Implantable Electronic Systems
Product Performance Report
2016 First 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 the previously published edition, 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.

As we continually strive to provide unbiased and reliable information on the performance of our products, St. Jude Medical is pleased to release the first 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 December 31, 2015, 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 December 31, 2015, 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 277-281). This section provides the latest Riata 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 282-286).

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 287-288).

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 305-307) 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 CD3357-40Q)*
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 First 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.SJMprofessional.com, or by contacting your local St. Jude Medical representative.

Cardiac Resynchronization Therapy (CRT) Devices

CRT ICDs

St. Jude Medical™

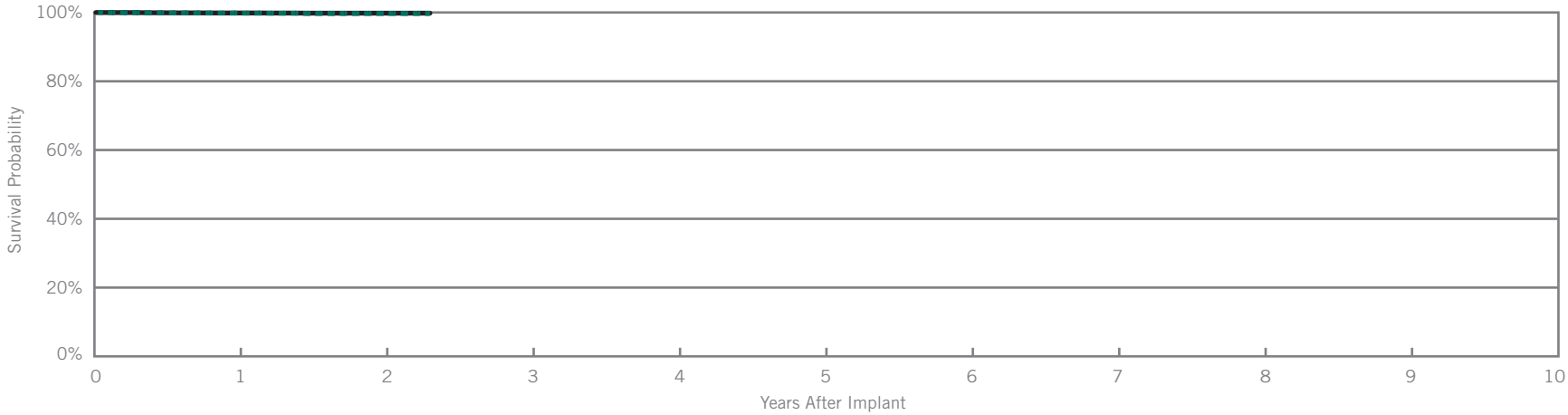
Quadra Assura™ CRT-D

Model CD3365-40Q*

US Regulatory Approval	June 2013
Registered US Implants	28,951
Estimated Active US Implants	25,343
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	5
Max. Delivered Energy	40 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	<0.01%	3	0.01%
Electrical Interconnect	3	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%	3	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	3	0.01%	0	0.00%
Total	**8**	**0.03%**	**8**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.81%	99.70%	99.70%							
± 1 standard error	0.03%	0.05%	0.05%							
Sample Size	20,920	7,110	230							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.85%	99.80%	99.80%							
± 1 standard error	0.03%	0.04%	0.04%							

**DF4-LLHH connector type.*

Actively Monitored Study Data

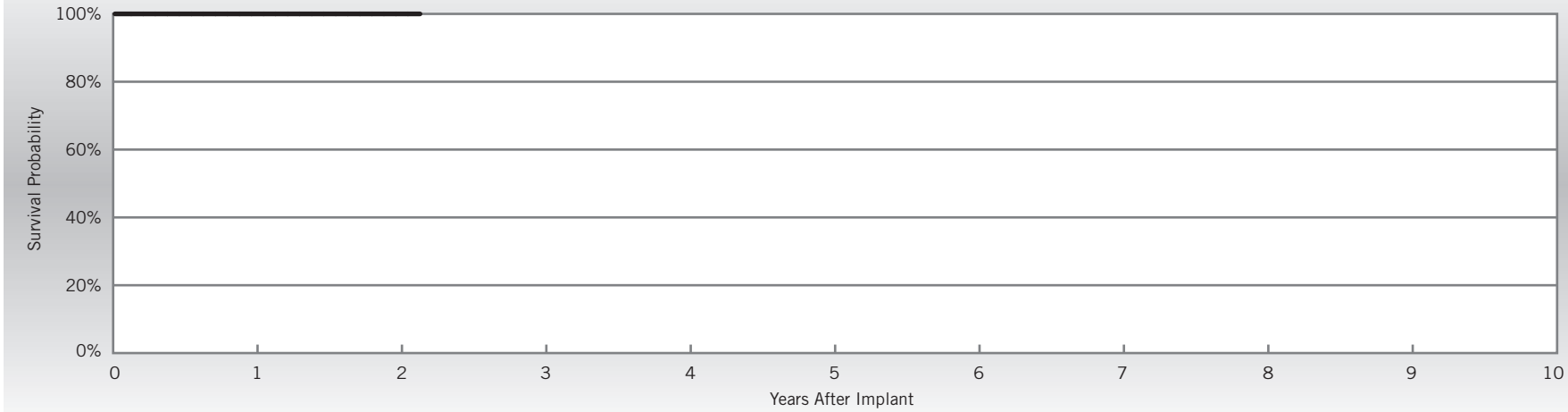
Quadra Assura™ CRT-D

Model CD3365-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	163
Active Devices Enrolled in Study	133
Cumulative Months of Follow-up	3,422
Estimated Longevity	(see table on page 46)
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 26 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	150	120	80							

**DF4-LLHH connector type.*

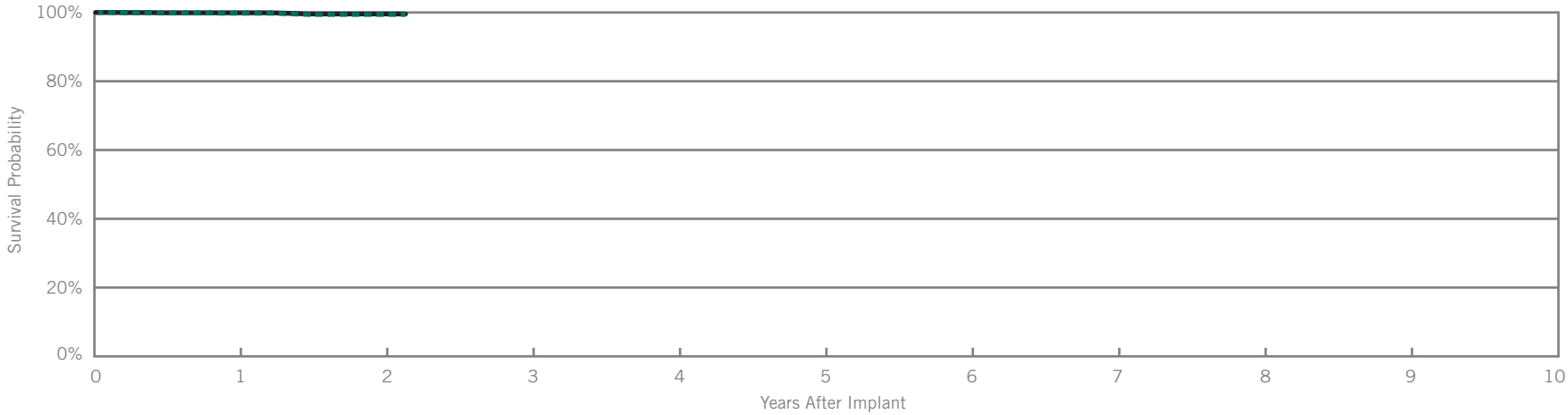
Quadra Assura™ CRT-D

Model CD3365-40C*

US Regulatory Approval	June 2013
Registered US Implants	5,757
Estimated Active US Implants	5,025
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	2
Max. Delivered Energy	40 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	0	0.00%	1	0.02%
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	0	0.00%	1	0.02%
Other	1	0.02%	1	0.02%
Total	**2**	**0.03%**	**3**	**0.05%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.78%	99.43%	99.43%							
± 1 standard error	0.07%	0.16%	0.16%							
Sample Size	4,220	1,510	240							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.91%	99.57%	99.57%							
± 1 standard error	0.04%	0.15%	0.15%							

**Parylene coating.*

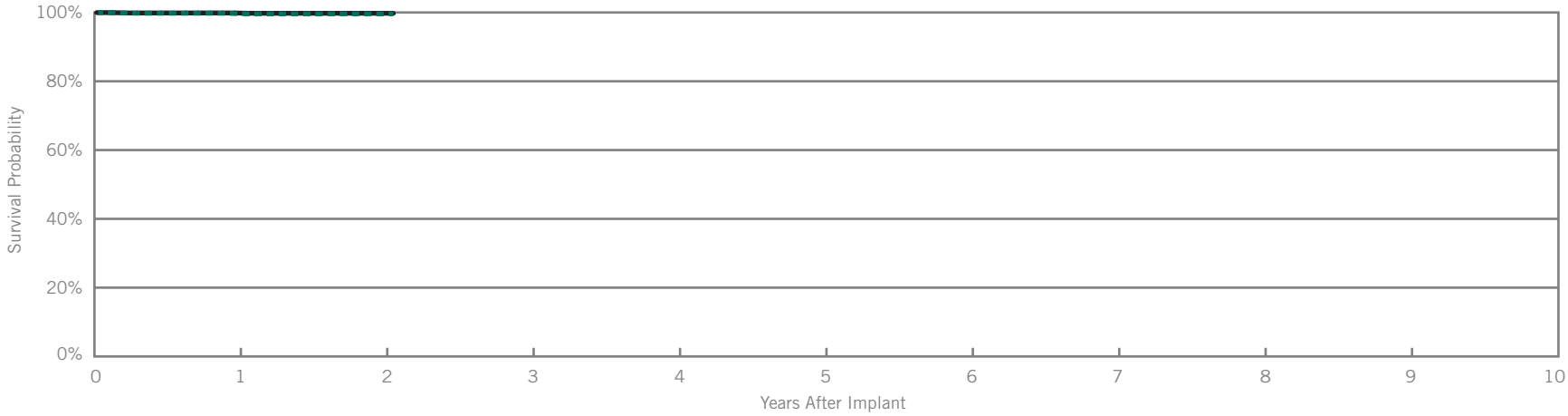
Unify Assura™ CRT-D

Model CD3357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	5,790
Estimated Active US Implants	5,046
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	3
Max. Delivered Energy	40 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	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	0.02%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.05%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.70%	99.61%	99.61%							
± 1 standard error	0.07%	0.11%	0.11%							
Sample Size	4,030	1,280	280							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.86%	99.77%	99.77%							
± 1 standard error	0.05%	0.08%	0.08%							

**DF4-LLHH connector type.*

Actively Monitored Study Data

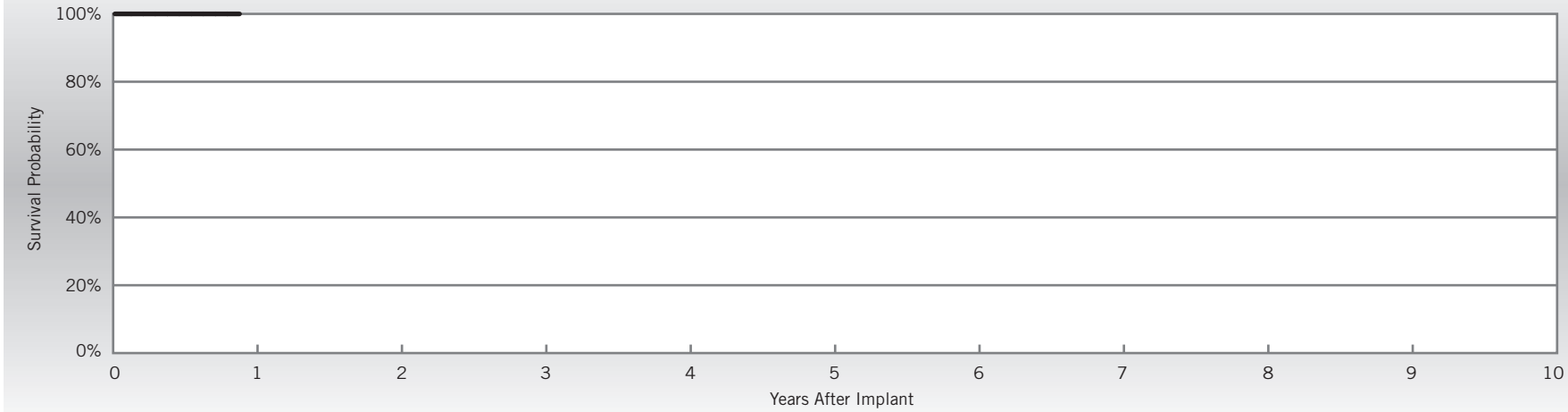
Unify Assura™ CRT-D

Model CD3357-40Q*

US Regulatory Approval	June 2013
Number of Devices Enrolled in Study	101
Active Devices Enrolled in Study	93
Cumulative Months of Follow-up	1,088
Estimated Longevity	(see table on page 46)
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	at 11 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

**DF4-LLHH connector type.*

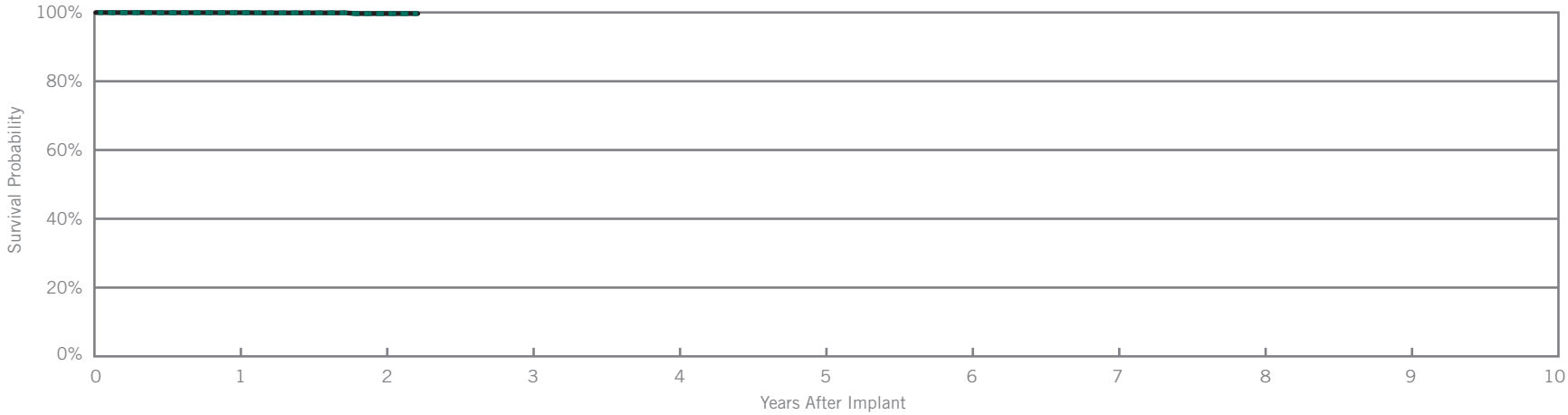
Unify Assura™ CRT-D

Model CD3357-40C*

US Regulatory Approval	June 2013
Registered US Implants	10,958
Estimated Active US Implants	9,562
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	1
Max. Delivered Energy	40 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	1	<0.01%	1	<0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.03%**	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.92%	99.67%	99.67%							
± 1 standard error	0.03%	0.15%	0.15%							
Sample Size	7,880	2,630	220							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.94%	99.69%	99.69%							
± 1 standard error	0.03%	0.15%	0.15%							

**Parylene coating.*

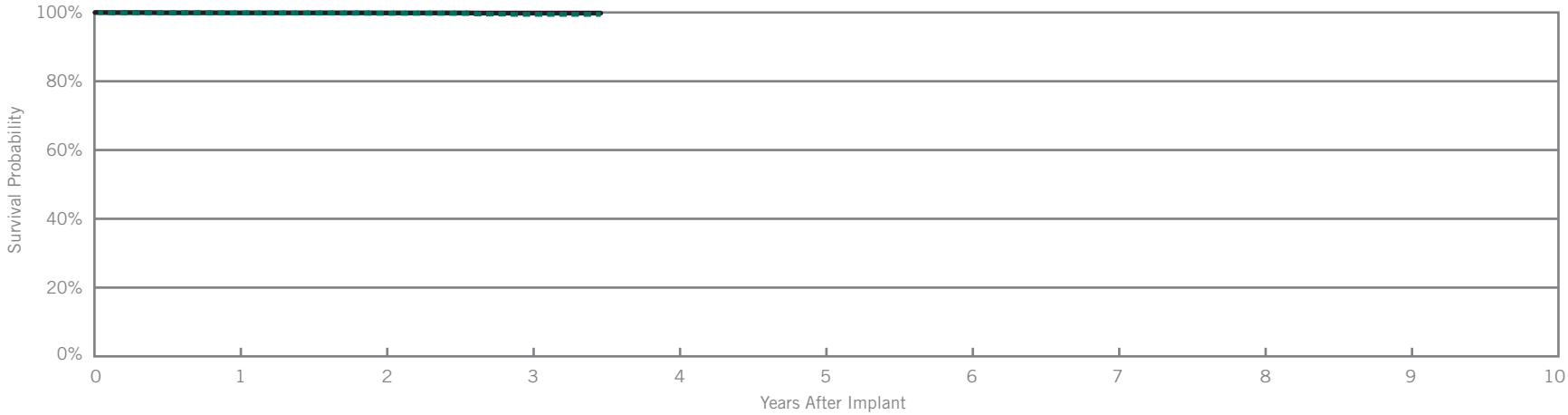
Quadra Assura™ CRT-D

Model CD3265-40Q*

US Regulatory Approval	May 2012
Registered US Implants	13,523
Estimated Active US Implants	10,142
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	10
Max. Delivered Energy	40 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	1	<0.01%	2	0.01%
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%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**4**	**0.03%**	**4**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.84%	99.75%	99.46%	99.46%						
± 1 standard error	0.03%	0.04%	0.10%	0.10%						
Sample Size	12,660	10,540	5,520	310						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.89%	99.87%	99.82%	99.82%						
± 1 standard error	0.03%	0.03%	0.05%	0.05%						

**DF4-LLHH connector type.*

Actively Monitored Study Data

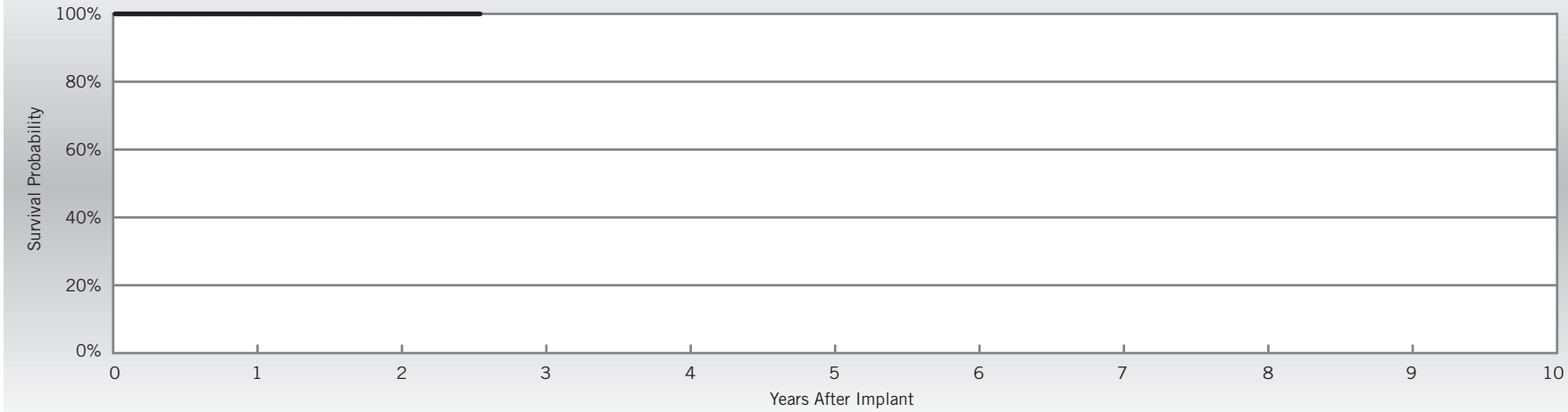
Quadra Assura™ CRT-D

Model CD3265-40Q*

US Regulatory Approval	May 2012
Number of Devices Enrolled in Study	418
Active Devices Enrolled in Study	306
Cumulative Months of Follow-up	9,731
Estimated Longevity	(see table on page 46)
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	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	390	330	70							

**DF4-LLHH connector type.*

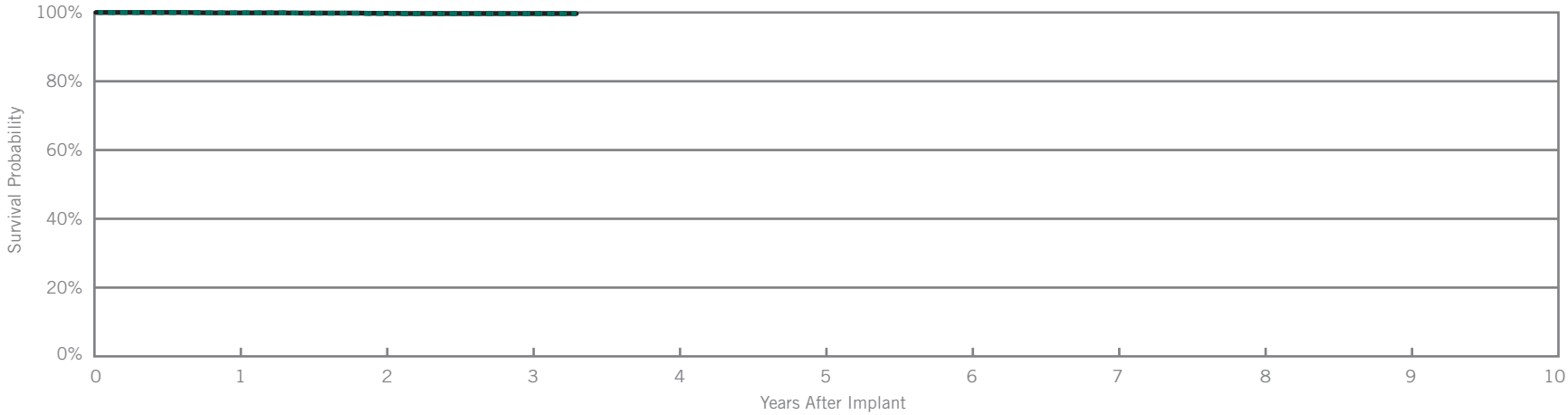
Quadra Assura™ CRT-D

Model CD3265-40

US Regulatory Approval	May 2012
Registered US Implants	4,020
Estimated Active US Implants	3,053
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	1
Max. Delivered Energy	40 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	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 40 months						
Survival Probability	99.89%	99.70%	99.61%	99.61%						
± 1 standard error	0.06%	0.10%	0.11%	0.11%						
Sample Size	3,740	3,060	1,590	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	99.89%	99.76%	99.68%	99.68%						
± 1 standard error	0.06%	0.09%	0.10%	0.10%						

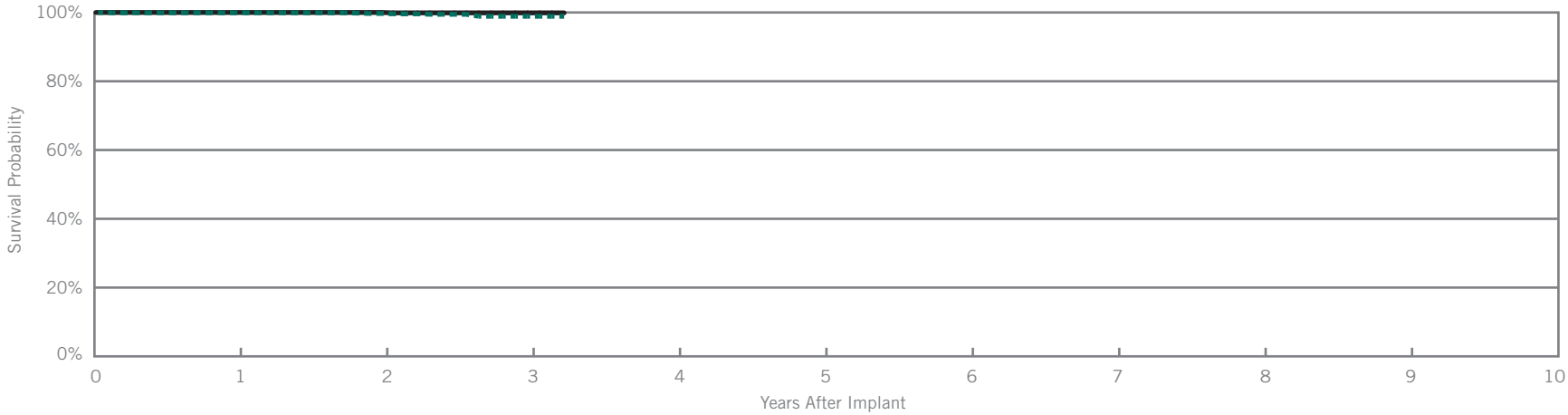
Unify Assura™ CRT-D

Model CD3257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	2,710
Estimated Active US Implants	2,001
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	6
Max. Delivered Energy	40 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	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	0.04%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.04%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	99.92%	99.72%	98.89%	98.89%						
± 1 standard error	0.05%	0.12%	0.31%	0.31%						
Sample Size	2,520	2,070	1,070	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	100.00%	100.00%	99.89%	99.89%						
± 1 standard error	0.00%	0.00%	0.08%	0.08%						

**DF4-LLHH connector type.*

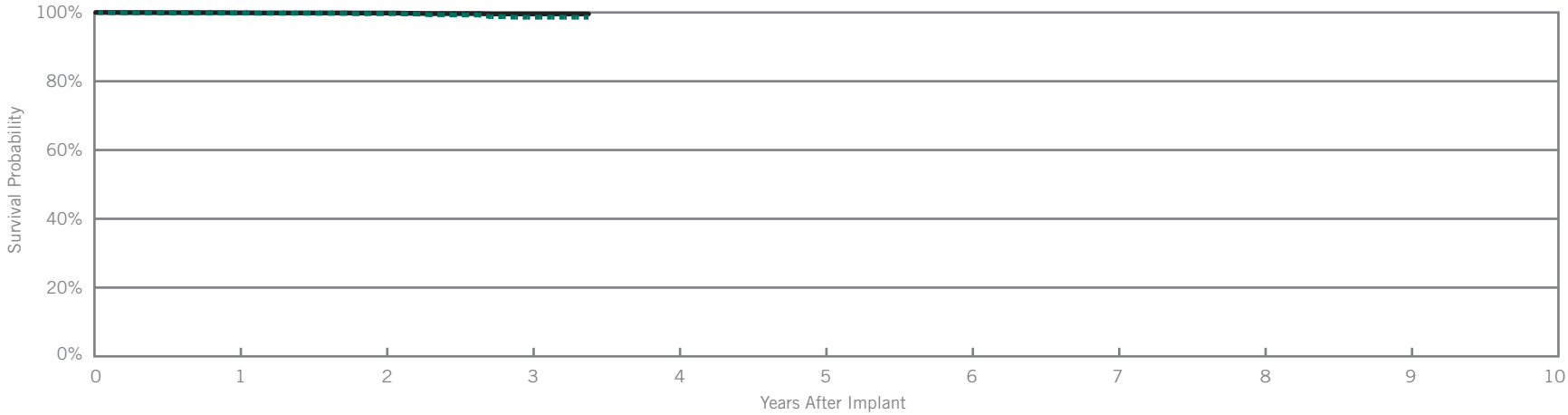
Unify Assura™ CRT-D

Model CD3257-40

US Regulatory Approval	May 2012
Registered US Implants	6,728
Estimated Active US Implants	4,992
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	12
Max. Delivered Energy	40 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	0.04%	2	0.03%
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	0.01%	1	0.01%
Other	1	0.01%	1	0.01%
Total	**5**	**0.07%**	**4**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.81%	99.66%	98.63%	98.63%						
± 1 standard error	0.05%	0.08%	0.22%	0.22%						
Sample Size	6,300	5,190	2,790	270						

Excluding Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.90%	99.83%	99.57%	99.57%						
± 1 standard error	0.03%	0.05%	0.11%	0.11%						

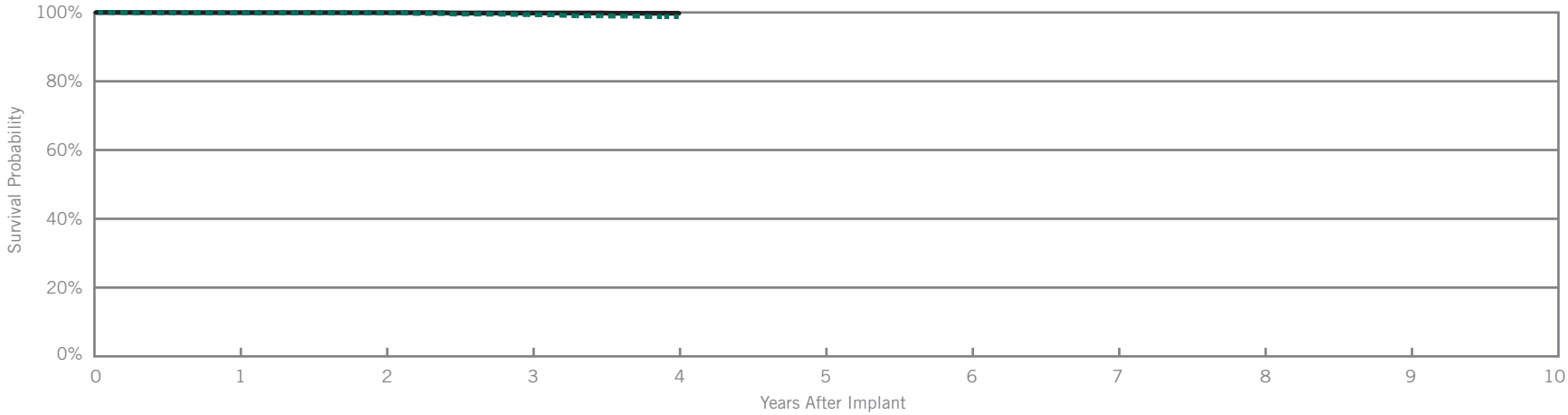
Unify Quadra™ CRT-D

Model CD3249-40Q*

US Regulatory Approval	Nov 2011
Registered US Implants	8,931
Estimated Active US Implants	6,151
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	20
Max. Delivered Energy	40 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	1	0.01%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.03%	0	0.00%
Other	2	0.02%	0	0.00%
Total	**6**	**0.07%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.87%	99.84%	99.37%	98.80%						
± 1 standard error	0.04%	0.04%	0.09%	0.18%						
Sample Size	8,400	7,410	6,050	530						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.95%	99.95%	99.84%	99.77%						
± 1 standard error	0.02%	0.02%	0.05%	0.07%						

**DF4-LLHH connector type.*

Actively Monitored Study Data

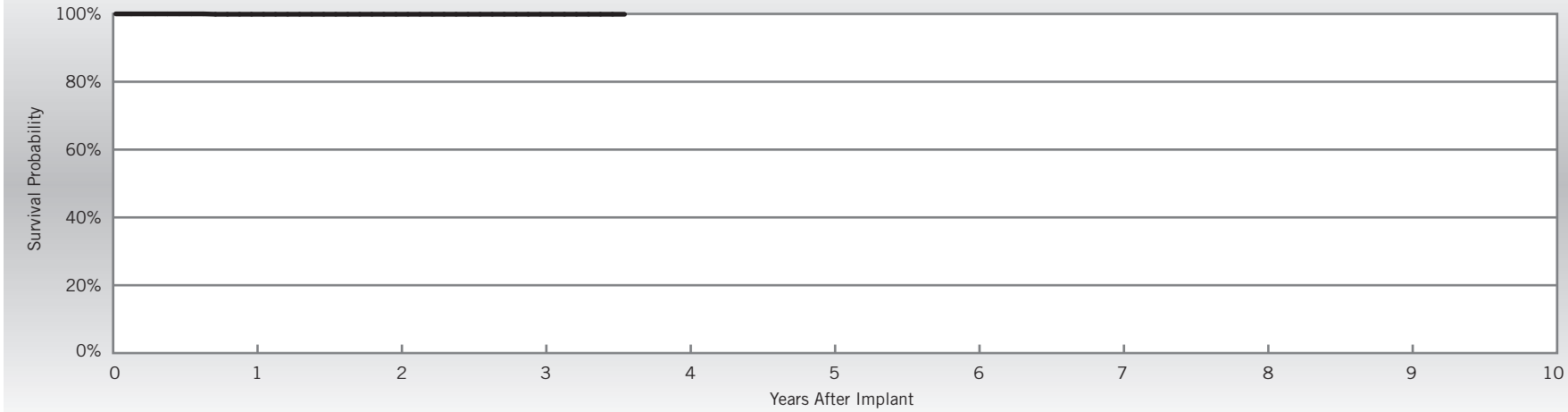
Unify Quadra™ CRT-D

Model CD3249-40Q*

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	991
Active Devices Enrolled in Study	653
Cumulative Months of Follow-up	27,874
Estimated Longevity	(see table on page 46)
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%	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	99.89%	99.89%	99.89%	99.89%						
± 1 standard error	0.11%	0.11%	0.11%	0.11%						
Sample Size	930	790	510	50						

**DF4-LLHH connector type.*

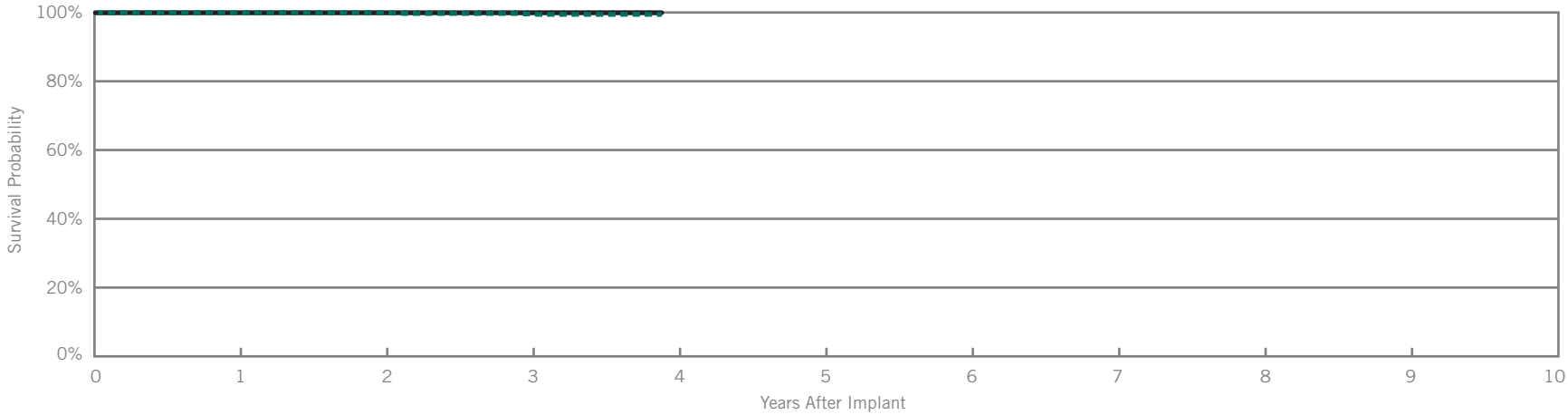
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	Nov 2011
Registered US Implants	2,520
Estimated Active US Implants	1,726
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	4
Max. Delivered Energy	40 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	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	0.04%	0	0.00%
Total	**1**	**0.04%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.92%	99.92%	99.58%	99.45%						
± 1 standard error	0.06%	0.06%	0.12%	0.18%						
Sample Size	2,360	2,090	1,730	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.92%	99.92%	99.92%	99.92%						
± 1 standard error	0.06%	0.06%	0.06%	0.06%						

Actively Monitored Study Data

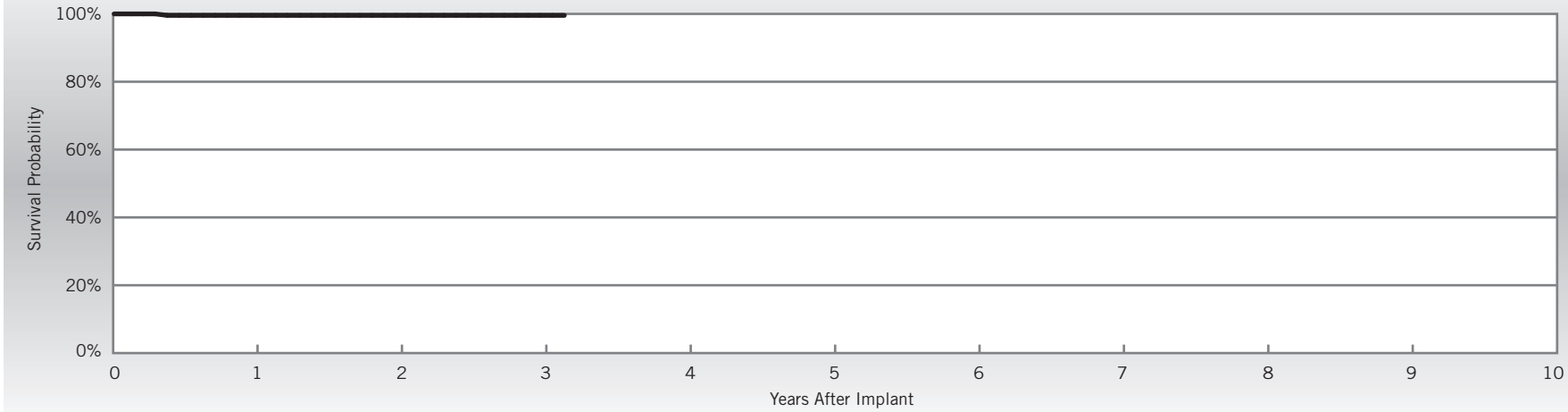
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	242
Active Devices Enrolled in Study	159
Cumulative Months of Follow-up	6,712
Estimated Longevity	(see table on page 46)
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 38 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	120	50						

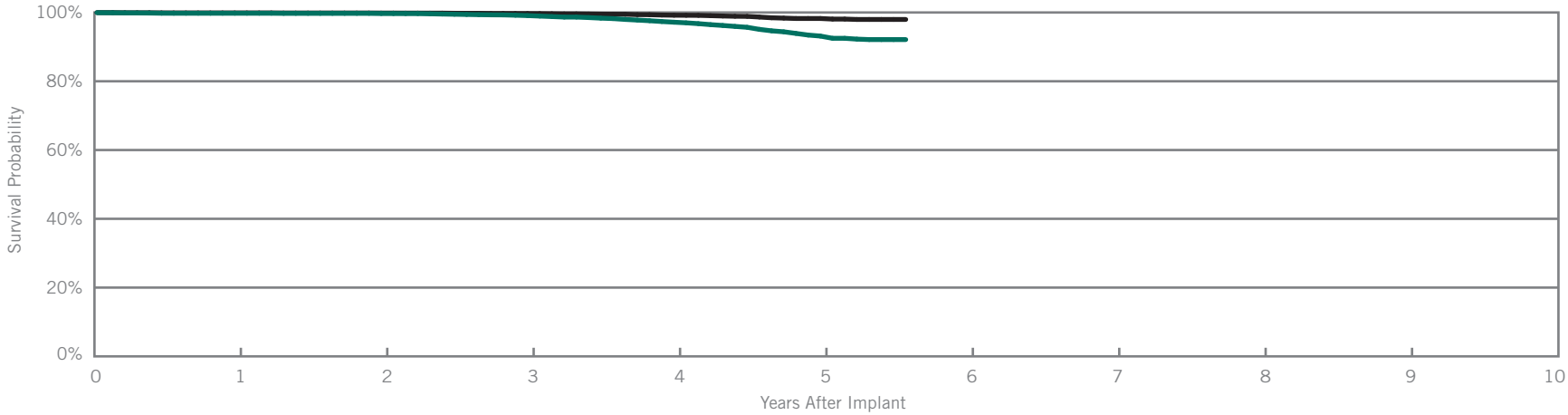
Customer Reported Performance Data

Unify™ CRT-D

Model CD3231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	18,982
Estimated Active US Implants	10,940
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	183
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.01%	3	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	8	0.04%	2	0.01%
High Voltage Capacitor	7	0.04%	2	0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	1	<0.01%	2	0.01%
Possible Early Battery Depletion	27	0.14%	10	0.05%
Other	4	0.02%	2	0.01%
Total	**50**	**0.26%**	**22**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.77%	99.70%	99.09%	97.17%	93.14%	92.12%				
± 1 standard error	0.04%	0.04%	0.07%	0.14%	0.28%	0.36%				
Sample Size	17,720	15,590	13,840	11,350	6,430	370				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.88%	99.83%	99.69%	99.20%	98.25%	97.97%				
± 1 standard error	0.03%	0.03%	0.04%	0.08%	0.15%	0.18%				

**DF4-LLHH connector type.*

Actively Monitored Study Data

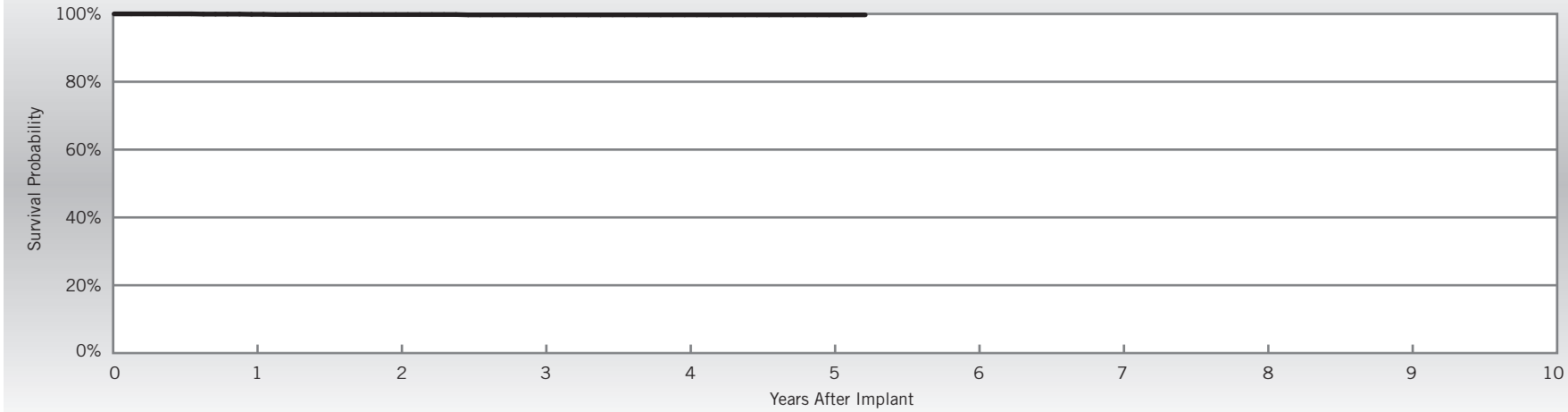
Unify™ CRT-D

Model CD3231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	1,677
Active Devices Enrolled in Study	937
Cumulative Months of Follow-up	65,987
Estimated Longevity	(see table on page 46)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	2	0.12%
Premature Battery Depletion	1	0.06%
Skin Erosion	1	0.06%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.06%
Electrical Interconnect	0	0.00%	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%	0	0.00%
Possible Early Battery Depletion	5	0.30%	1	0.06%
Other	2	0.12%	0	0.00%
Total	**8**	**0.48%**	**2**	**0.12%**



Year	1	2	3	4	5	at 63 months				
Survival Probability	99.87%	99.80%	99.71%	99.71%	99.71%	99.71%				
± 1 standard error	0.07%	0.12%	0.14%	0.14%	0.14%	0.14%				
Sample Size	1,570	1,370	1,190	950	460	70				

**DF4-LLHH connector type.*

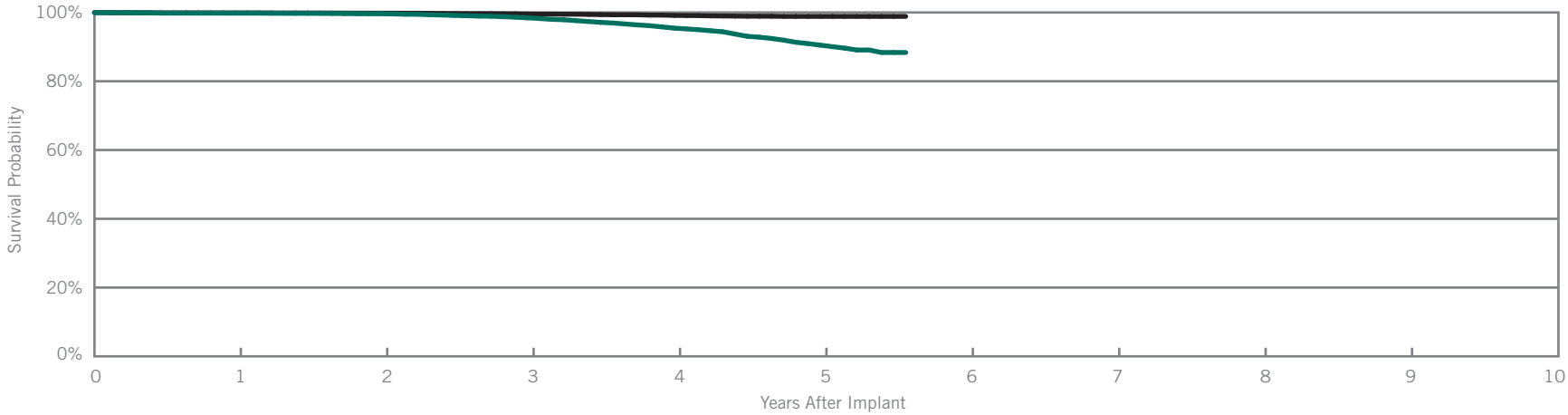
Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	20,470
Estimated Active US Implants	11,632
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	286
Max. Delivered Energy	40 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	7	0.03%	3	0.01%
Electrical Interconnect	3	0.01%	0	0.00%
Battery	4	0.02%	1	<0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	0	0.00%
Possible Early Battery Depletion	13	0.06%	5	0.02%
Other	9	0.04%	11	0.05%
Total	**37**	**0.18%**	**20**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.79%	99.64%	98.44%	95.44%	90.49%	88.36%				
± 1 standard error	0.03%	0.04%	0.09%	0.18%	0.35%	0.56%				
Sample Size	19,110	16,690	14,370	10,640	5,200	210				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.88%	99.80%	99.54%	99.14%	98.86%	98.86%				
± 1 standard error	0.02%	0.03%	0.05%	0.08%	0.11%	0.11%				

Actively Monitored Study Data

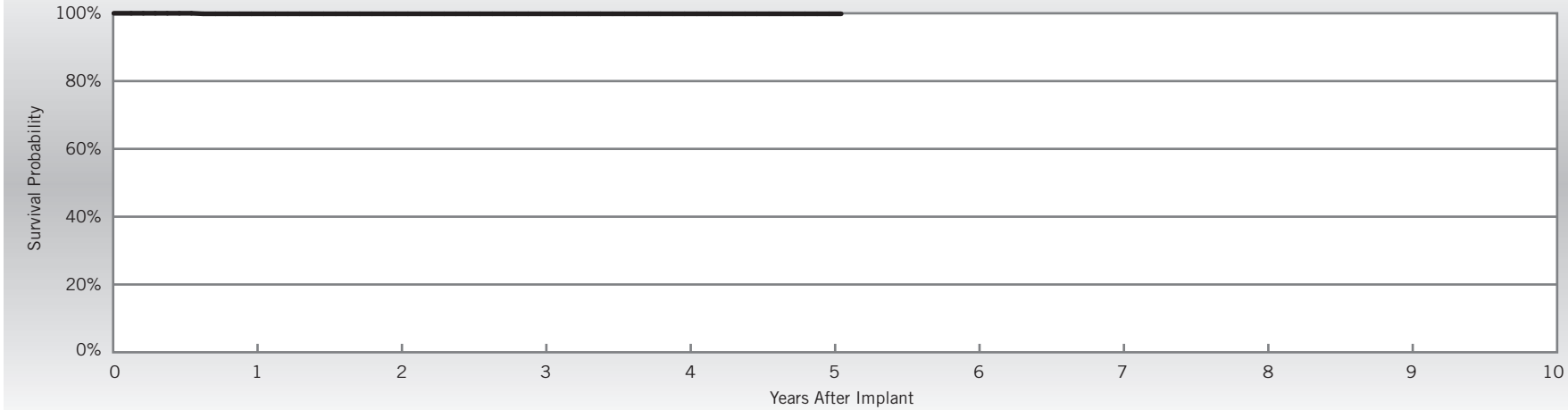
Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	681
Active Devices Enrolled in Study	319
Cumulative Months of Follow-up	24,613
Estimated Longevity	(see table on page 46)
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	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.15%**	**3**	**0.44%**



Year	1	2	3	4	5	at 61 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	620	510	420	340	180	60				

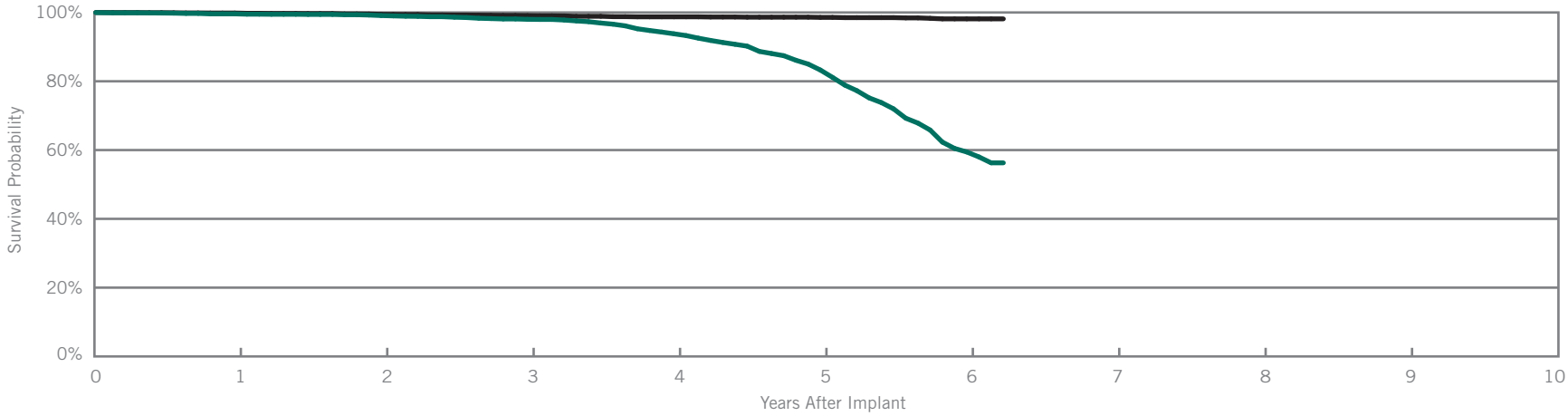
Promote™ + CRT-D

Model CD3211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	6,900
Estimated Active US Implants	2,386
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	540
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%	3	0.04%
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%**	**15**	**0.22%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.59%	99.10%	98.01%	93.80%	83.27%	59.44%	56.28%			
± 1 standard error	0.08%	0.11%	0.18%	0.34%	0.55%	0.90%	1.11%			
Sample Size	6,380	5,570	4,990	4,390	3,600	1,860	260			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.84%	99.46%	99.09%	98.73%	98.57%	98.14%	98.14%			
± 1 standard error	0.05%	0.09%	0.13%	0.16%	0.16%	0.23%	0.23%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

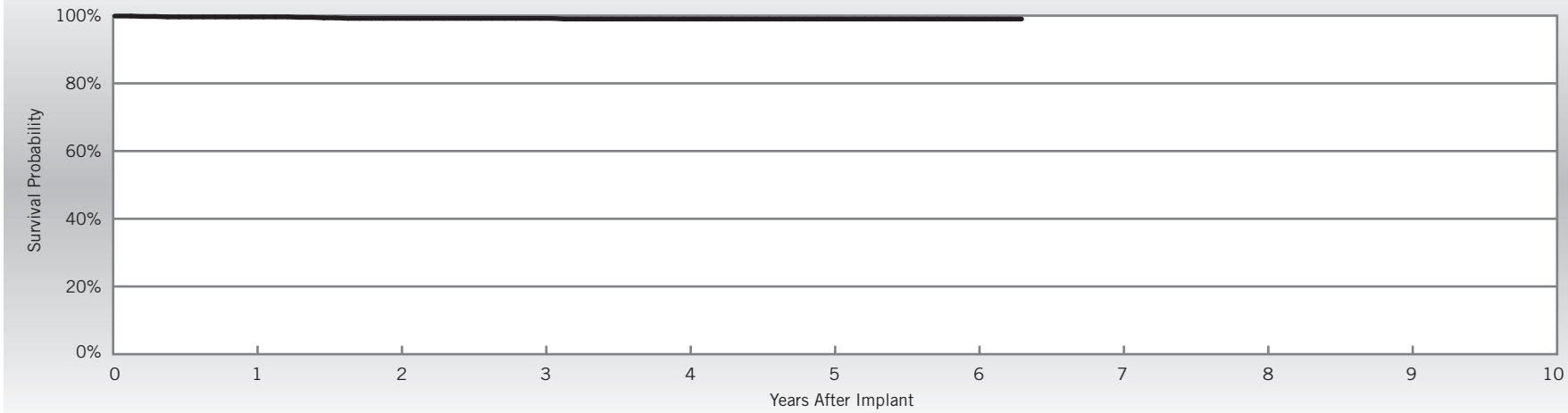
Promote™ + CRT-D

Model CD3211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	854
Active Devices Enrolled in Study	312
Cumulative Months of Follow-up	37,861
Estimated Longevity	(see table on page 46)
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	1	0.12%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.35%**	**3**	**0.35%**



Year	1	2	3	4	5	6	at 76 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	230	50			

**DF4-LLHH connector type.*

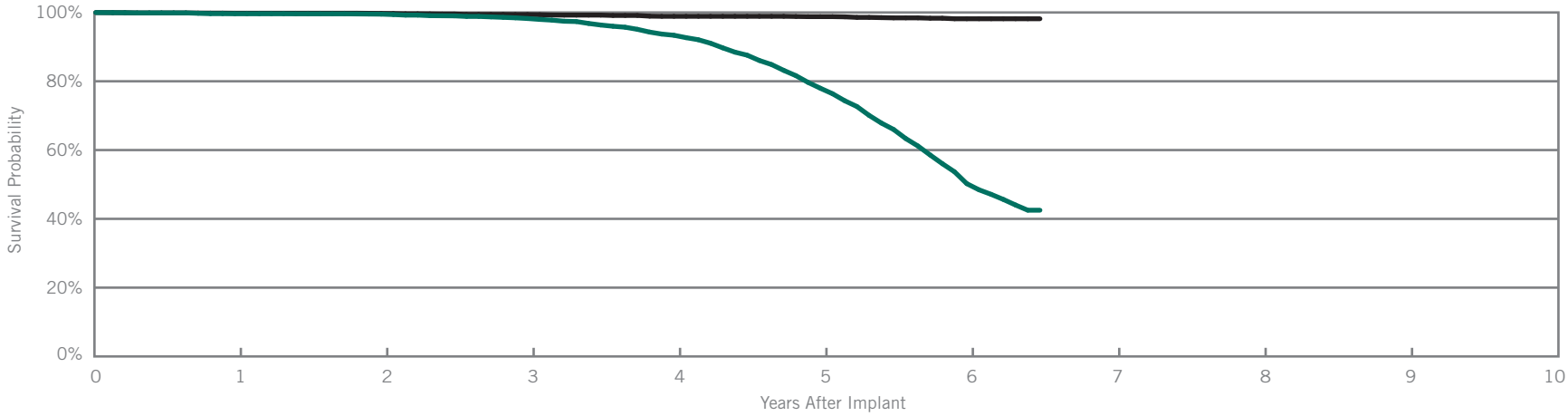
Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,645
Estimated Active US Implants	2,478
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	823
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	0	0.00%	5	0.06%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.03%	1	0.01%
Other	5	0.06%	3	0.03%
Total	**24**	**0.28%**	**15**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.63%	99.51%	98.24%	93.37%	77.97%	50.24%	42.51%			
± 1 standard error	0.07%	0.08%	0.15%	0.32%	0.57%	0.82%	1.07%			
Sample Size	8,000	6,910	6,080	5,220	4,100	2,220	230			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.79%	99.73%	99.39%	98.89%	98.79%	98.17%	98.17%			
± 1 standard error	0.05%	0.06%	0.09%	0.14%	0.15%	0.22%	0.22%			

Actively Monitored Study Data

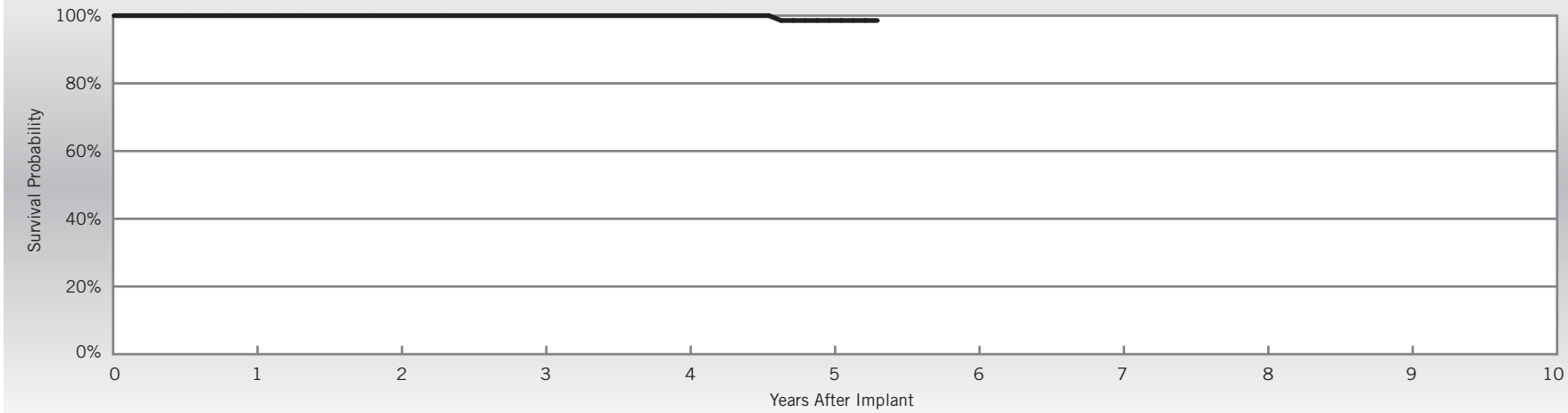
Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	223
Active Devices Enrolled in Study	51
Cumulative Months of Follow-up	8,878
Estimated Longevity	(see table on page 46)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Skin Erosion	1	0.45%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.45%
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**	**0.45%**



Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	100.00%	100.00%	100.00%	98.57%	98.57%				
± 1 standard error	0.00%	0.00%	0.00%	0.00%	1.42%	1.42%				
Sample Size	210	170	130	100	70	50				

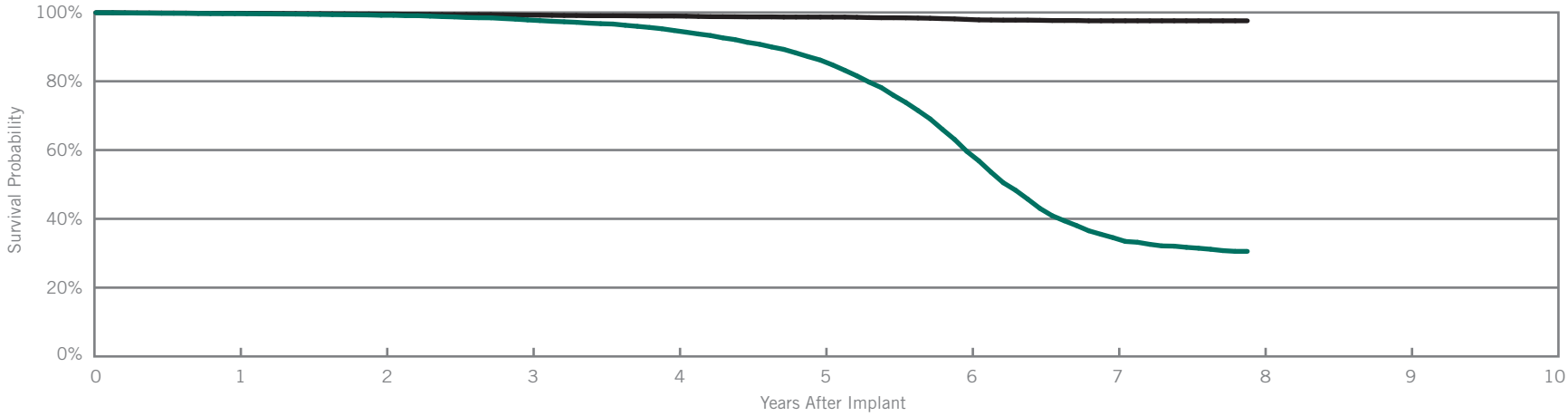
Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	24,001
Estimated Active US Implants	3,996
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	2,724
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%	12	0.05%
Mechanical	3	0.01%	7	0.03%
Possible Early Battery Depletion	10	0.04%	5	0.02%
Other	17	0.07%	16	0.07%
Total	**62**	**0.26%**	**59**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.67%	99.18%	97.83%	94.76%	86.15%	59.63%	34.52%	30.55%		
± 1 standard error	0.04%	0.06%	0.10%	0.17%	0.28%	0.45%	0.50%	0.59%		
Sample Size	22,190	19,060	16,620	14,390	11,840	8,240	3,870	250		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.77%	99.54%	99.24%	98.97%	98.67%	97.98%	97.58%	97.58%		
± 1 standard error	0.03%	0.04%	0.06%	0.08%	0.09%	0.12%	0.16%	0.16%		

Actively Monitored Study Data

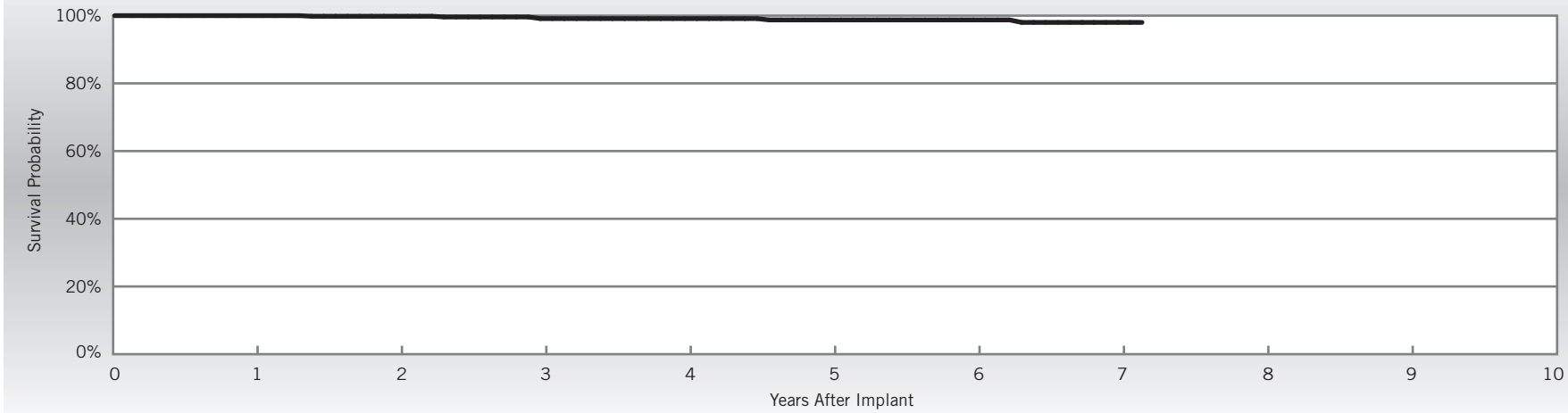
Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	677
Active Devices Enrolled in Study	122
Cumulative Months of Follow-up	30,412
Estimated Longevity	(see table on page 46)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.15%
Premature Battery Depletion	3	0.44%
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 86 months		
Survival Probability	100.00%	99.82%	99.13%	99.13%	98.74%	98.74%	98.00%	98.00%		
± 1 standard error	0.00%	0.18%	0.27%	0.44%	0.58%	0.58%	0.94%	0.94%		
Sample Size	630	550	460	350	260	190	110	50		

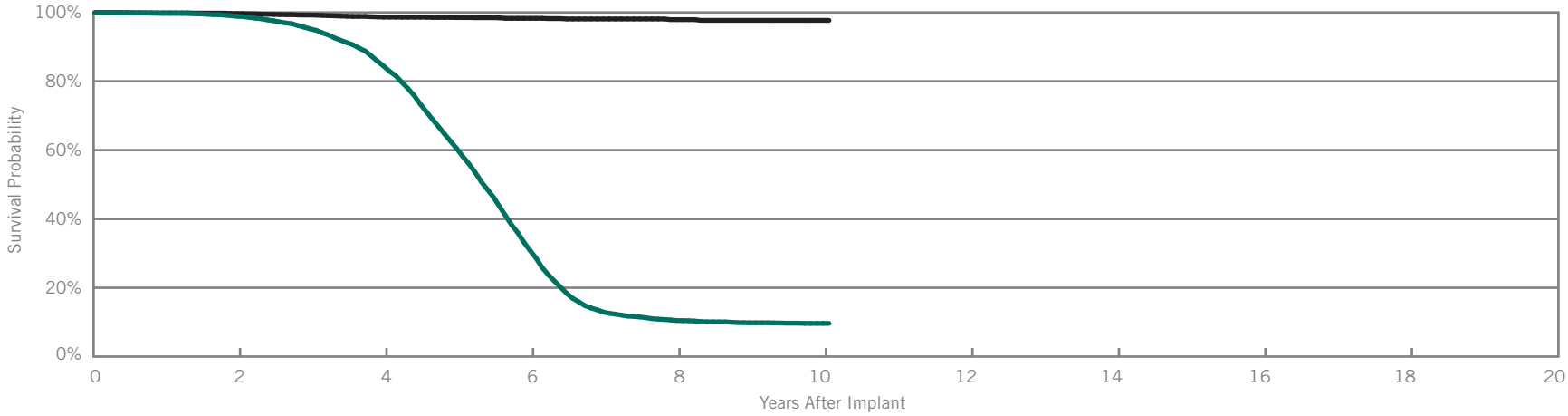
Atlas™ + HF CRT-D

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,777
Estimated Active US Implants	946
Estimated Longevity	(see table on page 46)
Normal Battery Depletion	3,422
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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 121 months				
Survival Probability	98.89%	84.45%	30.86%	10.49%	9.65%	9.65%				
± 1 standard error	0.08%	0.32%	0.49%	0.32%	0.31%	0.31%				
Sample Size	15,140	10,350	4,160	1,150	450	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 121 months				
Survival Probability	99.67%	98.65%	98.30%	97.92%	97.70%	97.70%				
± 1 standard error	0.04%	0.10%	0.13%	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
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
CD3365-40Q	Quadra Assura™ CRT-D	99.81%	99.70%								
CD3365-40C	Quadra Assura™ CRT-D	99.78%	99.43%								
CD3357-40Q	Unify Assura™ CRT-D	99.70%	99.61%								
CD3357-40C	Unify Assura™ CRT-D	99.92%	99.67%								
CD3265-40Q	Quadra Assura™ CRT-D	99.84%	99.75%	99.46%							
CD3265-40	Quadra Assura™ CRT-D	99.89%	99.70%	99.61%							
CD3257-40Q	Unify Assura™ CRT-D	99.92%	99.72%	98.89%							
CD3257-40	Unify Assura™ CRT-D	99.81%	99.66%	98.63%							
CD3249-40Q	Unify Quadra™ CRT-D	99.87%	99.84%	99.37%	98.80%						
CD3249-40	Unify Quadra™ CRT-D	99.92%	99.92%	99.58%							
CD3231-40Q	Unify™ CRT-D	99.77%	99.70%	99.09%	97.17%	93.14%					
CD3231-40	Unify™ CRT-D	99.79%	99.64%	98.44%	95.44%	90.49%					
CD3211-36Q	Promote™ + CRT-D	99.59%	99.10%	98.01%	93.80%	83.27%	59.44%				
CD3211-36	Promote™ + CRT-D	99.63%	99.51%	98.24%	93.37%	77.97%	50.24%				
3207-36	Promote™ RF CRT-D	99.67%	99.18%	97.83%	94.76%	86.15%	59.63%	34.52%			
V-343	Atlas™ + HF CRT-D	99.73%	98.89%	95.22%	84.45%	60.44%	30.86%	12.93%	10.49%	9.82%	9.65%

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
CD3365-40Q	Quadra Assura™ CRT-D	99.85%	99.80%								
CD3365-40C	Quadra Assura™ CRT-D	99.91%	99.57%								
CD3357-40Q	Unify Assura™ CRT-D	99.86%	99.77%								
CD3357-40C	Unify Assura™ CRT-D	99.94%	99.69%								
CD3265-40Q	Quadra Assura™ CRT-D	99.89%	99.87%	99.82%							
CD3265-40	Quadra Assura™ CRT-D	99.89%	99.76%	99.68%							
CD3257-40Q	Unify Assura™ CRT-D	100.00%	100.00%	99.89%							
CD3257-40	Unify Assura™ CRT-D	99.90%	99.83%	99.57%							
CD3249-40Q	Unify Quadra™ CRT-D	99.95%	99.95%	99.84%	99.77%						
CD3249-40	Unify Quadra™ CRT-D	99.92%	99.92%	99.92%							
CD3231-40Q	Unify™ CRT-D	99.88%	99.83%	99.69%	99.20%	98.25%					
CD3231-40	Unify™ CRT-D	99.88%	99.80%	99.54%	99.14%	98.86%					
CD3211-36Q	Promote™ + CRT-D	99.84%	99.46%	99.09%	98.73%	98.57%	98.14%				
CD3211-36	Promote™ + CRT-D	99.79%	99.73%	99.39%	98.89%	98.79%	98.17%				
3207-36	Promote™ RF CRT-D	99.77%	99.54%	99.24%	98.97%	98.67%	97.98%	97.58%			
V-343	Atlas™ + HF CRT-D	99.88%	99.67%	99.26%	98.65%	98.52%	98.30%	98.11%	97.92%	97.70%	97.70%

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
CD3365-40Q	Quadra Assura™ CRT-D	28,951	1.20%	2	<0.01%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.01%	**8**	**0.03%**
CD3365-40C	Quadra Assura™ CRT-D	5,757	1.80%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**2**	**0.03%**
CD3357-40Q	Unify Assura™ CRT-D	5,790	2.00%	0	0.00%	2	0.03%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.05%**
CD3357-40C	Unify Assura™ CRT-D	10,958	1.40%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**3**	**0.03%**
CD3265-40Q	Quadra Assura™ CRT-D	13,523	2.60%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	**4**	**0.03%**
CD3265-40	Quadra Assura™ CRT-D	4,020	3.30%	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	3.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	**1**	**0.04%**
CD3257-40	Unify Assura™ CRT-D	6,728	3.30%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**5**	**0.07%**
CD3249-40Q	Unify Quadra™ CRT-D	8,931	3.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.03%	2	0.02%	**6**	**0.07%**
CD3249-40	Unify Quadra™ CRT-D	2,520	4.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**1**	**0.04%**
CD3231-40Q	Unify™ CRT-D	18,982	5.30%	2	0.01%	1	<0.01%	8	0.04%	7	0.04%	0	0.00%	1	<0.01%	27	0.14%	4	0.02%	**50**	**0.26%**
CD3231-40	Unify™ CRT-D	20,470	6.50%	7	0.03%	3	0.01%	4	0.02%	0	0.00%	0	0.00%	1	<0.01%	13	0.06%	9	0.04%	**37**	**0.18%**
CD3211-36Q	Promote™ + CRT-D	6,900	15.80%	4	0.06%	0	0.00%	9	0.13%	1	0.01%	0	0.00%	1	0.01%	2	0.03%	5	0.07%	**22**	**0.32%**
CD3211-36	Promote™ + CRT-D	8,645	19.90%	3	0.03%	0	0.00%	11	0.13%	2	0.02%	0	0.00%	0	0.00%	3	0.03%	5	0.06%	**24**	**0.28%**
3207-36	Promote™ RF CRT-D	24,001	24.20%	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	24.80%	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	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
CD3365-40Q	Quadra Assura™ CRT-D	28,951	1.20%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	3	0.01%	0	0.00%	0	0.00%	**8**	**0.03%**
CD3365-40C	Quadra Assura™ CRT-D	5,757	1.80%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.05%**
CD3357-40Q	Unify Assura™ CRT-D	5,790	2.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**1**	**0.02%**
CD3357-40C	Unify Assura™ CRT-D	10,958	1.40%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD3265-40Q	Quadra Assura™ CRT-D	13,523	2.60%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	**4**	**0.03%**
CD3265-40	Quadra Assura™ CRT-D	4,020	3.30%	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	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%**
CD3257-40	Unify Assura™ CRT-D	6,728	3.30%	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	3.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	Unify Quadra™ CRT-D	2,520	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%**
CD3231-40Q	Unify™ CRT-D	18,982	5.30%	3	0.02%	0	0.00%	2	0.01%	2	0.01%	1	<0.01%	2	0.01%	10	0.05%	2	0.01%	**22**	**0.12%**
CD3231-40	Unify™ CRT-D	20,470	6.50%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	5	0.02%	11	0.05%	**20**	**0.10%**
CD3211-36Q	Promote™ + CRT-D	6,900	15.80%	3	0.04%	0	0.00%	5	0.07%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	4	0.06%	**15**	**0.22%**
CD3211-36	Promote™ + CRT-D	8,645	19.90%	3	0.03%	0	0.00%	3	0.03%	0	0.00%	5	0.06%	0	0.00%	1	0.01%	3	0.03%	**15**	**0.17%**
3207-36	Promote™ RF CRT-D	24,001	24.20%	6	0.02%	3	0.01%	9	0.04%	1	<0.01%	12	0.05%	7	0.03%	5	0.02%	16	0.07%	**59**	**0.25%**
V-343	Atlas™ + HF CRT-D	18,777	24.80%	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	Worldwide Sales	Percent Returned for Analysis	Worldwide Malfunctions w/ 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
CD3365-40Q	Quadra Assura™ CRT-D	30,416	1.44%	2	<0.01%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	**8**	**0.03%**
CD3365-40C	Quadra Assura™ CRT-D	6,049	2.28%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**2**	**0.03%**
CD3357-40Q	Unify Assura™ CRT-D	6,194	2.47%	0	0.00%	2	0.03%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.05%**
CD3357-40C	Unify Assura™ CRT-D	11,410	1.78%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**3**	**0.03%**
CD3265-40Q	Quadra Assura™ CRT-D	13,975	2.92%	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	**5**	**0.04%**
CD3265-40	Quadra Assura™ CRT-D	4,049	4.00%	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	2,738	4.64%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	**1**	**0.04%**
CD3257-40	Unify Assura™ CRT-D	6,742	3.72%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**5**	**0.07%**
CD3249-40Q	Unify Quadra™ CRT-D	10,300	3.19%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.03%	2	0.02%	**6**	**0.06%**
CD3249-40	Unify Quadra™ CRT-D	3,137	4.72%	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	20,916	5.81%	3	0.01%	1	<0.01%	9	0.04%	7	0.03%	0	0.00%	1	<0.01%	32	0.15%	6	0.03%	**59**	**0.28%**
CD3231-40	Unify™ CRT-D	21,713	6.84%	7	0.03%	4	0.02%	4	0.02%	0	0.00%	0	0.00%	1	<0.01%	14	0.06%	9	0.04%	**39**	**0.18%**
CD3211-36Q	Promote™ + CRT-D	15,415	9.04%	11	0.07%	0	0.00%	11	0.07%	3	0.02%	0	0.00%	2	0.01%	4	0.03%	5	0.03%	**36**	**0.23%**
CD3211-36	Promote™ + CRT-D	20,242	9.44%	12	0.06%	1	<0.01%	15	0.07%	4	0.02%	0	0.00%	0	0.00%	4	0.02%	10	0.05%	**46**	**0.23%**
3207-36	Promote™ RF CRT-D	25,838	24.13%	5	0.02%	5	0.02%	20	0.08%	5	0.02%	0	0.00%	3	0.01%	10	0.04%	20	0.08%	**68**	**0.26%**
V-343	Atlas™ + HF CRT-D	19,292	24.63%	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	Worldwide Sales	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
CD3365-40Q	Quadra Assura™ CRT-D	30,416	1.44%	3	<0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	**8**	**0.03%**
CD3365-40C	Quadra Assura™ CRT-D	6,049	2.28%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**3**	**0.05%**
CD3357-40Q	Unify Assura™ CRT-D	6,194	2.47%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**1**	**0.02%**
CD3357-40C	Unify Assura™ CRT-D	11,410	1.78%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD3265-40Q	Quadra Assura™ CRT-D	13,975	2.92%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	**4**	**0.03%**
CD3265-40	Quadra Assura™ CRT-D	4,049	4.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	**2**	**0.05%**
CD3257-40Q	Unify Assura™ CRT-D	2,738	4.64%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3257-40	Unify Assura™ CRT-D	6,742	3.72%	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	10,300	3.19%	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%**
CD3249-40	Unify Quadra™ CRT-D	3,137	4.72%	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	20,916	5.81%	4	0.02%	0	0.00%	2	<0.01%	2	<0.01%	1	<0.01%	2	<0.01%	11	0.05%	2	<0.01%	**24**	**0.11%**
CD3231-40	Unify™ CRT-D	21,713	6.84%	4	0.02%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	5	0.02%	11	0.05%	**24**	**0.11%**
CD3211-36Q	Promote™ + CRT-D	15,415	9.04%	5	0.03%	0	0.00%	7	0.05%	0	0.00%	3	0.02%	2	0.01%	2	0.01%	6	0.04%	**25**	**0.16%**
CD3211-36	Promote™ + CRT-D	20,242	9.44%	6	0.03%	0	0.00%	4	0.02%	0	0.00%	6	0.03%	1	<0.01%	1	<0.01%	4	0.02%	**22**	**0.11%**
3207-36	Promote™ RF CRT-D	25,838	24.13%	7	0.03%	3	0.01%	10	0.04%	1	<0.01%	13	0.05%	7	0.03%	6	0.02%	17	0.07%	**64**	**0.25%**
V-343	Atlas™ + HF CRT-D	19,292	24.63%	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	163	133	3,422	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3357-40Q	101	93	1,088	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3265-40Q	418	306	9,731	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40Q	991	653	27,874	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	**1**	**0.10%**
CD3249-40	242	159	6,712	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.41%	**1**	**0.41%**
CD3231-40Q	1,677	937	65,987	2	0.12%	0	0.00%	0	0.00%	1	0.06%	1	0.06%	**4**	**0.24%**
CD3231-40	681	319	24,613	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	**1**	**0.15%**
CD3211-36Q	854	312	37,861	3	0.35%	0	0.00%	0	0.00%	2	0.23%	2	0.23%	**7**	**0.82%**
CD3211-36	223	51	8,878	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.45%	**1**	**0.45%**
3207-36	677	122	30,412	1	0.15%	0	0.00%	0	0.00%	3	0.44%	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	163	3.70%	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%**
CD3357-40Q	Unify Assura™ CRT-D	101	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%**
CD3265-40Q	Quadra Assura™ CRT-D	418	3.60%	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	2.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	Unify Quadra™ CRT-D	242	4.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	Unify™ CRT-D	1,677	6.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	5	0.30%	2	0.12%	**8**	**0.48%**
CD3231-40	Unify™ CRT-D	681	8.40%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.15%**
CD3211-36Q	Promote™ + CRT-D	854	21.30%	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	**3**	**0.35%**
CD3211-36	Promote™ + CRT-D	223	16.60%	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%**
3207-36	Promote™ RF CRT-D	677	31.90%	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	163	3.70%	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%**
CD3357-40Q	Unify Assura™ CRT-D	101	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%**
CD3265-40Q	Quadra Assura™ CRT-D	418	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%**
CD3249-40Q	Unify Quadra™ CRT-D	991	2.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	Unify Quadra™ CRT-D	242	4.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	Unify™ CRT-D	1,677	6.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**2**	**0.12%**
CD3231-40	Unify™ CRT-D	681	8.40%	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	854	21.30%	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	**3**	**0.35%**
CD3211-36	Promote™ + CRT-D	223	16.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.45%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.45%**
3207-36	Promote™ RF CRT-D	677	31.90%	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

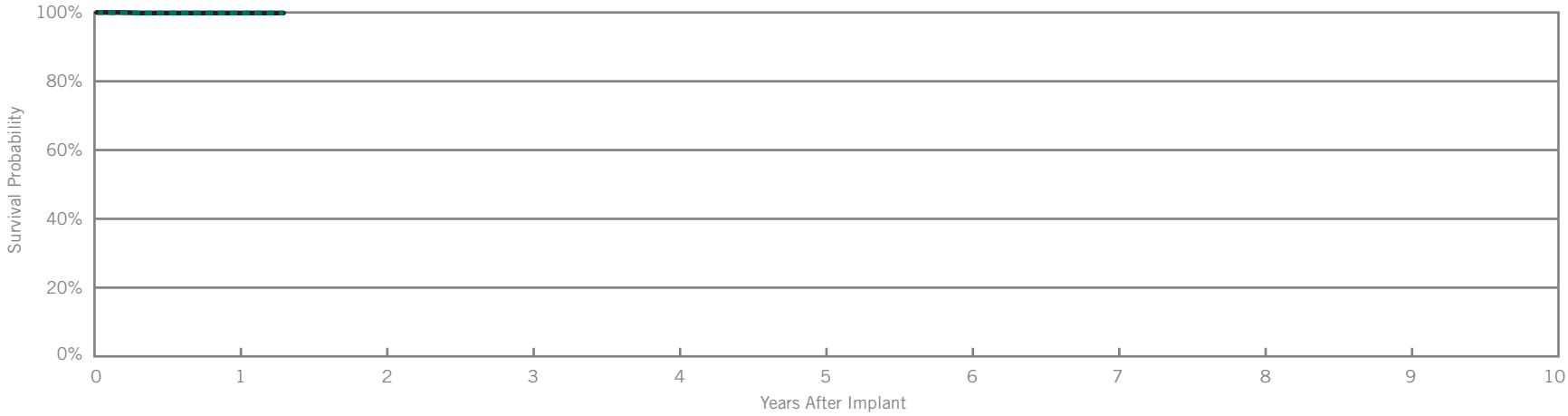
Allure™ RF CRT-P

Model PM3222

US Regulatory Approval	March 2014
Registered US Implants	1,857
Estimated Active US Implants	1,693
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	0.05%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.05%**



Including Normal Battery Depletion

Year	1	at 16 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.11%	0.11%								
Sample Size	1,130	210								

Excluding Normal Battery Depletion

Year	1	at 16 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.11%	0.11%								

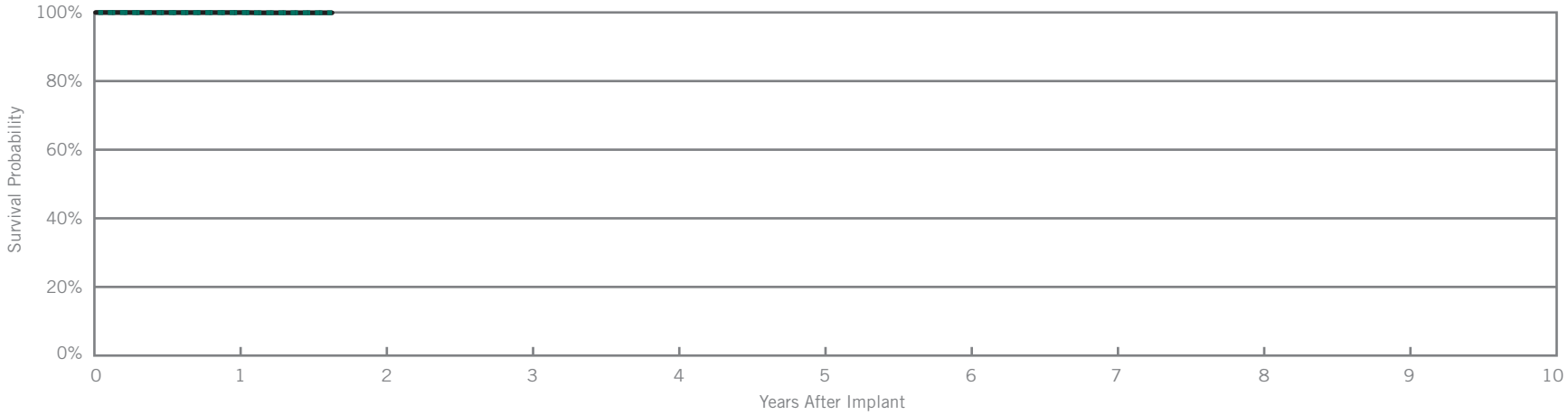
Allure Quadra™ RF CRT-P

Model PM3242

US Regulatory Approval	March 2014
Registered US Implants	12,440
Estimated Active US Implants	11,307
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%	2	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	at 20 months								
Survival Probability	99.96%	99.90%								
± 1 standard error	0.02%	0.05%								
Sample Size	8,100	460								

Excluding Normal Battery Depletion

Year	1	at 20 months								
Survival Probability	99.96%	99.90%								
± 1 standard error	0.02%	0.05%								

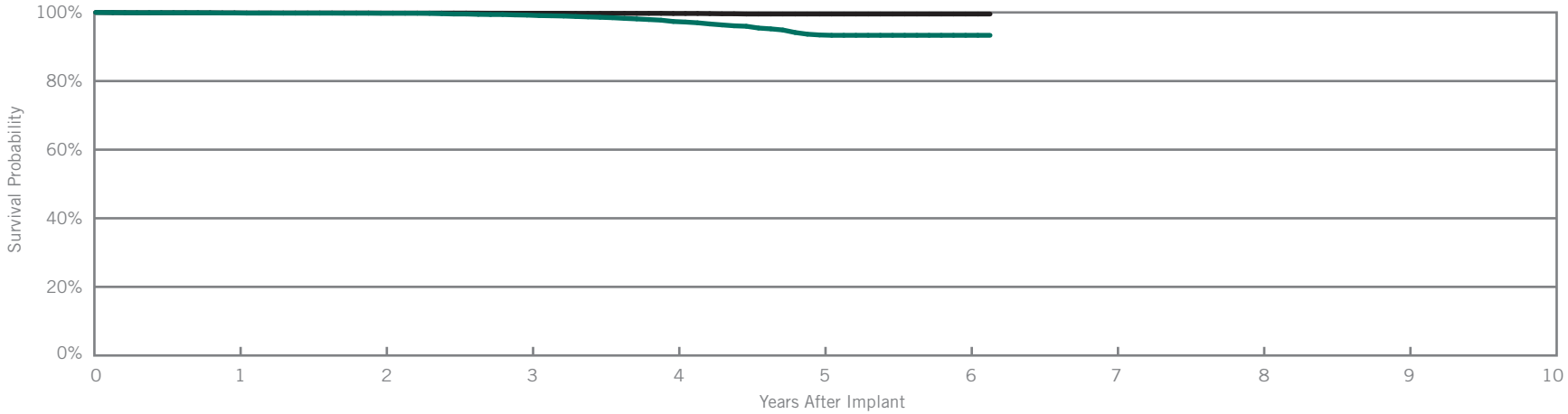
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	20,440
Estimated Active US Implants	12,647
Estimated Longevity	8 Years
Normal Battery Depletion	119
Number of US Advisories (see pgs. 296-300)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	2	<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%	2	<0.01%
Other	0	0.00%	7	0.03%
Total	**7**	**0.03%**	**16**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.84%	99.77%	99.22%	97.36%	93.43%	93.33%	93.33%			
± 1 standard error	0.03%	0.03%	0.08%	0.17%	0.38%	0.40%	0.40%			
Sample Size	18,750	15,050	10,700	6,640	3,420	1,110	220			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.87%	99.82%	99.76%	99.69%	99.54%	99.54%	99.54%			
± 1 standard error	0.03%	0.03%	0.04%	0.04%	0.08%	0.08%	0.08%			

Actively Monitored Study Data

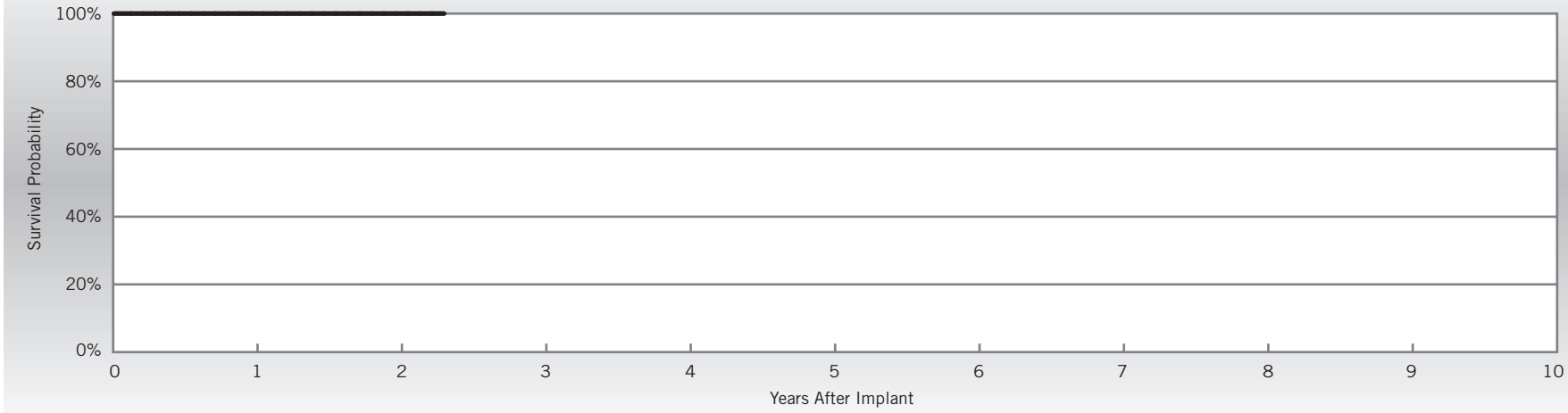
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	199
Active Devices Enrolled in Study	32
Cumulative Months of Follow-up	4,341
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							

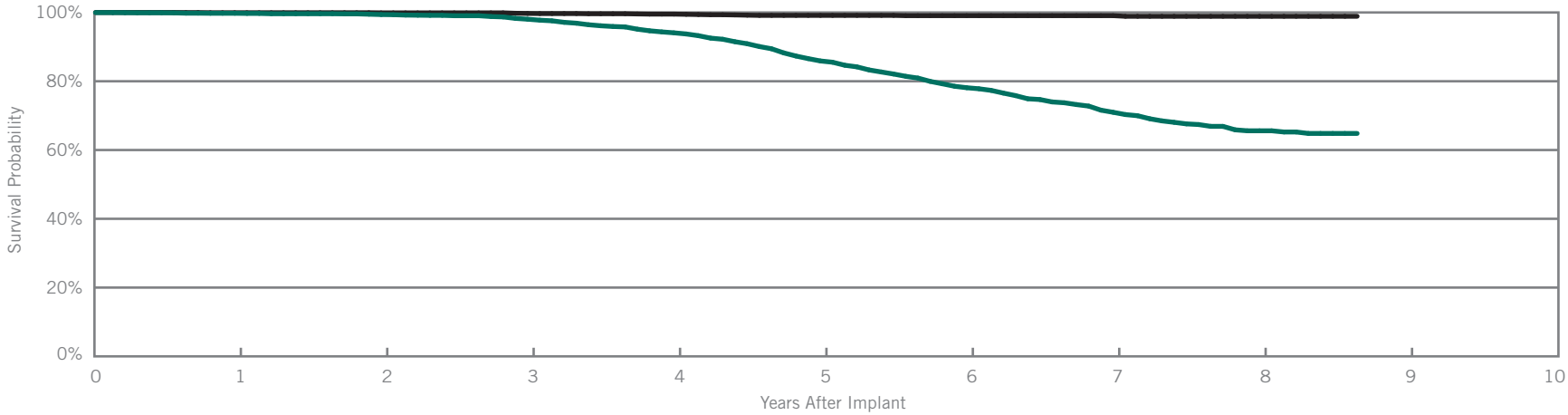
Frontier™ II CRT-P

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,909
Estimated Active US Implants	1,371
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	at 104 months
Survival Probability	99.76%	99.39%	98.04%	94.08%	85.90%	78.11%	70.97%	65.59%	64.82%
± 1 standard error	0.06%	0.10%	0.19%	0.36%	0.56%	0.71%	0.84%	1.05%	1.10%
Sample Size	6,250	5,210	4,480	3,800	3,130	2,460	1,620	770	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 104 months
Survival Probability	99.93%	99.89%	99.72%	99.52%	99.15%	99.07%	99.07%	98.89%	98.89%
± 1 standard error	0.03%	0.03%	0.07%	0.11%	0.15%	0.16%	0.16%	0.21%	0.21%

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
PM3222	Allure™ RF CRT-P*	99.84%									
PM3242	Allure Quadra™ RF CRT-P	99.96%									
PM3210	Anthem™ RF CRT-P	99.84%	99.77%	99.22%	97.36%	93.43%	93.33%				
5586	Frontier™ II CRT-P	99.76%	99.39%	98.04%	94.08%	85.90%	78.11%	70.97%	65.59%		

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
PM3222	Allure™ RF CRT-P*	99.84%									
PM3242	Allure Quadra™ RF CRT-P	99.96%									
PM3210	Anthem™ RF CRT-P	99.87%	99.82%	99.76%	99.69%	99.54%	99.54%				
5586	Frontier™ II CRT-P	99.93%	99.89%	99.72%	99.52%	99.15%	99.07%	99.07%	98.89%		

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
PM3222	Allure™ RF CRT-P	1,857	0.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM3242	Allure Quadra™ RF CRT-P	12,440	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM3210	Anthem™ RF CRT-P	20,440	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
PM3222	Allure™ RF CRT-P	1,857	0.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	**1**	**0.05%**
PM3242	Allure Quadra™ RF CRT-P	12,440	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	**2**	**0.02%**
PM3210	Anthem™ RF CRT-P	20,440	4.30%	2	<0.01%	0	0.00%	0	0.00%	5	0.02%	0	0.00%	2	<0.01%	7	0.03%	**16**	**0.08%**
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
PM3222	Allure™ RF CRT-P	7,164	0.82%	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	24,496	0.96%	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	21,058	5.21%	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
PM3222	Allure™ RF CRT-P	7,164	0.82%	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	24,496	0.96%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**2**	**<0.01%**
PM3210	Anthem™ RF CRT-P	21,058	5.21%	1	<0.01%	0	0.00%	0	0.00%	5	0.02%	0	0.00%	2	<0.01%	7	0.03%	**15**	**0.07%**

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

Left-Heart Leads

St. Jude Medical

Customer Reported Performance Data

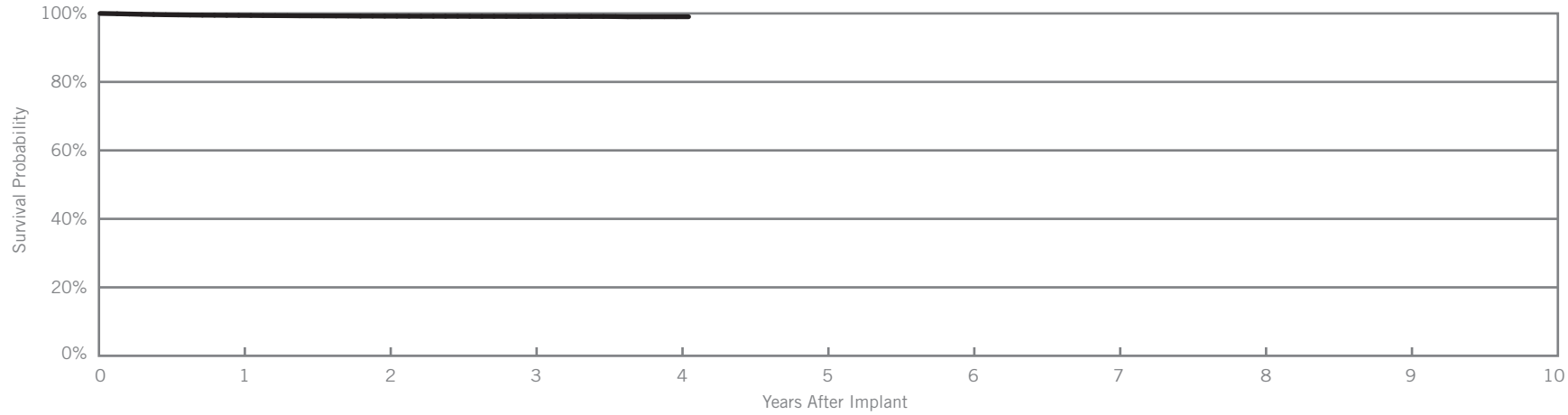
Quartet™

Model 1458Q

US Regulatory Approval	November 2011
Registered US Implants	82,351
Estimated Active US Implants	69,487
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%	4	<0.01%
Lead Dislodgement	110	0.13%	387	0.47%
Failure to Capture	45	0.05%	126	0.15%
Oversensing	2	<0.01%	4	<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%	19	0.02%
Extracardiac Stimulation	57	0.07%	77	0.09%
Other	66	0.08%	19	0.02%
Total	**287**	**0.35%**	**640**	**0.78%**
Total Returned for Analysis	**111**		**280**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	0	0.00%
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	276	0.34%
Total	**285**	**0.35%**



Year	1	2	3	4	at 49 months					
Survival Probability	99.41%	99.20%	99.12%	99.02%	99.02%					
± 1 standard error	0.03%	0.04%	0.04%	0.07%	0.07%					
Sample Size	64,480	35,160	16,910	5,250	400					

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

Actively Monitored Study Data

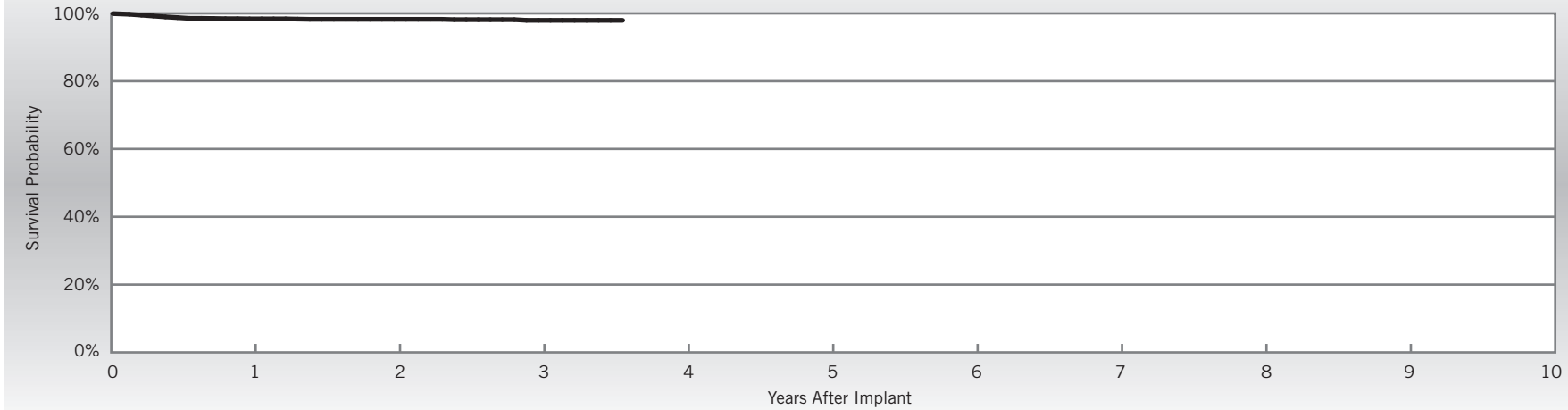
Quartet™

Model 1458Q

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	2,030
Active Devices Enrolled in Study	1,383
Cumulative Months of Follow-up	51,521
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	1	0.05%
Lead Dislodgement	30	1.48%

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	17	0.84%
Total	**17**	**0.84%**



Year	1	2	3	at 43 months						
Survival Probability	98.38%	98.25%	97.95%	97.95%						
± 1 standard error	0.28%	0.30%	0.38%	0.38%						
Sample Size	1,870	1,550	880	70						

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

Customer Reported Performance Data

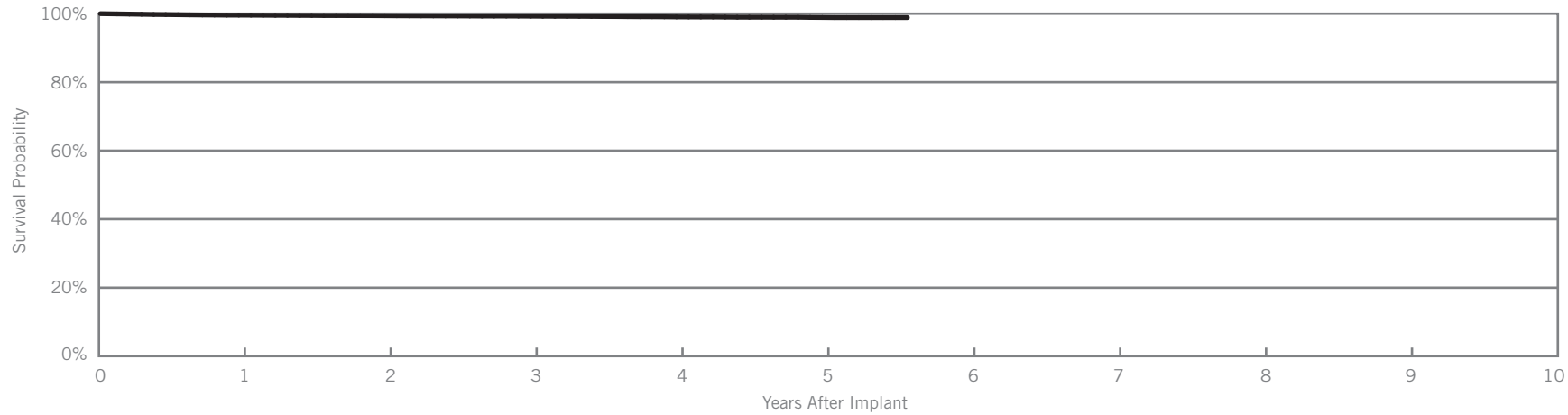
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	44,487
Estimated Active US Implants	29,778
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%	11	0.02%
Lead Dislodgement	44	0.10%	152	0.34%
Failure to Capture	16	0.04%	98	0.22%
Oversensing	0	0.00%	8	0.02%
Failure to Sense	1	<0.01%	1	<0.01%
Insulation Breach	0	0.00%	3	<0.01%
Abnormal Pacing Impedance	5	0.01%	24	0.05%
Extracardiac Stimulation	19	0.04%	51	0.11%
Other	12	0.03%	5	0.01%
Total	**97**	**0.22%**	**353**	**0.79%**
Total Returned for Analysis	**50**		**165**	

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	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	1	<0.01%
Extrinsic Factors	182	0.41%
Total	**189**	**0.42%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	99.58%	99.42%	99.29%	99.07%	98.89%	98.86%				
± 1 standard error	0.03%	0.04%	0.04%	0.06%	0.07%	0.08%				
Sample Size	40,230	31,880	23,530	15,730	7,870	510				

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

Actively Monitored Study Data

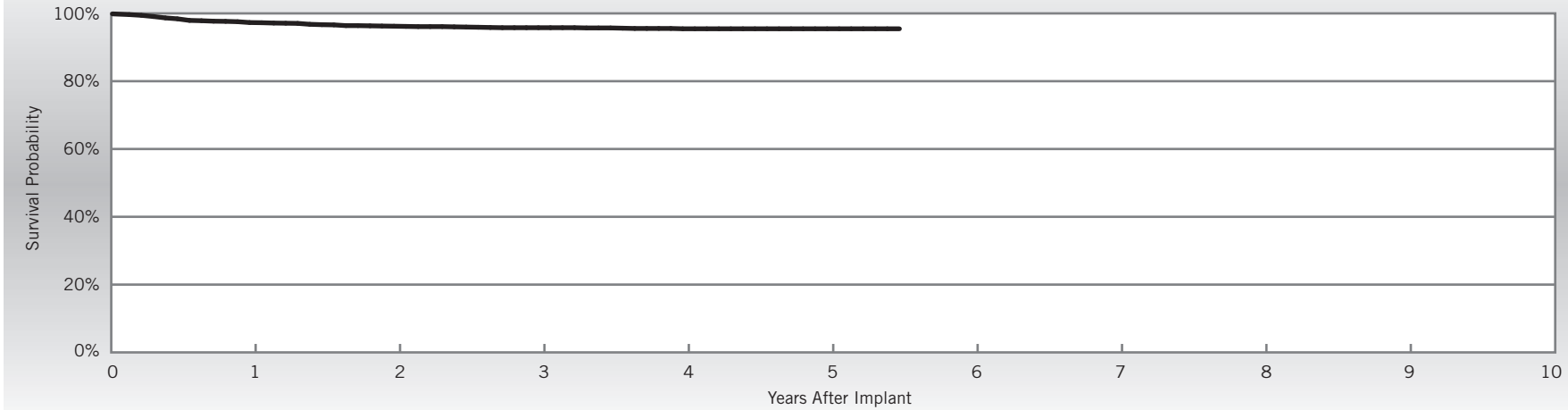
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	2,355
Active Devices Enrolled in Study	1,242
Cumulative Months of Follow-up	86,807
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	6	0.25%
Conductor Fracture	1	0.04%
Extracardiac Stimulation	6	0.25%
Failure to Capture	32	1.36%
Lead Dislodgement	45	1.91%

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	31	1.32%
Total	**32**	**1.36%**



Year	1	2	3	4	5	at 66 months				
Survival Probability	97.30%	96.22%	95.78%	95.46%	95.46%	95.46%				
± 1 standard error	0.33%	0.42%	0.45%	0.47%	0.48%	0.48%				
Sample Size	2,150	1,790	1,520	1,210	590	50				

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

Customer Reported Performance Data

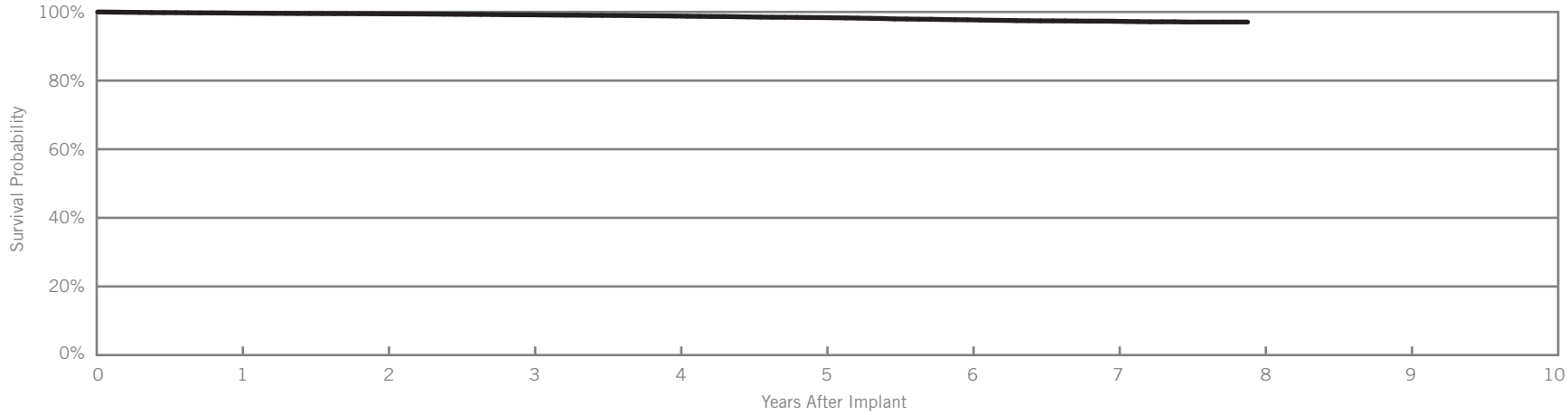
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	27,639
Estimated Active US Implants	13,617
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 301)	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%	5	0.02%
Lead Dislodgement	11	0.04%	122	0.44%
Failure to Capture	4	0.01%	149	0.54%
Oversensing	0	0.00%	10	0.04%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	35	0.13%
Abnormal Pacing Impedance	0	0.00%	43	0.16%
Extracardiac Stimulation	13	0.05%	70	0.25%
Other	9	0.03%	5	0.02%
Total	**37**	**0.13%**	**439**	**1.59%**
Total Returned for Analysis	**14**		**140**	

Malfunctions	Qty.	Rate
Conductor Fracture	5	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	5	0.02%
Insulation Breach	70	0.25%
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	55	0.20%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	122	0.44%
Total	**197**	**0.71%**



Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.67%	99.47%	99.19%	98.82%	98.35%	97.70%	97.30%	97.06%		
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.09%	0.12%	0.15%	0.19%		
Sample Size	25,380	21,760	19,340	17,200	14,310	9,980	5,100	300		

Actively Monitored Study Data

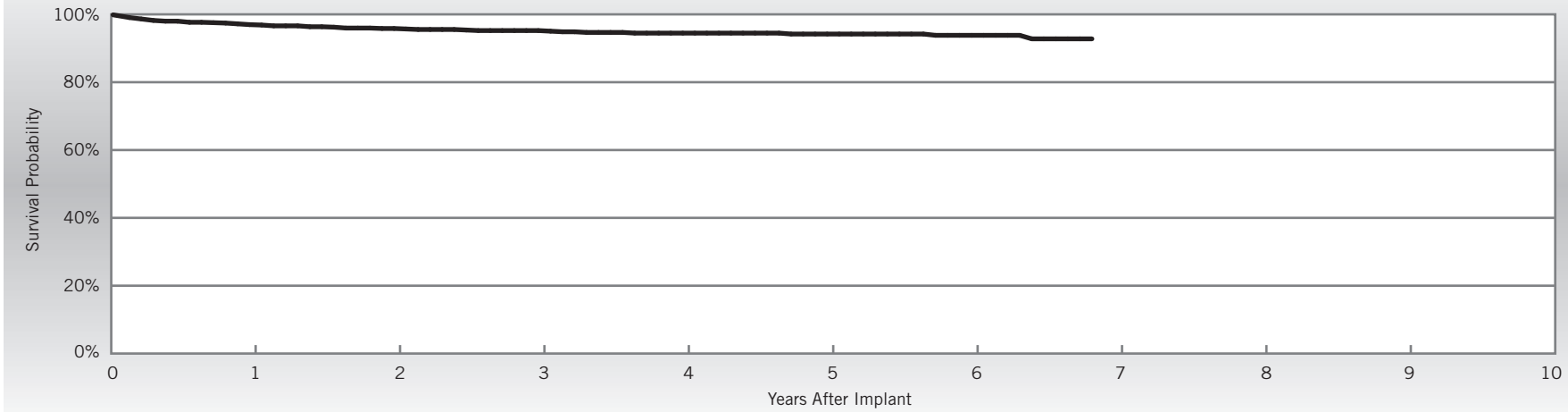
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	982
Active Devices Enrolled in Study	355
Cumulative Months of Follow-up	41,167
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	15	1.53%
Failure to Capture	8	0.81%
Lead Dislodgement	24	2.44%

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	0.10%
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	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	17	1.73%
Total	**18**	**1.83%**



Year	1	2	3	4	5	6	at 82 months			
Survival Probability	96.97%	95.83%	95.22%	94.47%	94.20%	93.82%	92.78%			
± 1 standard error	0.54%	0.67%	0.74%	0.82%	0.86%	0.94%	1.39%			
Sample Size	900	750	610	480	370	250	50			

Customer Reported Performance Data

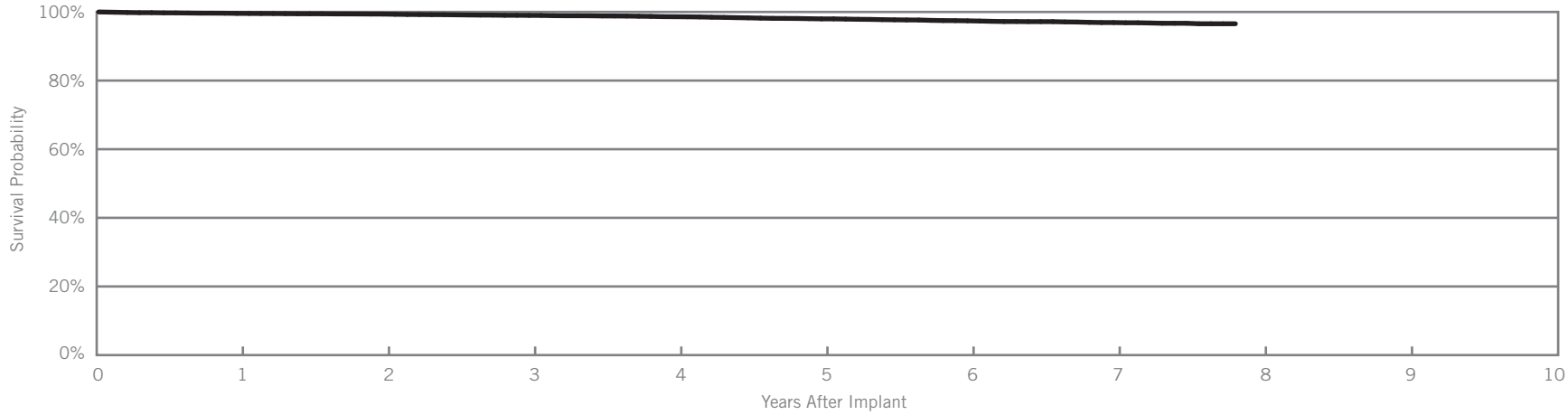
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,333
Estimated Active US Implants	7,691
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 301)	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%	3	0.02%
Lead Dislodgement	9	0.06%	85	0.55%
Failure to Capture	2	0.01%	106	0.69%
Oversensing	0	0.00%	1	<0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	0	0.00%	28	0.18%
Abnormal Pacing Impedance	2	0.01%	19	0.12%
Extracardiac Stimulation	6	0.04%	26	0.17%
Other	6	0.04%	6	0.04%
Total	**25**	**0.16%**	**275**	**1.79%**
Total Returned for Analysis	**13**		**101**	

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	44	0.29%
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	35	0.23%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	81	0.53%
Total	**131**	**0.85%**



Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.59%	99.41%	99.05%	98.67%	98.06%	97.50%	96.99%	96.63%		
± 1 standard error	0.05%	0.07%	0.09%	0.11%	0.13%	0.17%	0.22%	0.29%		
Sample Size	14,100	12,130	10,810	9,600	7,810	5,290	2,780	320		

Actively Monitored Study Data

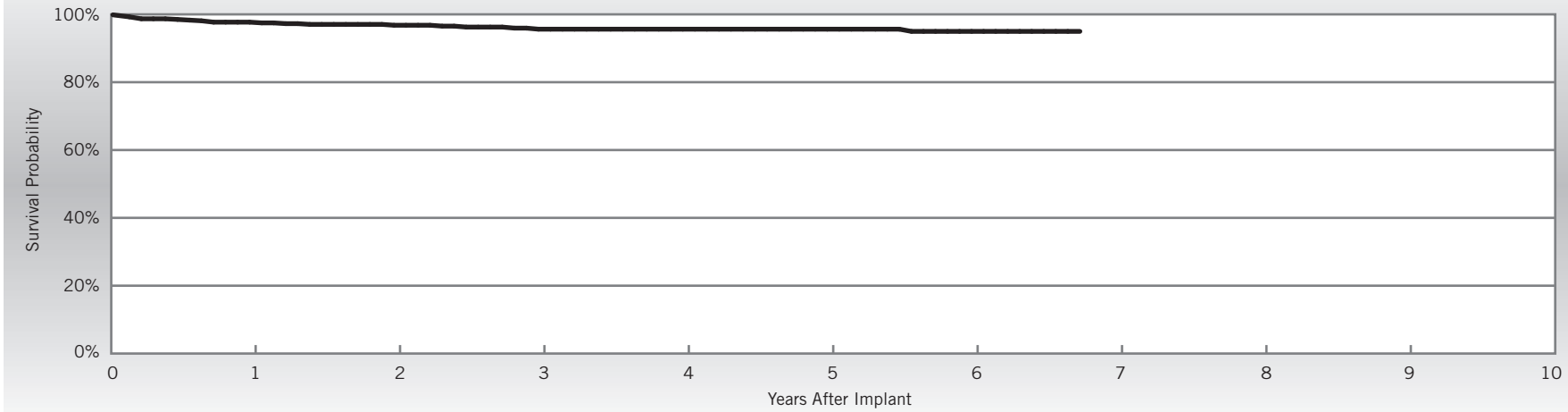
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	559
Active Devices Enrolled in Study	177
Cumulative Months of Follow-up	23,358
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	9	1.61%
Failure to Capture	4	0.72%
Insulation Breach	1	0.18%
Lead Dislodgement	6	1.07%
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	1.25%
Total	**8**	**1.43%**



Year	1	2	3	4	5	6	at 81 months			
Survival Probability	97.70%	96.79%	95.63%	95.63%	95.63%	94.98%	94.98%			
± 1 standard error	0.66%	0.75%	0.93%	0.97%	0.97%	1.17%	1.17%			
Sample Size	510	430	350	270	200	140	50			

Customer Reported Performance Data

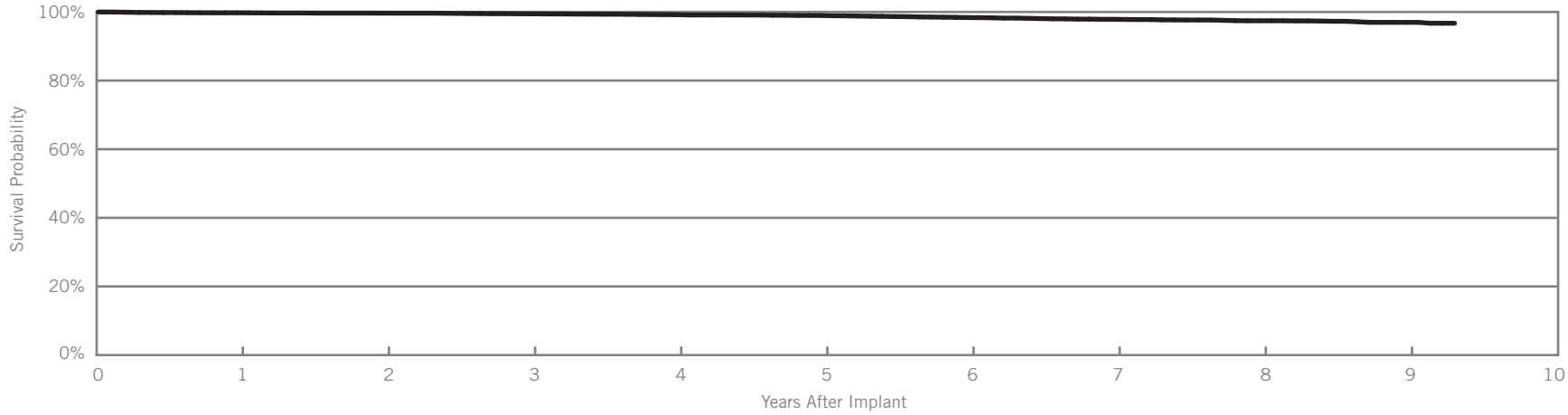
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	9,951
Estimated Active US Implants	4,010
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 301)	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%	2	0.02%
Lead Dislodgement	10	0.10%	29	0.29%
Failure to Capture	3	0.03%	69	0.69%
Oversensing	1	0.01%	2	0.02%
Failure to Sense	0	0.00%	2	0.02%
Insulation Breach	0	0.00%	29	0.29%
Abnormal Pacing Impedance	2	0.02%	18	0.18%
Extracardiac Stimulation	9	0.09%	20	0.20%
Other	1	0.01%	2	0.02%
Total	**26**	**0.26%**	**173**	**1.74%**
Total Returned for Analysis	**11**		**34**	

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	21	0.21%
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	14	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	28	0.28%
Total	**52**	**0.52%**



Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.74%	99.64%	99.42%	99.20%	98.93%	98.26%	97.78%	97.36%	96.78%	96.53%
± 1 standard error	0.05%	0.06%	0.08%	0.10%	0.12%	0.17%	0.20%	0.23%	0.30%	0.39%
Sample Size	9,180	7,910	6,960	6,140	5,480	4,880	4,230	3,370	1,700	220

Actively Monitored Study Data

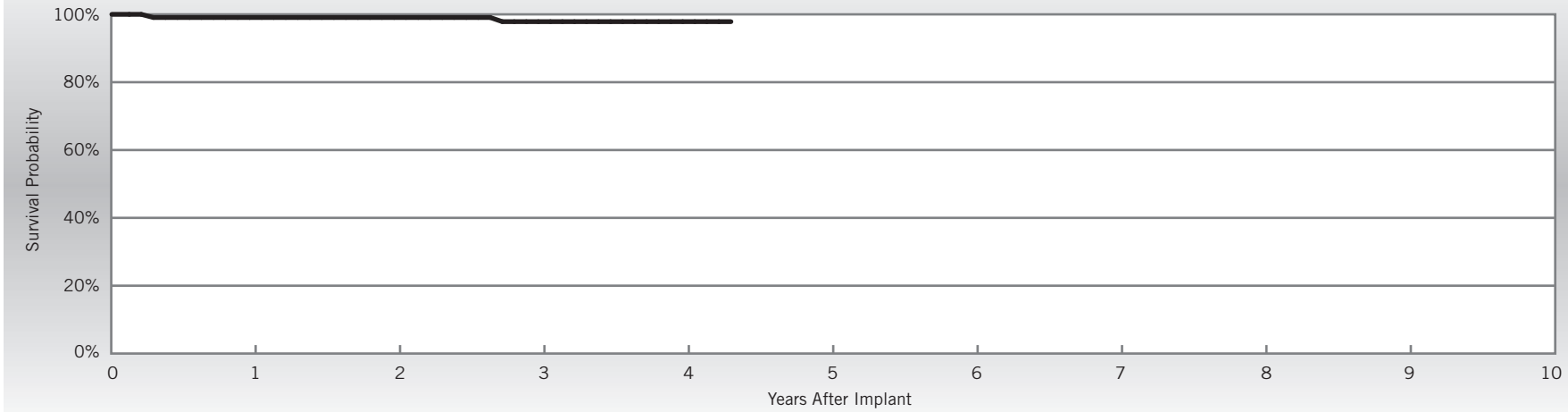
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	111
Active Devices Enrolled in Study	42
Cumulative Months of Follow-up	5,605
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	2	1.80%

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 52 months					
Survival Probability	99.07%	99.07%	97.85%	97.85%	97.85%					
± 1 standard error	0.92%	0.92%	1.52%	1.52%	1.52%					
Sample Size	100	90	80	70	50					

Customer Reported Performance Data

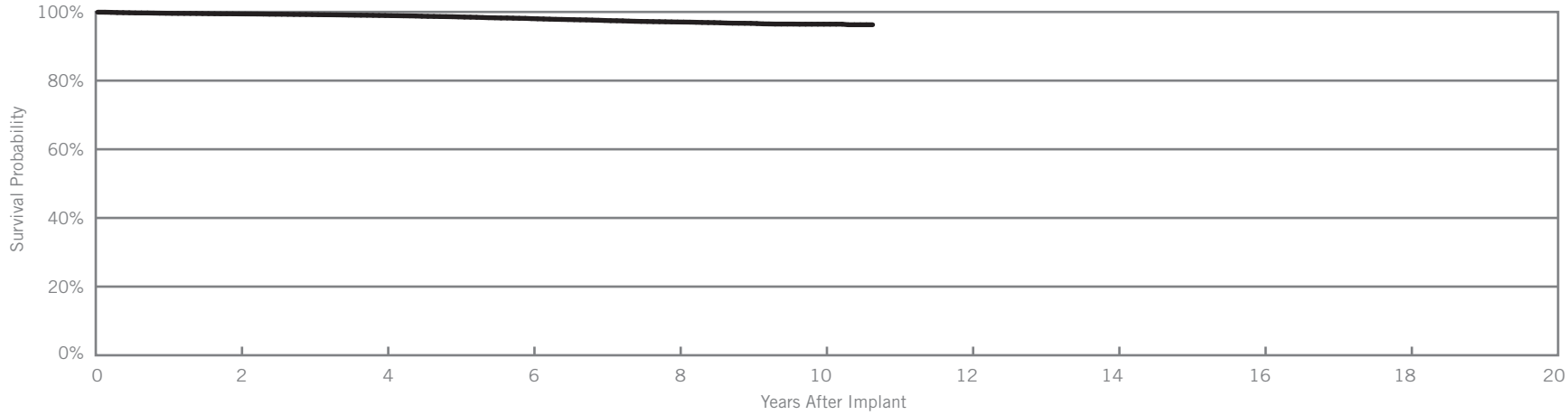
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	32,326
Estimated Active US Implants	11,797
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pg. 301)	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%	6	0.02%
Lead Dislodgement	31	0.10%	158	0.49%
Failure to Capture	15	0.05%	247	0.76%
Oversensing	2	<0.01%	19	0.06%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	99	0.31%
Abnormal Pacing Impedance	3	<0.01%	48	0.15%
Extracardiac Stimulation	22	0.07%	95	0.29%
Other	9	0.03%	19	0.06%
Total	**83**	**0.26%**	**692**	**2.14%**
Total Returned for Analysis	**27**		**182**	

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	80	0.25%
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	37	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	152	0.47%
Total	**239**	**0.74%**



Year	2	4	6	8	10	at 128 months				
Survival Probability	99.43%	98.96%	98.06%	97.08%	96.45%	96.28%				
± 1 standard error	0.04%	0.06%	0.10%	0.13%	0.16%	0.20%				
Sample Size	25,720	19,970	15,360	11,150	4,000	250				

Actively Monitored Study Data

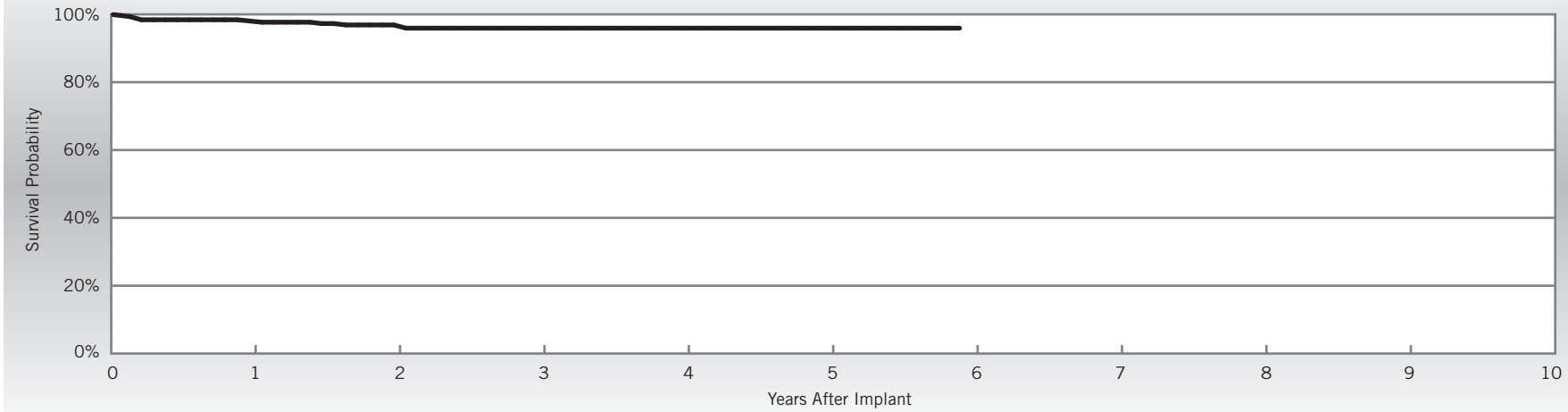
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	321
Active Devices Enrolled in Study	100
Cumulative Months of Follow-up	12,822
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	3	0.93%
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	at 71 months				
Survival Probability	98.04%	96.87%	95.93%	95.93%	95.93%	95.93%				
± 1 standard error	0.71%	1.03%	1.22%	1.22%	1.22%	1.22%				
Sample Size	300	240	190	140	100	50				

Customer Reported Performance Data

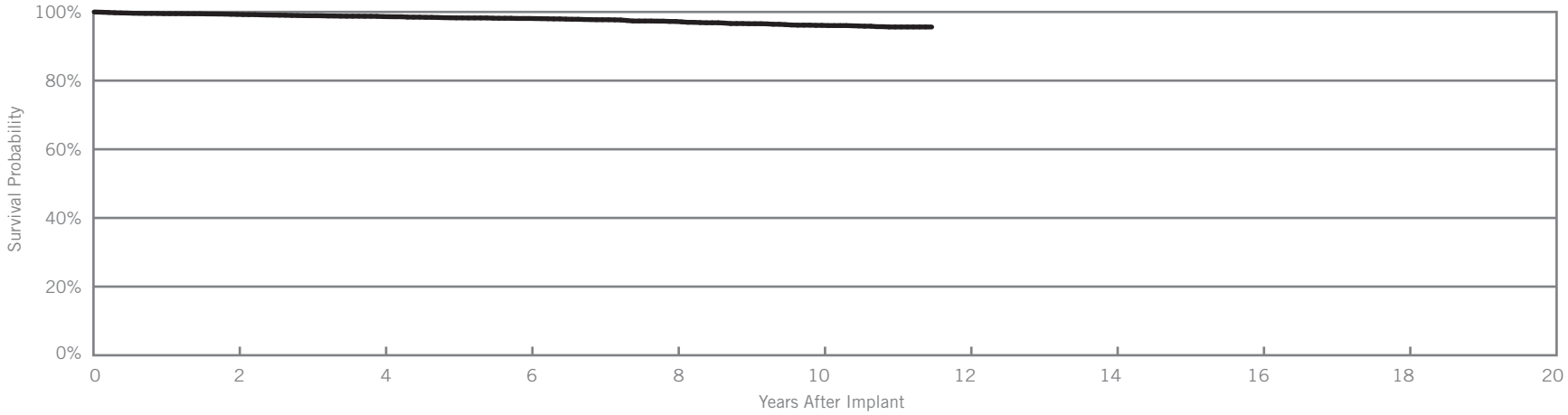
QuickSite™

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	7,871
Estimated Active US Implants	2,082
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%	4	0.05%
Lead Dislodgement	10	0.13%	34	0.43%
Failure to Capture	3	0.04%	66	0.84%
Oversensing	0	0.00%	1	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	3	0.04%
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%**	**156**	**1.98%**
Total Returned for Analysis	**13**		**45**	

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	1	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	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	49	0.62%
Total	**53**	**0.67%**



Year	2	4	6	8	10	at 138 months				
Survival Probability	99.29%	98.65%	98.10%	97.23%	96.09%	95.62%				
± 1 standard error	0.10%	0.15%	0.19%	0.26%	0.35%	0.39%				
Sample Size	6,220	4,660	3,420	2,530	1,820	270				

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™	99.41%	99.20%	99.12%	99.02%						
1258T	QuickFlex™ µ	99.58%	99.42%	99.29%	99.07%	98.89%					
1156T	QuickFlex™	99.67%	99.47%	99.19%	98.82%	98.35%	97.70%	97.30%			
1158T	QuickFlex™ XL	99.59%	99.41%	99.05%	98.67%	98.06%	97.50%	96.99%			
1058T	QuickSite™ XL	99.74%	99.64%	99.42%	99.20%	98.93%	98.26%	97.78%	97.36%	96.78%	
1056T	QuickSite™	99.62%	99.43%	99.23%	98.96%	98.56%	98.06%	97.52%	97.08%	96.69%	96.45%
1056K	QuickSite™	99.50%	99.29%	98.90%	98.65%	98.27%	98.10%	97.73%	97.23%	96.57%	96.09%

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	82,351	69,487	2	<0.01%	0	0.00%	110	0.13%	45	0.05%	2	<0.01%	0	0.00%	1	<0.01%	4	<0.01%	57	0.07%	66	0.08%	**287**	**0.35%**	**111**
1258T	May-10	44,487	29,778	0	0.00%	0	0.00%	44	0.10%	16	0.04%	0	0.00%	1	<0.01%	0	0.00%	5	0.01%	19	0.04%	12	0.03%	**97**	**0.22%**	**50**
1156T	Jul-07	27,639	13,617	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	15,333	7,691	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	9,951	4,010	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	32,326	11,797	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	7,871	2,082	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	82,351	69,487	2	<0.01%	4	<0.01%	387	0.47%	126	0.15%	4	<0.01%	0	0.00%	2	<0.01%	19	0.02%	77	0.09%	19	0.02%	**640**	**0.78%**	**280**
1258T	May-10	44,487	29,778	0	0.00%	11	0.02%	152	0.34%	98	0.22%	8	0.02%	1	<0.01%	3	<0.01%	24	0.05%	51	0.11%	5	0.01%	**353**	**0.79%**	**165**
1156T	Jul-07	27,639	13,617	0	0.00%	5	0.02%	122	0.44%	149	0.54%	10	0.04%	0	0.00%	35	0.13%	43	0.16%	70	0.25%	5	0.02%	**439**	**1.59%**	**140**
1158T	Jul-07	15,333	7,691	0	0.00%	3	0.02%	85	0.55%	106	0.69%	1	<0.01%	1	<0.01%	28	0.18%	19	0.12%	26	0.17%	6	0.04%	**275**	**1.79%**	**101**
1058T	Feb-06	9,951	4,010	0	0.00%	2	0.02%	29	0.29%	69	0.69%	2	0.02%	2	0.02%	29	0.29%	18	0.18%	20	0.20%	2	0.02%	**173**	**1.74%**	**34**
1056T	Apr-05	32,326	11,797	0	0.00%	6	0.02%	158	0.49%	247	0.76%	19	0.06%	1	<0.01%	99	0.31%	48	0.15%	95	0.29%	19	0.06%	**692**	**2.14%**	**182**
1056K	Jun-04	7,871	2,082	0	0.00%	4	0.05%	34	0.43%	66	0.84%	1	0.01%	0	0.00%	3	0.04%	7	0.09%	31	0.39%	10	0.13%	**156**	**1.98%**	**45**

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	82,351	4.80%	0	0.00%	1	<0.01%	0	0.00%	**1**	**<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%	276	0.34%	**285**	**0.35%**
1258T	44,487	8.70%	1	<0.01%	1	<0.01%	3	<0.01%	**5**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**	0	0.00%	1	<0.01%	182	0.41%	**189**	**0.42%**
1156T	27,639	8.00%	0	0.00%	0	0.00%	5	0.02%	**5**	**0.02%**	0	0.00%	2	<0.01%	0	0.00%	13	0.05%	55	0.20%	**70**	**0.25%**	0	0.00%	0	0.00%	122	0.44%	**197**	**0.71%**
1158T	15,333	9.10%	0	0.00%	1	<0.01%	4	0.03%	**5**	**0.03%**	0	0.00%	2	0.01%	0	0.00%	7	0.05%	35	0.23%	**44**	**0.29%**	1	<0.01%	0	0.00%	81	0.53%	**131**	**0.85%**
1058T	9,951	9.00%	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**	0	0.00%	1	0.01%	0	0.00%	6	0.06%	14	0.14%	**21**	**0.21%**	0	0.00%	1	0.01%	28	0.28%	**52**	**0.52%**
1056T	32,326	8.90%	0	0.00%	2	<0.01%	4	0.01%	**6**	**0.02%**	1	<0.01%	11	0.03%	0	0.00%	31	0.10%	37	0.11%	**80**	**0.25%**	0	0.00%	1	<0.01%	152	0.47%	**239**	**0.74%**
1056K	7,871	14.80%	0	0.00%	0	0.00%	3	0.04%	**3**	**0.04%**	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**	0	0.00%	0	0.00%	49	0.62%	**53**	**0.67%**

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	166,114	3.0%	2	<0.01%	6	<0.01%	2	<0.01%	**10**	**0.01%**	1	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	3	<0.01%	**6**	**<0.01%**	0	0.00%	118	0.07%	454	0.27%	**588**	**0.35%**
1258T	142,996	3.5%	7	<0.01%	14	0.01%	10	0.01%	**31**	**0.02%**	1	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	3	<0.01%	**6**	**<0.01%**	0	0.00%	31	0.02%	309	0.22%	**377**	**0.26%**

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	2,030	1,383	51,521	1	0.05%	0	0.00%	0	0.00%	3	0.15%	1	0.05%	0	0.00%	0	0.00%	30	1.48%	0	0.00%	0	0.00%	0	0.00%	**35**	**1.72%**
1258T	2,355	1,242	86,807	6	0.25%	0	0.00%	1	0.04%	6	0.25%	32	1.36%	0	0.00%	0	0.00%	45	1.91%	0	0.00%	0	0.00%	0	0.00%	**90**	**3.82%**
1156T	982	355	41,167	1	0.10%	0	0.00%	0	0.00%	15	1.53%	8	0.81%	0	0.00%	0	0.00%	24	2.44%	0	0.00%	0	0.00%	0	0.00%	**48**	**4.89%**
1158T	559	177	23,358	0	0.00%	0	0.00%	0	0.00%	9	1.61%	4	0.72%	0	0.00%	1	0.18%	6	1.07%	0	0.00%	0	0.00%	1	0.18%	**21**	**3.76%**
1058T	111	42	5,605	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.80%**
1056T	321	100	12,822	1	0.31%	0	0.00%	0	0.00%	2	0.62%	3	0.93%	0	0.00%	0	0.00%	5	1.56%	0	0.00%	0	0.00%	0	0.00%	**11**	**3.43%**

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	2,030	3.50%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	17	0.84%	**17**	**0.84%**
1258T	2,355	4.40%	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%	31	1.32%	**32**	**1.36%**
1156T	982	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%	1	0.10%	**1**	**0.10%**	0	0.00%	0	0.00%	17	1.73%	**18**	**1.83%**
1158T	559	3.90%	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	1.25%	**8**	**1.43%**
1058T	111	2.70%	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%	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

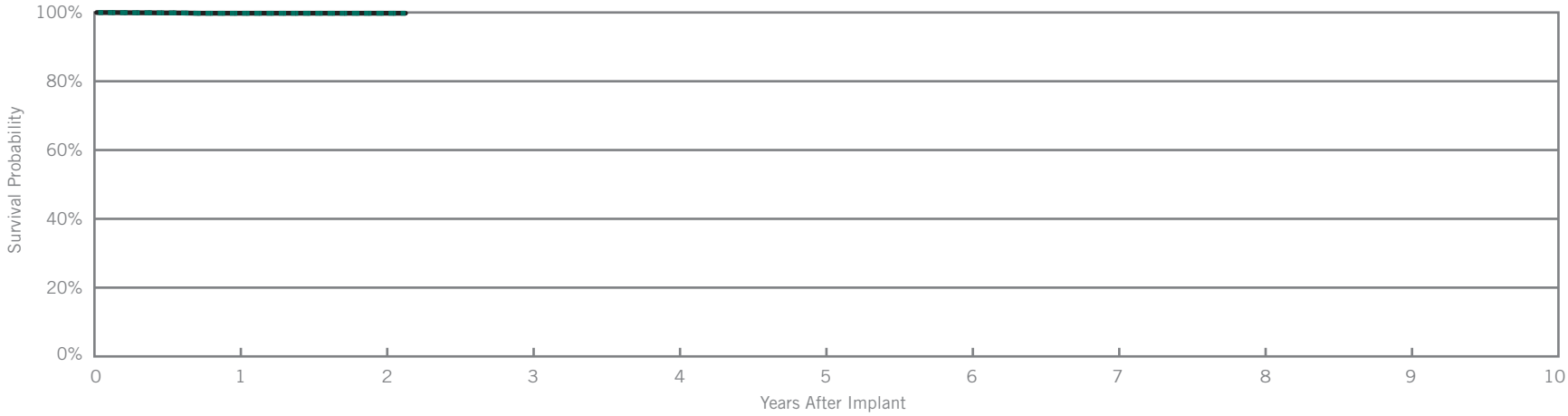
Ellipse™ DR

Model CD2411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	7,418
Estimated Active US Implants	6,464
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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%	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%	0	0.00%
Total	**4**	**0.05%**	**2**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.78%	99.78%	99.78%							
± 1 standard error	0.06%	0.06%	0.06%							
Sample Size	5,270	1,740	260							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.78%	99.78%	99.78%							
± 1 standard error	0.06%	0.06%	0.06%							

**DF4-LLHH connector type.*

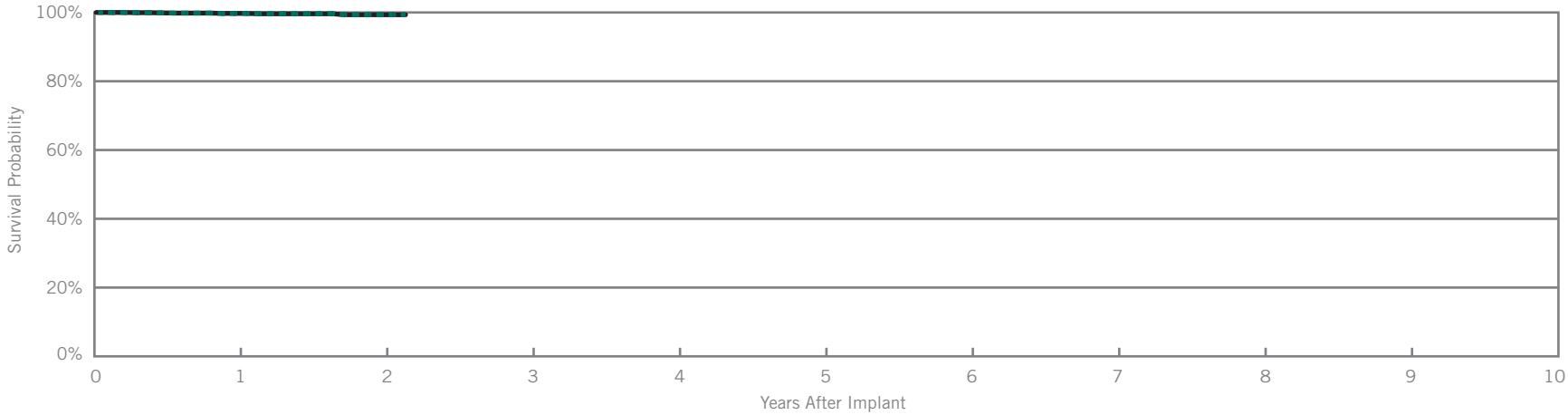
Ellipse™ DR

Model CD2411-36C*

US Regulatory Approval	June 2013
Registered US Implants	4,290
Estimated Active US Implants	3,732
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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	4	0.09%	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	**5**	**0.12%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.73%	99.34%	99.34%							
± 1 standard error	0.10%	0.23%	0.23%							
Sample Size	3,190	1,200	230							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.73%	99.34%	99.34%							
± 1 standard error	0.10%	0.23%	0.23%							

**Parylene coating.*

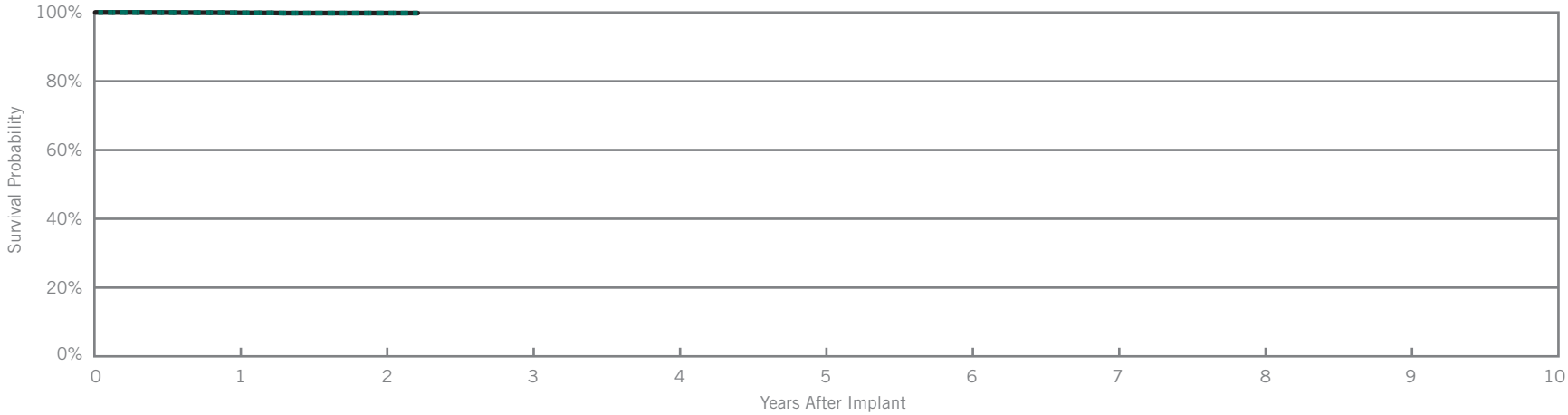
Fortify Assura™ DR

Model CD2357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	13,639
Estimated Active US Implants	11,869
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	0
Max. Delivered Energy	40 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	0.02%	2	0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.03%**	**2**	**0.01%**



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.90%	99.81%	99.81%							
± 1 standard error	0.03%	0.06%	0.06%							
Sample Size	9,690	3,150	230							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.90%	99.81%	99.81%							
± 1 standard error	0.03%	0.06%	0.06%							

**DF4-LLHH connector type.*

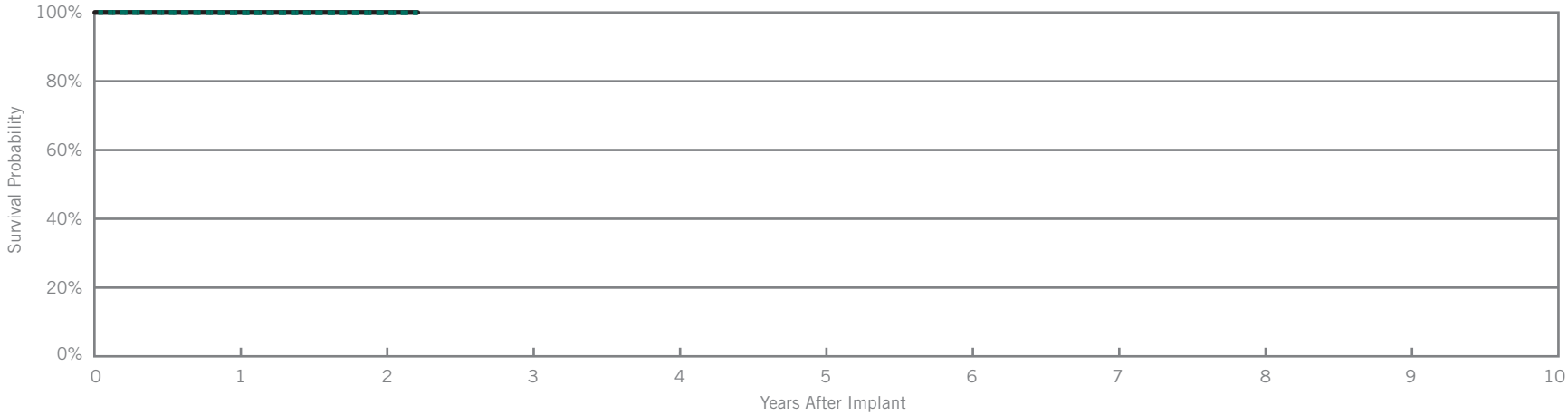
Fortify Assura™ DR

Model CD2357-40C*

US Regulatory Approval	June 2013
Registered US Implants	6,878
Estimated Active US Implants	5,964
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	2
Max. Delivered Energy	40 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	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.91%	99.91%	99.91%							
± 1 standard error	0.05%	0.05%	0.05%							
Sample Size	5,130	1,920	200							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

**Parylene coating.*

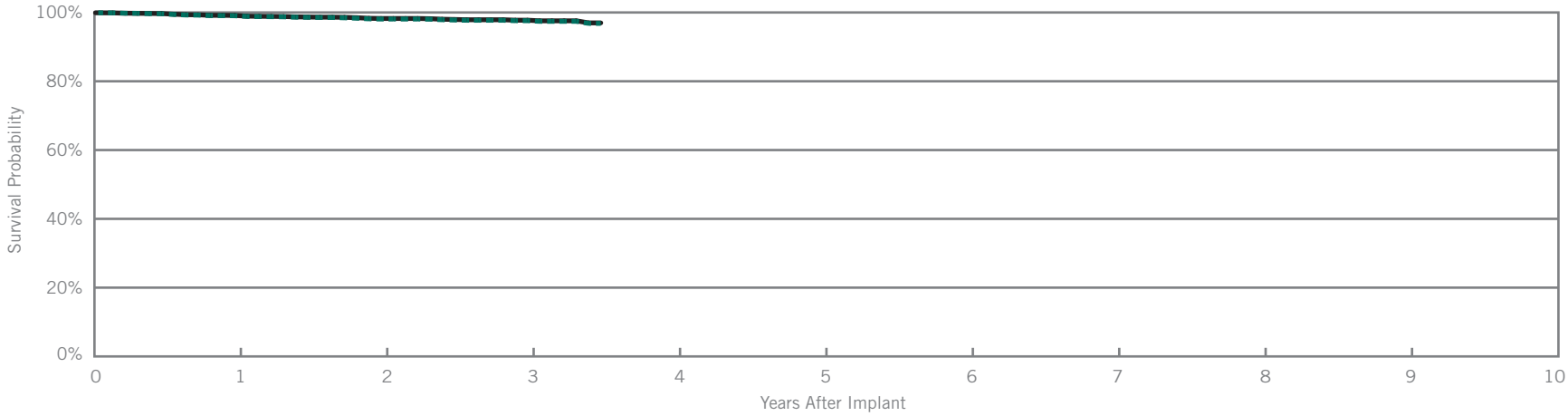
Ellipse™ DR

Model CD2311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	5,898
Estimated Active US Implants	4,297
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

Customer Reported Performance Data

	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	30	0.51%	4	0.07%
Software/Firmware	1	0.02%	0	0.00%
Mechanical	2	0.03%	2	0.03%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.02%	2	0.03%
Total	**37**	**0.63%**	**9**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.04%	98.09%	97.60%	96.82%						
± 1 standard error	0.13%	0.19%	0.24%	0.50%						
Sample Size	5,520	4,560	2,590	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.13%	98.25%	97.75%	96.97%						
± 1 standard error	0.12%	0.18%	0.23%	0.50%						

**DF4-LLHH connector type.*

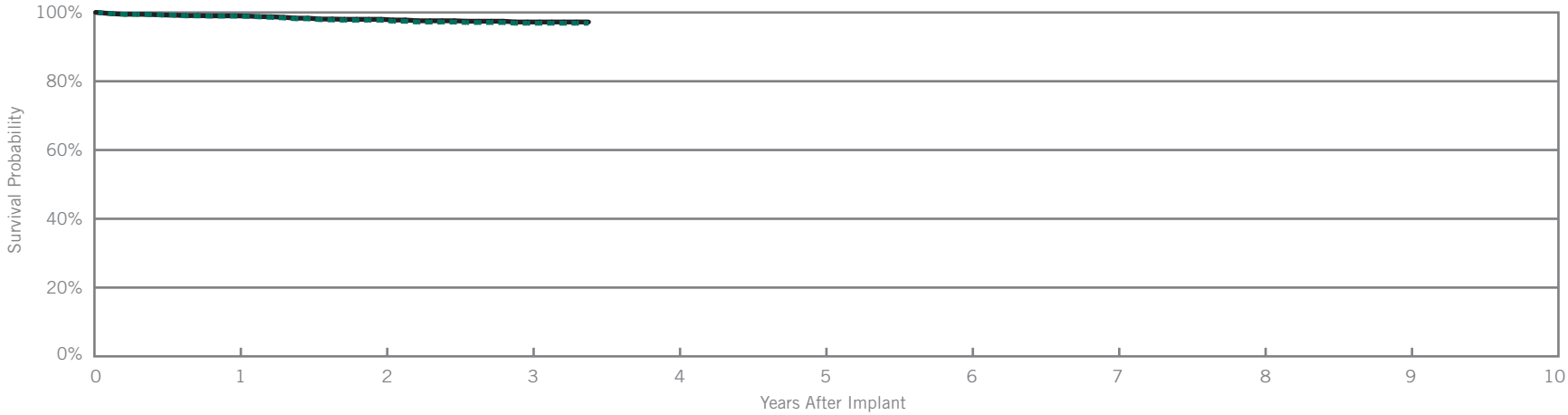
Customer Reported Performance Data

Ellipse™ DR

Model CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	3,744
Estimated Active US Implants	2,723
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	4
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.05%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	16	0.43%	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	**25**	**0.67%**	**9**	**0.24%**



Including Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	98.94%	97.76%	96.87%	96.87%						
± 1 standard error	0.17%	0.26%	0.35%	0.35%						
Sample Size	3,510	2,870	1,570	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.02%	98.01%	97.23%	97.23%						
± 1 standard error	0.16%	0.24%	0.33%	0.33%						

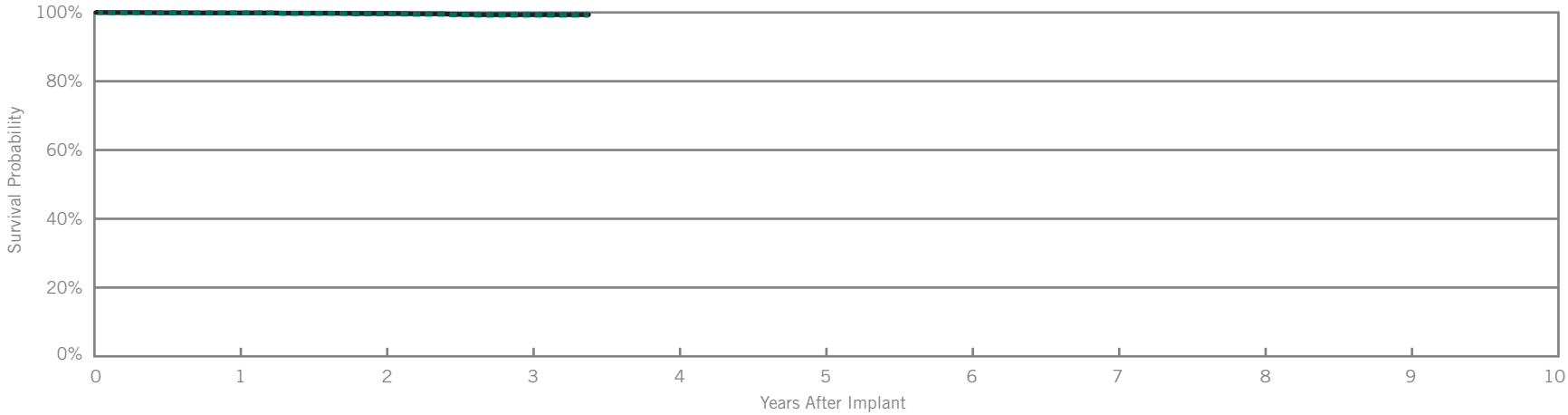
Fortify Assura™ DR

Model CD2257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	6,793
Estimated Active US Implants	4,982
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	3
Max. Delivered Energy	40 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	0.04%	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	3	0.04%	1	0.01%
Other	3	0.04%	0	0.00%
Total	**9**	**0.13%**	**4**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.87%	99.61%	99.21%	99.21%						
± 1 standard error	0.04%	0.08%	0.14%	0.14%						
Sample Size	6,350	5,250	2,710	240						

Excluding Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.87%	99.71%	99.35%	99.35%						
± 1 standard error	0.04%	0.07%	0.13%	0.13%						

**DF4-LLHH connector type.*

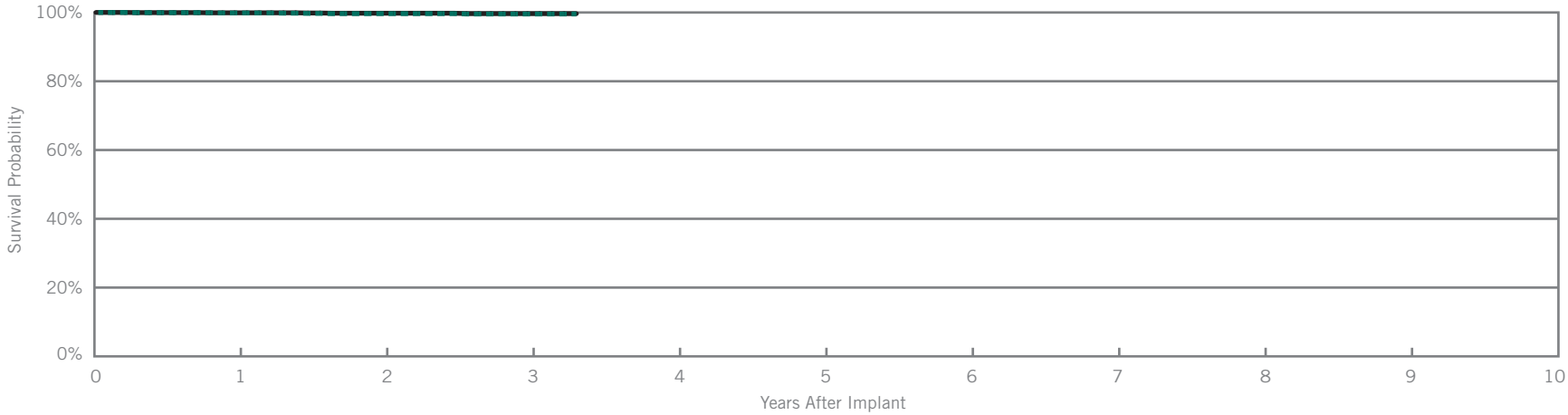
Fortify Assura™ DR

Model CD2257-40

US Regulatory Approval	May 2012
Registered US Implants	4,224
Estimated Active US Implants	3,140
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	2
Max. Delivered Energy	40 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	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	0	0.00%	1	0.02%
Other	0	0.00%	1	0.02%
Total	**2**	**0.05%**	**3**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	99.85%	99.67%	99.55%	99.55%						
± 1 standard error	0.06%	0.09%	0.13%	0.13%						
Sample Size	3,960	3,290	1,730	240						

Excluding Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	99.90%	99.78%	99.66%	99.66%						
± 1 standard error	0.05%	0.08%	0.12%	0.12%						

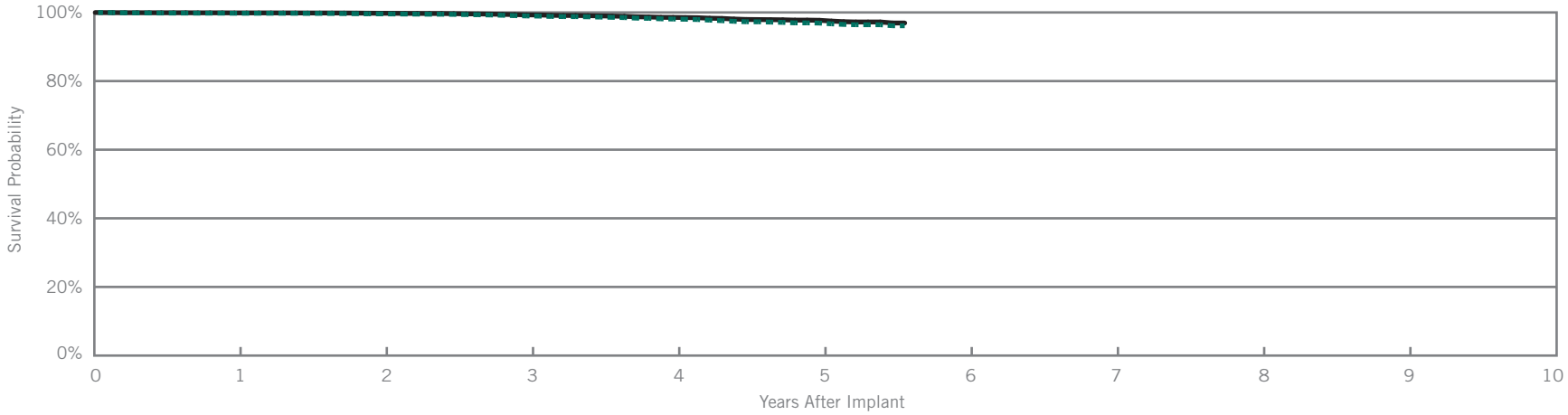
Fortify™ DR

Model CD2231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	26,841
Estimated Active US Implants	15,930
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	46
Max. Delivered Energy	40 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	5	0.02%	5	0.02%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	17	0.06%	11	0.04%
High Voltage Capacitor	2	<0.01%	0	0.00%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	58	0.22%	21	0.08%
Other	9	0.03%	4	0.01%
Total	**94**	**0.35%**	**43**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.76%	99.58%	98.97%	98.08%	96.90%	96.11%				
± 1 standard error	0.03%	0.04%	0.07%	0.10%	0.16%	0.29%				
Sample Size	25,120	22,060	19,210	14,430	7,430	430				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.87%	99.76%	99.29%	98.55%	97.71%	96.92%				
± 1 standard error	0.02%	0.03%	0.06%	0.09%	0.14%	0.28%				

**DF4-LLHH connector type.*

Actively Monitored Study Data

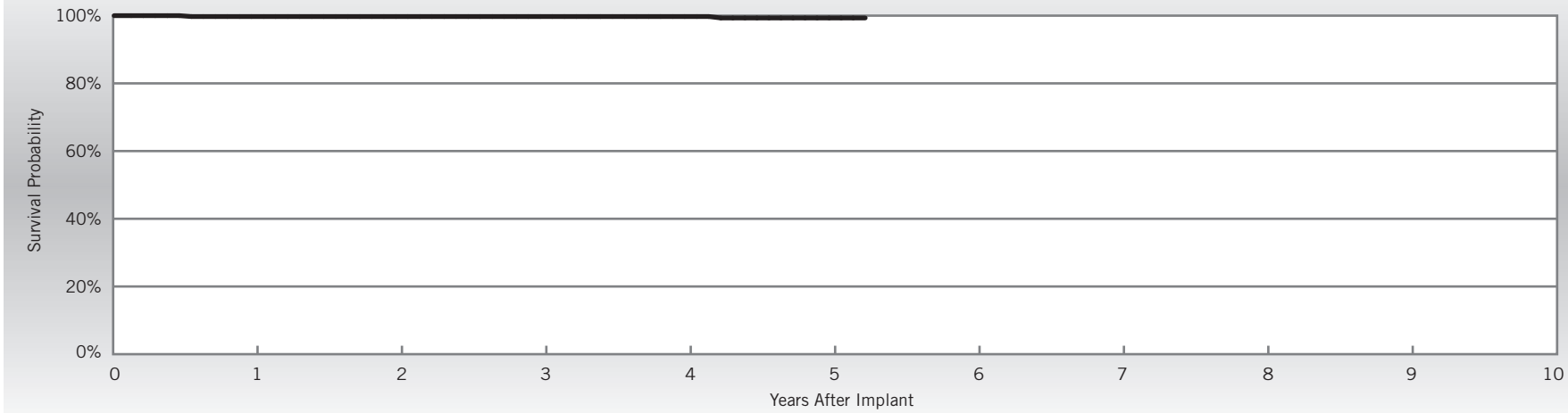
Fortify™ DR

Model CD2231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	390
Active Devices Enrolled in Study	247
Cumulative Months of Follow-up	17,882
Estimated Longevity	(see table on page 107)
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%	0	0.00%
Other	1	0.26%	0	0.00%
Total	**2**	**0.51%**	**0**	**0.00%**



Year	1	2	3	4	5	at 63 months				
Survival Probability	99.74%	99.74%	99.74%	99.74%	99.32%	99.32%				
± 1 standard error	0.26%	0.26%	0.26%	0.26%	0.49%	0.49%				
Sample Size	380	340	310	270	170	60				

**DF4-LLHH connector type.*

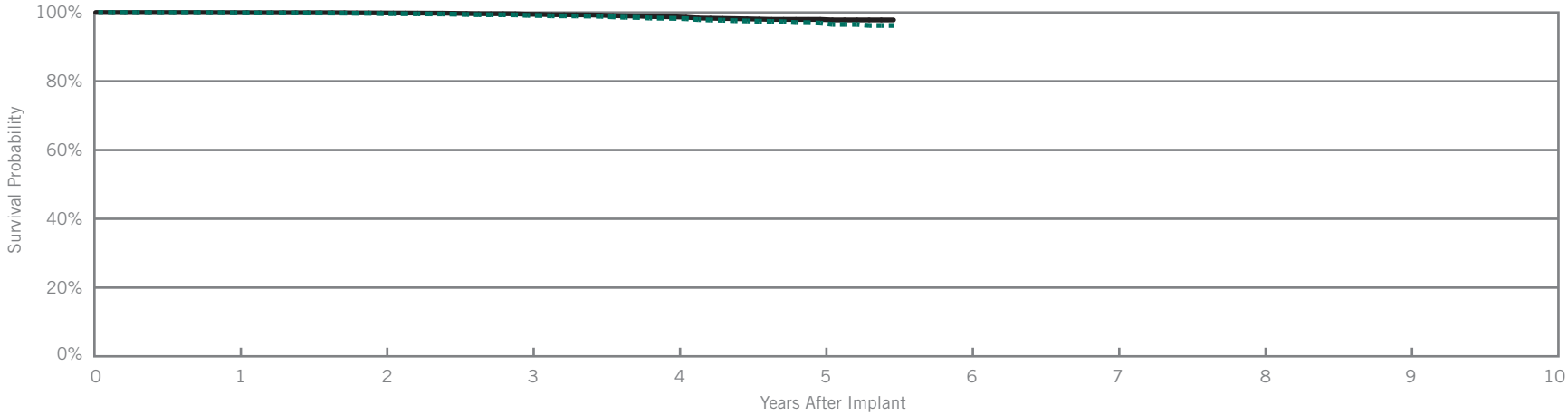
Customer Reported Performance Data

Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	12,072
Estimated Active US Implants	7,081
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	24
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	2	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	2	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%	0	0.00%
Possible Early Battery Depletion	21	0.17%	7	0.06%
Other	4	0.03%	2	0.02%
Total	**37**	**0.31%**	**16**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.88%	99.66%	99.14%	98.29%	96.92%	96.22%				
± 1 standard error	0.02%	0.05%	0.09%	0.15%	0.25%	0.39%				
Sample Size	11,300	9,860	8,470	6,120	2,930	320				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.95%	99.86%	99.47%	98.73%	97.99%	97.84%				
± 1 standard error	0.02%	0.03%	0.07%	0.13%	0.20%	0.23%				

Actively Monitored Study Data

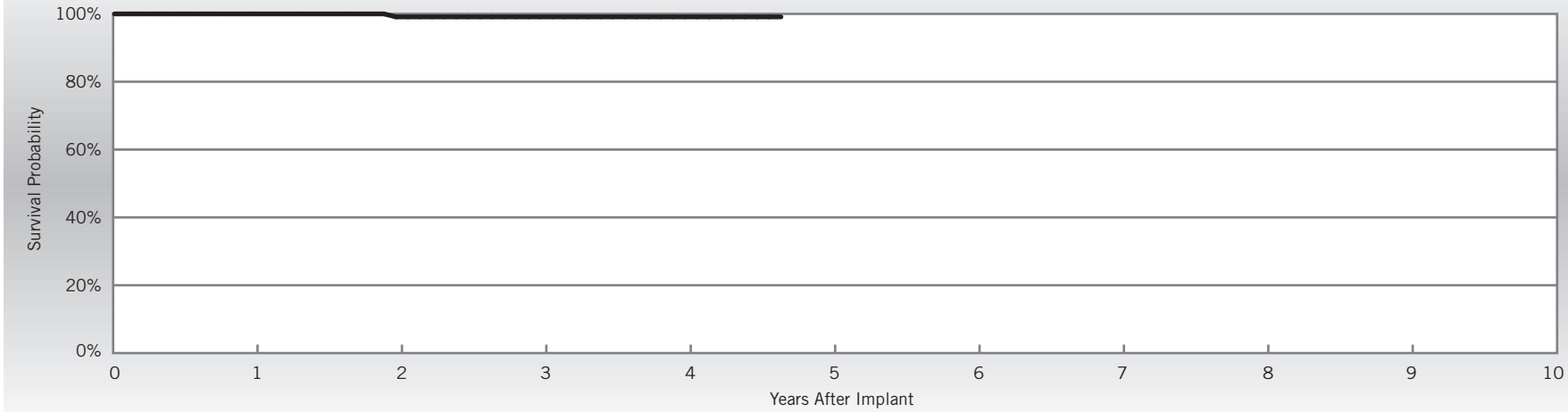
Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	177
Active Devices Enrolled in Study	82
Cumulative Months of Follow-up	6,508
Estimated Longevity	(see table on page 107)
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	at 56 months					
Survival Probability	100.00%	99.12%	99.12%	99.12%	99.12%					
± 1 standard error	0.00%	0.88%	0.88%	0.88%	0.88%					
Sample Size	160	130	100	90	50					

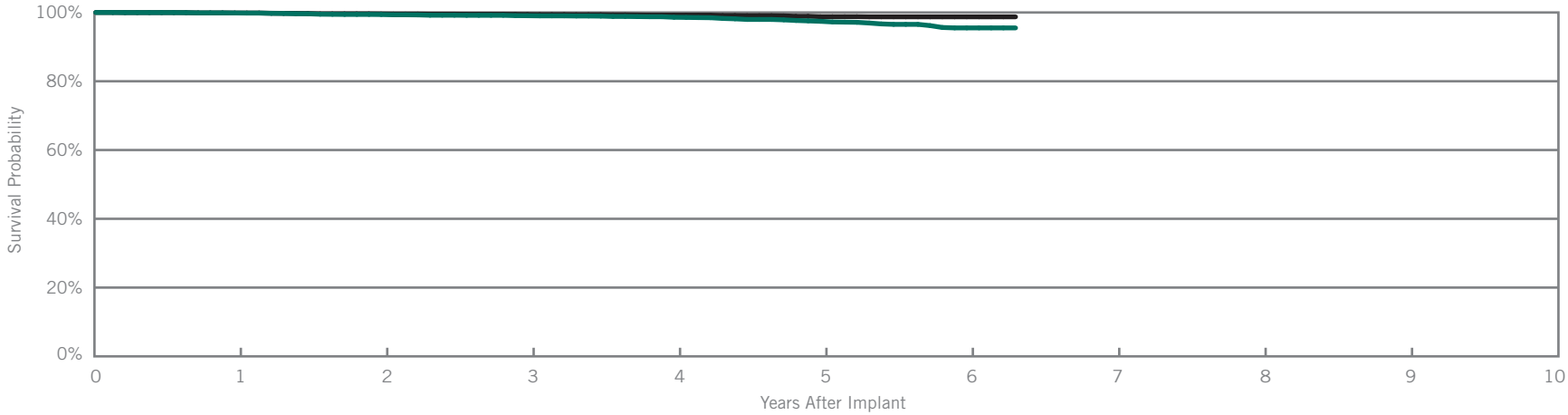
Customer Reported Performance Data

Current™ + DR

Model CD2211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	8,141
Estimated Active US Implants	4,046
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	50
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	5	0.06%	2	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	5	0.06%	6	0.07%
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	3	0.04%	3	0.04%
Other	4	0.05%	2	0.02%
Total	**18**	**0.22%**	**14**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.85%	99.40%	99.05%	98.60%	97.43%	95.51%	95.51%			
± 1 standard error	0.04%	0.09%	0.12%	0.14%	0.21%	0.34%	0.34%			
Sample Size	7,570	6,610	5,890	5,170	4,410	2,550	260			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.85%	99.58%	99.41%	99.22%	98.78%	98.73%	98.73%			
± 1 standard error	0.04%	0.07%	0.09%	0.11%	0.14%	0.15%	0.15%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

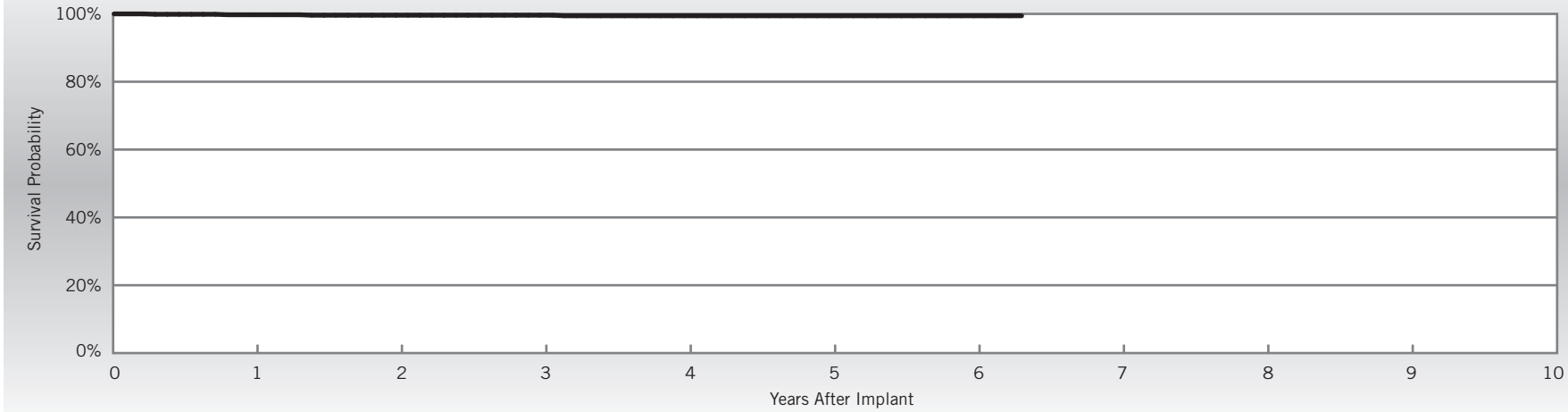
Current™ + DR

Model CD2211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	834
Active Devices Enrolled in Study	431
Cumulative Months of Follow-up	43,168
Estimated Longevity	(see table on page 107)
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%	0	0.00%
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%	0	0.00%
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%**	**3**	**0.36%**



Year	1	2	3	4	5	6	at 76 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	320	70			

**DF4-LLHH connector type.*

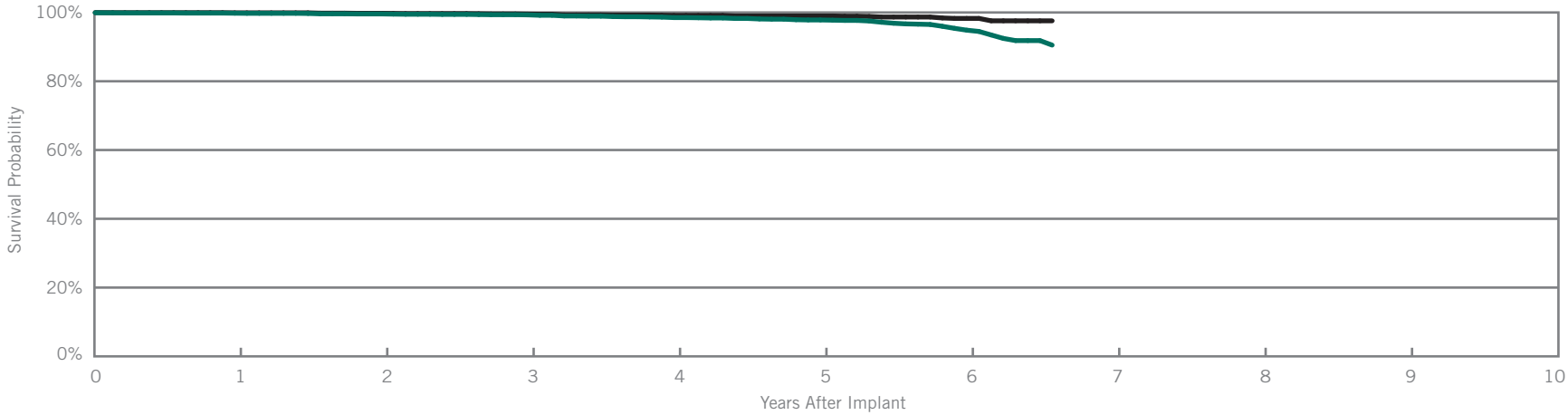
Customer Reported Performance Data

Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,270
Estimated Active US Implants	3,025
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	50
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	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	0	0.00%	2	0.03%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	5	0.08%	4	0.06%
Other	5	0.08%	0	0.00%
Total	**19**	**0.30%**	**11**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.78%	99.57%	99.30%	98.51%	97.82%	94.85%	90.51%			
± 1 standard error	0.05%	0.09%	0.11%	0.17%	0.23%	0.40%	0.69%			
Sample Size	5,850	5,080	4,460	3,900	3,300	2,170	210			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.90%	99.76%	99.53%	99.13%	98.98%	98.27%	97.57%			
± 1 standard error	0.03%	0.07%	0.09%	0.13%	0.15%	0.24%	0.34%			

Actively Monitored Study Data

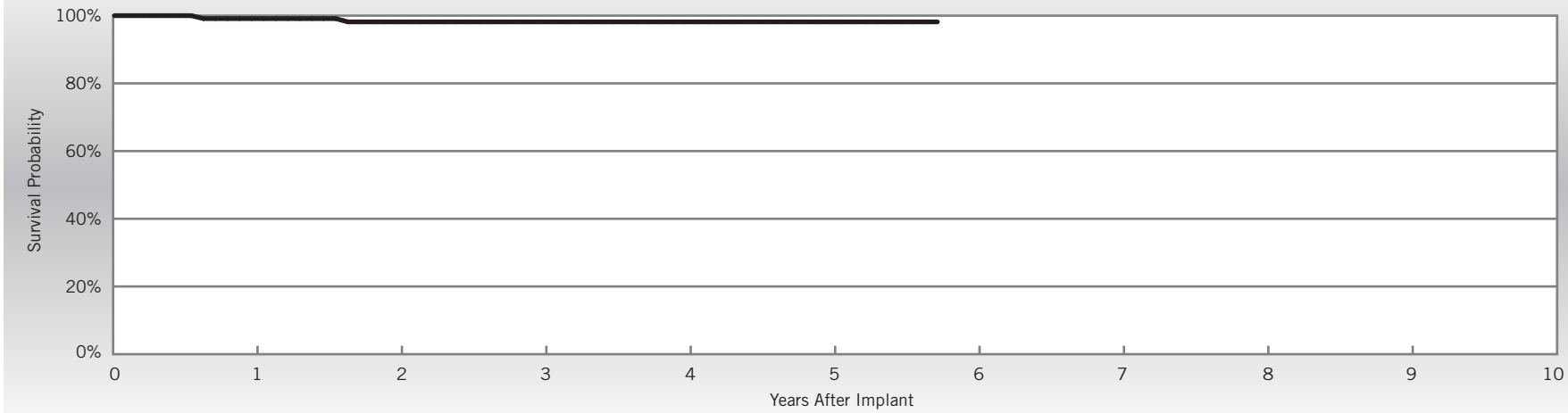
Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	122
Active Devices Enrolled in Study	53
Cumulative Months of Follow-up	5,706
Estimated Longevity	(see table on page 107)
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 69 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				

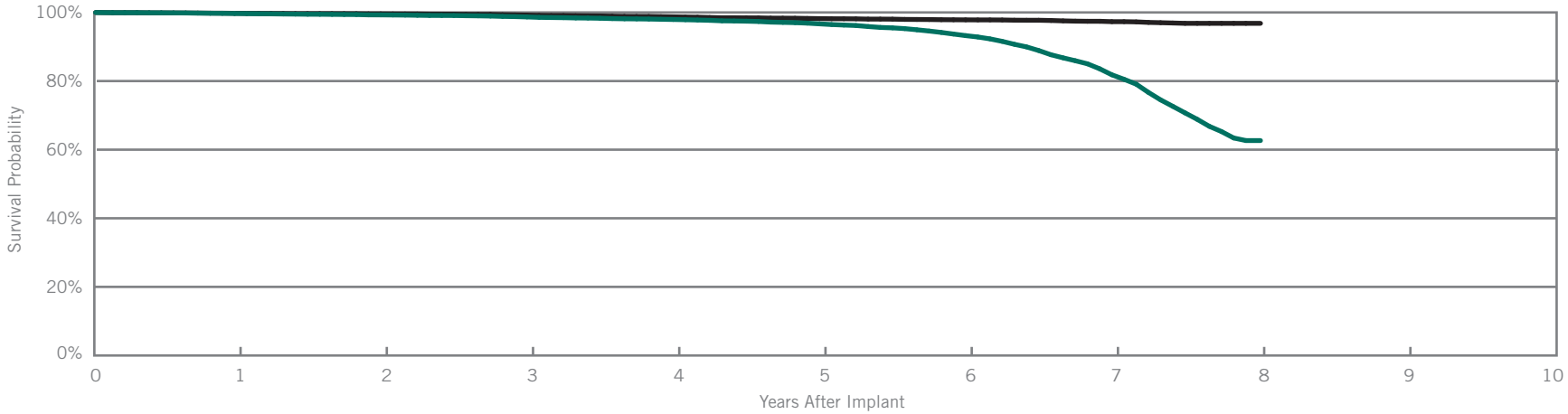
Customer Reported Performance Data

Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,372
Estimated Active US Implants	7,832
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	752
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	9	0.04%	11	0.05%
Electrical Interconnect	6	0.03%	2	<0.01%
Battery	19	0.08%	9	0.04%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	6	0.03%
Mechanical	1	<0.01%	5	0.02%
Possible Early Battery Depletion	32	0.14%	17	0.08%
Other	30	0.13%	6	0.03%
Total	**98**	**0.44%**	**56**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.70%	99.28%	98.68%	97.94%	96.67%	93.24%	81.82%	62.65%		
± 1 standard error	0.04%	0.06%	0.08%	0.11%	0.14%	0.21%	0.39%	0.95%		
Sample Size	20,860	18,180	16,010	14,170	12,550	10,700	6,860	330		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.75%	99.60%	99.22%	98.72%	98.20%	97.84%	97.31%	96.82%		
± 1 standard error	0.03%	0.05%	0.06%	0.09%	0.11%	0.12%	0.14%	0.21%		

Actively Monitored Study Data

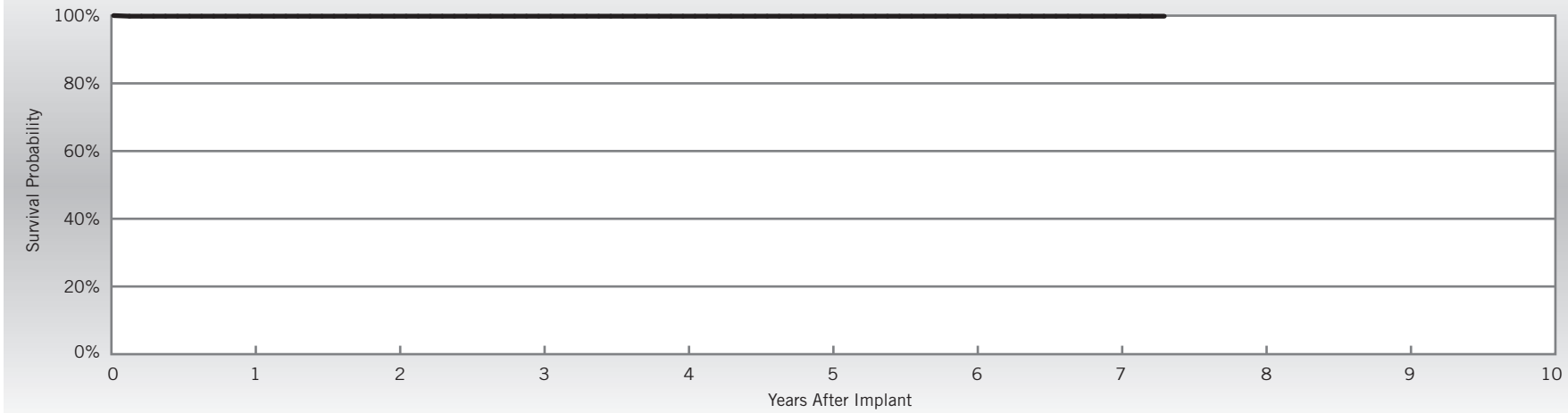
Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	630
Active Devices Enrolled in Study	188
Cumulative Months of Follow-up	30,930
Estimated Longevity	(see table on page 107)
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 88 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	160	60		

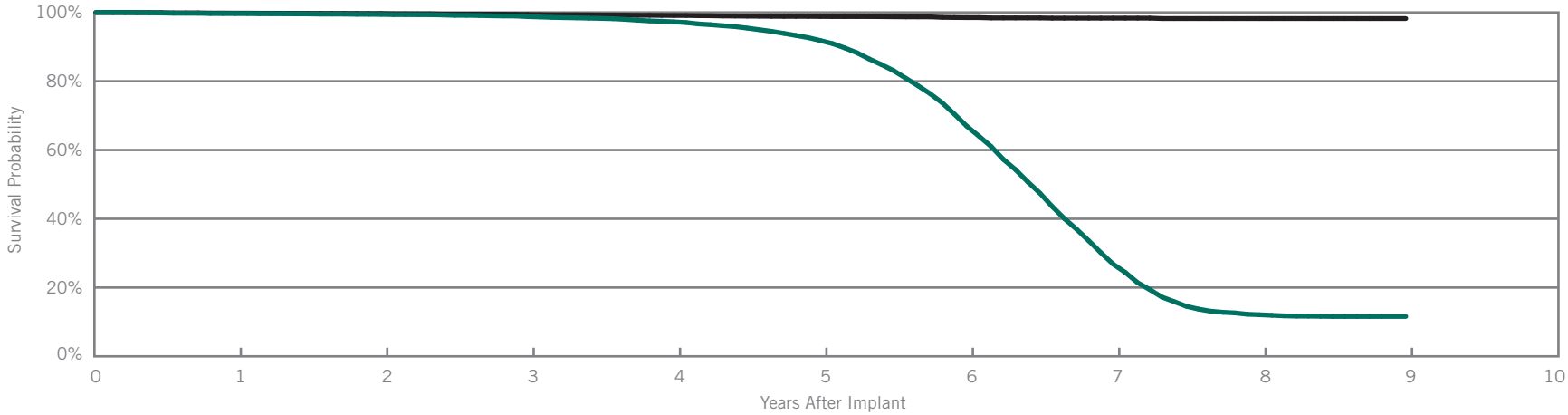
Atlas™ II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,807
Estimated Active US Implants	1,637
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	2,731
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

Customer Reported Performance Data

	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	at 107 months
Survival Probability	99.68%	99.43%	98.79%	97.26%	91.84%	66.94%	26.81%	12.10%	11.60%
± 1 standard error	0.05%	0.07%	0.09%	0.16%	0.27%	0.51%	0.52%	0.37%	0.36%
Sample Size	13,800	12,080	10,670	9,360	8,090	6,310	3,690	1,520	200

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	99.80%	99.68%	99.41%	99.12%	98.83%	98.51%	98.35%	98.23%	98.23%
± 1 standard error	0.04%	0.05%	0.07%	0.09%	0.11%	0.13%	0.14%	0.17%	0.17%

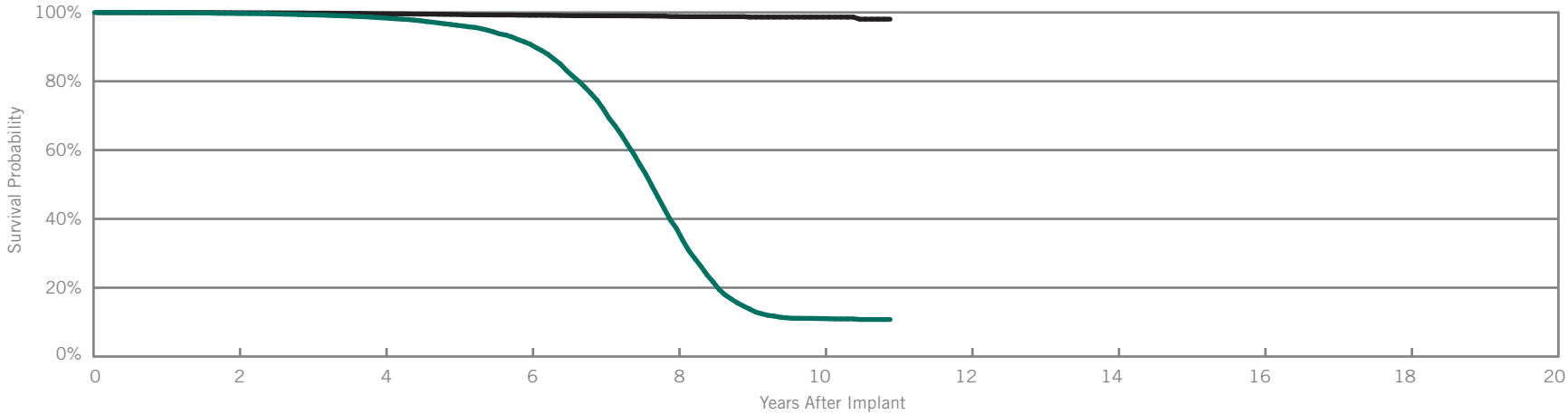
Customer Reported Performance Data

Atlas™ + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	21,081
Estimated Active US Implants	1,649
Estimated Longevity	(see table on page 107)
Normal Battery Depletion	3,436
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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 131 months				
Survival Probability	99.70%	98.43%	90.80%	37.22%	11.02%	10.77%				
± 1 standard error	0.04%	0.10%	0.26%	0.50%	0.31%	0.32%				
Sample Size	17,310	13,400	9,760	5,180	1,030	200				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.90%	99.63%	99.19%	98.83%	98.65%	98.05%				
± 1 standard error	0.02%	0.05%	0.08%	0.11%	0.15%	0.45%				

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	99.78%	99.78%								
CD2411-36C	Ellipse™ DR	99.73%	99.34%								
CD2357-40Q	Fortify Assura™ DR	99.90%	99.81%								
CD2357-40C	Fortify Assura™ DR	99.91%	99.91%								
CD2311-36Q	Ellipse™ DR	99.04%	98.09%	97.60%							
CD2311-36	Ellipse™ DR	98.94%	97.76%	96.87%							
CD2257-40Q	Fortify Assura™ DR	99.87%	99.61%	99.21%							
CD2257-40	Fortify Assura™ DR	99.85%	99.67%	99.55%							
CD2231-40Q	Fortify™ DR	99.76%	99.58%	98.97%	98.08%	96.90%					
CD2231-40	Fortify™ DR	99.88%	99.66%	99.14%	98.29%	96.92%					
CD2211-36Q	Current™ + DR	99.85%	99.40%	99.05%	98.60%	97.43%	95.51%				
CD2211-36	Current™ + DR	99.78%	99.57%	99.30%	98.51%	97.82%	94.85%				
2207-36	Current™ DR RF	99.70%	99.28%	98.68%	97.94%	96.67%	93.24%	81.82%	62.65%		
V-268	Atlas™ II + DR	99.68%	99.43%	98.79%	97.26%	91.84%	66.94%	26.81%	12.10%		
V-243	Atlas™ + DR	99.89%	99.70%	99.30%	98.43%	96.27%	90.80%	71.99%	37.22%	13.79%	11.02%

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	99.78%	99.78%								
CD2411-36C	Ellipse™ DR	99.73%	99.34%								
CD2357-40Q	Fortify Assura™ DR	99.90%	99.81%								
CD2357-40C	Fortify Assura™ DR	100.00%	100.00%								
CD2311-36Q	Ellipse™ DR	99.13%	98.25%	97.75%							
CD2311-36	Ellipse™ DR	99.02%	98.01%	97.23%							
CD2257-40Q	Fortify Assura™ DR	99.87%	99.71%	99.35%							
CD2257-40	Fortify Assura™ DR	99.90%	99.78%	99.66%							
CD2231-40Q	Fortify™ DR	99.87%	99.76%	99.29%	98.55%	97.71%					
CD2231-40	Fortify™ DR	99.95%	99.86%	99.47%	98.73%	97.99%					
CD2211-36Q	Current™ + DR	99.85%	99.58%	99.41%	99.22%	98.78%	98.73%				
CD2211-36	Current™ + DR	99.90%	99.76%	99.53%	99.13%	98.98%	98.27%				
2207-36	Current™ DR RF	99.75%	99.60%	99.22%	98.72%	98.20%	97.84%	97.31%	96.82%		
V-268	Atlas™ II + DR	99.80%	99.68%	99.41%	99.12%	98.83%	98.51%	98.35%	98.23%		
V-243	Atlas™ + DR	99.97%	99.90%	99.80%	99.63%	99.43%	99.19%	99.03%	98.83%	98.65%	98.65%

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	7,418	1.90%	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**	**0.05%**
CD2411-36C	Ellipse™ DR	4,290	1.80%	1	0.02%	0	0.00%	0	0.00%	4	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.12%**
CD2357-40Q	Fortify Assura™ DR	13,639	1.70%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.03%**
CD2357-40C	Fortify Assura™ DR	6,878	1.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2311-36Q	Ellipse™ DR	5,898	4.80%	3	0.05%	0	0.00%	0	0.00%	30	0.51%	1	0.02%	2	0.03%	0	0.00%	1	0.02%	**37**	**0.63%**
CD2311-36	Ellipse™ DR	3,744	5.10%	2	0.05%	0	0.00%	0	0.00%	16	0.43%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**25**	**0.67%**
CD2257-40Q	Fortify Assura™ DR	6,793	4.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	3	0.04%	**9**	**0.13%**
CD2257-40	Fortify Assura™ DR	4,224	4.50%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.05%**
CD2231-40Q	Fortify™ DR	26,841	5.50%	5	0.02%	2	<0.01%	17	0.06%	2	<0.01%	1	<0.01%	0	0.00%	58	0.22%	9	0.03%	**94**	**0.35%**
CD2231-40	Fortify™ DR	12,072	7.00%	3	0.02%	1	<0.01%	2	0.02%	6	0.05%	0	0.00%	0	0.00%	21	0.17%	4	0.03%	**37**	**0.31%**
CD2211-36Q	Current™ + DR	8,141	7.50%	5	0.06%	0	0.00%	5	0.06%	1	0.01%	0	0.00%	0	0.00%	3	0.04%	4	0.05%	**18**	**0.22%**
CD2211-36	Current™ + DR	6,270	9.40%	2	0.03%	2	0.03%	5	0.08%	0	0.00%	0	0.00%	0	0.00%	5	0.08%	5	0.08%	**19**	**0.30%**
2207-36	Current™ DR RF	22,372	13.40%	9	0.04%	6	0.03%	19	0.08%	1	<0.01%	0	0.00%	1	<0.01%	32	0.14%	30	0.13%	**98**	**0.44%**
V-268	Atlas™ II + DR	14,807	28.10%	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	21,081	26.10%	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	7,418	1.90%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
CD2411-36C	Ellipse™ DR	4,290	1.80%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.02%**
CD2357-40Q	Fortify Assura™ DR	13,639	1.70%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.01%**
CD2357-40C	Fortify Assura™ DR	6,878	1.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2311-36Q	Ellipse™ DR	5,898	4.80%	1	0.02%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	2	0.03%	0	0.00%	2	0.03%	**9**	**0.15%**
CD2311-36	Ellipse™ DR	3,744	5.10%	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	6,793	4.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	0	0.00%	**4**	**0.06%**
CD2257-40	Fortify Assura™ DR	4,224	4.50%	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	26,841	5.50%	5	0.02%	2	<0.01%	11	0.04%	0	0.00%	0	0.00%	0	0.00%	21	0.08%	4	0.01%	**43**	**0.16%**
CD2231-40	Fortify™ DR	12,072	7.00%	2	0.02%	0	0.00%	5	0.04%	0	0.00%	0	0.00%	0	0.00%	7	0.06%	2	0.02%	**16**	**0.13%**
CD2211-36Q	Current™ + DR	8,141	7.50%	2	0.02%	0	0.00%	6	0.07%	0	0.00%	0	0.00%	1	0.01%	3	0.04%	2	0.02%	**14**	**0.17%**
CD2211-36	Current™ + DR	6,270	9.40%	1	0.02%	0	0.00%	4	0.06%	0	0.00%	2	0.03%	0	0.00%	4	0.06%	0	0.00%	**11**	**0.18%**
2207-36	Current™ DR RF	22,372	13.40%	11	0.05%	2	<0.01%	9	0.04%	0	0.00%	6	0.03%	5	0.02%	17	0.08%	6	0.03%	**56**	**0.25%**
V-268	Atlas™ II + DR	14,807	28.10%	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	21,081	26.10%	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	7,925	2.25%	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**	**0.05%**
CD2411-36C	Ellipse™ DR	4,461	2.33%	1	0.02%	0	0.00%	0	0.00%	4	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.11%**
CD2357-40Q	Fortify Assura™ DR	14,332	1.88%	3	0.02%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.03%**
CD2357-40C	Fortify Assura™ DR	7,204	2.08%	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%**
CD2311-36Q	Ellipse™ DR	5,928	6.22%	3	0.05%	0	0.00%	0	0.00%	30	0.51%	1	0.02%	2	0.03%	0	0.00%	1	0.02%	**37**	**0.62%**
CD2311-36	Ellipse™ DR	3,762	5.98%	2	0.05%	0	0.00%	0	0.00%	16	0.43%	0	0.00%	4	0.11%	0	0.00%	3	0.08%	**25**	**0.66%**
CD2257-40Q	Fortify Assura™ DR	6,794	4.40%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	3	0.04%	**9**	**0.13%**
CD2257-40	Fortify Assura™ DR	4,242	5.02%	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**	**0.05%**
CD2231-40Q	Fortify™ DR	27,893	5.76%	5	0.02%	2	<0.01%	17	0.06%	2	<0.01%	1	<0.01%	0	0.00%	59	0.21%	10	0.04%	**96**	**0.34%**
CD2231-40	Fortify™ DR	13,006	7.30%	3	0.02%	1	<0.01%	2	0.02%	6	0.05%	0	0.00%	0	0.00%	22	0.17%	5	0.04%	**39**	**0.30%**
CD2211-36Q	Current™ + DR	14,637	5.16%	6	0.04%	0	0.00%	7	0.05%	2	0.01%	0	0.00%	0	0.00%	5	0.03%	8	0.05%	**28**	**0.19%**
CD2211-36	Current™ + DR	12,809	5.40%	2	0.02%	3	0.02%	5	0.04%	0	0.00%	0	0.00%	0	0.00%	7	0.05%	7	0.05%	**24**	**0.19%**
2207-36	Current™ DR RF	33,048	11.08%	16	0.05%	11	0.03%	25	0.08%	9	0.03%	0	0.00%	2	<0.01%	47	0.14%	38	0.11%	**148**	**0.45%**
V-268	Atlas™ II + DR	25,779	18.44%	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	18.24%	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	7,925	2.25%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
CD2411-36C	Ellipse™ DR	4,461	2.33%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.02%**
CD2357-40Q	Fortify Assura™ DR	14,332	1.88%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.01%**
CD2357-40C	Fortify Assura™ DR	7,204	2.08%	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%**
CD2311-36Q	Ellipse™ DR	5,928	6.22%	1	0.02%	0	0.00%	0	0.00%	4	0.07%	0	0.00%	2	0.03%	0	0.00%	2	0.03%	**9**	**0.15%**
CD2311-36	Ellipse™ DR	3,762	5.98%	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	6,794	4.40%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	0	0.00%	**4**	**0.06%**
CD2257-40	Fortify Assura™ DR	4,242	5.02%	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	27,893	5.76%	5	0.02%	2	<0.01%	12	0.04%	0	0.00%	0	0.00%	0	0.00%	21	0.08%	4	0.01%	**44**	**0.16%**
CD2231-40	Fortify™ DR	13,006	7.30%	2	0.02%	0	0.00%	5	0.04%	0	0.00%	0	0.00%	1	<0.01%	7	0.05%	2	0.02%	**17**	**0.13%**
CD2211-36Q	Current™ + DR	14,637	5.16%	4	0.03%	0	0.00%	8	0.05%	0	0.00%	0	0.00%	2	0.01%	5	0.03%	2	0.01%	**21**	**0.14%**
CD2211-36	Current™ + DR	12,809	5.40%	1	<0.01%	0	0.00%	4	0.03%	0	0.00%	2	0.02%	1	<0.01%	4	0.03%	1	<0.01%	**13**	**0.10%**
2207-36	Current™ DR RF	33,048	11.08%	16	0.05%	5	0.02%	13	0.04%	4	0.01%	11	0.03%	9	0.03%	23	0.07%	10	0.03%	**91**	**0.28%**
V-268	Current™ DR RF	25,779	18.44%	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™ II + DR	34,105	18.24%	6	0.02%	0	0.00%	6	0.02%	0	0.00%	0	0.00%	5	0.01%	6	0.02%	3	<0.01%	**26**	**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
CD2231-40Q	390	247	17,882	0	0.00%	0	0.00%	0	0.00%	2	0.51%	0	0.00%	**2**	**0.51%**
CD2231-40	177	82	6,508	0	0.00%	0	0.00%	0	0.00%	1	0.56%	0	0.00%	**1**	**0.56%**
CD2211-36Q	834	431	43,168	0	0.00%	0	0.00%	0	0.00%	3	0.36%	1	0.12%	**4**	**0.48%**
CD2211-36	122	53	5,706	1	0.82%	0	0.00%	0	0.00%	1	0.82%	0	0.00%	**2**	**1.64%**
2207-36	630	188	30,930	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	390	7.40%	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	8.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.12%**
CD2211-36	Current™ + DR	122	10.70%	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	15.90%	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	390	7.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
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	8.00%	0	0.00%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	**3**	**0.36%**
CD2211-36	Current™ + DR	122	10.70%	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	15.90%	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

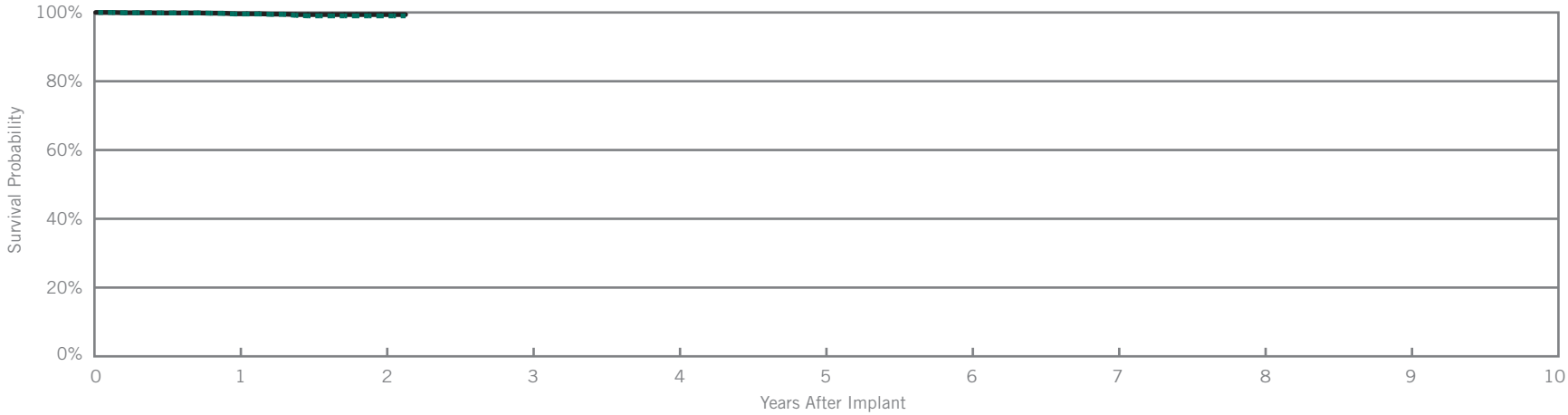
Ellipse™ VR

Model CD1411-36Q*

US Regulatory Approval	June 2013
Registered US Implants	6,271
Estimated Active US Implants	5,468
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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	4	0.06%	1	0.02%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	1	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**5**	**0.08%**	**3**	**0.05%**



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.55%	99.00%	99.00%							
± 1 standard error	0.08%	0.22%	0.22%							
Sample Size	4,440	1,460	230							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.62%	99.39%	99.39%							
± 1 standard error	0.07%	0.15%	0.15%							

**DF4-LLHH connector type.*

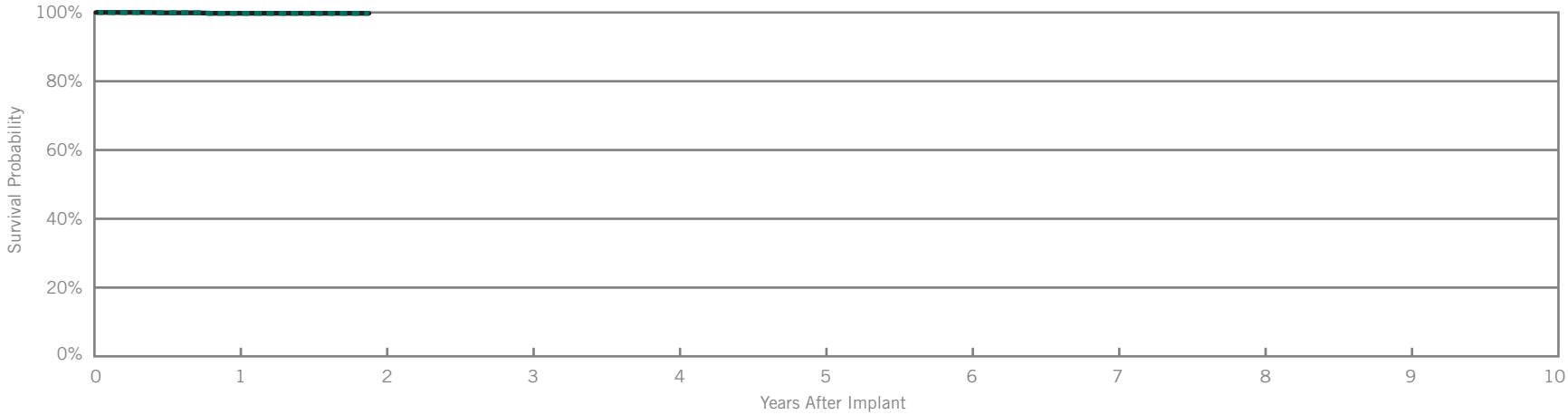
Ellipse™ VR

Model CD1411-36C*

US Regulatory Approval	June 2013
Registered US Implants	2,766
Estimated Active US Implants	2,442
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.12%	0.12%								
Sample Size	1,930	240								

Excluding Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.12%	0.12%								

**Parylene coating.*

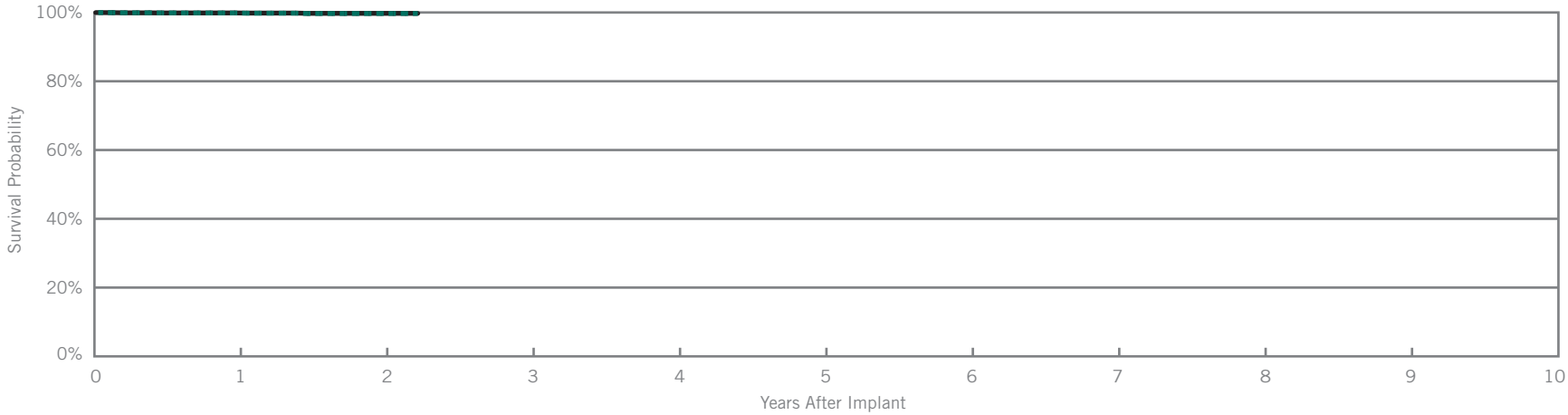
Fortify Assura™ VR

Model CD1357-40Q*

US Regulatory Approval	June 2013
Registered US Implants	11,582
Estimated Active US Implants	9,963
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	1
Max. Delivered Energy	40 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	0	0.00%	3	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	0	0.00%	0	0.00%
Other	2	0.02%	2	0.02%
Total	**3**	**0.03%**	**5**	**0.04%**



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.84%	99.71%	99.71%							
± 1 standard error	0.04%	0.08%	0.08%							
Sample Size	8,200	2,650	240							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.86%	99.74%	99.74%							
± 1 standard error	0.04%	0.08%	0.08%							

**DF4-LLHH connector type.*

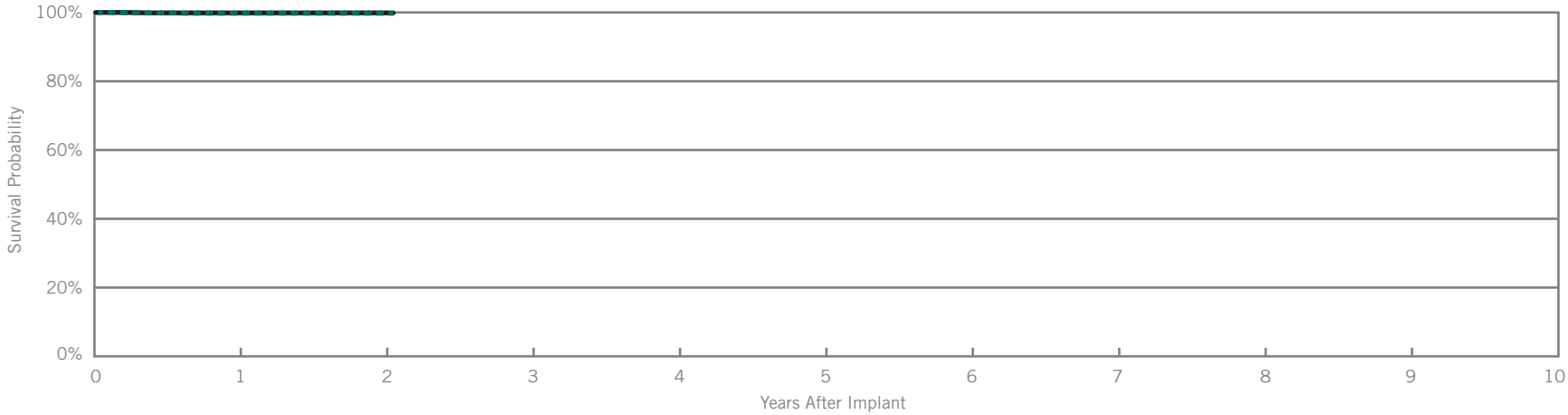
Fortify Assura™ VR

Model CD1357-40C*

US Regulatory Approval	June 2013
Registered US Implants	4,222
Estimated Active US Implants	3,680
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	2
Max. Delivered Energy	40 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	1	0.02%	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%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.05%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.75%	99.75%	99.75%							
± 1 standard error	0.09%	0.09%	0.09%							
Sample Size	2,970	960	200							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.88%	99.88%	99.88%							
± 1 standard error	0.06%	0.06%	0.06%							

**Parylene coating.*

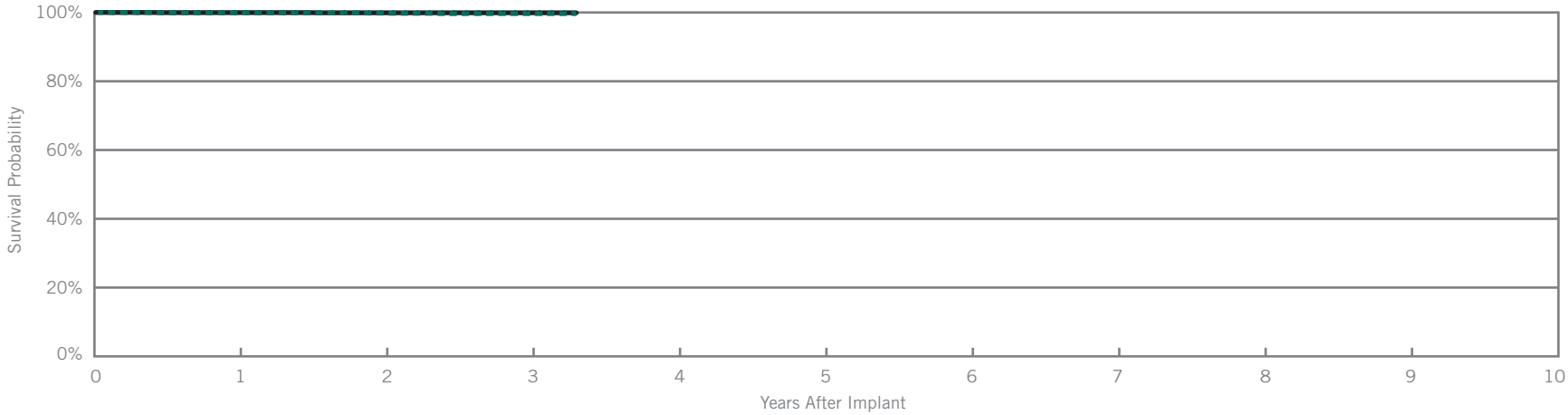
Fortify Assura™ VR

Model CD1257-40Q*

US Regulatory Approval	May 2012
Registered US Implants	5,068
Estimated Active US Implants	3,697
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	4
Max. Delivered Energy	40 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	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	0.02%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**2**	**0.04%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	99.92%	99.81%	99.67%	99.67%						
± 1 standard error	0.04%	0.07%	0.10%	0.10%						
Sample Size	4,750	3,920	2,000	240						

Excluding Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	99.96%	99.91%	99.91%	99.91%						
± 1 standard error	0.03%	0.05%	0.05%	0.05%						

**DF4-LLHH connector type.*

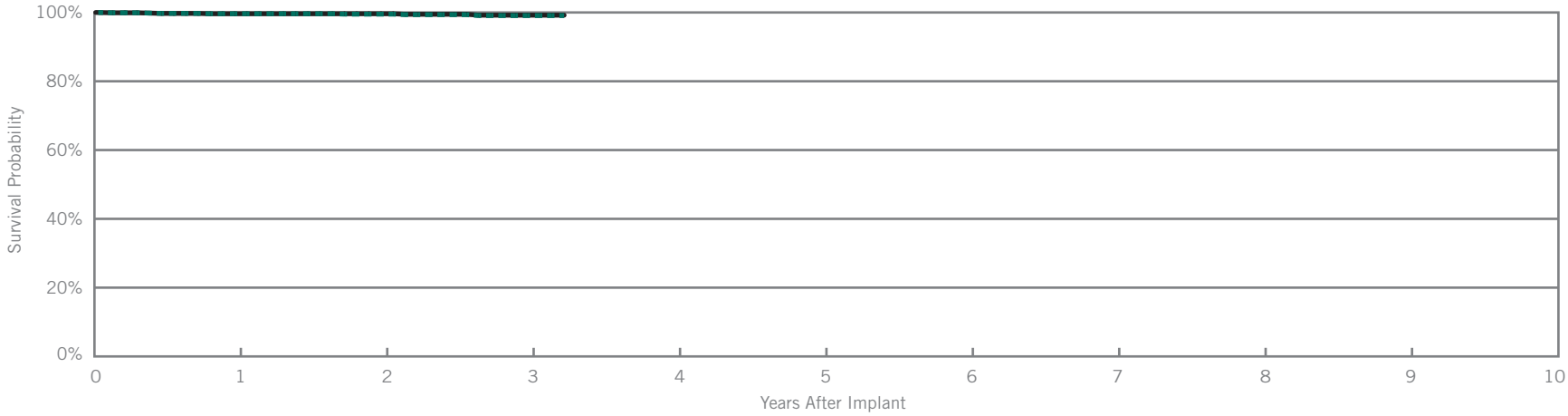
Fortify Assura™ VR

Model CD1257-40

US Regulatory Approval	May 2012
Registered US Implants	2,288
Estimated Active US Implants	1,712
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	1
Max. Delivered Energy	40 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	0	0.00%	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	0	0.00%	0	0.00%
Other	1	0.04%	1	0.04%
Total	**4**	**0.17%**	**2**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	99.63%	99.51%	99.09%	99.09%						
± 1 standard error	0.13%	0.16%	0.27%	0.27%						
Sample Size	2,130	1,700	870	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	99.63%	99.63%	99.21%	99.21%						
± 1 standard error	0.13%	0.13%	0.25%	0.25%						

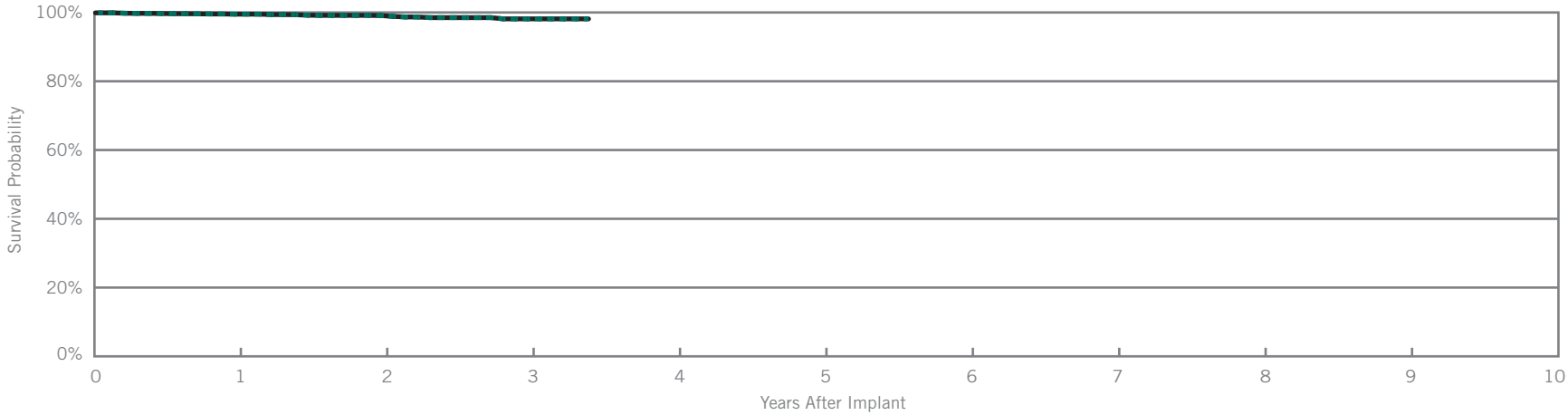
Ellipse™ VR

Model CD1311-36Q*

US Regulatory Approval	May 2012
Registered US Implants	4,736
Estimated Active US Implants	3,466
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

Customer Reported Performance Data

	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	17	0.36%	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	**21**	**0.44%**	**5**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.51%	99.10%	98.14%	98.14%						
± 1 standard error	0.10%	0.14%	0.26%	0.26%						
Sample Size	4,460	3,710	2,060	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	99.51%	99.10%	98.14%	98.14%						
± 1 standard error	0.10%	0.14%	0.26%	0.26%						

**DF4-LLHH connector type.*

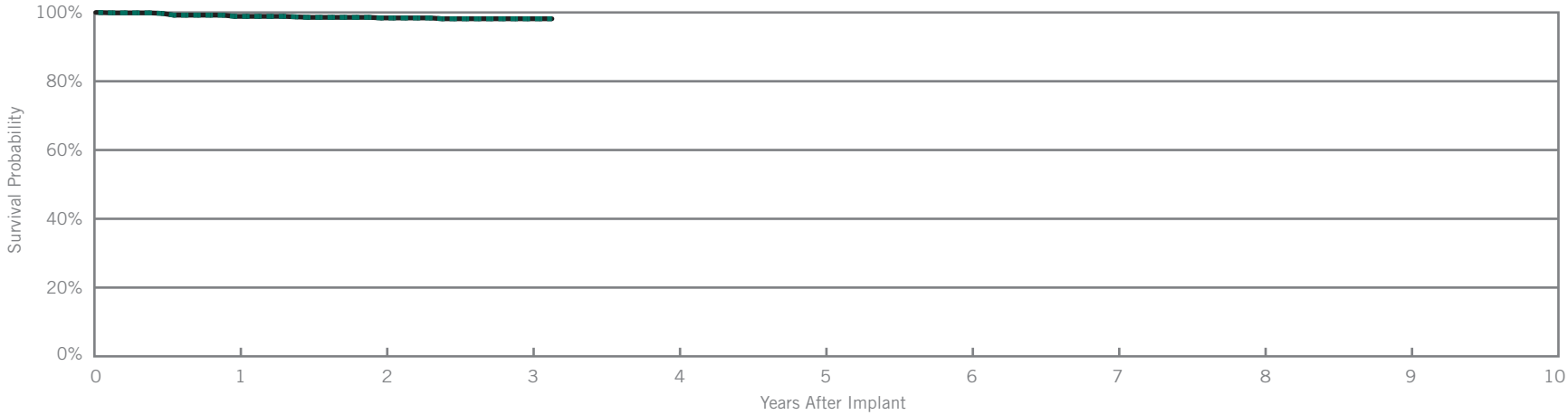
Ellipse™ VR

Model CD1311-36

US Regulatory Approval	May 2012
Registered US Implants	1,620
Estimated Active US Implants	1,197
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	One

Customer Reported Performance Data

	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	2	0.12%	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	**7**	**0.43%**	**4**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	at 38 months						
Survival Probability	98.87%	98.41%	98.17%	98.17%						
± 1 standard error	0.22%	0.31%	0.37%	0.37%						
Sample Size	1,520	1,260	690	240						

Excluding Normal Battery Depletion

Year	1	2	3	at 38 months						
Survival Probability	98.87%	98.41%	98.17%	98.17%						
± 1 standard error	0.22%	0.31%	0.37%	0.37%						

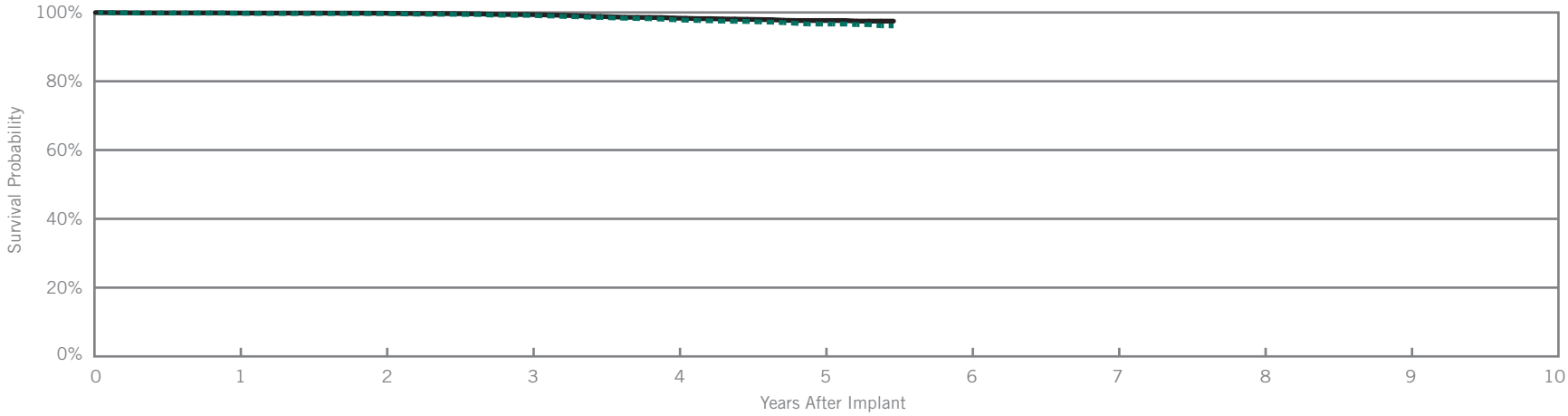
Fortify™ VR

Model CD1231-40Q*

US Regulatory Approval	May 2010
Registered US Implants	16,152
Estimated Active US Implants	9,584
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	29
Max. Delivered Energy	40 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	5	0.03%	2	0.01%
Electrical Interconnect	2	0.01%	0	0.00%
Battery	8	0.05%	8	0.05%
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	32	0.20%	18	0.11%
Other	5	0.03%	2	0.01%
Total	**53**	**0.33%**	**30**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.75%	99.67%	99.17%	97.88%	96.64%	96.10%				
± 1 standard error	0.04%	0.05%	0.08%	0.14%	0.24%	0.37%				
Sample Size	15,100	13,260	11,510	8,410	4,050	390				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.84%	99.79%	99.40%	98.37%	97.66%	97.48%				
± 1 standard error	0.03%	0.04%	0.07%	0.12%	0.19%	0.22%				

**DF4-LLHH connector type.*

Actively Monitored Study Data

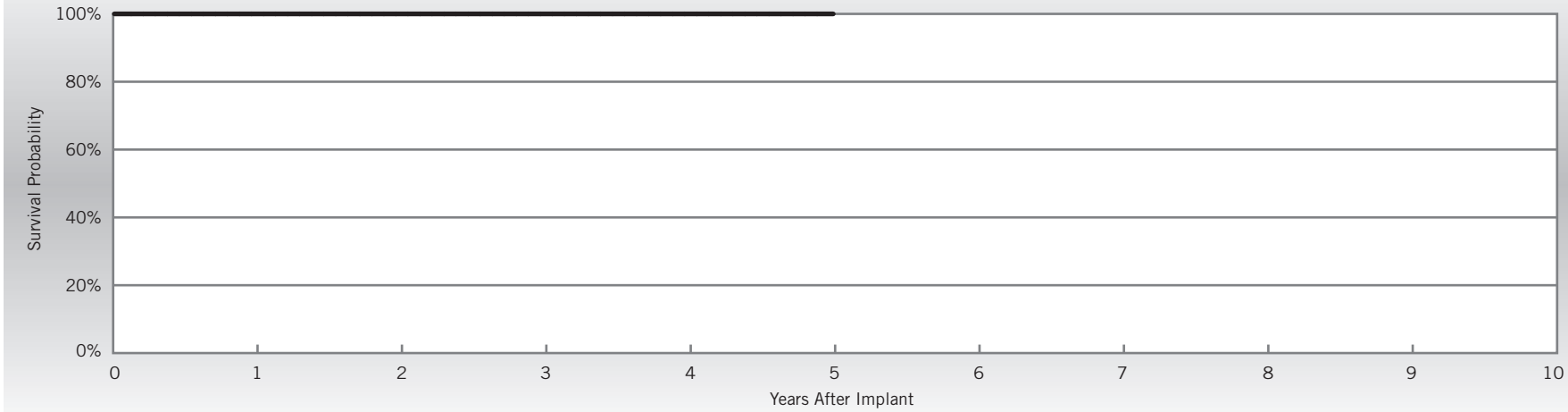
Fortify™ VR

Model CD1231-40Q*

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	158
Active Devices Enrolled in Study	111
Cumulative Months of Follow-up	7,656
Estimated Longevity	(see table on page 136)
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%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.63%**	**0**	**0.00%**



Year	1	2	3	4	5					
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	160	150	130	120	50					

**DF4-LLHH connector type.*

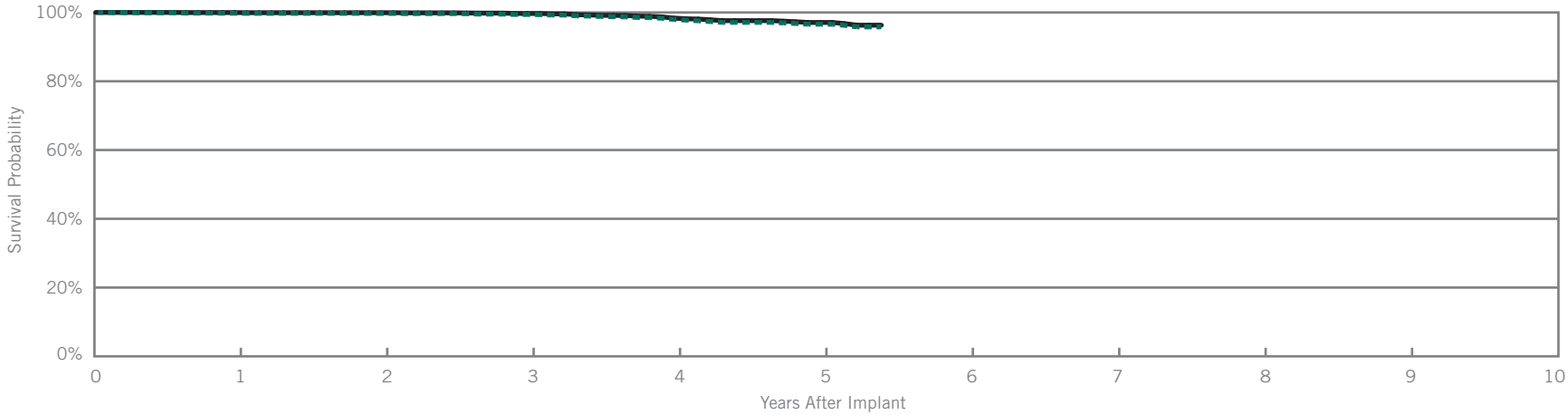
Customer Reported Performance Data

Fortify™ VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	6,776
Estimated Active US Implants	3,983
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	10
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	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%	0	0.00%
Possible Early Battery Depletion	14	0.21%	7	0.10%
Other	2	0.03%	3	0.04%
Total	**25**	**0.37%**	**13**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.78%	99.71%	99.41%	97.97%	96.59%	95.81%				
± 1 standard error	0.06%	0.07%	0.10%	0.20%	0.37%	0.53%				
Sample Size	6,350	5,560	4,820	3,530	1,700	260				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.97%	99.93%	99.70%	98.35%	97.09%	96.30%				
± 1 standard error	0.02%	0.03%	0.08%	0.18%	0.35%	0.53%				

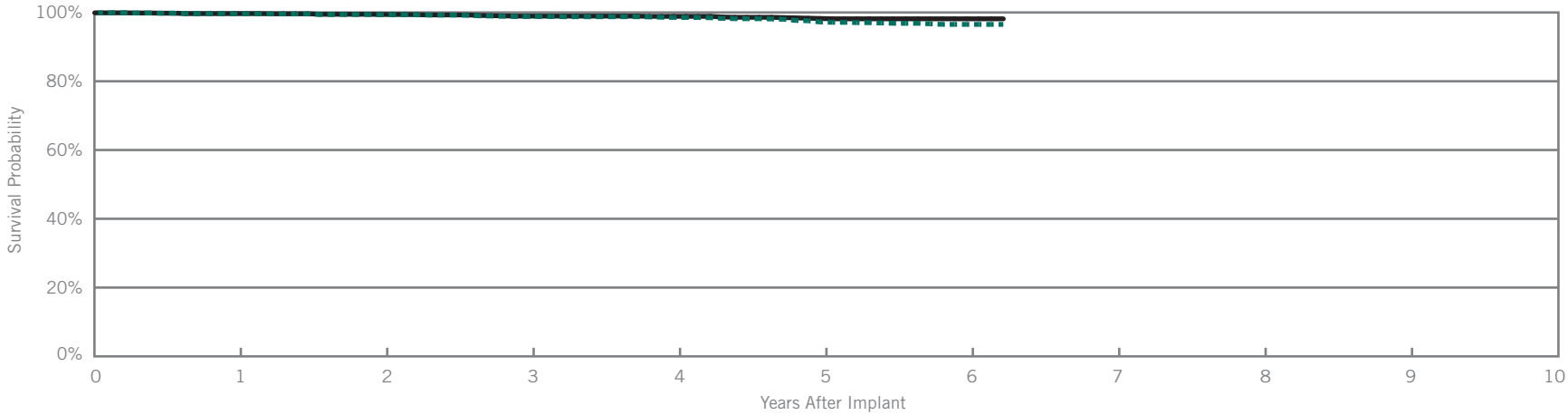
Customer Reported Performance Data

Current™ + VR

Model CD1211-36Q*

US Regulatory Approval	February 2009
Registered US Implants	4,430
Estimated Active US Implants	2,267
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	16
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 75 months			
Survival Probability	99.61%	99.36%	98.83%	98.54%	97.22%	96.53%	96.53%			
± 1 standard error	0.09%	0.12%	0.18%	0.20%	0.29%	0.37%	0.37%			
Sample Size	4,120	3,600	3,200	2,790	2,380	1,380	260			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.67%	99.41%	98.94%	98.87%	98.24%	98.15%	98.15%			
± 1 standard error	0.09%	0.12%	0.17%	0.18%	0.23%	0.25%	0.25%			

**DF4-LLHH connector type.*

Actively Monitored Study Data

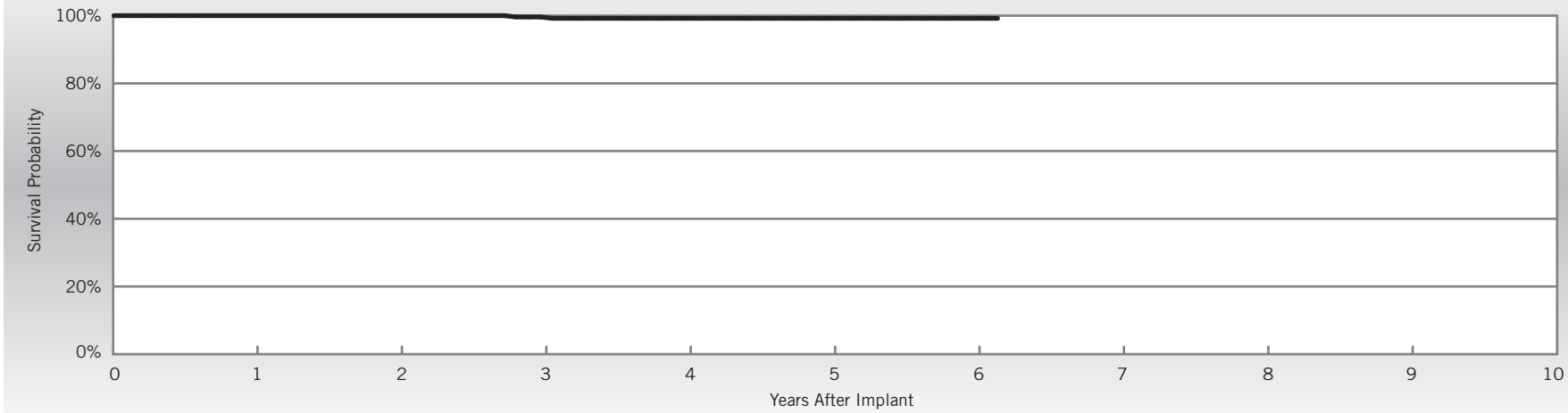
Current™ + VR

Model CD1211-36Q*

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	364
Active Devices Enrolled in Study	182
Cumulative Months of Follow-up	18,215
Estimated Longevity	(see table on page 136)
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 74 months			
Survival Probability	100.00%	100.00%	99.61%	99.21%	99.21%	99.21%	99.21%			
± 1 standard error	0.00%	0.00%	0.39%	0.55%	0.55%	0.55%	0.55%			
Sample Size	350	310	270	240	210	130	60			

**DF4-LLHH connector type.*

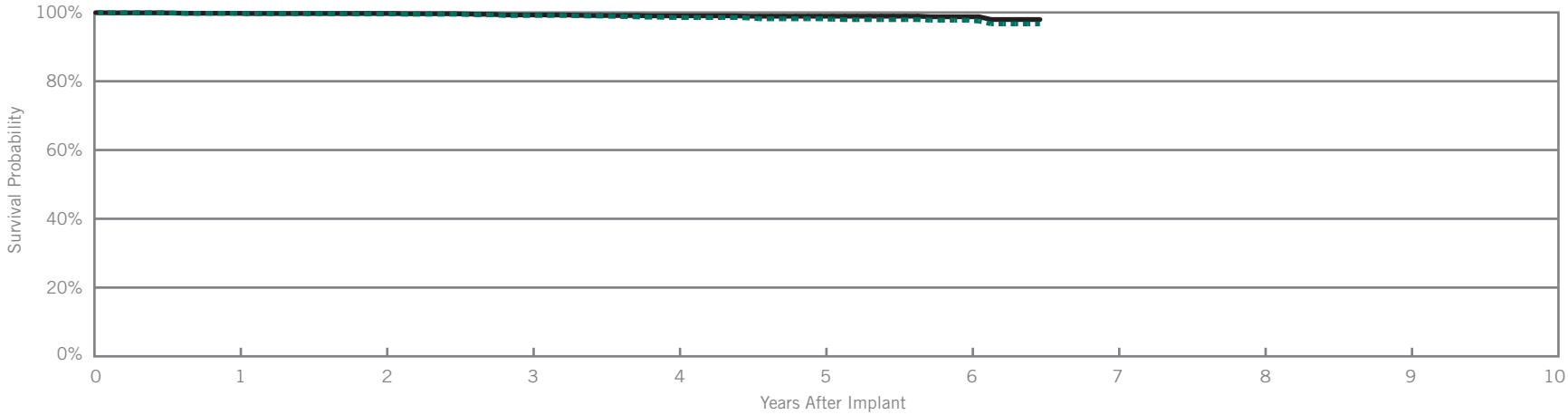
Customer Reported Performance Data

Current™ + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,636
Estimated Active US Implants	1,822
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	11
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	2	0.06%	2	0.06%
Electrical Interconnect	2	0.06%	0	0.00%
Battery	3	0.08%	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%	1	0.03%
Other	1	0.03%	0	0.00%
Total	**14**	**0.39%**	**3**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.77%	99.57%	99.14%	98.52%	98.16%	97.76%	96.69%			
± 1 standard error	0.08%	0.12%	0.17%	0.23%	0.27%	0.32%	0.51%			
Sample Size	3,390	2,960	2,620	2,260	1,890	1,240	240			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.77%	99.70%	99.28%	99.02%	98.92%	98.75%	97.95%			
± 1 standard error	0.08%	0.09%	0.16%	0.19%	0.20%	0.23%	0.43%			

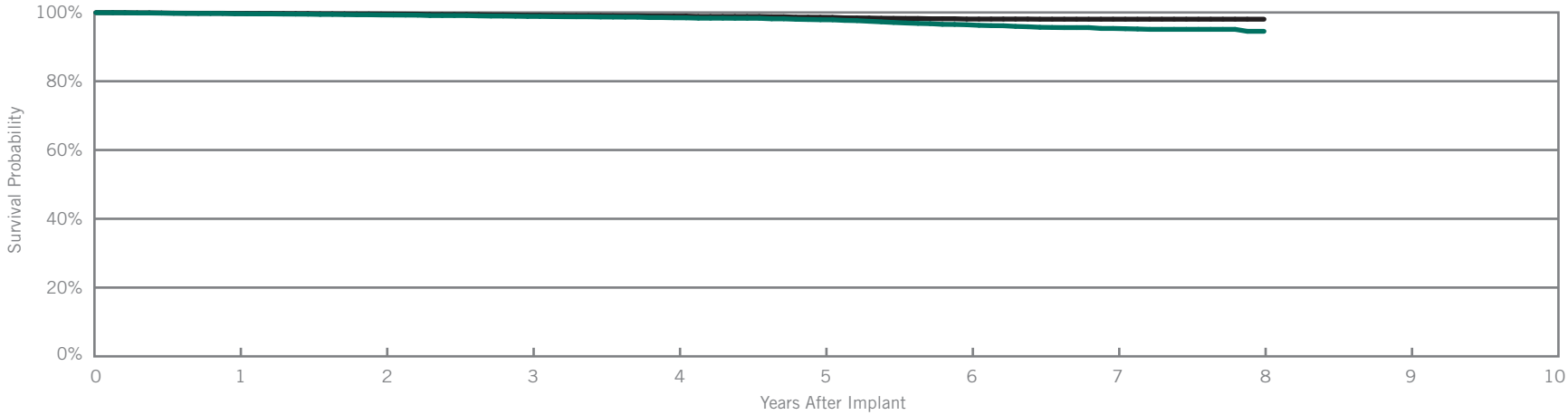
Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,273
Estimated Active US Implants	5,622
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	75
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	0.05%	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%	2	0.02%
Possible Early Battery Depletion	11	0.08%	13	0.10%
Other	8	0.06%	3	0.02%
Total	**44**	**0.33%**	**30**	**0.23%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.62%	99.28%	98.85%	98.46%	97.88%	96.43%	95.35%	94.52%		
± 1 standard error	0.05%	0.08%	0.10%	0.12%	0.15%	0.20%	0.26%	0.49%		
Sample Size	12,370	10,760	9,510	8,490	7,560	6,390	4,150	260		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.73%	99.57%	99.19%	98.94%	98.61%	98.08%	98.04%	98.04%		
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.15%	0.15%	0.15%		

Actively Monitored Study Data

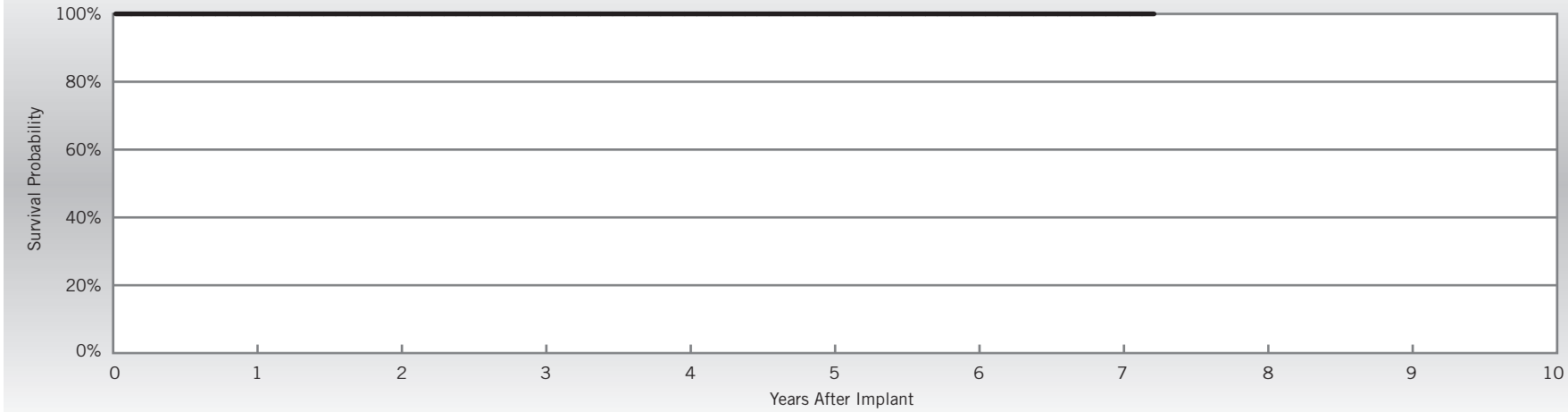
Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Active Devices Enrolled in Study	123
Cumulative Months of Follow-up	19,628
Estimated Longevity	(see table on page 136)
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 87 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	220	170	140	100	50		

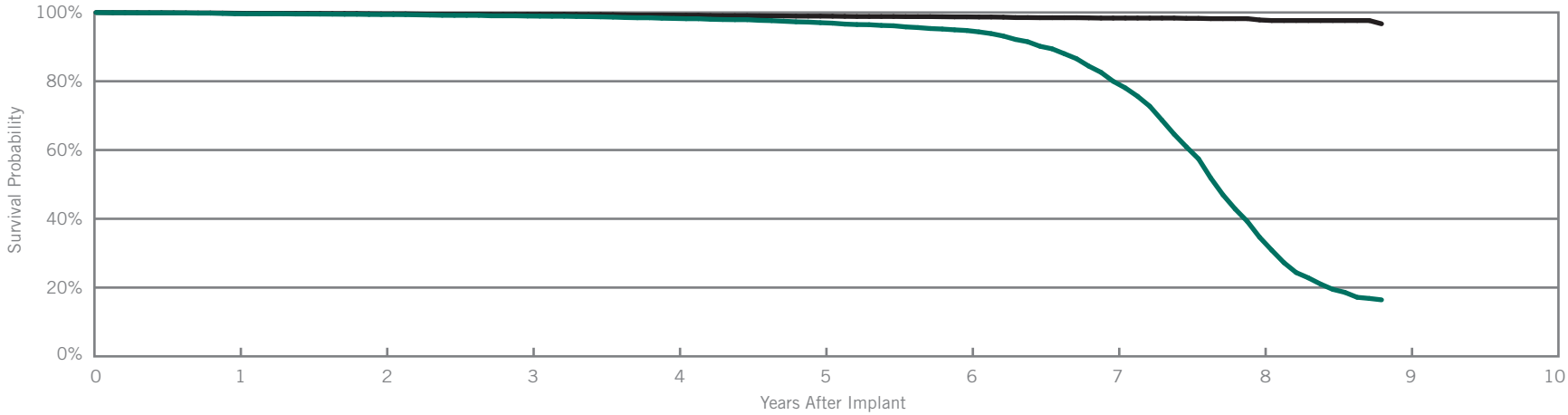
Atlas™ II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,599
Estimated Active US Implants	1,843
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	1,239
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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%	3	0.03%
Possible Early Battery Depletion	10	0.09%	5	0.05%
Other	10	0.09%	5	0.05%
Total	**38**	**0.36%**	**18**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.63%	99.40%	98.96%	98.26%	97.03%	94.75%	79.99%	34.65%	16.43%
± 1 standard error	0.05%	0.08%	0.11%	0.15%	0.20%	0.28%	0.54%	0.78%	0.71%
Sample Size	9,940	8,730	7,680	6,720	5,920	5,200	4,120	2,320	230

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.78%	99.60%	99.45%	99.22%	98.94%	98.72%	98.37%	97.82%	96.70%
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.14%	0.16%	0.18%	0.28%

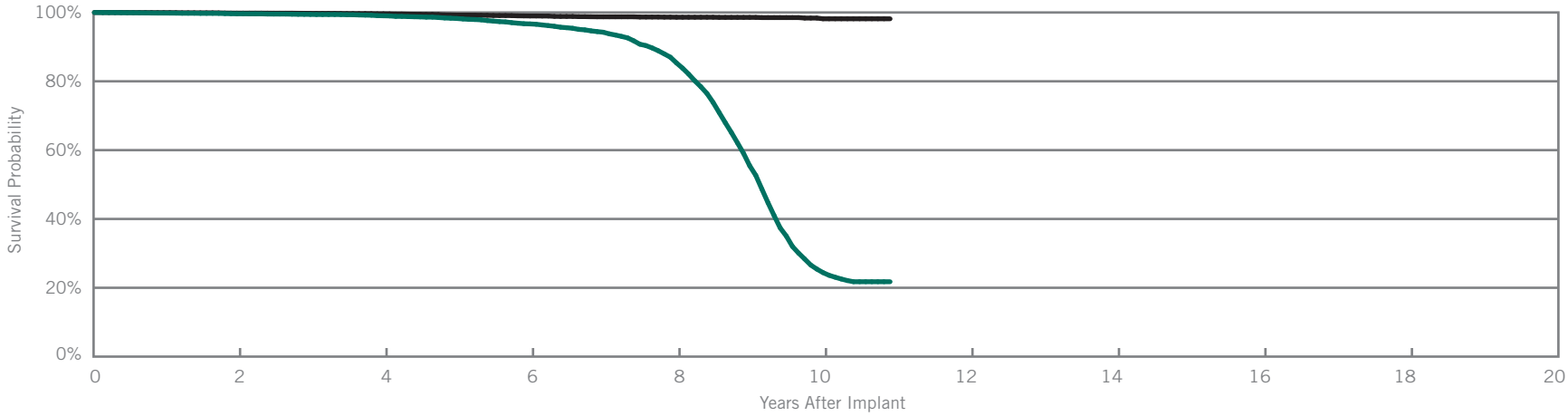
Customer Reported Performance Data

Atlas™ + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,778
Estimated Active US Implants	3,145
Estimated Longevity	(see table on page 136)
Normal Battery Depletion	1,990
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 290-295)	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	8	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%	1	<0.01%
Possible Early Battery Depletion	26	0.13%	5	0.02%
Other	12	0.06%	6	0.03%
Total	**55**	**0.26%**	**19**	**0.09%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.61%	99.03%	96.67%	85.34%	24.42%	21.76%				
± 1 standard error	0.04%	0.08%	0.17%	0.36%	0.58%	0.59%				
Sample Size	17,110	13,170	9,870	7,080	2,250	230				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.81%	99.61%	98.98%	98.61%	98.16%	98.16%				
± 1 standard error	0.03%	0.05%	0.09%	0.11%	0.16%	0.22%				

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	99.55%	99.00%								
CD1411-36C	Ellipse™ VR	99.76%									
CD1357-40Q	Fortify Assura™ VR	99.84%	99.71%								
CD1357-40C	Fortify Assura™ VR	99.75%	99.75%								
CD1257-40Q	Fortify Assura™ VR	99.92%	99.81%	99.67%							
CD1257-40	Fortify Assura™ VR	99.63%	99.51%	99.09%							
CD1311-36Q	Ellipse™ VR	99.51%	99.10%	98.14%							
CD1311-36	Ellipse™ VR	98.87%	98.41%	98.17%							
CD1231-40Q	Fortify™ VR	99.75%	99.67%	99.17%	97.88%	96.64%					
CD1231-40	Fortify™ VR	99.78%	99.71%	99.41%	97.97%	96.59%					
CD1211-36Q	Current™ + VR	99.61%	99.36%	98.83%	98.54%	97.22%	96.53%				
CD1211-36	Current™ + VR	99.77%	99.57%	99.14%	98.52%	98.16%	97.76%				
1207-36	Current™ VR RF	99.62%	99.28%	98.85%	98.46%	97.88%	96.43%	95.35%	94.52%		
V-168	Atlas™ II VR	99.63%	99.40%	98.96%	98.26%	97.03%	94.75%	79.99%	34.65%		
V-193	Atlas™ + VR	99.82%	99.61%	99.43%	99.03%	98.25%	96.67%	94.26%	85.34%	55.45%	24.42%

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	99.62%	99.39%								
CD1411-36C	Ellipse™ VR	99.76%									
CD1357-40Q	Fortify Assura™ VR	99.86%	99.74%								
CD1357-40C	Fortify Assura™ VR	99.88%	99.88%								
CD1257-40Q	Fortify Assura™ VR	99.96%	99.91%	99.91%							
CD1257-40	Fortify Assura™ VR	99.63%	99.63%	99.21%							
CD1311-36Q	Ellipse™ VR	99.51%	99.10%	98.14%							
CD1311-36	Ellipse™ VR	98.87%	98.41%	98.17%							
CD1231-40Q	Fortify™ VR	99.84%	99.79%	99.40%	98.37%	97.66%					
CD1231-40	Fortify™ VR	99.97%	99.93%	99.70%	98.35%	97.09%					
CD1211-36Q	Current™ + VR	99.67%	99.41%	98.94%	98.87%	98.24%	98.15%				
CD1211-36	Current™ + VR	99.77%	99.70%	99.28%	99.02%	98.92%	98.75%				
1207-36	Current™ VR RF	99.73%	99.57%	99.19%	98.94%	98.61%	98.08%	98.04%	98.04%		
V-168	Atlas™ II VR	99.78%	99.60%	99.45%	99.22%	98.94%	98.72%	98.37%	97.82%		
V-193	Atlas™ + VR	99.95%	99.81%	99.74%	99.61%	99.23%	98.98%	98.74%	98.61%	98.57%	98.16%

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	6,271	1.50%	1	0.02%	0	0.00%	0	0.00%	4	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.08%**
CD1411-36C	Ellipse™ VR	2,766	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%**
CD1357-40Q	Fortify Assura™ VR	11,582	1.50%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**3**	**0.03%**
CD1357-40C	Fortify Assura™ VR	4,222	1.90%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**2**	**0.05%**
CD1257-40Q	Fortify Assura™ VR	5,068	3.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**2**	**0.04%**
CD1257-40	Fortify Assura™ VR	2,288	4.90%	0	0.00%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**4**	**0.17%**
CD1311-36Q	Ellipse™ VR	4,736	4.20%	1	0.02%	0	0.00%	0	0.00%	17	0.36%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**21**	**0.44%**
CD1311-36	Ellipse™ VR	1,620	5.60%	2	0.12%	1	0.06%	0	0.00%	2	0.12%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**7**	**0.43%**
CD1231-40Q	Fortify™ VR	16,152	6.20%	5	0.03%	2	0.01%	8	0.05%	1	<0.01%	0	0.00%	0	0.00%	32	0.20%	5	0.03%	**53**	**0.33%**
CD1231-40	Fortify™ VR	6,776	7.50%	1	0.01%	0	0.00%	3	0.04%	5	0.07%	0	0.00%	0	0.00%	14	0.21%	2	0.03%	**25**	**0.37%**
CD1211-36Q	Current™ + VR	4,430	7.50%	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	7.40%	2	0.06%	2	0.06%	3	0.08%	2	0.06%	0	0.00%	0	0.00%	4	0.11%	1	0.03%	**14**	**0.39%**
1207-36	Current™ VR RF	13,273	9.30%	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	10,599	22.30%	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	20,778	20.70%	2	<0.01%	5	0.02%	8	0.04%	2	<0.01%	0	0.00%	0	0.00%	26	0.13%	12	0.06%	**55**	**0.26%**

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	6,271	1.50%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	**3**	**0.05%**
CD1411-36C	Ellipse™ VR	2,766	1.50%	1	0.04%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.07%**
CD1357-40Q	Fortify Assura™ VR	11,582	1.50%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**5**	**0.04%**
CD1357-40C	Fortify Assura™ VR	4,222	1.90%	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%**
CD1257-40Q	Fortify Assura™ VR	5,068	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%	**0**	**0.00%**
CD1257-40	Fortify Assura™ VR	2,288	4.90%	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	4,736	4.20%	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	5.60%	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	16,152	6.20%	2	0.01%	0	0.00%	8	0.05%	0	0.00%	0	0.00%	0	0.00%	18	0.11%	2	0.01%	**30**	**0.19%**
CD1231-40	Fortify™ VR	6,776	7.50%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	3	0.04%	**13**	**0.19%**
CD1211-36Q	Current™ + VR	4,430	7.50%	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	7.40%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	**3**	**0.08%**
1207-36	Current™ VR RF	13,273	9.30%	6	0.05%	0	0.00%	4	0.03%	1	<0.01%	1	<0.01%	2	0.02%	13	0.10%	3	0.02%	**30**	**0.23%**
V-168	Atlas™ II VR	10,599	22.30%	3	0.03%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	3	0.03%	5	0.05%	5	0.05%	**18**	**0.17%**
V-193	Atlas™ + VR	20,778	20.70%	2	<0.01%	1	<0.01%	2	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	5	0.02%	6	0.03%	**19**	**0.09%**

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	6,613	1.97%	1	0.02%	0	0.00%	0	0.00%	4	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.08%**
CD1411-36C	Ellipse™ VR	2,937	2.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1357-40Q	Fortify Assura™ VR	12,009	1.68%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**3**	**0.02%**
CD1357-40C	Fortify Assura™ VR	4,443	2.30%	2	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**3**	**0.07%**
CD1257-40Q	Fortify Assura™ VR	5,046	3.79%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**2**	**0.04%**
CD1257-40	Fortify Assura™ VR	2,302	5.60%	0	0.00%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**4**	**0.17%**
CD1311-36Q	Ellipse™ VR	4,813	4.80%	1	0.02%	0	0.00%	0	0.00%	17	0.35%	1	0.02%	1	0.02%	0	0.00%	1	0.02%	**21**	**0.44%**
CD1311-36	Ellipse™ VR	1,637	7.39%	2	0.12%	1	0.06%	0	0.00%	3	0.18%	0	0.00%	2	0.12%	0	0.00%	0	0.00%	**8**	**0.49%**
CD1231-40Q	Fortify™ VR	17,201	6.26%	5	0.03%	2	0.01%	8	0.05%	1	<0.01%	0	0.00%	0	0.00%	34	0.20%	5	0.03%	**55**	**0.32%**
CD1231-40	Fortify™ VR	7,272	7.73%	1	0.01%	0	0.00%	3	0.04%	5	0.07%	0	0.00%	0	0.00%	14	0.19%	2	0.03%	**25**	**0.34%**
CD1211-36Q	Current™ + VR	14,677	2.95%	7	0.05%	1	<0.01%	6	0.04%	1	<0.01%	0	0.00%	0	0.00%	7	0.05%	3	0.02%	**25**	**0.17%**
CD1211-36	Current™ + VR	13,936	2.48%	2	0.01%	2	0.01%	3	0.02%	3	0.02%	0	0.00%	0	0.00%	4	0.03%	4	0.03%	**18**	**0.13%**
1207-36	Current™ VR RF	24,845	6.62%	11	0.04%	30	0.12%	13	0.05%	1	<0.01%	0	0.00%	0	0.00%	22	0.09%	10	0.04%	**87**	**0.35%**
V-168	Atlas™ II VR	23,946	12.66%	8	0.03%	5	0.02%	19	0.08%	1	<0.01%	0	0.00%	1	<0.01%	22	0.09%	20	0.08%	**76**	**0.32%**
V-193	Atlas™ + VR	39,597	13.58%	5	0.01%	9	0.02%	14	0.04%	4	0.01%	1	<0.01%	1	<0.01%	70	0.18%	30	0.08%	**134**	**0.34%**

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	6,613	1.97%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	**3**	**0.05%**
CD1411-36C	Ellipse™ VR	2,937	2.18%	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**	**0.07%**
CD1357-40Q	Fortify Assura™ VR	12,009	1.68%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**5**	**0.04%**
CD1357-40C	Fortify Assura™ VR	4,443	2.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1257-40Q	Fortify Assura™ VR	5,046	3.79%	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%**
CD1257-40	Fortify Assura™ VR	2,302	5.60%	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	4,813	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**	**0.10%**
CD1311-36	Ellipse™ VR	1,637	7.39%	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	17,201	6.26%	3	0.02%	1	<0.01%	8	0.05%	0	0.00%	0	0.00%	0	0.00%	18	0.10%	2	0.01%	**32**	**0.19%**
CD1231-40	Fortify™ VR	7,272	7.73%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	3	0.04%	**13**	**0.18%**
CD1211-36Q	Current™ + VR	14,677	2.95%	4	0.03%	0	0.00%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	4	0.03%	**14**	**0.10%**
CD1211-36	Current™ + VR	13,936	2.48%	3	0.02%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**5**	**0.04%**
1207-36	Current™ VR RF	24,845	6.62%	12	0.05%	3	0.01%	11	0.04%	1	<0.01%	3	0.01%	3	0.01%	19	0.08%	7	0.03%	**59**	**0.24%**
V-168	Atlas™ II VR	23,946	12.66%	4	0.02%	0	0.00%	6	0.03%	0	0.00%	0	0.00%	8	0.03%	9	0.04%	9	0.04%	**36**	**0.15%**
V-193	Atlas™ + VR	39,597	13.58%	4	0.01%	3	<0.01%	8	0.02%	1	<0.01%	1	<0.01%	1	<0.01%	11	0.03%	11	0.03%	**40**	**0.10%**

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	111	7,656	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	364	182	18,215	1	0.27%	0	0.00%	0	0.00%	1	0.27%	0	0.00%	**2**	**0.55%**
1207-36	396	123	19,628	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	6.30%	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	6.90%	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	396	11.40%	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%**

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	6.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	Current™ + VR	364	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%	**0**	**0.00%**
1207-36	Current™ VR RF	396	11.40%	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.25%**

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

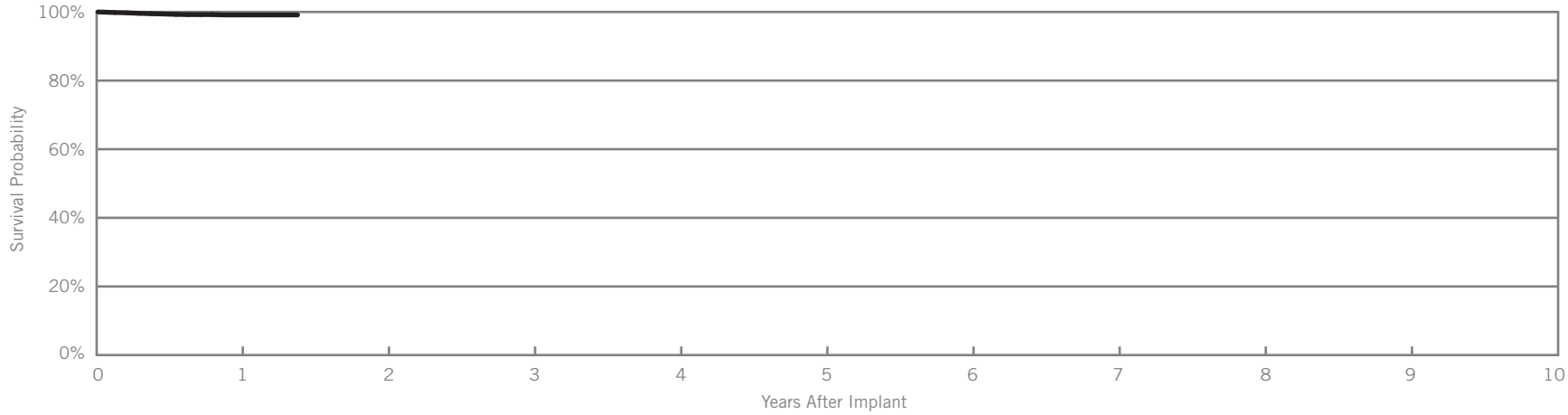
Optisure™ DF4

Model LDA220Q

US Regulatory Approval	February 2014
Registered US Implants	3,297
Estimated Active US Implants	2,962
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.12%	3	0.09%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.30%	14	0.42%
Failure to Capture	7	0.21%	7	0.21%
Oversensing	1	0.03%	2	0.06%
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	2	0.06%	0	0.00%
Extracardiac Stimulation	1	0.03%	0	0.00%
Other	2	0.06%	0	0.00%
Total	**27**	**0.82%**	**26**	**0.79%**
Total Returned for Analysis	**10**		**9**	

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	9	0.27%
Total	**9**	**0.27%**



Year	1	at 17 months								
Survival Probability	99.18%	99.18%								
± 1 standard error	0.20%	0.20%								
Sample Size	2,020	210								

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

Customer Reported Performance Data

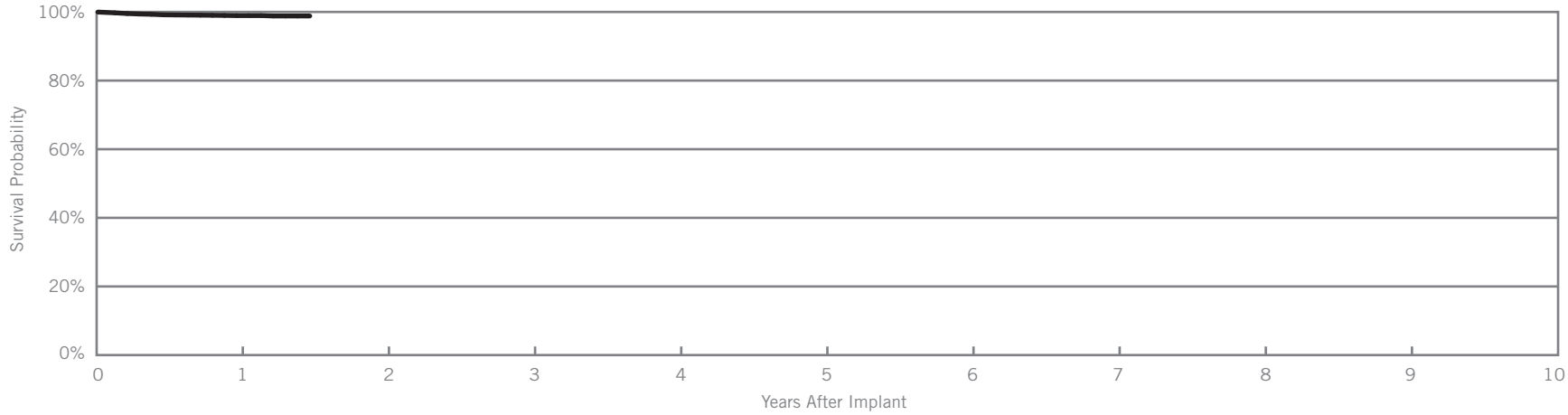
Optisure™ DF4

Model LDA210Q

US Regulatory Approval	February 2014
Registered US Implants	8,132
Estimated Active US Implants	7,552
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	9	0.11%	5	0.06%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	19	0.23%	37	0.45%
Failure to Capture	10	0.12%	13	0.16%
Oversensing	4	0.05%	8	0.10%
Failure to Sense	6	0.07%	3	0.04%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.01%
Abnormal Defibrillation Impedance	2	0.02%	3	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	5	0.06%	4	0.05%
Total	**55**	**0.68%**	**74**	**0.91%**
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	0.37%
Total	**30**	**0.37%**



Year	1	at 19 months								
Survival Probability	98.95%	98.84%								
± 1 standard error	0.14%	0.18%								
Sample Size	4,930	200								

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

Customer Reported Performance Data

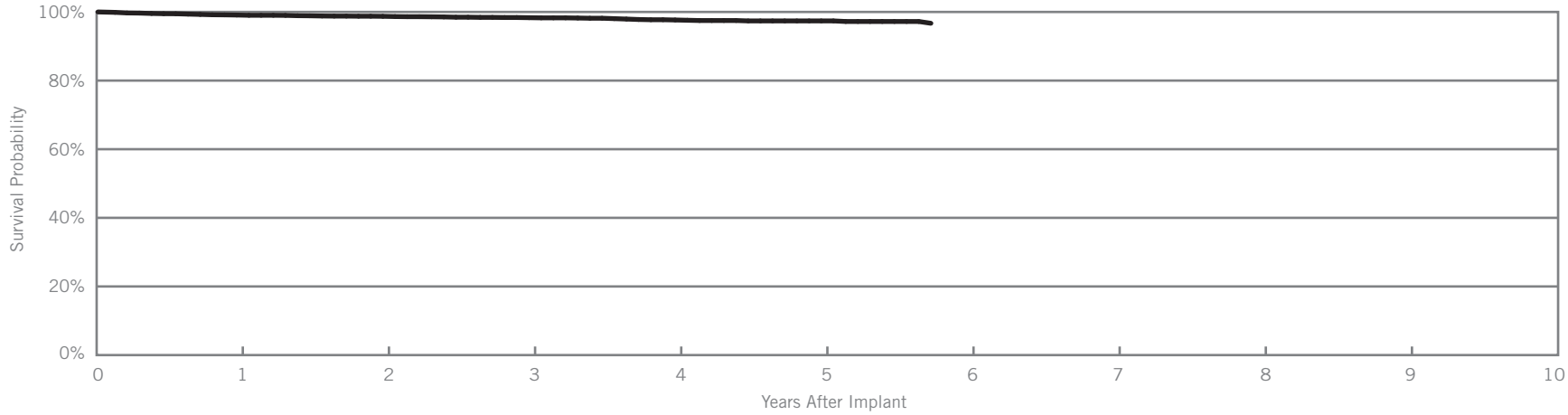
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	5,159
Estimated Active US Implants	3,438
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	0.12%	4	0.08%
Conductor Fracture	1	0.02%	5	0.10%
Lead Dislodgement	11	0.21%	18	0.35%
Failure to Capture	8	0.16%	30	0.58%
Oversensing	3	0.06%	20	0.39%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	2	0.04%
Abnormal Pacing Impedance	1	0.02%	8	0.16%
Abnormal Defibrillation Impedance	0	0.00%	6	0.12%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**31**	**0.60%**	**93**	**1.80%**
Total Returned for Analysis	**13**		**31**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.02%
Insulation Breach	4	0.08%
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	29	0.56%
Total	**34**	**0.66%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	99.14%	98.73%	98.29%	97.68%	97.41%	96.69%				
± 1 standard error	0.13%	0.17%	0.22%	0.28%	0.33%	0.37%				
Sample Size	4,490	3,330	2,420	1,630	950	200				

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

Actively Monitored Study Data

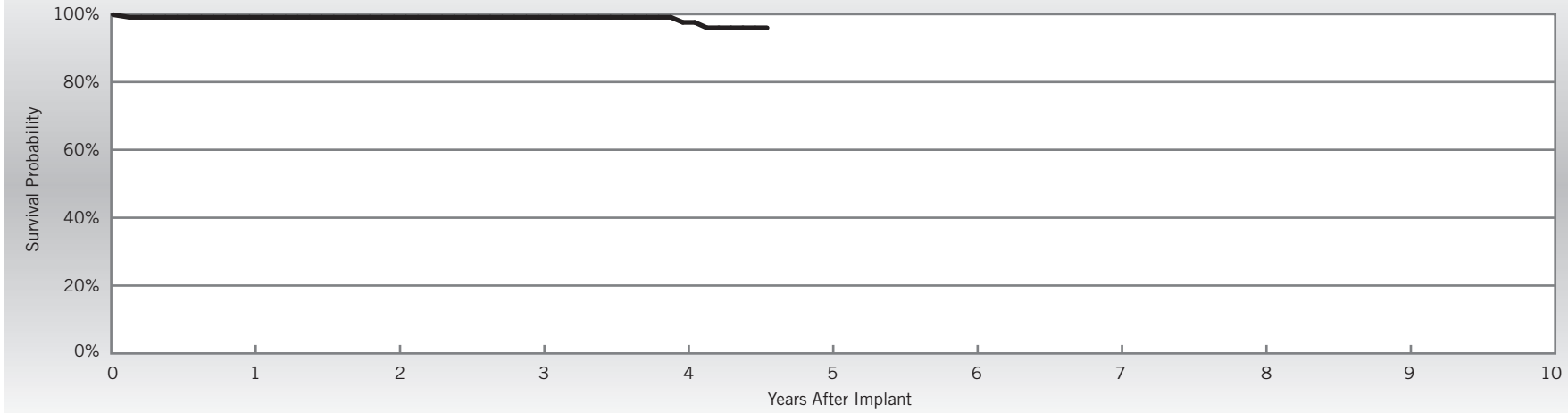
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	114
Active Devices Enrolled in Study	63
Cumulative Months of Follow-up	5,066
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	at 55 months					
Survival Probability	99.09%	99.09%	99.09%	97.59%	95.99%					
± 1 standard error	0.90%	0.90%	0.90%	0.90%	2.33%					
Sample Size	110	100	80	70	50					

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

Customer Reported Performance Data

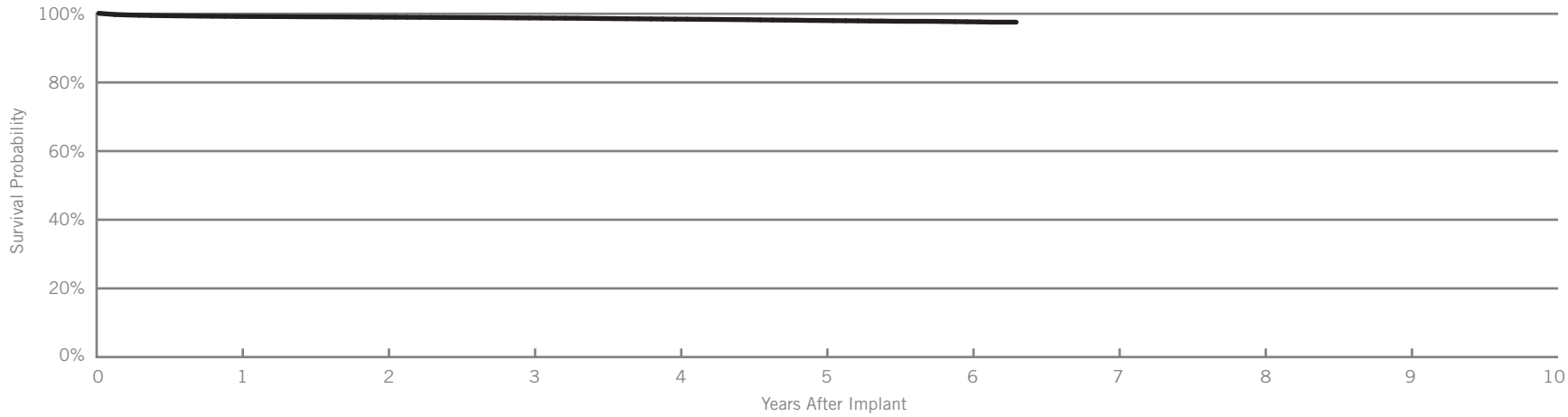
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	112,642
Estimated Active US Implants	74,227
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	70	0.06%	31	0.03%
Conductor Fracture	1	<0.01%	65	0.06%
Lead Dislodgement	195	0.17%	468	0.42%
Failure to Capture	86	0.08%	364	0.32%
Oversensing	39	0.03%	302	0.27%
Failure to Sense	12	0.01%	50	0.04%
Insulation Breach	0	0.00%	16	0.01%
Abnormal Pacing Impedance	5	<0.01%	55	0.05%
Abnormal Defibrillation Impedance	8	<0.01%	156	0.14%
Extracardiac Stimulation	3	<0.01%	5	<0.01%
Other	31	0.03%	46	0.04%
Total	**450**	**0.40%**	**1558**	**1.38%**
Total Returned for Analysis	**227**		**692**	

Malfunctions	Qty.	Rate
Conductor Fracture	21	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	5	<0.01%
Intravascular	14	0.01%
Insulation Breach	97	0.09%
Lead-to-Can Contact	45	0.04%
Lead-to-Lead Contact	9	<0.01%
Clavicular Crush	16	0.01%
Externalized Conductors	0	0.00%
Other	27	0.02%
Crimps, Welds & Bonds	2	<0.01%
Other	32	0.03%
Extrinsic Factors	618	0.55%
Total	**770**	**0.68%**



Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.23%	99.01%	98.78%	98.43%	98.03%	97.65%	97.54%			
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.06%	0.09%	0.13%			
Sample Size	100,390	78,470	59,650	41,850	24,950	9,570	560			

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

Actively Monitored Study Data

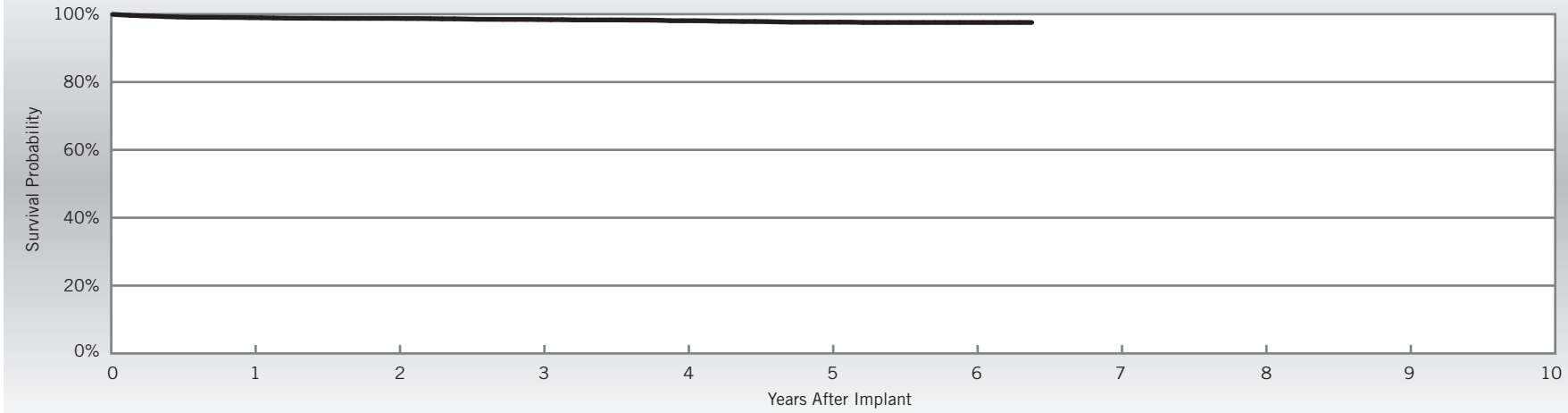
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	4,301
Active Devices Enrolled in Study	2,378
Cumulative Months of Follow-up	180,394
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	10	0.23%
Failure to Capture	7	0.16%
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	4	0.09%
Lead-to-Can Contact	2	0.05%
Lead-to-Lead Contact	1	0.02%
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	42	0.98%
Total	**52**	**1.21%**



Year	1	2	3	4	5	6	at 77 months			
Survival Probability	98.97%	98.76%	98.42%	98.07%	97.65%	97.56%	97.56%			
± 1 standard error	0.15%	0.18%	0.20%	0.24%	0.28%	0.30%	0.30%			
Sample Size	4,020	3,500	2,930	2,310	1,590	790	80			

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

Customer Reported Performance Data

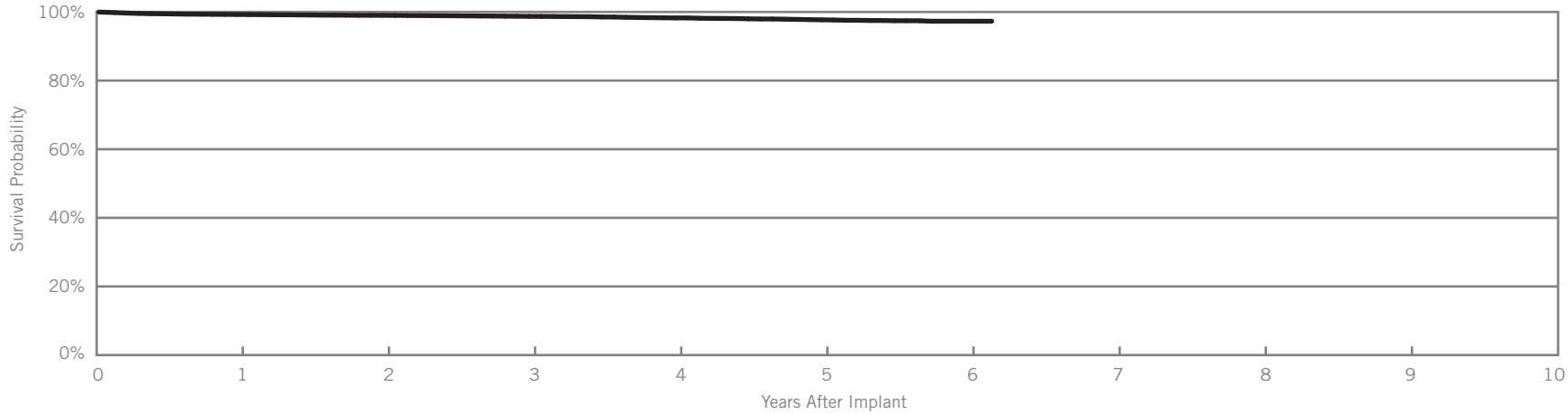
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	59,643
Estimated Active US Implants	43,746
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	69	0.12%	30	0.05%
Conductor Fracture	2	<0.01%	23	0.04%
Lead Dislodgement	111	0.19%	225	0.38%
Failure to Capture	51	0.09%	134	0.22%
Oversensing	18	0.03%	127	0.21%
Failure to Sense	7	0.01%	24	0.04%
Insulation Breach	0	0.00%	8	0.01%
Abnormal Pacing Impedance	4	<0.01%	27	0.05%
Abnormal Defibrillation Impedance	5	<0.01%	41	0.07%
Extracardiac Stimulation	3	<0.01%	8	0.01%
Other	26	0.04%	22	0.04%
Total	**296**	**0.50%**	**669**	**1.12%**
Total Returned for Analysis	**135**		**321**	

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	38	0.06%
Lead-to-Can Contact	21	0.04%
Lead-to-Lead Contact	5	<0.01%
Clavicular Crush	5	<0.01%
Externalized Conductors	0	0.00%
Other	7	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	11	0.02%
Extrinsic Factors	302	0.51%
Total	**359**	**0.60%**



Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.25%	99.02%	98.71%	98.27%	97.72%	97.27%	97.27%			
± 1 standard error	0.04%	0.05%	0.06%	0.09%	0.14%	0.24%	0.24%			
Sample Size	49,250	31,020	18,000	9,660	4,540	1,420	260			

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

Actively Monitored Study Data

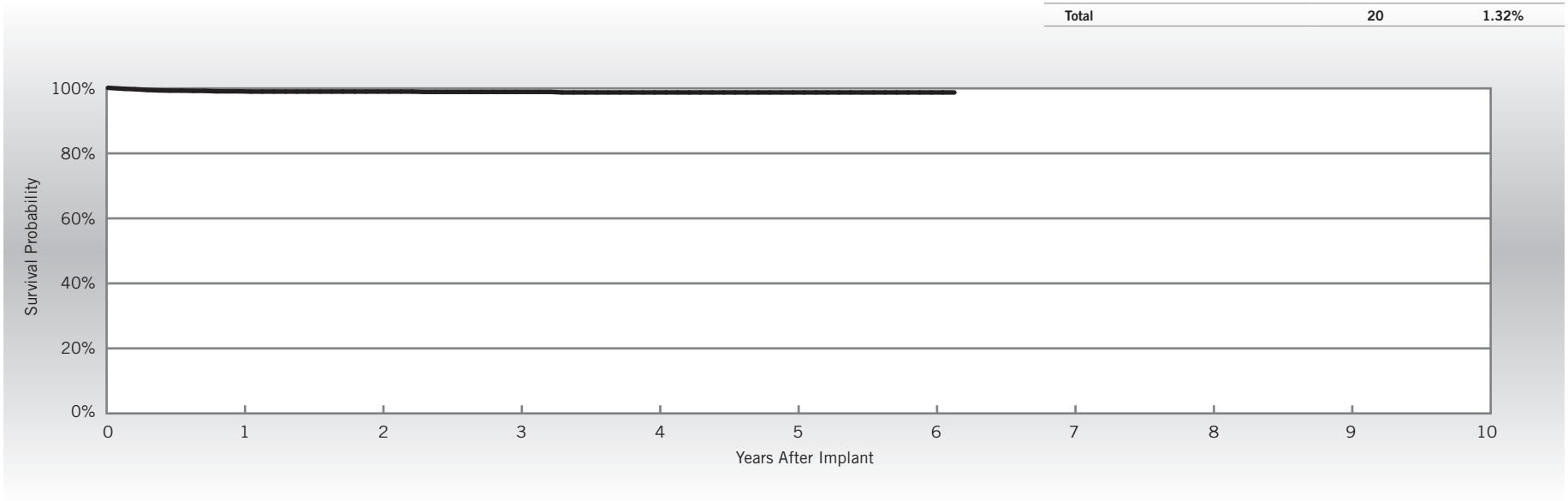
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	1,515
Active Devices Enrolled in Study	953
Cumulative Months of Follow-up	54,545
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	1	0.07%
Conductor Fracture	3	0.20%
Failure to Capture	3	0.20%
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**	**1.32%**



Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.10%	99.02%	98.92%	98.75%	98.75%	98.75%	98.75%			
± 1 standard error	0.25%	0.26%	0.28%	0.32%	0.32%	0.32%	0.32%			
Sample Size	1,420	1,230	900	570	360	160	70			

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

Customer Reported Performance Data

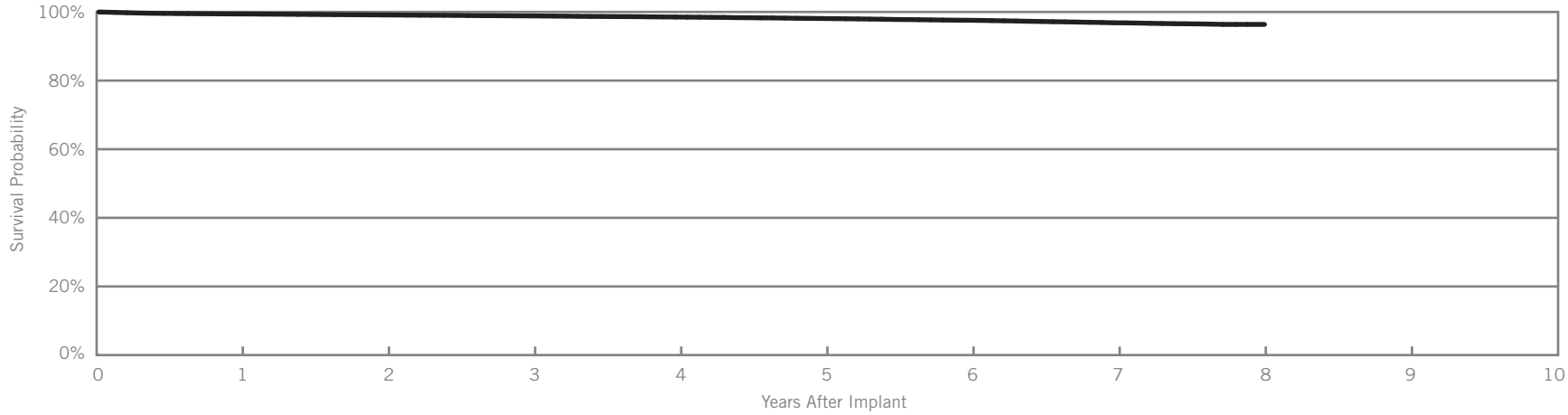
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	59,218
Estimated Active US Implants	30,907
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	39	0.07%	15	0.03%
Conductor Fracture	1	<0.01%	101	0.17%
Lead Dislodgement	69	0.12%	173	0.29%
Failure to Capture	22	0.04%	218	0.37%
Oversensing	48	0.08%	398	0.67%
Failure to Sense	5	<0.01%	53	0.09%
Insulation Breach	0	0.00%	39	0.07%
Abnormal Pacing Impedance	1	<0.01%	124	0.21%
Abnormal Defibrillation Impedance	19	0.03%	175	0.30%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	21	0.04%	32	0.05%
Total	**225**	**0.38%**	**1329**	**2.24%**
Total Returned for Analysis	**91**		**413**	

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	96	0.16%
Lead-to-Can Contact	47	0.08%
Lead-to-Lead Contact	20	0.03%
Clavicular Crush	12	0.02%
Externalized Conductors	0	0.00%
Other	17	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	9	0.02%
Extrinsic Factors	345	0.58%
Total	**481**	**0.81%**



Year	1	2	3	4	5	6	7	8		
Survival Probability	99.42%	99.14%	98.87%	98.51%	98.06%	97.55%	96.81%	96.12%		
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.08%	0.10%	0.23%		
Sample Size	54,800	47,290	41,520	36,320	30,590	23,890	14,220	220		

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

Actively Monitored Study Data

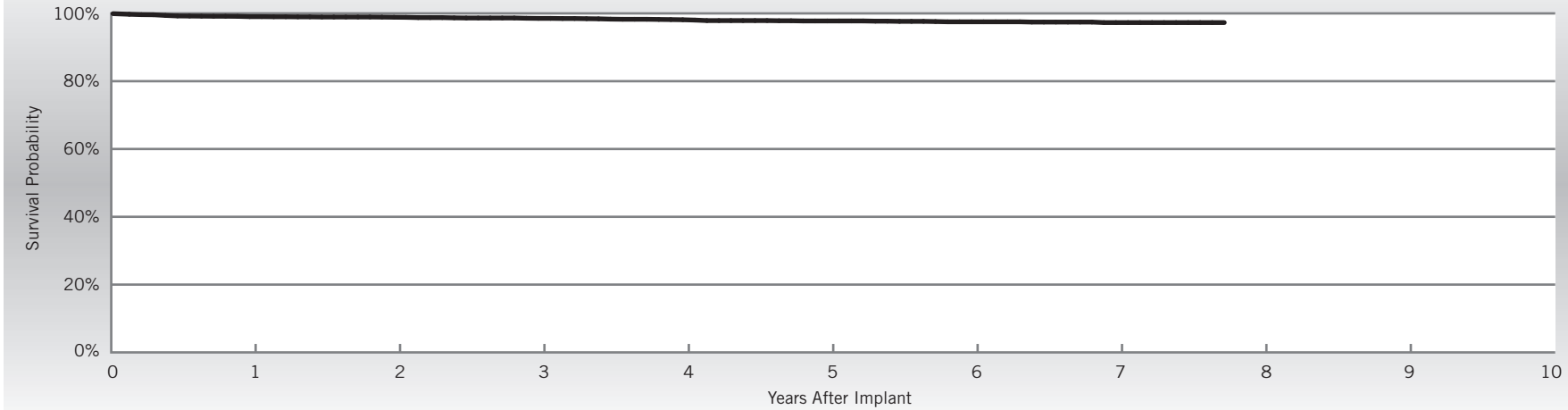
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	3,571
Active Devices Enrolled in Study	1,499
Cumulative Months of Follow-up	188,193
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	8	0.22%
Failure to Sense	2	0.06%
Inappropriate Shock	2	0.06%
Insulation Breach	9	0.25%
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	10	0.28%
Lead-to-Can Contact	5	0.14%
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	25	0.70%
Total	**37**	**1.04%**



Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.04%	98.87%	98.53%	98.13%	97.77%	97.52%	97.29%	97.29%		
± 1 standard error	0.16%	0.18%	0.21%	0.25%	0.28%	0.31%	0.35%	0.35%		
Sample Size	3,380	2,980	2,590	2,230	1,870	1,570	990	60		

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

Customer Reported Performance Data

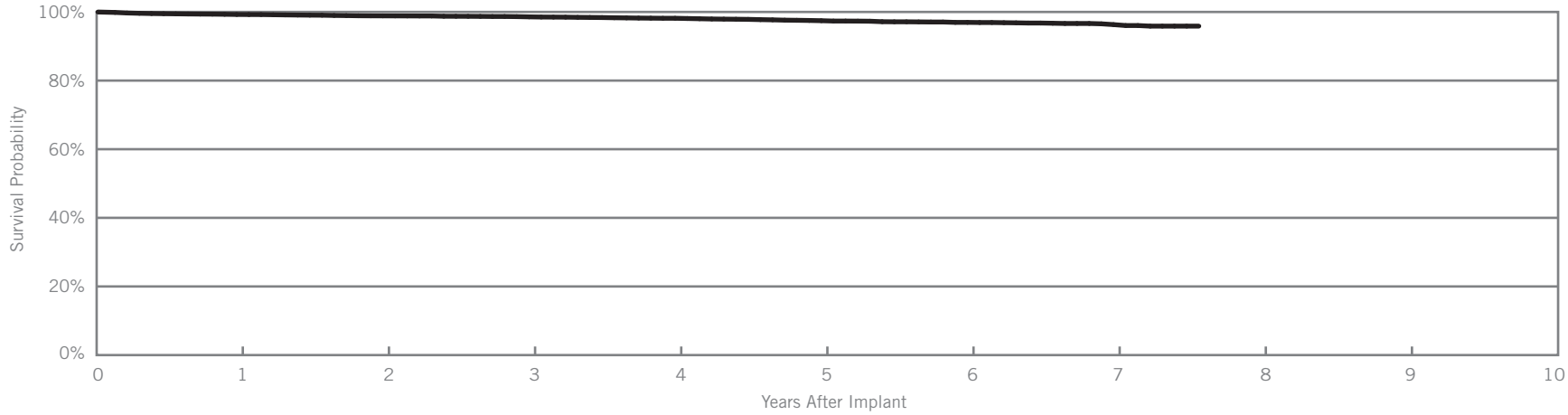
Durata™

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	13,785
Estimated Active US Implants	8,077
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%	21	0.15%
Lead Dislodgement	18	0.13%	49	0.36%
Failure to Capture	15	0.11%	49	0.36%
Oversensing	10	0.07%	76	0.55%
Failure to Sense	0	0.00%	8	0.06%
Insulation Breach	0	0.00%	19	0.14%
Abnormal Pacing Impedance	2	0.01%	28	0.20%
Abnormal Defibrillation Impedance	1	<0.01%	20	0.15%
Extracardiac Stimulation	1	<0.01%	2	0.01%
Other	4	0.03%	6	0.04%
Total	**62**	**0.45%**	**280**	**2.03%**
Total Returned for Analysis	**30**		**141**	

Malfunctions	Qty.	Rate
Conductor Fracture	15	0.11%
Clavicular Crush	0	0.00%
In the Pocket	12	0.09%
Intravascular	3	0.02%
Insulation Breach	40	0.29%
Lead-to-Can Contact	23	0.17%
Lead-to-Lead Contact	11	0.08%
Clavicular Crush	0	0.00%
Externalized Conductors	1	<0.01%
Other	5	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	4	0.03%
Extrinsic Factors	107	0.78%
Total	**166**	**1.20%**



Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.24%	98.85%	98.51%	98.06%	97.28%	96.81%	96.14%	95.68%		
± 1 standard error	0.07%	0.10%	0.11%	0.14%	0.18%	0.22%	0.28%	0.42%		
Sample Size	12,430	10,040	8,130	6,570	4,970	3,240	1,590	290		

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

Actively Monitored Study Data

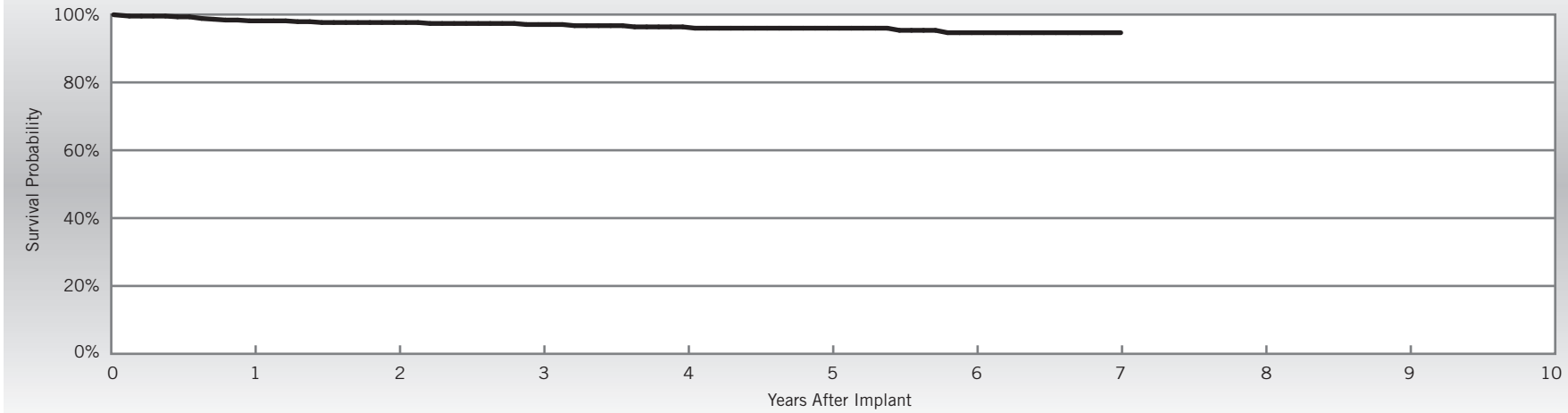
Durata™

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	447
Active Devices Enrolled in Study	245
Cumulative Months of Follow-up	22,530
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	2	0.45%
Conductor Fracture	5	1.12%
Failure to Capture	2	0.45%
Failure to Sense	1	0.22%
Lead Dislodgement	4	0.89%
Oversensing	3	0.67%

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	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	5	1.12%
Total	**7**	**1.57%**



Year	1	2	3	4	5	6	7			
Survival Probability	98.14%	97.65%	97.06%	96.36%	95.98%	94.65%	94.65%			
± 1 standard error	0.61%	0.74%	0.84%	0.97%	1.04%	1.39%	1.39%			
Sample Size	430	390	330	280	220	150	50			

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

Customer Reported Performance Data

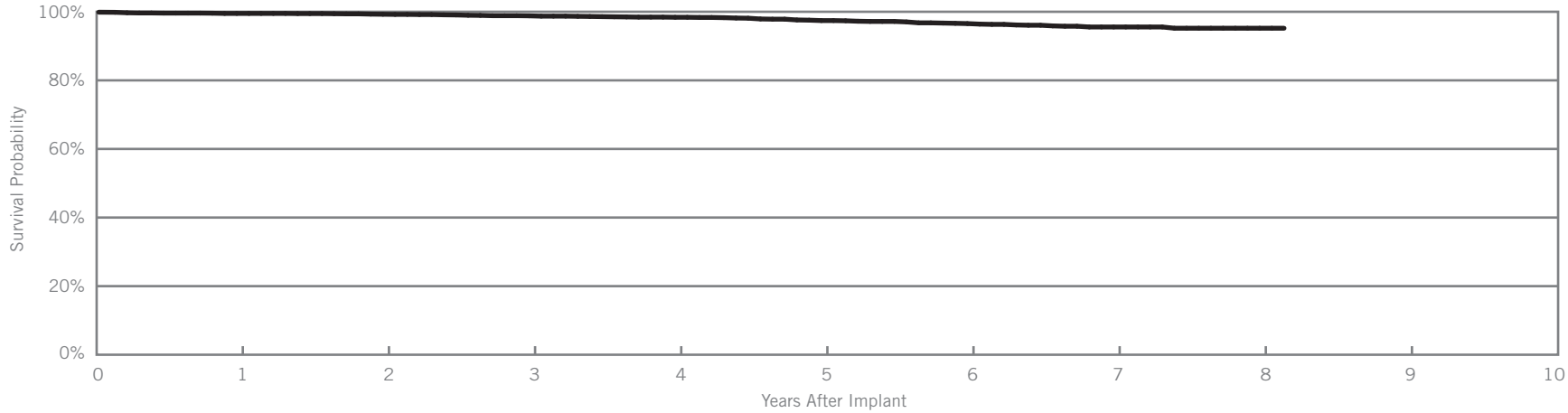
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,311
Estimated Active US Implants	1,570
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%	37	1.12%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	4	0.12%
Abnormal Pacing Impedance	0	0.00%	10	0.30%
Abnormal Defibrillation Impedance	0	0.00%	10	0.30%
Extracardiac Stimulation	0	0.00%	1	0.03%
Other	0	0.00%	2	0.06%
Total	**19**	**0.57%**	**118**	**3.56%**
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 98 months	
Survival Probability	99.44%	99.21%	98.78%	98.35%	97.23%	96.42%	95.45%	95.10%	95.10%	
± 1 standard error	0.14%	0.16%	0.21%	0.25%	0.34%	0.42%	0.51%	0.56%	0.56%	
Sample Size	3,040	2,620	2,340	2,080	1,760	1,440	1,010	490	210	

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

Actively Monitored Study Data

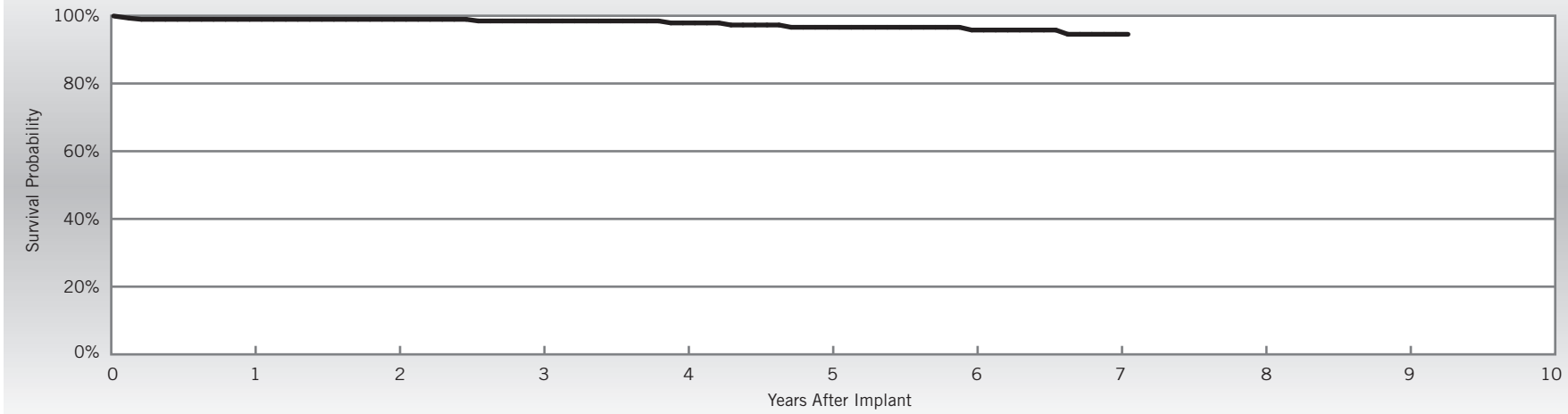
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	288
Active Devices Enrolled in Study	109
Cumulative Months of Follow-up	15,216
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 85 months		
Survival Probability	98.94%	98.94%	98.46%	97.88%	96.60%	95.78%	94.53%	94.53%		
± 1 standard error	0.61%	0.61%	0.77%	0.96%	1.31%	1.31%	1.96%	1.96%		
Sample Size	270	240	210	180	150	130	80	50		

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

Customer Reported Performance Data

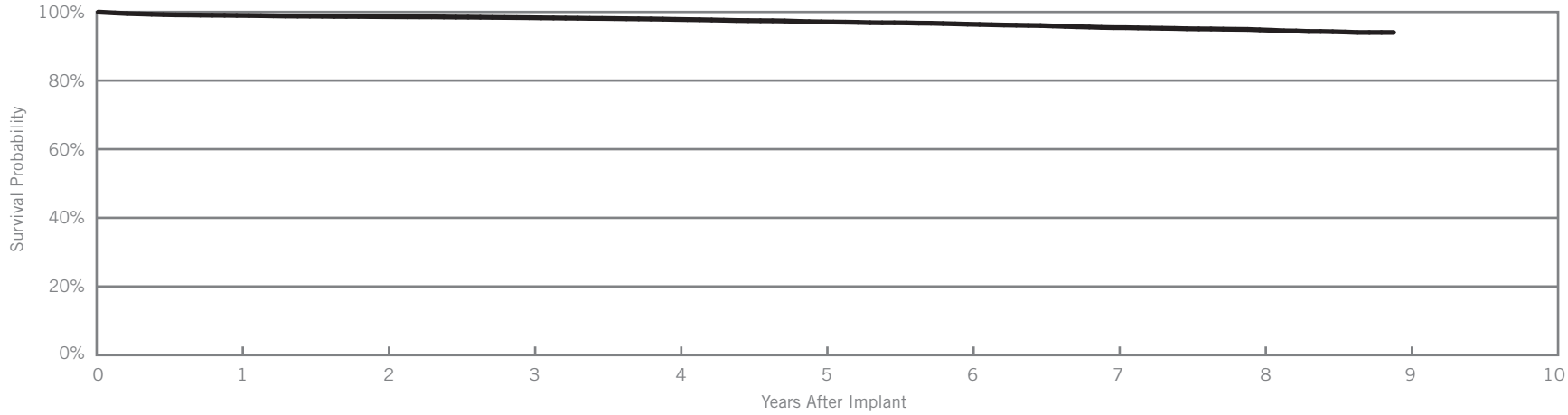
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	14,236
Estimated Active US Implants	6,042
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%	48	0.34%
Lead Dislodgement	27	0.19%	63	0.44%
Failure to Capture	17	0.12%	122	0.86%
Oversensing	19	0.13%	179	1.26%
Failure to Sense	8	0.06%	16	0.11%
Insulation Breach	0	0.00%	22	0.15%
Abnormal Pacing Impedance	1	<0.01%	31	0.22%
Abnormal Defibrillation Impedance	4	0.03%	66	0.46%
Extracardiac Stimulation	3	0.02%	2	0.01%
Other	0	0.00%	26	0.18%
Total	**112**	**0.79%**	**591**	**4.15%**
Total Returned for Analysis	**53**		**174**	

Malfunctions	**Qty.**	**Rate**
Conductor Fracture	8	0.06%
Clavicular Crush	1	<0.01%
In the Pocket	2	0.01%
Intravascular	5	0.04%
Insulation Breach	32	0.22%
Lead-to-Can Contact	12	0.08%
Lead-to-Lead Contact	4	0.03%
Clavicular Crush	4	0.03%
Externalized Conductors	0	0.00%
Other	12	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	158	1.11%
Total	**198**	**1.39%**



Year	1	2	3	4	5	6	7	8	at 107 months	
Survival Probability	98.99%	98.65%	98.37%	97.91%	97.19%	96.51%	95.56%	94.86%	94.01%	
± 1 standard error	0.09%	0.10%	0.11%	0.13%	0.16%	0.18%	0.22%	0.24%	0.34%	
Sample Size	13,120	11,310	10,060	9,000	8,130	7,320	6,370	4,600	230	

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

Actively Monitored Study Data

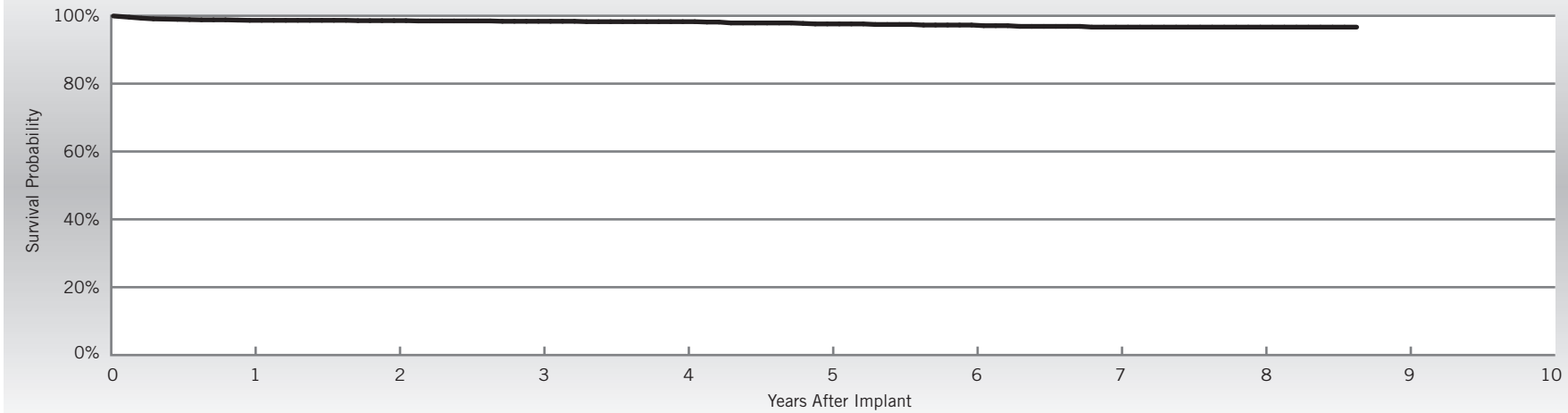
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	1,472
Active Devices Enrolled in Study	413
Cumulative Months of Follow-up	79,563
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	5	0.34%
Conductor Fracture	5	0.34%
Failure to Capture	6	0.41%
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	at 104 months	
Survival Probability	98.66%	98.57%	98.38%	98.27%	97.60%	97.27%	96.66%	96.66%	96.66%	
± 1 standard error	0.30%	0.32%	0.34%	0.36%	0.47%	0.52%	0.62%	0.62%	0.62%	
Sample Size	1,380	1,200	1,020	870	720	590	470	320	70	

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

Customer Reported Performance Data

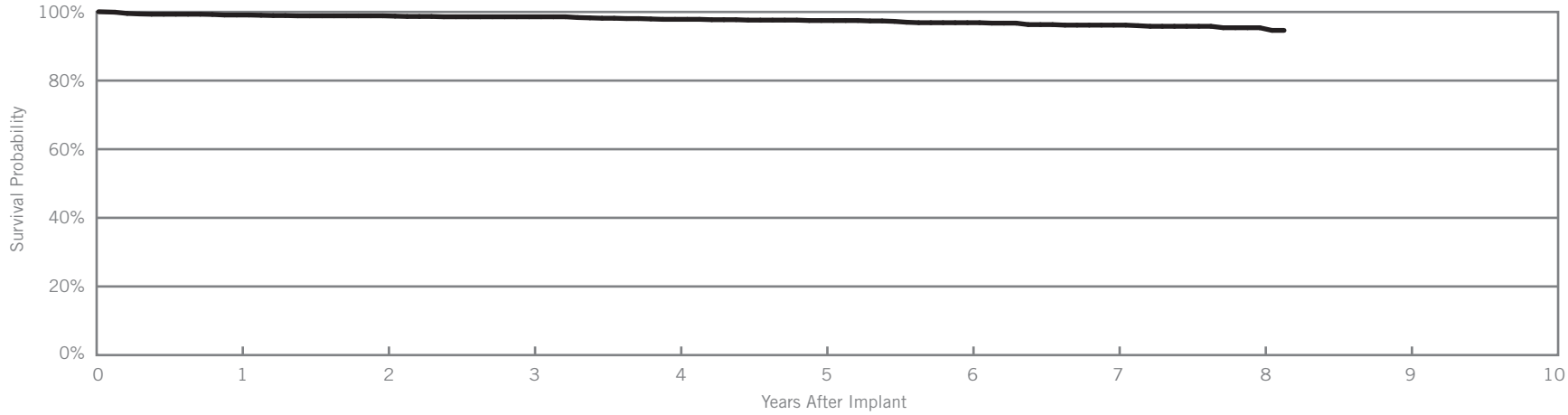
Riata™ ST Optim™

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,468
Estimated Active US Implants	664
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	5	0.34%	2	0.14%
Conductor Fracture	0	0.00%	7	0.48%
Lead Dislodgement	3	0.20%	10	0.68%
Failure to Capture	1	0.07%	8	0.54%
Oversensing	0	0.00%	15	1.02%
Failure to Sense	0	0.00%	1	0.07%
Insulation Breach	0	0.00%	5	0.34%
Abnormal Pacing Impedance	1	0.07%	2	0.14%
Abnormal Defibrillation Impedance	0	0.00%	2	0.14%
Extracardiac Stimulation	0	0.00%	1	0.07%
Other	0	0.00%	1	0.07%
Total	**10**	**0.68%**	**54**	**3.68%**
Total Returned for Analysis	**3**		**18**	

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	5	0.34%
Lead-to-Can Contact	4	0.27%
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	16	1.09%
Total	**24**	**1.63%**



Year	1	2	3	4	5	6	7	8	at 98 months	
Survival Probability	99.04%	98.87%	98.60%	97.88%	97.32%	96.71%	95.88%	95.13%	94.38%	
± 1 standard error	0.27%	0.29%	0.33%	0.43%	0.49%	0.56%	0.65%	0.75%	0.91%	
Sample Size	1,360	1,190	1,060	950	860	790	680	450	230	

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

Customer Reported Performance Data

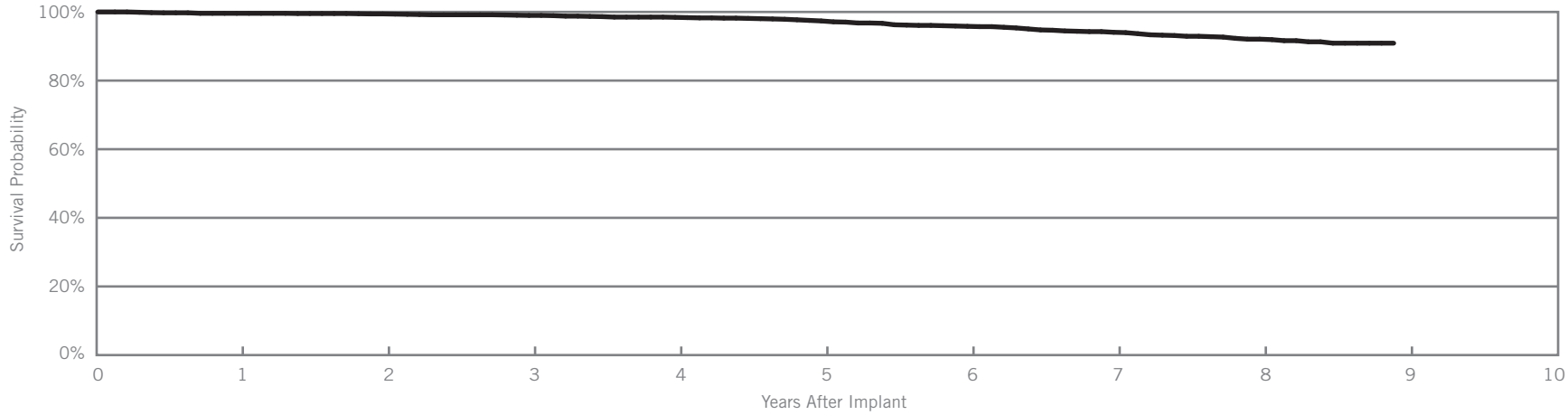
Riata™ ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,199
Estimated Active US Implants	868
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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%	4	0.18%
Lead Dislodgement	1	0.05%	8	0.36%
Failure to Capture	2	0.09%	6	0.27%
Oversensing	2	0.09%	34	1.55%
Failure to Sense	1	0.05%	3	0.14%
Insulation Breach	0	0.00%	38	1.73%
Abnormal Pacing Impedance	1	0.05%	18	0.82%
Abnormal Defibrillation Impedance	0	0.00%	14	0.64%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	2	0.09%
Total	**11**	**0.50%**	**130**	**5.91%**
Total Returned for Analysis	**4**		**30**	

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	32	1.46%
Lead-to-Can Contact	9	0.41%
Lead-to-Lead Contact	16	0.73%
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	**43**	**1.96%**



Year	1	2	3	4	5	6	7	8	at 107 months	
Survival Probability	99.60%	99.43%	99.05%	98.77%	97.56%	96.00%	94.18%	91.95%	90.56%	
± 1 standard error	0.14%	0.17%	0.22%	0.26%	0.39%	0.54%	0.66%	0.82%	0.95%	
Sample Size	2,040	1,780	1,590	1,410	1,240	1,110	990	810	240	

Customer Reported Performance Data

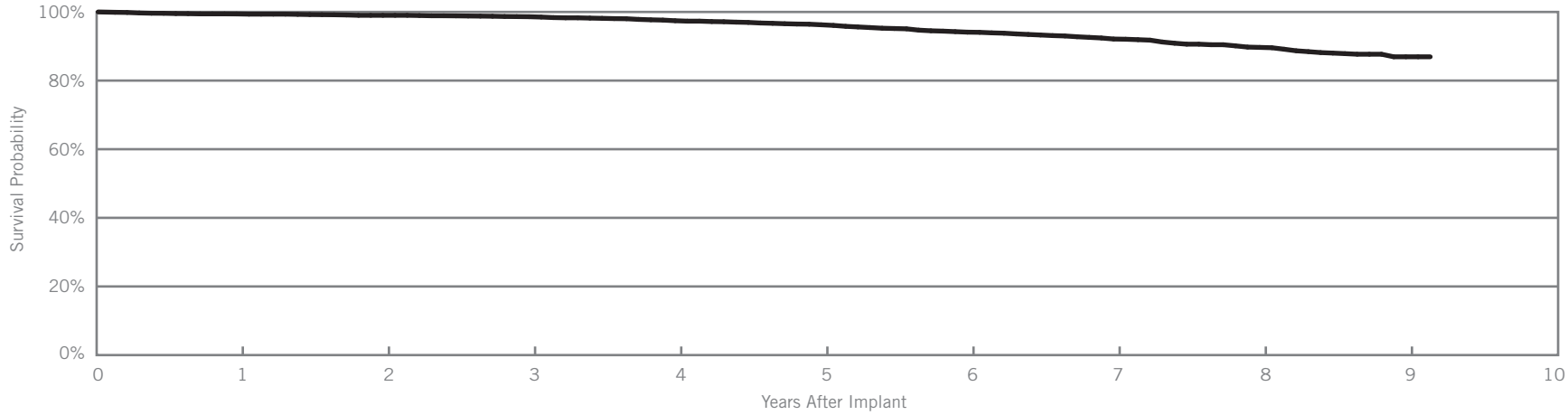
Riata™ ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,054
Estimated Active US Implants	1,595
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	One

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.10%	3	0.07%
Conductor Fracture	0	0.00%	29	0.72%
Lead Dislodgement	5	0.12%	6	0.15%
Failure to Capture	0	0.00%	42	1.04%
Oversensing	3	0.07%	82	2.02%
Failure to Sense	0	0.00%	14	0.35%
Insulation Breach	0	0.00%	50	1.23%
Abnormal Pacing Impedance	2	0.05%	14	0.35%
Abnormal Defibrillation Impedance	0	0.00%	19	0.47%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	6	0.15%
Total	**15**	**0.37%**	**265**	**6.54%**
Total Returned for Analysis	**3**		**57**	

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	44	1.09%
Lead-to-Can Contact	20	0.49%
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	26	0.64%
Total	**74**	**1.83%**



Year	1	2	3	4	5	6	7	8	9	at 110 months
Survival Probability	99.41%	99.11%	98.66%	97.46%	96.29%	94.21%	92.15%	89.62%	86.86%	86.86%
± 1 standard error	0.12%	0.16%	0.20%	0.28%	0.35%	0.46%	0.55%	0.69%	0.95%	0.95%
Sample Size	3,760	3,280	2,930	2,610	2,340	2,050	1,690	1,200	590	210

Customer Reported Performance Data

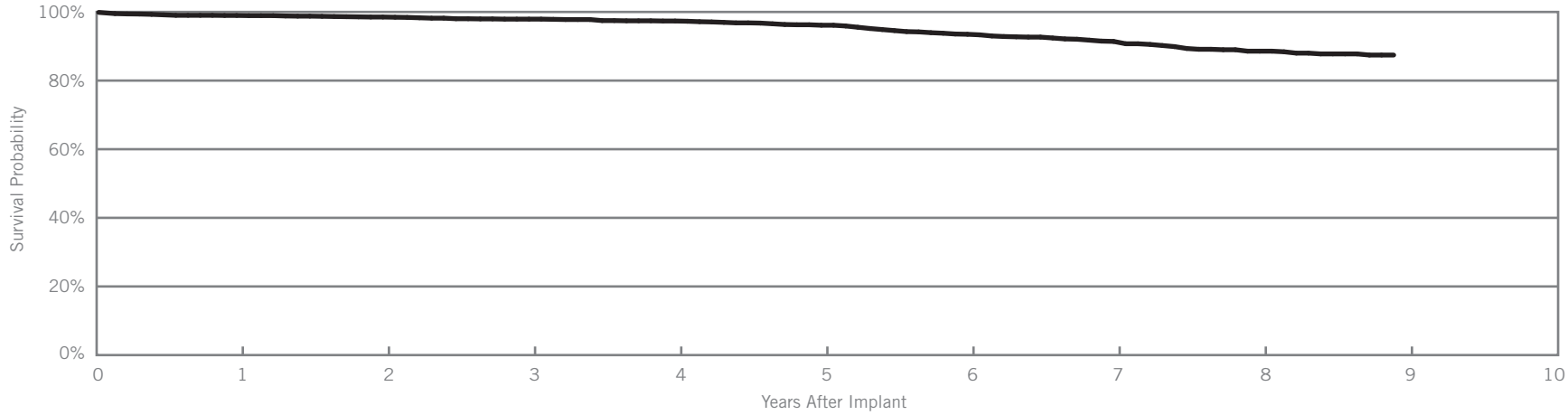
Riata™ ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,405
Estimated Active US Implants	911
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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	2	0.08%	9	0.37%
Failure to Capture	4	0.17%	17	0.71%
Oversensing	4	0.17%	54	2.25%
Failure to Sense	0	0.00%	2	0.08%
Insulation Breach	0	0.00%	60	2.49%
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%	6	0.25%
Total	**20**	**0.83%**	**171**	**7.11%**
Total Returned for Analysis	**11**		**63**	

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	57	2.37%
Lead-to-Can Contact	29	1.21%
Lead-to-Lead Contact	13	0.54%
Clavicular Crush	0	0.00%
Externalized Conductors	5	0.21%
Other	10	0.42%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	22	0.91%
Total	**84**	**3.49%**



Year	1	2	3	4	5	6	7	8	at 107 months	
Survival Probability	99.02%	98.51%	97.96%	97.28%	95.95%	93.28%	91.25%	88.21%	87.04%	
± 1 standard error	0.21%	0.26%	0.31%	0.37%	0.46%	0.64%	0.75%	0.93%	1.07%	
Sample Size	2,220	1,950	1,750	1,560	1,390	1,230	1,050	740	210	

Customer Reported Performance Data

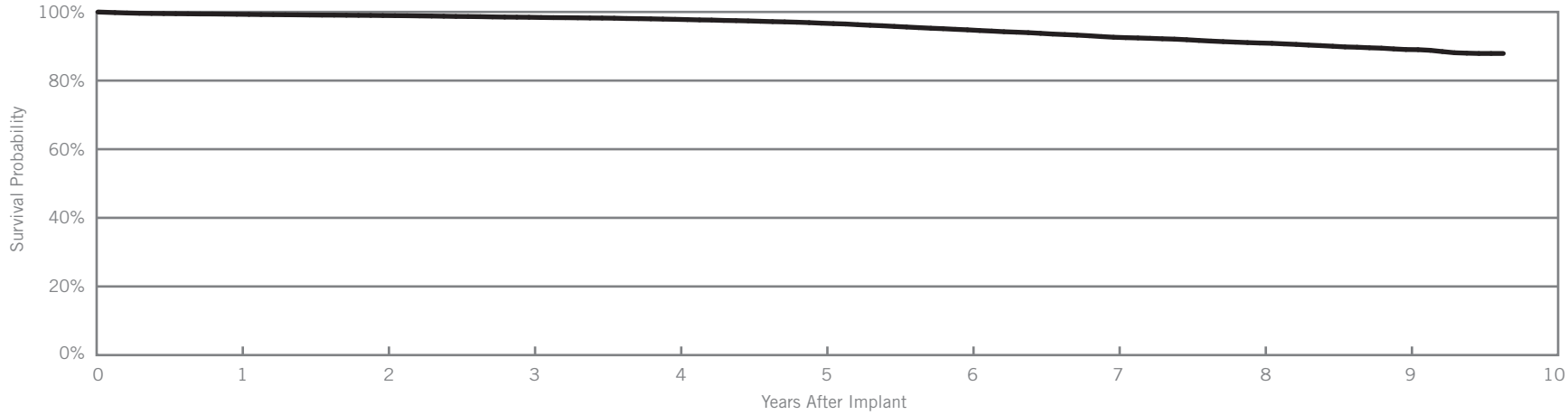
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,864
Estimated Active US Implants	12,963
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	42	0.12%	29	0.08%
Conductor Fracture	0	0.00%	126	0.36%
Lead Dislodgement	38	0.11%	57	0.16%
Failure to Capture	42	0.12%	271	0.78%
Oversensing	40	0.11%	708	2.03%
Failure to Sense	7	0.02%	61	0.17%
Insulation Breach	1	<0.01%	632	1.81%
Abnormal Pacing Impedance	8	0.02%	97	0.28%
Abnormal Defibrillation Impedance	4	0.01%	156	0.45%
Extracardiac Stimulation	3	<0.01%	4	0.01%
Other	11	0.03%	86	0.25%
Total	**196**	**0.56%**	**2227**	**6.39%**
Total Returned for Analysis	**96**		**617**	

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	499	1.43%
Lead-to-Can Contact	264	0.76%
Lead-to-Lead Contact	132	0.38%
Clavicular Crush	10	0.03%
Externalized Conductors	30	0.09%
Other	63	0.18%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	271	0.78%
Total	**795**	**2.28%**



Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.34%	98.99%	98.49%	97.89%	96.81%	94.88%	92.70%	91.00%	89.13%	88.01%
± 1 standard error	0.04%	0.06%	0.07%	0.09%	0.11%	0.15%	0.18%	0.21%	0.25%	0.33%
Sample Size	32,500	28,530	25,450	22,670	20,190	17,910	15,580	12,520	7,400	420

Actively Monitored Study Data

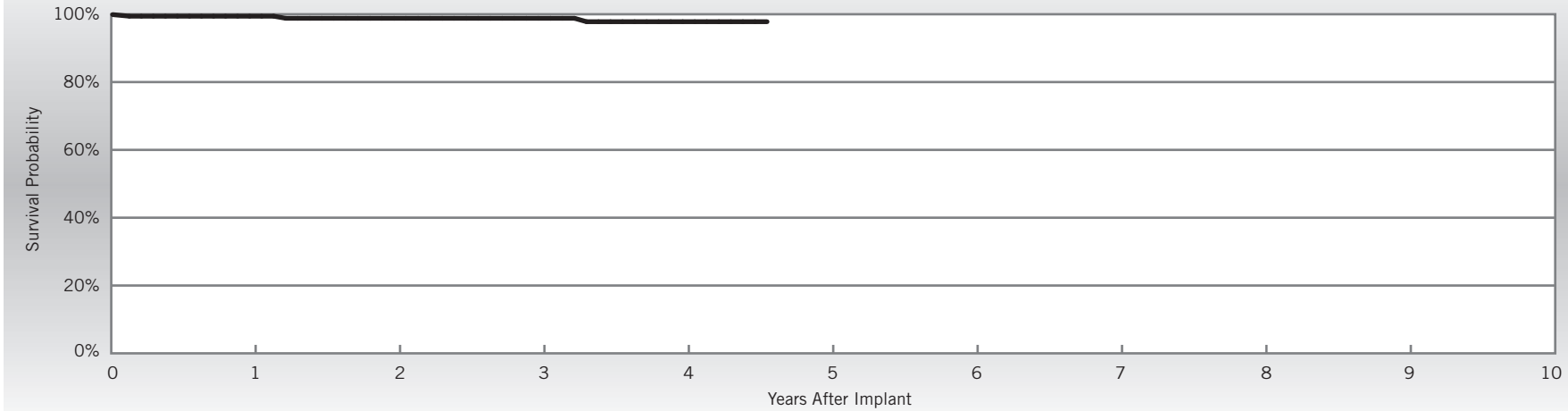
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	180
Active Devices Enrolled in Study	44
Cumulative Months of Follow-up	7,398
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	1	0.56%
Insulation Breach	1	0.56%
Lead Dislodgement	1	0.56%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	3	1.67%
Lead-to-Can Contact	2	1.11%
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**	**2.22%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.43%	98.81%	98.81%	97.80%	97.80%					
± 1 standard error	0.56%	0.84%	0.84%	1.30%	1.30%					
Sample Size	170	150	120	90	50					

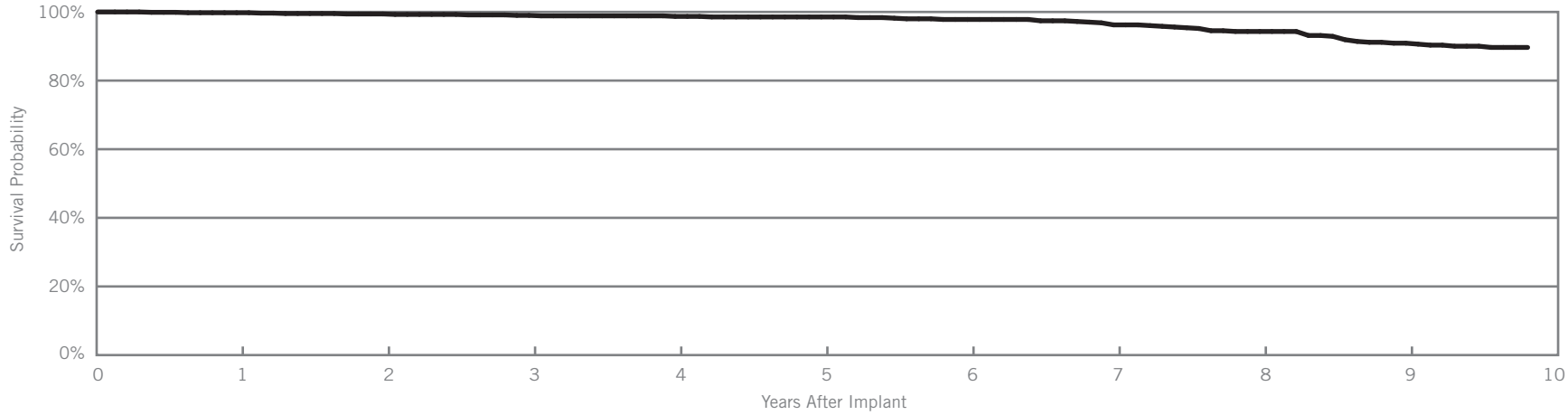
Customer Reported Performance Data

Riata™ *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	981
Estimated Active US Implants	352
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.78%	99.41%	99.00%	98.71%	98.21%	97.48%	95.88%	93.73%	90.30%	89.07%
± 1 standard error	0.16%	0.26%	0.35%	0.38%	0.50%	0.61%	0.75%	1.05%	1.35%	1.47%
Sample Size	920	810	730	660	590	530	490	440	370	200

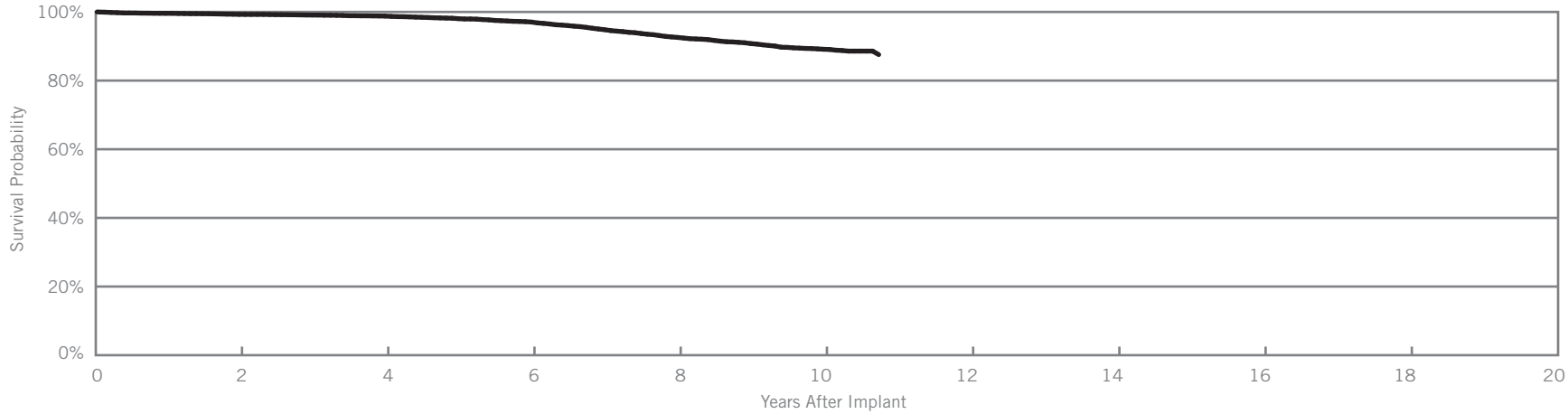
Customer Reported Performance Data

Riata™ *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,697
Estimated Active US Implants	3,181
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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	147	1.52%
Lead-to-Can Contact	55	0.57%
Lead-to-Lead Contact	45	0.46%
Clavicular Crush	2	0.02%
Externalized Conductors	17	0.18%
Other	28	0.29%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	49	0.51%
Total	**204**	**2.10%**



Year	2	4	6	8	10	at 129 months				
Survival Probability	99.31%	98.79%	97.00%	92.54%	89.25%	87.69%				
± 1 standard error	0.09%	0.12%	0.21%	0.37%	0.48%	0.51%				
Sample Size	8,100	6,480	5,070	3,920	2,270	310				

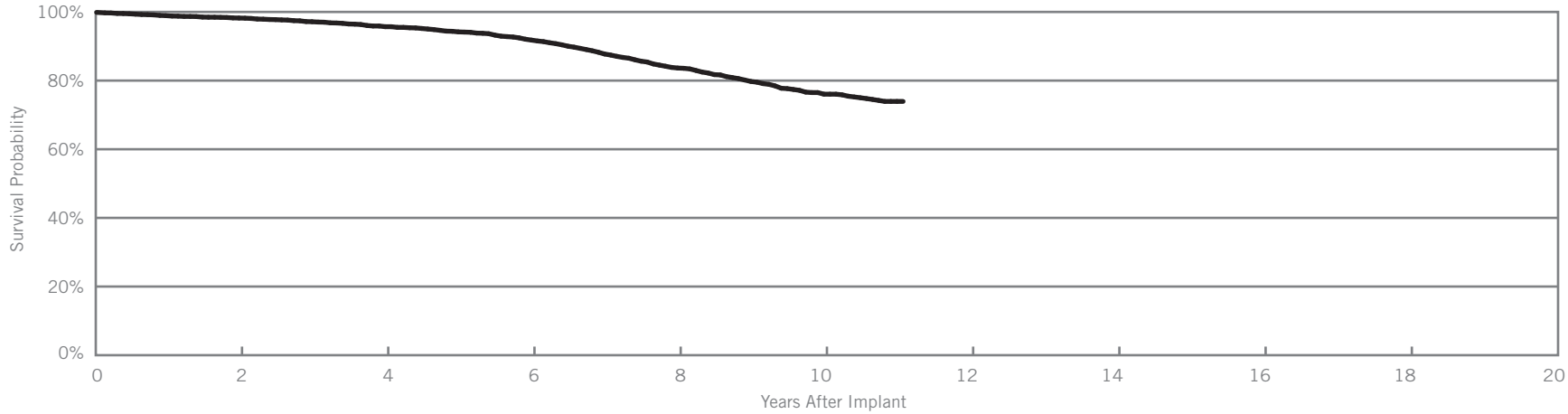
Customer Reported Performance Data

Riata™

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,129
Estimated Active US Implants	851
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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	150	4.79%
Lead-to-Can Contact	47	1.50%
Lead-to-Lead Contact	27	0.86%
Clavicular Crush	2	0.06%
Externalized Conductors	45	1.44%
Other	29	0.93%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	34	1.09%
Total	**187**	**5.98%**



Year	2	4	6	8	10	at 133 months				
Survival Probability	98.26%	95.73%	91.81%	83.72%	76.12%	74.04%				
± 1 standard error	0.25%	0.41%	0.60%	0.92%	1.19%	1.36%				
Sample Size	2,560	2,040	1,560	1,080	620	210				

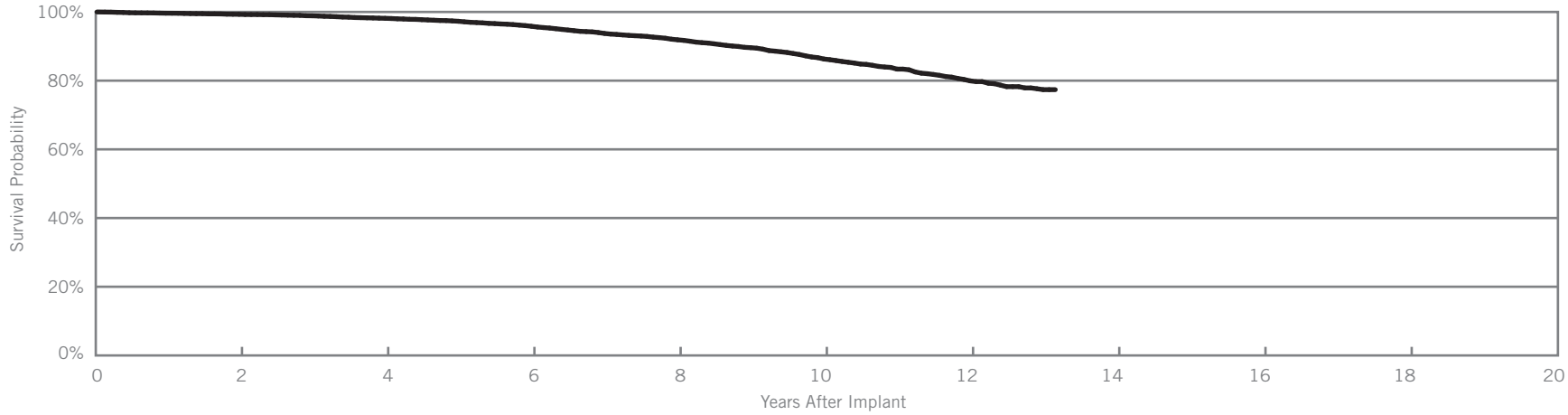
Customer Reported Performance Data

Riata™

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,278
Estimated Active US Implants	2,966
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	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	191	1.86%
Lead-to-Can Contact	94	0.91%
Lead-to-Lead Contact	33	0.32%
Clavicular Crush	1	<0.01%
Externalized Conductors	36	0.35%
Other	27	0.26%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	52	0.51%
Total	**248**	**2.41%**



Year	2	4	6	8	10	12	at 158 months			
Survival Probability	99.34%	98.26%	95.88%	92.00%	86.39%	79.97%	77.40%			
± 1 standard error	0.08%	0.15%	0.24%	0.37%	0.53%	0.79%	1.02%			
Sample Size	8,650	7,030	5,460	3,900	2,520	1,040	230			

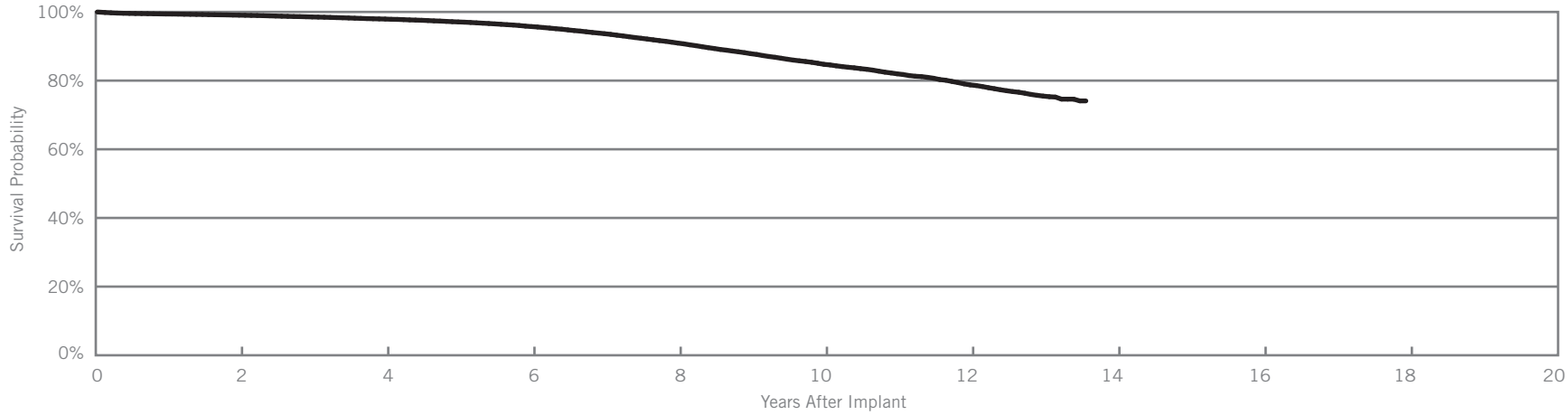
Customer Reported Performance Data

Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	68,383
Estimated Active US Implants	18,612
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 302-304)	One

Malfunctions	Qty.	Rate
Conductor Fracture	30	0.04%
Clavicular Crush	4	<0.01%
In the Pocket	11	0.02%
Intravascular	15	0.02%
Insulation Breach	1500	2.19%
Lead-to-Can Contact	609	0.89%
Lead-to-Lead Contact	306	0.45%
Clavicular Crush	17	0.02%
Externalized Conductors	309	0.45%
Other	259	0.38%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	497	0.73%
Total	**2,030**	**2.97%**



Year	2	4	6	8	10	12	at 163 months			
Survival Probability	99.07%	97.93%	95.77%	90.97%	84.81%	78.87%	74.20%			
± 1 standard error	0.04%	0.06%	0.09%	0.15%	0.22%	0.34%	0.69%			
Sample Size	56,670	45,330	35,050	25,670	16,400	4,900	240			

Actively Monitored Study Data

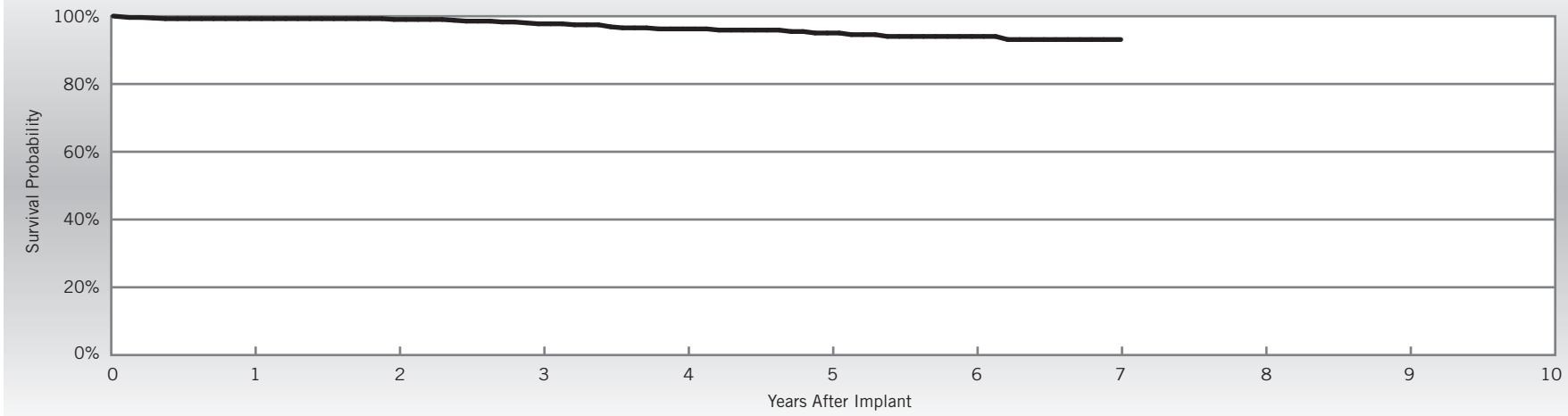
Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	566
Active Devices Enrolled in Study	220
Cumulative Months of Follow-up	26,597
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Conductor Fracture	2	0.35%
Failure to Capture	1	0.18%
Insulation Breach	9	1.59%
Lead Dislodgement	2	0.35%
Oversensing	6	1.06%
Skin Erosion	1	0.18%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	17	3.00%
Lead-to-Can Contact	5	0.88%
Lead-to-Lead Contact	5	0.88%
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	6	1.06%
Total	**23**	**4.06%**



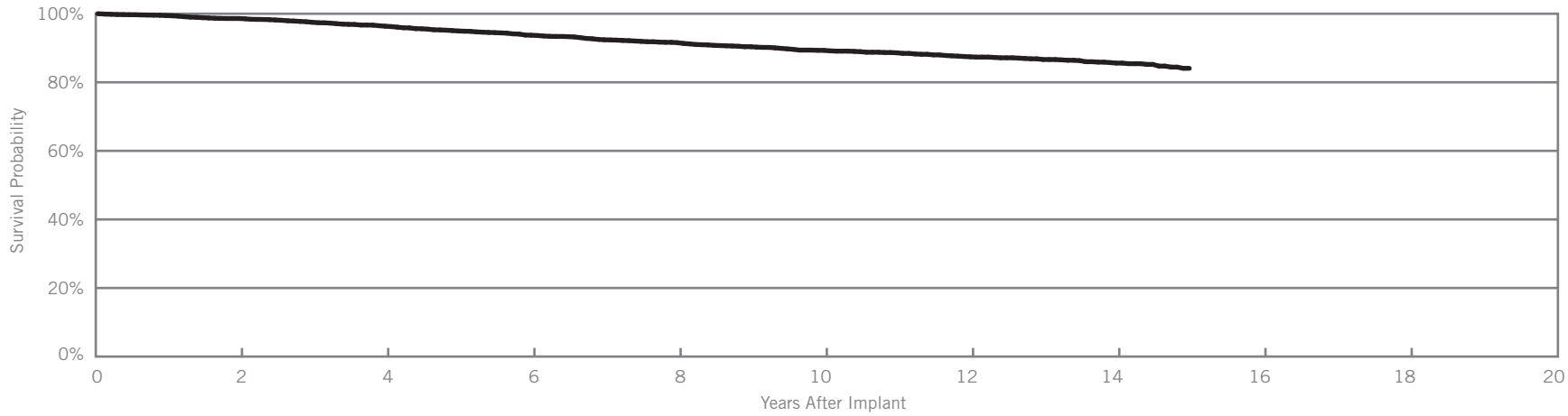
Year	1	2	3	4	5	6	7			
Survival Probability	99.28%	99.05%	97.76%	96.26%	95.05%	94.04%	93.12%			
± 1 standard error	0.36%	0.36%	0.66%	0.97%	1.18%	1.37%	1.64%			
Sample Size	530	470	400	320	250	170	60			

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,559
Estimated Active US Implants	767
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



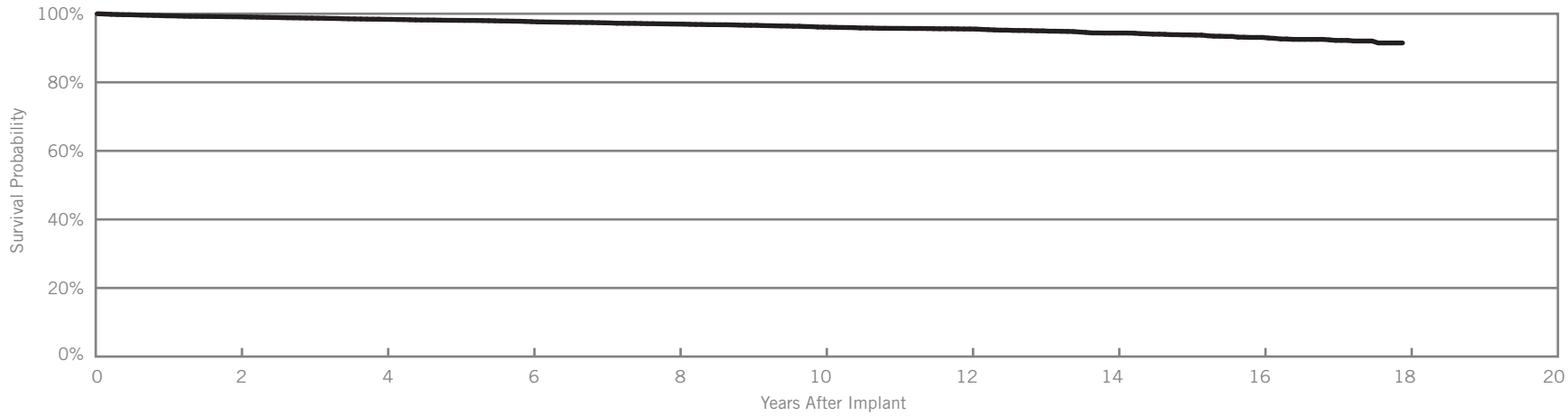
Year	2	4	6	8	10	12	14	at 180 months		
Survival Probability	98.61%	96.36%	93.73%	91.55%	89.32%	87.44%	85.60%	84.08%		
± 1 standard error	0.19%	0.31%	0.44%	0.54%	0.65%	0.75%	0.85%	1.05%		
Sample Size	3,730	2,960	2,290	1,720	1,260	980	700	220		

Customer Reported Performance Data

SPL™

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,373
Estimated Active US Implants	2,339
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	at 215 months	
Survival Probability	99.11%	98.36%	97.69%	96.99%	96.10%	95.56%	94.37%	93.10%	91.49%	
± 1 standard error	0.09%	0.12%	0.15%	0.19%	0.23%	0.26%	0.33%	0.42%	0.68%	
Sample Size	10,400	8,490	6,880	5,450	4,210	3,270	2,560	1,350	200	

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
LDA220Q	Optisure™ DF4	99.18%									
LDA210Q	Optisure™ DF4	98.95%									
7170Q/7171Q	Durata™ DF4	99.14%	98.73%	98.29%	97.68%	97.41%					
7120Q/7121Q	Durata™ DF4	99.23%	99.01%	98.78%	98.43%	98.03%	97.65%				
7122Q	Durata™ DF4	99.25%	99.02%	98.71%	98.27%	97.72%	97.27%				
7120/7121	Durata™	99.42%	99.14%	98.87%	98.51%	98.06%	97.55%	96.81%	96.12%		
7122	Durata™	99.24%	98.85%	98.51%	98.06%	97.28%	96.81%	96.14%			
7070/7071	Riata™ ST Optim™	99.44%	99.21%	98.78%	98.35%	97.23%	96.42%	95.45%	95.10%		
7020/7021	Riata™ ST Optim™	98.99%	98.65%	98.37%	97.91%	97.19%	96.51%	95.56%	94.86%		
7022	Riata™ ST Optim™	99.04%	98.87%	98.60%	97.88%	97.32%	96.71%	95.88%	95.13%		
7010/7011	Riata™ ST	99.60%	99.43%	99.05%	98.77%	97.56%	96.00%	94.18%	91.95%		
7040/7041	Riata™ ST	99.41%	99.11%	98.66%	97.46%	96.29%	94.21%	92.15%	89.62%	86.86%	
7002	Riata™ ST	99.02%	98.51%	97.96%	97.28%	95.95%	93.28%	91.25%	88.21%		
7000/7001	Riata™ ST	99.34%	98.99%	98.49%	97.89%	96.81%	94.88%	92.70%	91.00%	89.13%	
1560/1561	Riata™ i	99.78%	99.41%	99.00%	98.71%	98.21%	97.48%	95.88%	93.73%	90.30%	
1590/1591	Riata™ i	99.61%	99.31%	99.08%	98.79%	98.03%	97.00%	94.78%	92.54%	90.79%	89.25%
1582	Riata™	98.95%	98.26%	97.06%	95.73%	94.12%	91.81%	87.76%	83.72%	79.63%	76.12%
1570/1571	Riata™	99.65%	99.34%	98.99%	98.26%	97.39%	95.88%	93.81%	92.00%	89.77%	86.39%
1580/1581	Riata™	99.40%	99.07%	98.54%	97.93%	97.10%	95.77%	93.68%	90.97%	87.88%	84.81%
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%	98.07%	97.69%	97.34%	96.99%	96.63%	96.10%

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		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	
LDA220Q	Feb-14	3,297	2,962	4	0.12%	0	0.00%	10	0.30%	7	0.21%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.06%	1	0.03%	2	0.06%	**27**	**0.82%**	**10**
LDA210Q	Feb-14	8,132	7,552	9	0.11%	0	0.00%	19	0.23%	10	0.12%	4	0.05%	6	0.07%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	5	0.06%	**55**	**0.68%**	**12**
7170Q/7171Q	Jul-09	5,159	3,438	6	0.12%	1	0.02%	11	0.21%	8	0.16%	3	0.06%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	**31**	**0.60%**	**13**
7120Q/7121Q	Jan-09	112,642	74,227	70	0.06%	1	<0.01%	195	0.17%	86	0.08%	39	0.03%	12	0.01%	0	0.00%	5	<0.01%	8	<0.01%	3	<0.01%	31	0.03%	**450**	**0.40%**	**227**
7122Q	Jan-09	59,643	43,746	69	0.12%	2	<0.01%	111	0.19%	51	0.09%	18	0.03%	7	0.01%	0	0.00%	4	<0.01%	5	<0.01%	3	<0.01%	26	0.04%	**296**	**0.50%**	**135**
7120/7121	Sep-07	59,218	30,907	39	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%	**225**	**0.38%**	**91**
7122	Sep-07	13,785	8,077	10	0.07%	1	<0.01%	18	0.13%	15	0.11%	10	0.07%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	1	<0.01%	4	0.03%	**62**	**0.45%**	**30**
7070/7071	Jul-06	3,311	1,570	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	14,236	6,042	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	1,468	664	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.68%**	**3**
7010/7011	Mar-06	2,199	868	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	4,054	1,595	4	0.10%	0	0.00%	5	0.12%	0	0.00%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**15**	**0.37%**	**3**
7002	Jun-05	2,405	911	6	0.25%	0	0.00%	2	0.08%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	**20**	**0.83%**	**11**
7000/7001	Jun-05	34,864	12,963	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%**	**96**

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	
LDA220Q	Feb-14	3,297	2,962	3	0.09%	0	0.00%	14	0.42%	7	0.21%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**26**	**0.79%**	**9**
LDA210Q	Feb-14	8,132	7,552	5	0.06%	0	0.00%	37	0.45%	13	0.16%	8	0.10%	3	0.04%	0	0.00%	1	0.01%	3	0.04%	0	0.00%	4	0.05%	**74**	**0.91%**	**29**
7170Q/7171Q	Jul-09	5,159	3,438	4	0.08%	5	0.10%	18	0.35%	30	0.58%	20	0.39%	0	0.00%	2	0.04%	8	0.16%	6	0.12%	0	0.00%	0	0.00%	**93**	**1.80%**	**31**
7120Q/7121Q	Jan-09	112,642	74,227	31	0.03%	65	0.06%	468	0.42%	364	0.32%	302	0.27%	50	0.04%	16	0.01%	55	0.05%	156	0.14%	5	<0.01%	46	0.04%	**1558**	**1.38%**	**692**
7122Q	Jan-09	59,643	43,746	30	0.05%	23	0.04%	225	0.38%	134	0.22%	127	0.21%	24	0.04%	8	0.01%	27	0.05%	41	0.07%	8	0.01%	22	0.04%	**669**	**1.12%**	**321**
7120/7121	Sep-07	59,218	30,907	15	0.03%	101	0.17%	173	0.29%	218	0.37%	398	0.67%	53	0.09%	39	0.07%	124	0.21%	175	0.30%	1	<0.01%	32	0.05%	**1329**	**2.24%**	**413**
7122	Sep-07	13,785	8,077	2	0.01%	21	0.15%	49	0.36%	49	0.36%	76	0.55%	8	0.06%	19	0.14%	28	0.20%	20	0.15%	2	0.01%	6	0.04%	**280**	**2.03%**	**141**
7070/7071	Jul-06	3,311	1,570	2	0.06%	15	0.45%	12	0.36%	23	0.69%	37	1.12%	2	0.06%	4	0.12%	10	0.30%	10	0.30%	1	0.03%	2	0.06%	**118**	**3.56%**	**26**
7020/7021	Jul-06	14,236	6,042	16	0.11%	48	0.34%	63	0.44%	122	0.86%	179	1.26%	16	0.11%	22	0.15%	31	0.22%	66	0.46%	2	0.01%	26	0.18%	**591**	**4.15%**	**174**
7022	Jul-06	1,468	664	2	0.14%	7	0.48%	10	0.68%	8	0.54%	15	1.02%	1	0.07%	5	0.34%	2	0.14%	2	0.14%	1	0.07%	1	0.07%	**54**	**3.68%**	**18**
7010/7011	Mar-06	2,199	868	3	0.14%	4	0.18%	8	0.36%	6	0.27%	34	1.55%	3	0.14%	38	1.73%	18	0.82%	14	0.64%	0	0.00%	2	0.09%	**130**	**5.91%**	**30**
7040/7041	Mar-06	4,054	1,595	3	0.07%	29	0.72%	6	0.15%	42	1.04%	82	2.02%	14	0.35%	50	1.23%	14	0.35%	19	0.47%	0	0.00%	6	0.15%	**265**	**6.54%**	**57**
7002	Jun-05	2,405	911	5	0.21%	9	0.37%	9	0.37%	17	0.71%	54	2.25%	2	0.08%	60	2.49%	3	0.12%	6	0.25%	0	0.00%	6	0.25%	**171**	**7.11%**	**63**
7000/7001	Jun-05	34,864	12,963	29	0.08%	126	0.36%	57	0.16%	271	0.78%	708	2.03%	61	0.17%	632	1.81%	97	0.28%	156	0.45%	4	0.01%	86	0.25%	**2227**	**6.39%**	**617**

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
LDA220Q	3,297	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%	**0**	**0.00%**	0	0.00%	0	0.00%	9	0.27%	**9**	**0.27%**
LDA210Q	8,132	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%	30	0.37%	**30**	**0.37%**
7170Q/7171Q	5,159	3.40%	0	0.00%	0	0.00%	1	0.02%	**1**	**0.02%**	3	0.06%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.08%**	0	0.00%	0	0.00%	29	0.56%	**34**	**0.66%**
7120Q/7121Q	112,642	3.50%	2	<0.01%	5	<0.01%	14	0.01%	**21**	**0.02%**	45	0.04%	9	<0.01%	16	0.01%	0	0.00%	27	0.02%	**97**	**0.09%**	2	<0.01%	32	0.03%	618	0.55%	**770**	**0.68%**
7122Q	59,643	3.20%	0	0.00%	6	0.01%	2	<0.01%	**8**	**0.01%**	21	0.04%	5	<0.01%	5	<0.01%	0	0.00%	7	0.01%	**38**	**0.06%**	0	0.00%	11	0.02%	302	0.51%	**359**	**0.60%**
7120/7121	59,218	4.50%	2	<0.01%	20	0.03%	8	0.01%	**30**	**0.05%**	47	0.08%	20	0.03%	12	0.02%	0	0.00%	17	0.03%	**96**	**0.16%**	1	<0.01%	9	0.02%	345	0.58%	**481**	**0.81%**
7122	13,785	5.50%	0	0.00%	12	0.09%	3	0.02%	**15**	**0.11%**	23	0.17%	11	0.08%	0	0.00%	1	<0.01%	5	0.04%	**40**	**0.29%**	0	0.00%	4	0.03%	107	0.78%	**166**	**1.20%**
7070/7071	3,311	6.60%	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	14,236	6.00%	1	<0.01%	2	0.01%	5	0.04%	**8**	**0.06%**	12	0.08%	4	0.03%	4	0.03%	0	0.00%	12	0.08%	**32**	**0.22%**	0	0.00%	0	0.00%	158	1.11%	**198**	**1.39%**
7022	1,468	8.70%	0	0.00%	2	0.14%	1	0.07%	**3**	**0.20%**	4	0.27%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**5**	**0.34%**	0	0.00%	0	0.00%	16	1.09%	**24**	**1.63%**
7010/7011	2,199	7.40%	0	0.00%	2	0.09%	0	0.00%	**2**	**0.09%**	9	0.41%	16	0.73%	1	0.05%	2	0.09%	4	0.18%	**32**	**1.46%**	0	0.00%	0	0.00%	9	0.41%	**43**	**1.96%**
7040/7041	4,054	7.10%	0	0.00%	1	0.02%	3	0.07%	**4**	**0.10%**	20	0.49%	13	0.32%	0	0.00%	2	0.05%	9	0.22%	**44**	**1.09%**	0	0.00%	0	0.00%	26	0.64%	**74**	**1.83%**
7002	2,405	8.10%	0	0.00%	2	0.08%	3	0.12%	**5**	**0.21%**	29	1.21%	13	0.54%	0	0.00%	5	0.21%	10	0.42%	**57**	**2.37%**	0	0.00%	0	0.00%	22	0.91%	**84**	**3.49%**
7000/7001	34,864	6.50%	4	0.01%	7	0.02%	12	0.03%	**23**	**0.07%**	264	0.76%	132	0.38%	10	0.03%	30	0.09%	63	0.18%	**499**	**1.43%**	1	<0.01%	1	<0.01%	271	0.78%	**795**	**2.28%**
1560/1561	981	8.70%	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	9,697	6.40%	1	0.01%	1	0.01%	5	0.05%	**7**	**0.07%**	55	0.57%	45	0.46%	2	0.02%	17	0.18%	28	0.29%	**147**	**1.52%**	0	0.00%	1	0.01%	49	0.51%	**204**	**2.10%**
1582	3,129	10.10%	0	0.00%	0	0.00%	3	0.10%	**3**	**0.10%**	47	1.50%	27	0.86%	2	0.06%	45	1.44%	29	0.93%	**150**	**4.79%**	0	0.00%	0	0.00%	34	1.09%	**187**	**5.98%**
1570/1571	10,278	7.30%	2	0.02%	3	0.03%	0	0.00%	**5**	**0.05%**	94	0.91%	33	0.32%	1	<0.01%	36	0.35%	27	0.26%	**191**	**1.86%**	0	0.00%	0	0.00%	52	0.51%	**248**	**2.41%**
1580/1581	68,383	7.20%	4	<0.01%	11	0.02%	15	0.02%	**30**	**0.04%**	609	0.89%	306	0.45%	17	0.02%	309	0.45%	259	0.38%	**1500**	**2.19%**	3	<0.01%	0	0.00%	497	0.73%	**2030**	**2.97%**

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	5,002	1.4%	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	0.02%	15	0.30%	**16**	**0.32%**
LDA210Q	13,927	1.6%	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%	5	0.04%	57	0.41%	**63**	**0.45%**
7170Q/7171Q	15,802	2.1%	0	0.00%	2	0.01%	4	0.03%	**6**	**0.04%**	6	0.04%	1	0.01%	3	0.02%	0	0.00%	2	0.01%	**12**	**0.08%**	7	0.04%	0	0.00%	55	0.35%	**80**	**0.51%**
7120Q/7121Q	187,663	2.8%	6	<0.01%	16	0.01%	22	0.01%	**44**	**0.02%**	64	0.03%	12	0.01%	29	0.02%	0	0.00%	33	0.02%	**138**	**0.07%**	3	<0.01%	128	0.07%	987	0.53%	**1300**	**0.69%**
7122Q	154,167	2.2%	2	<0.01%	21	0.01%	6	<0.01%	**29**	**0.02%**	59	0.04%	7	<0.01%	17	0.01%	0	0.00%	13	0.01%	**96**	**0.06%**	2	<0.01%	197	0.13%	735	0.48%	**1059**	**0.69%**
7120/7121	136,543	2.7%	7	0.01%	81	0.06%	21	0.02%	**109**	**0.08%**	89	0.07%	27	0.02%	20	0.01%	0	0.00%	32	0.02%	**168**	**0.12%**	2	<0.01%	51	0.04%	657	0.48%	**987**	**0.72%**
7122	57,548	2.7%	2	<0.01%	82	0.14%	8	0.01%	**92**	**0.16%**	63	0.11%	17	0.03%	6	0.01%	1	<0.01%	12	0.02%	**99**	**0.17%**	1	<0.01%	39	0.07%	361	0.63%	**592**	**1.03%**

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	63	5,066	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	4,301	2,378	180,394	4	0.09%	2	0.05%	1	0.02%	10	0.23%	0	0.00%	7	0.16%	4	0.09%	4	0.09%	1	0.02%	38	0.88%	5	0.12%	0	0.00%	0	0.00%	**76**	**1.77%**
7122Q	1,515	953	54,545	1	0.07%	0	0.00%	0	0.00%	3	0.20%	0	0.00%	3	0.20%	0	0.00%	0	0.00%	0	0.00%	7	0.46%	0	0.00%	2	0.13%	0	0.00%	**16**	**1.06%**
7120/7121	3,571	1,499	188,193	1	0.03%	8	0.22%	0	0.00%	11	0.31%	0	0.00%	8	0.22%	2	0.06%	2	0.06%	9	0.25%	20	0.56%	8	0.22%	0	0.00%	0	0.00%	**69**	**1.93%**
7122	447	245	22,530	0	0.00%	2	0.45%	0	0.00%	5	1.12%	0	0.00%	2	0.45%	1	0.22%	0	0.00%	0	0.00%	4	0.89%	3	0.67%	0	0.00%	0	0.00%	**17**	**3.80%**
7070/7071	288	109	15,216	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	1,472	413	79,563	0	0.00%	5	0.34%	0	0.00%	5	0.34%	0	0.00%	6	0.41%	1	0.07%	0	0.00%	2	0.14%	9	0.61%	4	0.27%	0	0.00%	1	0.07%	**33**	**2.24%**
7000/7001	180	44	7,398	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.56%	0	0.00%	0	0.00%	1	0.56%	1	0.56%	0	0.00%	0	0.00%	0	0.00%	**3**	**1.67%**
1580/1581	566	220	26,597	0	0.00%	0	0.00%	0	0.00%	2	0.35%	0	0.00%	1	0.18%	0	0.00%	0	0.00%	9	1.59%	2	0.35%	6	1.06%	0	0.00%	1	0.18%	**21**	**3.71%**

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	4,301	4.60%	1	0.02%	2	0.05%	2	0.05%	**5**	**0.12%**	2	0.05%	1	0.02%	0	0.00%	0	0.00%	1	0.02%	**4**	**0.09%**	0	0.00%	1	0.02%	42	0.98%	**52**	**1.21%**
7122Q	1,515	4.40%	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**	**1.32%**
7120/7121	3,571	3.60%	0	0.00%	1	0.03%	0	0.00%	**1**	**0.03%**	5	0.14%	4	0.11%	0	0.00%	0	0.00%	1	0.03%	**10**	**0.28%**	0	0.00%	1	0.03%	25	0.70%	**37**	**1.04%**
7122	447	4.00%	0	0.00%	1	0.22%	1	0.22%	**2**	**0.45%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	5	1.12%	**7**	**1.57%**
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	1,472	4.70%	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	180	6.10%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	2	1.11%	1	0.56%	0	0.00%	0	0.00%	0	0.00%	**3**	**1.67%**	1	0.56%	0	0.00%	0	0.00%	**4**	**2.22%**
1580/1581	566	5.50%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	5	0.88%	5	0.88%	0	0.00%	6	1.06%	1	0.18%	**17**	**3.00%**	0	0.00%	0	0.00%	6	1.06%	**23**	**4.06%**

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

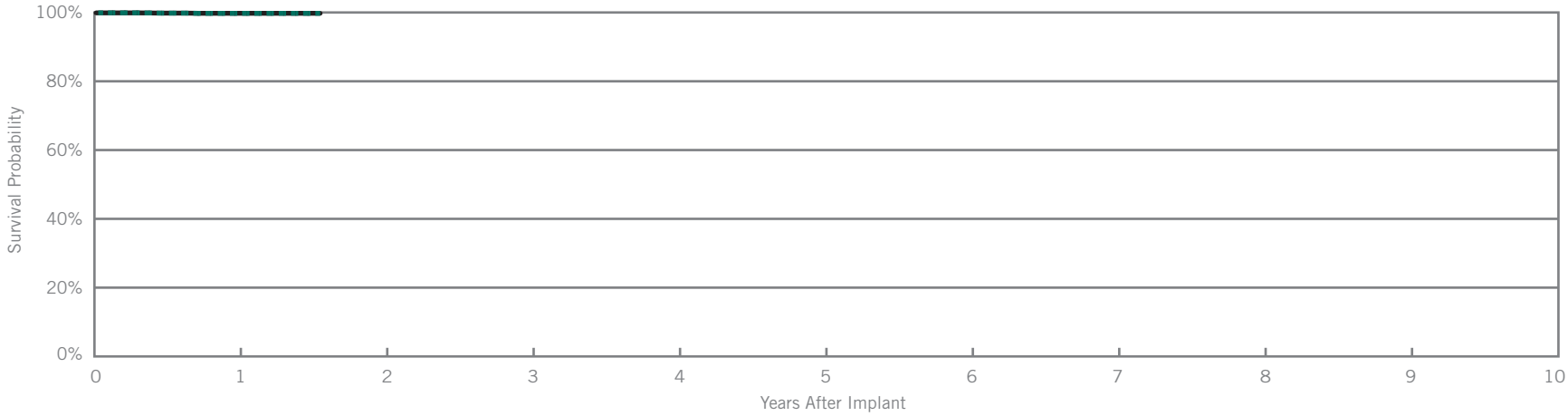
Endurity™ DR

Model PM2160

US Regulatory Approval	March 2014
Registered US Implants	7,024
Estimated Active US Implants	6,326
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	0.07%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**0**	**0.00%**	**6**	**0.09%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.07%	0.07%								
Sample Size	4,990	350								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.07%	0.07%								

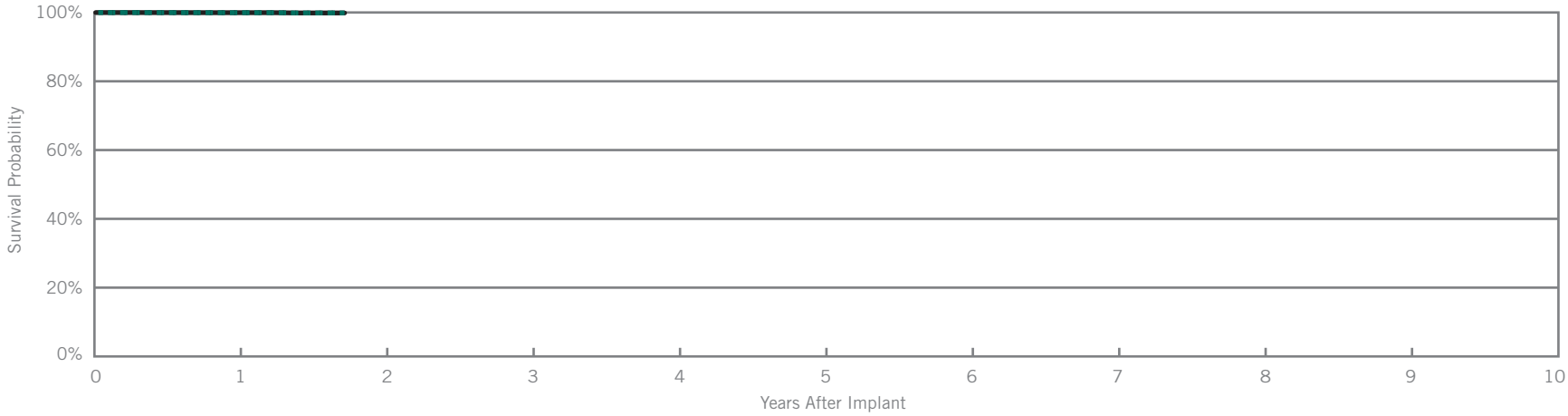
Assurity™ DR RF

Model PM2240

US Regulatory Approval	March 2014
Registered US Implants	82,203
Estimated Active US Implants	76,669
Estimated Longevity	9.4 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%	15	0.02%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	3	<0.01%
Total	**0**	**0.00%**	**18**	**0.02%**



Including Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.94%	99.86%								
± 1 standard error	0.01%	0.04%								
Sample Size	51,210	220								

Excluding Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.94%	99.86%								
± 1 standard error	0.01%	0.04%								

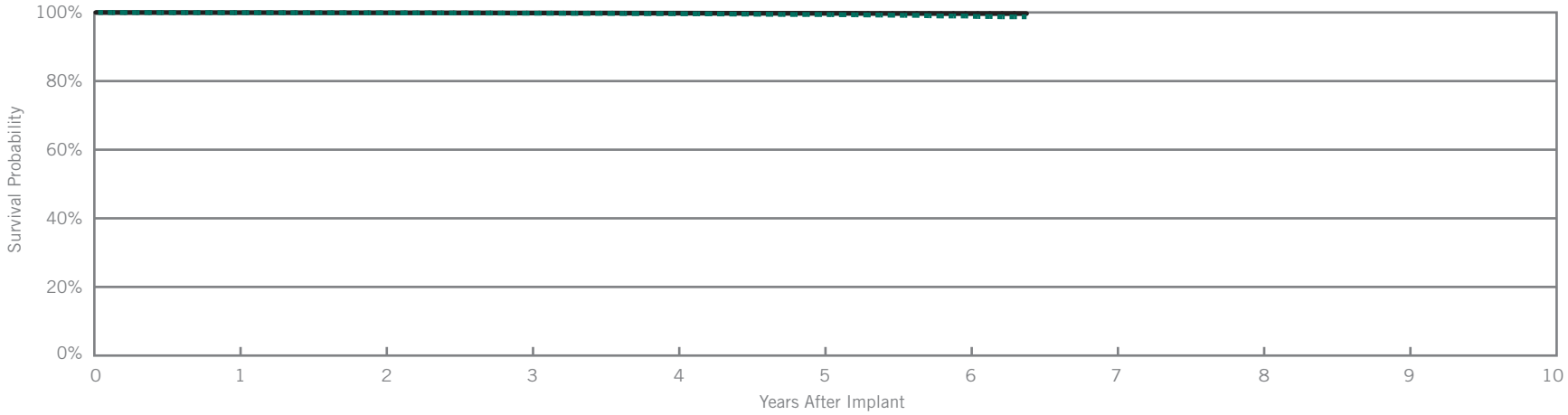
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	242,999
Estimated Active US Implants	158,888
Estimated Longevity	8 Years
Normal Battery Depletion	145
Number of US Advisories (see pgs. 296-300)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	15	<0.01%	33	0.01%
Electrical Interconnect	6	<0.01%	30	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	0	0.00%	10	<0.01%
Possible Early Battery Depletion	7	<0.01%	17	<0.01%
Other	5	<0.01%	31	0.01%
Total	**33**	**0.01%**	**123**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.93%	99.87%	99.78%	99.62%	99.38%	98.96%	98.73%			
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.03%	0.06%	0.09%			
Sample Size	227,220	188,030	138,150	90,130	50,900	19,680	780			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.94%	99.90%	99.84%	99.79%	99.74%	99.68%	99.68%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%			

Actively Monitored Study Data

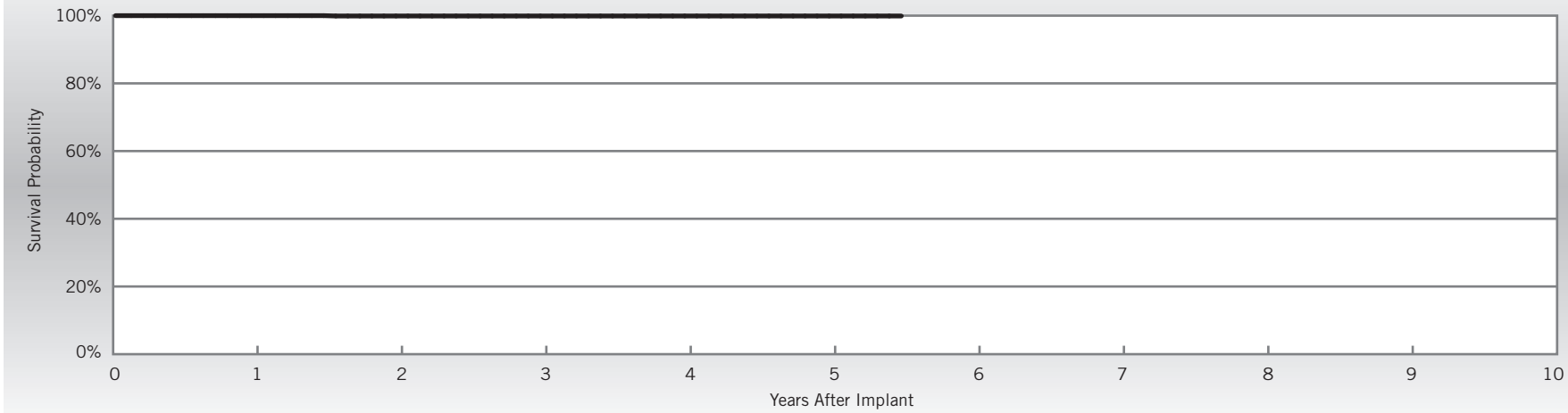
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,773
Active Devices Enrolled in Study	418
Cumulative Months of Follow-up	47,446
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	at 66 months				
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	660	470	290	60				

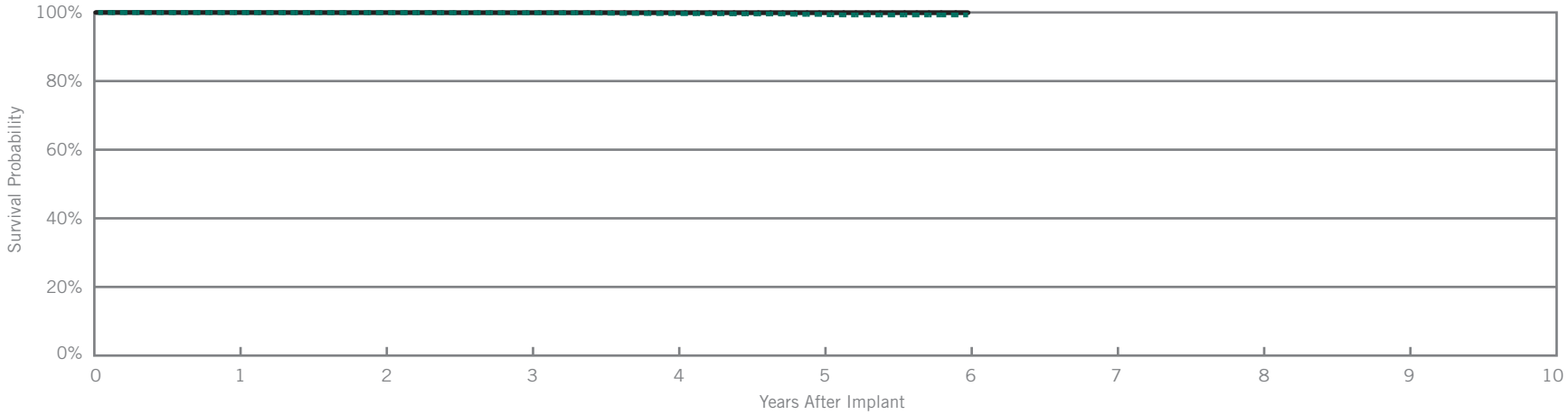
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	48,889
Estimated Active US Implants	32,703
Estimated Longevity	9.2 Years
Normal Battery Depletion	32
Number of US Advisories (see pgs. 296-300)	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%	3	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**3**	**<0.01%**	**10**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.97%	99.93%	99.87%	99.67%	99.44%	99.27%				
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.07%	0.09%				
Sample Size	45,750	38,030	27,980	17,700	8,730	240				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.97%	99.95%	99.93%	99.93%	99.93%	99.93%				
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%				

Actively Monitored Study Data

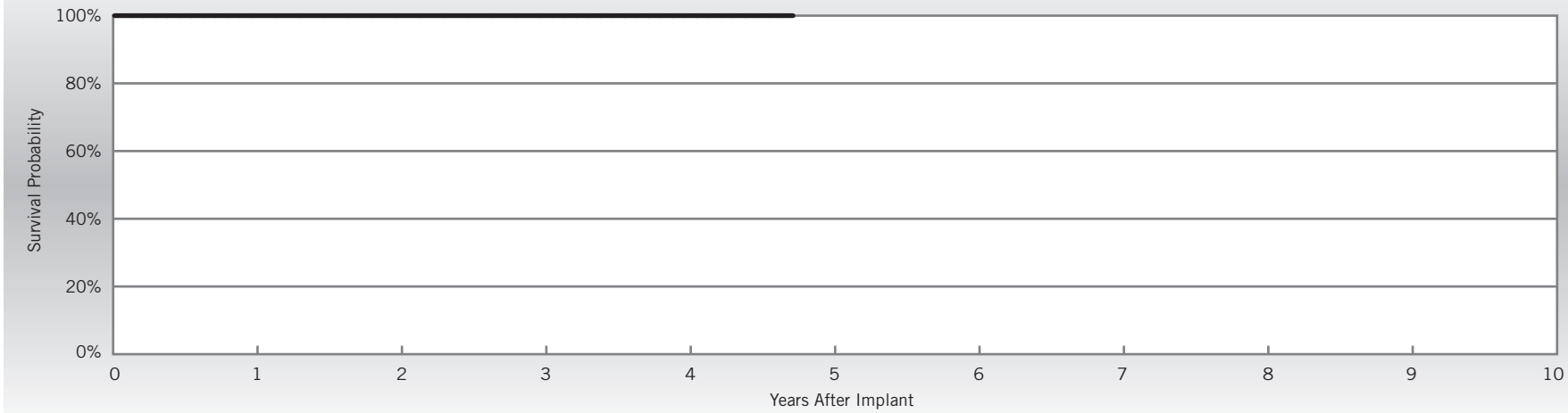
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	226
Active Devices Enrolled in Study	79
Cumulative Months of Follow-up	7,413
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	at 57 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	210	150	100	90	60					

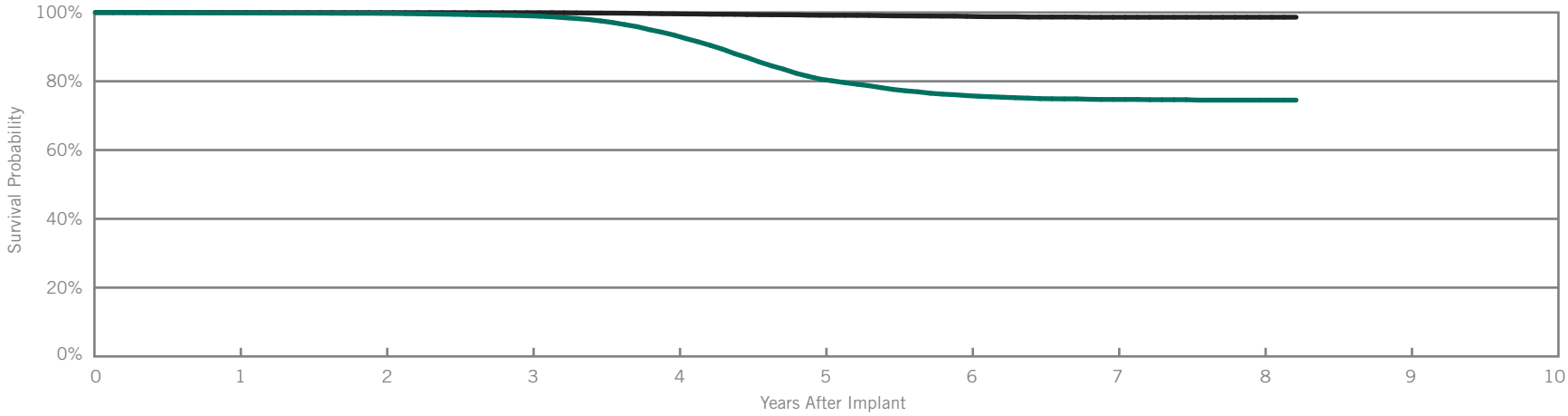
Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	52,880
Estimated Active US Implants	22,993
Estimated Longevity	6.5 Years
Normal Battery Depletion	1,934
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%	47	0.09%
Total	**2**	**<0.01%**	**93**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.85%	99.75%	99.04%	93.43%	80.61%	75.83%	74.71%	74.51%	74.51%
± 1 standard error	0.02%	0.02%	0.05%	0.14%	0.26%	0.31%	0.34%	0.35%	0.35%
Sample Size	48,480	40,390	33,080	25,580	17,570	10,300	4,860	1,480	250

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.97%	99.96%	99.93%	99.62%	99.19%	98.87%	98.62%	98.62%	98.62%
± 1 standard error	0.01%	0.01%	0.01%	0.04%	0.06%	0.08%	0.11%	0.11%	0.11%

Actively Monitored Study Data

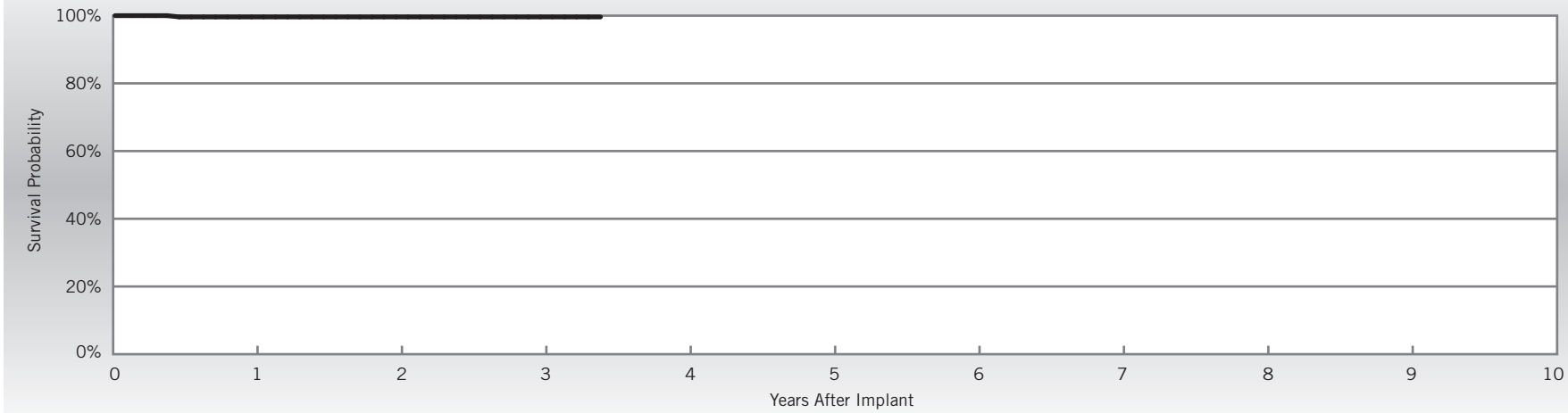
Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	283
Active Devices Enrolled in Study	19
Cumulative Months of Follow-up	7,659
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						

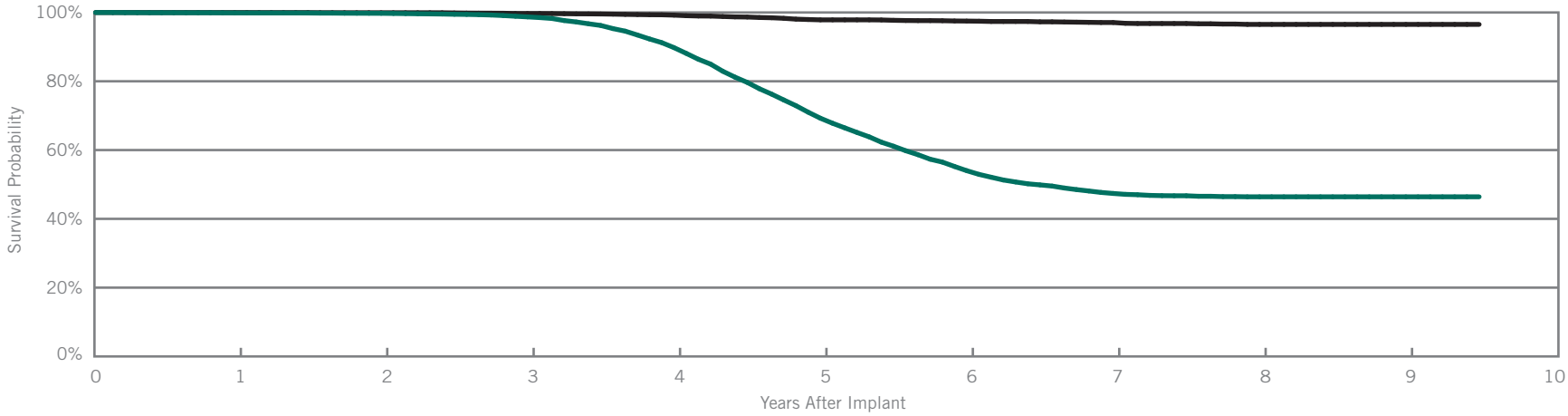
Victory™ DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,306
Estimated Active US Implants	3,722
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,761
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%	28	0.11%
Total	**1**	**<0.01%**	**144**	**0.55%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.87%	99.75%	98.71%	89.78%	69.26%	54.00%	47.38%	46.41%	46.41%	46.41%
± 1 standard error	0.02%	0.03%	0.08%	0.22%	0.37%	0.42%	0.45%	0.46%	0.46%	0.46%
Sample Size	24,460	21,230	18,520	15,490	11,690	7,840	4,750	2,680	1,280	210

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.98%	99.93%	99.70%	99.22%	97.85%	97.50%	97.08%	96.53%	96.53%	96.53%
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.12%	0.14%	0.17%	0.22%	0.22%	0.22%

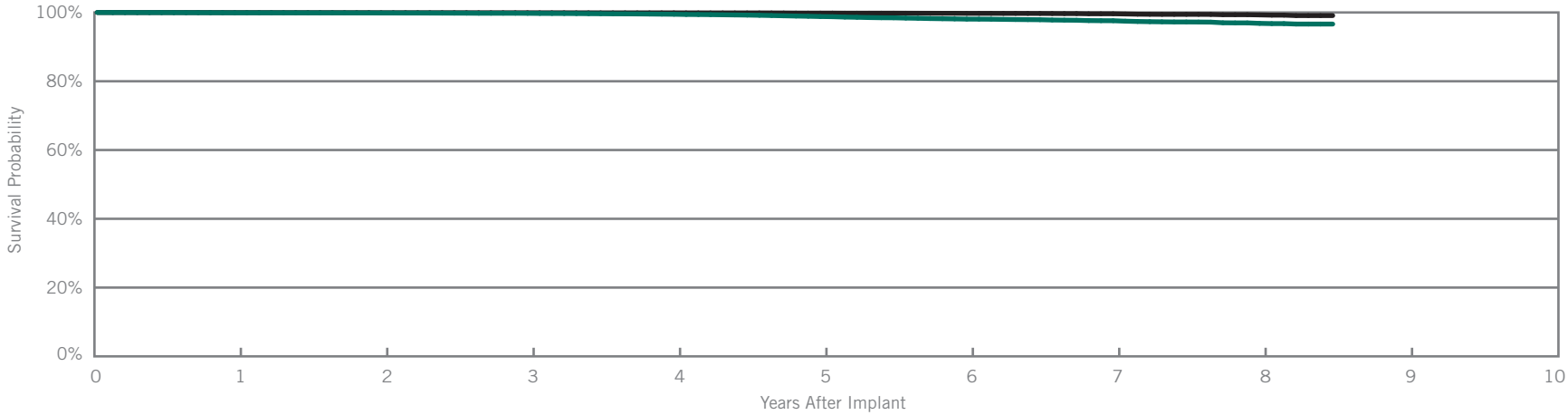
Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	112,010
Estimated Active US Implants	49,181
Estimated Longevity	11.7 Years
Normal Battery Depletion	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	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%	66	0.06%
Total	**6**	**<0.01%**	**105**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.91%	99.84%	99.75%	99.48%	98.82%	98.07%	97.60%	96.83%	96.63%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.04%	0.06%	0.07%	0.10%	0.16%
Sample Size	104,810	91,540	80,120	69,980	60,280	49,410	31,420	11,230	460

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.96%	99.93%	99.92%	99.89%	99.82%	99.74%	99.62%	99.29%	99.09%
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.06%	0.13%

Actively Monitored Study Data

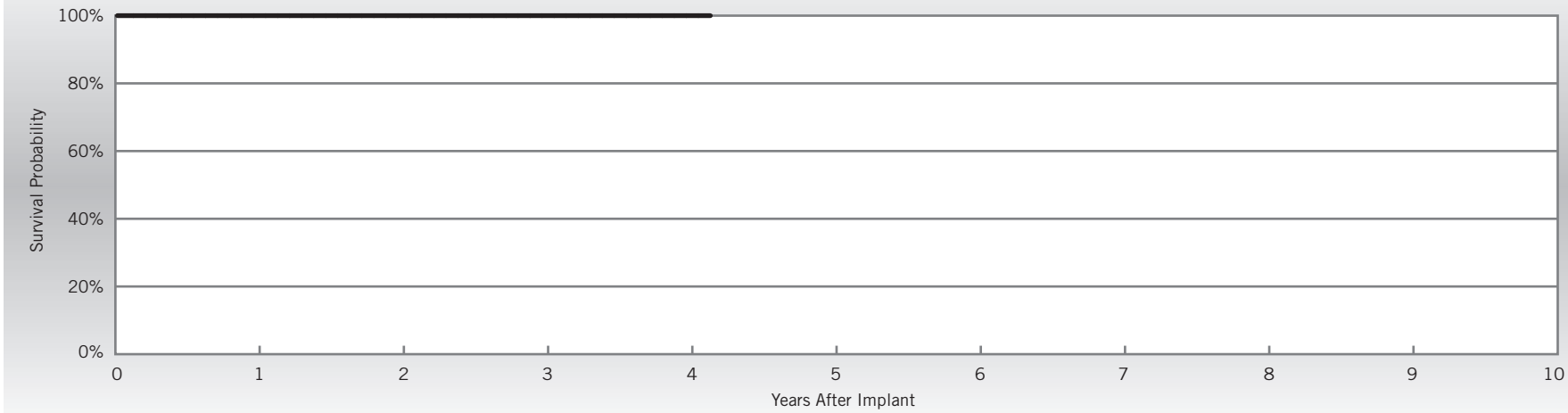
Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,517
Active Devices Enrolled in Study	22
Cumulative Months of Follow-up	47,564
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 50 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	50					

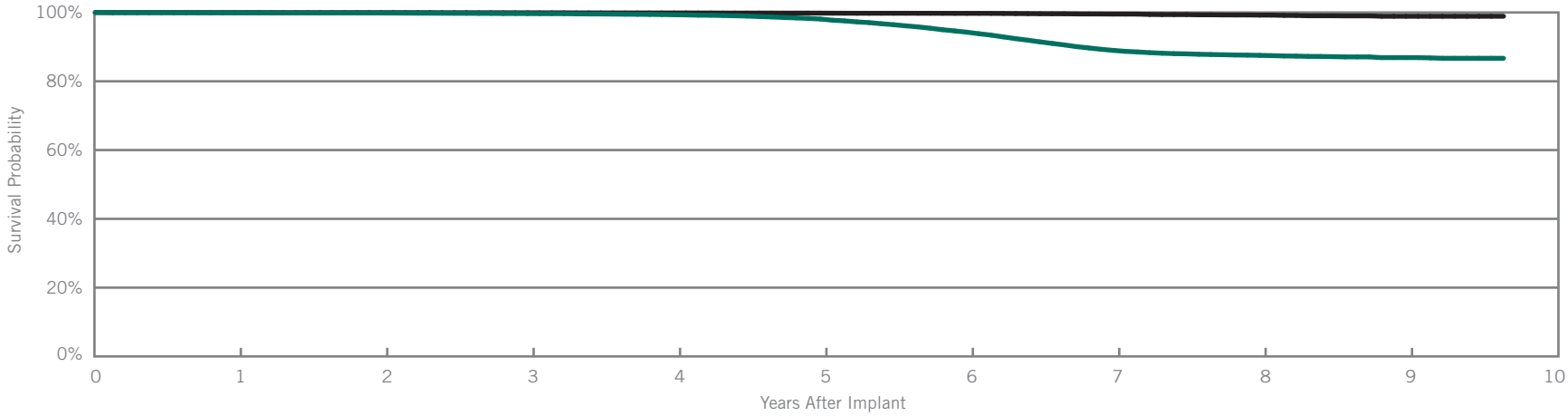
Victory™ XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,639
Estimated Active US Implants	17,526
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,450
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%	6	<0.01%
Mechanical	0	0.00%	7	0.01%
Possible Early Battery Depletion	0	0.00%	5	<0.01%
Other	1	<0.01%	57	0.09%
Total	**3**	**<0.01%**	**100**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.91%	99.84%	99.67%	99.34%	98.09%	94.27%	88.98%	87.53%	86.87%	86.68%
± 1 standard error	0.01%	0.02%	0.02%	0.04%	0.07%	0.12%	0.17%	0.19%	0.21%	0.23%
Sample Size	58,950	52,280	46,550	41,370	36,830	32,160	25,280	16,300	7,150	330

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.97%	99.95%	99.91%	99.86%	99.81%	99.74%	99.53%	99.23%	98.90%	98.90%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.05%	0.09%	0.09%

Actively Monitored Study Data

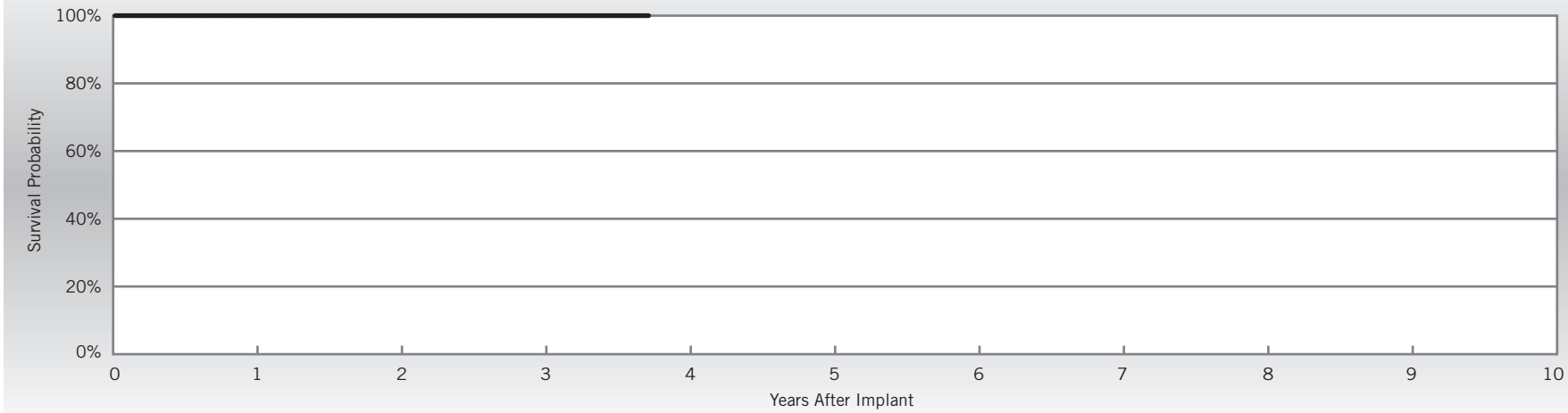
Victory™ XL DR

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	10,627
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%**



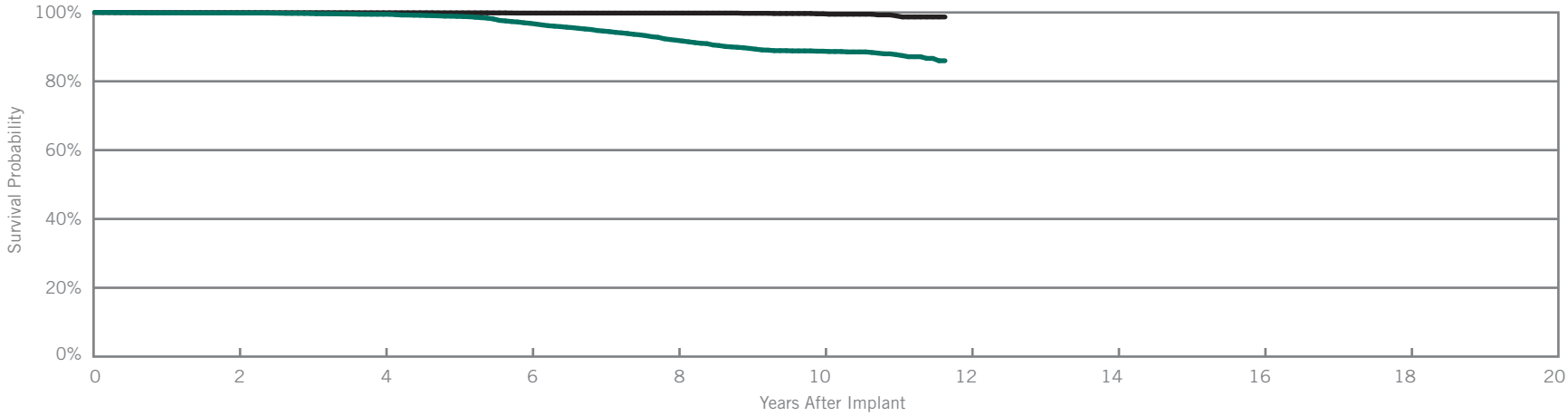
Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	280	200	50						

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	17,297
Estimated Active US Implants	4,876
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%	5	0.03%
Total	**1**	**<0.01%**	**16**	**0.09%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 140 months				
Survival Probability	99.83%	99.47%	96.85%	91.92%	88.74%	85.97%				
± 1 standard error	0.03%	0.06%	0.18%	0.31%	0.41%	0.82%				
Sample Size	14,200	10,960	8,140	5,740	2,650	230				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 140 months				
Survival Probability	99.95%	99.91%	99.82%	99.82%	99.60%	98.69%				
± 1 standard error	0.02%	0.03%	0.04%	0.04%	0.10%	0.35%				

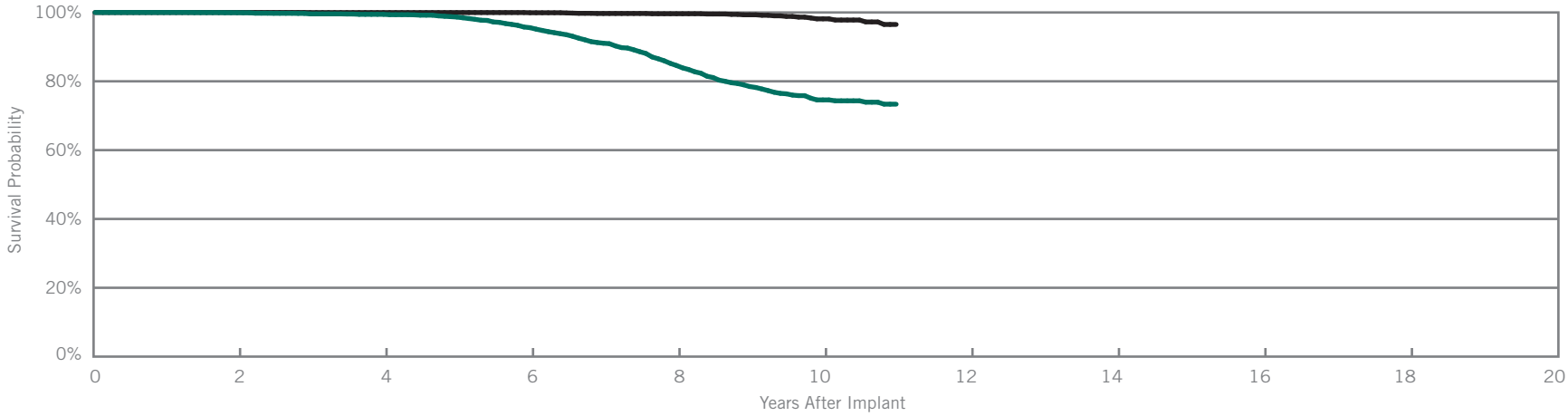
Integrity™ ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,075
Estimated Active US Implants	1,749
Estimated Longevity	6.9 Years
Normal Battery Depletion	317
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%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	10	0.12%
Total	**0**	**0.00%**	**19**	**0.24%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 132 months				
Survival Probability	99.94%	99.45%	95.58%	84.59%	74.59%	73.35%				
± 1 standard error	0.03%	0.10%	0.30%	0.57%	0.85%	0.99%				
Sample Size	6,820	5,420	4,250	3,100	1,090	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 132 months				
Survival Probability	100.00%	99.97%	99.92%	99.63%	98.14%	96.51%				
± 1 standard error	0.00%	0.02%	0.02%	0.10%	0.38%	0.79%				

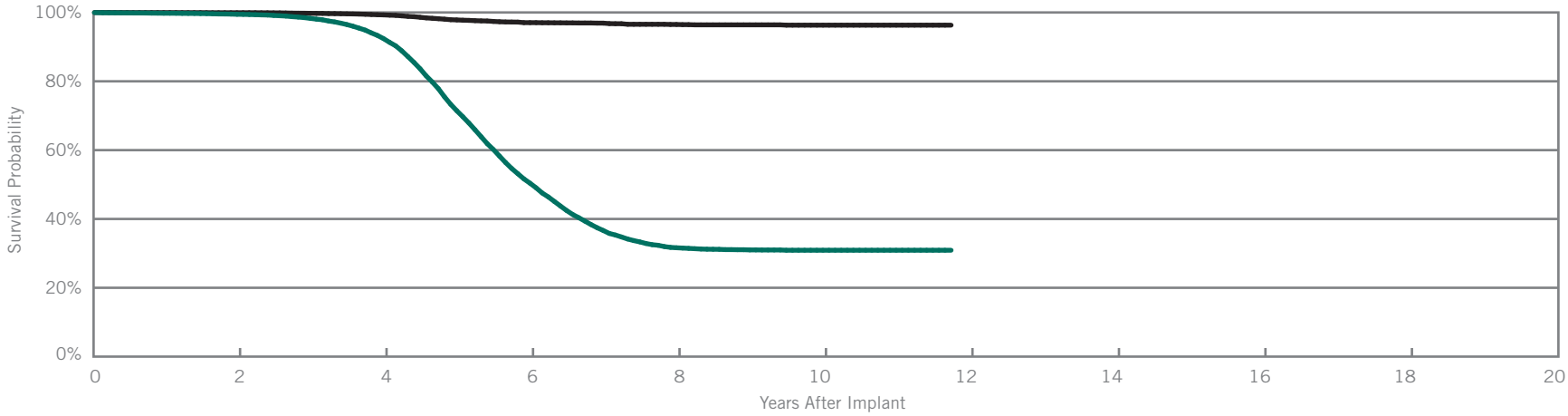
Identity ADx™ DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	54,043
Estimated Active US Implants	3,885
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,196
Number of US Advisories (see pgs. 296-300)	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%	15	0.03%
Total	**5**	**<0.01%**	**296**	**0.55%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 141 months				
Survival Probability	99.46%	92.40%	50.39%	31.63%	30.91%	30.91%				
± 1 standard error	0.03%	0.13%	0.32%	0.34%	0.35%	0.35%				
Sample Size	44,210	32,530	13,860	4,570	2,050	220				

Excluding Normal Battery Depletion

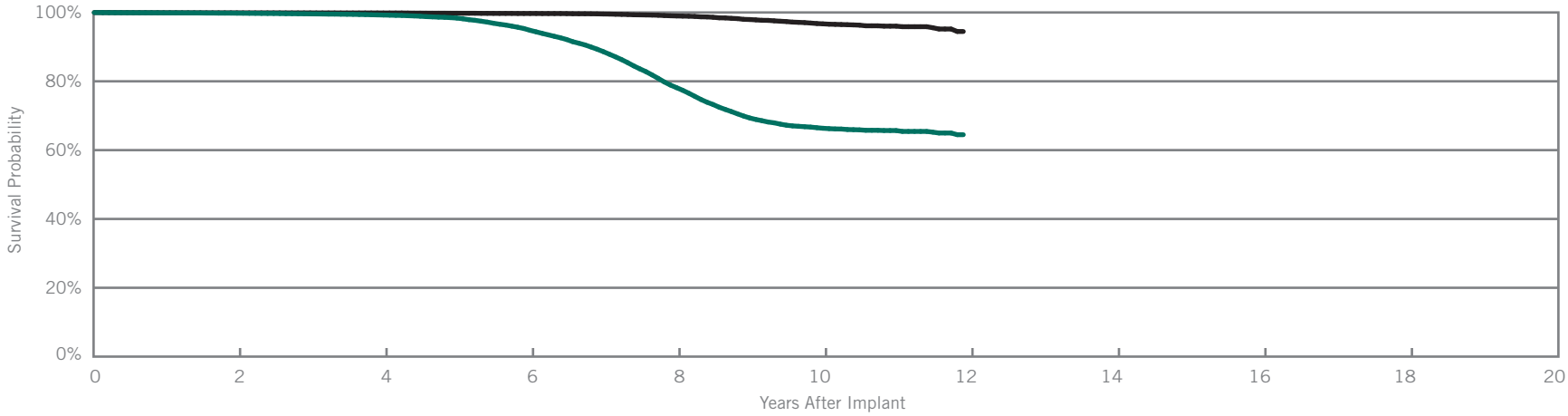
Year	2	4	6	8	10	at 141 months				
Survival Probability	99.93%	99.29%	97.04%	96.51%	96.31%	96.31%				
± 1 standard error	0.01%	0.04%	0.12%	0.15%	0.17%	0.17%				

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

US Regulatory Approval	March 2003
Registered US Implants	67,331
Estimated Active US Implants	13,766
Estimated Longevity	6.9 Years
Normal Battery Depletion	3,265
Number of US Advisories (see pgs. 296-300)	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%	83	0.12%
Total	**2**	**<0.01%**	**239**	**0.35%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 143 months				
Survival Probability	99.78%	99.25%	94.81%	78.16%	66.35%	64.48%				
± 1 standard error	0.02%	0.04%	0.11%	0.24%	0.32%	0.55%				
Sample Size	56,570	44,850	33,770	21,920	7,800	240				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 143 months				
Survival Probability	99.90%	99.85%	99.70%	98.98%	96.69%	94.47%				
± 1 standard error	0.01%	0.02%	0.03%	0.06%	0.16%	0.66%				

Actively Monitored Study Data

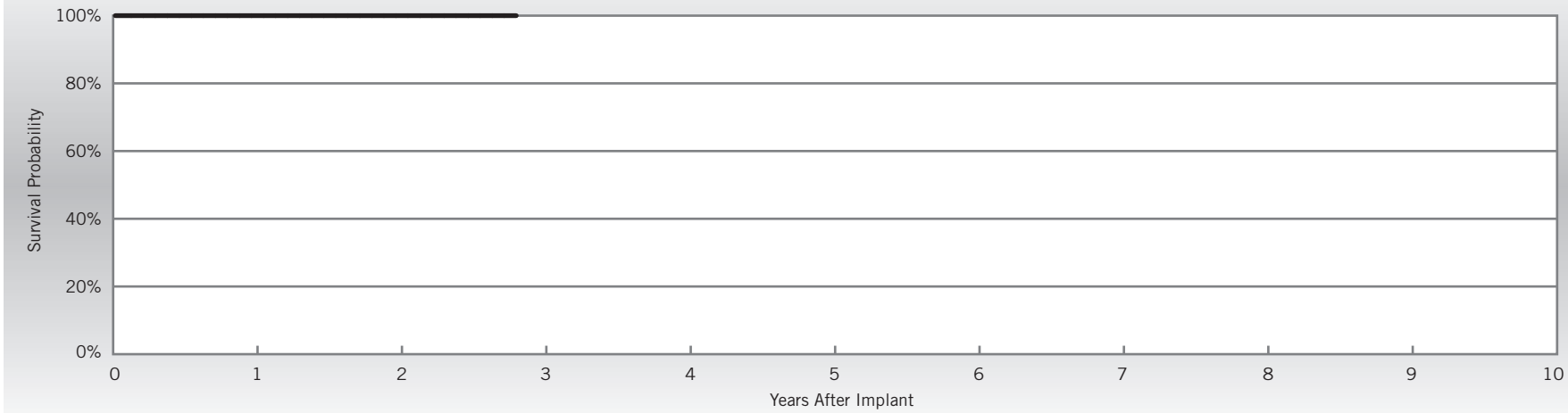
Identity ADx™ XL DR

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							

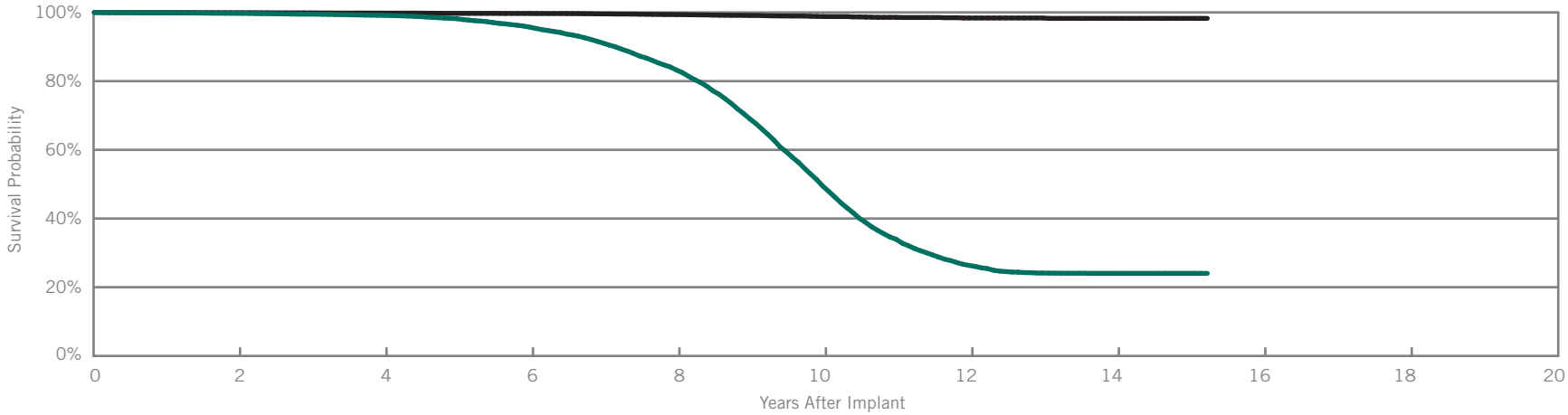
Integrity™ AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,441
Estimated Active US Implants	1,961
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 183 months		
Survival Probability	99.73%	99.14%	95.70%	83.23%	49.40%	26.34%	24.04%	24.04%		
± 1 standard error	0.02%	0.05%	0.11%	0.25%	0.40%	0.39%	0.39%	0.39%		
Sample Size	40,340	33,110	25,740	17,210	8,340	3,340	1,440	240		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 183 months		
Survival Probability	99.92%	99.81%	99.70%	99.36%	98.82%	98.38%	98.27%	98.27%		
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.09%	0.14%	0.16%	0.16%		

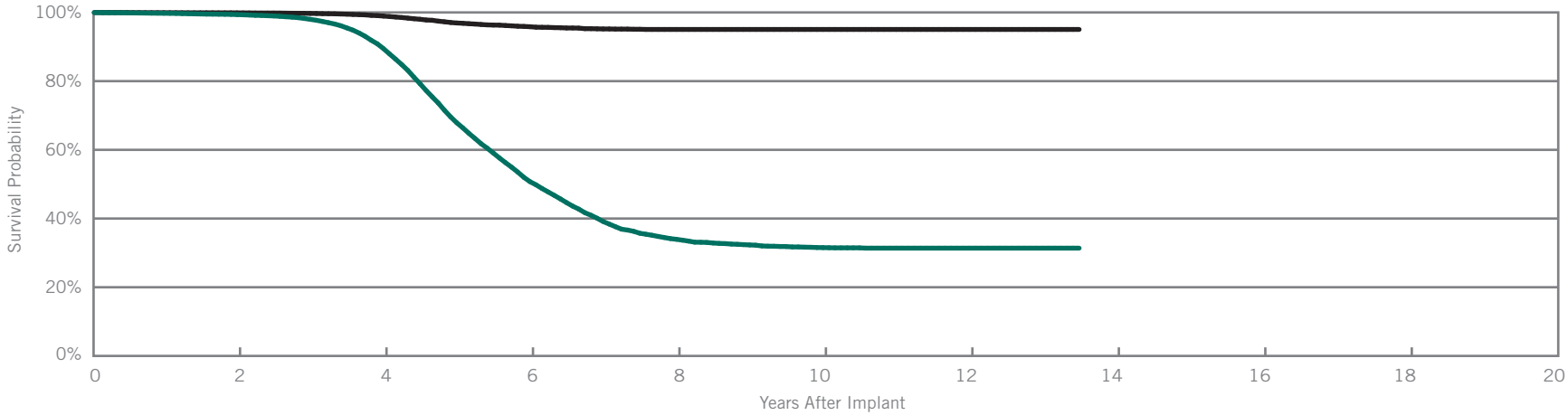
Identity™

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,365
Estimated Active US Implants	2,258
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,068
Number of US Advisories (see pgs. 296-300)	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	at 162 months			
Survival Probability	99.37%	89.46%	50.74%	33.95%	31.53%	31.38%	31.38%			
± 1 standard error	0.03%	0.15%	0.32%	0.37%	0.38%	0.38%	0.38%			
Sample Size	48,150	35,200	12,640	4,050	2,360	1,400	230			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 162 months			
Survival Probability	99.88%	98.94%	95.84%	95.05%	95.05%	95.05%	95.05%			
± 1 standard error	0.01%	0.05%	0.14%	0.18%	0.18%	0.18%	0.18%			

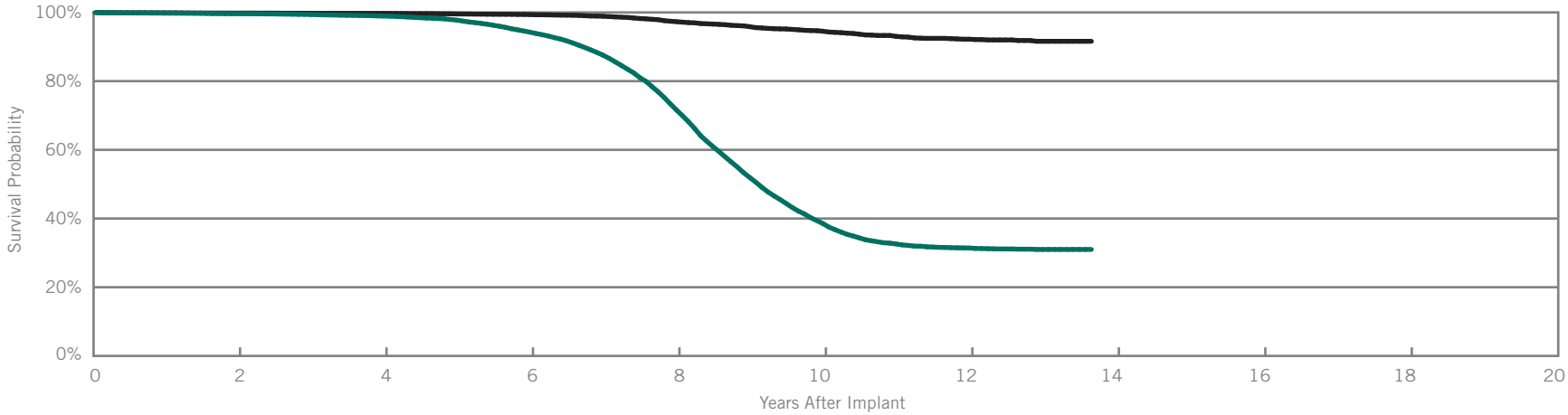
Identity™ XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,506
Estimated Active US Implants	4,637
Estimated Longevity	6.9 Years
Normal Battery Depletion	5,315
Number of US Advisories (see pgs. 296-300)	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%	77	0.15%
Total	**8**	**0.02%**	**412**	**0.80%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 164 months			
Survival Probability	99.64%	98.94%	94.26%	71.61%	38.54%	31.42%	31.00%			
± 1 standard error	0.03%	0.05%	0.13%	0.29%	0.35%	0.36%	0.37%			
Sample Size	43,960	35,480	27,170	18,160	7,970	2,690	220			

Excluding Normal Battery Depletion

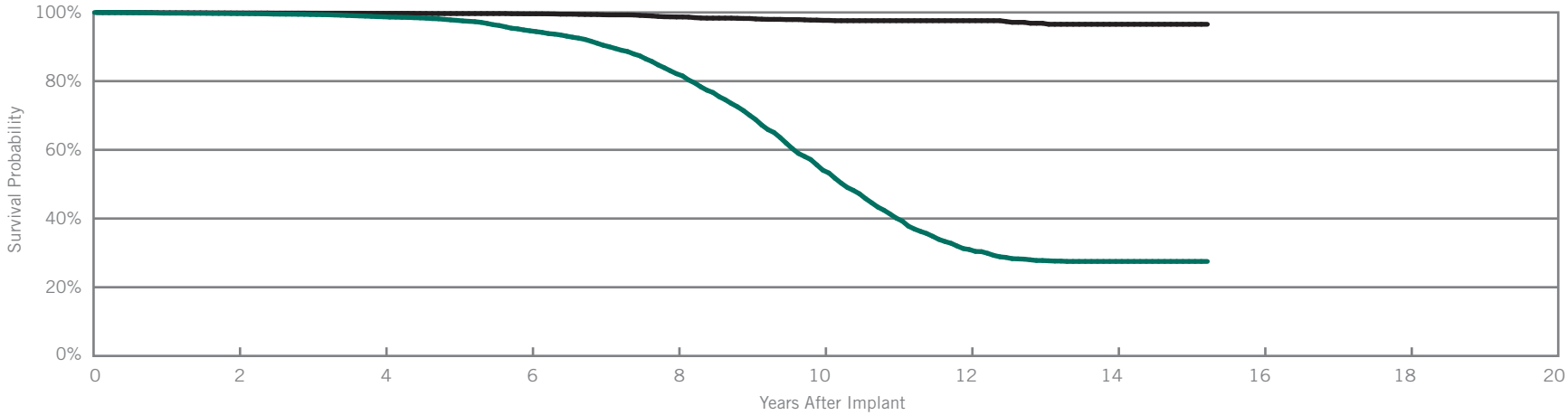
Year	2	4	6	8	10	12	at 164 months			
Survival Probability	99.81%	99.71%	99.37%	97.31%	94.53%	92.20%	91.60%			
± 1 standard error	0.02%	0.03%	0.04%	0.11%	0.19%	0.31%	0.38%			

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	710
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 183 months		
Survival Probability	99.66%	98.73%	94.65%	82.16%	54.07%	30.97%	27.51%	27.51%		
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.66%	0.71%	0.71%	0.71%		
Sample Size	17,840	14,050	10,280	6,320	3,000	1,280	560	200		

Excluding Normal Battery Depletion

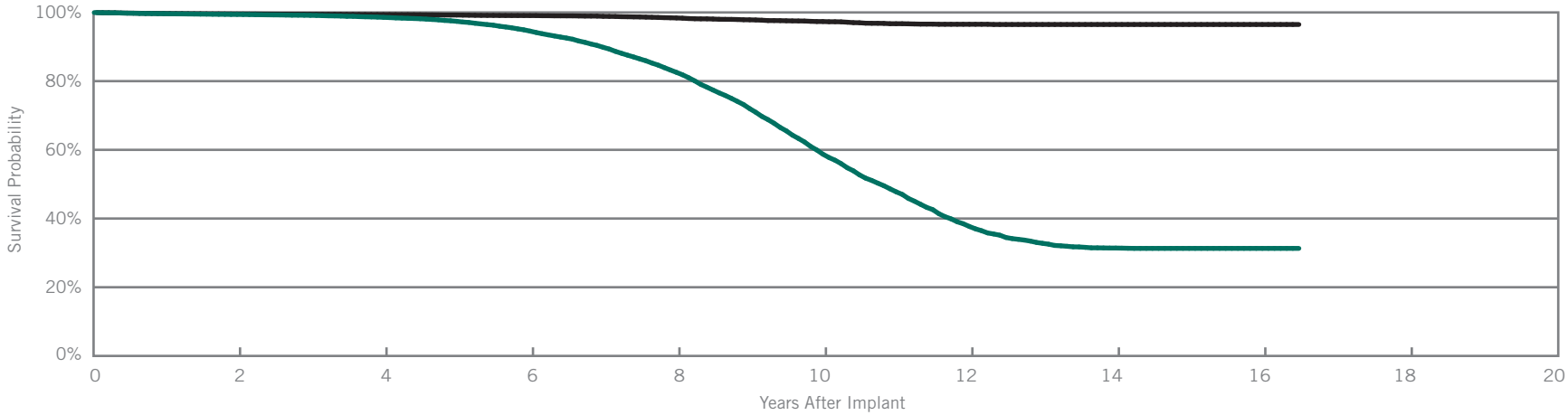
Year	2	4	6	8	10	12	14	at 183 months		
Survival Probability	99.85%	99.74%	99.60%	98.68%	97.69%	97.60%	96.55%	96.55%		
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.20%	0.22%	0.43%	0.43%		

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

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,713
Estimated Active US Implants	2,338
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,543
Number of US Advisories (see pgs. 296-300)	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 198 months
Survival Probability	99.42%	98.57%	94.57%	82.56%	58.74%	37.69%	31.41%	31.31%	31.31%
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.36%	0.42%	0.43%	0.43%	0.43%
Sample Size	55,290	44,820	33,820	21,140	9,920	4,370	2,290	1,020	220

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	16	at 198 months
Survival Probability	99.56%	99.36%	99.08%	98.39%	97.35%	96.55%	96.49%	96.49%	96.49%
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.11%	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	99.76%									
PM2240	Assurity™ DR RF	99.94%									
PM2210	Accent™ DR RF	99.93%	99.87%	99.78%	99.62%	99.38%	98.96%				
PM2110	Accent™ DR	99.97%	99.93%	99.87%	99.67%	99.44%	99.27%				
5820	Zephyr™ DR	99.85%	99.75%	99.04%	93.43%	80.61%	75.83%	74.71%	74.51%		
5810	Victory™ DR	99.87%	99.75%	98.71%	89.78%	69.26%	54.00%	47.38%	46.41%	46.41%	
5826	Zephyr™ XL DR	99.91%	99.84%	99.75%	99.48%	98.82%	98.07%	97.60%	96.83%		
5816	Victory™ XL DR	99.91%	99.84%	99.67%	99.34%	98.09%	94.27%	88.98%	87.53%	86.87%	
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.89%	99.83%	99.69%	99.47%	98.87%	96.85%	94.59%	91.92%	89.54%	88.74%
5366	Integrity™ ADx XL DR	100.00%	99.94%	99.58%	99.45%	98.67%	95.58%	91.06%	84.59%	78.47%	74.59%
5380	Identity ADx™ DR	99.77%	99.46%	98.28%	92.40%	71.45%	50.39%	36.65%	31.63%	31.00%	30.91%
5386/5286	Identity ADx™ XL DR/DC	99.88%	99.78%	99.58%	99.25%	98.37%	94.81%	88.63%	78.16%	69.34%	66.35%
5342/5346	Integrity™ AFx DR	99.87%	99.73%	99.49%	99.14%	98.18%	95.70%	91.07%	83.23%	69.05%	49.40%
5370	Identity™	99.75%	99.37%	97.99%	89.46%	67.89%	50.74%	39.13%	33.95%	32.31%	31.53%
5376	Identity™ XL	99.79%	99.64%	99.39%	98.94%	97.76%	94.26%	87.53%	71.61%	51.96%	38.54%
5326/5226	Entity™ DR/DC	99.79%	99.66%	99.40%	98.73%	97.70%	94.65%	90.45%	82.16%	70.06%	54.07%
5330/5331/5230	Affinity™ DR/DC	99.64%	99.42%	99.15%	98.57%	97.41%	94.57%	89.84%	82.56%	72.00%	58.74%

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	99.76%									
PM2240	Assurity™ DR RF	99.94%									
PM2210	Accent™ DR RF	99.94%	99.90%	99.84%	99.79%	99.74%	99.68%				
PM2110	Accent™ DR	99.97%	99.95%	99.93%	99.93%	99.93%	99.93%				
5820	Zephyr™ DR	99.97%	99.96%	99.93%	99.62%	99.19%	98.87%	98.62%	98.62%		
5810	Victory™ DR	99.98%	99.93%	99.70%	99.22%	97.85%	97.50%	97.08%	96.53%	96.53%	
5826	Zephyr™ XL DR	99.96%	99.93%	99.92%	99.89%	99.82%	99.74%	99.62%	99.29%		
5816	Victory™ XL DR	99.97%	99.95%	99.91%	99.86%	99.81%	99.74%	99.53%	99.23%	98.90%	
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%	99.82%	99.76%	99.60%
5366	Integrity™ ADx XL DR	100.00%	100.00%	99.97%	99.97%	99.97%	99.92%	99.70%	99.63%	99.32%	98.14%
5380	Identity ADx™ DR	99.96%	99.93%	99.75%	99.29%	97.83%	97.04%	96.90%	96.51%	96.40%	96.31%
5386/5286	Identity ADx™ XL DR/DC	99.92%	99.90%	99.88%	99.85%	99.78%	99.70%	99.55%	98.98%	97.95%	96.69%
5342/5346	Integrity™ AFx DR	99.96%	99.92%	99.86%	99.81%	99.73%	99.70%	99.57%	99.36%	99.12%	98.82%
5370	Identity™	99.93%	99.88%	99.71%	98.94%	96.93%	95.84%	95.19%	95.05%	95.05%	95.05%
5376	Identity™ XL	99.90%	99.81%	99.76%	99.71%	99.56%	99.37%	98.89%	97.31%	95.85%	94.53%
5326/5226	Entity™ DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.32%	98.68%	98.24%	97.69%
5330/5331/5230	Affinity™ DR/DC	99.69%	99.56%	99.46%	99.36%	99.24%	99.08%	98.87%	98.39%	97.85%	97.35%

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	7,024	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2240	Assurity™ DR RF	82,203	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%**
PM2210	Accent™ DR RF	242,999	2.70%	15	<0.01%	6	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	<0.01%	5	<0.01%	**33**	**0.01%**
PM2110	Accent™ DR	48,899	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	52,880	8.20%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5810	Victory™ DR	26,306	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	112,010	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	62,639	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	17,297	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	8,075	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	54,043	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	67,331	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	51,506	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	65,713	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	7,024	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.07%	0	0.00%	1	0.01%	**6**	**0.09%**
PM2240	Assurity™ DR RF	82,203	0.30%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	15	0.02%	0	0.00%	3	<0.01%	**18**	**0.02%**
PM2210	Accent™ DR RF	242,999	2.70%	33	0.01%	30	0.01%	0	0.00%	2	<0.01%	10	<0.01%	17	<0.01%	31	0.01%	**123**	**0.05%**
PM2110	Accent™ DR	48,899	2.70%	3	<0.01%	0	0.00%	0	0.00%	3	<0.01%	3	<0.01%	1	<0.01%	0	0.00%	**10**	**0.02%**
5820	Zephyr™ DR	52,880	8.20%	34	0.06%	0	0.00%	0	0.00%	9	0.02%	2	<0.01%	1	<0.01%	47	0.09%	**93**	**0.18%**
5810	Victory™ DR	26,306	16.80%	89	0.34%	0	0.00%	0	0.00%	8	0.03%	2	<0.01%	17	0.06%	28	0.11%	**144**	**0.55%**
5826	Zephyr™ XL DR	112,010	6.00%	17	0.02%	0	0.00%	0	0.00%	10	<0.01%	9	<0.01%	3	<0.01%	66	0.06%	**105**	**0.09%**
5816	Victory™ XL DR	62,639	11.50%	25	0.04%	0	0.00%	0	0.00%	6	<0.01%	7	0.01%	5	<0.01%	57	0.09%	**100**	**0.16%**
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	17,297	6.60%	9	0.05%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	5	0.03%	**16**	**0.09%**
5366	Integrity™ ADx XL DR	8,075	10.90%	7	0.09%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	10	0.12%	**19**	**0.24%**
5380	Identity ADx™ DR	54,043	15.60%	262	0.48%	0	0.00%	0	0.00%	2	<0.01%	6	0.01%	11	0.02%	15	0.03%	**296**	**0.55%**
5386/5286	Identity ADx™ XL DR/DC	67,331	13.10%	131	0.19%	2	<0.01%	0	0.00%	7	0.01%	10	0.01%	6	<0.01%	83	0.12%	**239**	**0.35%**
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	51,506	17.50%	311	0.60%	2	<0.01%	0	0.00%	12	0.02%	5	<0.01%	5	<0.01%	77	0.15%	**412**	**0.80%**
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	65,713	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	42,573	0.44%	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	92,473	0.82%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	Accent™ DR RF	246,809	3.28%	15	<0.01%	6	<0.01%	0	0.00%	0	0.00%	0	0.00%	6	<0.01%	5	<0.01%	**32**	**0.01%**
PM2110	Accent™ DR	49,742	3.19%	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	42,573	0.44%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	7	0.02%	0	0.00%	2	<0.01%	**10**	**0.02%**
PM2240	Assurity™ DR RF	92,473	0.82%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	15	0.02%	0	0.00%	2	<0.01%	**18**	**0.02%**
PM2210	Accent™ DR RF	246,809	3.28%	35	0.01%	31	0.01%	0	0.00%	2	<0.01%	10	<0.01%	17	<0.01%	30	0.01%	**125**	**0.05%**
PM2110	Accent™ DR	49,742	3.19%	3	<0.01%	0	0.00%	0	0.00%	3	<0.01%	3	<0.01%	1	<0.01%	0	0.00%	**10**	**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	1,773	418	47,446	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**1**	**0.06%**
PM2110	226	79	7,413	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	283	19	7,659	0	0.00%	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
5826	1,517	22	47,564	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	332	0	10,627	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	1,773	4.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2110	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	1,773	4.20%	1	0.06%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.11%**
PM2110	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

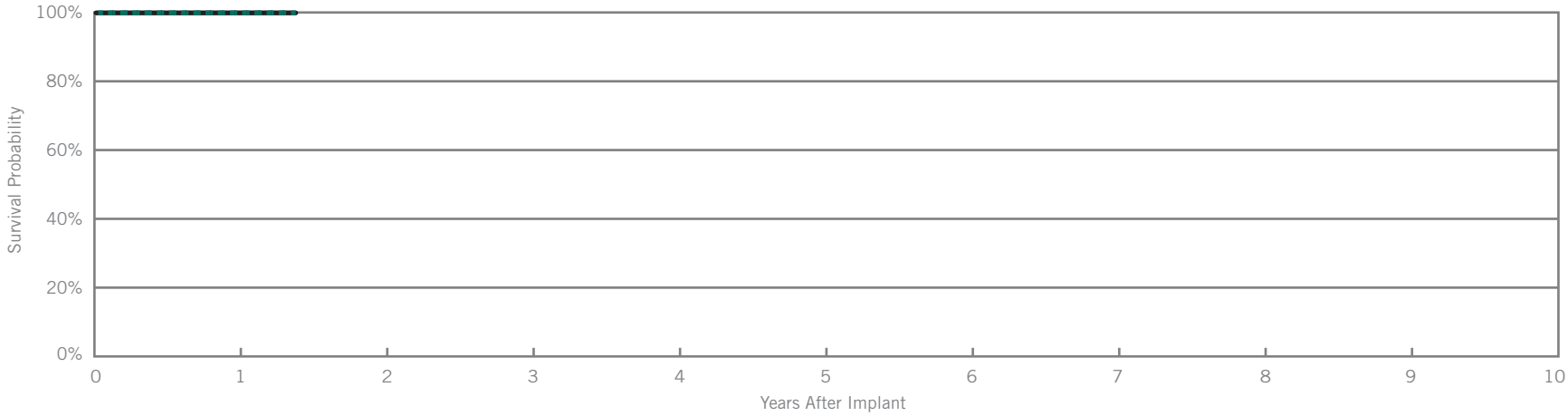
Endurity™ VR

Model PM1160

US Regulatory Approval	March 2014
Registered US Implants	1,787
Estimated Active US Implants	1,599
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	0.06%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.06%**



Including Normal Battery Depletion

Year	1	at 17 months								
Survival Probability	99.88%	99.88%								
± 1 standard error	0.08%	0.08%								
Sample Size	1,180	220								

Excluding Normal Battery Depletion

Year	1	at 17 months								
Survival Probability	99.88%	99.88%								
± 1 standard error	0.08%	0.08%								

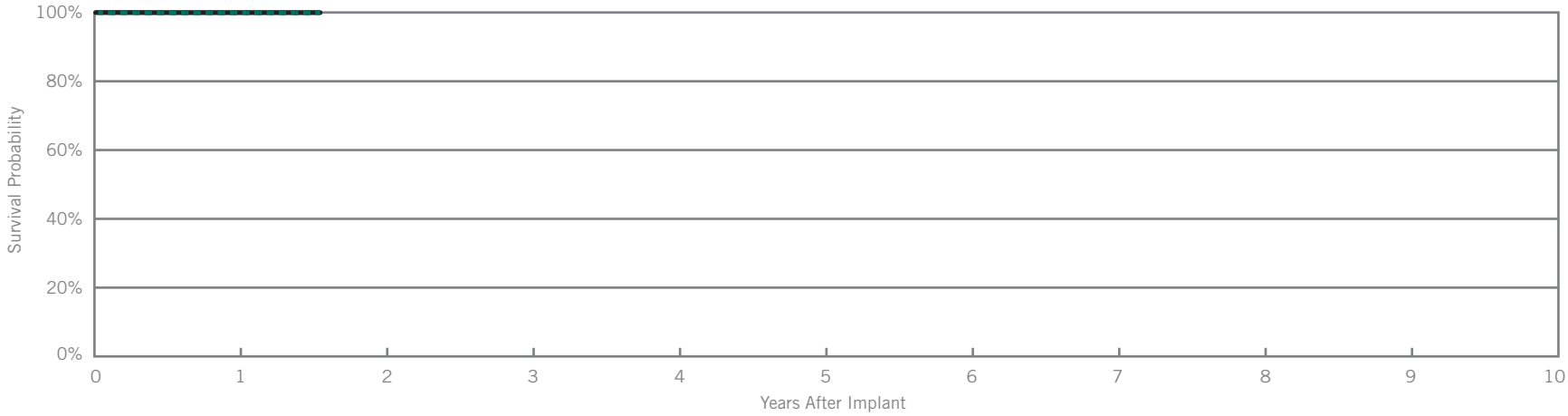
Assurity™ VR

Model PM1240

US Regulatory Approval	March 2014
Registered US Implants	12,265
Estimated Active US Implants	11,029
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%	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%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.96%	99.96%								
± 1 standard error	0.02%	0.02%								
Sample Size	7,560	270								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.96%	99.96%								
± 1 standard error	0.02%	0.02%								

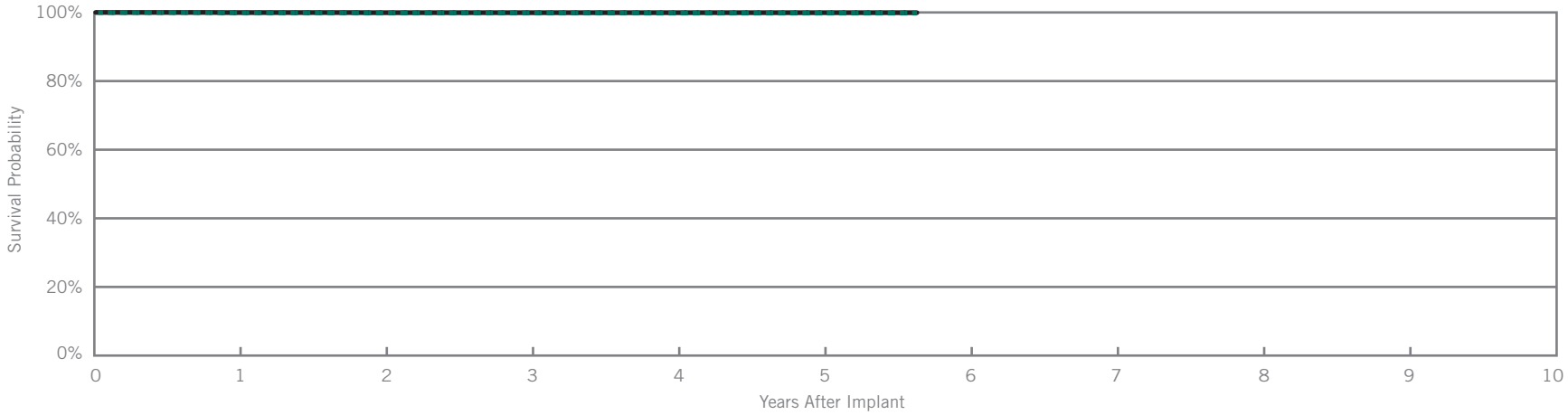
Accent™ SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	13,587
Estimated Active US Implants	9,002
Estimated Longevity	12.9 Years
Normal Battery Depletion	4
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%	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%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.94%	99.88%	99.88%	99.82%	99.82%	99.82%				
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.05%	0.05%				
Sample Size	12,500	10,060	7,130	4,230	1,900	240				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.96%	99.93%	99.93%	99.93%	99.93%	99.93%				
± 1 standard error	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%				

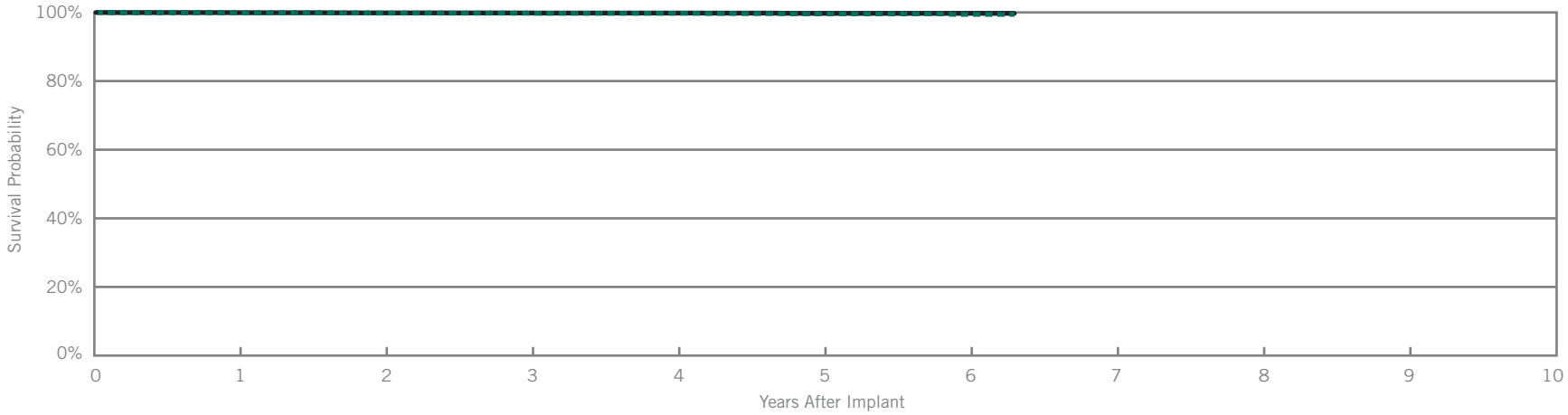
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	39,809
Estimated Active US Implants	25,613
Estimated Longevity	10.9 Years
Normal Battery Depletion	11
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 76 months			
Survival Probability	99.89%	99.80%	99.78%	99.76%	99.61%	99.44%	99.44%			
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.06%	0.13%	0.13%			
Sample Size	36,550	29,430	21,200	13,350	7,190	2,690	280			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.93%	99.86%	99.84%	99.82%	99.73%	99.73%	99.73%			
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.05%	0.05%	0.05%			

Actively Monitored Study Data

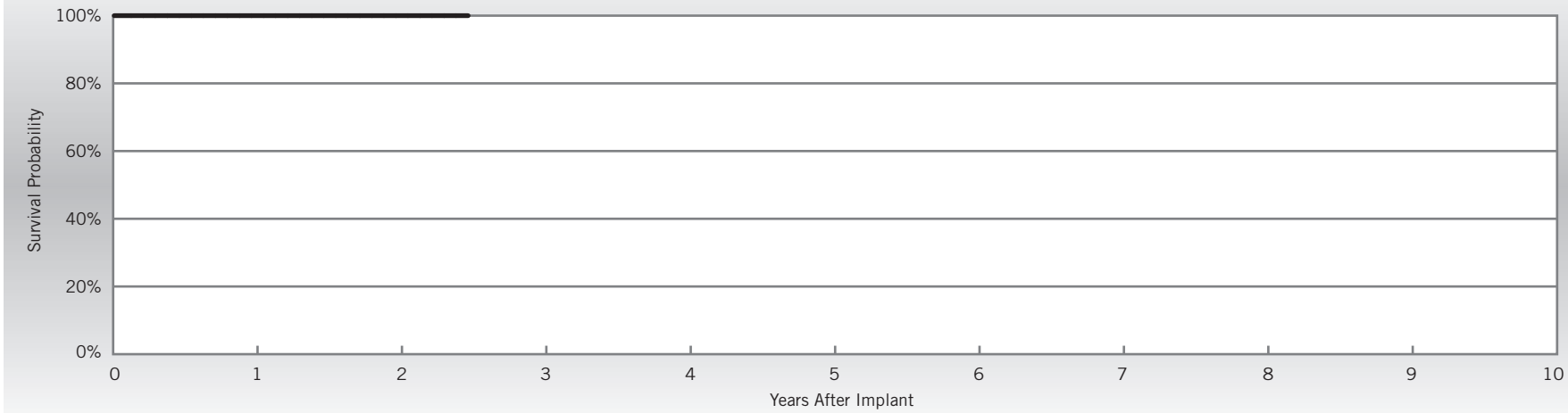
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	236
Active Devices Enrolled in Study	34
Cumulative Months of Follow-up	5,191
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 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	200	120	50							

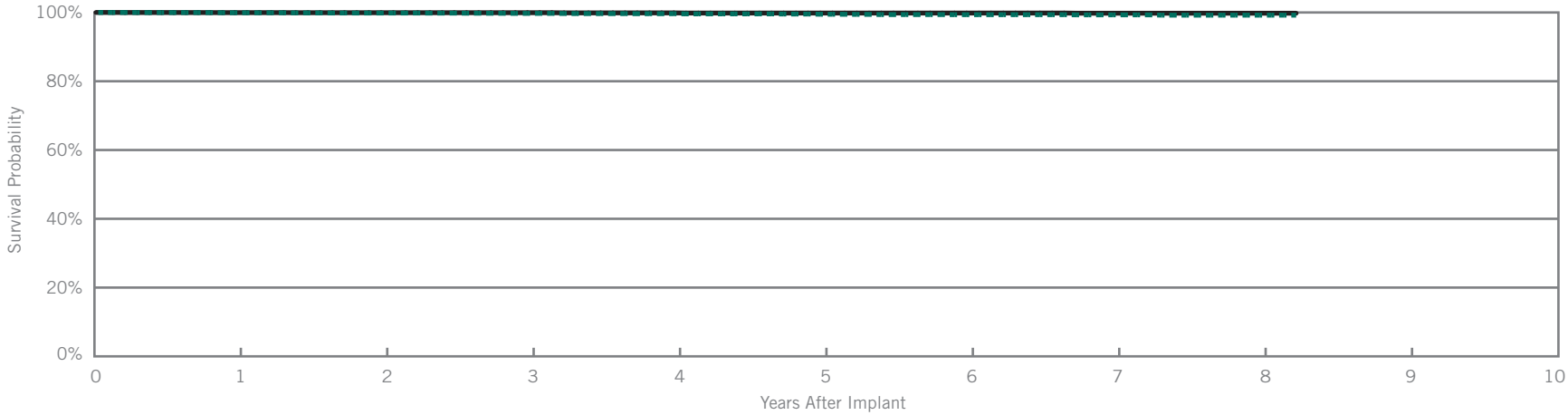
Zephyr™ XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	20,619
Estimated Active US Implants	9,777
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%	6	0.03%
Total	**2**	**<0.01%**	**10**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.92%	99.83%	99.73%	99.64%	99.48%	99.35%	99.30%	99.21%	99.21%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.06%	0.08%	0.08%	0.10%	0.10%
Sample Size	18,840	15,830	13,540	11,570	9,800	7,870	4,960	1,800	260

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.95%	99.93%	99.93%	99.88%	99.83%	99.83%	99.78%	99.78%	99.78%
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%	0.05%	0.05%	0.05%

Actively Monitored Study Data

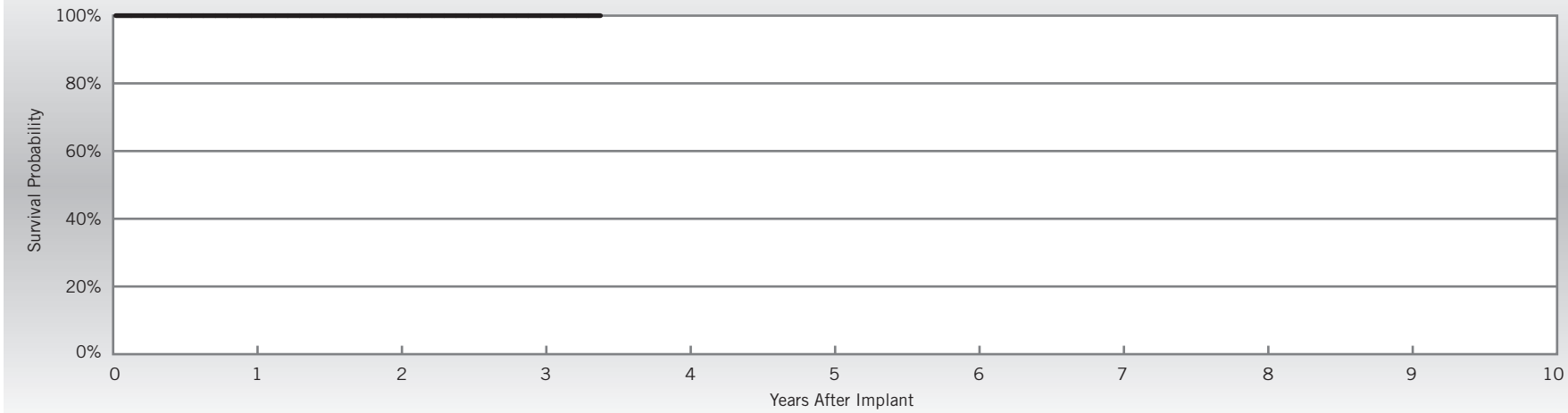
Zephyr™ XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	230
Active Devices Enrolled in Study	3
Cumulative Months of Follow-up	6,515
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						

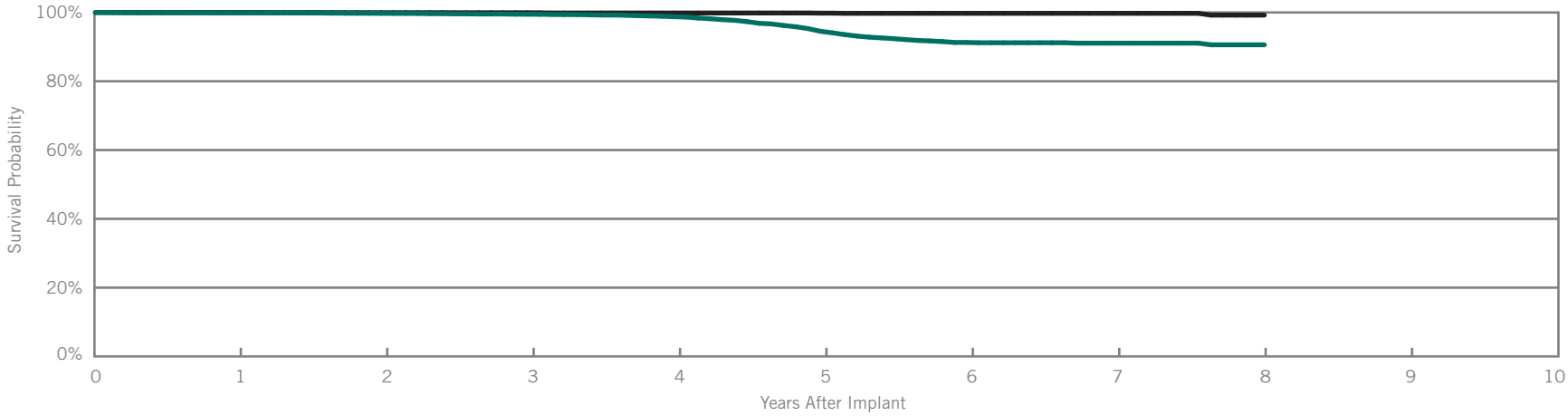
Zephyr™ SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	16,974
Estimated Active US Implants	8,438
Estimated Longevity	8.8 Years
Normal Battery Depletion	176
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%	4	0.02%
Total	**0**	**0.00%**	**10**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.87%	99.74%	99.49%	98.76%	94.53%	91.28%	91.08%	90.60%		
± 1 standard error	0.03%	0.04%	0.07%	0.11%	0.28%	0.41%	0.43%	0.54%		
Sample Size	15,160	12,060	9,590	7,310	5,230	3,370	1,750	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.99%	99.95%	99.93%	99.85%	99.80%	99.75%	99.75%	99.23%		
± 1 standard error	0.01%	0.02%	0.02%	0.04%	0.04%	0.06%	0.06%	0.38%		

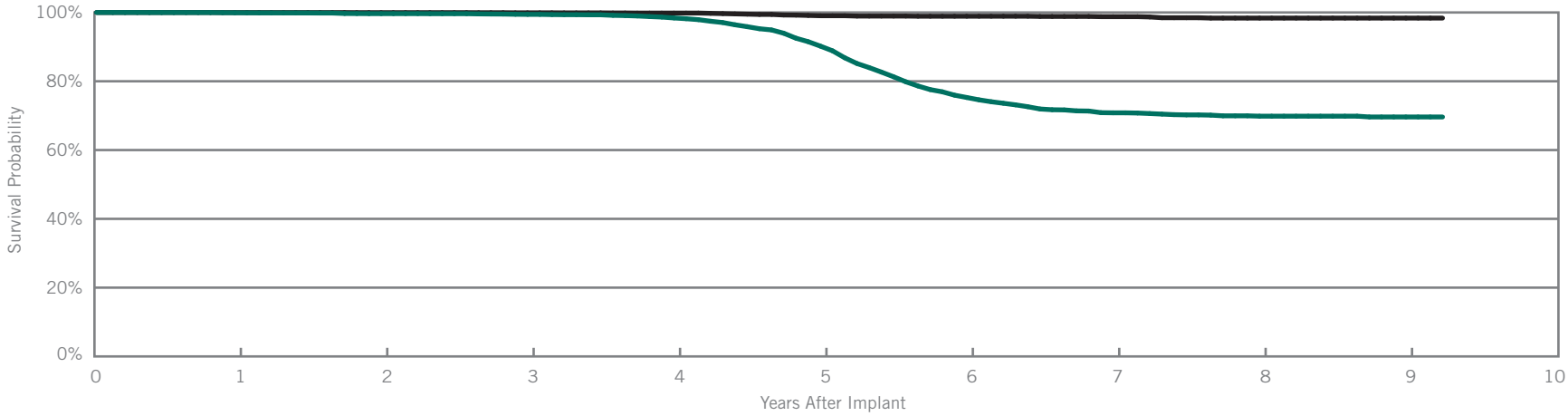
Customer Reported Performance Data

Victory™ SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,681
Estimated Active US Implants	2,655
Estimated Longevity	8.8 Years
Normal Battery Depletion	662
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	23	0.17%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	9	0.07%
Total	**1**	**<0.01%**	**34**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.92%	99.66%	99.44%	98.40%	90.22%	75.28%	70.82%	69.85%	69.62%	69.62%
± 1 standard error	0.02%	0.06%	0.07%	0.13%	0.35%	0.55%	0.61%	0.62%	0.65%	0.65%
Sample Size	12,340	10,130	8,540	7,260	6,070	4,690	3,260	2,020	880	220

Excluding Normal Battery Depletion

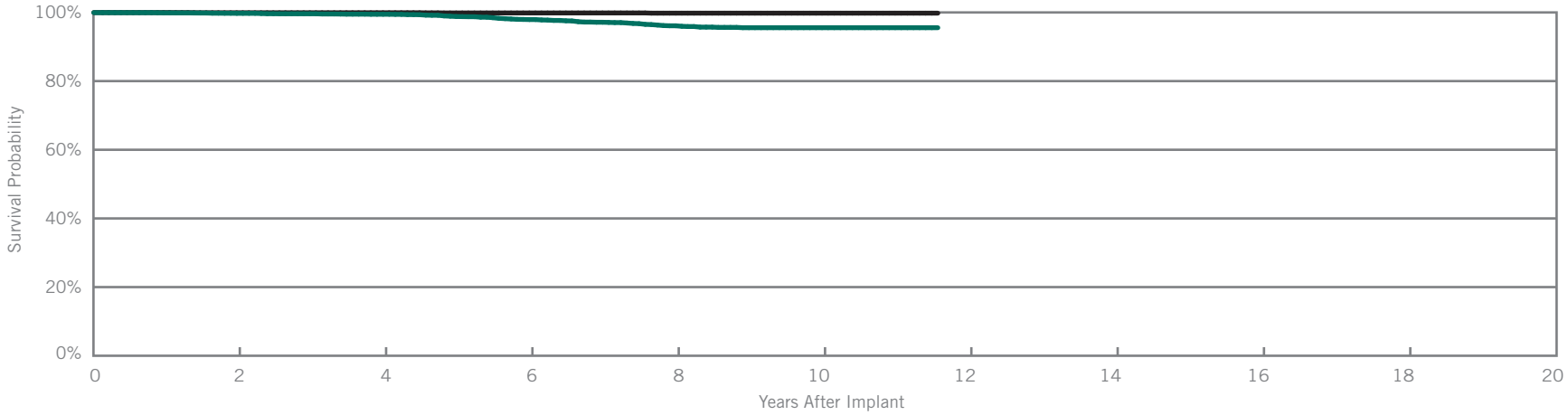
Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.98%	99.96%	99.91%	99.83%	99.05%	98.91%	98.78%	98.37%	98.37%	98.37%
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.12%	0.13%	0.15%	0.20%	0.20%	0.20%

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	14,479
Estimated Active US Implants	3,928
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%	2	0.01%
Total	**1**	**<0.01%**	**7**	**0.05%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 139 months				
Survival Probability	99.73%	99.46%	97.92%	96.11%	95.55%	95.55%				
± 1 standard error	0.05%	0.07%	0.18%	0.27%	0.31%	0.31%				
Sample Size	10,850	7,730	5,430	3,580	1,470	200				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 139 months				
Survival Probability	99.91%	99.91%	99.85%	99.79%	99.79%	99.79%				
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.06%	0.06%				

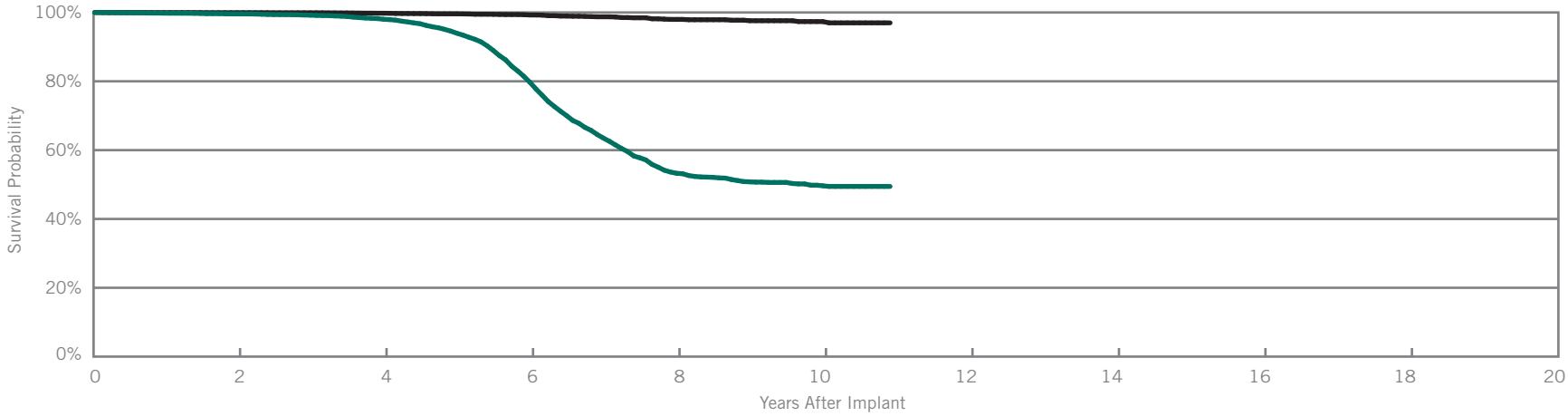
Identity™ ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,862
Estimated Active US Implants	2,506
Estimated Longevity	5.7 Years
Normal Battery Depletion	1,238
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 131 months				
Survival Probability	99.57%	98.02%	79.68%	53.27%	49.63%	49.45%				
± 1 standard error	0.05%	0.12%	0.44%	0.65%	0.71%	0.73%				
Sample Size	15,440	10,880	6,600	2,760	910	210				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.94%	99.78%	99.26%	97.98%	97.35%	96.98%				
± 1 standard error	0.02%	0.04%	0.09%	0.22%	0.32%	0.41%				

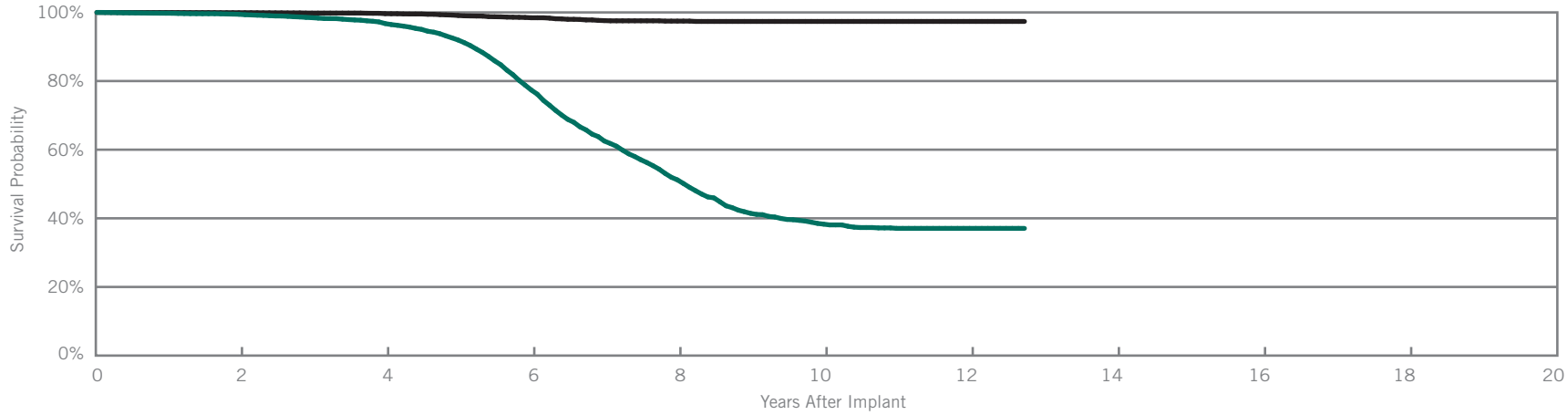
Identity™ SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,884
Estimated Active US Implants	1,151
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,470
Number of US Advisories (see pgs. 296-300)	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 153 months			
Survival Probability	99.45%	96.75%	77.39%	51.21%	38.30%	37.07%	37.07%			
± 1 standard error	0.05%	0.14%	0.45%	0.65%	0.73%	0.75%	0.75%			
Sample Size	16,210	11,390	6,580	2,730	1,080	450	200			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 153 months			
Survival Probability	99.92%	99.63%	98.44%	97.47%	97.37%	97.37%	97.37%			
± 1 standard error	0.02%	0.04%	0.13%	0.21%	0.22%	0.22%	0.22%			

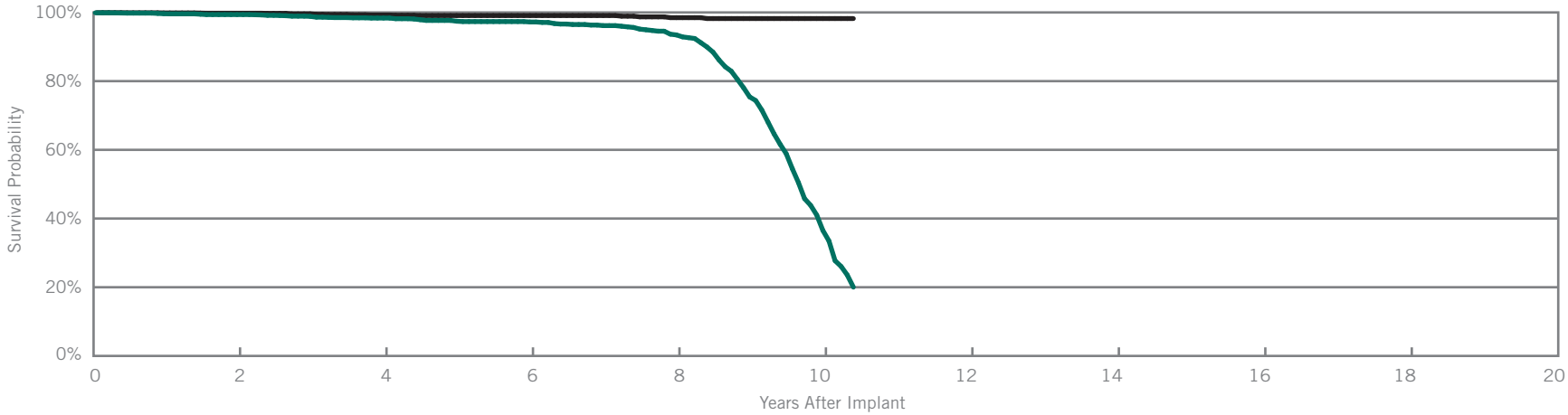
Customer Reported Performance Data

Microny™

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	7,584
Estimated Active US Implants	1,376
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 125 months				
Survival Probability	99.37%	98.36%	97.22%	93.45%	36.54%	20.02%				
± 1 standard error	0.11%	0.20%	0.29%	0.63%	1.78%	1.49%				
Sample Size	4,850	3,060	1,820	990	430	220				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 125 months				
Survival Probability	99.78%	99.25%	99.09%	98.48%	98.22%	98.22%				
± 1 standard error	0.06%	0.14%	0.16%	0.29%	0.35%	0.35%				

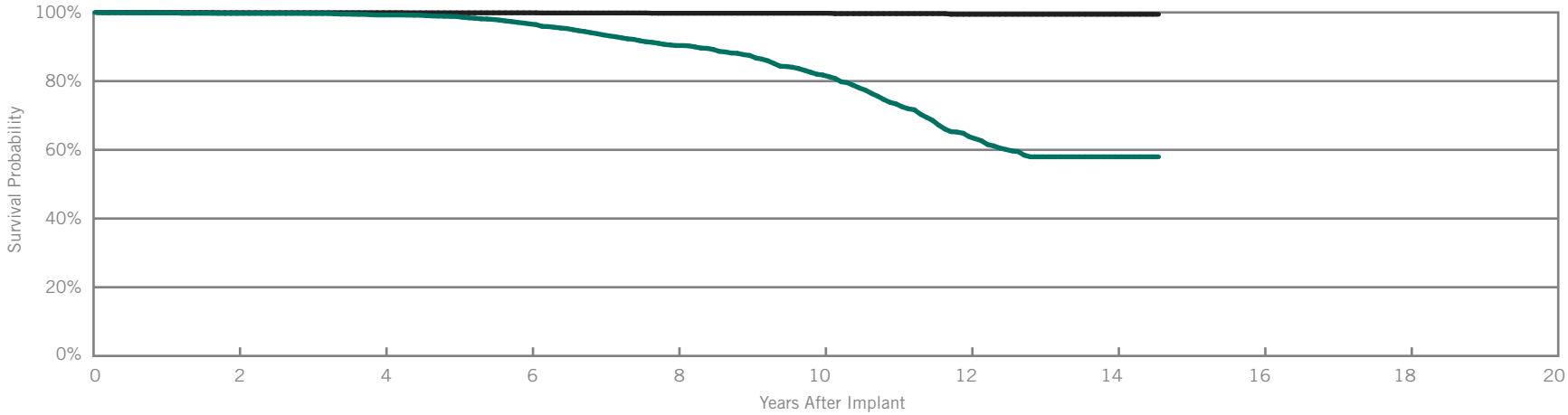
Integrity™ SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,489
Estimated Active US Implants	705
Estimated Longevity	8.6 Years
Normal Battery Depletion	384
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 175 months		
Survival Probability	99.71%	99.26%	96.65%	90.35%	81.78%	63.79%	57.97%	57.97%		
± 1 standard error	0.06%	0.10%	0.25%	0.48%	0.72%	1.05%	1.17%	1.17%		
Sample Size	8,050	5,870	4,200	2,890	1,920	1,120	440	200		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 175 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%	0.18%	0.18%	0.18%		

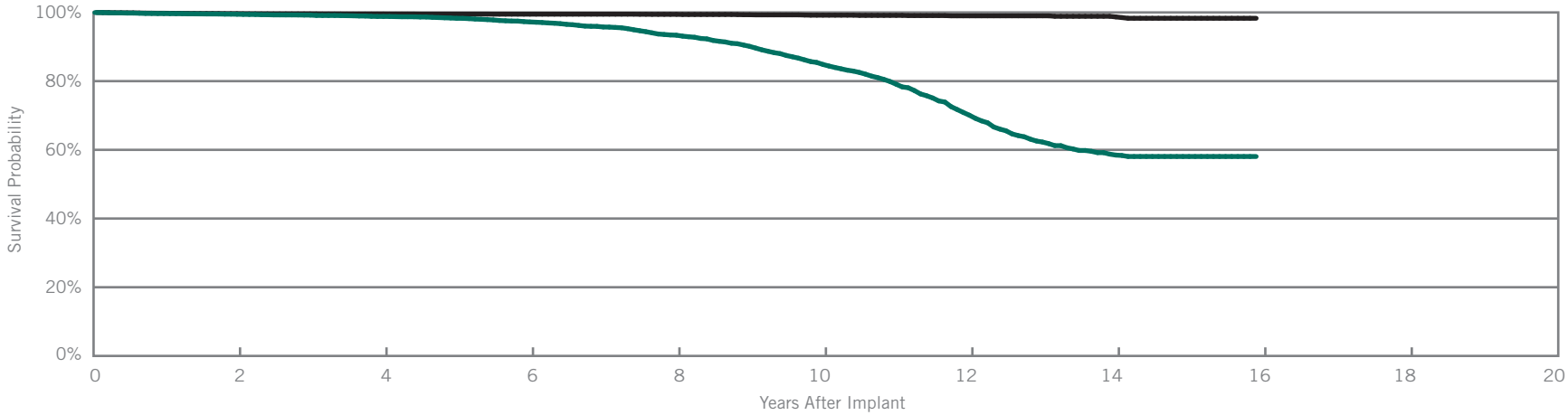
Affinity™ SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,796
Estimated Active US Implants	1,448
Estimated Longevity	8.6 Years
Normal Battery Depletion	792
Number of US Advisories (see pgs. 296-300)	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	at 191 months		
Survival Probability	99.47%	98.83%	97.23%	93.37%	84.86%	70.09%	58.47%	58.06%		
± 1 standard error	0.05%	0.08%	0.14%	0.25%	0.43%	0.66%	0.81%	0.83%		
Sample Size	21,460	15,250	10,680	7,180	4,560	2,830	1,350	210		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	at 191 months		
Survival Probability	99.64%	99.54%	99.49%	99.44%	99.20%	99.01%	98.69%	98.30%		
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.09%	0.12%	0.15%	0.28%		

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	99.88%									
PM1240	Assurity™ SR	99.96%									
PM1110	Accent™ SR	99.94%	99.88%	99.88%	99.82%	99.82%					
PM1210	Accent™ SR RF	99.89%	99.80%	99.78%	99.76%	99.61%	99.44%				
5626	Zephyr™ XL SR	99.92%	99.83%	99.73%	99.64%	99.48%	99.35%	99.30%	99.21%		
5620	Zephyr™ SR	99.87%	99.74%	99.49%	98.76%	94.53%	91.28%	91.08%	90.60%		
5610	Victory™ SR	99.92%	99.66%	99.44%	98.40%	90.22%	75.28%	70.82%	69.85%	69.62%	
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	99.87%	99.73%	99.60%	99.46%	98.81%	97.92%	97.14%	96.11%	95.55%	95.55%
5180	Identity™ ADx SR	99.79%	99.57%	99.21%	98.02%	93.97%	79.68%	63.52%	53.27%	50.78%	49.63%
5172	Identity™ SR	99.76%	99.45%	98.46%	96.75%	91.95%	77.39%	62.52%	51.21%	41.45%	38.30%
2425T/2525T/2535T	Microny™	99.62%	99.37%	98.85%	98.36%	97.44%	97.22%	96.16%	93.45%	75.42%	36.54%
5142	Integrity™ SR	99.86%	99.71%	99.68%	99.26%	98.81%	96.65%	93.46%	90.35%	87.49%	81.78%
5130/5131	Affinity™ SR	99.69%	99.47%	99.22%	98.83%	98.29%	97.23%	95.76%	93.37%	90.12%	84.86%

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
PM1160	Endurity™ SR	99.88%									
PM1240	Assurity™ SR	99.96%									
PM1110	Accent™ SR	99.96%	99.93%	99.93%	99.93%	99.93%					
PM1210	Accent™ SR RF	99.93%	99.86%	99.84%	99.82%	99.73%	99.73%				
5626	Zephyr™ XL SR	99.95%	99.93%	99.93%	99.88%	99.83%	99.83%	99.78%	99.78%		
5620	Zephyr™ SR	99.99%	99.95%	99.93%	99.85%	99.80%	99.75%	99.75%	99.23%		
5610	Victory™ SR	99.98%	99.96%	99.91%	99.83%	99.05%	98.91%	98.78%	98.37%	98.37%	
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	99.96%	99.91%	99.91%	99.91%	99.85%	99.85%	99.85%	99.79%	99.79%	99.79%
5180	Identity™ ADx SR	99.96%	99.94%	99.91%	99.78%	99.60%	99.26%	98.74%	97.98%	97.60%	97.35%
5172	Identity™ SR	99.97%	99.92%	99.81%	99.63%	99.10%	98.44%	97.61%	97.47%	97.37%	97.37%
2425T/2525T/2535T	Microny™	99.86%	99.78%	99.59%	99.25%	99.09%	99.09%	99.09%	98.48%	98.22%	98.22%
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	1,787	0.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1240	Assurity™ SR	12,265	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	13,587	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	39,809	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	20,619	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	16,974	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	13,681	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	14,479	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	20,862	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™	7,584	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	10,489	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	28,796	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	1,787	0.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	**1**	**0.06%**
PM1240	Assurity™ SR	12,265	0.20%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
PM1110	Accent™ SR	13,587	3.60%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	**3**	**0.02%**
PM1210	Accent™ SR RF	39,809	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	20,619	5.40%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.03%	**10**	**0.05%**
5620	Zephyr™ SR	16,974	5.80%	4	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	4	0.02%	**10**	**0.06%**
5610	Victory™ SR	13,681	12.70%	23	0.17%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	9	0.07%	**34**	**0.25%**
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	14,479	5.80%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	2	0.01%	**7**	**0.05%**
5180	Identity™ ADx SR	20,862	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™	7,584	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	10,489	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	28,796	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	17,991	0.29%	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	14,811	0.82%	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	52,402	1.38%	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	47,556	3.65%	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	17,991	0.29%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**1**	**<0.01%**
PM1240	Assurity™ SR RF	14,811	0.82%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**2**	**0.01%**
PM1110	Accent™ SR	52,402	1.38%	1	<0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	2	<0.01%	**6**	**0.01%**
PM1210	Accent™ SR RF	47,556	3.65%	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	34	5,191	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	230	3	6,515	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

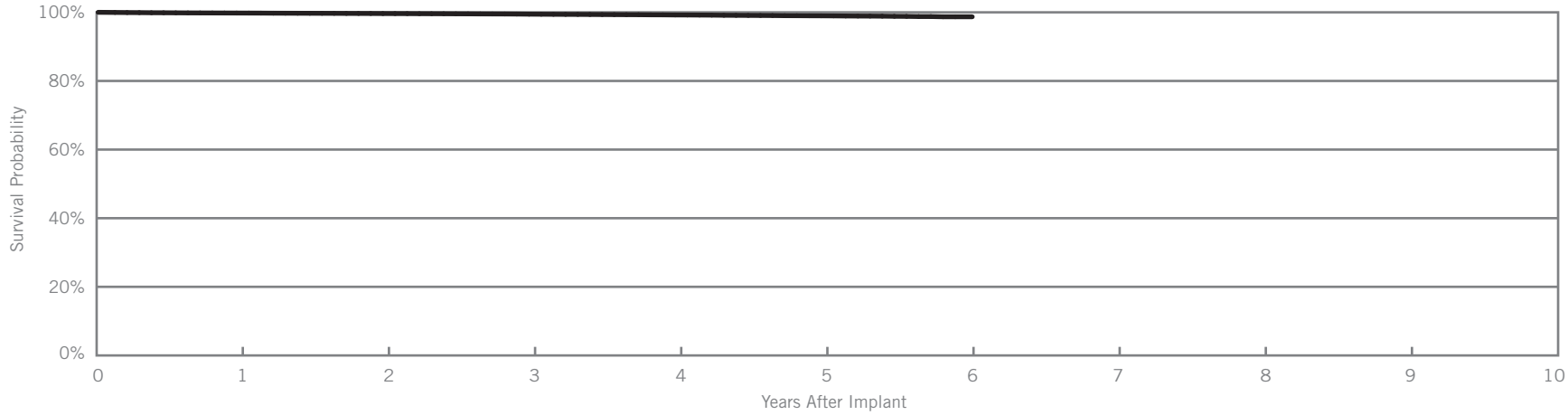
Tendril™ STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	425,470
Estimated Active US Implants	327,035
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	66	0.02%	35	<0.01%
Conductor Fracture	5	<0.01%	100	0.02%
Lead Dislodgement	378	0.09%	476	0.11%
Failure to Capture	103	0.02%	346	0.08%
Oversensing	31	<0.01%	863	0.20%
Failure to Sense	17	<0.01%	64	0.02%
Insulation Breach	10	<0.01%	115	0.03%
Abnormal Pacing Impedance	24	<0.01%	75	0.02%
Extracardiac Stimulation	3	<0.01%	14	<0.01%
Other	87	0.02%	84	0.02%
Total	**724**	**0.17%**	**2172**	**0.51%**
Total Returned for Analysis	**346**		**853**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	25	<0.01%
Insulation Breach	309	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	22	<0.01%
Extrinsic Factors	652	0.15%
Total	**1008**	**0.24%**



Year	1	2	3	4	5	6				
Survival Probability	99.79%	99.64%	99.47%	99.24%	98.99%	98.74%				
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.03%	0.09%				
Sample Size	361,600	250,510	165,760	97,890	44,700	350				

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

Tendril™ STS

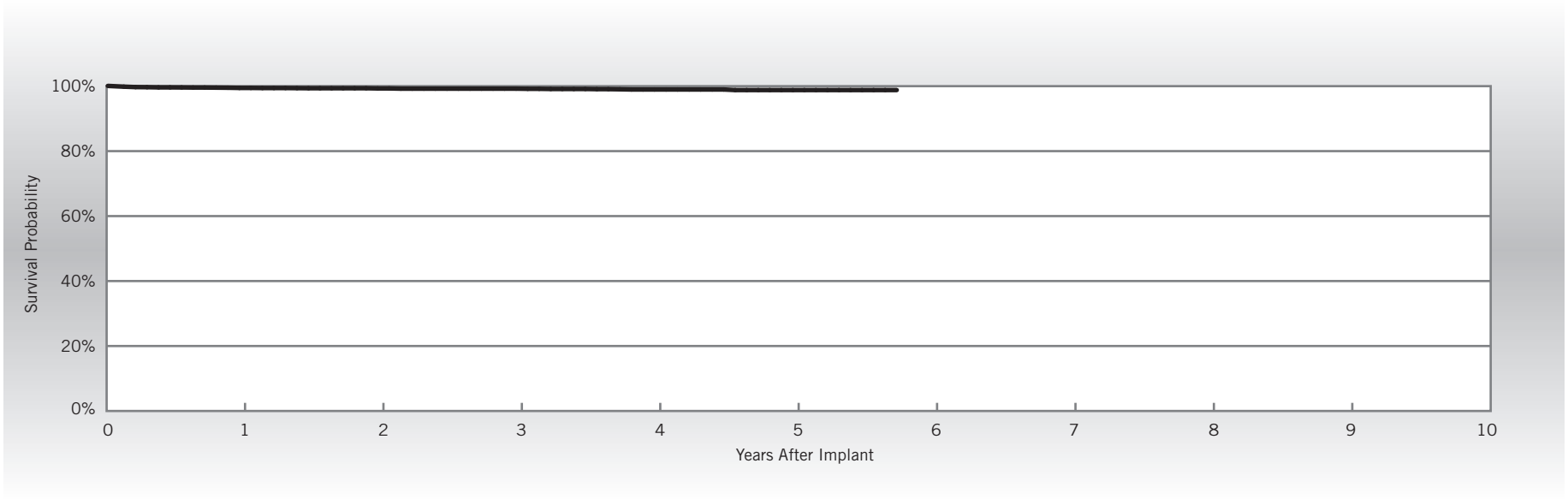
Model 2088TC

Actively Monitored Study Data

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	3,804
Active Devices Enrolled in Study	2,297
Cumulative Months of Follow-up	150,734
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%
Failure to Capture	2	0.05%
Failure to Sense	1	0.03%
Insulation Breach	5	0.13%
Lead Dislodgement	14	0.37%
Oversensing	8	0.21%
Pericardial Effusion	1	0.03%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	11	0.29%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	10	0.26%
Total	**21**	**0.55%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	99.45%	99.30%	99.23%	98.97%	98.80%	98.80%				
± 1 standard error	0.12%	0.13%	0.15%	0.19%	0.22%	0.22%				
Sample Size	3,600	3,190	2,600	1,980	1,170	80				

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

Customer Reported Performance Data

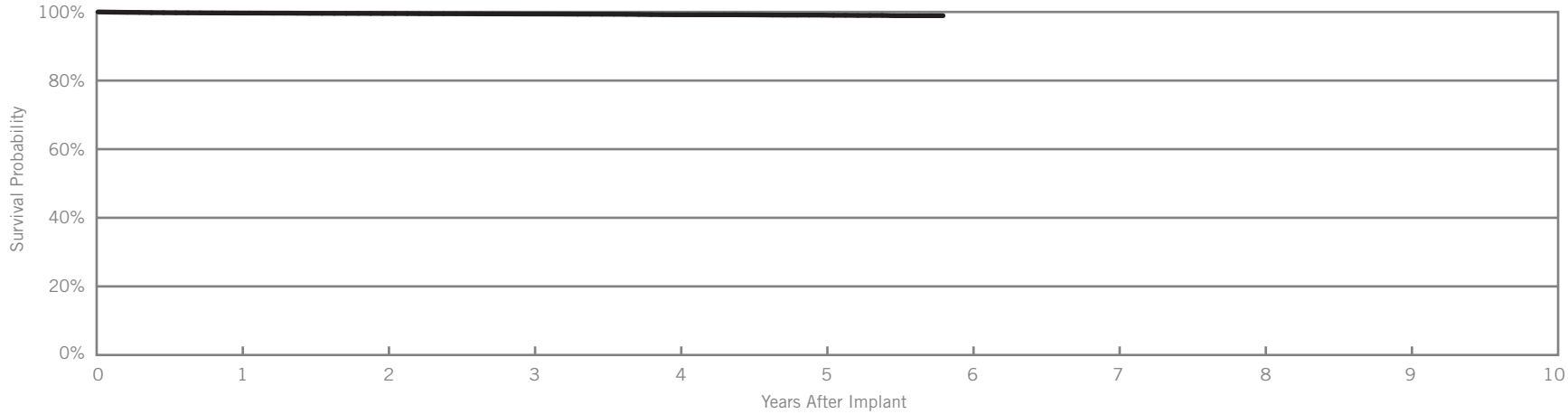
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	40,670
Estimated Active US Implants	28,533
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	2	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	2	<0.01%
Lead Dislodgement	48	0.12%	111	0.27%
Failure to Capture	6	0.01%	32	0.08%
Oversensing	5	0.01%	68	0.17%
Failure to Sense	3	<0.01%	14	0.03%
Insulation Breach	1	<0.01%	21	0.05%
Abnormal Pacing Impedance	0	0.00%	3	<0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	10	0.02%	11	0.03%
Total	**75**	**0.18%**	**262**	**0.64%**
Total Returned for Analysis	**44**		**122**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	20	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	4	<0.01%
Extrinsic Factors	111	0.27%
Total	**138**	**0.34%**



Year	1	2	3	4	5	at 70 months				
Survival Probability	99.69%	99.55%	99.38%	99.16%	99.06%	98.84%				
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.08%	0.13%				
Sample Size	35,250	25,770	18,220	11,780	6,150	360				

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

Actively Monitored Study Data

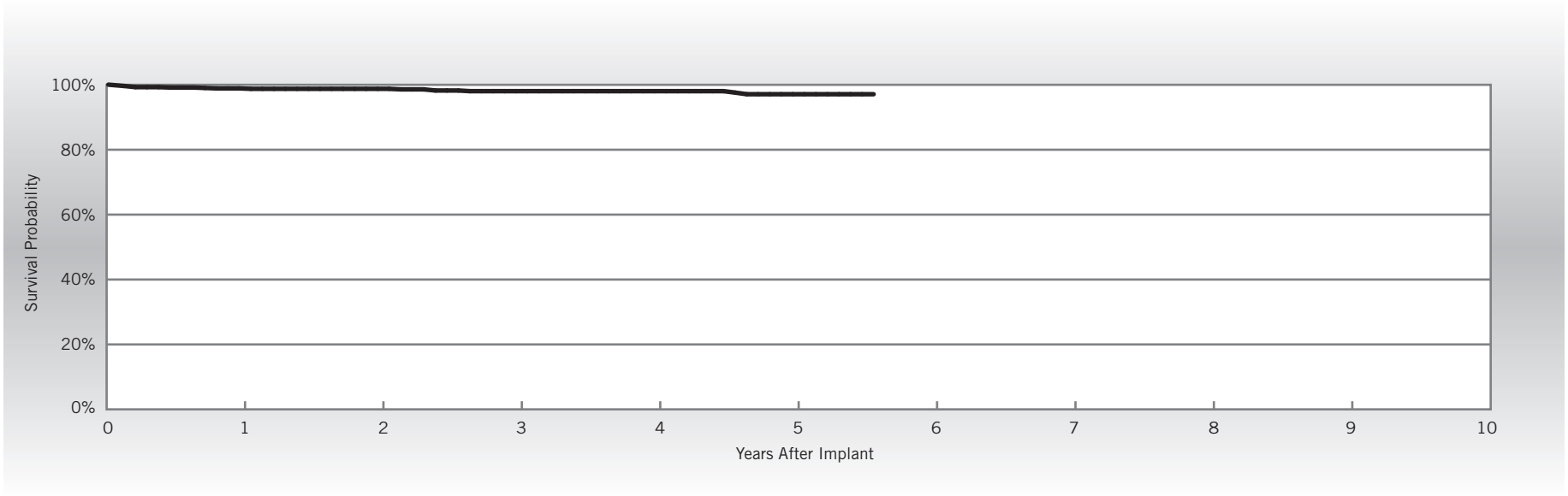
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	855
Active Devices Enrolled in Study	501
Cumulative Months of Follow-up	31,661
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	1.17%
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	0.94%
Total	**10**	**1.17%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	98.90%	98.76%	98.04%	98.04%	97.10%	97.10%				
± 1 standard error	0.37%	0.39%	0.53%	0.53%	0.84%	0.84%				
Sample Size	790	680	530	400	240	60				

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

Customer Reported Performance Data

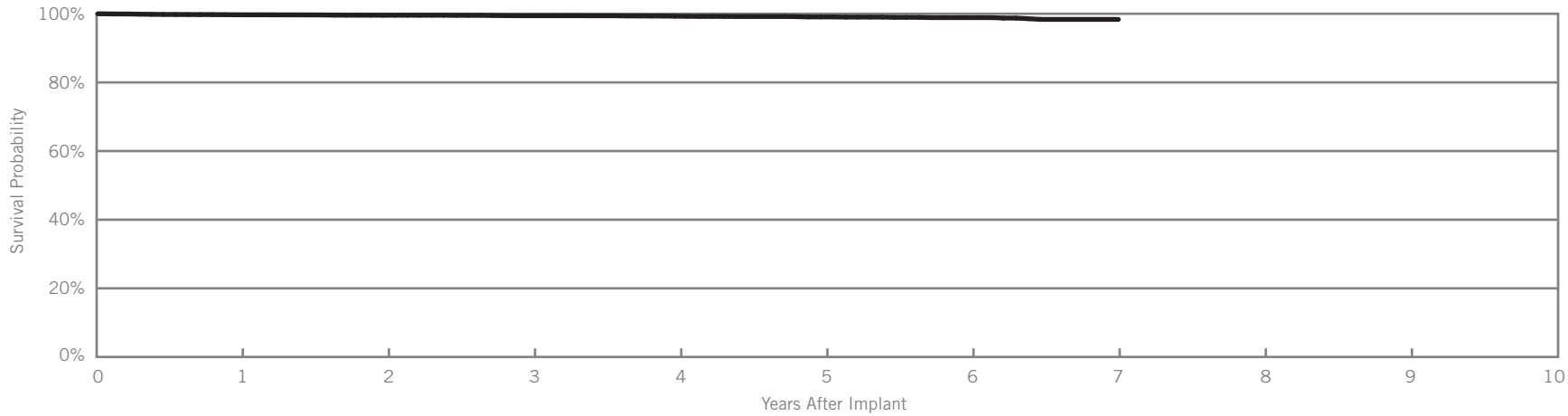
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	14,223
Estimated Active US Implants	9,491
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%	4	0.03%
Lead Dislodgement	49	0.34%	35	0.25%
Failure to Capture	7	0.05%	17	0.12%
Oversensing	0	0.00%	24	0.17%
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	**61**	**0.43%**	**93**	**0.65%**
Total Returned for Analysis	**35**		**19**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	5	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	16	0.11%
Total	**22**	**0.15%**



Year	1	2	3	4	5	6	7			
Survival Probability	99.71%	99.59%	99.45%	99.31%	99.10%	98.90%	98.40%			
± 1 standard error	0.05%	0.06%	0.08%	0.09%	0.13%	0.17%	0.34%			
Sample Size	12,450	9,360	6,910	4,790	2,990	1,560	220			

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

Actively Monitored Study Data

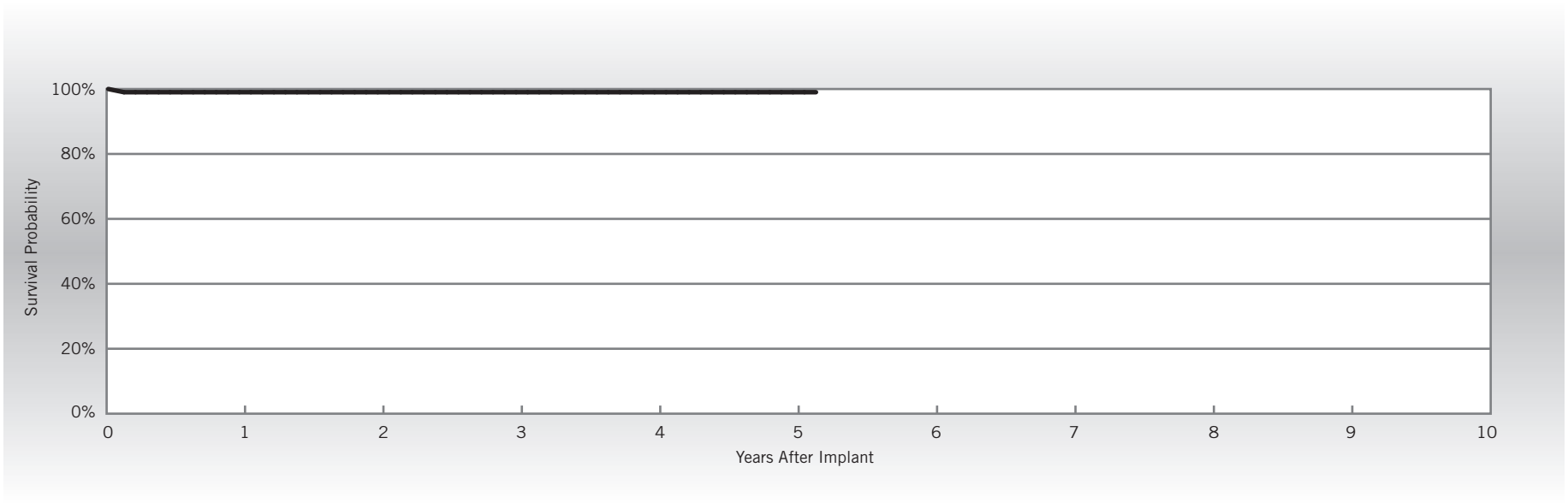
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	104
Active Devices Enrolled in Study	39
Cumulative Months of Follow-up	5,162
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	50	50				

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

Customer Reported Performance Data

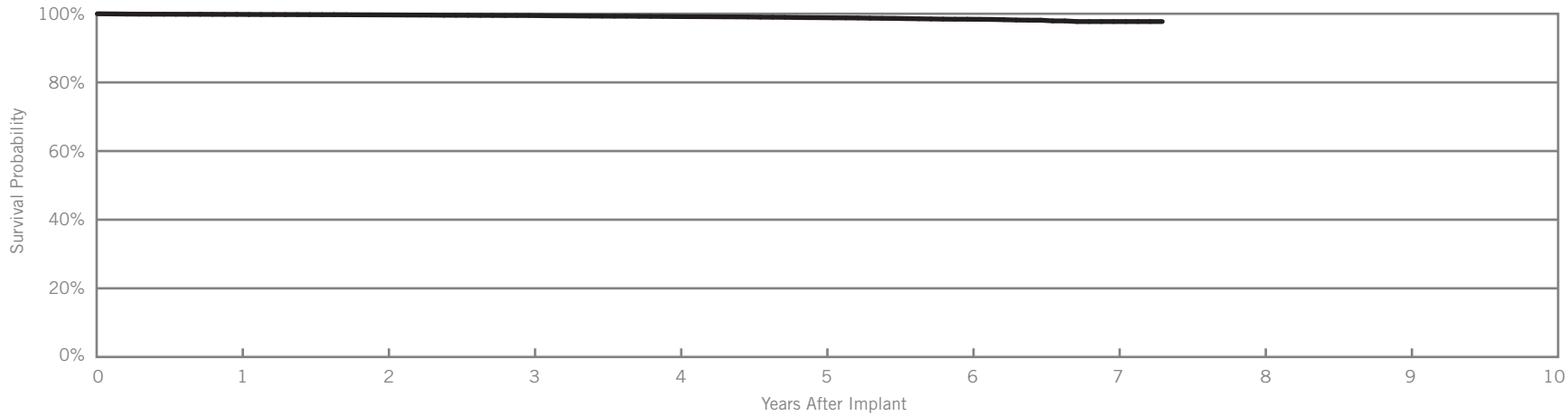
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	53,449
Estimated Active US Implants	35,836
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%	42	0.08%
Lead Dislodgement	36	0.07%	44	0.08%
Failure to Capture	23	0.04%	72	0.13%
Oversensing	1	<0.01%	109	0.20%
Failure to Sense	1	<0.01%	2	<0.01%
Insulation Breach	4	<0.01%	28	0.05%
Abnormal Pacing Impedance	1	<0.01%	19	0.04%
Extracardiac Stimulation	1	<0.01%	2	<0.01%
Other	5	<0.01%	4	<0.01%
Total	**74**	**0.14%**	**331**	**0.62%**
Total Returned for Analysis	**38**		**72**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	7	0.01%
Insulation Breach	40	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	50	0.09%
Total	**98**	**0.18%**



Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.81%	99.68%	99.50%	99.22%	98.88%	98.46%	97.77%	97.77%		
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.08%	0.12%	0.24%	0.24%		
Sample Size	46,550	34,510	24,810	16,550	10,080	5,210	1,810	230		

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

Actively Monitored Study Data

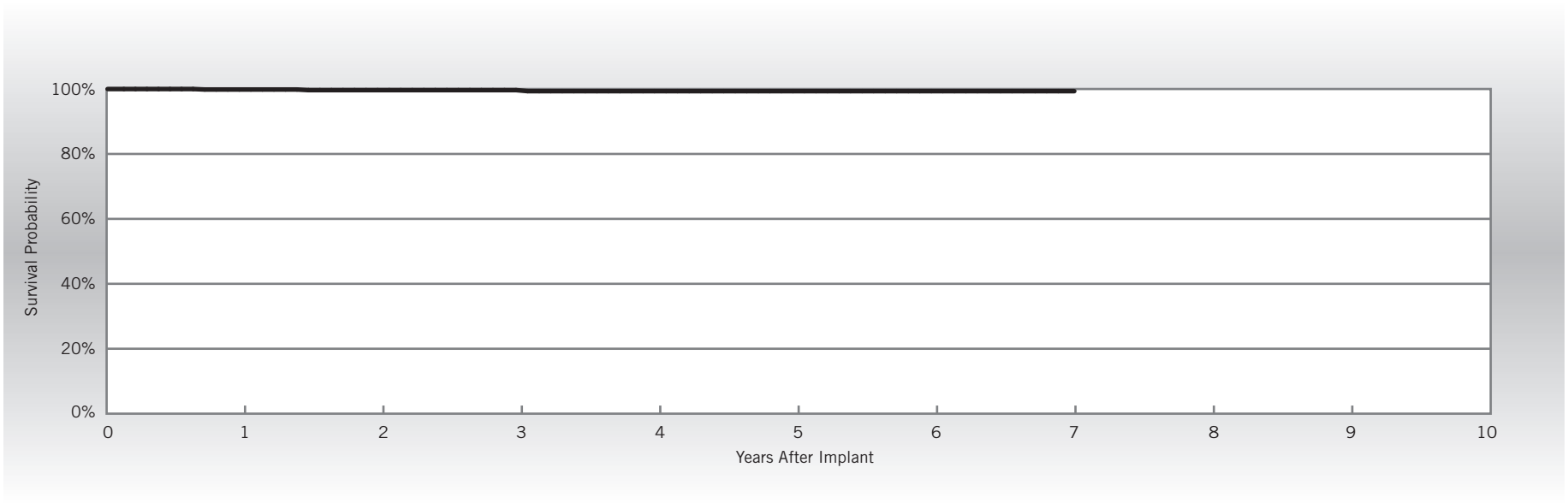
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	766
Active Devices Enrolled in Study	241
Cumulative Months of Follow-up	29,927
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
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			
Survival Probability	99.85%	99.66%	99.66%	99.34%	99.34%	99.34%	99.34%			
± 1 standard error	0.15%	0.24%	0.24%	0.40%	0.40%	0.40%	0.40%			
Sample Size	690	530	380	300	270	230	60			

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

Customer Reported Performance Data

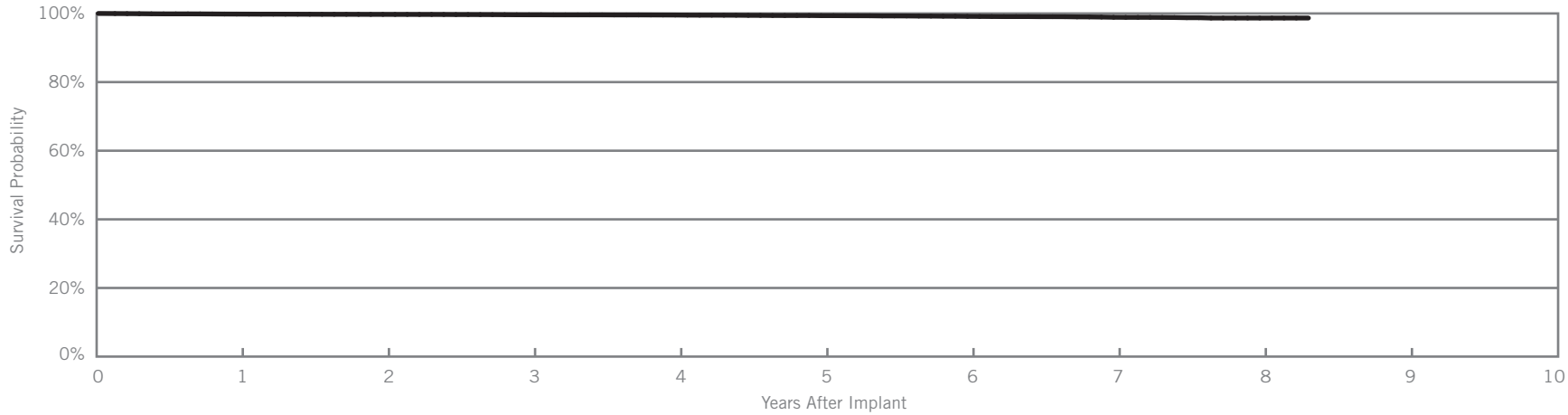
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	22,873
Estimated Active US Implants	11,497
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%	11	0.05%
Lead Dislodgement	4	0.02%	40	0.17%
Failure to Capture	3	0.01%	30	0.13%
Oversensing	2	<0.01%	62	0.27%
Failure to Sense	8	0.03%	18	0.08%
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%**	**187**	**0.82%**
Total Returned for Analysis	**16**		**61**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	13	0.06%
Insulation Breach	19	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	49	0.21%
Total	**81**	**0.35%**



Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.82%	99.72%	99.58%	99.50%	99.32%	99.09%	98.81%	98.54%	98.54%	
± 1 standard error	0.03%	0.04%	0.05%	0.05%	0.06%	0.08%	0.09%	0.14%	0.14%	
Sample Size	21,320	18,760	16,870	15,230	13,650	11,370	7,460	2,940	270	

Actively Monitored Study Data

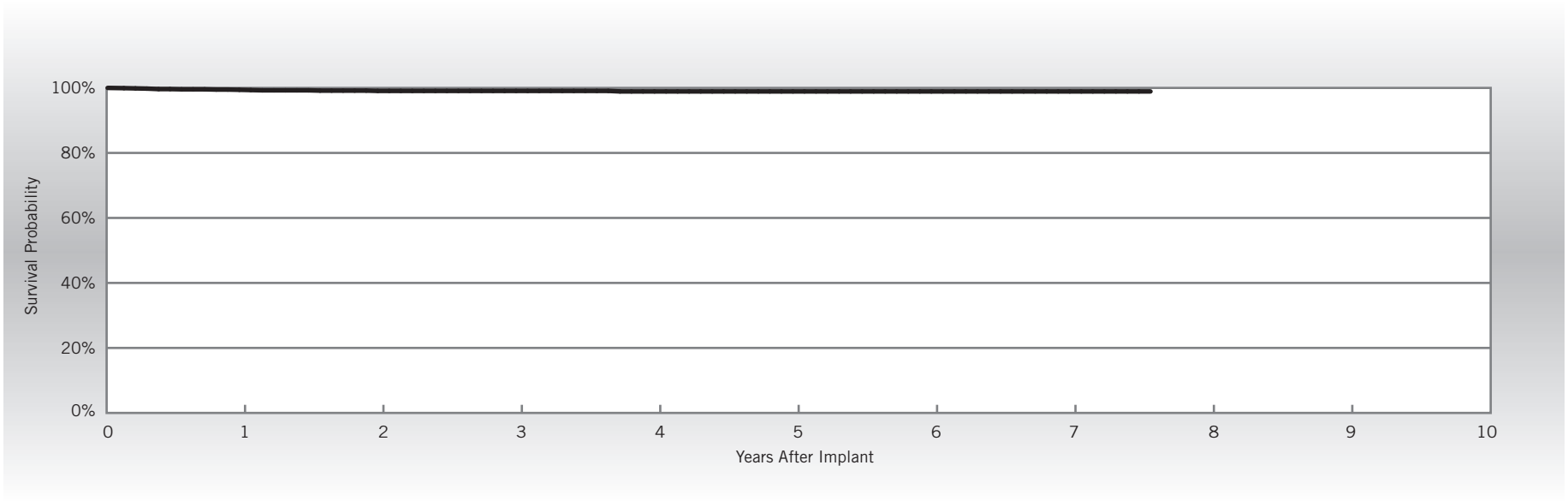
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,451
Active Devices Enrolled in Study	419
Cumulative Months of Follow-up	63,583
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	1	0.07%
Conductor Fracture	1	0.07%
Failure to Capture	1	0.07%
Insulation Breach	1	0.07%
Lead Dislodgement	8	0.55%
Oversensing	1	0.07%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.34%
Total	**6**	**0.41%**



Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.42%	99.08%	99.08%	98.92%	98.92%	98.92%	98.92%	98.92%		
± 1 standard error	0.19%	0.25%	0.27%	0.31%	0.31%	0.31%	0.31%	0.31%		
Sample Size	1,360	1,160	940	690	510	400	230	60		

Customer Reported Performance Data

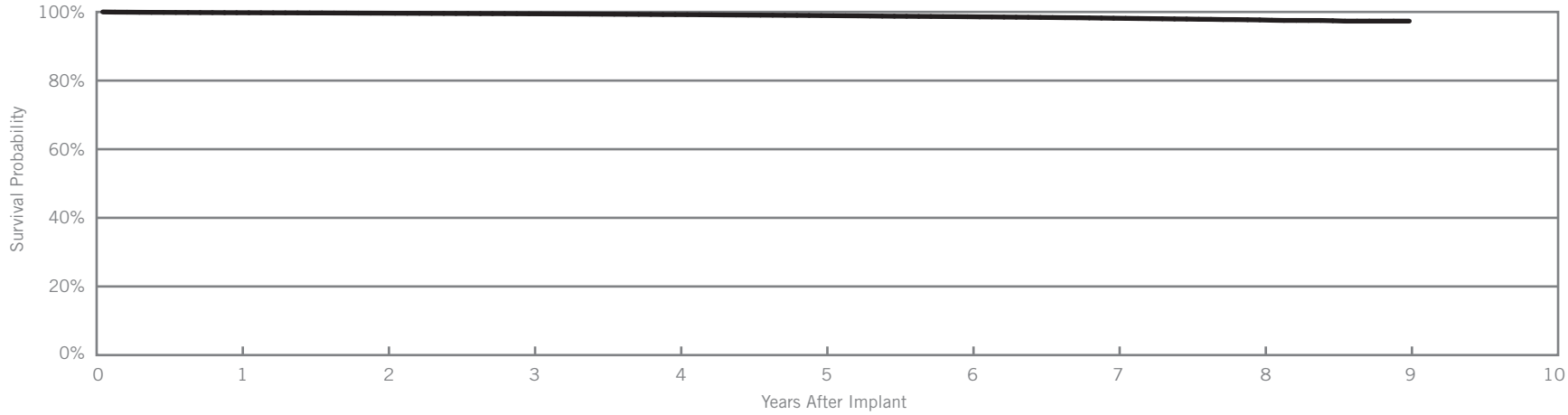
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	299,938
Estimated Active US Implants	168,571
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%	163	0.05%
Lead Dislodgement	153	0.05%	458	0.15%
Failure to Capture	84	0.03%	539	0.18%
Oversensing	16	<0.01%	1130	0.38%
Failure to Sense	14	<0.01%	91	0.03%
Insulation Breach	7	<0.01%	223	0.07%
Abnormal Pacing Impedance	9	<0.01%	167	0.06%
Extracardiac Stimulation	5	<0.01%	30	0.01%
Other	40	0.01%	78	0.03%
Total	**374**	**0.12%**	**2916**	**0.97%**
Total Returned for Analysis	**197**		**979**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	28	<0.01%
Insulation Breach	561	0.19%
Crimps, Welds & Bonds	1	<0.01%
Other	12	<0.01%
Extrinsic Factors	690	0.23%
Total	**1292**	**0.43%**



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.79%	99.64%	99.46%	99.24%	98.95%	98.61%	98.17%	97.69%	97.34%	
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.06%	0.11%	
Sample Size	274,460	228,800	190,780	156,590	124,150	88,940	51,260	21,480	310	

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

Actively Monitored Study Data

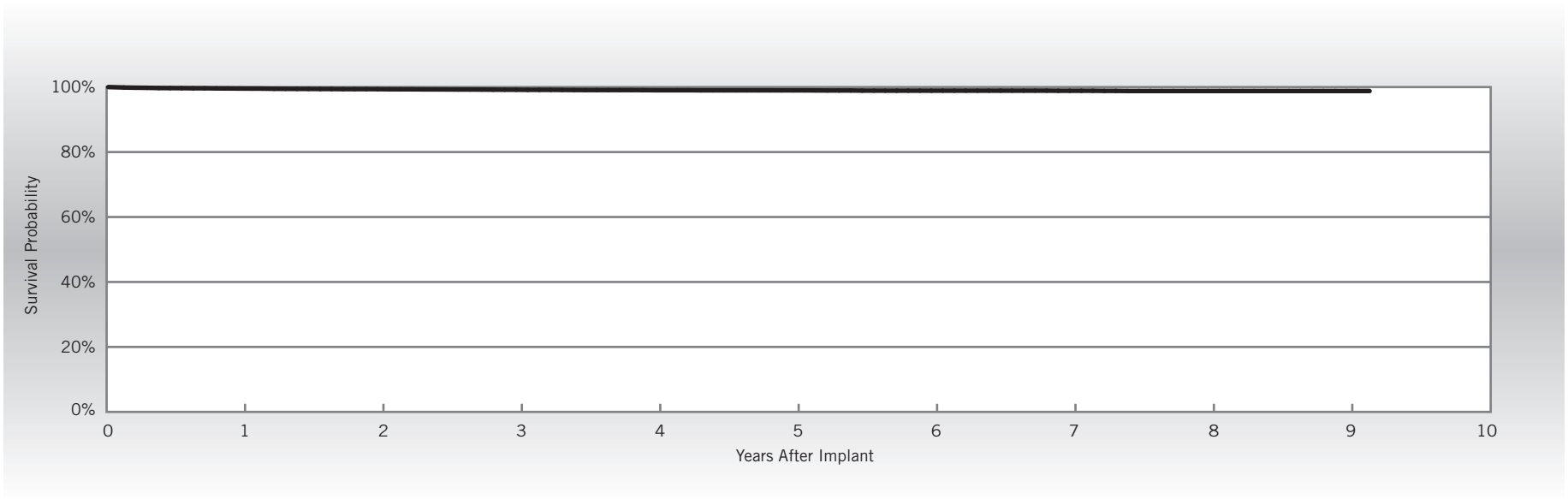
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	14,513
Active Devices Enrolled in Study	5,435
Cumulative Months of Follow-up	731,028
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	4	0.03%
Failure to Capture	8	0.06%
Failure to Sense	4	0.03%
Insulation Breach	25	0.17%
Lead Dislodgement	55	0.38%
Oversensing	15	0.10%
Skin Erosion	1	<0.01%

Malfunctions	Qty	Rate
Conductor Fracture	3	0.02%
Insulation Breach	21	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	33	0.23%
Total	**57**	**0.39%**



Year	1	2	3	4	5	6	7	8	9	at 110 months
Survival Probability	99.55%	99.36%	99.18%	99.03%	98.99%	98.90%	98.87%	98.79%	98.79%	98.79%
± 1 standard error	0.06%	0.07%	0.08%	0.09%	0.10%	0.10%	0.11%	0.12%	0.12%	0.12%
Sample Size	13,720	11,930	9,760	7,670	6,220	5,380	4,060	2,200	720	50

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

Customer Reported Performance Data

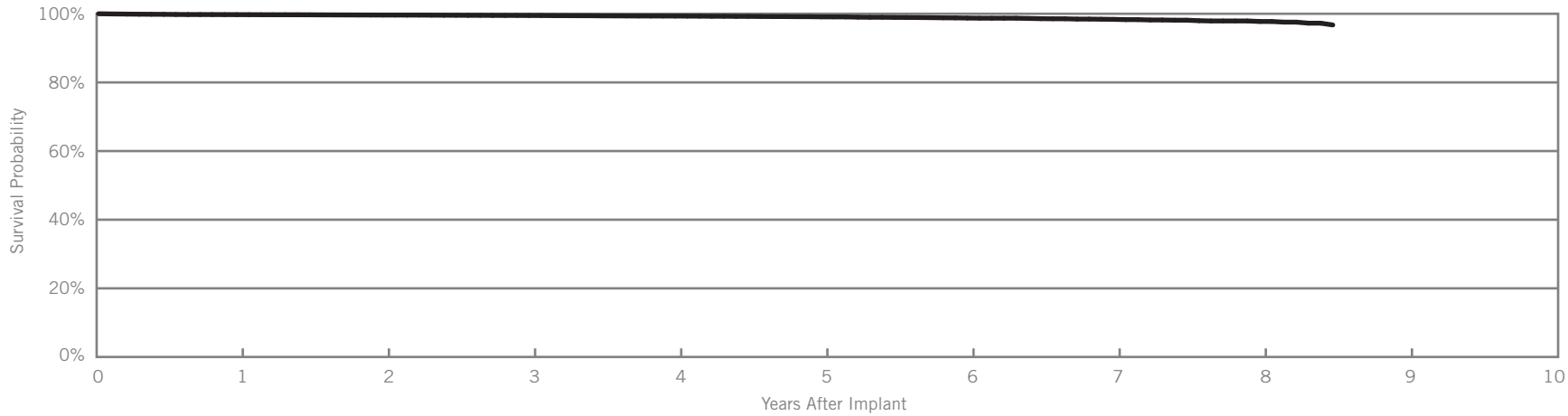
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	43,633
Estimated Active US Implants	27,867
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%	7	0.02%
Lead Dislodgement	38	0.09%	93	0.21%
Failure to Capture	10	0.02%	50	0.11%
Oversensing	5	0.01%	95	0.22%
Failure to Sense	4	<0.01%	11	0.03%
Insulation Breach	0	0.00%	27	0.06%
Abnormal Pacing Impedance	0	0.00%	8	0.02%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	13	0.03%	18	0.04%
Total	**73**	**0.17%**	**313**	**0.72%**
Total Returned for Analysis	**42**		**118**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Insulation Breach	38	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	102	0.23%
Total	**145**	**0.33%**



Year	1	2	3	4	5	6	7	8	at 102 months	
Survival Probability	99.73%	99.62%	99.50%	99.36%	99.14%	98.79%	98.44%	97.76%	96.79%	
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.06%	0.09%	0.13%	0.23%	0.43%	
Sample Size	38,600	29,840	22,950	16,960	11,790	7,470	3,960	1,560	230	

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

Actively Monitored Study Data

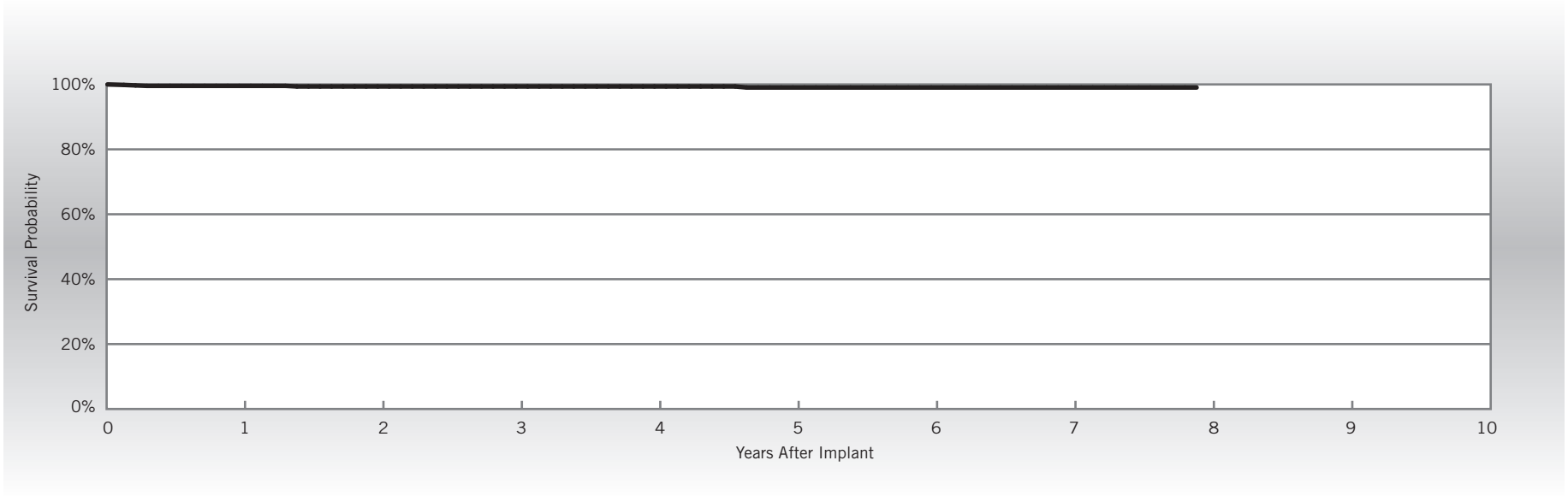
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	689
Active Devices Enrolled in Study	303
Cumulative Months of Follow-up	34,107
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Extracardiac Stimulation	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	at 95 months		
Survival Probability	99.56%	99.38%	99.38%	99.38%	99.05%	99.05%	99.05%	99.05%		
± 1 standard error	0.26%	0.31%	0.31%	0.31%	0.45%	0.45%	0.45%	0.45%		
Sample Size	650	560	450	370	310	260	180	60		

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

Customer Reported Performance Data

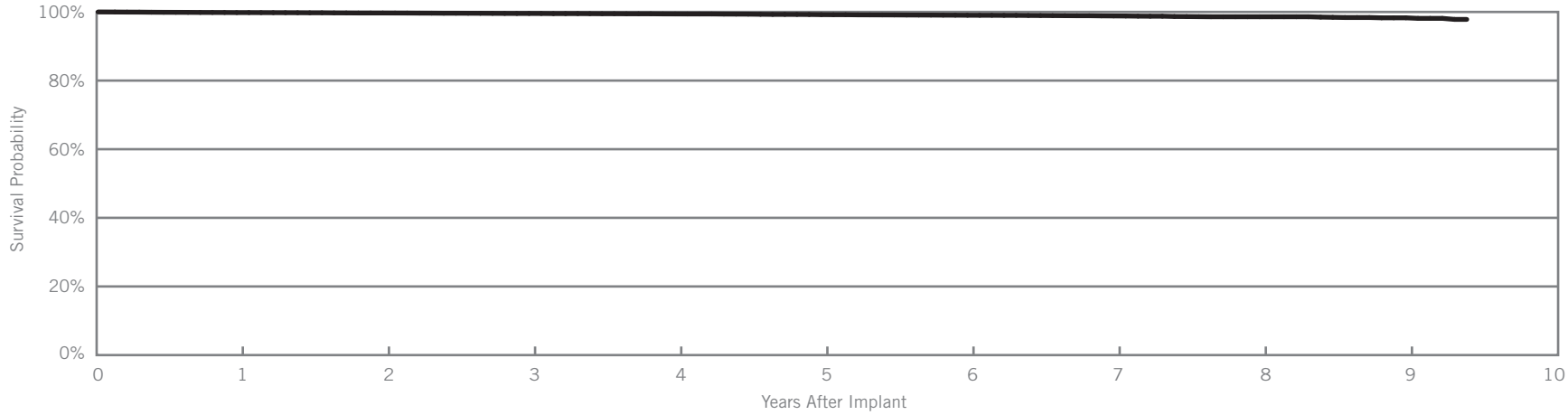
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,399
Estimated Active US Implants	7,848
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%	2	0.01%
Lead Dislodgement	13	0.08%	42	0.26%
Failure to Capture	5	0.03%	34	0.21%
Oversensing	0	0.00%	36	0.22%
Failure to Sense	0	0.00%	5	0.03%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	2	0.01%	13	0.08%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	2	0.01%
Total	**29**	**0.18%**	**138**	**0.84%**
Total Returned for Analysis	**16**		**53**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	20	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	46	0.28%
Total	**67**	**0.41%**



Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.82%	99.70%	99.56%	99.41%	99.19%	99.01%	98.81%	98.57%	98.26%	97.55%
± 1 standard error	0.03%	0.04%	0.06%	0.07%	0.08%	0.10%	0.11%	0.14%	0.20%	0.47%
Sample Size	15,310	13,540	12,200	10,840	9,320	7,540	5,640	3,710	1,700	280

Actively Monitored Study Data

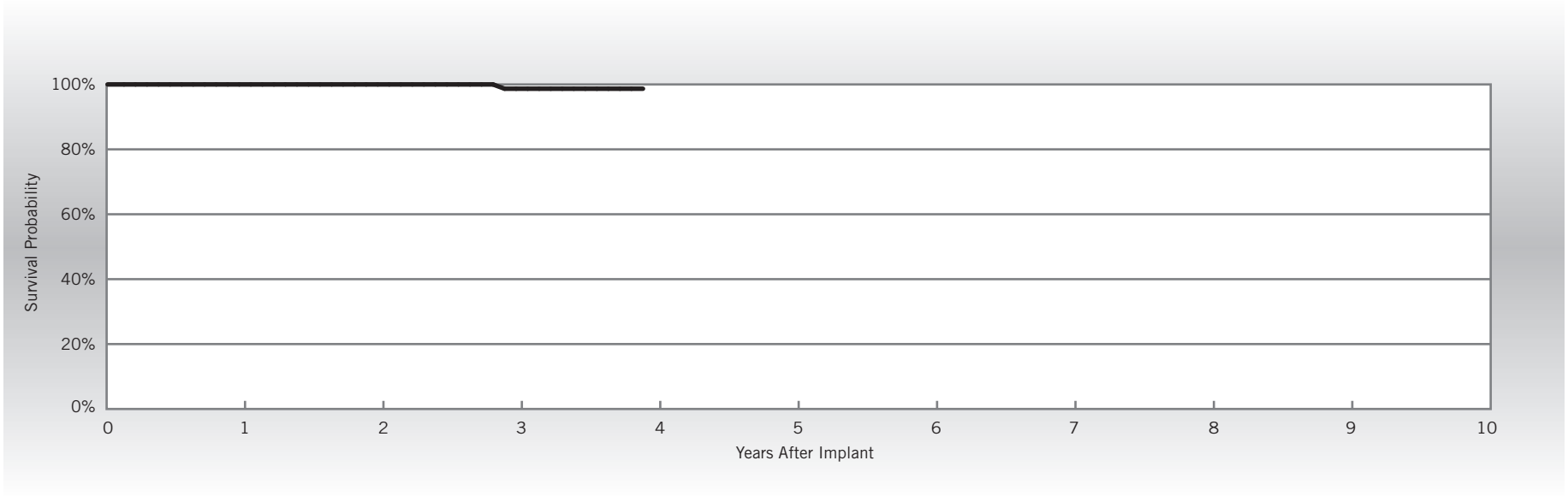
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	165
Active Devices Enrolled in Study	26
Cumulative Months of Follow-up	5,747
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 47 months						
Survival Probability	100.00%	100.00%	98.68%	98.68%						
± 1 standard error	0.00%	0.00%	1.32%	1.32%						
Sample Size	150	120	80	50						

Customer Reported Performance Data

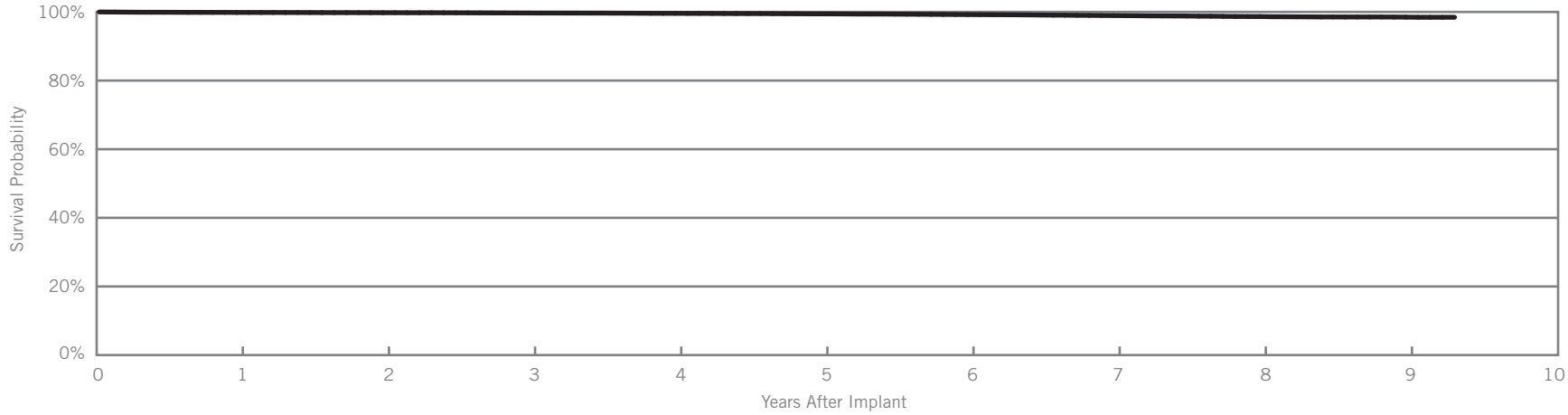
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,181
Estimated Active US Implants	28,597
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%	20	0.03%
Lead Dislodgement	31	0.05%	72	0.11%
Failure to Capture	30	0.05%	129	0.20%
Oversensing	2	<0.01%	135	0.21%
Failure to Sense	2	<0.01%	21	0.03%
Insulation Breach	1	<0.01%	28	0.04%
Abnormal Pacing Impedance	9	0.01%	38	0.06%
Extracardiac Stimulation	2	<0.01%	6	<0.01%
Other	20	0.03%	24	0.04%
Total	**110**	**0.17%**	**480**	**0.74%**
Total Returned for Analysis	**46**		**138**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	8	0.01%
Insulation Breach	89	0.14%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	98	0.15%
Total	**197**	**0.30%**



Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.84%	99.78%	99.68%	99.58%	99.44%	99.25%	98.96%	98.68%	98.47%	98.43%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.08%	0.09%
Sample Size	60,620	53,030	47,290	42,200	37,620	32,950	27,200	19,620	9,240	500

Actively Monitored Study Data

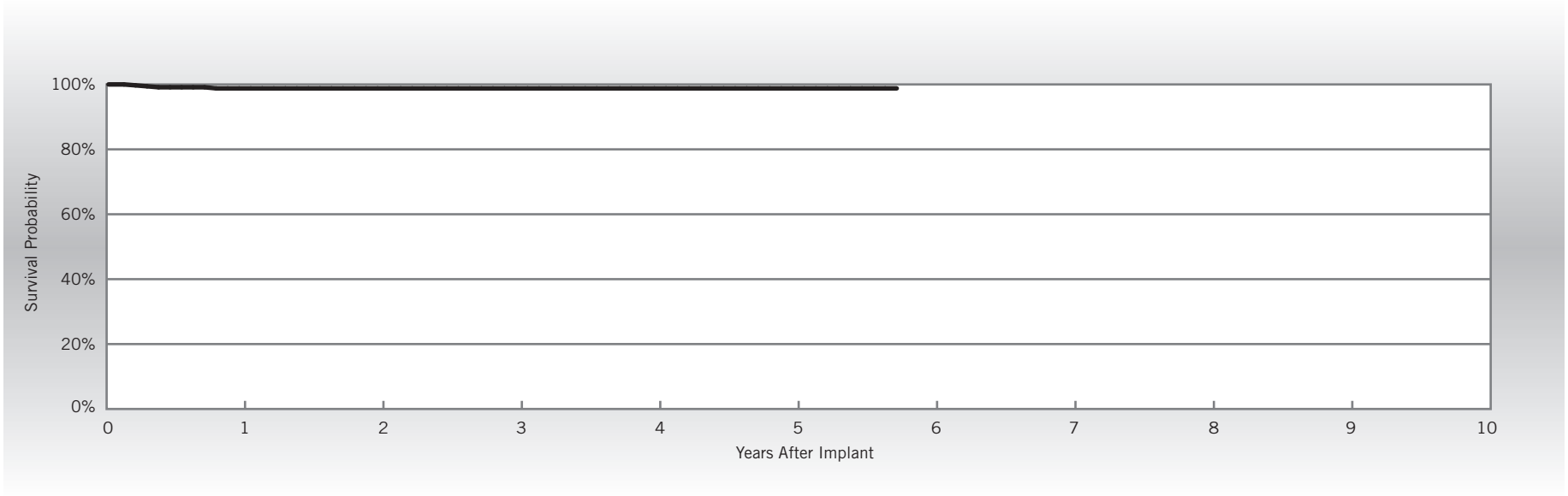
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	363
Active Devices Enrolled in Study	73
Cumulative Months of Follow-up	11,569
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	at 69 months				
Survival Probability	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%				
Sample Size	320	240	180	110	70	50				

Customer Reported Performance Data

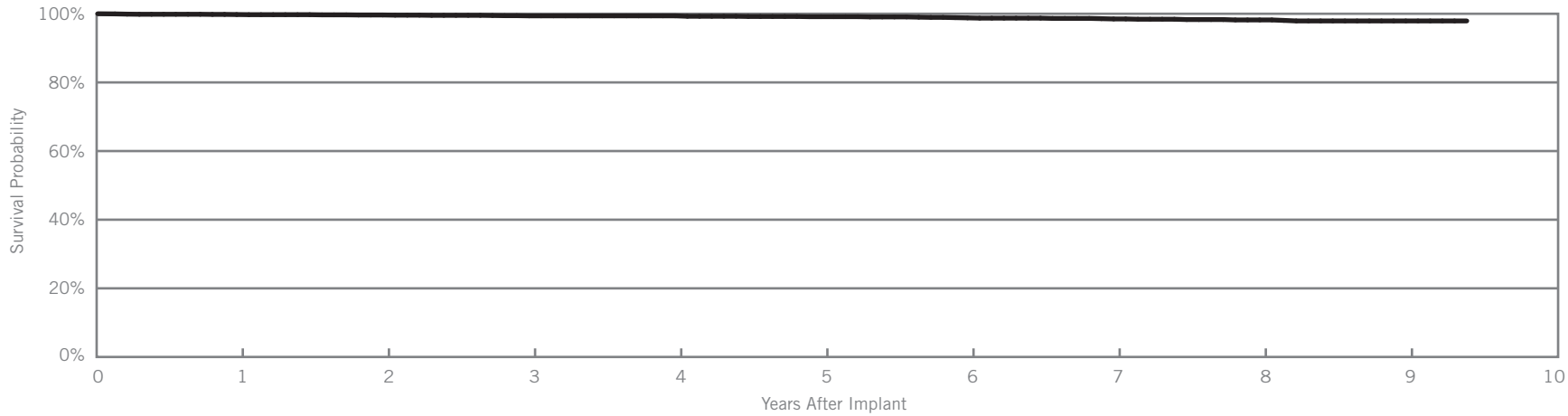
IsoFlex™ P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,834
Estimated Active US Implants	1,196
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%	7	0.25%
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%**	**30**	**1.06%**
Total Returned for Analysis	**1**		**5**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	10	0.35%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.07%
Extrinsic Factors	4	0.14%
Total	**16**	**0.56%**



Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.77%	99.64%	99.39%	99.39%	99.15%	98.80%	98.49%	98.20%	97.91%	97.91%
± 1 standard error	0.08%	0.12%	0.16%	0.16%	0.20%	0.24%	0.29%	0.34%	0.40%	0.40%
Sample Size	2,620	2,270	2,020	1,820	1,640	1,470	1,290	980	530	210

Customer Reported Performance Data

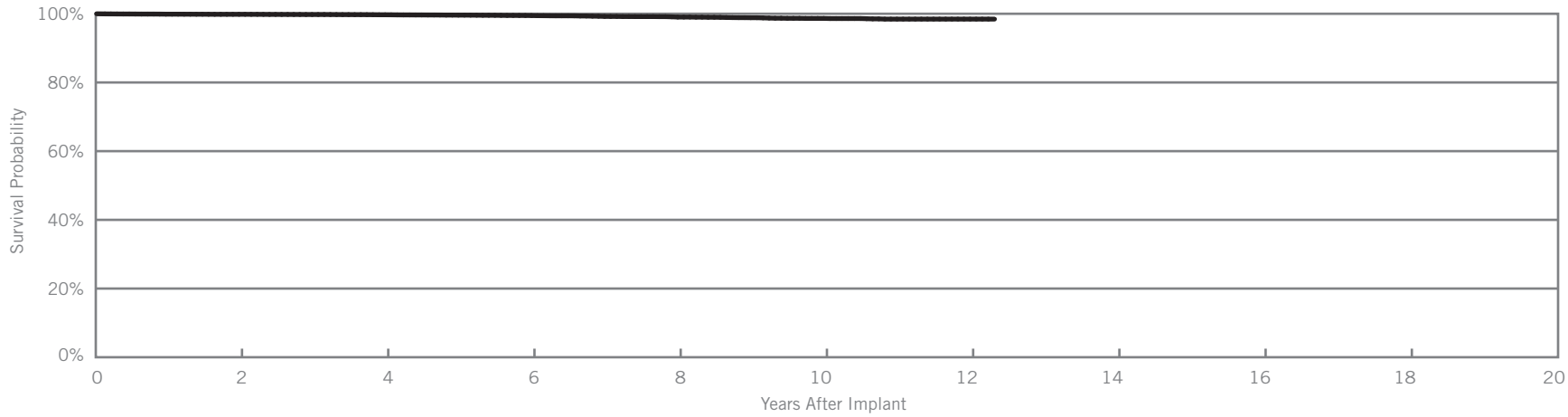
IsoFlex™ S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	27,093
Estimated Active US Implants	11,268
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%	39	0.14%
Failure to Capture	6	0.02%	49	0.18%
Oversensing	0	0.00%	30	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%	6	0.02%
Extracardiac Stimulation	1	<0.01%	2	<0.01%
Other	0	0.00%	2	<0.01%
Total	**62**	**0.23%**	**155**	**0.57%**
Total Returned for Analysis	**39**		**23**	

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	17	0.06%
Total	**39**	**0.14%**



Year	2	4	6	8	10	12	at 148 months			
Survival Probability	99.83%	99.70%	99.48%	99.06%	98.69%	98.49%	98.49%			
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.13%	0.16%	0.16%			
Sample Size	22,200	17,760	13,080	8,070	3,710	910	210			

Customer Reported Performance Data

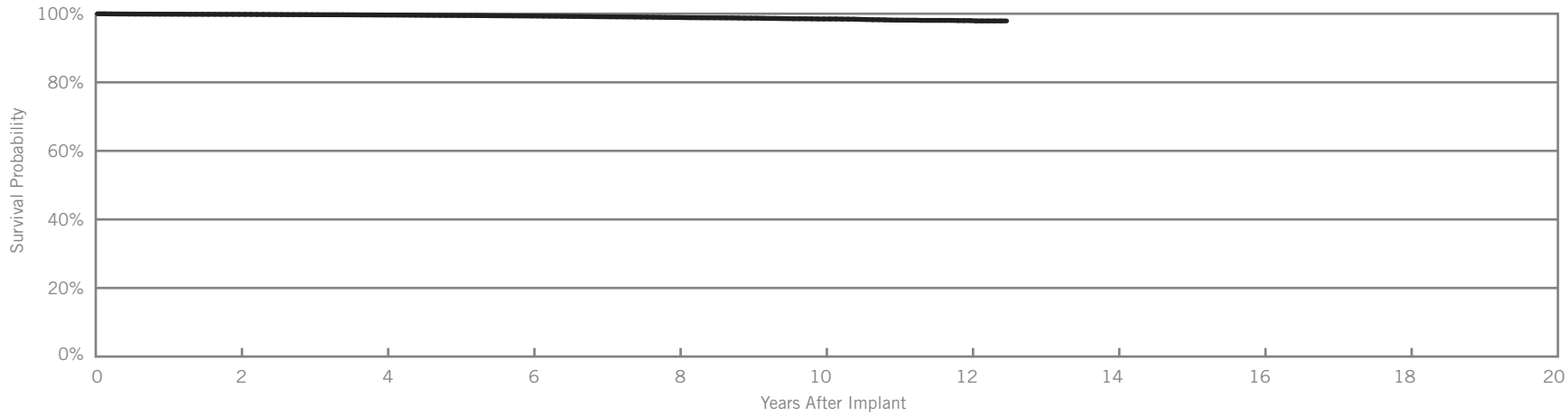
IsoFlex™ S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	90,287
Estimated Active US Implants	36,323
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%	86	0.10%
Lead Dislodgement	37	0.04%	34	0.04%
Failure to Capture	33	0.04%	246	0.27%
Oversensing	0	0.00%	95	0.11%
Failure to Sense	2	<0.01%	11	0.01%
Insulation Breach	2	<0.01%	38	0.04%
Abnormal Pacing Impedance	6	<0.01%	92	0.10%
Extracardiac Stimulation	0	0.00%	3	<0.01%
Other	2	<0.01%	17	0.02%
Total	**88**	**0.10%**	**624**	**0.69%**
Total Returned for Analysis	**38**		**86**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	20	0.02%
Insulation Breach	43	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	6	<0.01%
Extrinsic Factors	61	0.07%
Total	**130**	**0.14%**



Year	2	4	6	8	10	12	at 150 months			
Survival Probability	99.81%	99.62%	99.33%	98.90%	98.44%	97.96%	97.87%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.08%	0.13%	0.16%			
Sample Size	72,700	56,950	40,670	24,760	11,220	2,620	290			

Actively Monitored Study Data

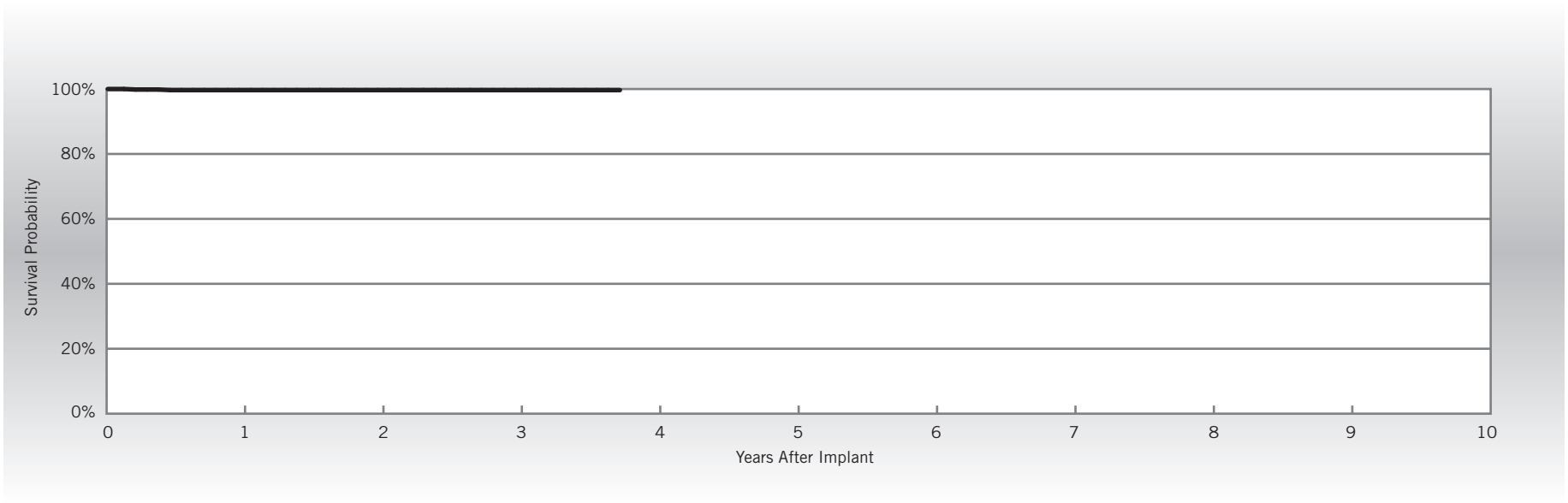
IsoFlex™ S

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	15,751
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	1	0.16%
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	99.67%	99.67%	99.67%	99.67%						
± 1 standard error	0.23%	0.23%	0.23%	0.23%						
Sample Size	570	410	250	60						

Customer Reported Performance Data

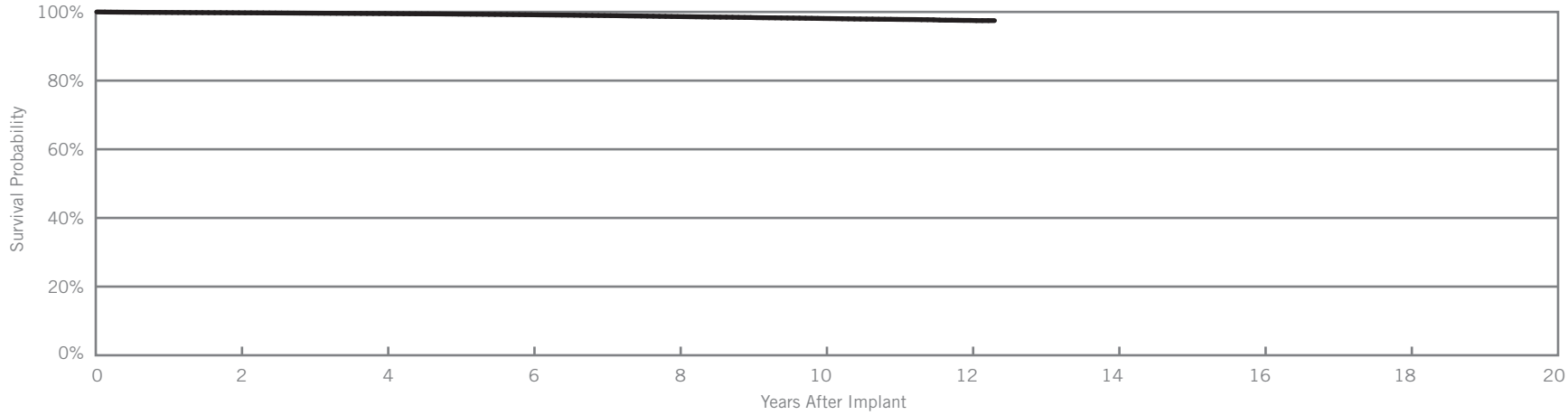
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	472,130
Estimated Active US Implants	260,979
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	73	0.02%	33	<0.01%
Conductor Fracture	4	<0.01%	370	0.08%
Lead Dislodgement	291	0.06%	463	0.10%
Failure to Capture	175	0.04%	1065	0.23%
Oversensing	16	<0.01%	1081	0.23%
Failure to Sense	31	<0.01%	114	0.02%
Insulation Breach	10	<0.01%	185	0.04%
Abnormal Pacing Impedance	28	<0.01%	456	0.10%
Extracardiac Stimulation	6	<0.01%	35	<0.01%
Other	59	0.01%	130	0.03%
Total	**693**	**0.15%**	**3932**	**0.83%**
Total Returned for Analysis	**323**		**1095**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	189	0.04%
Insulation Breach	641	0.14%
Crimps, Welds & Bonds	2	<0.01%
Other	14	<0.01%
Extrinsic Factors	657	0.14%
Total	**1503**	**0.32%**



Year	2	4	6	8	10	12	at 148 months			
Survival Probability	99.75%	99.52%	99.19%	98.66%	98.09%	97.54%	97.48%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%	0.08%	0.10%			
Sample Size	373,590	275,720	194,280	124,670	62,050	9,370	530			

Actively Monitored Study Data

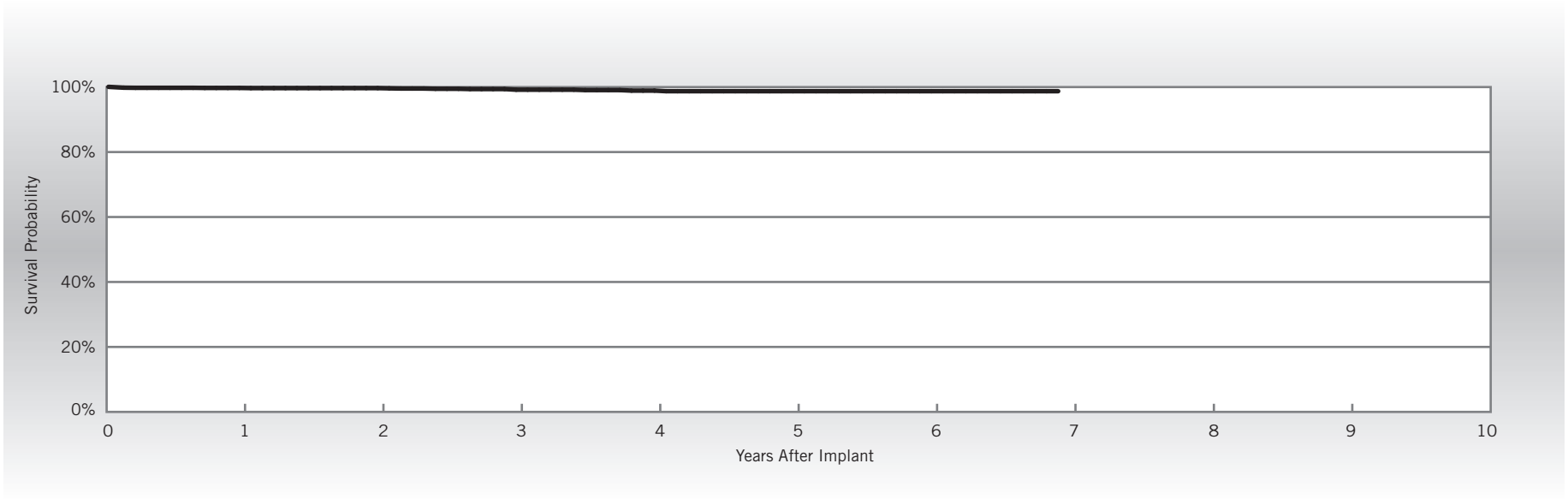
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	2,637
Active Devices Enrolled in Study	532
Cumulative Months of Follow-up	82,855
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	3	0.11%
Conductor Fracture	1	0.04%
Failure to Capture	2	0.08%
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	at 83 months			
Survival Probability	99.73%	99.68%	99.19%	98.91%	98.73%	98.73%	98.73%			
± 1 standard error	0.10%	0.11%	0.18%	0.30%	0.35%	0.35%	0.35%			
Sample Size	2,380	1,840	1,280	790	430	220	50			

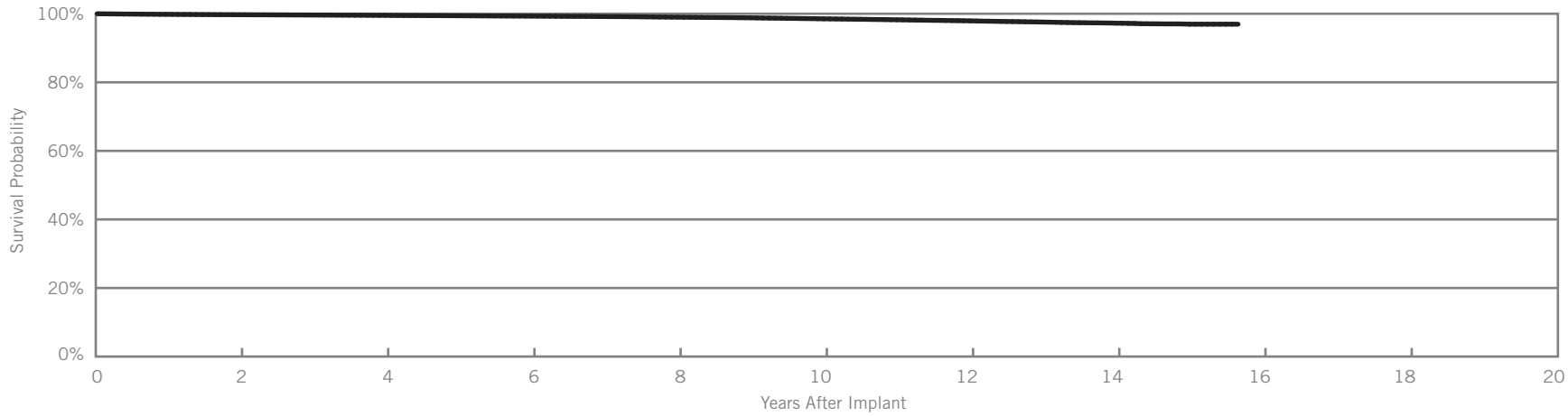
Customer Reported Performance Data

Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	271,461
Estimated Active US Implants	69,416
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	154	0.06%
Insulation Breach	245	0.09%
Crimps, Welds & Bonds	5	<0.01%
Other	3	<0.01%
Extrinsic Factors	347	0.13%
Total	**754**	**0.28%**



Year	2	4	6	8	10	12	14	at 188 months		
Survival Probability	99.71%	99.52%	99.29%	99.00%	98.51%	97.92%	97.24%	96.96%		
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.07%	0.10%		
Sample Size	224,320	181,400	141,840	108,670	81,800	53,410	19,650	350		

Actively Monitored Study Data

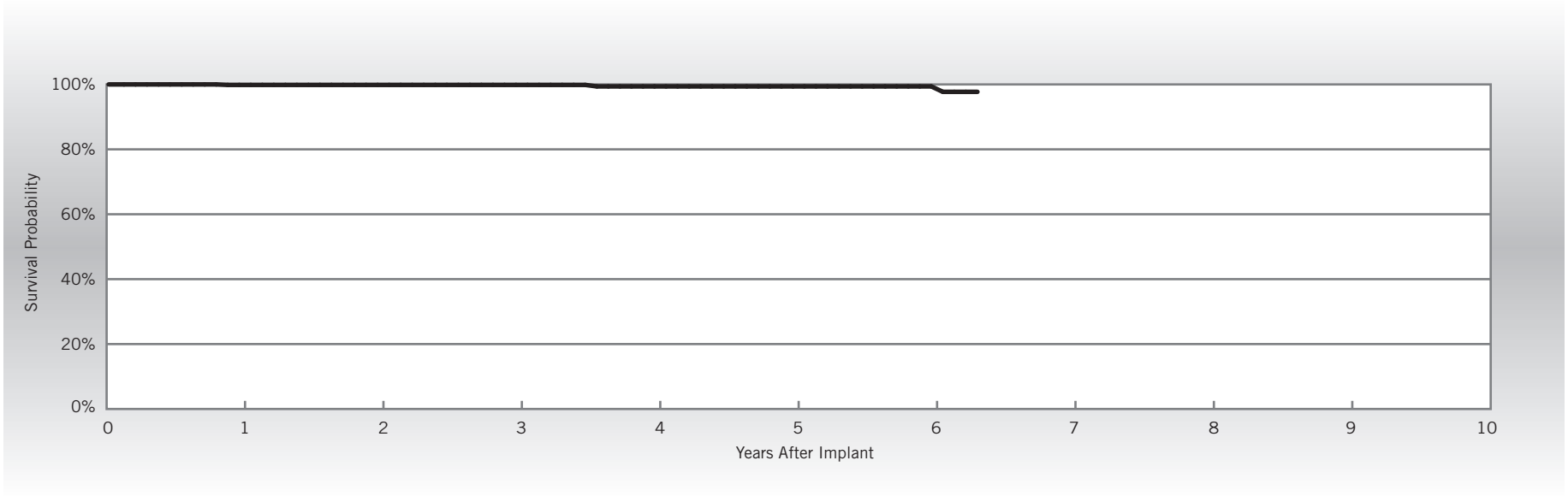
Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	802
Active Devices Enrolled in Study	102
Cumulative Months of Follow-up	25,711
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%**



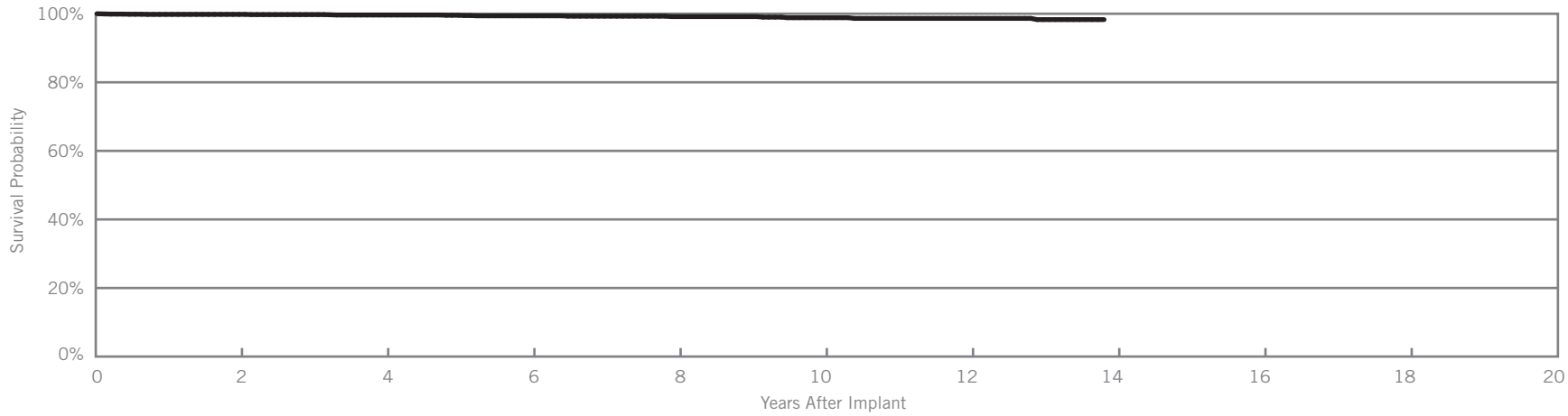
Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.85%	99.85%	99.85%	99.39%	99.39%	99.39%	97.72%			
± 1 standard error	0.15%	0.15%	0.15%	0.48%	0.48%	0.48%	1.72%			
Sample Size	730	580	400	220	110	70	50			

Customer Reported Performance Data

AV Plus™ DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,811
Estimated Active US Implants	836
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



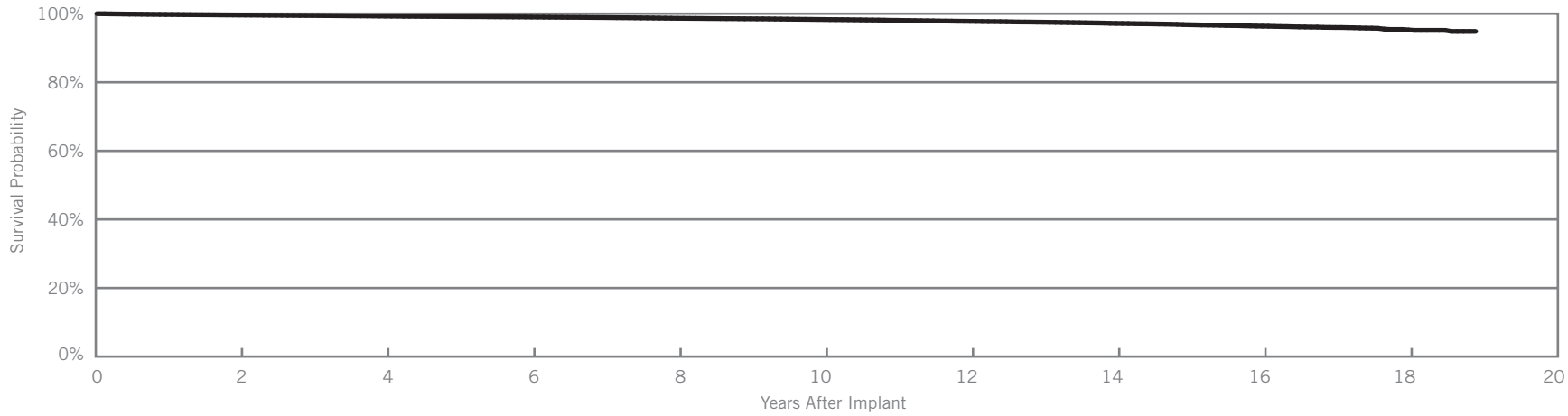
Year	2	4	6	8	10	12	at 166 months			
Survival Probability	99.81%	99.63%	99.39%	99.16%	98.84%	98.64%	98.29%			
± 1 standard error	0.09%	0.13%	0.19%	0.25%	0.34%	0.39%	0.53%			
Sample Size	2,130	1,570	1,140	840	600	390	200			

Customer Reported Performance Data

Tendril™ DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Registered US Implants	266,491
Estimated Active US Implants	53,526
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 227 months
Survival Probability	99.62%	99.31%	99.03%	98.67%	98.32%	97.78%	97.19%	96.38%	95.28%	94.85%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.05%	0.06%	0.08%	0.16%	0.37%
Sample Size	219,980	177,640	140,560	108,520	78,330	53,490	34760	18,700	4,220	200

Actively Monitored Study Data

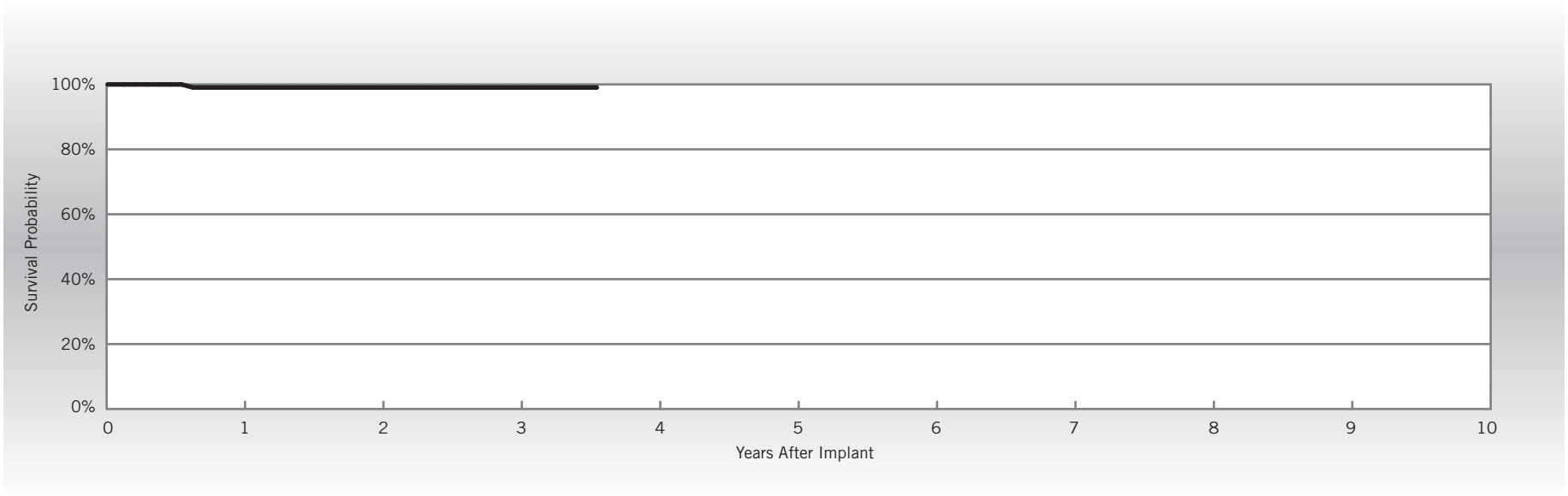
Tendril™ DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Number of Devices Enrolled in Study	238
Active Devices Enrolled in Study	17
Cumulative Months of Follow-up	7,001
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	1	0.42%
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%**



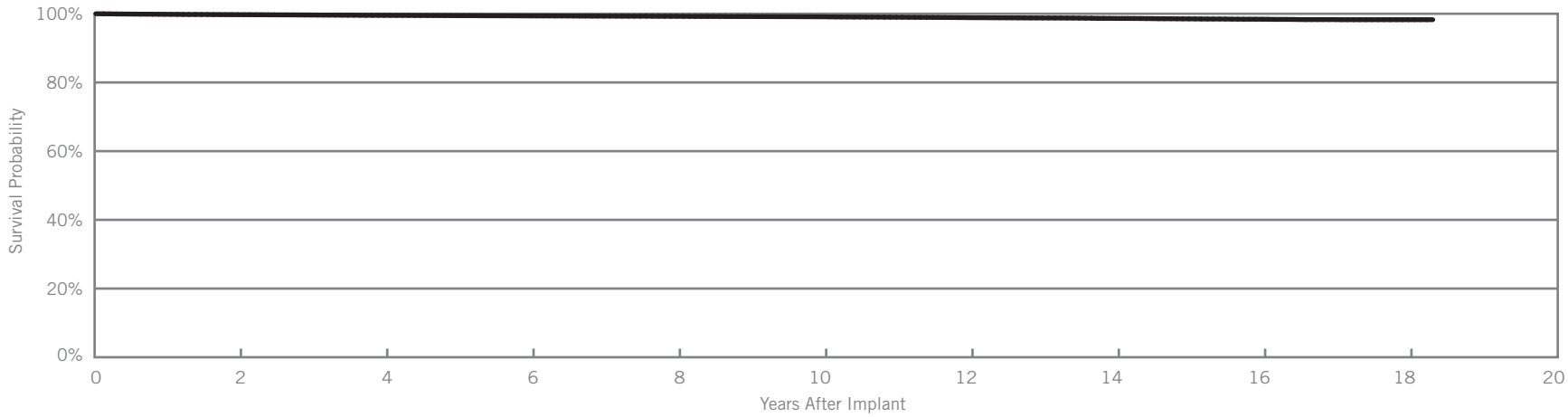
Year	1	2	3	at 43 months						
Survival Probability	99.05%	99.05%	99.05%	99.05%						
± 1 standard error	0.67%	0.67%	0.67%	0.67%						
Sample Size	220	170	110	50						

Customer Reported Performance Data

Passive Plus™ DX

Models 1336T, 1342T & 1346T

US Regulatory Approval	(1336T) August 1999; (1342T, 1346T) January 1998
Registered US Implants	198,469
Estimated Active US Implants	39,497
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 220 months
Survival Probability	99.73%	99.53%	99.37%	99.26%	99.11%	98.86%	98.63%	98.40%	98.27%	98.27%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%	0.06%	0.08%	0.08%
Sample Size	161,310	128,930	100,950	77,720	58,490	43,260	26,960	11,940	1,830	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	99.79%	99.64%	99.47%	99.24%	98.99%	98.74%				
1999	OptiSense™ Optim™	99.69%	99.55%	99.38%	99.16%	99.06%					
1944	IsoFlex™ Optim™	99.71%	99.59%	99.45%	99.31%	99.10%	98.90%	98.40%			
1948	IsoFlex™ Optim™	99.81%	99.68%	99.50%	99.22%	98.88%	98.46%	97.77%			
1699T/TC	OptiSense™	99.82%	99.72%	99.58%	99.50%	99.32%	99.09%	98.81%	98.54%		
1888T/TC	Tendril™ ST Optim™	99.79%	99.64%	99.46%	99.24%	98.95%	98.61%	98.17%	97.69%	97.34%	
1882T/TC	Tendril™ ST Optim™	99.73%	99.62%	99.50%	99.36%	99.14%	98.79%	98.44%	97.76%		
1782T/TC	Tendril™	99.82%	99.70%	99.56%	99.41%	99.19%	99.01%	98.81%	98.57%	98.26%	
1788T/TC	Tendril™	99.84%	99.78%	99.68%	99.58%	99.44%	99.25%	98.96%	98.68%	98.47%	
1648T	IsoFlex™ P	99.77%	99.64%	99.39%	99.39%	99.15%	98.80%	98.49%	98.20%	97.91%	
1642T	IsoFlex™ S	99.88%	99.83%	99.78%	99.70%	99.61%	99.48%	99.26%	99.06%	98.88%	98.69%
1646T	IsoFlex™ S	99.87%	99.81%	99.71%	99.62%	99.49%	99.33%	99.11%	98.90%	98.69%	98.44%
1688T/TC	Tendril™ SDX	99.85%	99.75%	99.64%	99.52%	99.37%	99.19%	98.95%	98.66%	98.39%	98.09%
1488T/TC	Tendril™ SDX	99.82%	99.71%	99.62%	99.52%	99.41%	99.29%	99.18%	99.00%	98.81%	98.51%
1368	AV Plus™ DX	99.81%	99.81%	99.75%	99.63%	99.55%	99.39%	99.29%	99.16%	99.16%	98.84%
1388T/TC	Tendril™ + DX	99.77%	99.62%	99.48%	99.31%	99.16%	99.03%	98.88%	98.67%	98.52%	98.32%
1336T, 1342T, 1346T	Passive Plus™ DX	99.84%	99.73%	99.63%	99.53%	99.45%	99.37%	99.31%	99.26%	99.19%	99.11%

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	425,470	327,035	66	0.02%	5	<0.01%	378	0.09%	103	0.02%	31	<0.01%	17	<0.01%	10	<0.01%	24	<0.01%	3	<0.01%	87	0.02%	**724**	**0.17%**	**346**
1999	May-07	40,670	28,533	2	<0.01%	0	0.00%	48	0.12%	6	0.01%	5	0.01%	3	<0.01%	1	<0.01%	0	0.00%	0	0.00%	10	0.02%	**75**	**0.18%**	**44**
1944	Mar-08	14,223	9,491	0	0.00%	0	0.00%	49	0.34%	7	0.05%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	**61**	**0.43%**	**35**
1948	Mar-08	53,449	35,836	2	<0.01%	0	0.00%	36	0.07%	23	0.04%	1	<0.01%	1	<0.01%	4	<0.01%	1	<0.01%	1	<0.01%	5	<0.01%	**74**	**0.14%**	**38**
1699T/TC	May-07	22,873	11,497	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	299,938	168,571	39	0.01%	7	<0.01%	153	0.05%	84	0.03%	16	<0.01%	14	<0.01%	7	<0.01%	9	<0.01%	5	<0.01%	40	0.01%	**374**	**0.12%**	**197**
1882T/TC	Jun-06	43,633	27,867	3	<0.01%	0	0.00%	38	0.09%	10	0.02%	5	0.01%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	13	0.03%	**73**	**0.17%**	**42**
1782T/TC	Feb-06	16,399	7,848	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	65,181	28,597	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	1,196	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	27,093	11,268	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	90,287	36,323	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	472,130	260,979	73	0.02%	4	<0.01%	291	0.06%	175	0.04%	16	<0.01%	31	<0.01%	10	<0.01%	28	<0.01%	6	<0.01%	59	0.01%	**693**	**0.15%**	**323**

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	425,470	327,035	35	<0.01%	100	0.02%	476	0.11%	346	0.08%	863	0.20%	64	0.02%	115	0.03%	75	0.02%	14	<0.01%	84	0.02%	**2172**	**0.51%**	**853**
1999	May-07	40,670	28,533	0	0.00%	2	<0.01%	111	0.27%	32	0.08%	68	0.17%	14	0.03%	21	0.05%	3	<0.01%	0	0.00%	11	0.03%	**262**	**0.64%**	**122**
1944	Mar-08	14,223	9,491	1	<0.01%	4	0.03%	35	0.25%	17	0.12%	24	0.17%	4	0.03%	4	0.03%	1	<0.01%	1	<0.01%	2	0.01%	**93**	**0.65%**	**19**
1948	Mar-08	53,449	35,836	9	0.02%	42	0.08%	44	0.08%	72	0.13%	109	0.20%	2	<0.01%	28	0.05%	19	0.04%	2	<0.01%	4	<0.01%	**331**	**0.62%**	**72**
1699T/TC	May-07	22,873	11,497	0	0.00%	11	0.05%	40	0.17%	30	0.13%	62	0.27%	18	0.08%	4	0.02%	16	0.07%	3	0.01%	3	0.01%	**187**	**0.82%**	**61**
1888T/TC	Jun-06	299,938	168,571	37	0.01%	163	0.05%	458	0.15%	539	0.18%	1130	0.38%	91	0.03%	223	0.07%	167	0.06%	30	0.01%	78	0.03%	**2916**	**0.97%**	**979**
1882T/TC	Jun-06	43,633	27,867	3	<0.01%	7	0.02%	93	0.21%	50	0.11%	95	0.22%	11	0.03%	27	0.06%	8	0.02%	1	<0.01%	18	0.04%	**313**	**0.72%**	**118**
1782T/TC	Feb-06	16,399	7,848	0	0.00%	2	0.01%	42	0.26%	34	0.21%	36	0.22%	5	0.03%	3	0.02%	13	0.08%	1	<0.01%	2	0.01%	**138**	**0.84%**	**53**
1788T/TC	Feb-06	65,181	28,597	7	0.01%	20	0.03%	72	0.11%	129	0.20%	135	0.21%	21	0.03%	28	0.04%	38	0.06%	6	<0.01%	24	0.04%	**480**	**0.74%**	**138**
1648T	Apr-05	2,834	1,196	0	0.00%	4	0.14%	2	0.07%	8	0.28%	2	0.07%	1	0.04%	7	0.25%	3	0.11%	0	0.00%	3	0.11%	**30**	**1.06%**	**5**
1642T	May-02	27,093	11,268	0	0.00%	6	0.02%	39	0.14%	49	0.18%	30	0.11%	15	0.06%	6	0.02%	6	0.02%	2	<0.01%	2	<0.01%	**155**	**0.57%**	**23**
1646T	May-02	90,287	36,323	2	<0.01%	86	0.10%	34	0.04%	246	0.27%	95	0.11%	11	0.01%	38	0.04%	92	0.10%	3	<0.01%	17	0.02%	**624**	**0.69%**	**86**
1688T/TC	Jun-03	472,130	260,979	33	<0.01%	370	0.08%	463	0.10%	1065	0.23%	1081	0.23%	114	0.02%	185	0.04%	456	0.10%	35	<0.01%	130	0.03%	**3932**	**0.83%**	**1095**

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	425,470	2.40%	25	<0.01%	309	0.07%	0	0.00%	22	<0.01%	652	0.15%	**1008**	**0.24%**
1999	40,670	2.50%	3	<0.01%	20	0.05%	0	0.00%	4	<0.01%	111	0.27%	**138**	**0.34%**
1944	14,223	3.40%	0	0.00%	5	0.04%	0	0.00%	1	<0.01%	16	0.11%	**22**	**0.15%**
1948	53,449	2.20%	7	0.01%	40	0.07%	0	0.00%	1	<0.01%	50	0.09%	**98**	**0.18%**
1699T/TC	22,873	3.90%	13	0.06%	19	0.08%	0	0.00%	0	0.00%	49	0.21%	**81**	**0.35%**
1888T/TC	299,938	3.10%	28	<0.01%	561	0.19%	1	<0.01%	12	<0.01%	690	0.23%	**1292**	**0.43%**
1882T/TC	43,633	2.70%	2	<0.01%	38	0.09%	0	0.00%	3	<0.01%	102	0.23%	**145**	**0.33%**
1782T/TC	16,399	4.10%	1	<0.01%	20	0.12%	0	0.00%	0	0.00%	46	0.28%	**67**	**0.41%**
1788T/TC	65,181	4.30%	8	0.01%	89	0.14%	1	<0.01%	1	<0.01%	98	0.15%	**197**	**0.30%**
1648T	2,834	4.10%	0	0.00%	10	0.35%	0	0.00%	2	0.07%	4	0.14%	**16**	**0.56%**
1642T	27,093	3.60%	0	0.00%	19	0.07%	1	<0.01%	2	<0.01%	17	0.06%	**39**	**0.14%**
1646T	90,287	3.70%	20	0.02%	43	0.05%	0	0.00%	6	<0.01%	61	0.07%	**130**	**0.14%**
1688T/TC	472,130	3.80%	189	0.04%	641	0.14%	2	<0.01%	14	<0.01%	657	0.14%	**1503**	**0.32%**
1488T/TC	271,461	4.00%	154	0.06%	245	0.09%	5	<0.01%	3	<0.01%	347	0.13%	**754**	**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	949,931	1.3%	35	<0.01%	390	0.04%	3	<0.01%	231	0.02%	890	0.09%	**1549**	**0.16%**
1888T/TC	1,027,459	1.2%	47	<0.01%	700	0.07%	2	<0.01%	162	0.02%	1,117	0.11%	**2028**	**0.20%**

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	3,804	2,297	150,734	1	0.03%	1	0.03%	1	0.03%	0	0.00%	2	0.05%	1	0.03%	5	0.13%	14	0.37%	8	0.21%	1	0.03%	0	0.00%	**34**	**0.89%**
1999	855	501	31,661	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	2	0.23%	1	0.12%	10	1.17%	1	0.12%	0	0.00%	0	0.00%	**16**	**1.87%**
1944	104	39	5,162	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	241	29,927	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.13%	2	0.26%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.39%**
1699T/TC	1,451	419	63,583	1	0.07%	0	0.00%	1	0.07%	0	0.00%	1	0.07%	0	0.00%	1	0.07%	8	0.55%	1	0.07%	0	0.00%	0	0.00%	**13**	**0.90%**
1888T/TC	14,513	5,435	731,028	6	0.04%	2	0.01%	6	0.04%	4	0.03%	8	0.06%	4	0.03%	25	0.17%	55	0.38%	15	0.10%	0	0.00%	1	<0.01%	**126**	**0.87%**
1882T/TC	689	303	34,107	0	0.00%	0	0.00%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	2	0.29%	1	0.15%	0	0.00%	1	0.15%	**5**	**0.73%**
1782T/TC	165	26	5,747	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	73	11,569	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	15,751	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.16%	0	0.00%	0	0.00%	1	0.16%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.31%**
1688T/TC	2,637	532	82,855	3	0.11%	0	0.00%	1	0.04%	0	0.00%	2	0.08%	0	0.00%	3	0.11%	5	0.19%	2	0.08%	1	0.04%	0	0.00%	**17**	**0.64%**
1488T/TC	802	102	25,711	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	17	7,001	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.42%	0	0.00%	1	0.42%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.84%**

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	3,804	2.80%	0	0.00%	11	0.29%	0	0.00%	0	0.00%	10	0.26%	**21**	**0.55%**
1999	855	3.70%	0	0.00%	2	0.23%	0	0.00%	0	0.00%	8	0.94%	**10**	**1.17%**
1944	104	1.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	766	3.10%	0	0.00%	4	0.52%	0	0.00%	0	0.00%	1	0.13%	**5**	**0.65%**
1699T/TC	1,451	2.60%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	5	0.34%	**6**	**0.41%**
1888T/TC	14,513	2.50%	3	0.02%	21	0.14%	0	0.00%	0	0.00%	33	0.23%	**57**	**0.39%**
1882T/TC	689	3.00%	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	0.90%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	2,637	3.80%	1	0.04%	4	0.15%	0	0.00%	0	0.00%	5	0.19%	**10**	**0.38%**
1488T/TC	802	3.00%	0	0.00%	4	0.50%	0	0.00%	0	0.00%	1	0.12%	**5**	**0.62%**
1388T/TC	238	1.70%	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

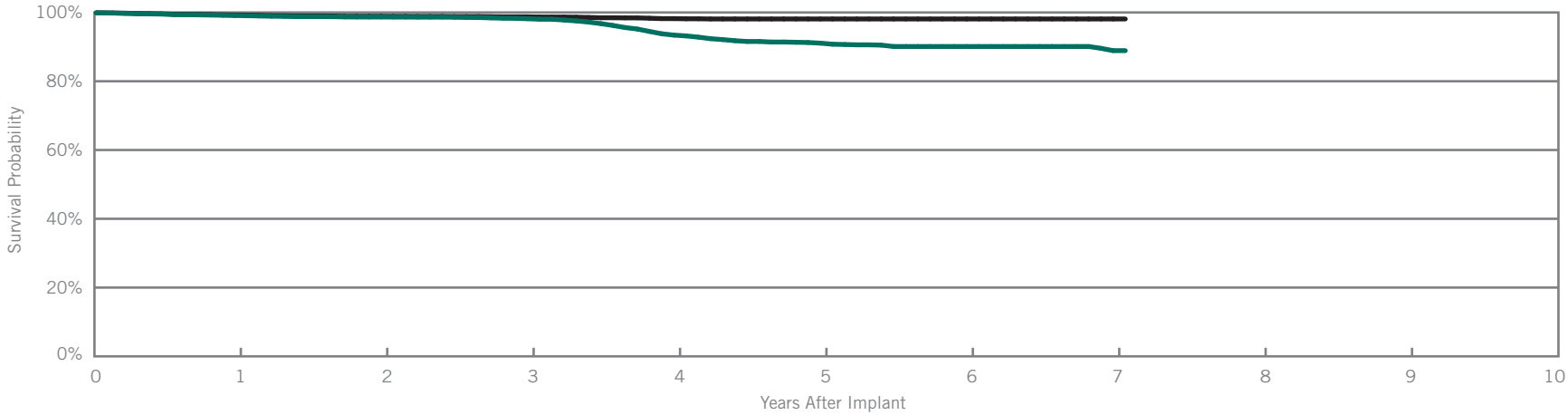
Customer Reported Performance Data

SJM Confirm™

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	18,676
Estimated Active US Implants	8,926
Estimated Longevity	3 Years*
Normal Battery Depletion	157
Number of US Advisories (see pg. 305)	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	36	0.19%
Total	**85**	**0.46%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.12%	98.68%	98.17%	93.41%	91.08%	90.10%	88.90%	88.90%		
± 1 standard error	0.07%	0.09%	0.12%	0.30%	0.39%	0.44%	0.58%	0.74%		
Sample Size	16,130	11,770	8,350	5,460	3,280	1,800	720	230		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.27%	98.90%	98.74%	98.21%	98.11%	98.11%	98.11%	98.11%		
± 1 standard error	0.07%	0.09%	0.10%	0.14%	0.15%	0.15%	0.15%	0.15%		

**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™	99.12%	98.68%	98.17%	93.41%	91.08%	90.10%	88.90%			

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™	99.27%	98.90%	98.74%	98.21%	98.11%	98.11%	98.11%			

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™	18,676	14.70%	13	0.07%	1	<0.01%	17	0.09%	10	0.05%	0	0.00%	8	0.04%	36	0.19%	**85**	**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 February 29, 2016. The Durata leads CLAS summary is available on page 282.

[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 February 29, 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 546 patients (70%) 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% (3/176) in 7F leads and 4.3% (12/279) in 8F leads (p = 0.13). A total of 425 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 2.2% (3/138) in 7F leads and 7.2% (15/208) in 8F leads (p = 0.04). A total of 293 patients (38%) 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% (1/109) in 7F leads and 10.2% (13/128) in 8F leads (p = 0.003). 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. Fluoroscopy data for 28 additional leads are pending adjudication and the minimum enrollment of Riata/Riata ST leads has been met in the Cardiac Lead Assessment Study.

QuickSite™/QuickFlex™ CLAS Summary (as of February 29, 2016): A total of 600 patients implanted with QuickSite/QuickFlex Left Ventricular CRT leads at 42 centers underwent fluoroscopic evaluation. These include 93 leads implanted in 2006, 113 leads in 2007, 135 leads in 2008, 171 leads in 2009, and 88 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 1.5%. A total of 405 patients (68%) completed at least 1 year of follow-up with fluoroscopic evaluation. The incidence of new EC at 1 year of follow-up was 4.0% (16/400). A total of 216 patients (36%) 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% (2/208). A total of 2 leads were identified as having electrical dysfunction. Neither of these 2 leads exhibited externalized conductors. Fluoroscopy data for 35 additional leads are pending adjudication and enrollment of QuickSite/QuickFlex leads is on-going in the Cardiac Lead Assessment Study.

Customer Reported Performance Data

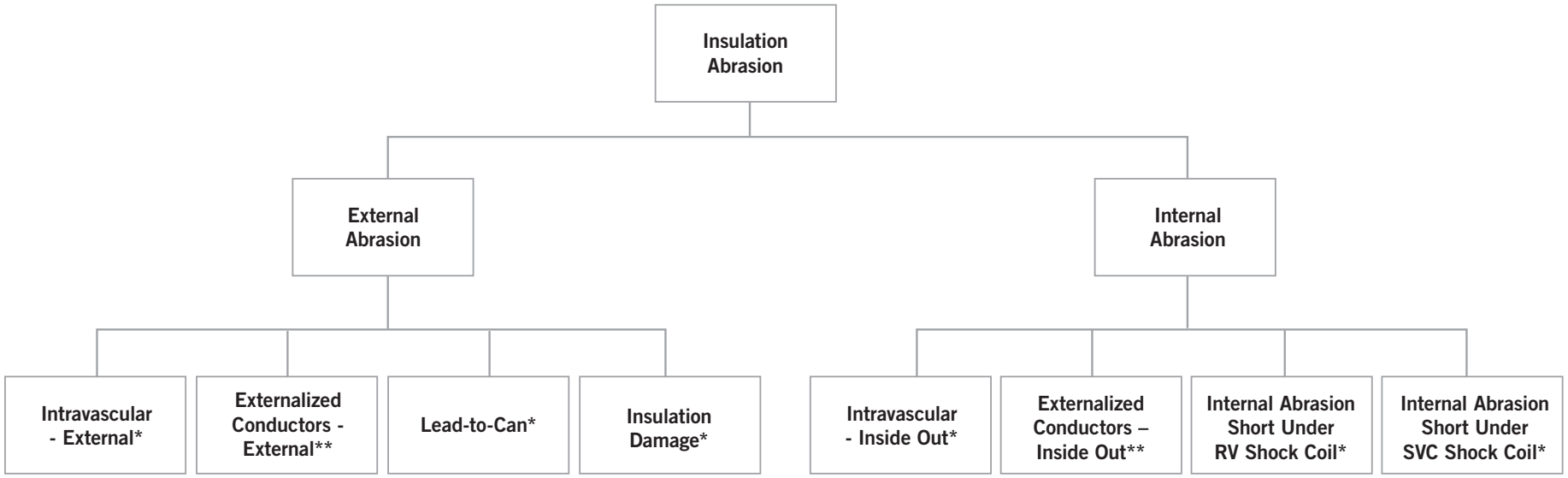
St. Jude Medical understands that the passive system of complaint reporting and returned product analysis results in under-reporting and hence underestimates the true failure rate associated with any given failure mechanism. This is especially true for externalized conductors since most manifest as visual 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 February 29, 2016, there were

5,258 cases of externalized conductors reported to St. Jude Medical worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 2.85% (4,444/156,000) incidence rate for Riata (8F) and 1.15% (814/70,600) for Riata ST (7F) leads. Of these 5,258 leads, 3,960 were not returned and 1,298 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 12,700 Riata and Riata ST leads have been returned for analysis worldwide through February 29, 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	0.45%	0.45%
Externalized Conductors – External**	External Abrasion	0.39%	0.20%
Lead-to-Can*	External Abrasion	0.84%	0.77%
Insulation Damage*	External Abrasion	0.10%	0.06%
Intravascular - Inside Out*	Internal Abrasion	0.48%	0.31%
Externalized Conductors - Inside Out**	Internal Abrasion	2.47%	0.96%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.10%	0.04%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.08%	0.016%

*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 280, 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 February 29, 2016, a total of 893 patients implanted with Durata leads at 42 centers underwent fluoroscopic evaluation. These include 271 leads implanted in 2008, 377 leads in 2009, and 245 leads in 2010, with an implant duration of 4.4±1.0 years (mean±stdev; median = 4.4 years; IQR = 3.6 to 5.1 years) at enrollment. None of the 893 leads at enrollment exhibited externalized conductors. A total of 658 patients (74%) completed 1 year follow-up with fluoroscopic evaluation. The incidence of new EC at 1 year of follow-up was 0.15% (1/658). 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 333 patients (37%) completed 2 years of follow-up with fluoroscopic evaluation. The incidence of new EC at 2 years of follow-up was 0.30% (1/332). 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 10 leads (1.1%) out of the 893 enrolled patients were identified as having electrical dysfunction. None of these 10 leads exhibited externalized conductors. Fluoroscopy data for 28 additional leads are pending adjudication 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 11,099 Optim insulated leads (8,233 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 February 29, 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 February 29, 2016)

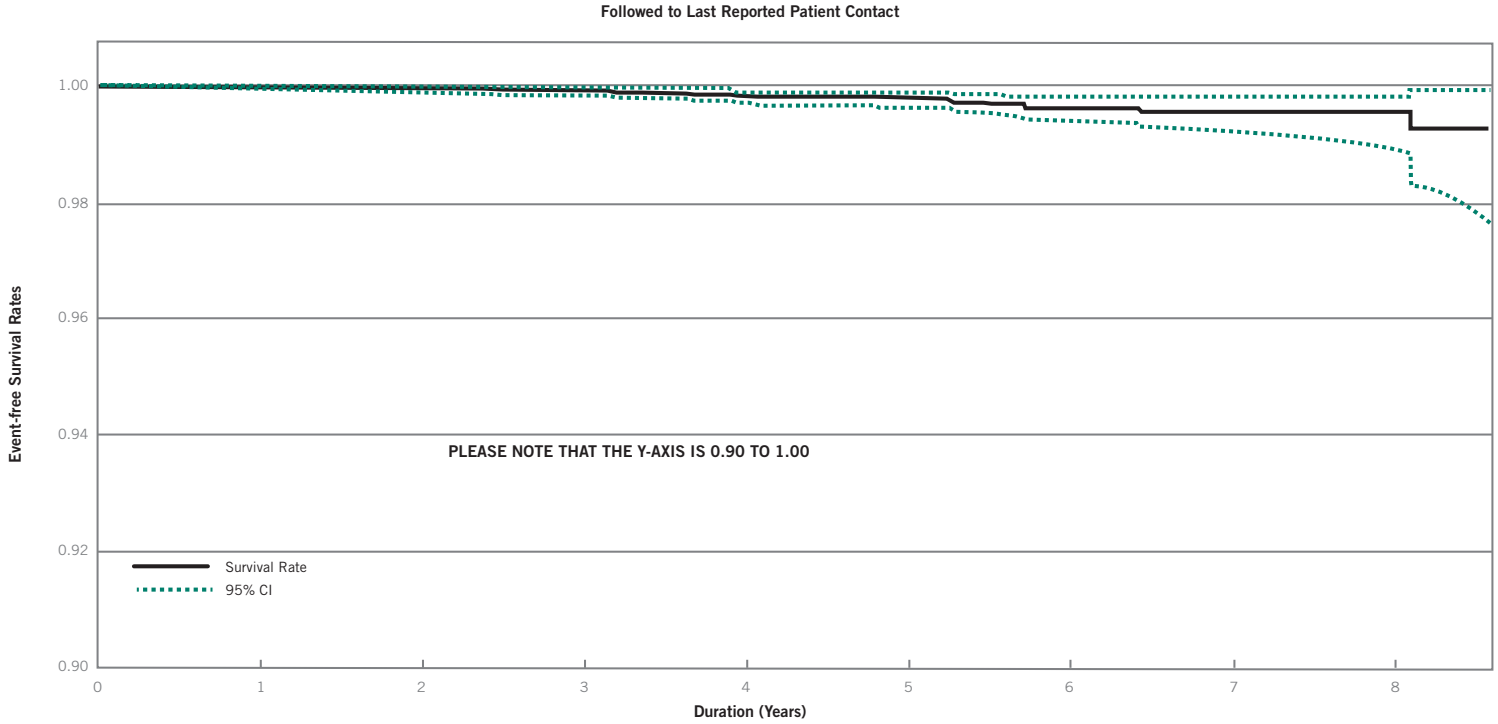
Failure Category	Durata and Riata ST Optim %	Durata and Riata ST Optim 95% CI	Freedom from failures at 8 years (%)
Externalized Conductors	0.00%	0.00% - 0.03%	100%
All-Cause Insulation Abrasion	0.23%	0.15% - 0.32%	99.6%
All-Cause Mechanical Failures	1.02%	0.84% - 1.21%	97.4%

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 adjudicated by PHRI as of October 2014 and those which have not yet been adjudicated by PHRI. The final calculated rates may change slightly once adjudication is completed.

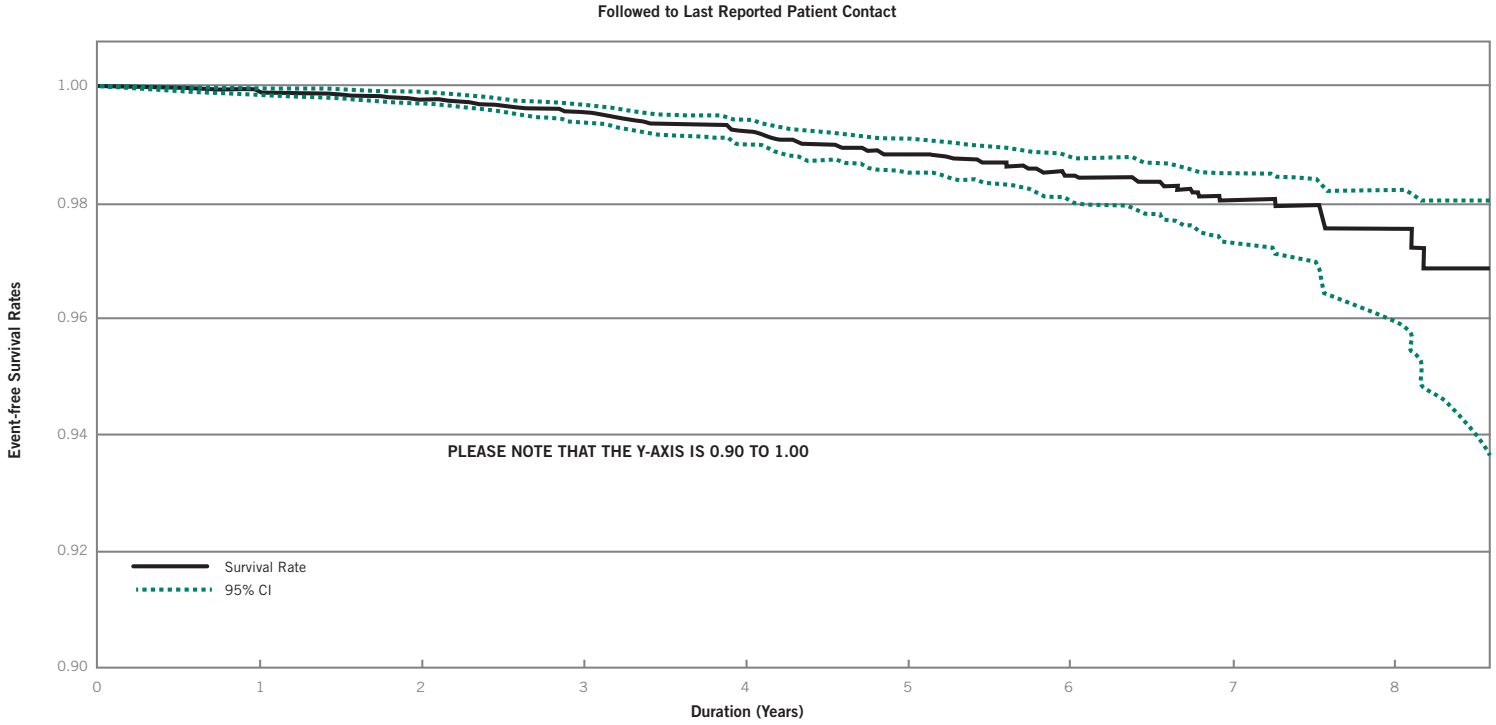
[1] John A. Cairns, Andrew E. Epstein, John Rickard, Stuart J. Connolly, Christopher Buller, Bruce L. Wilkoff, Janice Pogue, Ellison Themeles, Jeff S. Healey, *Prospective long-term evaluation of Optim-insulated (Riata ST Optim and Durata) implantable cardioverter-defibrillator leads,* Heart Rhythm, 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
Leads at Risk	11,099	9,769	8,476	7,251	6,090	4,430	2,769	1,257	343

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
Leads at Risk	11,099	9,768	8,475	7,248	6,087	4,428	2,767	1,254	342

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 17,000 Riata ST Optim and Durata leads have been returned for analysis worldwide through February 29, 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 583,000) 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 = 616,000)
Intravascular – External*	External Abrasion	0.018%
Externalized Conductors – External**	External Abrasion	0.005%
Lead-to-Can*	External Abrasion	0.059%
Insulation Damage*	External Abrasion	0.021%
Intravascular - Inside Out*	Internal Abrasion	0.0008%***
Externalized Conductors - Inside Out**	Internal Abrasion	0.0002%***
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.007%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.006%

*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 a total of six cases of 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 281).

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 >3.9 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.

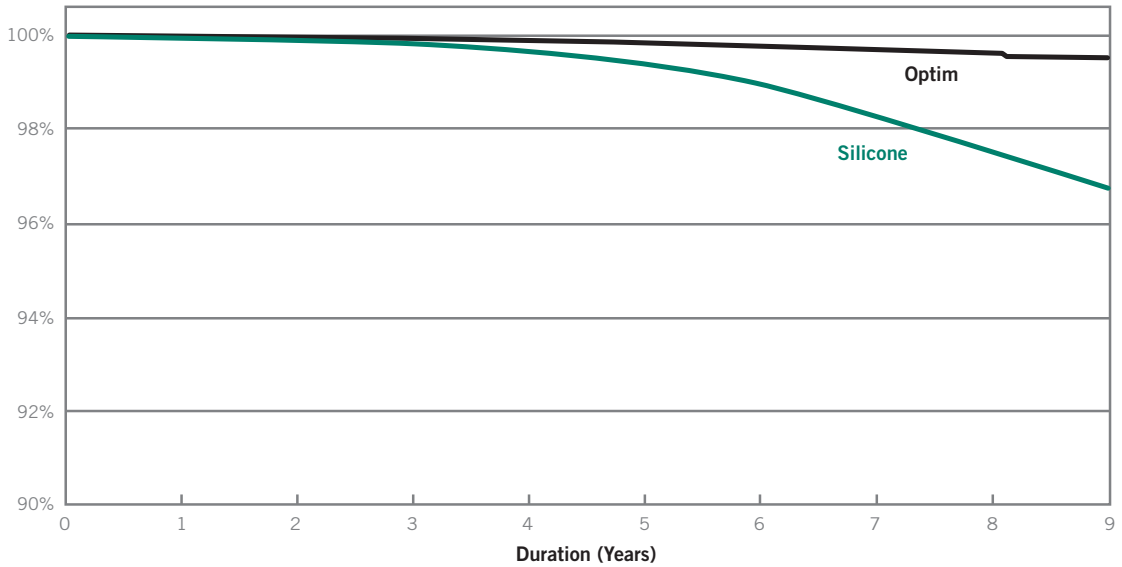
This product performance report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on St. Jude Medical tachycardia leads. A Kaplan-Meier analysis including all U.S. data through December 31, 2015 was performed on two groups of leads: (1) tachycardia leads with silicone 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 110 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 110 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 110 months by 85%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test.

Optim™ Lead Insulation Effects on SJM Tachycardia Lead Abrasion

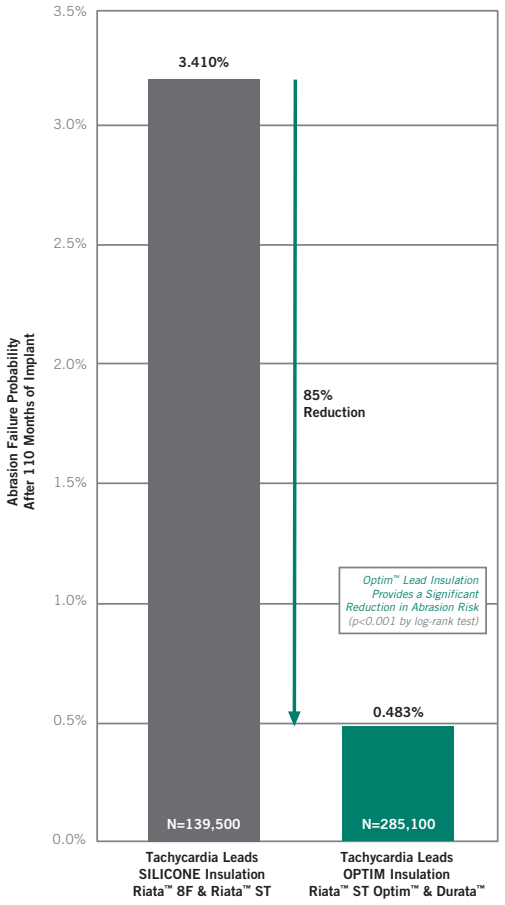
Kaplan-Meier Analysis of U.S. Returns Analysis Data

Freedom from Abrasion Failure (%)



Year	1	2	3	4	5	6	7	8	9
Optim	257,213	211,260	171,039	134,833	99,977	65,147	35,475	14,342	3,019
Silicone	129,519	116,106	105,806	96,156	87,166	78,605	69,878	59,629	46,082

Abrasion Malfunction Probability after 110 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
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 (December 31, 2015):** At the time of the advisory, the 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 December 31, 2015, there were additional reports and the rate is now 0.67%. 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 (December 31, 2015):** 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 (December 31, 2015):** At the time of the advisory there were 20 devices confirmed to be affected by this issue. As of December 31, 2015 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 (December 31, 2015):** 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 December 31, 2015, 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 (December 31, 2015):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2015 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 (December 31, 2015):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2015 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 (December 31, 2015):** 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 (December 31, 2015):** 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
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 (December 31, 2015):** 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 (December 31, 2015):** 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 (December 31, 2015):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2015 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 (December 31, 2015):** 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 (December 31, 2015):** At the time of the advisory there was a worldwide reported externalized conductor rate of 0.023% in QuickSite and QuickFlex leads. As of December 31, 2015, the worldwide reported externalized conductor rate for QuickSite and QuickFlex leads was 0.19%.

Defibrillation Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Optisure™ Defibrillation Lead (Models LDA220, LDA220Q, LDA230Q, LDP220Q)	11/3/2015 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™ 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 277-281 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 (February 29, 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 February 29, 2016, there have been additional reports. The worldwide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 4.26% and 2.33% 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 (February 29, 2016):** At the time of the advisory there was a worldwide insulation abrasion rate of 0.47% for Riata silicone leads. As of February 29, 2016, there have been additional reports and the worldwide reported insulation abrasion rate is 4.26%.

[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 (December 31, 2015):** 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 (December 31, 2015):** 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 December 31, 2015, there were additional reports and the rate for Ellipse, Fortify Assura, Unify Assura and Quadra Assura ICDs, was 0.42%. For Assurity and Allure pacemakers, the rate of occurrence was 0.10%.

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.

St. Jude Medical Inc.
Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
T +1 651 756 2000 I **F** +1 651 756 3301

St. Jude Medical Inc.
Implantable Electronic Systems
15900 Valley View Court
Sylmar, California 91342
USA
T +1 818 362 6822 I **F** +1 818 364 5814

St. Jude Medical S.C., Inc.
Americas Division
6300 Bee Cave Road
Bldg. Two, Suite 100
Austin, Texas 78746
USA
T +1 512 286 4000 I **F** +1 512 732 2418

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11-Box F1
B-1935 Zaventem, Belgium
T +32 2 774 68 11 I **F** +32 2 772 83 84

SJMprofessional.com

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