 0.05% | 1 | 0.03% | **11** | **0.30%** |
| 1207-36 | Current™ VR RF | 13,293 | 26.20% | 10 | 0.08% | 0 | 0.00% | 5 | 0.04% | 1 | <0.01% | 18 | 0.14% | 7 | 0.05% | 18 | 0.14% | 9 | 0.07% | **68** | **0.51%** |
| V-168 | Atlas™ II VR | 10,605 | 28.10% | 3 | 0.03% | 0 | 0.00% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 4 | 0.04% | 5 | 0.05% | 5 | 0.05% | **19** | **0.18%** |
| V-193 | Atlas™ + VR | 20,794 | 25.70% | 2 | <0.01% | 1 | <0.01% | 2 | <0.01% | 1 | <0.01% | 1 | <0.01% | 5 | 0.02% | 5 | 0.02% | 7 | 0.03% | **24** | **0.12%** |

*Definitions of malfunction categories can be found on* *pages 5-6.*
*†Premature battery depletion advisory population.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices
## Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1411-36Q | Ellipse™ VR | 23,229 | 4.33% | 5 | 0.02% | 0 | 0.00% | 0 | 0.00% | 10 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | **17** | **0.07%** |
| CD1411-36C | Ellipse™ VR | 7,072 | 6.32% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| CD1357-40Q | Fortify Assura™ VR | 34,404 | 7.31% | 7 | 0.02% | 3 | <0.01% | 0 | 0.00% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | 65 | 0.19% | 7 | 0.02% | **85** | **0.25%** |
| CD1357-40C | Fortify Assura™ VR | 9,651 | 11.00% | 3 | 0.03% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 9 | 0.09% | 0 | 0.00% | **15** | **0.16%** |
| CD1257-40Q | Fortify Assura™ VR | 5,038 | 14.79% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 20 | 0.40% | 1 | 0.02% | **23** | **0.46%** |
| CD1257-40 | Fortify Assura™ VR | 2,298 | 17.01% | 1 | 0.04% | 2 | 0.09% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.30% | 2 | 0.09% | **13** | **0.57%** |
| CD1311-36Q | Ellipse™ VR | 4,912 | 9.69% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 38 | 0.77% | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | **43** | **0.88%** |
| CD1311-36 | Ellipse™ VR | 1,629 | 14.00% | 4 | 0.25% | 1 | 0.06% | 0 | 0.00% | 9 | 0.55% | 0 | 0.00% | 2 | 0.12% | 0 | 0.00% | 1 | 0.06% | **17** | **1.04%** |
| CD1231-40Q | Fortify™ VR† | 18,233 | 14.68% | 8 | 0.04% | 2 | 0.01% | 18 | 0.10% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 144 | 0.79% | 9 | 0.05% | **183** | **1.00%** |
| CD1231-40 | Fortify™ VR† | 10,172 | 12.19% | 6 | 0.06% | 0 | 0.00% | 5 | 0.05% | 10 | 0.10% | 0 | 0.00% | 0 | 0.00% | 47 | 0.46% | 6 | 0.06% | **74** | **0.73%** |
| CD1211-36Q | Current™ + VR | 16,551 | 8.15% | 15 | 0.09% | 3 | 0.02% | 9 | 0.05% | 7 | 0.04% | 0 | 0.00% | 0 | 0.00% | 8 | 0.05% | 8 | 0.05% | **50** | **0.30%** |
| CD1211-36 | Current™ + VR | 14,877 | 6.67% | 5 | 0.03% | 4 | 0.03% | 5 | 0.03% | 6 | 0.04% | 0 | 0.00% | 0 | 0.00% | 11 | 0.07% | 10 | 0.07% | **41** | **0.28%** |
| 1207-36 | Current™ VR RF | 24,846 | 17.58% | 12 | 0.05% | 31 | 0.12% | 18 | 0.07% | 1 | <0.01% | 2 | <0.01% | 1 | <0.01% | 32 | 0.13% | 12 | 0.05% | **109** | **0.44%** |
| V-168 | Atlas™ II VR | 23,946 | 15.45% | 8 | 0.03% | 5 | 0.02% | 19 | 0.08% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 22 | 0.09% | 21 | 0.09% | **77** | **0.32%** |
| V-193 | Atlas™ + VR | 39,596 | 16.41% | 6 | 0.02% | 9 | 0.02% | 15 | 0.04% | 5 | 0.01% | 1 | <0.01% | 1 | <0.01% | 71 | 0.18% | 32 | 0.08% | **140** | **0.35%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

## Worldwide Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1411-36Q | Ellipse™ VR | 23,229 | 4.33% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 1 | <0.01% | 3 | 0.01% | 2 | <0.01% | 2 | <0.01% | **12** | **0.05%** |
| CD1411-36C | Ellipse™ VR | 7,072 | 6.32% | 2 | 0.03% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 2 | 0.03% | **6** | **0.08%** |
| CD1357-40Q | Fortify Assura™ VR | 34,404 | 7.31% | 9 | 0.03% | 0 | 0.00% | 4 | 0.01% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 508 | 1.48% | 6 | 0.02% | **529** | **1.54%** |
| CD1357-40C | Fortify Assura™ VR | 9,651 | 11.00% | 2 | 0.02% | 0 | 0.00% | 4 | 0.04% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 172 | 1.78% | 2 | 0.02% | **182** | **1.89%** |
| CD1257-40Q | Fortify Assura™ VR | 5,038 | 14.79% | 2 | 0.04% | 0 | 0.00% | 3 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 142 | 2.82% | 0 | 0.00% | **147** | **2.92%** |
| CD1257-40 | Fortify Assura™ VR | 2,298 | 17.01% | 0 | 0.00% | 0 | 0.00% | 2 | 0.09% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 38 | 1.65% | 1 | 0.04% | **41** | **1.78%** |
| CD1311-36Q | Ellipse™ VR | 4,912 | 9.69% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 8 | 0.16% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.06% | **13** | **0.26%** |
| CD1311-36 | Ellipse™ VR | 1,629 | 14.00% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 2 | 0.12% | 1 | 0.06% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | **5** | **0.31%** |
| CD1231-40Q | Fortify™ VR† | 18,233 | 14.68% | 10 | 0.05% | 1 | <0.01% | 47 | 0.26% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 406 | 2.23% | 6 | 0.03% | **472** | **2.59%** |
| CD1231-40 | Fortify™ VR† | 10,172 | 12.19% | 6 | 0.06% | 0 | 0.00% | 12 | 0.12% | 3 | 0.03% | 0 | 0.00% | 1 | <0.01% | 139 | 1.37% | 6 | 0.06% | **167** | **1.64%** |
| CD1211-36Q | Current™ + VR | 16,551 | 8.15% | 7 | 0.04% | 0 | 0.00% | 7 | 0.04% | 3 | 0.02% | 3 | 0.02% | 1 | <0.01% | 9 | 0.05% | 13 | 0.08% | **43** | **0.26%** |
| CD1211-36 | Current™ + VR | 14,877 | 6.67% | 6 | 0.04% | 0 | 0.00% | 3 | 0.02% | 0 | 0.00% | 9 | 0.06% | 0 | 0.00% | 6 | 0.04% | 4 | 0.03% | **28** | **0.19%** |
| 1207-36 | Current™ VR RF | 24,846 | 17.58% | 17 | 0.07% | 3 | 0.01% | 13 | 0.05% | 1 | <0.01% | 52 | 0.21% | 12 | 0.05% | 29 | 0.12% | 15 | 0.06% | **142** | **0.57%** |
| V-168 | Atlas™ II VR | 23,946 | 15.45% | 4 | 0.02% | 0 | 0.00% | 6 | 0.03% | 0 | 0.00% | 0 | 0.00% | 12 | 0.05% | 10 | 0.04% | 9 | 0.04% | **41** | **0.17%** |
| V-193 | Atlas™ + VR | 39,596 | 16.41% | 4 | 0.01% | 3 | <0.01% | 8 | 0.02% | 1 | <0.01% | 2 | <0.01% | 14 | 0.04% | 11 | 0.03% | 13 | 0.03% | **56** | **0.14%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | INAPPROPRIATE SHOCK | | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1231-40Q | 160 | 52 | 11,995 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 1.25% | 0 | 0.00% | **2** | **1.25%** |
| CD1211-36Q | 363 | 140 | 28,133 | 1 | 0.28% | 0 | 0.00% | 0 | 0.00% | 1 | 0.28% | 0 | 0.00% | **2** | **0.55%** |
| 1207-36 | 395 | 14 | 22,031 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*A list of of complications can be found on page 12.*

## Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

Actively Monitored Study Data Summary

### MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1231-40Q | Fortify™ VR | 160 | 20.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.63% | 0 | 0.00% | 0 | 0.00% | 2 | 1.25% | 0 | 0.00% | **3** | **1.88%** |
| CD1211-36Q | Current™ + VR | 363 | 32.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.28% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.28%** |
| 1207-36 | Current™ VR RF | 395 | 36.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

### MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | HIGH VOLTAGE CAPACITOR | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| CD1231-40Q | Fortify™ VR | 160 | 20.60% | 0 | 0.00% | 0 | 0.00% | 1 | 0.63% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 8 | 5.00% | 0 | 0.00% | **9** | **5.63%** |
| CD1211-36Q | Current™ + VR | 363 | 32.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.28% | 0 | 0.00% | 1 | 0.28% | 0 | 0.00% | **2** | **0.55%** |
| 1207-36 | Current™ VR RF | 395 | 36.70% | 1 | 0.25% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.25%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Defibrillation Leads

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

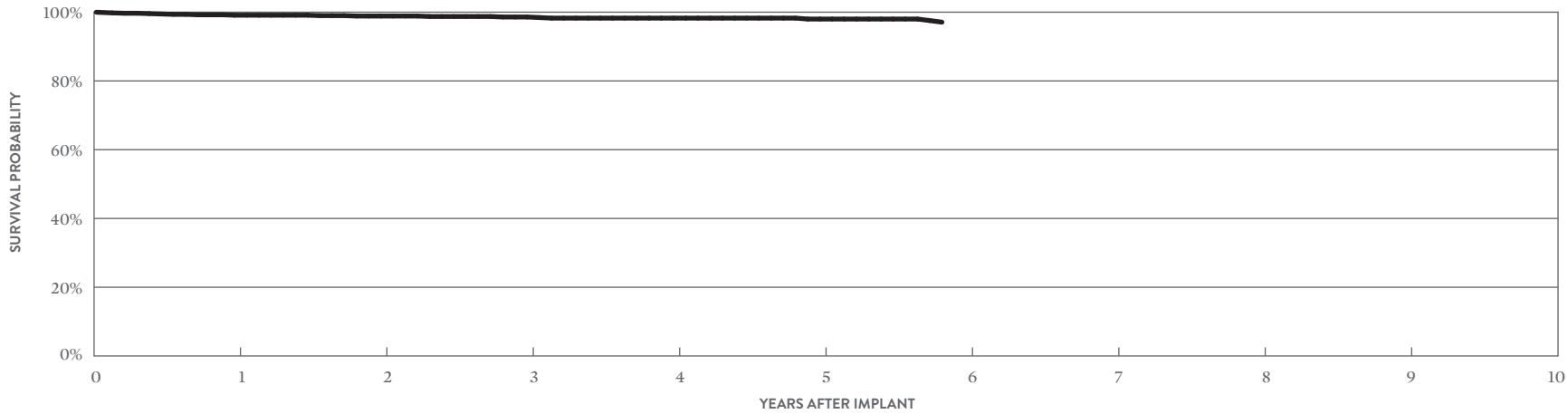
## Optisure™ DF4

### MODEL LDA230Q

| | |
|---|---|
| US Regulatory Approval | February 2014 |
| Registered US Implants | 1,039 |
| Estimated Active US Implants | 630 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 326) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 1 | 0.10% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 1 | 0.10% | 3 | 0.29% |
| Failure to Capture | 0 | 0.00% | 4 | 0.38% |
| Oversensing | 0 | 0.00% | 4 | 0.38% |
| Failure to Sense | 0 | 0.00% | 1 | 0.10% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 1 | 0.10% | 1 | 0.10% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 1 | 0.10% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **4** | **0.38%** | **13** | **1.25%** |
| **Total Returned for Analysis** | **1** | | **7** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.10% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 1 | 0.10% |
| Insulation Breach | 2 | 0.19% |
| Lead-to-Can Contact | 1 | 0.10% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 1 | 0.10% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 8 | 0.77% |
| **Total** | **11** | **1.06%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | AT 70 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.12% | 98.87% | 98.59% | 98.27% | 98.00% | 97.09% |
| ± 1 STANDARD ERROR | 0.29% | 0.35% | 0.41% | 0.46% | 0.53% | 0.69% |
| SAMPLE SIZE | 940 | 800 | 690 | 580 | 440 | 220 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

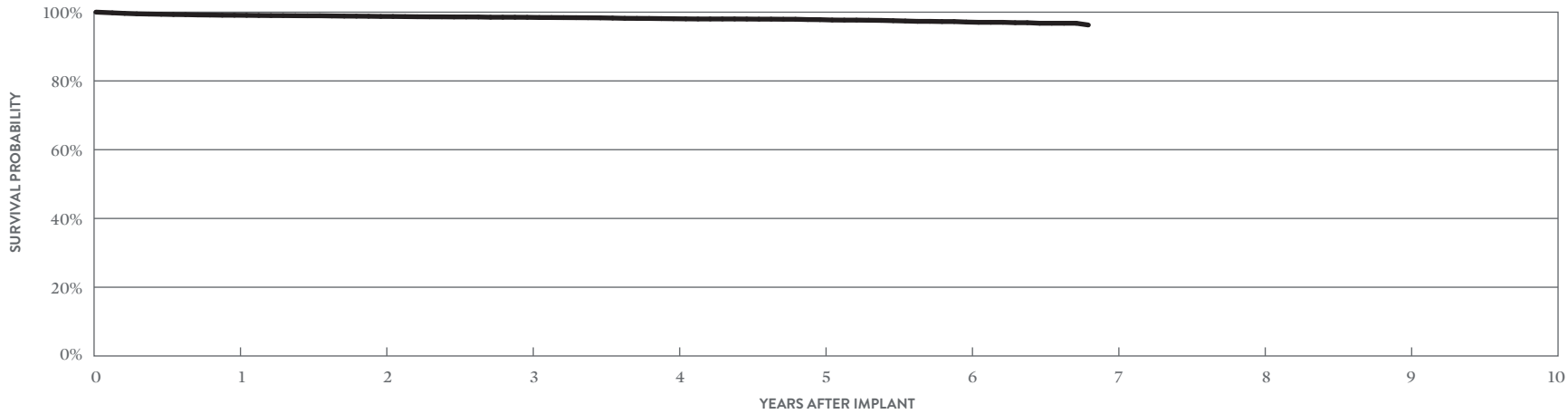
## Optisure™ DF4

### MODEL LDA220Q

| | |
|---|---|
| US Regulatory Approval | February 2014 |
| Registered US Implants | 11,715 |
| Estimated Active US Implants | 7,763 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 326) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 10 | 0.09% | 4 | 0.03% |
| Conductor Fracture | 0 | 0.00% | 5 | 0.04% |
| Lead Dislodgement | 50 | 0.43% | 72 | 0.61% |
| Failure to Capture | 22 | 0.19% | 68 | 0.58% |
| Oversensing | 5 | 0.04% | 55 | 0.47% |
| Failure to Sense | 2 | 0.02% | 8 | 0.07% |
| Insulation Breach | 0 | 0.00% | 2 | 0.02% |
| Abnormal Pacing Impedance | 0 | 0.00% | 11 | 0.09% |
| Abnormal Defibrillation Impedance | 5 | 0.04% | 17 | 0.15% |
| Extracardiac Stimulation | 1 | <0.01% | 0 | 0.00% |
| Other | 6 | 0.05% | 3 | 0.03% |
| **Total** | **101** | **0.86%** | **245** | **2.09%** |
| **Total Returned for Analysis** | **36** | | **74** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | <0.01% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 1 | <0.01% |
| Insulation Breach | 6 | 0.05% |
| Lead-to-Can Contact | 2 | 0.02% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 1 | <0.01% |
| Externalized Conductors | 0 | 0.00% |
| Other | 3 | 0.03% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 70 | 0.60% |
| **Total** | **77** | **0.66%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 82 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.11% | 98.76% | 98.50% | 98.09% | 97.82% | 97.13% | 96.27% |
| ± 1 STANDARD ERROR | 0.09% | 0.11% | 0.13% | 0.15% | 0.17% | 0.23% | 0.33% |
| SAMPLE SIZE | 10,490 | 8,420 | 6,800 | 5,300 | 3,800 | 2,190 | 230 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

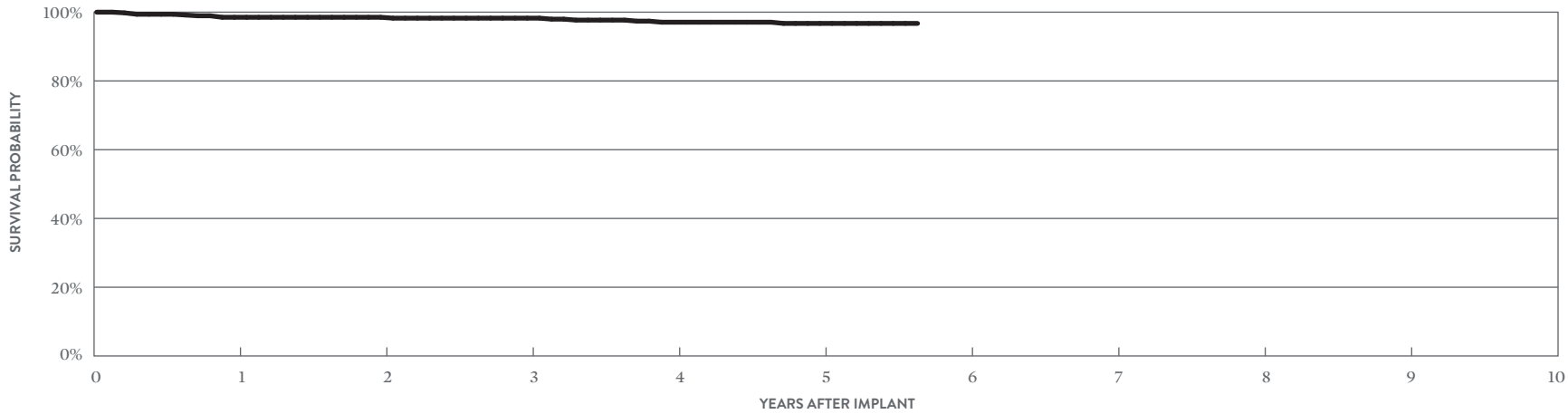
## Optisure™

### MODEL LDA220

| | |
|---|---|
| US Regulatory Approval | February 2014 |
| Registered US Implants | 588 |
| Estimated Active US Implants | 351 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 326) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 1 | 0.17% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 0 | 0.00% | 5 | 0.85% |
| Failure to Capture | 0 | 0.00% | 3 | 0.51% |
| Oversensing | 0 | 0.00% | 5 | 0.85% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 3 | 0.51% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 1 | 0.17% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **1** | **0.17%** | **17** | **2.89%** |
| **Total Returned for Analysis** | **0** | | **4** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 6 | 1.02% |
| **Total** | **6** | **1.02%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.51% | 98.51% | 98.26% | 97.08% | 96.73% | 96.73% |
| ± 1 STANDARD ERROR | 0.56% | 0.56% | 0.61% | 0.84% | 0.91% | 0.91% |
| SAMPLE SIZE | 510 | 410 | 380 | 330 | 280 | 210 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

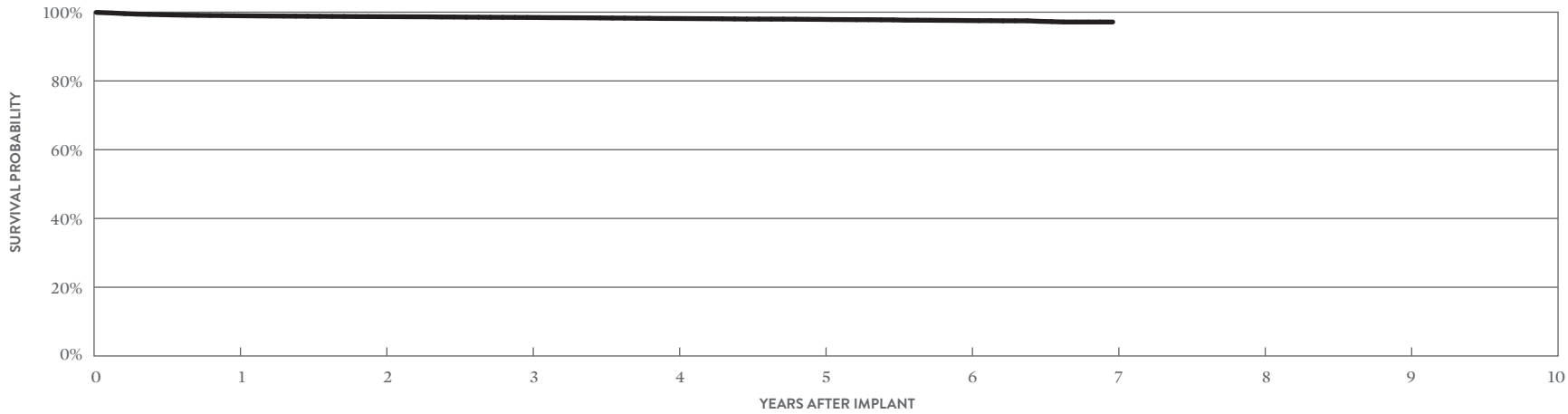
## Optisure™ DF4

### MODEL LDA210Q

| | |
|---|---|
| US Regulatory Approval | February 2014 |
| Registered US Implants | 50,410 |
| Estimated Active US Implants | 34,888 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 88 | 0.17% | 21 | 0.04% |
| Conductor Fracture | 2 | <0.01% | 17 | 0.03% |
| Lead Dislodgement | 179 | 0.36% | 280 | 0.56% |
| Failure to Capture | 90 | 0.18% | 186 | 0.37% |
| Oversensing | 38 | 0.08% | 148 | 0.29% |
| Failure to Sense | 12 | 0.02% | 19 | 0.04% |
| Insulation Breach | 2 | <0.01% | 2 | <0.01% |
| Abnormal Pacing Impedance | 9 | 0.02% | 37 | 0.07% |
| Abnormal Defibrillation Impedance | 10 | 0.02% | 33 | 0.07% |
| Extracardiac Stimulation | 3 | <0.01% | 5 | <0.01% |
| Other | 17 | 0.03% | 27 | 0.05% |
| **Total** | **450** | **0.89%** | **775** | **1.54%** |
| **Total Returned for Analysis** | **152** | | **285** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 7 | 0.01% |
| Clavicular Crush | 1 | <0.01% |
| In the Pocket | 2 | <0.01% |
| Intravascular | 4 | <0.01% |
| Insulation Breach | 14 | 0.03% |
| Lead-to-Can Contact | 8 | 0.02% |
| Lead-to-Lead Contact | 5 | <0.01% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | <0.01% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 5 | <0.01% |
| Extrinsic Factors | 273 | 0.54% |
| **Total** | **299** | **0.59%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.97% | 98.70% | 98.47% | 98.16% | 97.90% | 97.57% | 97.14% |
| ± 1 STANDARD ERROR | 0.05% | 0.06% | 0.06% | 0.08% | 0.09% | 0.12% | 0.22% |
| SAMPLE SIZE | 43,540 | 32,110 | 23,710 | 16,600 | 10,740 | 5,610 | 250 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

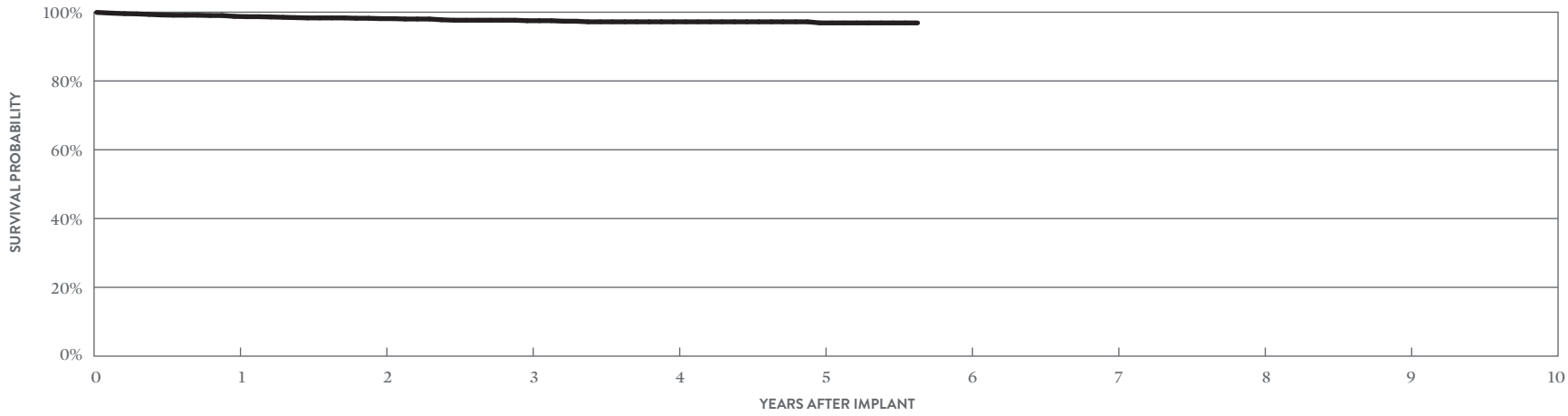
## Optisure™

### MODEL LDA210

| | |
|---|---|
| US Regulatory Approval | February 2014 |
| Registered US Implants | 1,525 |
| Estimated Active US Implants | 1,035 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 3 | 0.20% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 2 | 0.13% |
| Lead Dislodgement | 7 | 0.46% | 7 | 0.46% |
| Failure to Capture | 2 | 0.13% | 10 | 0.66% |
| Oversensing | 2 | 0.13% | 10 | 0.66% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 2 | 0.13% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 1 | 0.07% |
| Extracardiac Stimulation | 0 | 0.00% | 1 | 0.07% |
| Other | 1 | 0.07% | 2 | 0.13% |
| **Total** | **15** | **0.98%** | **35** | **2.30%** |
| **Total Returned for Analysis** | **5** | | **12** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 1 | 0.07% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 1 | 0.07% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 14 | 0.92% |
| **Total** | **15** | **0.98%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | AT 68 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.78% | 98.12% | 97.52% | 97.20% | 96.88% | 96.88% |
| ± 1 STANDARD ERROR | 0.27% | 0.38% | 0.45% | 0.52% | 0.52% | 0.61% |
| SAMPLE SIZE | 1,340 | 1,040 | 810 | 580 | 380 | 210 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

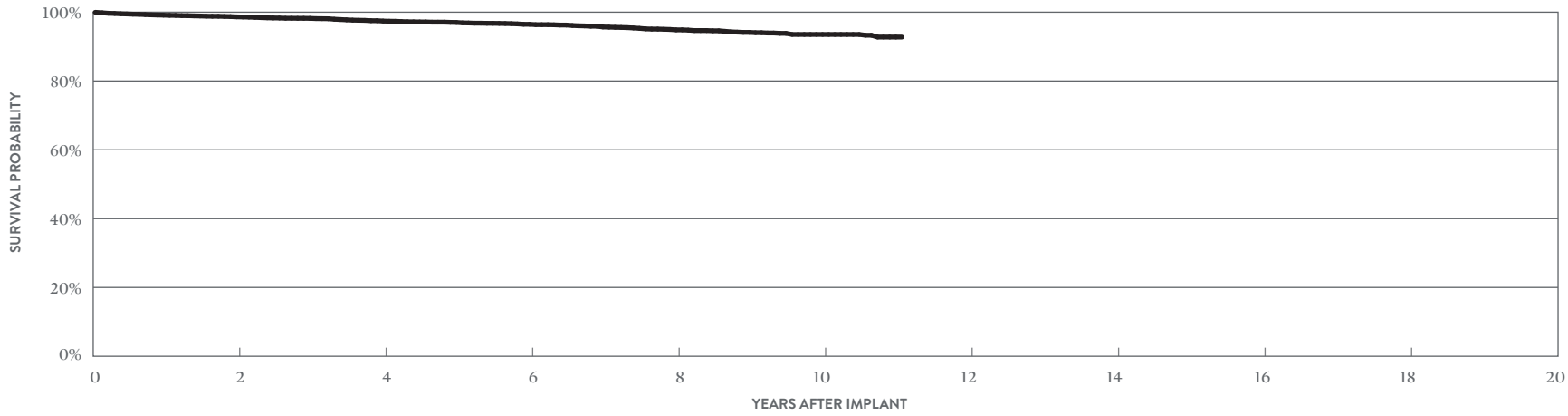
## Durata™ DF4

### MODELS 7170Q & 7171Q

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 6,971 |
| Estimated Active US Implants | 3,266 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 6 | 0.09% | 7 | 0.10% |
| Conductor Fracture | 1 | 0.01% | 28 | 0.40% |
| Lead Dislodgement | 21 | 0.30% | 32 | 0.46% |
| Failure to Capture | 14 | 0.20% | 78 | 1.12% |
| Oversensing | 3 | 0.04% | 67 | 0.96% |
| Failure to Sense | 0 | 0.00% | 1 | 0.01% |
| Insulation Breach | 0 | 0.00% | 4 | 0.06% |
| Abnormal Pacing Impedance | 1 | 0.01% | 22 | 0.32% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 20 | 0.29% |
| Extracardiac Stimulation | 1 | 0.01% | 0 | 0.00% |
| Other | 1 | 0.01% | 3 | 0.04% |
| **Total** | **48** | **0.69%** | **262** | **3.76%** |
| **Total Returned for Analysis** | **22** | | **68** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 5 | 0.07% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 2 | 0.03% |
| Intravascular | 3 | 0.04% |
| Insulation Breach | 14 | 0.20% |
| Lead-to-Can Contact | 7 | 0.10% |
| Lead-to-Lead Contact | 5 | 0.07% |
| Clavicular Crush | 1 | 0.01% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.01% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 52 | 0.75% |
| **Total** | **71** | **1.02%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 133 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.64% | 97.42% | 96.48% | 94.86% | 93.53% | 92.77% |
| ± 1 STANDARD ERROR | 0.14% | 0.22% | 0.28% | 0.38% | 0.51% | 0.67% |
| SAMPLE SIZE | 5,460 | 4,160 | 2,920 | 1,830 | 880 | 210 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

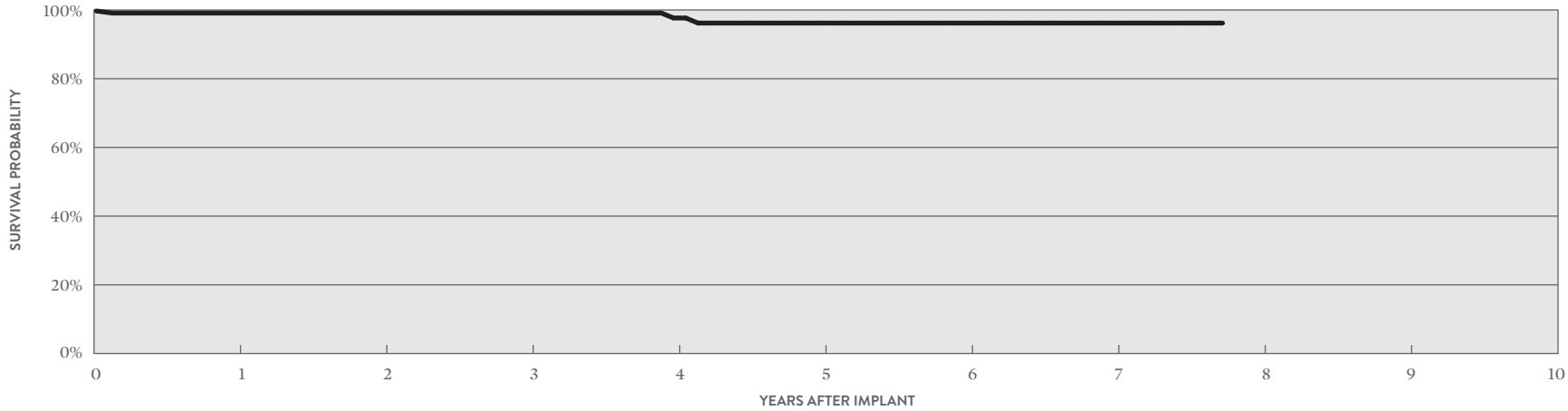
## Durata™ DF4

### MODELS 7170Q & 7171Q

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Number of Devices Enrolled in Study | 115 |
| Active Devices Enrolled in Study | 39 |
| Cumulative Months of Follow-up | 8,178 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.87% |
| Conductor Fracture | 1 | 0.87% |
| Lead Dislodgement | 1 | 0.87% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Lead-to-Can Contact | 0 | 0.00% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 2 | 1.74% |
| **Total** | **2** | **1.74%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 93 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.10% | 99.10% | 99.10% | 97.66% | 96.19% | 96.19% | 96.19% | 96.19% |
| ± 1 STANDARD ERROR | 0.90% | 0.90% | 0.90% | 0.90% | 2.20% | 2.20% | 2.20% | 2.20% |
| SAMPLE SIZE | 110 | 100 | 80 | 70 | 60 | 60 | 50 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

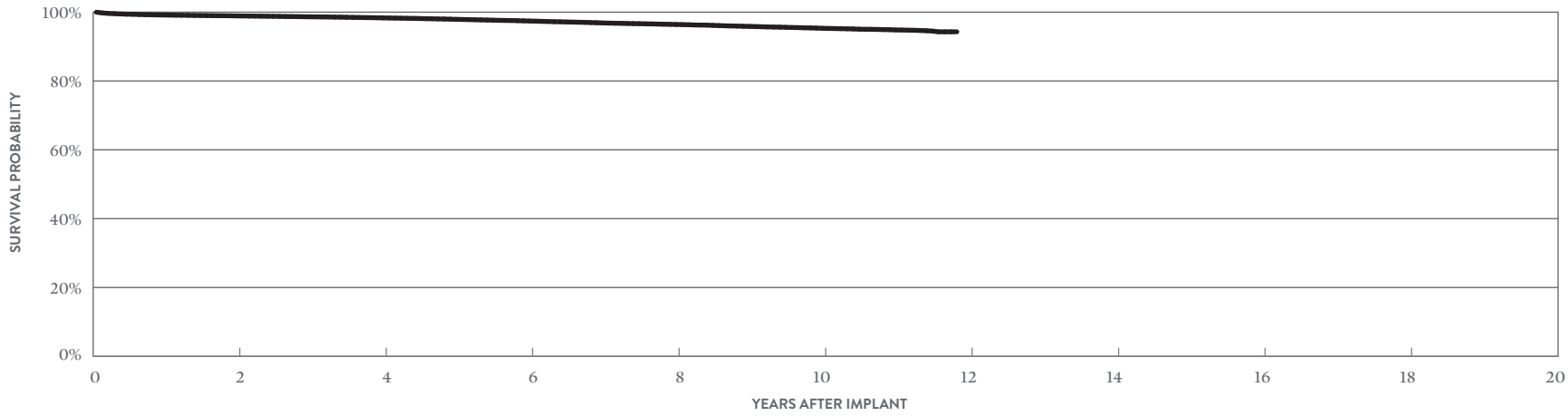
## Durata™ DF4

### MODELS 7120Q & 7121Q

| | |
|---|---|
| US Regulatory Approval | January 2009 |
| Registered US Implants | 138,345 |
| Estimated Active US Implants | 63,636 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 105 | 0.08% | 46 | 0.03% |
| Conductor Fracture | 2 | <0.01% | 248 | 0.18% |
| Lead Dislodgement | 289 | 0.21% | 700 | 0.51% |
| Failure to Capture | 138 | 0.10% | 1005 | 0.73% |
| Oversensing | 54 | 0.04% | 1008 | 0.73% |
| Failure to Sense | 16 | 0.01% | 99 | 0.07% |
| Insulation Breach | 0 | 0.00% | 65 | 0.05% |
| Abnormal Pacing Impedance | 7 | <0.01% | 215 | 0.16% |
| Abnormal Defibrillation Impedance | 11 | <0.01% | 451 | 0.33% |
| Extracardiac Stimulation | 6 | <0.01% | 10 | <0.01% |
| Other | 44 | 0.03% | 95 | 0.07% |
| **Total** | **672** | **0.49%** | **3942** | **2.85%** |
| **Total Returned for Analysis** | **326** | | **1182** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 34 | 0.02% |
| Clavicular Crush | 5 | <0.01% |
| In the Pocket | 11 | <0.01% |
| Intravascular | 18 | 0.01% |
| Insulation Breach | 320 | 0.23% |
| Lead-to-Can Contact | 183 | 0.13% |
| Lead-to-Lead Contact | 33 | 0.02% |
| Clavicular Crush | 35 | 0.03% |
| Externalized Conductors | 0 | 0.00% |
| Other | 69 | 0.05% |
| Crimps, Welds & Bonds | 2 | <0.01% |
| Other | 38 | 0.03% |
| Extrinsic Factors | 927 | 0.67% |
| **Total** | **1321** | **0.95%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 142 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.91% | 98.33% | 97.42% | 96.42% | 95.31% | 94.29% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.05% | 0.07% | 0.09% | 0.20% |
| SAMPLE SIZE | 110,370 | 85,910 | 64,960 | 43,930 | 22,230 | 360 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

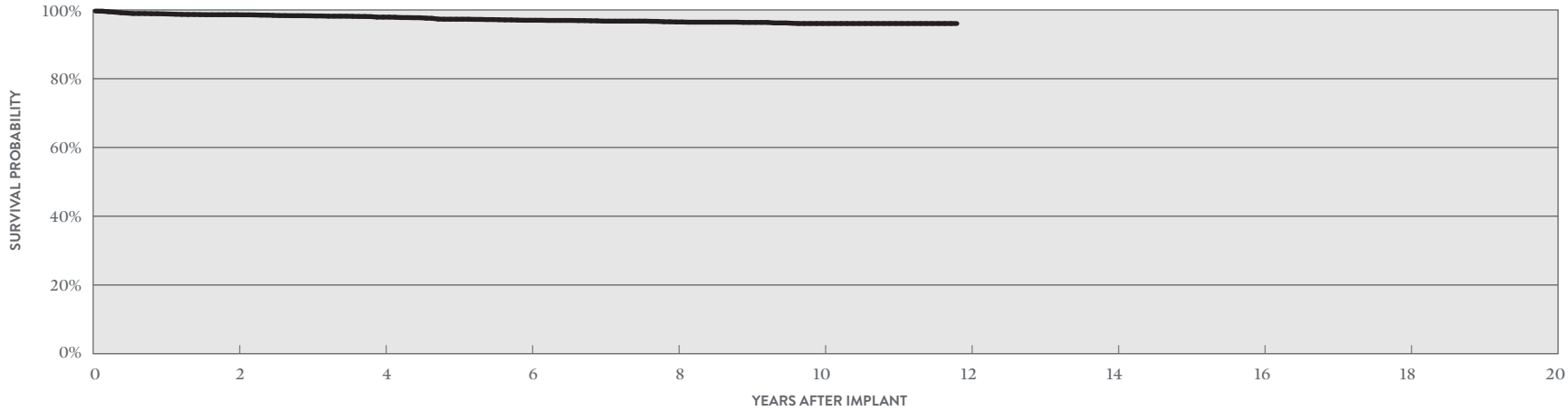
## Durata™ DF4

### MODELS 7120Q & 7121Q

| | |
|---|---|
| US Regulatory Approval | January 2009 |
| Number of Devices Enrolled in Study | 4,322 |
| Active Devices Enrolled in Study | 1,585 |
| Cumulative Months of Follow-up | 292,939 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 5 | 0.12% |
| Abnormal Pacing Impedance | 5 | 0.12% |
| Cardiac Perforation | 1 | 0.02% |
| Conductor Fracture | 18 | 0.42% |
| Failure to Capture | 20 | 0.46% |
| Failure to Sense | 5 | 0.12% |
| Inappropriate Shock | 5 | 0.12% |
| Insulation Breach | 5 | 0.12% |
| Lead Dislodgement | 39 | 0.90% |
| Oversensing | 8 | 0.19% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 5 | 0.12% |
| Clavicular Crush | 1 | 0.02% |
| In the Pocket | 2 | 0.05% |
| Intravascular | 2 | 0.05% |
| Insulation Breach | 14 | 0.32% |
| Lead-to-Can Contact | 10 | 0.23% |
| Lead-to-Lead Contact | 3 | 0.07% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.02% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | 0.02% |
| Extrinsic Factors | 51 | 1.18% |
| **Total** | **71** | **1.64%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 142 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.61% | 97.91% | 97.00% | 96.50% | 96.05% | 96.05% |
| ± 1 STANDARD ERROR | 0.18% | 0.24% | 0.31% | 0.35% | 0.40% | 0.40% |
| SAMPLE SIZE | 3,500 | 2,630 | 2,000 | 1,700 | 1,150 | 80 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

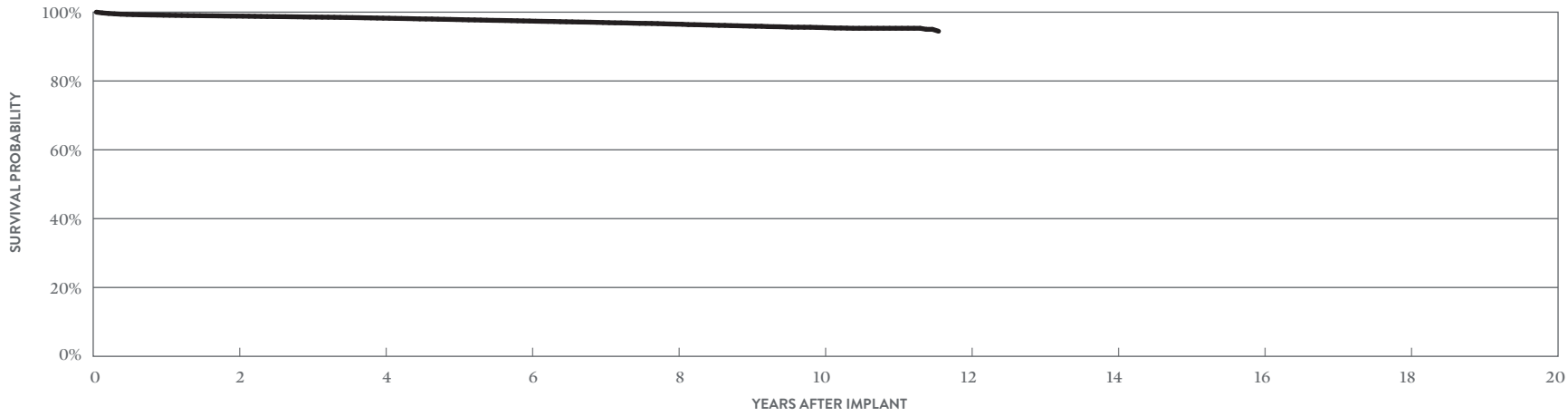
## Durata™ DF4

### MODEL 7122Q

| | |
|---|---|
| US Regulatory Approval | January 2009 |
| Registered US Implants | 136,401 |
| Estimated Active US Implants | 77,444 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 178 | 0.13% | 57 | 0.04% |
| Conductor Fracture | 3 | <0.01% | 101 | 0.07% |
| Lead Dislodgement | 344 | 0.25% | 686 | 0.50% |
| Failure to Capture | 177 | 0.13% | 697 | 0.51% |
| Oversensing | 61 | 0.04% | 616 | 0.45% |
| Failure to Sense | 14 | 0.01% | 66 | 0.05% |
| Insulation Breach | 1 | <0.01% | 38 | 0.03% |
| Abnormal Pacing Impedance | 14 | 0.01% | 134 | 0.10% |
| Abnormal Defibrillation Impedance | 12 | <0.01% | 140 | 0.10% |
| Extracardiac Stimulation | 3 | <0.01% | 10 | <0.01% |
| Other | 51 | 0.04% | 91 | 0.07% |
| **Total** | **858** | **0.63%** | **2636** | **1.93%** |
| **Total Returned for Analysis** | **349** | | **959** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 17 | 0.01% |
| Clavicular Crush | 1 | <0.01% |
| In the Pocket | 9 | <0.01% |
| Intravascular | 7 | <0.01% |
| Insulation Breach | 206 | 0.15% |
| Lead-to-Can Contact | 126 | 0.09% |
| Lead-to-Lead Contact | 30 | 0.02% |
| Clavicular Crush | 19 | 0.01% |
| Externalized Conductors | 0 | 0.00% |
| Other | 31 | 0.02% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 20 | 0.01% |
| Extrinsic Factors | 821 | 0.60% |
| **Total** | **1064** | **0.78%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 139 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.86% | 98.26% | 97.42% | 96.52% | 95.52% | 94.46% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.06% | 0.09% | 0.15% | 0.35% |
| SAMPLE SIZE | 94,240 | 60,520 | 36,350 | 16,330 | 4,850 | 200 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

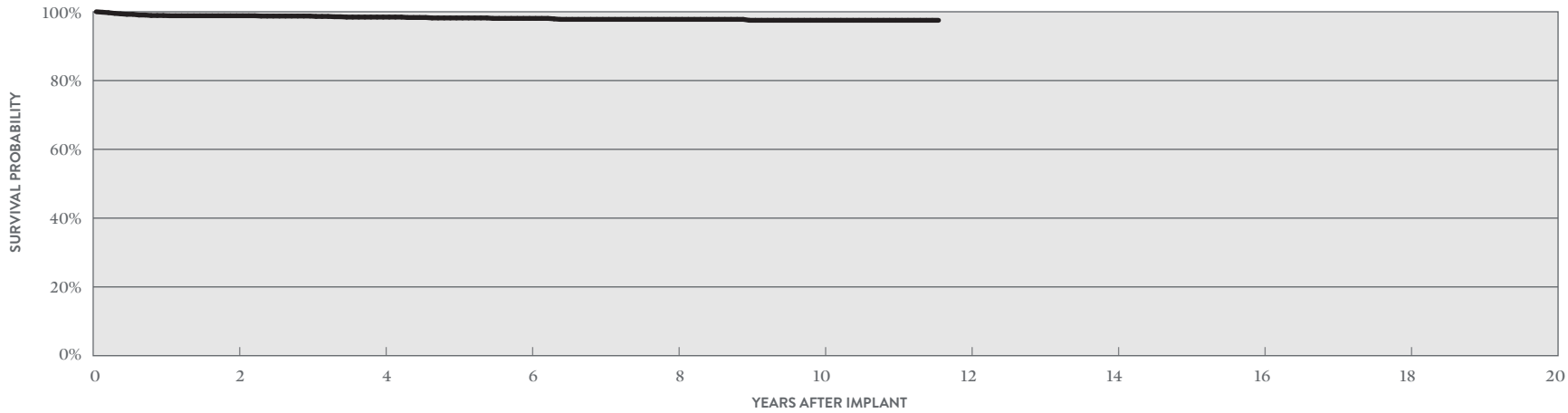
## Durata™ DF4

### MODEL 7122Q

| | |
|---|---|
| US Regulatory Approval | January 2009 |
| Number of Devices Enrolled in Study | 1,561 |
| Active Devices Enrolled in Study | 673 |
| Cumulative Months of Follow-up | 101,892 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 3 | 0.19% |
| Conductor Fracture | 4 | 0.26% |
| Failure to Capture | 7 | 0.45% |
| Failure to Sense | 2 | 0.13% |
| Lead Dislodgement | 7 | 0.45% |
| Oversensing | 2 | 0.13% |
| Pericardial Effusion | 2 | 0.13% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 2 | 0.13% |
| Clavicular Crush | 1 | 0.06% |
| In the Pocket | 1 | 0.06% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 5 | 0.32% |
| Lead-to-Can Contact | 4 | 0.26% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.06% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 15 | 0.96% |
| **Total** | **22** | **1.41%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 139 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.84% | 98.45% | 98.07% | 97.79% | 97.52% | 97.52% |
| ± 1 STANDARD ERROR | 0.28% | 0.34% | 0.40% | 0.45% | 0.52% | 0.52% |
| SAMPLE SIZE | 1,270 | 940 | 740 | 610 | 290 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

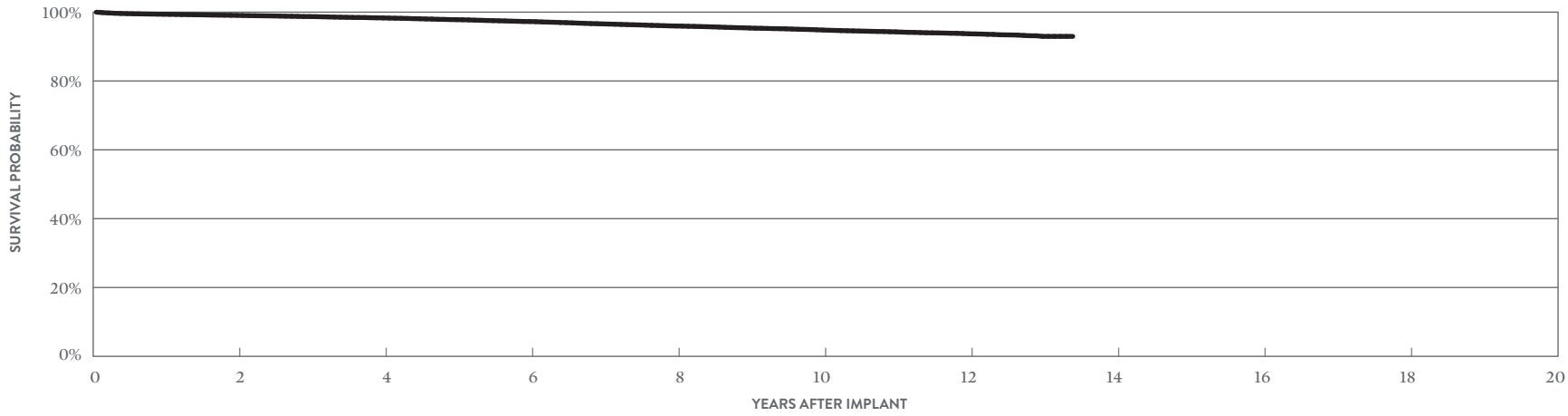
## Durata™

### MODELS 7120 & 7121

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 60,128 |
| Estimated Active US Implants | 20,706 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 40 | 0.07% | 18 | 0.03% |
| Conductor Fracture | 2 | <0.01% | 172 | 0.29% |
| Lead Dislodgement | 70 | 0.12% | 190 | 0.32% |
| Failure to Capture | 25 | 0.04% | 421 | 0.70% |
| Oversensing | 51 | 0.08% | 847 | 1.41% |
| Failure to Sense | 5 | <0.01% | 71 | 0.12% |
| Insulation Breach | 0 | 0.00% | 75 | 0.12% |
| Abnormal Pacing Impedance | 2 | <0.01% | 222 | 0.37% |
| Abnormal Defibrillation Impedance | 21 | 0.03% | 336 | 0.56% |
| Extracardiac Stimulation | 0 | 0.00% | 3 | <0.01% |
| Other | 21 | 0.03% | 58 | 0.10% |
| **Total** | **237** | **0.39%** | **2413** | **4.01%** |
| **Total Returned for Analysis** | **93** | | **618** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 34 | 0.06% |
| Clavicular Crush | 2 | <0.01% |
| In the Pocket | 23 | 0.04% |
| Intravascular | 9 | 0.01% |
| Insulation Breach | 204 | 0.34% |
| Lead-to-Can Contact | 105 | 0.17% |
| Lead-to-Lead Contact | 39 | 0.06% |
| Clavicular Crush | 18 | 0.03% |
| Externalized Conductors | 0 | 0.00% |
| Other | 42 | 0.07% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 9 | 0.01% |
| Extrinsic Factors | 450 | 0.75% |
| **Total** | **698** | **1.16%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.06% | 98.32% | 97.27% | 95.97% | 94.81% | 93.71% | 92.96% |
| ± 1 STANDARD ERROR | 0.04% | 0.06% | 0.08% | 0.10% | 0.12% | 0.15% | 0.20% |
| SAMPLE SIZE | 48,400 | 39,130 | 32,000 | 26,130 | 20,780 | 12,650 | 300 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

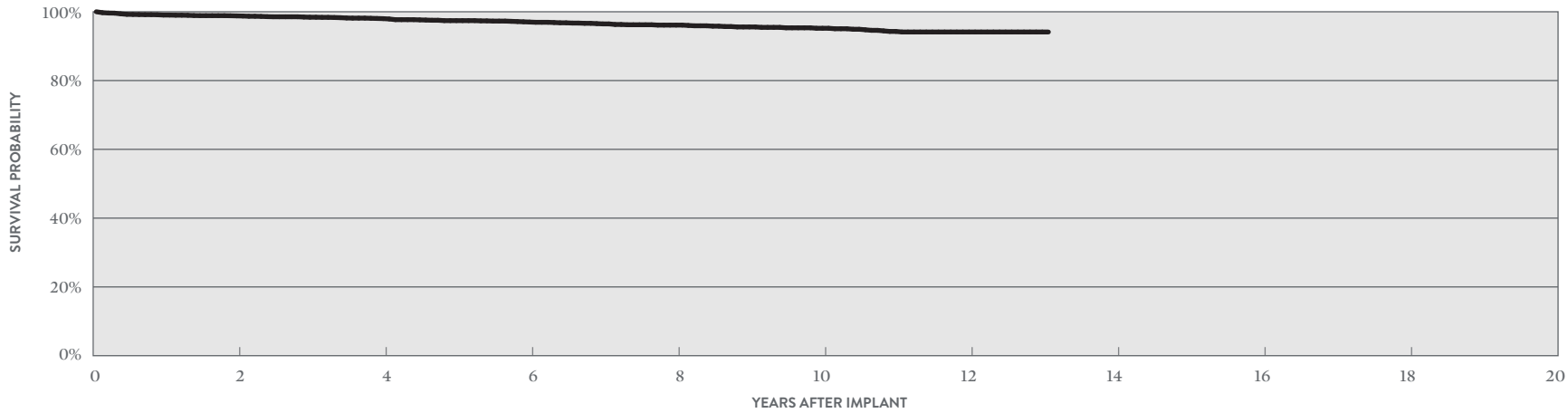
## Durata™

### MODELS 7120 & 7121

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Number of Devices Enrolled in Study | 3,560 |
| Active Devices Enrolled in Study | 636 |
| Cumulative Months of Follow-up | 233,694 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 5 | 0.14% |
| Abnormal Pacing Impedance | 11 | 0.31% |
| Conductor Fracture | 17 | 0.48% |
| Failure to Capture | 15 | 0.42% |
| Failure to Sense | 2 | 0.06% |
| Inappropriate Shock | 2 | 0.06% |
| Insulation Breach | 13 | 0.37% |
| Lead Dislodgement | 20 | 0.56% |
| Oversensing | 15 | 0.42% |
| Skin Erosion | 2 | 0.06% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.03% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 1 | 0.03% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 13 | 0.37% |
| Lead-to-Can Contact | 6 | 0.17% |
| Lead-to-Lead Contact | 6 | 0.17% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.03% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | 0.03% |
| Extrinsic Factors | 29 | 0.81% |
| **Total** | **44** | **1.24%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 157 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.80% | 98.00% | 97.01% | 96.12% | 95.20% | 94.12% | 94.12% |
| ± 1 STANDARD ERROR | 0.19% | 0.26% | 0.35% | 0.44% | 0.55% | 0.68% | 0.68% |
| SAMPLE SIZE | 2,950 | 2,160 | 1,500 | 1,070 | 740 | 490 | 70 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

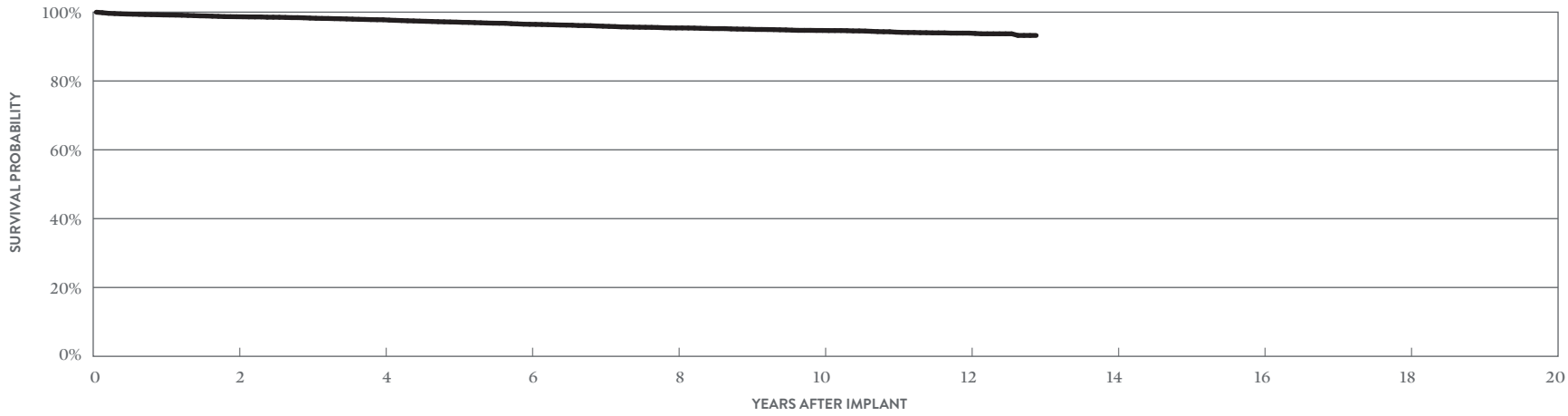
## Durata™

### MODEL 7122

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 16,001 |
| Estimated Active US Implants | 6,382 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 12 | 0.07% | 4 | 0.02% |
| Conductor Fracture | 1 | <0.01% | 45 | 0.28% |
| Lead Dislodgement | 24 | 0.15% | 76 | 0.47% |
| Failure to Capture | 19 | 0.12% | 113 | 0.71% |
| Oversensing | 12 | 0.07% | 177 | 1.11% |
| Failure to Sense | 0 | 0.00% | 13 | 0.08% |
| Insulation Breach | 1 | <0.01% | 24 | 0.15% |
| Abnormal Pacing Impedance | 3 | 0.02% | 50 | 0.31% |
| Abnormal Defibrillation Impedance | 2 | 0.01% | 46 | 0.29% |
| Extracardiac Stimulation | 2 | 0.01% | 2 | 0.01% |
| Other | 4 | 0.02% | 11 | 0.07% |
| **Total** | **80** | **0.50%** | **561** | **3.51%** |
| **Total Returned for Analysis** | **37** | | **194** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 16 | 0.10% |
| Clavicular Crush | 1 | <0.01% |
| In the Pocket | 12 | 0.07% |
| Intravascular | 3 | 0.02% |
| Insulation Breach | 70 | 0.44% |
| Lead-to-Can Contact | 37 | 0.23% |
| Lead-to-Lead Contact | 22 | 0.14% |
| Clavicular Crush | 2 | 0.01% |
| Externalized Conductors | 1 | <0.01% |
| Other | 8 | 0.05% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 4 | 0.02% |
| Extrinsic Factors | 147 | 0.92% |
| **Total** | **237** | **1.48%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 155 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.67% | 97.79% | 96.47% | 95.41% | 94.68% | 93.91% | 93.23% |
| ± 1 STANDARD ERROR | 0.10% | 0.13% | 0.18% | 0.22% | 0.26% | 0.31% | 0.48% |
| SAMPLE SIZE | 12,700 | 9,850 | 7,520 | 5,370 | 3,590 | 1,570 | 240 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

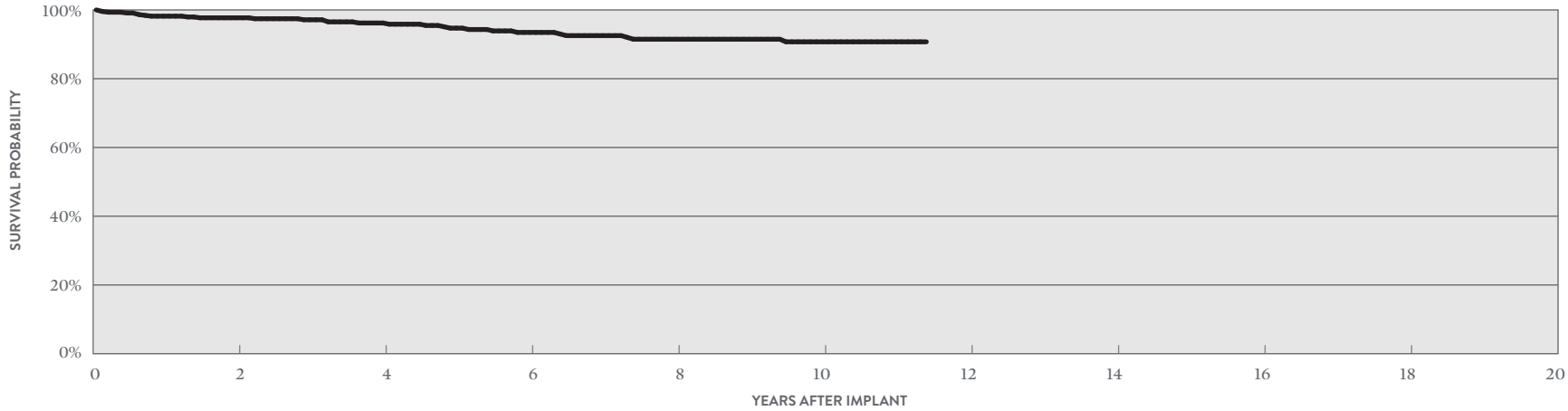
## Durata™

### MODEL 7122

| | |
|---|---|
| US Regulatory Approval | September 2007 |
| Number of Devices Enrolled in Study | 457 |
| Active Devices Enrolled in Study | 129 |
| Cumulative Months of Follow-up | 32,444 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 1 | 0.22% |
| Abnormal Pacing Impedance | 5 | 1.09% |
| Conductor Fracture | 6 | 1.31% |
| Failure to Capture | 5 | 1.09% |
| Failure to Sense | 1 | 0.22% |
| Insulation Breach | 1 | 0.22% |
| Lead Dislodgement | 5 | 1.09% |
| Oversensing | 3 | 0.66% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 2 | 0.44% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 1 | 0.22% |
| Intravascular | 1 | 0.22% |
| Insulation Breach | 3 | 0.66% |
| Lead-to-Can Contact | 2 | 0.44% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.22% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 8 | 1.75% |
| **Total** | **13** | **2.84%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 137 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 97.71% | 96.20% | 93.46% | 91.48% | 90.73% | 90.73% |
| ± 1 STANDARD ERROR | 0.72% | 0.97% | 1.39% | 1.68% | 1.83% | 1.83% |
| SAMPLE SIZE | 400 | 300 | 220 | 170 | 110 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

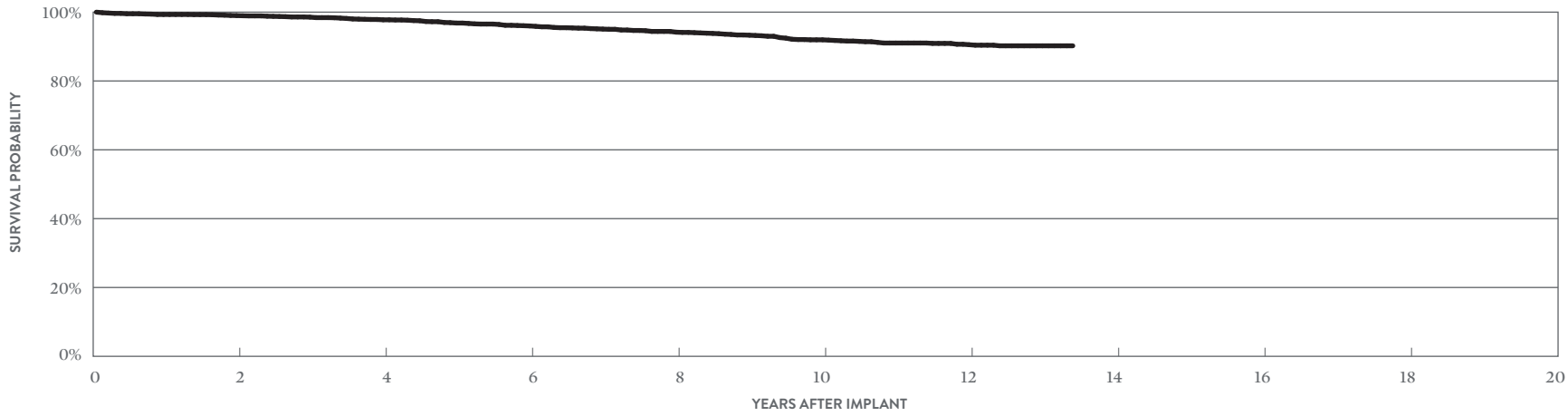
## Riata™ ST Optim™

### MODELS 7070 & 7071

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 3,311 |
| Estimated Active US Implants | 1,003 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 3 | 0.09% | 2 | 0.06% |
| Conductor Fracture | 1 | 0.03% | 28 | 0.85% |
| Lead Dislodgement | 3 | 0.09% | 13 | 0.39% |
| Failure to Capture | 6 | 0.18% | 40 | 1.21% |
| Oversensing | 4 | 0.12% | 64 | 1.93% |
| Failure to Sense | 3 | 0.09% | 3 | 0.09% |
| Insulation Breach | 0 | 0.00% | 9 | 0.27% |
| Abnormal Pacing Impedance | 0 | 0.00% | 15 | 0.45% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 22 | 0.66% |
| Extracardiac Stimulation | 0 | 0.00% | 1 | 0.03% |
| Other | 0 | 0.00% | 3 | 0.09% |
| **Total** | **20** | **0.60%** | **200** | **6.04%** |
| **Total Returned for Analysis** | **6** | | **44** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 2 | 0.06% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 2 | 0.06% |
| Insulation Breach | 23 | 0.69% |
| Lead-to-Can Contact | 9 | 0.27% |
| Lead-to-Lead Contact | 4 | 0.12% |
| Clavicular Crush | 2 | 0.06% |
| Externalized Conductors | 1 | 0.03% |
| Other | 7 | 0.21% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 23 | 0.69% |
| **Total** | **48** | **1.45%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 161 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.00% | 97.77% | 95.99% | 94.18% | 91.96% | 90.54% | 90.22% |
| ± 1 STANDARD ERROR | 0.19% | 0.30% | 0.43% | 0.54% | 0.67% | 0.75% | 0.79% |
| SAMPLE SIZE | 2,530 | 2,010 | 1,610 | 1,360 | 1,150 | 790 | 200 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

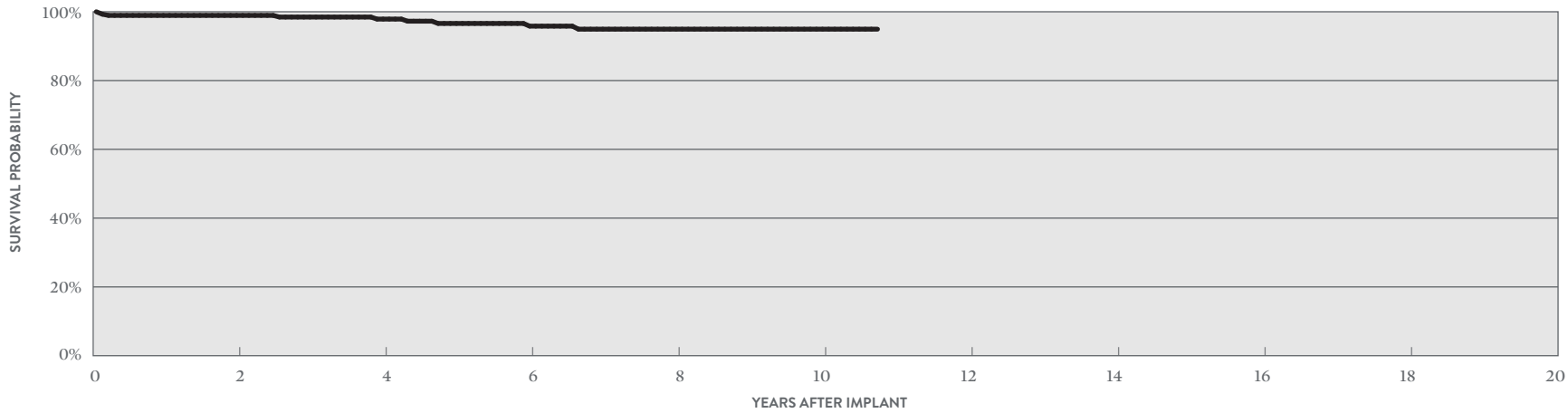
## Riata™ ST Optim™

### MODELS 7070 & 7071

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Number of Devices Enrolled in Study | 288 |
| Active Devices Enrolled in Study | 49 |
| Cumulative Months of Follow-up | 19,775 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 1 | 0.35% |
| Abnormal Pacing Impedance | 2 | 0.69% |
| Cardiac Perforation | 1 | 0.35% |
| Conductor Fracture | 2 | 0.69% |
| Failure to Capture | 1 | 0.35% |
| Lead Dislodgement | 1 | 0.35% |
| Oversensing | 1 | 0.35% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 1 | 0.35% |
| Lead-to-Can Contact | 1 | 0.35% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 1 | 0.35% |
| **Total** | **2** | **0.69%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 129 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.94% | 97.87% | 95.82% | 94.94% | 94.94% | 94.94% |
| ± 1 STANDARD ERROR | 0.61% | 0.96% | 1.31% | 1.73% | 1.73% | 1.73% |
| SAMPLE SIZE | 240 | 180 | 130 | 100 | 70 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

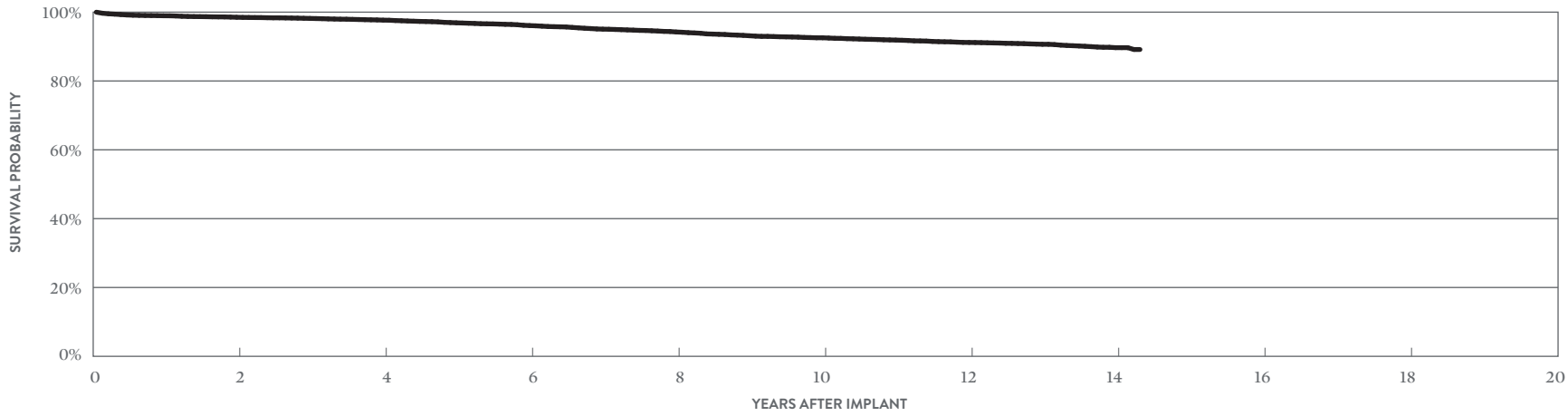
## Riata™ ST Optim™

### MODELS 7020 & 7021

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 14,252 |
| Estimated Active US Implants | 3,917 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 33 | 0.23% | 17 | 0.12% |
| Conductor Fracture | 0 | 0.00% | 67 | 0.47% |
| Lead Dislodgement | 27 | 0.19% | 66 | 0.46% |
| Failure to Capture | 17 | 0.12% | 176 | 1.23% |
| Oversensing | 19 | 0.13% | 290 | 2.03% |
| Failure to Sense | 8 | 0.06% | 21 | 0.15% |
| Insulation Breach | 0 | 0.00% | 29 | 0.20% |
| Abnormal Pacing Impedance | 2 | 0.01% | 59 | 0.41% |
| Abnormal Defibrillation Impedance | 4 | 0.03% | 113 | 0.79% |
| Extracardiac Stimulation | 3 | 0.02% | 2 | 0.01% |
| Other | 0 | 0.00% | 29 | 0.20% |
| **Total** | **113** | **0.79%** | **869** | **6.10%** |
| **Total Returned for Analysis** | **53** | | **230** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 11 | 0.08% |
| Clavicular Crush | 1 | <0.01% |
| In the Pocket | 5 | 0.04% |
| Intravascular | 5 | 0.04% |
| Insulation Breach | 65 | 0.46% |
| Lead-to-Can Contact | 31 | 0.22% |
| Lead-to-Lead Contact | 7 | 0.05% |
| Clavicular Crush | 4 | 0.03% |
| Externalized Conductors | 0 | 0.00% |
| Other | 23 | 0.16% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 181 | 1.27% |
| **Total** | **257** | **1.80%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 172 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.51% | 97.68% | 96.10% | 94.24% | 92.55% | 91.19% | 89.68% | 89.15% |
| ± 1 STANDARD ERROR | 0.11% | 0.14% | 0.20% | 0.25% | 0.31% | 0.34% | 0.41% | 0.56% |
| SAMPLE SIZE | 11,210 | 8,790 | 7,150 | 5,920 | 5,060 | 4,270 | 2,000 | 280 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

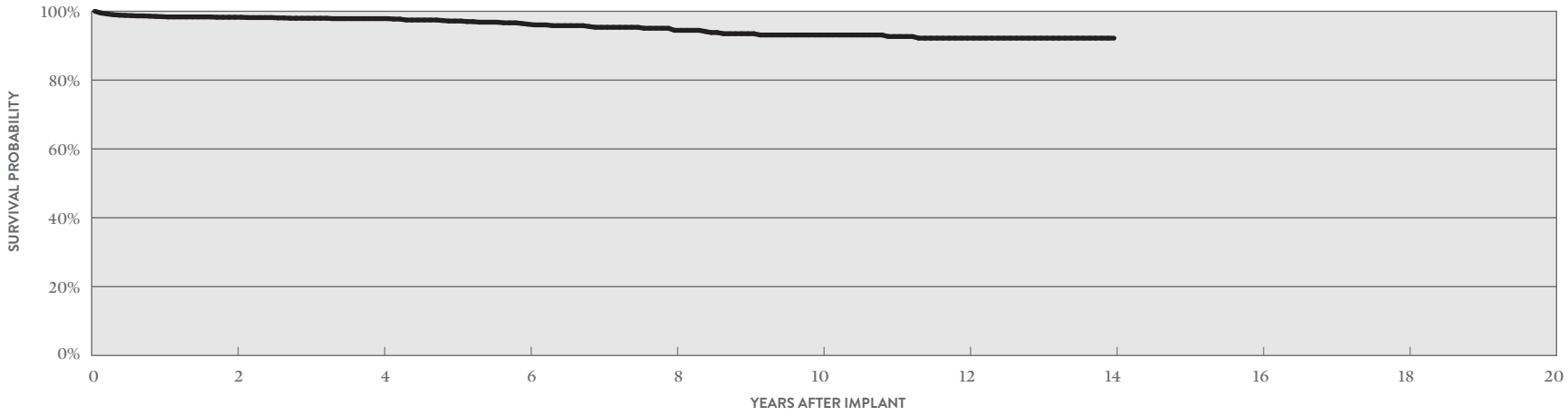
## Riata™ ST Optim™

### MODELS 7020 & 7021

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Number of Devices Enrolled in Study | 1,469 |
| Active Devices Enrolled in Study | 181 |
| Cumulative Months of Follow-up | 90,656 |
| Insulation | Optim™* |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 6 | 0.41% |
| Cardiac Perforation | 1 | 0.07% |
| Conductor Fracture | 9 | 0.61% |
| Failure to Capture | 16 | 1.09% |
| Failure to Sense | 1 | 0.07% |
| Insulation Breach | 2 | 0.14% |
| Lead Dislodgement | 9 | 0.61% |
| Oversensing | 6 | 0.41% |
| Skin Erosion | 1 | 0.07% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.20% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 3 | 0.20% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 4 | 0.27% |
| Lead-to-Can Contact | 2 | 0.14% |
| Lead-to-Lead Contact | 0 | 0.00% |
| Clavicular Crush | 2 | 0.14% |
| Externalized Conductors | 0 | 0.00% |
| Other | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 15 | 1.02% |
| **Total** | **22** | **1.50%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.27% | 97.87% | 96.25% | 94.47% | 93.12% | 92.20% | 92.20% |
| ± 1 STANDARD ERROR | 0.35% | 0.40% | 0.62% | 0.83% | 1.13% | 1.30% | 1.30% |
| SAMPLE SIZE | 1,180 | 840 | 540 | 350 | 240 | 190 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

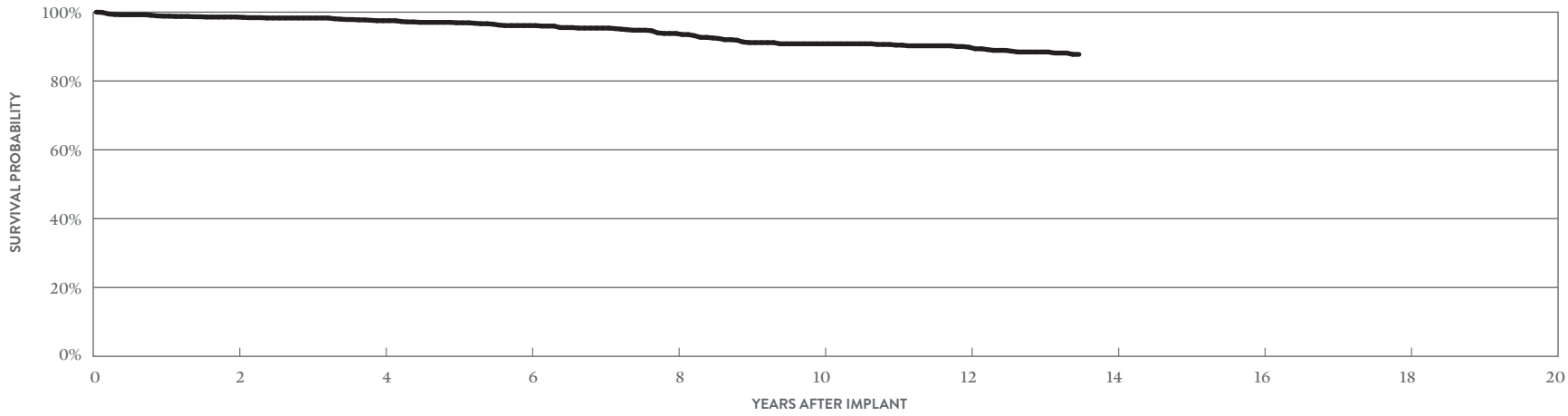
## Riata™ ST Optim™

### MODEL 7022

| | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 1,472 |
| Estimated Active US Implants | 411 |
| Insulation | Optim™* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 5 | 0.34% | 2 | 0.14% |
| Conductor Fracture | 0 | 0.00% | 12 | 0.82% |
| Lead Dislodgement | 3 | 0.20% | 11 | 0.75% |
| Failure to Capture | 1 | 0.07% | 15 | 1.02% |
| Oversensing | 0 | 0.00% | 31 | 2.11% |
| Failure to Sense | 0 | 0.00% | 1 | 0.07% |
| Insulation Breach | 0 | 0.00% | 10 | 0.68% |
| Abnormal Pacing Impedance | 1 | 0.07% | 5 | 0.34% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 5 | 0.34% |
| Extracardiac Stimulation | 0 | 0.00% | 1 | 0.07% |
| Other | 0 | 0.00% | 3 | 0.20% |
| **Total** | **10** | **0.68%** | **96** | **6.52%** |
| **Total Returned for Analysis** | **3** | | **33** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.20% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 2 | 0.14% |
| Intravascular | 1 | 0.07% |
| Insulation Breach | 12 | 0.82% |
| Lead-to-Can Contact | 7 | 0.48% |
| Lead-to-Lead Contact | 3 | 0.20% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 2 | 0.14% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 25 | 1.70% |
| **Total** | **40** | **2.72%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 162 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.58% | 97.52% | 96.10% | 93.81% | 90.80% | 89.80% | 87.73% |
| ± 1 STANDARD ERROR | 0.33% | 0.47% | 0.63% | 0.85% | 1.08% | 1.14% | 1.35% |
| SAMPLE SIZE | 1,130 | 890 | 720 | 610 | 510 | 440 | 210 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

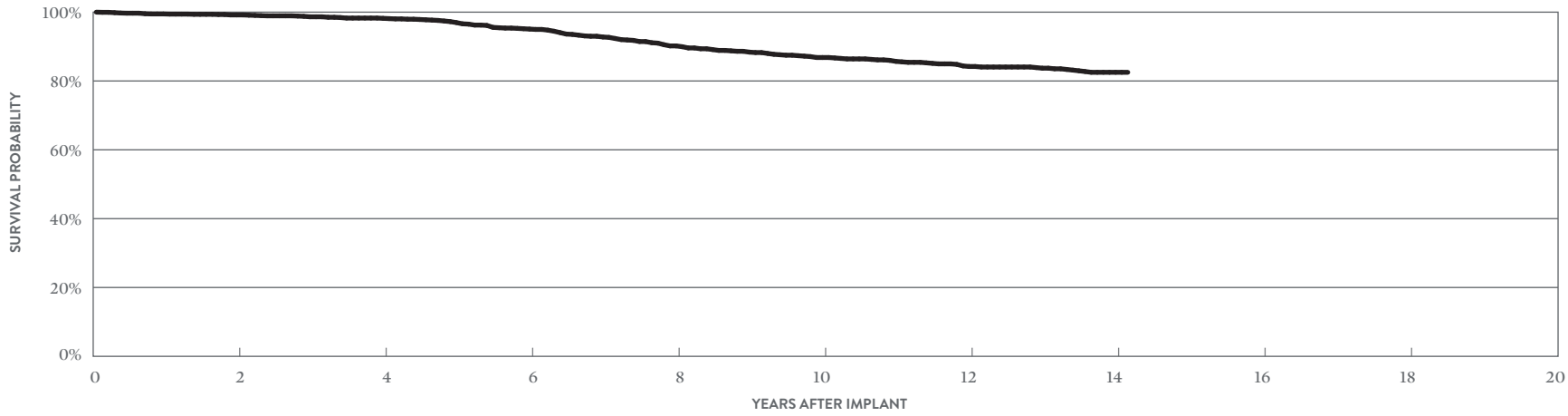
## Riata™ ST

### MODELS 7010 & 7011

| | |
|---|---|
| US Regulatory Approval | March 2006 |
| Registered US Implants | 2,200 |
| Estimated Active US Implants | 519 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Integrated Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 3 | 0.14% | 3 | 0.14% |
| Conductor Fracture | 0 | 0.00% | 8 | 0.36% |
| Lead Dislodgement | 1 | 0.05% | 8 | 0.36% |
| Failure to Capture | 2 | 0.09% | 12 | 0.55% |
| Oversensing | 2 | 0.09% | 56 | 2.55% |
| Failure to Sense | 1 | 0.05% | 3 | 0.14% |
| Insulation Breach | 0 | 0.00% | 47 | 2.14% |
| Abnormal Pacing Impedance | 1 | 0.05% | 29 | 1.32% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 21 | 0.95% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.05% | 3 | 0.14% |
| **Total** | **11** | **0.50%** | **190** | **8.64%** |
| **Total Returned for Analysis** | **4** | | **43** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.14% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 3 | 0.14% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 43 | 1.95% |
| Lead-to-Can Contact | 13 | 0.59% |
| Lead-to-Lead Contact | 19 | 0.86% |
| Clavicular Crush | 1 | 0.05% |
| Externalized Conductors | 3 | 0.14% |
| Other | 7 | 0.32% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 12 | 0.55% |
| **Total** | **58** | **2.64%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 170 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.19% | 98.20% | 95.08% | 90.19% | 86.82% | 84.21% | 82.52% | 82.52% |
| ± 1 STANDARD ERROR | 0.21% | 0.33% | 0.61% | 0.92% | 1.09% | 1.21% | 1.32% | 1.32% |
| SAMPLE SIZE | 1,700 | 1,310 | 1,010 | 810 | 680 | 580 | 360 | 230 |

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

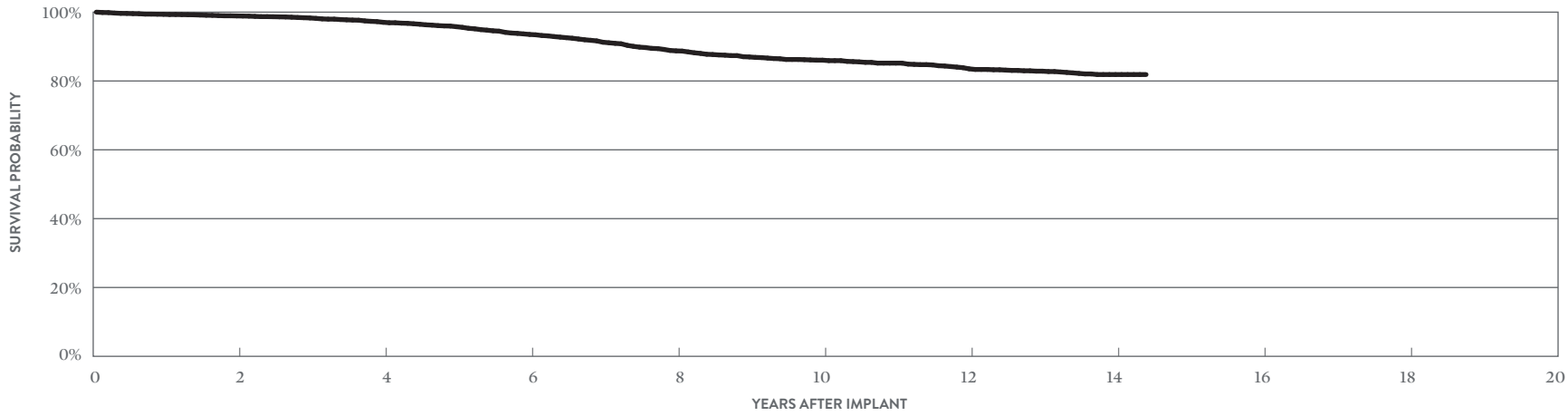
## Riata™ ST

### MODELS 7040 & 7041

| | |
|---|---|
| US Regulatory Approval | March 2006 |
| Registered US Implants | 4,057 |
| Estimated Active US Implants | 994 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 4 | 0.10% | 3 | 0.07% |
| Conductor Fracture | 0 | 0.00% | 37 | 0.91% |
| Lead Dislodgement | 5 | 0.12% | 5 | 0.12% |
| Failure to Capture | 0 | 0.00% | 53 | 1.31% |
| Oversensing | 3 | 0.07% | 112 | 2.76% |
| Failure to Sense | 0 | 0.00% | 16 | 0.39% |
| Insulation Breach | 0 | 0.00% | 64 | 1.58% |
| Abnormal Pacing Impedance | 2 | 0.05% | 22 | 0.54% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 32 | 0.79% |
| Extracardiac Stimulation | 0 | 0.00% | 1 | 0.02% |
| Other | 1 | 0.02% | 9 | 0.22% |
| **Total** | **15** | **0.37%** | **354** | **8.73%** |
| **Total Returned for Analysis** | **3** | | **80** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 4 | 0.10% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 1 | 0.02% |
| Intravascular | 3 | 0.07% |
| Insulation Breach | 69 | 1.70% |
| Lead-to-Can Contact | 34 | 0.84% |
| Lead-to-Lead Contact | 21 | 0.52% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 2 | 0.05% |
| Other | 12 | 0.30% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 30 | 0.74% |
| **Total** | **103** | **2.54%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 173 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.90% | 97.05% | 93.52% | 88.75% | 86.05% | 83.53% | 81.87% | 81.87% |
| ± 1 STANDARD ERROR | 0.17% | 0.30% | 0.50% | 0.69% | 0.79% | 0.87% | 0.97% | 0.97% |
| SAMPLE SIZE | 3,190 | 2,500 | 1,940 | 1,550 | 1,290 | 1,070 | 540 | 220 |

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

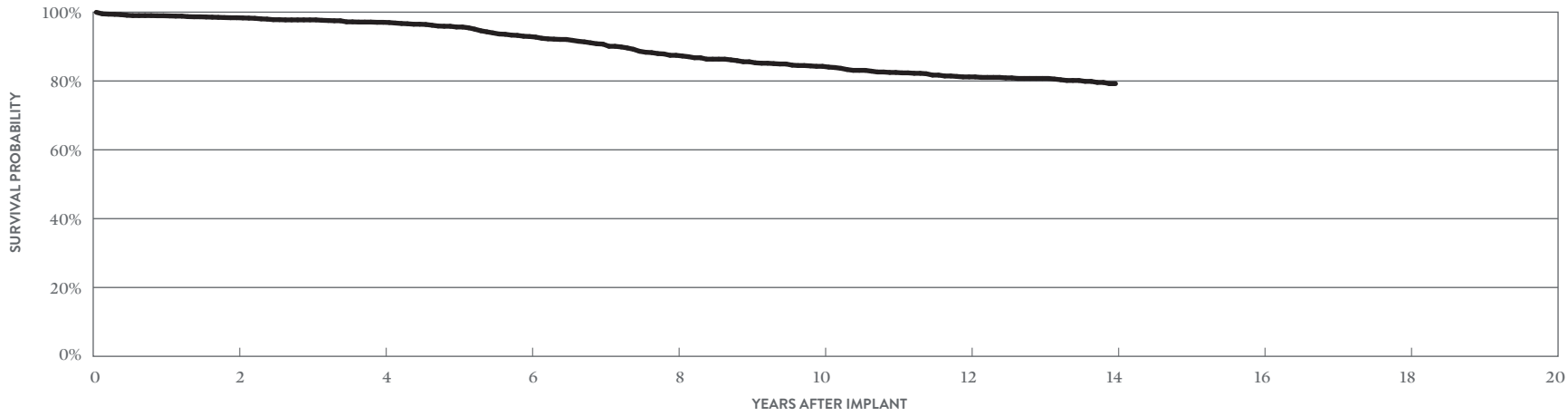
## Riata™ ST

### MODEL 7002

| | |
|---|---|
| US Regulatory Approval | June 2005 |
| Registered US Implants | 2,409 |
| Estimated Active US Implants | 558 |
| Insulation | Silicone |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 6 | 0.25% | 5 | 0.21% |
| Conductor Fracture | 0 | 0.00% | 11 | 0.46% |
| Lead Dislodgement | 2 | 0.08% | 9 | 0.37% |
| Failure to Capture | 4 | 0.17% | 27 | 1.12% |
| Oversensing | 4 | 0.17% | 73 | 3.03% |
| Failure to Sense | 0 | 0.00% | 3 | 0.12% |
| Insulation Breach | 0 | 0.00% | 73 | 3.03% |
| Abnormal Pacing Impedance | 2 | 0.08% | 5 | 0.21% |
| Abnormal Defibrillation Impedance | 1 | 0.04% | 10 | 0.42% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.04% | 8 | 0.33% |
| **Total** | **20** | **0.83%** | **224** | **9.30%** |
| **Total Returned for Analysis** | **11** | | **75** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 6 | 0.25% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 3 | 0.12% |
| Intravascular | 3 | 0.12% |
| Insulation Breach | 81 | 3.36% |
| Lead-to-Can Contact | 36 | 1.49% |
| Lead-to-Lead Contact | 18 | 0.75% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 11 | 0.46% |
| Other | 16 | 0.66% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 24 | 1.00% |
| **Total** | **111** | **4.61%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.38% | 97.05% | 92.92% | 87.46% | 84.26% | 81.18% | 79.22% |
| ± 1 STANDARD ERROR | 0.28% | 0.39% | 0.66% | 0.93% | 1.07% | 1.19% | 1.35% |
| SAMPLE SIZE | 1,880 | 1,500 | 1,190 | 930 | 760 | 630 | 210 |

# Defibrillation Leads

## CUSTOMER REPORTED PERFORMANCE DATA

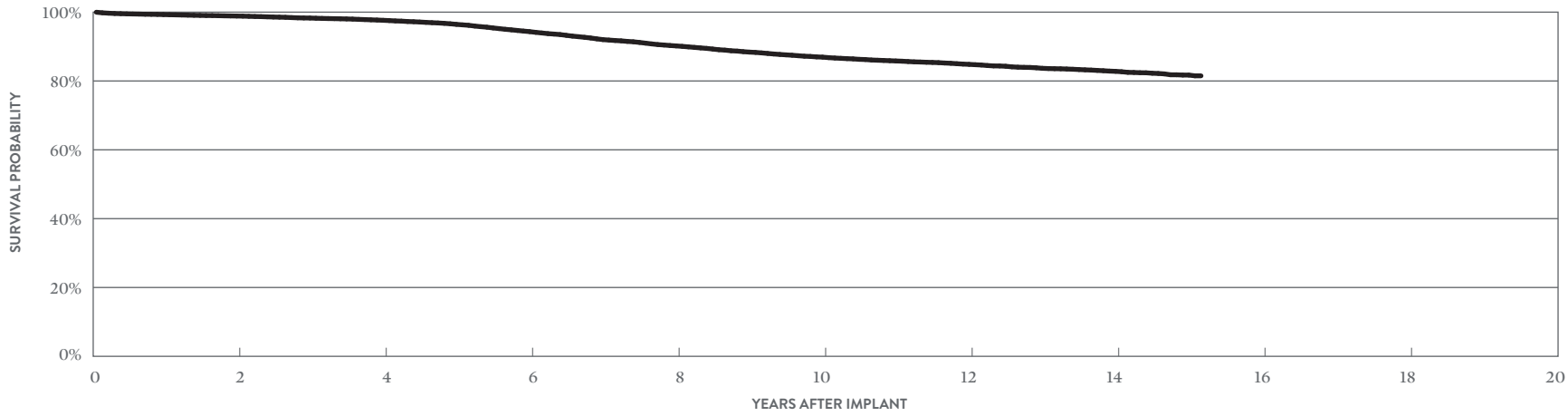
## Riata™ ST

### MODELS 7000 & 7001

| | |
|---|---|
| US Regulatory Approval | June 2005 |
| Registered US Implants | 34,882 |
| Estimated Active US Implants | 8,157 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 42 | 0.12% | 33 | 0.09% |
| Conductor Fracture | 0 | 0.00% | 181 | 0.52% |
| Lead Dislodgement | 38 | 0.11% | 60 | 0.17% |
| Failure to Capture | 43 | 0.12% | 387 | 1.11% |
| Oversensing | 40 | 0.11% | 975 | 2.80% |
| Failure to Sense | 7 | 0.02% | 66 | 0.19% |
| Insulation Breach | 2 | <0.01% | 787 | 2.26% |
| Abnormal Pacing Impedance | 8 | 0.02% | 138 | 0.40% |
| Abnormal Defibrillation Impedance | 4 | 0.01% | 258 | 0.74% |
| Extracardiac Stimulation | 3 | <0.01% | 6 | 0.02% |
| Other | 11 | 0.03% | 102 | 0.29% |
| **Total** | **198** | **0.57%** | **2993** | **8.58%** |
| **Total Returned for Analysis** | **97** | | **803** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 25 | 0.07% |
| Clavicular Crush | 4 | 0.01% |
| In the Pocket | 7 | 0.02% |
| Intravascular | 14 | 0.04% |
| Insulation Breach | 661 | 1.89% |
| Lead-to-Can Contact | 345 | 0.99% |
| Lead-to-Lead Contact | 177 | 0.51% |
| Clavicular Crush | 12 | 0.03% |
| Externalized Conductors | 42 | 0.12% |
| Other | 85 | 0.24% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 330 | 0.95% |
| **Total** | **1018** | **2.92%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 182 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.87% | 97.63% | 94.34% | 90.19% | 86.93% | 84.83% | 82.80% | 81.50% |
| ± 1 STANDARD ERROR | 0.06% | 0.09% | 0.16% | 0.22% | 0.26% | 0.29% | 0.32% | 0.43% |
| SAMPLE SIZE | 28,090 | 21,920 | 17,080 | 13,370 | 10,960 | 9,400 | 6,220 | 260 |

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

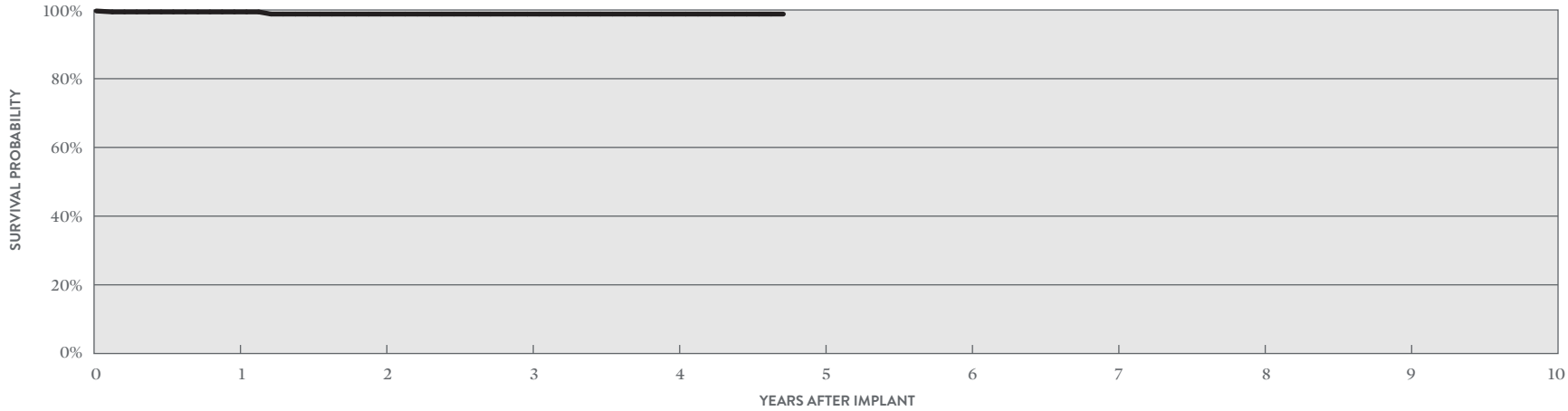
## Riata™ ST

### MODELS 7000 & 7001

| | |
|---|---|
| US Regulatory Approval | June 2005 |
| Number of Devices Enrolled in Study | 180 |
| Active Devices Enrolled in Study | 9 |
| Cumulative Months of Follow-up | 8,439 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.56% |
| Insulation Breach | 1 | 0.56% |
| Lead Dislodgement | 1 | 0.56% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 0 | 0.00% |
| Insulation Breach | 5 | 2.78% |
| Lead-to-Can Contact | 3 | 1.67% |
| Lead-to-Lead Contact | 1 | 0.56% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 0 | 0.00% |
| Other | 1 | 0.56% |
| Crimps, Welds & Bonds | 1 | 0.56% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **6** | **3.33%** |




| YEAR | 1 | 2 | 3 | 4 | AT 57 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.43% | 98.81% | 98.81% | 98.81% | 98.81% |
| ± 1 STANDARD ERROR | 0.56% | 0.84% | 0.84% | 0.84% | 0.84% |
| SAMPLE SIZE | 170 | 150 | 120 | 90 | 50 |

# Defibrillation Leads

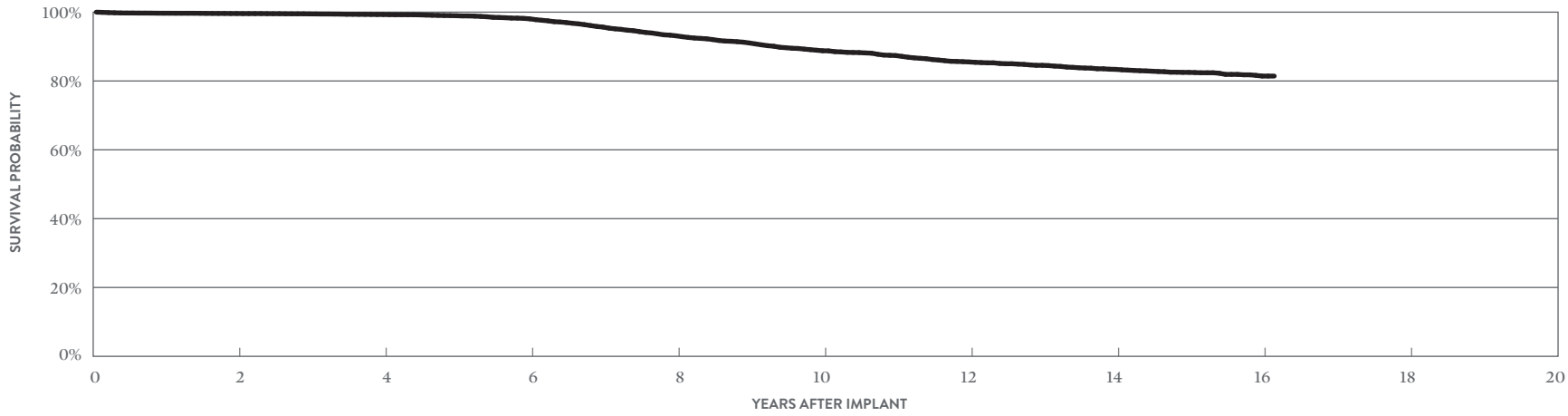
## CUSTOMER REPORTED PERFORMANCE DATA

## Riata™ i

### MODELS 1590 & 1591

| | |
|---|---|
| US Regulatory Approval | April 2004 |
| Registered US Implants | 9,700 |
| Estimated Active US Implants | 1,938 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Integrated Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 7 | 0.07% |
| Clavicular Crush | 1 | 0.01% |
| In the Pocket | 1 | 0.01% |
| Intravascular | 5 | 0.05% |
| Insulation Breach | 211 | 2.18% |
| Lead-to-Can Contact | 88 | 0.91% |
| Lead-to-Lead Contact | 58 | 0.60% |
| Clavicular Crush | 2 | 0.02% |
| Externalized Conductors | 21 | 0.22% |
| Other | 42 | 0.43% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | 0.01% |
| Extrinsic Factors | 56 | 0.58% |
| **Total** | **275** | **2.84%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 194 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.60% | 99.31% | 98.06% | 93.12% | 88.78% | 85.53% | 83.38% | 81.43% | 81.43% |
| ± 1 STANDARD ERROR | 0.07% | 0.09% | 0.18% | 0.38% | 0.50% | 0.59% | 0.64% | 0.72% | 0.74% |
| SAMPLE SIZE | 7,910 | 6,210 | 4,750 | 3,660 | 2,890 | 2,420 | 2,050 | 940 | 260 |

# Defibrillation Leads

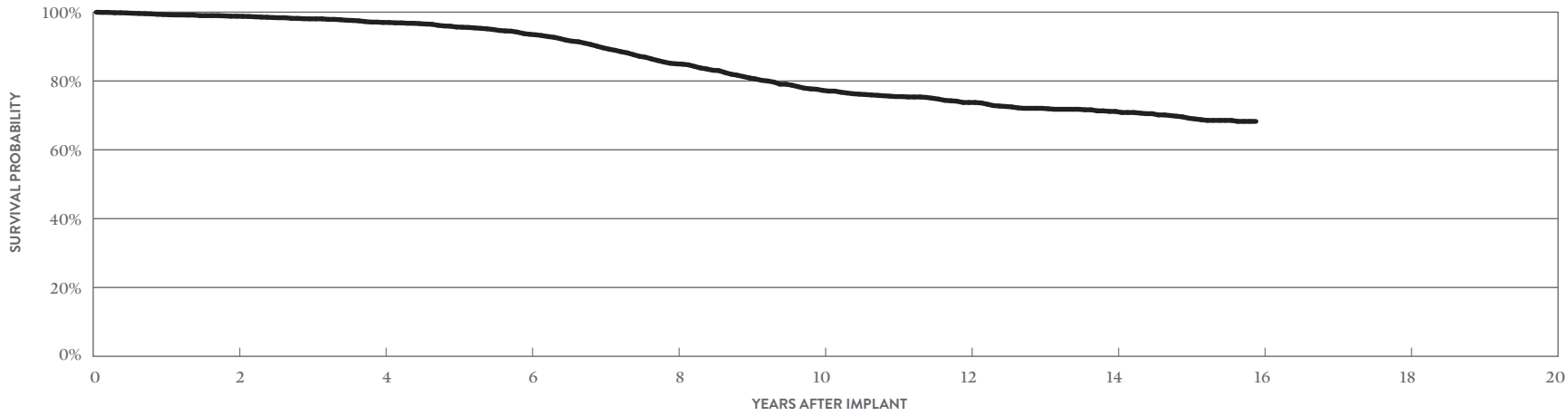
## CUSTOMER REPORTED PERFORMANCE DATA

## Riata™

### MODEL 1582

| | |
|---|---|
| US Regulatory Approval | March 2003 |
| Registered US Implants | 3,132 |
| Estimated Active US Implants | 494 |
| Insulation | Silicone |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.10% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 3 | 0.10% |
| Insulation Breach | 182 | 5.81% |
| Lead-to-Can Contact | 57 | 1.82% |
| Lead-to-Lead Contact | 32 | 1.02% |
| Clavicular Crush | 2 | 0.06% |
| Externalized Conductors | 51 | 1.63% |
| Other | 40 | 1.28% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 35 | 1.12% |
| **Total** | **220** | **7.02%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 191 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.82% | 97.00% | 93.57% | 84.98% | 77.28% | 73.75% | 71.16% | 68.26% |
| ± 1 STANDARD ERROR | 0.21% | 0.35% | 0.57% | 0.95% | 1.20% | 1.31% | 1.39% | 1.53% |
| SAMPLE SIZE | 2,450 | 1,900 | 1,410 | 1,020 | 760 | 610 | 480 | 200 |

# Defibrillation Leads

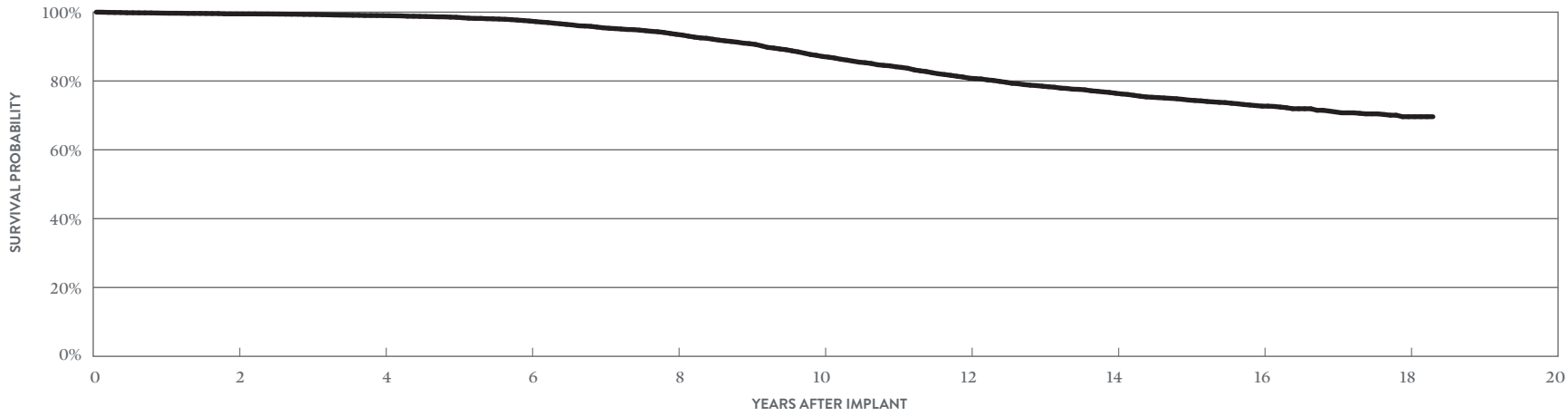
## CUSTOMER REPORTED PERFORMANCE DATA

## Riata™

### MODELS 1570 & 1571

| | |
|---|---|
| US Regulatory Approval | March 2002 |
| Registered US Implants | 10,279 |
| Estimated Active US Implants | 1,622 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 6 | 0.06% |
| Clavicular Crush | 2 | 0.02% |
| In the Pocket | 3 | 0.03% |
| Intravascular | 1 | <0.01% |
| Insulation Breach | 274 | 2.67% |
| Lead-to-Can Contact | 128 | 1.25% |
| Lead-to-Lead Contact | 47 | 0.46% |
| Clavicular Crush | 2 | 0.02% |
| Externalized Conductors | 53 | 0.52% |
| Other | 44 | 0.43% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 69 | 0.67% |
| **Total** | **349** | **3.40%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 220 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.50% | 99.00% | 97.42% | 93.56% | 87.11% | 80.82% | 76.43% | 72.69% | 69.62% | 69.62% |
| ± 1 STANDARD ERROR | 0.07% | 0.11% | 0.20% | 0.35% | 0.52% | 0.66% | 0.75% | 0.85% | 1.04% | 1.04% |
| SAMPLE SIZE | 8,460 | 6,700 | 5,080 | 3,820 | 2,970 | 2,290 | 1,710 | 1,100 | 420 | 210 |

# Defibrillation Leads

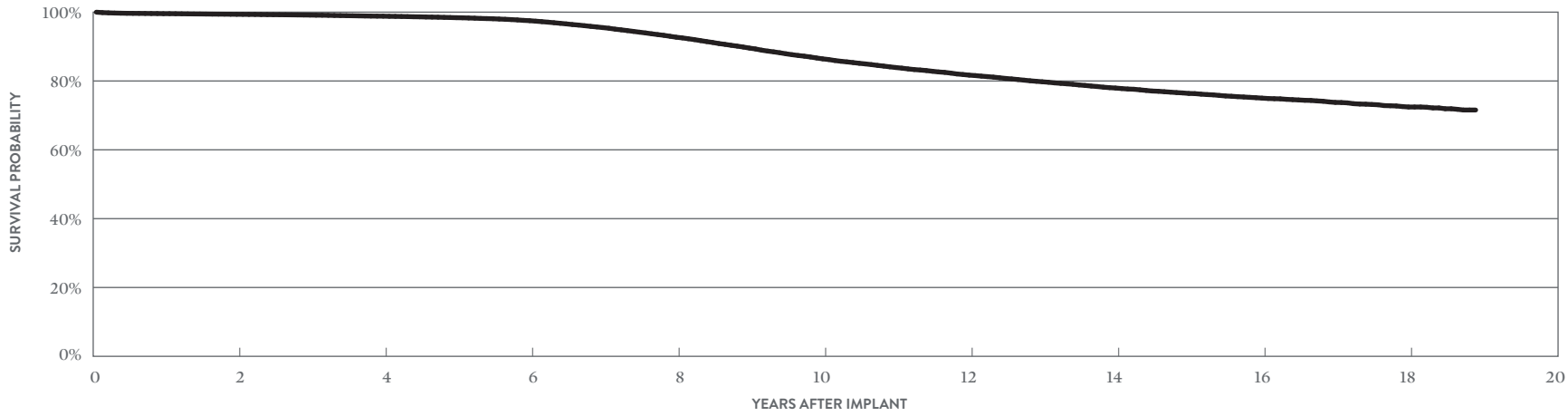
## CUSTOMER REPORTED PERFORMANCE DATA

## Riata™

### MODELS 1580 & 1581

| | |
|---|---|
| US Regulatory Approval | March 2002 |
| Registered US Implants | 68,403 |
| Estimated Active US Implants | 11,108 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories (see pg. 327) | One |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 34 | 0.05% |
| Clavicular Crush | 4 | <0.01% |
| In the Pocket | 11 | 0.02% |
| Intravascular | 19 | 0.03% |
| Insulation Breach | 1942 | 2.84% |
| Lead-to-Can Contact | 808 | 1.18% |
| Lead-to-Lead Contact | 384 | 0.56% |
| Clavicular Crush | 20 | 0.03% |
| Externalized Conductors | 375 | 0.55% |
| Other | 355 | 0.52% |
| Crimps, Welds & Bonds | 3 | <0.01% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 574 | 0.84% |
| **Total** | **2553** | **3.73%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 227 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.37% | 98.83% | 97.52% | 92.72% | 86.43% | 81.70% | 77.95% | 75.02% | 72.44% | 71.57% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.07% | 0.14% | 0.21% | 0.25% | 0.28% | 0.31% | 0.41% | 0.54% |
| SAMPLE SIZE | 55,850 | 43,940 | 33,540 | 25,260 | 19,220 | 15,290 | 12,010 | 7,500 | 1,820 | 260 |

# Defibrillation Leads

## ACTIVELY MONITORED STUDY DATA

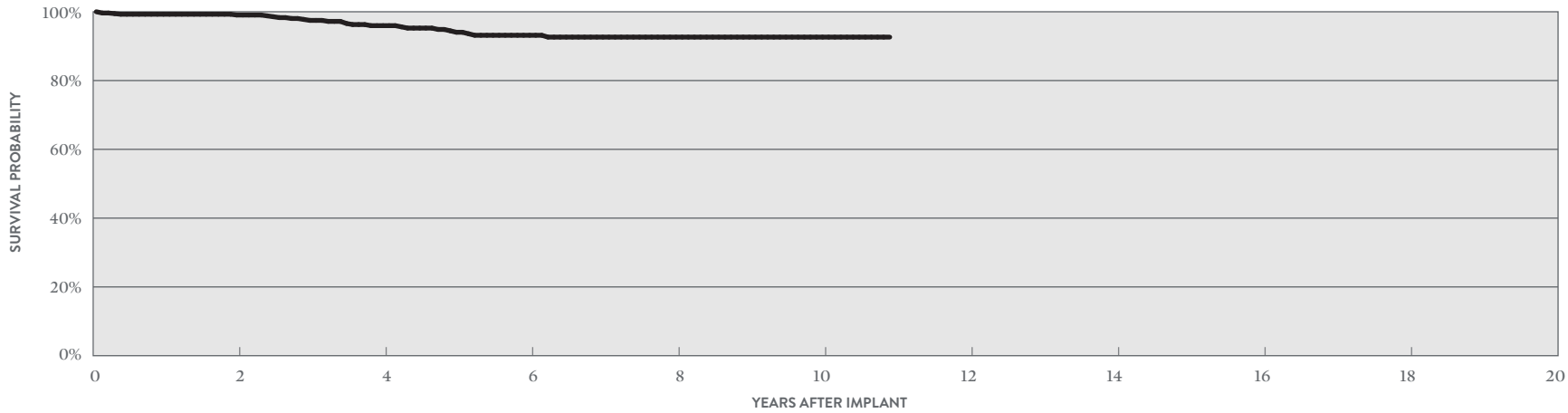
## Riata™

### MODELS 1580 & 1581

| | |
|---|---|
| US Regulatory Approval | March 2002 |
| Number of Devices Enrolled in Study | 566 |
| Active Devices Enrolled in Study | 69 |
| Cumulative Months of Follow-up | 32,490 |
| Insulation | Silicone |
| Type and/or Fixation | Dual Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Defibrillation Impedance | 1 | 0.18% |
| Conductor Fracture | 3 | 0.53% |
| Failure to Capture | 1 | 0.18% |
| Insulation Breach | 10 | 1.77% |
| Lead Dislodgement | 2 | 0.35% |
| Oversensing | 6 | 1.06% |
| Skin Erosion | 1 | 0.18% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.18% |
| Clavicular Crush | 0 | 0.00% |
| In the Pocket | 0 | 0.00% |
| Intravascular | 1 | 0.18% |
| Insulation Breach | 24 | 4.24% |
| Lead-to-Can Contact | 7 | 1.24% |
| Lead-to-Lead Contact | 7 | 1.24% |
| Clavicular Crush | 0 | 0.00% |
| Externalized Conductors | 6 | 1.06% |
| Other | 4 | 0.71% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 7 | 1.24% |
| **Total** | **32** | **5.65%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 131 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.05% | 95.96% | 93.16% | 92.63% | 92.63% | 92.63% |
| ± 1 STANDARD ERROR | 0.36% | 1.01% | 1.43% | 1.52% | 1.52% | 1.52% |
| SAMPLE SIZE | 470 | 320 | 200 | 130 | 80 | 50 |

## SUMMARY INFORMATION

# Defibrillation Leads

## Defibrillation Leads

# Survival Probability Summary

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| LDA230Q | Optisure™ DF4 | 99.12% | 98.87% | 98.59% | 98.27% | 98.00% | | | | | |
| LDA220Q | Optisure™ DF4 | 99.11% | 98.76% | 98.50% | 98.09% | 97.82% | 97.13% | | | | |
| LDA220 | Optisure™ | 98.51% | 98.51% | 98.26% | 97.08% | 96.73% | | | | | |
| LDA210Q | Optisure™ DF4 | 98.97% | 98.70% | 98.47% | 98.16% | 97.90% | 97.57% | 97.14% | | | |
| LDA210 | Optisure™ | 98.78% | 98.12% | 97.52% | 97.20% | 96.88% | | | | | |
| 7170Q/7171Q | Durata™ DF4 | 99.13% | 98.64% | 98.20% | 97.42% | 97.01% | 96.48% | 95.70% | 94.86% | 94.13% | 93.53% |
| 7120Q/7121Q | Durata™ DF4 | 99.17% | 98.91% | 98.65% | 98.33% | 97.91% | 97.42% | 96.86% | 96.42% | 95.86% | 95.31% |
| 7122Q | Durata™ DF4 | 99.12% | 98.86% | 98.58% | 98.26% | 97.85% | 97.42% | 96.99% | 96.52% | 95.96% | 95.52% |
| 7120/7121 | Durata™ | 99.38% | 99.06% | 98.72% | 98.32% | 97.81% | 97.27% | 96.58% | 95.97% | 95.39% | 94.81% |
| 7122 | Durata™ | 99.19% | 98.67% | 98.28% | 97.79% | 97.11% | 96.47% | 95.92% | 95.41% | 95.04% | 94.68% |
| 7070/7071 | Riata™ ST Optim™ | 99.32% | 99.00% | 98.55% | 97.77% | 96.83% | 95.99% | 95.08% | 94.18% | 93.30% | 91.96% |
| 7020/7021 | Riata™ ST Optim™ | 98.95% | 98.51% | 98.18% | 97.68% | 96.90% | 96.10% | 95.06% | 94.24% | 93.14% | 92.55% |
| 7022 | Riata™ ST Optim™ | 98.84% | 98.58% | 98.30% | 97.52% | 96.91% | 96.10% | 95.37% | 93.81% | 91.15% | 90.80% |
| 7010/7011 | Riata™ ST | 99.48% | 99.19% | 98.65% | 98.20% | 96.97% | 95.08% | 92.78% | 90.19% | 88.38% | 86.82% |
| 7040/7041 | Riata™ ST | 99.37% | 98.90% | 98.31% | 97.05% | 95.77% | 93.52% | 91.26% | 88.75% | 86.98% | 86.05% |
| 7002 | Riata™ ST | 98.95% | 98.38% | 97.75% | 97.05% | 95.68% | 92.92% | 90.72% | 87.46% | 85.59% | 84.26% |
| 7000/7001 | Riata™ ST | 99.29% | 98.87% | 98.29% | 97.63% | 96.45% | 94.34% | 92.02% | 90.19% | 88.39% | 86.93% |
| 1590/1591 | Riata™ i | 99.69% | 99.60% | 99.49% | 99.31% | 98.96% | 98.06% | 95.67% | 93.12% | 91.04% | 88.78% |
| 1582 | Riata™ | 99.31% | 98.82% | 98.05% | 97.00% | 95.68% | 93.57% | 89.65% | 84.98% | 80.89% | 77.28% |
| 1570/1571 | Riata™ | 99.71% | 99.50% | 99.34% | 99.00% | 98.51% | 97.42% | 95.46% | 93.56% | 90.85% | 87.11% |
| 1580/1581 | Riata™ | 99.56% | 99.37% | 99.15% | 98.83% | 98.39% | 97.52% | 95.51% | 92.72% | 89.56% | 86.43% |

## Defibrillation Leads
# Acute Observation Summary

### POST IMPLANT ≤30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | ABNORMAL DEFIBRILLATION IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| LDA230Q | Feb-14 | 1,039 | 630 | 1 | 0.10% | 0 | 0.00% | 1 | 0.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.10% | 0 | 0.00% | 1 | 0.10% | 0 | 0.00% | **4** | **0.38%** | **1** |
| LDA220Q | Feb-14 | 11,715 | 7,763 | 10 | 0.09% | 0 | 0.00% | 50 | 0.43% | 22 | 0.19% | 5 | 0.04% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 5 | 0.04% | 1 | <0.01% | 6 | 0.05% | **101** | **0.86%** | **36** |
| LDA220 | Feb-14 | 588 | 351 | 1 | 0.17% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.17%** | **0** |
| LDA210Q | Feb-14 | 50,410 | 34,888 | 88 | 0.17% | 2 | <0.01% | 179 | 0.36% | 90 | 0.18% | 38 | 0.08% | 12 | 0.02% | 2 | <0.01% | 9 | 0.02% | 10 | 0.02% | 3 | <0.01% | 17 | 0.03% | **450** | **0.89%** | **152** |
| LDA210 | Feb-14 | 1,525 | 1,035 | 3 | 0.20% | 0 | 0.00% | 7 | 0.46% | 2 | 0.13% | 2 | 0.13% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.07% | **15** | **0.98%** | **5** |
| 7170Q/7171Q | Jul-09 | 6,971 | 3,266 | 6 | 0.09% | 1 | 0.01% | 21 | 0.30% | 14 | 0.20% | 3 | 0.04% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | **48** | **0.69%** | **22** |
| 7120Q/7121Q | Jan-09 | 138,345 | 63,636 | 105 | 0.08% | 2 | <0.01% | 289 | 0.21% | 138 | 0.10% | 54 | 0.04% | 16 | 0.01% | 0 | 0.00% | 7 | <0.01% | 11 | <0.01% | 6 | <0.01% | 44 | 0.03% | **672** | **0.49%** | **326** |
| 7122Q | Jan-09 | 136,401 | 77,444 | 178 | 0.13% | 3 | <0.01% | 344 | 0.25% | 177 | 0.13% | 61 | 0.04% | 14 | 0.01% | 1 | <0.01% | 14 | 0.01% | 12 | <0.01% | 3 | <0.01% | 51 | 0.04% | **858** | **0.63%** | **349** |
| 7120/7121 | Sep-07 | 60,128 | 20,706 | 40 | 0.07% | 2 | <0.01% | 70 | 0.12% | 25 | 0.04% | 51 | 0.08% | 5 | <0.01% | 0 | 0.00% | 2 | <0.01% | 21 | 0.03% | 0 | 0.00% | 21 | 0.03% | **237** | **0.39%** | **93** |
| 7122 | Sep-07 | 16,001 | 6,382 | 12 | 0.07% | 1 | <0.01% | 24 | 0.15% | 19 | 0.12% | 12 | 0.07% | 0 | 0.00% | 1 | <0.01% | 3 | 0.02% | 2 | 0.01% | 2 | 0.01% | 4 | 0.02% | **80** | **0.50%** | **37** |
| 7070/7071 | Jul-06 | 3,311 | 1,003 | 3 | 0.09% | 1 | 0.03% | 3 | 0.09% | 6 | 0.18% | 4 | 0.12% | 3 | 0.09% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **20** | **0.60%** | **6** |
| 7020/7021 | Jul-06 | 14,252 | 3,917 | 33 | 0.23% | 0 | 0.00% | 27 | 0.19% | 17 | 0.12% | 19 | 0.13% | 8 | 0.06% | 0 | 0.00% | 2 | 0.01% | 4 | 0.03% | 3 | 0.02% | 0 | 0.00% | **113** | **0.79%** | **53** |
| 7022 | Jul-06 | 1,472 | 411 | 5 | 0.34% | 0 | 0.00% | 3 | 0.20% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **10** | **0.68%** | **3** |
| 7010/7011 | Mar-06 | 2,200 | 519 | 3 | 0.14% | 0 | 0.00% | 1 | 0.05% | 2 | 0.09% | 2 | 0.09% | 1 | 0.05% | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 1 | 0.05% | **11** | **0.50%** | **4** |
| 7040/7041 | Mar-06 | 4,057 | 994 | 4 | 0.10% | 0 | 0.00% | 5 | 0.12% | 0 | 0.00% | 3 | 0.07% | 0 | 0.00% | 0 | 0.00% | 2 | 0.05% | 0 | 0.00% | 0 | 0.00% | 1 | 0.02% | **15** | **0.37%** | **3** |
| 7002 | Jun-05 | 2,409 | 558 | 6 | 0.25% | 0 | 0.00% | 2 | 0.08% | 4 | 0.17% | 4 | 0.17% | 0 | 0.00% | 0 | 0.00% | 2 | 0.08% | 1 | 0.04% | 0 | 0.00% | 1 | 0.04% | **20** | **0.83%** | **11** |
| 7000/7001 | Jun-05 | 34,882 | 8,157 | 42 | 0.12% | 0 | 0.00% | 38 | 0.11% | 43 | 0.12% | 40 | 0.11% | 7 | 0.02% | 2 | <0.01% | 8 | 0.02% | 4 | 0.01% | 3 | <0.01% | 11 | 0.03% | **198** | **0.57%** | **97** |

*Definitions of observations and complications can be found on page 7.*

## Defibrillation Leads
# Chronic Complication Summary

### >30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | ABNORMAL DEFIBRILLATION IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| LDA230Q | Feb-14 | 1,039 | 630 | 0 | 0.00% | 0 | 0.00% | 3 | 0.29% | 4 | 0.38% | 4 | 0.38% | 1 | 0.10% | 0 | 0.00% | 1 | 0.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **13** | **1.25%** | **7** |
| LDA220Q | Feb-14 | 11,715 | 7,763 | 4 | 0.03% | 5 | 0.04% | 72 | 0.61% | 68 | 0.58% | 55 | 0.47% | 8 | 0.07% | 2 | 0.02% | 11 | 0.09% | 17 | 0.15% | 0 | 0.00% | 3 | 0.03% | **245** | **2.09%** | **74** |
| LDA220 | Feb-14 | 588 | 351 | 0 | 0.00% | 0 | 0.00% | 5 | 0.85% | 3 | 0.51% | 5 | 0.85% | 0 | 0.00% | 0 | 0.00% | 3 | 0.51% | 1 | 0.17% | 0 | 0.00% | 0 | 0.00% | **17** | **2.89%** | **4** |
| LDA210Q | Feb-14 | 50,410 | 34,888 | 21 | 0.04% | 17 | 0.03% | 280 | 0.56% | 186 | 0.37% | 148 | 0.29% | 19 | 0.04% | 2 | <0.01% | 37 | 0.07% | 33 | 0.07% | 5 | <0.01% | 27 | 0.05% | **775** | **1.54%** | **285** |
| LDA210 | Feb-14 | 1,525 | 1,035 | 0 | 0.00% | 2 | 0.13% | 7 | 0.46% | 10 | 0.66% | 10 | 0.66% | 0 | 0.00% | 0 | 0.00% | 2 | 0.13% | 1 | 0.07% | 1 | 0.07% | 2 | 0.13% | **35** | **2.30%** | **12** |
| 7170Q/7171Q | Jul-09 | 6,971 | 3,266 | 7 | 0.10% | 28 | 0.40% | 32 | 0.46% | 78 | 1.12% | 67 | 0.96% | 1 | 0.01% | 4 | 0.06% | 22 | 0.32% | 20 | 0.29% | 0 | 0.00% | 3 | 0.04% | **262** | **3.76%** | **68** |
| 7120Q/7121Q | Jan-09 | 138,345 | 63,636 | 46 | 0.03% | 248 | 0.18% | 700 | 0.51% | 1005 | 0.73% | 1008 | 0.73% | 99 | 0.07% | 65 | 0.05% | 215 | 0.16% | 451 | 0.33% | 10 | <0.01% | 95 | 0.07% | **3942** | **2.85%** | **1182** |
| 7122Q | Jan-09 | 136,401 | 77,444 | 57 | 0.04% | 101 | 0.07% | 686 | 0.50% | 697 | 0.51% | 616 | 0.45% | 66 | 0.05% | 38 | 0.03% | 134 | 0.10% | 140 | 0.10% | 10 | <0.01% | 91 | 0.07% | **2636** | **1.93%** | **959** |
| 7120/7121 | Sep-07 | 60,128 | 20,706 | 18 | 0.03% | 172 | 0.29% | 190 | 0.32% | 421 | 0.70% | 847 | 1.41% | 71 | 0.12% | 75 | 0.12% | 222 | 0.37% | 336 | 0.56% | 3 | <0.01% | 58 | 0.10% | **2413** | **4.01%** | **618** |
| 7122 | Sep-07 | 16,001 | 6,382 | 4 | 0.02% | 45 | 0.28% | 76 | 0.47% | 113 | 0.71% | 177 | 1.11% | 13 | 0.08% | 24 | 0.15% | 50 | 0.31% | 46 | 0.29% | 2 | 0.01% | 11 | 0.07% | **561** | **3.51%** | **194** |
| 7070/7071 | Jul-06 | 3,311 | 1,003 | 2 | 0.06% | 28 | 0.85% | 13 | 0.39% | 40 | 1.21% | 64 | 1.93% | 3 | 0.09% | 9 | 0.27% | 15 | 0.45% | 22 | 0.66% | 1 | 0.03% | 3 | 0.09% | **200** | **6.04%** | **44** |
| 7020/7021 | Jul-06 | 14,252 | 3,917 | 17 | 0.12% | 67 | 0.47% | 66 | 0.46% | 176 | 1.23% | 290 | 2.03% | 21 | 0.15% | 29 | 0.20% | 59 | 0.41% | 113 | 0.79% | 2 | 0.01% | 29 | 0.20% | **869** | **6.10%** | **230** |
| 7022 | Jul-06 | 1,472 | 411 | 2 | 0.14% | 12 | 0.82% | 11 | 0.75% | 15 | 1.02% | 31 | 2.11% | 1 | 0.07% | 10 | 0.68% | 5 | 0.34% | 5 | 0.34% | 1 | 0.07% | 3 | 0.20% | **96** | **6.52%** | **33** |
| 7010/7011 | Mar-06 | 2,200 | 519 | 3 | 0.14% | 8 | 0.36% | 8 | 0.36% | 12 | 0.55% | 56 | 2.55% | 3 | 0.14% | 47 | 2.14% | 29 | 1.32% | 21 | 0.95% | 0 | 0.00% | 3 | 0.14% | **190** | **8.64%** | **43** |
| 7040/7041 | Mar-06 | 4,057 | 994 | 3 | 0.07% | 37 | 0.91% | 5 | 0.12% | 53 | 1.31% | 112 | 2.76% | 16 | 0.39% | 64 | 1.58% | 22 | 0.54% | 32 | 0.79% | 1 | 0.02% | 9 | 0.22% | **354** | **8.73%** | **80** |
| 7002 | Jun-05 | 2,409 | 558 | 5 | 0.21% | 11 | 0.46% | 9 | 0.37% | 27 | 1.12% | 73 | 3.03% | 3 | 0.12% | 73 | 3.03% | 5 | 0.21% | 10 | 0.42% | 0 | 0.00% | 8 | 0.33% | **224** | **9.30%** | **75** |
| 7000/7001 | Jun-05 | 34,882 | 8,157 | 33 | 0.09% | 181 | 0.52% | 60 | 0.17% | 387 | 1.11% | 975 | 2.80% | 66 | 0.19% | 787 | 2.26% | 138 | 0.40% | 258 | 0.74% | 6 | 0.02% | 102 | 0.29% | **2993** | **8.58%** | **803** |

*Definitions of observations and complications can be found on page 7.*

## Defibrillation Leads

U.S. Malfunction Summary

| MODELS | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| LDA230Q | 1,039 | 4.10% | 1 | 0.10% | 2 | 0.19% | 0 | 0.00% | 0 | 0.00% | 8 | 0.77% | **11** | **1.06%** |
| LDA220Q | 11,715 | 4.10% | 1 | <0.01% | 6 | 0.05% | 0 | 0.00% | 0 | 0.00% | 70 | 0.60% | **77** | **0.66%** |
| LDA220 | 588 | 4.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 6 | 1.02% | **6** | **1.02%** |
| LDA210Q | 50,410 | 3.80% | 7 | 0.01% | 14 | 0.03% | 0 | 0.00% | 5 | <0.01% | 273 | 0.54% | **299** | **0.59%** |
| LDA210 | 1,525 | 5.10% | 0 | 0.00% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 14 | 0.92% | **15** | **0.98%** |
| 7170Q/7171Q | 6,971 | 5.60% | 5 | 0.07% | 14 | 0.20% | 0 | 0.00% | 0 | 0.00% | 52 | 0.75% | **71** | **1.02%** |
| 7120Q/7121Q | 138,345 | 5.40% | 34 | 0.02% | 320 | 0.23% | 2 | <0.01% | 38 | 0.03% | 927 | 0.67% | **1321** | **0.95%** |
| 7122Q | 136,401 | 5.30% | 17 | 0.01% | 206 | 0.15% | 0 | 0.00% | 20 | 0.01% | 821 | 0.60% | **1064** | **0.78%** |
| 7120/7121 | 60,128 | 6.70% | 34 | 0.06% | 204 | 0.34% | 1 | <0.01% | 9 | 0.01% | 450 | 0.75% | **698** | **1.16%** |
| 7122 | 16,001 | 9.60% | 16 | 0.10% | 70 | 0.44% | 0 | 0.00% | 4 | 0.02% | 147 | 0.92% | **237** | **1.48%** |
| 7070/7071 | 3,311 | 9.10% | 2 | 0.06% | 23 | 0.69% | 0 | 0.00% | 0 | 0.00% | 23 | 0.69% | **48** | **1.45%** |
| 7020/7021 | 14,252 | 8.10% | 11 | 0.08% | 65 | 0.46% | 0 | 0.00% | 0 | 0.00% | 181 | 1.27% | **257** | **1.80%** |
| 7022 | 1,472 | 11.50% | 3 | 0.20% | 12 | 0.82% | 0 | 0.00% | 0 | 0.00% | 25 | 1.70% | **40** | **2.72%** |
| 7010/7011 | 2,200 | 10.00% | 3 | 0.14% | 43 | 1.95% | 0 | 0.00% | 0 | 0.00% | 12 | 0.55% | **58** | **2.64%** |
| 7040/7041 | 4,057 | 9.30% | 4 | 0.10% | 69 | 1.70% | 0 | 0.00% | 0 | 0.00% | 30 | 0.74% | **103** | **2.54%** |
| 7002 | 2,409 | 11.30% | 6 | 0.25% | 81 | 3.36% | 0 | 0.00% | 0 | 0.00% | 24 | 1.00% | **111** | **4.61%** |
| 7000/7001 | 34,882 | 8.40% | 25 | 0.07% | 661 | 1.89% | 1 | <0.01% | 1 | <0.01% | 330 | 0.95% | **1018** | **2.92%** |
| 1590/1591 | 9,700 | 8.40% | 7 | 0.07% | 211 | 2.18% | 0 | 0.00% | 1 | 0.01% | 56 | 0.58% | **275** | **2.84%** |
| 1582 | 3,132 | 12.90% | 3 | 0.10% | 182 | 5.81% | 0 | 0.00% | 0 | 0.00% | 35 | 1.12% | **220** | **7.02%** |
| 1570/1571 | 10,279 | 9.70% | 6 | 0.06% | 274 | 2.67% | 0 | 0.00% | 0 | 0.00% | 69 | 0.67% | **349** | **3.40%** |
| 1580/1581 | 68,403 | 8.90% | 34 | 0.05% | 1942 | 2.84% | 3 | <0.01% | 0 | 0.00% | 574 | 0.84% | **2553** | **3.73%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Defibrillation Leads

Worldwide Malfunction Summary

| MODELS | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| LDA230Q | 1,075 | 4.00% | 1 | 0.09% | 2 | 0.19% | 0 | 0.00% | 0 | 0.00% | 8 | 0.74% | **11** | **1.02%** |
| LDA220Q | 16,407 | 3.07% | 1 | 0.01% | 6 | 0.04% | 0 | 0.00% | 1 | 0.01% | 91 | 0.55% | **99** | **0.60%** |
| LDA210Q | 89,933 | 2.22% | 13 | 0.01% | 33 | 0.04% | 0 | 0.00% | 11 | 0.01% | 432 | 0.48% | **489** | **0.54%** |
| LDA210 | 1,668 | 4.68% | 0 | 0.00% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 14 | 0.84% | **15** | **0.90%** |
| 7170Q/7171Q | 19,313 | 2.82% | 11 | 0.06% | 24 | 0.12% | 2 | 0.01% | 0 | 0.00% | 84 | 0.43% | **121** | **0.63%** |
| 7120Q/7121Q | 239,602 | 3.74% | 68 | 0.03% | 435 | 0.18% | 3 | <0.01% | 96 | 0.04% | 1431 | 0.60% | **2033** | **0.85%** |
| 7122Q | 389,316 | 2.26% | 59 | 0.02% | 396 | 0.10% | 2 | <0.01% | 146 | 0.04% | 1908 | 0.49% | **2511** | **0.64%** |
| 7120/7121 | 147,850 | 3.49% | 119 | 0.08% | 308 | 0.21% | 1 | <0.01% | 25 | 0.02% | 860 | 0.58% | **1313** | **0.89%** |
| 7122 | 79,216 | 2.97% | 120 | 0.15% | 185 | 0.23% | 1 | <0.01% | 24 | 0.03% | 563 | 0.71% | **893** | **1.13%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Defibrillation Leads

# Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | ABNORMAL DEFIBRILLATION IMPEDANCE | | ABNORMAL PACING IMPEDANCE | | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | EXTRACARDIAC STIMULATION | | FAILURE TO CAPTURE | | FAILURE TO SENSE | | INAPPROPRIATE SHOCK | | INSULATION BREACH | | LEAD DISLODGEMENT | | OVERSENSING | | PERICARDIAL EFFUSION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 7170Q/7171Q | 115 | 39 | 8,178 | 0 | 0.00% | 1 | 0.87% | 0 | 0.00% | 1 | 0.87% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.87% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 2.61% |
| 7120Q/7121Q | 4,322 | 1,585 | 292,939 | 5 | 0.12% | 5 | 0.12% | 1 | 0.02% | 18 | 0.42% | 0 | 0.00% | 20 | 0.46% | 5 | 0.12% | 5 | 0.12% | 5 | 0.12% | 39 | 0.90% | 8 | 0.19% | 0 | 0.00% | 0 | 0.00% | 111 | 2.57% |
| 7122Q | 1,561 | 673 | 101,892 | 3 | 0.19% | 0 | 0.00% | 0 | 0.00% | 4 | 0.26% | 0 | 0.00% | 7 | 0.45% | 2 | 0.13% | 0 | 0.00% | 0 | 0.00% | 7 | 0.45% | 2 | 0.13% | 2 | 0.13% | 0 | 0.00% | 27 | 1.73% |
| 7120/7121 | 3,560 | 636 | 233,694 | 5 | 0.14% | 11 | 0.31% | 0 | 0.00% | 17 | 0.48% | 0 | 0.00% | 15 | 0.42% | 2 | 0.06% | 2 | 0.06% | 13 | 0.37% | 20 | 0.56% | 15 | 0.42% | 0 | 0.00% | 2 | 0.06% | 102 | 2.87% |
| 7122 | 457 | 129 | 32,444 | 1 | 0.22% | 5 | 1.09% | 0 | 0.00% | 6 | 1.31% | 0 | 0.00% | 5 | 1.09% | 1 | 0.22% | 0 | 0.00% | 1 | 0.22% | 5 | 1.09% | 3 | 0.66% | 0 | 0.00% | 0 | 0.00% | 27 | 5.91% |
| 7070/7071 | 288 | 49 | 19,775 | 1 | 0.35% | 2 | 0.69% | 1 | 0.35% | 2 | 0.69% | 0 | 0.00% | 1 | 0.35% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.35% | 1 | 0.35% | 0 | 0.00% | 0 | 0.00% | 9 | 3.13% |
| 7020/7021 | 1,469 | 181 | 90,656 | 0 | 0.00% | 6 | 0.41% | 1 | 0.07% | 9 | 0.61% | 0 | 0.00% | 16 | 1.09% | 1 | 0.07% | 0 | 0.00% | 2 | 0.14% | 9 | 0.61% | 6 | 0.41% | 0 | 0.00% | 1 | 0.07% | 51 | 3.47% |
| 7000/7001 | 180 | 9 | 8,439 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.56% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.56% | 1 | 0.56% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 1.67% |
| 1580/1581 | 566 | 69 | 32,490 | 1 | 0.18% | 0 | 0.00% | 0 | 0.00% | 3 | 0.53% | 0 | 0.00% | 1 | 0.18% | 0 | 0.00% | 0 | 0.00% | 10 | 1.77% | 2 | 0.35% | 6 | 1.06% | 0 | 0.00% | 1 | 0.18% | 24 | 4.24% |

*A list of complications can be found on page 12.*

## Defibrillation Leads

Actively Monitored Study Data Summary

### MALFUNCTIONS

| MODELS | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 7170Q/7171Q | 115 | 7.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 1.74% | **2** | **1.74%** |
| 7120Q/7121Q | 4,322 | 6.90% | 5 | 0.12% | 14 | 0.32% | 0 | 0.00% | 1 | 0.02% | 51 | 1.18% | **71** | **1.64%** |
| 7122Q | 1,561 | 7.20% | 2 | 0.13% | 5 | 0.32% | 0 | 0.00% | 0 | 0.00% | 15 | 0.96% | **22** | **1.41%** |
| 7120/7121 | 3,560 | 5.80% | 1 | 0.03% | 13 | 0.37% | 0 | 0.00% | 1 | 0.03% | 29 | 0.81% | **44** | **1.24%** |
| 7122 | 457 | 7.40% | 2 | 0.44% | 3 | 0.66% | 0 | 0.00% | 0 | 0.00% | 8 | 1.75% | **13** | **2.84%** |
| 7070/7071 | 288 | 3.80% | 0 | 0.00% | 1 | 0.35% | 0 | 0.00% | 0 | 0.00% | 1 | 0.35% | **2** | **0.69%** |
| 7020/7021 | 1,469 | 6.70% | 3 | 0.20% | 4 | 0.27% | 0 | 0.00% | 0 | 0.00% | 15 | 1.02% | **22** | **1.50%** |
| 7000/7001 | 180 | 8.90% | 0 | 0.00% | 5 | 2.78% | 1 | 0.56% | 0 | 0.00% | 0 | 0.00% | **6** | **3.33%** |
| 1580/1581 | 566 | 8.80% | 1 | 0.18% | 24 | 4.24% | 0 | 0.00% | 0 | 0.00% | 7 | 1.24% | **32** | **5.65%** |

*Definitions of malfunction categories can be found on pages 8-9.*

# Dual-Chamber Pacemakers

# Dual-Chamber Pacemakers

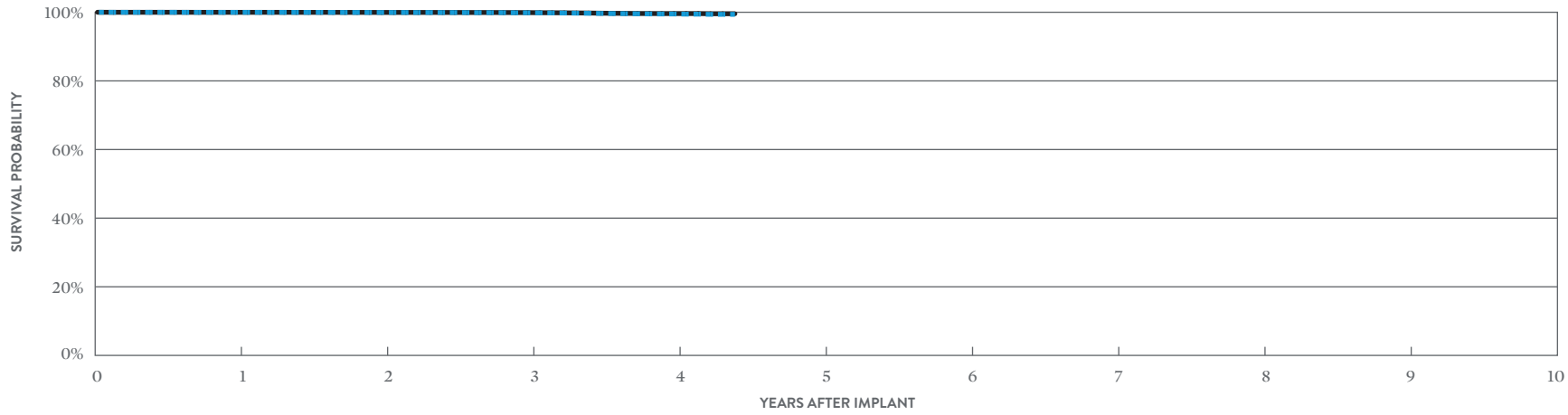
## CUSTOMER REPORTED PERFORMANCE DATA

## Assurity MRI™

### MODEL PM2272

| | |
|---|---|
| US Regulatory Approval | January 2017 |
| Registered US Implants | 247,949 |
| Estimated Active US Implants | 198,381 |
| Estimated Longevity | 9.4 Years |
| Normal Battery Depletion | 26 |
| Number of US Advisories (see pgs. 319, 321) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 9 | <0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 1 | <0.01% | 15 | <0.01% |
| Mechanical | 13 | <0.01% | 37 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 1 | <0.01% | 3 | <0.01% |
| **Total** | **16** | **<0.01%** | **65** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | AT 53 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.94% | 99.85% | 99.50% | 99.39% |
| ± 1 STANDARD ERROR | 0.00% | 0.01% | 0.01% | 0.04% | 0.06% |
| SAMPLE SIZE | 205,450 | 132,220 | 75,770 | 30,230 | 930 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | AT 53 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.95% | 99.90% | 99.62% | 99.57% |
| ± 1 STANDARD ERROR | 0.00% | 0.01% | 0.01% | 0.03% | 0.05% |

# Dual-Chamber Pacemakers

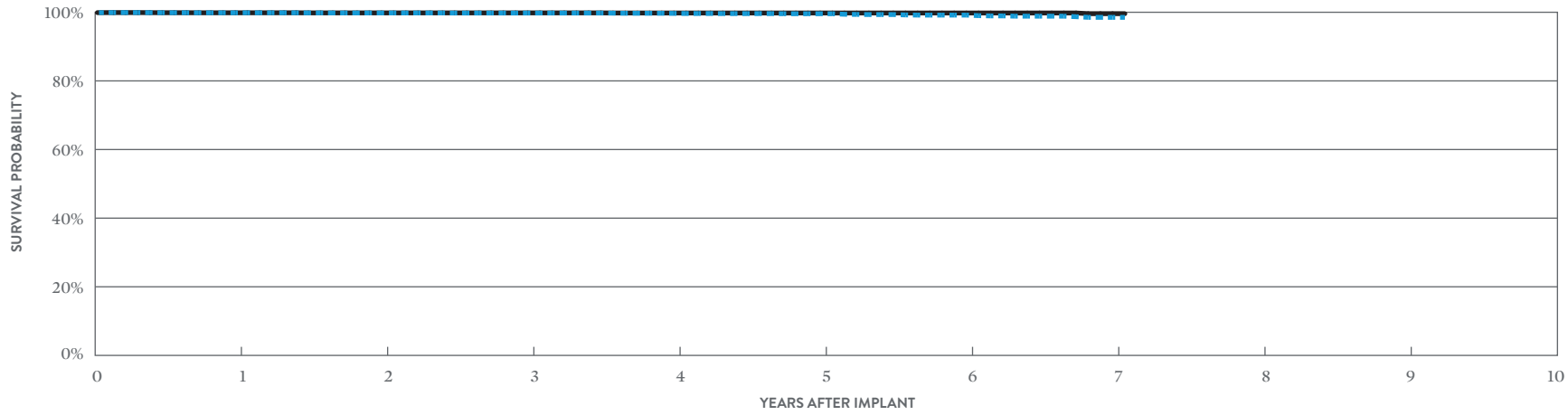
## CUSTOMER REPORTED PERFORMANCE DATA

## Endurity™ DR

### MODEL PM2160

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 9,368 |
| Estimated Active US Implants | 5,547 |
| Estimated Longevity | 9.7 Years |
| Normal Battery Depletion | 20 |
| Number of US Advisories (see pg. 319) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 7 | 0.07% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 2 | 0.02% |
| **Total** | **0** | **0.00%** | **9** | **0.10%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.80% | 99.77% | 99.67% | 99.57% | 99.17% | 98.52% | 98.52% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.05% | 0.06% | 0.08% | 0.12% | 0.23% | 0.23% |
| SAMPLE SIZE | 8,850 | 7,970 | 7,250 | 6,520 | 5,680 | 4,200 | 1,710 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.85% | 99.82% | 99.82% | 99.79% | 99.79% | 99.79% | 99.59% | 99.59% |
| ± 1 STANDARD ERROR | 0.04% | 0.04% | 0.04% | 0.05% | 0.05% | 0.05% | 0.15% | 0.15% |

# Dual-Chamber Pacemakers

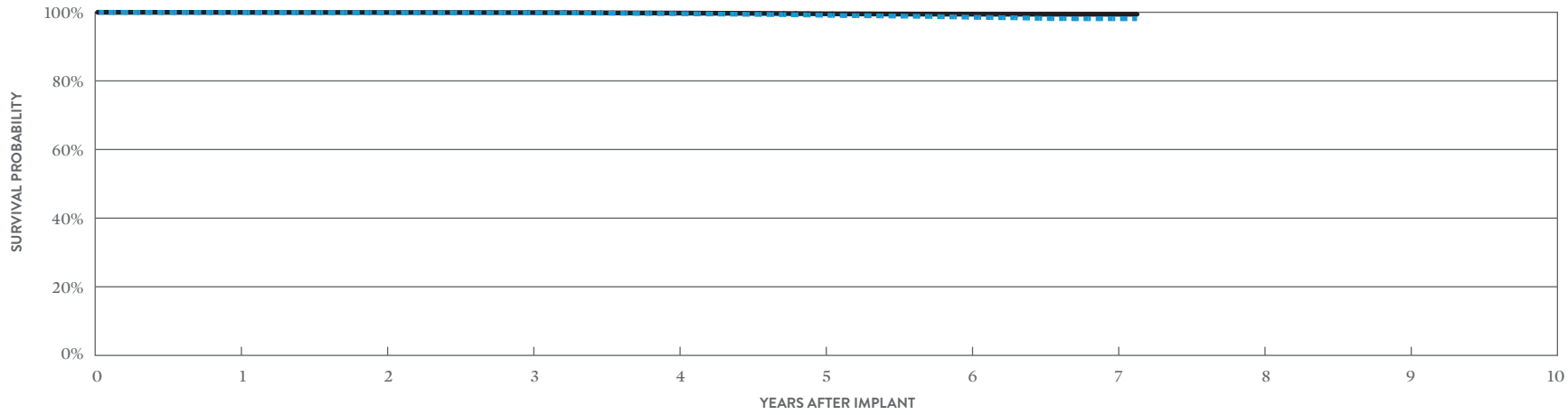
## CUSTOMER REPORTED PERFORMANCE DATA

## Assurity™ DR RF

### MODEL PM2240

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 183,930 |
| Estimated Active US Implants | 112,337 |
| Estimated Longevity | 9.4 Years |
| Normal Battery Depletion | 298 |
| Number of US Advisories (see pgs. 319, 321) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 5 | <0.01% | 17 | <0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 1 | <0.01% | 11 | <0.01% |
| Mechanical | 55 | 0.03% | 129 | 0.07% |
| Possible Early Battery Depletion | 3 | <0.01% | 4 | <0.01% |
| Other | 0 | 0.00% | 10 | <0.01% |
| **Total** | **64** | **0.03%** | **171** | **0.09%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 86 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.91% | 99.84% | 99.60% | 99.14% | 98.58% | 98.12% | 98.12% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.01% | 0.02% | 0.03% | 0.04% | 0.07% | 0.07% |
| SAMPLE SIZE | 173,600 | 155,140 | 138,910 | 120,720 | 91,910 | 52,240 | 16,150 | 490 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 86 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.93% | 99.90% | 99.77% | 99.55% | 99.45% | 99.43% | 99.43% |
| ± 1 STANDARD ERROR | 0.00% | 0.01% | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.03% |

# Dual-Chamber Pacemakers

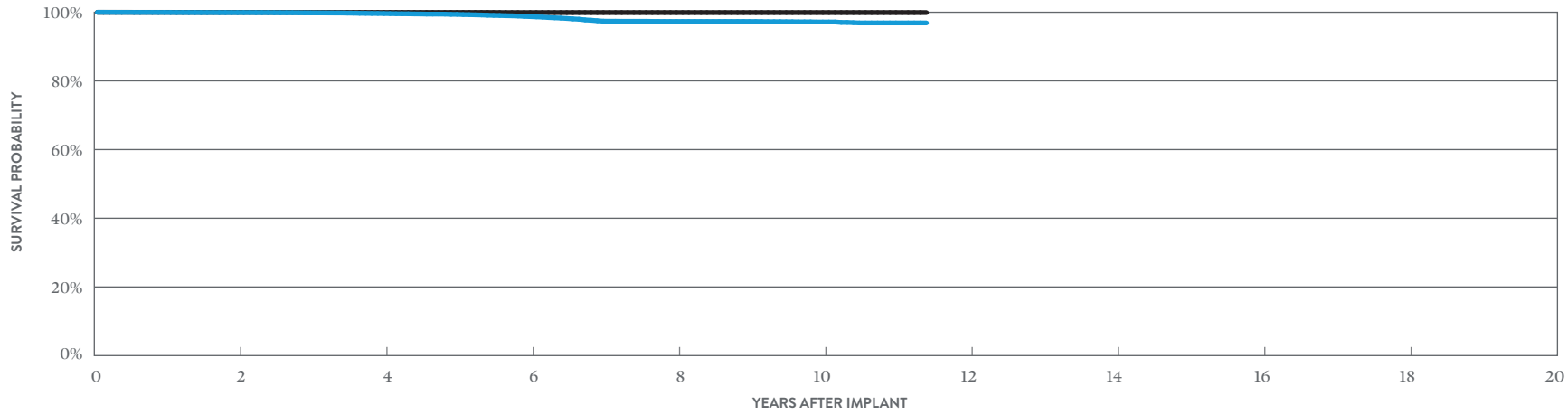
## CUSTOMER REPORTED PERFORMANCE DATA

## Accent™ DR RF

### MODEL PM2210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 243,105 |
| Estimated Active US Implants | 88,244 |
| Estimated Longevity | 8 Years |
| Normal Battery Depletion | 1,582 |
| Number of US Advisories (see pgs. 321, 323) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 17 | <0.01% | 48 | 0.02% |
| Electrical Interconnect | 8 | <0.01% | 33 | 0.01% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 4 | <0.01% |
| Mechanical | 1 | <0.01% | 22 | <0.01% |
| Possible Early Battery Depletion | 7 | <0.01% | 23 | <0.01% |
| Other | 5 | <0.01% | 44 | 0.02% |
| **Total** | **38** | **0.02%** | **174** | **0.07%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.86% | 99.60% | 98.64% | 96.93% | 96.54% | 96.22% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.03% | 0.05% | 0.05% | 0.11% |
| SAMPLE SIZE | 203,200 | 166,470 | 138,210 | 98,600 | 37,470 | 330 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 143 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.79% | 99.74% | 99.72% | 99.70% | 99.70% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% |

# Dual-Chamber Pacemakers

**ACTIVELY MONITORED STUDY DATA**

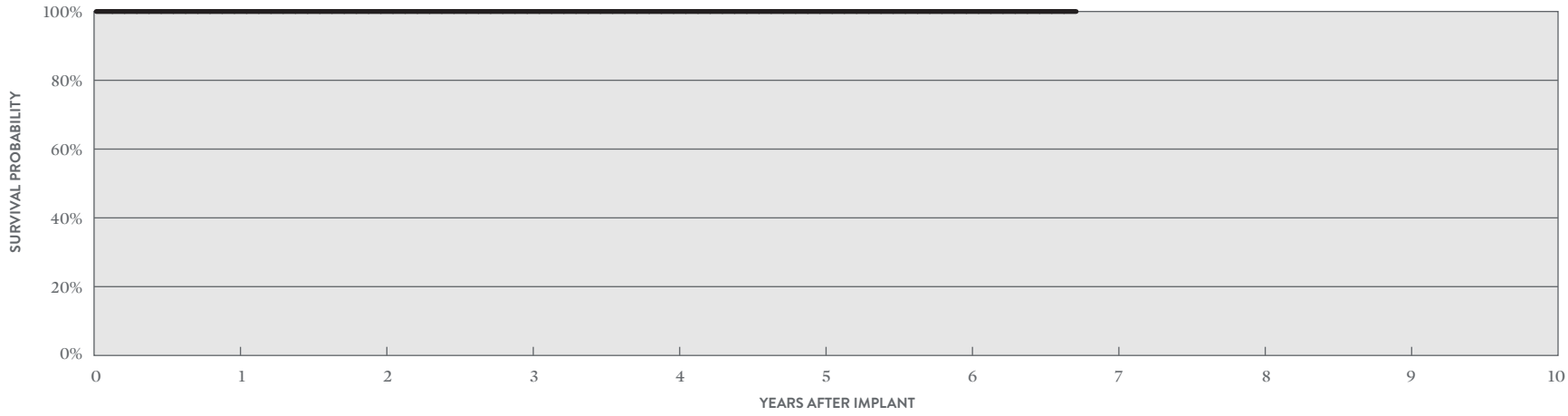
## Accent™ DR RF

### MODEL PM2210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Number of Devices Enrolled in Study | 1,773 |
| Active Devices Enrolled in Study | 152 |
| Cumulative Months of Follow-up | 61,556 |
| Estimated Longevity | 8 Years |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Premature Battery Depletion | 1 | 0.06% |
| Skin Erosion | 1 | 0.06% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.06% |
| Electrical Interconnect | 0 | 0.00% | 1 | 0.06% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **2** | **0.11%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 125 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.90% | 99.90% | 99.45% | 99.45% | 99.45% |
| ± 1 STANDARD ERROR | 0.10% | 0.10% | 0.10% | 0.46% | 0.46% | 0.46% |
| SAMPLE SIZE | 1,060 | 450 | 320 | 220 | 130 | 60 |

# Dual-Chamber Pacemakers

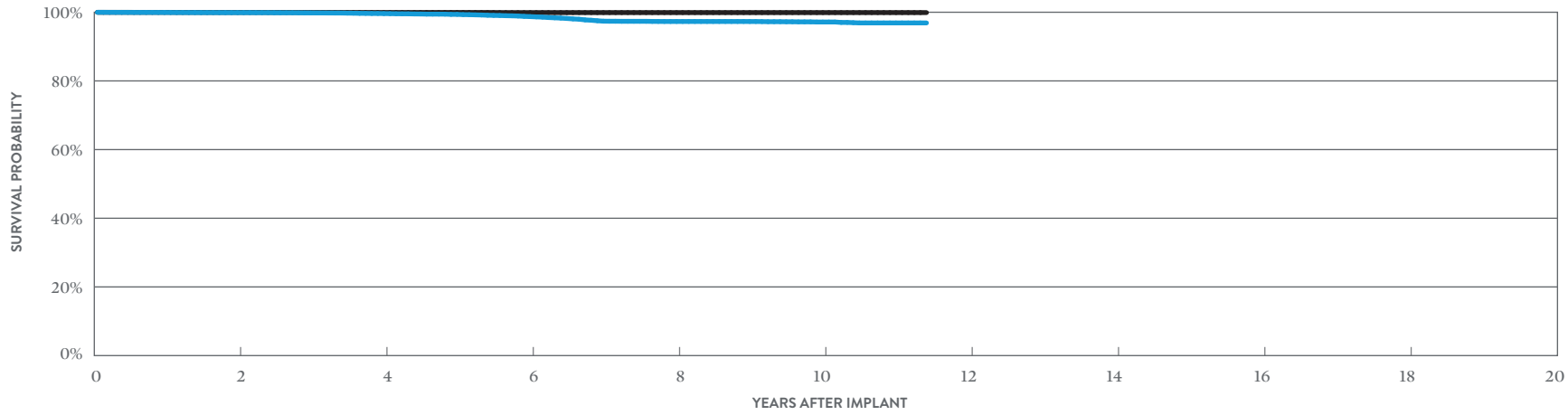
## CUSTOMER REPORTED PERFORMANCE DATA

## Accent™ DR

### MODEL PM2110

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 48,908 |
| Estimated Active US Implants | 19,299 |
| Estimated Longevity | 9.2 Years |
| Normal Battery Depletion | 298 |
| Number of US Advisories (see pg. 323) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 3 | <0.01% |
| Electrical Interconnect | 2 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 3 | <0.01% |
| Mechanical | 0 | 0.00% | 5 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 2 | <0.01% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **4** | **<0.01%** | **13** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 137 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.61% | 98.73% | 97.31% | 97.16% | 96.89% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.06% | 0.10% | 0.11% | 0.14% |
| SAMPLE SIZE | 40,820 | 33,300 | 27,810 | 20,280 | 7,560 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 137 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.93% | 99.90% | 99.90% | 99.90% | 99.90% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.02% | 0.02% | 0.02% | 0.02% |

# Dual-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Accent™ DR

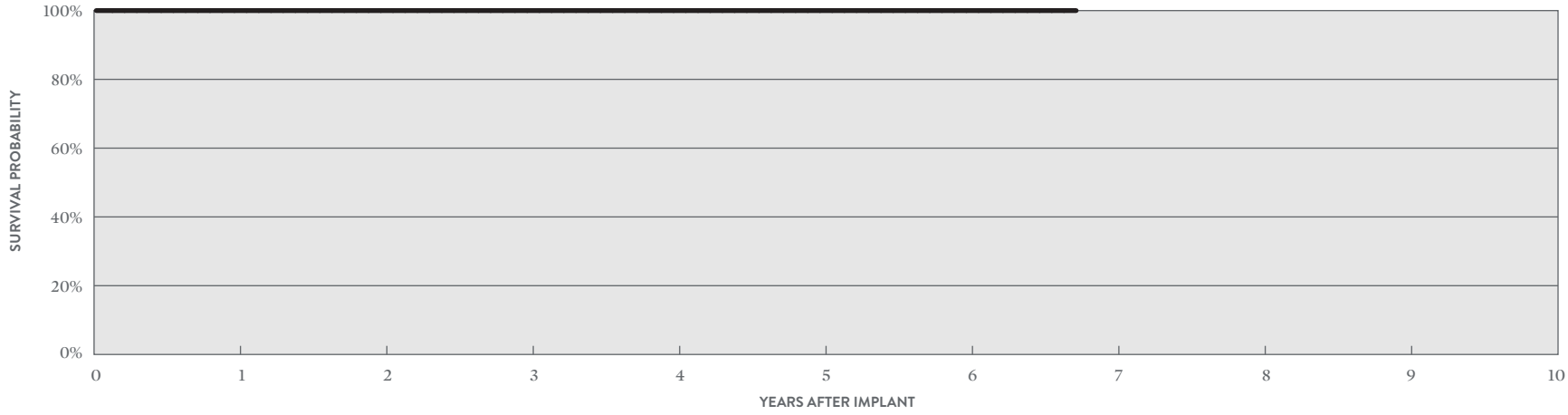
### MODEL PM2110

| | |
|---|---|
| US Regulatory Approval | June 2013 |
| Number of Devices Enrolled in Study | 228 |
| Active Devices Enrolled in Study | 27 |
| Cumulative Months of Follow-up | 10,493 |
| Estimated Longevity | 9.2 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 81 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 210 | 160 | 100 | 90 | 80 | 70 | 50 |

# Dual-Chamber Pacemakers

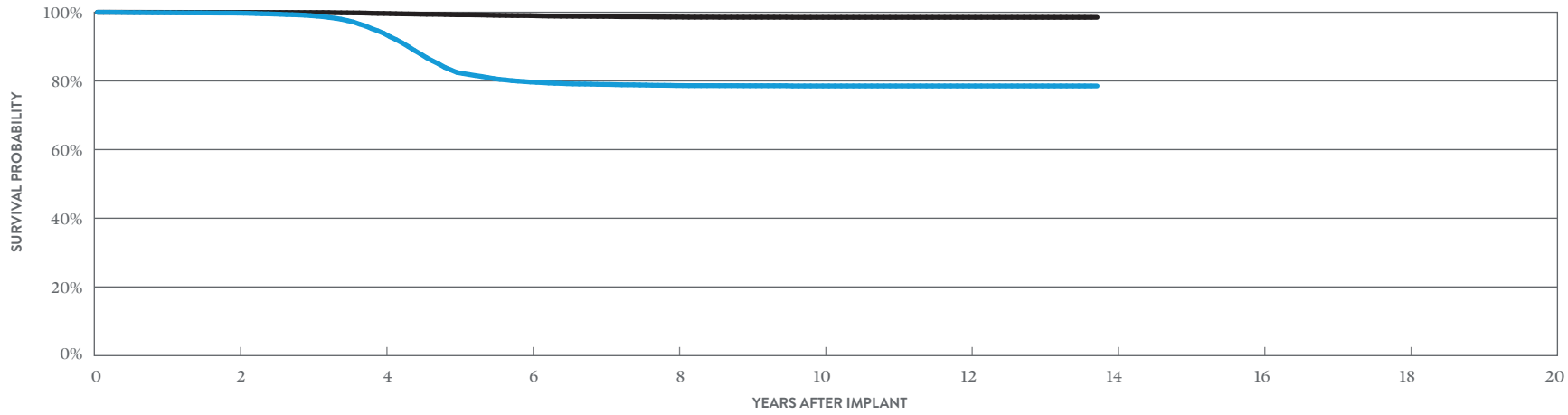
## CUSTOMER REPORTED PERFORMANCE DATA

## Zephyr™ DR

### MODEL 5820

| | |
|---|---|
| US Regulatory Approval | March 2007 |
| Registered US Implants | 54,348 |
| Estimated Active US Implants | 12,045 |
| Estimated Longevity | 6.5 Years |
| Normal Battery Depletion | 2,423 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 36 | 0.07% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 9 | 0.02% |
| Mechanical | 0 | 0.00% | 2 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 0 | 0.00% | 92 | 0.17% |
| **Total** | **2** | **<0.01%** | **140** | **0.26%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 165 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.75% | 93.85% | 79.68% | 78.66% | 78.54% | 78.54% | 78.54% |
| ± 1 STANDARD ERROR | 0.02% | 0.12% | 0.23% | 0.24% | 0.24% | 0.24% | 0.24% |
| SAMPLE SIZE | 42,570 | 31,940 | 20,860 | 12,230 | 6,810 | 3,180 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 165 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.65% | 99.02% | 98.62% | 98.53% | 98.53% | 98.53% |
| ± 1 STANDARD ERROR | 0.01% | 0.03% | 0.06% | 0.08% | 0.09% | 0.09% | 0.09% |

# Dual-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

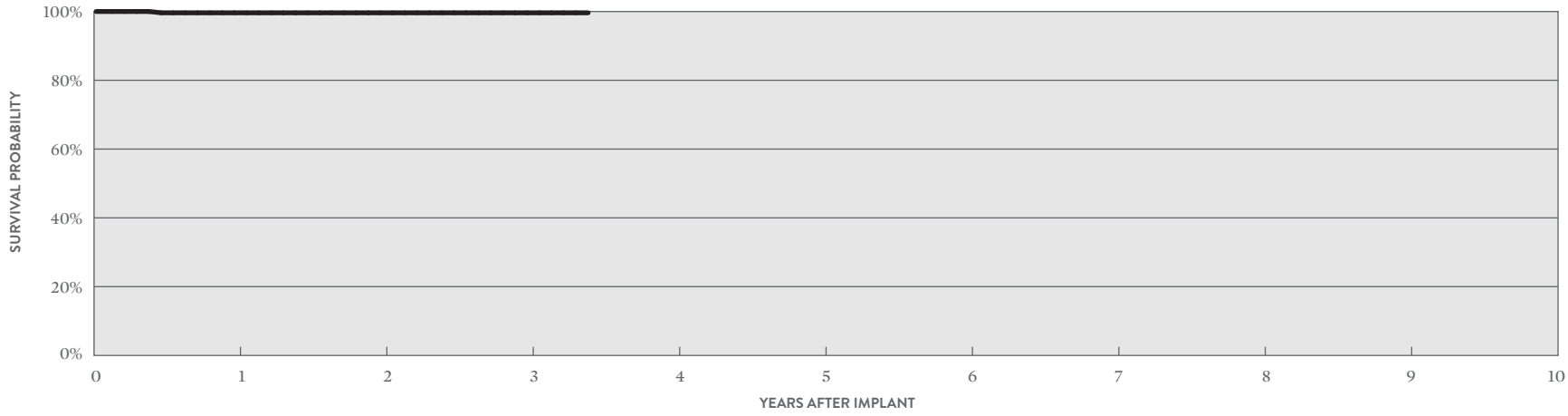
## Zephyr™ DR

### MODEL 5820

| | |
|---|---|
| US Regulatory Approval | March 2007 |
| Number of Devices Enrolled in Study | 284 |
| Active Devices Enrolled in Study | 3 |
| Cumulative Months of Follow-up | 8,019 |
| Estimated Longevity | 6.5 Years |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Skin Erosion | 1 | 0.35% |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




ACTIVELY MONITORED STUDY DATA

| YEAR | 1 | 2 | 3 | AT 41 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.62% | 99.62% | 99.62% | 99.62% |
| ± 1 STANDARD ERROR | 0.38% | 0.38% | 0.38% | 0.38% |
| SAMPLE SIZE | 260 | 200 | 120 | 50 |

# Dual-Chamber Pacemakers

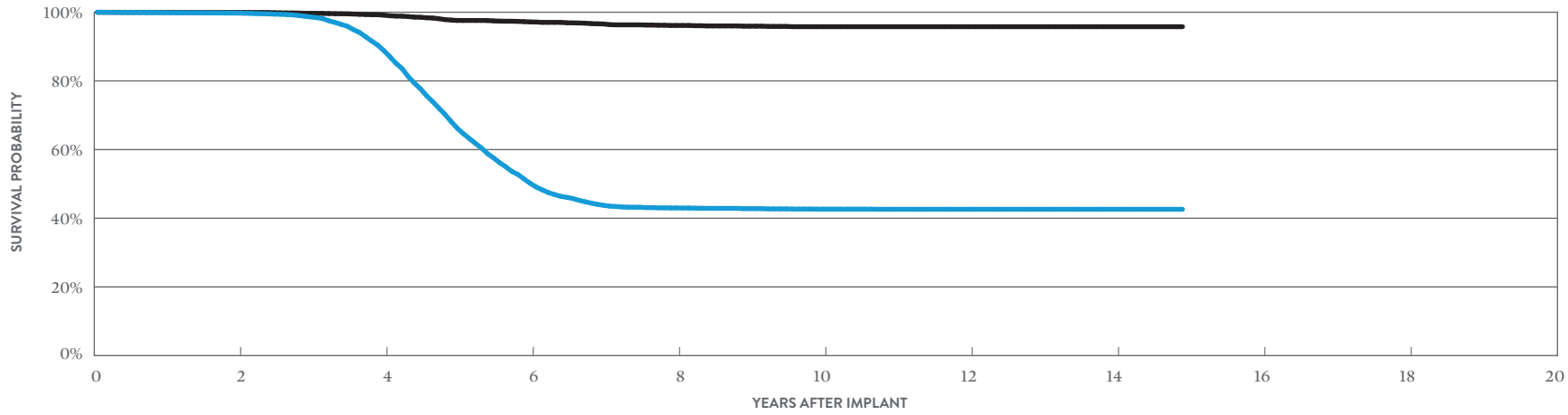
## CUSTOMER REPORTED PERFORMANCE DATA

## Victory™ DR

### MODEL 5810

| | |
|---|---|
| US Regulatory Approval | December 2005 |
| Registered US Implants | 26,313 |
| Estimated Active US Implants | 2,247 |
| Estimated Longevity | 6.5 Years |
| Normal Battery Depletion | 2,778 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 89 | 0.34% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 8 | 0.03% |
| Mechanical | 0 | 0.00% | 2 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 17 | 0.06% |
| Other | 0 | 0.00% | 37 | 0.14% |
| **Total** | **1** | **<0.01%** | **153** | **0.58%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 179 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.75% | 88.82% | 50.17% | 43.00% | 42.65% | 42.61% | 42.61% | 42.61% |
| ± 1 STANDARD ERROR | 0.03% | 0.24% | 0.44% | 0.46% | 0.46% | 0.46% | 0.46% | 0.46% |
| SAMPLE SIZE | 20,500 | 14,160 | 7,040 | 3,380 | 2,580 | 2,160 | 1,230 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 179 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.93% | 99.15% | 97.18% | 96.15% | 95.79% | 95.79% | 95.79% | 95.79% |
| ± 1 STANDARD ERROR | 0.02% | 0.07% | 0.16% | 0.23% | 0.25% | 0.25% | 0.25% | 0.25% |

# Dual-Chamber Pacemakers

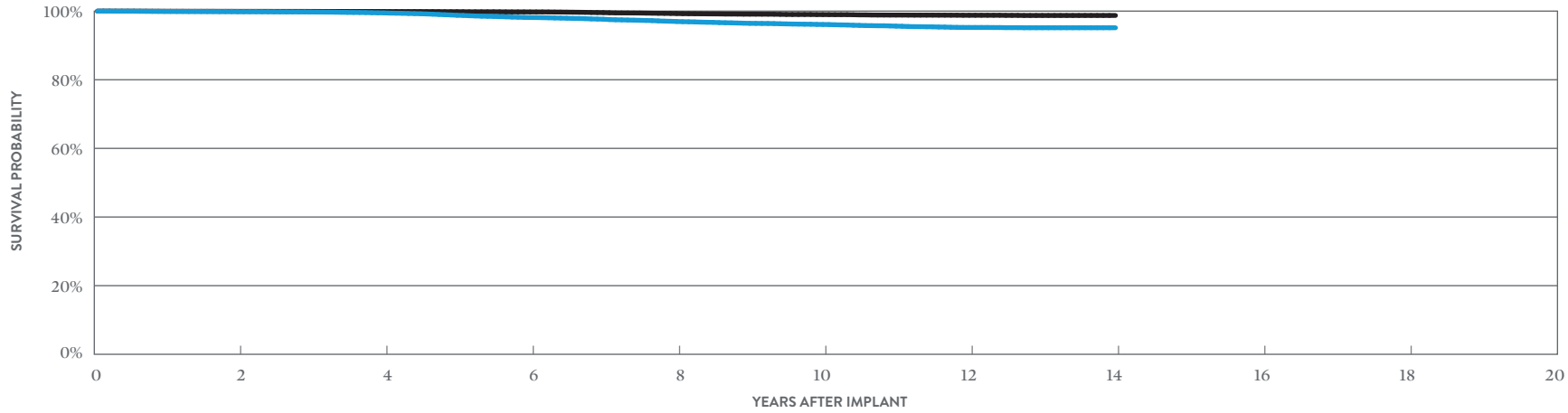
## CUSTOMER REPORTED PERFORMANCE DATA

## Zephyr™ XL DR

### MODEL 5826

| | |
|---|---|
| US Regulatory Approval | March 2007 |
| Registered US Implants | 112,293 |
| Estimated Active US Implants | 22,464 |
| Estimated Longevity | 11.7 Years |
| Normal Battery Depletion | 672 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 25 | 0.02% |
| Electrical Interconnect | 4 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 16 | 0.01% |
| Mechanical | 1 | <0.01% | 9 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 3 | <0.01% |
| Other | 2 | <0.01% | 155 | 0.14% |
| **Total** | **8** | **<0.01%** | **208** | **0.19%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.48% | 98.13% | 96.97% | 96.10% | 95.23% | 95.15% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.05% | 0.07% | 0.09% | 0.11% | 0.12% |
| SAMPLE SIZE | 91,620 | 72,090 | 56,970 | 39,560 | 25,660 | 15,260 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.93% | 99.89% | 99.76% | 99.29% | 98.99% | 98.79% | 98.73% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.02% | 0.04% | 0.05% | 0.06% | 0.07% |

# Dual-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Zephyr™ XL DR

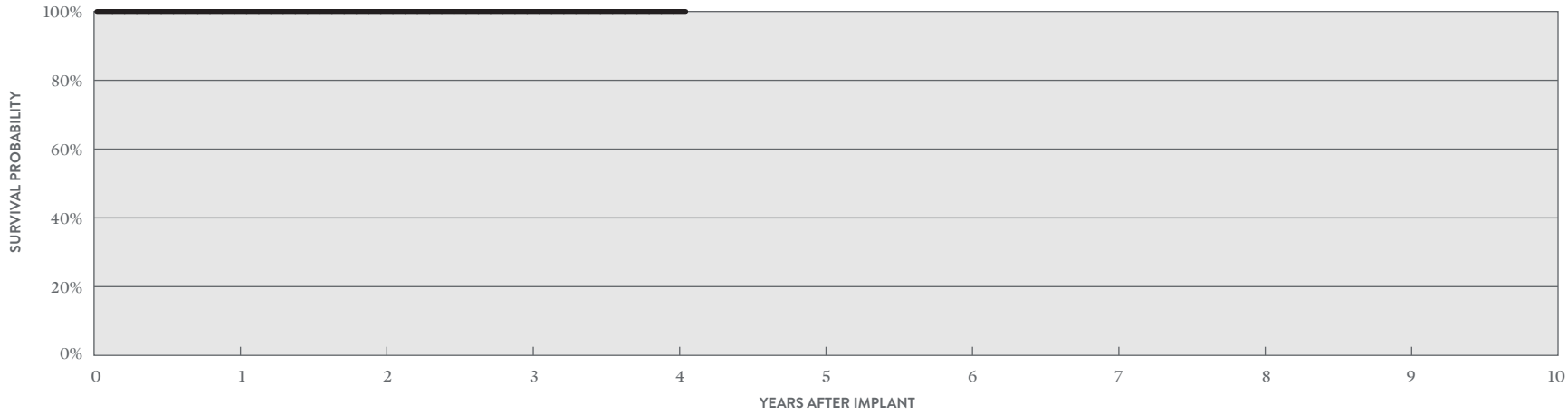
### MODEL 5826

| | |
|---|---|
| US Regulatory Approval | March 2007 |
| Number of Devices Enrolled in Study | 1,516 |
| Active Devices Enrolled in Study | 7 |
| Cumulative Months of Follow-up | 48,198 |
| Estimated Longevity | 11.7 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.07% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **1** | **0.07%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | 4 | AT 49 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 1,440 | 1,270 | 900 | 350 | 70 |

# Dual-Chamber Pacemakers

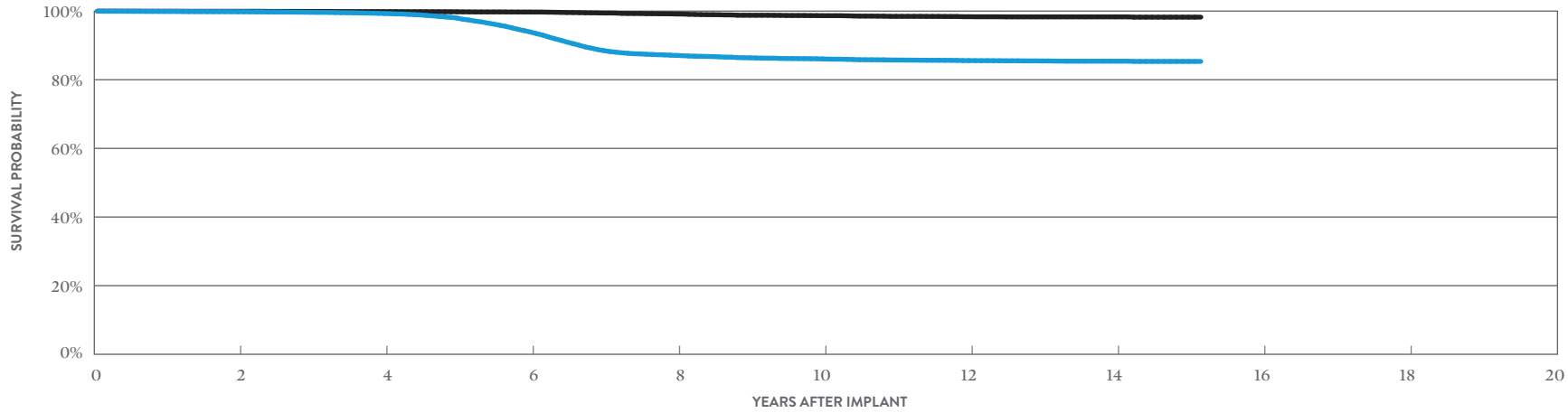
## CUSTOMER REPORTED PERFORMANCE DATA

## Victory™ XL DR

### MODEL 5816

| | |
|---|---|
| US Regulatory Approval | December 2005 |
| Registered US Implants | 62,719 |
| Estimated Active US Implants | 8,391 |
| Estimated Longevity | 11.7 Years |
| Normal Battery Depletion | 1,512 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 31 | 0.05% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 8 | 0.01% |
| Mechanical | 0 | 0.00% | 9 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 5 | <0.01% |
| Other | 1 | <0.01% | 91 | 0.15% |
| **Total** | **3** | **<0.01%** | **144** | **0.23%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 182 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.30% | 93.92% | 87.08% | 86.07% | 85.58% | 85.41% | 85.34% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.13% | 0.20% | 0.21% | 0.22% | 0.22% | 0.23% |
| SAMPLE SIZE | 51,390 | 39,590 | 30,370 | 19,540 | 12,750 | 9,320 | 4,820 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 182 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.85% | 99.73% | 99.15% | 98.67% | 98.37% | 98.32% | 98.24% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.03% | 0.06% | 0.08% | 0.10% | 0.10% | 0.12% |

# Dual-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Victory™ XL DR

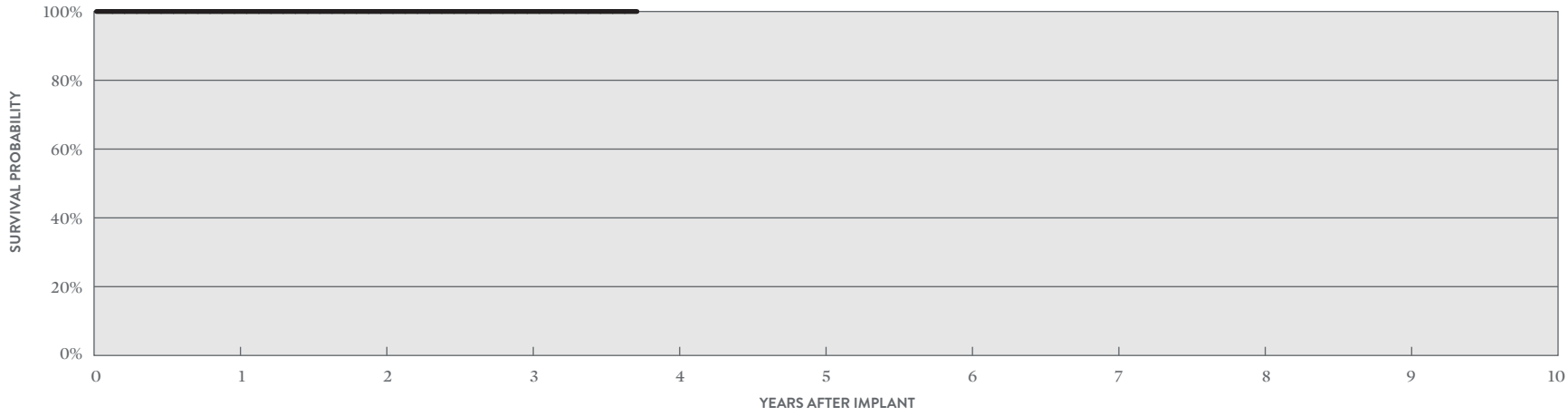
### MODEL 5816

| | |
|---|---|
| US Regulatory Approval | December 2005 |
| Number of Devices Enrolled in Study | 332 |
| Active Devices Enrolled in Study | 0 |
| Cumulative Months of Follow-up | 10,615 |
| Estimated Longevity | 11.7 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | AT 45 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 320 | 280 | 200 | 50 |

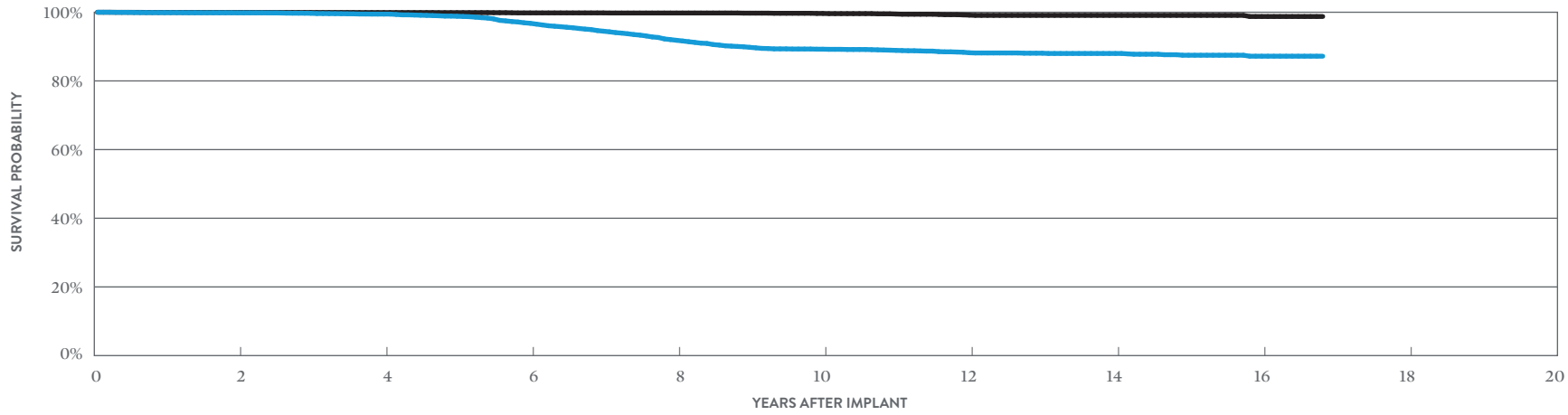
# Dual-Chamber Pacemakers

## CUSTOMER REPORTED PERFORMANCE DATA

## Verity ADx™ XL DR MODEL 5356
## Verity ADx™ XL DR M/S MODEL 5357M/S
## Verity ADx™ XL DC MODEL 5256

| | |
|---|---|
| US Regulatory Approval | May 2003 |
| Registered US Implants | 17,393 |
| Estimated Active US Implants | 2,475 |
| Estimated Longevity | 6.9 Years |
| Normal Battery Depletion | 314 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 11 | 0.06% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 0 | 0.00% | 10 | 0.06% |
| **Total** | **1** | **<0.01%** | **23** | **0.13%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 202 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.46% | 96.78% | 91.83% | 89.24% | 88.20% | 87.99% | 87.20% | 87.20% |
| ± 1 STANDARD ERROR | 0.03% | 0.07% | 0.18% | 0.32% | 0.38% | 0.41% | 0.42% | 0.49% | 0.49% |
| SAMPLE SIZE | 14,090 | 10,800 | 8,020 | 5,890 | 4,310 | 3,120 | 2,040 | 790 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 202 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.95% | 99.91% | 99.81% | 99.78% | 99.65% | 99.16% | 99.09% | 98.76% | 98.76% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.05% | 0.07% | 0.13% | 0.15% | 0.27% | 0.27% |

# Dual-Chamber Pacemakers

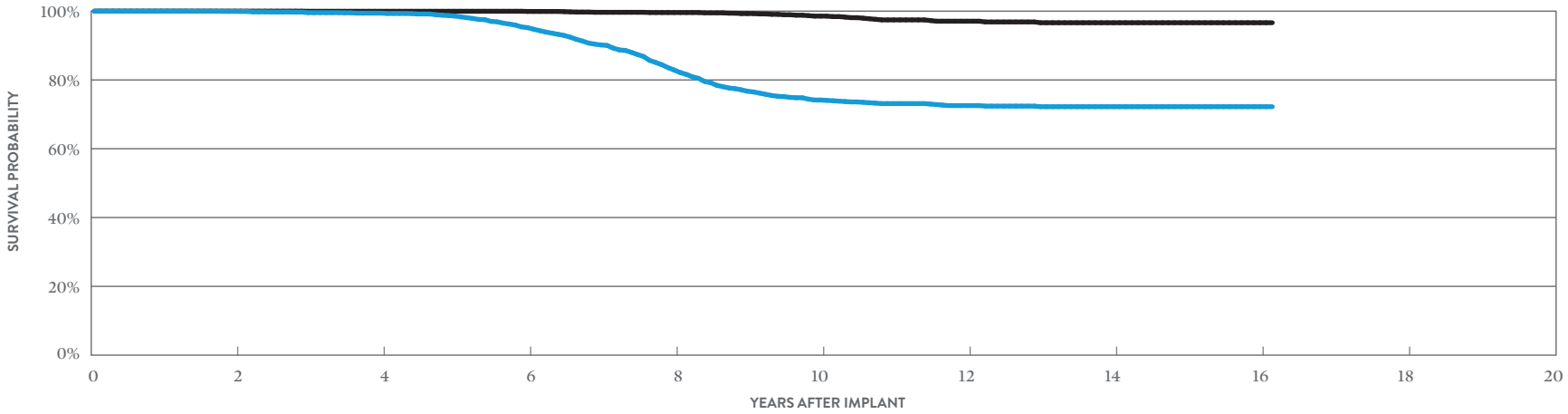
## CUSTOMER REPORTED PERFORMANCE DATA

## Integrity ADx™ DR

### MODEL 5366

| | |
|---|---|
| US Regulatory Approval | May 2003 |
| Registered US Implants | 8,087 |
| Estimated Active US Implants | 766 |
| Estimated Longevity | 6.9 Years |
| Normal Battery Depletion | 322 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 9 | 0.11% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.02% |
| Mechanical | 0 | 0.00% | 1 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.01% |
| Other | 0 | 0.00% | 14 | 0.17% |
| **Total** | **0** | **0.00%** | **27** | **0.33%** |




INCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 194 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.42% | 95.20% | 82.89% | 74.16% | 72.54% | 72.22% | 72.22% | 72.22% |
| ± 1 STANDARD ERROR | 0.03% | 0.10% | 0.32% | 0.63% | 0.80% | 0.84% | 0.86% | 0.86% | 0.86% |
| SAMPLE SIZE | 6,670 | 5,140 | 3,880 | 2,740 | 1,630 | 1,040 | 760 | 330 | 210 |

EXCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 194 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 99.96% | 99.91% | 99.59% | 98.55% | 97.07% | 96.63% | 96.63% | 96.63% |
| ± 1 STANDARD ERROR | 0.00% | 0.03% | 0.03% | 0.11% | 0.27% | 0.44% | 0.49% | 0.49% | 0.49% |

# Dual-Chamber Pacemakers

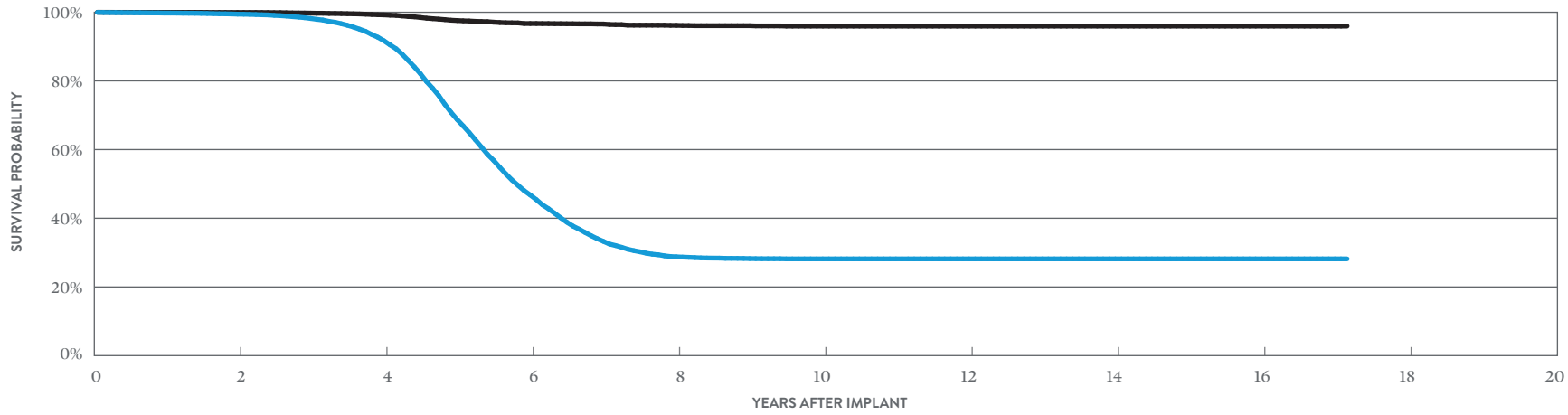
## CUSTOMER REPORTED PERFORMANCE DATA

## Identity ADx™ DR

### MODEL 5380

| | |
|---|---|
| US Regulatory Approval | March 2003 |
| Registered US Implants | 54,050 |
| Estimated Active US Implants | 2,503 |
| Estimated Longevity | 3.8 Years |
| Normal Battery Depletion | 6,222 |
| Number of US Advisories | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 136 | 0.20% |
| Electrical Interconnect | 0 | 0.00% | 2 | <0.01% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 7 | 0.01% |
| Mechanical | 0 | 0.00% | 10 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 6 | <0.01% |
| Other | 0 | 0.00% | 111 | 0.16% |
| **Total** | **2** | **<0.01%** | **272** | **0.40%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 206 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.44% | 91.71% | 46.78% | 28.77% | 28.17% | 28.17% | 28.17% | 28.17% | 28.17% |
| ± 1 STANDARD ERROR | 0.03% | 0.14% | 0.33% | 0.33% | 0.33% | 0.33% | 0.33% | 0.33% | 0.33% |
| SAMPLE SIZE | 42,720 | 29,850 | 12,550 | 4,640 | 3,100 | 2,580 | 2,080 | 1,100 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 206 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.93% | 99.23% | 96.72% | 96.19% | 95.97% | 95.97% | 95.97% | 95.97% | 95.97% |
| ± 1 STANDARD ERROR | 0.01% | 0.05% | 0.13% | 0.16% | 0.18% | 0.18% | 0.18% | 0.18% | 0.18% |

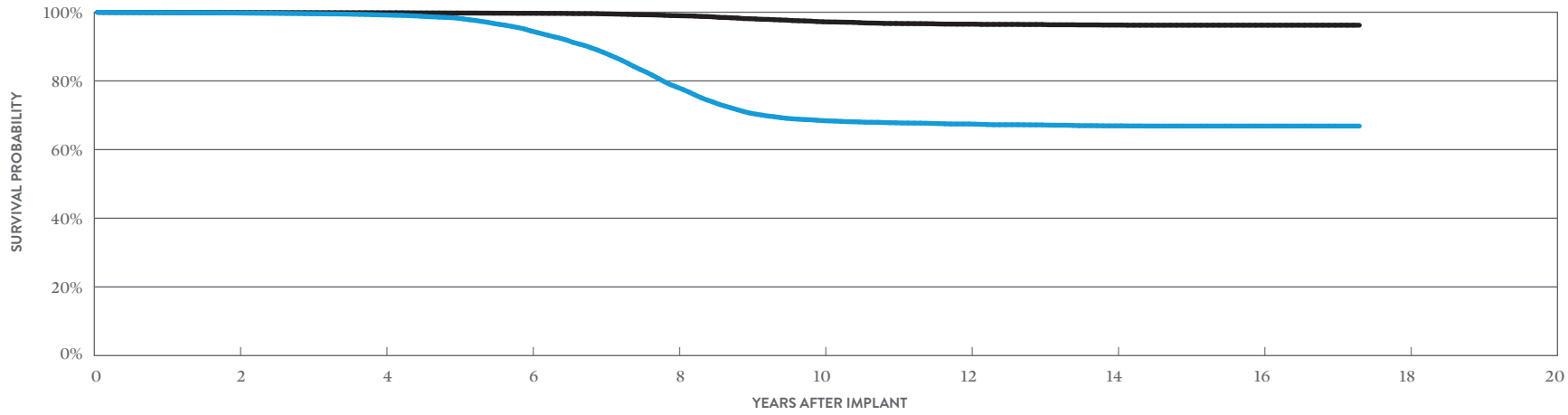
# Dual-Chamber Pacemakers

## CUSTOMER REPORTED PERFORMANCE DATA

## Identity ADx™ XL DR MODEL 5386
## Identity ADx™ XL DC MODEL 5286

| | |
|---|---|
| US Regulatory Approval | March 2003 |
| Registered US Implants | 67,419 |
| Estimated Active US Implants | 6,875 |
| Estimated Longevity | 6.9 Years |
| Normal Battery Depletion | 3,330 |
| Number of US Advisories | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 4 | <0.01% | 262 | 0.48% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | <0.01% |
| Mechanical | 0 | 0.00% | 6 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 11 | 0.02% |
| Other | 0 | 0.00% | 17 | 0.03% |
| **Total** | **5** | **<0.01%** | **298** | **0.55%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 208 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.77% | 99.21% | 94.61% | 78.23% | 68.43% | 67.45% | 66.91% | 66.85% | 66.85% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.11% | 0.24% | 0.29% | 0.30% | 0.30% | 0.31% | 0.31% |
| SAMPLE SIZE | 55,650 | 43,310 | 32,600 | 22,720 | 12,980 | 8,230 | 5,340 | 2,300 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 208 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.90% | 99.85% | 99.69% | 99.00% | 97.22% | 96.53% | 96.27% | 96.23% | 96.23% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.03% | 0.06% | 0.12% | 0.15% | 0.16% | 0.16% | 0.16% |

# Dual-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Identity ADx™ XL DR

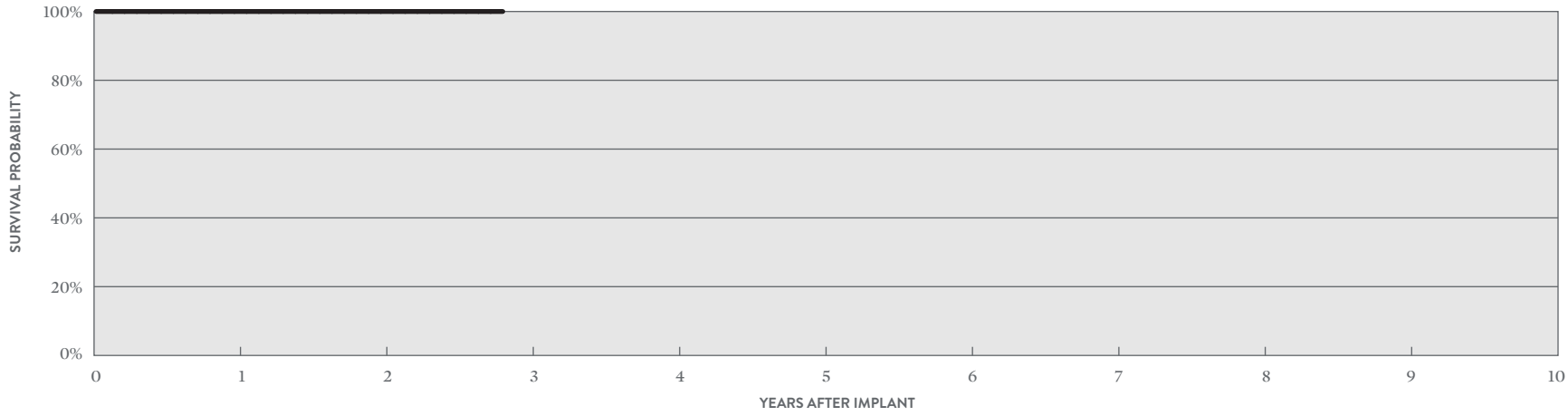
### MODEL 5386

| | |
|---|---|
| US Regulatory Approval | March 2003 |
| Number of Devices Enrolled in Study | 101 |
| Active Devices Enrolled in Study | 0 |
| Cumulative Months of Follow-up | 3,221 |
| Estimated Longevity | 6.9 Years |

**QUALIFYING COMPLICATIONS**

| |
|---|
| None Reported |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | AT 34 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 100 | 80 | 50 |

# Dual-Chamber Pacemakers

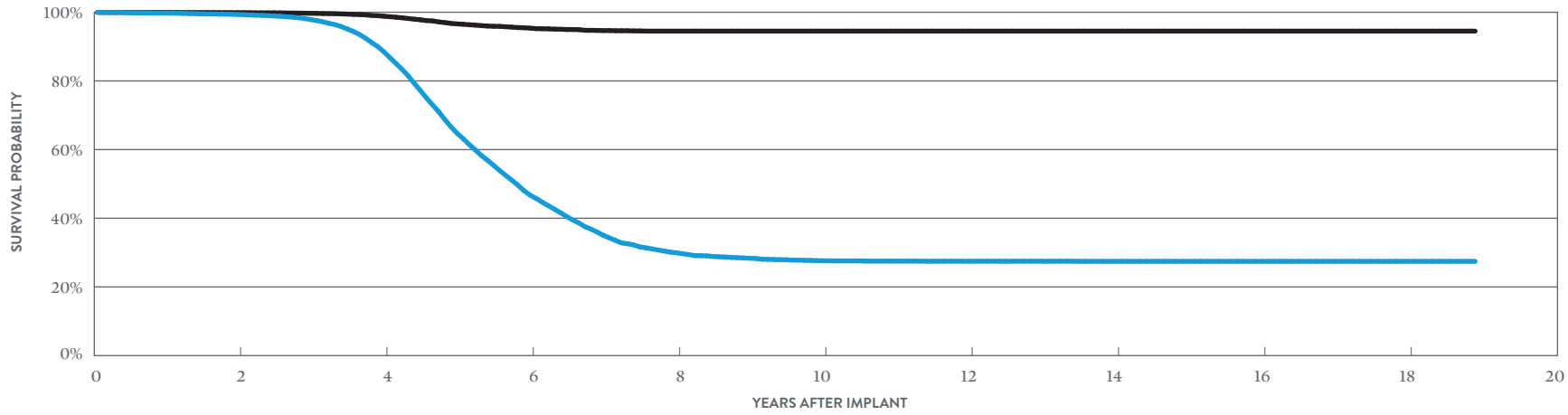
## CUSTOMER REPORTED PERFORMANCE DATA

## Identity™

### MODEL 5370

| | |
|---|---|
| US Regulatory Approval | November 2001 |
| Registered US Implants | 58,366 |
| Estimated Active US Implants | 1,623 |
| Estimated Longevity | 3.8 Years |
| Normal Battery Depletion | 6,084 |
| Number of US Advisories (see pg. 324) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | <0.01% | 398 | 0.68% |
| Electrical Interconnect | 2 | <0.01% | 2 | <0.01% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 5 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 12 | 0.02% |
| Other | 0 | 0.00% | 12 | 0.02% |
| **Total** | **5** | **<0.01%** | **430** | **0.74%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 227 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.36% | 88.54% | 46.97% | 29.97% | 27.63% | 27.48% | 27.45% | 27.45% | 27.45% | 27.45% |
| ± 1 STANDARD ERROR | 0.03% | 0.16% | 0.33% | 0.37% | 0.37% | 0.37% | 0.37% | 0.37% | 0.37% | 0.37% |
| SAMPLE SIZE | 46,530 | 32,260 | 11,340 | 3,620 | 2,270 | 1,920 | 1,740 | 1,400 | 810 | 220 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 227 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 98.85% | 95.40% | 94.53% | 94.53% | 94.53% | 94.53% | 94.53% | 94.53% | 94.53% |
| ± 1 STANDARD ERROR | 0.01% | 0.05% | 0.15% | 0.20% | 0.20% | 0.20% | 0.20% | 0.20% | 0.20% | 0.20% |

# Dual-Chamber Pacemakers

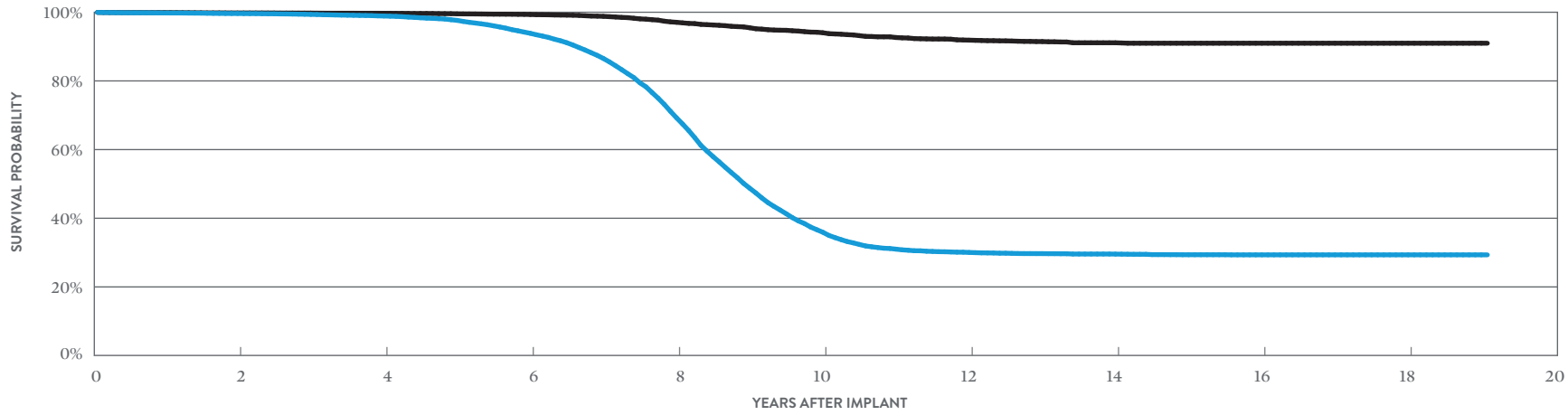
## CUSTOMER REPORTED PERFORMANCE DATA

## Identity™ XL

### MODEL 5376

| | |
|---|---|
| US Regulatory Approval | November 2001 |
| Registered US Implants | 51,535 |
| Estimated Active US Implants | 2,571 |
| Estimated Longevity | 6.9 Years |
| Normal Battery Depletion | 5,337 |
| Number of US Advisories (see pg. 324) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 2 | <0.01% | 314 | 0.61% |
| Electrical Interconnect | 4 | <0.01% | 2 | <0.01% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 12 | 0.02% |
| Mechanical | 2 | <0.01% | 6 | 0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 5 | <0.01% |
| Other | 0 | 0.00% | 94 | 0.18% |
| **Total** | **8** | **0.02%** | **433** | **0.84%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 229 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.63% | 98.90% | 93.87% | 69.25% | 35.92% | 30.04% | 29.56% | 29.34% | 29.34% | 29.34% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.14% | 0.30% | 0.34% | 0.34% | 0.34% | 0.34% | 0.34% | 0.34% |
| SAMPLE SIZE | 43,080 | 33,830 | 25,240 | 16,410 | 7,830 | 4,210 | 3,080 | 2,130 | 1,060 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 229 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.80% | 99.70% | 99.34% | 97.07% | 94.03% | 91.87% | 91.11% | 90.98% | 90.98% | 90.98% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.12% | 0.21% | 0.29% | 0.32% | 0.32% | 0.32% | 0.32% |

SUMMARY INFORMATION

# Dual-Chamber Pacemakers

# Dual-Chamber Pacemakers
## Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM2272 | Assurity MRI™ | 99.98% | 99.94% | 99.85% | 99.50% | | | | | | |
| PM2160 | Endurity™ DR | 99.85% | 99.80% | 99.77% | 99.67% | 99.57% | 99.17% | 98.52% | | | |
| PM2240 | Assurity™ DR RF | 99.95% | 99.91% | 99.84% | 99.60% | 99.14% | 98.58% | 98.12% | | | |
| PM2210 | Accent™ DR RF | 99.92% | 99.86% | 99.77% | 99.60% | 99.31% | 98.64% | 97.04% | 96.93% | 96.81% | 96.54% |
| PM2110 | Accent™ DR | 99.94% | 99.89% | 99.81% | 99.61% | 99.38% | 98.73% | 97.40% | 97.31% | 97.30% | 97.16% |
| 5820 | Zephyr™ DR | 99.85% | 99.75% | 99.02% | 93.85% | 82.45% | 79.68% | 78.98% | 78.66% | 78.60% | 78.54% |
| 5810 | Victory™ DR | 99.87% | 99.75% | 98.63% | 88.82% | 66.28% | 50.17% | 43.77% | 43.00% | 42.80% | 42.65% |
| 5826 | Zephyr™ XL DR | 99.91% | 99.84% | 99.74% | 99.48% | 98.78% | 98.13% | 97.64% | 96.97% | 96.43% | 96.10% |
| 5816 | Victory™ XL DR | 99.91% | 99.83% | 99.65% | 99.30% | 97.97% | 93.92% | 88.51% | 87.08% | 86.39% | 86.07% |
| 5356/5357/5256 | Verity ADx™ XL DR/ DR(M/S) / DC | 99.89% | 99.83% | 99.69% | 99.46% | 98.83% | 96.78% | 94.48% | 91.83% | 89.78% | 89.24% |
| 5366 | Integrity ADx™ XL DR | 100.00% | 99.94% | 99.56% | 99.42% | 98.59% | 95.20% | 90.17% | 82.89% | 76.72% | 74.16% |
| 5380 | Identity ADx™ DR | 99.76% | 99.44% | 98.18% | 91.71% | 68.78% | 46.78% | 33.27% | 28.77% | 28.25% | 28.17% |
| 5386/5286 | Identity ADx™ XL DR/DC | 99.88% | 99.77% | 99.57% | 99.21% | 98.29% | 94.61% | 88.32% | 78.23% | 70.64% | 68.43% |
| 5370 | Identity™ | 99.75% | 99.35% | 97.87% | 88.47% | 64.78% | 46.71% | 35.01% | 29.93% | 28.34% | 27.63% |
| 5376 | Identity™ XL | 99.79% | 99.63% | 99.37% | 98.90% | 97.64% | 93.87% | 86.54% | 69.25% | 48.75% | 35.92% |

## Dual-Chamber Pacemakers

# Survival Probability Summary

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM2272 | Assurity MRI™ | 99.98% | 99.95% | 99.90% | 99.62% | | | | | | |
| PM2160 | Endurity™ DR | 99.85% | 99.82% | 99.82% | 99.79% | 99.79% | 99.79% | 99.59% | | | |
| PM2240 | Assurity™ DR RF | 99.96% | 99.93% | 99.90% | 99.77% | 99.55% | 99.45% | 99.43% | | | |
| PM2210 | Accent™ DR RF | 99.95% | 99.90% | 99.85% | 99.79% | 99.76% | 99.74% | 99.72% | 99.72% | 99.71% | 99.70% |
| PM2110 | Accent™ DR | 99.97% | 99.95% | 99.93% | 99.93% | 99.93% | 99.90% | 99.90% | 99.90% | 99.90% | 99.90% |
| 5820 | Zephyr™ DR | 99.97% | 99.96% | 99.92% | 99.65% | 99.26% | 99.02% | 98.80% | 98.62% | 98.56% | 98.53% |
| 5810 | Victory™ DR | 99.98% | 99.93% | 99.68% | 99.15% | 97.61% | 97.18% | 96.59% | 96.15% | 95.94% | 95.79% |
| 5826 | Zephyr™ XL DR | 99.96% | 99.93% | 99.91% | 99.89% | 99.83% | 99.76% | 99.56% | 99.29% | 99.11% | 98.99% |
| 5816 | Victory™ XL DR | 99.97% | 99.95% | 99.91% | 99.85% | 99.80% | 99.73% | 99.44% | 99.15% | 98.79% | 98.67% |
| 5356/5357/5256 | Verity ADx™ XL DR/ DR(M/S) / DC | 99.96% | 99.95% | 99.93% | 99.91% | 99.89% | 99.81% | 99.81% | 99.78% | 99.74% | 99.65% |
| 5366 | Integrity ADx™ XL DR | 100.00% | 100.00% | 99.96% | 99.96% | 99.96% | 99.91% | 99.66% | 99.59% | 99.29% | 98.55% |
| 5380 | Identity ADx™ DR | 99.96% | 99.93% | 99.74% | 99.23% | 97.59% | 96.72% | 96.58% | 96.19% | 96.09% | 95.97% |
| 5386/5286 | Identity ADx™ XL DR/DC | 99.92% | 99.90% | 99.87% | 99.85% | 99.77% | 99.69% | 99.53% | 99.00% | 98.12% | 97.22% |
| 5370 | Identity™ | 99.92% | 99.87% | 99.70% | 98.84% | 96.60% | 95.37% | 94.66% | 94.50% | 94.50% | 94.50% |
| 5376 | Identity™ XL | 99.90% | 99.80% | 99.76% | 99.70% | 99.54% | 99.34% | 98.81% | 97.07% | 95.48% | 94.03% |

# Dual-Chamber Pacemakers
## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2272 | Assurity MRI™ | 247,949 | 2.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 13 | <0.01% | 0 | 0.00% | 1 | <0.01% | **16** | **<0.01%** |
| PM2160 | Endurity™ DR | 9,368 | 4.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM2240 | Assurity™ DR RF | 183,930 | 4.60% | 5 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 55 | 0.03% | 3 | <0.01% | 0 | 0.00% | **64** | **0.03%** |
| PM2210 | Accent™ DR RF | 243,105 | 11.90% | 17 | <0.01% | 8 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 7 | <0.01% | 5 | <0.01% | **38** | **0.02%** |
| PM2110 | Accent™ DR | 48,909 | 10.00% | 2 | <0.01% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **<0.01%** |
| 5820 | Zephyr™ DR | 54,383 | 16.20% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **<0.01%** |
| 5810 | Victory™ DR | 26,313 | 19.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| 5826 | Zephyr™ XL DR | 112,293 | 18.90% | 1 | <0.01% | 4 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 2 | <0.01% | **8** | **<0.01%** |
| 5816 | Victory™ XL DR | 62,719 | 20.90% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | **3** | **<0.01%** |
| 5356/5357/5256 | Verity ADx™ XL DR/ DR(M/S) / DC | 17,393 | 11.90% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| 5366 | Integrity ADx™ XL DR | 8,087 | 19.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5380 | Identity ADx™ DR | 54,050 | 16.20% | 4 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **5** | **<0.01%** |
| 5386/5286 | Identity ADx™ XL DR/DC | 67,419 | 19.60% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **<0.01%** |
| 5370 | Identity™ | 58,366 | 13.70% | 3 | <0.01% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **5** | **<0.01%** |
| 5376 | Identity™ XL | 51,535 | 20.00% | 2 | <0.01% | 4 | <0.01% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | **8** | **0.02%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Dual-Chamber Pacemakers
## US Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2272 | Assurity MRI™ | 247,949 | 2.00% | 9 | <0.01% | 0 | 0.00% | 0 | 0.00% | 15 | <0.01% | 37 | 0.01% | 1 | <0.01% | 3 | <0.01% | **65** | **0.03%** |
| PM2160 | Endurity™ DR | 9,368 | 4.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.07% | 0 | 0.00% | 2 | 0.02% | **9** | **0.10%** |
| PM2240 | Assurity™ DR RF | 183,930 | 4.60% | 17 | <0.01% | 0 | 0.00% | 0 | 0.00% | 11 | <0.01% | 129 | 0.07% | 4 | <0.01% | 10 | <0.01% | **171** | **0.09%** |
| PM2210 | Accent™ DR RF | 243,105 | 11.90% | 48 | 0.02% | 33 | 0.01% | 0 | 0.00% | 4 | <0.01% | 22 | <0.01% | 23 | <0.01% | 44 | 0.02% | **174** | **0.07%** |
| PM2110 | Accent™ DR | 48,909 | 10.00% | 3 | <0.01% | 0 | 0.00% | 0 | 0.00% | 3 | <0.01% | 5 | 0.01% | 2 | <0.01% | 0 | 0.00% | **13** | **0.03%** |
| 5820 | Zephyr™ DR | 54,383 | 16.20% | 36 | 0.07% | 0 | 0.00% | 0 | 0.00% | 9 | 0.02% | 2 | <0.01% | 1 | <0.01% | 92 | 0.17% | **140** | **0.26%** |
| 5810 | Victory™ DR | 26,313 | 19.00% | 89 | 0.34% | 0 | 0.00% | 0 | 0.00% | 8 | 0.03% | 2 | <0.01% | 17 | 0.06% | 37 | 0.14% | **153** | **0.58%** |
| 5826 | Zephyr™ XL DR | 112,293 | 18.90% | 25 | 0.02% | 0 | 0.00% | 0 | 0.00% | 16 | 0.01% | 9 | <0.01% | 3 | <0.01% | 155 | 0.14% | **208** | **0.19%** |
| 5816 | Victory™ XL DR | 62,719 | 20.90% | 31 | 0.05% | 0 | 0.00% | 0 | 0.00% | 8 | 0.01% | 9 | 0.01% | 5 | <0.01% | 91 | 0.15% | **144** | **0.23%** |
| 5356/5357/5256 | Verity ADx™ XL DR/ DR(M/S) / DC | 17,393 | 11.90% | 11 | 0.06% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 10 | 0.06% | **23** | **0.13%** |
| 5366 | Integrity ADx™ XL DR | 8,087 | 19.70% | 9 | 0.11% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 1 | 0.01% | 1 | 0.01% | 14 | 0.17% | **27** | **0.33%** |
| 5380 | Identity ADx™ DR | 54,050 | 16.20% | 262 | 0.48% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 6 | 0.01% | 11 | 0.02% | 17 | 0.03% | **298** | **0.55%** |
| 5386/5286 | Identity ADx™ XL DR/DC | 67,419 | 19.60% | 136 | 0.20% | 2 | <0.01% | 0 | 0.00% | 7 | 0.01% | 10 | 0.01% | 6 | <0.01% | 111 | 0.16% | **272** | **0.40%** |
| 5370 | Identity™ | 58,366 | 13.70% | 398 | 0.68% | 2 | <0.01% | 0 | 0.00% | 1 | <0.01% | 5 | <0.01% | 12 | 0.02% | 12 | 0.02% | **430** | **0.74%** |
| 5376 | Identity™ XL | 51,535 | 20.00% | 314 | 0.61% | 2 | <0.01% | 0 | 0.00% | 12 | 0.02% | 6 | 0.01% | 5 | <0.01% | 94 | 0.18% | **433** | **0.84%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Dual-Chamber Pacemakers
## Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2272 | Assurity MRI™ | 573,821 | 0.85% | 2 | <0.01% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 15 | <0.01% | 0 | 0.00% | 2 | <0.01% | **21** | **<0.01%** |
| PM2160 | Endurity™ DR | 61,341 | 0.93% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | **3** | **<0.01%** |
| PM2240 | Assurity™ DR RF | 201,165 | 4.05% | 5 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 56 | 0.03% | 3 | <0.01% | 0 | 0.00% | **65** | **0.03%** |
| PM2210 | Accent™ DR RF | 246,722 | 11.45% | 17 | 0.01% | 8 | <0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 6 | <0.01% | 5 | <0.01% | **37** | **0.01%** |
| PM2110 | Accent™ DR | 49,730 | 9.57% | 2 | <0.01% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **0.01%** |

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2272 | Assurity MRI™ | 573,821 | 0.85% | 20 | <0.01% | 0 | 0.00% | 0 | 0.00% | 17 | <0.01% | 41 | 0.01% | 7 | <0.01% | 6 | <0.01% | **91** | **0.02%** |
| PM2160 | Endurity™ DR | 61,341 | 0.93% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 12 | 0.02% | 0 | 0.00% | 3 | <0.01% | **16** | **0.03%** |
| PM2240 | Assurity™ DR RF | 201,165 | 4.05% | 19 | 0.01% | 0 | 0.00% | 0 | 0.00% | 10 | <0.01% | 117 | 0.06% | 5 | <0.01% | 11 | 0.01% | **162** | **0.08%** |
| PM2210 | Accent™ DR RF | 246,722 | 11.45% | 51 | 0.02% | 34 | 0.01% | 0 | 0.00% | 4 | <0.01% | 22 | 0.01% | 23 | 0.01% | 43 | 0.02% | **177** | **0.07%** |
| PM2110 | Accent™ DR | 49,730 | 9.57% | 3 | 0.01% | 0 | 0.00% | 0 | 0.00% | 3 | 0.01% | 5 | 0.01% | 2 | <0.01% | 0 | 0.00% | **13** | **0.03%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Dual-Chamber Pacemakers

Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2210 | 1,773 | 152 | 61,556 | 0 | 0.00% | 0 | 0.00% | 1 | 0.06% | 1 | 0.06% | **2** | **0.11%** |
| PM2110 | 228 | 27 | 10,493 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5820 | 284 | 3 | 8,019 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.35% | **1** | **0.35%** |
| 5826 | 1,516 | 7 | 48,198 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5816 | 332 | 0 | 10,615 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5386 | 101 | 0 | 3,221 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*A list of of complications can be found on page 12.*

# Dual-Chamber Pacemakers

## Actively Monitored Study Data Summary

### MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRM-WARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2210 | Accent™ DR RF | 24.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |
| PM2110 | Accent™ DR | 14.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |
| 5820 | Zephyr™ DR | 22.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |
| 5826 | Zephyr™ XL DR | 27.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |
| 5816 | Victory™ XL DR | 17.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |
| 5386 | Indentity ADx™ XL DR | 18.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | **0.00%** | **0.00%** |

### MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRM-WARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM2210 | Accent™ DR RF | 1,773 | 24.70% | 1 | 0.06% | 1 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **0.11%** |
| PM2110 | Accent™ DR | 228 | 14.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5820 | Zephyr™ DR | 284 | 22.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5826 | Zephyr™ XL DR | 1,516 | 27.60% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.07%** |
| 5816 | Victory™ XL DR | 332 | 17.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5386 | Indentity ADx™ XL DR | 101 | 18.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Single-Chamber Pacemakers

# Single-Chamber Pacemakers

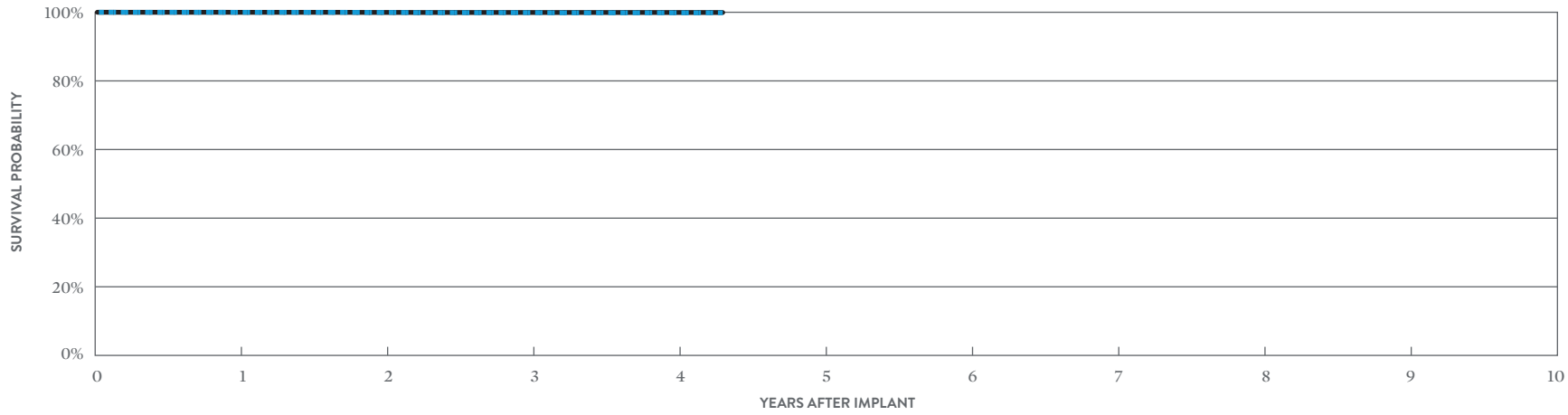
## CUSTOMER REPORTED PERFORMANCE DATA

## Assurity MRI™

### MODEL PM1272

| | |
|---|---|
| US Regulatory Approval | January 2017 |
| Registered US Implants | 25,351 |
| Estimated Active US Implants | 19,910 |
| Estimated Longevity | 13.7 Years |
| Normal Battery Depletion | 2 |
| Number of US Advisories (see pgs. 319, 321) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | <0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 4 | 0.02% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **5** | **0.02%** |




INCLUDING NORMAL BATTERY DEPLETION

| YEAR | 1 | 2 | 3 | 4 | AT 52 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.95% | 99.89% | 99.85% | 99.85% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.03% | 0.04% | 0.04% |
| SAMPLE SIZE | 21,430 | 14,570 | 8,810 | 3,640 | 360 |

EXCLUDING NORMAL BATTERY DEPLETION

| YEAR | 1 | 2 | 3 | 4 | AT 52 MONTHS |
|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.95% | 99.93% | 99.93% | 99.93% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.02% | 0.02% | 0.02% |

# Single-Chamber Pacemakers

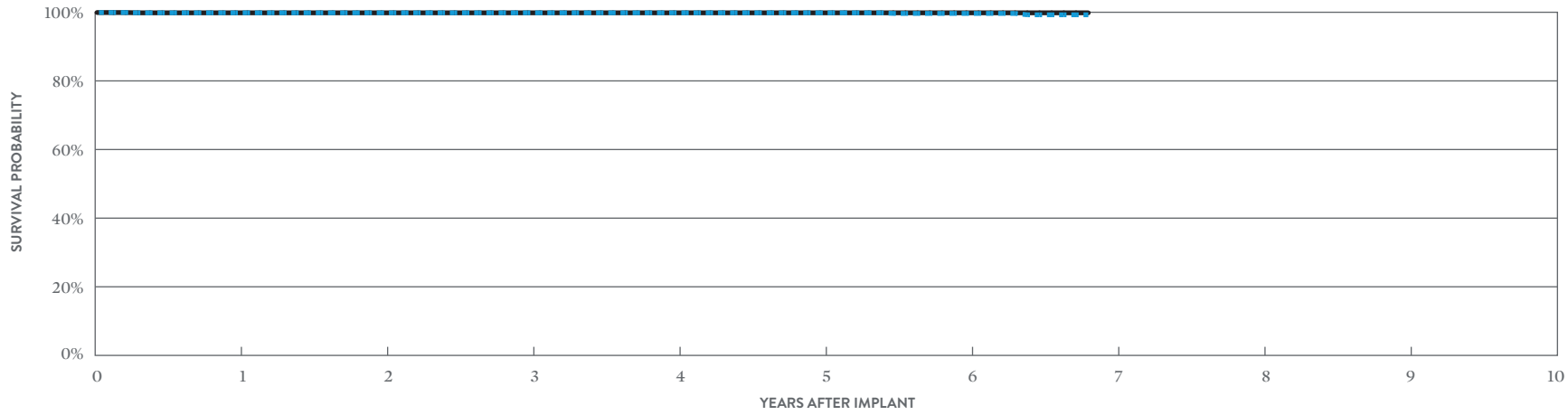
## CUSTOMER REPORTED PERFORMANCE DATA

## Endurity™ VR

### MODEL PM1160

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 2,549 |
| Estimated Active US Implants | 1,470 |
| Estimated Longevity | 14.6 Years |
| Normal Battery Depletion | 2 |
| Number of US Advisories (see pg. 319) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 1 | 0.04% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 1 | 0.04% |
| **Total** | **0** | **0.00%** | **2** | **0.08%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 82 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.66% | 99.26% |
| ± 1 STANDARD ERROR | 0.08% | 0.08% | 0.08% | 0.08% | 0.08% | 0.15% | 0.32% |
| SAMPLE SIZE | 2,360 | 2,070 | 1,870 | 1,690 | 1,460 | 1,040 | 250 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 82 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% |
| ± 1 STANDARD ERROR | 0.08% | 0.08% | 0.08% | 0.08% | 0.08% | 0.08% | 0.08% |

# Single-Chamber Pacemakers

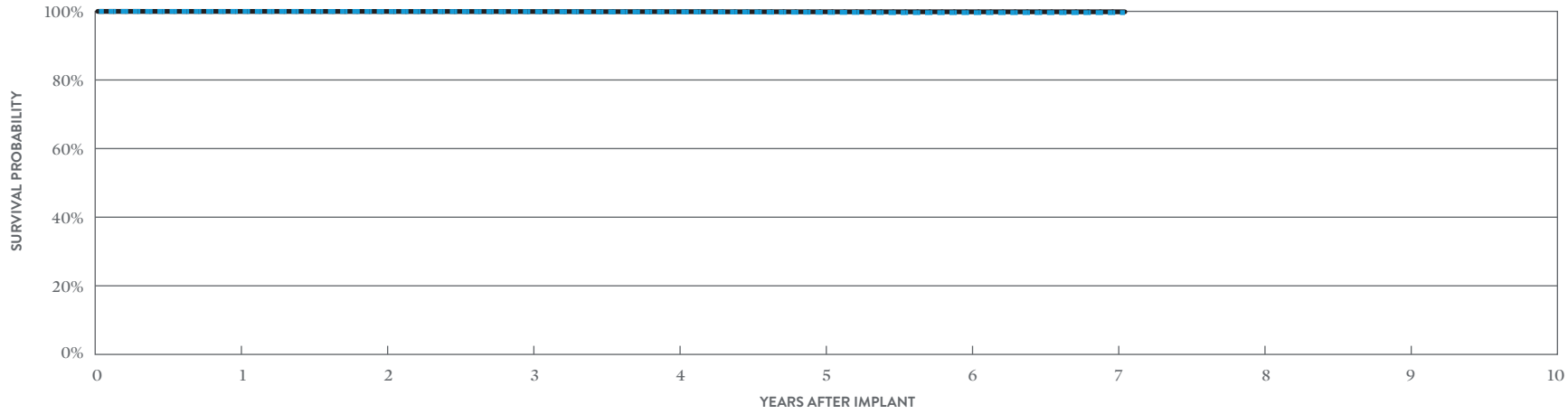
## CUSTOMER REPORTED PERFORMANCE DATA

## Assurity™ VR

### MODEL PM1240

| | |
|---|---|
| US Regulatory Approval | March 2014 |
| Registered US Implants | 28,536 |
| Estimated Active US Implants | 17,676 |
| Estimated Longevity | 14.1 Years |
| Normal Battery Depletion | 13 |
| Number of US Advisories (see pgs. 319, 321) | Two |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 4 | 0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 2 | <0.01% | 6 | 0.02% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **2** | **<0.01%** | **11** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.96% | 99.91% | 99.84% | 99.72% | 99.63% | 99.63% | 99.63% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.02% | 0.03% | 0.04% | 0.05% | 0.05% | 0.05% |
| SAMPLE SIZE | 26,700 | 23,690 | 21,290 | 18,450 | 13,910 | 7,830 | 2,430 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | AT 85 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.98% | 99.96% | 99.94% | 99.91% | 99.87% | 99.87% | 99.87% | 99.87% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.01% | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% |

# Single-Chamber Pacemakers

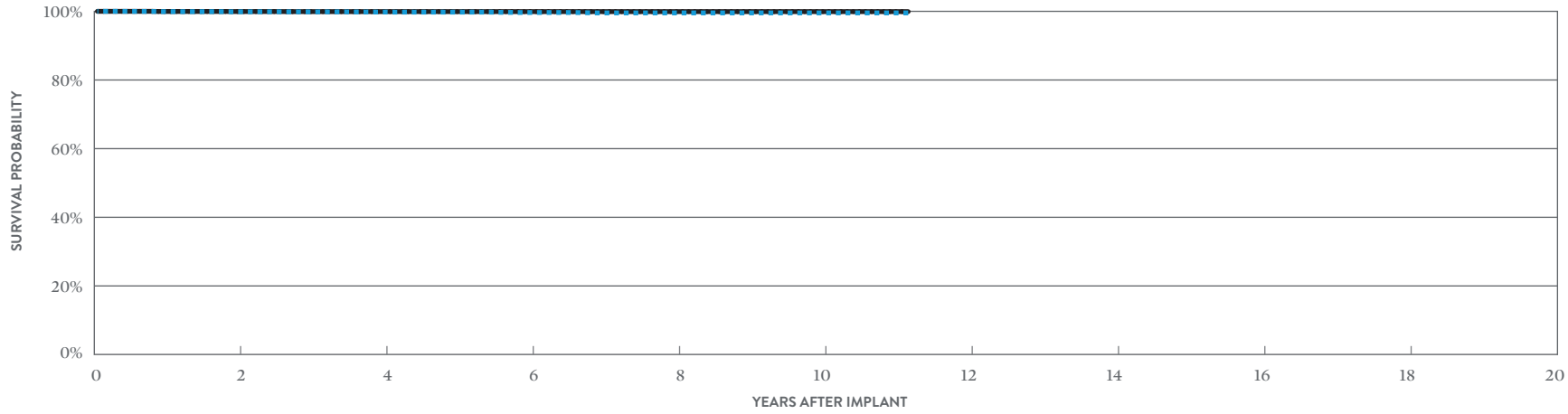
## CUSTOMER REPORTED PERFORMANCE DATA

## Accent™ SR

### MODEL PM1110

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 13,593 |
| Estimated Active US Implants | 5,808 |
| Estimated Longevity | 12.9 Years |
| Normal Battery Depletion | 15 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 2 | 0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **4** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 134 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.80% | 99.66% | 99.54% | 99.54% | 99.54% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.06% | 0.08% | 0.08% | 0.08% |
| SAMPLE SIZE | 10,760 | 8,590 | 7,260 | 5,300 | 1,960 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 134 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.92% | 99.92% | 99.92% | 99.92% | 99.92% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% |

# Single-Chamber Pacemakers

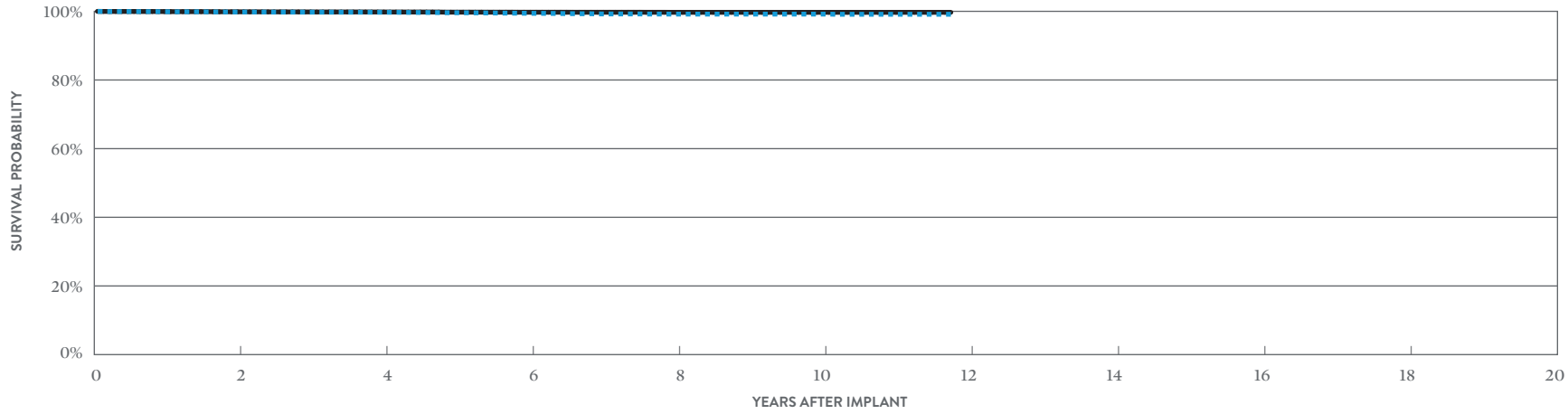
## CUSTOMER REPORTED PERFORMANCE DATA

## Accent™ SR RF

### MODEL PM1210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Registered US Implants | 39,813 |
| Estimated Active US Implants | 16,122 |
| Estimated Longevity | 10.9 Years |
| Normal Battery Depletion | 48 |
| Number of US Advisories (see pg. 321) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 3 | <0.01% | 11 | 0.03% |
| Electrical Interconnect | 1 | <0.01% | 3 | <0.01% |
| Battery | 0 | 0.00% | 1 | <0.01% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 4 | 0.01% |
| Possible Early Battery Depletion | 2 | <0.01% | 3 | <0.01% |
| Other | 0 | 0.00% | 8 | 0.02% |
| **Total** | **6** | **0.02%** | **31** | **0.08%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.80% | 99.73% | 99.42% | 99.19% | 99.19% | 99.14% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.05% | 0.06% | 0.06% | 0.07% |
| SAMPLE SIZE | 31,350 | 24,880 | 20,700 | 15,030 | 6,180 | 310 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.87% | 99.81% | 99.74% | 99.71% | 99.71% | 99.71% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% |

# Single-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Accent™ SR RF

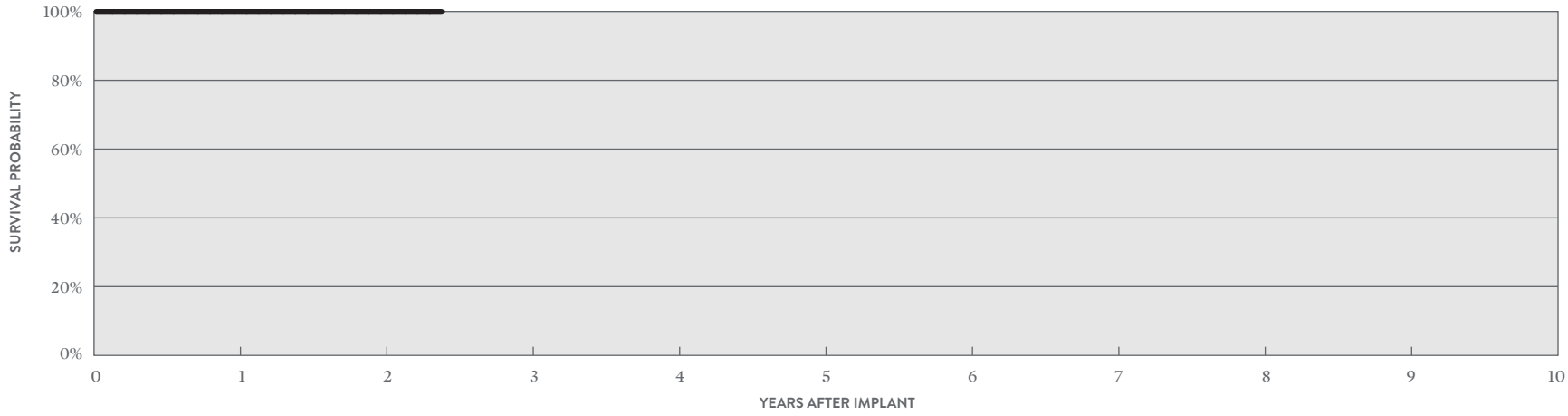
### MODEL PM1210

| | |
|---|---|
| US Regulatory Approval | July 2009 |
| Number of Devices Enrolled in Study | 236 |
| Active Devices Enrolled in Study | 10 |
| Cumulative Months of Follow-up | 6,142 |
| Estimated Longevity | 10.9 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | AT 29 MONTHS |
|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 200 | 120 | 50 |

# Single-Chamber Pacemakers

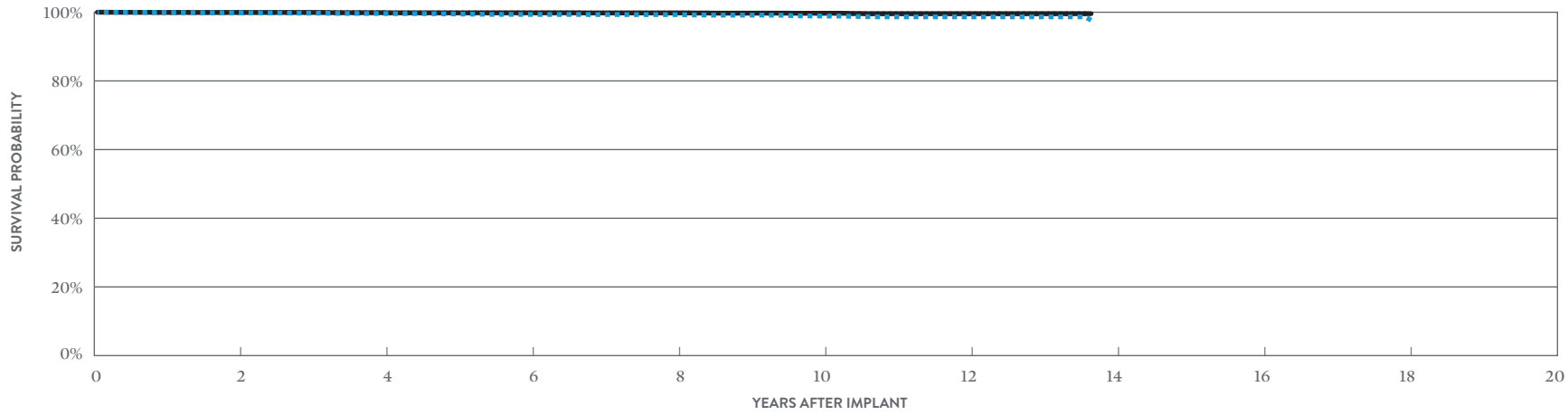
## CUSTOMER REPORTED PERFORMANCE DATA

## Zephyr™ XL SR

### MODEL 5626

| | |
|---|---|
| US Regulatory Approval | May 2007 |
| Registered US Implants | 20,658 |
| Estimated Active US Implants | 5,441 |
| Estimated Longevity | 15.8 Years |
| Normal Battery Depletion | 39 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 4 | 0.02% |
| Electrical Interconnect | 1 | <0.01% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | <0.01% | 12 | 0.06% |
| **Total** | **2** | **<0.01%** | **16** | **0.08%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 164 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.63% | 99.35% | 99.30% | 98.88% | 98.66% | 97.68% |
| ± 1 STANDARD ERROR | 0.03% | 0.05% | 0.07% | 0.08% | 0.11% | 0.13% | 0.13% |
| SAMPLE SIZE | 15,560 | 11,660 | 9,140 | 7,370 | 5,540 | 3,420 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 164 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.93% | 99.87% | 99.83% | 99.80% | 99.71% | 99.58% | 99.58% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.04% | 0.06% | 0.08% | 0.08% |

# Single-Chamber Pacemakers

## ACTIVELY MONITORED STUDY DATA

## Zephyr™ XL SR

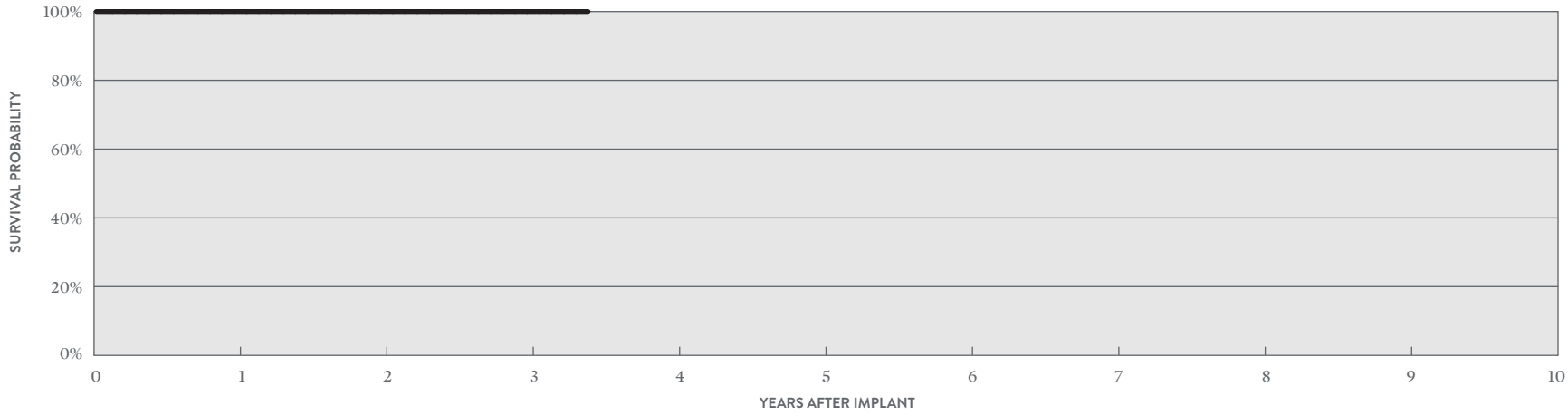
### MODEL 5626

| | |
|---|---|
| US Regulatory Approval | May 2007 |
| Number of Devices Enrolled in Study | 230 |
| Active Devices Enrolled in Study | 2 |
| Cumulative Months of Follow-up | 6,648 |
| Estimated Longevity | 15.8 Years |

**QUALIFYING COMPLICATIONS**

None Reported

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 0 | 0.00% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **0** | **0.00%** |




**ACTIVELY MONITORED STUDY DATA**

| YEAR | 1 | 2 | 3 | AT 41 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 100.00% | 100.00% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 0.00% | 0.00% |
| SAMPLE SIZE | 220 | 180 | 120 | 50 |

# Single-Chamber Pacemakers

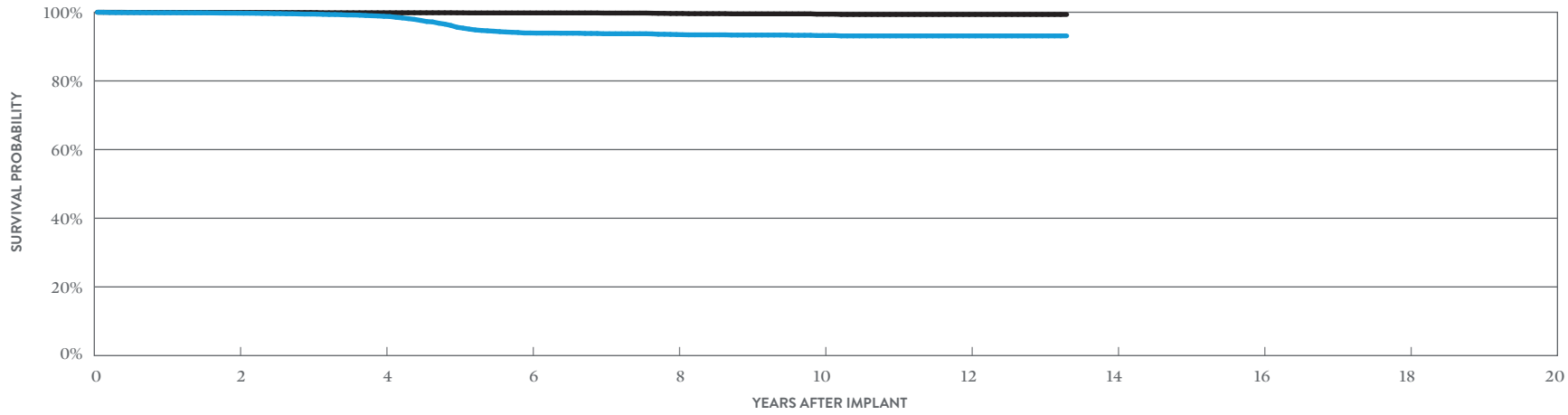
## CUSTOMER REPORTED PERFORMANCE DATA

## Zephyr™ SR

### MODEL 5620

| | |
|---|---|
| US Regulatory Approval | March 2007 |
| Registered US Implants | 17,510 |
| Estimated Active US Implants | 4,868 |
| Estimated Longevity | 8.8 Years |
| Normal Battery Depletion | 208 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 4 | 0.02% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 2 | 0.01% |
| Mechanical | 1 | <0.01% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 11 | 0.06% |
| **Total** | **1** | **<0.01%** | **17** | **0.10%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.74% | 98.81% | 93.96% | 93.51% | 93.21% | 93.11% | 93.11% |
| ± 1 STANDARD ERROR | 0.04% | 0.10% | 0.26% | 0.27% | 0.29% | 0.30% | 0.30% |
| SAMPLE SIZE | 12,610 | 9,350 | 7,070 | 4,860 | 2,620 | 1,200 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.85% | 99.80% | 99.63% | 99.44% | 99.34% | 99.34% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.04% | 0.07% | 0.11% | 0.13% | 0.13% |

# Single-Chamber Pacemakers

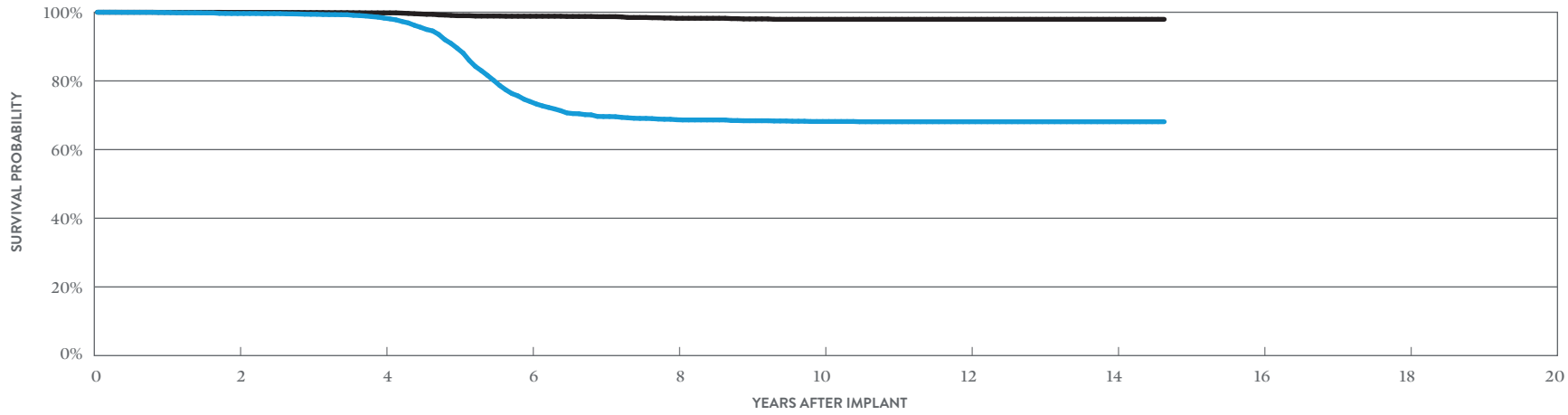
## CUSTOMER REPORTED PERFORMANCE DATA

## Victory™ SR

### MODEL 5610

| | |
|---|---|
| US Regulatory Approval | December 2005 |
| Registered US Implants | 13,690 |
| Estimated Active US Implants | 1,733 |
| Estimated Longevity | 8.8 Years |
| Normal Battery Depletion | 670 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 25 | 0.18% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | <0.01% |
| Other | 1 | <0.01% | 12 | 0.09% |
| **Total** | **1** | **<0.01%** | **39** | **0.28%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 176 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.63% | 98.30% | 73.97% | 68.69% | 68.18% | 68.11% | 68.11% | 68.11% |
| ± 1 STANDARD ERROR | 0.06% | 0.14% | 0.58% | 0.63% | 0.64% | 0.64% | 0.64% | 0.64% |
| SAMPLE SIZE | 9,950 | 6,930 | 4,460 | 2,670 | 1,930 | 1,620 | 880 | 240 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 176 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.96% | 99.82% | 98.84% | 98.24% | 97.94% | 97.94% | 97.94% | 97.94% |
| ± 1 STANDARD ERROR | 0.02% | 0.05% | 0.14% | 0.20% | 0.24% | 0.24% | 0.24% | 0.24% |

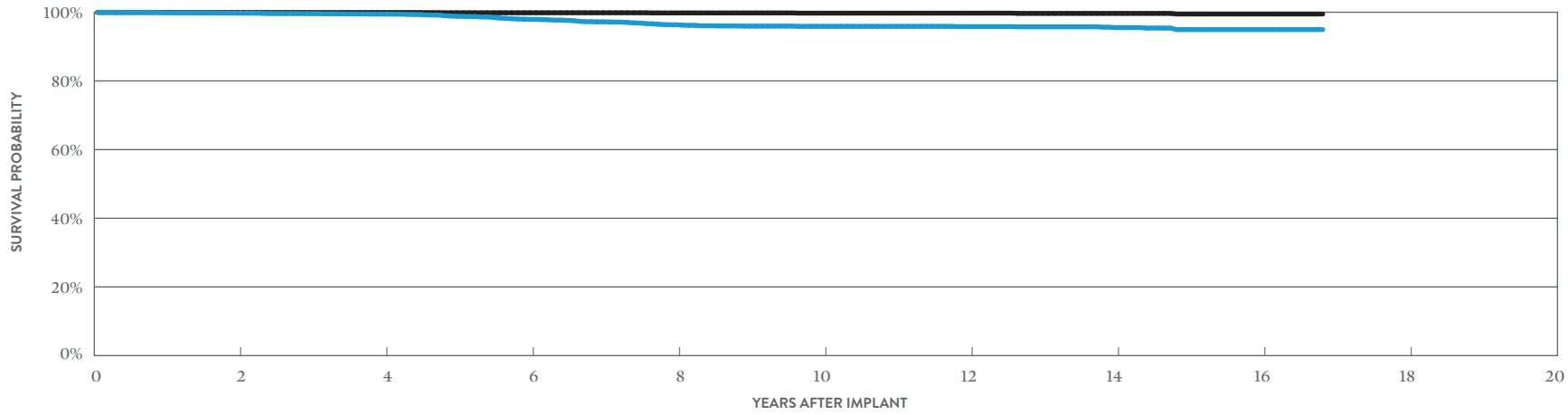
# Single-Chamber Pacemakers

## CUSTOMER REPORTED PERFORMANCE DATA

## Verity ADx™ XL SR MODEL 5156
## Verity ADx™ XL SR M/S MODEL 5157M/S
## Verity ADx™ XL SC MODEL 5056

| | |
|---|---|
| US Regulatory Approval | May 2003 |
| Registered US Implants | 14,515 |
| Estimated Active US Implants | 2,873 |
| Estimated Longevity | 10.2 Years |
| Normal Battery Depletion | 96 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 4 | 0.03% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 4 | 0.03% |
| **Total** | **1** | **<0.01%** | **10** | **0.07%** |




INCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 202 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.73% | 99.46% | 97.94% | 96.35% | 95.89% | 95.82% | 95.53% | 94.95% | 94.95% |
| ± 1 STANDARD ERROR | 0.05% | 0.07% | 0.17% | 0.25% | 0.27% | 0.28% | 0.29% | 0.37% | 0.37% |
| SAMPLE SIZE | 10,810 | 7,750 | 5,560 | 4,250 | 3,430 | 2,880 | 1,970 | 710 | 210 |

EXCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 202 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.91% | 99.91% | 99.85% | 99.80% | 99.74% | 99.74% | 99.66% | 99.48% | 99.48% |
| ± 1 STANDARD ERROR | 0.03% | 0.03% | 0.04% | 0.05% | 0.07% | 0.07% | 0.09% | 0.16% | 0.16% |

# Single-Chamber Pacemakers

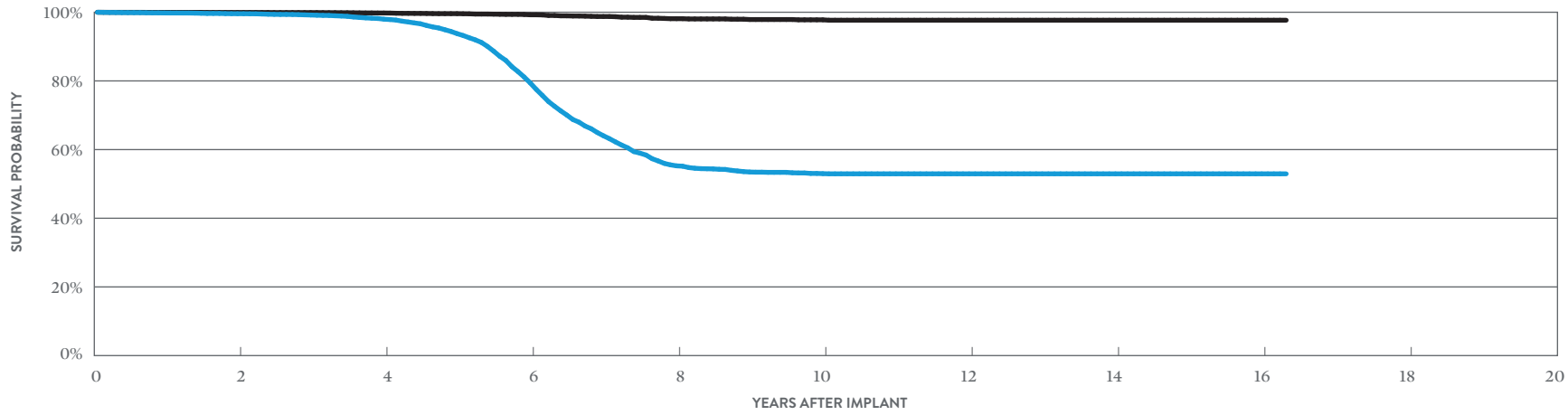
## CUSTOMER REPORTED PERFORMANCE DATA

## Identity ADx™ SR

### MODEL 5180

| | |
|---|---|
| US Regulatory Approval | May 2003 |
| Registered US Implants | 20,872 |
| Estimated Active US Implants | 1,733 |
| Estimated Longevity | 5.7 Years |
| Normal Battery Depletion | 1,243 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 35 | 0.17% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 6 | 0.03% |
| Mechanical | 0 | 0.00% | 1 | <0.01% |
| Possible Early Battery Depletion | 0 | 0.00% | 8 | 0.04% |
| Other | 0 | 0.00% | 8 | 0.04% |
| **Total** | **0** | **0.00%** | **58** | **0.28%** |




INCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.57% | 97.98% | 79.42% | 55.26% | 52.99% | 52.94% | 52.94% | 52.94% | 52.94% |
| ± 1 STANDARD ERROR | 0.05% | 0.12% | 0.44% | 0.62% | 0.63% | 0.64% | 0.64% | 0.64% | 0.64% |
| SAMPLE SIZE | 15,260 | 10,600 | 6,570 | 3,290 | 2,080 | 1,550 | 1,100 | 450 | 210 |

EXCLUDING NORMAL BATTERY DEPLETION

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 196 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.94% | 99.78% | 99.25% | 98.12% | 97.79% | 97.68% | 97.68% | 97.68% | 97.68% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.09% | 0.20% | 0.23% | 0.24% | 0.24% | 0.24% | 0.24% |

# Single-Chamber Pacemakers

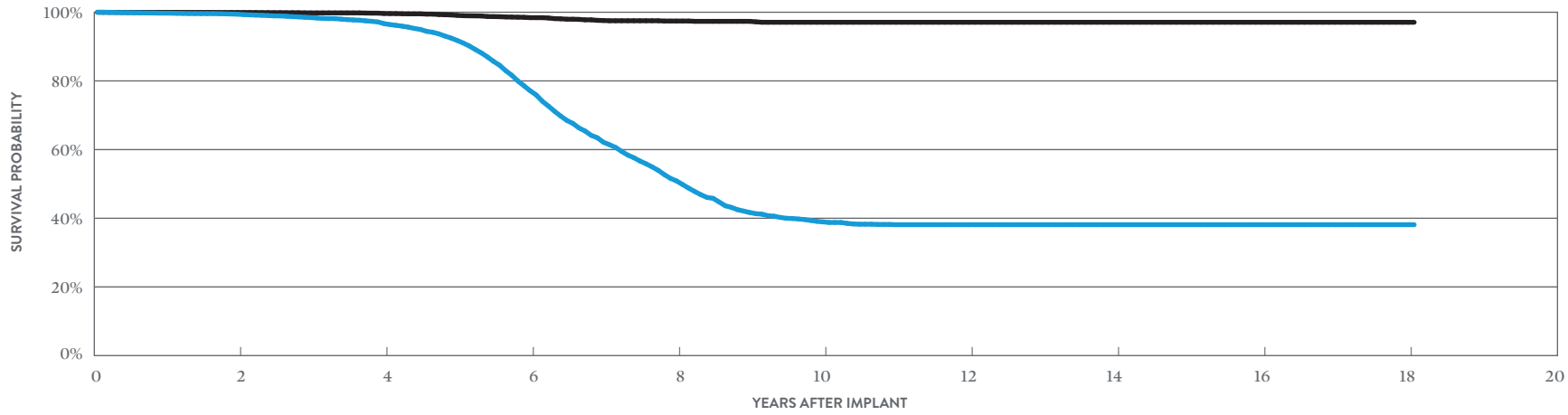
## CUSTOMER REPORTED PERFORMANCE DATA

## Identity™ SR

### MODEL 5172

| | |
|---|---|
| US Regulatory Approval | November 2001 |
| Registered US Implants | 21,885 |
| Estimated Active US Implants | 973 |
| Estimated Longevity | 7.8 Years |
| Normal Battery Depletion | 1,474 |
| Number of US Advisories (see pg. 324) | One |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 1 | <0.01% | 62 | 0.28% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 1 | <0.01% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 8 | 0.04% |
| Other | 0 | 0.00% | 6 | 0.03% |
| **Total** | **1** | **<0.01%** | **77** | **0.35%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 217 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.43% | 96.69% | 77.12% | 50.87% | 38.94% | 38.12% | 38.12% | 38.12% | 38.12% | 38.12% |
| ± 1 STANDARD ERROR | 0.05% | 0.14% | 0.45% | 0.65% | 0.70% | 0.71% | 0.71% | 0.71% | 0.71% | 0.71% |
| SAMPLE SIZE | 16,180 | 11,330 | 6,510 | 2,730 | 1,340 | 1,040 | 950 | 680 | 290 | 200 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | AT 217 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.92% | 99.63% | 98.42% | 97.44% | 97.08% | 97.08% | 97.08% | 97.08% | 97.08% | 97.08% |
| ± 1 STANDARD ERROR | 0.02% | 0.04% | 0.13% | 0.21% | 0.26% | 0.26% | 0.26% | 0.26% | 0.26% | 0.26% |

# Single-Chamber Pacemakers

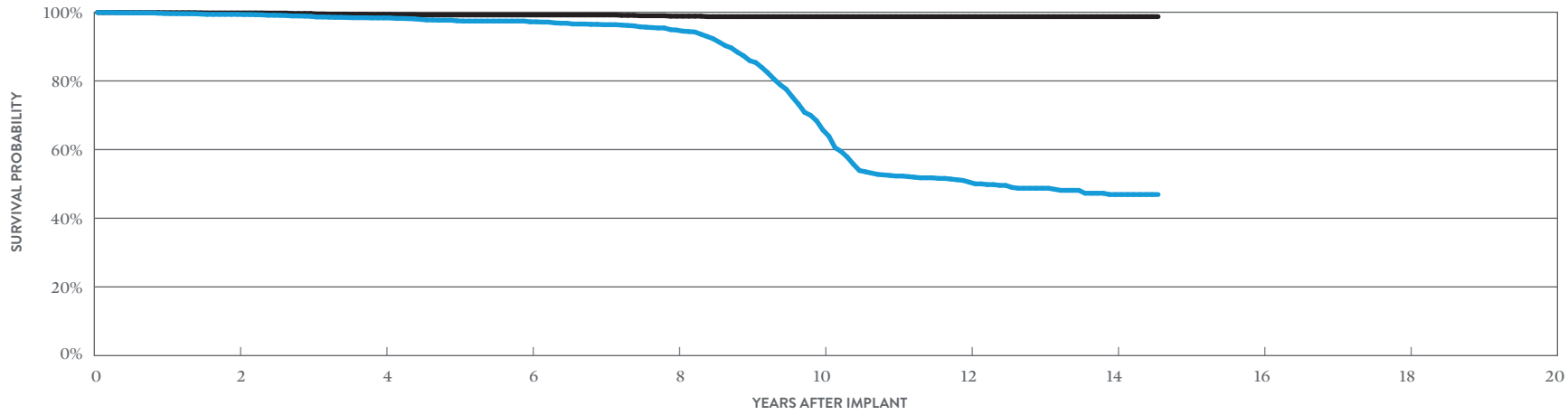
## CUSTOMER REPORTED PERFORMANCE DATA

## Microny™

### MODELS 2425T, 2525T & 2535K

| | |
|---|---|
| US Regulatory Approval | April 2001 |
| Registered US Implants | 7,922 |
| Estimated Active US Implants | 1,467 |
| Estimated Longevity | 7.5 Years |
| Normal Battery Depletion | 312 |
| Number of US Advisories | None |

| | MALFUNCTIONS W/ COMPROMISED THERAPY | | MALFUNCTIONS W/O COMPROMISED THERAPY | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Electrical Component | 0 | 0.00% | 1 | 0.01% |
| Electrical Interconnect | 0 | 0.00% | 0 | 0.00% |
| Battery | 0 | 0.00% | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% | 0 | 0.00% |
| Mechanical | 0 | 0.00% | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% | 1 | 0.01% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **0** | **0.00%** | **2** | **0.03%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 175 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.38% | 98.35% | 97.21% | 94.81% | 65.73% | 50.52% | 46.91% | 46.91% |
| ± 1 STANDARD ERROR | 0.10% | 0.19% | 0.25% | 0.44% | 1.22% | 1.34% | 1.43% | 1.43% |
| SAMPLE SIZE | 5,260 | 3,640 | 2,490 | 1,700 | 1,060 | 570 | 300 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 175 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.79% | 99.34% | 99.21% | 98.86% | 98.72% | 98.72% | 98.72% | 98.72% |
| ± 1 STANDARD ERROR | 0.06% | 0.12% | 0.14% | 0.20% | 0.22% | 0.22% | 0.22% | 0.22% |

SUMMARY INFORMATION

# Single-Chamber Pacemakers

## Single-Chamber Pacemakers

# Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM1272 | AssurityMRI™ | 99.98% | 99.95% | 99.89% | 99.85% | | | | | | |
| PM1160 | Endurity™ SR | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.66% | | | | |
| PM1240 | Assurity™ SR | 99.98% | 99.96% | 99.91% | 99.84% | 99.72% | 99.63% | 99.63% | | | |
| PM1110 | Accent™ SR | 99.92% | 99.87% | 99.85% | 99.80% | 99.77% | 99.66% | 99.54% | 99.54% | 99.54% | 99.54% |
| PM1210 | Accent™ SR RF | 99.89% | 99.80% | 99.76% | 99.73% | 99.60% | 99.42% | 99.24% | 99.19% | 99.19% | 99.19% |
| 5626 | Zephyr™ XL SR | 99.92% | 99.83% | 99.73% | 99.63% | 99.47% | 99.35% | 99.32% | 99.30% | 99.15% | 98.88% |
| 5620 | Zephyr™ SR | 99.86% | 99.74% | 99.47% | 98.81% | 95.62% | 93.96% | 93.74% | 93.51% | 93.36% | 93.21% |
| 5610 | Victory™ SR | 99.92% | 99.63% | 99.40% | 98.30% | 89.56% | 73.97% | 69.62% | 68.69% | 68.40% | 68.18% |
| 5156/5157/5056 | Verity ADx™ XL SR/SR(M/S)/SC | 99.87% | 99.73% | 99.60% | 99.46% | 98.82% | 97.94% | 97.21% | 96.35% | 95.95% | 95.89% |
| 5180 | Identity ADx™ SR | 99.79% | 99.57% | 99.19% | 97.98% | 93.77% | 79.42% | 64.03% | 55.26% | 53.47% | 52.99% |
| 5172 | Identity™ SR | 99.74% | 99.43% | 98.44% | 96.69% | 91.80% | 77.12% | 62.15% | 50.87% | 41.67% | 38.94% |
| 2425T/2525T/2535T | Microny™ | 99.64% | 99.38% | 98.82% | 98.35% | 97.50% | 97.21% | 96.37% | 94.81% | 85.90% | 65.73% |

## Single-Chamber Pacemakers

# Survival Probability Summary

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM1272 | AssurityMRI™ | 99.98% | 99.95% | 99.93% | 99.93% | | | | | | |
| PM1160 | Endurity™ SR | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | 99.84% | | | | |
| PM1240 | Assurity™ SR | 99.98% | 99.96% | 99.94% | 99.91% | 99.87% | 99.87% | 99.87% | | | |
| PM1110 | Accent™ SR | 99.96% | 99.94% | 99.92% | 99.92% | 99.92% | 99.92% | 99.92% | 99.92% | 99.92% | 99.92% |
| PM1210 | Accent™ SR RF | 99.93% | 99.87% | 99.83% | 99.81% | 99.76% | 99.74% | 99.73% | 99.71% | 99.71% | 99.71% |
| 5626 | Zephyr™ XL SR | 99.94% | 99.93% | 99.93% | 99.87% | 99.83% | 99.83% | 99.80% | 99.80% | 99.74% | 99.71% |
| 5620 | Zephyr™ SR | 99.97% | 99.94% | 99.92% | 99.85% | 99.83% | 99.80% | 99.76% | 99.63% | 99.53% | 99.44% |
| 5610 | Victory™ SR | 99.98% | 99.96% | 99.91% | 99.82% | 98.99% | 98.84% | 98.72% | 98.24% | 98.05% | 97.94% |
| 5156/5157/5056 | Verity ADx™ XL SR/SR(M/S)/SC | 99.97% | 99.91% | 99.91% | 99.91% | 99.85% | 99.85% | 99.85% | 99.80% | 99.80% | 99.74% |
| 5180 | Identity ADx™ SR | 99.96% | 99.94% | 99.91% | 99.78% | 99.59% | 99.25% | 98.76% | 98.12% | 97.88% | 97.79% |
| 5172 | Identity™ SR | 99.97% | 99.92% | 99.81% | 99.63% | 99.09% | 98.42% | 97.59% | 97.44% | 97.35% | 97.08% |
| 2425T/2525T/2535T | Microny™ | 99.87% | 99.79% | 99.63% | 99.34% | 99.21% | 99.21% | 99.21% | 98.86% | 98.72% | 98.72% |

# Single-Chamber Pacemakers
## US Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1272 | Assurity MRI™ | 25,351 | 3.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM1160 | Endurity™ SR | 2,549 | 5.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM1240 | Assurity™ SR | 28,536 | 5.60% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | **2** | **<0.01%** |
| PM1110 | Accent™ SR | 13,593 | 7.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM1210 | Accent™ SR RF | 39,813 | 7.70% | 3 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 0 | 0.00% | **6** | **0.02%** |
| 5626 | Zephyr™ XL SR | 20,658 | 11.40% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | **2** | **<0.01%** |
| 5620 | Zephyr™ SR | 17,510 | 11.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| 5610 | Victory™ SR | 13,690 | 15.70% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | **1** | **<0.01%** |
| 5156/5157/5056 | Verity ADx™ XL SR/SR(M/S)/SC | 14,515 | 7.80% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| 5180 | Identity ADx™ SR | 20,872 | 13.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5172 | Identity™ SR | 21,885 | 11.60% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| 2425T/2525T/2535T | Microny™ | 7,922 | 7.40% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Single-Chamber Pacemakers
## US Malfunction Summary

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1272 | Assurity MRI™ | 25,351 | 3.30% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 0 | 0.00% | 0 | 0.00% | **5** | **0.02%** |
| PM1160 | Endurity™ SR | 2,549 | 5.50% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 1 | 0.04% | **2** | **0.08%** |
| PM1240 | Assurity™ SR | 28,536 | 5.60% | 4 | 0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 6 | 0.02% | 0 | 0.00% | 0 | 0.00% | **11** | **0.04%** |
| PM1110 | Accent™ SR | 13,593 | 7.80% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | **4** | **0.03%** |
| PM1210 | Accent™ SR RF | 39,813 | 7.70% | 11 | 0.03% | 3 | <0.01% | 1 | <0.01% | 1 | <0.01% | 4 | 0.01% | 3 | <0.01% | 8 | 0.02% | **31** | **0.08%** |
| 5626 | Zephyr™ XL SR | 20,658 | 11.40% | 4 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 12 | 0.06% | **16** | **0.08%** |
| 5620 | Zephyr™ SR | 17,510 | 11.70% | 4 | 0.02% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 11 | 0.06% | **17** | **0.10%** |
| 5610 | Victory™ SR | 13,690 | 15.70% | 25 | 0.18% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 12 | 0.09% | **39** | **0.28%** |
| 5156/5157/5056 | Verity ADx™ XL SR/SR(M/S)/SC | 14,515 | 7.80% | 4 | 0.03% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 1 | <0.01% | 0 | 0.00% | 4 | 0.03% | **10** | **0.07%** |
| 5180 | Identity ADx™ SR | 20,872 | 13.40% | 35 | 0.17% | 0 | 0.00% | 0 | 0.00% | 6 | 0.03% | 1 | <0.01% | 8 | 0.04% | 8 | 0.04% | **58** | **0.28%** |
| 5172 | Identity™ SR | 21,885 | 11.60% | 62 | 0.28% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 8 | 0.04% | 6 | 0.03% | **77** | **0.35%** |
| 2425T/2525T/2535T | Microny™ | 7,922 | 7.40% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | **2** | **0.03%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Single-Chamber Pacemakers
Worldwide Malfunction Summary

### WITH COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1272 | Assurity MRI™ | 105,526 | 0.85% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | **3** | **<0.01%** |
| PM1160 | Endurity™ SR | 27,135 | 0.77% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **<0.01%** |
| PM1240 | Assurity™ SR | 32,227 | 4.75% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | **2** | **0.01%** |
| PM1110 | Accent™ SR | 57,702 | 2.18% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| PM1210 | Accent™ SR RF | 49,582 | 6.29% | 5 | 0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 0 | 0.00% | **8** | **0.02%** |

### WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1272 | Assurity MRI™ | 105,526 | 0.85% | 2 | <0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | <0.01% | 0 | 0.00% | 0 | 0.00% | **6** | **0.01%** |
| PM1160 | Endurity™ SR | 27,135 | 0.77% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 1 | <0.01% | **4** | **0.01%** |
| PM1240 | Assurity™ SR | 32,227 | 4.75% | 5 | 0.02% | 0 | 0.00% | 0 | 0.00% | 1 | <0.01% | 6 | 0.02% | 0 | 0.00% | 0 | 0.00% | **12** | **0.04%** |
| PM1110 | Accent™ SR | 57,702 | 2.18% | 4 | 0.01% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 0 | 0.00% | 1 | <0.01% | 3 | 0.01% | **10** | **0.02%** |
| PM1210 | Accent™ SR RF | 49,582 | 6.29% | 14 | 0.03% | 4 | 0.01% | 1 | <0.01% | 1 | <0.01% | 4 | 0.01% | 3 | 0.01% | 10 | 0.02% | **37** | **0.07%** |

*Definitions of malfunction categories can be found on pages 5-6.*

## Single-Chamber Pacemakers

Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | LOSS OF TELEMETRY | | PERICARDIAL EFFUSION | | PREMATURE BATTERY DEPLETION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1210 | 236 | 10 | 6,142 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5626 | 230 | 2 | 6,648 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

### MALFUNCTIONS WITH COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRM-WARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1210 | Accent™ VR | 236 | 9.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5626 | Zephyr™ XL SR | 230 | 14.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

### MALFUNCTIONS WITHOUT COMPROMISED THERAPY

| MODELS | FAMILY | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRM-WARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| PM1210 | Accent™ VR | 236 | 9.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 5626 | Zephyr™ XL SR | 230 | 14.80% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |

*A list of of complications can be found on page 12.*
*Definitions of malfunction categories can be found on pages 5-6.*

# Pacing Leads

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

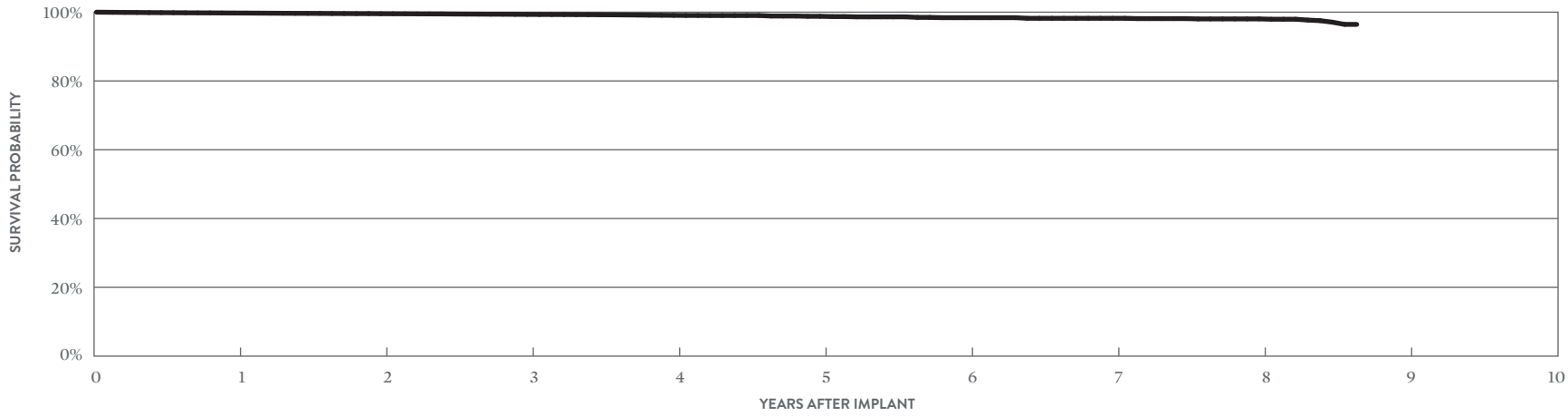
## Tendril MRI™

### MODEL LPA1200M

| | |
|---|---|
| US Regulatory Approval | January 2017 |
| Registered US Implants | 167,469 |
| Estimated Active US Implants | 112,498 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 42 | 0.03% | 18 | 0.01% |
| Conductor Fracture | 3 | <0.01% | 68 | 0.04% |
| Lead Dislodgement | 364 | 0.22% | 370 | 0.22% |
| Failure to Capture | 56 | 0.03% | 199 | 0.12% |
| Oversensing | 18 | 0.01% | 338 | 0.20% |
| Failure to Sense | 26 | 0.02% | 38 | 0.02% |
| Insulation Breach | 1 | <0.01% | 20 | 0.01% |
| Abnormal Pacing Impedance | 2 | <0.01% | 44 | 0.03% |
| Extracardiac Stimulation | 6 | <0.01% | 10 | <0.01% |
| Other | 61 | 0.04% | 33 | 0.02% |
| **Total** | **579** | **0.35%** | **1138** | **0.68%** |
| **Total Returned for Analysis** | **216** | | **329** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 43 | 0.03% |
| Insulation Breach | 65 | 0.04% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 7 | <0.01% |
| Extrinsic Factors | 223 | 0.13% |
| **Total** | **338** | **0.20%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | AT 104 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.75% | 99.55% | 99.35% | 99.08% | 98.80% | 98.40% | 98.22% | 98.04% | 96.45% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.02% | 0.04% | 0.14% | 0.23% | 0.26% | 0.29% | 0.67% |
| SAMPLE SIZE | 151,060 | 121,960 | 88,590 | 41,910 | 8,580 | 1,220 | 1,140 | 1,080 | 240 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

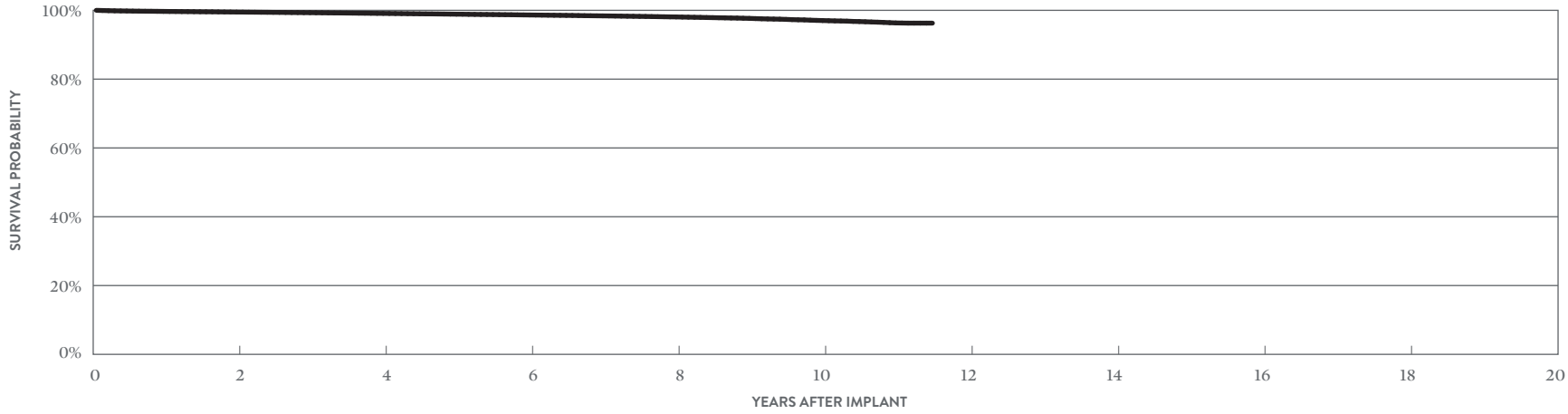
# Tendril™ STS

## MODEL 2088TC

| | |
|---|---|
| US Regulatory Approval | May 2009 |
| Registered US Implants | 918,999 |
| Estimated Active US Implants | 516,982 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 213 | 0.02% | 110 | 0.01% |
| Conductor Fracture | 9 | <0.01% | 402 | 0.04% |
| Lead Dislodgement | 1312 | 0.14% | 1864 | 0.20% |
| Failure to Capture | 375 | 0.04% | 1528 | 0.17% |
| Oversensing | 106 | 0.01% | 5006 | 0.54% |
| Failure to Sense | 55 | <0.01% | 204 | 0.02% |
| Insulation Breach | 19 | <0.01% | 383 | 0.04% |
| Abnormal Pacing Impedance | 49 | <0.01% | 342 | 0.04% |
| Extracardiac Stimulation | 10 | <0.01% | 65 | <0.01% |
| Other | 207 | 0.02% | 296 | 0.03% |
| **Total** | **2355** | **0.26%** | **10200** | **1.11%** |
| **Total Returned for Analysis** | **826** | | **2777** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 86 | <0.01% |
| Insulation Breach | 1123 | 0.12% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 33 | <0.01% |
| Extrinsic Factors | 1871 | 0.20% |
| **Total** | **3113** | **0.34%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 138 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.50% | 99.11% | 98.65% | 98.08% | 97.03% | 96.28% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.02% | 0.03% | 0.05% | 0.10% |
| SAMPLE SIZE | 619,310 | 413,020 | 263,230 | 138,470 | 48,720 | 240 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

## ACTIVELY MONITORED STUDY DATA

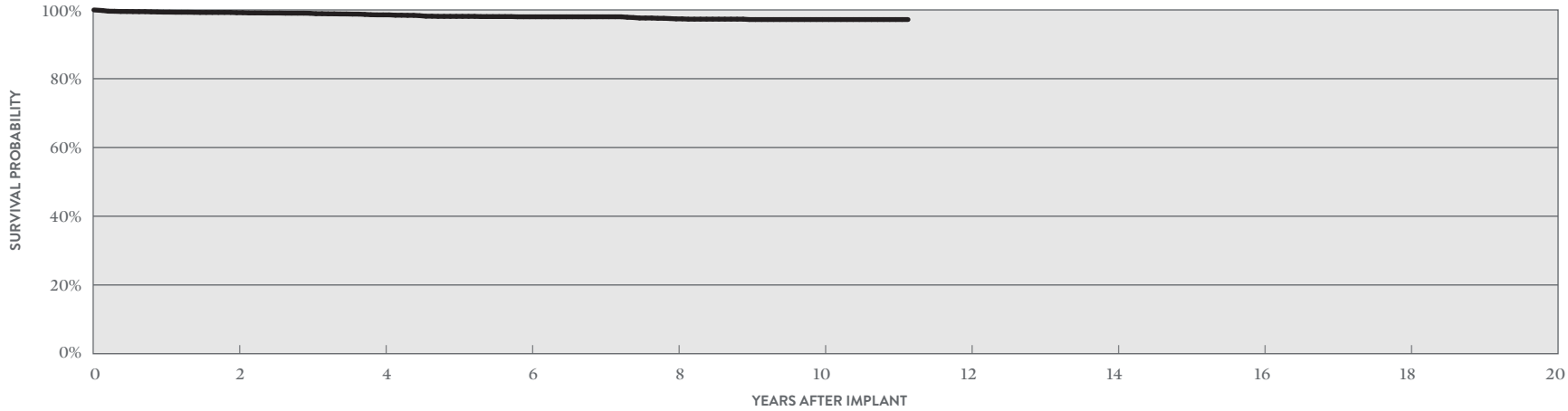
# Tendril™ STS

## MODEL 2088TC

| | |
|---|---|
| US Regulatory Approval | May 2009 |
| Number of Devices Enrolled in Study | 3,886 |
| Active Devices Enrolled in Study | 1,216 |
| Cumulative Months of Follow-up | 244,633 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.03% |
| Cardiac Perforation | 1 | 0.03% |
| Conductor Fracture | 8 | 0.21% |
| Extracardiac Stimulation | 1 | 0.03% |
| Failure to Capture | 11 | 0.28% |
| Failure to Sense | 4 | 0.10% |
| Insulation Breach | 8 | 0.21% |
| Lead Dislodgement | 15 | 0.39% |
| Oversensing | 16 | 0.41% |
| Pericardial Effusion | 1 | 0.03% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.03% |
| Insulation Breach | 15 | 0.39% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 13 | 0.33% |
| **Total** | **29** | **0.75%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 134 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.20% | 98.57% | 98.01% | 97.40% | 97.21% | 97.21% |
| ± 1 STANDARD ERROR | 0.14% | 0.22% | 0.27% | 0.34% | 0.37% | 0.37% |
| SAMPLE SIZE | 3,260 | 2,370 | 1,710 | 1,290 | 670 | 70 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

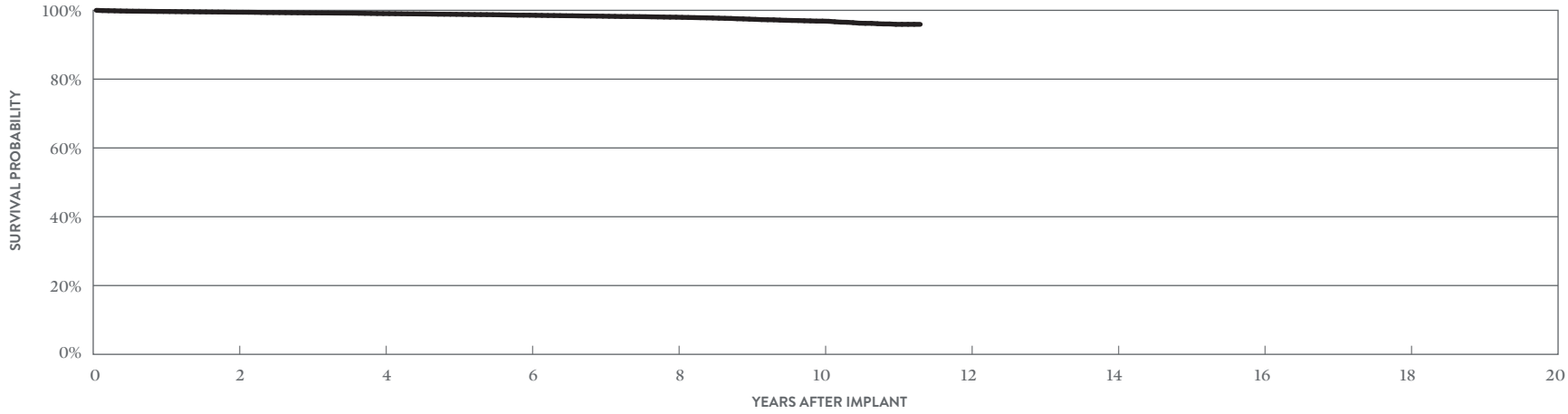
## OptiSense™

### MODEL 1999

| | |
|---|---|
| US Regulatory Approval | May 2007 |
| Registered US Implants | 47,419 |
| Estimated Active US Implants | 22,669 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 4 | <0.01% | 2 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 17 | 0.04% |
| Lead Dislodgement | 64 | 0.13% | 186 | 0.39% |
| Failure to Capture | 8 | 0.02% | 93 | 0.20% |
| Oversensing | 10 | 0.02% | 431 | 0.91% |
| Failure to Sense | 3 | <0.01% | 44 | 0.09% |
| Insulation Breach | 1 | <0.01% | 54 | 0.11% |
| Abnormal Pacing Impedance | 0 | 0.00% | 20 | 0.04% |
| Extracardiac Stimulation | 0 | 0.00% | 2 | <0.01% |
| Other | 14 | 0.03% | 25 | 0.05% |
| **Total** | **104** | **0.22%** | **874** | **1.84%** |
| **Total Returned for Analysis** | **59** | | **240** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 7 | 0.01% |
| Insulation Breach | 85 | 0.18% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 7 | 0.01% |
| Extrinsic Factors | 176 | 0.37% |
| **Total** | **275** | **0.58%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 136 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.46% | 99.05% | 98.59% | 98.01% | 96.87% | 95.93% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.06% | 0.09% | 0.15% | 0.26% |
| SAMPLE SIZE | 39,830 | 32,520 | 23,980 | 14,130 | 5,880 | 220 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

## ACTIVELY MONITORED STUDY DATA

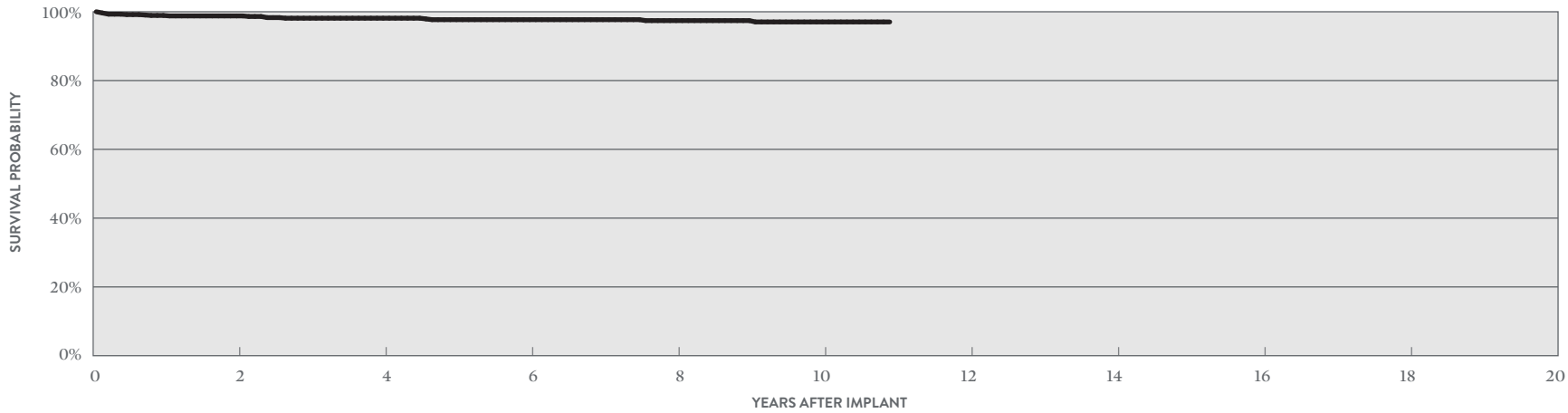
# OptiSense™

## MODEL 1999

| | |
|---|---|
| US Regulatory Approval | October 2009 |
| Number of Devices Enrolled in Study | 877 |
| Active Devices Enrolled in Study | 361 |
| Cumulative Months of Follow-up | 57,389 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.11% |
| Conductor Fracture | 2 | 0.23% |
| Failure to Sense | 2 | 0.23% |
| Insulation Breach | 1 | 0.11% |
| Lead Dislodgement | 11 | 1.25% |
| Oversensing | 1 | 0.11% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 6 | 0.68% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 10 | 1.14% |
| **Total** | **16** | **1.82%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 131 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.79% | 98.13% | 97.70% | 97.43% | 97.04% | 97.04% |
| ± 1 STANDARD ERROR | 0.38% | 0.50% | 0.59% | 0.64% | 0.75% | 0.75% |
| SAMPLE SIZE | 700 | 510 | 410 | 350 | 200 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

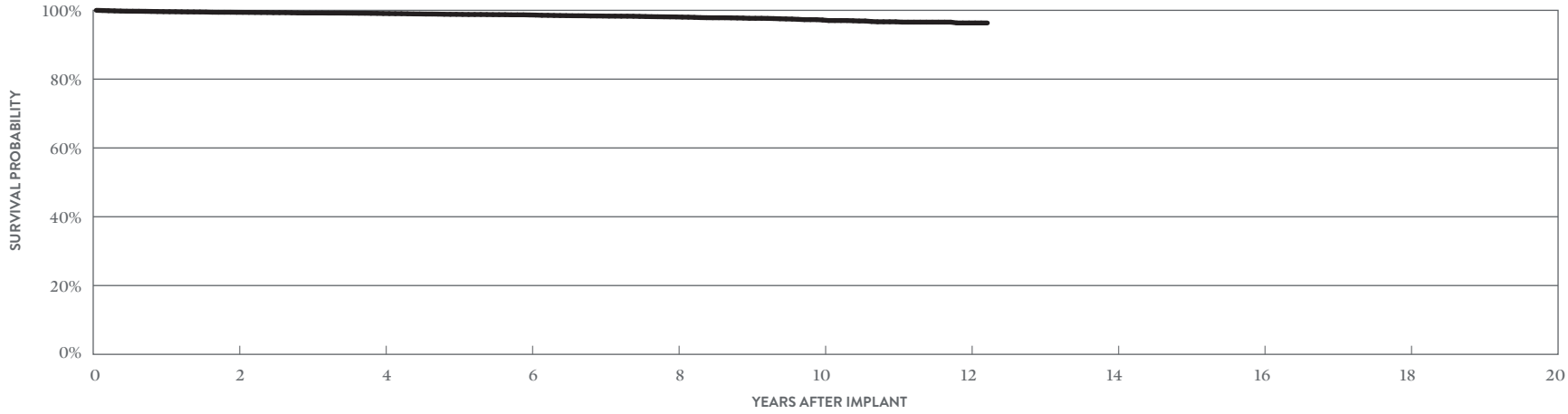
## IsoFlex™ Optim™

### MODEL 1944

| | |
|---|---|
| US Regulatory Approval | March 2008 |
| Registered US Implants | 19,672 |
| Estimated Active US Implants | 9,320 |
| Insulation | Optim™* |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 1 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 12 | 0.06% |
| Lead Dislodgement | 99 | 0.50% | 68 | 0.35% |
| Failure to Capture | 13 | 0.07% | 48 | 0.24% |
| Oversensing | 1 | <0.01% | 152 | 0.77% |
| Failure to Sense | 3 | 0.02% | 11 | 0.06% |
| Insulation Breach | 0 | 0.00% | 9 | 0.05% |
| Abnormal Pacing Impedance | 0 | 0.00% | 5 | 0.03% |
| Extracardiac Stimulation | 3 | 0.02% | 1 | <0.01% |
| Other | 4 | 0.02% | 5 | 0.03% |
| **Total** | **123** | **0.63%** | **312** | **1.59%** |
| **Total Returned for Analysis** | **59** | | **49** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 17 | 0.09% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 38 | 0.19% |
| **Total** | **56** | **0.28%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 147 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.42% | 99.08% | 98.66% | 98.08% | 97.19% | 96.33% | 96.33% |
| ± 1 STANDARD ERROR | 0.06% | 0.08% | 0.10% | 0.14% | 0.22% | 0.39% | 0.39% |
| SAMPLE SIZE | 15,080 | 11,190 | 8,120 | 5,090 | 2,490 | 640 | 220 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

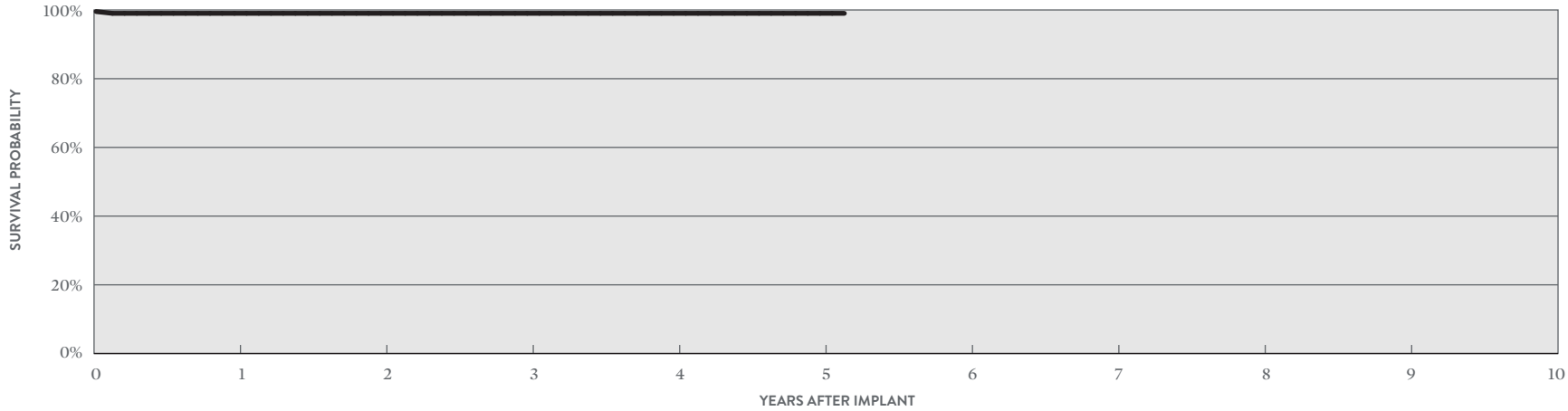
# IsoFlex™ Optim™

## MODEL 1944

| | |
|---|---|
| US Regulatory Approval | March 2008 |
| Number of Devices Enrolled in Study | 104 |
| Active Devices Enrolled in Study | 28 |
| Cumulative Months of Follow-up | 6,902 |
| Insulation | Optim™* |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Lead Dislodgement | 1 | 0.96% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **0** | **0.00%** |




| YEAR | 1 | 2 | 3 | 5 | 4 | AT 62 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.02% | 99.02% | 99.02% | 99.02% | 99.02% | 99.02% |
| ± 1 STANDARD ERROR | 0.97% | 0.97% | 0.97% | 0.97% | 0.97% | 0.97% |
| SAMPLE SIZE | 100 | 80 | 70 | 60 | 60 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

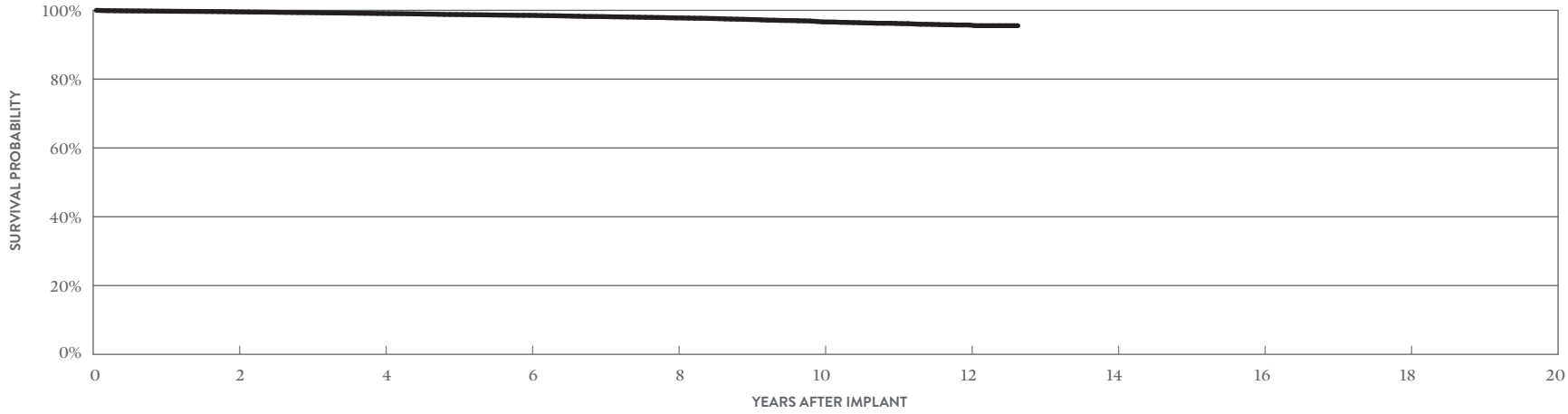
## IsoFlex™ Optim™

### MODEL 1948

| | |
|---|---|
| US Regulatory Approval | March 2008 |
| Registered US Implants | 73,132 |
| Estimated Active US Implants | 34,534 |
| Insulation | Optim™* |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 5 | <0.01% | 12 | 0.02% |
| Conductor Fracture | 1 | <0.01% | 117 | 0.16% |
| Lead Dislodgement | 72 | 0.10% | 83 | 0.11% |
| Failure to Capture | 49 | 0.07% | 246 | 0.34% |
| Oversensing | 3 | <0.01% | 439 | 0.60% |
| Failure to Sense | 2 | <0.01% | 5 | <0.01% |
| Insulation Breach | 4 | <0.01% | 96 | 0.13% |
| Abnormal Pacing Impedance | 1 | <0.01% | 52 | 0.07% |
| Extracardiac Stimulation | 2 | <0.01% | 7 | <0.01% |
| Other | 8 | 0.01% | 25 | 0.03% |
| **Total** | **147** | **0.20%** | **1082** | **1.48%** |
| **Total Returned for Analysis** | **66** | | **171** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 17 | 0.02% |
| Insulation Breach | 141 | 0.19% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 99 | 0.14% |
| **Total** | **258** | **0.35%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 152 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.56% | 99.08% | 98.54% | 97.79% | 96.64% | 95.74% | 95.54% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.06% | 0.08% | 0.13% | 0.22% | 0.26% |
| SAMPLE SIZE | 56,800 | 42,570 | 30,010 | 18,230 | 8,380 | 2,170 | 260 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

## ACTIVELY MONITORED STUDY DATA

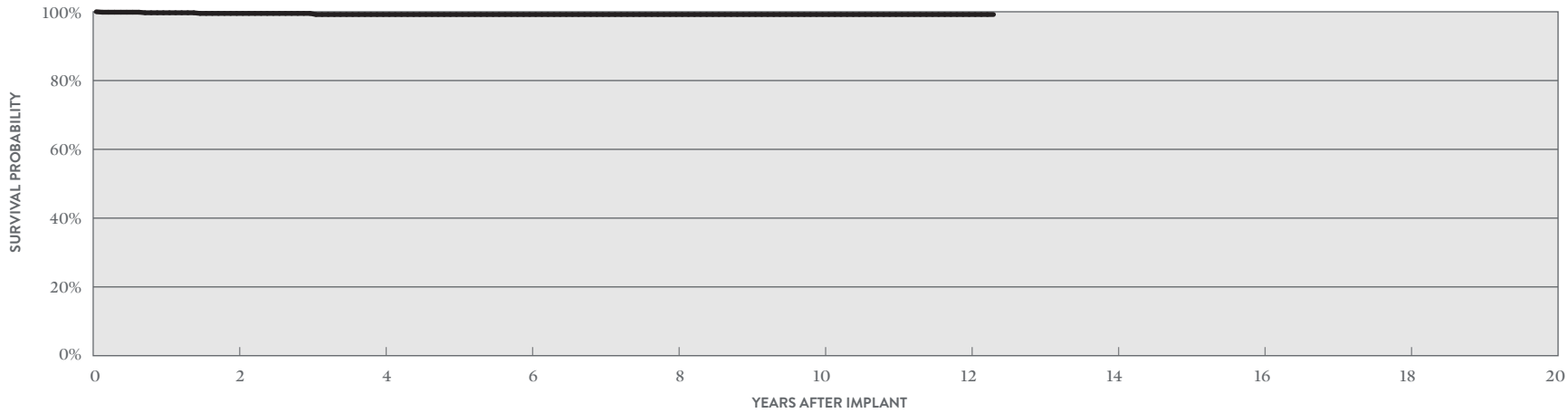
# IsoFlex™ Optim™

## MODEL 1948

| | |
|---|---|
| US Regulatory Approval | March 2008 |
| Number of Devices Enrolled in Study | 765 |
| Active Devices Enrolled in Study | 186 |
| Cumulative Months of Follow-up | 41,129 |
| Insulation | Optim™* |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Failure to Capture | 1 | 0.13% |
| Insulation Breach | 1 | 0.13% |
| Lead Dislodgement | 2 | 0.26% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 5 | 0.65% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 1 | 0.13% |
| **Total** | **6** | **0.78%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 148 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.52% | 99.20% | 99.20% | 99.20% | 99.20% | 99.20% | 99.20% |
| ± 1 STANDARD ERROR | 0.28% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% |
| SAMPLE SIZE | 520 | 300 | 220 | 190 | 180 | 130 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

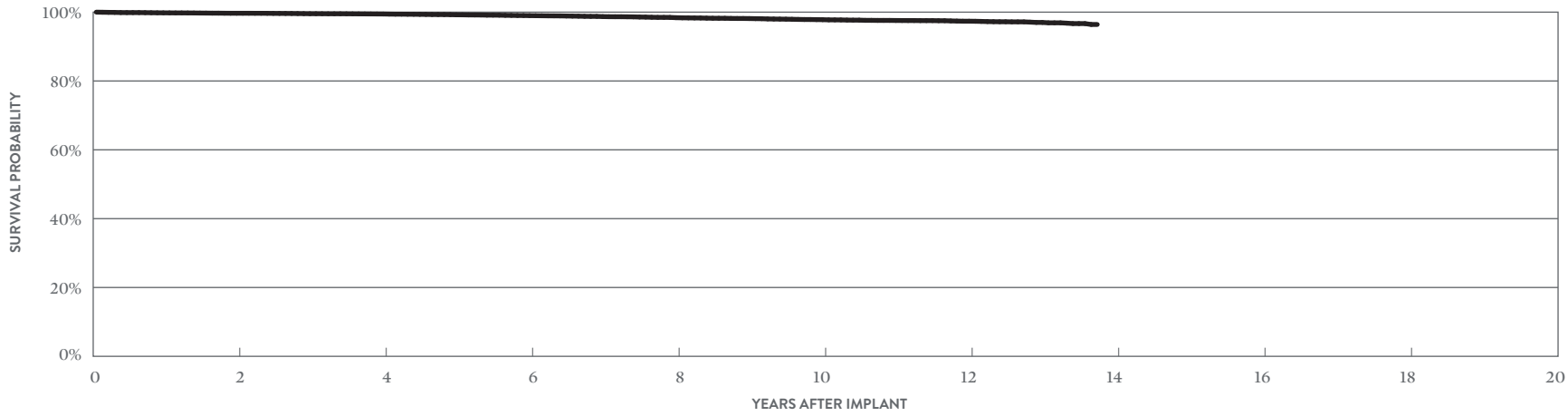
## OptiSense™

### MODELS 1699T & 1699TC

| | |
|---|---|
| US Regulatory Approval | May 2007 |
| Registered US Implants | 22,887 |
| Estimated Active US Implants | 7,515 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 1 | <0.01% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 19 | 0.08% |
| Lead Dislodgement | 4 | 0.02% | 54 | 0.24% |
| Failure to Capture | 4 | 0.02% | 55 | 0.24% |
| Oversensing | 3 | 0.01% | 145 | 0.63% |
| Failure to Sense | 8 | 0.03% | 34 | 0.15% |
| Insulation Breach | 0 | 0.00% | 9 | 0.04% |
| Abnormal Pacing Impedance | 0 | 0.00% | 24 | 0.10% |
| Extracardiac Stimulation | 0 | 0.00% | 3 | 0.01% |
| Other | 2 | <0.01% | 9 | 0.04% |
| **Total** | **22** | **0.10%** | **352** | **1.54%** |
| **Total Returned for Analysis** | **16** | | **84** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 14 | 0.06% |
| Insulation Breach | 47 | 0.21% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 57 | 0.25% |
| **Total** | **118** | **0.52%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 165 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.68% | 99.46% | 98.99% | 98.39% | 97.81% | 97.37% | 96.42% |
| ± 1 STANDARD ERROR | 0.04% | 0.05% | 0.08% | 0.11% | 0.13% | 0.15% | 0.37% |
| SAMPLE SIZE | 18,570 | 15,060 | 12,510 | 10,540 | 9,050 | 6,210 | 310 |

# Pacing Leads

## ACTIVELY MONITORED STUDY DATA

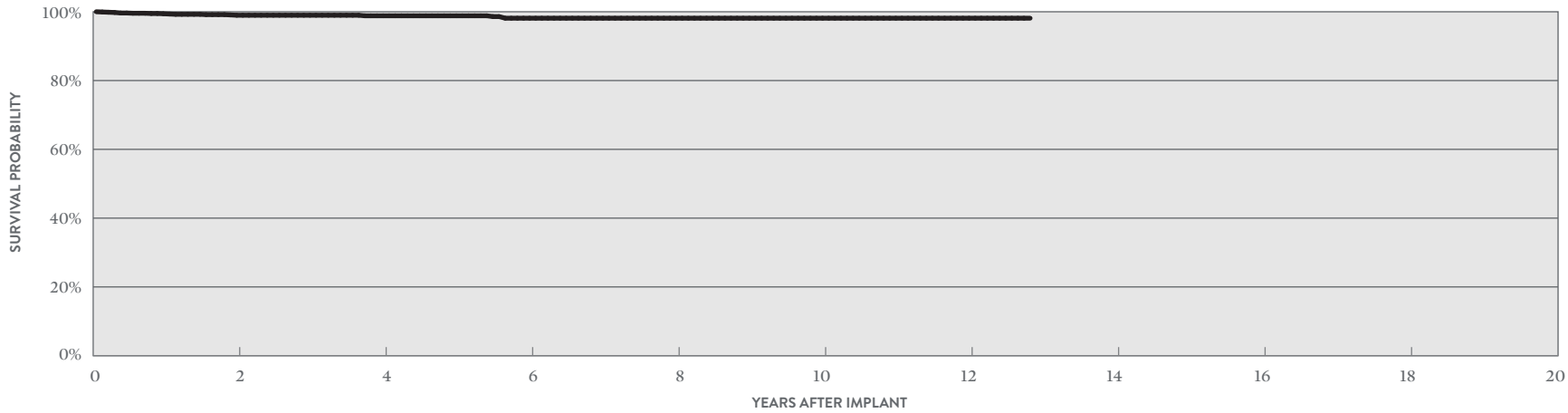
## OptiSense™

### MODELS 1699T & 1699TC

| | |
|---|---|
| US Regulatory Approval | May 2007 |
| Number of Devices Enrolled in Study | 1,451 |
| Active Devices Enrolled in Study | 245 |
| Cumulative Months of Follow-up | 81,243 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.07% |
| Conductor Fracture | 2 | 0.14% |
| Failure to Capture | 4 | 0.28% |
| Insulation Breach | 1 | 0.07% |
| Lead Dislodgement | 8 | 0.55% |
| Oversensing | 1 | 0.07% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 3 | 0.21% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 6 | 0.41% |
| **Total** | **9** | **0.62%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 154 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.99% | 98.83% | 98.13% | 98.13% | 98.13% | 98.13% | 98.13% |
| ± 1 STANDARD ERROR | 0.27% | 0.32% | 0.52% | 0.52% | 0.52% | 0.52% | 0.52% |
| SAMPLE SIZE | 1,160 | 680 | 420 | 330 | 270 | 170 | 50 |

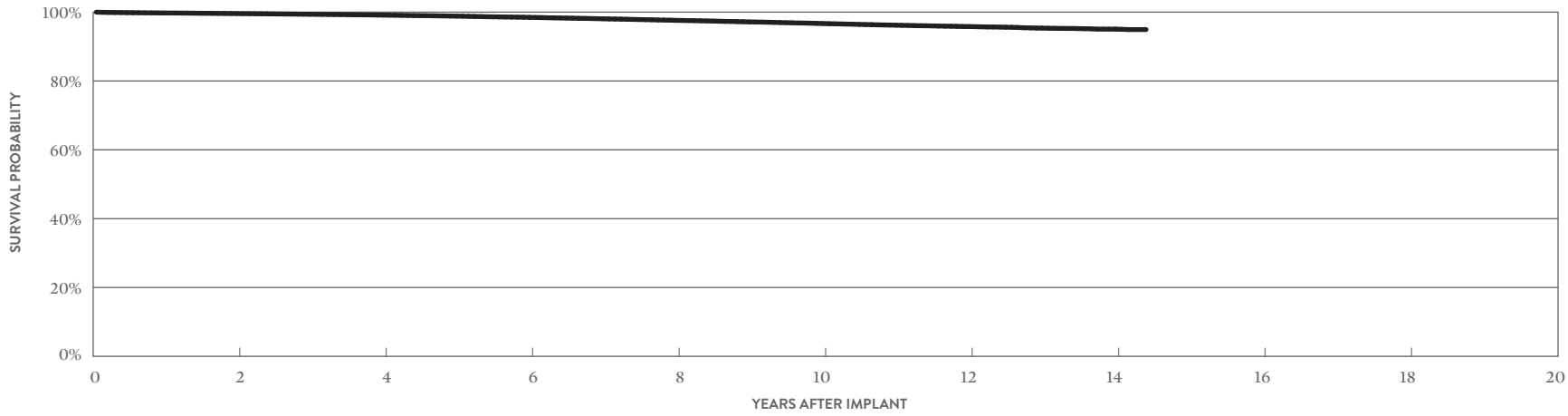
# Tendril™ ST Optim™

## MODELS 1888T & 1888TC

| | |
|---|---|
| US Regulatory Approval | June 2006 |
| Registered US Implants | 302,004 |
| Estimated Active US Implants | 106,539 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 41 | 0.01% | 44 | 0.01% |
| Conductor Fracture | 8 | <0.01% | 318 | 0.11% |
| Lead Dislodgement | 158 | 0.05% | 604 | 0.20% |
| Failure to Capture | 88 | 0.03% | 1066 | 0.35% |
| Oversensing | 21 | <0.01% | 3471 | 1.15% |
| Failure to Sense | 14 | <0.01% | 138 | 0.05% |
| Insulation Breach | 7 | <0.01% | 472 | 0.16% |
| Abnormal Pacing Impedance | 10 | <0.01% | 290 | 0.10% |
| Extracardiac Stimulation | 5 | <0.01% | 47 | 0.02% |
| Other | 42 | 0.01% | 166 | 0.05% |
| **Total** | **394** | **0.13%** | **6616** | **2.19%** |
| **Total Returned for Analysis** | **206** | | **1555** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 48 | 0.02% |
| Insulation Breach | 1124 | 0.37% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 15 | <0.01% |
| Extrinsic Factors | 914 | 0.30% |
| **Total** | **2102** | **0.70%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 173 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.59% | 99.14% | 98.48% | 97.62% | 96.69% | 95.82% | 95.07% | 94.94% |
| ± 1 STANDARD ERROR | 0.01% | 0.02% | 0.03% | 0.04% | 0.05% | 0.06% | 0.10% | 0.14% |
| SAMPLE SIZE | 243,570 | 196,000 | 159,180 | 121,460 | 86,110 | 45,080 | 7,520 | 290 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

ACTIVELY MONITORED STUDY DATA

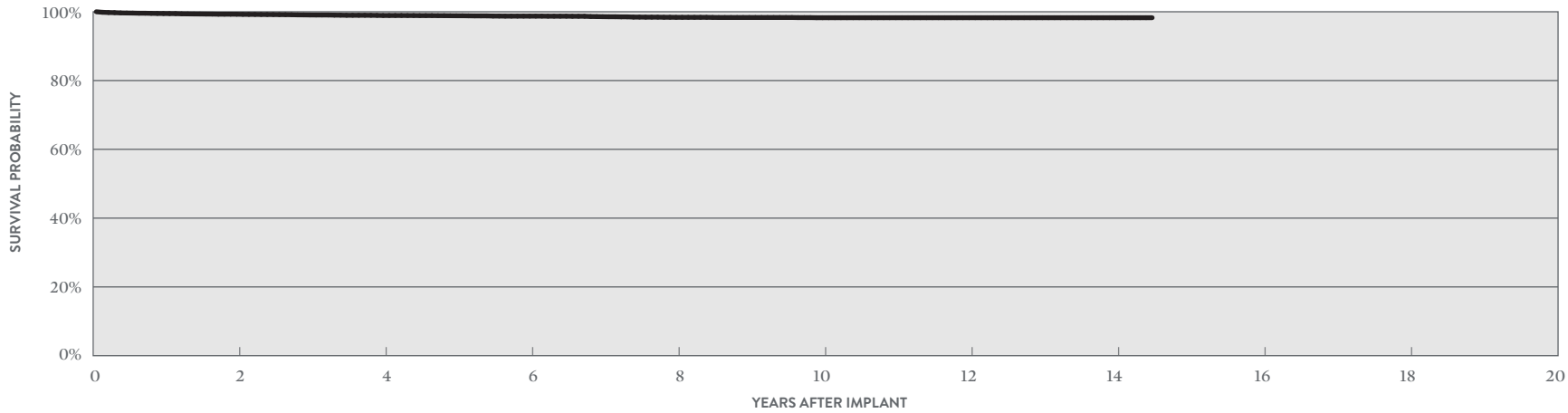
# Tendril™ ST Optim™

## MODELS 1888T & 1888TC

| | |
|---|---|
| US Regulatory Approval | June 2006 |
| Number of Devices Enrolled in Study | 14,505 |
| Active Devices Enrolled in Study | 3,697 |
| Cumulative Months of Follow-up | 942,252 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 7 | 0.05% |
| Cardiac Perforation | 2 | 0.01% |
| Conductor Fracture | 10 | 0.07% |
| Extracardiac Stimulation | 4 | 0.03% |
| Failure to Capture | 19 | 0.13% |
| Failure to Sense | 5 | 0.03% |
| Insulation Breach | 29 | 0.20% |
| Lead Dislodgement | 58 | 0.40% |
| Oversensing | 22 | 0.15% |
| Skin Erosion | 1 | <0.01% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 3 | 0.02% |
| Insulation Breach | 31 | 0.21% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 36 | 0.25% |
| **Total** | **70** | **0.48%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 174 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.28% | 98.92% | 98.73% | 98.38% | 98.27% | 98.27% | 98.27% | 98.27% |
| ± 1 STANDARD ERROR | 0.07% | 0.10% | 0.11% | 0.14% | 0.15% | 0.15% | 0.15% | 0.15% |
| SAMPLE SIZE | 11,860 | 7,530 | 4,840 | 4,080 | 3,670 | 3,040 | 970 | 70 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

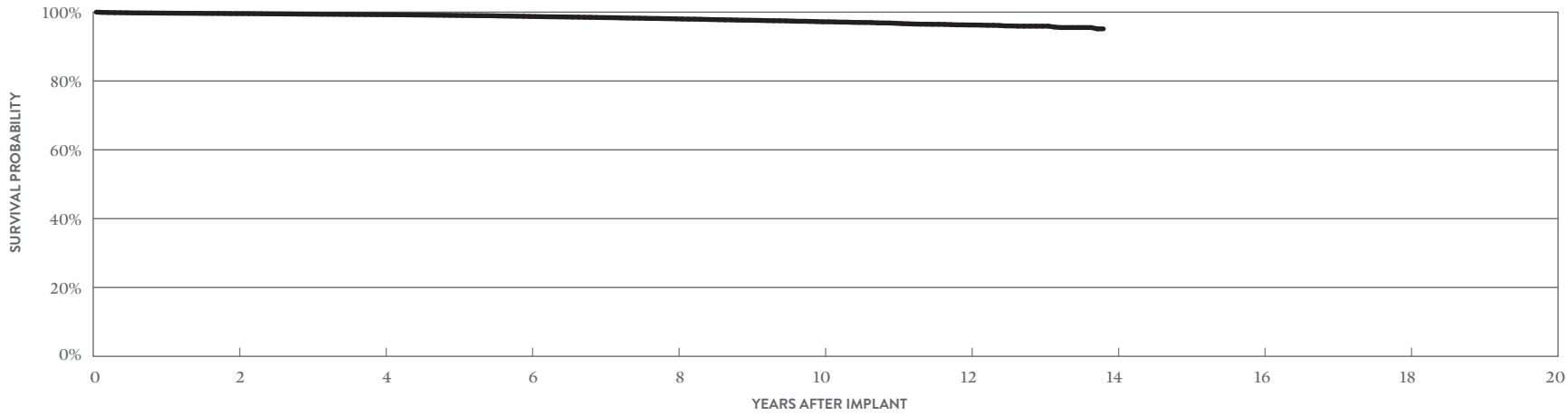
# Tendril™ ST Optim™

## MODELS 1882T & 1882TC

| | |
|---|---|
| US Regulatory Approval | June 2006 |
| Registered US Implants | 49,648 |
| Estimated Active US Implants | 20,972 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 4 | <0.01% | 4 | <0.01% |
| Conductor Fracture | 0 | 0.00% | 23 | 0.05% |
| Lead Dislodgement | 49 | 0.10% | 158 | 0.32% |
| Failure to Capture | 12 | 0.02% | 109 | 0.22% |
| Oversensing | 6 | 0.01% | 369 | 0.74% |
| Failure to Sense | 3 | <0.01% | 32 | 0.06% |
| Insulation Breach | 0 | 0.00% | 50 | 0.10% |
| Abnormal Pacing Impedance | 1 | <0.01% | 30 | 0.06% |
| Extracardiac Stimulation | 0 | 0.00% | 4 | <0.01% |
| Other | 15 | 0.03% | 32 | 0.06% |
| **Total** | **90** | **0.18%** | **811** | **1.63%** |
| **Total Returned for Analysis** | **49** | | **206** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 2 | <0.01% |
| Insulation Breach | 98 | 0.20% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 3 | <0.01% |
| Extrinsic Factors | 152 | 0.31% |
| **Total** | **255** | **0.51%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 166 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.58% | 99.27% | 98.75% | 98.05% | 97.20% | 96.27% | 95.15% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.06% | 0.09% | 0.12% | 0.19% | 0.50% |
| SAMPLE SIZE | 40,810 | 32,640 | 24,280 | 16,010 | 8,870 | 3,500 | 230 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

ACTIVELY MONITORED STUDY DATA

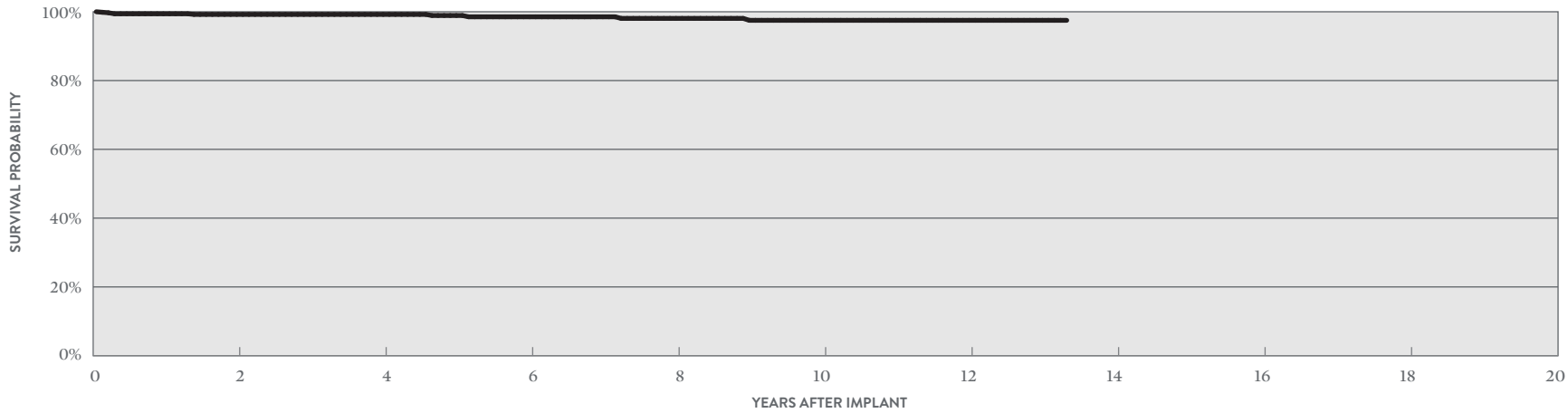
# Tendril™ ST Optim™

## MODELS 1882T & 1882TC

| | |
|---|---|
| US Regulatory Approval | June 2006 |
| Number of Devices Enrolled in Study | 690 |
| Active Devices Enrolled in Study | 177 |
| Cumulative Months of Follow-up | 45,027 |
| Insulation | Optim™* |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 1 | 0.14% |
| Extracardiac Stimulation | 1 | 0.14% |
| Failure to Capture | 1 | 0.14% |
| Failure to Sense | 1 | 0.14% |
| Lead Dislodgement | 2 | 0.29% |
| Oversensing | 2 | 0.29% |
| Skin Erosion | 1 | 0.14% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 3 | 0.43% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **3** | **0.43%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 160 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.23% | 99.23% | 98.53% | 98.07% | 97.51% | 97.51% | 97.51% |
| ± 1 STANDARD ERROR | 0.34% | 0.34% | 0.60% | 0.75% | 0.94% | 0.94% | 0.94% |
| SAMPLE SIZE | 560 | 380 | 250 | 210 | 160 | 130 | 50 |

**Optim™ lead insulation is a copolymer of silicone and polyurethane.*

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

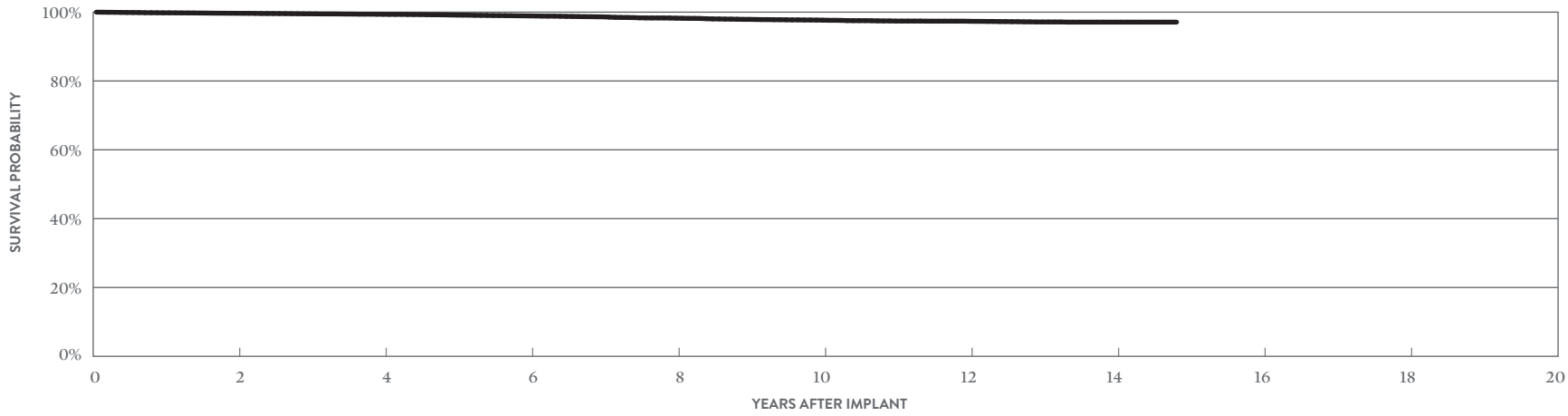
## Tendril™

### MODELS 1782T & 1782TC

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 16,412 |
| Estimated Active US Implants | 4,961 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 6 | 0.04% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 6 | 0.04% |
| Lead Dislodgement | 13 | 0.08% | 54 | 0.33% |
| Failure to Capture | 5 | 0.03% | 56 | 0.34% |
| Oversensing | 0 | 0.00% | 75 | 0.46% |
| Failure to Sense | 0 | 0.00% | 8 | 0.05% |
| Insulation Breach | 0 | 0.00% | 5 | 0.03% |
| Abnormal Pacing Impedance | 2 | 0.01% | 19 | 0.12% |
| Extracardiac Stimulation | 1 | <0.01% | 1 | <0.01% |
| Other | 2 | 0.01% | 4 | 0.02% |
| **Total** | **29** | **0.18%** | **228** | **1.39%** |
| **Total Returned for Analysis** | **16** | | **72** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | <0.01% |
| Insulation Breach | 48 | 0.29% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 51 | 0.31% |
| **Total** | **100** | **0.61%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 178 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.67% | 99.37% | 98.91% | 98.25% | 97.68% | 97.35% | 97.10% | 97.10% |
| ± 1 STANDARD ERROR | 0.05% | 0.07% | 0.10% | 0.14% | 0.17% | 0.18% | 0.21% | 0.21% |
| SAMPLE SIZE | 13,300 | 10,610 | 8,460 | 6,900 | 5,660 | 3,970 | 1,730 | 240 |

# Pacing Leads

## ACTIVELY MONITORED STUDY DATA

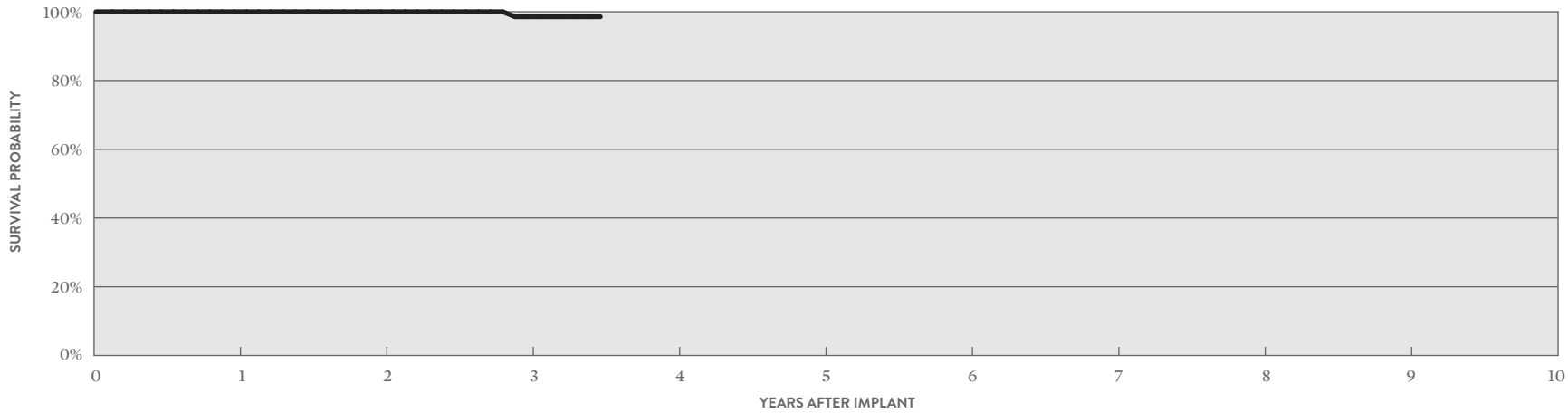
## Tendril™

### MODELS 1782T & 1782TC

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Number of Devices Enrolled in Study | 165 |
| Active Devices Enrolled in Study | 7 |
| Cumulative Months of Follow-up | 6,007 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Oversensing | 1 | 0.61% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 1 | 0.61% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **1** | **0.61%** |




| YEAR | 1 | 2 | 3 | AT 42 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100.00% | 100.00% | 98.54% | 98.54% |
| ± 1 STANDARD ERROR | 0.00% | 0.00% | 1.45% | 1.45% |
| SAMPLE SIZE | 150 | 120 | 80 | 60 |

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

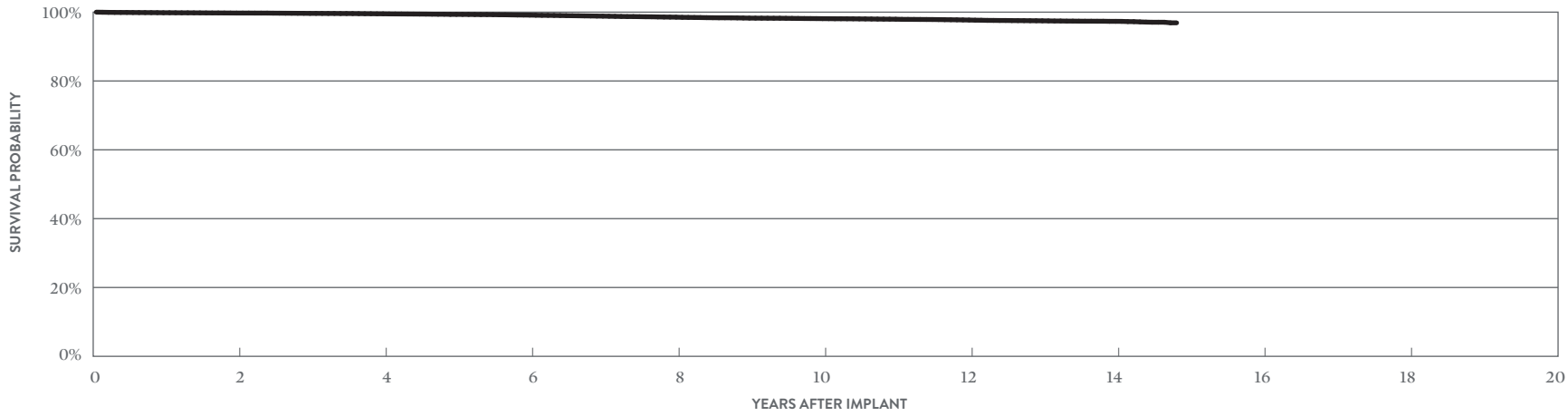
## Tendril™

### MODELS 1788T & 1788TC

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 65,264 |
| Estimated Active US Implants | 18,802 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 12 | 0.02% | 8 | 0.01% |
| Conductor Fracture | 1 | <0.01% | 36 | 0.06% |
| Lead Dislodgement | 31 | 0.05% | 80 | 0.12% |
| Failure to Capture | 31 | 0.05% | 202 | 0.31% |
| Oversensing | 4 | <0.01% | 279 | 0.43% |
| Failure to Sense | 2 | <0.01% | 25 | 0.04% |
| Insulation Breach | 1 | <0.01% | 36 | 0.06% |
| Abnormal Pacing Impedance | 9 | 0.01% | 54 | 0.08% |
| Extracardiac Stimulation | 2 | <0.01% | 7 | 0.01% |
| Other | 20 | 0.03% | 36 | 0.06% |
| **Total** | **113** | **0.17%** | **763** | **1.17%** |
| **Total Returned for Analysis** | **49** | | **167** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 10 | 0.02% |
| Insulation Breach | 132 | 0.20% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 1 | <0.01% |
| Extrinsic Factors | 106 | 0.16% |
| **Total** | **250** | **0.38%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 178 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.74% | 99.52% | 99.14% | 98.54% | 98.11% | 97.71% | 97.33% | 96.90% |
| ± 1 STANDARD ERROR | 0.02% | 0.03% | 0.04% | 0.06% | 0.08% | 0.09% | 0.10% | 0.22% |
| SAMPLE SIZE | 52,250 | 40,860 | 32,830 | 27,080 | 23,230 | 18,820 | 9,730 | 330 |

# Pacing Leads

## ACTIVELY MONITORED STUDY DATA

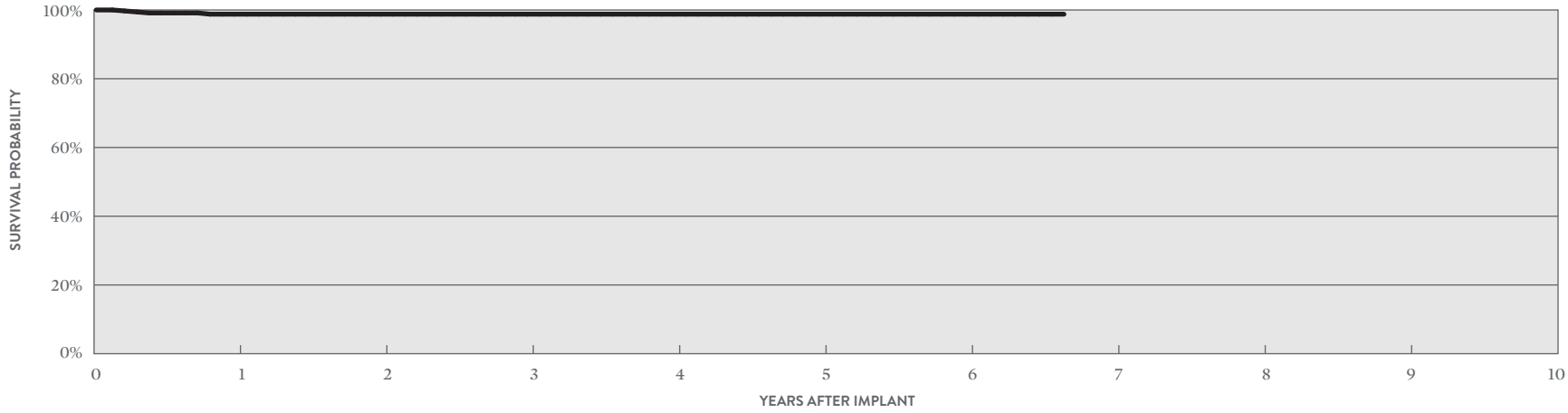
## Tendril™

### MODELS 1788T & 1788TC

| | |
|---|---|
| US Regulatory Approval | February 2006 |
| Number of Devices Enrolled in Study | 363 |
| Active Devices Enrolled in Study | 32 |
| Cumulative Months of Follow-up | 13,794 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Extracardiac Stimulation | 1 | 0.28% |
| Lead Dislodgement | 3 | 0.83% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 2 | 0.55% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **2** | **0.55%** |




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 80 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.78% | 98.78% | 98.78% | 98.78% | 98.78% | 98.78% | 98.78% |
| ± 1 STANDARD ERROR | 0.61% | 0.61% | 0.61% | 0.61% | 0.61% | 0.61% | 0.61% |
| SAMPLE SIZE | 310 | 240 | 170 | 100 | 70 | 60 | 50 |

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

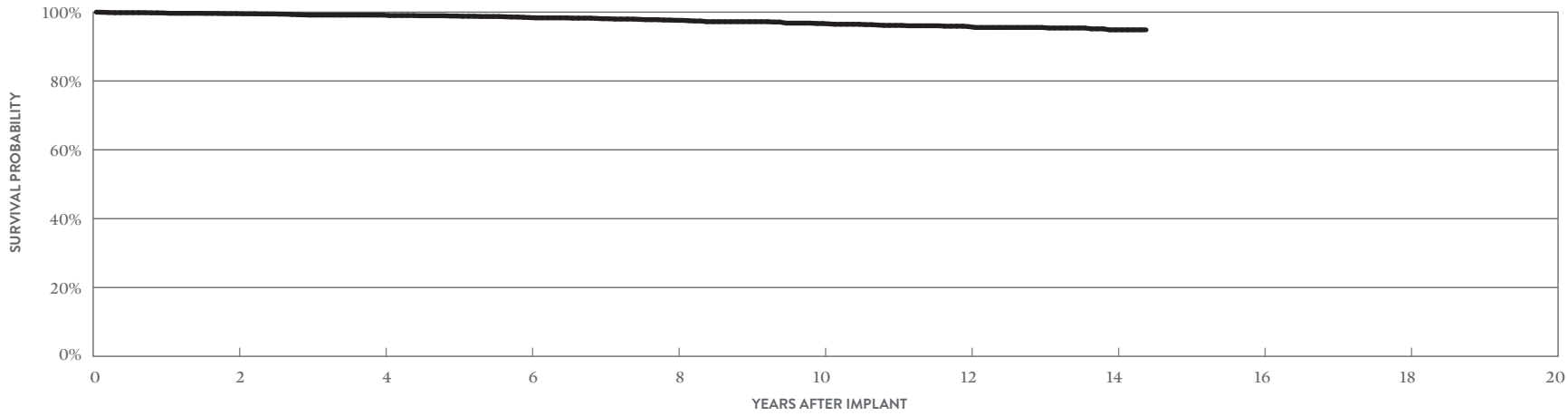
## IsoFlex™ P

### MODEL 1648T

| | |
|---|---|
| US Regulatory Approval | April 2005 |
| Registered US Implants | 2,836 |
| Estimated Active US Implants | 759 |
| Insulation | Polyurethane |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 6 | 0.21% |
| Lead Dislodgement | 2 | 0.07% | 2 | 0.07% |
| Failure to Capture | 2 | 0.07% | 16 | 0.56% |
| Oversensing | 0 | 0.00% | 3 | 0.11% |
| Failure to Sense | 1 | 0.04% | 1 | 0.04% |
| Insulation Breach | 0 | 0.00% | 14 | 0.49% |
| Abnormal Pacing Impedance | 0 | 0.00% | 4 | 0.14% |
| Extracardiac Stimulation | 1 | 0.04% | 0 | 0.00% |
| Other | 0 | 0.00% | 6 | 0.21% |
| **Total** | **6** | **0.21%** | **52** | **1.83%** |
| **Total Returned for Analysis** | **1** | | **8** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 18 | 0.63% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 2 | 0.07% |
| Extrinsic Factors | 6 | 0.21% |
| **Total** | **26** | **0.92%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | AT 173 MONTHS |
|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.58% | 99.15% | 98.42% | 97.62% | 96.70% | 95.79% | 94.86% | 94.86% |
| ± 1 STANDARD ERROR | 0.13% | 0.20% | 0.29% | 0.39% | 0.50% | 0.58% | 0.73% | 0.73% |
| SAMPLE SIZE | 2,160 | 1,660 | 1,300 | 1,070 | 930 | 810 | 450 | 210 |

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

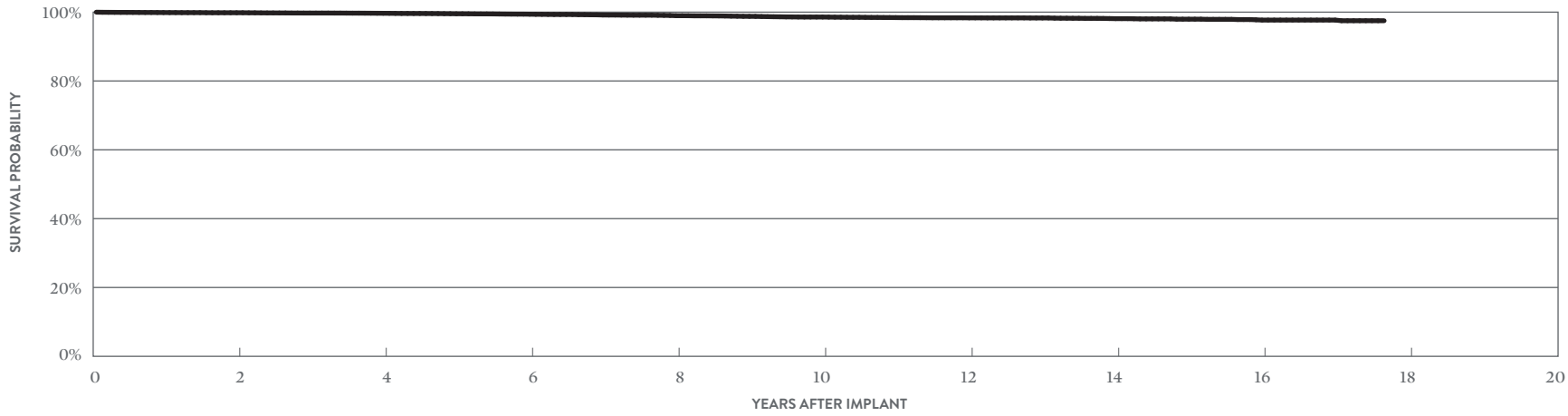
## IsoFlex™ S

### MODEL 1642T

| | |
|---|---|
| US Regulatory Approval | May 2002 |
| Registered US Implants | 27,144 |
| Estimated Active US Implants | 7,024 |
| Insulation | Silicone |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 1 | <0.01% | 11 | 0.04% |
| Lead Dislodgement | 49 | 0.18% | 43 | 0.16% |
| Failure to Capture | 6 | 0.02% | 69 | 0.25% |
| Oversensing | 0 | 0.00% | 59 | 0.22% |
| Failure to Sense | 3 | 0.01% | 17 | 0.06% |
| Insulation Breach | 0 | 0.00% | 7 | 0.03% |
| Abnormal Pacing Impedance | 3 | 0.01% | 15 | 0.06% |
| Extracardiac Stimulation | 1 | <0.01% | 3 | 0.01% |
| Other | 1 | <0.01% | 5 | 0.02% |
| **Total** | **64** | **0.24%** | **229** | **0.84%** |
| **Total Returned for Analysis** | **39** | | **39** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 40 | 0.15% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 2 | <0.01% |
| Extrinsic Factors | 22 | 0.08% |
| **Total** | **65** | **0.24%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 212 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.83% | 99.67% | 99.40% | 98.97% | 98.58% | 98.34% | 98.11% | 97.70% | 97.51% |
| ± 1 STANDARD ERROR | 0.03% | 0.04% | 0.06% | 0.08% | 0.11% | 0.12% | 0.14% | 0.19% | 0.28% |
| SAMPLE SIZE | 21,870 | 17,440 | 13,770 | 11,070 | 8,970 | 6,660 | 3,990 | 1,710 | 220 |

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

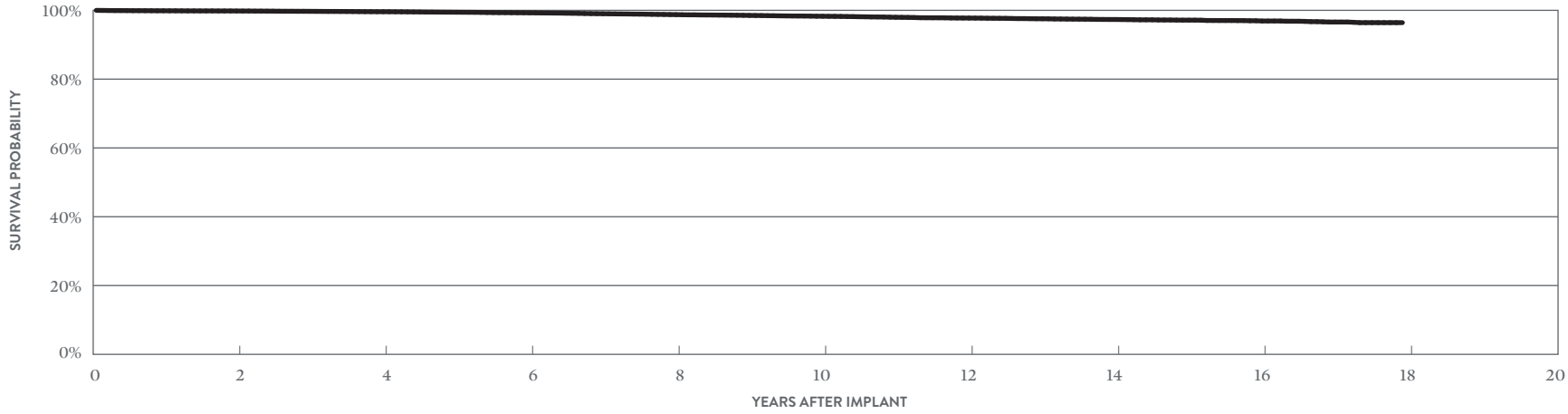
## IsoFlex™ S

### MODEL 1646T

| | |
|---|---|
| US Regulatory Approval | May 2002 |
| Registered US Implants | 90,423 |
| Estimated Active US Implants | 22,562 |
| Insulation | Silicone |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 4 | <0.01% | 2 | <0.01% |
| Conductor Fracture | 2 | <0.01% | 124 | 0.14% |
| Lead Dislodgement | 37 | 0.04% | 36 | 0.04% |
| Failure to Capture | 35 | 0.04% | 394 | 0.44% |
| Oversensing | 2 | <0.01% | 206 | 0.23% |
| Failure to Sense | 2 | <0.01% | 14 | 0.02% |
| Insulation Breach | 2 | <0.01% | 50 | 0.06% |
| Abnormal Pacing Impedance | 6 | <0.01% | 138 | 0.15% |
| Extracardiac Stimulation | 0 | 0.00% | 7 | <0.01% |
| Other | 3 | <0.01% | 34 | 0.04% |
| **Total** | **93** | **0.10%** | **1005** | **1.11%** |
| **Total Returned for Analysis** | **38** | | **128** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 22 | 0.02% |
| Insulation Breach | 84 | 0.09% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 6 | <0.01% |
| Extrinsic Factors | 75 | 0.08% |
| **Total** | **187** | **0.21%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 215 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.81% | 99.60% | 99.27% | 98.75% | 98.28% | 97.75% | 97.34% | 96.90% | 96.42% |
| ± 1 STANDARD ERROR | 0.02% | 0.02% | 0.04% | 0.05% | 0.06% | 0.08% | 0.10% | 0.12% | 0.21% |
| SAMPLE SIZE | 71,310 | 55,330 | 42,980 | 34,620 | 28,200 | 20,770 | 12,380 | 5,230 | 250 |

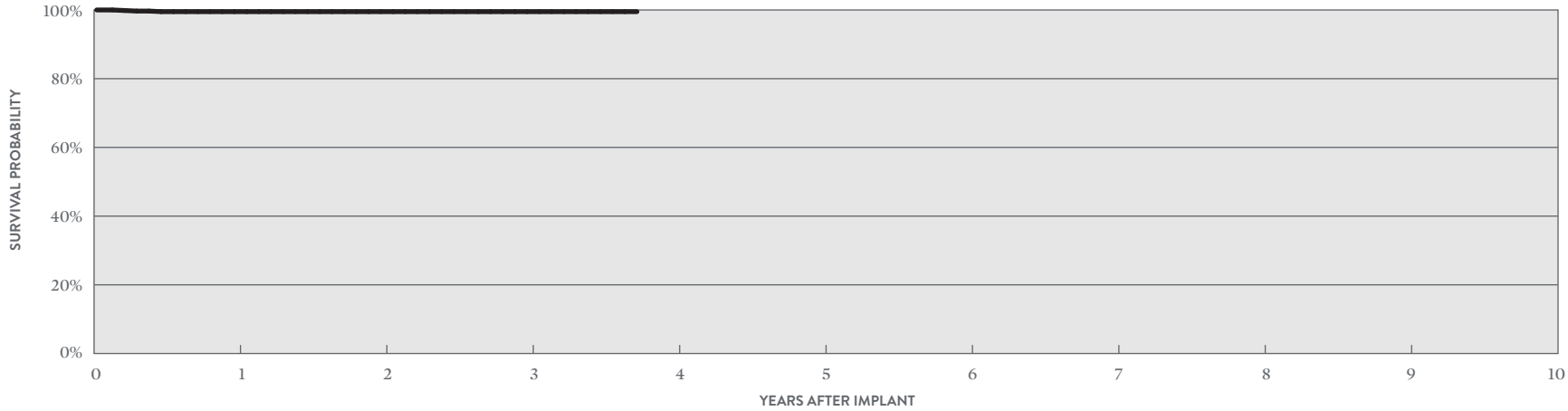
# IsoFlex™ S

## MODEL 1646T

| | |
|---|---|
| US Regulatory Approval | May 2002 |
| Number of Devices Enrolled in Study | 641 |
| Active Devices Enrolled in Study | 3 |
| Cumulative Months of Follow-up | 15,917 |
| Insulation | Silicone |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Failure to Capture | 2 | 0.31% |
| Lead Dislodgement | 1 | 0.16% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 0 | 0.00% |
| **Total** | **0** | **0.00%** |




| YEAR | 1 | 2 | 3 | AT 45 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.51% | 99.51% | 99.51% | 99.51% |
| ± 1 STANDARD ERROR | 0.28% | 0.28% | 0.28% | 0.28% |
| SAMPLE SIZE | 570 | 410 | 250 | 60 |

# Pacing Leads

## CUSTOMER REPORTED PERFORMANCE DATA

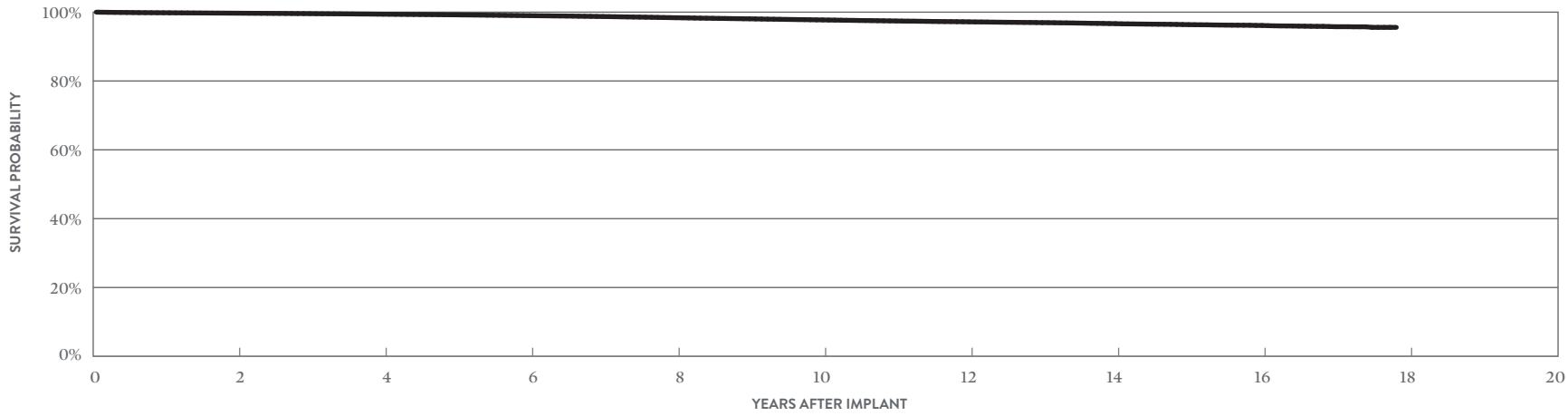
## Tendril™ SDX

### MODELS 1688T & 1688TC

| | |
|---|---|
| US Regulatory Approval | June 2003 |
| Registered US Implants | 491,763 |
| Estimated Active US Implants | 145,442 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of US Advisories | None |

| | ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS) | | CHRONIC COMPLICATIONS (>30 DAYS) | |
|---|---|---|---|---|
| | QTY | RATE | QTY | RATE |
| Cardiac Perforation | 81 | 0.02% | 44 | <0.01% |
| Conductor Fracture | 6 | <0.01% | 607 | 0.12% |
| Lead Dislodgement | 322 | 0.07% | 630 | 0.13% |
| Failure to Capture | 203 | 0.04% | 1749 | 0.36% |
| Oversensing | 24 | <0.01% | 2198 | 0.45% |
| Failure to Sense | 34 | <0.01% | 173 | 0.04% |
| Insulation Breach | 10 | <0.01% | 256 | 0.05% |
| Abnormal Pacing Impedance | 30 | <0.01% | 660 | 0.13% |
| Extracardiac Stimulation | 8 | <0.01% | 51 | 0.01% |
| Other | 68 | 0.01% | 212 | 0.04% |
| **Total** | **786** | **0.16%** | **6580** | **1.34%** |
| **Total Returned for Analysis** | **352** | | **1600** | |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 221 | 0.04% |
| Insulation Breach | 1106 | 0.22% |
| Crimps, Welds & Bonds | 2 | <0.01% |
| Other | 21 | <0.01% |
| Extrinsic Factors | 857 | 0.17% |
| **Total** | **2207** | **0.45%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | AT 214 MONTHS |
|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.70% | 99.40% | 98.99% | 98.38% | 97.74% | 97.19% | 96.66% | 96.13% | 95.58% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.04% | 0.05% | 0.06% | 0.15% |
| SAMPLE SIZE | 398,500 | 314,030 | 239,060 | 174,440 | 126,140 | 88,540 | 56,770 | 23,780 | 280 |

# Pacing Leads

## ACTIVELY MONITORED STUDY DATA

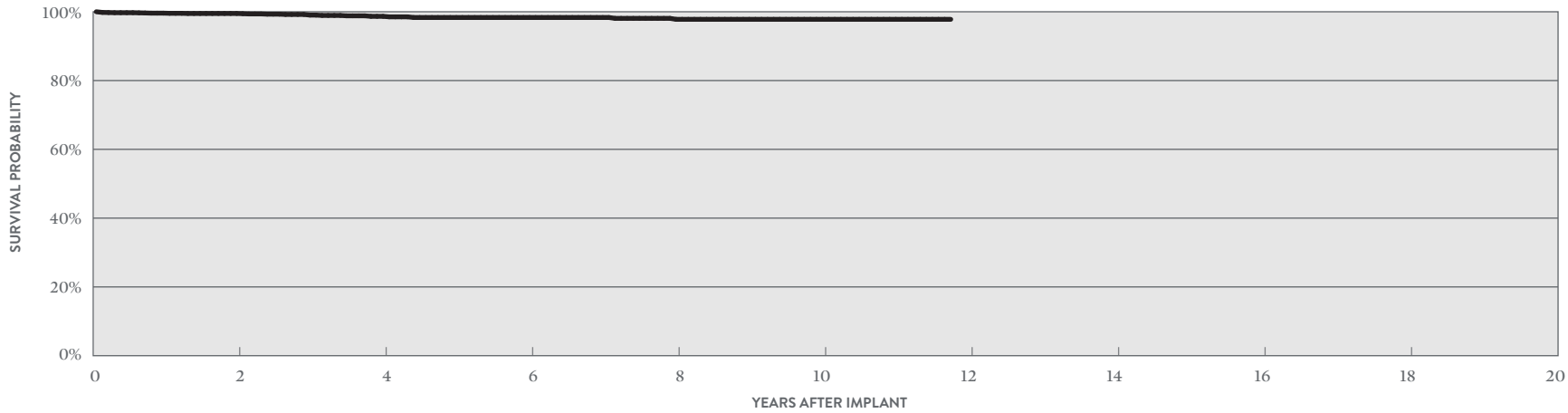
## Tendril™ SDX

### MODELS 1688T & 1688TC

| | |
|---|---|
| US Regulatory Approval | June 2003 |
| Number of Devices Enrolled in Study | 2,645 |
| Active Devices Enrolled in Study | 328 |
| Cumulative Months of Follow-up | 106,378 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |

| QUALIFYING COMPLICATIONS | QTY | RATE |
|---|---|---|
| Abnormal Pacing Impedance | 5 | 0.19% |
| Conductor Fracture | 3 | 0.11% |
| Failure to Capture | 3 | 0.11% |
| Insulation Breach | 3 | 0.11% |
| Lead Dislodgement | 6 | 0.23% |
| Oversensing | 3 | 0.11% |
| Pericardial Effusion | 1 | 0.04% |
| Skin Erosion | 1 | 0.04% |

| MALFUNCTIONS | QTY | RATE |
|---|---|---|
| Conductor Fracture | 1 | 0.04% |
| Insulation Breach | 6 | 0.23% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 5 | 0.19% |
| **Total** | **12** | **0.45%** |




| YEAR | 2 | 4 | 6 | 8 | 10 | AT 141 MONTHS |
|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.50% | 98.67% | 98.33% | 97.80% | 97.80% | 97.80% |
| ± 1 STANDARD ERROR | 0.14% | 0.32% | 0.40% | 0.47% | 0.55% | 0.55% |
| SAMPLE SIZE | 1,840 | 850 | 460 | 370 | 250 | 60 |

## SUMMARY INFORMATION

# Pacing Leads

## Pacing Leads

# Survival Probability Summary

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| LPA1200M | Tendril MRI™ | 99.76% | 99.57% | 99.35% | 99.10% | 98.82% | 98.11% | 97.93% | 97.75% | | |
| 2088TC | Tendril™ STS | 99.69% | 99.50% | 99.32% | 99.11% | 98.88% | 98.65% | 98.39% | 98.08% | 97.66% | 97.03% |
| 1999 | OptiSense™ Optim™ | 99.65% | 99.46% | 99.27% | 99.07% | 98.86% | 98.65% | 98.36% | 98.02% | 97.42% | 96.85% |
| 1944 | IsoFlex™ Optim™ | 99.60% | 99.40% | 99.18% | 99.00% | 98.80% | 98.62% | 98.28% | 98.02% | 97.63% | 97.19% |
| 1948 | IsoFlex™ Optim™ | 99.76% | 99.57% | 99.34% | 99.09% | 98.81% | 98.55% | 98.17% | 97.75% | 97.28% | 96.57% |
| 1699T/TC | OptiSense™ | 99.80% | 99.69% | 99.53% | 99.44% | 99.24% | 99.03% | 98.78% | 98.47% | 98.23% | 97.93% |
| 1888T/TC | Tendril™ ST Optim™ | 99.76% | 99.59% | 99.39% | 99.14% | 98.83% | 98.48% | 98.07% | 97.62% | 97.15% | 96.67% |
| 1882T/TC | Tendril™ ST Optim™ | 99.71% | 99.55% | 99.42% | 99.26% | 99.05% | 98.76% | 98.43% | 98.08% | 97.65% | 97.20% |
| 1782T/TC | Tendril™ | 99.81% | 99.70% | 99.55% | 99.40% | 99.15% | 98.91% | 98.60% | 98.23% | 97.83% | 97.62% |
| 1788T/TC | Tendril™ | 99.84% | 99.75% | 99.66% | 99.54% | 99.36% | 99.14% | 98.86% | 98.57% | 98.30% | 98.15% |
| 1648T | IsoFlex™ P | 99.72% | 99.58% | 99.32% | 99.32% | 98.98% | 98.51% | 98.17% | 97.71% | 97.31% | 96.78% |
| 1642T | IsoFlex™ S | 99.88% | 99.83% | 99.76% | 99.68% | 99.59% | 99.45% | 99.22% | 99.03% | 98.84% | 98.63% |
| 1646T | IsoFlex™ S | 99.87% | 99.80% | 99.70% | 99.59% | 99.44% | 99.26% | 99.02% | 98.76% | 98.54% | 98.28% |
| 1688T/TC | Tendril™ SDX | 99.82% | 99.70% | 99.56% | 99.41% | 99.23% | 99.00% | 98.74% | 98.39% | 98.07% | 97.76% |

## Pacing Leads

# Acute Observation Summary

### POST IMPLANT ≤30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| LPA1200M | Jan-17 | 167,468 | 112,800 | 42 | 0.03% | 3 | <0.01% | 364 | 0.22% | 56 | 0.03% | 18 | 0.01% | 26 | 0.02% | 1 | <0.01% | 2 | <0.01% | 6 | <0.01% | 61 | 0.04% | **579** | **0.35%** | **216** |
| 2088TC | May-09 | 918,999 | 516,982 | 213 | 0.02% | 9 | <0.01% | 1312 | 0.14% | 375 | 0.04% | 106 | 0.01% | 55 | <0.01% | 19 | <0.01% | 49 | <0.01% | 10 | <0.01% | 207 | 0.02% | **2355** | **0.26%** | **826** |
| 1999 | Oct-09 | 47,419 | 22,808 | 4 | <0.01% | 0 | 0.00% | 64 | 0.13% | 8 | 0.02% | 10 | 0.02% | 3 | <0.01% | 1 | <0.01% | 0 | 0.00% | 0 | 0.00% | 14 | 0.03% | **104** | **0.22%** | **59** |
| 1944 | Mar-08 | 19,671 | 9,353 | 0 | 0.00% | 0 | 0.00% | 99 | 0.50% | 13 | 0.07% | 1 | <0.01% | 3 | 0.02% | 0 | 0.00% | 0 | 0.00% | 3 | 0.02% | 4 | 0.02% | **123** | **0.63%** | **59** |
| 1948 | Mar-08 | 73,129 | 34,481 | 5 | <0.01% | 1 | <0.01% | 72 | 0.10% | 49 | 0.07% | 3 | <0.01% | 2 | <0.01% | 4 | <0.01% | 1 | <0.01% | 2 | <0.01% | 8 | 0.01% | **147** | **0.20%** | **66** |
| 1699T/TC | May-07 | 22,887 | 7,516 | 1 | <0.01% | 0 | 0.00% | 4 | 0.02% | 4 | 0.02% | 3 | 0.01% | 8 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | **22** | **0.10%** | **16** |
| 1888T/TC | Jun-06 | 302,004 | 106,757 | 41 | 0.01% | 8 | <0.01% | 158 | 0.05% | 88 | 0.03% | 21 | <0.01% | 14 | <0.01% | 7 | <0.01% | 10 | <0.01% | 5 | <0.01% | 42 | 0.01% | **394** | **0.13%** | **206** |
| 1882T/TC | Jun-06 | 49,648 | 20,975 | 4 | <0.01% | 0 | 0.00% | 49 | 0.10% | 12 | 0.02% | 6 | 0.01% | 3 | <0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 15 | 0.03% | **90** | **0.18%** | **49** |
| 1782T/TC | Feb-06 | 16,412 | 4,894 | 6 | 0.04% | 0 | 0.00% | 13 | 0.08% | 5 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 1 | <0.01% | 2 | 0.01% | **29** | **0.18%** | **16** |
| 1788T/TC | Feb-06 | 65,264 | 18,948 | 12 | 0.02% | 1 | <0.01% | 31 | 0.05% | 31 | 0.05% | 4 | <0.01% | 2 | <0.01% | 1 | <0.01% | 9 | 0.01% | 2 | <0.01% | 20 | 0.03% | **113** | **0.17%** | **49** |
| 1648T | Apr-05 | 2,836 | 758 | 0 | 0.00% | 0 | 0.00% | 2 | 0.07% | 2 | 0.07% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | **6** | **0.21%** | **1** |
| 1642T | May-02 | 27,144 | 7,006 | 0 | 0.00% | 1 | <0.01% | 49 | 0.18% | 6 | 0.02% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 3 | 0.01% | 1 | <0.01% | 1 | <0.01% | **64** | **0.24%** | **39** |
| 1646T | May-02 | 90,423 | 22,477 | 4 | <0.01% | 2 | <0.01% | 37 | 0.04% | 35 | 0.04% | 2 | <0.01% | 2 | <0.01% | 2 | <0.01% | 6 | <0.01% | 0 | 0.00% | 3 | <0.01% | **93** | **0.10%** | **38** |
| 1688T/TC | Jun-03 | 491,763 | 146,391 | 81 | 0.02% | 6 | <0.01% | 322 | 0.07% | 203 | 0.04% | 24 | <0.01% | 34 | <0.01% | 10 | <0.01% | 30 | <0.01% | 8 | <0.01% | 68 | 0.01% | **786** | **0.16%** | **352** |

# Chronic Complication Summary

### >30 DAYS

| MODELS | US REGULATORY APPROVAL | REGISTERED US IMPLANTS | ESTIMATED ACTIVE US IMPLANTS | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | LEAD DISLODGEMENT | | FAILURE TO CAPTURE | | OVERSENSING | | FAILURE TO SENSE | | INSULATION BREACH | | ABNORMAL PACING IMPEDANCE | | EXTRACARDIAC STIMULATION | | OTHER | | TOTAL | | TOTAL RETURNED FOR ANALYSIS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | |
| LPA1200M | Jan-17 | 167,468 | 112,800 | 18 | 0.01% | 68 | 0.04% | 370 | 0.22% | 199 | 0.12% | 338 | 0.20% | 38 | 0.02% | 20 | 0.01% | 44 | 0.03% | 10 | <0.01% | 33 | 0.02% | **1138** | **0.68%** | **329** |
| 2088TC | May-09 | 918,999 | 516,982 | 110 | 0.01% | 402 | 0.04% | 1864 | 0.20% | 1528 | 0.17% | 5006 | 0.54% | 204 | 0.02% | 383 | 0.04% | 342 | 0.04% | 65 | <0.01% | 296 | 0.03% | **10200** | **1.11%** | **2777** |
| 1999 | Oct-09 | 47,419 | 22,808 | 2 | <0.01% | 17 | 0.04% | 186 | 0.39% | 93 | 0.20% | 431 | 0.91% | 44 | 0.09% | 54 | 0.11% | 20 | 0.04% | 2 | <0.01% | 25 | 0.05% | **874** | **1.84%** | **240** |
| 1944 | Mar-08 | 19,671 | 9,353 | 1 | <0.01% | 12 | 0.06% | 68 | 0.35% | 48 | 0.24% | 152 | 0.77% | 11 | 0.06% | 9 | 0.05% | 5 | 0.03% | 1 | <0.01% | 5 | 0.03% | **312** | **1.59%** | **49** |
| 1948 | Mar-08 | 73,129 | 34,481 | 12 | 0.02% | 117 | 0.16% | 83 | 0.11% | 246 | 0.34% | 439 | 0.60% | 5 | <0.01% | 96 | 0.13% | 52 | 0.07% | 7 | <0.01% | 25 | 0.03% | **1082** | **1.48%** | **171** |
| 1699T/TC | May-07 | 22,887 | 7,516 | 0 | 0.00% | 19 | 0.08% | 54 | 0.24% | 55 | 0.24% | 145 | 0.63% | 34 | 0.15% | 9 | 0.04% | 24 | 0.10% | 3 | 0.01% | 9 | 0.04% | **352** | **1.54%** | **84** |
| 1888T/TC | Jun-06 | 302,004 | 106,757 | 44 | 0.01% | 318 | 0.11% | 604 | 0.20% | 1066 | 0.35% | 3471 | 1.15% | 138 | 0.05% | 472 | 0.16% | 290 | 0.10% | 47 | 0.02% | 166 | 0.05% | **6616** | **2.19%** | **1555** |
| 1882T/TC | Jun-06 | 49,648 | 20,975 | 4 | <0.01% | 23 | 0.05% | 158 | 0.32% | 109 | 0.22% | 369 | 0.74% | 32 | 0.06% | 50 | 0.10% | 30 | 0.06% | 4 | <0.01% | 32 | 0.06% | **811** | **1.63%** | **206** |
| 1782T/TC | Feb-06 | 16,412 | 4,894 | 0 | 0.00% | 6 | 0.04% | 54 | 0.33% | 56 | 0.34% | 75 | 0.46% | 8 | 0.05% | 5 | 0.03% | 19 | 0.12% | 1 | <0.01% | 4 | 0.02% | **228** | **1.39%** | **72** |
| 1788T/TC | Feb-06 | 65,264 | 18,948 | 8 | 0.01% | 36 | 0.06% | 80 | 0.12% | 202 | 0.31% | 279 | 0.43% | 25 | 0.04% | 36 | 0.06% | 54 | 0.08% | 7 | 0.01% | 36 | 0.06% | **763** | **1.17%** | **167** |
| 1648T | Apr-05 | 2,836 | 758 | 0 | 0.00% | 6 | 0.21% | 2 | 0.07% | 16 | 0.56% | 3 | 0.11% | 1 | 0.04% | 14 | 0.49% | 4 | 0.14% | 0 | 0.00% | 6 | 0.21% | **52** | **1.83%** | **8** |
| 1642T | May-02 | 27,144 | 7,006 | 0 | 0.00% | 11 | 0.04% | 43 | 0.16% | 69 | 0.25% | 59 | 0.22% | 17 | 0.06% | 7 | 0.03% | 15 | 0.06% | 3 | 0.01% | 5 | 0.02% | **229** | **0.84%** | **39** |
| 1646T | May-02 | 90,423 | 22,477 | 2 | <0.01% | 124 | 0.14% | 36 | 0.04% | 394 | 0.44% | 206 | 0.23% | 14 | 0.02% | 50 | 0.06% | 138 | 0.15% | 7 | <0.01% | 34 | 0.04% | **1005** | **1.11%** | **128** |
| 1688T/TC | Jun-03 | 491,763 | 146,391 | 44 | <0.01% | 607 | 0.12% | 630 | 0.13% | 1749 | 0.36% | 2198 | 0.45% | 173 | 0.04% | 256 | 0.05% | 660 | 0.13% | 51 | 0.01% | 212 | 0.04% | **6580** | **1.34%** | **1600** |

*Definitions of observations and complications can be found on page 7.*

## Pacing Leads
# U.S. Malfunction Summary

| MODELS | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| LPA1200M | 167,468 | 0.00% | 43 | 0.03% | 65 | 0.04% | 0 | 0.00% | 7 | <0.01% | 223 | 0.13% | **338** | **0.20%** |
| 2088TC | 918,999 | 3.90% | 86 | <0.01% | 1123 | 0.12% | 0 | 0.00% | 33 | <0.01% | 1871 | 0.20% | **3113** | **0.34%** |
| 1999 | 47,419 | 5.00% | 7 | 0.01% | 85 | 0.18% | 0 | 0.00% | 7 | 0.01% | 176 | 0.37% | **275** | **0.58%** |
| 1944 | 19,671 | 7.70% | 0 | 0.00% | 17 | 0.09% | 0 | 0.00% | 1 | <0.01% | 38 | 0.19% | **56** | **0.28%** |
| 1948 | 73,129 | 4.50% | 17 | 0.02% | 141 | 0.19% | 0 | 0.00% | 1 | <0.01% | 99 | 0.14% | **258** | **0.35%** |
| 1699T/TC | 22,887 | 5.60% | 14 | 0.06% | 47 | 0.21% | 0 | 0.00% | 0 | 0.00% | 57 | 0.25% | **118** | **0.52%** |
| 1888T/TC | 302,004 | 5.20% | 48 | 0.02% | 1124 | 0.37% | 1 | <0.01% | 15 | <0.01% | 914 | 0.30% | **2102** | **0.70%** |
| 1882T/TC | 49,648 | 4.40% | 2 | <0.01% | 98 | 0.20% | 0 | 0.00% | 3 | <0.01% | 152 | 0.31% | **255** | **0.51%** |
| 1782T/TC | 16,412 | 5.50% | 1 | <0.01% | 48 | 0.29% | 0 | 0.00% | 0 | 0.00% | 51 | 0.31% | **100** | **0.61%** |
| 1788T/TC | 65,264 | 5.80% | 10 | 0.02% | 132 | 0.20% | 1 | <0.01% | 1 | <0.01% | 106 | 0.16% | **250** | **0.38%** |
| 1648T | 2,836 | 0.00% | 0 | 0.00% | 18 | 0.63% | 0 | 0.00% | 2 | 0.07% | 6 | 0.21% | **26** | **0.92%** |
| 1642T | 27,144 | 0.00% | 0 | 0.00% | 40 | 0.15% | 1 | <0.01% | 2 | <0.01% | 22 | 0.08% | **65** | **0.24%** |
| 1646T | 90,423 | 5.40% | 22 | 0.02% | 84 | 0.09% | 0 | 0.00% | 6 | <0.01% | 75 | 0.08% | **187** | **0.21%** |
| 1688T/TC | 491,763 | 5.40% | 221 | 0.04% | 1106 | 0.22% | 2 | <0.01% | 21 | <0.01% | 857 | 0.17% | **2207** | **0.45%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Pacing Leads
# Worldwide Malfunction Summary

| MODELS | WORLDWIDE SALES | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| LPA1200M | 481,560 | 1.06% | 73 | 0.02% | 125 | 0.03% | 0 | 0.00% | 17 | <0.01% | 335 | 0.07% | **550** | **0.11%** |
| 2088TC | 3,073,537 | 1.23% | 118 | <0.01% | 1381 | 0.04% | 0 | 0.00% | 84 | <0.01% | 2470 | 0.08% | **4053** | **0.13%** |
| 1888T/TC | 1,144,936 | 1.63% | 72 | 0.01% | 1329 | 0.12% | 1 | <0.01% | 34 | <0.01% | 1298 | 0.11% | **2734** | **0.24%** |

*Definitions of malfunction categories can be found on pages 8-9.*

## Pacing Leads
# Actively Monitored Study Data Summary

### QUALIFYING COMPLICATIONS

| MODELS | NUMBER OF DEVICES ENROLLED | ACTIVE DEVICES ENROLLED | CUMULATIVE MONTHS OF FOLLOW-UP | ABNORMAL PACING IMPEDANCE | | CARDIAC PERFORATION | | CONDUCTOR FRACTURE | | EXTRACARDIAC STIMULATION | | FAILURE TO CAPTURE | | FAILURE TO SENSE | | INSULATION BREACH | | LEAD DISLODGEMENT | | OVERSENSING | | PERICARDIAL EFFUSION | | SKIN EROSION | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 2088 | 3,886 | 1,216 | 244,633 | 1 | 0.03% | 1 | 0.03% | 8 | 0.21% | 1 | 0.03% | 11 | 0.28% | 4 | 0.10% | 8 | 0.21% | 15 | 0.39% | 16 | 0.41% | 1 | 0.03% | 0 | 0.00% | **66** | **1.70%** |
| 1999 | 877 | 361 | 57,389 | 1 | 0.11% | 0 | 0.00% | 2 | 0.23% | 0 | 0.00% | 0 | 0.00% | 2 | 0.23% | 1 | 0.11% | 11 | 1.25% | 1 | 0.11% | 0 | 0.00% | 0 | 0.00% | **18** | **2.05%** |
| 1944 | 104 | 28 | 6,902 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.96% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.96%** |
| 1948 | 765 | 186 | 41,129 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.13% | 0 | 0.00% | 1 | 0.13% | 2 | 0.26% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **0.52%** |
| 1699T/TC | 1,451 | 245 | 81,243 | 1 | 0.07% | 0 | 0.00% | 2 | 0.14% | 0 | 0.00% | 4 | 0.28% | 0 | 0.00% | 1 | 0.07% | 8 | 0.55% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | **17** | **1.17%** |
| 1888T/TC | 14,505 | 3,697 | 942,252 | 7 | 0.05% | 2 | 0.01% | 10 | 0.07% | 4 | 0.03% | 19 | 0.13% | 5 | 0.03% | 29 | 0.20% | 58 | 0.40% | 22 | 0.15% | 0 | 0.00% | 1 | <0.01% | **157** | **1.08%** |
| 1882T/TC | 690 | 177 | 45,027 | 1 | 0.14% | 0 | 0.00% | 0 | 0.00% | 1 | 0.14% | 1 | 0.14% | 1 | 0.14% | 0 | 0.00% | 2 | 0.29% | 2 | 0.29% | 0 | 0.00% | 1 | 0.14% | **9** | **1.30%** |
| 1782T/TC | 165 | 7 | 6,007 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.61% | 0 | 0.00% | 0 | 0.00% | **1** | **0.61%** |
| 1788T/TC | 363 | 32 | 13,794 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.28% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.83% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **1.10%** |
| 1646T | 641 | 3 | 15,917 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.31% | 0 | 0.00% | 0 | 0.00% | 1 | 0.16% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **0.47%** |
| 1688T/TC | 2,645 | 328 | 106,378 | 5 | 0.19% | 0 | 0.00% | 3 | 0.11% | 0 | 0.00% | 3 | 0.11% | 0 | 0.00% | 3 | 0.11% | 6 | 0.23% | 3 | 0.11% | 1 | 0.04% | 1 | 0.04% | **25** | **0.95%** |

*A list of complications can be found on page 12.*

## Pacing Leads
# Actively Monitored Study Data Summary

### MALFUNCTIONS

| MODELS | NUMBER OF DEVICES ENROLLED | PERCENT RETURNED FOR ANALYSIS | CONDUCTOR FRACTURE | | INSULATION BREACH | | CRIMPS, WELDS & BONDS | | OTHER | | EXTRINSIC FACTORS | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| 2088TC | 3,886 | 5.50% | 1 | 0.03% | 15 | 0.39% | 0 | 0.00% | 0 | 0.00% | 13 | 0.33% | **29** | **0.75%** |
| 1999 | 877 | 7.10% | 0 | 0.00% | 6 | 0.68% | 0 | 0.00% | 0 | 0.00% | 10 | 1.14% | **16** | **1.82%** |
| 1944 | 104 | 2.90% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 1948 | 765 | 6.70% | 0 | 0.00% | 5 | 0.65% | 0 | 0.00% | 0 | 0.00% | 1 | 0.13% | **6** | **0.78%** |
| 1699T/TC | 1,451 | 3.90% | 0 | 0.00% | 3 | 0.21% | 0 | 0.00% | 0 | 0.00% | 6 | 0.41% | **9** | **0.62%** |
| 1888T/TC | 14,505 | 4.60% | 3 | 0.02% | 31 | 0.21% | 0 | 0.00% | 0 | 0.00% | 36 | 0.25% | **70** | **0.48%** |
| 1882T/TC | 690 | 5.20% | 0 | 0.00% | 3 | 0.43% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **0.43%** |
| 1782T/TC | 165 | 6.10% | 0 | 0.00% | 1 | 0.61% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.61%** |
| 1788T/TC | 363 | 5.50% | 0 | 0.00% | 2 | 0.55% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **2** | **0.55%** |
| 1646T | 641 | 2.30% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 1688T/TC | 2,645 | 6.80% | 1 | 0.04% | 6 | 0.23% | 0 | 0.00% | 0 | 0.00% | 5 | 0.19% | **12** | **0.45%** |

*Definitions of malfunction categories can be found on pages 8-9.*

# Implantable Cardiac Monitors (ICM) Devices

# Implantable Cardiac Monitors (ICMs) Devices

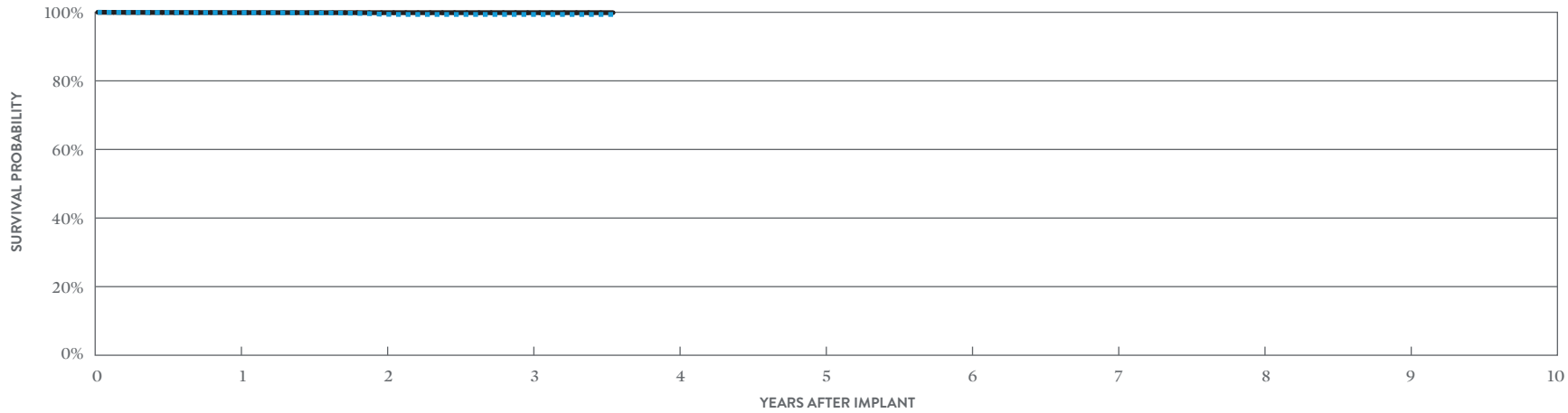
**CUSTOMER REPORTED PERFORMANCE DATA**

## Confirm Rx™ ICM

### MODEL DM3500

| | |
|---|---|
| US Regulatory Approval | September 2017 |
| Registered US Implants | 71,222 |
| Estimated Active US Implants | 56,174 |
| Estimated Longevity | 2 Years |
| Normal Battery Depletion | 59 |
| Number of US Advisories (see pg. 329) | One |

| | MALFUNCTIONS | |
|---|---|---|
| | QTY | RATE |
| Electrical Component | 7 | <0.01% |
| Electrical Interconnect | 9 | 0.01% |
| Battery | 0 | 0.00% |
| Software/Firmware | 0 | 0.00% |
| Mechanical | 2 | <0.01% |
| Possible Early Battery Depletion | 5 | <0.01% |
| Other | 4 | <0.01% |
| **Total** | **27** | **0.04%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | AT 43 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.88% | 99.43% | 99.36% | 99.36% |
| ± 1 STANDARD ERROR | 0.01% | 0.03% | 0.05% | 0.05% |
| SAMPLE SIZE | 57,530 | 33,640 | 15,400 | 710 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | AT 43 MONTHS |
|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.89% | 99.88% | 99.88% | 99.88% |
| ± 1 STANDARD ERROR | 0.01% | 0.01% | 0.01% | 0.01% |

# Implantable Cardiac Monitors (ICMs) Devices

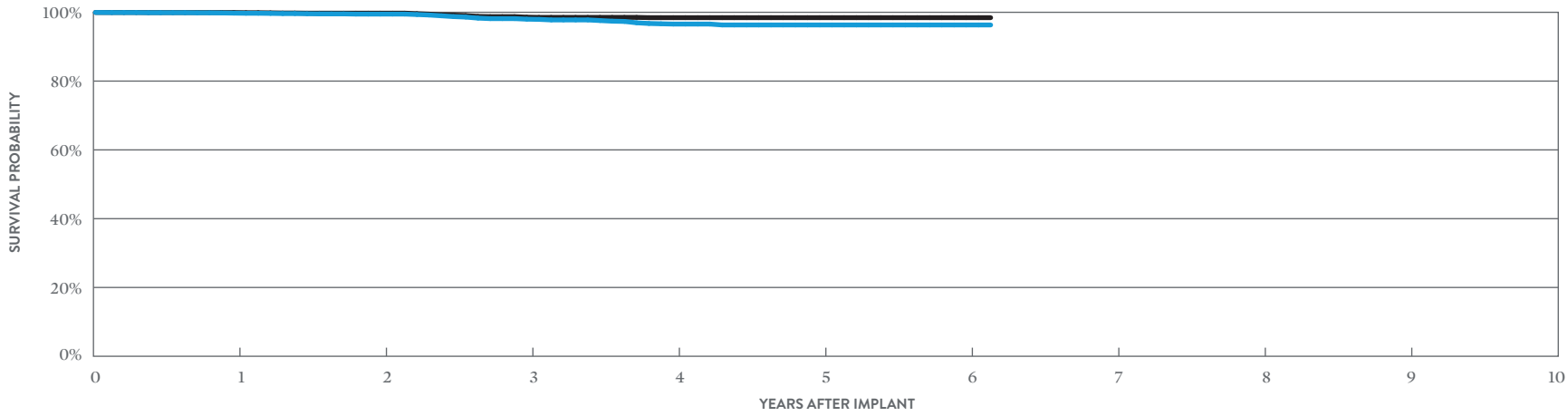
**CUSTOMER REPORTED PERFORMANCE DATA**

## SJM Confirm™ ICM

### MODEL DM2102

| | |
|---|---|
| US Regulatory Approval | May 2014 |
| Registered US Implants | 5,794 |
| Estimated Active US Implants | 3,413 |
| Estimated Longevity | 3 Years |
| Normal Battery Depletion | 26 |
| Number of US Advisories (see pg. 330) | One |

| | MALFUNCTIONS | |
|---|---|---|
| | QTY | RATE |
| Electrical Component | 19 | 0.33% |
| Electrical Interconnect | 0 | 0.00% |
| Battery | 1 | 0.02% |
| Software/Firmware | 0 | 0.00% |
| Mechanical | 0 | 0.00% |
| Possible Early Battery Depletion | 0 | 0.00% |
| Other | 4 | 0.07% |
| **Total** | **24** | **0.41%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 74 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.76% | 99.48% | 98.00% | 96.58% | 96.32% | 96.32% | 96.32% |
| ± 1 STANDARD ERROR | 0.06% | 0.11% | 0.22% | 0.32% | 0.34% | 0.34% | 0.34% |
| SAMPLE SIZE | 5,200 | 4,190 | 3,440 | 2,640 | 1,650 | 720 | 230 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | AT 74 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.93% | 99.75% | 98.58% | 98.44% | 98.44% | 98.44% | 98.44% |
| ± 1 STANDARD ERROR | 0.04% | 0.07% | 0.18% | 0.21% | 0.21% | 0.21% | 0.21% |

# Implantable Cardiac Monitors (ICMs) Devices

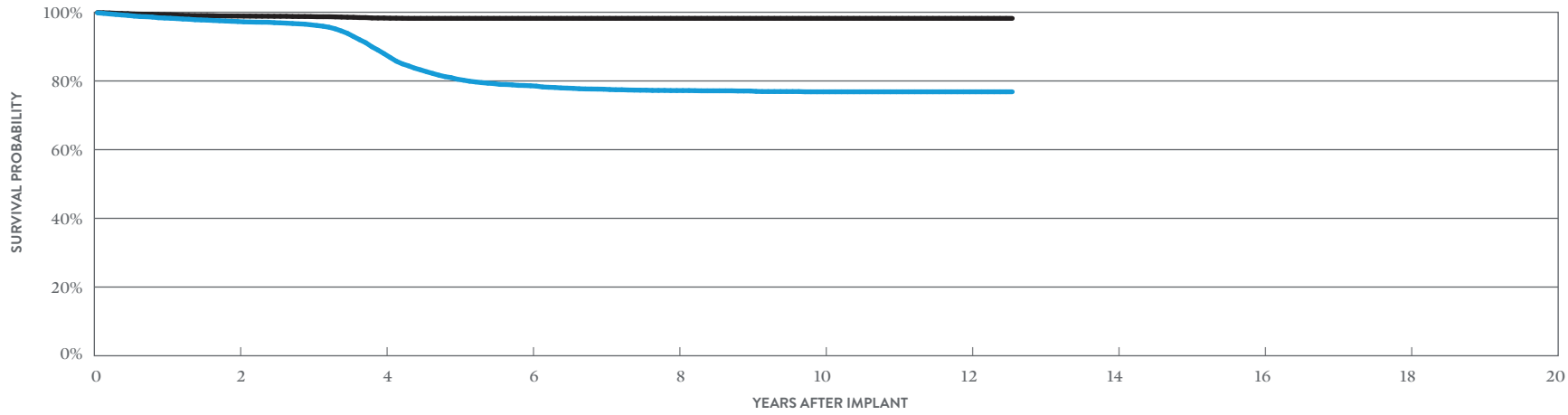
**CUSTOMER REPORTED PERFORMANCE DATA**

## SJM Confirm™ ICM

### MODEL DM2100

| | |
|---|---|
| US Regulatory Approval | August 2008 |
| Registered US Implants | 18,687 |
| Estimated Active US Implants | 5,640 |
| Estimated Longevity | 3 Years |
| Normal Battery Depletion | 887 |
| Number of US Advisories (see pg. 330) | One |

| | MALFUNCTIONS | |
|---|---|---|
| | QTY | RATE |
| Electrical Component | 15 | 0.08% |
| Electrical Interconnect | 1 | <0.01% |
| Battery | 20 | 0.11% |
| Software/Firmware | 10 | 0.05% |
| Mechanical | 0 | 0.00% |
| Possible Early Battery Depletion | 7 | 0.04% |
| Other | 42 | 0.22% |
| **Total** | **95** | **0.51%** |




**INCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 151 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 97.30% | 87.94% | 78.60% | 77.20% | 76.84% | 76.84% | 76.84% |
| ± 1 STANDARD ERROR | 0.13% | 0.30% | 0.40% | 0.41% | 0.42% | 0.42% | 0.42% |
| SAMPLE SIZE | 12,900 | 9,740 | 7,580 | 5,360 | 2,600 | 870 | 210 |

**EXCLUDING NORMAL BATTERY DEPLETION**

| YEAR | 2 | 4 | 6 | 8 | 10 | 12 | AT 151 MONTHS |
|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 98.90% | 98.32% | 98.22% | 98.22% | 98.22% | 98.22% | 98.22% |
| ± 1 STANDARD ERROR | 0.09% | 0.11% | 0.12% | 0.12% | 0.12% | 0.12% | 0.12% |

SUMMARY INFORMATION

# Implantable Cardiac Monitors (ICMS)

# Implantable Cardiac Monitors (ICMs) Devices

## Survival Probability Summary

### INCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DM3500 | Confirm Rx™ ICM | 99.88% | 99.43% | 99.36% | | | | | | | |
| DM2102 | SJM Confirm™ ICM | 99.76% | 99.48% | 98.00% | 96.58% | 96.32% | 96.32% | | | | |
| DM2100 | SJM Confirm™ ICM | 98.32% | 97.30% | 96.34% | 87.94% | 80.51% | 78.60% | 77.60% | 77.20% | 77.08% | 76.84% |

### EXCLUDING NORMAL BATTERY DEPLETION

| MODELS | FAMILY | 1 YEAR | 2 YEAR | 3 YEAR | 4 YEAR | 5 YEAR | 6 YEAR | 7 YEAR | 8 YEAR | 9 YEAR | 10 YEAR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DM3500 | Confirm Rx™ ICM | 99.89% | 99.88% | 99.88% | | | | | | | |
| DM2102 | SJM Confirm™ ICM | 99.93% | 99.75% | 98.58% | 98.44% | 98.44% | 98.44% | | | | |
| DM2100 | SJM Confirm™ ICM | 99.29% | 98.90% | 98.75% | 98.32% | 98.22% | 98.22% | 98.22% | 98.22% | 98.22% | 98.22% |

## Implantable Cardiac Monitors (ICMs) Devices

US Malfunction Summary

| MODELS | FAMILY | REGISTERED US IMPLANTS | PERCENT RETURNED FOR ANALYSIS | ELECTRICAL COMPONENT | | ELECTRICAL INTERCONNECT | | BATTERY | | SOFTWARE/ FIRMWARE | | MECHANICAL | | POSSIBLE EARLY BATTERY DEPLETION | | OTHER | | TOTAL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE | QTY | RATE |
| DM3500 | Confirm Rx™ ICM | 71,222 | 2.50% | 7 | <0.01% | 9 | 0.01% | 0 | 0.00% | 0 | 0.00% | 2 | <0.01% | 5 | <0.01% | 4 | <0.01% | **27** | **0.04%** |
| DM2102 | SJM Confirm™ ICM | 5,794 | 7.50% | 19 | 0.33% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 4 | 0.07% | **24** | **0.41%** |
| DM2100 | SJM Confirm™ ICM | 18,687 | 21.10% | 15 | 0.08% | 1 | <0.01% | 20 | 0.11% | 10 | 0.05% | 0 | 0.00% | 7 | 0.04% | 42 | 0.22% | **95** | **0.51%** |

*Definitions of malfunction categories can be found on pages 5-6.*

# Focus on Clinical Performance

# ICD Premature Battery Depletion Advisory Update – December 2021

Since the original October 11, 2016 communication, Abbott (formerly St. Jude Medical) has continued to analyze and review the performance data from the affected device population. The rates reported below summarize performance data through August 31, 2021.

Importantly, the information contained in this notice has not altered our previously communicated patient management recommendations. This information is designed to keep you informed of ongoing analysis of products returned to the company.

## RATES

The table below summarizes the updated worldwide experience for the affected devices that were returned for product analysis due to premature battery depletion (PBD). The table includes the updated data through August 31, 2021.

### UPDATED (THROUGH AUGUST 31, 2021)

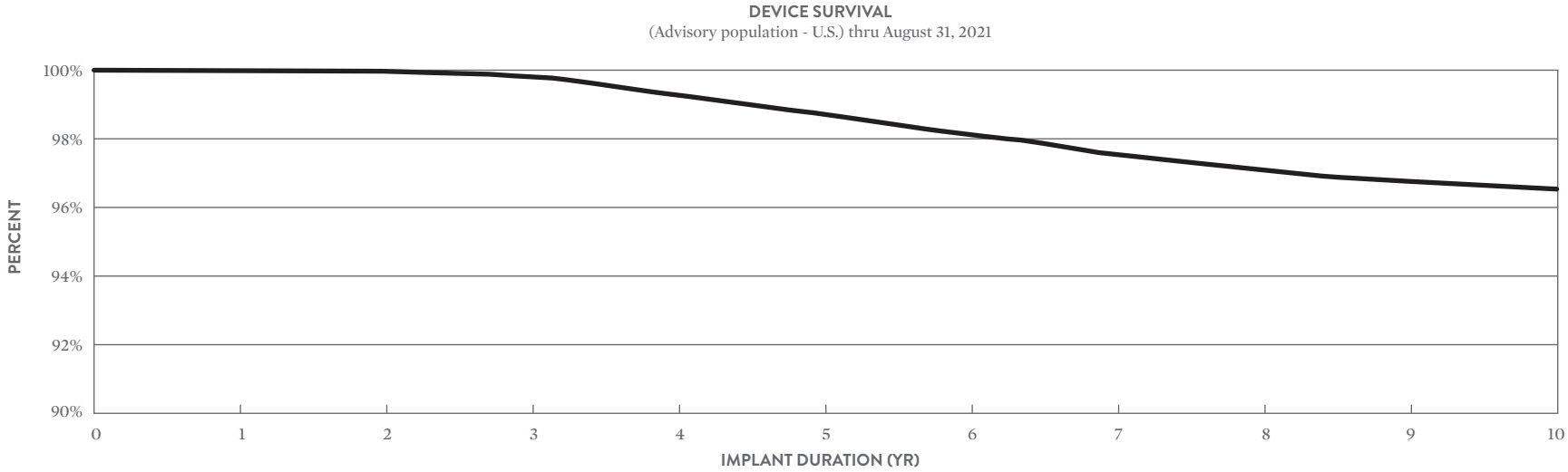
| WORLDWIDE PATIENT IMPACT | NUMBER / RATE THROUGH AUGUST 31, 2021 |
|---|---|
| No Harm Reported/Additional Surgery Only* | 8,476/2.126% |
| Loss of Pacing – Minor (Dizziness) | 58/0.01% |
| Loss of Pacing – Major (Syncope) | 29/<0.01% |
| Loss of Defibrillation – Emergency | 4/<0.01% |
| Loss of Defibrillation – Death | 2/<0.01% |
| **Grand Total** | **8,569/2.149%** |
| | |
| **Total Units Sold** | **398,740** |

**All impacts in this table were related to a replacement surgery, as the data are from units explanted and returned for analysis. The category "No Harm Reported/Additional Surgery Only" means there was no associated report of patient symptoms in addition to the replacement of the affected unit.*

*Note: The calculation also includes investigations primarily associated with the Battery Performance Alert notifications. These are reflected in the "No Harm Reported/Additional Surgery Only" category.*

# Estimated Performance of Affected Fortify™ Implantable Cardioverter Defibrillator (ICD), Fortify Assura™ ICD, Quadra Assura™ Cardiac Resynchronization Therapy Defibrillator (CRT-D), Unify™ CRT-D, Unify Assura™ CRT-D and Unify Quadra™ CRT-D Devices

**TEN-YEAR COMBINED KAPLAN-MEIER SURVIVAL CURVE OF FREEDOM FROM PREMATURE BATTERY DEPLETION ASSOCIATED WITH LITHIUM DEPOSITS IN AFFECTED U.S. ADVISORY DEVICE POPULATION**




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 99.997% | 99.970% | 99.750% | 99.224% | 98.573% | 97.939% | 97.389% | 96.964% | 96.688% | 96.491% |
| SAMPLE SIZE | 227,000 | 210,000 | 197,000 | 184,900 | 173,000 | 156,000 | 114,000 | 76,000 | 49,000 | 23,600 |

## SURVIVAL CALCULATION GENERAL METHODS

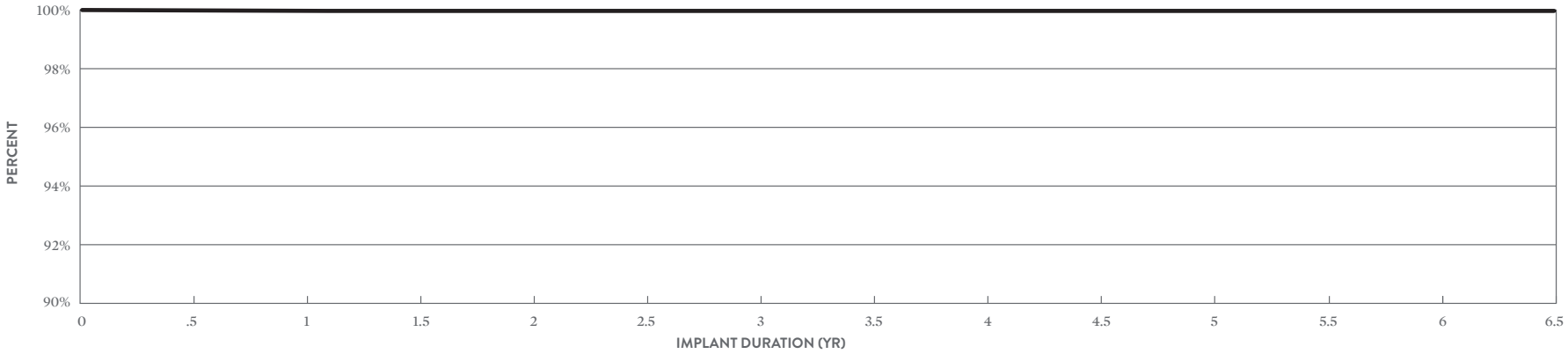
Internal modeling based on an analysis of field returns related to premature battery depletions associated with lithium clusters; updated with data through August 31, 2021.

## Non-Advisory Population Update

Fortify™, Fortify Assura™, Quadra Assura™, Quadra Assura MP™, Unify™, Unify Assura™ and Unify Quadra™ Devices manufactured after May 23, 2015 were built with an improved battery design with additional insulation and thus not included in the advisory population. Through August 2021 there have been zero (N=0) occurrences, worldwide, of premature depletion due to Li clusters with the improved design.

In the US there have been ~ 211,000 implanted devices with the improved battery design with no occurrences of premature depletion associated with Li clusters. Of the implanted US population, ~93% (or ~197,000) have exceed 1 year of implant duration and ~78% (or ~164,000) have exceed 2.0 years of implant duration with no occurrences of premature depletion due to Li clusters.

**SURVIVAL PLOT FOR NON-ADVISORY POPULATION**
**KAPLAN-MEIER METHOD**
**CENSORING FOR NON-ADVISORY POPULATION WITH CLUSTER**




| YEAR | .5 | 1 | 1.5 | 2 | 2.5 | 3 | 3.5 | 4 | 4.5 | 5 | 5.5 | 6 | 6.5 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SURVIVAL PROBABILITY | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| SAMPLE SIZE | ~211,000 | ~197,000 | ~181,000 | ~164,000 | ~146,000 | ~128,000 | ~111,000 | ~93,500 | ~77,000 | ~58,500 | ~33,700 | ~16,500 | ~2,500 |

# Update on Riata™ Lead Performance

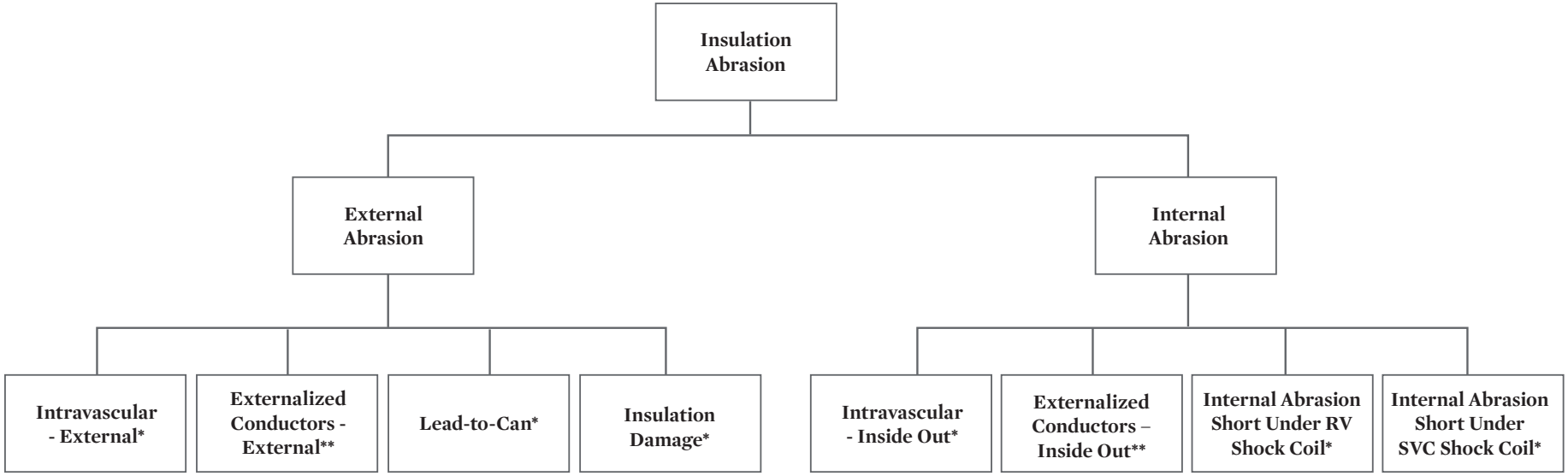
## CUSTOMER REPORTED PERFORMANCE DATA

Abbott understands that the passive system of complaint reporting and returned product analysis results in under-reporting and hence underestimates the true failure rate associated with any given failure mechanism. This is especially true for externalized conductors since most manifest as visual anomalies only with normal electrical performance. While acknowledging these limitations, Abbott provides externalized conductor rates from the passive data system to maintain continuity with previously published data and to provide full disclosure of the data available to Abbott. As of August 31, 2021, there were 6,553 cases of externalized conductors reported to Abbott worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 3.52% (5,493/156,000) incidence rate for Riata (8F) and 1.50% (1,060/70,600) for Riata ST (7F) leads. Of these 6,553 leads, 4,787 were not returned and 1,766 were returned for analysis.

As with any lead, there are failure mechanisms other than externalized conductors which result from insulation abrasion. Historically, the rate of all-cause insulation abrasion failures has been reported in the range of 3 to 10% (Kleemann et al., Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter Defibrillators over a Period > 10 years, Circulation 2007; 115:2474-2480). The most common form of insulation abrasion has been lead-to-can abrasion occurring in the pocket area. Externalization of conductors is another manifestation of insulation abrasion. It is most commonly caused by a mechanism referred to as inside-out abrasion, where the conductor cables become visible outside the insulation body. Approximately 87% of confirmed externalized conductors from product returns analysis are caused by inside-out abrasion, while 13% result from external sources of abrasion.

A flow diagram depicting specific insulation abrasion failure mechanisms for Riata™ and Riata™ ST silicone leads is shown in the following figure.

**FLOW DIAGRAM OF INSULATION ABRASION TYPES AND FAILURE MECHANISMS**




**Determined by returned product analysis.*
***Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.*

Definitions of the failure mechanisms are provided below:

- **External Abrasion:** Abrasion resulting from direct contact with an implanted device (e.g., pulse generator can, another lead), calcified anatomy, or anatomical structure that results in an outer insulation breach.
- **Internal Abrasion:** "Inside-out" abrasion between a lead conductor and the outer insulation that results in an insulation breach.
- **Intravascular Abrasion - External:** Direct contact with a foreign body (e.g., another lead), calcified anatomy, or cardiac structure within the vascular system or the heart that results in an outer insulation breach. The nature of the breach does not result in the conductors becoming visible outside the lead body. Determined by returned product analysis.
- **Externalized Conductors – External Source of Abrasion:** Direct contact with a foreign body (e.g., another lead), calcified anatomy, or cardiac structure within the vascular system or the heart that results in an outer insulation breach and the normally contained conductors becoming visible outside the lead body. Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads. For those cases not returned, the assignment of an external source of abrasion is based on the fraction of externalized conductor cases identified by returned product analysis as external.
- **Lead-to-Can Abrasion:** Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) that results in an outer insulation breach. Determined by returned product analysis.
- **Insulation Damage:** Insulation breaches that result from external mechanisms, including clavicular crush and outside-in abrasion by lead conductors. Determined by returned product analysis.
- **Intravascular Abrasion – Inside Out:** "Inside-out" abrasion between a lead conductor and the outer insulation within the vascular system or the heart that results in an outer insulation breach. The nature of the breach does not result in the conductors becoming visible outside the lead body. Determined by returned product analysis.
- **Externalized Conductors – Inside-Out:** Outward abrasion of conductors that results in an outer insulation breach within the vascular system or heart and the normally contained conductors becoming visible outside the lead body. Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads. For those cases not returned, the assignment of an inside-out source of abrasion is based on the fraction of externalized conductor cases identified by returned product analysis as inside-out.
- **Internal Abrasion Short under RV Shock Coil:** Outward abrasion of the conductor cables under the RV shock coil that results in breaches of the outermost silicone insulation and the ETFE cable insulator, allowing the exposed metal surface of the conductor cables to make direct contact with, and potentially short against, the overlying RV shock coil. Determined by returned product analysis.
- **Internal Abrasion Short under SVC Shock Coil:** Outward abrasion of the conductor cables under the SVC shock coil that results in breaches of the outermost silicone insulation and the ETFE cable insulator, allowing the exposed metal surface of the conductor cables to make direct contact with, and potentially short against, the overlying SVC shock coil. Determined by returned product analysis.

The table below summarizes the incidence of insulation abrasion failure mechanisms confirmed by returns analysis of Riata™ and Riata™ ST leads. Approximately 15,060 Riata and Riata ST leads have been returned for analysis worldwide through August 31, 2021. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive. Note that the rates for externalized conductors also include visual-only observations that have been reported for leads remaining implanted.

### RIATA™ (8F) AND RIATA™ ST (7F) LEAD INSULATION ABRASION FAILURE MECHANISMS FROM COMPLAINTS AND RETURNS

| INSULATION FAILURE MECHANISM | ABRASION TYPE | RIATA (8F) WORLDWIDE (WW) INCIDENCE RATE (WW SALES = 156,100) | RIATA ST (7F) WORLDWIDE (WW) INCIDENCE RATE (WW SALES = 70,600) |
|---|---|---|---|
| Intravascular – External* | External Abrasion | 0.54% | 0.58% |
| Externalized Conductors – External** | External Abrasion | 0.42% | 0.21% |
| Lead-to-Can* | External Abrasion | 1.06% | 0.97% |
| Insulation Damage* | External Abrasion | 0.11% | 0.07% |
| Intravascular - Inside Out* | Internal Abrasion | 0.63% | 0.44% |
| Externalized Conductors - Inside Out** | Internal Abrasion | 3.13% | 1.29% |
| Internal Abrasion Short Under RV Shock Coil* | Internal Abrasion | 0.13% | 0.05% |
| Internal Abrasion Short Under SVC Shock Coil* | Internal Abrasion | 0.13% | 0.021% |

**Determined by returned product analysis.*
***Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.*

# Update on Durata™ Lead Performance

## CUSTOMER REPORTED PERFORMANCE DATA

While large active registry data are robust for determining the true incidence rate of failures, passively collected data from worldwide complaints and returns analysis provides an important data source for better understanding the root cause of lead failures, as well as an appropriate method for comparing relative incidence rates of failure between lead models. The table below summarizes the incidence of insulation abrasion failure mechanisms confirmed by returns analysis of Riata™ ST Optim™ and Durata™ leads. Approximately 28,040 Riata ST Optim and Durata leads have been returned for analysis worldwide through August 31, 2021. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive.

**DURATA™ (WW SALES 909,320) AND RIATA™ ST OPTIM™ (WW SALES = 33,108) LEADS INSULATION FAILURE MECHANISMS FROM COMPLAINTS AND RETURNS ANALYSIS**

| INSULATION FAILURE MECHANISM | ABRASION TYPE | OPTIM DEFIB LEAD WORLDWIDE (WW) INCIDENCE RATE (WW SALES = 942,429) |
|---|---|---|
| Intravascular – External* | External Abrasion | 0.033% |
| Externalized Conductors – External** | External Abrasion | 0.007% |
| Lead-to-Can* | External Abrasion | 0.102% |
| Insulation Damage* | External Abrasion | 0.026% |
| Intravascular - Inside Out* | Internal Abrasion | 0.00202%*** |
| Externalized Conductors - Inside Out** | Internal Abrasion | 0.00042%*** |
| Internal Abrasion Short Under RV Shock Coil* | Internal Abrasion | 0.015% |
| Internal Abrasion Short Under SVC Shock Coil* | Internal Abrasion | 0.009% |

**Determined by returned product analysis.*
***Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.*
****These values reflect returns with a silicone insulation breach due to inside-out abrasion in the short region not protected by Optim insulation.*

These incidence rates from complaints and returns analysis demonstrate the effectiveness of the Riata ST Optim and Durata lead design changes in reducing insulation-related failures when compared to the same type of data for Riata and Riata ST silicone leads (see page 305).

# Update on Optim™ Lead Insulation

In 2006 Abbott brought to the cardiac rhythm management (CRM) market the first novel insulation technology in over 20 years: a silicone-polyurethane co-polymer known as Optim™ lead insulation, now featured in IsoFlex™ Optim™, Tendril™ STS, OptiSense™, QuickFlex™ µ, Quartet™, Durata™, and Optisure™ lead families. Optim lead insulation consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone.

The polyurethane content of Optim lead insulation imparts lubricity, strength, and abrasion resistance while the nearly 50% silicone content imparts flexibility and biostability.[1,2] The clinical performance of >7.7 million Optim insulated pacing and tachycardia leads implanted worldwide continues to be excellent. All aspects of Optim lead insulation performance can be appreciated by referring to the Acute Observation, Chronic Complication, Lead Malfunction, and Survival Probability data found in this Product Performance Report. One noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[3] Insulation abrasion can occur as a result of lead motion and contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. Abrasion within a lead can occur as a result of contact between internal components, as noted in our November 2011 Riata™ lead advisory. The clinical effects associated with all types of insulation abrasion malfunctions can include sensing noise and changes in both pacing and defibrillation impedances and thresholds. As indicated in our December 2010 Riata communication, the presence of Optim™ lead insulation on the Riata™ ST Optim™ and Durata™ defibrillation lead family has greatly reduced the quantity of all abrasion types.

This Product Performance Report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on Abbott tachycardia leads. A Kaplan-Meier analysis including all U.S. data through June 30, 2021 was performed on two groups of leads: (1) tachycardia leads with silicone insulation [Riata and Riata ST lead families], and (2) tachycardia leads with Optim lead insulation [Riata ST Optim and Durata lead families]. For each group, the U.S. registration and tracking data was combined with data from all U.S. confirmed abrasion malfunctions. This analysis does not include data from prospective registries or non-returned complaints. A Kaplan-Meier curve representing freedom from abrasion for both groups is provided below. The longest implant duration that is common to both model groups was 176 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 176 months of implant time is also presented in graphical format below.

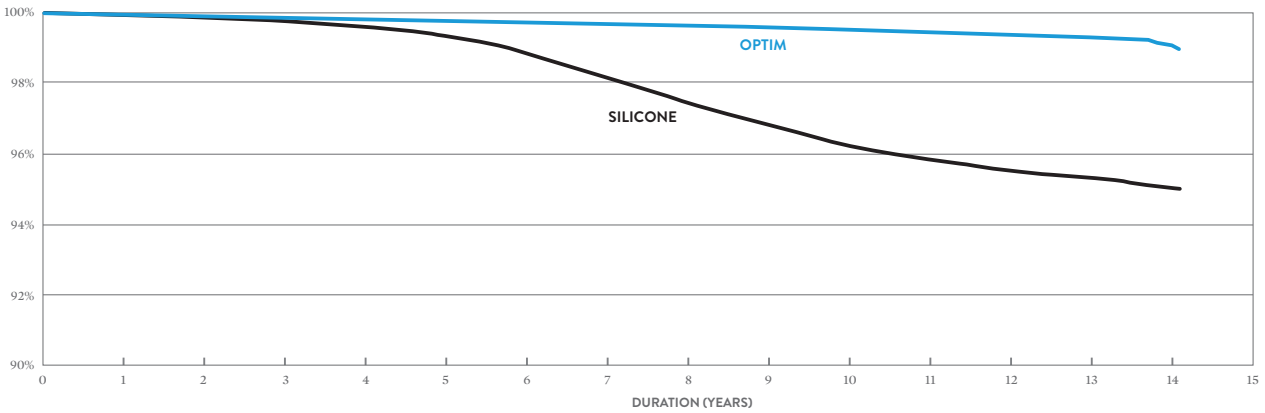
1 C. Jenney, J. Tan, A. Karicherla, J. Burke, and J. Helland, *"A New Insulation Material for Cardiac Leads with Potential for Improved Performance,"* HRS 2005, HeartRhythm, 2, S318-S319 (2005).
2 J. Tan and C. Jenney, *"Comparative In Vivo Biostability Study of A New Lead Insulation Material Versus Polyurethanes,"* HRS2006, Heart Rhythm, 3, S146 (2006).
3 T. Kleemann, T. Becker, K. Doenges, M. Vater, J. Senges, S. Schneider, W. Saggau, U. Weisse, and K. Seidl, *"Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years,"* Circulation, 115, 2474-2480 (2007).

The data show that the presence of Optim™ lead insulation dramatically reduces the probability of abrasion malfunction in tachycardia leads at 176 months by 79%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test.

## OPTIM™ LEAD INSULATION EFFECTS ON ABBOTT TACHYCARDIA LEAD ABRASION

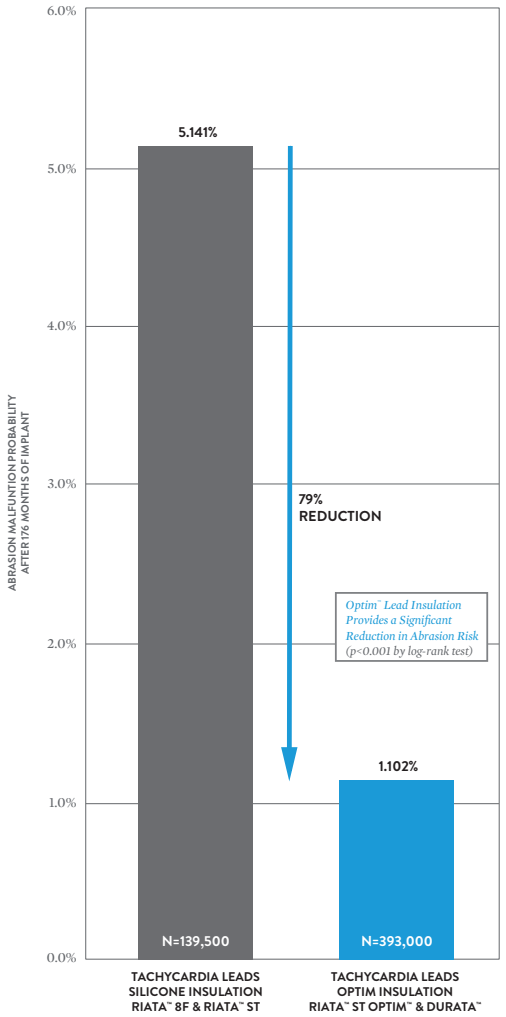
### KAPLAN-MEIER ANALYSIS OF U.S. RETURNS ANALYSIS DATA

FREEDOM FROM ABRASION FAILURE (%)




| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 176 MONTHS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| OPTIM | 343,452 | 312,821 | 283,492 | 256,635 | 231,582 | 205,196 | 176,584 | 143,910 | 117,284 | 89,906 | 59,581 | 31,630 | 12,645 | 2,282 | 0 |
| SILICONE | 121,520 | 110,955 | 100,987 | 91,529 | 82,924 | 75,203 | 68,488 | 62,890 | 58,531 | 55,260 | 52,839 | 50,292 | 46,026 | 36,808 | 29,118 |

ABRASION MALFUNCTION PROBABILITY
AFTER 176 MONTHS OF IMPLANT



# Advisories & Safety Alerts

# Advisories & Safety Alerts

The following table summarizes advisories and safety alerts regarding Abbott implantable device systems since 2005. These advisories and alerts have been previously communicated to physicians. For more information please access our Product Advisory web page at Cardiovascular Product Advisories | Abbott or contact Abbott Technical Services at 1-800-722-3774.

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| **GLOBAL MODELS**<br>Subset of Ellipse™ (Models CD2411-36C, CD1277-36, CD1377-36C, CD1377-36QC, CD2277-36Q, CD2377-36QC) | **1/22/2020**<br>**Class II**<br><br>Abbott is notifying physicians that a small number of Ellipse™ Implantable Cardioverter Defibrillators (ICDs) may lose wireless radiofrequency (RF) communication. Devices will continue to function normally, but remote monitoring and data transmission capabilities may be interrupted. | Abbott has developed a software patch for the Merlin™ PCS Programmer which restores wireless RF communication capability in affected devices. This solution does not present additional risk to patients and device explant is not required for the update. The solution is available in Merlin™ PCS Programmer software Model 3330 v24.6.1 or later and Abbott will assist in updating programmer software and restoring wireless RF communication for these devices.<br><br>We recommend working with your Abbott representative to help correct affected devices during the patient's next regularly scheduled visit.<br><br>**Current Status (June 30, 2021):** No occurrences have been reported following the field communication and correction. |

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| **GLOBAL MODELS**<br>Ellipse™ (Models CD1411-36Q, CD2411-36Q, CD2411-36C) | **6/21/2019**<br>**Class I**<br><br>The potential for electrical failures was identified in implantable cardioverter defibrillators (ICDs) due to a manufacturing error with aluminum wires. The affected ICDs may contain electrical wire connections which may not be completely insulated. The potential patient impact could be the inability to deliver high voltage therapy. There is no available option to verify the vulnerability status for implanted devices. | On June 20, 2019 Abbott began voluntarily recalling a small number (204 devices globally) of Ellipse implantable cardioverter defibrillators (ICDs) from our customers and hospitals to prevent implant of devices that may have a latent vulnerability in the electronics circuitry. We have currently received zero (0) product performance complaints related to this issue. On June 21, 2019, hand-delivery of Urgent Medical Device Recall Notices to physicians supporting implanted patients commenced. Device explant and replacement are recommended. Customers were advised to: 1) Review the device model and serial numbers in the appendix of the customer letter to identify the impacted patients and return the acknowledgement form to the Abbott sales representative; and 2) Device explant and replacement are recommended. A copy of this letter is available on Cardiovascular Product Advisories \| Abbott. Customers with additional questions are encouraged to call 1-800-727-7846 (Opt3), 8:30am - 5:30pm Central Time, Monday thru Friday.<br><br>**Current Status (June 30, 2021):**<br>No occurrences of failure to deliver high voltage therapy have been reported following the field communication. Potentially affected devices have been or are planned for explant per recommendations. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| **GLOBAL MODELS**<br>Current™ (Models 1207-30, 1207-36, 2207-30, 2207-36, CD1211-36, CD1211-36Q, CD1215-36, CD1215-36Q, CD1217-36, CD1219-36, CD1219-36Q, CD2211-36, CD2211-36Q, CD2215-36, CD2215-36Q, CD2217-36, CD2219-36, CD2219-36Q)<br>Ellipse™ (Models CD1275-36, CD1275-36Q, CD1277-36, CD1277-36Q, CD1293-36Q, CD1309-36, CD1309-36Q, CD1311-36, CD1311-36Q, CD1377-36, CD1377-36C, CD1377-36Q, CD1377-36QC, CD1393-36C, CD1393-36QC, CD1409-36Q, CD1411-36C, CD1411-36Q, CD1411-36QC, CD2275-36, CD2275-36Q, CD2277-36, CD2277-36Q, CD2293-36, CD2293-36Q, CD2309-36, CD2309-36Q, CD2311-36, CD2311-36Q, CD2377-36, CD2377-36C, CD2377-36Q, CD2377-36QC, CD2393-36C, CD2393-36QC, CD2409-36C, CD2409-36Q, CD2411-36C, CD2411-36Q)<br>Excelis Quadra™ (Models CD3281-40, CD3281-40Q)<br>Excelis™ (Models CD3389-40C, CD3389-40QC)<br>Excelis™ CRT-D (Models CD3297-40, CD3297-40Q)<br>Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC)<br>Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2363-40C, CD2363-40Q)<br>Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q)<br>Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC)<br>Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q)<br>Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q)<br>Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q)<br>Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q)<br>HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC)<br>HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC)<br>HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q)<br>Promote™ (Models 3207-30, 3207-36, 3213-36, CD3211-36, CD3211-36Q, CD3215-36, CD3215-36Q)<br>Promote Quadra™ (Models CD3221-36, CD3223-36P, CD3239-40, CD3239-40Q)<br>Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC, CD3387-40C, CD3387-40QC)<br>Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3369-40C, CD3369-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC)<br>Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC)<br>Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC)<br>Unify Quadra MP™ (Models CD3255-40, CD3255-40Q)<br>Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q)<br>Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q) | **4/16/2018**<br>**Class II**<br><br>Abbott released a planned upgrade to the firmware installed on our implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) devices. The cybersecurity firmware update provides an additional layer of protection against unauthorized device access. | Prophylactic replacement of affected devices is not recommended.<br><br>**Recommendations for Devices Eligible for Firmware Upgrade**<br>While not intended to serve as a substitute for your professional judgment, we, along with our Medical Advisory Boards, recommend the firmware upgrade for all eligible patients at the next regularly scheduled visit or when appropriate depending on the preferences of the patient and physician.<br>Please consider the following:<br>• Discuss the risks and benefits of the firmware update with your patients. As part of this discussion, it is important to consider patient specific issues such as pacemaker dependence, frequency of high voltage therapy, age of device, and patient preference.<br>• If deemed appropriate, install this firmware update following the instructions on the programmer.<br>• The update should be performed with appropriate monitoring and external defibrillation equipment available.<br><br>**Recommendations for Current™ & Promote™ Devices not Eligible for Cybersecurity Firmware Update**<br>If you have any concerns relating to device cybersecurity for those patients implanted with Current™/Promote™ devices, you do have the option to permanently disable the RF communication capability in the device. However, if you choose that option, the patient can no longer be monitored remotely using an RF Merlin@home transmitter. For most patients, permanently disabling RF is not advisable given the proven benefits and improved survival associated with home monitoring. [1,2] Therefore we, along with our Medical Advisory Boards, recommend the following:<br>• Discuss the risks of cybersecurity vulnerabilities and proven benefits of remote monitoring with your patients at the next regularly scheduled visit.<br>• If deemed appropriate, RF communication may be permanently disabled during an in-clinic device interrogation with Merlin programmer software version 24.2.x or later by selecting the RF icon in the upper left corner of the FastPath summary screen.<br><br>**Current Status (June 30, 2021):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.<br><br>If you have any questions about the cybersecurity firmware update you can contact your Abbott representative or our dedicated customer technical support hotline at 1-800-722-3774 (U.S.).<br><br>Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories \| Abbott.<br>[1] Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). Remote monitoring of ICD patients is associated with reduced mortality irrespective of device type. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and had limitations.<br>[2] Mittal, S., Piccini, J., Fischer, A., Snell, J., Dalal, N., & Varma, N. (2014, May). Increased adherence to remote monitoring is associated with reduced mortality in both pacemaker and defibrillator patients. Presented at the meeting of the Heart Rhythm Society, San Francisco, CA. This was a retrospective data review and has limitations. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| **GLOBAL MODELS**<br>Excelis Quadra™ (Models CD3281-40, CD3281-40Q)<br>Excelis™ + (Models CD3389-40C, CD3389-40QC)<br>Excelis™ CRT-D (Models CD3297-40, CD3297-40Q)<br>Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC)<br>Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2363-40C, CD2363-40Q)<br>Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q)<br>Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC)<br>Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q)<br>Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q)<br>Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q)<br>Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q)<br>HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC)<br>HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC)<br>HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q)<br>HeartMinder™ ST VR (Models CD1299-40, CD1299-40Q)<br>Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC)<br>Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC)<br>Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC)<br>Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC)<br>Unify Quadra MP™ (Models CD3255-40, CD3255-40Q)<br>Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q)<br>Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q) | **10/11/2016**<br>**Class I**<br><br>High voltage devices (ICDs and CRT-Ds) that utilize Lithium-based battery chemistries are subject to Lithium cluster formation during high voltage charging. Depending on their location, Lithium clusters may cause a short circuit that can lead to premature battery depletion. Our investigation indicates that if a short circuit occurs, battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy.<br><br>**8/28/2017**<br>**Class I**<br><br>Customers were made aware of the availability of a new battery performance management tool for detection of abnormal battery performance in devices subject to the October 2016 advisory.<br><br>A follow up was provided on April 16, 2018 regarding the availability of a firmware upgrade for devices subject to the October 2016 advisory which provides further detection capability for premature battery depletion. | In consultation with our Medical Advisory Board, we recommend the following:<br><br>• Do not implant unused affected devices.<br>• Conduct patient follow-up per standard practice.<br>• Prophylactic device replacement is NOT recommended because complications following replacement have been reported to occur at a greater rate than the rate of harm associated with premature battery depletion due to lithium cluster induced shorts (see below for selected references).<br>• In the event of an ERI indicator in these devices, immediate device change is recommended. At this time there is no factor, method or test to identify devices with this form of premature battery depletion approaching ERI or to accurately predict remaining battery life once ERI appears.<br>• Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.<br>• Enroll patients in Merlin.net™ Patient Care Network (PCN) utilizing the "DirectAlerts™" feature to provide you with an immediate alert notification in the event ERI is reached. For patients currently enrolled in Merlin.net PCN, remind them of the importance of using remote monitoring.<br>• Review the most recent Programmed Parameters printout.<br>  • Ensure that under the "Trigger Alerts When" section, that the "Device at ERI" parameter is ON (it is normally ON) for both "Show on FastPath" and "Notify Patient" selections.<br>  • If the "Device at ERI" alert is OFF, we recommend that the patient be seen promptly to program this parameter ON.<br>• Advise patients that an ERI indication triggers a vibratory alert. At the next scheduled office visit:<br>  • Interrogate the patient's device to determine if an ERI alert has been triggered. Premature battery depletion can be identified by physicians through home monitoring showing ERI or more advanced battery depletion.<br>  • Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.<br>  • Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness.<br>  • Advise the patient to contact your office promptly should they feel a vibratory alert.<br>  • In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.<br><br>The following additional recommendations were communicated in April 2018 follow up advisory:<br>• Patients receiving the firmware update should be advised that the device-based Battery Performance Alert (BPA) will trigger a vibratory alert.<br>• In the absence of a BPA being triggered in a patient's device, through Merlin.net or the Merlin programmer, we continue to recommend adhering to the original patient management recommendations from the 2016 Premature Battery Depletion advisory. However, if the BPA is triggered, **immediate device explant and replacement is recommended.**<br><br>Device Replacement Complication Publications<br><br>1. John W. Moore III, William Barrington, et. al.; "Complications of replacing implantable devices in response to advisories: A single center experience"; International Journal of Cardiology 134 (2009) 42–46 (5.5% overall, 2.1% major complications)<br>2. Paul A. Gould, MBBS, PhD, Lorne J. Gula, MD, et. al.; "Outcome of advisory implantable cardioverter- defibrillator replacement: One-year follow-up"; Heart Rhythm, Vol 5, No 12, December 2008 (9.1% overall, 5.9% major complications, including two deaths)<br>3. Krystina B. Lewis, Dawn Stacey, R.N., Ph.D, et. al.; "Estimating the Risks and Benefits of Implantable Cardioverter Defibrillator Generator Replacement: A Systematic Review; PACE, Vol. 39, July 2016 (7.5% overall, 4.0% major complications)<br><br>**Current Status (August 31, 2021):** At the time of the advisory, 841 returned devices (0.21%) of 398,740 devices worldwide had premature depletion in association with lithium clusters, including 549 in the US. As of August 31, 2021, there were additional occurrences for a cumulative worldwide total of 8,569 and the rate is now 2.15%.<br><br>For additional information and to determine if a device serial number is subject to this advisory, please go to the following website: Cardiovascular Product Advisories \| Abbott. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Ellipse™ and Ellipse ST VR/DR<br>US: CD1309, CD1311*, CD1409, CD1411*, CD2309, CD2311*, CD2409, CD2411* (all -36, -36Q, -36C and -36QC suffixes).<br>*Denotes models also sold OUS.<br>OUS: CD1277, CD1279, CD1293, CD1295, CD1377, CD1393, CD2277, CD2279, CD2293, CD2295, CD2377, CD2393 (all -36, -36Q, -36C and -36QC suffixes). | **8/19/2014**<br>**Class II**<br><br>Extended Charge Time may result in delayed delivery of high voltage therapy or prevent delivery of part or all of a programmed high voltage therapy shock. The anomaly most commonly presents as a vibratory patient notification and upon interrogation, a programmer or Merlin.net™ Patient Care Network (PCN) alert indicating a "Capacitor Charge Time Limit reached" message. This may occur during a capacitor maintenance or charging for high voltage therapy. The anomaly occurs as a result of internal damage to the capacitors used in the high voltage charging circuitry of the subject devices, which may result in an extended charge time. As designed, the device will deliver the available energy on the capacitors once the charge time limit of 32 seconds is reached, even if the energy is less than the programmed value. This condition is detectable as the device will initiate a vibratory patient alert and, for patients enrolled and actively being followed, a Merlin.net PCN notification. Additionally, upon device interrogation, an alert message will indicate "Capacitor Charge Time Limit reached" on a specific date. Approximately 97% of Ellipse ICD extended charge time events reported to Abbott have been detected during capacitor maintenance with the remainder detected during defibrillation threshold (DFT) testing. There have been no reported cases of an Ellipse device failing to deliver high voltage therapy to a patient when needed. | Abbott recommends that patients with affected devices be enrolled in Merlin.net Patient Care Network (PCN) so that any extended charge time alert ("Capacitor Charge Time Limit reached" message) will be transmitted to Merlin.net PCN for patients being actively monitored and can be viewed by your clinic staff.<br>If your patient has received a vibratory notification and/or if a programmer or Merlin.net alert for an extended charge time has been observed:<br>• Schedule your Ellipse ICD patient for an in-office follow-up evaluation as soon as possible.<br>• Interrogate the Ellipse ICD and perform a manual capacitor maintenance charge. Note the charge time to full charge; it should be approximately 15 seconds or less.<br>• Contact Abbott CRM Technical Services Department at 800-722-3774 to review the results of the capacitor maintenance test and discuss if additional evaluation is required.<br>• A device that has experienced repeated extended charge time out warnings should be considered for replacement.<br><br>As the large majority of the extended charge time events have presented at the routine 6 month automatic capacitor maintenance interval, programming the interval to every 4 months at your patient's next scheduled follow up visit may provide an earlier indication of this potential anomaly. It should be noted that changing the device programming to a 4 month capacitor maintenance interval will reduce device longevity by approximately 9%. Device replacement is not recommended for an Ellipse device exhibiting normal charge times, and patients should continue to be followed at routine follow up intervals, per HRS/EHRA Expert Consensus on Monitoring Cardiovascular Implantable Electronic Devices (CIED), April 2008.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, the worldwide event rate of extended charge time on the affected population was 0.42%, based on 179 extended charge time events out of 43,000 worldwide sales. As of June 30, 2021, there were additional reports and the rate is now 1.45%. There have been no reports of serious injury or death within this population. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| AnalyST Accel™ DR RF (Models CD2219-36, CD2219-36Q)<br>AnalyST Accel™ VR RF (Models CD1219-36, CD1219-36Q)<br>Current Accel™ DR RF (Models CD2215-36, CD2215-36Q)<br>Current Accel™ VR RF (Models CD1215-36, CD1215-36Q)<br>Current™ DR (Model 2207-36)<br>Current™ VR (Model 1207-36)<br>Ellipse™ DR (Models CD2277-36, CD2277-36Q, CD2377-36, CD2377-36Q, CD2377-36C, CD2377-36QC)<br>Ellipse™ VR (Models CD1277-36, CD1277-36Q, CD1377-36, CD1377-36Q, CD1377-36C, CD1377-36QC)<br>Fortify Assura™ DR (Models CD2259-40, CD2259-40Q, CD2359-40, CD2359-40Q, CD2359-40C, CD2359-40QC)<br>Fortify Assura™ VR (Models CD1259-40, CD1259-40Q, CD1359-40, CD1359-40Q, CD1359-40C, CD1359-40QC)<br>Fortify™ ST DR (Models CD2235-40, CD2235-40Q)<br>Fortify™ ST VR (Models CD1235-40, CD1235-40Q)<br>Promote Accel™ RF (Models CD3215-36, CD3215-36Q)<br>Promote Quadra™ (Models CD3239-40, CD3239-40Q)<br>Promote™ (Model 3213-36)<br>Quadra Assura™ (Models CD3267-40, CD3267-40Q, CD3367-40, CD3367-40Q, CD3367-40C, CD3367-40QC)<br>Quadra Assura MP™ (Models CD3371-40, CD3371-40Q, CD3371-40C, CD3371-40QC)<br>Unify Assura™ (Models CD3261-40, CD3261-40Q, CD3361-40, CD3361-40Q, CD3361-40C, CD3361-40QC)<br>Unify Quadra™ (Models CD3251-40, CD3251-40Q)<br>Unify™ (Models CD3235-40, CD3235-40Q) | **1/23/2014**<br>**Outside US only**<br><br>In November 2013, Abbott released the Merlin™ Programmer Software version 17.2.2 rev. 0 (herein after referred to as 17.2.2) as an upgrade to existing programmers. Testing has shown that, when using a programmer with the 17.2.2 software, an incorrect value for sinus redetection, potentially affecting the high voltage therapy delivery sequence can occur when a device is programmed to a single VF detection zone. The issue can be introduced during programming of certain families of Abbott ICD/CRTD devices. The issue is not present when a device is programmed to a two or three zone configuration. When using the 17.2.2 software and any parameter is programmed as part of a single VF detection zone configuration, the sinus redetection value will be inappropriately set to zero milliseconds. As a result, any intrinsic activity following the first shock will be considered a "sinus rate" and the device will diagnose "return to sinus". Therefore, if the arrhythmia was not terminated by the initial high voltage therapy, the ongoing arrhythmia would be considered a new episode causing the next high voltage therapy to also be delivered at the first programmed energy level. For example, if the first shock is programmed to 20 joules and subsequent shocks are programmed to higher energy values, the only HV therapy the patient would receive if the arrhythmia continues and is redetected, would be 20 joules, rather than the increasing HV energy levels as programmed. | Immediate Resolution Steps:<br><br>• Review your SJM™ ICD/CRT-D patient records for patients with affected devices implanted or seen in clinic starting in September 2013 and programmed to a single VF detection zone with the 17.2.2 software. For patients identified during this review we recommend that you schedule an immediate follow-up visit. The programmer software version is printed on the bottom of each report page.<br>• For patient devices programmed as described above with 17.2.2 software, a new software version 17.2.3 will correct this issue and is expected to be available by February 2014. Your Abbott representative will assist you with obtaining and installing the 17.2.3 software on your programmer. Using this software, programming any parameter will reset the return to sinus criteria to normal function.<br>• If a patient is seen before the 17.2.3 software is installed, then program the device to a two or three zone configuration, even if one of the zones is strictly a monitor zone. This will resolve the issue when using a programmer with 17.2.2 software.<br><br>**Current Status (June 30, 2021):** Software version 17.2.3 which corrected the issue was released in early 2014. No occurrences have been reported or are expected following the field communication and correction. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Fortify™ ST (Models CD1235-40, CD1235-40Q, CD2235-40, CD2235-40Q) | **4/18/2013**<br>**Outside US only**<br><br>The Merlin™ PCS programmer software Model 3330 versions 14.2.2, 16.2.1 and 17.2.1.1 provide new features for Abbott ICDs, including an option to enhance the ST diagnostic features in Abbott Fortify™ ST ICD models CD1235-40, CD1235-40Q, CD2235-40 and CD2235-40Q via a device software upgrade. During a device software upgrade, implanted devices are temporarily placed into the back-up pacing (BVVI) and back-up defibrillation only (BDFO) mode. The back-up mode parameter settings will be in effect for the two minute upgrade process. Once the upgrade successfully completes, the device will revert to the previously programmed parameter settings. Depending on the individual patient, this temporary change in parameter values while in back-up defibrillation only mode could make the device susceptible to oversensing and potentially deliver high voltage therapy during the upgrade procedure. | In order to prevent the potential for inappropriate therapy during the software upgrade process, consider programming the "Tachy Therapy Enabled/Disabled" function to Disabled prior to proceeding with the software upgrade. It is imperative to re-interrogate the device and program the "Tachy Therapy Enabled/Disabled" function to Enabled after the upgrade has been successfully completed. As with any device evaluation and programming, ECG monitoring and availability of back up external defibrillation equipment is recommended during the entire software upgrade process.<br><br>**Current Status (June 30, 2021):** At the time of the advisory there were 20 devices confirmed to be affected by this issue. As of June 30, 2021 there were an additional 52 devices confirmed with this issue. There have been no reports of serious injury or death. |

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Convert™+ (Model V-195) | **5/6/2010**<br>**Outside US only**<br><br>A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin™ Patient Care System (PCS) programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful. | If a patient's device is already programmed to a two zone configuration with a Merlin™ PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below:<br><br>A permanent correction is available in the new release of the Merlin™ PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin™ programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON.<br><br>1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration.<br>2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON.<br>3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON).<br><br>If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action.<br><br>As these actions fully correct the potential issue there is no need to consider any device explant.<br><br>**Current Status (June 30, 2021):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of June 30, 2021. there have been no additional reports associated with this advisory. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Epic™ ICDs<br>(Models V-197, V-235, V-337, V-338, V-339),<br>Epic™ + ICDs<br>(Models V-196, V-233, V-236, V-239, V-350)<br>Epic™ II ICDs<br>(Models V-158, V-255, V-258, V-355, V-356, V-357)<br>Atlas™ + ICDs<br>(Model V-340, V-341, V-343, V-193, V-242, V-243)<br>Atlas™ II ICDs<br>(Models V-168, V-265, V-268, V-365, V-366, V-367) | **1/16/2008**<br>**Class II**<br><br>A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic™ and Atlas™ family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window. | A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin™ Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available.<br><br>Abbott, along with our independent Medical Advisory Board members, has determined that no other action is recommended.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2021 there have been no additional devices confirmed to have this issue since the time of the advisory. |

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Photon™ DR (V-230HV) (certain serial numbers), Photon™ Micro VR/DR (Models V-194, V-232), Atlas™ VR/DR (Models V-199, V-240) | **10/7/2005**<br>**Class II**<br><br>A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support. | In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation.<br><br>To assist in your patient care and following discussions with our independent Medical Advisory Board, Abbott recommends:<br>If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above.<br>In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias.<br>If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2021 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue.<br>This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Epic™ DR/HF (V-233, V-337, V-338), Epic™ Plus DR/VR/HF (V-236, V-239, V-196, V-239T, V-196T, V-350), Atlas™ DR (V-242), and Atlas™ Plus DR/VR/HF (V-243, V-193, V-193C, V-340, V-341, V-343) | **6/13/2005**<br>**Class II**<br><br>Two anomalies have been identified:<br>1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped.<br>2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. | Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to Abbott. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers:<br>Epic™ DR/HF (V-233/V-337/V-338), Epic™ Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas™ DR (V-242), and Atlas™ Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period.<br><br>A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to Abbott by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior.<br><br>Abbott has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download.<br><br>The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), Abbott recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period.<br><br>In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, Abbott defers to your clinical judgment on any decisions regarding the management of your patients.<br><br>**Current Status (June 30, 2021):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory. |

## ICD AND CRT-D DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Epic™ (V-197, V-235),<br>Epic™+ (V-196, V-236),<br>Epic™ HF CRT-D (V-338),<br>Epic™+ HF CRT-D (V-350),<br>Atlas™+ (V-193, V-243),<br>Atlas™+ HF CRT-D (V-340),<br>or Atlas™ (model V-242) ICDs | **3/10/2005**<br>**Class II**<br><br>A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. | During routine product evaluation, Abbott Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed.<br><br>The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, Abbott Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion.<br><br>**Current Status (June 30, 2021):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| A subset of Assurity™ (Models PM1240, PM2240), Assurity™ + (Model PM2260), Assurity MRI™ (Models PM1272, PM2272), Endurity™ (Models PM1160, PM2160), Endurity™ Core (Models PM1152, PM2152), Endurity MRI™ (Models PM1172, PM2172) | **3/15/2021**<br>**Class I**<br><br>Abbott informed customers of an issue which may affect a subset of Assurity™ and Endurity™ pacemakers. The issue is caused by intermittent incomplete mixing of epoxy during manufacture, which may introduce a risk of moisture ingress and interruption of device functionality.<br><br>Abbott provided a follow up safety notification on October 5, 2021 to communicate additional units in the advisory and the availability of a new Electronics Performance Indicator (EPI) tool to assist in patient management for those pacemakers monitored with Merlin.net. The EPI tool supplements information available on Merlin.net to identify abnormal electrical system performance resulting from moisture ingress. | Recognizing that each patient requires individual consideration by their physician, in consultation with Abbott CRM's Medical Advisory Board (MAB), Abbott provides the following guidelines:<br><br>• Prophylactic generator replacement is **not** recommended. This is due to the very low rate of occurrence, and the low potential for patient harm when replacement is performed following an EPI notification or an ERI/EOS alert.<br>• Routine follow-up should remain as per standard of care and clinical protocol. Review device function including measured battery voltage or any unexpected change in battery consumption. Also, evaluate the potential for risk in patients who are pacemaker dependent and are unable to be reliably followed using remote monitoring.<br>• Prompt replacement for devices that receive an EPI notification, reach ERI/EOS, or experience one of these clinical impacts (loss of telemetry, reduced battery longevity, loss of pacing, or reduced ERI to EOS duration), commensurate with the patient's underlying clinical condition.<br>• When possible, monitor patients using Merlin.net to benefit from alert monitoring between routine device checks. For patients currently enrolled in Merlin.net, remind them of the importance of using remote monitoring, which provides daily monitoring of ERI and EOS alerts and includes monitoring of the safety notification population by the EPI tool.<br><br>**Current Status (October 5, 2021):** At the time of the advisory update, 231 devices of 337,987 worldwide (0.068%) had exhibited moisture ingress into the pulse generator, resulting in a loss of functionality.<br><br>To determine if a device serial number is subject to this advisory, please go to the following website: https://www.cardiovascular.abbott/us/en/hcp/product-advisories/pacemaker-lookup.html. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP) | **11/17/2017**<br>**Outside US and US Investigational Device Exemption (IDE) only**<br><br>Abbott was made aware of docking button detachments that have occurred following implant or during attempted retrieval of Nanostim™ Leadless Cardiac Pacemaker (LCP) devices. The docking button is a small component (3.6 mm diameter) and is connected to the end of the LCP by two cables. This component is necessary for docking the LCP to the retrieval catheter during a retrieval procedure. | The following patient management recommendations have been developed in consultation with our Leadless Steering Committee members after discussions detailing the occurrences and the potential clinical impact associated with detached docking buttons:<br><br>• Continue following patients as per recommendations of the October 2016 Battery Malfunction for Nanostim™ LCP advisory.<br>• Retrieval of an implanted Nanostim™ LCP with an intact docking button confirmed radiographically remains an option, but should only be considered if the procedure can be performed as per the specifications contained in the instructions for use.<br>  • If a detached docking button has been identified, Nanostim™ LCP retrieval is not recommended. In the rare situation where retrieval is the only management option, Abbott recommends the procedure be performed by physicians experienced in foreign body removal, including using the femoral approach. Please contact the Abbott Clinical Study Team for further guidance.<br>• Prophylactic imaging for the sole purpose of determining if the docking button is intact is not recommended due to the effects of radiation and lack of any clear clinical actions based on results of imaging alone. If the option of Nanostim™ LCP retrieval is being considered, final imaging decisions should take into account the individual patient circumstances and preferences.<br>• If a detached docking button is identified, continue to follow the patient as per the Clinical Study Protocol and report the incident to Abbott and relevant Competent Authority, as appropriate.<br><br>**Current Status: (October 28, 2021):** At the time of advisory, three (0.21%) of 1,423 devices implanted worldwide have been reported to have a detached docking button. As of October 28, 2021, a total of 7 have been reported and the rate remains at 0.5% (7/1,423). There have been no reports of serious injury or death. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| **Global Models**<br>Accent MRI™ (Model PM1224)<br>Accent™ DR RF (Models PM2210, PM2212)<br>Accent MRI™ (Models PM2218, PM2224)<br>Accent™ SR RF (Model (PM1210)<br>Accent™ ST DR RF (Models PM2216, PM2222)<br>Accent™ ST MRI DR RF (Model PM2226)<br>Accent™ ST MRI SR RF (Model PM1226)<br>Accent™ ST SR RF (Model PM1222)<br>Allure Quadra™ RF CRT-P (Model PM3242)<br>Allure™ RF CRT-P (Model PM3222)<br>Anthem™ RF CRT-P (Models PM3210, PM3212)<br>Assurity™ + DR RF (Model PM2260)<br>Assurity™ + SR RF (Model PM1260)<br>Assurity™ DR RF (Model PM2240)<br>Assurity MRI™ (Model PM2272)<br>Assurity™ SR RF (Model PM1240)<br>Assurity MRI™ (Model PM1272)<br>Nuance™ DR RF (Model PM2214)<br>Nuance™ MRI DR RF (Model PM2230)<br>Nuance™ MRI SR RF (Model PM1230)<br>Nuance™ SR RF (Model PM1214)<br>Nuance™ ST DR RF (Model PM2228)<br>Nuance™ ST SR RF (Model PM1228)<br>Quadra Allure MP™ (Model PM3562)<br>Quadra Allure MP™ RF CRT-P (Model PM3262)<br>Quadra Allure™ (Model PM3542)<br>Quadra Relieve MP™ (Model PM3564)<br>Quadra Relieve MP™ RF CRT-P (Model PM3264)<br>Quadra Relieve™ (Model PM3544)<br>Quadra Relieve™ RF CRT-P (Model PM3244)<br>Relieve™ RF CRT-P (Model PM3224)<br>Zenex™ + DR RF (Model PM2270)<br>Zenex™ + SR RF (Model PM1270)<br>Zenex™ DR RF (Model PM2250)<br>Zenex™ DR RF MRI (Model PM2282)<br>Zenex™ SR RF (Model PM1250)<br>Zenex™ SR RF MRI (Model PM1282) | **8/28/2017**<br>**Class II**<br><br>New pacemaker firmware was developed to further mitigate the risk of unauthorized access to our pacemakers that utilize radio frequency (RF) communications. The firmware update provides an additional layer of security against unauthorized access to these devices that further reduces the potential for a successful cybersecurity attack. | **Patient Management Recommendations**<br><br>Prophylactic replacement of affected devices is not recommended.<br><br>While not intended to serve as a substitute for your professional judgment as to whether the firmware update is advisable for a particular patient, we, along with our Cyber Security Medical Advisory Board, recommend the following:<br><br>• Discuss the risks and benefits of the cybersecurity vulnerabilities and associated firmware update with your patients at the next regularly scheduled visit. As part of this discussion, it is important to consider patient specific issues such as pacemaker dependence, age of device, and patient preference and provide them with the "Patient Communication".<br>• Determine if the update is appropriate given the risk of update for the patient. If deemed appropriate, install this firmware update following the instructions on the programmer (and listed below).<br>• For pacing dependent patients, consider performing the cybersecurity firmware update in a facility where temporary pacing and pacemaker generator change are readily available, due to the very small estimated risk of firmware update malfunction.<br><br>**Current Status (June 30, 2021):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication.<br><br>If you have any questions about the cybersecurity firmware update you can contact your Abbott representative or our dedicated customer technical support hotline at 1-800-722-3774 (U.S.).<br><br>Additional materials, including a Patient Communication, can be found on Cardiovascular Product Advisories \| Abbott. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP) | **10/28/2016**<br>**Outside US and US Investigational Device Exemption (IDE) only**<br><br>Abbott was made aware of seven (7) reports worldwide of lost telemetry and pacing output as a result of a battery malfunction associated with Nanostim Leadless Cardiac Pacemaker (LCP) devices. Due to these events, we have decided to pause Nanostim LCP implants in the Leadless II IDE/CAP study.<br><br>Analysis of returned units has found decreased battery capacity due to reduced electrolyte, resulting in high internal battery resistance. This disrupts the required capacity for proper device function and reduces device longevity.<br><br>Referring to a previously measured battery voltage may not provide an indication of continued normal operation as battery voltage remains normal under these circumstances. The Recommended Replacement Time (RRT) indicator will not be triggered as the battery voltage will remain above RRT in these devices. Battery malfunction may be indicated with a loss of telemetry/communication with the implanted device and/or loss of pacing and magnet mode operation. | In consultation with our Leadless II IDE and our Leadless Postmarket Study Steering Committees we recommend the following:<br><br>• Do not implant unused devices and return them to Abbott.<br>• Do not rely on the RRT indicator to identify a battery that may potentially malfunction. However, if the RRT indicator does trigger, replace the device per standard practice.<br>• Do not perform AV Node ablation in patients with an existing Nanostim LCP without another functional pacing system implanted.<br>• For patients who have not previously been documented to be pacemaker dependent, re-assess patients in-office for pacemaker dependence.<br>• **For non-pacemaker dependent patients with devices of implant duration ≥ 24 months, more intensive follow-up and monitoring is recommended.**<br>  • Implant Duration ≥ 24 months: Request follow-up as soon as possible to assess the status of the battery. Then, monthly follow-up is recommended through in-office visits or a reliable method of tele-monitoring of heart rate and electrocardiogram.<br>  • Implant Duration < 24 months: Continue follow up per protocol.<br>• **For pacemaker dependent patients, device replacement is recommended (priority should be for patients with implants of longer duration).**<br>  • Identify and treat patients as quickly as possible.<br>  • Interrogate the device and identify the ability to communicate with the device and the patient's underlying rhythm.<br>  • Determine the strategy for management, including a decision whether to retrieve or abandon the Nanostim LCP, based on the individual patient's clinical history and overall medical condition. Use a temporary pacemaker for backup pacing while replacing the Nanostim device where clinically indicated.<br>  • If the device is to be retrieved, use the Nanostim retrieval system as per the standard procedure described in the instructions for use.<br>  • If the device will not be retrieved or if retrieval was attempted and not possible, implant a new pacemaker lead (bipolar) at a distance from the existing LCP to prevent long-term mechanical and electrical interactions. Confirm the location using multiple radiographic views.<br>  • After implantation of the new pacing system, if it is possible to communicate with the LCP, turn "OFF" the abandoned LCP system. If the LCP device cannot be turned "OFF", consider programming the newly implanted system a minimum of 5 bpm faster than the LCP in order to inhibit the Nanostim device.<br><br>**Current Status: (October 28, 2021):** At the time of advisory, seven (7) reported devices (0.50%) of 1,423 implanted devices worldwide have exhibited battery malfunction at 29-37 months after implant. As of October 28, 2021, there were additional reports and the rate is now 23.75%. There have been no reports of serious injury or death. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Accent™ SR (Model PM1110)<br>Accent™ DR (Model PM2112) | **12/7/2012**<br>**Outside US Only**<br><br>Due to an incorrect software setting, a specific subset of the Accent™ SR and Accent™ DR devices shipped to certain countries outside the US will not provide a change in the sensor driven (rate responsive) pacing rates in response to patient physical activity. All other programmed parameters, features and functions operate as designed, e.g. an Accent DR device programmed to DDDR will appropriately track atrial activity and properly function in the DDD mode. A non-invasive programmer software solution that will correct the issue in all affected, implanted devices will be available once regulatory approval has been completed. | Abbott makes the following recommendations:<br><br>Identify affected patient<br>• Review your patient's clinical indications for pacing and determine the clinical need for rate responsive, sensor driven pacing.<br>• In the event that a patient requires rate responsive sensor driven activity pacing and exhibits clinical symptoms due to the lack of increased pacing rates with exercise, please contact your local Sales Representative or our Technical Support<br>• Continue to follow patients on their standard follow-up schedule.<br><br>**Current Status (June 30, 2021):** The programmer software update was released in April 2013. At the time of the advisory, approximately 6,000 affected devices were implanted. There have been no additional devices confirmed to have this issue since the time of the software release in April 2013. |

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Accent™ DR (Models PM2110, PM2112, PM2210, PM2212),<br>Anthem™ CRT-P (Models PM3110, PM3112, PM3210, PM3212) | **9/22/2011**<br>**Class II**<br><br>A small amount of electrical charge may accumulate within an internal capacitor which results in a low or varying pacing lead impedance (PLI) value during the automatic daily measurements. An out of range lead impedance measurement may result in a patient notifier alert, a remote monitoring Merlin.net™ Patient Care Network alert, or a prior alert message to be displayed on the programmer screen at the next in-clinic follow-up. | In order to prevent a false reading, a new Merlin™ Patient Care System programmer software version is available. When used to interrogate an Accent DR or Anthem CRT-P pacemaker this software will eliminate the potential for this anomaly to occur. With the new software, the programmer will automatically activate circuitry in the pacemaker during the interrogation process to ensure that any residual charge on the capacitor is discharged prior to performing the daily PLI measurement. The onetime upgrade is performed automatically on affected devices and will not change the operation of the implanted device. Your Abbott Sales Representative will assist you in loading the new programmer software onto your Merlin programmer.<br><br>If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, Abbott makes the following recommendations, which are consistent with standard best practices:<br><br>• Ensure that the new programmer software version is loaded on your programmers as soon as practical.<br>• Continue to follow patients on their standard follow-up schedule. Since the likelihood of the low lead impedance measurement is low, the device interrogation can be performed at the patient's next regular scheduled follow-up visit.<br>• In the event that a patient receives a low lead impedance alert before the new programmer software has been loaded, we suggest that you evaluate the device as you normally would for any such instance. If the daily pacing lead impedance value is out-of range, re-interrogate the device's measured data and look at the lead impedance values. This "in-clinic" measurement is not affected by the aforementioned capacitor charge build-up and will provide an accurate lead impedance measurement.<br><br>**Current Status (June 30, 2021):** Worldwide, 13 Accent DR (<0.01%) and 225 Anthem CRT-P (1.6%) devices have exhibited this diagnostic anomaly. |

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Identity™ SR (Model 5172)<br>Identity™ DR (Model 5370)<br>Identity™ XL DR (Model 5376) | **10/12/2006**<br>**Class II**<br><br>A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in Abbott Identity™ pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the Abbott Identity™ family of pacemakers when programmed by the Abbott APS™ III Model 3500/3510 or Merlin™ Patient Care System Model 3650 programmers. | No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2021 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix. |

## LEFT-HEART LEADS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| QuickSite™ (Models 1056T, 1058T)<br>QuickFlex™ (Models 1156T, 1158T) | **4/3/2012**<br>**Class II**<br><br>Abrasion of the silicone insulation in the distal portion of QuickSite and QuickFlex leads has led to visual observations of externalized conductors.<br><br>There have been no reports of death or serious injury associated with the externalized conductors; likewise there have been no electrical dysfunctions attributable to the externalized conductors.<br><br>The reported rate of externalized conductors in the QuickSite and QuickFlex leads is 0.023%, based on 39 confirmed cases of externalized conductors in a population of approximately 82,000 QuickSite and 89,000 QuickFlex leads sold worldwide.<br><br>This issue is under-detected because these cases are visual observations without any signs of electrical dysfunction and fluoroscopic/xray imaging is not routine. Based on a review of returned leads and available fluoroscopic and x-ray images of patients with QuickSite and QuickFlex leads (1,219 leads), it is estimated that the incidence of conductor externalization on these leads may be 3% to 4%. | Abbott and its Medical Advisory Board recommend that physicians continue to monitor their patient's implanted system at regularly scheduled intervals with attention paid to diagnostic information related to LV pacing performance, in particular LV lead impedance and capture thresholds. Programming of alerts that monitor lead impedance changes outside of the nominal range and enabling the patient notifier should be considered. A special X-ray or fluoroscopic imaging is not recommended for LV CRT leads with normal electrical function. CRT pacing functionality should be evaluated during routine device checks and only leads exhibiting electrical anomalies that cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement.<br><br>**Current Status (June 30, 2021):** At the time of the advisory there was a worldwide reported externalized conductor rate of 0.023% in QuickSite and QuickFlex leads. As of June 30, 2021, the cumulative worldwide reported externalized conductor rate (based on both returns and non-returns) for QuickSite and QuickFlex leads was 0.27%. |

## DEFIBRILLATION LEADS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Optisure™ Defibrillation Lead (Models LDA220, LDA220Q, LDA230Q, LDP220Q) | **11/3/2015**<br>**Class I**<br><br>A limited number of dual coil Optisure defibrillation leads may have been compromised during the manufacturing process. A trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.<br><br>A thorough investigation has determined the probability of a lead malfunction as a result of this trim technique is very low. A total of 447 leads subjected to the trim technique were distributed globally. Of those, 278 were implanted in the United States. Abbott is not aware of any adverse clinical events related to this matter. Furthermore, an analysis of patients implanted with the subject leads that are being actively monitored via Merlin.net™ Patient Care Network has shown that none of these patients have experienced any recorded electrical issues. | Abbott recommends the following actions depending on the device the affected patients have implanted. According to our records the vast majority of patients with the subject leads have devices with the DynamicTx™ feature that provides additional protection to help ensure therapy delivery in the case of a compromised lead.<br><br>For patients implanted with a potentially-impacted Optisure lead connected to a device WITH DynamicTx™* technology, we recommend:<br><br>Review the Patient Records:<br>1. Ensure DynamicTx™ technology is programmed "On"<br>2. Enroll these patients in our Merlin.net™ Patient Care Network<br>3. Monitor patients as normal, with no additional testing or follow-up needed.<br><br>For patients implanted with a potentially-impacted Optisure lead connected to a device WITHOUT DynamicTx™* technology we recommend:<br>1. Enroll these patients in our Merlin.net™ Patient Care Network<br>2. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector)<br>3. If dual coil shocking configuration is desired, consider performing a high voltage test using maximum energy.<br>a. If shock delivery is normal - no additional testing is required<br>b. If shock delivery identifies a short circuit – consider lead replacement<br><br>• DynamicTx™ technology automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur.<br><br>We recommend at your patient's next follow-up visit an Abbott representative be present to program an alert message into the implanted device. This will provide clinicians following patients with impacted subject lead an alert message on the Merlin™ Programmer upon interrogation, ensuring that future caregivers assessing the diagnostics of these devices receive the latest information and be made aware of this corrective action. We believe such actions will further the ability of our clinician partners to most optimally manage the care of their patients. |

## DEFIBRILLATION LEADS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Riata™ Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582)<br>Riata™ i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592)<br>Riata™ ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042) | **11/28/2011**<br>**Class I**<br><br>Externalized conductors occur when an abrasion results in an outer insulation breach, allowing the normally contained conductors to become visible outside the lead body. Even though causality cannot be established, when externalized conductors are accompanied by reports of electrical malfunction, these reports typically include pacing or defibrillation impedance changes, inappropriate therapy, noise and oversensing, and pacing threshold rise. Externalized conductors have not been observed in Riata ST Optim™ and Durata™ models due to the presence of an abrasion resistant outer Optim™ lead insulation sheath.<br><br>A summary of the types and incidence rates of Riata lead abrasion malfunctions is presented on pages 302-305 of this Product Performance Report. | Abbott and its Medical Advisory Board (MAB) make the following recommendations, which are consistent with standard best practices and our December 2010 product communication.<br><br>Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. Abbott™ remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors.<br><br>Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.<br><br>Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits.<br><br>If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing, if necessary, could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem associated with any source of lead electrical failure if one exists.<br><br>The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time and is therefore not recommended.<br><br>In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended.<br><br>Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalized conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances.<br><br>Based on input from the MAB, Abbott continues to monitor post-market surveillance data to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities.<br><br>**Current Status (August 31, 2021):** At the time of the advisory there was a worldwide reported all-cause insulation abrasion rate of 0.63% for Riata silicone leads. The worldwide reported rate for the subcategory of externalized conductors in Riata silicone leads was 0.10%. As of August 31, 2021, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 4.83% and 2.92% respectively. The latest information related to the silicone Riata lead advisory, including the final results of the Cardiac Lead Assesment Study (CLAS) and references to independent studies of Riata lead performance, can be obtained at https://www.cardiovascular.abbott/us/en/hcp/product-advisories/riata.html. |

1 Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." *Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 4th ed.* Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2011. 889-910.

## DEFIBRILLATION LEADS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Riata™ Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582)<br>Riata™ i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592)<br>Riata™ ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042) | **12/15/2010**<br>**Outside US Only**<br><br>Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10%. After more than 9 years of clinical use and approximately 227,000 implants, silicone insulated Riata™, Riata™ i, and Riata™ ST defibrillation leads have exhibited an insulation abrasion rate of 0.47% (inclusive of confirmed returns and complaints/observations with no associated return).<br>There are several factors that can contribute to lead abrasion in implanted pacing and defibrillation systems, including physiological stresses placed on the lead due to patient anatomy, implant orientation, and mechanical stresses applied from concomitant devices in the body.<br><br>A summary of the types and incidence rates of Riata lead abrasion malfunctions is presented on pages 302-305 of this Product Performance Report. | Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person or remote monitoring are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.<br><br>Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedure in particular looking for significant changes from the patient's previous follow-up visits.<br><br>If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing if necessary could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem if one exists.<br><br>Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events.<br><br>**Current Status (August 31, 2021):** At the time of the advisory there was a worldwide insulation abrasion rate of 0.47% for Riata silicone leads. As of August 31, 2021, there have been additional reports and the worldwide reported insulation abrasion rate is 4.83%. |

1 Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." *Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 4th ed.* Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2011. 889-910.

## ICM DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Confirm Rx™<br>(Model DM3500) | **5/18/2018**<br>**Class II**<br>**US Only**<br><br>Abbott advised physicians that exposure to sub-freezing temperatures during our supply chain process caused a transient battery voltage drop for a small number of Confirm Rx™ Model DM3500 Insertable Cardiac Monitoring (ICM) devices. | Prophylactic replacement of affected devices is not recommended.<br><br>To correct implanted devices or detect affected units before implant, it is required to update to Merlin™ programmer software version 24.2.x or later. If you do not yet have this software version, you may contact your Abbott representative to facilitate in upgrading your programmer(s).<br><br>**Recommendations for Patients with Implanted Devices**<br>Abbott reviewed data in Merlin.net™ Patient Care Network to identify implanted devices with an incorrect low battery indicator. Patients confirmed to be impacted can be found in the enclosed Patient List. Additionally, implanted patients who could not be assessed for this condition through data available in Merlin.net™ PCN are included in this list. We recommend performing the following actions at the patient's next regularly scheduled visit:<br>• For patients confirmed to be impacted, contact Abbott Technical Services to assist in correcting the battery indicator.<br>• For Confirm Rx™ device patients requiring further assessment to determine potential impact, review post-implant programmer printouts or session records to determine whether a low battery indicator is present.<br>• If a low battery indicator is observed, contact Abbott Technical Services to assist in confirmation and correction of the battery indicator display.<br><br>**Recommendations for Devices not yet Implanted**<br>For new implants, Merlin™ programmer software version 24.2.x or later will detect this incorrect low battery indicator condition. Interrogate all new Confirm Rx devices prior to implant. If the notification pop-up is displayed, follow the on-screen instructions to proceed with contacting Abbott Technical Services and select an alternate device for the implant.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, 0.41% devices distributed worldwide have been reported to have experienced incorrect display of low battery indicator. As of June 30, 2021 there have been no additional reports of low battery indicator and the rate remains at 0.283%. There have been no reports of serious injury or death.<br><br>If you have any questions about this communication or the patient management recommendations, please contact your Abbott representative or Abbott Technical Support at 1-800-722-3774 (U.S.). Additional materials, can be found on Cardiovascular Product Advisories \| Abbott. |

## ICM DEVICES

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| SJM Confirm™ ICM<br>(Models DM2100, DM2102) | **3/11/2011**<br>**Class II**<br>**US and Germany**<br><br>A product firmware upgrade using the Merlin™ Patient Care System (PCS) programmer running software versions 10.1.1.3, 10.1.1.2, or 11.2.2 leaves the implantable cardiac monitor device in a state which results in increased current usage. If not corrected this state could result in premature battery depletion. | If you are following any patients implanted with the SJM Confirm ICM Models DM2100 or DM2102 and their device was upgraded using the Merlin programmer with the above mentioned software versions it is recommended to determine the patient's clinical reason for the implant and their continued need for the device:<br><br>• If the device has previously been used to record and assist in the diagnosis of an arrhythmia and is no longer needed, no further action is required. The device will exhaust its battery capacity prior to the 3 year expected longevity.<br>• If the unit is still indicated for diagnosing a potential clinical arrhythmia, contact your Field Clinical Engineer and he/she will assist in calculating the projected remaining longevity. If appropriate, the microprocessor operation can be reset to the nominal current drain.<br>• If the device is no longer indicated it can be left implanted until such time that a routine explant is desired.<br><br>If the device is determined to be necessary and is experiencing increased current usage as described above, it can be corrected with assistance from your Sales Representative or Abbott Technical Services.<br><br>**Current Status (June 30, 2021):** At the time of the advisory, 83 implanted devices world-wide were identified as having undergone the problematic firmware upgrade. All of these devices have been corrected using the Merlin PCS programmer or were determined by the clinician to not require further action because the device had already provided the necessary diagnostic information and was no longer required. There have been no additional implanted devices confirmed to have been affected by this issue. Updated Merlin PCS programmer software has been implemented which prevents this issue from occurring in the future. |

## REMOTE MONITORING/TRANSMITTERS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Merlin@home™ Software Model EX2000 v8.2.2 for Merlin@home™ Transmitter (Models EX1150, EX1150W, EX1100, EX1100W) | **4/3/2017**<br>**Class II**<br><br>In recognition of the changing cybersecurity landscape, and the increased public attention on medical device cyber risks, we have informed the clinical community about available updates to Merlin@home™ transmitter software. The Merlin@home™ patient transmitter software version 8.2.2 includes security updates that complement the company's existing security measures and further reduce the already extremely low cybersecurity risks. | • Patients should ensure that their Merlin@home™ transmitter is plugged in and connected via cellular adapter, wi-fi or landline so the transmitter can receive these and any future updates.<br>• Health Care Providers should continue to conduct patient management using the Merlin.net™ Patient Care Network (PCN) and in-office follow-ups per normal routine with patients who have an implantable cardiac device that is monitored using the Merlin@home™ transmitter.<br>• For further information, health care providers can contact their local sales representative. In addition, both health care providers and patients can visit Connectivity and Remote Care for Cardiac Rhythm Management \| Abbott (cardiovascular.abbott) for answers to questions and additional information regarding Abbott's implantable cardiac rhythm devices, or the Merlin@home™ transmitter.<br><br>**Current Status (June 30, 2021):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication. |

## REMOTE MONITORING/TRANSMITTERS

| MODEL IDENTIFICATION | ADVISORY | FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY |
|---|---|---|
| Merlin@home™ RF Remote Monitoring Transmitter EX1150 | **12/18/2014**<br>**Class II**<br><br>A low incidence of Merlin@home transmitters initiating a software reset resulting in backup operation in some implanted Abbott Radio Frequency (RF) enabled Implantable Cardioverter Defibrillators (ICDs) and Pacemakers. Potentially affected RF devices include the Abbott Ellipse™, Fortify Assura™, Unify Assura™, and Quadra Assura™ ICDs and Assurity™ and Allure™ Pacemakers.<br><br>In the event that an Ellipse, Fortify Assura, Unify Assura, or Quadra Assura ICD enters backup mode, the nominal operational settings will be VVI pacing mode, 67 ppm, 5.0v/0.6ms with bipolar pacing output and defibrillation settings of a VF detection rate of 146 bpm and 36J high voltage therapy. In the event an Assurity or Allure pacemaker enters backup mode, it will have output settings of VVI pacing mode, 67 ppm, 5.0v/0.6ms with unipolar pacing. This issue can only occur when the patient is being actively monitored by a Merlin@home™ RF bedside transmitter. If a device enters backup mode, the Merlin@home system will detect it and an alert will be provided to the clinic. Additionally, the ICD will deliver a patient vibratory alert and the pacemaker will deliver a patient audible alert.<br><br>For Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs, the rate of occurrence is 0.25% based on 55,000 devices followed via Merlin.net™ remote monitoring. For Assurity and Allure pacemakers, the rate of occurrence is 0.016% based on 12,000 devices followed remotely. All pacemakers and the vast majority (approximately 90%) of ICDs reported to exhibit backup operation as a result of this anomaly were non-invasively restored to normal operation. In approximately 10% of the ICD cases, software was unable to be successfully restored and a device replacement was performed. The software download procedure was revised to ensure a successful download if an incident of a software reset were to occur in the future.<br><br>There have been no reported cases of serious injury or death associated with this anomaly. The issue will be resolved with a software update of the Merlin@home transmitter that will be performed automatically over its telephone, broadband, or cellular connection without requiring any action from you or your patients.<br><br>**9/19/2015**<br>An additional software upgrade was implemented to address a second software anomaly which coexisted in the Merlin@home transmitter system that also had the potential to cause software resets for potentially affected Abbott devices. | The Merlin@home transmitter software has been modified to prevent this issue from occurring and has received FDA approval. A Merlin@home software update will be performed automatically over its telephone, broadband, or cellular connection without requiring any action from you or your patients. No changes to your patient's remote or in-clinic follow up schedules are required. Patients with implanted devices not mentioned above, patients who are being remotely followed with inductive telemetry (wand directly over the device) and patients not being followed remotely are not affected by this issue.<br><br>**Current Status (June 30, 2021):** In December 2014, the worldwide event rate of Merlin@home transmitters initiating a software reset resulting in backup operation for Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs was 0.30% based on 83,000 devices followed via Merlin.net Patient Care Network (Merlin remote monitoring). For Assurity and Allure pacemakers, the rate of occurrence was 0.06% based on 12,000 devices followed remotely. As of June 30, 2021, the cumulative incidence rate based on worldwide sales for Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs is 0.19%. |

# Healthcare Professional Communications

## PACEMAKER AND CRT-P DEVICES

| MODEL IDENTIFICATION | COMMUNICATION | DETAILS |
|---|---|---|
| Affinity™, Entity™, Integrity™, Identity™, Sustain™, Frontier™, Victory™ and Zephyr™ models | **1/29/2014**<br>**Worldwide**<br><br>As part of Abbott's commitment to communications on device performance, and in consultation with our Medical Advisory Board, we provided Health Care Professionals information regarding possible effects of electrocautery on older generation Abbott pacemakers. | Abbott has reviewed incident reports on specific older generation pacemaker models exposed to electrocautery. When devices from these pacemaker families are exposed to electrocautery (as well as the PEAK PlasmaBlade™ blade), they may exhibit a temporary change in function that could persist for 30 seconds or longer after the electrocautery exposure has been terminated. The duration of the effect depends on several factors including the battery voltage of the device, the energy of the electrocautery output, and the distance from the electrocautery source to the implanted system. The most clinically significant observation has been loss of capture due to a transient reduction in the pacing output voltage. Placing a magnet over the device or programming to an asynchronous pacing mode will not prevent this temporary reduction in pacing output.<br><br>The effects of electrocautery on cardiac implantable electronic device operation are well documented in the scientific literature and most, if not all, pacemaker and implantable cardioverter defibrillator (ICD) User's Manuals include labeling about the use of electrosurgery equipment and its possible effects on the operational characteristics and/or internal circuitry of these devices.<br><br>As is the case with all perioperative assessments in patients with cardiac implantable electronic devices, evaluating the individual patient's dependence on the implanted device should be assessed prior to any procedure that would ordinarily require electrocautery, particularly a pacemaker procedure. If pacemaker dependency is identified, either do not use electrocautery or employ appropriate precautions to ensure that the heart rate will be supported in the presence of electrocautery. Consideration of placing a temporary transvenous pacemaker is appropriate.[1,2]<br><br>All Abbott pacemaker and ICD User's Manuals provide Warnings and Precautions regarding the use of electrosurgical devices in the vicinity of an implanted device.<br><br>Importantly, the more recent families of Abbott pacemakers (Accent and Anthem) and all ICDs are not subject to this temporary change in function from the extended effects of electrocautery.<br><br>References:<br>[1] Hayes and Friedman, Cardiac Pacing, Defibrillation and Resynchronization, 2nd Edition, p. 192<br>[2] Ellenbogen and Wood, Cardiac Pacing and ICDs, 4th Edition, p. 227 |

# Index

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# Index of Phased-out Models

# Phased-out Models

As stated in the introduction of this Product Performance Report, product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report. As such, models that no longer meet the criteria for inclusion have been phased-out of the Product Performance Report over time. In order to provide our customers with information on these phased-out models, an index including the final edition for each phased-out model has been included. Previous Product Performance Reports can be viewed on the web at Cardiovascular Product Advisories | Abbott.

| CRT DEVICES | FINAL EDITION |
|---|---|
| Atlas™ + HF (V-340) | Apr 2011 |
| Atlas™ II HF (V-365) | Dec 2015 |
| Atlas™ II + HF (V-366) | Dec 2015 |
| Epic™ HF (V-337) | Apr 2011 |
| Epic™ HF (V-338) | May 2010 |
| Epic™ II HF (V-355) | Apr 2011 |
| Frontier™ (5508) | May 2010 |
| Promote™ (3107-36) | Nov 2010 |
| Promote™ RF (3207-30) | May 2014 |

| ICDS | FINAL EDITION |
|---|---|
| Atlas™ DR (V-240) | May 2010 |
| Atlas™ DR (V-242) | Dec 2014 |
| Atlas™ II DR (V-265) | May 2014 |
| Atlas™ VR (V-199) | Nov 2010 |
| Contour™ II (V-185, V-185AC, V-185B, V-185C, V-185D) | May 2008 |
| Contour™ MD (V-175, V-175AC, V-175B, V-175C, V-175D) | May 2010 |
| Current™ DR (2107-36) | Nov 2010 |
| Current™ DR RF (2207-30) | Dec 2015 |
| Current™ VR (1107-36) | May 2010 |
| Current™ VR (1207-30) | Nov 2013 |
| Epic™ + DR (V-236) | May 2010 |
| Epic™ + DR (V-239) | May 2014 |
| Epic™ DR (V-233) | Apr 2011 |
| Epic™ DR (V-235) | Nov 2010 |
| Epic™ II DR (V-255) | May 2010 |
| Epic™ II DR (V-258) | Nov 2013 |
| Epic™ II VR (V-158) | Nov 2013 |
| Epic™ + VR (V-196) | Dec 2015 |
| Epic™ VR (V-197) | Nov 2010 |
| Photon™ DR (V-230HV) | Oct 2007 |

| ICDS | FINAL EDITION |
|---|---|
| Photon™ µ DR (V-232) | Oct 2009 |
| Photon™ µ VR (V-194) | May 2010 |
| Profile™ (V-186F, V-186HV3) | Oct 2007 |

| DEFIBRILLATION LEADS | FINAL EDITION |
|---|---|
| Riata™ i (1560, 1561) | Dec 2016 |
| Riata™ ST Optim™ (7030, 7031) | Nov 2013 |
| TVL™ ADX (1559) | Dec 2019 |
| TVL™ RV (RV01, RV02, RV03, RV06, RV07) | May 2010 |
| TVL™ SVC (SV01, SV02, SV03) | May 2010 |
| SPL™ (SP01, SP02, SP03 & SP04) | May 2018 |

| PACEMAKERS | FINAL EDITION |
|---|---|
| AddVent™ (2060) | May 2010 |
| Affinity™ DC (5230) | May 2019 |
| Affinity™ DR (5330, 5331) | May 2019 |
| Affinity™ SR (5130, 5131) | May 2019 |
| Affinity™ VDR (5430) | May 2010 |
| Entity™ DC (5226) | May 2019 |
| Entity™ DR (5326) | May 2019 |
| Integrity™ SR (5142) | May 2020 |
| Integrity™ µ SR (5136) | Nov 2013 |
| Integrity ADx™ DR (5360) | Nov 2013 |
| Integrity ADx™ SR (5160) | Nov 2013 |
| Integrity™ AFx DR (5342, 5346) | May 2020 |
| Integrity™ µ DR (5336) | Nov 2010 |
| Meta™ DDDR (1256) | Oct 2008 |
| Meta™ DDDR (1256D) | Oct 2008 |
| Paragon™ (2010, 2011, 2012) | Nov 2010 |
| Paragon™ II (2016) | Nov 2010 |
| Paragon™ III (2304, 2314, 2315) | May 2010 |
| Phoenix™ II (2005, 2008, 2009) | Nov 2010 |
| Phoenix™ III (2204, 2205) | Apr 2009 |

# Phased-out Models

| PACEMAKERS | FINAL EDITION |
|---|---|
| Regency™ SC+ (2400L, 2402L) | May 2010 |
| Solus™ (2002, 2003) | Nov 2010 |
| Solus™ II (2006, 2007) | Nov 2010 |
| Synchrony™ II (2022, 2023) | Oct 2009 |
| Synchrony™ III (2028, 2029) | May 2010 |
| Tempo™ D (2902) | Oct 2008 |
| Tempo™ DR (2102) | Oct 2008 |
| Tempo™ V (1102) | May 2010 |
| Tempo™ VR (1902) | May 2010 |
| Trilogy™ DC (2308) | Oct 2006 |
| Trilogy™ DC+ (2318) | Oct 2009 |
| Trilogy™ DR (2350) | Apr 2007 |
| Trilogy™ DR+ (2360, 2364) | May 2010 |
| Trilogy™ SR (2250) | Oct 2009 |
| Trilogy™ SR+ (2260, 2264) | Nov 2010 |

| PACING LEADS | FINAL EDITION |
|---|---|
| ACE™ (1015M, 1025M) | Oct 2009 |
| AV Plus™ DX (1368) | May 2019 |
| Fast-Pass™ (1018T, 1028T) | Oct 2009 |
| IsoFlex™ P (1644T) | Apr 2011 |
| Passive Plus™ (1135K, 1143K, 1145K,1235K, 1243K, 1245K) | May 2010 |
| Passive Plus™ (1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) | Dec 2014 |
| Passive Plus™ DX (1336T, 1342T, 1346T) | May 2018 |
| Passive Plus™ DX (1343K, 1345K) | May 2010 |
| Permathane™ ACE (1035M) | May 2010 |
| Permathane™ ACE (1036T, 1038T) | May 2010 |
| Tendril™ (1148T, 1188T) | Dec 2015 |
| Tendril™ (1188K) | May 2010 |
| Tendril™ DX (1388K) | May 2010 |
| Tendril™ DX (1388T, 1388TC) | May 2017 |
| Tendril™ SDX (1488T, 1488TC) | May 2020 |
| Unipolar Lead (1007) | May 2010 |

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**Rx Only**
**Brief Summary:** Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.


SJM-ELP-90869810 REV A | Item approved for U.S. use only.

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