Implantable Electronic Systems Division
Product Performance Report
2013 Second Edition

St. Jude Medical™

Letter from St. Jude Medical

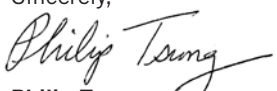
As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, St. Jude Medical continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose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

In keeping with this commitment, we publish a Product Performance Report (PPR) semi-annually to ensure that the healthcare community and the patients it serves are informed about the overall performance of our cardiac devices, which include implantable cardiac monitors (ICMs), implantable cardioverter defibrillators (ICDs), implantable pacemakers, and implantable pacing and defibrillation leads. St. Jude Medical recognizes that such performance data must be transparent and consistent. In order to meet these goals we continue our commitment to the reporting methods described in the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", which set new standards for lead performance reporting and specifically addressed the reporting of active registry performance data. Determined to provide the highest level of transparency, St. Jude Medical goes beyond the AdvaMed recommendations by identifying the root cause of each ICM, ICD, and pacemaker laboratory-confirmed malfunction and providing subcategories of laboratory-confirmed lead abrasion and fracture malfunctions.

Continuing within this edition of the PPR and consistent with 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 59,000 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, starting in this addition with world-wide confirmed malfunctions in Durata™ lead 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 second edition of the 2013 Product Performance Report containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,



Philip Tsung
Vice President, Quality Assurance

St. Jude Medical

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Serving Our Mission

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

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

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

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

What You'll Find in This Report

- Table of Contents
- A summary of the methods St. Jude Medical has used for measuring product performance, including key definitions of terms used in preparing this report
- For each Implantable Cardioverter Defibrillator (ICD), Pacemaker, Implantable Cardiac Monitor (ICM), and Lead model with at least 500 active devices in service, St. Jude Medical provides product performance data, according to industry guidelines, collected through June 30, 2013, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - For the more recent products, the quantity, rate, and type of product malfunctions are detailed
  - For the more recent lead models, the quantity, rate, and type of customer complaints (acute observations and chronic complications) are detailed
- Summary tables of performance data, organized by product type and model
- For all ICD, pacemaker, ICM, and lead models that meet Actively Monitored Study Data Registry inclusion criteria, St. Jude Medical provides active registry performance data, collected through June 30, 2013, 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 PHRI
  - The effect of Optim™ lead insulation on HV lead abrasion
- An updated summary of advisories on all implantable devices since 1999
- 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 Actively Monitored Study Data

Since 2007 the Product Performance Report has included data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). This comprehensive, monitored study provided key performance data on pacemakers, ICDs, and leads. Now that product-specific, post-market registries have become standard practice, St. Jude Medical has decided to complement the SCORE registry with data from the SJ4 Post-Approval Study, the Quickflex™ µ Post-Approval Study, the Quadripolar Pacing System Post-Approval Study, and OPTIMUM registry. The purpose of the OPTIMUM registry is to produce a prospective, outcome-oriented registry of patients implanted with St. Jude Medical Optim™ leads and further complement the updated SCORE registry and Post-Approval Study data. Representing >59,000 implants, this compilation of actively monitored study data continues to be a valuable source of product performance information.

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 259-263). 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 over 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 264-268).

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 269-270).

World-Wide Laboratory Analysis of Durata™ Leads

Added to this Product Performance Report are world-wide laboratory analysis results of returned Durata™ leads, categorized into the five categories of malfunctions as outlined on pages 10-11. This summary can be found on page 166. St. Jude Medical is dedicated to full transparency, and will continue to incorporate additional world-wide laboratory analysis results of specific 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 SCORE registry or 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.

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 a 2.5V dual-chamber output, 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 5841-2:2000(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.

Because of the large size of the U.S. data pool, and because 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.

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 the AdvaMed guidance document, the survival calculations for ICDs, pacemakers, and ICMs are adjusted to reduce the bias caused by underreporting of malfunctions and normal battery depletions.

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 Premature 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, all 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.

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.

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, 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. 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 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 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 282-283) 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 removed from service 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). For this particular category, malfunctions will only be included in survival calculations for leads implanted greater than 30 days.

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. Now that product-specific, post-market registries have become standard practice, St. Jude Medical has decided to complement the SCORE registry with data from the SJ4 Post-Approval Study, the QuickFlex™ µ Post-Approval Study, and the Quadripolar CRT-D Post-Approval Study. The SCORE registry and three Post-Approval Studies are now further complemented with the OPTIMUM registry. This registry evaluates the chronic clinical performance of leads with Optim™ insulation material. With the OPTIMUM registry, this actively monitored study data now represents >59,000 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	60	10957	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	1701	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	1930	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	70	1331	Unify Quadra™ 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	14124	Leads (any model with Optim™ Insulation)

The models included in the actively monitored dataset are listed below:

ICDs

Unify Quadra™ CRT-D (Model 3249-40Q)
Unify Quadra™ CRT-D (Model 3249-40)*
Unify™ CRT-D (Model CD3231-40Q)
Unify™ CRT-D (Model CD3231-40)
Fortify™ DR (Model CD2231-40Q)
Fortify™ DR (Model CD2231-40)
Fortify™ VR (Model CD1231-40Q)
Current™ + DR (Model CD2211-36Q)
Current™ + VR (Model 1211-36Q)
Current™ VR RF (Model 1207-36)
Current™ DR RF (Model 2207-36)
Current™ + DR (Model CD2211-36)
Promote™ RF CRT-D (Model 3207-36)
Promote™ + CRT-D (Model CD3211-36)
Promote™ + CRT-D (Model CD3211-36Q)

Defibrillation Leads

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

CRT Leads

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

Pacemakers

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

Pacing Leads

Tendril™ STS (Model 2088)
Tendril™ ST Optim™ (Model 1888)
Tendril™ ST Optim™ (Model 1882)
Tendril™ (Model 1788)
Tendril™ (Model 1782)
Tendril™ SDX (Model 1688)
Tendril™ SDX (Model 1488)
Tendril™ DX (Model 1388)
OptiSense™ (Model 1999)
OptiSense™ (Model 1699)
IsoFlex™ S (Model 1646)
IsoFlex™ Optim™ (Model 1948)
IsoFlex™ Optim™ (Model 1944)

*New for 2013 Second Edition.

Qualifying Complications

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

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

Survival Calculation Methods

Survival calculations for actively monitored studies are made in a manner consistent with the ISO 5841-2:2000(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 greater 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 also 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. Steven Bailin, Des Moines, Iowa

Dr. Jim Baker, Nashville, Tennessee

Dr. Anne Curtis, Buffalo, New York

Dr. Roger Freedman, Salt Lake City, Utah

Dr. Steven Kalbfleisch, Columbus, Ohio

Dr. Steven Kutalek, Philadelphia, Pennsylvania

Dr. Thomas Mattioni, Paradise Valley, Arizona

Dr. Raymond Schaerf, Burbank, California

Dr. Gery Tomassoni, Lexington, Kentucky

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™

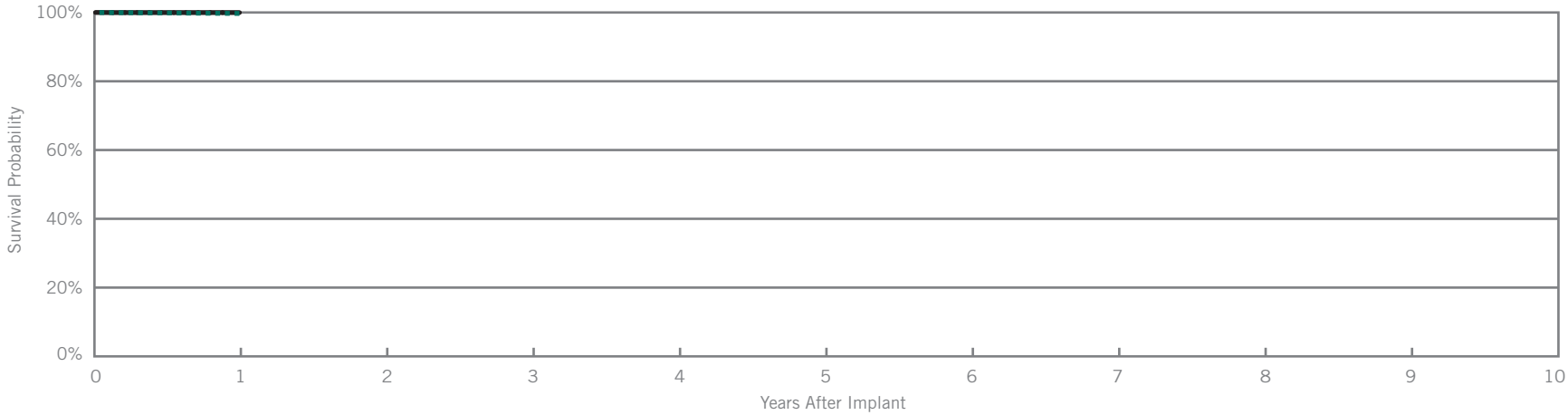
Quadra Assura™ CRT-D

Model CD3265-40Q

US Regulatory Approval	May 2012
Registered US Implants	7,320
Estimated Active US Implants	6,916
Estimated Longevity	(see table on page 42)
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%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	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**	**0.01%**



Including Normal Battery Depletion

Year	1									
Survival Probability	99.72%									
± 1 standard error	0.17%									
Sample Size	370									

Excluding Normal Battery Depletion

Year	1									
Survival Probability	99.97%									
± 1 standard error	0.02%									

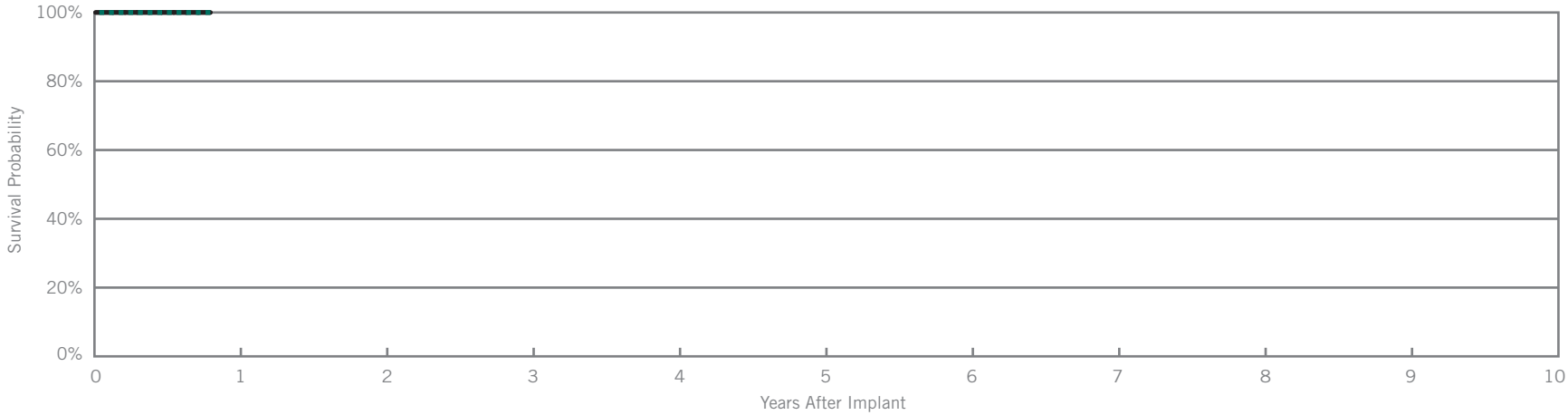
Quadra Assura™ CRT-D

Model CD3265-40

US Regulatory Approval	May 2012
Registered US Implants	2,149
Estimated Active US Implants	2,041
Estimated Longevity	(see table on page 42)
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	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	270										

Excluding Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

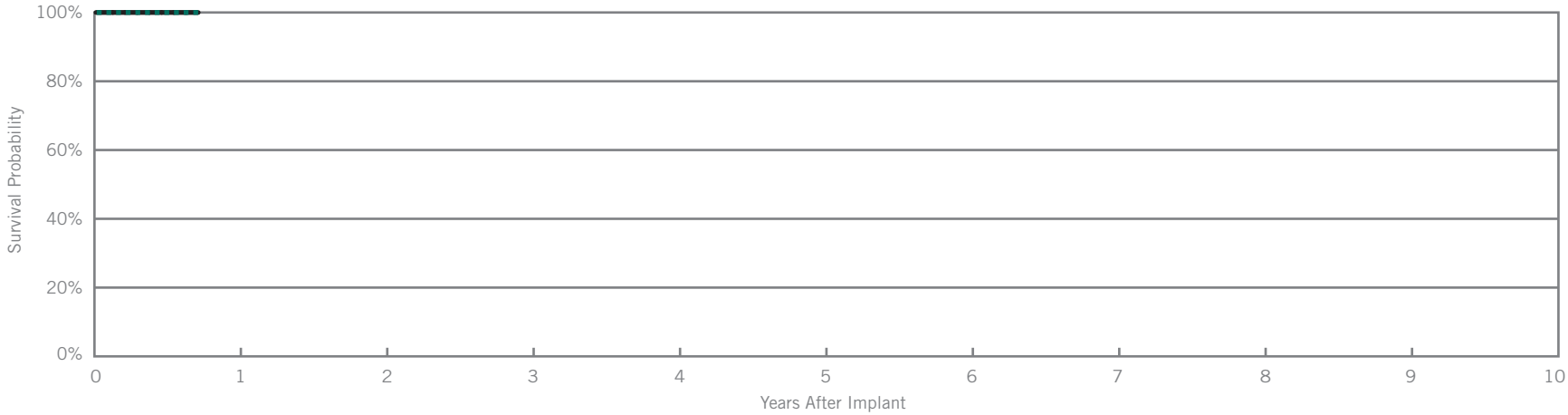
Unify Assura™ CRT-D

Model CD3257-40Q

US Regulatory Approval	May 2012
Registered US Implants	1,409
Estimated Active US Implants	1,330
Estimated Longevity	(see table on page 42)
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	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 9 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	240										

Excluding Normal Battery Depletion

Year	at 9 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

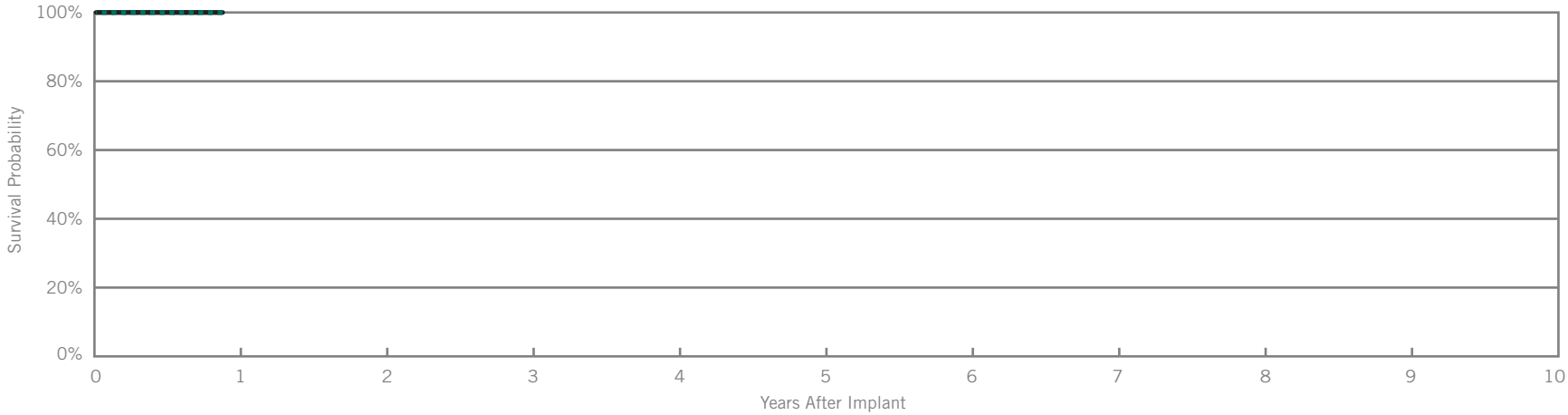
Unify Assura™ CRT-D

Model CD3257-40

US Regulatory Approval	May 2012
Registered US Implants	3,677
Estimated Active US Implants	3,468
Estimated Longevity	(see table on page 42)
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	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	320										

Excluding Normal Battery Depletion

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

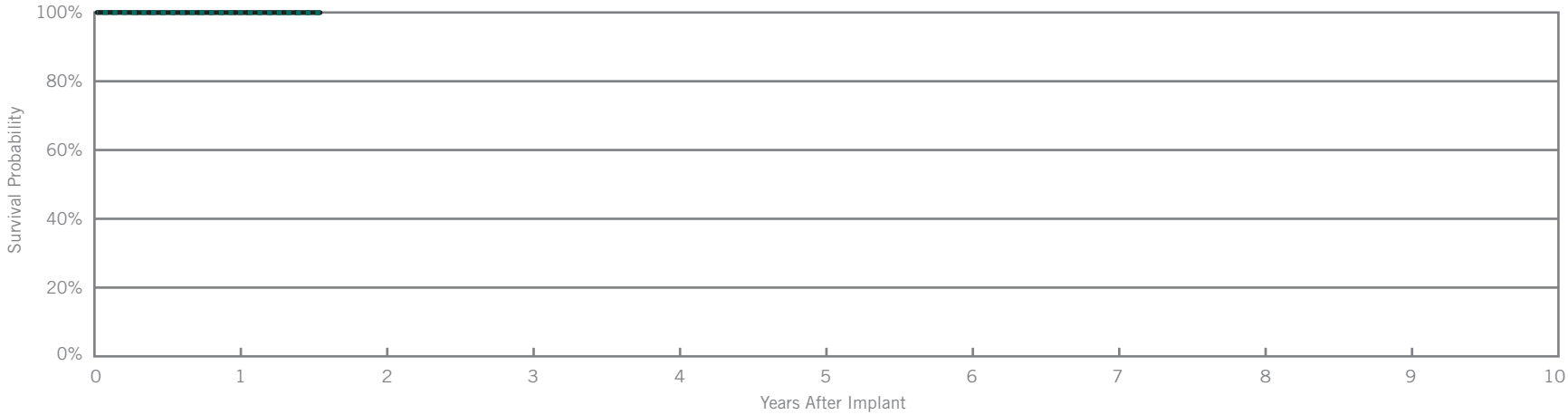
Unify Quadra™ CRT-D

Model CD3249-40Q

US Regulatory Approval	Nov 2011
Registered US Implants	8,450
Estimated Active US Implants	7,535
Estimated Longevity	(see table on page 42)
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	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.04%	0.04%								
Sample Size	6260	240								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.02%	0.02%								

Actively Monitored Study Data

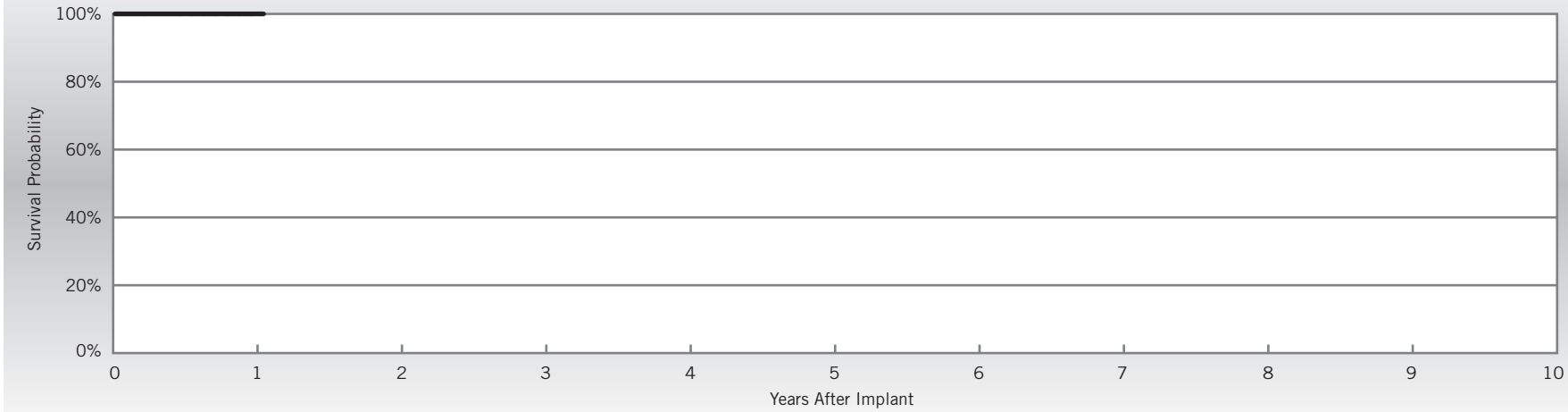
Unify Quadra™ CRT-D

Model CD3249-40Q

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	869
Cumulative Months of Follow-up	5,023
Estimated Longevity	(see table on page 42)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	470	70								

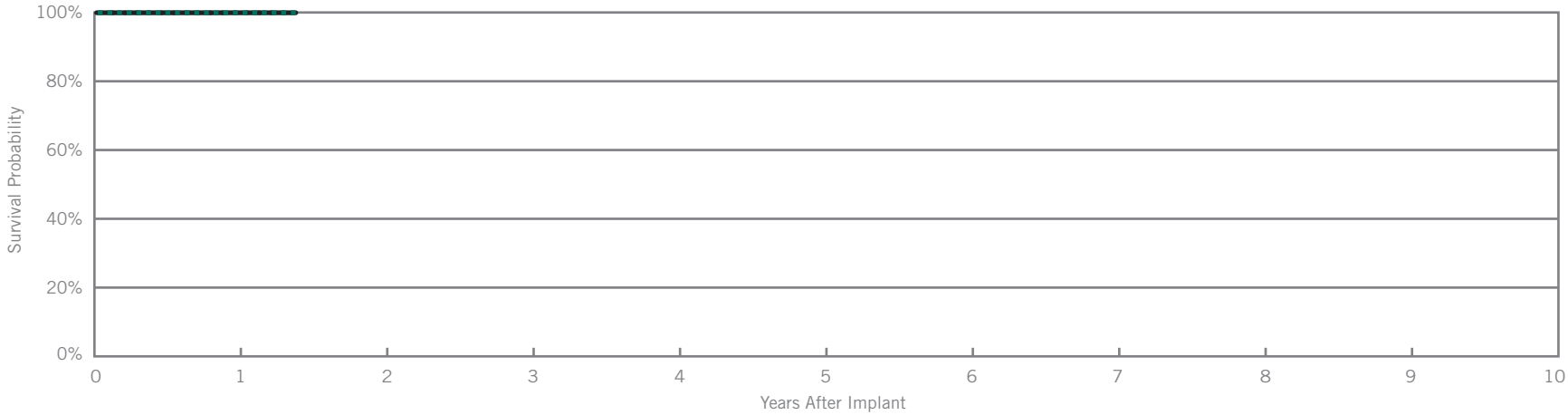
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	Nov 2011
Registered US Implants	2,402
Estimated Active US Implants	2,142
Estimated Longevity	(see table on page 42)
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	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	at 17 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.06%	0.06%								
Sample Size	1810	380								

Excluding Normal Battery Depletion

Year	1	at 17 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.06%	0.06%								

Actively Monitored Study Data

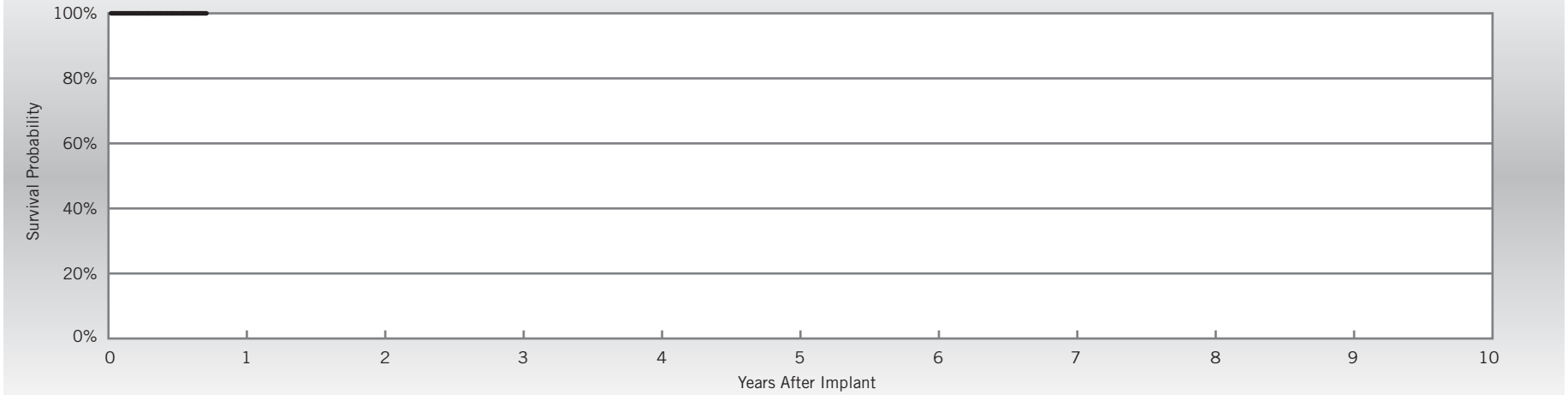
Unify Quadra™ CRT-D

Model CD3249-40

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	209
Cumulative Months of Follow-up	1,179
Estimated Longevity	(see table on page 42)
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 9 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	60										

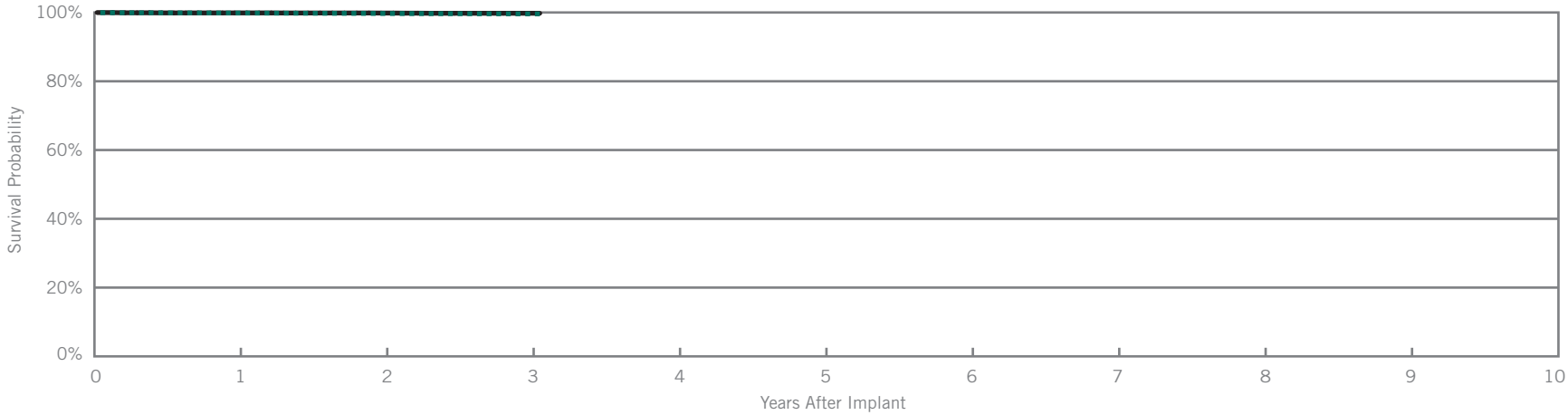
Customer Reported Performance Data

Unify™ CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Registered US Implants	18,868
Estimated Active US Implants	14,865
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	9
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	2	0.01%	1	<0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	2	0.01%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	1	<0.01%	1	<0.01%
Total	**7**	**0.04%**	**7**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.77%	99.73%	99.58%	99.58%						
± 1 standard error	0.04%	0.04%	0.06%	0.06%						
Sample Size	17120	11960	4530	500						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.87%	99.83%	99.77%	99.77%						
± 1 standard error	0.03%	0.03%	0.04%	0.04%						

Actively Monitored Study Data

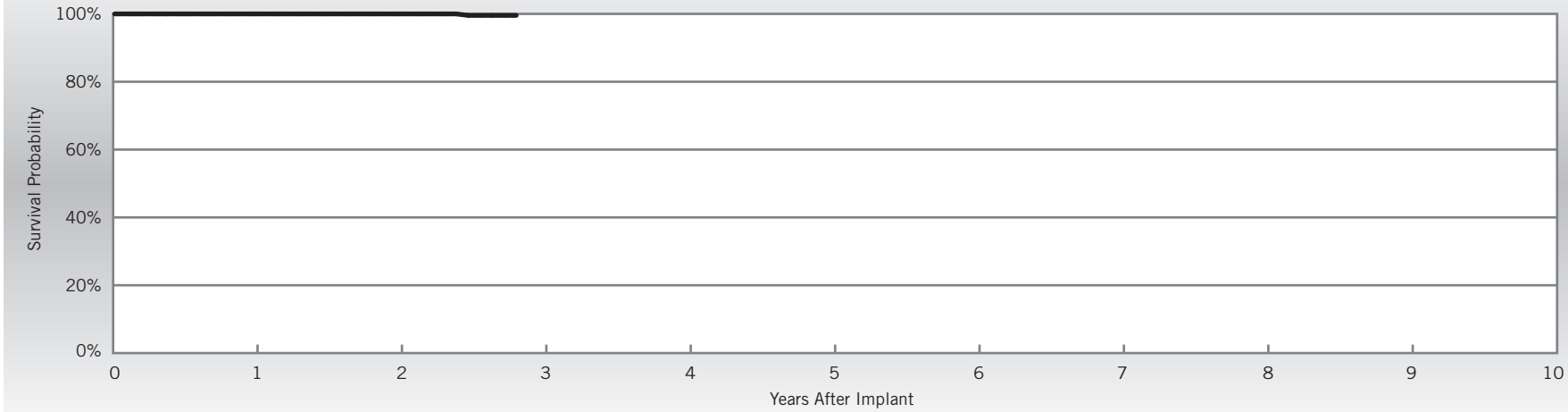
Unify™ CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	1,671
Cumulative Months of Follow-up	33,422
Estimated Longevity	(see table on page 42)
Max. Delivered Energy	40 joules

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%	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	0.06%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**2**	**0.12%**



Year	1	2	at 34 months							
Survival Probability	100.00%	100.00%	99.56%							
± 1 standard error	0.00%	0.00%	0.44%							
Sample Size	1550	1030	60							

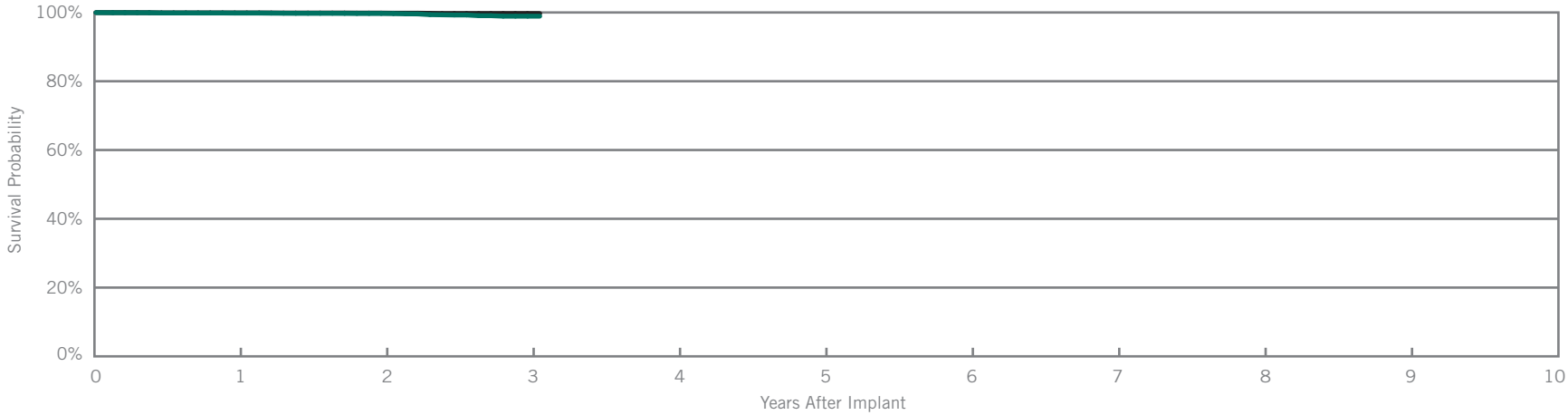
Customer Reported Performance Data

Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	20,156
Estimated Active US Implants	16,061
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	17
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	0.01%	0	0.00%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	<0.01%	1	<0.01%
Other	4	0.02%	5	0.02%
Total	**10**	**0.05%**	**6**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.82%	99.71%	98.92%	98.92%						
± 1 standard error	0.03%	0.04%	0.17%	0.17%						
Sample Size	17720	11230	3740	290						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.87%	99.82%	99.70%	99.70%						
± 1 standard error	0.02%	0.03%	0.06%	0.06%						

Actively Monitored Study Data

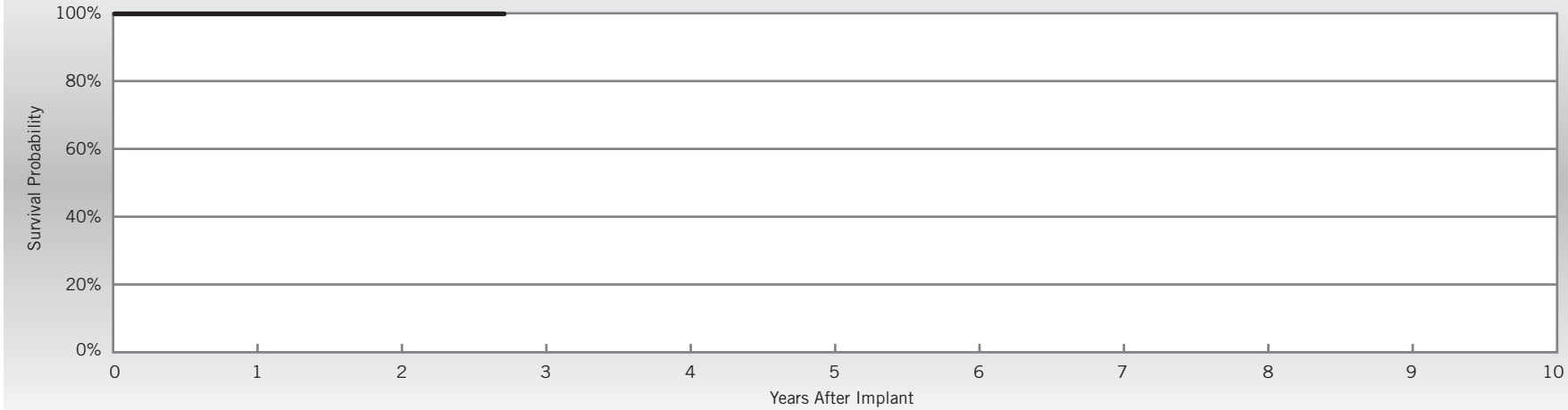
Unify™ CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	670
Cumulative Months of Follow-up	13,470
Estimated Longevity	(see table on page 42)
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	0.15%	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**	**0.15%**	**0**	**0.00%**



Year	1	2	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	610	400	50							

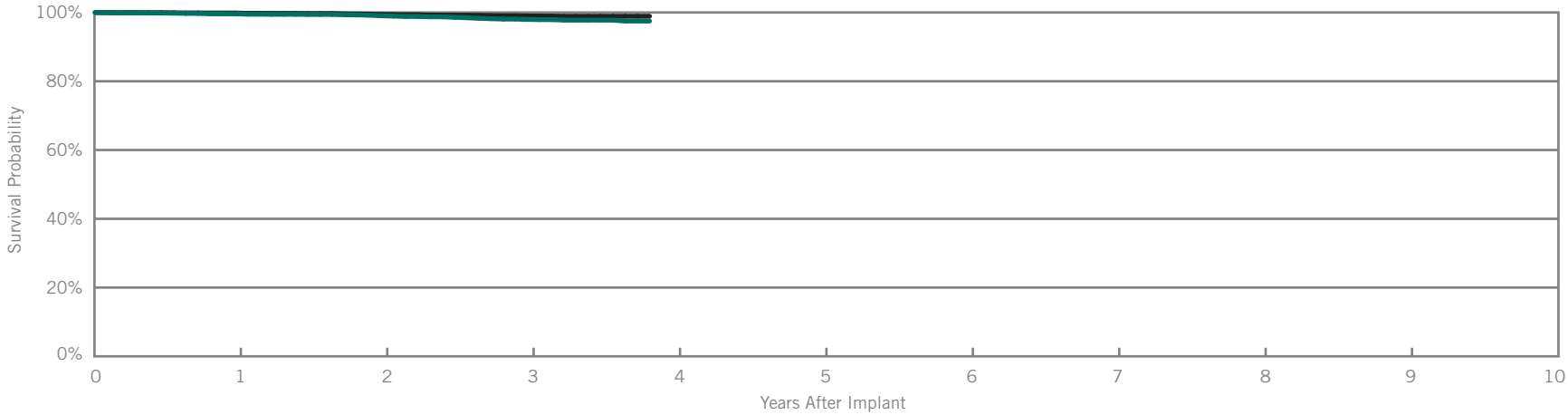
Customer Reported Performance Data

Promote™ + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	6,867
Estimated Active US Implants	4,723
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	21
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	0.06%	2	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	7	0.10%	5	0.07%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	1	0.01%	0	0.00%
Other	2	0.03%	3	0.04%
Total	**16**	**0.23%**	**10**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.59%	99.04%	97.97%	97.50%						
± 1 standard error	0.08%	0.12%	0.19%	0.28%						
Sample Size	6330	5430	4640	280						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.84%	99.41%	99.01%	98.90%						
± 1 standard error	0.05%	0.09%	0.13%	0.15%						

Actively Monitored Study Data

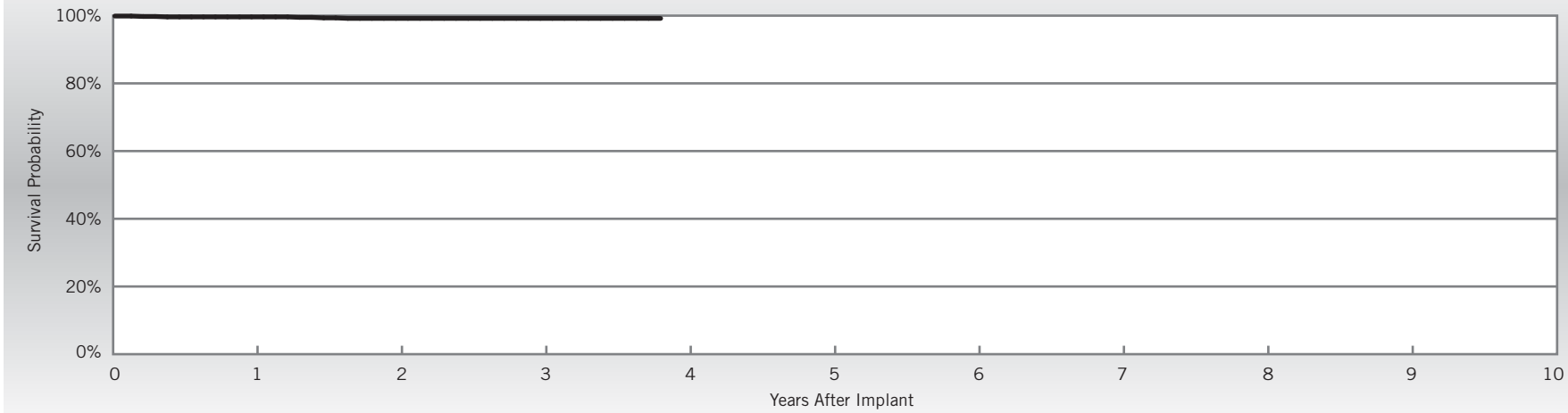
Promote™ + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	853
Cumulative Months of Follow-up	26,586
Estimated Longevity	(see table on page 42)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Inappropriate Shock	3	0.35%
Premature Battery Depletion	1	0.12%
Skin Erosion	2	0.23%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.12%	0	0.00%
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%**	**2**	**0.23%**



Year	1	2	3	at 46 months						
Survival Probability	99.63%	99.19%	99.19%	99.19%						
± 1 standard error	0.21%	0.33%	0.33%	0.33%						
Sample Size	790	670	570	80						

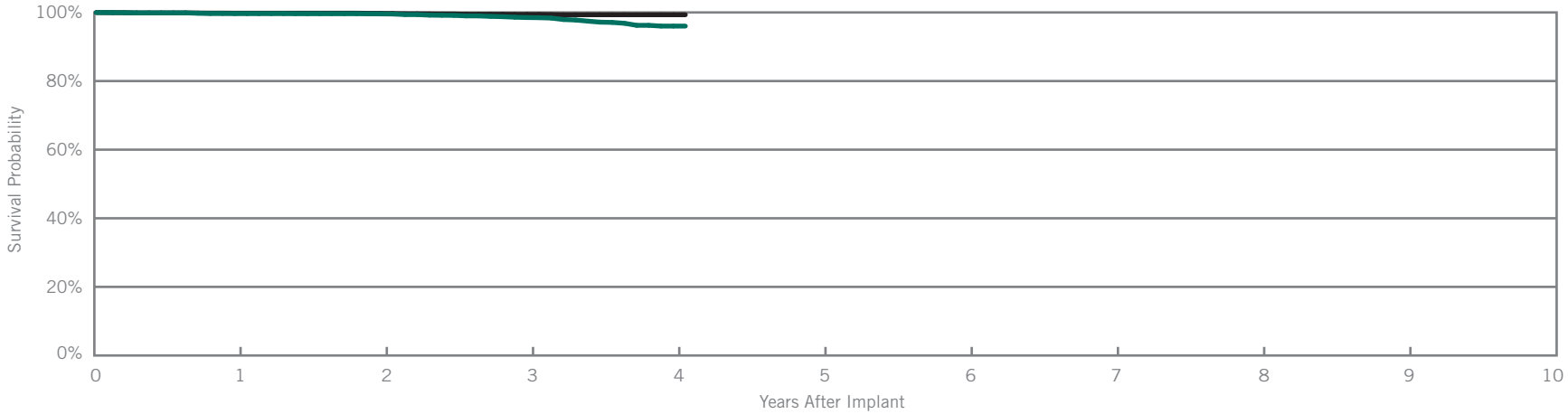
Customer Reported Performance Data

Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,575
Estimated Active US Implants	5,581
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	45
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	3	0.03%	2	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	9	0.10%	2	0.02%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**14**	**0.16%**	**6**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.67%	99.57%	98.51%	96.02%	96.02%					
± 1 standard error	0.06%	0.07%	0.15%	0.37%	0.37%					
Sample Size	7880	6650	5590	2700	350					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.79%	99.72%	99.41%	99.32%	99.32%					
± 1 standard error	0.05%	0.06%	0.10%	0.11%	0.11%					

Actively Monitored Study Data

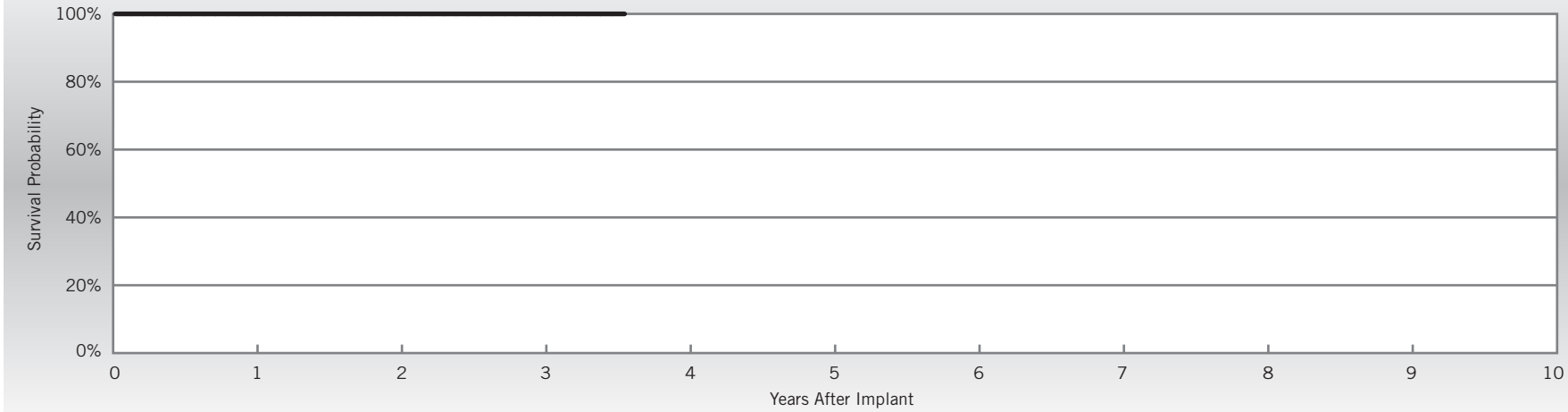
Promote™ + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	222
Cumulative Months of Follow-up	6,707
Estimated Longevity	(see table on page 42)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	2	3	at 43 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	210	170	130	60						

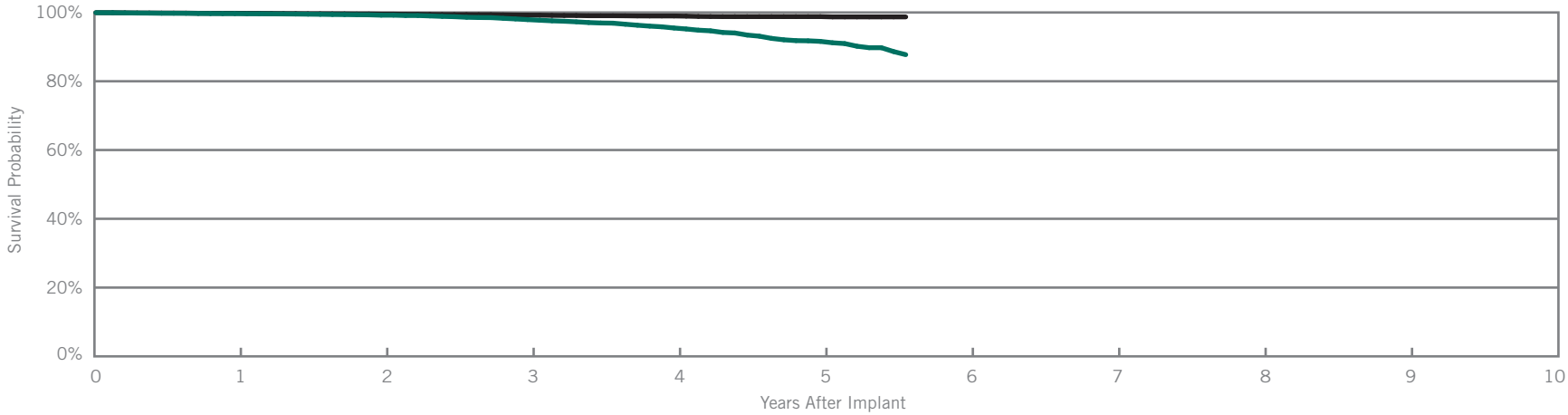
Customer Reported Performance Data

Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,974
Estimated Active US Implants	12,190
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	320
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	0.02%	5	0.02%
Electrical Interconnect	5	0.02%	0	0.00%
Battery	15	0.06%	8	0.03%
High Voltage Capacitor	5	0.02%	1	<0.01%
Software/Firmware	0	0.00%	5	0.02%
Mechanical	2	<0.01%	1	<0.01%
Possible Early Battery Depletion	7	0.03%	4	0.02%
Other	9	0.04%	11	0.05%
Total	**47**	**0.20%**	**35**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.67%	99.21%	97.92%	95.48%	91.59%	87.73%				
± 1 standard error	0.04%	0.06%	0.10%	0.16%	0.29%	0.66%				
Sample Size	22180	19040	16500	12990	6610	290				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.77%	99.52%	99.22%	98.98%	98.80%	98.71%				
± 1 standard error	0.03%	0.05%	0.06%	0.08%	0.09%	0.11%				

Actively Monitored Study Data

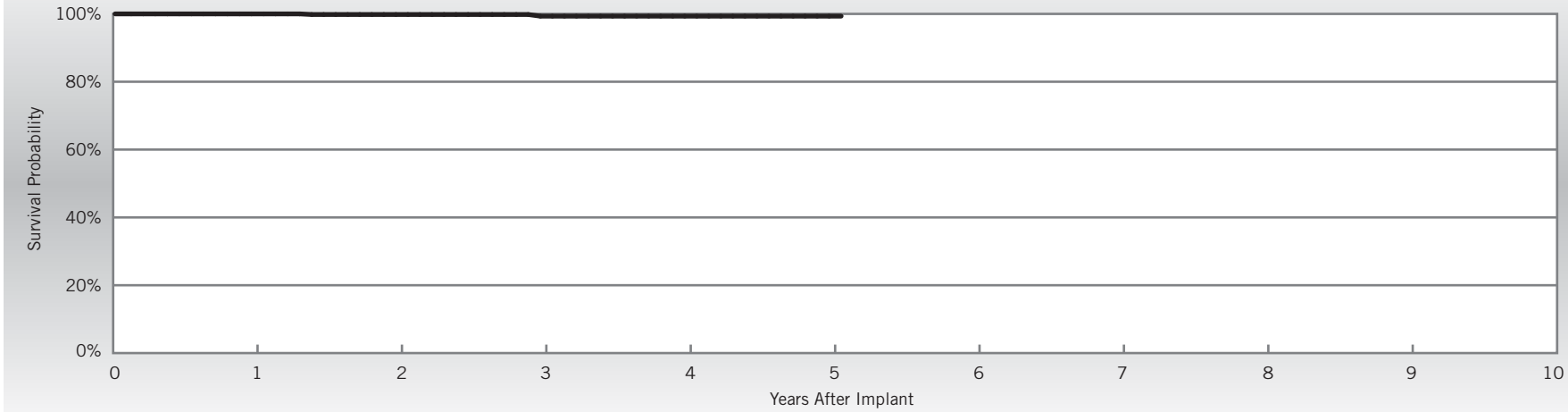
Promote™ RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	674
Cumulative Months of Follow-up	25,547
Estimated Longevity	(see table on page 42)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.15%
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%	0	0.00%
Total	**2**	**0.30%**	**3**	**0.45%**



Year	1	2	3	4	5	at 61 months				
Survival Probability	100.00%	99.82%	99.34%	99.34%	99.34%	99.34%				
± 1 standard error	0.00%	0.18%	0.18%	0.38%	0.38%	0.38%				
Sample Size	630	550	460	340	160	60				

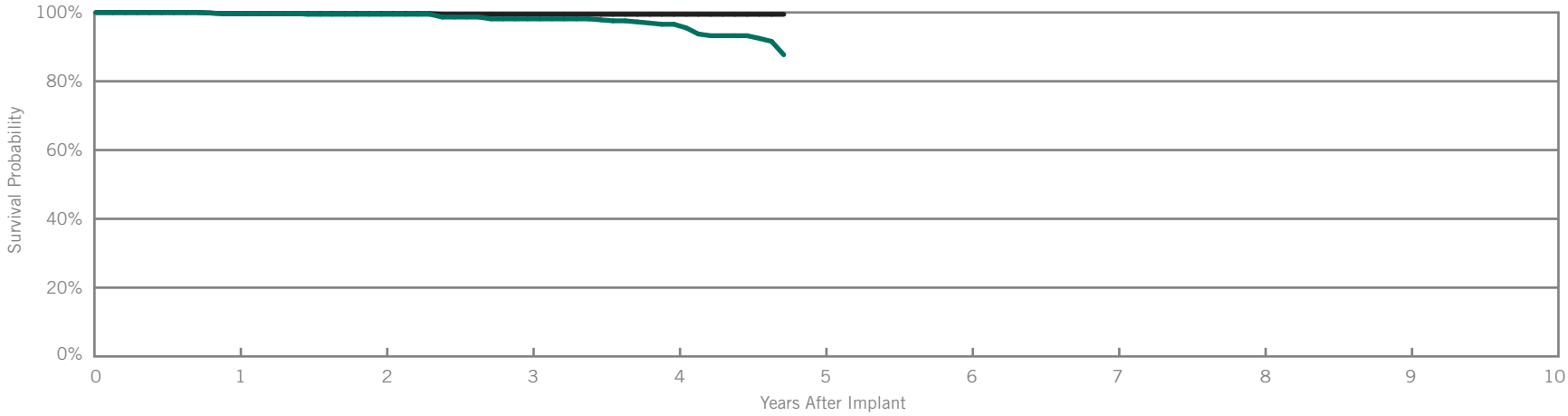
Customer Reported Performance Data

Promote™ RF CRT-D

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,395
Estimated Active US Implants	672
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	24
Max. Delivered Energy	30 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	1	0.07%
Battery	0	0.00%	1	0.07%
High Voltage Capacitor	1	0.07%	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**	**0.07%**	**2**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	at 57 months					
Survival Probability	99.67%	99.48%	98.13%	96.57%	87.70%					
± 1 standard error	0.17%	0.21%	0.43%	0.65%	1.32%					
Sample Size	1280	1090	940	680	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 57 months					
Survival Probability	99.67%	99.67%	99.46%	99.46%	99.46%					
± 1 standard error	0.17%	0.17%	0.22%	0.22%	0.22%					

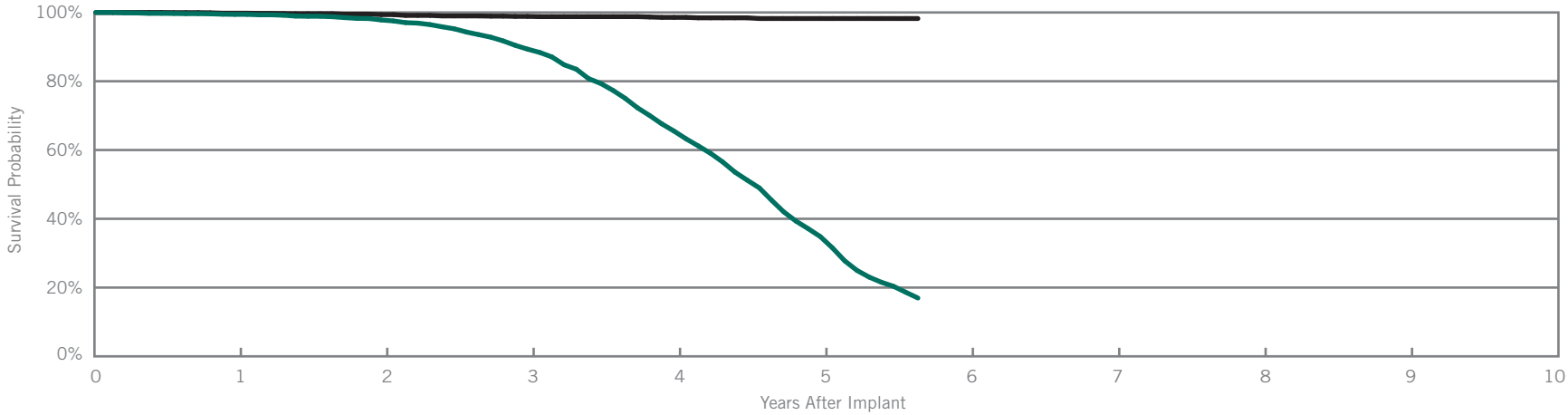
Atlas™ II + HF CRT-D

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	4,921
Estimated Active US Implants	910
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	740
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.02%	3	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.08%	2	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	2	0.04%	4	0.08%
Other	7	0.14%	0	0.00%
Total	**14**	**0.28%**	**9**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.44%	97.82%	89.33%	65.52%	34.82%	16.96%				
± 1 standard error	0.11%	0.21%	0.50%	0.87%	1.04%	0.97%				
Sample Size	4540	3860	3200	2230	1100	210				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.79%	99.37%	98.86%	98.57%	98.24%	98.24%				
± 1 standard error	0.07%	0.11%	0.18%	0.21%	0.27%	0.27%				

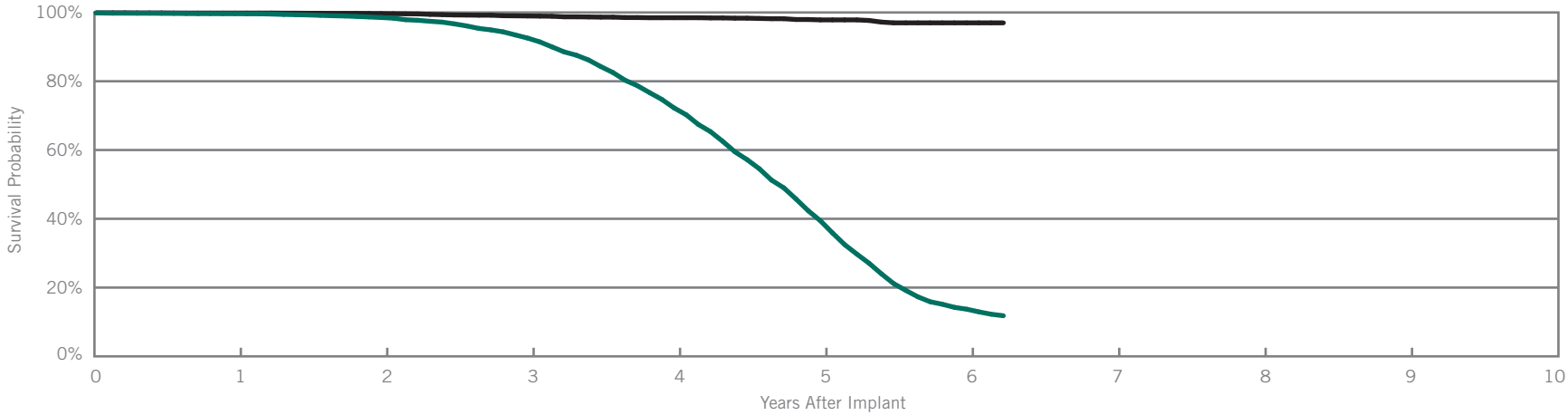
Atlas™ II HF CRT-D

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	8,377
Estimated Active US Implants	764
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	1,555
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	2	0.02%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	16	0.19%	3	0.04%
High Voltage Capacitor	2	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	0.07%	5	0.06%
Other	8	0.10%	5	0.06%
Total	**35**	**0.42%**	**15**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.64%	98.53%	92.55%	72.26%	39.44%	13.71%	11.81%			
± 1 standard error	0.07%	0.14%	0.32%	0.60%	0.72%	0.56%	0.55%			
Sample Size	7800	6750	5670	4280	2600	1040	250			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.83%	99.68%	98.98%	98.47%	97.84%	96.98%	96.98%			
± 1 standard error	0.05%	0.06%	0.13%	0.17%	0.22%	0.37%	0.37%			

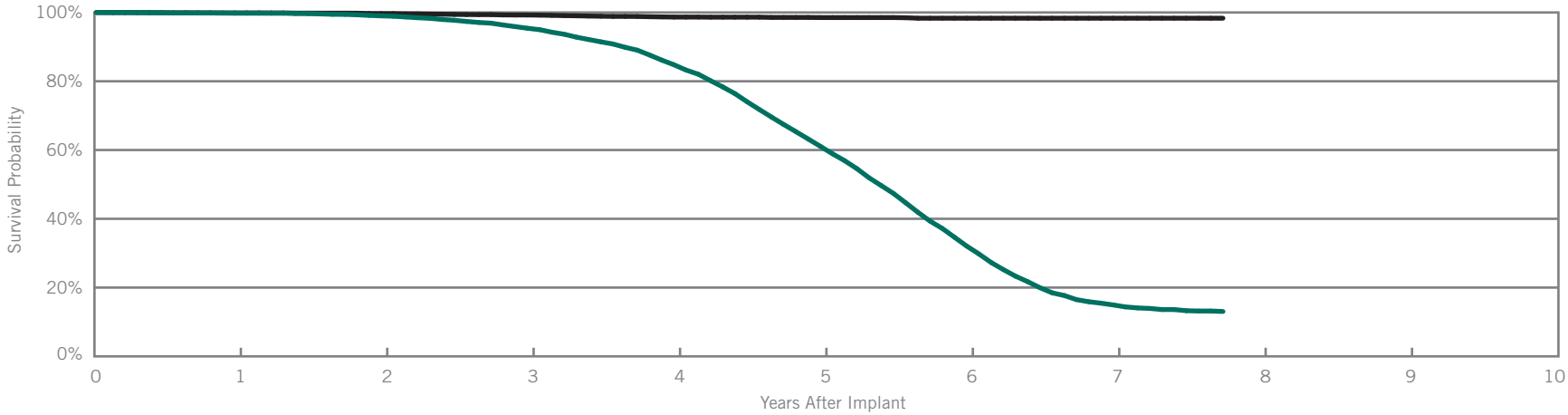
Atlas™ + HF CRT-D

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,739
Estimated Active US Implants	1,692
Estimated Longevity	(see table on page 42)
Normal Battery Depletion	3,013
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

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	37	0.20%	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	5	0.03%	11	0.06%
Other	10	0.05%	4	0.02%
Total	**55**	**0.29%**	**22**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.78%	99.01%	95.40%	84.79%	61.07%	32.05%	14.95%	13.05%		
± 1 standard error	0.03%	0.07%	0.17%	0.32%	0.48%	0.51%	0.42%	0.43%		
Sample Size	17440	15130	12960	10350	7170	3980	1610	230		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.88%	99.67%	99.26%	98.66%	98.52%	98.33%	98.33%	98.33%		
± 1 standard error	0.03%	0.04%	0.07%	0.10%	0.11%	0.13%	0.13%	0.13%		

Battery Longevity Summary

CRT ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
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
3207-30	Promote™ RF CRT-D**	6.5	5.7	5.1	4.2
V-366	Atlas™ II + HF CRT-D**	8.2	7.2	6.5	5.4
V-365	Atlas™ II HF 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
CD3265-40Q	Quadra Assura™ CRT-D	99.72%									
CD3265-40	Quadra Assura™ CRT-D*										
CD3257-40Q	Unify Assura™ CRT-D*										
CD3257-40	Unify Assura™ CRT-D*										
CD3249-40Q	Unify Quadra™ CRT-D	99.91%									
CD3249-40	Unify Quadra™ CRT-D	99.92%									
CD3231-40Q	Unify™ CRT-D	99.77%	99.73%	99.58%							
CD3231-40	Unify™ CRT-D	99.82%	99.71%	98.92%							
CD3211-36Q	Promote™ + CRT-D	99.59%	99.04%	97.97%							
CD3211-36	Promote™ + CRT-D	99.67%	99.57%	98.51%	96.02%						
3207-36	Promote™ RF CRT-D	99.67%	99.21%	97.92%	95.48%	91.59%					
3207-30	Promote™ RF CRT-D	99.67%	99.48%	98.13%	96.57%						
V-366	Atlas™ II + HF CRT-D	99.44%	97.82%	89.33%	65.52%	34.82%					
V-365	Atlas™ II HF CRT-D	99.64%	98.53%	92.55%	72.26%	39.44%	13.71%				
V-343	Atlas™ + HF CRT-D	99.78%	99.01%	95.40%	84.79%	61.07%	32.05%	14.95%			

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3265-40Q	Quadra Assura™ CRT-D	99.97%									
CD3265-40	Quadra Assura™ CRT-D*										
CD3257-40Q	Unify Assura™ CRT-D*										
CD3257-40	Unify Assura™ CRT-D*										
CD3249-40Q	Unify Quadra™ CRT-D	99.97%									
CD3249-40	Unify Quadra™ CRT-D	99.92%									
CD3231-40Q	Unify™ CRT-D	99.87%	99.83%	99.77%							
CD3231-40	Unify™ CRT-D	99.87%	99.82%	99.70%							
CD3211-36Q	Promote™ + CRT-D	99.84%	99.41%	99.01%							
CD3211-36	Promote™ + CRT-D	99.79%	99.72%	99.41%	99.32%						
3207-36	Promote™ RF CRT-D	99.77%	99.52%	99.22%	98.98%	98.80%					
3207-30	Promote™ RF CRT-D	99.67%	99.67%	99.46%	99.46%						
V-366	Atlas™ II + HF CRT-D	99.79%	99.37%	98.86%	98.57%	98.24%					
V-365	Atlas™ II HF CRT-D	99.83%	99.68%	98.98%	98.47%	97.84%	96.98%				
V-343	Atlas™ + HF CRT-D	99.88%	99.67%	99.26%	98.66%	98.52%	98.33%	98.33%			

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD3265-40Q	Quadra Assura™ CRT-D	7320	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3265-40	Quadra Assura™ CRT-D	2149	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%**
CD3257-40Q	Unify Assura™ CRT-D	1409	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	3677	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	8450	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	2402	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	18868	0	0.00%	1	<0.01%	2	0.01%	1	<0.01%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**7**	**0.04%**
CD3231-40	Unify™ CRT-D	20156	3	0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	4	0.02%	**10**	**0.05%**
CD3211-36Q	Promote™ + CRT-D	6867	4	0.06%	0	0.00%	7	0.10%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	2	0.03%	**16**	**0.23%**
CD3211-36	Promote™ + CRT-D	8575	3	0.03%	0	0.00%	9	0.10%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**14**	**0.16%**
3207-36	Promote™ RF CRT-D	23974	4	0.02%	5	0.02%	15	0.06%	5	0.02%	0	0.00%	2	<0.01%	7	0.03%	9	0.04%	**47**	**0.20%**
3207-30	Promote™ RF CRT-D	1395	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
V-366	Atlas™ II + HF CRT-D	4921	1	0.02%	0	0.00%	4	0.08%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	7	0.14%	**14**	**0.28%**
V-365	Atlas™ II HF CRT-D	8377	1	0.01%	2	0.02%	16	0.19%	2	0.02%	0	0.00%	0	0.00%	6	0.07%	8	0.10%	**35**	**0.42%**
V-343	Atlas™ + HF CRT-D	18739	3	0.02%	0	0.00%	37	0.20%	0	0.00%	0	0.00%	0	0.00%	5	0.03%	10	0.05%	**55**	**0.29%**

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD3265-40Q	Quadra Assura™ CRT-D	7320	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
CD3265-40	Quadra Assura™ CRT-D	2149	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%**
CD3257-40Q	Unify Assura™ CRT-D	1409	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	3677	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	8450	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	2402	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	18868	3	0.02%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	**7**	**0.04%**
CD3231-40	Unify™ CRT-D	20156	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	5	0.02%	**6**	**0.03%**
CD3211-36Q	Promote™ + CRT-D	6867	2	0.03%	0	0.00%	5	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	**10**	**0.15%**
CD3211-36	Promote™ + CRT-D	8575	2	0.02%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	**6**	**0.07%**
3207-36	Promote™ RF CRT-D	23974	5	0.02%	0	0.00%	8	0.03%	1	<0.01%	5	0.02%	1	<0.01%	4	0.02%	11	0.05%	**35**	**0.15%**
3207-30	Promote™ RF CRT-D	1395	0	0.00%	1	0.07%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.14%**
V-366	Atlas™ II + HF CRT-D	4921	3	0.06%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	4	0.08%	0	0.00%	**9**	**0.18%**
V-365	Atlas™ II HF CRT-D	8377	2	0.02%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	5	0.06%	5	0.06%	**15**	**0.18%**
V-343	Atlas™ + HF CRT-D	18739	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.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of 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
CD3249-40Q	869	5023	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	209	1179	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	1671	33422	0	0.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**1**	**0.06%**
CD3231-40	670	13470	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	853	26586	3	0.35%	0	0.00%	0	0.00%	1	0.12%	2	0.23%	**6**	**0.70%**
CD3211-36	222	6707	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	674	25547	1	0.15%	0	0.00%	0	0.00%	0	0.00%	2	0.30%	**3**	**0.45%**

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

Actively Monitored Study Data Summary

Malfunctions

Models	Family	Number of Devices Enrolled	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
CD3249-40Q	Unify Quadra™ CRT-D	869	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	209	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	1671	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%**
CD3231-40	Unify™ CRT-D	670	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	853	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	222	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote™ RF CRT-D	674	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	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
CD3249-40Q	Unify Quadra™ CRT-D	869	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	209	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	1671	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	670	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%**
CD3211-36Q	Promote™ + CRT-D	853	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	**2**	**0.23%**
CD3211-36	Promote™ + CRT-D	222	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote™ RF CRT-D	674	1	0.15%	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	0	0.00%	**3**	**0.45%**

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

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical

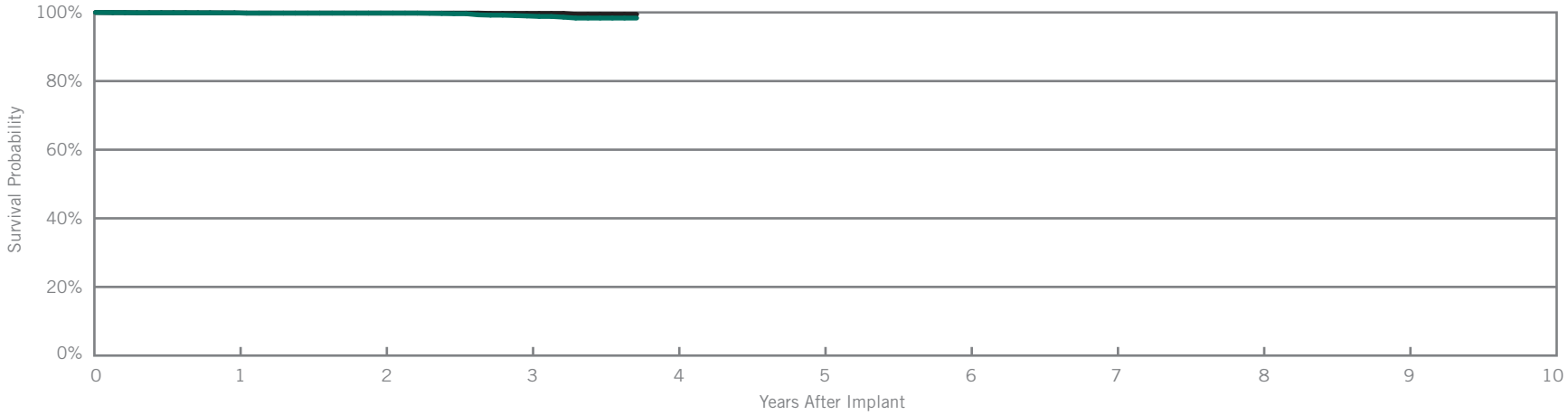
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	15,001
Estimated Active US Implants	11,877
Estimated Longevity	8 Years
Normal Battery Depletion	10
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	0	0.00%
Electrical Interconnect	3	0.02%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	3	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**7**	**0.05%**	**4**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.87%	99.81%	98.97%	98.36%						
± 1 standard error	0.03%	0.04%	0.18%	0.32%						
Sample Size	11990	6910	3170	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.87%	99.81%	99.72%	99.46%						
± 1 standard error	0.03%	0.04%	0.08%	0.20%						

Actively Monitored Study Data

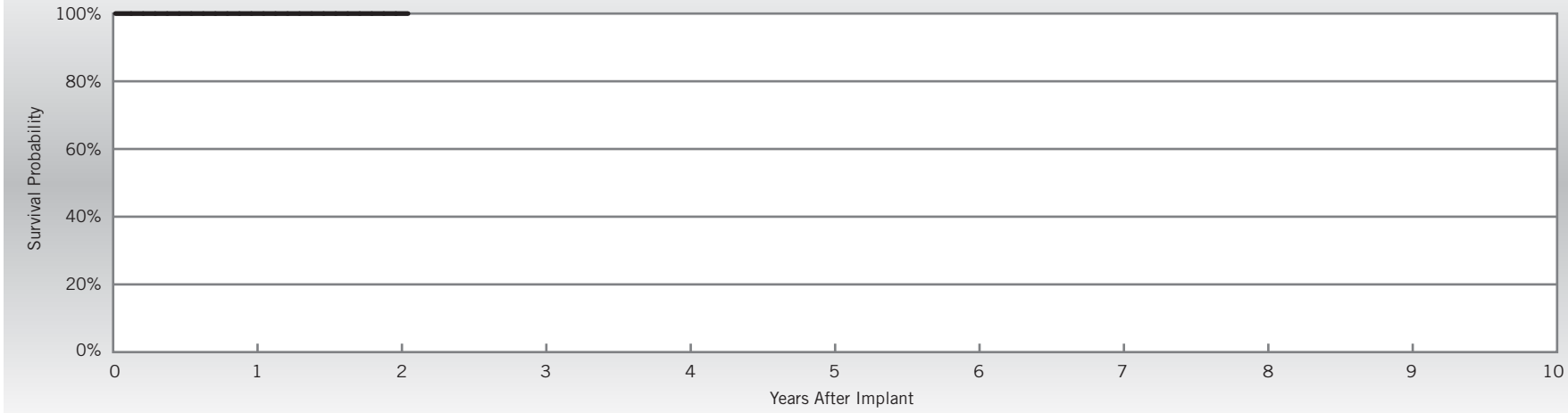
Anthem™ RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	195
Cumulative Months of Follow-up	3,270
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 25 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	160	90	50							

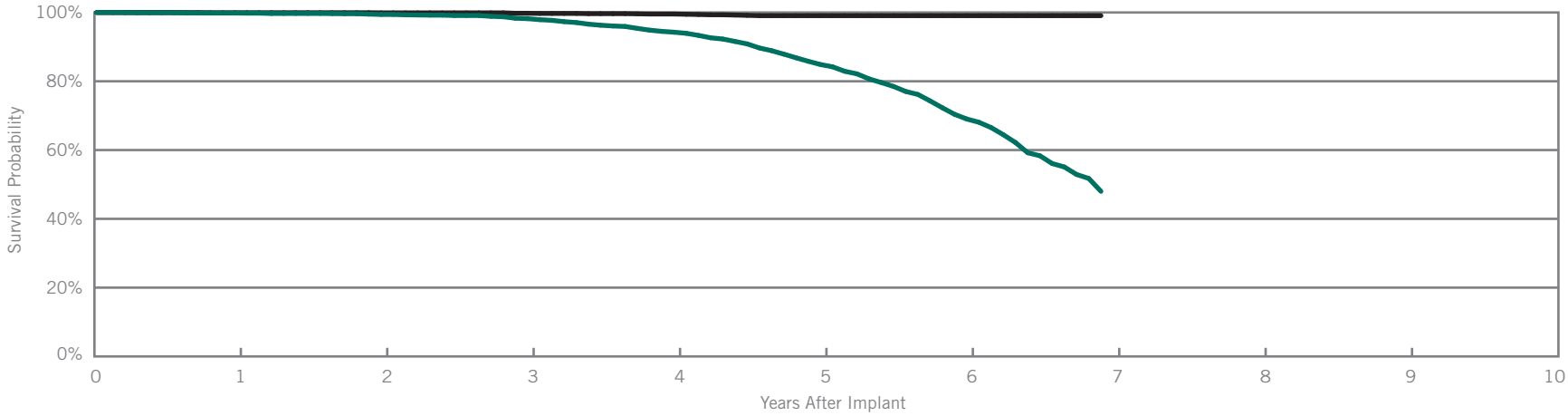
Customer Reported Performance Data

Frontier™ II CRT-P

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,807
Estimated Active US Implants	2,459
Estimated Longevity	6.5 Years
Normal Battery Depletion	310
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	7	0.10%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	7	0.10%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**14**	**0.21%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.84%	99.42%	98.20%	94.26%	84.87%	69.03%	48.00%			
± 1 standard error	0.05%	0.09%	0.19%	0.36%	0.66%	1.16%	1.76%			
Sample Size	6150	5110	4370	3520	2300	1080	220			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.93%	99.89%	99.77%	99.55%	99.07%	99.07%	99.07%			
± 1 standard error	0.03%	0.03%	0.07%	0.11%	0.17%	0.17%	0.17%			

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
PM3210	Anthem™ RF CRT-P	99.87%	99.81%	98.97%							
5586	Frontier™ II CRT-P	99.84%	99.42%	98.20%	94.26%	84.87%	69.03%				

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
PM3210	Anthem™ RF CRT-P	99.87%	99.81%	99.72%							
5586	Frontier™ II CRT-P	99.93%	99.89%	99.77%	99.55%	99.07%	99.07%				

Malfunction Summary

Models	Family	Registered US Implants	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
PM3210	Anthem™ RF CRT-P	15001	3	0.02%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	7	0.05%
5586	Frontier™ II CRT-P	6807	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	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
PM3210	Anthem™ RF CRT-P	15001	0	0.00%	0	0.00%	0	0.00%	3	0.02%	0	0.00%	0	0.00%	1	<0.01%	4	0.03%
5586	Frontier™ II CRT-P	6807	7	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	0	0.00%	14	0.21%

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

Left-Heart Leads

St. Jude Medical

Customer Reported Performance Data

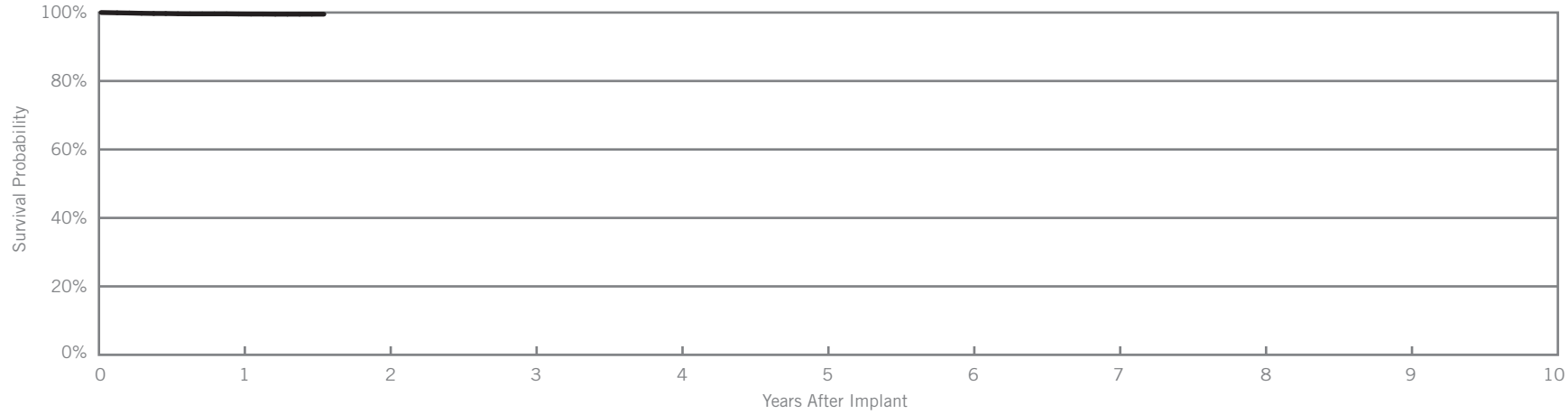
Quartet™

Model 1458Q

US Regulatory Approval	November 2011
Registered US Implants	20,592
Estimated Active US Implants	18,606
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	18	0.09%	39	0.19%
Failure to Capture	5	0.02%	8	0.04%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	1	<0.01%
Extracardiac Stimulation	9	0.04%	2	<0.01%
Other	1	<0.01%	2	<0.01%
Total	**34**	**0.17%**	**52**	**0.25%**
Total Returned for Analysis	**10**		**32**	

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	<0.01%
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	2	<0.01%
Extrinsic Factors	37	0.18%
Total	**40**	**0.19%**



Year	1	at 19 months								
Survival Probability	99.57%	99.52%								
± 1 standard error	0.05%	0.07%								
Sample Size	13080	430								

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

Actively Monitored Study Data

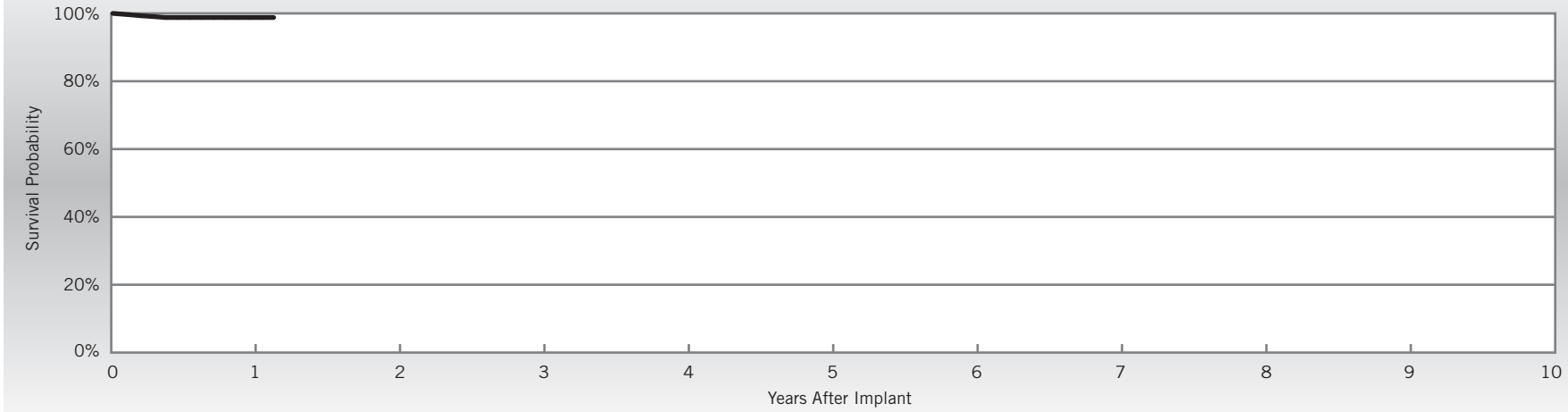
Quartet™

Model 1458Q

US Regulatory Approval	Nov 2011
Number of Devices Enrolled in Study	1,199
Cumulative Months of Follow-up	6,582
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	11	0.92%

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	3	0.25%
Total	**3**	**0.25%**



Year	1	at 14 months								
Survival Probability	98.79%	98.79%								
± 1 standard error	0.37%	0.37%								
Sample Size	650	60								

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

Customer Reported Performance Data

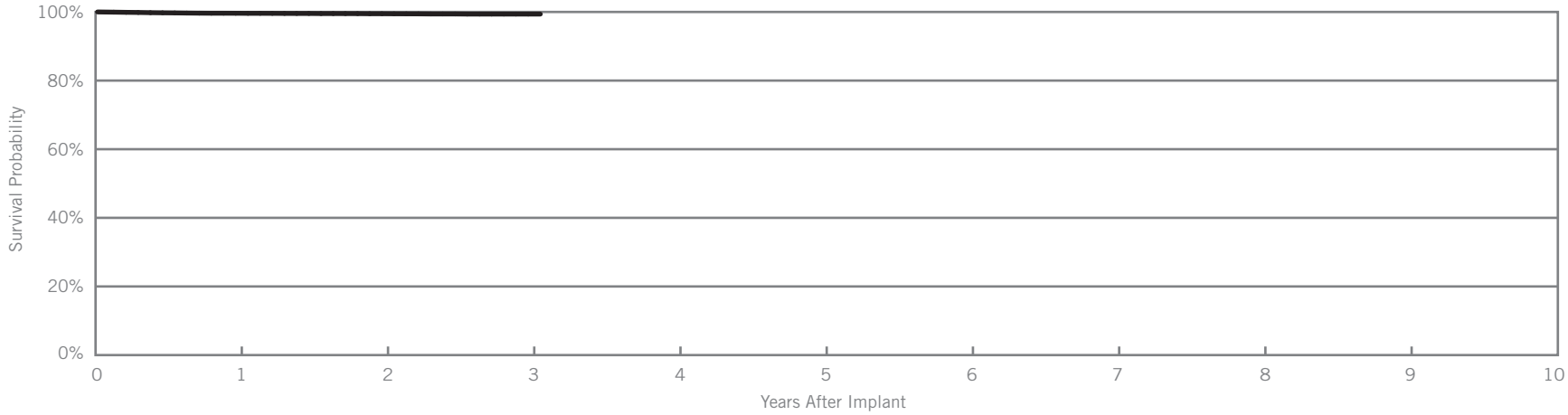
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	31,964
Estimated Active US Implants	25,885
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	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	<0.01%
Lead Dislodgement	23	0.07%	61	0.19%
Failure to Capture	8	0.03%	26	0.08%
Oversensing	0	0.00%	1	<0.01%
Failure to Sense	1	<0.01%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	<0.01%	0	0.00%
Extracardiac Stimulation	6	0.02%	10	0.03%
Other	4	0.01%	3	<0.01%
Total	**44**	**0.14%**	**103**	**0.32%**
Total Returned for Analysis	**25**		**72**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Clavicular Crush	1	<0.01%
In the Pocket	0	0.00%
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	1	<0.01%
Extrinsic Factors	97	0.30%
Total	**100**	**0.31%**



Year	1	2	3	at 37 months						
Survival Probability	99.62%	99.48%	99.38%	99.38%						
± 1 standard error	0.04%	0.05%	0.06%	0.06%						
Sample Size	26240	15330	5380	620						

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

Actively Monitored Study Data

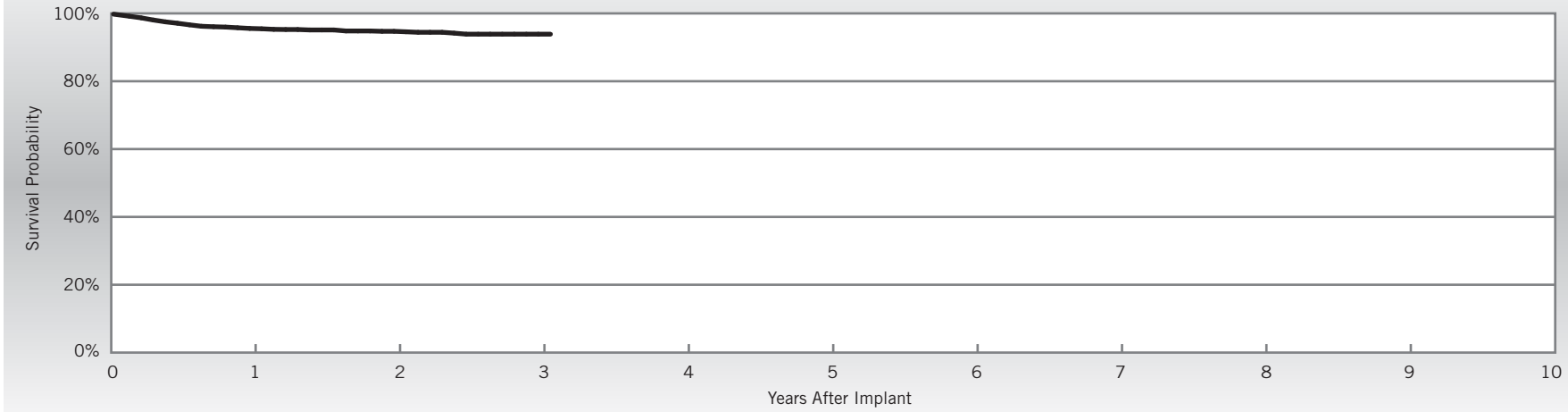
QuickFlex™ µ

Model 1258T

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	2,339
Cumulative Months of Follow-up	44,651
Insulation	Optim™*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	3	0.13%
Conductor Fracture	1	0.04%
Extracardiac Stimulation	45	1.92%
Failure to Capture	28	1.20%
Lead Dislodgement	37	1.58%

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	20	0.86%
Total	**21**	**0.90%**



Year	1	2	3	at 37 months						
Survival Probability	95.57%	94.72%	93.88%	93.88%						
± 1 standard error	0.43%	0.50%	0.66%	0.66%						
Sample Size	2100	1320	420	60						

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

Customer Reported Performance Data

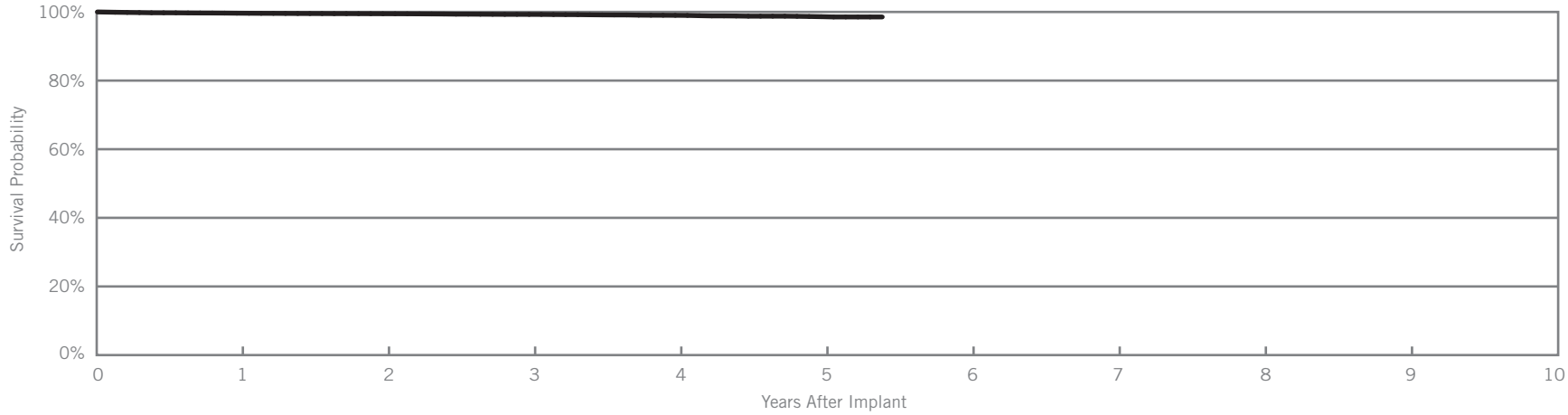
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	27,589
Estimated Active US Implants	17,677
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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%	1	<0.01%
Lead Dislodgement	11	0.04%	64	0.23%
Failure to Capture	4	0.01%	48	0.17%
Oversensing	0	0.00%	4	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	5	0.02%
Abnormal Pacing Impedance	0	0.00%	4	0.01%
Extracardiac Stimulation	13	0.05%	30	0.11%
Other	9	0.03%	1	<0.01%
Total	**37**	**0.13%**	**157**	**0.57%**
Total Returned for Analysis	**13**		**80**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	<0.01%
Insulation Breach	16	0.06%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	12	0.04%
Other	3	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	88	0.32%
Total	**106**	**0.38%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	99.64%	99.48%	99.29%	99.02%	98.62%	98.54%				
± 1 standard error	0.04%	0.05%	0.06%	0.08%	0.12%	0.16%				
Sample Size	25260	20730	15980	9930	3950	400				

Actively Monitored Study Data

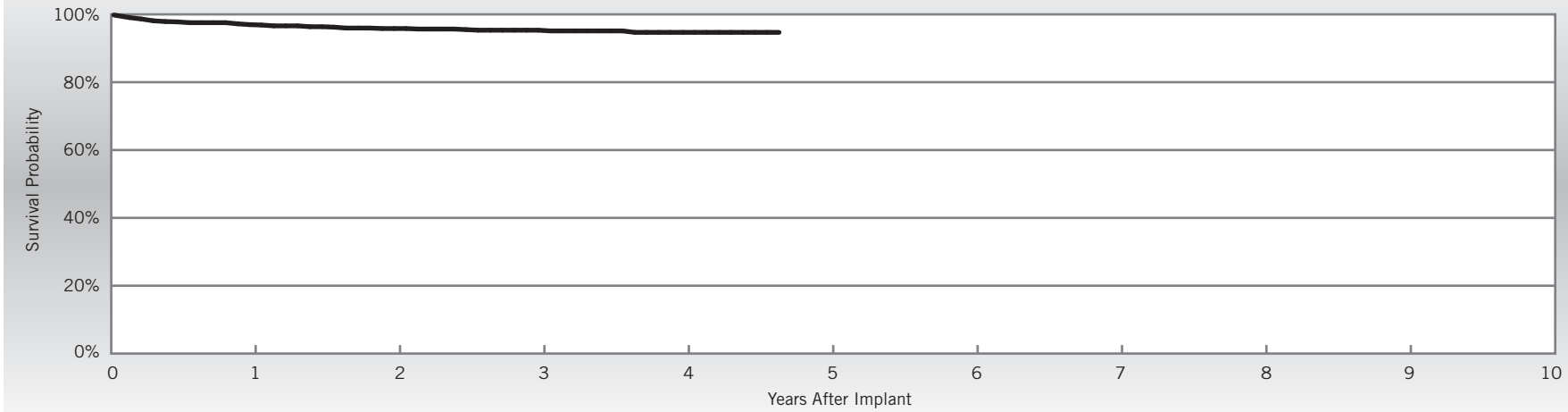
QuickFlex™

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	980
Cumulative Months of Follow-up	29,943
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	13	1.33%
Failure to Capture	10	1.02%
Lead Dislodgement	18	1.84%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	12	1.22%
Total	**12**	**1.22%**



Year	1	2	3	4	at 56 months					
Survival Probability	96.97%	95.82%	95.33%	94.69%	94.69%					
± 1 standard error	0.54%	0.68%	0.73%	0.87%	0.87%					
Sample Size	900	740	570	290	50					

Customer Reported Performance Data

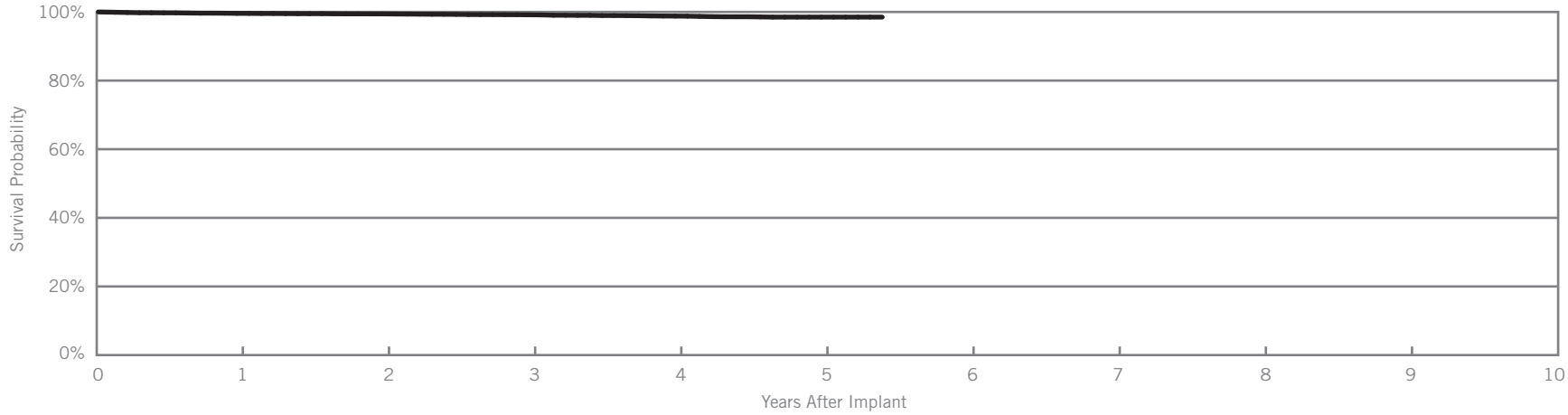
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,311
Estimated Active US Implants	9,904
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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	0.01%
Lead Dislodgement	9	0.06%	47	0.31%
Failure to Capture	2	0.01%	34	0.22%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	2	0.01%	1	<0.01%
Extracardiac Stimulation	5	0.03%	10	0.07%
Other	6	0.04%	3	0.02%
Total	**24**	**0.16%**	**101**	**0.66%**
Total Returned for Analysis	**13**		**56**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	1	<0.01%
Insulation Breach	14	0.09%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	7	0.05%
Other	7	0.05%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	60	0.39%
Total	**77**	**0.50%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	99.59%	99.43%	99.17%	98.80%	98.50%	98.50%				
± 1 standard error	0.05%	0.07%	0.08%	0.12%	0.16%	0.16%				
Sample Size	14050	11440	8650	5370	2250	250				

Actively Monitored Study Data

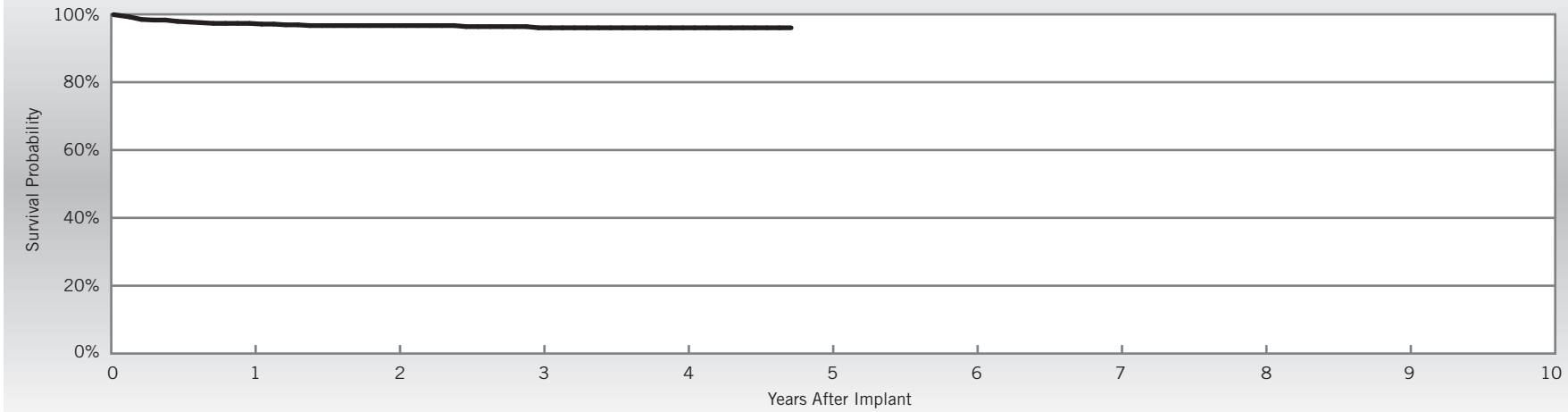
QuickFlex™ XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	558
Cumulative Months of Follow-up	17,679
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	7	1.25%
Failure to Capture	5	0.90%
Lead Dislodgement	5	0.90%
Oversensing	1	0.18%
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	at 57 months					
Survival Probability	97.34%	96.69%	96.04%	96.04%	96.04%					
± 1 standard error	0.70%	0.79%	0.84%	0.91%	0.91%					
Sample Size	510	420	330	190	50					

Customer Reported Performance Data

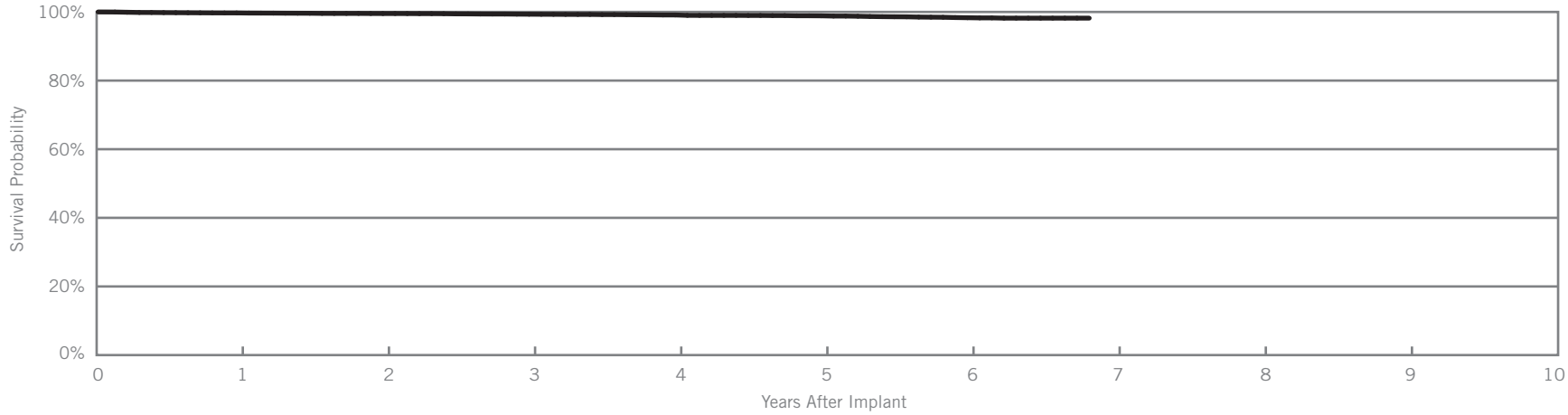
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	9,943
Estimated Active US Implants	5,153
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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%	19	0.19%
Failure to Capture	3	0.03%	31	0.31%
Oversensing	1	0.01%	1	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	3	0.03%
Abnormal Pacing Impedance	2	0.02%	3	0.03%
Extracardiac Stimulation	9	0.09%	9	0.09%
Other	1	0.01%	1	0.01%
Total	**26**	**0.26%**	**69**	**0.69%**
Total Returned for Analysis	**8**		**21**	

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	10	0.10%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	6	0.06%
Other	4	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	19	0.19%
Total	**32**	**0.32%**



Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.72%	99.54%	99.34%	99.12%	98.87%	98.32%	98.20%			
± 1 standard error	0.06%	0.07%	0.09%	0.11%	0.13%	0.18%	0.20%			
Sample Size	9170	7910	6960	5990	4980	3270	280			

Actively Monitored Study Data

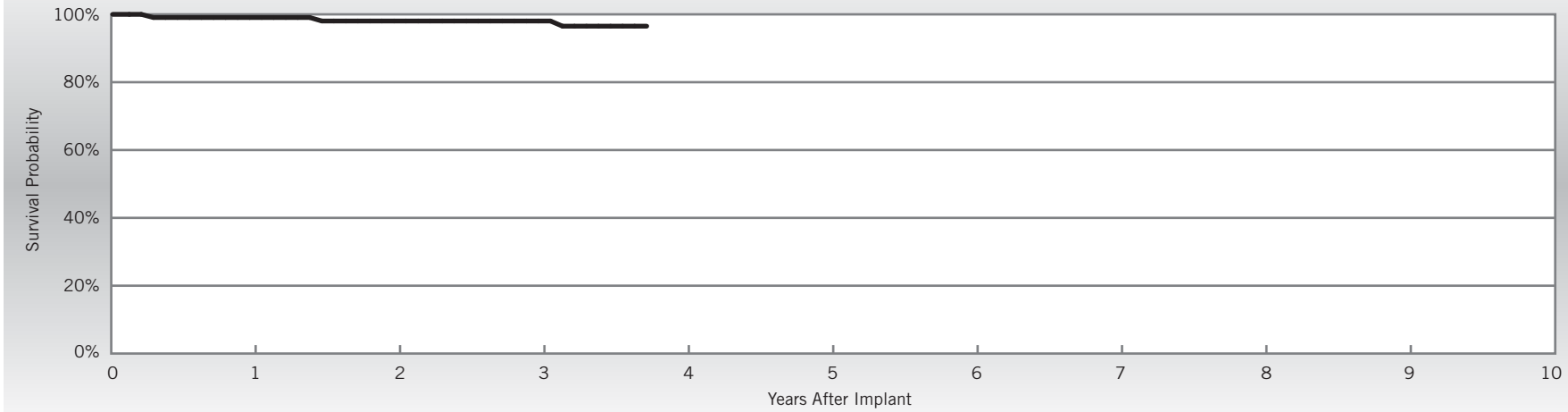
QuickSite™ XL

Model 1058T

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	111
Cumulative Months of Follow-up	4,464
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	3	2.70%

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



Year	1	2	3	at 45 months						
Survival Probability	99.07%	98.04%	98.04%	96.52%						
± 1 standard error	0.92%	1.38%	1.38%	2.03%						
Sample Size	100	90	80	50						

Customer Reported Performance Data

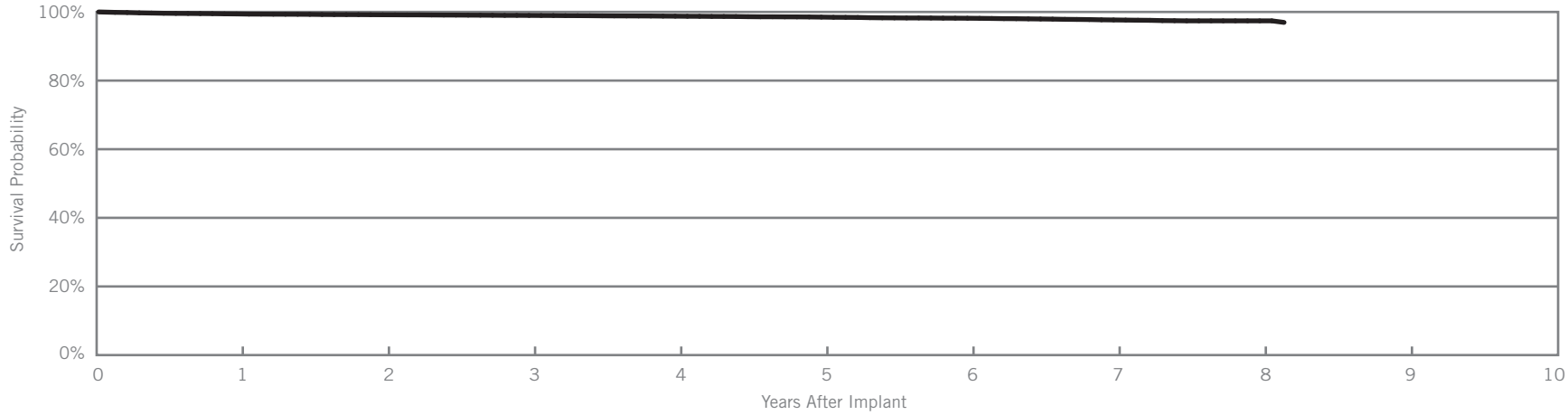
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	32,306
Estimated Active US Implants	14,678
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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	30	0.09%	114	0.35%
Failure to Capture	14	0.04%	117	0.36%
Oversensing	1	<0.01%	6	0.02%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	11	0.03%
Abnormal Pacing Impedance	3	<0.01%	4	0.01%
Extracardiac Stimulation	22	0.07%	56	0.17%
Other	9	0.03%	9	0.03%
Total	**80**	**0.25%**	**323**	**1.00%**
Total Returned for Analysis	**27**		**130**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	3	<0.01%
Insulation Breach	42	0.13%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	6	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	25	0.08%
Other	11	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	121	0.37%
Total	**168**	**0.52%**



Year	1	2	3	4	5	6	7	8	at 98 months	
Survival Probability	99.42%	99.18%	98.99%	98.77%	98.50%	98.17%	97.67%	97.41%	96.95%	
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.08%	0.09%	0.12%	0.15%	0.15%	
Sample Size	29750	25550	22370	19210	16060	12240	7540	2840	300	

Actively Monitored Study Data

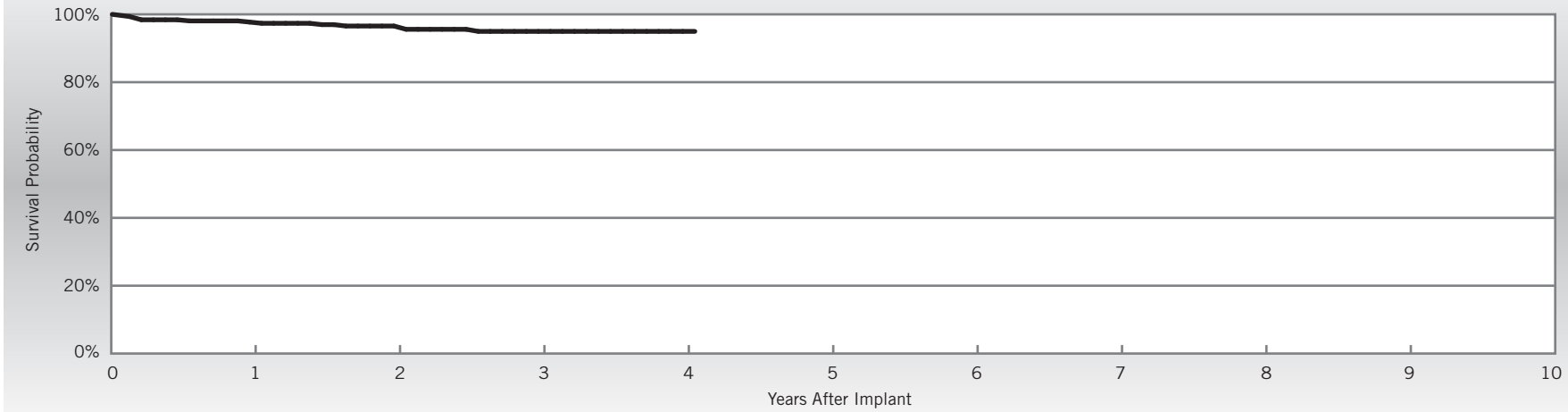
QuickSite™

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	320
Cumulative Months of Follow-up	9,755
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.31%
Extracardiac Stimulation	2	0.63%
Failure to Capture	4	1.25%
Lead Dislodgement	6	1.88%

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	3	0.94%
Total	**3**	**0.94%**



Year	1	2	3	4	at 49 months					
Survival Probability	97.72%	96.56%	94.98%	94.98%	94.98%					
± 1 standard error	0.78%	1.08%	1.39%	1.39%	1.39%					
Sample Size	300	240	160	90	50					

Customer Reported Performance Data

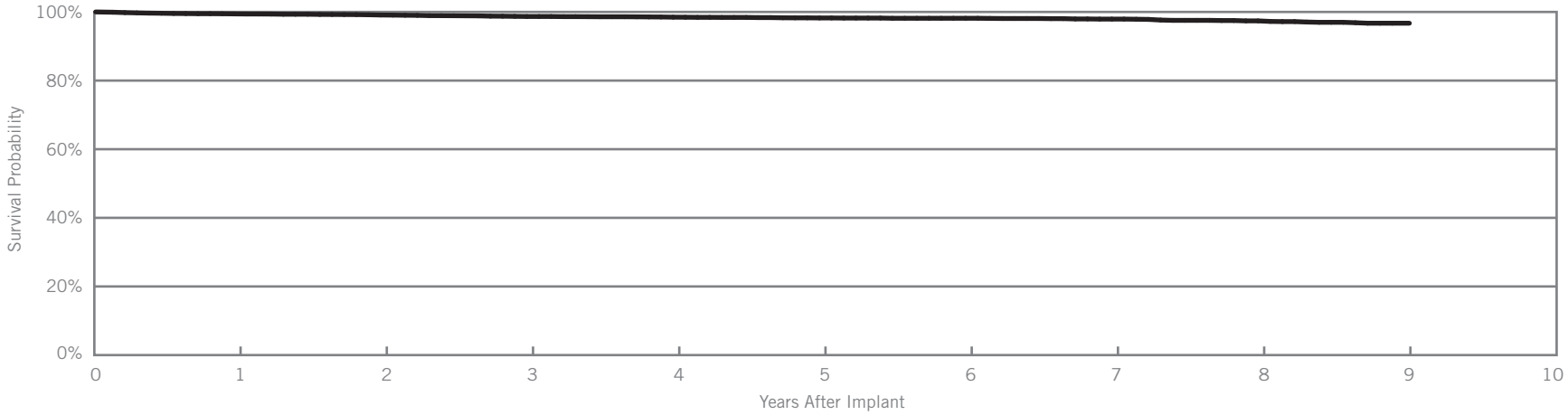
QuickSite™

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	7,802
Estimated Active US Implants	2,485
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%	2	0.03%
Lead Dislodgement	10	0.13%	31	0.40%
Failure to Capture	3	0.04%	41	0.53%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	3	0.04%
Extracardiac Stimulation	10	0.13%	17	0.22%
Other	2	0.03%	9	0.12%
Total	**25**	**0.32%**	**103**	**1.32%**
Total Returned for Analysis	**13**		**43**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.03%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.03%
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	44	0.56%
Total	**47**	**0.60%**



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.43%	99.11%	98.68%	98.48%	98.25%	98.16%	97.92%	97.40%	96.72%	
± 1 standard error	0.09%	0.11%	0.14%	0.16%	0.17%	0.18%	0.21%	0.26%	0.35%	
Sample Size	7170	6120	5300	4530	3820	3150	2530	2070	310	

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™	99.57%									
1258T	QuickFlex™ µ	99.62%	99.48%	99.38%							
1156T	QuickFlex™	99.64%	99.48%	99.29%	99.02%	98.62%					
1158T	QuickFlex™ XL	99.59%	99.43%	99.17%	98.80%	98.50%					
1058T	QuickSite™ XL	99.72%	99.54%	99.34%	99.12%	98.87%	98.32%				
1056T	QuickSite™	99.42%	99.18%	98.99%	98.77%	98.50%	98.17%	97.67%	97.41%		
1056K	QuickSite™	99.43%	99.11%	98.68%	98.48%	98.25%	98.16%	97.92%	97.40%	96.72%	

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	20592	18606	0	0.00%	0	0.00%	18	0.09%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	9	0.04%	1	<0.01%	**34**	**0.17%**	**10**
1258T	May-10	31964	25885	0	0.00%	0	0.00%	23	0.07%	8	0.03%	0	0.00%	1	<0.01%	0	0.00%	2	<0.01%	6	0.02%	4	0.01%	**44**	**0.14%**	**25**
1156T	Jul-07	27589	17677	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%**	**13**
1158T	Jul-07	15311	9904	0	0.00%	0	0.00%	9	0.06%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	5	0.03%	6	0.04%	**24**	**0.16%**	**13**
1058T	Feb-06	9943	5153	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%**	**8**
1056T	Apr-05	32306	14678	0	0.00%	0	0.00%	30	0.09%	14	0.04%	1	<0.01%	0	0.00%	1	<0.01%	3	<0.01%	22	0.07%	9	0.03%	**80**	**0.25%**	**27**
1056K	Jun-04	7802	2485	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	20592	18606	0	0.00%	0	0.00%	39	0.19%	8	0.04%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	2	<0.01%	**52**	**0.25%**	**32**
1258T	May-10	31964	25885	0	0.00%	2	<0.01%	61	0.19%	26	0.08%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	10	0.03%	3	<0.01%	**103**	**0.32%**	**72**
1156T	Jul-07	27589	17677	0	0.00%	1	<0.01%	64	0.23%	48	0.17%	4	0.01%	0	0.00%	5	0.02%	4	0.01%	30	0.11%	1	<0.01%	**157**	**0.57%**	**80**
1158T	Jul-07	15311	9904	0	0.00%	2	0.01%	47	0.31%	34	0.22%	0	0.00%	1	<0.01%	3	0.02%	1	<0.01%	10	0.07%	3	0.02%	**101**	**0.66%**	**56**
1058T	Feb-06	9943	5153	0	0.00%	2	0.02%	19	0.19%	31	0.31%	1	0.01%	0	0.00%	3	0.03%	3	0.03%	9	0.09%	1	0.01%	**69**	**0.69%**	**21**
1056T	Apr-05	32306	14678	0	0.00%	5	0.02%	114	0.35%	117	0.36%	6	0.02%	1	<0.01%	11	0.03%	4	0.01%	56	0.17%	9	0.03%	**323**	**1.00%**	**130**
1056K	Jun-04	7802	2485	0	0.00%	2	0.03%	31	0.40%	41	0.53%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	17	0.22%	9	0.12%	**103**	**1.32%**	**43**

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

Malfunction Summary

		Conductor Fracture								Insulation Breach																			
		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		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	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	20592	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%	2	<0.01%	37	0.18%	**40**	**0.19%**
1258T	31964	1	<0.01%	0	0.00%	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%	1	<0.01%	97	0.30%	**100**	**0.31%**
1156T	27589	0	0.00%	0	0.00%	2	<0.01%	**2**	**<0.01%**	0	0.00%	1	<0.01%	0	0.00%	12	0.04%	3	0.01%	**16**	**0.06%**	0	0.00%	0	0.00%	88	0.32%	**106**	**0.38%**
1158T	15311	0	0.00%	1	<0.01%	1	<0.01%	**2**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	7	0.05%	7	0.05%	**14**	**0.09%**	1	<0.01%	0	0.00%	60	0.39%	**77**	**0.50%**
1058T	9943	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**	0	0.00%	0	0.00%	0	0.00%	6	0.06%	4	0.04%	**10**	**0.10%**	0	0.00%	1	0.01%	19	0.19%	**32**	**0.32%**
1056T	32306	0	0.00%	1	<0.01%	3	<0.01%	**4**	**0.01%**	0	0.00%	6	0.02%	0	0.00%	25	0.08%	11	0.03%	**42**	**0.13%**	0	0.00%	1	<0.01%	121	0.37%	**168**	**0.52%**
1056K	7802	0	0.00%	0	0.00%	2	0.03%	**2**	**0.03%**	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**	0	0.00%	0	0.00%	44	0.56%	**47**	**0.60%**

Definitions of malfunction categories can be found on pages 10-11.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Pacing Impedance		Cardiac Perforation		Conductor Fracture		Extracardiac Stimulation		Failure to Capture		Failure to Sense		Insulation Breach		Lead Dislodgement		Oversensing		Pericardial Effusion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1458Q	1199	6582	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	11	0.92%	0	0.00%	0	0.00%	0	0.00%	**11**	**0.92%**
1258T	2339	44651	3	0.13%	0	0.00%	1	0.04%	45	1.92%	28	1.20%	0	0.00%	0	0.00%	37	1.58%	0	0.00%	0	0.00%	0	0.00%	**114**	**4.87%**
1156T	980	29943	1	0.10%	0	0.00%	0	0.00%	13	1.33%	10	1.02%	0	0.00%	0	0.00%	18	1.84%	0	0.00%	0	0.00%	0	0.00%	**42**	**4.29%**
1158T	558	17679	0	0.00%	0	0.00%	0	0.00%	7	1.25%	5	0.90%	0	0.00%	0	0.00%	5	0.90%	1	0.18%	0	0.00%	1	0.18%	**19**	**3.41%**
1058T	111	4464	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	2.70%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**2.70%**
1056T	320	9755	1	0.31%	0	0.00%	0	0.00%	2	0.63%	4	1.25%	0	0.00%	0	0.00%	6	1.88%	0	0.00%	0	0.00%	0	0.00%	**13**	**4.06%**

Malfunctions

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	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	1199	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%	3	0.25%	**3**	**0.25%**
1258T	2339	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%	20	0.86%	**21**	**0.90%**
1156T	980	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%	12	1.22%	**12**	**1.22%**
1158T	558	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	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	320	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%	3	0.94%	**3**	**0.94%**

Definitions of malfunction categories can be found on pages 10-11.
A list of complications can be found on page 15.

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical

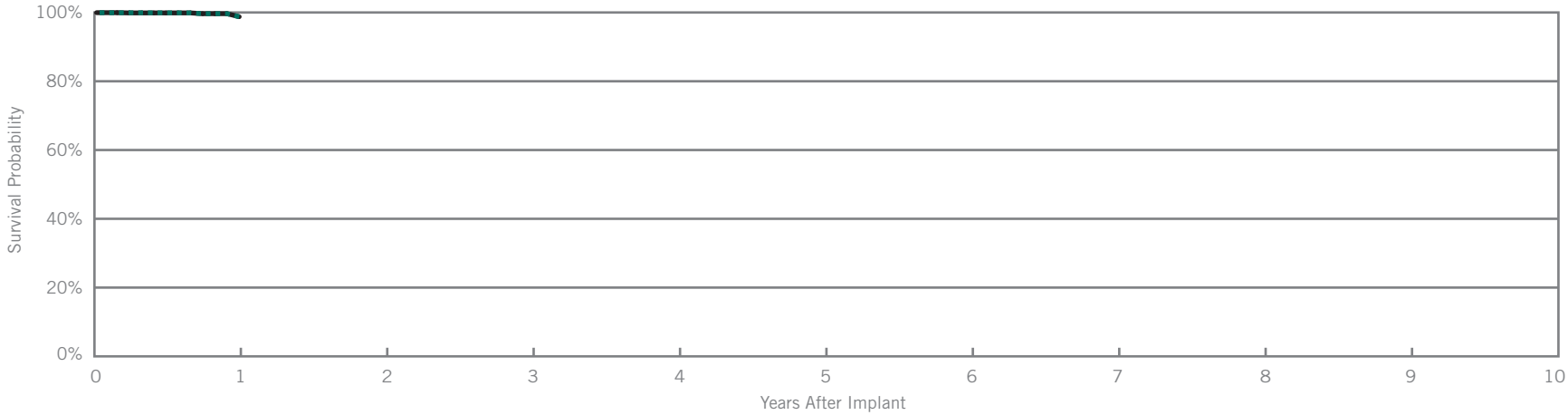
Customer Reported Performance Data

Ellipse™ DR

Model CD2311-36Q

US Regulatory Approval	May 2012
Registered US Implants	3,608
Estimated Active US Implants	3,367
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	0.03%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	0.06%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.03%
Total	**2**	**0.06%**	**2**	**0.06%**



Including Normal Battery Depletion

Year	1									
Survival Probability	98.76%									
± 1 standard error	0.17%									
Sample Size	290									

Excluding Normal Battery Depletion

Year	1									
Survival Probability	98.76%									
± 1 standard error	0.17%									

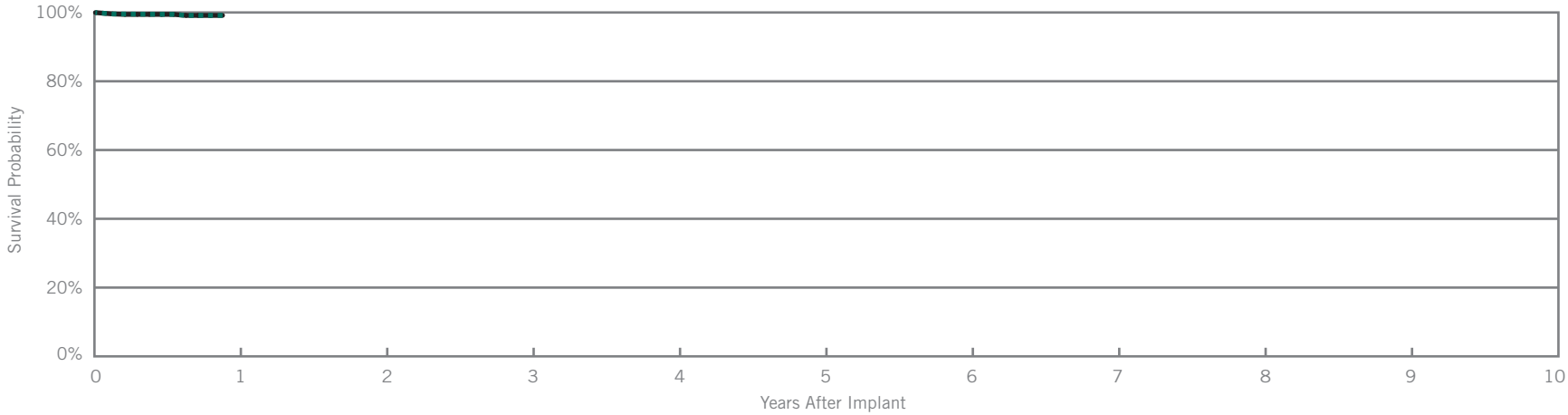
Customer Reported Performance Data

Ellipse™ DR

Model CD2311-36

US Regulatory Approval	May 2012
Registered US Implants	2,144
Estimated Active US Implants	2,012
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	2	0.09%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	0.05%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	0.09%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.14%**	**2**	**0.09%**



Including Normal Battery Depletion

Year	at 11 months										
Survival Probability	99.14%										
± 1 standard error	0.27%										
Sample Size	240										

Excluding Normal Battery Depletion

Year	at 11 months										
Survival Probability	99.14%										
± 1 standard error	0.27%										

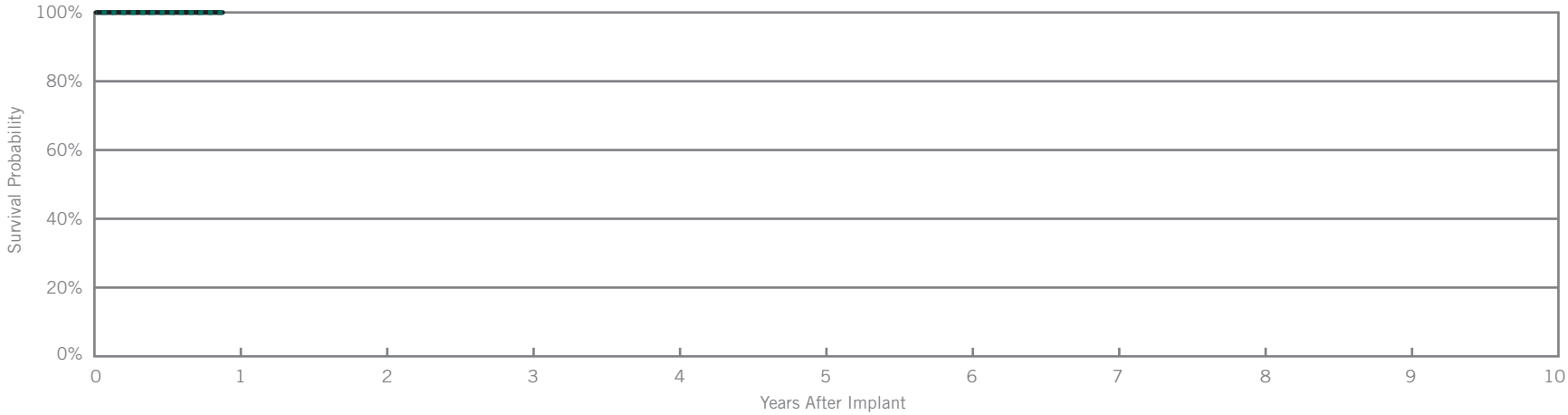
Customer Reported Performance Data

Fortify Assura™ DR

Model CD2257-40Q

US Regulatory Approval	May 2012
Registered US Implants	3,656
Estimated Active US Implants	3,439
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	290										

Excluding Normal Battery Depletion

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

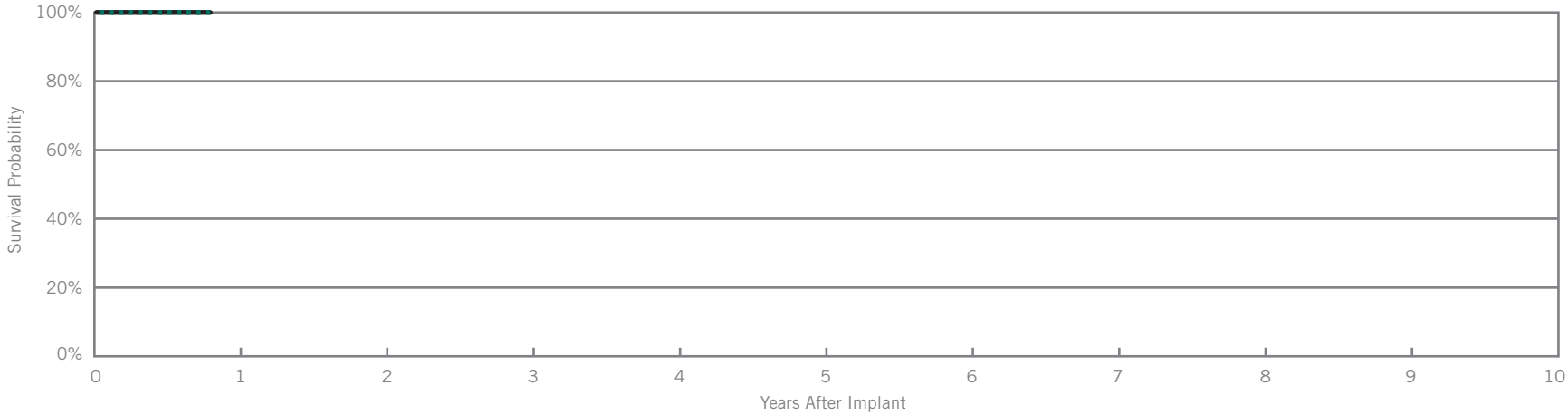
Customer Reported Performance Data

Fortify Assura™ DR

Model CD2257-40

US Regulatory Approval	May 2012
Registered US Implants	2,285
Estimated Active US Implants	2,164
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	290										

Excluding Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

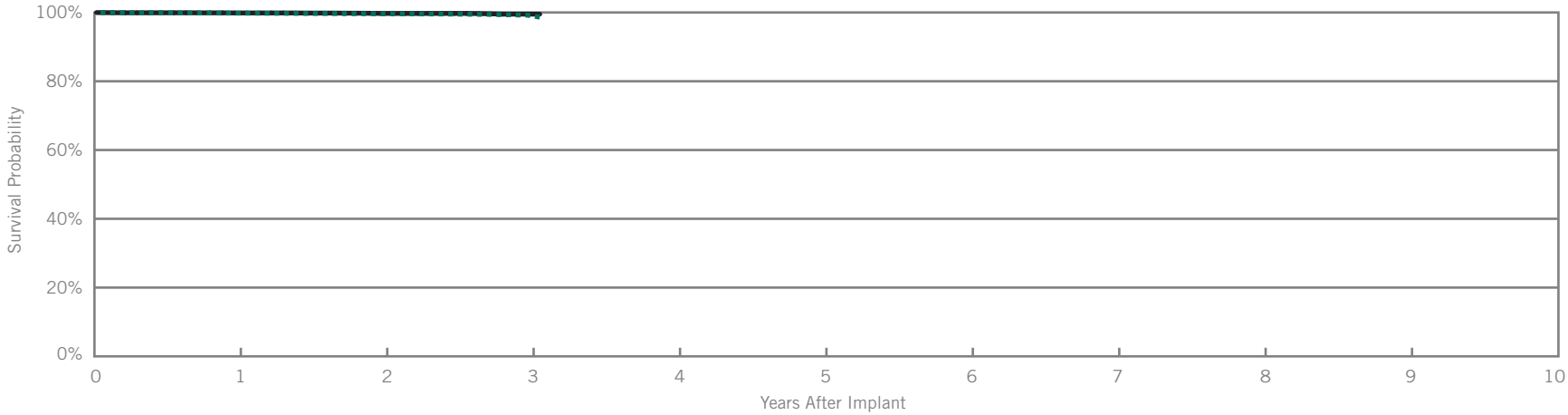
Customer Reported Performance Data

Fortify™ DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	26,529
Estimated Active US Implants	21,008
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	16
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%	4	0.02%
Electrical Interconnect	1	<0.01%	2	<0.01%
Battery	2	<0.01%	0	0.00%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	1	<0.01%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.01%	1	<0.01%
Other	5	0.02%	2	<0.01%
Total	**15**	**0.06%**	**9**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.76%	99.55%	99.21%	98.63%						
± 1 standard error	0.03%	0.05%	0.14%	0.14%						
Sample Size	23300	14930	5160	550						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.86%	99.72%	99.51%	99.51%						
± 1 standard error	0.02%	0.04%	0.10%	0.10%						

Actively Monitored Study Data

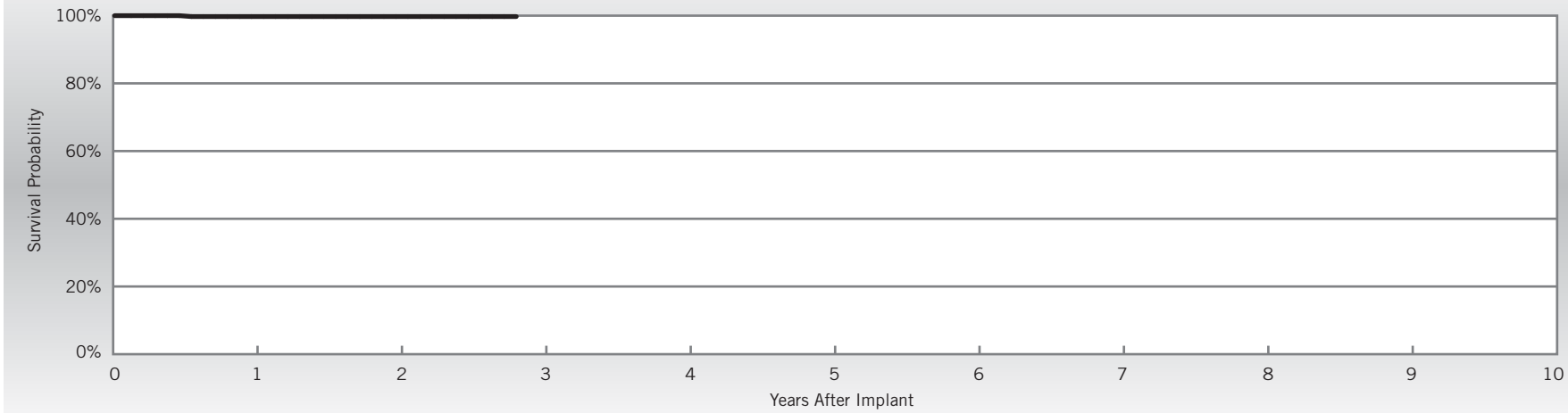
Fortify™ DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	387
Cumulative Months of Follow-up	9,824
Estimated Longevity	(see table on page 99)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	1	0.26%

	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	0.26%	0	0.00%
Total	**1**	**0.26%**	**0**	**0.00%**



Year	1	2	at 34 months							
Survival Probability	99.74%	99.74%	99.74%							
± 1 standard error	0.26%	0.26%	0.26%							
Sample Size	380	310	50							

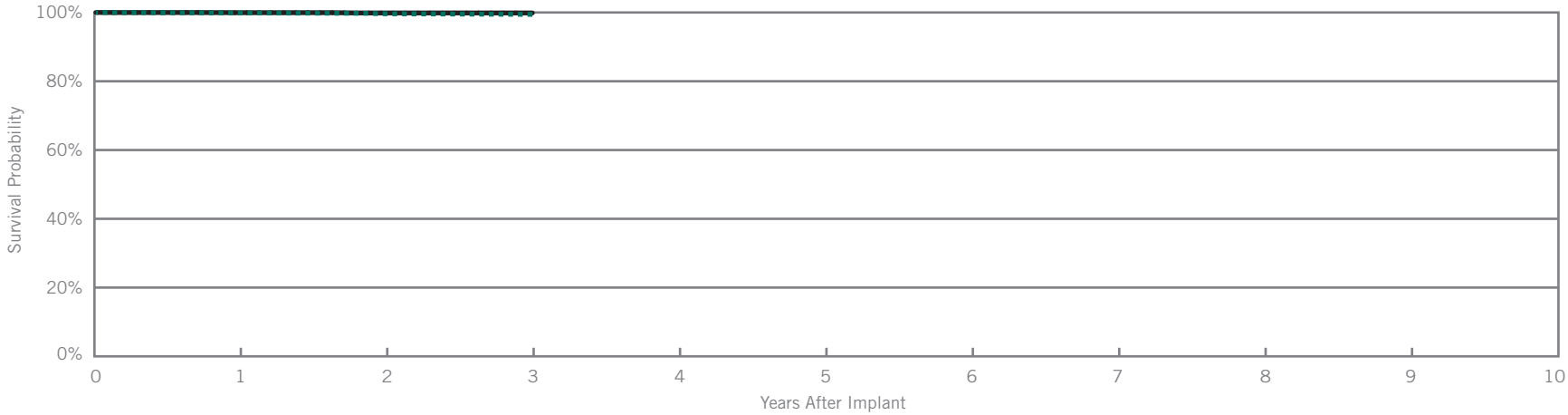
Customer Reported Performance Data

Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	11,863
Estimated Active US Implants	9,454
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	8
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%	1	<0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**4**	**0.03%**	**1**	**<0.01%**



Including Normal Battery Depletion

Year	1	2	3							
Survival Probability	99.87%	99.63%	99.45%							
± 1 standard error	0.03%	0.06%	0.12%							
Sample Size	10310	6320	420							

Excluding Normal Battery Depletion

Year	1	2	3							
Survival Probability	99.94%	99.86%	99.86%							
± 1 standard error	0.02%	0.05%	0.05%							

Actively Monitored Study Data

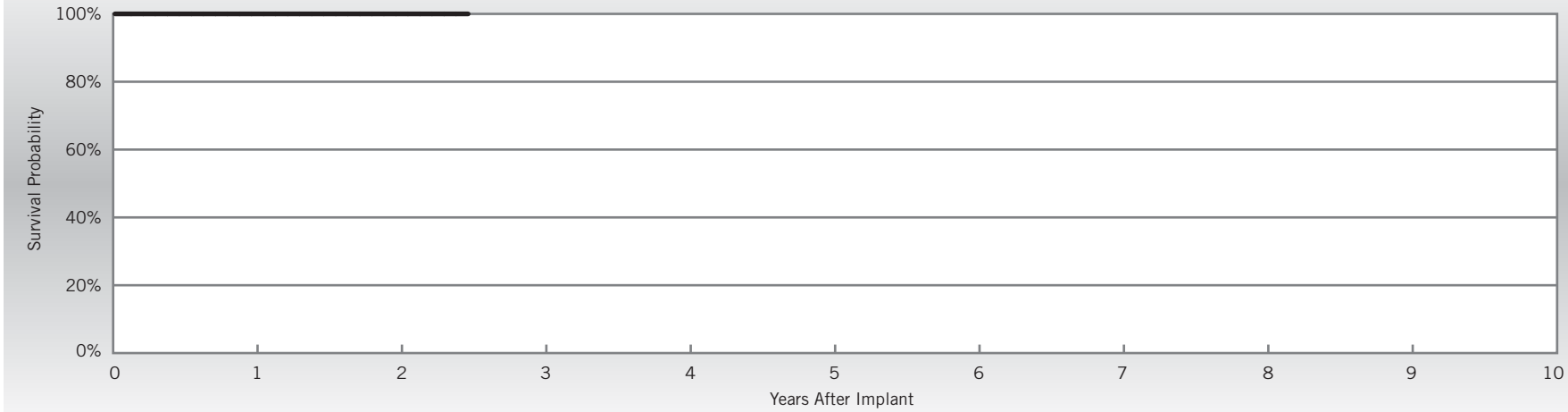
Fortify™ DR

Model CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	176
Cumulative Months of Follow-up	3,960
Estimated Longevity	(see table on page 99)
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 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	160	120	60							

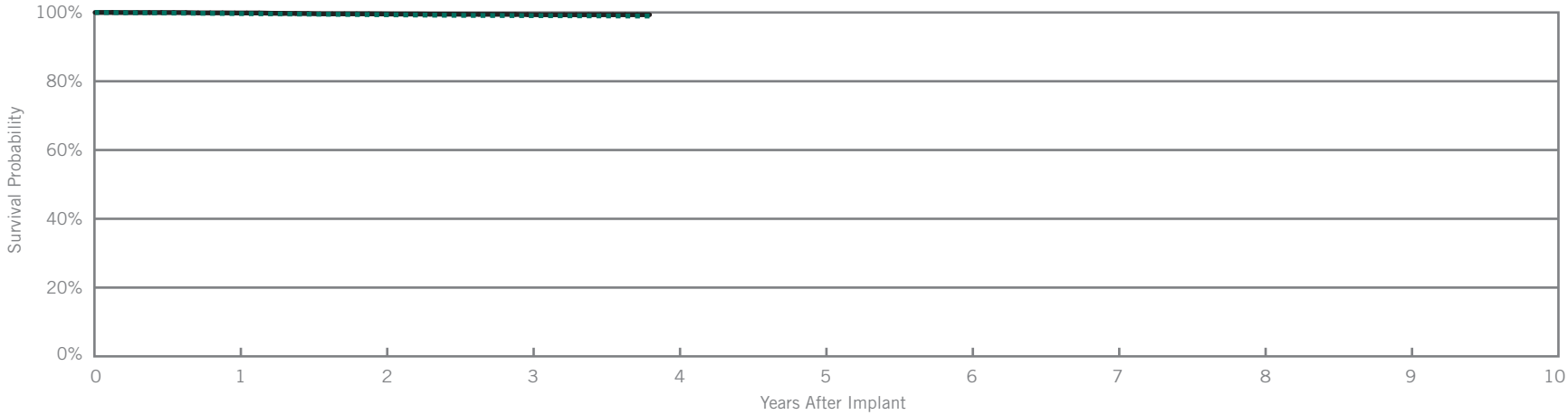
Customer Reported Performance Data

Current™ + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	8,110
Estimated Active US Implants	5,557
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	9
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	0.05%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.04%	5	0.06%
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%	1	0.01%
Other	1	0.01%	1	0.01%
Total	**10**	**0.12%**	**9**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.85%	99.38%	99.00%	98.96%						
± 1 standard error	0.04%	0.09%	0.12%	0.13%						
Sample Size	7500	6400	5400	330						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.85%	99.57%	99.38%	99.34%						
± 1 standard error	0.04%	0.08%	0.09%	0.10%						

Actively Monitored Study Data

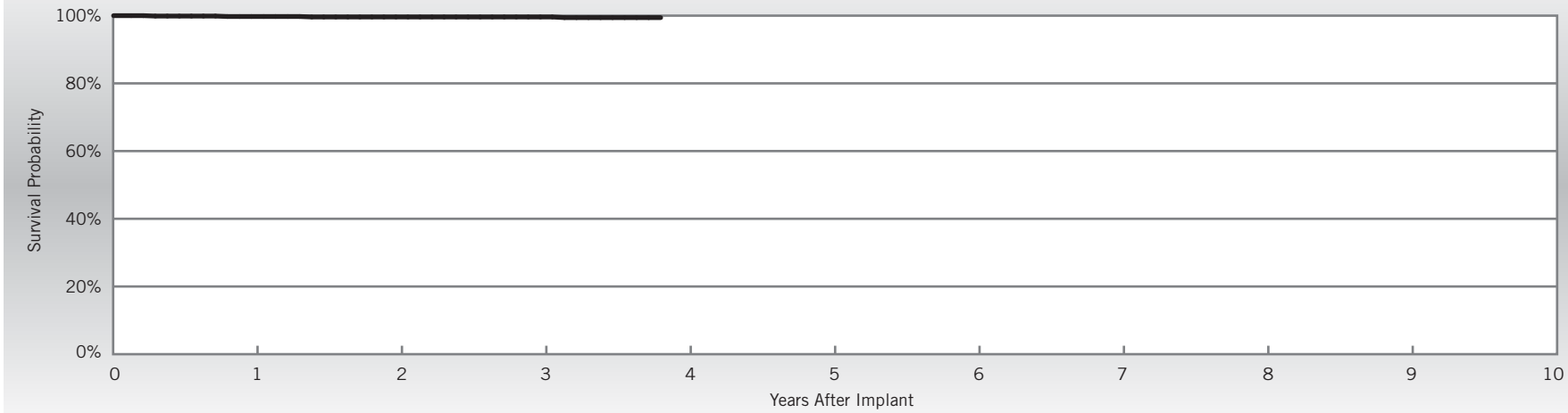
Current™ + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	834
Cumulative Months of Follow-up	28,588
Estimated Longevity	(see table on page 99)
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	at 46 months						
Survival Probability	99.75%	99.61%	99.61%	99.42%						
± 1 standard error	0.18%	0.23%	0.23%	0.29%						
Sample Size	790	710	640	90						

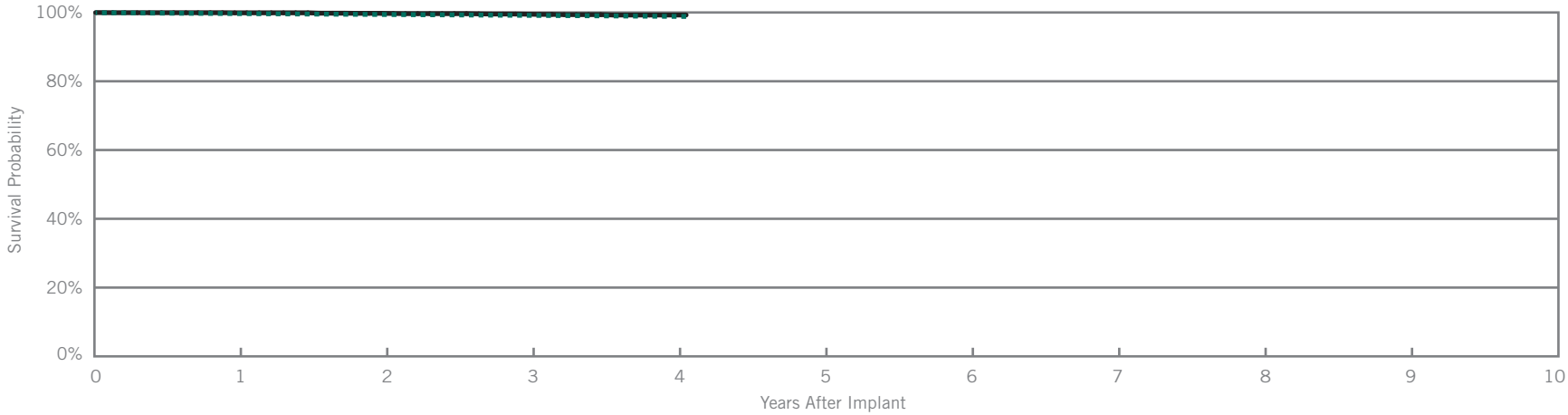
Customer Reported Performance Data

Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,214
Estimated Active US Implants	4,198
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	8
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	1	0.02%	0	0.00%
Battery	2	0.03%	3	0.05%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.03%	2	0.03%
Other	1	0.02%	0	0.00%
Total	**8**	**0.13%**	**6**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.78%	99.55%	99.25%	98.84%	98.84%					
± 1 standard error	0.06%	0.09%	0.12%	0.18%	0.18%					
Sample Size	5750	4820	3960	1920	290					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.90%	99.75%	99.50%	99.26%	99.26%					
± 1 standard error	0.03%	0.07%	0.10%	0.15%	0.15%					

Actively Monitored Study Data

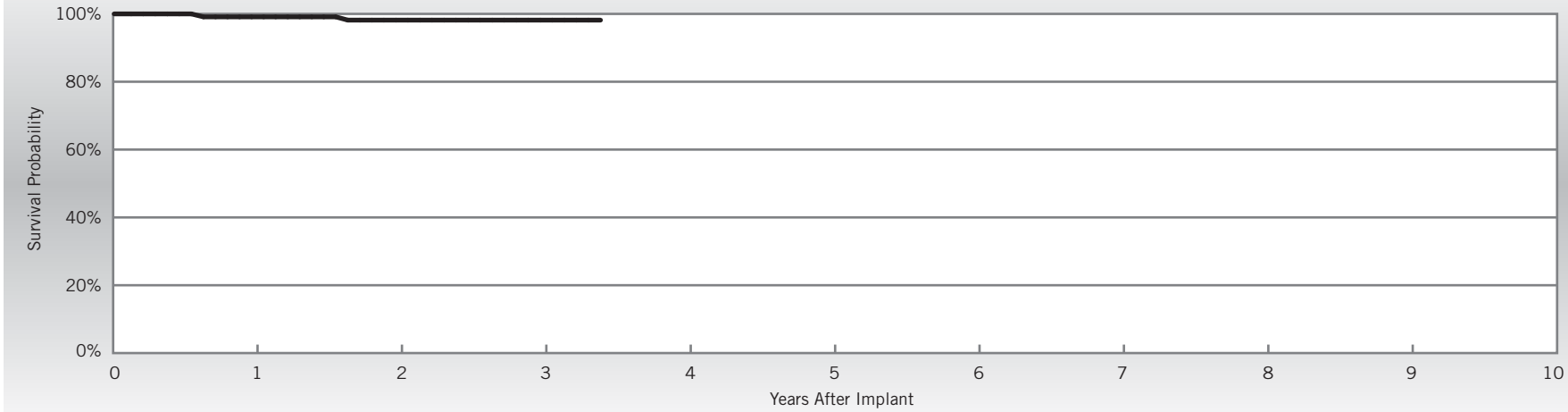
Current™ + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	121
Cumulative Months of Follow-up	4,027
Estimated Longevity	(see table on page 99)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.83%
Premature Battery Depletion	1	0.83%

	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%	1	0.83%
Total	**0**	**0.00%**	**1**	**0.83%**



Year	1	2	3	at 41 months						
Survival Probability	99.13%	98.17%	98.17%	98.17%						
± 1 standard error	0.87%	1.28%	1.28%	1.28%						
Sample Size	120	100	80	50						

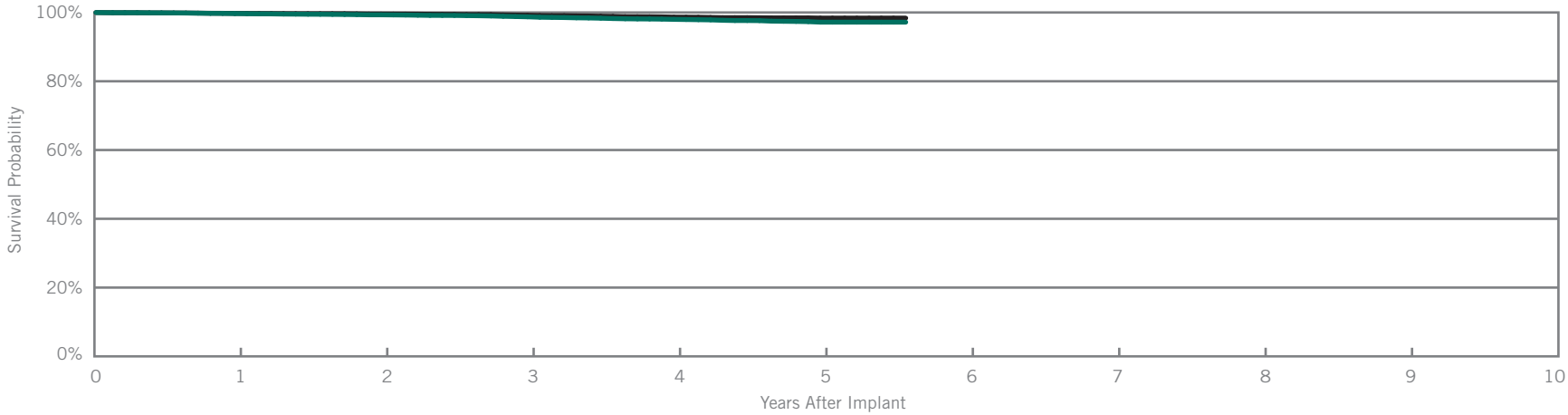
Customer Reported Performance Data

Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,359
Estimated Active US Implants	12,741
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	53
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	0.02%	9	0.04%
Electrical Interconnect	6	0.03%	2	<0.01%
Battery	7	0.03%	7	0.03%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	4	0.02%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	20	0.09%	13	0.06%
Other	17	0.08%	5	0.02%
Total	**56**	**0.25%**	**41**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.69%	99.31%	98.73%	97.99%	97.18%	97.18%				
± 1 standard error	0.04%	0.06%	0.08%	0.11%	0.15%	0.17%				
Sample Size	20810	18030	15740	12700	6820	360				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.73%	99.56%	99.19%	98.65%	98.37%	98.37%				
± 1 standard error	0.03%	0.05%	0.07%	0.09%	0.11%	0.12%				

Actively Monitored Study Data

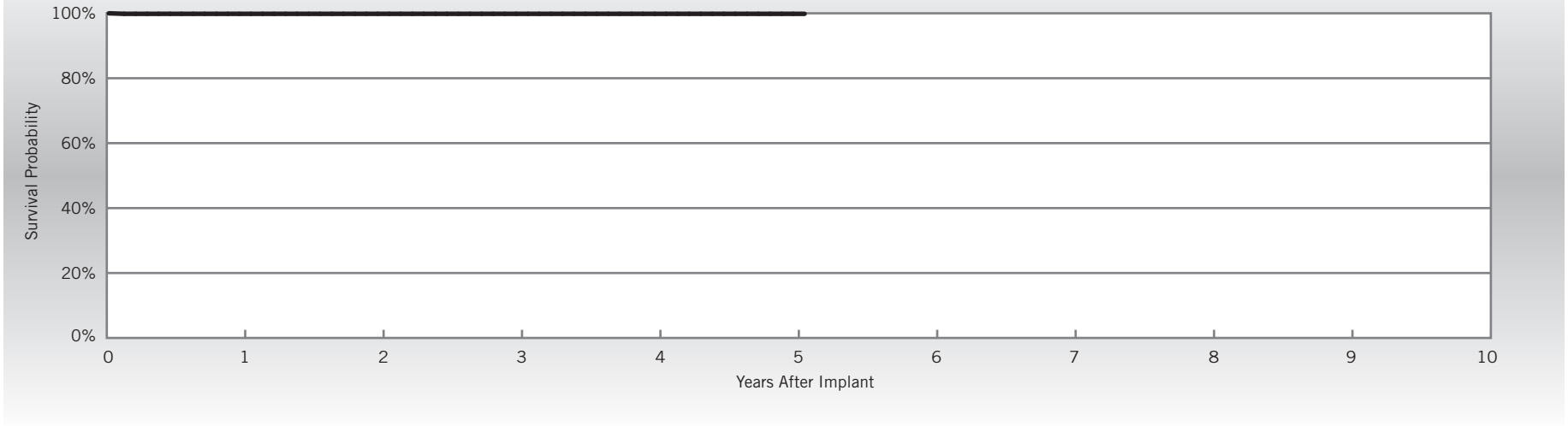
Current™ DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	631
Cumulative Months of Follow-up	24,596
Estimated Longevity	(see table on page 99)
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	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	600	520	430	330	170	50				

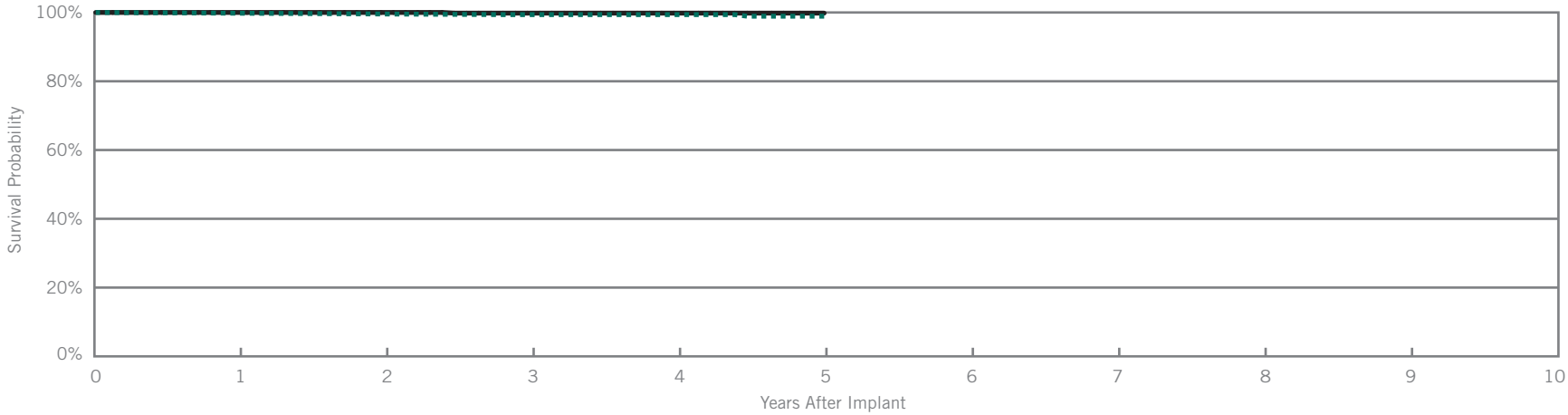
Customer Reported Performance Data

Current™ DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,522
Estimated Active US Implants	885
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	4
Max. Delivered Energy	30 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.07%
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**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	99.71%	99.56%	99.37%	99.37%	98.91%					
± 1 standard error	0.10%	0.18%	0.22%	0.22%	0.40%					
Sample Size	1420	1230	1080	840	230					

Excluding Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	100.00%	100.00%	99.81%	99.81%	99.81%					
± 1 standard error	0.00%	0.00%	0.13%	0.13%	0.13%					

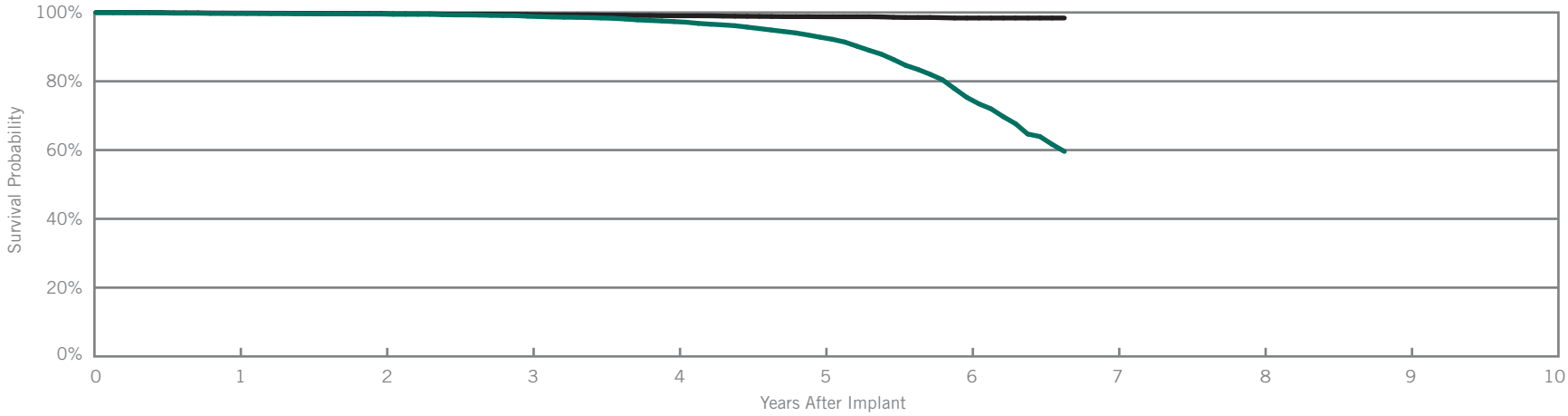
Customer Reported Performance Data

Atlas™ II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,682
Estimated Active US Implants	6,001
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	526
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.03%	3	0.02%
Electrical Interconnect	4	0.03%	0	0.00%
Battery	9	0.06%	2	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	14	0.10%	6	0.04%
Other	13	0.09%	2	0.01%
Total	**45**	**0.31%**	**13**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.71%	99.55%	98.91%	97.35%	92.79%	75.32%	59.60%			
± 1 standard error	0.04%	0.06%	0.09%	0.16%	0.28%	0.62%	1.24%			
Sample Size	13680	11930	10440	8860	6810	3710	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.81%	99.69%	99.41%	99.04%	98.77%	98.39%	98.39%			
± 1 standard error	0.04%	0.05%	0.07%	0.09%	0.11%	0.16%	0.16%			

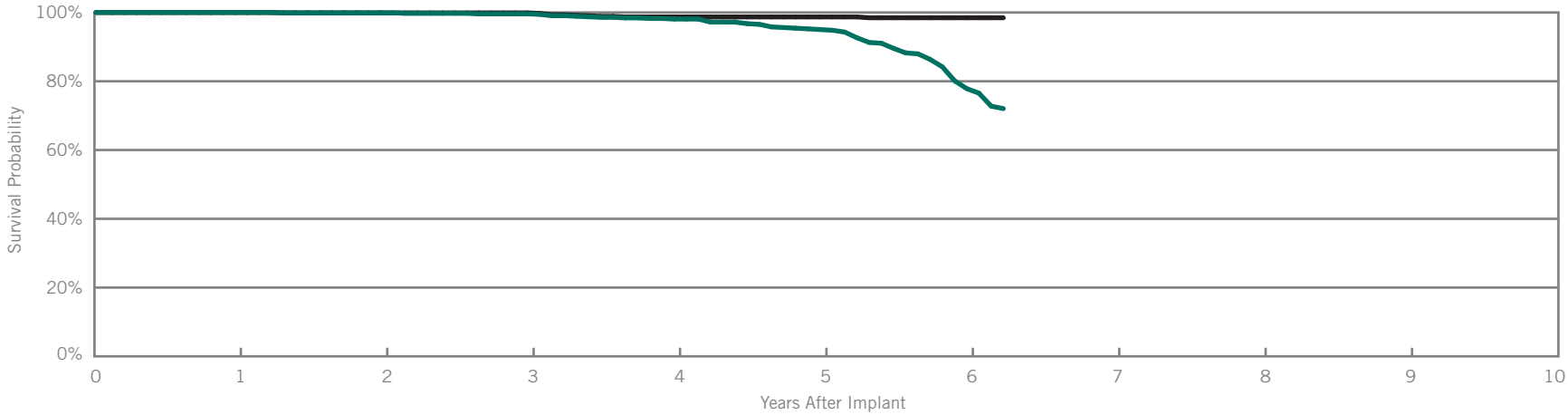
Customer Reported Performance Data

Atlas™ II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,918
Estimated Active US Implants	748
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	79
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.21%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.10%	3	0.16%
Other	0	0.00%	0	0.00%
Total	**6**	**0.31%**	**3**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	100.00%	99.88%	99.59%	98.08%	95.03%	77.85%	72.04%			
± 1 standard error	0.00%	0.09%	0.17%	0.36%	0.63%	1.51%	1.94%			
Sample Size	1800	1580	1400	1230	1040	630	220			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	100.00%	99.88%	99.88%	98.70%	98.70%	98.46%	98.46%			
± 1 standard error	0.00%	0.09%	0.09%	0.31%	0.31%	0.36%	0.36%			

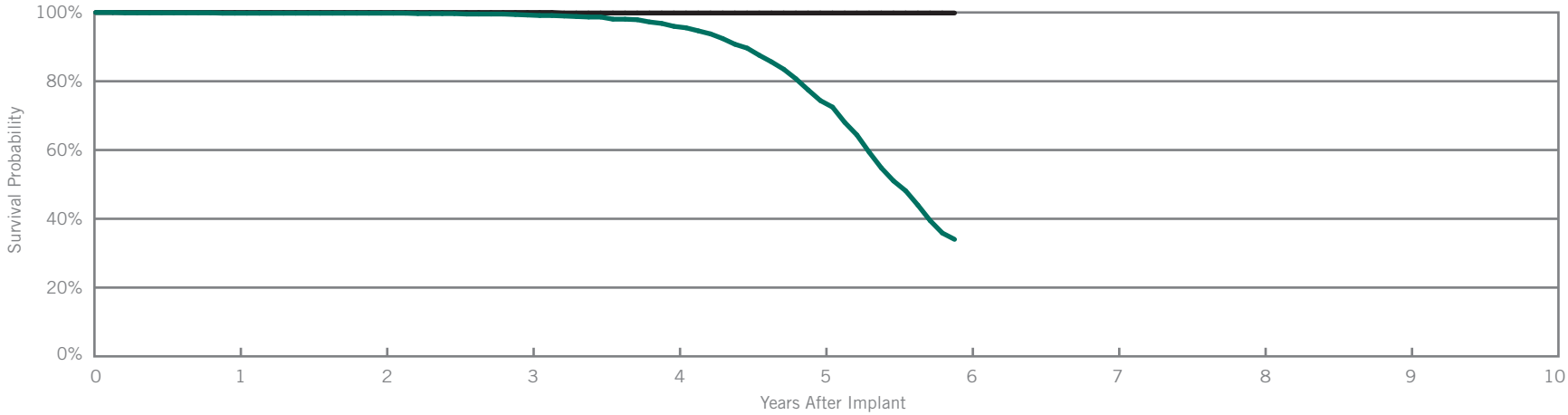
Customer Reported Performance Data

Epic™ II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,111
Estimated Active US Implants	504
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	255
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	1	0.05%
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**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.79%	99.79%	99.26%	95.96%	74.38%	34.02%				
± 1 standard error	0.10%	0.10%	0.19%	0.48%	1.28%	1.72%				
Sample Size	1970	1720	1510	1270	920	210				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	100.00%	100.00%	100.00%	99.85%	99.85%	99.85%				
± 1 standard error	0.00%	0.00%	0.00%	0.10%	0.10%	0.10%				

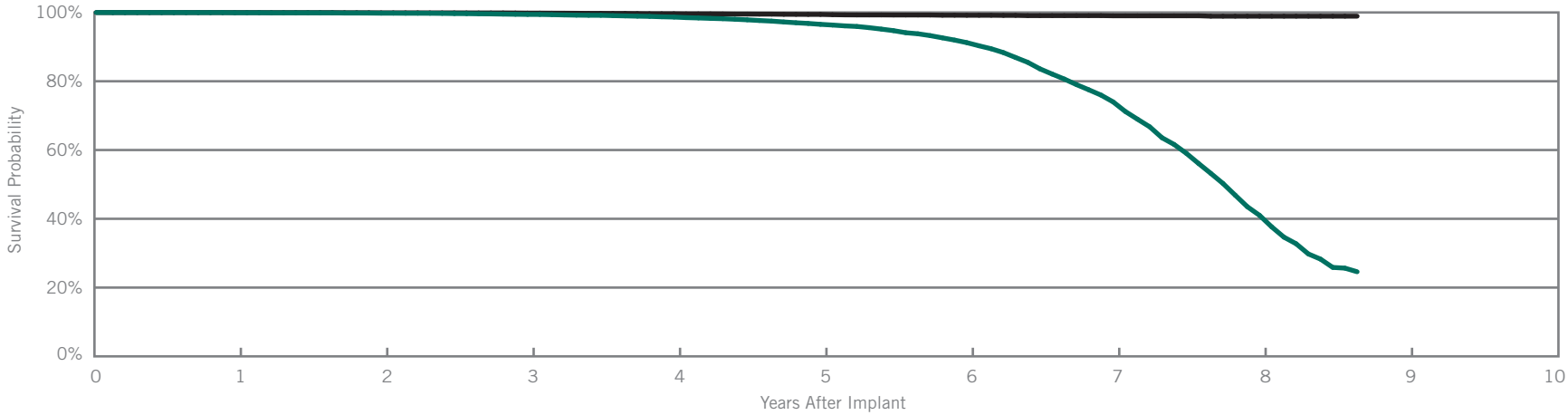
Customer Reported Performance Data

Atlas™ + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	21,020
Estimated Active US Implants	5,465
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	1,407
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.02%	2	<0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	10	0.05%	4	0.02%
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	6	0.03%	4	0.02%
Other	15	0.07%	2	<0.01%
Total	**37**	**0.18%**	**13**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 104 months
Survival Probability	99.93%	99.79%	99.43%	98.66%	96.55%	91.23%	73.99%	41.00%	24.60%
± 1 standard error	0.01%	0.03%	0.06%	0.09%	0.16%	0.26%	0.48%	0.80%	0.99%
Sample Size	19720	17340	15260	13290	11320	9150	6090	2530	210

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 104 months
Survival Probability	99.97%	99.90%	99.82%	99.63%	99.43%	99.18%	99.03%	98.92%	98.92%
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.07%	0.08%	0.09%	0.13%	0.13%

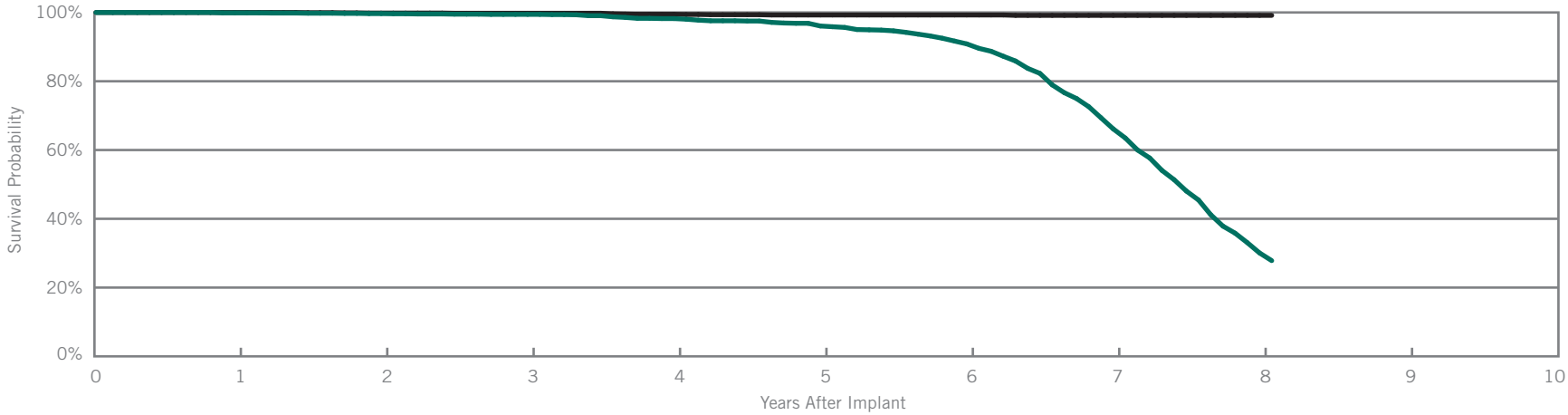
Customer Reported Performance Data

Atlas™ DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,654
Estimated Active US Implants	1,009
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	450
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	6	0.13%	1	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	0.02%	0	0.00%
Other	2	0.04%	0	0.00%
Total	**10**	**0.21%**	**2**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 97 months
Survival Probability	99.88%	99.67%	99.44%	98.22%	96.06%	90.86%	66.16%	30.07%	27.83%
± 1 standard error	0.05%	0.09%	0.12%	0.23%	0.32%	0.55%	1.05%	1.37%	1.38%
Sample Size	4370	3870	3440	3010	2600	2190	1500	620	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 97 months
Survival Probability	100.00%	99.84%	99.78%	99.48%	99.26%	99.26%	99.15%	99.15%	99.15%
± 1 standard error	0.00%	0.06%	0.08%	0.13%	0.16%	0.16%	0.17%	0.17%	0.17%

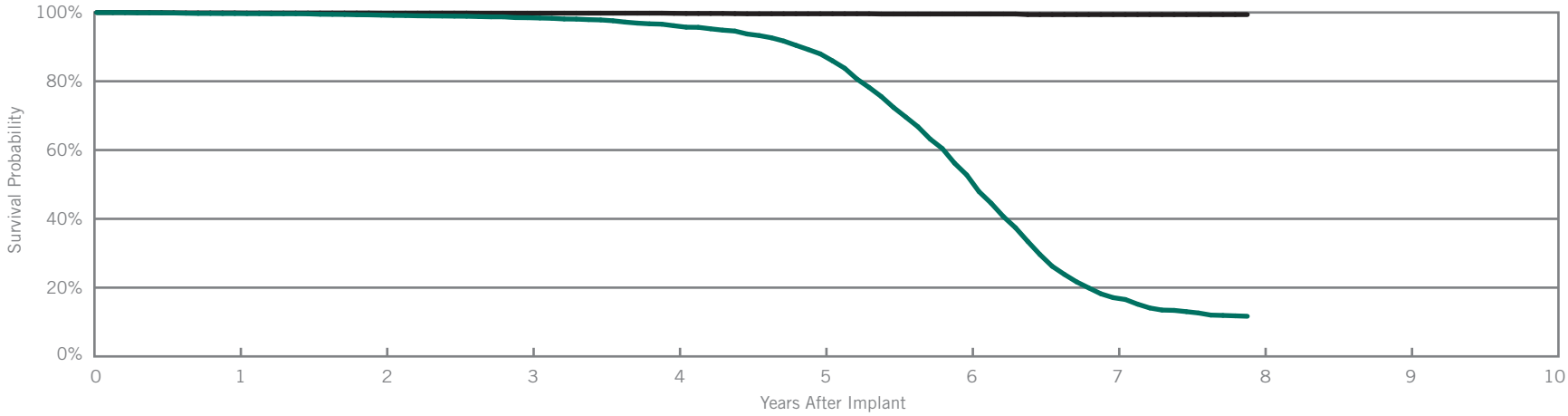
Customer Reported Performance Data

Epic™ + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,862
Estimated Active US Implants	716
Estimated Longevity	(see table on page 99)
Normal Battery Depletion	1,266
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 272-284)	Two

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	4	0.05%
High Voltage Capacitor	2	0.03%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	2	0.03%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**5**	**0.06%**	**8**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.69%	99.23%	98.48%	96.14%	87.95%	52.76%	17.09%	11.68%		
± 1 standard error	0.07%	0.10%	0.15%	0.24%	0.45%	0.80%	0.67%	0.60%		
Sample Size	7400	6580	5840	5050	4090	2700	1180	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.89%	99.83%	99.80%	99.75%	99.62%	99.55%	99.38%	99.38%		
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.08%	0.10%	0.15%	0.15%		

Battery Longevity Summary

Dual-Chamber ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
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
2207-30	Current™ DR RF**	6.5	5.9	5.4	4.6
V-268	Atlas™ II + DR**	8.2	7.5	7.0	6.1
V-265	Atlas™ II DR**	8.2	7.5	7.0	6.1
V-258	Epic™ II + DR**	6.5	5.9	5.4	4.6
V-243	Atlas™ + DR**	7.9	7.3	6.9	6.1
V-242	Atlas™ DR**	7.9	7.3	6.9	6.1
V-239	Epic™ + DR**	6.4	6.0	5.6	4.5

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
CD2311-36Q	Ellipse™ DR	98.76%									
CD2311-36	Ellipse™ DR*										
CD2257-40Q	Fortify Assura™ DR*										
CD2257-40	Fortify Assura™ DR*										
CD2231-40Q	Fortify™ DR	99.76%	99.55%	99.21%							
CD2231-40	Fortify™ DR	99.87%	99.63%	99.45%							
CD2211-36Q	Current™ + DR	99.85%	99.38%	99.00%							
CD2211-36	Current™ + DR	99.78%	99.55%	99.25%	98.84%						
2207-36	Current™ DR RF	99.69%	99.31%	98.73%	97.99%	97.18%					
2207-30	Current™ DR RF	99.71%	99.56%	99.37%	99.37%	98.91%					
V-268	Atlas™ II + DR	99.71%	99.55%	98.91%	97.35%	92.79%	75.32%				
V-265	Atlas™ II DR	100.00%	99.88%	99.59%	98.08%	95.03%	77.85%				
V-258	Epic™ II + DR	99.79%	99.79%	99.26%	95.96%	74.38%					
V-243	Atlas™ + DR	99.93%	99.79%	99.43%	98.66%	96.55%	91.23%	73.99%	41.00%		
V-242	Atlas™ DR	99.88%	99.67%	99.44%	98.22%	96.06%	90.86%	66.16%	30.07%		
V-239	Epic™ + DR	99.69%	99.23%	98.48%	96.14%	87.95%	52.76%	17.09%			

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2311-36Q	Ellipse™ DR	98.76%									
CD2311-36	Ellipse™ DR*										
CD2257-40Q	Fortify Assura™ DR*										
CD2257-40	Fortify Assura™ DR*										
CD2231-40Q	Fortify™ DR	99.86%	99.72%	99.51%							
CD2231-40	Fortify™ DR	99.94%	99.86%	99.86%							
CD2211-36Q	Current™ + DR	99.85%	99.57%	99.38%							
CD2211-36	Current™ + DR	99.90%	99.75%	99.50%	99.26%						
2207-36	Current™ DR RF	99.73%	99.56%	99.19%	98.65%	98.37%					
2207-30	Current™ DR RF	100.00%	100.00%	99.81%	99.81%	99.81%					
V-268	Atlas™ II + DR	99.81%	99.69%	99.41%	99.04%	98.77%	98.39%				
V-265	Atlas™ II DR	100.00%	99.88%	99.88%	98.70%	98.70%	98.46%				
V-258	Epic™ II + DR	100.00%	100.00%	100.00%	99.85%	99.85%					
V-243	Atlas™ + DR	99.97%	99.90%	99.82%	99.63%	99.43%	99.18%	99.03%	98.92%		
V-242	Atlas™ DR	100.00%	99.84%	99.78%	99.48%	99.26%	99.26%	99.15%	99.15%		
V-239	Epic™ + DR	99.89%	99.83%	99.80%	99.75%	99.62%	99.55%	99.38%			

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD2311-36Q	Ellipse™ DR	3608	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.06%	0	0.00%	0	0.00%	**2**	**0.06%**
CD2311-36	Ellipse™ DR	2144	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	**3**	**0.14%**
CD2257-40Q	Fortify Assura™ DR	3656	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%**
CD2257-40	Fortify Assura™ DR	2285	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%**
CD2231-40Q	Fortify™ DR	26529	2	<0.01%	1	<0.01%	2	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	3	0.01%	5	0.02%	**15**	**0.06%**
CD2231-40	Fortify™ DR	11863	1	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**0.03%**
CD2211-36Q	Current™ + DR	8110	4	0.05%	0	0.00%	3	0.04%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	**10**	**0.12%**
CD2211-36	Current™ + DR	6214	2	0.03%	1	0.02%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	1	0.02%	**8**	**0.13%**
2207-36	Current™ DR RF	22359	5	0.02%	6	0.03%	7	0.03%	1	<0.01%	0	0.00%	0	0.00%	20	0.09%	17	0.08%	**56**	**0.25%**
2207-30	Current™ DR RF	1522	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%**
V-268	Atlas™ II + DR	14682	5	0.03%	4	0.03%	9	0.06%	0	0.00%	0	0.00%	0	0.00%	14	0.10%	13	0.09%	**45**	**0.31%**
V-265	Atlas™ II DR	1918	0	0.00%	0	0.00%	4	0.21%	0	0.00%	0	0.00%	0	0.00%	2	0.10%	0	0.00%	**6**	**0.31%**
V-258	Epic™ II + DR	2111	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%**
V-243	Atlas™ + DR	21020	4	0.02%	1	<0.01%	10	0.05%	1	<0.01%	0	0.00%	0	0.00%	6	0.03%	15	0.07%	**37**	**0.18%**
V-242	Atlas™ DR	4654	0	0.00%	1	0.02%	6	0.13%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	2	0.04%	**10**	**0.21%**
V-239	Epic™ + DR	7862	2	0.03%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**5**	**0.06%**

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD2311-36Q	Ellipse™ DR	3608	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	**2**	**0.06%**
CD2311-36	Ellipse™ DR	2144	2	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.09%**
CD2257-40Q	Fortify Assura™ DR	3656	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%**
CD2257-40	Fortify Assura™ DR	2285	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%**
CD2231-40Q	Fortify™ DR	26529	4	0.02%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	2	<0.01%	**9**	**0.03%**
CD2231-40	Fortify™ DR	11863	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
CD2211-36Q	Current™ + DR	8110	1	0.01%	0	0.00%	5	0.06%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	**9**	**0.11%**
CD2211-36	Current™ + DR	6214	1	0.02%	0	0.00%	3	0.05%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	**6**	**0.10%**
2207-36	Current™ DR RF	22359	9	0.04%	2	<0.01%	7	0.03%	0	0.00%	4	0.02%	1	<0.01%	13	0.06%	5	0.02%	**41**	**0.18%**
2207-30	Current™ DR RF	1522	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
V-268	Atlas™ II + DR	14682	3	0.02%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	2	0.01%	**13**	**0.09%**
V-265	Atlas™ II DR	1918	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.16%	0	0.00%	**3**	**0.16%**
V-258	Epic™ II + DR	2111	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**
V-243	Atlas™ + DR	21020	2	<0.01%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	1	<0.01%	4	0.02%	2	<0.01%	**13**	**0.06%**
V-242	Atlas™ DR	4654	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.04%**
V-239	Epic™ + DR	7862	1	0.01%	0	0.00%	4	0.05%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	**8**	**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	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	387	9824	0	0.00%	0	0.00%	0	0.00%	1	0.26%	0	0.00%	**1**	**0.26%**
CD2231-40	176	3960	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	834	28588	0	0.00%	0	0.00%	0	0.00%	3	0.36%	1	0.12%	**4**	**0.48%**
CD2211-36	121	4027	1	0.83%	0	0.00%	0	0.00%	1	0.83%	0	0.00%	**2**	**1.65%**
2207-36	631	24596	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	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	387	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.26%	**1**	**0.26%**
CD2231-40	Fortify™ DR	176	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	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	121	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%**
2207-36	Current™ DR RF	631	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	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	387	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	176	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	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	121	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.83%	**1**	**0.83%**
2207-36	Current™ DR RF	631	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%**

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

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical

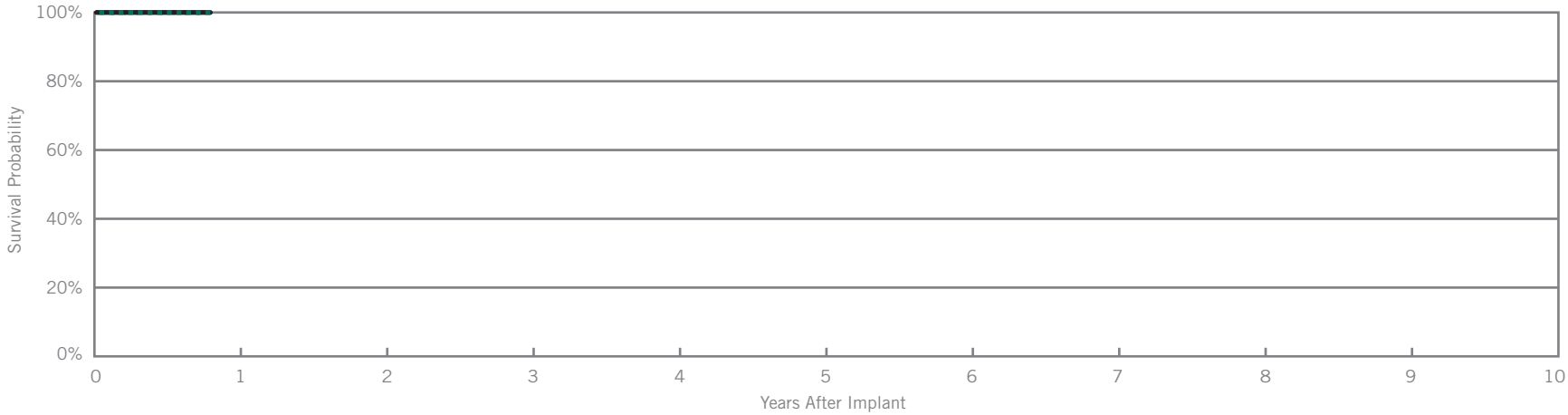
Customer Reported Performance Data

Fortify Assura™ VR

Model CD1257-40Q

US Regulatory Approval	May 2012
Registered US Implants	2,695
Estimated Active US Implants	2,557
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	280										

Excluding Normal Battery Depletion

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

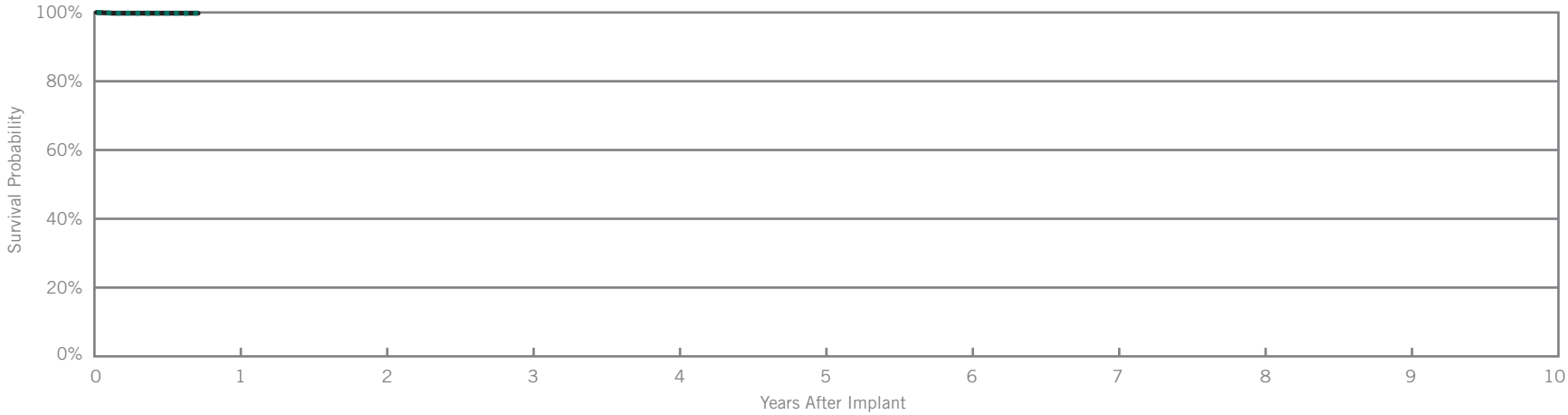
Customer Reported Performance Data

Fortify Assura™ VR

Model CD1257-40

US Regulatory Approval	May 2012
Registered US Implants	1,180
Estimated Active US Implants	1,108
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	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%	1	0.08%
Total	**0**	**0.00%**	**1**	**0.08%**



Including Normal Battery Depletion

Year	at 9 months										
Survival Probability	99.79%										
± 1 standard error	0.15%										
Sample Size	260										

Excluding Normal Battery Depletion

Year	at 9 months										
Survival Probability	99.79%										
± 1 standard error	0.15%										

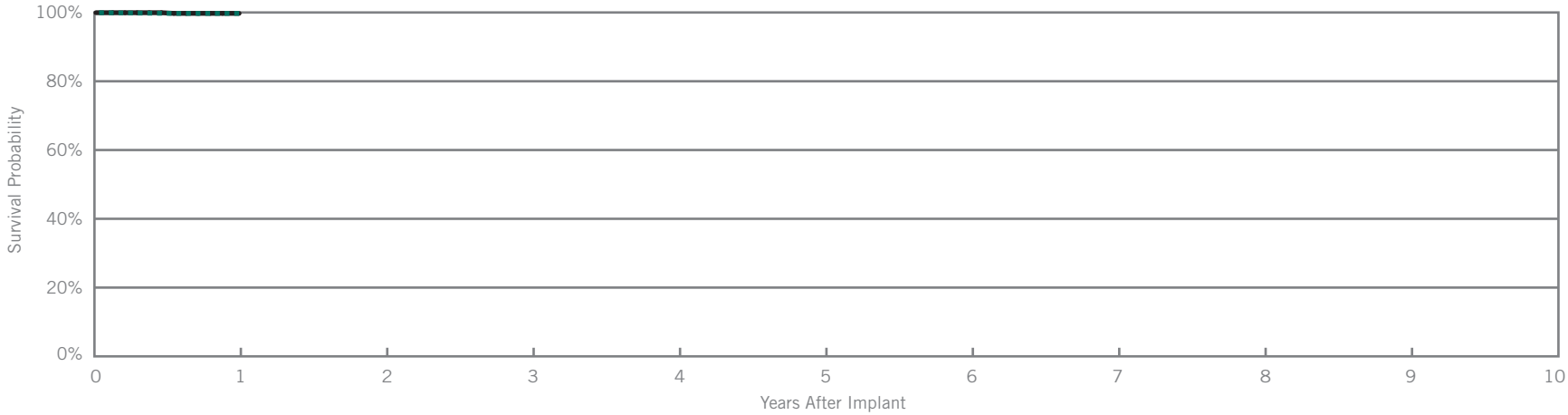
Customer Reported Performance Data

Ellipse™ VR

Model CD1311-36Q

US Regulatory Approval	May 2012
Registered US Implants	2,864
Estimated Active US Implants	2,685
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1									
Survival Probability	99.74%									
± 1 standard error	0.14%									
Sample Size	240									

Excluding Normal Battery Depletion

Year	1									
Survival Probability	99.74%									
± 1 standard error	0.14%									

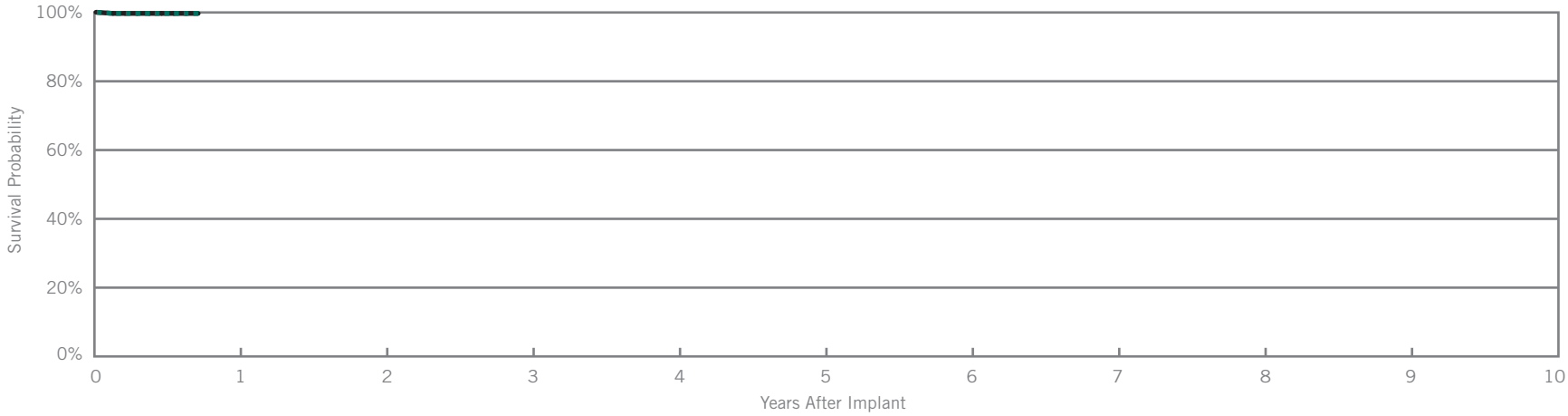
Customer Reported Performance Data

Ellipse™ VR

Model CD1311-36

US Regulatory Approval	May 2012
Registered US Implants	901
Estimated Active US Implants	849
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.11%	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	0.11%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.11%**	**1**	**0.11%**



Including Normal Battery Depletion

Year	at 9 months										
Survival Probability	99.73%										
± 1 standard error	0.19%										
Sample Size	240										

Excluding Normal Battery Depletion

Year	at 9 months										
Survival Probability	99.73%										
± 1 standard error	0.19%										

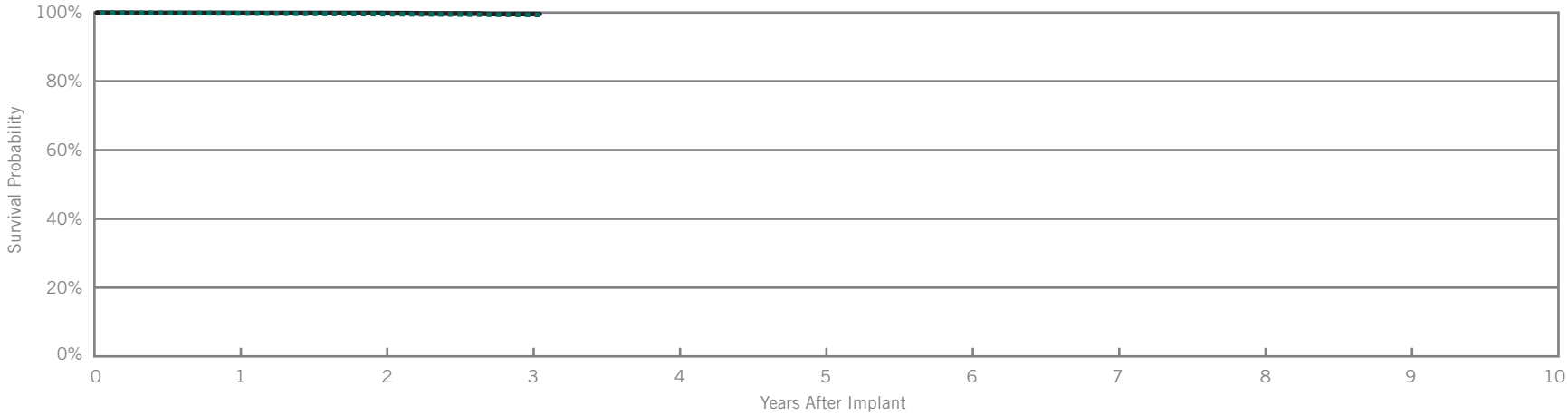
Customer Reported Performance Data

Fortify™ VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Registered US Implants	15,892
Estimated Active US Implants	12,668
Estimated Longevity	(see table on page 125)
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	4	0.03%	1	<0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	1	<0.01%	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%	2	0.01%
Other	3	0.02%	1	<0.01%
Total	**10**	**0.06%**	**4**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.75%	99.70%	99.30%	99.30%						
± 1 standard error	0.04%	0.05%	0.14%	0.14%						
Sample Size	13840	8530	2760	230						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.85%	99.84%	99.56%	99.56%						
± 1 standard error	0.03%	0.03%	0.12%	0.12%						

Actively Monitored Study Data

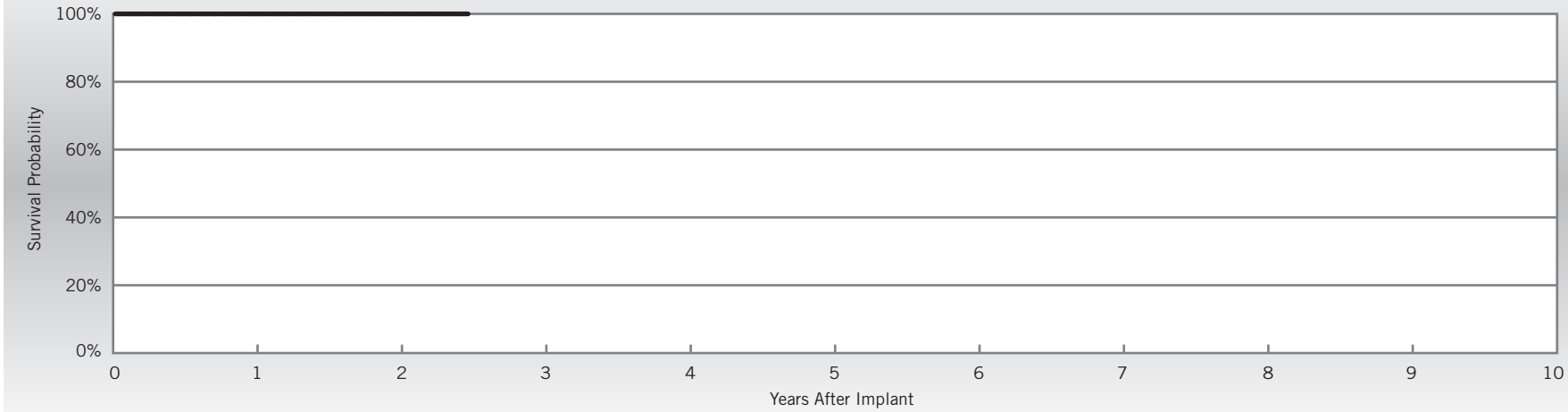
Fortify™ VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	160
Cumulative Months of Follow-up	4,142
Estimated Longevity	(see table on page 125)
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 30 months**							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	160	130	60							

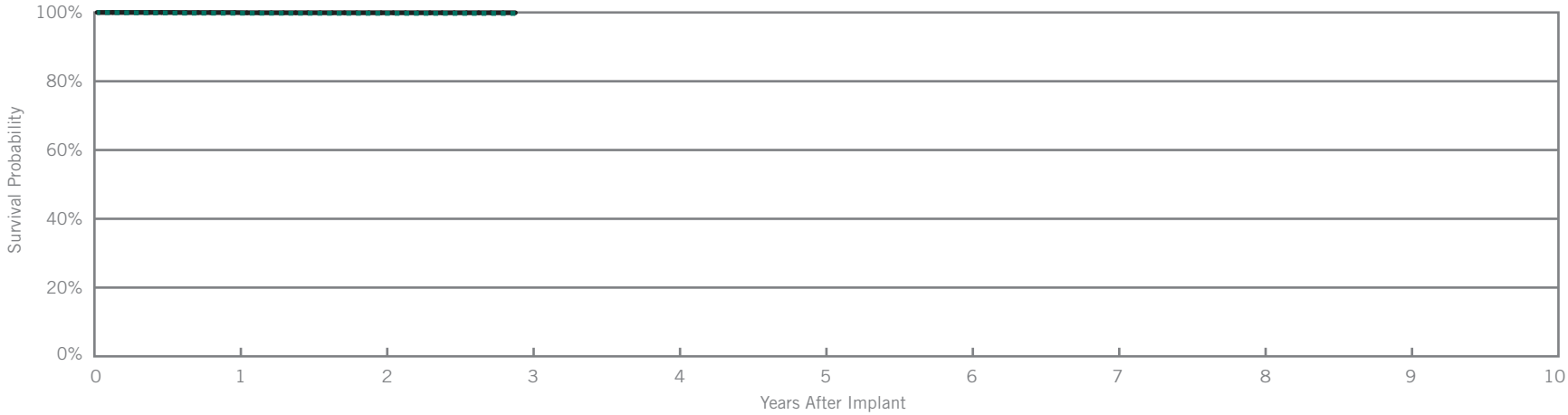
Customer Reported Performance Data

Fortify™ VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	6,643
Estimated Active US Implants	5,276
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	5
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	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%	2	0.03%
Total	**0**	**0.00%**	**2**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	99.76%	99.72%	99.72%							
± 1 standard error	0.06%	0.07%	0.07%							
Sample Size	5820	3600	340							

Excluding Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	99.97%	99.92%	99.92%							
± 1 standard error	0.02%	0.04%	0.04%							

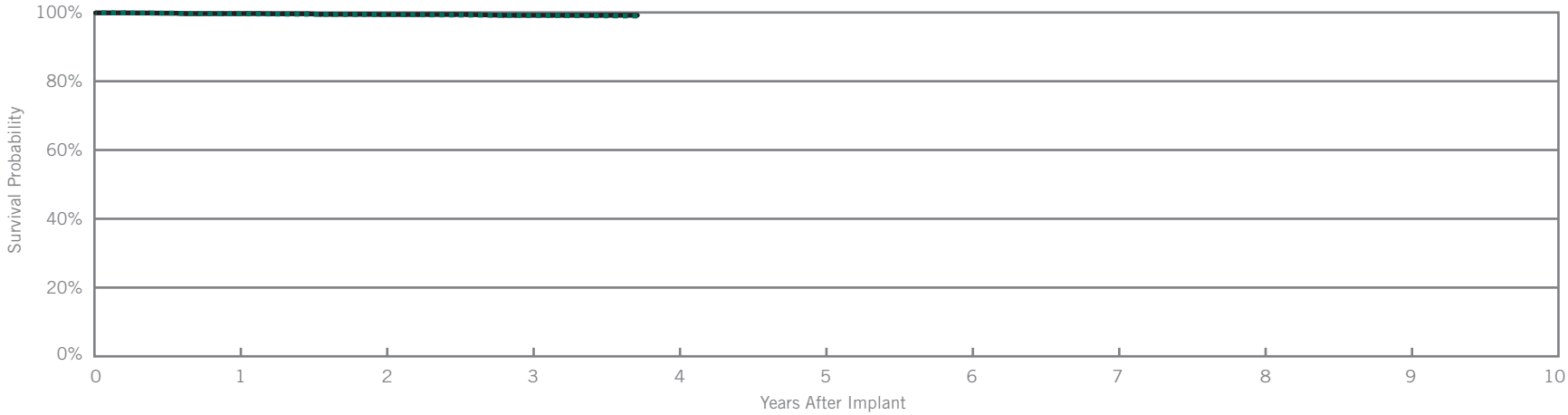
Customer Reported Performance Data

Current™ + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	4,386
Estimated Active US Implants	3,018
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	3
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	0.05%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.07%	3	0.07%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.05%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**8**	**0.18%**	**5**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.61%	99.34%	99.06%	98.96%						
± 1 standard error	0.09%	0.12%	0.16%	0.18%						
Sample Size	4040	3440	2870	330						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.66%	99.40%	99.18%	99.18%						
± 1 standard error	0.09%	0.12%	0.15%	0.15%						

Actively Monitored Study Data

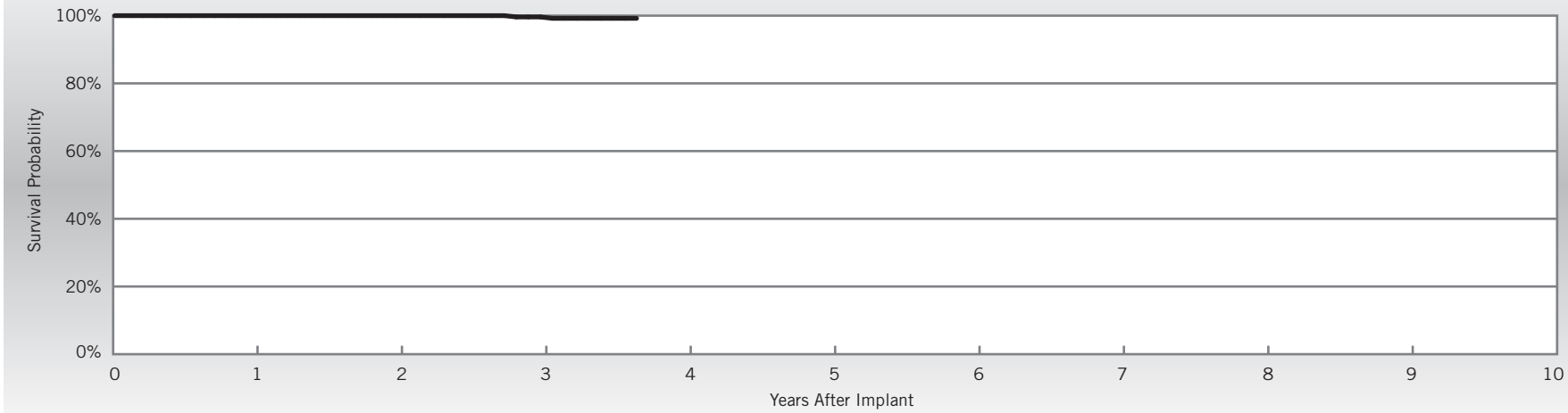
Current™ + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	363
Cumulative Months of Follow-up	12,142
Estimated Longevity	(see table on page 125)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.28%
Premature Battery Depletion	1	0.28%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	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 44 months						
Survival Probability	100.00%	100.00%	99.62%	99.21%						
± 1 standard error	0.00%	0.00%	0.38%	0.56%						
Sample Size	350	310	270	60						

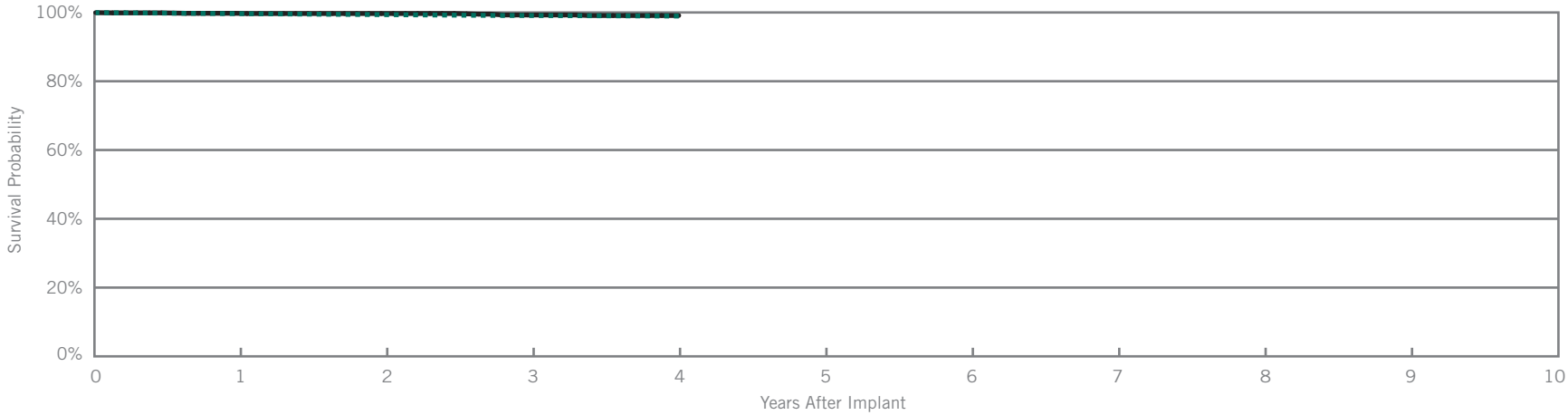
Customer Reported Performance Data

Current™ + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,528
Estimated Active US Implants	2,399
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	2
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%	1	0.03%
Electrical Interconnect	1	0.03%	0	0.00%
Battery	1	0.03%	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	2	0.06%	0	0.00%
Other	1	0.03%	0	0.00%
Total	**9**	**0.26%**	**1**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.76%	99.54%	99.12%	98.95%						
± 1 standard error	0.09%	0.12%	0.19%	0.22%						
Sample Size	3240	2700	2210	300						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.76%	99.69%	99.27%	99.11%						
± 1 standard error	0.09%	0.10%	0.17%	0.21%						

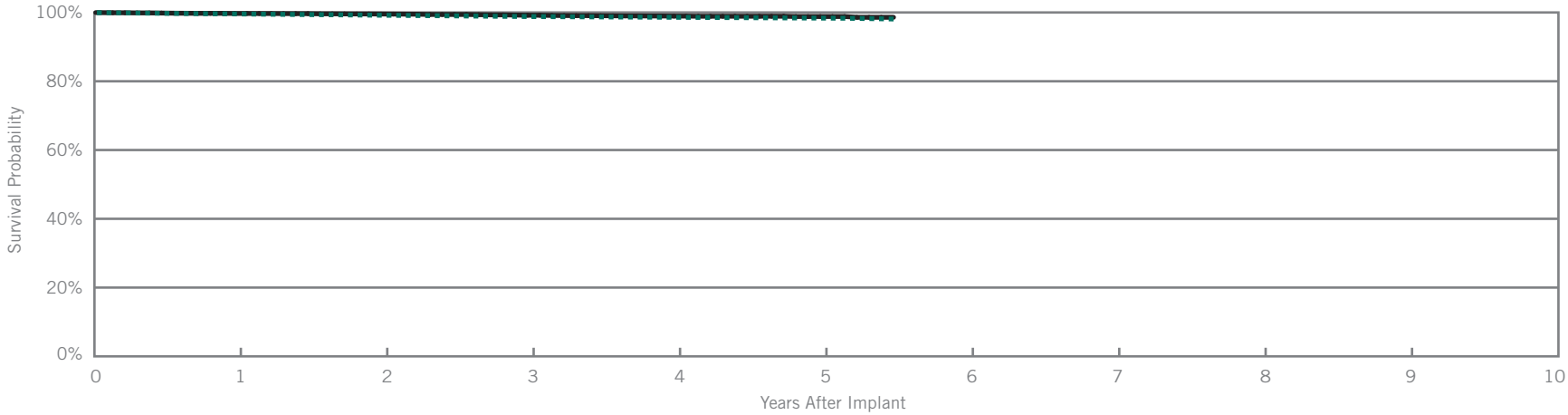
Customer Reported Performance Data

Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,268
Estimated Active US Implants	7,695
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	18
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	6	0.05%	5	0.04%
Electrical Interconnect	7	0.05%	0	0.00%
Battery	2	0.02%	3	0.02%
High Voltage Capacitor	1	<0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	5	0.04%	8	0.06%
Other	6	0.05%	3	0.02%
Total	**27**	**0.20%**	**22**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.60%	99.23%	98.81%	98.44%	98.32%	98.10%				
± 1 standard error	0.05%	0.08%	0.10%	0.12%	0.14%	0.21%				
Sample Size	12340	10690	9330	7420	3830	350				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.71%	99.55%	99.19%	98.94%	98.82%	98.59%				
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.20%				

Actively Monitored Study Data

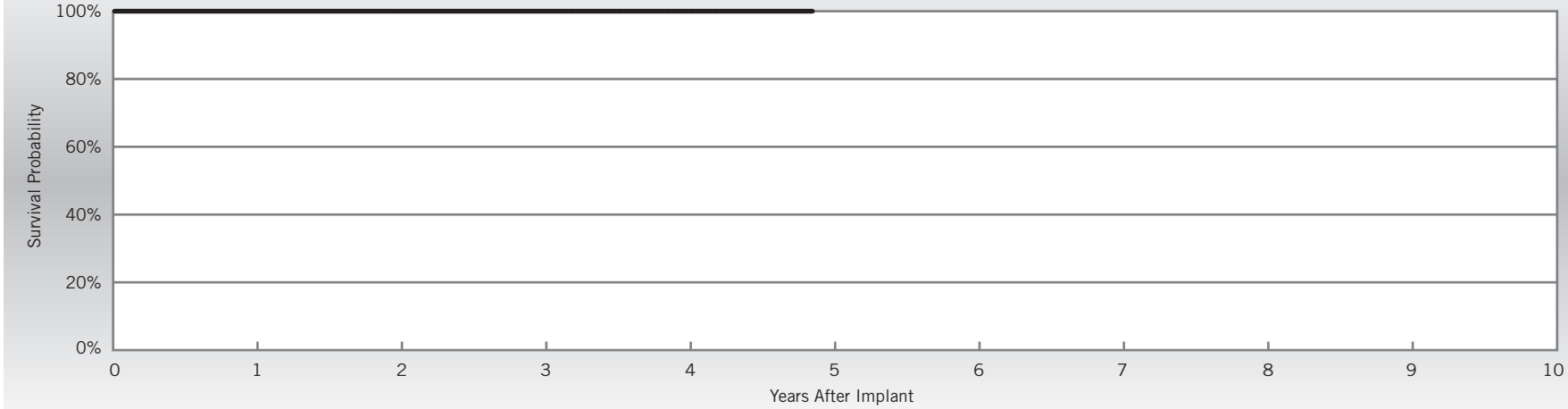
Current™ VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	15,581
Estimated Longevity	(see table on page 125)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	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	at 59 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	380	340	280	210	50					

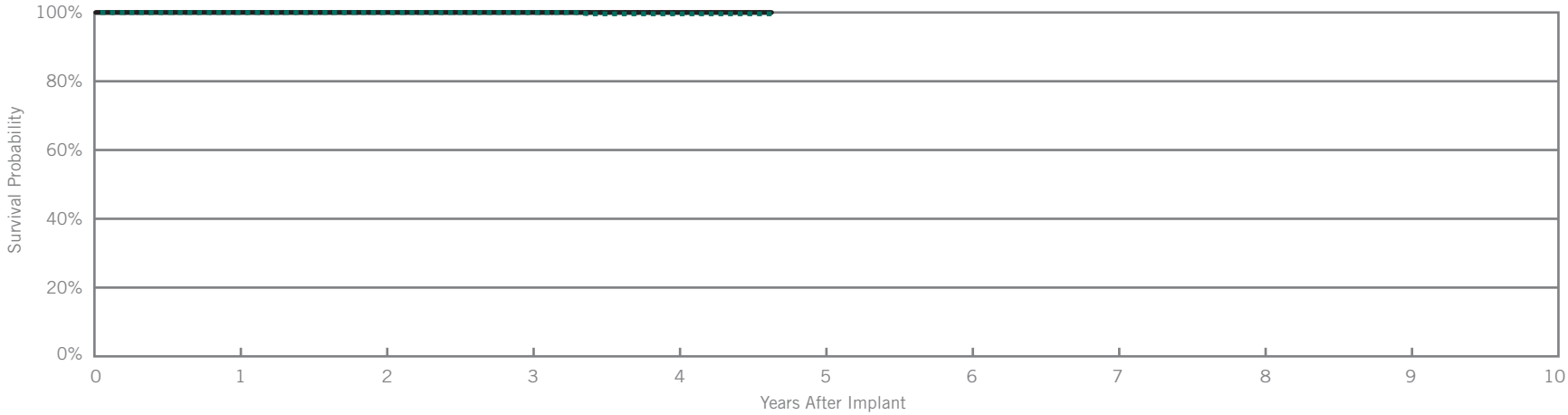
Customer Reported Performance Data

Current™ VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	861
Estimated Active US Implants	511
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	1
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	100.00%	100.00%	100.00%	99.60%	99.60%					
± 1 standard error	0.00%	0.00%	0.00%	0.28%	0.28%					
Sample Size	810	710	620	470	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 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%					

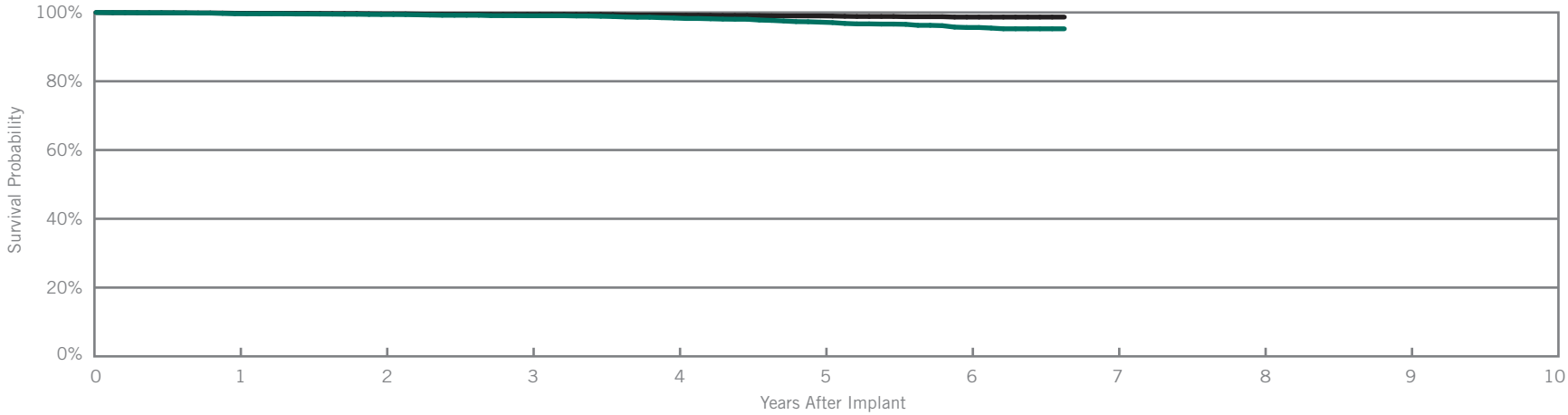
Customer Reported Performance Data

Atlas™ II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,478
Estimated Active US Implants	5,092
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	55
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.02%	2	0.02%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	8	0.08%	1	<0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	0	0.00%
Possible Early Battery Depletion	9	0.09%	4	0.04%
Other	6	0.06%	3	0.03%
Total	**29**	**0.28%**	**10**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.64%	99.41%	99.05%	98.39%	97.18%	95.63%	95.25%			
± 1 standard error	0.05%	0.08%	0.10%	0.14%	0.21%	0.31%	0.37%			
Sample Size	9800	8560	7470	6310	4900	2800	210			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.77%	99.59%	99.44%	99.23%	99.00%	98.66%	98.66%			
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.12%	0.16%	0.16%			

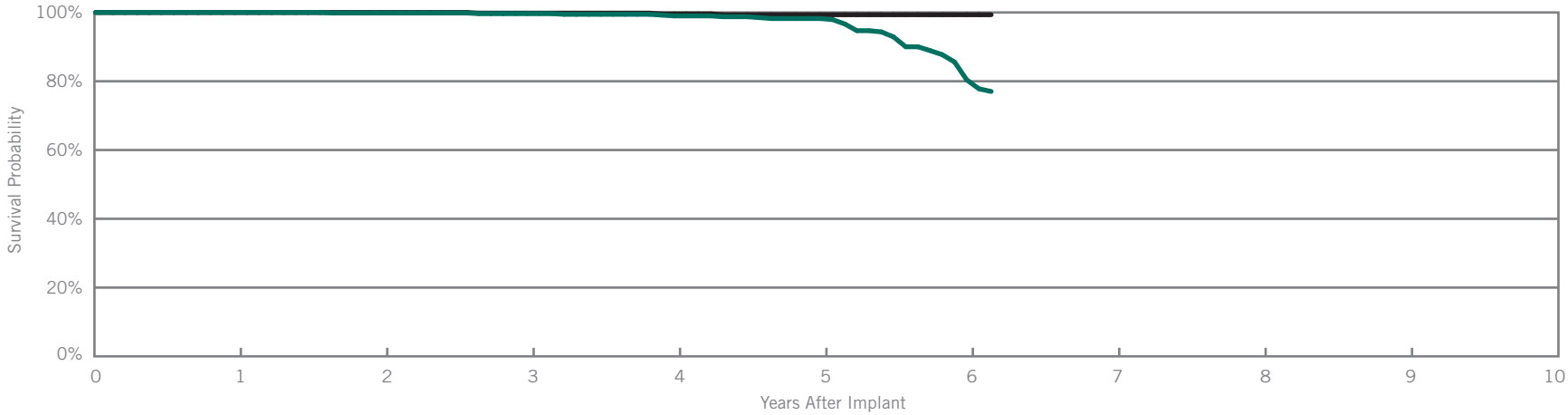
Customer Reported Performance Data

Epic™ II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,578
Estimated Active US Implants	608
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	55
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	1	0.06%
Battery	0	0.00%	2	0.13%
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%**	**3**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	100.00%	99.84%	99.66%	99.00%	98.23%	80.39%	77.03%			
± 1 standard error	0.00%	0.11%	0.17%	0.27%	0.44%	1.55%	2.03%			
Sample Size	1470	1280	1120	940	760	460	220			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	100.00%	100.00%	99.81%	99.59%	99.34%	99.34%	99.34%			
± 1 standard error	0.00%	0.00%	0.13%	0.21%	0.27%	0.27%	0.27%			

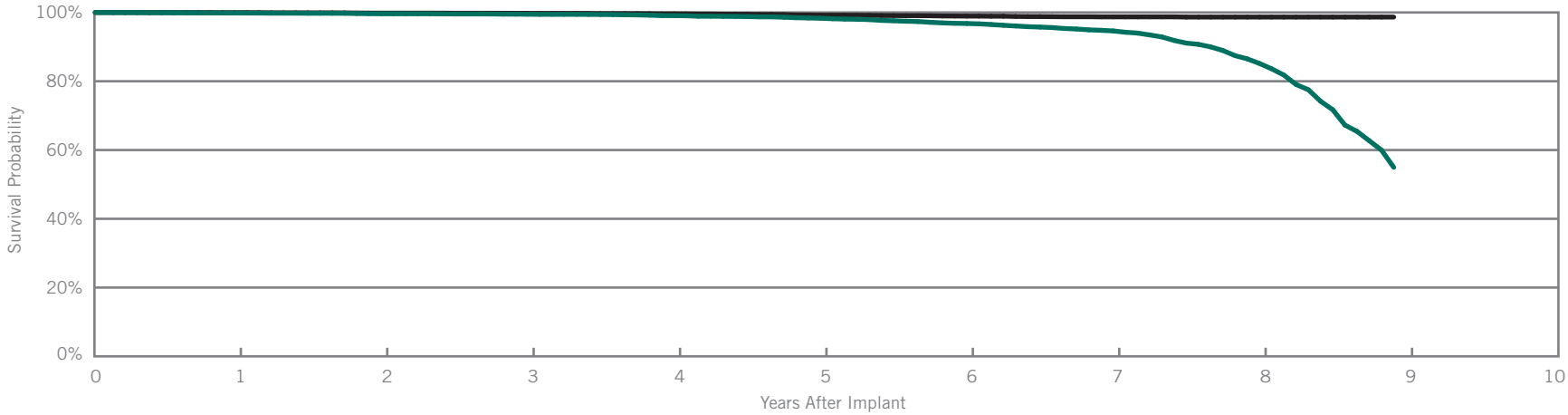
Customer Reported Performance Data

Atlas™ + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,703
Estimated Active US Implants	7,165
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	353
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 272-284)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	2	<0.01%
Electrical Interconnect	5	0.02%	1	<0.01%
Battery	7	0.03%	2	<0.01%
High Voltage Capacitor	2	<0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	25	0.12%	4	0.02%
Other	10	0.05%	4	0.02%
Total	**50**	**0.24%**	**15**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	99.84%	99.63%	99.49%	99.07%	98.32%	96.79%	94.63%	85.16%	54.96%
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.11%	0.17%	0.24%	0.55%	1.75%
Sample Size	19410	17010	14860	12850	10970	9010	6520	3290	200

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	99.95%	99.81%	99.74%	99.60%	99.20%	98.94%	98.72%	98.66%	98.66%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.08%	0.09%	0.11%	0.12%	0.12%

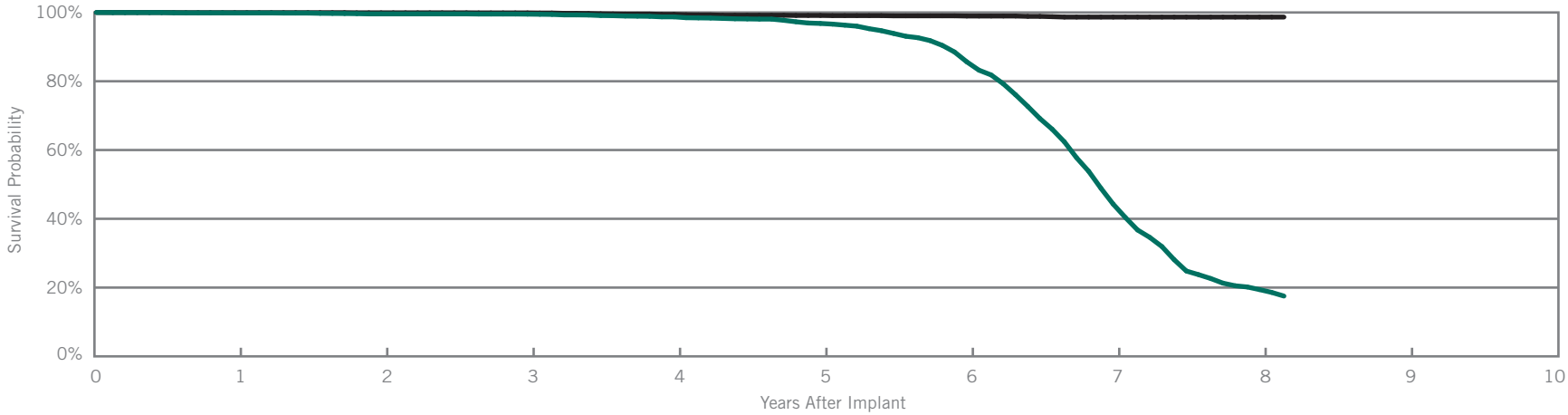
Customer Reported Performance Data

Epic™ + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,978
Estimated Active US Implants	1,158
Estimated Longevity	(see table on page 125)
Normal Battery Depletion	904
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 272-284)	Three

	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%	16	0.20%
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	1	0.01%	0	0.00%
Other	3	0.04%	0	0.00%
Total	**8**	**0.10%**	**18**	**0.23%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 98 months
Survival Probability	99.85%	99.58%	99.51%	98.72%	96.81%	85.65%	44.28%	19.41%	17.53%
± 1 standard error	0.04%	0.08%	0.08%	0.15%	0.25%	0.52%	0.92%	0.86%	0.86%
Sample Size	7500	6660	5910	5140	4350	3410	2020	710	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 98 months
Survival Probability	99.95%	99.91%	99.88%	99.44%	99.13%	98.96%	98.66%	98.66%	98.66%
± 1 standard error	0.03%	0.03%	0.04%	0.10%	0.13%	0.14%	0.19%	0.19%	0.19%

Battery Longevity Summary

Single-Chamber ICDs

St. Jude Medical

Battery Longevity

Models	Family	Approximate Duration (years)			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
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
1207-30	Current™ VR RF**	6.7	6.4	6.1	5.6
V-168	Atlas™ II VR**	8.4	8.0	7.6	7.0
V-158	Epic™ II VR**	6.7	6.4	6.1	5.6
V-193	Atlas™ + VR**	8.6	8.2	7.9	7.3
V-196	Epic™ + VR <115000**	6.3	6	5.8	5.4
V-196	Epic™ + VR >115000**	6.9	6.6	6.4	5.9

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
CD1257-40Q	Fortify Assura™ VR*										
CD1257-40	Fortify Assura™ VR*										
CD1311-36Q	Ellipse™ VR	99.74%									
CD1311-36	Ellipse™ VR*										
CD1231-40Q	Fortify™ VR	99.75%	99.70%	99.30%							
CD1231-40	Fortify™ VR	99.76%	99.72%								
CD1211-36Q	Current™ + VR	99.61%	99.34%	99.06%							
CD1211-36	Current™ + VR	99.76%	99.54%	99.12%	98.95%						
1207-36	Current™ VR RF	99.60%	99.23%	98.81%	98.44%	98.32%					
1207-30	Current™ VR RF	100.00%	100.00%	100.00%	99.60%						
V-168	Atlas™ II VR	99.64%	99.41%	99.05%	98.39%	97.18%	95.63%				
V-158	Epic™ II VR	100.00%	99.84%	99.66%	99.00%	98.23%	80.39%				
V-193	Atlas™ + VR	99.84%	99.63%	99.49%	99.07%	98.32%	96.79%	94.63%	85.16%		
V-196	Epic™ + VR	99.85%	99.58%	99.51%	98.72%	96.81%	85.65%	44.28%	19.41%		

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1257-40Q	Fortify Assura™ VR*										
CD1257-40	Fortify Assura™ VR*										
CD1311-36Q	Ellipse™ VR	99.74%									
CD1311-36	Ellipse™ VR*										
CD1231-40Q	Fortify™ VR	99.85%	99.84%	99.56%							
CD1231-40	Fortify™ VR	99.97%	99.92%								
CD1211-36Q	Current™ + VR	99.66%	99.40%	99.18%							
CD1211-36	Current™ + VR	99.76%	99.69%	99.27%	99.11%						
1207-36	Current™ VR RF	99.71%	99.55%	99.19%	98.94%	98.82%					
1207-30	Current™ VR RF	100.00%	100.00%	100.00%	100.00%						
V-168	Atlas™ II VR	99.77%	99.59%	99.44%	99.23%	99.00%	98.66%				
V-158	Epic™ II VR	100.00%	100.00%	99.81%	99.59%	99.34%	99.34%				
V-193	Atlas™ + VR	99.95%	99.81%	99.74%	99.60%	99.20%	98.94%	98.72%	98.66%		
V-196	Epic™ + VR	99.95%	99.91%	99.88%	99.44%	99.13%	98.96%	98.66%	98.66%		

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD1257-40Q	Fortify Assura™ VR	2695	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	1180	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%**
CD1311-36Q	Ellipse™ VR	2864	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.03%**
CD1311-36	Ellipse™ VR	901	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.11%**
CD1231-40Q	Fortify™ VR	15892	4	0.03%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	3	0.02%	**10**	**0.06%**
CD1231-40	Fortify™ VR	6643	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	4386	2	0.05%	0	0.00%	3	0.07%	0	0.00%	0	0.00%	0	0.00%	2	0.05%	1	0.02%	**8**	**0.18%**
CD1211-36	Current™ + VR	3528	2	0.06%	1	0.03%	1	0.03%	2	0.06%	0	0.00%	0	0.00%	2	0.06%	1	0.03%	**9**	**0.26%**
1207-36	Current™ VR RF	13268	6	0.05%	7	0.05%	2	0.02%	1	<0.01%	0	0.00%	0	0.00%	5	0.04%	6	0.05%	**27**	**0.20%**
1207-30	Current™ VR RF	861	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%**
V-168	Atlas™ II VR	10478	2	0.02%	2	0.02%	8	0.08%	1	<0.01%	0	0.00%	1	<0.01%	9	0.09%	6	0.06%	**29**	**0.28%**
V-158	Epic™ II VR	1578	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%**
V-193	Atlas™ + VR	20703	1	<0.01%	5	0.02%	7	0.03%	2	<0.01%	0	0.00%	0	0.00%	25	0.12%	10	0.05%	**50**	**0.24%**
V-196	Epic™ + VR	7978	3	0.04%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	3	0.04%	**8**	**0.10%**

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

Malfunction Summary

Models	Family	Registered US Implants	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
CD1257-40Q	Fortify Assura™ VR	2695	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	1180	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.08%	**1**	**0.08%**
CD1311-36Q	Ellipse™ VR	2864	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.03%**
CD1311-36	Ellipse™ VR	901	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	**1**	**0.11%**
CD1231-40Q	Fortify™ VR	15892	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	<0.01%	**4**	**0.03%**
CD1231-40	Fortify™ VR	6643	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	**2**	**0.03%**
CD1211-36Q	Current™ + VR	4386	2	0.05%	0	0.00%	3	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.11%**
CD1211-36	Current™ + VR	3528	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.03%**
1207-36	Current™ VR RF	13268	5	0.04%	0	0.00%	3	0.02%	1	<0.01%	1	<0.01%	1	<0.01%	8	0.06%	3	0.02%	**22**	**0.17%**
1207-30	Current™ VR RF	861	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%**
V-168	Atlas™ II VR	10478	2	0.02%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	0.04%	3	0.03%	**10**	**0.10%**
V-158	Epic™ II VR	1578	0	0.00%	1	0.06%	2	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.19%**
V-193	Atlas™ + VR	20703	2	<0.01%	1	<0.01%	2	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	4	0.02%	4	0.02%	**15**	**0.07%**
V-196	Epic™ + VR	7978	2	0.03%	0	0.00%	16	0.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**18**	**0.23%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Inappropriate Shock		Loss of Telemetry		Pericardial Effusion		Premature Battery Depletion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	160	4142	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	363	12142	1	0.28%	0	0.00%	0	0.00%	1	0.28%	0	0.00%	**2**	**0.55%**
1207-36	396	15581	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	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	160	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	363	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	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	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	160	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	363	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	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.25%**

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

Defibrillation Leads

St. Jude Medical

Customer Reported Performance Data

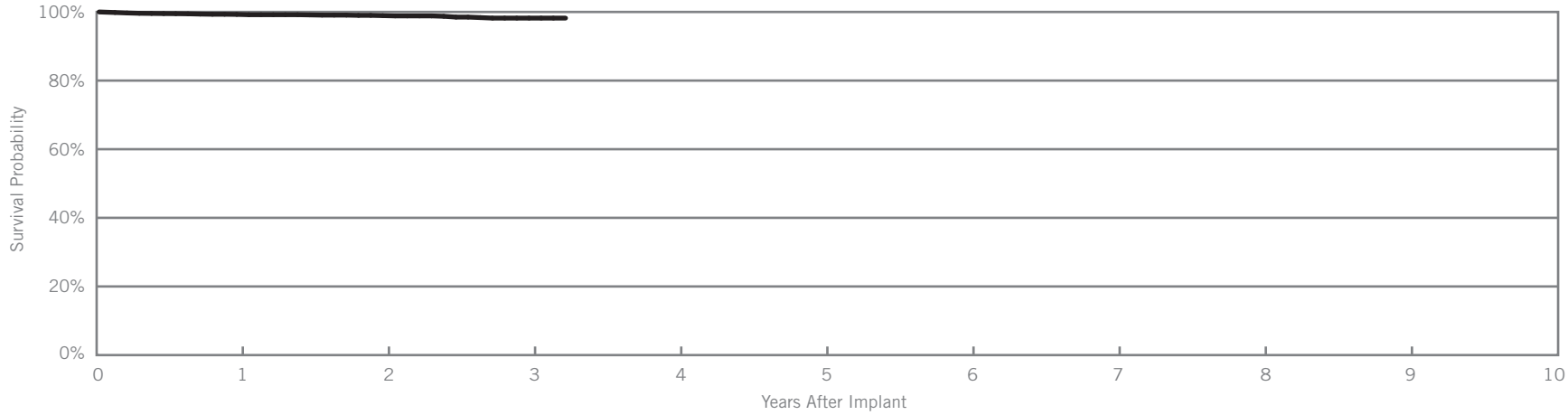
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	3,398
Estimated Active US Implants	2,650
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	2	0.06%	0	0.00%
Conductor Fracture	0	0.00%	1	0.03%
Lead Dislodgement	4	0.12%	7	0.21%
Failure to Capture	3	0.09%	14	0.41%
Oversensing	2	0.06%	4	0.12%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	2	0.06%
Abnormal Pacing Impedance	0	0.00%	1	0.03%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.03%	0	0.00%
Total	**12**	**0.35%**	**30**	**0.88%**
Total Returned for Analysis	**8**		**21**	

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	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	22	0.65%
Total	**23**	**0.68%**



Year	1	2	3	at 39 months						
Survival Probability	99.29%	98.93%	98.21%	98.21%						
± 1 standard error	0.15%	0.20%	0.37%	0.37%						
Sample Size	2790	1700	810	260						

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

Actively Monitored Study Data

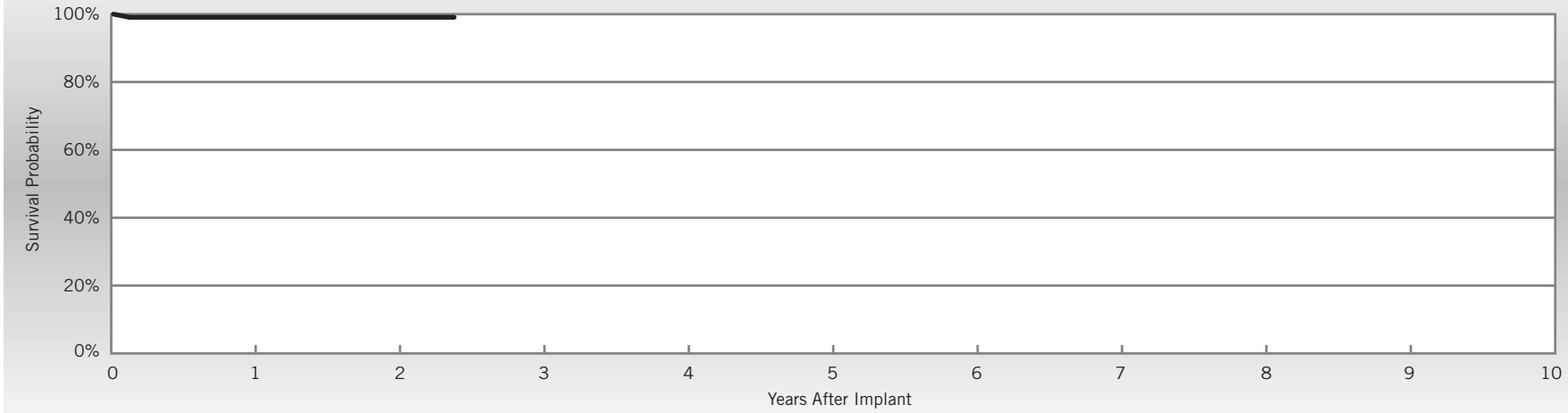
Durata™ DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	113
Cumulative Months of Follow-up	2,865
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
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	1	0.88%
Total	**1**	**0.88%**



Year	1	2	at 29 months							
Survival Probability	99.08%	99.08%	99.08%							
± 1 standard error	0.91%	0.91%	0.91%							
Sample Size	110	80	50							

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

Customer Reported Performance Data

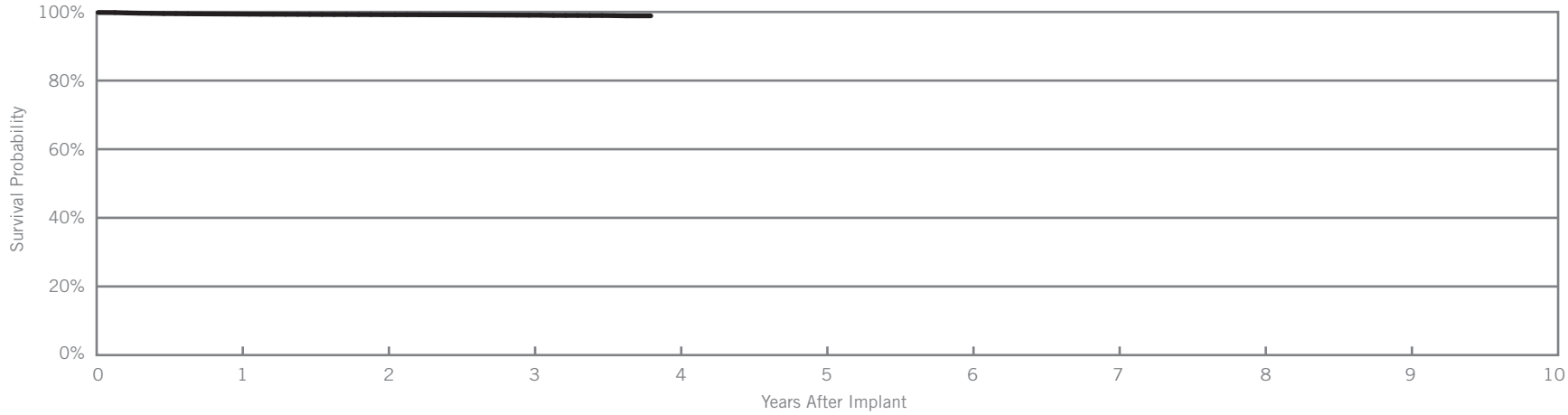
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	80,495
Estimated Active US Implants	63,350
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	36	0.04%	15	0.02%
Conductor Fracture	0	0.00%	16	0.02%
Lead Dislodgement	108	0.13%	232	0.29%
Failure to Capture	46	0.06%	117	0.15%
Oversensing	27	0.03%	62	0.08%
Failure to Sense	7	<0.01%	15	0.02%
Insulation Breach	0	0.00%	8	<0.01%
Abnormal Pacing Impedance	4	<0.01%	8	<0.01%
Abnormal Defibrillation Impedance	5	<0.01%	18	0.02%
Extracardiac Stimulation	1	<0.01%	2	<0.01%
Other	8	<0.01%	18	0.02%
Total	**242**	**0.30%**	**511**	**0.63%**
Total Returned for Analysis	**142**		**359**	

Malfunctions	Qty.	Rate
Conductor Fracture	10	0.01%
Clavicular Crush	1	<0.01%
In the Pocket	2	<0.01%
Intravascular	7	<0.01%
Insulation Breach	12	0.01%
Lead-to-Can Contact	6	<0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	2	<0.01%
Externalized Conductors	0	0.00%
Other	4	<0.01%
Crimps, Welds & Bonds	2	<0.01%
Other	27	0.03%
Extrinsic Factors	365	0.45%
Total	**416**	**0.52%**



Year	1	2	3	at 46 months						
Survival Probability	99.38%	99.22%	99.06%	98.87%						
± 1 standard error	0.03%	0.03%	0.04%	0.09%						
Sample Size	67150	42700	21390	670						

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

Actively Monitored Study Data

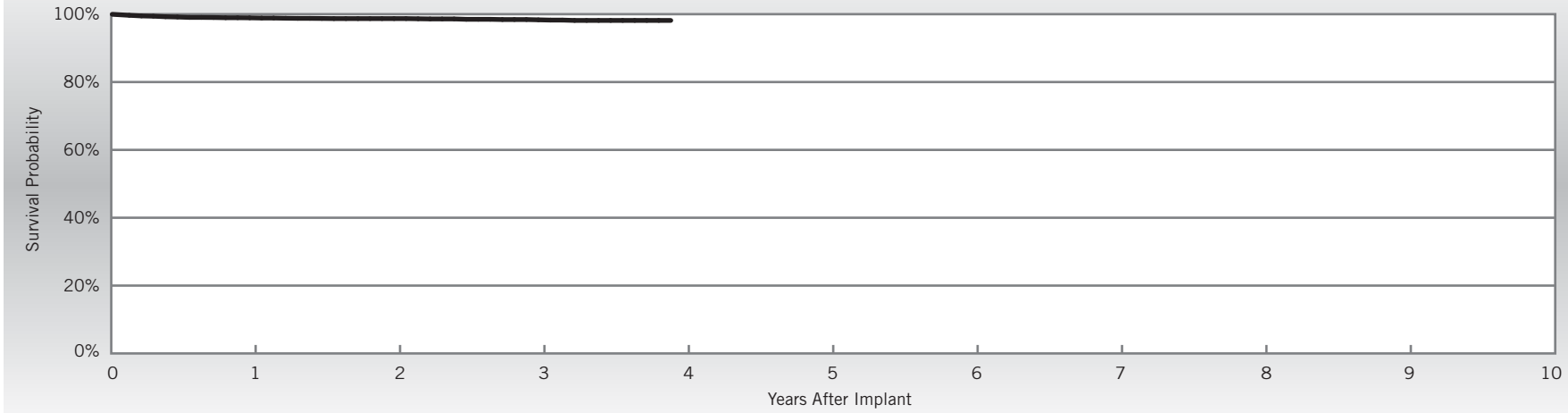
Durata™ DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	4,045
Cumulative Months of Follow-up	101,136
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	4	0.10%
Cardiac Perforation	1	0.02%
Conductor Fracture	3	0.07%
Failure to Capture	10	0.25%
Failure to Sense	2	0.05%
Inappropriate Shock	2	0.05%
Lead Dislodgement	31	0.77%
Oversensing	1	0.02%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.02%
Clavicular Crush	0	0.00%
In the Pocket	1	0.02%
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	1	0.02%
Extrinsic Factors	32	0.79%
Total	**34**	**0.84%**



Year	1	2	3	at 47 months						
Survival Probability	98.93%	98.70%	98.34%	98.16%						
± 1 standard error	0.17%	0.19%	0.23%	0.27%						
Sample Size	3610	2710	1770	100						

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

Customer Reported Performance Data

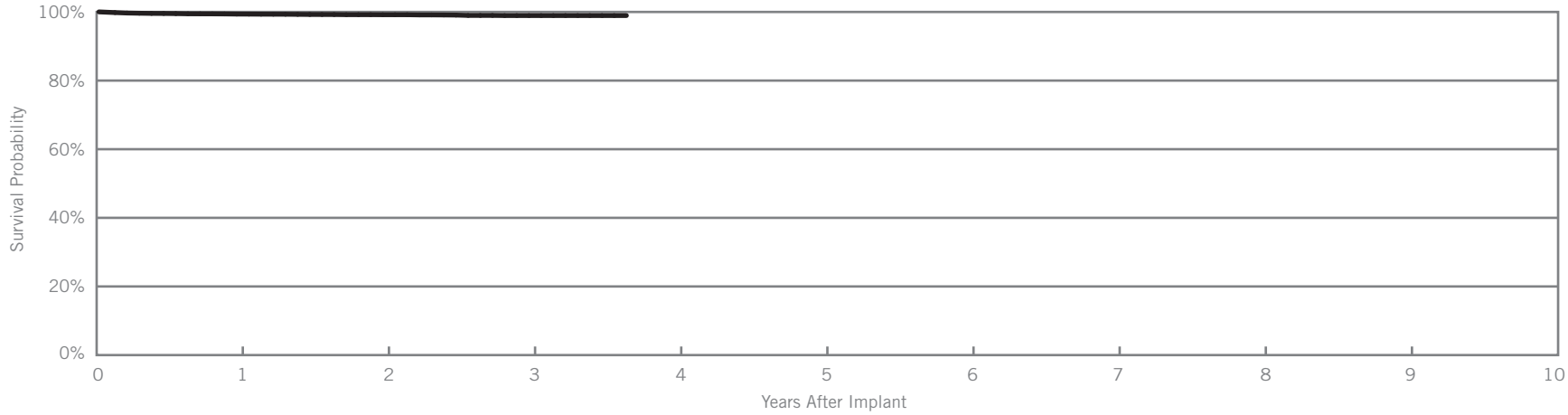
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	23,177
Estimated Active US Implants	19,142
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	16	0.07%	12	0.05%
Conductor Fracture	1	<0.01%	3	0.01%
Lead Dislodgement	25	0.11%	51	0.22%
Failure to Capture	15	0.06%	22	0.09%
Oversensing	5	0.02%	17	0.07%
Failure to Sense	3	0.01%	5	0.02%
Insulation Breach	0	0.00%	2	<0.01%
Abnormal Pacing Impedance	0	0.00%	4	0.02%
Abnormal Defibrillation Impedance	1	<0.01%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	4	0.02%
Total	**67**	**0.29%**	**120**	**0.52%**
Total Returned for Analysis	**47**		**88**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	2	<0.01%
Intravascular	0	0.00%
Insulation Breach	7	0.03%
Lead-to-Can Contact	3	0.01%
Lead-to-Lead Contact	2	<0.01%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	10	0.04%
Extrinsic Factors	87	0.38%
Total	**106**	**0.46%**



Year	1	2	3	at 44 months						
Survival Probability	99.38%	99.19%	98.95%	98.95%						
± 1 standard error	0.06%	0.07%	0.12%	0.12%						
Sample Size	17560	8750	3540	240						

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

Actively Monitored Study Data

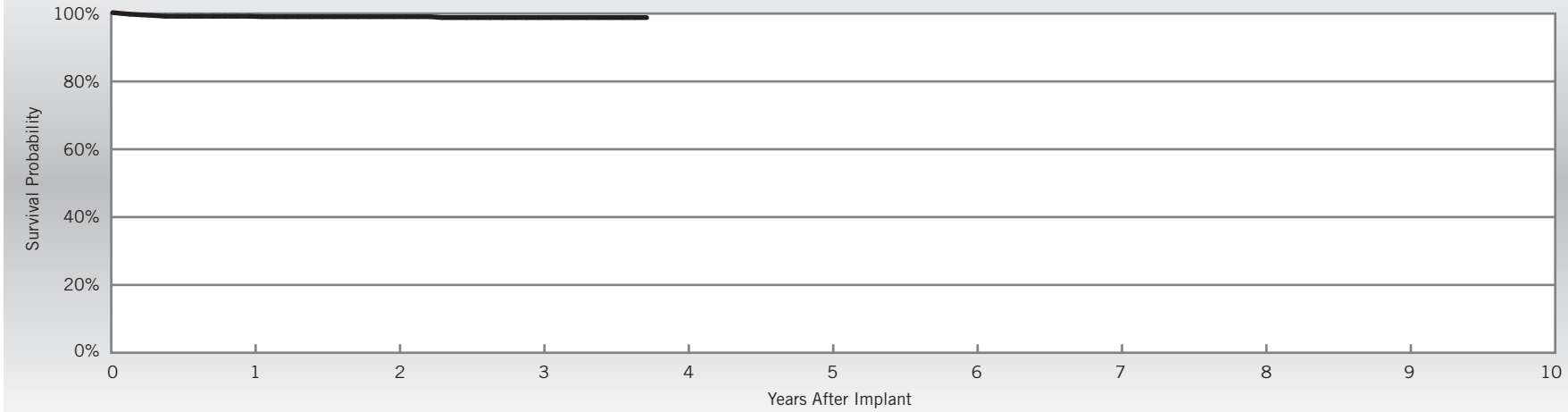
Durata™ DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	1,168
Cumulative Months of Follow-up	23,129
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	1	0.09%
Conductor Fracture	1	0.09%
Failure to Capture	1	0.09%
Lead Dislodgement	5	0.43%
Pericardial Effusion	2	0.17%

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	0.09%
Lead-to-Can Contact	1	0.09%
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	8	0.68%
Total	**9**	**0.77%**



Year	1	2	3	at 45 months						
Survival Probability	99.21%	99.08%	98.82%	98.82%						
± 1 standard error	0.28%	0.31%	0.40%	0.40%						
Sample Size	950	600	370	50						

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

Customer Reported Performance Data

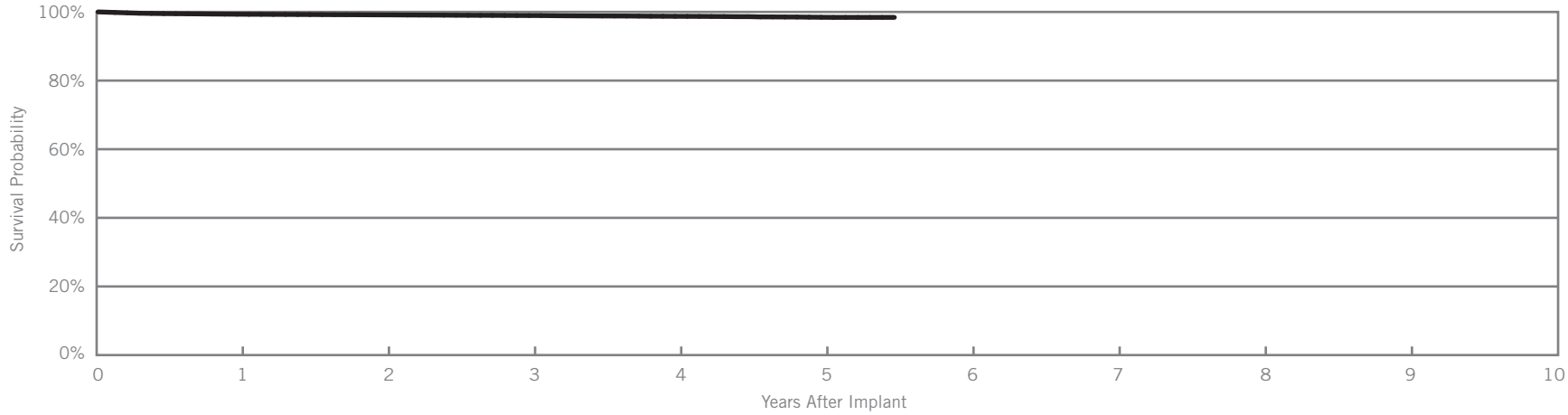
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	56,947
Estimated Active US Implants	36,889
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	36	0.06%	6	0.01%
Conductor Fracture	1	<0.01%	29	0.05%
Lead Dislodgement	65	0.11%	128	0.22%
Failure to Capture	17	0.03%	76	0.13%
Oversensing	45	0.08%	86	0.15%
Failure to Sense	4	<0.01%	20	0.04%
Insulation Breach	0	0.00%	13	0.02%
Abnormal Pacing Impedance	1	<0.01%	38	0.07%
Abnormal Defibrillation Impedance	17	0.03%	36	0.06%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	18	0.03%	16	0.03%
Total	**204**	**0.36%**	**448**	**0.79%**
Total Returned for Analysis	**81**		**249**	

Malfunctions	Qty.	Rate
Conductor Fracture	21	0.04%
Clavicular Crush	1	<0.01%
In the Pocket	16	0.03%
Intravascular	4	<0.01%
Insulation Breach	27	0.05%
Lead-to-Can Contact	9	0.02%
Lead-to-Lead Contact	7	0.01%
Clavicular Crush	6	0.01%
Externalized Conductors	0	0.00%
Other	5	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	9	0.02%
Extrinsic Factors	233	0.41%
Total	**291**	**0.51%**



Year	1	2	3	4	5	at 66 months				
Survival Probability	99.34%	99.15%	98.96%	98.73%	98.45%	98.42%				
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.08%	0.09%				
Sample Size	51890	42670	34310	24400	11060	280				

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

Actively Monitored Study Data

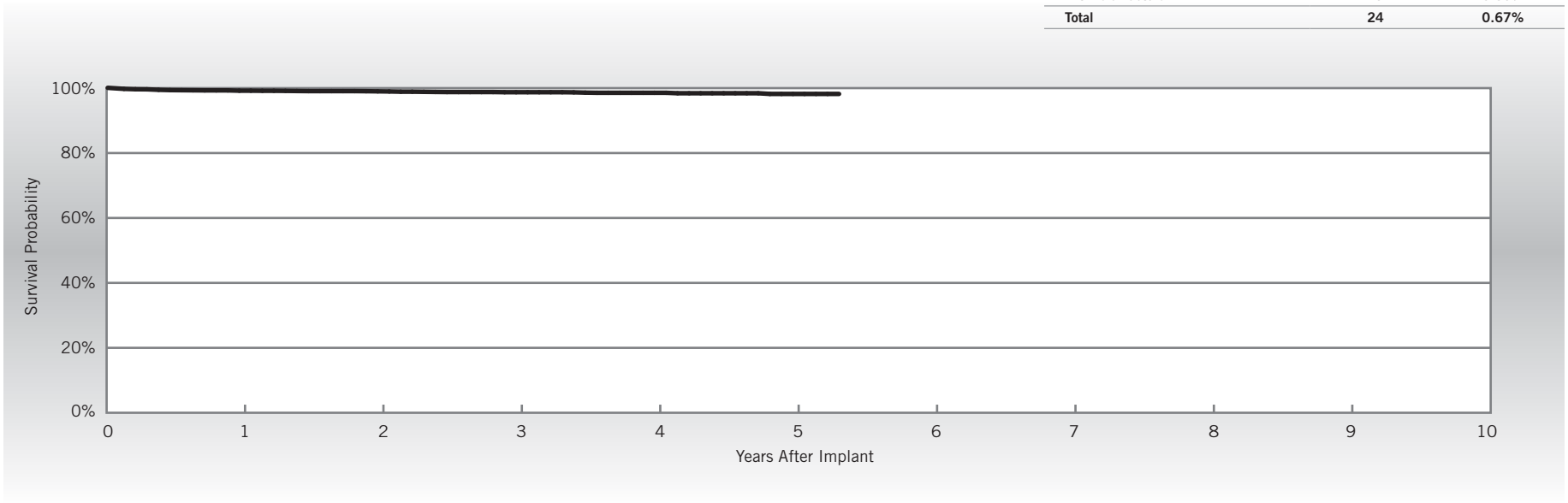
Durata™

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	3,560
Cumulative Months of Follow-up	140,167
Insulation	Optim™*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.03%
Conductor Fracture	8	0.22%
Failure to Capture	9	0.25%
Failure to Sense	1	0.03%
Inappropriate Shock	2	0.06%
Insulation Breach	4	0.11%
Lead Dislodgement	19	0.53%
Oversensing	3	0.08%

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	3	0.08%
Lead-to-Can Contact	2	0.06%
Lead-to-Lead Contact	1	0.03%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.03%
Extrinsic Factors	19	0.53%
Total	**24**	**0.67%**



Year	1	2	3	4	5	at 64 months				
Survival Probability	99.21%	99.01%	98.74%	98.56%	98.21%	98.21%				
± 1 standard error	0.14%	0.17%	0.20%	0.22%	0.31%	0.31%				
Sample Size	3370	2960	2530	1950	920	60				

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

Customer Reported Performance Data

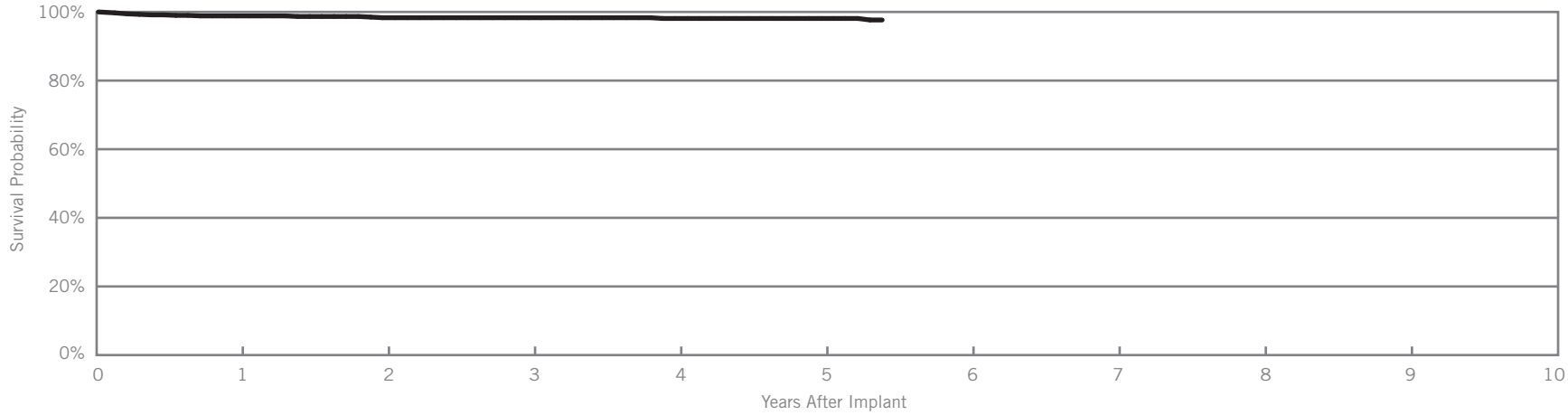
Riata™ ST Optim™

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	768
Estimated Active US Implants	419
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	1	0.13%
Conductor Fracture	0	0.00%	1	0.13%
Lead Dislodgement	4	0.52%	0	0.00%
Failure to Capture	0	0.00%	4	0.52%
Oversensing	2	0.26%	6	0.78%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.13%
Abnormal Pacing Impedance	0	0.00%	2	0.26%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**6**	**0.78%**	**15**	**1.95%**
Total Returned for Analysis	**3**		**3**	

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	0.13%
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	0.13%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.52%
Total	**5**	**0.65%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	98.85%	98.32%	98.32%	98.10%	98.10%	97.66%				
± 1 standard error	0.41%	0.47%	0.50%	0.55%	0.55%	0.70%				
Sample Size	690	580	520	450	340	210				

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

Customer Reported Performance Data

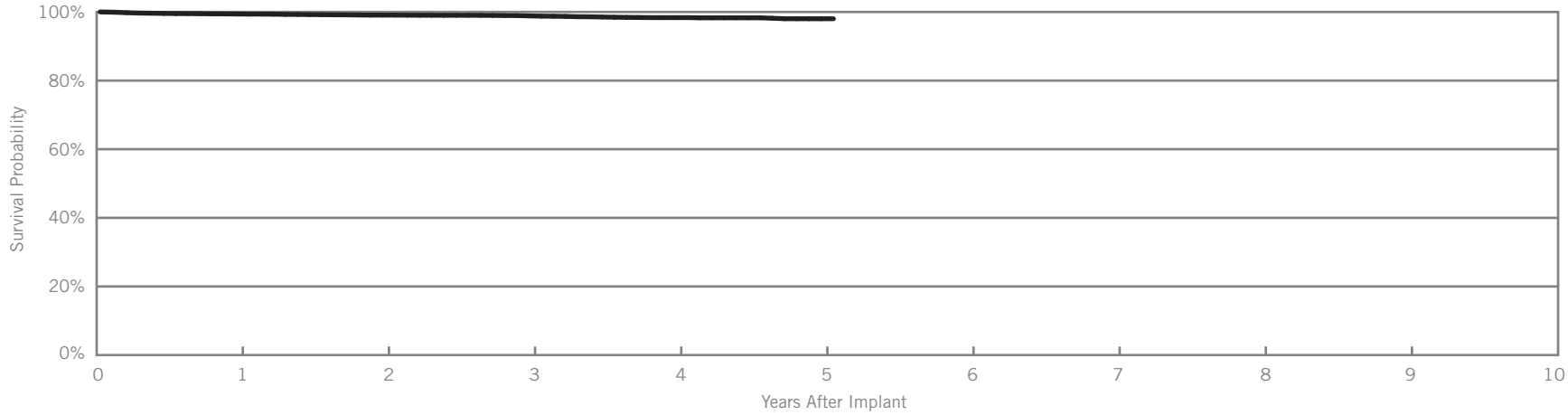
Durata™

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	10,929
Estimated Active US Implants	7,688
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.05%	2	0.02%
Conductor Fracture	1	<0.01%	4	0.04%
Lead Dislodgement	10	0.09%	23	0.21%
Failure to Capture	10	0.09%	18	0.16%
Oversensing	4	0.04%	18	0.16%
Failure to Sense	0	0.00%	5	0.05%
Insulation Breach	0	0.00%	8	0.07%
Abnormal Pacing Impedance	1	<0.01%	11	0.10%
Abnormal Defibrillation Impedance	1	<0.01%	4	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	4	0.04%
Total	**33**	**0.30%**	**97**	**0.89%**
Total Returned for Analysis	**19**		**74**	

Malfunctions	Qty.	Rate
Conductor Fracture	8	0.07%
Clavicular Crush	0	0.00%
In the Pocket	6	0.05%
Intravascular	2	0.02%
Insulation Breach	17	0.16%
Lead-to-Can Contact	10	0.09%
Lead-to-Lead Contact	5	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	1	<0.01%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	4	0.04%
Extrinsic Factors	60	0.55%
Total	**89**	**0.81%**



Year	1	2	3	4	5	at 61 months				
Survival Probability	99.40%	99.08%	98.85%	98.35%	98.02%	98.02%				
± 1 standard error	0.08%	0.10%	0.11%	0.17%	0.27%	0.27%				
Sample Size	9710	7420	5260	3090	1130	240				

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

Actively Monitored Study Data

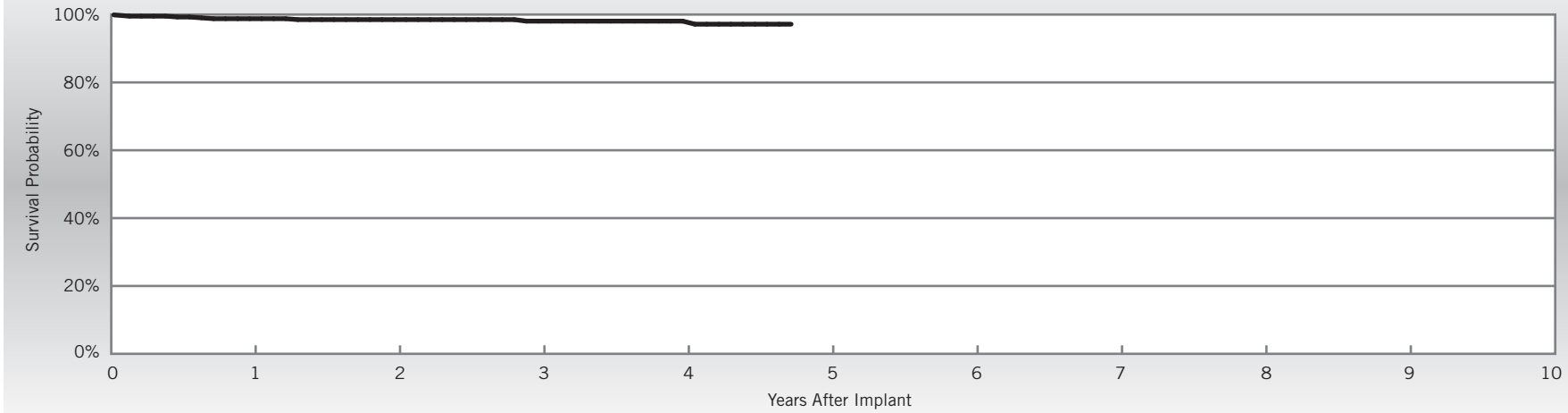
Durata™

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	427
Cumulative Months of Follow-up	14,815
Insulation	Optim™*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	2	0.47%
Failure to Capture	1	0.23%
Lead Dislodgement	4	0.94%
Oversensing	1	0.23%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.23%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.23%
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	3	0.70%
Total	**4**	**0.94%**



Year	1	2	3	4	at 57 months					
Survival Probability	98.78%	98.51%	98.06%	98.06%	97.16%					
± 1 standard error	0.54%	0.60%	0.75%	0.75%	1.16%					
Sample Size	400	350	260	160	50					

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

Customer Reported Performance Data

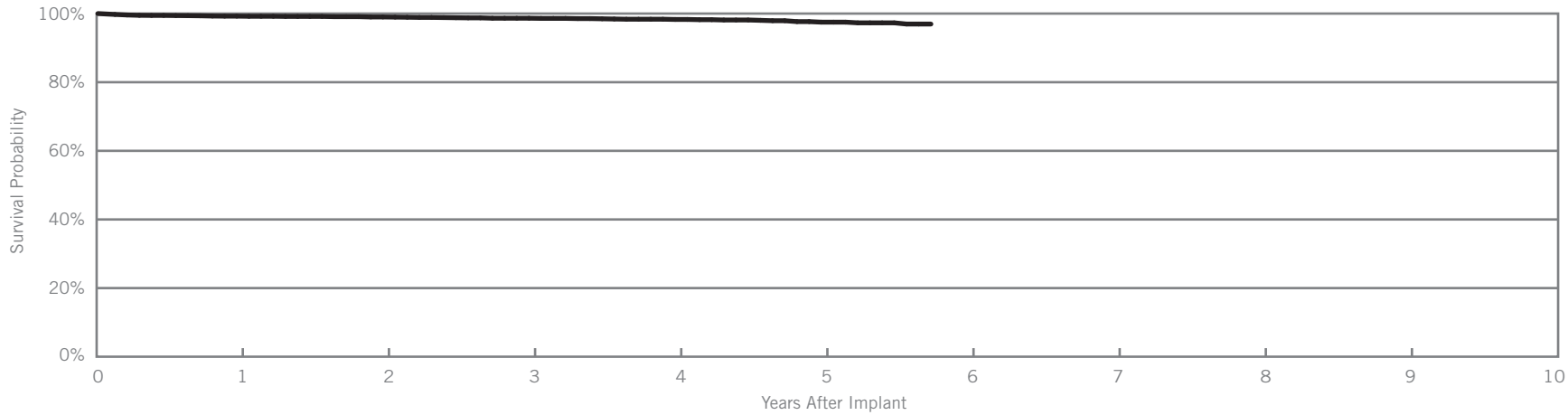
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,308
Estimated Active US Implants	2,062
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	0.09%	2	0.06%
Conductor Fracture	1	0.03%	8	0.24%
Lead Dislodgement	3	0.09%	6	0.18%
Failure to Capture	5	0.15%	5	0.15%
Oversensing	4	0.12%	9	0.27%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	3	0.09%
Abnormal Pacing Impedance	0	0.00%	2	0.06%
Abnormal Defibrillation Impedance	0	0.00%	2	0.06%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	1	0.03%
Total	**19**	**0.57%**	**40**	**1.21%**
Total Returned for Analysis	**6**		**15**	

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	6	0.18%
Lead-to-Can Contact	1	0.03%
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	11	0.33%
Total	**18**	**0.54%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	99.25%	99.01%	98.65%	98.29%	97.50%	96.95%				
± 1 standard error	0.16%	0.18%	0.22%	0.26%	0.37%	0.57%				
Sample Size	3040	2570	2140	1650	1000	210				

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

Actively Monitored Study Data

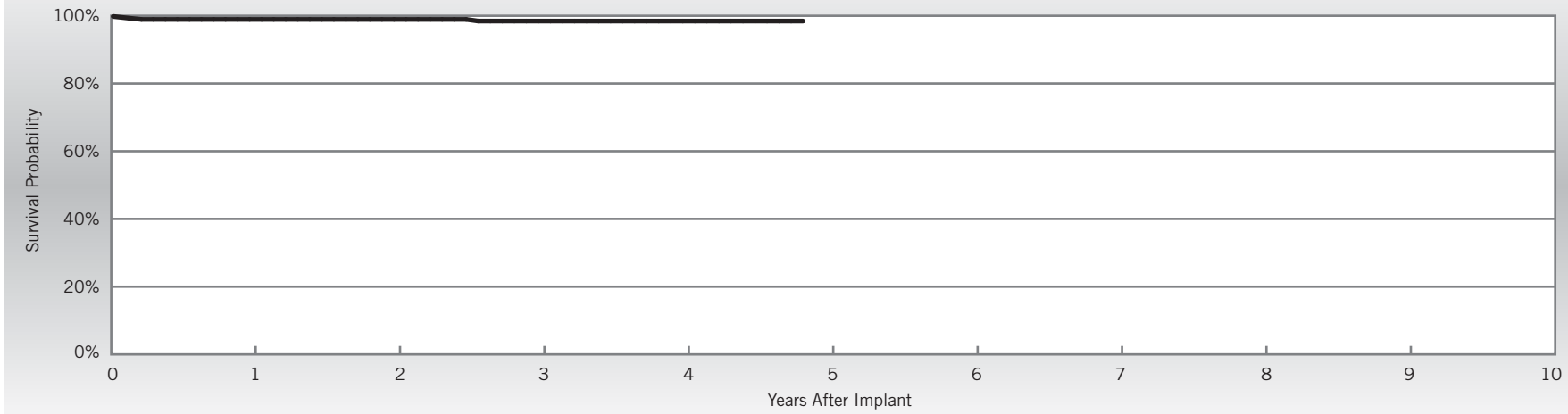
Riata™ ST Optim™

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	287
Cumulative Months of Follow-up	11,420
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Cardiac Perforation	1	0.35%
Conductor Fracture	1	0.35%
Failure to Capture	1	0.35%
Lead Dislodgement	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	at 58 months					
Survival Probability	98.93%	98.93%	98.44%	98.44%	98.44%					
± 1 standard error	0.61%	0.61%	0.79%	0.79%	0.79%					
Sample Size	270	240	200	150	50					

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

Customer Reported Performance Data

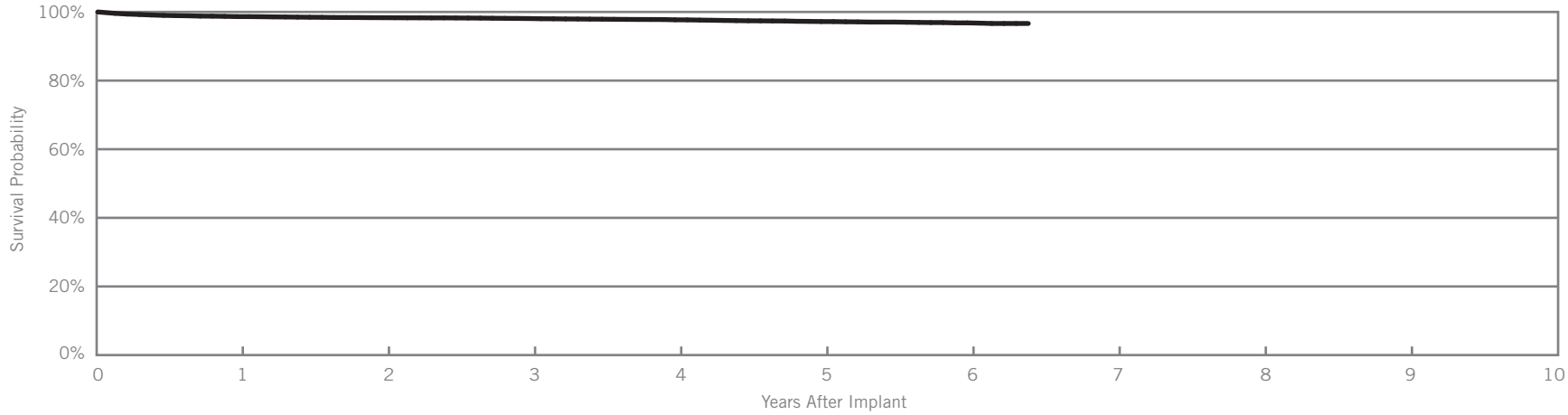
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	14,212
Estimated Active US Implants	7,630
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	33	0.23%	9	0.06%
Conductor Fracture	0	0.00%	22	0.15%
Lead Dislodgement	27	0.19%	47	0.33%
Failure to Capture	17	0.12%	57	0.40%
Oversensing	18	0.13%	57	0.40%
Failure to Sense	8	0.06%	11	0.08%
Insulation Breach	0	0.00%	10	0.07%
Abnormal Pacing Impedance	1	<0.01%	6	0.04%
Abnormal Defibrillation Impedance	4	0.03%	13	0.09%
Extracardiac Stimulation	3	0.02%	2	0.01%
Other	0	0.00%	13	0.09%
Total	**111**	**0.78%**	**247**	**1.74%**
Total Returned for Analysis	**53**		**139**	

Malfunctions	Qty.	Rate
Conductor Fracture	7	0.05%
Clavicular Crush	1	<0.01%
In the Pocket	1	<0.01%
Intravascular	5	0.04%
Insulation Breach	17	0.12%
Lead-to-Can Contact	6	0.04%
Lead-to-Lead Contact	2	0.01%
Clavicular Crush	3	0.02%
Externalized Conductors	0	0.00%
Other	6	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	133	0.94%
Total	**157**	**1.10%**



Year	1	2	3	4	5	6	at 77 months			
Survival Probability	98.65%	98.33%	98.08%	97.71%	97.20%	96.82%	96.64%			
± 1 standard error	0.10%	0.11%	0.12%	0.14%	0.16%	0.19%	0.23%			
Sample Size	13050	11200	9890	8630	7190	3920	290			

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

Actively Monitored Study Data

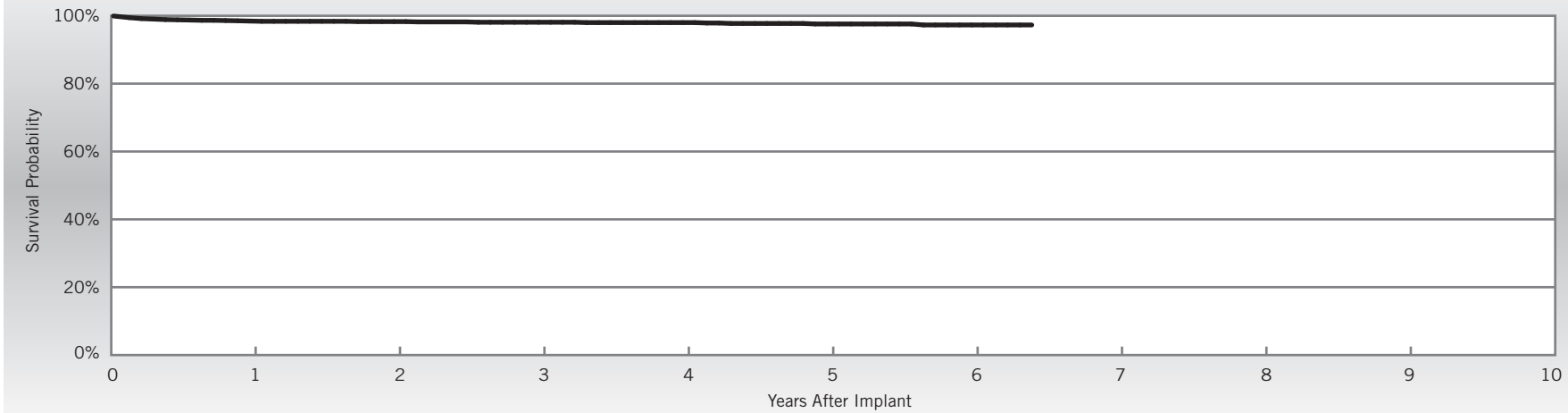
Riata™ ST Optim™

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	1,471
Cumulative Months of Follow-up	67,198
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	3	0.20%
Cardiac Perforation	1	0.07%
Conductor Fracture	4	0.27%
Failure to Capture	8	0.54%
Failure to Sense	1	0.07%
Insulation Breach	2	0.14%
Lead Dislodgement	10	0.68%
Oversensing	1	0.07%
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	1	0.07%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	0.07%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	13	0.88%
Total	**17**	**1.16%**



Year	1	2	3	4	5	6	at 77 months			
Survival Probability	98.45%	98.29%	98.10%	98.00%	97.59%	97.30%	97.30%			
± 1 standard error	0.32%	0.35%	0.37%	0.38%	0.45%	0.53%	0.53%			
Sample Size	1380	1200	1030	880	700	390	60			

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

Customer Reported Performance Data

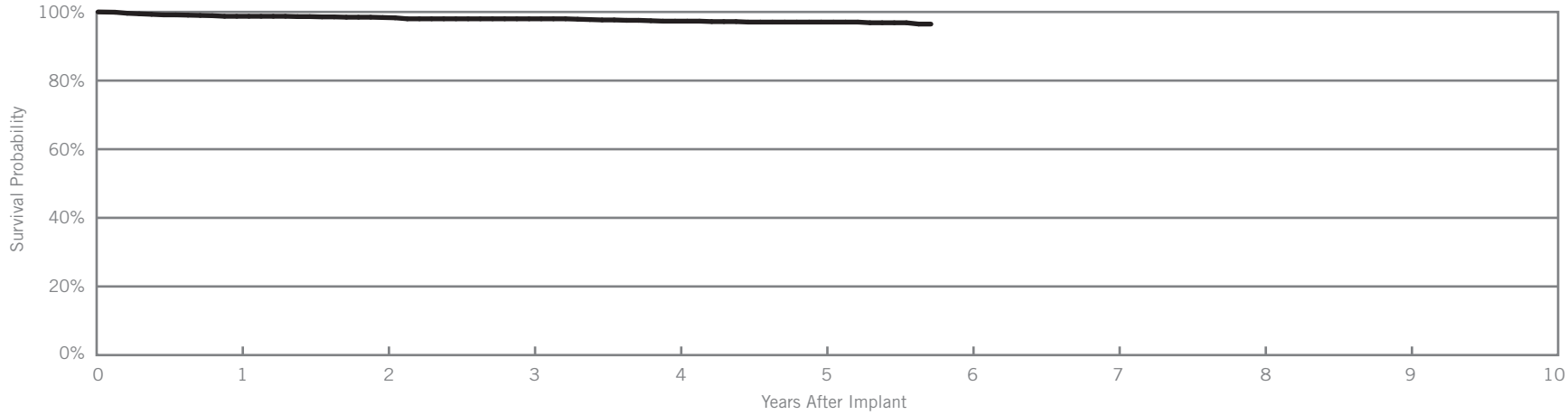
Riata™ ST Optim™

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,387
Estimated Active US Implants	789
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	5	0.36%	2	0.14%
Conductor Fracture	0	0.00%	4	0.29%
Lead Dislodgement	3	0.22%	6	0.43%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	6	0.43%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	3	0.22%
Abnormal Pacing Impedance	1	0.07%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**10**	**0.72%**	**22**	**1.59%**
Total Returned for Analysis	**3**		**13**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.07%
Insulation Breach	2	0.14%
Lead-to-Can Contact	1	0.07%
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	1.01%
Total	**17**	**1.23%**



Year	1	2	3	4	5	at 69 months				
Survival Probability	98.74%	98.38%	98.00%	97.32%	97.05%	96.47%				
± 1 standard error	0.31%	0.35%	0.41%	0.49%	0.52%	0.67%				
Sample Size	1290	1120	990	860	690	220				

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

Customer Reported Performance Data

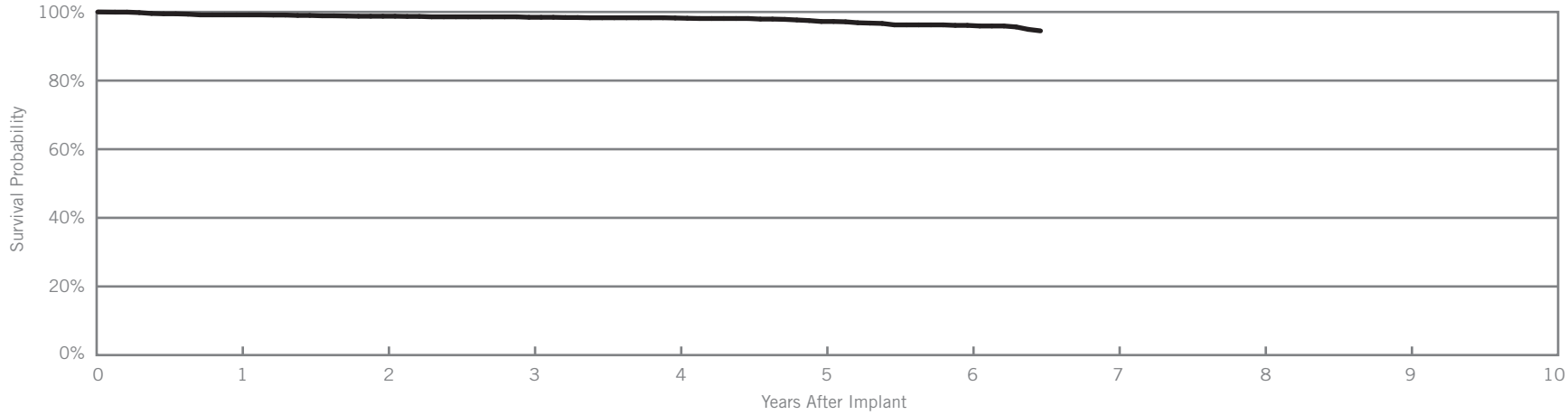
Riata™ ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,185
Estimated Active US Implants	1,118
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	1	0.05%
Lead Dislodgement	1	0.05%	6	0.27%
Failure to Capture	2	0.09%	3	0.14%
Oversensing	2	0.09%	7	0.32%
Failure to Sense	1	0.05%	2	0.09%
Insulation Breach	0	0.00%	10	0.46%
Abnormal Pacing Impedance	1	0.05%	3	0.14%
Abnormal Defibrillation Impedance	0	0.00%	3	0.14%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	1	0.05%
Total	**11**	**0.50%**	**37**	**1.69%**
Total Returned for Analysis	**3**		**13**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.05%
Clavicular Crush	0	0.00%
In the Pocket	1	0.05%
Intravascular	0	0.00%
Insulation Breach	14	0.64%
Lead-to-Can Contact	4	0.18%
Lead-to-Lead Contact	6	0.27%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.05%
Other	3	0.14%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	7	0.32%
Total	**22**	**1.01%**



Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.15%	98.76%	98.45%	98.24%	97.22%	96.09%	94.49%			
± 1 standard error	0.20%	0.25%	0.27%	0.30%	0.40%	0.54%	0.80%			
Sample Size	2030	1780	1590	1400	1200	840	240			

Customer Reported Performance Data

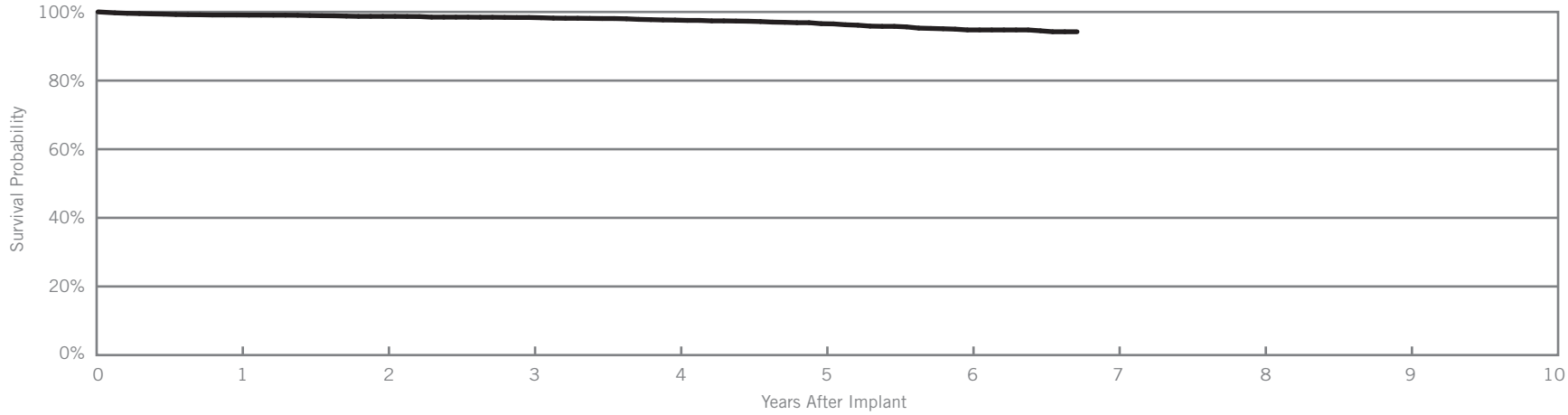
Riata™ ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,013
Estimated Active US Implants	2,089
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	14	0.35%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	0	0.00%	16	0.40%
Oversensing	3	0.07%	30	0.75%
Failure to Sense	0	0.00%	4	0.10%
Insulation Breach	0	0.00%	14	0.35%
Abnormal Pacing Impedance	2	0.05%	5	0.12%
Abnormal Defibrillation Impedance	0	0.00%	6	0.15%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**15**	**0.37%**	**94**	**2.34%**
Total Returned for Analysis	**3**		**28**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.05%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.05%
Insulation Breach	22	0.55%
Lead-to-Can Contact	10	0.25%
Lead-to-Lead Contact	7	0.17%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.02%
Other	4	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.35%
Total	**38**	**0.95%**



Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.12%	98.72%	98.39%	97.63%	96.58%	94.76%	94.23%			
± 1 standard error	0.15%	0.19%	0.22%	0.27%	0.34%	0.50%	0.64%			
Sample Size	3730	3250	2870	2450	1930	1210	240			

Customer Reported Performance Data

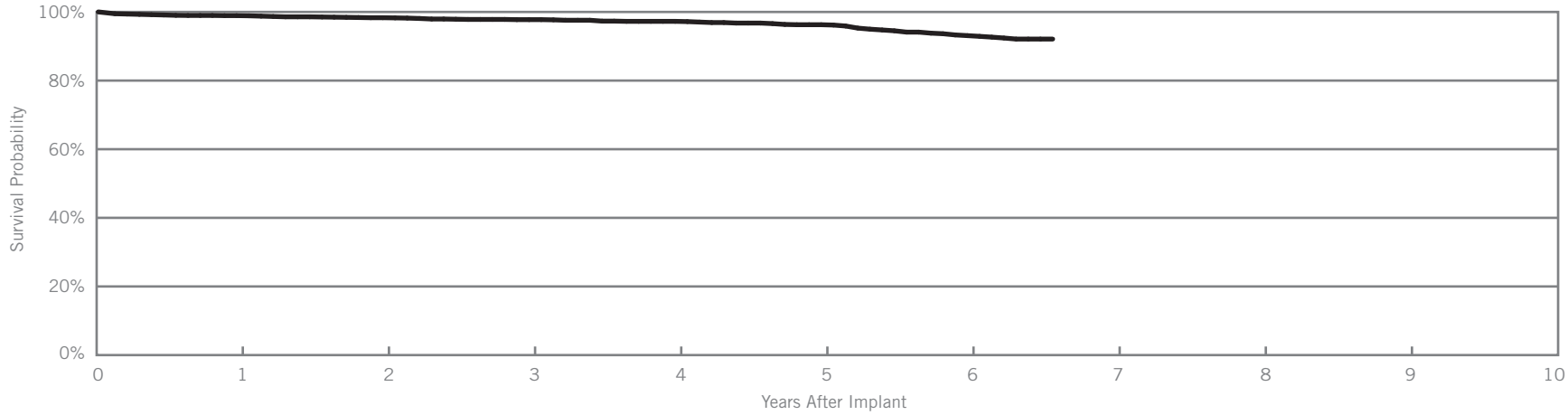
Riata™ ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,391
Estimated Active US Implants	1,213
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.25%	3	0.13%
Conductor Fracture	0	0.00%	5	0.21%
Lead Dislodgement	2	0.08%	9	0.38%
Failure to Capture	4	0.17%	9	0.38%
Oversensing	4	0.17%	21	0.88%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	17	0.71%
Abnormal Pacing Impedance	2	0.08%	1	0.04%
Abnormal Defibrillation Impedance	1	0.04%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	5	0.21%
Total	**20**	**0.84%**	**71**	**2.97%**
Total Returned for Analysis	**11**		**35**	

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.13%
Clavicular Crush	0	0.00%
In the Pocket	1	0.04%
Intravascular	2	0.08%
Insulation Breach	31	1.30%
Lead-to-Can Contact	18	0.75%
Lead-to-Lead Contact	3	0.13%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.13%
Other	7	0.29%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	18	0.75%
Total	**52**	**2.17%**



Year	1	2	3	4	5	6	at 79 months			
Survival Probability	98.93%	98.32%	97.76%	97.26%	96.28%	93.10%	92.10%			
± 1 standard error	0.22%	0.28%	0.33%	0.37%	0.46%	0.75%	0.91%			
Sample Size	2210	1930	1720	1510	1240	760	210			

Customer Reported Performance Data

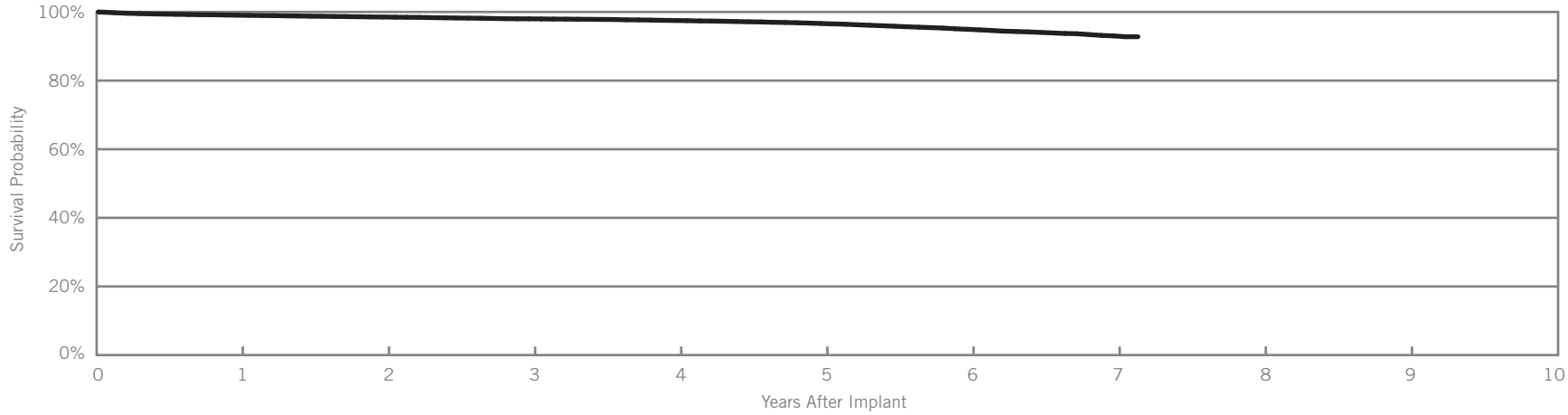
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,769
Estimated Active US Implants	17,140
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	42	0.12%	18	0.05%
Conductor Fracture	0	0.00%	60	0.17%
Lead Dislodgement	38	0.11%	47	0.14%
Failure to Capture	43	0.12%	132	0.38%
Oversensing	40	0.12%	256	0.74%
Failure to Sense	7	0.02%	29	0.08%
Insulation Breach	1	<0.01%	223	0.64%
Abnormal Pacing Impedance	8	0.02%	43	0.12%
Abnormal Defibrillation Impedance	4	0.01%	35	0.10%
Extracardiac Stimulation	3	<0.01%	2	<0.01%
Other	11	0.03%	39	0.11%
Total	**197**	**0.57%**	**884**	**2.54%**
Total Returned for Analysis	**95**		**358**	

Malfunctions	Qty.	Rate
Conductor Fracture	14	0.04%
Clavicular Crush	2	<0.01%
In the Pocket	5	0.01%
Intravascular	7	0.02%
Insulation Breach	263	0.76%
Lead-to-Can Contact	151	0.43%
Lead-to-Lead Contact	50	0.14%
Clavicular Crush	9	0.03%
Externalized Conductors	17	0.05%
Other	36	0.10%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	204	0.59%
Total	**482**	**1.39%**



Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.06%	98.52%	98.00%	97.51%	96.63%	94.94%	93.02%	92.78%		
± 1 standard error	0.05%	0.07%	0.08%	0.09%	0.11%	0.15%	0.25%	0.32%		
Sample Size	32320	28180	25000	21980	18670	13480	5560	540		

Actively Monitored Study Data

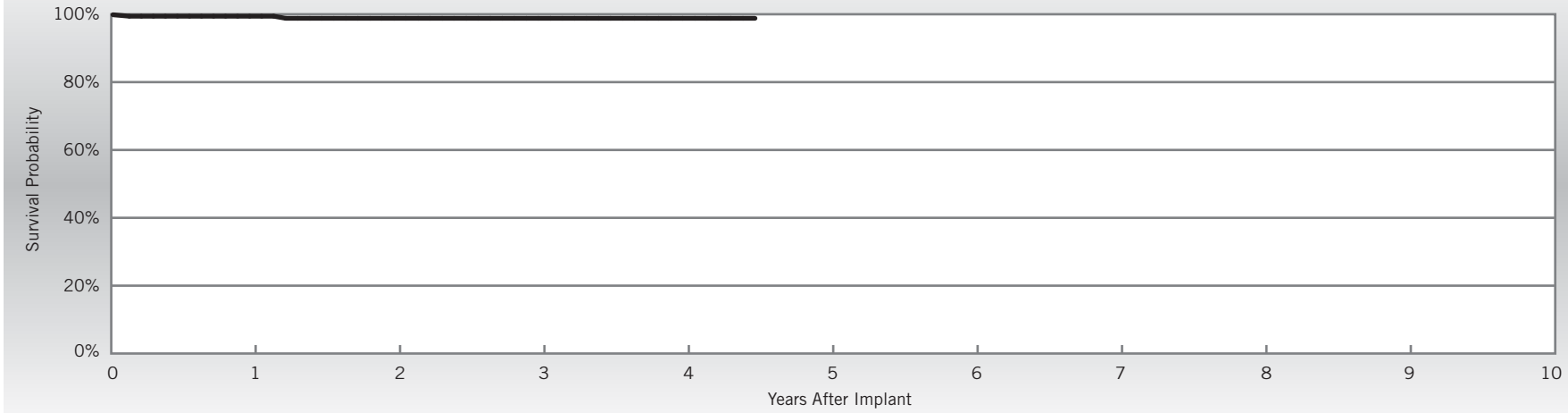
Riata™ ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	180
Cumulative Months of Follow-up	6,571
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Insulation Breach	1	0.56%
Lead Dislodgement	1	0.56%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	3	1.67%
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 54 months					
Survival Probability	99.43%	98.81%	98.81%	98.81%	98.81%					
± 1 standard error	0.56%	0.84%	0.84%	0.84%	0.84%					
Sample Size	170	140	110	70	50					

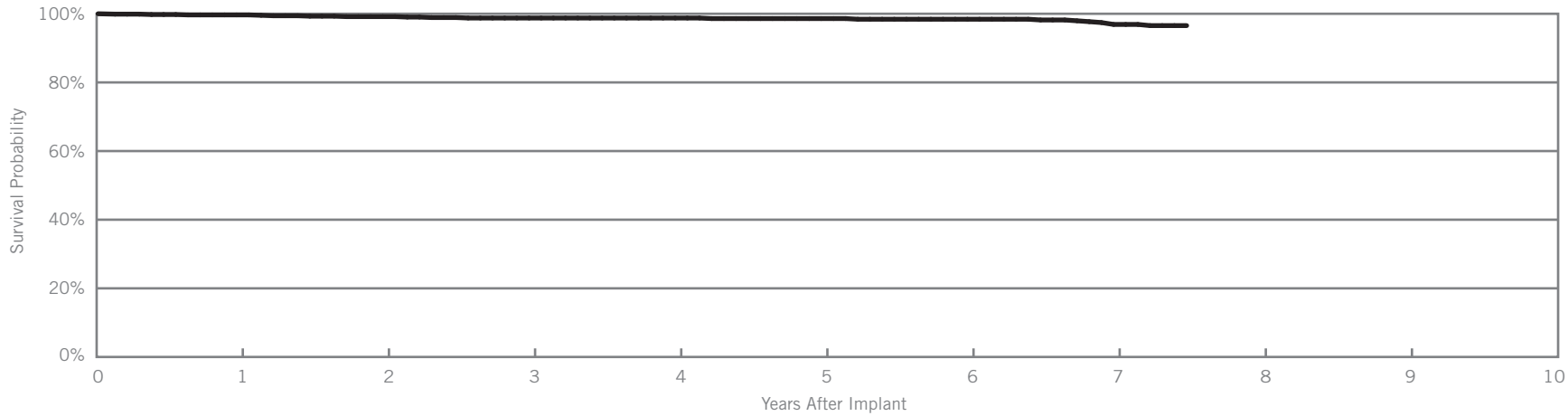
Customer Reported Performance Data

Riata™ *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	958
Estimated Active US Implants	461
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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	4	0.42%
Lead-to-Can Contact	2	0.21%
Lead-to-Lead Contact	1	0.10%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.10%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.10%
Total	**5**	**0.52%**



Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.67%	99.17%	98.76%	98.76%	98.60%	98.41%	96.89%	96.55%		
± 1 standard error	0.19%	0.31%	0.39%	0.39%	0.42%	0.46%	0.67%	0.84%		
Sample Size	900	790	720	640	570	510	410	210		

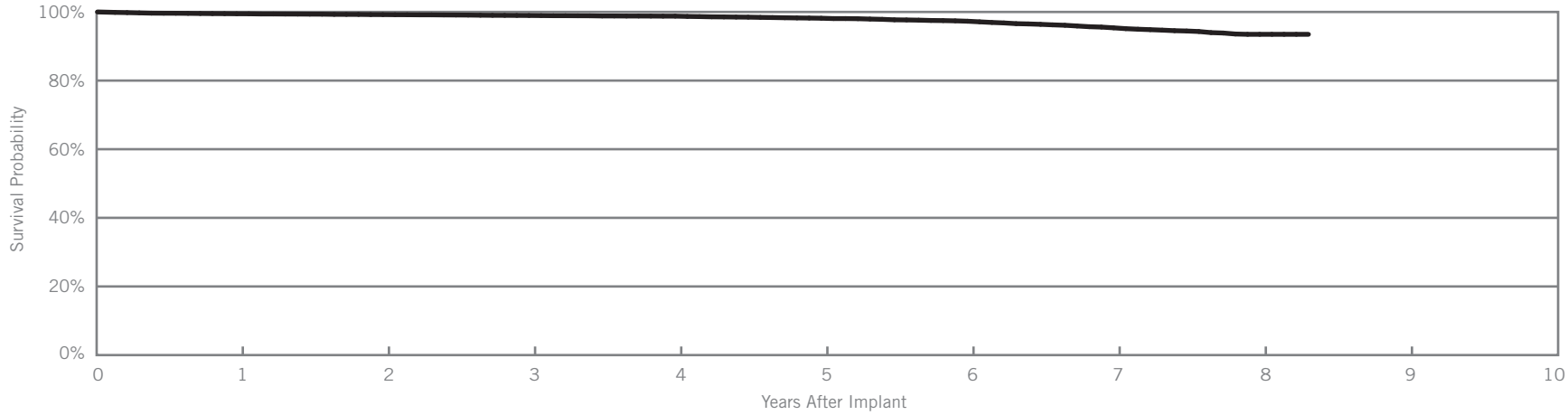
Customer Reported Performance Data

Riata™ *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,630
Estimated Active US Implants	4,226
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

Malfunctions	Qty.	Rate
Conductor Fracture	6	0.06%
Clavicular Crush	1	0.01%
In the Pocket	1	0.01%
Intravascular	4	0.04%
Insulation Breach	77	0.80%
Lead-to-Can Contact	24	0.25%
Lead-to-Lead Contact	19	0.20%
Clavicular Crush	0	0.00%
Externalized Conductors	13	0.13%
Other	21	0.22%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	35	0.36%
Total	**119**	**1.24%**



Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.47%	99.23%	98.97%	98.78%	98.17%	97.30%	95.37%	93.48%	93.48%	
± 1 standard error	0.07%	0.09%	0.11%	0.12%	0.16%	0.20%	0.29%	0.42%	0.42%	
Sample Size	9050	8060	7230	6400	5590	4770	3820	2040	260	

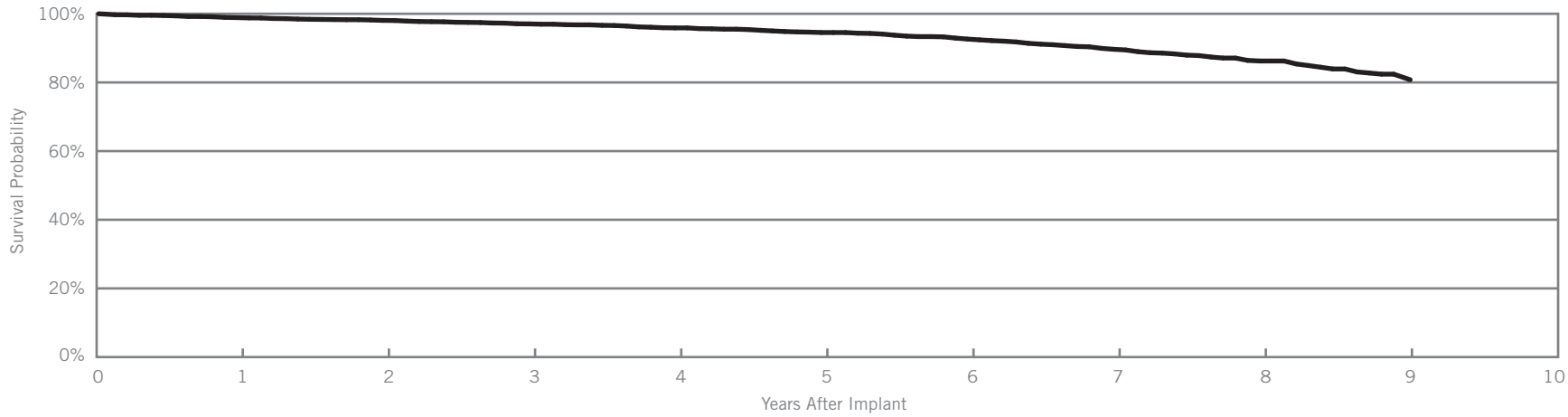
Customer Reported Performance Data

Riata™

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,103
Estimated Active US Implants	1,224
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	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	103	3.32%
Lead-to-Can Contact	39	1.26%
Lead-to-Lead Contact	10	0.32%
Clavicular Crush	2	0.06%
Externalized Conductors	28	0.90%
Other	24	0.77%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	25	0.81%
Total	**131**	**4.22%**



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	98.88%	98.07%	97.05%	95.88%	94.53%	92.63%	89.65%	86.24%	81.18%	
± 1 standard error	0.19%	0.25%	0.33%	0.40%	0.48%	0.58%	0.74%	0.97%	1.36%	
Sample Size	2890	2550	2290	2010	1710	1410	1100	710	210	

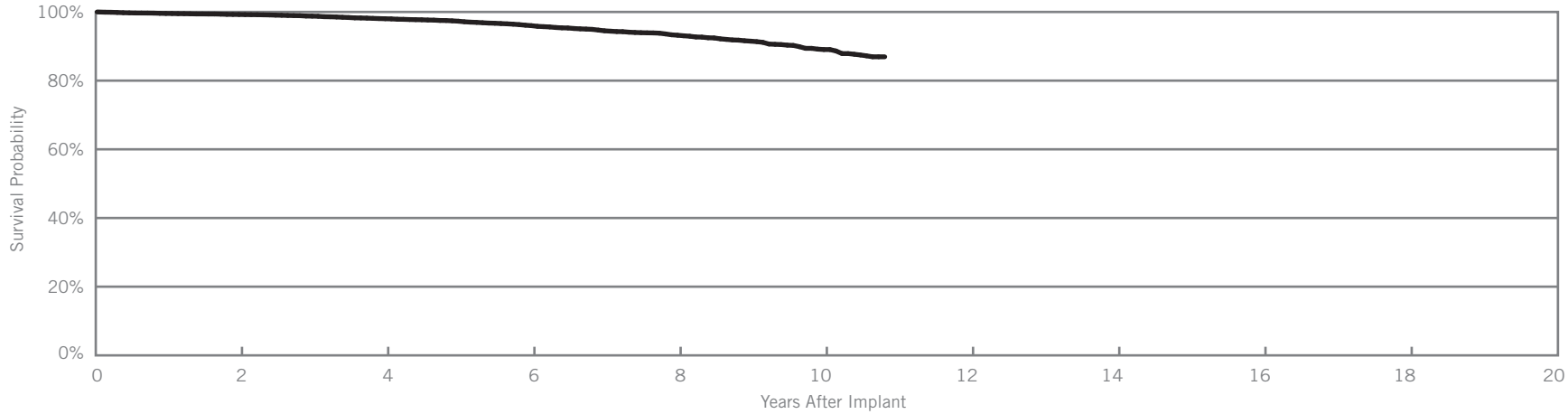
Customer Reported Performance Data

Riata™

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,186
Estimated Active US Implants	4,052
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	2	0.02%
In the Pocket	2	0.02%
Intravascular	0	0.00%
Insulation Breach	108	1.06%
Lead-to-Can Contact	52	0.51%
Lead-to-Lead Contact	10	0.10%
Clavicular Crush	1	<0.01%
Externalized Conductors	23	0.23%
Other	22	0.22%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	32	0.31%
Total	**144**	**1.41%**



Year	2	4	6	8	10	At 130 months				
Survival Probability	99.26%	98.02%	96.01%	93.22%	89.05%	86.94%				
± 1 standard error	0.09%	0.15%	0.24%	0.36%	0.63%	0.88%				
Sample Size	8600	6850	4890	2930	1070	230				

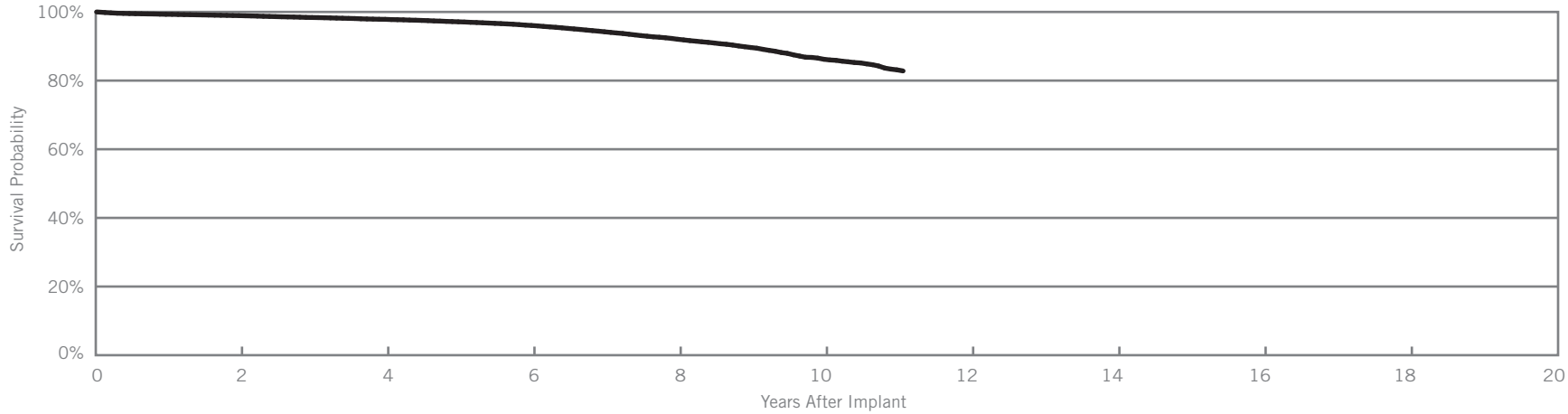
Customer Reported Performance Data

Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	68,317
Estimated Active US Implants	25,767
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 272-284)	One

Malfunctions	Qty.	Rate
Conductor Fracture	19	0.03%
Clavicular Crush	2	<0.01%
In the Pocket	8	0.01%
Intravascular	9	0.01%
Insulation Breach	889	1.30%
Lead-to-Can Contact	375	0.55%
Lead-to-Lead Contact	146	0.21%
Clavicular Crush	14	0.02%
Externalized Conductors	186	0.27%
Other	171	0.25%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	359	0.53%
Total	**1270**	**1.86%**



Year	2	4	6	8	10	At 133 months				
Survival Probability	98.93%	97.85%	96.06%	92.04%	86.21%	82.81%				
± 1 standard error	0.04%	0.06%	0.09%	0.15%	0.32%	0.62%				
Sample Size	56640	44780	32720	18700	4510	320				

Actively Monitored Study Data

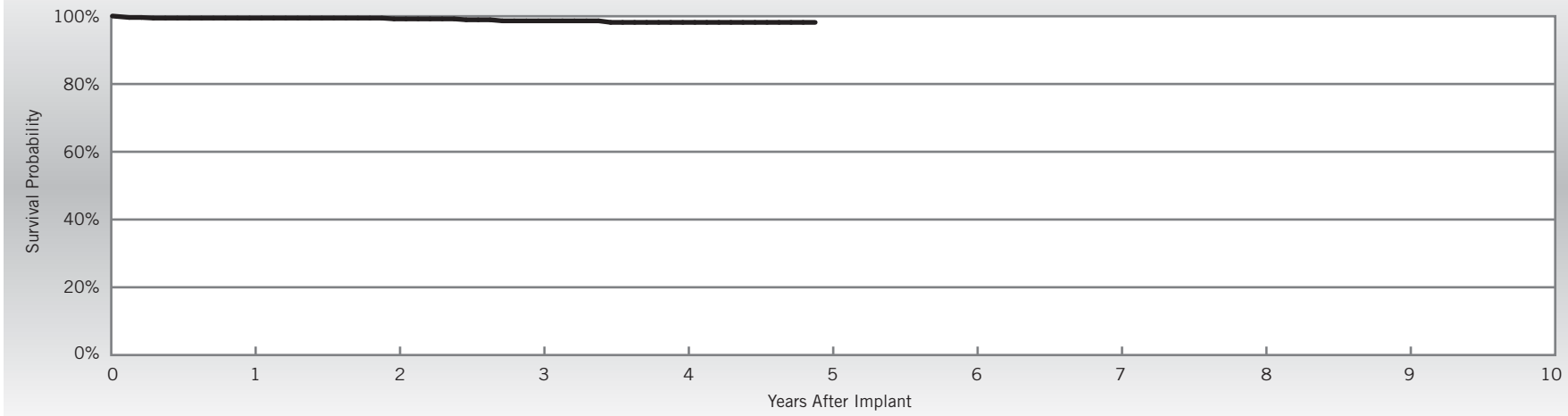
Riata™

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	564
Cumulative Months of Follow-up	19,786
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Insulation Breach	4	0.71%
Lead Dislodgement	2	0.35%
Oversensing	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	8	1.42%
Lead-to-Can Contact	1	0.18%
Lead-to-Lead Contact	2	0.35%
Clavicular Crush	0	0.00%
Externalized Conductors	5	0.89%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.71%
Total	**12**	**2.13%**



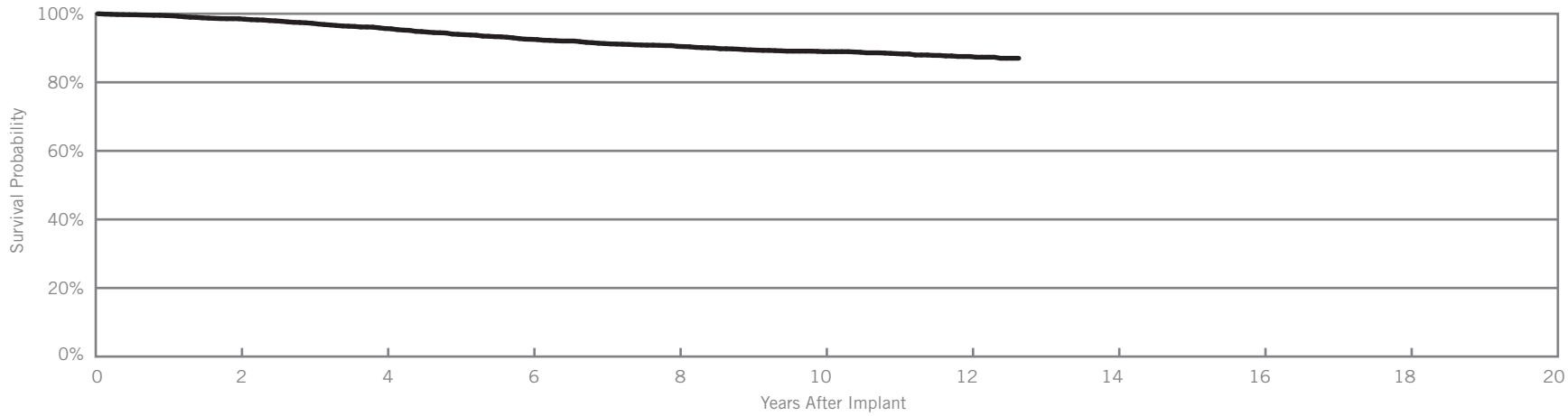
Year	1	2	3	4	at 59 months					
Survival Probability	99.46%	99.22%	98.64%	98.19%	98.19%					
± 1 standard error	0.31%	0.31%	0.56%	0.72%	0.72%					
Sample Size	530	460	350	220	60					

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,551
Estimated Active US Implants	920
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



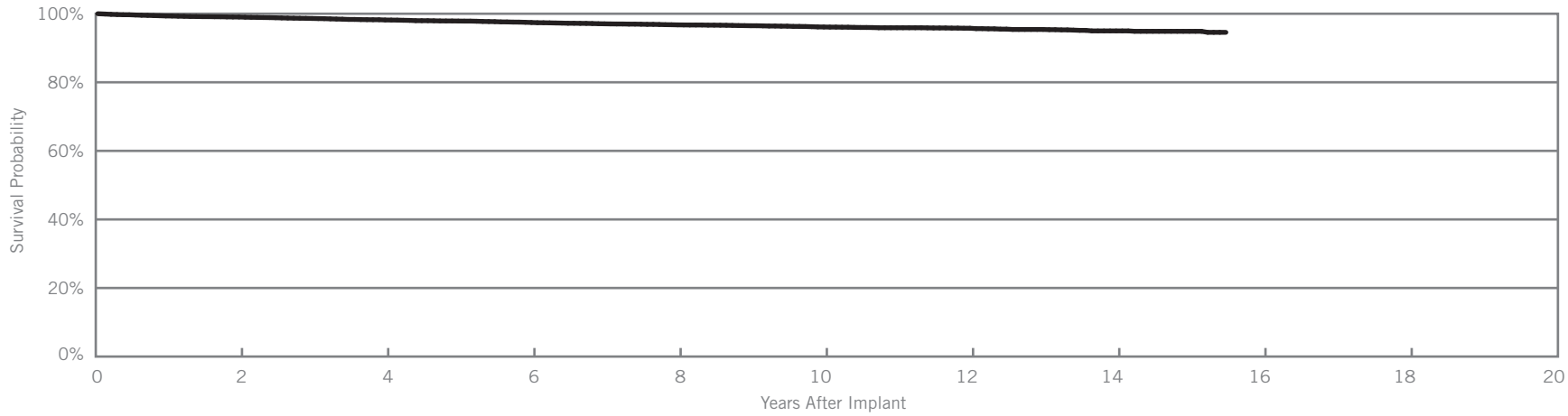
Year	2	4	6	8	10	12	At 152 months			
Survival Probability	98.53%	95.68%	92.54%	90.48%	88.94%	87.53%	87.01%			
± 1 standard error	0.19%	0.34%	0.48%	0.56%	0.64%	0.74%	0.83%			
Sample Size	3720	2930	2250	1670	1210	710	200			

Customer Reported Performance Data

SPL™

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,336
Estimated Active US Implants	2,836
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	At 186 months		
Survival Probability	99.04%	98.18%	97.44%	96.75%	96.13%	95.77%	94.99%	94.57%		
± 1 standard error	0.09%	0.13%	0.16%	0.20%	0.23%	0.25%	0.33%	0.46%		
Sample Size	10360	8450	6840	5390	4120	2830	1290	210		

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
7170Q/7171Q	Durata™ DF4	99.29%	98.93%	98.21%							
7120Q/7121Q	Durata™ DF4	99.38%	99.22%	99.06%							
7122Q	Durata™ DF4	99.38%	99.19%	98.95%							
7120/7121	Durata™	99.34%	99.15%	98.96%	98.73%	98.45%					
7030/7031	Riata™ ST Optim™	98.85%	98.32%	98.32%	98.10%	98.10%					
7122	Durata™	99.40%	99.08%	98.85%	98.35%	98.02%					
7070/7071	Riata™ ST Optim™	99.25%	99.01%	98.65%	98.29%	97.50%					
7020/7021	Riata™ ST Optim™	98.65%	98.33%	98.08%	97.71%	97.20%	96.82%				
7022	Riata™ ST Optim™	98.74%	98.38%	98.00%	97.32%	97.05%					
7010/7011	Riata™ ST	99.15%	98.76%	98.45%	98.24%	97.22%	96.09%				
7040/7041	Riata™ ST	99.12%	98.72%	98.39%	97.63%	96.58%	94.76%				
7002	Riata™ ST	98.93%	98.32%	97.76%	97.26%	96.28%	93.10%				
7000/7001	Riata™ ST	99.06%	98.52%	98.00%	97.51%	96.63%	94.94%	93.02%			
1560/1561	Riata™ i	99.67%	99.17%	98.76%	98.76%	98.60%	98.41%	96.89%			
1590/1591	Riata™ i	99.47%	99.23%	98.97%	98.78%	98.17%	97.30%	95.37%	93.48%		
1582	Riata™	98.88%	98.07%	97.05%	95.88%	94.53%	92.63%	89.65%	86.24%	81.18%	
1570/1571	Riata™	99.56%	99.26%	98.78%	98.02%	97.31%	96.01%	94.51%	93.22%	91.49%	89.05%
1580/1581	Riata™	99.31%	98.93%	98.38%	97.85%	97.13%	96.06%	94.22%	92.04%	89.64%	86.21%
1559	TVL™ ADX	99.47%	98.53%	97.22%	95.68%	93.99%	92.54%	91.30%	90.48%	89.45%	88.94%
SP01/SP02/SP03/SP04	SPL™	99.35%	99.04%	98.62%	98.18%	97.87%	97.44%	97.06%	96.75%	96.50%	96.13%

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	
7170Q/7171Q	Jul-09	3398	2650	2	0.06%	0	0.00%	4	0.12%	3	0.09%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	**12**	**0.35%**	**8**
7120Q/7121Q	Jan-09	80495	63350	36	0.04%	0	0.00%	108	0.13%	46	0.06%	27	0.03%	7	<0.01%	0	0.00%	4	<0.01%	5	<0.01%	1	<0.01%	8	<0.01%	**242**	**0.30%**	**142**
7122Q	Jan-09	23177	19142	16	0.07%	1	<0.01%	25	0.11%	15	0.06%	5	0.02%	3	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**67**	**0.29%**	**47**
7120/7121	Sep-07	56947	36889	36	0.06%	1	<0.01%	65	0.11%	17	0.03%	45	0.08%	4	<0.01%	0	0.00%	1	<0.01%	17	0.03%	0	0.00%	18	0.03%	**204**	**0.36%**	**81**
7030/7031	Jul-06	768	419	0	0.00%	0	0.00%	4	0.52%	0	0.00%	2	0.26%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.78%**	**3**
7122	Sep-07	10929	7688	6	0.05%	1	<0.01%	10	0.09%	10	0.09%	4	0.04%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	**33**	**0.30%**	**19**
7070/7071	Jul-06	3308	2062	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	14212	7630	33	0.23%	0	0.00%	27	0.19%	17	0.12%	18	0.13%	8	0.06%	0	0.00%	1	<0.01%	4	0.03%	3	0.02%	0	0.00%	**111**	**0.78%**	**53**
7022	Jul-06	1387	789	5	0.36%	0	0.00%	3	0.22%	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**	**0.72%**	**3**
7010/7011	Mar-06	2185	1118	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%**	**3**
7040/7041	Mar-06	4013	2089	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	2391	1213	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**	**0.84%**	**11**
7000/7001	Jun-05	34769	17140	42	0.12%	0	0.00%	38	0.11%	43	0.12%	40	0.12%	7	0.02%	1	<0.01%	8	0.02%	4	0.01%	3	<0.01%	11	0.03%	**197**	**0.57%**	**95**

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	
7170Q/7171Q	Jul-09	3398	2650	0	0.00%	1	0.03%	7	0.21%	14	0.41%	4	0.12%	0	0.00%	2	0.06%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	**30**	**0.88%**	**21**
7120Q/7121Q	Jan-09	80495	63350	15	0.02%	16	0.02%	232	0.29%	117	0.15%	62	0.08%	15	0.02%	8	<0.01%	8	<0.01%	18	0.02%	2	<0.01%	18	0.02%	**511**	**0.63%**	**359**
7122Q	Jan-09	23177	19142	12	0.05%	3	0.01%	51	0.22%	22	0.09%	17	0.07%	5	0.02%	2	<0.01%	4	0.02%	0	0.00%	0	0.00%	4	0.02%	**120**	**0.52%**	**88**
7120/7121	Sep-07	56947	36889	6	0.01%	29	0.05%	128	0.22%	76	0.13%	86	0.15%	20	0.04%	13	0.02%	38	0.07%	36	0.06%	0	0.00%	16	0.03%	**448**	**0.79%**	**249**
7030/7031	Jul-06	768	419	1	0.13%	1	0.13%	0	0.00%	4	0.52%	6	0.78%	0	0.00%	1	0.13%	2	0.26%	0	0.00%	0	0.00%	0	0.00%	**15**	**1.95%**	**3**
7122	Sep-07	10929	7688	2	0.02%	4	0.04%	23	0.21%	18	0.16%	18	0.16%	5	0.05%	8	0.07%	11	0.10%	4	0.04%	0	0.00%	4	0.04%	**97**	**0.89%**	**74**
7070/7071	Jul-06	3308	2062	2	0.06%	8	0.24%	6	0.18%	5	0.15%	9	0.27%	2	0.06%	3	0.09%	2	0.06%	2	0.06%	0	0.00%	1	0.03%	**40**	**1.21%**	**15**
7020/7021	Jul-06	14212	7630	9	0.06%	22	0.15%	47	0.33%	57	0.40%	57	0.40%	11	0.08%	10	0.07%	6	0.04%	13	0.09%	2	0.01%	13	0.09%	**247**	**1.74%**	**139**
7022	Jul-06	1387	789	2	0.14%	4	0.29%	6	0.43%	1	0.07%	6	0.43%	0	0.00%	3	0.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**22**	**1.59%**	**13**
7010/7011	Mar-06	2185	1118	1	0.05%	1	0.05%	6	0.27%	3	0.14%	7	0.32%	2	0.09%	10	0.46%	3	0.14%	3	0.14%	0	0.00%	1	0.05%	**37**	**1.69%**	**13**
7040/7041	Mar-06	4013	2089	2	0.05%	14	0.35%	3	0.07%	16	0.40%	30	0.75%	4	0.10%	14	0.35%	5	0.12%	6	0.15%	0	0.00%	0	0.00%	**94**	**2.34%**	**28**
7002	Jun-05	2391	1213	3	0.13%	5	0.21%	9	0.38%	9	0.38%	21	0.88%	0	0.00%	17	0.71%	1	0.04%	1	0.04%	0	0.00%	5	0.21%	**71**	**2.97%**	**35**
7000/7001	Jun-05	34769	17140	18	0.05%	60	0.17%	47	0.14%	132	0.38%	256	0.74%	29	0.08%	223	0.64%	43	0.12%	35	0.10%	2	<0.01%	39	0.11%	**884**	**2.54%**	**358**

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

Malfunction Summary

		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									
Models	Registered US Implants	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	3398	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	22	0.65%	**23**	**0.68%**
7120Q/7121Q	80495	1	<0.01%	2	<0.01%	7	<0.01%	**10**	**0.01%**	6	<0.01%	0	0.00%	2	<0.01%	0	0.00%	4	<0.01%	**12**	**0.01%**	2	<0.01%	27	0.03%	365	0.45%	**416**	**0.52%**
7122Q	23177	0	0.00%	2	<0.01%	0	0.00%	**2**	**<0.01%**	3	0.01%	2	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**7**	**0.03%**	0	0.00%	10	0.04%	87	0.38%	**106**	**0.46%**
7120/7121	56947	1	<0.01%	16	0.03%	4	<0.01%	**21**	**0.04%**	9	0.02%	7	0.01%	6	0.01%	0	0.00%	5	<0.01%	**27**	**0.05%**	1	<0.01%	9	0.02%	233	0.41%	**291**	**0.51%**
7030/7031	768	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	0.13%	**1**	**0.13%**	0	0.00%	0	0.00%	4	0.52%	**5**	**0.65%**
7122	10929	0	0.00%	6	0.05%	2	0.02%	**8**	**0.07%**	10	0.09%	5	0.05%	0	0.00%	1	<0.01%	1	<0.01%	**17**	**0.16%**	0	0.00%	4	0.04%	60	0.55%	**89**	**0.81%**
7070/7071	3308	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	1	0.03%	2	0.06%	1	0.03%	1	0.03%	1	0.03%	**6**	**0.18%**	0	0.00%	0	0.00%	11	0.33%	**18**	**0.54%**
7020/7021	14212	1	<0.01%	1	<0.01%	5	0.04%	**7**	**0.05%**	6	0.04%	2	0.01%	3	0.02%	0	0.00%	6	0.04%	**17**	**0.12%**	0	0.00%	0	0.00%	133	0.94%	**157**	**1.10%**
7022	1387	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**2**	**0.14%**	0	0.00%	0	0.00%	14	1.01%	**17**	**1.23%**
7010/7011	2185	0	0.00%	1	0.05%	0	0.00%	**1**	**0.05%**	4	0.18%	6	0.27%	0	0.00%	1	0.05%	3	0.14%	**14**	**0.64%**	0	0.00%	0	0.00%	7	0.32%	**22**	**1.01%**
7040/7041	4013	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	10	0.25%	7	0.17%	0	0.00%	1	0.02%	4	0.10%	**22**	**0.55%**	0	0.00%	0	0.00%	14	0.35%	**38**	**0.95%**
7002	2391	0	0.00%	1	0.04%	2	0.08%	**3**	**0.13%**	18	0.75%	3	0.13%	0	0.00%	3	0.13%	7	0.29%	**31**	**1.30%**	0	0.00%	0	0.00%	18	0.75%	**52**	**2.17%**
7000/7001	34769	2	<0.01%	5	0.01%	7	0.02%	**14**	**0.04%**	151	0.43%	50	0.14%	9	0.03%	17	0.05%	36	0.10%	**263**	**0.76%**	1	<0.01%	0	0.00%	204	0.59%	**482**	**1.39%**
1560/1561	958	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	2	0.21%	1	0.10%	0	0.00%	1	0.10%	0	0.00%	**4**	**0.42%**	0	0.00%	0	0.00%	1	0.10%	**5**	**0.52%**
1590/1591	9630	1	0.01%	1	0.01%	4	0.04%	**6**	**0.06%**	24	0.25%	19	0.20%	0	0.00%	13	0.13%	21	0.22%	**77**	**0.80%**	0	0.00%	1	0.01%	35	0.36%	**119**	**1.24%**
1582	3103	0	0.00%	0	0.00%	3	0.10%	**3**	**0.10%**	39	1.26%	10	0.32%	2	0.06%	28	0.90%	24	0.77%	**103**	**3.32%**	0	0.00%	0	0.00%	25	0.81%	**131**	**4.22%**
1570/1571	10186	2	0.02%	2	0.02%	0	0.00%	**4**	**0.04%**	52	0.51%	10	0.10%	1	<0.01%	23	0.23%	22	0.22%	**108**	**1.06%**	0	0.00%	0	0.00%	32	0.31%	**144**	**1.41%**
1580/1581	68317	2	<0.01%	8	0.01%	9	0.01%	**19**	**0.03%**	375	0.55%	146	0.21%	14	0.02%	186	0.27%	171	0.25%	**889**	**1.30%**	3	<0.01%	0	0.00%	359	0.53%	**1270**	**1.86%**

Definitions of malfunction categories can be found on pages 10-11.

Worldwide Malfunction Summary (Durata)

		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									
Models	Worldwide Sales	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	11161	0	0.00%	1	0.01%	4	0.04%	**5**	**0.04%**	1	0.01%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	**4**	**0.04%**	7	0.06%	0	0.00%	40	0.36%	**56**	**0.50%**
7120Q/7121Q	129031	2	<0.01%	5	<0.01%	9	0.01%	**16**	**0.01%**	10	0.01%	0	0.00%	8	0.01%	0	0.00%	5	<0.01%	**23**	**0.02%**	3	<0.01%	40	0.03%	621	0.48%	**703**	**0.54%**
7122Q	59602	1	<0.01%	3	0.01%	1	<0.01%	**5**	**0.01%**	16	0.03%	3	0.01%	6	0.01%	0	0.00%	1	<0.01%	**26**	**0.04%**	1	<0.01%	19	0.03%	294	0.49%	**345**	**0.58%**
7120/7121	120054	3	<0.01%	61	0.05%	14	0.01%	**78**	**0.06%**	31	0.03%	8	0.01%	9	0.01%	0	0.00%	10	0.01%	**58**	**0.05%**	2	<0.01%	35	0.03%	474	0.39%	**647**	**0.54%**
7122	44707	0	0.00%	63	0.14%	5	0.01%	**68**	**0.15%**	28	0.06%	8	0.02%	5	0.01%	0	0.00%	4	0.01%	**45**	**0.10%**	1	<0.01%	11	0.02%	231	0.52%	**356**	**0.80%**

Definitions of malfunction categories can be found on pages 10-11.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of 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	113	2865	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	0.88%	0	0.00%	0	0.00%	0	0.00%	1	0.88%
7120Q/7121Q	4045	101136	4	0.10%	0	0.00%	1	0.02%	3	0.07%	0	0.00%	10	0.25%	2	0.05%	2	0.05%	0	0.00%	31	0.77%	1	0.02%	0	0.00%	0	0.00%	54	1.33%
7122Q	1168	23129	1	0.09%	0	0.00%	0	0.00%	1	0.09%	0	0.00%	1	0.09%	0	0.00%	0	0.00%	0	0.00%	5	0.43%	0	0.00%	2	0.17%	0	0.00%	10	0.86%
7120/7121	3560	140167	0	0.00%	1	0.03%	0	0.00%	8	0.22%	0	0.00%	9	0.25%	1	0.03%	2	0.06%	4	0.11%	19	0.53%	3	0.08%	0	0.00%	0	0.00%	47	1.32%
7122	427	14815	0	0.00%	2	0.47%	0	0.00%	0	0.00%	0	0.00%	1	0.23%	0	0.00%	0	0.00%	0	0.00%	4	0.94%	1	0.23%	0	0.00%	0	0.00%	8	1.87%
7070/7071	287	11420	0	0.00%	0	0.00%	1	0.35%	1	0.35%	0	0.00%	1	0.35%	0	0.00%	0	0.00%	0	0.00%	1	0.35%	0	0.00%	0	0.00%	0	0.00%	4	1.39%
7020/7021	1471	67198	0	0.00%	3	0.20%	1	0.07%	4	0.27%	0	0.00%	8	0.54%	1	0.07%	0	0.00%	2	0.14%	10	0.68%	1	0.07%	0	0.00%	1	0.07%	31	2.11%
7000/7001	180	6571	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.56%	1	0.56%	0	0.00%	0	0.00%	0	0.00%	2	1.11%
1580/1581	564	19786	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	0.71%	2	0.35%	1	0.18%	0	0.00%	0	0.00%	7	1.24%

Malfunctions

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	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	113	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	0.88%	**1**	**0.88%**
7120Q/7121Q	4045	0	0.00%	1	0.02%	0	0.00%	**1**	**0.02%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	1	0.02%	32	0.79%	**34**	**0.84%**
7122Q	1168	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.09%**	0	0.00%	0	0.00%	8	0.68%	**9**	**0.77%**
7120/7121	3560	0	0.00%	1	0.03%	0	0.00%	**1**	**0.03%**	2	0.06%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.08%**	0	0.00%	1	0.03%	19	0.53%	**24**	**0.67%**
7122	427	0	0.00%	0	0.00%	1	0.23%	**1**	**0.23%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	3	0.70%	**4**	**0.94%**
7070/7071	287	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	1471	0	0.00%	3	0.20%	0	0.00%	**3**	**0.20%**	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	**1**	**0.07%**	0	0.00%	0	0.00%	13	0.88%	**17**	**1.16%**
7000/7001	180	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	564	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.18%	2	0.35%	0	0.00%	5	0.89%	0	0.00%	**8**	**1.42%**	0	0.00%	0	0.00%	4	0.71%	**12**	**2.13%**

Definitions of malfunction categories can be found on pages 10-11.
A list of complications can be found on page 15.

Pacemakers

Dual-Chamber

St. Jude Medical

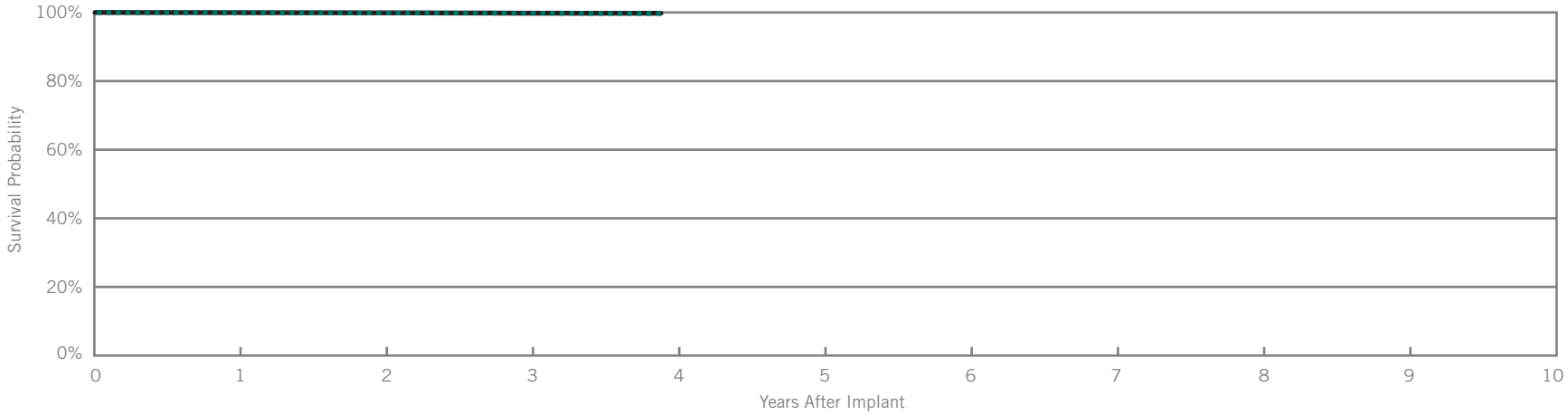
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	183,177
Estimated Active US Implants	146,418
Estimated Longevity	8 Years
Normal Battery Depletion	15
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	11	<0.01%	9	<0.01%
Electrical Interconnect	4	<0.01%	20	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	8	<0.01%
Possible Early Battery Depletion	4	<0.01%	8	<0.01%
Other	4	<0.01%	8	<0.01%
Total	**23**	**0.01%**	**53**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.93%	99.86%	99.75%	99.70%						
± 1 standard error	0.01%	0.01%	0.02%	0.03%						
Sample Size	149320	89950	44180	1030						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.94%	99.88%	99.79%	99.77%						
± 1 standard error	0.01%	0.01%	0.02%	0.02%						

Actively Monitored Study Data

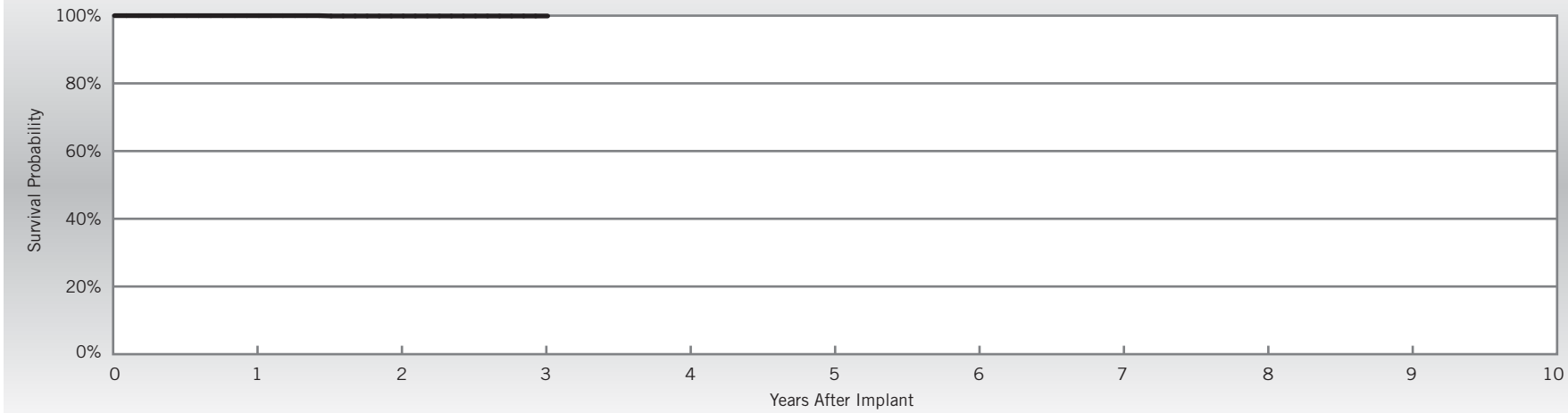
Accent™ DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,769
Cumulative Months of Follow-up	33,617
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%	0	0.00%
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%**	**1**	**0.06%**



Year	1	2	3	at 37 months						
Survival Probability	100.00%	99.90%	99.90%	99.90%						
± 1 standard error	0.00%	0.10%	0.10%	0.10%						
Sample Size	1540	980	360	60						

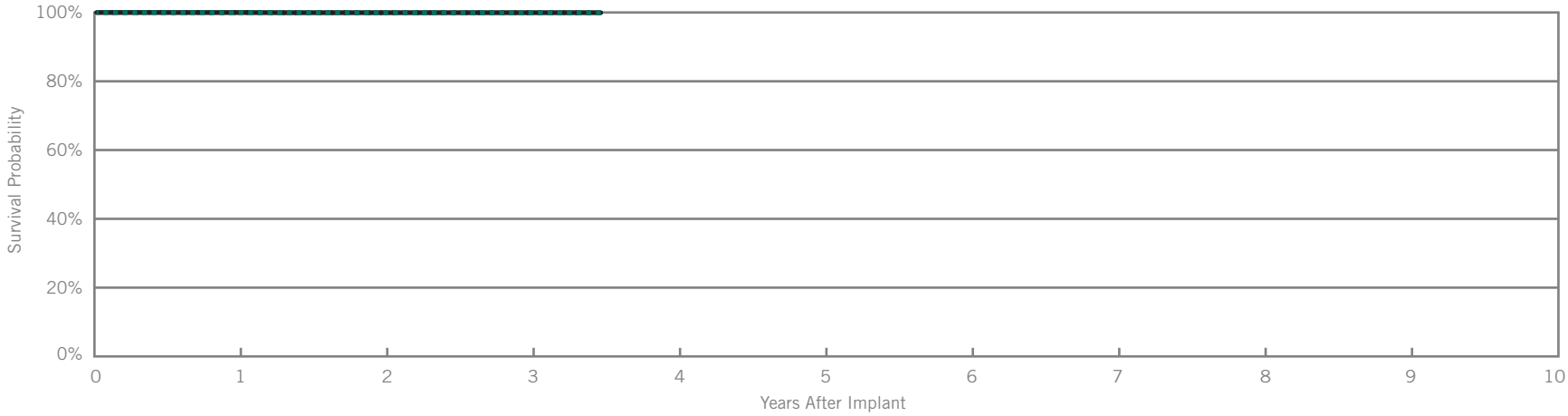
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	36,961
Estimated Active US Implants	30,278
Estimated Longevity	9.2 Years
Normal Battery Depletion	2
Number of US Advisories (see pgs. 272-284)	One

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%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**<0.01%**	**4**	**0.01%**



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.98%	99.94%	99.91%	99.91%						
± 1 standard error	0.01%	0.02%	0.02%	0.02%						
Sample Size	29750	16630	6340	270						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.98%	99.94%	99.94%	99.94%						
± 1 standard error	0.01%	0.02%	0.02%	0.02%						

Actively Monitored Study Data

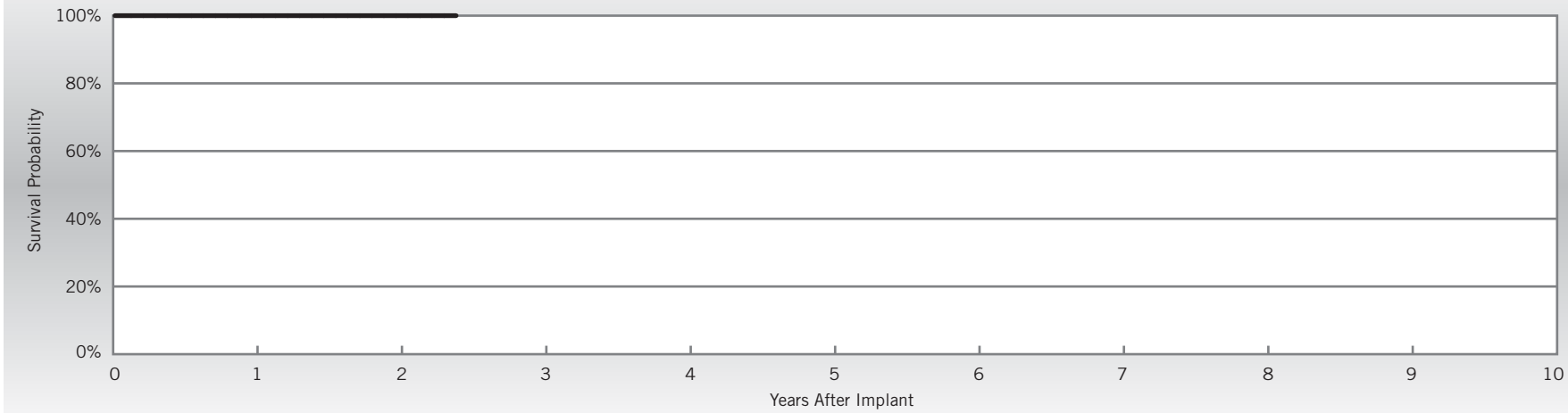
Accent™ DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	226
Cumulative Months of Follow-up	4,859
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	at 29 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	210	140	60							

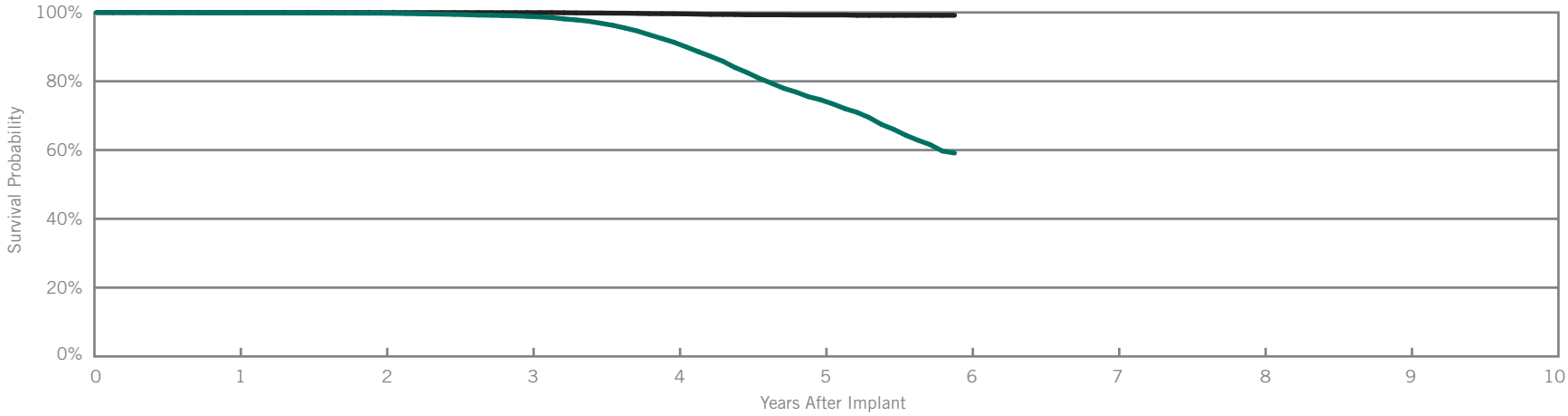
Customer Reported Performance Data

Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	46,643
Estimated Active US Implants	29,442
Estimated Longevity	6.5 Years
Normal Battery Depletion	1,109
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	33	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%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	2	<0.01%
Total	**2**	**<0.01%**	**37**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.86%	99.79%	98.87%	91.34%	74.64%	59.13%				
± 1 standard error	0.02%	0.02%	0.06%	0.22%	0.47%	1.07%				
Sample Size	41000	30740	22160	14310	6720	270				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.97%	99.96%	99.95%	99.63%	99.27%	99.17%				
± 1 standard error	0.01%	0.01%	0.01%	0.05%	0.09%	0.11%				

Actively Monitored Study Data

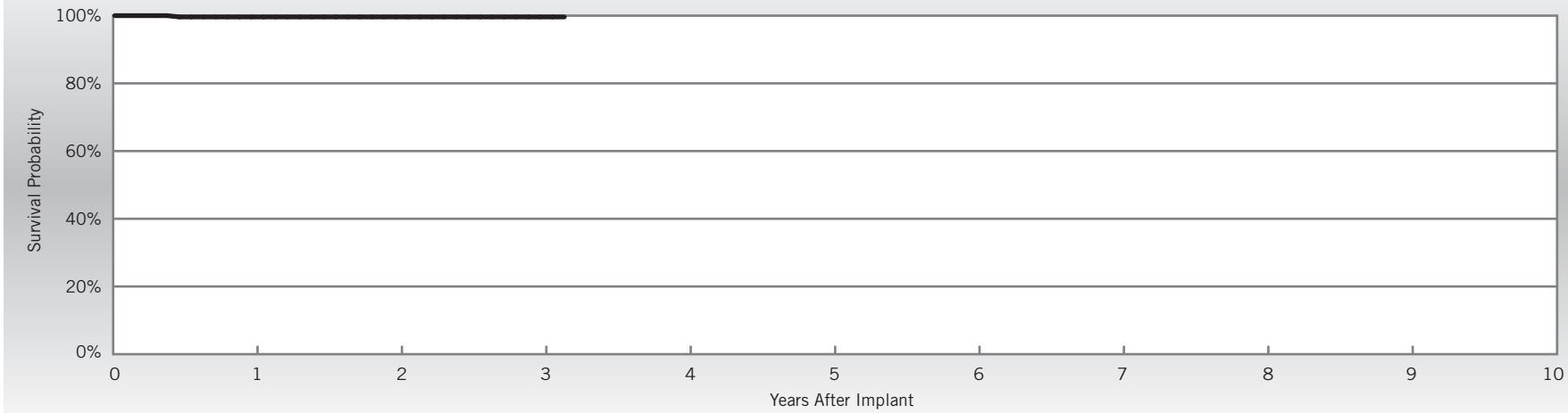
Zephyr™ DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	283
Cumulative Months of Follow-up	7,003
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 38 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	110	50						

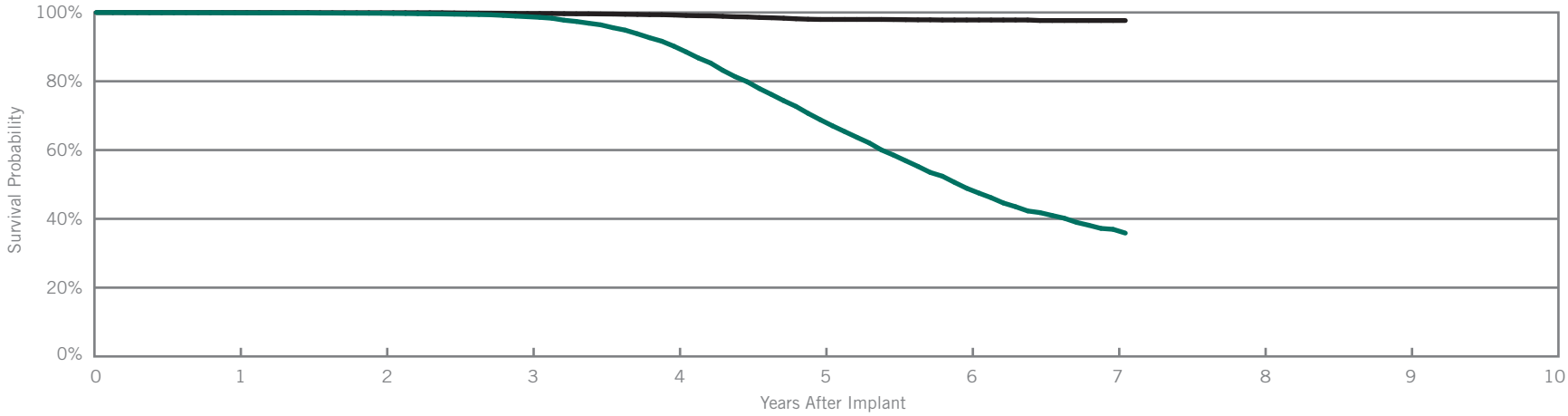
Customer Reported Performance Data

Victory™ DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,223
Estimated Active US Implants	7,712
Estimated Longevity	6.5 Years
Normal Battery Depletion	2,449
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	89	0.34%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	17	0.06%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**107**	**0.41%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.89%	99.77%	98.77%	90.18%	68.80%	48.88%	36.95%	35.86%		
± 1 standard error	0.02%	0.03%	0.07%	0.22%	0.40%	0.50%	0.71%	0.73%		
Sample Size	24460	21350	18600	15070	10200	5250	1630	220		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.98%	99.93%	99.70%	99.26%	97.97%	97.81%	97.66%	97.66%		
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.13%	0.14%	0.18%	0.18%		

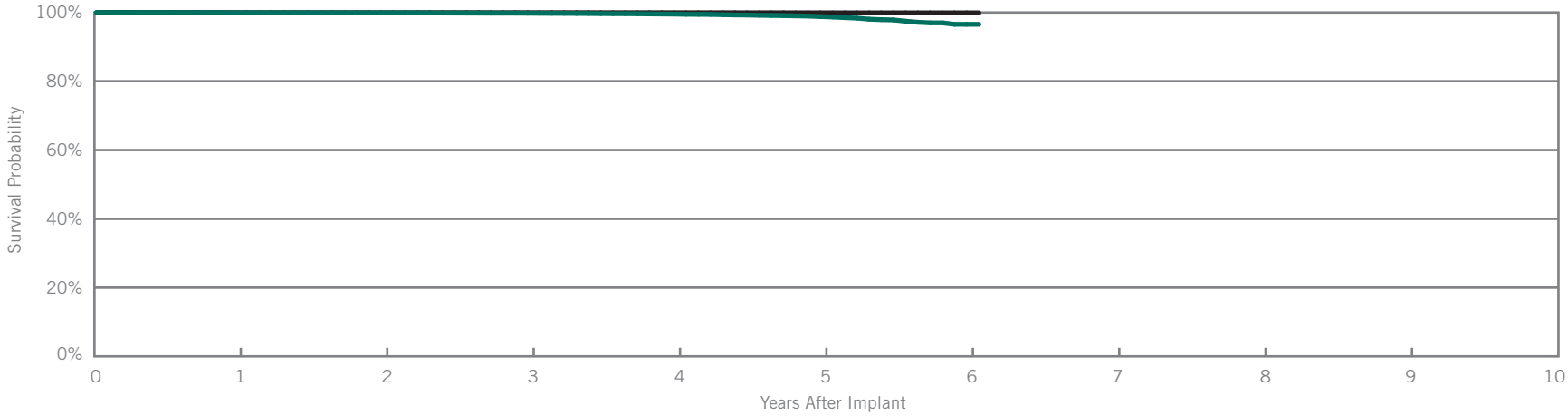
Customer Reported Performance Data

Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	108,535
Estimated Active US Implants	67,428
Estimated Longevity	11.7 Years
Normal Battery Depletion	231
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	16	0.01%
Electrical Interconnect	3	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	2	<0.01%
Other	1	<0.01%	4	<0.01%
Total	**5**	**<0.01%**	**27**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.92%	99.88%	99.78%	99.52%	98.81%	96.56%	96.56%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.05%	0.26%	0.26%			
Sample Size	100320	85070	71360	54350	29440	7610	340			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.96%	99.95%	99.94%	99.93%	99.90%	99.89%	99.89%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%			

Actively Monitored Study Data

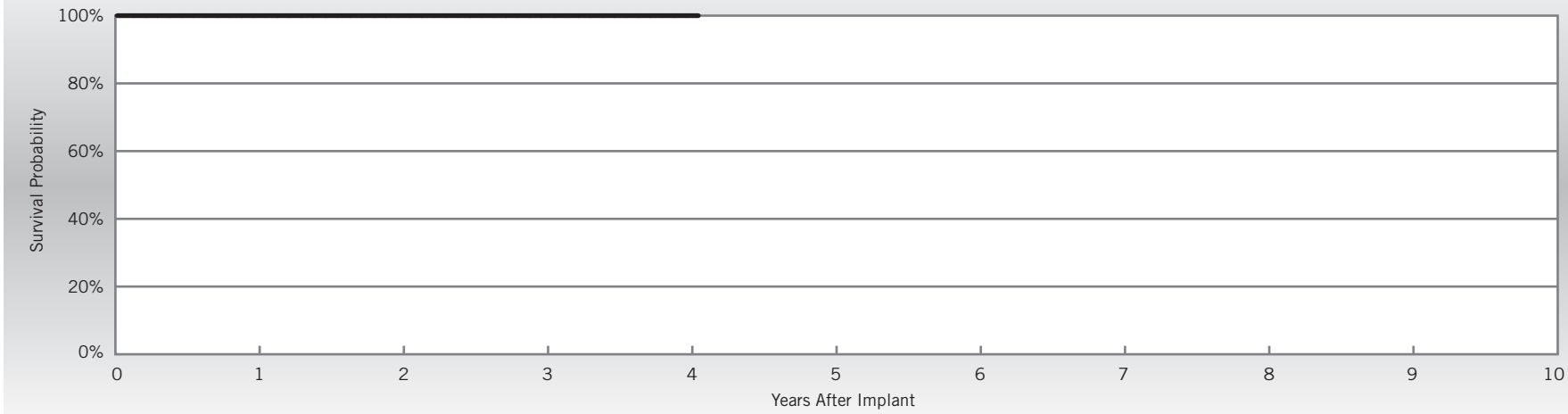
Zephyr™ XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,518
Cumulative Months of Follow-up	47,084
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.07%**



Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%					
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%					
Sample Size	1450	1270	900	340	50					

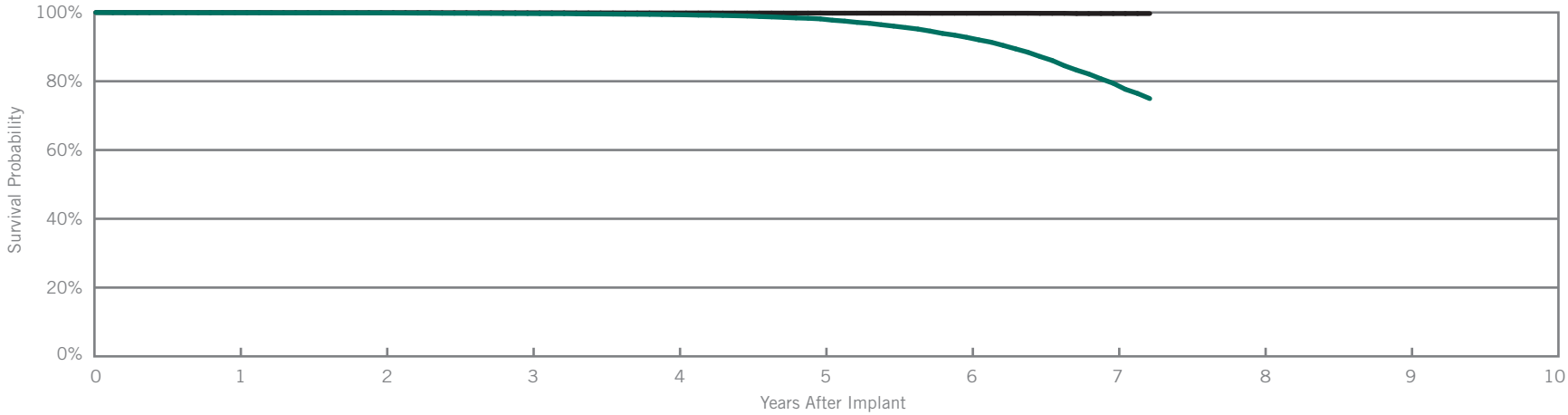
Customer Reported Performance Data

Victory™ XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,522
Estimated Active US Implants	31,215
Estimated Longevity	11.7 Years
Normal Battery Depletion	1,051
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	25	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	4	<0.01%
Other	1	<0.01%	4	<0.01%
Total	**3**	**<0.01%**	**38**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.92%	99.86%	99.69%	99.36%	98.13%	92.76%	79.42%	74.96%		
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.07%	0.16%	0.47%	0.77%		
Sample Size	58760	51840	45620	39010	31150	20640	7790	360		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.97%	99.95%	99.91%	99.85%	99.82%	99.78%	99.69%	99.69%		
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%	0.05%	0.05%		

Actively Monitored Study Data

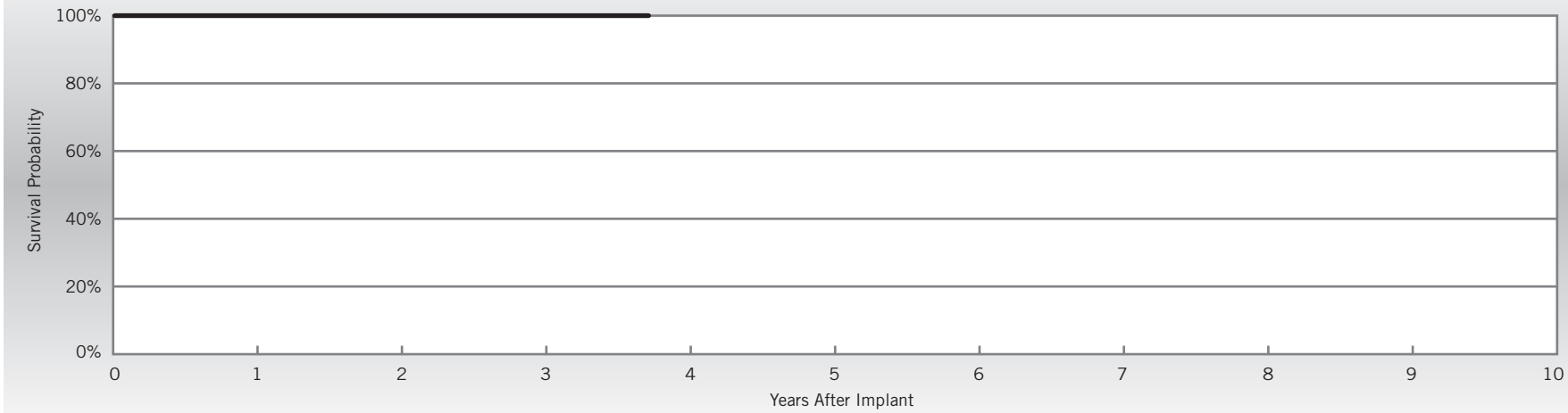
Victory™ XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	333
Cumulative Months of Follow-up	10,658
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

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



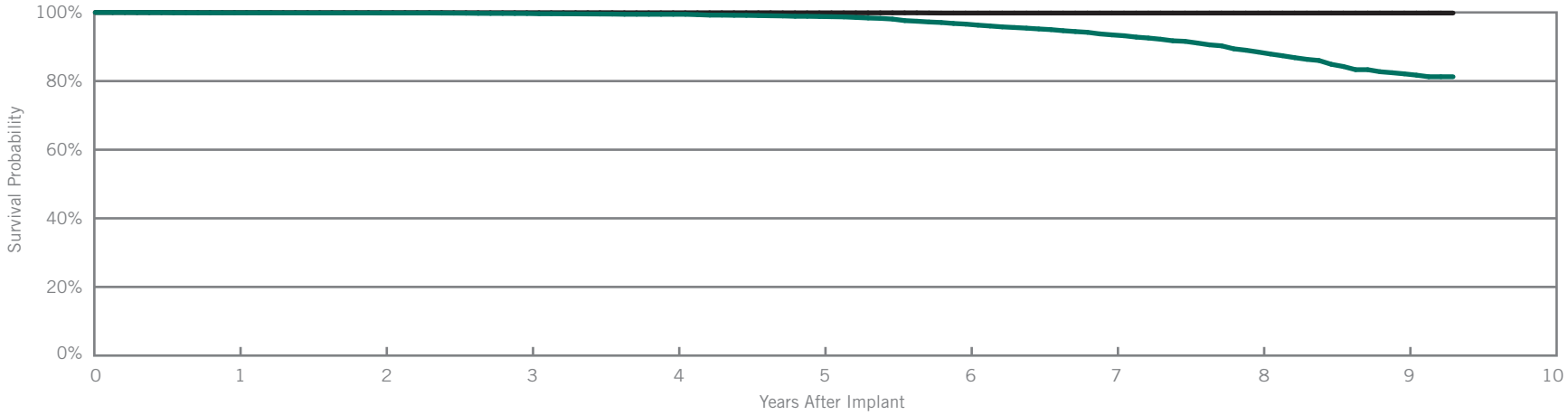
Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	280	210	50						

Verity ADx™ XL DR **Model 5356**
Verity ADx™ XL DR M/S **Model 5357M/S**
Verity ADx™ XL DC **Model 5256**

US Regulatory Approval	May 2003
Registered US Implants	17,124
Estimated Active US Implants	6,803
Estimated Longevity	6.9 Years
Normal Battery Depletion	269
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%	6	0.04%
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%	0	0.00%
Total	**1**	**<0.01%**	**8**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.89%	99.83%	99.69%	99.46%	98.82%	96.60%	93.46%	88.46%	82.10%	81.26%
± 1 standard error	0.03%	0.03%	0.05%	0.07%	0.10%	0.20%	0.31%	0.48%	0.81%	0.94%
Sample Size	15960	13960	12240	10530	8900	7040	4900	2880	1200	260

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.96%	99.95%	99.93%	99.91%	99.89%	99.83%	99.83%	99.83%	99.83%	99.83%
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%	0.04%

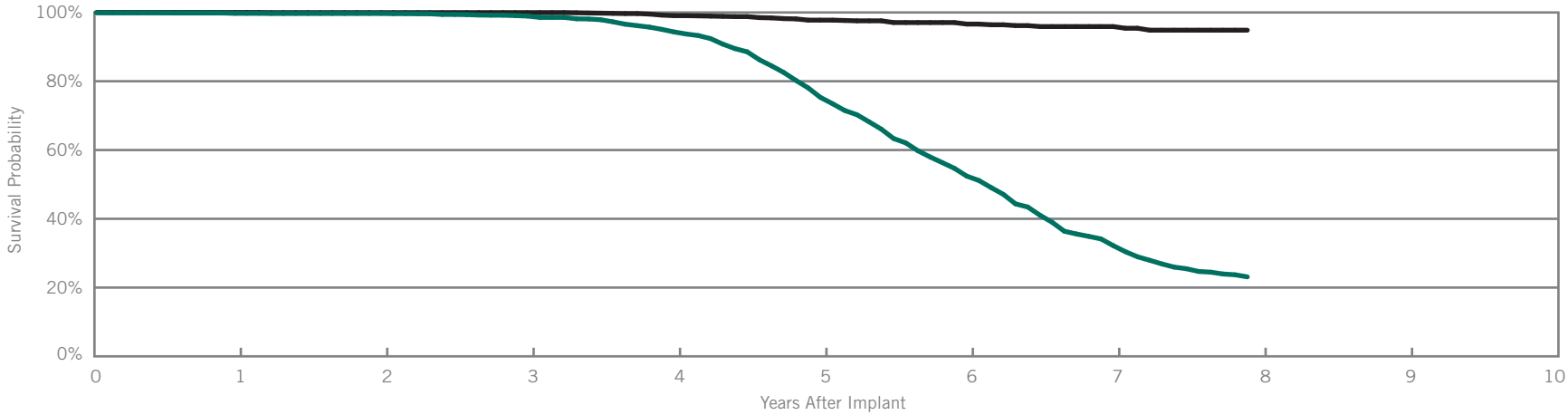
Integrity™ ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,829
Estimated Active US Implants	588
Estimated Longevity	3.8 Years
Normal Battery Depletion	662
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%	39	0.67%
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%	1	0.02%
Total	**0**	**0.00%**	**40**	**0.69%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.74%	99.70%	98.95%	94.34%	75.31%	52.41%	32.21%	23.11%		
± 1 standard error	0.05%	0.07%	0.14%	0.35%	0.75%	0.98%	1.08%	1.10%		
Sample Size	5420	4710	4140	3520	2610	1560	740	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	100.00%	99.96%	99.96%	99.07%	97.77%	96.62%	95.90%	94.85%		
± 1 standard error	0.00%	0.03%	0.03%	0.15%	0.28%	0.34%	0.49%	0.71%		

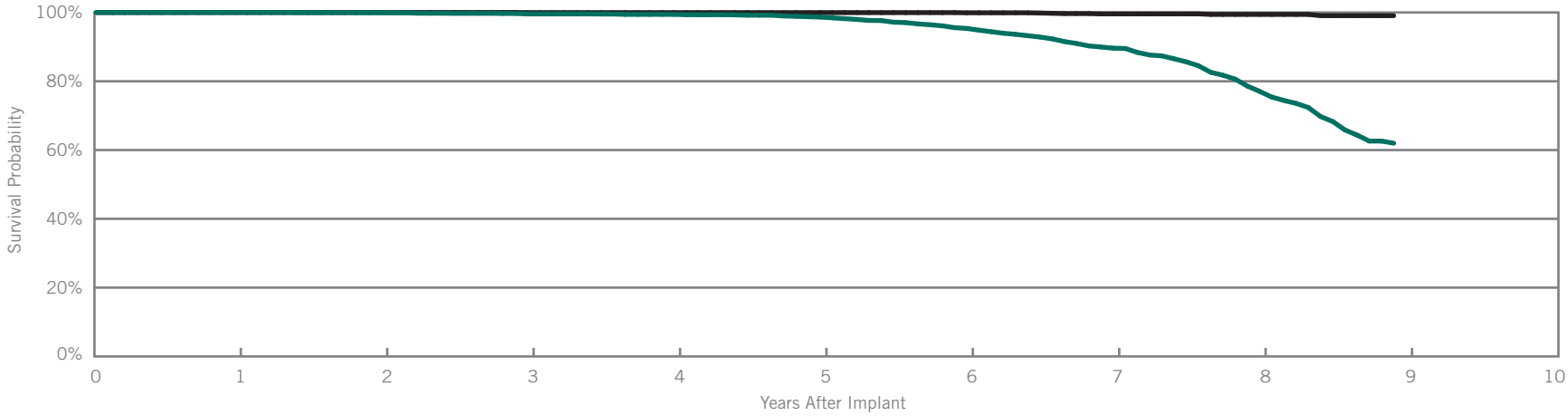
Customer Reported Performance Data

Integrity™ ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,038
Estimated Active US Implants	3,165
Estimated Longevity	6.9 Years
Normal Battery Depletion	274
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	7	0.09%
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%**	**8**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	100.00%	99.94%	99.57%	99.44%	98.65%	95.36%	89.62%	77.07%	61.99%
± 1 standard error	0.00%	0.03%	0.07%	0.10%	0.15%	0.31%	0.52%	0.92%	1.54%
Sample Size	7600	6780	6030	5350	4740	3930	2760	1480	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	100.00%	100.00%	99.96%	99.96%	99.96%	99.91%	99.59%	99.43%	99.07%
± 1 standard error	0.00%	0.00%	0.02%	0.02%	0.02%	0.02%	0.12%	0.17%	0.30%

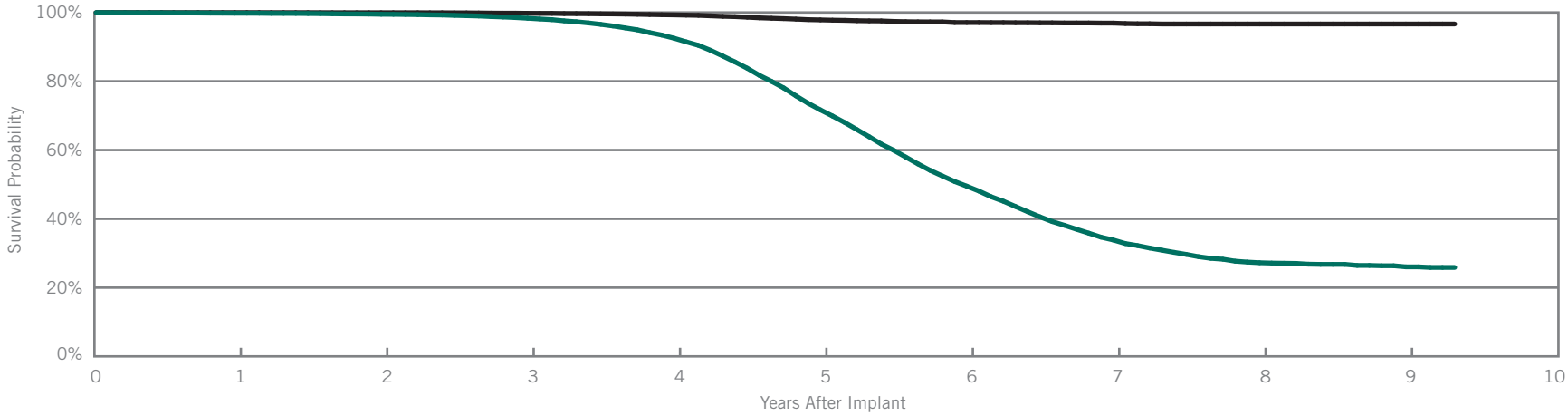
Identity ADx™ DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	54,013
Estimated Active US Implants	6,659
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,005
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	<0.01%	262	0.49%
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%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	11	0.02%
Other	0	0.00%	3	<0.01%
Total	**5**	**<0.01%**	**281**	**0.52%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.78%	99.47%	98.32%	92.52%	71.69%	49.50%	33.86%	27.24%	26.04%	25.87%
± 1 standard error	0.02%	0.03%	0.06%	0.13%	0.26%	0.33%	0.36%	0.38%	0.41%	0.44%
Sample Size	50540	44490	39150	32620	23070	12940	6230	2620	880	230

Excluding Normal Battery Depletion

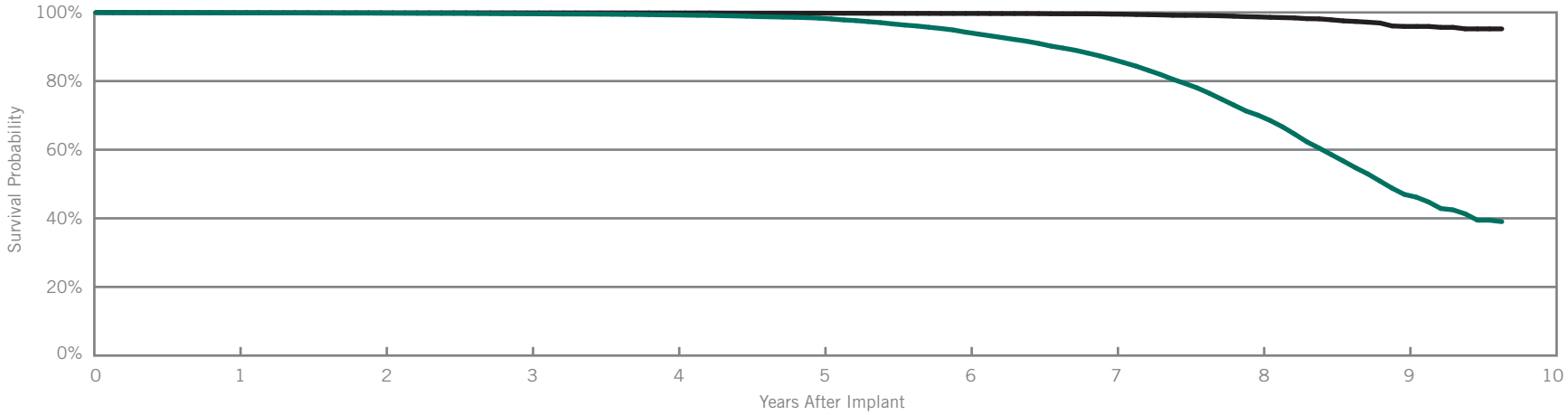
Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.96%	99.93%	99.75%	99.29%	97.84%	97.07%	96.91%	96.65%	96.65%	96.65%
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.09%	0.12%	0.13%	0.16%	0.16%	0.16%

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

US Regulatory Approval	March 2003
Registered US Implants	67,205
Estimated Active US Implants	25,135
Estimated Longevity	6.9 Years
Normal Battery Depletion	2,871
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	126	0.19%
Electrical Interconnect	0	0.00%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	7	0.01%
Possible Early Battery Depletion	0	0.00%	6	<0.01%
Other	0	0.00%	3	<0.01%
Total	**2**	**<0.01%**	**144**	**0.21%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.88%	99.78%	99.60%	99.27%	98.34%	94.25%	86.38%	70.05%	46.97%	39.03%
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.06%	0.12%	0.21%	0.35%	0.59%	0.89%
Sample Size	63320	56170	49550	42810	35940	28910	21350	12080	4040	210

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.92%	99.90%	99.87%	99.85%	99.79%	99.70%	99.51%	98.70%	95.92%	95.21%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.09%	0.33%	0.50%

Actively Monitored Study Data

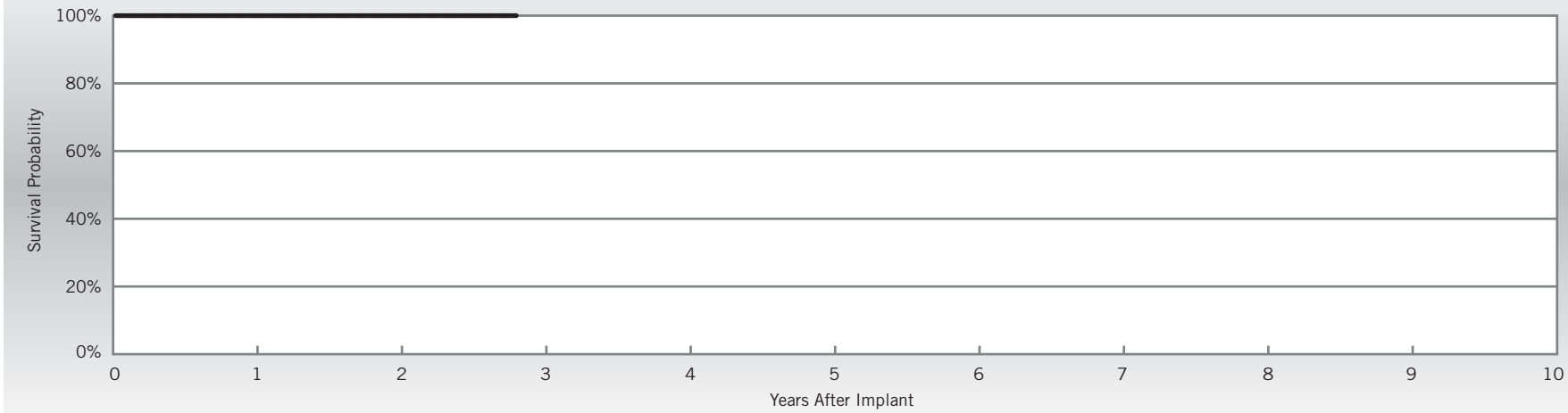
Identity ADx™ XL DR

Model 5386

US Regulatory Approval	March 2003
Number of Devices Enrolled in Study	102
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							

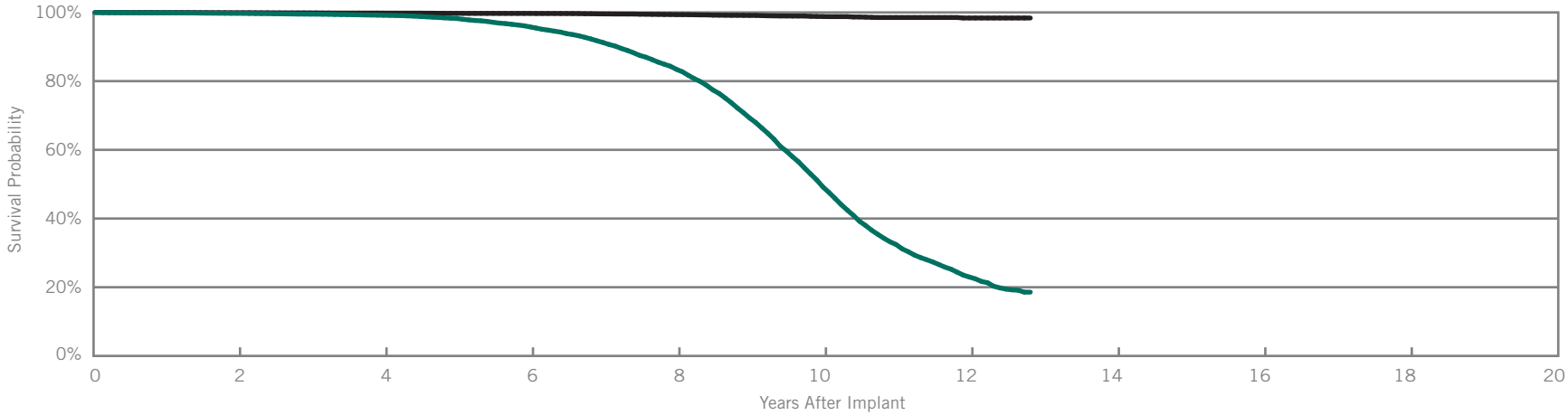
Integrity™ AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,429
Estimated Active US Implants	3,615
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,474
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%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**6**	**0.01%**	**98**	**0.21%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	At 154 months			
Survival Probability	99.74%	99.18%	95.80%	83.44%	49.21%	22.97%	18.57%			
± 1 standard error	0.02%	0.05%	0.11%	0.24%	0.41%	0.42%	0.50%			
Sample Size	40520	33460	26160	17380	8000	2170	230			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	At 154 months			
Survival Probability	99.92%	99.81%	99.71%	99.36%	98.81%	98.38%	98.38%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.09%	0.16%	0.16%			

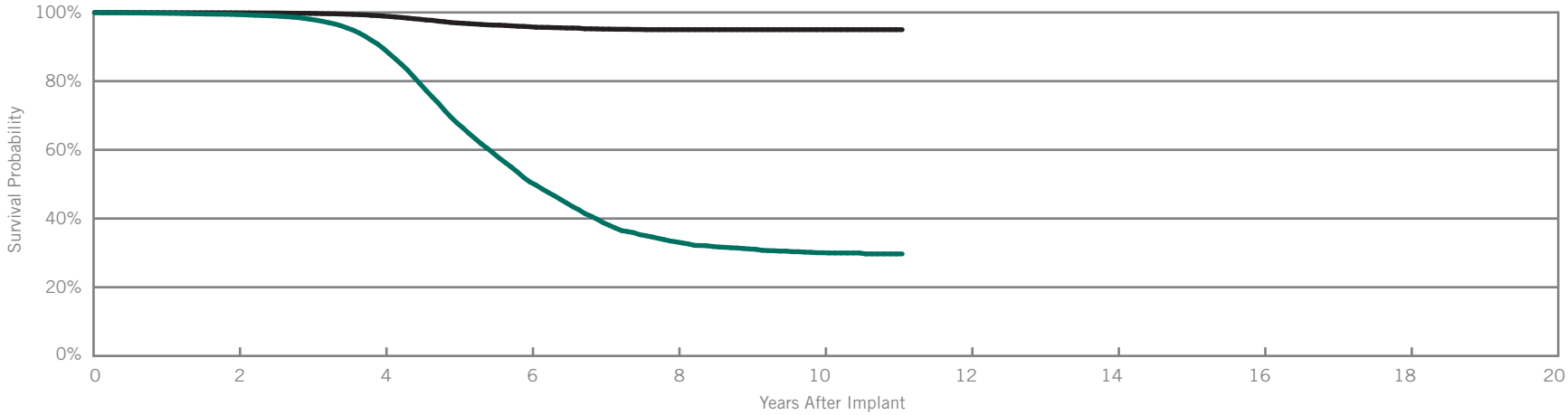
Customer Reported Performance Data

Identity™

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,352
Estimated Active US Implants	3,200
Estimated Longevity	3.8 Years
Normal Battery Depletion	6,006
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	<0.01%	398	0.68%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	12	0.02%
Other	0	0.00%	11	0.02%
Total	**5**	**<0.01%**	**428**	**0.73%**



Including Normal Battery Depletion

Year	2	4	6	8	10	At 133 months				
Survival Probability	99.39%	89.47%	50.64%	33.20%	30.04%	29.70%				
± 1 standard error	0.03%	0.15%	0.32%	0.38%	0.41%	0.43%				
Sample Size	48130	35150	12520	3450	1380	210				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	At 133 months				
Survival Probability	99.88%	98.94%	95.83%	94.99%	94.99%	94.99%				
± 1 standard error	0.01%	0.05%	0.14%	0.19%	0.19%	0.19%				

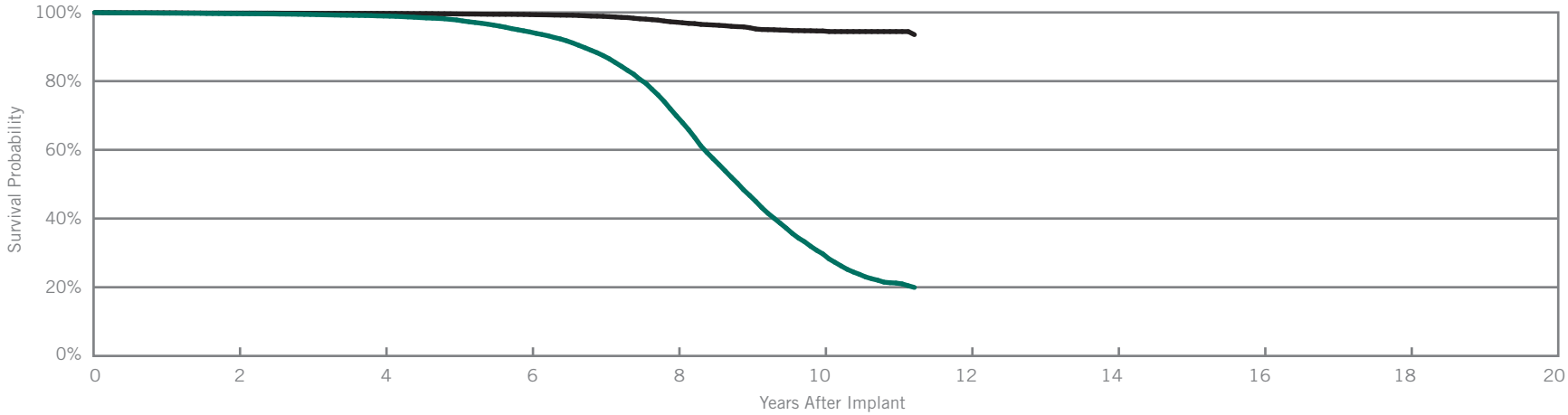
Identity™ XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,439
Estimated Active US Implants	9,243
Estimated Longevity	6.9 Years
Normal Battery Depletion	4,988
Number of US Advisories (see pgs. 272-284)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	309	0.60%
Electrical Interconnect	4	<0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	<0.01%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	5	<0.01%
Other	0	0.00%	7	0.01%
Total	**8**	**0.02%**	**328**	**0.64%**



Including Normal Battery Depletion

Year	2	4	6	8	10	At 135 months				
Survival Probability	99.65%	98.96%	94.31%	69.91%	29.70%	19.94%				
± 1 standard error	0.03%	0.05%	0.13%	0.31%	0.39%	0.47%				
Sample Size	44080	35620	27020	16090	4750	260				

Excluding Normal Battery Depletion

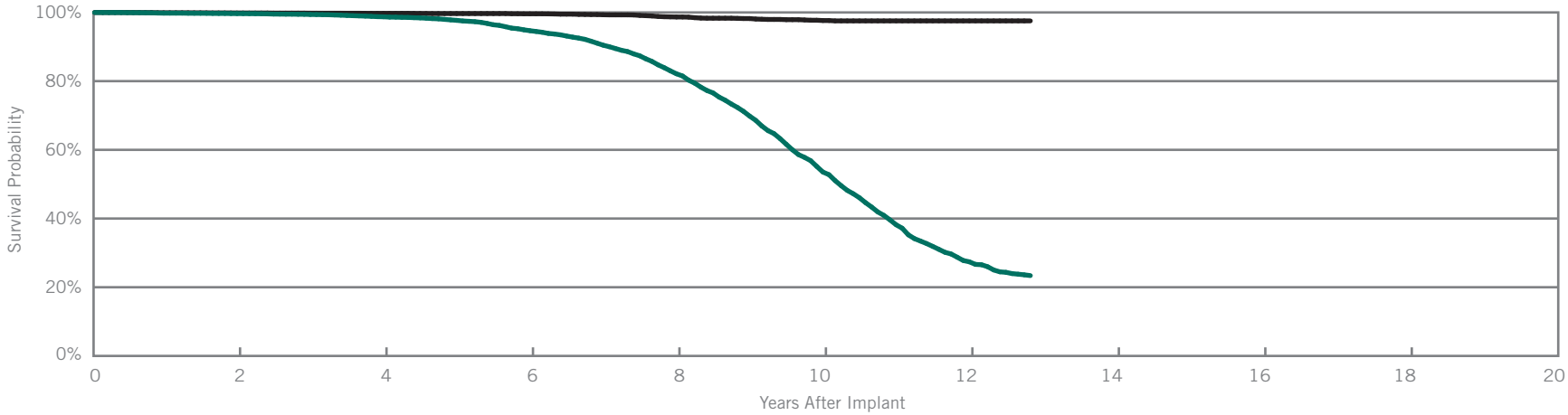
Year	2	4	6	8	10	At 135 months				
Survival Probability	99.81%	99.71%	99.37%	97.16%	94.61%	93.53%				
± 1 standard error	0.02%	0.03%	0.04%	0.12%	0.22%	0.23%				

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,822
Estimated Active US Implants	1,213
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,495
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%	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	**3**	**0.01%**	**69**	**0.32%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	At 154 months			
Survival Probability	99.66%	98.73%	94.68%	82.14%	53.54%	27.40%	23.39%			
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.67%	0.77%	0.81%			
Sample Size	17830	14040	10250	6250	2840	860	230			

Excluding Normal Battery Depletion

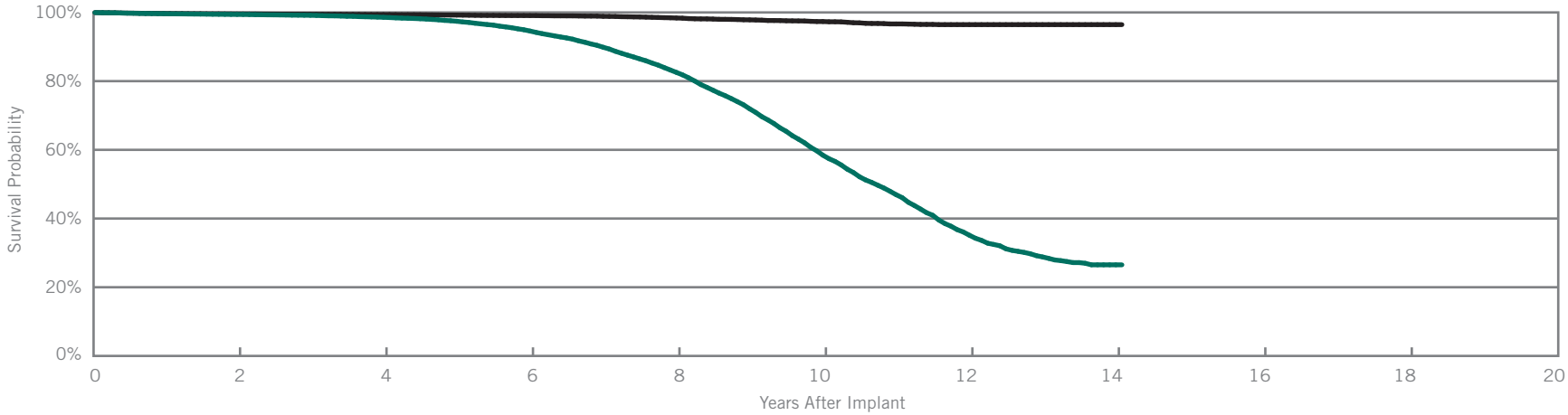
Year	2	4	6	8	10	12	At 154 months			
Survival Probability	99.85%	99.74%	99.60%	98.67%	97.64%	97.54%	97.54%			
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.21%	0.23%	0.23%			

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

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,696
Estimated Active US Implants	3,411
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,477
Number of US Advisories (see pgs. 272-284)	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%	3	<0.01%
Total	**15**	**0.02%**	**313**	**0.48%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	14	At 169 months		
Survival Probability	99.42%	98.58%	94.59%	82.54%	58.44%	35.14%	26.52%	26.52%		
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.36%	0.45%	0.50%	0.50%		
Sample Size	55280	44810	33780	21020	9580	3540	810	200		

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	14	At 169 months		
Survival Probability	99.56%	99.36%	99.08%	98.38%	97.35%	96.45%	96.45%	96.45%		
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	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
PM2210	Accent™ DR RF	99.93%	99.86%	99.75%							
PM2110	Accent™ DR	99.98%	99.94%	99.91%							
5820	Zephyr™ DR	99.86%	99.79%	98.87%	91.34%	74.64%					
5810	Victory™ DR	99.89%	99.77%	98.77%	90.18%	68.80%	48.88%	36.95%			
5826	Zephyr™ XL DR	99.92%	99.88%	99.78%	99.52%	98.81%	96.56%				
5816	Victory™ XL DR	99.92%	99.86%	99.69%	99.36%	98.13%	92.76%	79.42%			
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.89%	99.83%	99.69%	99.46%	98.82%	96.60%	93.46%	88.46%	82.10%	
5360	Integrity™ ADx DR	99.74%	99.70%	98.95%	94.34%	75.31%	52.41%	32.21%			
5366	Integrity™ ADx XL DR	100.00%	99.94%	99.57%	99.44%	98.65%	95.36%	89.62%	77.07%		
5380	Identity ADx™ DR	99.78%	99.47%	98.32%	92.52%	71.69%	49.50%	33.86%	27.24%	26.04%	
5386/5286	Identity ADx™ XL DR/DC	99.88%	99.78%	99.60%	99.27%	98.34%	94.25%	86.38%	70.05%	46.97%	
5342/5346	Integrity™ AFx DR	99.87%	99.74%	99.50%	99.18%	98.24%	95.80%	91.23%	83.44%	69.26%	49.21%
5370	Identity™	99.77%	99.39%	98.01%	89.47%	67.90%	50.64%	38.80%	33.20%	31.13%	30.04%
5376	Identity™ XL	99.79%	99.65%	99.41%	98.96%	97.81%	94.31%	87.43%	69.91%	46.72%	29.70%
5326/5226	Entity™ DR/DC	99.79%	99.66%	99.40%	98.73%	97.70%	94.68%	90.46%	82.14%	69.82%	53.54%
5330/5331/5230	Affinity™ DR/DC	99.64%	99.42%	99.16%	98.58%	97.43%	94.59%	89.86%	82.54%	71.94%	58.44%

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
PM2210	Accent™ DR RF	99.94%	99.88%	99.79%							
PM2110	Accent™ DR	99.98%	99.94%	99.94%							
5820	Zephyr™ DR	99.97%	99.96%	99.95%	99.63%	99.27%					
5810	Victory™ DR	99.98%	99.93%	99.70%	99.26%	97.97%	97.81%	97.66%			
5826	Zephyr™ XL DR	99.96%	99.95%	99.94%	99.93%	99.90%	99.89%				
5816	Victory™ XL DR	99.97%	99.95%	99.91%	99.85%	99.82%	99.78%	99.69%			
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	99.96%	99.95%	99.93%	99.91%	99.89%	99.83%	99.83%	99.83%	99.83%	
5360	Integrity™ ADx DR	100.00%	99.96%	99.96%	99.07%	97.77%	96.62%	95.90%			
5366	Integrity™ ADx XL DR	100.00%	100.00%	99.96%	99.96%	99.96%	99.91%	99.59%	99.43%		
5380	Identity ADx™ DR	99.96%	99.93%	99.75%	99.29%	97.84%	97.07%	96.91%	96.65%	96.65%	
5386/5286	Identity ADx™ XL DR/DC	99.92%	99.90%	99.87%	99.85%	99.79%	99.70%	99.51%	98.70%	95.92%	
5342/5346	Integrity™ AFx DR	99.96%	99.92%	99.86%	99.81%	99.73%	99.71%	99.57%	99.36%	99.13%	98.81%
5370	Identity™	99.93%	99.88%	99.71%	98.94%	96.94%	95.83%	95.15%	94.99%	94.99%	94.99%
5376	Identity™ XL	99.90%	99.81%	99.76%	99.71%	99.56%	99.37%	98.87%	97.16%	95.55%	94.61%
5326/5226	Entity™ DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.32%	98.67%	98.22%	97.64%
5330/5331/5230	Affinity™ DR/DC	99.69%	99.56%	99.46%	99.36%	99.23%	99.08%	98.87%	98.38%	97.84%	97.35%

Malfunction Summary

Models	Family	Registered US Implants	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	Accent™ DR RF	183177	11	<0.01%	4	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	4	<0.01%	**23**	**0.01%**
PM2110	Accent™ DR	36961	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5820	Zephyr™ DR	46643	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	26223	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	108535	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**5**	**<0.01%**
5816	Victory™ XL DR	62522	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	17124	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5360	Integrity™ ADx DR	5829	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5366	Integrity™ ADx XL DR	8038	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	54013	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	67205	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	47429	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™	58352	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	51439	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	21822	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	65696	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.

Malfunction Summary

Models	Family	Registered US Implants	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	Accent™ DR RF	183177	9	<0.01%	20	0.01%	0	0.00%	0	0.00%	8	<0.01%	8	<0.01%	8	<0.01%	**53**	**0.03%**
PM2110	Accent™ DR	36961	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**4**	**0.01%**
5820	Zephyr™ DR	46643	33	0.07%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	2	<0.01%	**37**	**0.08%**
5810	Victory™ DR	26223	89	0.34%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	17	0.06%	0	0.00%	**107**	**0.41%**
5826	Zephyr™ XL DR	108535	16	0.01%	0	0.00%	0	0.00%	0	0.00%	5	<0.01%	2	<0.01%	4	<0.01%	**27**	**0.02%**
5816	Victory™ XL DR	62522	25	0.04%	0	0.00%	0	0.00%	0	0.00%	5	<0.01%	4	<0.01%	4	<0.01%	**38**	**0.06%**
5356/5357/5256	Verity ADx™ XL DR/ DR(M/S) / DC	17124	6	0.04%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**8**	**0.05%**
5360	Integrity™ ADx DR	5829	39	0.67%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**40**	**0.69%**
5366	Integrity™ ADx XL DR	8038	7	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**8**	**0.10%**
5380	Identity ADx™ DR	54013	262	0.49%	0	0.00%	0	0.00%	0	0.00%	5	<0.01%	11	0.02%	3	<0.01%	**281**	**0.52%**
5386/5286	Identity ADx™ XL DR/DC	67205	126	0.19%	2	<0.01%	0	0.00%	0	0.00%	7	0.01%	6	<0.01%	3	<0.01%	**144**	**0.21%**
5342/5346	Integrity™ AFx DR	47429	92	0.19%	1	<0.01%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**98**	**0.21%**
5370	Identity™	58352	398	0.68%	2	<0.01%	0	0.00%	0	0.00%	5	<0.01%	12	0.02%	11	0.02%	**428**	**0.73%**
5376	Identity™ XL	51439	309	0.60%	2	<0.01%	0	0.00%	0	0.00%	5	<0.01%	5	<0.01%	7	0.01%	**328**	**0.64%**
5326/5226	Entity™ DR/DC	21822	65	0.30%	2	<0.01%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**69**	**0.32%**
5330/5331/5230	Affinity™ DR/DC	65696	283	0.43%	13	0.02%	6	<0.01%	2	<0.01%	5	<0.01%	1	<0.01%	3	<0.01%	**313**	**0.48%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of 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	1769	33617	0	0.00%	0	0.00%	1	0.06%	0	0.00%	**1**	**0.06%**
PM2110	226	4859	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	283	7003	0	0.00%	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**
5826	1518	47084	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	333	10658	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5386	102	3251	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	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	1769	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	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	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	1518	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	333	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	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	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	1769	0	0.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.06%**
PM2110	226	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	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	1518	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	333	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	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Pacemakers

Single-Chamber

St. Jude Medical

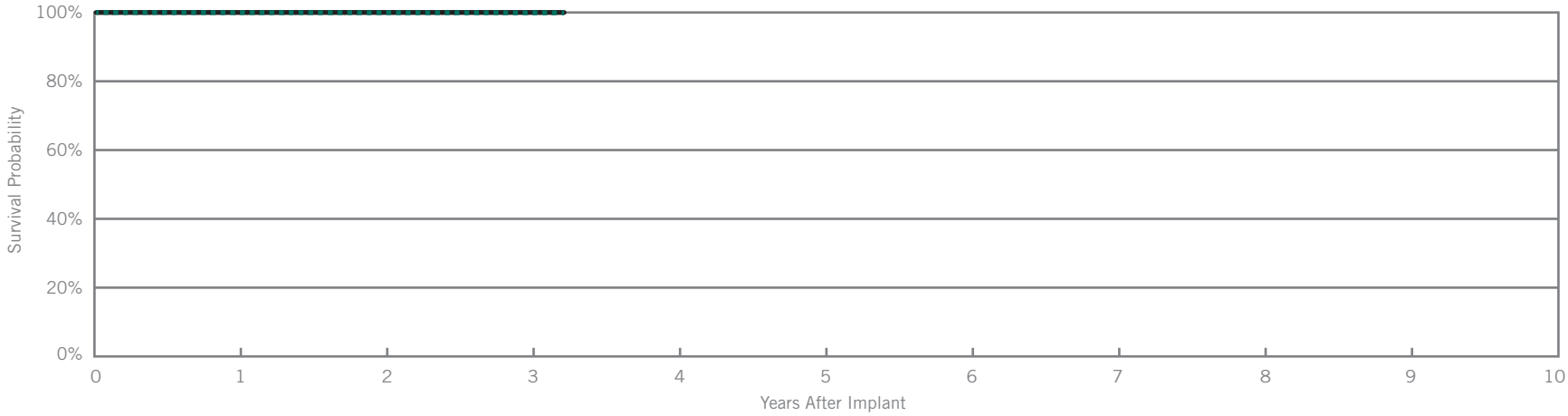
Customer Reported Performance Data

Accent™ SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	9,913
Estimated Active US Implants	8,154
Estimated Longevity	12.9 Years
Normal Battery Depletion	2
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	99.97%	99.90%	99.90%	99.90%						
± 1 standard error	0.02%	0.05%	0.05%	0.05%						
Sample Size	7740	3970	1380	210						

Excluding Normal Battery Depletion

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

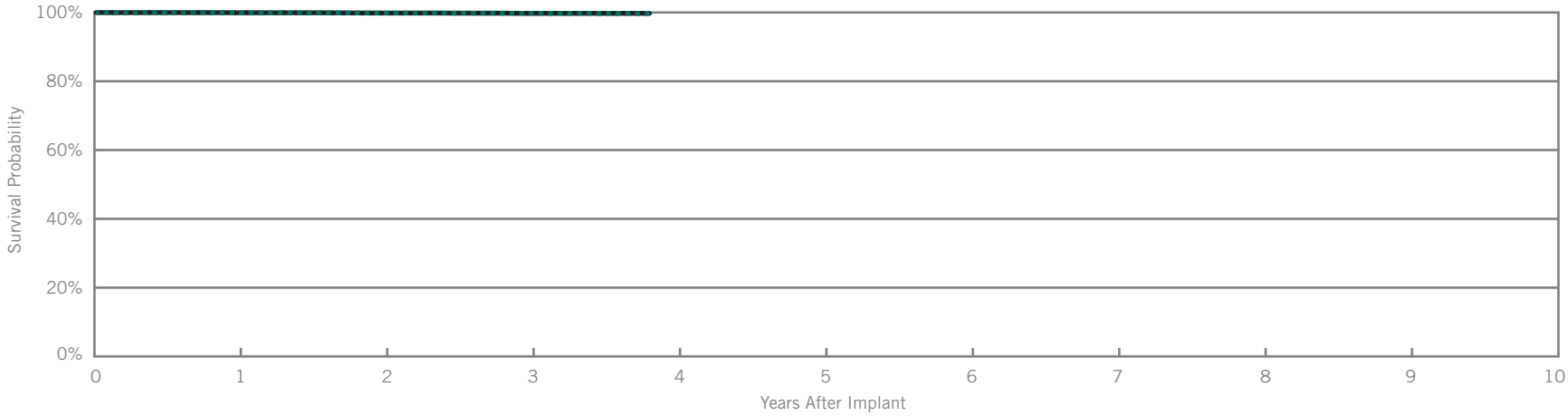
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	29,654
Estimated Active US Implants	23,524
Estimated Longevity	10.9 Years
Normal Battery Depletion	5
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	3	0.01%
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%	2	<0.01%
Possible Early Battery Depletion	2	<0.01%	1	<0.01%
Other	0	0.00%	1	<0.01%
Total	**4**	**0.01%**	**11**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.88%	99.78%	99.70%	99.70%						
± 1 standard error	0.02%	0.04%	0.06%	0.06%						
Sample Size	23630	13440	6300	340						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.92%	99.83%	99.75%	99.75%						
± 1 standard error	0.01%	0.03%	0.05%	0.05%						

Actively Monitored Study Data

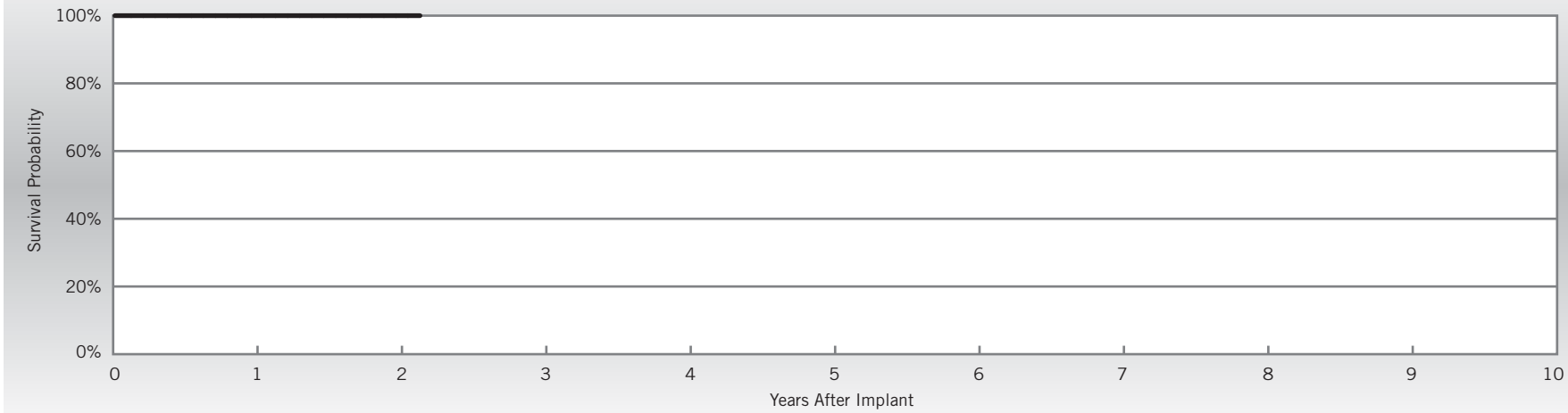
Accent™ SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	235
Cumulative Months of Follow-up	3,942
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 26 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	200	110	50							

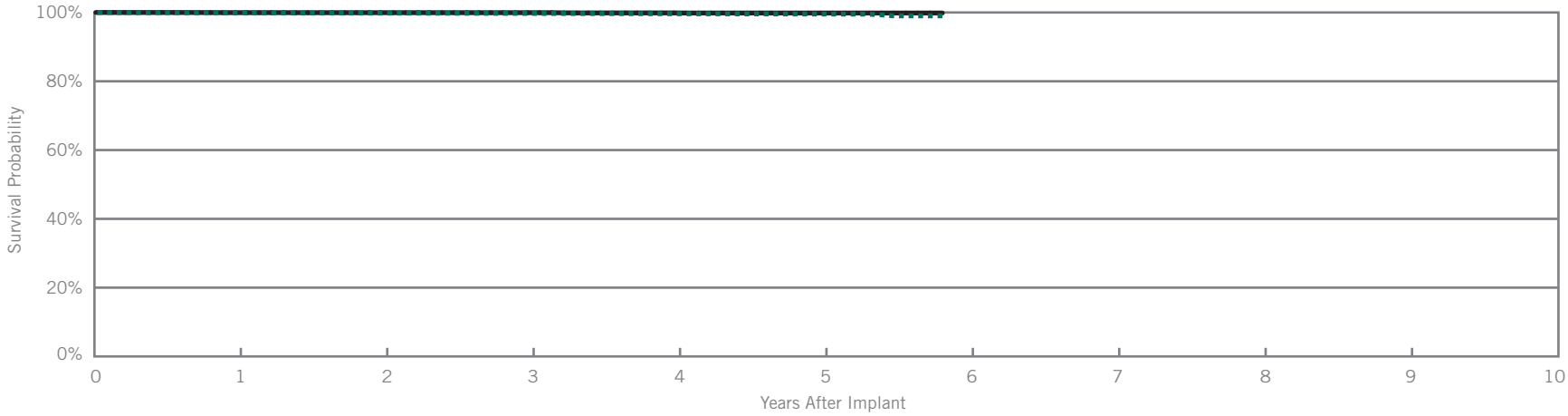
Customer Reported Performance Data

Zephyr™ XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	19,934
Estimated Active US Implants	12,162
Estimated Longevity	15.8 Years
Normal Battery Depletion	19
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	4	0.02%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	3	0.02%
Total	**2**	**0.01%**	**7**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 70 months				
Survival Probability	99.93%	99.83%	99.72%	99.60%	99.51%	99.01%				
± 1 standard error	0.02%	0.03%	0.05%	0.06%	0.08%	0.26%				
Sample Size	17980	14630	11900	8670	4420	210				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 70 months				
Survival Probability	99.95%	99.94%	99.94%	99.87%	99.84%	99.84%				
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%				

Actively Monitored Study Data

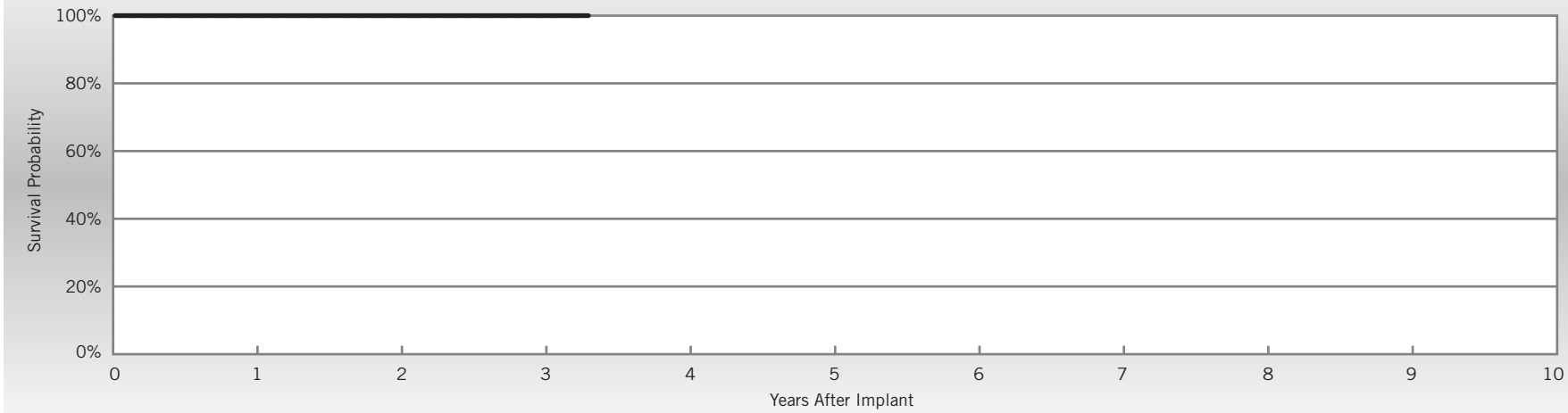
Zephyr™ XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	230
Cumulative Months of Follow-up	6,481
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 40 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						

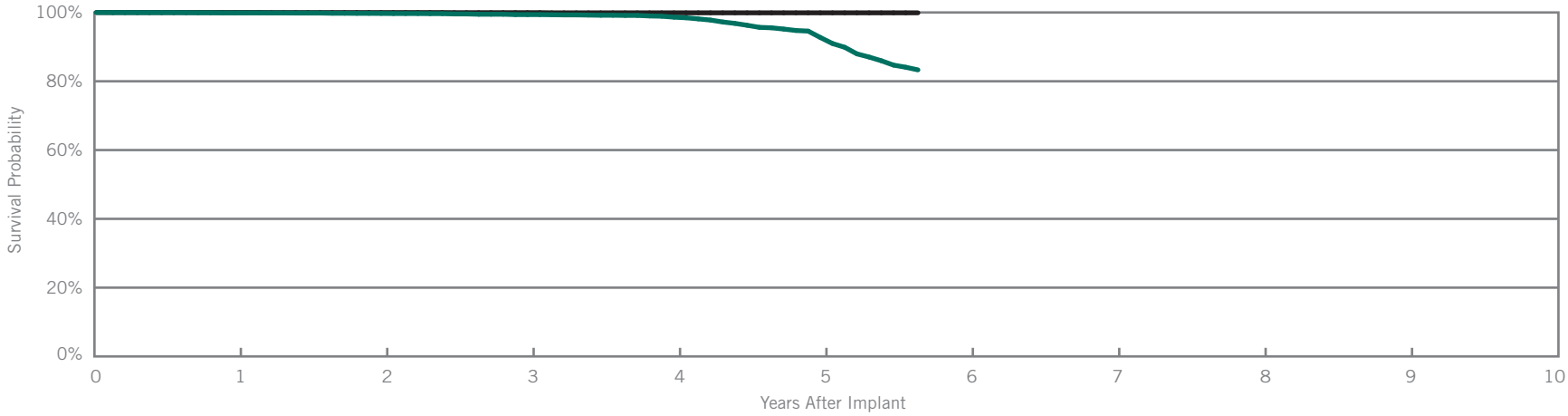
Customer Reported Performance Data

Zephyr™ SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	14,696
Estimated Active US Implants	9,240
Estimated Longevity	8.8 Years
Normal Battery Depletion	89
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.02%
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%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.87%	99.72%	99.38%	98.63%	92.72%	83.31%				
± 1 standard error	0.03%	0.05%	0.09%	0.15%	0.50%	1.34%				
Sample Size	12480	8680	5930	3750	1800	240				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	100.00%	99.98%	99.95%	99.90%	99.90%	99.90%				
± 1 standard error	0.00%	0.01%	0.03%	0.04%	0.04%	0.04%				

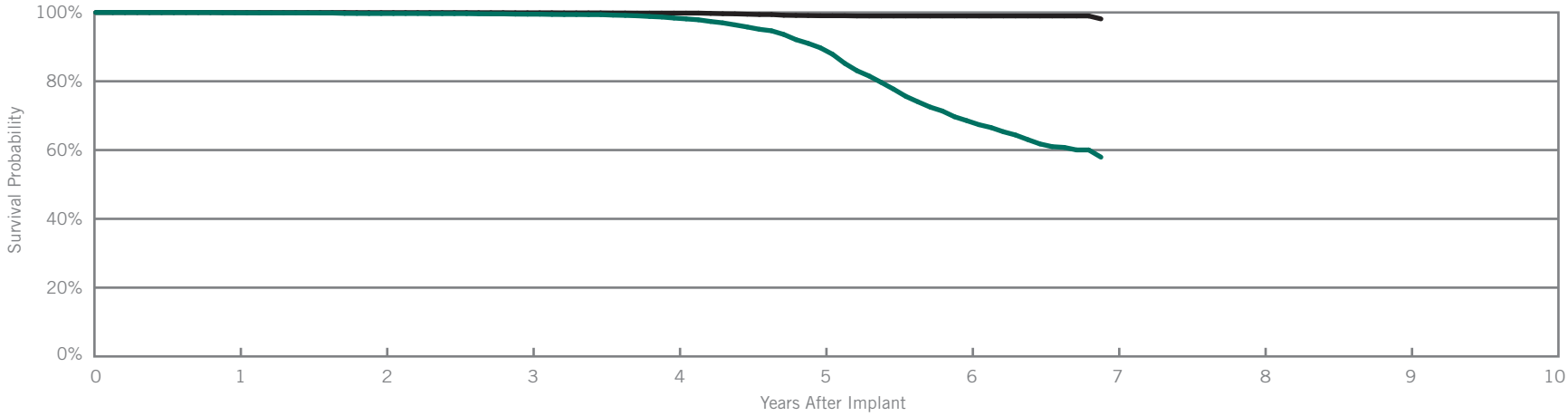
Customer Reported Performance Data

Victory™ SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,611
Estimated Active US Implants	4,678
Estimated Longevity	8.8 Years
Normal Battery Depletion	567
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%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	0	0.00%
Total	**1**	**<0.01%**	**24**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.92%	99.70%	99.50%	98.38%	89.73%	68.55%	57.94%			
± 1 standard error	0.02%	0.05%	0.07%	0.13%	0.39%	0.73%	1.00%			
Sample Size	12260	10020	8330	6730	4950	2860	270			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.98%	99.96%	99.91%	99.82%	99.05%	98.99%	98.13%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.13%	0.14%	0.14%			

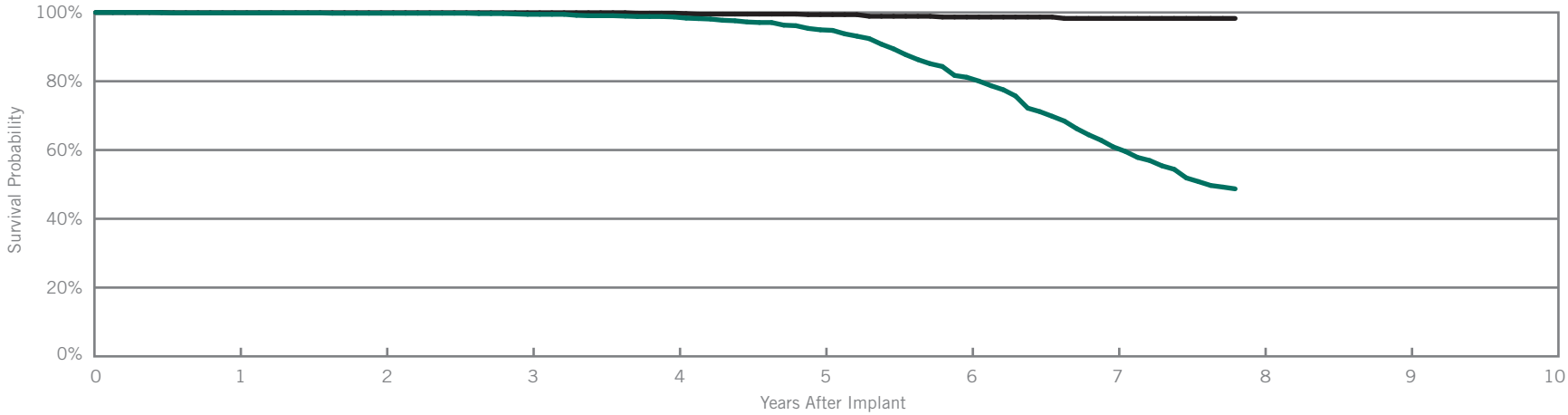
Customer Reported Performance Data

Integrity™ ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,396
Estimated Active US Implants	518
Estimated Longevity	5.7 Years
Normal Battery Depletion	179
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	8	0.24%
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	0.03%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**9**	**0.27%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.86%	99.78%	99.46%	98.69%	94.95%	81.15%	60.92%	48.71%		
± 1 standard error	0.07%	0.09%	0.14%	0.25%	0.55%	1.16%	1.65%	1.94%		
Sample Size	3020	2430	2020	1670	1330	960	560	200		

Excluding Normal Battery Depletion

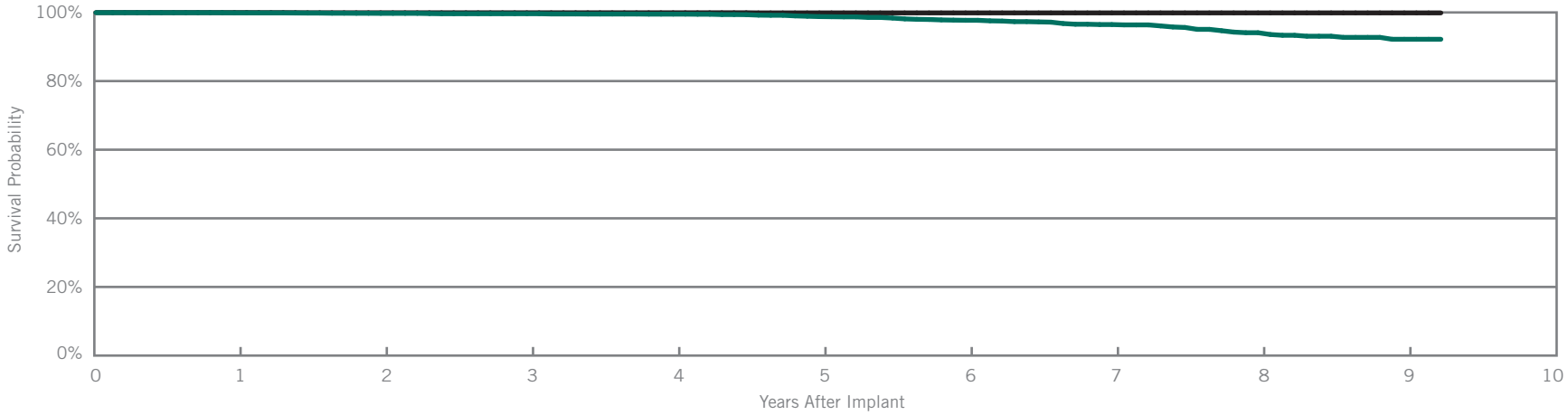
Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.93%	99.93%	99.93%	99.81%	99.37%	98.67%	98.27%	98.27%		
± 1 standard error	0.05%	0.05%	0.05%	0.10%	0.20%	0.34%	0.43%	0.43%		

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	14,326
Estimated Active US Implants	5,210
Estimated Longevity	10.2 Years
Normal Battery Depletion	85
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%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**1**	**<0.01%**	**5**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.87%	99.73%	99.62%	99.50%	98.79%	97.71%	96.47%	94.09%	92.18%	92.18%
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.13%	0.20%	0.30%	0.50%	0.75%	0.75%
Sample Size	12950	10650	8900	7280	5740	4190	2670	1450	600	200

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.87%	99.87%	99.87%	99.87%	99.87%	99.87%
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%	0.04%	0.04%

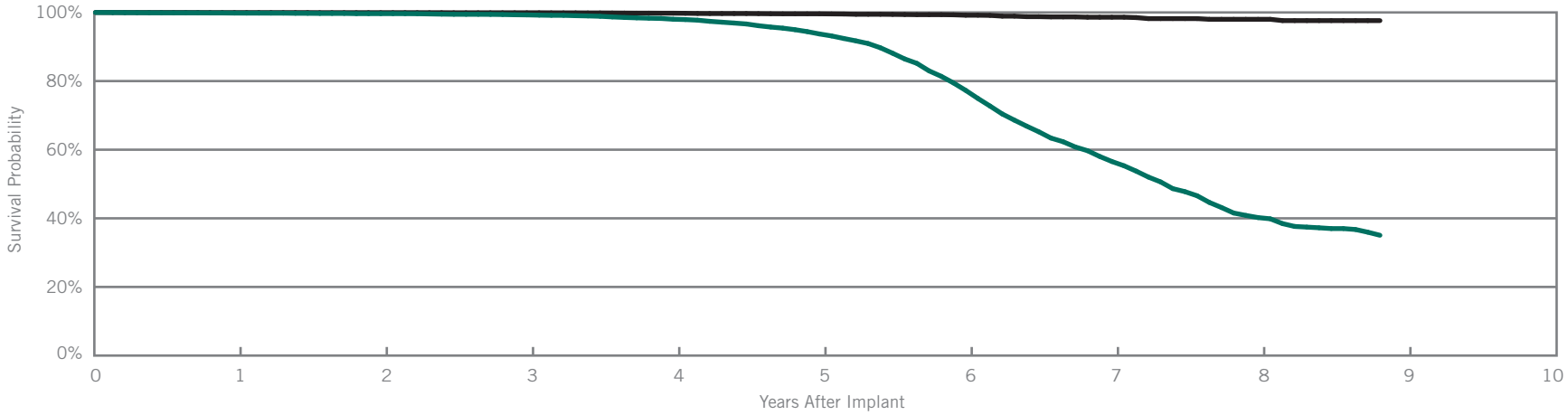
Customer Reported Performance Data

Integrity™ ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,826
Estimated Active US Implants	4,241
Estimated Longevity	5.7 Years
Normal Battery Depletion	1,162
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	35	0.17%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**44**	**0.21%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.81%	99.65%	99.28%	98.02%	93.73%	77.30%	56.56%	40.21%	35.06%
± 1 standard error	0.03%	0.05%	0.07%	0.12%	0.24%	0.49%	0.69%	0.86%	1.00%
Sample Size	18750	15300	12710	10320	8000	5530	3090	1280	220

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.96%	99.94%	99.91%	99.78%	99.60%	99.19%	98.61%	98.00%	97.62%
± 1 standard error	0.02%	0.02%	0.02%	0.04%	0.06%	0.09%	0.17%	0.27%	0.38%

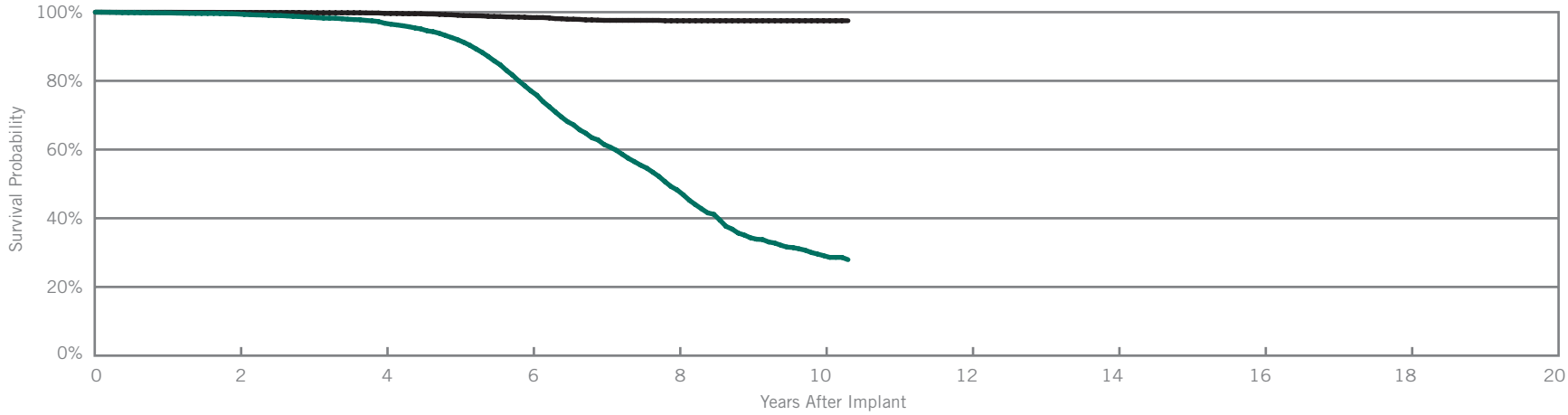
Identity™ SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,873
Estimated Active US Implants	1,816
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,429
Number of US Advisories (see pgs. 272-284)	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%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	1	<0.01%
Total	**1**	**<0.01%**	**73**	**0.33%**



Including Normal Battery Depletion

Year	2	4	6	8	10	At 124 months				
Survival Probability	99.46%	96.79%	77.08%	48.23%	29.11%	27.94%				
± 1 standard error	0.05%	0.14%	0.46%	0.71%	0.89%	0.91%				
Sample Size	16200	11340	6420	2150	480	230				

Excluding Normal Battery Depletion

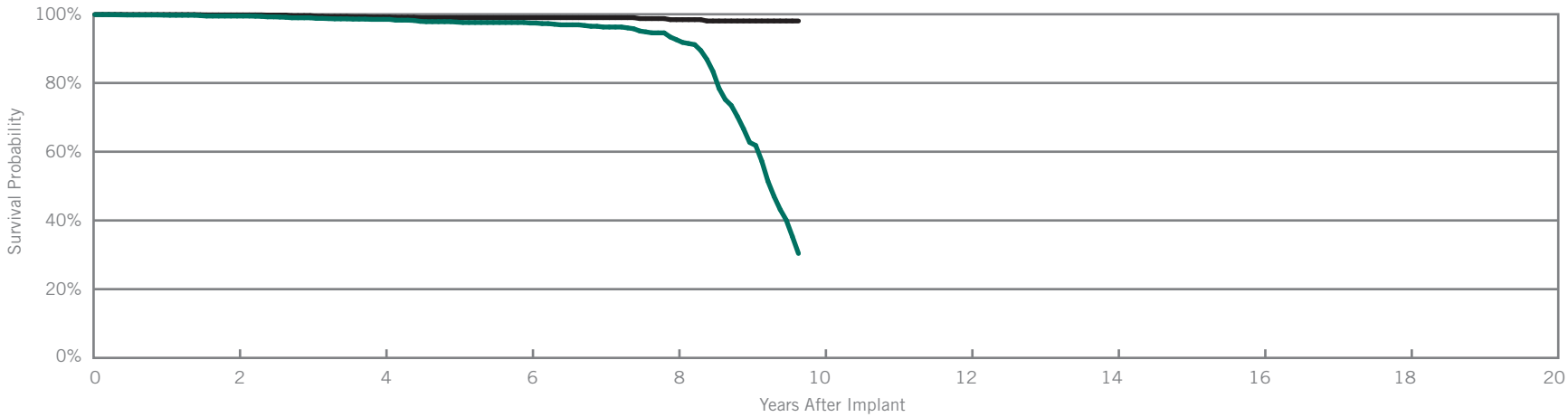
Year	2	4	6	8	10	At 124 months				
Survival Probability	99.92%	99.64%	98.43%	97.50%	97.50%	97.50%				
± 1 standard error	0.02%	0.04%	0.13%	0.22%	0.22%	0.22%				

Customer Reported Performance Data

Microny™

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	7,324
Estimated Longevity	7.5 Years
Number of US Advisories	None



Including Normal Battery Depletion

Year	2	4	6	8	at 116 months					
Survival Probability	99.48%	98.51%	97.44%	92.60%	30.39%					
± 1 standard error	0.10%	0.20%	0.29%	0.77%	1.98%					
Sample Size	4490	2680	1430	720	220					

Excluding Normal Battery Depletion

Year	2	4	6	8	at 116 months					
Survival Probability	99.81%	99.20%	99.01%	98.43%	98.04%					
± 1 standard error	0.06%	0.15%	0.18%	0.34%	0.44%					

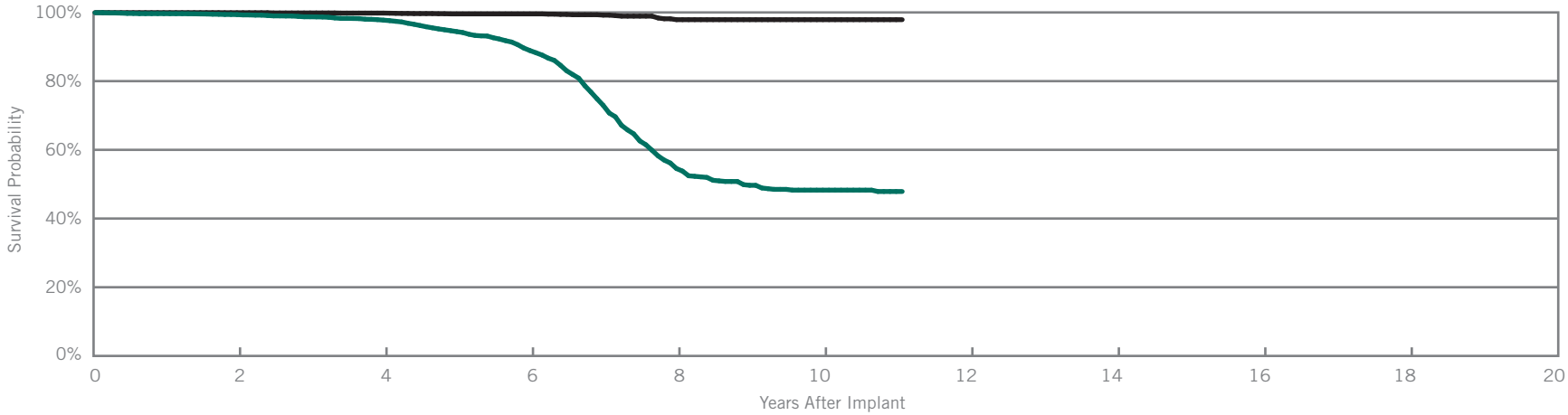
Customer Reported Performance Data

Integrity™ µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	12,017
Estimated Active US Implants	479
Estimated Longevity	5.3 Years
Normal Battery Depletion	525
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	22	0.18%
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%	1	<0.01%
Total	**0**	**0.00%**	**23**	**0.19%**



Including Normal Battery Depletion

Year	2	4	6	8	10	At 133 months				
Survival Probability	99.37%	97.76%	88.90%	54.56%	48.27%	47.87%				
± 1 standard error	0.08%	0.17%	0.45%	1.07%	1.19%	1.21%				
Sample Size	8670	5960	3630	1170	460	200				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	At 133 months				
Survival Probability	99.92%	99.81%	99.57%	97.89%	97.89%	97.89%				
± 1 standard error	0.03%	0.05%	0.09%	0.36%	0.40%	0.40%				

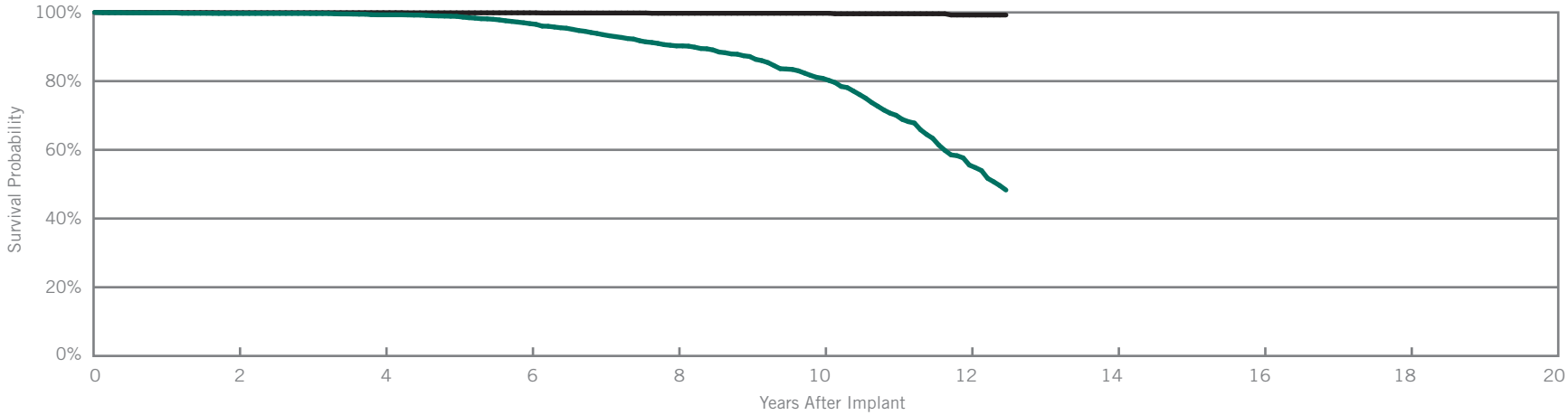
Customer Reported Performance Data

Integrity™ SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,486
Estimated Active US Implants	1,224
Estimated Longevity	8.6 Years
Normal Battery Depletion	365
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	5	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	0	0.00%
Total	**1**	**<0.01%**	**7**	**0.07%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	At 150 months			
Survival Probability	99.71%	99.31%	96.74%	90.26%	80.80%	55.57%	48.30%			
± 1 standard error	0.06%	0.10%	0.25%	0.49%	0.77%	1.32%	1.59%			
Sample Size	8050	5860	4180	2800	1650	640	210			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	At 150 months			
Survival Probability	99.93%	99.93%	99.89%	99.76%	99.76%	99.25%	99.25%			
± 1 standard error	0.03%	0.03%	0.04%	0.08%	0.08%	0.29%	0.29%			

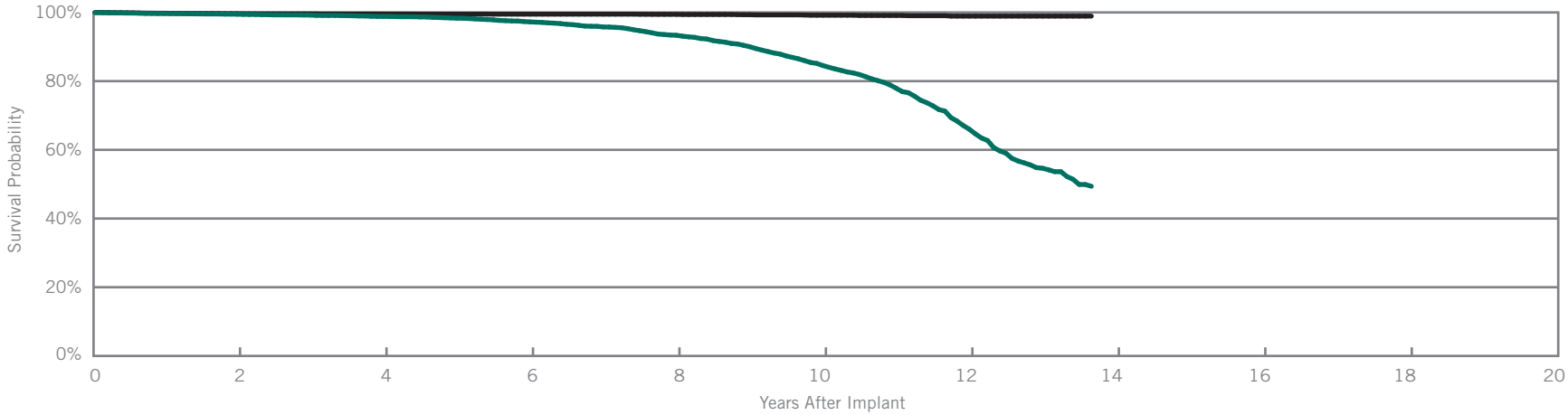
Affinity™ SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,788
Estimated Active US Implants	2,303
Estimated Longevity	8.6 Years
Normal Battery Depletion	748
Number of US Advisories (see pgs. 272-284)	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%	3	0.01%
Total	**4**	**0.01%**	**55**	**0.19%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	At 164 months			
Survival Probability	99.47%	98.84%	97.25%	93.35%	84.53%	65.99%	49.39%			
± 1 standard error	0.05%	0.08%	0.14%	0.25%	0.44%	0.77%	1.21%			
Sample Size	21450	15240	10650	7090	4310	2030	210			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	At 164 months			
Survival Probability	99.64%	99.54%	99.49%	99.44%	99.19%	98.93%	98.93%			
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.09%	0.14%	0.14%			

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
PM1110	Accent™ SR	99.97%	99.90%	99.90%							
PM1210	Accent™ SR RF	99.88%	99.78%	99.70%							
5626	Zephyr™ XL SR	99.93%	99.83%	99.72%	99.60%	99.51%					
5620	Zephyr™ SR	99.87%	99.72%	99.38%	98.63%	92.72%					
5610	Victory™ SR	99.92%	99.70%	99.50%	98.38%	89.73%	68.55%				
5160	Integrity™ ADx SR	99.86%	99.78%	99.46%	98.69%	94.95%	81.15%	60.92%			
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	99.87%	99.73%	99.62%	99.50%	98.79%	97.71%	96.47%	94.09%	92.18%	
5180	Integrity™ ADx SR	99.81%	99.65%	99.28%	98.02%	93.73%	77.30%	56.56%	40.21%		
5172	Identity™ SR	99.77%	99.46%	98.51%	96.79%	91.98%	77.08%	61.48%	48.23%	34.33%	29.11%
2425T/2525T/2535T	Microny™	99.75%	99.48%	98.97%	98.51%	97.72%	97.44%	96.28%	92.60%	62.71%	
5136	Integrity™ µ SR	99.65%	99.37%	98.73%	97.76%	94.42%	88.90%	72.96%	54.56%	49.67%	48.27%
5142	Integrity™ SR	99.86%	99.71%	99.68%	99.31%	98.86%	96.74%	93.51%	90.26%	87.17%	80.80%
5130/5131	Affinity™ SR	99.69%	99.47%	99.23%	98.84%	98.32%	97.25%	95.77%	93.35%	90.02%	84.53%

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
PM1110	Accent™ SR	100.00%	100.00%	100.00%							
PM1210	Accent™ SR RF	99.92%	99.83%	99.75%							
5626	Zephyr™ XL SR	99.95%	99.94%	99.94%	99.87%	99.84%					
5620	Zephyr™ SR	100.00%	99.98%	99.95%	99.90%	99.90%					
5610	Victory™ SR	99.98%	99.96%	99.91%	99.82%	99.05%	98.99%				
5160	Integrity™ ADx SR	99.93%	99.93%	99.93%	99.81%	99.37%	98.67%	98.27%			
5156/5157/5056	Verity ADx™ XL SR/SR(M/S) / SC	99.96%	99.91%	99.91%	99.91%	99.87%	99.87%	99.87%	99.87%	99.87%	
5180	Integrity™ ADx SR	99.96%	99.94%	99.91%	99.78%	99.60%	99.19%	98.61%	98.00%		
5172	Identity™ SR	99.97%	99.92%	99.82%	99.64%	99.11%	98.43%	97.61%	97.50%	97.50%	97.50%
2425T/2525T/2535T	Microny™	99.90%	99.81%	99.60%	99.20%	99.01%	99.01%	99.01%	98.43%	98.04%	
5136	Integrity™ µ SR	99.94%	99.92%	99.85%	99.81%	99.57%	99.57%	99.21%	97.89%	97.89%	97.89%
5142	Integrity™ SR	99.98%	99.93%	99.93%	99.93%	99.89%	99.89%	99.84%	99.76%	99.76%	99.76%
5130/5131	Affinity™ SR	99.78%	99.64%	99.58%	99.54%	99.51%	99.49%	99.49%	99.44%	99.33%	99.19%

Malfunction Summary

Models	Family	Registered US Implants	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
PM1110	Accent™ SR	9913	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	29654	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	19934	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	14696	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	13611	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**
5160	Integrity™ ADx SR	3396	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5356/5357/5256	Verity ADx™ XL SR/SR(M/S) / SC	14326	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	Integrity™ ADx SR	20826	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	21873	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5136	Integrity™ µ SR	12017	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	10486	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	28788	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	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
PM1110	Accent™ SR	9913	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	29654	3	0.01%	3	0.01%	1	<0.01%	0	0.00%	2	<0.01%	1	<0.01%	1	<0.01%	**11**	**0.04%**
5626	Zephyr™ XL SR	19934	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	**7**	**0.04%**
5620	Zephyr™ SR	14696	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.02%**
5610	Victory™ SR	13611	23	0.17%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**24**	**0.18%**
5160	Integrity™ ADx SR	3396	8	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	**9**	**0.27%**
5356/5357/5256	Verity ADx™ XL SR/SR(M/S) / SC	14326	3	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**5**	**0.03%**
5180	Integrity™ ADx SR	20826	35	0.17%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	8	0.04%	0	0.00%	**44**	**0.21%**
5172	Identity™ SR	21873	64	0.29%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.04%	1	<0.01%	**73**	**0.33%**
5136	Integrity™ µ SR	12017	22	0.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**23**	**0.19%**
5142	Integrity™ SR	10486	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	28788	46	0.16%	2	<0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	**55**	**0.19%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of 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	235	3942	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5626	230	6481	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	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	235	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	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	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	235	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	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Pacing Leads

St. Jude Medical

Customer Reported Performance Data

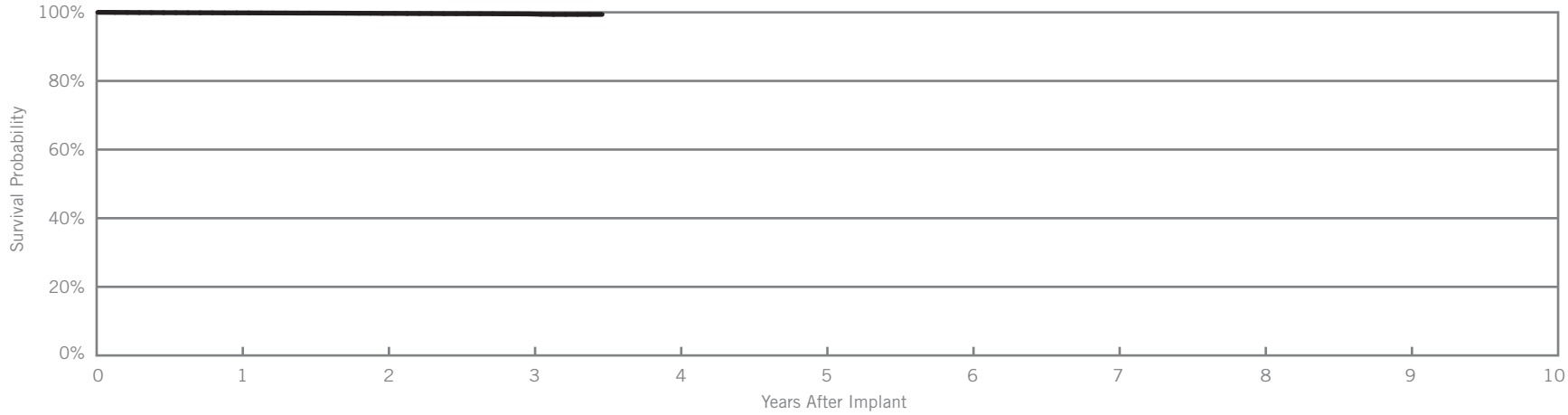
Tendril™ STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	214,435
Estimated Active US Implants	176,937
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	23	0.01%	9	<0.01%
Conductor Fracture	1	<0.01%	13	<0.01%
Lead Dislodgement	129	0.06%	129	0.06%
Failure to Capture	22	0.01%	74	0.03%
Oversensing	6	<0.01%	93	0.04%
Failure to Sense	7	<0.01%	14	<0.01%
Insulation Breach	4	<0.01%	37	0.02%
Abnormal Pacing Impedance	7	<0.01%	14	<0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	4	<0.01%	15	<0.01%
Total	**203**	**0.09%**	**399**	**0.19%**
Total Returned for Analysis	**126**		**280**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	8	<0.01%
Insulation Breach	82	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	13	<0.01%
Extrinsic Factors	239	0.11%
Total	**342**	**0.16%**



Year	1	2	3	at 42 months						
Survival Probability	99.84%	99.68%	99.52%	99.39%						
± 1 standard error	0.01%	0.02%	0.03%	0.05%						
Sample Size	167650	87250	31050	430						

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

Tendril™ STS

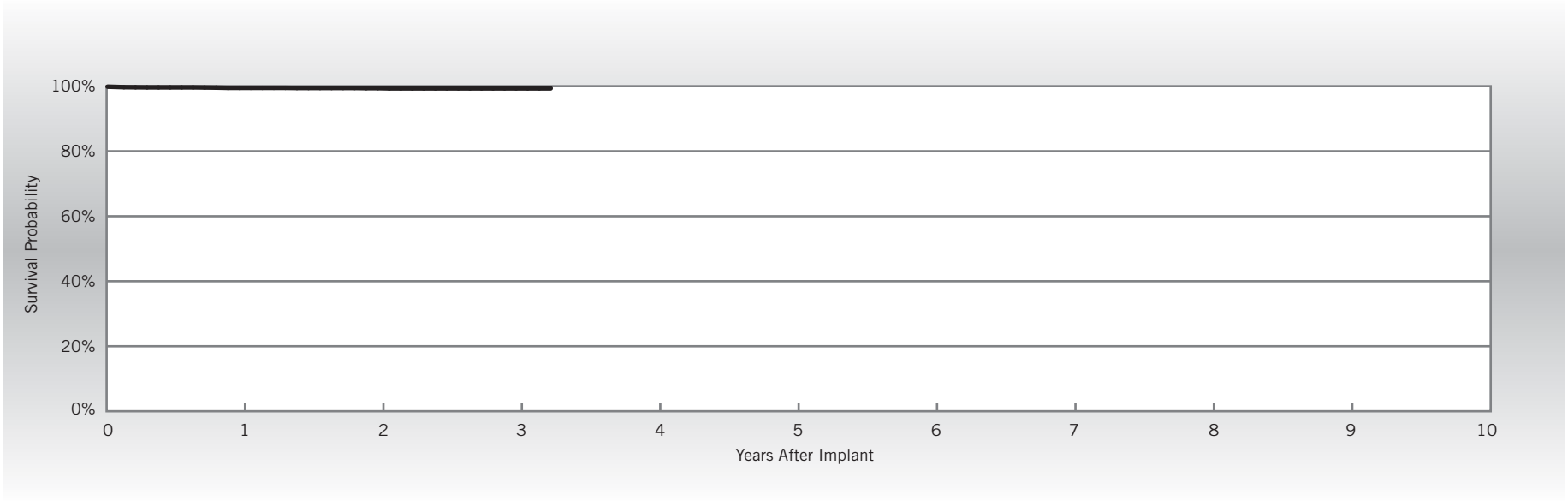
Model 2088TC

Actively Monitored Study Data

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	3,437
Cumulative Months of Follow-up	74,297
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%
Failure to Capture	2	0.06%
Failure to Sense	1	0.03%
Insulation Breach	4	0.12%
Lead Dislodgement	9	0.26%
Pericardial Effusion	1	0.03%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	3	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.06%
Total	**5**	**0.15%**



Year	1	2	3	at 40 months						
Survival Probability	99.49%	99.40%	99.33%	99.33%						
± 1 standard error	0.12%	0.13%	0.16%	0.16%						
Sample Size	3080	2200	980	50						

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

Customer Reported Performance Data

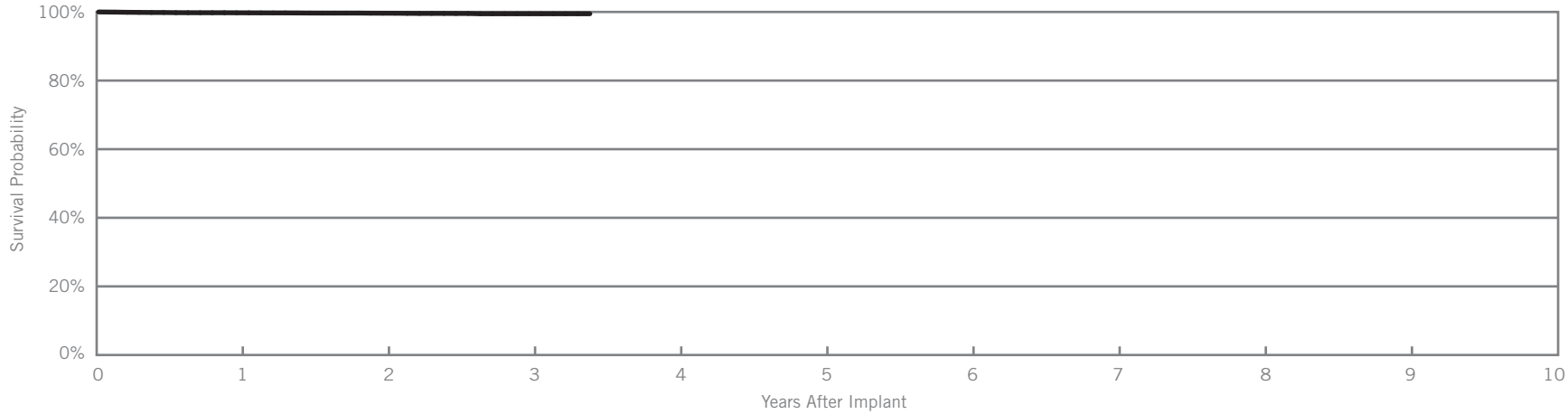
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	23,849
Estimated Active US Implants	19,545
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	15	0.06%	39	0.16%
Failure to Capture	2	<0.01%	9	0.04%
Oversensing	1	<0.01%	6	0.03%
Failure to Sense	1	<0.01%	1	<0.01%
Insulation Breach	1	<0.01%	8	0.03%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	2	<0.01%
Total	**20**	**0.08%**	**65**	**0.27%**
Total Returned for Analysis	**12**		**46**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Insulation Breach	3	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.01%
Extrinsic Factors	45	0.19%
Total	**53**	**0.22%**



Year	1	2	3	at 41 months						
Survival Probability	99.75%	99.63%	99.47%	99.47%						
± 1 standard error	0.03%	0.05%	0.08%	0.08%						
Sample Size	19310	11250	4600	220						

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

Actively Monitored Study Data

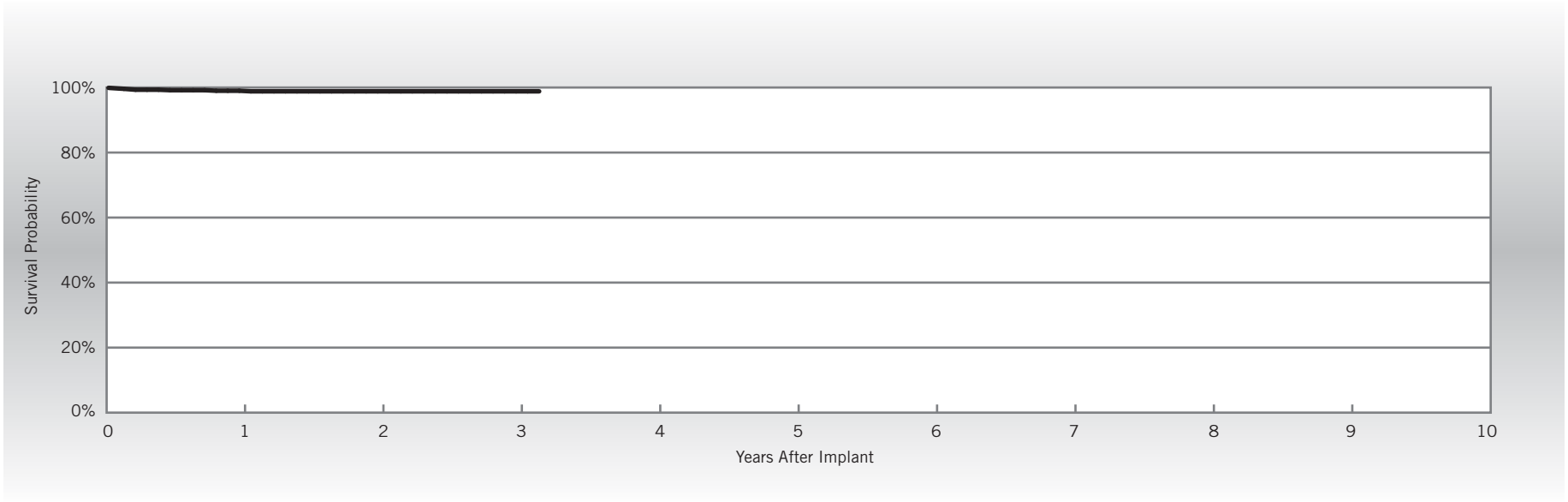
OptiSense™

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	767
Cumulative Months of Follow-up	15,408
Insulation	Optim™*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	1	0.13%
Lead Dislodgement	7	0.91%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.26%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	0.39%
Total	**5**	**0.65%**



Year	1	2	3	at 38 months						
Survival Probability	99.01%	98.83%	98.83%	98.83%						
± 1 standard error	0.37%	0.41%	0.41%	0.41%						
Sample Size	660	440	200	60						

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

Customer Reported Performance Data

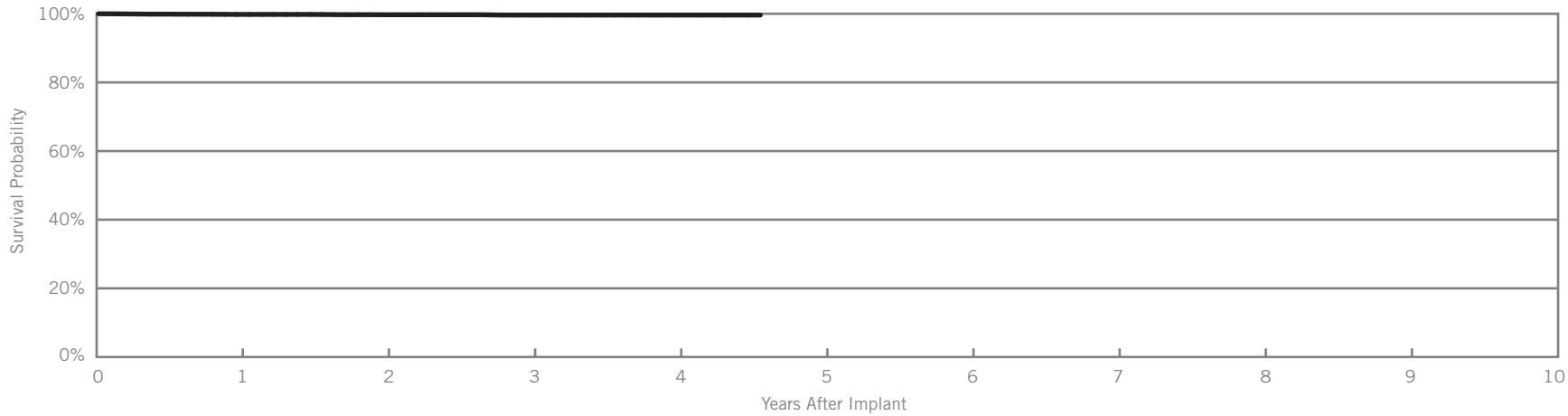
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	9,343
Estimated Active US Implants	7,208
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	24	0.26%	14	0.15%
Failure to Capture	3	0.03%	1	0.01%
Oversensing	0	0.00%	2	0.02%
Failure to Sense	2	0.02%	2	0.02%
Insulation Breach	0	0.00%	1	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**29**	**0.31%**	**21**	**0.22%**
Total Returned for Analysis	**19**		**9**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	7	0.07%
Total	**9**	**0.10%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.81%	99.71%	99.62%	99.62%	99.62%					
± 1 standard error	0.05%	0.07%	0.09%	0.09%	0.09%					
Sample Size	7710	4950	2860	1240	220					

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

Actively Monitored Study Data

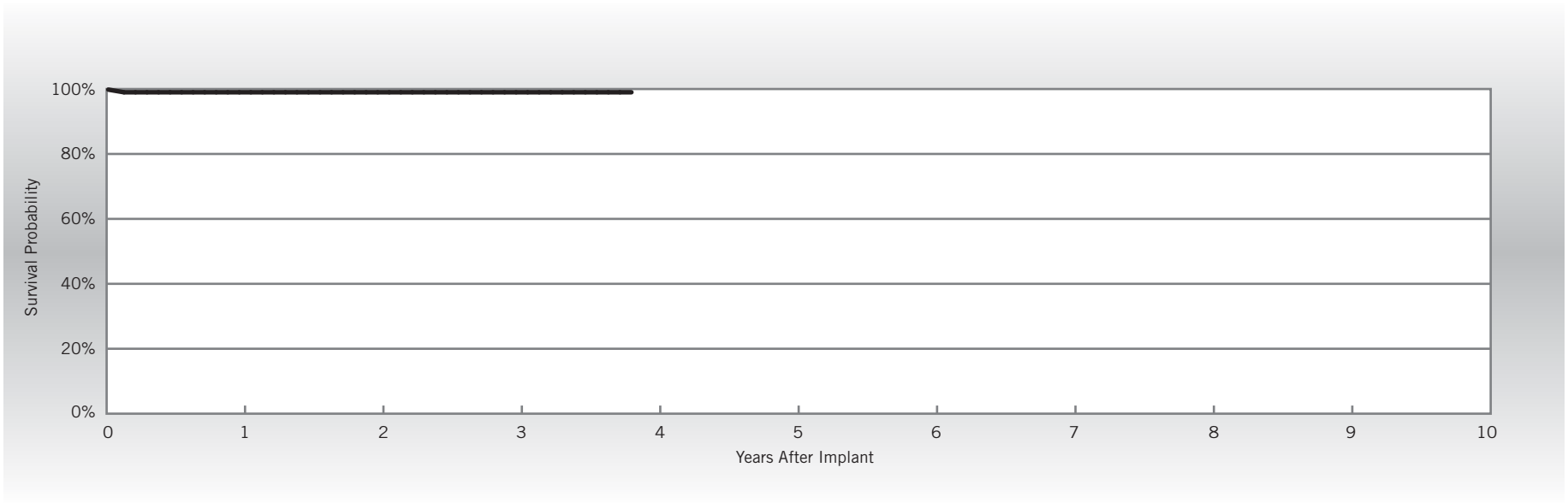
IsoFlex™ Optim™

Model 1944

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	101
Cumulative Months of Follow-up	3,765
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	1	0.99%

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 46 months						
Survival Probability	99.00%	99.00%	99.00%	99.00%						
± 1 standard error	0.99%	0.99%	0.99%	0.99%						
Sample Size	90	80	70	50						

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

Customer Reported Performance Data

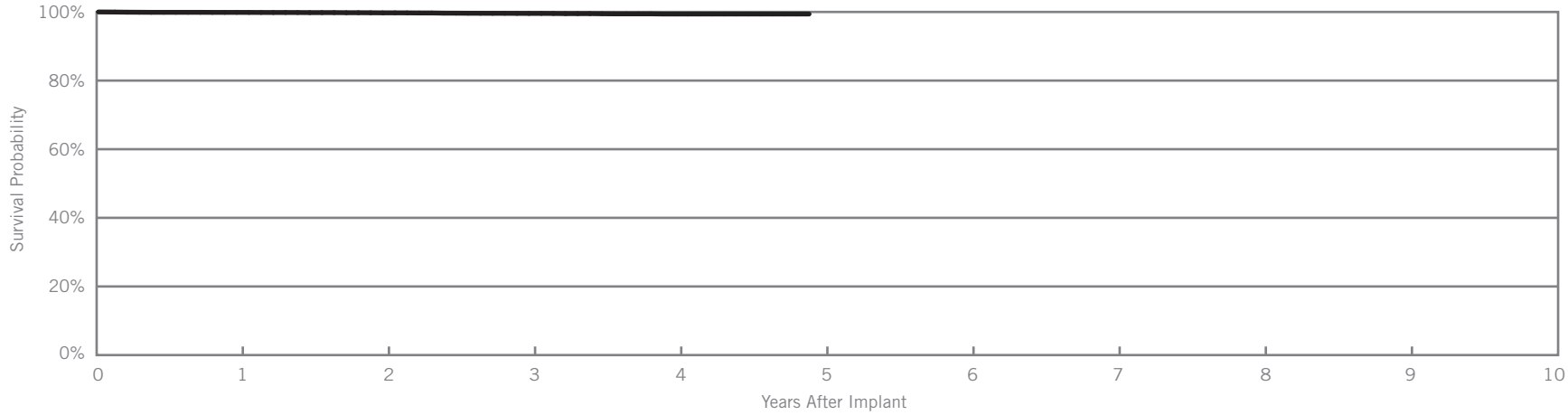
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	33,739
Estimated Active US Implants	26,007
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	<0.01%	3	<0.01%
Conductor Fracture	0	0.00%	13	0.04%
Lead Dislodgement	18	0.05%	10	0.03%
Failure to Capture	8	0.02%	20	0.06%
Oversensing	0	0.00%	14	0.04%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	<0.01%	5	0.01%
Abnormal Pacing Impedance	0	0.00%	5	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**29**	**0.09%**	**70**	**0.21%**
Total Returned for Analysis	**19**		**25**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	<0.01%
Insulation Breach	9	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	25	0.07%
Total	**37**	**0.11%**



Year	1	2	3	4	at 59 months					
Survival Probability	99.87%	99.74%	99.57%	99.40%	99.40%					
± 1 standard error	0.02%	0.03%	0.05%	0.09%	0.09%					
Sample Size	27340	16850	9620	4230	210					

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

Actively Monitored Study Data

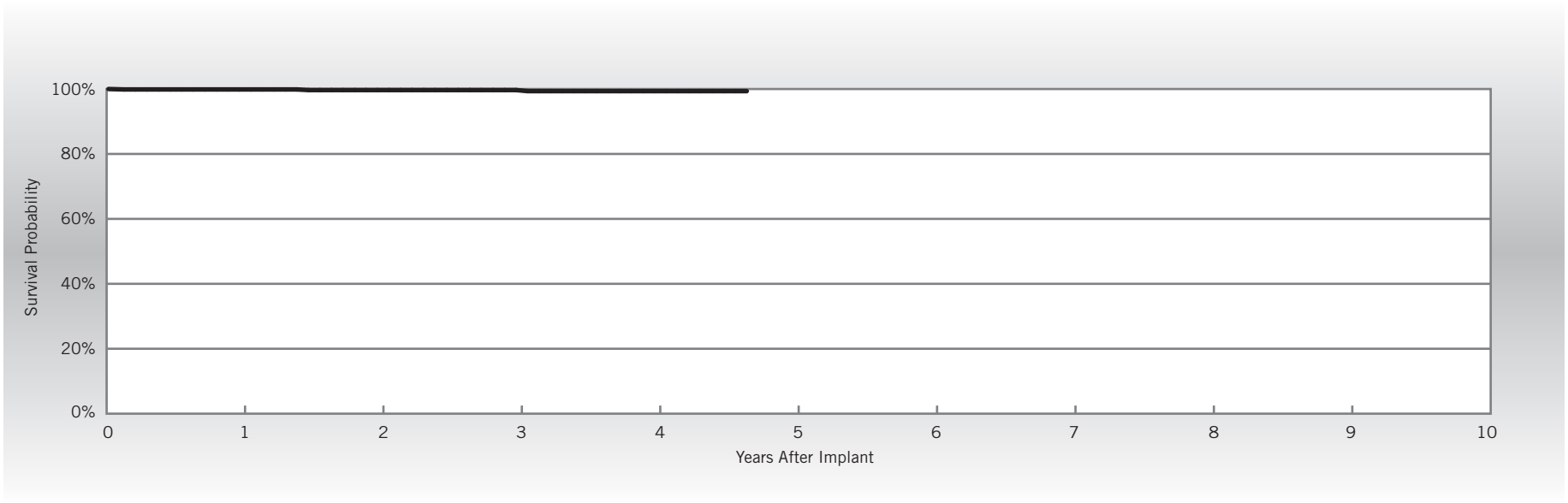
IsoFlex™ Optim™

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	766
Cumulative Months of Follow-up	22,740
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	1	0.13%
Insulation Breach	1	0.13%
Lead Dislodgement	1	0.13%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.13%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.13%
Total	**2**	**0.26%**



Year	1	2	3	4	at 56 months					
Survival Probability	99.87%	99.68%	99.68%	99.35%	99.35%					
± 1 standard error	0.13%	0.23%	0.23%	0.40%	0.40%					
Sample Size	690	530	380	240	50					

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

Customer Reported Performance Data

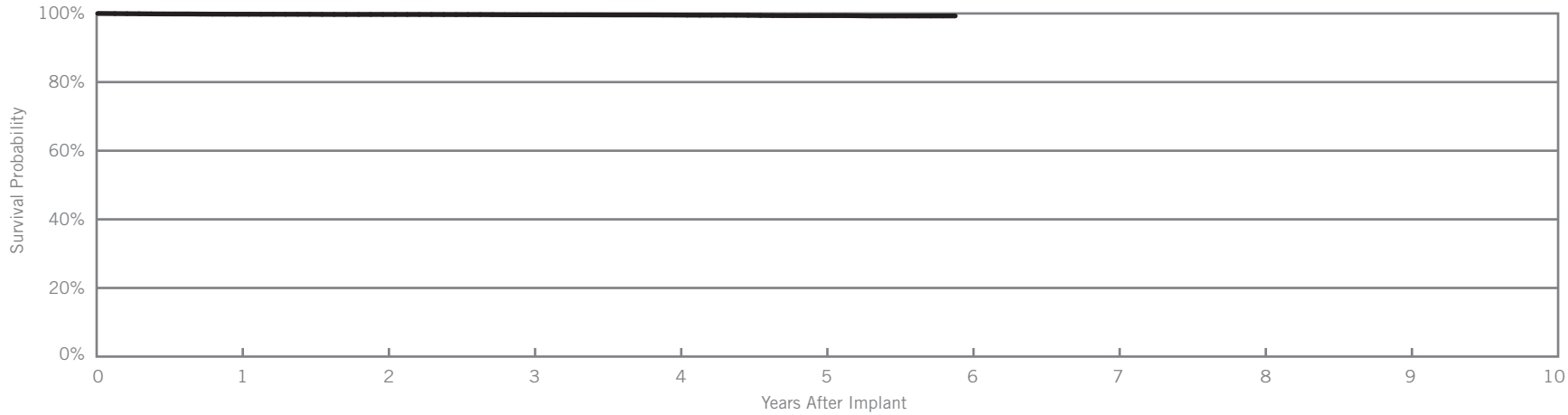
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	22,845
Estimated Active US Implants	14,340
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	6	0.03%
Lead Dislodgement	4	0.02%	23	0.10%
Failure to Capture	3	0.01%	11	0.05%
Oversensing	2	<0.01%	13	0.06%
Failure to Sense	8	0.04%	7	0.03%
Insulation Breach	0	0.00%	2	<0.01%
Abnormal Pacing Impedance	0	0.00%	5	0.02%
Extracardiac Stimulation	0	0.00%	2	<0.01%
Other	2	<0.01%	0	0.00%
Total	**20**	**0.09%**	**69**	**0.30%**
Total Returned for Analysis	**16**		**41**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	8	0.04%
Insulation Breach	10	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	39	0.17%
Total	**57**	**0.25%**



Year	1	2	3	4	5	at 71 months				
Survival Probability	99.78%	99.71%	99.61%	99.54%	99.37%	99.28%				
± 1 standard error	0.03%	0.04%	0.04%	0.05%	0.07%	0.10%				
Sample Size	21280	18560	16020	11870	6360	200				

Actively Monitored Study Data

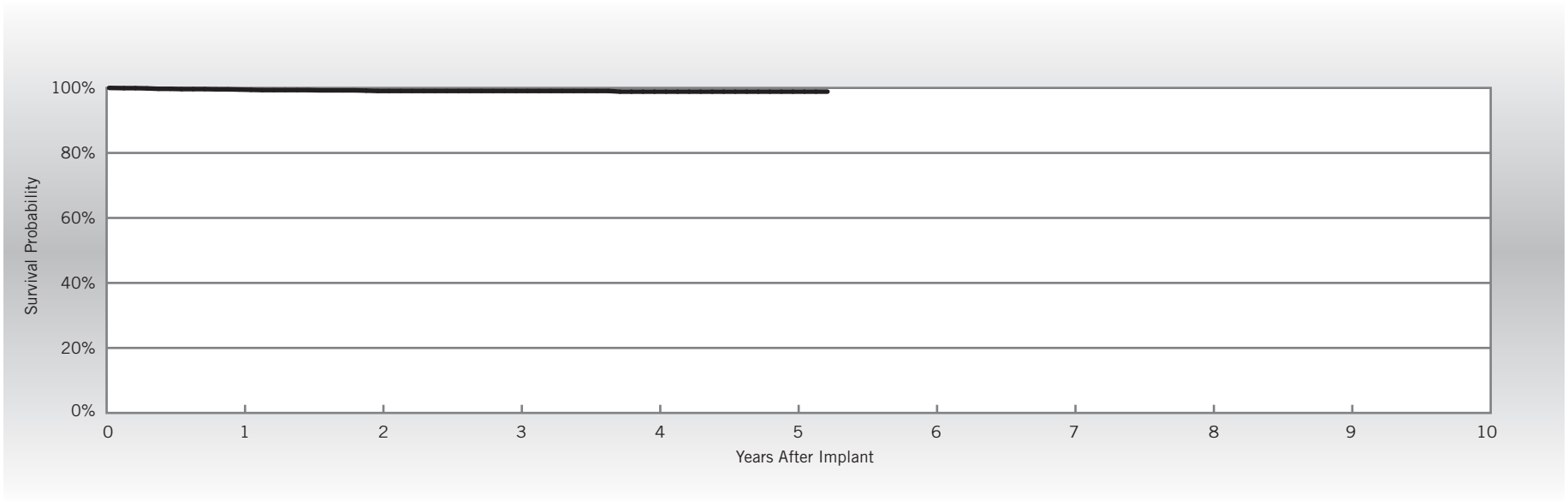
OptiSense™

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,451
Cumulative Months of Follow-up	50,355
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	2	0.14%
Insulation Breach	1	0.07%
Lead Dislodgement	7	0.48%
Oversensing	1	0.07%

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	5	0.34%
Total	**5**	**0.34%**



Year	1	2	3	4	5	at 63 months				
Survival Probability	99.49%	99.06%	99.06%	98.86%	98.86%	98.86%				
± 1 standard error	0.18%	0.25%	0.27%	0.34%	0.34%	0.34%				
Sample Size	1360	1170	920	550	210	50				

Customer Reported Performance Data

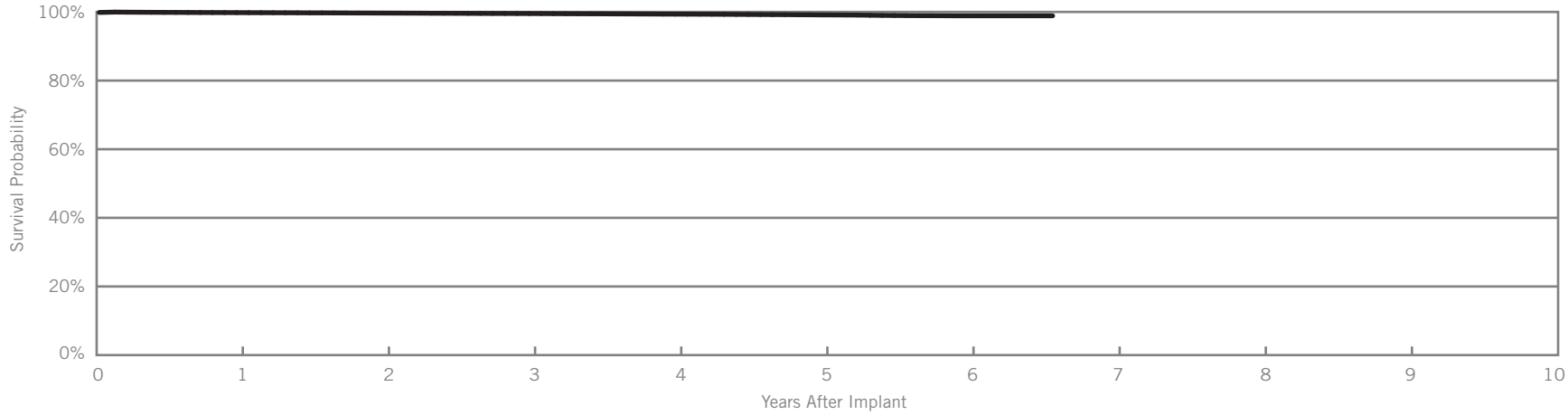
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	261,798
Estimated Active US Implants	172,940
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	32	0.01%	23	<0.01%
Conductor Fracture	6	<0.01%	58	0.02%
Lead Dislodgement	98	0.04%	249	0.10%
Failure to Capture	64	0.02%	214	0.08%
Oversensing	10	<0.01%	225	0.09%
Failure to Sense	10	<0.01%	27	0.01%
Insulation Breach	6	<0.01%	83	0.03%
Abnormal Pacing Impedance	5	<0.01%	39	0.01%
Extracardiac Stimulation	4	<0.01%	10	<0.01%
Other	18	<0.01%	42	0.02%
Total	**253**	**0.10%**	**970**	**0.37%**
Total Returned for Analysis	**135**		**547**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	19	<0.01%
Insulation Breach	222	0.08%
Crimps, Welds & Bonds	1	<0.01%
Other	10	<0.01%
Extrinsic Factors	464	0.18%
Total	**716**	**0.27%**



Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.80%	99.67%	99.53%	99.36%	99.14%	98.88%	98.88%			
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.06%	0.06%			
Sample Size	232400	180860	136890	88740	43600	14420	220			

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

Actively Monitored Study Data

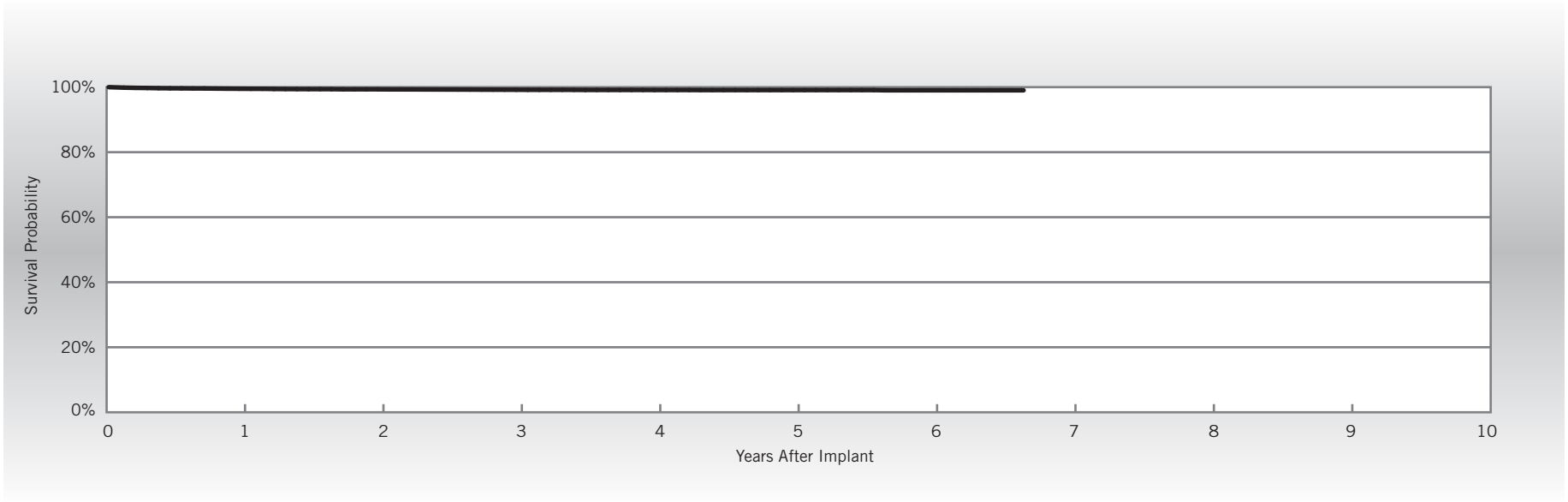
Tendril™ ST Optim™

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	14,387
Cumulative Months of Follow-up	562,618
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	4	0.03%
Extracardiac Stimulation	3	0.02%
Failure to Capture	16	0.11%
Failure to Sense	4	0.03%
Insulation Breach	11	0.08%
Lead Dislodgement	53	0.37%
Oversensing	9	0.06%
Skin Erosion	1	<0.01%

Malfunctions	Qty	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	12	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	23	0.16%
Total	**36**	**0.25%**



Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.51%	99.34%	99.20%	99.12%	99.10%	99.03%	99.03%			
± 1 standard error	0.06%	0.07%	0.08%	0.08%	0.09%	0.11%	0.11%			
Sample Size	13580	11720	9500	6790	3950	1690	60			

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

Customer Reported Performance Data

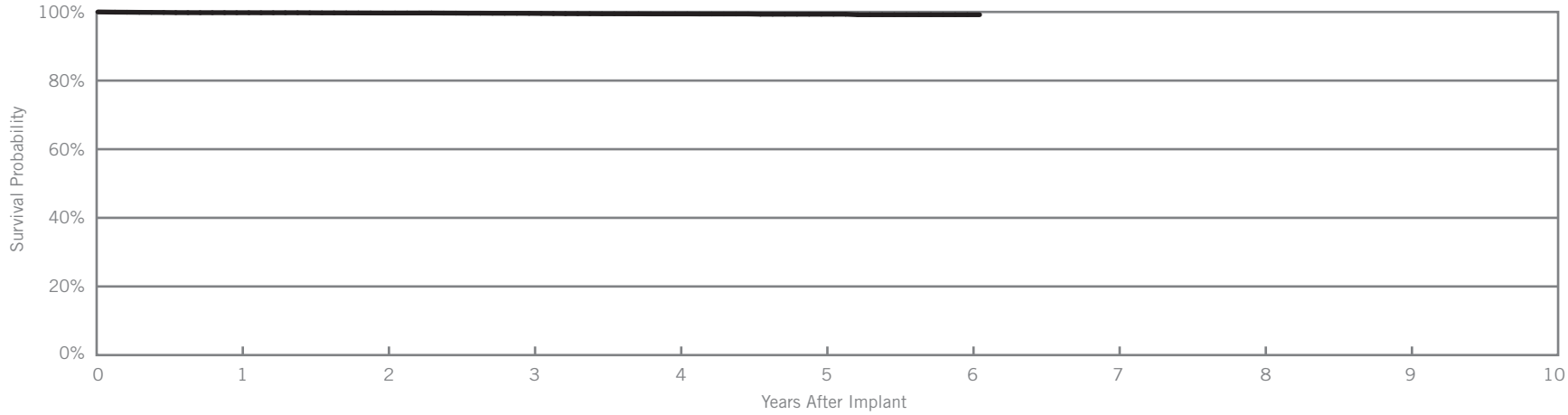
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	30,999
Estimated Active US Implants	22,670
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	2	<0.01%
Lead Dislodgement	15	0.05%	39	0.13%
Failure to Capture	5	0.02%	18	0.06%
Oversensing	2	<0.01%	11	0.04%
Failure to Sense	2	<0.01%	3	<0.01%
Insulation Breach	0	0.00%	8	0.03%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	<0.01%	7	0.02%
Total	**27**	**0.09%**	**88**	**0.28%**
Total Returned for Analysis	**12**		**51**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	14	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	46	0.15%
Total	**64**	**0.21%**



Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.78%	99.69%	99.59%	99.43%	99.34%	99.19%	99.19%			
± 1 standard error	0.03%	0.04%	0.05%	0.07%	0.08%	0.14%	0.14%			
Sample Size	26270	18060	11850	6990	3300	980	200			

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

Actively Monitored Study Data

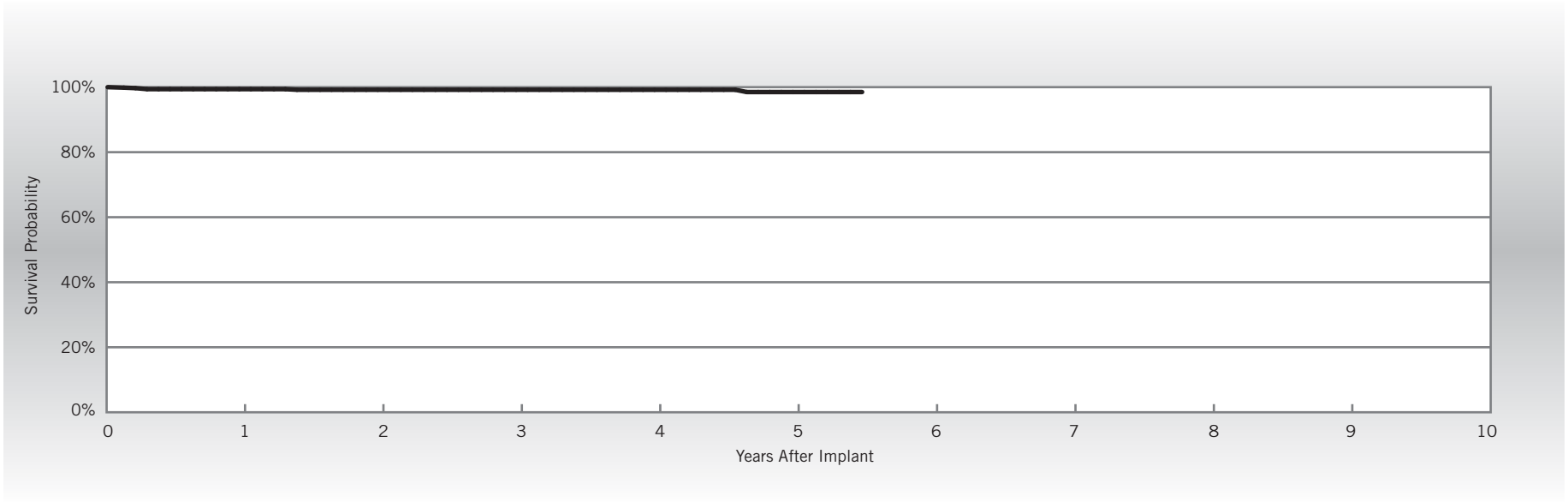
Tendril™ ST Optim™

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	673
Cumulative Months of Follow-up	24,366
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Extracardiac Stimulation	1	0.15%
Failure to Capture	1	0.15%
Lead Dislodgement	2	0.30%
Oversensing	1	0.15%
Skin Erosion	1	0.15%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.15%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**1**	**0.15%**



Year	1	2	3	4	5	at 66 months				
Survival Probability	99.39%	99.20%	99.20%	99.20%	98.50%	98.50%				
± 1 standard error	0.31%	0.36%	0.36%	0.36%	0.79%	0.79%				
Sample Size	630	530	400	290	170	50				

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

Customer Reported Performance Data

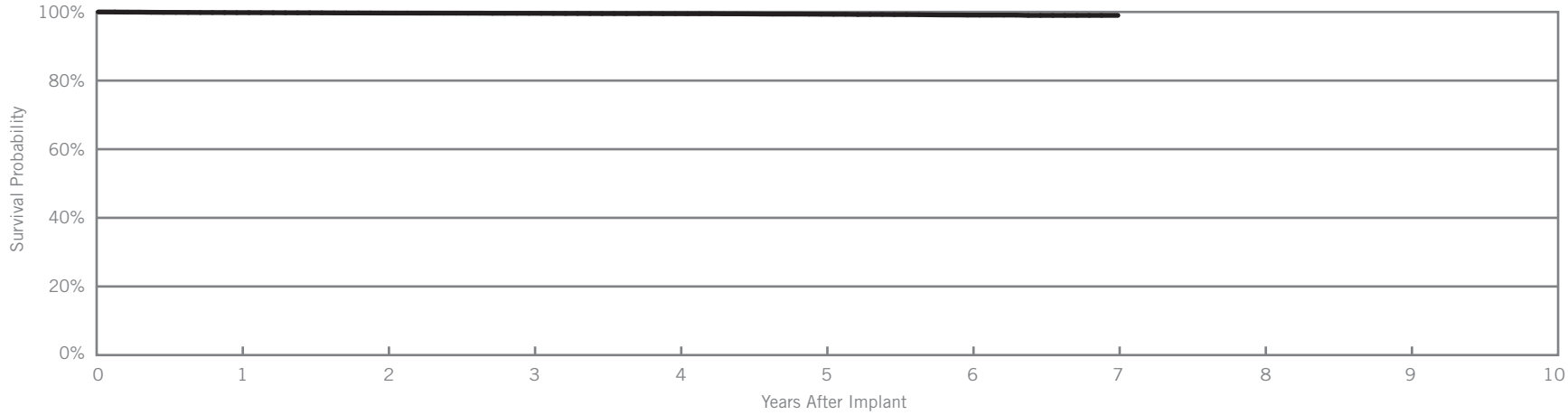
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,330
Estimated Active US Implants	10,430
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.04%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	13	0.08%	29	0.18%
Failure to Capture	5	0.03%	16	0.10%
Oversensing	0	0.00%	4	0.02%
Failure to Sense	0	0.00%	3	0.02%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	2	0.01%	4	0.02%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	2	0.01%	1	<0.01%
Total	**29**	**0.18%**	**60**	**0.37%**
Total Returned for Analysis	**16**		**40**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	7	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	42	0.26%
Total	**50**	**0.31%**



Year	1	2	3	4	5	6	7			
Survival Probability	99.80%	99.68%	99.60%	99.49%	99.34%	99.09%	99.00%			
± 1 standard error	0.03%	0.05%	0.05%	0.07%	0.08%	0.11%	0.15%			
Sample Size	15120	12850	10630	8280	5860	3340	210			

Actively Monitored Study Data

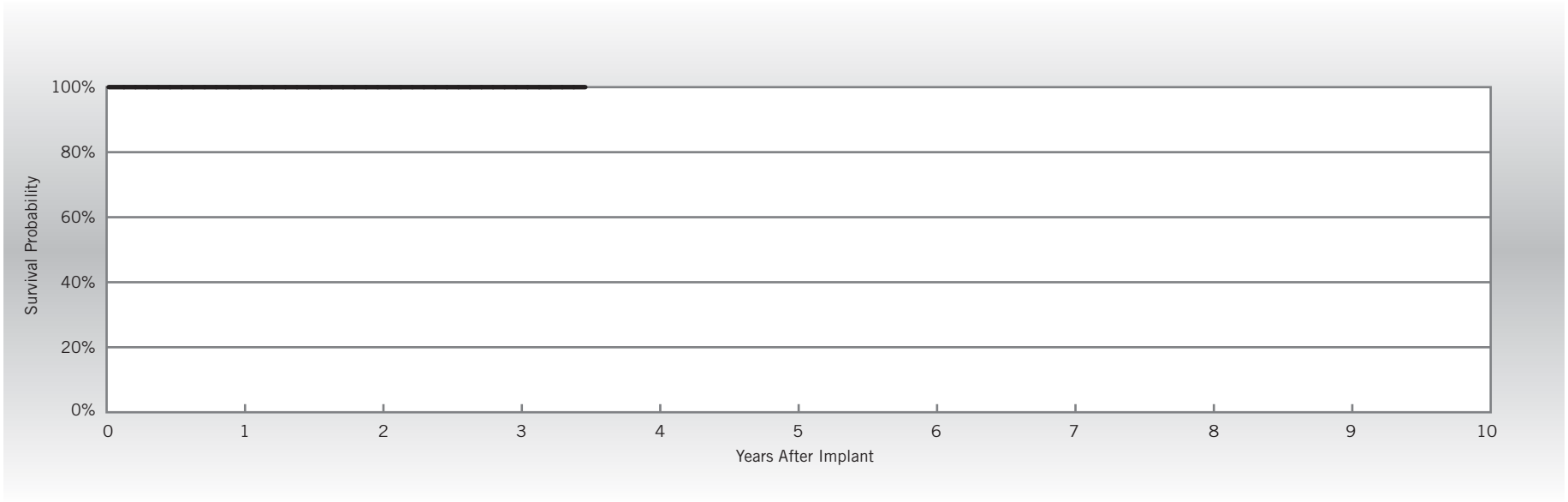
Tendril™

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	166
Cumulative Months of Follow-up	5,171
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

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 42 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	150	120	80	50						

Customer Reported Performance Data

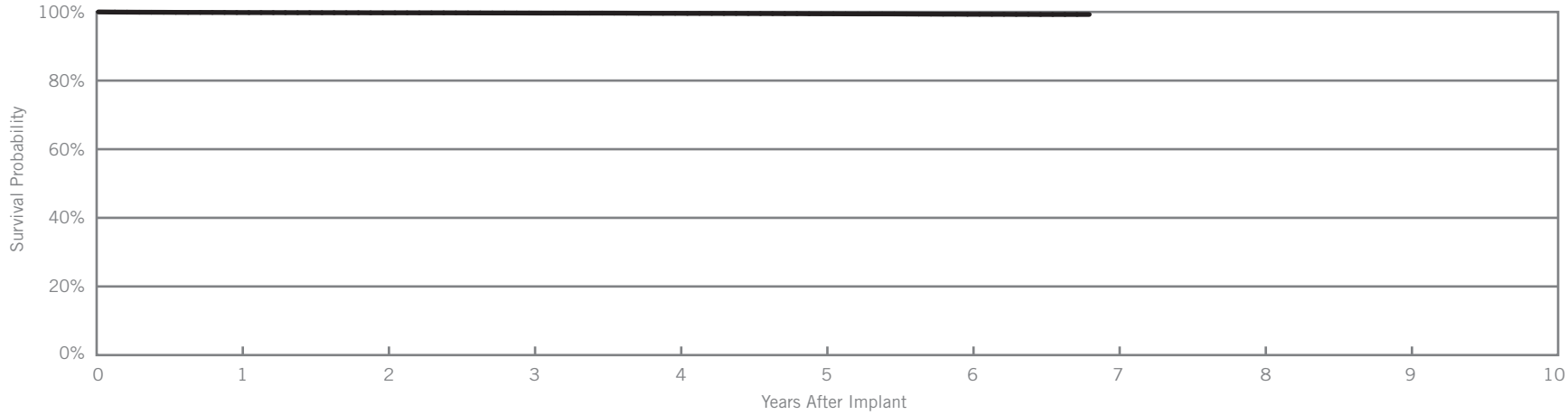
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,079
Estimated Active US Implants	36,421
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	12	0.02%	3	<0.01%
Conductor Fracture	1	<0.01%	7	0.01%
Lead Dislodgement	31	0.05%	42	0.06%
Failure to Capture	30	0.05%	53	0.08%
Oversensing	2	<0.01%	39	0.06%
Failure to Sense	2	<0.01%	7	0.01%
Insulation Breach	1	<0.01%	11	0.02%
Abnormal Pacing Impedance	9	0.01%	15	0.02%
Extracardiac Stimulation	2	<0.01%	2	<0.01%
Other	20	0.03%	8	0.01%
Total	**110**	**0.17%**	**187**	**0.29%**
Total Returned for Analysis	**43**		**98**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	43	0.07%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	83	0.13%
Total	**131**	**0.20%**



Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.83%	99.75%	99.68%	99.60%	99.46%	99.32%	99.27%			
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%	0.05%			
Sample Size	60430	52550	45850	38330	29610	18760	610			

Actively Monitored Study Data

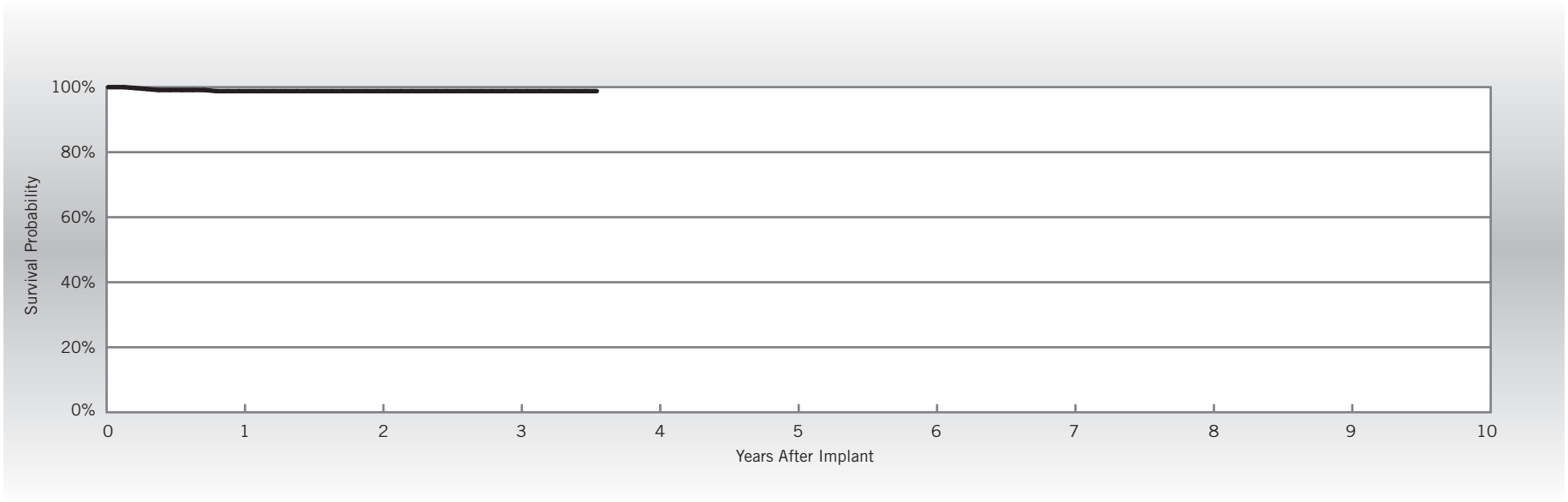
Tendril™

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	360
Cumulative Months of Follow-up	9,284
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	at 43 months						
Survival Probability	98.78%	98.78%	98.78%	98.78%						
± 1 standard error	0.61%	0.61%	0.61%	0.61%						
Sample Size	310	240	160	50						

Customer Reported Performance Data

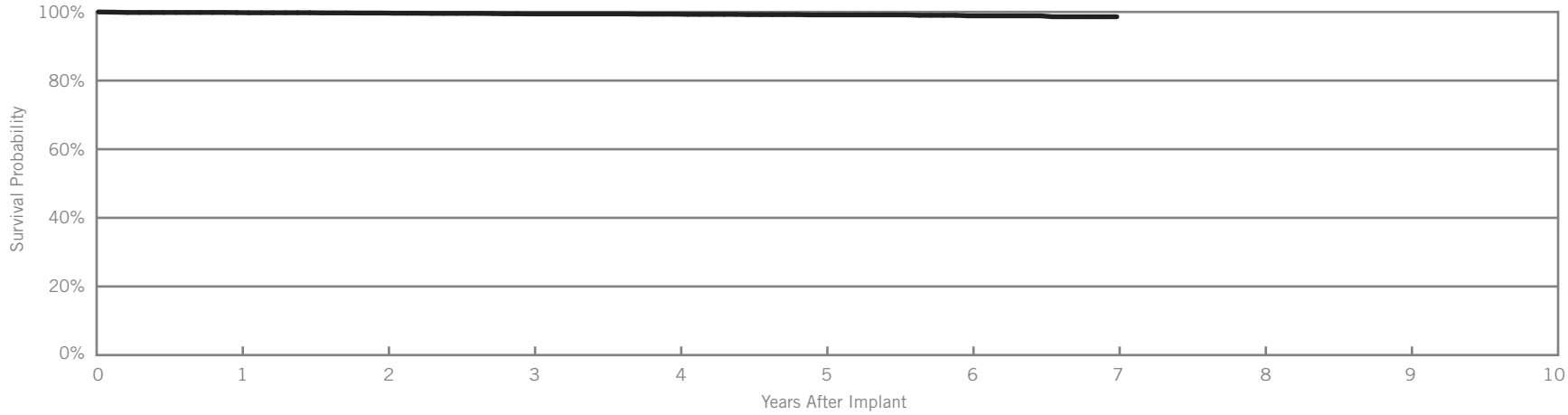
IsoFlex™ P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,823
Estimated Active US Implants	1,448
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	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	0.07%
Lead Dislodgement	2	0.07%	1	0.04%
Failure to Capture	2	0.07%	3	0.11%
Oversensing	0	0.00%	1	0.04%
Failure to Sense	1	0.04%	0	0.00%
Insulation Breach	0	0.00%	2	0.07%
Abnormal Pacing Impedance	0	0.00%	3	0.11%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	2	0.07%
Total	**6**	**0.21%**	**14**	**0.50%**
Total Returned for Analysis	**1**		**5**	

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



Year	1	2	3	4	5	6	7			
Survival Probability	99.81%	99.68%	99.42%	99.36%	99.15%	98.87%	98.60%			
± 1 standard error	0.07%	0.11%	0.15%	0.17%	0.21%	0.24%	0.40%			
Sample Size	2600	2240	1970	1730	1410	910	220			

Customer Reported Performance Data

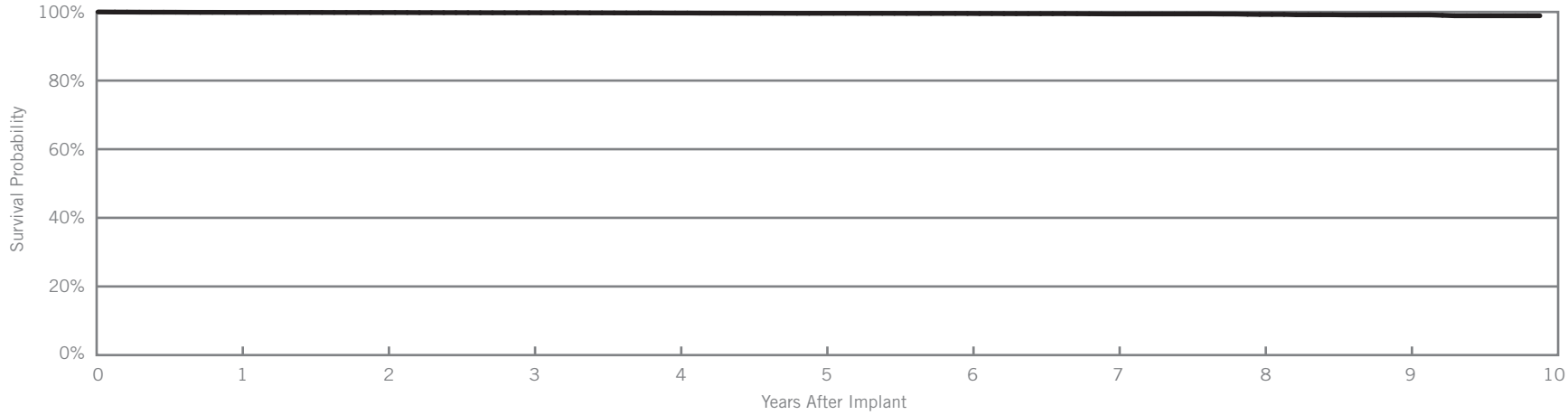
IsoFlex™ S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	26,871
Estimated Active US Implants	14,029
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	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	0.01%
Lead Dislodgement	49	0.18%	22	0.08%
Failure to Capture	6	0.02%	24	0.09%
Oversensing	0	0.00%	5	0.02%
Failure to Sense	3	0.01%	5	0.02%
Insulation Breach	0	0.00%	2	<0.01%
Abnormal Pacing Impedance	3	0.01%	2	<0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**62**	**0.23%**	**64**	**0.24%**
Total Returned for Analysis	**38**		**18**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	9	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	2	<0.01%
Extrinsic Factors	17	0.06%
Total	**29**	**0.11%**



Year	1	2	3	4	5	6	7	8	9	at 119 months
Survival Probability	99.87%	99.84%	99.77%	99.69%	99.61%	99.56%	99.42%	99.28%	99.14%	98.89%
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.05%	0.07%	0.09%	0.13%	0.22%
Sample Size	24880	21450	18510	15380	12090	8840	5960	3660	1860	210

Customer Reported Performance Data

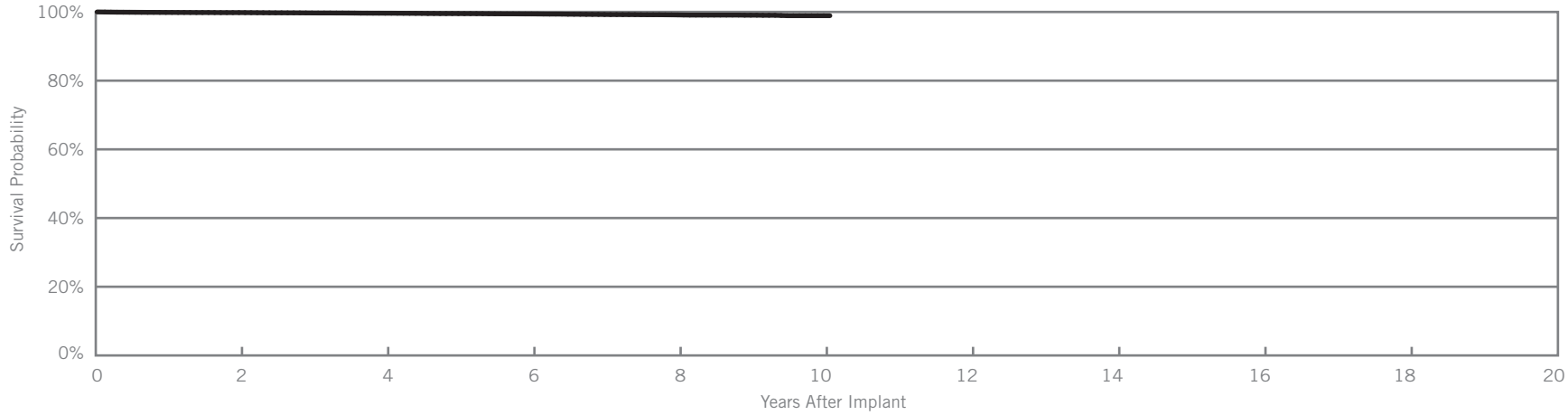
IsoFlex™ S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	90,098
Estimated Active US Implants	46,116
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	<0.01%	2	<0.01%
Conductor Fracture	2	<0.01%	50	0.06%
Lead Dislodgement	37	0.04%	28	0.03%
Failure to Capture	33	0.04%	119	0.13%
Oversensing	0	0.00%	27	0.03%
Failure to Sense	2	<0.01%	5	<0.01%
Insulation Breach	2	<0.01%	17	0.02%
Abnormal Pacing Impedance	6	<0.01%	33	0.04%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	<0.01%	11	0.01%
Total	**88**	**0.10%**	**293**	**0.33%**
Total Returned for Analysis	**38**		**63**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	16	0.02%
Insulation Breach	21	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	6	<0.01%
Extrinsic Factors	51	0.06%
Total	**94**	**0.10%**



Year	2	4	6	8	10	At 121 months				
Survival Probability	99.81%	99.63%	99.42%	99.14%	98.91%	98.91%				
± 1 standard error	0.02%	0.02%	0.03%	0.06%	0.11%	0.11%				
Sample Size	70840	48990	27270	10960	1700	200				

Actively Monitored Study Data

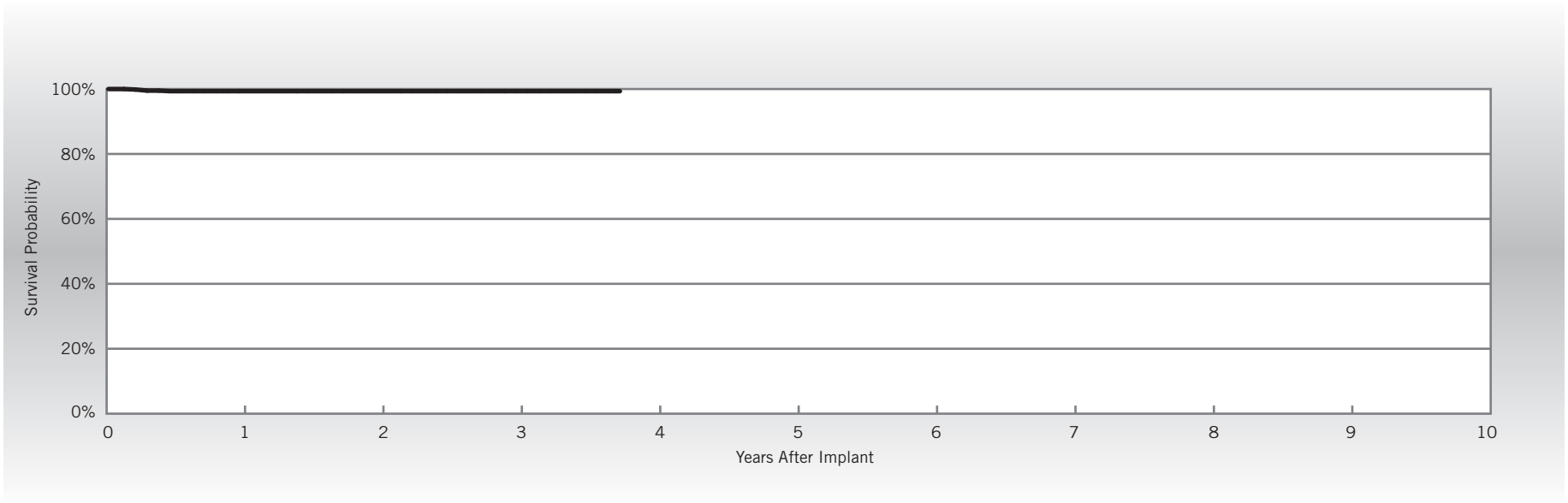
IsoFlex™ S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	639
Cumulative Months of Follow-up	15,615
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	3	0.47%
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	99.34%	99.34%	99.34%	99.34%						
± 1 standard error	0.33%	0.33%	0.33%	0.33%						
Sample Size	570	410	250	50						

Customer Reported Performance Data

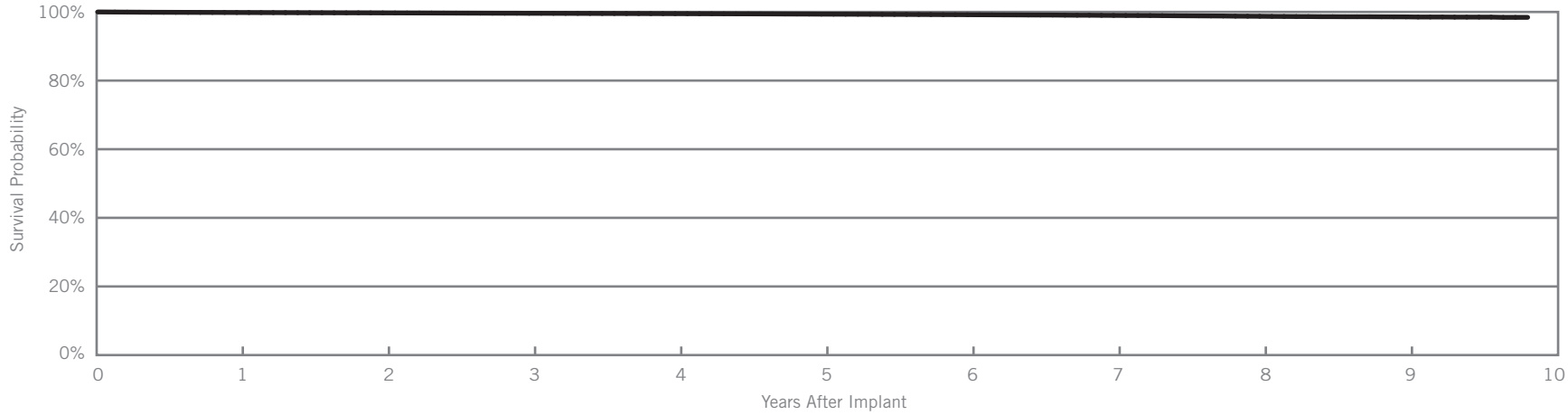
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	417,071
Estimated Active US Implants	226,190
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	54	0.01%	13	<0.01%
Conductor Fracture	4	<0.01%	174	0.04%
Lead Dislodgement	211	0.05%	280	0.07%
Failure to Capture	143	0.03%	527	0.13%
Oversensing	11	<0.01%	285	0.07%
Failure to Sense	22	<0.01%	37	<0.01%
Insulation Breach	7	<0.01%	88	0.02%
Abnormal Pacing Impedance	27	<0.01%	203	0.05%
Extracardiac Stimulation	4	<0.01%	17	<0.01%
Other	30	<0.01%	78	0.02%
Total	**513**	**0.12%**	**1702**	**0.41%**
Total Returned for Analysis	**232**		**722**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	141	0.03%
Insulation Breach	324	0.08%
Crimps, Welds & Bonds	2	<0.01%
Other	7	<0.01%
Extrinsic Factors	465	0.11%
Total	**939**	**0.23%**



Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.84%	99.73%	99.61%	99.50%	99.36%	99.20%	99.00%	98.74%	98.57%	98.43%
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.09%
Sample Size	378400	312380	259530	209780	164040	124390	86750	49290	19740	590

Actively Monitored Study Data

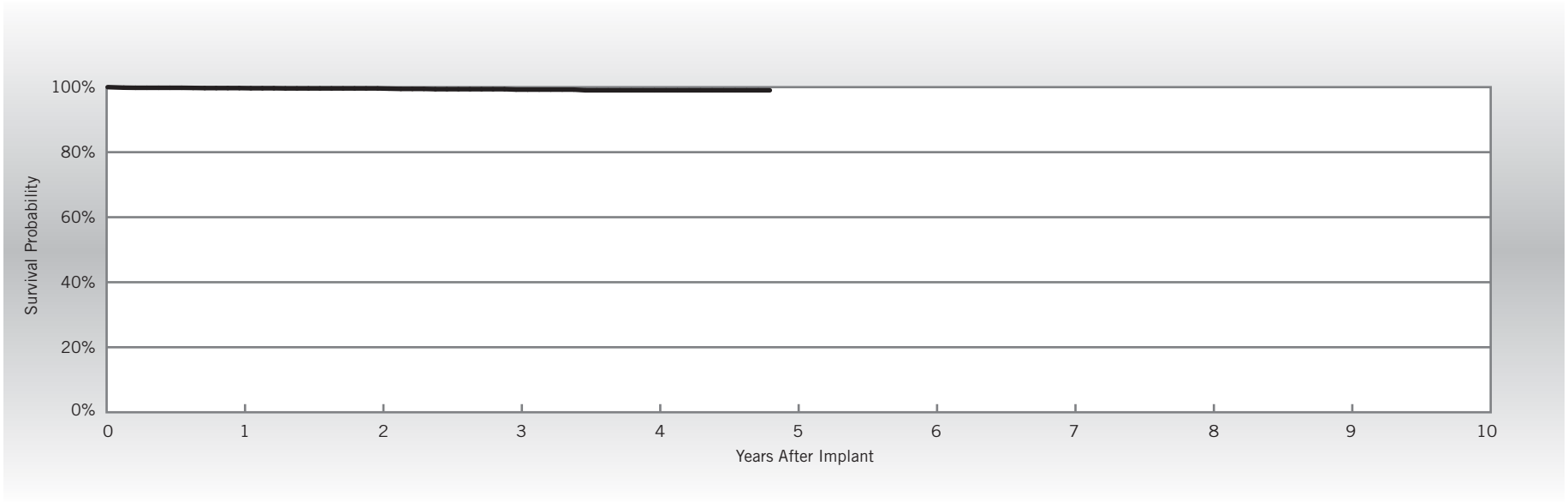
Tendril™ SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	2,577
Cumulative Months of Follow-up	65,936
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	2	0.08%
Conductor Fracture	2	0.08%
Failure to Capture	3	0.12%
Insulation Breach	2	0.08%
Lead Dislodgement	3	0.12%
Oversensing	1	0.04%
Pericardial Effusion	1	0.04%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.04%
Insulation Breach	3	0.12%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.19%
Total	**9**	**0.35%**



Year	1	2	3	4	at 58 months					
Survival Probability	99.71%	99.61%	99.24%	99.03%	99.03%					
± 1 standard error	0.11%	0.13%	0.19%	0.31%	0.31%					
Sample Size	2300	1700	1060	460	60					

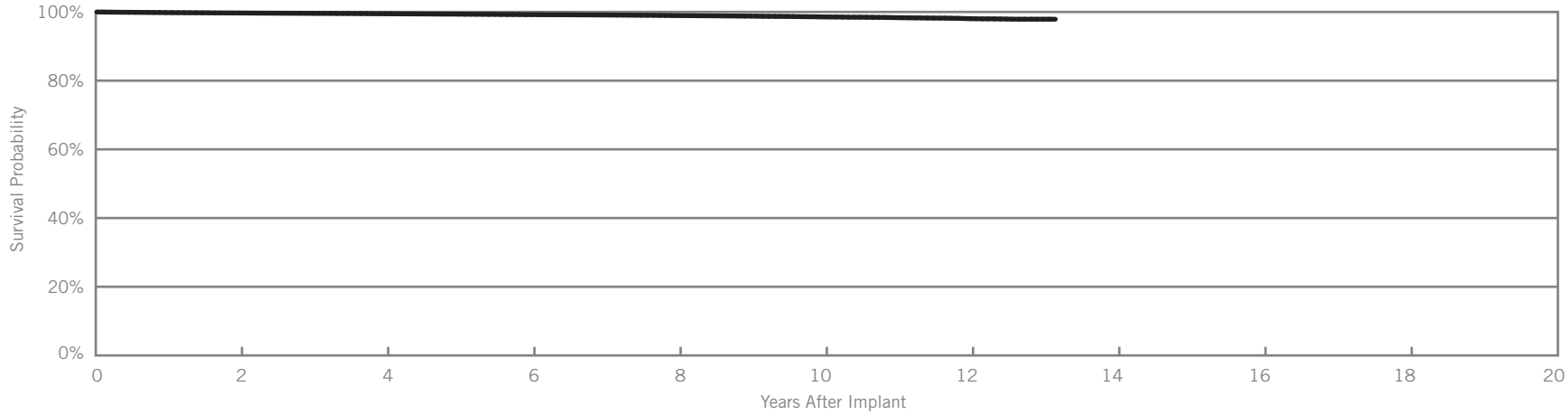
Customer Reported Performance Data

Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	270,663
Estimated Active US Implants	88,747
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	142	0.05%
Insulation Breach	142	0.05%
Crimps, Welds & Bonds	5	<0.01%
Other	2	<0.01%
Extrinsic Factors	319	0.12%
Total	**610**	**0.23%**



Year	2	4	6	8	10	12	At 158 months			
Survival Probability	99.69%	99.48%	99.22%	98.95%	98.55%	98.04%	97.89%			
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.06%	0.08%			
Sample Size	224620	182250	140770	100690	58730	16480	430			

Actively Monitored Study Data

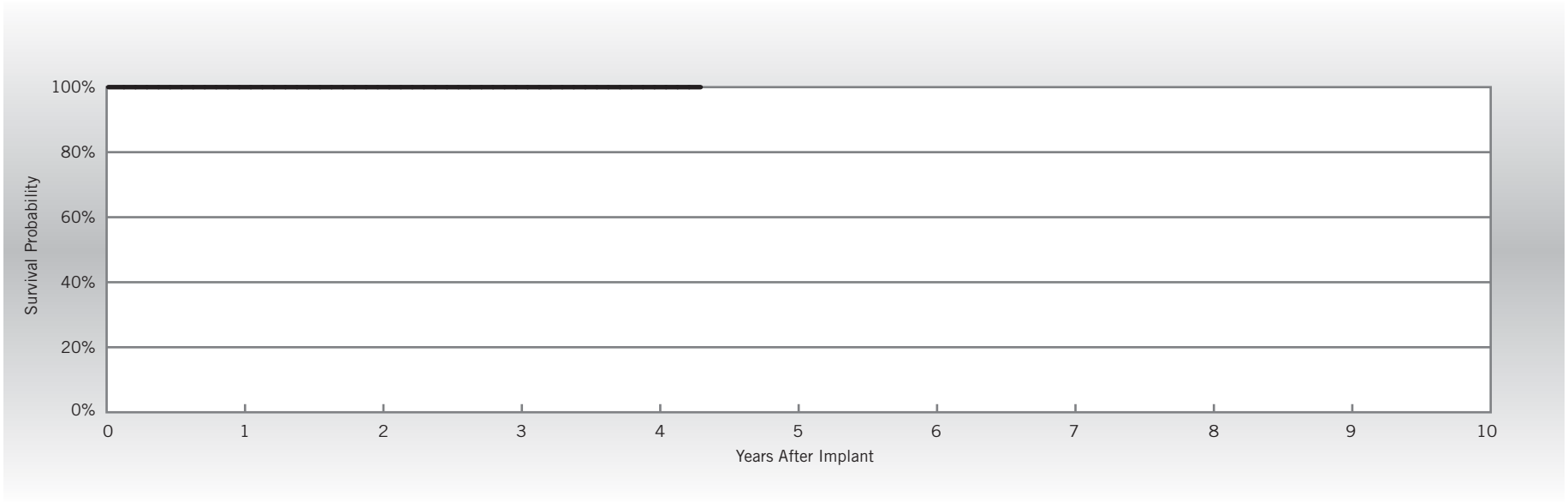
Tendril™ SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	796
Cumulative Months of Follow-up	22,288
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.13%
Total	**3**	**0.38%**



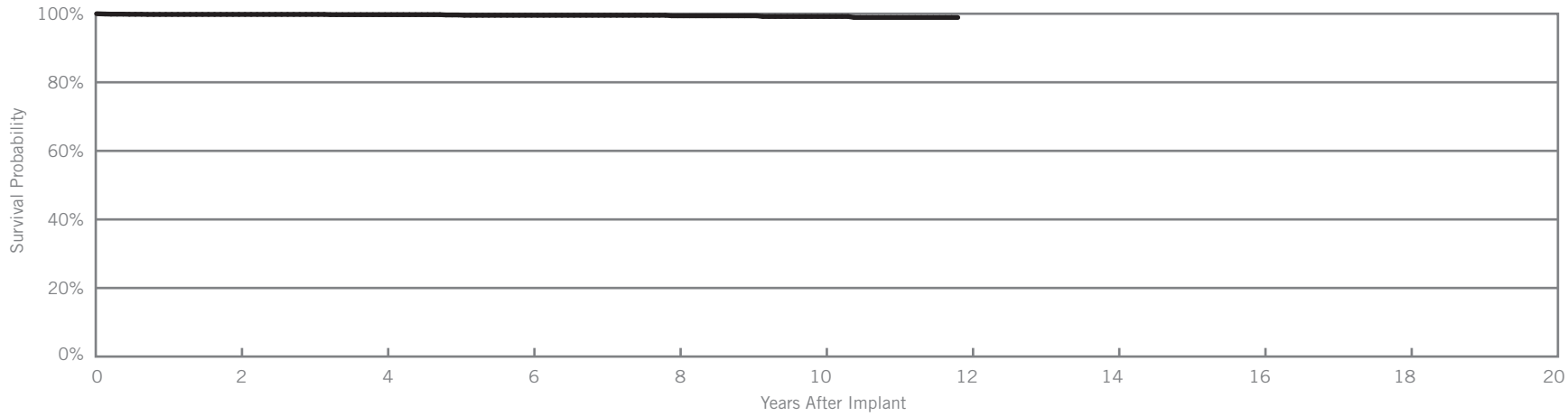
Year	1	2	3	4	at 52 months					
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%					
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%					
Sample Size	730	570	370	170	50					

Customer Reported Performance Data

AV Plus™ DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,690
Estimated Active US Implants	893
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



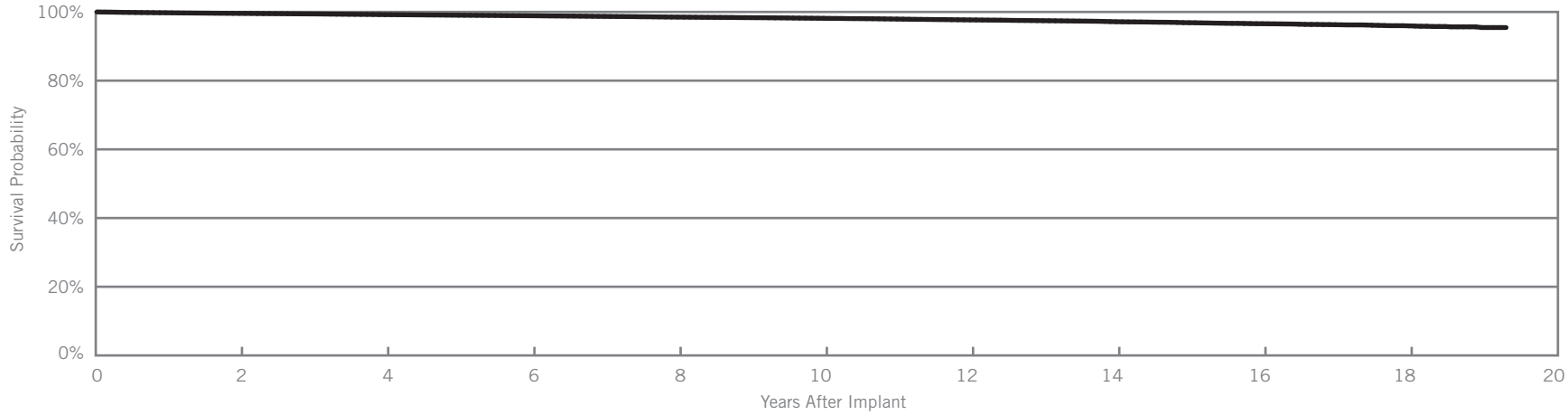
Year	2	4	6	8	10	At 142 months				
Survival Probability	99.80%	99.73%	99.55%	99.40%	99.20%	98.91%				
± 1 standard error	0.09%	0.11%	0.17%	0.23%	0.30%	0.42%				
Sample Size	1980	1450	1010	710	450	200				

Customer Reported Performance Data

Tendril™
Models 1148T & 1188T

Tendril™ DX
Models 1388T & 1388TC

US Regulatory Approval	(1148) June 1993; (1188T) June 1994; (1388T) June 1997
Registered US Implants	323,656
Estimated Active US Implants	71,391
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	(1148/1188) No; (1388) Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	At 232 months
Survival Probability	99.58%	99.22%	98.89%	98.50%	98.15%	97.68%	97.15%	96.58%	95.95%	95.46%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.04%	0.06%	0.09%	0.16%	0.30%
Sample Size	266830	215400	168140	123090	83660	52380	27330	9110	2680	250

Actively Monitored Study Data

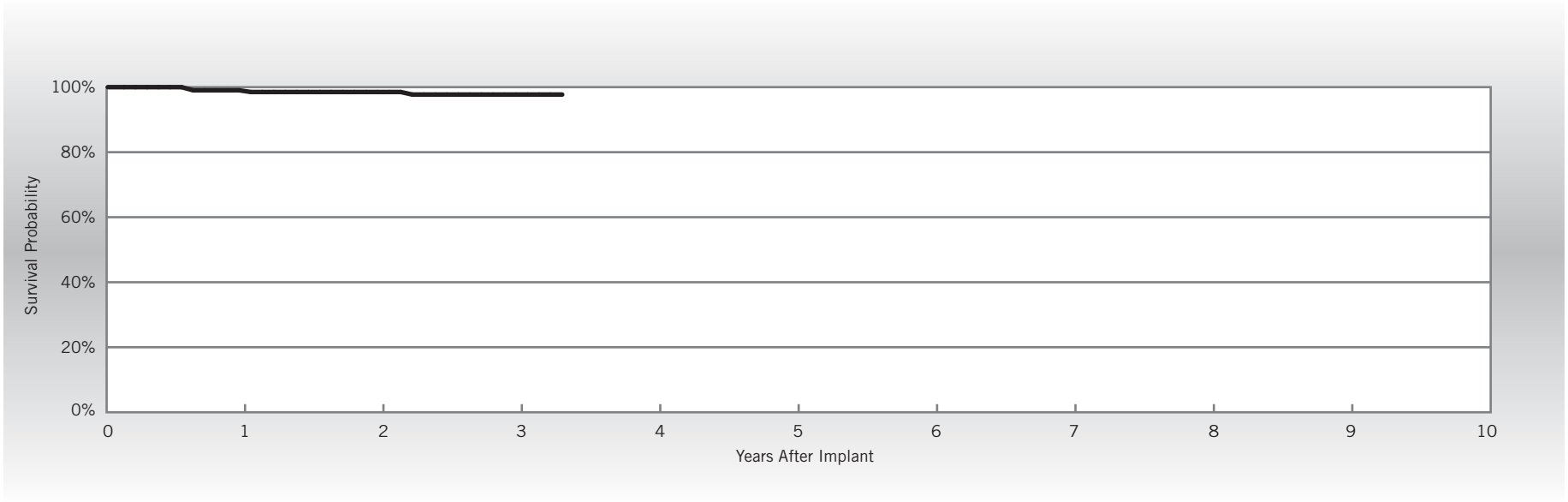
Tendril™ DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Number of Devices Enrolled in Study	228
Cumulative Months of Follow-up	6,216
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Conductor Fracture	1	0.44%
Failure to Capture	2	0.88%
Insulation Breach	1	0.44%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.44%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.44%
Total	**2**	**0.88%**



Year	1	2	3	at 40 months						
Survival Probability	99.03%	98.51%	97.72%	97.72%						
± 1 standard error	0.68%	0.85%	1.16%	1.16%						
Sample Size	210	170	100	60						

Customer Reported Performance Data

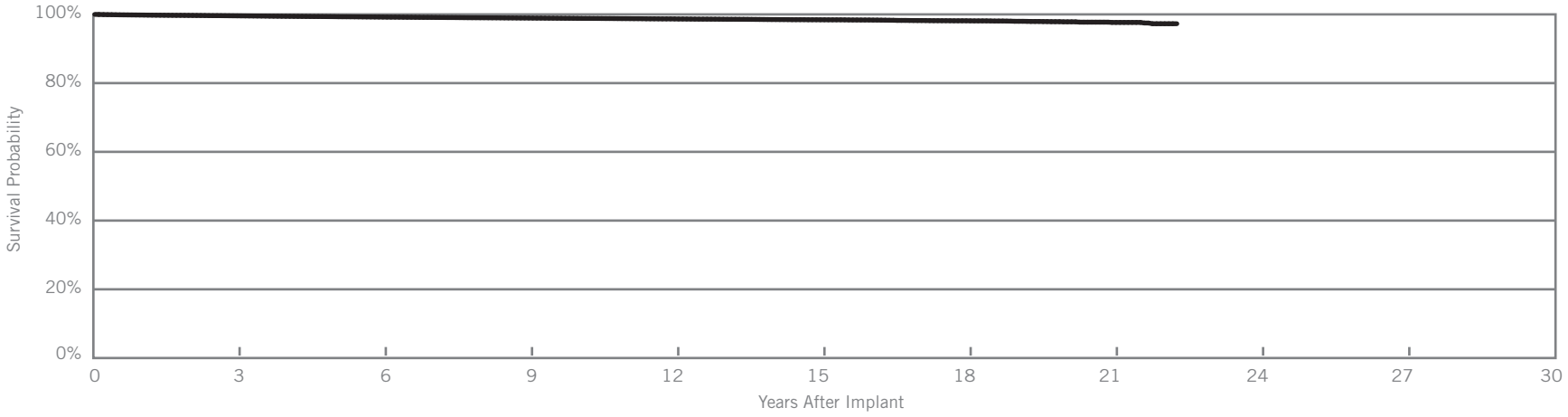
Passive Plus™

Models 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T

Passive Plus™ DX

Models 1336T, 1342T & 1346T

US Regulatory Approval	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990
Registered US Implants	371,176
Estimated Active US Implants	63,694
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Number of US Advisories	None



Year	3	6	9	12	15	18	21	at 268 months		
Survival Probability	99.58%	99.22%	98.94%	98.68%	98.43%	98.14%	97.66%	97.28%		
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.06%	0.13%	0.31%		
Sample Size	271520	189200	124010	68350	29400	9570	1840	220		

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	99.84%	99.68%	99.52%							
1999	OptiSense™ Optim™	99.75%	99.63%	99.47%							
1944	IsoFlex™ Optim™	99.81%	99.71%	99.62%	99.62%						
1948	IsoFlex™ Optim™	99.87%	99.74%	99.57%	99.40%						
1699T/TC	OptiSense™	99.78%	99.71%	99.61%	99.54%	99.37%					
1888T/TC	Tendril™ ST Optim™	99.80%	99.67%	99.53%	99.36%	99.14%	98.88%				
1882T/TC	Tendril™ ST Optim™	99.78%	99.69%	99.59%	99.43%	99.34%	99.19%				
1782T/TC	Tendril™	99.80%	99.68%	99.60%	99.49%	99.34%	99.09%	99.00%			
1788T/TC	Tendril™	99.83%	99.75%	99.68%	99.60%	99.46%	99.32%				
1648T	IsoFlex™ P	99.81%	99.68%	99.42%	99.36%	99.15%	98.87%	98.60%			
1642T	IsoFlex™ S	99.87%	99.84%	99.77%	99.69%	99.61%	99.56%	99.42%	99.28%	99.14%	
1646T	IsoFlex™ S	99.86%	99.81%	99.71%	99.63%	99.52%	99.42%	99.26%	99.14%	99.06%	98.91%
1688T/TC	Tendril™ SDX	99.84%	99.73%	99.61%	99.50%	99.36%	99.20%	99.00%	98.74%	98.57%	
1488T/TC	Tendril™ SDX	99.81%	99.69%	99.59%	99.48%	99.36%	99.22%	99.11%	98.95%	98.79%	98.55%

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	214435	176937	23	0.01%	1	<0.01%	129	0.06%	22	0.01%	6	<0.01%	7	<0.01%	4	<0.01%	7	<0.01%	0	0.00%	4	<0.01%	**203**	**0.09%**	**126**
1999	May-07	23849	19545	0	0.00%	0	0.00%	15	0.06%	2	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	**20**	**0.08%**	**12**
1944	Mar-08	9343	7208	0	0.00%	0	0.00%	24	0.26%	3	0.03%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**29**	**0.31%**	**19**
1948	Mar-08	33739	26007	1	<0.01%	0	0.00%	18	0.05%	8	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	**29**	**0.09%**	**19**
1699T/TC	May-07	22845	14340	1	<0.01%	0	0.00%	4	0.02%	3	0.01%	2	<0.01%	8	0.04%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**20**	**0.09%**	**16**
1888T/TC	Jun-06	261798	172940	32	0.01%	6	<0.01%	98	0.04%	64	0.02%	10	<0.01%	10	<0.01%	6	<0.01%	5	<0.01%	4	<0.01%	18	<0.01%	**253**	**0.10%**	**135**
1882T/TC	Jun-06	30999	22670	1	<0.01%	0	0.00%	15	0.05%	5	0.02%	2	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	<0.01%	**27**	**0.09%**	**12**
1782T/TC	Feb-06	16330	9848	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	65079	36421	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%**	**43**
1648T	Apr-05	2823	1448	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	26871	14029	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%**	**38**
1646T	May-02	90098	46116	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	417071	226190	54	0.01%	4	<0.01%	211	0.05%	143	0.03%	11	<0.01%	22	<0.01%	7	<0.01%	27	<0.01%	4	<0.01%	30	<0.01%	**513**	**0.12%**	**232**

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	214435	176937	9	<0.01%	13	<0.01%	129	0.06%	74	0.03%	93	0.04%	14	<0.01%	37	0.02%	14	<0.01%	1	<0.01%	15	<0.01%	**399**	**0.19%**	**280**
1999	May-07	23849	19545	0	0.00%	0	0.00%	39	0.16%	9	0.04%	6	0.03%	1	<0.01%	8	0.03%	0	0.00%	0	0.00%	2	<0.01%	**65**	**0.27%**	**46**
1944	Mar-08	9343	7208	0	0.00%	0	0.00%	14	0.15%	1	0.01%	2	0.02%	2	0.02%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	**21**	**0.22%**	**9**
1948	Mar-08	33739	26007	3	<0.01%	13	0.04%	10	0.03%	20	0.06%	14	0.04%	0	0.00%	5	0.01%	5	0.01%	0	0.00%	0	0.00%	**70**	**0.21%**	**25**
1699T/TC	May-07	22845	14340	0	0.00%	6	0.03%	23	0.10%	11	0.05%	13	0.06%	7	0.03%	2	<0.01%	5	0.02%	2	<0.01%	0	0.00%	**69**	**0.30%**	**41**
1888T/TC	Jun-06	261798	172940	23	<0.01%	58	0.02%	249	0.10%	214	0.08%	225	0.09%	27	0.01%	83	0.03%	39	0.01%	10	<0.01%	42	0.02%	**970**	**0.37%**	**547**
1882T/TC	Jun-06	30999	22670	0	0.00%	2	<0.01%	39	0.13%	18	0.06%	11	0.04%	3	<0.01%	8	0.03%	0	0.00%	0	0.00%	7	0.02%	**88**	**0.28%**	**51**
1782T/TC	Feb-06	16330	9848	0	0.00%	1	<0.01%	29	0.18%	16	0.10%	4	0.02%	3	0.02%	1	<0.01%	4	0.02%	1	<0.01%	1	<0.01%	**60**	**0.37%**	**40**
1788T/TC	Feb-06	65079	36421	3	<0.01%	7	0.01%	42	0.06%	53	0.08%	39	0.06%	7	0.01%	11	0.02%	15	0.02%	2	<0.01%	8	0.01%	**187**	**0.29%**	**98**
1648T	Apr-05	2823	1448	0	0.00%	2	0.07%	1	0.04%	3	0.11%	1	0.04%	0	0.00%	2	0.07%	3	0.11%	0	0.00%	2	0.07%	**14**	**0.50%**	**5**
1642T	May-02	26871	14029	0	0.00%	3	0.01%	22	0.08%	24	0.09%	5	0.02%	5	0.02%	2	<0.01%	2	<0.01%	0	0.00%	1	<0.01%	**64**	**0.24%**	**18**
1646T	May-02	90098	46116	2	<0.01%	50	0.06%	28	0.03%	119	0.13%	27	0.03%	5	<0.01%	17	0.02%	33	0.04%	1	<0.01%	11	0.01%	**293**	**0.33%**	**63**
1688T/TC	Jun-03	417071	226190	13	<0.01%	174	0.04%	280	0.07%	527	0.13%	285	0.07%	37	<0.01%	88	0.02%	203	0.05%	17	<0.01%	78	0.02%	**1702**	**0.41%**	**722**

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

Malfunction Summary

Models	Registered US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088TC	214435	8	<0.01%	82	0.04%	0	0.00%	13	<0.01%	239	0.11%	**342**	**0.16%**
1999	23849	2	<0.01%	3	0.01%	0	0.00%	3	0.01%	45	0.19%	**53**	**0.22%**
1944	9343	0	0.00%	1	0.01%	0	0.00%	1	0.01%	7	0.07%	**9**	**0.10%**
1948	33739	2	<0.01%	9	0.03%	0	0.00%	1	<0.01%	25	0.07%	**37**	**0.11%**
1699T/TC	22845	8	0.04%	10	0.04%	0	0.00%	0	0.00%	39	0.17%	**57**	**0.25%**
1888T/TC	261798	19	<0.01%	222	0.08%	1	<0.01%	10	<0.01%	464	0.18%	**716**	**0.27%**
1882T/TC	30999	1	<0.01%	14	0.05%	0	0.00%	3	<0.01%	46	0.15%	**64**	**0.21%**
1782T/TC	16330	1	<0.01%	7	0.04%	0	0.00%	0	0.00%	42	0.26%	**50**	**0.31%**
1788T/TC	65079	3	<0.01%	43	0.07%	1	<0.01%	1	<0.01%	83	0.13%	**131**	**0.20%**
1648T	2823	0	0.00%	4	0.14%	0	0.00%	2	0.07%	4	0.14%	**10**	**0.35%**
1642T	26871	0	0.00%	9	0.03%	1	<0.01%	2	<0.01%	17	0.06%	**29**	**0.11%**
1646T	90098	16	0.02%	21	0.02%	0	0.00%	6	<0.01%	51	0.06%	**94**	**0.10%**
1688T/TC	417071	141	0.03%	324	0.08%	2	<0.01%	7	<0.01%	465	0.11%	**939**	**0.23%**
1488T/TC	270663	142	0.05%	142	0.05%	5	<0.01%	2	<0.01%	319	0.12%	**610**	**0.23%**

Definitions of malfunction categories can be found on pages 10-11.

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	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
2088	3437	74297	1	0.03%	1	0.03%	0	0.00%	0	0.00%	2	0.06%	1	0.03%	4	0.12%	9	0.26%	0	0.00%	1	0.03%	0	0.00%	19	0.55%	13	0.41%
1999	767	15408	1	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.91%	0	0.00%	0	0.00%	0	0.00%	8	1.04%	6	0.86%
1944	101	3765	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.99%	0	0.00%	0	0.00%	0	0.00%	1	0.99%	1	1.00%
1948	766	22740	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.13%	0	0.00%	1	0.13%	1	0.13%	0	0.00%	0	0.00%	0	0.00%	3	0.39%	3	0.39%
1699T/TC	1451	50355	1	0.07%	0	0.00%	1	0.07%	0	0.00%	2	0.14%	0	0.00%	1	0.07%	7	0.48%	1	0.07%	0	0.00%	0	0.00%	13	0.90%	12	0.83%
1888T/TC	14387	562618	6	0.04%	2	0.01%	4	0.03%	3	0.02%	16	0.11%	4	0.03%	11	0.08%	53	0.37%	9	0.06%	0	0.00%	1	<0.01%	109	0.76%	109	0.76%
1882T/TC	673	24366	0	0.00%	0	0.00%	0	0.00%	1	0.15%	1	0.15%	0	0.00%	0	0.00%	2	0.30%	1	0.15%	0	0.00%	1	0.15%	6	0.89%	5	0.76%
1782T/TC	166	5171	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%
1788T/TC	360	9284	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	1.11%	4	1.11%
1646T	639	15615	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.47%	0	0.00%	0	0.00%	1	0.16%	0	0.00%	0	0.00%	0	0.00%	4	0.63%	3	0.47%
1688T/TC	2577	65936	2	0.08%	0	0.00%	2	0.08%	0	0.00%	3	0.12%	0	0.00%	2	0.08%	3	0.12%	1	0.04%	1	0.04%	0	0.00%	14	0.54%	13	0.51%
1488T/TC	796	22288	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%
1388T/TC	228	6216	0	0.00%	0	0.00%	1	0.44%	0	0.00%	2	0.88%	0	0.00%	1	0.44%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	1.75%	3	1.20%

Malfunctions

Models	Number of Devices Enrolled	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	3437	0	0.00%	3	0.09%	0	0.00%	0	0.00%	2	0.06%	**5**	**0.15%**
1999	767	0	0.00%	2	0.26%	0	0.00%	0	0.00%	3	0.39%	**5**	**0.65%**
1944	101	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	766	0	0.00%	1	0.13%	0	0.00%	0	0.00%	1	0.13%	**2**	**0.26%**
1699T/TC	1451	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.34%	**5**	**0.34%**
1888T/TC	14387	1	<0.01%	12	0.08%	0	0.00%	0	0.00%	23	0.16%	**36**	**0.25%**
1882T/TC	673	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.15%**
1782T/TC	166	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	360	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	639	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	2577	1	0.04%	3	0.12%	0	0.00%	0	0.00%	5	0.19%	**9**	**0.35%**
1488T/TC	796	0	0.00%	2	0.25%	0	0.00%	0	0.00%	1	0.13%	**3**	**0.38%**
1388T/TC	228	0	0.00%	1	0.44%	0	0.00%	0	0.00%	1	0.44%	**2**	**0.88%**

Definitions of malfunction categories can be found on pages 10-11.
A list of complications can be found on page 15.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical

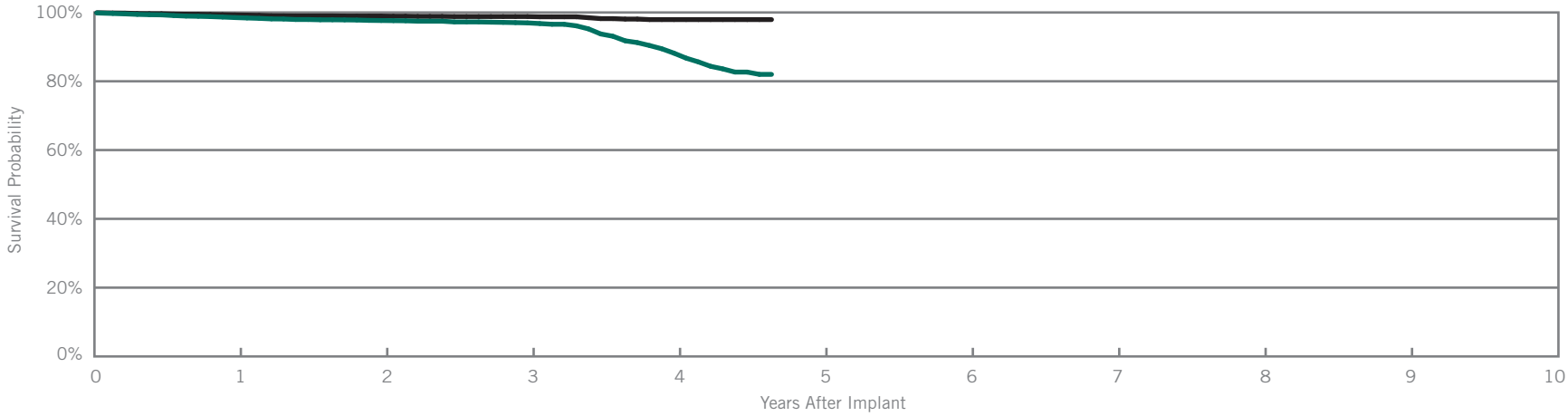
Customer Reported Performance Data

SJM Confirm™

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	14,161
Estimated Active US Implants	8,581
Estimated Longevity	3 Years*
Normal Battery Depletion	125
Number of US Advisories (see pgs. 272-284)	One

	Malfunctions	
	Qty	**Rate**
Electrical Component	1	<0.01%
Electrical Interconnect	1	<0.01%
Battery	10	0.07%
Software/Firmware	11	0.08%
Mechanical	0	0.00%
Possible Early Battery Depletion	3	0.02%
Other	25	0.18%
Total	**51**	**0.36%**



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	98.52%	97.66%	96.97%	88.17%	82.00%					
± 1 standard error	0.11%	0.16%	0.21%	0.67%	1.16%					
Sample Size	11100	6390	3660	1780	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.29%	98.96%	98.82%	97.93%	97.93%					
± 1 standard error	0.08%	0.11%	0.12%	0.25%	0.25%					

**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™	98.52%	97.66%	96.97%	88.17%						

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™	99.29%	98.96%	98.82%	97.93%						

Malfunction Summary

Models	Family	Registered US Implants	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™	14161	1	<0.00%	1	<0.00%	10	0.07%	11	0.08%	0	0.00%	3	0.02%	25	0.18%	51	0.36%

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 Heart Rhythm Society Scientific Sessions and detailed in a peer-reviewed manuscript.[1,2]

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. Enrollment is ongoing in CLAS. The following summaries for Riata/Riata ST and QuickSite/QuickFlex leads represent all data collected as of November 19, 2013. The Durata leads CLAS summary is available on page 264.

[1]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.
[2]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, in press, 2013.

Riata™/Riata™ ST CLAS Summary (as of Nov 19, 2013): 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 434 patients completed at least 1 year of follow-up with fluoroscopic evaluation (8F/7F=63.6%/36.4%). The time from implant for 8F Riata leads was 8.1±1.5 years (mean±stdev; median = 8.0 years; IQR = 7.1 to 9.0 years). The time from implant for 7F Riata ST leads was 6.4±0.9 years (mean±stdev; median = 6.6 years; IQR = 5.9 to 7.1 years). The incidence of new EC after 1 year in the study was 1.4% in 7F leads and 3.9% in 8F leads (p=0.21). During a mean follow-up period of 16.7±5.2 months (mean±stdev), a total of 14 leads (5 with EC, 9 without EC) were identified as having electrical dysfunction. There was no significant difference in the proportion of electrical failures in leads with and without EC (3.2% vs. 1.5%, p=0.16). Fluoroscopy data for 8 additional leads are pending adjudication and enrollment of Riata/Riata ST leads is on-going in the Cardiac Lead Assessment Study.

QuickSite™/QuickFlex™ CLAS Summary (as of Nov 19, 2013): A total of 179 patients implanted with QuickSite/QuickFlex Left Ventricular CRT leads at 26 centers underwent fluoroscopic evaluation. These include 20 leads implanted in 2006, 13 leads in 2007, 35 leads in 2008, 64 leads in 2009, and 47 leads in 2010, with an implant duration of 4.6±1.2 years (mean±stdev; median = 4.5 years; IQR = 3.6 to 5.5 years). The prevalence of externalized conductors at enrollment was 1.1%. The mean follow-up was 8.4±7.3 months (mean±stdev), during which there have been no cases of electrical dysfunction. Fluoroscopy data for 217 additional leads are pending adjudication and enrollment of QuickSite/QuickFlex leads is on-going in the Cardiac Lead Assessment Study.

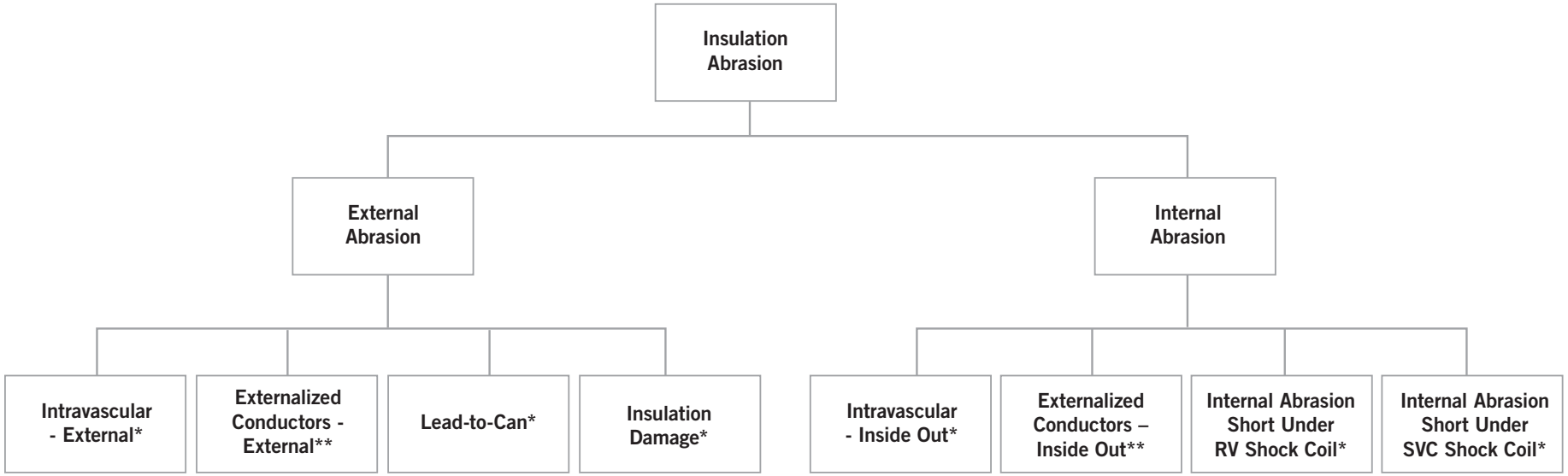
Customer Reported Performance Data

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 August 31, 2013, there were 3402 cases of externalized conductors reported to St. Jude Medical worldwide on Riata™ (8F) and Riata™ ST (7F) silicone defibrillation leads, equating to a 1.85% (2890/156,000) incidence rate for Riata (8F) and 0.73% (512/70,600) for Riata ST (7F) leads. Of these 3402 leads, 2660 were not returned and 742 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 9,800 Riata and Riata ST leads have been returned for analysis worldwide through August 31, 2013. 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) 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	0.28%	0.24%
Externalized Conductors – External**	External Abrasion	0.25%	0.12%
Lead-to-Can*	External Abrasion	0.60%	0.53%
Insulation Damage*	External Abrasion	0.07%	0.04%
Intravascular - Inside Out*	Internal Abrasion	0.30%	0.14%
Externalized Conductors - Inside Out**	Internal Abrasion	1.62%	0.61%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.07%	0.02%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.05%	0.004%

*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 pages 259-260, 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. While CLAS enrollment in ongoing, the data as of November 19, 2013 has found no evidence of conductor externalization in Durata leads. A total of 507 patients implanted with Durata leads at 26 centers underwent fluoroscopic evaluation. These include 111 leads implanted in 2008, 194 leads in 2009, and 202 leads in 2010, with an implant duration of 3.9±0.8 years (mean±stdev; median = 3.8 years; IQR = 3.2 to 4.5 years). None of the 507 leads exhibited externalized conductors. During a mean follow-up period of 3.5±1.8 months (mean±stdev), there have been no cases of electrical dysfunction. Fluoroscopy data for 34 additional leads are pending adjudication and enrollment of Durata leads is on-going in the Cardiac Lead Assessment Study.

Since 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). Currently, a total of 11,016 Optim insulated leads (8,149 Durata and 2,867 Riata ST Optim leads) are enrolled in these three studies at 293 sites. The raw data from these three registry studies, current as of August 31, 2013, were independently analyzed by the Population Health Research Institute (PHRI) of McMaster University/Hamilton Health Science.[1] 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. Overall incidence rates for these three failure categories are provided in the table on page 265.

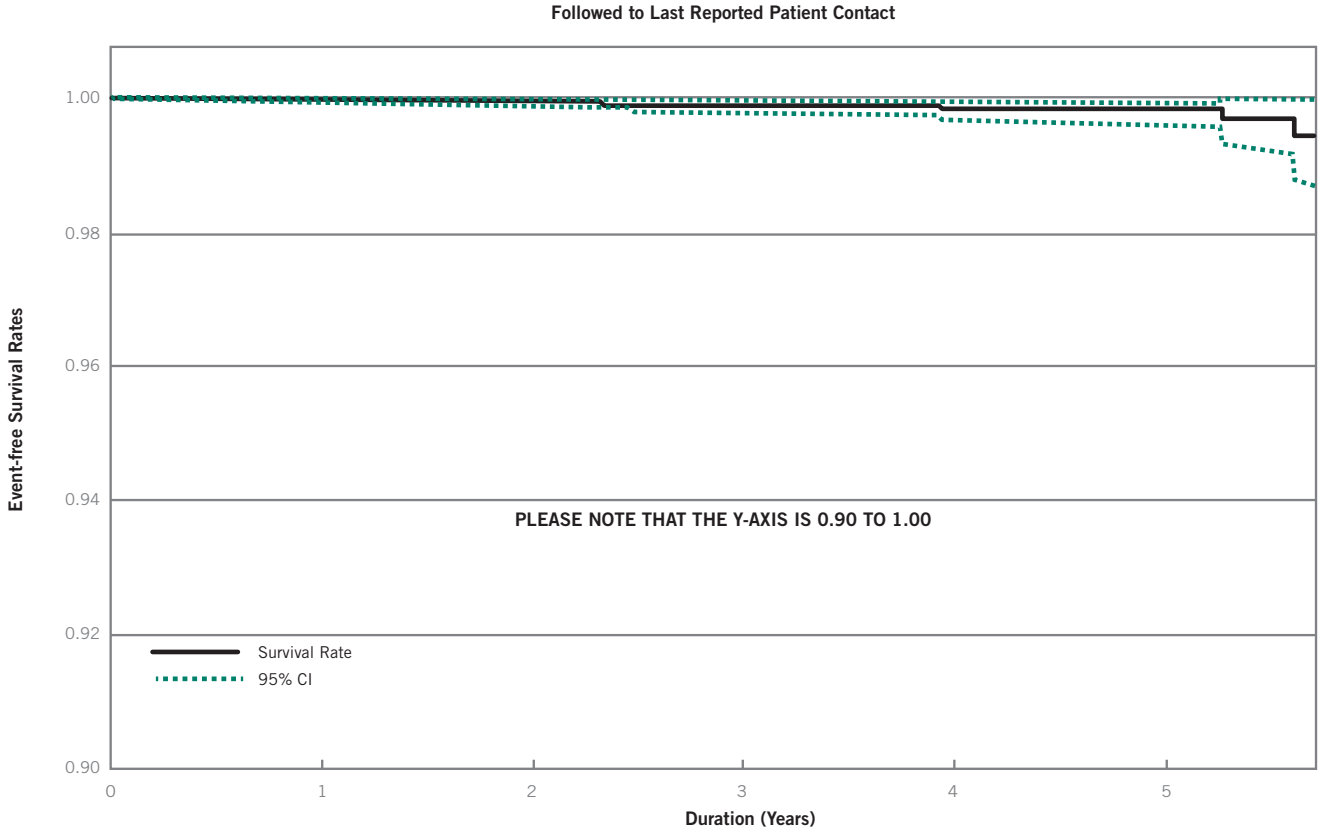
[1]John A. Cairns, John Rickard, Christopher E. Buller, Stuart J. Connolly, Andrew E. Epstein, Jeffrey S. Healey, Janice Pogue, Ellison Themeles and Bruce L. Wilkoff, *Optim ICD Lead Failures: Long-term Rates From An Independent Analysis Of >10,000 Leads In 3 Prospective Registries*, Heart Rhythm Society's Annual Scientific Sessions, Denver, CO, May 9, 2013.

An Independent Analysis of Durata™ and Riata™ ST Optim™ Lead Failure Rates in Active Registries by PHRI (data through August 31, 2013)

Failure Category	Durata and Riata ST Optim %	Durata and Riata ST Optim 95% CI	Freedom from failures at 5 years (%)
Externalized Conductors	0.00%	0.00% - 0.03%	100%
All-Cause Insulation Abrasion	0.12%	0.06% - 0.19%	99.8%
All-Cause Mechanical Failures	0.46%	0.34% - 0.60%	99.3%

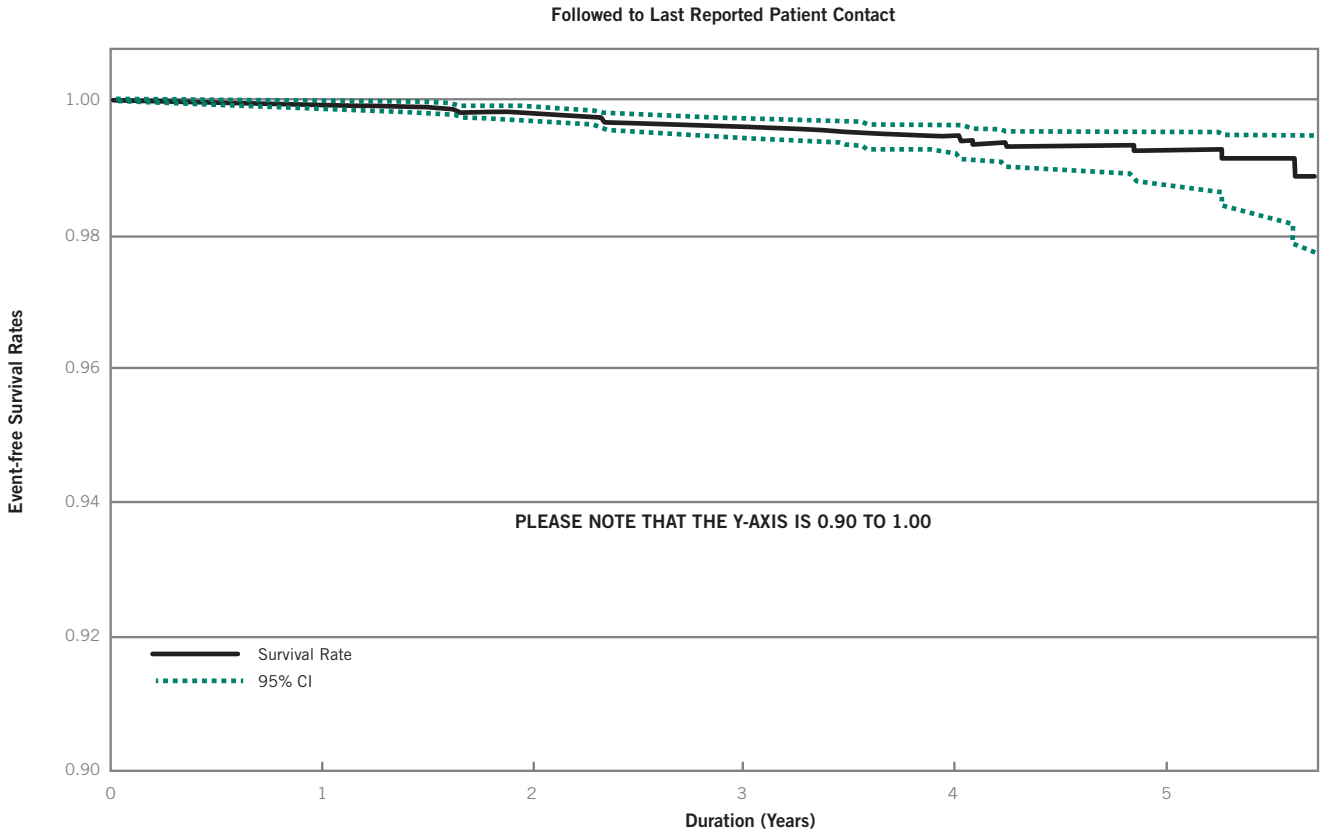
Event-Free Survival Rates for All-Cause Insulation Abrasion (Figure 1), and All-Cause Mechanical Failures (Figure 2) in Optim™ ICD leads were calculated by PHRI. The follow-up duration for active leads was based on last reported patient contact either in office or through remote monitoring. Lead implant date is used as time zero for these survival curves.

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
Leads at Risk	11016	9971	8407	6426	3391	1131

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
Leads at Risk	11016	9965	8397	6408	3380	1127

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 10,200 Riata ST Optim and Durata leads have been returned for analysis worldwide through August 31, 2013. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive.

Durata™ (WW Sales 392,300) and Riata™ ST Optim™ (WW Sales = 33,000) Leads Insulation Failure Mechanisms from Complaints and Returns Analysis

Insulation Failure Mechanism	Abrasion Type	Optim Defib Lead Worldwide (WW) Incidence Rate (WW Sales = 425,300)
Intravascular – External*	External Abrasion	0.011%
Externalized Conductors – External**	External Abrasion	0.004%
Lead-to-Can*	External Abrasion	0.030%
Insulation Damage*	External Abrasion	0.013%
Intravascular - Inside Out*	Internal Abrasion	0.0002%***
Externalized Conductors - Inside Out**	Internal Abrasion	0.0002%***
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.003%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.003%

*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.
***The Riata ST Optim lead design included short lengths (0.5" nominal) adjacent to the shock coils which were not covered by the Optim sheath. These values reflect a total of two cases of silicone insulation breach due to inside-out abrasion in the short region not protected by Optim.

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 263).

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™, and Durata™ 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 >2.3 million Optim insulated pacing and tachycardia leads implanted worldwide continues to be excellent.

All aspects of Optim lead insulation performance can be appreciated by referring to the Acute Observation, Chronic Complication, Lead Malfunction, and Survival Probability data found in this Product Performance Report. One noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[3] Insulation abrasion can occur as a result of lead motion and contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. Abrasion within a lead can occur as a result of contact between internal components, as noted in our November 2011 Riata™ lead advisory. The clinical effects associated with all types of insulation abrasion malfunctions can include sensing noise and changes in both pacing and defibrillation impedances and thresholds. As indicated in our December 2010 Riata communication, the presence of Optim lead insulation on the Riata™ ST Optim and Durata defibrillator lead family has greatly reduced the quantity of all abrasion types.

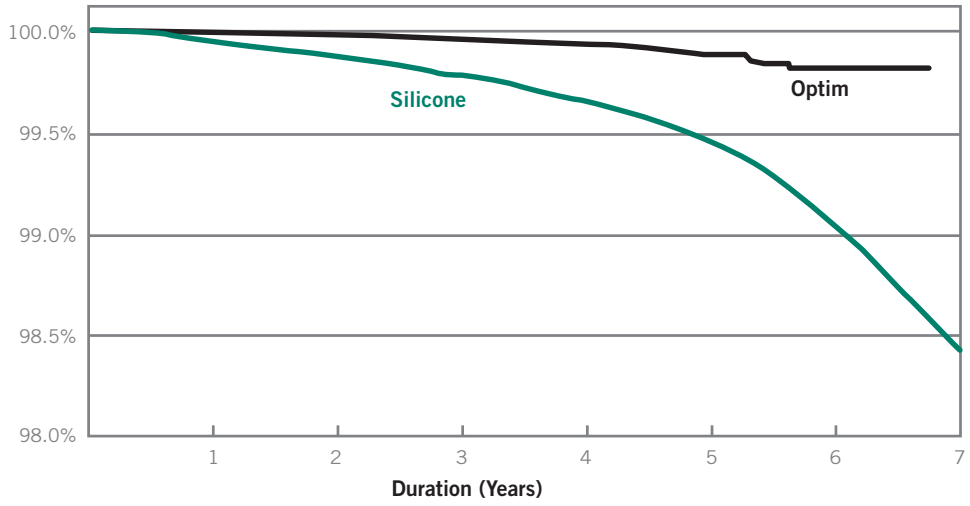
This product performance report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on St. Jude Medical tachycardia leads. A Kaplan-Meier analysis including all U.S. data through June 30, 2013 was performed on two groups of leads: (1) tachycardia leads with silicone 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 80 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 80 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 80 months by 86%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test.

Optim™ Lead Insulation Effects on SJM Tachycardia Lead Abrasion

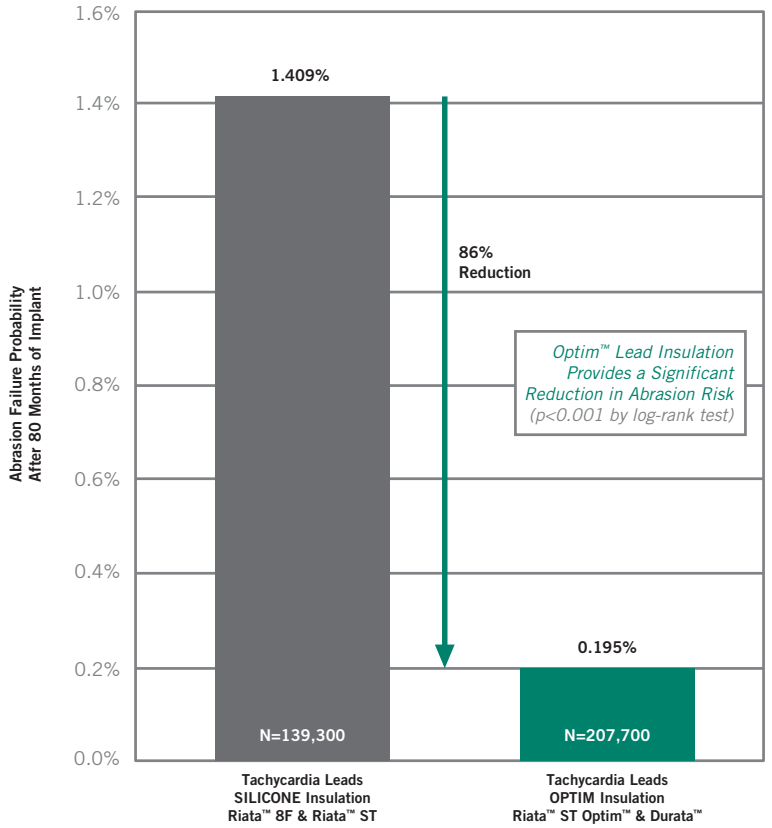
Kaplan-Meier Analysis of US Returns Analysis Data

Freedom from Abrasion Failure (%)



Year	1	2	3	4	5	6
Optim	181,130	135,613	94,378	56,889	27,356	8,626
Silicone	129,320	115,908	105,442	94,855	83,191	67,863

Abrasion Malfunction Probability after 80 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
Fortify ST™ (Models CD1235-40, CD1235-40Q, CD2235-40, and CD2235-40Q)	4/18/2013 Outside US only The Merlin™ PCS programmer software Model 3330 versions 14.2.2, 16.2.1 and 17.2.1.1 provide new features for St. Jude Medical ICDs, including an option to enhance the ST diagnostic features in St. Jude Medical Fortify ST™ ICD models CD1235-40, CD1235-40Q, CD2235-40 and CD2235-40Q via a device software upgrade. During a device software upgrade, implanted devices are temporarily placed into the back-up pacing (BVVI) and back-up defibrillation only (BDFO) mode. The back-up mode parameter settings will be in effect for the two minute upgrade process. Once the upgrade successfully completes, the device will revert to the previously programmed parameter settings. Depending on the individual patient, this temporary change in parameter values while in back-up defibrillation only mode could make the device susceptible to oversensing and potentially deliver high voltage therapy during the upgrade procedure.	In order to prevent the potential for inappropriate therapy during the software upgrade process, consider programming the "Tachy Therapy Enabled/Disabled" function to Disabled prior to proceeding with the software upgrade. It is imperative to re-interrogate the device and program the "Tachy Therapy Enabled/Disabled" function to Enabled after the upgrade has been successfully completed. As with any device evaluation and programming, ECG monitoring and availability of back up external defibrillation equipment is recommended during the entire software upgrade process. **Current Status (June 30, 2013):** Updates to be provided in the following PPR edition.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Convert™+ (Model V-195)	5/6/2010 Outside US only A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin™ Patient Care System (PCS) programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful.	If a patient's device is already programmed to a two zone configuration with a Merlin™ PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below: A permanent correction is available in the new release of the Merlin™ PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin™ programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (June 30, 2013):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of June 30, 2013, 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)	1/16/08 Class II A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic™ and Atlas™ family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window.	A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin™ Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (June 30, 2013):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2013 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)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (June 30, 2013):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2013 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).	6/13/05 Class II Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to St. Jude Medical. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic™ DR/HF (V-233/V-337/V-338), Epic™ Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas™ DR (V-242), and Atlas™ Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. St. Jude Medical has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (June 30, 2013):** 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	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (June 30, 2013):** 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	7/13/01 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) and Accent™ DR (Model PM2112)	12/7/12 Outside US Only Due to an incorrect software setting, a specific subset of the Accent™ SR and Accent™ DR shipped to certain countries outside the US will not provide a change in the sensor driven (rate responsive) pacing rates in response to patient physical activity. All other programmed parameters, features and functions operate as designed, e.g. an Accent DR device programmed to DDDR will appropriately track atrial activity and properly function in the DDD mode. A non-invasive programmer software solution that will correct the issue in all affected, implanted devices will be available once regulatory approval has been completed.	St. Jude Medical makes the following recommendations: ■ Identify affected patient ■ Review your patient's clinical indications for pacing and determine the clinical need for rate responsive, sensor driven pacing. ■ In the event that a patient requires rate responsive sensor driven activity pacing and exhibits clinical symptoms due to the lack of increased pacing rates with exercise, please contact your local Sales Representative or our Technical Support ■ Continue to follow patients on their standard follow-up schedule. **Current Status (June 30, 2013):** The programmer software update was released the software 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 through June 30, 2013.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Accent™ DR (Models PM2110, PM2112, PM2210 and PM2212) and Anthem™ CRT-P (Models PM3110, PM3112, PM3210 and PM3212)	9/22/11 Class II A small amount of electrical charge may accumulate within an internal capacitor which results in a low or varying pacing lead impedance (PLI) value during the automatic daily measurements. An out of range lead impedance measurement may result in a patient notifier alert, a remote monitoring Merlin.net™ Patient Care Network alert, or a prior alert message to be displayed on the programmer screen at the next in-clinic follow-up.	In order to prevent a false reading, a new Merlin™ Patient Care System programmer software version is available. When used to interrogate an Accent DR or Anthem CRT-P pacemaker this software will eliminate the potential for this anomaly to occur. With the new software, the programmer will automatically activate circuitry in the pacemaker during the interrogation process to ensure that any residual charge on the capacitor is discharged prior to performing the daily PLI measurement. The onetime upgrade is performed automatically on affected devices and will not change the operation of the implanted device. Your St. Jude Medical Sales Representative will assist you in loading the new programmer software onto your Merlin programmer. If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, St. Jude Medical makes the following recommendations, which are consistent with standard best practices: ■ Ensure that the new programmer software version is loaded on your programmers as soon as practical. ■ Continue to follow patients on their standard follow-up schedule. Since the likelihood of the low lead impedance measurement is low, the device interrogation can be performed at the patient's next regular scheduled follow-up visit. ■ In the event that a patient receives a low lead impedance alert before the new programmer software has been loaded, we suggest that you evaluate the device as you normally would for any such instance. If the daily pacing lead impedance value is out-of range, re-interrogate the device's measured data and look at the lead impedance values. This "in-clinic" measurement is not affected by the aforementioned capacitor charge build-up and will provide an accurate lead impedance measurement. **Current Status (June 30, 2013):** World-wide, 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 (5172) Identity™ DR (5370) Identity™ XL DR (5376)	10/12/06 Class II A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in St. Jude Medical Identity™ pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the St. Jude Medical Identity™ family of pacemakers when programmed by the St. Jude Medical APS™ III Model 3500/3510 or Merlin™ Patient Care System Model 3650 programmers.	No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process. **Current Status (June 30, 2013):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2013 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 and 5480	7/31/03 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. **To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval.** In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual-chamber device would have to satisfy both of the following conditions: Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower AutoCapture™ pacing system programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or AutoCapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program AutoCapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (June 30, 2013):** 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™ 2102 and Meta™ 1256D	11/04/02 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™ 1102, 1902, 2102, 2902 and Meta™ 1256D	11/04/02 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 1256	6/6/00 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™ 1102, 1902, 2102, 2902, and Meta™ 1256D	6/6/00 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™ 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	3/10/00 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™ 5130L, 5130R, 5330L, 5330R, 5230L, 5230R	2/14/00 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™ 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	7/19/99 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™ 1056T and 1058T, QuickFlex™ 1156T and 1158T	4/3/2012 Class II Abrasion of the silicone insulation in the distal portion of QuickSite and QuickFlex leads has led to visual observations of externalized conductors. There have been no reports of death or serious injury associated with the externalized conductors; likewise there have been no electrical dysfunctions attributable to the externalized conductors. The reported rate of externalized conductors in the QuickSite and QuickFlex leads is 0.023%, based on 39 confirmed cases of externalized conductors in a population of approximately 82,000 QuickSite and 89,000 QuickFlex leads sold worldwide. This issue is under-detected because these cases are visual observations without any signs of electrical dysfunction and fluoroscopic/xray imaging is not routine. Based on a review of returned leads and available fluoroscopic and x-ray images of patients with QuickSite and QuickFlex leads (1,219 leads), it is estimated that the incidence of conductor externalization on these leads may be 3% to 4%.	St. Jude Medical and its Medical Advisory Board recommend that physicians continue to monitor their patient's implanted system at regularly scheduled intervals with attention paid to diagnostic information related to LV pacing performance, in particular LV lead impedance and capture thresholds. Programming of alerts that monitor lead impedance changes outside of the nominal range and enabling the patient notifier should be considered. A special X-ray or fluoroscopic imaging is not recommended for LV CRT leads with normal electrical function. CRT pacing functionality should be evaluated during routine device checks and only leads exhibiting electrical anomalies that cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement. **Current Status (June 30, 2013):** At the time of the advisory there was a world-wide reported externalized conductor rate of 0.023% in QuickSite and QuickFlex leads. As of June 30, 2013, the world-wide reported externalized conductor rate for QuickSite and QuickFlex leads was 0.080%.

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 abrasion malfunctions is presented on pages 259-263 of this Product Performance Report.	St. Jude Medical and its Medical Advisory Board (MAB) make the following recommendations, which are consistent with standard best practices and our December 2010 product communication. Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. St. Jude Medical remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors. Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits. If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing, if necessary, could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem associated with any source of lead electrical failure if one exists. The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time and is therefore not recommended. In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended. Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalized conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances. Based on input from the MAB, St. Jude Medical is conducting a prospective study to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities. **Current Status (August 31, 2013):** At the time of the advisory there was a world-wide reported all-cause insulation abrasion rate of 0.63% for Riata silicone leads. The world-wide reported rate for the subcategory of externalized conductors in Riata silicone leads was 0.10%. As of August 31, 2013, there have been additional reports. The world-wide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 2.59% and 1.50%, respectively. The Riata ST Optim™ lead design included short lengths (0.5" nominal) adjacent to the shock coils which were not covered by the Optim sheath. Two cases of Riata ST Optim silicone insulation breach due to inside-out abrasion in the short region not protected by Optim have been identified. The latest information related to the silicone Riata lead advisory, including references to independent studies of Riata 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 abrasion malfunctions is presented on pages 259-263 of this Product Performance Report.	Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person or remote monitoring are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedure in particular looking for significant changes from the patient's previous follow-up visits. If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing if necessary could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem if one exists. Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events. **Current Status (August 31, 2013):** At the time of the advisory there was a world-wide reported insulation abrasion rate of 0.47% for Riata silicone leads. As of August 31, 2013, there have been additional reports and the world-wide reported insulation abrasion rate is 2.59%.

[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 and DM2102)	3/11/2011 Class II US and Germany A product firmware upgrade using the Merlin™ Patient Care System (PCS) programmer running software versions 10.1.1.3, 10.1.1.2, or 11.2.2 leaves the implantable cardiac monitor device in a state which results in increased current usage. If not corrected this state could result in premature battery depletion.	If you are following any patients implanted with the SJM Confirm Models DM2100 or DM2102 and their device was upgraded using the Merlin programmer with the above mentioned software versions it is recommended to determine the patient's clinical reason for the implant and their continued need for the device: ■ If the device has previously been used to record and assist in the diagnosis of an arrhythmia and is no longer needed, no further action is required. The device will exhaust its battery capacity prior to the 3 year expected longevity. ■ If the unit is still indicated for diagnosing a potential clinical arrhythmia, contact your Field Clinical Engineer and he/she will assist in calculating the projected remaining longevity. If appropriate, the microprocessor operation can be reset to the nominal current drain. ■ If the device is no longer indicated it can be left implanted until such time that a routine explant is desired. If the device is determined to be necessary and is experiencing increased current usage as described above, it can be corrected with assistance from your Sales Representative or St. Jude Medical Technical Services. St. Jude Medical is in the process of developing new Merlin PCS programmer software that will properly upgrade SJM Confirm devices. **Current Status (June 30, 2013):** 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.

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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
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

ICDs	Final Edition
Atlas™ DR (V-240)	May 2010
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™ VR (1107-36)	May 2010
Epic™ + DR (V-236)	May 2010
Epic™ DR (V-233)	Apr 2011
Epic™ DR (V-235)	Nov 2010
Epic™ II DR (V-255)	May 2010
Epic™ VR (V-197)	Nov 2010
Photon™ DR (V-230HV)	Oct 2007
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
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 DR (5336)	Nov 2010
Meta™ DDDR (1256)	Oct 2008

Pacemakers	Final Edition
Meta™ DDDR (1256D)	Oct 2008
Paragon™ (2010, 2011, 2012)	Nov 2010
Paragon™ II (2016)	Nov 2010
Paragon™ III (2304, 2314, 2315)	May 2010
Phoenix™ III (2204, 2205)	Apr 2009
Phoenix™ II (2005, 2008, 2009)	Nov 2010
Regency™ SC+ (2400L, 2402L)	May 2010
Solus™ (2002, 2003)	Nov 2010
Solus™ II (2006, 2007)	Nov 2010
Synchrony™ II (2022, 2023)	Oct 2009
Synchrony™ III (2028, 2029)	May 2010
Tempo™ D (2902)	Oct 2008
Tempo™ DR (2102)	Oct 2008
Tempo™ V (1102)	May 2010
Tempo™ VR (1902)	May 2010
Trilogy™ DC (2308)	Oct 2006
Trilogy™ DC+ (2318)	Oct 2009
Trilogy™ DR (2350)	Apr 2007
Trilogy™ SR (2250)	Oct 2009
Trilogy™ DR+ (2360, 2364)	May 2010
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™ DX (1343K, 1345K)	May 2010
Permathane™ ACE (1035M)	May 2010
Permathane™ ACE (1036T, 1038T)	May 2010
Tendril™ (1188K)	May 2010
Tendril™ DX (1388K)	May 2010
Unipolar Lead (Model 1007)	May 2010

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

IMPLANTABLE ELECTRONIC SYSTEMS

CARDIOVASCULAR AND ABLATION TECHNOLOGIES

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Implantable Electronic Systems Division
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

U.S. Division
6300 Bee Cave Road
Building Two, Suite 100
Austin, Texas 78746
USA
+1 512 732 7400
+1 512 732 2418 Fax

SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Australia Pty, Ltd.
17 Orion Road
Lane Cove, NSW 2066
Australia
+61 2 9936 1200
+61 2 9936 1222 fax

SJMprofessional.com

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ST. JUDE MEDICAL™