Implantable Electronic Systems
Product Performance Report
2016 Second Edition

St. Jude Medical™

Letter from St. Jude Medical

As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, St. Jude Medical 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, St. Jude Medical employees are dedicated to product quality and patient safety.

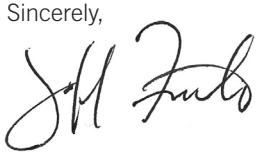
In keeping with this commitment, we publish a Product Performance Report (PPR) semi-annually to ensure that the healthcare community and the patients it serves are informed about the overall performance of our cardiac devices, which include implantable cardiac monitors (ICMs), implantable cardioverter defibrillators (ICDs), implantable pacemakers, and implantable pacing and defibrillation leads. St. Jude Medical 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, St. Jude Medical 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, St. Jude Medical 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 St. Jude Medical, 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 and our more recent ICD and pacemaker models, 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 1999 can be found beginning on page 294.

As we continually strive to provide unbiased and reliable information on the performance of our products, St. Jude Medical is pleased to release the second edition of the 2016 Product Performance Report containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,



Jeff Fecho
Vice President, Global Quality

St. Jude Medical

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Serving Our Mission

Our vision is to transform the treatment of expensive, epidemic diseases. It is our mission to create cost-effective medical technologies that save and improve lives. We carry out this vision and mission by pursuing new treatments, efficiencies and ideas that improve the lives of people affected by disease; keeping the highest ethical standards in all business practices; and continually adapting and responding to the rapidly changing health care environment.

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 St. Jude Medical Representative or St. Jude Medical Technical Services at 1-800-722-3774. Thank you for your input and continued support, allowing St. Jude Medical to positively impact the lives of thousands of patients every year.

What You'll Find in This Report

- Table of Contents
- A summary of the methods St. Jude Medical has used for measuring product performance, including key definitions of terms used in preparing this report
- For each Implantable Cardioverter Defibrillator (ICD), Pacemaker, Implantable Cardiac Monitor (ICM), and Lead model with at least 500 active devices in service, St. Jude Medical provides product performance data, according to industry guidelines, collected through June 30, 2016, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - For the more recent products, the quantity, rate, and type of product malfunctions are detailed
  - For the more recent lead models, the quantity, rate, and type of customer complaints (acute observations and chronic complications) are detailed
- Summary tables of performance data, organized by product type and model
- For all ICD, pacemaker, ICM, and lead models that meet Actively Monitored Study Data Registry inclusion criteria, St. Jude Medical provides active registry performance data, collected through June 30, 2016, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - A table of all Qualifying Complications including quantity and rate
  - A table with quantity, rate, and type of product malfunctions
- A Focus on Clinical Performance section which provides product performance data on a variety of unique topics, including:
  - Riata™ lead performance
  - Durata™ lead performance including an independent analysis of active registry data by Public Health Research Institute, PHRI
  - The effect of Optim™ lead insulation on HV lead abrasion
- An updated summary of advisories on all implantable devices since 1999
- A summary of communications to Healthcare Professionals
- An index by product type and model name
- An index of phased-out models by product type and model name

What's New in This Report

Update on Riata™ Lead Performance

In order to provide our physician customers and patients the most up-to-date information, St. Jude Medical has included an update on Riata lead performance in the Focus on Clinical Performance section (see pages 282-286). This section provides the latest Riata lead externalized conductor rates from the St. Jude Medical™ 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 St. Jude Medical 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 St. Jude Medical™ 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 287-291).

Update on Optim™ Lead Insulation

St. Jude Medical's 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 St. Jude Medical tachycardia leads (see pages 292-293).

Worldwide Laboratory Analysis

In addition to the previously added worldwide laboratory analysis results of returned Durata™ leads, this Product Performance Report includes worldwide laboratory analysis results for Optisure™ defibrillation leads and various low voltage leads, CRT leads, pacemakers and defibrillators categorized into the malfunction types as outlined on pages 7-8 and 10-12. These worldwide malfunction summaries can be found following the U.S. malfunction summaries in their respective sections. St. Jude Medical is dedicated to full transparency, and will continue to incorporate worldwide laboratory analysis results of additional models in future publications of this report.

Customer Reported Performance Data

Product performance data derived from customer-initiated complaints and returned products is referred to as Customer Reported Performance Data. While St. Jude Medical 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. St. Jude Medical 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 St. Jude Medical. 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 St. Jude Medical as explanted or otherwise out of service. An adjustment is made to account for the underreporting of patient mortality. St. Jude Medical performed an analysis of the data gathered from multiple clinical studies including some St. Jude Medical 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. In aligning with the ISO standard, certain reported chronic complications which remained in service were not included in survival probability

calculations in prior PPR revisions but are now provided in the tabular display of chronic complications. However, 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. To provide the highest level of transparency, St. Jude Medical 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 St. Jude Medical. 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. St. Jude Medical 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. For the purposes of this data, non-returned devices removed from service for battery depletion with no associated complaint are considered as normal battery depletions. 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 device registration information, chronic complications (>30 days) reported by the field, and the laboratory analysis of all domestically implanted leads returned to St. Jude Medical. 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 (chronic complication) report, is no longer in service as a result of the complication, and was implanted for more than 30 days, 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 St. Jude Medical as complaints. In aligning with the ISO 5841-2:2014 standard, some chronic complications previously not included in calculations for survival probability are now provided in the tabular display. 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 device, 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 St. Jude Medical™ 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 310-311) 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, St. Jude Medical continues to complement the SCORE registry with data from the SJ4 Post-Approval Study, the QuickFlex™ µ 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 St. Jude Medical cardiac rhythm management products using common definitions and criteria. In addition, each of these sites is regularly audited by St. Jude Medical 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 St. Jude Medical 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 St. Jude Medical 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 St. Jude Medical 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 St. Jude Medical™ 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 St. Jude Medical 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 CD3265-40Q)
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 1388)
Tendril™ SDX (Model 1488)
Tendril™ SDX (Model 1688)
Tendril™ ST Optim™ (Model 1882)
Tendril™ ST Optim™ (Model 1888)
Tendril™ STS (Model 2088)

**New for 2016 Second Edition*

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 St. Jude Medical. 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	Qualifying Clinical Action
Abnormal Defibrillation Impedance	Generator Pacing Mode Changed
Abnormal Pacing Impedance	Lead Electrically Abandoned/Capped
Cardiac Perforation	Lead/Generator Explanted
Conductor Fracture	Lead/Generator Replaced
Extracardiac Stimulation	Lead Polarity Changed
Failure to Capture	Lead Surgically Abandoned/Capped
Failure to Sense	Lead Surgically Repositioned
Inappropriate Shock	
Insulation Breach	
Lead Dislodgement	
Loss of Telemetry	
Oversensing	
Pericardial Effusion	
Premature Battery Depletion	
Skin Erosion	

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.

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

St. Jude Medical 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 St. Jude Medical

To maintain the continued accuracy of our performance reporting, St. Jude Medical 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 St. Jude Medical for laboratory evaluation whether or not a malfunction is suspected. To facilitate the return of explanted devices, St. Jude Medical 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 St. Jude Medical Customer Service (888-SJM-2763).

Contact Us

The St. Jude Medical 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 St. Jude Medical representative.

Cardiac Resynchronization Therapy (CRT) Devices

CRT ICDs

St. Jude Medical™

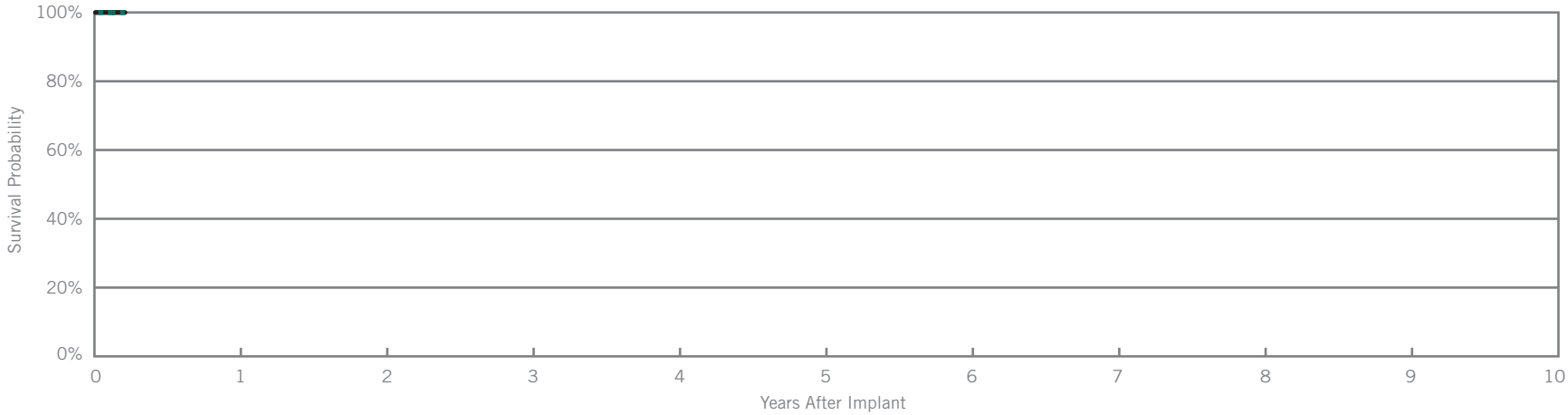
Quadra Assura MP™ CRT-D

Model CD3369-40Q*

US Regulatory Approval	February 2016
Registered US Implants	1,563
Estimated Active US Implants	1,557
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 3 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	220										

Excluding Normal Battery Depletion

Year	at 3 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

**DF4-LLHH connector type.*

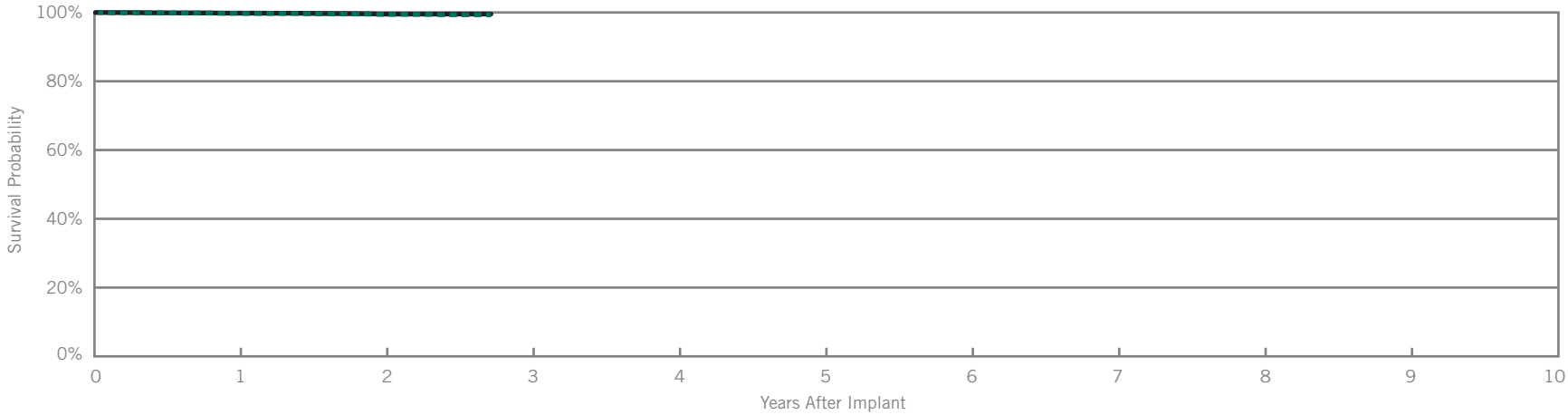
Quadra Assura™ CRT-D

Model CD3365-40Q*

US Regulatory Approval	June 2013
Registered US Implants	34,955
Estimated Active US Implants	29,678
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	9
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	<0.01%	5	0.01%
Electrical Interconnect	7	0.02%	0	0.00%
Battery	0	0.00%	1	<0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	<0.01%	1	<0.01%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	2	<0.01%	5	0.01%
Other	3	<0.01%	0	0.00%
Total	**16**	**0.05%**	**17**	**0.05%**



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.76%	99.45%	99.35%							
± 1 standard error	0.03%	0.05%	0.09%							
Sample Size	27,100	12,750	520							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.81%	99.54%	99.54%							
± 1 standard error	0.03%	0.05%	0.06%							

**DF4-LLHH connector type.*

Actively Monitored Study Data

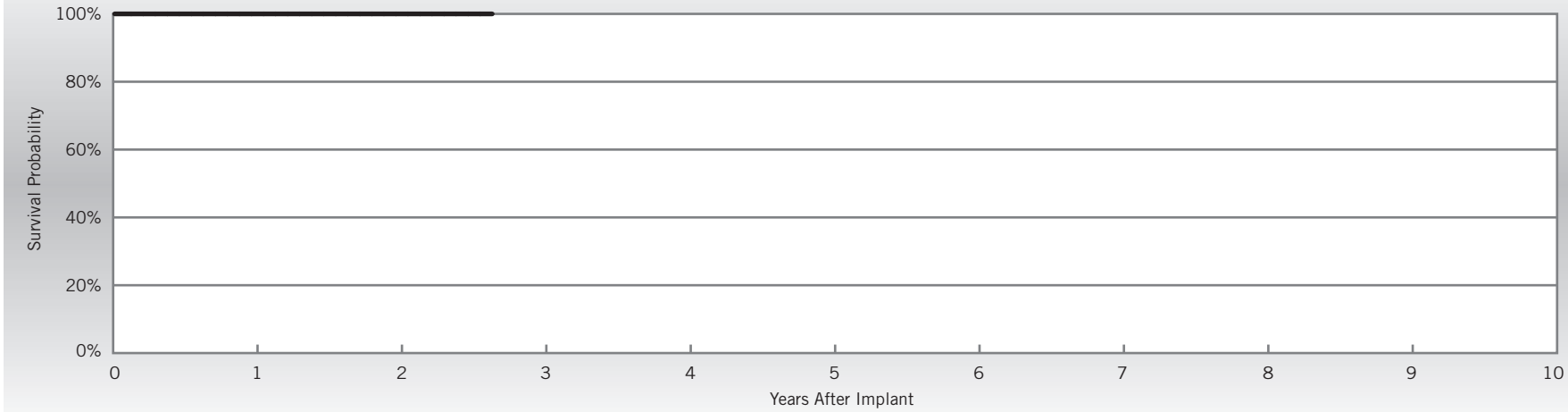
Quadra Assura™ CRT-D

Model CD3365-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	177
Active Devices Enrolled in Study	129
Cumulative Months of Follow-up	4,082
Estimated Longevity	(see table on page 48)
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%**



Year	1	2	at 32 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	160	130	60							

**DF4-LLHH connector type.*

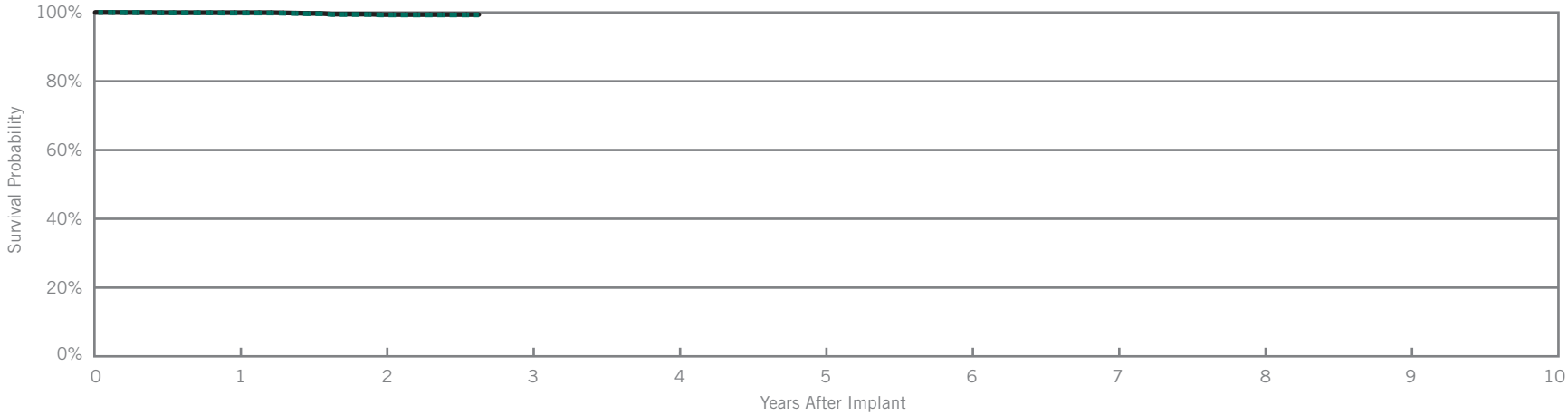
Quadra Assura™ CRT-D

Model CD3365-40C*

US Regulatory Approval	June 2013
Registered US Implants	6,852
Estimated Active US Implants	5,849
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.01%
Electrical Interconnect	1	0.01%	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%	0	0.00%
Possible Early Battery Depletion	1	0.01%	1	0.01%
Other	2	0.03%	1	0.01%
Total	**4**	**0.06%**	**4**	**0.06%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.83%	99.27%	99.27%							
± 1 standard error	0.06%	0.14%	0.17%							
Sample Size	5,390	2,630	230							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.93%	99.37%	99.37%							
± 1 standard error	0.03%	0.13%	0.17%							

**Parylene coating.*

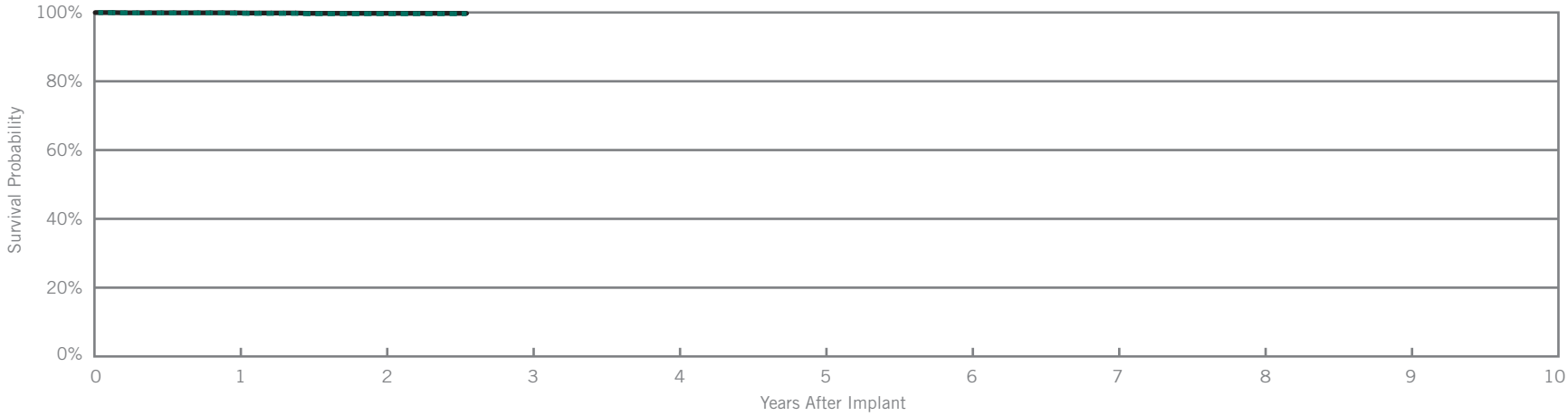
Unify Assura™ CRT-D

Model CD3357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	7,693
Estimated Active US Implants	6,551
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	2	0.03%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	1	0.01%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.05%**	**1**	**0.01%**



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.78%	99.64%	99.64%							
± 1 standard error	0.05%	0.10%	0.10%							
Sample Size	5,650	2,360	280							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.90%	99.75%	99.75%							
± 1 standard error	0.04%	0.08%	0.08%							

**DF4-LLHH connector type.*

Actively Monitored Study Data

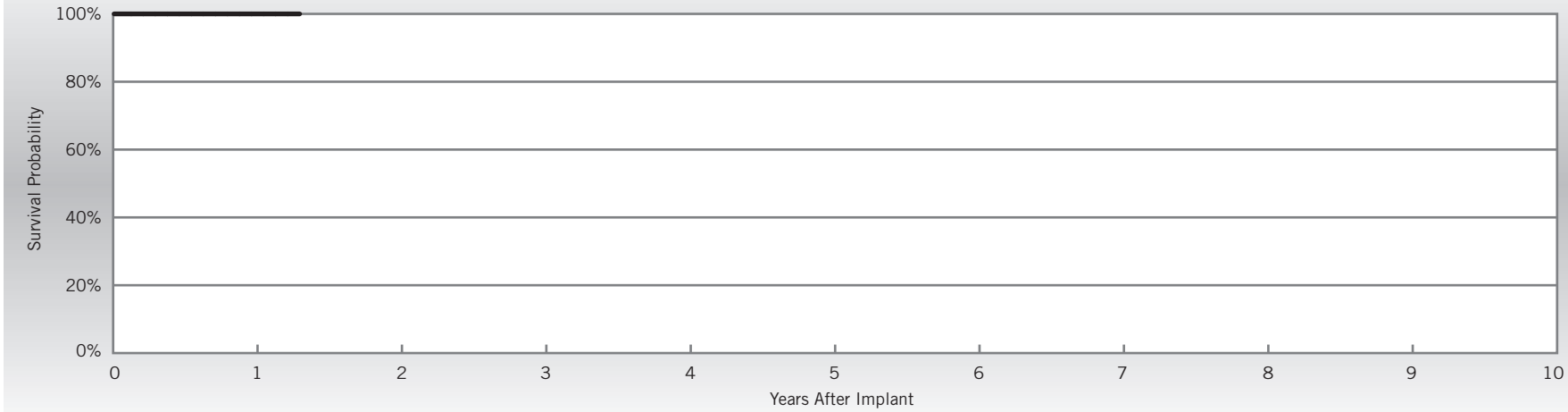
Unify Assura™ CRT-D

Model CD3357-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	136
Active Devices Enrolled in Study	119
Cumulative Months of Follow-up	1,760
Estimated Longevity	(see table on page 48)
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%**



Year	1	at 16 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	100	60								

**DF4-LLHH connector type.*

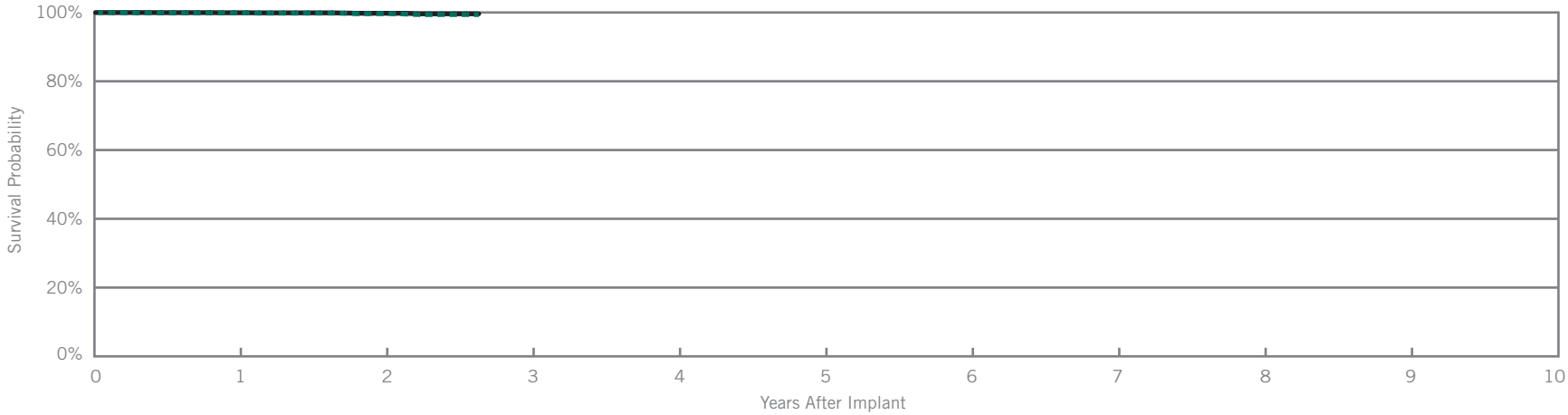
Unify Assura™ CRT-D

Model CD3357-40C*

US Regulatory Approval	June 2013
Registered US Implants	12,844
Estimated Active US Implants	10,865
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	1	<0.01%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**5**	**0.04%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.88%	99.68%	99.39%							
± 1 standard error	0.03%	0.08%	0.16%							
Sample Size	10,130	4,750	310							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.92%	99.77%	99.61%							
± 1 standard error	0.03%	0.07%	0.13%							

**Parylene coating.*

Actively Monitored Study Data

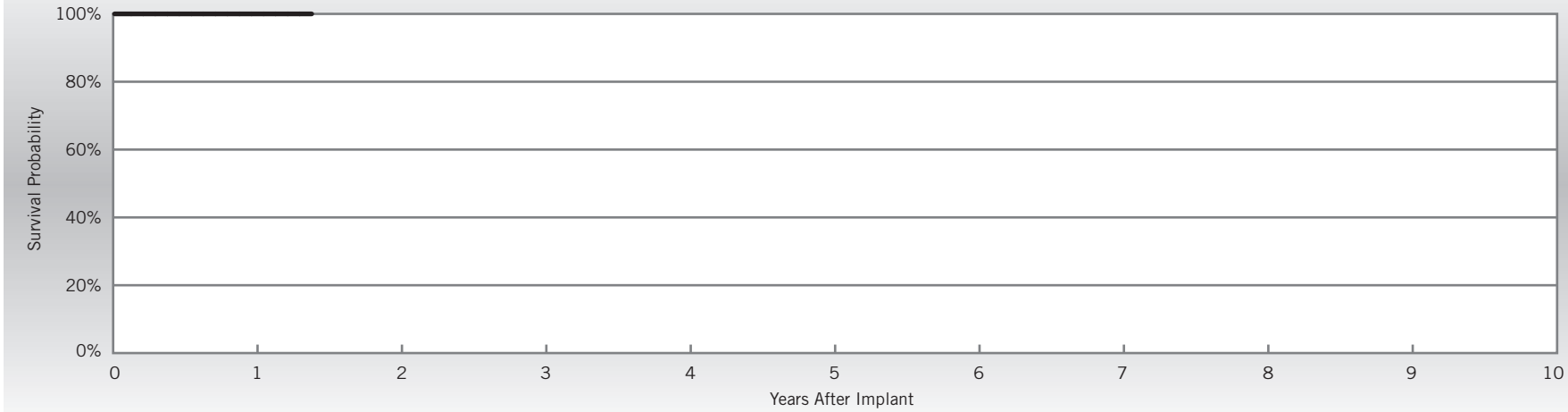
Unify Assura™ CRT-D

Model CD3357-40C*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	103
Active Devices Enrolled in Study	81
Cumulative Months of Follow-up	1,614
Estimated Longevity	(see table on page 48)
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%**



Year	1	at 17 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	90	50								

**Parylene coating.*

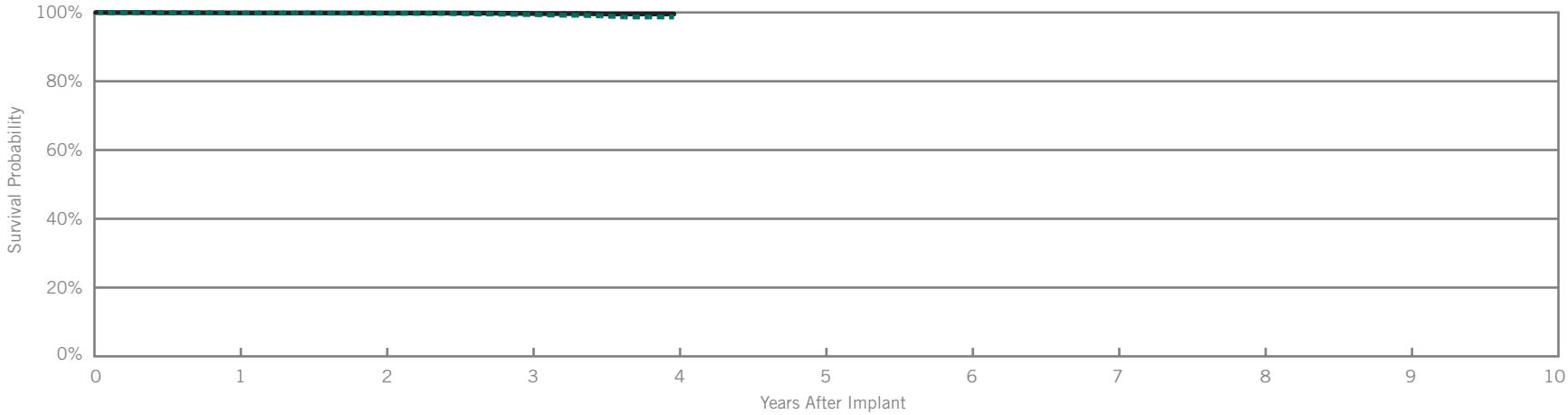
Quadra Assura™ CRT-D

Model CD3265-40Q*

US Regulatory Approval	May 2012
Registered US Implants	13,523
Estimated Active US Implants	9,766
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	18
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	3	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	1	<0.01%
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	4	0.03%	1	<0.01%
Other	1	<0.01%	0	0.00%
Total	**7**	**0.05%**	**8**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.83%	99.74%	99.40%	98.70%						
± 1 standard error	0.04%	0.04%	0.08%	0.21%						
Sample Size	12,720	11,250	7,960	290						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.87%	99.85%	99.71%	99.57%						
± 1 standard error	0.03%	0.03%	0.05%	0.10%						

**DF4-LLHH connector type.*

Actively Monitored Study Data

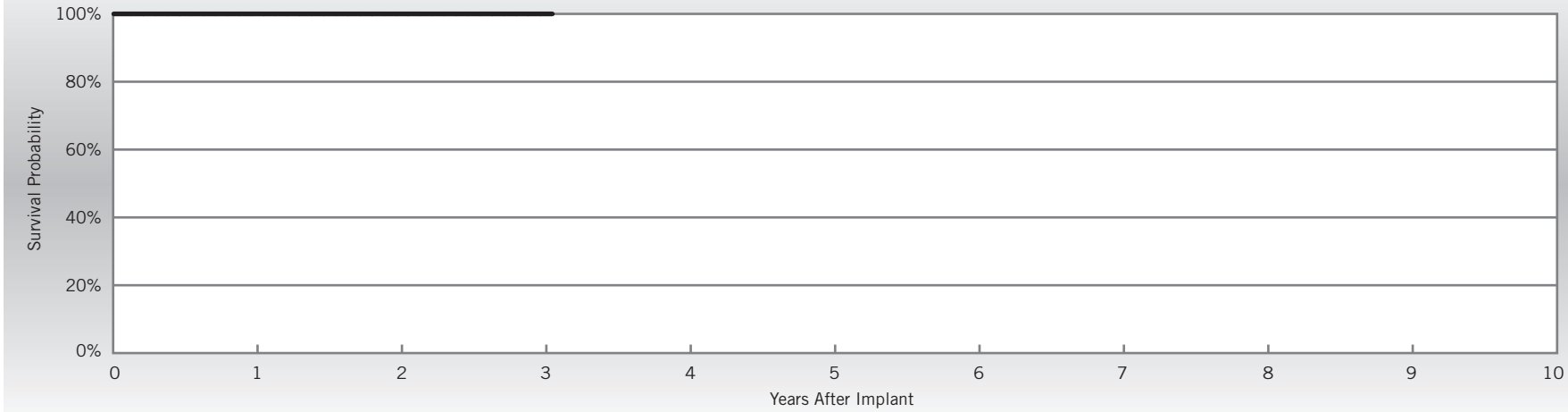
Quadra Assura™ CRT-D

Model CD3265-40Q*

US Regulatory Approval	May 2012
Number of Devices Enrolled in Study	419
Active Devices Enrolled in Study	277
Cumulative Months of Follow-up	11,258
Estimated Longevity	(see table on page 48)
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	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%**



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	390	330	180	60						

**DF4-LLHH connector type.*

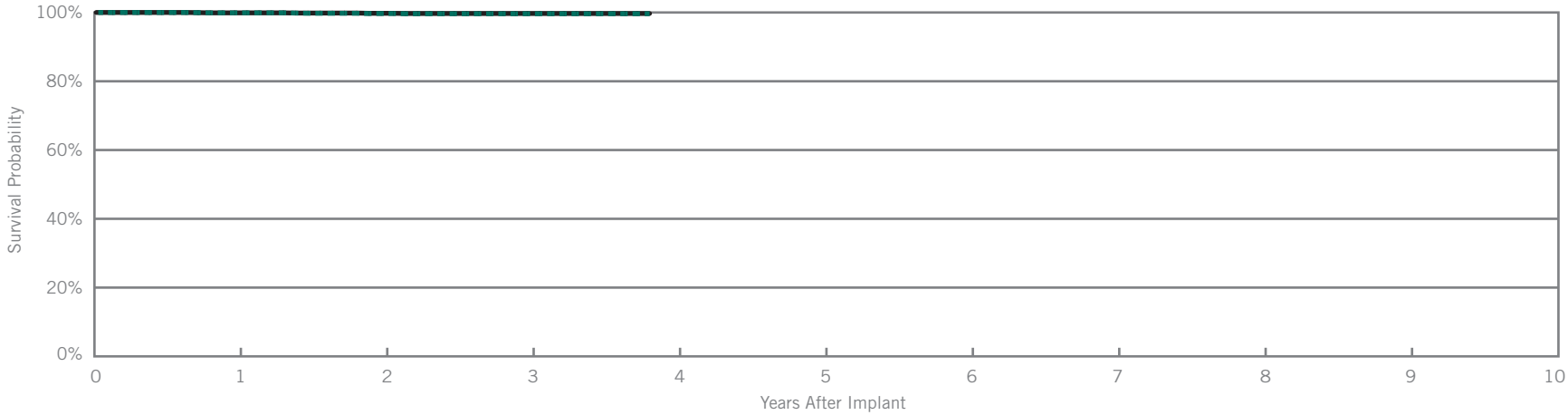
Quadra Assura™ CRT-D

Model CD3265-40

US Regulatory Approval	May 2012
Registered US Implants	4,020
Estimated Active US Implants	2,893
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	2	0.05%	1	0.02%
Total	**3**	**0.07%**	**2**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.89%	99.70%	99.64%	99.64%						
± 1 standard error	0.06%	0.09%	0.11%	0.11%						
Sample Size	3,760	3,260	2,300	220						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.89%	99.76%	99.70%	99.70%						
± 1 standard error	0.06%	0.08%	0.10%	0.10%						

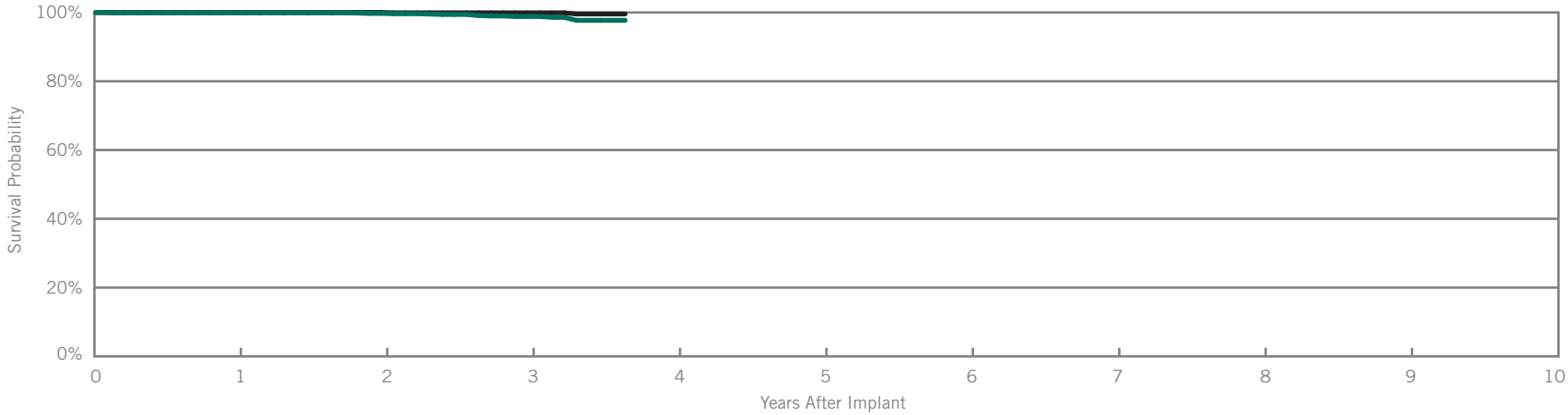
Unify Assura™ CRT-D

Model CD3257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	2,710
Estimated Active US Implants	1,905
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	11
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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	2	0.07%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.07%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.92%	99.73%	98.82%	97.72%						
± 1 standard error	0.05%	0.11%	0.26%	0.49%						
Sample Size	2,520	2,190	1,530	260						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	100.00%	100.00%	99.90%	99.56%						
± 1 standard error	0.00%	0.00%	0.07%	0.25%						

**DF4-LLHH connector type.*

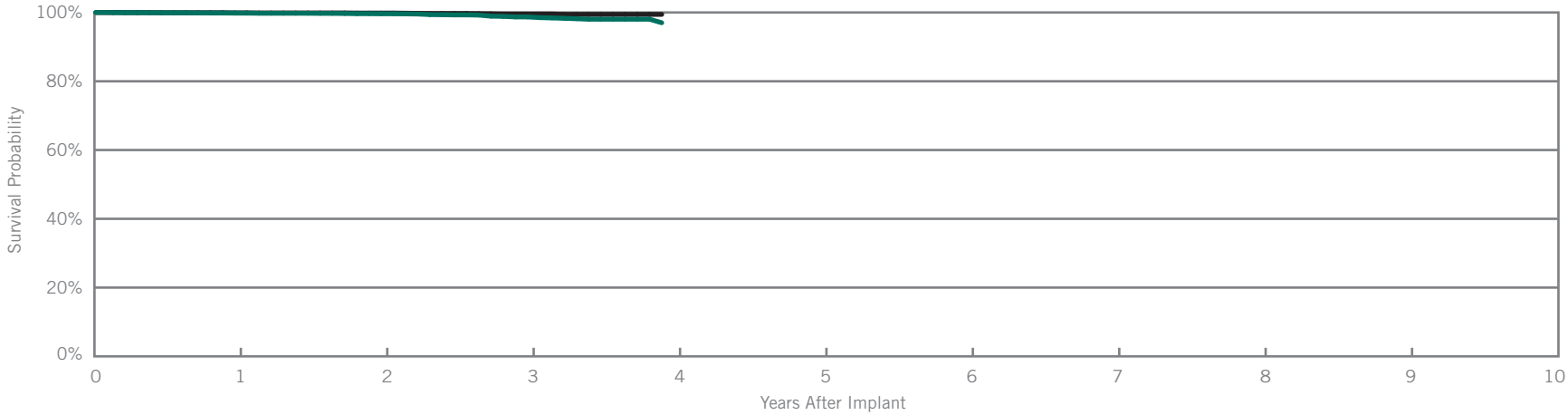
Unify Assura™ CRT-D

Model CD3257-40

US Regulatory Approval	May 2012
Registered US Implants	6,729
Estimated Active US Implants	4,750
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	22
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.06%	2	0.03%
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	2	0.03%	1	0.01%
Other	1	0.01%	1	0.01%
Total	**8**	**0.12%**	**4**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.81%	99.63%	98.70%	97.01%						
± 1 standard error	0.05%	0.08%	0.17%	0.25%						
Sample Size	6,320	5,540	3,900	250						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.90%	99.83%	99.55%	99.44%						
± 1 standard error	0.03%	0.05%	0.10%	0.12%						

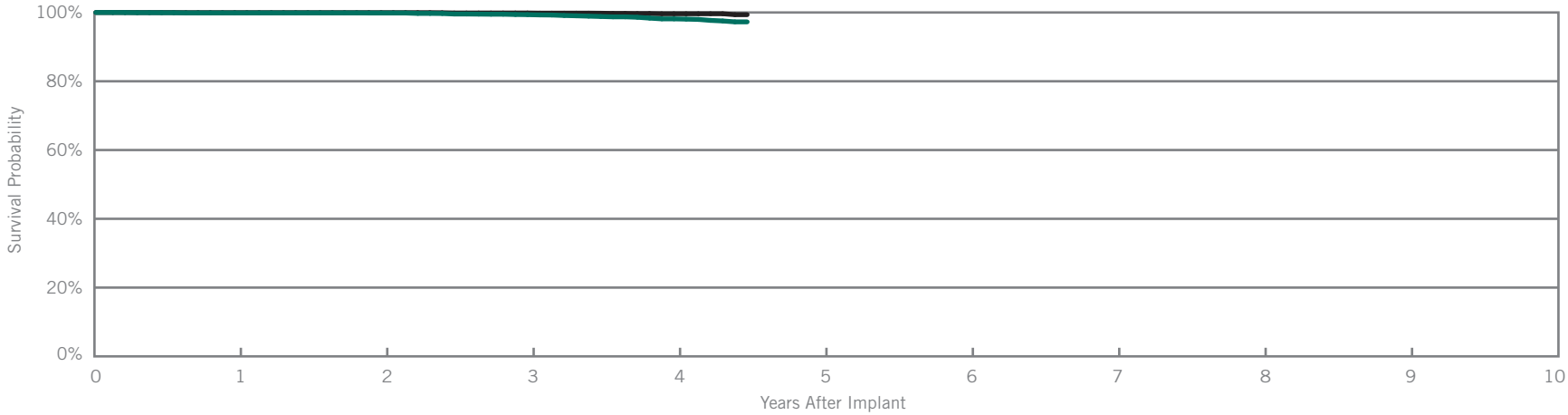
Unify Quadra™ CRT-D

Model CD3249-40Q*

US Regulatory Approval	November 2011
Registered US Implants	8,931
Estimated Active US Implants	5,878
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	37
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.03%	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	0.01%
Possible Early Battery Depletion	5	0.06%	0	0.00%
Other	2	0.02%	0	0.00%
Total	**10**	**0.11%**	**1**	**0.01%**



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.87%	99.84%	99.37%	98.14%	97.27%					
± 1 standard error	0.04%	0.04%	0.09%	0.19%	0.33%					
Sample Size	8,420	7,500	6,570	4,530	510					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.95%	99.95%	99.85%	99.63%	99.36%					
± 1 standard error	0.02%	0.02%	0.05%	0.08%	0.21%					

**DF4-LLHH connector type.*

Actively Monitored Study Data

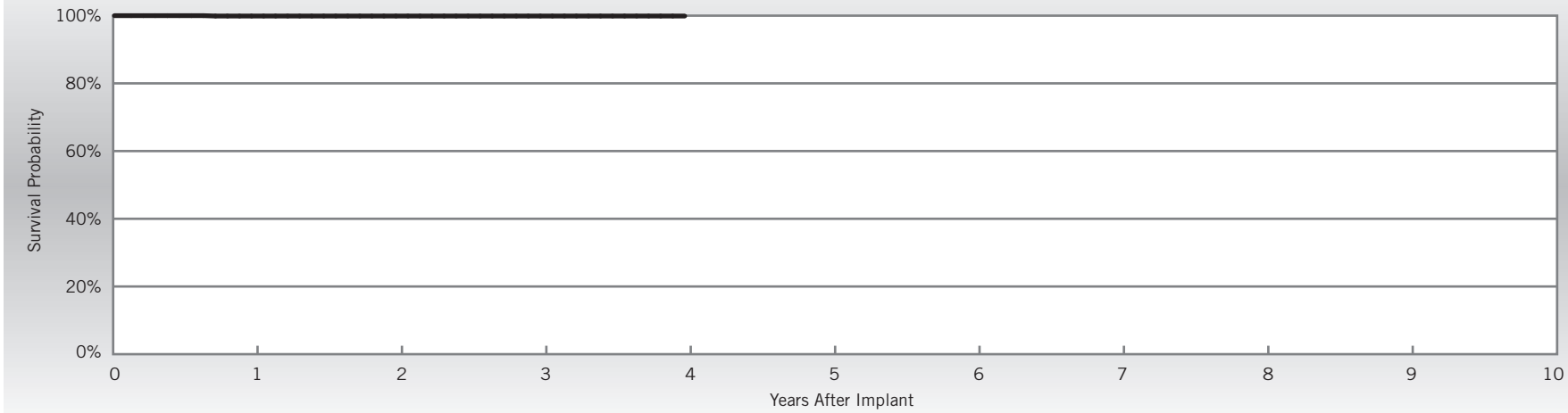
Unify Quadra™ CRT-D

Model CD3249-40Q*

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	991
Active Devices Enrolled in Study	610
Cumulative Months of Follow-up	31,460
Estimated Longevity	(see table on page 48)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
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	0	0.00%	1	0.10%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.10%**



Year	1	2	3	4						
Survival Probability	99.89%	99.89%	99.89%	99.89%						
± 1 standard error	0.11%	0.11%	0.11%	0.11%						
Sample Size	930	790	650	60						

**DF4-LLHH connector type.*

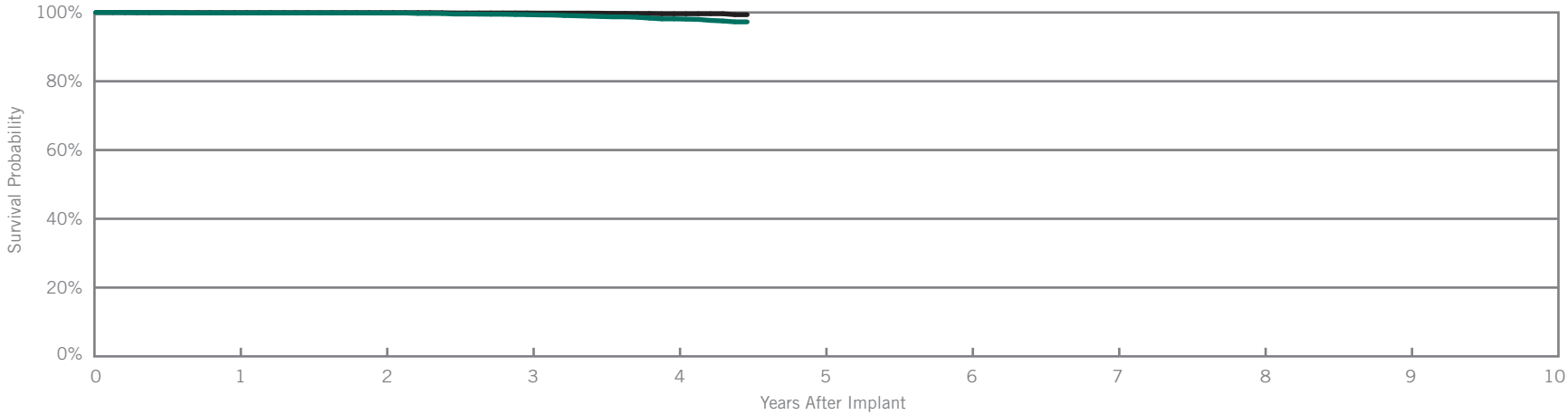
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	November 2011
Registered US Implants	2,520
Estimated Active US Implants	1,622
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	14
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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%	0	0.00%
Other	1	0.04%	0	0.00%
Total	**1**	**0.04%**	**1**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.92%	99.92%	99.60%	97.86%	97.62%					
± 1 standard error	0.06%	0.06%	0.12%	0.36%	0.42%					
Sample Size	2,370	2,100	1,830	1,290	290					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.92%	99.92%	99.92%	99.80%	99.80%					
± 1 standard error	0.06%	0.06%	0.06%	0.10%	0.10%					

Actively Monitored Study Data

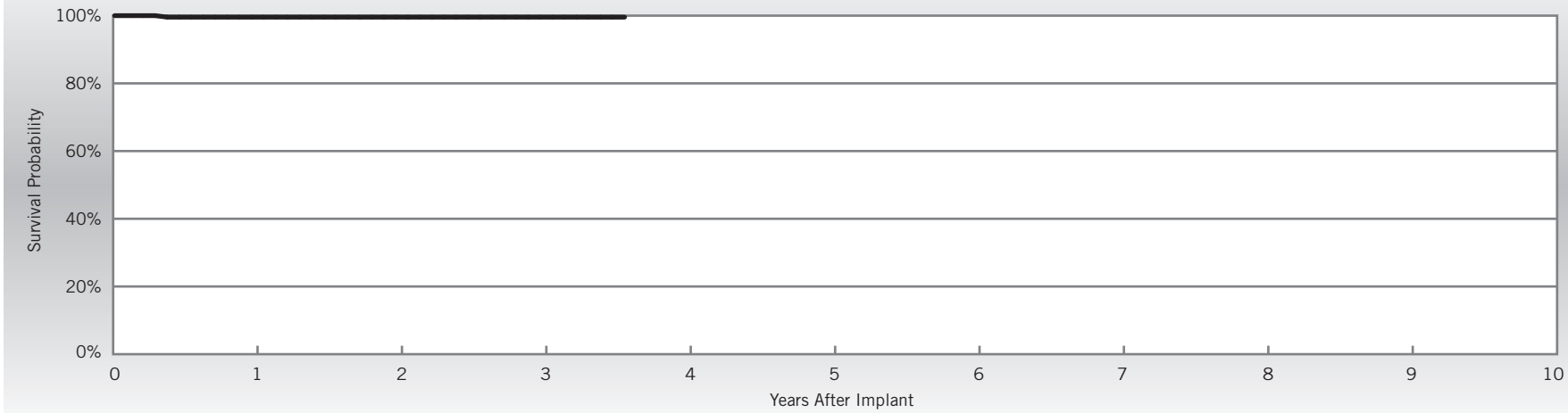
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	242
Active Devices Enrolled in Study	138
Cumulative Months of Follow-up	7,539
Estimated Longevity	(see table on page 48)
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%**



Year	1	2	3	at 43 months						
Survival Probability	99.56%	99.56%	99.56%	99.56%						
± 1 standard error	0.44%	0.44%	0.44%	0.44%						
Sample Size	220	190	160	60						

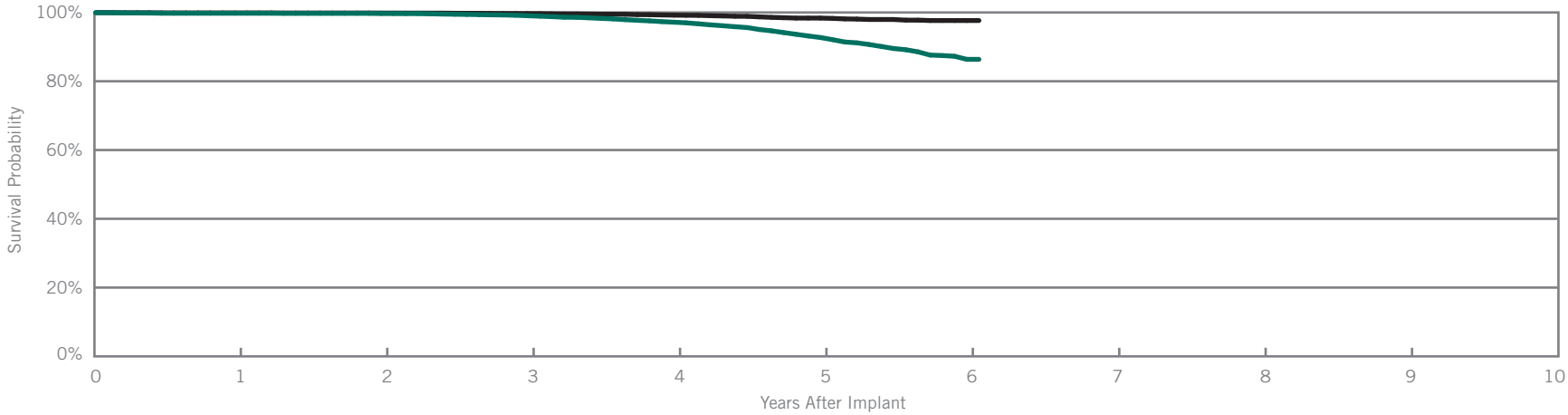
Unify™ CRT-D

Model CD3231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	18,986
Estimated Active US Implants	10,210
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	304
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.01%	3	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	9	0.05%	2	0.01%
High Voltage Capacitor	8	0.04%	2	0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	1	<0.01%	2	0.01%
Possible Early Battery Depletion	38	0.20%	11	0.06%
Other	5	0.03%	2	0.01%
Total	**64**	**0.34%**	**23**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.77%	99.70%	99.05%	97.17%	92.72%	86.37%	86.37%			
± 1 standard error	0.04%	0.04%	0.07%	0.14%	0.25%	0.49%	0.63%			
Sample Size	17,740	15,680	14,060	12,170	8,500	3,110	320			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.88%	99.83%	99.68%	99.22%	98.37%	97.66%	97.66%			
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	0.19%	0.19%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

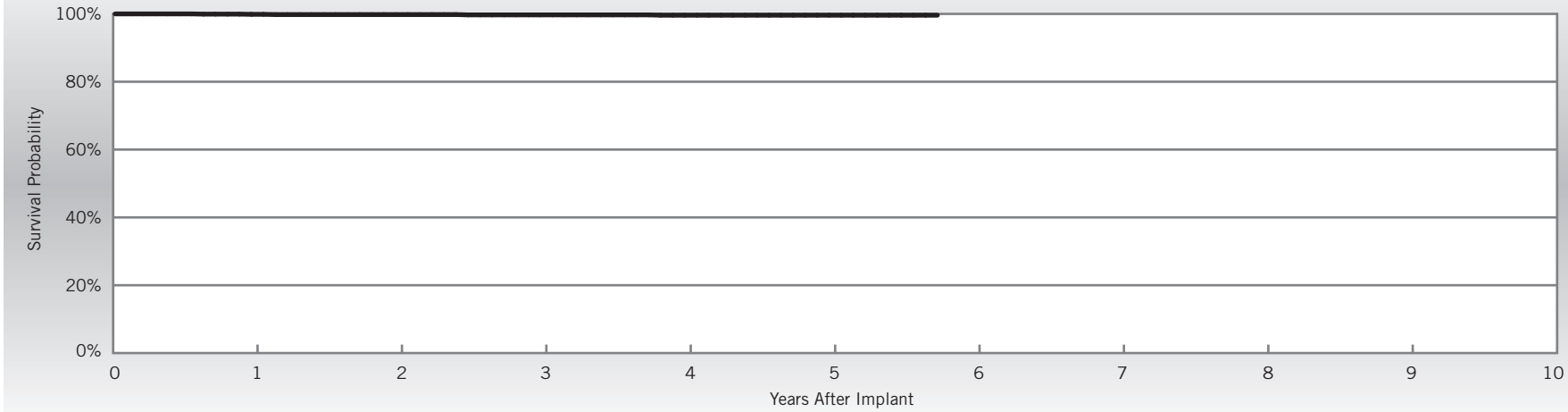
Unify™ CRT-D

Model CD3231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	1,676
Active Devices Enrolled in Study	862
Cumulative Months of Follow-up	70,867
Estimated Longevity	(see table on page 48)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	2	0.12%
Premature Battery Depletion	2	0.12%
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%	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	0.06%
Possible Early Battery Depletion	8	0.48%	1	0.06%
Other	2	0.12%	0	0.00%
Total	**11**	**0.66%**	**3**	**0.18%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	99.87%	99.80%	99.71%	99.61%	99.61%	99.61%				
± 1 standard error	0.07%	0.12%	0.14%	0.18%	0.18%	0.18%				
Sample Size	1,570	1,370	1,190	1,020	670	60				

**DF4-LLHH connector type.*

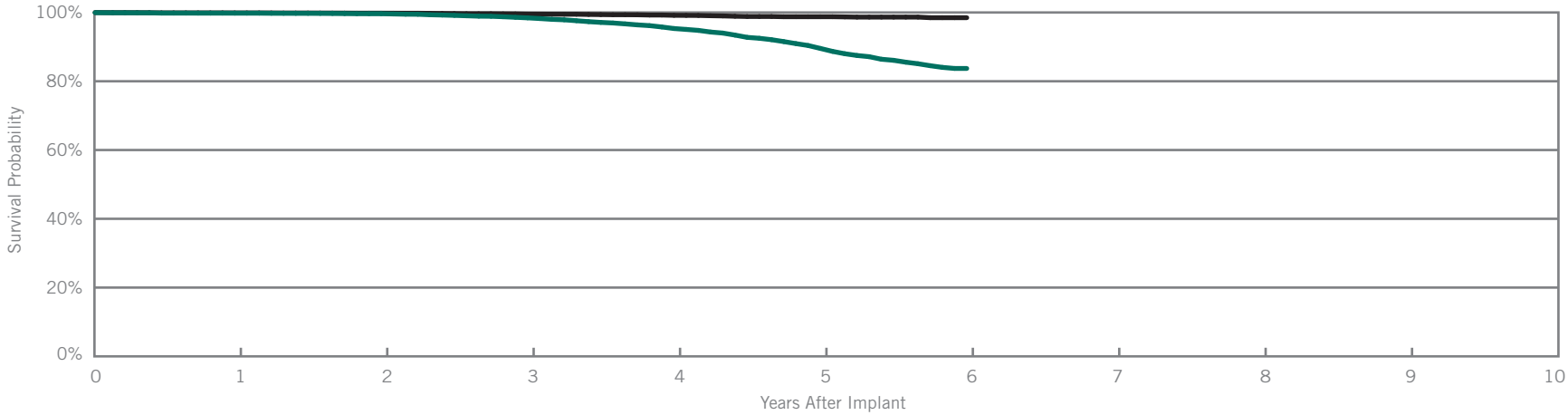
Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	20,475
Estimated Active US Implants	10,813
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	432
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	9	0.04%	4	0.02%
Electrical Interconnect	3	0.01%	0	0.00%
Battery	5	0.02%	2	<0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	0	0.00%
Possible Early Battery Depletion	16	0.08%	6	0.03%
Other	9	0.04%	11	0.05%
Total	**44**	**0.21%**	**23**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.79%	99.64%	98.43%	95.33%	89.54%	83.72%				
± 1 standard error	0.03%	0.04%	0.09%	0.17%	0.30%	0.60%				
Sample Size	19,110	16,700	14,660	12,050	7,510	400				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.88%	99.80%	99.52%	99.17%	98.76%	98.48%				
± 1 standard error	0.02%	0.03%	0.05%	0.07%	0.10%	0.17%				

Actively Monitored Study Data

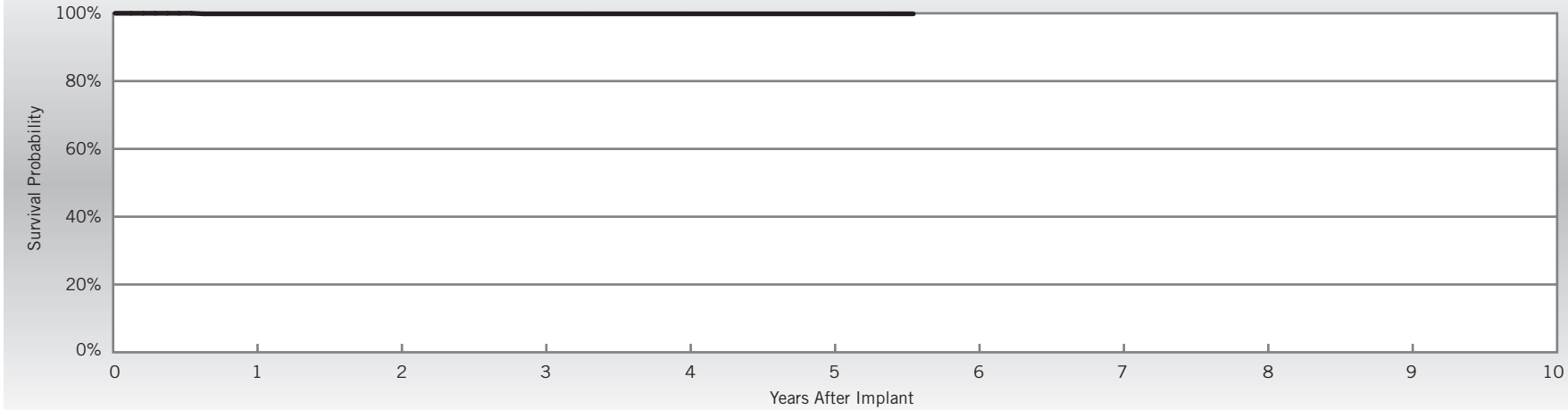
Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	683
Active Devices Enrolled in Study	286
Cumulative Months of Follow-up	26,291
Estimated Longevity	(see table on page 48)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Skin Erosion	1	0.15%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.15%	0	0.00%
Battery	0	0.00%	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%	0	0.00%
Total	**2**	**0.29%**	**3**	**0.44%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	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%				
Sample Size	630	510	420	360	230	50				

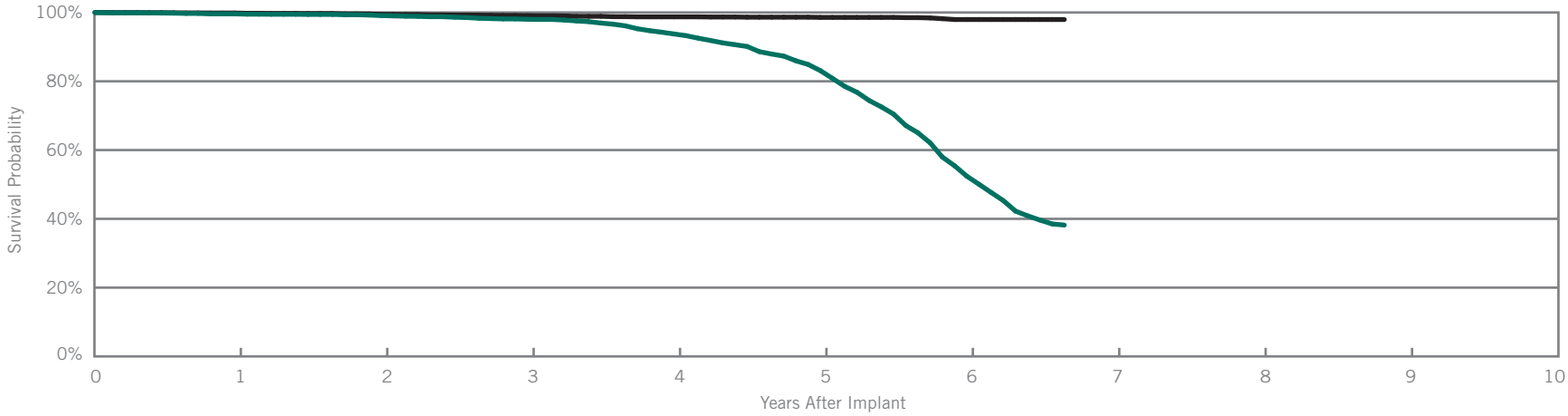
Promote™ + CRT-D

Model CD3211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	6,902
Estimated Active US Implants	1,730
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	841
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	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%	6	0.09%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	2	0.03%	0	0.00%
Other	5	0.07%	4	0.06%
Total	**22**	**0.32%**	**18**	**0.26%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.59%	99.10%	98.01%	93.75%	83.09%	52.41%	38.19%			
± 1 standard error	0.08%	0.11%	0.18%	0.34%	0.54%	0.80%	0.96%			
Sample Size	6,380	5,560	4,990	4,420	3,680	2,540	280			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.84%	99.46%	99.09%	98.73%	98.57%	97.95%	97.95%			
± 1 standard error	0.05%	0.09%	0.13%	0.16%	0.16%	0.24%	0.24%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

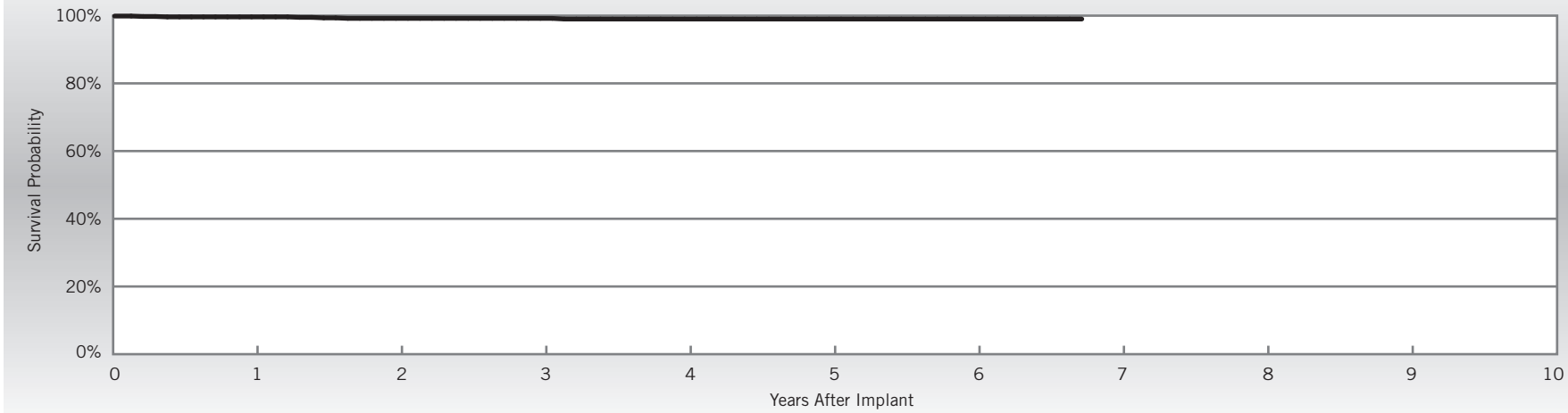
Promote™ + CRT-D

Model CD3211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	855
Active Devices Enrolled in Study	284
Cumulative Months of Follow-up	39,344
Estimated Longevity	(see table on page 48)
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%**



Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.63%	99.19%	99.19%	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%			
Sample Size	790	680	580	480	380	300	70			

**DF4-LLHH connector type.*

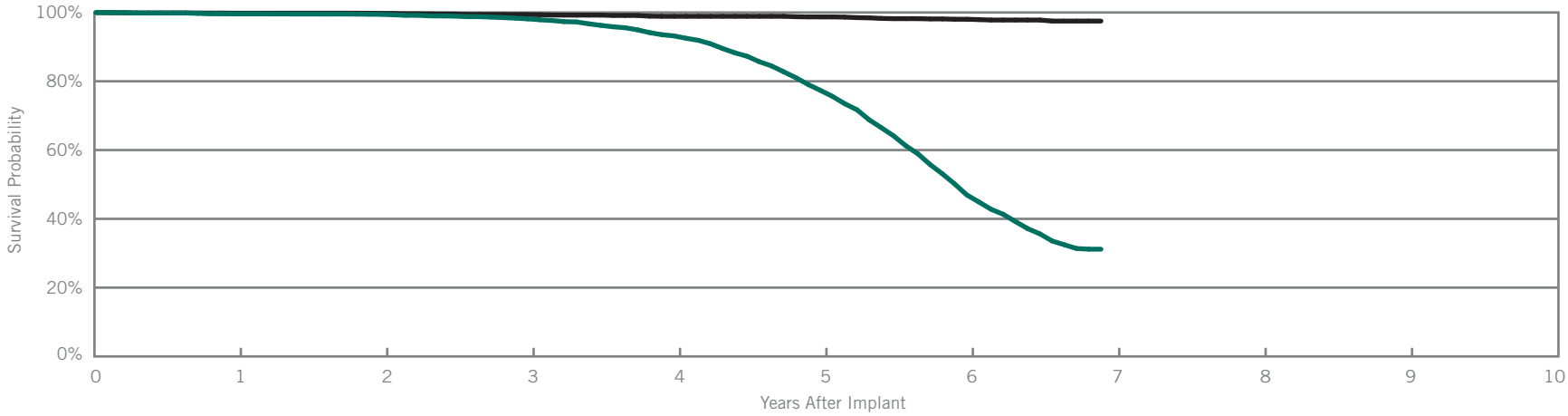
Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,644
Estimated Active US Implants	1,922
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	1,099
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	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%	9	0.10%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	3	0.03%	1	0.01%
Other	5	0.06%	3	0.03%
Total	**25**	**0.29%**	**20**	**0.23%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.59%	99.45%	98.14%	93.19%	77.36%	46.96%	31.18%			
± 1 standard error	0.07%	0.08%	0.16%	0.33%	0.58%	0.75%	0.85%			
Sample Size	8,000	6,910	6,070	5,210	4,150	2,740	290			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.79%	99.73%	99.39%	98.89%	98.71%	98.03%	97.50%			
± 1 standard error	0.05%	0.06%	0.09%	0.14%	0.15%	0.21%	0.32%			

Actively Monitored Study Data

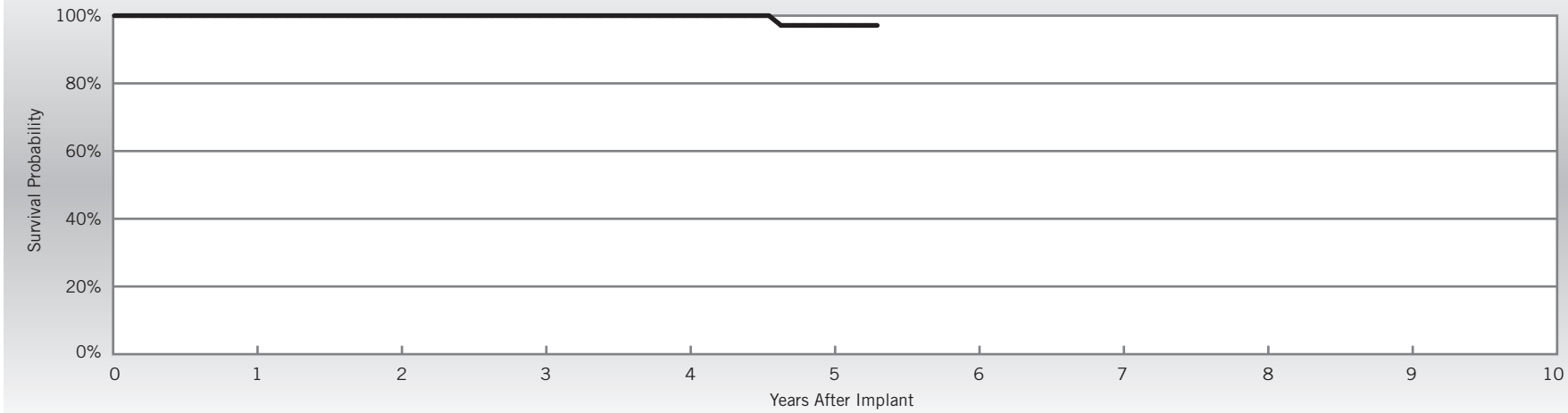
Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	225
Active Devices Enrolled in Study	45
Cumulative Months of Follow-up	9,121
Estimated Longevity	(see table on page 48)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Skin Erosion	2	0.89%

	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	0.89%
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**	**0.89%**



Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	100.00%	100.00%	100.00%	97.12%	97.12%				
± 1 standard error	0.00%	0.00%	0.00%	0.00%	2.01%	2.01%				
Sample Size	210	170	130	100	70	50				

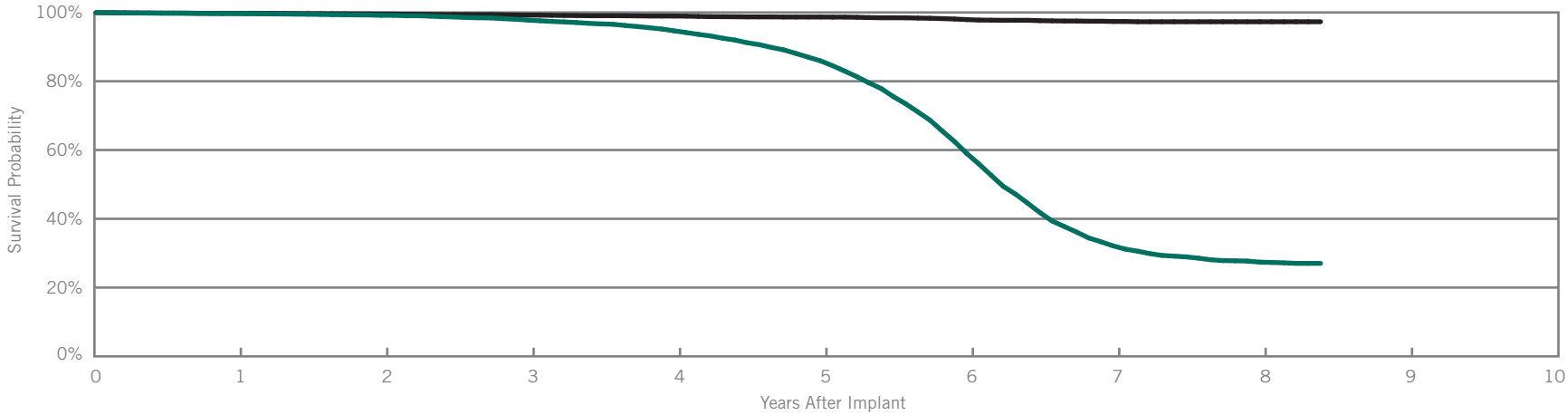
Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	24,004
Estimated Active US Implants	3,375
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	3,067
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	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	18	0.07%	9	0.04%
High Voltage Capacitor	5	0.02%	1	<0.01%
Software/Firmware	0	0.00%	15	0.06%
Mechanical	3	0.01%	9	0.04%
Possible Early Battery Depletion	10	0.04%	5	0.02%
Other	17	0.07%	17	0.07%
Total	**62**	**0.26%**	**65**	**0.27%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 101 months
Survival Probability	99.67%	99.17%	97.78%	94.66%	85.94%	59.00%	32.12%	27.40%	27.04%
± 1 standard error	0.04%	0.06%	0.10%	0.17%	0.29%	0.45%	0.46%	0.47%	0.50%
Sample Size	22,180	19,030	16,540	14,270	11,760	8,410	4,580	1,680	240

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 101 months
Survival Probability	99.77%	99.54%	99.24%	98.96%	98.67%	97.92%	97.38%	97.30%	97.30%
± 1 standard error	0.03%	0.04%	0.06%	0.08%	0.09%	0.12%	0.17%	0.18%	0.18%

Actively Monitored Study Data

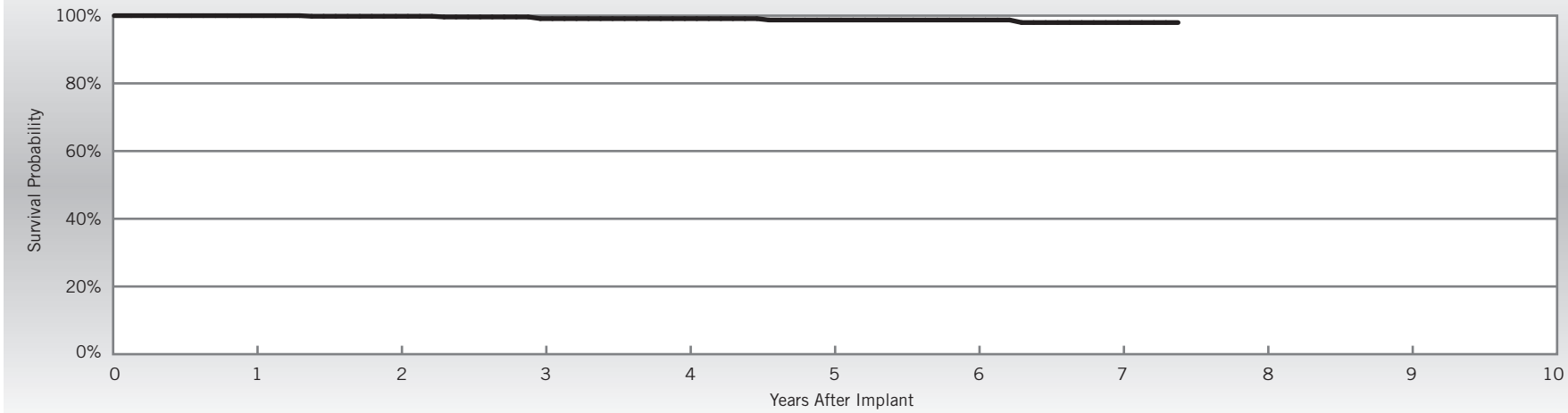
Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	674
Active Devices Enrolled in Study	95
Cumulative Months of Follow-up	30,338
Estimated Longevity	(see table on page 48)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.15%
Premature Battery Depletion	3	0.45%
Skin Erosion	2	0.30%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.15%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.15%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
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%**	**4**	**0.59%**



Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	100.00%	99.82%	99.12%	99.12%	98.72%	98.72%	97.96%	97.96%		
± 1 standard error	0.00%	0.18%	0.28%	0.44%	0.59%	0.59%	0.96%	0.96%		
Sample Size	630	550	450	340	250	180	110	50		

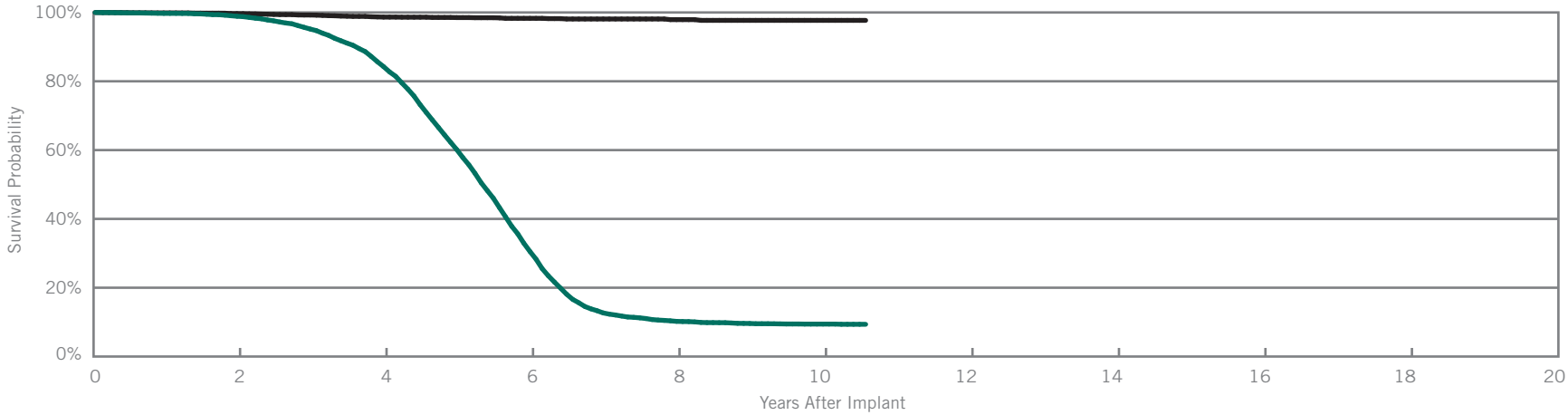
Atlas™ + HF CRT-D

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,777
Estimated Active US Implants	904
Estimated Longevity	(see table on page 48)
Normal Battery Depletion	3,434
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 299, 300)	Two

Customer Reported Performance Data

	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	at 127 months				
Survival Probability	98.89%	84.27%	30.52%	10.22%	9.43%	9.37%				
± 1 standard error	0.08%	0.32%	0.49%	0.31%	0.30%	0.30%				
Sample Size	15,080	10,270	4,130	1,150	610	210				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 127 months				
Survival Probability	99.67%	98.65%	98.29%	97.91%	97.70%	97.70%				
± 1 standard error	0.05%	0.10%	0.14%	0.21%	0.26%	0.26%				

Battery Longevity Summary

CRT ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3369-40Q	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

CRT ICDs

St. Jude Medical

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		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*										
CD3365-40Q	Quadra Assura™ CRT-D	99.76%	99.45%								
CD3365-40C	Quadra Assura™ CRT-D	99.83%	99.27%								
CD3357-40Q	Unify Assura™ CRT-D	99.78%	99.64%								
CD3357-40C	Unify Assura™ CRT-D	99.88%	99.68%								
CD3265-40Q	Quadra Assura™ CRT-D	99.83%	99.74%	99.40%	98.70%						
CD3265-40	Quadra Assura™ CRT-D	99.89%	99.70%	99.64%							
CD3257-40Q	Unify Assura™ CRT-D	99.92%	99.73%	98.82%							
CD3257-40	Unify Assura™ CRT-D	99.81%	99.63%	98.70%							
CD3249-40Q	Unify Quadra™ CRT-D	99.87%	99.84%	99.37%	98.14%						
CD3249-40	Unify Quadra™ CRT-D	99.92%	99.92%	99.60%	97.86%						
CD3231-40Q	Unify™ CRT-D	99.77%	99.70%	99.05%	97.17%	92.72%	86.37%				
CD3231-40	Unify™ CRT-D	99.79%	99.64%	98.43%	95.33%	89.54%	83.72%				
CD3211-36Q	Promote™ + CRT-D	99.59%	99.10%	98.01%	93.75%	83.09%	52.41%				
CD3211-36	Promote™ + CRT-D	99.59%	99.45%	98.14%	93.19%	77.36%	46.96%				
3207-36	Promote™ RF CRT-D	99.67%	99.17%	97.78%	94.66%	85.94%	59.00%	32.12%	27.40%		
V-343	Atlas™ + HF CRT-D	99.73%	98.89%	95.17%	84.27%	60.14%	30.52%	12.67%	10.22%	9.61%	9.43%

**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.*

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		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*										
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.54%								
CD3365-40C	Quadra Assura™ CRT-D	99.93%	99.37%								
CD3357-40Q	Unify Assura™ CRT-D	99.90%	99.75%								
CD3357-40C	Unify Assura™ CRT-D	99.92%	99.77%								
CD3265-40Q	Quadra Assura™ CRT-D	99.87%	99.85%	99.71%	99.57%						
CD3265-40	Quadra Assura™ CRT-D	99.89%	99.76%	99.70%							
CD3257-40Q	Unify Assura™ CRT-D	100.00%	100.00%	99.90%							
CD3257-40	Unify Assura™ CRT-D	99.90%	99.83%	99.55%							
CD3249-40Q	Unify Quadra™ CRT-D	99.95%	99.95%	99.85%	99.63%						
CD3249-40	Unify Quadra™ CRT-D	99.92%	99.92%	99.92%	99.80%						
CD3231-40Q	Unify™ CRT-D	99.88%	99.83%	99.68%	99.22%	98.37%	97.66%				
CD3231-40	Unify™ CRT-D	99.88%	99.80%	99.52%	99.17%	98.76%	98.48%				
CD3211-36Q	Promote™ + CRT-D	99.84%	99.46%	99.09%	98.73%	98.57%	97.95%				
CD3211-36	Promote™ + CRT-D	99.79%	99.73%	99.39%	98.89%	98.71%	98.03%				
3207-36	Promote™ RF CRT-D	99.77%	99.54%	99.24%	98.96%	98.67%	97.92%	97.38%	97.30%		
V-343	Atlas™ + HF CRT-D	99.88%	99.67%	99.25%	98.65%	98.51%	98.29%	98.10%	97.91%	97.70%	97.70%

**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.*

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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	1,563	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3365-40Q	Quadra Assura™ CRT-D	34,955	1.50%	3	<0.01%	7	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	<0.01%	3	<0.01%	**16**	**0.05%**
CD3365-40C	Quadra Assura™ CRT-D	6,852	2.10%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	**4**	**0.06%**
CD3357-40Q	Unify Assura™ CRT-D	7,693	2.10%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**4**	**0.05%**
CD3357-40C	Unify Assura™ CRT-D	12,844	1.80%	1	<0.01%	2	0.02%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**5**	**0.04%**
CD3265-40Q	Quadra Assura™ CRT-D	13,523	3.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	1	<0.01%	**7**	**0.05%**
CD3265-40	Quadra Assura™ CRT-D	4,020	3.70%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.05%	**3**	**0.07%**
CD3257-40Q	Unify Assura™ CRT-D	2,710	4.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.07%	0	0.00%	**2**	**0.07%**
CD3257-40	Unify Assura™ CRT-D	6,729	4.00%	4	0.06%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	1	0.01%	**8**	**0.12%**
CD3249-40Q	Unify Quadra™ CRT-D	8,931	3.40%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.06%	2	0.02%	**10**	**0.11%**
CD3249-40	Unify Quadra™ CRT-D	2,520	5.20%	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	18,986	6.40%	2	0.01%	1	<0.01%	9	0.05%	8	0.04%	0	0.00%	1	<0.01%	38	0.20%	5	0.03%	**64**	**0.34%**
CD3231-40	Unify™ CRT-D	20,475	7.80%	9	0.04%	3	0.01%	5	0.02%	1	<0.01%	0	0.00%	1	<0.01%	16	0.08%	9	0.04%	**44**	**0.21%**
CD3211-36Q	Promote™ + CRT-D	6,902	20.50%	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	8,644	23.40%	3	0.03%	0	0.00%	11	0.13%	2	0.02%	1	0.01%	0	0.00%	3	0.03%	5	0.06%	**25**	**0.29%**
3207-36	Promote™ RF CRT-D	24,004	25.60%	4	0.02%	5	0.02%	18	0.07%	5	0.02%	0	0.00%	3	0.01%	10	0.04%	17	0.07%	**62**	**0.26%**
V-343	Atlas™ + HF CRT-D	18,777	24.90%	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 7-8.

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromized Therapy															
				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	1,563	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3365-40Q	Quadra Assura™ CRT-D	34,955	1.50%	5	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	5	0.01%	5	0.01%	0	0.00%	**17**	**0.05%**
CD3365-40C	Quadra Assura™ CRT-D	6,852	2.10%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**4**	**0.06%**
CD3357-40Q	Unify Assura™ CRT-D	7,693	2.10%	0	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%**
CD3357-40C	Unify Assura™ CRT-D	12,844	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**	**0.02%**
CD3265-40Q	Quadra Assura™ CRT-D	13,523	3.00%	3	0.02%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	2	0.01%	1	<0.01%	0	0.00%	**8**	**0.06%**
CD3265-40	Quadra Assura™ CRT-D	4,020	3.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	**2**	**0.05%**
CD3257-40Q	Unify Assura™ CRT-D	2,710	4.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3257-40	Unify Assura™ CRT-D	6,729	4.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**4**	**0.06%**
CD3249-40Q	Unify Quadra™ CRT-D	8,931	3.40%	0	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%**
CD3249-40	Unify Quadra™ CRT-D	2,520	5.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	**1**	**0.04%**
CD3231-40Q	Unify™ CRT-D	18,986	6.40%	3	0.02%	0	0.00%	2	0.01%	2	0.01%	1	<0.01%	2	0.01%	11	0.06%	2	0.01%	**23**	**0.12%**
CD3231-40	Unify™ CRT-D	20,475	7.80%	4	0.02%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.03%	11	0.05%	**23**	**0.11%**
CD3211-36Q	Promote™ + CRT-D	6,902	20.50%	3	0.04%	0	0.00%	5	0.07%	0	0.00%	6	0.09%	0	0.00%	0	0.00%	4	0.06%	**18**	**0.26%**
CD3211-36	Promote™ + CRT-D	8,644	23.40%	3	0.03%	0	0.00%	3	0.03%	0	0.00%	9	0.10%	1	0.01%	1	0.01%	3	0.03%	**20**	**0.23%**
3207-36	Promote™ RF CRT-D	24,004	25.60%	6	0.02%	3	0.01%	9	0.04%	1	<0.01%	15	0.06%	9	0.04%	5	0.02%	17	0.07%	**65**	**0.27%**
V-343	Atlas™ + HF CRT-D	18,777	24.90%	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 7-8.

Worldwide Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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	2,712	0.04%	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%**
CD3365-40Q	Quadra Assura™ CRT-D	35,804	1.77%	3	<0.01%	7	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	<0.01%	3	<0.01%	**16**	**0.04%**
CD3365-40C	Quadra Assura™ CRT-D	7,087	2.71%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	**4**	**0.06%**
CD3357-40Q	Unify Assura™ CRT-D	8,055	2.59%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**4**	**0.05%**
CD3357-40C	Unify Assura™ CRT-D	13,373	2.23%	1	<0.01%	2	0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**5**	**0.04%**
CD3265-40Q	Quadra Assura™ CRT-D	13,970	3.37%	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	1	<0.01%	**8**	**0.06%**
CD3265-40	Quadra Assura™ CRT-D	4,049	4.42%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.05%	**3**	**0.07%**
CD3257-40Q	Unify Assura™ CRT-D	2,736	5.52%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.07%	0	0.00%	**2**	**0.07%**
CD3257-40	Unify Assura™ CRT-D	6,734	4.47%	4	0.06%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	1	0.01%	**8**	**0.12%**
CD3249-40Q	Unify Quadra™ CRT-D	10,446	3.61%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.05%	2	0.02%	**10**	**0.10%**
CD3249-40	Unify Quadra™ CRT-D	3,299	5.27%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**
CD3231-40Q	Unify™ CRT-D	20,945	6.93%	3	0.01%	1	<0.01%	10	0.05%	8	0.04%	0	0.00%	1	<0.01%	46	0.22%	7	0.03%	**76**	**0.36%**
CD3231-40	Unify™ CRT-D	21,865	8.04%	9	0.04%	4	0.02%	5	0.02%	1	<0.01%	0	0.00%	1	<0.01%	18	0.08%	9	0.04%	**47**	**0.21%**
CD3211-36Q	Promote™ + CRT-D	15,779	11.21%	12	0.08%	0	0.00%	11	0.07%	3	0.02%	1	<0.01%	2	0.01%	6	0.04%	5	0.03%	**40**	**0.25%**
CD3211-36	Promote™ + CRT-D	20,600	10.84%	13	0.06%	2	<0.01%	15	0.07%	4	0.02%	1	<0.01%	0	0.00%	5	0.02%	10	0.05%	**50**	**0.24%**
3207-36	Promote™ RF CRT-D	25,838	25.47%	5	0.02%	5	0.02%	21	0.08%	5	0.02%	0	0.00%	3	0.01%	10	0.04%	20	0.08%	**69**	**0.27%**
V-343	Atlas™ + HF CRT-D	19,292	24.69%	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 7-8.

Worldwide Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromized Therapy															
				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	2,712	0.04%	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%**
CD3365-40Q	Quadra Assura™ CRT-D	35,804	1.77%	5	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	5	0.01%	5	0.01%	0	0.00%	**17**	**0.05%**
CD3365-40C	Quadra Assura™ CRT-D	7,087	2.71%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**4**	**0.06%**
CD3357-40Q	Unify Assura™ CRT-D	8,055	2.59%	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%**
CD3357-40C	Unify Assura™ CRT-D	13,373	2.23%	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**	**0.02%**
CD3265-40Q	Quadra Assura™ CRT-D	13,970	3.37%	3	0.02%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	2	0.01%	1	<0.01%	0	0.00%	**8**	**0.06%**
CD3265-40	Quadra Assura™ CRT-D	4,049	4.42%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	**2**	**0.05%**
CD3257-40Q	Unify Assura™ CRT-D	2,736	5.52%	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%**
CD3257-40	Unify Assura™ CRT-D	6,734	4.47%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**4**	**0.06%**
CD3249-40Q	Unify Quadra™ CRT-D	10,446	3.61%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**3**	**0.03%**
CD3249-40	Unify Quadra™ CRT-D	3,299	5.27%	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%**
CD3231-40Q	Unify™ CRT-D	20,945	6.93%	4	0.02%	0	0.00%	2	<0.01%	2	<0.01%	1	<0.01%	3	0.01%	12	0.06%	2	<0.01%	**26**	**0.12%**
CD3231-40	Unify™ CRT-D	21,865	8.04%	5	0.02%	0	0.00%	4	0.02%	0	0.00%	1	<0.01%	0	0.00%	6	0.03%	11	0.05%	**27**	**0.12%**
CD3211-36Q	Promote™ + CRT-D	15,779	11.21%	6	0.04%	0	0.00%	7	0.04%	0	0.00%	7	0.04%	2	0.01%	2	0.01%	6	0.04%	**30**	**0.19%**
CD3211-36	Promote™ + CRT-D	20,600	10.84%	6	0.03%	0	0.00%	4	0.02%	0	0.00%	11	0.05%	2	<0.01%	2	<0.01%	6	0.03%	**31**	**0.15%**
3207-36	Promote™ RF CRT-D	25,838	25.47%	7	0.03%	3	0.01%	10	0.04%	1	<0.01%	16	0.06%	9	0.03%	6	0.02%	18	0.07%	**70**	**0.27%**
V-343	Atlas™ + HF CRT-D	19,292	24.69%	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 7-8.

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	177	129	4,082	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3357-40Q	136	119	1,760	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3357-40C	103	81	1,614	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3265-40Q	419	277	11,258	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40Q	991	610	31,460	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	**1**	**0.10%**
CD3249-40	242	138	7,539	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.41%	**1**	**0.41%**
CD3231-40Q	1,676	862	70,867	2	0.12%	0	0.00%	0	0.00%	2	0.12%	1	0.06%	**5**	**0.30%**
CD3231-40	683	286	26,291	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	**1**	**0.15%**
CD3211-36Q	855	284	39,344	3	0.35%	0	0.00%	0	0.00%	2	0.23%	2	0.23%	**7**	**0.82%**
CD3211-36	225	45	9,121	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.89%	**2**	**0.89%**
3207-36	674	95	30,338	1	0.15%	0	0.00%	0	0.00%	3	0.45%	2	0.30%	**6**	**0.89%**

A list of of complications can be found on page 15.

Actively Monitored Study Data Summary

Malfunctions

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy															
				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	177	4.50%	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%**
CD3357-40Q	Unify Assura™ CRT-D	136	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%**
CD3357-40C	Unify Assura™ CRT-D	103	1.00%	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%**
CD3265-40Q	Quadra Assura™ CRT-D	419	3.80%	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%**
CD3249-40Q	Unify Quadra™ CRT-D	991	3.20%	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%**
CD3249-40	Unify Quadra™ CRT-D	242	5.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	Unify™ CRT-D	1,676	7.60%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	8	0.48%	2	0.12%	**11**	**0.66%**
CD3231-40	Unify™ CRT-D	683	10.00%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	0	0.00%	**2**	**0.29%**
CD3211-36Q	Promote™ + CRT-D	855	26.10%	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	225	20.40%	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%**
3207-36	Promote™ RF CRT-D	674	33.40%	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%**

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy															
				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	177	4.50%	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%**
CD3357-40Q	Unify Assura™ CRT-D	136	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%**
CD3357-40C	Unify Assura™ CRT-D	103	1.00%	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%**
CD3265-40Q	Quadra Assura™ CRT-D	419	3.80%	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%**
CD3249-40Q	Unify Quadra™ CRT-D	991	3.20%	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	242	5.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	Unify™ CRT-D	1,676	7.60%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.06%	1	0.06%	0	0.00%	**3**	**0.18%**
CD3231-40	Unify™ CRT-D	683	10.00%	0	0.00%	0	0.00%	2	0.29%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.44%**
CD3211-36Q	Promote™ + CRT-D	855	26.10%	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	225	20.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.89%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.89%**
3207-36	Promote™ RF CRT-D	674	33.40%	1	0.15%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	1	0.15%	**4**	**0.59%**

Definitions of malfunction categories can be found on pages 7-8.

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical

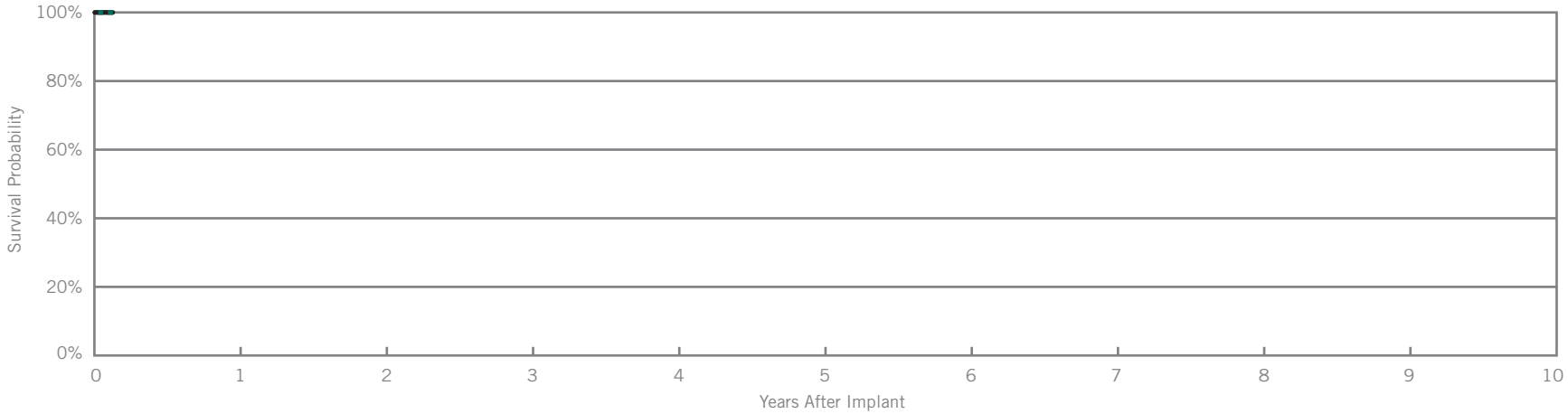
Allure Quadra MP™ CRT-P

Model PM3262

US Regulatory Approval	February 2016
Registered US Implants	743
Estimated Active US Implants	729
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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	at 2 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	300										

Excluding Normal Battery Depletion

Year	at 2 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

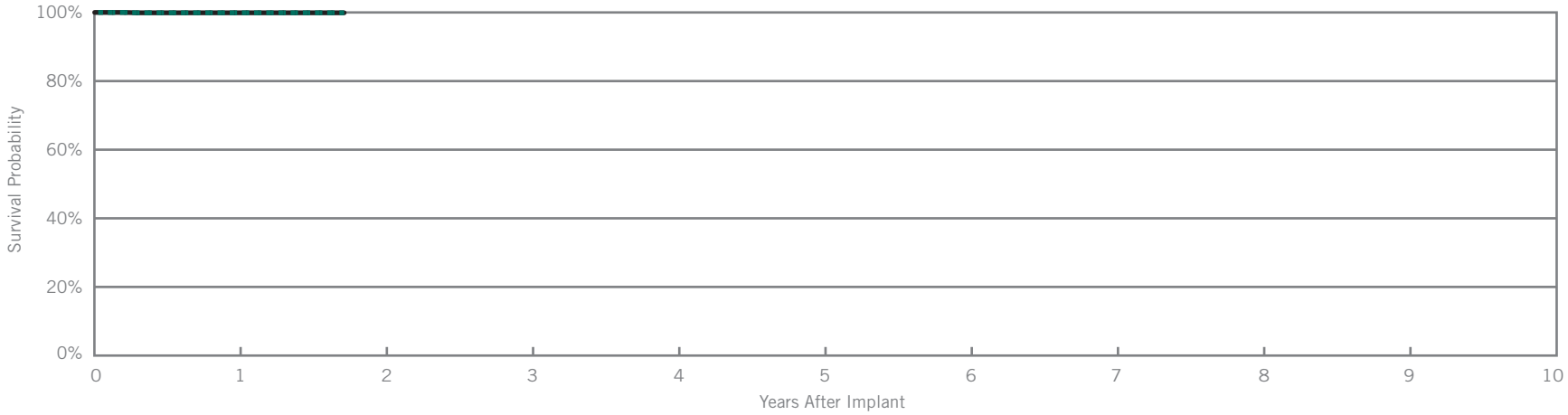
Allure™ RF CRT-P

Model PM3222

US Regulatory Approval	March 2014
Registered US Implants	2,642
Estimated Active US Implants	2,340
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.04%**



Including Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.90%	99.90%								
± 1 standard error	0.07%	0.07%								
Sample Size	1,780	250								

Excluding Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.90%	99.90%								
± 1 standard error	0.07%	0.07%								

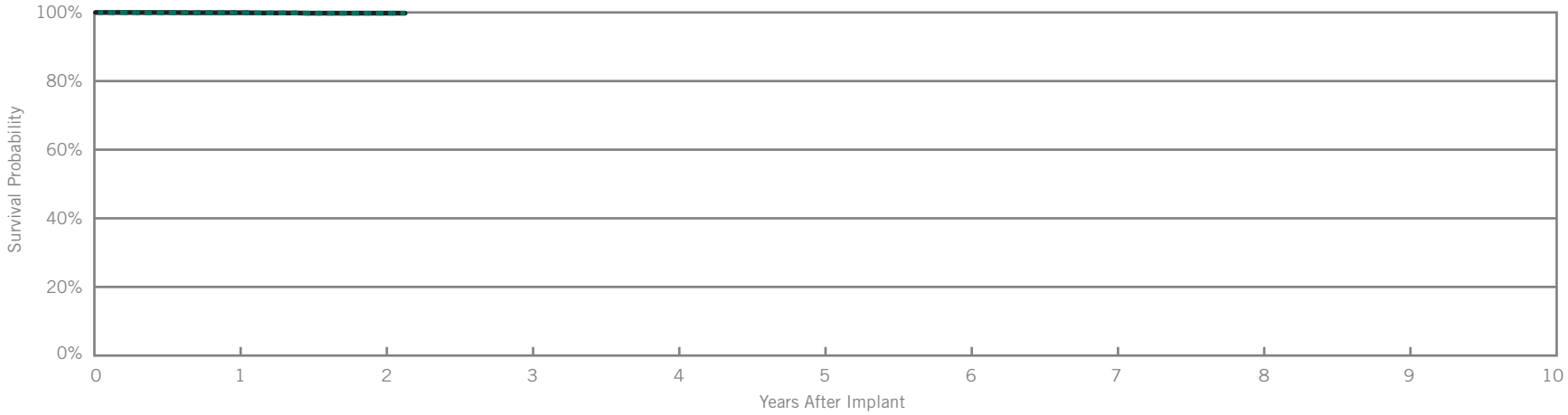
Allure Quadra™ RF CRT-P

Model PM3242

US Regulatory Approval	March 2014
Registered US Implants	16,032
Estimated Active US Implants	14,267
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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%	6	0.04%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**6**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.92%	99.79%	99.79%							
± 1 standard error	0.03%	0.06%	0.06%							
Sample Size	11,700	4,080	440							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.92%	99.79%	99.79%							
± 1 standard error	0.03%	0.06%	0.06%							

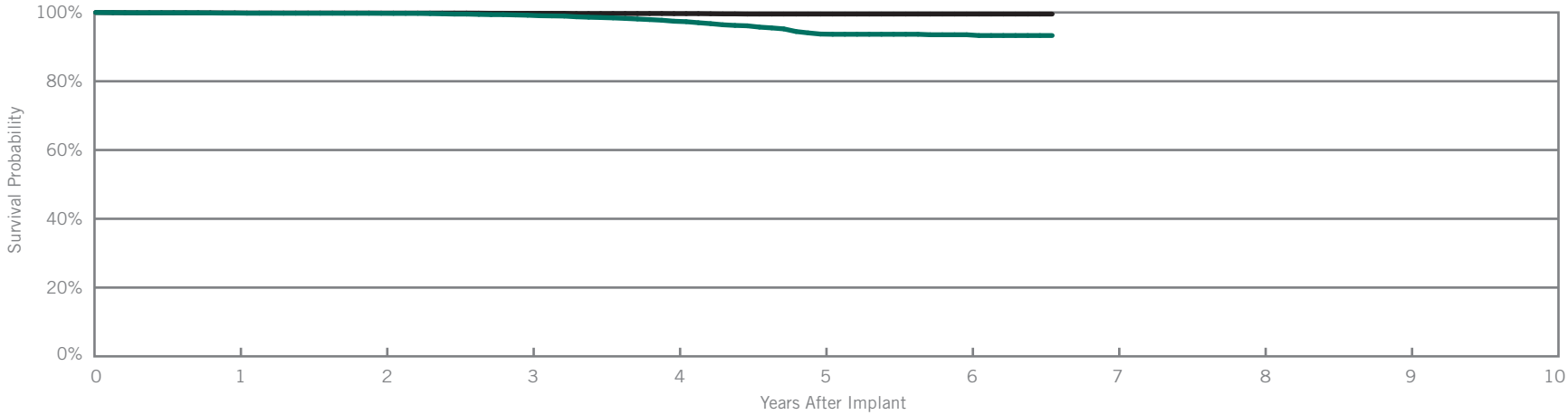
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	20,445
Estimated Active US Implants	11,874
Estimated Longevity	8 Years
Normal Battery Depletion	147
Number of US Advisories (see pg. 303)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	3	0.01%
Electrical Interconnect	3	0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	5	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	<0.01%	3	0.01%
Other	0	0.00%	7	0.03%
Total	**7**	**0.03%**	**18**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.82%	99.76%	99.20%	97.45%	93.72%	93.52%	93.29%			
± 1 standard error	0.03%	0.04%	0.07%	0.15%	0.31%	0.34%	0.38%			
Sample Size	18,870	16,030	12,420	8,160	4,720	2,050	260			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.87%	99.83%	99.75%	99.66%	99.54%	99.54%	99.54%			
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.07%	0.07%	0.07%			

Actively Monitored Study Data

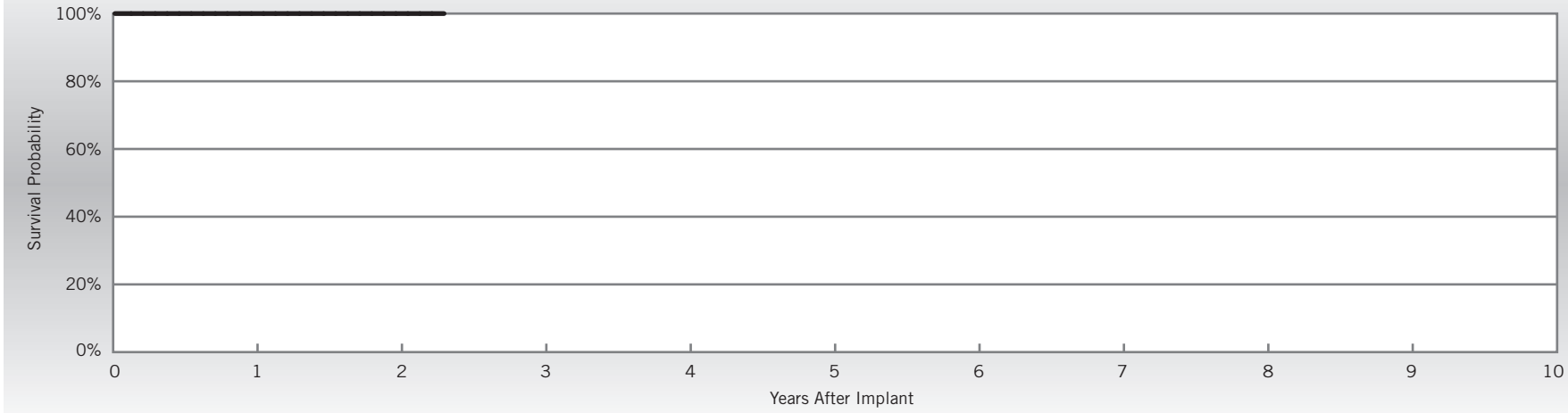
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	199
Active Devices Enrolled in Study	30
Cumulative Months of Follow-up	4,507
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%**



Year	1	2	at 28 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	170	100	50							

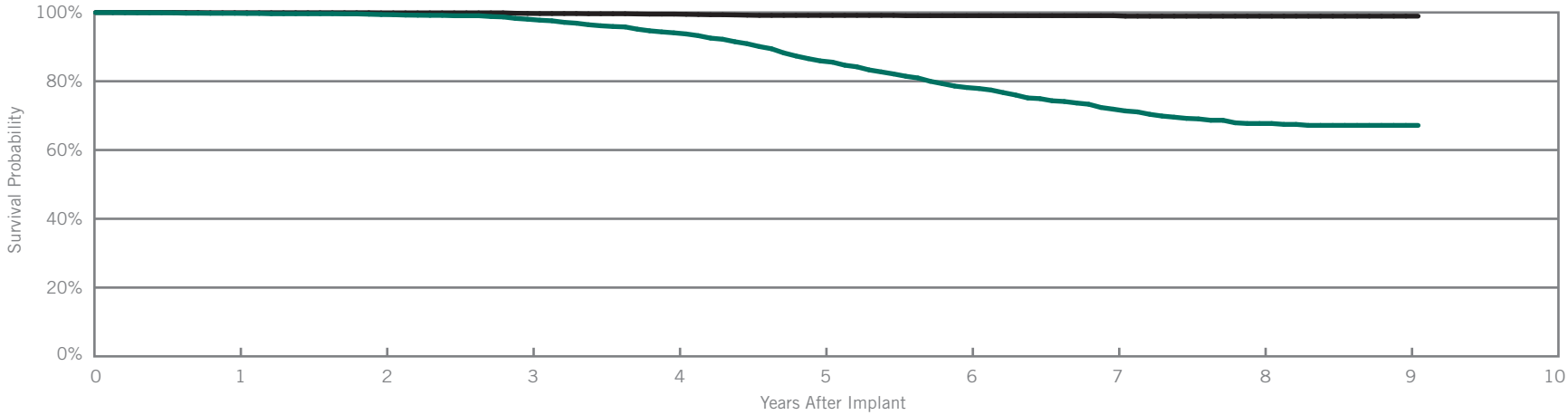
Frontier™ II CRT-P

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,909
Estimated Active US Implants	1,247
Estimated Longevity	6.5 Years
Normal Battery Depletion	376
Number of US Advisories	None

Customer Reported Performance Data

	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	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.76%	99.39%	98.04%	94.08%	85.91%	78.17%	71.88%	67.71%	67.16%	67.16%
± 1 standard error	0.06%	0.10%	0.19%	0.36%	0.56%	0.71%	0.81%	0.93%	0.97%	0.97%
Sample Size	6,250	5,210	4,480	3,800	3,130	2,490	1,800	1,010	410	210

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.93%	99.89%	99.72%	99.52%	99.15%	99.07%	99.07%	98.93%	98.93%	98.93%
± 1 standard error	0.03%	0.03%	0.07%	0.11%	0.15%	0.16%	0.16%	0.19%	0.19%	0.19%

Summary Information

CRT Pacemakers

St. Jude Medical

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		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*										
PM3222	Allure™ RF CRT-P*	99.90%									
PM3242	Allure Quadra™ RF CRT-P	99.92%	99.79%								
PM3210	Anthem™ RF CRT-P	99.82%	99.76%	99.20%	97.45%	93.72%	93.52%				
5586	Frontier™ II CRT-P	99.76%	99.39%	98.04%	94.08%	85.91%	78.17%	71.88%	67.71%	67.16%	

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		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*										
PM3222	Allure™ RF CRT-P*	99.90%									
PM3242	Allure Quadra™ RF CRT-P	99.92%	99.79%								
PM3210	Anthem™ RF CRT-P	99.87%	99.83%	99.75%	99.66%	99.54%	99.54%				
5586	Frontier™ II CRT-P	99.93%	99.89%	99.72%	99.52%	99.15%	99.07%	99.07%	98.93%	98.93%	

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

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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	743	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	2,642	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM3242	Allure Quadra™ RF CRT-P	16,032	0.50%	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	20,445	4.30%	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	6,909	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%**

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/o Compromised Therapy															
				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	743	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	2,642	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	**1**	**0.04%**
PM3242	Allure Quadra™ RF CRT-P	16,032	0.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	0	0.00%	0	0.00%	**6**	**0.04%**
PM3210	Anthem™ RF CRT-P	20,445	4.30%	3	0.01%	0	0.00%	0	0.00%	5	0.02%	0	0.00%	3	0.01%	7	0.03%	**18**	**0.09%**
5586	Frontier™ II CRT-P	6,909	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 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ Compromised Therapy															
				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	5,939	0.19%	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	9,440	0.99%	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	29,547	1.23%	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	21,084	6.20%	3	0.01%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**7**	**0.03%**

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromised Therapy															
				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	5,939	0.19%	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	9,440	0.99%	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	29,547	1.23%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.02%	1	<0.01%	1	<0.01%	**9**	**0.03%**
PM3210	Anthem™ RF CRT-P	21,084	6.20%	2	<0.01%	0	0.00%	0	0.00%	5	0.02%	0	0.00%	3	0.01%	7	0.03%	**17**	**0.08%**

Definitions of malfunction categories can be found on pages 7-8.

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
PM3210	199	30	4,507	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy																	
				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
PM3210	Anthem™ RF	199	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%	**0**	**0.00%**

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy																	
				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
PM3210	Anthem™ RF	199	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%	**0**	**0.00%**

Left-Heart Leads

St. Jude Medical

Customer Reported Performance Data

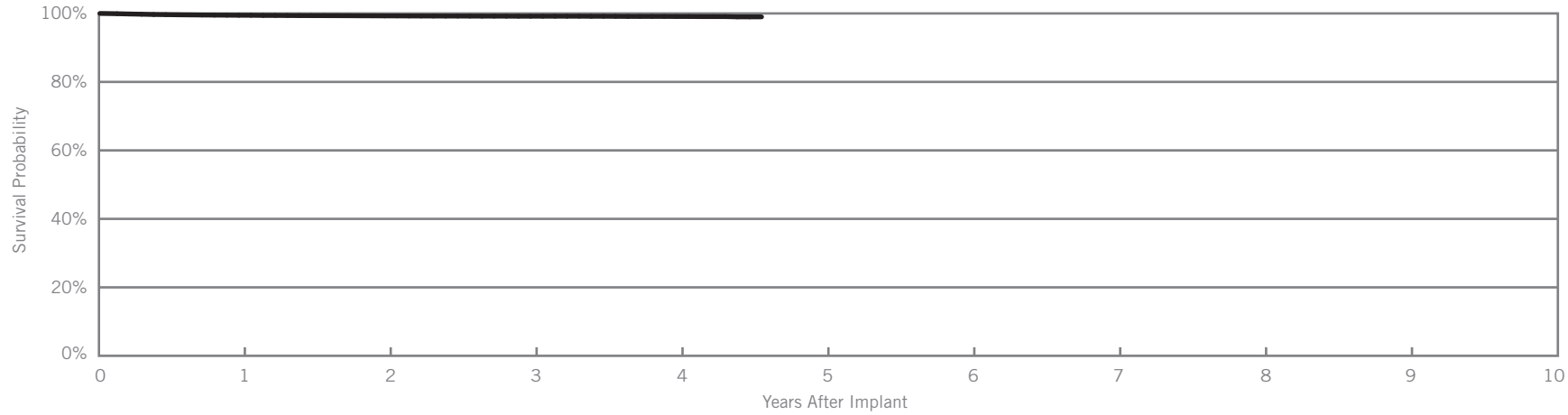
Quartet™

Model 1458Q

US Regulatory Approval	November 2011
Registered US Implants	95,968
Estimated Active US Implants	84,654
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	<0.01%	2	<0.01%
Conductor Fracture	0	0.00%	6	<0.01%
Lead Dislodgement	125	0.13%	459	0.48%
Failure to Capture	55	0.06%	151	0.16%
Oversensing	2	<0.01%	5	<0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	<0.01%	2	<0.01%
Abnormal Pacing Impedance	4	<0.01%	22	0.02%
Extracardiac Stimulation	62	0.06%	91	0.09%
Other	67	0.07%	21	0.02%
Total	**318**	**0.33%**	**759**	**0.79%**
Total Returned for Analysis	**119**		**326**	

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	1	<0.01%
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	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	7	<0.01%
Extrinsic Factors	317	0.33%
Total	**328**	**0.34%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.47%	99.28%	99.19%	99.11%	99.00%					
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.10%					
Sample Size	78,800	47,790	25,270	10,710	390					

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

Actively Monitored Study Data

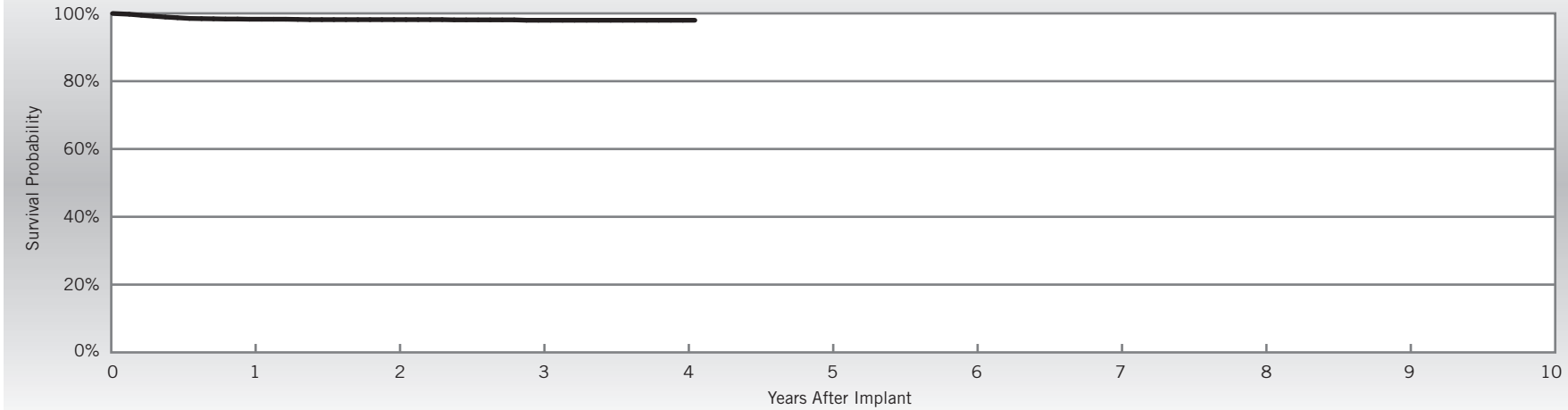
Quartet™

Model 1458Q

US Regulatory Approval	November 2011
Number of Devices Enrolled in Study	2,050
Active Devices Enrolled in Study	1,286
Cumulative Months of Follow-up	58,949
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	0.15%
Failure to Capture	2	0.10%
Lead Dislodgement	31	1.51%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	18	0.88%
Total	**18**	**0.88%**



Year	1	2	3	4	at 49 months					
Survival Probability	98.28%	98.16%	97.98%	97.98%	97.98%					
± 1 standard error	0.29%	0.31%	0.33%	0.33%	0.33%					
Sample Size	1,890	1,560	1,100	440	60					

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

Customer Reported Performance Data

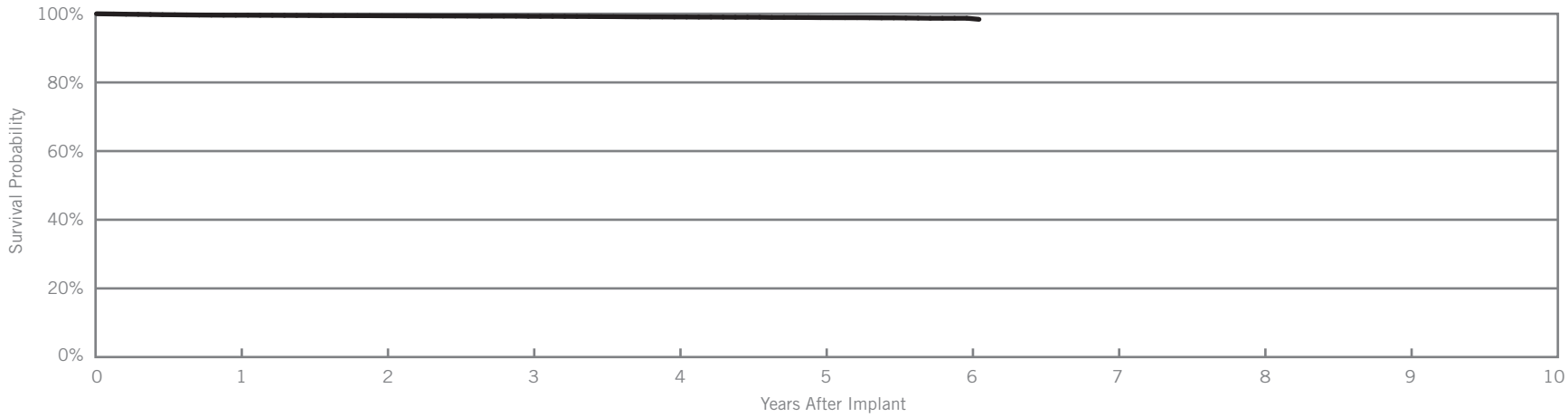
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	45,325
Estimated Active US Implants	29,048
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%	0	0.00%
Conductor Fracture	0	0.00%	15	0.03%
Lead Dislodgement	45	0.10%	160	0.35%
Failure to Capture	16	0.04%	111	0.24%
Oversensing	0	0.00%	9	0.02%
Failure to Sense	1	<0.01%	1	<0.01%
Insulation Breach	0	0.00%	4	<0.01%
Abnormal Pacing Impedance	5	0.01%	28	0.06%
Extracardiac Stimulation	19	0.04%	57	0.13%
Other	12	0.03%	5	0.01%
Total	**98**	**0.22%**	**390**	**0.86%**
Total Returned for Analysis	**52**		**169**	

Malfunctions	Qty.	Rate
Conductor Fracture	5	0.01%
Clavicular Crush	1	<0.01%
In the Pocket	1	<0.01%
Intravascular	3	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contact	0	0.00%
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	1	<0.01%
Extrinsic Factors	187	0.41%
Total	**195**	**0.43%**



Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.58%	99.42%	99.27%	99.07%	98.88%	98.70%	98.38%			
± 1 standard error	0.03%	0.04%	0.04%	0.06%	0.07%	0.10%	0.10%			
Sample Size	41,230	33,960	26,470	18,600	11,250	3,960	460			

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

Actively Monitored Study Data

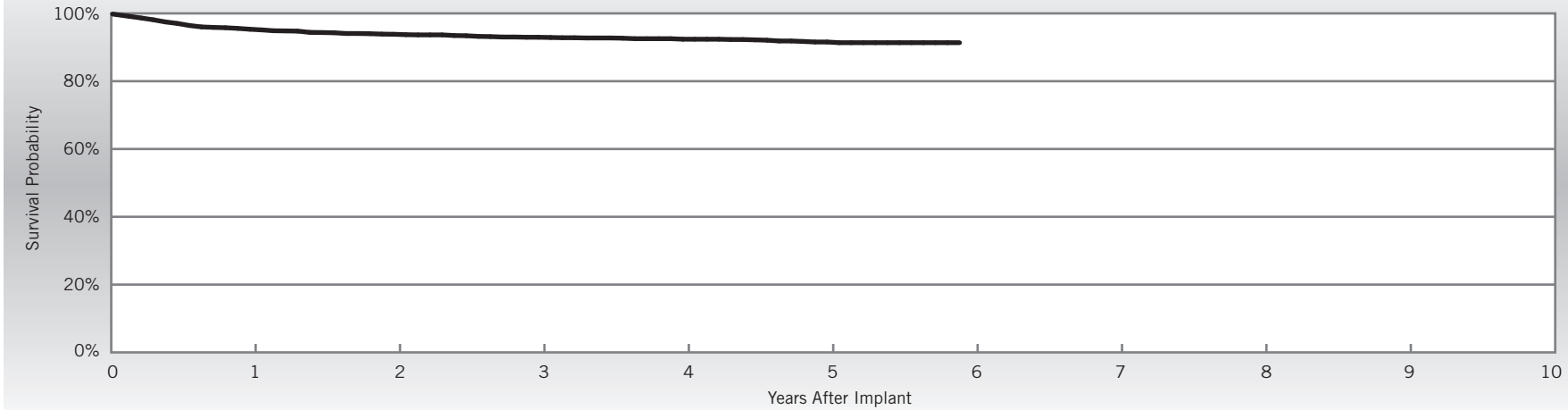
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	2,357
Active Devices Enrolled in Study	1,166
Cumulative Months of Follow-up	91,704
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	7	0.30%
Conductor Fracture	1	0.04%
Extracardiac Stimulation	57	2.42%
Failure to Capture	48	2.04%
Lead Dislodgement	48	2.04%

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	32	1.36%
Total	**33**	**1.40%**



Year	1	2	3	4	5	at 71 months				
Survival Probability	95.33%	93.84%	92.96%	92.38%	91.56%	91.36%				
± 1 standard error	0.44%	0.52%	0.57%	0.59%	0.67%	0.70%				
Sample Size	2,140	1,760	1,490	1,280	830	50				

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

Customer Reported Performance Data

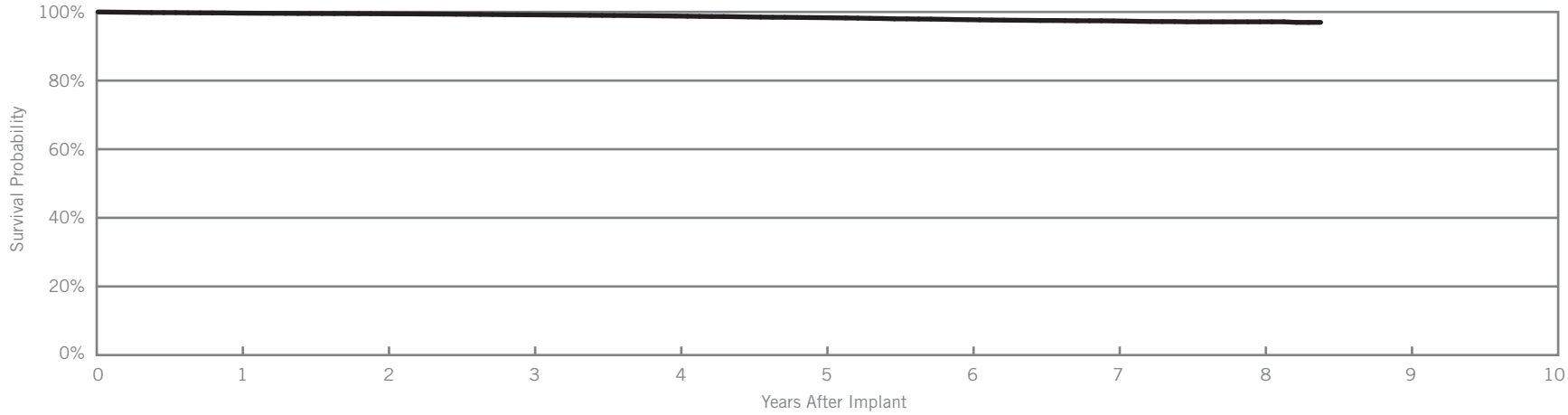
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	27,645
Estimated Active US Implants	13,008
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 308)	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	0.02%
Lead Dislodgement	11	0.04%	127	0.46%
Failure to Capture	4	0.01%	159	0.58%
Oversensing	0	0.00%	10	0.04%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	38	0.14%
Abnormal Pacing Impedance	0	0.00%	53	0.19%
Extracardiac Stimulation	13	0.05%	75	0.27%
Other	9	0.03%	5	0.02%
Total	**37**	**0.13%**	**472**	**1.71%**
Total Returned for Analysis	**14**		**147**	

Malfunctions	Qty.	Rate
Conductor Fracture	6	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	6	0.02%
Insulation Breach	74	0.27%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	2	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	13	0.05%
Other	59	0.21%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	123	0.44%
Total	**203**	**0.73%**



Year	1	2	3	4	5	6	7	8	at 101 months	
Survival Probability	99.66%	99.47%	99.17%	98.81%	98.34%	97.75%	97.39%	97.13%	96.96%	
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.09%	0.11%	0.13%	0.16%	0.23%	
Sample Size	25,380	21,730	19,270	17,320	15,040	11,840	7,390	2,910	290	

Actively Monitored Study Data

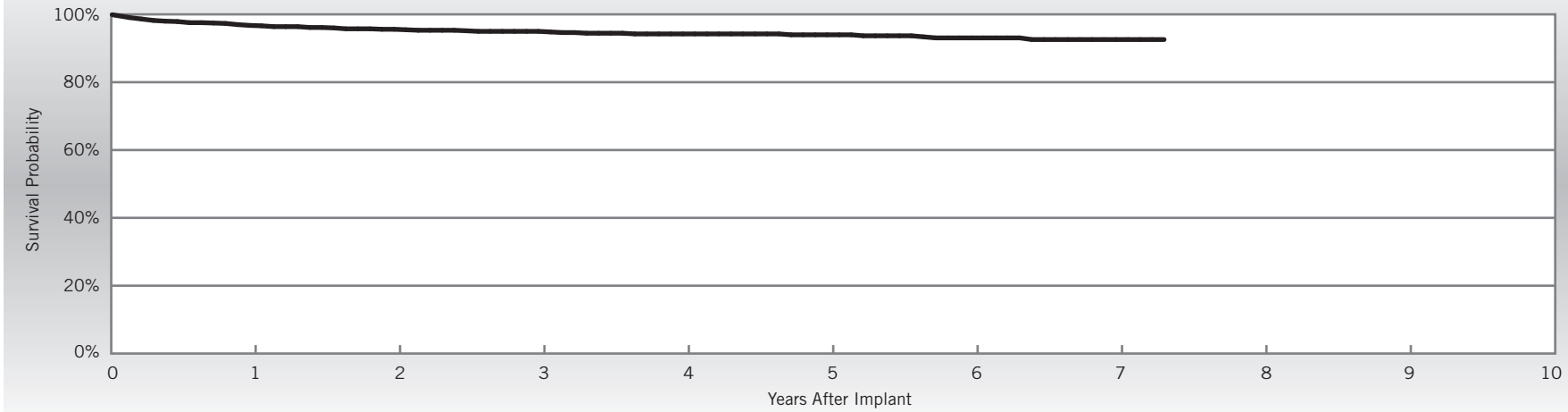
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	982
Active Devices Enrolled in Study	324
Cumulative Months of Follow-up	42,720
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	16	1.63%
Failure to Capture	9	0.92%
Lead Dislodgement	26	2.65%

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	0.31%
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	3	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	17	1.73%
Total	**20**	**2.04%**



Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	96.74%	95.60%	94.99%	94.23%	93.97%	93.06%	92.57%	92.57%		
± 1 standard error	0.56%	0.69%	0.75%	0.84%	0.87%	1.01%	1.12%	1.12%		
Sample Size	900	750	610	480	380	310	170	50		

Customer Reported Performance Data

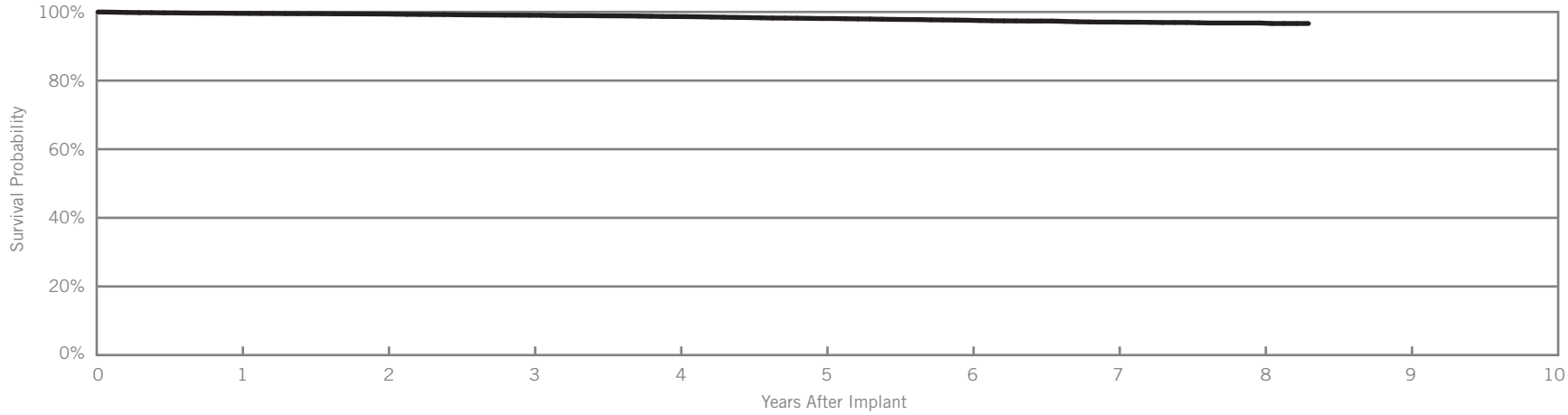
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,331
Estimated Active US Implants	7,343
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 308)	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%	3	0.02%
Lead Dislodgement	9	0.06%	85	0.55%
Failure to Capture	2	0.01%	112	0.73%
Oversensing	0	0.00%	1	<0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	0	0.00%	31	0.20%
Abnormal Pacing Impedance	2	0.01%	20	0.13%
Extracardiac Stimulation	6	0.04%	29	0.19%
Other	6	0.04%	6	0.04%
Total	**25**	**0.16%**	**288**	**1.88%**
Total Returned for Analysis	**13**		**103**	

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	47	0.31%
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	38	0.25%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	81	0.53%
Total	**134**	**0.87%**



Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.59%	99.40%	99.04%	98.66%	98.08%	97.58%	97.05%	96.78%	96.63%	
± 1 standard error	0.05%	0.07%	0.09%	0.11%	0.13%	0.16%	0.20%	0.23%	0.28%	
Sample Size	14,070	12,090	10,790	9700	8,300	6,340	3,940	1,670	280	

Actively Monitored Study Data

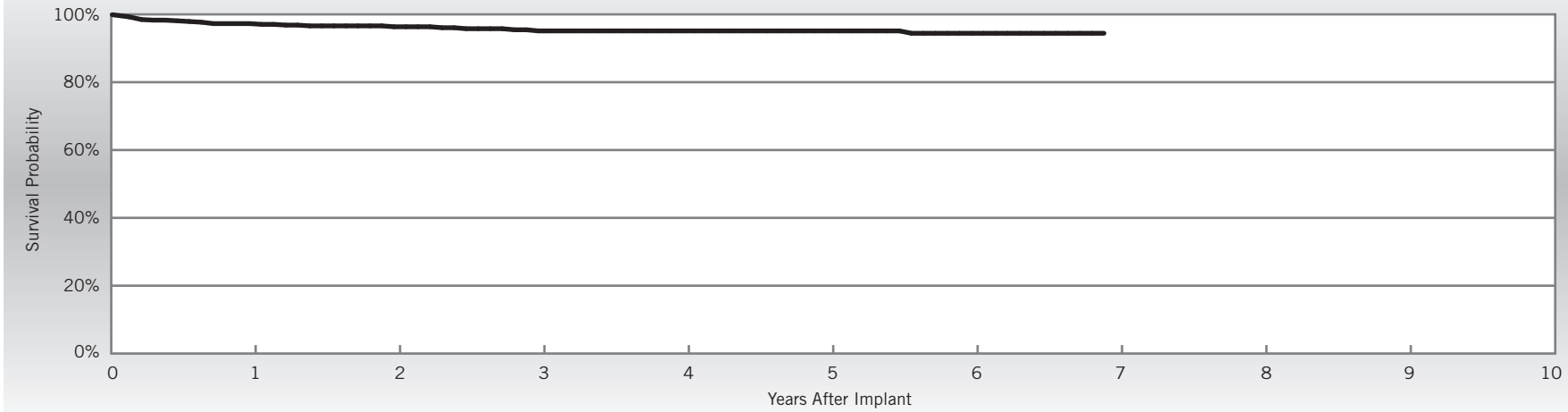
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	552
Active Devices Enrolled in Study	149
Cumulative Months of Follow-up	22,658
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	9	1.63%
Failure to Capture	6	1.09%
Insulation Breach	1	0.18%
Lead Dislodgement	6	1.09%
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	at 83 months			
Survival Probability	97.27%	96.34%	95.12%	95.12%	95.12%	94.42%	94.42%			
± 1 standard error	0.72%	0.81%	0.99%	1.04%	1.04%	1.25%	1.25%			
Sample Size	500	410	330	250	190	140	50			

Customer Reported Performance Data

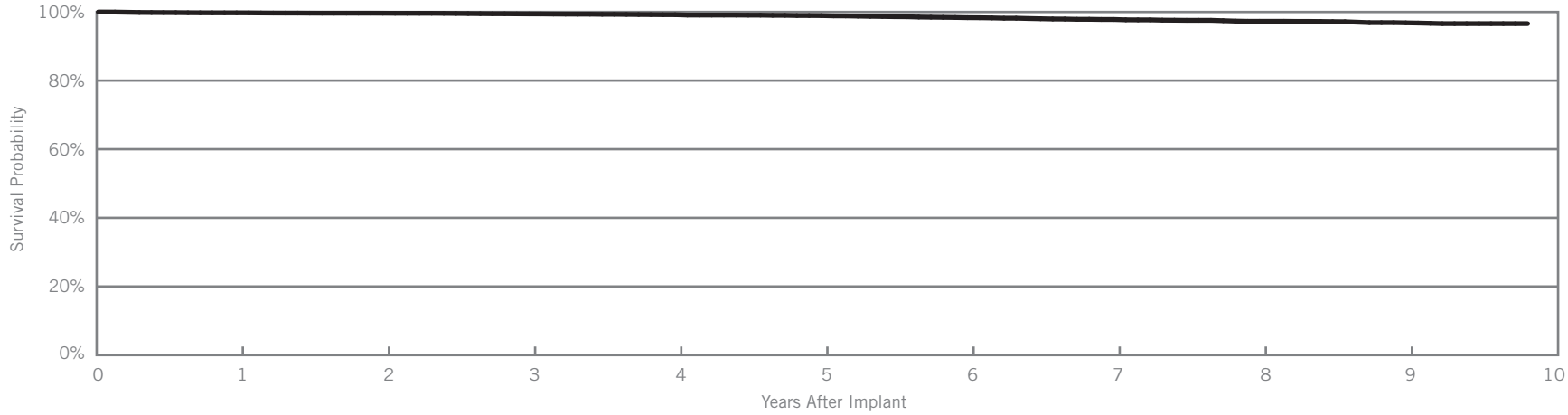
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	9,952
Estimated Active US Implants	3,840
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 308)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	4	0.04%
Lead Dislodgement	10	0.10%	29	0.29%
Failure to Capture	3	0.03%	76	0.76%
Oversensing	1	0.01%	2	0.02%
Failure to Sense	0	0.00%	2	0.02%
Insulation Breach	0	0.00%	30	0.30%
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%**	**187**	**1.88%**
Total Returned for Analysis	**11**		**35**	

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	22	0.22%
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	15	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	28	0.28%
Total	**53**	**0.53%**



Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.74%	99.63%	99.42%	99.20%	98.94%	98.34%	97.82%	97.29%	96.84%	96.61%
± 1 standard error	0.05%	0.06%	0.08%	0.10%	0.12%	0.16%	0.20%	0.23%	0.26%	0.30%
Sample Size	9,170	7,880	6,920	6,110	5,450	4,900	4,330	3,680	2,440	200

Actively Monitored Study Data

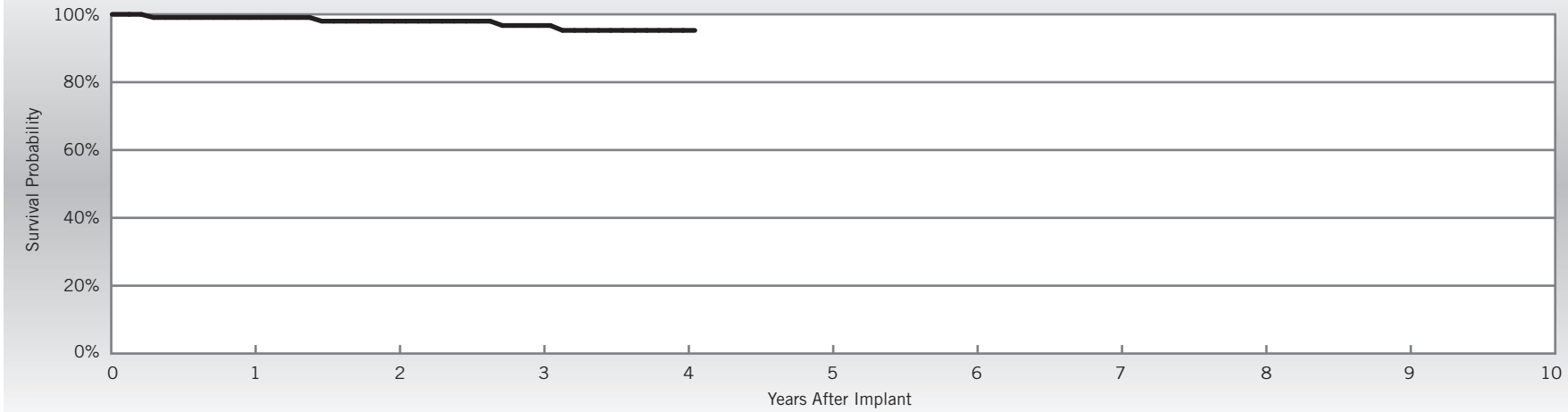
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	110
Active Devices Enrolled in Study	29
Cumulative Months of Follow-up	5,125
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	4	3.64%

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%	97.99%	96.71%	95.27%	95.27%					
± 1 standard error	0.93%	1.41%	1.89%	2.34%	2.34%					
Sample Size	100	90	80	60	50					

Customer Reported Performance Data

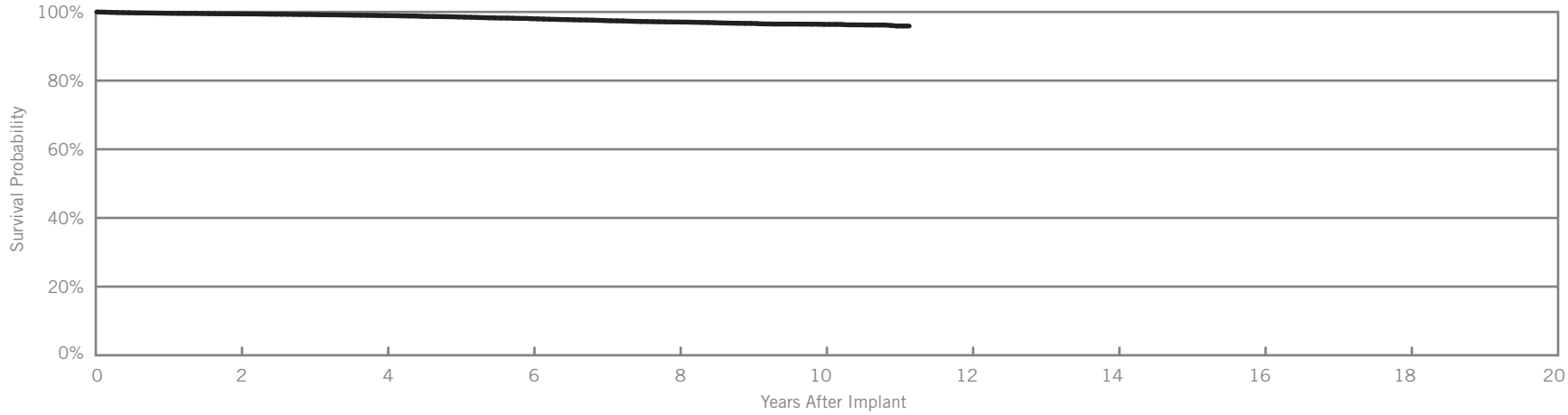
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	32,328
Estimated Active US Implants	11,184
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 308)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	6	0.02%
Lead Dislodgement	31	0.10%	159	0.49%
Failure to Capture	15	0.05%	257	0.79%
Oversensing	2	<0.01%	19	0.06%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	102	0.32%
Abnormal Pacing Impedance	3	<0.01%	50	0.15%
Extracardiac Stimulation	22	0.07%	97	0.30%
Other	9	0.03%	19	0.06%
Total	**83**	**0.26%**	**710**	**2.20%**
Total Returned for Analysis	**27**		**187**	

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	84	0.26%
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	41	0.13%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	153	0.47%
Total	**244**	**0.75%**



Year	2	4	6	8	10	at 134 months				
Survival Probability	99.43%	98.94%	98.03%	97.06%	96.38%	95.90%				
± 1 standard error	0.04%	0.06%	0.10%	0.13%	0.16%	0.28%				
Sample Size	25,630	19,780	15,280	11,590	5,660	220				

Actively Monitored Study Data

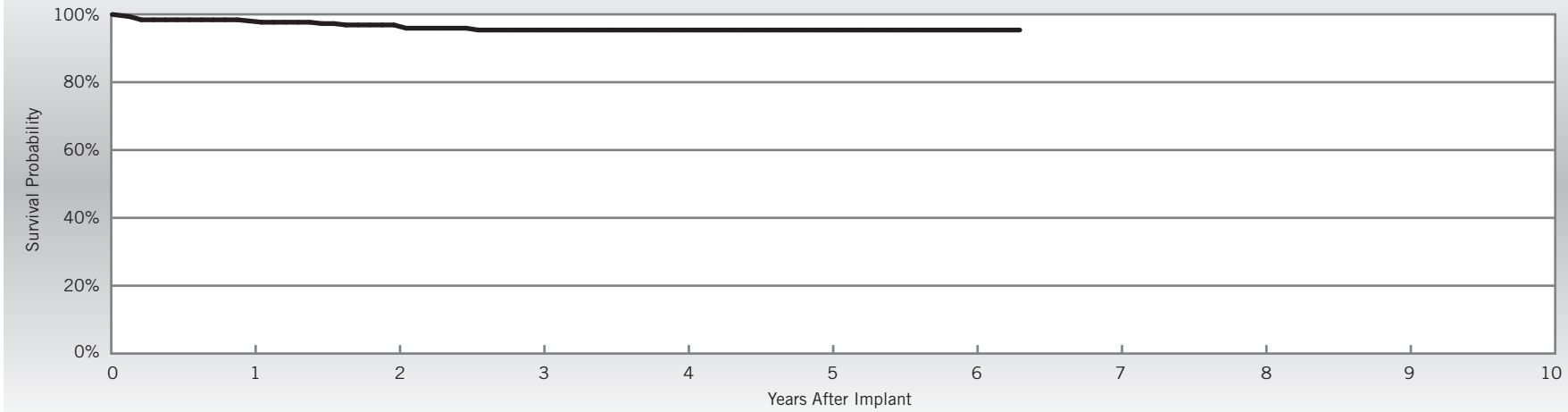
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	321
Active Devices Enrolled in Study	87
Cumulative Months of Follow-up	13,178
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	0.62%
Failure to Capture	4	1.25%
Lead Dislodgement	5	1.56%

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	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	4	1.25%
Total	**4**	**1.25%**



Year	1	2	3	4	5	6	at 76 months			
Survival Probability	98.04%	96.87%	95.38%	95.38%	95.38%	95.38%	95.38%			
± 1 standard error	0.71%	1.03%	1.33%	1.33%	1.33%	1.33%	1.33%			
Sample Size	300	240	180	140	110	80	50			

Customer Reported Performance Data

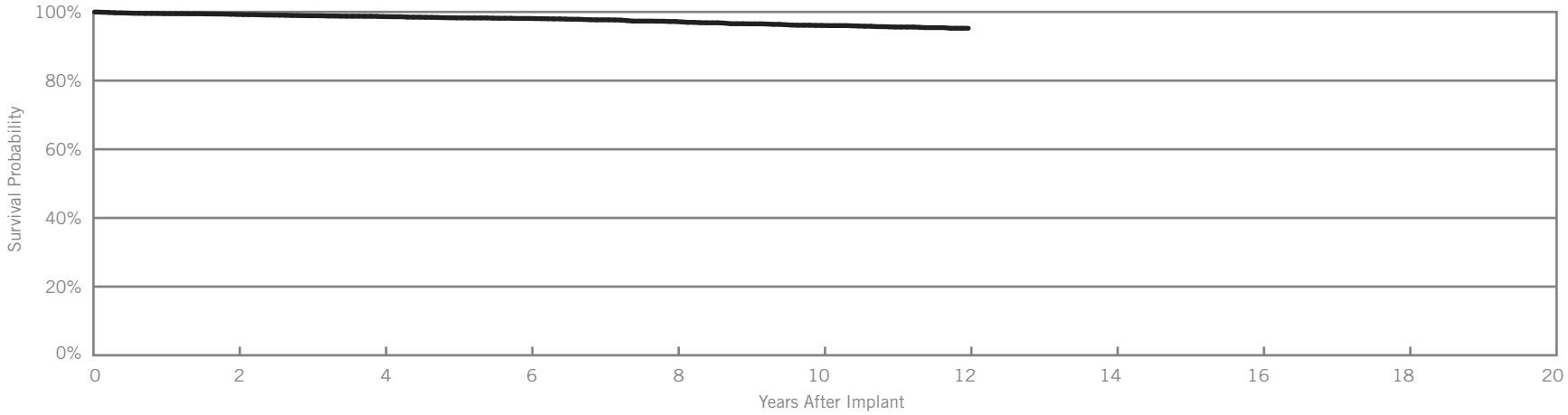
QuickSite™

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	7,872
Estimated Active US Implants	2,037
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%	5	0.06%
Lead Dislodgement	10	0.13%	35	0.44%
Failure to Capture	3	0.04%	73	0.93%
Oversensing	0	0.00%	1	0.01%
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%	31	0.39%
Other	2	0.03%	10	0.13%
Total	**25**	**0.32%**	**167**	**2.12%**
Total Returned for Analysis	**13**		**47**	

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				
Survival Probability	99.29%	98.65%	98.10%	97.21%	96.07%	95.25%				
± 1 standard error	0.10%	0.15%	0.19%	0.26%	0.34%	0.43%				
Sample Size	6,220	4,660	3,420	2,590	1,920	260				

Summary Information

Left-Heart Leads

St. Jude Medical

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
1458Q	Quartet™	99.47%	99.28%	99.19%	99.11%						
1258T	QuickFlex™ µ	99.58%	99.42%	99.27%	99.07%	98.88%	98.70%				
1156T	QuickFlex™	99.66%	99.47%	99.17%	98.81%	98.34%	97.75%	97.39%	97.13%		
1158T	QuickFlex™ XL	99.59%	99.40%	99.04%	98.66%	98.08%	97.58%	97.05%	96.78%		
1058T	QuickSite™ XL	99.74%	99.63%	99.42%	99.20%	98.94%	98.34%	97.82%	97.29%	96.84%	
1056T	QuickSite™	99.62%	99.43%	99.23%	98.94%	98.54%	98.03%	97.49%	97.06%	96.66%	96.38%
1056K	QuickSite™	99.50%	99.29%	98.90%	98.65%	98.27%	98.10%	97.70%	97.21%	96.53%	96.07%

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	
1458Q	Nov-11	95,968	84,654	2	<0.01%	0	0.00%	125	0.13%	55	0.06%	2	<0.01%	0	0.00%	1	<0.01%	4	<0.01%	62	0.06%	67	0.07%	**318**	**0.33%**	**119**
1258T	May-10	45,325	29,048	0	0.00%	0	0.00%	45	0.10%	16	0.04%	0	0.00%	1	<0.01%	0	0.00%	5	0.01%	19	0.04%	12	0.03%	**98**	**0.22%**	**52**
1156T	Jul-07	27,645	13,008	0	0.00%	0	0.00%	11	0.04%	4	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	13	0.05%	9	0.03%	**37**	**0.13%**	**14**
1158T	Jul-07	15,331	7,343	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	3,840	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	32,328	11,184	0	0.00%	0	0.00%	31	0.10%	15	0.05%	2	<0.01%	0	0.00%	1	<0.01%	3	<0.01%	22	0.07%	9	0.03%	**83**	**0.26%**	**27**
1056K	Jun-04	7,872	2,037	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	
1458Q	Nov-11	95,968	84,654	2	<0.01%	6	<0.01%	459	0.48%	151	0.16%	5	<0.01%	0	0.00%	2	<0.01%	22	0.02%	91	0.09%	21	0.02%	**759**	**0.79%**	**326**
1258T	May-10	45,325	29,048	0	0.00%	15	0.03%	160	0.35%	111	0.24%	9	0.02%	1	<0.01%	4	<0.01%	28	0.06%	57	0.13%	5	0.01%	**390**	**0.86%**	**169**
1156T	Jul-07	27,645	13,008	0	0.00%	5	0.02%	127	0.46%	159	0.58%	10	0.04%	0	0.00%	38	0.14%	53	0.19%	75	0.27%	5	0.02%	**472**	**1.71%**	**147**
1158T	Jul-07	15,331	7,343	0	0.00%	3	0.02%	85	0.55%	112	0.73%	1	<0.01%	1	<0.01%	31	0.20%	20	0.13%	29	0.19%	6	0.04%	**288**	**1.88%**	**103**
1058T	Feb-06	9,952	3,840	0	0.00%	4	0.04%	29	0.29%	76	0.76%	2	0.02%	2	0.02%	30	0.30%	19	0.19%	23	0.23%	2	0.02%	**187**	**1.88%**	**35**
1056T	Apr-05	32,328	11,184	0	0.00%	6	0.02%	159	0.49%	257	0.79%	19	0.06%	1	<0.01%	102	0.32%	50	0.15%	97	0.30%	19	0.06%	**710**	**2.20%**	**187**
1056K	Jun-04	7,872	2,037	0	0.00%	5	0.06%	35	0.44%	73	0.93%	1	0.01%	0	0.00%	5	0.06%	7	0.09%	31	0.39%	10	0.13%	**167**	**2.12%**	**47**

Definitions of observations and complications can be found on pages 9-10.

U.S. Malfunction Summary

			Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Percent Returned for Analysis	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
1458Q	95,968	5.00%	0	0.00%	1	<0.01%	2	<0.01%	**3**	**<0.01%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**	0	0.00%	7	<0.01%	317	0.33%	**328**	**0.34%**
1258T	45,325	9.20%	1	<0.01%	1	<0.01%	3	<0.01%	**5**	**0.01%**	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	**2**	**<0.01%**	0	0.00%	1	<0.01%	187	0.41%	**195**	**0.43%**
1156T	27,645	8.20%	0	0.00%	0	0.00%	6	0.02%	**6**	**0.02%**	0	0.00%	2	<0.01%	0	0.00%	13	0.05%	59	0.21%	**74**	**0.27%**	0	0.00%	0	0.00%	123	0.44%	**203**	**0.73%**
1158T	15,331	9.30%	0	0.00%	1	<0.01%	4	0.03%	**5**	**0.03%**	0	0.00%	2	0.01%	0	0.00%	7	0.05%	38	0.25%	**47**	**0.31%**	1	<0.01%	0	0.00%	81	0.53%	**134**	**0.87%**
1058T	9,952	9.20%	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**	0	0.00%	1	0.01%	0	0.00%	6	0.06%	15	0.15%	**22**	**0.22%**	0	0.00%	1	0.01%	28	0.28%	**53**	**0.53%**
1056T	32,328	9.10%	0	0.00%	2	<0.01%	4	0.01%	**6**	**0.02%**	1	<0.01%	11	0.03%	0	0.00%	31	0.10%	41	0.13%	**84**	**0.26%**	0	0.00%	1	<0.01%	153	0.47%	**244**	**0.75%**
1056K	7,872	14.90%	0	0.00%	0	0.00%	3	0.04%	**3**	**0.04%**	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**	0	0.00%	0	0.00%	51	0.65%	**56**	**0.71%**

Worldwide Malfunction Summary

			Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Worldwide Sales	Percent Returned for Analysis	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
1458Q	194,012	3.0%	5	<0.01%	6	<0.01%	4	<0.01%	**15**	**0.01%**	1	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**4**	**<0.01%**	0	0.00%	11	0.01%	508	0.26%	**538**	**0.28%**
1258T	148,956	3.6%	8	0.01%	16	0.01%	13	0.01%	**37**	**0.02%**	1	<0.01%	2	<0.01%	1	<0.01%	0	0.00%	2	<0.01%	**6**	**<0.01%**	0	0.00%	5	<0.01%	331	0.22%	**379**	**0.25%**

Definitions of malfunction categories can be found on pages 10-12.

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 Dislodge-ment		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	2,050	1,286	58,949	1	0.05%	0	0.00%	0	0.00%	3	0.15%	2	0.10%	0	0.00%	0	0.00%	31	1.51%	0	0.00%	0	0.00%	0	0.00%	**37**	**1.80%**
1258T	2,357	1,166	91,704	7	0.30%	0	0.00%	1	0.04%	57	2.42%	48	2.04%	0	0.00%	0	0.00%	48	2.04%	0	0.00%	0	0.00%	0	0.00%	**161**	**6.83%**
1156T	982	324	42,720	1	0.10%	0	0.00%	0	0.00%	16	1.63%	9	0.92%	0	0.00%	0	0.00%	26	2.65%	0	0.00%	0	0.00%	0	0.00%	**52**	**5.30%**
1158T	552	149	22,658	0	0.00%	0	0.00%	0	0.00%	9	1.63%	6	1.09%	0	0.00%	1	0.18%	6	1.09%	0	0.00%	0	0.00%	1	0.18%	**23**	**4.17%**
1058T	110	29	5,125	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	3.64%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**3.64%**
1056T	321	87	13,178	1	0.31%	0	0.00%	0	0.00%	2	0.62%	4	1.25%	0	0.00%	0	0.00%	5	1.56%	0	0.00%	0	0.00%	0	0.00%	**12**	**3.74%**

Malfunctions

			Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Percent Returned for Analysis	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
1458Q	2,050	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%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	18	0.88%	**18**	**0.88%**
1258T	2,357	4.80%	1	0.04%	0	0.00%	0	0.00%	**1**	**0.04%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	32	1.36%	**33**	**1.40%**
1156T	982	7.80%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.31%	**3**	**0.31%**	0	0.00%	0	0.00%	17	1.73%	**20**	**2.04%**
1158T	552	4.20%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	1	0.18%	0	0.00%	**1**	**0.18%**	0	0.00%	0	0.00%	7	1.27%	**8**	**1.45%**
1058T	110	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%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1056T	321	5.90%	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%	**0**	**0.00%**	0	0.00%	0	0.00%	4	1.25%	**4**	**1.25%**

A list of complications can be found on page 15.
Definitions of malfunction categories can be found on pages 10-12.

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical

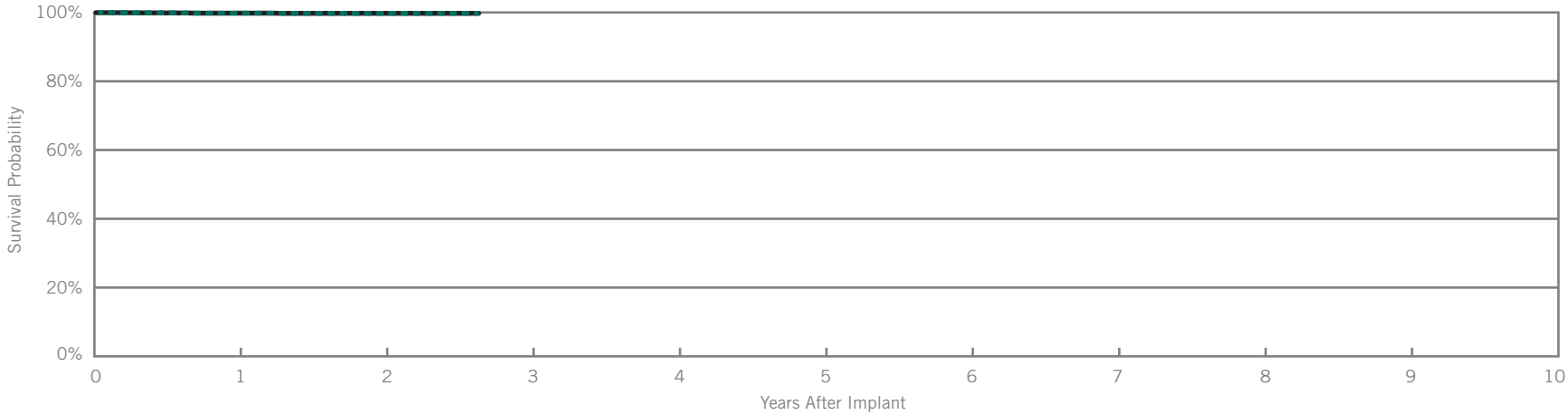
Ellipse™ DR

Model CD2411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	9,304
Estimated Active US Implants	7,908
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.01%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	0.01%
Software/Firmware	1	0.01%	0	0.00%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.01%	2	0.02%
Total	**4**	**0.04%**	**4**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.80%	99.75%	99.75%							
± 1 standard error	0.05%	0.06%	0.06%							
Sample Size	7,080	3,200	250							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.80%	99.75%	99.75%							
± 1 standard error	0.05%	0.06%	0.06%							

**DF4-LLHH connector type.*

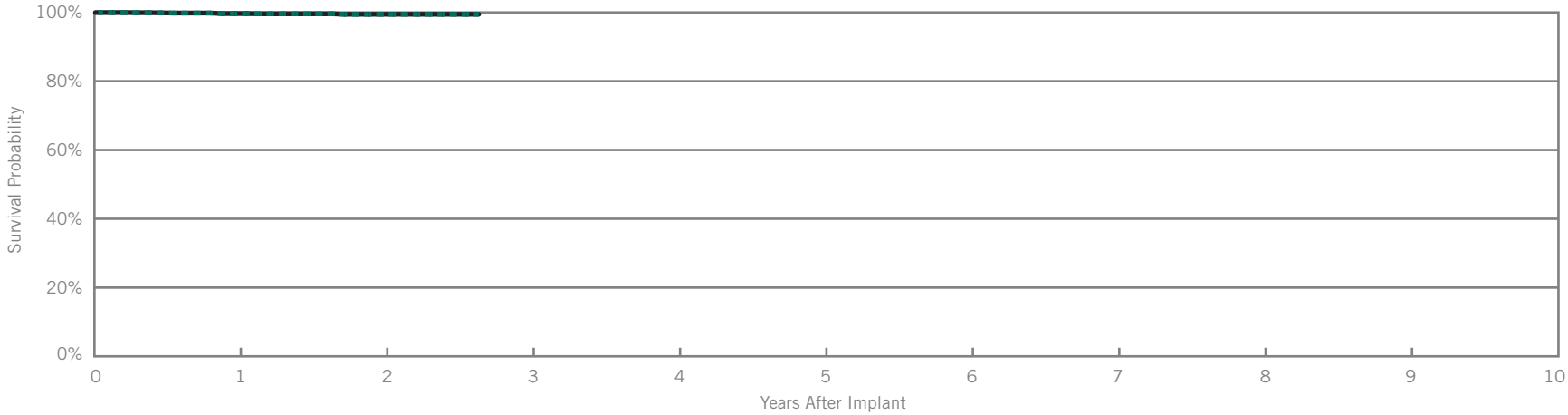
Ellipse™ DR

Model CD2411-36C*

US Regulatory Approval	June 2013
Registered US Implants	5,338
Estimated Active US Implants	4,475
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.04%	1	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	4	0.07%	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	**6**	**0.11%**	**2**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.66%	99.46%	99.46%							
± 1 standard error	0.09%	0.14%	0.14%							
Sample Size	4,150	2,020	220							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.66%	99.46%	99.46%							
± 1 standard error	0.09%	0.14%	0.14%							

**Parylene coating.*

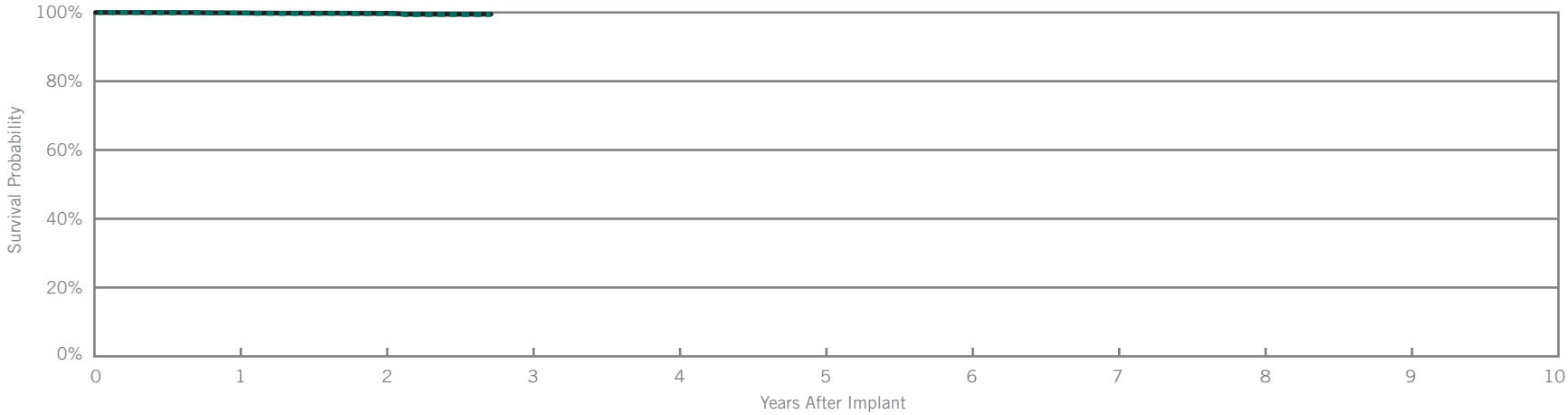
Fortify Assura™ DR

Model CD2357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	16,911
Estimated Active US Implants	14,518
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	3	0.02%	3	0.02%
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%	1	<0.01%
Possible Early Battery Depletion	3	0.02%	1	<0.01%
Other	0	0.00%	1	<0.01%
Total	**7**	**0.04%**	**6**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.82%	99.65%	99.40%							
± 1 standard error	0.04%	0.07%	0.13%							
Sample Size	12,940	5,760	230							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.87%	99.74%	99.49%							
± 1 standard error	0.03%	0.06%	0.13%							

**DF4-LLHH connector type.*

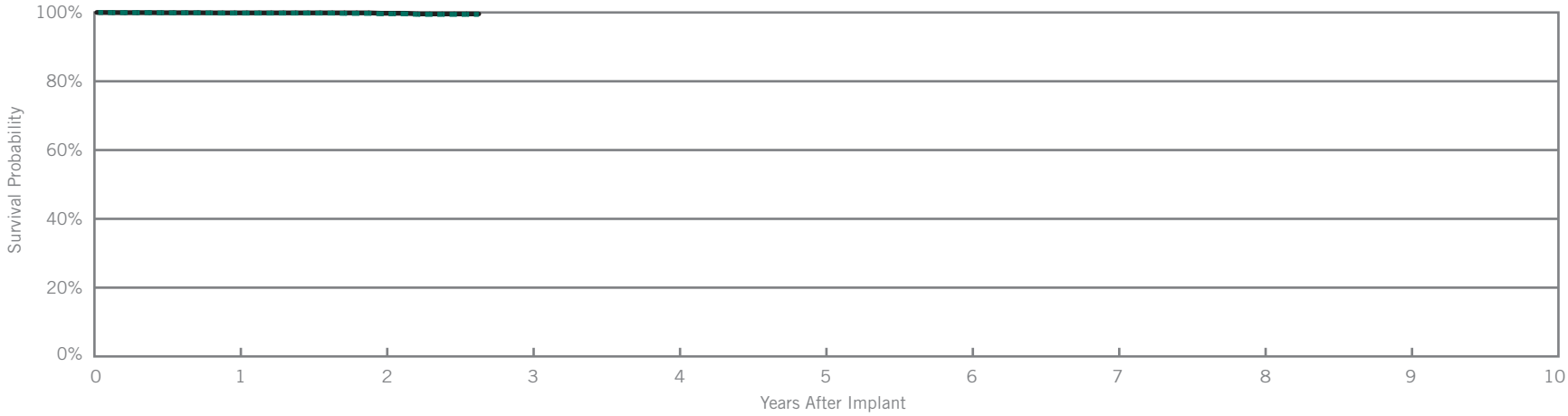
Fortify Assura™ DR

Model CD2357-40C*

US Regulatory Approval	June 2013
Registered US Implants	8,524
Estimated Active US Implants	7,159
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	2	0.02%	0	0.00%
Electrical Interconnect	0	0.00%	1	0.01%
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	2	0.02%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.05%**	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.81%	99.62%	99.43%							
± 1 standard error	0.06%	0.08%	0.17%							
Sample Size	6,650	3,200	290							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.88%	99.77%	99.58%							
± 1 standard error	0.04%	0.04%	0.16%							

**Parylene coating.*

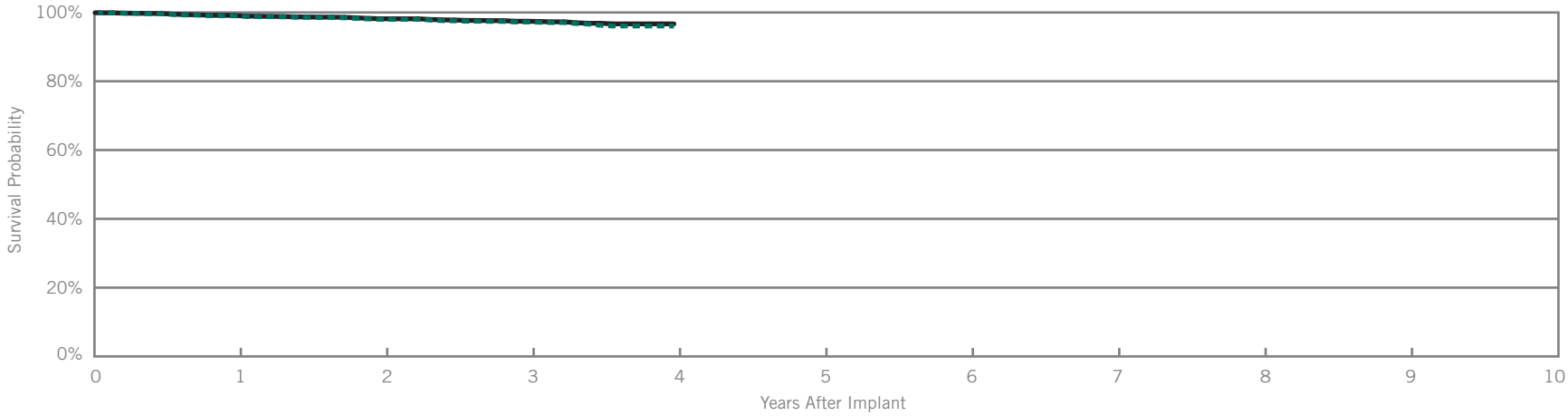
Customer Reported Performance Data

Ellipse™ DR

Model CD2311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	5,898
Estimated Active US Implants	4,102
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.05%	1	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	40	0.68%	4	0.07%
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	1	0.02%	2	0.03%
Total	**47**	**0.80%**	**10**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.04%	98.01%	97.23%	96.07%						
± 1 standard error	0.13%	0.19%	0.24%	0.37%						
Sample Size	5,540	4,880	3,570	210						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.13%	98.16%	97.45%	96.68%						
± 1 standard error	0.12%	0.18%	0.23%	0.32%						

**DF4-LLHH connector type.*

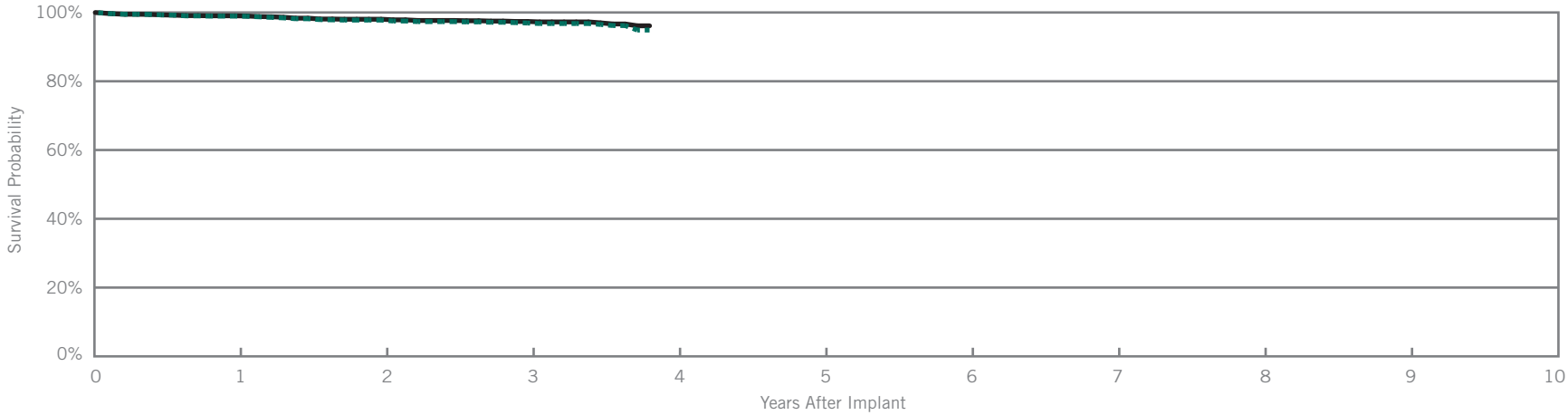
Customer Reported Performance Data

Ellipse™ DR

Model CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	3,744
Estimated Active US Implants	2,596
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.11%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	19	0.51%	4	0.11%
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	**30**	**0.80%**	**9**	**0.24%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	98.94%	97.78%	96.92%	94.88%						
± 1 standard error	0.17%	0.25%	0.31%	0.73%						
Sample Size	3,520	3,090	2,190	310						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.03%	98.03%	97.38%	96.12%						
± 1 standard error	0.16%	0.24%	0.29%	0.56%						

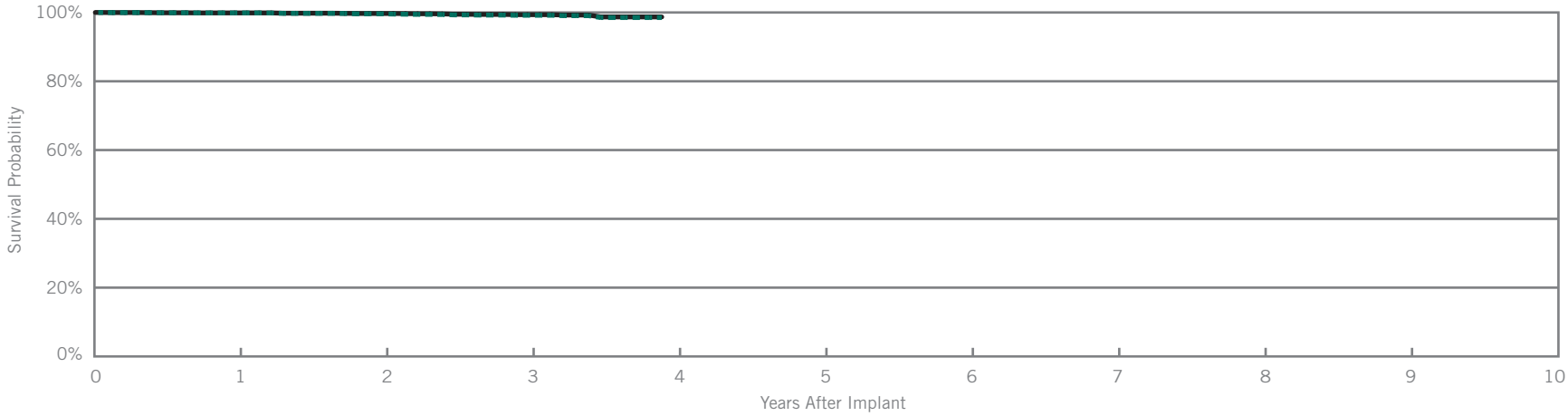
Fortify Assura™ DR

Model CD2257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	6,792
Estimated Active US Implants	4,744
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	4
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.04%	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%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	6	0.09%	3	0.04%
Other	3	0.04%	0	0.00%
Total	**12**	**0.18%**	**6**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.87%	99.62%	99.18%	98.52%						
± 1 standard error	0.04%	0.08%	0.13%	0.29%						
Sample Size	6,360	5,530	3,870	220						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.87%	99.71%	99.36%	98.70%						
± 1 standard error	0.04%	0.07%	0.11%	0.28%						

**DF4-LLHH connector type.*

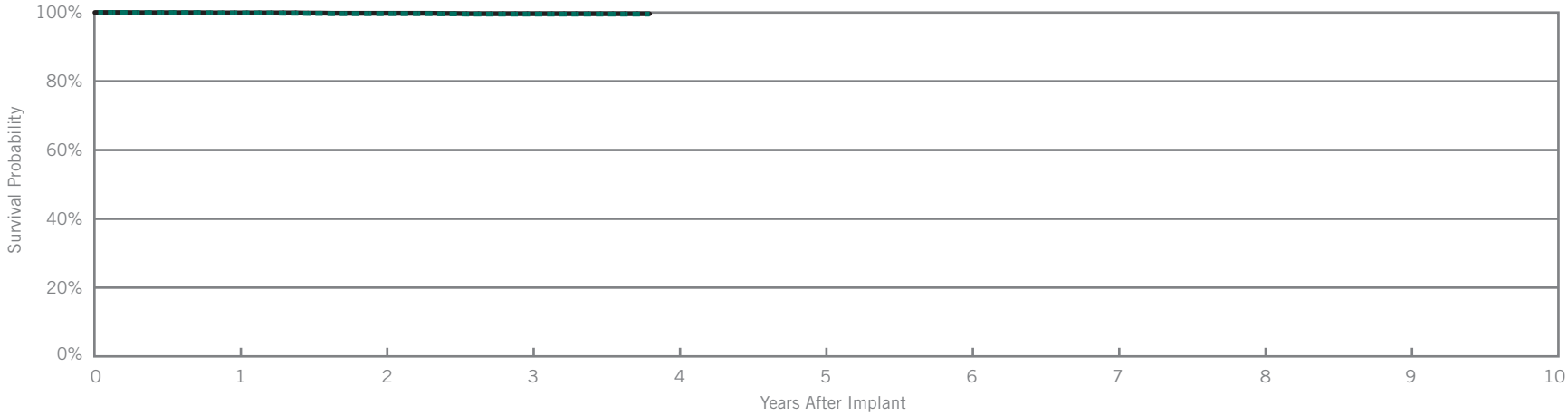
Fortify Assura™ DR

Model CD2257-40

US Regulatory Approval	May 2012
Registered US Implants	4,226
Estimated Active US Implants	2,947
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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	0	0.00%	0	0.00%
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	1	0.02%	1	0.02%
Other	0	0.00%	1	0.02%
Total	**3**	**0.07%**	**3**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.85%	99.67%	99.53%	99.53%						
± 1 standard error	0.06%	0.09%	0.12%	0.12%						
Sample Size	3,980	3,460	2,410	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.90%	99.78%	99.64%	99.64%						
± 1 standard error	0.05%	0.08%	0.11%	0.11%						

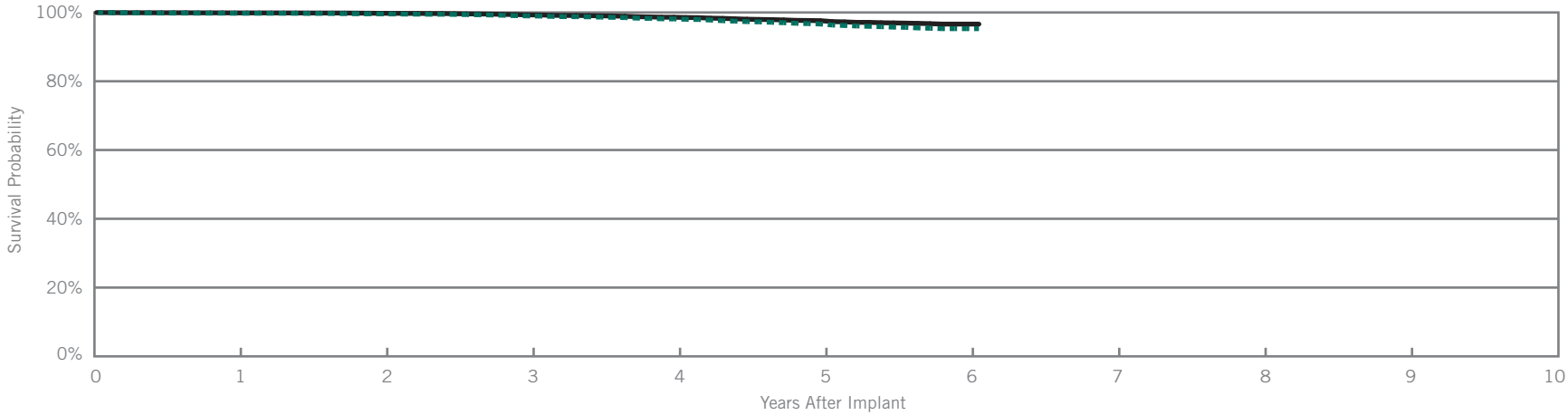
Fortify™ DR

Model CD2231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	26,842
Estimated Active US Implants	15,326
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	66
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.02%	7	0.03%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	18	0.07%	13	0.05%
High Voltage Capacitor	4	0.01%	1	<0.01%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	76	0.28%	27	0.10%
Other	10	0.04%	4	0.01%
Total	**116**	**0.43%**	**54**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.76%	99.58%	98.99%	98.11%	96.64%	95.28%	95.28%			
± 1 standard error	0.03%	0.04%	0.07%	0.10%	0.15%	0.24%	0.24%			
Sample Size	25,140	22,170	19,700	16,550	10,820	3,720	400			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.87%	99.76%	99.30%	98.61%	97.61%	96.62%	96.62%			
± 1 standard error	0.02%	0.03%	0.05%	0.09%	0.13%	0.21%	0.21%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

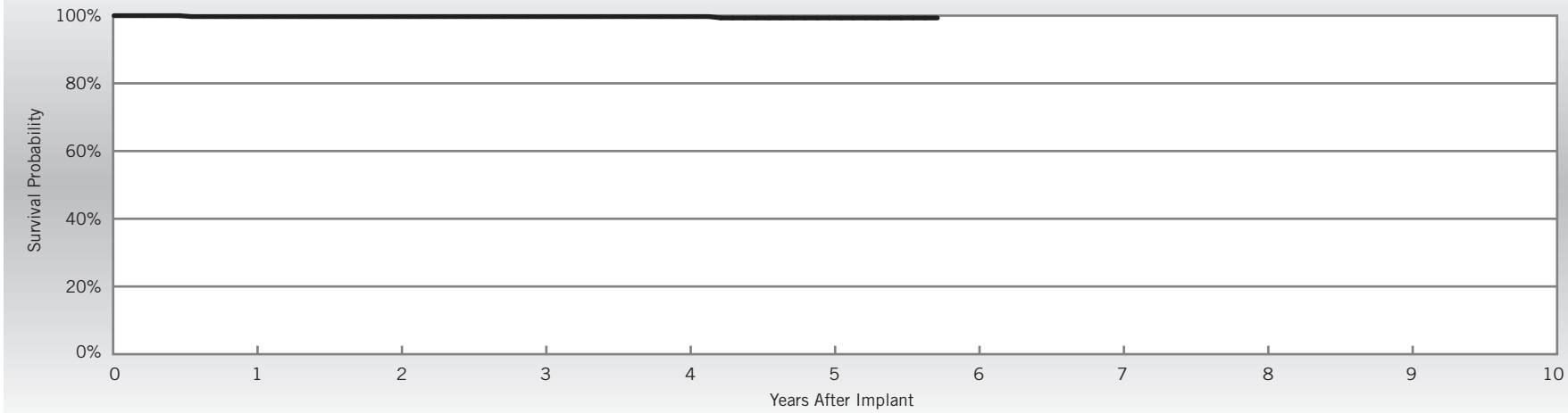
Fortify™ DR

Model CD2231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	389
Active Devices Enrolled in Study	225
Cumulative Months of Follow-up	18,878
Estimated Longevity	(see table on page 111)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	2	0.51%

	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	0.26%	1	0.26%
Other	1	0.26%	0	0.00%
Total	**2**	**0.51%**	**1**	**0.26%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	99.73%	99.73%	99.73%	99.73%	99.32%	99.32%				
± 1 standard error	0.27%	0.27%	0.27%	0.27%	0.49%	0.49%				
Sample Size	370	340	300	260	210	50				

**DF4-LLHH connector type.*

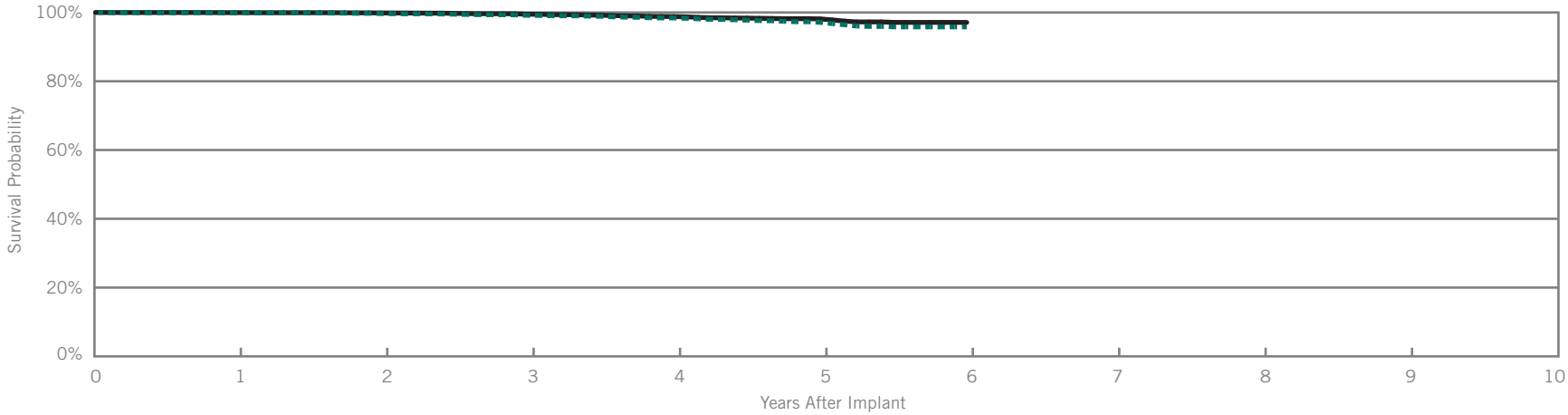
Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	12,074
Estimated Active US Implants	6,764
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	27
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	2	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	3	0.02%	5	0.04%
High Voltage Capacitor	6	0.05%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	29	0.24%	9	0.07%
Other	4	0.03%	2	0.02%
Total	**46**	**0.38%**	**19**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.88%	99.67%	99.16%	98.39%	97.12%	95.81%				
± 1 standard error	0.02%	0.05%	0.09%	0.14%	0.21%	0.33%				
Sample Size	11,300	9,930	8,720	7,170	4,460	320				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.95%	99.86%	99.48%	98.81%	98.12%	97.11%				
± 1 standard error	0.02%	0.03%	0.07%	0.12%	0.16%	0.27%				

Actively Monitored Study Data

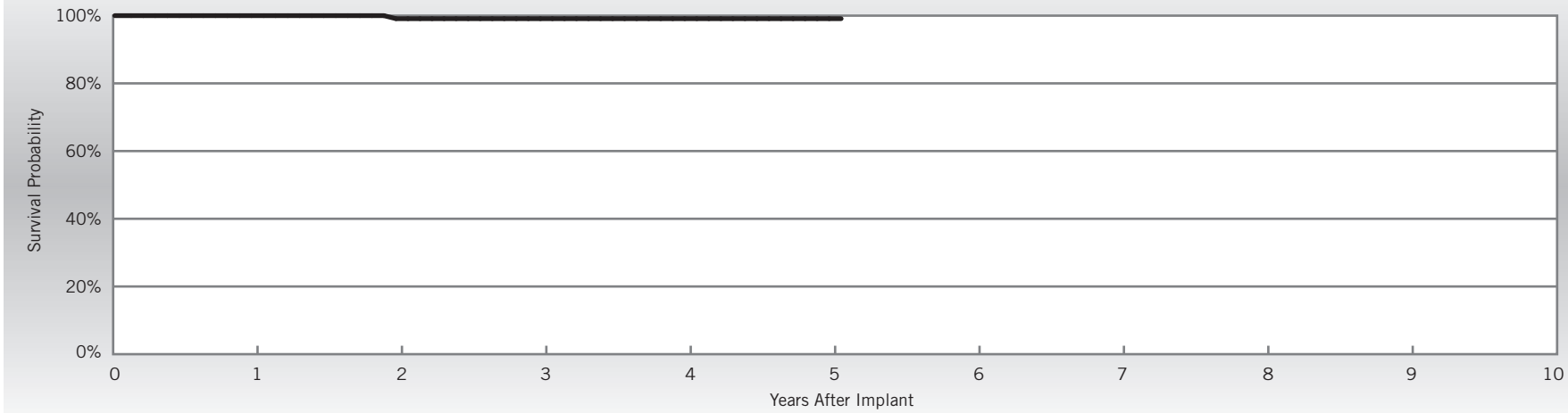
Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	177
Active Devices Enrolled in Study	79
Cumulative Months of Follow-up	6,908
Estimated Longevity	(see table on page 111)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	1	0.56%

	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%**



Year	1	2	3	4	5	at 61 months				
Survival Probability	100.00%	99.11%	99.11%	99.11%	99.11%	99.11%				
± 1 standard error	0.00%	0.89%	0.89%	0.89%	0.89%	0.89%				
Sample Size	160	130	100	90	70	60				

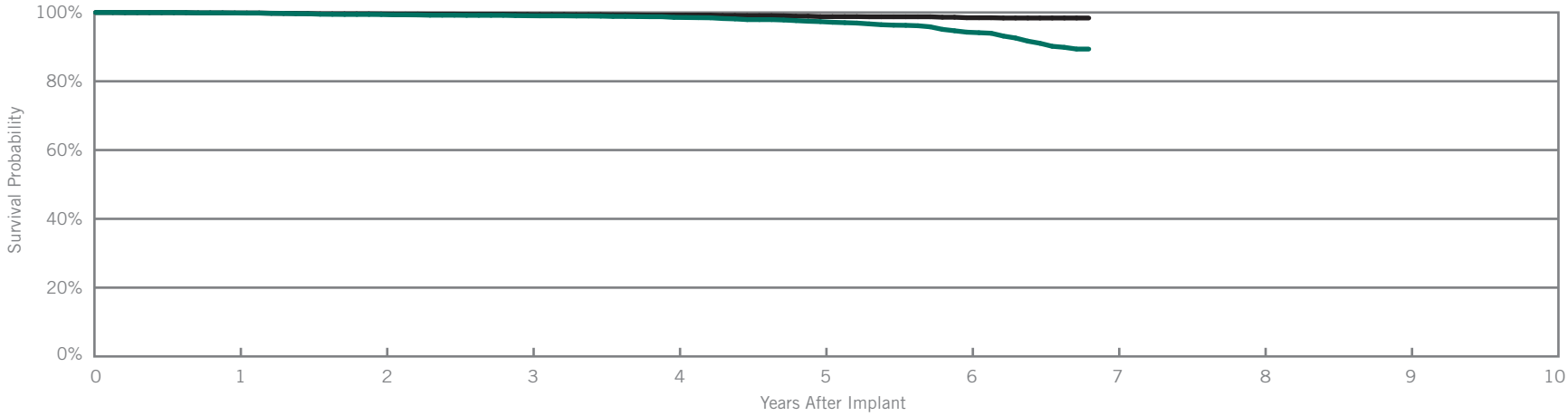
Current™ + DR

Model CD2211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	8,143
Estimated Active US Implants	3,780
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	104
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	6	0.07%	2	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	6	0.07%	6	0.07%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	1	0.01%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	3	0.04%	3	0.04%
Other	4	0.05%	3	0.04%
Total	**21**	**0.26%**	**16**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.85%	99.40%	99.05%	98.57%	97.34%	94.27%	89.36%			
± 1 standard error	0.04%	0.09%	0.12%	0.14%	0.22%	0.33%	0.73%			
Sample Size	7,570	6,630	5,930	5,260	4,580	3,800	240			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.85%	99.58%	99.41%	99.22%	98.80%	98.47%	98.39%			
± 1 standard error	0.04%	0.07%	0.09%	0.11%	0.14%	0.16%	0.18%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

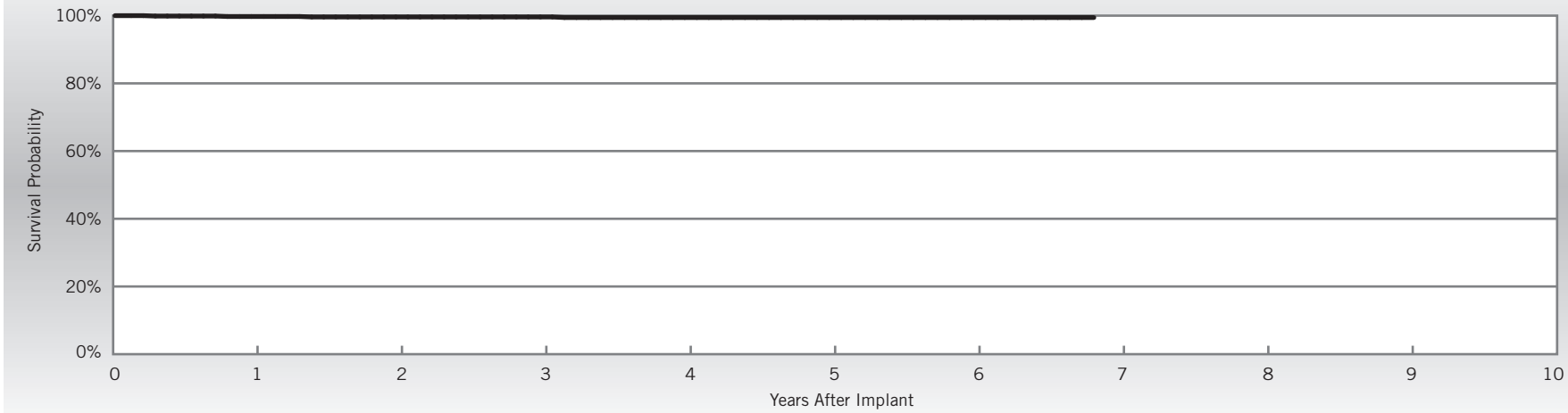
Current™ + DR

Model CD2211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	834
Active Devices Enrolled in Study	414
Cumulative Months of Follow-up	45,562
Estimated Longevity	(see table on page 111)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	3	0.36%
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%	1	0.12%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.12%
Other	0	0.00%	0	0.00%
Total	**1**	**0.12%**	**5**	**0.60%**



Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.75%	99.61%	99.61%	99.44%	99.44%	99.44%	99.44%			
± 1 standard error	0.18%	0.23%	0.23%	0.28%	0.28%	0.28%	0.28%			
Sample Size	790	710	640	570	500	440	60			

**DF4-LLHH connector type.*

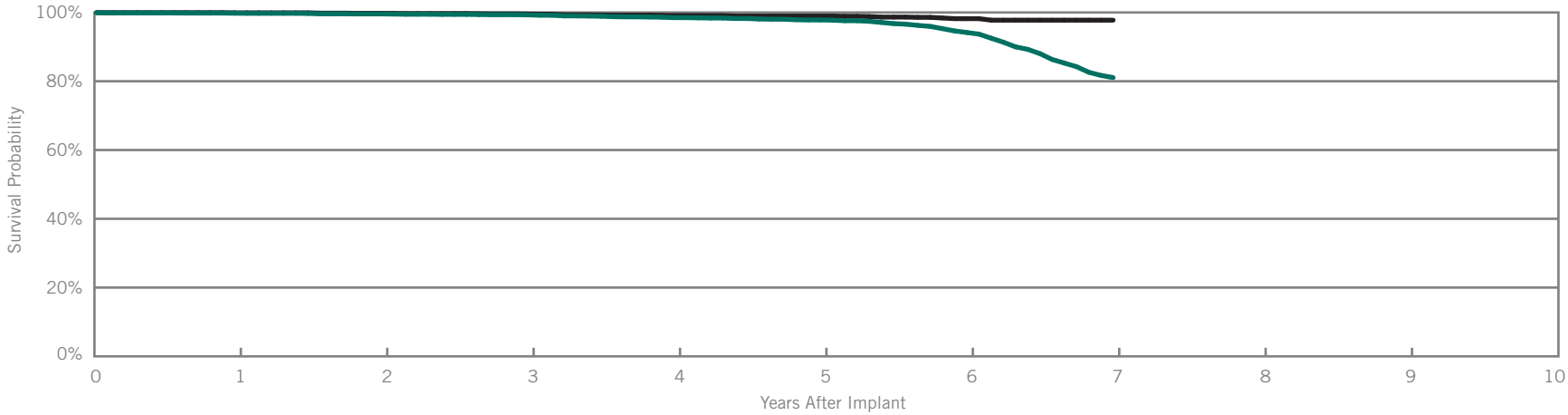
Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,270
Estimated Active US Implants	2,714
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	123
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	1	0.02%
Electrical Interconnect	2	0.03%	0	0.00%
Battery	5	0.08%	4	0.06%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	1	0.02%	3	0.05%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	7	0.11%	4	0.06%
Other	5	0.08%	0	0.00%
Total	**22**	**0.35%**	**12**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.78%	99.57%	99.30%	98.49%	97.82%	94.18%	81.07%			
± 1 standard error	0.05%	0.09%	0.11%	0.17%	0.23%	0.40%	1.04%			
Sample Size	5,850	5,110	4,520	3,980	3,420	2,790	350			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.90%	99.76%	99.54%	99.09%	98.95%	98.20%	97.76%			
± 1 standard error	0.03%	0.07%	0.09%	0.14%	0.16%	0.22%	0.26%			

Actively Monitored Study Data

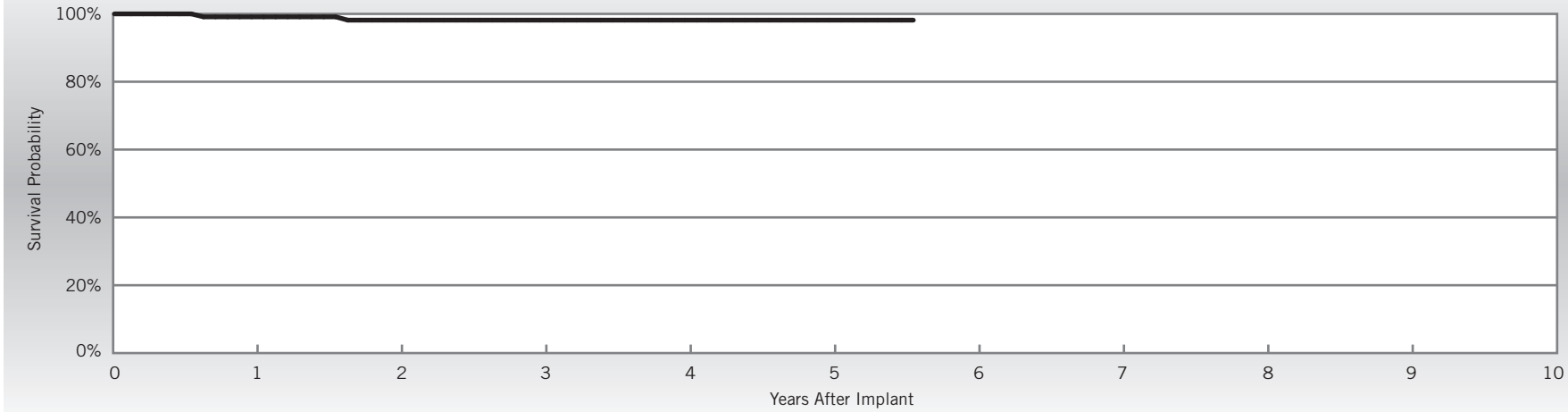
Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	122
Active Devices Enrolled in Study	48
Cumulative Months of Follow-up	5,947
Estimated Longevity	(see table on page 111)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.82%
Premature Battery Depletion	1	0.82%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.82%	1	0.82%
Total	**1**	**0.82%**	**1**	**0.82%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	99.13%	98.16%	98.16%	98.16%	98.16%	98.16%				
± 1 standard error	0.87%	1.29%	1.29%	1.29%	1.29%	1.29%				
Sample Size	120	100	80	70	60	50				

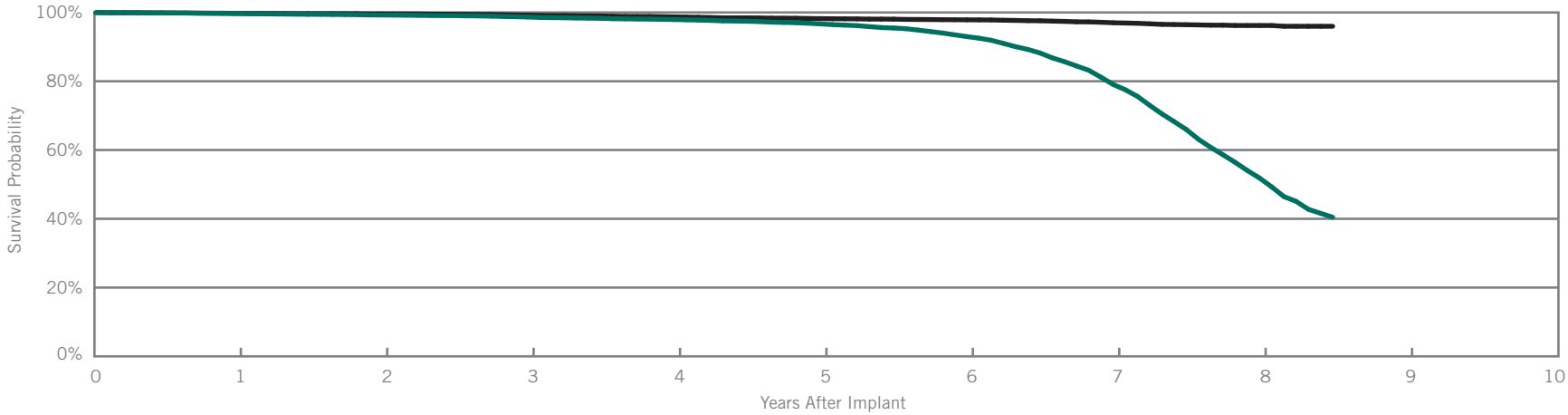
Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,377
Estimated Active US Implants	6,241
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	1,350
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	9	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%	13	0.06%
Mechanical	1	<0.01%	12	0.05%
Possible Early Battery Depletion	36	0.16%	18	0.08%
Other	31	0.14%	6	0.03%
Total	**106**	**0.47%**	**72**	**0.32%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.69%	99.26%	98.67%	97.93%	96.67%	92.98%	79.05%	51.85%	40.46%
± 1 standard error	0.04%	0.06%	0.08%	0.11%	0.14%	0.22%	0.38%	0.67%	1.00%
Sample Size	20,850	18,150	16,000	14,220	12,670	11,110	8,480	3,950	230

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.75%	99.59%	99.21%	98.72%	98.21%	97.86%	97.01%	96.21%	95.98%
± 1 standard error	0.03%	0.05%	0.06%	0.09%	0.11%	0.12%	0.15%	0.21%	0.27%

Actively Monitored Study Data

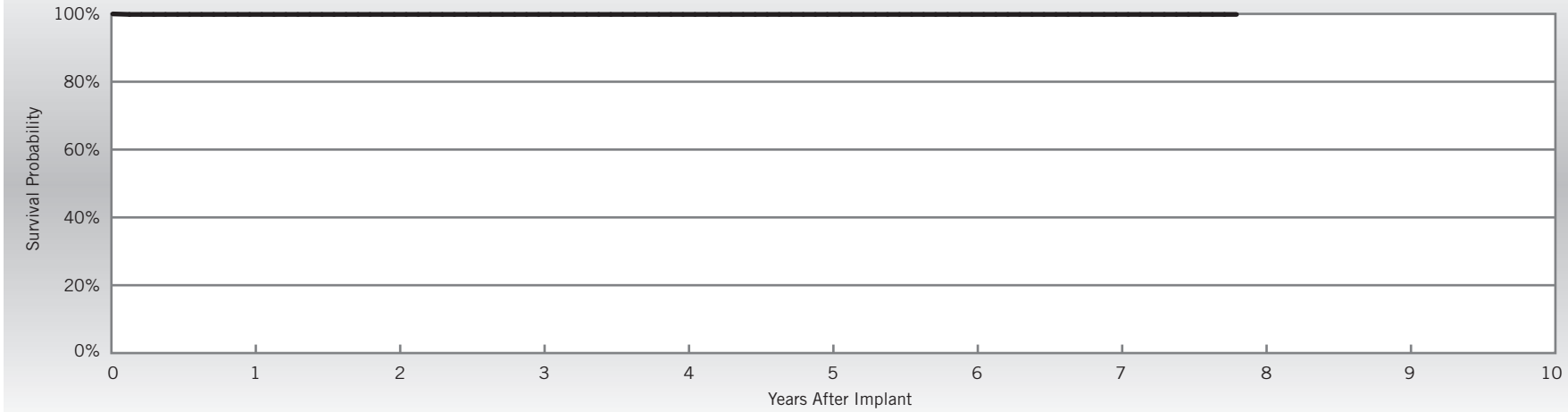
Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	630
Active Devices Enrolled in Study	158
Cumulative Months of Follow-up	31,791
Estimated Longevity	(see table on page 111)
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%	0	0.00%
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%**	**1**	**0.16%**



Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	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%		
Sample Size	600	520	430	340	280	240	190	50		

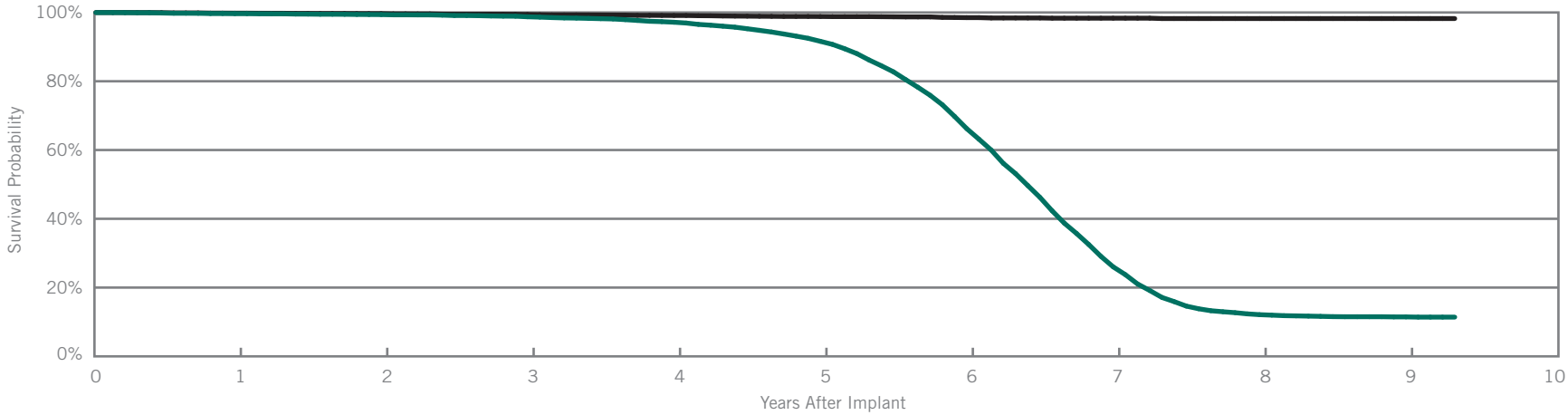
Customer Reported Performance Data

Atlas™ II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,808
Estimated Active US Implants	1,457
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	2,841
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 299)	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	18	0.12%	6	0.04%
Other	10	0.07%	5	0.03%
Total	**47**	**0.32%**	**19**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.66%	99.38%	98.74%	97.16%	91.61%	66.21%	26.03%	12.12%	11.47%	11.41%
± 1 standard error	0.05%	0.07%	0.10%	0.16%	0.28%	0.52%	0.51%	0.35%	0.34%	0.34%
Sample Size	13,780	12,040	10,620	9,290	8,010	6,250	3,750	1,700	720	240

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.80%	99.68%	99.41%	99.12%	98.83%	98.50%	98.34%	98.23%	98.23%	98.23%
± 1 standard error	0.04%	0.05%	0.07%	0.09%	0.11%	0.13%	0.14%	0.16%	0.16%	0.16%

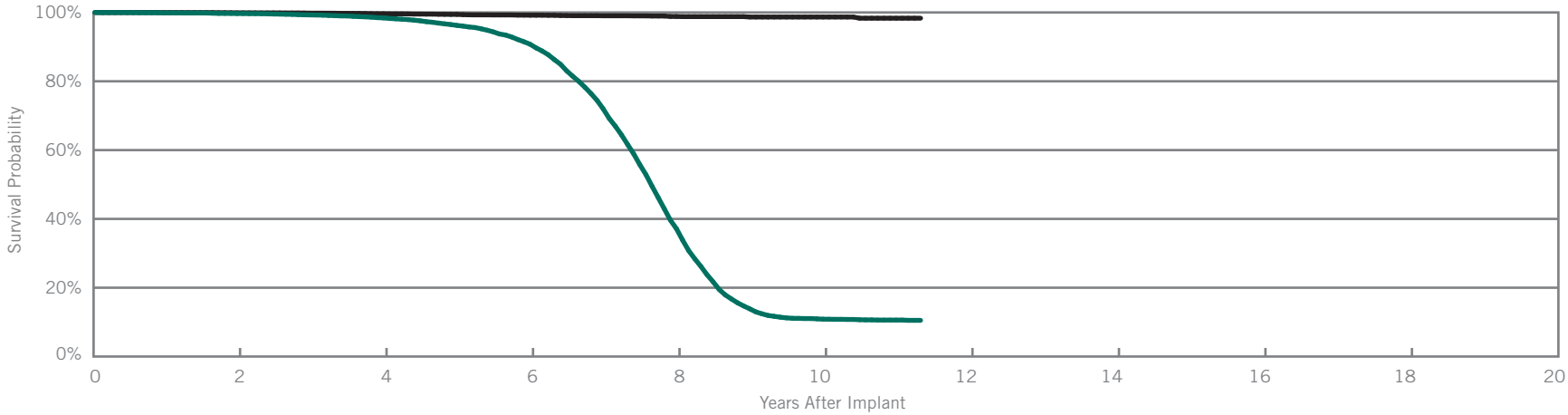
Customer Reported Performance Data

Atlas™ + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	21,082
Estimated Active US Implants	1,517
Estimated Longevity	(see table on page 111)
Normal Battery Depletion	3,558
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 299, 300, 301)	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%	3	0.01%
Possible Early Battery Depletion	6	0.03%	4	0.02%
Other	17	0.08%	2	<0.01%
Total	**42**	**0.20%**	**16**	**0.08%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 136 months				
Survival Probability	99.68%	98.41%	90.78%	37.14%	10.86%	10.52%				
± 1 standard error	0.04%	0.10%	0.26%	0.50%	0.30%	0.30%				
Sample Size	17,300	13,410	9,780	5,270	1,310	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 136 months				
Survival Probability	99.90%	99.63%	99.20%	98.84%	98.67%	98.33%				
± 1 standard error	0.02%	0.05%	0.08%	0.11%	0.14%	0.28%				

Battery Longevity Summary

Dual-Chamber ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		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
CD2357-40C	Fortify Assura™ DR*	11.1	10.2	9.5	8.3
CD2357-40Q	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 ICDs

St. Jude Medical

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2411-36Q	Ellipse™ DR	99.80%	99.75%								
CD2411-36C	Ellipse™ DR	99.66%	99.46%								
CD2357-40Q	Fortify Assura™ DR	99.82%	99.65%								
CD2357-40C	Fortify Assura™ DR	99.81%	99.62%								
CD2311-36Q	Ellipse™ DR	99.04%	98.01%	97.23%	96.07%						
CD2311-36	Ellipse™ DR	98.94%	97.78%	96.92%							
CD2257-40Q	Fortify Assura™ DR	99.87%	99.62%	99.18%							
CD2257-40	Fortify Assura™ DR	99.85%	99.67%	99.53%							
CD2231-40Q	Fortify™ DR	99.76%	99.58%	98.99%	98.11%	96.64%	95.28%				
CD2231-40	Fortify™ DR	99.88%	99.67%	99.16%	98.39%	97.12%	95.81%				
CD2211-36Q	Current™ + DR	99.85%	99.40%	99.05%	98.57%	97.34%	94.27%				
CD2211-36	Current™ + DR	99.78%	99.57%	99.30%	98.49%	97.82%	94.18%	81.07%			
2207-36	Current™ DR RF	99.69%	99.26%	98.67%	97.93%	96.67%	92.98%	79.05%	51.85%		
V-268	Atlas™ II + DR	99.66%	99.38%	98.74%	97.16%	91.61%	66.21%	26.03%	12.12%	11.47%	
V-243	Atlas™ + DR	99.87%	99.68%	99.28%	98.41%	96.24%	90.78%	71.96%	37.14%	13.87%	10.86%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2411-36Q	Ellipse™ DR	99.80%	99.75%								
CD2411-36C	Ellipse™ DR	99.66%	99.46%								
CD2357-40Q	Fortify Assura™ DR	99.87%	99.74%								
CD2357-40C	Fortify Assura™ DR	99.88%	99.77%								
CD2311-36Q	Ellipse™ DR	99.13%	98.16%	97.45%	96.68%						
CD2311-36	Ellipse™ DR	99.03%	98.03%	97.38%							
CD2257-40Q	Fortify Assura™ DR	99.87%	99.71%	99.36%							
CD2257-40	Fortify Assura™ DR	99.90%	99.78%	99.64%							
CD2231-40Q	Fortify™ DR	99.87%	99.76%	99.30%	98.61%	97.61%	96.62%				
CD2231-40	Fortify™ DR	99.95%	99.86%	99.48%	98.81%	98.12%	97.11%				
CD2211-36Q	Current™ + DR	99.85%	99.58%	99.41%	99.22%	98.80%	98.47%				
CD2211-36	Current™ + DR	99.90%	99.76%	99.54%	99.09%	98.95%	98.20%	97.76%			
2207-36	Current™ DR RF	99.75%	99.59%	99.21%	98.72%	98.21%	97.86%	97.01%	96.21%		
V-268	Atlas™ II + DR	99.80%	99.68%	99.41%	99.12%	98.83%	98.50%	98.34%	98.23%	98.23%	
V-243	Atlas™ + DR	99.97%	99.90%	99.80%	99.63%	99.43%	99.20%	99.03%	98.84%	98.67%	98.67%

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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	9,304	2.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	1	0.01%	**4**	**0.04%**
CD2411-36C	Ellipse™ DR	5,338	2.10%	2	0.04%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.11%**
CD2357-40Q	Fortify Assura™ DR	16,911	2.10%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	0	0.00%	**7**	**0.04%**
CD2357-40C	Fortify Assura™ DR	8,524	2.20%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	**4**	**0.05%**
CD2311-36Q	Ellipse™ DR	5,898	5.50%	3	0.05%	0	0.00%	0	0.00%	40	0.68%	1	0.02%	2	0.03%	0	0.00%	1	0.02%	**47**	**0.80%**
CD2311-36	Ellipse™ DR	3,744	6.20%	4	0.11%	0	0.00%	0	0.00%	19	0.51%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**30**	**0.80%**
CD2257-40Q	Fortify Assura™ DR	6,792	4.90%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.09%	3	0.04%	**12**	**0.18%**
CD2257-40	Fortify Assura™ DR	4,226	5.40%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	**3**	**0.07%**
CD2231-40Q	Fortify™ DR	26,842	6.20%	5	0.02%	2	<0.01%	18	0.07%	4	0.01%	1	<0.01%	0	0.00%	76	0.28%	10	0.04%	**116**	**0.43%**
CD2231-40	Fortify™ DR	12,074	7.70%	3	0.02%	1	<0.01%	3	0.02%	6	0.05%	0	0.00%	0	0.00%	29	0.24%	4	0.03%	**46**	**0.38%**
CD2211-36Q	Current™ + DR	8,143	8.80%	6	0.07%	0	0.00%	6	0.07%	1	0.01%	1	0.01%	0	0.00%	3	0.04%	4	0.05%	**21**	**0.26%**
CD2211-36	Current™ + DR	6,270	11.40%	2	0.03%	2	0.03%	5	0.08%	0	0.00%	1	0.02%	0	0.00%	7	0.11%	5	0.08%	**22**	**0.35%**
2207-36	Current™ DR RF	22,377	16.80%	9	0.04%	6	0.03%	20	0.09%	1	<0.01%	2	<0.01%	1	<0.01%	36	0.16%	31	0.14%	**106**	**0.47%**
V-268	Atlas™ II + DR	14,808	28.90%	6	0.04%	4	0.03%	9	0.06%	0	0.00%	0	0.00%	0	0.00%	18	0.12%	10	0.07%	**47**	**0.32%**
V-243	Atlas™ + DR	21,082	26.60%	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 7-8.

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/o Compromised Therapy															
				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	9,304	2.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**4**	**0.04%**
CD2411-36C	Ellipse™ DR	5,338	2.10%	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%**
CD2357-40Q	Fortify Assura™ DR	16,911	2.10%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**6**	**0.04%**
CD2357-40C	Fortify Assura™ DR	8,524	2.20%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD2311-36Q	Ellipse™ DR	5,898	5.50%	1	0.02%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	3	0.05%	0	0.00%	2	0.03%	**10**	**0.17%**
CD2311-36	Ellipse™ DR	3,744	6.20%	2	0.05%	0	0.00%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	0	0.00%	0	0.00%	**9**	**0.24%**
CD2257-40Q	Fortify Assura™ DR	6,792	4.90%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	3	0.04%	0	0.00%	**6**	**0.09%**
CD2257-40	Fortify Assura™ DR	4,226	5.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.07%**
CD2231-40Q	Fortify™ DR	26,842	6.20%	7	0.03%	2	<0.01%	13	0.05%	1	<0.01%	0	0.00%	0	0.00%	27	0.10%	4	0.01%	**54**	**0.20%**
CD2231-40	Fortify™ DR	12,074	7.70%	2	0.02%	0	0.00%	5	0.04%	0	0.00%	0	0.00%	1	<0.01%	9	0.07%	2	0.02%	**19**	**0.16%**
CD2211-36Q	Current™ + DR	8,143	8.80%	2	0.02%	0	0.00%	6	0.07%	0	0.00%	1	0.01%	1	0.01%	3	0.04%	3	0.04%	**16**	**0.20%**
CD2211-36	Current™ + DR	6,270	11.40%	1	0.02%	0	0.00%	4	0.06%	0	0.00%	3	0.05%	0	0.00%	4	0.06%	0	0.00%	**12**	**0.19%**
2207-36	Current™ DR RF	22,377	16.80%	12	0.05%	2	<0.01%	9	0.04%	0	0.00%	13	0.06%	12	0.05%	18	0.08%	6	0.03%	**72**	**0.32%**
V-268	Atlas™ II + DR	14,808	28.90%	4	0.03%	0	0.00%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	6	0.04%	5	0.03%	**19**	**0.13%**
V-243	Atlas™ + DR	21,082	26.60%	3	0.01%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	3	0.01%	4	0.02%	2	<0.01%	**16**	**0.08%**

Definitions of malfunction categories can be found on pages 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ Compromised Therapy															
				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	9,753	2.31%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	1	0.01%	**4**	**0.04%**
CD2411-36C	Ellipse™ DR	5,494	2.58%	2	0.04%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.11%**
CD2357-40Q	Fortify Assura™ DR	17,620	2.28%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	0	0.00%	**7**	**0.04%**
CD2357-40C	Fortify Assura™ DR	8,843	2.51%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	**4**	**0.05%**
CD2311-36Q	Ellipse™ DR	5,920	6.93%	3	0.05%	0	0.00%	0	0.00%	40	0.68%	1	0.02%	2	0.03%	0	0.00%	1	0.02%	**47**	**0.79%**
CD2311-36	Ellipse™ DR	3,759	7.05%	4	0.11%	0	0.00%	0	0.00%	19	0.51%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**30**	**0.80%**
CD2257-40Q	Fortify Assura™ DR	6,788	5.26%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.09%	3	0.04%	**12**	**0.18%**
CD2257-40	Fortify Assura™ DR	4,241	5.94%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	**3**	**0.07%**
CD2231-40Q	Fortify™ DR	27,952	6.47%	5	0.02%	2	<0.01%	18	0.06%	4	0.01%	1	<0.01%	0	0.00%	77	0.28%	11	0.04%	**118**	**0.42%**
CD2231-40	Fortify™ DR	13,237	7.80%	3	0.02%	1	<0.01%	3	0.02%	6	0.05%	0	0.00%	0	0.00%	30	0.23%	5	0.04%	**48**	**0.36%**
CD2211-36Q	Current™ + DR	14,895	5.93%	7	0.05%	1	<0.01%	8	0.05%	2	0.01%	1	<0.01%	0	0.00%	5	0.03%	8	0.05%	**32**	**0.21%**
CD2211-36	Current™ + DR	13,117	6.24%	3	0.02%	3	0.02%	5	0.04%	0	0.00%	1	<0.01%	0	0.00%	9	0.07%	9	0.07%	**30**	**0.23%**
2207-36	Current™ DR RF	33,051	13.56%	16	0.05%	11	0.03%	27	0.08%	9	0.03%	3	<0.01%	2	<0.01%	51	0.15%	39	0.12%	**158**	**0.48%**
V-268	Atlas™ II + DR	25,779	18.89%	15	0.06%	5	0.02%	19	0.07%	1	<0.01%	0	0.00%	0	0.00%	31	0.12%	19	0.07%	**90**	**0.35%**
V-243	Atlas™ + DR	34,105	18.61%	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 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromised Therapy															
				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	9,753	2.31%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**4**	**0.04%**
CD2411-36C	Ellipse™ DR	5,494	2.58%	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%**
CD2357-40Q	Fortify Assura™ DR	17,620	2.28%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**6**	**0.03%**
CD2357-40C	Fortify Assura™ DR	8,843	2.51%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD2311-36Q	Ellipse™ DR	5,920	6.93%	1	0.02%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	3	0.05%	0	0.00%	2	0.03%	**10**	**0.17%**
CD2311-36	Ellipse™ DR	3,759	7.05%	2	0.05%	0	0.00%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	0	0.00%	0	0.00%	**9**	**0.24%**
CD2257-40Q	Fortify Assura™ DR	6,788	5.26%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	3	0.04%	0	0.00%	**6**	**0.09%**
CD2257-40	Fortify Assura™ DR	4,241	5.94%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.07%**
CD2231-40Q	Fortify™ DR	27,952	6.47%	7	0.03%	2	<0.01%	14	0.05%	1	<0.01%	0	0.00%	0	0.00%	28	0.10%	4	0.01%	**56**	**0.20%**
CD2231-40	Fortify™ DR	13,237	7.80%	2	0.02%	0	0.00%	5	0.04%	0	0.00%	0	0.00%	2	0.02%	9	0.07%	2	0.02%	**20**	**0.15%**
CD2211-36Q	Current™ + DR	14,895	5.93%	5	0.03%	0	0.00%	8	0.05%	0	0.00%	2	0.01%	2	0.01%	5	0.03%	3	0.02%	**25**	**0.17%**
CD2211-36	Current™ + DR	13,117	6.24%	1	<0.01%	0	0.00%	4	0.03%	0	0.00%	3	0.02%	1	<0.01%	4	0.03%	1	<0.01%	**14**	**0.11%**
2207-36	Current™ DR RF	33,051	13.56%	17	0.05%	5	0.02%	14	0.04%	4	0.01%	22	0.07%	16	0.05%	24	0.07%	10	0.03%	**112**	**0.34%**
V-268	Atlas™ II + DR	25,779	18.89%	7	0.03%	0	0.00%	8	0.03%	1	<0.01%	0	0.00%	2	<0.01%	9	0.03%	6	0.02%	**33**	**0.13%**
V-243	Atlas™ + DR	34,105	18.61%	6	0.02%	0	0.00%	6	0.02%	0	0.00%	0	0.00%	7	0.02%	6	0.02%	4	0.01%	**29**	**0.09%**

Definitions of malfunction categories can be found on pages 7-8.

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	389	225	18,878	0	0.00%	0	0.00%	0	0.00%	2	0.51%	0	0.00%	**2**	**0.51%**
CD2231-40	177	79	6,908	0	0.00%	0	0.00%	0	0.00%	1	0.56%	0	0.00%	**1**	**0.56%**
CD2211-36Q	834	414	45,562	0	0.00%	0	0.00%	0	0.00%	3	0.36%	1	0.12%	**4**	**0.48%**
CD2211-36	122	48	5,947	1	0.82%	0	0.00%	0	0.00%	1	0.82%	0	0.00%	**2**	**1.64%**
2207-36	630	158	31,791	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

Malfunctions

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy															
				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	389	7.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.26%	1	0.26%	**2**	**0.51%**
CD2231-40	Fortify™ DR	177	9.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current™ + DR	834	10.10%	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	122	11.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.82%	**1**	**0.82%**
2207-36	Current™ DR RF	630	21.30%	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%**

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy															
				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	389	7.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.26%	0	0.00%	**1**	**0.26%**
CD2231-40	Fortify™ DR	177	9.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current™ + DR	834	10.10%	1	0.12%	0	0.00%	2	0.24%	0	0.00%	1	0.12%	0	0.00%	1	0.12%	0	0.00%	**5**	**0.60%**
CD2211-36	Current™ + DR	122	11.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.82%	**1**	**0.82%**
2207-36	Current™ DR RF	630	21.30%	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%**

A list of complications can be found on page 15.
Definitions of malfunction categories can be found on pages 7-8.

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical

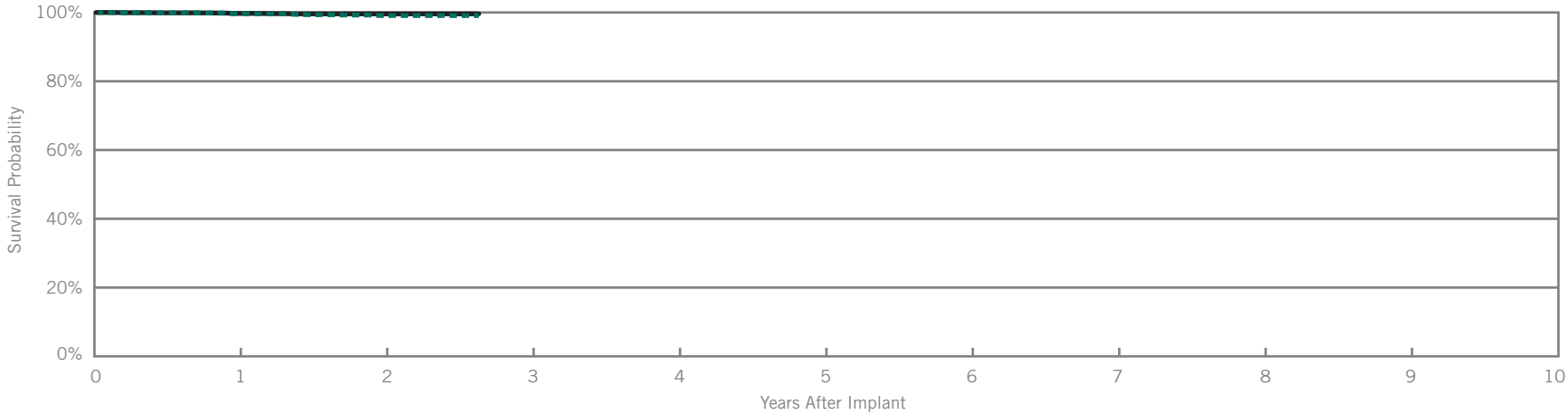
Ellipse™ VR

Model CD1411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	7,882
Estimated Active US Implants	6,734
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

Customer Reported Performance Data

	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	4	0.05%	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%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**5**	**0.06%**	**3**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.66%	99.10%	99.10%							
± 1 standard error	0.06%	0.15%	0.18%							
Sample Size	5,950	2,650	230							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.73%	99.60%	99.60%							
± 1 standard error	0.05%	0.10%	0.10%							

**DF4-LLHH connector type.*

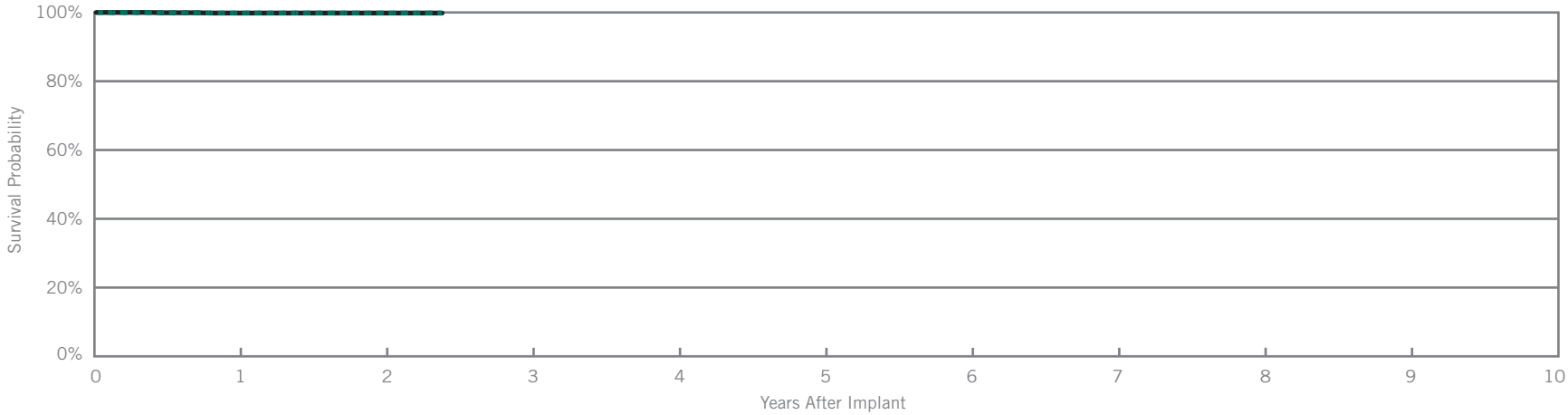
Ellipse™ VR

Model CD1411-36C*

US Regulatory Approval	June 2013
Registered US Implants	3,389
Estimated Active US Implants	2,895
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	0.03%
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**	**0.06%**



Including Normal Battery Depletion

Year	1	2	at 29 months							
Survival Probability	99.83%	99.83%	99.83%							
± 1 standard error	0.09%	0.09%	0.09%							
Sample Size	2,590	1,140	230							

Excluding Normal Battery Depletion

Year	1	2	at 29 months							
Survival Probability	99.83%	99.83%	99.83%							
± 1 standard error	0.09%	0.09%	0.09%							

**Parylene coating.*

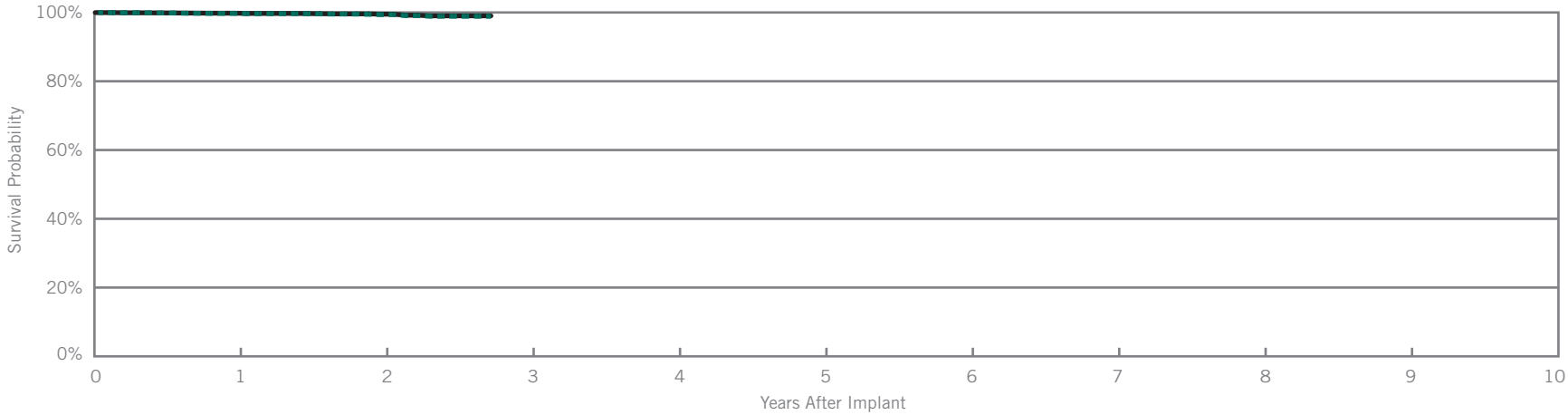
Fortify Assura™ VR

Model CD1357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	14,284
Estimated Active US Implants	12,027
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	5	0.04%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.02%	2	0.01%
Other	2	0.01%	2	0.01%
Total	**10**	**0.07%**	**10**	**0.07%**



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.73%	99.37%	98.89%							
± 1 standard error	0.05%	0.10%	0.22%							
Sample Size	10,950	4,870	230							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.79%	99.50%	99.02%							
± 1 standard error	0.04%	0.08%	0.21%							

**DF4-LLHH connector type.*

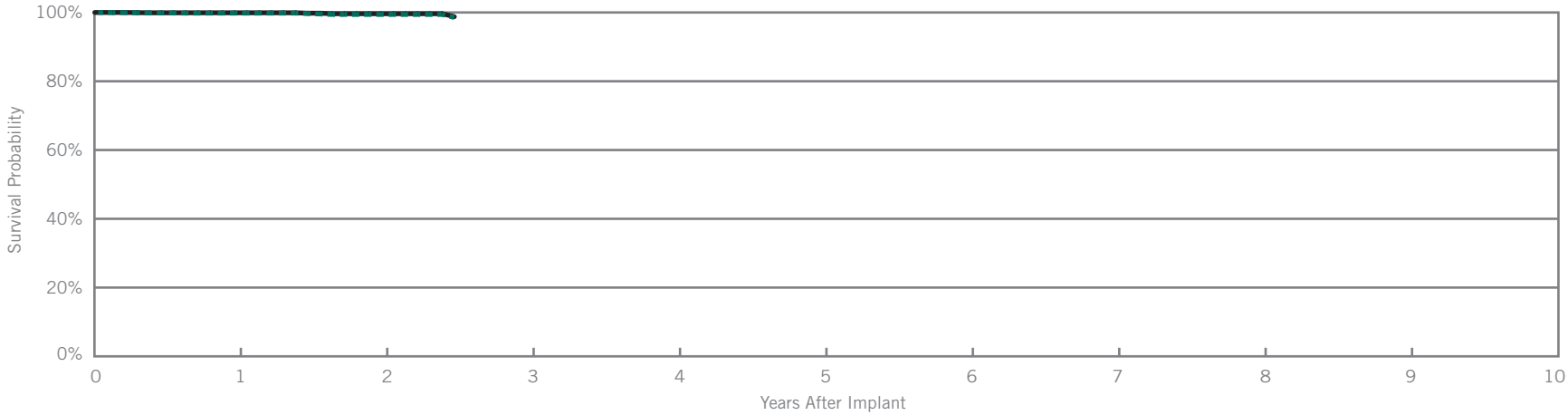
Fortify Assura™ VR

Model CD1357-40C*

US Regulatory Approval	June 2013
Registered US Implants	5,045
Estimated Active US Implants	4,243
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.04%	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	1	0.02%	0	0.00%
Possible Early Battery Depletion	0	0.00%	2	0.04%
Other	0	0.00%	0	0.00%
Total	**3**	**0.06%**	**2**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.81%	99.42%	98.54%							
± 1 standard error	0.07%	0.17%	0.17%							
Sample Size	3,900	1,740	250							

Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.91%	99.64%	98.77%							
± 1 standard error	0.05%	0.14%	0.14%							

**Parylene coating.*

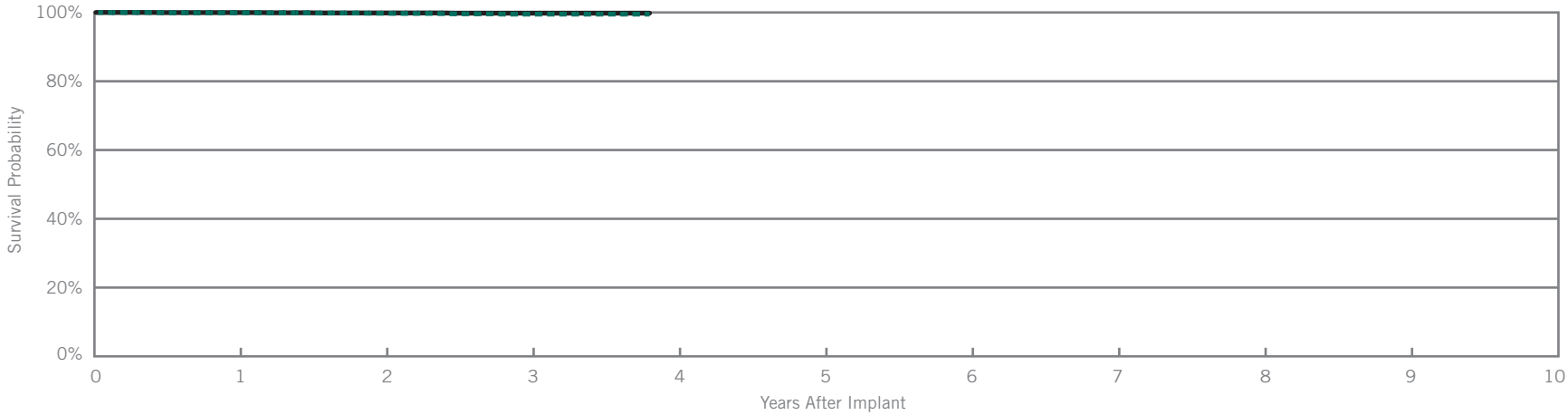
Fortify Assura™ VR

Model CD1257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	5,068
Estimated Active US Implants	3,546
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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%	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	0.02%	1	0.02%
Other	1	0.02%	0	0.00%
Total	**3**	**0.06%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.92%	99.77%	99.52%	99.52%						
± 1 standard error	0.04%	0.07%	0.11%	0.11%						
Sample Size	4,770	4,150	2,880	220						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.96%	99.86%	99.80%	99.80%						
± 1 standard error	0.03%	0.06%	0.07%	0.07%						

**DF4-LLHH connector type.*

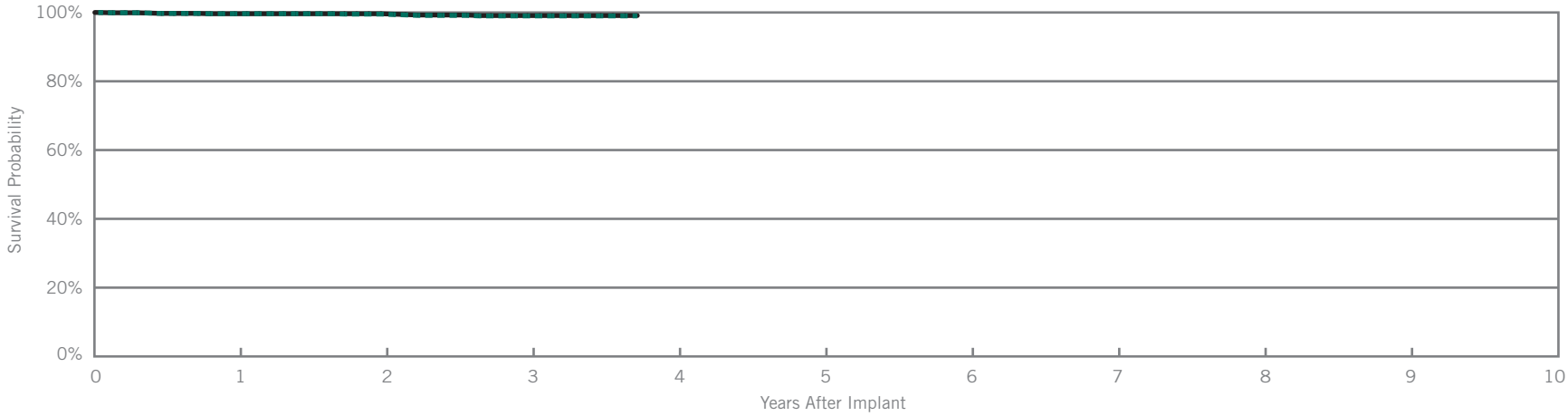
Fortify Assura™ VR

Model CD1257-40

US Regulatory Approval	May 2012
Registered US Implants	2,288
Estimated Active US Implants	1,615
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	1
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	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%	1	0.04%
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	0.04%	0	0.00%
Other	1	0.04%	1	0.04%
Total	**6**	**0.26%**	**2**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.63%	99.52%	98.99%	98.99%						
± 1 standard error	0.13%	0.15%	0.24%	0.24%						
Sample Size	2,160	1,850	1,260	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.63%	99.63%	99.10%	99.10%						
± 1 standard error	0.13%	0.13%	0.23%	0.23%						

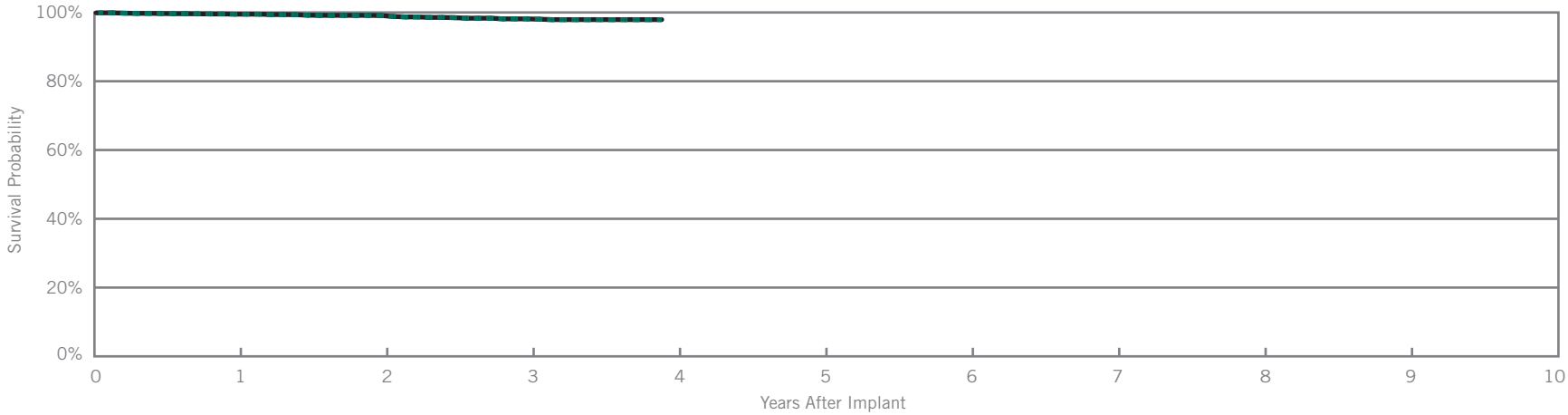
Customer Reported Performance Data

Ellipse™ VR

Model CD1311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	4,740
Estimated Active US Implants	3,318
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

	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	23	0.49%	2	0.04%
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	**27**	**0.57%**	**5**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.51%	99.11%	98.14%	97.92%						
± 1 standard error	0.10%	0.14%	0.22%	0.25%						
Sample Size	4,450	3,930	2,870	280						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.51%	99.11%	98.14%	97.92%						
± 1 standard error	0.10%	0.14%	0.22%	0.25%						

**DF4-LLHH connector type.*

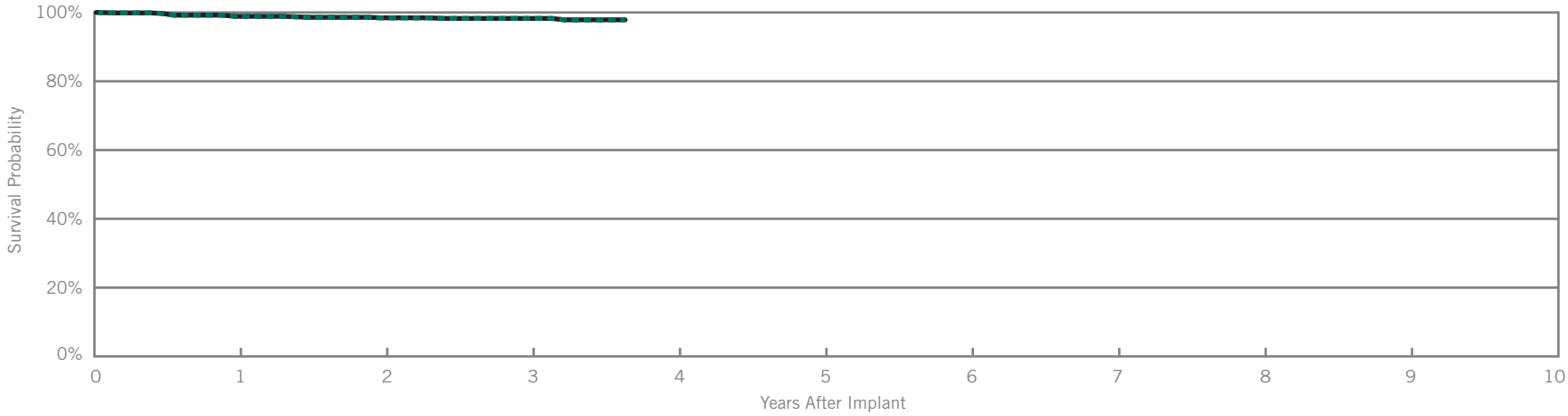
Customer Reported Performance Data

Ellipse™ VR

Model CD1311-36

US Regulatory Approval	May 2012
Registered US Implants	1,620
Estimated Active US Implants	1,142
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 296)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.12%	0	0.00%
Electrical Interconnect	1	0.06%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	3	0.19%	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	**8**	**0.49%**	**4**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	98.88%	98.44%	98.26%	97.86%						
± 1 standard error	0.22%	0.31%	0.35%	0.45%						
Sample Size	1,530	1,360	960	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	98.88%	98.44%	98.26%	97.86%						
± 1 standard error	0.22%	0.31%	0.35%	0.45%						

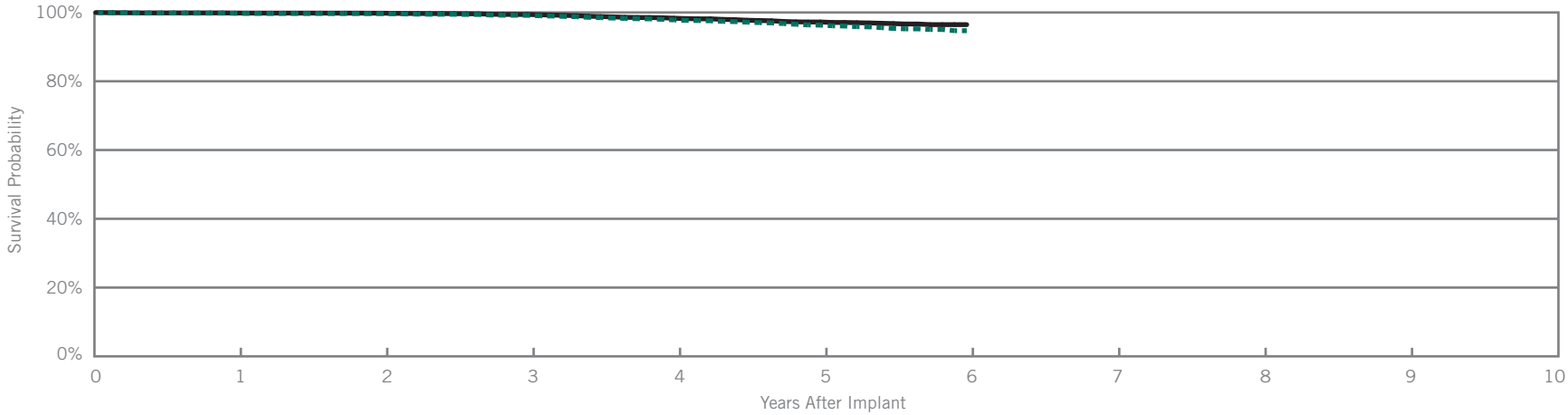
Fortify™ VR

Model CD1231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	16,156
Estimated Active US Implants	9,154
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	37
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	7	0.04%	2	0.01%
Electrical Interconnect	2	0.01%	0	0.00%
Battery	10	0.06%	9	0.06%
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	49	0.30%	25	0.15%
Other	5	0.03%	2	0.01%
Total	**74**	**0.46%**	**38**	**0.24%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.74%	99.67%	99.17%	97.84%	96.32%	94.70%				
± 1 standard error	0.04%	0.05%	0.08%	0.13%	0.21%	0.40%				
Sample Size	15,080	13,250	11,750	9,720	6,090	410				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.84%	99.79%	99.41%	98.32%	97.23%	96.46%				
± 1 standard error	0.03%	0.04%	0.07%	0.12%	0.18%	0.27%				

**DF4-LLHH connector type.*

Actively Monitored Study Data

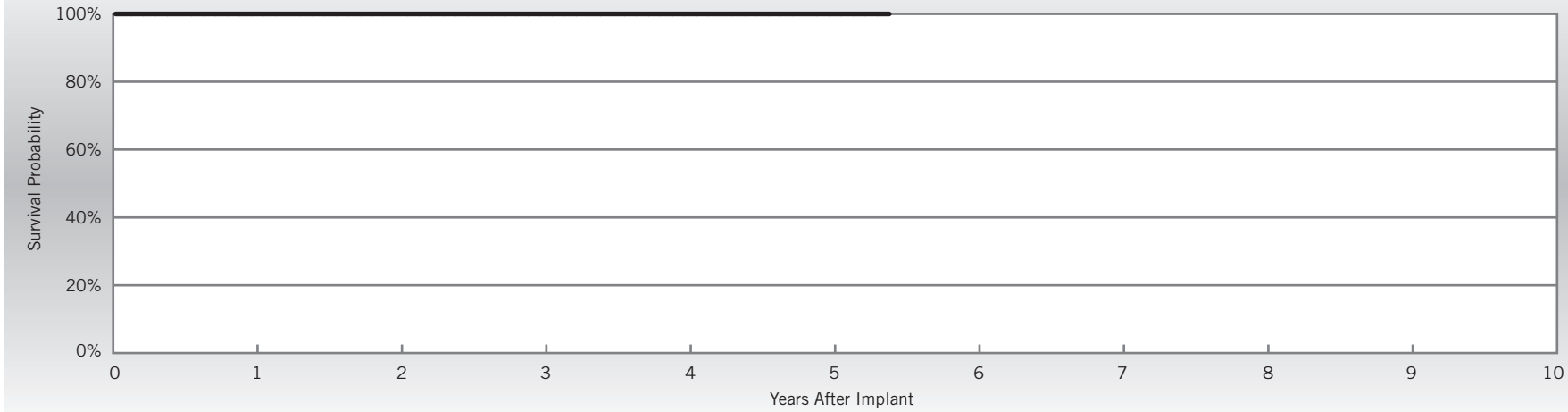
Fortify™ VR

Model CD1231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	158
Active Devices Enrolled in Study	102
Cumulative Months of Follow-up	8,095
Estimated Longevity	(see table on page 140)
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	1	0.63%	1	0.63%
Other	0	0.00%	0	0.00%
Total	**1**	**0.63%**	**1**	**0.63%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%				
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%				
Sample Size	160	150	130	110	90	50				

**DF4-LLHH connector type.*

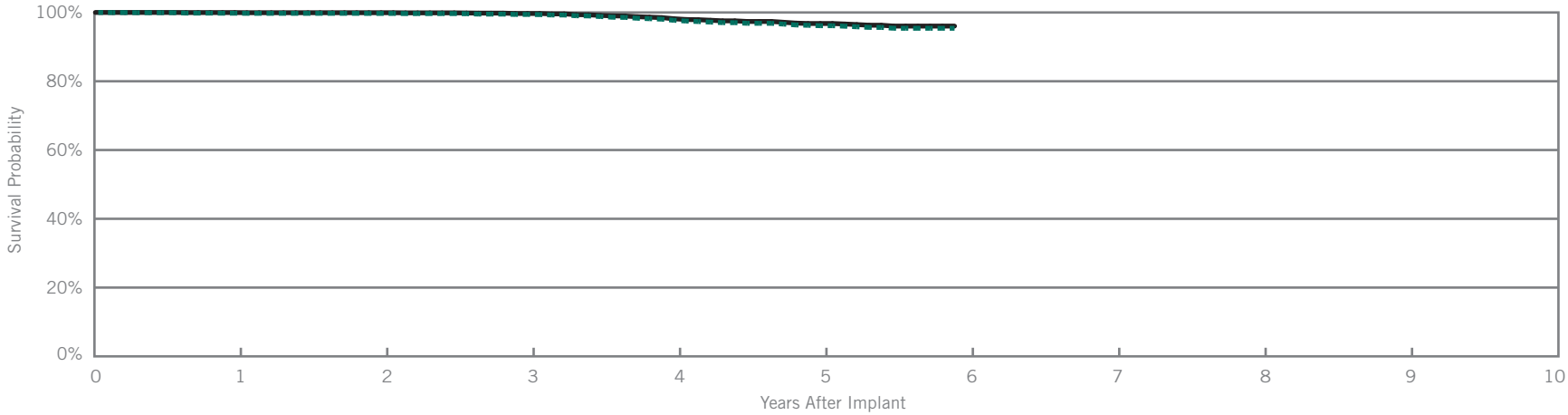
Fortify™ VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	6,776
Estimated Active US Implants	3,760
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	12
Max. Delivered Energy	40 joules
Number of US Advisories (see pg. 295)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	3	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.04%	0	0.00%
High Voltage Capacitor	5	0.07%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	20	0.30%	12	0.18%
Other	2	0.03%	3	0.04%
Total	**32**	**0.47%**	**19**	**0.28%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.78%	99.71%	99.42%	97.72%	96.14%	95.40%				
± 1 standard error	0.06%	0.07%	0.10%	0.21%	0.33%	0.43%				
Sample Size	6,340	5,550	4,880	4,070	2,570	250				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.97%	99.93%	99.70%	98.17%	96.79%	96.04%				
± 1 standard error	0.02%	0.03%	0.08%	0.19%	0.31%	0.41%				

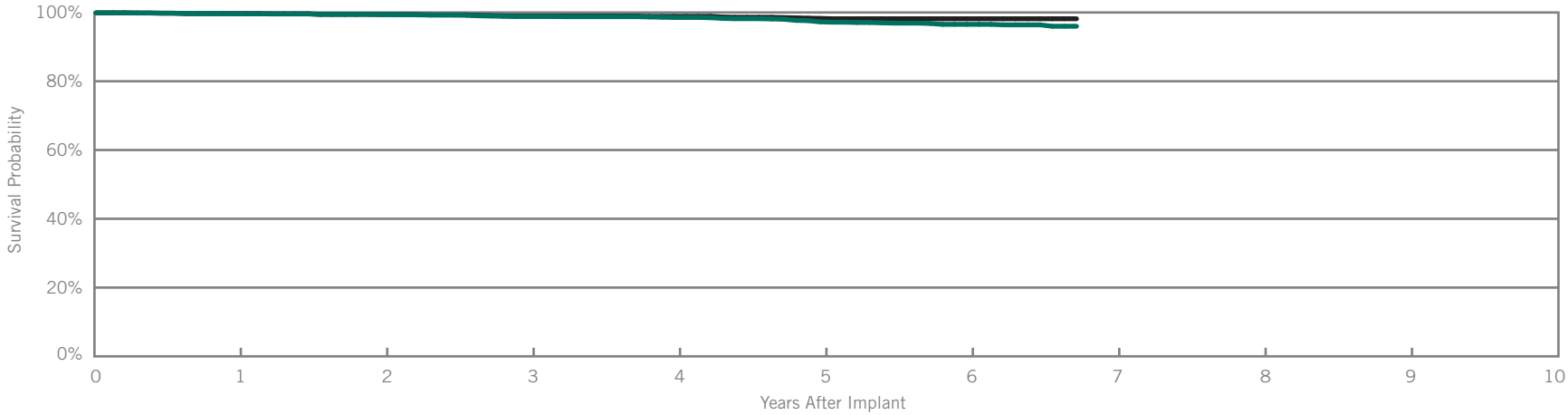
Customer Reported Performance Data

Current™ + VR

Model CD1211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	4,431
Estimated Active US Implants	2,161
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	19
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.09%	3	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.09%	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	**17**	**0.38%**	**9**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.61%	99.36%	98.83%	98.55%	97.26%	96.54%	95.99%			
± 1 standard error	0.09%	0.12%	0.18%	0.20%	0.28%	0.36%	0.47%			
Sample Size	4,130	3,620	3,210	2,820	2,430	2,000	260			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.67%	99.42%	98.95%	98.87%	98.26%	98.17%	98.17%			
± 1 standard error	0.09%	0.11%	0.17%	0.18%	0.23%	0.25%	0.25%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

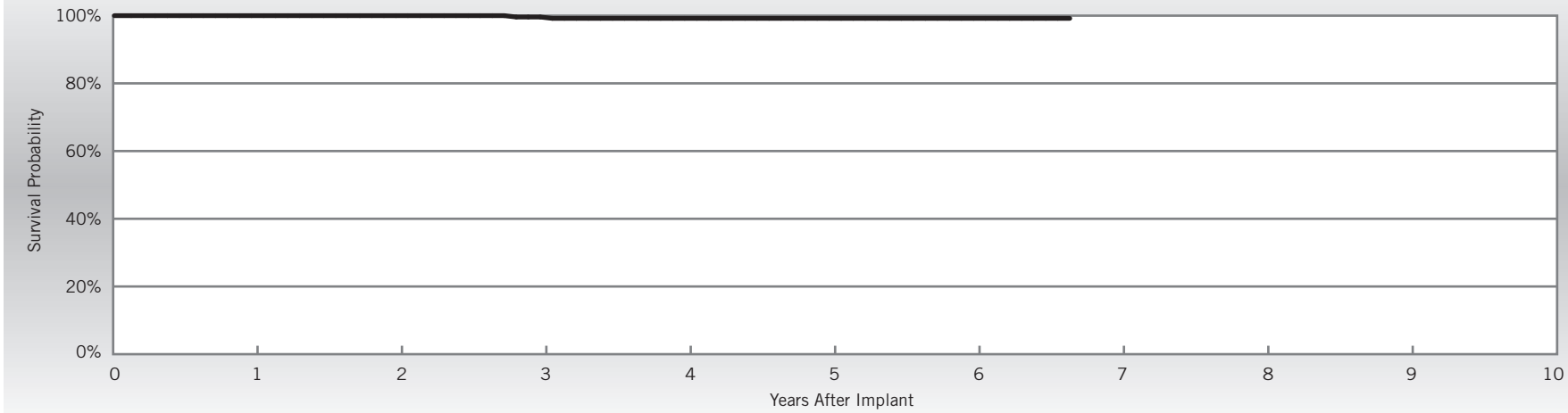
Current™ + VR

Model CD1211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	364
Active Devices Enrolled in Study	176
Cumulative Months of Follow-up	19,072
Estimated Longevity	(see table on page 140)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.27%
Premature Battery Depletion	1	0.27%

	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	0.27%	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**	**0.27%**	**0**	**0.00%**



Year	1	2	3	4	5	6	at 80 months			
Survival Probability	100.00%	100.00%	99.60%	99.20%	99.20%	99.20%	99.20%			
± 1 standard error	0.00%	0.00%	0.39%	0.56%	0.56%	0.56%	0.56%			
Sample Size	350	310	270	230	200	180	50			

**DF4-LLHH connector type.*

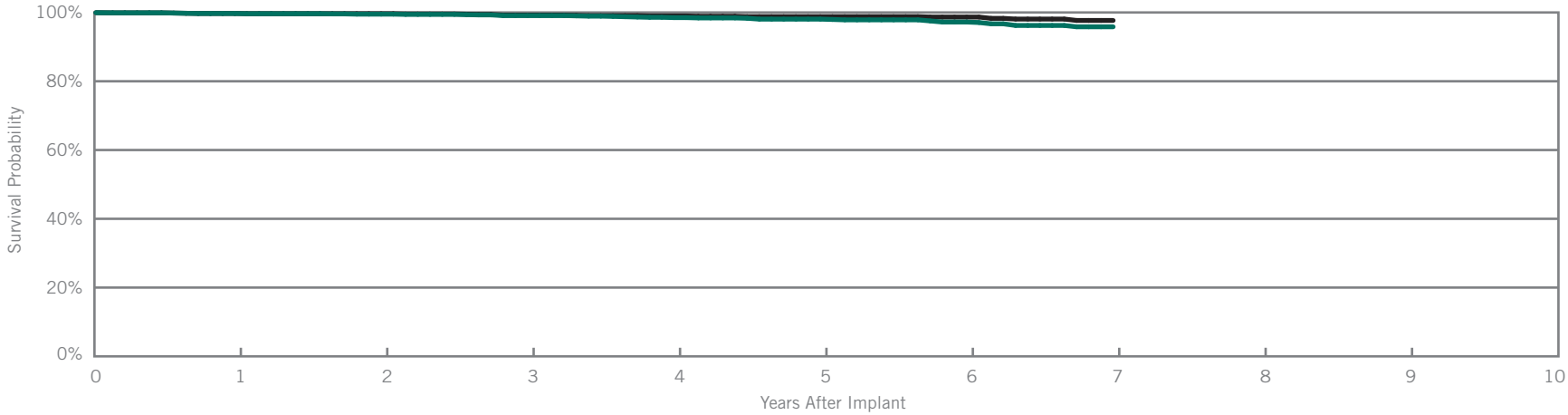
Current™ + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,636
Estimated Active US Implants	1,757
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	15
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.08%	3	0.08%
Electrical Interconnect	2	0.06%	0	0.00%
Battery	4	0.11%	0	0.00%
High Voltage Capacitor	2	0.06%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	4	0.11%	2	0.06%
Other	1	0.03%	0	0.00%
Total	**16**	**0.44%**	**5**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.71%	99.51%	99.09%	98.50%	98.06%	97.22%	95.83%			
± 1 standard error	0.09%	0.12%	0.17%	0.23%	0.28%	0.35%	0.53%			
Sample Size	3,400	3,000	2,670	2,350	2,010	1,640	220			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.71%	99.64%	99.23%	98.98%	98.79%	98.66%	97.68%			
± 1 standard error	0.09%	0.10%	0.16%	0.19%	0.21%	0.23%	0.43%			

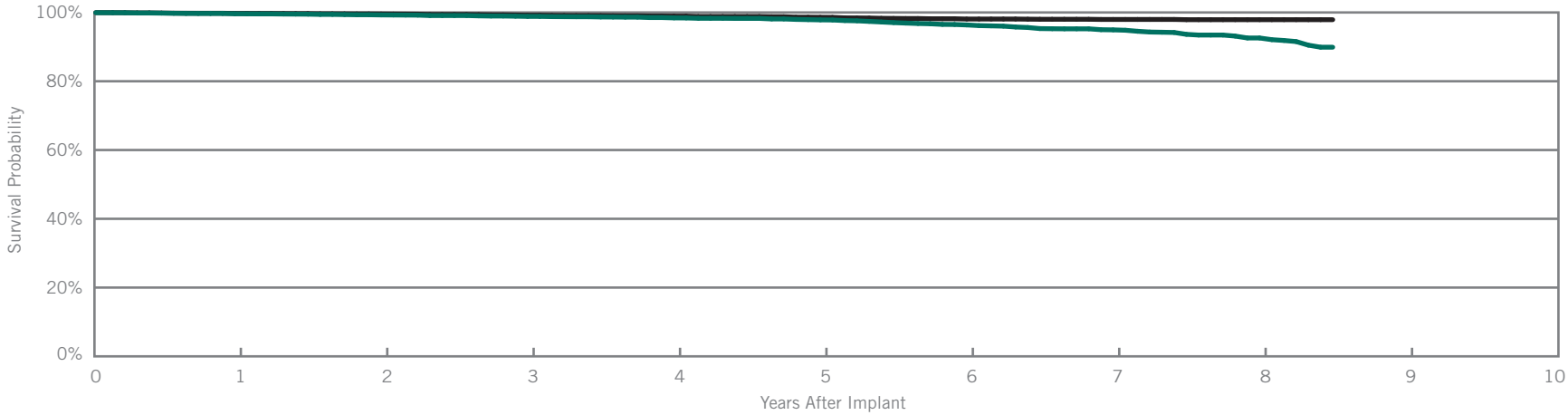
Customer Reported Performance Data

Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,275
Estimated Active US Implants	5,252
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	114
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	6	0.05%	6	0.05%
Electrical Interconnect	10	0.08%	0	0.00%
Battery	8	0.06%	4	0.03%
High Voltage Capacitor	1	<0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	3	0.02%
Possible Early Battery Depletion	11	0.08%	14	0.11%
Other	8	0.06%	4	0.03%
Total	**44**	**0.33%**	**33**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.62%	99.28%	98.85%	98.42%	97.84%	96.37%	94.94%	92.58%	89.90%
± 1 standard error	0.05%	0.08%	0.10%	0.12%	0.15%	0.20%	0.26%	0.41%	0.82%
Sample Size	12,350	10,730	9,480	8,430	7,510	6,590	5,170	2,630	240

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.73%	99.57%	99.19%	98.93%	98.60%	98.09%	97.97%	97.90%	97.90%
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.15%	0.16%	0.17%	0.17%

Actively Monitored Study Data

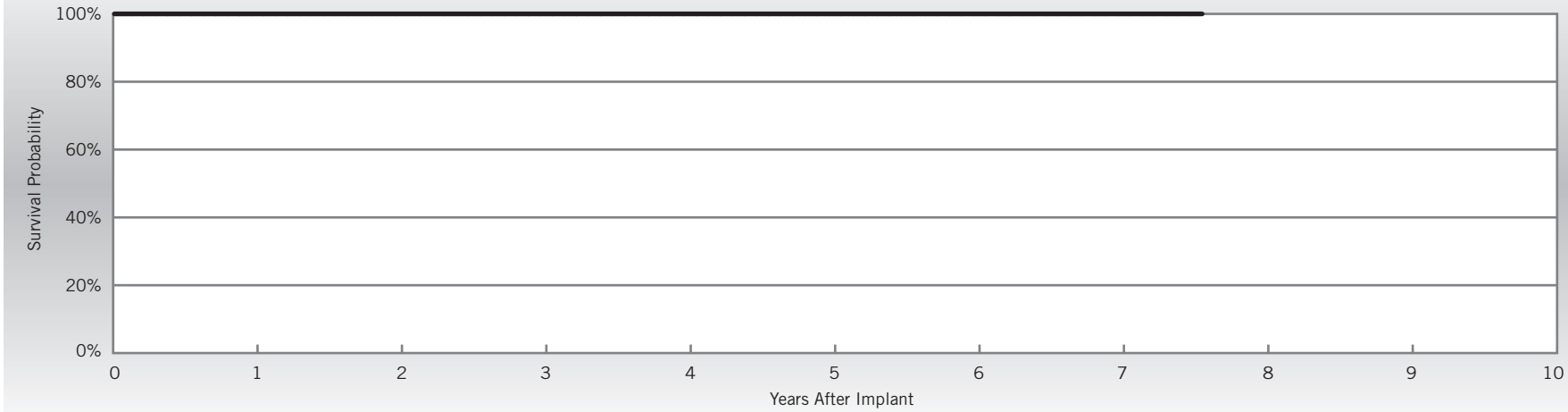
Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	395
Active Devices Enrolled in Study	103
Cumulative Months of Follow-up	20,119
Estimated Longevity	(see table on page 140)
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%**



Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	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%		
Sample Size	380	340	280	210	170	140	110	60		

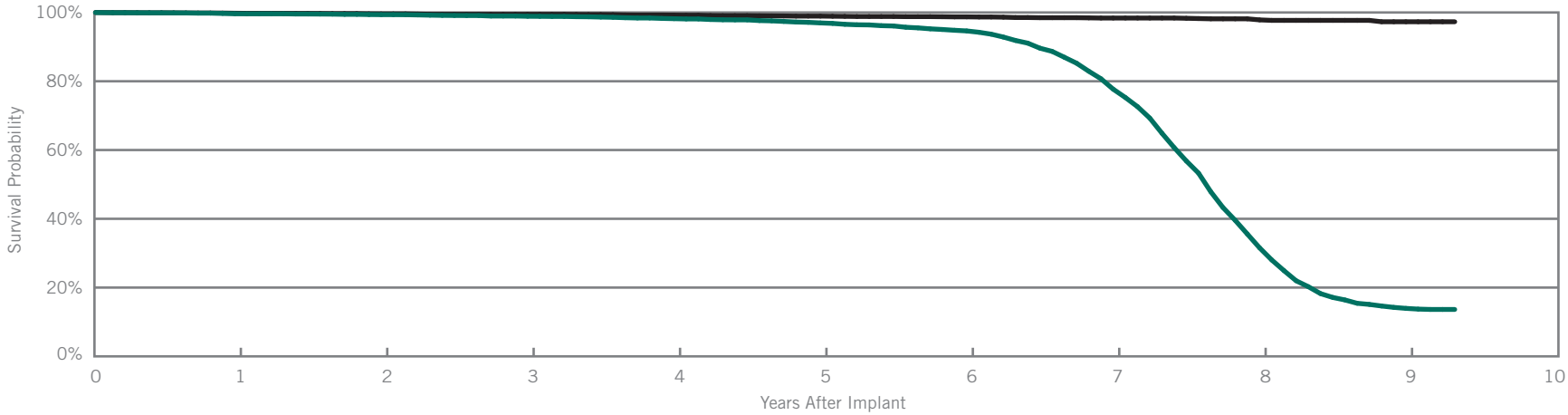
Atlas™ II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,602
Estimated Active US Implants	1,427
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	1,556
Max. Delivered Energy	36 joules
Number of US Advisories (see pg. 299)	One

Customer Reported Performance Data

	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	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.63%	99.36%	98.89%	98.19%	96.96%	94.63%	77.70%	31.57%	13.95%	13.64%
± 1 standard error	0.05%	0.08%	0.11%	0.15%	0.20%	0.28%	0.55%	0.71%	0.53%	0.53%
Sample Size	9,940	8,720	7,660	6,710	5,930	5,240	4,260	2,570	930	210

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.78%	99.60%	99.45%	99.22%	98.94%	98.72%	98.38%	97.84%	97.30%	97.30%
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.14%	0.16%	0.19%	0.37%	0.37%

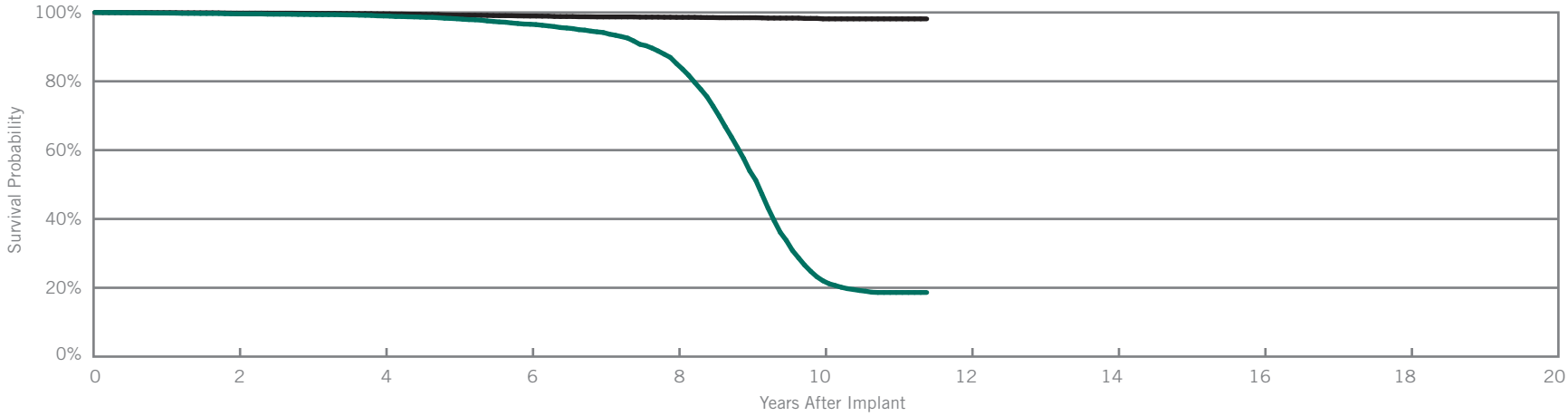
Customer Reported Performance Data

Atlas™ + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,787
Estimated Active US Implants	2,474
Estimated Longevity	(see table on page 140)
Normal Battery Depletion	2,368
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 299, 300, 301)	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%	3	0.01%
Possible Early Battery Depletion	26	0.13%	5	0.02%
Other	13	0.06%	6	0.03%
Total	**57**	**0.27%**	**21**	**0.10%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.58%	98.98%	96.58%	85.15%	22.03%	18.64%				
± 1 standard error	0.05%	0.08%	0.17%	0.36%	0.50%	0.48%				
Sample Size	17,140	13,180	9,890	7,210	2,700	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.81%	99.61%	98.96%	98.59%	98.14%	98.14%				
± 1 standard error	0.03%	0.05%	0.09%	0.11%	0.15%	0.18%				

Battery Longevity Summary

Single-Chamber ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		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 ICDs

St. Jude Medical

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1411-36Q	Ellipse™ VR	99.66%	99.10%								
CD1411-36C	Ellipse™ VR	99.83%	99.83%								
CD1357-40Q	Fortify Assura™ VR	99.73%	99.37%								
CD1357-40C	Fortify Assura™ VR	99.81%	99.42%								
CD1257-40Q	Fortify Assura™ VR	99.92%	99.77%	99.52%							
CD1257-40	Fortify Assura™ VR	99.63%	99.52%	98.99%							
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.14%							
CD1311-36	Ellipse™ VR	98.88%	98.44%	98.26%							
CD1231-40Q	Fortify™ VR	99.74%	99.67%	99.17%	97.84%	96.32%	94.70%				
CD1231-40	Fortify™ VR	99.78%	99.71%	99.42%	97.72%	96.14%					
CD1211-36Q	Current™ + VR	99.61%	99.36%	98.83%	98.55%	97.26%	96.54%				
CD1211-36	Current™ + VR	99.71%	99.51%	99.09%	98.50%	98.06%	97.22%	95.83%			
1207-36	Current™ VR RF	99.62%	99.28%	98.85%	98.42%	97.84%	96.37%	94.94%	92.58%		
V-168	Atlas™ II VR	99.63%	99.36%	98.89%	98.19%	96.96%	94.63%	77.70%	31.57%	13.95%	
V-193	Atlas™ + VR	99.82%	99.58%	99.40%	98.98%	98.17%	96.58%	94.18%	85.15%	53.98%	22.03%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1411-36Q	Ellipse™ VR	99.73%	99.60%								
CD1411-36C	Ellipse™ VR	99.83%	99.83%								
CD1357-40Q	Fortify Assura™ VR	99.79%	99.50%								
CD1357-40C	Fortify Assura™ VR	99.91%	99.64%								
CD1257-40Q	Fortify Assura™ VR	99.96%	99.86%	99.80%							
CD1257-40	Fortify Assura™ VR	99.63%	99.63%	99.10%							
CD1311-36Q	Ellipse™ VR	99.51%	99.11%	98.14%							
CD1311-36	Ellipse™ VR	98.88%	98.44%	98.26%							
CD1231-40Q	Fortify™ VR	99.84%	99.79%	99.41%	98.32%	97.23%	96.46%				
CD1231-40	Fortify™ VR	99.97%	99.93%	99.70%	98.17%	96.79%					
CD1211-36Q	Current™ + VR	99.67%	99.42%	98.95%	98.87%	98.26%	98.17%				
CD1211-36	Current™ + VR	99.71%	99.64%	99.23%	98.98%	98.79%	98.66%	97.68%			
1207-36	Current™ VR RF	99.73%	99.57%	99.19%	98.93%	98.60%	98.09%	97.97%	97.90%		
V-168	Atlas™ II VR	99.78%	99.60%	99.45%	99.22%	98.94%	98.72%	98.38%	97.84%	97.30%	
V-193	Atlas™ + VR	99.95%	99.81%	99.74%	99.61%	99.20%	98.96%	98.71%	98.59%	98.48%	98.14%

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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	7,882	1.70%	1	0.01%	0	0.00%	0	0.00%	4	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.06%**
CD1411-36C	Ellipse™ VR	3,389	2.00%	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%**
CD1357-40Q	Fortify Assura™ VR	14,284	1.90%	3	0.02%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	3	0.02%	2	0.01%	**10**	**0.07%**
CD1357-40C	Fortify Assura™ VR	5,045	2.50%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**3**	**0.06%**
CD1257-40Q	Fortify Assura™ VR	5,068	4.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.06%**
CD1257-40	Fortify Assura™ VR	2,288	5.80%	1	0.04%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	1	0.04%	**6**	**0.26%**
CD1311-36Q	Ellipse™ VR	4,740	4.80%	1	0.02%	0	0.00%	0	0.00%	23	0.49%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**27**	**0.57%**
CD1311-36	Ellipse™ VR	1,620	6.20%	2	0.12%	1	0.06%	0	0.00%	3	0.19%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**8**	**0.49%**
CD1231-40Q	Fortify™ VR	16,156	6.90%	7	0.04%	2	0.01%	10	0.06%	1	<0.01%	0	0.00%	0	0.00%	49	0.30%	5	0.03%	**74**	**0.46%**
CD1231-40	Fortify™ VR	6,776	8.20%	2	0.03%	0	0.00%	3	0.04%	5	0.07%	0	0.00%	0	0.00%	20	0.30%	2	0.03%	**32**	**0.47%**
CD1211-36Q	Current™ + VR	4,431	8.10%	4	0.09%	0	0.00%	4	0.09%	1	0.02%	0	0.00%	0	0.00%	6	0.14%	2	0.05%	**17**	**0.38%**
CD1211-36	Current™ + VR	3,636	8.20%	3	0.08%	2	0.06%	4	0.11%	2	0.06%	0	0.00%	0	0.00%	4	0.11%	1	0.03%	**16**	**0.44%**
1207-36	Current™ VR RF	13,275	10.10%	6	0.05%	10	0.08%	8	0.06%	1	<0.01%	0	0.00%	0	0.00%	11	0.08%	8	0.06%	**44**	**0.33%**
V-168	Atlas™ II VR	10,602	25.20%	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	20,787	22.60%	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 7-8.

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/o Compromised Therapy															
				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	7,882	1.70%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.04%**
CD1411-36C	Ellipse™ VR	3,389	2.00%	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.06%**
CD1357-40Q	Fortify Assura™ VR	14,284	1.90%	5	0.04%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	2	0.01%	**10**	**0.07%**
CD1357-40C	Fortify Assura™ VR	5,045	2.50%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	0	0.00%	**2**	**0.04%**
CD1257-40Q	Fortify Assura™ VR	5,068	4.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	**1**	**0.02%**
CD1257-40	Fortify Assura™ VR	2,288	5.80%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**2**	**0.09%**
CD1311-36Q	Ellipse™ VR	4,740	4.80%	1	0.02%	0	0.00%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	**5**	**0.11%**
CD1311-36	Ellipse™ VR	1,620	6.20%	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	16,156	6.90%	2	0.01%	0	0.00%	9	0.06%	0	0.00%	0	0.00%	0	0.00%	25	0.15%	2	0.01%	**38**	**0.24%**
CD1231-40	Fortify™ VR	6,776	8.20%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	12	0.18%	3	0.04%	**19**	**0.28%**
CD1211-36Q	Current™ + VR	4,431	8.10%	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	3,636	8.20%	3	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.06%	0	0.00%	**5**	**0.14%**
1207-36	Current™ VR RF	13,275	10.10%	6	0.05%	0	0.00%	4	0.03%	1	<0.01%	1	<0.01%	3	0.02%	14	0.11%	4	0.03%	**33**	**0.25%**
V-168	Atlas™ II VR	10,602	25.20%	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	20,787	22.60%	2	<0.01%	1	<0.01%	2	<0.01%	1	<0.01%	1	<0.01%	3	0.01%	5	0.02%	6	0.03%	**21**	**0.10%**

Definitions of malfunction categories can be found on pages 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ Compromised Therapy															
				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	8,243	2.06%	1	0.01%	0	0.00%	0	0.00%	4	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.06%**
CD1411-36C	Ellipse™ VR	3,555	2.56%	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	14,772	2.06%	3	0.02%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	3	0.02%	2	0.01%	**10**	**0.07%**
CD1357-40C	Fortify Assura™ VR	5,271	3.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**3**	**0.06%**
CD1257-40Q	Fortify Assura™ VR	5,045	4.44%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.06%**
CD1257-40	Fortify Assura™ VR	2,300	6.48%	1	0.04%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	1	0.04%	**6**	**0.26%**
CD1311-36Q	Ellipse™ VR	4,829	5.40%	1	0.02%	0	0.00%	0	0.00%	23	0.48%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**27**	**0.56%**
CD1311-36	Ellipse™ VR	1,635	8.01%	3	0.18%	1	0.06%	0	0.00%	4	0.24%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**10**	**0.61%**
CD1231-40Q	Fortify™ VR	17,283	6.93%	7	0.04%	2	0.01%	10	0.06%	1	<0.01%	0	0.00%	0	0.00%	54	0.31%	5	0.03%	**79**	**0.46%**
CD1231-40	Fortify™ VR	7,456	8.23%	2	0.03%	0	0.00%	3	0.04%	5	0.07%	0	0.00%	0	0.00%	20	0.27%	2	0.03%	**32**	**0.43%**
CD1211-36Q	Current™ + VR	15,321	3.00%	7	0.05%	2	0.01%	6	0.04%	1	<0.01%	0	0.00%	0	0.00%	7	0.05%	3	0.02%	**26**	**0.17%**
CD1211-36	Current™ + VR	14,308	2.68%	3	0.02%	2	0.01%	4	0.03%	3	0.02%	0	0.00%	0	0.00%	6	0.04%	5	0.03%	**23**	**0.16%**
1207-36	Current™ VR RF	24,845	7.11%	11	0.04%	30	0.12%	13	0.05%	1	<0.01%	0	0.00%	0	0.00%	24	0.10%	10	0.04%	**89**	**0.36%**
V-168	Atlas™ II VR	23,946	14.04%	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	14.64%	5	0.01%	9	0.02%	15	0.04%	5	0.01%	1	<0.01%	1	<0.01%	71	0.18%	32	0.08%	**139**	**0.35%**

Definitions of malfunction categories can be found on pages 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromised Therapy															
				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	8,243	2.06%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.04%**
CD1411-36C	Ellipse™ VR	3,555	2.56%	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.06%**
CD1357-40Q	Fortify Assura™ VR	14,772	2.06%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	2	0.01%	**10**	**0.07%**
CD1357-40C	Fortify Assura™ VR	5,271	3.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	0	0.00%	**2**	**0.04%**
CD1257-40Q	Fortify Assura™ VR	5,045	4.44%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	**1**	**0.02%**
CD1257-40	Fortify Assura™ VR	2,300	6.48%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**2**	**0.09%**
CD1311-36Q	Ellipse™ VR	4,829	5.40%	1	0.02%	0	0.00%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	**5**	**0.10%**
CD1311-36	Ellipse™ VR	1,635	8.01%	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	17,283	6.93%	3	0.02%	1	<0.01%	9	0.05%	0	0.00%	0	0.00%	0	0.00%	27	0.16%	2	0.01%	**42**	**0.24%**
CD1231-40	Fortify™ VR	7,456	8.23%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	12	0.16%	3	0.04%	**19**	**0.25%**
CD1211-36Q	Current™ + VR	15,321	3.00%	4	0.03%	0	0.00%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	4	0.03%	**15**	**0.10%**
CD1211-36	Current™ + VR	14,308	2.68%	4	0.03%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	**7**	**0.05%**
1207-36	Current™ VR RF	24,845	7.11%	12	0.05%	3	0.01%	11	0.04%	1	<0.01%	3	0.01%	4	0.02%	20	0.08%	8	0.03%	**62**	**0.25%**
V-168	Atlas™ II VR	23,946	14.04%	4	0.02%	0	0.00%	6	0.03%	0	0.00%	0	0.00%	10	0.04%	10	0.04%	9	0.04%	**39**	**0.16%**
V-193	Atlas™ + VR	39,596	14.64%	4	0.01%	3	<0.01%	8	0.02%	1	<0.01%	1	<0.01%	5	0.01%	11	0.03%	11	0.03%	**44**	**0.11%**

Definitions of malfunction categories can be found on pages 7-8.

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	158	102	8,095	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	364	176	19,072	1	0.27%	0	0.00%	0	0.00%	1	0.27%	0	0.00%	**2**	**0.55%**
1207-36	395	103	20,119	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy															
				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	158	7.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	**1**	**0.63%**
CD1211-36Q	Current™ + VR	364	7.10%	0	0.00%	0	0.00%	1	0.27%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.27%**
1207-36	Current™ VR RF	395	13.20%	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%**

Models	Family	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy															
				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	158	7.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.00%	1	0.63%	0	0.00%	**1**	**0.63%**
CD1211-36Q	Current™ + VR	364	7.10%	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%**
1207-36	Current™ VR RF	395	13.20%	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.25%	**1**	**0.25%**

A list of complications can be found on page 15.
Definitions of malfunction categories can be found on pages 7-8.

Defibrillation Leads

St. Jude Medical

Customer Reported Performance Data

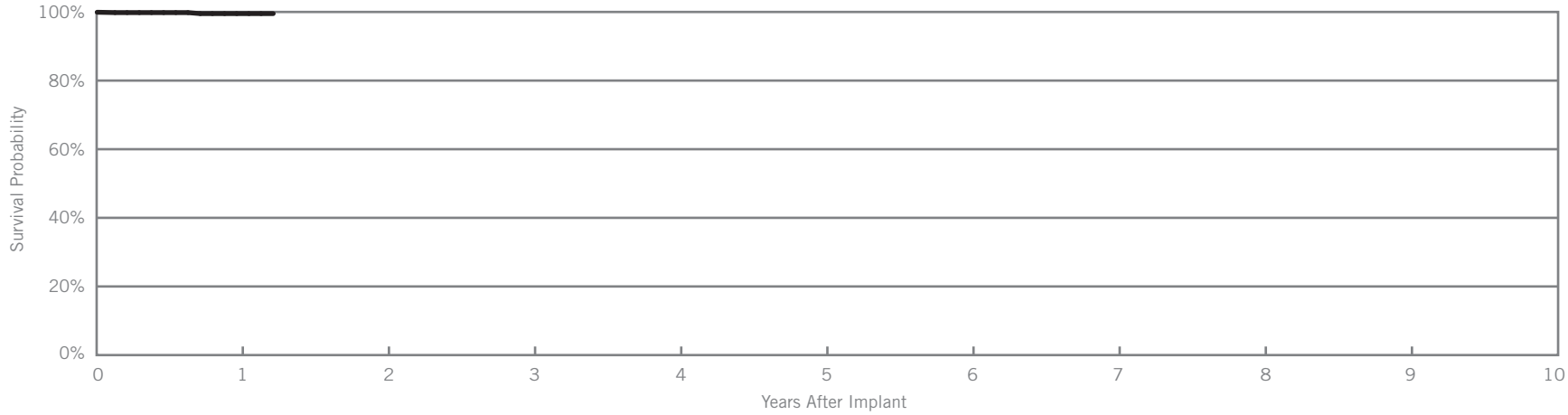
Optisure™ DF4

Model LDA230Q

US Regulatory Approval	February 2014
Registered US Implants	580
Estimated Active US Implants	516
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 309)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.17%	0	0.00%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	1	0.17%
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%
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	**1**	**0.17%**	**1**	**0.17%**
Total Returned for Analysis	**0**		**0**	

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	0.34%
Total	**2**	**0.34%**



Year	1	at 15 months								
Survival Probability	99.52%	99.52%								
± 1 standard error	0.35%	0.35%								
Sample Size	420	220								

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

Customer Reported Performance Data

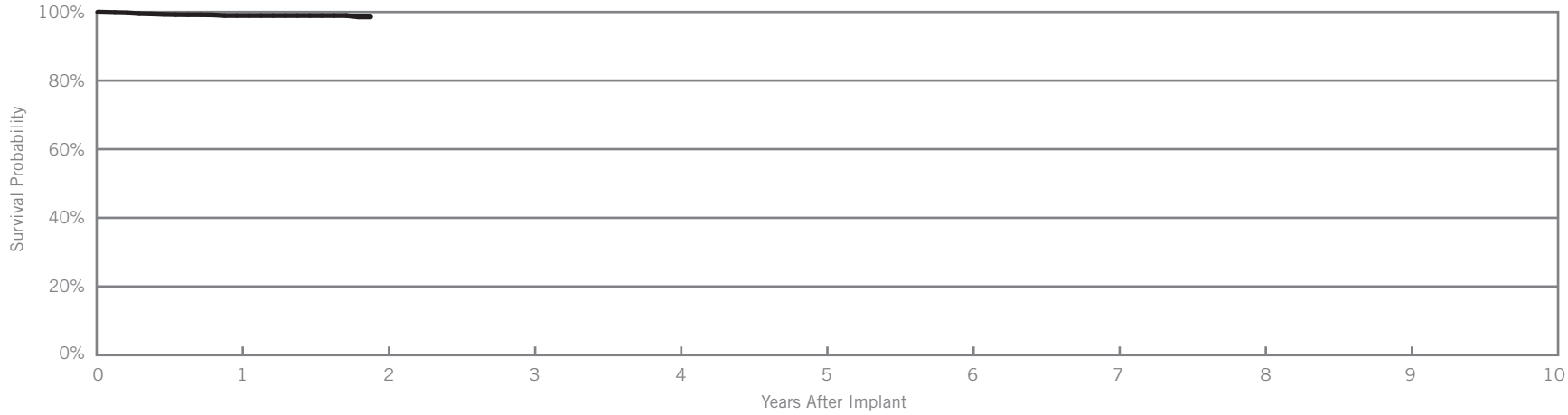
Optisure™ DF4

Model LDA220Q

US Regulatory Approval	February 2014
Registered US Implants	4,478
Estimated Active US Implants	3,908
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 309)	One

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.09%	3	0.07%
Conductor Fracture	0	0.00%	1	0.02%
Lead Dislodgement	17	0.38%	23	0.51%
Failure to Capture	7	0.16%	11	0.25%
Oversensing	2	0.04%	5	0.11%
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%
Abnormal Defibrillation Impedance	3	0.07%	1	0.02%
Extracardiac Stimulation	1	0.02%	0	0.00%
Other	2	0.04%	0	0.00%
Total	**36**	**0.80%**	**44**	**0.98%**
Total Returned for Analysis	**13**		**16**	

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	0.02%
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	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	15	0.33%
Total	**16**	**0.36%**



Year	1	at 23 months								
Survival Probability	98.97%	98.58%								
± 1 standard error	0.18%	0.43%								
Sample Size	3,140	200								

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

Customer Reported Performance Data

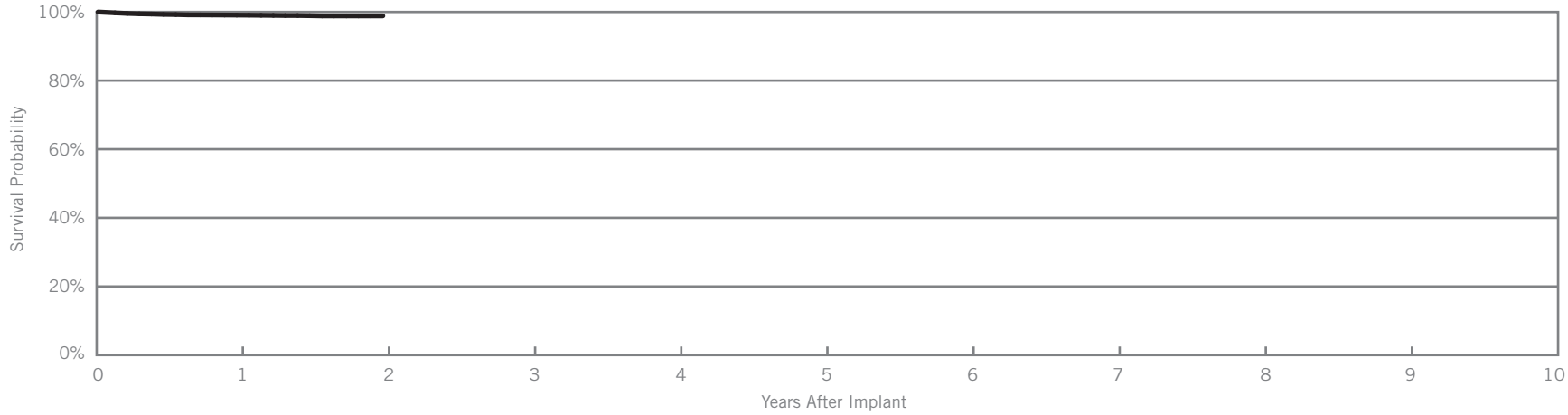
Optisure™ DF4

Model LDA210Q

US Regulatory Approval	February 2014
Registered US Implants	11,755
Estimated Active US Implants	11,127
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	0.09%	8	0.07%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	28	0.24%	57	0.48%
Failure to Capture	12	0.10%	18	0.15%
Oversensing	5	0.04%	18	0.15%
Failure to Sense	6	0.05%	6	0.05%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	<0.01%
Abnormal Defibrillation Impedance	2	0.02%	4	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	6	0.05%	5	0.04%
Total	**70**	**0.60%**	**117**	**1.00%**
Total Returned for Analysis	**12**		**29**	

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	30	0.26%
Total	**30**	**0.26%**



Year	1	2								
Survival Probability	99.08%	98.85%								
± 1 standard error	0.10%	0.14%								
Sample Size	8,050	360								

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

Customer Reported Performance Data

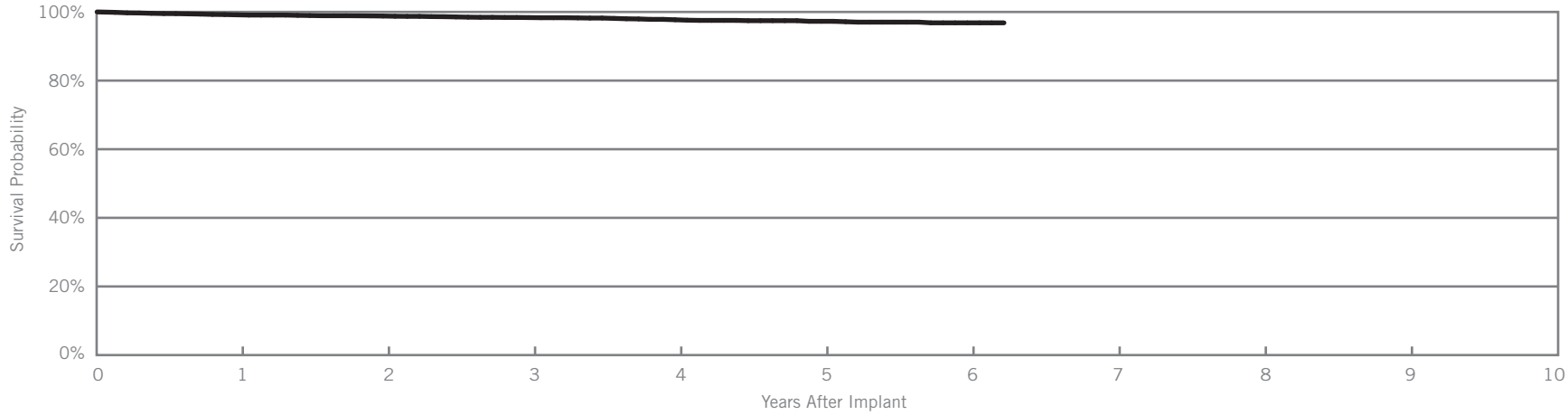
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	5,416
Estimated Active US Implants	3,543
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	0.11%	4	0.07%
Conductor Fracture	1	0.02%	5	0.09%
Lead Dislodgement	11	0.20%	18	0.33%
Failure to Capture	8	0.15%	33	0.61%
Oversensing	3	0.06%	24	0.44%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	2	0.04%
Abnormal Pacing Impedance	1	0.02%	9	0.17%
Abnormal Defibrillation Impedance	0	0.00%	8	0.15%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	1	0.02%
Total	**31**	**0.57%**	**104**	**1.92%**
Total Returned for Analysis	**13**		**34**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.04%
Clavicular Crush	0	0.00%
In the Pocket	1	0.02%
Intravascular	1	0.02%
Insulation Breach	4	0.07%
Lead-to-Can Contact	3	0.06%
Lead-to-Lead Contact	1	0.02%
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	30	0.55%
Total	**36**	**0.66%**



Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.16%	98.81%	98.36%	97.72%	97.27%	96.83%	96.83%			
± 1 standard error	0.13%	0.16%	0.20%	0.26%	0.33%	0.42%	0.42%			
Sample Size	4,760	3,640	2,760	1,970	1,270	620	200			

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

Actively Monitored Study Data

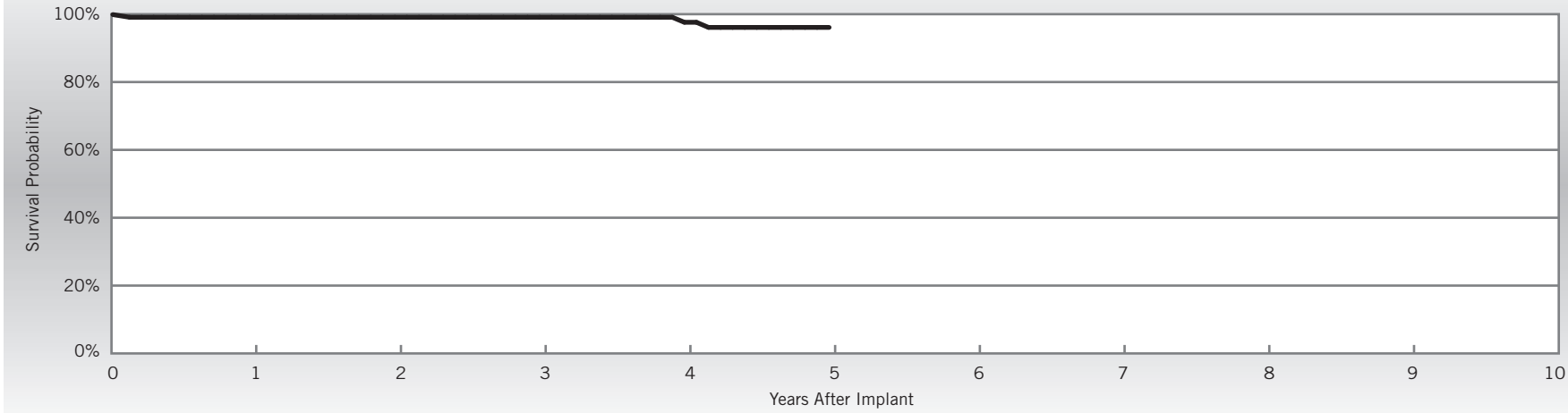
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	114
Active Devices Enrolled in Study	58
Cumulative Months of Follow-up	5,394
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.88%
Conductor Fracture	1	0.88%
Lead Dislodgement	1	0.88%

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	1.75%
Total	**2**	**1.75%**



Year	1	2	3	4	5					
Survival Probability	99.09%	99.09%	99.09%	97.61%	96.10%					
± 1 standard error	0.90%	0.90%	0.90%	0.90%	2.26%					
Sample Size	110	100	80	70	50					

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

Customer Reported Performance Data

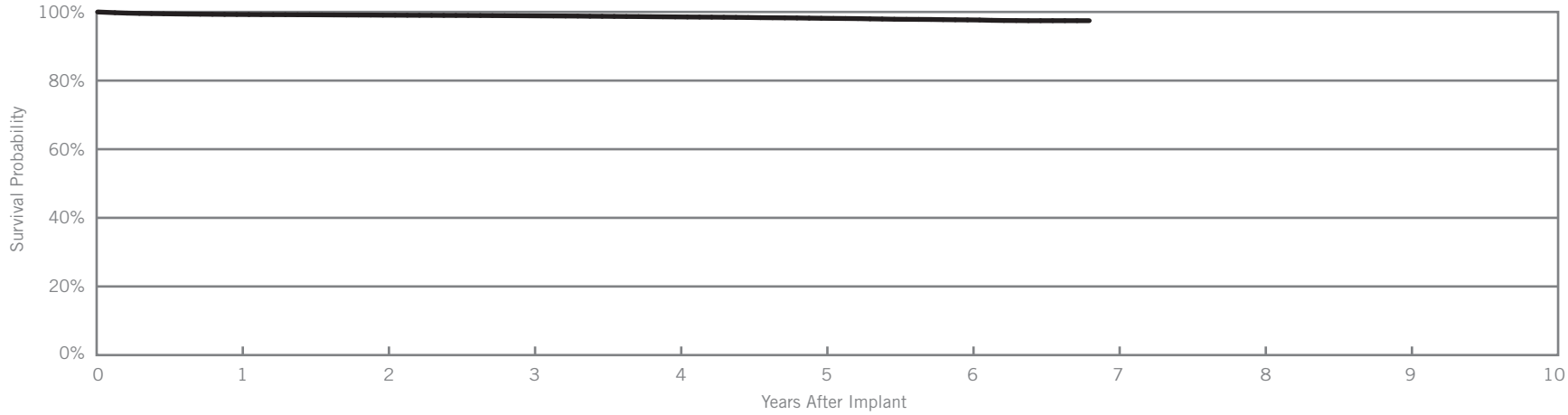
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	116,702
Estimated Active US Implants	84,862
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	74	0.06%	32	0.03%
Conductor Fracture	2	<0.01%	80	0.07%
Lead Dislodgement	202	0.17%	491	0.42%
Failure to Capture	86	0.07%	417	0.36%
Oversensing	41	0.04%	351	0.30%
Failure to Sense	12	0.01%	60	0.05%
Insulation Breach	0	0.00%	19	0.02%
Abnormal Pacing Impedance	5	<0.01%	67	0.06%
Abnormal Defibrillation Impedance	8	<0.01%	181	0.16%
Extracardiac Stimulation	3	<0.01%	5	<0.01%
Other	32	0.03%	49	0.04%
Total	**465**	**0.40%**	**1752**	**1.50%**
Total Returned for Analysis	**237**		**750**	

Malfunctions	Qty.	Rate
Conductor Fracture	22	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	6	<0.01%
Intravascular	14	0.01%
Insulation Breach	126	0.11%
Lead-to-Can Contact	56	0.05%
Lead-to-Lead Contact	13	0.01%
Clavicular Crush	20	0.02%
Externalized Conductors	0	0.00%
Other	37	0.03%
Crimps, Welds & Bonds	2	<0.01%
Other	33	0.03%
Extrinsic Factors	649	0.56%
Total	**832**	**0.71%**



Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.27%	99.07%	98.88%	98.56%	98.16%	97.69%	97.46%			
± 1 standard error	0.03%	0.03%	0.03%	0.04%	0.05%	0.08%	0.10%			
Sample Size	106,590	88,030	69,980	51,370	33,310	16,320	510			

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

Actively Monitored Study Data

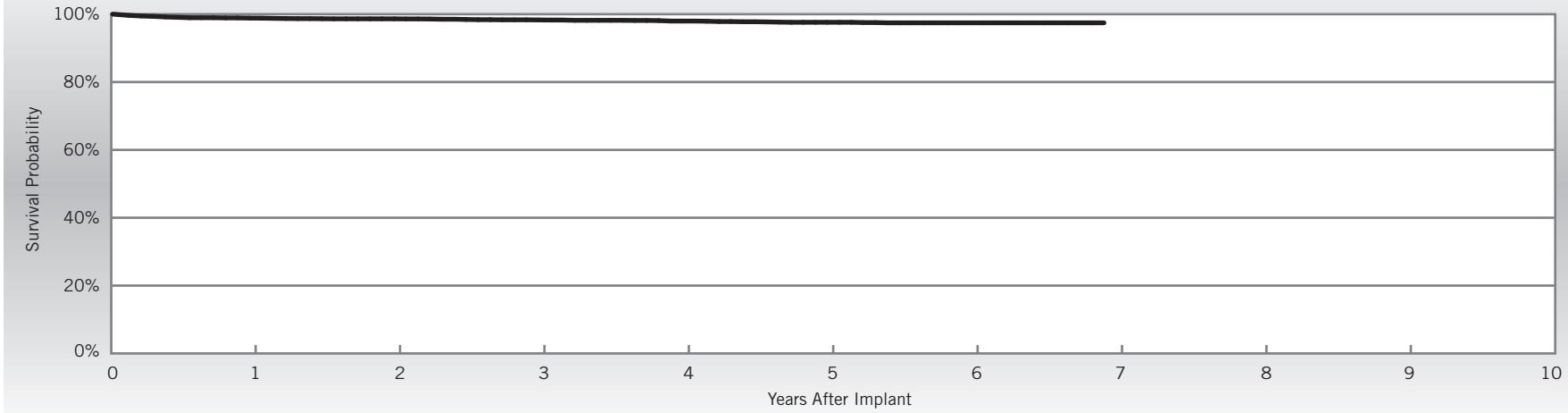
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	4,305
Active Devices Enrolled in Study	2,212
Cumulative Months of Follow-up	191,796
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	4	0.09%
Abnormal Pacing Impedance	2	0.05%
Cardiac Perforation	1	0.02%
Conductor Fracture	11	0.26%
Failure to Capture	12	0.28%
Failure to Sense	4	0.09%
Inappropriate Shock	4	0.09%
Insulation Breach	1	0.02%
Lead Dislodgement	38	0.88%
Oversensing	5	0.12%

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	5	0.12%
Lead-to-Can Contact	2	0.05%
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	43	1.00%
Total	**54**	**1.25%**



Year	1	2	3	4	5	6	at 83 months			
Survival Probability	98.85%	98.63%	98.30%	97.97%	97.61%	97.45%	97.45%			
± 1 standard error	0.16%	0.18%	0.21%	0.24%	0.28%	0.30%	0.30%			
Sample Size	4,020	3,490	2,970	2,420	1,790	1,160	70			

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

Customer Reported Performance Data

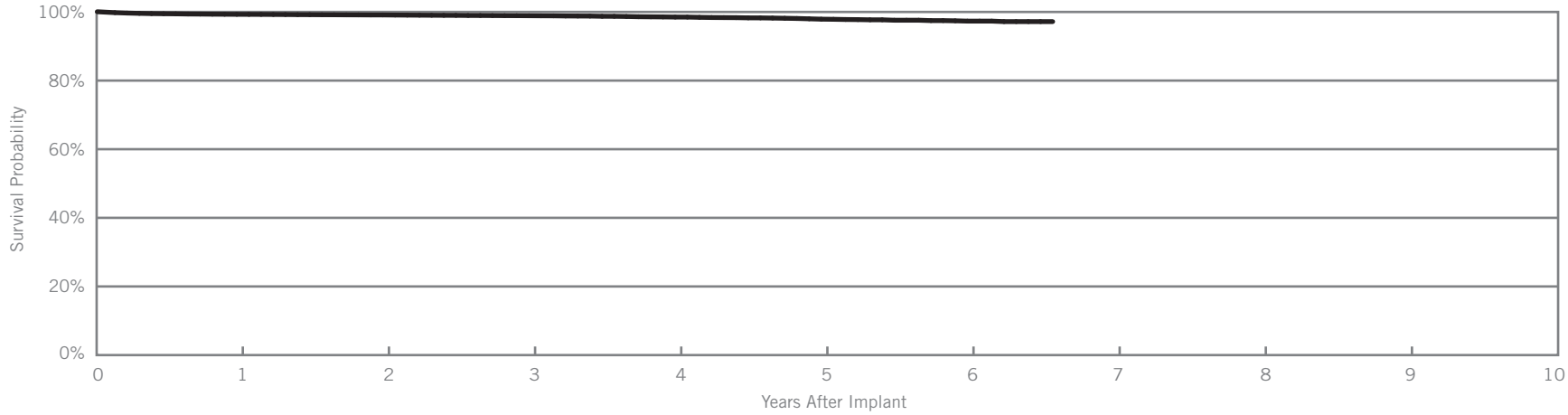
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	66,458
Estimated Active US Implants	54,962
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	76	0.11%	32	0.05%
Conductor Fracture	2	<0.01%	28	0.04%
Lead Dislodgement	121	0.18%	253	0.38%
Failure to Capture	56	0.08%	162	0.24%
Oversensing	18	0.03%	154	0.23%
Failure to Sense	7	0.01%	27	0.04%
Insulation Breach	0	0.00%	10	0.02%
Abnormal Pacing Impedance	4	<0.01%	32	0.05%
Abnormal Defibrillation Impedance	5	<0.01%	51	0.08%
Extracardiac Stimulation	3	<0.01%	8	0.01%
Other	26	0.04%	24	0.04%
Total	**318**	**0.48%**	**781**	**1.18%**
Total Returned for Analysis	**148**		**362**	

Malfunctions	Qty.	Rate
Conductor Fracture	8	0.01%
Clavicular Crush	0	0.00%
In the Pocket	6	<0.01%
Intravascular	2	<0.01%
Insulation Breach	48	0.07%
Lead-to-Can Contact	27	0.04%
Lead-to-Lead Contact	7	0.01%
Clavicular Crush	6	<0.01%
Externalized Conductors	0	0.00%
Other	8	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	12	0.02%
Extrinsic Factors	339	0.51%
Total	**407**	**0.61%**



Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.31%	99.13%	98.90%	98.51%	97.90%	97.33%	97.19%			
± 1 standard error	0.03%	0.04%	0.05%	0.07%	0.12%	0.19%	0.25%			
Sample Size	57,140	39,850	24,820	13,630	6,810	2,610	260			

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

Actively Monitored Study Data

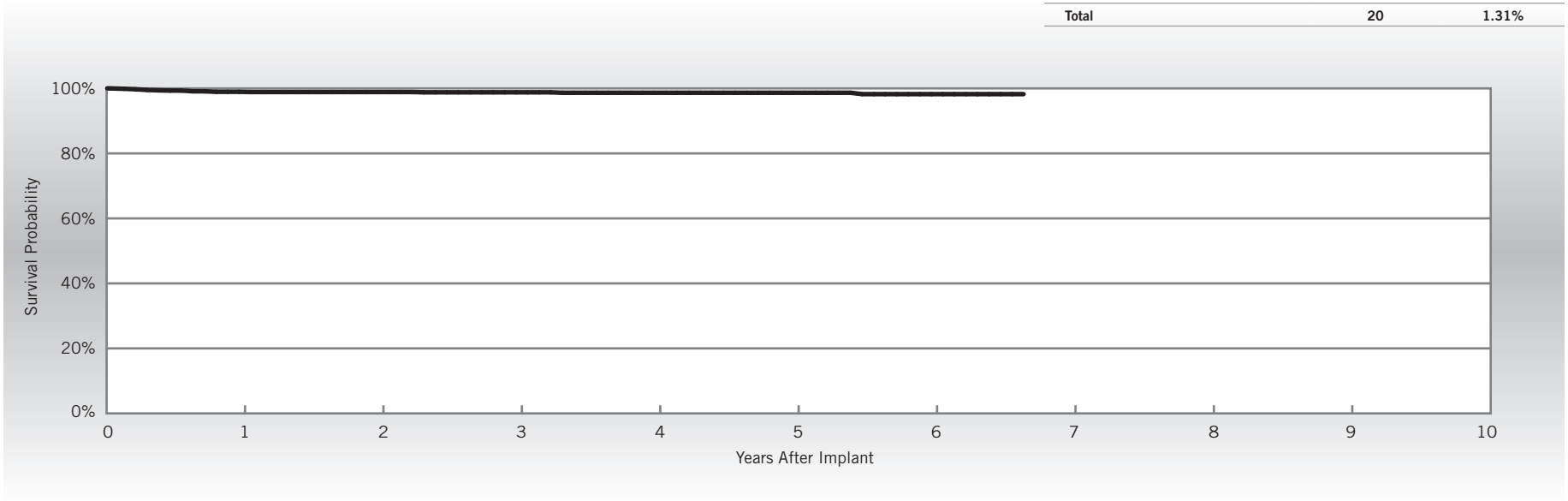
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	1,521
Active Devices Enrolled in Study	901
Cumulative Months of Follow-up	59,751
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	3	0.20%
Failure to Capture	4	0.26%
Failure to Sense	1	0.07%
Lead Dislodgement	7	0.46%
Pericardial Effusion	2	0.13%

Malfunctions	Qty	Rate
Conductor Fracture	2	0.13%
Clavicular Crush	1	0.07%
In the Pocket	1	0.07%
Intravascular	0	0.00%
Insulation Breach	4	0.26%
Lead-to-Can Contact	3	0.20%
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	14	0.92%
Total	**20**	**1.31%**



Year	1	2	3	4	5	6	at 80 months			
Survival Probability	98.95%	98.88%	98.79%	98.65%	98.65%	98.23%	98.23%			
± 1 standard error	0.27%	0.28%	0.29%	0.33%	0.33%	0.53%	0.53%			
Sample Size	1,420	1,240	980	670	420	260	60			

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

Customer Reported Performance Data

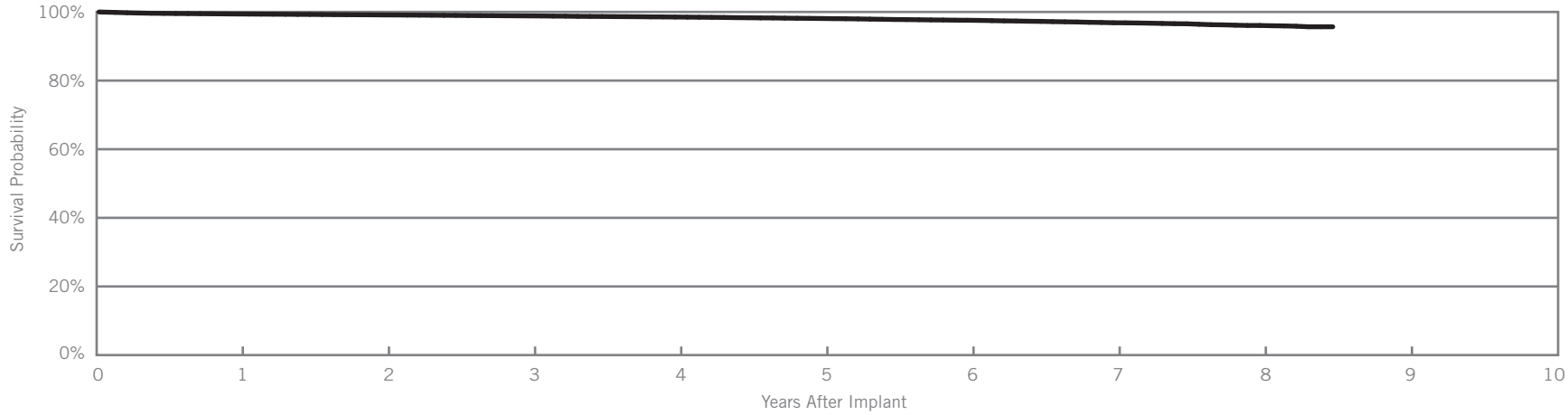
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	59,406
Estimated Active US Implants	29,742
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	1	<0.01%	111	0.19%
Lead Dislodgement	69	0.12%	176	0.30%
Failure to Capture	22	0.04%	249	0.42%
Oversensing	48	0.08%	435	0.73%
Failure to Sense	5	<0.01%	59	0.10%
Insulation Breach	0	0.00%	44	0.07%
Abnormal Pacing Impedance	1	<0.01%	143	0.24%
Abnormal Defibrillation Impedance	19	0.03%	208	0.35%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	21	0.04%	39	0.07%
Total	**226**	**0.38%**	**1481**	**2.49%**
Total Returned for Analysis	**92**		**441**	

Malfunctions	Qty.	Rate
Conductor Fracture	30	0.05%
Clavicular Crush	2	<0.01%
In the Pocket	20	0.03%
Intravascular	8	0.01%
Insulation Breach	105	0.18%
Lead-to-Can Contact	53	0.09%
Lead-to-Lead Contact	21	0.04%
Clavicular Crush	13	0.02%
Externalized Conductors	0	0.00%
Other	18	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	9	0.02%
Extrinsic Factors	364	0.61%
Total	**509**	**0.86%**



Year	1	2	3	4	5	6	7	8	at 102 months	
Survival Probability	99.40%	99.13%	98.85%	98.52%	98.09%	97.58%	96.85%	96.06%	95.68%	
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.08%	0.10%	0.14%	0.24%	
Sample Size	54,950	47,590	41,990	37,000	31,910	26,140	18,750	8,540	220	

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

Actively Monitored Study Data

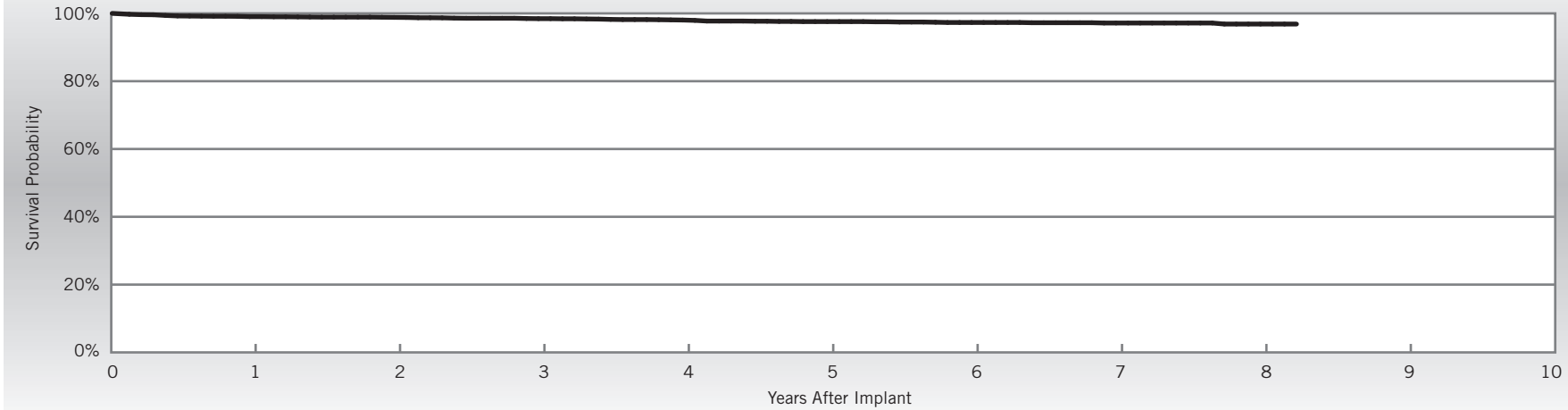
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	3,561
Active Devices Enrolled in Study	1,369
Cumulative Months of Follow-up	192,763
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	1	0.03%
Abnormal Pacing Impedance	8	0.22%
Conductor Fracture	11	0.31%
Failure to Capture	12	0.34%
Failure to Sense	2	0.06%
Inappropriate Shock	2	0.06%
Insulation Breach	10	0.28%
Lead Dislodgement	20	0.56%
Oversensing	8	0.22%

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	11	0.31%
Lead-to-Can Contact	6	0.17%
Lead-to-Lead Contact	4	0.11%
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	28	0.79%
Total	**41**	**1.15%**



Year	1	2	3	4	5	6	7	8	at 99 months	
Survival Probability	99.04%	98.83%	98.45%	98.04%	97.58%	97.32%	97.16%	96.86%	96.86%	
± 1 standard error	0.16%	0.18%	0.22%	0.25%	0.30%	0.33%	0.35%	0.45%	0.45%	
Sample Size	3,360	2,960	2,560	2,190	1,840	1,540	1,190	560	60	

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

Customer Reported Performance Data

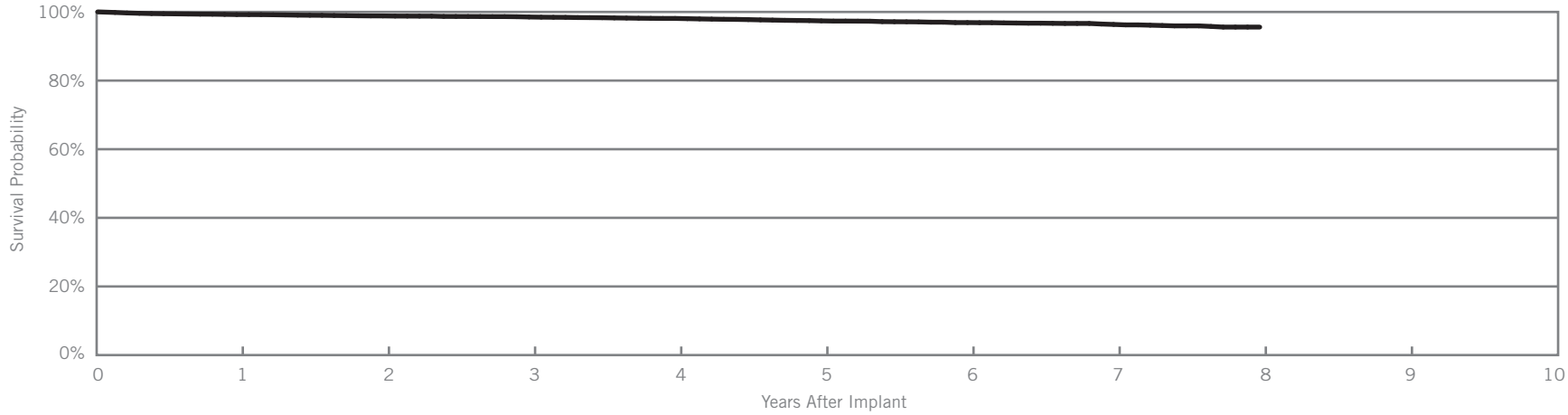
Durata™

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	14,199
Estimated Active US Implants	8,161
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	10	0.07%	2	0.01%
Conductor Fracture	1	<0.01%	24	0.17%
Lead Dislodgement	18	0.13%	52	0.37%
Failure to Capture	16	0.11%	57	0.40%
Oversensing	10	0.07%	85	0.60%
Failure to Sense	0	0.00%	9	0.06%
Insulation Breach	0	0.00%	20	0.14%
Abnormal Pacing Impedance	2	0.01%	31	0.22%
Abnormal Defibrillation Impedance	1	<0.01%	21	0.15%
Extracardiac Stimulation	2	0.01%	2	0.01%
Other	4	0.03%	7	0.05%
Total	**64**	**0.45%**	**310**	**2.18%**
Total Returned for Analysis	**30**		**154**	

Malfunctions	Qty.	Rate
Conductor Fracture	15	0.11%
Clavicular Crush	0	0.00%
In the Pocket	12	0.08%
Intravascular	3	0.02%
Insulation Breach	47	0.33%
Lead-to-Can Contact	27	0.19%
Lead-to-Lead Contact	13	0.09%
Clavicular Crush	1	<0.01%
Externalized Conductors	1	<0.01%
Other	5	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	4	0.03%
Extrinsic Factors	112	0.79%
Total	**178**	**1.25%**



Year	1	2	3	4	5	6	7	8		
Survival Probability	99.24%	98.84%	98.53%	98.11%	97.40%	96.90%	96.36%	95.59%		
± 1 standard error	0.07%	0.10%	0.11%	0.14%	0.17%	0.21%	0.25%	0.40%		
Sample Size	12,860	10,530	8,620	7,030	5,570	3,980	2,350	280		

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

Actively Monitored Study Data

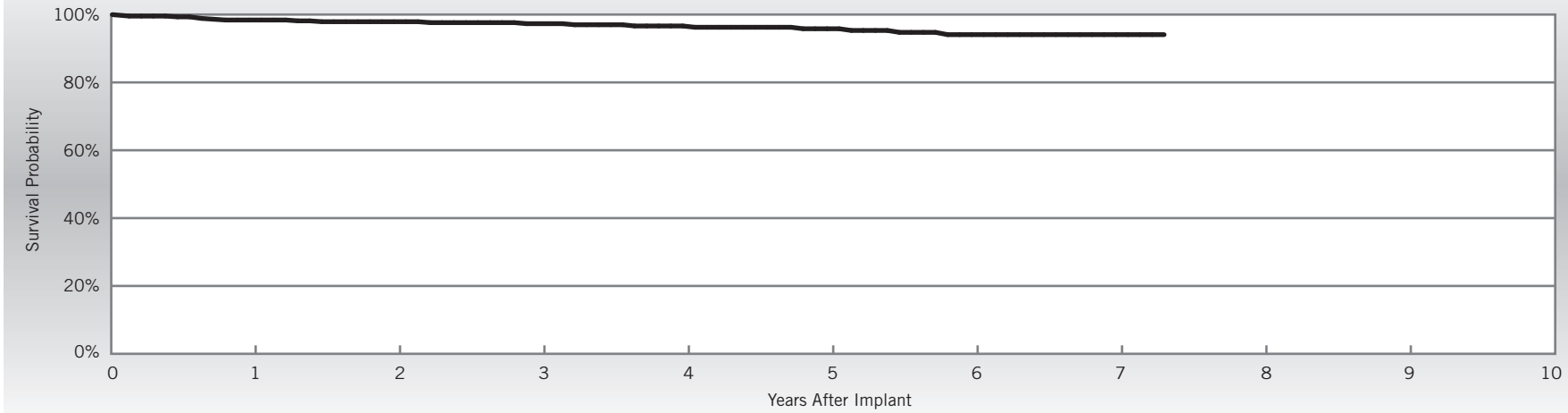
Durata™

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	449
Active Devices Enrolled in Study	216
Cumulative Months of Follow-up	23,676
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	3	0.67%
Conductor Fracture	5	1.11%
Failure to Capture	3	0.67%
Failure to Sense	1	0.22%
Lead Dislodgement	4	0.89%
Oversensing	2	0.45%

Malfunctions	Qty	Rate
Conductor Fracture	2	0.45%
Clavicular Crush	0	0.00%
In the Pocket	1	0.22%
Intravascular	1	0.22%
Insulation Breach	1	0.22%
Lead-to-Can Contact	1	0.22%
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	7	1.56%
Total	**10**	**2.23%**



Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	98.39%	97.89%	97.31%	96.63%	95.81%	94.08%	94.08%	94.08%		
± 1 standard error	0.60%	0.69%	0.80%	0.93%	1.09%	1.46%	1.46%	1.46%		
Sample Size	430	390	340	280	230	170	100	50		

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

Customer Reported Performance Data

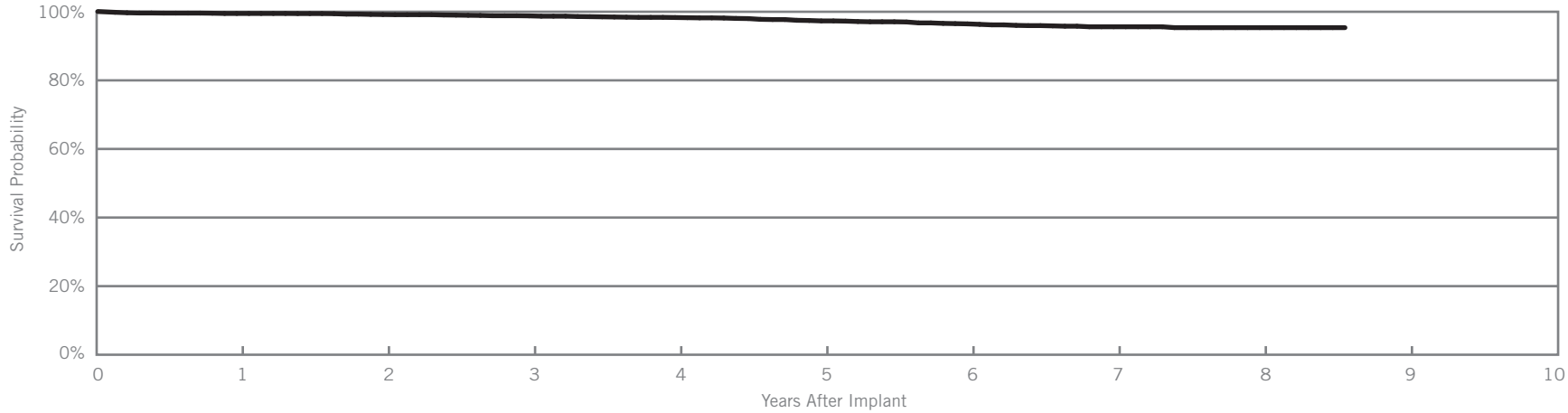
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,312
Estimated Active US Implants	1,505
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%	15	0.45%
Lead Dislodgement	3	0.09%	12	0.36%
Failure to Capture	5	0.15%	23	0.69%
Oversensing	4	0.12%	39	1.18%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	5	0.15%
Abnormal Pacing Impedance	0	0.00%	10	0.30%
Abnormal Defibrillation Impedance	0	0.00%	11	0.33%
Extracardiac Stimulation	0	0.00%	1	0.03%
Other	0	0.00%	2	0.06%
Total	**19**	**0.57%**	**122**	**3.68%**
Total Returned for Analysis	**6**		**26**	

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	8	0.24%
Lead-to-Can Contact	3	0.09%
Lead-to-Lead Contact	2	0.06%
Clavicular Crush	1	0.03%
Externalized Conductors	1	0.03%
Other	1	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	19	0.57%
Total	**28**	**0.85%**



Year	1	2	3	4	5	6	7	8	at 103 months	
Survival Probability	99.50%	99.19%	98.80%	98.32%	97.33%	96.47%	95.62%	95.37%	95.37%	
± 1 standard error	0.13%	0.16%	0.21%	0.25%	0.34%	0.41%	0.49%	0.52%	0.52%	
Sample Size	3,030	2,590	2,310	2,060	1,790	1,500	1,170	720	210	

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

Actively Monitored Study Data

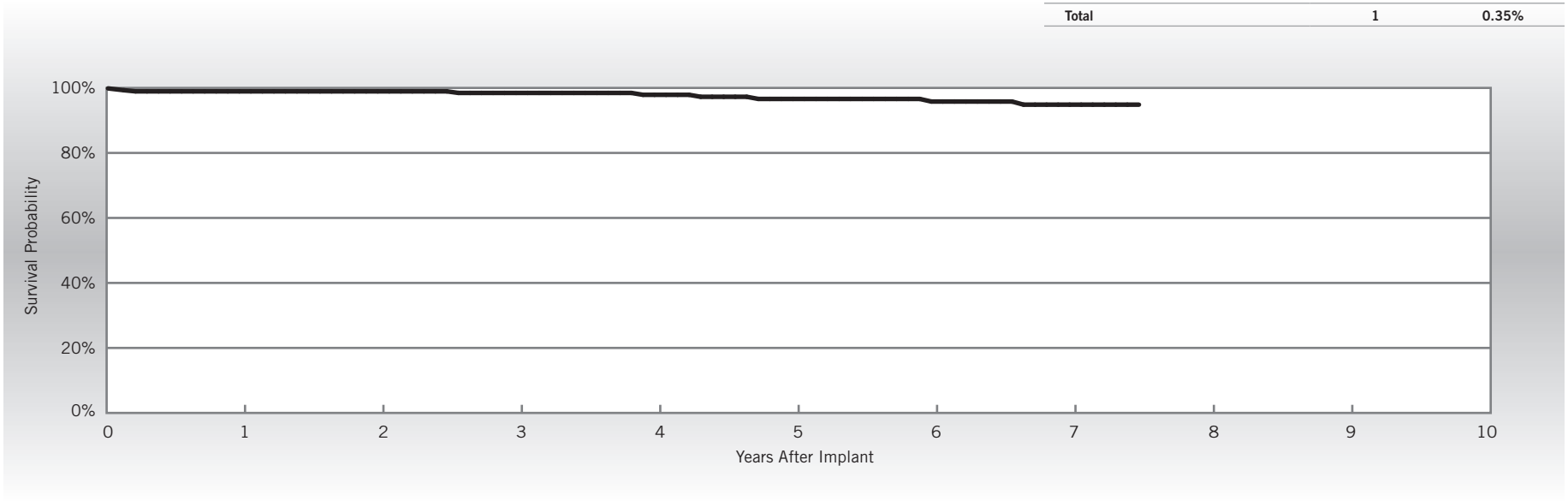
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	288
Active Devices Enrolled in Study	104
Cumulative Months of Follow-up	15,818
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	at 90 months		
Survival Probability	98.94%	98.94%	98.46%	97.88%	96.61%	95.81%	94.85%	94.85%		
± 1 standard error	0.61%	0.61%	0.77%	0.96%	1.30%	1.30%	1.78%	1.78%		
Sample Size	270	240	210	180	150	130	100	50		

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

Customer Reported Performance Data

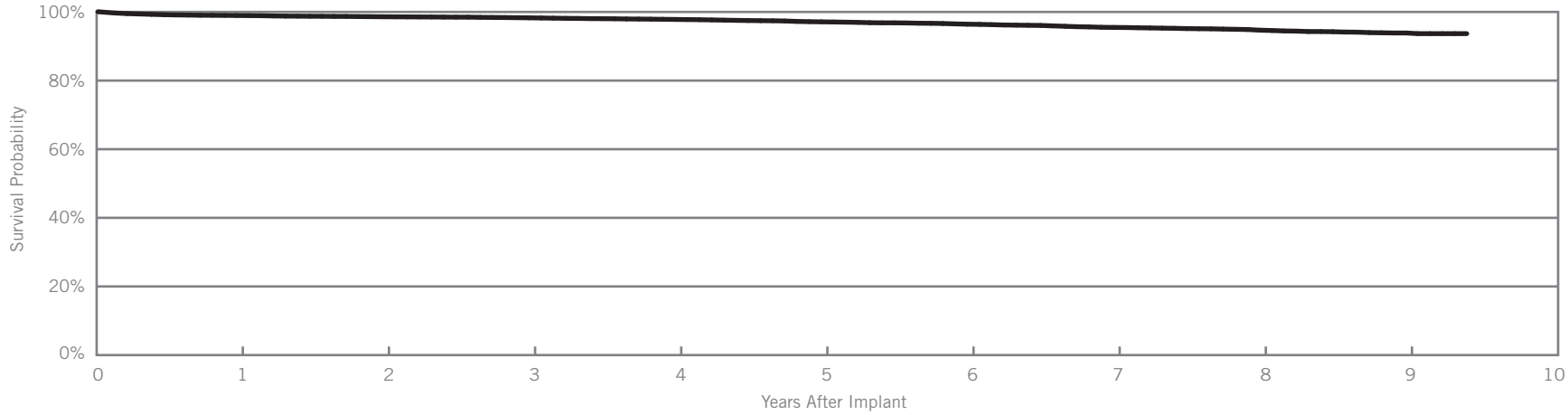
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	14,242
Estimated Active US Implants	5,777
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%	16	0.11%
Conductor Fracture	0	0.00%	50	0.35%
Lead Dislodgement	27	0.19%	63	0.44%
Failure to Capture	17	0.12%	129	0.91%
Oversensing	19	0.13%	199	1.40%
Failure to Sense	8	0.06%	19	0.13%
Insulation Breach	0	0.00%	22	0.15%
Abnormal Pacing Impedance	1	<0.01%	37	0.26%
Abnormal Defibrillation Impedance	4	0.03%	75	0.53%
Extracardiac Stimulation	3	0.02%	2	0.01%
Other	0	0.00%	27	0.19%
Total	**112**	**0.79%**	**639**	**4.49%**
Total Returned for Analysis	**53**		**186**	

Malfunctions	Qty.	Rate
Conductor Fracture	9	0.06%
Clavicular Crush	1	<0.01%
In the Pocket	3	0.02%
Intravascular	5	0.04%
Insulation Breach	39	0.27%
Lead-to-Can Contact	14	0.10%
Lead-to-Lead Contact	6	0.04%
Clavicular Crush	4	0.03%
Externalized Conductors	0	0.00%
Other	15	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	163	1.14%
Total	**211**	**1.48%**



Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	98.97%	98.60%	98.29%	97.82%	97.12%	96.43%	95.49%	94.69%	93.87%	93.68%
± 1 standard error	0.09%	0.10%	0.12%	0.14%	0.16%	0.19%	0.22%	0.24%	0.29%	0.32%
Sample Size	13,120	11,340	10,100	9,020	8,140	7,380	6,580	5,560	3,030	230

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

Actively Monitored Study Data

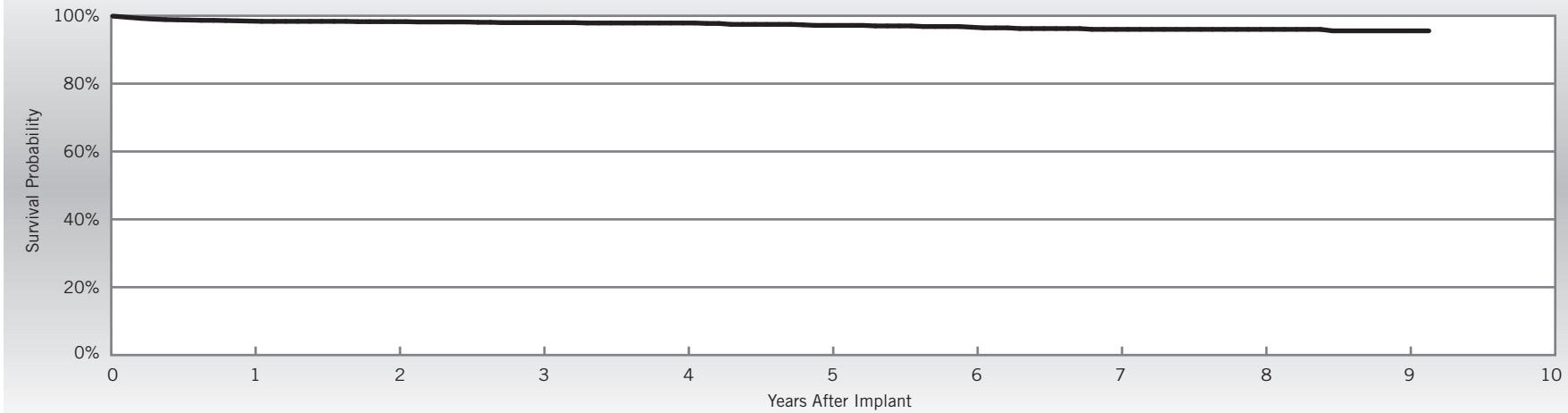
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	1,469
Active Devices Enrolled in Study	351
Cumulative Months of Follow-up	79,377
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	6	0.41%
Failure to Capture	10	0.68%
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	1	2	3	4	5	6	7	8	9	at 110 months
Survival Probability	98.44%	98.27%	97.98%	97.87%	97.17%	96.63%	96.00%	96.00%	95.56%	95.56%
± 1 standard error	0.32%	0.35%	0.39%	0.40%	0.51%	0.56%	0.69%	0.69%	0.82%	0.82%
Sample Size	1,380	1,180	1,000	840	690	560	450	350	190	60

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

Customer Reported Performance Data

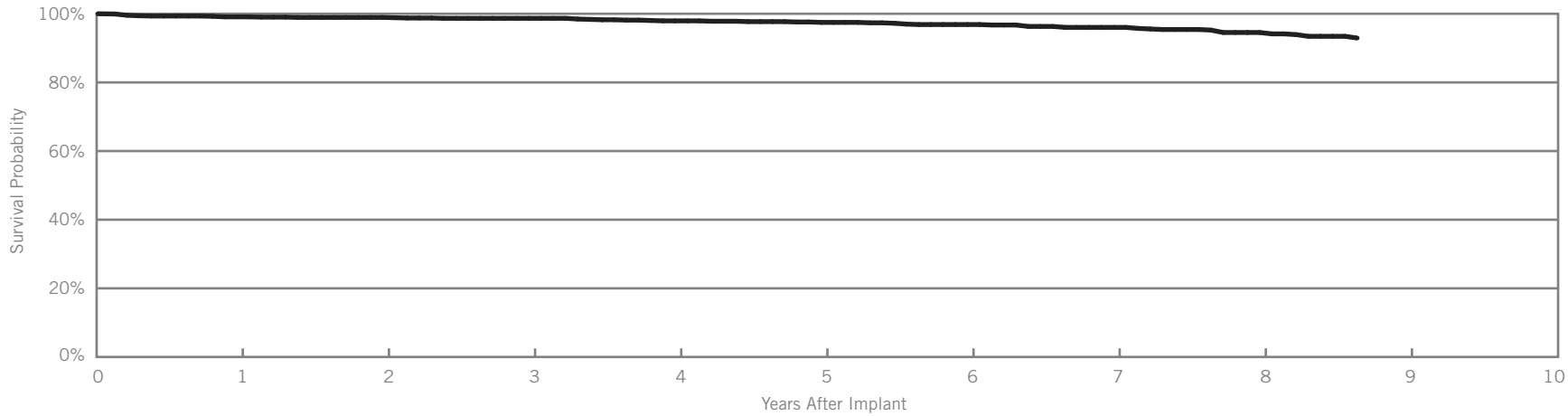
Riata™ ST Optim™

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,469
Estimated Active US Implants	624
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%	3	0.20%
Conductor Fracture	0	0.00%	8	0.54%
Lead Dislodgement	3	0.20%	10	0.68%
Failure to Capture	1	0.07%	10	0.68%
Oversensing	0	0.00%	19	1.29%
Failure to Sense	0	0.00%	1	0.07%
Insulation Breach	0	0.00%	6	0.41%
Abnormal Pacing Impedance	2	0.14%	2	0.14%
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	**11**	**0.75%**	**64**	**4.36%**
Total Returned for Analysis	**4**		**20**	

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	5	0.34%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	2	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	17	1.16%
Total	**27**	**1.84%**



Year	1	2	3	4	5	6	7	8	at 104 months	
Survival Probability	99.10%	98.94%	98.67%	97.93%	97.48%	96.86%	96.03%	94.54%	92.93%	
± 1 standard error	0.26%	0.28%	0.32%	0.42%	0.46%	0.55%	0.64%	0.80%	0.93%	
Sample Size	1,360	1,180	1,050	950	860	780	690	560	210	

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

Customer Reported Performance Data

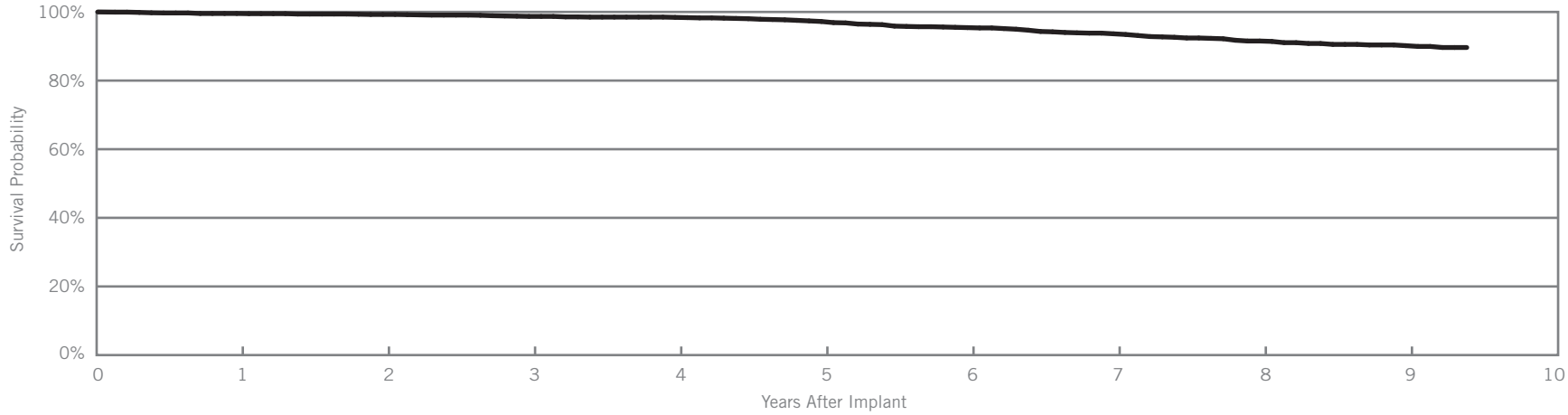
Riata™ ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,199
Estimated Active US Implants	825
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) 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%	8	0.36%
Oversensing	2	0.09%	37	1.68%
Failure to Sense	1	0.05%	3	0.14%
Insulation Breach	0	0.00%	39	1.77%
Abnormal Pacing Impedance	1	0.05%	19	0.86%
Abnormal Defibrillation Impedance	0	0.00%	16	0.73%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	2	0.09%
Total	**11**	**0.50%**	**140**	**6.37%**
Total Returned for Analysis	**4**		**31**	

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	34	1.55%
Lead-to-Can Contact	10	0.45%
Lead-to-Lead Contact	17	0.77%
Clavicular Crush	1	0.05%
Externalized Conductors	2	0.09%
Other	4	0.18%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	9	0.41%
Total	**45**	**2.05%**



Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.55%	99.27%	98.70%	98.42%	97.22%	95.43%	93.63%	91.53%	90.17%	89.64%
± 1 standard error	0.15%	0.19%	0.26%	0.30%	0.41%	0.57%	0.68%	0.82%	0.90%	0.99%
Sample Size	2,040	1,770	1,580	1,400	1,250	1,110	1,000	870	610	220

Customer Reported Performance Data

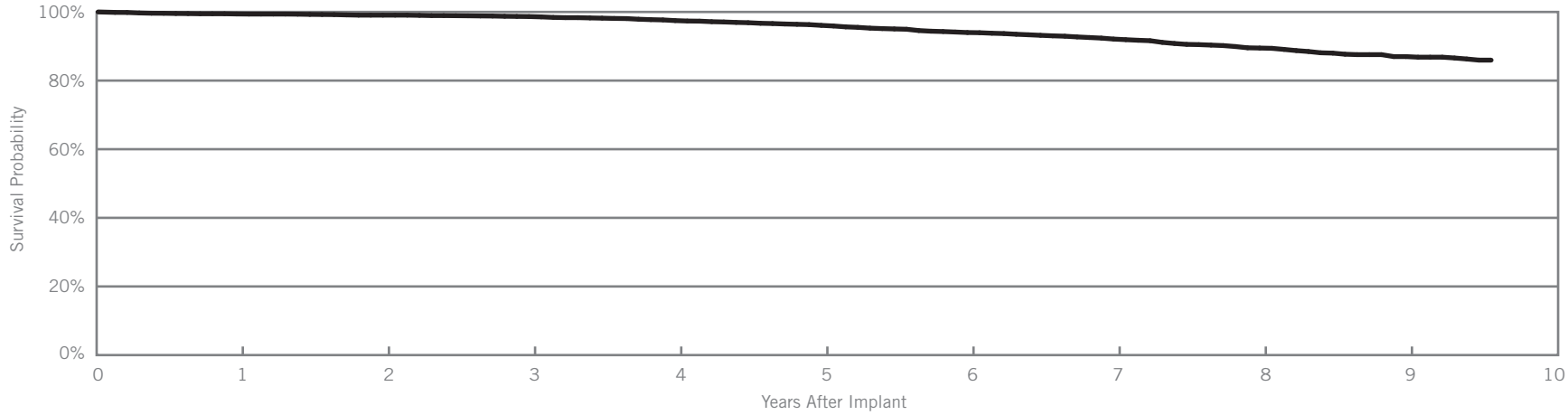
Riata™ ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,055
Estimated Active US Implants	1,502
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.10%	3	0.07%
Conductor Fracture	0	0.00%	31	0.76%
Lead Dislodgement	5	0.12%	6	0.15%
Failure to Capture	1	0.02%	46	1.13%
Oversensing	3	0.07%	88	2.17%
Failure to Sense	0	0.00%	14	0.35%
Insulation Breach	0	0.00%	52	1.28%
Abnormal Pacing Impedance	2	0.05%	17	0.42%
Abnormal Defibrillation Impedance	0	0.00%	21	0.52%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	6	0.15%
Total	**16**	**0.39%**	**284**	**7.00%**
Total Returned for Analysis	**3**		**61**	

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	47	1.16%
Lead-to-Can Contact	23	0.57%
Lead-to-Lead Contact	13	0.32%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.05%
Other	9	0.22%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	28	0.69%
Total	**79**	**1.95%**



Year	1	2	3	4	5	6	7	8	9	at 115 months
Survival Probability	99.41%	99.07%	98.66%	97.48%	96.09%	94.00%	92.10%	89.48%	86.99%	85.96%
± 1 standard error	0.12%	0.16%	0.20%	0.28%	0.36%	0.47%	0.55%	0.68%	0.83%	0.98%
Sample Size	3,760	3,270	2,910	2,590	2,310	2,040	1,760	1,390	860	240

Customer Reported Performance Data

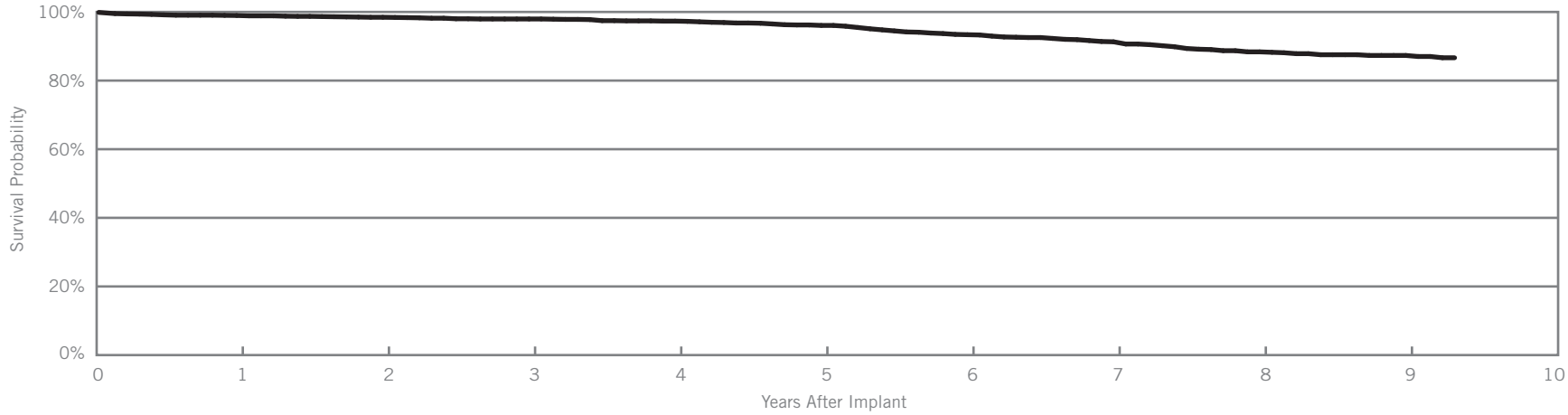
Riata™ ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,405
Estimated Active US Implants	874
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.25%	5	0.21%
Conductor Fracture	0	0.00%	9	0.37%
Lead Dislodgement	3	0.12%	9	0.37%
Failure to Capture	4	0.17%	17	0.71%
Oversensing	4	0.17%	56	2.33%
Failure to Sense	0	0.00%	2	0.08%
Insulation Breach	0	0.00%	63	2.62%
Abnormal Pacing Impedance	2	0.08%	3	0.12%
Abnormal Defibrillation Impedance	1	0.04%	6	0.25%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	7	0.29%
Total	**21**	**0.87%**	**177**	**7.36%**
Total Returned for Analysis	**11**		**65**	

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	60	2.49%
Lead-to-Can Contact	29	1.21%
Lead-to-Lead Contact	13	0.54%
Clavicular Crush	0	0.00%
Externalized Conductors	7	0.29%
Other	11	0.46%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	22	0.91%
Total	**87**	**3.62%**



Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	98.97%	98.45%	97.95%	97.33%	96.07%	93.37%	91.30%	88.37%	87.32%	86.65%
± 1 standard error	0.21%	0.27%	0.31%	0.37%	0.46%	0.64%	0.75%	0.91%	0.98%	1.08%
Sample Size	2,220	1,930	1,740	1,550	1,380	1,220	1,070	860	520	220

Customer Reported Performance Data

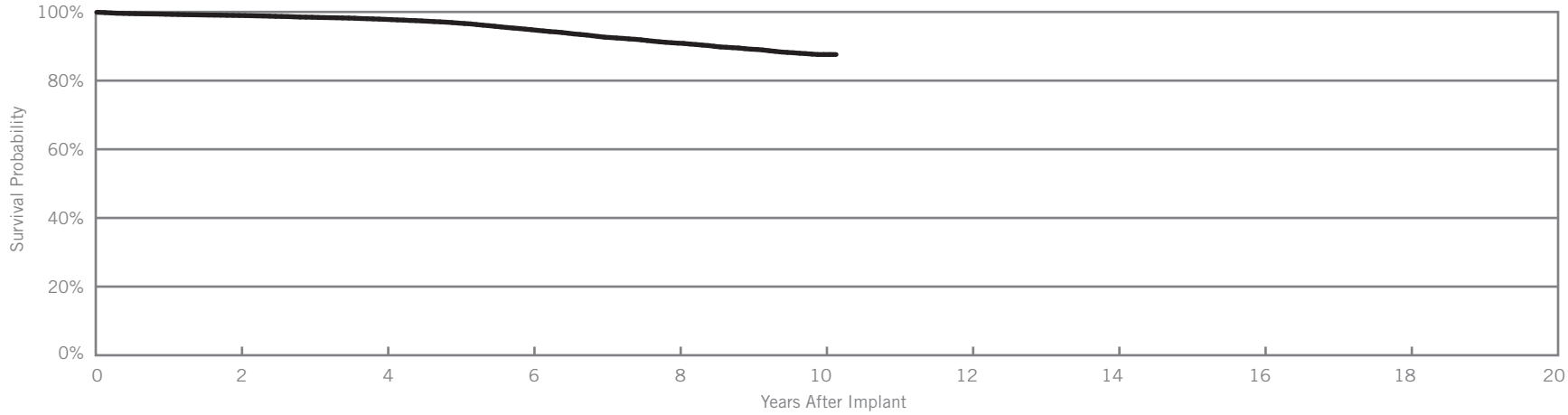
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,875
Estimated Active US Implants	12,339
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	42	0.12%	30	0.09%
Conductor Fracture	0	0.00%	133	0.38%
Lead Dislodgement	38	0.11%	59	0.17%
Failure to Capture	42	0.12%	289	0.83%
Oversensing	40	0.11%	739	2.12%
Failure to Sense	7	0.02%	62	0.18%
Insulation Breach	1	<0.01%	664	1.90%
Abnormal Pacing Impedance	8	0.02%	104	0.30%
Abnormal Defibrillation Impedance	4	0.01%	172	0.49%
Extracardiac Stimulation	3	<0.01%	5	0.01%
Other	11	0.03%	89	0.26%
Total	**196**	**0.56%**	**2346**	**6.73%**
Total Returned for Analysis	**97**		**647**	

Malfunctions	Qty.	Rate
Conductor Fracture	23	0.07%
Clavicular Crush	4	0.01%
In the Pocket	7	0.02%
Intravascular	12	0.03%
Insulation Breach	524	1.50%
Lead-to-Can Contact	277	0.79%
Lead-to-Lead Contact	141	0.40%
Clavicular Crush	11	0.03%
Externalized Conductors	32	0.09%
Other	63	0.18%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	284	0.81%
Total	**833**	**2.39%**



Year	2	4	6	8	10	at 122 months				
Survival Probability	98.97%	97.84%	94.83%	90.91%	87.60%	87.60%				
± 1 standard error	0.06%	0.09%	0.15%	0.21%	0.31%	0.31%				
Sample Size	28,510	22,620	17,910	13,450	4,060	400				

Actively Monitored Study Data

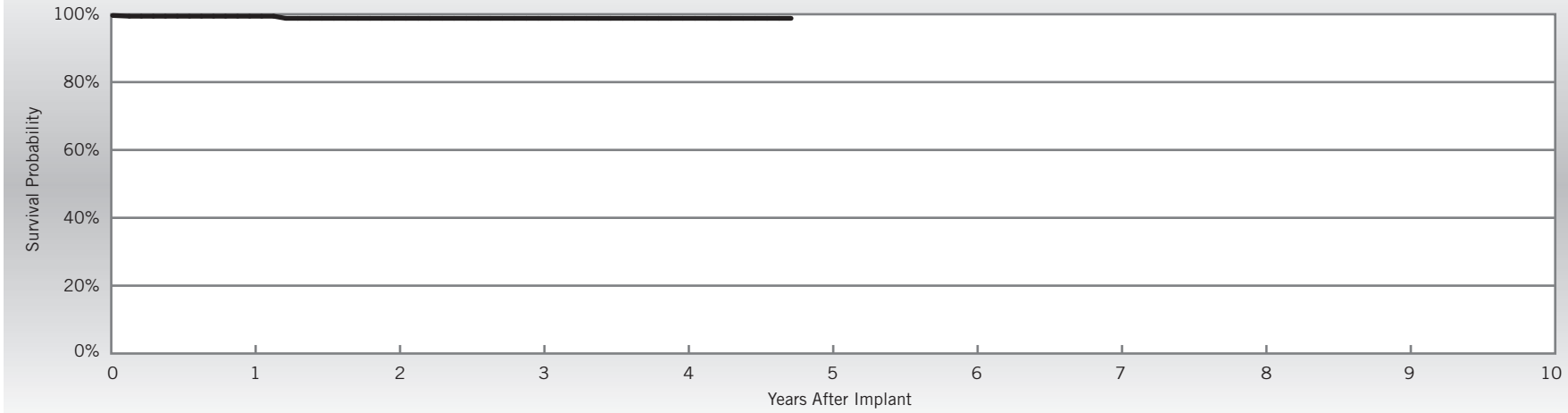
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	179
Active Devices Enrolled in Study	38
Cumulative Months of Follow-up	7,557
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
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	3	1.68%
Lead-to-Can Contact	2	1.12%
Lead-to-Lead Contact	1	0.56%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.56%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**4**	**2.23%**



Year	1	2	3	4	at 57 months					
Survival Probability	99.43%	98.80%	98.80%	98.80%	98.80%					
± 1 standard error	0.57%	0.84%	0.84%	0.84%	0.84%					
Sample Size	170	150	120	90	50					

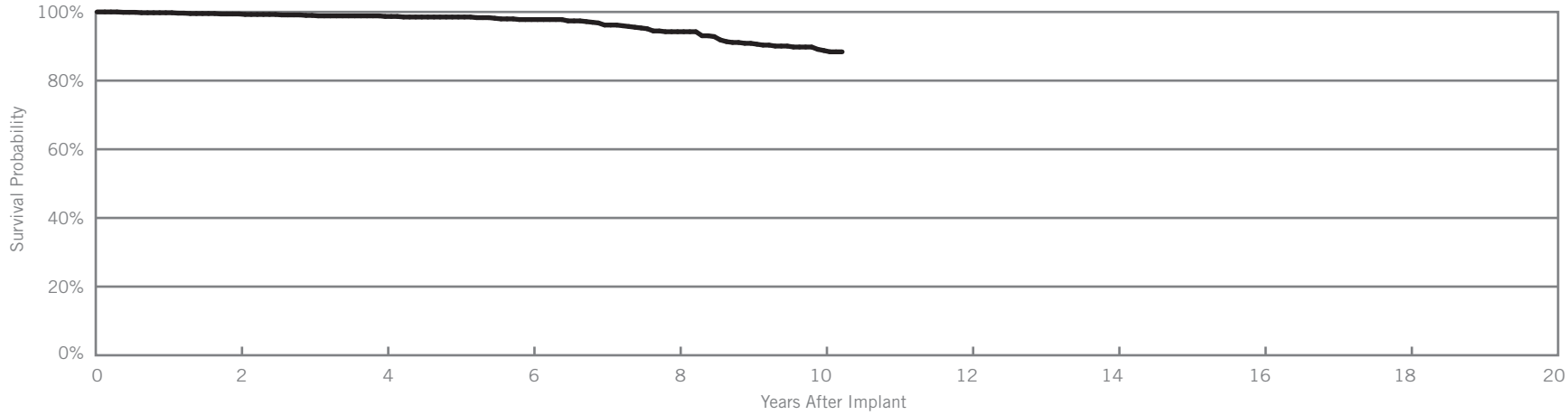
Customer Reported Performance Data

Riata™ *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	981
Estimated Active US Implants	333
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

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	18	1.83%
Lead-to-Can Contact	8	0.82%
Lead-to-Lead Contact	6	0.61%
Clavicular Crush	1	0.10%
Externalized Conductors	2	0.20%
Other	1	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.20%
Total	**20**	**2.04%**



Year	2	4	6	8	10	at 123 months				
Survival Probability	99.41%	98.69%	97.78%	94.24%	88.76%	88.38%				
± 1 standard error	0.27%	0.38%	0.58%	1.01%	1.48%	1.55%				
Sample Size	800	650	530	440	300	210				

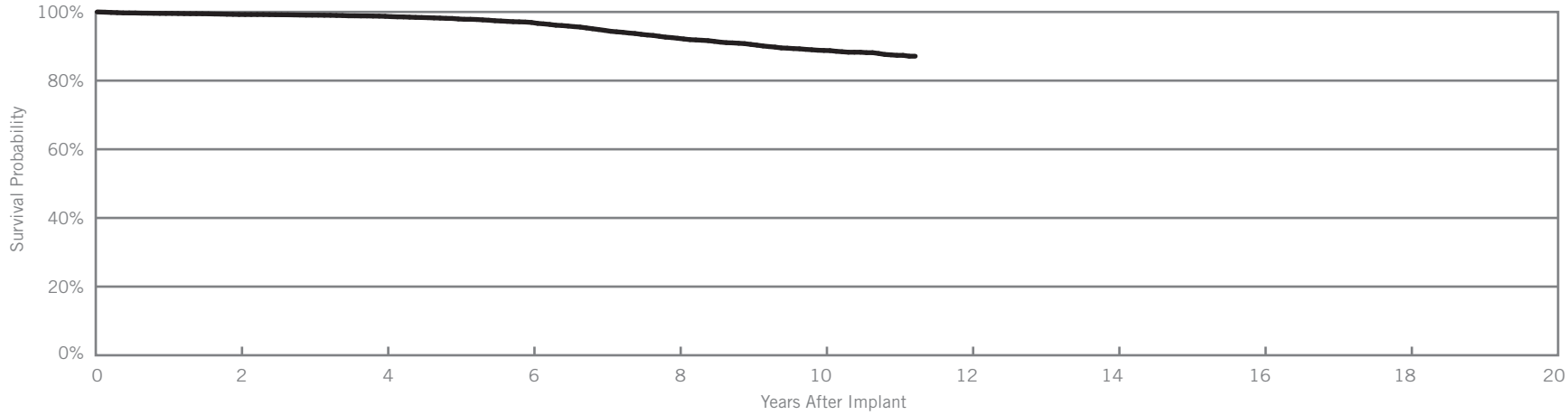
Customer Reported Performance Data

Riata™ *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,700
Estimated Active US Implants	2,964
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	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	155	1.60%
Lead-to-Can Contact	60	0.62%
Lead-to-Lead Contact	46	0.47%
Clavicular Crush	2	0.02%
Externalized Conductors	18	0.19%
Other	29	0.30%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	50	0.52%
Total	**213**	**2.20%**



Year	2	4	6	8	10	At 135 months				
Survival Probability	99.26%	98.73%	96.94%	92.33%	88.78%	87.11%				
± 1 standard error	0.09%	0.12%	0.21%	0.37%	0.48%	0.63%				
Sample Size	8,090	6,460	5,040	3,940	2,740	300				

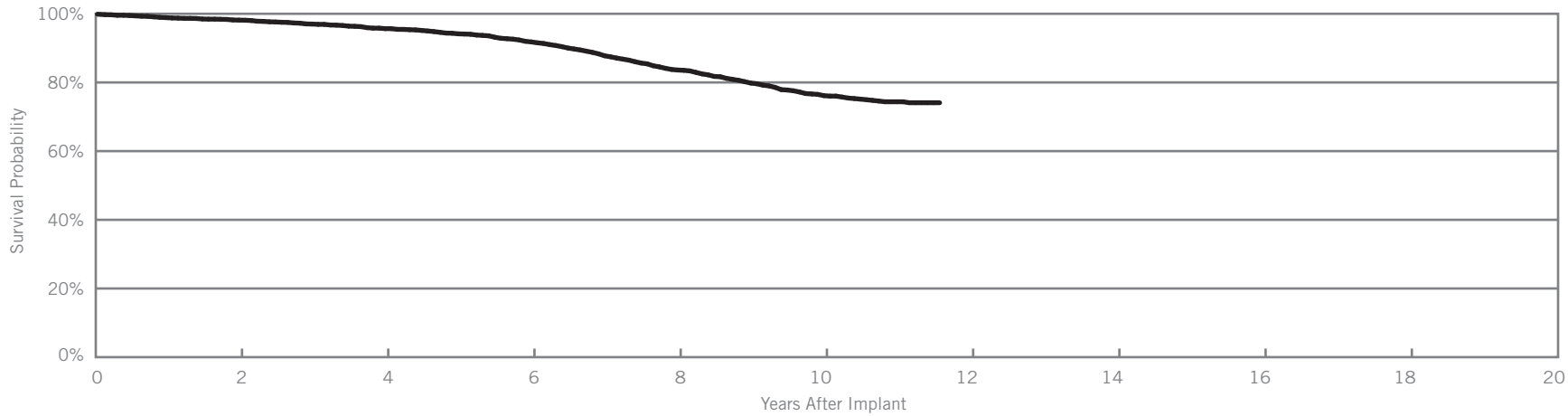
Customer Reported Performance Data

Riata™

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,130
Estimated Active US Implants	802
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	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	157	5.02%
Lead-to-Can Contact	48	1.53%
Lead-to-Lead Contact	27	0.86%
Clavicular Crush	2	0.06%
Externalized Conductors	50	1.60%
Other	30	0.96%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	34	1.09%
Total	**194**	**6.20%**



Year	2	4	6	8	10	at 139 months				
Survival Probability	98.15%	95.66%	91.79%	83.61%	76.15%	74.09%				
± 1 standard error	0.25%	0.41%	0.60%	0.92%	1.17%	1.30%				
Sample Size	2,560	2,030	1,550	1,090	700	210				

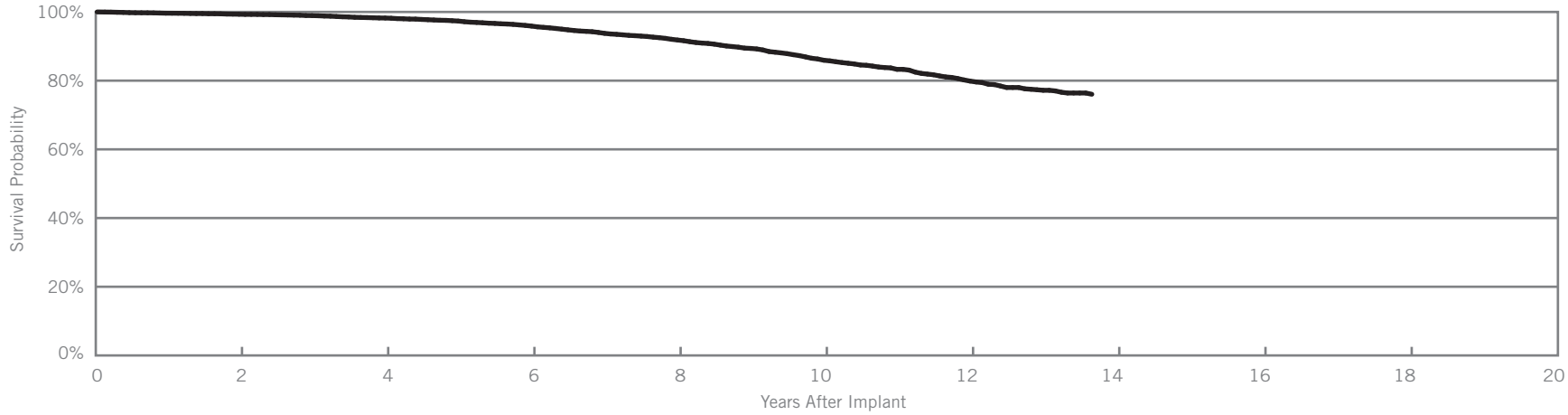
Customer Reported Performance Data

Riata™

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,280
Estimated Active US Implants	2,742
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	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	199	1.94%
Lead-to-Can Contact	97	0.94%
Lead-to-Lead Contact	36	0.35%
Clavicular Crush	1	<0.01%
Externalized Conductors	37	0.36%
Other	28	0.27%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	55	0.54%
Total	**259**	**2.52%**



Year	2	4	6	8	10	12	at 164 months			
Survival Probability	99.33%	98.23%	95.89%	91.83%	85.94%	79.87%	76.04%			
± 1 standard error	0.08%	0.15%	0.24%	0.37%	0.53%	0.75%	0.99%			
Sample Size	8,620	6,970	5,400	3,920	2,630	1,240	230			

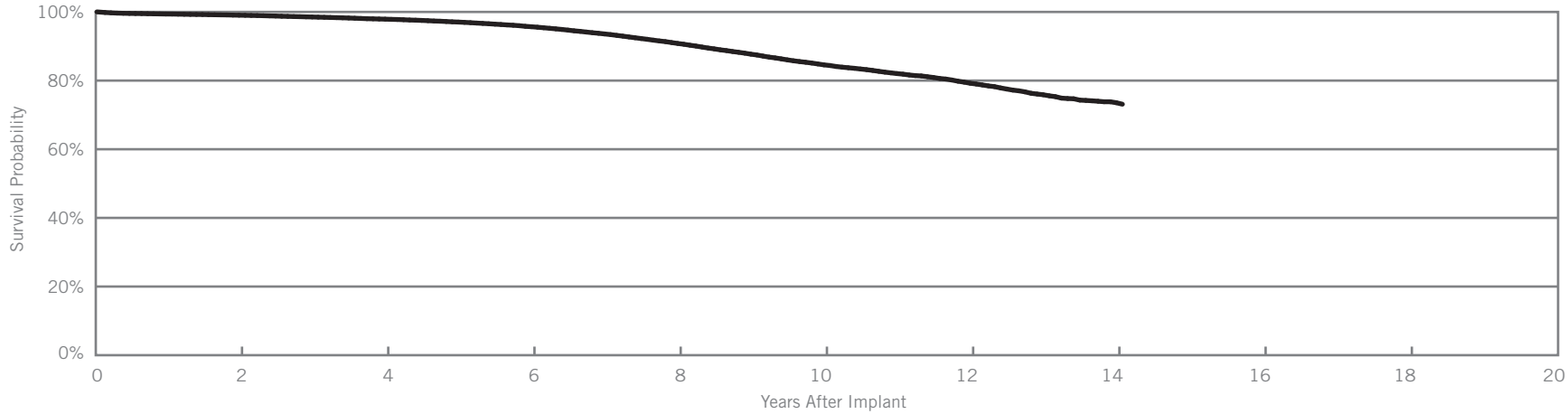
Customer Reported Performance Data

Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	68,386
Estimated Active US Implants	17,493
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 310)	One

Malfunctions	Qty.	Rate
Conductor Fracture	31	0.05%
Clavicular Crush	4	<0.01%
In the Pocket	11	0.02%
Intravascular	16	0.02%
Insulation Breach	1573	2.30%
Lead-to-Can Contact	640	0.94%
Lead-to-Lead Contact	324	0.47%
Clavicular Crush	17	0.02%
Externalized Conductors	321	0.47%
Other	271	0.40%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	507	0.74%
Total	**2114**	**3.09%**



Year	2	4	6	8	10	12	14	at 169 months		
Survival Probability	99.05%	97.90%	95.69%	90.82%	84.58%	79.23%	73.55%	73.12%		
± 1 standard error	0.04%	0.06%	0.10%	0.15%	0.21%	0.30%	0.56%	0.63%		
Sample Size	56,570	45,200	34,950	26,050	17,890	6,710	1,000	220		

Actively Monitored Study Data

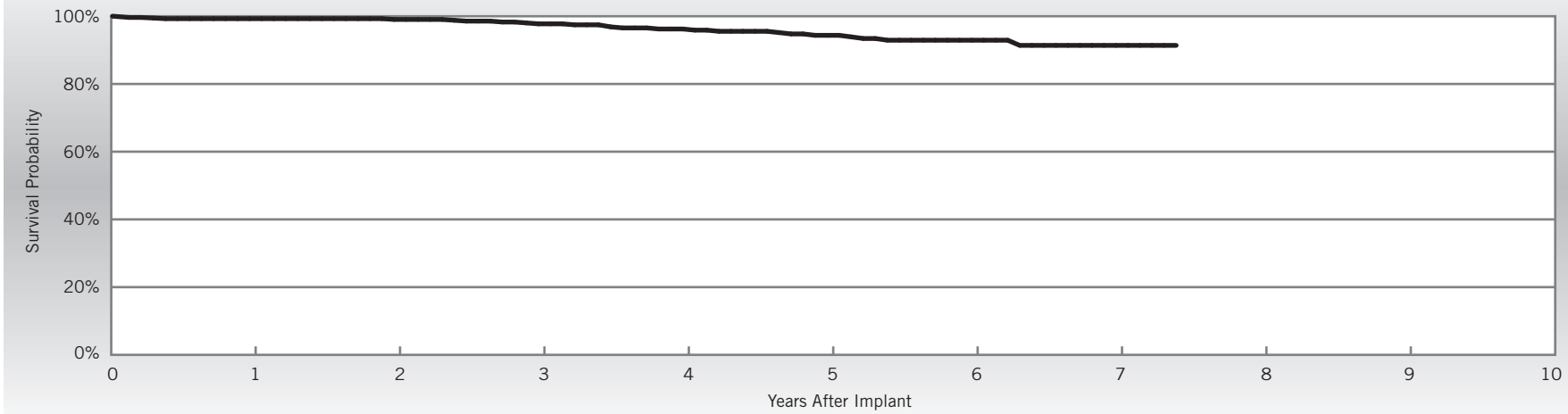
Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	566
Active Devices Enrolled in Study	182
Cumulative Months of Follow-up	27,288
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	2	0.35%
Insulation Breach	11	1.94%
Lead Dislodgement	2	0.35%
Oversensing	7	1.24%
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	19	3.36%
Lead-to-Can Contact	6	1.06%
Lead-to-Lead Contact	6	1.06%
Clavicular Crush	0	0.00%
Externalized Conductors	6	1.06%
Other	1	0.18%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	7	1.24%
Total	**26**	**4.59%**



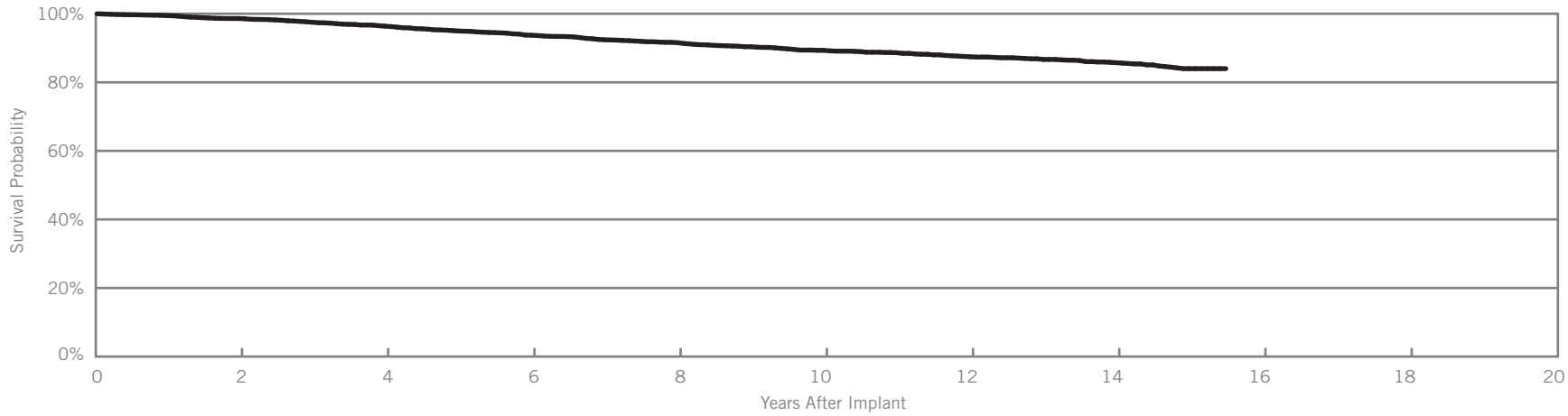
Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.28%	99.05%	97.75%	96.23%	94.36%	92.92%	91.39%	91.39%		
± 1 standard error	0.36%	0.36%	0.66%	0.97%	1.27%	1.50%	1.82%	1.82%		
Sample Size	530	470	390	320	250	180	110	50		

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,559
Estimated Active US Implants	741
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



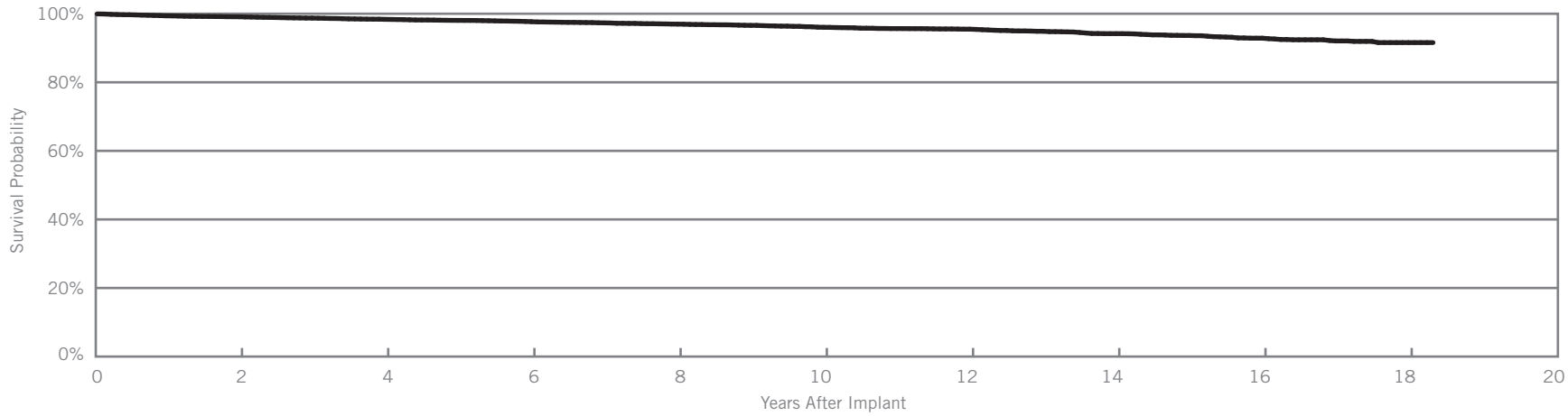
Year	2	4	6	8	10	12	14	at 186 months		
Survival Probability	98.61%	96.36%	93.73%	91.55%	89.32%	87.45%	85.71%	83.98%		
± 1 standard error	0.19%	0.31%	0.44%	0.54%	0.65%	0.74%	0.84%	0.98%		
Sample Size	3,730	2,960	2,290	1,720	1,260	990	810	220		

Customer Reported Performance Data

SPL™

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,373
Estimated Active US Implants	2,222
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	at 220 months
Survival Probability	99.11%	98.36%	97.68%	96.97%	96.04%	95.50%	94.19%	92.87%	91.58%	91.58%
± 1 standard error	0.09%	0.12%	0.16%	0.19%	0.24%	0.27%	0.34%	0.42%	0.57%	0.57%
Sample Size	10,370	8,450	6,830	5,380	4,140	3,210	2,630	1,540	550	220

Summary Information

Defibrillation Leads

St. Jude Medical

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
LDA230Q	Optisure™ DF4	99.52%									
LDA220Q	Optisure™ DF4	98.97%									
LDA210Q	Optisure™ DF4	99.08%	98.85%								
7170Q/7171Q	Durata™ DF4	99.16%	98.81%	98.36%	97.72%	97.27%	96.83%				
7120Q/7121Q	Durata™ DF4	99.27%	99.07%	98.88%	98.56%	98.16%	97.69%				
7122Q	Durata™ DF4	99.31%	99.13%	98.90%	98.51%	97.90%	97.33%				
7120/7121	Durata™	99.40%	99.13%	98.85%	98.52%	98.09%	97.58%	96.85%	96.06%		
7122	Durata™	99.24%	98.84%	98.53%	98.11%	97.40%	96.90%	96.36%	95.59%		
7070/7071	Riata™ ST Optim™	99.50%	99.19%	98.80%	98.32%	97.33%	96.47%	95.62%	95.37%		
7020/7021	Riata™ ST Optim™	98.97%	98.60%	98.29%	97.82%	97.12%	96.43%	95.49%	94.69%	93.87%	
7022	Riata™ ST Optim™	99.10%	98.94%	98.67%	97.93%	97.48%	96.86%	96.03%	94.54%		
7010/7011	Riata™ ST	99.55%	99.27%	98.70%	98.42%	97.22%	95.43%	93.63%	91.53%	90.17%	
7040/7041	Riata™ ST	99.41%	99.07%	98.66%	97.48%	96.09%	94.00%	92.10%	89.48%	86.99%	
7002	Riata™ ST	98.97%	98.45%	97.95%	97.33%	96.07%	93.37%	91.30%	88.37%	87.32%	
7000/7001	Riata™ ST	99.33%	98.97%	98.46%	97.84%	96.76%	94.83%	92.65%	90.91%	89.15%	87.60%
1560/1561	Riata™ i	99.77%	99.41%	98.99%	98.69%	98.52%	97.78%	96.18%	94.24%	90.86%	88.76%
1590/1591	Riata™ i	99.57%	99.26%	99.07%	98.73%	97.95%	96.94%	94.64%	92.33%	90.54%	88.78%
1582	Riata™	98.88%	98.15%	97.00%	95.66%	94.15%	91.79%	87.76%	83.61%	79.81%	76.15%
1570/1571	Riata™	99.64%	99.33%	98.94%	98.23%	97.35%	95.89%	93.77%	91.83%	89.38%	85.94%
1580/1581	Riata™	99.39%	99.05%	98.53%	97.90%	97.05%	95.69%	93.59%	90.82%	87.70%	84.58%
1559	TVL™ ADX	99.47%	98.61%	97.51%	96.36%	94.97%	93.73%	92.40%	91.55%	90.38%	89.32%
SP01/SP02/SP03/SP04	SPL™	99.39%	99.11%	98.73%	98.36%	98.06%	97.68%	97.33%	96.97%	96.60%	96.04%

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	580	516	0	0.00%	0	0.00%	1	0.17%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.17%**	**0**
LDA220Q	Feb-14	4,478	3,908	4	0.09%	0	0.00%	17	0.38%	7	0.16%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	3	0.07%	1	0.02%	2	0.04%	**36**	**0.80%**	**13**
LDA210Q	Feb-14	11,755	11,127	11	0.09%	0	0.00%	28	0.24%	12	0.10%	5	0.04%	6	0.05%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	6	0.05%	**70**	**0.60%**	**12**
7170Q/7171Q	Jul-09	5,416	3,543	6	0.11%	1	0.02%	11	0.20%	8	0.15%	3	0.06%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	**31**	**0.57%**	**13**
7120Q/7121Q	Jan-09	116,702	84,862	74	0.06%	2	<0.01%	202	0.17%	86	0.07%	41	0.04%	12	0.01%	0	0.00%	5	<0.01%	8	<0.01%	3	<0.01%	32	0.03%	**465**	**0.40%**	**237**
7122Q	Jan-09	66,458	54,962	76	0.11%	2	<0.01%	121	0.18%	56	0.08%	18	0.03%	7	0.01%	0	0.00%	4	<0.01%	5	<0.01%	3	<0.01%	26	0.04%	**318**	**0.48%**	**148**
7120/7121	Sep-07	59,406	29,742	40	0.07%	1	<0.01%	69	0.12%	22	0.04%	48	0.08%	5	<0.01%	0	0.00%	1	<0.01%	19	0.03%	0	0.00%	21	0.04%	**226**	**0.38%**	**92**
7122	Sep-07	14,199	8,161	10	0.07%	1	<0.01%	18	0.13%	16	0.11%	10	0.07%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	4	0.03%	**64**	**0.45%**	**30**
7070/7071	Jul-06	3,312	1,505	3	0.09%	1	0.03%	3	0.09%	5	0.15%	4	0.12%	3	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**19**	**0.57%**	**6**
7020/7021	Jul-06	14,242	5,777	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	1,469	624	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	2	0.14%	0	0.00%	0	0.00%	0	0.00%	**11**	**0.75%**	**4**
7010/7011	Mar-06	2,199	825	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	4,055	1,502	4	0.10%	0	0.00%	5	0.12%	1	0.02%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**16**	**0.39%**	**3**
7002	Jun-05	2,405	874	6	0.25%	0	0.00%	3	0.12%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	**21**	**0.87%**	**11**
7000/7001	Jun-05	34,875	12,339	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 pages 9-10.

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	580	516	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.17%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.17%**	**0**
LDA220Q	Feb-14	4,478	3,908	3	0.07%	1	0.02%	23	0.51%	11	0.25%	5	0.11%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**44**	**0.98%**	**16**
LDA210Q	Feb-14	11,755	11,127	8	0.07%	0	0.00%	57	0.48%	18	0.15%	18	0.15%	6	0.05%	0	0.00%	1	<0.01%	4	0.03%	0	0.00%	5	0.04%	**117**	**1.00%**	**29**
7170Q/7171Q	Jul-09	5,416	3,543	4	0.07%	5	0.09%	18	0.33%	33	0.61%	24	0.44%	0	0.00%	2	0.04%	9	0.17%	8	0.15%	0	0.00%	1	0.02%	**104**	**1.92%**	**34**
7120Q/7121Q	Jan-09	116,702	84,862	32	0.03%	80	0.07%	491	0.42%	417	0.36%	351	0.30%	60	0.05%	19	0.02%	67	0.06%	181	0.16%	5	<0.01%	49	0.04%	**1752**	**1.50%**	**750**
7122Q	Jan-09	66,458	54,962	32	0.05%	28	0.04%	253	0.38%	162	0.24%	154	0.23%	27	0.04%	10	0.02%	32	0.05%	51	0.08%	8	0.01%	24	0.04%	**781**	**1.18%**	**362**
7120/7121	Sep-07	59,406	29,742	16	0.03%	111	0.19%	176	0.30%	249	0.42%	435	0.73%	59	0.10%	44	0.07%	143	0.24%	208	0.35%	1	<0.01%	39	0.07%	**1481**	**2.49%**	**441**
7122	Sep-07	14,199	8,161	2	0.01%	24	0.17%	52	0.37%	57	0.40%	85	0.60%	9	0.06%	20	0.14%	31	0.22%	21	0.15%	2	0.01%	7	0.05%	**310**	**2.18%**	**154**
7070/7071	Jul-06	3,312	1,505	2	0.06%	15	0.45%	12	0.36%	23	0.69%	39	1.18%	2	0.06%	5	0.15%	10	0.30%	11	0.33%	1	0.03%	2	0.06%	**122**	**3.68%**	**26**
7020/7021	Jul-06	14,242	5,777	16	0.11%	50	0.35%	63	0.44%	129	0.91%	199	1.40%	19	0.13%	22	0.15%	37	0.26%	75	0.53%	2	0.01%	27	0.19%	**639**	**4.49%**	**186**
7022	Jul-06	1,469	624	3	0.20%	8	0.54%	10	0.68%	10	0.68%	19	1.29%	1	0.07%	6	0.41%	2	0.14%	3	0.20%	1	0.07%	1	0.07%	**64**	**4.36%**	**20**
7010/7011	Mar-06	2,199	825	3	0.14%	5	0.23%	8	0.36%	8	0.36%	37	1.68%	3	0.14%	39	1.77%	19	0.86%	16	0.73%	0	0.00%	2	0.09%	**140**	**6.37%**	**31**
7040/7041	Mar-06	4,055	1,502	3	0.07%	31	0.76%	6	0.15%	46	1.13%	88	2.17%	14	0.35%	52	1.28%	17	0.42%	21	0.52%	0	0.00%	6	0.15%	**284**	**7.00%**	**61**
7002	Jun-05	2,405	874	5	0.21%	9	0.37%	9	0.37%	17	0.71%	56	2.33%	2	0.08%	63	2.62%	3	0.12%	6	0.25%	0	0.00%	7	0.29%	**177**	**7.36%**	**65**
7000/7001	Jun-05	34,875	12,339	30	0.09%	133	0.38%	59	0.17%	289	0.83%	739	2.12%	62	0.18%	664	1.90%	104	0.30%	172	0.49%	5	0.01%	89	0.26%	**2346**	**6.73%**	**647**

Definitions of observations and complications can be found on pages 9-10.

U.S. Malfunction Summary

			Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Percent Returned for Analysis	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
LDA230Q	580	1.60%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	0.34%	**2**	**0.34%**
LDA220Q	4,478	2.20%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**1**	**0.02%**	0	0.00%	0	0.00%	15	0.33%	**16**	**0.36%**
LDA210Q	11,755	1.20%	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%	**0**	**0.00%**	0	0.00%	0	0.00%	30	0.26%	**30**	**0.26%**
7170Q/7171Q	5,416	3.60%	0	0.00%	1	0.02%	1	0.02%	**2**	**0.04%**	3	0.06%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.07%**	0	0.00%	0	0.00%	30	0.55%	**36**	**0.66%**
7120Q/7121Q	116,702	3.70%	2	<0.01%	6	<0.01%	14	0.01%	**22**	**0.02%**	56	0.05%	13	0.01%	20	0.02%	0	0.00%	37	0.03%	**126**	**0.11%**	2	<0.01%	33	0.03%	649	0.56%	**832**	**0.71%**
7122Q	66,458	3.50%	0	0.00%	6	<0.01%	2	<0.01%	**8**	**0.01%**	27	0.04%	7	0.01%	6	<0.01%	0	0.00%	8	0.01%	**48**	**0.07%**	0	0.00%	12	0.02%	339	0.51%	**407**	**0.61%**
7120/7121	59,406	4.80%	2	<0.01%	20	0.03%	8	0.01%	**30**	**0.05%**	53	0.09%	21	0.04%	13	0.02%	0	0.00%	18	0.03%	**105**	**0.18%**	1	<0.01%	9	0.02%	364	0.61%	**509**	**0.86%**
7122	14,199	5.90%	0	0.00%	12	0.08%	3	0.02%	**15**	**0.11%**	27	0.19%	13	0.09%	1	<0.01%	1	<0.01%	5	0.04%	**47**	**0.33%**	0	0.00%	4	0.03%	112	0.79%	**178**	**1.25%**
7070/7071	3,312	6.70%	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	3	0.09%	2	0.06%	1	0.03%	1	0.03%	1	0.03%	**8**	**0.24%**	0	0.00%	0	0.00%	19	0.57%	**28**	**0.85%**
7020/7021	14,242	6.30%	1	<0.01%	3	0.02%	5	0.04%	**9**	**0.06%**	14	0.10%	6	0.04%	4	0.03%	0	0.00%	15	0.11%	**39**	**0.27%**	0	0.00%	0	0.00%	163	1.14%	**211**	**1.48%**
7022	1,469	9.30%	0	0.00%	2	0.14%	1	0.07%	**3**	**0.20%**	5	0.34%	0	0.00%	0	0.00%	0	0.00%	2	0.14%	**7**	**0.48%**	0	0.00%	0	0.00%	17	1.16%	**27**	**1.84%**
7010/7011	2,199	7.80%	0	0.00%	2	0.09%	0	0.00%	**2**	**0.09%**	10	0.45%	17	0.77%	1	0.05%	2	0.09%	4	0.18%	**34**	**1.55%**	0	0.00%	0	0.00%	9	0.41%	**45**	**2.05%**
7040/7041	4,055	7.60%	0	0.00%	1	0.02%	3	0.07%	**4**	**0.10%**	23	0.57%	13	0.32%	0	0.00%	2	0.05%	9	0.22%	**47**	**1.16%**	0	0.00%	0	0.00%	28	0.69%	**79**	**1.95%**
7002	2,405	8.70%	0	0.00%	2	0.08%	3	0.12%	**5**	**0.21%**	29	1.21%	13	0.54%	0	0.00%	7	0.29%	11	0.46%	**60**	**2.49%**	0	0.00%	0	0.00%	22	0.91%	**87**	**3.62%**
7000/7001	34,875	6.70%	4	0.01%	7	0.02%	12	0.03%	**23**	**0.07%**	277	0.79%	141	0.40%	11	0.03%	32	0.09%	63	0.18%	**524**	**1.50%**	1	<0.01%	1	<0.01%	284	0.81%	**833**	**2.39%**
1560/1561	981	9.10%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	8	0.82%	6	0.61%	1	0.10%	2	0.20%	1	0.10%	**18**	**1.83%**	0	0.00%	0	0.00%	2	0.20%	**20**	**2.04%**
1590/1591	9,700	6.70%	1	0.01%	1	0.01%	5	0.05%	**7**	**0.07%**	60	0.62%	46	0.47%	2	0.02%	18	0.19%	29	0.30%	**155**	**1.60%**	0	0.00%	1	0.01%	50	0.52%	**213**	**2.20%**
1582	3,130	10.70%	0	0.00%	0	0.00%	3	0.10%	**3**	**0.10%**	48	1.53%	27	0.86%	2	0.06%	50	1.60%	30	0.96%	**157**	**5.02%**	0	0.00%	0	0.00%	34	1.09%	**194**	**6.20%**
1570/1571	10,280	7.80%	2	0.02%	3	0.03%	0	0.00%	**5**	**0.05%**	97	0.94%	36	0.35%	1	<0.01%	37	0.36%	28	0.27%	**199**	**1.94%**	0	0.00%	0	0.00%	55	0.54%	**259**	**2.52%**
1580/1581	68,383	7.40%	4	<0.01%	11	0.02%	16	0.02%	**31**	**0.05%**	640	0.94%	324	0.47%	17	0.02%	321	0.47%	271	0.40%	**1573**	**2.30%**	3	<0.01%	0	0.00%	507	0.74%	**2114**	**3.09%**

Definitions of malfunction categories can be found on pages 10-12.

Worldwide Malfunction Summary

			Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Worldwide Sales	Percent Returned for Analysis	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
LDA220Q	6,456	1.9%	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	0.02%	**1**	**0.02%**	0	0.00%	1	0.02%	23	0.36%	**25**	**0.39%**
LDA210Q	20,235	1.1%	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	<0.01%	**1**	**<0.01%**	0	0.00%	4	0.02%	56	0.28%	**61**	**0.30%**
7170Q/7171Q	16,242	2.1%	0	0.00%	3	0.02%	4	0.02%	**7**	**0.04%**	6	0.04%	1	0.01%	3	0.02%	0	0.00%	2	0.01%	**12**	**0.07%**	2	0.01%	0	0.00%	57	0.35%	**78**	**0.48%**
7120Q/7121Q	194,872	2.9%	6	<0.01%	18	0.01%	23	0.01%	**47**	**0.02%**	79	0.04%	17	0.01%	33	0.02%	0	0.00%	42	0.02%	**171**	**0.09%**	3	<0.01%	89	0.05%	1069	0.55%	**1379**	**0.71%**
7122Q	175,419	2.2%	3	<0.01%	23	0.01%	7	<0.01%	**33**	**0.02%**	75	0.04%	10	0.01%	21	0.01%	0	0.00%	14	0.01%	**120**	**0.07%**	2	<0.01%	126	0.07%	867	0.49%	**1148**	**0.65%**
7120/7121	138,911	2.8%	7	0.01%	81	0.06%	22	0.02%	**110**	**0.08%**	97	0.07%	28	0.02%	21	0.02%	0	0.00%	35	0.03%	**181**	**0.13%**	1	<0.01%	25	0.02%	729	0.52%	**1046**	**0.75%**
7122	59,693	2.7%	2	<0.01%	98	0.16%	8	0.01%	**108**	**0.18%**	70	0.12%	19	0.03%	7	0.01%	1	<0.01%	14	0.02%	**111**	**0.19%**	1	<0.01%	23	0.04%	416	0.70%	**659**	**1.10%**

Definitions of malfunction categories can be found on pages 10-12.

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	Qty.	Rate
7170Q/7171Q	114	58	5,394	0	0.00%	1	0.88%	0	0.00%	1	0.88%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.88%	0	0.00%	0	0.00%	0	0.00%	**3**	**2.63%**
7120Q/7121Q	4,305	2,212	191,796	4	0.09%	2	0.05%	1	0.02%	11	0.26%	0	0.00%	12	0.28%	4	0.09%	4	0.09%	1	0.02%	38	0.88%	5	0.12%	0	0.00%	0	0.00%	**82**	**1.90%**
7122Q	1,521	901	59,751	2	0.13%	0	0.00%	0	0.00%	3	0.20%	0	0.00%	4	0.26%	1	0.07%	0	0.00%	0	0.00%	7	0.46%	0	0.00%	2	0.13%	0	0.00%	**19**	**1.25%**
7120/7121	3,561	1,369	192,763	1	0.03%	8	0.22%	0	0.00%	11	0.31%	0	0.00%	12	0.34%	2	0.06%	2	0.06%	10	0.28%	20	0.56%	8	0.22%	0	0.00%	0	0.00%	**74**	**2.08%**
7122	449	216	23,676	0	0.00%	3	0.67%	0	0.00%	5	1.11%	0	0.00%	3	0.67%	1	0.22%	0	0.00%	0	0.00%	4	0.89%	2	0.45%	0	0.00%	0	0.00%	**18**	**4.01%**
7070/7071	288	104	15,818	1	0.35%	2	0.69%	1	0.35%	2	0.69%	0	0.00%	1	0.35%	0	0.00%	0	0.00%	0	0.00%	1	0.35%	1	0.35%	0	0.00%	0	0.00%	**9**	**3.13%**
7020/7021	1,469	351	79,377	0	0.00%	6	0.41%	1	0.07%	6	0.41%	0	0.00%	10	0.68%	1	0.07%	0	0.00%	2	0.14%	9	0.61%	4	0.27%	0	0.00%	1	0.07%	**40**	**2.72%**
7000/7001	179	38	7,557	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	0.56%	1	0.56%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.12%**
1580/1581	566	182	27,288	0	0.00%	0	0.00%	0	0.00%	2	0.35%	0	0.00%	2	0.35%	0	0.00%	0	0.00%	11	1.94%	2	0.35%	7	1.24%	0	0.00%	1	0.18%	**25**	**4.42%**

Malfunctions

Models	Number of Devices Enrolled	Percent Returned for Analysis	Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
			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	Qty.	Rate
7170Q/7171Q	114	4.40%	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%	**0**	**0.00%**	0	0.00%	0	0.00%	2	1.75%	**2**	**1.75%**
7120Q/7121Q	4,305	4.90%	1	0.02%	2	0.05%	2	0.05%	**5**	**0.12%**	2	0.05%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**5**	**0.12%**	0	0.00%	1	0.02%	43	1.00%	**54**	**1.25%**
7122Q	1,521	4.70%	1	0.07%	1	0.07%	0	0.00%	**2**	**0.13%**	3	0.20%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**4**	**0.26%**	0	0.00%	0	0.00%	14	0.92%	**20**	**1.31%**
7120/7121	3,561	4.10%	0	0.00%	1	0.03%	0	0.00%	**1**	**0.03%**	6	0.17%	4	0.11%	0	0.00%	0	0.00%	1	0.03%	**11**	**0.31%**	0	0.00%	1	0.03%	28	0.79%	**41**	**1.15%**
7122	449	4.70%	0	0.00%	1	0.22%	1	0.22%	**2**	**0.45%**	1	0.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.22%**	0	0.00%	0	0.00%	7	1.56%	**10**	**2.23%**
7070/7071	288	1.70%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
7020/7021	1,469	4.90%	0	0.00%	3	0.20%	0	0.00%	**3**	**0.20%**	1	0.07%	0	0.00%	2	0.14%	0	0.00%	0	0.00%	**3**	**0.20%**	0	0.00%	0	0.00%	14	0.95%	**20**	**1.36%**
7000/7001	179	6.70%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	2	1.12%	1	0.56%	0	0.00%	0	0.00%	0	0.00%	**3**	**1.68%**	1	0.56%	0	0.00%	0	0.00%	**4**	**2.23%**
1580/1581	566	6.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	6	1.06%	6	1.06%	0	0.00%	6	1.06%	1	0.18%	**19**	**3.36%**	0	0.00%	0	0.00%	7	1.24%	**26**	**4.59%**

A list of complications can be found on page 15.
Definitions of malfunction categories can be found on pages 10-12.

Pacemakers

Dual-Chamber

St. Jude Medical

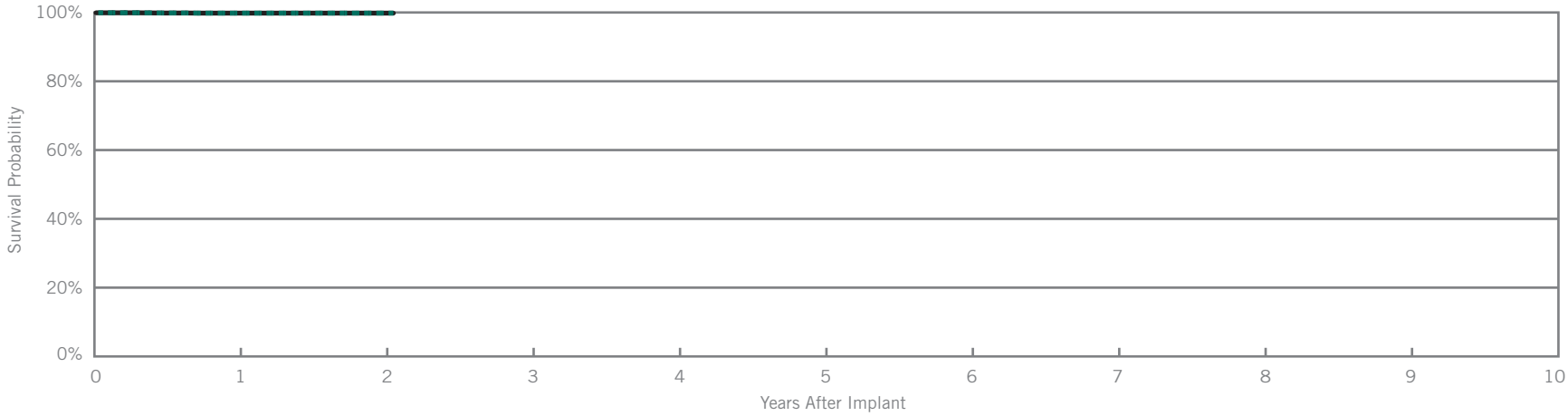
Endurity™ DR

Model PM2160

US Regulatory Approval	March 2014
Registered US Implants	8,029
Estimated Active US Implants	6,971
Estimated Longevity	9.7 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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%	1	0.01%
Total	**0**	**0.00%**	**6**	**0.07%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.81%	99.81%	99.81%							
± 1 standard error	0.05%	0.05%	0.05%							
Sample Size	6,350	2,490	310							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.81%	99.81%	99.81%							
± 1 standard error	0.05%	0.05%	0.05%							

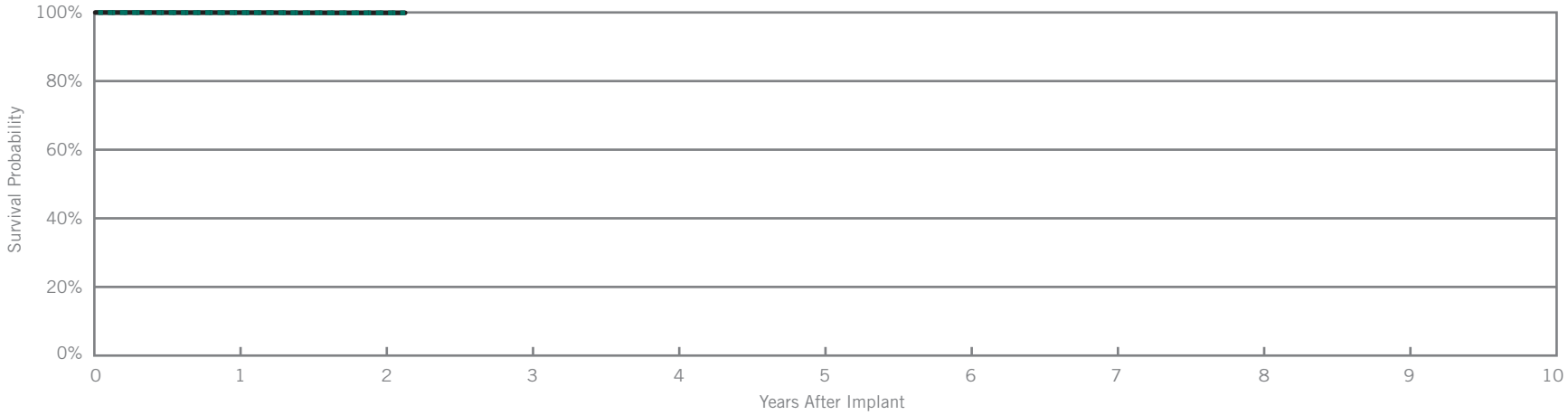
Assurity™ DR RF

Model PM2240

US Regulatory Approval	March 2014
Registered US Implants	113,414
Estimated Active US Implants	105,085
Estimated Longevity	9.4 Years
Normal Battery Depletion	1
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	1	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	19	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	5	<0.01%
Total	**1**	**<0.01%**	**26**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.95%	99.87%	99.87%							
± 1 standard error	0.01%	0.02%	0.02%							
Sample Size	80,020	24,020	670							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.95%	99.89%	99.89%							
± 1 standard error	0.01%	0.02%	0.02%							

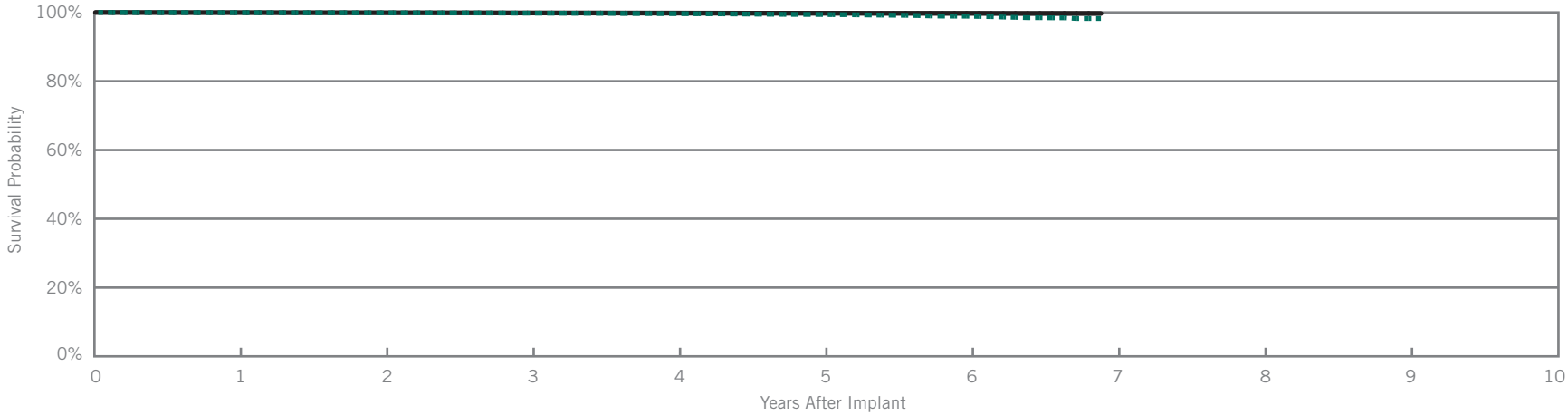
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	243,008
Estimated Active US Implants	164,835
Estimated Longevity	8 Years
Normal Battery Depletion	213
Number of US Advisories (see pg. 303)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	15	<0.01%	35	0.01%
Electrical Interconnect	7	<0.01%	31	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	0	0.00%	13	<0.01%
Possible Early Battery Depletion	7	<0.01%	19	<0.01%
Other	5	<0.01%	34	0.01%
Total	**34**	**0.01%**	**134**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.93%	99.87%	99.79%	99.64%	99.39%	98.90%	98.23%			
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.05%	0.12%			
Sample Size	230,670	205,570	162,910	108,740	65,840	32,330	760			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.95%	99.90%	99.84%	99.80%	99.75%	99.72%	99.69%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%			

Actively Monitored Study Data

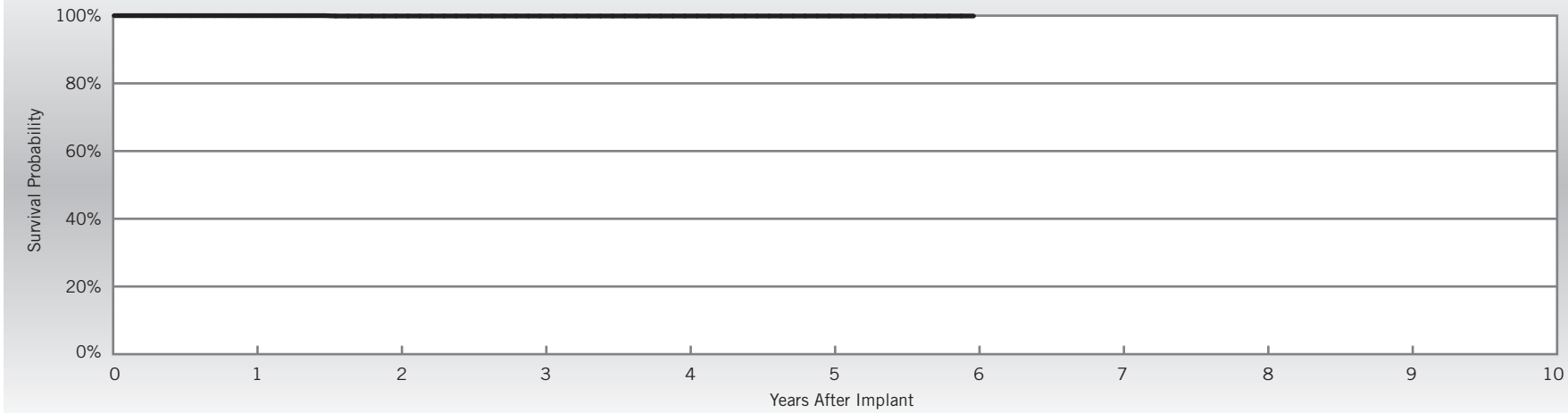
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,774
Active Devices Enrolled in Study	396
Cumulative Months of Follow-up	49,661
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%**



Year	1	2	3	4	5	6				
Survival Probability	100.00%	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%				
Sample Size	1,540	1,060	650	460	360	60				

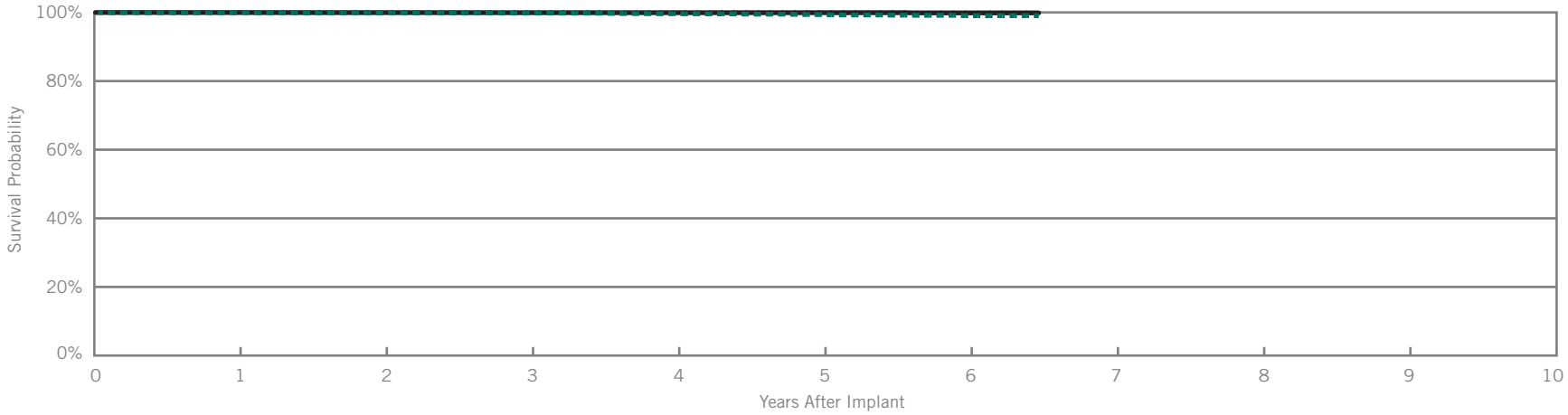
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	48,904
Estimated Active US Implants	31,028
Estimated Longevity	9.2 Years
Normal Battery Depletion	48
Number of US Advisories (see pg. 303)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<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%	4	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**3**	**<0.01%**	**11**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.97%	99.93%	99.85%	99.62%	99.39%	99.04%	99.04%			
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.06%	0.09%	0.12%			
Sample Size	45,910	40,130	31,820	21,470	12,280	4,690	240			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.97%	99.95%	99.93%	99.93%	99.93%	99.87%	99.87%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%	0.04%	0.04%			

Actively Monitored Study Data

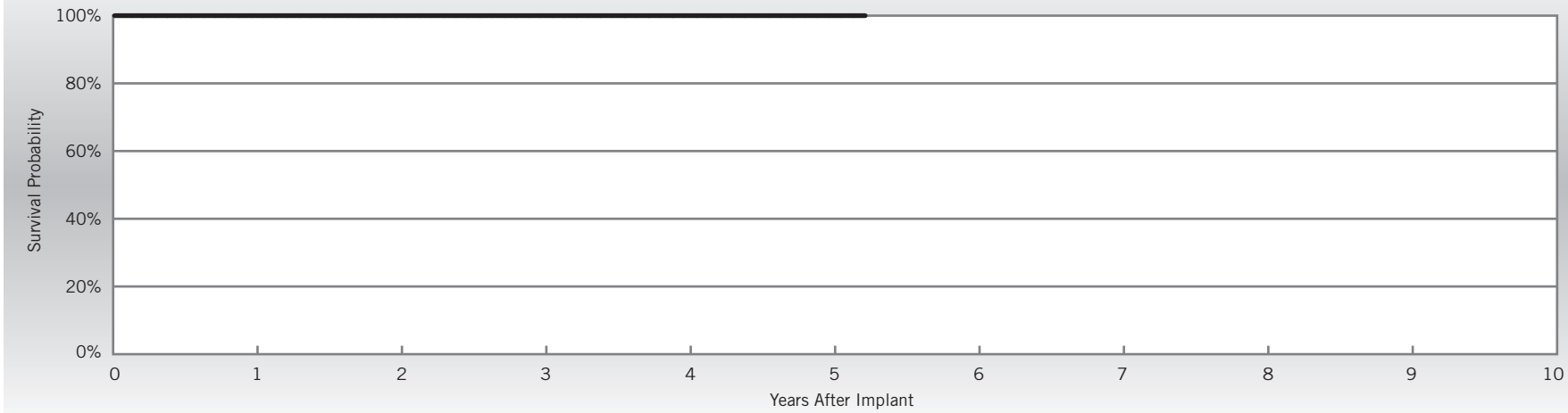
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	226
Active Devices Enrolled in Study	70
Cumulative Months of Follow-up	7,853
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%**



Year	1	2	3	4	5	at 63 months				
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%				
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%				
Sample Size	210	150	100	90	70	50				

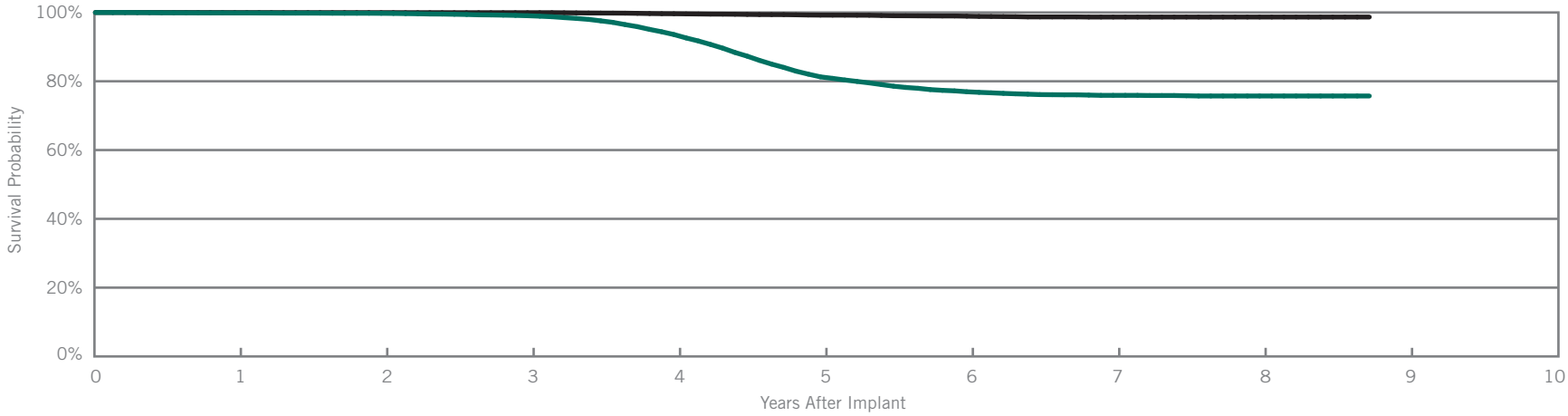
Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	53,298
Estimated Active US Implants	21,280
Estimated Longevity	6.5 Years
Normal Battery Depletion	2024
Number of US Advisories	None

Customer Reported Performance Data

	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%	52	0.10%
Total	**2**	**<0.01%**	**98**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 105 months
Survival Probability	99.85%	99.75%	99.05%	93.58%	81.28%	76.95%	75.90%	75.72%	75.72%
± 1 standard error	0.02%	0.02%	0.05%	0.14%	0.25%	0.29%	0.31%	0.32%	0.32%
Sample Size	48,910	41,190	34,350	27,140	19,350	11,900	6,250	2,540	240

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 105 months
Survival Probability	99.97%	99.96%	99.94%	99.63%	99.23%	98.92%	98.67%	98.67%	98.67%
± 1 standard error	0.01%	0.01%	0.01%	0.04%	0.06%	0.07%	0.10%	0.10%	0.10%

Actively Monitored Study Data

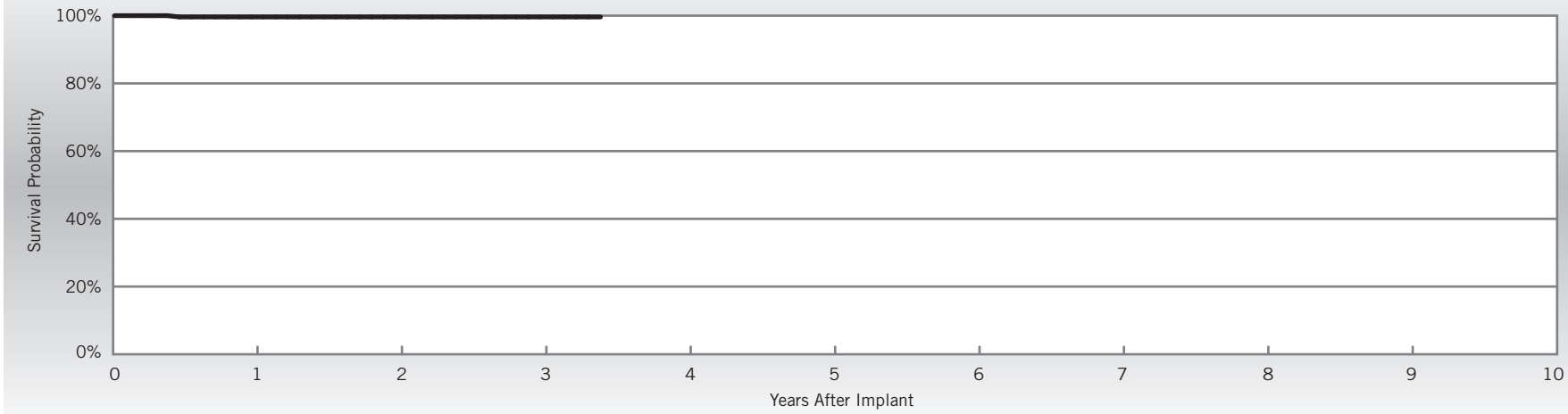
Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	283
Active Devices Enrolled in Study	16
Cumulative Months of Follow-up	7,759
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%**



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						

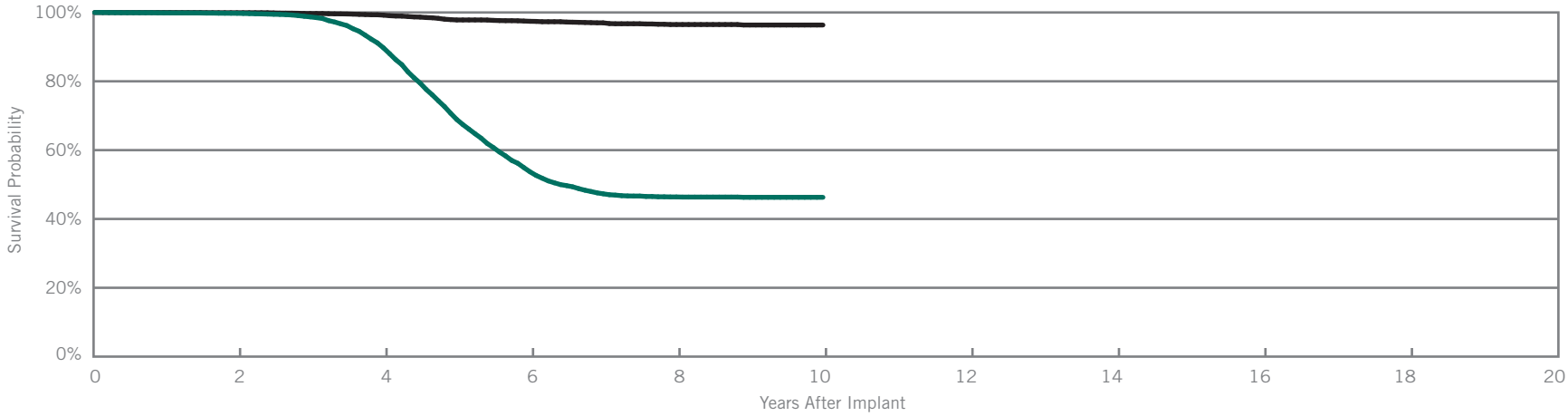
Victory™ DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,308
Estimated Active US Implants	3,321
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,768
Number of US Advisories	None

Customer Reported Performance Data

	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%	31	0.12%
Total	**1**	**<0.01%**	**147**	**0.56%**



Including Normal Battery Depletion

Year	2	4	6	8	10					
Survival Probability	99.75%	89.70%	53.70%	46.40%	46.29%					
± 1 standard error	0.03%	0.22%	0.43%	0.45%	0.46%					
Sample Size	21,170	15,340	7,830	2,980	200					

Excluding Normal Battery Depletion

Year	2	4	6	8	10					
Survival Probability	99.93%	99.21%	97.43%	96.49%	96.35%					
± 1 standard error	0.02%	0.06%	0.14%	0.21%	0.24%					

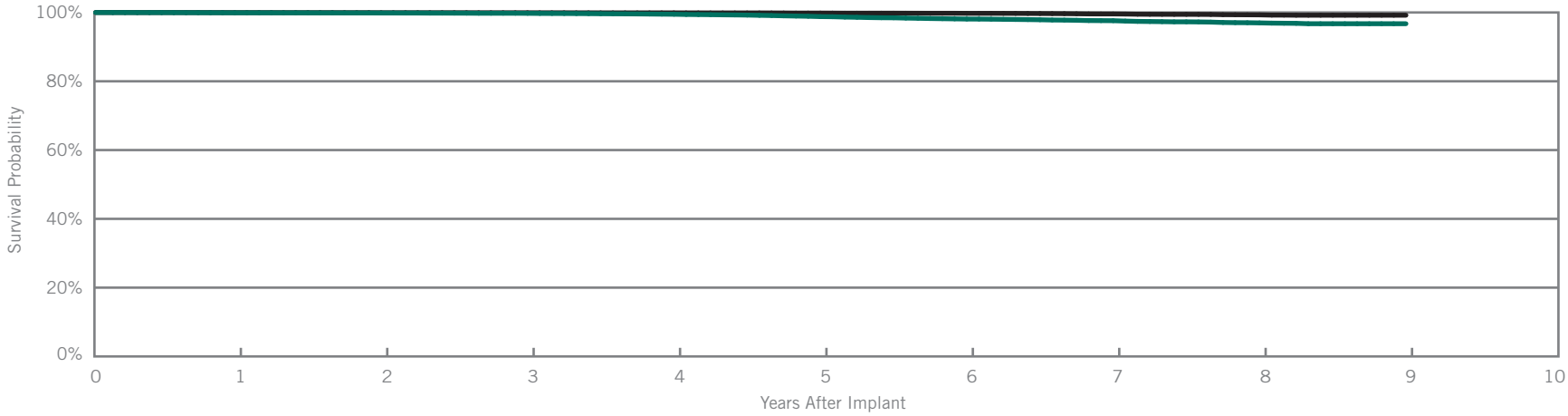
Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	112,121
Estimated Active US Implants	44,261
Estimated Longevity	11.7 Years
Normal Battery Depletion	489
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	17	0.02%
Electrical Interconnect	4	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	10	<0.01%
Mechanical	0	0.00%	9	<0.01%
Possible Early Battery Depletion	0	0.00%	3	<0.01%
Other	1	<0.01%	85	0.08%
Total	**6**	**<0.01%**	**124**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9
Survival Probability	99.91%	99.84%	99.75%	99.48%	98.80%	98.09%	97.61%	96.97%	96.73%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.04%	0.05%	0.06%	0.09%	0.11%
Sample Size	105,000	91,960	80,760	70,760	61,460	51,850	37,910	18,530	430

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9
Survival Probability	99.96%	99.93%	99.92%	99.89%	99.83%	99.75%	99.57%	99.30%	99.20%
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.06%

Actively Monitored Study Data

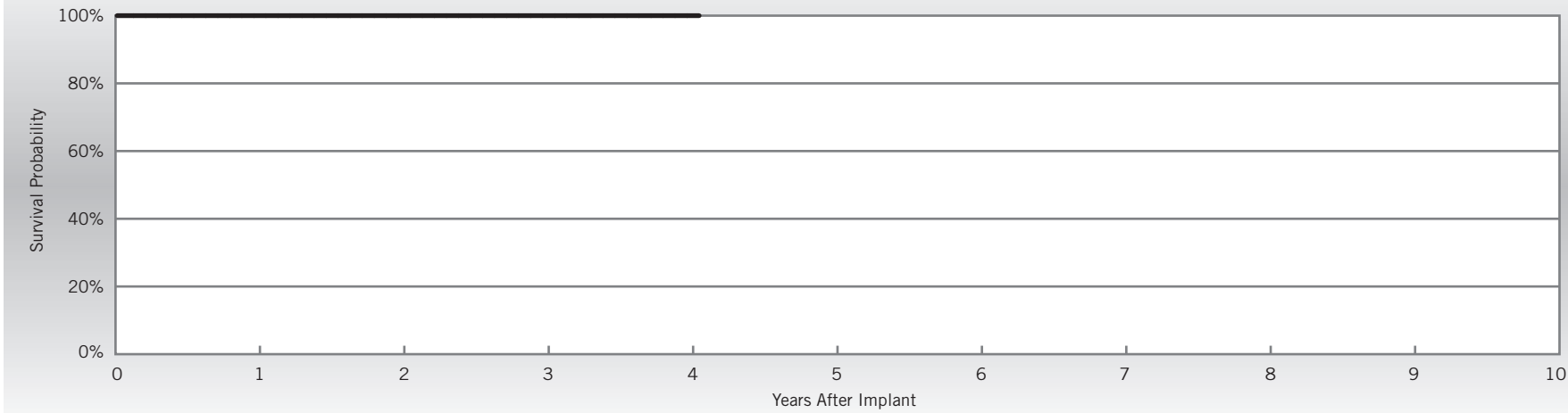
Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,517
Active Devices Enrolled in Study	20
Cumulative Months of Follow-up	47,663
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%**



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	1,450	1,270	900	360	70					

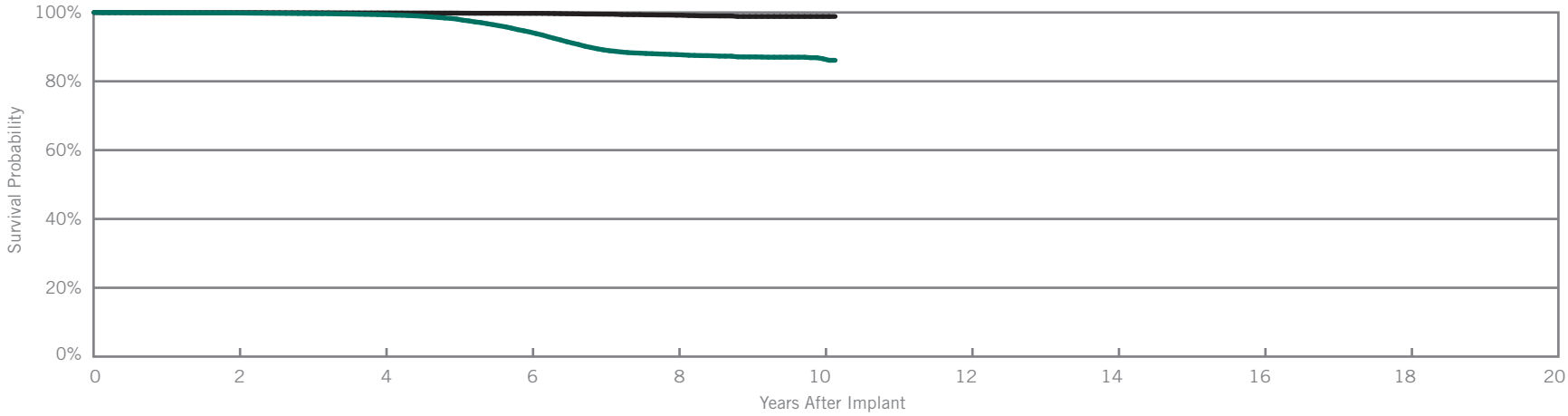
Victory™ XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,657
Estimated Active US Implants	15,615
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,465
Number of US Advisories	None

Customer Reported Performance Data

	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%	7	0.01%
Mechanical	0	0.00%	8	0.01%
Possible Early Battery Depletion	0	0.00%	5	<0.01%
Other	1	<0.01%	66	0.11%
Total	**3**	**<0.01%**	**111**	**0.18%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 122 months				
Survival Probability	99.84%	99.34%	94.30%	87.76%	86.55%	86.10%				
± 1 standard error	0.02%	0.04%	0.12%	0.19%	0.23%	0.44%				
Sample Size	52,310	41,350	32,410	18,160	3,360	290				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 122 months				
Survival Probability	99.95%	99.86%	99.74%	99.20%	98.84%	98.84%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.08%	0.08%				

Actively Monitored Study Data

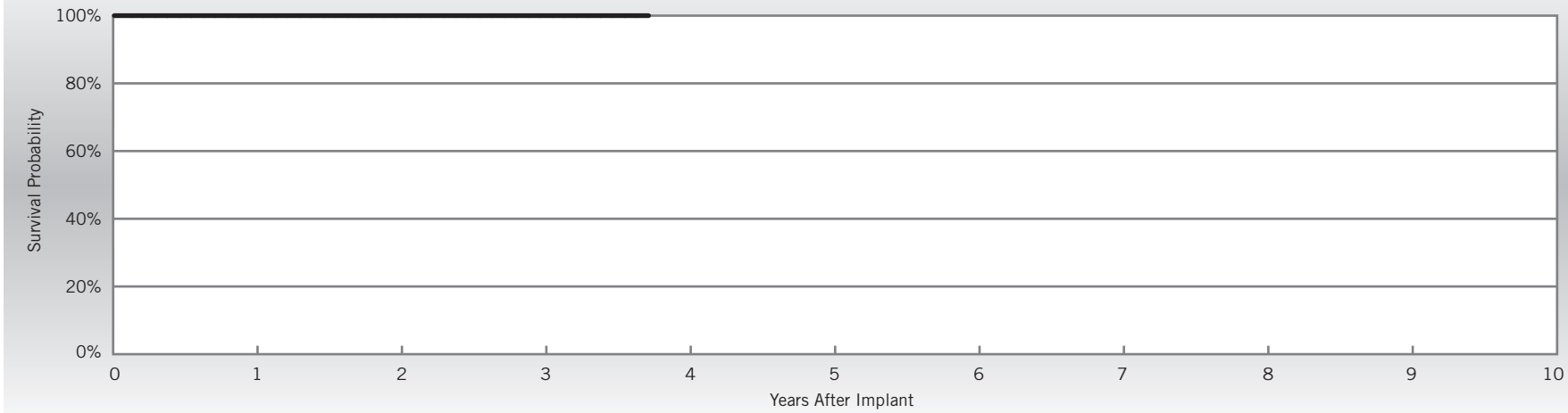
Victory™ XL DR

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	10,674
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%**



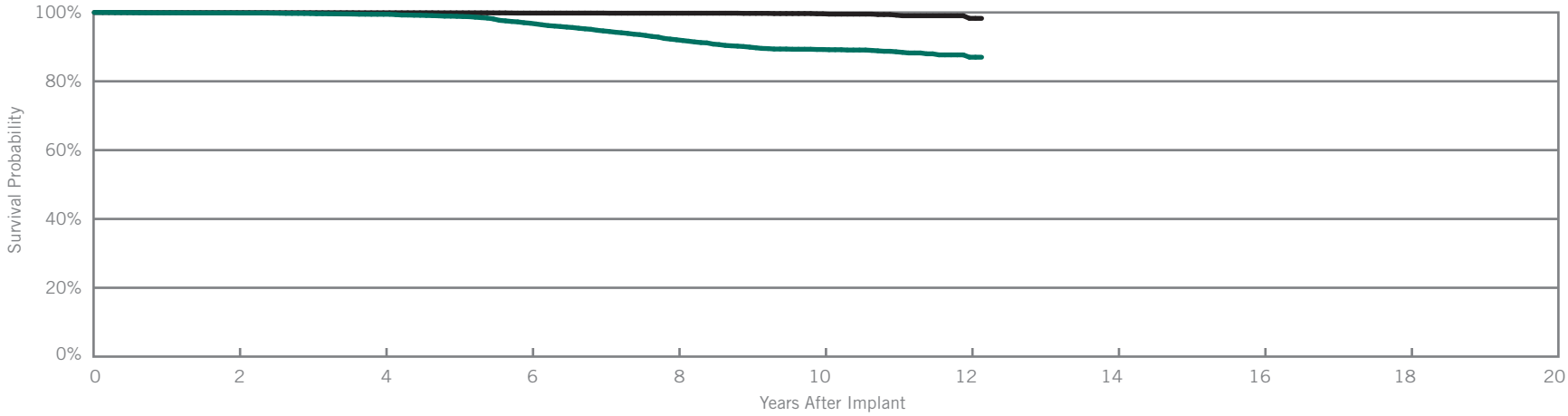
Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	280	210	50						

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	17,320
Estimated Active US Implants	4,603
Estimated Longevity	6.9 Years
Normal Battery Depletion	302
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	9	0.05%
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%	7	0.04%
Total	**1**	**<0.01%**	**18**	**0.10%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 146 months			
Survival Probability	99.83%	99.47%	96.88%	92.06%	89.24%	87.00%	87.00%			
± 1 standard error	0.03%	0.06%	0.18%	0.31%	0.39%	0.54%	0.71%			
Sample Size	14,240	11,020	8,230	6,020	3,190	700	200			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 146 months			
Survival Probability	99.95%	99.91%	99.82%	99.79%	99.61%	98.28%	98.28%			
± 1 standard error	0.02%	0.02%	0.04%	0.05%	0.09%	0.22%	0.58%			

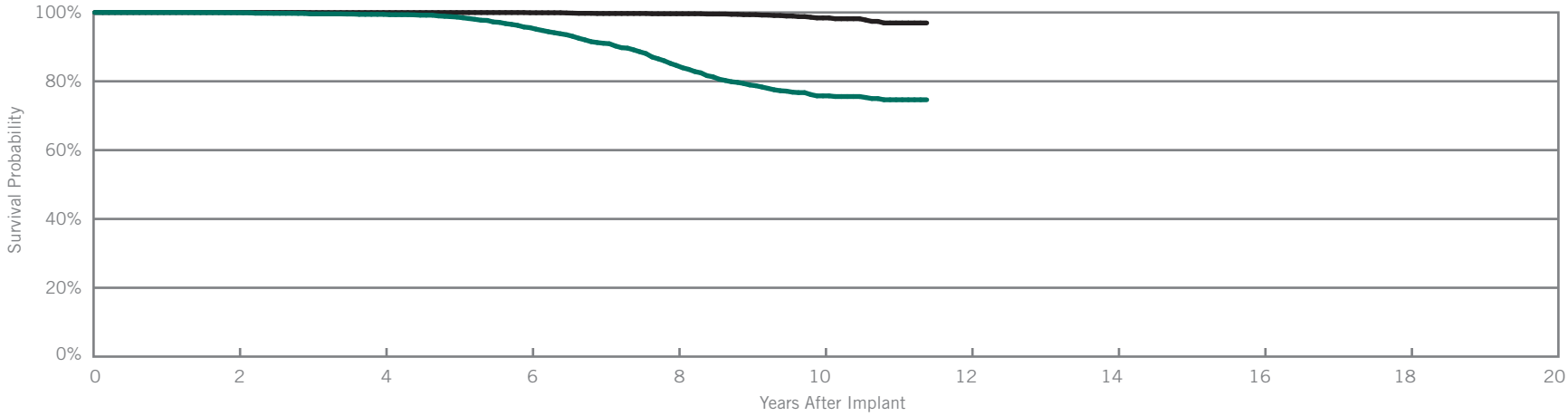
Integrity ADx™ DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,077
Estimated Active US Implants	1,510
Estimated Longevity	6.9 Years
Normal Battery Depletion	318
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	7	0.09%
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%	10	0.12%
Total	**0**	**0.00%**	**21**	**0.26%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.94%	99.45%	95.58%	84.60%	75.76%	74.63%				
± 1 standard error	0.03%	0.10%	0.30%	0.57%	0.79%	0.87%				
Sample Size	6,810	5,410	4,240	3,130	1,360	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	100.00%	99.97%	99.92%	99.63%	98.41%	96.95%				
± 1 standard error	0.00%	0.02%	0.02%	0.10%	0.31%	0.61%				

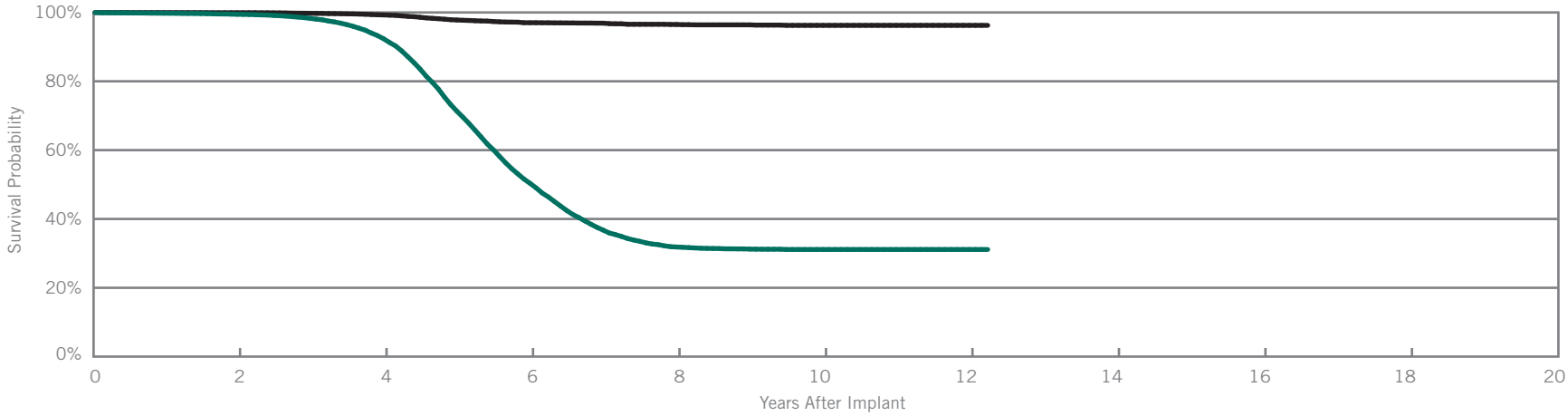
Identity ADx™ DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	54,044
Estimated Active US Implants	3,611
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,204
Number of US Advisories (see pg. 304)	One

Customer Reported Performance Data

	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	at 147 months			
Survival Probability	99.46%	92.37%	50.36%	31.85%	31.13%	31.13%	31.13%			
± 1 standard error	0.03%	0.13%	0.32%	0.34%	0.34%	0.34%	0.34%			
Sample Size	44,150	32,410	13,880	4,700	2,400	640	220			

Excluding Normal Battery Depletion

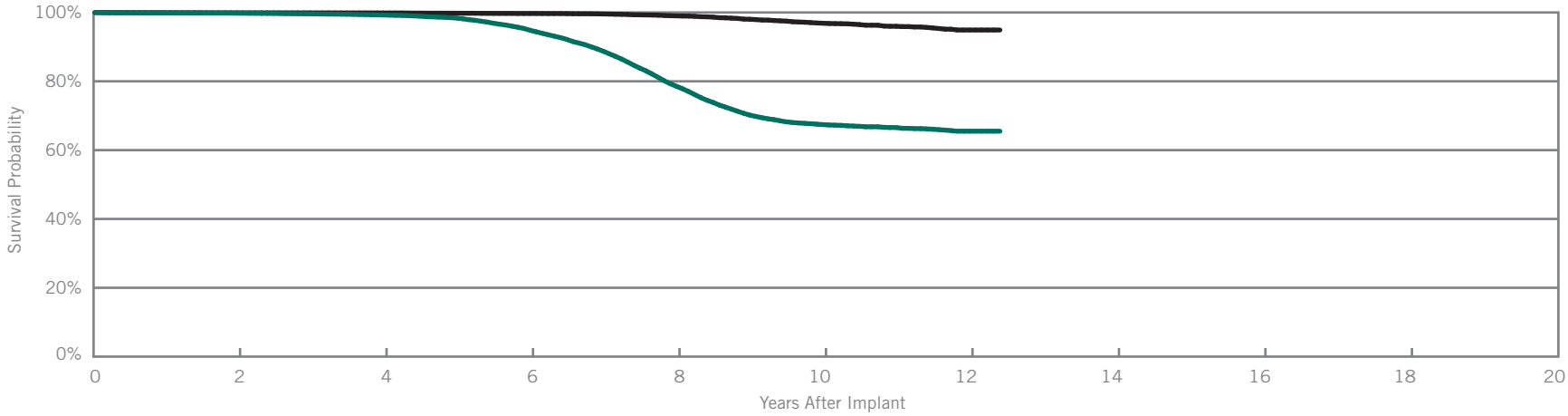
Year	2	4	6	8	10	12	at 147 months			
Survival Probability	99.93%	99.28%	97.02%	96.51%	96.25%	96.25%	96.25%			
± 1 standard error	0.01%	0.04%	0.12%	0.15%	0.18%	0.18%	0.18%			

Identity ADx™ XL DR **Model 5386**
Identity ADx™ XL DC **Model 5286**

US Regulatory Approval	March 2003
Registered US Implants	67,350
Estimated Active US Implants	12,363
Estimated Longevity	6.9 Years
Normal Battery Depletion	3,281
Number of US Advisories (see pg. 304)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	2	<0.01%	131	0.19%
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%	96	0.14%
Total	**2**	**<0.01%**	**252**	**0.37%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 149 months			
Survival Probability	99.78%	99.25%	94.82%	78.54%	67.41%	65.50%	65.50%			
± 1 standard error	0.02%	0.04%	0.11%	0.24%	0.31%	0.40%	0.40%			
Sample Size	56,480	44,730	33,960	22,560	9,250	1,450	230			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 149 months			
Survival Probability	99.90%	99.85%	99.70%	99.01%	96.87%	94.90%	94.90%			
± 1 standard error	0.01%	0.02%	0.03%	0.06%	0.15%	0.36%	0.36%			

Actively Monitored Study Data

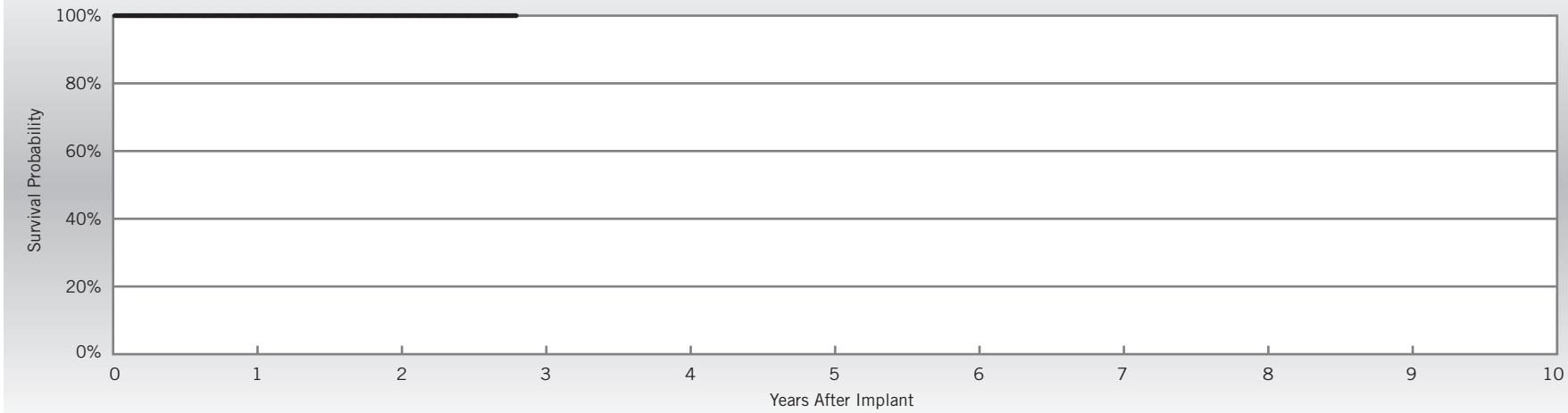
Identity ADx™ XL DR

Model 5386

US Regulatory Approval	March 2003
Number of Devices Enrolled in Study	102
Active Devices Enrolled in Study	0
Cumulative Months of Follow-up	3,251
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%**



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							

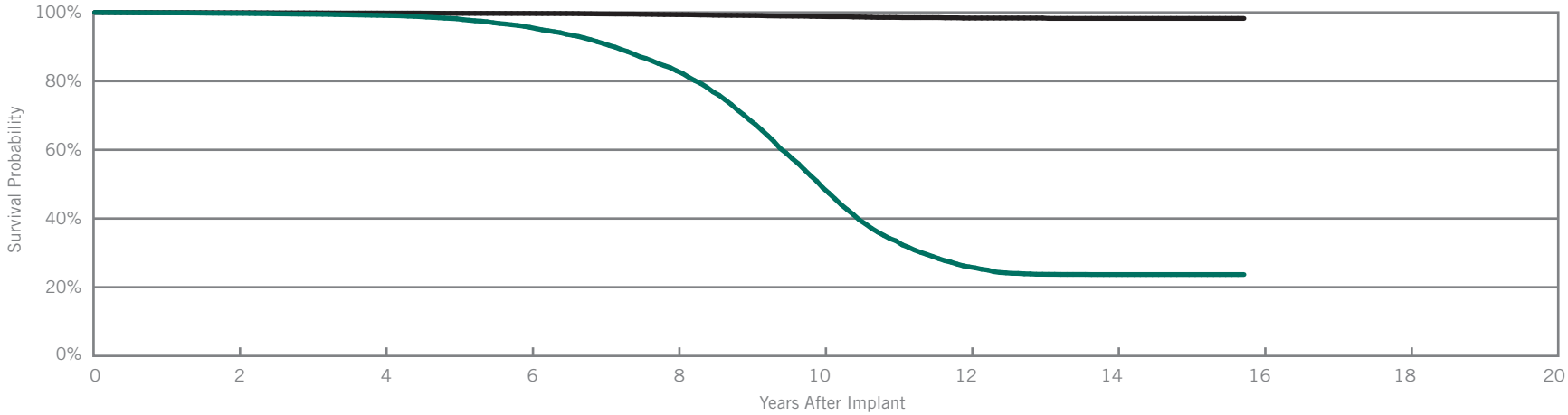
Integrity AFx™ DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,441
Estimated Active US Implants	1,830
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,610
Number of US Advisories	None

Customer Reported Performance Data

	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%	5	0.01%
Total	**6**	**0.01%**	**103**	**0.22%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 189 months		
Survival Probability	99.73%	99.13%	95.66%	83.02%	48.93%	25.92%	23.70%	23.70%		
± 1 standard error	0.02%	0.05%	0.12%	0.25%	0.40%	0.39%	0.38%	0.38%		
Sample Size	40,210	32,900	25,480	16,960	8,240	3,320	1,570	220		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 189 months		
Survival Probability	99.92%	99.81%	99.70%	99.35%	98.80%	98.37%	98.26%	98.26%		
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.09%	0.14%	0.16%	0.16%		

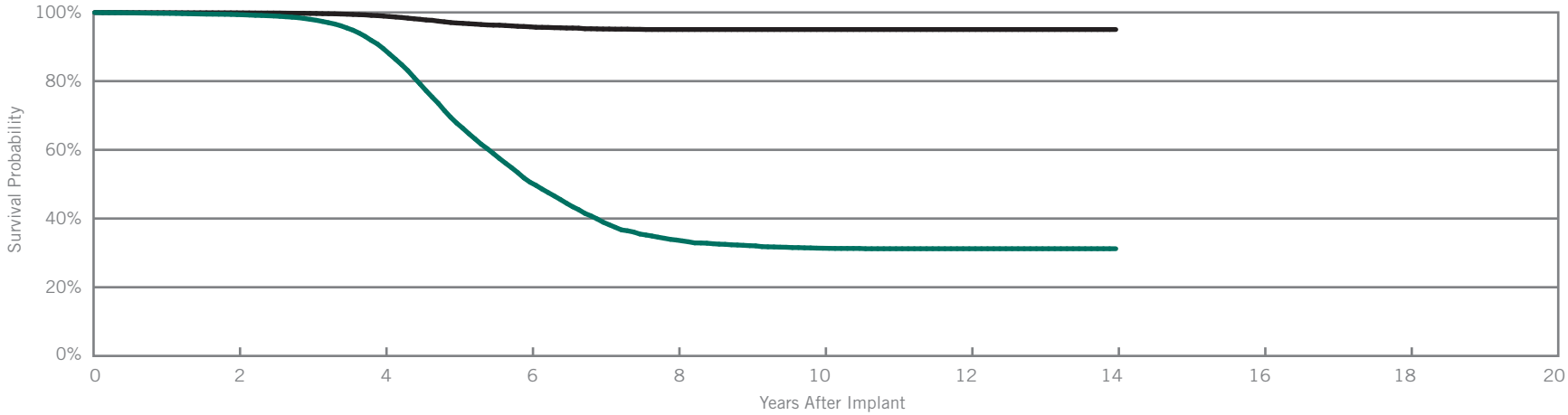
Identity™

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,365
Estimated Active US Implants	2,146
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,069
Number of US Advisories (see pg. 304)	One

Customer Reported Performance Data

	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			
Survival Probability	99.37%	89.43%	50.59%	33.74%	31.35%	31.21%	31.21%			
± 1 standard error	0.03%	0.15%	0.32%	0.37%	0.38%	0.38%	0.38%			
Sample Size	48,100	35,100	12,580	4,030	2,440	1,570	220			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14			
Survival Probability	99.88%	98.94%	95.82%	95.03%	95.03%	95.03%	95.03%			
± 1 standard error	0.01%	0.05%	0.14%	0.18%	0.18%	0.18%	0.18%			

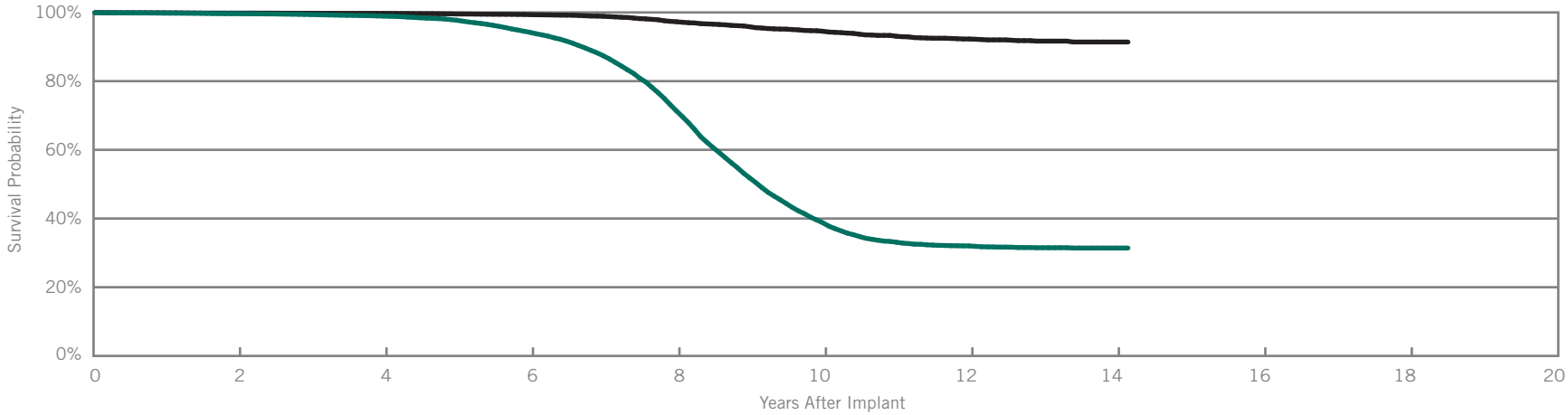
Identity™ XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,509
Estimated Active US Implants	4,180
Estimated Longevity	6.9 Years
Normal Battery Depletion	5,319
Number of US Advisories (see pg. 304)	One

Customer Reported Performance Data

	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%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	5	<0.01%
Other	0	0.00%	83	0.16%
Total	**8**	**0.02%**	**418**	**0.81%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 170 months		
Survival Probability	99.64%	98.93%	94.20%	71.34%	38.75%	32.02%	31.41%	31.41%		
± 1 standard error	0.03%	0.05%	0.13%	0.29%	0.35%	0.35%	0.36%	0.36%		
Sample Size	43,860	35,260	26,960	17,960	8,190	3,010	690	210		

Excluding Normal Battery Depletion

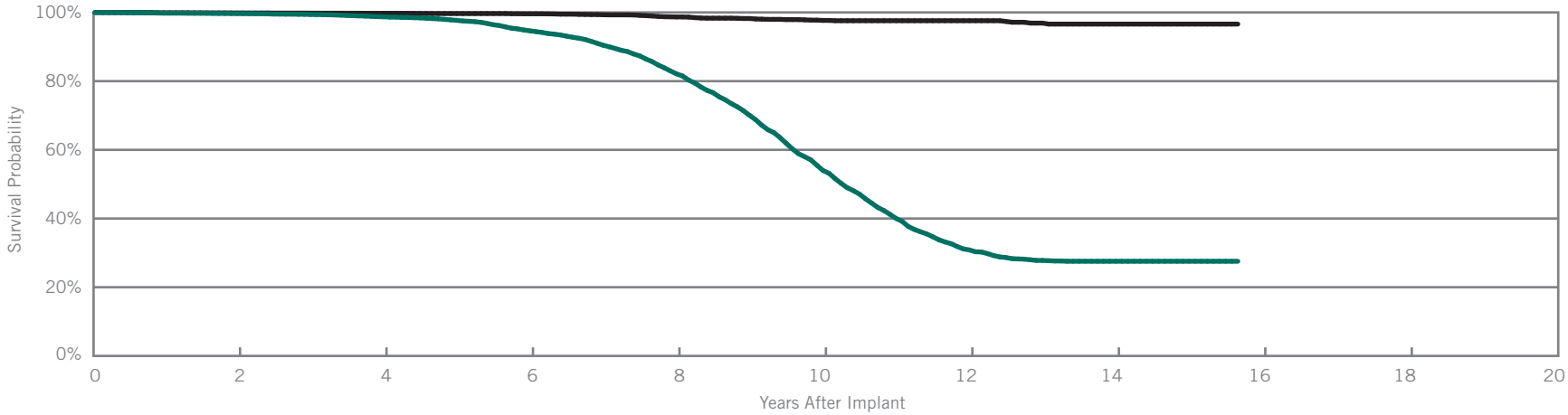
Year	2	4	6	8	10	12	14	at 170 months		
Survival Probability	99.81%	99.71%	99.36%	97.29%	94.52%	92.27%	91.39%	91.39%		
± 1 standard error	0.02%	0.03%	0.04%	0.11%	0.19%	0.29%	0.39%	0.39%		

Customer Reported Performance Data

Entity™ DR **Model 5326**
Entity™ DC **Model 5226**

US Regulatory Approval	June 1999
Registered US Implants	21,828
Estimated Active US Implants	673
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%	2	<0.01%
Total	**3**	**0.01%**	**73**	**0.33%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 188 months		
Survival Probability	99.66%	98.73%	94.64%	82.13%	54.00%	30.86%	27.56%	27.56%		
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.66%	0.71%	0.70%	0.70%		
Sample Size	17,830	14,030	10,260	6,300	2,990	1,280	610	220		

Excluding Normal Battery Depletion

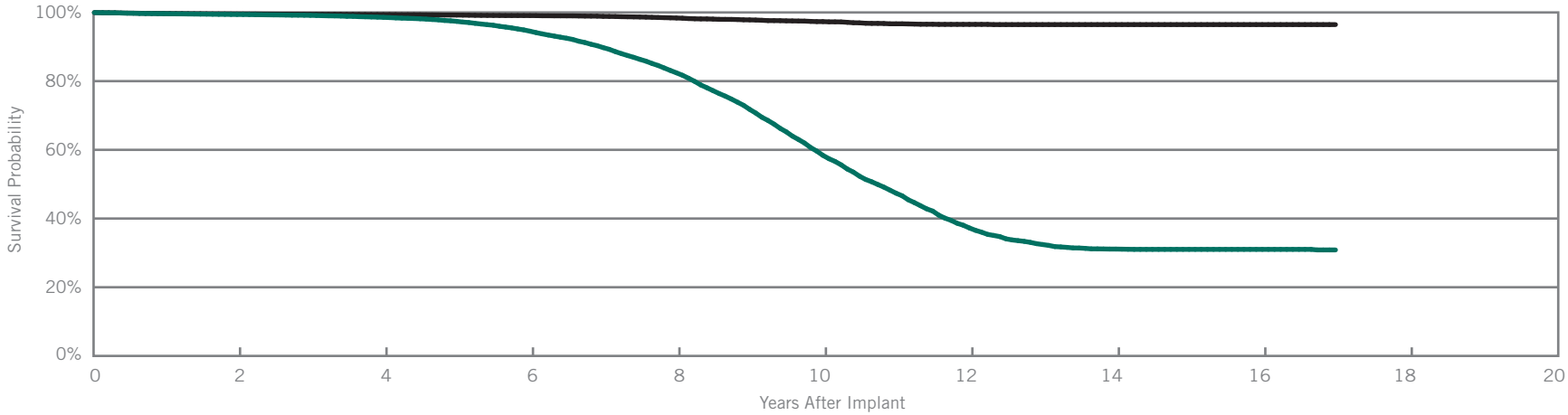
Year	2	4	6	8	10	12	14	at 188 months		
Survival Probability	99.85%	99.74%	99.60%	98.68%	97.68%	97.59%	96.61%	96.61%		
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.20%	0.22%	0.41%	0.41%		

Affinity™ DR **Models 5330 & 5331**
Affinity™ DC **Model 5230**

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,714
Estimated Active US Implants	2,214
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,544
Number of US Advisories (see pg. 307)	One

Customer Reported Performance Data

	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	at 204 months
Survival Probability	99.41%	98.57%	94.54%	82.42%	58.40%	37.26%	31.11%	31.02%	30.86%
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.36%	0.43%	0.43%	0.43%	0.44%
Sample Size	55,190	44,610	33,560	20,940	9,800	4,320	2,350	1,330	220

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	16	at 204 months
Survival Probability	99.56%	99.36%	99.08%	98.38%	97.33%	96.52%	96.46%	96.46%	96.46%
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	0.16%	0.17%	0.17%	0.17%

Summary Information

Dual-Chamber Pacemakers

St. Jude Medical™

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2160	Endurity™ DR	99.81%	99.81%								
PM2240	Assurity™ DR RF	99.95%	99.87%								
PM2210	Accent™ DR RF	99.93%	99.87%	99.79%	99.64%	99.39%	98.90%				
PM2110	Accent™ DR	99.97%	99.93%	99.85%	99.62%	99.39%	99.04%				
5820	Zephyr™ DR	99.85%	99.75%	99.05%	93.58%	81.28%	76.95%	75.90%	75.72%		
5810	Victory™ DR	99.87%	99.75%	98.71%	89.70%	68.90%	53.70%	47.30%	46.40%	46.29%	46.29%
5826	Zephyr™ XL DR	99.91%	99.84%	99.75%	99.48%	98.80%	98.09%	97.61%	96.97%	96.73%	
5816	Victory™ XL DR	99.91%	99.84%	99.67%	99.34%	98.09%	94.30%	89.14%	87.76%	87.08%	86.55%
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.89%	99.83%	99.69%	99.47%	98.88%	96.88%	94.64%	92.06%	89.92%	89.24%
5366	Integrity ADx™ XL DR	100.00%	99.94%	99.58%	99.45%	98.67%	95.58%	91.05%	84.60%	78.93%	75.76%
5380	Identity ADx™ DR	99.77%	99.46%	98.27%	92.37%	71.35%	50.36%	36.75%	31.85%	31.24%	31.13%
5386/5286	Identity ADx™ XL DR/DC	99.88%	99.78%	99.58%	99.25%	98.36%	94.82%	88.73%	78.54%	70.17%	67.41%
5342/5346	Integrity AFx™ DR	99.87%	99.73%	99.49%	99.13%	98.16%	95.66%	90.97%	83.02%	68.70%	48.93%
5370	Identity™	99.75%	99.37%	97.99%	89.43%	67.78%	50.59%	38.93%	33.74%	32.10%	31.35%
5376	Identity™ XL	99.79%	99.64%	99.38%	98.93%	97.73%	94.20%	87.40%	71.34%	51.82%	38.75%
5326/5226	Entity™ DR/DC	99.79%	99.66%	99.40%	98.73%	97.70%	94.64%	90.44%	82.13%	70.02%	54.00%
5330/5331/5230	Affinity™ DR/DC	99.64%	99.41%	99.15%	98.57%	97.40%	94.54%	89.76%	82.42%	71.78%	58.40%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2160	Endurity™ DR	99.81%	99.81%								
PM2240	Assurity™ DR RF	99.95%	99.89%								
PM2210	Accent™ DR RF	99.95%	99.90%	99.84%	99.80%	99.75%	99.72%				
PM2110	Accent™ DR	99.97%	99.95%	99.93%	99.93%	99.93%	99.87%				
5820	Zephyr™ DR	99.97%	99.96%	99.94%	99.63%	99.23%	98.92%	98.67%	98.67%		
5810	Victory™ DR	99.98%	99.93%	99.69%	99.21%	97.82%	97.43%	96.99%	96.49%	96.35%	96.35%
5826	Zephyr™ XL DR	99.96%	99.93%	99.92%	99.89%	99.83%	99.75%	99.57%	99.30%	99.20%	
5816	Victory™ XL DR	99.97%	99.95%	99.91%	99.86%	99.81%	99.74%	99.51%	99.20%	98.84%	98.84%
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%	99.74%	99.61%
5366	Integrity ADx™ XL DR	100.00%	100.00%	99.97%	99.97%	99.97%	99.92%	99.70%	99.63%	99.36%	98.41%
5380	Identity ADx™ DR	99.96%	99.93%	99.75%	99.28%	97.81%	97.02%	96.89%	96.51%	96.40%	96.25%
5386/5286	Identity ADx™ XL DR/DC	99.92%	99.90%	99.88%	99.85%	99.78%	99.70%	99.55%	99.01%	98.03%	96.87%
5342/5346	Integrity AFx™ DR	99.96%	99.92%	99.86%	99.81%	99.73%	99.70%	99.56%	99.35%	99.11%	98.80%
5370	Identity™	99.93%	99.88%	99.71%	98.94%	96.92%	95.82%	95.17%	95.03%	95.03%	95.03%
5376	Identity™ XL	99.90%	99.81%	99.76%	99.71%	99.55%	99.36%	98.88%	97.29%	95.83%	94.52%
5326/5226	Entity™ DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.32%	98.68%	98.23%	97.68%
5330/5331/5230	Affinity™ DR/DC	99.69%	99.56%	99.46%	99.36%	99.23%	99.08%	98.86%	98.38%	97.83%	97.33%

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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
PM2160	Endurity™ DR	8,029	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	113,414	0.20%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM2210	Accent™ DR RF	243,008	2.70%	15	<0.01%	7	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	<0.01%	5	<0.01%	**34**	**0.01%**
PM2110	Accent™ DR	48,904	2.70%	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**<0.01%**
5820	Zephyr™ DR	53,298	8.10%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5810	Victory™ DR	26,308	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	112,121	6.00%	1	<0.01%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**6**	**<0.01%**
5816	Victory™ XL DR	62,657	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	17,320	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	8,077	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	54,044	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	67,350	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	47,441	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™	58,365	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	51,509	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	21,828	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	65,714	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 7-8.

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/o Compromised Therapy															
				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
PM2160	Endurity™ DR	8,029	0.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.06%	0	0.00%	1	0.01%	**6**	**0.07%**
PM2240	Assurity™ DR RF	113,414	0.20%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	19	0.02%	0	0.00%	5	<0.01%	**26**	**0.02%**
PM2210	Accent™ DR RF	243,008	2.70%	35	0.01%	31	0.01%	0	0.00%	2	<0.01%	13	<0.01%	19	<0.01%	34	0.01%	**134**	**0.06%**
PM2110	Accent™ DR	48,904	2.70%	3	<0.01%	0	0.00%	0	0.00%	3	<0.01%	4	<0.01%	1	<0.01%	0	0.00%	**11**	**0.02%**
5820	Zephyr™ DR	53,298	8.10%	34	0.06%	0	0.00%	0	0.00%	9	0.02%	2	<0.01%	1	<0.01%	52	0.10%	**98**	**0.18%**
5810	Victory™ DR	26,308	16.80%	89	0.34%	0	0.00%	0	0.00%	8	0.03%	2	<0.01%	17	0.06%	31	0.12%	**147**	**0.56%**
5826	Zephyr™ XL DR	112,121	6.00%	17	0.02%	0	0.00%	0	0.00%	10	<0.01%	9	<0.01%	3	<0.01%	85	0.08%	**124**	**0.11%**
5816	Victory™ XL DR	62,657	11.50%	25	0.04%	0	0.00%	0	0.00%	7	0.01%	8	0.01%	5	<0.01%	66	0.11%	**111**	**0.18%**
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	17,320	6.60%	9	0.05%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	7	0.04%	**18**	**0.10%**
5366	Integrity ADx™ XL DR	8,077	10.90%	7	0.09%	0	0.00%	0	0.00%	2	0.02%	1	0.01%	1	0.01%	10	0.12%	**21**	**0.26%**
5380	Identity ADx™ DR	54,044	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	67,350	13.10%	131	0.19%	2	<0.01%	0	0.00%	7	0.01%	10	0.01%	6	<0.01%	96	0.14%	**252**	**0.37%**
5342/5346	Integrity AFx™ DR	47,441	14.20%	92	0.19%	1	<0.01%	2	<0.01%	0	0.00%	3	<0.01%	0	0.00%	5	0.01%	**103**	**0.22%**
5370	Identity™	58,365	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	51,509	17.50%	311	0.60%	2	<0.01%	0	0.00%	12	0.02%	5	<0.01%	5	<0.01%	83	0.16%	**418**	**0.81%**
5326/5226	Entity™ DR/DC	21,828	11.10%	65	0.30%	2	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	2	<0.01%	**73**	**0.33%**
5330/5331/5230	Affinity™ DR/DC	65,714	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 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ Compromised Therapy															
				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
PM2160	Endurity™ DR	46,722	0.47%	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	126,142	0.98%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM2210	Accent™ DR RF	246,805	3.71%	15	<0.01%	7	<0.01%	0	0.00%	0	0.00%	0	0.00%	6	<0.01%	5	<0.01%	**33**	**0.01%**
PM2110	Accent™ DR	49,738	3.70%	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**<0.01%**

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromised Therapy															
				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
PM2160	Endurity™ DR	46,722	0.47%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	0.01%	0	0.00%	2	<0.01%	**10**	**0.02%**
PM2240	Assurity™ DR RF	126,142	0.98%	3	<0.01%	0	0.00%	0	0.00%	1	<0.01%	22	0.02%	0	0.00%	4	<0.01%	**30**	**0.02%**
PM2210	Accent™ DR RF	246,805	3.71%	38	0.02%	32	0.01%	0	0.00%	2	<0.01%	13	<0.01%	19	<0.01%	33	0.01%	**137**	**0.06%**
PM2110	Accent™ DR	49,738	3.70%	3	<0.01%	0	0.00%	0	0.00%	3	<0.01%	4	<0.01%	1	<0.01%	0	0.00%	**11**	**0.02%**

Definitions of malfunction categories can be found on pages 7-8.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Active Devices Enrolled	Cumulative Months of Follow-Up	Loss Telemetry		Pericardial Effusion		Premature Battery Depletion		Skin Erosion		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	1,774	396	49,661	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**1**	**0.06%**
PM2110	226	70	7,853	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	283	16	7,759	0	0.00%	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
5826	1,517	20	47,663	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	332	0	10,674	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5386	102	0	3,251	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy															
			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
PM2210	1,774	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	226	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	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	1,517	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	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	102	2.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Models	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy															
			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
PM2210	1,774	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	226	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	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	1,517	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	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	102	2.90%	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 complications can be found on page 15.
Definitions of malfunction categories can be found on pages 7-8.

Pacemakers

Single-Chamber

St. Jude Medical

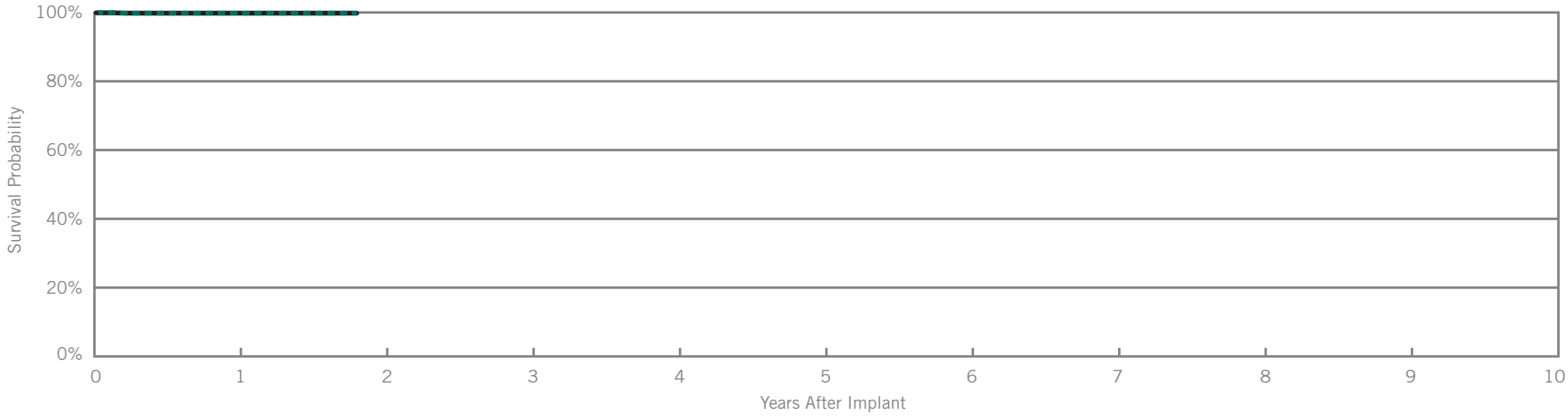
Endurity™ VR

Model PM1160

US Regulatory Approval	March 2014
Registered US Implants	2,127
Estimated Active US Implants	1,921
Estimated Longevity	14.6 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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	0.05%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.05%
Total	**0**	**0.00%**	**2**	**0.09%**



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.80%	99.80%								
± 1 standard error	0.10%	0.10%								
Sample Size	1,620	220								

Excluding Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.80%	99.80%								
± 1 standard error	0.10%	0.10%								

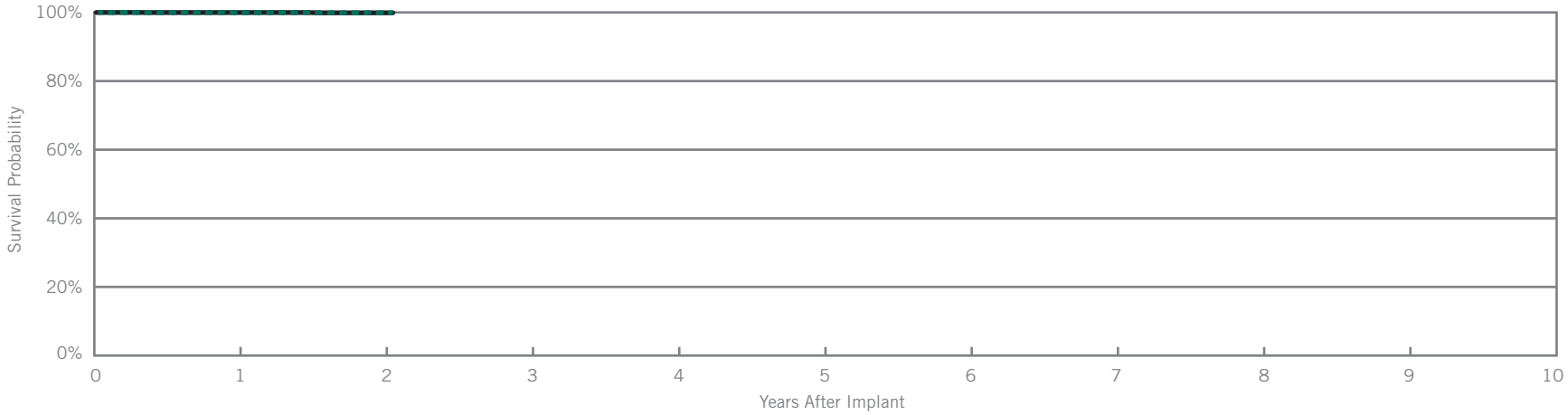
Assurity™ VR

Model PM1240

US Regulatory Approval	March 2014
Registered US Implants	17,062
Estimated Active US Implants	15,229
Estimated Longevity	14.1 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

	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%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.97%	99.89%	99.89%							
± 1 standard error	0.01%	0.06%	0.06%							
Sample Size	11,880	3,480	260							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.97%	99.89%	99.89%							
± 1 standard error	0.01%	0.06%	0.06%							

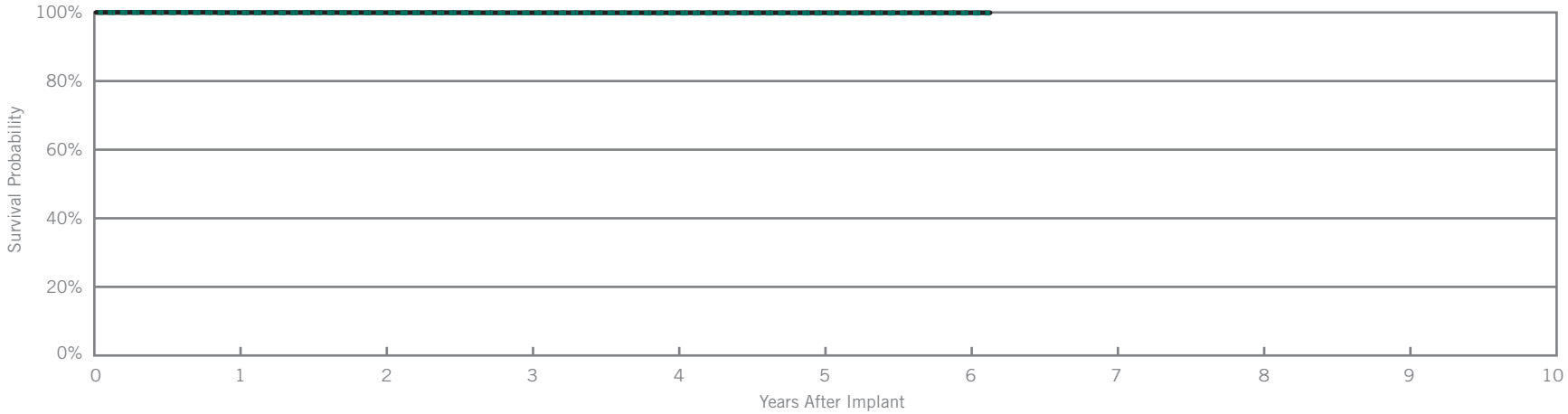
Accent™ SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	13,588
Estimated Active US Implants	8,540
Estimated Longevity	12.9 Years
Normal Battery Depletion	5
Number of US Advisories	None

Customer Reported Performance Data

	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	at 74 months			
Survival Probability	99.92%	99.87%	99.84%	99.80%	99.80%	99.80%	99.80%			
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.05%	0.05%	0.05%			
Sample Size	12,560	10,620	8,170	5,280	2,810	1,010	240			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.96%	99.94%	99.91%	99.91%	99.91%	99.91%	99.91%			
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%			

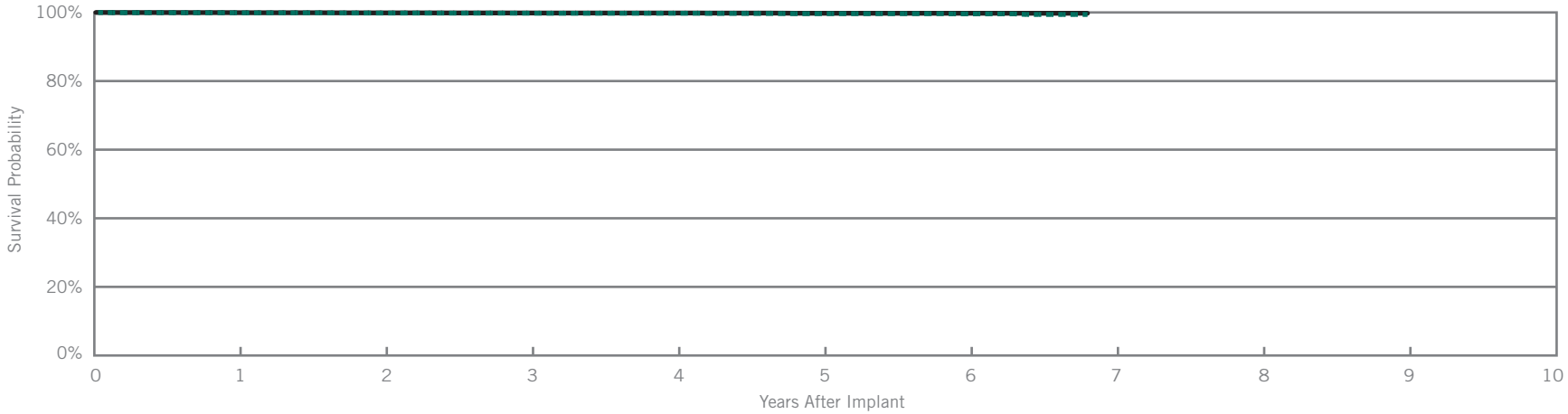
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	39,811
Estimated Active US Implants	24,372
Estimated Longevity	10.9 Years
Normal Battery Depletion	13
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	7	0.02%
Electrical Interconnect	1	<0.01%	3	<0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	3	<0.01%
Possible Early Battery Depletion	2	<0.01%	2	<0.01%
Other	0	0.00%	7	0.02%
Total	**4**	**0.01%**	**23**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.89%	99.81%	99.78%	99.76%	99.65%	99.58%	99.40%			
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.04%	0.07%	0.14%			
Sample Size	36,740	31,040	24,140	16,190	9,560	4,510	250			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.93%	99.87%	99.84%	99.83%	99.76%	99.76%	99.76%			
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.04%	0.04%	0.04%			

Actively Monitored Study Data

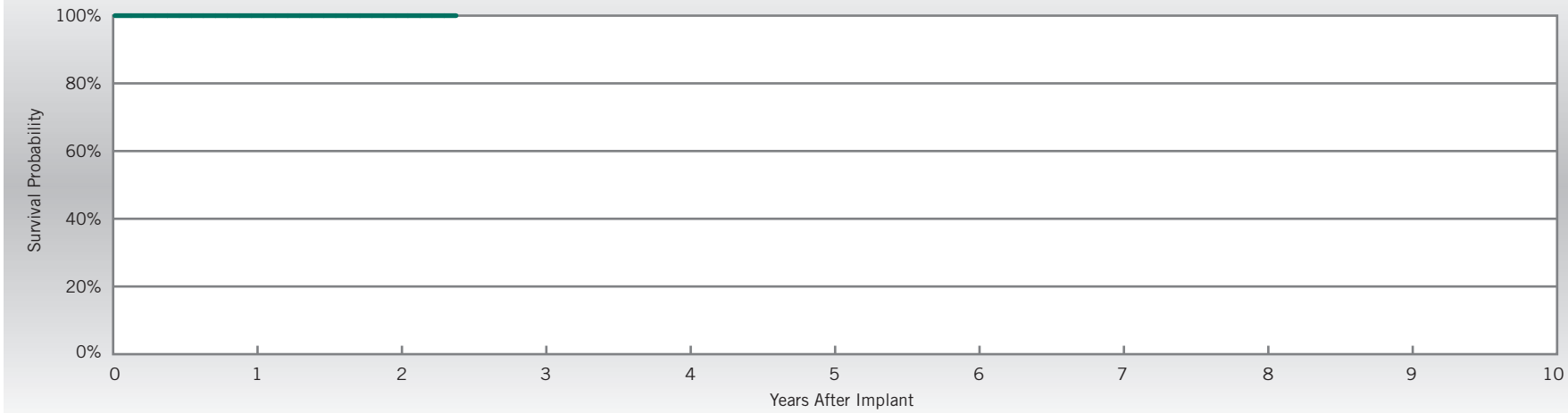
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	236
Active Devices Enrolled in Study	30
Cumulative Months of Follow-up	5,309
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%**



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							

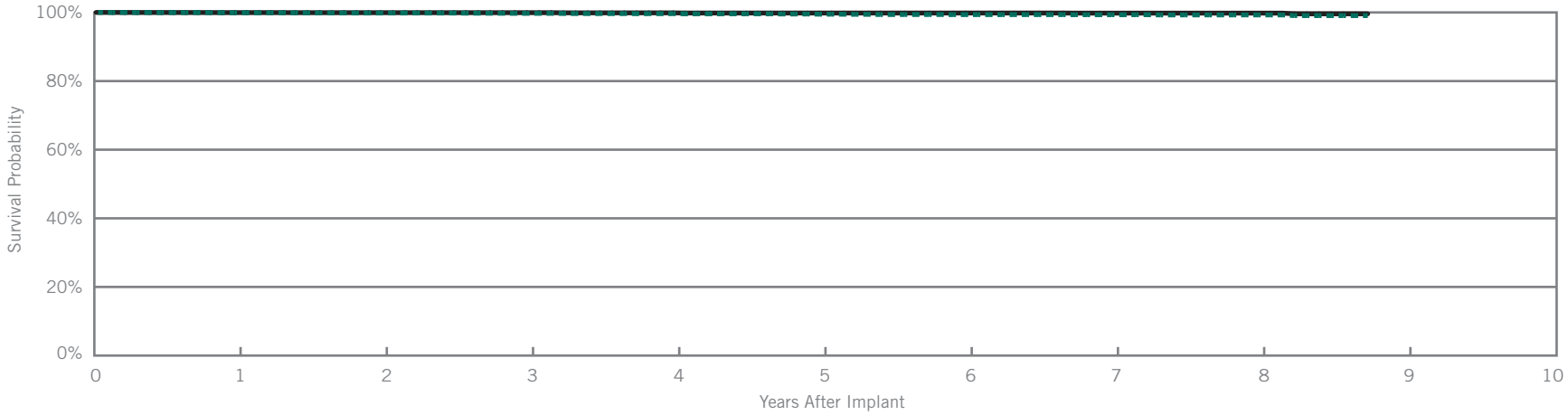
Zephyr™ XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	20632
Estimated Active US Implants	9239
Estimated Longevity	15.8 Years
Normal Battery Depletion	26
Number of US Advisories	None

Customer Reported Performance Data

	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%	7	0.03%
Total	**2**	**<0.01%**	**11**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 105 months
Survival Probability	99.92%	99.83%	99.73%	99.64%	99.49%	99.36%	99.33%	99.27%	99.07%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.06%	0.07%	0.08%	0.09%	0.17%
Sample Size	18,860	15,880	13,640	11,720	10,030	8,380	6,200	3,190	240

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 105 months
Survival Probability	99.95%	99.93%	99.93%	99.88%	99.83%	99.83%	99.80%	99.80%	99.59%
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%	0.04%	0.04%	0.15%

Actively Monitored Study Data

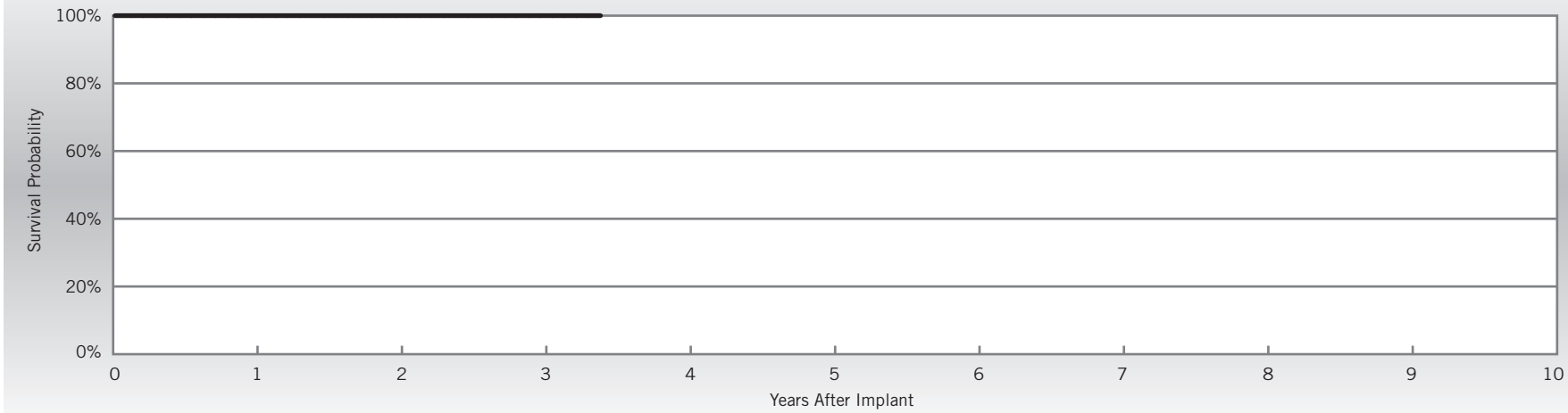
Zephyr™ XL SR

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	6,528
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%**



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						

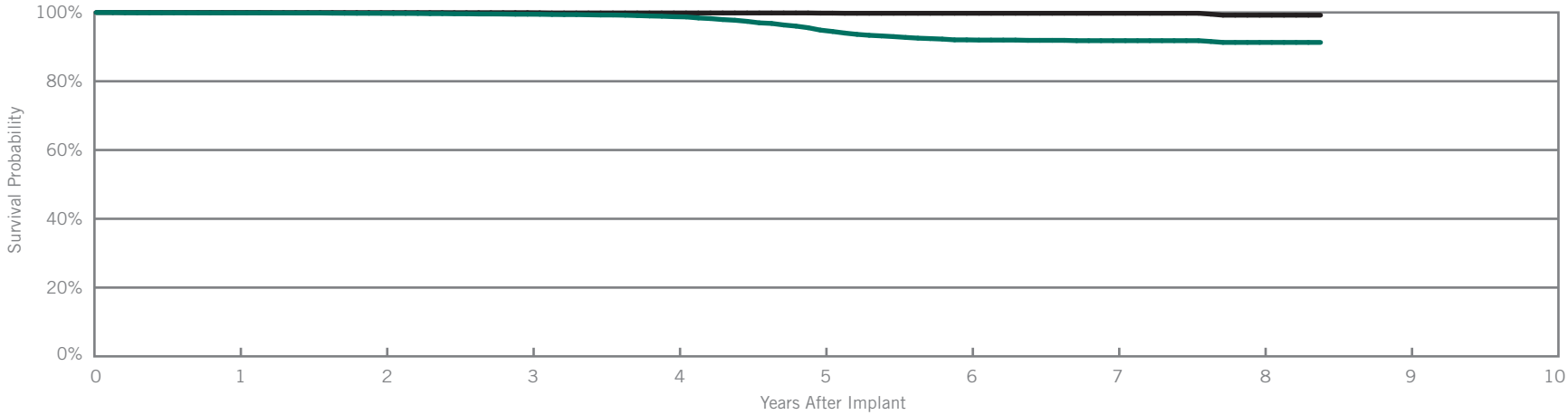
Zephyr™ SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	17,102
Estimated Active US Implants	8,018
Estimated Longevity	8.8 Years
Normal Battery Depletion	182
Number of US Advisories	None

Customer Reported Performance Data

	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	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	6	0.04%
Total	**0**	**0.00%**	**12**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 101 months
Survival Probability	99.87%	99.75%	99.49%	98.77%	94.87%	92.03%	91.80%	91.29%	91.29%
± 1 standard error	0.03%	0.04%	0.07%	0.11%	0.26%	0.37%	0.38%	0.46%	0.46%
Sample Size	15,300	12,370	10,100	7,920	5,850	3,910	2,300	1,010	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 101 months
Survival Probability	99.99%	99.96%	99.94%	99.86%	99.81%	99.77%	99.77%	99.21%	99.21%
± 1 standard error	0.01%	0.02%	0.02%	0.04%	0.04%	0.06%	0.06%	0.28%	0.28%

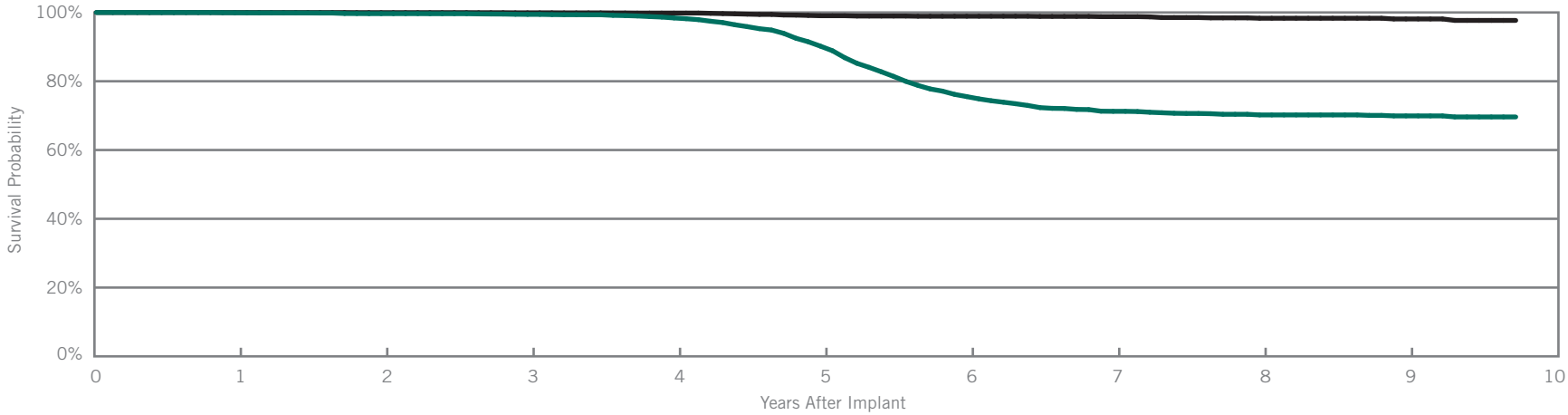
Victory™ SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,685
Estimated Active US Implants	2,491
Estimated Longevity	8.8 Years
Normal Battery Depletion	665
Number of US Advisories	None

Customer Reported Performance Data

	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%	12	0.09%
Total	**1**	**<0.01%**	**37**	**0.27%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.92%	99.66%	99.44%	98.40%	90.21%	75.53%	71.25%	70.20%	69.92%	69.62%
± 1 standard error	0.02%	0.06%	0.07%	0.13%	0.35%	0.55%	0.60%	0.61%	0.63%	0.66%
Sample Size	12,340	10,130	8,550	7,260	6,100	4,790	3,480	2,330	1,280	200

Excluding Normal Battery Depletion

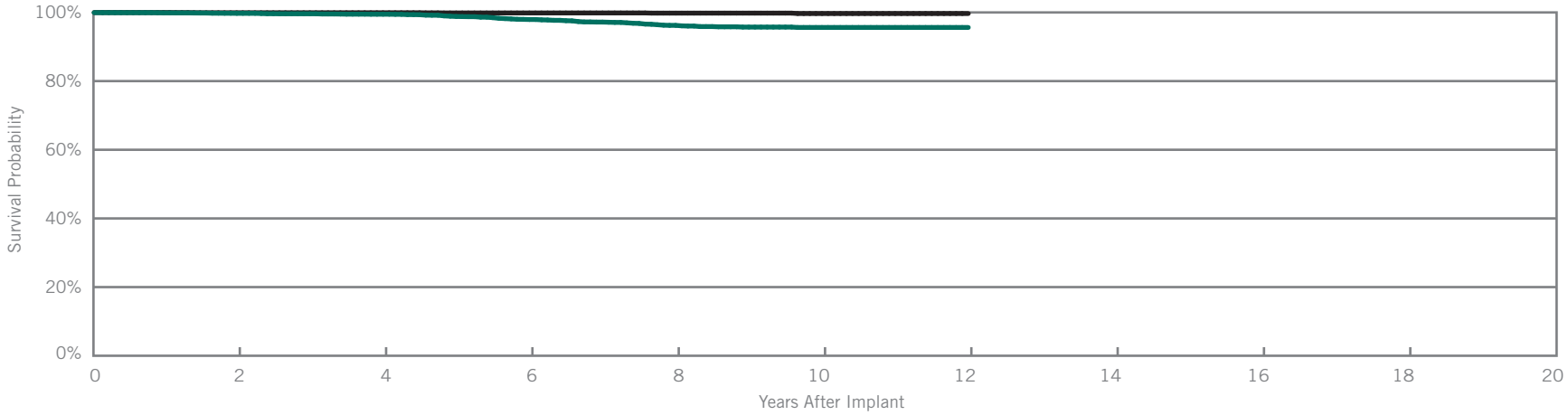
Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.98%	99.96%	99.91%	99.83%	99.05%	98.91%	98.79%	98.32%	98.11%	97.69%
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.12%	0.13%	0.15%	0.19%	0.25%	0.39%

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	14,494
Estimated Active US Implants	3,787
Estimated Longevity	10.2 Years
Normal Battery Depletion	91
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	1	<0.01%	3	0.02%
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%**	**8**	**0.06%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12				
Survival Probability	99.73%	99.47%	97.94%	96.23%	95.62%	95.62%				
± 1 standard error	0.05%	0.07%	0.17%	0.26%	0.30%	0.30%				
Sample Size	10,870	7,770	5,500	3,850	1,870	230				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12				
Survival Probability	99.91%	99.91%	99.85%	99.80%	99.68%	99.68%				
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.10%	0.10%				

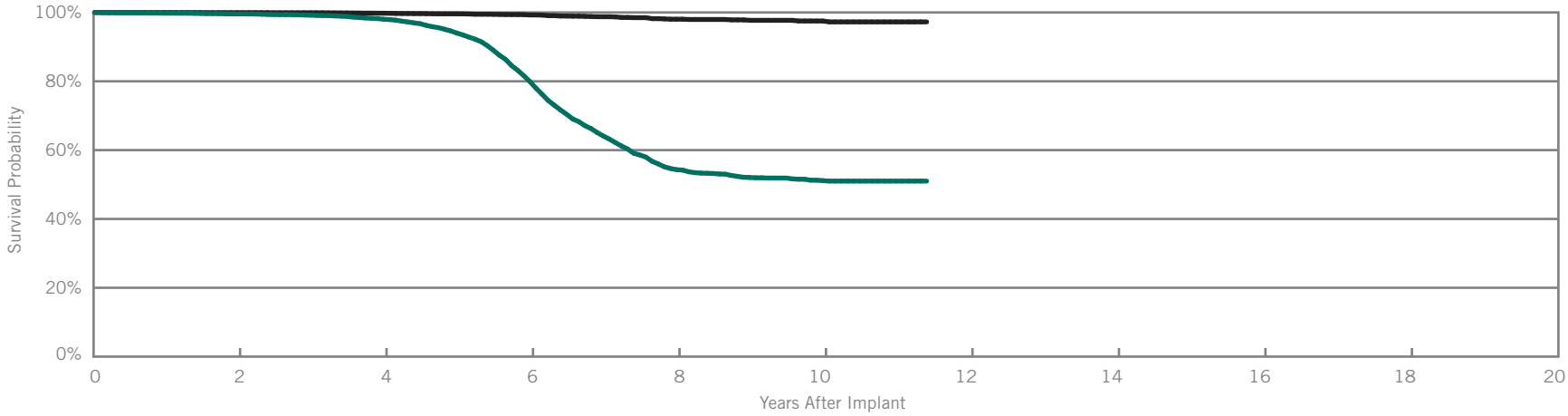
Identity ADx™ SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,866
Estimated Active US Implants	2,337
Estimated Longevity	5.7 Years
Normal Battery Depletion	1239
Number of US Advisories	None

Customer Reported Performance Data

	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	at 137 months				
Survival Probability	99.57%	98.03%	79.89%	54.32%	51.13%	51.00%				
± 1 standard error	0.05%	0.12%	0.43%	0.64%	0.68%	0.69%				
Sample Size	15,440	10,910	6,700	2,920	1,130	210				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.94%	99.78%	99.27%	98.04%	97.52%	97.26%				
± 1 standard error	0.02%	0.04%	0.08%	0.21%	0.29%	0.34%				

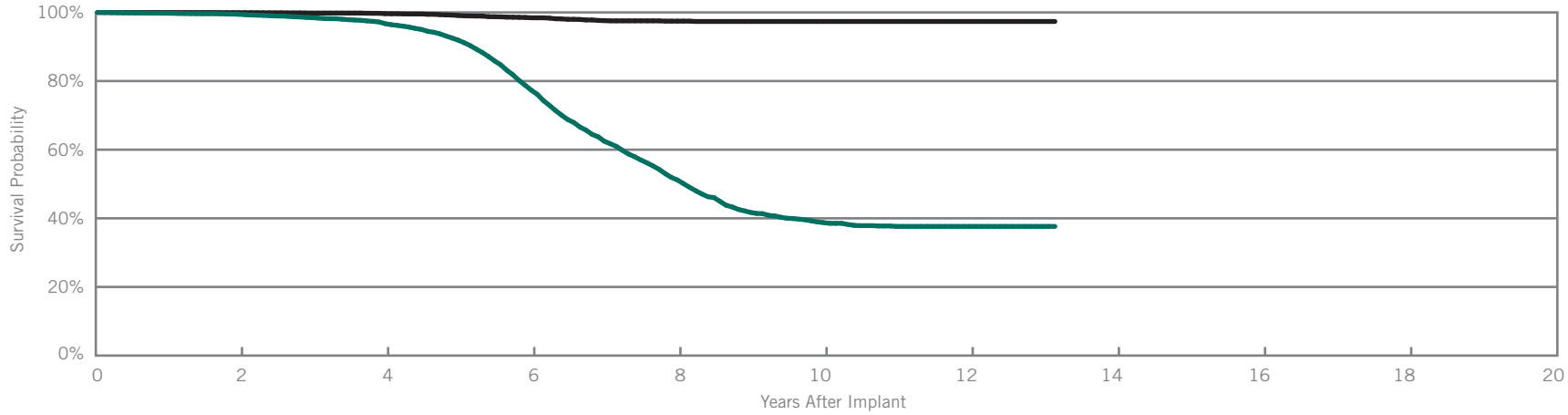
Identity™ SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,884
Estimated Active US Implants	1,074
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,471
Number of US Advisories (see pg. 304)	One

Customer Reported Performance Data

	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%	4	0.02%
Total	**1**	**<0.01%**	**77**	**0.35%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 158 months			
Survival Probability	99.45%	96.72%	77.35%	51.17%	38.75%	37.64%	37.64%			
± 1 standard error	0.05%	0.14%	0.45%	0.65%	0.72%	0.73%	0.73%			
Sample Size	16,210	11,380	6,570	2,740	1,170	530	200			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 158 months			
Survival Probability	99.92%	99.63%	98.43%	97.46%	97.36%	97.36%	97.36%			
± 1 standard error	0.02%	0.04%	0.13%	0.21%	0.22%	0.22%	0.22%			

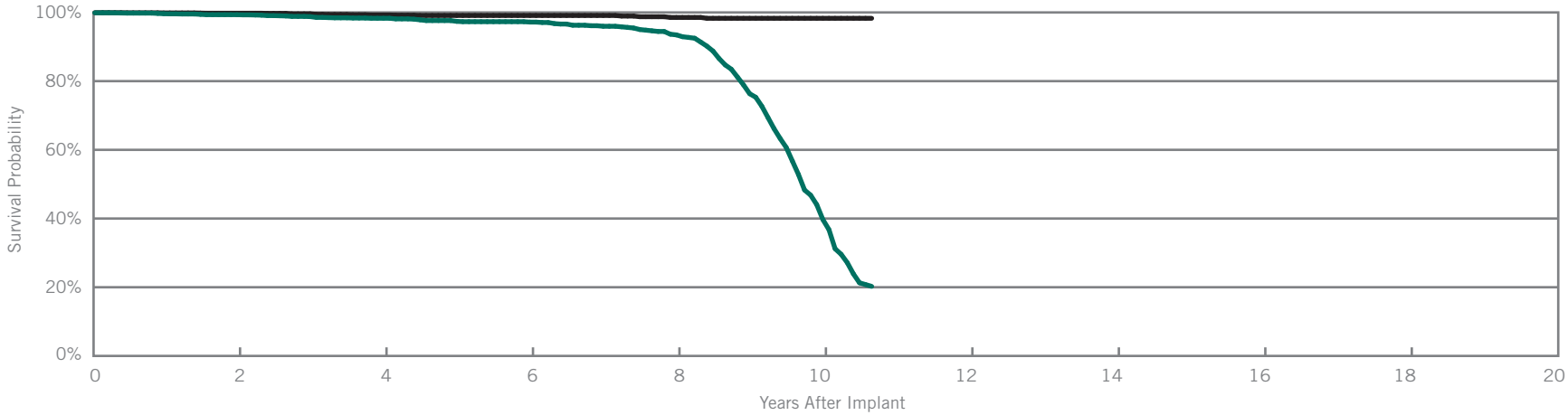
Customer Reported Performance Data

Microny™

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	7,650
Estimated Active US Implants	1,386
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	at 128 months				
Survival Probability	99.34%	98.30%	97.19%	93.46%	39.71%	20.25%				
± 1 standard error	0.11%	0.20%	0.28%	0.61%	1.75%	1.38%				
Sample Size	4,900	3,130	1,880	1,070	470	200				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 128 months				
Survival Probability	99.78%	99.26%	99.11%	98.54%	98.29%	98.29%				
± 1 standard error	0.06%	0.14%	0.16%	0.28%	0.33%	0.33%				

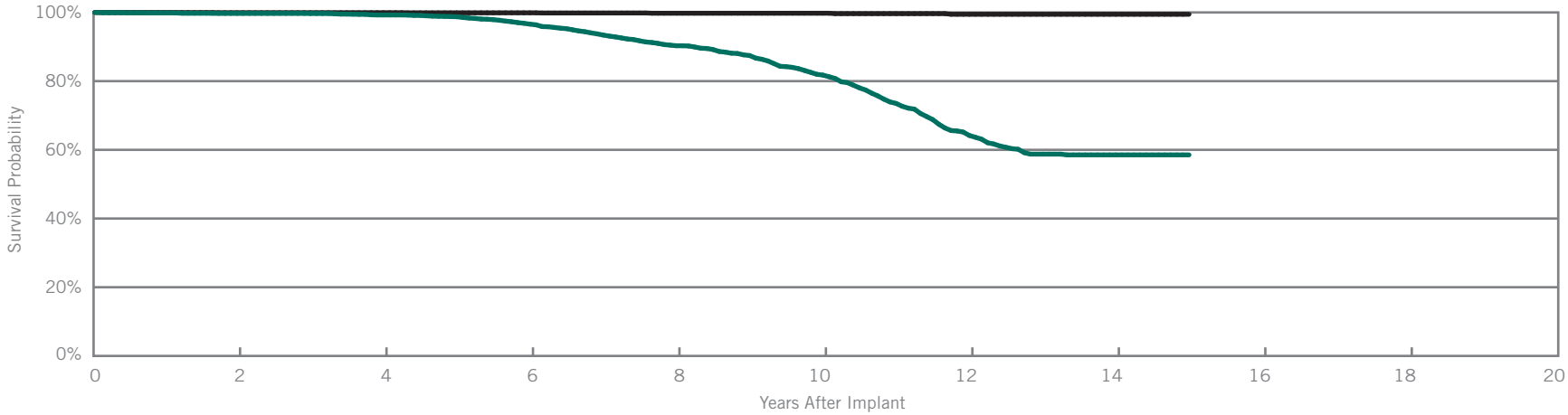
Integrity™ SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,490
Estimated Active US Implants	668
Estimated Longevity	8.6 Years
Normal Battery Depletion	386
Number of US Advisories	None

Customer Reported Performance Data

	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	at 180 months		
Survival Probability	99.71%	99.26%	96.59%	90.30%	81.76%	64.18%	58.53%	58.53%		
± 1 standard error	0.06%	0.10%	0.25%	0.48%	0.71%	1.03%	1.14%	1.14%		
Sample Size	8,050	5,860	4,200	2,900	1,940	1,160	500	200		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 180 months		
Survival Probability	99.93%	99.93%	99.89%	99.77%	99.77%	99.46%	99.46%	99.46%		
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.07%	0.17%	0.17%	0.17%		

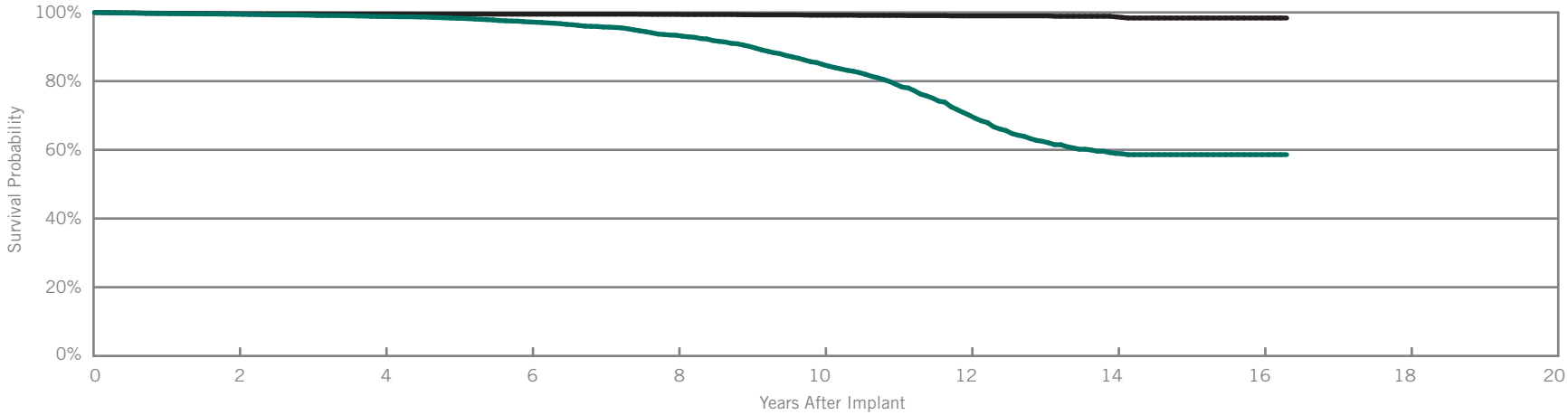
Affinity™ SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,798
Estimated Active US Implants	1,354
Estimated Longevity	8.6 Years
Normal Battery Depletion	792
Number of US Advisories (see pg. 307)	One

Customer Reported Performance Data

	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	at 196 months
Survival Probability	99.47%	98.83%	97.22%	93.35%	84.82%	70.07%	58.96%	58.60%	58.60%
± 1 standard error	0.05%	0.08%	0.14%	0.25%	0.43%	0.66%	0.80%	0.81%	0.81%
Sample Size	21,440	15,220	10,650	7,150	4,550	2,840	1,480	530	230

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	16	at 196 months
Survival Probability	99.64%	99.54%	99.49%	99.44%	99.20%	99.00%	98.72%	98.38%	98.38%
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.09%	0.12%	0.15%	0.25%	0.25%

Summary Information

Single-Chamber Pacemakers

St. Jude Medical™

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1160	Endurity™ SR	99.80%									
PM1240	Assurity™ SR	99.97%	99.89%								
PM1110	Accent™ SR	99.92%	99.87%	99.84%	99.80%	99.80%	99.80%				
PM1210	Accent™ SR RF	99.89%	99.81%	99.78%	99.76%	99.65%	99.58%				
5626	Zephyr™ XL SR	99.92%	99.83%	99.73%	99.64%	99.49%	99.36%	99.33%	99.27%		
5620	Zephyr™ SR	99.87%	99.75%	99.49%	98.77%	94.87%	92.03%	91.80%	91.29%		
5610	Victory™ SR	99.92%	99.66%	99.44%	98.40%	90.21%	75.53%	71.25%	70.20%	69.92%	
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	99.87%	99.73%	99.60%	99.47%	98.82%	97.94%	97.19%	96.23%	95.73%	95.62%
5180	Identity ADx™ SR	99.79%	99.57%	99.21%	98.03%	94.01%	79.89%	64.12%	54.32%	52.04%	51.13%
5172	Identity™ SR	99.76%	99.45%	98.46%	96.72%	91.92%	77.35%	62.45%	51.17%	41.72%	38.75%
2425T/2525T/2535T	Microny™	99.62%	99.34%	98.78%	98.30%	97.40%	97.19%	95.97%	93.46%	76.34%	39.71%
5142	Integrity™ SR	99.86%	99.71%	99.68%	99.26%	98.75%	96.59%	93.41%	90.30%	87.45%	81.76%
5130/5131	Affinity™ SR	99.69%	99.47%	99.21%	98.83%	98.29%	97.22%	95.74%	93.35%	90.09%	84.82%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1160	Endurity™ SR	99.80%									
PM1240	Assurity™ SR	99.97%	99.89%								
PM1110	Accent™ SR	99.96%	99.94%	99.91%	99.91%	99.91%	99.91%				
PM1210	Accent™ SR RF	99.93%	99.87%	99.84%	99.83%	99.76%	99.76%				
5626	Zephyr™ XL SR	99.95%	99.93%	99.93%	99.88%	99.83%	99.83%	99.80%	99.80%		
5620	Zephyr™ SR	99.99%	99.96%	99.94%	99.86%	99.81%	99.77%	99.77%	99.21%		
5610	Victory™ SR	99.98%	99.96%	99.91%	99.83%	99.05%	98.91%	98.79%	98.32%	98.11%	
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%	99.68%
5180	Identity ADx™ SR	99.96%	99.94%	99.91%	99.78%	99.60%	99.27%	98.76%	98.04%	97.71%	97.52%
5172	Identity™ SR	99.97%	99.92%	99.81%	99.63%	99.10%	98.43%	97.60%	97.46%	97.36%	97.36%
2425T/2525T/2535T	Microny™	99.86%	99.78%	99.60%	99.26%	99.11%	99.11%	99.11%	98.54%	98.29%	98.29%
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%

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/ Compromised Therapy															
				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
PM1160	Endurity™ SR	2,127	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1240	Assurity™ SR	17,062	0.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1110	Accent™ SR	13,588	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	39,811	3.60%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	**4**	**0.01%**
5626	Zephyr™ XL SR	20,632	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	17,102	5.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5610	Victory™ SR	13,685	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	14,494	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	20,866	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™	7,650	6.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5142	Integrity™ SR	10,490	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	28,798	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%**

Models	Family	Registered US Implants	Percent Returned for Analysis	U.S. Malfunctions w/o Compromised Therapy															
				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
PM1160	Endurity™ SR	2,127	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	1	0.05%	**2**	**0.09%**
PM1240	Assurity™ SR	17,062	0.20%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**3**	**0.02%**
PM1110	Accent™ SR	13,588	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	39,811	3.60%	7	0.02%	3	<0.01%	1	<0.01%	0	0.00%	3	<0.01%	2	<0.01%	7	0.02%	**23**	**0.06%**
5626	Zephyr™ XL SR	20,632	5.40%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.03%	**11**	**0.05%**
5620	Zephyr™ SR	17,102	5.80%	4	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	6	0.04%	**12**	**0.07%**
5610	Victory™ SR	13,685	12.70%	23	0.17%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	12	0.09%	**37**	**0.27%**
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	14,494	5.80%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	3	0.02%	**8**	**0.06%**
5180	Identity ADx™ SR	20,866	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%	4	0.02%	**77**	**0.35%**
2425T/2525T/2535T	Microny™	7,650	6.60%	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	10,490	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	28,798	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 7-8.

Worldwide Malfunction Summary

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ Compromised Therapy															
				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
PM1160	Endurity™ SR	20,435	0.35%	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 RF	19,909	1.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1110	Accent™ SR	52,809	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%**
PM1210	Accent™ SR RF	47,680	4.00%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	**6**	**0.01%**

Models	Family	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/o Compromised Therapy															
				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
PM1160	Endurity™ SR	20,435	0.35%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**3**	**0.01%**
PM1240	Assurity™ SR RF	19,909	1.20%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	**4**	**0.02%**
PM1110	Accent™ SR	52,809	1.50%	3	<0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	2	<0.01%	**8**	**0.02%**
PM1210	Accent™ SR RF	47,680	4.00%	9	0.02%	3	<0.01%	1	<0.01%	0	0.00%	3	<0.01%	2	<0.01%	8	0.02%	**26**	**0.05%**

Definitions of malfunction categories can be found on pages 7-8.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Active Devices Enrolled	Cumulative Months of Follow-Up	Loss Telemetry		Pericardial Effusion		Premature Battery Depletion		Skin Erosion		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1210	236	30	5,309	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	230	2	6,528	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/ Compromised Therapy															
			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
PM1210	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	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%**

Models	Number of Devices Enrolled	Percent Returned for Analysis	Malfunctions w/o Compromised Therapy															
			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
PM1210	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	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 complications can be found on page 15.
Definitions of malfunction categories can be found on pages 7-8.

Pacing Leads

St. Jude Medical

Customer Reported Performance Data

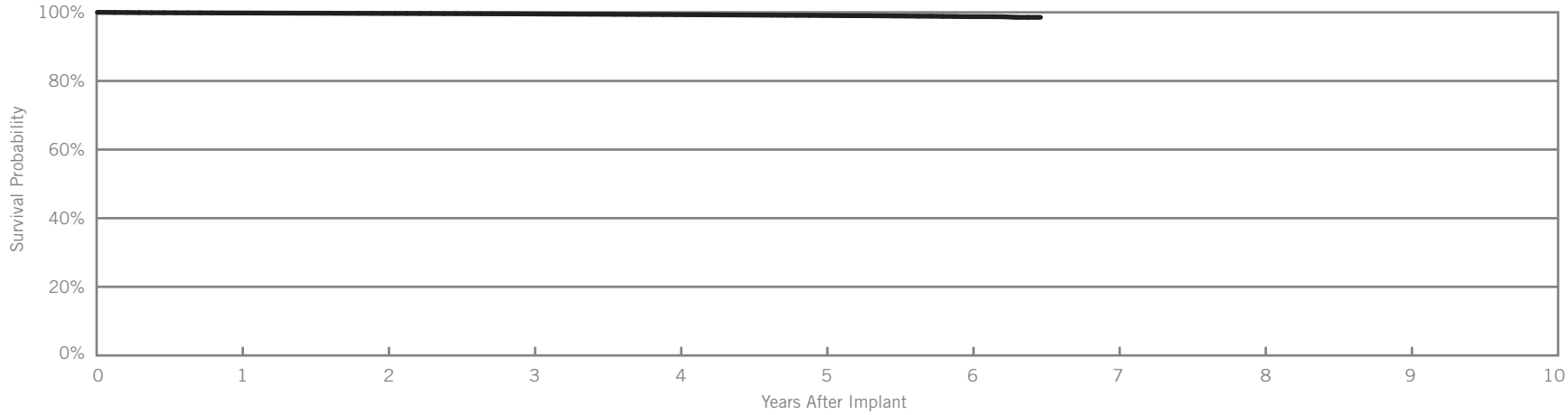
Tendril™ STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	475,458
Estimated Active US Implants	396,105
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	68	0.01%	39	<0.01%
Conductor Fracture	5	<0.01%	115	0.02%
Lead Dislodgement	429	0.09%	542	0.11%
Failure to Capture	113	0.02%	394	0.08%
Oversensing	35	<0.01%	1066	0.22%
Failure to Sense	18	<0.01%	73	0.02%
Insulation Breach	10	<0.01%	124	0.03%
Abnormal Pacing Impedance	26	<0.01%	89	0.02%
Extracardiac Stimulation	3	<0.01%	18	<0.01%
Other	89	0.02%	96	0.02%
Total	**796**	**0.17%**	**2556**	**0.54%**
Total Returned for Analysis	**377**		**960**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	30	<0.01%
Insulation Breach	372	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	25	<0.01%
Extrinsic Factors	713	0.15%
Total	**1140**	**0.24%**



Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.81%	99.68%	99.53%	99.32%	99.09%	98.75%	98.54%			
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.03%	0.05%	0.13%			
Sample Size	412,440	301,490	210,770	132,810	69,670	24,030	330			

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

Tendril™ STS

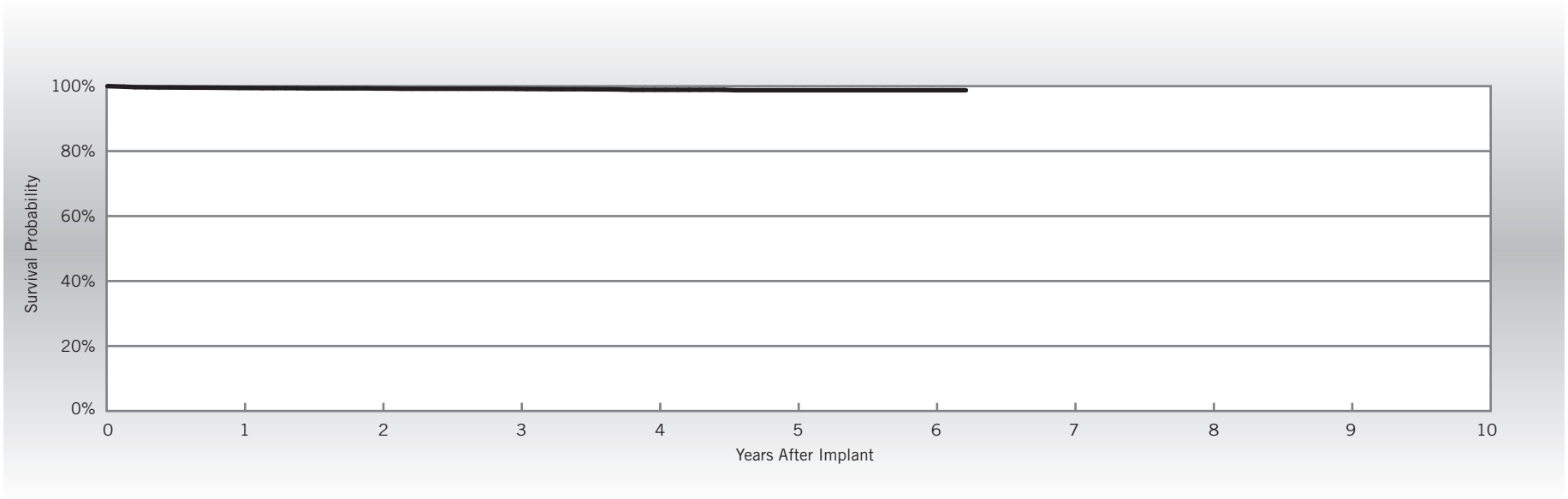
Model 2088TC

Actively Monitored Study Data

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	3,808
Active Devices Enrolled in Study	2,139
Cumulative Months of Follow-up	162,474
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	1	0.03%
Extracardiac Stimulation	1	0.03%
Failure to Capture	3	0.08%
Failure to Sense	1	0.03%
Insulation Breach	6	0.16%
Lead Dislodgement	14	0.37%
Oversensing	8	0.21%
Pericardial Effusion	1	0.03%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.03%
Insulation Breach	12	0.32%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	11	0.29%
Total	**24**	**0.63%**



Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.43%	99.27%	99.16%	98.87%	98.74%	98.74%	98.74%			
± 1 standard error	0.12%	0.14%	0.15%	0.20%	0.22%	0.22%	0.22%			
Sample Size	3,610	3,200	2,680	2,090	1,440	640	80			

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

Customer Reported Performance Data

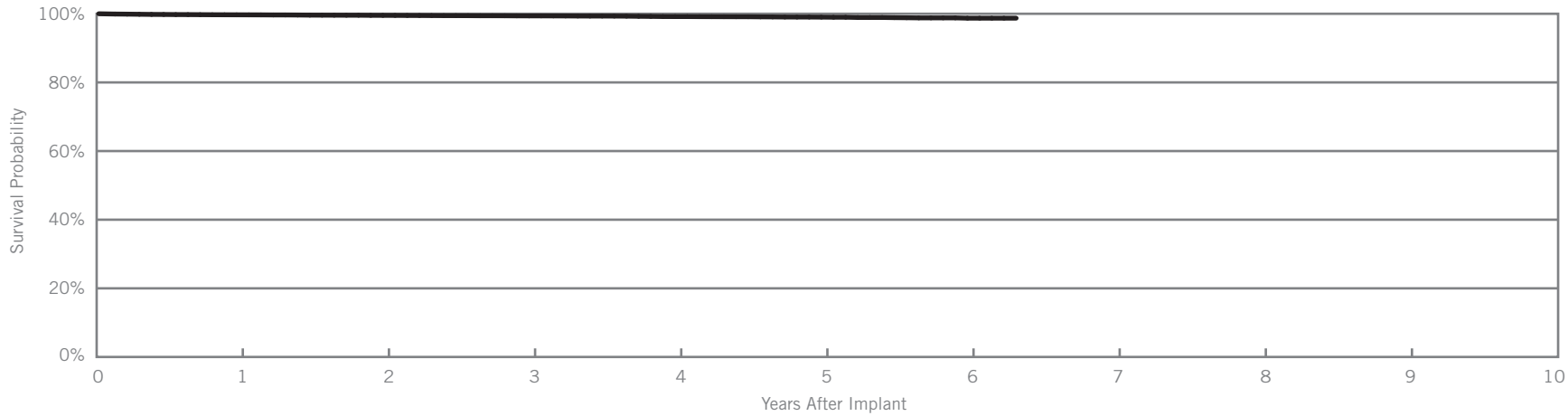
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	43,154
Estimated Active US Implants	29,517
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%	0	0.00%
Conductor Fracture	0	0.00%	4	<0.01%
Lead Dislodgement	54	0.13%	117	0.27%
Failure to Capture	6	0.01%	35	0.08%
Oversensing	5	0.01%	89	0.21%
Failure to Sense	3	<0.01%	16	0.04%
Insulation Breach	1	<0.01%	22	0.05%
Abnormal Pacing Impedance	0	0.00%	6	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	11	0.03%	13	0.03%
Total	**83**	**0.19%**	**302**	**0.70%**
Total Returned for Analysis	**47**		**132**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	5	0.01%
Insulation Breach	23	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	5	0.01%
Extrinsic Factors	117	0.27%
Total	**150**	**0.35%**



Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.69%	99.53%	99.38%	99.18%	99.02%	98.72%	98.72%			
± 1 standard error	0.03%	0.04%	0.04%	0.06%	0.07%	0.11%	0.13%			
Sample Size	37,870	28,560	20,920	14,280	8,540	3,460	360			

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

Actively Monitored Study Data

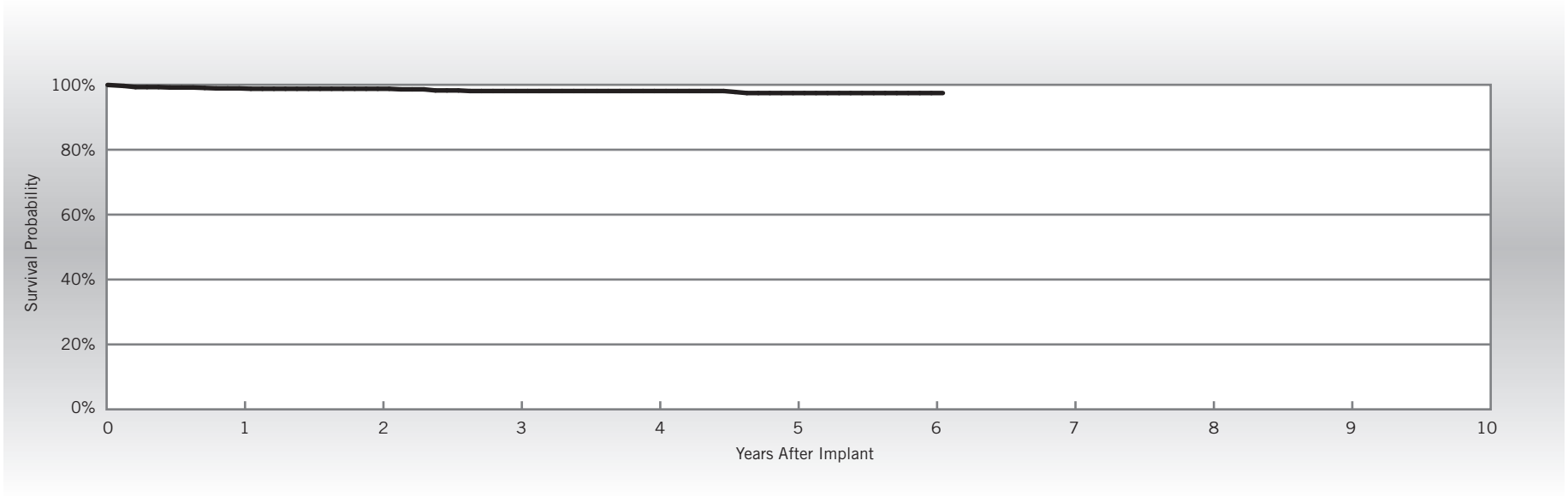
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	860
Active Devices Enrolled in Study	476
Cumulative Months of Follow-up	34,358
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	1	0.12%
Conductor Fracture	1	0.12%
Failure to Sense	2	0.23%
Insulation Breach	1	0.12%
Lead Dislodgement	10	1.16%
Oversensing	1	0.12%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.23%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.93%
Total	**10**	**1.16%**



Year	1	2	3	4	5	6	at 73 months			
Survival Probability	98.90%	98.77%	98.08%	98.08%	97.46%	97.46%	97.46%			
± 1 standard error	0.36%	0.39%	0.52%	0.52%	0.67%	0.67%	0.67%			
Sample Size	800	680	550	420	290	140	60			

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

Customer Reported Performance Data

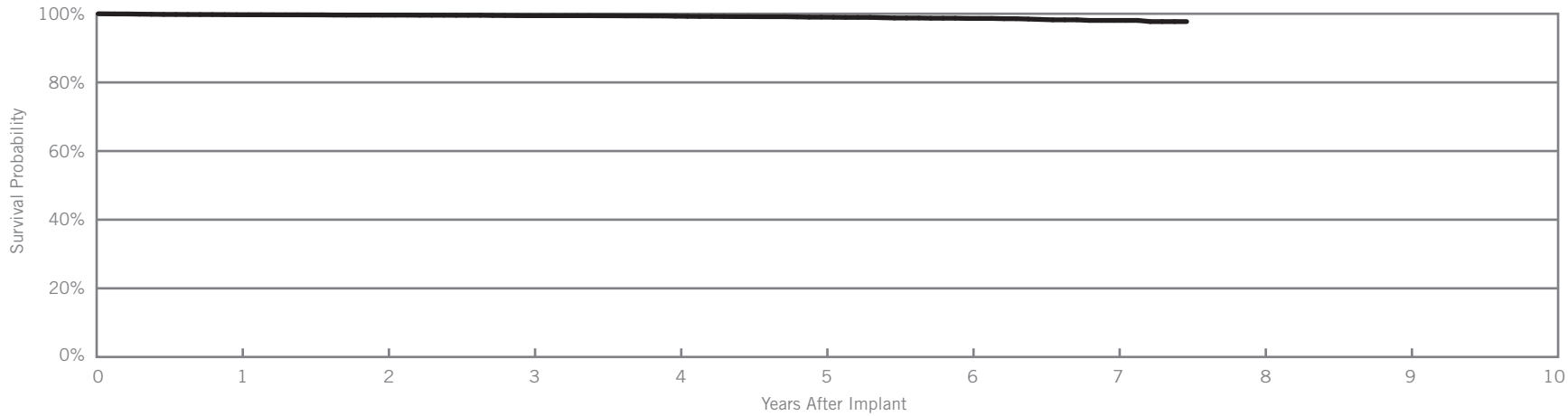
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	14,941
Estimated Active US Implants	9,599
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%	5	0.03%
Lead Dislodgement	54	0.36%	37	0.25%
Failure to Capture	7	0.05%	19	0.13%
Oversensing	0	0.00%	30	0.20%
Failure to Sense	2	0.01%	4	0.03%
Insulation Breach	0	0.00%	4	0.03%
Abnormal Pacing Impedance	0	0.00%	1	<0.01%
Extracardiac Stimulation	2	0.01%	1	<0.01%
Other	1	<0.01%	2	0.01%
Total	**66**	**0.44%**	**104**	**0.70%**
Total Returned for Analysis	**40**		**22**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	6	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	19	0.13%
Total	**26**	**0.17%**



Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.72%	99.61%	99.44%	99.30%	99.02%	98.64%	98.06%	97.72%		
± 1 standard error	0.04%	0.06%	0.07%	0.08%	0.13%	0.17%	0.33%	0.47%		
Sample Size	13,190	10,120	7,670	5,520	3,660	2,100	910	200		

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

Actively Monitored Study Data

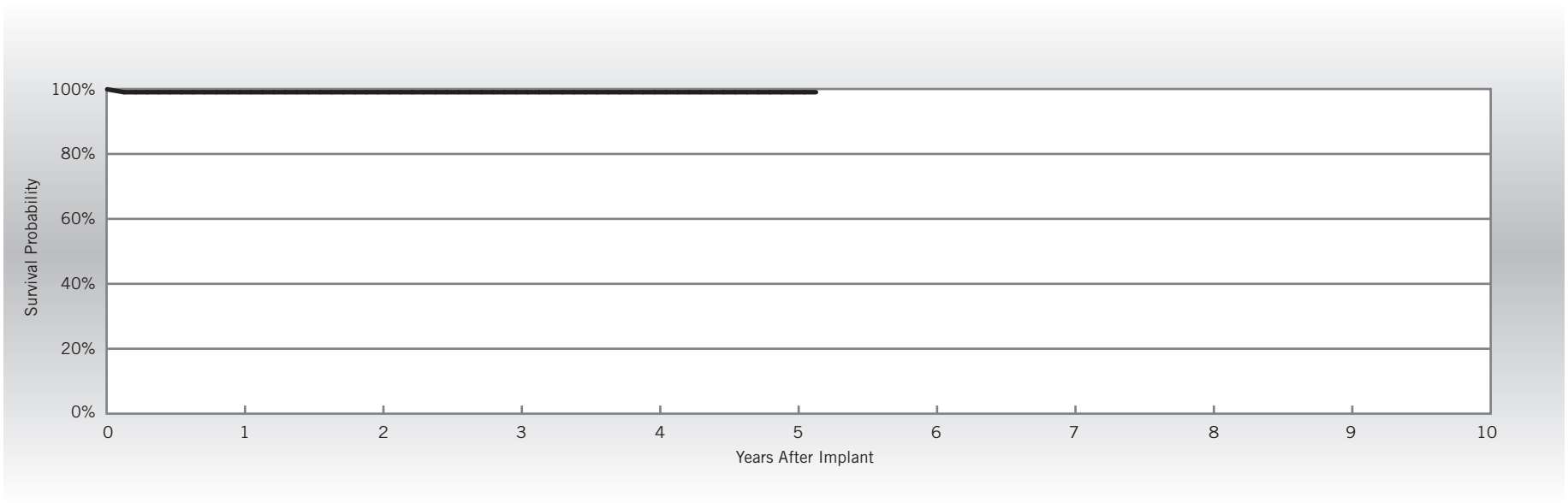
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	104
Active Devices Enrolled in Study	38
Cumulative Months of Follow-up	5,391
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	4	5	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.*

Customer Reported Performance Data

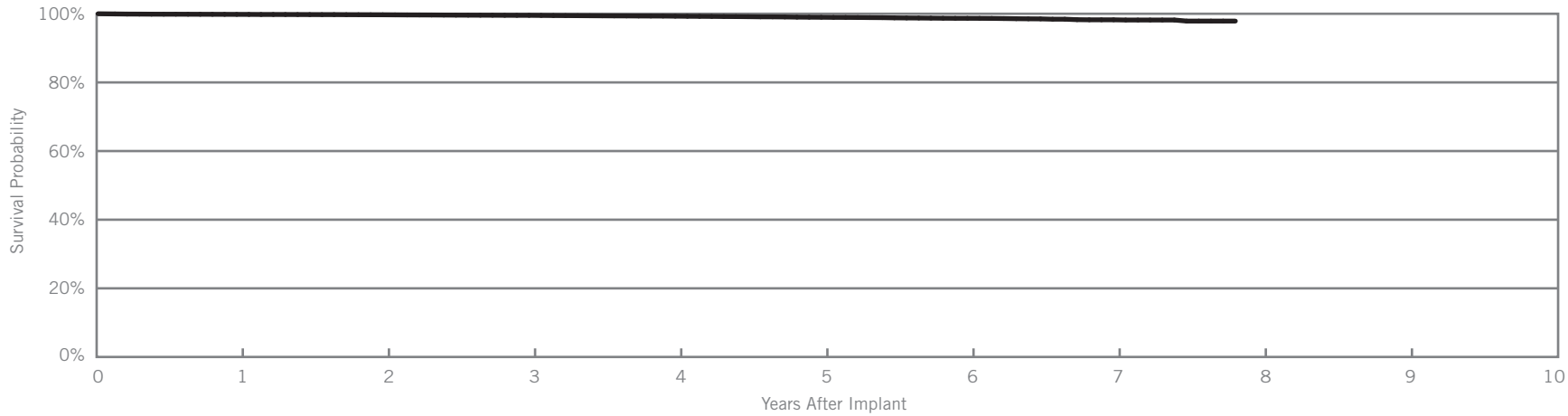
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	56,732
Estimated Active US Implants	44,700
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	2	<0.01%	9	0.02%
Conductor Fracture	0	0.00%	48	0.08%
Lead Dislodgement	40	0.07%	48	0.08%
Failure to Capture	23	0.04%	93	0.16%
Oversensing	1	<0.01%	124	0.22%
Failure to Sense	2	<0.01%	2	<0.01%
Insulation Breach	4	<0.01%	31	0.05%
Abnormal Pacing Impedance	1	<0.01%	21	0.04%
Extracardiac Stimulation	2	<0.01%	4	<0.01%
Other	5	<0.01%	5	<0.01%
Total	**80**	**0.14%**	**385**	**0.68%**
Total Returned for Analysis	**44**		**82**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	9	0.02%
Insulation Breach	50	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	56	0.10%
Total	**116**	**0.20%**



Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.82%	99.70%	99.54%	99.30%	98.98%	98.68%	98.24%	97.87%		
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.07%	0.09%	0.14%	0.27%		
Sample Size	50,960	40,310	30,800	21,890	14,290	8,300	3,700	260		

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

Actively Monitored Study Data

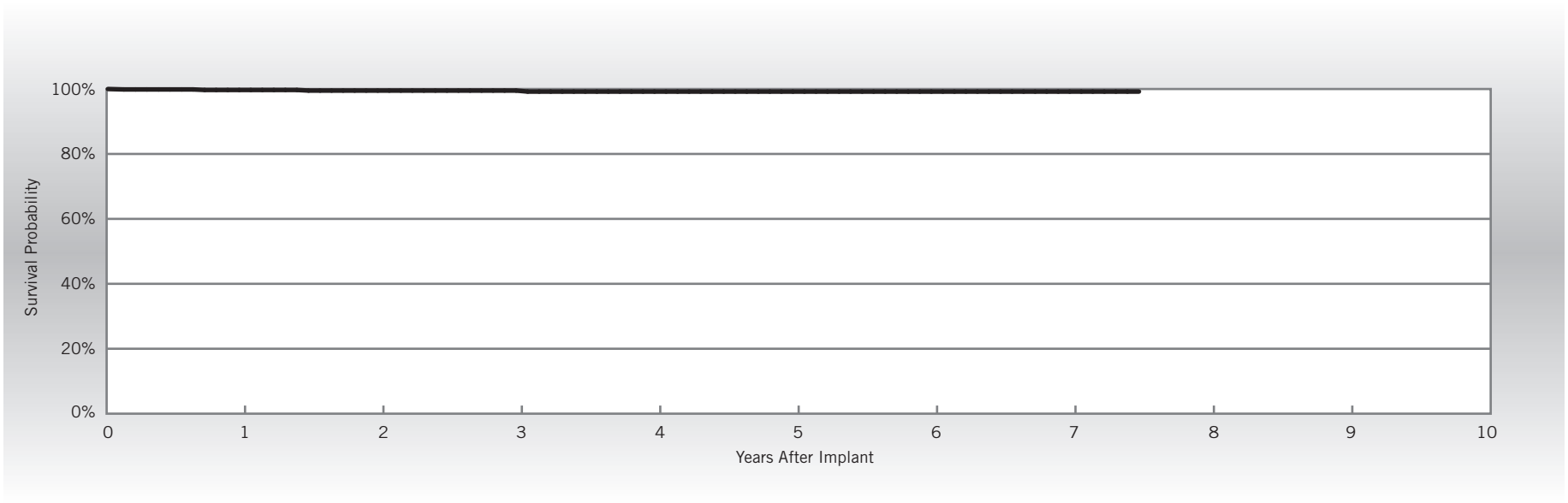
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	766
Active Devices Enrolled in Study	237
Cumulative Months of Follow-up	31,305
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	at 90 months		
Survival Probability	99.71%	99.52%	99.52%	99.21%	99.21%	99.21%	99.21%	99.21%		
± 1 standard error	0.20%	0.28%	0.28%	0.42%	0.42%	0.42%	0.42%	0.42%		
Sample Size	680	530	380	300	270	240	170	60		

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

Customer Reported Performance Data

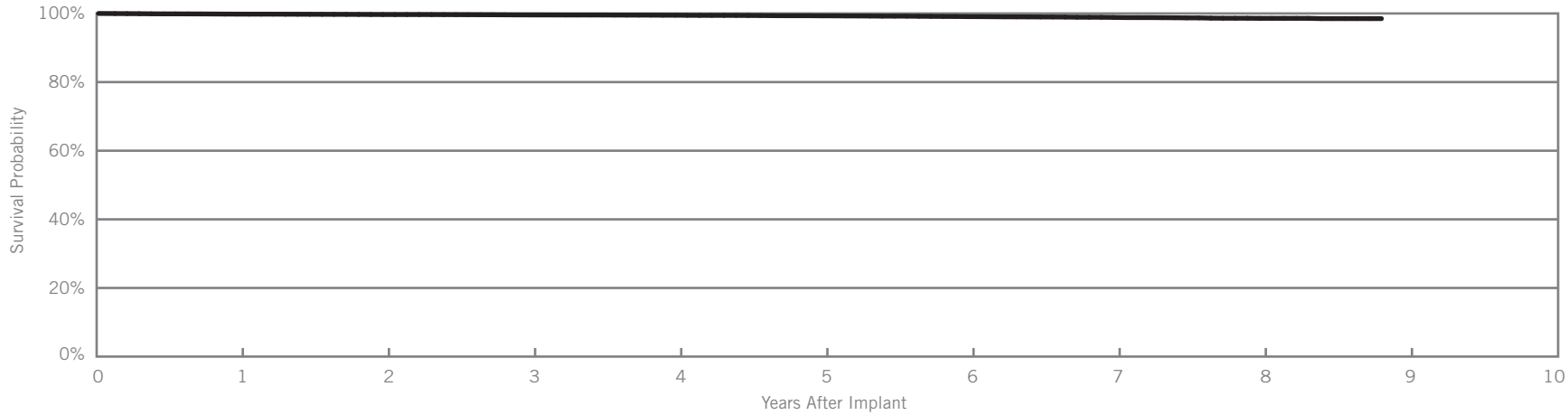
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	22,876
Estimated Active US Implants	10,952
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%	13	0.06%
Lead Dislodgement	4	0.02%	44	0.19%
Failure to Capture	3	0.01%	34	0.15%
Oversensing	2	<0.01%	67	0.29%
Failure to Sense	8	0.03%	20	0.09%
Insulation Breach	0	0.00%	4	0.02%
Abnormal Pacing Impedance	0	0.00%	16	0.07%
Extracardiac Stimulation	0	0.00%	3	0.01%
Other	2	<0.01%	3	0.01%
Total	**20**	**0.09%**	**204**	**0.89%**
Total Returned for Analysis	**16**		**63**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	13	0.06%
Insulation Breach	23	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	49	0.21%
Total	**85**	**0.37%**



Year	1	2	3	4	5	6	7	8	at 106 months	
Survival Probability	99.81%	99.69%	99.57%	99.49%	99.31%	99.08%	98.85%	98.58%	98.50%	
± 1 standard error	0.03%	0.04%	0.05%	0.05%	0.06%	0.07%	0.09%	0.11%	0.14%	
Sample Size	21,290	18,680	16,790	15,190	13,770	12,160	9,140	4,920	270	

Actively Monitored Study Data

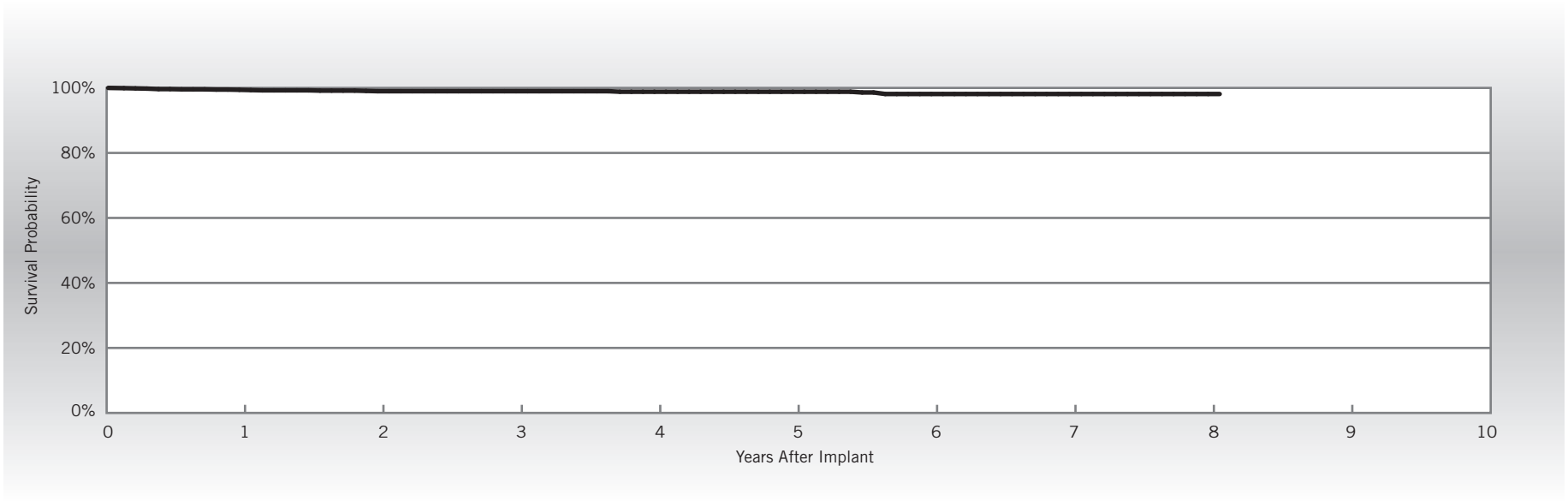
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,451
Active Devices Enrolled in Study	385
Cumulative Months of Follow-up	65,463
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	2	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.34%
Total	**7**	**0.48%**



Year	1	2	3	4	5	6	7	8	at 97 months	
Survival Probability	99.42%	98.99%	98.99%	98.83%	98.83%	98.13%	98.13%	98.13%	98.13%	
± 1 standard error	0.19%	0.27%	0.28%	0.32%	0.32%	0.52%	0.52%	0.52%	0.52%	
Sample Size	1,360	1,160	940	680	510	420	290	130	50	

Customer Reported Performance Data

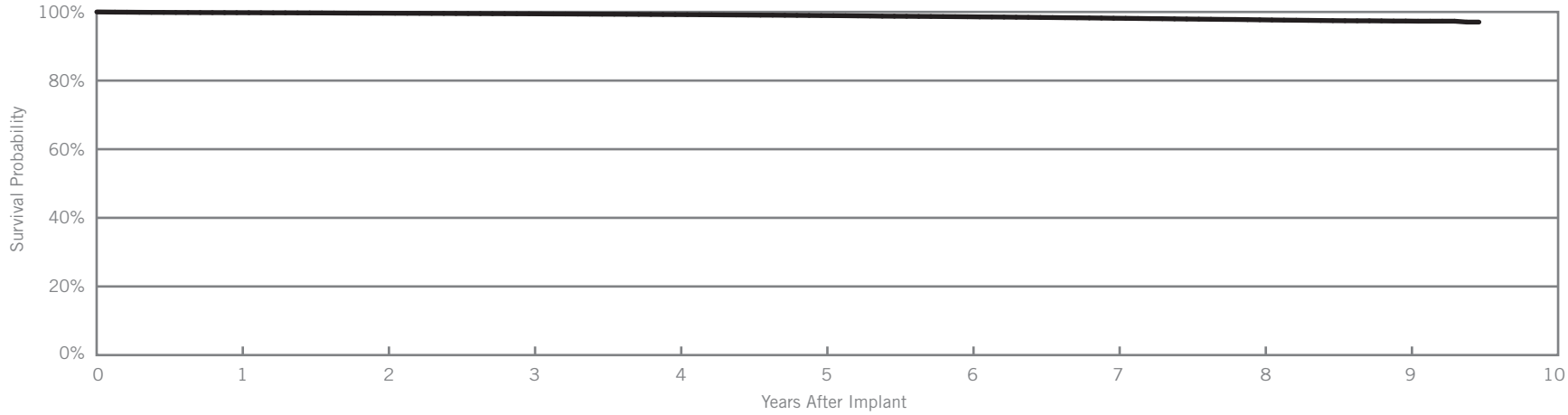
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	301,003
Estimated Active US Implants	162,511
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	39	0.01%	37	0.01%
Conductor Fracture	7	<0.01%	178	0.06%
Lead Dislodgement	156	0.05%	473	0.16%
Failure to Capture	85	0.03%	605	0.20%
Oversensing	16	<0.01%	1303	0.43%
Failure to Sense	14	<0.01%	97	0.03%
Insulation Breach	7	<0.01%	243	0.08%
Abnormal Pacing Impedance	9	<0.01%	176	0.06%
Extracardiac Stimulation	5	<0.01%	31	0.01%
Other	40	0.01%	95	0.03%
Total	**378**	**0.13%**	**3238**	**1.08%**
Total Returned for Analysis	**198**		**1020**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	31	0.01%
Insulation Breach	604	0.20%
Crimps, Welds & Bonds	1	<0.01%
Other	12	<0.01%
Extrinsic Factors	705	0.23%
Total	**1353**	**0.45%**



Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.79%	99.64%	99.46%	99.24%	98.95%	98.60%	98.17%	97.71%	97.35%	97.05%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.05%	0.08%	0.27%
Sample Size	277,750	235,280	198,440	164,790	133,500	102,400	66,960	33,140	11,000	280

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

Actively Monitored Study Data

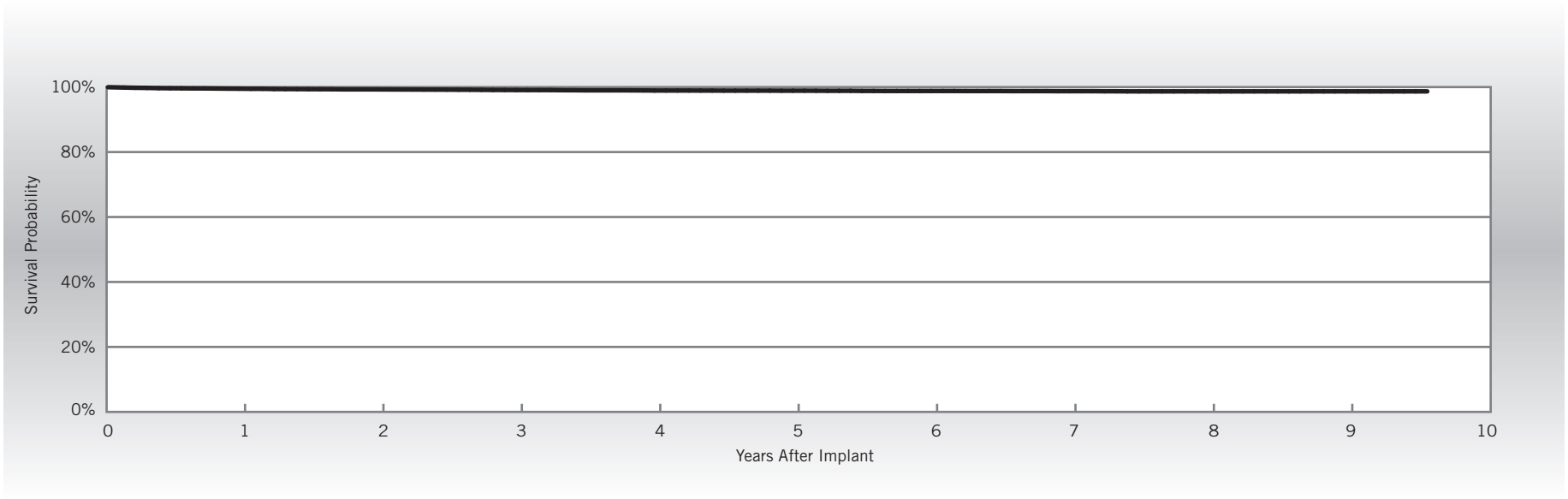
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	14,505
Active Devices Enrolled in Study	5,207
Cumulative Months of Follow-up	754,337
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	6	0.04%
Extracardiac Stimulation	3	0.02%
Failure to Capture	19	0.13%
Failure to Sense	4	0.03%
Insulation Breach	25	0.17%
Lead Dislodgement	57	0.39%
Oversensing	16	0.11%
Skin Erosion	1	<0.01%

Malfunctions	Qty	Rate
Conductor Fracture	3	0.02%
Insulation Breach	22	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	33	0.23%
Total	**58**	**0.40%**



Year	1	2	3	4	5	6	7	8	9	at 115 months
Survival Probability	99.50%	99.29%	99.09%	98.94%	98.89%	98.80%	98.74%	98.68%	98.68%	98.68%
± 1 standard error	0.06%	0.07%	0.08%	0.09%	0.10%	0.11%	0.11%	0.12%	0.12%	0.12%
Sample Size	13,700	11,900	9,730	7,640	6,190	5,400	4,470	2,920	1,320	50

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

Customer Reported Performance Data

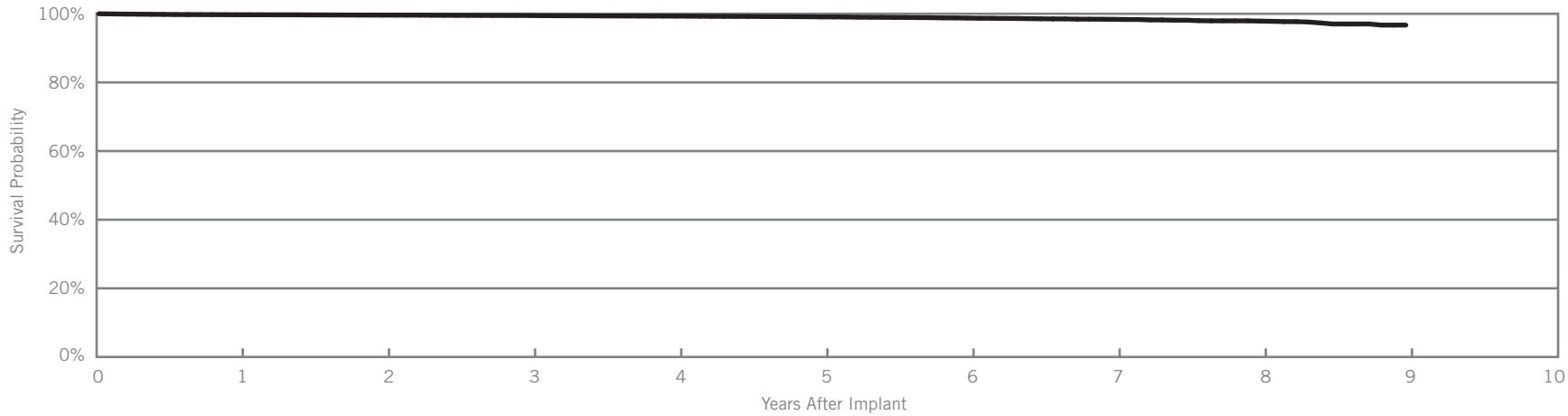
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	45,255
Estimated Active US Implants	27,888
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%	11	0.02%
Lead Dislodgement	41	0.09%	112	0.25%
Failure to Capture	10	0.02%	53	0.12%
Oversensing	5	0.01%	113	0.25%
Failure to Sense	4	<0.01%	16	0.04%
Insulation Breach	0	0.00%	28	0.06%
Abnormal Pacing Impedance	1	<0.01%	8	0.02%
Extracardiac Stimulation	0	0.00%	3	<0.01%
Other	13	0.03%	20	0.04%
Total	**77**	**0.17%**	**367**	**0.81%**
Total Returned for Analysis	**43**		**125**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Insulation Breach	42	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	108	0.24%
Total	**155**	**0.34%**



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.72%	99.60%	99.48%	99.32%	99.09%	98.74%	98.38%	97.87%	96.70%	
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.06%	0.09%	0.12%	0.18%	0.49%	
Sample Size	40,420	31,900	25,040	18,990	13,620	9,060	5,340	2,510	210	

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

Actively Monitored Study Data

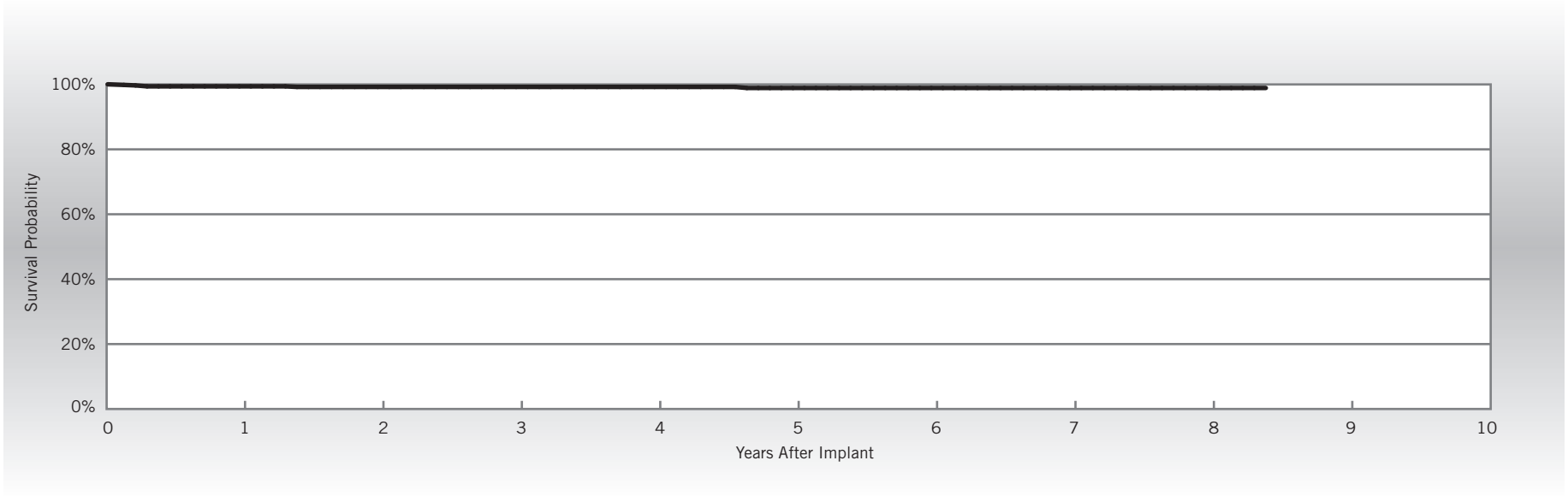
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	689
Active Devices Enrolled in Study	286
Cumulative Months of Follow-up	35,348
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Extracardiac Stimulation	1	0.15%
Failure to Capture	1	0.15%
Lead Dislodgement	2	0.29%
Oversensing	1	0.15%
Skin Erosion	1	0.15%

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	1	2	3	4	5	6	7	8	at 101 months	
Survival Probability	99.41%	99.23%	99.23%	99.23%	98.91%	98.91%	98.91%	98.91%	98.91%	
± 1 standard error	0.30%	0.34%	0.34%	0.34%	0.47%	0.47%	0.47%	0.47%	0.47%	
Sample Size	650	560	450	370	310	260	210	130	50	

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

Customer Reported Performance Data

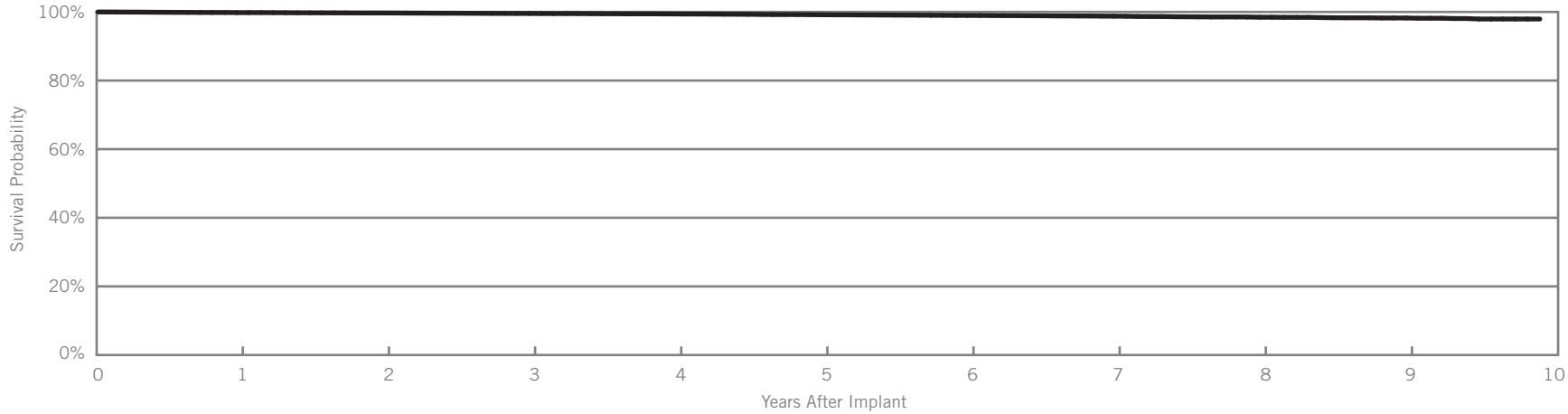
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,401
Estimated Active US Implants	7,512
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%	3	0.02%
Lead Dislodgement	13	0.08%	45	0.27%
Failure to Capture	5	0.03%	39	0.24%
Oversensing	0	0.00%	40	0.24%
Failure to Sense	0	0.00%	5	0.03%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	2	0.01%	14	0.09%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	3	0.02%
Total	**29**	**0.18%**	**153**	**0.93%**
Total Returned for Analysis	**16**		**55**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	22	0.13%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	47	0.29%
Total	**70**	**0.43%**



Year	1	2	3	4	5	6	7	8	9	at 119 months
Survival Probability	99.81%	99.70%	99.55%	99.41%	99.19%	98.99%	98.77%	98.46%	98.24%	97.94%
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.08%	0.10%	0.11%	0.13%	0.17%	0.24%
Sample Size	15,310	13,540	12,220	10,970	9,620	8,040	6,290	4,460	2,580	260

Actively Monitored Study Data

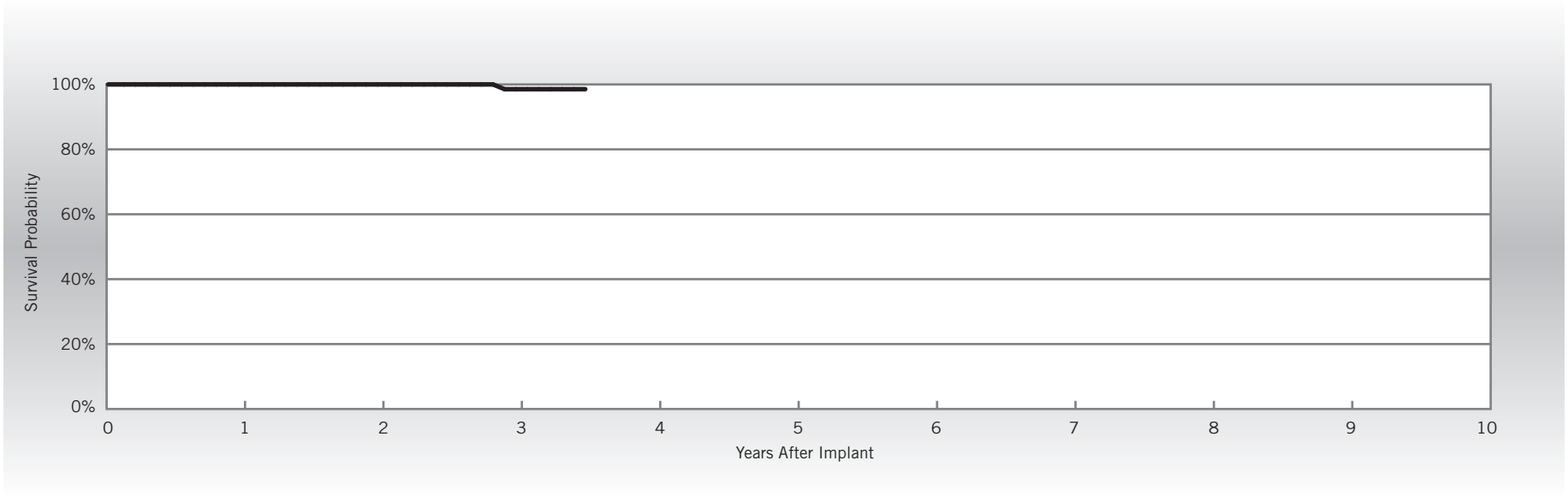
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	165
Active Devices Enrolled in Study	19
Cumulative Months of Follow-up	5,525
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						

Customer Reported Performance Data

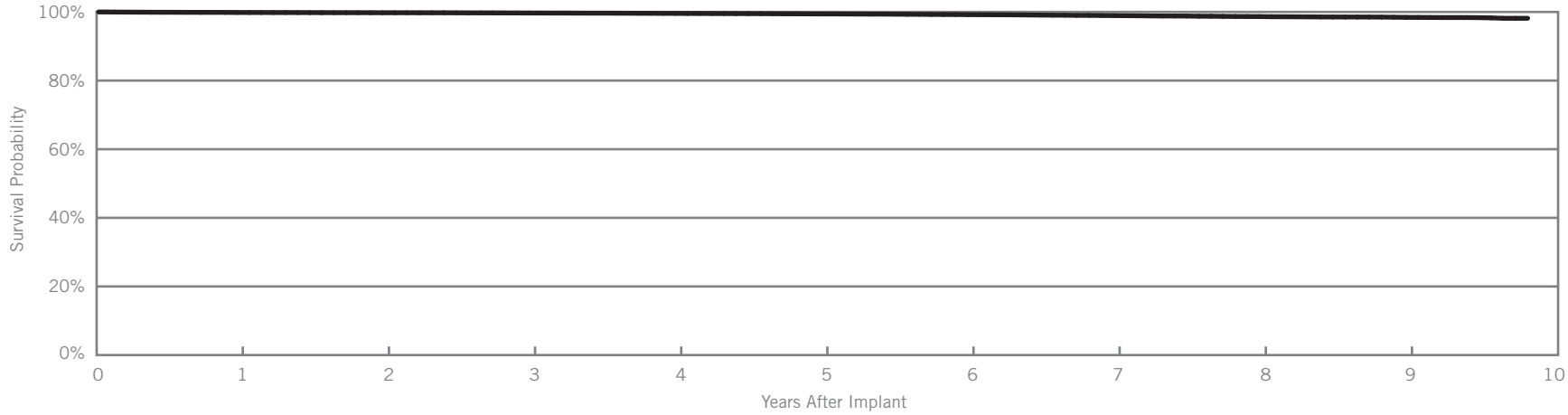
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,200
Estimated Active US Implants	27,428
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%	22	0.03%
Lead Dislodgement	31	0.05%	74	0.11%
Failure to Capture	30	0.05%	137	0.21%
Oversensing	2	<0.01%	148	0.23%
Failure to Sense	2	<0.01%	22	0.03%
Insulation Breach	1	<0.01%	28	0.04%
Abnormal Pacing Impedance	9	0.01%	41	0.06%
Extracardiac Stimulation	2	<0.01%	7	0.01%
Other	20	0.03%	24	0.04%
Total	**110**	**0.17%**	**510**	**0.78%**
Total Returned for Analysis	**46**		**141**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	8	0.01%
Insulation Breach	98	0.15%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	98	0.15%
Total	**206**	**0.32%**



Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.85%	99.77%	99.69%	99.58%	99.42%	99.22%	98.94%	98.65%	98.42%	98.15%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.04%	0.05%	0.06%	0.07%	0.13%
Sample Size	60,610	52,980	47,240	42,200	37,810	33,610	28,680	22,450	14,260	470

Actively Monitored Study Data

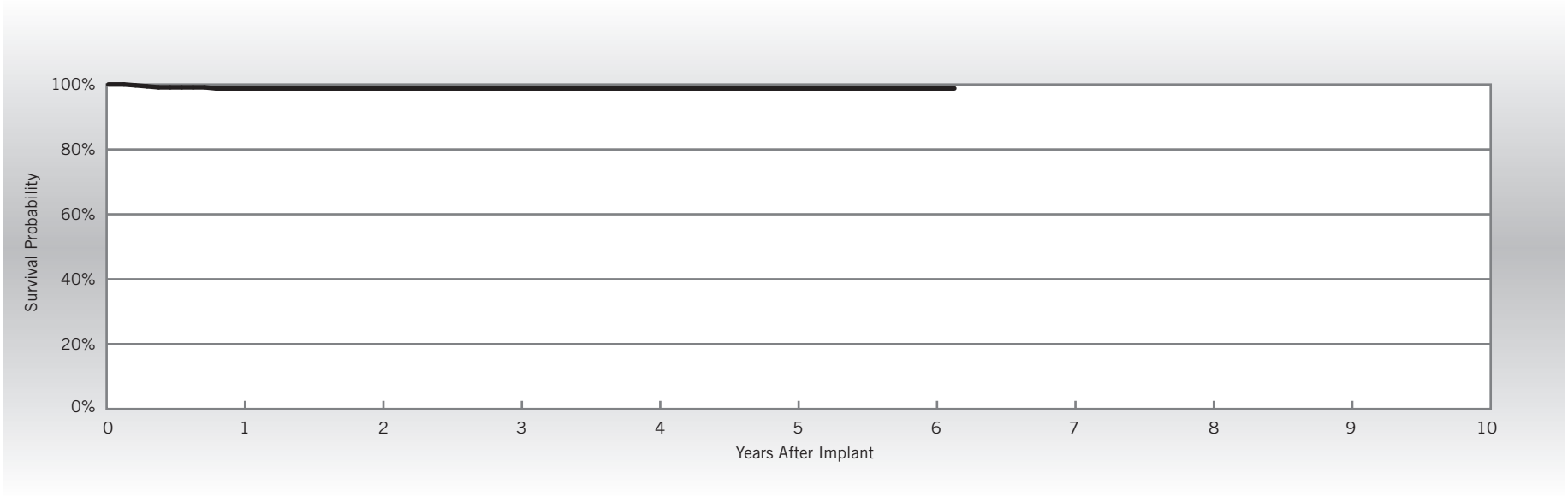
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	363
Active Devices Enrolled in Study	70
Cumulative Months of Follow-up	11,921
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	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	5	6	at 74 months			
Survival Probability	98.79%	98.79%	98.79%	98.79%	98.79%	98.79%	98.79%			
± 1 standard error	0.61%	0.61%	0.61%	0.61%	0.61%	0.61%	0.61%			
Sample Size	320	240	180	110	80	60	50			

Customer Reported Performance Data

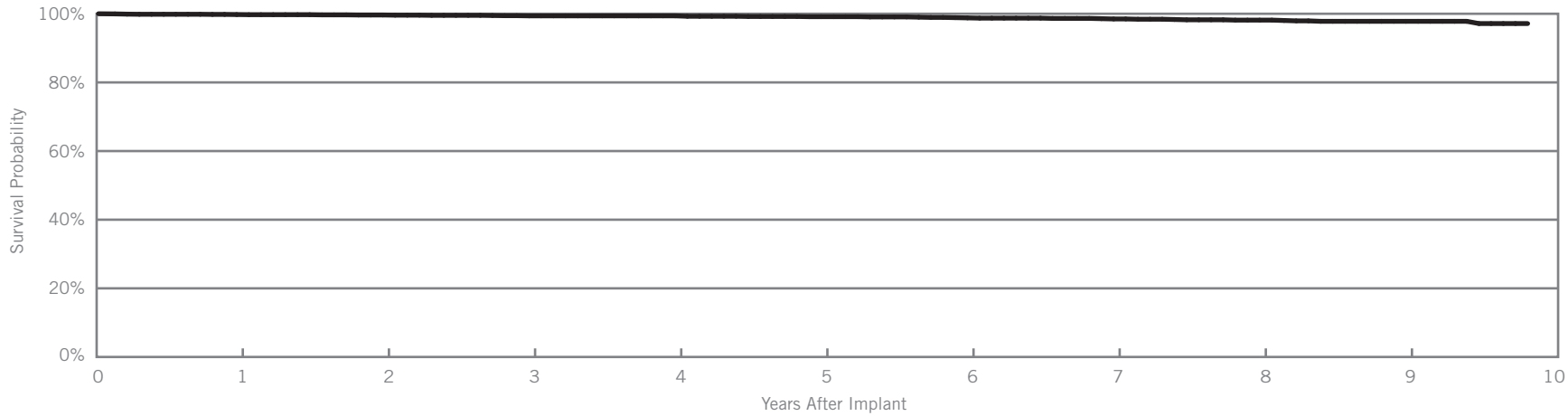
IsoFlex™ P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,834
Estimated Active US Implants	1,144
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%	4	0.14%
Lead Dislodgement	2	0.07%	2	0.07%
Failure to Capture	2	0.07%	8	0.28%
Oversensing	0	0.00%	2	0.07%
Failure to Sense	1	0.04%	1	0.04%
Insulation Breach	0	0.00%	8	0.28%
Abnormal Pacing Impedance	0	0.00%	3	0.11%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	3	0.11%
Total	**6**	**0.21%**	**31**	**1.09%**
Total Returned for Analysis	**1**		**6**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	11	0.39%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.07%
Extrinsic Factors	5	0.18%
Total	**18**	**0.64%**



Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.77%	99.64%	99.39%	99.39%	99.15%	98.80%	98.49%	98.15%	97.80%	97.15%
± 1 standard error	0.08%	0.12%	0.16%	0.16%	0.20%	0.25%	0.29%	0.34%	0.40%	0.60%
Sample Size	2,610	2,260	2,010	1,810	1,630	1,460	1,310	1,100	720	210

Customer Reported Performance Data

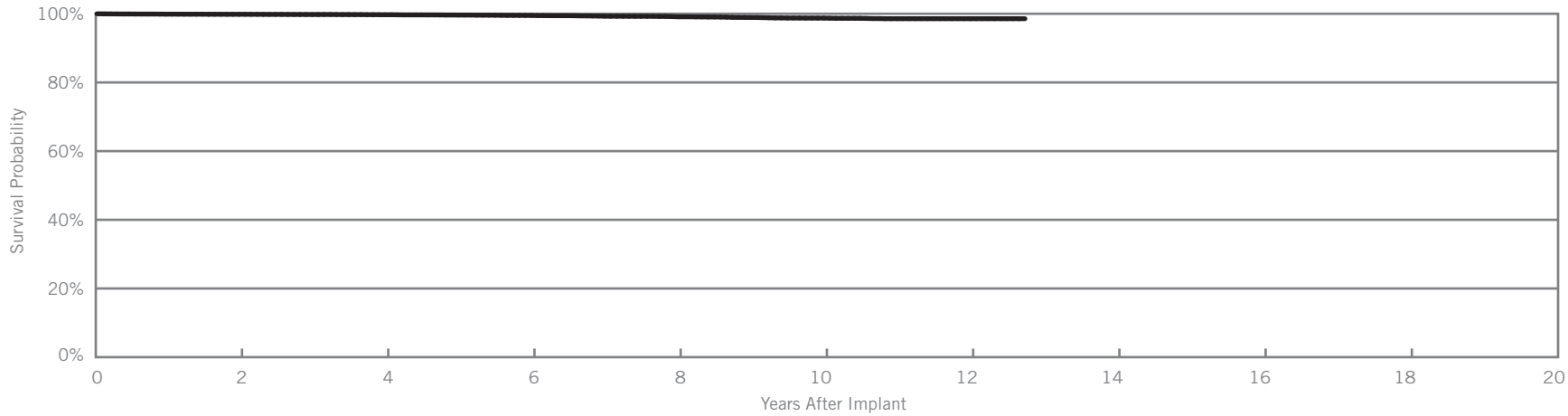
IsoFlex™ S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	27,101
Estimated Active US Implants	10,704
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	0	0.00%	6	0.02%
Lead Dislodgement	49	0.18%	40	0.15%
Failure to Capture	6	0.02%	50	0.18%
Oversensing	0	0.00%	31	0.11%
Failure to Sense	3	0.01%	15	0.06%
Insulation Breach	0	0.00%	6	0.02%
Abnormal Pacing Impedance	3	0.01%	7	0.03%
Extracardiac Stimulation	1	<0.01%	2	<0.01%
Other	0	0.00%	2	<0.01%
Total	**62**	**0.23%**	**159**	**0.59%**
Total Returned for Analysis	**39**		**24**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	19	0.07%
Crimps, Welds & Bonds	1	<0.01%
Other	2	<0.01%
Extrinsic Factors	18	0.07%
Total	**40**	**0.15%**



Year	2	4	6	8	10	12	at 153 months			
Survival Probability	99.84%	99.71%	99.50%	99.12%	98.74%	98.56%	98.56%			
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.12%	0.14%	0.14%			
Sample Size	22,170	17,850	13,460	8,760	4,360	1,350	250			

Customer Reported Performance Data

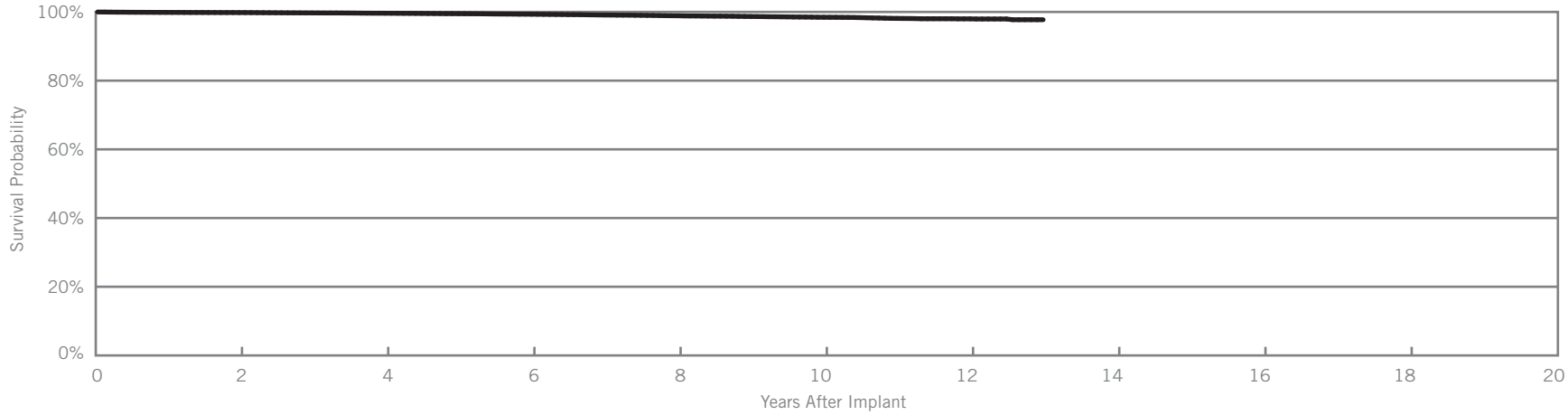
IsoFlex™ S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	90,309
Estimated Active US Implants	34,680
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%	90	0.10%
Lead Dislodgement	37	0.04%	35	0.04%
Failure to Capture	33	0.04%	262	0.29%
Oversensing	0	0.00%	104	0.12%
Failure to Sense	2	<0.01%	11	0.01%
Insulation Breach	2	<0.01%	39	0.04%
Abnormal Pacing Impedance	6	<0.01%	100	0.11%
Extracardiac Stimulation	0	0.00%	5	<0.01%
Other	2	<0.01%	20	0.02%
Total	**88**	**0.10%**	**668**	**0.74%**
Total Returned for Analysis	**38**		**91**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	21	0.02%
Insulation Breach	47	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	6	<0.01%
Extrinsic Factors	63	0.07%
Total	**137**	**0.15%**



Year	2	4	6	8	10	12	at 156 months			
Survival Probability	99.81%	99.62%	99.33%	98.89%	98.45%	97.99%	97.74%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.07%	0.11%	0.19%			
Sample Size	72,480	57,180	42,070	27,070	13,410	4,050	280			

Actively Monitored Study Data

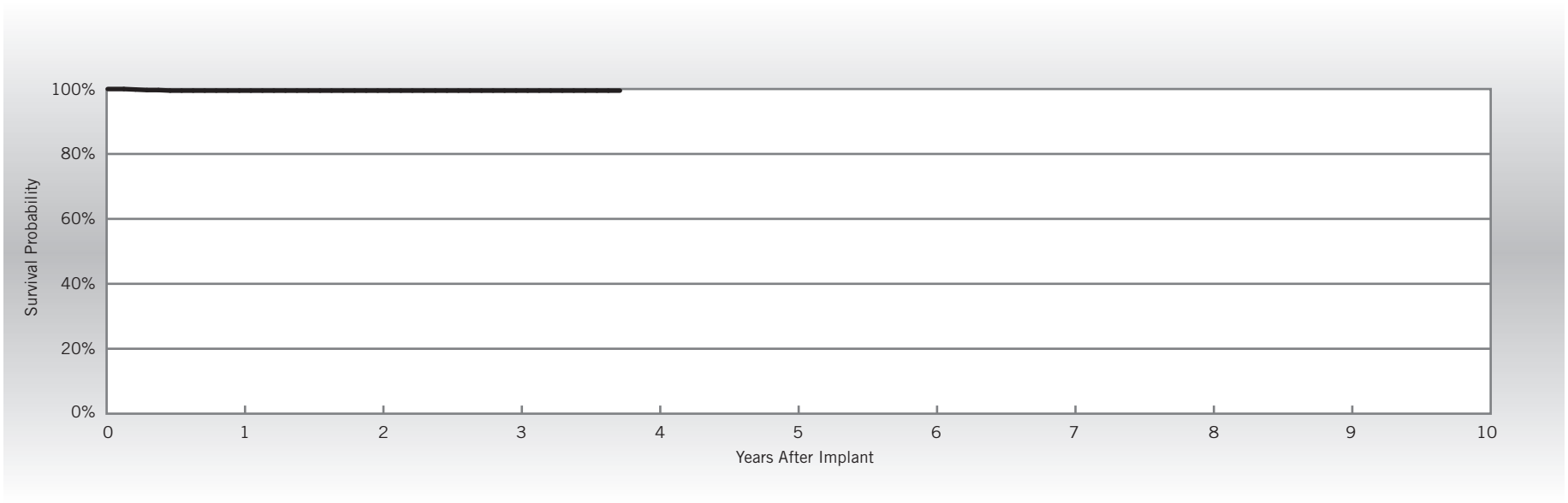
IsoFlex™ S

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	15,737
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						

Customer Reported Performance Data

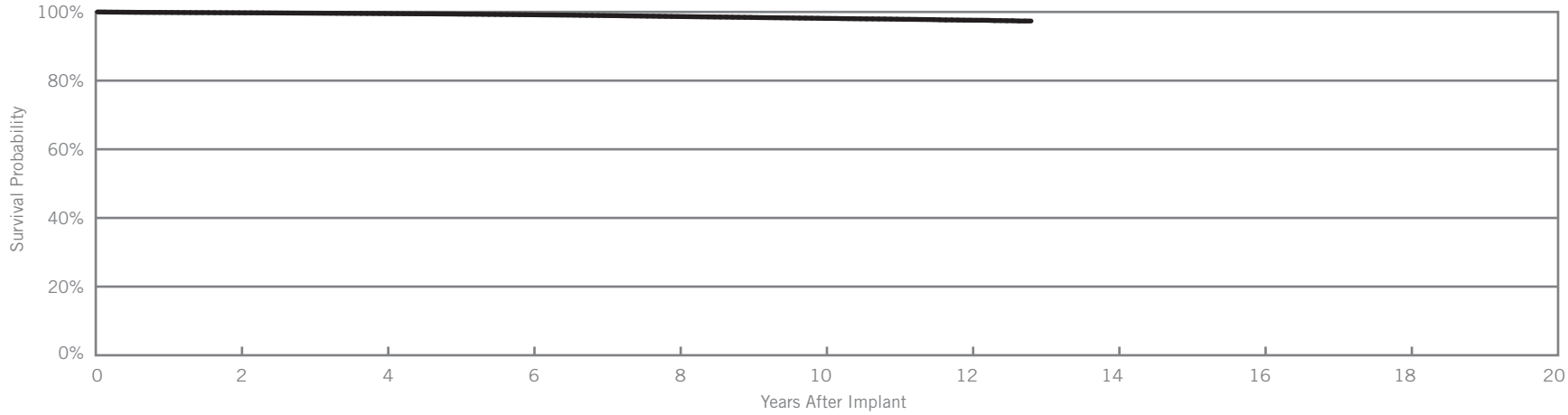
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	480,012
Estimated Active US Implants	263,917
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	77	0.02%	37	<0.01%
Conductor Fracture	4	<0.01%	401	0.08%
Lead Dislodgement	296	0.06%	487	0.10%
Failure to Capture	182	0.04%	1129	0.24%
Oversensing	16	<0.01%	1171	0.24%
Failure to Sense	33	<0.01%	124	0.03%
Insulation Breach	10	<0.01%	193	0.04%
Abnormal Pacing Impedance	28	<0.01%	479	0.10%
Extracardiac Stimulation	7	<0.01%	36	<0.01%
Other	59	0.01%	139	0.03%
Total	**712**	**0.15%**	**4196**	**0.87%**
Total Returned for Analysis	**327**		**1169**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	194	0.04%
Insulation Breach	708	0.15%
Crimps, Welds & Bonds	2	<0.01%
Other	16	<0.01%
Extrinsic Factors	689	0.14%
Total	**1609**	**0.34%**



Year	2	4	6	8	10	12	at 154 months			
Survival Probability	99.75%	99.52%	99.18%	98.67%	98.13%	97.60%	97.36%			
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.06%	0.12%			
Sample Size	383,590	285,990	205,010	135,900	76,130	17,890	520			

Actively Monitored Study Data

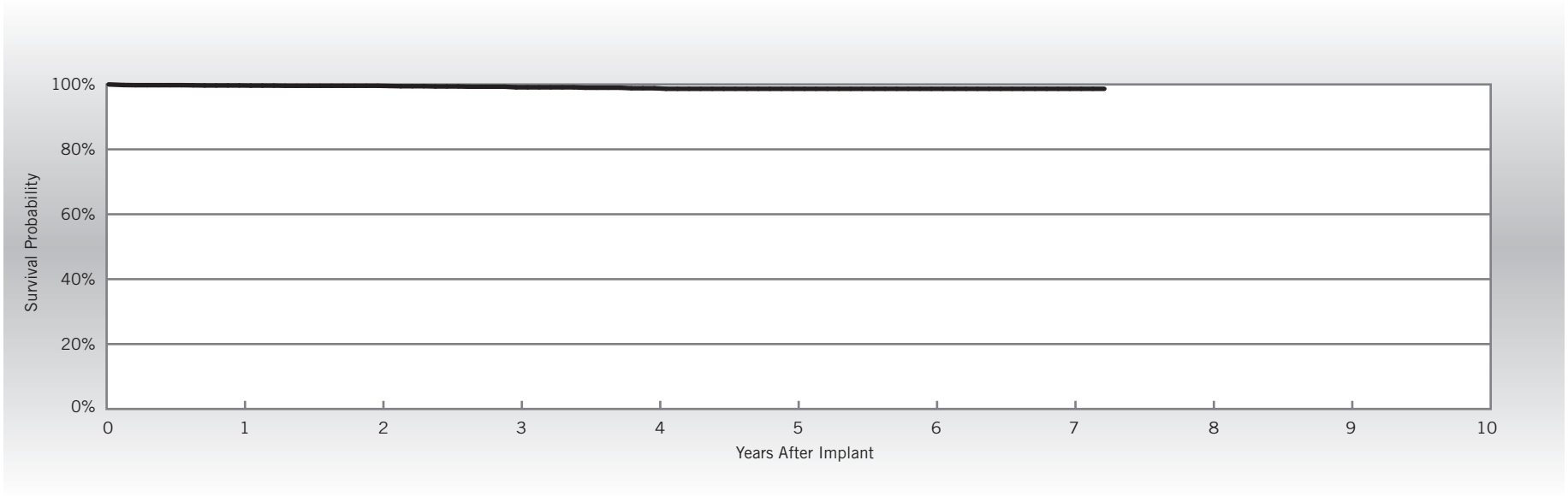
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	2,642
Active Devices Enrolled in Study	503
Cumulative Months of Follow-up	85,579
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	3	0.11%
Conductor Fracture	2	0.08%
Failure to Capture	3	0.11%
Insulation Breach	3	0.11%
Lead Dislodgement	5	0.19%
Oversensing	2	0.08%
Pericardial Effusion	1	0.04%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.04%
Insulation Breach	4	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.19%
Total	**10**	**0.38%**



Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.68%	99.59%	99.11%	98.83%	98.66%	98.66%	98.66%	98.66%		
± 1 standard error	0.11%	0.13%	0.19%	0.31%	0.35%	0.35%	0.35%	0.35%		
Sample Size	2,380	1,840	1,290	800	470	290	140	50		

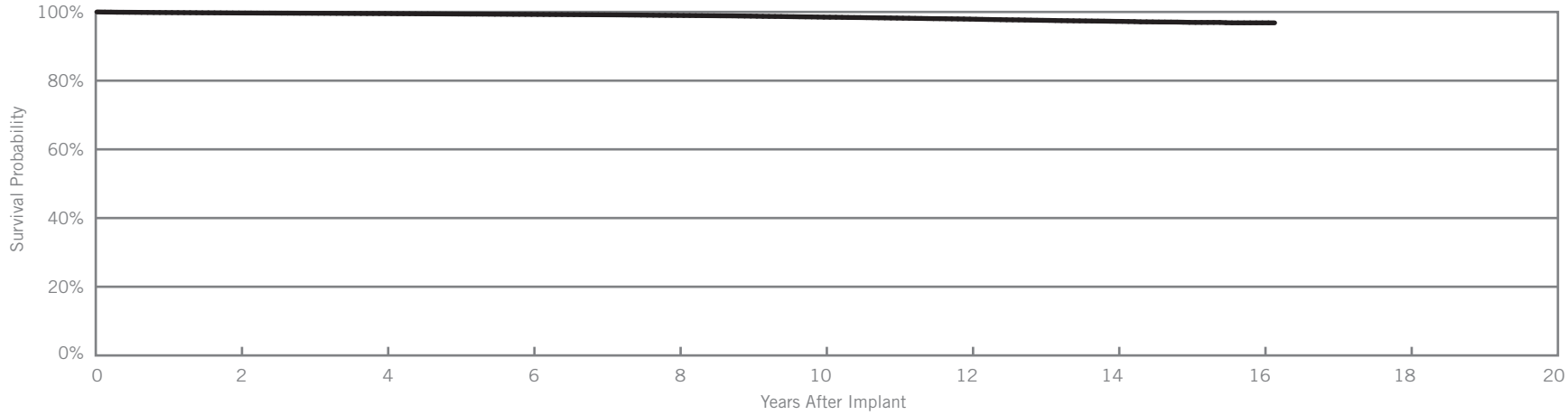
Customer Reported Performance Data

Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	270,792
Estimated Active US Implants	65,840
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	155	0.06%
Insulation Breach	257	0.09%
Crimps, Welds & Bonds	5	<0.01%
Other	3	<0.01%
Extrinsic Factors	349	0.13%
Total	**769**	**0.28%**



Year	2	4	6	8	10	12	14	16	at 194 months	
Survival Probability	99.70%	99.52%	99.29%	98.99%	98.49%	97.91%	97.26%	96.83%	96.83%	
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.06%	0.10%	0.10%	
Sample Size	223,280	180,040	140400	107,680	82,610	57,000	26,250	3,570	320	

Actively Monitored Study Data

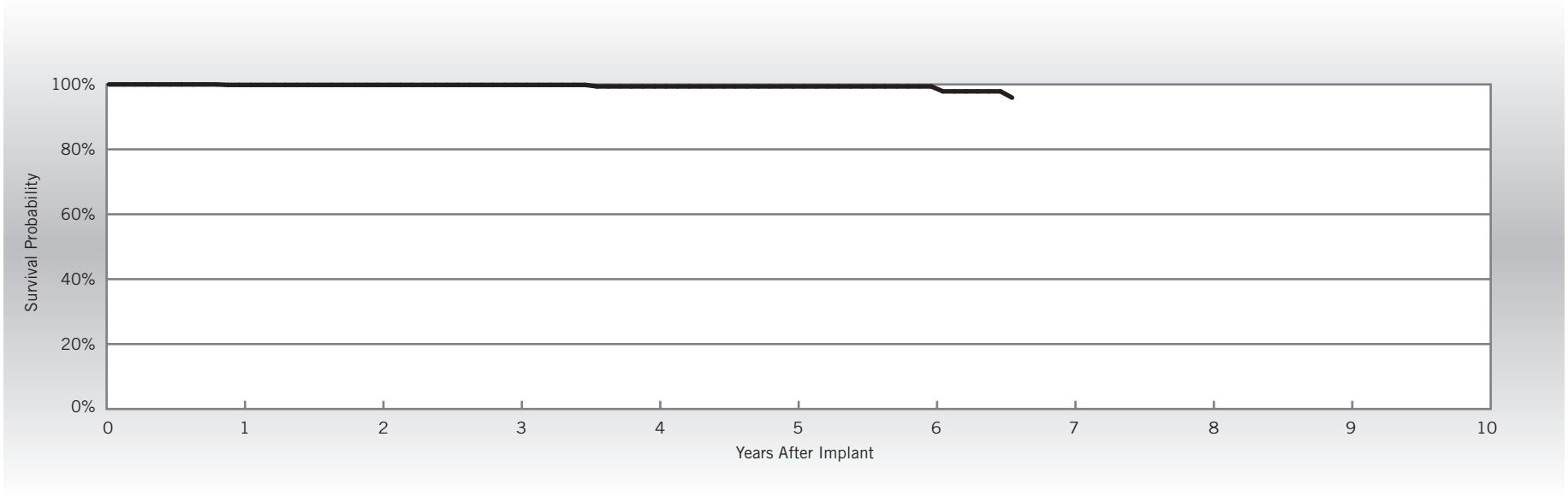
Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	802
Active Devices Enrolled in Study	84
Cumulative Months of Follow-up	26,121
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%
Oversensing	2	0.25%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	4	0.50%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.12%
Total	**5**	**0.62%**



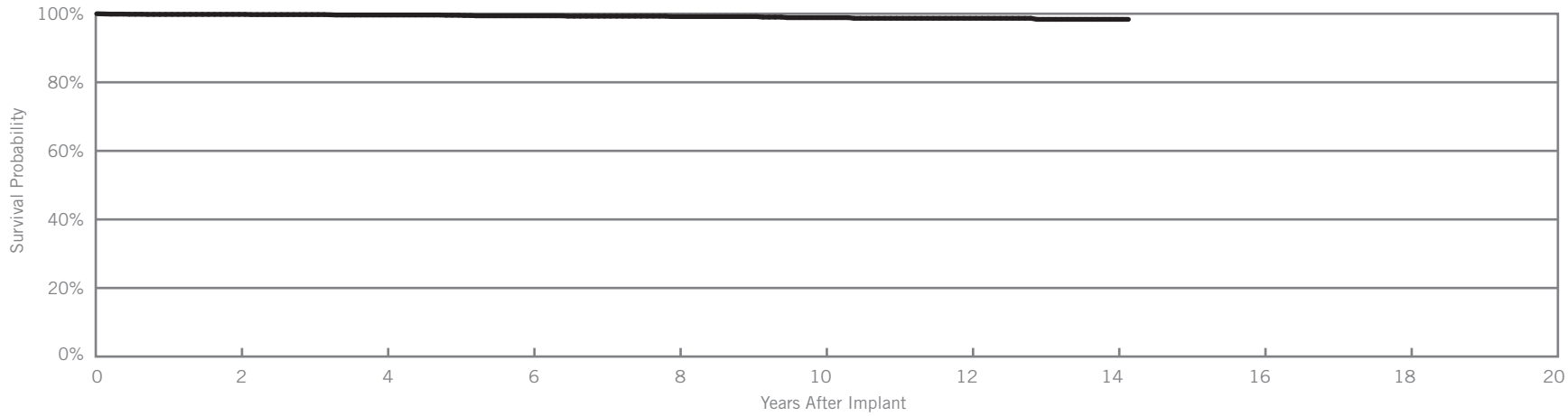
Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.85%	99.85%	99.85%	99.39%	99.39%	99.39%	95.92%			
± 1 standard error	0.15%	0.15%	0.15%	0.48%	0.48%	0.48%	1.58%			
Sample Size	730	580	400	220	120	80	50			

Customer Reported Performance Data

AV Plus™ DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,814
Estimated Active US Implants	823
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



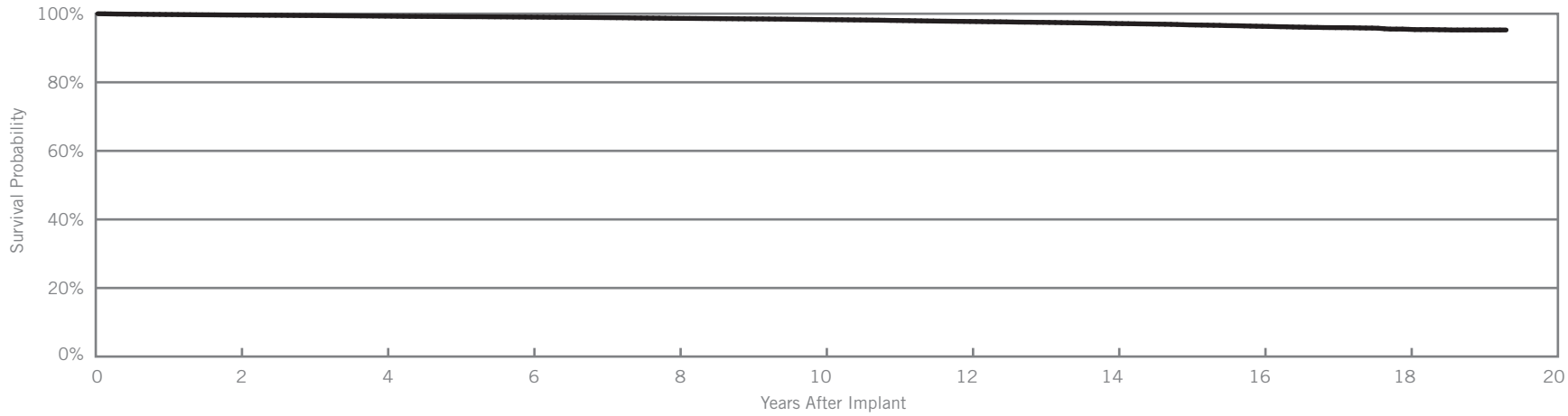
Year	2	4	6	8	10	12	14	at 170 months		
Survival Probability	99.81%	99.63%	99.39%	99.17%	98.86%	98.67%	98.36%	98.36%		
± 1 standard error	0.09%	0.13%	0.19%	0.25%	0.33%	0.38%	0.49%	0.49%		
Sample Size	2,140	1,590	1,160	860	620	410	250	200		

Customer Reported Performance Data

Tendril™ DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Registered US Implants	266,282
Estimated Active US Implants	50,665
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	at 232 months
Survival Probability	99.62%	99.30%	99.02%	98.66%	98.29%	97.74%	97.14%	96.33%	95.45%	95.26%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.05%	0.06%	0.08%	0.13%	0.16%
Sample Size	219,310	176,550	139,340	107,570	78,670	54,510	36,360	21,410	6,600	220

Actively Monitored Study Data

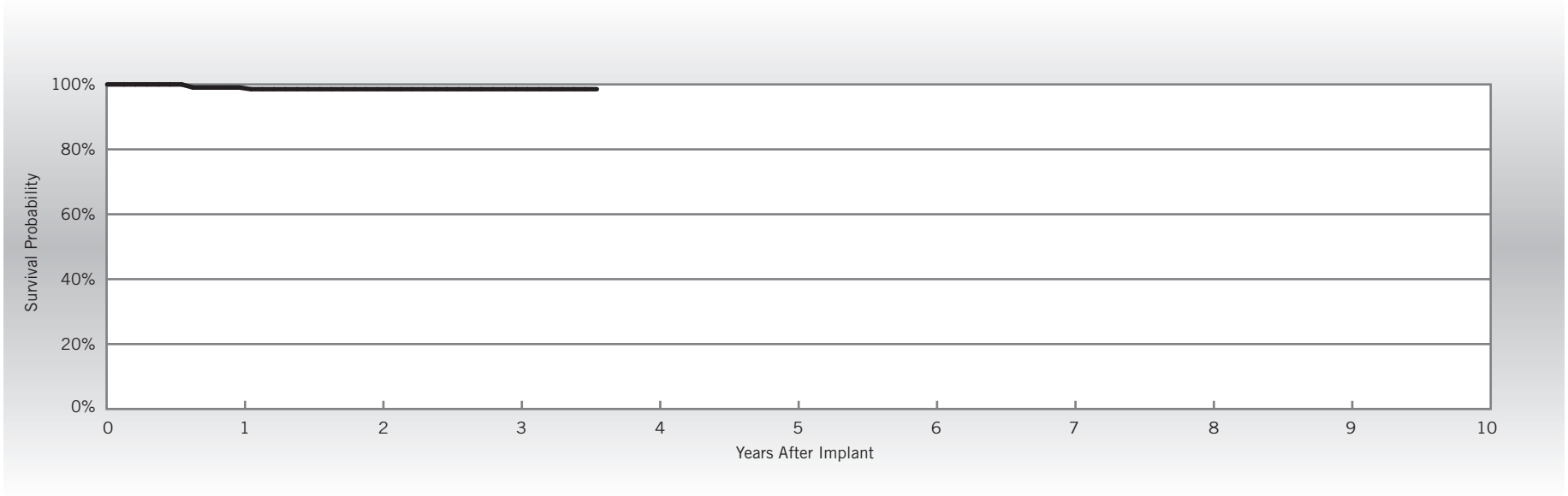
Tendril™ DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Number of Devices Enrolled in Study	238
Active Devices Enrolled in Study	15
Cumulative Months of Follow-up	7,108
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	2	0.84%
Insulation Breach	1	0.42%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.42%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.42%
Total	**2**	**0.84%**



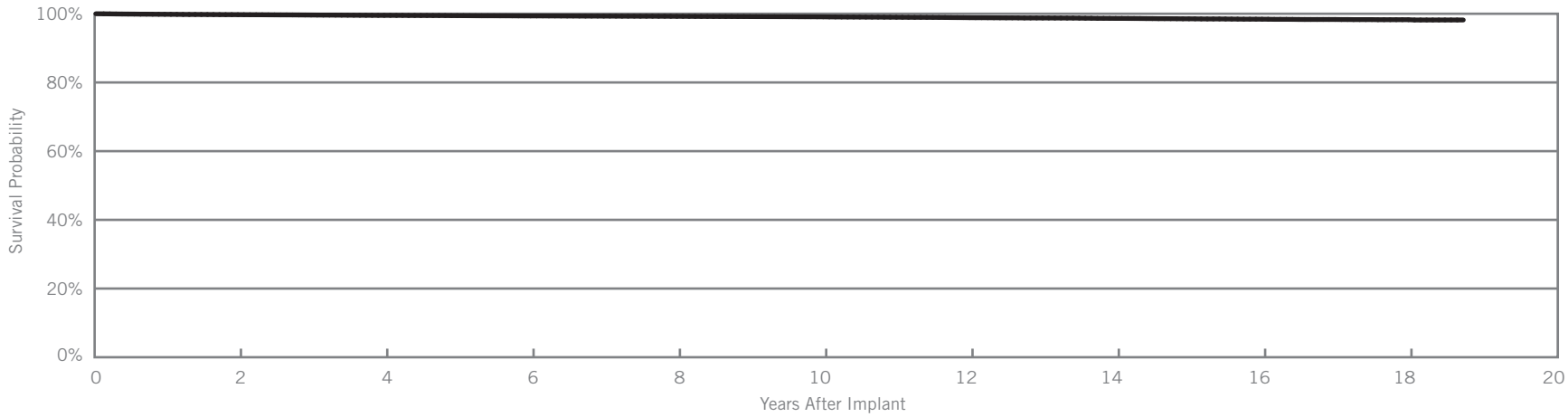
Year	1	2	3	at 43 months						
Survival Probability	99.05%	98.55%	98.55%	98.55%						
± 1 standard error	0.67%	0.83%	0.83%	0.83%						
Sample Size	220	170	110	50						

Customer Reported Performance Data

Passive Plus™ DX

Models 1336T, 1342T & 1346T

US Regulatory Approval	(1336T) August 1999; (1342T, 1346T) January 1998
Registered US Implants	198,474
Estimated Active US Implants	38,736
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	at 225 months
Survival Probability	99.73%	99.53%	99.37%	99.25%	99.10%	98.86%	98.65%	98.42%	98.27%	98.19%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%	0.06%	0.08%	0.11%
Sample Size	161,250	128,820	100,830	77,810	58,900	44,600	30,150	14,720	3,500	200

Summary Information

Pacing Leads

St. Jude Medical

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
2088TC	Tendril™ STS	99.81%	99.68%	99.53%	99.32%	99.09%	98.75%				
1999	OptiSense™ Optim™	99.69%	99.53%	99.38%	99.18%	99.02%	98.72%				
1944	IsoFlex™ Optim™	99.72%	99.61%	99.44%	99.30%	99.02%	98.64%	98.06%			
1948	IsoFlex™ Optim™	99.82%	99.70%	99.54%	99.30%	98.98%	98.68%	98.24%			
1699T/TC	OptiSense™	99.81%	99.69%	99.57%	99.49%	99.31%	99.08%	98.85%	98.58%		
1888T/TC	Tendril™ ST Optim™	99.79%	99.64%	99.46%	99.24%	98.95%	98.60%	98.17%	97.71%	97.35%	
1882T/TC	Tendril™ ST Optim™	99.72%	99.60%	99.48%	99.32%	99.09%	98.74%	98.38%	97.87%	96.70%	
1782T/TC	Tendril™	99.81%	99.70%	99.55%	99.41%	99.19%	98.99%	98.77%	98.46%	98.24%	
1788T/TC	Tendril™	99.85%	99.77%	99.69%	99.58%	99.42%	99.22%	98.94%	98.65%	98.42%	
1648T	IsoFlex™ P	99.77%	99.64%	99.39%	99.39%	99.15%	98.80%	98.49%	98.15%	97.80%	
1642T	IsoFlex™ S	99.88%	99.84%	99.78%	99.71%	99.62%	99.50%	99.29%	99.12%	98.91%	98.74%
1646T	IsoFlex™ S	99.87%	99.81%	99.72%	99.62%	99.49%	99.33%	99.11%	98.89%	98.68%	98.45%
1688T/TC	Tendril™ SDX	99.85%	99.75%	99.64%	99.52%	99.37%	99.18%	98.95%	98.67%	98.41%	98.13%
1488T/TC	Tendril™ SDX	99.82%	99.70%	99.62%	99.52%	99.40%	99.29%	99.17%	98.99%	98.79%	98.49%
1368	AV Plus™ DX	99.81%	99.81%	99.75%	99.63%	99.56%	99.39%	99.29%	99.17%	99.17%	98.86%
1388T/TC	Tendril™ + DX	99.77%	99.62%	99.48%	99.30%	99.16%	99.02%	98.86%	98.66%	98.50%	98.29%
1336T, 1342T, 1346T	Passive Plus™ DX	99.84%	99.73%	99.63%	99.53%	99.45%	99.37%	99.31%	99.25%	99.18%	99.10%

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	
2088TC	May-09	475,458	396,105	68	0.01%	5	<0.01%	429	0.09%	113	0.02%	35	<0.01%	18	<0.01%	10	<0.01%	26	<0.01%	3	<0.01%	89	0.02%	**796**	**0.17%**	**377**
1999	May-07	43,154	29,517	3	<0.01%	0	0.00%	54	0.13%	6	0.01%	5	0.01%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	11	0.03%	**83**	**0.19%**	**47**
1944	Mar-08	14,941	9,599	0	0.00%	0	0.00%	54	0.36%	7	0.05%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	**66**	**0.44%**	**40**
1948	Mar-08	56,732	44,700	2	<0.01%	0	0.00%	40	0.07%	23	0.04%	1	<0.01%	2	<0.01%	4	<0.01%	1	<0.01%	2	<0.01%	5	<0.01%	**80**	**0.14%**	**44**
1699T/TC	May-07	22,876	10,952	1	<0.01%	0	0.00%	4	0.02%	3	0.01%	2	<0.01%	8	0.03%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**20**	**0.09%**	**16**
1888T/TC	Jun-06	301,003	162,511	39	0.01%	7	<0.01%	156	0.05%	85	0.03%	16	<0.01%	14	<0.01%	7	<0.01%	9	<0.01%	5	<0.01%	40	0.01%	**378**	**0.13%**	**198**
1882T/TC	Jun-06	45,255	27,888	3	<0.01%	0	0.00%	41	0.09%	10	0.02%	5	0.01%	4	<0.01%	0	0.00%	1	<0.01%	0	0.00%	13	0.03%	**77**	**0.17%**	**43**
1782T/TC	Feb-06	16,401	7,512	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	65,200	27,428	12	0.02%	1	<0.01%	31	0.05%	30	0.05%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**110**	**0.17%**	**46**
1648T	Apr-05	2,834	1,144	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	27,101	10,704	0	0.00%	0	0.00%	49	0.18%	6	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**62**	**0.23%**	**39**
1646T	May-02	90,309	34,680	4	<0.01%	2	<0.01%	37	0.04%	33	0.04%	0	0.00%	2	<0.01%	2	<0.01%	6	<0.01%	0	0.00%	2	<0.01%	**88**	**0.10%**	**38**
1688T/TC	Jun-03	480,012	263,917	77	0.02%	4	<0.01%	296	0.06%	182	0.04%	16	<0.01%	33	<0.01%	10	<0.01%	28	<0.01%	7	<0.01%	59	0.01%	**712**	**0.15%**	**327**

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	
2088TC	May-09	475,458	396,105	39	<0.01%	115	0.02%	542	0.11%	394	0.08%	1066	0.22%	73	0.02%	124	0.03%	89	0.02%	18	<0.01%	96	0.02%	**2556**	**0.54%**	**960**
1999	May-07	43,154	29,517	0	0.00%	4	<0.01%	117	0.27%	35	0.08%	89	0.21%	16	0.04%	22	0.05%	6	0.01%	0	0.00%	13	0.03%	**302**	**0.70%**	**132**
1944	Mar-08	14,941	9,599	1	<0.01%	5	0.03%	37	0.25%	19	0.13%	30	0.20%	4	0.03%	4	0.03%	1	<0.01%	1	<0.01%	2	0.01%	**104**	**0.70%**	**22**
1948	Mar-08	56,732	44,700	9	0.02%	48	0.08%	48	0.08%	93	0.16%	124	0.22%	2	<0.01%	31	0.05%	21	0.04%	4	<0.01%	5	<0.01%	**385**	**0.68%**	**82**
1699T/TC	May-07	22,876	10,952	0	0.00%	13	0.06%	44	0.19%	34	0.15%	67	0.29%	20	0.09%	4	0.02%	16	0.07%	3	0.01%	3	0.01%	**204**	**0.89%**	**63**
1888T/TC	Jun-06	301,003	162,511	37	0.01%	178	0.06%	473	0.16%	605	0.20%	1303	0.43%	97	0.03%	243	0.08%	176	0.06%	31	0.01%	95	0.03%	**3238**	**1.08%**	**1020**
1882T/TC	Jun-06	45,255	27,888	3	<0.01%	11	0.02%	112	0.25%	53	0.12%	113	0.25%	16	0.04%	28	0.06%	8	0.02%	3	<0.01%	20	0.04%	**367**	**0.81%**	**125**
1782T/TC	Feb-06	16,401	7,512	0	0.00%	3	0.02%	45	0.27%	39	0.24%	40	0.24%	5	0.03%	3	0.02%	14	0.09%	1	<0.01%	3	0.02%	**153**	**0.93%**	**55**
1788T/TC	Feb-06	65,200	27,428	7	0.01%	22	0.03%	74	0.11%	137	0.21%	148	0.23%	22	0.03%	28	0.04%	41	0.06%	7	0.01%	24	0.04%	**510**	**0.78%**	**141**
1648T	Apr-05	2,834	1,144	0	0.00%	4	0.14%	2	0.07%	8	0.28%	2	0.07%	1	0.04%	8	0.28%	3	0.11%	0	0.00%	3	0.11%	**31**	**1.09%**	**6**
1642T	May-02	27,101	10,704	0	0.00%	6	0.02%	40	0.15%	50	0.18%	31	0.11%	15	0.06%	6	0.02%	7	0.03%	2	<0.01%	2	<0.01%	**159**	**0.59%**	**24**
1646T	May-02	90,309	34,680	2	<0.01%	90	0.10%	35	0.04%	262	0.29%	104	0.12%	11	0.01%	39	0.04%	100	0.11%	5	<0.01%	20	0.02%	**668**	**0.74%**	**91**
1688T/TC	Jun-03	480,012	263,917	37	<0.01%	401	0.08%	487	0.10%	1129	0.24%	1171	0.24%	124	0.03%	193	0.04%	479	0.10%	36	<0.01%	139	0.03%	**4196**	**0.87%**	**1169**

Definitions of observations and complications can be found on pages 9-10.

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
2088TC	475,458	2.50%	30	<0.01%	372	0.08%	0	0.00%	25	<0.01%	713	0.15%	**1140**	**0.24%**
1999	43,154	2.70%	5	0.01%	23	0.05%	0	0.00%	5	0.01%	117	0.27%	**150**	**0.35%**
1944	14,941	3.60%	0	0.00%	6	0.04%	0	0.00%	1	<0.01%	19	0.13%	**26**	**0.17%**
1948	56,732	2.40%	9	0.02%	50	0.09%	0	0.00%	1	<0.01%	56	0.10%	**116**	**0.20%**
1699T/TC	22,876	4.20%	13	0.06%	23	0.10%	0	0.00%	0	0.00%	49	0.21%	**85**	**0.37%**
1888T/TC	301,003	3.40%	31	0.01%	604	0.20%	1	<0.01%	12	<0.01%	705	0.23%	**1353**	**0.45%**
1882T/TC	45,255	2.80%	2	<0.01%	42	0.09%	0	0.00%	3	<0.01%	108	0.24%	**155**	**0.34%**
1782T/TC	16,401	4.20%	1	<0.01%	22	0.13%	0	0.00%	0	0.00%	47	0.29%	**70**	**0.43%**
1788T/TC	65,200	4.50%	8	0.01%	98	0.15%	1	<0.01%	1	<0.01%	98	0.15%	**206**	**0.32%**
1648T	2,834	5.40%	0	0.00%	11	0.39%	0	0.00%	2	0.07%	5	0.18%	**18**	**0.64%**
1642T	27,101	3.90%	0	0.00%	19	0.07%	1	<0.01%	2	<0.01%	18	0.07%	**40**	**0.15%**
1646T	90,309	3.90%	21	0.02%	47	0.05%	0	0.00%	6	<0.01%	63	0.07%	**137**	**0.15%**
1688T/TC	480,012	3.90%	194	0.04%	708	0.15%	2	<0.01%	16	<0.01%	689	0.14%	**1609**	**0.34%**
1488T/TC	270,792	4.10%	155	0.06%	257	0.09%	5	<0.01%	3	<0.01%	349	0.13%	**769**	**0.28%**

Worldwide Malfunction Summary (Tendril™ 2088 & 1888)

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
2088TC	1,100,386	1.3%	43	<0.01%	452	0.04%	0	0.00%	59	0.01%	932	0.08%	**1486**	**0.14%**
1888T/TC	1,046,935	1.2%	51	<0.01%	753	0.07%	1	<0.01%	31	<0.01%	1032	0.10%	**1868**	**0.18%**

Definitions of malfunction categories can be found on pages 10-12.

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	3,808	2,139	162,474	1	0.03%	1	0.03%	1	0.03%	1	0.03%	3	0.08%	1	0.03%	6	0.16%	14	0.37%	8	0.21%	1	0.03%	0	0.00%	**37**	**0.97%**
1999	860	476	34,358	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	2	0.23%	1	0.12%	10	1.16%	1	0.12%	0	0.00%	0	0.00%	**16**	**1.86%**
1944	104	38	5,391	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	766	237	31,305	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.13%	0	0.00%	1	0.13%	2	0.26%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.52%**
1699T/TC	1,451	385	65,463	1	0.07%	0	0.00%	2	0.14%	0	0.00%	4	0.28%	0	0.00%	1	0.07%	8	0.55%	1	0.07%	0	0.00%	0	0.00%	**17**	**1.17%**
1888T/TC	14,505	5,207	754,337	6	0.04%	2	0.01%	6	0.04%	3	0.02%	19	0.13%	4	0.03%	25	0.17%	57	0.39%	16	0.11%	0	0.00%	1	<0.01%	**139**	**0.96%**
1882T/TC	689	286	35,348	0	0.00%	0	0.00%	0	0.00%	1	0.15%	1	0.15%	0	0.00%	0	0.00%	2	0.29%	1	0.15%	0	0.00%	1	0.15%	**6**	**0.87%**
1782T/TC	165	19	5,525	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	70	11,921	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	15,737	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	2,642	503	85,579	3	0.11%	0	0.00%	2	0.08%	0	0.00%	3	0.11%	0	0.00%	3	0.11%	5	0.19%	2	0.08%	1	0.04%	0	0.00%	**19**	**0.72%**
1488T/TC	802	84	26,121	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	1	0.12%	0	0.00%	2	0.25%	0	0.00%	0	0.00%	**4**	**0.50%**
1388T/TC	238	15	7,108	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.84%	0	0.00%	1	0.42%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**1.26%**

Malfunction Summary

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
2088	3,808	3.50%	1	0.03%	12	0.32%	0	0.00%	0	0.00%	11	0.29%	**24**	**0.63%**
1999	860	4.50%	0	0.00%	2	0.23%	0	0.00%	0	0.00%	8	0.93%	**10**	**1.16%**
1944	104	1.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	766	3.30%	0	0.00%	4	0.52%	0	0.00%	0	0.00%	1	0.13%	**5**	**0.65%**
1699T/TC	1,451	2.80%	0	0.00%	2	0.14%	0	0.00%	0	0.00%	5	0.34%	**7**	**0.48%**
1888T/TC	14,505	2.80%	3	0.02%	22	0.15%	0	0.00%	0	0.00%	33	0.23%	**58**	**0.40%**
1882T/TC	689	3.30%	0	0.00%	2	0.29%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.29%**
1782T/TC	165	2.40%	0	0.00%	1	0.61%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.61%**
1788T/TC	363	1.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	641	1.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	2,642	3.90%	1	0.04%	4	0.15%	0	0.00%	0	0.00%	5	0.19%	**10**	**0.38%**
1488T/TC	802	3.10%	0	0.00%	4	0.50%	0	0.00%	0	0.00%	1	0.12%	**5**	**0.62%**
1388T/TC	238	2.10%	0	0.00%	1	0.42%	0	0.00%	0	0.00%	1	0.42%	**2**	**0.84%**

A list of complications can be found on page 15.
Definitions of malfunction categories can be found on pages 10-12.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical

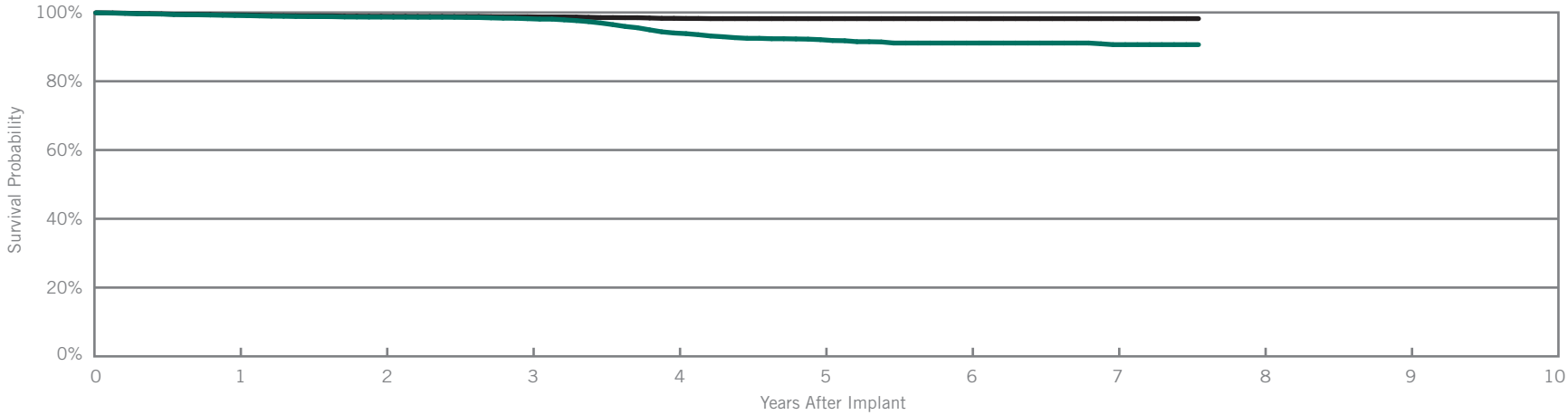
Customer Reported Performance Data

SJM Confirm™

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	18,681
Estimated Active US Implants	8,423
Estimated Longevity	3 Years*
Normal Battery Depletion	161
Number of US Advisories (see pg. 312)	One

	Malfunctions	
	Qty	Rate
Electrical Component	13	0.07%
Electrical Interconnect	1	<0.01%
Battery	17	0.09%
Software/Firmware	10	0.05%
Mechanical	0	0.00%
Possible Early Battery Depletion	8	0.04%
Other	37	0.20%
Total	**86**	**0.46%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.13%	98.66%	98.19%	94.03%	92.09%	91.11%	90.64%	90.64%		
± 1 standard error	0.07%	0.09%	0.11%	0.27%	0.34%	0.39%	0.42%	0.45%		
Sample Size	16,280	12,370	9,230	6,290	3,980	2,340	1,190	230		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.30%	98.90%	98.76%	98.29%	98.21%	98.21%	98.21%	98.21%		
± 1 standard error	0.06%	0.09%	0.09%	0.13%	0.13%	0.13%	0.13%	0.13%		

**After 12 month shelf-life.*

Summary Information

Implantable Cardiac Monitors (ICMs)

St. Jude Medical

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
DM2100	SJM Confirm™	99.13%	98.66%	98.19%	94.03%	92.09%	91.11%	90.64%			

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
DM2100	SJM Confirm™	99.30%	98.90%	98.76%	98.29%	98.21%	98.21%	98.21%			

U.S. Malfunction Summary

Models	Family	Registered US Implants	Percent Returned for Analysis	Malfunctions															
				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
DM2100	SJM Confirm™	18,681	15.20%	13	0.07%	1	<0.01%	17	0.09%	10	0.05%	0	0.00%	8	0.04%	37	0.20%	**86**	**0.46%**

Definitions of malfunction categories can be found on pages 7-8.

Focus on Clinical Performance

St. Jude Medical

Update on Riata™ Lead Performance

Registry and Post-Market Studies

Prospective, monitored registries continue to provide the best data to support clinical decision making. St. Jude Medical 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 St. Jude Medical 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, St. Jude Medical 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 and cinefluoroscopy will be done 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 is ongoing in CLAS. The following summaries for Riata/Riata ST and QuickSite/QuickFlex leads represent all data collected as of August 31, 2016. The Durata leads CLAS summary is available on page 287.

[1] David Hayes, Roger Freedman, Mark Niebauer, Vance Plumb, Jay Dinerman, Scott Beau, Anne Curtis, I*ncidence 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 CLAS Summary (as of August 31, 2016): A total of 776 patients with Riata/Riata ST silicone leads across 23 centers (8F/7F= 66.6%/33.4%) were analyzed at enrollment. The prevalence of externalized conductors (EC) at enrollment was significantly lower in 7F Riata ST leads compared to 8F Riata leads (9.3% vs. 24.0%, p<0.0001). A total of 548 patients (71%) completed at least 1 year of follow-up with fluoroscopic evaluation. The incidence of new EC during the first year of follow-up in the study was 1.7% (3/177) in 7F leads and 4.3% (12/280) in 8F leads (p = 0.13). A total of 430 patients (55%) completed at least 2 years of follow-up with fluoroscopic evaluation. The incidence of new EC during the second year of follow-up in the study was 2.1% (3/140) in 7F leads and 7.1% (15/210) in 8F leads (p = 0.04). A total of 329 patients (42%) completed at least 3 years of follow-up with fluoroscopic evaluation. The incidence of new EC during the third year of follow-up in the study was 0.9% (1/115) in 7F leads and 8.8% (13/148) in 8F leads (p = 0.005). A total of 28 leads (10 with EC, 18 without EC) were identified as having electrical dysfunction. The electrical failure rate is 5.1% (10/195) in leads with EC and 3.1% (18/581) in leads without EC; the difference is not statistically significant at p= 0.19. All pending fluoroscopy data has been adjudicated and the minimum enrollment of Riata/Riata ST leads has been met in the Cardiac Lead Assessment Study.

QuickSite™/QuickFlex™ CLAS Summary (as of August 31, 2016): A total of701 patients implanted with QuickSite/QuickFlex Left Ventricular CRT leads at 43 centers underwent fluoroscopic evaluation. These include 101 leads implanted in 2006, 123 leads in 2007, 148 leads in 2008, 205 leads in 2009, and 124 leads in 2010, with an implant duration of 5.0±1.4 years (mean±stdev; median = 4.9 years; IQR = 4.0 to 5.9 years) at enrollment. The prevalence of externalized conductors at enrollment was 1.28%. A total of 452 patients (64%) completed at least 1 year of follow-up with fluoroscopic evaluation. The incidence of new EC at 1 year of follow-up was 3.6% (16/445). A total of 216 patients (31%) completed at least 2 years of follow-up with fluoroscopic evaluation. The incidence of new EC at 2 years of follow-up was 1.0% (3/296). A total of 130 patients (19%) completed at least 3 years of follow-up with fluoroscopic evaluation. There was no incidence of new EC at 3 years of follow-up. A total of 2 leads were identified as having electrical dysfunction. Neither of these 2 leads exhibited externalized conductors. All pending fluoroscopy data has been adjudicated and the minimum enrollment of QuickSite/QuickFlex leads has been met in the Cardiac Lead Assessment Study.

Customer Reported Performance Data

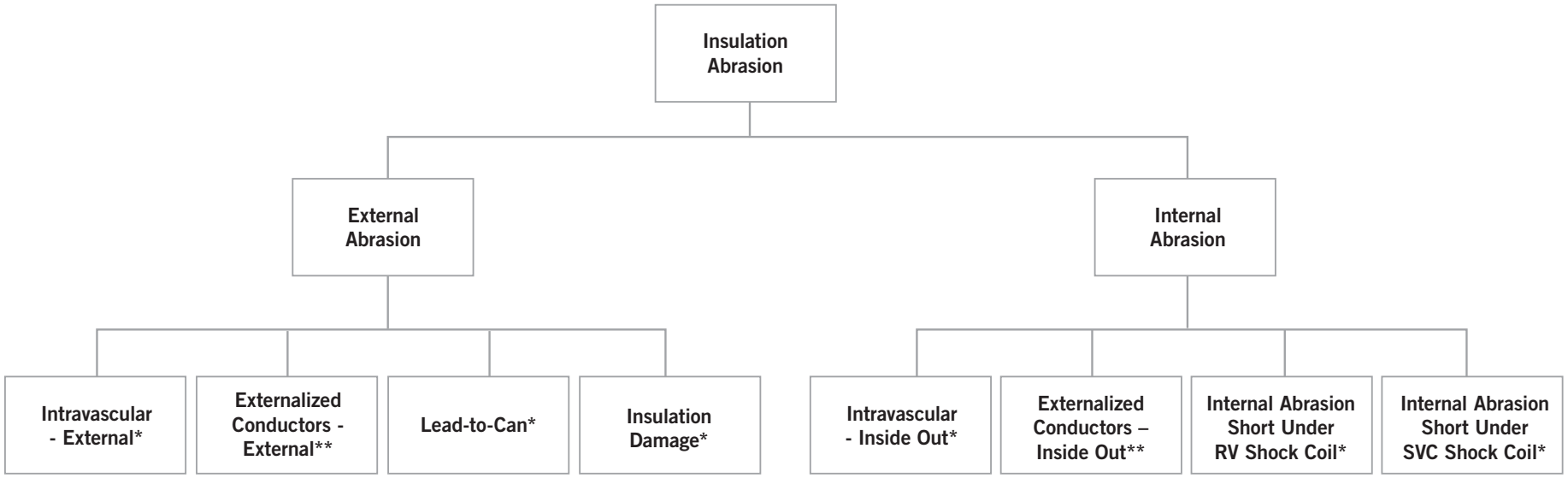
St. Jude Medical understands that the passive system of complaint reporting and returned product analysis results in under-reporting and hence underestimates the true failure rate associated with any given failure mechanism. This is especially true for externalized conductors since most manifest as visual anomalies only with normal electrical performance. While acknowledging these limitations, St. Jude Medical 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 St. Jude Medical. As of August 31, 2016, there were

5,539 cases of externalized conductors reported to St. Jude Medical worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 3.00% (4,680/156,000) incidence rate for Riata (8F) and 1.22% (859/70,600) for Riata ST (7F) leads. Of these 5,539 leads, 4,124 were not returned and 1,415 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 86% of confirmed externalized conductors from product returns analysis are caused by inside-out abrasion, while 14% 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 13,100 Riata and Riata ST leads have been returned for analysis worldwide through August 31, 2016. 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	0.47%	0.48%
Externalized Conductors – External**	External Abrasion	0.41%	0.20%
Lead-to-Can*	External Abrasion	0.88%	0.81%
Insulation Damage*	External Abrasion	0.11%	0.06%
Intravascular - Inside Out*	Internal Abrasion	0.52%	0.34%
Externalized Conductors - Inside Out**	Internal Abrasion	2.60%	1.02%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.11%	0.04%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.09%	0.018%

*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 is 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 282, 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, 2016, a total of 961 patients implanted with Durata leads at 42 centers underwent fluoroscopic evaluation. These include 282 leads implanted in 2008, 407 leads in 2009, and 272 leads in 2010 with an implant duration of 4.5±1.1 years (mean±stdev; median = 4.5 years; IQR = 3.6 to 5.3 years) at enrollment. None of the 961 leads at enrollment exhibited externalized conductors. A total of 706 patients (73%) completed 1 year follow-up with fluoroscopic evaluation. The incidence of new EC at 1 year of follow-up was 0.14% (1/706). Based on fluoroscopic images of this lead, the externalization appears to be extravascular, under the clavicle and is likely due to clavicular crush. The electrical function of this lead has been normal. A total of 498 patients (52%) completed 2 years of follow-up with fluoroscopic evaluation. The incidence of new EC at 2 years of follow-up was 0.20% (1/498). Based on fluoroscopic images of this lead, the location of externalized conductors is coincident with an annuloplasty tricuspid ring. Therefore, the mechanism of externalization is likely to be external insulation abrasion due to friction with this triscupid ring. The electrical function of this lead has been normal. A total of 152 patients (16%) completed 3 years of follow-up with fluoroscopic evaluation. There was no incidence of new EC at 3 years of follow-up. A total of 18 leads (1.9%) out of the 961 enrolled patients were identified as having electrical dysfunction. None of these 18 leads exhibited externalized conductors. All pending fluoroscopy data has been adjudicated and the minimum enrollment of Durata leads has been met in the Cardiac Lead Assessment Study.

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 11,105 Optim insulated leads (8,239 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, 2016, 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, 2016)

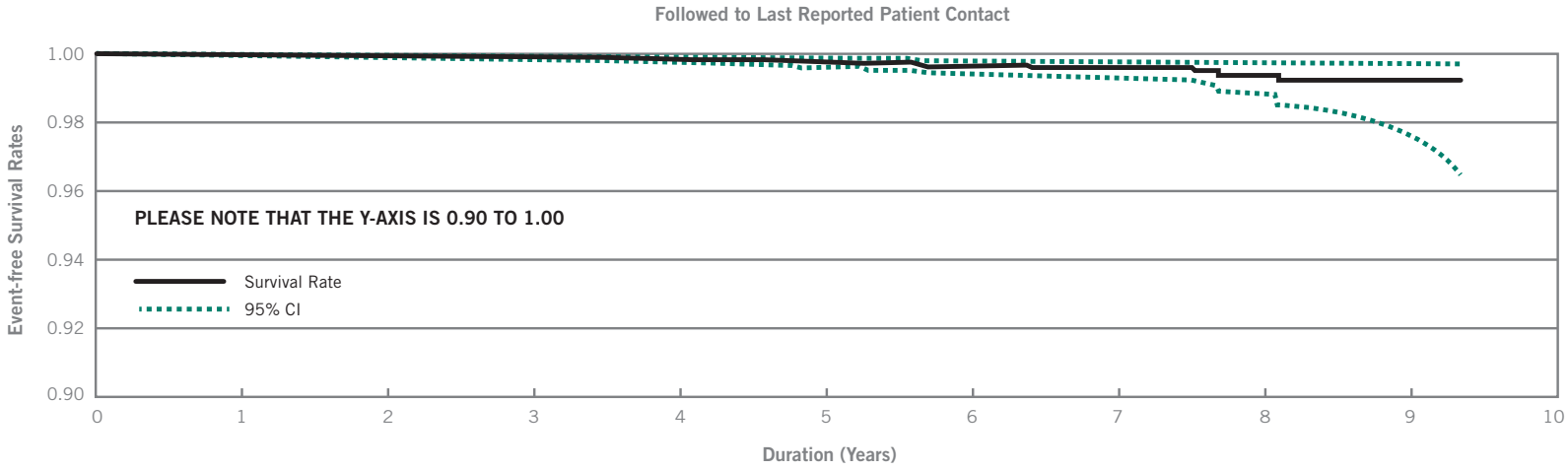
Failure Category	Durata and Riata ST Optim %	Durata and Riata ST Optim 95% CI	Freedom from failures at 9 years (%)
Externalized Conductors	0.00%	0.00% - 0.03%	100%
All-Cause Insulation Abrasion	0.23%	0.15% - 0.33%	99.2%
All-Cause Mechanical Failures	1.05%	0.87% - 1.25%	96.9%

Event-Free Survival Rates for All-Cause Insulation Abrasion (Figure 1), and All-Cause Mechanical Failures (Figure 2) 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 SJM 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.

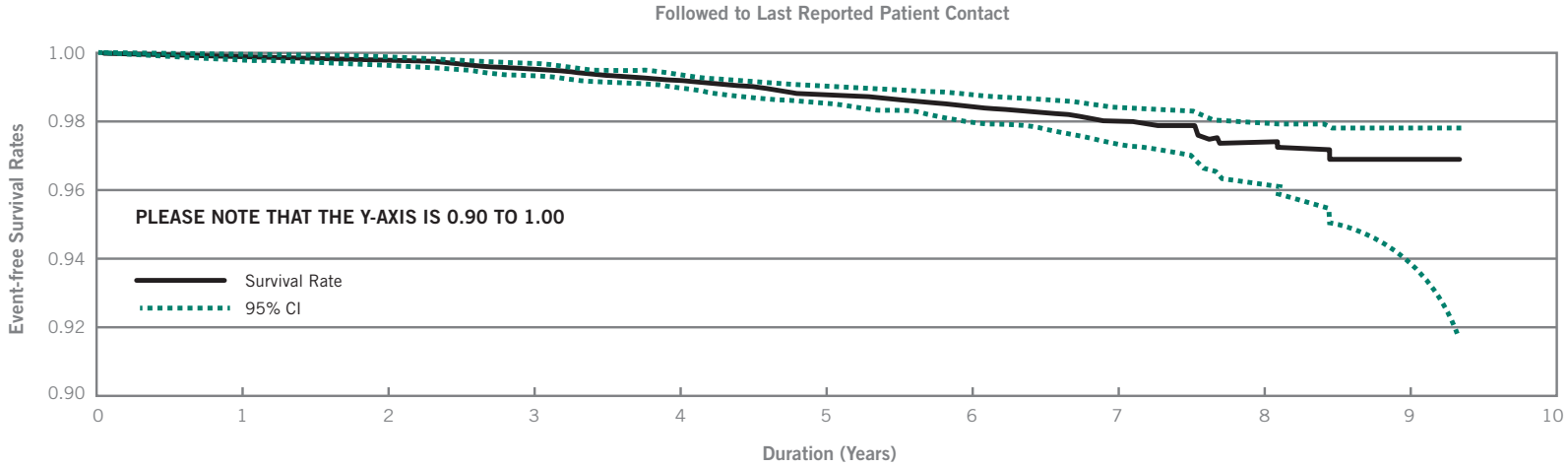
[1] John A. Cairns, Andrew E. Epstein, John Rickard, Stuart J. Connolly, Christopher Buller, Bruce L. Wilkoff, Janice Pogue, Ellison Themeles, Jeff S. Healey, *Prospective long-term evaluation of Optim-insulated (Riata ST Optim and Durata) implantable cardioverter-defibrillator leads,* Heart Rhythm,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

Figure 1: 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	
Leads at Risk	11,105	9,798	8,504	7,288	6,158	4,696	3,140	1,763	633	119	

Figure 2: 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	
Leads at Risk	11,105	9,797	8,503	7,285	6,154	4,694	3,138	1,759	630	119	

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 18,000 Riata ST Optim and Durata leads have been returned for analysis worldwide through August 31, 2016. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive.

Durata™ (WW Sales 616,000) 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 = 649,000)
Intravascular – External*	External Abrasion	0.020%
Externalized Conductors – External**	External Abrasion	0.004%
Lead-to-Can*	External Abrasion	0.065%
Insulation Damage*	External Abrasion	0.021%
Intravascular - Inside Out*	Internal Abrasion	0.0015%***
Externalized Conductors - Inside Out**	Internal Abrasion	0.0002%***
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.008%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.007%

*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, Riata ST silicone leads (see page 286).

Update on Optim™ Lead Insulation

In 2006 St. Jude Medical 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 >4.3 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.

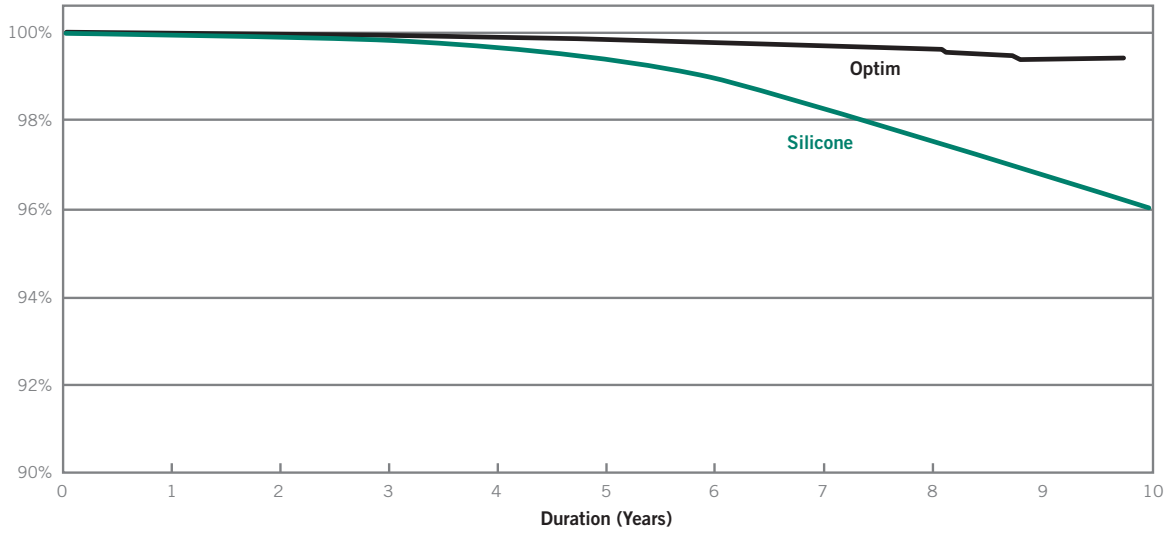
This product performance report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on St. Jude Medical™ tachycardia leads. A Kaplan-Meier analysis including all U.S. data through June 30, 2016 was performed on two groups of leads: (1) tachycardia leads with silicone 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 116 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 116 months of implant time is also presented in graphical format below.

The data show that the presence of Optim™ lead insulation dramatically reduces the probability of abrasion malfunction in tachycardia leads at 116 months by 84%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test.

Optim™ Lead Insulation Effects on SJM Tachycardia Lead Abrasion

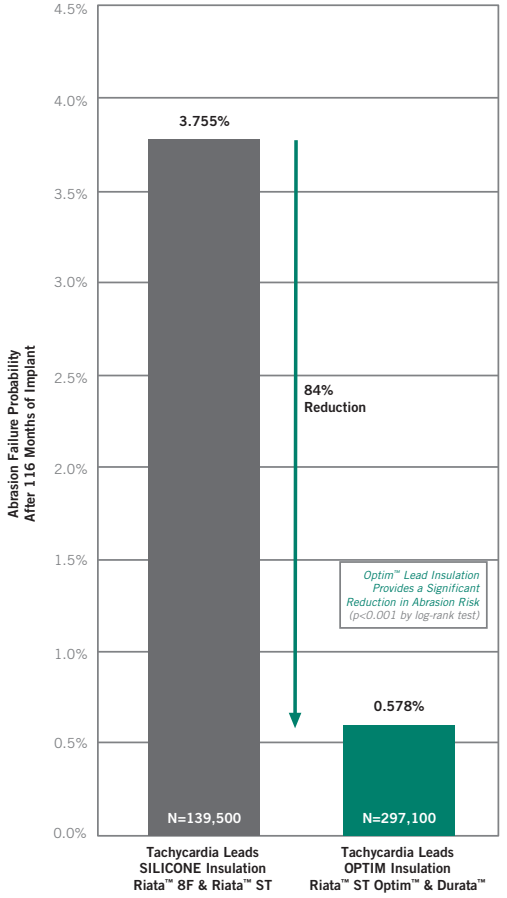
Kaplan-Meier Analysis of U.S. Returns Analysis Data

Freedom from Abrasion Failure (%)



Year	1	2	3	4	5	6	7	8	9
Optim	245,491	206,718	166,346	132,728	98,143	63,628	36,671	12,985	3,571
Silicone	121,434	110,985	101,005	91,466	82,815	74,852	66,838	57,906	44,592

Abrasion Malfunction Probability after 116 Months of Implant



[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).

Advisories & Safety Alerts

St. Jude Medical

The following table summarizes recalls, advisories and safety alerts regarding St. Jude Medical implantable devices since 1999. These advisories have been previously communicated to physicians. Advisories associated with non-implantable devices such as catheters are not included in the table. For more information please contact St. Jude Medical Technical Services at 1-800-722-3774.

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, 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)
	Advisory
	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.
		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.
		
		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: 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. Forty-six (46) devices worldwide had visible electrical shorting due to lithium clusters.
		
		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, 2016):** 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, 2016, there were additional reports and the rate is now 0.77%. 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, 2016):** 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 St. Jude Medical 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, 2016):** At the time of the advisory there were 20 devices confirmed to be affected by this issue. As of June 30, 2016 there were an additional 52 devices confirmed with this issue. There have been no reports of serious injury or death.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Convert™+ (Model V-195)	5/6/2010 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, 2016):** 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, 2016, 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, 2016):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of 30, 2016 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, St. Jude Medical 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, 2016):** 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, 2016 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 St. Jude Medical. **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 St. Jude Medical 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. St. Jude Medical 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), St. Jude Medical 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, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (June 30, 2016):** 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, St. Jude Medical 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, St. Jude Medical 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, 2016):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Profile™ V-186	7/13/2001 Class II Failure of a ceramic capacitor could lead to sensing anomalies/ early battery depletion	This Advisory applies to a well-defined group of Profile™ MD (Model V-186HV3) implantable cardioverter-defibrillators (ICDs) which have been observed to exhibit decreased reliability. These devices had specific modules (subcircuits) manufactured during a five-month period during the first half of 1999. **Those potentially affected devices that have not exhibited any anomalous behavior within 24 months of manufacture are not at increased risk of failure at a later date.** These failures were caused by a component anomaly that is limited to a specific, traceable lot (group) of capacitors. If these capacitors fail, two different clinical manifestations may be observed, depending on the location of the failed capacitors: **Low Voltage Module:** The devices may exhibit sudden loss of sensing or oversensing of internally generated interference (noise) resulting in aborted or delivered shocks. Due to the potential for sudden loss of sensing, which would prevent the ICD from detecting ventricular tachyarrhythmias, device replacement should be considered for patients with devices incorporating the suspect capacitors in this location. In making this decision, you should weigh the likelihood that your patient will have one of the few additional devices expected to fail against the risk associated with the replacement procedure. For patients who do not have their devices replaced, St. Jude Medical recommends monthly monitoring for the remaining months during which additional failures are expected to occur and every three months thereafter. **High-Voltage Module:** The devices may exhibit premature battery depletion with no other clinical manifestations. While the battery voltage may drop rapidly to a value near or below the device's ERI, it stabilizes for several months at a value at which the device continues to detect arrhythmias and deliver therapy appropriately. In addition, some of these devices may exhibit oversensing of internally generated electrical interference (noise), which may result in false detection of tachyarrhythmias. However, during charging, the interference abates, and the therapy is usually aborted without the delivery of inappropriate shocks to the patient. Because these devices generally continue to respond appropriately to spontaneous tachyarrhythmias, and because the battery voltage stabilizes for several months at a level that does not compromise device function, St. Jude Medical recommends that patients with devices incorporating suspect capacitors in this location be monitored monthly for the remaining months during which additional failures are expected to occur and every three months thereafter.

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
	
	St. Jude Medical 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 St. Jude Medical.
		■ 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: 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. 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.	St. Jude Medical 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, 2016):** 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, 2016):** 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 St. Jude Medical 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 St. Jude Medical Identity™ family of pacemakers when programmed by the St. Jude Medical 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, 2016):** 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, 2016 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity ADx™ DR (Models 5286, 5380, 5386, 5480)	7/31/2003 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval. In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual-chamber device would have to satisfy both of the following conditions: Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower AutoCapture™ pacing system programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or AutoCapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program AutoCapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (June 30, 2016):** 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
Tempo™ (Model 2102) Meta™ (Model 1256D)	11/04/2002 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	Decreased reliability has been observed in a group of these devices. The devices in the advisory population were manufactured at the Telectronics' manufacturing facility between the second quarter of 1996 and the second quarter of 1997. Premature battery depletion resulting from bridging between adjacent connectors has resulted in no output or no telemetry in 1% of this population of devices to date. The following recommendations are made: Physicians are advised to review patients who have 1256D/2102 pacemakers at an early date to evaluate pacemaker function. **For patients who are pacemaker dependent,** the physician should give consideration to explantation and replacement as soon as practicable. **For patients who are not considered pacemaker dependent,** the physician should consider replacement only if any abnormal function is identified (such as no output, telemetry loss, telemetry abnormality or premature end of life indication). All remaining non-pacemaker dependent patients with 1256D/2102 pacemakers should subsequently be reviewed at least every six months.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Tempo™ (Models 1102, 1902, 2102, 2902) Meta™ (Model 1256D)	11/04/2002 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	This Advisory applies to a well-defined group of Tempo™ and Meta™ 1256D pacemakers which have been observed to exhibit premature battery depletion. This is an extension of a previous Tempo™/Meta™ advisory dated 6/6/00. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Meta™ DDDR (Model 1256)	6/6/2000 Class II Integrated circuit failure due to electrostatic discharge during manufacturing resulting in no output or sensing anomalies.	This Advisory applies to a well-defined group of Meta™ 1256 pacemakers, which have been observed to exhibit decreased reliability. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Tempo™ (Models 1102, 1902, 2102, 2902) Meta™ (Model 1256D)	6/6/2000 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	This Advisory applies to a well-defined group of Tempo™ and Meta™ 1256D pacemakers, which have been observed to exhibit premature battery depletion. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Trilogy™ (Models 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L)	3/10/2000 Class II Risk of malfunction due to an anomaly of the pacemaker's microprocessor. Typical manifestations of this anomaly are dashes observed on the programmer screen, unexpected rate variation, abnormally high battery current drain, and mode change.	Continued monitoring of Trilogy™ devices affected by an Advisory issued in July 1999 has revealed an additional low level of adverse events. A sub-population of the above models, principally those manufactured before January 1999, is potentially affected by a risk of malfunction due to an anomaly of the pacemaker's microprocessor. To date this has been reported in only 0.11% of the implanted population. Typical manifestations of this anomaly are: Interrogation/programming difficulties, including the presence of dashes (—) on the programmer screen for some parameter values after interrogation Unexpected rate variations Abnormally high battery current drain Mode change The presence of dashes on the programmer screen is typically caused by partial programming of one or more of the programmed parameters and may be corrected by reprogramming. In the event that observed dashes (—-) cannot be resolved by reprogramming, please contact your St. Jude Medical representative, as it may be possible to resolve the situation non-invasively via special programming and may not be indicative of a microprocessor anomaly. Considering the low level of incidence of this anomaly, the following steps are recommended: 1. Assess the patient population, relative to the potential for an inappropriate mode change to single-chamber atrial pacing, to determine which patients are pacemaker-dependent and have an inadequate ventricular escape rhythm. 2. Replacement of a device always remains a matter of clinical judgement, including balancing the clinical risk associated with pacemaker replacement against the risk of device malfunction. 3. Almost all microprocessor malfunctions described in this notification were found during routine follow-up. This reinforces the importance that pacemaker patients should be followed regularly in accordance with best prevailing medical practices.

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Affinity™ (Models 5130L, 5130R, 5330L, 5330R, 5230L, 5230R)	2/14/2000 Class II An unsecured resistor connection to the hybrid circuit might cause abnormal measured data, false RRT indication, backup VVI mode, or intermittent loss of output.	This advisory applies to a very specific, well-defined group of Affinity devices that have been implanted worldwide. The device may exhibit any or all of the following output anomalies: Abnormal measured battery data, A false recommended replacement (RRT) indication, Reversion to back-up VVI mode, Intermittent loss of output. One marker of an affected device that may be apparent during a routine follow-up interrogation is an abnormally high reading for battery current (taking into consideration the device's programmed output parameters). If this or an early indication of RRT or reversion to back-up VVI mode is observed, please contact your local St. Jude Medical representative or Technical Services. Although the time course is variable, these behavioral anomalies will occur before there is any affect on device output.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Trilogy™ (Models 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L)	7/19/1999 Class II Premature battery depletion caused by a current leakage path that could be created during the laser welding process to attach the battery to the device hybrid	Analysis of the clinical data associated with the failed devices has shown that an early increase in battery impedance could be observed at one or more previous routine follow-up visits prior to reaching RRT. The observed rise in battery impedance is an earlier and more reliable indicator than the reported battery voltage. The battery depletion, although accelerated, does not occur abruptly and patients can be monitored using the measured data telemetry in the pacemaker. The following follow-up schedule and device monitoring is advised. 1. For patients who have had a follow-up visit at least 12 months after their device was implanted, check the measured data printout from the last follow-up evaluation. If a battery impedance of "< 1 kOhm" was recorded, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every 6 months is not your routine schedule, then an additional visit at 18 months should be performed. 2. For patients who have not yet had a follow-up visit at least 12 months after their device was implanted, the following is recommended: If the patient has had their device implanted for less than two months or has not had a device interrogation with measured data within the last three months, an evaluation of the battery impedance is recommended as soon as possible. This should be printed and a copy retained in the patient's pacemaker or office chart. Otherwise, if the battery impedance from the most recent evaluation is "< 1 kOhm," begin an every 3-month follow-up schedule with respect to measured data telemetry until that value has been recorded at least 12 months post-implant. Thereafter, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every six months is not your routine schedule, then an additional visit at 18 months should be performed. If the battery impedance reading is 1 kOhm or higher and the pacemaker has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services.

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%.	St. Jude Medical 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, 2016):** 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, 2016, the worldwide reported externalized conductor rate for QuickSite and QuickFlex leads was 0.22%.

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.	St. Jude Medical 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™ 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 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 282-286 of this Product Performance Report.	St. Jude Medical 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. St. Jude Medical™ 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, St. Jude Medical 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, 2016):** 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, 2016, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 4.10% and 2.46% 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, 3rd ed. Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2007. 1063-1086.

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 277-281 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, 2016):** At the time of the advisory there was a worldwide insulation abrasion rate of 0.47% for Riata silicone leads. As of August 31, 2016, there have been additional reports and the worldwide reported insulation abrasion rate is 4.10%.

[1] Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 3rd ed. Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2007. 1063-1086.

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 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, 2016):** 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™ 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 St. Jude Medical Radio Frequency (RF) enabled Implantable Cardioverter Defibrillators (ICDs) and Pacemakers. Potentially affected RF devices include the St. Jude Medical 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. August 19, 2015 An additional software upgrade was implemented to address a second software anomaly coexisted in the Merlin@home system that also had the potential to cause software resets for potentially affected St. Jude Medical 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, 2016):** 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™ remote monitoring. For Assurity and Allure pacemakers, the rate of occurrence was 0.06% based on 12,000 devices followed remotely. As of June 30, 2016, there were additional reports and the rate for Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs, was 0.46%. For Assurity and Allure pacemakers, the rate of occurrence was 0.11%.

Healthcare Professional Communications

St. Jude Medical

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 St. Jude Medical'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 St. Jude Medical pacemakers.	St. Jude Medical 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 St. Jude Medical 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 St. Jude Medical 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

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Index of Phased-out Models

St. Jude Medical

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.SJMprofessional.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™ ST Optim™ (7030, 7031)	Nov 2013
TVL™ RV (RV01, RV02, RV03, RV06, RV07)	May 2010
TVL™ SVC (SV01, SV02, SV03)	May 2010

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
Tempo™ VR (1902)	May 2010

Phased-out Models

Pacemakers	Final Edition
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 (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
Unipolar Lead (Model 1007)	May 2010

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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