CARDIAC ARRHYTHMIA AND HEART FAILURE

Product Performance Report

2018 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 a Product Performance Report (PPR) semi-annually to ensure that the healthcare community and the patients it serves are informed about the overall 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 new 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 laboratory-confirmed malfunction and providing subcategories of laboratory-confirmed lead abrasion and fracture malfunctions.

Continuing within this edition of the PPR and consistent with previously published editions, Abbott reports on expanded data from actively monitored studies. Since 2007, the PPR has featured pacemaker, ICD, and lead data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). Post-Approval studies are now 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 also features a product performance data set which includes OPTIMUM, SCORE and three Post-Approval Studies. This combined dataset 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. We are continuing to expand the scope of confirmed product malfunction summaries with worldwide confirmed malfunctions in Durata™ and Optisure™ defibrillation lead models, our more recent ICD and pacemaker models and various low voltage and CRT leads which will further expand to different devices and leads in future additions.

In addition to providing performance data, a summary of advisories on implantable devices since 2005 can be found beginning on page 323.

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 2018 Product Performance Report containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,

Robert Blunt
Divisional Vice President, Quality

Table of Contents

Table of Contents

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 in the Focus on Clinical Performance section (see pages 302-305). This section includes an update 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.

UPDATE ON RIATA™ LEAD PERFORMANCE

Abbott continues to include an update on Riata lead performance in the Focus on Clinical Performance section (see pages 306-314). This section provides the latest Riata lead externalized conductor rates from the Abbott Riata Lead Evaluation Study, 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, an independent, third-party, is presented in this special Focus on Clinical Performance section (see pages 315-320).

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 benefits of Optim lead insulation on Abbott defibrillation leads (see pages 321-322).

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.

Malfunction Definitions

Malfunction - Having characteristics that are outside the performance limits established by the manufacturer while implanted and in service, as confirmed by laboratory analysis, except changes to characteristics due to normal battery depletion or induced malfunction. Device damage caused after or during explant is not considered a malfunction. Note that lead-related malfunctions of a pacemaker or ICD system are assigned to the lead.

Malfunction with Compromised Therapy - The condition when a device is found to have "malfunctioned," as defined above, in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if no therapy is available or critical patient-protective pacing or defibrillation therapy is not available.

A malfunction with compromised therapy does not imply that a patient has actually experienced a serious complication or death as a result of the malfunction although it does imply that the potential for a serious complication or death did exist during the period of the malfunction.

Malfunction without Compromised Therapy - The condition when a device is found to have "malfunctioned," as defined above, in a manner that did not compromise pacing or defibrillation therapy while implanted and in service, as confirmed by laboratory analysis. Therapy is not compromised as long as the critical patient-protective pacing and defibrillation therapies are available. Changes in device settings that occur as intended by the design (for example, reversion to a designed Safe Mode) that do not result in loss of critical patient-protective therapies but are the reported reasons for explant are categorized as a Malfunction without Compromised 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 339-340) 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 www.RiataCommunication.com.

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 dataset 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)
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 1488)
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 (888-SJM-2763) 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 (888-SJM-2763).

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 888-SJM-2763, on the web at www.SJM.com, or by contacting your local Abbott representative.

Cardiac Resynchronization Therapy (CRT) ICDs

Cardiac Resynchronization Therapy (CRT) ICDs

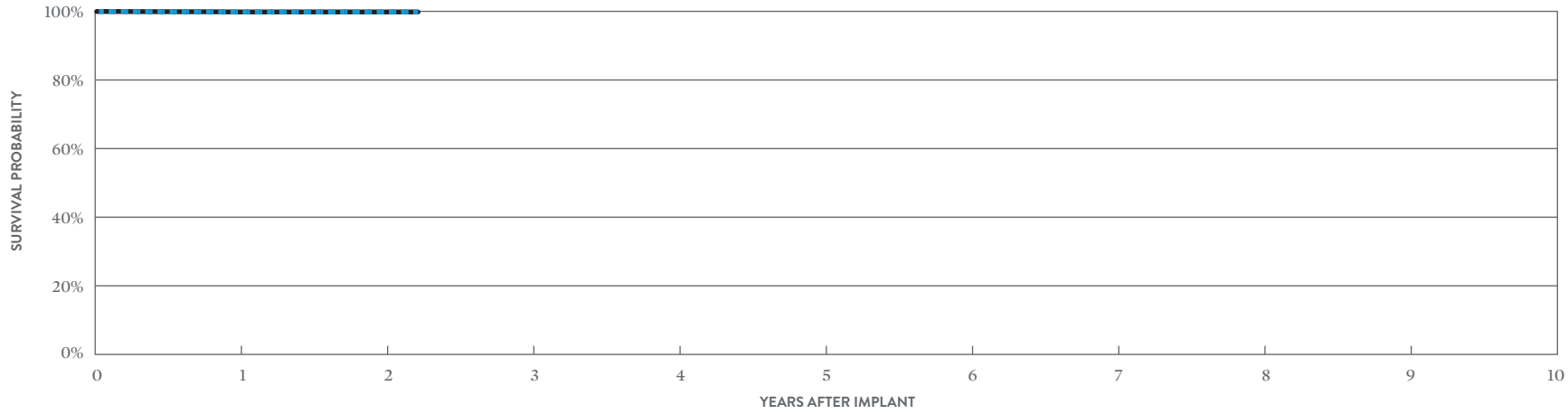
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura MP™ CRT-D

MODEL CD3369-40Q*

US Regulatory Approval	February 2016
Registered US Implants	28,899
Estimated Active US Implants	25,513
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
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%	3	0.01%
Electrical Interconnect	5	0.02%	0	0.00%
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%	3	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**8**	**0.03%**	**8**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 27 MONTHS
SURVIVAL PROBABILITY	99.83%	99.83%	99.83%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%
SAMPLE SIZE	21,640	7,860	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 27 MONTHS
SURVIVAL PROBABILITY	99.83%	99.83%	99.83%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

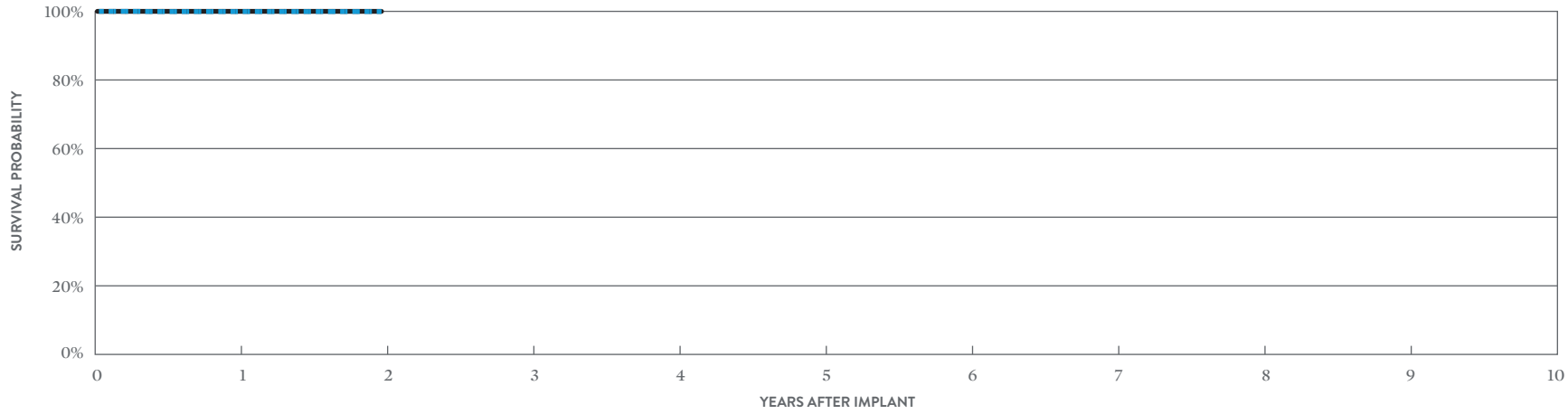
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura MP™ CRT-D

MODEL CD3369-40C*

US Regulatory Approval	February 2016
Registered US Implants	4,032
Estimated Active US Implants	3,504
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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%	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
SURVIVAL PROBABILITY	99.94%	99.94%
± 1 STANDARD ERROR	0.04%	0.04%
SAMPLE SIZE	3,110	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2
SURVIVAL PROBABILITY	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

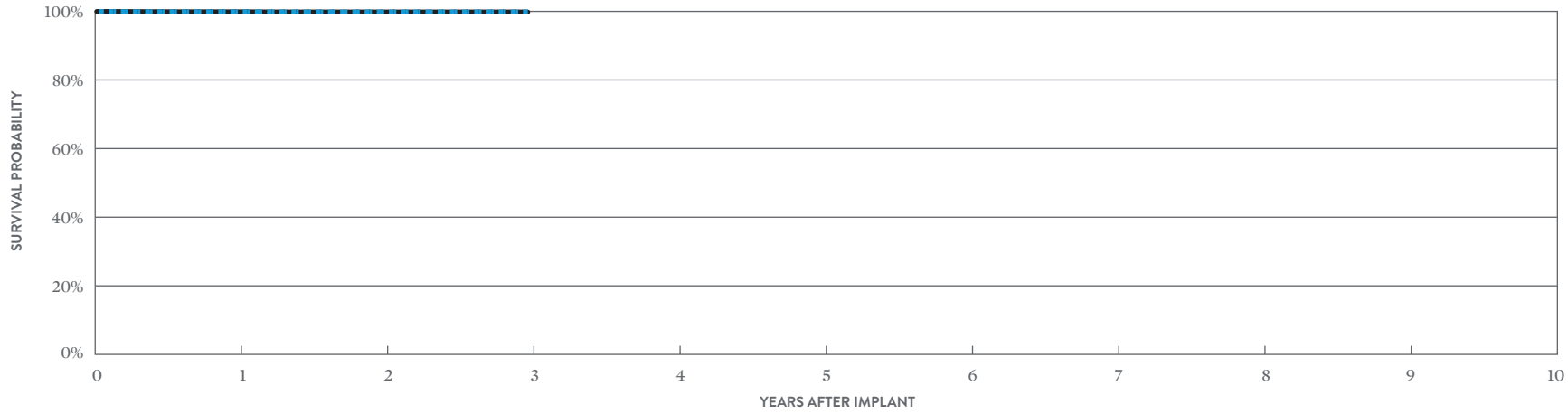
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	14,921
Estimated Active US Implants	11,907
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	One

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



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3
SURVIVAL PROBABILITY	99.87%	99.82%	99.82%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%
SAMPLE SIZE	13,740	10,790	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3
SURVIVAL PROBABILITY	99.87%	99.82%	99.82%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

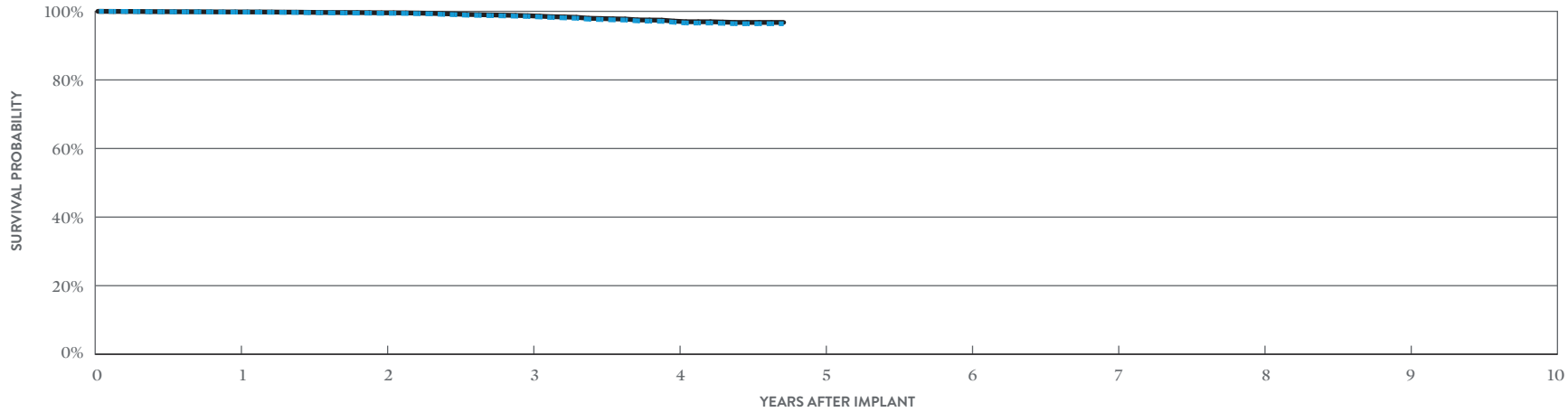
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

MODEL CD3365-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	24,081
Estimated Active US Implants	15,005
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	22
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.02%	9	0.04%
Electrical Interconnect	8	0.03%	0	0.00%
Battery	2	<0.01%	15	0.06%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	3	0.01%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	17	0.07%	91	0.38%
Other	5	0.02%	3	0.01%
Total	**38**	**0.16%**	**123**	**0.51%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 57 MONTHS
SURVIVAL PROBABILITY	99.78%	99.43%	98.51%	96.82%	96.39%
± 1 STANDARD ERROR	0.03%	0.05%	0.09%	0.15%	0.21%
SAMPLE SIZE	22,660	19,960	16,700	9,750	420

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 57 MONTHS
SURVIVAL PROBABILITY	99.83%	99.57%	98.73%	97.15%	96.77%
± 1 STANDARD ERROR	0.03%	0.04%	0.08%	0.14%	0.20%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

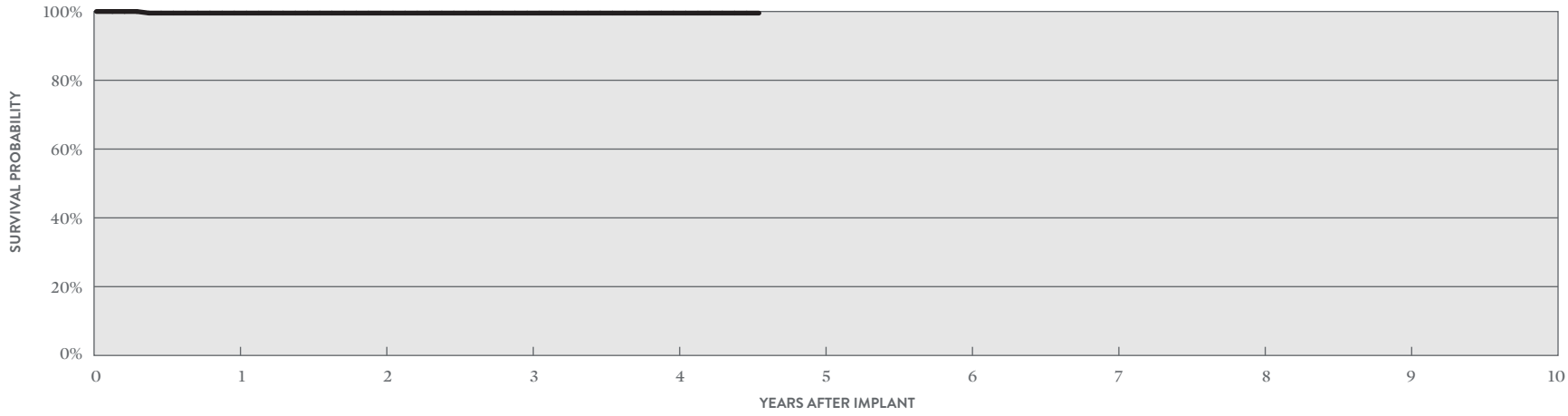
Quadra Assura™ CRT-D

MODEL CD3365-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	231
Active Devices Enrolled in Study	124
Cumulative Months of Follow-up	7,342
Estimated Longevity	(see table on page 51)
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%	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 55 MONTHS
SURVIVAL PROBABILITY	99.54%	99.54%	99.54%	99.54%	99.54%
± 1 STANDARD ERROR	0.45%	0.45%	0.45%	0.45%	0.45%
SAMPLE SIZE	220	170	120	80	50

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

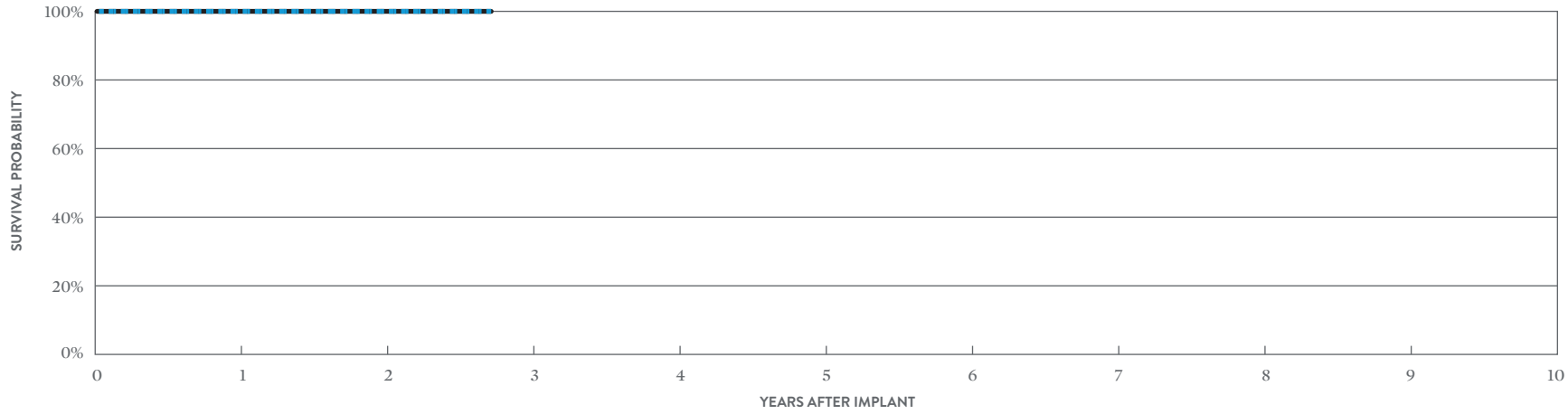
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	2,413
Estimated Active US Implants	1,944
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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%	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 33 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%
SAMPLE SIZE	2,160	1,490	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 33 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

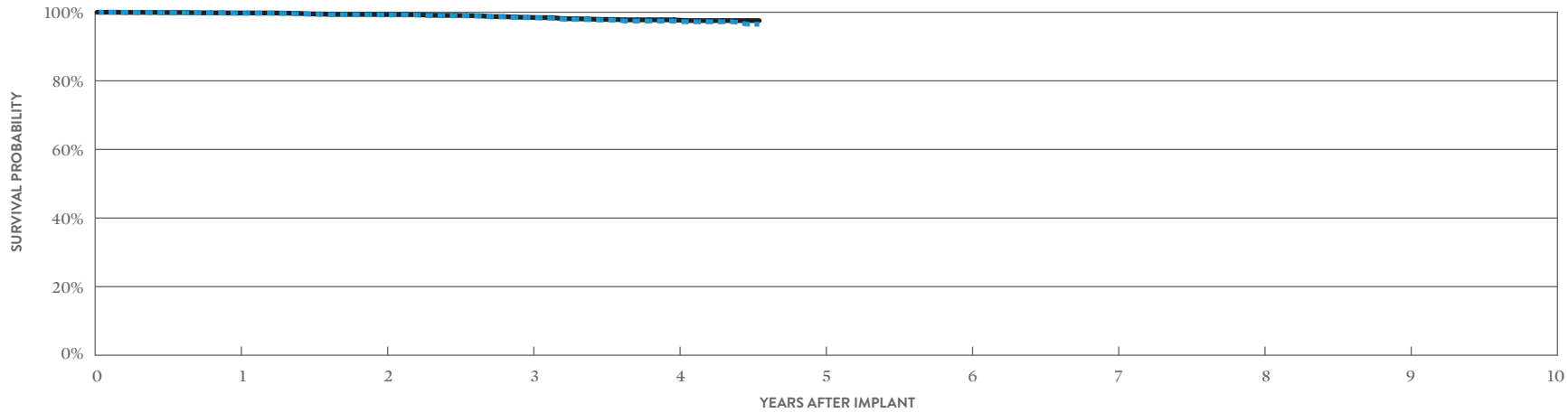
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

MODEL CD3365-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,626
Estimated Active US Implants	3,334
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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	3	0.05%	15	0.27%
Other	2	0.04%	1	0.02%
Total	**14**	**0.25%**	**20**	**0.36%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.69%	99.22%	98.41%	97.44%	96.51%
± 1 STANDARD ERROR	0.07%	0.12%	0.19%	0.29%	0.60%
SAMPLE SIZE	5,240	4,500	3,490	1,900	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.79%	99.32%	98.51%	97.79%	97.57%
± 1 STANDARD ERROR	0.06%	0.12%	0.19%	0.26%	0.31%

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

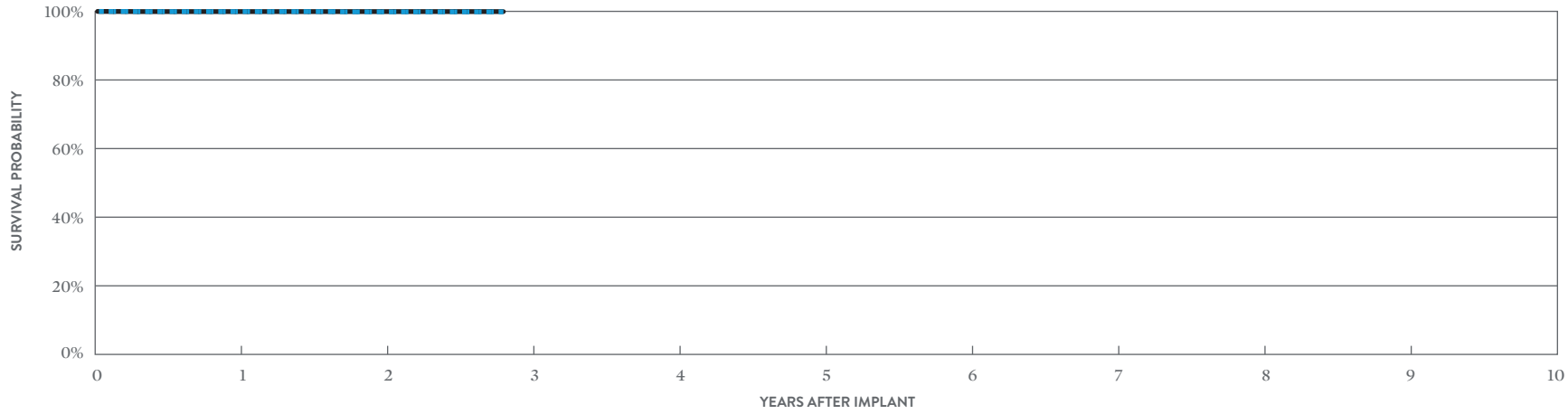
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	9,976
Estimated Active US Implants	8,369
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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%
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%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**0**	**0.00%**	**3**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.93%	99.86%	99.86%
± 1 STANDARD ERROR	0.03%	0.06%	0.06%
SAMPLE SIZE	8,090	4,120	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 34 MONTHS
SURVIVAL PROBABILITY	99.93%	99.93%	99.93%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

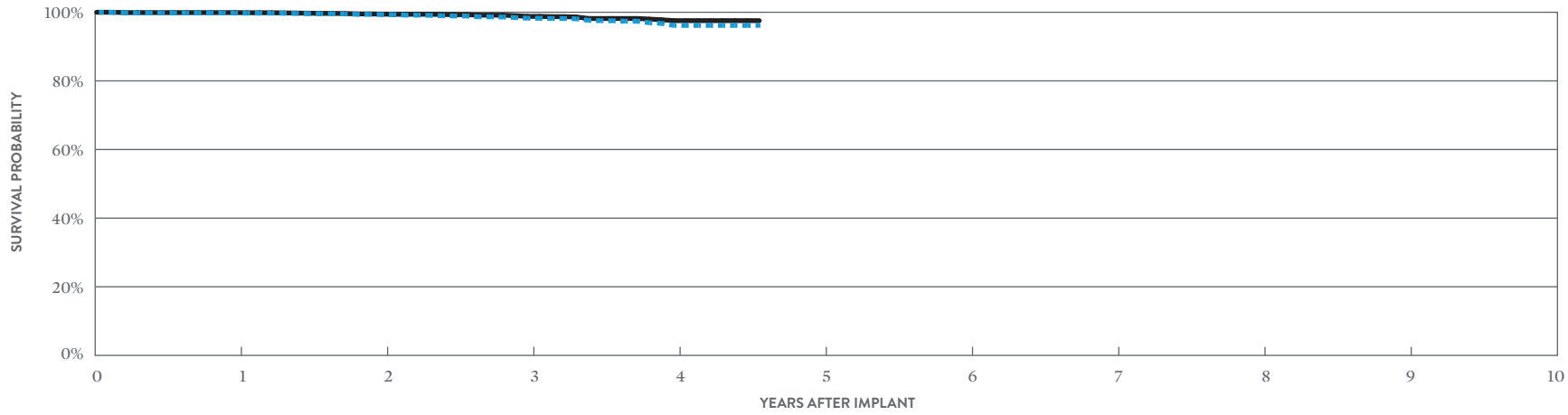
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

MODEL CD3357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	5,342
Estimated Active US Implants	3,189
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	13
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.02%	1	0.02%
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	8	0.15%	13	0.24%
Other	0	0.00%	1	0.02%
Total	**13**	**0.24%**	**15**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.78%	99.34%	98.26%	96.17%	96.17%
± 1 STANDARD ERROR	0.06%	0.12%	0.20%	0.39%	0.46%
SAMPLE SIZE	4,980	4,280	3,300	1,730	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.90%	99.46%	98.80%	97.56%	97.56%
± 1 STANDARD ERROR	0.04%	0.11%	0.16%	0.32%	0.36%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

Unify Assura™ CRT-D

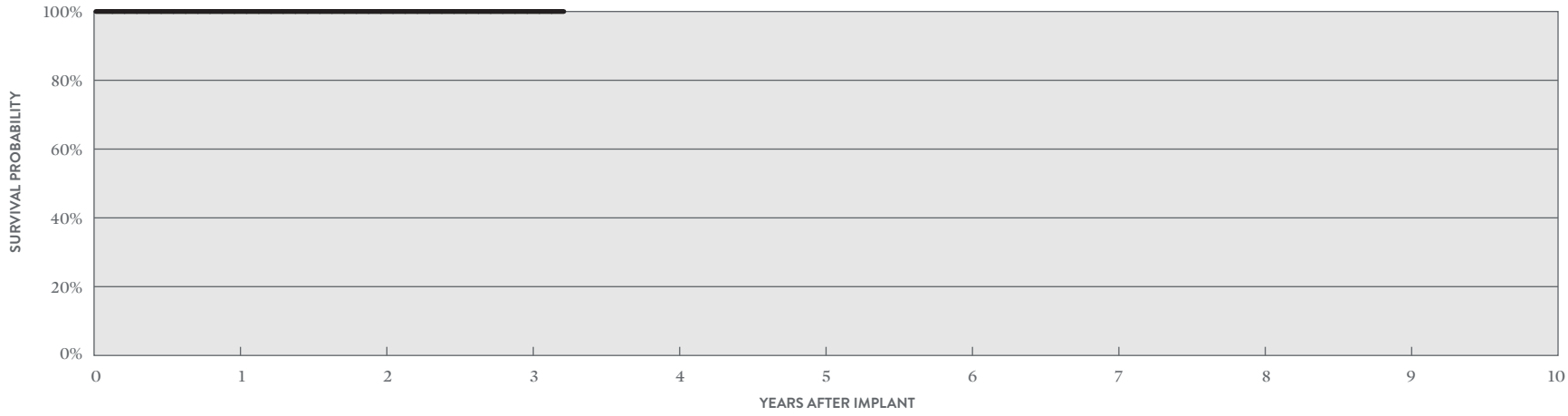
MODEL CD3357-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	241
Active Devices Enrolled in Study	179
Cumulative Months of Follow-up	6,117
Estimated Longevity	(see table on page 51)
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	AT 39 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	160	90	50

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

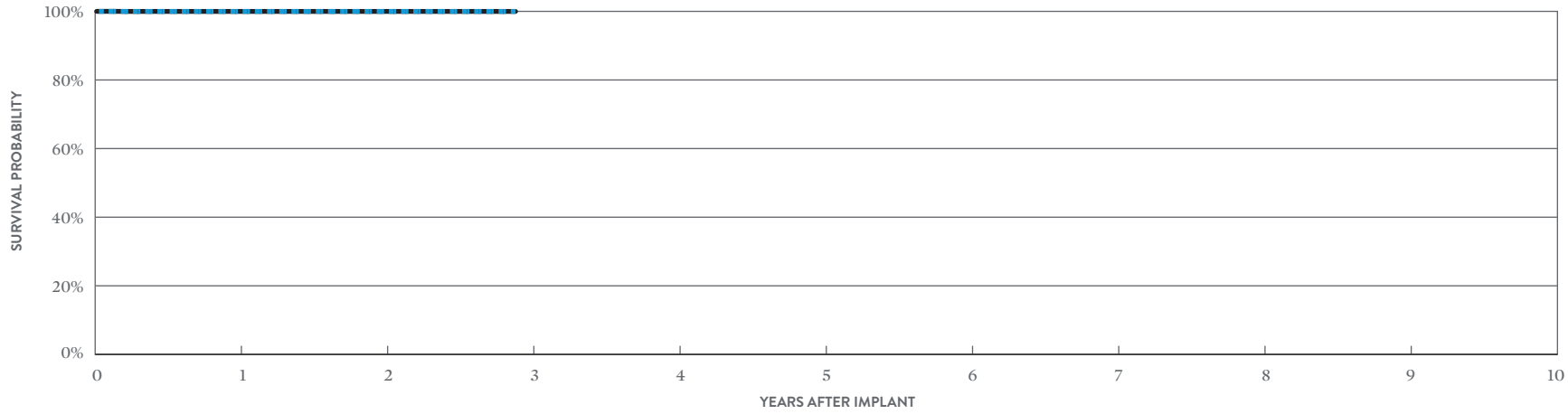
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

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

US Regulatory Approval	June 2013
Registered US Implants	10,273
Estimated Active US Implants	8,535
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	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	**1**	**<0.01%**	**0**	**0.00%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.98%	99.98%	99.98%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%
SAMPLE SIZE	8,730	4,980	310

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.98%	99.98%	99.98%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

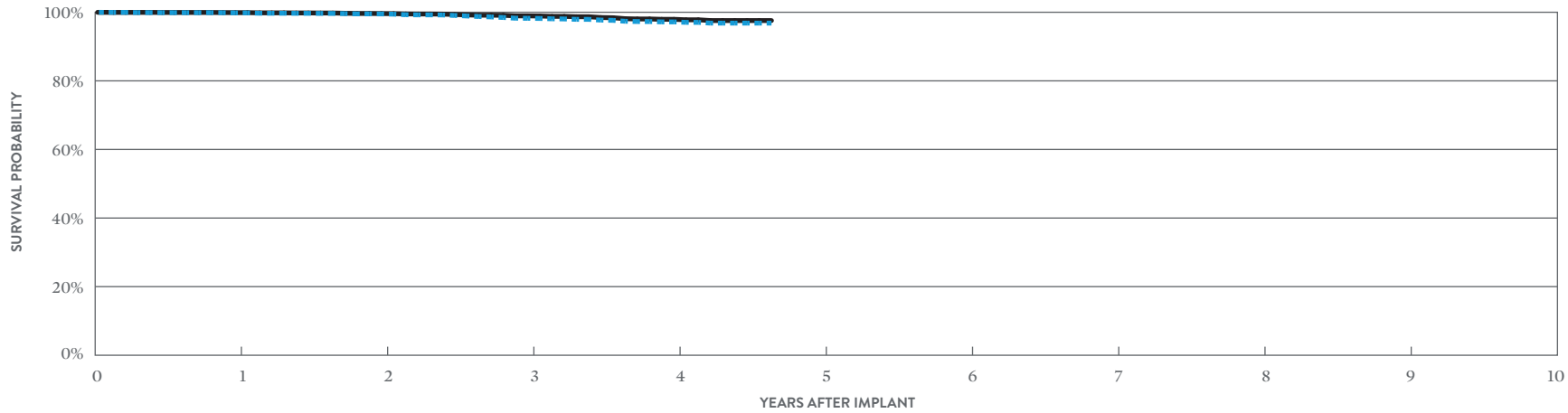
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

MODEL CD3357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	9,597
Estimated Active US Implants	5,815
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	21
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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%	0	0.00%
Battery	0	0.00%	4	0.04%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	9	0.09%	22	0.23%
Other	0	0.00%	3	0.03%
Total	**14**	**0.15%**	**34**	**0.35%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.83%	99.51%	98.23%	97.19%	96.83%
± 1 STANDARD ERROR	0.04%	0.07%	0.16%	0.24%	0.30%
SAMPLE SIZE	9,010	7,860	6,370	3,480	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.89%	99.62%	98.94%	97.94%	97.58%
± 1 STANDARD ERROR	0.03%	0.07%	0.12%	0.22%	0.28%

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

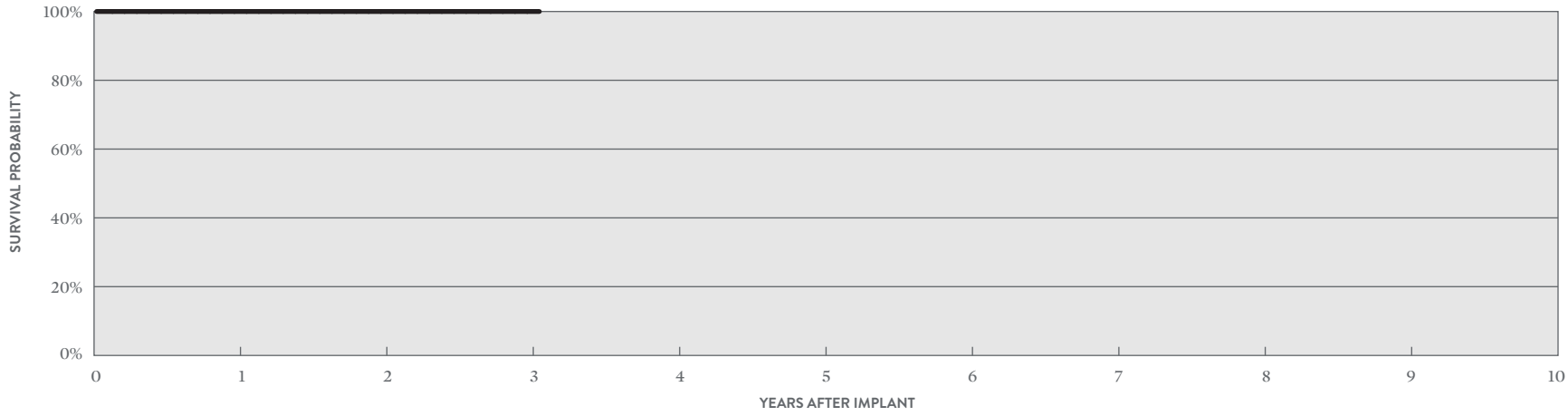
Unify Assura™ CRT-D

MODEL CD3357-40C*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	193
Active Devices Enrolled in Study	109
Cumulative Months of Follow-up	4,658
Estimated Longevity	(see table on page 51)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	1	0.52%
Skin Erosion	1	0.52%

	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	AT 37 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%	0.00%
SAMPLE SIZE	170	120	70	50

**Parylene coating.*

Cardiac Resynchronization Therapy (CRT) ICDs

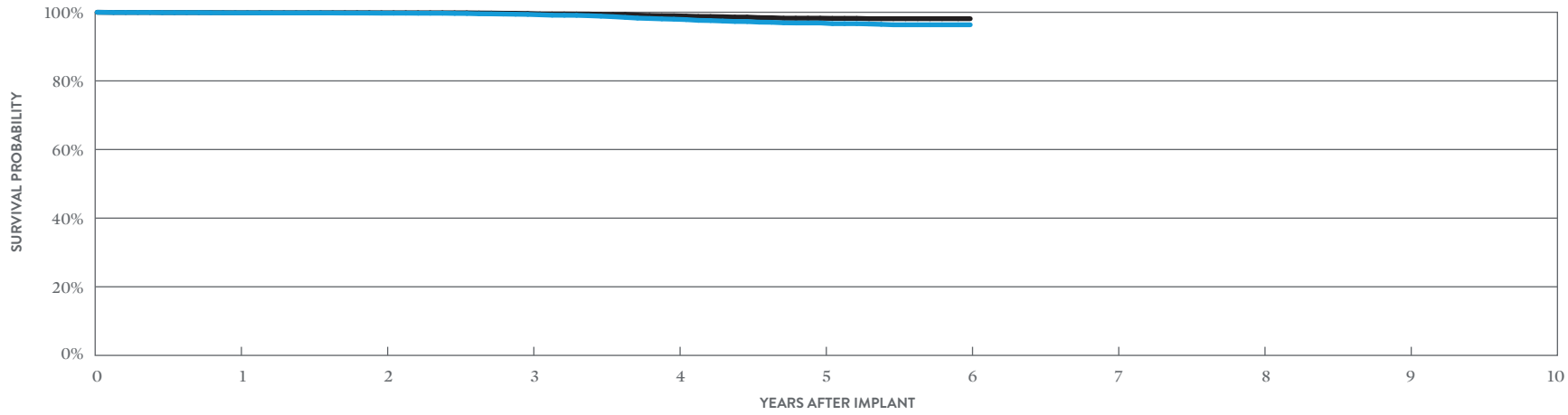
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

MODEL CD3265-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	13,540
Estimated Active US Implants	7,351
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	55
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.01%	5	0.04%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	1	<0.01%	5	0.04%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	2	0.01%
Possible Early Battery Depletion	13	0.10%	33	0.24%
Other	1	<0.01%	0	0.00%
Total	**18**	**0.13%**	**46**	**0.34%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6
SURVIVAL PROBABILITY	99.83%	99.74%	99.38%	97.98%	96.88%	96.35%
± 1 STANDARD ERROR	0.04%	0.04%	0.07%	0.14%	0.19%	0.24%
SAMPLE SIZE	12,750	11,400	10,270	8,990	6,160	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6
SURVIVAL PROBABILITY	99.87%	99.85%	99.65%	98.98%	98.27%	98.13%
± 1 STANDARD ERROR	0.03%	0.03%	0.05%	0.10%	0.14%	0.16%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

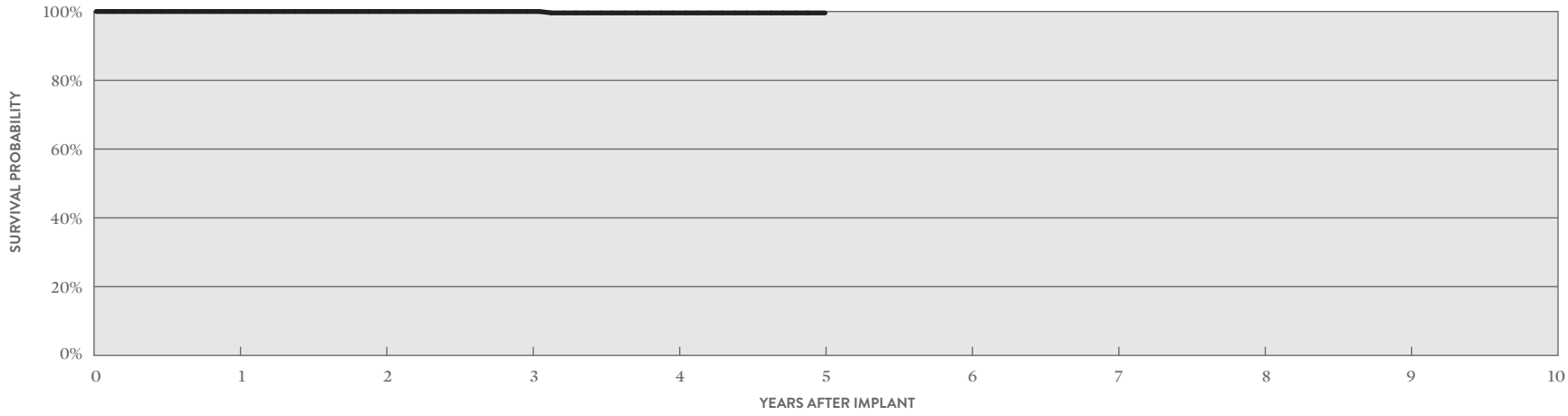
Quadra Assura™ CRT-D

MODEL CD3265-40Q*

US Regulatory Approval	May 2012
Number of Devices Enrolled in Study	421
Active Devices Enrolled in Study	168
Cumulative Months of Follow-up	15,881
Estimated Longevity	(see table on page 51)
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%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.24%**	**0**	**0.00%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%	99.59%	99.59%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%	0.41%	0.41%
SAMPLE SIZE	390	330	270	220	60

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

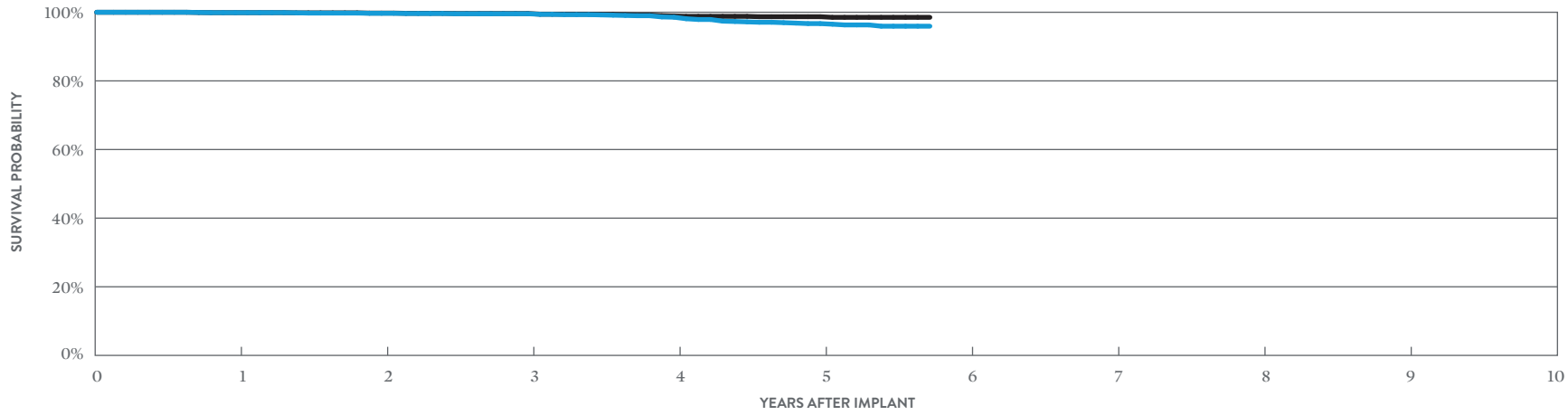
CUSTOMER REPORTED PERFORMANCE DATA

Quadra Assura™ CRT-D

MODEL CD3265-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	3,926
Estimated Active US Implants	2,047
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	20
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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%	0	0.00%
Mechanical	0	0.00%	1	0.03%
Possible Early Battery Depletion	3	0.08%	3	0.08%
Other	6	0.15%	1	0.03%
Total	**10**	**0.25%**	**7**	**0.18%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 69 MONTHS
SURVIVAL PROBABILITY	99.89%	99.70%	99.57%	98.56%	96.70%	95.94%
± 1 STANDARD ERROR	0.06%	0.09%	0.12%	0.22%	0.38%	0.50%
SAMPLE SIZE	3,670	3,260	2,930	2,500	1,700	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 69 MONTHS
SURVIVAL PROBABILITY	99.89%	99.76%	99.63%	98.90%	98.70%	98.52%
± 1 STANDARD ERROR	0.06%	0.08%	0.11%	0.19%	0.23%	0.26%

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

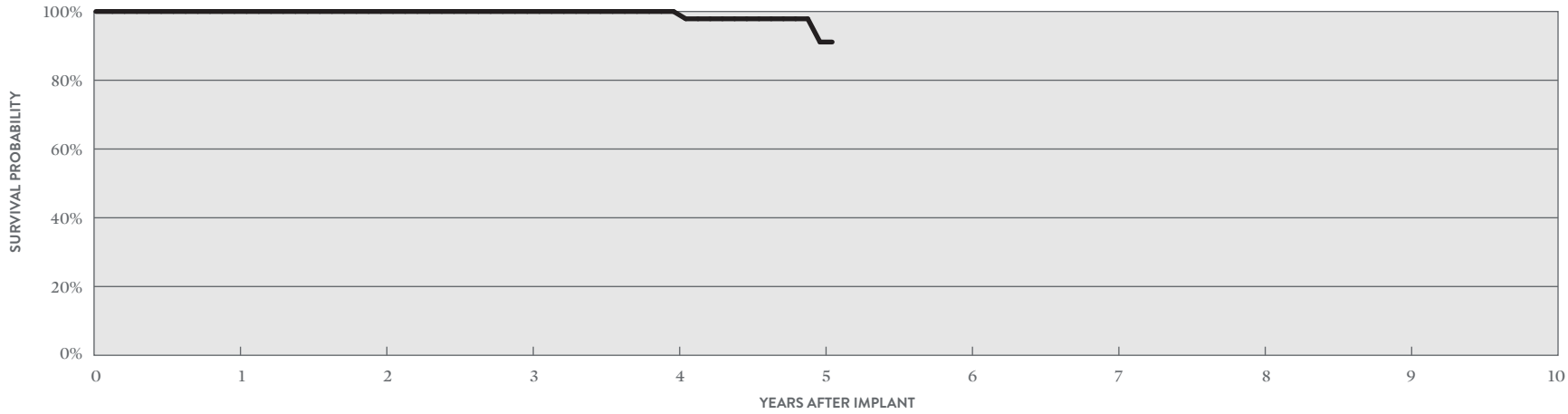
Quadra Assura™ CRT-D

MODEL CD3265-40

US Regulatory Approval	May 2012
Number of Devices Enrolled in Study	100
Active Devices Enrolled in Study	44
Cumulative Months of Follow-up	3,895
Estimated Longevity	(see table on page 51)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	2	2.00%

	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	0	0.00%	1	1.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**1.00%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	AT 61 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%	100.00%	91.12%	91.12%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%	0.00%	2.10%	6.80%
SAMPLE SIZE	100	80	60	50	30	10

Cardiac Resynchronization Therapy (CRT) ICDs

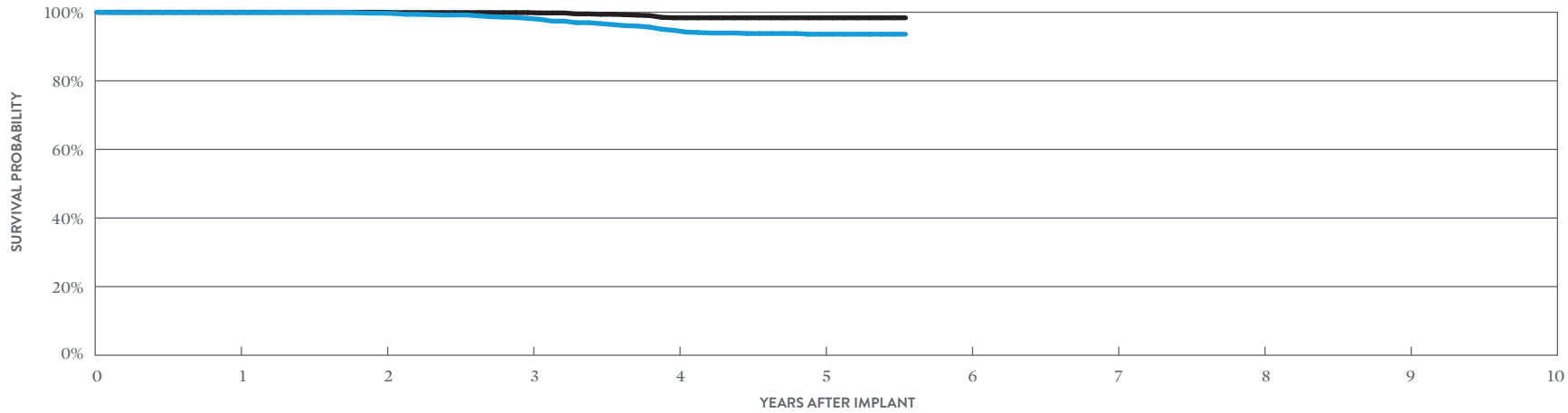
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

MODEL CD3257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,716
Estimated Active US Implants	1,340
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	35
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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%	1	0.04%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	0.04%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.11%	7	0.26%
Other	0	0.00%	0	0.00%
Total	**4**	**0.15%**	**8**	**0.29%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 67 MONTHS
SURVIVAL PROBABILITY	99.92%	99.74%	98.22%	94.73%	93.60%	93.60%
± 1 STANDARD ERROR	0.05%	0.11%	0.27%	0.51%	0.59%	0.59%
SAMPLE SIZE	2,530	2,230	1,970	1,670	1,130	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 67 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	99.90%	98.38%	98.38%	98.38%
± 1 STANDARD ERROR	0.00%	0.00%	0.07%	0.30%	0.31%	0.31%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

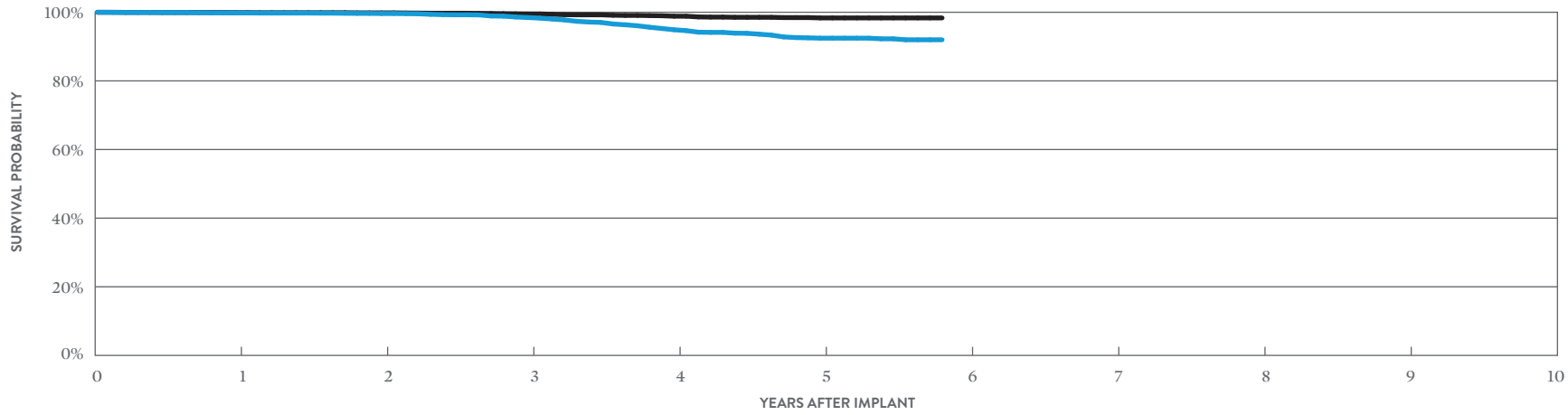
CUSTOMER REPORTED PERFORMANCE DATA

Unify Assura™ CRT-D

MODEL CD3257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,744
Estimated Active US Implants	3,365
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	99
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	4	0.06%	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%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	6	0.09%	13	0.19%
Other	1	0.01%	1	0.01%
Total	**13**	**0.19%**	**19**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.81%	99.63%	98.46%	94.90%	92.45%	91.98%
± 1 STANDARD ERROR	0.05%	0.07%	0.16%	0.31%	0.42%	0.48%
SAMPLE SIZE	6,330	5,610	4,990	4,250	2,850	310

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.90%	99.83%	99.51%	98.85%	98.35%	98.35%
± 1 STANDARD ERROR	0.03%	0.05%	0.09%	0.15%	0.19%	0.20%

Cardiac Resynchronization Therapy (CRT) ICDs

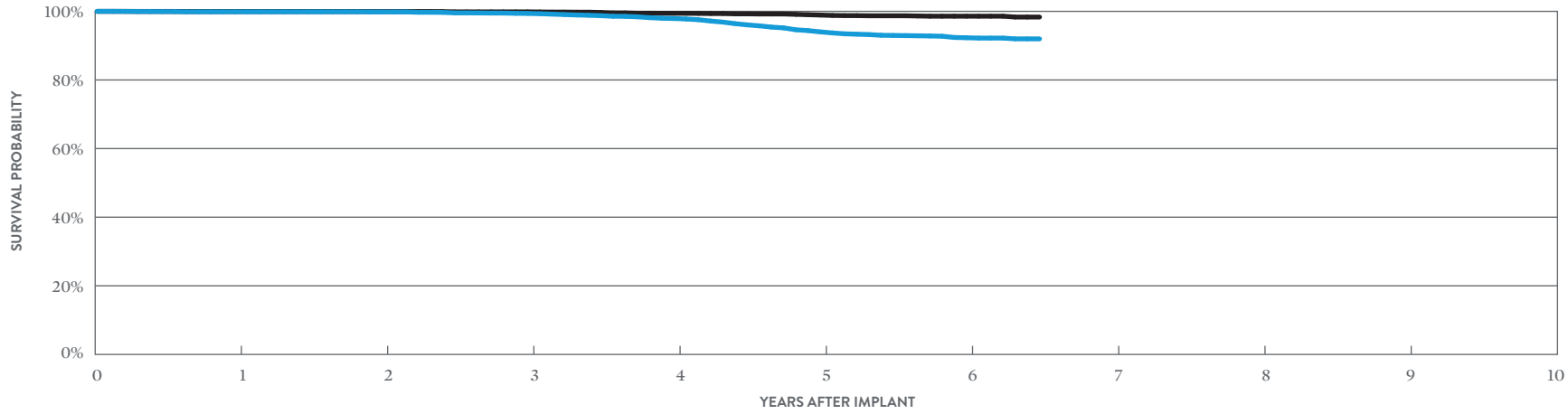
CUSTOMER REPORTED PERFORMANCE DATA

Unify Quadra™ CRT-D

MODEL CD3249-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	8,948
Estimated Active US Implants	4,217
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	135
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	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	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	10	0.11%	13	0.15%
Other	2	0.02%	0	0.00%
Total	**16**	**0.18%**	**18**	**0.20%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 78 MONTHS
SURVIVAL PROBABILITY	99.87%	99.84%	99.39%	97.91%	94.02%	92.31%	91.98%
± 1 STANDARD ERROR	0.04%	0.04%	0.09%	0.17%	0.30%	0.37%	0.41%
SAMPLE SIZE	8,430	7,540	6,840	6,150	5,170	3,330	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 78 MONTHS
SURVIVAL PROBABILITY	99.95%	99.95%	99.85%	99.43%	98.92%	98.59%	98.34%
± 1 STANDARD ERROR	0.02%	0.02%	0.05%	0.09%	0.13%	0.16%	0.24%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

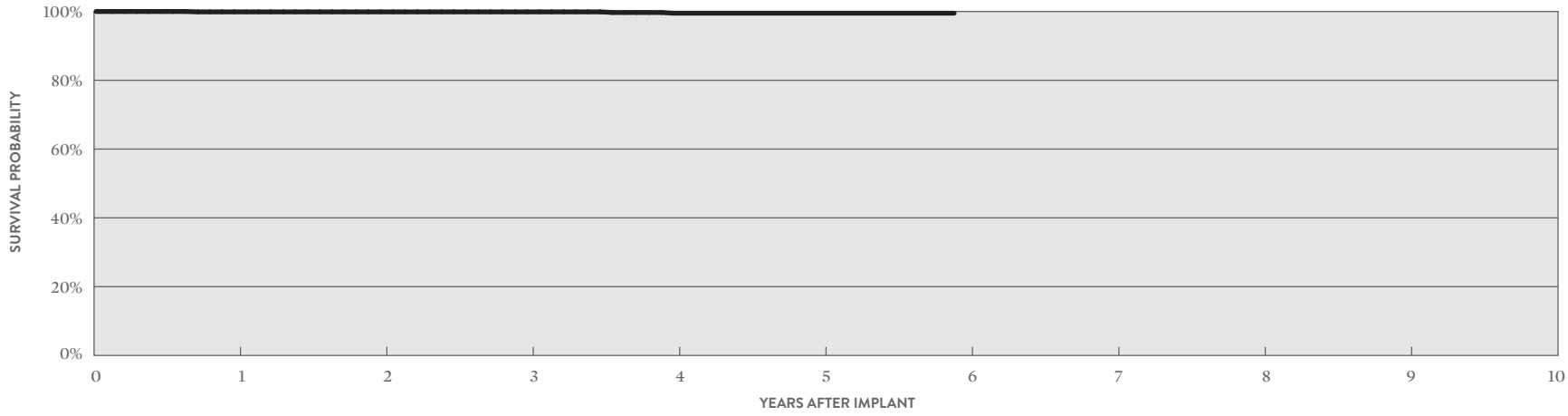
Unify Quadra™ CRT-D

MODEL CD3249-40Q*

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	990
Active Devices Enrolled in Study	395
Cumulative Months of Follow-up	41,944
Estimated Longevity	(see table on page 51)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	2	0.20%
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%	1	0.10%
Other	0	0.00%	0	0.00%
Total	**1**	**0.10%**	**1**	**0.10%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	AT 71 MONTHS
SURVIVAL PROBABILITY	99.89%	99.89%	99.89%	99.51%	99.51%	99.51%
± 1 STANDARD ERROR	0.11%	0.11%	0.11%	0.21%	0.29%	0.29%
SAMPLE SIZE	930	790	660	550	430	70

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

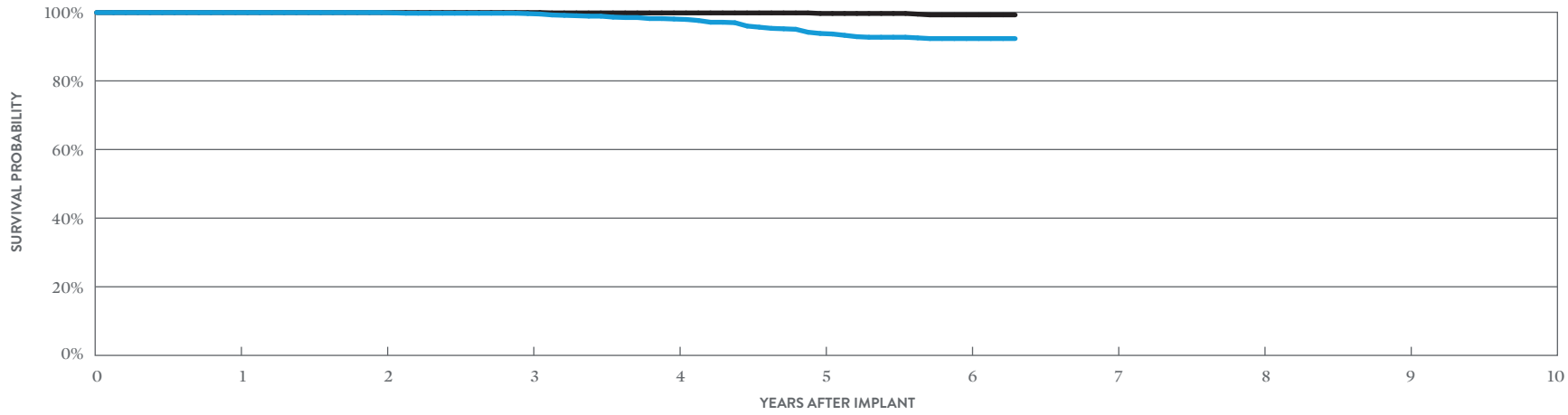
CUSTOMER REPORTED PERFORMANCE DATA

Unify Quadra™ CRT-D

MODEL CD3249-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	November 2011
Registered US Implants	2,523
Estimated Active US Implants	1,160
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	45
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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%	3	0.12%
Other	1	0.04%	0	0.00%
Total	**1**	**0.04%**	**4**	**0.16%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 76 MONTHS
SURVIVAL PROBABILITY	99.92%	99.92%	99.61%	98.03%	93.82%	92.33%	92.33%
± 1 STANDARD ERROR	0.06%	0.06%	0.12%	0.32%	0.59%	0.69%	0.69%
SAMPLE SIZE	2,370	2,100	1,880	1,690	1,430	960	300

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	AT 76 MONTHS
SURVIVAL PROBABILITY	99.92%	99.92%	99.92%	99.81%	99.65%	99.23%	99.23%
± 1 STANDARD ERROR	0.06%	0.06%	0.06%	0.10%	0.10%	0.26%	0.26%

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

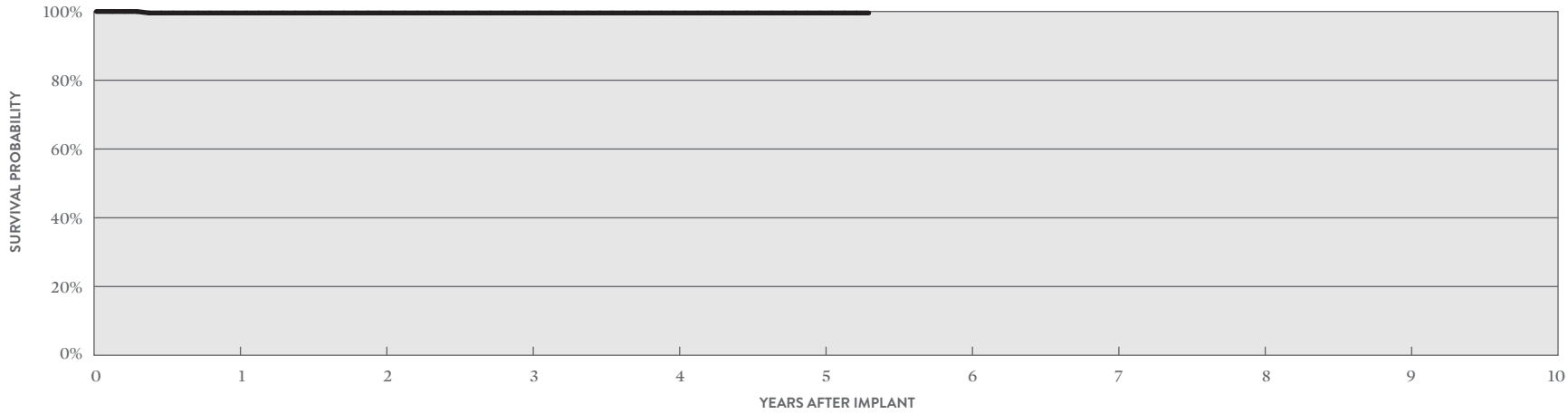
Unify Quadra™ CRT-D

MODEL CD3249-40

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	245
Active Devices Enrolled in Study	72
Cumulative Months of Follow-up	9,777
Estimated Longevity	(see table on page 51)
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	AT 64 MONTHS
SURVIVAL PROBABILITY	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%
SAMPLE SIZE	230	190	160	130	80	50

Cardiac Resynchronization Therapy (CRT) ICDs

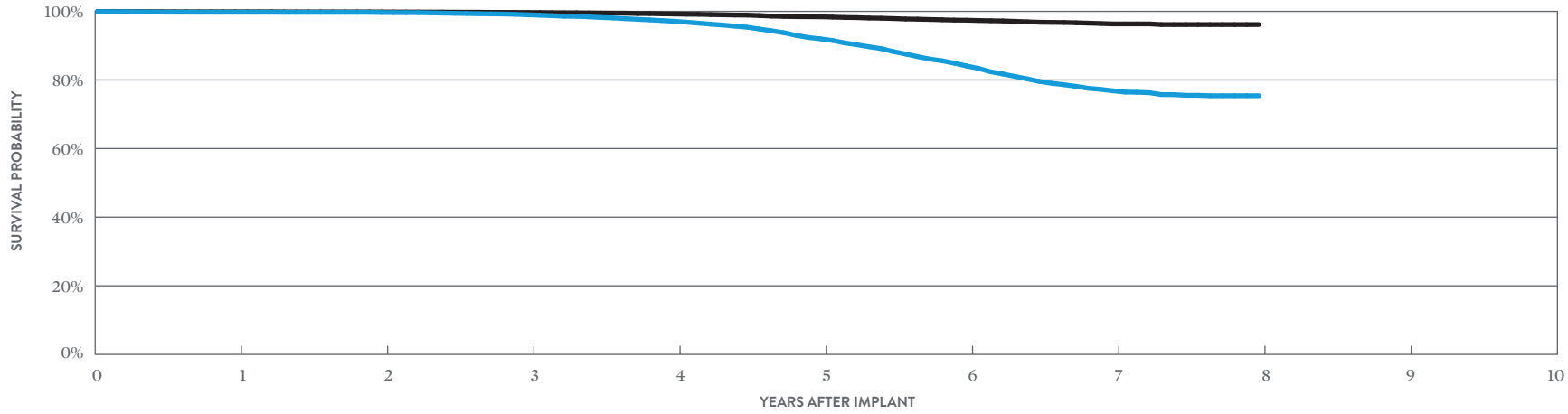
CUSTOMER REPORTED PERFORMANCE DATA

Unify™ CRT-D

MODEL CD3231-40Q (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	19,030
Estimated Active US Implants	6,502
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	834
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.01%	4	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	13	0.07%	9	0.05%
High Voltage Capacitor	14	0.07%	5	0.03%
Software/Firmware	0	0.00%	2	0.01%
Mechanical	1	<0.01%	2	0.01%
Possible Early Battery Depletion	51	0.27%	36	0.19%
Other	7	0.04%	3	0.02%
Total	**89**	**0.47%**	**61**	**0.32%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.76%	99.67%	99.01%	97.12%	92.01%	84.08%	76.85%	75.41%
± 1 STANDARD ERROR	0.04%	0.04%	0.07%	0.14%	0.24%	0.34%	0.42%	0.47%
SAMPLE SIZE	17,820	15,800	14,250	12,800	11,280	9,280	5,970	380

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.88%	99.83%	99.67%	99.23%	98.42%	97.43%	96.35%	96.16%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.07%	0.11%	0.15%	0.19%	0.22%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

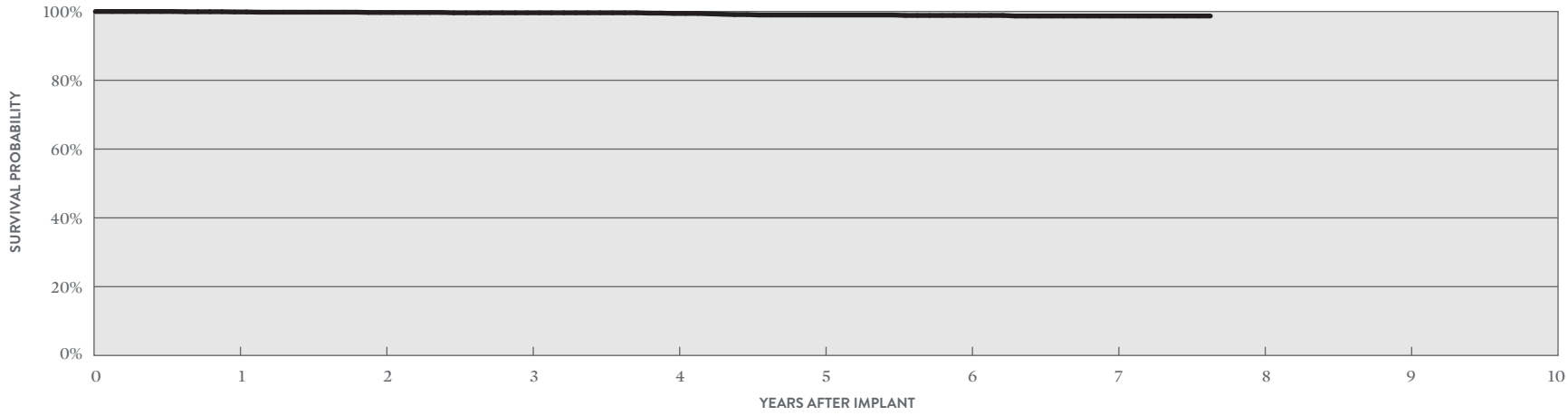
Unify™ CRT-D

MODEL CD3231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	1,679
Active Devices Enrolled in Study	687
Cumulative Months of Follow-up	87,493
Estimated Longevity	(see table on page 51)
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	11	0.66%	3	0.18%
Other	2	0.12%	0	0.00%
Total	**15**	**0.89%**	**6**	**0.36%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	AT 92 MONTHS
SURVIVAL PROBABILITY	99.87%	99.72%	99.63%	99.43%	98.98%	98.85%	98.69%	98.69%
± 1 STANDARD ERROR	0.07%	0.14%	0.16%	0.19%	0.31%	0.34%	0.37%	0.37%
SAMPLE SIZE	1,570	1,360	1,180	1,020	860	740	510	50

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

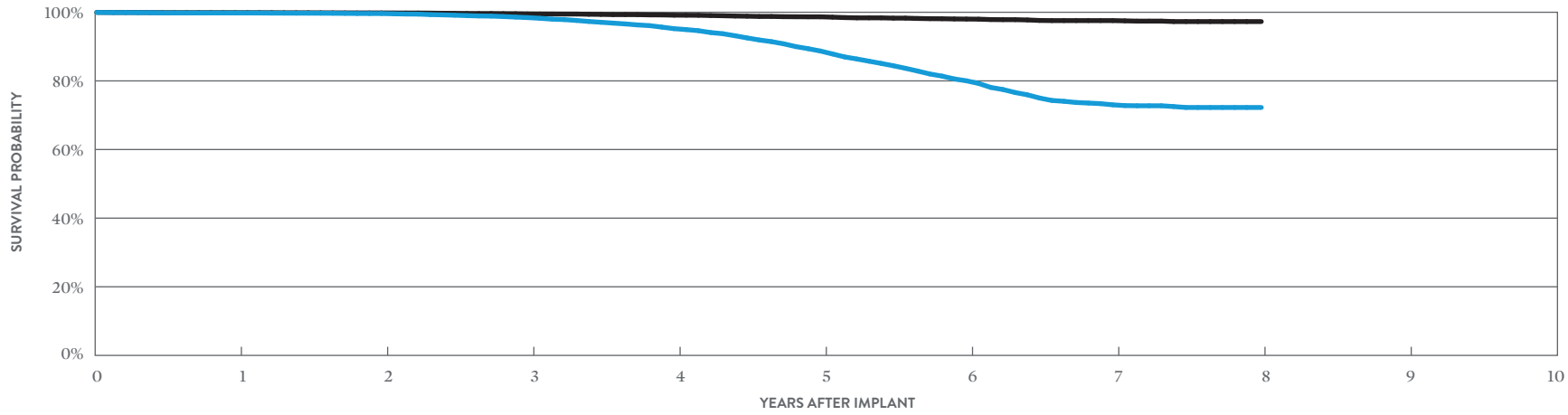
CUSTOMER REPORTED PERFORMANCE DATA

Unify™ CRT-D

MODEL CD3231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	20,500
Estimated Active US Implants	7,040
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	1,046
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	10	0.05%	4	0.02%
Electrical Interconnect	3	0.01%	0	0.00%
Battery	9	0.04%	3	0.01%
High Voltage Capacitor	6	0.03%	0	0.00%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	1	<0.01%	0	0.00%
Possible Early Battery Depletion	29	0.14%	25	0.12%
Other	10	0.05%	11	0.05%
Total	**68**	**0.33%**	**45**	**0.22%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.79%	99.63%	98.44%	95.22%	88.71%	80.02%	73.02%	72.25%
± 1 STANDARD ERROR	0.03%	0.05%	0.09%	0.17%	0.27%	0.37%	0.45%	0.49%
SAMPLE SIZE	19,160	16,790	14,880	13,100	11,190	8,700	5,090	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.88%	99.81%	99.53%	99.15%	98.67%	98.02%	97.57%	97.29%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.07%	0.10%	0.13%	0.16%	0.19%

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

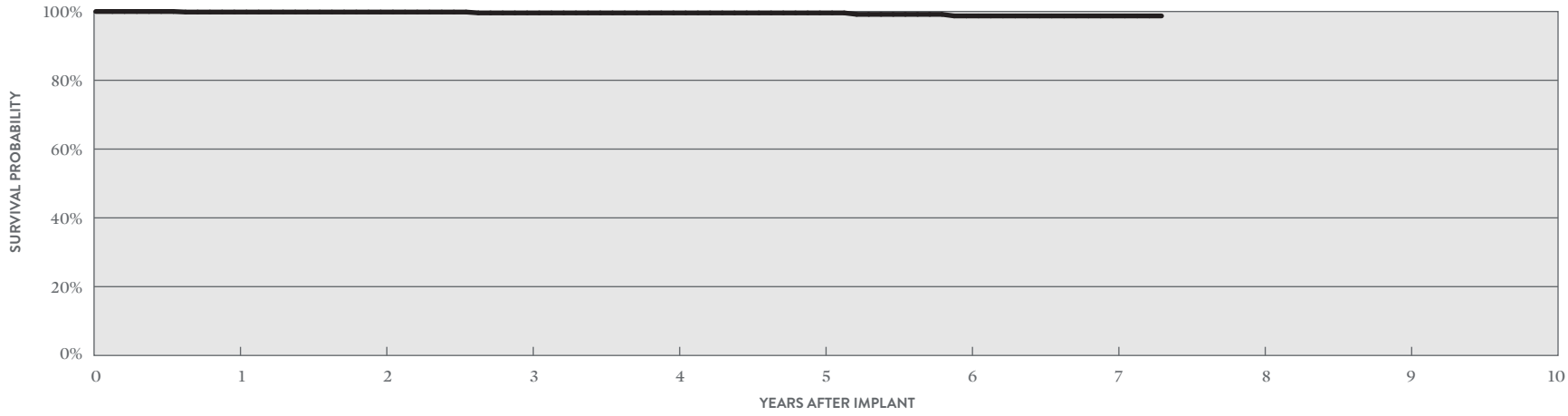
Unify™ CRT-D

MODEL CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	689
Active Devices Enrolled in Study	189
Cumulative Months of Follow-up	31,024
Estimated Longevity	(see table on page 51)
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%	0	0.00%
Other	0	0.00%	1	0.15%
Total	**4**	**0.58%**	**4**	**0.58%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	AT 88 MONTHS
SURVIVAL PROBABILITY	99.84%	99.84%	99.59%	99.59%	99.59%	98.71%	98.71%	98.71%
± 1 STANDARD ERROR	0.16%	0.16%	0.29%	0.29%	0.29%	0.69%	0.69%	0.69%
SAMPLE SIZE	630	510	410	350	280	230	150	60

Cardiac Resynchronization Therapy (CRT) ICDs

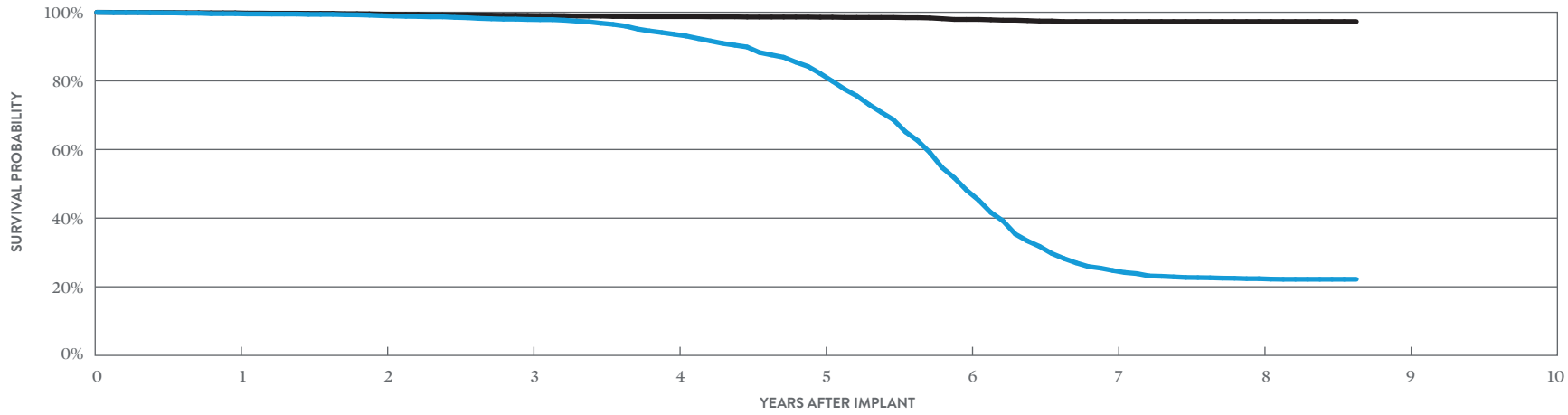
CUSTOMER REPORTED PERFORMANCE DATA

Promote™ + CRT-D

MODEL CD3211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	6,903
Estimated Active US Implants	1,109
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	1,270
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	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%	9	0.13%
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%**	**23**	**0.33%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	99.59%	99.00%	97.90%	93.59%	82.15%	48.17%	24.75%	22.37%	22.19%
± 1 STANDARD ERROR	0.08%	0.12%	0.19%	0.34%	0.55%	0.78%	0.67%	0.63%	0.63%
SAMPLE SIZE	6,370	5,510	4,910	4,350	3,680	2,670	1,610	1,070	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	99.84%	99.46%	99.07%	98.72%	98.56%	97.91%	97.29%	97.29%	97.29%
± 1 STANDARD ERROR	0.05%	0.09%	0.13%	0.16%	0.17%	0.23%	0.30%	0.30%	0.30%

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

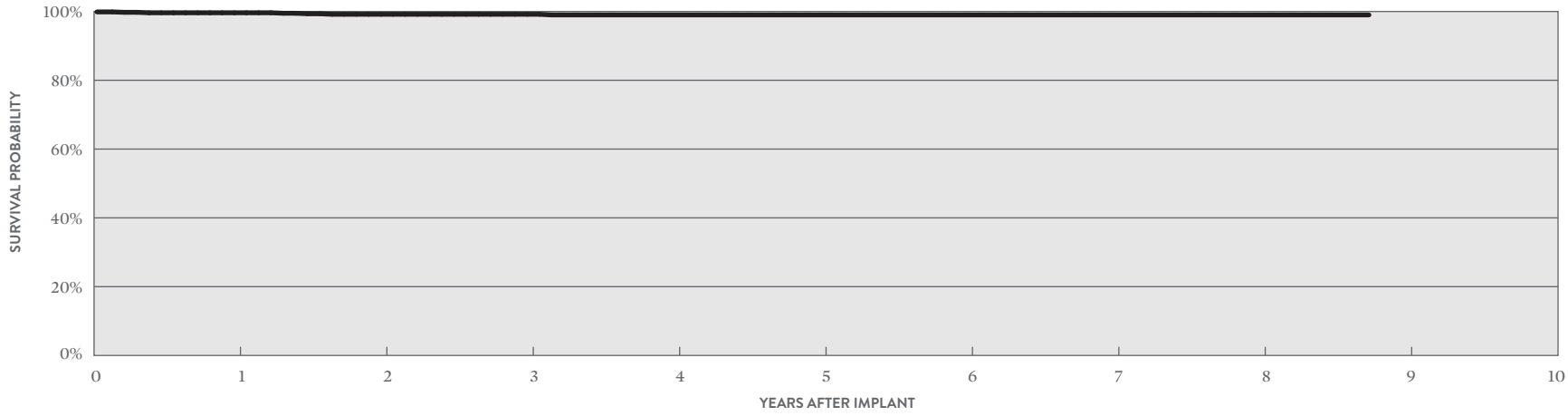
Promote™ + CRT-D

MODEL CD3211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	856
Active Devices Enrolled in Study	232
Cumulative Months of Follow-up	44,921
Estimated Longevity	(see table on page 51)
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	1	2	3	4	5	6	7	8	AT 105 MONTHS
SURVIVAL PROBABILITY	99.63%	99.19%	99.19%	99.00%	99.00%	99.00%	99.00%	99.00%	99.00%
± 1 STANDARD ERROR	0.21%	0.33%	0.33%	0.38%	0.38%	0.38%	0.38%	0.38%	0.38%
SAMPLE SIZE	790	680	580	480	380	300	260	230	60

**DF4-LLHH connector type.*

Cardiac Resynchronization Therapy (CRT) ICDs

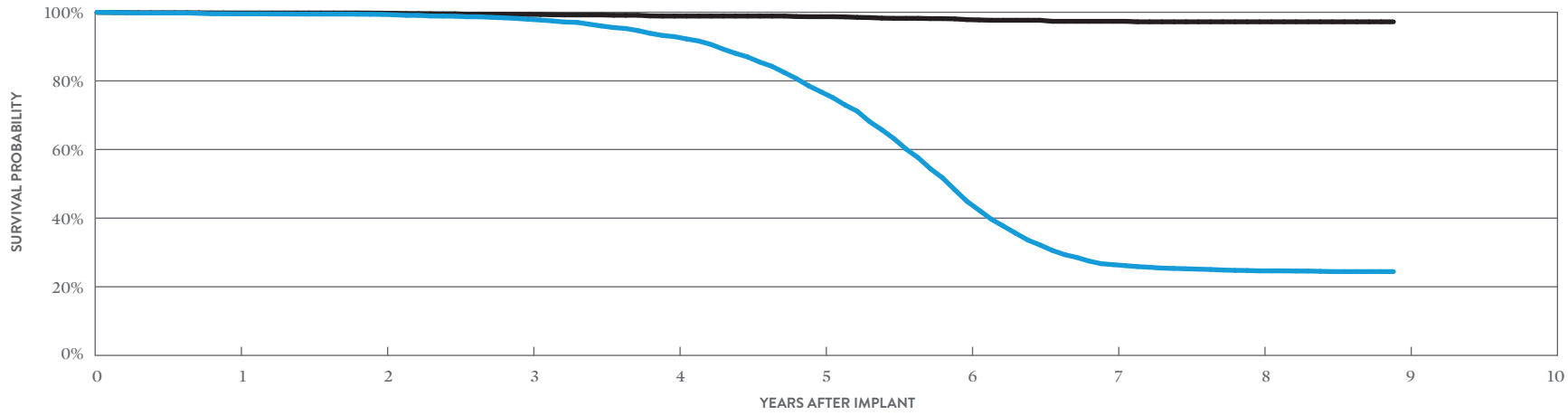
CUSTOMER REPORTED PERFORMANCE DATA

Promote™ + CRT-D

MODEL CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,645
Estimated Active US Implants	1,370
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	1,432
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.03%	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	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.53%	99.38%	97.95%	92.89%	76.84%	44.89%	26.44%	24.63%	24.42%
± 1 STANDARD ERROR	0.07%	0.09%	0.16%	0.33%	0.58%	0.73%	0.63%	0.62%	0.62%
SAMPLE SIZE	7,980	6,870	6,040	5,200	4,210	2,920	1,790	1,270	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.79%	99.73%	99.38%	98.89%	98.71%	97.85%	97.36%	97.22%	97.22%
± 1 STANDARD ERROR	0.05%	0.06%	0.10%	0.14%	0.15%	0.21%	0.28%	0.30%	0.30%

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

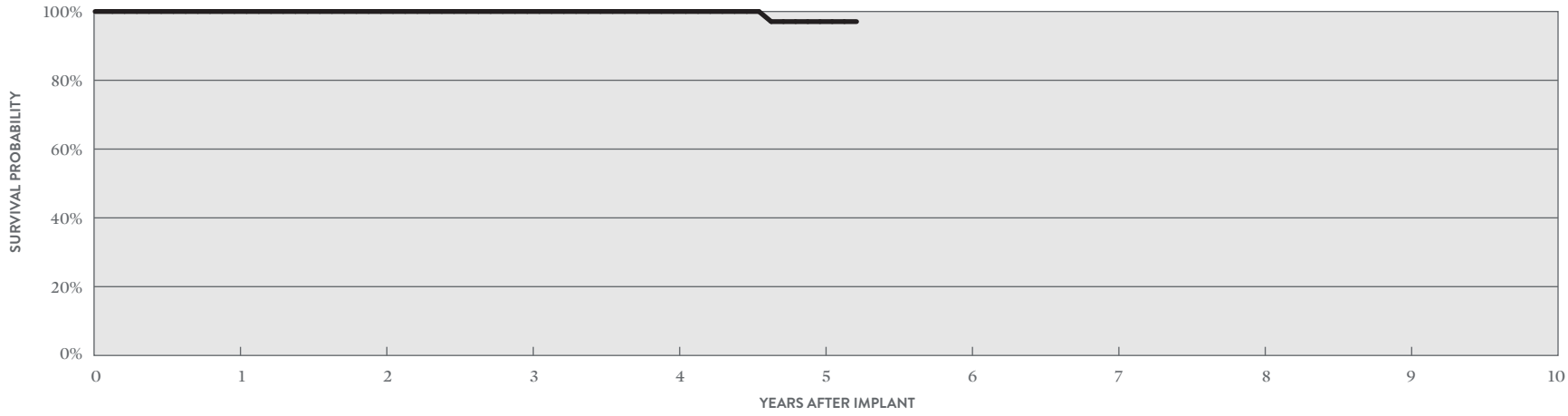
Promote™ + CRT-D

MODEL CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	223
Active Devices Enrolled in Study	22
Cumulative Months of Follow-up	9,387
Estimated Longevity	(see table on page 51)
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%	2	0.90%
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**	**0.90%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	AT 63 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%	100.00%	97.06%	97.06%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%	0.00%	2.05%	2.05%
SAMPLE SIZE	210	170	130	100	70	50

Cardiac Resynchronization Therapy (CRT) ICDs

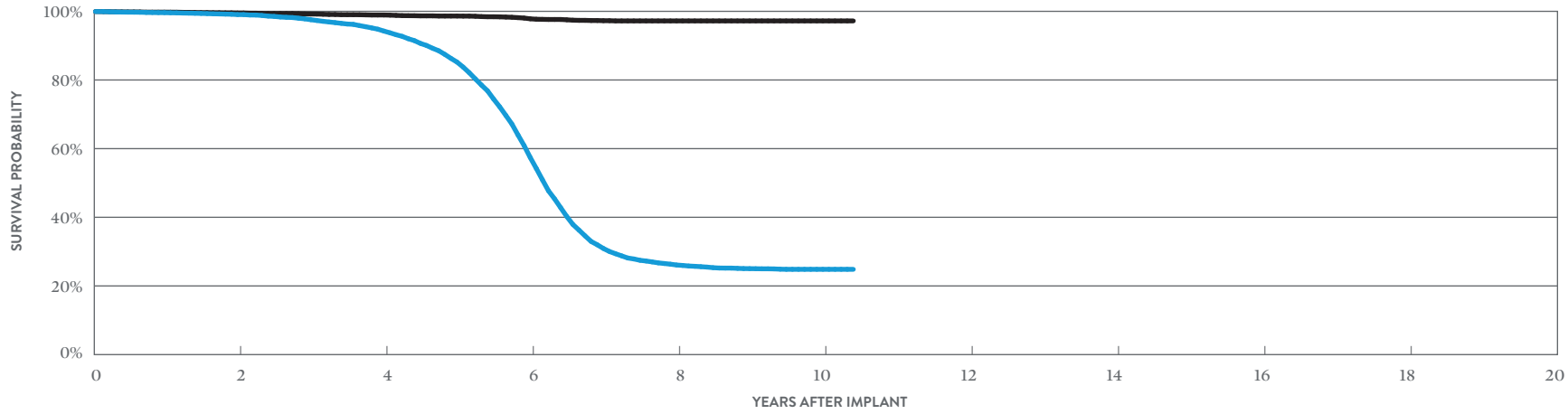
CUSTOMER REPORTED PERFORMANCE DATA

Promote™ RF CRT-D

MODEL 3207-36

US Regulatory Approval	September 2007
Registered US Implants	24,005
Estimated Active US Implants	2,821
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	3,386
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	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	AT 125 MONTHS
SURVIVAL PROBABILITY	99.05%	94.25%	57.43%	26.10%	24.84%	24.84%
± 1 STANDARD ERROR	0.06%	0.18%	0.45%	0.41%	0.41%	0.41%
SAMPLE SIZE	18,830	13,960	8,250	3,290	1,360	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 125 MONTHS
SURVIVAL PROBABILITY	99.52%	98.93%	97.82%	97.21%	97.21%	97.21%
± 1 STANDARD ERROR	0.05%	0.08%	0.13%	0.18%	0.18%	0.18%

Cardiac Resynchronization Therapy (CRT) ICDs

ACTIVELY MONITORED STUDY DATA

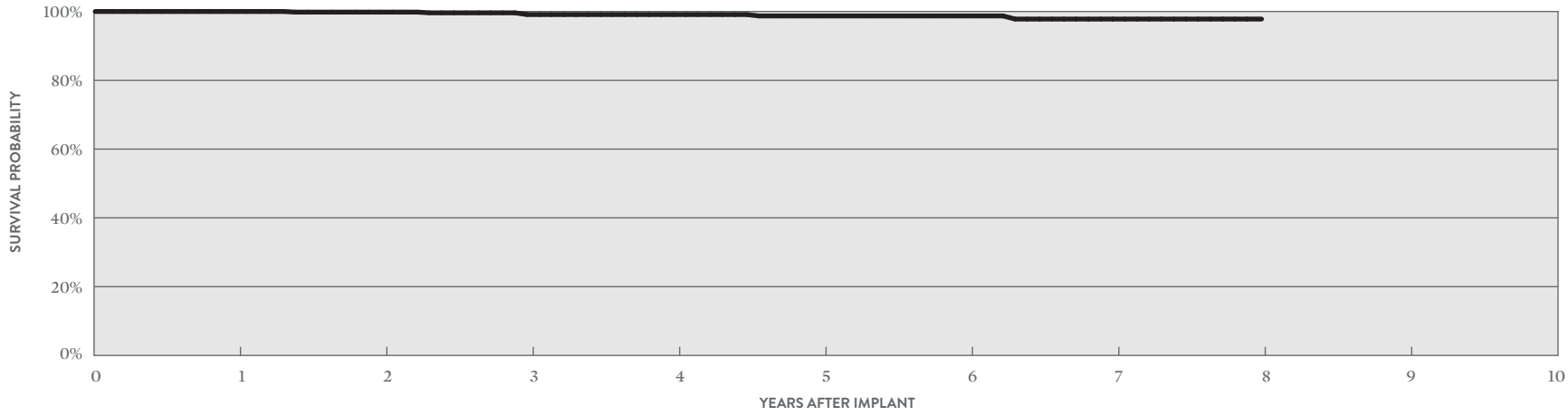
Promote™ RF CRT-D

MODEL 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	672
Active Devices Enrolled in Study	37
Cumulative Months of Follow-up	30,571
Estimated Longevity	(see table on page 51)
Max. Delivered Energy	36 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Inappropriate Shock	1	0.15%
Premature Battery Depletion	3	0.45%
Skin Erosion	3	0.45%

	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	8
SURVIVAL PROBABILITY	100.00%	99.82%	99.11%	99.11%	98.71%	98.71%	97.80%	97.80%
± 1 STANDARD ERROR	0.00%	0.18%	0.28%	0.45%	0.60%	0.60%	1.08%	1.08%
SAMPLE SIZE	630	540	450	340	240	170	100	50

Cardiac Resynchronization Therapy (CRT) ICDs

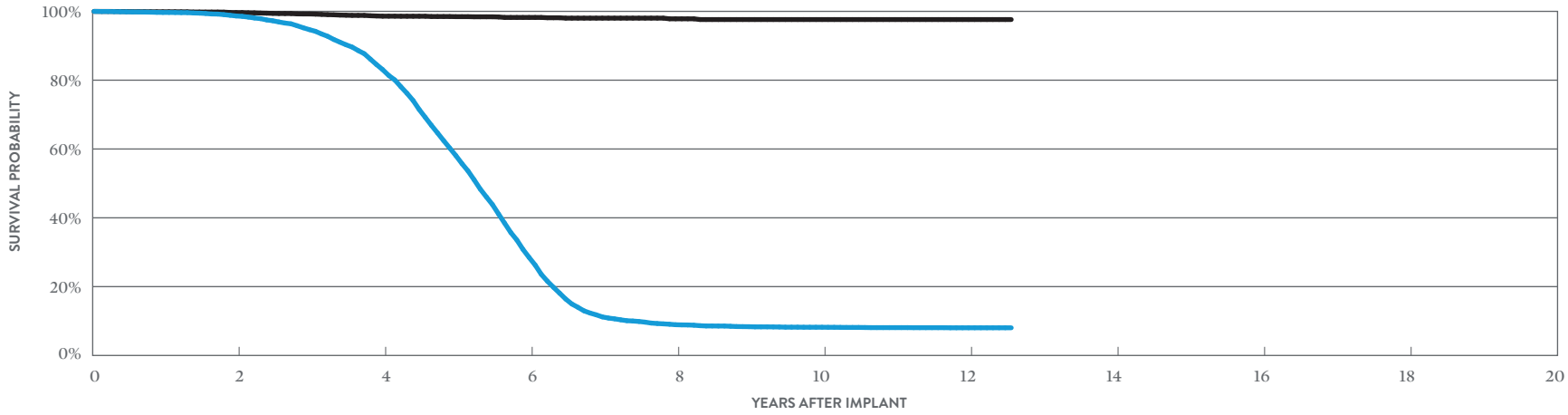
CUSTOMER REPORTED PERFORMANCE DATA

Atlas™ + HF CRT-D

MODEL V-343

US Regulatory Approval	November 2004
Registered US Implants	18,776
Estimated Active US Implants	781
Estimated Longevity	(see table on page 51)
Normal Battery Depletion	3,490
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 329, 330)	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	AT 151 MONTHS
SURVIVAL PROBABILITY	98.66%	83.08%	28.49%	8.93%	8.20%	8.04%	8.04%
± 1 STANDARD ERROR	0.09%	0.34%	0.48%	0.29%	0.28%	0.27%	0.27%
SAMPLE SIZE	14,820	9,860	3,940	1,090	830	530	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 151 MONTHS
SURVIVAL PROBABILITY	99.66%	98.60%	98.23%	97.83%	97.62%	97.62%	97.62%
± 1 STANDARD ERROR	0.05%	0.11%	0.14%	0.22%	0.27%	0.27%	0.27%

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
CD3369-40Q	Quadra Assura MP™ CRT-D*	11.1	9.9	8.9	7.4
CD3369-40C	Quadra Assura MP™ CRT-D*	11.1	9.9	8.9	7.4
CD3365-40Q	Quadra Assura™ CRT-D*	11.1	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.*

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
CD3369-40Q	Quadra Assura MP™ CRT-D	99.83%	99.83%								
CD3369-40C	Quadra Assura MP™ CRT-D	99.94%	99.94%								
CD3365-40Q	Quadra Assura™ CRT-D	99.87%	99.82%	99.82%							
CD3365-40Q	Quadra Assura™ CRT-D†	99.78%	99.43%	98.51%	96.82%						
CD3365-40C	Quadra Assura™ CRT-D	100.00%	100.00%								
CD3365-40C	Quadra Assura™ CRT-D†	99.69%	99.22%	98.41%	97.44%						
CD3357-40Q	Unify Assura™ CRT-D	99.93%	99.86%								
CD3357-40Q	Unify Assura™ CRT-D†	99.78%	99.34%	98.26%	96.17%						
CD3357-40C	Unify Assura™ CRT-D	99.98%	99.98%								
CD3357-40C	Unify Assura™ CRT-D†	99.83%	99.51%	98.23%	97.19%						
CD3265-40Q	Quadra Assura™ CRT-D†	99.83%	99.74%	99.38%	97.98%	96.88%	96.35%				
CD3265-40	Quadra Assura™ CRT-D†	99.89%	99.70%	99.57%	98.56%	96.70%					
CD3257-40Q	Unify Assura™ CRT-D†	99.92%	99.74%	98.22%	94.73%	93.60%					
CD3257-40	Unify Assura™ CRT-D†	99.81%	99.63%	98.46%	94.90%	92.45%					
CD3249-40Q	Unify Quadra™ CRT-D†	99.87%	99.84%	99.39%	97.91%	94.02%	92.31%				
CD3249-40	Unify Quadra™ CRT-D†	99.92%	99.92%	99.61%	98.03%	93.82%	92.33%				
CD3231-40Q	Unify™ CRT-D†	99.76%	99.67%	99.01%	97.12%	92.01%	84.08%	76.85%	75.41%		
CD3231-40	Unify™ CRT-D†	99.79%	99.63%	98.44%	95.22%	88.71%	80.02%	73.02%	72.25%		
CD3211-36Q	Promote™ + CRT-D	99.59%	99.00%	97.90%	93.59%	82.15%	48.17%	24.75%	22.37%		
CD3211-36	Promote™ + CRT-D	99.53%	99.38%	97.95%	92.89%	76.84%	44.89%	26.44%	24.63%		
3207-36	Promote™ RF CRT-D	99.62%	99.05%	97.56%	94.25%	85.21%	57.43%	30.92%	26.10%	25.04%	24.84%
V-343	Atlas™ + HF CRT-D	99.68%	98.66%	94.69%	83.08%	58.09%	28.49%	11.20%	8.93%	8.36%	8.20%

†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
CD3369-40Q	Quadra Assura MP™ CRT-D	99.83%	99.83%								
CD3369-40C	Quadra Assura MP™ CRT-D	100.00%	100.00%								
CD3365-40Q	Quadra Assura™ CRT-D	99.87%	99.82%	99.82%							
CD3365-40Q	Quadra Assura™ CRT-D†	99.83%	99.57%	98.73%	97.15%						
CD3365-40C	Quadra Assura™ CRT-D	100.00%	100.00%								
CD3365-40C	Quadra Assura™ CRT-D†	99.79%	99.32%	98.51%	97.79%						
CD3357-40Q	Unify Assura™ CRT-D	99.93%	99.93%								
CD3357-40Q	Unify Assura™ CRT-D†	99.90%	99.46%	98.80%	97.56%						
CD3357-40C	Unify Assura™ CRT-D	99.98%	99.98%								
CD3357-40C	Unify Assura™ CRT-D†	99.89%	99.62%	98.94%	97.94%						
CD3265-40Q	Quadra Assura™ CRT-D†	99.87%	99.85%	99.65%	98.98%	98.27%	98.13%				
CD3265-40	Quadra Assura™ CRT-D†	99.89%	99.76%	99.63%	98.90%	98.70%					
CD3257-40Q	Unify Assura™ CRT-D†	100.00%	100.00%	99.90%	98.38%	98.38%					
CD3257-40	Unify Assura™ CRT-D†	99.90%	99.83%	99.51%	98.85%	98.35%					
CD3249-40Q	Unify Quadra™ CRT-D†	99.95%	99.95%	99.85%	99.43%	98.92%	98.59%				
CD3249-40	Unify Quadra™ CRT-D†	99.92%	99.92%	99.92%	99.81%	99.65%	99.23%				
CD3231-40Q	Unify™ CRT-D†	99.88%	99.83%	99.67%	99.23%	98.42%	97.43%	96.35%	96.16%		
CD3231-40	Unify™ CRT-D†	99.88%	99.81%	99.53%	99.15%	98.67%	98.02%	97.57%	97.29%		
CD3211-36Q	Promote™ + CRT-D	99.84%	99.46%	99.07%	98.72%	98.56%	97.91%	97.29%	97.29%		
CD3211-36	Promote™ + CRT-D	99.79%	99.73%	99.38%	98.89%	98.71%	97.85%	97.36%	97.22%		
3207-36	Promote™ RF CRT-D	99.77%	99.52%	99.21%	98.93%	98.63%	97.82%	97.27%	97.21%	97.21%	97.21%
V-343	Atlas™ + HF CRT-D	99.88%	99.66%	99.24%	98.60%	98.46%	98.23%	98.03%	97.83%	97.62%	97.62%

†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
CD3369-40Q	Quadra Assura MP™ CRT-D	28,899	1.40%	3	0.01%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.03%**
CD3369-40C	Quadra Assura MP™ CRT-D	4,032	1.50%	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**	**0.00%**
CD3365-40Q	Quadra Assura™ CRT-D	14,921	2.40%	0	0.00%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	1	<0.01%	**6**	**0.04%**
CD3365-40Q	Quadra Assura™ CRT-D†	24,081	12.10%	5	0.02%	8	0.03%	2	<0.01%	0	0.00%	1	<0.01%	0	0.00%	17	0.07%	5	0.02%	**38**	**0.16%**
CD3365-40C	Quadra Assura™ CRT-D	2,413	2.40%	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%**
CD3365-40C	Quadra Assura™ CRT-D†	5,626	16.40%	6	0.11%	2	0.04%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	3	0.05%	2	0.04%	**14**	**0.25%**
CD3357-40Q	Unify Assura™ CRT-D	9,976	1.80%	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%**
CD3357-40Q	Unify Assura™ CRT-D†	5,342	15.20%	1	0.02%	2	0.04%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	8	0.15%	0	0.00%	**13**	**0.24%**
CD3357-40C	Unify Assura™ CRT-D	10,273	2.10%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
CD3357-40C	Unify Assura™ CRT-D†	9,597	14.90%	2	0.02%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	9	0.09%	0	0.00%	**14**	**0.15%**
CD3265-40Q	Quadra Assura™ CRT-D†	13,540	12.10%	2	0.01%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	13	0.10%	1	<0.01%	**18**	**0.13%**
CD3265-40	Quadra Assura™ CRT-D†	3,926	14.80%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.08%	6	0.15%	**10**	**0.25%**
CD3257-40Q	Unify Assura™ CRT-D†	2,716	17.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	3	0.11%	0	0.00%	**4**	**0.15%**
CD3257-40	Unify Assura™ CRT-D†	6,744	15.10%	4	0.06%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.09%	1	0.01%	**13**	**0.19%**
CD3249-40Q	Unify Quadra™ CRT-D†	8,948	13.00%	3	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	10	0.11%	2	0.02%	**16**	**0.18%**
CD3249-40	Unify Quadra™ CRT-D†	2,523	15.00%	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†	19,030	16.50%	2	0.01%	1	<0.01%	13	0.07%	14	0.07%	0	0.00%	1	<0.01%	51	0.27%	7	0.04%	**89**	**0.47%**
CD3231-40	Unify™ CRT-D†	20,500	18.10%	10	0.05%	3	0.01%	9	0.04%	6	0.03%	0	0.00%	1	<0.01%	29	0.14%	10	0.05%	**68**	**0.33%**
CD3211-36Q	Promote™ + CRT-D	6,903	27.20%	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	8,645	27.60%	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	24,005	27.00%	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	25.20%	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
CD3369-40Q	Quadra Assura MP™ CRT-D	28,899	1.40%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	**8**	**0.03%**
CD3369-40C	Quadra Assura MP™ CRT-D	4,032	1.50%	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**	**0.00%**
CD3365-40Q	Quadra Assura™ CRT-D	14,921	2.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	1	<0.01%	1	<0.01%	**6**	**0.04%**
CD3365-40Q	Quadra Assura™ CRT-D†	24,081	12.10%	9	0.04%	0	0.00%	15	0.06%	0	0.00%	3	0.01%	2	<0.01%	91	0.38%	3	0.01%	**123**	**0.51%**
CD3365-40C	Quadra Assura™ CRT-D	2,413	2.40%	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%**
CD3365-40C	Quadra Assura™ CRT-D†	5,626	16.40%	2	0.04%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	0	0.00%	15	0.27%	1	0.02%	**20**	**0.36%**
CD3357-40Q	Unify Assura™ CRT-D	9,976	1.80%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	**3**	**0.03%**
CD3357-40Q	Unify Assura™ CRT-D†	5,342	15.20%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	13	0.24%	1	0.02%	**15**	**0.28%**
CD3357-40C	Unify Assura™ CRT-D	10,273	2.10%	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%**
CD3357-40C	Unify Assura™ CRT-D†	9,597	14.90%	3	0.03%	0	0.00%	4	0.04%	0	0.00%	1	0.01%	1	0.01%	22	0.23%	3	0.03%	**34**	**0.35%**
CD3265-40Q	Quadra Assura™ CRT-D†	13,540	12.10%	5	0.04%	0	0.00%	5	0.04%	0	0.00%	1	<0.01%	2	0.01%	33	0.24%	0	0.00%	**46**	**0.34%**
CD3265-40	Quadra Assura™ CRT-D†	3,926	14.80%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.03%	3	0.08%	1	0.03%	**7**	**0.18%**
CD3257-40Q	Unify Assura™ CRT-D†	2,716	17.30%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	7	0.26%	0	0.00%	**8**	**0.29%**
CD3257-40	Unify Assura™ CRT-D†	6,744	15.10%	3	0.04%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	13	0.19%	1	0.01%	**19**	**0.28%**
CD3249-40Q	Unify Quadra™ CRT-D†	8,948	13.00%	3	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	13	0.15%	0	0.00%	**18**	**0.20%**
CD3249-40	Unify Quadra™ CRT-D†	2,523	15.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	3	0.12%	0	0.00%	**4**	**0.16%**
CD3231-40Q	Unify™ CRT-D†	19,030	16.50%	4	0.02%	0	0.00%	9	0.05%	5	0.03%	2	0.01%	2	0.01%	36	0.19%	3	0.02%	**61**	**0.32%**
CD3231-40	Unify™ CRT-D†	20,500	18.10%	4	0.02%	0	0.00%	3	0.01%	0	0.00%	2	<0.01%	0	0.00%	25	0.12%	11	0.05%	**45**	**0.22%**
CD3211-36Q	Promote™ + CRT-D	6,903	27.20%	3	0.04%	0	0.00%	5	0.07%	0	0.00%	9	0.13%	0	0.00%	0	0.00%	6	0.09%	**23**	**0.33%**
CD3211-36	Promote™ + CRT-D	8,645	27.60%	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	24,005	27.00%	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	25.20%	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
CD3369-40Q	Quadra Assura MP™ CRT-D	29,844	1.48%	3	0.01%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.03%**
CD3369-40C	Quadra Assura MP™ CRT-D	4,271	1.92%	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	39,307	8.65%	5	0.01%	11	0.03%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	18	0.05%	6	0.02%	**44**	**0.11%**
CD3365-40C	Quadra Assura™ CRT-D	8,101	12.86%	6	0.07%	2	0.02%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	2	0.02%	**14**	**0.17%**
CD3357-40Q	Unify Assura™ CRT-D	15,804	6.93%	1	<0.01%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	8	0.05%	0	0.00%	**13**	**0.08%**
CD3357-40C	Unify Assura™ CRT-D	20,367	8.74%	2	<0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	9	0.04%	0	0.00%	**15**	**0.07%**
CD3265-40Q	Quadra Assura™ CRT-D	13,958	12.60%	2	0.01%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	13	0.09%	1	<0.01%	**19**	**0.14%**
CD3265-40	Quadra Assura™ CRT-D	4,046	15.42%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.07%	6	0.15%	**10**	**0.25%**
CD3257-40Q	Unify Assura™ CRT-D	2,728	18.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	3	0.11%	0	0.00%	**4**	**0.15%**
CD3257-40	Unify Assura™ CRT-D	6,723	15.65%	4	0.06%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.09%	1	0.01%	**13**	**0.19%**
CD3249-40Q	Unify Quadra™ CRT-D	10,787	12.48%	4	0.04%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	11	0.10%	2	0.02%	**18**	**0.17%**
CD3249-40	Unify Quadra™ CRT-D	3,876	12.02%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	**3**	**0.08%**
CD3231-40Q	Unify™ CRT-D	20,969	17.02%	3	0.01%	1	<0.01%	14	0.07%	15	0.07%	0	0.00%	1	<0.01%	62	0.30%	9	0.04%	**105**	**0.50%**
CD3231-40	Unify™ CRT-D	22,563	17.56%	11	0.05%	4	0.02%	10	0.04%	6	0.03%	0	0.00%	1	<0.01%	31	0.14%	10	0.04%	**73**	**0.32%**
CD3211-36Q	Promote™ + CRT-D	16,017	14.39%	13	0.08%	0	0.00%	13	0.08%	7	0.04%	1	<0.01%	2	0.01%	7	0.04%	6	0.04%	**49**	**0.31%**
CD3211-36	Promote™ + CRT-D	21,011	12.49%	14	0.07%	2	<0.01%	15	0.07%	5	0.02%	1	<0.01%	0	0.00%	8	0.04%	13	0.06%	**58**	**0.28%**
3207-36	Promote™ RF CRT-D	25,838	26.89%	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	24.98%	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
CD3369-40Q	Quadra Assura MP™ CRT-D	29,844	1.48%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	**8**	**0.03%**
CD3369-40C	Quadra Assura MP™ CRT-D	4,271	1.92%	3	0.07%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	3	0.07%	0	0.00%	1	0.02%	**8**	**0.19%**
CD3365-40Q	Quadra Assura™ CRT-D	39,307	8.65%	9	0.02%	0	0.00%	15	0.04%	0	0.00%	3	<0.01%	6	0.02%	92	0.23%	4	0.01%	**129**	**0.33%**
CD3365-40C	Quadra Assura™ CRT-D	8,101	12.86%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	15	0.19%	1	0.01%	**20**	**0.25%**
CD3357-40Q	Unify Assura™ CRT-D	15,804	6.93%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	13	0.08%	2	0.01%	**18**	**0.11%**
CD3357-40C	Unify Assura™ CRT-D	20,367	8.74%	3	0.01%	0	0.00%	4	0.02%	0	0.00%	1	<0.01%	1	<0.01%	22	0.11%	3	0.01%	**34**	**0.17%**
CD3265-40Q	Quadra Assura™ CRT-D	13,958	12.60%	5	0.04%	0	0.00%	5	0.04%	0	0.00%	1	<0.01%	2	0.01%	33	0.24%	0	0.00%	**46**	**0.33%**
CD3265-40	Quadra Assura™ CRT-D	4,046	15.42%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	4	0.10%	1	0.02%	**8**	**0.20%**
CD3257-40Q	Unify Assura™ CRT-D	2,728	18.11%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	7	0.26%	0	0.00%	**8**	**0.29%**
CD3257-40	Unify Assura™ CRT-D	6,723	15.65%	3	0.04%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	13	0.19%	1	0.01%	**19**	**0.28%**
CD3249-40Q	Unify Quadra™ CRT-D	10,787	12.48%	3	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	14	0.13%	2	0.02%	**21**	**0.19%**
CD3249-40	Unify Quadra™ CRT-D	3,876	12.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	3	0.08%	0	0.00%	**4**	**0.10%**
CD3231-40Q	Unify™ CRT-D	20,969	17.02%	5	0.02%	0	0.00%	10	0.05%	5	0.02%	2	<0.01%	3	0.01%	39	0.19%	3	0.01%	**67**	**0.32%**
CD3231-40	Unify™ CRT-D	22,563	17.56%	5	0.02%	0	0.00%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	26	0.12%	12	0.05%	**51**	**0.23%**
CD3211-36Q	Promote™ + CRT-D	16,017	14.39%	6	0.04%	0	0.00%	7	0.04%	0	0.00%	11	0.07%	2	0.01%	3	0.02%	9	0.06%	**38**	**0.24%**
CD3211-36	Promote™ + CRT-D	21,011	12.49%	7	0.03%	0	0.00%	4	0.02%	0	0.00%	16	0.08%	2	<0.01%	2	<0.01%	6	0.03%	**37**	**0.18%**
3207-36	Promote™ RF CRT-D	25,838	26.89%	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	24.98%	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
CD3365-40Q	231	124	7,342	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.43%	**1**	**0.43%**
CD3357-40Q	241	179	6,117	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3357-40C	193	109	4,658	0	0.00%	0	0.00%	0	0.00%	1	0.52%	1	0.52%	**2**	**1.04%**
CD3265-40Q	421	168	15,881	0	0.00%	0	0.00%	0	0.00%	1	0.24%	0	0.00%	**1**	**0.24%**
CD3265-40	100	44	3,895	0	0.00%	0	0.00%	0	0.00%	2	2.00%	0	0.00%	**2**	**2.00%**
CD3249-40Q	990	395	41,944	0	0.00%	0	0.00%	0	0.00%	2	0.20%	1	0.10%	**3**	**0.30%**
CD3249-40	245	72	9,777	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.41%	**1**	**0.41%**
CD3231-40Q	1,679	687	87,493	2	0.12%	0	0.00%	0	0.00%	10	0.60%	1	0.06%	**13**	**0.77%**
CD3231-40	689	189	31,024	0	0.00%	0	0.00%	0	0.00%	3	0.44%	1	0.15%	**4**	**0.58%**
CD3211-36Q	856	232	44,921	3	0.35%	0	0.00%	0	0.00%	2	0.23%	2	0.23%	**7**	**0.82%**
CD3211-36	223	22	9,387	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.90%	**2**	**0.90%**
3207-36	672	37	30,571	1	0.15%	0	0.00%	0	0.00%	3	0.45%	3	0.45%	**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
CD3365-40Q	Quadra Assura™ CRT-D	231	12.10%	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%**
CD3357-40Q	Unify Assura™ CRT-D	241	11.20%	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%**
CD3357-40C	Unify Assura™ CRT-D	193	13.50%	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**	**0.00%**
CD3265-40Q	Quadra Assura™ CRT-D	421	18.10%	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	12.00%	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%**
CD3249-40Q	Unify Quadra™ CRT-D	990	14.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	0	0.00%	**1**	**0.10%**
CD3249-40	Unify Quadra™ CRT-D	245	21.20%	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%**
CD3231-40Q	Unify™ CRT-D	1,679	19.20%	0	0.00%	0	0.00%	1	0.06%	1	0.06%	0	0.00%	0	0.00%	11	0.66%	2	0.12%	**15**	**0.89%**
CD3231-40	Unify™ CRT-D	689	21.80%	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	32.10%	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	223	26.00%	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%**
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
CD3365-40Q	Quadra Assura™ CRT-D	231	12.10%	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%**
CD3357-40Q	Unify Assura™ CRT-D	241	11.20%	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%**
CD3357-40C	Unify Assura™ CRT-D	193	13.50%	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**	**0.00%**
CD3265-40Q	Quadra Assura™ CRT-D	421	18.10%	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%**
CD3265-40	Quadra Assura™ CRT-D	100	12.00%	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	990	14.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	0	0.00%	**1**	**0.10%**
CD3249-40	Unify Quadra™ CRT-D	245	21.20%	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%**
CD3231-40Q	Unify™ CRT-D	1,679	19.20%	1	0.06%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	1	0.06%	3	0.18%	0	0.00%	**6**	**0.36%**
CD3231-40	Unify™ CRT-D	689	21.80%	0	0.00%	0	0.00%	2	0.29%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	1	0.15%	**4**	**0.58%**
CD3211-36Q	Promote™ + CRT-D	856	32.10%	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	223	26.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.90%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.90%**
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

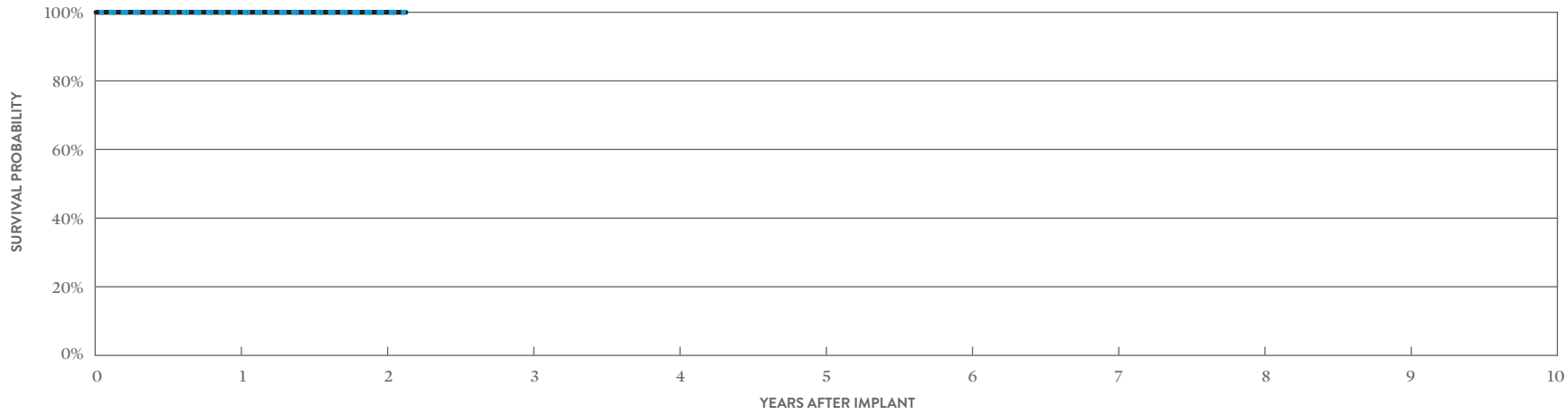
CUSTOMER REPORTED PERFORMANCE DATA

Allure Quadra MP™ CRT-P

MODEL PM3262

US Regulatory Approval	February 2016
Registered US Implants	13,878
Estimated Active US Implants	12,205
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories (see pg. 333)	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	1	<0.01%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**0**	**0.00%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 26 MONTHS
SURVIVAL PROBABILITY	99.99%	99.99%	99.99%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%
SAMPLE SIZE	10,450	3,820	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 26 MONTHS
SURVIVAL PROBABILITY	99.99%	99.99%	99.99%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%

Cardiac Resynchronization Therapy (CRT) Pacemakers

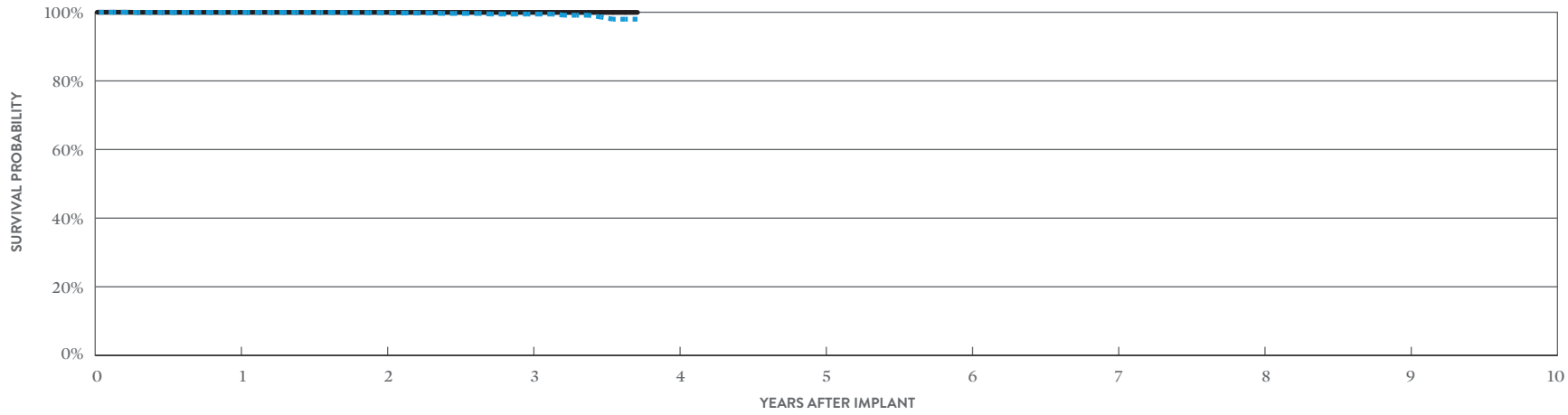
CUSTOMER REPORTED PERFORMANCE DATA

Allure™ RF CRT-P

MODEL PM3222

US Regulatory Approval	March 2014
Registered US Implants	5,672
Estimated Active US Implants	4,490
Estimated Longevity	8 Years
Normal Battery Depletion	7
Number of US Advisories (see pg. 333)	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	0.02%
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	1	2	3	AT 45 MONTHS
SURVIVAL PROBABILITY	99.96%	99.88%	99.48%	97.98%
± 1 STANDARD ERROR	0.03%	0.06%	0.18%	0.65%
SAMPLE SIZE	4,650	2,880	1,450	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 45 MONTHS
SURVIVAL PROBABILITY	99.96%	99.96%	99.96%	99.96%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%	0.03%

Cardiac Resynchronization Therapy (CRT) Pacemakers

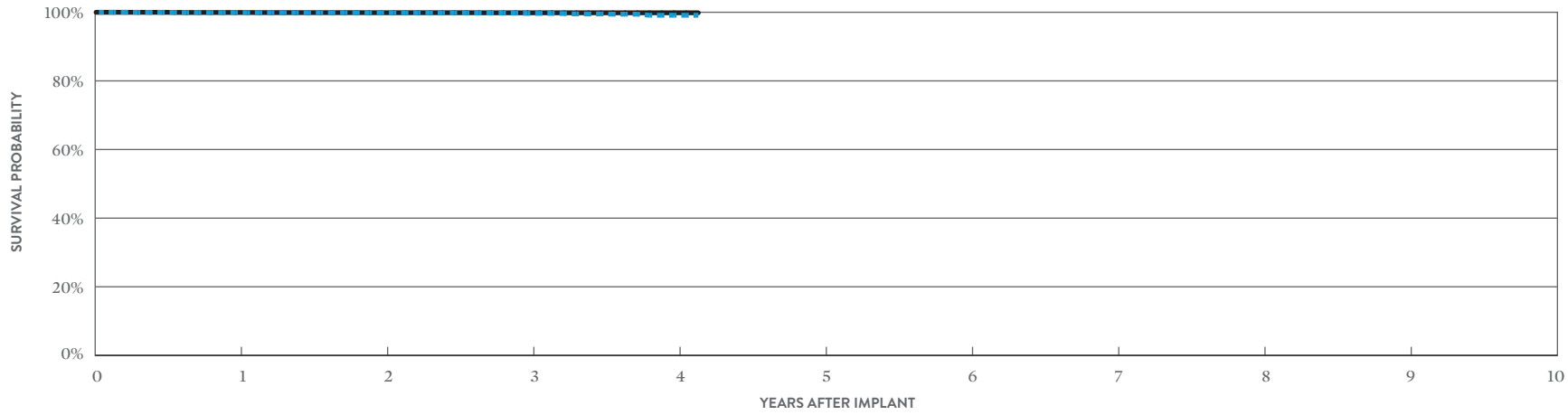
CUSTOMER REPORTED PERFORMANCE DATA

Allure Quadra™ RF CRT-P

MODEL PM3242

US Regulatory Approval	March 2014
Registered US Implants	17,865
Estimated Active US Implants	13,016
Estimated Longevity	8 Years
Normal Battery Depletion	13
Number of US Advisories (see pg. 333)	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%	7	0.04%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**9**	**0.05%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 50 MONTHS
SURVIVAL PROBABILITY	99.93%	99.86%	99.67%	99.12%	99.12%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.17%	0.17%
SAMPLE SIZE	16,590	14,010	9,450	3,440	400

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 50 MONTHS
SURVIVAL PROBABILITY	99.93%	99.87%	99.85%	99.85%	99.85%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.03%	0.03%

Cardiac Resynchronization Therapy (CRT) Pacemakers

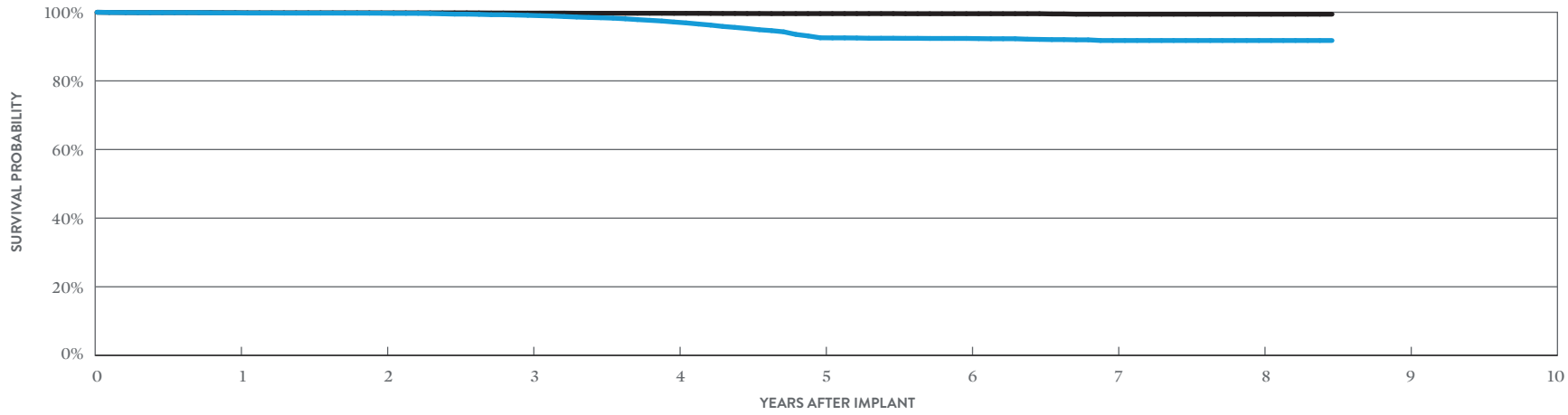
CUSTOMER REPORTED PERFORMANCE DATA

Anthem™ RF CRT-P

MODEL PM3210

US Regulatory Approval	July 2009
Registered US Implants	20,448
Estimated Active US Implants	8,944
Estimated Longevity	8 Years
Normal Battery Depletion	322
Number of US Advisories (see pgs. 333, 335)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.01%	4	0.02%
Electrical Interconnect	3	0.01%	1	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	6	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%**	**23**	**0.11%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	99.81%	99.72%	99.11%	97.16%	92.56%	92.37%	91.77%	91.77%	91.77%
± 1 STANDARD ERROR	0.03%	0.04%	0.07%	0.14%	0.24%	0.26%	0.29%	0.29%	0.29%
SAMPLE SIZE	18,850	16,250	14,380	12,510	9,550	6,050	3,350	1,380	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	99.87%	99.83%	99.75%	99.69%	99.61%	99.58%	99.44%	99.44%	99.44%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.04%	0.05%	0.06%	0.09%	0.09%	0.09%

Cardiac Resynchronization Therapy (CRT) Pacemakers

ACTIVELY MONITORED STUDY DATA

Anthem™ RF CRT-P

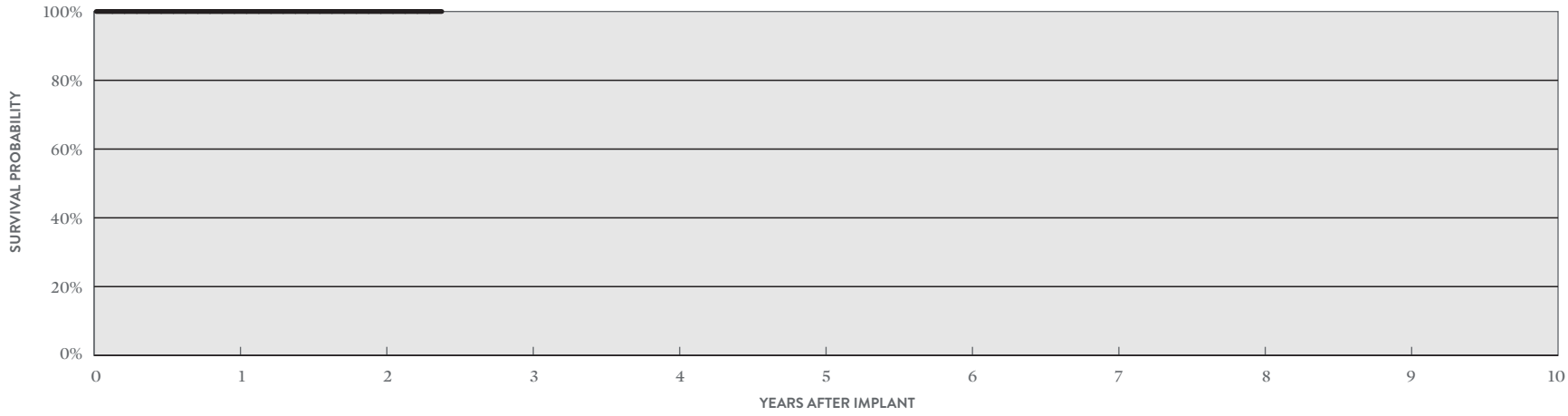
MODEL PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	201
Active Devices Enrolled in Study	20
Cumulative Months of Follow-up	5,014
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	100	50

Cardiac Resynchronization Therapy (CRT) Pacemakers

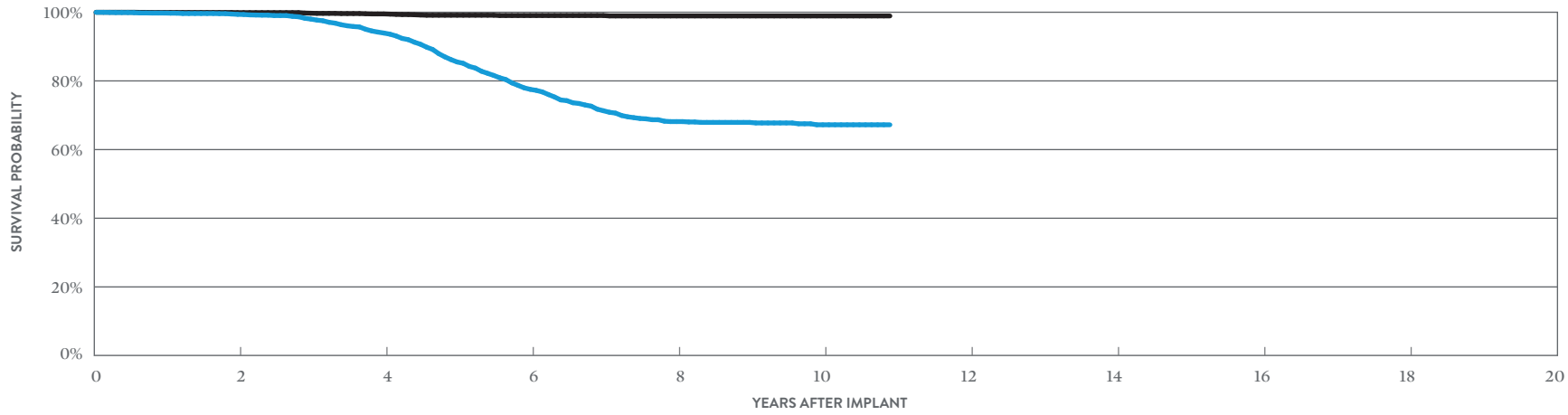
CUSTOMER REPORTED PERFORMANCE DATA

Frontier™ II CRT-P

MODEL 5586

US Regulatory Approval	August 2004
Registered US Implants	6,911
Estimated Active US Implants	939
Estimated Longevity	6.5 Years
Normal Battery Depletion	380
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	AT 131 MONTHS
SURVIVAL PROBABILITY	99.38%	93.94%	77.54%	68.15%	67.22%	67.22%
± 1 STANDARD ERROR	0.10%	0.37%	0.72%	0.88%	0.92%	0.92%
SAMPLE SIZE	5,150	3,700	2,400	1,390	630	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 131 MONTHS
SURVIVAL PROBABILITY	99.89%	99.51%	99.04%	98.92%	98.92%	98.92%
± 1 STANDARD ERROR	0.03%	0.11%	0.16%	0.19%	0.19%	0.19%

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
PM3262	Allure Quadra MP™ CRT-P	99.99%	99.99%								
PM3222	Allure™ RF CRT-P	99.96%	99.88%	99.48%							
PM3242	Allure Quadra™ RF CRT-P	99.93%	99.86%	99.67%	99.12%						
PM3210	Anthem™ RF CRT-P	99.81%	99.72%	99.11%	97.16%	92.56%	92.37%	91.77%	91.77%		
5586	Frontier™ II CRT-P	99.76%	99.38%	98.01%	93.94%	85.52%	77.54%	71.31%	68.15%	67.91%	67.22%

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
PM3262	Allure Quadra MP™ CRT-P	99.99%	99.99%								
PM3222	Allure™ RF CRT-P	99.96%	99.96%	99.96%							
PM3242	Allure Quadra™ RF CRT-P	99.93%	99.87%	99.85%	99.85%						
PM3210	Anthem™ RF CRT-P	99.87%	99.83%	99.75%	99.69%	99.61%	99.58%	99.44%	99.44%		
5586	Frontier™ II CRT-P	99.93%	99.89%	99.72%	99.51%	99.13%	99.04%	99.04%	98.92%	98.92%	98.92%

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
PM3262	Allure Quadra MP™ CRT-P	13,878	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3222	Allure™ RF CRT-P	5,672	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%**
PM3242	Allure Quadra™ RF CRT-P	17,865	0.40%	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	4.20%	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	14.30%	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
PM3262	Allure Quadra MP™ CRT-P	13,878	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%**
PM3222	Allure™ RF CRT-P	5,672	0.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**1**	**0.02%**
PM3242	Allure Quadra™ RF CRT-P	17,865	0.40%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	7	0.04%	0	0.00%	0	0.00%	**9**	**0.05%**
PM3210	Anthem™ RF CRT-P	20,448	4.20%	4	0.02%	1	<0.01%	0	0.00%	6	0.03%	0	0.00%	3	0.01%	9	0.04%	**23**	**0.11%**
5586	Frontier™ II CRT-P	6,911	14.30%	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
PM3262	Allure Quadra MP™ CRT-P	27,289	1.14%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3222	Allure™ RF CRT-P	18,086	1.34%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3242	Allure Quadra™ RF CRT-P	34,951	2.35%	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	21,093	11.43%	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
PM3262	Allure Quadra MP™ CRT-P	27,289	1.14%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM3222	Allure™ RF CRT-P	18,086	1.34%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3242	Allure Quadra™ RF CRT-P	34,951	2.35%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	9	0.03%	1	<0.01%	1	<0.01%	**14**	**0.04%**
PM3210	Anthem™ RF CRT-P	21,093	11.43%	3	0.01%	1	<0.01%	0	0.00%	6	0.03%	0	0.00%	3	0.01%	9	0.04%	**22**	**0.10%**

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	201	20	5,014	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	201	6.00%	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		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	201	6.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

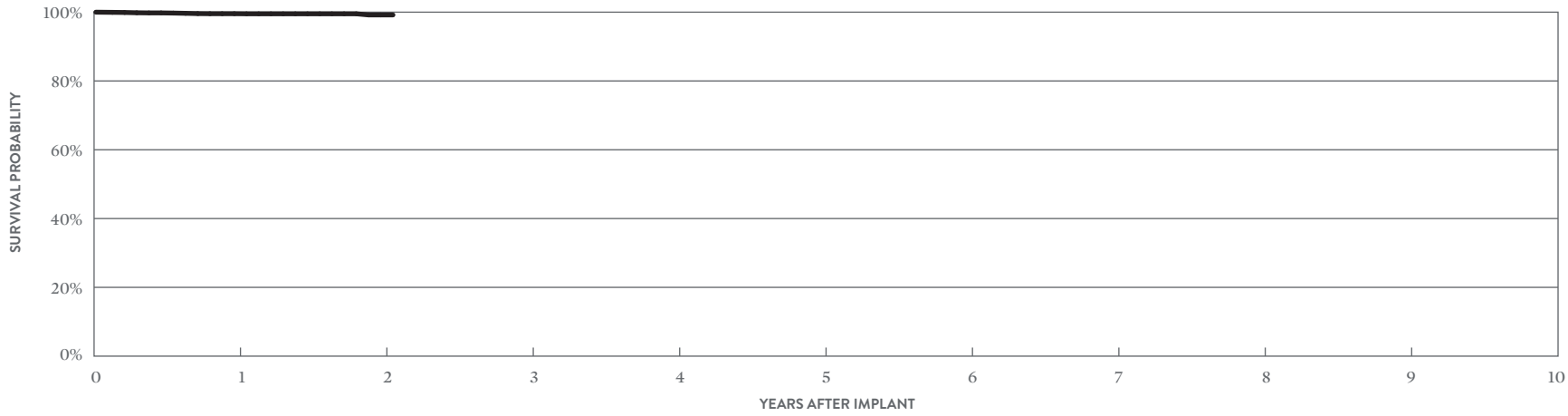
Quartet™

MODEL 1458QL

US Regulatory Approval	October 2015
Registered US Implants	6,109
Estimated Active US Implants	5,337
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	0	0.00%	0	0.00%
Lead Dislodgement	11	0.18%	22	0.36%
Failure to Capture	10	0.16%	7	0.11%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	0.02%	0	0.00%
Abnormal Pacing Impedance	2	0.03%	0	0.00%
Extracardiac Stimulation	14	0.23%	16	0.26%
Other	3	0.05%	0	0.00%
Total	**41**	**0.67%**	**45**	**0.74%**
Total Returned for Analysis	**8**		**13**	

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	12	0.20%
Total	**12**	**0.20%**



YEAR	1	2	AT 25 MONTHS
SURVIVAL PROBABILITY	99.56%	99.20%	99.20%
± 1 STANDARD ERROR	0.10%	0.25%	0.25%
SAMPLE SIZE	4,580	1,670	290

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

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

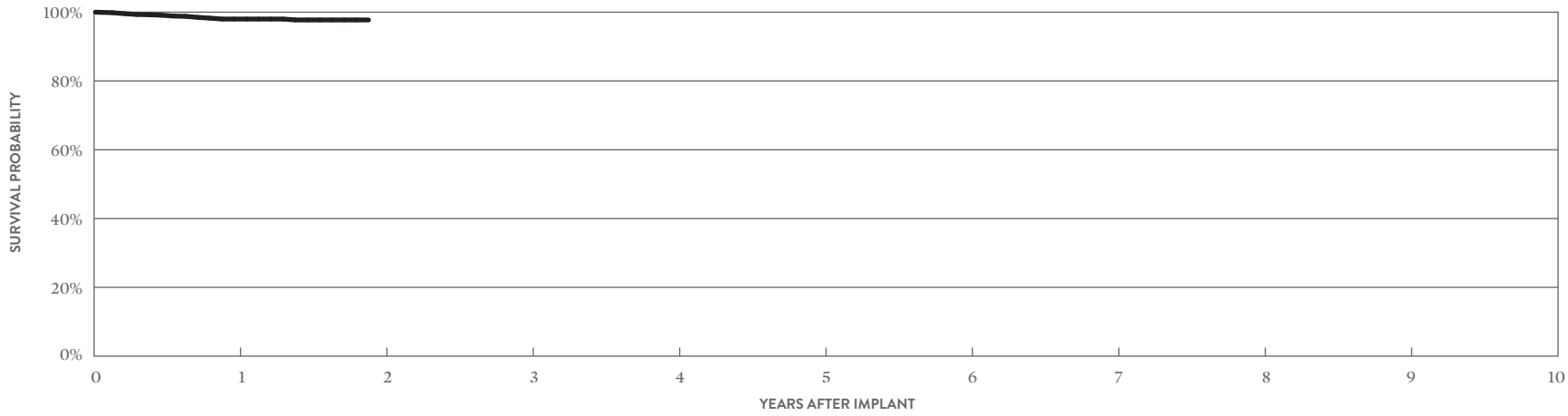
Quartet™

MODEL 1457Q

US Regulatory Approval	March 2017
Registered US Implants	2,262
Estimated Active US Implants	1,969
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	0.04%	0	0.00%
Lead Dislodgement	12	0.53%	21	0.93%
Failure to Capture	2	0.09%	3	0.13%
Oversensing	1	0.04%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	12	0.53%	5	0.22%
Other	4	0.18%	2	0.09%
Total	**32**	**1.41%**	**31**	**1.37%**
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	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	18	0.80%
Total	**18**	**0.80%**



YEAR	1	AT 23 MONTHS
SURVIVAL PROBABILITY	98.00%	97.74%
± 1 STANDARD ERROR	0.41%	0.48%
SAMPLE SIZE	1,430	240

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

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

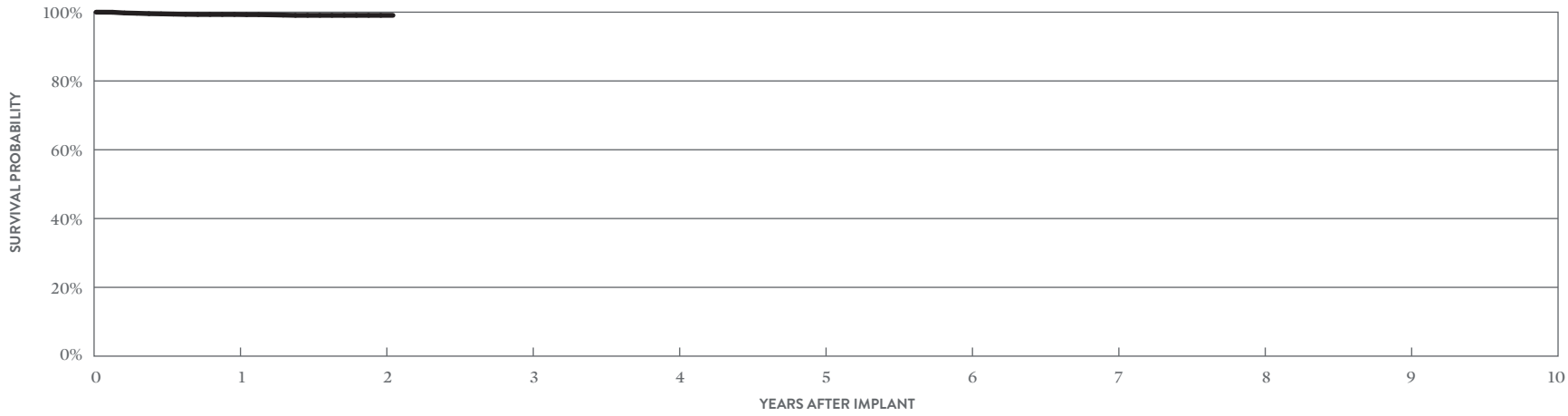
Quartet™

MODEL 1456Q

US Regulatory Approval	October 2015
Registered US Implants	4,475
Estimated Active US Implants	3,896
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	0.02%	0	0.00%
Conductor Fracture	2	0.04%	0	0.00%
Lead Dislodgement	11	0.25%	23	0.51%
Failure to Capture	0	0.00%	6	0.13%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	3	0.07%	0	0.00%
Extracardiac Stimulation	9	0.20%	5	0.11%
Other	4	0.09%	1	0.02%
Total	**30**	**0.67%**	**35**	**0.78%**
Total Returned for Analysis	**4**		**20**	

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	20	0.45%
Total	**20**	**0.45%**



YEAR	1	2	AT 25 MONTHS
SURVIVAL PROBABILITY	99.33%	99.08%	99.08%
± 1 STANDARD ERROR	0.14%	0.19%	0.19%
SAMPLE SIZE	3,270	1,130	200

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

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

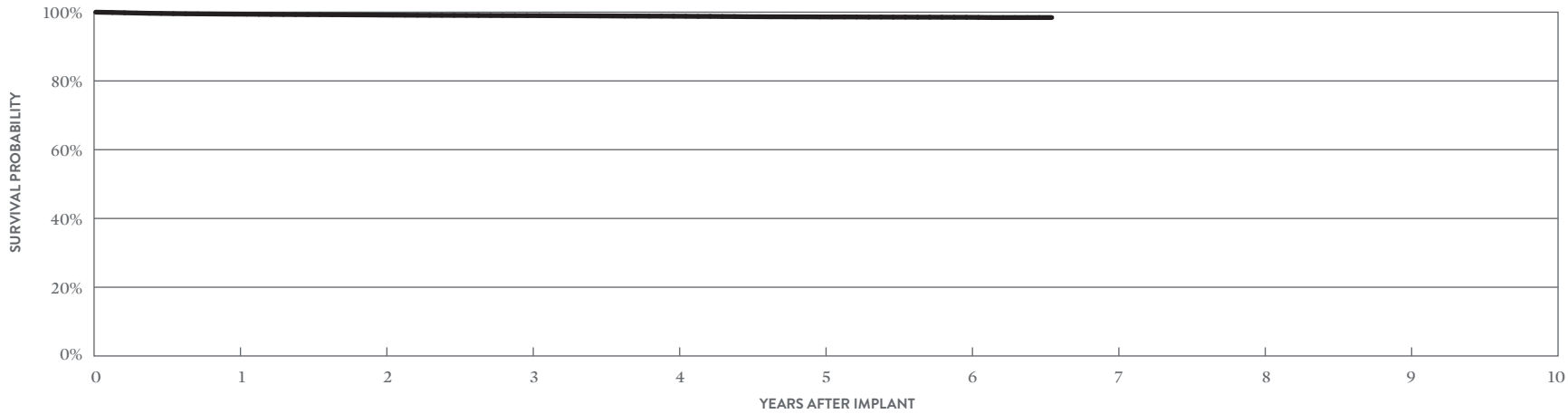
Quartet™

MODEL 1458Q

US Regulatory Approval	November 2011
Registered US Implants	129,711
Estimated Active US Implants	89,700
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	5	<0.01%	2	<0.01%
Conductor Fracture	0	0.00%	16	0.01%
Lead Dislodgement	186	0.14%	741	0.57%
Failure to Capture	79	0.06%	308	0.24%
Oversensing	2	<0.01%	9	<0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	<0.01%	6	<0.01%
Abnormal Pacing Impedance	4	<0.01%	51	0.04%
Extracardiac Stimulation	94	0.07%	165	0.13%
Other	95	0.07%	33	0.03%
Total	**466**	**0.36%**	**1331**	**1.03%**
Total Returned for Analysis	**174**		**535**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	9	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	3	<0.01%
Intravascular	6	<0.01%
Insulation Breach	3	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	2	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	11	<0.01%
Extrinsic Factors	515	0.40%
Total	**539**	**0.42%**



YEAR	1	2	3	4	5	6	AT 79 MONTHS
SURVIVAL PROBABILITY	99.43%	99.17%	99.00%	98.83%	98.62%	98.51%	98.44%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.08%
SAMPLE SIZE	114,490	87,420	62,340	37,980	19,860	8,300	300

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

Left-Heart Leads

ACTIVELY MONITORED STUDY DATA

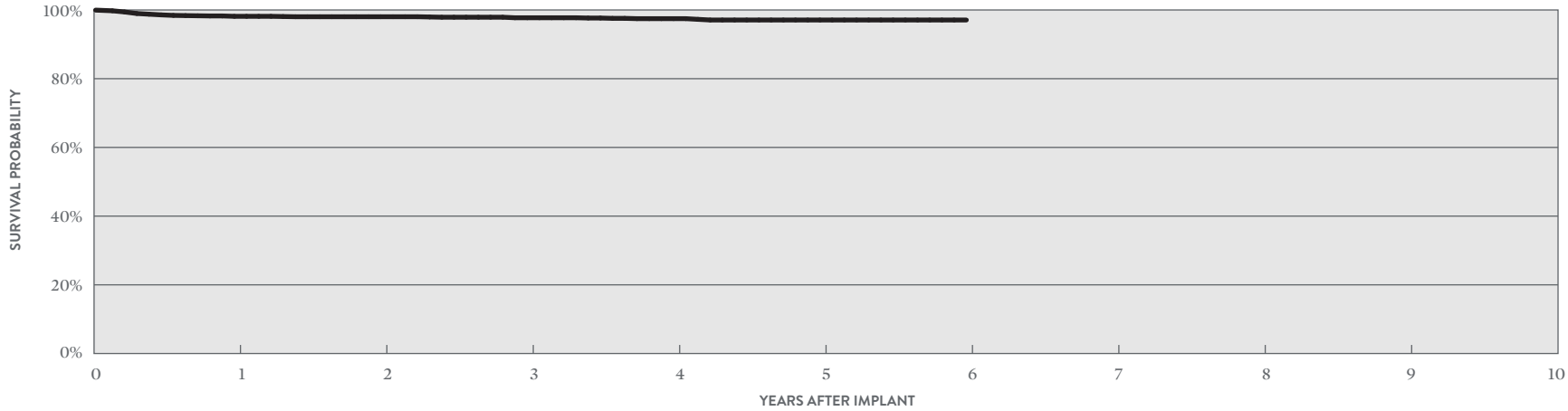
Quartet™

MODEL 1458Q

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	2,121
Active Devices Enrolled in Study	985
Cumulative Months of Follow-up	84,954
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	7	0.33%
Lead Dislodgement	38	1.79%
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	1.04%
Total	**22**	**1.04%**



YEAR	1	2	3	4	5	6
SURVIVAL PROBABILITY	98.15%	98.03%	97.73%	97.47%	97.08%	97.08%
± 1 STANDARD ERROR	0.29%	0.31%	0.35%	0.38%	0.42%	0.42%
SAMPLE SIZE	1,960	1,630	1,350	1,130	800	60

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

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

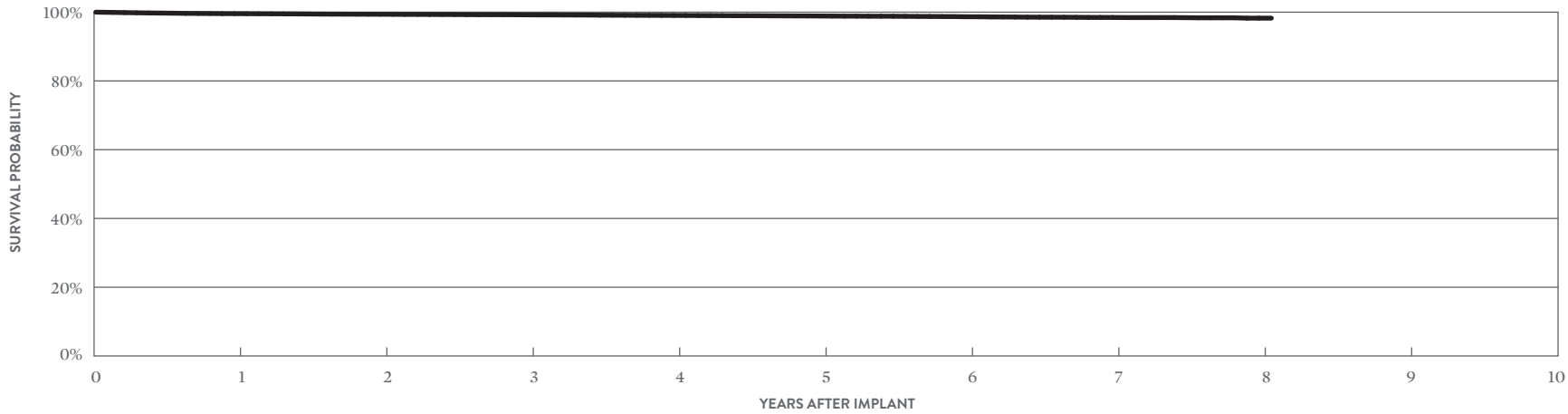
QuickFlex™ µ

MODEL 1258T

US Regulatory Approval	May 2010
Registered US Implants	47,016
Estimated Active US Implants	26,048
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%	22	0.05%
Lead Dislodgement	47	0.10%	192	0.41%
Failure to Capture	18	0.04%	163	0.35%
Oversensing	0	0.00%	16	0.03%
Failure to Sense	1	<0.01%	2	<0.01%
Insulation Breach	0	0.00%	8	0.02%
Abnormal Pacing Impedance	5	0.01%	44	0.09%
Extracardiac Stimulation	20	0.04%	71	0.15%
Other	14	0.03%	10	0.02%
Total	**105**	**0.22%**	**529**	**1.13%**
Total Returned for Analysis	**55**		**201**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	6	0.01%
Clavicular Crush	2	<0.01%
In the Pocket	1	<0.01%
Intravascular	3	<0.01%
Insulation Breach	3	<0.01%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	2	<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	216	0.46%
Total	**226**	**0.48%**



YEAR	1	2	3	4	5	6	7	8	AT 97 MONTHS
SURVIVAL PROBABILITY	99.57%	99.39%	99.22%	99.05%	98.88%	98.67%	98.46%	98.26%	98.26%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%	0.05%	0.06%	0.07%	0.08%	0.14%	0.14%
SAMPLE SIZE	43,340	37,260	32,570	27,940	22,090	15,740	9,680	3,450	420

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

Left-Heart Leads

ACTIVELY MONITORED STUDY DATA

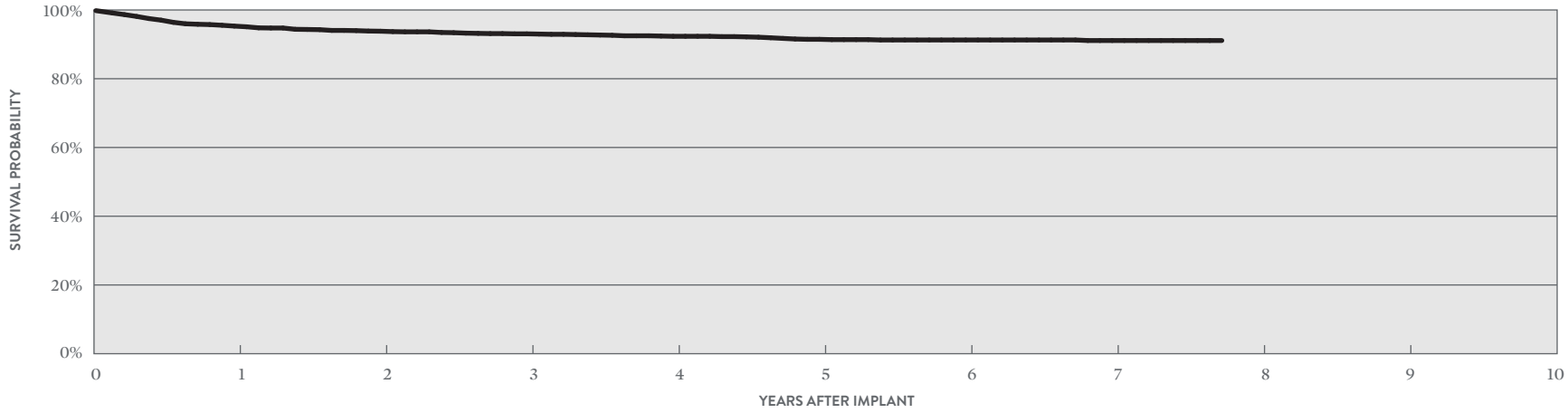
QuickFlex™ µ

MODEL 1258T

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	2,368
Active Devices Enrolled in Study	981
Cumulative Months of Follow-up	113,061
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Pacing Impedance	6	0.25%
Conductor Fracture	3	0.13%
Extracardiac Stimulation	56	2.36%
Failure to Capture	49	2.07%
Insulation Breach	1	0.04%
Lead Dislodgement	52	2.20%

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	39	1.65%
Total	**40**	**1.69%**



YEAR	1	2	3	4	5	6	7	AT 93 MONTHS
SURVIVAL PROBABILITY	95.31%	93.82%	93.06%	92.34%	91.46%	91.27%	91.11%	91.11%
± 1 STANDARD ERROR	0.44%	0.52%	0.56%	0.60%	0.66%	0.67%	0.69%	0.69%
SAMPLE SIZE	2,150	1,760	1,480	1,270	1,080	950	650	60

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

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

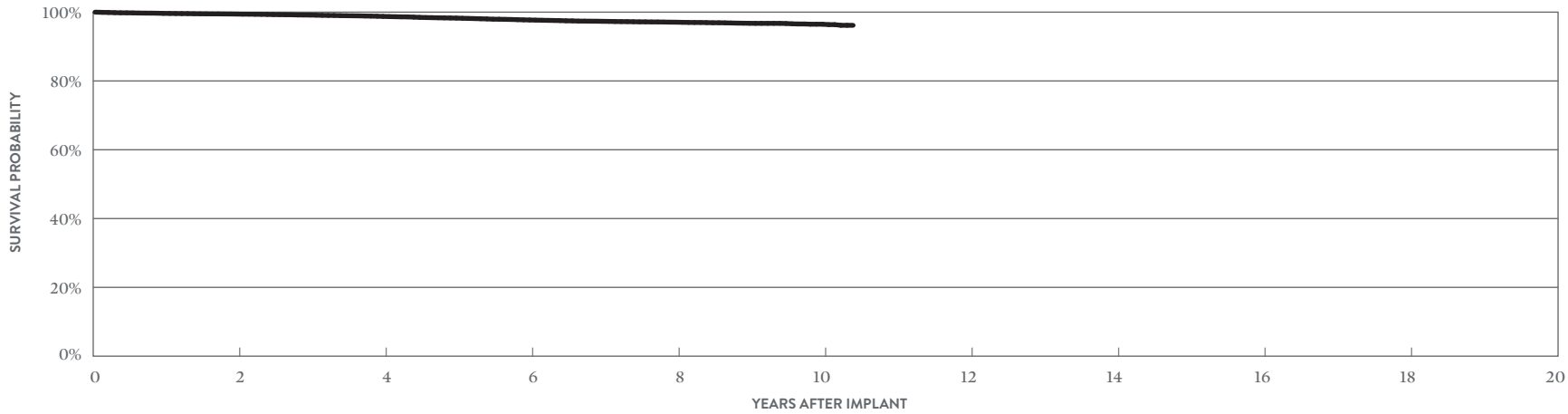
QuickFlex™

MODEL 1156T

US Regulatory Approval	July 2007
Registered US Implants	27,658
Estimated Active US Implants	11,141
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 337)	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	0.02%
Lead Dislodgement	11	0.04%	135	0.49%
Failure to Capture	4	0.01%	188	0.68%
Oversensing	0	0.00%	15	0.05%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	48	0.17%
Abnormal Pacing Impedance	0	0.00%	62	0.22%
Extracardiac Stimulation	14	0.05%	85	0.31%
Other	9	0.03%	8	0.03%
Total	**38**	**0.14%**	**547**	**1.98%**
Total Returned for Analysis	**14**		**158**	

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	83	0.30%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	4	0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	13	0.05%
Other	66	0.24%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	128	0.46%
Total	**218**	**0.79%**



YEAR	2	4	6	8	10	AT 125 MONTHS
SURVIVAL PROBABILITY	99.44%	98.76%	97.72%	97.08%	96.49%	96.17%
± 1 STANDARD ERROR	0.05%	0.08%	0.11%	0.13%	0.19%	0.30%
SAMPLE SIZE	21,630	17,120	13,970	9,790	2,460	240

Left-Heart Leads

ACTIVELY MONITORED STUDY DATA

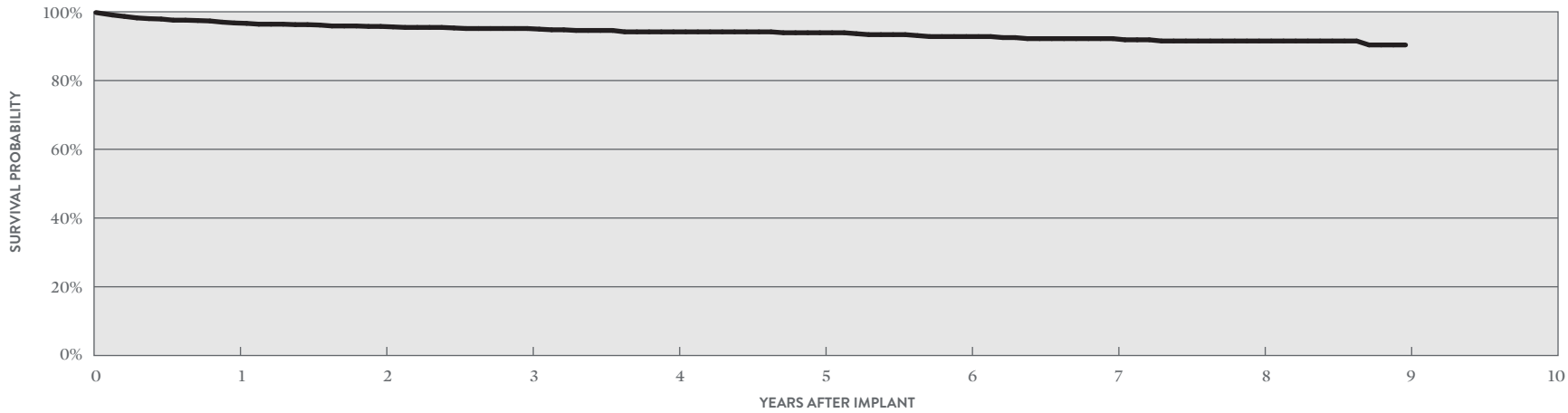
QuickFlex™

MODEL 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	985
Active Devices Enrolled in Study	248
Cumulative Months of Follow-up	48,918
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	17	1.73%
Failure to Capture	10	1.02%
Insulation Breach	1	0.10%
Lead Dislodgement	27	2.74%
Skin Erosion	1	0.10%

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**	**2.34%**



YEAR	1	2	3	4	5	6	7	8	9
SURVIVAL PROBABILITY	96.75%	95.74%	95.13%	94.16%	93.90%	92.79%	92.19%	91.50%	90.35%
± 1 STANDARD ERROR	0.56%	0.68%	0.74%	0.85%	0.89%	1.04%	1.11%	1.21%	1.65%
SAMPLE SIZE	900	750	610	480	380	340	300	250	50

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

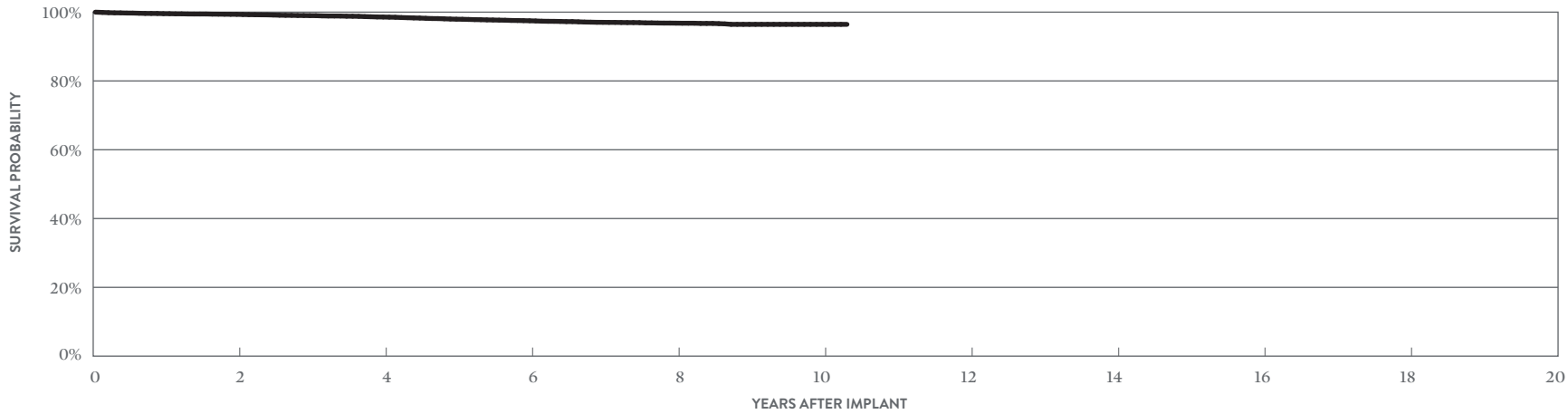
QuickFlex™ XL

MODEL 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,339
Estimated Active US Implants	6,281
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 337)	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%	4	0.03%
Lead Dislodgement	9	0.06%	95	0.62%
Failure to Capture	2	0.01%	129	0.84%
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%	23	0.15%
Extracardiac Stimulation	6	0.04%	32	0.21%
Other	6	0.04%	8	0.05%
Total	**25**	**0.16%**	**331**	**2.16%**
Total Returned for Analysis	**13**		**113**	

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	53	0.35%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	2	0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	7	0.05%
Other	44	0.29%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	86	0.56%
Total	**145**	**0.95%**



YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.36%	98.58%	97.49%	96.80%	96.45%	96.45%
± 1 STANDARD ERROR	0.07%	0.11%	0.16%	0.19%	0.21%	0.21%
SAMPLE SIZE	12,060	9,640	7,850	5,270	1,400	240

Left-Heart Leads

ACTIVELY MONITORED STUDY DATA

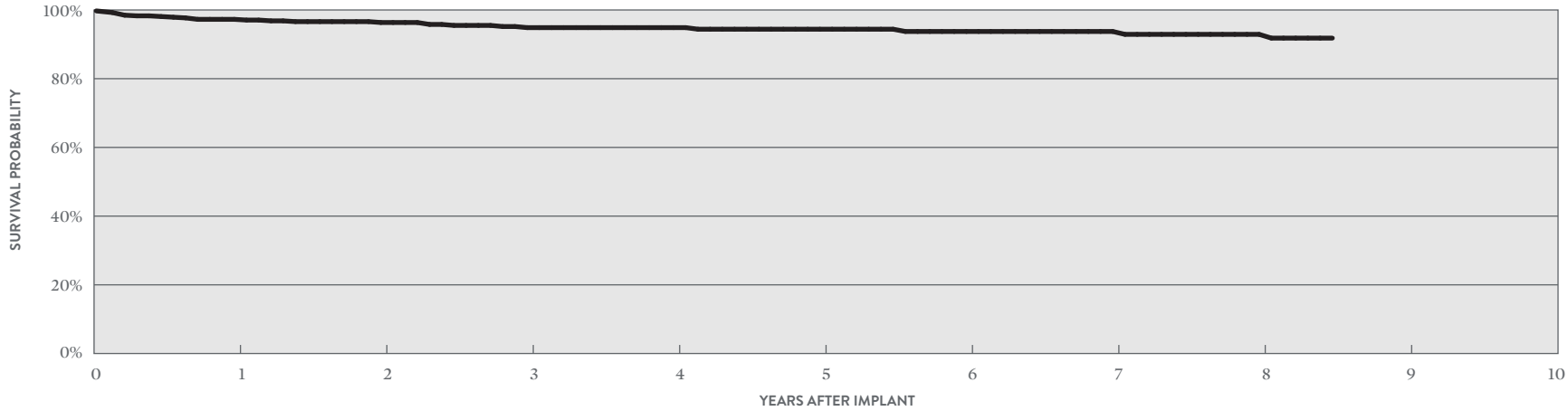
QuickFlex™ XL

MODEL 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	553
Active Devices Enrolled in Study	102
Cumulative Months of Follow-up	24,959
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Extracardiac Stimulation	10	1.81%
Failure to Capture	9	1.63%
Insulation Breach	1	0.18%
Lead Dislodgement	6	1.08%
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	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	97.27%	96.35%	94.86%	94.86%	94.40%	93.74%	93.74%	92.90%	91.81%
± 1 STANDARD ERROR	0.72%	0.81%	1.02%	1.07%	1.15%	1.32%	1.32%	1.55%	1.88%
SAMPLE SIZE	500	410	330	250	190	150	120	100	60

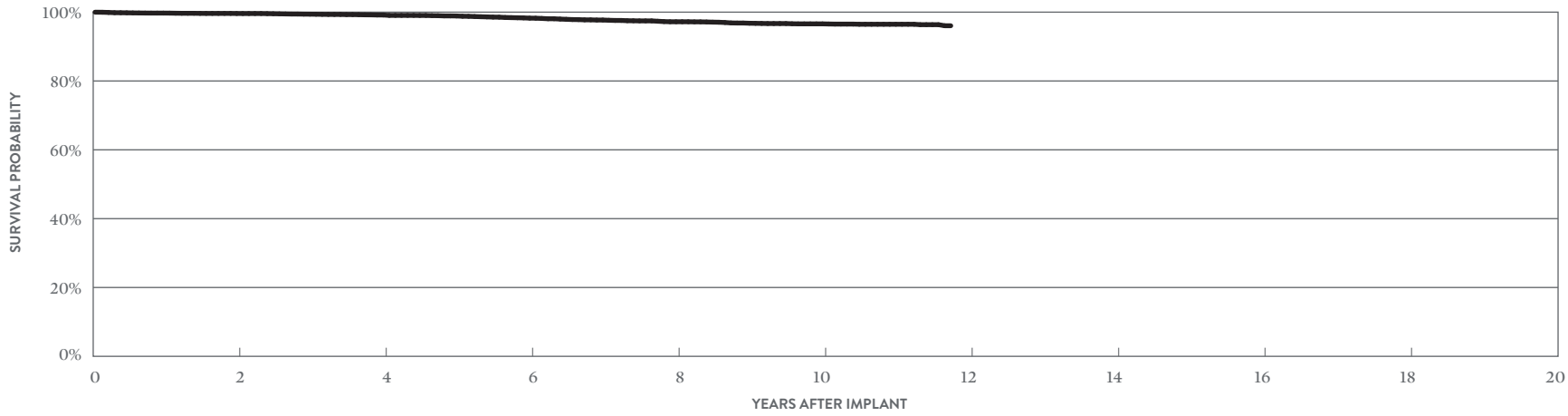
QuickSite™ XL

MODEL 1058T

US Regulatory Approval	February 2006
Registered US Implants	9,952
Estimated Active US Implants	3,271
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 337)	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%	5	0.05%
Lead Dislodgement	10	0.10%	29	0.29%
Failure to Capture	3	0.03%	86	0.86%
Oversensing	1	0.01%	2	0.02%
Failure to Sense	0	0.00%	2	0.02%
Insulation Breach	0	0.00%	32	0.32%
Abnormal Pacing Impedance	2	0.02%	19	0.19%
Extracardiac Stimulation	9	0.09%	23	0.23%
Other	1	0.01%	2	0.02%
Total	**26**	**0.26%**	**200**	**2.01%**
Total Returned for Analysis	**11**		**36**	

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	24	0.24%
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	17	0.17%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	29	0.29%
Total	**56**	**0.56%**



YEAR	2	4	6	8	10	AT 141 MONTHS
SURVIVAL PROBABILITY	99.61%	99.17%	98.26%	97.21%	96.60%	96.05%
± 1 STANDARD ERROR	0.06%	0.11%	0.17%	0.23%	0.27%	0.43%
SAMPLE SIZE	7,790	5,950	4,710	3,880	3,030	260

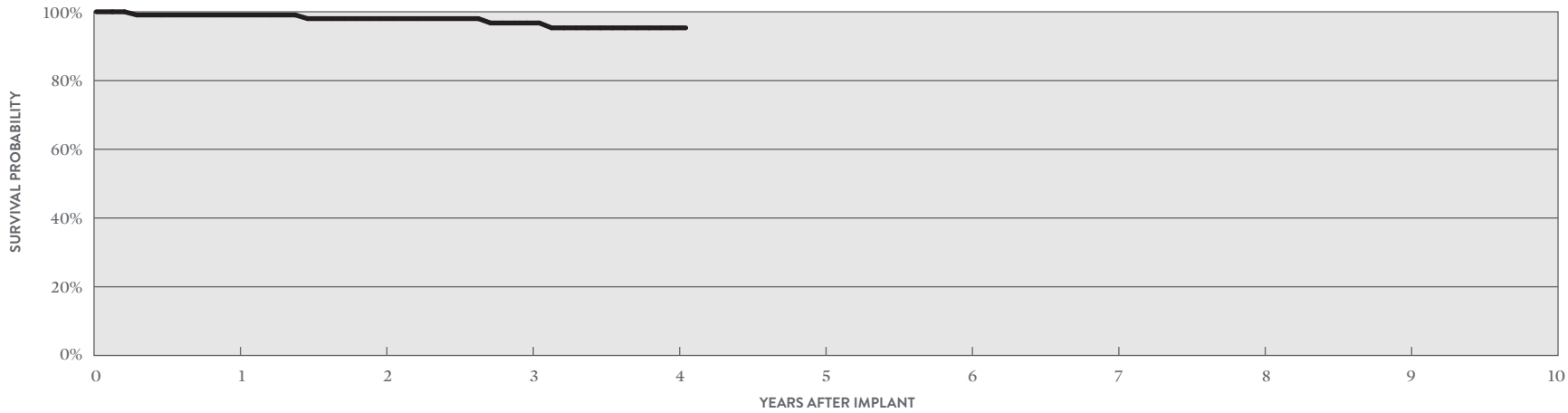
QuickSite™ XL

MODEL 1058T

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	111
Active Devices Enrolled in Study	14
Cumulative Months of Follow-up	5,518
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

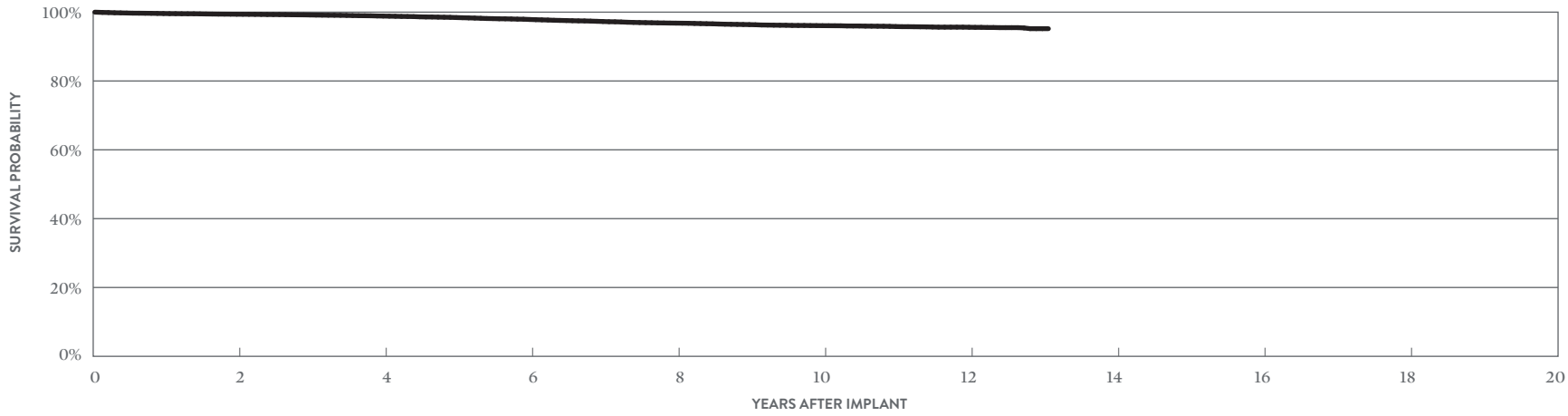
QuickSite™

MODEL 1056T

US Regulatory Approval	April 2005
Registered US Implants	32,334
Estimated Active US Implants	9,515
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 337)	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%	10	0.03%
Lead Dislodgement	32	0.10%	167	0.52%
Failure to Capture	15	0.05%	273	0.84%
Oversensing	2	<0.01%	22	0.07%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	106	0.33%
Abnormal Pacing Impedance	3	<0.01%	60	0.19%
Extracardiac Stimulation	22	0.07%	104	0.32%
Other	9	0.03%	23	0.07%
Total	**84**	**0.26%**	**766**	**2.37%**
Total Returned for Analysis	**28**		**201**	

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	88	0.27%
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	45	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	160	0.49%
Total	**255**	**0.79%**



YEAR	2	4	6	8	10	12	AT 157 MONTHS
SURVIVAL PROBABILITY	99.39%	98.86%	97.87%	96.81%	96.07%	95.61%	95.20%
± 1 STANDARD ERROR	0.05%	0.07%	0.10%	0.14%	0.16%	0.18%	0.26%
SAMPLE SIZE	25,360	19,320	14,780	11,920	9,380	4,740	340

Left-Heart Leads

ACTIVELY MONITORED STUDY DATA

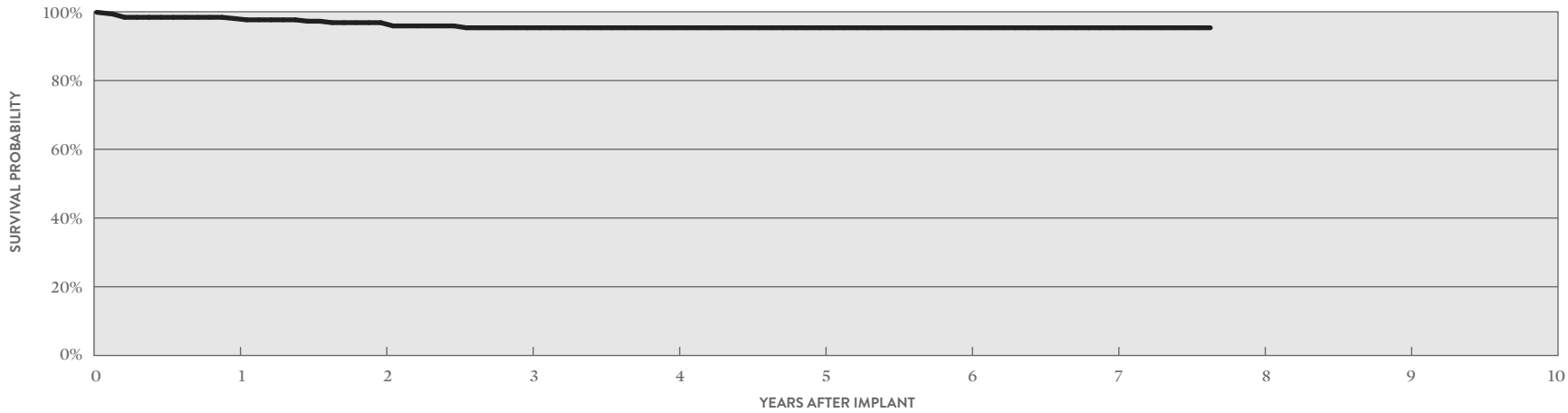
QuickSite™

MODEL 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	319
Active Devices Enrolled in Study	55
Cumulative Months of Follow-up	14,483
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	AT 92 MONTHS
SURVIVAL PROBABILITY	98.03%	96.84%	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%
SAMPLE SIZE	290	240	180	140	110	90	70	50

Left-Heart Leads

CUSTOMER REPORTED PERFORMANCE DATA

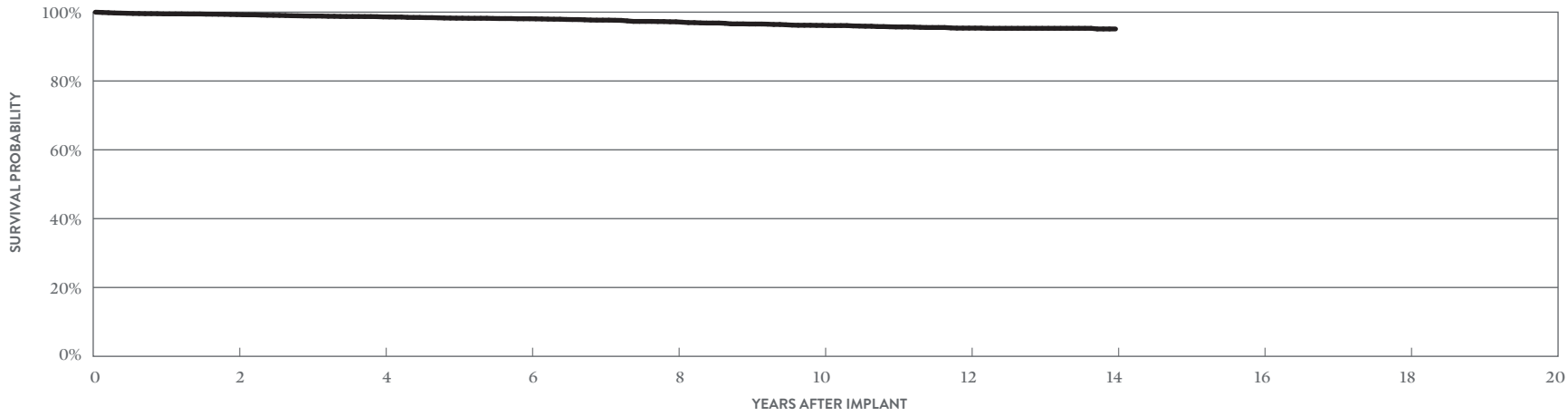
QuickSite™

MODEL 1056K

US Regulatory Approval	June 2004
Registered US Implants	7,874
Estimated Active US Implants	1,950
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%	70	0.89%
Oversensing	0	0.00%	2	0.03%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	5	0.06%
Abnormal Pacing Impedance	0	0.00%	7	0.09%
Extracardiac Stimulation	10	0.13%	32	0.41%
Other	2	0.03%	11	0.14%
Total	**25**	**0.32%**	**170**	**2.16%**
Total Returned for Analysis	**13**		**48**	

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	2	0.03%
Lead-to-Can Contact	1	0.01%
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	51	0.65%
Total	**56**	**0.71%**



YEAR	2	4	6	8	10	12	14
SURVIVAL PROBABILITY	99.29%	98.62%	98.08%	97.20%	96.15%	95.36%	95.12%
± 1 STANDARD ERROR	0.10%	0.15%	0.19%	0.26%	0.33%	0.39%	0.43%
SAMPLE SIZE	6,200	4,640	3,420	2,630	2,170	1,710	250

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™	99.56%	99.20%								
1457Q	QuickFlex™ µ	98.00%									
1456Q	QuickFlex™ µ	99.33%	99.08%								
1458Q	Quartet™	99.43%	99.17%	99.00%	98.83%	98.62%	98.51%				
1258T	QuickFlex™ µ	99.57%	99.39%	99.22%	99.05%	98.88%	98.67%	98.46%	98.26%		
1156T	QuickFlex™	99.64%	99.44%	99.15%	98.76%	98.27%	97.72%	97.33%	97.08%	96.76%	96.49%
1158T	QuickFlex™ XL	99.56%	99.36%	98.99%	98.58%	97.95%	97.49%	97.04%	96.80%	96.45%	96.45%
1058T	QuickSite™ XL	99.73%	99.61%	99.41%	99.17%	98.89%	98.26%	97.71%	97.21%	96.78%	96.60%
1056T	QuickSite™	99.60%	99.39%	99.18%	98.86%	98.43%	97.87%	97.28%	96.81%	96.38%	96.07%
1056K	QuickSite™	99.50%	99.29%	98.88%	98.62%	98.25%	98.08%	97.68%	97.20%	96.55%	96.15%

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	6,109	5337	0	0.00%	0	0.00%	11	0.18%	10	0.16%	0	0.00%	0	0.00%	1	0.02%	2	0.03%	14	0.23%	3	0.05%	**41**	**0.67%**	**8**
1457Q	Oct-15	2,262	1969	0	0.00%	1	0.04%	12	0.53%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	12	0.53%	4	0.18%	**32**	**1.41%**	**5**
1456Q	Oct-15	4,475	3896	1	0.02%	2	0.04%	11	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.07%	9	0.20%	4	0.09%	**30**	**0.67%**	**4**
1458Q	Nov-11	129,711	89700	5	<0.01%	0	0.00%	186	0.14%	79	0.06%	2	<0.01%	0	0.00%	1	<0.01%	4	<0.01%	94	0.07%	95	0.07%	**466**	**0.36%**	**174**
1258T	May-10	47,016	26048	0	0.00%	0	0.00%	47	0.10%	18	0.04%	0	0.00%	1	<0.01%	0	0.00%	5	0.01%	20	0.04%	14	0.03%	**105**	**0.22%**	**55**
1156T	Jul-07	27,658	11141	0	0.00%	0	0.00%	11	0.04%	4	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	14	0.05%	9	0.03%	**38**	**0.14%**	**14**
1158T	Jul-07	15,339	6281	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	9,952	3271	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	32,334	9515	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	1950	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	6,109	5337	0	0.00%	0	0.00%	22	0.36%	7	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.26%	0	0.00%	**45**	**0.74%**	**13**
1457Q	Oct-15	2,262	1969	0	0.00%	0	0.00%	21	0.93%	3	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.22%	2	0.09%	**31**	**1.37%**	**12**
1456Q	Oct-15	4,475	3896	0	0.00%	0	0.00%	23	0.51%	6	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.11%	1	0.02%	**35**	**0.78%**	**20**
1458Q	Nov-11	129,711	89700	2	<0.01%	16	0.01%	741	0.57%	308	0.24%	9	<0.01%	0	0.00%	6	<0.01%	51	0.04%	165	0.13%	33	0.03%	**1331**	**1.03%**	**535**
1258T	May-10	47,016	26048	1	<0.01%	22	0.05%	192	0.41%	163	0.35%	16	0.03%	2	<0.01%	8	0.02%	44	0.09%	71	0.15%	10	0.02%	**529**	**1.13%**	**201**
1156T	Jul-07	27,658	11141	1	<0.01%	5	0.02%	135	0.49%	188	0.68%	15	0.05%	0	0.00%	48	0.17%	62	0.22%	85	0.31%	8	0.03%	**547**	**1.98%**	**158**
1158T	Jul-07	15,339	6281	1	<0.01%	4	0.03%	95	0.62%	129	0.84%	3	0.02%	1	<0.01%	35	0.23%	23	0.15%	32	0.21%	8	0.05%	**331**	**2.16%**	**113**
1058T	Feb-06	9,952	3271	0	0.00%	5	0.05%	29	0.29%	86	0.86%	2	0.02%	2	0.02%	32	0.32%	19	0.19%	23	0.23%	2	0.02%	**200**	**2.01%**	**36**
1056T	Apr-05	32,334	9515	0	0.00%	10	0.03%	167	0.52%	273	0.84%	22	0.07%	1	<0.01%	106	0.33%	60	0.19%	104	0.32%	23	0.07%	**766**	**2.37%**	**201**
1056K	Jun-04	7,874	1950	0	0.00%	7	0.09%	36	0.46%	70	0.89%	2	0.03%	0	0.00%	5	0.06%	7	0.09%	32	0.41%	11	0.14%	**170**	**2.16%**	**48**

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	6,109	4.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	12	0.20%	**12**	**0.20%**
1457Q	2,262	6.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	18	0.80%	**18**	**0.80%**
1456Q	4,475	7.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	20	0.45%	**20**	**0.45%**
1458Q	129,711	6.10%	9	<0.01%	3	<0.01%	0	0.00%	11	<0.01%	515	0.40%	**538**	**0.41%**
1258T	47,016	10.80%	6	0.01%	3	<0.01%	0	0.00%	1	<0.01%	216	0.46%	**226**	**0.48%**
1156T	27,658	9.00%	7	0.03%	83	0.30%	0	0.00%	0	0.00%	128	0.46%	**218**	**0.79%**
1158T	15,339	10.00%	5	0.03%	53	0.35%	1	<0.01%	0	0.00%	86	0.56%	**145**	**0.95%**
1058T	9,952	9.90%	2	0.02%	24	0.24%	0	0.00%	1	0.01%	29	0.29%	**56**	**0.56%**
1056T	32,334	9.60%	6	0.02%	88	0.27%	0	0.00%	1	<0.01%	160	0.49%	**255**	**0.79%**
1056K	7,874	15.40%	3	0.04%	2	0.03%	0	0.00%	0	0.00%	51	0.65%	**56**	**0.71%**

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	11,930	2.4%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.13%	**16**	**0.13%**
1457Q	7,810	2.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	20	0.26%	**20**	**0.26%**
1456Q	11,400	3.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	28	0.25%	**28**	**0.25%**
1458Q	272,053	3.3%	23	0.01%	7	<0.01%	0	0.00%	21	0.01%	784	0.29%	**835**	**0.31%**
1258T	165,203	3.8%	43	0.03%	9	0.01%	0	0.00%	5	<0.01%	384	0.23%	**441**	**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	2,121	985	84,954	1	0.05%	0	0.00%	0	0.00%	3	0.14%	7	0.33%	0	0.00%	0	0.00%	38	1.79%	1	0.05%	0	0.00%	0	0.00%	**50**	**2.36%**
1258T	2,368	981	113,061	6	0.25%	0	0.00%	3	0.13%	56	2.36%	49	2.07%	0	0.00%	1	0.04%	52	2.20%	0	0.00%	0	0.00%	0	0.00%	**167**	**7.05%**
1156T	985	248	48,918	1	0.10%	0	0.00%	0	0.00%	17	1.73%	10	1.02%	0	0.00%	1	0.10%	27	2.74%	0	0.00%	0	0.00%	1	0.10%	**57**	**5.79%**
1158T	553	102	24,959	0	0.00%	0	0.00%	0	0.00%	10	1.81%	9	1.63%	0	0.00%	1	0.18%	6	1.08%	0	0.00%	0	0.00%	1	0.18%	**27**	**4.88%**
1058T	111	14	5,518	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	55	14,483	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	2,121	5.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	22	1.04%	**22**	**1.04%**
1258T	2,368	6.10%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	39	1.65%	**40**	**1.69%**
1156T	985	8.90%	0	0.00%	3	0.30%	0	0.00%	0	0.00%	20	2.03%	**23**	**2.34%**
1158T	553	5.20%	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	7.50%	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

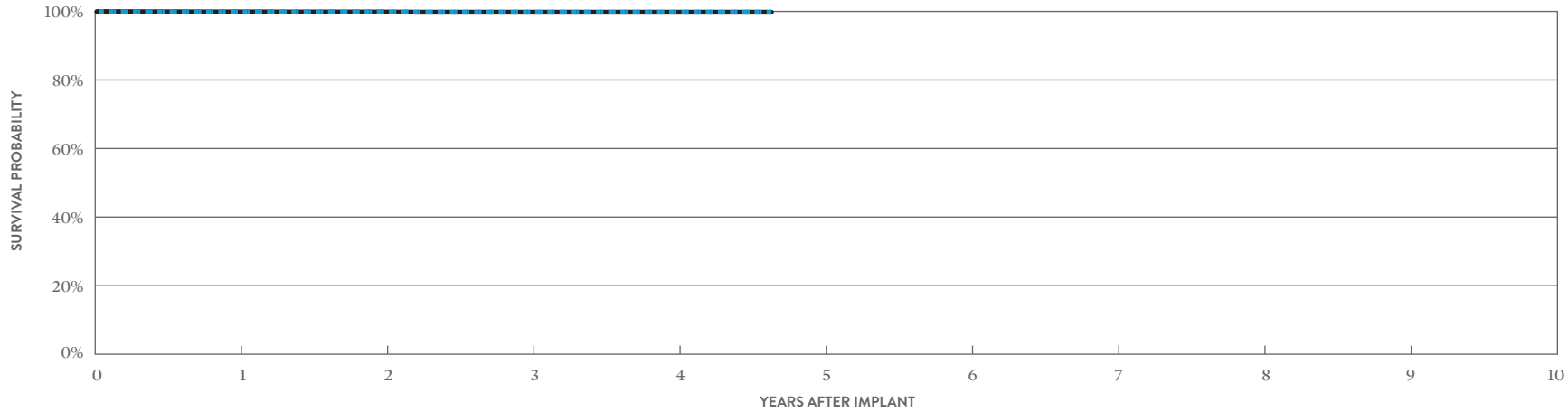
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ DR

MODEL CD2411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	18,545
Estimated Active US Implants	14,234
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	2	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%	2	0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	2	0.01%
Total	**6**	**0.03%**	**8**	**0.04%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.86%	99.83%	99.77%	99.77%	99.77%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.04%	0.04%
SAMPLE SIZE	14,960	9,470	5,860	2,760	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.86%	99.83%	99.77%	99.77%	99.77%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.04%	0.04%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

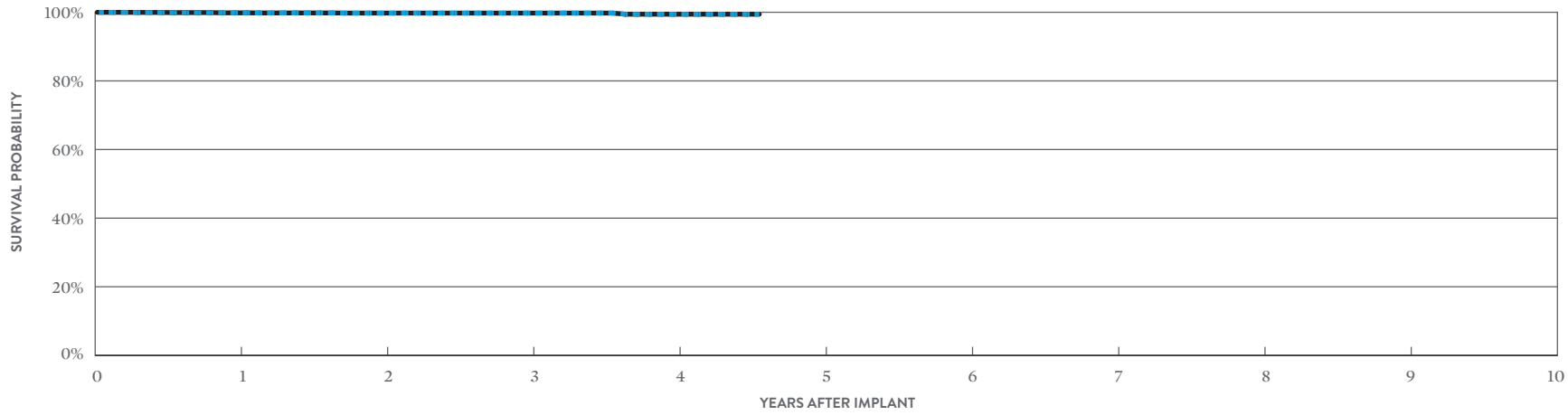
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ DR

MODEL CD2411-36C*

US Regulatory Approval	June 2013
Registered US Implants	8,875
Estimated Active US Implants	6,582
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.02%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	5	0.06%	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%	0	0.00%
Total	**7**	**0.08%**	**3**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.83%	99.76%	99.76%	99.43%	99.43%
± 1 STANDARD ERROR	0.05%	0.06%	0.06%	0.16%	0.16%
SAMPLE SIZE	7,780	5,490	3,400	1,710	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.83%	99.76%	99.76%	99.43%	99.43%
± 1 STANDARD ERROR	0.05%	0.06%	0.06%	0.16%	0.16%

**Parylene coating.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

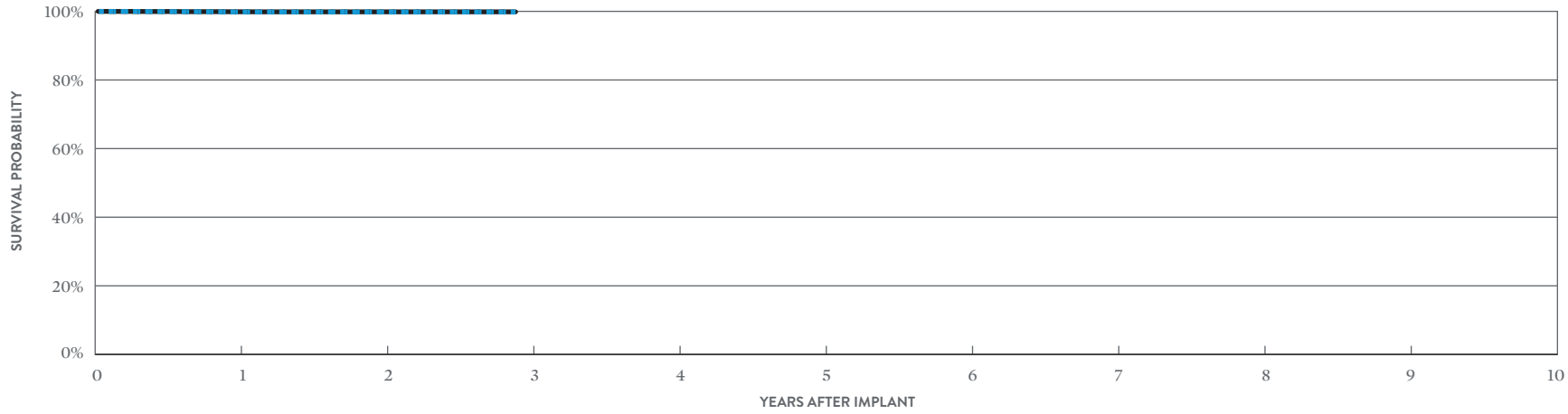
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

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

US Regulatory Approval	June 2013
Registered US Implants	18,316
Estimated Active US Implants	15,279
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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	1	<0.01%	0	0.00%
High Voltage Capacitor	3	0.02%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	2	0.01%	0	0.00%
Total	**6**	**0.03%**	**3**	**0.02%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.84%	99.82%	99.82%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%
SAMPLE SIZE	14,480	7,290	340

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.88%	99.86%	99.86%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

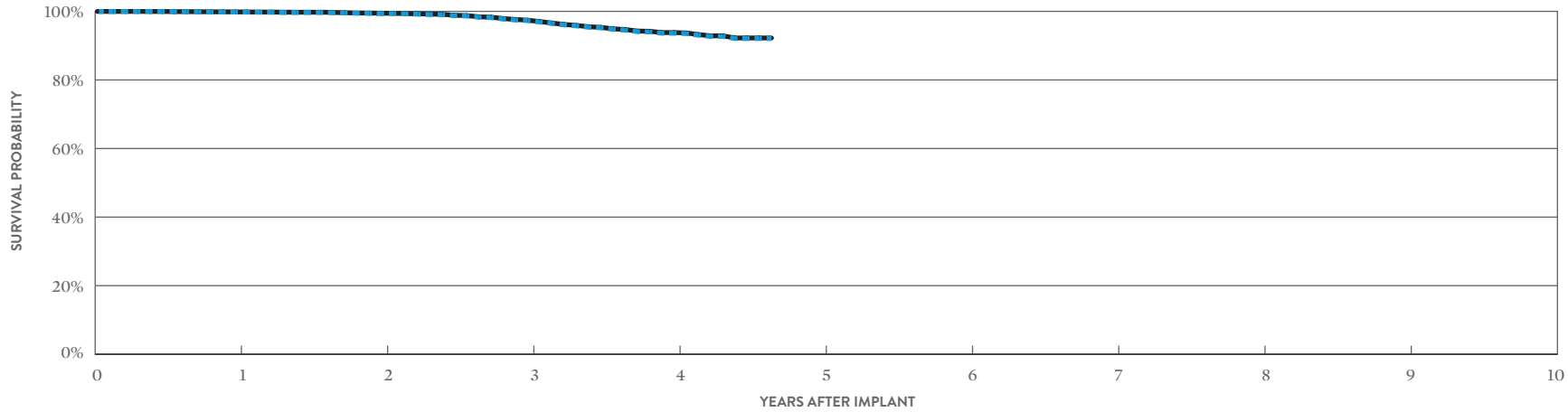
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

MODEL CD2357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	12,264
Estimated Active US Implants	7,759
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	6
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.02%	4	0.03%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	10	0.08%
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	33	0.27%	113	0.92%
Other	0	0.00%	3	0.02%
Total	**37**	**0.30%**	**132**	**1.08%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.79%	99.37%	97.29%	93.62%	92.06%
± 1 STANDARD ERROR	0.04%	0.07%	0.17%	0.33%	0.49%
SAMPLE SIZE	11,500	10,100	8,250	4,520	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.84%	99.45%	97.42%	93.81%	92.24%
± 1 STANDARD ERROR	0.04%	0.07%	0.16%	0.33%	0.49%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

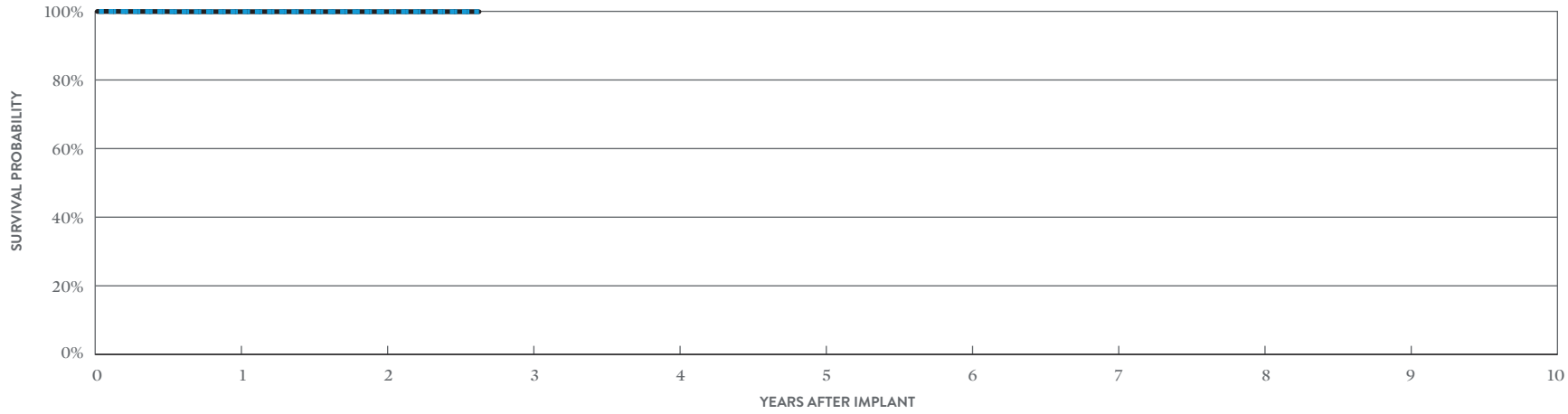
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

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

US Regulatory Approval	June 2013
Registered US Implants	6,869
Estimated Active US Implants	5,739
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
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%	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%	2	0.03%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.01%**	**2**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 32 MONTHS
SURVIVAL PROBABILITY	99.90%	99.90%	99.90%
± 1 STANDARD ERROR	0.04%	0.04%	0.04%
SAMPLE SIZE	5,780	3,060	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 32 MONTHS
SURVIVAL PROBABILITY	99.90%	99.90%	99.90%
± 1 STANDARD ERROR	0.04%	0.04%	0.04%

**Parylene coating.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

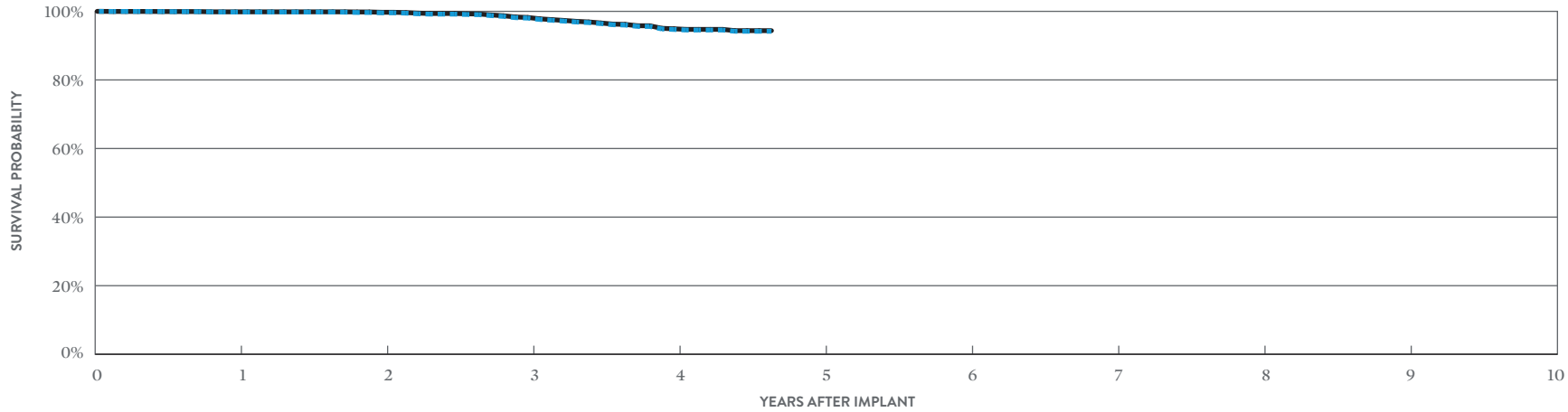
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

MODEL CD2357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	6,956
Estimated Active US Implants	4,369
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.04%	0	0.00%
Electrical Interconnect	1	0.01%	1	0.01%
Battery	0	0.00%	2	0.03%
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	9	0.13%	53	0.76%
Other	0	0.00%	0	0.00%
Total	**13**	**0.19%**	**56**	**0.81%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.80%	99.58%	98.03%	94.72%	94.19%
± 1 STANDARD ERROR	0.06%	0.07%	0.20%	0.41%	0.51%
SAMPLE SIZE	6,540	5,720	4,530	2,490	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.86%	99.73%	98.22%	94.91%	94.37%
± 1 STANDARD ERROR	0.05%	0.05%	0.19%	0.41%	0.51%

**Parylene coating.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

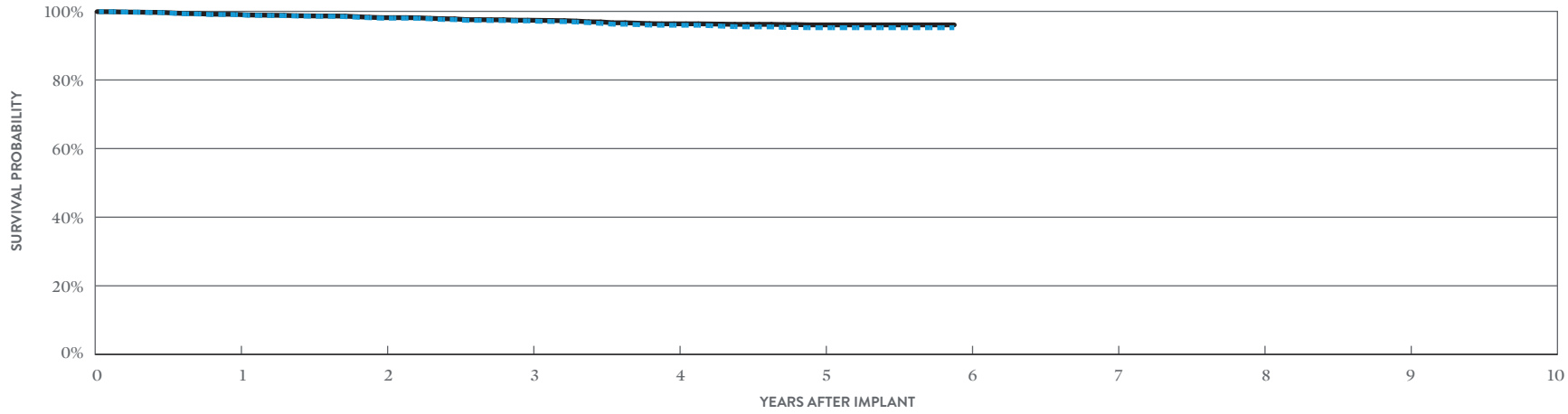
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ DR

MODEL CD2311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	5,897
Estimated Active US Implants	3,385
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	12
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.05%	4	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	52	0.88%	7	0.12%
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	3	0.05%	2	0.03%
Total	**61**	**1.03%**	**16**	**0.27%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 71 MONTHS
SURVIVAL PROBABILITY	99.05%	98.02%	97.21%	95.95%	95.23%	95.23%
± 1 STANDARD ERROR	0.13%	0.19%	0.23%	0.29%	0.32%	0.32%
SAMPLE SIZE	5,560	4,940	4,420	3,960	2,940	350

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 71 MONTHS
SURVIVAL PROBABILITY	99.14%	98.17%	97.42%	96.37%	96.06%	96.06%
± 1 STANDARD ERROR	0.12%	0.18%	0.22%	0.27%	0.29%	0.29%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

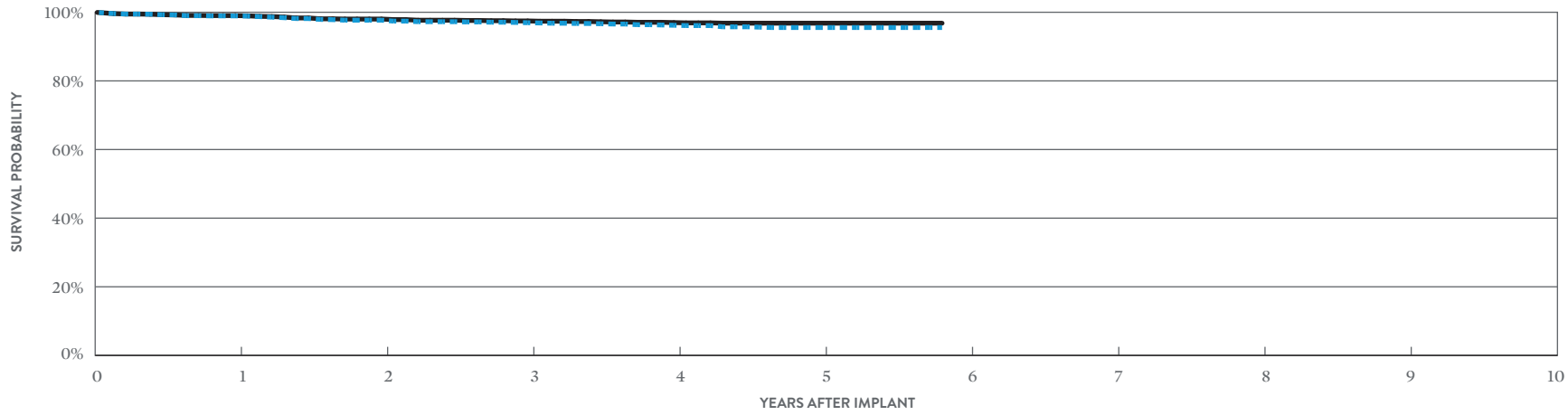
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ DR

MODEL CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	3,746
Estimated Active US Implants	2,129
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	13
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.13%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	21	0.56%	5	0.13%
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	3	0.08%	0	0.00%
Total	**33**	**0.88%**	**10**	**0.27%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	98.94%	97.69%	96.95%	96.21%	95.55%	95.55%
± 1 STANDARD ERROR	0.17%	0.26%	0.30%	0.34%	0.39%	0.39%
SAMPLE SIZE	3,520	3,100	2,760	2,460	1,770	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.03%	98.02%	97.47%	96.99%	96.82%	96.82%
± 1 STANDARD ERROR	0.16%	0.24%	0.28%	0.30%	0.32%	0.32%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

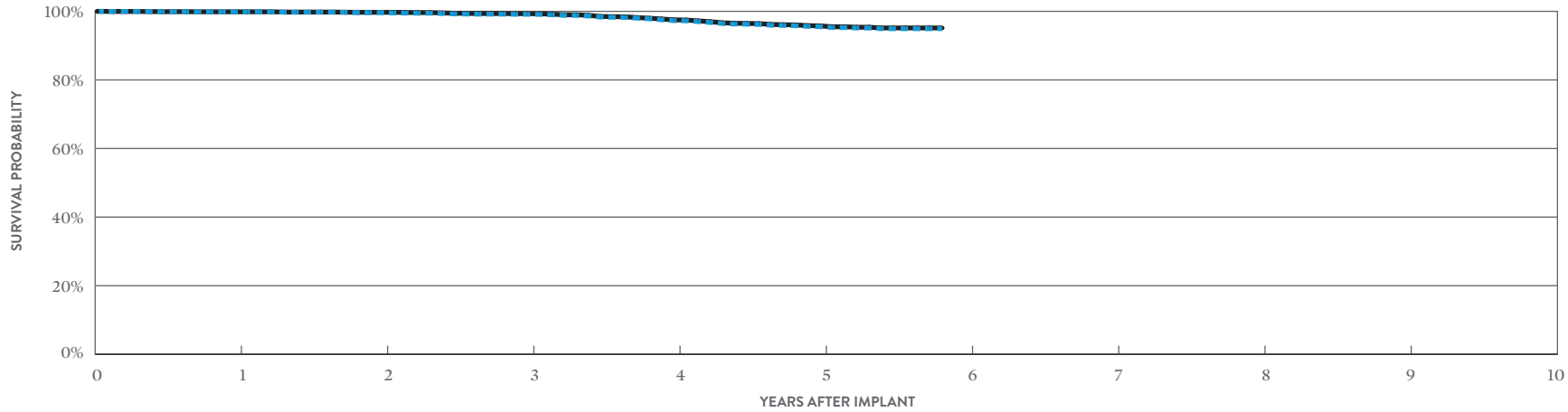
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

MODEL CD2257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	6,798
Estimated Active US Implants	3,720
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	0.07%	1	0.01%
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%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	17	0.25%	48	0.71%
Other	3	0.04%	1	0.01%
Total	**26**	**0.38%**	**53**	**0.78%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.87%	99.63%	99.14%	97.29%	95.53%	94.94%
± 1 STANDARD ERROR	0.04%	0.08%	0.13%	0.23%	0.32%	0.38%
SAMPLE SIZE	6,380	5,650	5,040	4,410	3,070	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.87%	99.72%	99.32%	97.52%	95.75%	95.16%
± 1 STANDARD ERROR	0.04%	0.07%	0.11%	0.22%	0.31%	0.38%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

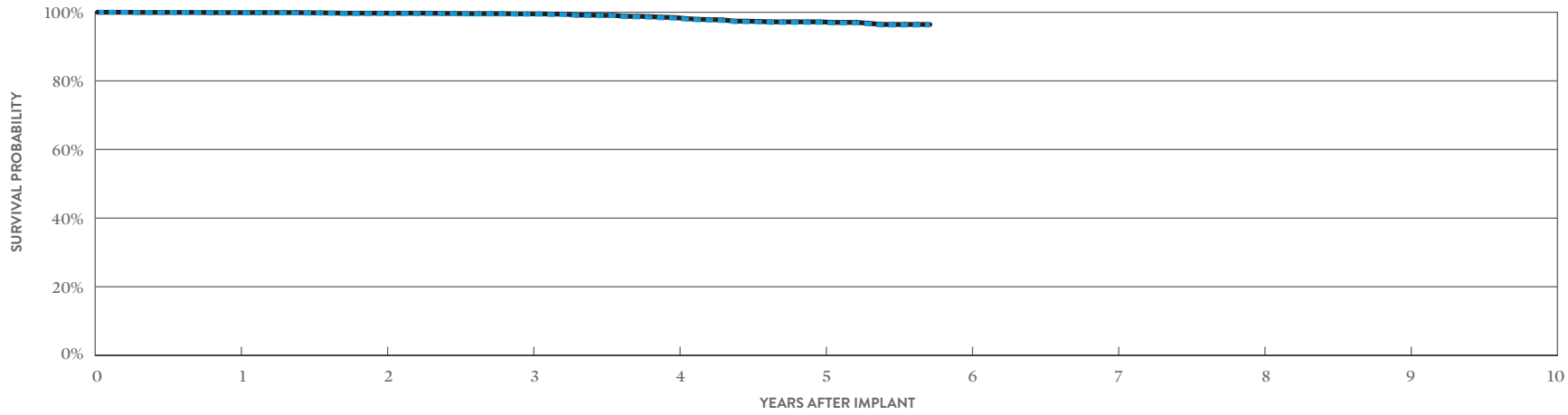
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ DR

MODEL CD2257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	4,235
Estimated Active US Implants	2,259
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.02%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.02%	3	0.07%
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	10	0.24%	17	0.40%
Other	0	0.00%	1	0.02%
Total	**13**	**0.31%**	**22**	**0.52%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 69 MONTHS
SURVIVAL PROBABILITY	99.85%	99.62%	99.43%	98.29%	97.04%	96.27%
± 1 STANDARD ERROR	0.06%	0.10%	0.13%	0.23%	0.33%	0.46%
SAMPLE SIZE	3,990	3,540	3,150	2,710	1,850	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 69 MONTHS
SURVIVAL PROBABILITY	99.90%	99.73%	99.54%	98.47%	97.21%	96.45%
± 1 STANDARD ERROR	0.05%	0.09%	0.12%	0.22%	0.32%	0.45%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

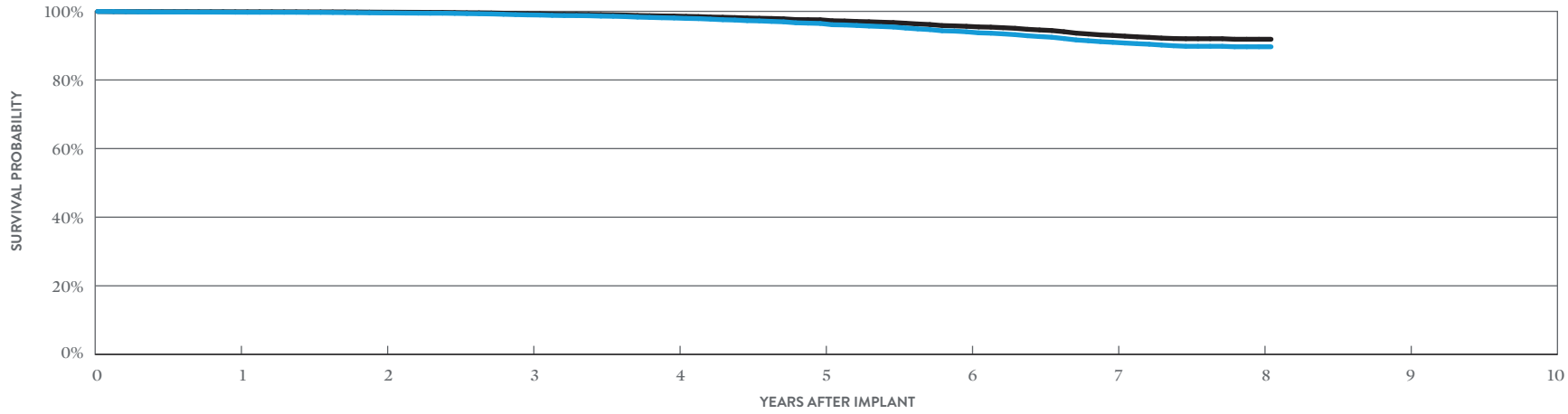
CUSTOMER REPORTED PERFORMANCE DATA

Fortify™ DR

MODEL CD2231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	26,870
Estimated Active US Implants	12,118
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	135
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	8	0.03%	8	0.03%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	27	0.10%	47	0.17%
High Voltage Capacitor	4	0.01%	2	<0.01%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	133	0.49%	149	0.55%
Other	12	0.04%	4	0.01%
Total	**187**	**0.70%**	**212**	**0.79%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 97 MONTHS
SURVIVAL PROBABILITY	99.75%	99.55%	98.97%	98.07%	96.48%	94.05%	90.98%	89.68%	89.68%
± 1 STANDARD ERROR	0.03%	0.04%	0.07%	0.10%	0.13%	0.18%	0.25%	0.32%	0.32%
SAMPLE SIZE	25,180	22,290	20,060	18,070	16,090	13,420	8,670	2,940	320

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 97 MONTHS
SURVIVAL PROBABILITY	99.87%	99.76%	99.31%	98.63%	97.54%	95.64%	92.98%	91.87%	91.87%
± 1 STANDARD ERROR	0.02%	0.03%	0.05%	0.08%	0.11%	0.16%	0.23%	0.29%	0.29%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

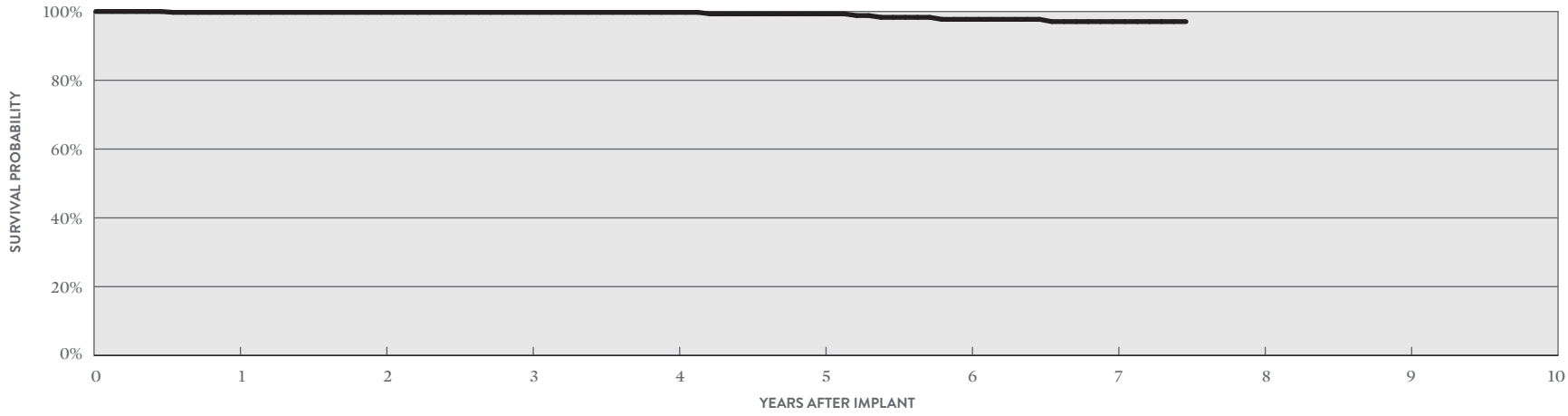
Fortify™ DR

MODEL CD2231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	390
Active Devices Enrolled in Study	135
Cumulative Months of Follow-up	22,309
Estimated Longevity	(see table on page 120)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	6	1.54%

	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%	4	1.03%
Other	1	0.26%	0	0.00%
Total	**4**	**1.03%**	**5**	**1.28%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	AT 90 MONTHS
SURVIVAL PROBABILITY	99.74%	99.74%	99.74%	99.74%	99.31%	97.72%	97.06%	97.06%
± 1 STANDARD ERROR	0.26%	0.26%	0.26%	0.26%	0.50%	1.04%	1.22%	1.22%
SAMPLE SIZE	380	340	300	260	230	190	140	50

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

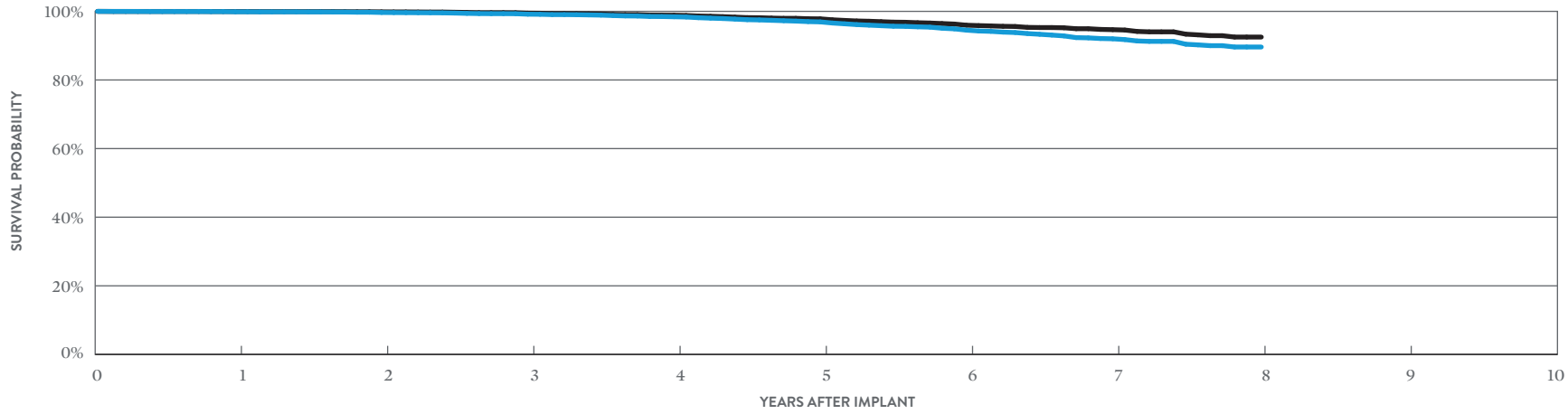
CUSTOMER REPORTED PERFORMANCE DATA

Fortify™ DR

MODEL CD2231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	12,095
Estimated Active US Implants	5,188
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	64
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.05%	2	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	5	0.04%	8	0.07%
High Voltage Capacitor	6	0.05%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	50	0.41%	57	0.47%
Other	4	0.03%	3	0.02%
Total	**72**	**0.60%**	**72**	**0.60%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.88%	99.67%	99.17%	98.42%	96.93%	94.52%	92.00%	89.61%
± 1 STANDARD ERROR	0.02%	0.05%	0.09%	0.13%	0.19%	0.26%	0.37%	0.60%
SAMPLE SIZE	11,320	9,960	8,870	7,890	6,940	5,660	34,90	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.95%	99.86%	99.49%	98.87%	97.82%	95.96%	94.66%	92.51%
± 1 STANDARD ERROR	0.02%	0.03%	0.06%	0.11%	0.16%	0.23%	0.30%	0.55%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

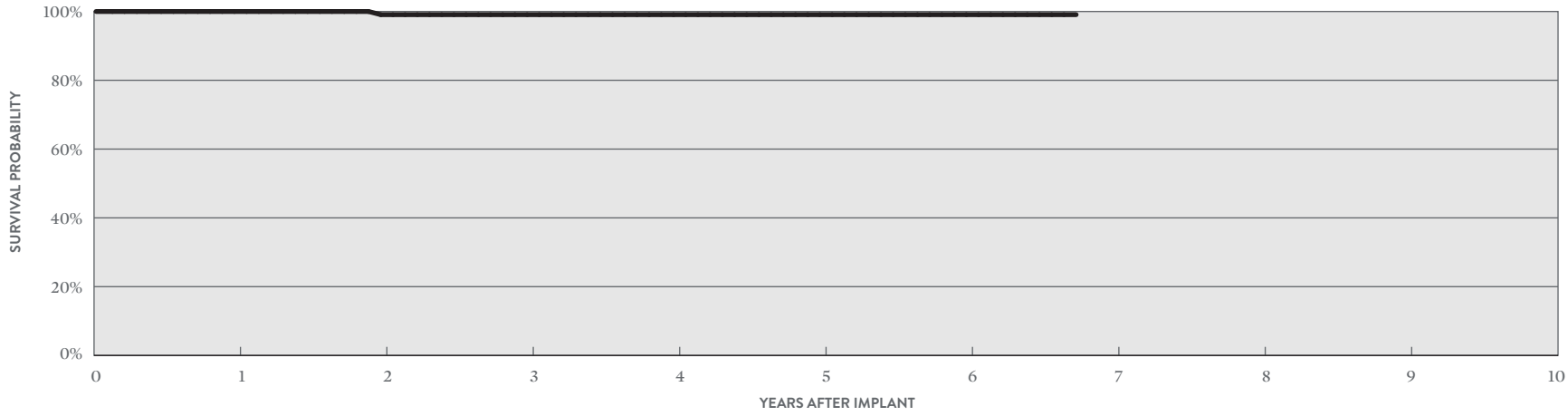
Fortify™ DR

MODEL CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	175
Active Devices Enrolled in Study	52
Cumulative Months of Follow-up	8,011
Estimated Longevity	(see table on page 120)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	1	0.57%

	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	0.57%	1	0.57%
Other	0	0.00%	0	0.00%
Total	**1**	**0.57%**	**1**	**0.57%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	AT 81 MONTHS
SURVIVAL PROBABILITY	100.00%	99.08%	99.08%	99.08%	99.08%	99.08%	99.08%
± 1 STANDARD ERROR	0.00%	0.00%	0.91%	0.91%	0.91%	0.91%	0.91%
SAMPLE SIZE	160	130	100	80	70	60	50

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

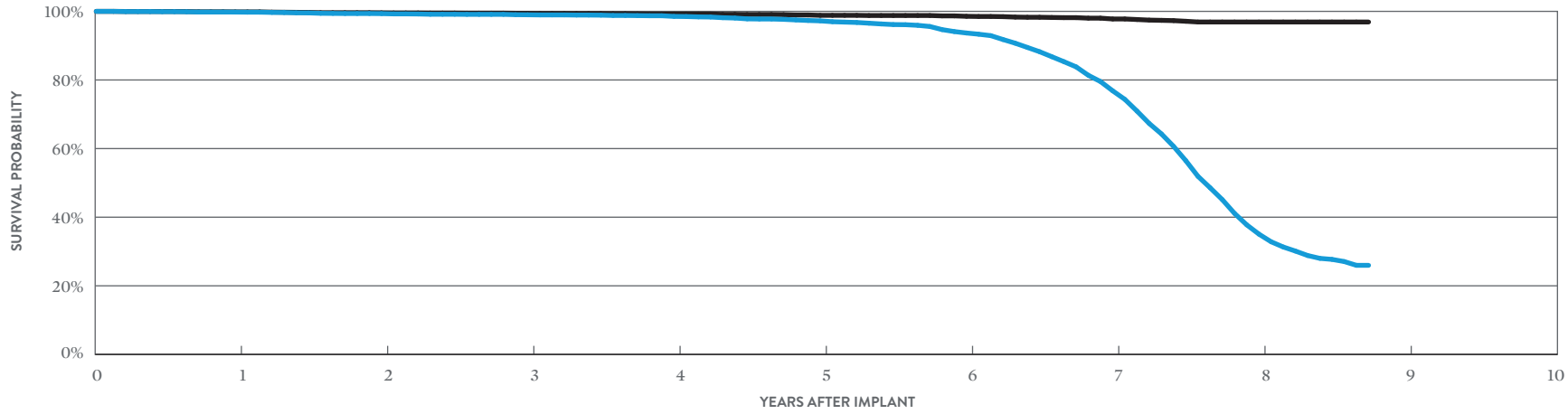
CUSTOMER REPORTED PERFORMANCE DATA

Current™ + DR

MODEL CD2211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	8,147
Estimated Active US Implants	1,602
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	1,159
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.07%	5	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	6	0.07%	7	0.09%
High Voltage Capacitor	2	0.02%	0	0.00%
Software/Firmware	1	0.01%	14	0.17%
Mechanical	0	0.00%	2	0.02%
Possible Early Battery Depletion	4	0.05%	3	0.04%
Other	5	0.06%	3	0.04%
Total	**24**	**0.29%**	**34**	**0.42%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 105 MONTHS
SURVIVAL PROBABILITY	99.79%	99.34%	99.00%	98.53%	97.23%	93.69%	76.84%	35.07%	25.97%
± 1 STANDARD ERROR	0.05%	0.09%	0.12%	0.14%	0.22%	0.34%	0.61%	0.75%	0.79%
SAMPLE SIZE	7,600	6,690	6,020	5,400	4,860	4,340	3,610	2,360	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 105 MONTHS
SURVIVAL PROBABILITY	99.85%	99.58%	99.42%	99.23%	98.84%	98.56%	97.78%	96.90%	96.90%
± 1 STANDARD ERROR	0.04%	0.07%	0.09%	0.11%	0.13%	0.15%	0.20%	0.28%	0.28%

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

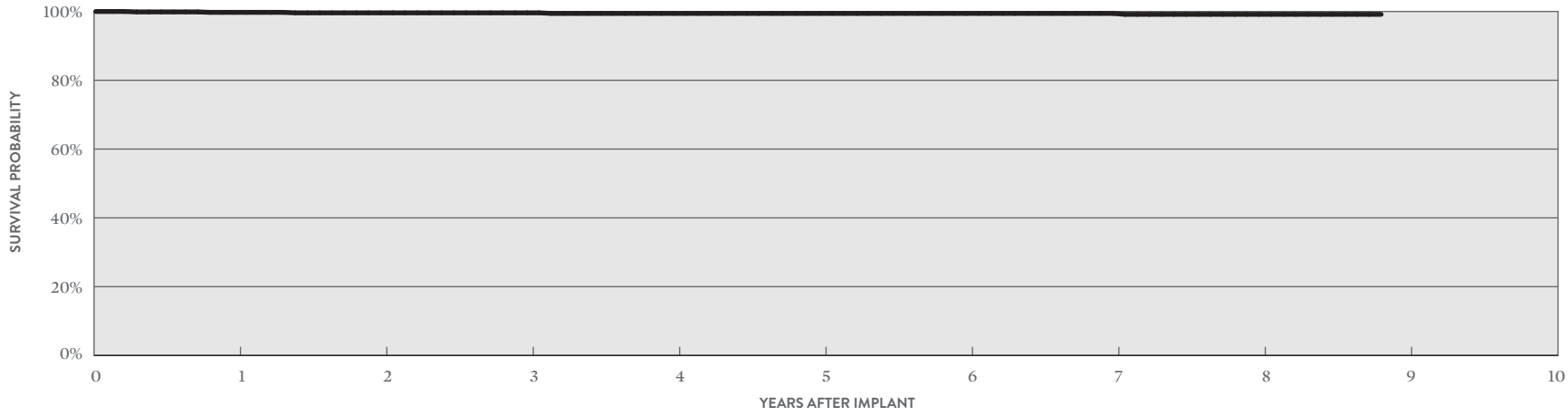
Current™ + DR

MODEL CD2211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	835
Active Devices Enrolled in Study	337
Cumulative Months of Follow-up	54,076
Estimated Longevity	(see table on page 120)
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	0	0.00%	2	0.24%
Total	**1**	**0.12%**	**8**	**0.96%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	8	AT 106 MONTHS
SURVIVAL PROBABILITY	99.75%	99.61%	99.61%	99.44%	99.44%	99.44%	99.44%	99.17%	99.17%
± 1 STANDARD ERROR	0.18%	0.23%	0.23%	0.28%	0.28%	0.28%	0.28%	0.39%	0.39%
SAMPLE SIZE	790	710	640	570	500	440	390	360	60

**DF4-LLHH connector type.*

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

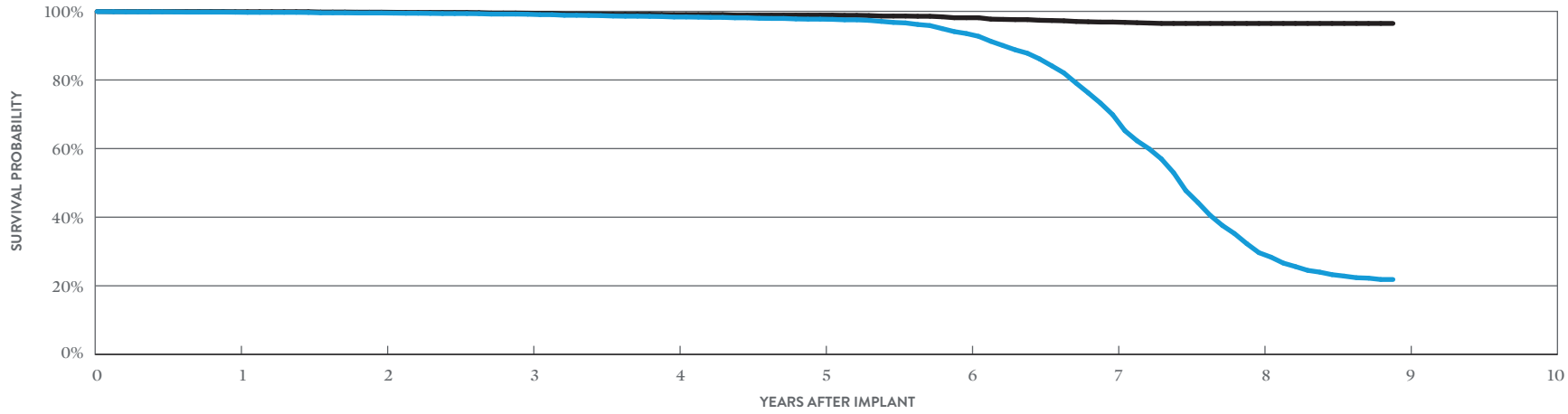
CUSTOMER REPORTED PERFORMANCE DATA

Current™ + DR

MODEL CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,271
Estimated Active US Implants	1,222
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	924
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.05%	1	0.02%
Electrical Interconnect	2	0.03%	0	0.00%
Battery	8	0.13%	4	0.06%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	0.02%	13	0.21%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	9	0.14%	4	0.06%
Other	5	0.08%	1	0.02%
Total	**28**	**0.45%**	**23**	**0.37%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.75%	99.53%	99.16%	98.36%	97.73%	93.53%	69.88%	29.66%	21.84%
± 1 STANDARD ERROR	0.06%	0.09%	0.12%	0.18%	0.23%	0.40%	0.80%	0.83%	0.77%
SAMPLE SIZE	5,840	5,110	4,550	4,060	3,620	3,180	2,530	1,580	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.90%	99.76%	99.47%	99.04%	98.90%	98.14%	96.88%	96.48%	96.48%
± 1 STANDARD ERROR	0.03%	0.07%	0.10%	0.14%	0.16%	0.22%	0.31%	0.34%	0.34%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

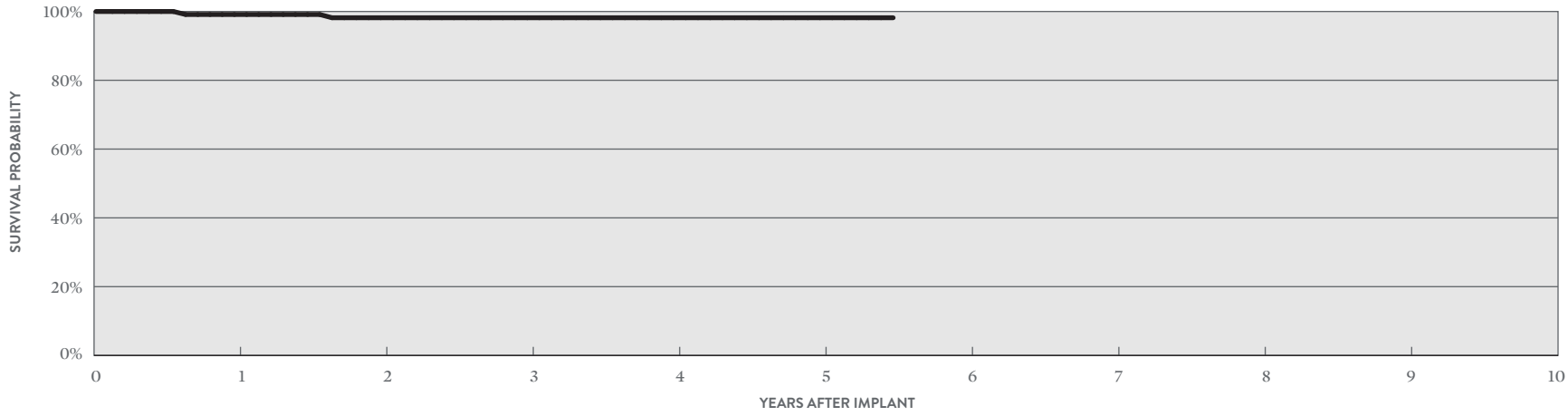
Current™ + DR

MODEL CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	123
Active Devices Enrolled in Study	17
Cumulative Months of Follow-up	6,384
Estimated Longevity	(see table on page 120)
Max. Delivered Energy	36 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Inappropriate Shock	1	0.81%
Premature Battery Depletion	1	0.81%

	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	1	0.81%	1	0.81%
Total	**1**	**0.81%**	**1**	**0.81%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	5	4	AT 66 MONTHS
SURVIVAL PROBABILITY	99.13%	98.18%	98.18%	98.18%	98.18%	98.18%
± 1 STANDARD ERROR	0.86%	1.28%	1.28%	1.28%	1.28%	1.28%
SAMPLE SIZE	120	100	80	60	60	50

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

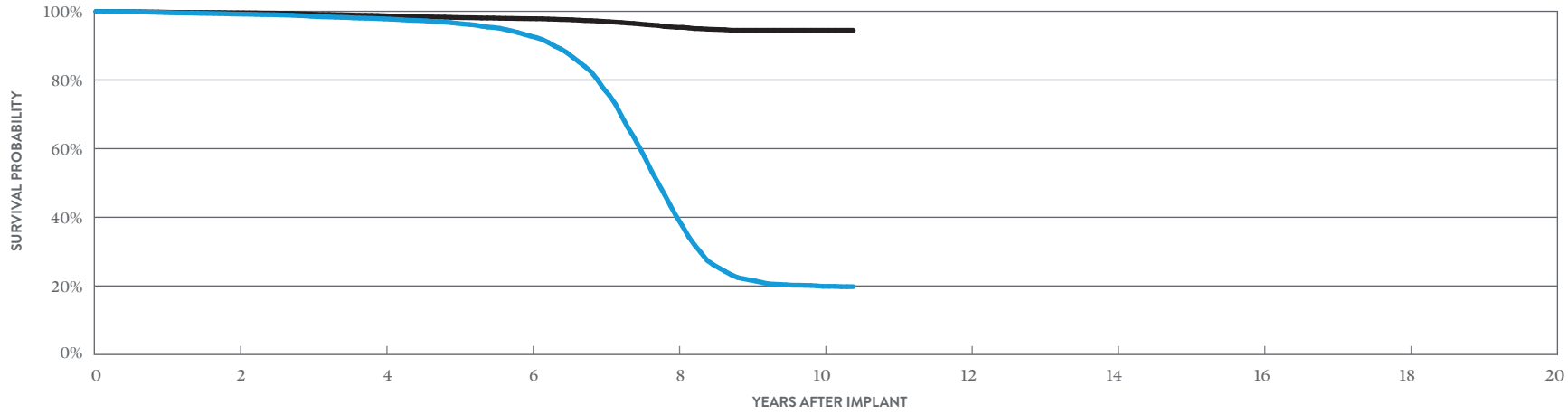
CUSTOMER REPORTED PERFORMANCE DATA

Current™ DR RF

MODEL 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,388
Estimated Active US Implants	3,011
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	3,490
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	10	0.04%	12	0.05%
Electrical Interconnect	6	0.03%	2	<0.01%
Battery	20	0.09%	9	0.04%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	2	<0.01%	43	0.19%
Mechanical	1	<0.01%	21	0.09%
Possible Early Battery Depletion	40	0.18%	19	0.08%
Other	35	0.16%	6	0.03%
Total	**115**	**0.51%**	**112**	**0.50%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 125 MONTHS
SURVIVAL PROBABILITY	99.20%	97.80%	92.81%	40.15%	19.89%	19.79%
± 1 STANDARD ERROR	0.06%	0.11%	0.22%	0.47%	0.37%	0.38%
SAMPLE SIZE	18,110	14,310	11,420	6,680	1,600	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 125 MONTHS
SURVIVAL PROBABILITY	99.58%	98.71%	97.86%	95.34%	94.48%	94.48%
± 1 STANDARD ERROR	0.05%	0.09%	0.12%	0.21%	0.26%	0.26%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

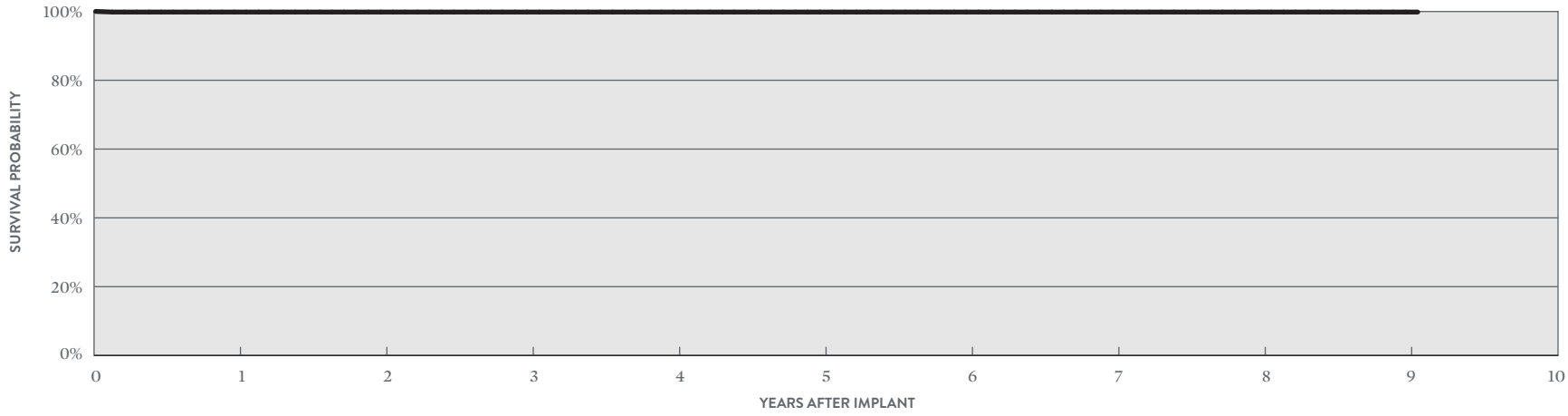
Current™ DR RF

MODEL 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	631
Active Devices Enrolled in Study	52
Cumulative Months of Follow-up	32,807
Estimated Longevity	(see table on page 120)
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	9	AT 109 MONTHS
SURVIVAL PROBABILITY	99.84%	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%	0.16%
SAMPLE SIZE	600	520	420	340	280	230	180	110	60	50

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

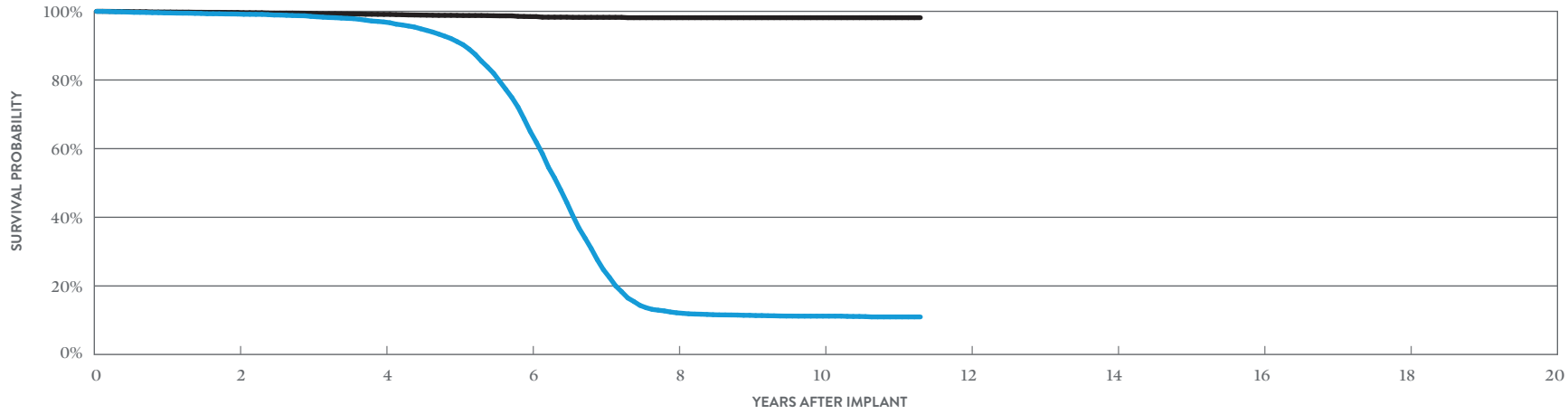
CUSTOMER REPORTED PERFORMANCE DATA

Atlas™ II + DR

MODEL V-268

US Regulatory Approval	July 2006
Registered US Implants	14,810
Estimated Active US Implants	1,283
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	2,968
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 329)	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	8	0.05%	5	0.03%
Total	**46**	**0.31%**	**19**	**0.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	99.21%	96.90%	65.03%	12.18%	11.21%	10.98%
± 1 STANDARD ERROR	0.08%	0.17%	0.53%	0.34%	0.32%	0.32%
SAMPLE SIZE	11,930	9,110	6,100	1,950	1,060	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	99.67%	99.11%	98.47%	98.15%	98.15%	98.15%
± 1 STANDARD ERROR	0.05%	0.09%	0.13%	0.17%	0.17%	0.17%

Dual-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

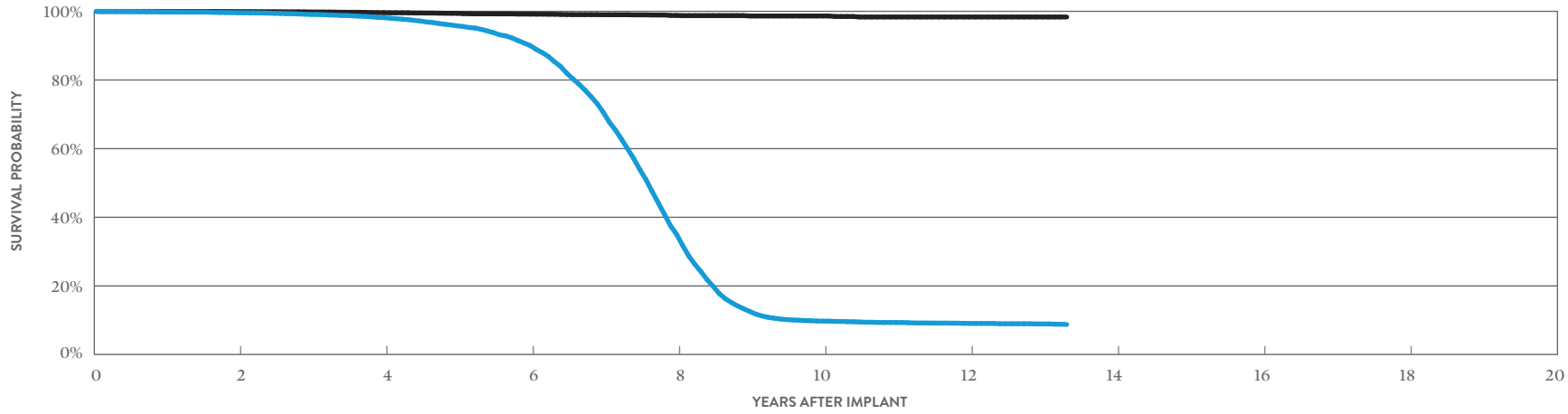
CUSTOMER REPORTED PERFORMANCE DATA

Atlas™ + DR

MODEL V-243

US Regulatory Approval	October 2003
Registered US Implants	21,082
Estimated Active US Implants	1,230
Estimated Longevity	(see table on page 120)
Normal Battery Depletion	3,696
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 329, 330, 331)	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	AT 160 MONTHS
SURVIVAL PROBABILITY	99.59%	98.16%	90.02%	35.07%	9.76%	9.08%	8.77%
± 1 STANDARD ERROR	0.05%	0.11%	0.28%	0.50%	0.27%	0.26%	0.27%
SAMPLE SIZE	17,100	13,100	9,450	5,070	1,610	960	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 160 MONTHS
SURVIVAL PROBABILITY	99.90%	99.62%	99.18%	98.80%	98.64%	98.35%	98.35%
± 1 STANDARD ERROR	0.02%	0.05%	0.08%	0.12%	0.14%	0.20%	0.20%

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
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. 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

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
CD2411-36Q	Ellipse™ DR	99.86%	99.83%	99.77%	99.77%						
CD2411-36C	Ellipse™ DR	99.83%	99.76%	99.76%	99.43%						
CD2357-40Q	Fortify Assura™ DR	99.84%	99.82%								
CD2357-40Q	Fortify Assura™ DR†	99.79%	99.37%	97.29%	93.62%						
CD2357-40C	Fortify Assura™ DR	99.90%	99.90%								
CD2357-40C	Fortify Assura™ DR†	99.80%	99.58%	98.03%	94.72%						
CD2311-36Q	Ellipse™ DR	99.05%	98.02%	97.21%	95.95%	95.23%					
CD2311-36	Ellipse™ DR	98.94%	97.69%	96.95%	96.21%	95.55%					
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.63%	99.14%	97.29%	95.53%					
CD2257-40	Fortify Assura™ DR†	99.85%	99.62%	99.43%	98.29%	97.04%					
CD2231-40Q	Fortify™ DR†	99.75%	99.55%	98.97%	98.07%	96.48%	94.05%	90.98%	89.68%		
CD2231-40	Fortify™ DR†	99.88%	99.67%	99.17%	98.42%	96.93%	94.52%	92.00%	89.61%		
CD2211-36Q	Current™ + DR	99.79%	99.34%	99.00%	98.53%	97.23%	93.69%	76.84%	35.07%		
CD2211-36	Current™ + DR	99.75%	99.53%	99.16%	98.36%	97.73%	93.53%	69.88%	29.66%		
2207-36	Current™ DR RF	99.66%	99.20%	98.57%	97.80%	96.52%	92.81%	77.56%	40.15%	21.75%	19.89%
V-268	Atlas™ II + DR	99.54%	99.21%	98.53%	96.90%	91.19%	65.03%	24.75%	12.18%	11.45%	11.21%
V-243	Atlas™ + DR	99.81%	99.59%	99.10%	98.16%	95.77%	90.02%	70.55%	35.07%	12.57%	9.76%

†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
CD2411-36Q	Ellipse™ DR	99.86%	99.83%	99.77%	99.77%						
CD2411-36C	Ellipse™ DR	99.83%	99.76%	99.76%	99.43%						
CD2357-40Q	Fortify Assura™ DR	99.88%	99.86%								
CD2357-40Q	Fortify Assura™ DR†	99.84%	99.45%	97.42%	93.81%						
CD2357-40C	Fortify Assura™ DR	99.90%	99.90%								
CD2357-40C	Fortify Assura™ DR†	99.86%	99.73%	98.22%	94.91%						
CD2311-36Q	Ellipse™ DR	99.14%	98.17%	97.42%	96.37%	96.06%					
CD2311-36	Ellipse™ DR	99.03%	98.02%	97.47%	96.99%	96.82%					
CD2257-40Q	Fortify Assura™ DR†	99.87%	99.72%	99.32%	97.52%	95.75%					
CD2257-40	Fortify Assura™ DR†	99.90%	99.73%	99.54%	98.47%	97.21%					
CD2231-40Q	Fortify™ DR†	99.87%	99.76%	99.31%	98.63%	97.54%	95.64%	92.98%	91.87%		
CD2231-40	Fortify™ DR†	99.95%	99.86%	99.49%	98.87%	97.82%	95.96%	94.66%	92.51%		
CD2211-36Q	Current™ + DR	99.85%	99.58%	99.42%	99.23%	98.84%	98.56%	97.78%	96.90%		
CD2211-36	Current™ + DR	99.90%	99.76%	99.47%	99.04%	98.90%	98.14%	96.88%	96.48%		
2207-36	Current™ DR RF	99.75%	99.58%	99.20%	98.71%	98.20%	97.86%	97.07%	95.34%	94.48%	94.48%
V-268	Atlas™ II + DR	99.80%	99.67%	99.40%	99.11%	98.81%	98.47%	98.25%	98.15%	98.15%	98.15%
V-243	Atlas™ + DR	99.97%	99.90%	99.80%	99.62%	99.42%	99.18%	99.01%	98.80%	98.64%	98.64%

†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
CD2411-36Q	Ellipse™ DR	18,545	2.70%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	1	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**6**	**0.03%**
CD2411-36C	Ellipse™ DR	8,875	3.60%	2	0.02%	0	0.00%	0	0.00%	5	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.08%**
CD2357-40Q	Fortify Assura™ DR	18,316	2.10%	0	0.00%	0	0.00%	1	<0.01%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**6**	**0.03%**
CD2357-40Q	Fortify Assura™ DR†	12,264	10.40%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	33	0.27%	0	0.00%	**37**	**0.30%**
CD2357-40C	Fortify Assura™ DR	6,869	2.20%	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%**
CD2357-40C	Fortify Assura™ DR†	6,956	11.60%	3	0.04%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	9	0.13%	0	0.00%	**13**	**0.19%**
CD2311-36Q	Ellipse™ DR	5,897	7.90%	3	0.05%	0	0.00%	0	0.00%	52	0.88%	1	0.02%	2	0.03%	0	0.00%	3	0.05%	**61**	**1.03%**
CD2311-36	Ellipse™ DR	3,746	8.80%	5	0.13%	0	0.00%	0	0.00%	21	0.56%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**33**	**0.88%**
CD2257-40Q	Fortify Assura™ DR†	6,798	12.00%	5	0.07%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	17	0.25%	3	0.04%	**26**	**0.38%**
CD2257-40	Fortify Assura™ DR†	4,235	13.40%	1	0.02%	0	0.00%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	10	0.24%	0	0.00%	**13**	**0.31%**
CD2231-40Q	Fortify™ DR†	26,870	12.20%	8	0.03%	2	<0.01%	27	0.10%	4	0.01%	1	<0.01%	0	0.00%	133	0.49%	12	0.04%	**187**	**0.70%**
CD2231-40	Fortify™ DR†	12,095	14.60%	6	0.05%	1	<0.01%	5	0.04%	6	0.05%	0	0.00%	0	0.00%	50	0.41%	4	0.03%	**72**	**0.60%**
CD2211-36Q	Current™ + DR	8,147	24.50%	6	0.07%	0	0.00%	6	0.07%	2	0.02%	1	0.01%	0	0.00%	4	0.05%	5	0.06%	**24**	**0.29%**
CD2211-36	Current™ + DR	6,271	26.40%	3	0.05%	2	0.03%	8	0.13%	0	0.00%	1	0.02%	0	0.00%	9	0.14%	5	0.08%	**28**	**0.45%**
2207-36	Current™ DR RF	22,388	27.70%	10	0.04%	6	0.03%	20	0.09%	1	<0.01%	2	<0.01%	1	<0.01%	40	0.18%	35	0.16%	**115**	**0.51%**
V-268	Atlas™ II + DR	14,810	29.50%	6	0.04%	4	0.03%	9	0.06%	0	0.00%	0	0.00%	0	0.00%	19	0.13%	8	0.05%	**46**	**0.31%**
V-243	Atlas™ + DR	21,082	27.30%	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
CD2411-36Q	Ellipse™ DR	18,545	2.70%	2	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	**8**	**0.04%**
CD2411-36C	Ellipse™ DR	8,875	3.60%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.03%**
CD2357-40Q	Fortify Assura™ DR	18,316	2.10%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	**3**	**0.02%**
CD2357-40Q	Fortify Assura™ DR†	12,264	10.40%	4	0.03%	0	0.00%	10	0.08%	0	0.00%	1	<0.01%	1	<0.01%	113	0.92%	3	0.02%	**132**	**1.08%**
CD2357-40C	Fortify Assura™ DR	6,869	2.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	**2**	**0.03%**
CD2357-40C	Fortify Assura™ DR†	6,956	11.60%	0	0.00%	1	0.01%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	53	0.76%	0	0.00%	**56**	**0.81%**
CD2311-36Q	Ellipse™ DR	5,897	7.90%	4	0.07%	0	0.00%	0	0.00%	7	0.12%	0	0.00%	3	0.05%	0	0.00%	2	0.03%	**16**	**0.27%**
CD2311-36	Ellipse™ DR	3,746	8.80%	2	0.05%	0	0.00%	0	0.00%	5	0.13%	0	0.00%	3	0.08%	0	0.00%	0	0.00%	**10**	**0.27%**
CD2257-40Q	Fortify Assura™ DR†	6,798	12.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	48	0.71%	1	0.01%	**53**	**0.78%**
CD2257-40	Fortify Assura™ DR†	4,235	13.40%	0	0.00%	0	0.00%	3	0.07%	0	0.00%	1	0.02%	0	0.00%	17	0.40%	1	0.02%	**22**	**0.52%**
CD2231-40Q	Fortify™ DR†	26,870	12.20%	8	0.03%	2	<0.01%	47	0.17%	2	<0.01%	0	0.00%	0	0.00%	149	0.55%	4	0.01%	**212**	**0.79%**
CD2231-40	Fortify™ DR†	12,095	14.60%	2	0.02%	0	0.00%	8	0.07%	1	<0.01%	0	0.00%	1	<0.01%	57	0.47%	3	0.02%	**72**	**0.60%**
CD2211-36Q	Current™ + DR	8,147	24.50%	5	0.06%	0	0.00%	7	0.09%	0	0.00%	14	0.17%	2	0.02%	3	0.04%	3	0.04%	**34**	**0.42%**
CD2211-36	Current™ + DR	6,271	26.40%	1	0.02%	0	0.00%	4	0.06%	0	0.00%	13	0.21%	0	0.00%	4	0.06%	1	0.02%	**23**	**0.37%**
2207-36	Current™ DR RF	22,388	27.70%	12	0.05%	2	<0.01%	9	0.04%	0	0.00%	43	0.19%	21	0.09%	19	0.08%	6	0.03%	**112**	**0.50%**
V-268	Atlas™ II + DR	14,810	29.50%	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	27.30%	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
CD2411-36Q	Ellipse™ DR	19,105	2.85%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	1	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**6**	**0.03%**
CD2411-36C	Ellipse™ DR	9,018	4.10%	2	0.02%	0	0.00%	0	0.00%	5	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.08%**
CD2357-40Q	Fortify Assura™ DR	31,065	5.54%	3	<0.01%	1	<0.01%	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	33	0.11%	2	<0.01%	**43**	**0.14%**
CD2357-40C	Fortify Assura™ DR	14,079	7.21%	4	0.03%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	9	0.06%	0	0.00%	**14**	**0.10%**
CD2311-36Q	Ellipse™ DR	5,900	9.32%	3	0.05%	0	0.00%	0	0.00%	52	0.88%	1	0.02%	2	0.03%	0	0.00%	3	0.05%	**61**	**1.03%**
CD2311-36	Ellipse™ DR	3,756	9.69%	5	0.13%	0	0.00%	0	0.00%	21	0.56%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**33**	**0.88%**
CD2257-40Q	Fortify Assura™ DR	6,780	12.43%	5	0.07%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	17	0.25%	3	0.04%	**26**	**0.38%**
CD2257-40	Fortify Assura™ DR	4,235	13.96%	1	0.02%	0	0.00%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	10	0.24%	0	0.00%	**13**	**0.31%**
CD2231-40Q	Fortify™ DR	28,216	12.28%	8	0.03%	2	<0.01%	28	0.10%	4	0.01%	1	<0.01%	0	0.00%	136	0.48%	13	0.05%	**192**	**0.68%**
CD2231-40	Fortify™ DR	14,159	13.35%	6	0.04%	2	0.01%	5	0.04%	6	0.04%	0	0.00%	0	0.00%	52	0.37%	5	0.04%	**76**	**0.54%**
CD2211-36Q	Current™ + DR	15,213	15.53%	8	0.05%	1	<0.01%	8	0.05%	5	0.03%	1	<0.01%	0	0.00%	7	0.05%	12	0.08%	**42**	**0.28%**
CD2211-36	Current™ + DR	13,484	13.39%	7	0.05%	5	0.04%	10	0.07%	1	<0.01%	1	<0.01%	0	0.00%	11	0.08%	9	0.07%	**44**	**0.33%**
2207-36	Current™ DR RF	33,051	22.11%	17	0.05%	11	0.03%	29	0.09%	12	0.04%	3	<0.01%	2	<0.01%	59	0.18%	45	0.14%	**178**	**0.54%**
V-268	Atlas™ II + DR	25,779	19.44%	15	0.06%	5	0.02%	19	0.07%	1	<0.01%	0	0.00%	0	0.00%	32	0.12%	19	0.07%	**91**	**0.35%**
V-243	Atlas™ + DR	34,105	19.05%	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
CD2411-36Q	Ellipse™ DR	19,105	2.85%	2	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	**8**	**0.04%**
CD2411-36C	Ellipse™ DR	9,018	4.10%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.03%**
CD2357-40Q	Fortify Assura™ DR	31,065	5.54%	5	0.02%	0	0.00%	10	0.03%	0	0.00%	1	<0.01%	3	<0.01%	113	0.36%	3	<0.01%	**135**	**0.43%**
CD2357-40C	Fortify Assura™ DR	14,079	7.21%	0	0.00%	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	2	0.01%	53	0.38%	0	0.00%	**58**	**0.41%**
CD2311-36Q	Ellipse™ DR	5,900	9.32%	4	0.07%	0	0.00%	0	0.00%	7	0.12%	0	0.00%	3	0.05%	0	0.00%	2	0.03%	**16**	**0.27%**
CD2311-36	Ellipse™ DR	3,756	9.69%	2	0.05%	0	0.00%	0	0.00%	5	0.13%	0	0.00%	3	0.08%	0	0.00%	0	0.00%	**10**	**0.27%**
CD2257-40Q	Fortify Assura™ DR	6,780	12.43%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	48	0.71%	1	0.01%	**53**	**0.78%**
CD2257-40	Fortify Assura™ DR	4,235	13.96%	0	0.00%	0	0.00%	3	0.07%	0	0.00%	1	0.02%	0	0.00%	17	0.40%	1	0.02%	**22**	**0.52%**
CD2231-40Q	Fortify™ DR	28,216	12.28%	8	0.03%	2	<0.01%	49	0.17%	2	<0.01%	0	0.00%	0	0.00%	155	0.55%	4	0.01%	**220**	**0.78%**
CD2231-40	Fortify™ DR	14,159	13.35%	2	0.01%	0	0.00%	8	0.06%	1	<0.01%	0	0.00%	2	0.01%	60	0.42%	3	0.02%	**76**	**0.54%**
CD2211-36Q	Current™ + DR	15,213	15.53%	10	0.07%	0	0.00%	10	0.07%	0	0.00%	16	0.11%	3	0.02%	6	0.04%	5	0.03%	**50**	**0.33%**
CD2211-36	Current™ + DR	13,484	13.39%	1	<0.01%	0	0.00%	4	0.03%	1	<0.01%	13	0.10%	1	<0.01%	5	0.04%	2	0.01%	**27**	**0.20%**
2207-36	Current™ DR RF	33,051	22.11%	19	0.06%	5	0.02%	14	0.04%	4	0.01%	90	0.27%	33	0.10%	26	0.08%	11	0.03%	**202**	**0.61%**
V-268	Atlas™ II + DR	25,779	19.44%	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	19.05%	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	135	22,309	0	0.00%	0	0.00%	0	0.00%	6	1.54%	0	0.00%	**6**	**1.54%**
CD2231-40	175	52	8,011	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	**1**	**0.57%**
CD2211-36Q	835	337	54,076	0	0.00%	0	0.00%	0	0.00%	4	0.48%	1	0.12%	**5**	**0.60%**
CD2211-36	123	17	6,384	1	0.81%	0	0.00%	0	0.00%	1	0.81%	0	0.00%	**2**	**1.63%**
2207-36	631	52	32,807	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

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	17.40%	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	175	16.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	**1**	**0.57%**
CD2211-36Q	Current™ + DR	835	32.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.12%**
CD2211-36	Current™ + DR	123	32.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.81%	**1**	**0.81%**
2207-36	Current™ DR RF	631	36.60%	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%**

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	17.40%	0	0.00%	0	0.00%	1	0.26%	0	0.00%	0	0.00%	0	0.00%	4	1.03%	0	0.00%	**5**	**1.28%**
CD2231-40	Fortify™ DR	175	16.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	**1**	**0.57%**
CD2211-36Q	Current™ + DR	835	32.00%	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	123	32.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.81%	**1**	**0.81%**
2207-36	Current™ DR RF	631	36.60%	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%**

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

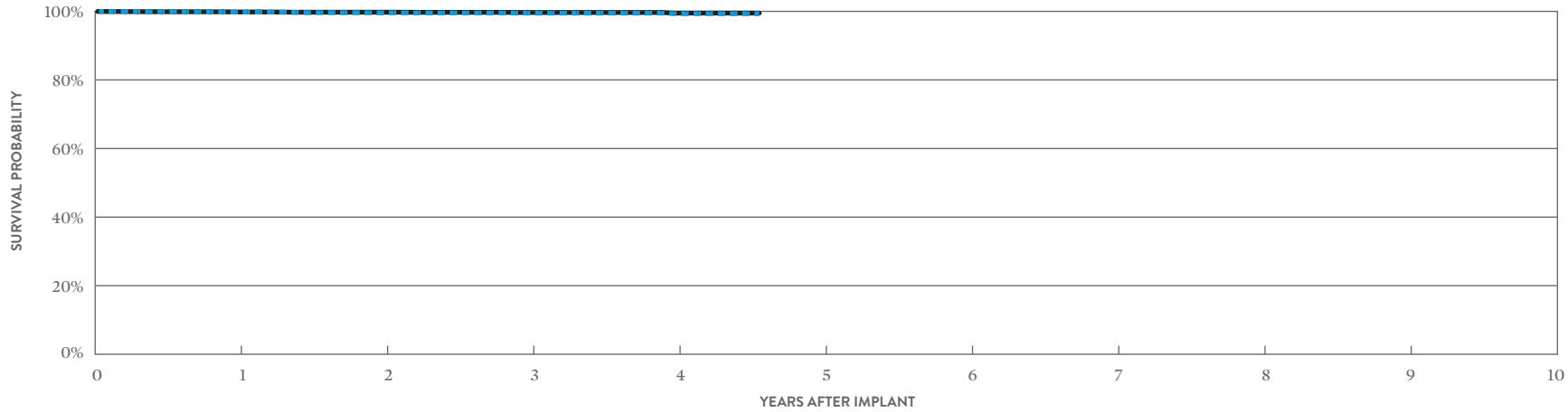
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ VR

MODEL CD1411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	14,526
Estimated Active US Implants	11,128
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	7
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.02%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	6	0.04%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	2	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	0.01%
Total	**9**	**0.06%**	**6**	**0.04%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.79%	99.56%	99.48%	99.31%	99.31%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.08%	0.14%
SAMPLE SIZE	12,040	7,990	4,930	2,260	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 55 MONTHS
SURVIVAL PROBABILITY	99.82%	99.75%	99.67%	99.50%	99.50%
± 1 STANDARD ERROR	0.03%	0.05%	0.07%	0.07%	0.14%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

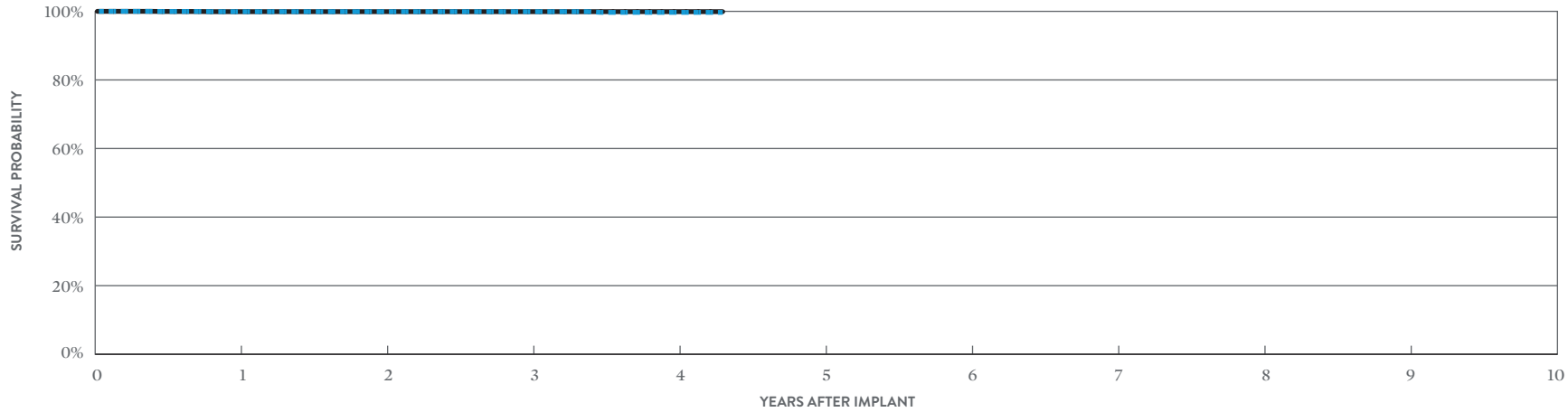
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ VR

MODEL CD1411-36C*

US Regulatory Approval	June 2013
Registered US Implants	5,687
Estimated Active US Implants	4,280
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	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%	1	0.02%
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**	**0.04%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 52 MONTHS
SURVIVAL PROBABILITY	99.91%	99.91%	99.91%	99.70%	99.70%
± 1 STANDARD ERROR	0.04%	0.04%	0.04%	0.16%	0.16%
SAMPLE SIZE	4,810	3,340	2,120	960	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 52 MONTHS
SURVIVAL PROBABILITY	99.91%	99.91%	99.91%	99.91%	99.91%
± 1 STANDARD ERROR	0.04%	0.04%	0.04%	0.04%	0.04%

**Parylene coating.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

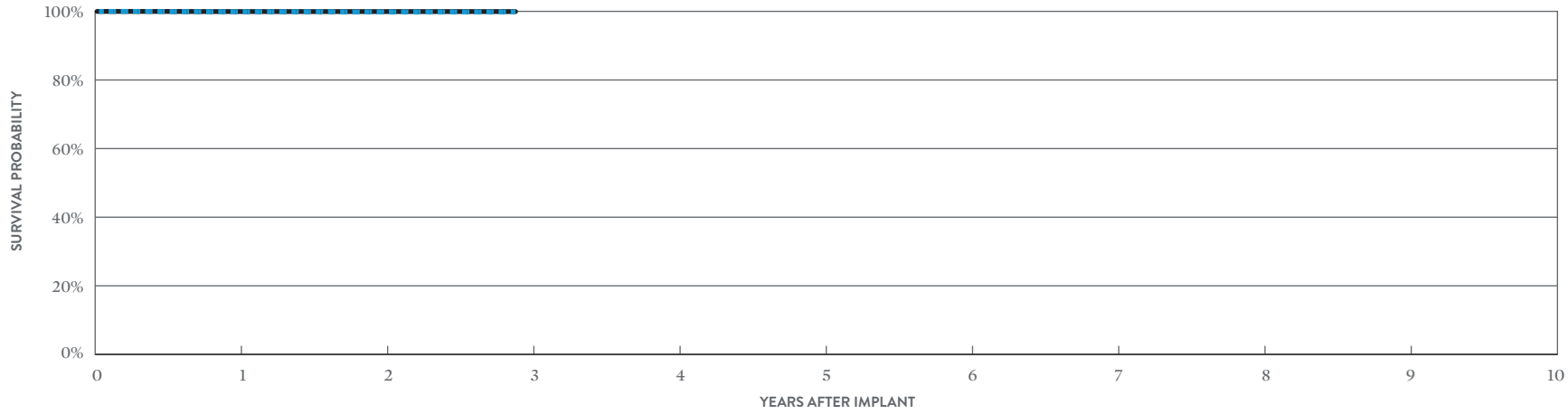
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

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

US Regulatory Approval	June 2013
Registered US Implants	12,800
Estimated Active US Implants	10,680
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**1**	**<0.01%**	**2**	**0.02%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.90%	99.86%	99.86%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%
SAMPLE SIZE	10,330	5,680	330

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.94%	99.94%	99.94%
± 1 STANDARD ERROR	0.02%	0.02%	0.02%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

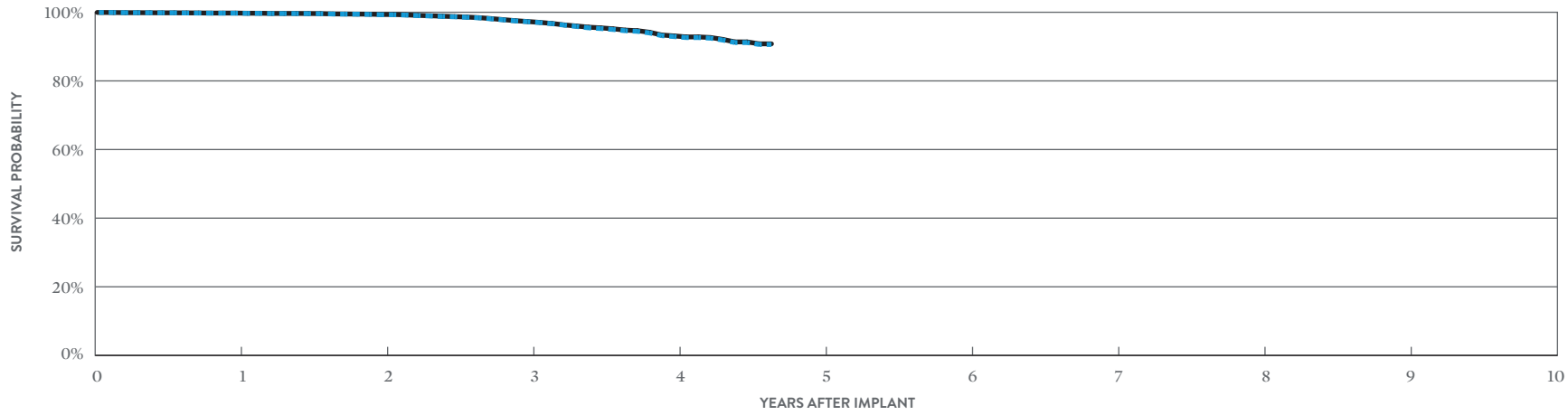
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

MODEL CD1357-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	10,215
Estimated Active US Implants	6,528
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	4
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.03%	8	0.08%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	4	0.04%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	23	0.23%	106	1.04%
Other	3	0.03%	3	0.03%
Total	**31**	**0.30%**	**121**	**1.18%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.74%	99.28%	97.24%	92.92%	90.61%
± 1 STANDARD ERROR	0.05%	0.08%	0.18%	0.38%	0.71%
SAMPLE SIZE	9,600	8,460	6,960	3,840	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 56 MONTHS
SURVIVAL PROBABILITY	99.77%	99.35%	97.30%	93.11%	90.80%
± 1 STANDARD ERROR	0.05%	0.08%	0.18%	0.38%	0.71%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

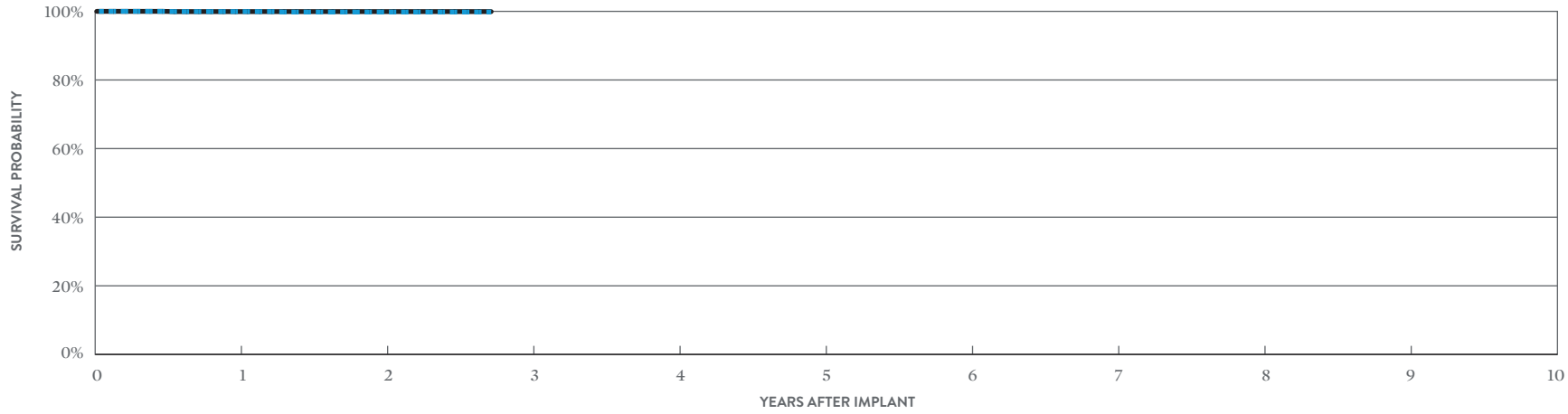
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

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

US Regulatory Approval	June 2013
Registered US Implants	3,887
Estimated Active US Implants	3,255
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 324)	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	0.03%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.03%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 33 MONTHS
SURVIVAL PROBABILITY	99.93%	99.81%	99.81%
± 1 STANDARD ERROR	0.05%	0.10%	0.10%
SAMPLE SIZE	3,010	1,490	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	AT 33 MONTHS
SURVIVAL PROBABILITY	99.93%	99.93%	99.93%
± 1 STANDARD ERROR	0.05%	0.05%	0.05%

**Parylene coating.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

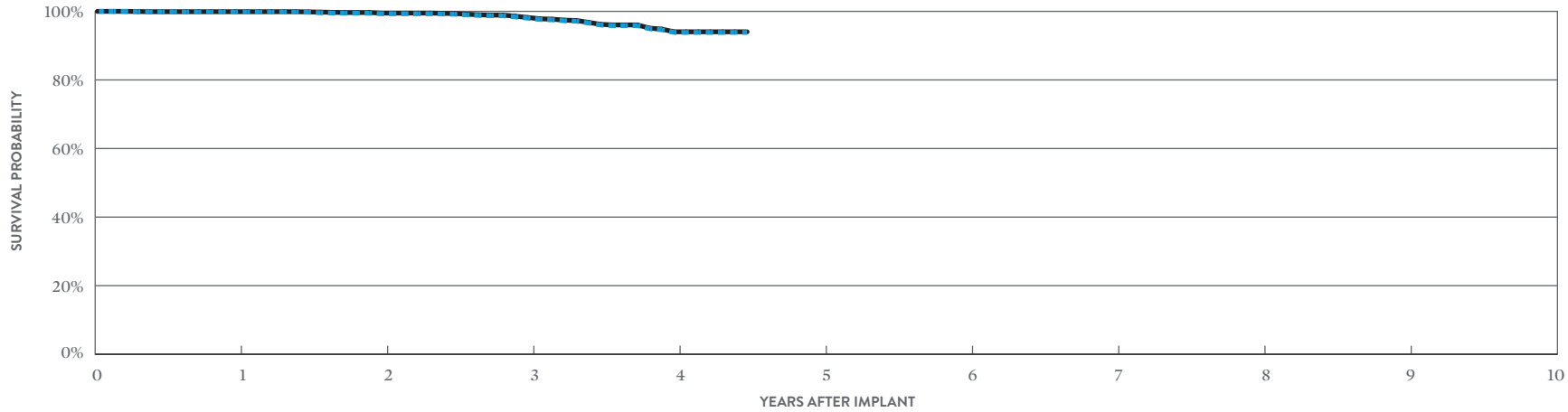
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

MODEL CD1357-40C* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	June 2013
Registered US Implants	4,131
Estimated Active US Implants	2,608
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.07%	0	0.00%
Electrical Interconnect	0	0.00%	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	0.02%
Mechanical	1	0.02%	0	0.00%
Possible Early Battery Depletion	4	0.10%	30	0.73%
Other	0	0.00%	0	0.00%
Total	**8**	**0.19%**	**33**	**0.80%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 54 MONTHS
SURVIVAL PROBABILITY	99.80%	99.31%	98.02%	93.86%	93.86%
± 1 STANDARD ERROR	0.07%	0.12%	0.24%	0.59%	0.68%
SAMPLE SIZE	3,890	3,390	2,620	1,340	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 54 MONTHS
SURVIVAL PROBABILITY	99.90%	99.50%	98.21%	94.04%	94.04%
± 1 STANDARD ERROR	0.05%	0.10%	0.22%	0.58%	0.67%

**Parylene coating.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

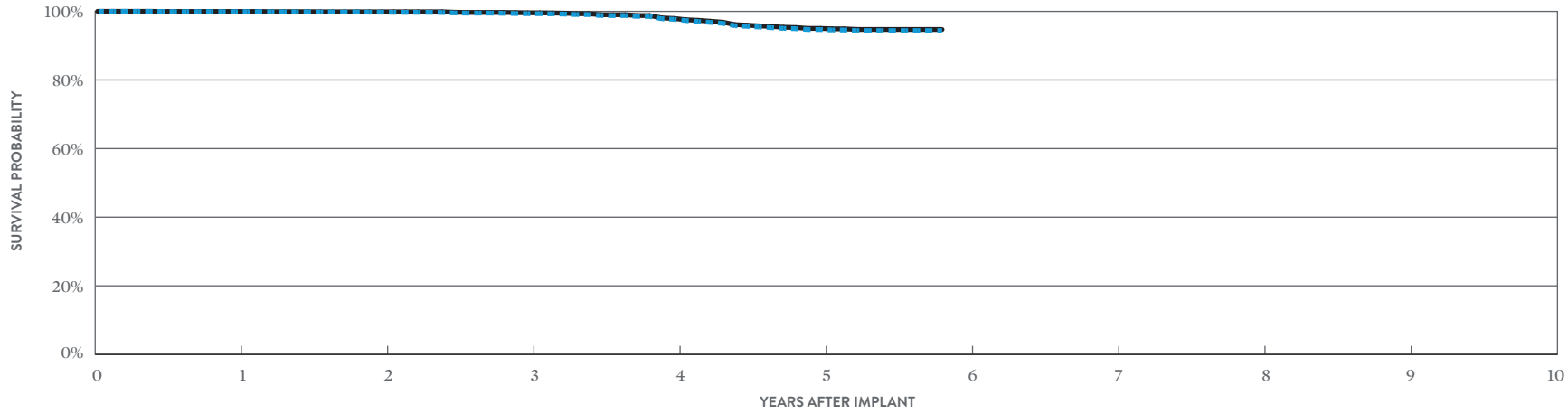
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

MODEL CD1257-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	5,077
Estimated Active US Implants	2,811
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	6
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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	0.02%	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	12	0.24%	47	0.93%
Other	1	0.02%	0	0.00%
Total	**14**	**0.28%**	**50**	**0.98%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.92%	99.77%	99.33%	97.69%	94.71%	94.40%
± 1 STANDARD ERROR	0.04%	0.07%	0.12%	0.25%	0.41%	0.44%
SAMPLE SIZE	4,790	4,260	3,800	3,320	2,330	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 70 MONTHS
SURVIVAL PROBABILITY	99.96%	99.87%	99.57%	97.93%	95.04%	94.73%
± 1 STANDARD ERROR	0.03%	0.05%	0.10%	0.23%	0.40%	0.43%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

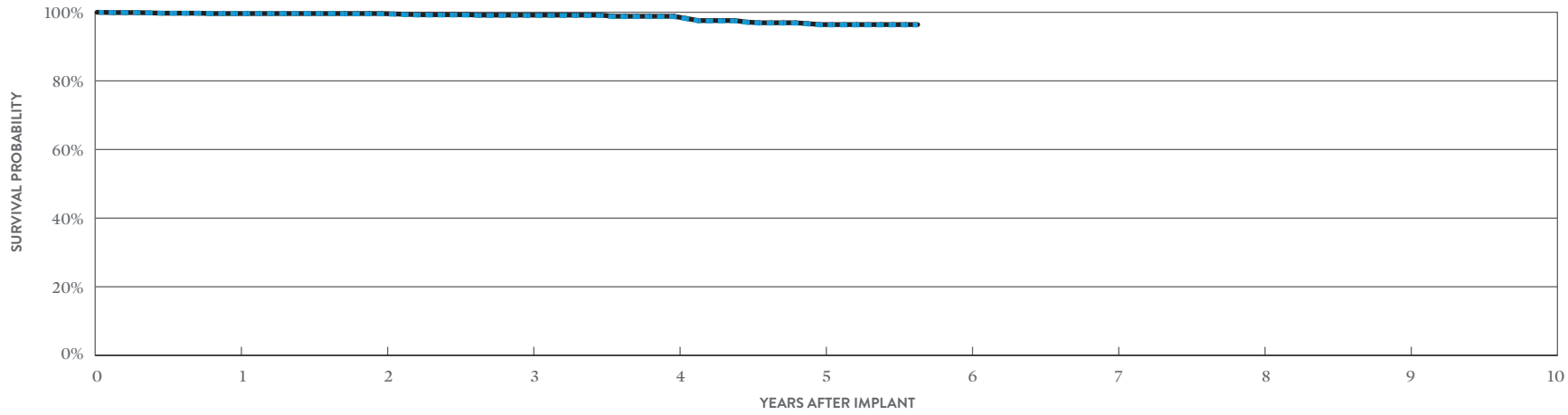
CUSTOMER REPORTED PERFORMANCE DATA

Fortify Assura™ VR

MODEL CD1257-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2012
Registered US Implants	2,294
Estimated Active US Implants	1,260
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	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	3	0.13%	10	0.44%
Other	1	0.04%	1	0.04%
Total	**8**	**0.35%**	**13**	**0.57%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 68 MONTHS
SURVIVAL PROBABILITY	99.63%	99.52%	99.06%	98.72%	96.30%	96.30%
± 1 STANDARD ERROR	0.13%	0.15%	0.22%	0.27%	0.50%	0.54%
SAMPLE SIZE	2,150	1,900	1,690	1,440	990	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 68 MONTHS
SURVIVAL PROBABILITY	99.63%	99.63%	99.17%	98.83%	96.41%	96.41%
± 1 STANDARD ERROR	0.13%	0.13%	0.21%	0.26%	0.50%	0.53%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

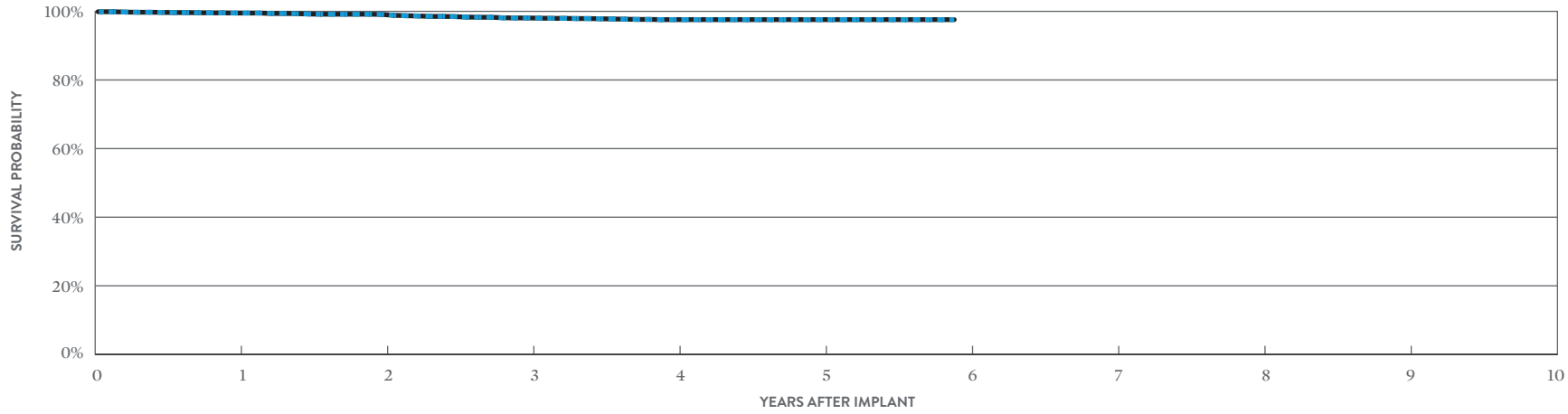
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ VR

MODEL CD1311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	4,742
Estimated Active US Implants	2,779
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	0.02%	1	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	31	0.65%	3	0.06%
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%	2	0.04%
Total	**35**	**0.74%**	**6**	**0.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 71 MONTHS
SURVIVAL PROBABILITY	99.51%	99.11%	98.08%	97.59%	97.59%	97.59%
± 1 STANDARD ERROR	0.10%	0.14%	0.22%	0.25%	0.25%	0.25%
SAMPLE SIZE	4,470	3,980	3,560	3,190	2,380	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 71 MONTHS
SURVIVAL PROBABILITY	99.51%	99.11%	98.08%	97.59%	97.59%	97.59%
± 1 STANDARD ERROR	0.10%	0.14%	0.22%	0.25%	0.25%	0.25%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

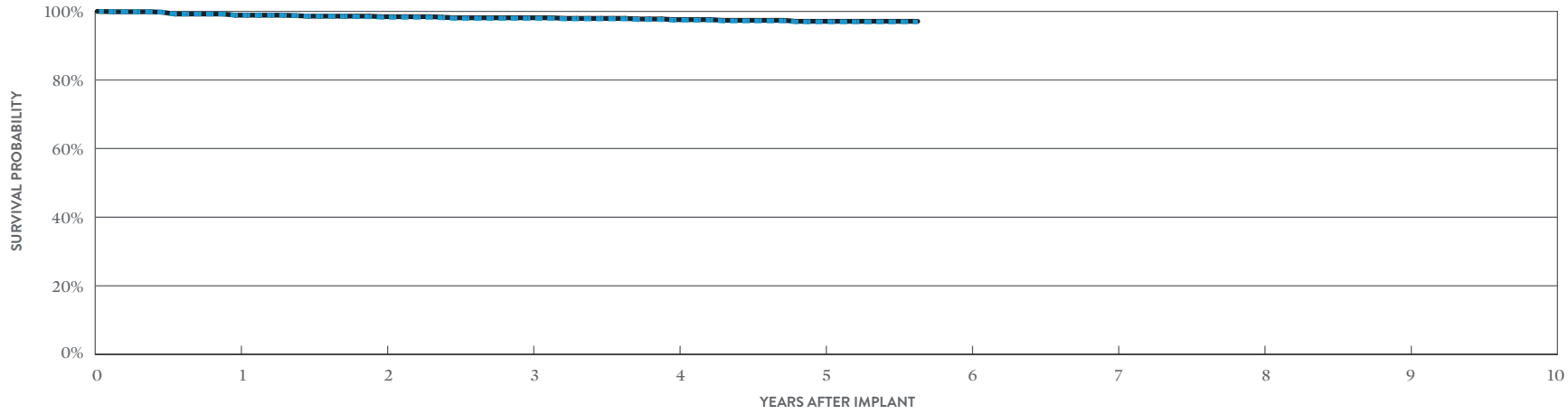
CUSTOMER REPORTED PERFORMANCE DATA

Ellipse™ VR

MODEL CD1311-36

US Regulatory Approval	May 2012
Registered US Implants	1,620
Estimated Active US Implants	943
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 324, 326)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.19%	0	0.00%
Electrical Interconnect	1	0.06%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	7	0.43%	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	0	0.00%	0	0.00%
Total	**13**	**0.80%**	**4**	**0.25%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 68 MONTHS
SURVIVAL PROBABILITY	98.88%	98.30%	97.98%	97.44%	96.95%	96.95%
± 1 STANDARD ERROR	0.22%	0.32%	0.37%	0.41%	0.49%	0.49%
SAMPLE SIZE	1,530	1,370	1,230	1,100	800	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	AT 68 MONTHS
SURVIVAL PROBABILITY	98.88%	98.45%	98.13%	97.58%	97.10%	97.10%
± 1 STANDARD ERROR	0.22%	0.30%	0.36%	0.40%	0.48%	0.48%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

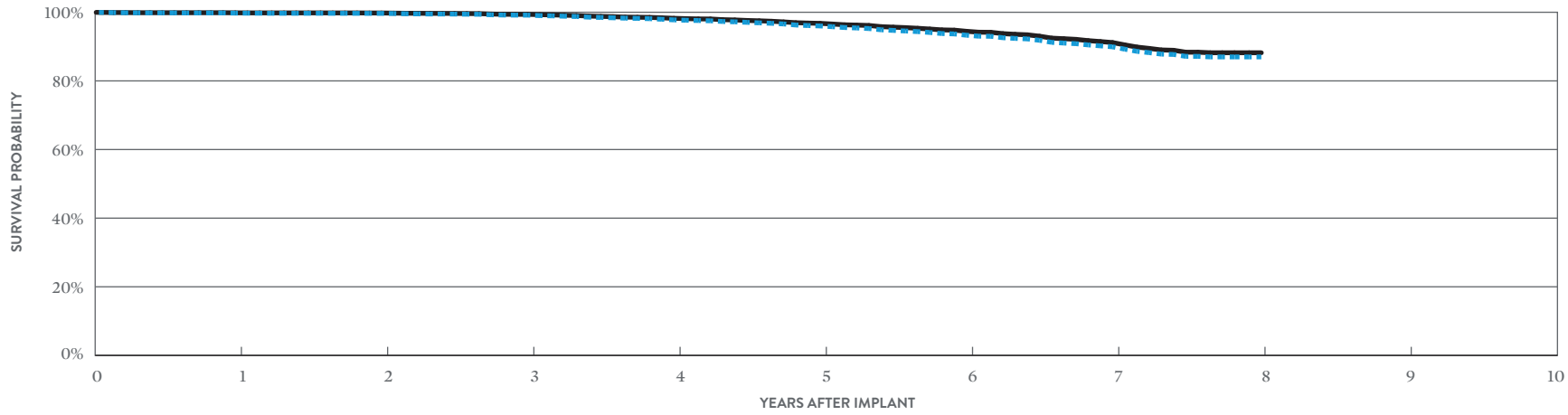
CUSTOMER REPORTED PERFORMANCE DATA

Fortify™ VR

MODEL CD1231-40Q* (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	16,186
Estimated Active US Implants	7,375
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	52
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	7	0.04%	6	0.04%
Electrical Interconnect	2	0.01%	0	0.00%
Battery	16	0.10%	43	0.27%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	99	0.61%	131	0.81%
Other	6	0.04%	2	0.01%
Total	**131**	**0.81%**	**182**	**1.12%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.75%	99.67%	99.16%	97.78%	96.01%	93.31%	89.93%	86.99%
± 1 STANDARD ERROR	0.04%	0.05%	0.08%	0.13%	0.19%	0.25%	0.35%	0.49%
SAMPLE SIZE	15,130	13,340	11,980	10,750	9,520	7,860	4,920	350

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8
SURVIVAL PROBABILITY	99.84%	99.79%	99.39%	98.24%	96.77%	94.45%	91.17%	88.20%
± 1 STANDARD ERROR	0.03%	0.04%	0.07%	0.12%	0.17%	0.23%	0.33%	0.48%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

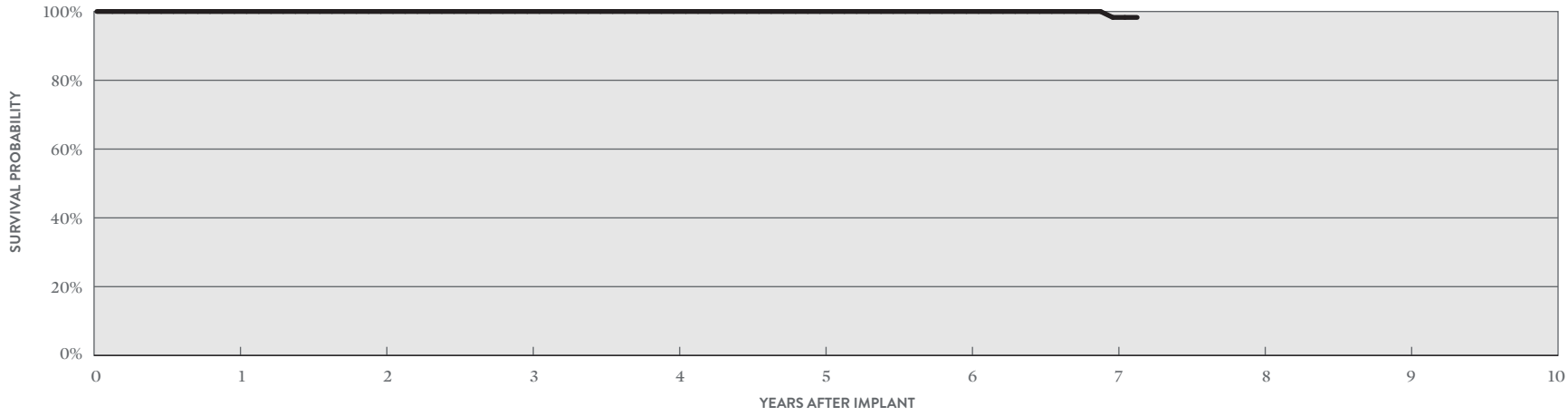
Fortify™ VR

MODEL CD1231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	159
Active Devices Enrolled in Study	72
Cumulative Months of Follow-up	9,943
Estimated Longevity	(see table on page 152)
Max. Delivered Energy	40 joules

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	1	0.63%

	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	1.26%	2	1.26%
Other	0	0.00%	0	0.00%
Total	**3**	**1.89%**	**3**	**1.89%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	AT 86 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	98.28%	98.28%
± 1 STANDARD ERROR	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	1.71%
SAMPLE SIZE	160	150	130	110	100	90	70	50

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

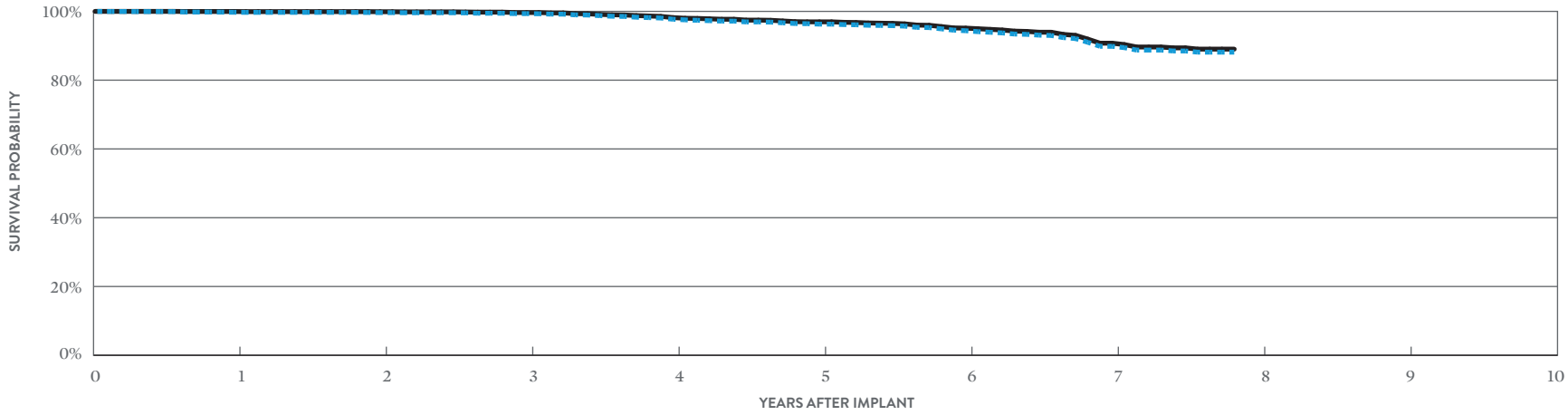
CUSTOMER REPORTED PERFORMANCE DATA

Fortify™ VR

MODEL CD1231-40 (BATTERY ADVISORY POPULATION)

US Regulatory Approval	May 2010
Registered US Implants	6,781
Estimated Active US Implants	3,015
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	17
Max. Delivered Energy	40 joules
Number of US Advisories (see pgs. 324, 325)	Three

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	0.03%	5	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.06%	10	0.15%
High Voltage Capacitor	7	0.10%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	34	0.50%	50	0.74%
Other	4	0.06%	3	0.04%
Total	**51**	**0.75%**	**69**	**1.02%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 94 MONTHS
SURVIVAL PROBABILITY	99.74%	99.64%	99.35%	97.72%	96.29%	94.37%	89.84%	88.14%
± 1 STANDARD ERROR	0.06%	0.07%	0.11%	0.20%	0.28%	0.36%	0.60%	0.72%
SAMPLE SIZE	6,360	5,610	4,980	4,430	3,920	3,250	2,020	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	AT 94 MONTHS
SURVIVAL PROBABILITY	99.97%	99.90%	99.67%	98.19%	96.96%	95.13%	90.75%	89.03%
± 1 STANDARD ERROR	0.02%	0.03%	0.08%	0.18%	0.26%	0.34%	0.58%	0.72%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

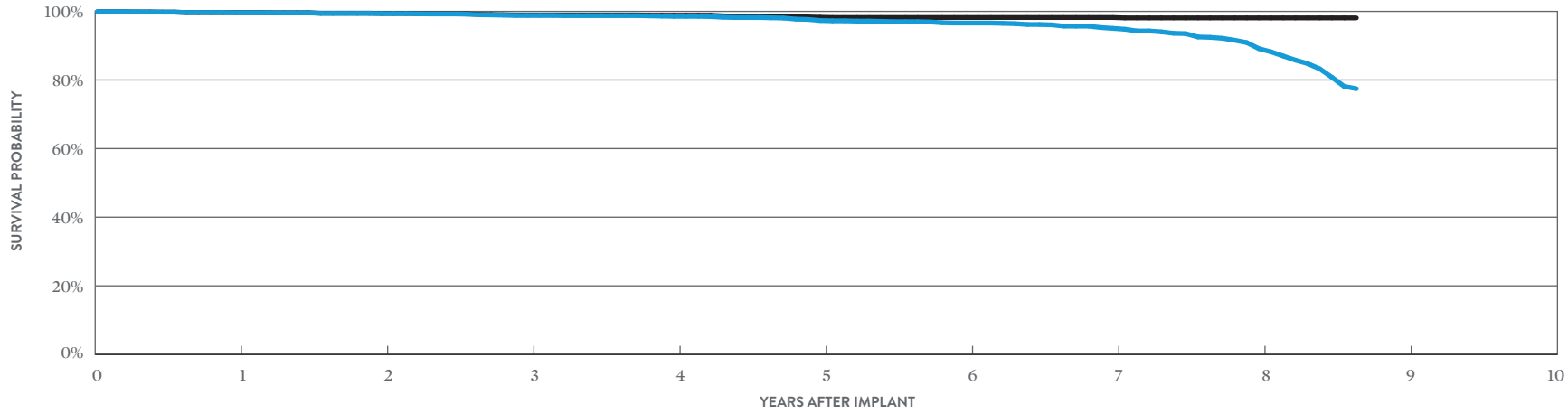
CUSTOMER REPORTED PERFORMANCE DATA

Current™ + VR

MODEL CD1211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	4,431
Estimated Active US Implants	1,679
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	113
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	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%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	6	0.14%	1	0.02%
Other	2	0.05%	2	0.05%
Total	**18**	**0.41%**	**9**	**0.20%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	99.61%	99.36%	98.83%	98.55%	97.34%	96.60%	95.05%	89.13%	77.46%
± 1 STANDARD ERROR	0.09%	0.12%	0.18%	0.20%	0.28%	0.34%	0.42%	0.62%	1.32%
SAMPLE SIZE	4,110	3,600	3,220	2,880	2,560	2,270	2,020	1,700	300

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	99.66%	99.41%	98.95%	98.87%	98.29%	98.21%	98.21%	98.10%	98.10%
± 1 STANDARD ERROR	0.09%	0.12%	0.17%	0.18%	0.23%	0.24%	0.24%	0.25%	0.25%

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

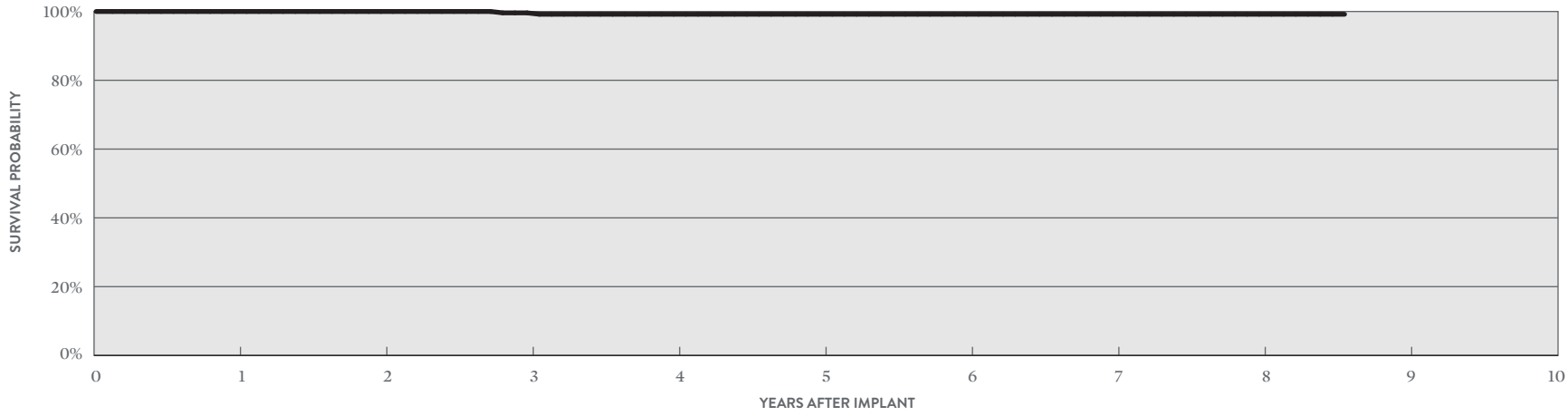
Current™ + VR

MODEL CD1211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	363
Active Devices Enrolled in Study	162
Cumulative Months of Follow-up	22,997
Estimated Longevity	(see table on page 152)
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%	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	**1**	**0.28%**	**0**	**0.00%**



ACTIVELY MONITORED STUDY DATA

YEAR	1	2	3	4	5	6	7	8	AT 103 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%	99.60%	99.20%	99.20%	99.20%	99.20%	99.20%	99.20%
± 1 STANDARD ERROR	0.00%	0.00%	0.40%	0.57%	0.57%	0.57%	0.57%	0.57%	0.57%
SAMPLE SIZE	350	310	260	230	200	180	170	160	70

**DF4-LLHH connector type.*

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

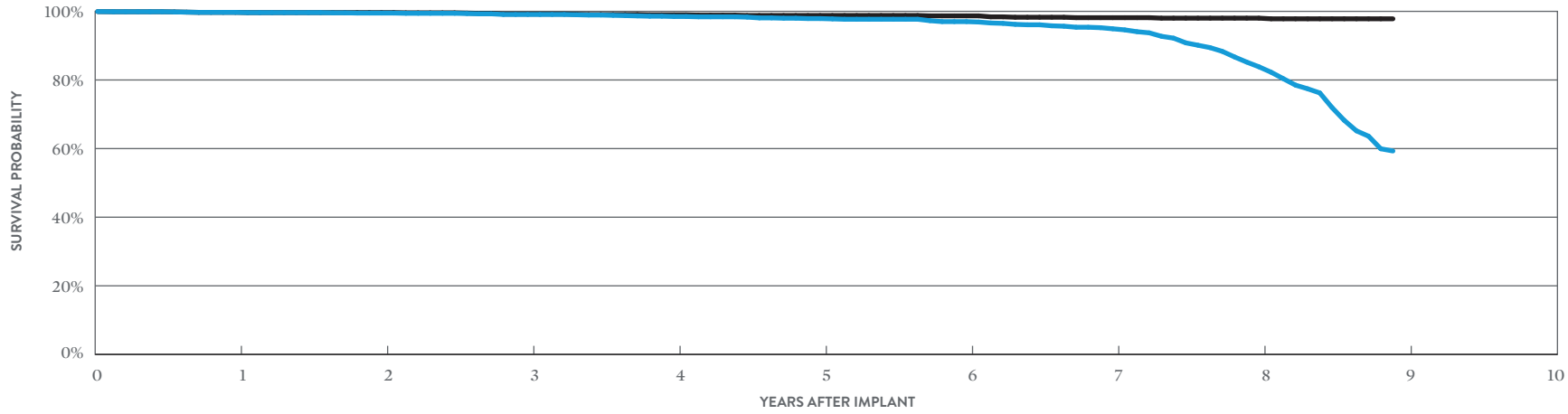
CUSTOMER REPORTED PERFORMANCE DATA

Current™ + VR

MODEL CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,637
Estimated Active US Implants	1,185
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	160
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	3	0.08%	3	0.08%
Electrical Interconnect	2	0.05%	0	0.00%
Battery	4	0.11%	0	0.00%
High Voltage Capacitor	2	0.05%	0	0.00%
Software/Firmware	0	0.00%	1	0.03%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	4	0.11%	2	0.05%
Other	1	0.03%	1	0.03%
Total	**16**	**0.44%**	**7**	**0.19%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.71%	99.50%	99.09%	98.50%	97.90%	97.01%	94.92%	83.84%	59.30%
± 1 STANDARD ERROR	0.09%	0.12%	0.18%	0.23%	0.29%	0.36%	0.47%	0.90%	1.78%
SAMPLE SIZE	3,380	2,970	2,660	2,380	2,130	1,870	1,610	1,290	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.71%	99.64%	99.23%	98.98%	98.80%	98.69%	98.16%	98.02%	97.83%
± 1 STANDARD ERROR	0.09%	0.10%	0.16%	0.19%	0.21%	0.22%	0.28%	0.30%	0.33%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

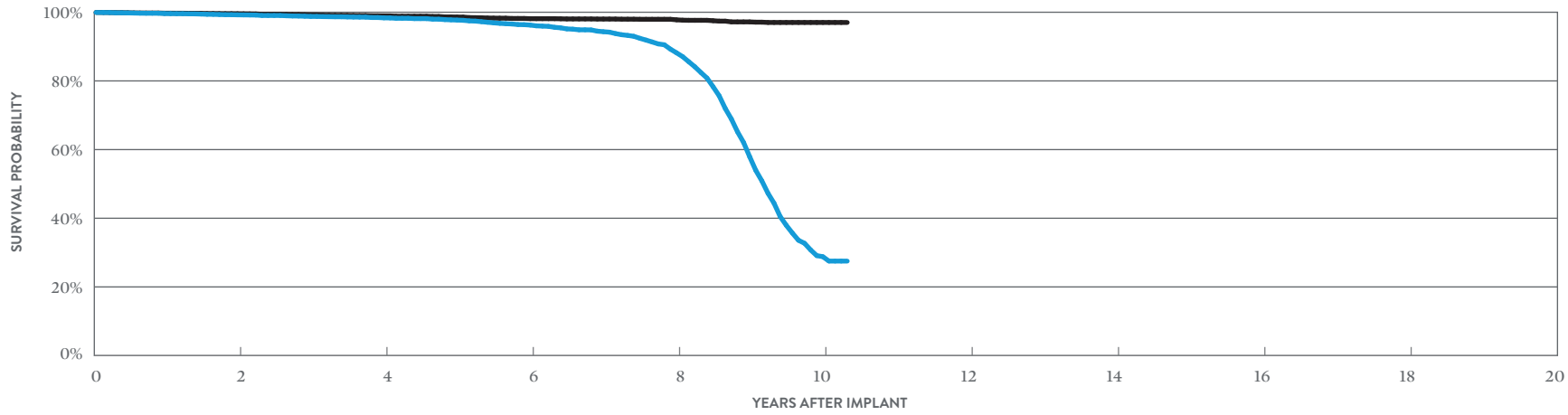
CUSTOMER REPORTED PERFORMANCE DATA

Current™ VR RF

MODEL 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,292
Estimated Active US Implants	2,649
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1,246
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 324)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	6	0.05%	8	0.06%
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	0	0.00%	5	0.04%
Mechanical	0	0.00%	4	0.03%
Possible Early Battery Depletion	13	0.10%	16	0.12%
Other	9	0.07%	6	0.05%
Total	**49**	**0.37%**	**45**	**0.34%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.24%	98.36%	96.26%	88.18%	28.81%	27.52%
± 1 STANDARD ERROR	0.08%	0.12%	0.21%	0.38%	0.78%	0.81%
SAMPLE SIZE	10,730	8,520	6,870	5,360	1,550	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.57%	98.94%	98.12%	97.79%	97.02%	97.02%
± 1 STANDARD ERROR	0.06%	0.10%	0.14%	0.16%	0.22%	0.22%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

ACTIVELY MONITORED STUDY DATA

Current™ VR RF

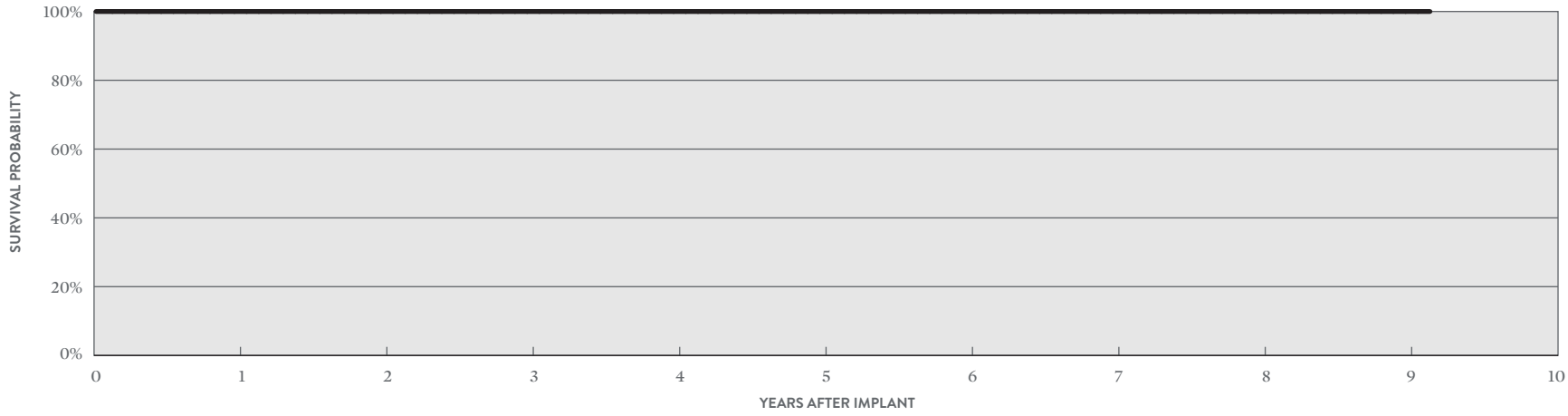
MODEL 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	395
Active Devices Enrolled in Study	43
Cumulative Months of Follow-up	21,819
Estimated Longevity	(see table on page 152)
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	220	170	140	120	100	70	50

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

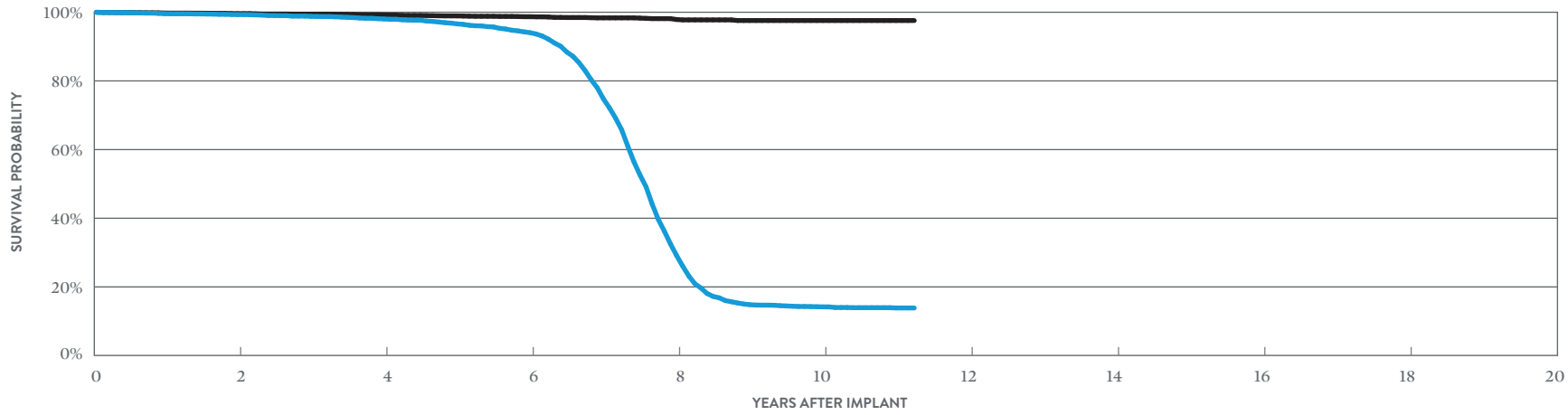
CUSTOMER REPORTED PERFORMANCE DATA

Atlas™ II VR

MODEL V-168

US Regulatory Approval	July 2006
Registered US Implants	10,605
Estimated Active US Implants	1,040
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	1,827
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 329)	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	AT 135 MONTHS
SURVIVAL PROBABILITY	99.31%	98.04%	94.04%	29.18%	14.19%	13.87%
± 1 STANDARD ERROR	0.08%	0.15%	0.30%	0.65%	0.45%	0.45%
SAMPLE SIZE	8,640	6,610	5,120	2,730	930	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	99.60%	99.21%	98.70%	97.88%	97.59%	97.59%
± 1 STANDARD ERROR	0.06%	0.10%	0.14%	0.19%	0.26%	0.26%

Single-Chamber Implantable Cardioverter Defibrillator (ICD) Devices

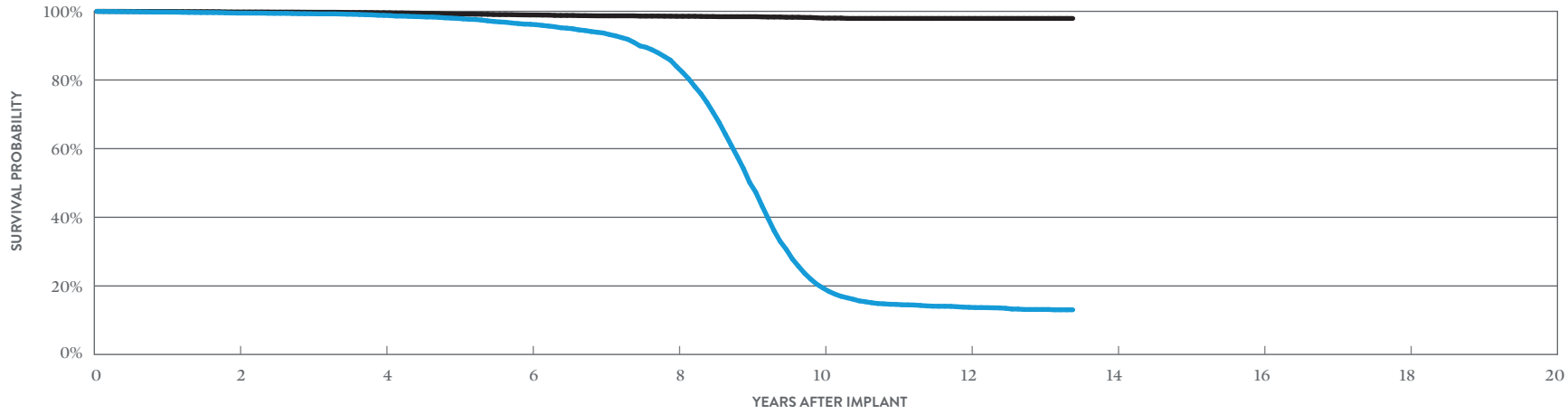
CUSTOMER REPORTED PERFORMANCE DATA

Atlas™ + VR

MODEL V-193

US Regulatory Approval	October 2003
Registered US Implants	20,794
Estimated Active US Implants	1,655
Estimated Longevity	(see table on page 152)
Normal Battery Depletion	2,922
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 329, 330, 331)	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	AT 161 MONTHS
SURVIVAL PROBABILITY	99.49%	98.82%	96.23%	83.93%	19.42%	13.77%	13.05%
± 1 STANDARD ERROR	0.05%	0.09%	0.18%	0.38%	0.43%	0.35%	0.36%
SAMPLE SIZE	16,910	12,900	9,680	7,040	3,170	1,260	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 161 MONTHS
SURVIVAL PROBABILITY	99.81%	99.60%	98.94%	98.56%	98.03%	97.93%	97.93%
± 1 STANDARD ERROR	0.03%	0.05%	0.09%	0.11%	0.16%	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. 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	99.79%	99.56%	99.48%	99.31%						
CD1411-36C	Ellipse™ VR	99.91%	99.91%	99.91%	99.70%						
CD1357-40Q	Fortify Assura™ VR	99.90%	99.86%								
CD1357-40Q	Fortify Assura™ VR†	99.74%	99.28%	97.24%	92.92%						
CD1357-40C	Fortify Assura™ VR	99.93%	99.81%								
CD1357-40C	Fortify Assura™ VR†	99.80%	99.31%	98.02%	93.86%						
CD1257-40Q	Fortify Assura™ VR†	99.92%	99.77%	99.33%	97.69%	94.71%					
CD1257-40	Fortify Assura™ VR†	99.63%	99.52%	99.06%	98.72%	96.30%					
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.08%	97.59%	97.59%					
CD1311-36	Ellipse™ VR	98.88%	98.30%	97.98%	97.44%	96.95%					
CD1231-40Q	Fortify™ VR†	99.75%	99.67%	99.16%	97.78%	96.01%	93.31%	89.93%	86.99%		
CD1231-40	Fortify™ VR†	99.74%	99.64%	99.35%	97.72%	96.29%	94.37%	89.84%			
CD1211-36Q	Current™ + VR	99.61%	99.36%	98.83%	98.55%	97.34%	96.60%	95.05%	89.13%		
CD1211-36	Current™ + VR	99.71%	99.50%	99.09%	98.50%	97.90%	97.01%	94.92%	83.84%		
1207-36	Current™ VR RF	99.62%	99.24%	98.78%	98.36%	97.72%	96.26%	94.33%	88.18%	57.91%	28.81%
V-168	Atlas™ II VR	99.58%	99.31%	98.80%	98.04%	96.61%	94.04%	74.79%	29.18%	14.83%	14.19%
V-193	Atlas™ + VR	99.78%	99.49%	99.30%	98.82%	97.94%	96.23%	93.69%	83.93%	50.11%	19.42%

†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	99.82%	99.75%	99.67%	99.50%						
CD1411-36C	Ellipse™ VR	99.91%	99.91%	99.91%	99.91%						
CD1357-40Q	Fortify Assura™ VR	99.94%	99.94%								
CD1357-40Q	Fortify Assura™ VR†	99.77%	99.35%	97.30%	93.11%						
CD1357-40C	Fortify Assura™ VR	99.93%	99.93%								
CD1357-40C	Fortify Assura™ VR†	99.90%	99.50%	98.21%	94.04%						
CD1257-40Q	Fortify Assura™ VR†	99.96%	99.87%	99.57%	97.93%	95.04%					
CD1257-40	Fortify Assura™ VR†	99.63%	99.63%	99.17%	98.83%	96.41%					
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.08%	97.59%	97.59%					
CD1311-36	Ellipse™ VR	98.88%	98.45%	98.13%	97.58%	97.10%					
CD1231-40Q	Fortify™ VR†	99.84%	99.79%	99.39%	98.24%	96.77%	94.45%	91.17%	88.20%		
CD1231-40	Fortify™ VR†	99.97%	99.90%	99.67%	98.19%	96.96%	95.13%	90.75%			
CD1211-36Q	Current™ + VR	99.66%	99.41%	98.95%	98.87%	98.29%	98.21%	98.21%	98.10%		
CD1211-36	Current™ + VR	99.71%	99.64%	99.23%	98.98%	98.80%	98.69%	98.16%	98.02%		
1207-36	Current™ VR RF	99.73%	99.57%	99.20%	98.94%	98.61%	98.12%	98.02%	97.79%	97.19%	97.02%
V-168	Atlas™ II VR	99.77%	99.60%	99.44%	99.21%	98.93%	98.70%	98.36%	97.88%	97.59%	97.59%
V-193	Atlas™ + VR	99.95%	99.81%	99.74%	99.60%	99.19%	98.94%	98.69%	98.56%	98.45%	98.03%

†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	14,526	2.70%	3	0.02%	0	0.00%	0	0.00%	6	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**9**	**0.06%**
CD1411-36C	Ellipse™ VR	5,687	3.50%	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**	**0.00%**
CD1357-40Q	Fortify Assura™ VR	12,800	2.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**
CD1357-40Q	Fortify Assura™ VR†	10,215	8.50%	3	0.03%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	23	0.23%	3	0.03%	**31**	**0.30%**
CD1357-40C	Fortify Assura™ VR	3,887	2.40%	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%**
CD1357-40C	Fortify Assura™ VR†	4,131	10.40%	3	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	4	0.10%	0	0.00%	**8**	**0.19%**
CD1257-40Q	Fortify Assura™ VR†	5,077	9.70%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	12	0.24%	1	0.02%	**14**	**0.28%**
CD1257-40	Fortify Assura™ VR†	2,294	12.10%	1	0.04%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	3	0.13%	1	0.04%	**8**	**0.35%**
CD1311-36Q	Ellipse™ VR	4,742	6.90%	1	0.02%	0	0.00%	0	0.00%	31	0.65%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**35**	**0.74%**
CD1311-36	Ellipse™ VR	1,620	9.00%	3	0.19%	1	0.06%	0	0.00%	7	0.43%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**13**	**0.80%**
CD1231-40Q	Fortify™ VR†	16,186	11.90%	7	0.04%	2	0.01%	16	0.10%	1	<0.01%	0	0.00%	0	0.00%	99	0.61%	6	0.04%	**131**	**0.81%**
CD1231-40	Fortify™ VR†	6,781	13.40%	2	0.03%	0	0.00%	4	0.06%	7	0.10%	0	0.00%	0	0.00%	34	0.50%	4	0.06%	**51**	**0.75%**
CD1211-36Q	Current™ + VR	4,431	12.10%	4	0.09%	0	0.00%	5	0.11%	1	0.02%	0	0.00%	0	0.00%	6	0.14%	2	0.05%	**18**	**0.41%**
CD1211-36	Current™ + VR	3,637	14.20%	3	0.08%	2	0.05%	4	0.11%	2	0.05%	0	0.00%	0	0.00%	4	0.11%	1	0.03%	**16**	**0.44%**
1207-36	Current™ VR RF	13,292	20.90%	6	0.05%	10	0.08%	10	0.08%	1	<0.01%	0	0.00%	0	0.00%	13	0.10%	9	0.07%	**49**	**0.37%**
V-168	Atlas™ II VR	10,605	27.70%	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	25.30%	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	14,526	2.70%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	2	0.01%	0	0.00%	2	0.01%	**6**	**0.04%**
CD1411-36C	Ellipse™ VR	5,687	3.50%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.04%**
CD1357-40Q	Fortify Assura™ VR	12,800	2.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD1357-40Q	Fortify Assura™ VR†	10,215	8.50%	8	0.08%	0	0.00%	4	0.04%	0	0.00%	0	0.00%	0	0.00%	106	1.04%	3	0.03%	**121**	**1.18%**
CD1357-40C	Fortify Assura™ VR	3,887	2.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	**1**	**0.03%**
CD1357-40C	Fortify Assura™ VR†	4,131	10.40%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	1	0.02%	0	0.00%	30	0.73%	0	0.00%	**33**	**0.80%**
CD1257-40Q	Fortify Assura™ VR†	5,077	9.70%	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	47	0.93%	0	0.00%	**50**	**0.98%**
CD1257-40	Fortify Assura™ VR†	2,294	12.10%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	10	0.44%	1	0.04%	**13**	**0.57%**
CD1311-36Q	Ellipse™ VR	4,742	6.90%	1	0.02%	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	**6**	**0.13%**
CD1311-36	Ellipse™ VR	1,620	9.00%	0	0.00%	0	0.00%	0	0.00%	2	0.12%	1	0.06%	1	0.06%	0	0.00%	0	0.00%	**4**	**0.25%**
CD1231-40Q	Fortify™ VR†	16,186	11.90%	6	0.04%	0	0.00%	43	0.27%	0	0.00%	0	0.00%	0	0.00%	131	0.81%	2	0.01%	**182**	**1.12%**
CD1231-40	Fortify™ VR†	6,781	13.40%	5	0.07%	0	0.00%	10	0.15%	0	0.00%	0	0.00%	1	0.01%	50	0.74%	3	0.04%	**69**	**1.02%**
CD1211-36Q	Current™ + VR	4,431	12.10%	3	0.07%	0	0.00%	3	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	2	0.05%	**9**	**0.20%**
CD1211-36	Current™ + VR	3,637	14.20%	3	0.08%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	2	0.05%	1	0.03%	**7**	**0.19%**
1207-36	Current™ VR RF	13,292	20.90%	8	0.06%	0	0.00%	5	0.04%	1	<0.01%	5	0.04%	4	0.03%	16	0.12%	6	0.05%	**45**	**0.34%**
V-168	Atlas™ II VR	10,605	27.70%	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	25.30%	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	14,924	2.89%	3	0.02%	0	0.00%	0	0.00%	6	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**9**	**0.06%**
CD1411-36C	Ellipse™ VR	5,820	4.04%	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	23,328	5.10%	3	0.01%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	23	0.10%	4	0.02%	**32**	**0.14%**
CD1357-40C	Fortify Assura™ VR	8,152	6.99%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	4	0.05%	0	0.00%	**8**	**0.10%**
CD1257-40Q	Fortify Assura™ VR	5,039	10.16%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	12	0.24%	1	0.02%	**14**	**0.28%**
CD1257-40	Fortify Assura™ VR	2,299	12.74%	1	0.04%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	3	0.13%	1	0.04%	**8**	**0.35%**
CD1311-36Q	Ellipse™ VR	4,920	7.32%	1	0.02%	0	0.00%	0	0.00%	31	0.63%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**35**	**0.71%**
CD1311-36	Ellipse™ VR	1,633	10.78%	3	0.18%	1	0.06%	0	0.00%	8	0.49%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**14**	**0.86%**
CD1231-40Q	Fortify™ VR†	17,672	11.50%	7	0.04%	2	0.01%	16	0.09%	2	0.01%	0	0.00%	0	0.00%	109	0.62%	6	0.03%	**142**	**0.80%**
CD1231-40	Fortify™ VR†	8,279	11.81%	2	0.02%	0	0.00%	4	0.05%	7	0.08%	0	0.00%	0	0.00%	35	0.42%	4	0.05%	**52**	**0.63%**
CD1211-36Q	Current™ + VR	16,261	4.24%	11	0.07%	3	0.02%	8	0.05%	4	0.02%	0	0.00%	0	0.00%	8	0.05%	7	0.04%	**41**	**0.25%**
CD1211-36	Current™ + VR	14,877	4.10%	3	0.02%	4	0.03%	4	0.03%	5	0.03%	0	0.00%	0	0.00%	8	0.05%	6	0.04%	**30**	**0.20%**
1207-36	Current™ VR RF	24,846	13.87%	11	0.04%	30	0.12%	17	0.07%	1	<0.01%	0	0.00%	1	<0.01%	30	0.12%	11	0.04%	**101**	**0.41%**
V-168	Atlas™ II VR	23,946	15.27%	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	16.20%	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	14,924	2.89%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	2	0.01%	0	0.00%	2	0.01%	**6**	**0.04%**
CD1411-36C	Ellipse™ VR	5,820	4.04%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
CD1357-40Q	Fortify Assura™ VR	23,328	5.10%	8	0.03%	0	0.00%	4	0.02%	0	0.00%	1	<0.01%	1	<0.01%	106	0.45%	3	0.01%	**123**	**0.53%**
CD1357-40C	Fortify Assura™ VR	8,152	6.99%	1	0.01%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	1	0.01%	30	0.37%	0	0.00%	**35**	**0.43%**
CD1257-40Q	Fortify Assura™ VR	5,039	10.16%	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	48	0.95%	0	0.00%	**51**	**1.01%**
CD1257-40	Fortify Assura™ VR	2,299	12.74%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	10	0.43%	1	0.04%	**13**	**0.57%**
CD1311-36Q	Ellipse™ VR	4,920	7.32%	1	0.02%	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	**6**	**0.12%**
CD1311-36	Ellipse™ VR	1,633	10.78%	0	0.00%	0	0.00%	0	0.00%	2	0.12%	1	0.06%	1	0.06%	0	0.00%	0	0.00%	**4**	**0.24%**
CD1231-40Q	Fortify™ VR†	17,672	11.50%	7	0.04%	1	<0.01%	44	0.25%	0	0.00%	0	0.00%	0	0.00%	138	0.78%	2	0.01%	**192**	**1.09%**
CD1231-40	Fortify™ VR†	8,279	11.81%	5	0.06%	0	0.00%	10	0.12%	0	0.00%	0	0.00%	1	0.01%	51	0.62%	3	0.04%	**70**	**0.85%**
CD1211-36Q	Current™ + VR	16,261	4.24%	6	0.04%	0	0.00%	5	0.03%	1	<0.01%	0	0.00%	0	0.00%	3	0.02%	4	0.02%	**19**	**0.12%**
CD1211-36	Current™ + VR	14,877	4.10%	5	0.03%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	0	0.00%	3	0.02%	1	<0.01%	**12**	**0.08%**
1207-36	Current™ VR RF	24,846	13.87%	14	0.06%	3	0.01%	12	0.05%	1	<0.01%	17	0.07%	8	0.03%	23	0.09%	10	0.04%	**88**	**0.35%**
V-168	Atlas™ II VR	23,946	15.27%	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	16.20%	4	0.01%	3	<0.01%	8	0.02%	1	<0.01%	1	<0.01%	14	0.04%	11	0.03%	13	0.03%	**55**	**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	159	72	9,943	0	0.00%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	**1**	**0.63%**
CD1211-36Q	363	162	22,997	1	0.28%	0	0.00%	0	0.00%	1	0.28%	0	0.00%	**2**	**0.55%**
1207-36	395	43	21,819	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	159	14.50%	0	0.00%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	0	0.00%	2	1.26%	0	0.00%	**3**	**1.89%**
CD1211-36Q	Current™ + VR	363	12.90%	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	29.10%	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%**

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	159	14.50%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	0	0.00%	0	0.00%	2	1.26%	0	0.00%	**3**	**1.89%**
CD1211-36Q	Current™ + VR	363	12.90%	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%**
1207-36	Current™ VR RF	395	29.10%	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

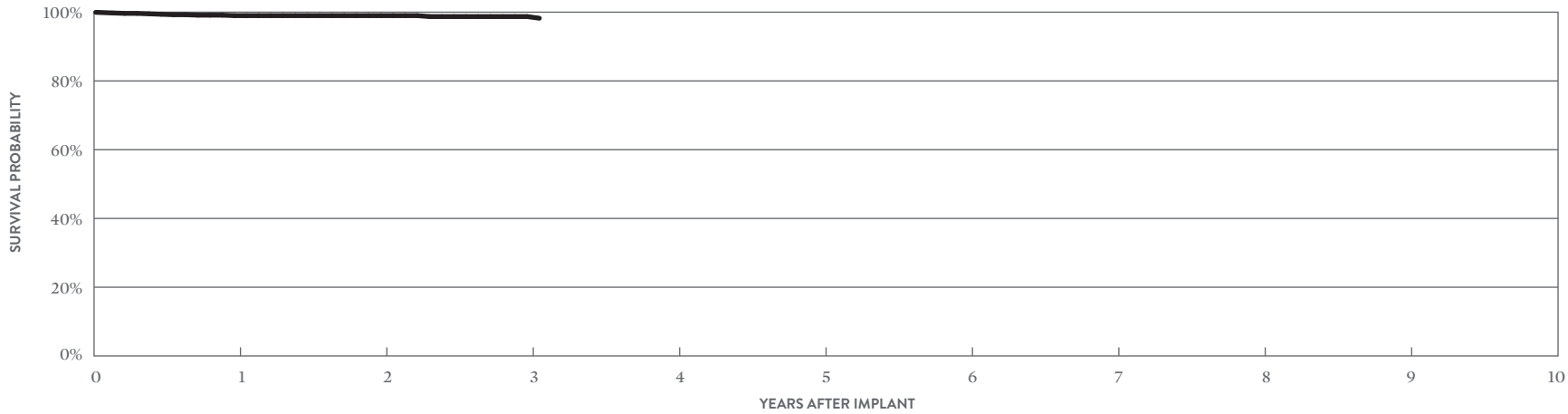
Optisure™ DF4

MODEL LDA230Q

US Regulatory Approval	February 2014
Registered US Implants	910
Estimated Active US Implants	703
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 338)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	1	0.11%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.11%	3	0.33%
Failure to Capture	0	0.00%	3	0.33%
Oversensing	0	0.00%	2	0.22%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.11%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	1	0.11%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.44%**	**8**	**0.88%**
Total Returned for Analysis	**1**		**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	1	0.11%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	0.11%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.66%
Total	**7**	**0.77%**



YEAR	1	2	3	AT 37 MONTHS
SURVIVAL PROBABILITY	98.99%	98.99%	98.72%	98.24%
± 1 STANDARD ERROR	0.33%	0.36%	0.44%	0.44%
SAMPLE SIZE	800	570	340	220

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

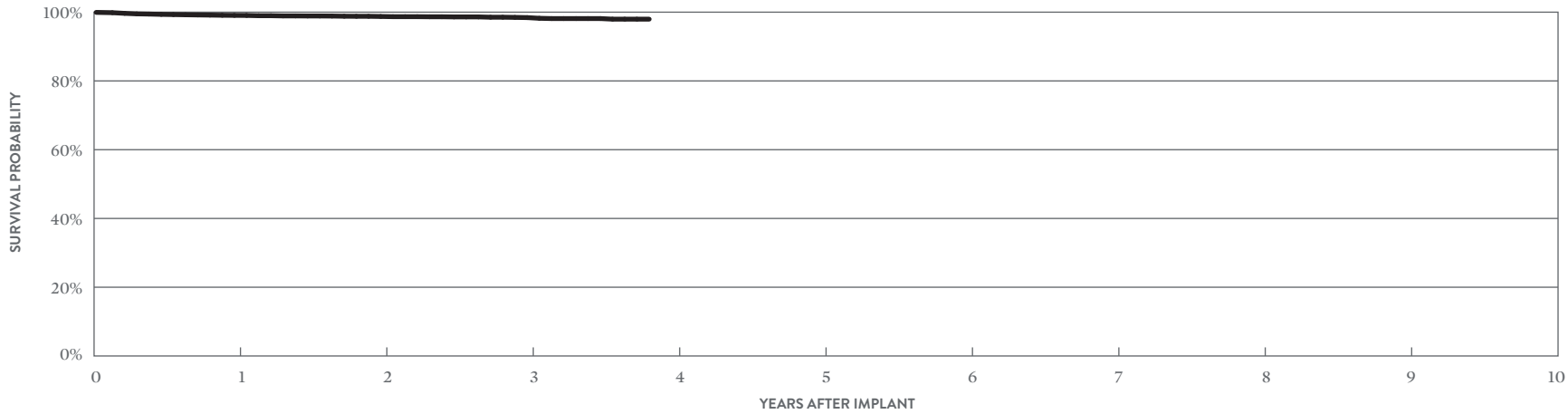
Optisure™ DF4

MODEL LDA220Q

US Regulatory Approval	February 2014
Registered US Implants	7,937
Estimated Active US Implants	6,194
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 338)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	5	0.06%	3	0.04%
Conductor Fracture	0	0.00%	3	0.04%
Lead Dislodgement	26	0.33%	43	0.54%
Failure to Capture	9	0.11%	31	0.39%
Oversensing	3	0.04%	17	0.21%
Failure to Sense	2	0.03%	3	0.04%
Insulation Breach	0	0.00%	1	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	4	0.05%	5	0.06%
Extracardiac Stimulation	1	0.01%	0	0.00%
Other	3	0.04%	2	0.03%
Total	**53**	**0.67%**	**108**	**1.36%**
Total Returned for Analysis	**22**		**39**	

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	0.03%
Lead-to-Can Contact	1	0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	41	0.52%
Total	**43**	**0.54%**



YEAR	1	2	3	AT 46 MONTHS
SURVIVAL PROBABILITY	99.07%	98.75%	98.42%	97.97%
± 1 STANDARD ERROR	0.11%	0.14%	0.18%	0.29%
SAMPLE SIZE	6,740	4,600	2,610	260

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

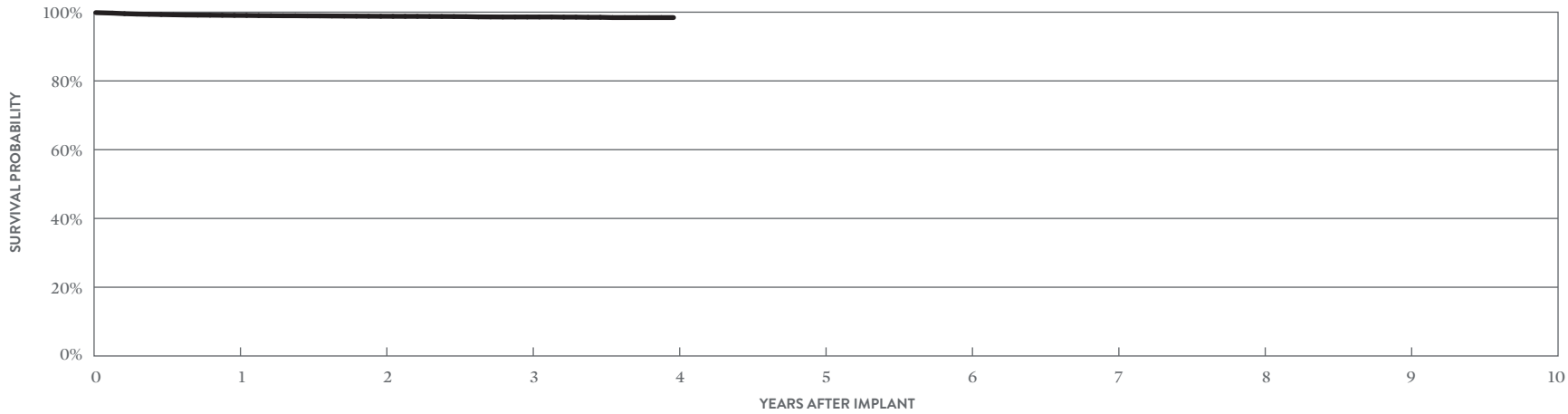
Optisure™ DF4

MODEL LDA210Q

US Regulatory Approval	February 2014
Registered US Implants	25,997
Estimated Active US Implants	20,627
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	34	0.13%	11	0.04%
Conductor Fracture	1	<0.01%	3	0.01%
Lead Dislodgement	79	0.30%	121	0.47%
Failure to Capture	36	0.14%	53	0.20%
Oversensing	11	0.04%	43	0.17%
Failure to Sense	6	0.02%	7	0.03%
Insulation Breach	1	<0.01%	2	<0.01%
Abnormal Pacing Impedance	3	0.01%	4	0.02%
Abnormal Defibrillation Impedance	6	0.02%	10	0.04%
Extracardiac Stimulation	0	0.00%	2	<0.01%
Other	13	0.05%	11	0.04%
Total	**190**	**0.73%**	**267**	**1.03%**
Total Returned for Analysis	**64**		**99**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	3	0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	2	<0.01%
Insulation Breach	3	0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	2	<0.01%
Extrinsic Factors	102	0.39%
Total	**110**	**0.42%**



YEAR	1	2	3	4
SURVIVAL PROBABILITY	99.07%	98.81%	98.60%	98.43%
± 1 STANDARD ERROR	0.06%	0.08%	0.10%	0.14%
SAMPLE SIZE	21,070	12,860	6,560	300

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

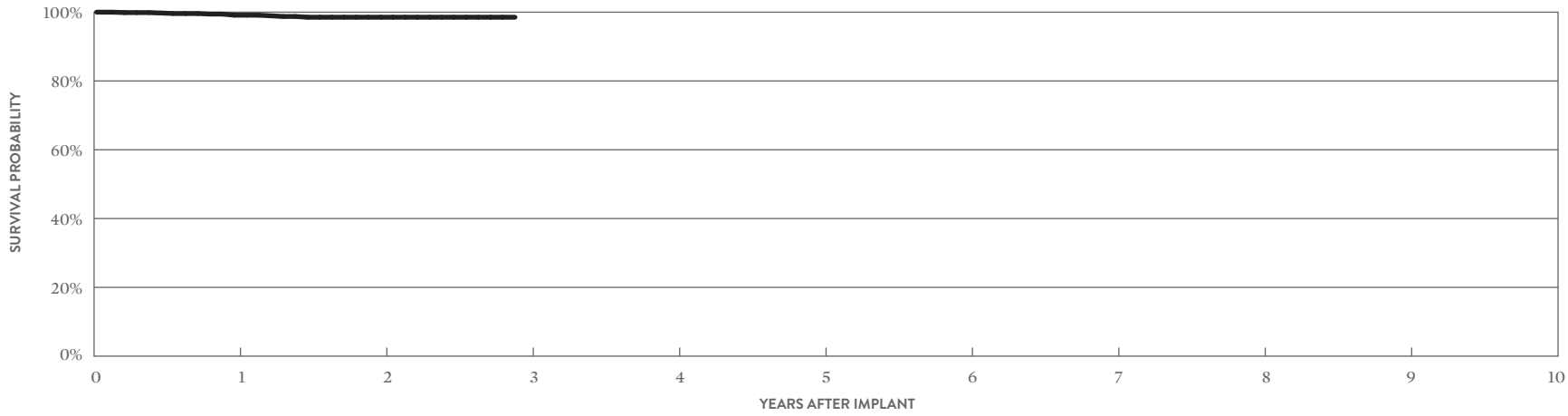
Optisure™ DF4

MODEL LDA210

US Regulatory Approval	February 2014
Registered US Implants	943
Estimated Active US Implants	762
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	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.11%
Lead Dislodgement	2	0.21%	4	0.42%
Failure to Capture	0	0.00%	2	0.21%
Oversensing	1	0.11%	4	0.42%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.11%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.32%**	**12**	**1.27%**
Total Returned for Analysis	**1**		**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	0.64%
Total	**6**	**0.64%**



YEAR	1	2	AT 35 MONTHS
SURVIVAL PROBABILITY	99.13%	98.53%	98.53%
± 1 STANDARD ERROR	0.27%	0.49%	0.49%
SAMPLE SIZE	770	480	210

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

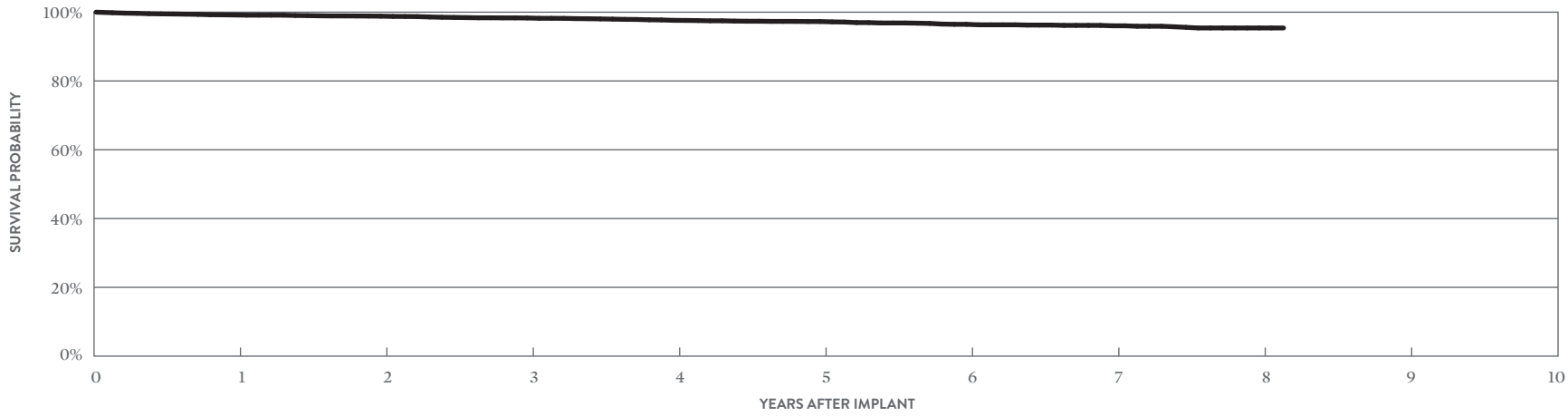
Durata™ DF4

MODELS 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	6,387
Estimated Active US Implants	3,734
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%	6	0.09%
Conductor Fracture	1	0.02%	13	0.20%
Lead Dislodgement	17	0.27%	25	0.39%
Failure to Capture	9	0.14%	53	0.83%
Oversensing	3	0.05%	29	0.45%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	2	0.03%
Abnormal Pacing Impedance	1	0.02%	15	0.23%
Abnormal Defibrillation Impedance	0	0.00%	12	0.19%
Extracardiac Stimulation	1	0.02%	0	0.00%
Other	1	0.02%	1	0.02%
Total	**39**	**0.61%**	**156**	**2.44%**
Total Returned for Analysis	**18**		**44**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	0.03%
Clavicular Crush	0	0.00%
In the Pocket	1	0.02%
Intravascular	1	0.02%
Insulation Breach	6	0.09%
Lead-to-Can Contact	3	0.05%
Lead-to-Lead Contact	3	0.05%
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	40	0.63%
Total	**48**	**0.75%**



YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.19%	98.84%	98.31%	97.63%	97.28%	96.47%	96.04%	95.41%	95.41%
± 1 STANDARD ERROR	0.12%	0.14%	0.18%	0.23%	0.26%	0.34%	0.37%	0.50%	0.50%
SAMPLE SIZE	5,710	4,600	3,810	3,080	2,360	1,690	1,100	540	220

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

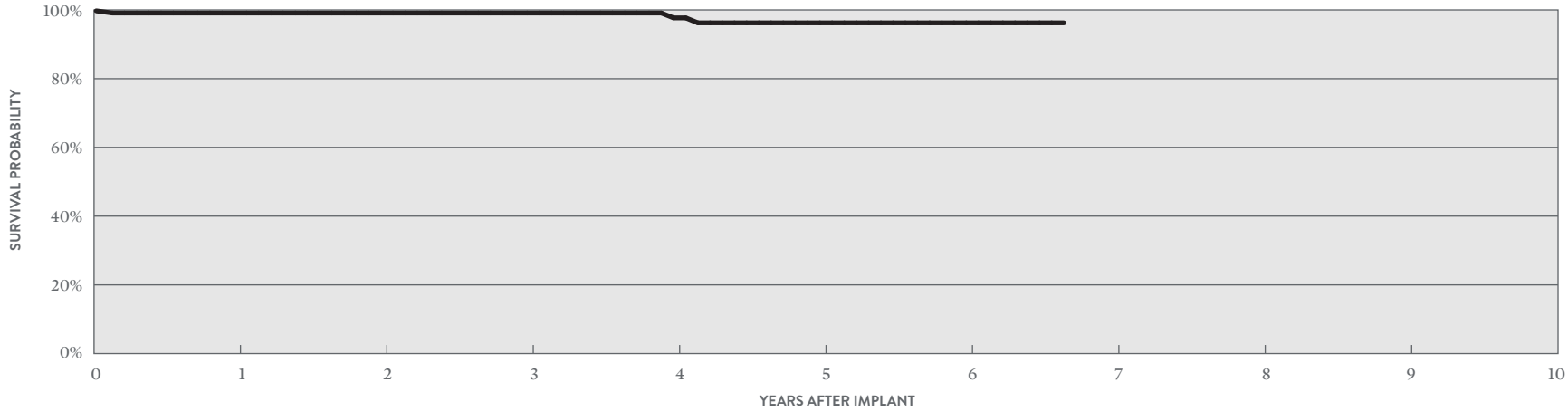
Durata™ DF4

MODELS 7170Q & 7171Q

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	115
Active Devices Enrolled in Study	54
Cumulative Months of Follow-up	6,774
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	AT 80 MONTHS
SURVIVAL PROBABILITY	99.10%	99.10%	99.10%	97.68%	96.24%	96.24%	96.24%
± 1 STANDARD ERROR	0.90%	0.90%	0.90%	0.90%	2.18%	2.18%	2.18%
SAMPLE SIZE	110	100	80	70	60	60	50

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

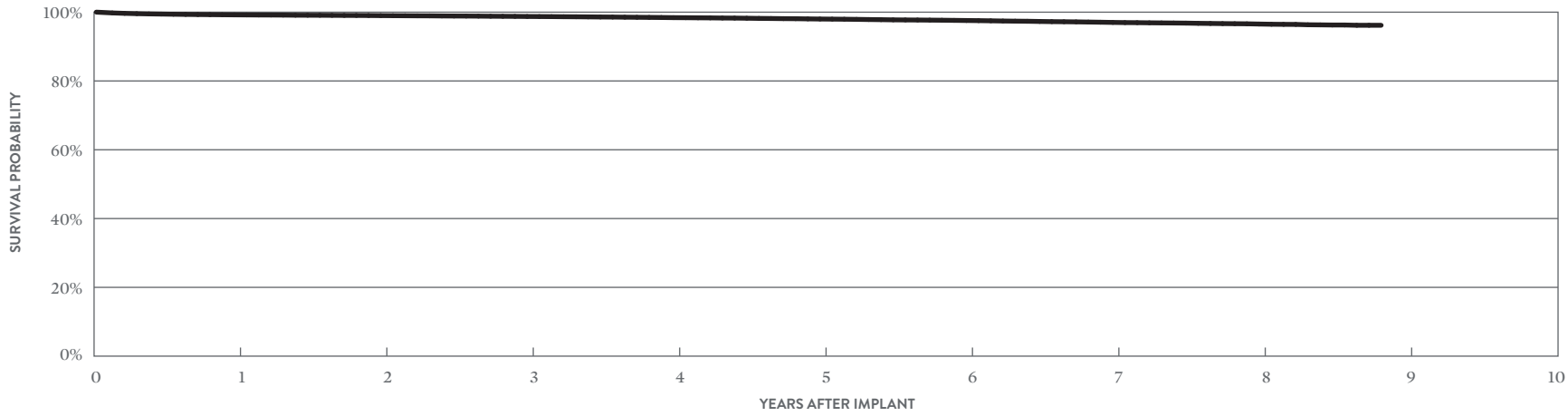
Durata™ DF4

MODELS 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	127,913
Estimated Active US Implants	72,283
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	85	0.07%	38	0.03%
Conductor Fracture	2	<0.01%	134	0.10%
Lead Dislodgement	238	0.19%	586	0.46%
Failure to Capture	108	0.08%	656	0.51%
Oversensing	47	0.04%	545	0.43%
Failure to Sense	14	0.01%	74	0.06%
Insulation Breach	0	0.00%	31	0.02%
Abnormal Pacing Impedance	6	<0.01%	115	0.09%
Abnormal Defibrillation Impedance	10	<0.01%	266	0.21%
Extracardiac Stimulation	3	<0.01%	7	<0.01%
Other	39	0.03%	64	0.05%
Total	**552**	**0.43%**	**2516**	**1.97%**
Total Returned for Analysis	**281**		**929**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	26	0.02%
Clavicular Crush	4	<0.01%
In the Pocket	7	<0.01%
Intravascular	15	0.01%
Insulation Breach	203	0.16%
Lead-to-Can Contact	100	0.08%
Lead-to-Lead Contact	27	0.02%
Clavicular Crush	28	0.02%
Externalized Conductors	0	0.00%
Other	48	0.04%
Crimps, Welds & Bonds	2	<0.01%
Other	36	0.03%
Extrinsic Factors	777	0.61%
Total	**1044**	**0.82%**



YEAR	1	2	3	4	5	6	7	8	AT 106 MONTHS
SURVIVAL PROBABILITY	99.22%	99.00%	98.75%	98.41%	98.01%	97.58%	97.02%	96.55%	96.19%
± 1 STANDARD ERROR	0.03%	0.03%	0.03%	0.04%	0.05%	0.06%	0.07%	0.09%	0.15%
SAMPLE SIZE	116,950	98,670	84,310	70,260	55,800	41,510	27,760	14,200	450

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

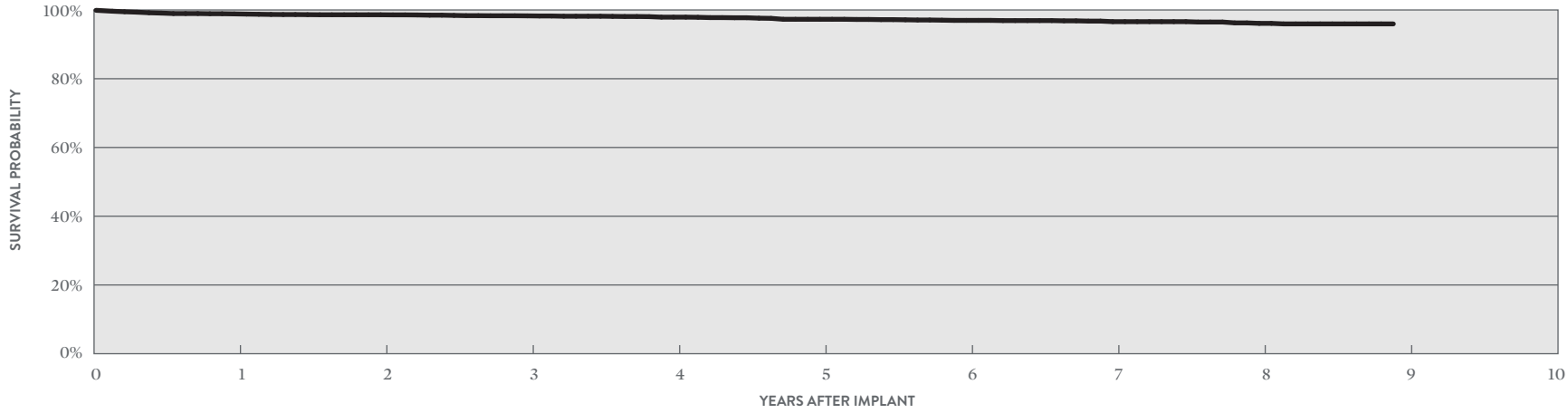
Durata™ DF4

MODELS 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	4,320
Active Devices Enrolled in Study	1,769
Cumulative Months of Follow-up	236,063
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	4	0.09%
Cardiac Perforation	1	0.02%
Conductor Fracture	15	0.35%
Failure to Capture	21	0.49%
Failure to Sense	5	0.12%
Inappropriate Shock	4	0.09%
Insulation Breach	4	0.09%
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	6	0.14%
Lead-to-Can Contact	3	0.07%
Lead-to-Lead Contact	2	0.05%
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	49	1.13%
Total	**61**	**1.41%**



YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	98.86%	98.61%	98.29%	97.91%	97.29%	96.97%	96.60%	96.10%	95.95%
± 1 STANDARD ERROR	0.16%	0.18%	0.21%	0.24%	0.29%	0.32%	0.34%	0.41%	0.46%
SAMPLE SIZE	4,040	3,500	3,040	2,630	2,230	1,830	1,410	940	50

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

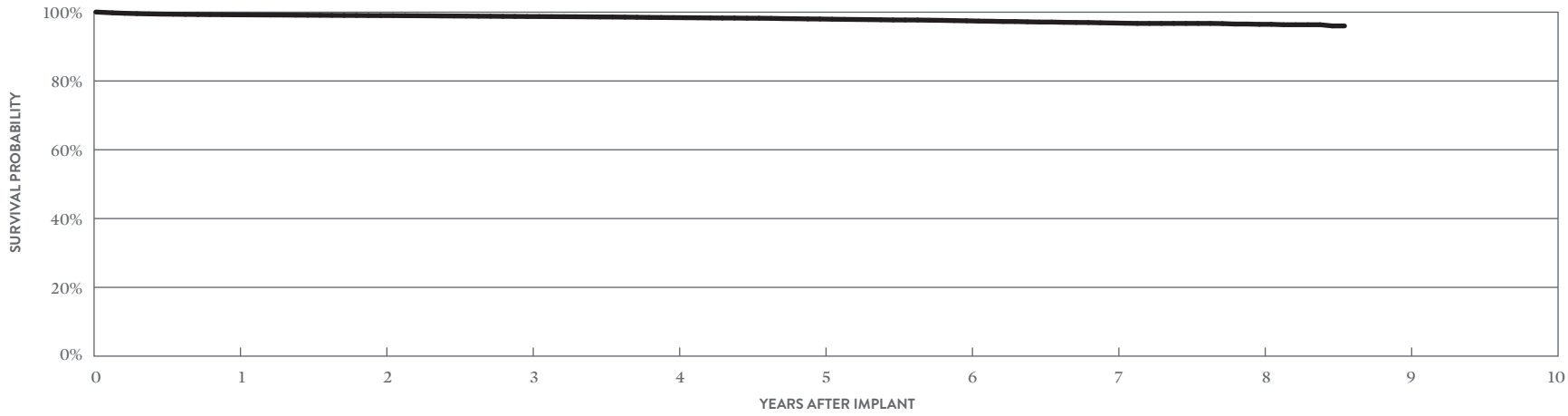
Durata™ DF4

MODEL 7122Q

US Regulatory Approval	January 2009
Registered US Implants	92,792
Estimated Active US Implants	60,471
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	114	0.12%	45	0.05%
Conductor Fracture	3	<0.01%	51	0.05%
Lead Dislodgement	204	0.22%	383	0.41%
Failure to Capture	93	0.10%	295	0.32%
Oversensing	31	0.03%	271	0.29%
Failure to Sense	7	<0.01%	33	0.04%
Insulation Breach	0	0.00%	17	0.02%
Abnormal Pacing Impedance	7	<0.01%	50	0.05%
Abnormal Defibrillation Impedance	8	<0.01%	81	0.09%
Extracardiac Stimulation	3	<0.01%	9	<0.01%
Other	42	0.05%	36	0.04%
Total	**512**	**0.55%**	**1271**	**1.37%**
Total Returned for Analysis	**234**		**569**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	12	0.01%
Clavicular Crush	0	0.00%
In the Pocket	8	<0.01%
Intravascular	4	<0.01%
Insulation Breach	101	0.11%
Lead-to-Can Contact	52	0.06%
Lead-to-Lead Contact	15	0.02%
Clavicular Crush	12	0.01%
Externalized Conductors	0	0.00%
Other	22	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	16	0.02%
Extrinsic Factors	522	0.56%
Total	**651**	**0.70%**



YEAR	1	2	3	4	5	6	7	8	AT 103 MONTHS
SURVIVAL PROBABILITY	99.24%	99.01%	98.74%	98.42%	98.01%	97.49%	96.85%	96.47%	96.00%
± 1 STANDARD ERROR	0.03%	0.04%	0.04%	0.05%	0.07%	0.10%	0.14%	0.19%	0.42%
SAMPLE SIZE	80,460	60,110	45,090	31,770	20,010	11,310	5,920	2,400	230

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

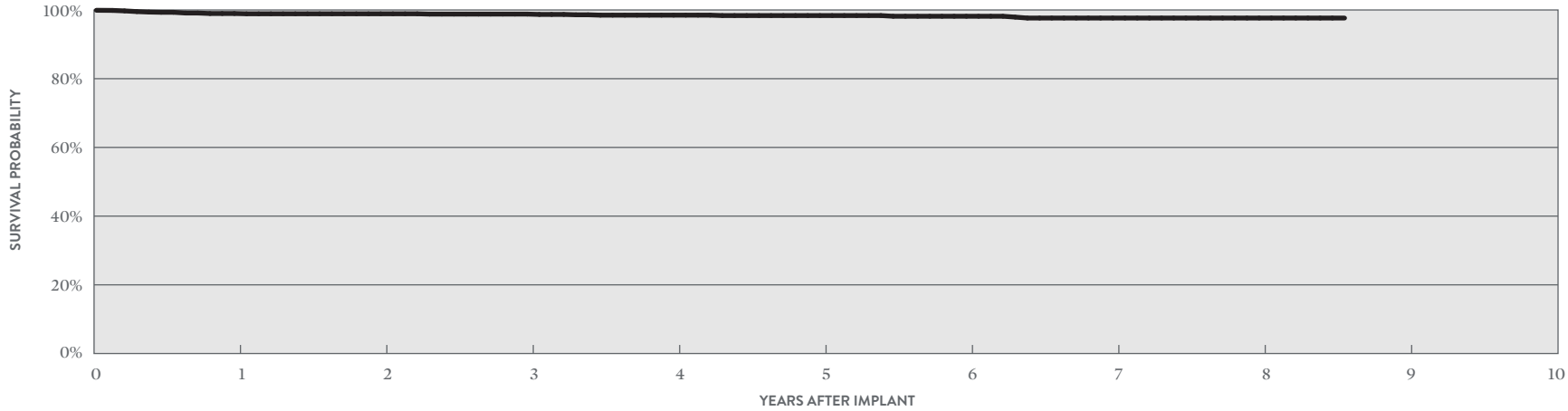
Durata™ DF4

MODEL 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	1,540
Active Devices Enrolled in Study	728
Cumulative Months of Follow-up	77,517
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Defibrillation Impedance	2	0.13%
Conductor Fracture	4	0.26%
Failure to Capture	7	0.45%
Failure to Sense	1	0.06%
Lead Dislodgement	7	0.45%
Oversensing	1	0.06%
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	14	0.91%
Total	**21**	**1.36%**



YEAR	1	2	3	4	5	6	7	8	AT 103 MONTHS
SURVIVAL PROBABILITY	98.97%	98.89%	98.80%	98.49%	98.37%	98.17%	97.65%	97.65%	97.65%
± 1 STANDARD ERROR	0.27%	0.28%	0.29%	0.34%	0.36%	0.41%	0.55%	0.55%	0.55%
SAMPLE SIZE	1,440	1,240	1,070	930	740	520	340	210	60

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

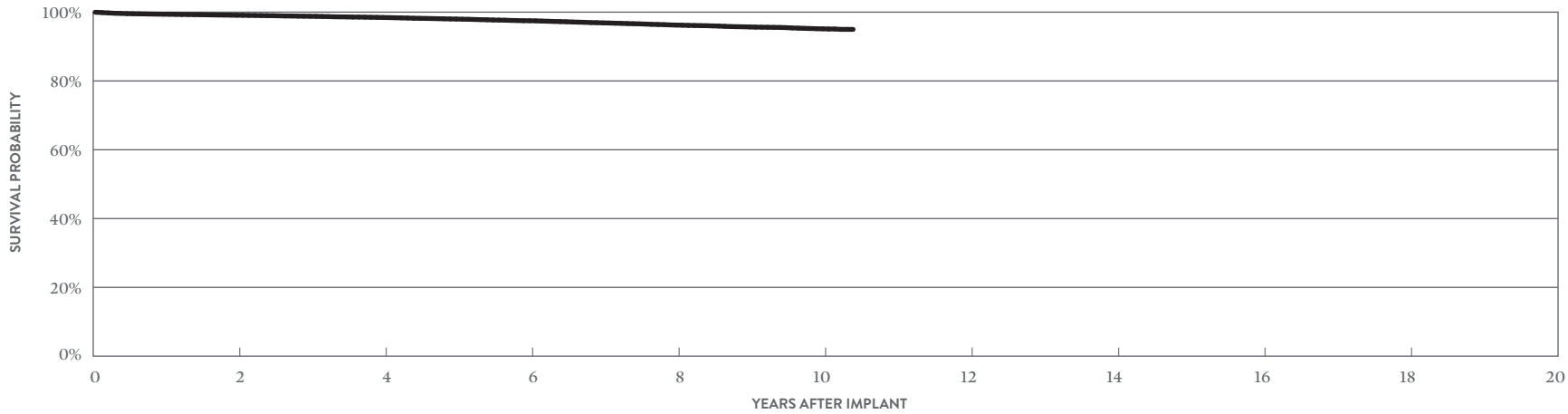
Durata™

MODELS 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	59,862
Estimated Active US Implants	25,534
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%	16	0.03%
Conductor Fracture	2	<0.01%	134	0.22%
Lead Dislodgement	69	0.12%	183	0.31%
Failure to Capture	25	0.04%	332	0.55%
Oversensing	51	0.09%	589	0.98%
Failure to Sense	5	<0.01%	64	0.11%
Insulation Breach	0	0.00%	65	0.11%
Abnormal Pacing Impedance	2	<0.01%	175	0.29%
Abnormal Defibrillation Impedance	19	0.03%	260	0.43%
Extracardiac Stimulation	0	0.00%	3	<0.01%
Other	21	0.04%	50	0.08%
Total	**234**	**0.39%**	**1871**	**3.13%**
Total Returned for Analysis	**92**		**520**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	33	0.06%
Clavicular Crush	2	<0.01%
In the Pocket	22	0.04%
Intravascular	9	0.02%
Insulation Breach	148	0.25%
Lead-to-Can Contact	76	0.13%
Lead-to-Lead Contact	29	0.05%
Clavicular Crush	17	0.03%
Externalized Conductors	0	0.00%
Other	26	0.04%
Crimps, Welds & Bonds	1	<0.01%
Other	9	0.02%
Extrinsic Factors	405	0.68%
Total	**596**	**1.00%**



YEAR	2	4	6	8	10	AT 125 MONTHS
SURVIVAL PROBABILITY	99.10%	98.45%	97.50%	96.24%	95.15%	94.99%
± 1 STANDARD ERROR	0.04%	0.06%	0.08%	0.10%	0.15%	0.20%
SAMPLE SIZE	48,170	38,600	30,380	21,810	7,200	370

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

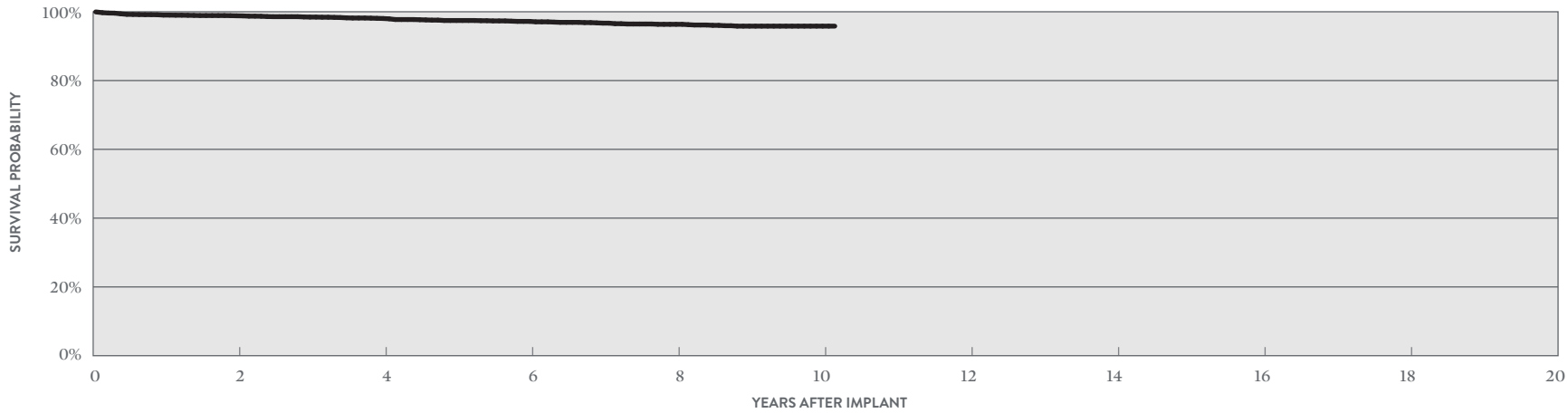
Durata™

MODELS 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	3,559
Active Devices Enrolled in Study	976
Cumulative Months of Follow-up	214,933
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Defibrillation Impedance	4	0.11%
Abnormal Pacing Impedance	10	0.28%
Conductor Fracture	15	0.42%
Failure to Capture	14	0.39%
Failure to Sense	2	0.06%
Inappropriate Shock	2	0.06%
Insulation Breach	11	0.31%
Lead Dislodgement	20	0.56%
Oversensing	10	0.28%
Skin Erosion	1	0.03%

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	12	0.34%
Lead-to-Can Contact	6	0.17%
Lead-to-Lead Contact	5	0.14%
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	**43**	**1.21%**



YEAR	2	4	6	8	10	AT 122 MONTHS
SURVIVAL PROBABILITY	98.83%	98.04%	97.20%	96.35%	95.82%	95.82%
± 1 STANDARD ERROR	0.18%	0.26%	0.34%	0.42%	0.48%	0.48%
SAMPLE SIZE	2,950	2,180	1,540	1,110	380	60

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

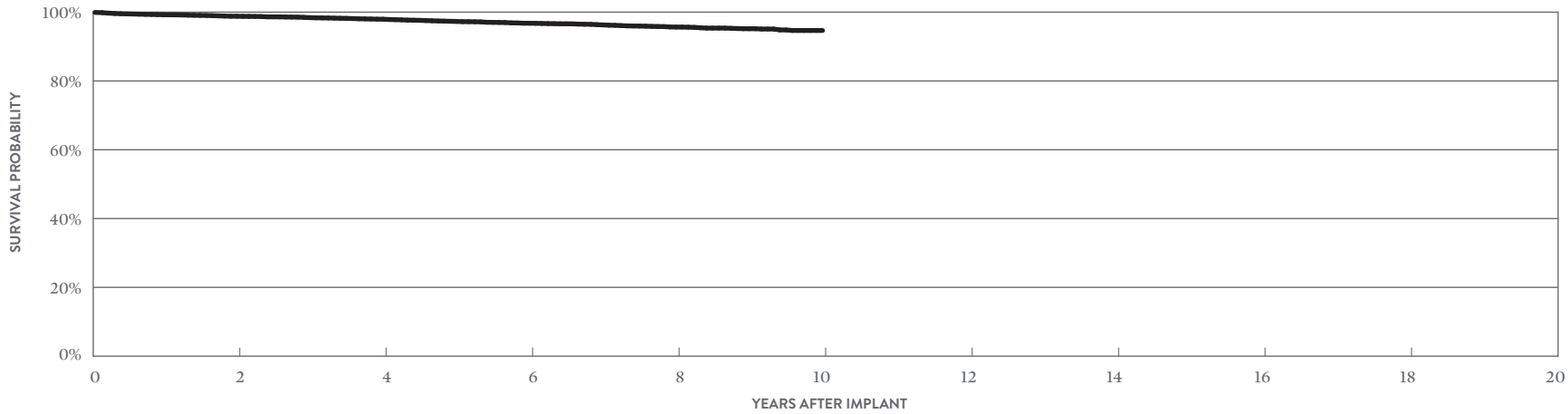
Durata™

MODEL 7122

US Regulatory Approval	September 2007
Registered US Implants	15,202
Estimated Active US Implants	7,569
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	11	0.07%	3	0.02%
Conductor Fracture	1	<0.01%	30	0.20%
Lead Dislodgement	23	0.15%	64	0.42%
Failure to Capture	19	0.12%	87	0.57%
Oversensing	13	0.09%	119	0.78%
Failure to Sense	0	0.00%	11	0.07%
Insulation Breach	0	0.00%	21	0.14%
Abnormal Pacing Impedance	3	0.02%	37	0.24%
Abnormal Defibrillation Impedance	1	<0.01%	29	0.19%
Extracardiac Stimulation	2	0.01%	2	0.01%
Other	4	0.03%	9	0.06%
Total	**77**	**0.51%**	**412**	**2.71%**
Total Returned for Analysis	**33**		**174**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	16	0.11%
Clavicular Crush	1	<0.01%
In the Pocket	12	0.08%
Intravascular	3	0.02%
Insulation Breach	58	0.38%
Lead-to-Can Contact	32	0.21%
Lead-to-Lead Contact	16	0.11%
Clavicular Crush	2	0.01%
Externalized Conductors	1	<0.01%
Other	7	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	4	0.03%
Extrinsic Factors	130	0.86%
Total	**208**	**1.37%**



YEAR	2	4	6	8	10
SURVIVAL PROBABILITY	98.81%	97.95%	96.77%	95.66%	94.67%
± 1 STANDARD ERROR	0.09%	0.13%	0.19%	0.25%	0.39%
SAMPLE SIZE	11,820	8,510	5,720	3,300	230

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

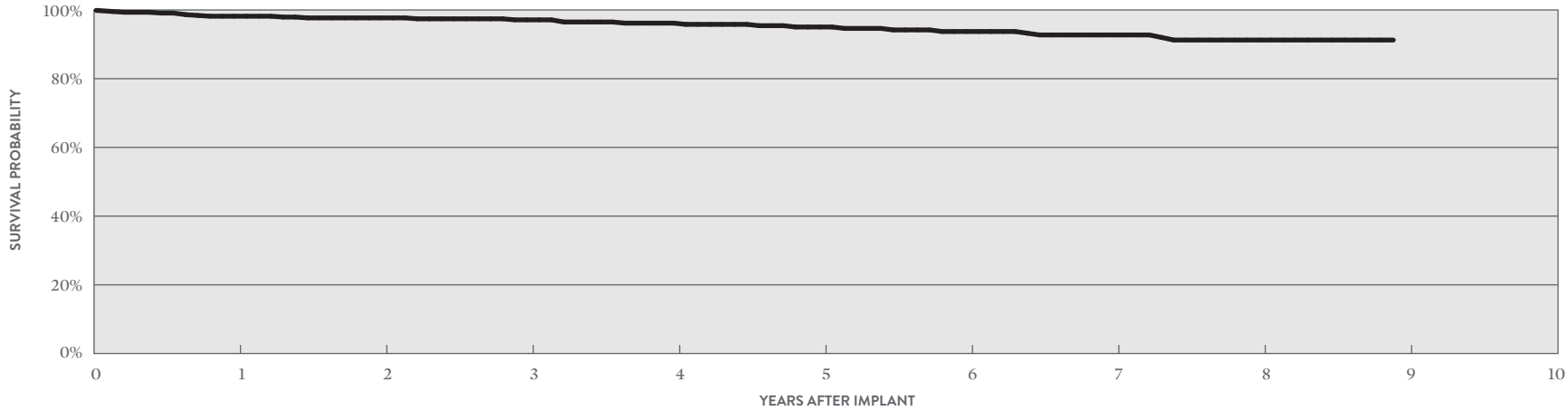
Durata™

MODEL 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	452
Active Devices Enrolled in Study	161
Cumulative Months of Follow-up	27,725
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	1.11%
Conductor Fracture	6	1.33%
Failure to Capture	5	1.11%
Failure to Sense	1	0.22%
Lead Dislodgement	5	1.11%
Oversensing	2	0.44%

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	1.77%
Total	**13**	**2.88%**



YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	98.18%	97.69%	97.12%	96.17%	95.04%	93.73%	92.73%	91.25%	91.25%
± 1 STANDARD ERROR	0.64%	0.72%	0.82%	0.98%	1.17%	1.38%	1.53%	1.83%	1.83%
SAMPLE SIZE	430	400	350	300	250	220	170	120	60

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

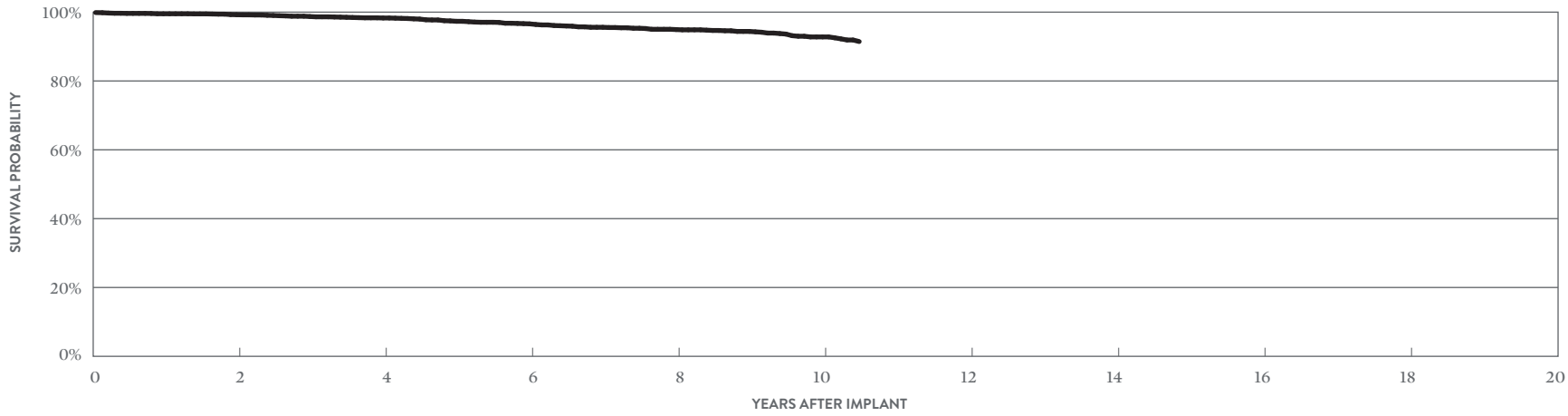
Riata™ ST Optim™

MODELS 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,311
Estimated Active US Implants	1,276
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%	20	0.60%
Lead Dislodgement	3	0.09%	13	0.39%
Failure to Capture	6	0.18%	34	1.03%
Oversensing	4	0.12%	53	1.60%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	7	0.21%
Abnormal Pacing Impedance	0	0.00%	13	0.39%
Abnormal Defibrillation Impedance	0	0.00%	16	0.48%
Extracardiac Stimulation	0	0.00%	1	0.03%
Other	0	0.00%	2	0.06%
Total	**20**	**0.60%**	**163**	**4.92%**
Total Returned for Analysis	**6**		**34**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	0.03%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.03%
Insulation Breach	14	0.42%
Lead-to-Can Contact	4	0.12%
Lead-to-Lead Contact	3	0.09%
Clavicular Crush	2	0.06%
Externalized Conductors	1	0.03%
Other	4	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	21	0.63%
Total	**36**	**1.09%**



YEAR	2	4	6	8	10	AT 126 MONTHS
SURVIVAL PROBABILITY	99.25%	98.30%	96.60%	94.94%	92.80%	91.46%
± 1 STANDARD ERROR	0.16%	0.26%	0.39%	0.51%	0.73%	0.89%
SAMPLE SIZE	2,570	2,060	1,680	1,300	640	220

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

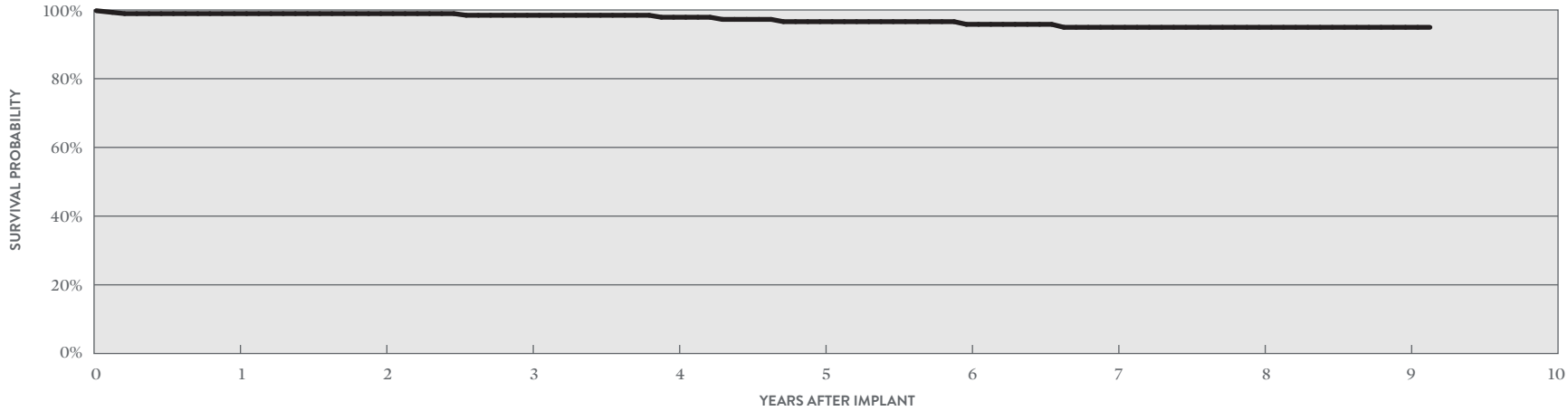
Riata™ ST Optim™

MODELS 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	288
Active Devices Enrolled in Study	80
Cumulative Months of Follow-up	17,933
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	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	1	0.35%
Total	**1**	**0.35%**



YEAR	1	2	3	4	5	6	7	8	9	AT 110 MONTHS
SURVIVAL PROBABILITY	98.94%	98.94%	98.46%	97.88%	96.60%	95.82%	94.95%	94.95%	94.95%	94.95%
± 1 STANDARD ERROR	0.61%	0.61%	0.77%	0.96%	1.31%	1.31%	1.73%	1.73%	1.73%	1.73%
SAMPLE SIZE	270	240	210	180	150	130	110	100	70	50

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

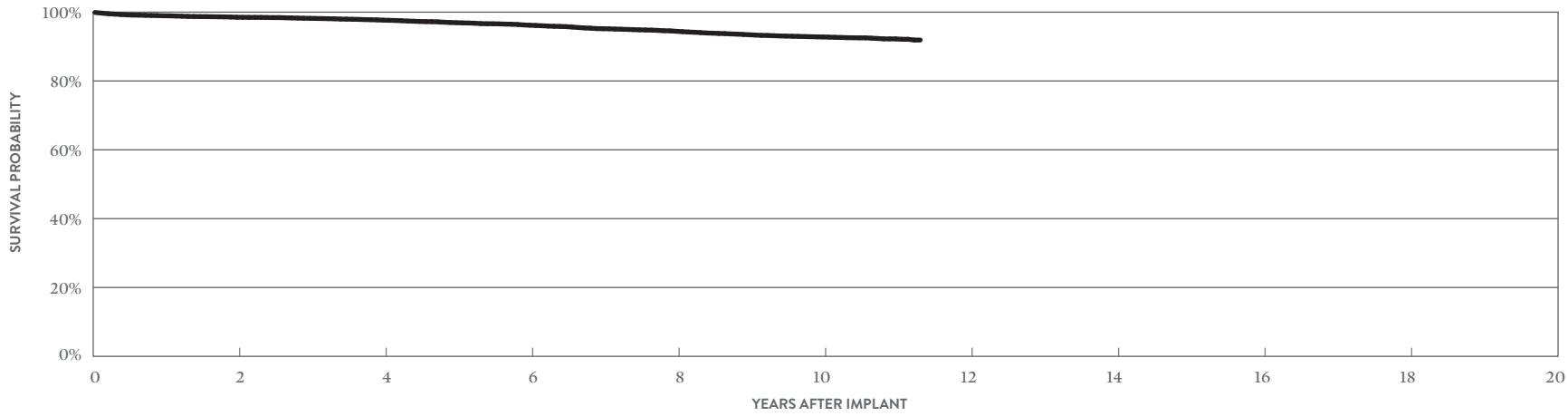
Riata™ ST Optim™

MODELS 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	14,247
Estimated Active US Implants	4,964
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%	56	0.39%
Lead Dislodgement	27	0.19%	63	0.44%
Failure to Capture	17	0.12%	150	1.05%
Oversensing	19	0.13%	239	1.68%
Failure to Sense	8	0.06%	20	0.14%
Insulation Breach	0	0.00%	24	0.17%
Abnormal Pacing Impedance	1	<0.01%	45	0.32%
Abnormal Defibrillation Impedance	4	0.03%	92	0.65%
Extracardiac Stimulation	3	0.02%	2	0.01%
Other	0	0.00%	28	0.20%
Total	**112**	**0.79%**	**736**	**5.17%**
Total Returned for Analysis	**53**		**211**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	10	0.07%
Clavicular Crush	1	<0.01%
In the Pocket	4	0.03%
Intravascular	5	0.04%
Insulation Breach	53	0.37%
Lead-to-Can Contact	23	0.16%
Lead-to-Lead Contact	7	0.05%
Clavicular Crush	4	0.03%
Externalized Conductors	0	0.00%
Other	19	0.13%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	174	1.22%
Total	**237**	**1.66%**



YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	98.52%	97.68%	96.20%	94.44%	92.79%	91.90%
± 1 STANDARD ERROR	0.11%	0.14%	0.19%	0.25%	0.30%	0.41%
SAMPLE SIZE	11,270	8,920	7,310	6,090	4,660	330

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

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

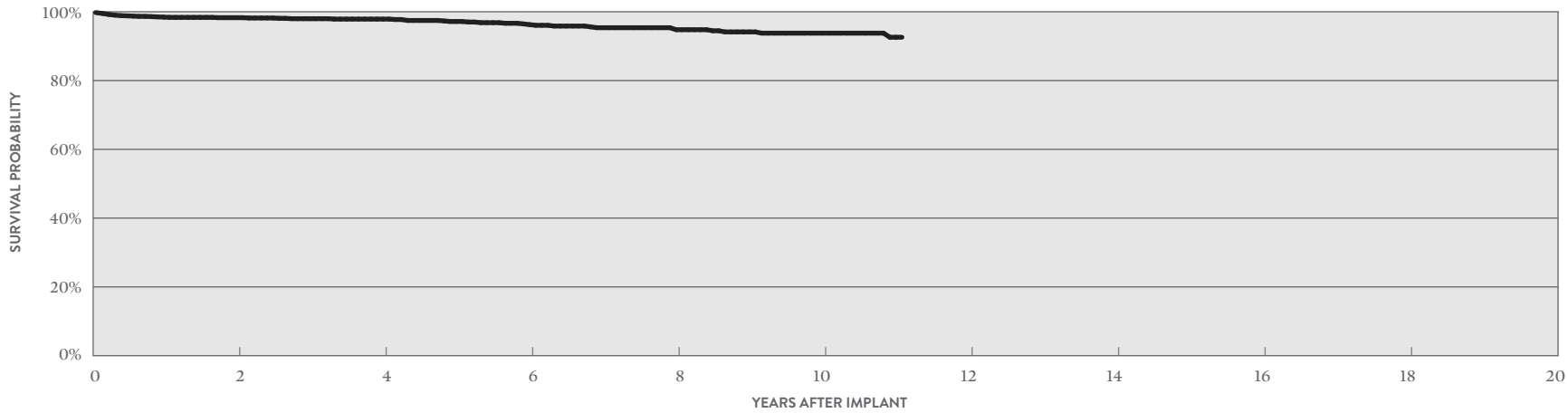
Riata™ ST Optim™

MODELS 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	1,470
Active Devices Enrolled in Study	239
Cumulative Months of Follow-up	84,590
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	8	0.54%
Failure to Capture	16	1.09%
Failure to Sense	1	0.07%
Insulation Breach	2	0.14%
Lead Dislodgement	9	0.61%
Oversensing	4	0.27%
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	3	0.20%
Lead-to-Can Contact	1	0.07%
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	14	0.95%
Total	**20**	**1.36%**



YEAR	2	4	6	8	10	AT 133 MONTHS
SURVIVAL PROBABILITY	98.28%	97.87%	96.26%	94.78%	93.78%	92.59%
± 1 STANDARD ERROR	0.35%	0.40%	0.62%	0.78%	1.04%	1.57%
SAMPLE SIZE	1,180	840	550	360	240	60

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

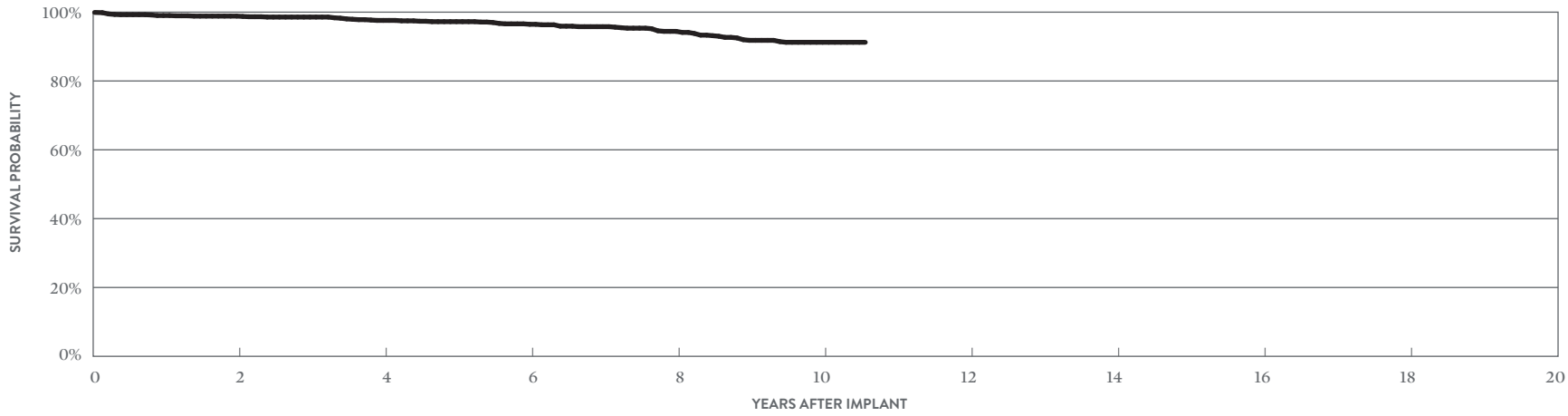
Riata™ ST Optim™

MODEL 7022

US Regulatory Approval	July 2006
Registered US Implants	1,471
Estimated Active US Implants	528
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%	11	0.75%
Oversensing	0	0.00%	23	1.56%
Failure to Sense	0	0.00%	1	0.07%
Insulation Breach	0	0.00%	7	0.48%
Abnormal Pacing Impedance	1	0.07%	4	0.27%
Abnormal Defibrillation Impedance	0	0.00%	3	0.20%
Extracardiac Stimulation	0	0.00%	1	0.07%
Other	0	0.00%	1	0.07%
Total	**10**	**0.68%**	**76**	**5.17%**
Total Returned for Analysis	**3**		**24**	

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	7	0.48%
Lead-to-Can Contact	6	0.41%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	21	1.43%
Total	**31**	**2.11%**



YEAR	2	4	6	8	10	AT 127 MONTHS
SURVIVAL PROBABILITY	98.85%	97.60%	96.47%	94.42%	91.24%	91.24%
± 1 STANDARD ERROR	0.30%	0.46%	0.58%	0.79%	1.05%	1.05%
SAMPLE SIZE	1,150	910	760	630	460	220

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

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

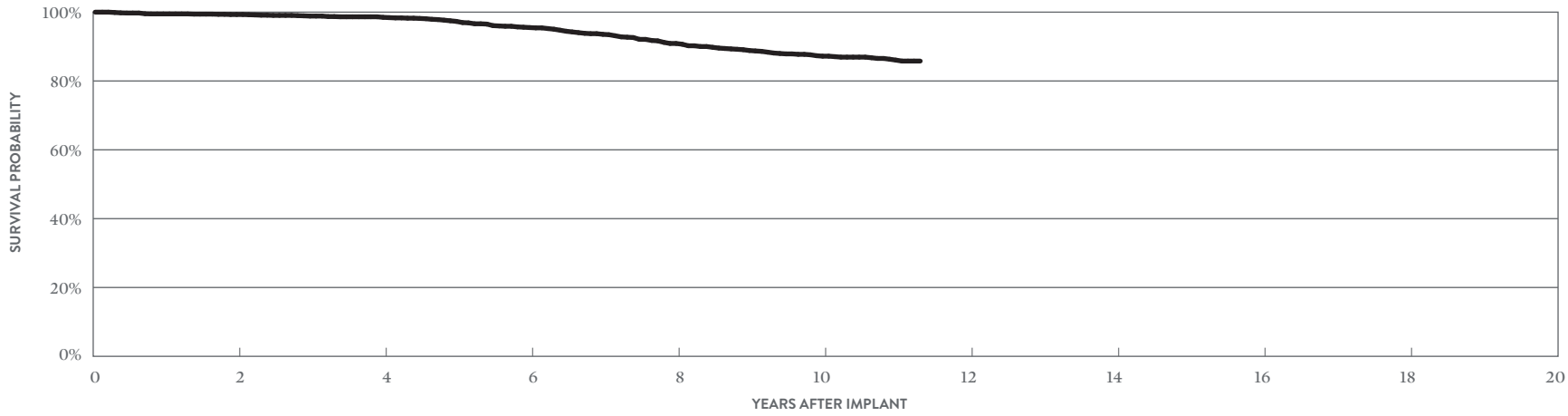
Riata™ ST

MODELS 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,200
Estimated Active US Implants	680
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	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%	5	0.23%
Lead Dislodgement	1	0.05%	8	0.36%
Failure to Capture	2	0.09%	10	0.45%
Oversensing	2	0.09%	45	2.05%
Failure to Sense	1	0.05%	3	0.14%
Insulation Breach	0	0.00%	41	1.86%
Abnormal Pacing Impedance	1	0.05%	28	1.27%
Abnormal Defibrillation Impedance	0	0.00%	19	0.86%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	3	0.14%
Total	**11**	**0.50%**	**165**	**7.50%**
Total Returned for Analysis	**4**		**38**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	0.09%
Clavicular Crush	0	0.00%
In the Pocket	2	0.09%
Intravascular	0	0.00%
Insulation Breach	39	1.77%
Lead-to-Can Contact	12	0.55%
Lead-to-Lead Contact	18	0.82%
Clavicular Crush	1	0.05%
Externalized Conductors	2	0.09%
Other	6	0.27%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	11	0.50%
Total	**52**	**2.36%**



YEAR	2	4	6	8	10	AT 136 MONTHS
SURVIVAL PROBABILITY	99.31%	98.49%	95.52%	90.90%	87.21%	85.79%
± 1 STANDARD ERROR	0.19%	0.28%	0.57%	0.87%	1.05%	1.18%
SAMPLE SIZE	1,740	1,360	1,060	870	700	200

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

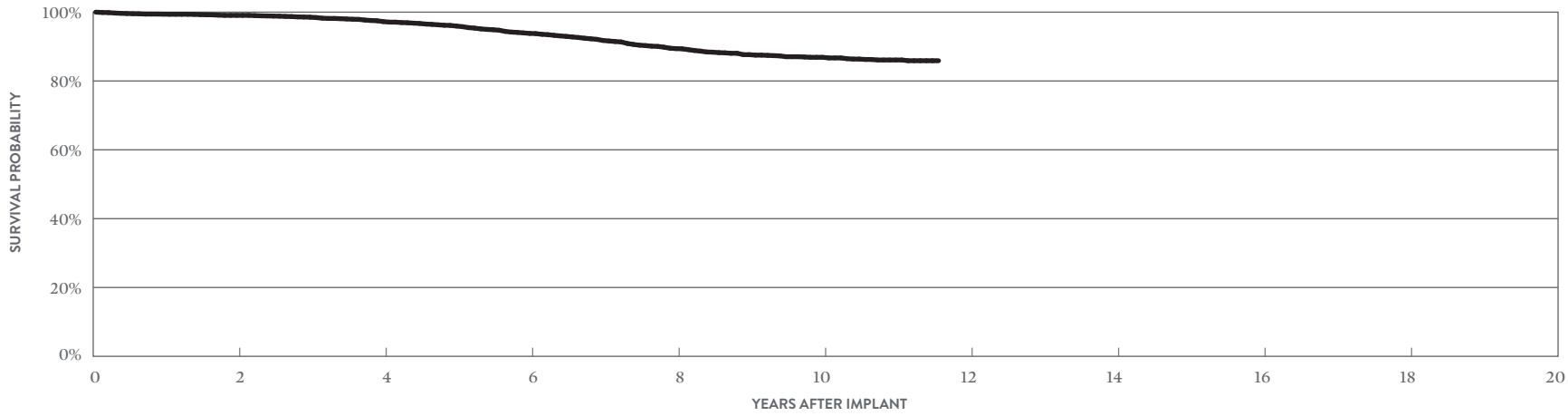
Riata™ ST

MODELS 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,056
Estimated Active US Implants	1,266
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	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%	33	0.81%
Lead Dislodgement	5	0.12%	5	0.12%
Failure to Capture	0	0.00%	48	1.18%
Oversensing	3	0.07%	96	2.37%
Failure to Sense	0	0.00%	14	0.35%
Insulation Breach	0	0.00%	56	1.38%
Abnormal Pacing Impedance	2	0.05%	19	0.47%
Abnormal Defibrillation Impedance	0	0.00%	23	0.57%
Extracardiac Stimulation	0	0.00%	1	0.02%
Other	1	0.02%	7	0.17%
Total	**15**	**0.37%**	**305**	**7.52%**
Total Returned for Analysis	**3**		**67**	

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	57	1.41%
Lead-to-Can Contact	29	0.71%
Lead-to-Lead Contact	16	0.39%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.05%
Other	10	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	29	0.71%
Total	**90**	**2.22%**



YEAR	2	4	6	8	10	AT 139 MONTHS
SURVIVAL PROBABILITY	99.07%	97.26%	93.82%	89.40%	86.88%	85.89%
± 1 STANDARD ERROR	0.16%	0.29%	0.48%	0.66%	0.77%	0.84%
SAMPLE SIZE	3,240	2,530	1,990	1,600	1,110	210

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

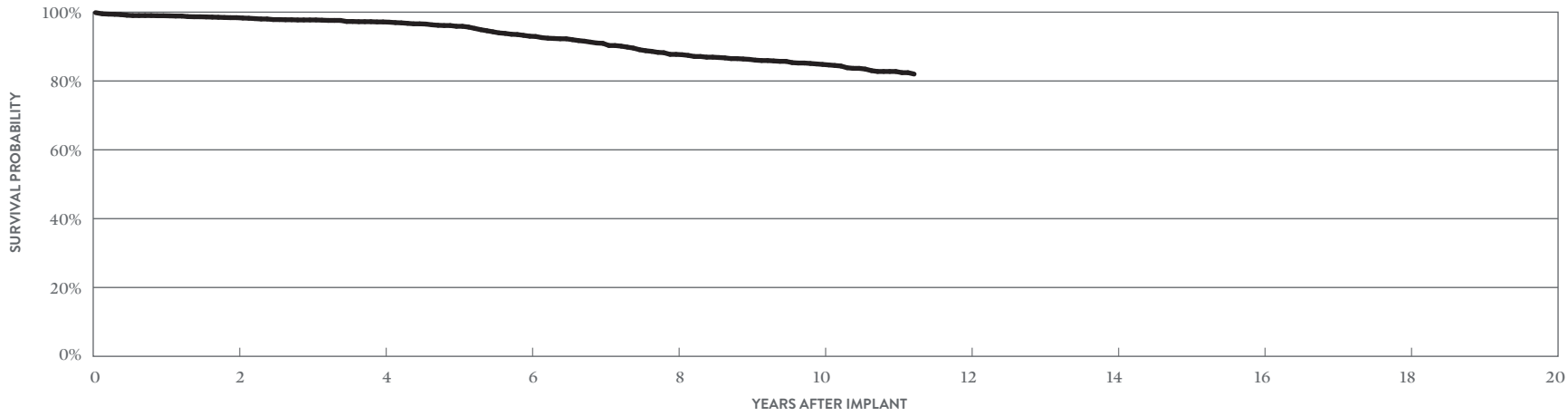
Riata™ ST

MODEL 7002

US Regulatory Approval	June 2005
Registered US Implants	2,408
Estimated Active US Implants	716
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	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%	9	0.37%
Lead Dislodgement	2	0.08%	9	0.37%
Failure to Capture	4	0.17%	25	1.04%
Oversensing	4	0.17%	63	2.62%
Failure to Sense	0	0.00%	2	0.08%
Insulation Breach	0	0.00%	71	2.95%
Abnormal Pacing Impedance	2	0.08%	5	0.21%
Abnormal Defibrillation Impedance	1	0.04%	9	0.37%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	8	0.33%
Total	**20**	**0.83%**	**206**	**8.55%**
Total Returned for Analysis	**11**		**70**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	5	0.21%
Clavicular Crush	0	0.00%
In the Pocket	2	0.08%
Intravascular	3	0.12%
Insulation Breach	71	2.95%
Lead-to-Can Contact	31	1.29%
Lead-to-Lead Contact	17	0.71%
Clavicular Crush	0	0.00%
Externalized Conductors	9	0.37%
Other	14	0.58%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	24	1.00%
Total	**100**	**4.15%**



YEAR	2	4	6	8	10	AT 135 MONTHS
SURVIVAL PROBABILITY	98.40%	97.16%	93.01%	87.73%	84.81%	82.01%
± 1 STANDARD ERROR	0.27%	0.38%	0.64%	0.92%	1.04%	1.24%
SAMPLE SIZE	1,910	1,540	1,210	950	690	210

Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

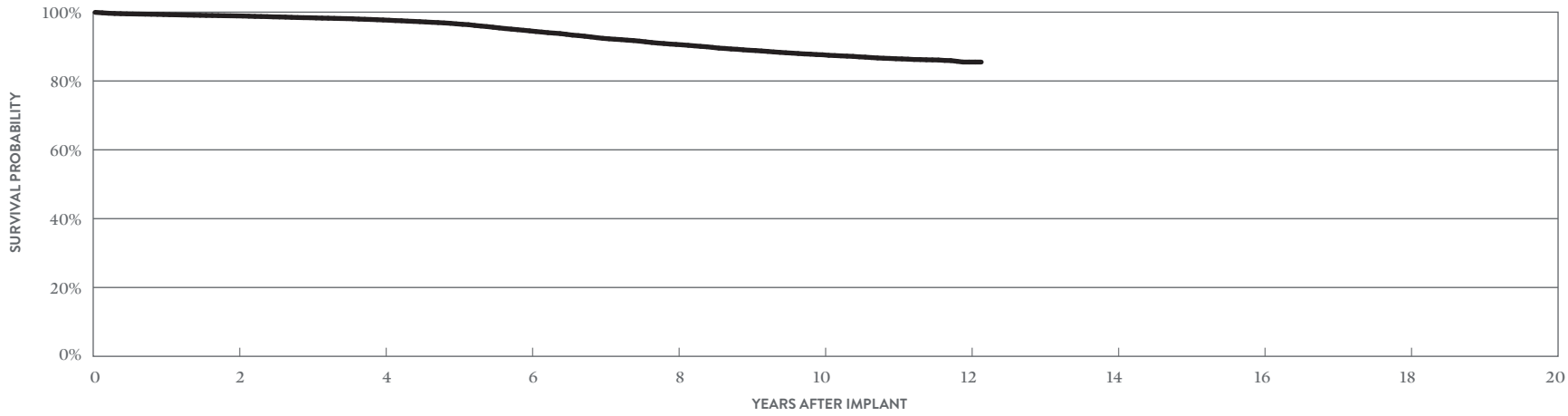
Riata™ ST

MODELS 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,881
Estimated Active US Implants	10,359
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	One

	ACUTE OBSERVATIONS (POST IMPLANT, ≤30 DAYS)		CHRONIC COMPLICATIONS (>30 DAYS)	
	QTY	RATE	QTY	RATE
Cardiac Perforation	42	0.12%	32	0.09%
Conductor Fracture	0	0.00%	150	0.43%
Lead Dislodgement	38	0.11%	58	0.17%
Failure to Capture	42	0.12%	342	0.98%
Oversensing	40	0.11%	828	2.37%
Failure to Sense	7	0.02%	63	0.18%
Insulation Breach	1	<0.01%	735	2.11%
Abnormal Pacing Impedance	8	0.02%	116	0.33%
Abnormal Defibrillation Impedance	4	0.01%	211	0.60%
Extracardiac Stimulation	3	<0.01%	5	0.01%
Other	11	0.03%	94	0.27%
Total	**196**	**0.56%**	**2634**	**7.55%**
Total Returned for Analysis	**97**		**722**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	24	0.07%
Clavicular Crush	4	0.01%
In the Pocket	7	0.02%
Intravascular	13	0.04%
Insulation Breach	601	1.72%
Lead-to-Can Contact	317	0.91%
Lead-to-Lead Contact	159	0.46%
Clavicular Crush	11	0.03%
Externalized Conductors	36	0.10%
Other	78	0.22%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	307	0.88%
Total	**934**	**2.68%**



YEAR	2	4	6	8	10	12	AT 146 MONTHS
SURVIVAL PROBABILITY	98.91%	97.73%	94.57%	90.62%	87.62%	85.50%	85.50%
± 1 STANDARD ERROR	0.06%	0.09%	0.15%	0.21%	0.25%	0.34%	0.34%
SAMPLE SIZE	28,330	22,300	17,470	13,790	10,730	3,350	310

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

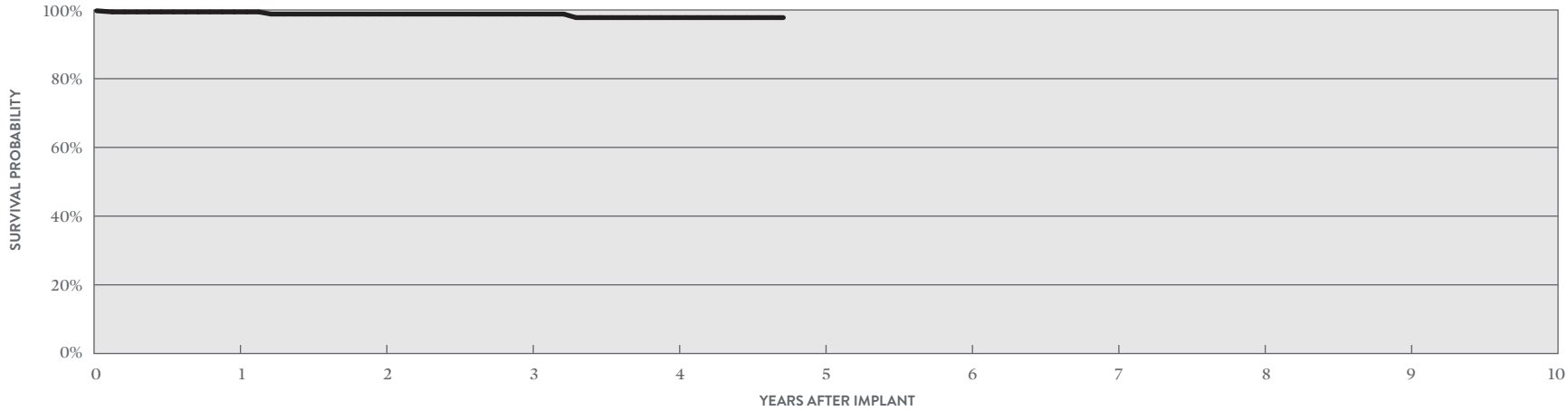
Riata™ ST

MODELS 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	180
Active Devices Enrolled in Study	22
Cumulative Months of Follow-up	8,140
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Failure to Capture	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%	97.78%	97.78%
± 1 STANDARD ERROR	0.56%	0.84%	0.84%	1.32%	1.32%
SAMPLE SIZE	170	150	120	90	50

Defibrillation Leads

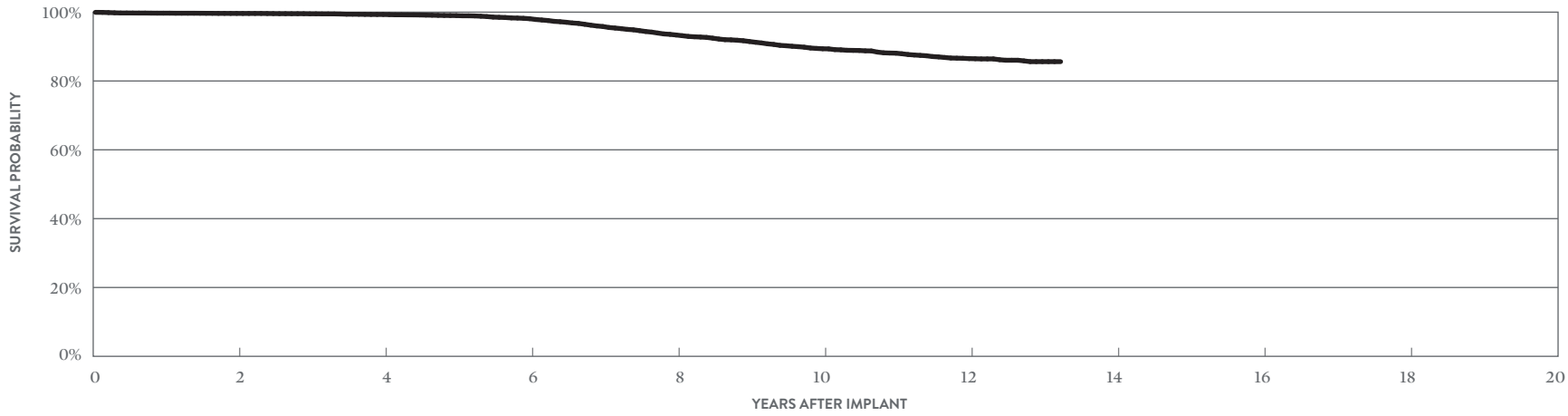
CUSTOMER REPORTED PERFORMANCE DATA

Riata™ i

MODELS 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,700
Estimated Active US Implants	2,509
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	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	184	1.90%
Lead-to-Can Contact	75	0.77%
Lead-to-Lead Contact	55	0.57%
Clavicular Crush	2	0.02%
Externalized Conductors	18	0.19%
Other	34	0.35%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	54	0.56%
Total	**246**	**2.54%**



YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	99.63%	99.32%	98.09%	93.36%	89.36%	86.50%	85.62%
± 1 STANDARD ERROR	0.06%	0.09%	0.17%	0.36%	0.48%	0.56%	0.62%
SAMPLE SIZE	8,040	6,380	4,930	3,840	3,070	2,240	250

Defibrillation Leads

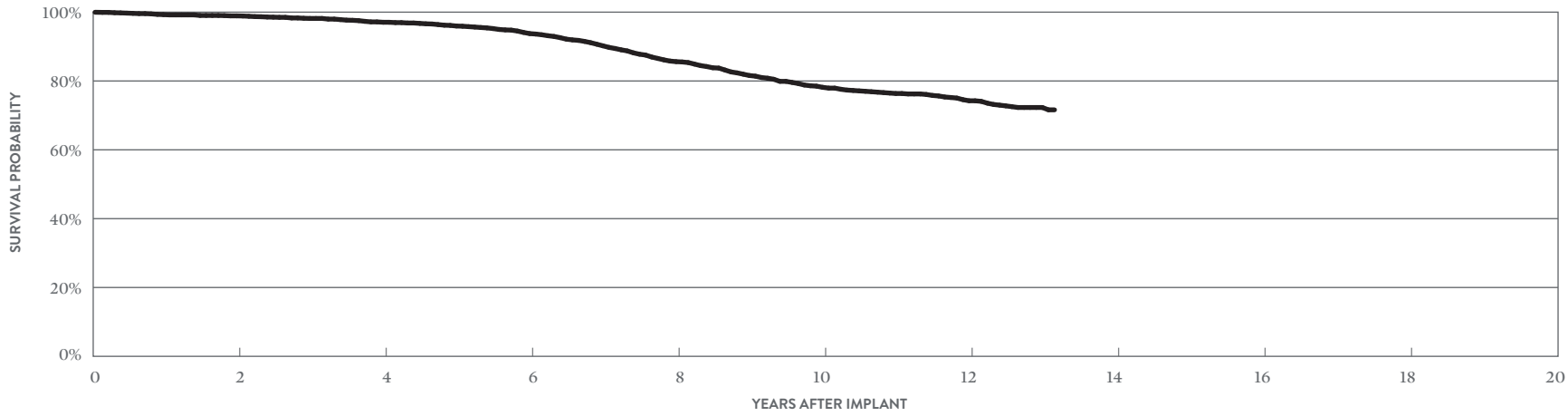
CUSTOMER REPORTED PERFORMANCE DATA

Riata™

MODEL 1582

US Regulatory Approval	March 2003
Registered US Implants	3,131
Estimated Active US Implants	643
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	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	173	5.53%
Lead-to-Can Contact	55	1.76%
Lead-to-Lead Contact	30	0.96%
Clavicular Crush	2	0.06%
Externalized Conductors	49	1.56%
Other	37	1.18%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	35	1.12%
Total	**211**	**6.74%**



YEAR	2	4	6	8	10	12	AT 158 MONTHS
SURVIVAL PROBABILITY	98.92%	97.06%	93.77%	85.62%	78.16%	74.25%	71.62%
± 1 STANDARD ERROR	0.20%	0.35%	0.54%	0.91%	1.16%	1.31%	1.49%
SAMPLE SIZE	2,500	1,960	1,490	1,080	770	510	200

Defibrillation Leads

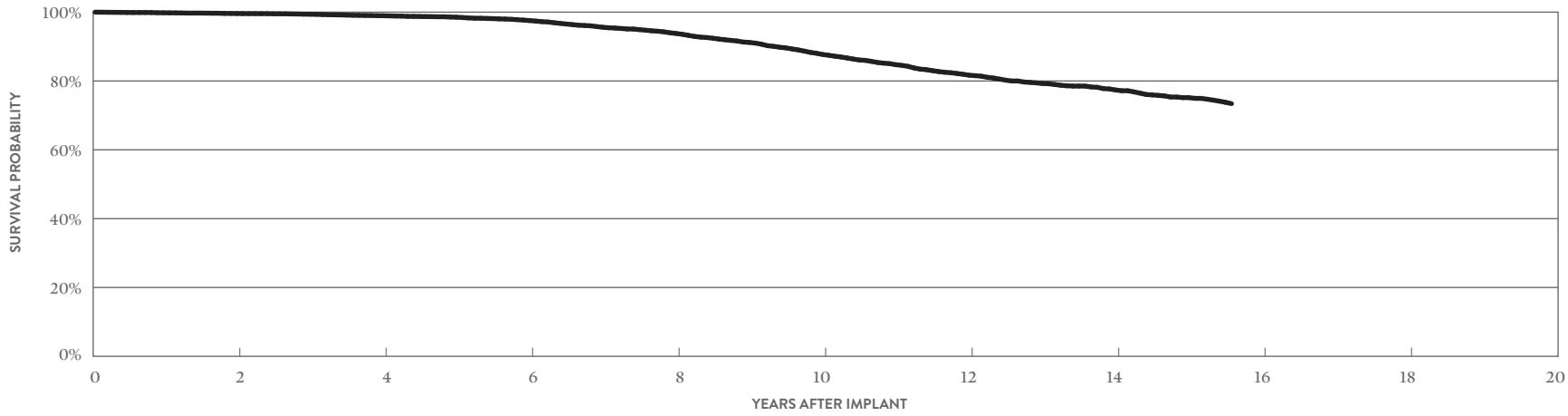
CUSTOMER REPORTED PERFORMANCE DATA

Riata™

MODELS 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,280
Estimated Active US Implants	2,156
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	One

MALFUNCTIONS	QTY	RATE
Conductor Fracture	5	0.05%
Clavicular Crush	2	0.02%
In the Pocket	3	0.03%
Intravascular	0	0.00%
Insulation Breach	224	2.18%
Lead-to-Can Contact	105	1.02%
Lead-to-Lead Contact	41	0.40%
Clavicular Crush	2	0.02%
Externalized Conductors	41	0.40%
Other	35	0.34%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	64	0.62%
Total	**293**	**2.85%**



YEAR	2	4	6	8	10	12	14	AT 187 MONTHS
SURVIVAL PROBABILITY	99.60%	98.96%	97.55%	93.80%	87.70%	81.68%	77.39%	73.42%
± 1 STANDARD ERROR	0.06%	0.11%	0.19%	0.34%	0.51%	0.66%	0.81%	1.13%
SAMPLE SIZE	8,520	6,790	5,210	3,940	2,940	1,980	970	200

Defibrillation Leads

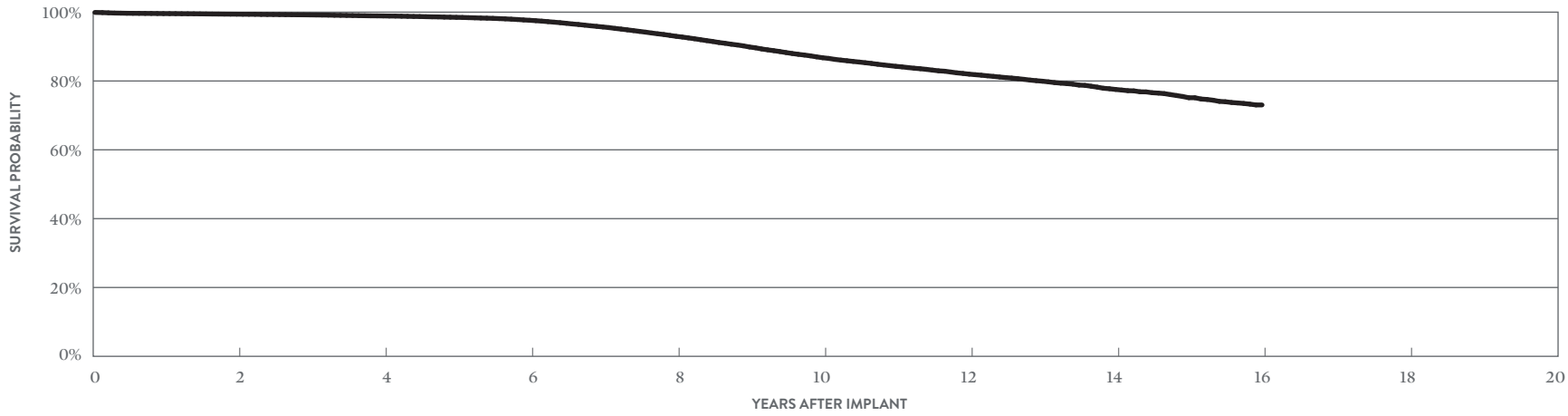
CUSTOMER REPORTED PERFORMANCE DATA

Riata™

MODELS 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	68,399
Estimated Active US Implants	14,147
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 339)	One

MALFUNCTIONS	QTY	RATE
Conductor Fracture	32	0.05%
Clavicular Crush	4	<0.01%
In the Pocket	11	0.02%
Intravascular	17	0.02%
Insulation Breach	1790	2.62%
Lead-to-Can Contact	734	1.07%
Lead-to-Lead Contact	358	0.52%
Clavicular Crush	20	0.03%
Externalized Conductors	352	0.51%
Other	326	0.48%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	547	0.80%
Total	**2372**	**3.47%**



YEAR	2	4	6	8	10	12	14	16
SURVIVAL PROBABILITY	99.41%	98.90%	97.64%	92.98%	86.75%	81.99%	77.54%	73.04%
± 1 STANDARD ERROR	0.03%	0.04%	0.07%	0.14%	0.21%	0.25%	0.33%	0.65%
SAMPLE SIZE	56,170	44,450	34,150	25,840	19,200	13,690	5,210	260

Defibrillation Leads

ACTIVELY MONITORED STUDY DATA

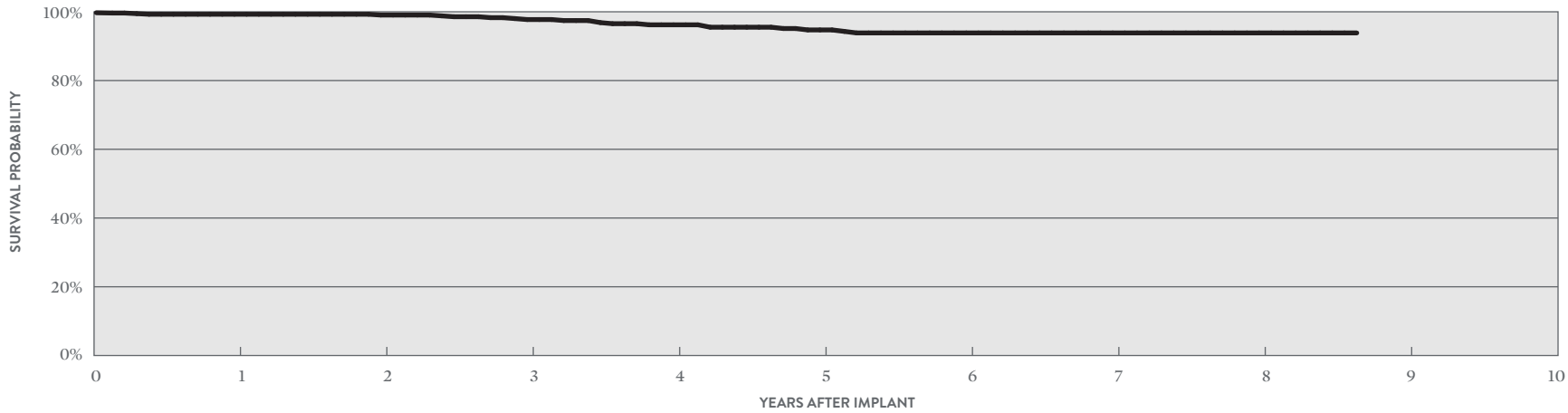
Riata™

MODELS 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	566
Active Devices Enrolled in Study	117
Cumulative Months of Follow-up	29,930
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Conductor Fracture	2	0.35%
Failure to Capture	1	0.18%
Insulation Breach	9	1.59%
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	23	4.06%
Lead-to-Can Contact	7	1.24%
Lead-to-Lead Contact	7	1.24%
Clavicular Crush	0	0.00%
Externalized Conductors	7	1.24%
Other	2	0.35%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	7	1.24%
Total	**31**	**5.48%**



YEAR	1	2	3	4	5	6	7	8	AT 104 MONTHS
SURVIVAL PROBABILITY	99.28%	99.05%	97.74%	96.21%	94.72%	93.85%	93.85%	93.85%	93.85%
± 1 STANDARD ERROR	0.36%	0.36%	0.66%	0.98%	1.22%	1.35%	1.35%	1.35%	1.35%
SAMPLE SIZE	530	470	390	320	260	200	160	110	50

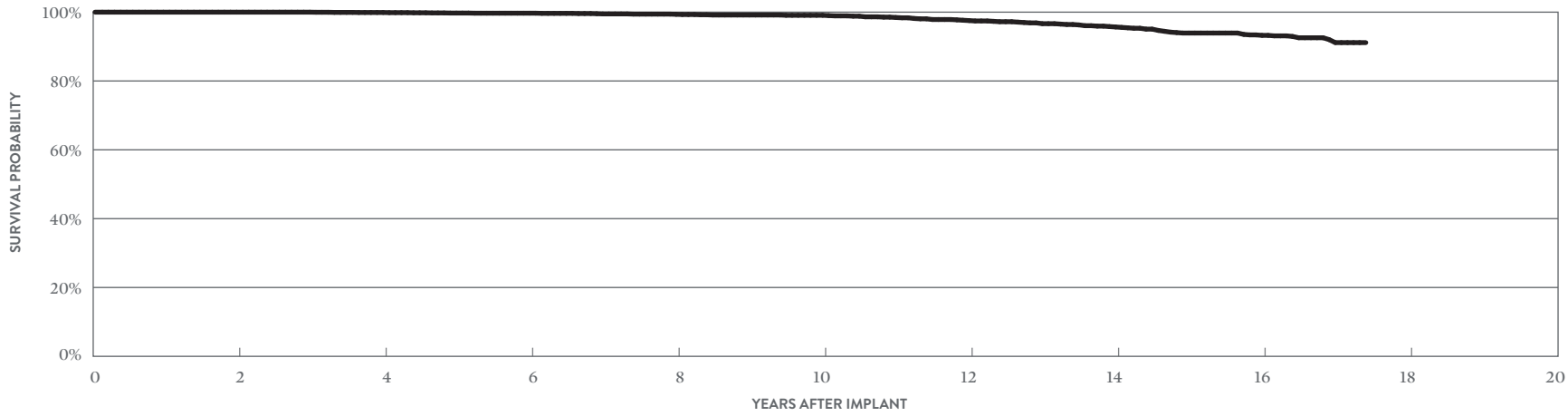
Defibrillation Leads

CUSTOMER REPORTED PERFORMANCE DATA

TVL™ ADX

MODEL 1559

US Regulatory Approval	November 1999
Registered US Implants	4,559
Estimated Active US Implants	672
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



YEAR	2	4	6	8	10	12	14	16	AT 209 MONTHS
SURVIVAL PROBABILITY	100.00%	99.90%	99.70%	99.37%	99.09%	97.55%	95.69%	93.25%	91.15%
± 1 STANDARD ERROR	0.00%	0.06%	0.11%	0.16%	0.22%	0.43%	0.62%	0.82%	1.08%
SAMPLE SIZE	3,700	2,920	2,250	1,680	1,240	970	810	700	220

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	98.99%	98.99%	98.72%							
LDA220Q	Optisure™ DF4	99.07%	98.75%	98.42%							
LDA210Q	Optisure™ DF4	99.07%	98.81%	98.60%	98.43%						
LDA210	Optisure™ DF4	99.13%	98.53%								
7170Q/7171Q	Durata™ DF4	99.19%	98.84%	98.31%	97.63%	97.28%	96.47%	96.04%	95.41%		
7120Q/7121Q	Durata™ DF4	99.22%	99.00%	98.75%	98.41%	98.01%	97.58%	97.02%	96.55%		
7122Q	Durata™ DF4	99.24%	99.01%	98.74%	98.42%	98.01%	97.49%	96.85%	96.47%		
7120/7121	Durata™	99.40%	99.10%	98.80%	98.45%	97.99%	97.50%	96.88%	96.24%	95.69%	95.15%
7122	Durata™	99.24%	98.81%	98.40%	97.95%	97.30%	96.77%	96.29%	95.66%	95.18%	94.67%
7070/7071	Riata™ ST Optim™	99.53%	99.25%	98.73%	98.30%	97.34%	96.60%	95.60%	94.94%	94.40%	92.80%
7020/7021	Riata™ ST Optim™	98.94%	98.52%	98.20%	97.68%	96.94%	96.20%	95.18%	94.44%	93.43%	92.79%
7022	Riata™ ST Optim™	99.02%	98.85%	98.57%	97.60%	97.24%	96.47%	95.78%	94.42%	91.81%	91.24%
7010/7011	Riata™ ST	99.49%	99.31%	98.86%	98.49%	97.32%	95.52%	93.55%	90.90%	88.85%	87.21%
7040/7041	Riata™ ST	99.41%	99.07%	98.54%	97.26%	95.96%	93.82%	91.78%	89.40%	87.65%	86.88%
7002	Riata™ ST	98.96%	98.40%	97.73%	97.16%	95.89%	93.01%	90.94%	87.73%	86.28%	84.81%
7000/7001	Riata™ ST	99.31%	98.91%	98.38%	97.73%	96.60%	94.57%	92.39%	90.62%	88.93%	87.62%
1590/1591	Riata™ i	99.71%	99.63%	99.52%	99.32%	99.00%	98.09%	95.83%	93.36%	91.47%	89.36%
1582	Riata™	99.28%	98.92%	98.17%	97.06%	95.97%	93.77%	90.22%	85.62%	81.59%	78.16%
1570/1571	Riata™	99.81%	99.60%	99.39%	98.96%	98.53%	97.55%	95.60%	93.80%	91.20%	87.70%
1580/1581	Riata™	99.58%	99.41%	99.20%	98.90%	98.49%	97.64%	95.69%	92.98%	89.88%	86.75%
1559	TVL™ ADX	100.00%	100.00%	100.00%	99.90%	99.74%	99.70%	99.49%	99.37%	99.17%	99.09%
SP01/SP02/SP03/SP04	SPL™	99.97%	99.93%	99.92%	99.87%	99.84%	99.81%	99.78%	99.72%	99.61%	99.46%

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	910	703	1	0.11%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.11%	0	0.00%	1	0.11%	0	0.00%	**4**	**0.44%**	**1**
LDA220Q	Feb-14	7,937	6,194	5	0.06%	0	0.00%	26	0.33%	9	0.11%	3	0.04%	2	0.03%	0	0.00%	0	0.00%	4	0.05%	1	0.01%	3	0.04%	**53**	**0.67%**	**22**
LDA210Q	Feb-14	25,997	20,627	34	0.13%	1	<0.01%	79	0.30%	36	0.14%	11	0.04%	6	0.02%	1	<0.01%	3	0.01%	6	0.02%	0	0.00%	13	0.05%	**190**	**0.73%**	**64**
LDA210	Feb-14	943	762	0	0.00%	0	0.00%	2	0.21%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.32%**	**1**
7170Q/7171Q	Jul-09	6,387	3,734	6	0.09%	1	0.02%	17	0.27%	9	0.14%	3	0.05%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	1	0.02%	**39**	**0.61%**	**18**
7120Q/7121Q	Jan-09	127,913	72,283	85	0.07%	2	<0.01%	238	0.19%	108	0.08%	47	0.04%	14	0.01%	0	0.00%	6	<0.01%	10	<0.01%	3	<0.01%	39	0.03%	**552**	**0.43%**	**281**
7122Q	Jan-09	92,792	60,471	114	0.12%	3	<0.01%	204	0.22%	93	0.10%	31	0.03%	7	<0.01%	0	0.00%	7	<0.01%	8	<0.01%	3	<0.01%	42	0.05%	**512**	**0.55%**	**234**
7120/7121	Sep-07	59,862	25,534	40	0.07%	2	<0.01%	69	0.12%	25	0.04%	51	0.09%	5	<0.01%	0	0.00%	2	<0.01%	19	0.03%	0	0.00%	21	0.04%	**234**	**0.39%**	**92**
7122	Sep-07	15,202	7,569	11	0.07%	1	<0.01%	23	0.15%	19	0.12%	13	0.09%	0	0.00%	0	0.00%	3	0.02%	1	<0.01%	2	0.01%	4	0.03%	**77**	**0.51%**	**33**
7070/7071	Jul-06	3,311	1,276	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	14,247	4,964	33	0.23%	0	0.00%	27	0.19%	17	0.12%	19	0.13%	8	0.06%	0	0.00%	1	<0.01%	4	0.03%	3	0.02%	0	0.00%	**112**	**0.79%**	**53**
7022	Jul-06	1,471	528	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	680	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	4,056	1,266	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	2,408	716	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	34,881	10,359	42	0.12%	0	0.00%	38	0.11%	42	0.12%	40	0.11%	7	0.02%	1	<0.01%	8	0.02%	4	0.01%	3	<0.01%	11	0.03%	**196**	**0.56%**	**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	910	703	0	0.00%	0	0.00%	3	0.33%	3	0.33%	2	0.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.88%**	**4**
LDA220Q	Feb-14	7,937	6,194	3	0.04%	3	0.04%	43	0.54%	31	0.39%	17	0.21%	3	0.04%	1	0.01%	0	0.00%	5	0.06%	0	0.00%	2	0.03%	**108**	**1.36%**	**39**
LDA210Q	Feb-14	25,997	20,627	11	0.04%	3	0.01%	121	0.47%	53	0.20%	43	0.17%	7	0.03%	2	<0.01%	4	0.02%	10	0.04%	2	<0.01%	11	0.04%	**267**	**1.03%**	**99**
LDA210	Feb-14	943	762	0	0.00%	1	0.11%	4	0.42%	2	0.21%	4	0.42%	0	0.00%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	**12**	**1.27%**	**4**
7170Q/7171Q	Jul-09	6,387	3,734	6	0.09%	13	0.20%	25	0.39%	53	0.83%	29	0.45%	0	0.00%	2	0.03%	15	0.23%	12	0.19%	0	0.00%	1	0.02%	**156**	**2.44%**	**44**
7120Q/7121Q	Jan-09	127,913	72,283	38	0.03%	134	0.10%	586	0.46%	656	0.51%	545	0.43%	74	0.06%	31	0.02%	115	0.09%	266	0.21%	7	<0.01%	64	0.05%	**2516**	**1.97%**	**929**
7122Q	Jan-09	92,792	60,471	45	0.05%	51	0.05%	383	0.41%	295	0.32%	271	0.29%	33	0.04%	17	0.02%	50	0.05%	81	0.09%	9	<0.01%	36	0.04%	**1271**	**1.37%**	**569**
7120/7121	Sep-07	59,862	25,534	16	0.03%	134	0.22%	183	0.31%	332	0.55%	589	0.98%	64	0.11%	65	0.11%	175	0.29%	260	0.43%	3	<0.01%	50	0.08%	**1871**	**3.13%**	**520**
7122	Sep-07	15,202	7,569	3	0.02%	30	0.20%	64	0.42%	87	0.57%	119	0.78%	11	0.07%	21	0.14%	37	0.24%	29	0.19%	2	0.01%	9	0.06%	**412**	**2.71%**	**174**
7070/7071	Jul-06	3,311	1,276	2	0.06%	20	0.60%	13	0.39%	34	1.03%	53	1.60%	2	0.06%	7	0.21%	13	0.39%	16	0.48%	1	0.03%	2	0.06%	**163**	**4.92%**	**34**
7020/7021	Jul-06	14,247	4,964	17	0.12%	56	0.39%	63	0.44%	150	1.05%	239	1.68%	20	0.14%	24	0.17%	45	0.32%	92	0.65%	2	0.01%	28	0.20%	**736**	**5.17%**	**211**
7022	Jul-06	1,471	528	2	0.14%	12	0.82%	11	0.75%	11	0.75%	23	1.56%	1	0.07%	7	0.48%	4	0.27%	3	0.20%	1	0.07%	1	0.07%	**76**	**5.17%**	**24**
7010/7011	Mar-06	2,200	680	3	0.14%	5	0.23%	8	0.36%	10	0.45%	45	2.05%	3	0.14%	41	1.86%	28	1.27%	19	0.86%	0	0.00%	3	0.14%	**165**	**7.50%**	**38**
7040/7041	Mar-06	4,056	1,266	3	0.07%	33	0.81%	5	0.12%	48	1.18%	96	2.37%	14	0.35%	56	1.38%	19	0.47%	23	0.57%	1	0.02%	7	0.17%	**305**	**7.52%**	**67**
7002	Jun-05	2,408	716	5	0.21%	9	0.37%	9	0.37%	25	1.04%	63	2.62%	2	0.08%	71	2.95%	5	0.21%	9	0.37%	0	0.00%	8	0.33%	**206**	**8.55%**	**70**
7000/7001	Jun-05	34,881	10,359	32	0.09%	150	0.43%	58	0.17%	342	0.98%	828	2.37%	63	0.18%	735	2.11%	116	0.33%	211	0.60%	5	0.01%	94	0.27%	**2634**	**7.55%**	**722**

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	910	3.20%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	6	0.66%	**7**	**0.77%**
LDA220Q	7,937	3.10%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	41	0.52%	**43**	**0.54%**
LDA210Q	25,997	3.00%	3	0.01%	3	0.01%	0	0.00%	2	<0.01%	102	0.39%	**110**	**0.42%**
LDA210	943	3.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.64%	**6**	**0.64%**
7170Q/7171Q	6,387	4.60%	2	0.03%	6	0.09%	0	0.00%	0	0.00%	40	0.63%	**48**	**0.75%**
7120Q/7121Q	127,913	4.60%	26	0.02%	203	0.16%	2	<0.01%	36	0.03%	777	0.61%	**1044**	**0.82%**
7122Q	92,792	4.70%	12	0.01%	101	0.11%	0	0.00%	16	0.02%	522	0.56%	**651**	**0.70%**
7120/7121	59,862	5.80%	33	0.06%	148	0.25%	1	<0.01%	9	0.02%	405	0.68%	**596**	**1.00%**
7122	15,202	7.60%	16	0.11%	58	0.38%	0	0.00%	4	0.03%	130	0.86%	**208**	**1.37%**
7070/7071	3,311	7.80%	1	0.03%	14	0.42%	0	0.00%	0	0.00%	21	0.63%	**36**	**1.09%**
7020/7021	14,247	7.30%	10	0.07%	53	0.37%	0	0.00%	0	0.00%	174	1.22%	**237**	**1.66%**
7022	1,471	10.30%	3	0.20%	7	0.48%	0	0.00%	0	0.00%	21	1.43%	**31**	**2.11%**
7010/7011	2,200	9.00%	2	0.09%	39	1.77%	0	0.00%	0	0.00%	11	0.50%	**52**	**2.36%**
7040/7041	4,056	8.40%	4	0.10%	57	1.41%	0	0.00%	0	0.00%	29	0.71%	**90**	**2.22%**
7002	2,408	10.20%	5	0.21%	71	2.95%	0	0.00%	0	0.00%	24	1.00%	**100**	**4.15%**
7000/7001	34,881	7.60%	24	0.07%	601	1.72%	1	<0.01%	1	<0.01%	307	0.88%	**934**	**2.68%**
1590/1591	9,700	7.60%	7	0.07%	184	1.90%	0	0.00%	1	0.01%	54	0.56%	**246**	**2.54%**
1582	3,131	11.80%	3	0.10%	173	5.53%	0	0.00%	0	0.00%	35	1.12%	**211**	**6.74%**
1570/1571	10,280	8.70%	5	0.05%	224	2.18%	0	0.00%	0	0.00%	64	0.62%	**293**	**2.85%**
1580/1581	68,399	8.20%	32	0.05%	1790	2.62%	3	<0.01%	0	0.00%	547	0.80%	**2372**	**3.47%**

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	941	3.1%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	6	0.64%	**7**	**0.74%**
LDA220Q	11,017	2.4%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	51	0.46%	**54**	**0.49%**
LDA210Q	45,866	1.9%	5	0.01%	10	0.02%	0	0.00%	7	0.02%	192	0.42%	**214**	**0.47%**
LDA210	1,037	3.7%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.68%	**7**	**0.68%**
7170Q/7171Q	18,309	2.4%	8	0.04%	16	0.09%	2	0.01%	0	0.00%	72	0.39%	**98**	**0.54%**
7120Q/7121Q	218,872	3.3%	56	0.03%	284	0.13%	3	<0.01%	93	0.04%	1244	0.57%	**1680**	**0.77%**
7122Q	254,606	2.3%	43	0.02%	226	0.09%	2	<0.01%	136	0.05%	1284	0.50%	**1691**	**0.66%**
7120/7121	145,212	3.1%	115	0.08%	244	0.17%	1	<0.01%	25	0.02%	795	0.55%	**1180**	**0.81%**
7122	66,285	3.0%	114	0.17%	141	0.21%	1	<0.01%	23	0.03%	484	0.73%	**763**	**1.15%**

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	54	6,774	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	4,320	1,769	236,063	5	0.12%	4	0.09%	1	0.02%	15	0.35%	0	0.00%	21	0.49%	5	0.12%	4	0.09%	4	0.09%	39	0.90%	8	0.19%	0	0.00%	0	0.00%	106	2.45%
7122Q	1,540	728	77,517	2	0.13%	0	0.00%	0	0.00%	4	0.26%	0	0.00%	7	0.45%	1	0.06%	0	0.00%	0	0.00%	7	0.45%	1	0.06%	2	0.13%	0	0.00%	24	1.56%
7120/7121	3,559	976	214,933	4	0.11%	10	0.28%	0	0.00%	15	0.42%	0	0.00%	14	0.39%	2	0.06%	2	0.06%	11	0.31%	20	0.56%	10	0.28%	0	0.00%	1	0.03%	89	2.50%
7122	452	161	27,725	1	0.22%	5	1.11%	0	0.00%	6	1.33%	0	0.00%	5	1.11%	1	0.22%	0	0.00%	0	0.00%	5	1.11%	2	0.44%	0	0.00%	0	0.00%	25	5.53%
7070/7071	288	80	17,933	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	1,470	239	84,590	0	0.00%	6	0.41%	1	0.07%	8	0.54%	0	0.00%	16	1.09%	1	0.07%	0	0.00%	2	0.14%	9	0.61%	4	0.27%	0	0.00%	1	0.07%	48	3.27%
7000/7001	180	22	8,140	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.56%	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	117	29,930	0	0.00%	0	0.00%	0	0.00%	2	0.35%	0	0.00%	1	0.18%	0	0.00%	0	0.00%	9	1.59%	2	0.35%	6	1.06%	0	0.00%	1	0.18%	21	3.71%

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	5.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.74%	**2**	**1.74%**
7120Q/7121Q	4,320	5.90%	5	0.12%	6	0.14%	0	0.00%	1	0.02%	49	1.13%	**61**	**1.41%**
7122Q	1,540	5.80%	2	0.13%	5	0.32%	0	0.00%	0	0.00%	14	0.91%	**21**	**1.36%**
7120/7121	3,559	5.00%	1	0.03%	12	0.34%	0	0.00%	1	0.03%	29	0.81%	**43**	**1.21%**
7122	452	6.40%	2	0.44%	3	0.66%	0	0.00%	0	0.00%	8	1.77%	**13**	**2.88%**
7070/7071	288	2.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
7020/7021	1,470	5.60%	3	0.20%	3	0.20%	0	0.00%	0	0.00%	14	0.95%	**20**	**1.36%**
7000/7001	180	8.30%	0	0.00%	5	2.78%	1	0.56%	0	0.00%	0	0.00%	**6**	**3.33%**
1580/1581	566	7.60%	1	0.18%	23	4.06%	0	0.00%	0	0.00%	7	1.24%	**31**	**5.48%**

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

Dual-Chamber Pacemakers

Dual-Chamber Pacemakers

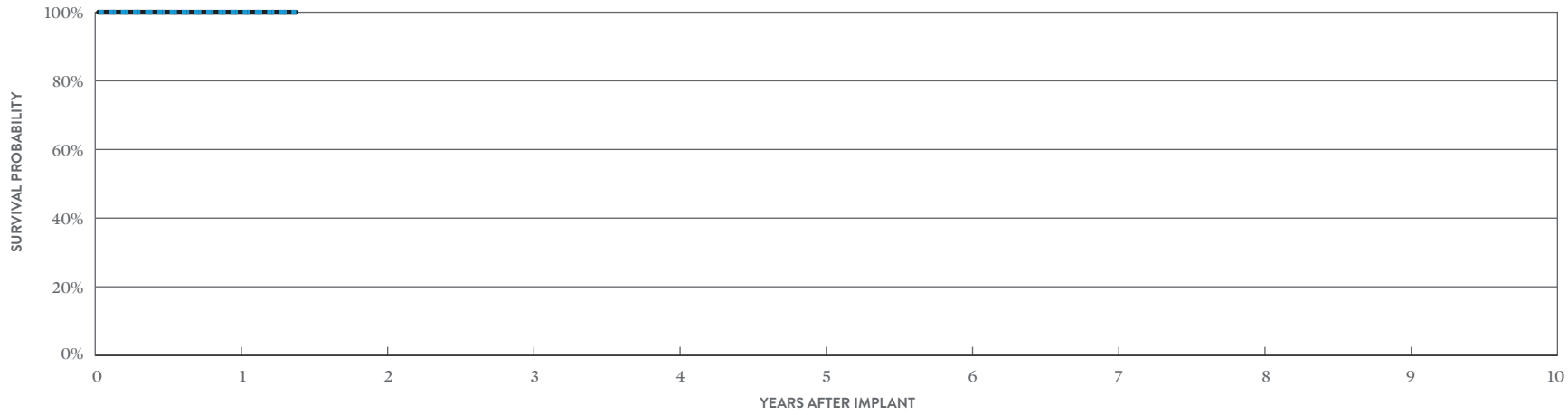
CUSTOMER REPORTED PERFORMANCE DATA

Assurity MRI™

MODEL PM2272

US Regulatory Approval	January 2017
Registered US Implants	61,717
Estimated Active US Implants	57,157
Estimated Longevity	9.4 Years
Normal Battery Depletion	0
Number of US Advisories (see pg. 333)	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	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**0**	**0.00%**	**2**	**<0.01%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	AT 17 MONTHS
SURVIVAL PROBABILITY	99.99%	99.99%
± 1 STANDARD ERROR	0.00%	0.00%
SAMPLE SIZE	36,990	1,100

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	AT 17 MONTHS
SURVIVAL PROBABILITY	99.99%	99.99%
± 1 STANDARD ERROR	0.00%	0.00%

Dual-Chamber Pacemakers

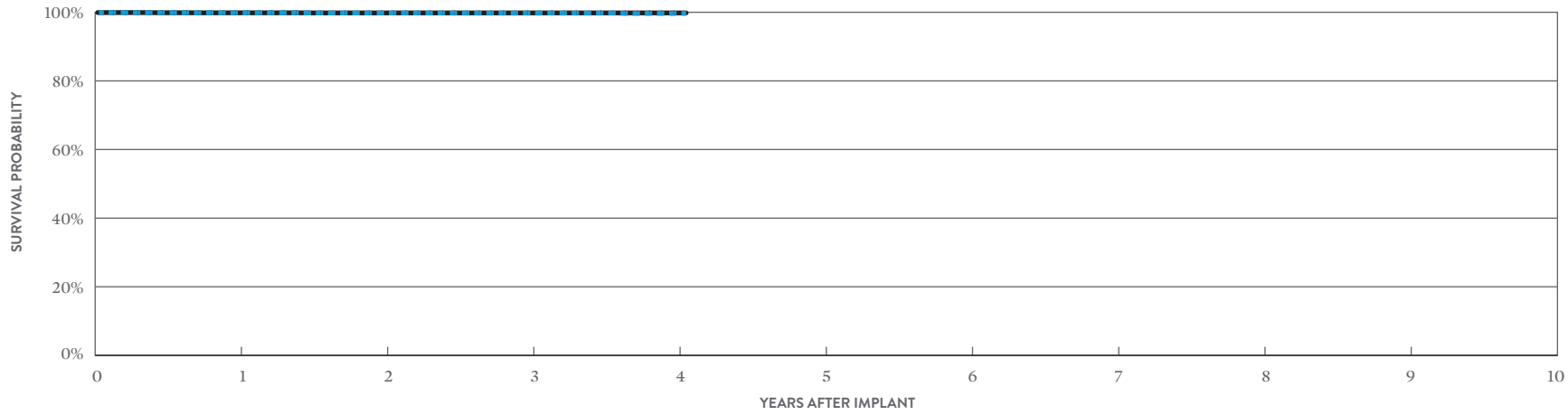
CUSTOMER REPORTED PERFORMANCE DATA

Endurity™ DR

MODEL PM2160

US Regulatory Approval	March 2014
Registered US Implants	9,068
Estimated Active US Implants	6,757
Estimated Longevity	9.7 Years
Normal Battery Depletion	3
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%	5	0.06%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	**0**	**0.00%**	**7**	**0.08%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 49 MONTHS
SURVIVAL PROBABILITY	99.84%	99.78%	99.75%	99.65%	99.65%
± 1 STANDARD ERROR	0.04%	0.05%	0.06%	0.09%	0.09%
SAMPLE SIZE	8,440	7,190	5,280	2,140	280

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 49 MONTHS
SURVIVAL PROBABILITY	99.84%	99.81%	99.81%	99.81%	99.81%
± 1 STANDARD ERROR	0.04%	0.05%	0.05%	0.05%	0.05%

Dual-Chamber Pacemakers

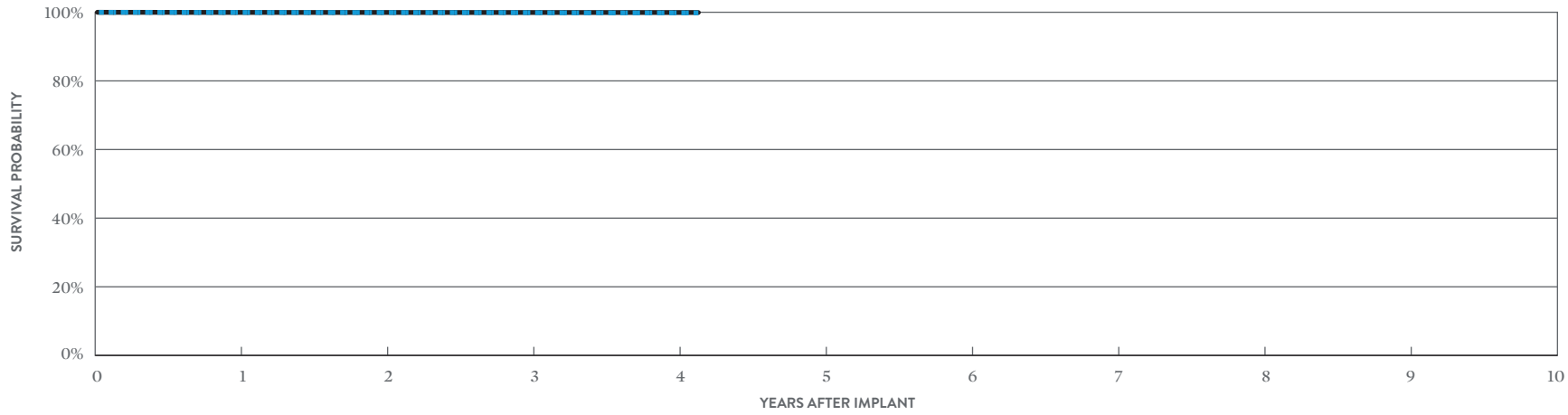
CUSTOMER REPORTED PERFORMANCE DATA

Assurity™ DR RF

MODEL PM2240

US Regulatory Approval	March 2014
Registered US Implants	173,934
Estimated Active US Implants	133,981
Estimated Longevity	9.4 Years
Normal Battery Depletion	21
Number of US Advisories (see pg. 333)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	3	<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	1	<0.01%	24	0.01%
Possible Early Battery Depletion	2	<0.01%	1	<0.01%
Other	0	0.00%	7	<0.01%
Total	**5**	**<0.01%**	**36**	**0.02%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 50 MONTHS
SURVIVAL PROBABILITY	99.95%	99.92%	99.89%	99.83%	99.83%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.02%	0.02%
SAMPLE SIZE	157,680	116,980	66,020	20,390	610

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 50 MONTHS
SURVIVAL PROBABILITY	99.95%	99.94%	99.93%	99.93%	99.93%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.01%

Dual-Chamber Pacemakers

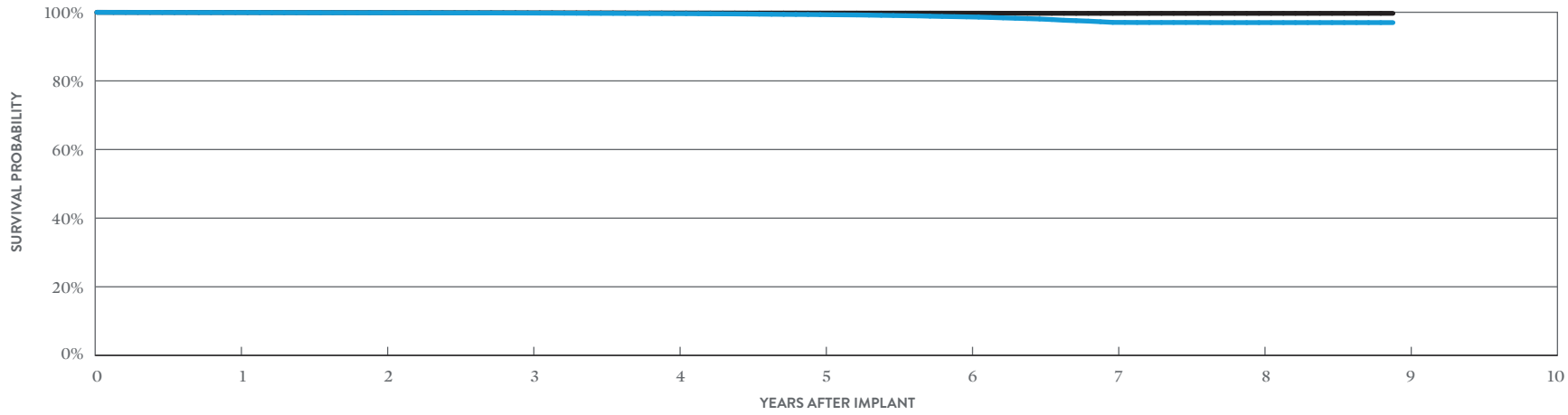
CUSTOMER REPORTED PERFORMANCE DATA

Accent™ DR RF

MODEL PM2210

US Regulatory Approval	July 2009
Registered US Implants	243,054
Estimated Active US Implants	125,011
Estimated Longevity	8 Years
Normal Battery Depletion	814
Number of US Advisories (see pgs. 333, 335)	Two

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	17	<0.01%	45	0.02%
Electrical Interconnect	7	<0.01%	33	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	4	<0.01%
Mechanical	0	0.00%	21	<0.01%
Possible Early Battery Depletion	7	<0.01%	22	<0.01%
Other	5	<0.01%	40	0.02%
Total	**36**	**0.01%**	**165**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.92%	99.86%	99.77%	99.61%	99.32%	98.66%	97.05%	96.99%	96.99%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.02%	0.03%	0.06%	0.07%	0.07%
SAMPLE SIZE	228,220	202,240	181,330	160,650	128,110	88,240	54,540	26,680	570

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.95%	99.90%	99.84%	99.79%	99.76%	99.73%	99.69%	99.69%	99.69%
± 1 STANDARD ERROR	0.00%	0.01%	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

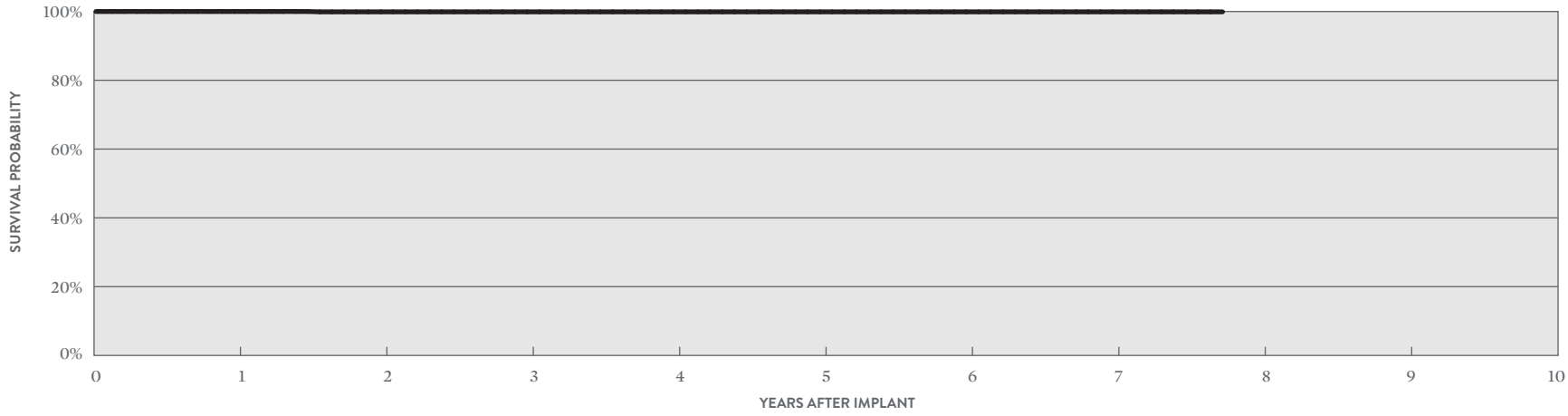
Accent™ DR RF

MODEL PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,773
Active Devices Enrolled in Study	243
Cumulative Months of Follow-up	55,443
Estimated Longevity	8 Years

QUALIFYING COMPLICATIONS	QTY	RATE
Premature Battery Depletion	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	1	2	3	4	5	6	7	AT 93 MONTHS
SURVIVAL PROBABILITY	100.00%	99.90%	99.90%	99.90%	99.90%	99.90%	99.90%	99.90%
± 1 STANDARD ERROR	0.00%	0.10%	0.10%	0.10%	0.10%	0.10%	0.10%	0.10%
SAMPLE SIZE	1,540	1,060	650	450	380	320	230	60

Dual-Chamber Pacemakers

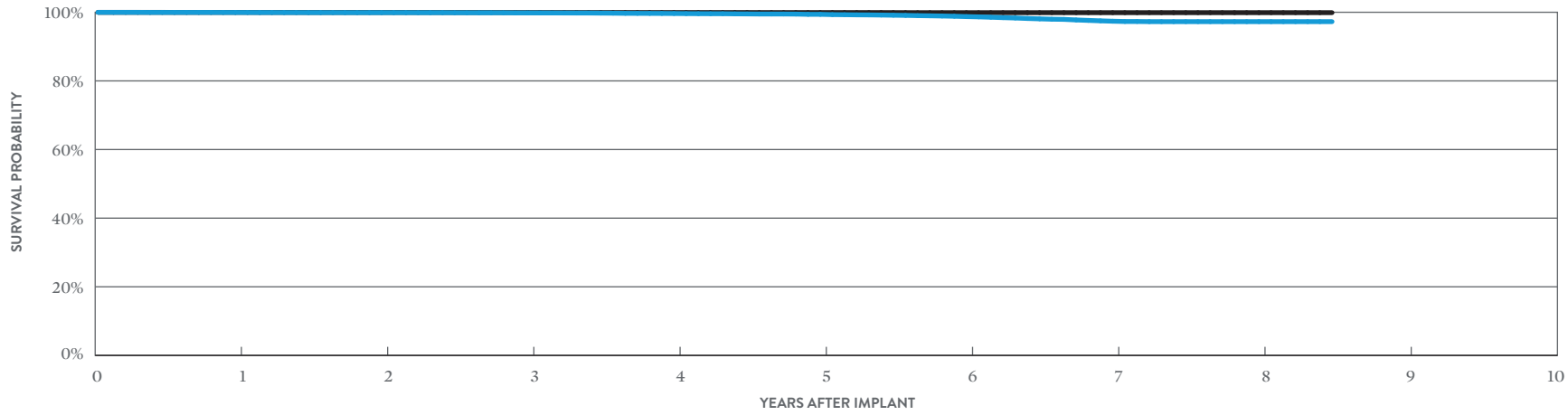
CUSTOMER REPORTED PERFORMANCE DATA

Accent™ DR

MODEL PM2110

US Regulatory Approval	July 2009
Registered US Implants	48,908
Estimated Active US Implants	26,158
Estimated Longevity	9.2 Years
Normal Battery Depletion	166
Number of US Advisories (see pg. 335)	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	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	99.95%	99.90%	99.82%	99.64%	99.40%	98.74%	97.39%	97.27%	97.27%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.03%	0.04%	0.07%	0.13%	0.15%	0.15%
SAMPLE SIZE	45,980	40,850	36,660	32,640	26,130	17,750	10,240	3,940	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	99.97%	99.95%	99.93%	99.93%	99.92%	99.89%	99.89%	99.89%	99.89%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%	0.02%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

Accent™ DR

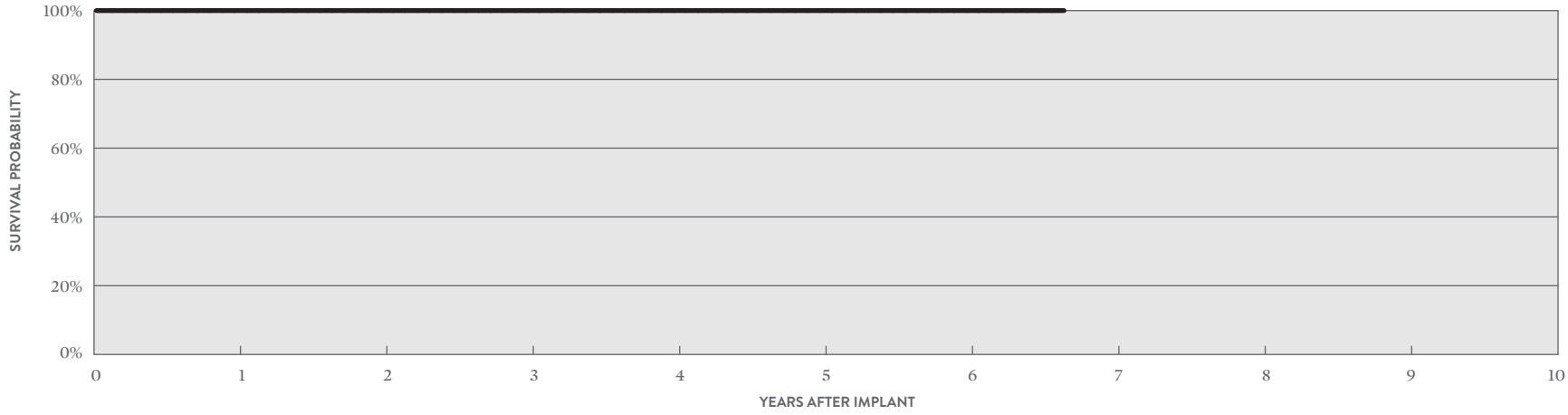
MODEL PM2110

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	227
Active Devices Enrolled in Study	47
Cumulative Months of Follow-up	9,169
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 80 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	150	100	90	80	70	50

Dual-Chamber Pacemakers

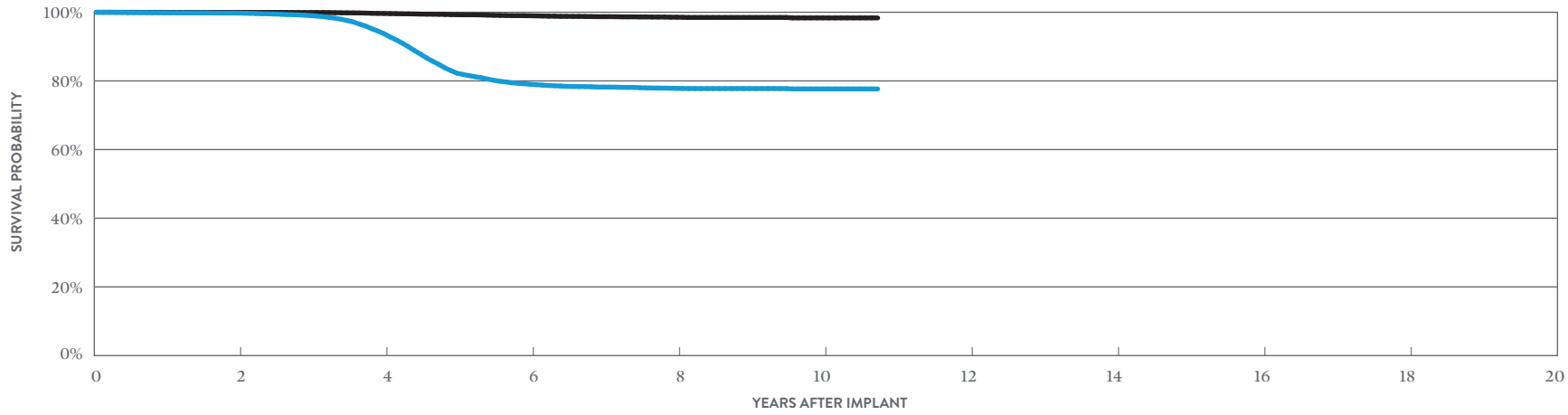
CUSTOMER REPORTED PERFORMANCE DATA

Zephyr™ DR

MODEL 5820

US Regulatory Approval	March 2007
Registered US Implants	54,063
Estimated Active US Implants	16,174
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,311
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	34	0.06%
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%	80	0.15%
Total	**2**	**<0.01%**	**126**	**0.23%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 129 MONTHS
SURVIVAL PROBABILITY	99.75%	93.77%	79.01%	77.83%	77.67%	77.67%
± 1 STANDARD ERROR	0.02%	0.13%	0.25%	0.26%	0.27%	0.27%
SAMPLE SIZE	42,470	31,200	17,130	6,610	1,830	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 129 MONTHS
SURVIVAL PROBABILITY	99.96%	99.64%	98.97%	98.56%	98.35%	98.35%
± 1 STANDARD ERROR	0.01%	0.03%	0.06%	0.09%	0.14%	0.14%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

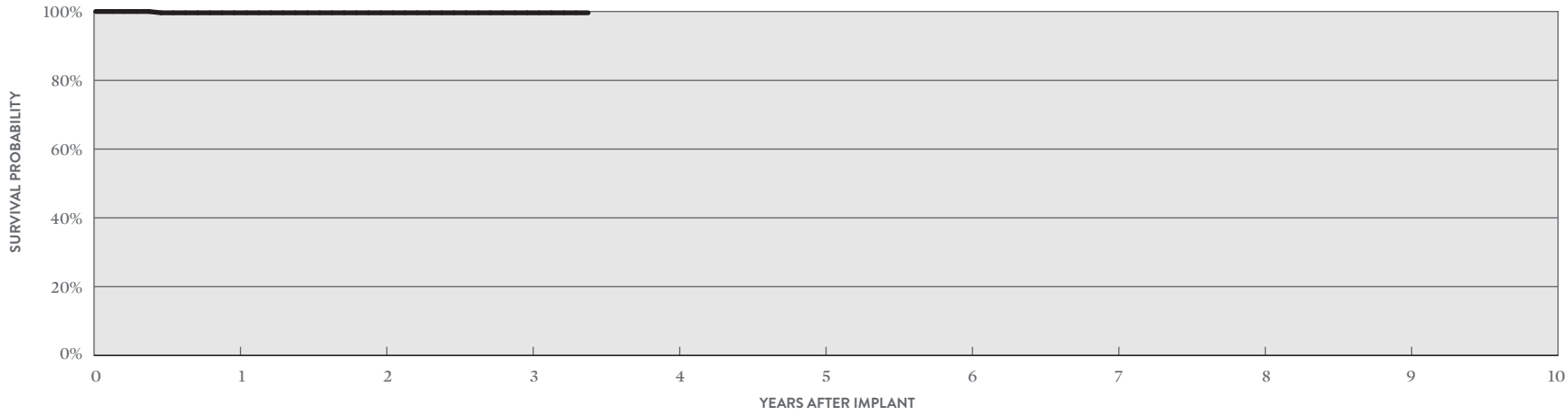
Zephyr™ DR

MODEL 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	283
Active Devices Enrolled in Study	7
Cumulative Months of Follow-up	7,899
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

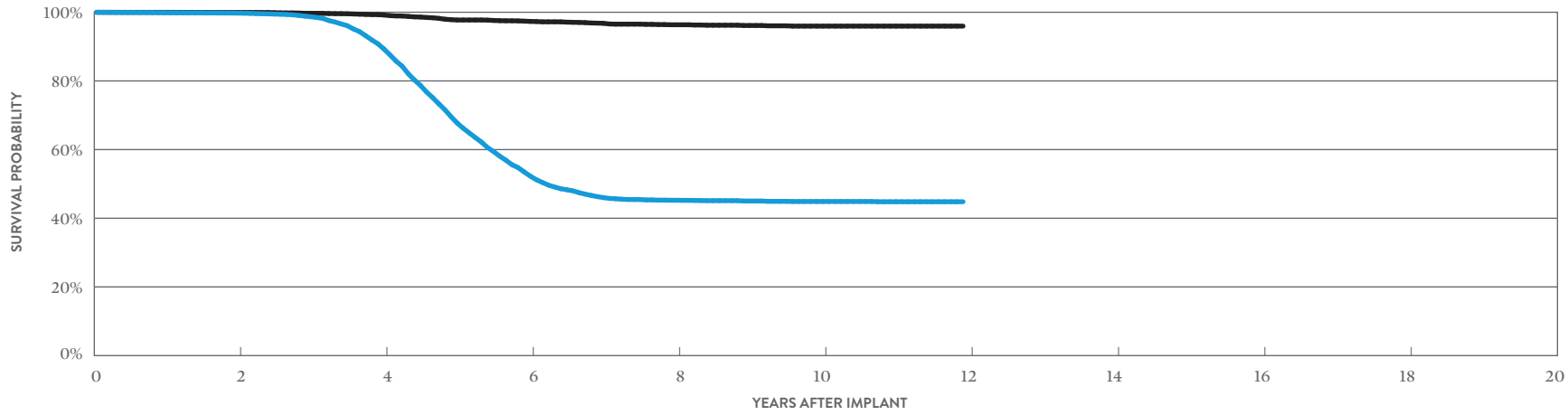
CUSTOMER REPORTED PERFORMANCE DATA

Victory™ DR

MODEL 5810

US Regulatory Approval	December 2005
Registered US Implants	26,312
Estimated Active US Implants	2,636
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,776
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	AT 143 MONTHS
SURVIVAL PROBABILITY	99.75%	89.31%	52.28%	45.24%	44.88%	44.81%
± 1 STANDARD ERROR	0.03%	0.23%	0.43%	0.45%	0.45%	0.46%
SAMPLE SIZE	20,880	14,820	7,530	3,500	2,080	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 143 MONTHS
SURVIVAL PROBABILITY	99.93%	99.19%	97.33%	96.35%	95.96%	95.96%
± 1 STANDARD ERROR	0.02%	0.07%	0.15%	0.21%	0.25%	0.25%

Dual-Chamber Pacemakers

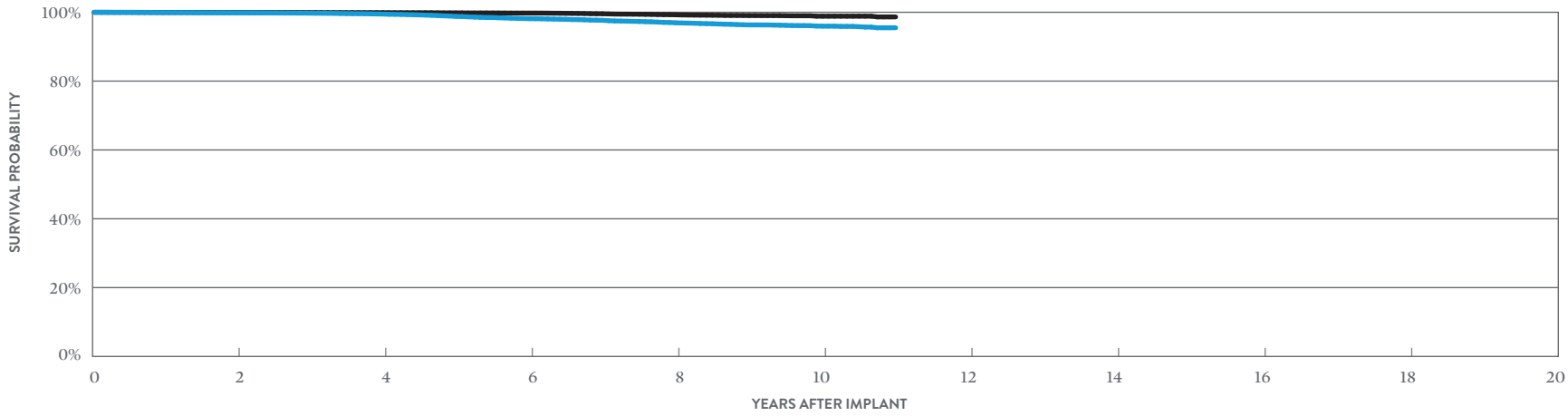
CUSTOMER REPORTED PERFORMANCE DATA

Zephyr™ XL DR

MODEL 5826

US Regulatory Approval	March 2007
Registered US Implants	112,244
Estimated Active US Implants	31,322
Estimated Longevity	11.7 Years
Normal Battery Depletion	585
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	19	0.02%
Electrical Interconnect	4	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	14	0.01%
Mechanical	1	<0.01%	9	<0.01%
Possible Early Battery Depletion	0	0.00%	3	<0.01%
Other	1	<0.01%	135	0.12%
Total	**7**	**<0.01%**	**180**	**0.16%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.84%	99.48%	98.14%	96.94%	95.96%	95.50%
± 1 STANDARD ERROR	0.01%	0.02%	0.05%	0.07%	0.11%	0.21%
SAMPLE SIZE	92,190	72,620	55,770	35,420	11,560	300

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 132 MONTHS
SURVIVAL PROBABILITY	99.93%	99.89%	99.76%	99.26%	98.86%	98.65%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.04%	0.07%	0.16%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

Zephyr™ XL DR

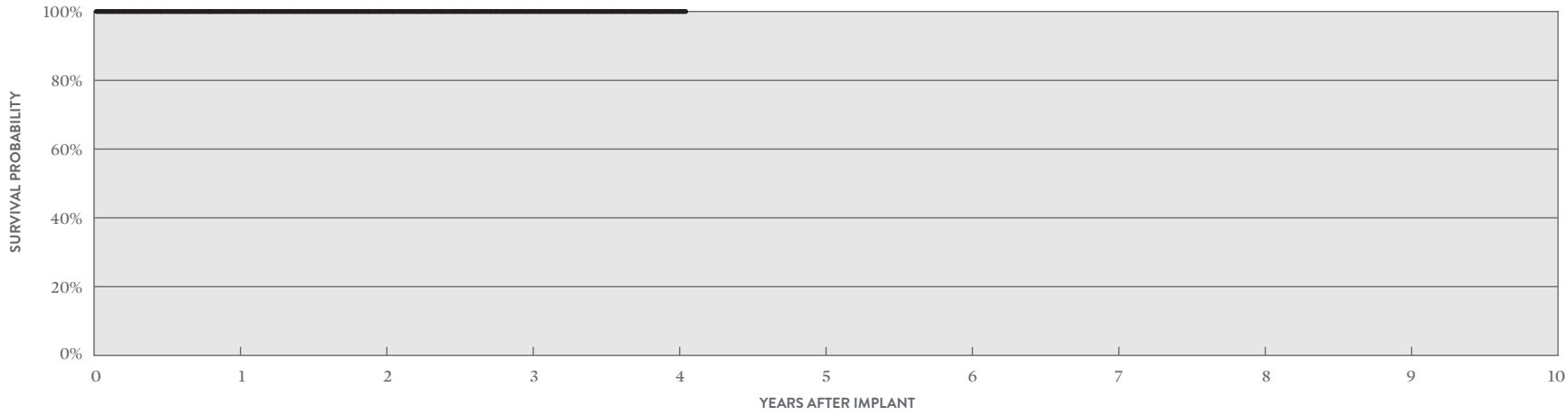
MODEL 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,516
Active Devices Enrolled in Study	10
Cumulative Months of Follow-up	47,950
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	360	70

Dual-Chamber Pacemakers

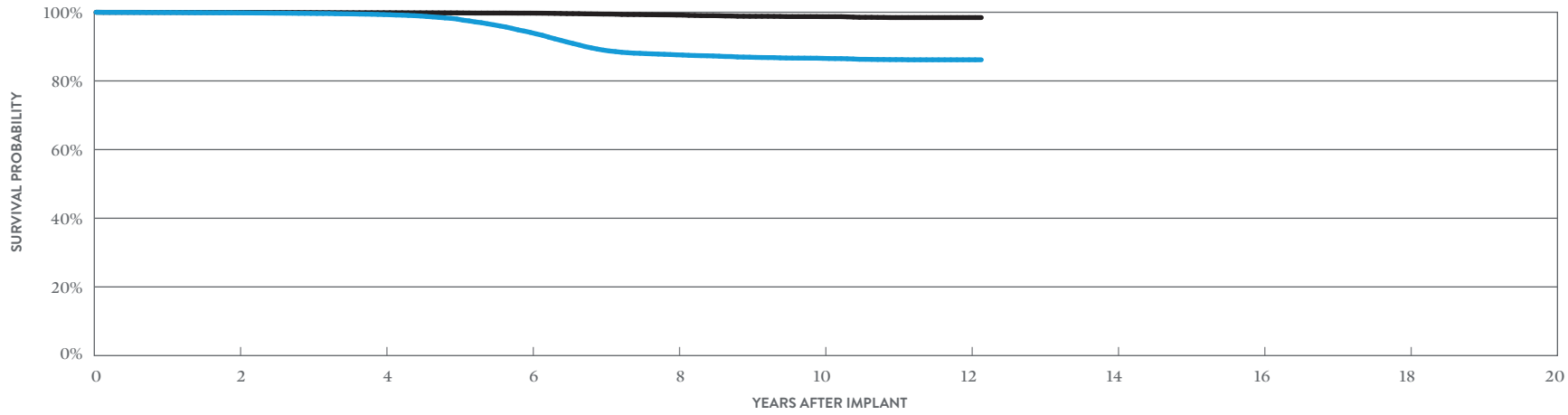
CUSTOMER REPORTED PERFORMANCE DATA

Victory™ XL DR

MODEL 5816

US Regulatory Approval	December 2005
Registered US Implants	62,700
Estimated Active US Implants	11,189
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,501
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	25	0.04%
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%	88	0.14%
Total	**3**	**<0.01%**	**135**	**0.22%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 146 MONTHS
SURVIVAL PROBABILITY	99.83%	99.32%	94.14%	87.60%	86.57%	86.15%	86.15%
± 1 STANDARD ERROR	0.02%	0.04%	0.12%	0.19%	0.20%	0.22%	0.22%
SAMPLE SIZE	51,910	40,610	31,670	20,370	10,890	2,380	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 146 MONTHS
SURVIVAL PROBABILITY	99.95%	99.86%	99.74%	99.19%	98.72%	98.45%	98.45%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.05%	0.08%	0.10%	0.10%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

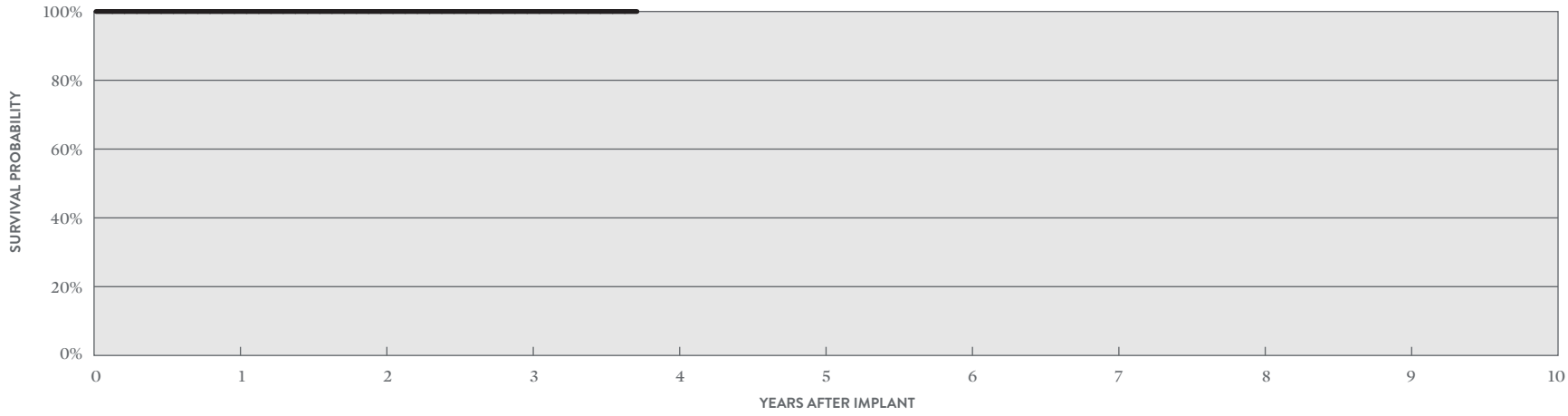
Victory™ XL DR

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

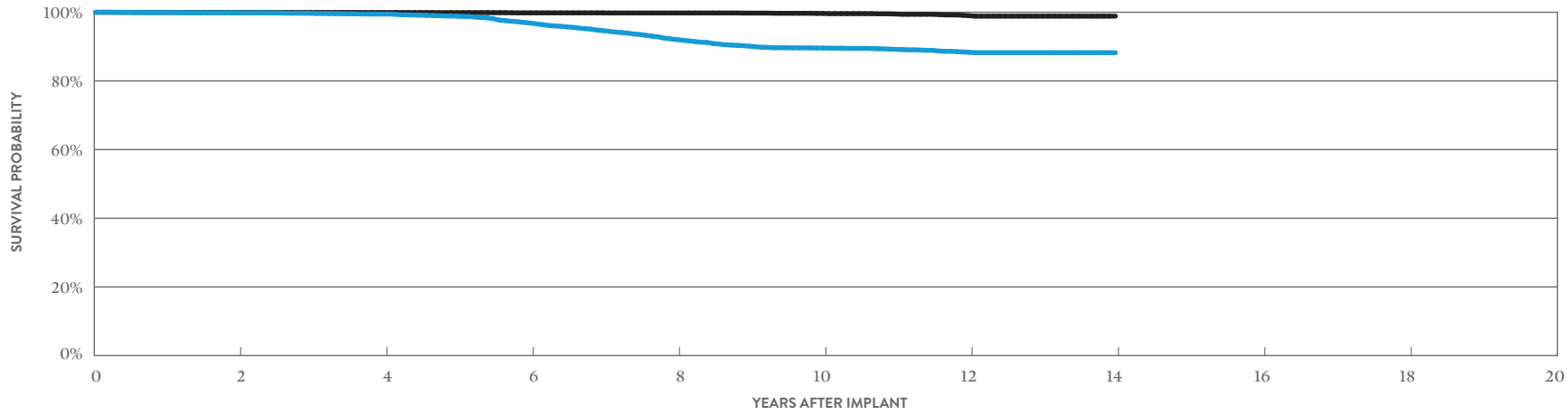
Dual-Chamber Pacemakers

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	17,371
Estimated Active US Implants	3,558
Estimated Longevity	6.9 Years
Normal Battery Depletion	306
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	10	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%**	**22**	**0.13%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14
SURVIVAL PROBABILITY	99.83%	99.47%	96.85%	92.05%	89.58%	88.33%	88.22%
± 1 STANDARD ERROR	0.03%	0.06%	0.18%	0.31%	0.37%	0.42%	0.43%
SAMPLE SIZE	14,220	10,990	8,240	6,080	4,410	2,240	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14
SURVIVAL PROBABILITY	99.95%	99.91%	99.82%	99.79%	99.65%	98.99%	98.86%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.05%	0.07%	0.17%	0.21%

Dual-Chamber Pacemakers

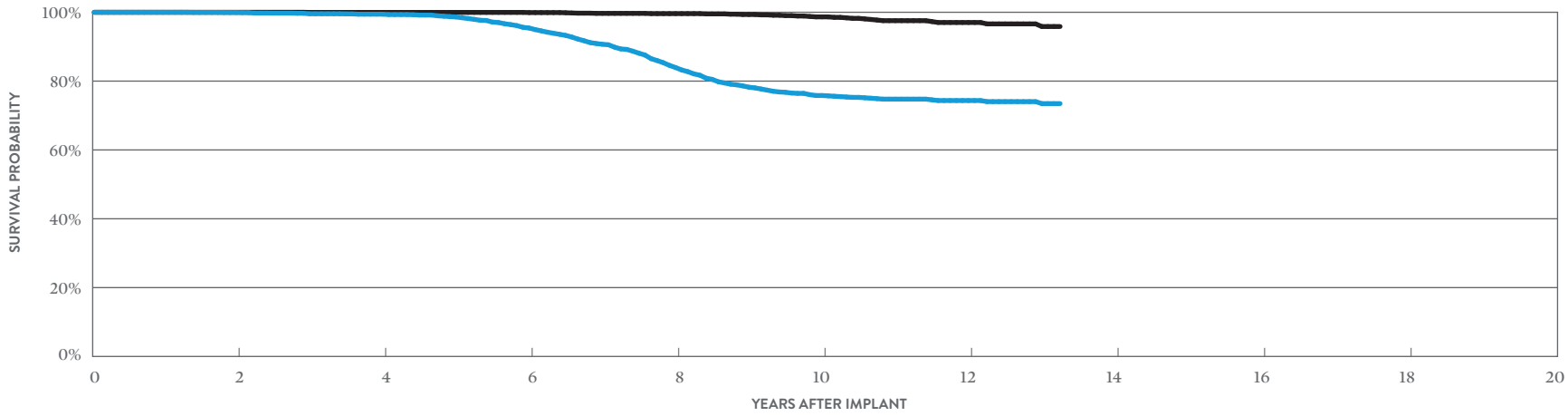
CUSTOMER REPORTED PERFORMANCE DATA

Integrity ADx™ DR

MODEL 5366

US Regulatory Approval	May 2003
Registered US Implants	8,085
Estimated Active US Implants	1,011
Estimated Longevity	6.9 Years
Normal Battery Depletion	320
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	AT 159 MONTHS
SURVIVAL PROBABILITY	99.94%	99.44%	95.42%	83.94%	75.81%	74.35%	73.46%
± 1 STANDARD ERROR	0.03%	0.10%	0.31%	0.59%	0.76%	0.81%	0.92%
SAMPLE SIZE	6,750	5,290	4,090	2,970	1,760	760	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 159 MONTHS
SURVIVAL PROBABILITY	100.00%	99.96%	99.91%	99.61%	98.66%	97.03%	95.86%
± 1 STANDARD ERROR	0.00%	0.03%	0.03%	0.10%	0.25%	0.46%	0.76%

Dual-Chamber Pacemakers

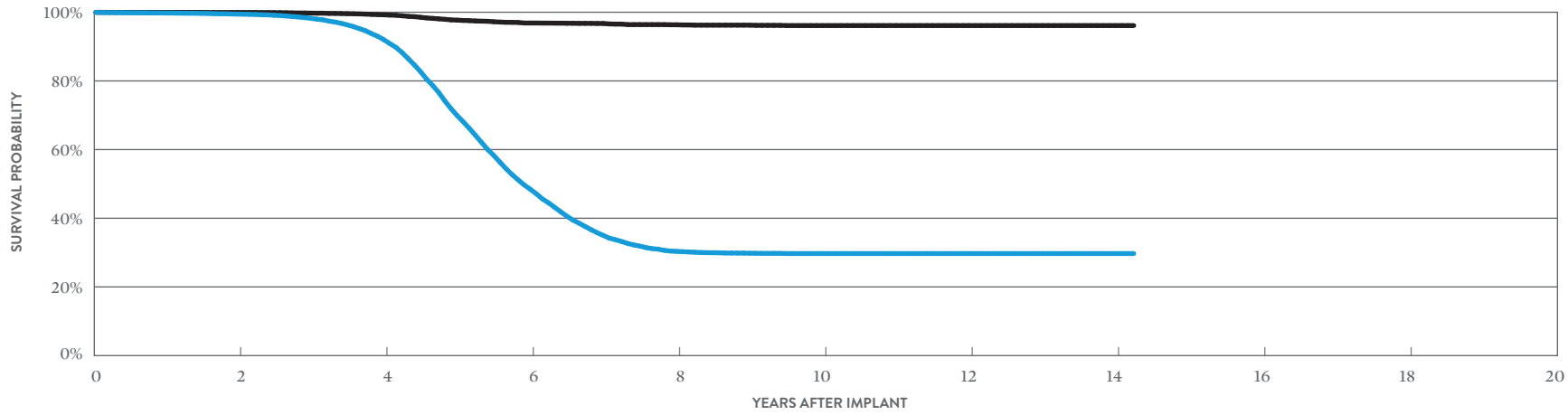
CUSTOMER REPORTED PERFORMANCE DATA

Identity ADx™ DR

MODEL 5380

US Regulatory Approval	March 2003
Registered US Implants	54,049
Estimated Active US Implants	2,977
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,220
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	AT 171 MONTHS
SURVIVAL PROBABILITY	99.45%	92.00%	48.46%	30.35%	29.72%	29.72%	29.72%	29.72%
± 1 STANDARD ERROR	0.03%	0.14%	0.33%	0.33%	0.33%	0.33%	0.33%	0.33%
SAMPLE SIZE	43,360	30,980	13,180	4,740	2,900	1,970	560	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 171 MONTHS
SURVIVAL PROBABILITY	99.93%	99.25%	96.86%	96.35%	96.12%	96.12%	96.12%	96.12%
± 1 STANDARD ERROR	0.01%	0.05%	0.12%	0.16%	0.18%	0.18%	0.18%	0.18%

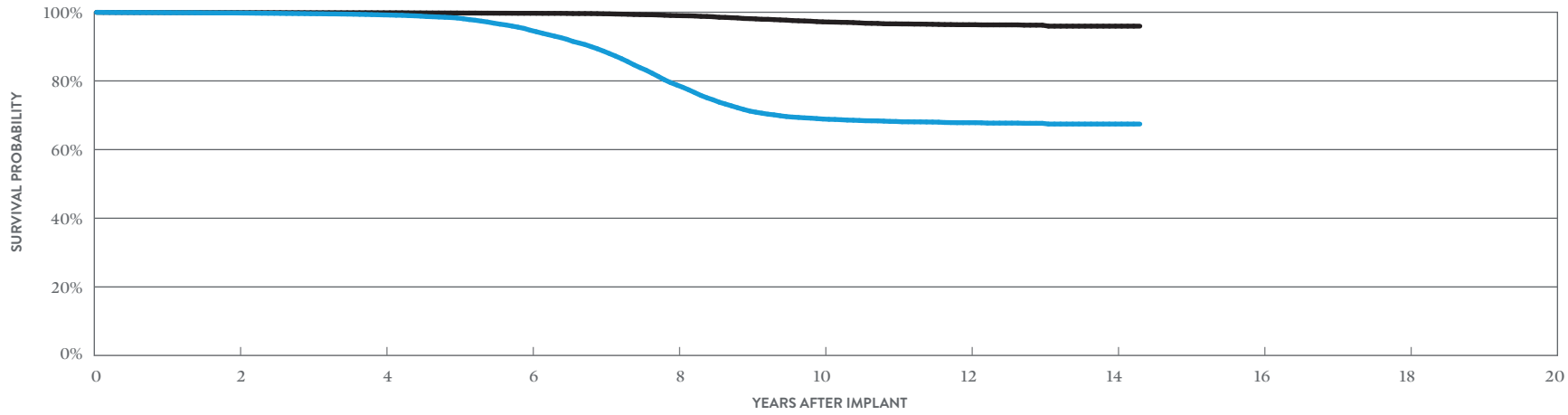
Dual-Chamber Pacemakers

CUSTOMER REPORTED PERFORMANCE DATA

Identity ADx™ XL DR MODEL 5386
Identity ADx™ XL DC MODEL 5286

US Regulatory Approval	March 2003
Registered US Implants	67,395
Estimated Active US Implants	9,067
Estimated Longevity	6.9 Years
Normal Battery Depletion	3,307
Number of US Advisories	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	132	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%	107	0.16%
Total	**2**	**<0.01%**	**264**	**0.39%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 172 MONTHS
SURVIVAL PROBABILITY	99.78%	99.22%	94.76%	78.84%	68.90%	67.83%	67.44%	67.44%
± 1 STANDARD ERROR	0.02%	0.04%	0.11%	0.23%	0.29%	0.30%	0.32%	0.32%
SAMPLE SIZE	56,170	44,180	33,660	23,400	12,020	5,520	1,070	240

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 172 MONTHS
SURVIVAL PROBABILITY	99.90%	99.85%	99.70%	99.02%	97.20%	96.37%	95.95%	95.95%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.06%	0.12%	0.16%	0.22%	0.22%

Dual-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

Identity ADx™ XL DR

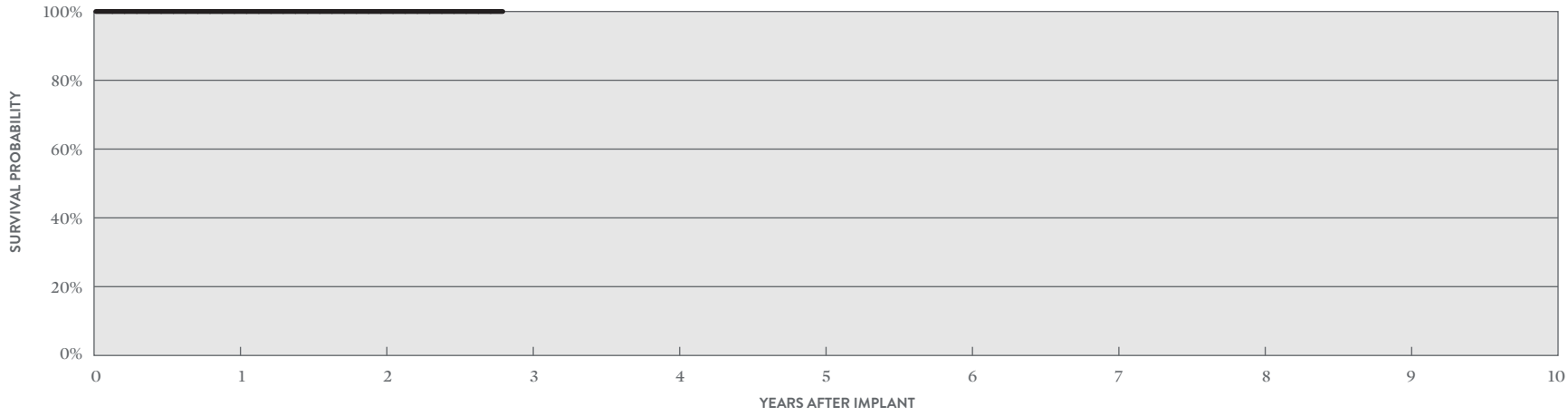
MODEL 5386

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

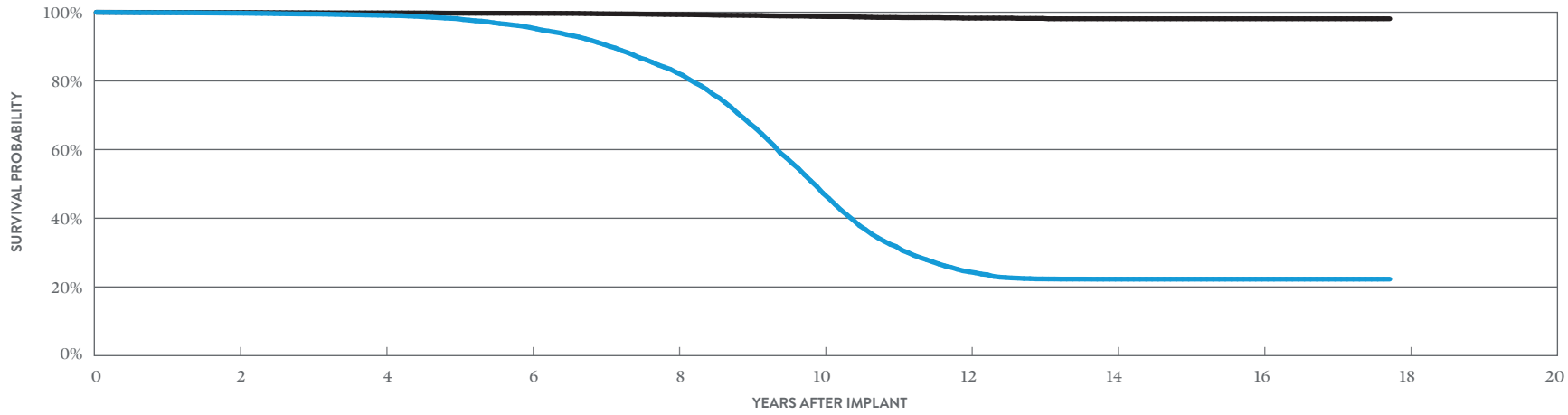
CUSTOMER REPORTED PERFORMANCE DATA

Integrity AFx™ DR

MODELS 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,442
Estimated Active US Implants	1,563
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,611
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	92	0.19%
Electrical Interconnect	3	<0.01%	1	<0.01%
Battery	0	0.00%	2	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	3	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	6	0.01%
Total	**6**	**0.01%**	**104**	**0.22%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 213 MONTHS
SURVIVAL PROBABILITY	99.73%	99.12%	95.55%	82.45%	47.32%	24.41%	22.27%	22.27%	22.27%
± 1 STANDARD ERROR	0.03%	0.05%	0.12%	0.26%	0.41%	0.38%	0.37%	0.37%	0.37%
SAMPLE SIZE	39,910	32,250	24,700	16,290	7,850	3,230	1,770	1,280	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 213 MONTHS
SURVIVAL PROBABILITY	99.92%	99.81%	99.70%	99.33%	98.76%	98.30%	98.11%	98.11%	98.11%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.05%	0.09%	0.14%	0.17%	0.17%	0.17%

Dual-Chamber Pacemakers

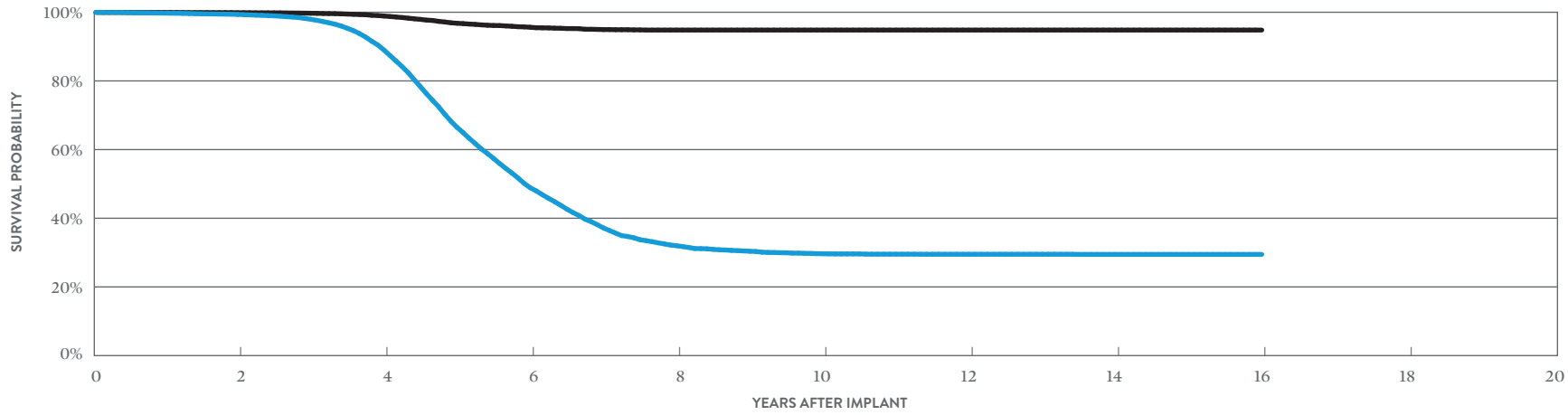
CUSTOMER REPORTED PERFORMANCE DATA

Identity™

MODEL 5370

US Regulatory Approval	November 2001
Registered US Implants	58,366
Estimated Active US Implants	1,883
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,084
Number of US Advisories	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
SURVIVAL PROBABILITY	99.36%	89.02%	48.89%	32.00%	29.66%	29.51%	29.47%	29.47%
± 1 STANDARD ERROR	0.03%	0.15%	0.33%	0.37%	0.38%	0.38%	0.38%	0.38%
SAMPLE SIZE	47,330	33,770	11,980	3,850	2,430	1,950	1,330	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16
SURVIVAL PROBABILITY	99.87%	98.90%	95.63%	94.81%	94.81%	94.81%	94.81%	94.81%
± 1 STANDARD ERROR	0.01%	0.05%	0.14%	0.19%	0.19%	0.19%	0.19%	0.19%

Dual-Chamber Pacemakers

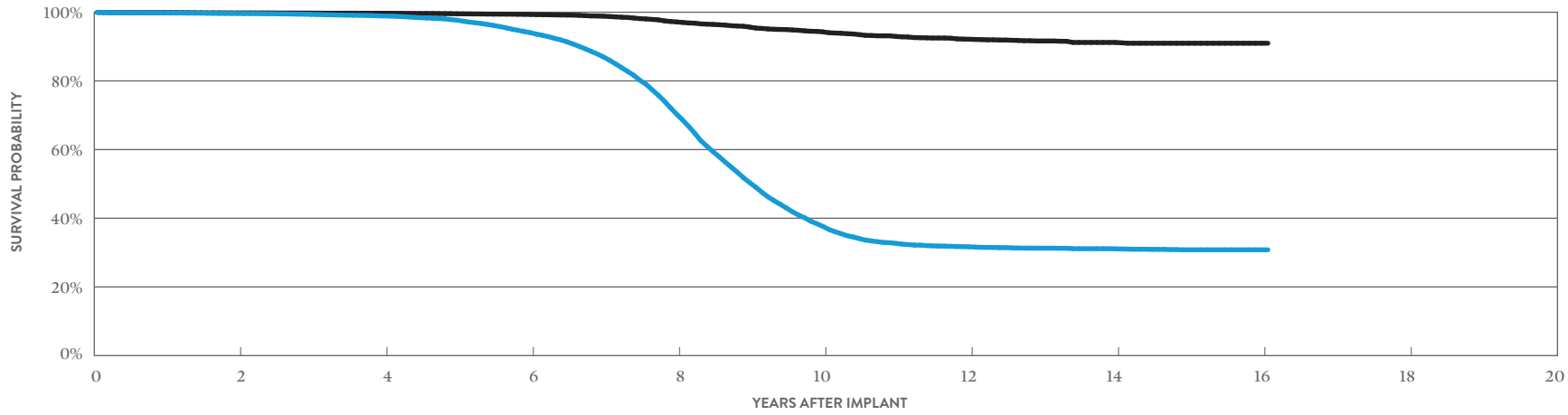
CUSTOMER REPORTED PERFORMANCE DATA

Identity™ XL

MODEL 5376

US Regulatory Approval	November 2001
Registered US Implants	51,525
Estimated Active US Implants	3,204
Estimated Longevity	6.9 Years
Normal Battery Depletion	5,332
Number of US Advisories	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	311	0.60%
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%	96	0.19%
Total	**8**	**0.02%**	**432**	**0.84%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 193 MONTHS
SURVIVAL PROBABILITY	99.64%	98.91%	94.05%	70.35%	37.64%	31.68%	31.09%	30.81%	30.81%
± 1 STANDARD ERROR	0.03%	0.05%	0.13%	0.30%	0.34%	0.34%	0.34%	0.35%	0.35%
SAMPLE SIZE	43,440	34,570	26,140	17,200	8,210	4,050	2,010	570	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 193 MONTHS
SURVIVAL PROBABILITY	99.80%	99.71%	99.35%	97.18%	94.29%	92.14%	91.20%	90.97%	90.97%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.11%	0.20%	0.28%	0.33%	0.35%	0.35%

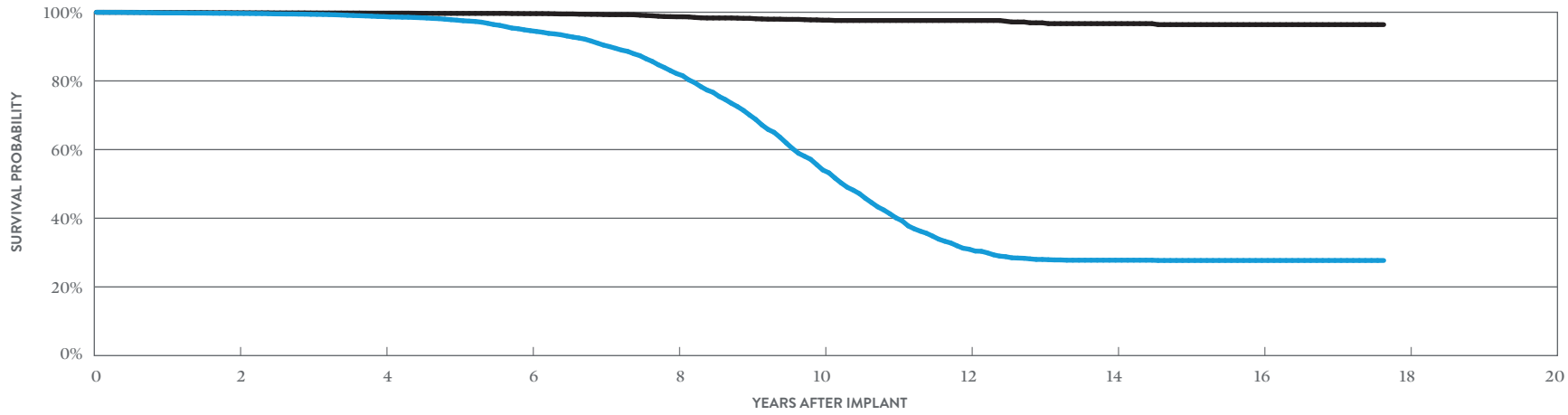
Dual-Chamber Pacemakers

CUSTOMER REPORTED PERFORMANCE DATA

Entity™ DR MODEL 5326
Entity™ DC MODEL 5226

US Regulatory Approval	June 1999
Registered US Implants	21,829
Estimated Active US Implants	647
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,546
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	65	0.30%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	3	0.01%
Total	**3**	**0.01%**	**74**	**0.34%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	99.66%	98.73%	94.64%	82.14%	54.05%	30.98%	27.78%	27.70%	27.70%
± 1 STANDARD ERROR	0.04%	0.09%	0.20%	0.41%	0.66%	0.71%	0.70%	0.70%	0.70%
SAMPLE SIZE	17,830	14,040	10,260	6,310	3,000	1,290	750	540	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 212 MONTHS
SURVIVAL PROBABILITY	99.85%	99.74%	99.60%	98.68%	97.69%	97.60%	96.68%	96.39%	96.39%
± 1 STANDARD ERROR	0.03%	0.04%	0.05%	0.13%	0.20%	0.22%	0.39%	0.44%	0.44%

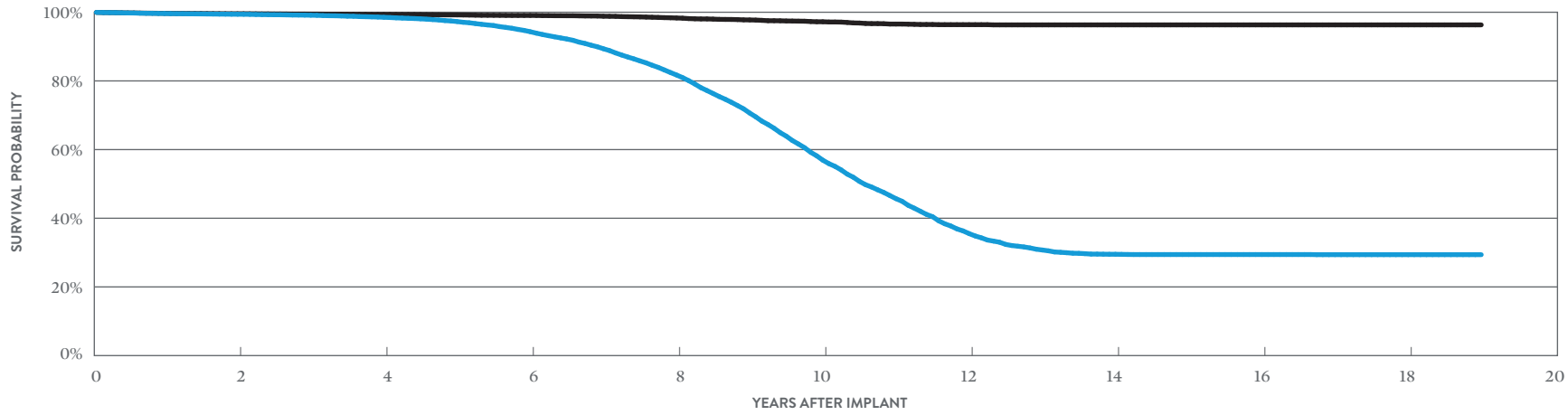
Dual-Chamber Pacemakers

CUSTOMER REPORTED PERFORMANCE DATA

Affinity™ DR MODELS 5330 & 5331
Affinity™ DC MODEL 5230

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,717
Estimated Active US Implants	1,931
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,557
Number of US Advisories	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	5	<0.01%	283	0.43%
Electrical Interconnect	9	0.01%	13	0.02%
Battery	0	0.00%	6	<0.01%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	5	<0.01%
Total	**15**	**0.02%**	**315**	**0.48%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 228 MONTHS
SURVIVAL PROBABILITY	99.41%	98.53%	94.33%	81.72%	56.91%	35.52%	29.51%	29.43%	29.39%	29.39%
± 1 STANDARD ERROR	0.03%	0.05%	0.11%	0.23%	0.37%	0.43%	0.43%	0.43%	0.43%	0.43%
SAMPLE SIZE	54,700	43,650	32,410	19,990	9,350	4,120	2,430	1,850	1,140	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 228 MONTHS
SURVIVAL PROBABILITY	99.56%	99.35%	99.07%	98.33%	97.23%	96.38%	96.32%	96.32%	96.32%	96.32%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.07%	0.12%	0.17%	0.18%	0.18%	0.18%	0.18%

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™	99.99%									
PM2160	Endurity™ DR	99.84%	99.78%	99.75%	99.65%						
PM2240	Assurity™ DR RF	99.95%	99.92%	99.89%	99.83%						
PM2210	Accent™ DR RF	99.92%	99.86%	99.77%	99.61%	99.32%	98.66%	97.05%	96.99%		
PM2110	Accent™ DR	99.95%	99.90%	99.82%	99.64%	99.40%	98.74%	97.39%	97.27%		
5820	Zephyr™ DR	99.84%	99.75%	99.02%	93.77%	82.23%	79.01%	78.20%	77.83%	77.77%	77.67%
5810	Victory™ DR	99.87%	99.75%	98.68%	89.31%	67.76%	52.28%	46.01%	45.24%	45.02%	44.88%
5826	Zephyr™ XL DR	99.91%	99.84%	99.74%	99.48%	98.80%	98.14%	97.67%	96.94%	96.33%	95.96%
5816	Victory™ XL DR	99.91%	99.83%	99.66%	99.32%	98.03%	94.14%	88.97%	87.60%	86.91%	86.57%
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.89%	99.83%	99.69%	99.47%	98.85%	96.85%	94.62%	92.05%	90.10%	89.58%
5366	Integrity ADx™ XL DR	100.00%	99.94%	99.57%	99.44%	98.64%	95.42%	90.70%	83.94%	78.23%	75.81%
5380	Identity ADx™ DR	99.77%	99.45%	98.22%	92.00%	69.94%	48.46%	34.99%	30.35%	29.81%	29.72%
5386/5286	Identity ADx™ XL DR/DC	99.88%	99.78%	99.57%	99.22%	98.33%	94.76%	88.69%	78.84%	71.22%	68.90%
5342/5346	Integrity AFx™ DR	99.87%	99.73%	99.48%	99.12%	98.13%	95.55%	90.69%	82.45%	67.61%	47.32%
5370	Identity™	99.75%	99.36%	97.94%	89.02%	66.47%	48.89%	37.18%	32.00%	30.38%	29.66%
5376	Identity™ XL	99.79%	99.64%	99.38%	98.91%	97.69%	94.05%	86.99%	70.35%	50.38%	37.64%
5326/5226	Entity™ DR/DC	99.79%	99.66%	99.40%	98.73%	97.70%	94.64%	90.44%	82.14%	70.04%	54.05%
5330/5331/5230	Affinity™ DR/DC	99.63%	99.41%	99.13%	98.53%	97.29%	94.33%	89.37%	81.72%	70.64%	56.91%

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™	99.99%									
PM2160	Endurity™ DR	99.84%	99.81%	99.81%	99.81%						
PM2240	Assurity™ DR RF	99.95%	99.94%	99.93%	99.93%						
PM2210	Accent™ DR RF	99.95%	99.90%	99.84%	99.79%	99.76%	99.73%	99.69%	99.69%		
PM2110	Accent™ DR	99.97%	99.95%	99.93%	99.93%	99.92%	99.89%	99.89%	99.89%		
5820	Zephyr™ DR	99.97%	99.96%	99.92%	99.64%	99.28%	98.97%	98.71%	98.56%	98.48%	98.35%
5810	Victory™ DR	99.98%	99.93%	99.69%	99.19%	97.74%	97.33%	96.78%	96.35%	96.14%	95.96%
5826	Zephyr™ XL DR	99.96%	99.93%	99.91%	99.89%	99.83%	99.76%	99.57%	99.26%	99.05%	98.86%
5816	Victory™ XL DR	99.97%	99.95%	99.91%	99.86%	99.81%	99.74%	99.47%	99.19%	98.82%	98.72%
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.96%	99.95%	99.93%	99.91%	99.89%	99.82%	99.82%	99.79%	99.75%	99.65%
5366	Integrity ADx™ XL DR	100.00%	100.00%	99.96%	99.96%	99.96%	99.91%	99.68%	99.61%	99.35%	98.66%
5380	Identity ADx™ DR	99.96%	99.93%	99.74%	99.25%	97.70%	96.86%	96.73%	96.35%	96.24%	96.12%
5386/5286	Identity ADx™ XL DR/DC	99.92%	99.90%	99.87%	99.85%	99.78%	99.70%	99.55%	99.02%	98.14%	97.20%
5342/5346	Integrity AFx™ DR	99.96%	99.92%	99.86%	99.81%	99.72%	99.70%	99.55%	99.33%	99.08%	98.76%
5370	Identity™	99.93%	99.87%	99.71%	98.90%	96.79%	95.63%	94.95%	94.81%	94.81%	94.81%
5376	Identity™ XL	99.90%	99.80%	99.76%	99.71%	99.55%	99.35%	98.85%	97.18%	95.67%	94.29%
5326/5226	Entity™ DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.32%	98.68%	98.23%	97.69%
5330/5331/5230	Affinity™ DR/DC	99.69%	99.56%	99.46%	99.35%	99.22%	99.07%	98.84%	98.33%	97.76%	97.23%

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™	61,717	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%**
PM2160	Endurity™ DR	9,068	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%**
PM2240	Assurity™ DR RF	173,934	0.20%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	0	0.00%	**5**	**<0.01%**
PM2210	Accent™ DR RF	243,054	2.70%	17	<0.01%	7	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	<0.01%	5	<0.01%	**36**	**0.01%**
PM2110	Accent™ DR	48,908	2.70%	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	54,063	8.00%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5810	Victory™ DR	26,312	16.80%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5826	Zephyr™ XL DR	112,244	5.90%	1	<0.01%	4	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**7**	**<0.01%**
5816	Victory™ XL DR	62,700	11.50%	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	17,371	6.60%	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	8,085	10.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5380	Identity ADx™ DR	54,049	15.60%	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	67,395	13.10%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5342/5346	Integrity AFx™ DR	47,442	14.20%	2	<0.01%	3	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**6**	**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	51,525	17.50%	2	<0.01%	4	<0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**8**	**0.02%**
5326/5226	Entity™ DR/DC	21,829	11.10%	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.01%**
5330/5331/5230	Affinity™ DR/DC	65,717	10.90%	5	<0.01%	9	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**15**	**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™	61,717	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**2**	**<0.01%**
PM2160	Endurity™ DR	9,068	0.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.06%	0	0.00%	2	0.02%	**7**	**0.08%**
PM2240	Assurity™ DR RF	173,934	0.20%	3	<0.01%	0	0.00%	0	0.00%	1	<0.01%	24	0.01%	1	<0.01%	7	<0.01%	**36**	**0.02%**
PM2210	Accent™ DR RF	243,054	2.70%	45	0.02%	33	0.01%	0	0.00%	4	<0.01%	21	<0.01%	22	<0.01%	40	0.02%	**165**	**0.07%**
PM2110	Accent™ DR	48,908	2.70%	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	54,063	8.00%	34	0.06%	0	0.00%	0	0.00%	9	0.02%	2	<0.01%	1	<0.01%	80	0.15%	**126**	**0.23%**
5810	Victory™ DR	26,312	16.80%	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	112,244	5.90%	19	0.02%	0	0.00%	0	0.00%	14	0.01%	9	<0.01%	3	<0.01%	135	0.12%	**180**	**0.16%**
5816	Victory™ XL DR	62,700	11.50%	25	0.04%	0	0.00%	0	0.00%	8	0.01%	9	0.01%	5	<0.01%	88	0.14%	**135**	**0.22%**
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	17,371	6.60%	10	0.06%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	10	0.06%	**22**	**0.13%**
5366	Integrity ADx™ XL DR	8,085	10.90%	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	54,049	15.60%	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	67,395	13.10%	132	0.20%	2	<0.01%	0	0.00%	7	0.01%	10	0.01%	6	<0.01%	107	0.16%	**264**	**0.39%**
5342/5346	Integrity AFx™ DR	47,442	14.20%	92	0.19%	1	<0.01%	2	<0.01%	0	0.00%	3	<0.01%	0	0.00%	6	0.01%	**104**	**0.22%**
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	51,525	17.50%	311	0.60%	2	<0.01%	0	0.00%	12	0.02%	6	0.01%	5	<0.01%	96	0.19%	**432**	**0.84%**
5326/5226	Entity™ DR/DC	21,829	11.10%	65	0.30%	2	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	3	0.01%	**74**	**0.34%**
5330/5331/5230	Affinity™ DR/DC	65,717	10.90%	283	0.43%	13	0.02%	6	<0.01%	2	<0.01%	5	<0.01%	1	<0.01%	5	<0.01%	**315**	**0.48%**

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™	199,750	0.32%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM2160	Endurity™ DR	57,003	0.65%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM2240	Assurity™ DR RF	190,071	2.14%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	0	0.00%	**5**	**<0.01%**
PM2210	Accent™ DR RF	246,744	5.87%	17	<0.01%	7	<0.01%	0	0.00%	0	0.00%	0	0.00%	6	<0.01%	5	<0.01%	**35**	**0.01%**
PM2110	Accent™ DR	49,731	5.53%	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™	199,750	0.32%	2	<0.01%	0	0.00%	0	0.00%	1	<0.01%	4	<0.01%	2	<0.01%	1	<0.01%	**10**	**<0.01%**
PM2160	Endurity™ DR	57,003	0.65%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	8	0.01%	0	0.00%	3	<0.01%	**12**	**0.02%**
PM2240	Assurity™ DR RF	190,071	2.14%	5	<0.01%	0	0.00%	0	0.00%	1	<0.01%	26	0.01%	1	<0.01%	7	<0.01%	**40**	**0.02%**
PM2210	Accent™ DR RF	246,744	5.87%	48	0.02%	34	0.01%	0	0.00%	4	<0.01%	21	<0.01%	22	<0.01%	39	0.02%	**168**	**0.07%**
PM2110	Accent™ DR	49,731	5.53%	3	<0.01%	0	0.00%	0	0.00%	3	<0.01%	5	0.01%	2	<0.01%	0	0.00%	**13**	**0.03%**

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	243	55443	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**1**	**0.06%**
PM2110	227	47	9169	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	283	7	7899	0	0.00%	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
5826	1,516	10	47950	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	332	0	10615	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5386	101	0	3221	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	Fortify™ VR	1,773	4.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2110	Current™ + VR	227	3.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	Current™ VR RF	283	17.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	Current™ + VR	1,516	6.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	Current™ + VR	332	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%**
5386	Current™ VR RF	101	3.00%	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		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	Fortify™ VR	1,773	4.20%	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	Current™ + VR	227	3.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	Current™ VR RF	283	17.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	Current™ + VR	1,516	6.90%	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	Current™ + VR	332	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%**
5386	Current™ VR RF	101	3.00%	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 Pacemakers

Single-Chamber Pacemakers

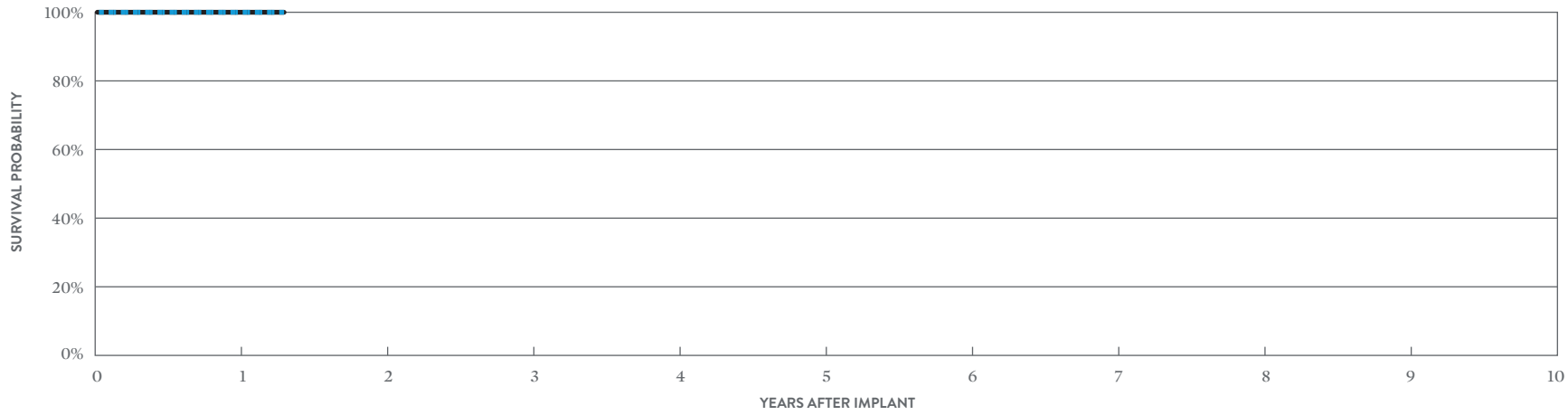
CUSTOMER REPORTED PERFORMANCE DATA

Assurity MRI™

MODEL PM1272

US Regulatory Approval	January 2017
Registered US Implants	7,527
Estimated Active US Implants	6,875
Estimated Longevity	13.7 Years
Normal Battery Depletion	0
Number of US Advisories (see pg. 333)	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%	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	AT 16 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%
SAMPLE SIZE	4,530	430

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	AT 16 MONTHS
SURVIVAL PROBABILITY	100.00%	100.00%
± 1 STANDARD ERROR	0.00%	0.00%

Single-Chamber Pacemakers

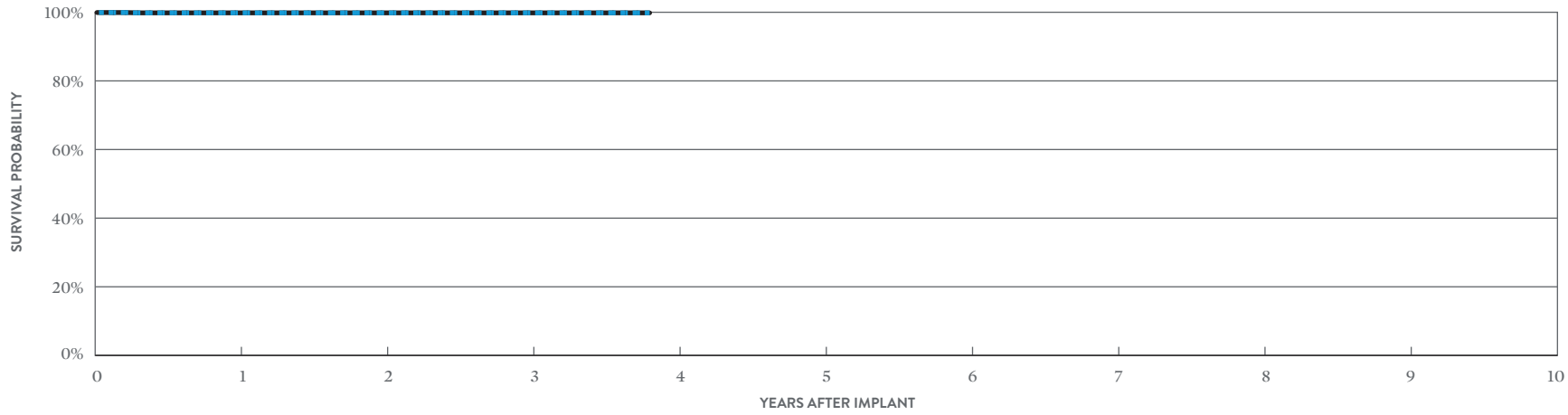
CUSTOMER REPORTED PERFORMANCE DATA

Endurity™ VR

MODEL PM1160

US Regulatory Approval	March 2014
Registered US Implants	2,493
Estimated Active US Implants	1,816
Estimated Longevity	14.6 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%	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	AT 46 MONTHS
SURVIVAL PROBABILITY	99.83%	99.83%	99.83%	99.83%
± 1 STANDARD ERROR	0.08%	0.08%	0.08%	0.08%
SAMPLE SIZE	2,270	1,850	1,290	260

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 46 MONTHS
SURVIVAL PROBABILITY	99.83%	99.83%	99.83%	99.83%
± 1 STANDARD ERROR	0.08%	0.08%	0.08%	0.08%

Single-Chamber Pacemakers

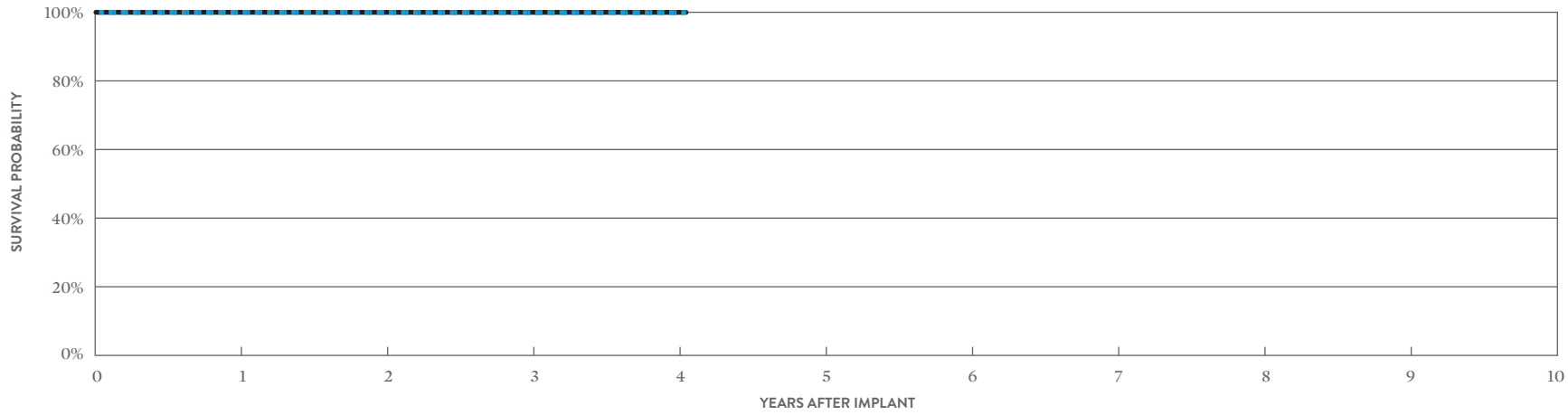
CUSTOMER REPORTED PERFORMANCE DATA

Assurity™ VR

MODEL PM1240

US Regulatory Approval	March 2014
Registered US Implants	27,039
Estimated Active US Implants	20,595
Estimated Longevity	14.1 Years
Normal Battery Depletion	2
Number of US Advisories (see pg. 333)	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	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**4**	**0.01%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 49 MONTHS
SURVIVAL PROBABILITY	99.98%	99.97%	99.92%	99.92%	99.92%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.02%	0.02%
SAMPLE SIZE	24,100	17,340	9,590	2,940	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	AT 49 MONTHS
SURVIVAL PROBABILITY	99.98%	99.97%	99.97%	99.97%	99.97%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.01%

Single-Chamber Pacemakers

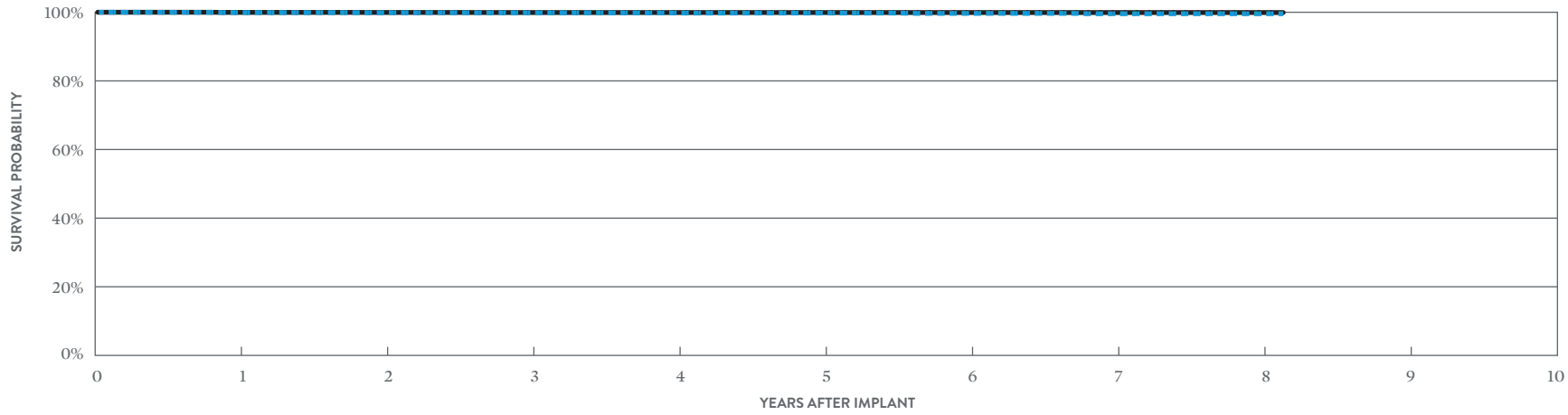
CUSTOMER REPORTED PERFORMANCE DATA

Accent™ SR

MODEL PM1110

US Regulatory Approval	July 2009
Registered US Implants	13,592
Estimated Active US Implants	7,125
Estimated Longevity	12.9 Years
Normal Battery Depletion	10
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	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.92%	99.87%	99.85%	99.80%	99.77%	99.67%	99.57%	99.57%	99.57%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.04%	0.05%	0.07%	0.10%	0.10%	0.10%
SAMPLE SIZE	12,540	10,810	9,540	8,320	6,560	4,340	2,370	870	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.96%	99.94%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%	0.03%

Single-Chamber Pacemakers

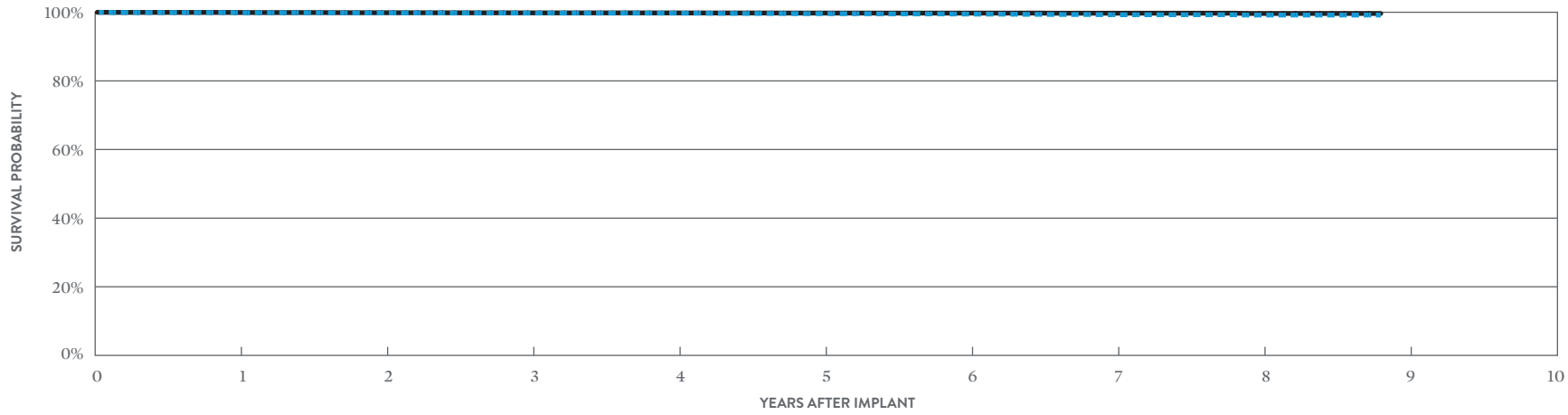
CUSTOMER REPORTED PERFORMANCE DATA

Accent™ SR RF

MODEL PM1210

US Regulatory Approval	July 2009
Registered US Implants	39,812
Estimated Active US Implants	20,098
Estimated Longevity	10.9 Years
Normal Battery Depletion	31
Number of US Advisories (see pg. 333)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	2	<0.01%	10	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%	7	0.02%
Total	**5**	**0.01%**	**29**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 106 MONTHS
SURVIVAL PROBABILITY	99.89%	99.80%	99.76%	99.73%	99.60%	99.48%	99.27%	99.18%	99.18%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.03%	0.04%	0.05%	0.07%	0.09%	0.09%
SAMPLE SIZE	36,610	31,380	27,720	24,270	19,150	12,960	7,760	3,720	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	AT 106 MONTHS
SURVIVAL PROBABILITY	99.93%	99.87%	99.83%	99.81%	99.77%	99.76%	99.73%	99.65%	99.65%
± 1 STANDARD ERROR	0.01%	0.02%	0.02%	0.02%	0.03%	0.03%	0.04%	0.07%	0.07%

Single-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

Accent™ SR RF

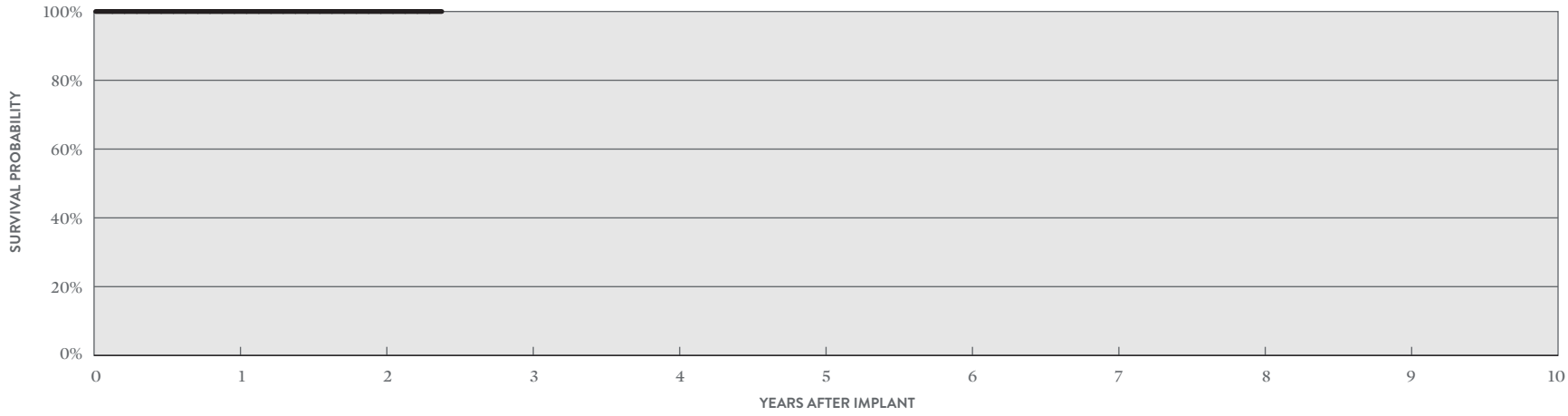
MODEL PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	236
Active Devices Enrolled in Study	17
Cumulative Months of Follow-up	5,724
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

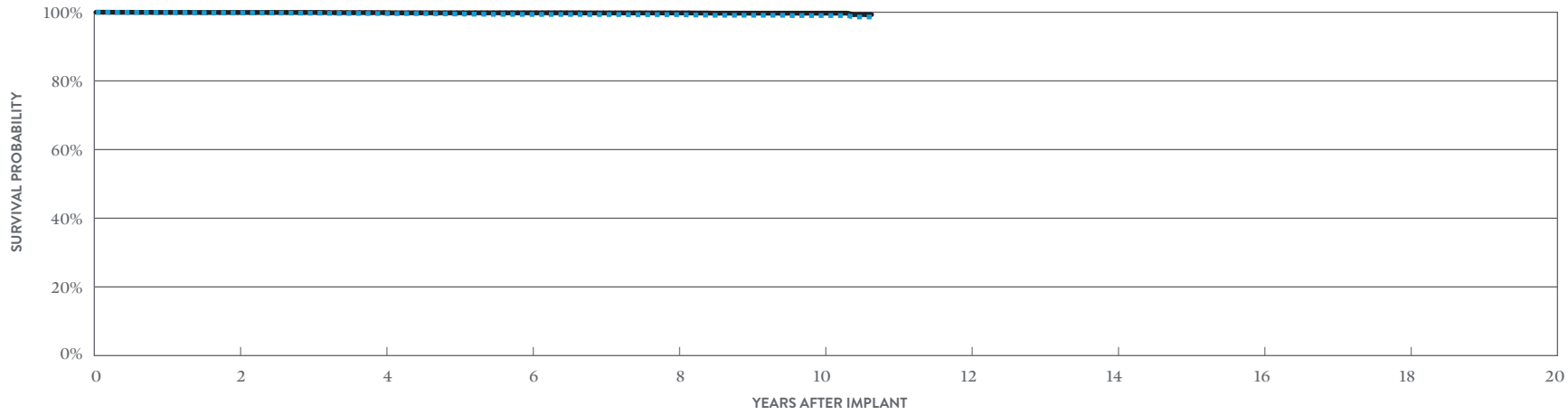
CUSTOMER REPORTED PERFORMANCE DATA

Zephyr™ XL SR

MODEL 5626

US Regulatory Approval	May 2007
Registered US Implants	20,649
Estimated Active US Implants	7,271
Estimated Longevity	15.8 Years
Normal Battery Depletion	31
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%	9	0.04%
Total	**2**	**<0.01%**	**13**	**0.06%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 128 MONTHS
SURVIVAL PROBABILITY	99.83%	99.64%	99.35%	99.30%	99.03%	98.62%
± 1 STANDARD ERROR	0.03%	0.05%	0.07%	0.08%	0.12%	0.31%
SAMPLE SIZE	15,760	11,880	9,010	6,660	2,430	270

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 128 MONTHS
SURVIVAL PROBABILITY	99.93%	99.88%	99.83%	99.80%	99.73%	99.32%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.04%	0.05%	0.29%

Single-Chamber Pacemakers

ACTIVELY MONITORED STUDY DATA

Zephyr™ XL SR

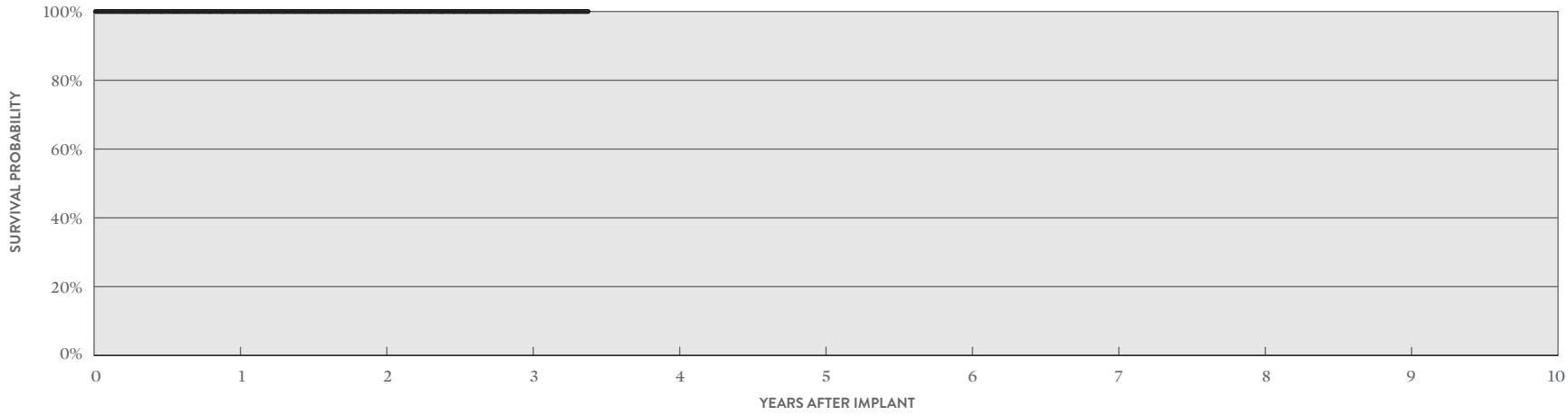
MODEL 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	230
Active Devices Enrolled in Study	2
Cumulative Months of Follow-up	6,576
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

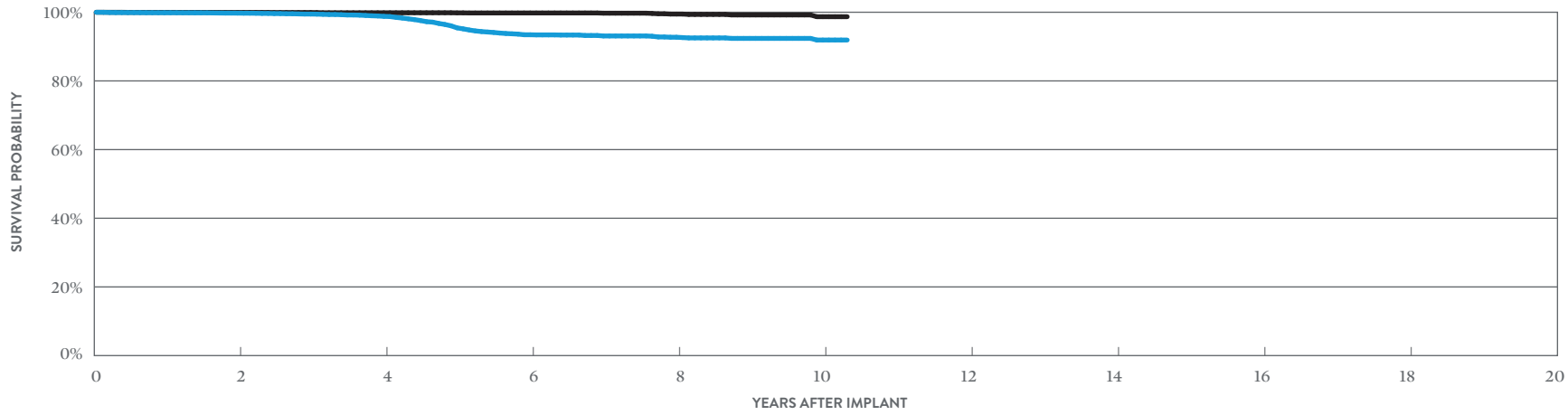
CUSTOMER REPORTED PERFORMANCE DATA

Zephyr™ SR

MODEL 5620

US Regulatory Approval	March 2007
Registered US Implants	17,382
Estimated Active US Implants	6,291
Estimated Longevity	8.8 Years
Normal Battery Depletion	201
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%	10	0.06%
Total	**1**	**<0.01%**	**16**	**0.09%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.74%	98.80%	93.44%	92.72%	91.91%	91.91%
± 1 STANDARD ERROR	0.04%	0.10%	0.29%	0.33%	0.48%	0.48%
SAMPLE SIZE	12,620	9,170	5,710	2,590	700	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.94%	99.85%	99.79%	99.47%	98.70%	98.70%
± 1 STANDARD ERROR	0.02%	0.04%	0.05%	0.13%	0.40%	0.40%

Single-Chamber Pacemakers

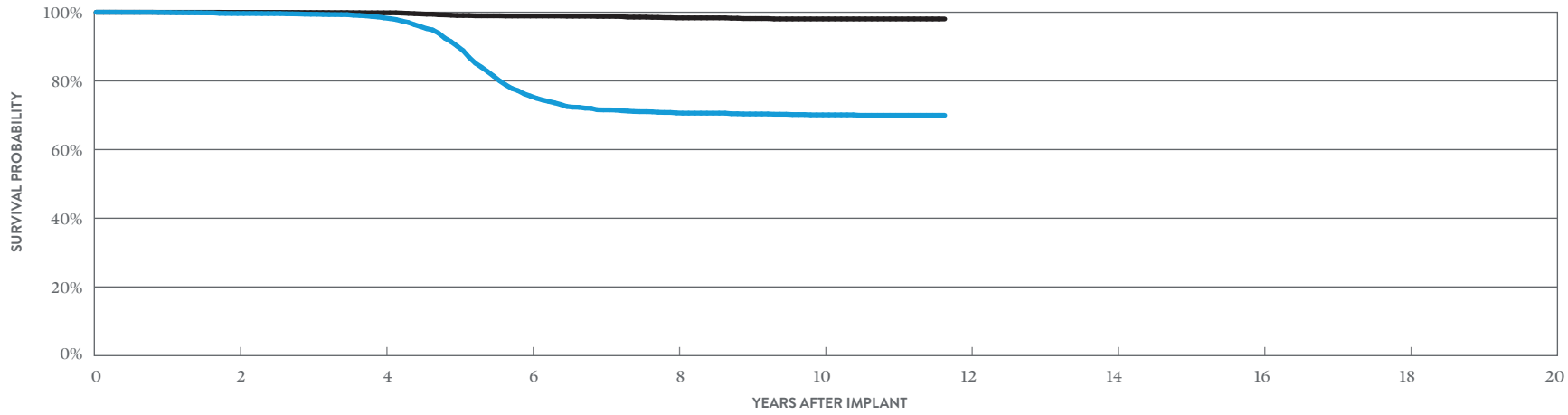
CUSTOMER REPORTED PERFORMANCE DATA

Victory™ SR

MODEL 5610

US Regulatory Approval	December 2005
Registered US Implants	13,690
Estimated Active US Implants	2,124
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%	23	0.17%
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%	14	0.10%
Total	**1**	**<0.01%**	**39**	**0.28%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 140 MONTHS
SURVIVAL PROBABILITY	99.63%	98.37%	75.60%	70.67%	70.11%	69.98%
± 1 STANDARD ERROR	0.06%	0.13%	0.55%	0.60%	0.61%	0.62%
SAMPLE SIZE	10,130	7,250	4,840	2,910	1,640	250

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	AT 140 MONTHS
SURVIVAL PROBABILITY	99.96%	99.83%	98.91%	98.36%	98.05%	98.05%
± 1 STANDARD ERROR	0.02%	0.05%	0.13%	0.18%	0.23%	0.23%

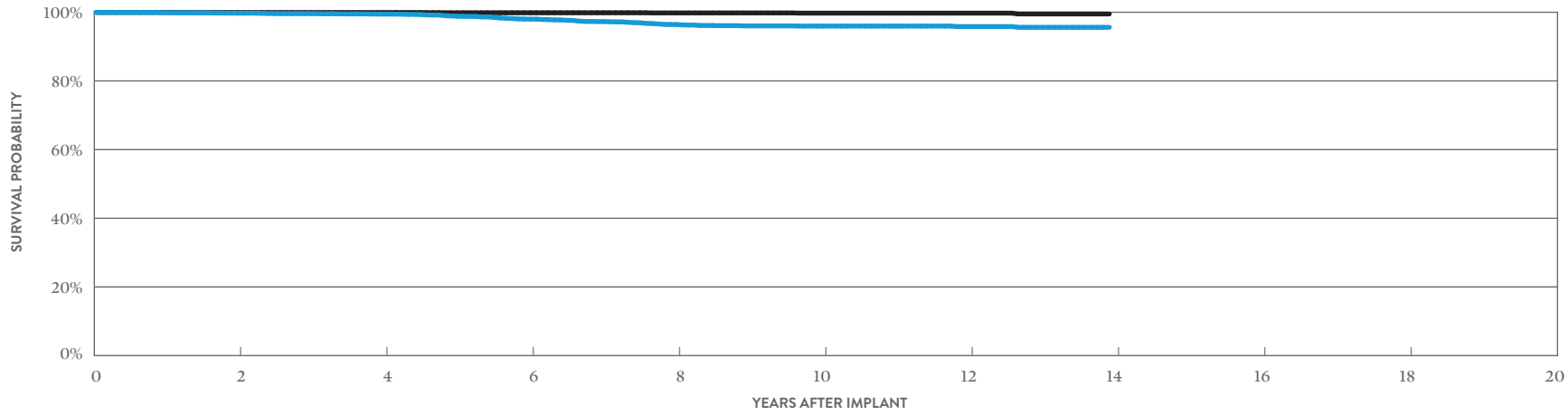
Single-Chamber Pacemakers

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	14,508
Estimated Active US Implants	3,552
Estimated Longevity	10.2 Years
Normal Battery Depletion	92
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%	3	0.02%
Total	**1**	**<0.01%**	**9**	**0.06%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 167 MONTHS
SURVIVAL PROBABILITY	99.73%	99.47%	97.99%	96.43%	95.97%	95.83%	95.61%
± 1 STANDARD ERROR	0.05%	0.07%	0.17%	0.25%	0.27%	0.28%	0.33%
SAMPLE SIZE	10,920	7,870	5,700	4,350	3,210	1,650	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 167 MONTHS
SURVIVAL PROBABILITY	99.91%	99.91%	99.85%	99.80%	99.74%	99.74%	99.50%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.05%	0.07%	0.07%	0.18%

Single-Chamber Pacemakers

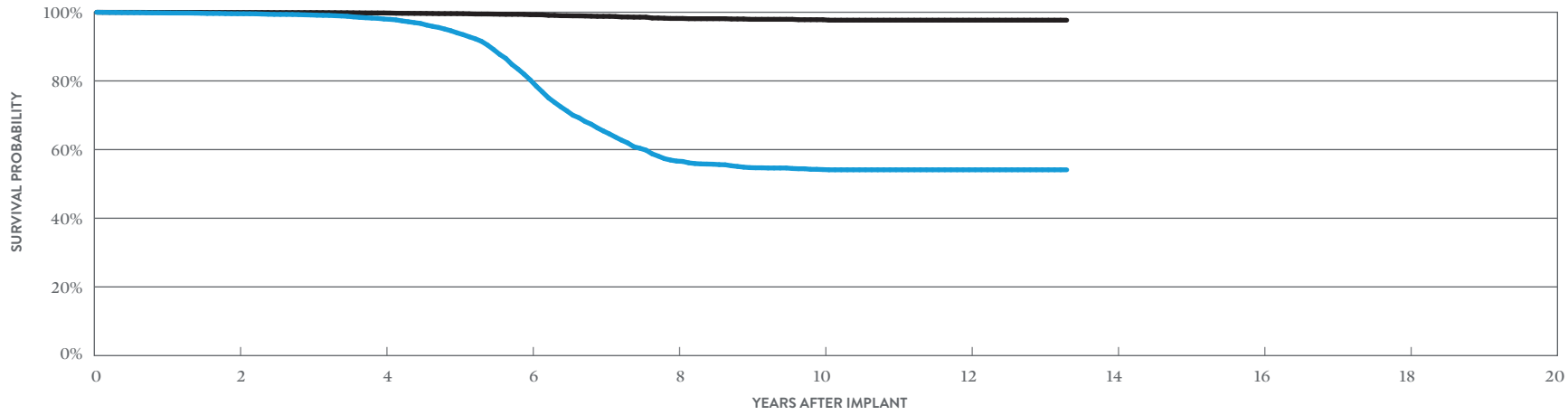
CUSTOMER REPORTED PERFORMANCE DATA

Identity ADx™ SR

MODEL 5180

US Regulatory Approval	May 2003
Registered US Implants	20,870
Estimated Active US Implants	2,064
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	AT 160 MONTHS
SURVIVAL PROBABILITY	99.57%	98.03%	80.30%	56.65%	54.18%	54.11%	54.11%
± 1 STANDARD ERROR	0.05%	0.12%	0.42%	0.61%	0.63%	0.63%	0.63%
SAMPLE SIZE	15,440	10,930	6,910	3,380	1,790	900	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 160 MONTHS
SURVIVAL PROBABILITY	99.94%	99.79%	99.28%	98.19%	97.83%	97.69%	97.69%
± 1 STANDARD ERROR	0.02%	0.04%	0.08%	0.19%	0.23%	0.25%	0.25%

Single-Chamber Pacemakers

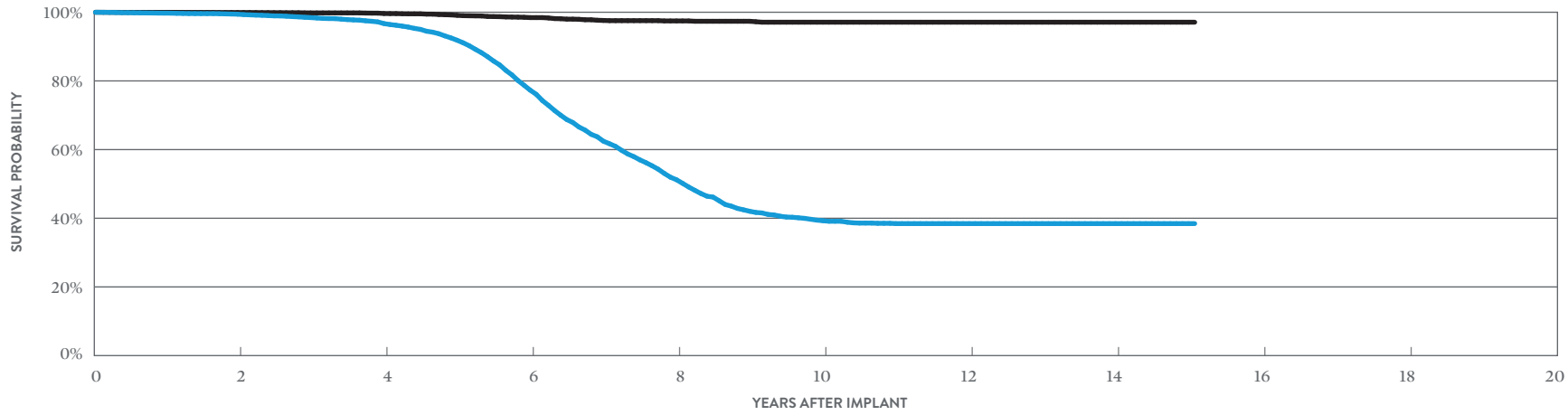
CUSTOMER REPORTED PERFORMANCE DATA

Identity™ SR

MODEL 5172

US Regulatory Approval	November 2001
Registered US Implants	21,884
Estimated Active US Implants	996
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,474
Number of US Advisories (see pg. 333)	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	1	<0.01%	64	0.29%
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%**	**79**	**0.36%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 181 MONTHS
SURVIVAL PROBABILITY	99.43%	96.70%	77.30%	51.21%	39.28%	38.44%	38.44%	38.44%
± 1 STANDARD ERROR	0.05%	0.14%	0.45%	0.65%	0.70%	0.71%	0.71%	0.71%
SAMPLE SIZE	16,210	11,390	6,580	2,760	1,340	910	490	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	AT 181 MONTHS
SURVIVAL PROBABILITY	99.92%	99.63%	98.44%	97.47%	97.10%	97.10%	97.10%	97.10%
± 1 STANDARD ERROR	0.02%	0.04%	0.13%	0.21%	0.26%	0.26%	0.26%	0.26%

Single-Chamber Pacemakers

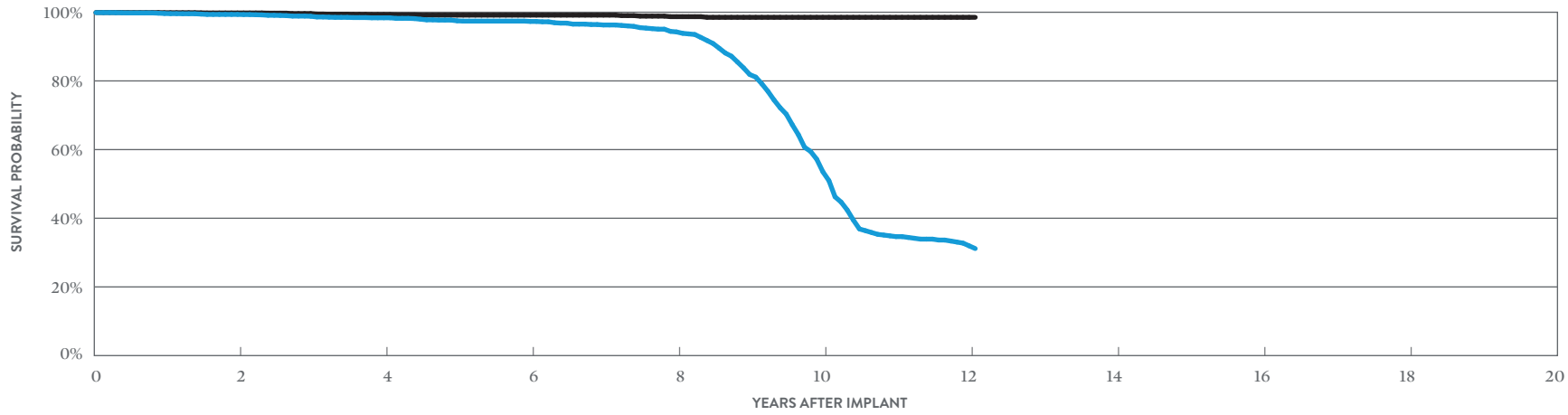
CUSTOMER REPORTED PERFORMANCE DATA

Microny™

MODELS 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	7,807
Estimated Active US Implants	1,421
Estimated Longevity	7.5 Years
Normal Battery Depletion	308
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	AT 145 MONTHS
SURVIVAL PROBABILITY	99.36%	98.38%	97.32%	94.27%	53.54%	31.96%	31.17%
± 1 STANDARD ERROR	0.10%	0.19%	0.27%	0.51%	1.53%	1.51%	1.52%
SAMPLE SIZE	5,110	3,380	2,150	1,320	690	250	200

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	AT 145 MONTHS
SURVIVAL PROBABILITY	99.79%	99.30%	99.16%	98.71%	98.52%	98.52%	98.52%
± 1 STANDARD ERROR	0.06%	0.13%	0.15%	0.24%	0.27%	0.27%	0.27%

Single-Chamber Pacemakers

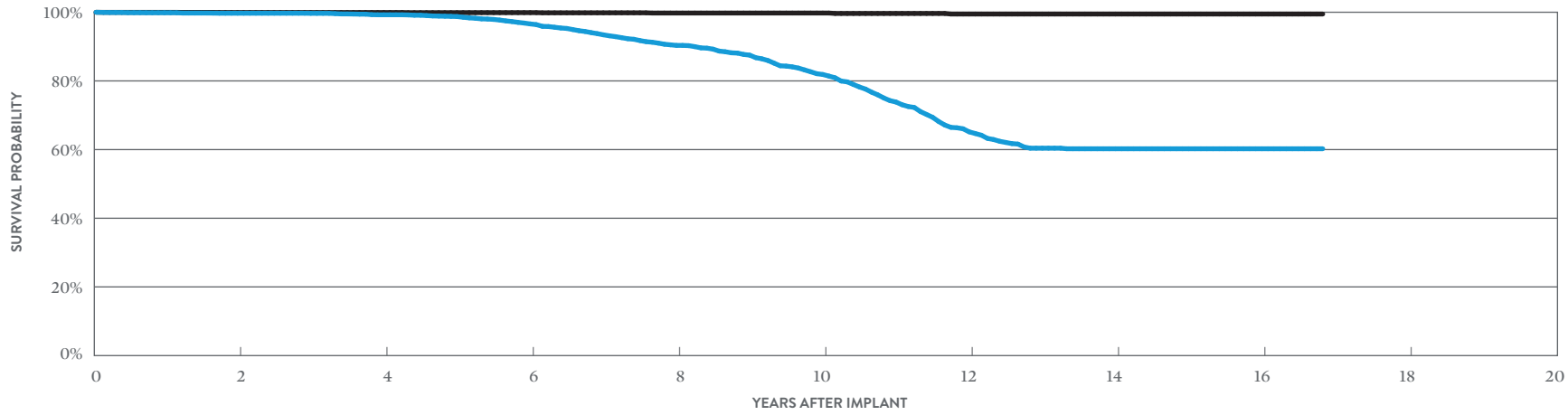
CUSTOMER REPORTED PERFORMANCE DATA

Integrity™ SR

MODEL 5142

US Regulatory Approval	April 2000
Registered US Implants	10,491
Estimated Active US Implants	581
Estimated Longevity	8.6 Years
Normal Battery Depletion	386
Number of US Advisories	None

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	5	0.05%
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	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	0	0.00%
Total	**1**	**<0.01%**	**7**	**0.07%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 202 MONTHS
SURVIVAL PROBABILITY	99.71%	99.26%	96.60%	90.34%	81.87%	65.16%	60.24%	60.24%	60.24%
± 1 STANDARD ERROR	0.06%	0.10%	0.25%	0.48%	0.71%	1.00%	1.09%	1.09%	1.09%
SAMPLE SIZE	8,050	5,870	4,210	2,910	1,960	1,250	700	370	210

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	AT 202 MONTHS
SURVIVAL PROBABILITY	99.93%	99.93%	99.89%	99.77%	99.77%	99.48%	99.48%	99.48%	99.48%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.07%	0.07%	0.16%	0.16%	0.16%	0.16%

Single-Chamber Pacemakers

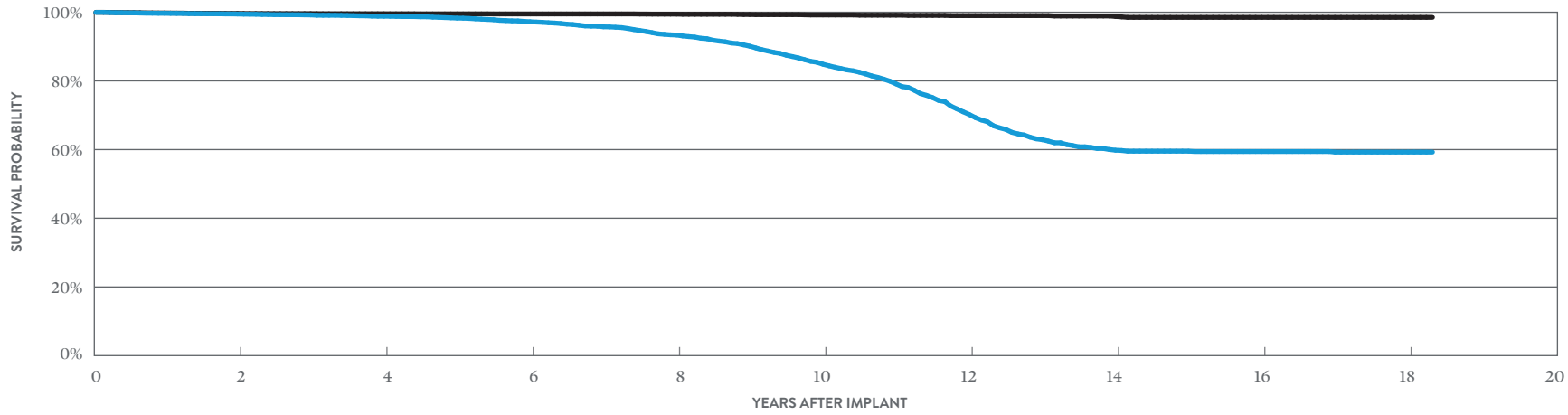
CUSTOMER REPORTED PERFORMANCE DATA

Affinity™ SR

MODELS 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,800
Estimated Active US Implants	1,244
Estimated Longevity	8.6 Years
Normal Battery Depletion	794
Number of US Advisories	One

	MALFUNCTIONS W/ COMPROMISED THERAPY		MALFUNCTIONS W/O COMPROMISED THERAPY	
	QTY	RATE	QTY	RATE
Electrical Component	0	0.00%	46	0.16%
Electrical Interconnect	3	0.01%	2	<0.01%
Battery	0	0.00%	3	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	1	<0.01%	7	0.02%
Total	**4**	**0.01%**	**59**	**0.20%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 220 MONTHS
SURVIVAL PROBABILITY	99.47%	98.83%	97.23%	93.36%	84.86%	70.23%	59.82%	59.44%	59.27%	59.27%
± 1 STANDARD ERROR	0.05%	0.08%	0.14%	0.25%	0.43%	0.65%	0.77%	0.78%	0.79%	0.79%
SAMPLE SIZE	21,440	15,220	10,660	7,170	4,570	2,880	1,720	1,100	490	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	2	4	6	8	10	12	14	16	18	AT 220 MONTHS
SURVIVAL PROBABILITY	99.64%	99.54%	99.49%	99.44%	99.20%	99.01%	98.77%	98.51%	98.51%	98.51%
± 1 STANDARD ERROR	0.04%	0.05%	0.05%	0.06%	0.09%	0.12%	0.14%	0.21%	0.21%	0.21%

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™	100.00%									
PM1160	Endurity™ SR	99.83%	99.83%	99.83%							
PM1240	Assurity™ SR	99.98%	99.97%	99.92%	99.92%						
PM1110	Accent™ SR	99.92%	99.87%	99.85%	99.80%	99.77%	99.67%	99.57%	99.57%		
PM1210	Accent™ SR RF	99.89%	99.80%	99.76%	99.73%	99.60%	99.48%	99.27%	99.18%		
5626	Zephyr™ XL SR	99.92%	99.83%	99.73%	99.64%	99.47%	99.35%	99.33%	99.30%	99.12%	99.03%
5620	Zephyr™ SR	99.86%	99.74%	99.47%	98.80%	95.45%	93.44%	93.09%	92.72%	92.38%	91.91%
5610	Victory™ SR	99.92%	99.63%	99.41%	98.37%	90.17%	75.60%	71.55%	70.67%	70.37%	70.11%
5156/5157/5056	Verity ADx™ XL SR/SR(M/S)/SC	99.87%	99.73%	99.60%	99.47%	98.84%	97.99%	97.28%	96.43%	96.03%	95.97%
5180	Identity ADx™ SR	99.79%	99.57%	99.21%	98.03%	94.00%	80.30%	65.41%	56.65%	54.75%	54.18%
5172	Identity™ SR	99.74%	99.43%	98.44%	96.70%	91.85%	77.30%	62.44%	51.21%	42.03%	39.28%
2425T/2525T/2535T	Microny™	99.63%	99.36%	98.83%	98.38%	97.50%	97.32%	96.29%	94.27%	81.87%	53.54%
5142	Integrity™ SR	99.86%	99.71%	99.68%	99.26%	98.75%	96.60%	93.42%	90.34%	87.51%	81.87%
5130/5131	Affinity™ SR	99.69%	99.47%	99.21%	98.83%	98.29%	97.23%	95.75%	93.36%	90.11%	84.86%

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™	100.00%									
PM1160	Endurity™ SR	99.83%	99.83%	99.83%							
PM1240	Assurity™ SR	99.98%	99.97%	99.97%	99.97%						
PM1110	Accent™ SR	99.96%	99.94%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%		
PM1210	Accent™ SR RF	99.93%	99.87%	99.83%	99.81%	99.77%	99.76%	99.73%	99.65%		
5626	Zephyr™ XL SR	99.95%	99.93%	99.93%	99.88%	99.83%	99.83%	99.80%	99.80%	99.73%	99.73%
5620	Zephyr™ SR	99.97%	99.94%	99.92%	99.85%	99.82%	99.79%	99.73%	99.47%	99.21%	98.70%
5610	Victory™ SR	99.98%	99.96%	99.91%	99.83%	99.05%	98.91%	98.80%	98.36%	98.16%	98.05%
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%	99.79%	99.60%	99.28%	98.81%	98.19%	97.94%	97.83%
5172	Identity™ SR	99.97%	99.92%	99.81%	99.63%	99.10%	98.44%	97.61%	97.47%	97.37%	97.10%
2425T/2525T/2535T	Microny™	99.87%	99.79%	99.62%	99.30%	99.16%	99.16%	99.16%	98.71%	98.52%	98.52%
5142	Integrity™ SR	99.98%	99.93%	99.93%	99.93%	99.89%	99.89%	99.84%	99.77%	99.77%	99.77%
5130/5131	Affinity™ SR	99.78%	99.64%	99.58%	99.54%	99.51%	99.49%	99.49%	99.44%	99.33%	99.20%

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™	7,527	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%**
PM1160	Endurity™ SR	2,493	0.50%	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	27,039	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1110	Accent™ SR	13,592	3.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent™ SR RF	39,812	3.60%	2	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	**5**	**0.01%**
5626	Zephyr™ XL SR	20,649	5.40%	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	17,382	5.70%	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	12.70%	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	14,508	5.80%	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	20,870	11.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5172	Identity™ SR	21,884	11.30%	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™	7,807	6.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5142	Integrity™ SR	10,491	8.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**
5130/5131	Affinity™ SR	28,800	7.00%	0	0.00%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**0.01%**

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™	7,527	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%**
PM1160	Endurity™ SR	2,493	0.50%	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	27,039	0.10%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**4**	**0.01%**
PM1110	Accent™ SR	13,592	3.60%	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	39,812	3.60%	10	0.03%	3	<0.01%	1	<0.01%	1	<0.01%	4	0.01%	3	<0.01%	7	0.02%	**29**	**0.07%**
5626	Zephyr™ XL SR	20,649	5.40%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	9	0.04%	**13**	**0.06%**
5620	Zephyr™ SR	17,382	5.70%	4	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	10	0.06%	**16**	**0.09%**
5610	Victory™ SR	13,690	12.70%	23	0.17%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	14	0.10%	**39**	**0.28%**
5156/5157/5056	Verity ADx™ XL SR/SR(M/S)/SC	14,508	5.80%	4	0.03%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	3	0.02%	**9**	**0.06%**
5180	Identity ADx™ SR	20,870	11.70%	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	21,884	11.30%	64	0.29%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	8	0.04%	6	0.03%	**79**	**0.36%**
2425T/2525T/2535T	Microny™	7,807	6.40%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**2**	**0.03%**
5142	Integrity™ SR	10,491	8.60%	5	0.05%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	**7**	**0.07%**
5130/5131	Affinity™ SR	28,800	7.00%	46	0.16%	2	<0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	7	0.02%	**59**	**0.20%**

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™	44,236	0.40%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
PM1160	Endurity™ SR	26,229	0.58%	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	30,636	2.94%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1110	Accent™ SR	54,444	1.92%	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	48,206	5.24%	4	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	**7**	**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
PM1272	Assurity MRI™	44,236	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM1160	Endurity™ SR	26,229	0.58%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	**4**	**0.02%**
PM1240	Assurity™ SR	30,636	2.94%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	0	0.00%	0	0.00%	**5**	**0.02%**
PM1110	Accent™ SR	54,444	1.92%	3	<0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	2	<0.01%	**8**	**0.01%**
PM1210	Accent™ SR RF	48,206	5.24%	13	0.03%	3	<0.01%	1	<0.01%	1	<0.01%	4	<0.01%	3	<0.01%	8	0.02%	**33**	**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	17	5,724	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	230	2	6,576	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	3.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	Zephyr™ XL SR	230	3.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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	3.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	Zephyr™ XL SR	230	3.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

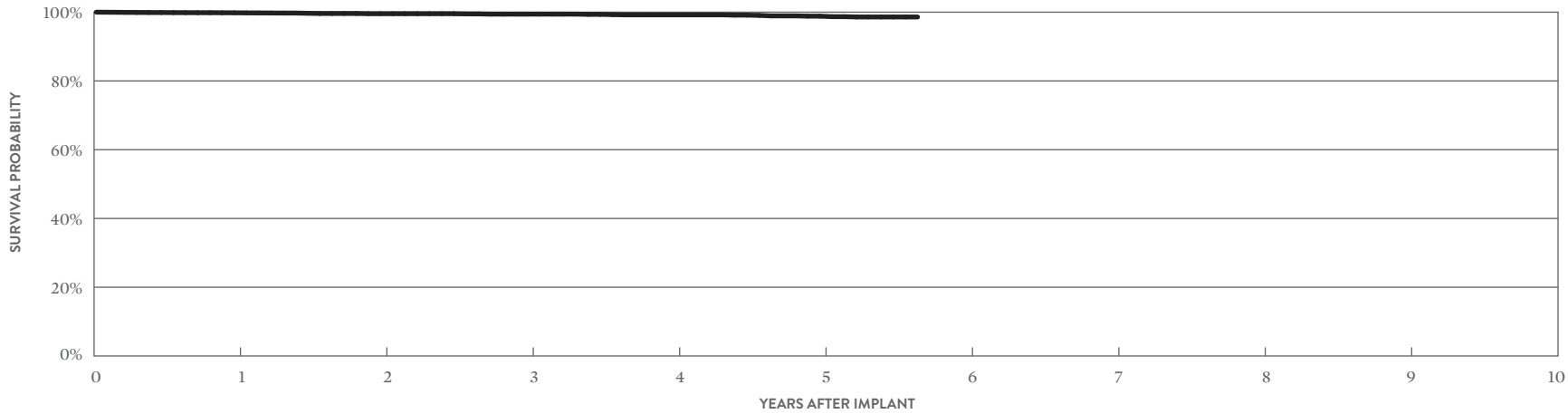
Tendril MRI™

MODEL LPA1200M

US Regulatory Approval	January 2017
Registered US Implants	94,111
Estimated Active US Implants	77,704
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	23	0.02%	7	<0.01%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	190	0.20%	82	0.09%
Failure to Capture	23	0.02%	33	0.04%
Oversensing	13	0.01%	29	0.03%
Failure to Sense	14	0.01%	8	<0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	3	<0.01%
Extracardiac Stimulation	3	<0.01%	3	<0.01%
Other	51	0.05%	5	<0.01%
Total	**318**	**0.34%**	**171**	**0.18%**
Total Returned for Analysis	**112**		**44**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	7	<0.01%
Insulation Breach	6	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	6	<0.01%
Extrinsic Factors	45	0.05%
Total	**64**	**0.07%**



YEAR	1	2	3	4	5	AT 68 MONTHS
SURVIVAL PROBABILITY	99.82%	99.56%	99.43%	99.22%	98.84%	98.60%
± 1 STANDARD ERROR	0.02%	0.11%	0.15%	0.19%	0.25%	0.29%
SAMPLE SIZE	56,910	10,630	1,510	1,420	1,340	290

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

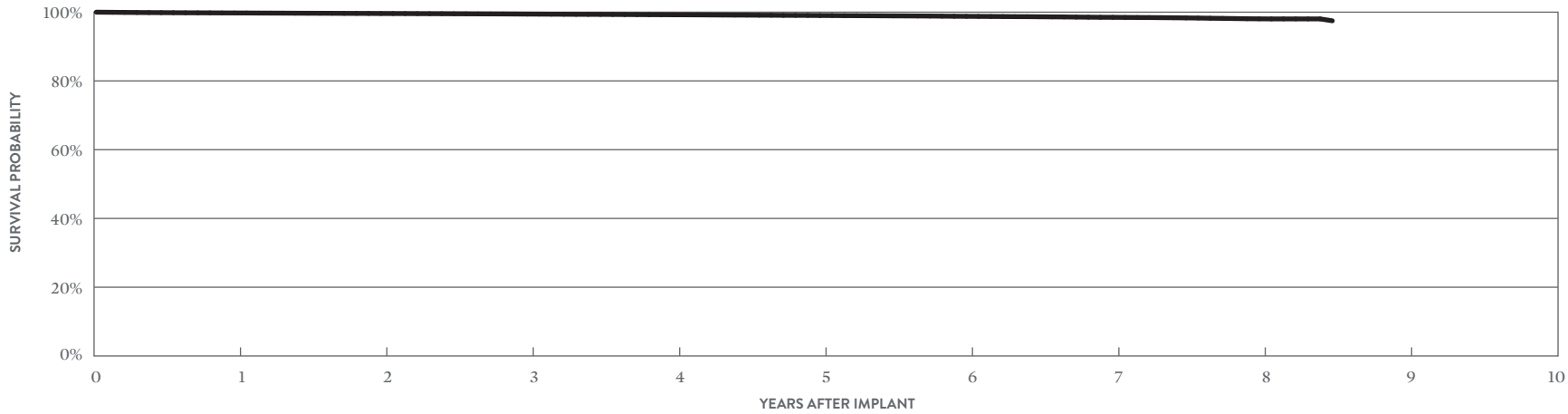
Tendril™ STS

MODEL 2088TC

US Regulatory Approval	May 2009
Registered US Implants	610,472
Estimated Active US Implants	387,787
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	94	0.02%	56	<0.01%
Conductor Fracture	8	<0.01%	213	0.03%
Lead Dislodgement	637	0.10%	903	0.15%
Failure to Capture	174	0.03%	716	0.12%
Oversensing	63	0.01%	1945	0.32%
Failure to Sense	27	<0.01%	100	0.02%
Insulation Breach	13	<0.01%	188	0.03%
Abnormal Pacing Impedance	36	<0.01%	140	0.02%
Extracardiac Stimulation	4	<0.01%	32	<0.01%
Other	125	0.02%	138	0.02%
Total	**1181**	**0.19%**	**4431**	**0.73%**
Total Returned for Analysis	**528**		**1512**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	45	<0.01%
Insulation Breach	626	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	28	<0.01%
Extrinsic Factors	1086	0.18%
Total	**1785**	**0.29%**



YEAR	1	2	3	4	5	6	7	8	AT 102 MONTHS
SURVIVAL PROBABILITY	99.77%	99.61%	99.44%	99.24%	99.03%	98.79%	98.50%	98.06%	97.49%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.06%	0.07%
SAMPLE SIZE	545,890	427,490	324,820	237,590	166,330	106,650	57,810	20,760	280

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

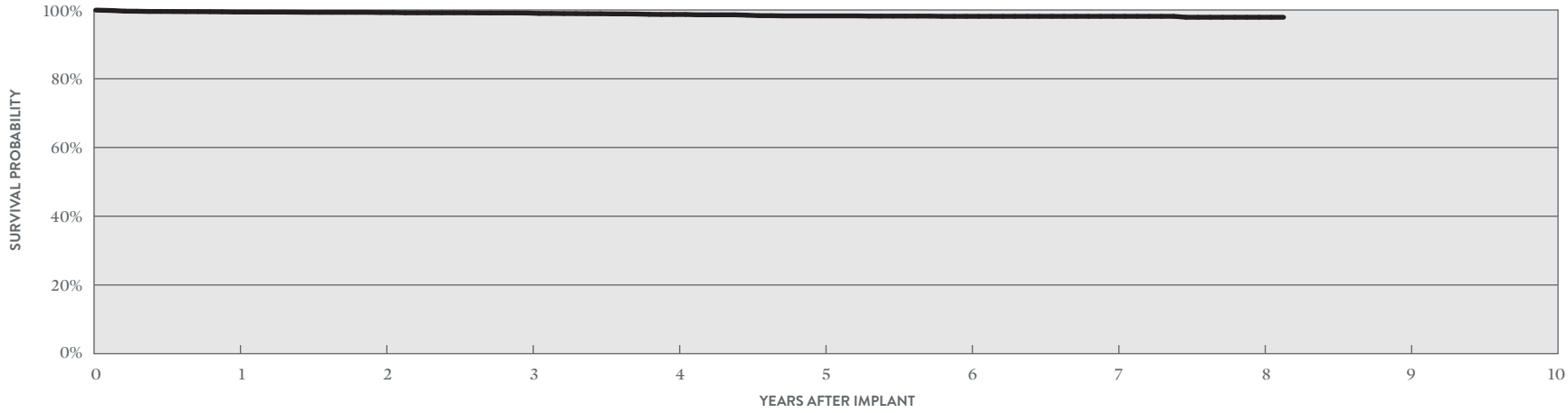
Tendril™ STS

MODEL 2088TC

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	3,848
Active Devices Enrolled in Study	1,513
Cumulative Months of Follow-up	199,452
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	3	0.08%
Extracardiac Stimulation	1	0.03%
Failure to Capture	8	0.21%
Failure to Sense	2	0.05%
Insulation Breach	7	0.18%
Lead Dislodgement	15	0.39%
Oversensing	13	0.34%
Pericardial Effusion	1	0.03%

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	0.03%
Insulation Breach	13	0.34%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.36%
Total	**28**	**0.73%**



YEAR	1	2	3	4	5	6	7	8	AT 98 MONTHS
SURVIVAL PROBABILITY	99.40%	99.25%	99.11%	98.69%	98.28%	98.15%	98.15%	97.88%	97.88%
± 1 STANDARD ERROR	0.12%	0.14%	0.16%	0.21%	0.25%	0.27%	0.27%	0.38%	0.38%
SAMPLE SIZE	3,650	3,230	2,780	2,340	1,920	1,480	990	410	90

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

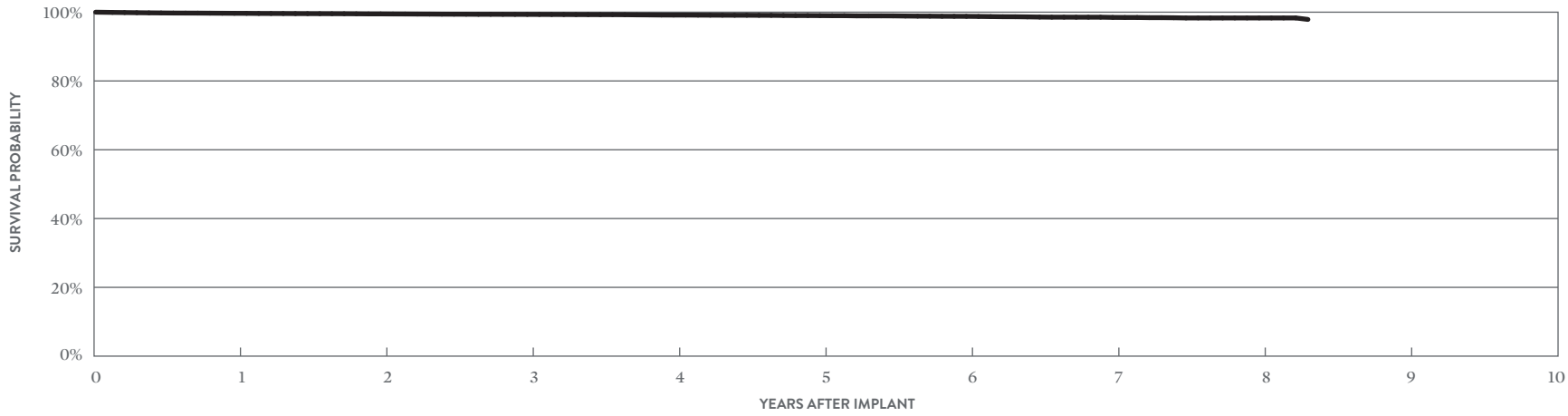
OptiSense™

MODEL 1999

US Regulatory Approval	May 2007
Registered US Implants	46,809
Estimated Active US Implants	28,159
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%	0	0.00%
Conductor Fracture	0	0.00%	8	0.02%
Lead Dislodgement	64	0.14%	163	0.35%
Failure to Capture	8	0.02%	54	0.12%
Oversensing	9	0.02%	165	0.35%
Failure to Sense	3	<0.01%	23	0.05%
Insulation Breach	1	<0.01%	25	0.05%
Abnormal Pacing Impedance	0	0.00%	11	0.02%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	12	0.03%	17	0.04%
Total	**101**	**0.22%**	**467**	**1.00%**
Total Returned for Analysis	**53**		**176**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	5	0.01%
Insulation Breach	46	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	7	0.01%
Extrinsic Factors	148	0.32%
Total	**206**	**0.44%**



YEAR	1	2	3	4	5	6	7	8	AT 100 MONTHS
SURVIVAL PROBABILITY	99.67%	99.50%	99.35%	99.16%	99.00%	98.79%	98.48%	98.32%	97.89%
± 1 STANDARD ERROR	0.03%	0.03%	0.04%	0.05%	0.06%	0.07%	0.09%	0.12%	0.12%
SAMPLE SIZE	43,540	37,230	30,720	23,970	17,720	12,210	7,360	3,000	300

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

Pacing Leads

ACTIVELY MONITORED STUDY DATA

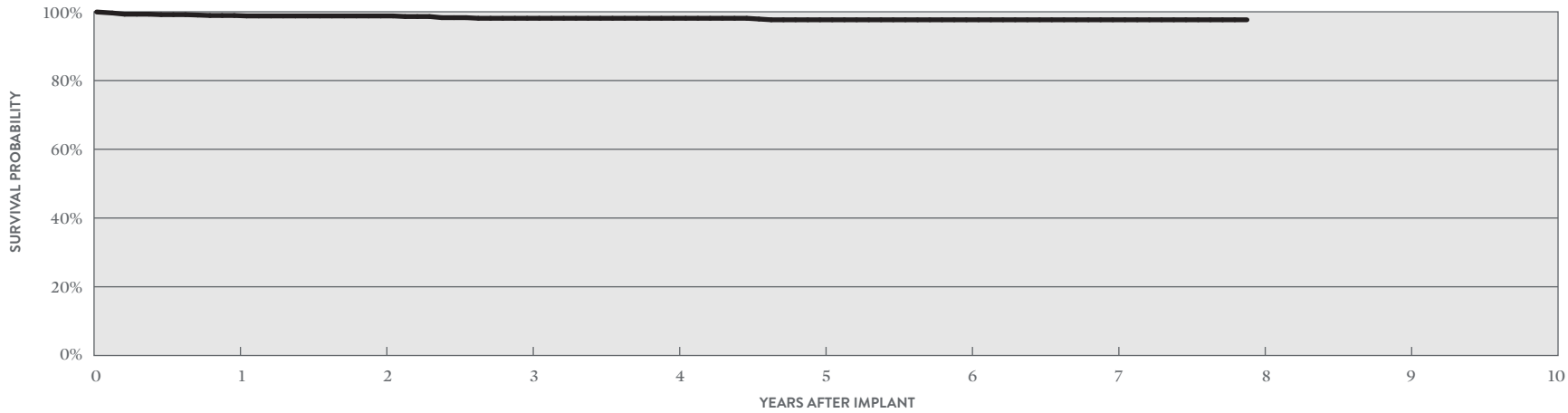
OptiSense™

MODEL 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	872
Active Devices Enrolled in Study	389
Cumulative Months of Follow-up	44,252
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Pacing Impedance	1	0.11%
Conductor Fracture	1	0.11%
Failure to Sense	2	0.23%
Insulation Breach	1	0.11%
Lead Dislodgement	10	1.15%
Oversensing	1	0.11%

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	6	0.69%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.92%
Total	**14**	**1.61%**



YEAR	1	2	3	4	5	6	7	AT 95 MONTHS
SURVIVAL PROBABILITY	98.92%	98.79%	98.11%	98.11%	97.67%	97.67%	97.67%	97.67%
± 1 STANDARD ERROR	0.36%	0.38%	0.51%	0.51%	0.60%	0.60%	0.60%	0.60%
SAMPLE SIZE	810	690	580	500	430	340	240	60

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

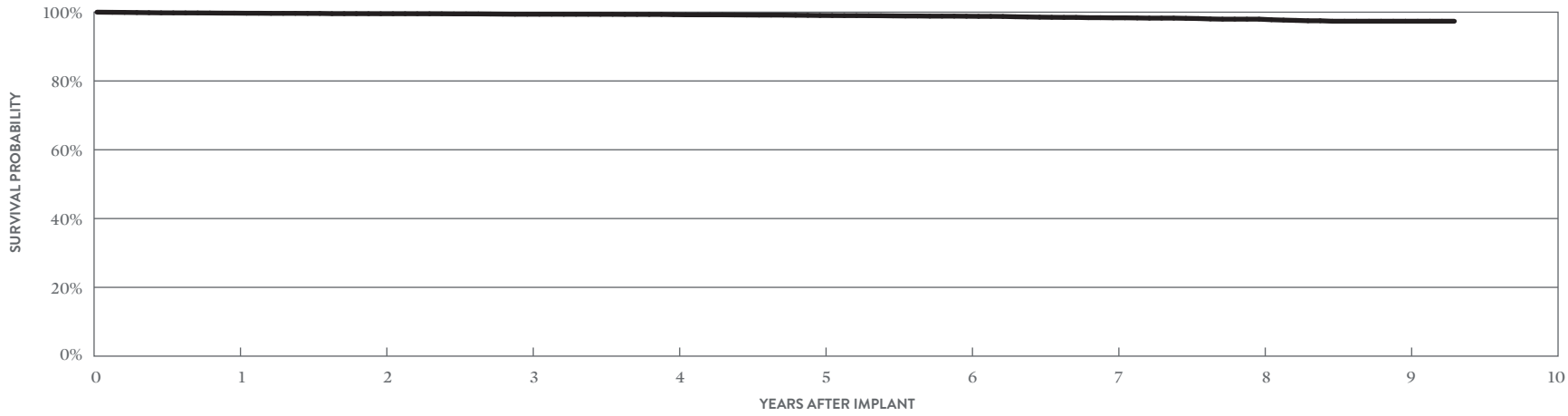
IsoFlex™ Optim™

MODEL 1944

US Regulatory Approval	March 2008
Registered US Implants	17,108
Estimated Active US Implants	9,510
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%	7	0.04%
Lead Dislodgement	71	0.42%	47	0.27%
Failure to Capture	10	0.06%	32	0.19%
Oversensing	1	<0.01%	56	0.33%
Failure to Sense	2	0.01%	6	0.04%
Insulation Breach	0	0.00%	6	0.04%
Abnormal Pacing Impedance	0	0.00%	1	<0.01%
Extracardiac Stimulation	3	0.02%	1	<0.01%
Other	2	0.01%	2	0.01%
Total	**89**	**0.52%**	**159**	**0.93%**
Total Returned for Analysis	**50**		**29**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	8	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	26	0.15%
Total	**35**	**0.20%**



YEAR	1	2	3	4	5	6	7	8	9	AT 112 MONTHS
SURVIVAL PROBABILITY	99.72%	99.55%	99.40%	99.28%	99.04%	98.82%	98.36%	97.97%	97.37%	97.37%
± 1 STANDARD ERROR	0.04%	0.06%	0.07%	0.07%	0.10%	0.12%	0.17%	0.23%	0.33%	0.33%
SAMPLE SIZE	15,360	12,480	10,300	8,210	6,260	4,540	3,030	1,760	780	230

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

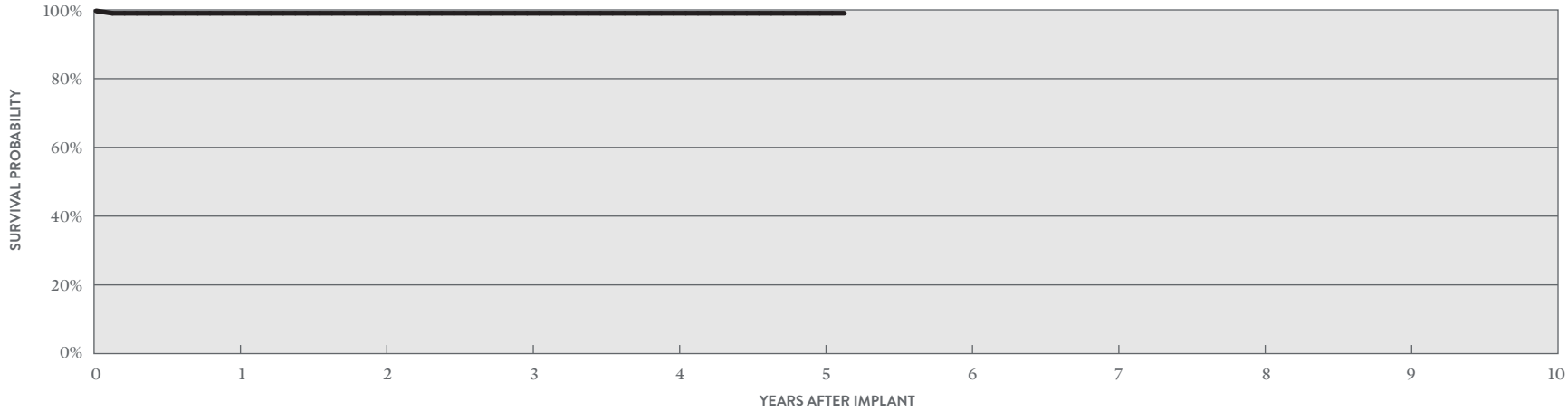
IsoFlex™ Optim™

MODEL 1944

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	104
Active Devices Enrolled in Study	31
Cumulative Months of Follow-up	5,926
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

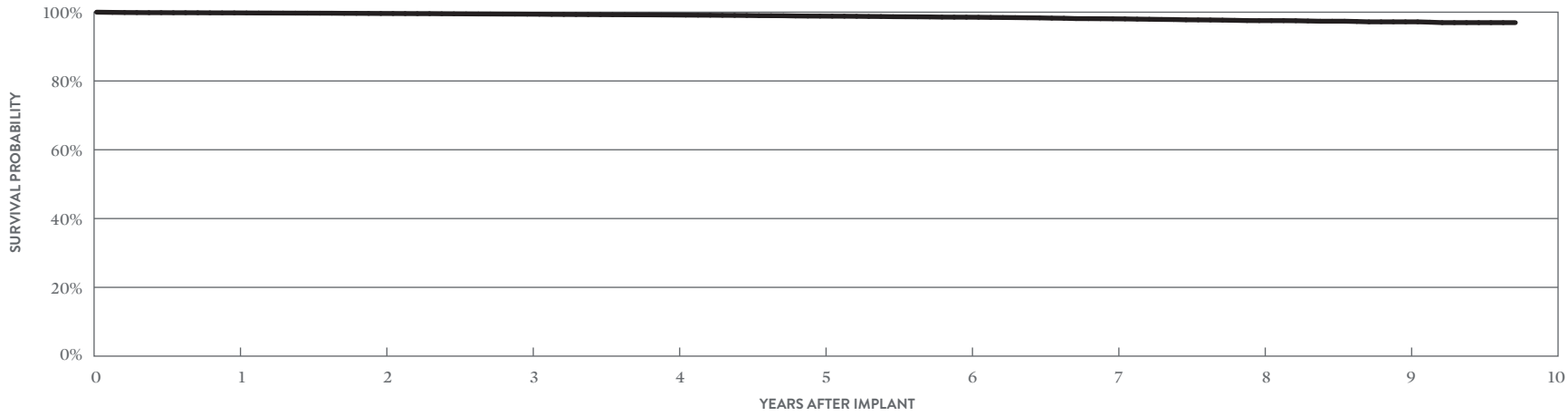
IsoFlex™ Optim™

MODEL 1948

US Regulatory Approval	March 2008
Registered US Implants	65,536
Estimated Active US Implants	36,975
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	4	<0.01%	10	0.02%
Conductor Fracture	1	<0.01%	72	0.11%
Lead Dislodgement	53	0.08%	67	0.10%
Failure to Capture	29	0.04%	144	0.22%
Oversensing	2	<0.01%	210	0.32%
Failure to Sense	2	<0.01%	2	<0.01%
Insulation Breach	4	<0.01%	46	0.07%
Abnormal Pacing Impedance	1	<0.01%	30	0.05%
Extracardiac Stimulation	2	<0.01%	5	<0.01%
Other	7	0.01%	14	0.02%
Total	**105**	**0.16%**	**600**	**0.92%**
Total Returned for Analysis	**53**		**118**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	11	0.02%
Insulation Breach	81	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	77	0.12%
Total	**170**	**0.26%**



YEAR	1	2	3	4	5	6	7	8	9	AT 117 MONTHS
SURVIVAL PROBABILITY	99.80%	99.62%	99.42%	99.18%	98.86%	98.54%	98.07%	97.54%	97.19%	96.96%
± 1 STANDARD ERROR	0.02%	0.03%	0.03%	0.04%	0.06%	0.07%	0.10%	0.14%	0.18%	0.24%
SAMPLE SIZE	58,950	47,750	38,790	30,410	22,680	15,800	10,230	5,920	2,610	250

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

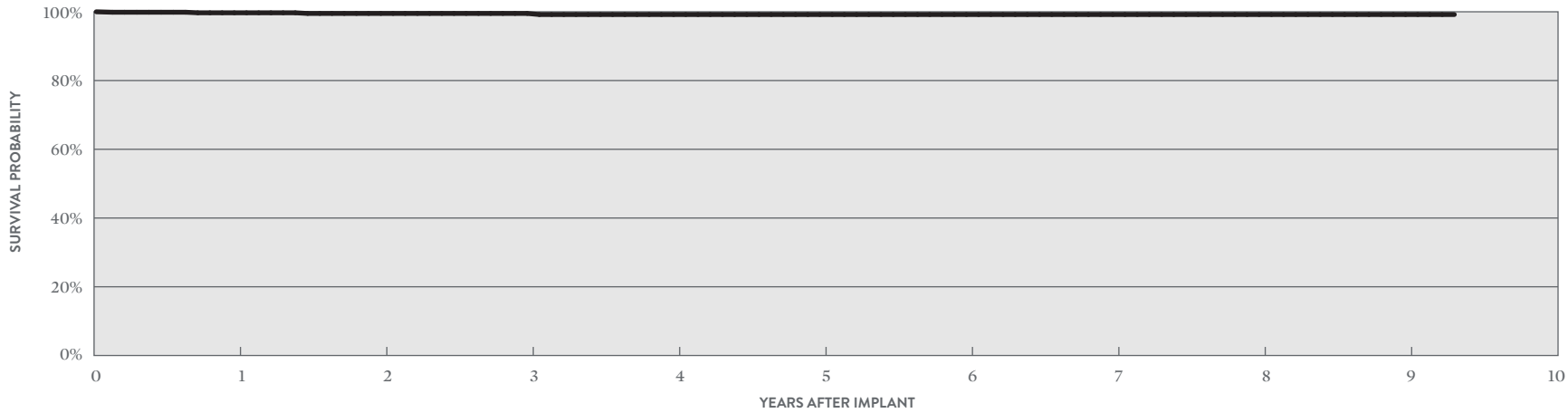
IsoFlex™ Optim™

MODEL 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	765
Active Devices Enrolled in Study	194
Cumulative Months of Follow-up	34,541
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	4	0.52%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.13%
Total	**5**	**0.65%**



YEAR	1	2	3	4	5	6	7	8	9	AT 112 MONTHS
SURVIVAL PROBABILITY	99.71%	99.52%	99.52%	99.20%	99.20%	99.20%	99.20%	99.20%	99.20%	99.20%
± 1 STANDARD ERROR	0.20%	0.28%	0.28%	0.43%	0.43%	0.43%	0.43%	0.43%	0.43%	0.43%
SAMPLE SIZE	680	520	380	300	260	220	200	180	130	50

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

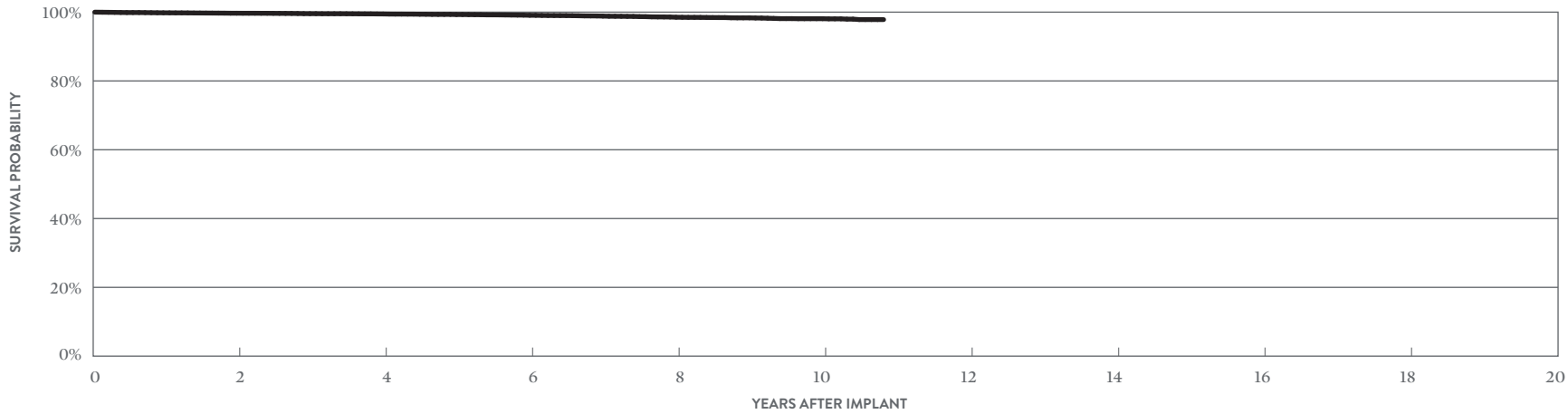
OptiSense™

MODELS 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	22,884
Estimated Active US Implants	9,470
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%	17	0.07%
Lead Dislodgement	4	0.02%	49	0.21%
Failure to Capture	4	0.02%	43	0.19%
Oversensing	3	0.01%	92	0.40%
Failure to Sense	8	0.03%	25	0.11%
Insulation Breach	0	0.00%	7	0.03%
Abnormal Pacing Impedance	0	0.00%	19	0.08%
Extracardiac Stimulation	0	0.00%	3	0.01%
Other	2	<0.01%	4	0.02%
Total	**22**	**0.10%**	**259**	**1.13%**
Total Returned for Analysis	**16**		**75**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	14	0.06%
Insulation Breach	34	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	53	0.23%
Total	**101**	**0.44%**



YEAR	2	4	6	8	10	AT 130 MONTHS
SURVIVAL PROBABILITY	99.69%	99.47%	99.09%	98.52%	98.09%	97.84%
± 1 STANDARD ERROR	0.04%	0.05%	0.07%	0.10%	0.13%	0.21%
SAMPLE SIZE	18,770	15,260	12,730	10,300	4,160	230

Pacing Leads

ACTIVELY MONITORED STUDY DATA

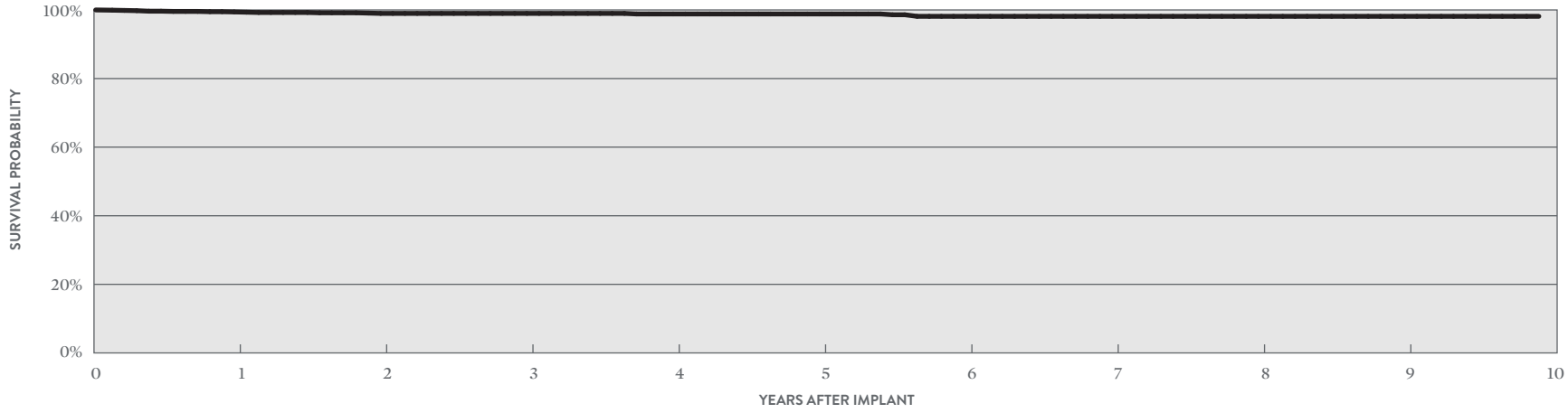
OptiSense™

MODELS 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,450
Active Devices Enrolled in Study	321
Cumulative Months of Follow-up	73,176
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	1	2	3	4	5	6	7	8	9	AT 119 MONTHS
SURVIVAL PROBABILITY	99.42%	98.99%	98.99%	98.83%	98.83%	98.14%	98.14%	98.14%	98.14%	98.14%
± 1 STANDARD ERROR	0.19%	0.27%	0.28%	0.32%	0.32%	0.51%	0.51%	0.51%	0.51%	0.51%
SAMPLE SIZE	1,360	1,160	940	680	500	430	390	340	240	50

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

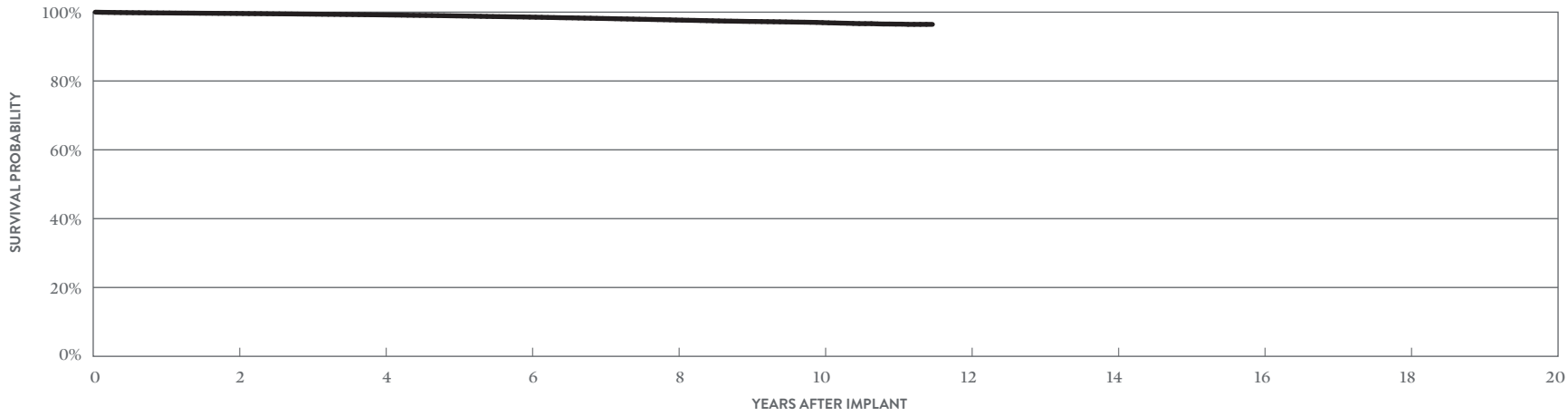
Tendril™ ST Optim™

MODELS 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	301,797
Estimated Active US Implants	131,899
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%	41	0.01%
Conductor Fracture	8	<0.01%	235	0.08%
Lead Dislodgement	158	0.05%	549	0.18%
Failure to Capture	88	0.03%	790	0.26%
Oversensing	21	<0.01%	1916	0.63%
Failure to Sense	14	<0.01%	113	0.04%
Insulation Breach	7	<0.01%	320	0.11%
Abnormal Pacing Impedance	9	<0.01%	215	0.07%
Extracardiac Stimulation	5	<0.01%	37	0.01%
Other	40	0.01%	124	0.04%
Total	**391**	**0.13%**	**4340**	**1.44%**
Total Returned for Analysis	**203**		**1237**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	41	0.01%
Insulation Breach	812	0.27%
Crimps, Welds & Bonds	1	<0.01%
Other	14	<0.01%
Extrinsic Factors	807	0.27%
Total	**1675**	**0.56%**



YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.62%	99.20%	98.56%	97.71%	96.96%	96.45%
± 1 STANDARD ERROR	0.01%	0.02%	0.03%	0.04%	0.06%	0.12%
SAMPLE SIZE	242,610	186,420	132,760	84,370	27,710	240

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

ACTIVELY MONITORED STUDY DATA

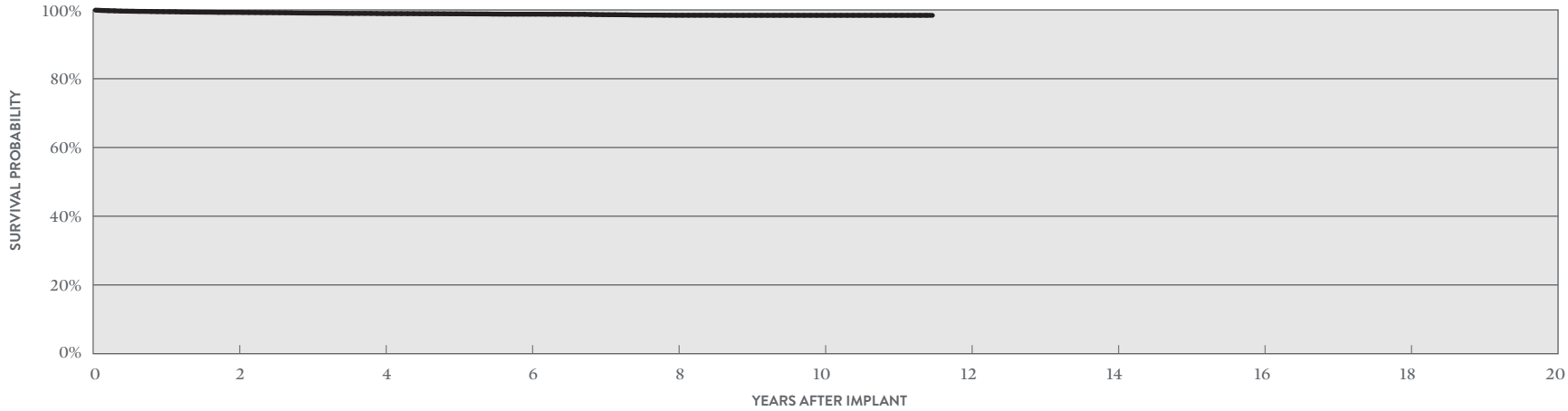
Tendril™ ST Optim™

MODELS 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	14,506
Active Devices Enrolled in Study	4,474
Cumulative Months of Follow-up	846,679
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Pacing Impedance	6	0.04%
Cardiac Perforation	2	0.01%
Conductor Fracture	9	0.06%
Extracardiac Stimulation	4	0.03%
Failure to Capture	19	0.13%
Failure to Sense	4	0.03%
Insulation Breach	27	0.19%
Lead Dislodgement	58	0.40%
Oversensing	22	0.15%
Skin Erosion	1	<0.01%

MALFUNCTIONS	QTY	RATE
Conductor Fracture	3	0.02%
Insulation Breach	24	0.17%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	35	0.24%
Total	**62**	**0.43%**



YEAR	2	4	6	8	10	AT 138 MONTHS
SURVIVAL PROBABILITY	99.29%	98.93%	98.77%	98.45%	98.43%	98.43%
± 1 STANDARD ERROR	0.07%	0.09%	0.11%	0.14%	0.14%	0.14%
SAMPLE SIZE	11,880	7,610	5,260	4,450	2,540	80

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

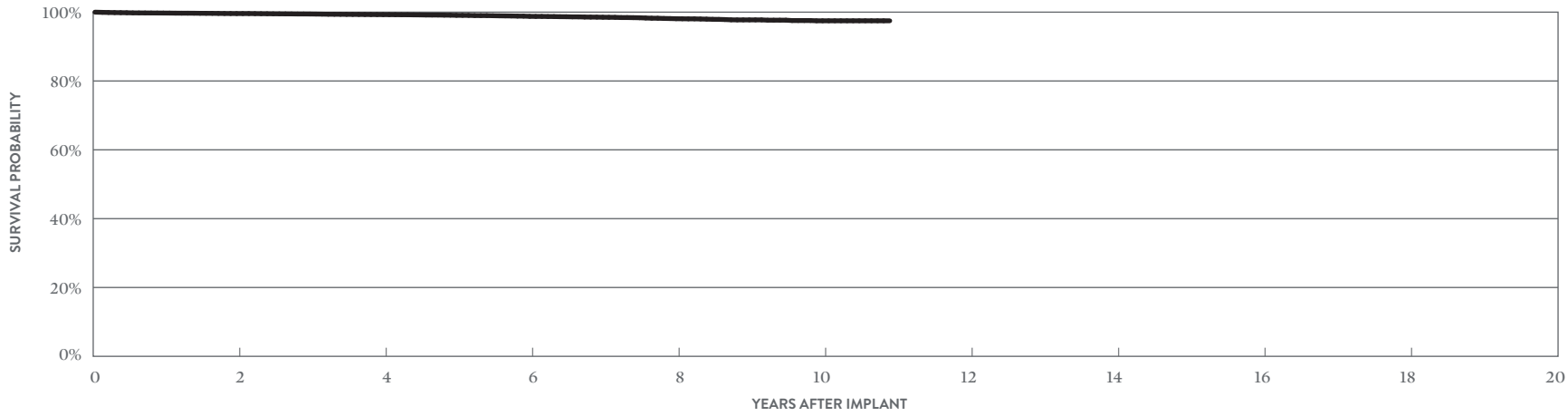
Tendril™ ST Optim™

MODELS 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	49,229
Estimated Active US Implants	26,002
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	3	<0.01%	3	<0.01%
Conductor Fracture	0	0.00%	13	0.03%
Lead Dislodgement	46	0.09%	133	0.27%
Failure to Capture	12	0.02%	69	0.14%
Oversensing	5	0.01%	169	0.34%
Failure to Sense	4	<0.01%	21	0.04%
Insulation Breach	0	0.00%	36	0.07%
Abnormal Pacing Impedance	1	<0.01%	13	0.03%
Extracardiac Stimulation	0	0.00%	3	<0.01%
Other	14	0.03%	22	0.04%
Total	**85**	**0.17%**	**482**	**0.98%**
Total Returned for Analysis	**47**		**153**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	2	<0.01%
Insulation Breach	60	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	127	0.26%
Total	**192**	**0.39%**



YEAR	2	4	6	8	10	AT 131 MONTHS
SURVIVAL PROBABILITY	99.59%	99.28%	98.78%	98.09%	97.49%	97.49%
± 1 STANDARD ERROR	0.03%	0.04%	0.07%	0.11%	0.19%	0.19%
SAMPLE SIZE	37,910	25,980	15,680	7,510	2,080	230

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

Pacing Leads

ACTIVELY MONITORED STUDY DATA

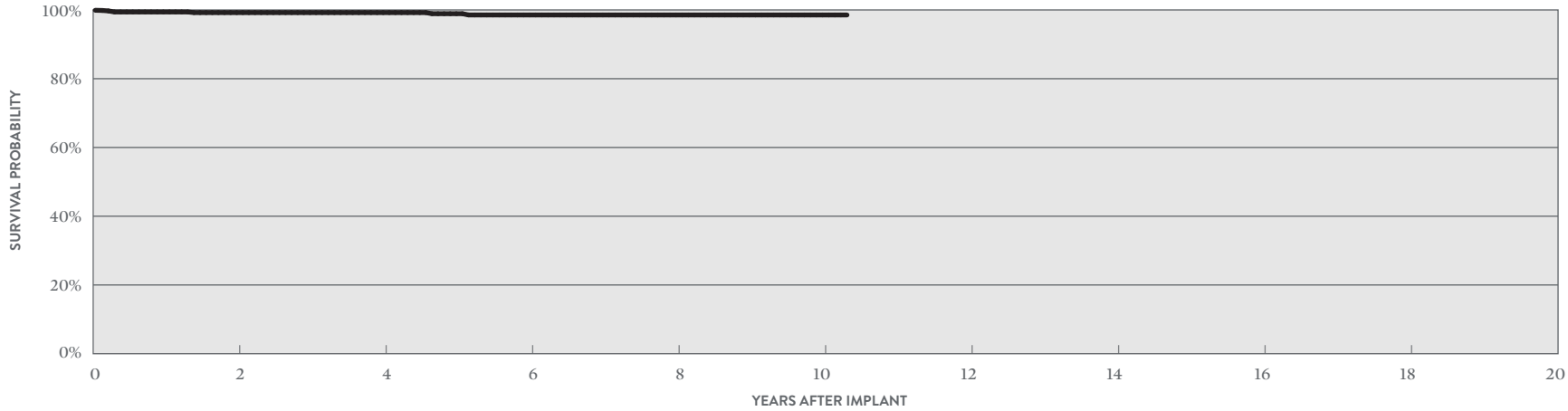
Tendril™ ST Optim™

MODELS 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	690
Active Devices Enrolled in Study	198
Cumulative Months of Follow-up	39,256
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Extracardiac Stimulation	1	0.14%
Failure to Capture	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	2	0.29%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**2**	**0.29%**



YEAR	2	4	6	8	10	AT 124 MONTHS
SURVIVAL PROBABILITY	99.23%	99.23%	98.54%	98.54%	98.54%	98.54%
± 1 STANDARD ERROR	0.34%	0.34%	0.60%	0.60%	0.60%	0.60%
SAMPLE SIZE	560	380	260	190	100	50

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

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

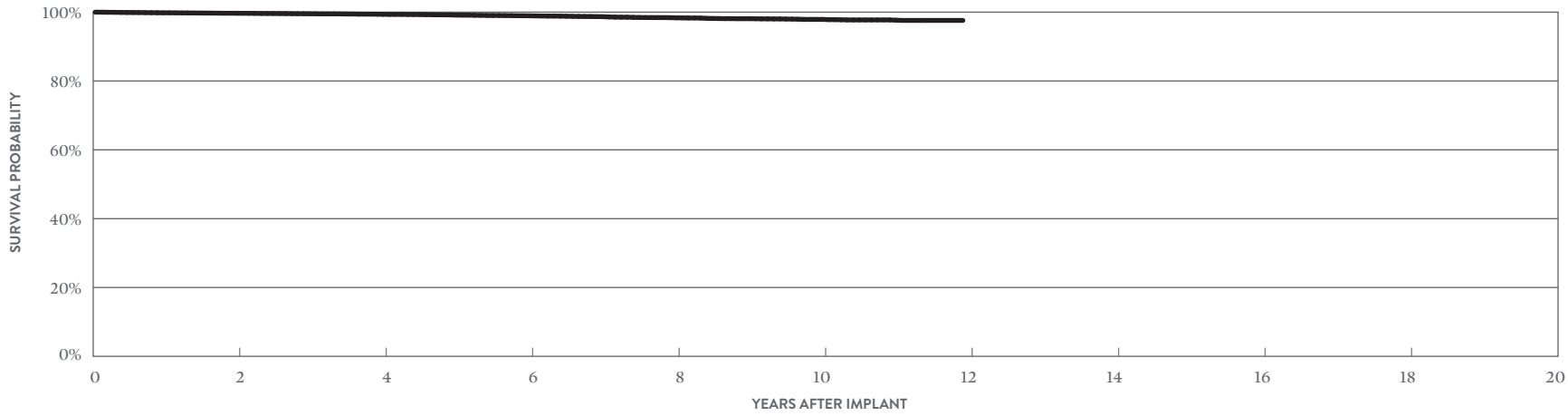
Tendril™

MODELS 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,406
Estimated Active US Implants	6,201
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%	5	0.03%
Lead Dislodgement	13	0.08%	50	0.30%
Failure to Capture	5	0.03%	47	0.29%
Oversensing	0	0.00%	50	0.30%
Failure to Sense	0	0.00%	7	0.04%
Insulation Breach	0	0.00%	4	0.02%
Abnormal Pacing Impedance	2	0.01%	16	0.10%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	3	0.02%
Total	**29**	**0.18%**	**183**	**1.12%**
Total Returned for Analysis	**16**		**62**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	1	<0.01%
Insulation Breach	37	0.23%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	49	0.30%
Total	**87**	**0.53%**



YEAR	2	4	6	8	10	AT 143 MONTHS
SURVIVAL PROBABILITY	99.68%	99.37%	98.94%	98.35%	97.89%	97.60%
± 1 STANDARD ERROR	0.05%	0.07%	0.10%	0.13%	0.17%	0.21%
SAMPLE SIZE	13,410	10,770	8,590	6,310	3,610	210

Pacing Leads

ACTIVELY MONITORED STUDY DATA

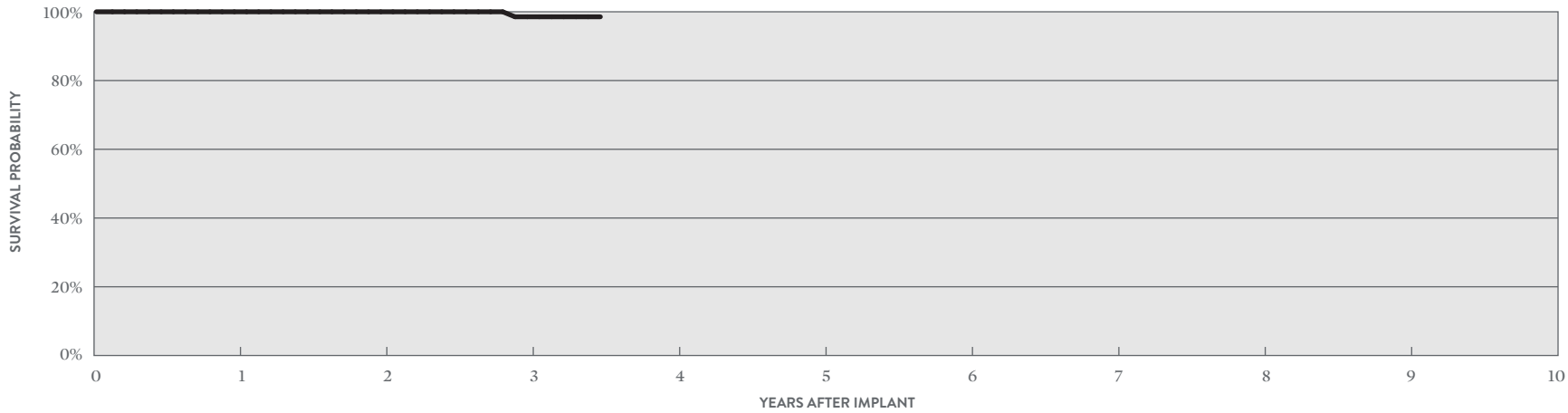
Tendril™

MODELS 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	165
Active Devices Enrolled in Study	14
Cumulative Months of Follow-up	5,839
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

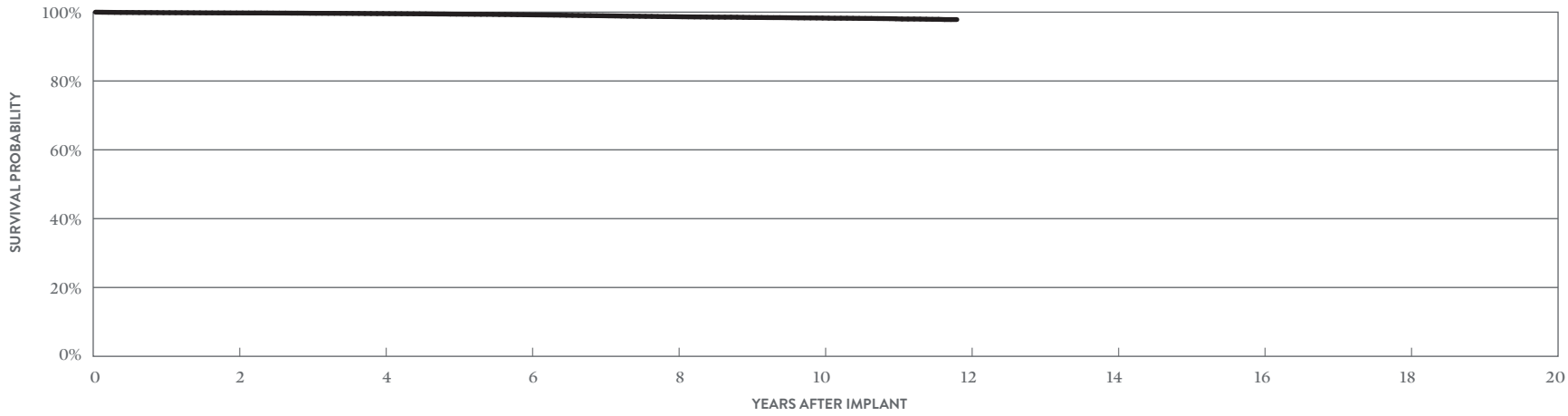
Tendril™

MODELS 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,248
Estimated Active US Implants	23,379
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%	7	0.01%
Conductor Fracture	1	<0.01%	28	0.04%
Lead Dislodgement	31	0.05%	77	0.12%
Failure to Capture	31	0.05%	159	0.24%
Oversensing	4	<0.01%	180	0.28%
Failure to Sense	2	<0.01%	24	0.04%
Insulation Breach	1	<0.01%	32	0.05%
Abnormal Pacing Impedance	9	0.01%	48	0.07%
Extracardiac Stimulation	2	<0.01%	7	0.01%
Other	20	0.03%	28	0.04%
Total	**113**	**0.17%**	**590**	**0.90%**
Total Returned for Analysis	**47**		**148**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	10	0.02%
Insulation Breach	113	0.17%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	102	0.16%
Total	**227**	**0.35%**



YEAR	2	4	6	8	10	AT 142 MONTHS
SURVIVAL PROBABILITY	99.77%	99.58%	99.22%	98.68%	98.29%	97.85%
± 1 STANDARD ERROR	0.02%	0.03%	0.04%	0.06%	0.07%	0.12%
SAMPLE SIZE	52,610	41,530	33,600	27,180	18,720	400

Pacing Leads

ACTIVELY MONITORED STUDY DATA

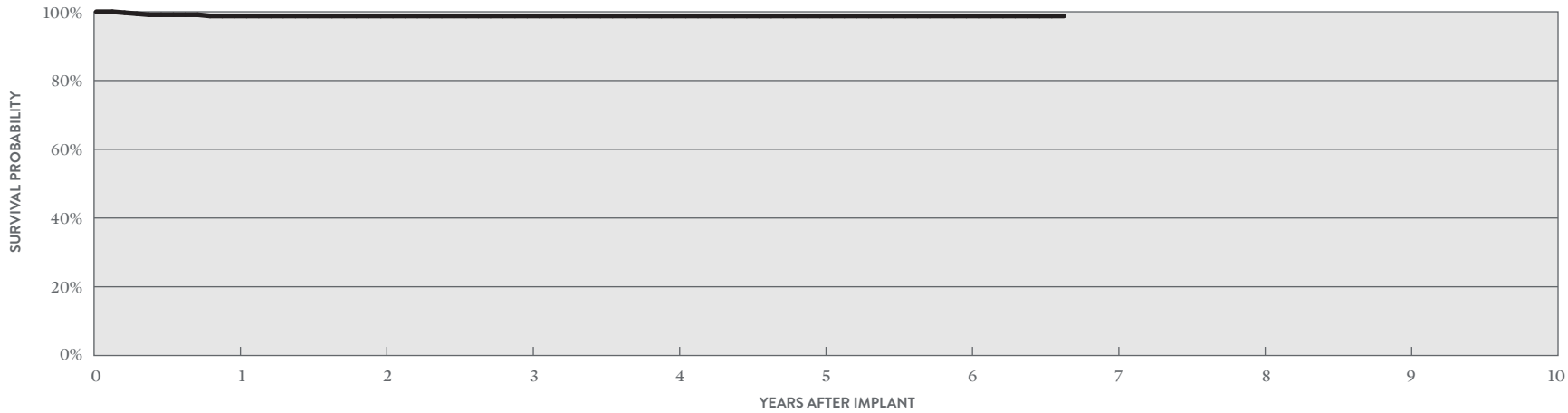
Tendril™

MODELS 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	363
Active Devices Enrolled in Study	38
Cumulative Months of Follow-up	12,581
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

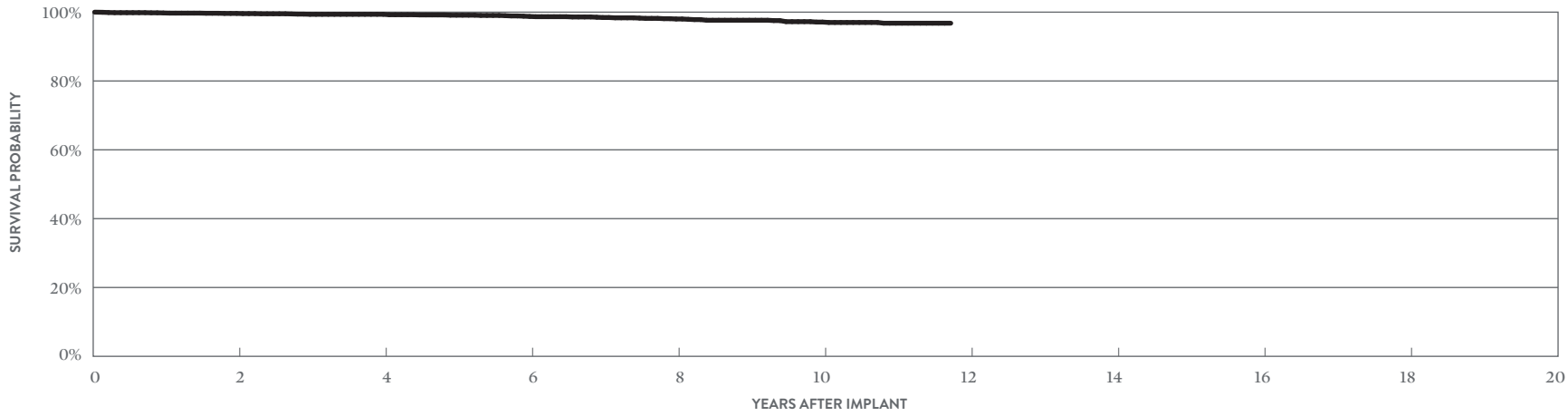
IsoFlex™ P

MODEL 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,835
Estimated Active US Implants	969
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%	10	0.35%
Oversensing	0	0.00%	2	0.07%
Failure to Sense	1	0.04%	1	0.04%
Insulation Breach	0	0.00%	12	0.42%
Abnormal Pacing Impedance	0	0.00%	3	0.11%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	6	0.21%
Total	**6**	**0.21%**	**42**	**1.48%**
Total Returned for Analysis	**1**		**8**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	12	0.42%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.07%
Extrinsic Factors	6	0.21%
Total	**20**	**0.71%**



YEAR	2	4	6	8	10	AT 141 MONTHS
SURVIVAL PROBABILITY	99.63%	99.37%	98.75%	98.01%	97.12%	96.79%
± 1 STANDARD ERROR	0.12%	0.17%	0.26%	0.35%	0.46%	0.52%
SAMPLE SIZE	2,200	1,740	1,380	1,170	900	200

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

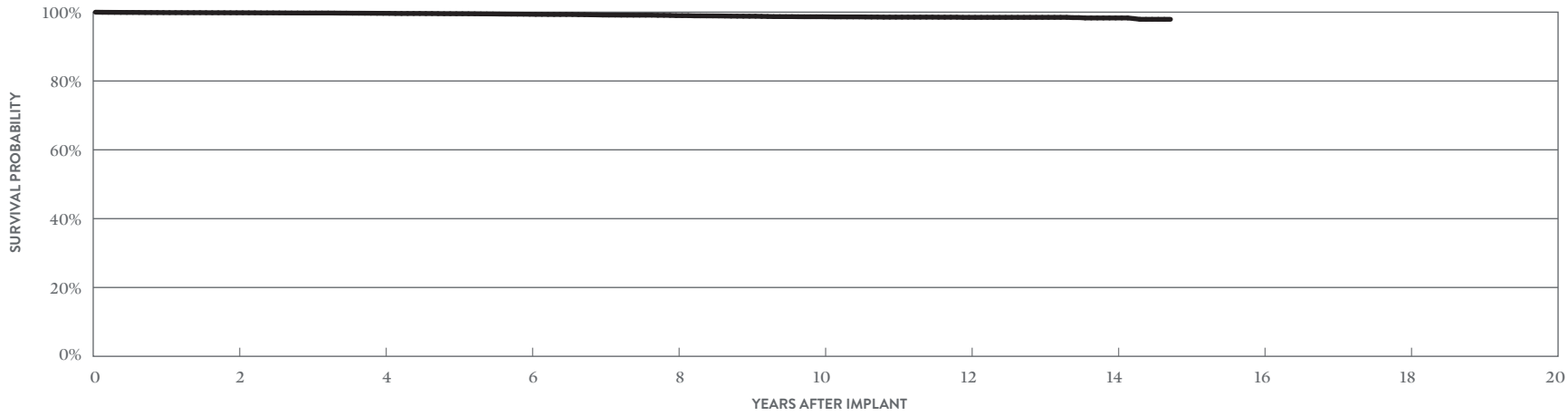
IsoFlex™ S

MODEL 1642T

US Regulatory Approval	May 2002
Registered US Implants	27,131
Estimated Active US Implants	8,859
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%	7	0.03%
Lead Dislodgement	49	0.18%	43	0.16%
Failure to Capture	6	0.02%	59	0.22%
Oversensing	0	0.00%	40	0.15%
Failure to Sense	3	0.01%	17	0.06%
Insulation Breach	0	0.00%	6	0.02%
Abnormal Pacing Impedance	3	0.01%	11	0.04%
Extracardiac Stimulation	1	<0.01%	2	<0.01%
Other	0	0.00%	2	<0.01%
Total	**63**	**0.23%**	**187**	**0.69%**
Total Returned for Analysis	**39**		**28**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	24	0.09%
Crimps, Welds & Bonds	1	<0.01%
Other	2	<0.01%
Extrinsic Factors	20	0.07%
Total	**47**	**0.17%**



YEAR	2	4	6	8	10	12	14	AT 177 MONTHS
SURVIVAL PROBABILITY	99.82%	99.66%	99.39%	99.00%	98.67%	98.49%	98.31%	97.92%
± 1 STANDARD ERROR	0.03%	0.04%	0.06%	0.08%	0.10%	0.12%	0.18%	0.33%
SAMPLE SIZE	22,000	17,630	13,860	10,520	6,960	3,520	1,120	230

Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

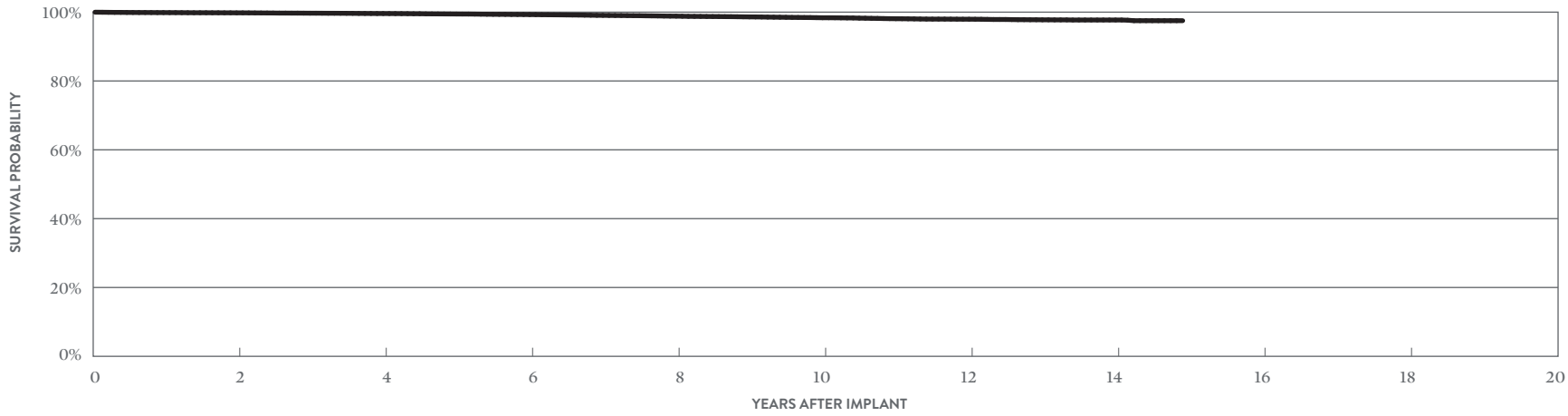
IsoFlex™ S

MODEL 1646T

US Regulatory Approval	May 2002
Registered US Implants	90,376
Estimated Active US Implants	28,438
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%	109	0.12%
Lead Dislodgement	37	0.04%	36	0.04%
Failure to Capture	35	0.04%	317	0.35%
Oversensing	1	<0.01%	135	0.15%
Failure to Sense	2	<0.01%	12	0.01%
Insulation Breach	2	<0.01%	43	0.05%
Abnormal Pacing Impedance	6	<0.01%	115	0.13%
Extracardiac Stimulation	0	0.00%	7	<0.01%
Other	2	<0.01%	22	0.02%
Total	**91**	**0.10%**	**798**	**0.88%**
Total Returned for Analysis	**38**		**102**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	21	0.02%
Insulation Breach	65	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	6	<0.01%
Extrinsic Factors	64	0.07%
Total	**156**	**0.17%**



YEAR	2	4	6	8	10	12	14	AT 179 MONTHS
SURVIVAL PROBABILITY	99.80%	99.60%	99.29%	98.84%	98.37%	97.95%	97.72%	97.52%
± 1 STANDARD ERROR	0.02%	0.02%	0.03%	0.05%	0.07%	0.09%	0.11%	0.16%
SAMPLE SIZE	71,810	56,130	43,780	32,710	21,440	10,700	3,290	310

Pacing Leads

ACTIVELY MONITORED STUDY DATA

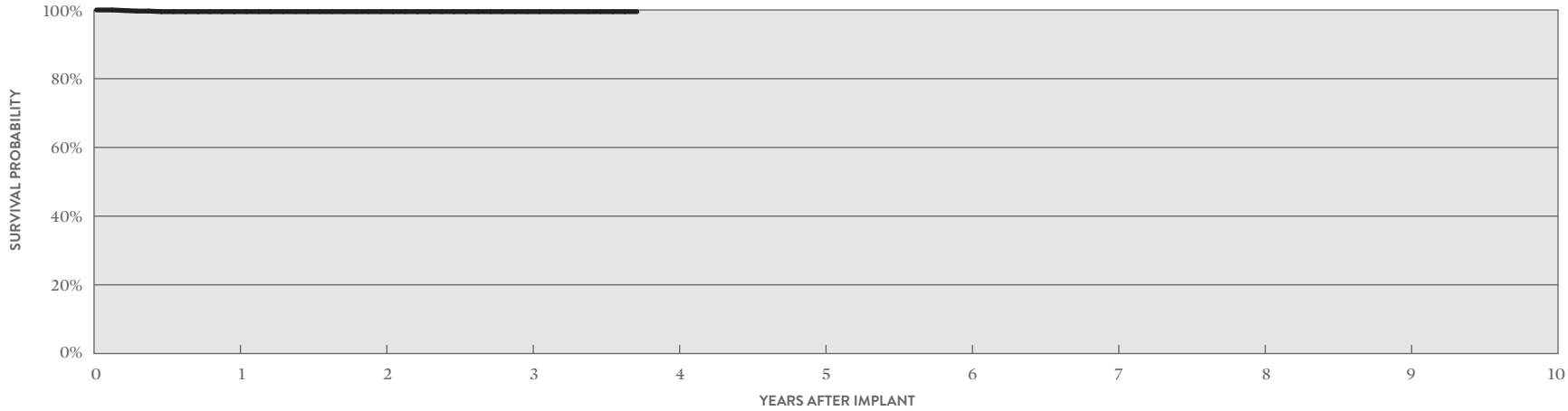
IsoFlex™ S

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	15,809
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

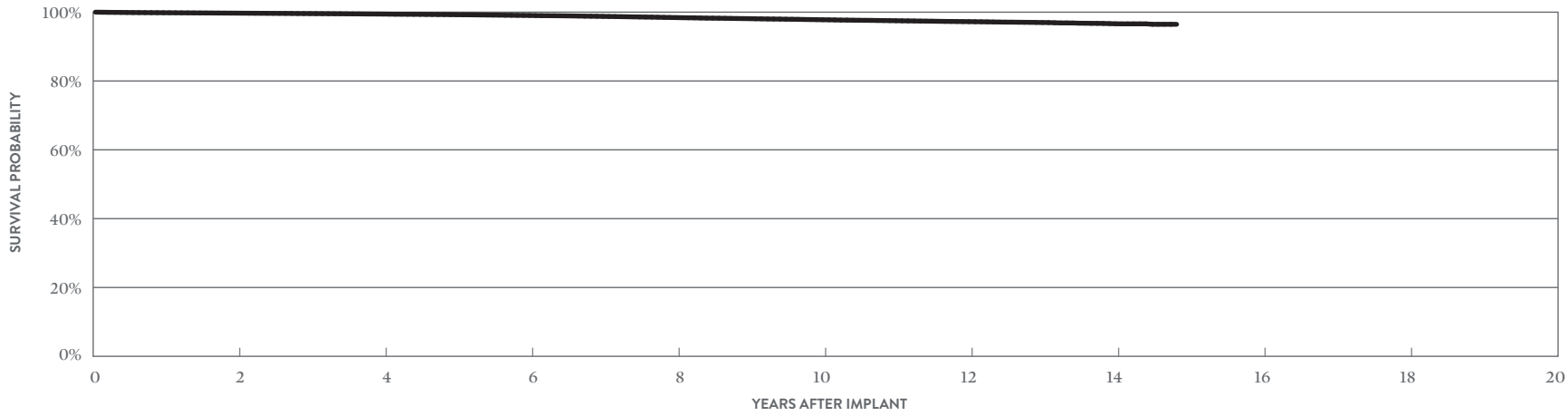
Tendril™ SDX

MODELS 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	490,933
Estimated Active US Implants	185,641
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%	40	<0.01%
Conductor Fracture	6	<0.01%	485	0.10%
Lead Dislodgement	318	0.06%	572	0.12%
Failure to Capture	203	0.04%	1372	0.28%
Oversensing	24	<0.01%	1517	0.31%
Failure to Sense	34	<0.01%	140	0.03%
Insulation Breach	10	<0.01%	220	0.04%
Abnormal Pacing Impedance	30	<0.01%	554	0.11%
Extracardiac Stimulation	7	<0.01%	43	<0.01%
Other	64	0.01%	170	0.03%
Total	**777**	**0.16%**	**5113**	**1.04%**
Total Returned for Analysis	**345**		**1368**	

MALFUNCTIONS	QTY	RATE
Conductor Fracture	210	0.04%
Insulation Breach	892	0.18%
Crimps, Welds & Bonds	2	<0.01%
Other	19	<0.01%
Extrinsic Factors	786	0.16%
Total	**1909**	**0.39%**



YEAR	2	4	6	8	10	12	14	AT 178 MONTHS
SURVIVAL PROBABILITY	99.71%	99.44%	99.04%	98.42%	97.79%	97.24%	96.62%	96.47%
± 1 STANDARD ERROR	0.01%	0.01%	0.02%	0.03%	0.04%	0.05%	0.08%	0.12%
SAMPLE SIZE	392,820	291,510	207,000	144,330	93,570	52,120	12,180	350

Pacing Leads

ACTIVELY MONITORED STUDY DATA

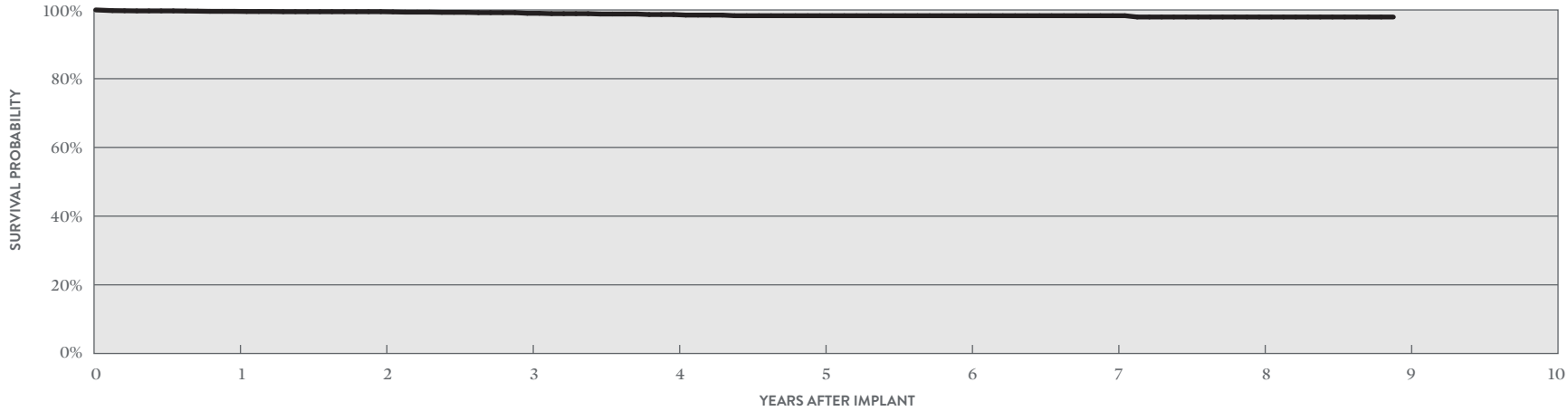
Tendril™ SDX

MODELS 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	2,646
Active Devices Enrolled in Study	393
Cumulative Months of Follow-up	94,790
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Abnormal Pacing Impedance	5	0.19%
Conductor Fracture	2	0.08%
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	0	0.00%
Insulation Breach	4	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.19%
Total	**9**	**0.34%**



YEAR	1	2	3	4	5	6	7	8	AT 107 MONTHS
SURVIVAL PROBABILITY	99.60%	99.50%	99.03%	98.67%	98.33%	98.33%	98.33%	97.95%	97.95%
± 1 STANDARD ERROR	0.13%	0.14%	0.20%	0.32%	0.40%	0.40%	0.40%	0.55%	0.55%
SAMPLE SIZE	2,390	1,840	1,310	850	550	420	330	220	50

Pacing Leads

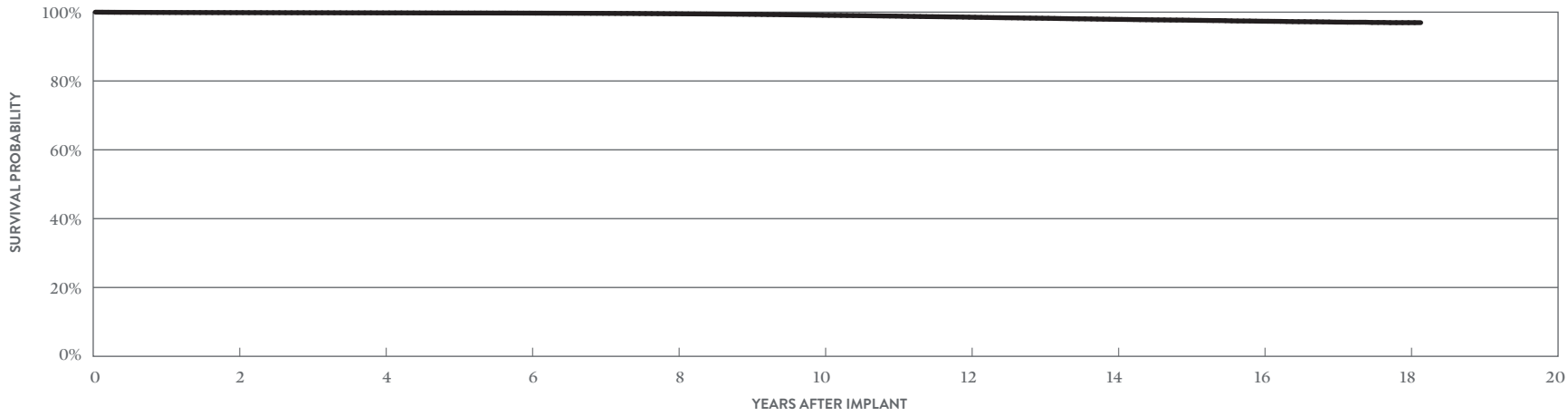
CUSTOMER REPORTED PERFORMANCE DATA

Tendril™ SDX

MODELS 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	270,816
Estimated Active US Implants	55,107
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

MALFUNCTIONS	QTY	RATE
Conductor Fracture	159	0.06%
Insulation Breach	309	0.11%
Crimps, Welds & Bonds	5	<0.01%
Other	3	<0.01%
Extrinsic Factors	365	0.13%
Total	**841**	**0.31%**



YEAR	2	4	6	8	10	12	14	16	18	AT 218 MONTHS
SURVIVAL PROBABILITY	99.86%	99.79%	99.72%	99.53%	99.10%	98.54%	97.91%	97.36%	96.95%	96.95%
± 1 STANDARD ERROR	0.01%	0.01%	0.01%	0.02%	0.03%	0.04%	0.05%	0.07%	0.12%	0.12%
SAMPLE SIZE	221,580	176,860	136,400	103,800	80,720	64,040	45,600	21,560	2,960	260

Pacing Leads

ACTIVELY MONITORED STUDY DATA

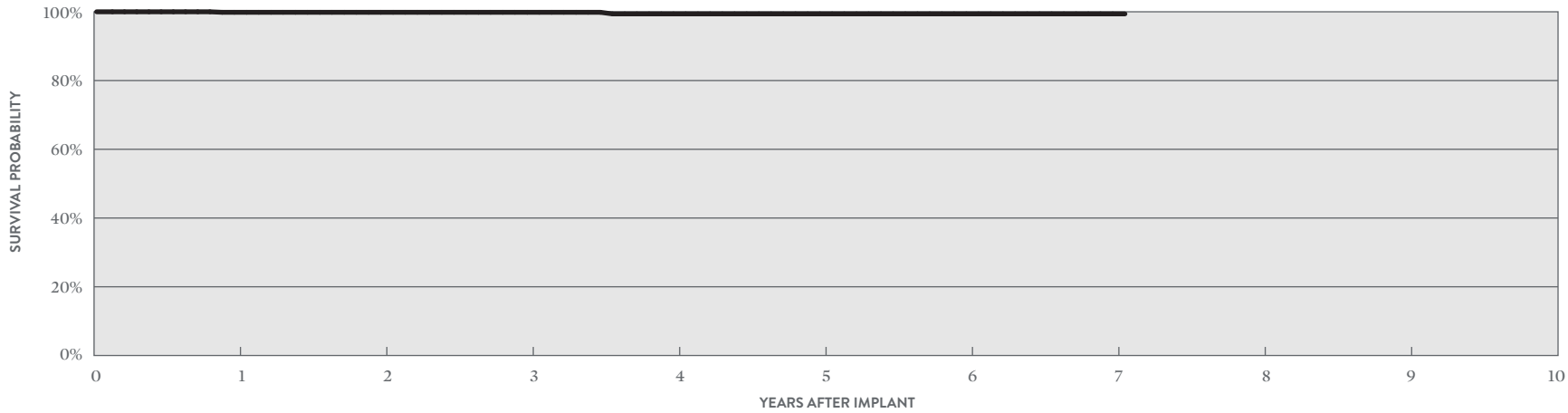
Tendril™ SDX

MODELS 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	803
Active Devices Enrolled in Study	38
Cumulative Months of Follow-up	26,948
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

QUALIFYING COMPLICATIONS	QTY	RATE
Failure to Capture	1	0.12%
Insulation Breach	1	0.12%

MALFUNCTIONS	QTY	RATE
Conductor Fracture	0	0.00%
Insulation Breach	5	0.62%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.12%
Total	**6**	**0.75%**



YEAR	1	2	3	4	5	6	7	AT 85 MONTHS
SURVIVAL PROBABILITY	99.85%	99.85%	99.85%	99.39%	99.39%	99.39%	99.39%	99.39%
± 1 STANDARD ERROR	0.15%	0.15%	0.15%	0.49%	0.49%	0.49%	0.49%	0.49%
SAMPLE SIZE	730	580	400	220	120	90	70	50

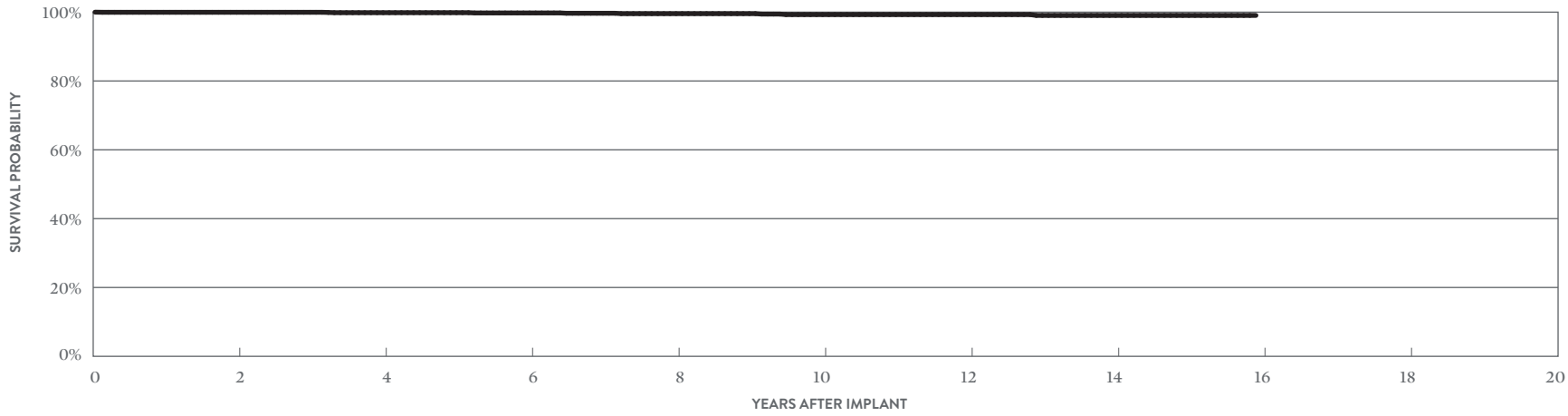
Pacing Leads

CUSTOMER REPORTED PERFORMANCE DATA

AV Plus™ DX

MODEL 1368

US Regulatory Approval	May 1999
Registered US Implants	2,829
Estimated Active US Implants	784
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



YEAR	2	4	6	8	10	12	14	AT 191 MONTHS
SURVIVAL PROBABILITY	99.96%	99.85%	99.77%	99.57%	99.29%	99.29%	99.05%	99.05%
± 1 STANDARD ERROR	0.04%	0.09%	0.12%	0.18%	0.27%	0.27%	0.36%	0.36%
SAMPLE SIZE	2,160	1,670	1,230	930	690	500	360	200

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™	99.82%	99.56%	99.43%	99.22%	98.84%					
2088TC	Tendril™ STS	99.77%	99.61%	99.44%	99.24%	99.03%	98.79%	98.50%	98.06%		
1999	OptiSense™ Optim™	99.67%	99.50%	99.35%	99.16%	99.00%	98.79%	98.48%	98.32%		
1944	IsoFlex™ Optim™	99.72%	99.55%	99.40%	99.28%	99.04%	98.82%	98.36%	97.97%	97.37%	
1948	IsoFlex™ Optim™	99.80%	99.62%	99.42%	99.18%	98.86%	98.54%	98.07%	97.54%	97.19%	
1699T/TC	OptiSense™	99.81%	99.69%	99.56%	99.47%	99.30%	99.09%	98.85%	98.52%	98.34%	98.09%
1888T/TC	Tendril™ ST Optim™	99.77%	99.62%	99.43%	99.20%	98.91%	98.56%	98.16%	97.71%	97.30%	96.96%
1882T/TC	Tendril™ ST Optim™	99.74%	99.59%	99.46%	99.28%	99.08%	98.78%	98.52%	98.09%	97.75%	97.49%
1782T/TC	Tendril™	99.81%	99.68%	99.53%	99.37%	99.15%	98.94%	98.69%	98.35%	98.10%	97.89%
1788T/TC	Tendril™	99.84%	99.77%	99.68%	99.58%	99.42%	99.22%	98.95%	98.68%	98.46%	98.29%
1648T	IsoFlex™ P	99.77%	99.63%	99.37%	99.37%	99.12%	98.75%	98.44%	98.01%	97.65%	97.12%
1642T	IsoFlex™ S	99.87%	99.82%	99.75%	99.66%	99.54%	99.39%	99.17%	99.00%	98.82%	98.67%
1646T	IsoFlex™ S	99.87%	99.80%	99.70%	99.60%	99.46%	99.29%	99.07%	98.84%	98.62%	98.37%
1688T/TC	Tendril™ SDX	99.83%	99.71%	99.58%	99.44%	99.26%	99.04%	98.77%	98.42%	98.11%	97.79%
1488T/TC	Tendril™ SDX	99.91%	99.86%	99.82%	99.79%	99.76%	99.72%	99.65%	99.53%	99.37%	99.10%
1368	AV Plus™ DX	99.96%	99.96%	99.96%	99.85%	99.85%	99.77%	99.68%	99.57%	99.57%	99.29%

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	94,111	77,704	23	0.02%	0	0.00%	190	0.20%	23	0.02%	13	0.01%	14	0.01%	0	0.00%	1	<0.01%	3	<0.01%	51	0.05%	**318**	**0.34%**	**112**
2088TC	May-09	610,472	387,787	94	0.02%	8	<0.01%	637	0.10%	174	0.03%	63	0.01%	27	<0.01%	13	<0.01%	36	<0.01%	4	<0.01%	125	0.02%	**1181**	**0.19%**	**528**
1999	May-07	46,809	28,159	4	<0.01%	0	0.00%	64	0.14%	8	0.02%	9	0.02%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	12	0.03%	**101**	**0.22%**	**53**
1944	Mar-08	17,108	9,510	0	0.00%	0	0.00%	71	0.42%	10	0.06%	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	3	0.02%	2	0.01%	**89**	**0.52%**	**50**
1948	Mar-08	65,536	36,975	4	<0.01%	1	<0.01%	53	0.08%	29	0.04%	2	<0.01%	2	<0.01%	4	<0.01%	1	<0.01%	2	<0.01%	7	0.01%	**105**	**0.16%**	**53**
1699T/TC	May-07	22,884	9,470	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	301,797	131,899	41	0.01%	8	<0.01%	158	0.05%	88	0.03%	21	<0.01%	14	<0.01%	7	<0.01%	9	<0.01%	5	<0.01%	40	0.01%	**391**	**0.13%**	**203**
1882T/TC	Jun-06	49,229	26,002	3	<0.01%	0	0.00%	46	0.09%	12	0.02%	5	0.01%	4	<0.01%	0	0.00%	1	<0.01%	0	0.00%	14	0.03%	**85**	**0.17%**	**47**
1782T/TC	Feb-06	16,406	6,201	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	65,248	23,379	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%**	**47**
1648T	Apr-05	2,835	969	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	27,131	8,859	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%	0	0.00%	**63**	**0.23%**	**39**
1646T	May-02	90,376	28,438	4	<0.01%	2	<0.01%	37	0.04%	35	0.04%	1	<0.01%	2	<0.01%	2	<0.01%	6	<0.01%	0	0.00%	2	<0.01%	**91**	**0.10%**	**38**
1688T/TC	Jun-03	490,933	185,641	81	0.02%	6	<0.01%	318	0.06%	203	0.04%	24	<0.01%	34	<0.01%	10	<0.01%	30	<0.01%	7	<0.01%	64	0.01%	**777**	**0.16%**	**345**

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	94,111	77,704	7	<0.01%	1	<0.01%	82	0.09%	33	0.04%	29	0.03%	8	<0.01%	0	0.00%	3	<0.01%	3	<0.01%	5	<0.01%	**171**	**0.18%**	**44**
2088TC	May-09	610,472	387,787	56	<0.01%	213	0.03%	903	0.15%	716	0.12%	1945	0.32%	100	0.02%	188	0.03%	140	0.02%	32	<0.01%	138	0.02%	**4431**	**0.73%**	**1512**
1999	May-07	46,809	28,159	0	0.00%	8	0.02%	163	0.35%	54	0.12%	165	0.35%	23	0.05%	25	0.05%	11	0.02%	1	<0.01%	17	0.04%	**467**	**1.00%**	**176**
1944	Mar-08	17,108	9,510	1	<0.01%	7	0.04%	47	0.27%	32	0.19%	56	0.33%	6	0.04%	6	0.04%	1	<0.01%	1	<0.01%	2	0.01%	**159**	**0.93%**	**29**
1948	Mar-08	65,536	36,975	10	0.02%	72	0.11%	67	0.10%	144	0.22%	210	0.32%	2	<0.01%	46	0.07%	30	0.05%	5	<0.01%	14	0.02%	**600**	**0.92%**	**118**
1699T/TC	May-07	22,884	9,470	0	0.00%	17	0.07%	49	0.21%	43	0.19%	92	0.40%	25	0.11%	7	0.03%	19	0.08%	3	0.01%	4	0.02%	**259**	**1.13%**	**75**
1888T/TC	Jun-06	301,797	131,899	41	0.01%	235	0.08%	549	0.18%	790	0.26%	1916	0.63%	113	0.04%	320	0.11%	215	0.07%	37	0.01%	124	0.04%	**4340**	**1.44%**	**1237**
1882T/TC	Jun-06	49,229	26,002	3	<0.01%	13	0.03%	133	0.27%	69	0.14%	169	0.34%	21	0.04%	36	0.07%	13	0.03%	3	<0.01%	22	0.04%	**482**	**0.98%**	**153**
1782T/TC	Feb-06	16,406	6,201	0	0.00%	5	0.03%	50	0.30%	47	0.29%	50	0.30%	7	0.04%	4	0.02%	16	0.10%	1	<0.01%	3	0.02%	**183**	**1.12%**	**62**
1788T/TC	Feb-06	65,248	23,379	7	0.01%	28	0.04%	77	0.12%	159	0.24%	180	0.28%	24	0.04%	32	0.05%	48	0.07%	7	0.01%	28	0.04%	**590**	**0.90%**	**148**
1648T	Apr-05	2,835	969	0	0.00%	6	0.21%	2	0.07%	10	0.35%	2	0.07%	1	0.04%	12	0.42%	3	0.11%	0	0.00%	6	0.21%	**42**	**1.48%**	**8**
1642T	May-02	27,131	8,859	0	0.00%	7	0.03%	43	0.16%	59	0.22%	40	0.15%	17	0.06%	6	0.02%	11	0.04%	2	<0.01%	2	<0.01%	**187**	**0.69%**	**28**
1646T	May-02	90,376	28,438	2	<0.01%	109	0.12%	36	0.04%	317	0.35%	135	0.15%	12	0.01%	43	0.05%	115	0.13%	7	<0.01%	22	0.02%	**798**	**0.88%**	**102**
1688T/TC	Jun-03	490,933	185,641	40	<0.01%	485	0.10%	572	0.12%	1372	0.28%	1517	0.31%	140	0.03%	220	0.04%	554	0.11%	43	<0.01%	170	0.03%	**5113**	**1.04%**	**1368**

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	94,111	1.40%	7	<0.01%	6	<0.01%	0	0.00%	6	<0.01%	45	0.05%	**64**	**0.07%**
2088TC	610,472	3.40%	45	<0.01%	626	0.10%	0	0.00%	28	<0.01%	1086	0.18%	**1785**	**0.29%**
1999	46,809	3.80%	5	0.01%	46	0.10%	0	0.00%	7	0.01%	148	0.32%	**206**	**0.44%**
1944	17,108	5.30%	0	0.00%	8	0.05%	0	0.00%	1	<0.01%	26	0.15%	**35**	**0.20%**
1948	65,536	3.40%	11	0.02%	81	0.12%	0	0.00%	1	<0.01%	77	0.12%	**170**	**0.26%**
1699T/TC	22,884	4.80%	14	0.06%	34	0.15%	0	0.00%	0	0.00%	53	0.23%	**101**	**0.44%**
1888T/TC	301,797	4.20%	41	0.01%	812	0.27%	1	<0.01%	14	<0.01%	807	0.27%	**1675**	**0.56%**
1882T/TC	49,229	3.50%	2	<0.01%	60	0.12%	0	0.00%	3	<0.01%	127	0.26%	**192**	**0.39%**
1782T/TC	16,406	4.90%	1	<0.01%	37	0.23%	0	0.00%	0	0.00%	49	0.30%	**87**	**0.53%**
1788T/TC	65,248	5.20%	10	0.02%	113	0.17%	1	<0.01%	1	<0.01%	102	0.16%	**227**	**0.35%**
1648T	2,835	5.70%	0	0.00%	12	0.42%	0	0.00%	2	0.07%	6	0.21%	**20**	**0.71%**
1642T	27,131	4.80%	0	0.00%	24	0.09%	1	<0.01%	2	<0.01%	20	0.07%	**47**	**0.17%**
1646T	90,376	4.60%	21	0.02%	65	0.07%	0	0.00%	6	<0.01%	64	0.07%	**156**	**0.17%**
1688T/TC	490,933	4.60%	210	0.04%	892	0.18%	2	<0.01%	19	<0.01%	786	0.16%	**1909**	**0.39%**
1488T/TC	270,816	4.50%	159	0.06%	309	0.11%	5	<0.01%	3	<0.01%	365	0.13%	**841**	**0.31%**

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	379,929	0.6%	25	0.01%	33	0.01%	0	0.00%	15	<0.01%	132	0.03%	**205**	**0.05%**
2088TC	1,757,740	1.3%	66	<0.01%	754	0.04%	0	0.00%	68	<0.01%	1435	0.08%	**2323**	**0.13%**
1888T/TC	1,091,730	1.4%	63	0.01%	959	0.09%	1	<0.01%	33	<0.01%	1166	0.11%	**2222**	**0.20%**

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	3,848	1,513	199,452	1	0.03%	1	0.03%	3	0.08%	1	0.03%	8	0.21%	2	0.05%	7	0.18%	15	0.39%	13	0.34%	1	0.03%	0	0.00%	**52**	**1.35%**
1999	872	389	44,252	1	0.11%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	2	0.23%	1	0.11%	10	1.15%	1	0.11%	0	0.00%	0	0.00%	**16**	**1.83%**
1944	104	31	5,926	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	194	34,541	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	1,450	321	73,176	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	14,506	4,474	846,679	6	0.04%	2	0.01%	9	0.06%	4	0.03%	19	0.13%	4	0.03%	27	0.19%	58	0.40%	22	0.15%	0	0.00%	1	<0.01%	**152**	**1.05%**
1882T/TC	690	198	39,256	0	0.00%	0	0.00%	0	0.00%	1	0.14%	1	0.14%	0	0.00%	0	0.00%	2	0.29%	2	0.29%	0	0.00%	1	0.14%	**7**	**1.01%**
1782T/TC	165	14	5,839	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	38	12,581	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	15,809	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	2,646	393	94,790	5	0.19%	0	0.00%	2	0.08%	0	0.00%	3	0.11%	0	0.00%	3	0.11%	6	0.23%	3	0.11%	1	0.04%	1	0.04%	**24**	**0.91%**
1488T/TC	803	38	26,948	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.25%**

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	3,848	4.50%	1	0.03%	13	0.34%	0	0.00%	0	0.00%	14	0.36%	**28**	**0.73%**
1999	872	6.20%	0	0.00%	6	0.69%	0	0.00%	0	0.00%	8	0.92%	**14**	**1.61%**
1944	104	1.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	765	5.20%	0	0.00%	4	0.52%	0	0.00%	0	0.00%	1	0.13%	**5**	**0.65%**
1699T/TC	1,450	3.20%	0	0.00%	3	0.21%	0	0.00%	0	0.00%	6	0.41%	**9**	**0.62%**
1888T/TC	14,506	3.70%	3	0.02%	24	0.17%	0	0.00%	0	0.00%	35	0.24%	**62**	**0.43%**
1882T/TC	690	3.90%	0	0.00%	2	0.29%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.29%**
1782T/TC	165	3.00%	0	0.00%	1	0.61%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.61%**
1788T/TC	363	3.90%	0	0.00%	2	0.55%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.55%**
1646T	641	1.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	2,646	5.50%	0	0.00%	4	0.15%	0	0.00%	0	0.00%	5	0.19%	**9**	**0.34%**
1488T/TC	803	3.60%	0	0.00%	5	0.62%	0	0.00%	0	0.00%	1	0.12%	**6**	**0.75%**

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

Implantable Cardiac Monitors (ICM) Devices

Implantable Cardiac Monitors (ICMs) Devices

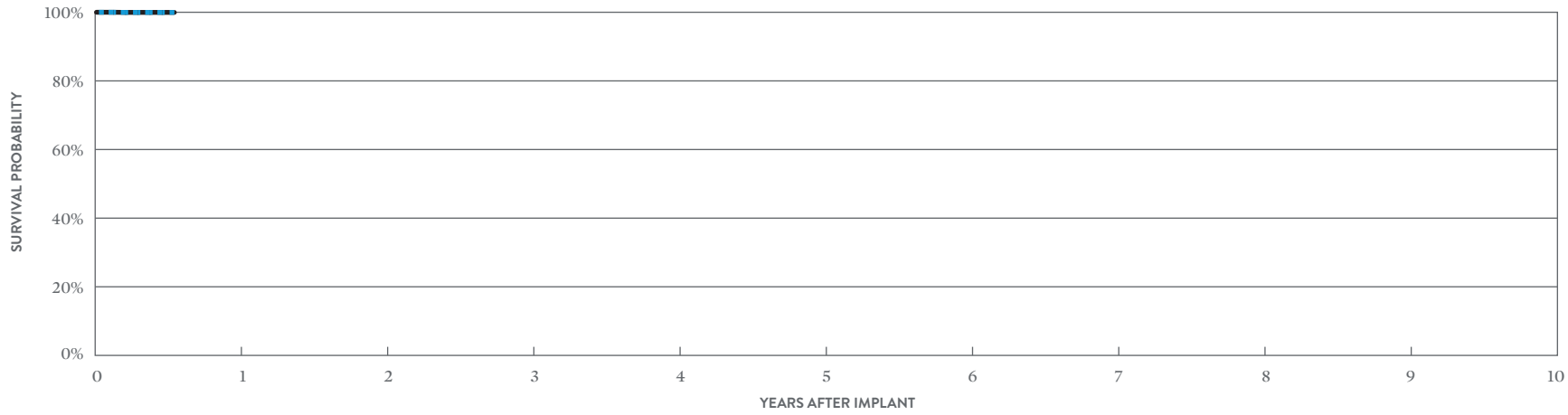
CUSTOMER REPORTED PERFORMANCE DATA

Confirm Rx™ ICM

MODEL DM3500

US Regulatory Approval	September 2017
Registered US Implants	9,859
Estimated Active US Implants	9,120
Estimated Longevity	2 Years
Normal Battery Depletion	0
Number of US Advisories	None

	MALFUNCTIONS	
	QTY	RATE
Electrical Component	0	0.00%
Electrical Interconnect	0	0.00%
Battery	0	0.00%
Software/Firmware	0	0.00%
Mechanical	0	0.00%
Possible Early Battery Depletion	0	0.00%
Other	1	0.01%
Total	**1**	**0.01%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	AT 7 MONTHS
SURVIVAL PROBABILITY	99.96%
± 1 STANDARD ERROR	0.03%
SAMPLE SIZE	880

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	AT 7 MONTHS
SURVIVAL PROBABILITY	99.96%
± 1 STANDARD ERROR	0.03%

Implantable Cardiac Monitors (ICMs) Devices

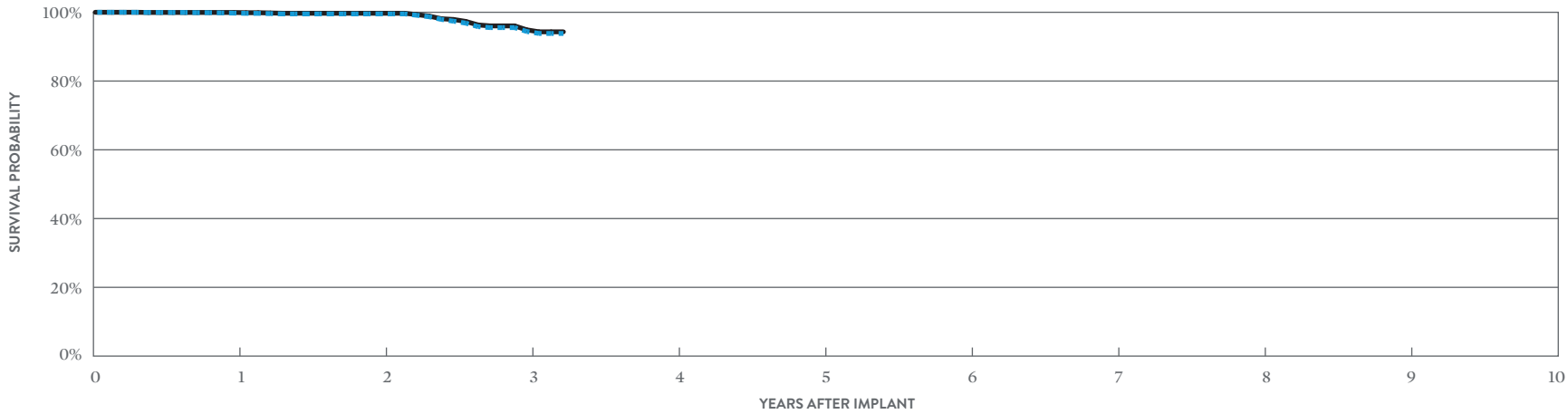
CUSTOMER REPORTED PERFORMANCE DATA

SJM Confirm™ ICM

MODEL DM2102

US Regulatory Approval	May 2014
Registered US Implants	4,688
Estimated Active US Implants	3,382
Estimated Longevity	3 Years
Normal Battery Depletion	11
Number of US Advisories (see pg. 342)	One

MALFUNCTIONS		
	QTY	RATE
Electrical Component	19	0.41%
Electrical Interconnect	0	0.00%
Battery	0	0.00%
Software/Firmware	0	0.00%
Mechanical	0	0.00%
Possible Early Battery Depletion	0	0.00%
Other	3	0.06%
Total	**22**	**0.47%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 39 MONTHS
SURVIVAL PROBABILITY	99.76%	99.53%	94.41%	93.84%
± 1 STANDARD ERROR	0.07%	0.13%	0.65%	0.91%
SAMPLE SIZE	3,790	2,210	950	230

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	AT 39 MONTHS
SURVIVAL PROBABILITY	99.95%	99.72%	94.89%	94.32%
± 1 STANDARD ERROR	0.04%	0.10%	0.63%	0.89%

Implantable Cardiac Monitors (ICMs) Devices

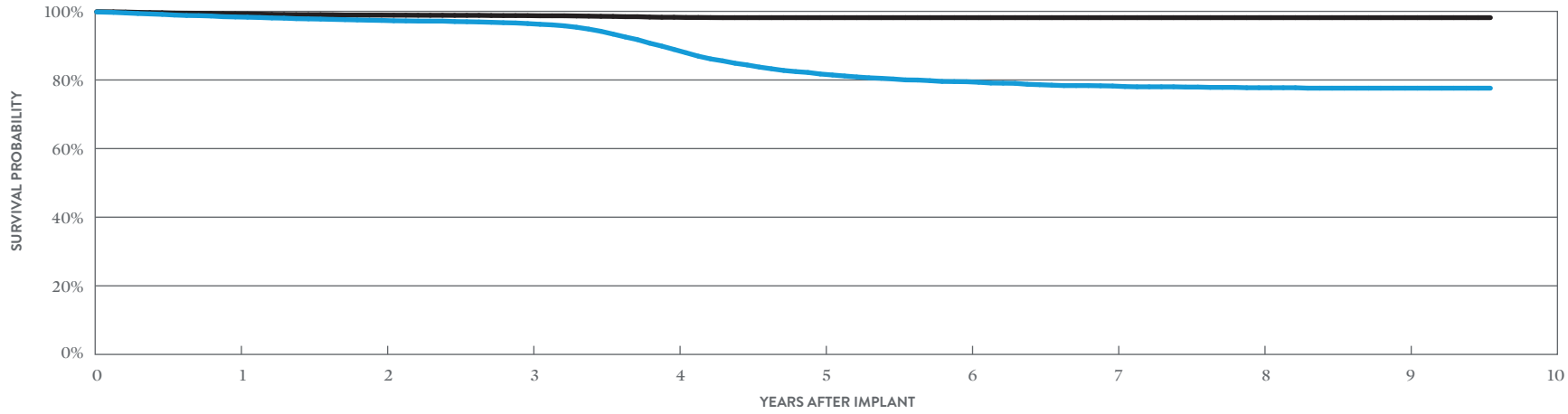
CUSTOMER REPORTED PERFORMANCE DATA

SJM Confirm™ ICM

MODEL DM2100

US Regulatory Approval	August 2008
Registered US Implants	18,687
Estimated Active US Implants	6,968
Estimated Longevity	3 Years
Normal Battery Depletion	727
Number of US Advisories (see pg. 342)	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	8	0.04%
Other	42	0.22%
Total	**96**	**0.51%**



INCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 115 MONTHS
SURVIVAL PROBABILITY	98.37%	97.36%	96.44%	88.90%	81.74%	79.49%	78.24%	77.74%	77.61%	77.61%
± 1 STANDARD ERROR	0.10%	0.13%	0.15%	0.29%	0.39%	0.43%	0.45%	0.47%	0.48%	0.48%
SAMPLE SIZE	16,350	12,960	11,170	9,340	7,000	4,830	3,210	1,970	1,010	220

EXCLUDING NORMAL BATTERY DEPLETION

YEAR	1	2	3	4	5	6	7	8	9	AT 115 MONTHS
SURVIVAL PROBABILITY	99.30%	98.91%	98.76%	98.28%	98.17%	98.17%	98.17%	98.17%	98.17%	98.17%
± 1 STANDARD ERROR	0.06%	0.09%	0.09%	0.12%	0.12%	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*										
DM2102	SJM Confirm™ ICM	99.76%	99.53%	94.41%							
DM2100	SJM Confirm™ ICM	98.37%	97.36%	96.44%	88.90%	81.74%	79.49%	78.24%	77.74%	77.61%	

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*										
DM2102	SJM Confirm™ ICM	99.95%	99.72%	94.89%							
DM2100	SJM Confirm™ ICM	99.30%	98.91%	98.76%	98.28%	98.17%	98.17%	98.17%	98.17%	98.17%	

**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.*

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*	9,859	1.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
DM2102	SJM Confirm™ ICM	4,688	4.00%	19	0.41%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.06%	**22**	**0.47%**
DM2100	SJM Confirm™ ICM	18,687	16.80%	15	0.08%	1	<0.01%	20	0.11%	10	0.05%	0	0.00%	8	0.04%	42	0.22%	**96**	**0.51%**

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

Focus on Clinical Performance

ICD Premature Battery Depletion Advisory Update – October 2018

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, 2018.

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). We have included both confirmed and unconfirmed shorts in the table below. The table includes both the updated data through August 31, 2018, and data from the original (October 11, 2016) and periodic (May 31, 2018) communications.

UPDATED (THROUGH AUGUST 31, 2018)

WORLDWIDE PATIENT IMPACT	NUMBER / RATE ORIGINAL OCTOBER 11, 2016	NUMBER / RATE THROUGH MAY 31, 2018	NUMBER / RATE THROUGH AUGUST 31, 2018
No Harm Reported/Additional Surgery Only*	792/0.20%	2,080/0.52%	3,281/0.82%
Loss of Pacing – Minor (Dizziness)	37/<0.01%	51/0.01%	53/0.01%
Loss of Pacing – Major (Syncope)	10/<0.01%	14/<0.01%	16/<0.01%
Loss of Defibrillation – Emergency	0/0%	3/<0.01%	3/<0.01%
Loss of Defibrillation – Death	2/<0.01%	2/<0.01%	2/<0.01%
Grand Total	**841/0.21%**	**2,150/0.54%**	**3,355/0.84%**

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 includes an increased number of investigations primarily associated with Battery Performance Alert notifications. These are reflected in the "No Harm Reported/Additional Surgery Only" category.

Elective Replacement Interval (ERI) and End of Life (EOL) Analysis Update

WORLDWIDE ERI TO EOL IMPACT TABLE:

The following table represents the analysis results of the time interval between ERI and EOL for devices returned to Abbott for analysis where premature battery depletion was determined, no electronic or other assignable cause was found, battery testing found lithium clusters and the battery voltage was sufficient to allow retrieval of device diagnostic data. Of the 3,355 units returned to Abbott as of the date of analysis, 1,046 units met the above criteria.

ERI TO EOL DURATION (FOR RETURNED UNITS WITH LITHIUM CLUSTER PBD AND DEVICE RETRIEVABLE DATA)**	NUMBER OF UNITS
ERI detected, patient notifier alert was triggered	1,032/98.66%
≤1 day; patient notifier alert was triggered	153
>1 and ≤10 days patient notifier alert was triggered	162
>10 and ≤30 days patient notifier alert was triggered	96
>30 days; patient notifier alert was triggered	56
Above EOL, therefore ERI to EOL duration not applicable; patient notifier alert was triggered if ERI was reached	565
ERI not detected, patient notifier was not triggered, but below ERI threshold of 2.59V	14/1.34%
Total Number of Units	**1,046**
Total Units Sold	**398,740**

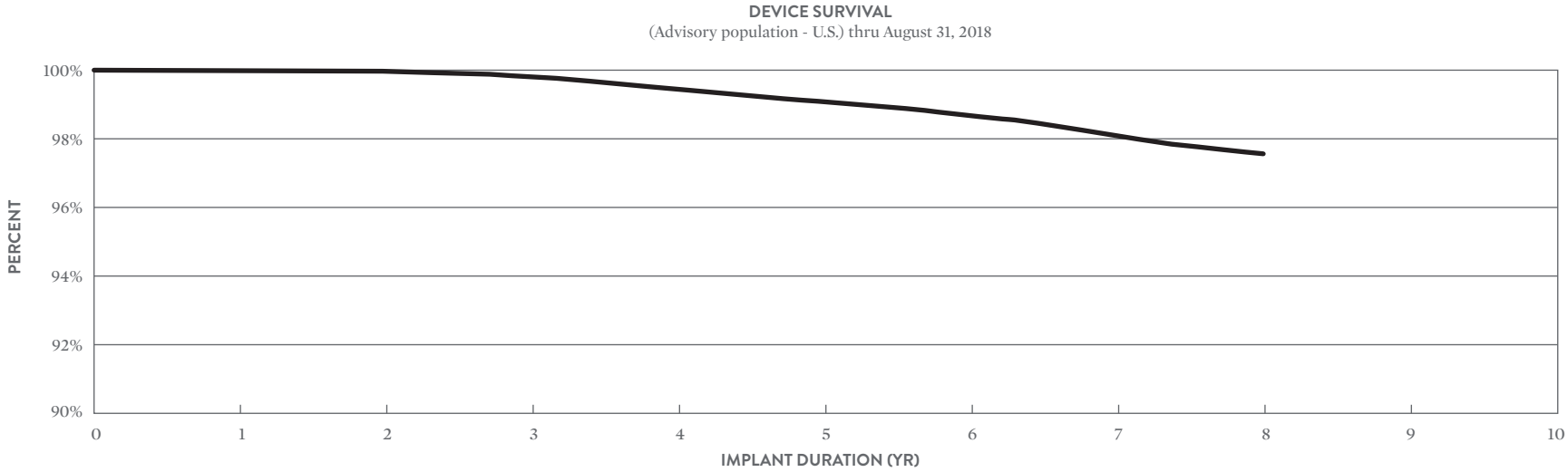
***Our intent is to provide these data to help explain the statement "battery depletion can occur in these devices within a day to a few weeks, which may result in the inability to deliver therapy" in the original field advisory notification.*

These data are provided for information only and should not be used to make specific patient management decisions that would depart from recommendations previously communicated by the company. The patient management recommendations in the original advisory letter remain applicable.

The number of units in each of the groups above is not a predictor of future performance of a specific unit currently implanted.

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

EIGHT-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
SURVIVAL PROBABILITY	99.999%	99.977%	99.871%	99.408%	99.061%	98.636%	98.057%	97.532%
SAMPLE SIZE	224,000	209,000	190,000	144,000	101,000	65,000	30,900	4,900

SURVIVAL CALCULATION GENERAL METHODS

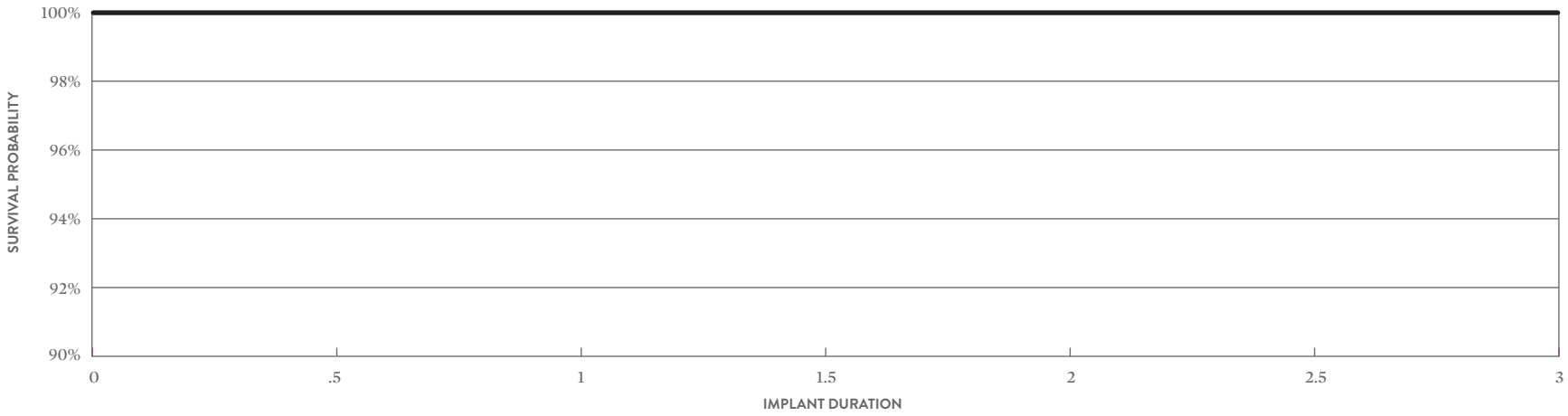
Internal modeling based on an analysis of field returns related to premature battery depletions associated with lithium clusters; updated with data through August 31, 2018.

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 February 2018 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 ~ 120,000 implanted devices with the improved battery design with no occurrences of premature depletion associated with Li clusters. Of the implanted US population, ~68% (or ~81,000) have exceed 1 year of implant duration and ~29% (or ~35,000) 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



UNIFY/FORTIFY/ASSURA (NON-ADVISORY POPULATION)

YEAR	.5	1	1.5	2	2.5	3
SURVIVAL PROBABILITY	100%	100%	100%	100%	100%	100%
SAMPLE SIZE	~99,000	~81,000	~61,500	~35,000	~17,000	~2,500

Update on Riata™ Lead Performance

REGISTRY AND POST-MARKET STUDIES

Prospective, monitored registries continue to provide the best data to support clinical decision making. Abbott initiated the Riata Lead Evaluation Study (RLES), which began in December 2011 and has enrolled 782 patients with Riata leads at sites in U.S., Canada and Japan. Phase I of the study involved enrollment, collection of patient information, thorough (3 angle) cinefluoroscopic imaging, and adjudication of cinefluoroscopic data by experienced, independent electrophysiologists for the presence of externalized conductors. U.S., Canadian, and Japanese data from Phase I were first reported by Abbott in the November 2012 Product Performance Report 2nd Edition. RLES data was subsequently presented at the 2013 and 2014 Heart Rhythm Society Scientific Sessions and detailed in a peer-reviewed manuscript.[1,2,3]

In 2013, Abbott expanded the RLES to include Durata™ and Quicksite™/Quickflex™ leads and to increase the quantity of Riata™ and Riata™ ST leads. The expanded study, known as the "St. Jude Medical Cardiac Lead Assessment Study" (CLAS), began enrollment in February 2013 to ensure at least 500 leads in each of the following lead families: Riata, Riata ST, Durata and Quicksite/Quickflex. Under the new CLAS protocol, patients will be followed every six months for three years a cinefluoroscopy will be performed at the enrollment, 1-year, 2-year and 3-year follow-up visits. The main objective of the study is to determine the prevalence and incidence of lead compromise evidenced by imaging (includes externalized conductors and other visual lead anomalies) and electrical dysfunction in Riata, Riata ST, Quicksite/Quickflex and Durata leads. All images were adjudicated by an independent panel of experienced electrophysiologists for determining the presence of externalized conductors. Additionally, upon occurrence of a lead revision during follow-up, another physician panel determined whether electrical dysfunction had occurred based upon predefined criteria.[4] Enrollment has been completed for CLAS. The following summaries for Riata/Riata ST and QuickSite/QuickFlex leads represent all data collected as of August 31, 2018. The Durata leads CLAS summary is available on page 315.

1 David Hayes, Roger Freedman, Mark Niebauer, Vance Plumb, Jay Dinerman, Scott Beau, Anne Curtis, *Incidence of New Externalized Conductors and Electrical Dysfunction in Riata and Riata ST Silicone ICD Leads: 1 year Results from a Prospective, Multicenter Study*, Heart Rhythm Society's Annual Scientific Sessions, San Francisco, CA, May 8, 2014.

2 David Hayes, Roger Freedman, Anne Curtis, Mark Niebauer, G.Neal Kay, Jay Dinerman, Scott Beau, Wilson Wong, *Prevalence of Externalized Conductors in Riata and Riata ST Silicone ICD Leads: Results from a Prospective, Multicenter Study*, Heart Rhythm Society's Annual Scientific Sessions, Denver, CO, May 9, 2013.

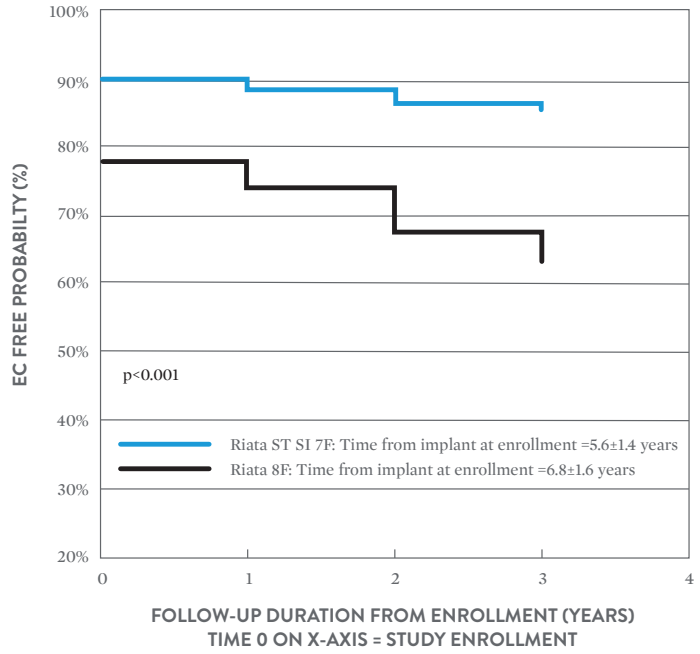
3 David Hayes, Roger Freedman, Anne B. Curtis, Mark Niebauer, G. Neal Kay, Jay Dinerman, Scott Beau, *Prevalence of Externalized Conductors in Riata and Riata ST Silicone Leads: Results from the Prospective, Multicenter, Riata Lead Evaluation Study, Heart Rhythm*, Vol. 10, Issue 12, Pages 1778-1782, December 2013.

4 Electrical dysfunction is defined as a lead that exhibits at least one of the following criteria: 1) Presence of non-physiologic noise not due to external interference. 2) Rise in pace/sense (p/s) conductor impedance to > 2000 Ω or increase of more than 200 Ω over previous 6 months or increase of 400 Ω over any period of time. 3) Decrease of more than 200 Ω over previous 6 months or to impedance < 200 Ω from baseline impedance > 300 Ω or decrease of 400 Ω over any period of time. 4) Change in any high voltage coil impedance of > 25 Ω or to > 125 Ω or < 20 Ω. 5) A capture threshold > 5 V or an increase of > 2 V from baseline (all measurements) of < 1 V.

RIATA™/RIATA™ ST LEAD CLAS SUMMARY (AS OF AUGUST 31, 2018): This summary includes all Riata/Riata ST silicone leads that were enrolled in the initial RLES study as well as those enrolled in the subsequent CLAS study. A total of 1,111 patients with Riata/Riata ST silicone leads across 42 centers (8F/7F= 59.3%/40.7%) underwent fluoroscopic evaluation. The average implant duration at enrollment was 6.8 ± 1.6 years for 8F Riata leads and 5.6 ± 1.4 years for 7F Riata ST leads. The prevalence of externalized conductors (EC) at enrollment was significantly lower in 7F Riata ST leads compared to 8F Riata leads (9.7% vs. 21.9%, $p<0.0001$). A total of 821 patients (72.8%) completed at least 1 year of follow-up, 652 patients (57.8%) completed at least 2 years of follow up, and 482 (42.7%) completed at least three years of follow up with fluoroscopic evaluations. The event-free survival rate for externalized conductors in Riata and Riata ST leads through 3 years of follow-up is shown in Figure 1. At 3 years of follow up, the freedom from externalized conductors is 86.3% in Riata ST 7F leads and 63.6% in Riata 8F leads. In 1,111 Riata and Riata ST leads evaluated, 96.4% have been free from electrical dysfunction. Of the 39 leads (14 Riata ST 7F and 25 Riata 8F) exhibiting electrical dysfunction, 15 leads (5 Riata ST 7F and 10 Riata 8F) had externalized conductors. The electrical failure rate in leads with and without EC is statistically significant ($p= 0.0306$) as shown in Table 1.

All pending fluoroscopy data has been adjudicated and the minimum enrollment of Riata/Riata ST silicone leads has been met in the Cardiac Lead Assessment Study.

FIGURE 1: KAPLAN-MEIER ESTIMATE OF FREEDOM FROM EXTERNALIZED CONDUCTORS (EC) RIATA (8F) VS. RIATA ST SI (7F) LEADS



RIATA ST (7F)

YEAR	0	1	2	3
AT RISK	452	315	252	190
CUMULATIVE EC EVENTS	44	49	55	56
EC FREE PROBABILITY	90.3%	88.8%	86.7%	86.3%

RIATA ST (8F)

YEAR	0	1	2	3
AT RISK	659	374	284	192
CUMULATIVE EC EVENTS	144	162	187	199
EC FREE PROBABILITY	78.1%	74.4%	67.8%	63.6%

TABLE 1: RIATA/ RIATA ST LEADS: CORRELATION BETWEEN EC AND ED

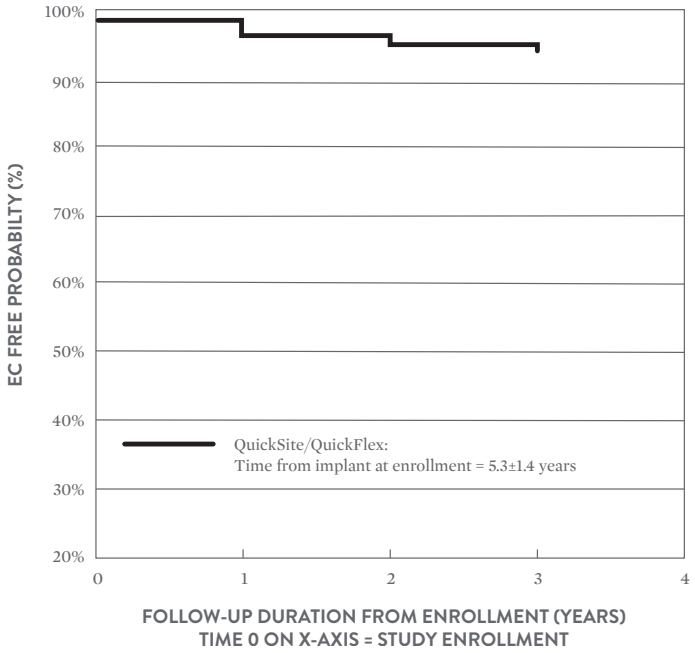
	PROPORTION OF LEADS WITH ELECTRICAL DYSFUNCTION (ED), %	P-VALUE*
With EC	5.9% (15/255)[1]	0.0306
Without EC	2.8% (24/856)[2]	

**p-value was calculated using Fisher's exact test.*
[1]Denominator = Total # of leads with EC
[2]Denominator = Total # of leads without EC

QUICKSITE™/QUICKFLEX™ LEAD CLAS SUMMARY (AUGUST 31, 2018): A total of 789 patients implanted with QuickSite/QuickFlex Left Ventricular CRT leads at 43 centers underwent fluoroscopic evaluation. The average implant duration at enrollment was 5.3 4 years. A total of 633 patients (78.6%) completed at least one year of follow- up, 499 patients (62.0%) completed at least two years of follow up, and 324 (40.2%) completed at least three years of follow up with fluoroscopic evaluations. The event-free survival rate for externalized conductors through 3 years of follow-up is shown in Figure 2. The prevalence of externalized conductors (EC) was 1.7% (13/789) at enrollment. At 3 years of follow up, the freedom from externalized conductors is 93.6%. In 789 QuickSite/QuickFlex leads evaluated, 99.7% have been free from electrical dysfunction. Neither of the 2 leads with electrical dysfunction exhibited externalized conductors as shown in Table 2.

In QuickSite/QuickFlex leads the presence of externalized conductors was not significantly associated with an increased risk of electrical dysfunction. All pending fluoroscopy data has been adjudicated and the minimum enrollment of the QuickSite/QuickFlex leads has been met in the Cardiac Lead Assessment Study.

FIGURE 2: EVENT FREE SURVIVAL RATE FOR QUICKSITE/QUICKFLEX LEADS



YEAR	0	1	2	3
AT RISK	789	611	471	297
CUMULATIVE EC EVENTS	13	29	35	38
EC FREE PROBABILITY	98.4%	95.8%	94.6%	93.6%

TABLE 2: QUICKSITE/QUICKFLEX LEADS: CORRELATION BETWEEN EC AND ED

	PROPORTION OF LEADS WITH ELECTRICAL DYSFUNCTION (ED), %	P-VALUE*
With EC	0% (0/38)[1]	1.0000
Without EC	0.3% (2/751)[2]	

**p-value was calculated using Fisher's exact test.*
[1]Denominator = Total # of leads with EC
[2]Denominator = Total # of leads without EC

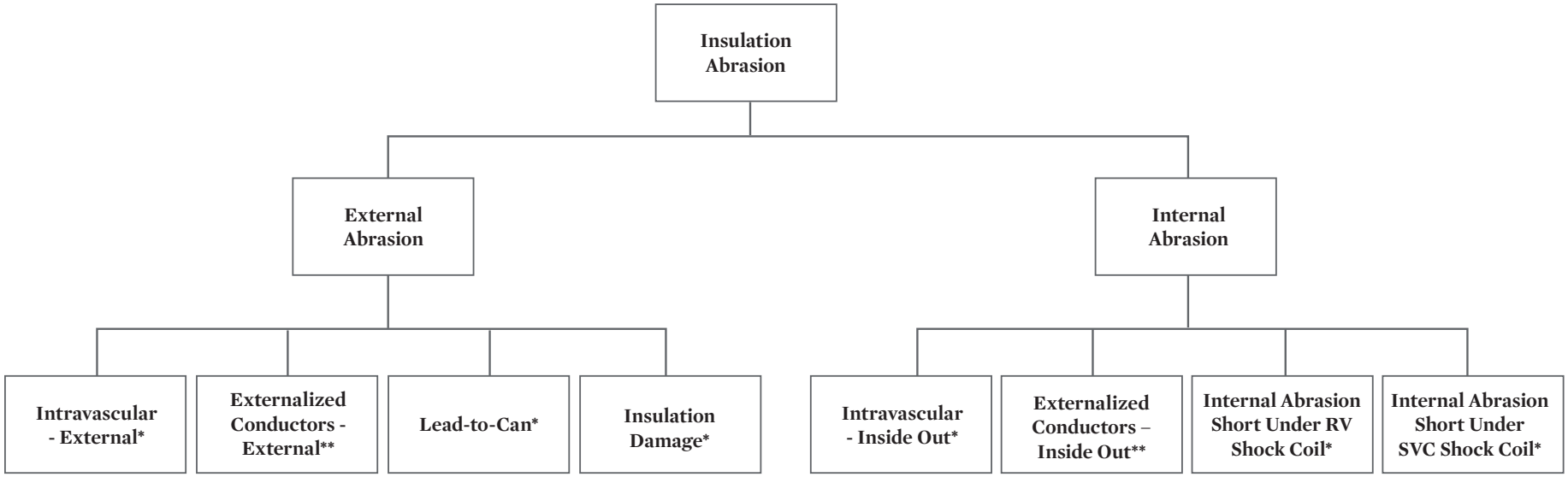
CUSTOMER REPORTED PERFORMANCE DATA

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, 2018, there were 6,149 cases of externalized conductors reported to Abbott worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 3.35% (5174/156,000) incidence rate for Riata (8F) and 1.39% (975/70,600) for Riata ST (7F) leads. Of these 6,149 leads, 4,518 were not returned and 1,631 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 13,960 Riata and Riata ST leads have been returned for analysis worldwide through August 31, 2018. 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	0.51%	0.53%
Externalized Conductors – External**	External Abrasion	0.42%	0.21%
Lead-to-Can*	External Abrasion	0.98%	0.90%
Insulation Damage*	External Abrasion	0.11%	0.06%
Intravascular - Inside Out*	Internal Abrasion	0.58%	0.40%
Externalized Conductors - Inside Out**	Internal Abrasion	2.92%	1.18%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.12%	0.05%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.12%	0.02%

**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

REGISTRY AND POST-MARKET STUDIES

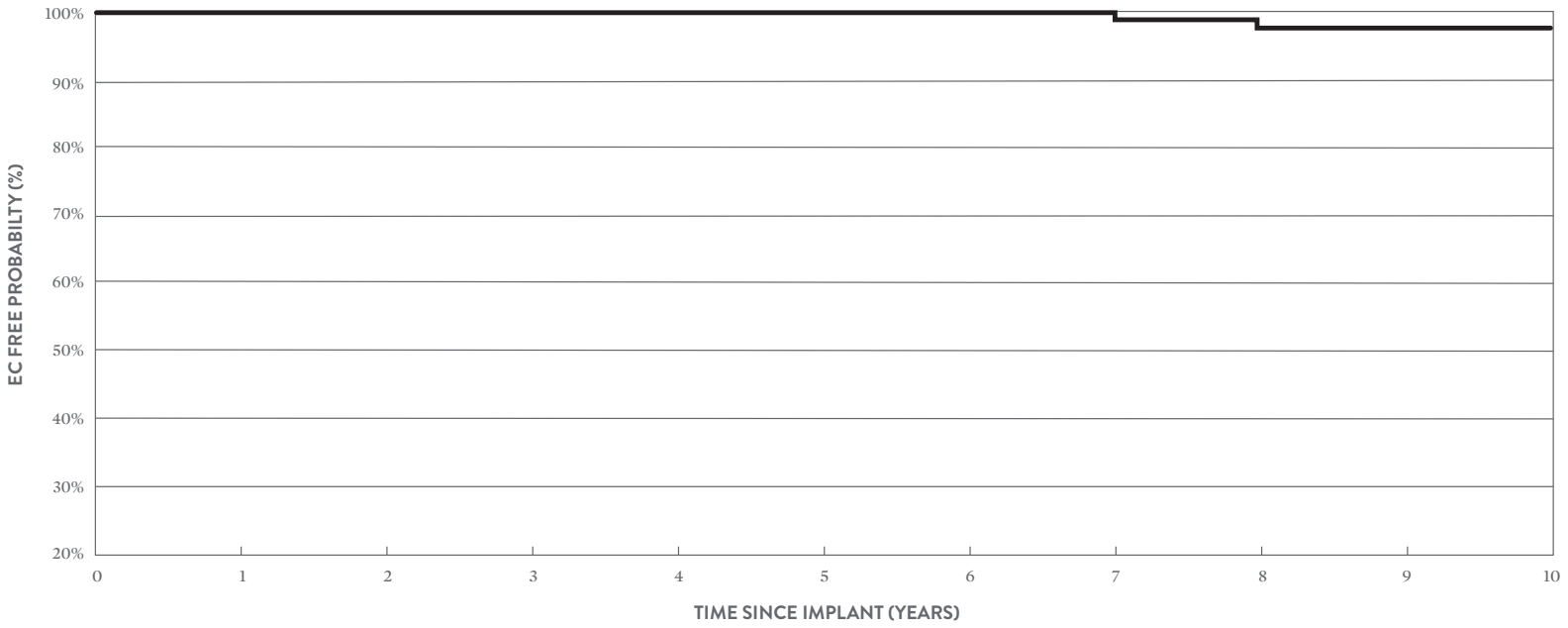
The safety and reliability of our Durata™ high voltage leads are supported by robust post-market surveillance monitoring. Data are collected on case report forms at each scheduled and unscheduled patient visit with additional information documented for any adverse event. We also employ a dedicated field monitoring organization to ensure that the data from the clinical site are accurately and completely submitted. Because of the size and scope of these actively monitored registries, they represent the true commercial experience with our current generation high voltage leads.

As described on page 306, the Durata lead family was added to the CLAS registry study in 2013 to determine the prevalence and incidence of lead compromise evidenced by imaging (includes externalized conductors and other visual lead anomalies) and electrical dysfunction. As of August 31, 2018, a total of 972 patients implanted with Durata leads at 43 centers underwent fluoroscopic evaluation. The average implant duration at enrollment was 4.5 ± 1.1 years for the Durata leads. At enrollment, 100% of the 972 leads were free of externalized conductors (EC). A total of 804 patients (82%) completed one year follow-up, 665 patients (67.8%) completed two years of follow up, and 515 (52.5%) completed three years of follow up. Through August 31,2018, the average implant duration of these Durata leads was 8.1±1.7 years with a mean follow up duration after enrollment of 3.6 ± 1.7 years.

The event-free survival rate for Externalized Conductors through 10 years since implant is 98.4% as shown in Figure 1. There were 5 cases of externalized conductors for which two leads were due to external abrasion (one due to clavicular crush and one due to a tricuspid annuloplasty ring); one lead, implanted for 7.5 years, showed EC in a short region just proximal to the RV coil not protected by Optim™ insulation; and two leads, implanted for 7.5 and 8.5 years, exhibited EC with no external mechanism identified on fluoroscopy. The electrical function of all 5 of these leads with externalized conductors was normal. In 972 Durata leads evaluated, 97.7% have been free of electrical dysfunction (ED). Of the leads with ED, none had externalized conductors.

During an average implant duration of 8.1 years, with complete ascertainment via annual fluoroscopy, performance of Durata leads remains strong, with 97.7% leads free of electrical dysfunction, and 98.4% without externalized conductors through 10 years. None of the leads with externalized conductors exhibited electrical dysfunction and none of the leads with electrical dysfunction were associated with an externalized conductor. All pending fluoroscopy data has been adjudicated and the minimum enrollment of Durata leads has been met in the Cardiac Lead Assessment Study.

FIGURE 1: KAPLAN-MEIER ESTIMATE OF FREEDOM FROM EXTERNALIZED CONDUCTORS (EC) FOR DURATA LEADS



YEAR	0	1	2	3	4	5	6	7	8	9	10
AT RISK	972	972	972	963	927	869	735	506	248	65	3
CUMULATIVE EC EVENTS	0	0	0	0	0	1	1	2	4	5	5
EC FREE PROBABILITY	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.7%	99.2%	98.4%	98.4%

Beginning in 2006, three prospective, outcome-oriented, actively monitored registry studies have enrolled Durata™ and Riata™ ST Optim™ leads: the OPTIMUM registry, SCORE registry, and the SJ4 Post Approval Study (PAS). A total of 11,132 Optim insulated leads (8,266 Durata and 2,866 Riata ST Optim leads) were enrolled in these studies at 293 sites. The raw data from these registries, current as of August 31, 2018, were independently analyzed by the Population Health Research Institute (PHRI of McMaster University/Hamilton Health Science. Their results quantify the performance of the Durata and Riata ST Optim™ leads in the categories of externalized conductors, all-cause insulation breach, and all-cause mechanical failures. An externalized conductor represents an outer insulation breach within the vascular or cardiac systems resulting in the normally contained conductors becoming visible outside the lead body. All-cause insulation breach includes all types of abrasion and other mechanical types of insulation damage, including externalized conductors. The all-cause mechanical failure category includes any insulation breach (including abrasion), conductor fracture, failure of a crimp, weld, or bond, or other mechanical failure. Additionally, if the lead is reported to have been "taken out of service" (extracted, capped, or electrically abandoned) and the site reports (i) noise artifact, abnormal pacing impedance, or abnormal high-voltage lead impedance or (ii) a large impedance change coupled with any of elevated pacing threshold, loss of sensing, loss of capture, oversensing, or undersensing then that is also included in the all-cause mechanical failure category.1 Overall incidence rates for these three failure categories are provided in the table below.

AN INDEPENDENT ANALYSIS OF DURATA™ AND RIATA™ ST OPTIM™ LEAD FAILURE RATES IN ACTIVE REGISTRIES BY PHRI (DATA THROUGH AUGUST 31, 2018)

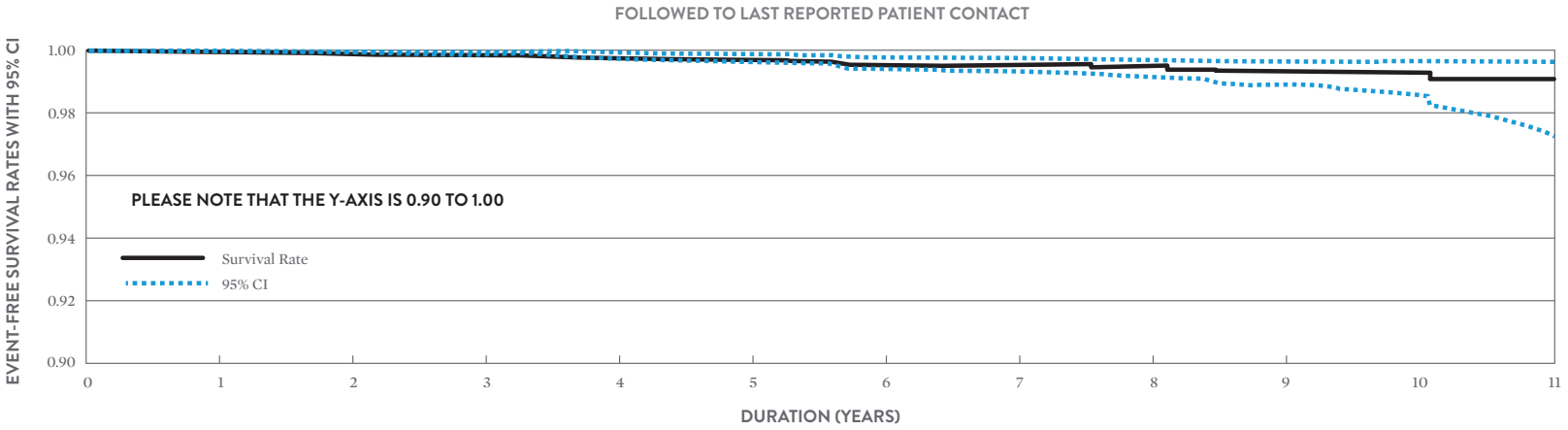
FAILURE CATEGORY	DURATA AND RIATA ST OPTIM %	DURATA AND RIATA ST OPTIM 95% CI	FREEDOM FROM FAILURES AT 10 YEARS (%)
Externalized Conductors	0.00%	0.00% - 0.03%	100%
All-Cause Insulation Abrasion	0.30%	0.20% - 0.41%	99.1%
All-Cause Mechanical Failures	1.55%	1.33% - 1.79%	96.1%

Event-Free Survival Rates for All-Cause Insulation Abrasion (Figure 2), and All-Cause Mechanical Failures (Figure 3) in Optim™ ICD leads were calculated by PHRI. The follow-up duration for active leads was based on last reported patient contact either in office or through remote monitoring. Lead implant date is used as time zero for these survival curves.

NOTE: The rates of all-cause mechanical failure, all-cause insulation abrasion and externalized conductors have been calculated based upon independent analyses of Abbott databases by PHRI. The total number of each event is derived from the sum of those events which have been independently adjudicated by PHRI and the recorded events awaiting adjudication. The final calculated rates may change slightly once adjudication is completed.

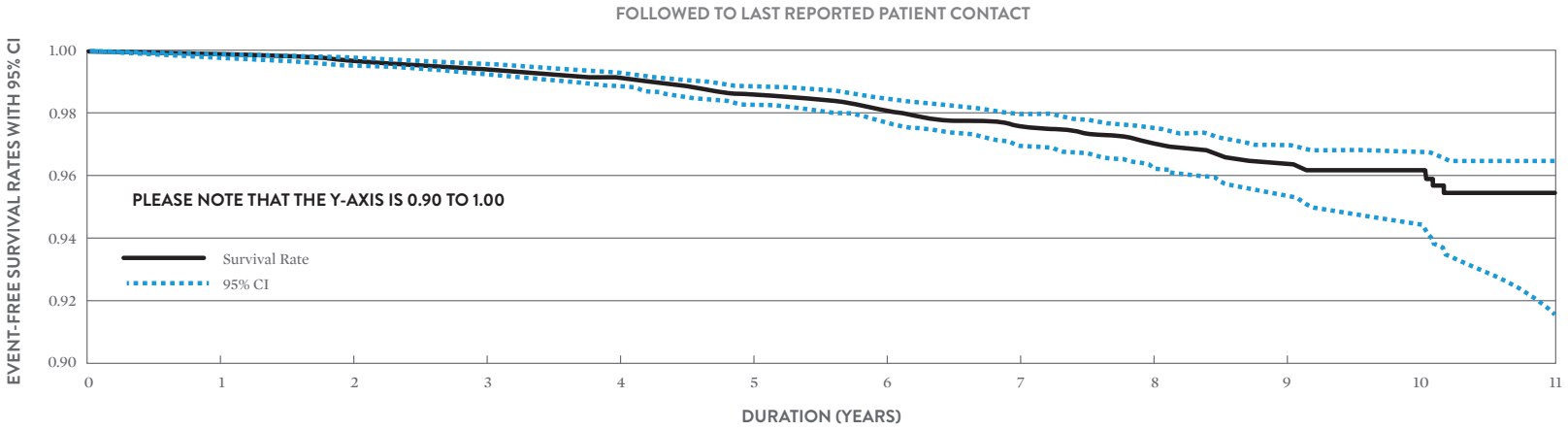
1 John A. Cairns, Andrew E. Epstein, John Rickard, Stuart J. Connolly, Christopher Buller, Bruce L. Wilkoff, Janice Pogue, Ellison Themeles, Jeff S. Healey, *Prospective long-term evaluation of Optim-insulated (Riata ST Optim and Durata) implantable cardioverter-defibrillator leads*, Heart Rhythm, Vol 11, Issue 12, Pages 2156–2162, December 2014.

FIGURE 2: EVENT FREE SURVIVAL RATES FOR ALL-CAUSE INSULATION ABRASION IN OPTIM™ ICD LEADS AS CALCULATED BY PHRI



YEAR	0	1	2	3	4	5	6	7	8	9	10	11
LEADS AT RISK	11,132	9,894	8,583	7,368	6,236	4,944	3,815	3,002	2.103	1,196	465	98

FIGURE 3: EVENT FREE SURVIVAL RATES FOR ALL-CAUSE MECHANICAL FAILURE IN OPTIM™ ICD LEADS AS CALCULATED BY PHRI



YEAR	0	1	2	3	4	5	6	7	8	9	10	11
LEADS AT RISK	11,132	9,891	8,580	7,364	6,231	4,941	3,813	2,995	2,098	1,192	463	97

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 21,900 Riata ST Optim and Durata leads have been returned for analysis worldwide through August 31, 2018. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive.

DURATA™ (WW SALES 735,300) AND RIATA™ ST OPTIM™ (WW SALES = 33,000) LEADS INSULATION FAILURE MECHANISMS FROM COMPLAINTS AND RETURNS ANALYSIS

INSULATION FAILURE MECHANISM	ABRASION TYPE	OPTIM DEFIB LEAD WORLDWIDE (WW) INCIDENCE RATE (WW SALES = 768,400)
Intravascular – External*	External Abrasion	0.027%
Externalized Conductors – External**	External Abrasion	0.006%
Lead-to-Can*	External Abrasion	0.083%
Insulation Damage*	External Abrasion	0.026%
Intravascular - Inside Out*	Internal Abrasion	0.00169%***
Externalized Conductors - Inside Out**	Internal Abrasion	0.00013%***
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.011%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.008%

**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 314).

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 >5.6 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.

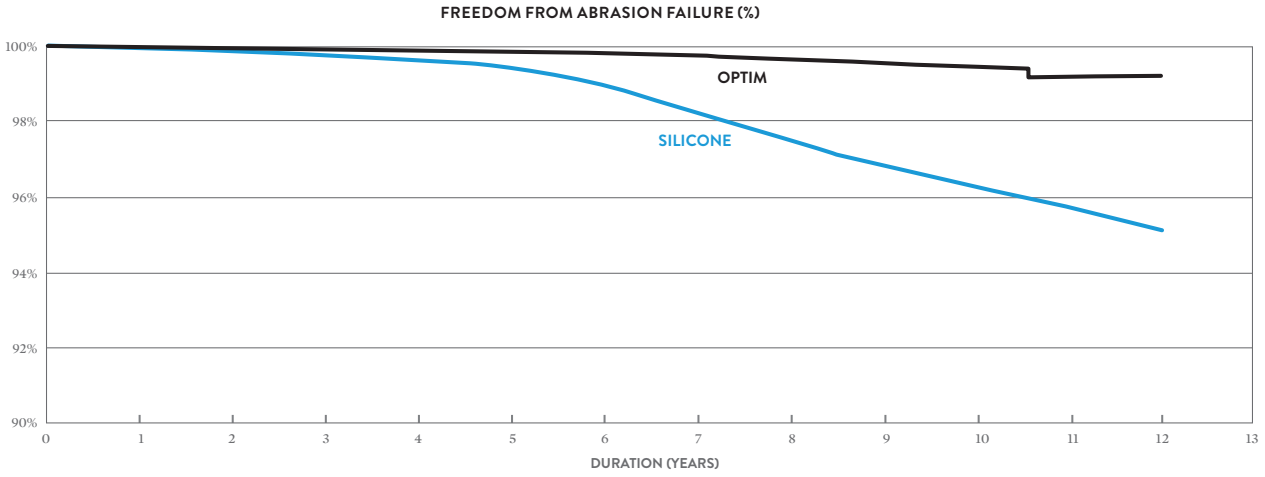
This Product Performance Report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on Abbott tachycardia leads. A Kaplan-Meier analysis including all U.S. data through June 30, 2018 was performed on two groups of leads: (1) tachycardia leads with silicone insulation [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 140 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 140 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).

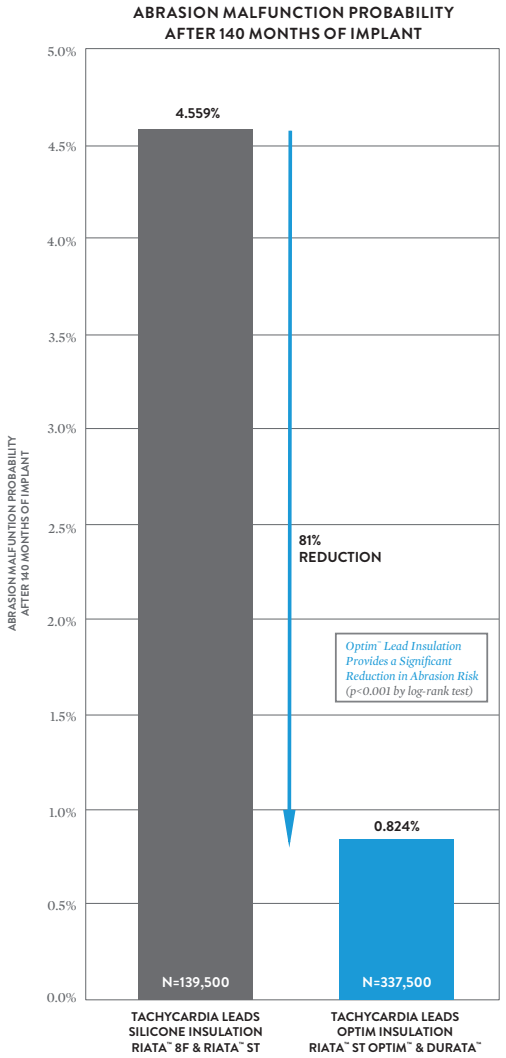
The data show that the presence of Optim™ lead insulation dramatically reduces the probability of abrasion malfunction in tachycardia leads at 140 months by 81%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test.

OPTIM™ LEAD INSULATION EFFECTS ON ABBOTT TACHYCARDIA LEAD ABRASION

KAPLAN-MEIER ANALYSIS OF U.S. RETURNS ANALYSIS DATA



YEAR	1	2	3	4	5	6	7	8	9	10	11	12	140 MONTHS
OPTIM	287,951	255,712	223,063	190,072	153,595	122,978	92,443	60,043	33,335	12,668	1,692	0	0
SILICONE	121,395	110,955	100,988	91,455	82,814	75,139	68,430	62,555	56,916	50,443	39,574	30,074	30,857



Advisories & Safety Alerts

Advisories & Safety Alerts

The following table summarizes advisories and safety alerts regarding Abbott implantable devices since 2005. These advisories have been previously communicated to physicians. For more information please 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 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) 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) Excelis Quadra™ (Models CD3281-40, CD3281-40Q) Excelis™ (Models CD3389-40C, CD3389-40QC) Excelis™ CRT-D (Models CD3297-40, CD3297-40Q) Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC) Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2363-40C, CD2363-40Q) Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q) Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC) Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q) Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q) Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q) Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q) HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC) HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC) HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q) Promote™ (Models 3207-30, 3207-36, 3213-36, CD3211-36, CD3211-36Q, CD3215-36, CD3215-36Q) Promote Quadra™ (Models CD3221-36, CD3223-36P, CD3239-40, CD3239-40Q) Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC, CD3387-40C, CD3387-40QC) Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3369-40C, CD3369-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC) Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC) Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC) Unify Quadra MP™ (Models CD3255-40, CD3255-40Q) Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q) Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q)	**4/16/2018** **Class II** 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. **Recommendations for Devices Eligible for Firmware Upgrade** 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. Please consider the following: • 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. • If deemed appropriate, install this firmware update following the instructions on the programmer. • The update should be performed with appropriate monitoring and external defibrillation equipment available. **Recommendations for Current™ & Promote™ Devices not Eligible for Cybersecurity Firmware Update** 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: • Discuss the risks of cybersecurity vulnerabilities and proven benefits of remote monitoring with your patients at the next regularly scheduled visit. • 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. **Current Status (June 30, 2018):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication. This release is part of planned system updates to ensure effective and secure products for our patients. 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.). Additional materials, including a Patient Communication, can be found on www.sjm.com/notices [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. [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
Excelis Quadra™ (Models CD3281-40, CD3281-40Q)
Excelis™ + (Models CD3389-40C, CD3389-40QC)
Excelis™ CRT-D (Models CD3297-40, CD3297-40Q)
Fortify Assura™ DR (Models CD2257-40, CD2257-40Q, CD2259-40, CD2259-40Q, CD2357-40C, CD2357-40Q, CD2359-40, CD2359-40C, CD2359-40Q, CD2359-40QC)
Fortify Assura™ ST DR (Models CD2263-40, CD2263-40Q, CD2363-40C, CD2363-40Q)
Fortify Assura™ ST VR (Models CD1263-40, CD1263-40Q, CD1363-40C, CD1363-40Q)
Fortify Assura™ VR (Models CD1257-40, CD1257-40Q, CD1259-40, CD1259-40Q, CD1357-40C, CD1357-40Q, CD1359-40, CD1359-40C, CD1359-40Q, CD1359-40QC)
Fortify™ DR (Models CD2231-40, CD2231-40Q, CD2233-40, CD2233-40Q)
Fortify™ ST DR (Models CD2235-40, CD2235-40Q, CD2241-40, CD2241-40Q)
Fortify™ ST VR (Models CD1235-40, CD1235-40Q, CD1241-40, CD1241-40Q)
Fortify™ VR (Models CD1231-40, CD1231-40Q, CD1233-40, CD1233-40Q)
HeartMinder™ + DR (Models CD2391-40C, CD2391-40QC)
HeartMinder™ + VR (Models CD1391-40C, CD1391-40QC)
HeartMinder™ ST DR (Models CD2299-40, CD2299-40Q)
HeartMinder™ ST VR (Models CD1299-40, CD1299-40Q)
Quadra + Excelis™ (Models CD3385-40C, CD3385-40QC)
Quadra Assura MP™ (Models CD3269-40, CD3269-40Q, CD3271-40, CD3271-40Q, CD3371-40, CD3371-40C, CD3371-40Q, CD3371-40QC)
Quadra Assura™ (Models CD3265-40, CD3265-40Q, CD3267-40, CD3267-40Q, CD3365-40C, CD3365-40Q, CD3367-40, CD3367-40C, CD3367-40Q, CD3367-40QC)
Unify Assura™ (Models CD3257-40, CD3257-40Q, CD3261-40, CD3261-40Q, CD3357-40C, CD3357-40Q, CD3361-40, CD3361-40C, CD3361-40Q, CD3361-40QC)
Unify Quadra MP™ (Models CD3255-40, CD3255-40Q)
Unify Quadra™ (Models CD3249-40, CD3249-40Q, CD3251-40, CD3251-40Q)
Unify™ (Models CD3231-40, CD3231-40Q, CD3235-40, CD3235-40Q)
	10/11/2016
	Class I
	
	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.
	
	8/28/2017
	Class I
	
	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.
	
	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:
		
		• Do not implant unused affected devices.
		• Conduct patient follow-up per standard practice.
		• 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).
		• 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.
		• Physicians should reaffirm the availability of home monitoring to avoid or minimize time without device therapy for bradycardia and tachycardia events.
		• 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.
		• Review the most recent Programmed Parameters printout.
		  • 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.
		  • If the "Device at ERI" alert is OFF, we recommend that the patient be seen promptly to program this parameter ON.
		• Advise patients that an ERI indication triggers a vibratory alert. At the next scheduled office visit:
		  • 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.
		  • Perform a patient notifier test to confirm that the patient feels and recognizes the vibratory alert.
		  • Patients who cannot feel the vibratory alert may experience loss of battery and/or loss of device function without their awareness.
		  • Advise the patient to contact your office promptly should they feel a vibratory alert.
		  • In-office evaluation should be performed to determine the reason for the alert as other non-critical events can also trigger a vibratory alert.
		
		The following additional recommendations were communicated in April 2018 follow up advisory:
		• Patients receiving the firmware update should be advised that the device-based Battery Performance Alert (BPA) will trigger a vibratory alert.
		• 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.**
		
		Device Replacement Complication Publications
		
		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)
		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)
		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)
		
		Current Status (August 31, 2018): At the time of the advisory, 841 returned devices (0.21%) of 398,740 devices worldwide have premature depletion in association with lithium clusters, including 549 in the US. As of August 31, 2018, there were additional occurrences for a cumulative worldwide total of 3,355 and the rate is now 0.84%.
		
		For additional information and to determine if a device serial number is subject to this advisory, please go to the following website: www.sjm.com/batteryadvisory

ICD AND CRT-D DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Ellipse™ and Ellipse ST VR/DR US: CD1309, CD1311*, CD1409, CD1411*, CD2309, CD2311*, CD2409, CD2411* (all -36, -36Q, -36C and -36QC suffixes). *Denotes models also sold OUS. OUS: CD1277, CD1279, CD1293, CD1295, CD1377, CD1393, CD2277, CD2279, CD2293, CD2295, CD2377, CD2393 (all -36, -36Q, -36C and -36QC suffixes).	**8/19/2014** **Class II** 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 St. Jude Medical 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.	St. Jude Medical 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. 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: • Schedule your Ellipse ICD patient for an in-office follow-up evaluation as soon as possible. • 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. • Contact St. Jude Medical's Technical Services Department at 800-722-3774 to review the results of the capacitor maintenance test and discuss if additional evaluation is required. • A device that has experienced repeated extended charge time out warnings should be considered for replacement. 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. **Current Status (June 30, 2018):** 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, 2018, there were additional reports and the rate is now 1.17%. 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) AnalyST Accel™ VR RF (Models CD1219-36, CD1219-36Q) Current Accel™ DR RF (Models CD2215-36, CD2215-36Q) Current Accel™ VR RF (Models CD1215-36, CD1215-36Q) Current™ DR (Model 2207-36) Current™ VR (Model 1207-36) Ellipse™ DR (Models CD2277-36, CD2277-36Q, CD2377-36, CD2377-36Q, CD2377-36C, CD2377-36QC) Ellipse™ VR (Models CD1277-36, CD1277-36Q, CD1377-36, CD1377-36Q, CD1377-36C, CD1377-36QC) Fortify Assura™ DR (Models CD2259-40, CD2259-40Q, CD2359-40, CD2359-40Q, CD2359-40C, CD2359-40QC) Fortify Assura™ VR (Models CD1259-40, CD1259-40Q, CD1359-40, CD1359-40Q, CD1359-40C, CD1359-40QC) Fortify™ ST DR (Models CD2235-40, CD2235-40Q) Fortify™ ST VR (Models CD1235-40, CD1235-40Q) Promote Accel™ RF (Models CD3215-36, CD3215-36Q) Promote Quadra™ (Models CD3239-40, CD3239-40Q) Promote™ (Model 3213-36) Quadra Assura™ (Models CD3267-40, CD3267-40Q, CD3367-40, CD3367-40Q, CD3367-40C, CD3367-40QC) Quadra Assura MP™ (Models CD3371-40, CD3371-40Q, CD3371-40C, CD3371-40QC) Unify Assura™ (Models CD3261-40, CD3261-40Q, CD3361-40, CD3361-40Q, CD3361-40C, CD3361-40QC) Unify Quadra™ (Models CD3251-40, CD3251-40Q) Unify™ (Models CD3235-40, CD3235-40Q)	**1/23/2014** **Outside US only** In November 2013, St. Jude Medical 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 St. Jude Medical™ 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: • 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. • 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 St. Jude Medical 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. • 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. **Current Status (June 30, 2018):** No occurrences have been reported 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** **Outside US only** The Merlin™ PCS programmer software Model 3330 versions 14.2.2, 16.2.1 and 17.2.1.1 provide new features for St. Jude Medical™ 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. **Current Status (June 30, 2018):** At the time of the advisory there were 20 devices confirmed to be affected by this issue. As of June 30, 2018 there were an additional 52 devices confirmed with this issue. There have been no reports of erious injury or death.

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Convert™+ (Model V-195)	**5/6/2010** **Outside US only** 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: 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. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (June 30, 2018):** 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, 2018, 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 (Models V-197, V-235, V-337, V-338, V-339), Epic™ + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic™ II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas™ + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas™ II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	**1/16/2008** **Class II** 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. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (June 30, 2018):** 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, 2018 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** **Class II** 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. To assist in your patient care and following discussions with our independent Medical Advisory Board, Abbott recommends: 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. 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. 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. **Current Status (June 30, 2018):** 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, 2018 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue. 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** **Class II** Two anomalies have been identified: 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. 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: 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. 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. 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. 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. 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. **Current Status (June 30, 2018):** 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), Epic™+ (V-196, V-236), Epic™ HF CRT-D (V-338), Epic™+ HF CRT-D (V-350), Atlas™+ (V-193, V-243), Atlas™+ HF CRT-D (V-340), or Atlas™ (model V-242) ICDs	**3/10/2005** **Class II** 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. 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. **Current Status (June 30, 2018):** 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
Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP)	**11/17/2017** **Outside US and US Investigational Device Exemption (IDE) only** 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: • Continue following patients as per recommendations of the October 2016 Battery Malfunction for Nanostim™ LCP advisory. • 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. • 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. • 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. • 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. **Current Status: (October 24, 2018)** At the time of the advisory, three (0.21%) of 1,423 devices implanted worldwide have been reported to have a detached docking button. As of October 24, 2018, a total of 6 have been reported and the rate is now 0.42%. 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 Accent MRI™ (Model PM1224) Accent™ DR RF (Models PM2210, PM2212) Accent MRI™ (Models PM2218, PM2224) Accent™ SR RF (Model (PM1210) Accent™ ST DR RF (Models PM2216, PM2222) Accent™ ST MRI DR RF (Model PM2226) Accent™ ST MRI SR RF (Model PM1226) Accent™ ST SR RF (Model PM1222) Allure Quadra™ RF CRT-P (Model PM3242) Allure™ RF CRT-P (Model PM3222) Anthem™ RF CRT-P (Models PM3210, PM3212) Assurity™ + DR RF (Model PM2260) Assurity™ + SR RF (Model PM1260) Assurity™ DR RF (Model PM2240) Assurity MRI™ (Model PM2272) Assurity™ SR RF (Model PM1240) Assurity MRI™ (Model PM1272) Nuance™ DR RF (Model PM2214) Nuance™ MRI DR RF (Model PM2230) Nuance™ MRI SR RF (Model PM1230) Nuance™ SR RF (Model PM1214) Nuance™ ST DR RF (Model PM2228) Nuance™ ST SR RF (Model PM1228) Quadra Allure MP™ (Model PM3562) Quadra Allure MP™ RF CRT-P (Model PM3262) Quadra Allure™ (Model PM3542) Quadra Relieve MP™ (Model PM3564) Quadra Relieve MP™ RF CRT-P (Model PM3264) Quadra Relieve™ (Model PM3544) Quadra Relieve™ RF CRT-P (Model PM3244) Relieve™ RF CRT-P (Model PM3224) Zenex™ + DR RF (Model PM2270) Zenex™ + SR RF (Model PM1270) Zenex™ DR RF (Model PM2250) Zenex™ DR RF MRI (Model PM2282) Zenex™ SR RF (Model PM1250) Zenex™ SR RF MRI (Model PM1282)	**8/28/2017** **Class II** 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** Prophylactic replacement of affected devices is not recommended. 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: • 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”. • 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). • 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. **Current Status (June 30, 2018):** We have received no reports of device compromise related to the cybersecurity vulnerabilities in the implanted devices impacted by this communication. This release is part of planned system updates to ensure effective and secure products for our patients. 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.). Additional materials, including a Patient Communication, can be found on www.sjm.com/notices.

PACEMAKER AND CRT-P DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY

Nanostim™ Leadless Cardiac Pacemaker (Model S1DLCP)	**10/28/2016**
	Outside US and US Investigational Device Exemption (IDE) only
	
	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.
	
	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.
	
	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:
		
		• Do not implant unused devices and return them to Abbott.
		• 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.
		• Do not perform AV Node ablation in patients with an existing Nanostim LCP without another functional pacing system implanted.
		• For patients who have not previously been documented to be pacemaker dependent, re-assess patients in-office for pacemaker dependence.
		• **For non-pacemaker dependent patients with devices of implant duration ≥ 24 months, more intensive follow-up and monitoring is recommended.**
		  • 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.
		  • Implant Duration < 24 months: Continue follow up per protocol.
		• **For pacemaker dependent patients, device replacement is recommended (priority should be for patients with implants of longer duration).**
		  • Identify and treat patients as quickly as possible.
		  • Interrogate the device and identify the ability to communicate with the device and the patient's underlying rhythm.
		  • 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.
		  • If the device is to be retrieved, use the Nanostim retrieval system as per the standard procedure described in the instructions for use.
		  • 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.
		  • 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.
		
		Current Status (October 24, 2018): At the time of the advisory, seven (7) reported devices (0.50%) of 1,423 implanted devices worldwide have exhibited battery malfunction at 29 to 37 months after implant. As of October 24, 2018, there were additional reports and the rate is now 6.6%. 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) Accent™ DR (Model PM2112)	**12/7/2012** **Outside US Only** 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: Identify affected patient • Review your patient's clinical indications for pacing and determine the clinical need for rate responsive, sensor driven pacing. • 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 • Continue to follow patients on their standard follow-up schedule. **Current Status (June 30, 2018):** 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), Anthem™ CRT-P (Models PM3110, PM3112, PM3210, PM3212)	**9/22/2011** **Class II** 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 St. Jude Medical Sales Representative will assist you in loading the new programmer software onto your Merlin programmer. If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, St. Jude Medical makes the following recommendations, which are consistent with standard best practices: • Ensure that the new programmer software version is loaded on your programmers as soon as practical. • 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. • 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. **Current Status (June 30, 2018):** 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) Identity™ DR (Model 5370) Identity™ XL DR (Model 5376)	**10/12/2006** **Class II** 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. **Current Status (June 30, 2018):** 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, 2018 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) QuickFlex™ (Models 1156T, 1158T)	**4/3/2012** **Class II** Abrasion of the silicone insulation in the distal portion of QuickSite and QuickFlex leads has led to visual observations of externalized conductors. 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. 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. 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. **Current Status (June 30, 2018):** 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, 2018, the worldwide reported externalized conductor rate for QuickSite and QuickFlex leads was 0.26%.

DEFIBRILLATION LEADS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Optisure™ Defibrillation Lead (Models LDA220, LDA220Q, LDA230Q, LDP220Q)	**11/3/2015** **Class I** 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. 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. St. Jude Medical 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. For patients implanted with a potentially-impacted Optisure lead connected to a device WITH DynamicTx™* technology, we recommend: Review the Patient Records: 1. Ensure DynamicTx™ technology is programmed "On" 2. Enroll these patients in our Merlin.net™ Patient Care Network 3. Monitor patients as normal, with no additional testing or follow-up needed. For patients implanted with a potentially-impacted Optisure lead connected to a device WITHOUT DynamicTx™* technology we recommend: 1. Enroll these patients in our Merlin.net™ Patient Care Network 2. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector) 3. If dual coil shocking configuration is desired, consider performing a high voltage test using maximum energy. a. If shock delivery is normal - no additional testing is required b. If shock delivery identifies a short circuit – consider lead replacement • DynamicTx™ technology automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur. We recommend at your patient's next follow-up visit a St. Jude Medical 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) Riata™ i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata™ ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)	**11/28/2011** **Class I** 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. A summary of the types and incidence rates of Riata lead abrasion malfunctions is presented on pages 306-314 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. 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. 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. 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. 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. 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. In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended. 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. Based on input from the MAB, Abbott is conducting a prospective study to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities. **Current Status (August 31, 2018):** 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, 2018, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 4.51% and 2.73% respectively. The latest information related to the silicone Riata lead advisory, including references to independent studies of Riata lead performance, can be obtained at www.RiataCommunication.com.

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) Riata™ i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata™ ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)	**12/15/2010** **Outside US Only** 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). 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. A summary of the types and incidence rates of Riata lead abrasion malfunctions is presented on pages 306-314 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. 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. 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. Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events. **Current Status (August 31, 2018):** At the time of the advisory there was a worldwide insulation abrasion rate of 0.47% for Riata silicone leads. As of August 31, 2018, there have been additional reports and the worldwide reported insulation abrasion rate is 4.51%.

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™ (Model DM3500)	**5/18/2018** **Class II** **US Only** 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. 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). **Recommendations for Patients with Implanted Devices** 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: • For patients confirmed to be impacted, contact Abbott Technical Services to assist in correcting the battery indicator. • 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. • If a low battery indicator is observed, contact Abbott Technical Services to assist in confirmation and correction of the battery indicator display. **Recommendations for Devices not yet Implanted** 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. **Current Status:** At the time of the advisory, 0.41% devices distributed worldwide have been reported to have experienced incorrect display of low battery indicator. There have been no reports of serious injury or death. 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 www.sjm.com/notices.

ICM DEVICES

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
SJM Confirm™ ICM (Models DM2100, DM2102)	**3/11/2011** **Class II** **US and Germany** 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: • 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. • 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. • If the device is no longer indicated it can be left implanted until such time that a routine explant is desired. 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 St. Jude Medical Technical Services. St. Jude Medical is in the process of developing new Merlin PCS programmer software that will properly upgrade SJM Confirm devices. **Current Status (June 30, 2018):** 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** **Class II** 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. • 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. • For further information, health care providers can contact the local sales representative. In addition, both health care providers and patients can visit www.sjm.com/Merlin for answers to questions and additional information regarding Abbott's implantable cardiac rhythm devices, or the Merlin@home™ transmitter. **Current Status (June 30, 2018):** Abbott has not received any reports that a specific Abbott device or system in clinical use has been targeted and is not aware of any patient harm associated with cybersecurity incidents related to an Abbott device.

REMOTE MONITORING/TRANSMITTERS

MODEL IDENTIFICATION	ADVISORY	FOLLOW-UP RECOMMENDATIONS AT TIME OF ADVISORY
Merlin@home™ RF Remote Monitoring Transmitter EX1150	**12/18/2014** **Class II** 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. 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. 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. 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. **9/19/2015** 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. The process of automatically "uploading" this new version of software to patient transmitters has begun. 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. **Current Status (June 30, 2018):** 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.

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** **Worldwide** 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. 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. 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] 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. 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. References: [1] Hayes and Friedman, Cardiac Pacing, Defibrillation and Resynchronization, 2nd Edition, p. 192 [2] Ellenbogen and Wood, Cardiac Pacing and ICDs, 4th Edition, p. 227

Index

Index

Index

Index of Phased-out Models

Abbott

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 www.SJM.com.

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™ 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™ VDR (5430)	May 2010
Integrity™ µ SR (5136)	Nov 2013
Integrity ADx™ DR (5360)	Nov 2013
Integrity ADx™ SR (5160)	Nov 2013
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
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

Phased-out Models

PACEMAKERS	FINAL EDITION
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
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
Unipolar Lead (1007)	May 2010

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
SJM.com
St. Jude Medical is now Abbott.

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-60094962 REV A | Item approved for U.S. use only.

Abbott