Cardiac Rhythm Management Division
Product Performance Report
2012 First Edition

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

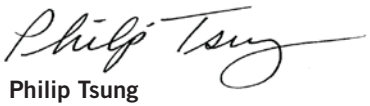
As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, St. Jude Medical continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose 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 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 malfunctions and providing subcategories of laboratory-confirmed lead abrasion and fracture malfunctions.

In addition to traditional performance reporting methods based on customer complaints and returns, this report includes data from the St. Jude Medical Product Longevity and Performance Registry (SCORE), which has now been actively collecting data on the reliability and performance of St. Jude Medical cardiac rhythm management products for over 4 years. Unlike other active registries, SCORE tracks information on multiple product families, including leads as well as ICDs and pacemakers, making it the most comprehensive registry in the industry. This prospective, non-randomized, multi-center registry monitors the performance of all implanted St. Jude Medical products at participating sites and is thus designed to include new products as they are introduced. SCORE is just one example of how we are working to reduce risk and set new standards for quality, performance and reliability.

As we continually strive to provide unbiased and reliable information on the performance of our products, St. Jude Medical is pleased to release the first of two reports in 2012 containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,



Philip Tsung
Vice President, Quality Assurance

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Serving Our Mission

The St. Jude Medical mission is to develop medical technology and services that put more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. We do this because we are dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient.

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 ICD, pacemaker, ICM, and lead model with at least 500 active devices in service, St. Jude Medical provides product performance data, according to industry guidelines, collected through December 31, 2011, 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 SCORE Registry inclusion criteria, St. Jude Medical provides active registry performance data, collected through December 31, 2011, 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 an update on Riata® lead performance, a summary of Durata® lead performance, and specialized analyses of Optim® lead insulation, DF4 connector system performance, and a novel Low Frequency Attenuation Filter from St. Jude Medical
- An updated summary of advisories on all implantable devices since 2003
- 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

Updates 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 228-231). This section provides the latest Riata externalized conductor rates from passive complaint and returns handling and describes in considerable detail the rates of other types of Riata insulation abrasion failure mechanisms that St. Jude Medical has identified from returns analysis. Also present is a discussion of the Riata Lead Evaluation Study which is now well underway.

Durata® Lead Performance

Durata® lead performance continues to meet expectations by all measures. Our confidence in Durata performance is based on combined data from three prospective, actively monitored registries that include 10,950 Optim-insulated defibrillation leads. A special Focus on Clinical Performance section has been included in this Product Performance Report to provide the details and results from these studies (see pages 232-233). 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.

Expansion of Left-Heart Lead Malfunction Details

Since November 2010, the St. Jude Medical Product Performance Report has provided additional sub-categories for defibrillation lead Conductor Fracture and Insulation Breach malfunctions. In order to maintain transparency, St. Jude Medical is now providing these sub-categories for Left-Heart Leads as well. "Conductor Fracture" malfunctions will now be further identified as "Clavicular Crush", "In the Pocket" or "Intravascular". "Insulation Breach" malfunctions will now be further identified as "Lead-to-Can Contact", "Lead-to-Lead Contact", "Clavicular Crush", "Externalized Conductors" or "Other". The definitions of these new subcategories are provided in the Leads Malfunction Reporting section on pages 9-10.

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 audited like registry data, such as SCORE. Under reporting 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 under reporting 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 estimated longevity for Accent® DR pacemakers 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. Using these parameters, the estimated longevity of a typical Accent DR pacemaker model PM2110 is 9.2 years. 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 under reporting.

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 be accurately representative of 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 under reporting 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 SCORE Registry Performance 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 shall be 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 for more than 30 days, 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 the each malfunction type is provided in a tabular format on the Customer Reported Performance Data and SCORE Registry Performance 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 254-255). Additional information regarding externalized conductors 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.

SCORE Registry Performance Data

Summary Information

SCORE (**S**t. Jude Medi**c**al Pr**o**duct Longevity and Perfo**r**manc**e**) Registry is an active, ongoing source of reliability and performance information for St. Jude Medical market-released cardiac rhythm management products – including multiple product families of leads, ICDs and pacemakers. SCORE Registry Performance Data complements the data collected from Customer Reported Performance Data, further enhancing performance reporting from St. Jude Medical.

To ensure a sufficiently large and appropriately representative source of data, more than 60 clinical sites are participating in the SCORE Registry with approximately 11,000 patients enrolled as of December 31, 2011. Using a common protocol, these sites are individually monitoring and reporting on the performance of all St. Jude Medical cardiac rhythm management products used at their site. The SCORE registry is designed to include new products as they become available.

ICDs

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

Defibrillation Leads

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

CRT Leads

QuickFlex® µ (Model 1258T)
QuickFlex® XL (Model 1158T)
QuickFlex® (Model 1156T)
QuickSite® (Model 1056T)

Pacemakers

Anthem® RF (Model PM3210)

Accent® DR (Model PM2110)

Accent® SR RF (Model PM1210)

Accent® DR RF (Model PM2210)

Zephyr® DR (Model 5820)

Zephyr® DR (Model 5826)

Zephyr® SR (Model 5626)

Victory® XL DR (Model 5816)

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)

OptiSense® Optim® (Model 1999)

OptiSense® (Model 1699)

IsoFlex® S (Model 1646)

IsoFlex® Optim® (Model 1948)

*New for 2012 First Edition.

Qualifying Complications

When abnormal performance is suspected of a SCORE-registered 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
Lead Dislodgement	Lead Surgically Repositioned
Lead Conductor Fracture	Lead Surgically Abandoned/Capped
Insulation Breach	Lead Electrically Abandoned/Capped
Phrenic Nerve/Diaphragmatic Stimulation	Lead/Generator Explanted
Elevated Pacing Thresholds	Lead/Generator Replaced
Failure to Capture	Lead Polarity Changed
Failure to Sense	Generator Pacing Mode Changed
Abnormal Pacing Impedance	
Abnormal Defibrillation Impedance	
Skin Erosion	
Cardiac Perforation	
Pericardial Effusion	
Oversensing	
Premature Battery Depletion	
Inappropriate Shock	
Loss of Telemetry	

Survival Calculation Methods

SCORE survival calculations are made in a manner consistent with the ISO5841-2:2000(E) method used for Customer Reported Performance Data. 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 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 SCORE survival calculations are excluded from the Customer Reported Performance Data.

SCORE Malfunction Reporting

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

Medical Advisory Board Review

St. Jude Medical has established separate and independent device-focused and lead-focused Medical Advisory Boards (MABs). One of the important tasks assigned to the MABs 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:

Device-Focused (Pacemakers, ICDs, ICMs)

Dr. Steven Bailin, Des Moines, Iowa

Dr. Jim Baker, Nashville, Tennessee

Dr. Anne Curtis, Buffalo, New York

Dr. Steve Greenberg, Roslyn, New York

Dr. Thomas Mattioni, Phoenix, Arizona

Dr. Gery Tomassoni, Lexington, Kentucky

Lead-Focused

Dr. Roger Freedman, Salt Lake City, Utah

Dr. David Hayes, Rochester, Minnesota

Dr. Steven Kalbfleisch, Columbus, Ohio

Dr. Steven Kutalek, Philadelphia, Pennsylvania

Dr. Raymond Schaerf, Burbank, California

Dr. Bruce Wilkoff, Cleveland, Ohio

Returning Devices To St. Jude Medical

To maintain the continued accuracy of our performance reporting, St. Jude Medical strongly encourages physicians to notify our Patient Records department (888-SJM-CRMD) 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-CRMD).

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-CRMD, 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
More control. Less risk.

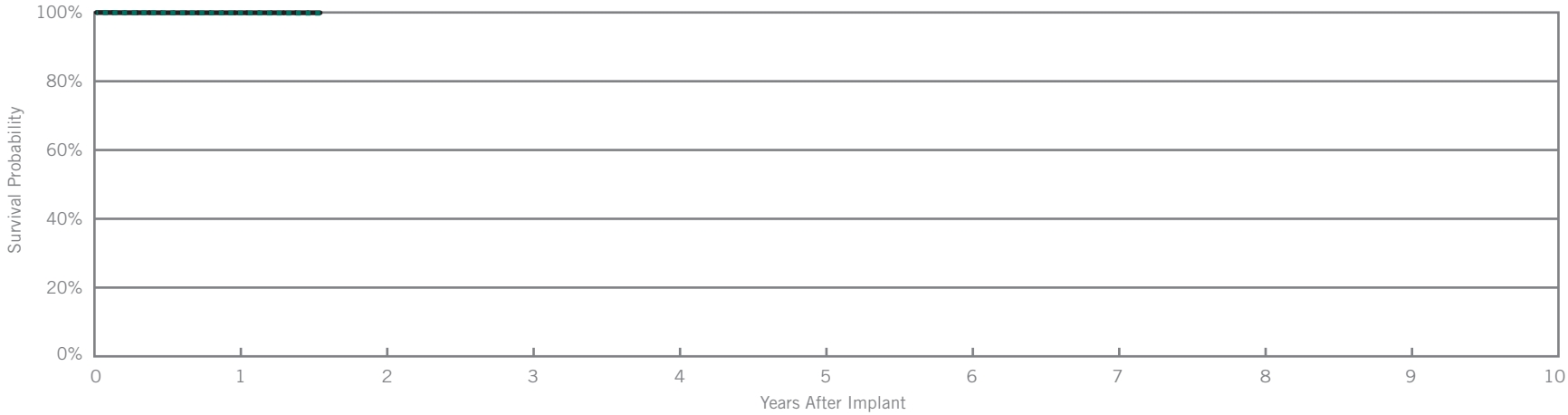
Customer Reported Performance Data

Unify® CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Registered US Implants	16,543
Estimated Active US Implants	14,821
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	6
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%	2	0.01%
Electrical Interconnect	0	0.00%	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	1	0.01%	1	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.01%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.79%	99.79%								
± 1 standard error	0.04%	0.04%								
Sample Size	11600	600								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.02%	0.02%								

SCORE Registry Performance Data

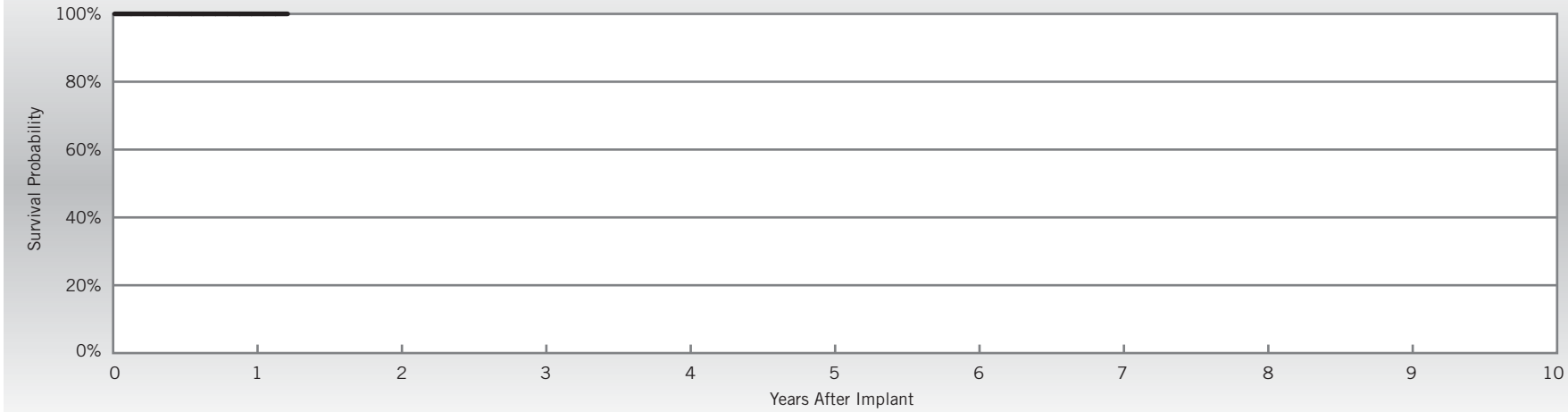
Unify® CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	347
Cumulative Months of Follow-up	3,430
Estimated Longevity	(see table on page 32)
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 15 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	230	70								

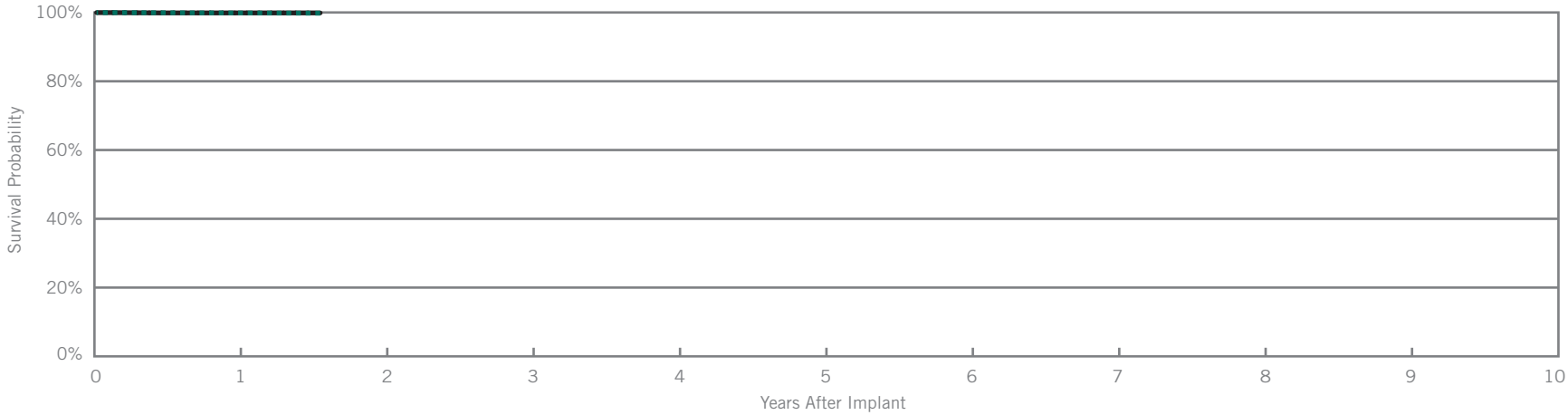
Customer Reported Performance Data

Unify® CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	14,162
Estimated Active US Implants	12,742
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	1
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	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	0	0.00%	0	0.00%
Other	3	0.02%	2	0.01%
Total	**5**	**0.04%**	**2**	**0.01%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.87%	99.79%								
± 1 standard error	0.03%	0.07%								
Sample Size	9700	400								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.03%	0.03%								

SCORE Registry Performance Data

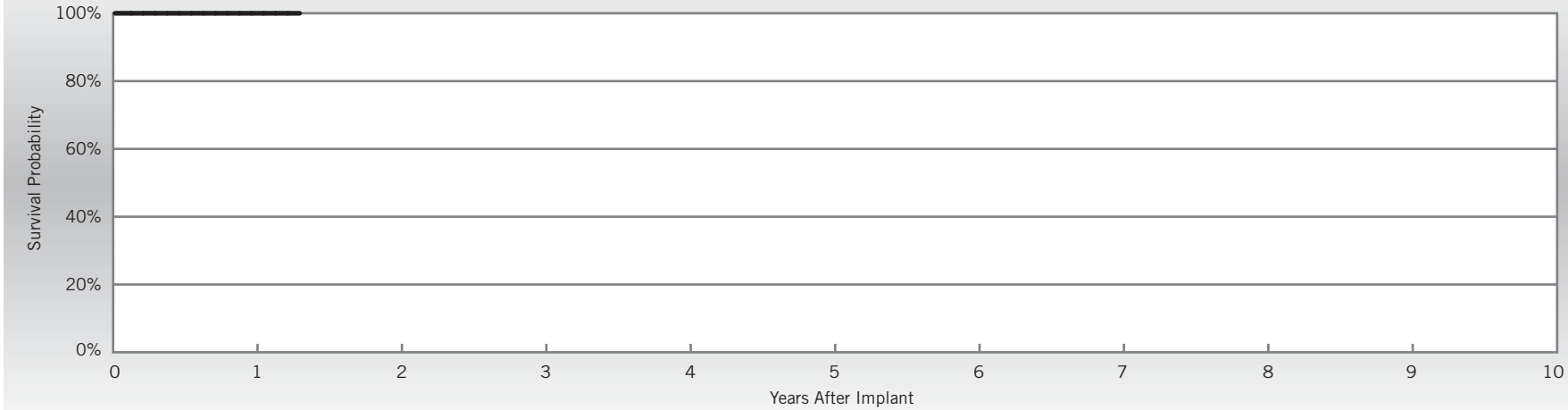
Unify® CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	348
Cumulative Months of Follow-up	3,488
Estimated Longevity	(see table on page 32)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	1	at 16 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	240	60								

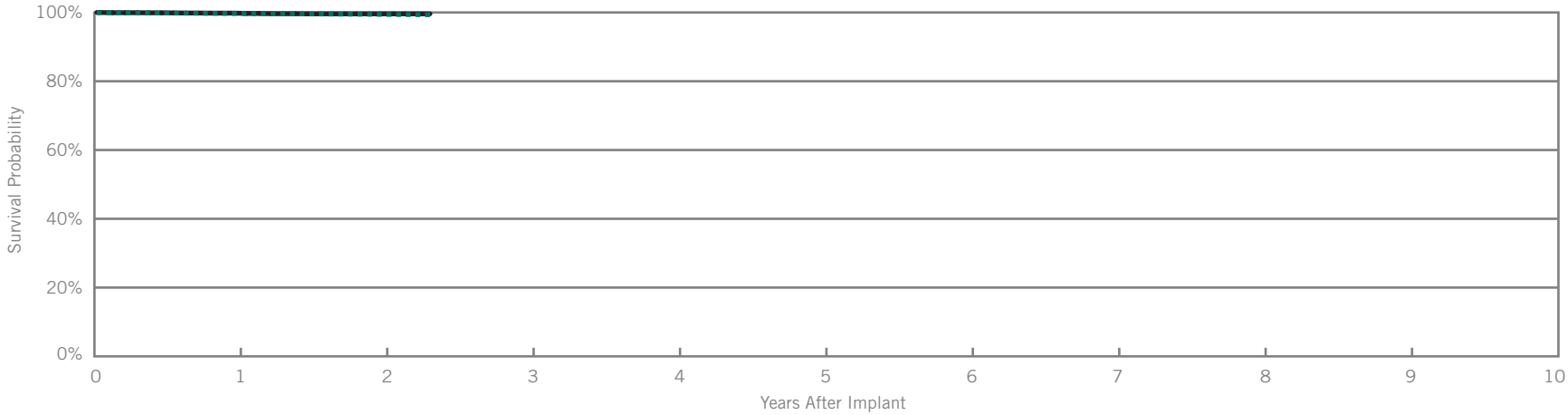
Customer Reported Performance Data

Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	7,333
Estimated Active US Implants	5,852
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	6
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	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.04%	2	0.03%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	1	0.01%
Possible Early Battery Depletion	2	0.03%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**7**	**0.10%**	**4**	**0.05%**



Including Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.61%	99.35%	99.35%							
± 1 standard error	0.08%	0.10%	0.10%							
Sample Size	7200	4100	400							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.81%	99.60%	99.60%							
± 1 standard error	0.05%	0.08%	0.08%							

SCORE Registry Performance Data

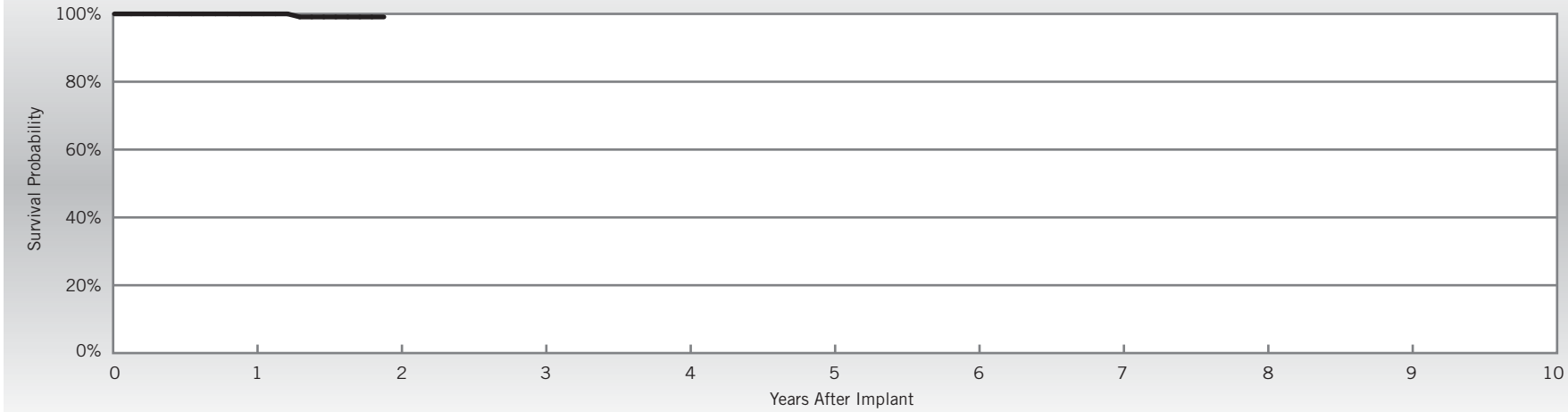
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	136
Cumulative Months of Follow-up	2,739
Estimated Longevity	(see table on page 32)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Inappropriate Shock	1	0.74%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.74%	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	**1**	**0.74%**	**0**	**0.00%**



Year	1	at 23 months								
Survival Probability	100.00%	99.10%								
± 1 standard error	0.00%	0.90%								
Sample Size	130	50								

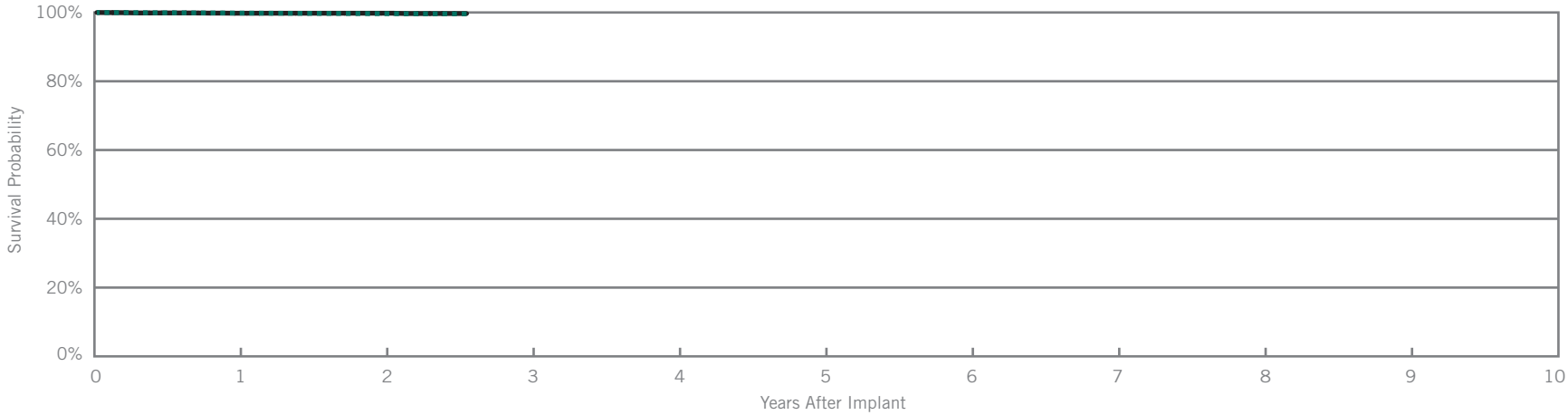
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,403
Estimated Active US Implants	6,541
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.70%	99.66%	99.58%							
± 1 standard error	0.06%	0.07%	0.09%							
Sample Size	8200	5200	400							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.78%	99.78%	99.69%							
± 1 standard error	0.05%	0.05%	0.08%							

SCORE Registry Performance Data

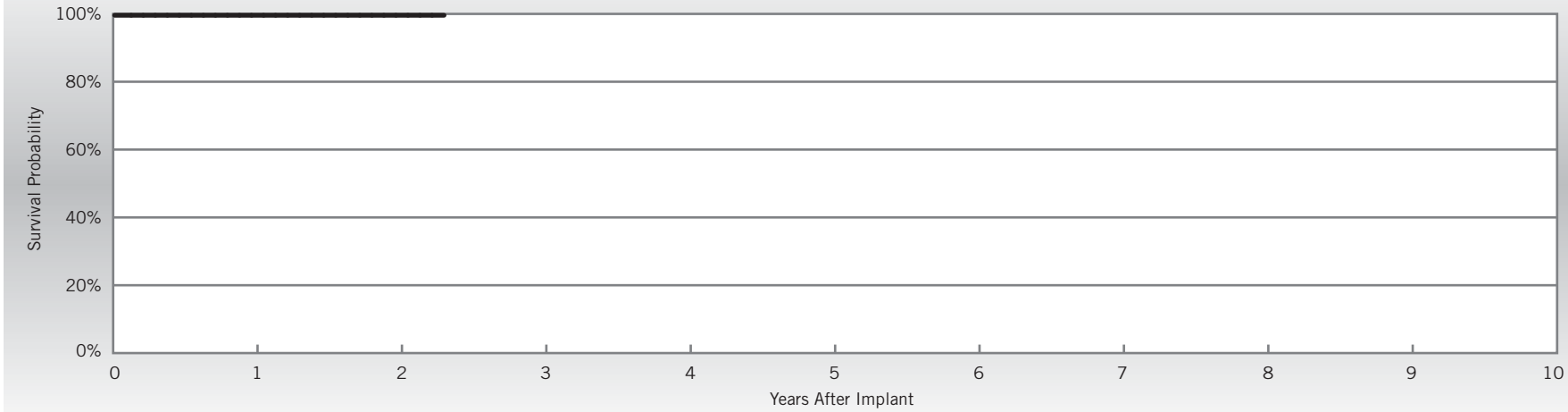
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	259
Cumulative Months of Follow-up	5,598
Estimated Longevity	(see table on page 32)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	1	0.39%

	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 28 months							
Survival Probability	99.60%	99.60%	99.60%							
± 1 standard error	0.40%	0.40%	0.40%							
Sample Size	240	170	60							

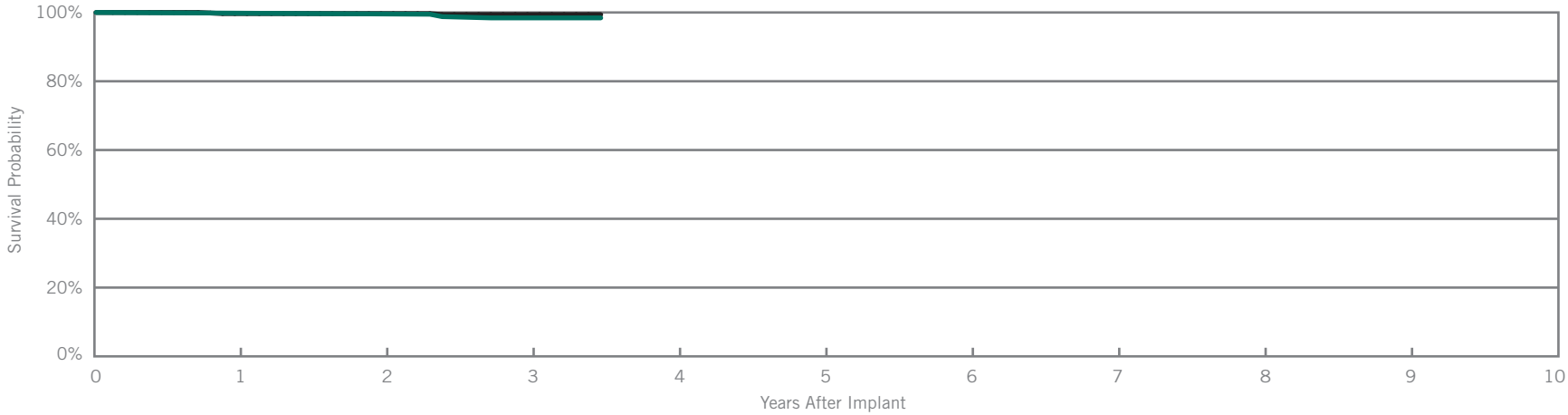
Customer Reported Performance Data

Promote® RF

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,411
Estimated Active US Implants	926
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	3
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	at 42 months						
Survival Probability	99.67%	99.49%	98.42%	98.42%						
± 1 standard error	0.16%	0.21%	0.46%	0.46%						
Sample Size	1400	1100	700	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.67%	99.67%	99.39%	99.39%						
± 1 standard error	0.16%	0.16%	0.26%	0.26%						

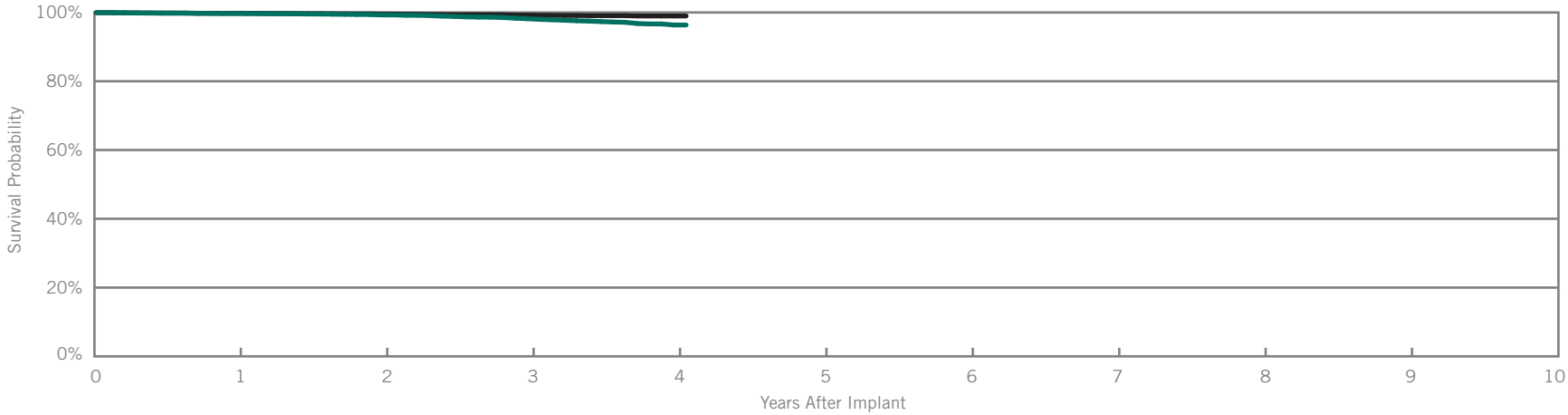
Customer Reported Performance Data

Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,812
Estimated Active US Implants	15,892
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	77
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	0.01%	5	0.02%
Electrical Interconnect	4	0.02%	0	0.00%
Battery	7	0.03%	7	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%	3	0.01%
Other	5	0.02%	6	0.03%
Total	**33**	**0.14%**	**28**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.70%	99.29%	98.18%	96.36%	96.36%					
± 1 standard error	0.04%	0.05%	0.11%	0.24%	0.32%					
Sample Size	23800	19600	12900	4400	500					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.77%	99.53%	99.21%	98.98%	98.98%					
± 1 standard error	0.03%	0.05%	0.07%	0.11%	0.11%					

SCORE Registry Performance Data

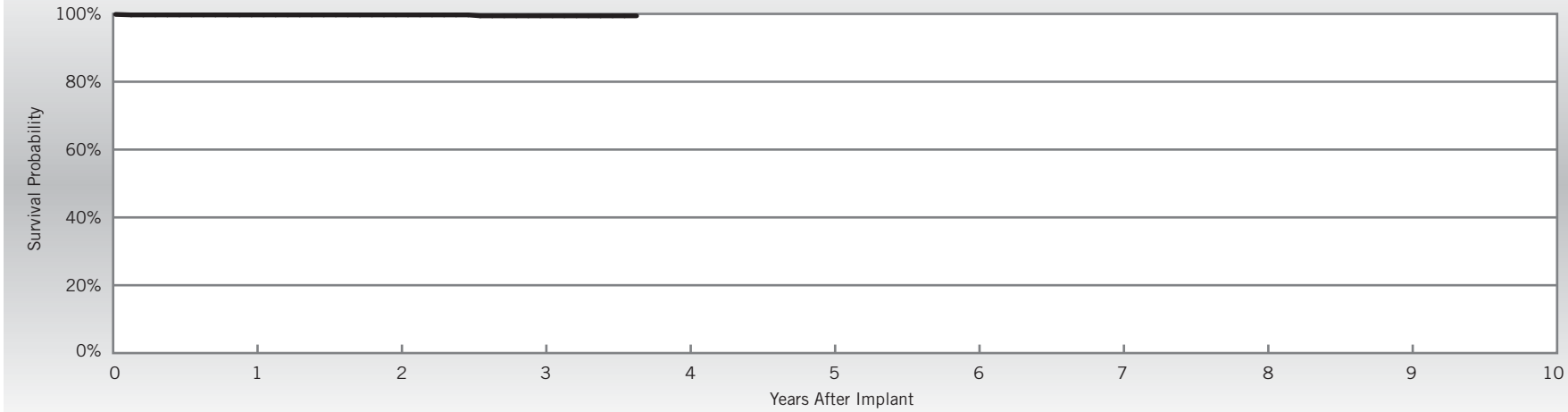
Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	674
Cumulative Months of Follow-up	20,026
Estimated Longevity	(see table on page 32)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.30%
Other	1	0.15%

	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	at 44 months						
Survival Probability	99.70%	99.70%	99.43%	99.43%						
± 1 standard error	0.21%	0.21%	0.34%	0.34%						
Sample Size	630	540	360	60						

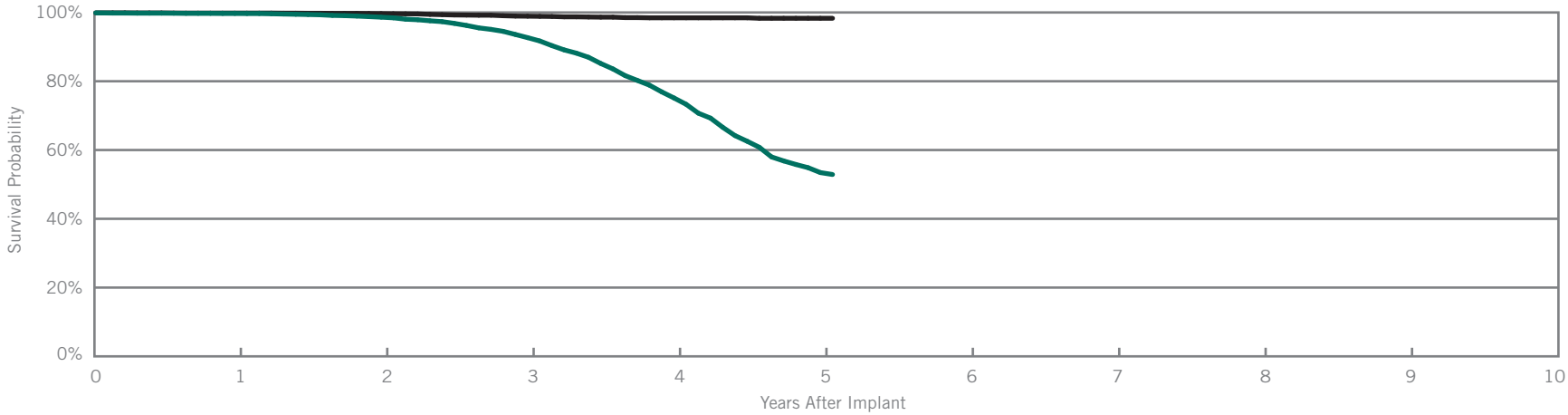
Customer Reported Performance Data

Atlas® II HF

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	8,404
Estimated Active US Implants	2,620
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	679
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	1	0.01%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	14	0.17%	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	4	0.05%	4	0.05%
Other	4	0.05%	4	0.05%
Total	**27**	**0.32%**	**12**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.71%	98.63%	92.68%	75.14%	53.44%	52.88%				
± 1 standard error	0.06%	0.13%	0.32%	0.60%	0.96%	1.06%				
Sample Size	8400	7200	6200	4700	2000	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.83%	99.68%	98.92%	98.45%	98.31%	98.31%				
± 1 standard error	0.05%	0.06%	0.13%	0.17%	0.20%	0.20%				

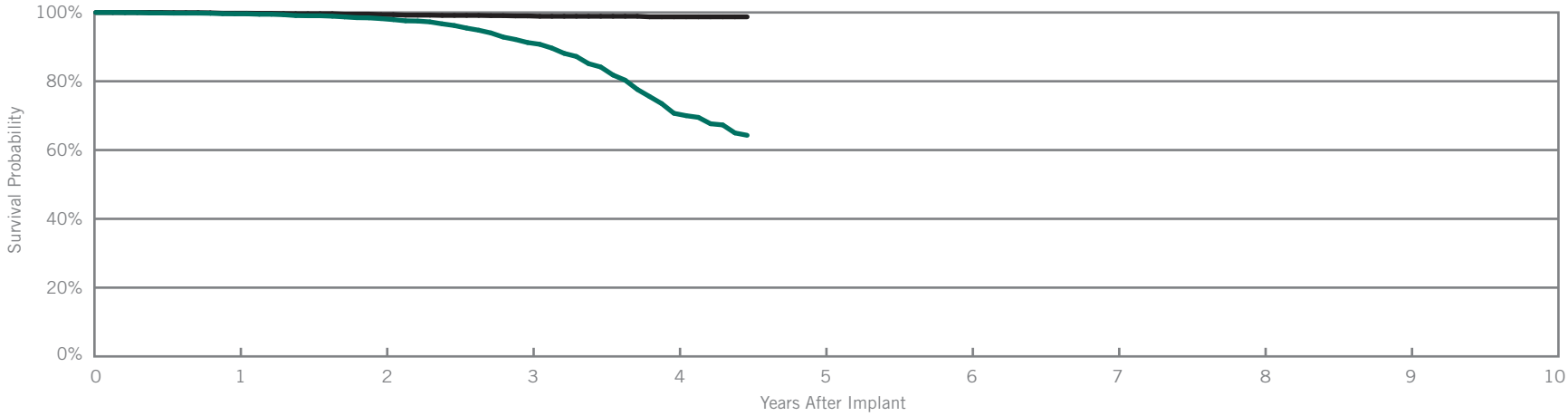
Customer Reported Performance Data

Atlas® II + HF

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	4,998
Estimated Active US Implants	2,253
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	246
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.06%	1	0.02%
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	5	0.10%	0	0.00%
Total	**10**	**0.20%**	**8**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.60%	98.21%	91.26%	70.68%	64.29%					
± 1 standard error	0.09%	0.20%	0.49%	1.02%	1.37%					
Sample Size	5000	4100	3100	1800	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.79%	99.37%	99.00%	98.73%	98.73%					
± 1 standard error	0.07%	0.11%	0.17%	0.22%	0.22%					

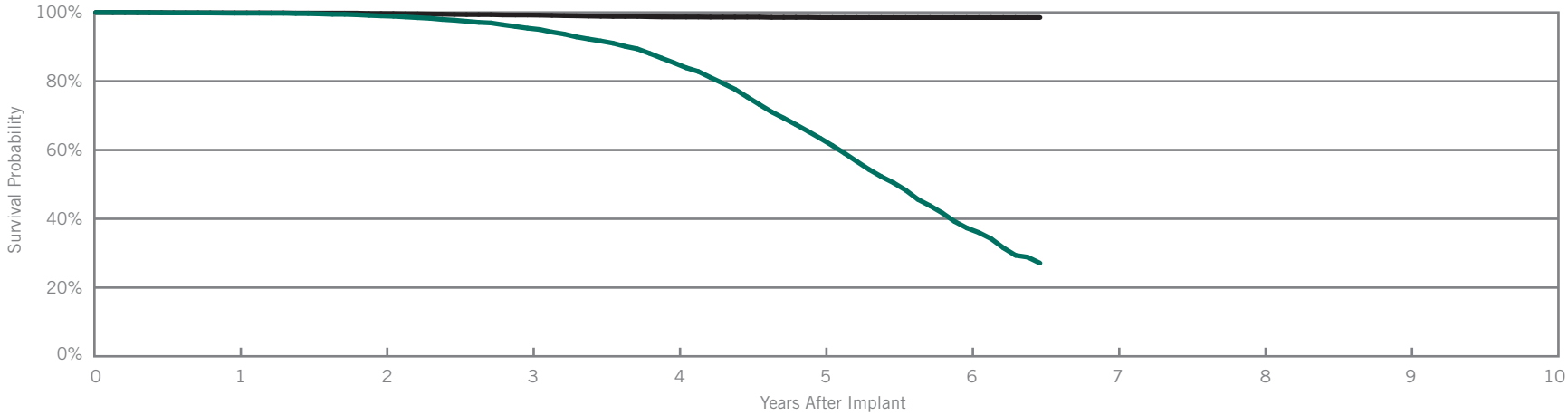
Customer Reported Performance Data

Atlas® + HF

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,685
Estimated Active US Implants	4,124
Estimated Longevity	(see table on page 32)
Normal Battery Depletion	1841
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	One

	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	35	0.19%	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%	10	0.05%
Other	9	0.05%	3	0.02%
Total	**52**	**0.28%**	**20**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.78%	99.00%	95.42%	85.37%	63.39%	37.34%	27.11%			
± 1 standard error	0.03%	0.07%	0.17%	0.32%	0.50%	0.71%	0.91%			
Sample Size	18700	16000	14000	11500	7900	3200	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.88%	99.67%	99.25%	98.69%	98.53%	98.53%	98.53%			
± 1 standard error	0.03%	0.05%	0.07%	0.10%	0.11%	0.12%	0.12%			

Battery Longevity Summary

CRT ICDs

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3231-40Q	Unify® CRT-D**	10.2	9.0	8.1	6.7
CD3231-40	Unify® CRT-D**	10.2	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
3207-30	Promote® RF	6.5	5.7	5.1	4.2
3207-36	Promote® RF	8.2	7.2	6.5	5.4
V-365	Atlas® II HF	8.2	7.2	6.5	5.4
V-366	Atlas® II HF	8.2	7.2	6.5	5.4
V-343	Atlas® + HF	7.9	7.1	6.4	5.4

**Battery longevity calculated with one EGM storage.*
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 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.
***Three maximum charges per year. Battery voltage range: 3.20-2.59.*

Summary Information

CRT ICDs

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
CD3231-40Q	Unify® CRT-D	99.79%									
CD3231-40	Unify® CRT-D	99.87%									
CD3211-36Q	Promote® + CRT-D	99.61%	99.35%								
CD3211-36	Promote® + CRT-D	99.70%	99.66%								
3207-30	Promote® RF	99.67%	99.49%	98.42%							
3207-36	Promote® RF	99.70%	99.29%	98.18%	96.36%						
V-365	Atlas® II HF	99.71%	98.63%	92.68%	75.14%	53.44%					
V-366	Atlas® II + HF	99.60%	98.21%	91.26%	70.68%						
V-343	Atlas® + HF	99.78%	99.00%	95.42%	85.37%	63.39%	37.34%				

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
CD3231-40Q	Unify® CRT-D	99.92%									
CD3231-40	Unify® CRT-D	99.87%									
CD3211-36Q	Promote® + CRT-D	99.81%	99.60%								
CD3211-36	Promote® + CRT-D	99.78%	99.78%								
3207-30	Promote® RF	99.67%	99.67%	99.39%							
3207-36	Promote® RF	99.77%	99.53%	99.21%	98.98%						
V-365	Atlas® II HF	99.83%	99.68%	98.92%	98.45%	98.31%					
V-366	Atlas® II + HF	99.79%	99.37%	99.00%	98.73%						
V-343	Atlas® + HF	99.88%	99.67%	99.25%	98.69%	98.53%	98.53%				

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
CD3231-40Q	Unify® CRT-D	16543	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**2**	**0.01%**
CD3231-40	Unify® CRT-D	14162	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	**5**	**0.04%**
CD3211-36Q	Promote® + CRT-D	7333	0	0.00%	0	0.00%	3	0.04%	1	0.01%	0	0.00%	1	0.01%	2	0.03%	0	0.00%	**7**	**0.10%**
CD3211-36	Promote® + CRT-D	8403	2	0.02%	0	0.00%	4	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.07%**
3207-30	Promote® RF	1411	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%**
3207-36	Promote® RF	23812	3	0.01%	4	0.02%	7	0.03%	5	0.02%	0	0.00%	2	0.01%	7	0.03%	5	0.02%	**33**	**0.14%**
V-365	Atlas® II HF	8404	1	0.01%	2	0.02%	14	0.17%	2	0.02%	0	0.00%	0	0.00%	4	0.05%	4	0.05%	**27**	**0.32%**
V-366	Atlas® II + HF	4998	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	5	0.10%	**10**	**0.20%**
V-343	Atlas® + HF	18685	3	0.02%	0	0.00%	35	0.19%	0	0.00%	0	0.00%	0	0.00%	5	0.03%	9	0.05%	**52**	**0.28%**

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
CD3231-40Q	Unify® CRT-D	16543	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.02%**
CD3231-40	Unify® CRT-D	14162	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**2**	**0.01%**
CD3211-36Q	Promote® + CRT-D	7333	1	0.01%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**4**	**0.05%**
CD3211-36	Promote® + CRT-D	8403	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	**3**	**0.04%**
3207-30	Promote® RF	1411	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%**
3207-36	Promote® RF	23812	5	0.02%	0	0.00%	7	0.03%	1	<0.01%	5	0.02%	1	<0.01%	3	0.01%	6	0.03%	**28**	**0.12%**
V-365	Atlas® II HF	8404	1	0.01%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	4	0.05%	4	0.05%	**12**	**0.14%**
V-366	Atlas® II + HF	4998	3	0.06%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	4	0.08%	0	0.00%	**8**	**0.16%**
V-343	Atlas® + HF	18685	1	0.01%	0	0.00%	4	0.02%	0	0.00%	1	0.01%	1	0.01%	10	0.05%	3	0.02%	**20**	**0.11%**

Definitions of malfunction root cause categories can be found on pages 6-7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Extracardiac Stimulation		Inappropriate Shock		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	347	3430	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	348	3488	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	136	2739	0	0.00%	0	0.00%	1	0.74%	0	0.00%	**1**	**0.74%**
CD3211-36	259	5598	0	0.00%	1	0.39%	0	0.00%	0	0.00%	**1**	**0.39%**
3207-36	674	20026	2	0.30%	0	0.00%	0	0.00%	1	0.15%	**3**	**0.45%**

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
CD3231-40Q	Unify® CRT-D	347	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	348	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	136	1	0.74%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.74%**
CD3211-36	Promote® + CRT-D	259	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	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
CD3231-40Q	Unify® CRT-D	347	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	348	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	136	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%**
CD3211-36	Promote® + CRT-D	259	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	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 complications can be found on page 13.
Definitions of malfunction root cause categories can be found on pages 6-7.

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical
More control. Less risk.

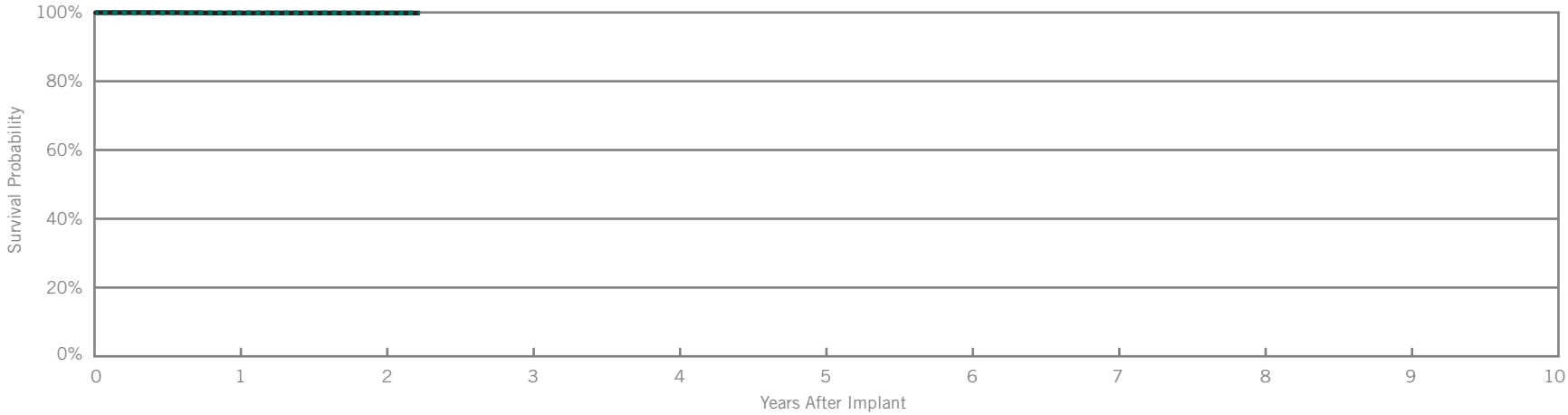
Anthem® RF

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	8,517
Estimated Active US Implants	7,444
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	0	0.00%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	2	0.02%
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	**2**	**0.02%**	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.90%	99.84%	99.84%							
± 1 standard error	0.04%	0.06%	0.06%							
Sample Size	6600	2100	300							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	99.90%	99.84%	99.84%							
± 1 standard error	0.04%	0.06%	0.06%							

SCORE Registry Performance Data

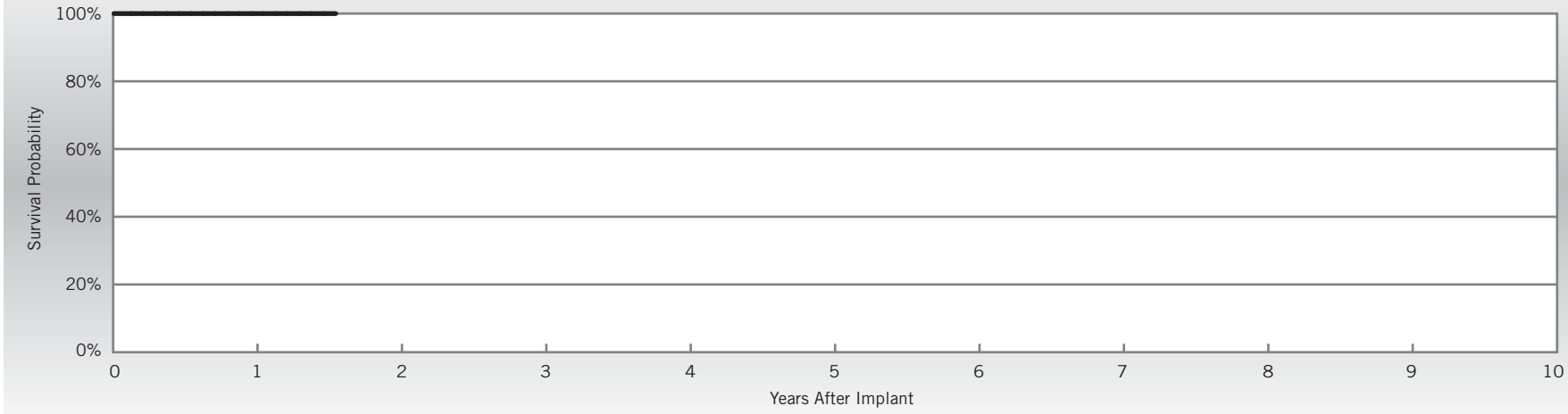
Anthem®

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	180
Cumulative Months of Follow-up	2,417
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	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	140	50								

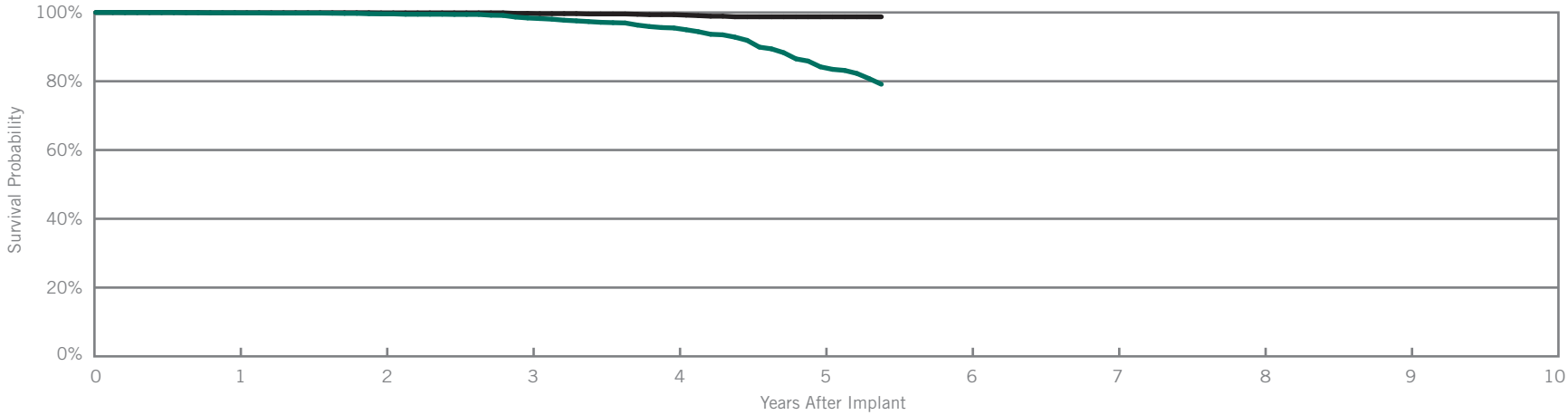
Customer Reported Performance Data

Frontier® II

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,717
Estimated Active US Implants	3,178
Estimated Longevity	6.5 Years
Normal Battery Depletion	119
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	5	0.07%
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%	7	0.10%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**12**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.90%	99.59%	98.40%	95.49%	84.19%	71.48%				
± 1 standard error	0.04%	0.08%	0.19%	0.41%	1.00%	1.29%				
Sample Size	6700	5400	4000	2400	1200	400				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.93%	99.89%	99.73%	99.36%	98.74%	98.74%				
± 1 standard error	0.04%	0.04%	0.08%	0.16%	0.27%	0.27%				

Summary Information

CRT Pacemakers

St. Jude Medical
More control. Less risk.

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®	99.90%	99.84%								
5586	Frontier® II	99.90%	99.59%	98.40%	95.49%	84.19%					

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®	99.90%	99.84%								
5586	Frontier® II	99.93%	99.89%	99.73%	99.36%	98.74%					

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®	8517	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%
5586	Frontier® II	6717	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®	8517	0	0.00%	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.02%
5586	Frontier® II	6717	5	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	0	0.00%	12	0.18%

Definitions of malfunction root cause categories can be found on pages 6-7.

Left-Heart Leads

St. Jude Medical™
More control. Less risk.

Customer Reported Performance Data

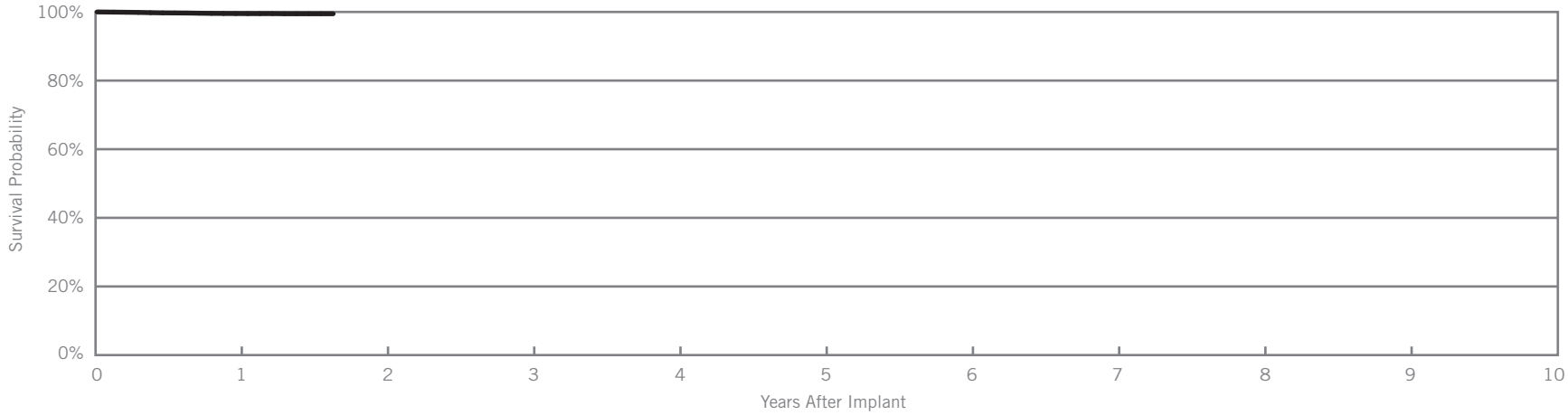
QuickFlex® µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	21,855
Estimated Active US Implants	18,399
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%	0	0.00%
Lead Dislodgement	23	0.11%	36	0.16%
Failure to Capture	9	0.04%	7	0.03%
Oversensing	0	0.00%	1	<0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	0	0.00%
Extracardiac Stimulation	12	0.05%	5	0.02%
Other	4	0.02%	1	<0.01%
Total	**49**	**0.22%**	**50**	**0.23%**
Total Returned for Analysis	**20**		**33**	

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	0	0.00%
Extrinsic Factors	43	0.20%
Total	**45**	**0.21%**



Year	1	at 20 months								
Survival Probability	99.53%	99.47%								
± 1 standard error	0.06%	0.08%								
Sample Size	14200	200								

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

SCORE Registry Performance Data

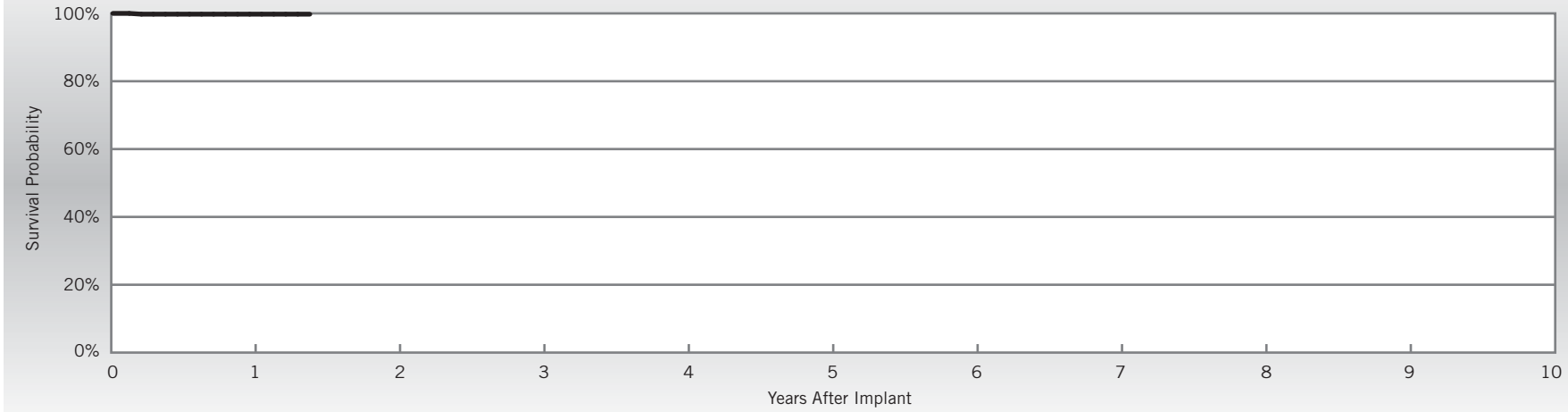
QuickFlex® µ

Model 1258T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	489
Cumulative Months of Follow-up	4,907
Insulation	Optim®*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.20%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.41%
Total	**2**	**0.41%**



Year	1	at 17 months								
Survival Probability	99.77%	99.77%								
± 1 standard error	0.23%	0.23%								
Sample Size	330	50								

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

Customer Reported Performance Data

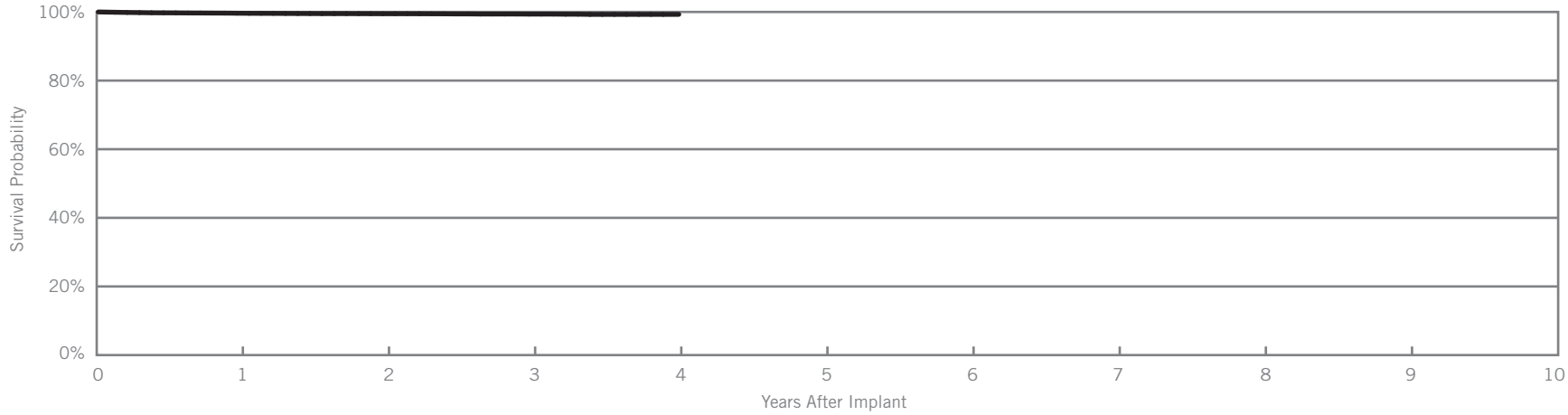
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	27,933
Estimated Active US Implants	19,964
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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	13	0.05%	42	0.15%
Failure to Capture	5	0.02%	20	0.07%
Oversensing	0	0.00%	3	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	0	0.00%	5	0.02%
Extracardiac Stimulation	16	0.06%	19	0.07%
Other	9	0.03%	1	<0.01%
Total	**43**	**0.15%**	**92**	**0.33%**
Total Returned for Analysis	**14**		**46**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	<0.01%
Insulation Breach	6	0.02%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	6	0.02%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	48	0.17%
Total	**55**	**0.20%**



Year	1	2	3	4						
Survival Probability	99.63%	99.48%	99.37%	99.29%						
± 1 standard error	0.04%	0.05%	0.06%	0.08%						
Sample Size	25500	16500	8100	2100						

SCORE Registry Performance Data

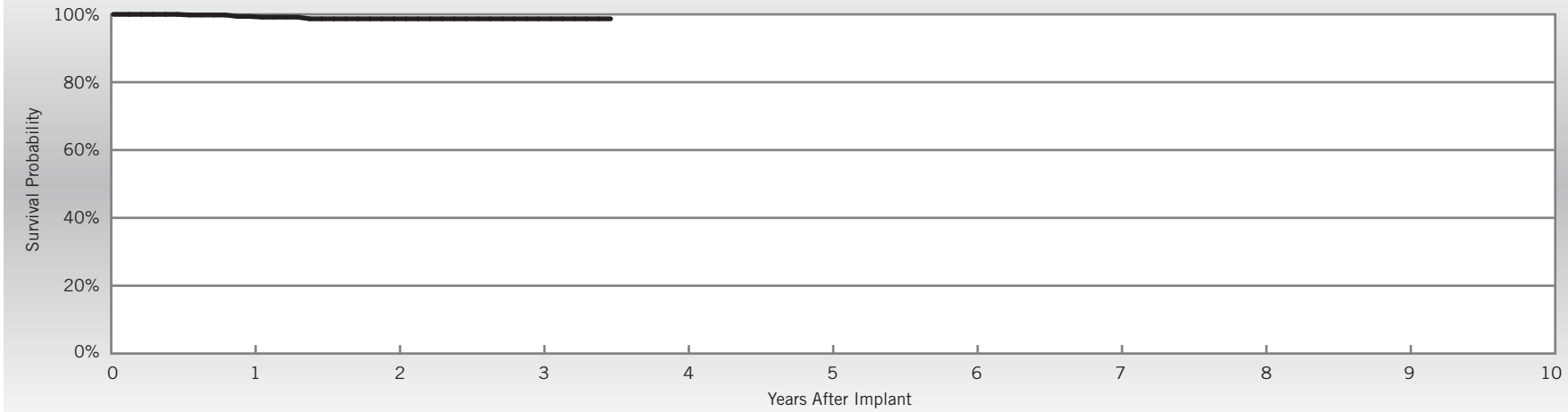
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	584
Cumulative Months of Follow-up	14,053
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.17%
Failure to Capture	3	0.51%
Extracardiac Stimulation	2	0.34%

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	0.17%
Total	**1**	**0.17%**



Year	1	2	3	at 42 months						
Survival Probability	99.39%	98.69%	98.69%	98.69%						
± 1 standard error	0.35%	0.53%	0.53%	0.53%						
Sample Size	520	380	200	50						

Customer Reported Performance Data

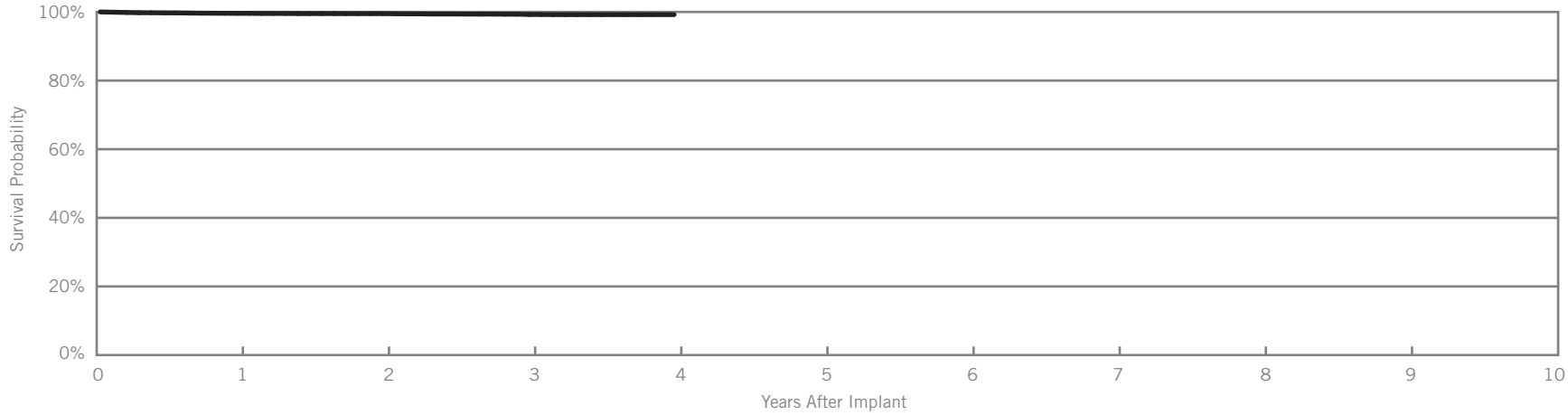
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,449
Estimated Active US Implants	10,955
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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	9	0.06%	33	0.21%
Failure to Capture	2	0.01%	8	0.05%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	0.01%
Insulation Breach	0	0.00%	1	0.01%
Abnormal Pacing Impedance	2	0.01%	1	0.01%
Extracardiac Stimulation	6	0.04%	5	0.03%
Other	6	0.04%	1	0.01%
Total	**25**	**0.16%**	**51**	**0.33%**
Total Returned for Analysis	**12**		**32**	

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	3	0.02%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.01%
Other	1	0.01%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	35	0.23%
Total	**41**	**0.27%**



Year	1	2	3	at 47 months						
Survival Probability	99.59%	99.51%	99.26%	99.22%						
± 1 standard error	0.05%	0.06%	0.09%	0.11%						
Sample Size	13800	8700	4500	300						

SCORE Registry Performance Data

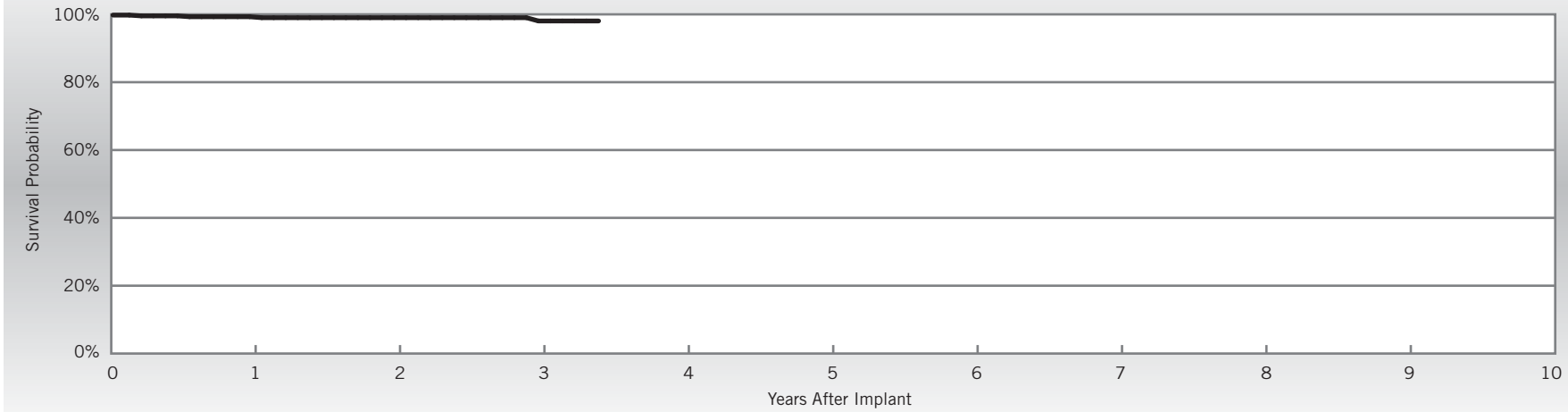
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	455
Cumulative Months of Follow-up	11,238
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.22%
Failure to Capture	2	0.44%
Extracardiac Stimulation	2	0.44%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	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	0.66%
Total	**3**	**0.66%**



Year	1	2	3	at 41 months						
Survival Probability	99.30%	99.02%	98.05%	98.05%						
± 1 standard error	0.40%	0.49%	0.49%	1.08%						
Sample Size	410	300	170	60						

Customer Reported Performance Data

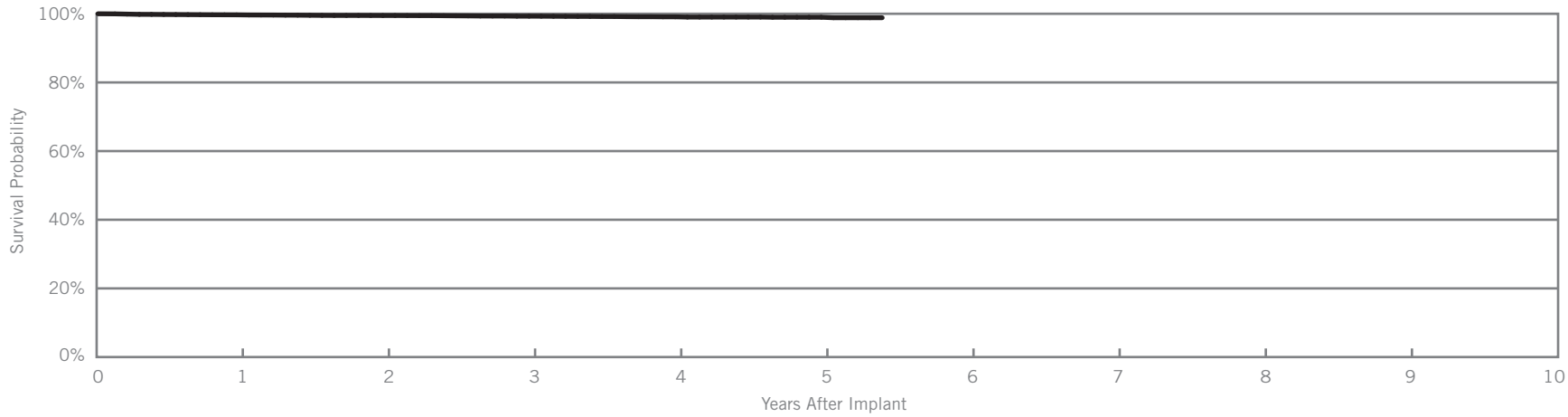
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,405
Estimated Active US Implants	5,696
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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	10	0.10%	11	0.11%
Failure to Capture	3	0.03%	21	0.20%
Oversensing	1	0.01%	1	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	2	0.02%
Extracardiac Stimulation	9	0.09%	5	0.05%
Other	1	0.01%	1	0.01%
Total	**26**	**0.25%**	**42**	**0.40%**
Total Returned for Analysis	**8**		**14**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.01%
Insulation Breach	4	0.04%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.03%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	12	0.12%
Total	**18**	**0.17%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	99.69%	99.49%	99.30%	99.11%	98.99%	98.85%				
± 1 standard error	0.06%	0.08%	0.09%	0.11%	0.13%	0.19%				
Sample Size	10000	8300	7000	5300	2600	200				

Customer Reported Performance Data

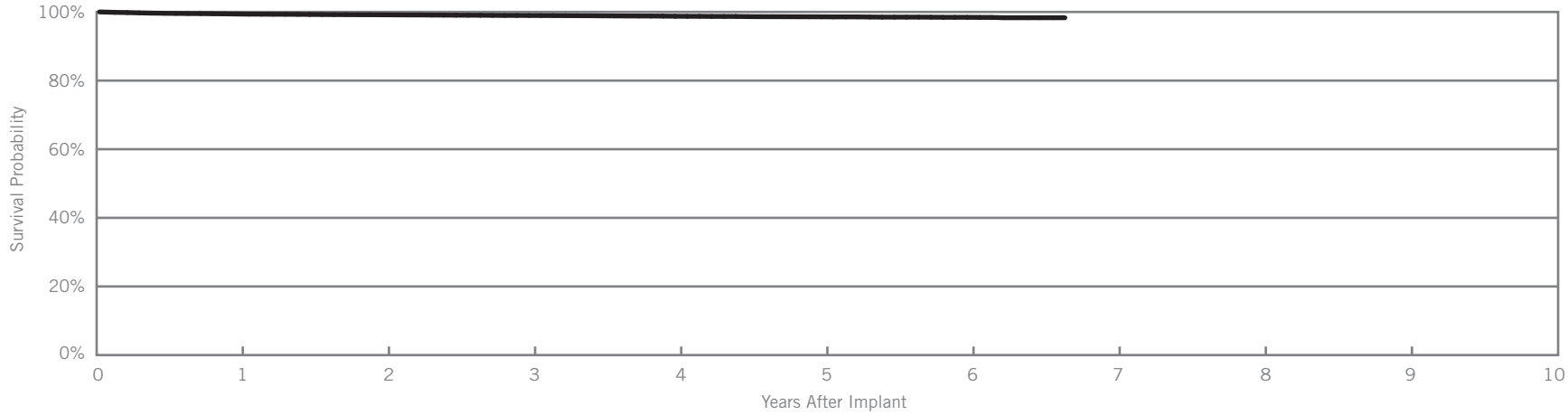
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	34,358
Estimated Active US Implants	16,556
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	30	0.09%	90	0.26%
Failure to Capture	14	0.04%	80	0.23%
Oversensing	1	<0.01%	4	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	1	<0.01%
Abnormal Pacing Impedance	3	0.01%	4	0.01%
Extracardiac Stimulation	22	0.06%	45	0.13%
Other	9	0.03%	8	0.02%
Total	**80**	**0.23%**	**237**	**0.69%**
Total Returned for Analysis	**26**		**98**	

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	15	0.04%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	13	0.04%
Other	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	87	0.25%
Total	**107**	**0.31%**



Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.40%	99.17%	98.97%	98.75%	98.58%	98.44%	98.32%			
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.08%	0.09%	0.12%			
Sample Size	32200	26700	22700	18500	12700	6300	400			

SCORE Registry Performance Data

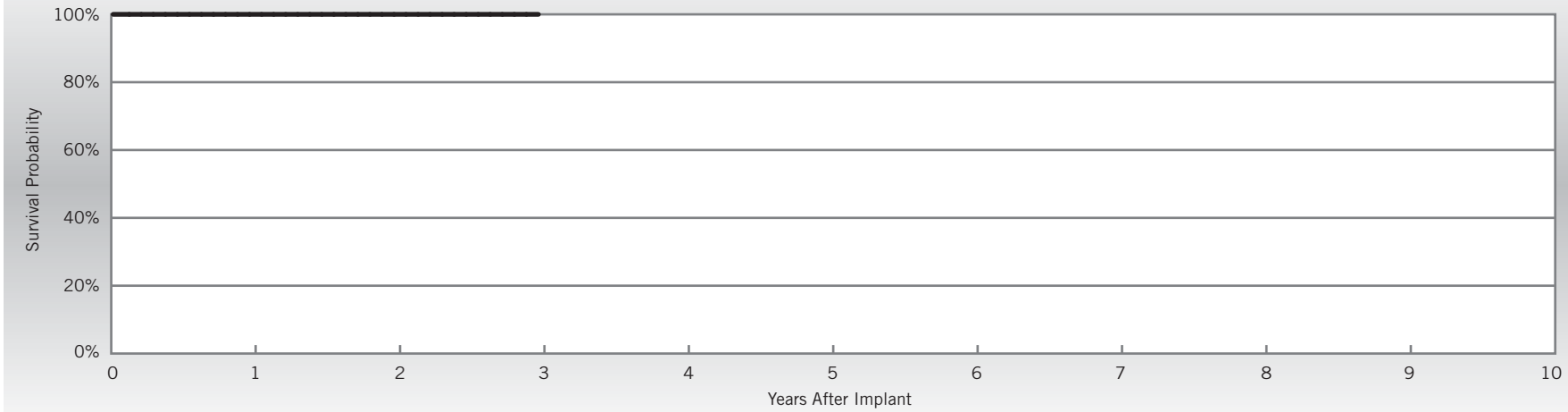
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	140
Cumulative Months of Follow-up	3,950
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	1.43%
Total	**2**	**1.43%**



Year	1	2	3							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	130	100	60							

Customer Reported Performance Data

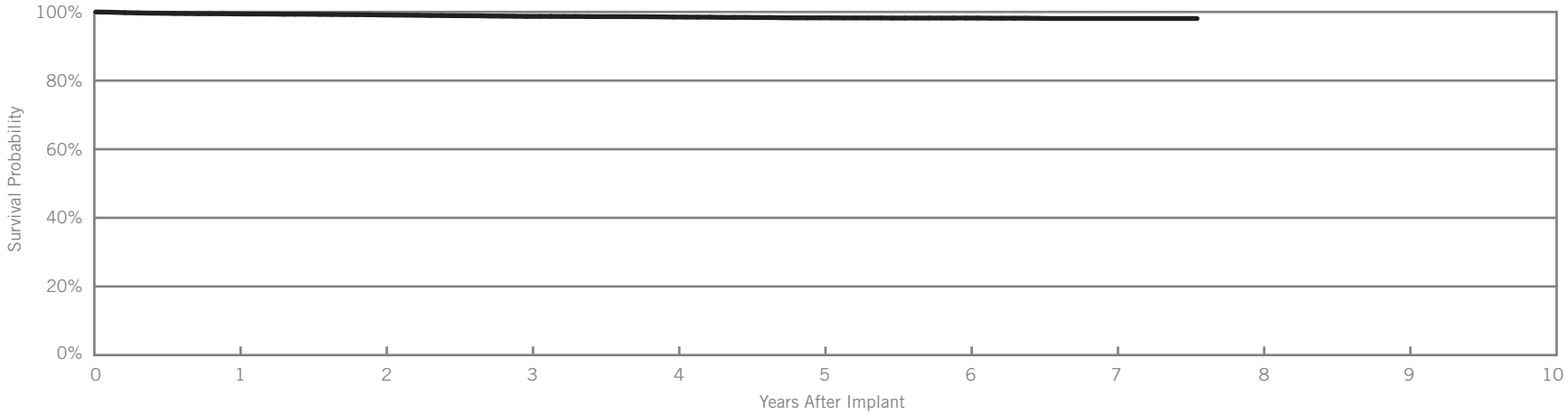
QuickSite®

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	8,824
Estimated Active US Implants	2,710
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
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	10	0.11%	26	0.29%
Failure to Capture	3	0.03%	30	0.34%
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%	2	0.02%
Extracardiac Stimulation	10	0.11%	13	0.15%
Other	2	0.02%	9	0.10%
Total	**25**	**0.28%**	**80**	**0.91%**
Total Returned for Analysis	**13**		**38**	

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	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	26	0.29%
Total	**28**	**0.32%**



Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.43%	99.14%	98.71%	98.52%	98.28%	98.22%	98.09%	98.09%		
± 1 standard error	0.09%	0.11%	0.14%	0.15%	0.18%	0.18%	0.20%	0.20%		
Sample Size	7900	6600	5700	4800	3900	3100	2000	200		

Summary Information

Left-Heart Leads

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
1258T	QuickFlex® µ	99.53%									
1156T	QuickFlex®	99.63%	99.48%	99.37%	99.29%						
1158T	QuickFlex® XL	99.59%	99.51%	99.26%							
1058T	QuickSite® XL	99.69%	99.49%	99.30%	99.11%	98.99%					
1056T	QuickSite®	99.40%	99.17%	98.97%	98.75%	98.58%	98.44%				
1056K	QuickSite®	99.43%	99.14%	98.71%	98.52%	98.28%	98.22%	98.09%			

Acute Observation Summary

Post Implant ≤30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1258T	May-10	21855	18399	0	0.00%	0	0.00%	23	0.11%	9	0.04%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	12	0.05%	4	0.02%	**49**	**0.22%**	**20**
1156T	Jul-07	27933	19964	0	0.00%	0	0.00%	13	0.05%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.06%	9	0.03%	**43**	**0.15%**	**14**
1158T	Jul-07	15449	10955	0	0.00%	0	0.00%	9	0.06%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	6	0.04%	6	0.04%	**25**	**0.16%**	**12**
1058T	Feb-06	10405	5696	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**	**0.25%**	**8**
1056T	Apr-05	34358	16556	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	0.06%	9	0.03%	**80**	**0.23%**	**26**
1056K	Jun-04	8824	2710	0	0.00%	0	0.00%	10	0.11%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	10	0.11%	2	0.02%	**25**	**0.28%**	**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	
1258T	May-10	21855	18399	0	0.00%	0	0.00%	36	0.16%	7	0.03%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	5	0.02%	1	<0.01%	**50**	**0.23%**	**33**
1156T	Jul-07	27933	19964	0	0.00%	1	<0.01%	42	0.15%	20	0.07%	3	0.01%	0	0.00%	1	<0.01%	5	0.02%	19	0.07%	1	<0.01%	**92**	**0.33%**	**46**
1158T	Jul-07	15449	10955	0	0.00%	1	0.01%	33	0.21%	8	0.05%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	5	0.03%	1	0.01%	**51**	**0.33%**	**32**
1058T	Feb-06	10405	5696	0	0.00%	1	0.01%	11	0.11%	21	0.20%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	5	0.05%	1	0.01%	**42**	**0.40%**	**14**
1056T	Apr-05	34358	16556	1	<0.01%	3	0.01%	90	0.26%	80	0.23%	4	0.01%	1	<0.01%	1	<0.01%	4	0.01%	45	0.13%	8	0.02%	**237**	**0.69%**	**98**
1056K	Jun-04	8824	2710	0	0.00%	0	0.00%	26	0.29%	30	0.34%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	13	0.15%	9	0.10%	**80**	**0.91%**	**38**

Definitions of observations and complications can be found on pages 8-9.

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
1258T	21855	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%	0	0.00%	43	0.20%	**45**	**0.21%**
1156T	27933	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**	0	0.00%	0	0.00%	0	0.00%	6	0.02%	0	0.00%	**6**	**0.02%**	0	0.00%	0	0.00%	48	0.17%	**55**	**0.20%**
1158T	15449	0	0.00%	1	0.01%	1	0.01%	**2**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	0.01%	**3**	**0.02%**	1	0.01%	0	0.00%	35	0.23%	**41**	**0.27%**
1058T	10405	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	3	0.03%	1	0.01%	**4**	**0.04%**	0	0.01%	1	0.01%	12	0.12%	**18**	**0.17%**
1056T	34358	0	0.00%	1	<0.01%	3	0.01%	**4**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	13	0.04%	2	0.01%	**15**	**0.04%**	0	0.00%	1	<0.01%	87	0.25%	**107**	**0.31%**
1056K	8824	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	26	0.29%	**28**	**0.32%**

Definitions of malfunction categories can be found on pages 9-10.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1258T	489	4907	0	0.00%	0	0.00%	1	0.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.20%**
1156T	584	14053	0	0.00%	0	0.00%	1	0.17%	3	0.51%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.34%	0	0.00%	**6**	**1.03%**
1158T	455	11238	0	0.00%	0	0.00%	1	0.22%	2	0.44%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.44%	0	0.00%	**5**	**1.10%**
1056T	140	3950	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%**

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
1258T	489	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	0.41%	**2**	**0.41%**
1156T	584	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	0.17%	**1**	**0.17%**
1158T	455	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	0.66%	**3**	**0.66%**
1056T	140	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	1.43%	**2**	**1.43%**

Definitions of complications can be found on page 13.
Definitions of malfunction categories can be found on pages 9-10.

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical
More control. Less risk.

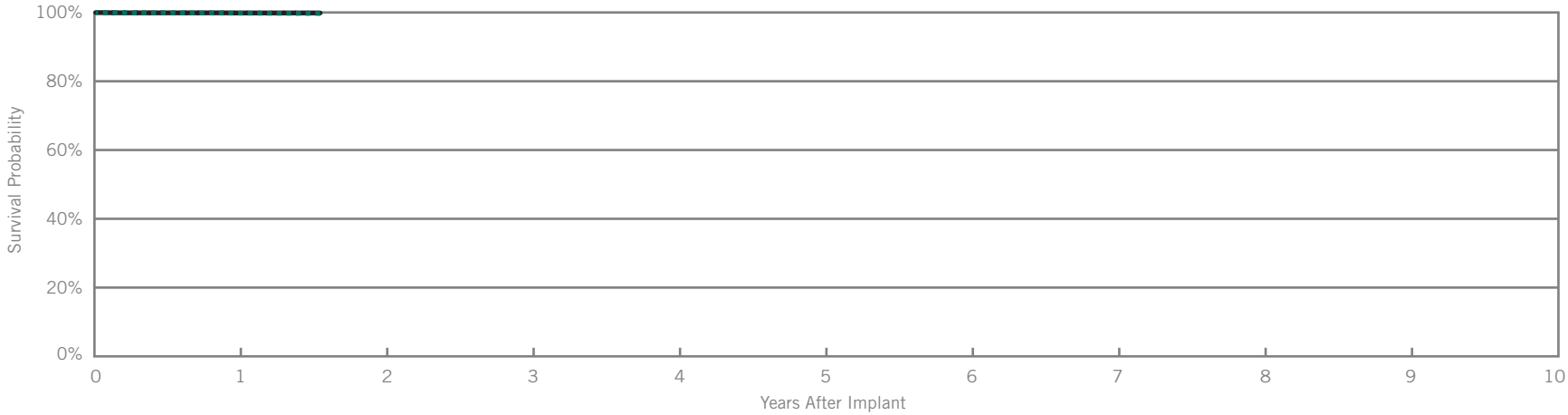
Customer Reported Performance Data

Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	17,921
Estimated Active US Implants	15,942
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	7
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	0	0.00%	2	0.01%
Battery	1	0.01%	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	**3**	**0.02%**	**5**	**0.03%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.72%	99.72%								
± 1 standard error	0.04%	0.05%								
Sample Size	12700	700								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.86%	99.86%								
± 1 standard error	0.03%	0.04%								

SCORE Registry Performance Data

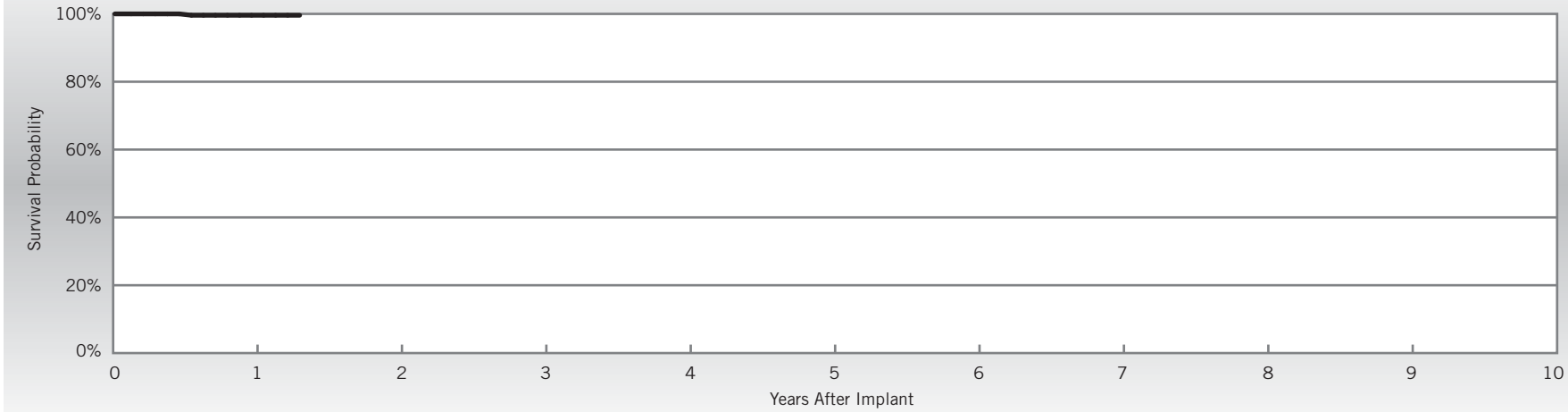
Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	349
Cumulative Months of Follow-up	3,564
Estimated Longevity	(see table on page 82)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	1	0.29%

	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	0.29%	0	0.00%
Total	**1**	**0.29%**	**0**	**0.00%**



Year	1	at 16 months								
Survival Probability	99.60%	99.60%								
± 1 standard error	0.40%	0.40%								
Sample Size	230	50								

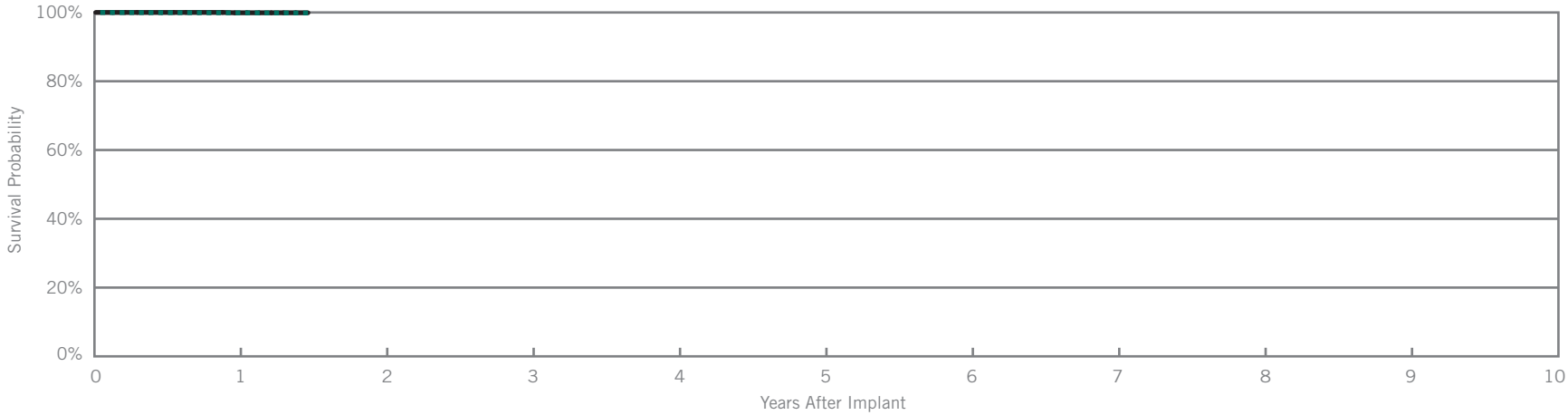
Customer Reported Performance Data

Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	7,403
Estimated Active US Implants	6,628
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	2
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	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	0	0.00%	0	0.00%
Total	**1**	**0.01%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	at 18 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.04%	0.07%								
Sample Size	5100	500								

Excluding Normal Battery Depletion

Year	1	at 18 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.00%	0.06%								

SCORE Registry Performance Data

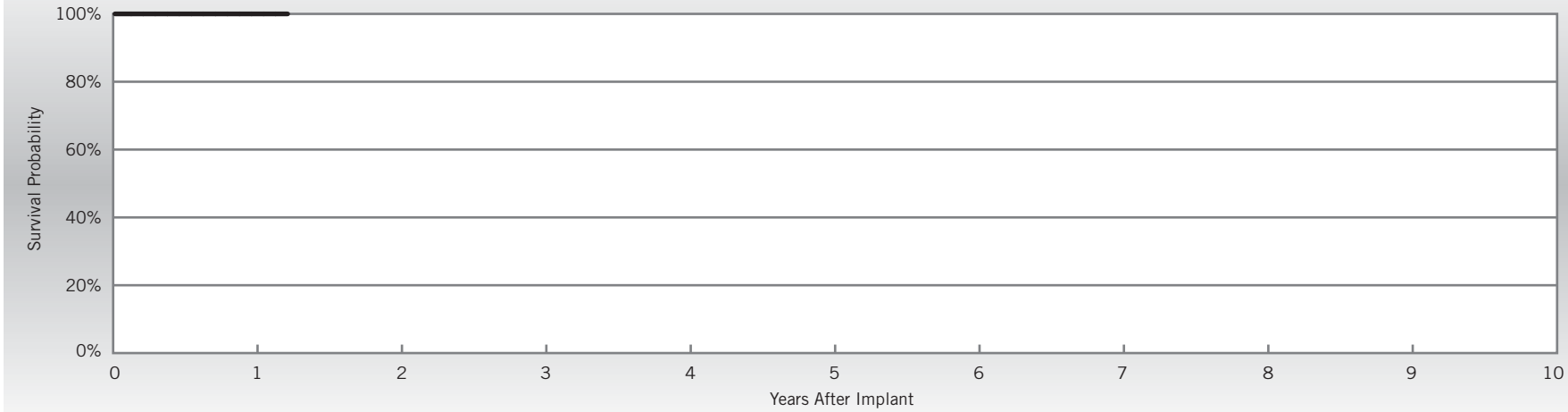
Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	202
Cumulative Months of Follow-up	2,171
Estimated Longevity	(see table on page 82)
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 15 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	140	60								

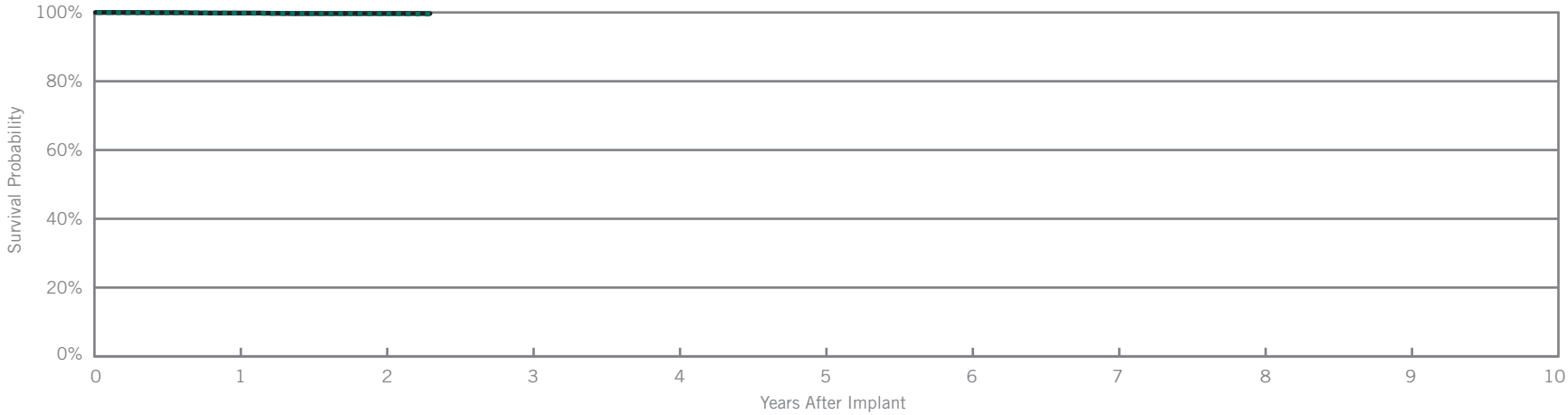
Customer Reported Performance Data

Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	8,500
Estimated Active US Implants	6,726
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	4
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	0.04%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	2	0.02%	2	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	0	0.00%	1	0.01%
Other	0	0.00%	0	0.00%
Total	**6**	**0.07%**	**4**	**0.05%**



Including Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.83%	99.54%	99.54%							
± 1 standard error	0.05%	0.08%	0.08%							
Sample Size	8300	4800	500							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.83%	99.69%	99.69%							
± 1 standard error	0.05%	0.07%	0.07%							

SCORE Registry Performance Data

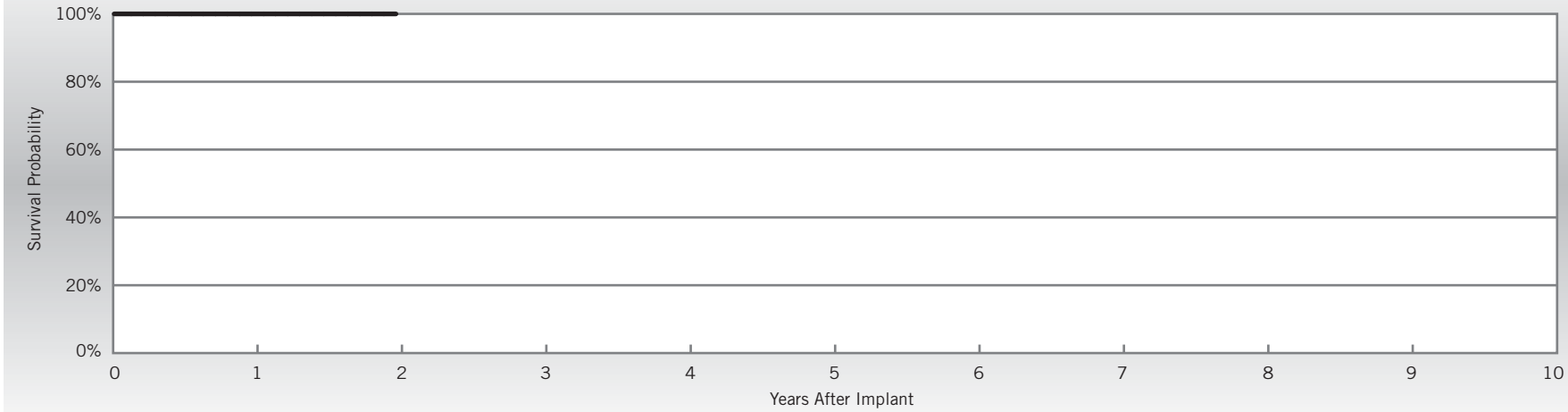
Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	167
Cumulative Months of Follow-up	3,528
Estimated Longevity	(see table on page 82)
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								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	160	100								

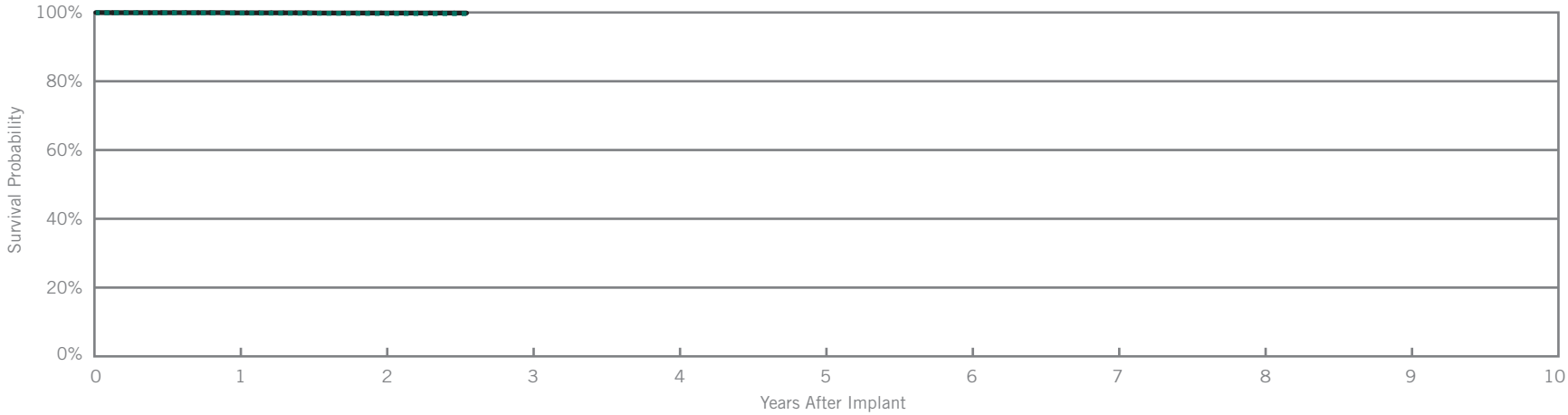
Customer Reported Performance Data

Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	5,944
Estimated Active US Implants	4,645
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	4
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	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.02%
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	**2**	**0.03%**	**2**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.80%	99.66%	99.66%							
± 1 standard error	0.05%	0.08%	0.08%							
Sample Size	5800	3700	300							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.89%	99.84%	99.84%							
± 1 standard error	0.03%	0.06%	0.06%							

SCORE Registry Performance Data

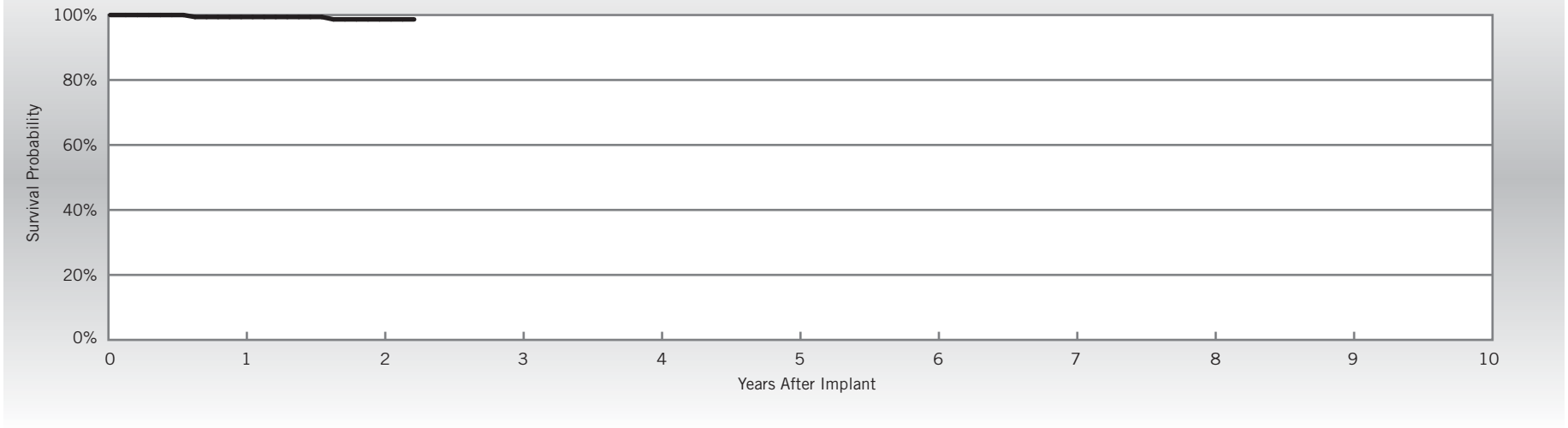
Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	185
Cumulative Months of Follow-up	4,045
Estimated Longevity	(see table on page 101)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.54%
Premature Battery Depletion	1	0.54%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.54%
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	0.54%
Total	**0**	**0.00%**	**2**	**1.08%**



Year	1	2	at 27 months							
Survival Probability	99.40%	98.66%	98.66%							
± 1 standard error	0.60%	0.95%	0.95%							
Sample Size	170	120	60							

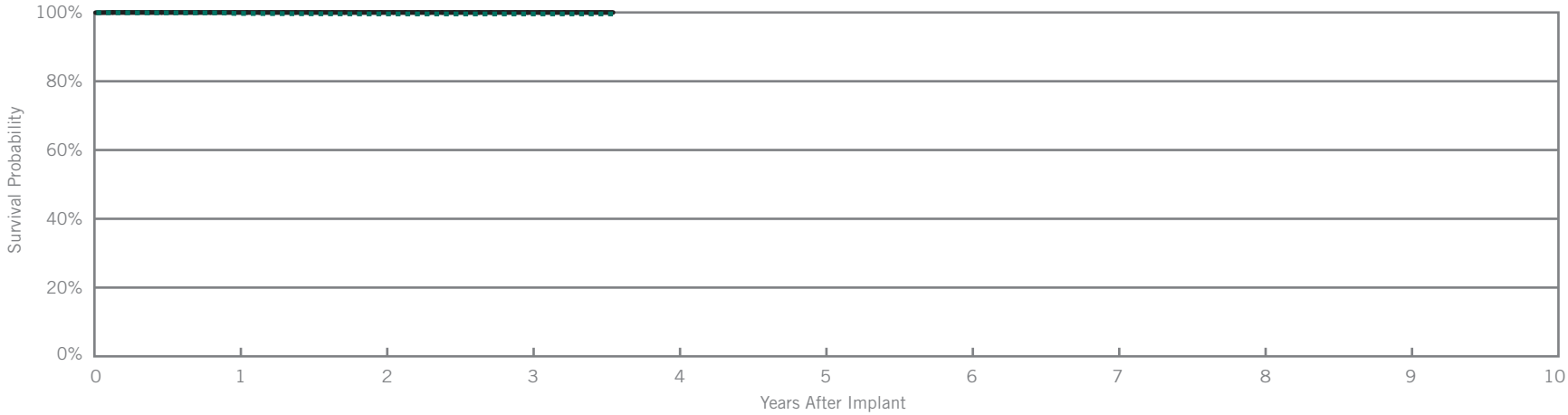
Customer Reported Performance Data

Current® DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,559
Estimated Active US Implants	1,090
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	3
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	at 43 months						
Survival Probability	99.72%	99.57%	99.57%	99.57%						
± 1 standard error	0.09%	0.18%	0.18%	0.18%						
Sample Size	1600	1300	800	200						

Excluding Normal Battery Depletion

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%						

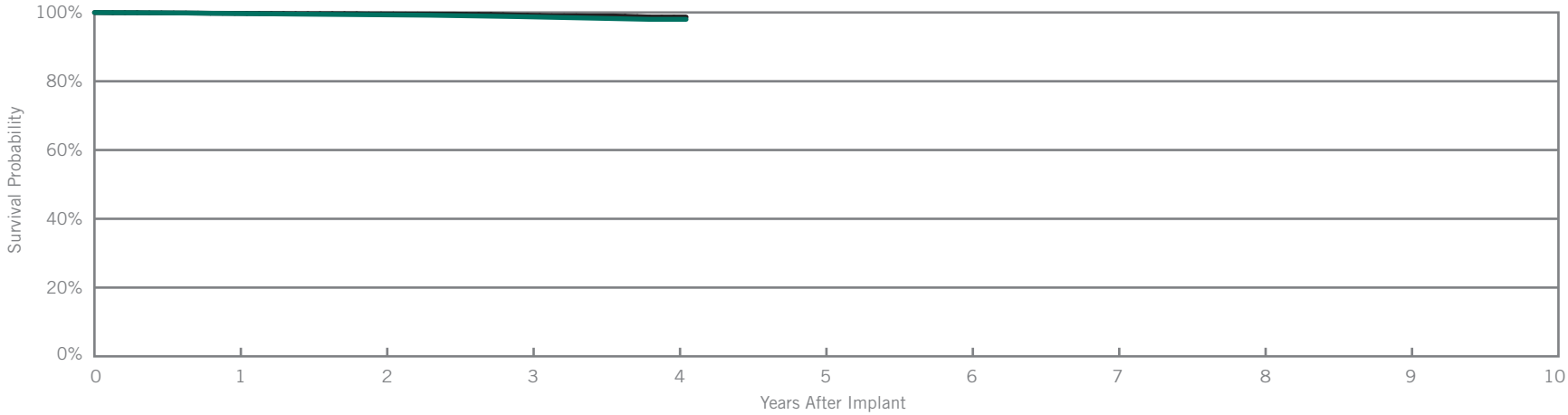
Customer Reported Performance Data

Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,297
Estimated Active US Implants	15,062
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	31
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	0.01%	8	0.04%
Electrical Interconnect	4	0.02%	1	<0.01%
Battery	2	0.01%	3	0.01%
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	16	0.07%	7	0.03%
Other	7	0.03%	2	0.01%
Total	**33**	**0.15%**	**26**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.70%	99.33%	98.71%	98.00%	98.00%					
± 1 standard error	0.04%	0.06%	0.09%	0.18%	0.18%					
Sample Size	22300	18700	12700	4100	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.75%	99.59%	99.19%	98.68%	98.68%					
± 1 standard error	0.03%	0.05%	0.07%	0.16%	0.16%					

SCORE Registry Performance Data

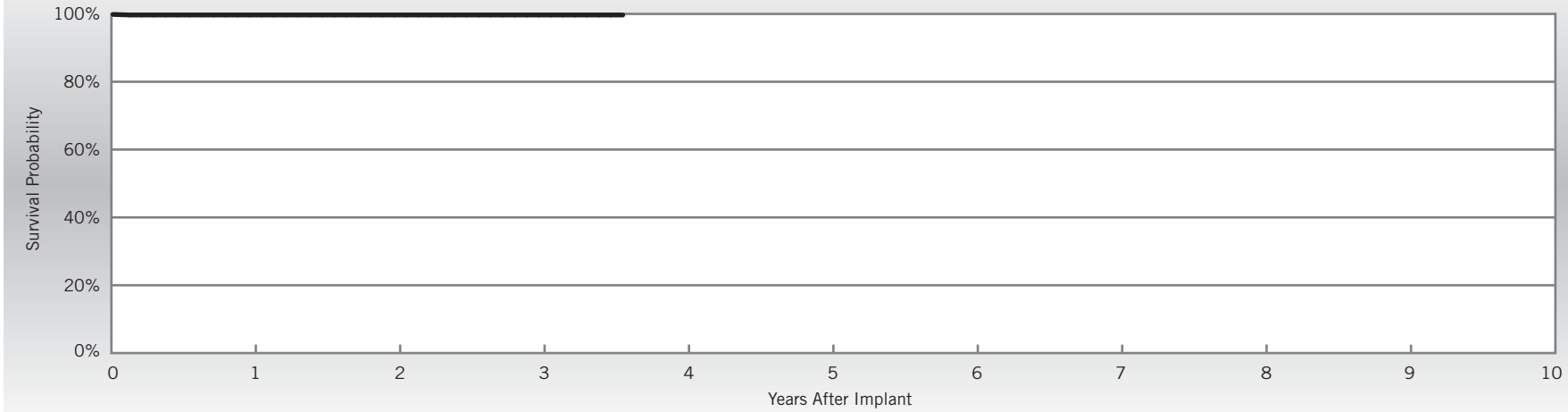
Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	631
Cumulative Months of Follow-up	19,084
Estimated Longevity	(see table on page 82)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Failure To Sense	1	0.16%
Inappropriate Shock	1	0.16%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.16%
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**	**0.16%**



Year	1	2	3	at 43 months						
Survival Probability	99.68%	99.68%	99.68%	99.68%						
± 1 standard error	0.23%	0.23%	0.23%	0.23%						
Sample Size	600	520	340	60						

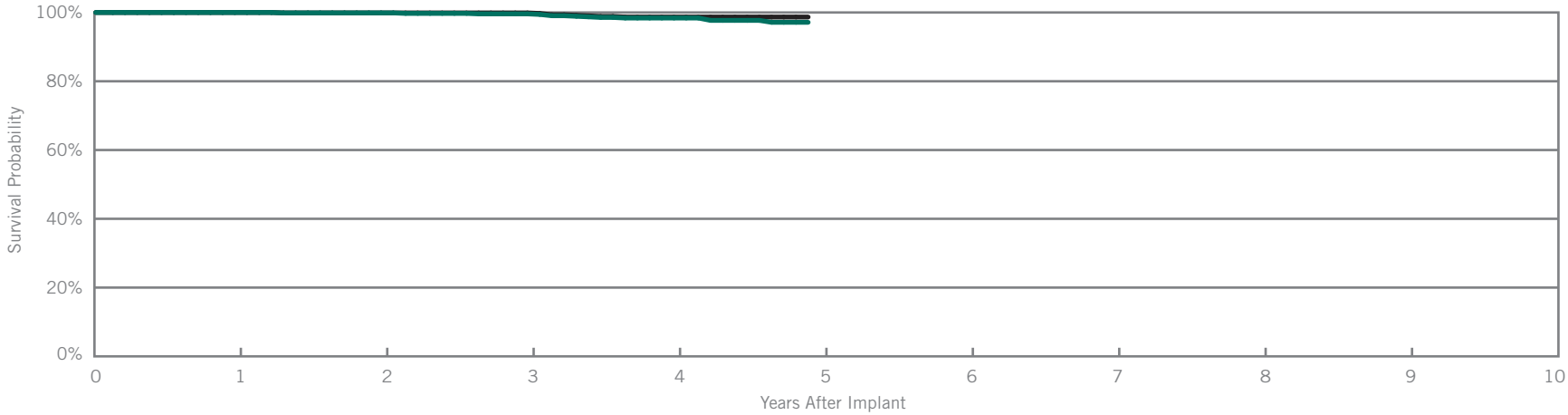
Customer Reported Performance Data

Atlas® II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,880
Estimated Active US Implants	1,098
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	5
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	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	0.11%	2	0.11%
Other	0	0.00%	0	0.00%
Total	**6**	**0.32%**	**2**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	100.00%	99.87%	99.59%	98.39%	97.14%					
± 1 standard error	0.00%	0.09%	0.17%	0.35%	0.61%					
Sample Size	1900	1700	1500	1200	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	100.00%	99.87%	99.87%	98.67%	98.67%					
± 1 standard error	0.00%	0.09%	0.09%	0.32%	0.32%					

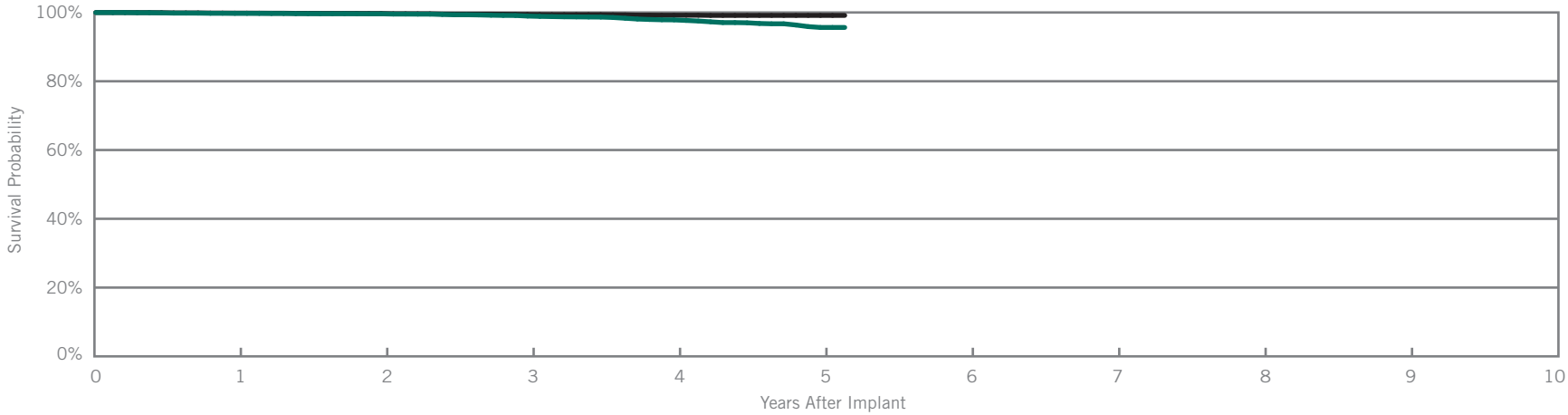
Customer Reported Performance Data

Atlas® II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,751
Estimated Active US Implants	8,461
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	63
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.03%	2	0.01%
Electrical Interconnect	4	0.03%	0	0.00%
Battery	6	0.04%	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	8	0.05%	6	0.04%
Other	3	0.02%	1	0.01%
Total	**26**	**0.18%**	**11**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.74%	99.60%	98.95%	97.84%	95.64%	95.64%				
± 1 standard error	0.04%	0.06%	0.09%	0.16%	0.35%	0.39%				
Sample Size	14800	12600	10500	7400	3100	400				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.82%	99.70%	99.41%	99.19%	99.14%	99.14%				
± 1 standard error	0.03%	0.05%	0.07%	0.09%	0.10%	0.10%				

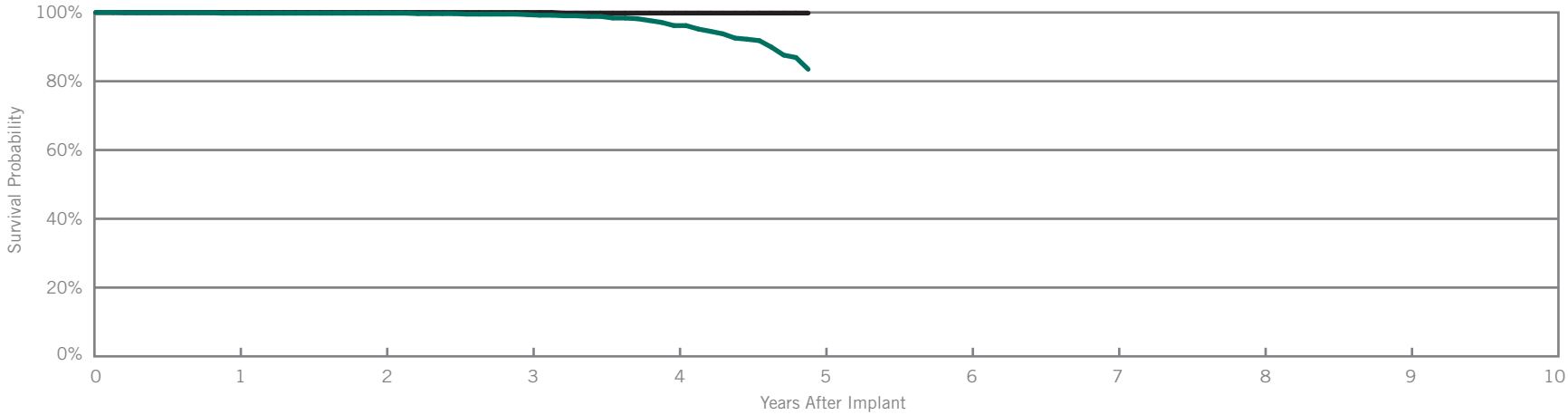
Customer Reported Performance Data

Epic® II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,099
Estimated Active US Implants	1,104
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	45
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 244-256)	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	at 59 months					
Survival Probability	99.79%	99.79%	99.36%	96.18%	83.49%					
± 1 standard error	0.10%	0.10%	0.17%	0.51%	1.46%					
Sample Size	2100	1800	1500	1100	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	100.00%	100.00%	100.00%	99.83%	99.83%					
± 1 standard error	0.00%	0.00%	0.00%	0.12%	0.12%					

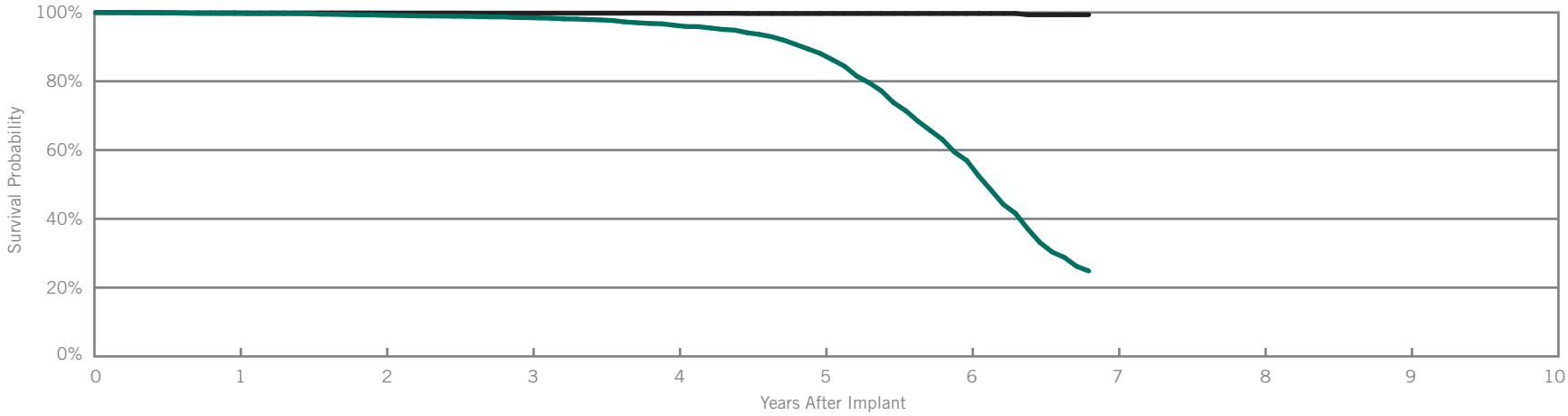
Customer Reported Performance Data

Epic® + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,847
Estimated Active US Implants	1,754
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	731
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 244-256)	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%	2	0.03%
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%	0	0.00%
Total	**5**	**0.06%**	**5**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.69%	99.21%	98.49%	96.29%	88.08%	56.95%	24.84%			
± 1 standard error	0.07%	0.10%	0.15%	0.24%	0.46%	0.92%	1.17%			
Sample Size	7800	6900	6200	5500	4400	2800	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.89%	99.83%	99.80%	99.75%	99.70%	99.70%	99.34%			
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.07%	0.07%	0.27%			

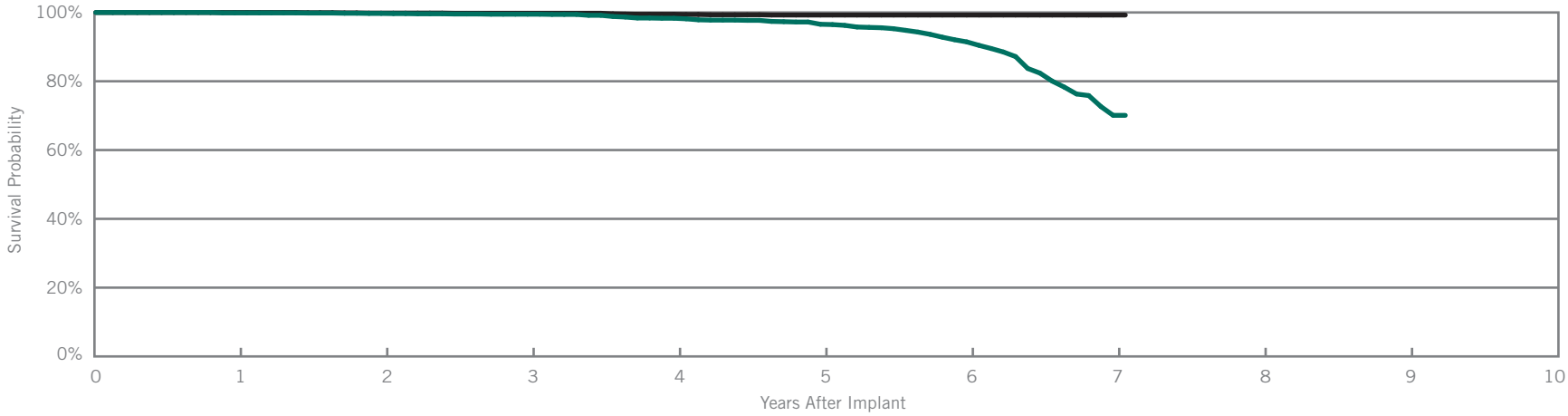
Customer Reported Performance Data

Atlas® DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,648
Estimated Active US Implants	1,855
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	122
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	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%	0	0.00%
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**	**0.22%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.88%	99.72%	99.49%	98.32%	96.57%	91.45%	70.09%	70.09%		
± 1 standard error	0.05%	0.08%	0.12%	0.23%	0.30%	0.61%	1.67%	1.84%		
Sample Size	4600	4000	3700	3200	2700	1800	800	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	85 months		
Survival Probability	100.00%	99.84%	99.78%	99.48%	99.25%	99.25%	99.25%	99.25%		
± 1 standard error	0.00%	0.06%	0.08%	0.13%	0.16%	0.16%	0.16%	0.16%		

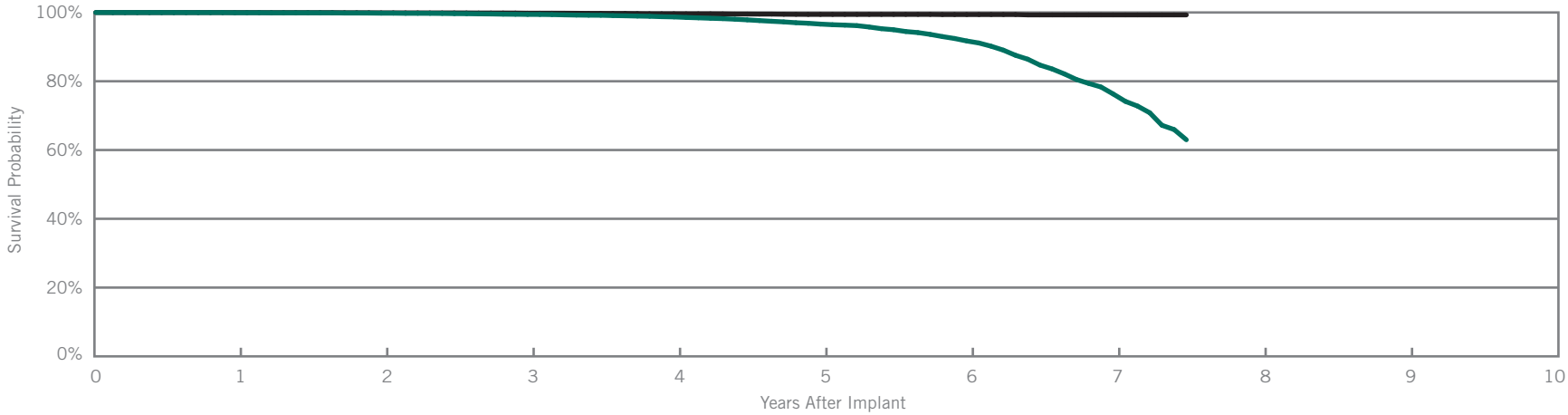
Customer Reported Performance Data

Atlas® + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	20,997
Estimated Active US Implants	8,548
Estimated Longevity	(see table on page 82)
Normal Battery Depletion	405
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	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%	2	0.01%
Other	5	0.02%	1	<0.01%
Total	**26**	**0.12%**	**10**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.93%	99.79%	99.43%	98.70%	96.62%	91.71%	76.30%	62.98%		
± 1 standard error	0.01%	0.03%	0.06%	0.09%	0.16%	0.31%	0.82%	1.49%		
Sample Size	21000	18300	16200	14000	11100	6700	2400	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.97%	99.90%	99.80%	99.63%	99.43%	99.39%	99.29%	99.29%		
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.07%	0.07%	0.10%	0.10%		

Battery Longevity Summary

Dual-Chamber ICDs

St. Jude Medical™
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD2231-40Q	Fortify® DR**	10.2	9.4	8.7	7.6
CD2231-40	Fortify® DR**	10.2	9.4	8.7	7.6
CD2211-36Q	Current® + DR	8.2	7.5	7.0	6.1
CD2211-36	Current® + DR	8.2	7.5	7.0	6.1
2207-30	Current® DR RF	6.5	5.9	5.4	4.6
2207-36	Current® DR RF	8.2	7.5	7.0	6.1
V-265	Atlas® II DR	8.2	7.5	7.0	6.1
V-268	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-239	Epic® + DR	6.4	6.0	5.6	4.5
V-242	Atlas® DR	7.9	7.3	6.9	6.1
V-243	Atlas® + DR	7.9	7.3	6.9	6.1

**Battery longevity calculated with one EGM storage.*
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 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.
***Three maximum charges per year. Battery voltage range: 3.20-2.59.*

Summary Information

Dual-Chamber ICDs

St. Jude Medical
More control. Less risk.

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
CD2231-40Q	Fortify® DR	99.72%									
CD2231-40	Fortify® DR	99.84%									
CD2211-36Q	Current® + DR	99.83%	99.54%								
CD2211-36	Current® + DR	99.80%	99.66%								
2207-30	Current® DR RF	99.72%	99.57%	99.57%							
2207-36	Current® DR RF	99.70%	99.33%	98.71%	98.00%						
V-265	Atlas® II DR	100.00%	99.87%	99.59%	98.39%						
V-268	Atlas® II + DR	99.74%	99.60%	98.95%	97.84%	95.64%					
V-258	Epic® II + DR	99.79%	99.79%	99.36%	96.18%						
V-239	Epic® + DR	99.69%	99.21%	98.49%	96.29%	88.08%	56.95%				
V-242	Atlas® DR	99.88%	99.72%	99.49%	98.32%	96.57%	91.45%	70.09%			
V-243	Atlas® + DR	99.93%	99.79%	99.43%	98.70%	96.62%	91.71%	76.30%			

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
CD2231-40Q	Fortify® DR	99.86%									
CD2231-40	Fortify® DR	99.91%									
CD2211-36Q	Current® + DR	99.83%	99.69%								
CD2211-36	Current® + DR	99.89%	99.84%								
2207-30	Current® DR RF	100.00%	100.00%	100.00%							
2207-36	Current® DR RF	99.75%	99.59%	99.19%	98.68%						
V-265	Atlas® II DR	100.00%	99.87%	99.87%	98.67%						
V-268	Atlas® II + DR	99.82%	99.70%	99.41%	99.19%	99.14%					
V-258	Epic® II + DR	100.00%	100.00%	100.00%	99.83%						
V-239	Epic® + DR	99.89%	99.83%	99.80%	99.75%	99.70%					
V-242	Atlas® DR	100.00%	99.84%	99.78%	99.48%	99.25%	99.25%	99.25%			
V-243	Atlas® + DR	99.97%	99.90%	99.80%	99.63%	99.43%	99.39%	99.29%			

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
CD2231-40Q	Fortify® DR	17921	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**3**	**0.02%**
CD2231-40	Fortify® DR	7403	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
CD2211-36Q	Current® + DR	8500	3	0.04%	0	0.00%	2	0.02%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.07%**
CD2211-36	Current® + DR	5944	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
2207-30	Current® DR RF	1559	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	22297	3	0.01%	4	0.02%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	16	0.07%	7	0.03%	**33**	**0.15%**
V-265	Atlas® II DR	1880	0	0.00%	0	0.00%	4	0.21%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**6**	**0.32%**
V-268	Atlas® II + DR	14751	5	0.03%	4	0.03%	6	0.04%	0	0.00%	0	0.00%	0	0.00%	8	0.05%	3	0.02%	**26**	**0.18%**
V-258	Epic® II + DR	2099	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-239	Epic® + DR	7847	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%**
V-242	Atlas® DR	4648	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**	**0.22%**
V-243	Atlas® + DR	20997	3	0.01%	1	<0.01%	10	0.05%	1	<0.01%	0	0.00%	0	0.00%	6	0.03%	5	0.02%	**26**	**0.12%**

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
CD2231-40Q	Fortify® DR	17921	3	0.02%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.03%**
CD2231-40	Fortify® DR	7403	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	8500	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	**4**	**0.05%**
CD2211-36	Current® + DR	5944	1	0.02%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
2207-30	Current® DR RF	1559	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	22297	8	0.04%	1	<0.01%	3	0.01%	0	0.00%	4	0.02%	1	<0.01%	7	0.03%	2	0.01%	**26**	**0.12%**
V-265	Atlas® II DR	1880	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**2**	**0.11%**
V-268	Atlas® II + DR	14751	2	0.01%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	1	0.01%	**11**	**0.07%**
V-258	Epic® II + DR	2099	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-239	Epic® + DR	7847	1	0.01%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	**5**	**0.06%**
V-242	Atlas® DR	4648	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.02%**
V-243	Atlas® + DR	20997	2	0.01%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	1	<0.01%	2	0.01%	1	<0.01%	**10**	**0.05%**

Definitions of malfunction root cause categories can be found on pages 6-7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Failure to Sense		Inappropriate Shock		Premature Battery Depletion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	349	3564	0	0.00%	0	0.00%	1	0.29%	**1**	**0.29%**
CD2231-40	202	2171	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	167	3528	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36	185	4045	0	0.00%	1	0.54%	1	0.54%	**2**	**1.08%**
2207-36	631	19084	1	0.16%	1	0.16%	0	0.00%	**2**	**0.32%**

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	349	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.29%	**1**	**0.29%**
CD2231-40	Fortify DR	202	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	167	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%**
CD2211-36	Current + DR	185	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%	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
CD2231-40Q	Fortify DR	349	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	202	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	167	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%**
CD2211-36	Current + DR	185	0	0.00%	0	0.00%	1	0.54%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.54%	**2**	**1.08%**
2207-36	Current DR RF	631	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

Definitions of complications can be found on page 13.
Definitions of malfunction root cause categories can be found on pages 6-7.

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical
More control. Less risk.

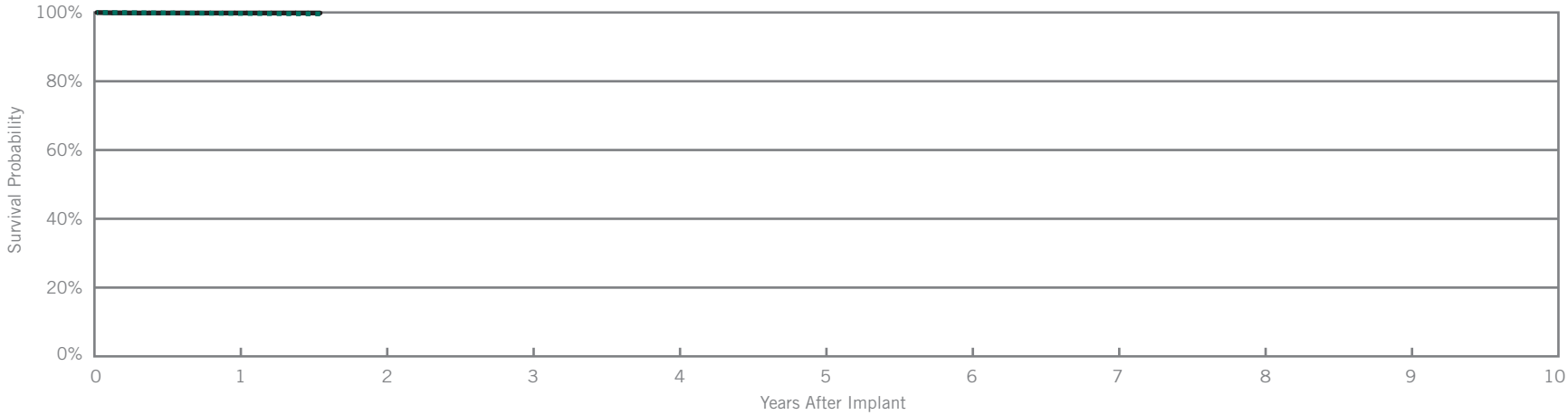
Customer Reported Performance Data

Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Registered US Implants	10,163
Estimated Active US Implants	9,096
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	6
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	0.03%	1	0.01%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.01%	0	0.00%
Total	**5**	**0.05%**	**1**	**0.01%**



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.70%	99.58%								
± 1 standard error	0.06%	0.10%								
Sample Size	7000	300								

Excluding Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.04%	0.04%								

SCORE Registry Performance Data

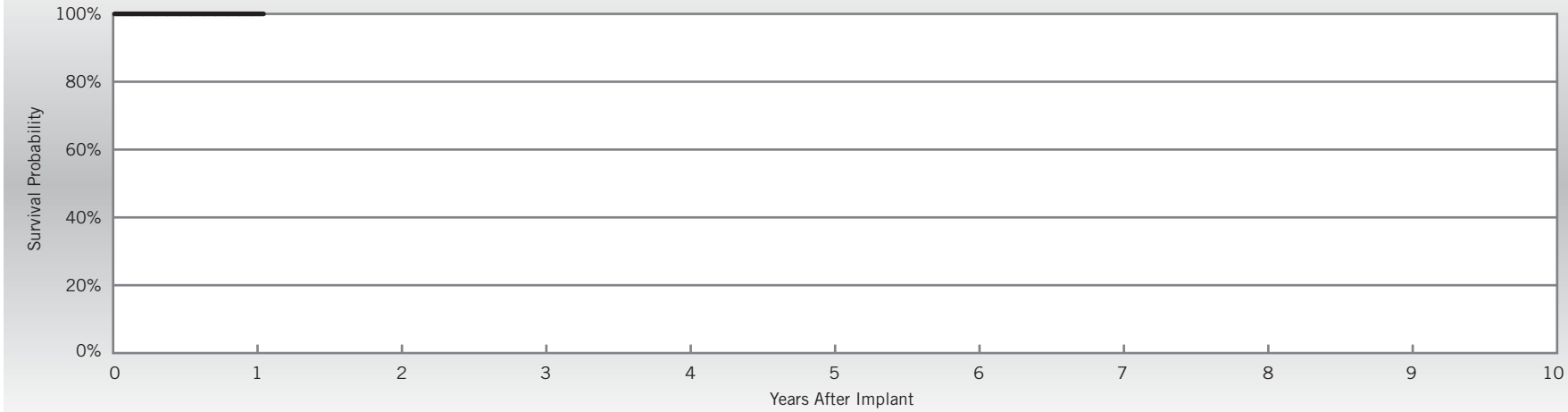
Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	143
Cumulative Months of Follow-up	1,505
Estimated Longevity	(see table on page 101)
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	100	50								

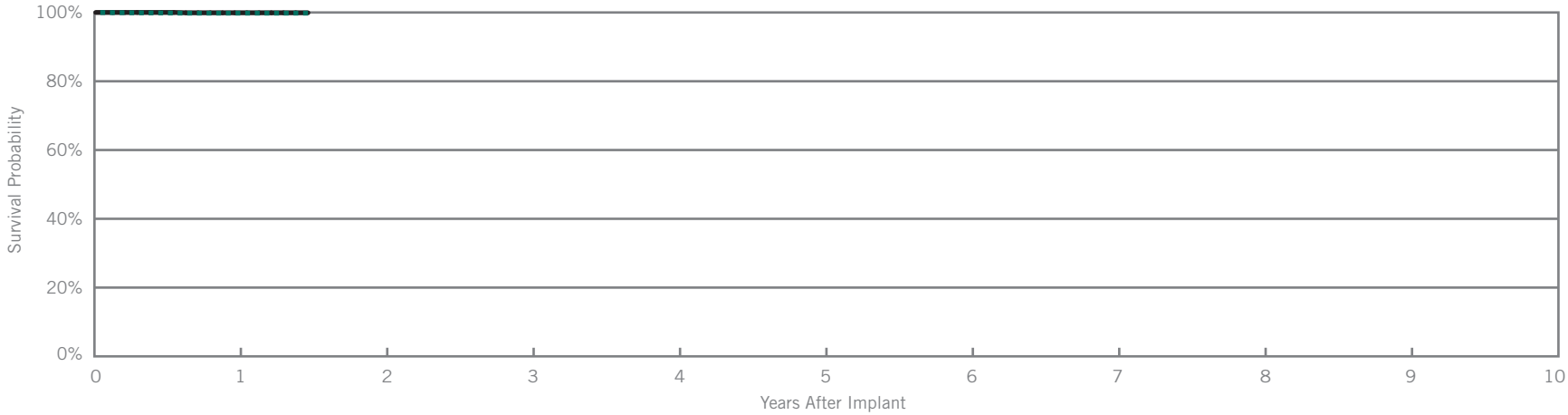
Customer Reported Performance Data

Fortify® VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	4,309
Estimated Active US Implants	3,869
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	2
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	0.02%
Total	**0**	**0.00%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	at 18 months								
Survival Probability	99.80%	99.80%								
± 1 standard error	0.09%	0.09%								
Sample Size	3000	200								

Excluding Normal Battery Depletion

Year	1	at 18 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.06%	0.06%								

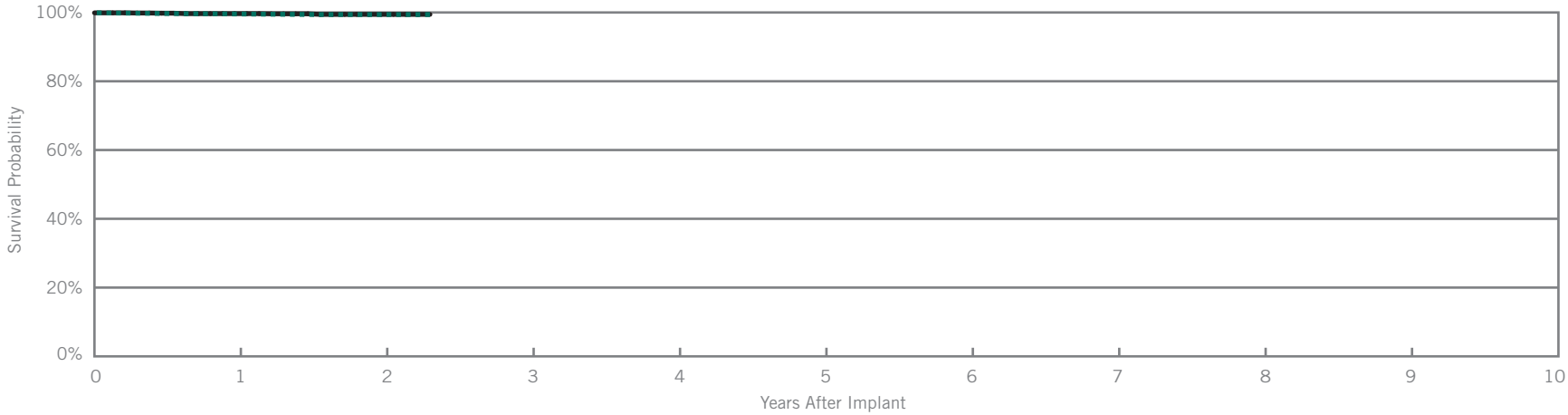
Customer Reported Performance Data

Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	4,472
Estimated Active US Implants	3,512
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	1
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	0.04%	2	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.02%	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	1	0.02%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**5**	**0.11%**	**4**	**0.09%**



Including Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.61%	99.39%	99.39%							
± 1 standard error	0.09%	0.13%	0.13%							
Sample Size	4400	2500	200							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.66%	99.44%	99.44%							
± 1 standard error	0.09%	0.12%	0.12%							

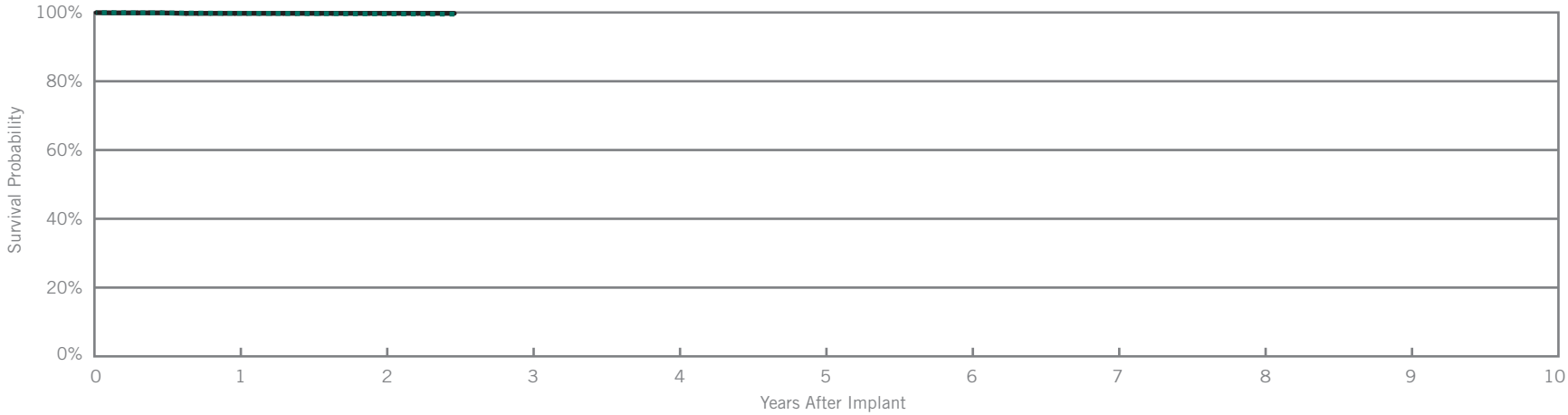
Customer Reported Performance Data

Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,355
Estimated Active US Implants	2,639
Estimated Longevity	(see table on page 101)
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%	0	0.00%
Electrical Interconnect	1	0.03%	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	**4**	**0.12%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.74%	99.52%	99.52%							
± 1 standard error	0.09%	0.14%	0.14%							
Sample Size	3200	2000	400							

Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.74%	99.74%	99.74%							
± 1 standard error	0.09%	0.09%	0.09%							

SCORE Registry Performance Data

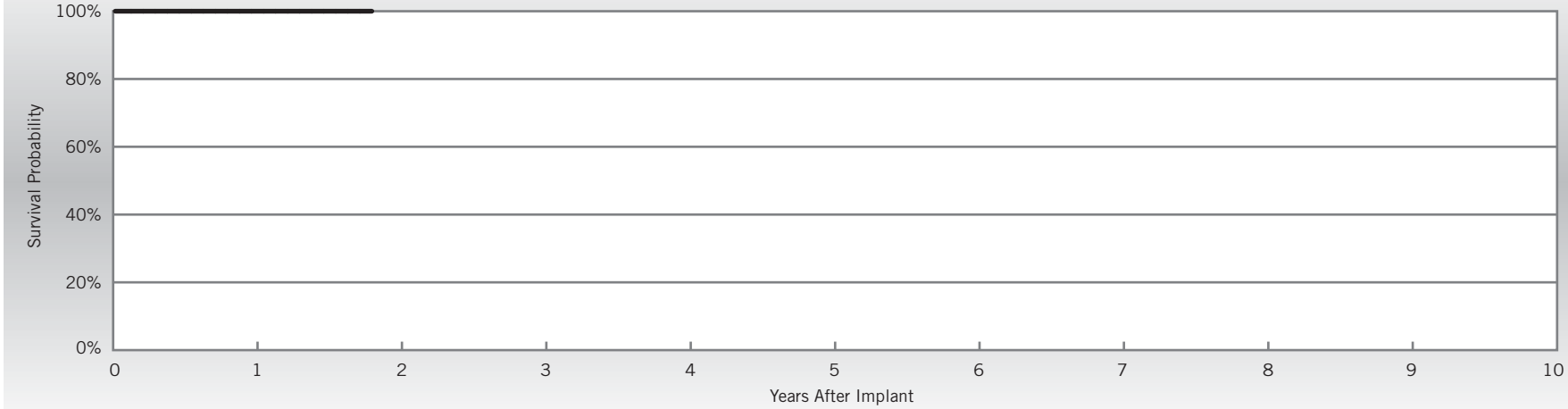
Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	108
Cumulative Months of Follow-up	2,264
Estimated Longevity	(see table on page 101)
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	1	0.93%	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**	**0.93%**	**0**	**0.00%**



Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	100	60								

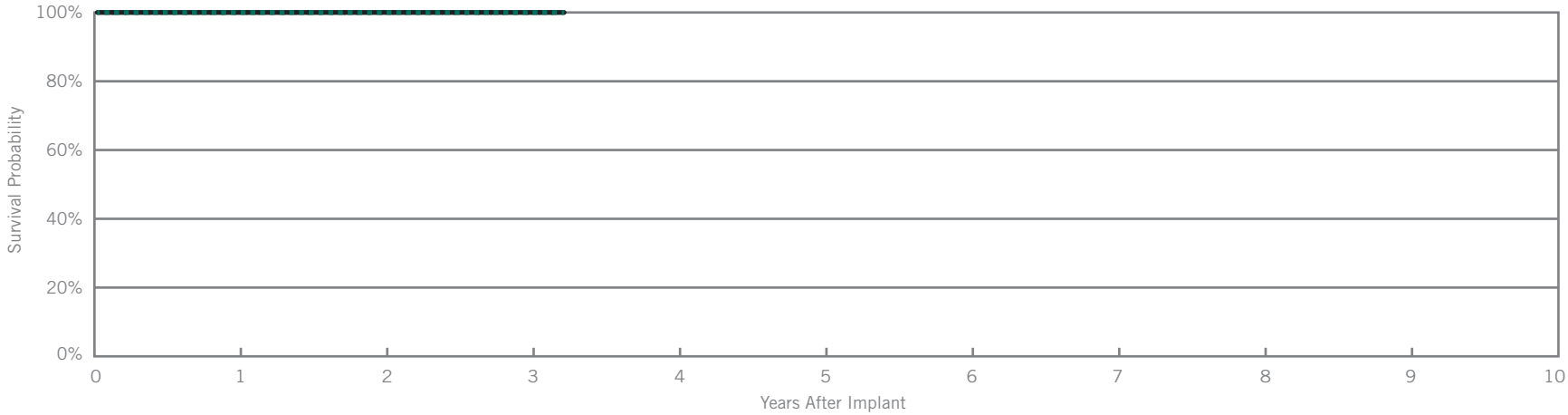
Customer Reported Performance Data

Current® VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	876
Estimated Active US Implants	613
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	0
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	at 39 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	900	700	500	200						

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%						

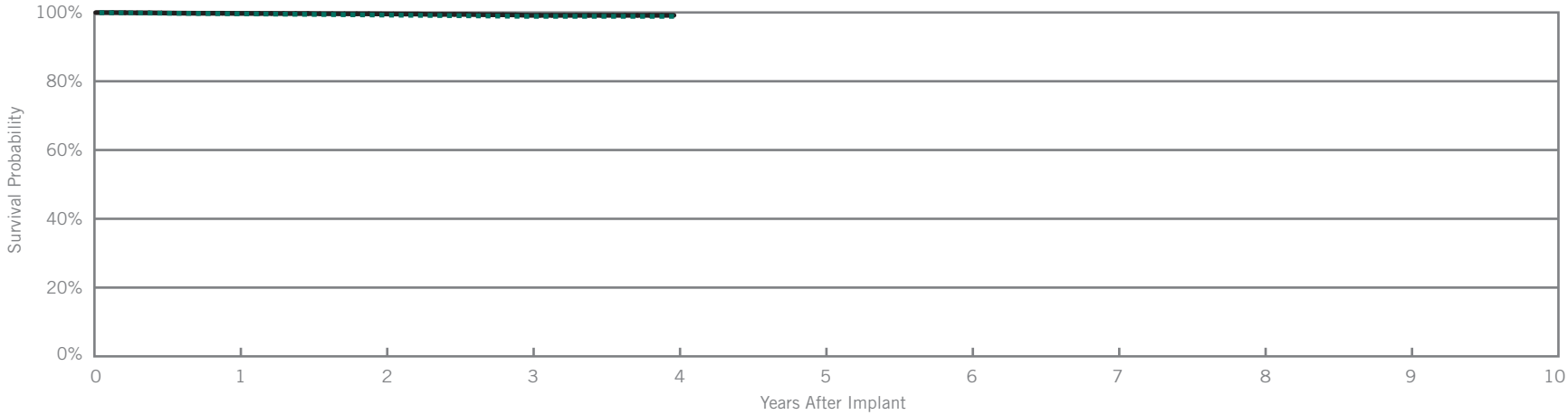
Customer Reported Performance Data

Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,170
Estimated Active US Implants	8,909
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	12
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%	3	0.02%
Electrical Interconnect	6	0.05%	0	0.00%
Battery	1	0.01%	3	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	2	0.02%	3	0.02%
Other	3	0.02%	3	0.02%
Total	**19**	**0.14%**	**13**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.63%	99.30%	98.87%	98.87%						
± 1 standard error	0.05%	0.07%	0.10%	0.12%						
Sample Size	13200	10800	6900	2200						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.73%	99.58%	99.17%	99.17%						
± 1 standard error	0.04%	0.06%	0.09%	0.10%						

SCORE Registry Performance Data

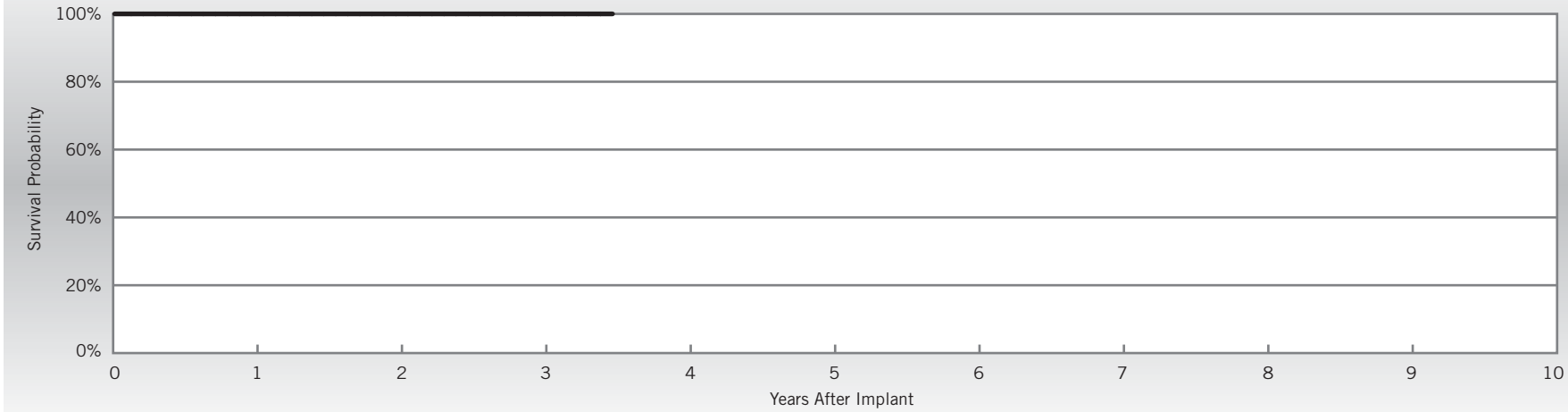
Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	12,308
Estimated Longevity	(see table on page 101)
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 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	380	340	230	60						

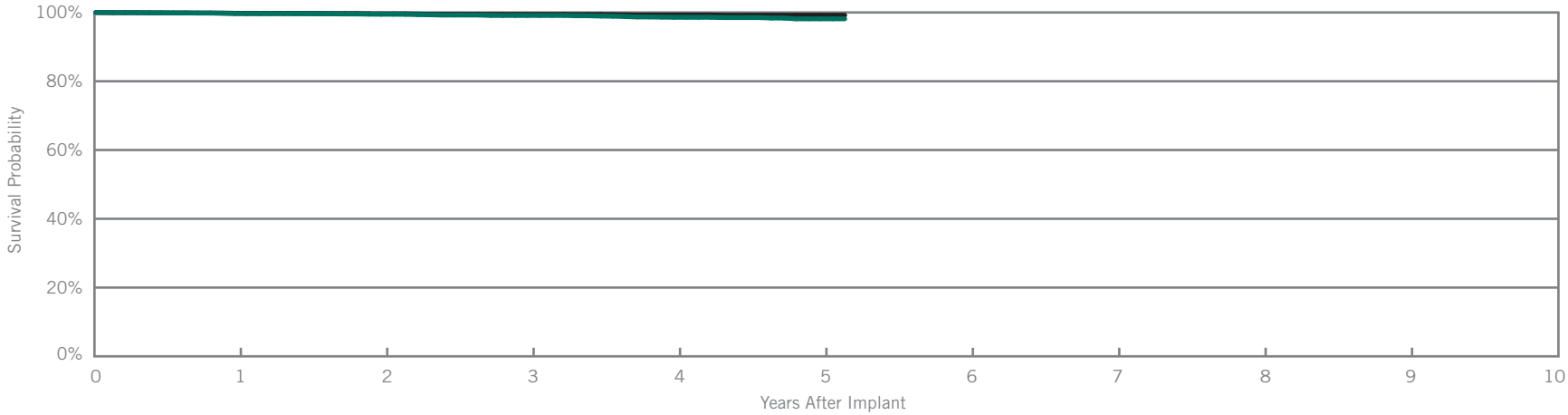
Customer Reported Performance Data

Atlas® II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,506
Estimated Active US Implants	6,248
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	18
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	2	0.02%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	6	0.06%	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	6	0.06%	2	0.02%
Other	5	0.05%	2	0.02%
Total	**21**	**0.20%**	**7**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.68%	99.48%	99.13%	98.59%	98.15%	98.15%				
± 1 standard error	0.05%	0.07%	0.10%	0.14%	0.24%	0.24%				
Sample Size	10500	9100	7500	5300	2100	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.77%	99.60%	99.43%	99.27%	99.19%	99.19%				
± 1 standard error	0.04%	0.06%	0.08%	0.10%	0.11%	0.11%				

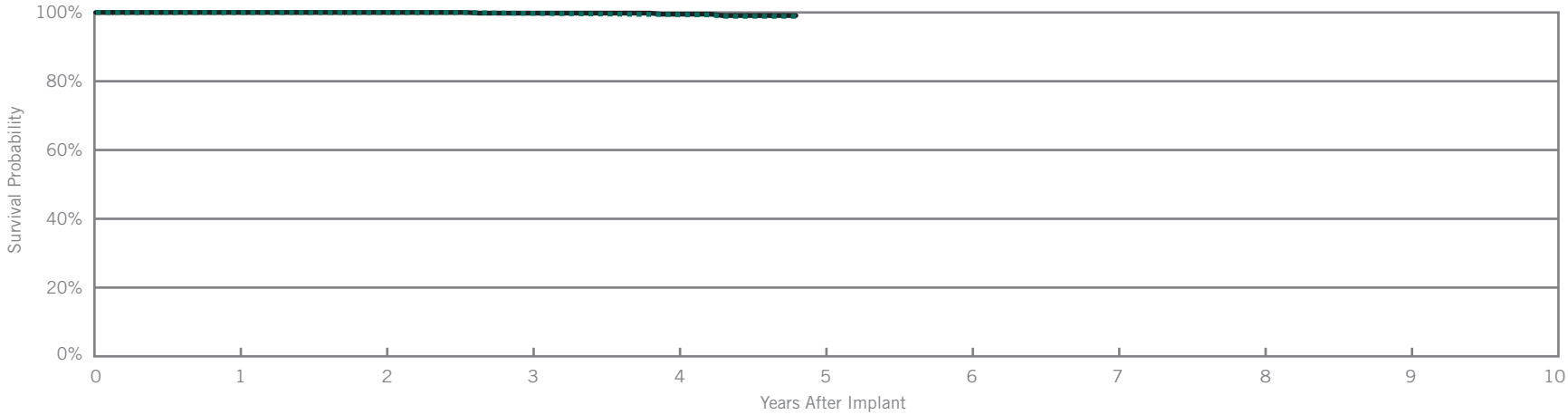
Customer Reported Performance Data

Epic® II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,572
Estimated Active US Implants	893
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	1
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 244-256)	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%	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	at 58 months					
Survival Probability	100.00%	100.00%	99.81%	99.29%	98.88%					
± 1 standard error	0.00%	0.00%	0.14%	0.29%	0.41%					
Sample Size	1600	1300	1100	900	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	100.00%	100.00%	99.81%	99.51%	99.10%					
± 1 standard error	0.00%	0.00%	0.14%	0.25%	0.38%					

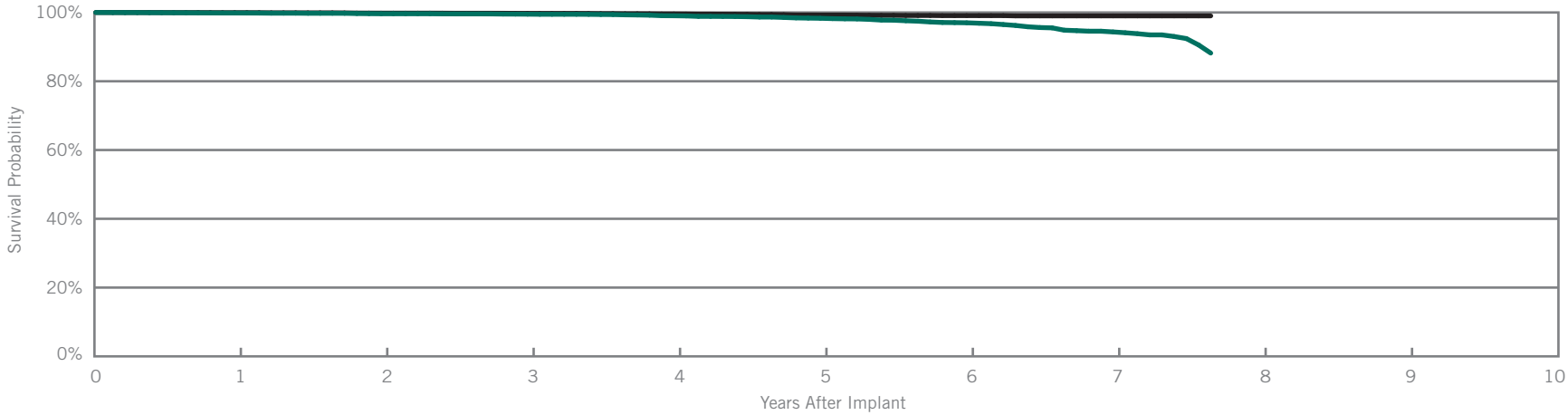
Customer Reported Performance Data

Atlas® + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,582
Estimated Active US Implants	9,244
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	112
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 244-256)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	2	0.01%
Electrical Interconnect	4	0.02%	1	<0.01%
Battery	4	0.02%	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	21	0.10%	3	0.01%
Other	5	0.02%	2	0.01%
Total	**37**	**0.18%**	**12**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 92 months		
Survival Probability	99.84%	99.63%	99.50%	99.04%	98.31%	97.00%	94.34%	88.19%		
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.12%	0.18%	0.38%	1.10%		
Sample Size	20600	17900	15800	13500	10700	6700	2600	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 92 months		
Survival Probability	99.95%	99.81%	99.74%	99.57%	99.24%	99.08%	99.01%	99.01%		
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.08%	0.09%	0.11%	0.11%		

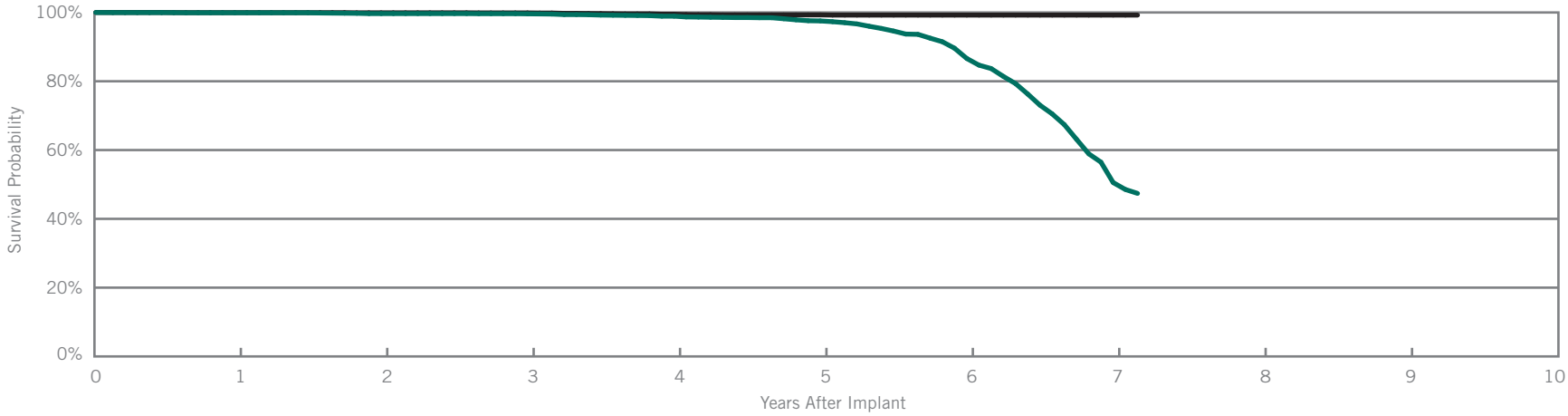
Customer Reported Performance Data

Epic® + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,967
Estimated Active US Implants	2,402
Estimated Longevity	(see table on page 101)
Normal Battery Depletion	318
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 244-256)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	14	0.18%
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	2	0.03%	0	0.00%
Total	**4**	**0.05%**	**14**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.92%	99.67%	99.60%	98.92%	97.54%	86.63%	50.55%	47.40%		
± 1 standard error	0.03%	0.07%	0.07%	0.14%	0.23%	0.57%	1.51%	1.73%		
Sample Size	8000	7000	6200	5400	4500	3000	1300	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.95%	99.91%	99.88%	99.49%	99.29%	99.23%	99.23%	99.23%		
± 1 standard error	0.03%	0.04%	0.04%	0.10%	0.12%	0.12%	0.12%	0.12%		

Battery Longevity Summary

Single-Chamber ICDs

St. Jude Medical
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD1231-40Q	Fortify® VR**	10.5	10.1	9.7	9.1
CD1231-40	Fortify® VR**	10.5	10.1	9.7	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
1207-30	Current® VR RF	6.7	6.4	6.1	5.6
1207-36	Current® VR RF	8.4	8.0	7.6	7.0
V-168	Atlas® II VR	8.4	8.0	7.6	7.0
V-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

**Battery longevity calculated with one EGM storage.*
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 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.
***Three maximum charges per year. Battery voltage range: 3.20-2.59.*

Summary Information

Single-Chamber ICDs

St. Jude Medical
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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
CD1231-40Q	Fortify® VR	99.70%									
CD1231-40	Fortify® VR	99.80%									
CD1211-36Q	Current® + VR	99.61%	99.39%								
CD1211-36	Current® + VR	99.74%	99.52%								
1207-30	Current® VR RF	100.00%	100.00%	100.00%							
1207-36	Current® VR RF	99.63%	99.30%	98.87%	98.87%						
V-168	Atlas® II VR	99.68%	99.48%	99.13%	98.59%	98.15%					
V-158	Epic® II VR	100.00%	100.00%	99.81%	99.29%						
V-193	Atlas® + VR	99.84%	99.63%	99.50%	99.04%	98.31%	97.00%	94.34%			
V-196	Epic® + VR	99.92%	99.67%	99.60%	98.92%	97.54%	86.63%	50.55%			

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
CD1231-40Q	Fortify® VR	99.84%									
CD1231-40	Fortify® VR	99.91%									
CD1211-36Q	Current® + VR	99.66%	99.44%								
CD1211-36	Current® + VR	99.74%	99.74%								
1207-30	Current® VR RF	100.00%	100.00%	100.00%							
1207-36	Current® VR RF	99.73%	99.58%	99.17%	99.17%						
V-168	Atlas® II VR	99.77%	99.60%	99.43%	99.27%	99.19%					
V-158	Epic® II VR	100.00%	100.00%	99.81%	99.51%						
V-193	Atlas® + VR	99.95%	99.81%	99.74%	99.57%	99.24%	99.08%	99.01%			
V-196	Epic® + VR	99.95%	99.91%	99.88%	99.49%	99.29%	99.23%	99.23%			

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
CD1231-40Q	Fortify® VR	10163	3	0.03%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**5**	**0.05%**
CD1231-40	Fortify® VR	4309	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	4472	2	0.04%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%	**5**	**0.11%**
CD1211-36	Current® + VR	3355	2	0.06%	1	0.03%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.12%**
1207-30	Current® VR RF	876	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	13170	6	0.05%	6	0.05%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	3	0.02%	**19**	**0.14%**
V-168	Atlas® II VR	10506	1	0.01%	1	0.01%	6	0.06%	1	0.01%	0	0.00%	1	0.01%	6	0.06%	5	0.05%	**21**	**0.20%**
V-158	Epic® II VR	1572	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	20582	1	<0.01%	4	0.02%	4	0.02%	2	0.01%	0	0.00%	0	0.00%	21	0.10%	5	0.02%	**37**	**0.18%**
V-196	Epic® + VR	7967	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	**4**	**0.05%**

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
CD1231-40Q	Fortify® VR	10163	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%**
CD1231-40	Fortify® VR	4309	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**1**	**0.02%**
CD1211-36Q	Current® + VR	4472	2	0.04%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.09%**
CD1211-36	Current® + VR	3355	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%**
1207-30	Current® VR RF	876	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	13170	3	0.02%	0	0.00%	3	0.02%	0	0.00%	1	0.01%	0	0.00%	3	0.02%	3	0.02%	**13**	**0.10%**
V-168	Atlas® II VR	10506	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	2	0.02%	**7**	**0.07%**
V-158	Epic® II VR	1572	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	20582	2	0.01%	1	<0.01%	2	0.01%	1	<0.01%	1	<0.01%	0	0.00%	3	0.01%	2	0.01%	**12**	**0.06%**
V-196	Epic® + VR	7967	0	0.00%	0	0.00%	14	0.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**14**	**0.18%**

Definitions of malfunction root cause categories can be found on pages 6-7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Failure to Sense		Inappropriate Shock		Premature Battery Depletion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	143	1505	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36	108	2264	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	396	12308	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	143	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%**
CD1211-36	Current + VR	108	0	0.00%	1	0.93%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.93%**
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	143	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%**
CD1211-36	Current + VR	108	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%**

Definitions of complications can be found on page 13.
Definitions of malfunction root cause categories can be found on pages 6-7.

Defibrillation Leads

St. Jude Medical™
More control. Less risk.

Customer Reported Performance Data

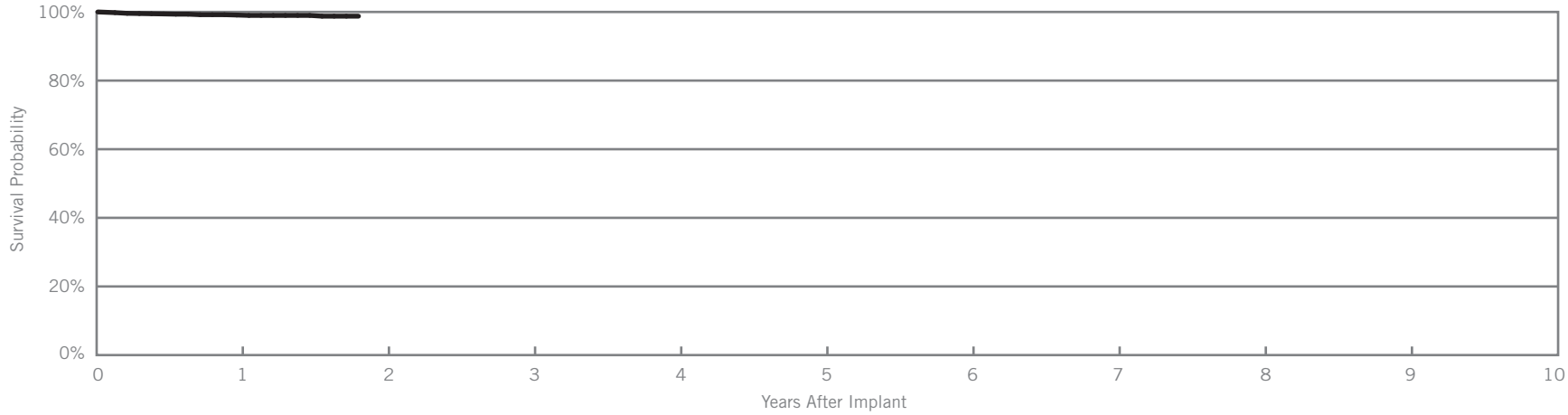
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	2,267
Estimated Active US Implants	1,866
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	1	0.04%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.09%	4	0.18%
Failure to Capture	1	0.04%	8	0.35%
Oversensing	0	0.00%	1	0.04%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
Abnormal Pacing Impedance	0	0.00%	1	0.04%
Abnormal Defibrillation Impedance	0	0.00%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	0	0.00%
Total	**5**	**0.22%**	**16**	**0.71%**
Total Returned for Analysis	**3**		**12**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.04%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.04%
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	10	0.44%
Total	**11**	**0.49%**



Year	1	at 22 months								
Survival Probability	99.10%	98.77%								
± 1 standard error	0.22%	0.35%								
Sample Size	1800	200								

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

Customer Reported Performance Data

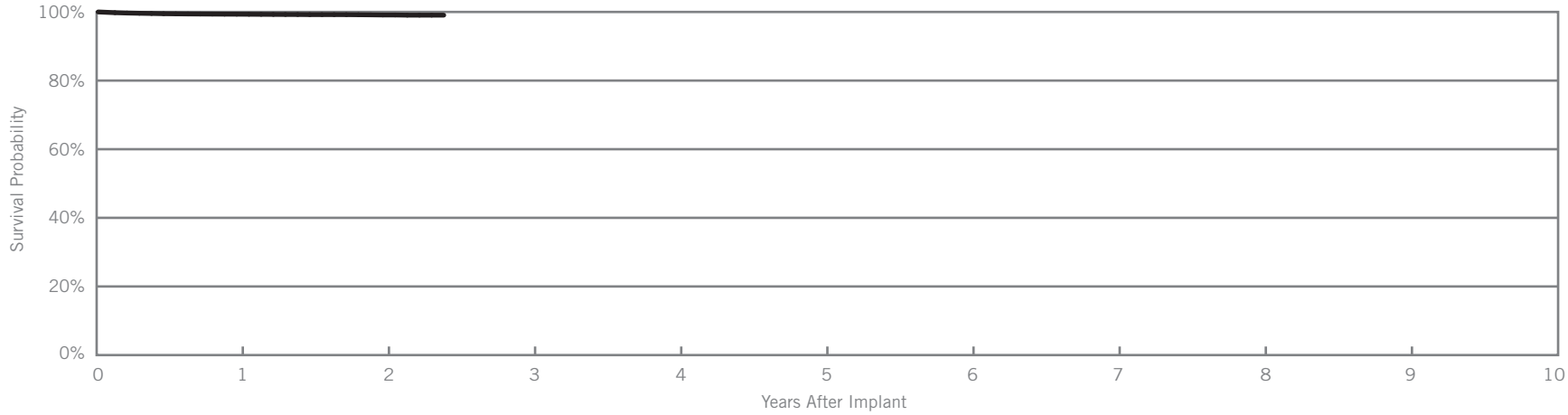
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	54,132
Estimated Active US Implants	45,309
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	32	0.06%	8	0.01%
Conductor Fracture	0	0.00%	11	0.02%
Lead Dislodgement	104	0.19%	165	0.30%
Failure to Capture	39	0.07%	62	0.11%
Oversensing	23	0.04%	27	0.05%
Failure to Sense	6	0.01%	10	0.02%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	<0.01%	2	<0.01%
Abnormal Defibrillation Impedance	2	<0.01%	12	0.02%
Extracardiac Stimulation	2	<0.01%	2	<0.01%
Other	5	0.01%	7	0.01%
Total	**215**	**0.40%**	**306**	**0.57%**
Total Returned for Analysis	**98**		**215**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.01%
Clavicular Crush	0	0.00%
In the Pocket	2	<0.01%
Intravascular	2	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	6	0.01%
Extrinsic Factors	190	0.35%
Total	**202**	**0.37%**



Year	1	2	at 29 months							
Survival Probability	99.35%	99.12%	99.07%							
± 1 standard error	0.04%	0.06%	0.08%							
Sample Size	43100	15400	300							

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

SCORE Registry Performance Data

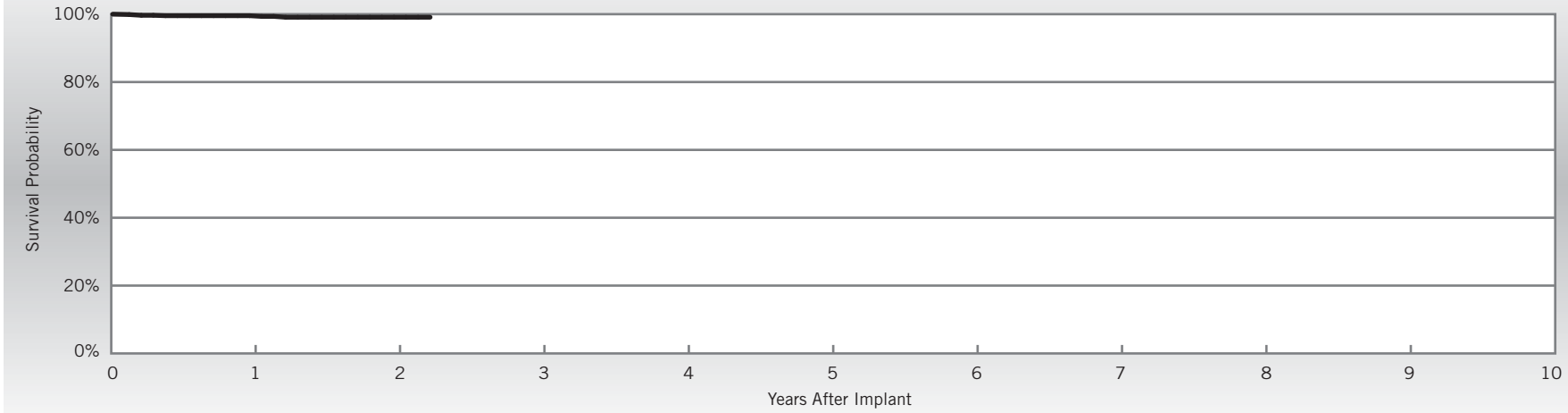
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	969
Cumulative Months of Follow-up	13,434
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	3	0.31%
Failure to Capture	1	0.10%
Abnormal Defibrillation Impedance	2	0.21%

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	5	0.52%
Total	**5**	**0.52%**



Year	1	2	at 27 months							
Survival Probability	99.55%	99.10%	99.10%							
± 1 standard error	0.22%	0.39%	0.39%							
Sample Size	740	310	50							

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

Customer Reported Performance Data

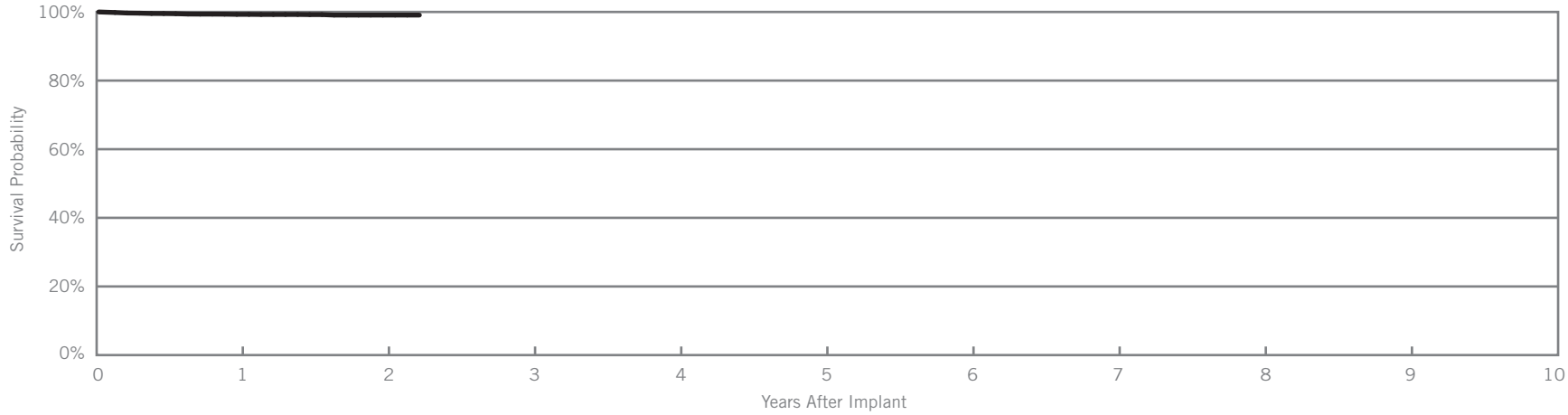
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	10,554
Estimated Active US Implants	9,052
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	8	0.08%	6	0.06%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	21	0.20%	25	0.24%
Failure to Capture	11	0.10%	9	0.09%
Oversensing	5	0.05%	8	0.08%
Failure to Sense	3	0.03%	3	0.03%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	1	0.01%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.03%	0	0.00%
Total	**52**	**0.49%**	**52**	**0.49%**
Total Returned for Analysis	**32**		**41**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.02%
Clavicular Crush	0	0.00%
In the Pocket	2	0.02%
Intravascular	0	0.00%
Insulation Breach	1	0.01%
Lead-to-Can Contact	1	0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.02%
Extrinsic Factors	34	0.32%
Total	**39**	**0.37%**



Year	1	2	at 27 months							
Survival Probability	99.30%	99.09%	99.09%							
± 1 standard error	0.09%	0.15%	0.15%							
Sample Size	7800	2300	200							

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

SCORE Registry Performance Data

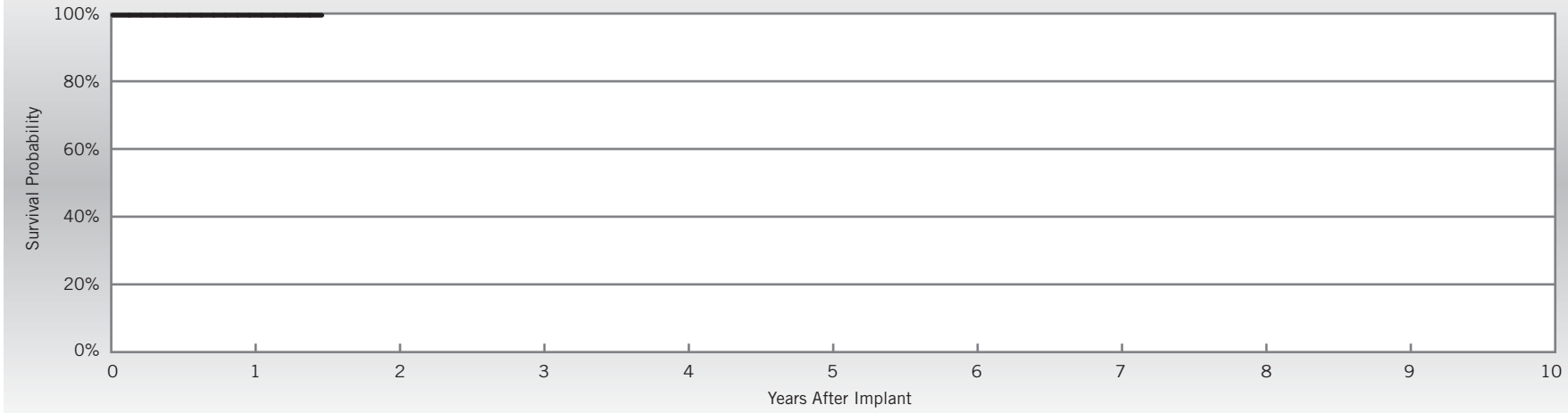
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	205
Cumulative Months of Follow-up	2,608
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	1	0.49%

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	0.49%
Total	**1**	**0.49%**



Year	1	at 18 months								
Survival Probability	99.51%	99.51%								
± 1 standard error	0.49%	0.49%								
Sample Size	150	50								

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

Customer Reported Performance Data

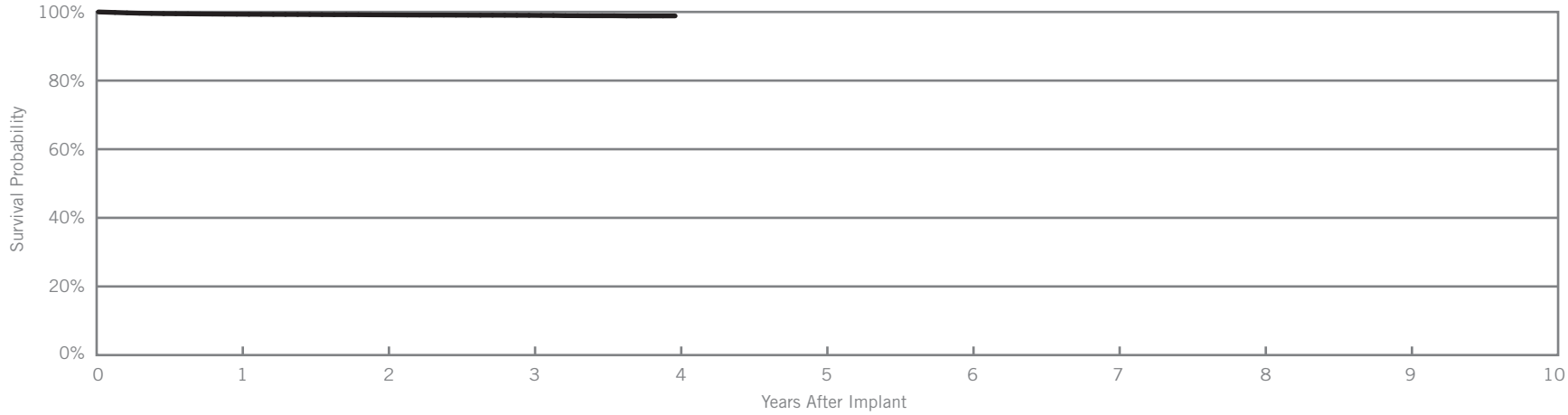
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	55,683
Estimated Active US Implants	40,309
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	0.06%	5	0.01%
Conductor Fracture	1	<0.01%	17	0.03%
Lead Dislodgement	70	0.13%	122	0.22%
Failure to Capture	18	0.03%	58	0.10%
Oversensing	45	0.08%	62	0.11%
Failure to Sense	4	0.01%	14	0.03%
Insulation Breach	0	0.00%	5	0.01%
Abnormal Pacing Impedance	1	<0.01%	12	0.02%
Abnormal Defibrillation Impedance	17	0.03%	23	0.04%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	16	0.03%	11	0.02%
Total	**206**	**0.37%**	**329**	**0.59%**
Total Returned for Analysis	**71**		**174**	

Malfunctions	Qty.	Rate
Conductor Fracture	11	0.02%
Clavicular Crush	1	<0.01%
In the Pocket	8	0.01%
Intravascular	2	<0.01%
Insulation Breach	9	0.02%
Lead-to-Can Contact	5	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	1	<0.01%
Other	3	0.01%
Extrinsic Factors	136	0.24%
Total	**160**	**0.29%**



Year	1	2	3	4						
Survival Probability	99.34%	99.16%	99.02%	98.85%						
± 1 standard error	0.04%	0.04%	0.05%	0.07%						
Sample Size	52900	38900	22500	6200						

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

SCORE Registry Performance Data

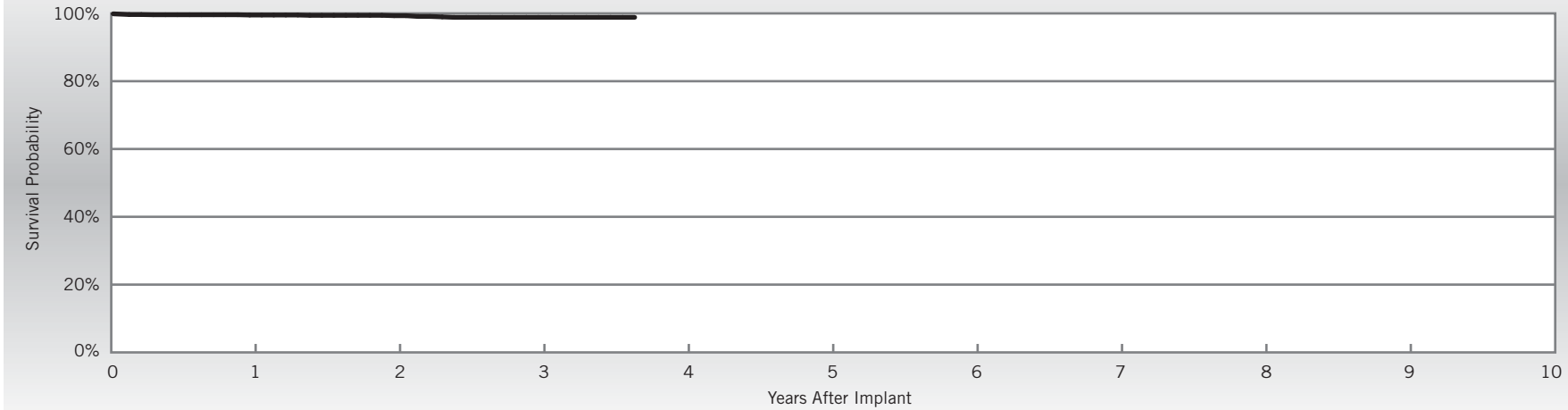
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,501
Cumulative Months of Follow-up	40,458
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	2	0.13%
Lead Dislodgement	5	0.33%
Failure to Capture	3	0.20%
Oversensing	1	0.07%
Failure to Sense	1	0.07%
Extracardiac Stimulation	1	0.07%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	1	0.07%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.13%
Total	**3**	**0.20%**



Year	1	2	3	at 44 months						
Survival Probability	99.52%	99.32%	98.84%	98.84%						
± 1 standard error	0.17%	0.20%	0.33%	0.33%						
Sample Size	1400	1110	650	70						

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

Customer Reported Performance Data

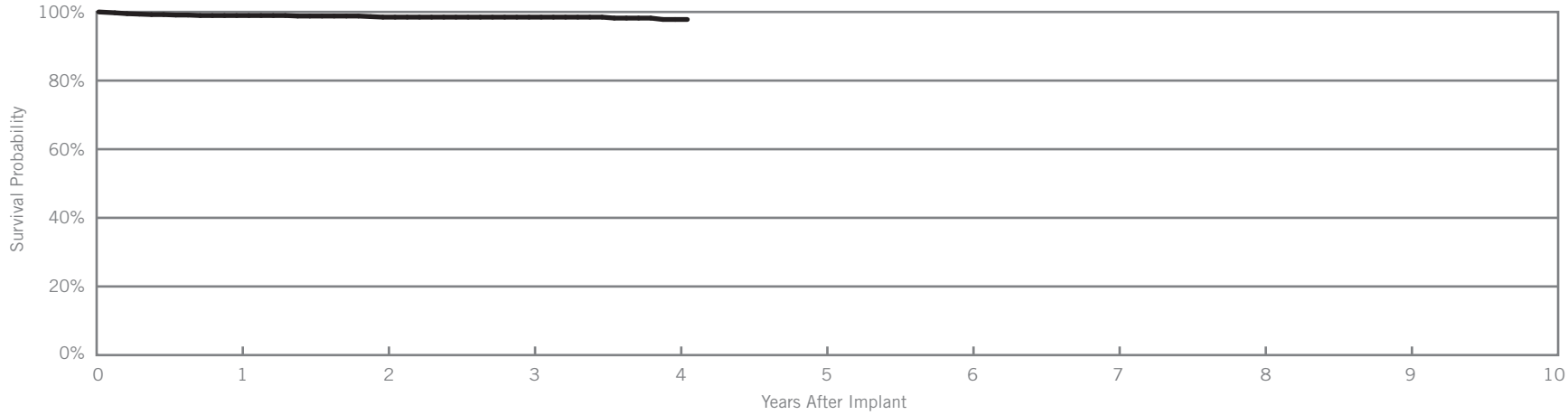
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	851
Estimated Active US Implants	504
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	0.12%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.47%	0	0.00%
Failure to Capture	0	0.00%	4	0.47%
Oversensing	2	0.24%	6	0.71%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.12%
Abnormal Pacing Impedance	0	0.00%	1	0.12%
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**	**0.71%**	**13**	**1.53%**
Total Returned for Analysis	**3**		**2**	

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	0.35%
Total	**3**	**0.35%**



Year	1	2	3	4	at 49 months					
Survival Probability	98.96%	98.49%	98.49%	97.81%	97.81%					
± 1 standard error	0.37%	0.43%	0.45%	0.66%	0.66%					
Sample Size	800	700	600	400	200					

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

Customer Reported Performance Data

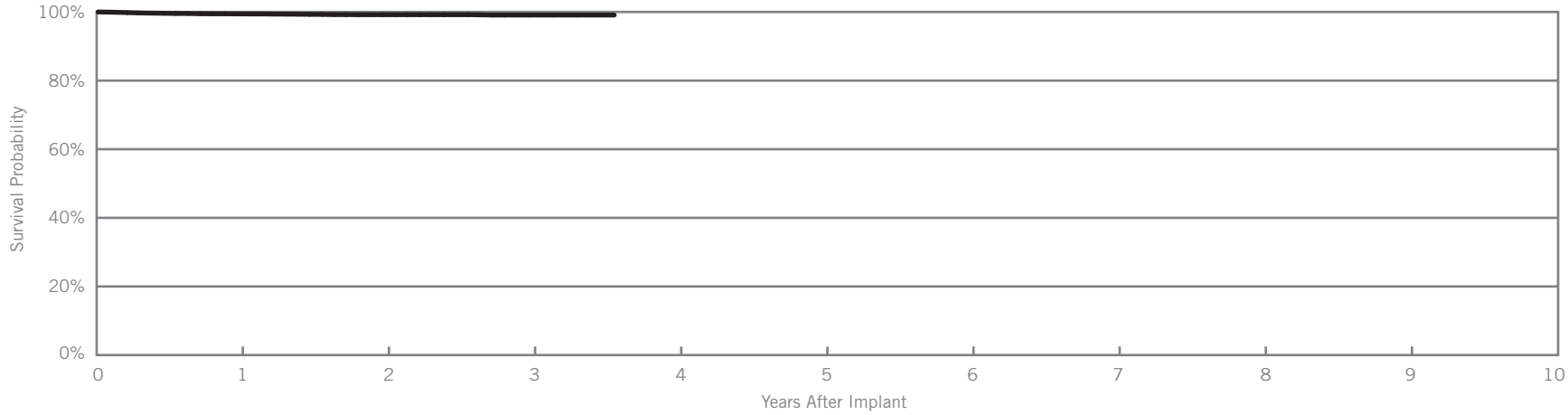
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	9,413
Estimated Active US Implants	7,200
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	0.05%	1	0.01%
Conductor Fracture	1	0.01%	2	0.02%
Lead Dislodgement	9	0.10%	14	0.15%
Failure to Capture	7	0.07%	10	0.11%
Oversensing	4	0.04%	10	0.11%
Failure to Sense	0	0.00%	4	0.04%
Insulation Breach	0	0.00%	4	0.04%
Abnormal Pacing Impedance	1	0.01%	5	0.05%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	**28**	**0.30%**	**53**	**0.56%**
Total Returned for Analysis	**12**		**38**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	0	0.00%
In the Pocket	3	0.03%
Intravascular	1	0.01%
Insulation Breach	4	0.04%
Lead-to-Can Contact	1	0.01%
Lead-to-Lead Contact	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	26	0.28%
Total	**34**	**0.36%**



Year	1	2	3	at 43 months						
Survival Probability	99.43%	99.21%	99.10%	99.10%						
± 1 standard error	0.08%	0.11%	0.13%	0.13%						
Sample Size	8400	5100	2500	300						

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

SCORE Registry Performance Data

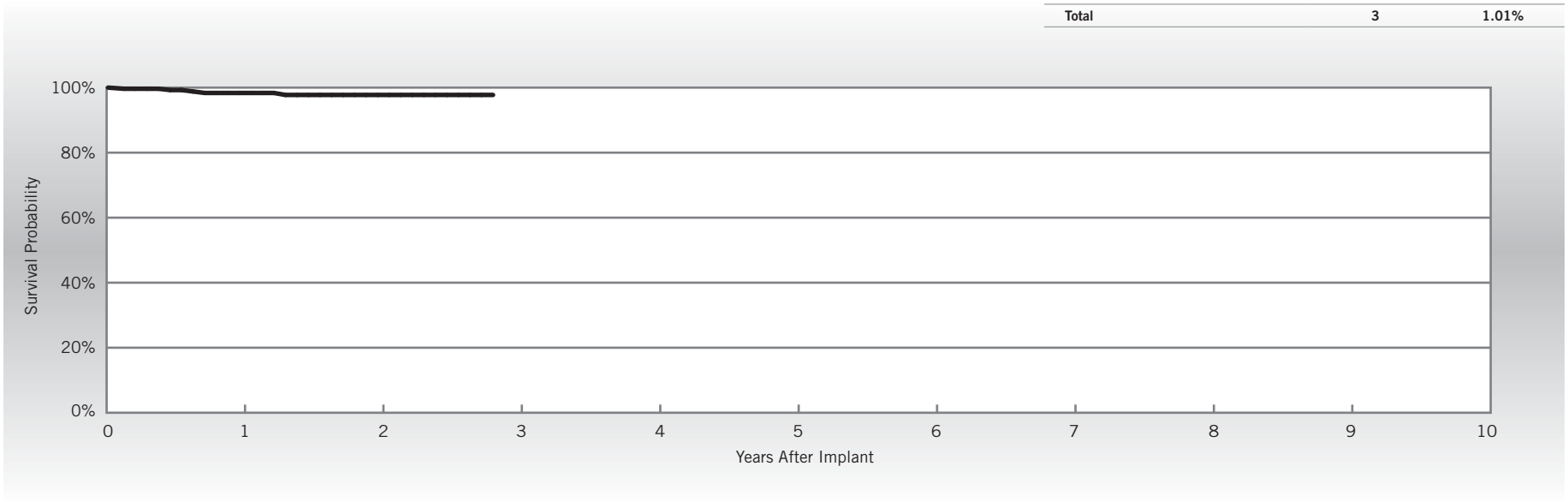
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	297
Cumulative Months of Follow-up	5,937
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	3	1.01%
Oversensing	1	0.34%
Abnormal Pacing Impedance	1	0.34%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.34%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.34%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.67%
Total	**3**	**1.01%**



Year	1	2	at 34 months							
Survival Probability	98.36%	97.75%	97.75%							
± 1 standard error	0.82%	1.01%	1.01%							
Sample Size	250	150	50							

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

Customer Reported Performance Data

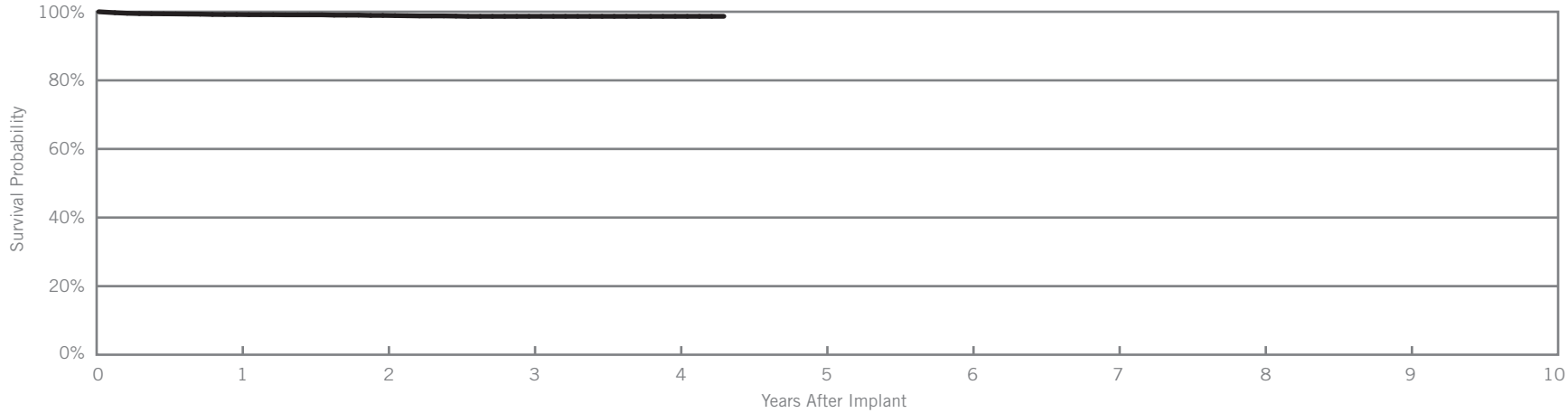
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,424
Estimated Active US Implants	2,450
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%	2	0.06%
Lead Dislodgement	3	0.09%	4	0.12%
Failure to Capture	5	0.15%	4	0.12%
Oversensing	4	0.12%	6	0.18%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.06%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**19**	**0.55%**	**23**	**0.67%**
Total Returned for Analysis	**8**		**7**	

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	1	0.03%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	0.03%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.15%
Total	**7**	**0.20%**



Year	1	2	3	4	at 52 months					
Survival Probability	99.19%	98.93%	98.67%	98.67%	98.67%					
± 1 standard error	0.16%	0.19%	0.23%	0.23%	0.23%					
Sample Size	3200	2500	1700	800	200					

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

SCORE Registry Performance Data

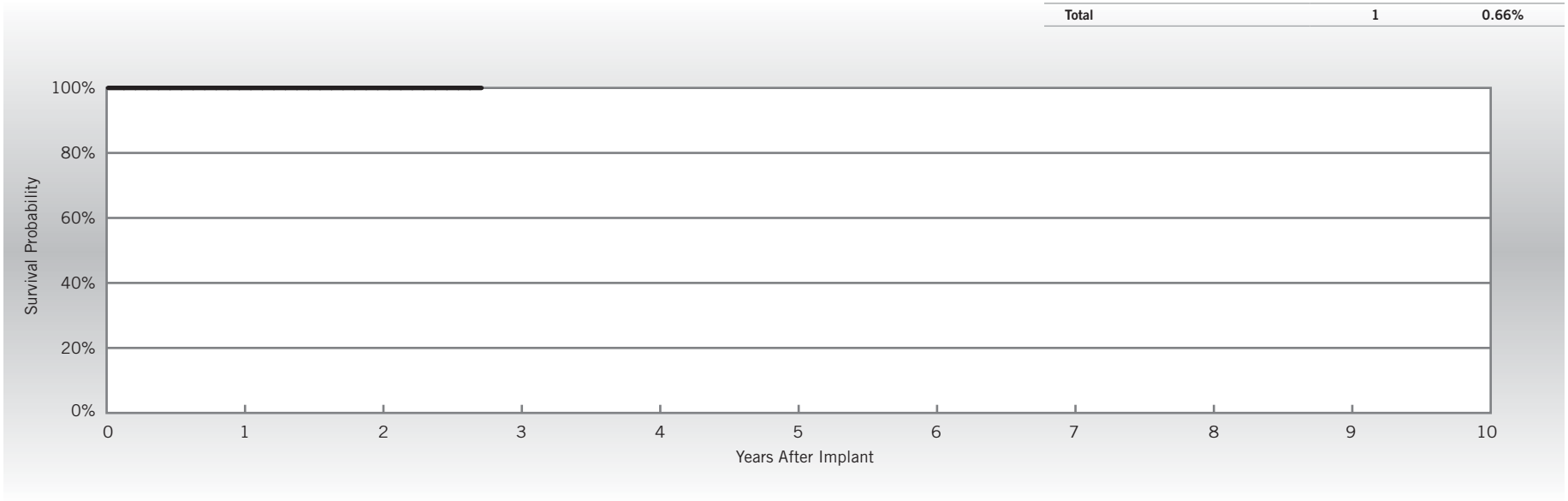
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	152
Cumulative Months of Follow-up	4,207
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

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	0.66%
Total	**1**	**0.66%**



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	140	120	60							

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

Customer Reported Performance Data

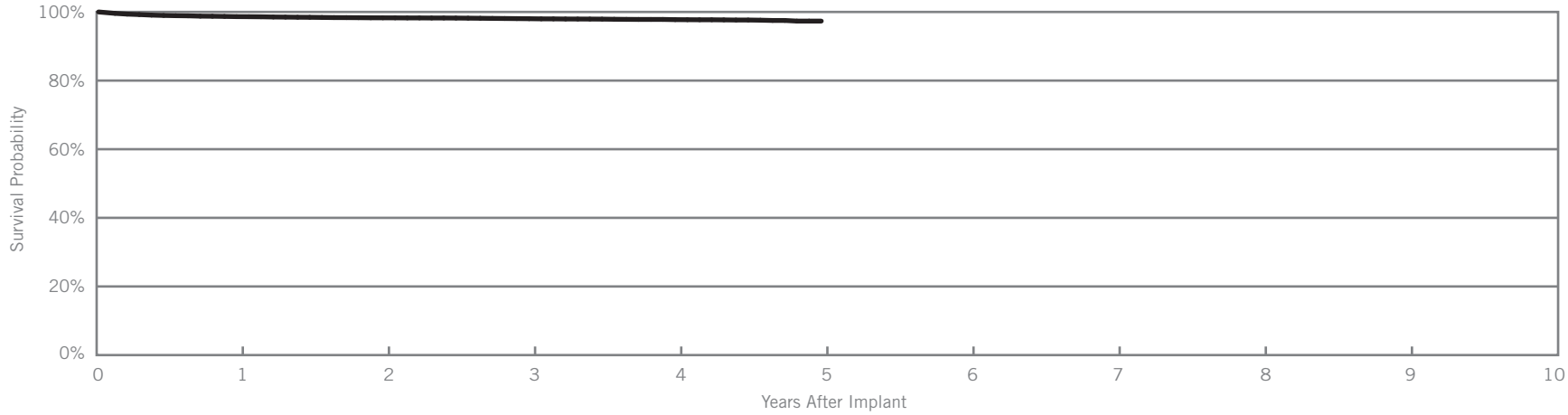
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,476
Estimated Active US Implants	9,363
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	38	0.25%	10	0.06%
Conductor Fracture	0	0.00%	11	0.07%
Lead Dislodgement	34	0.22%	49	0.32%
Failure to Capture	19	0.12%	42	0.27%
Oversensing	19	0.12%	51	0.33%
Failure to Sense	8	0.05%	11	0.07%
Insulation Breach	0	0.00%	3	0.02%
Abnormal Pacing Impedance	1	0.01%	4	0.03%
Abnormal Defibrillation Impedance	4	0.03%	9	0.06%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	14	0.09%
Total	**127**	**0.82%**	**206**	**1.33%**
Total Returned for Analysis	**46**		**123**	

Malfunctions	Qty.	Rate
Conductor Fracture	5	0.03%
Clavicular Crush	1	0.01%
In the Pocket	1	0.01%
Intravascular	3	0.02%
Insulation Breach	11	0.07%
Lead-to-Can Contact	4	0.03%
Lead-to-Lead Contact	3	0.02%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Other	3	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	91	0.59%
Total	**107**	**0.69%**



Year	1	2	3	4	5					
Survival Probability	98.64%	98.29%	98.03%	97.76%	97.34%					
± 1 standard error	0.09%	0.11%	0.12%	0.13%	0.25%					
Sample Size	15300	12800	10800	7600	2700					

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

SCORE Registry Performance Data

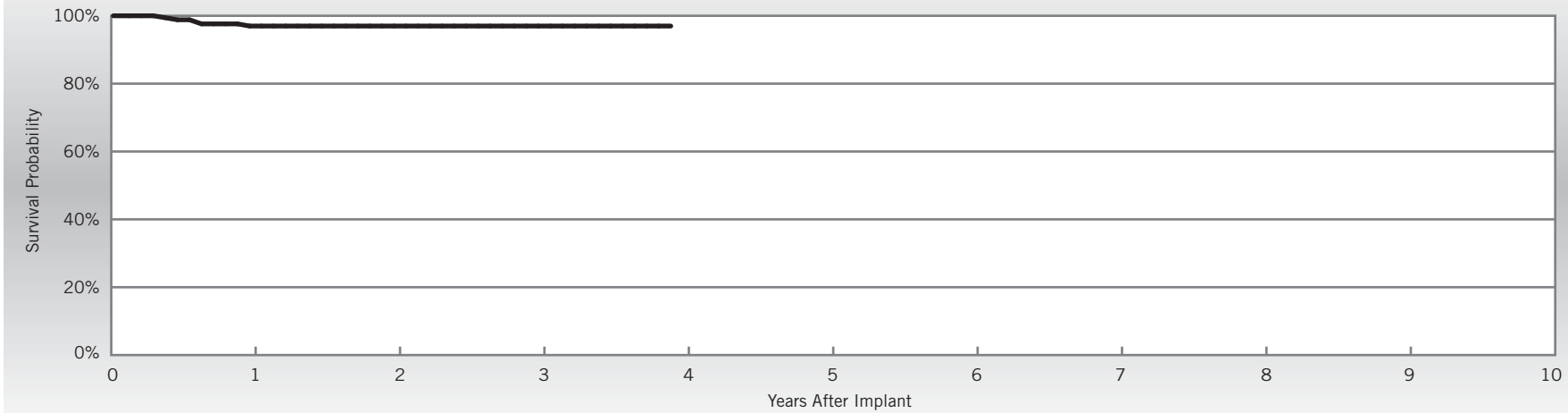
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	176
Cumulative Months of Follow-up	6,353
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Cardiac Perforation	1	0.57%
Conductor Fracture	2	1.14%
Failure to Sense	1	0.57%
Abnormal Pacing Impedance	1	0.57%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.57%
Clavicular Crush	0	0.00%
In the Pocket	1	0.57%
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	0.57%
Total	**2**	**1.14%**



Year	1	2	3	at 47 months						
Survival Probability	96.98%	96.98%	96.98%	96.98%						
± 1 standard error	1.18%	1.33%	1.33%	1.33%						
Sample Size	170	140	120	60						

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

Customer Reported Performance Data

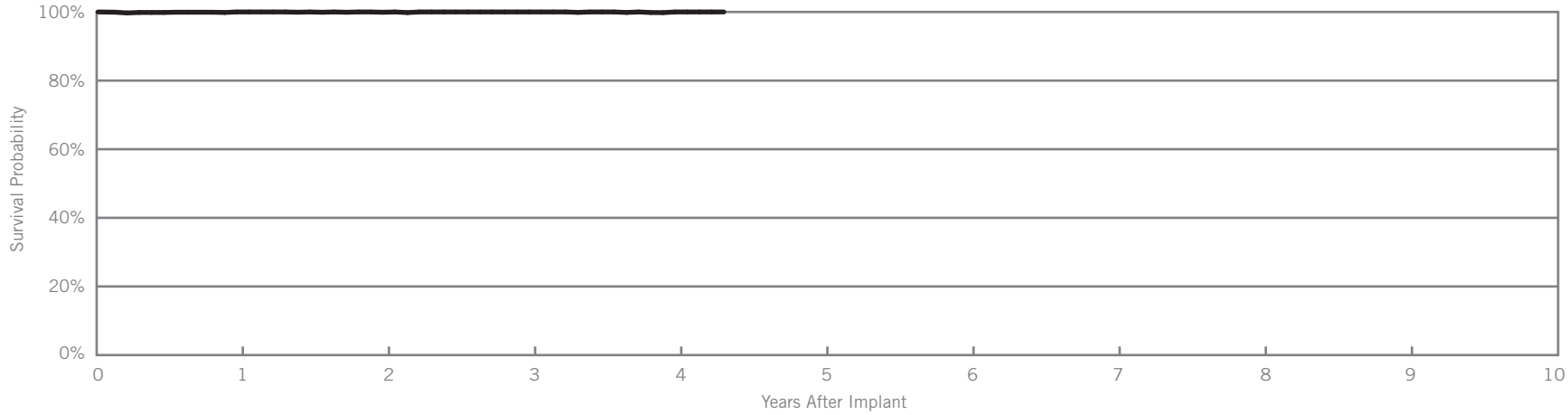
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,485
Estimated Active US Implants	958
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	0.34%	2	0.13%
Conductor Fracture	0	0.00%	3	0.20%
Lead Dislodgement	3	0.20%	6	0.40%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	6	0.40%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.07%
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**	**0.67%**	**19**	**1.28%**
Total Returned for Analysis	**1**		**10**	

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	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	8	0.54%
Total	**9**	**0.61%**



Year	1	2	3	4	at 52 months					
Survival Probability	98.74%	98.40%	98.21%	97.58%	97.58%					
± 1 standard error	0.30%	0.34%	0.37%	0.49%	0.49%					
Sample Size	1500	1200	1000	700	200					

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

Customer Reported Performance Data

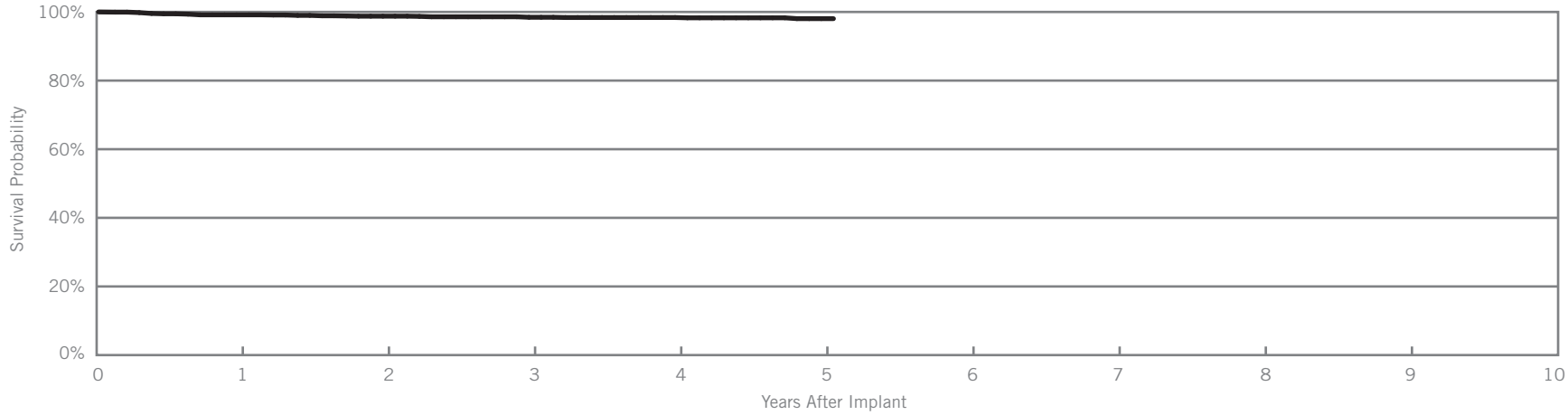
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,211
Estimated Active US Implants	1,309
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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%	0	0.00%
Lead Dislodgement	1	0.05%	5	0.23%
Failure to Capture	3	0.14%	2	0.09%
Oversensing	2	0.09%	4	0.18%
Failure to Sense	1	0.05%	2	0.09%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.05%	1	0.05%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	1	0.05%
Total	**12**	**0.54%**	**16**	**0.72%**
Total Returned for Analysis	**4**		**6**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	3	0.14%
Lead-to-Can Contact	1	0.05%
Lead-to-Lead Contact	2	0.09%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.18%
Total	**7**	**0.32%**



Year	1	2	3	4	5	at 61 months				
Survival Probability	99.16%	98.77%	98.45%	98.38%	98.05%	98.05%				
± 1 standard error	0.20%	0.25%	0.27%	0.30%	0.39%	0.39%				
Sample Size	2200	1900	1600	1300	700	200				

Customer Reported Performance Data

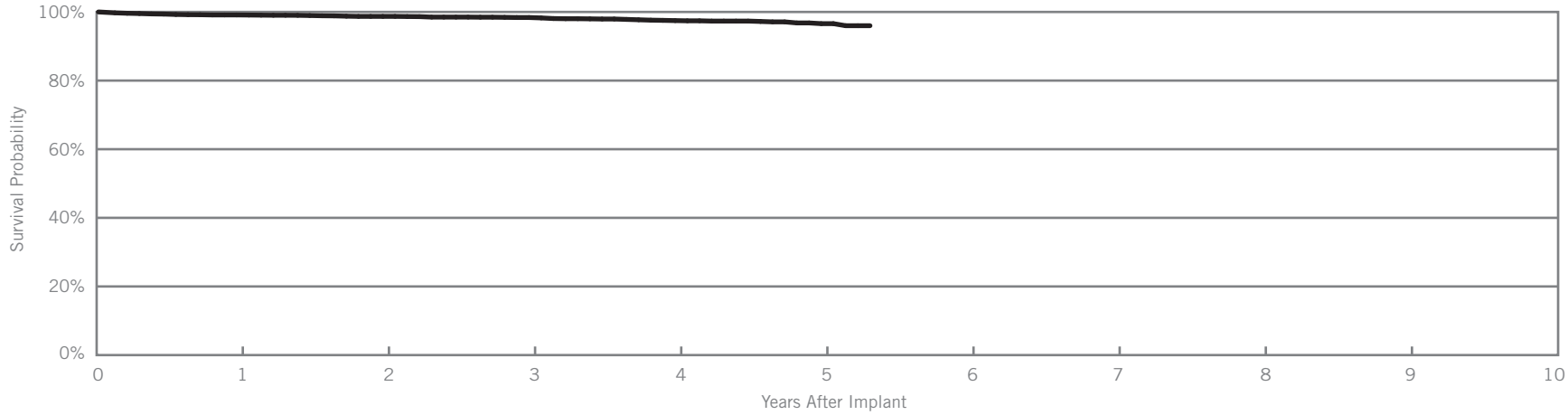
Riata® ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,089
Estimated Active US Implants	2,459
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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%	10	0.24%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	1	0.02%	10	0.24%
Oversensing	3	0.07%	20	0.49%
Failure to Sense	0	0.00%	4	0.10%
Insulation Breach	0	0.00%	1	0.02%
Abnormal Pacing Impedance	2	0.05%	3	0.07%
Abnormal Defibrillation Impedance	0	0.00%	4	0.10%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**16**	**0.39%**	**57**	**1.39%**
Total Returned for Analysis	**2**		**14**	

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	10	0.24%
Lead-to-Can Contact	6	0.15%
Lead-to-Lead Contact	2	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	2	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	7	0.17%
Total	**19**	**0.46%**



Year	1	2	3	4	5	at 64 months				
Survival Probability	99.13%	98.71%	98.38%	97.48%	96.59%	95.99%				
± 1 standard error	0.15%	0.19%	0.22%	0.30%	0.42%	0.63%				
Sample Size	4000	3400	2800	2000	1000	200				

Customer Reported Performance Data

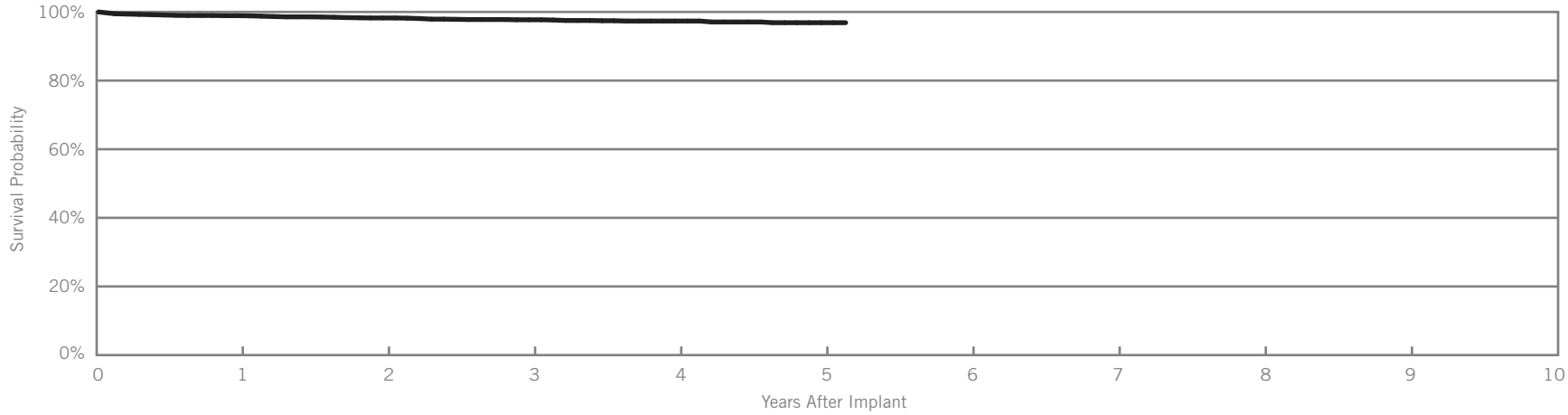
Riata® ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,415
Estimated Active US Implants	1,438
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.25%	2	0.08%
Conductor Fracture	0	0.00%	3	0.12%
Lead Dislodgement	2	0.08%	9	0.37%
Failure to Capture	4	0.17%	7	0.29%
Oversensing	4	0.17%	14	0.58%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
Abnormal Pacing Impedance	2	0.08%	0	0.00%
Abnormal Defibrillation Impedance	1	0.04%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	4	0.17%
Total	**20**	**0.83%**	**41**	**1.70%**
Total Returned for Analysis	**8**		**18**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.08%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.08%
Insulation Breach	6	0.25%
Lead-to-Can Contact	5	0.21%
Lead-to-Lead Contact	1	0.04%
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	10	0.41%
Total	**18**	**0.75%**



Year	1	2	3	4	5	at 62 months				
Survival Probability	98.92%	98.25%	97.72%	97.35%	96.87%	96.87%				
± 1 standard error	0.22%	0.29%	0.33%	0.37%	0.47%	0.47%				
Sample Size	2400	2000	1700	1200	600	200				

Customer Reported Performance Data

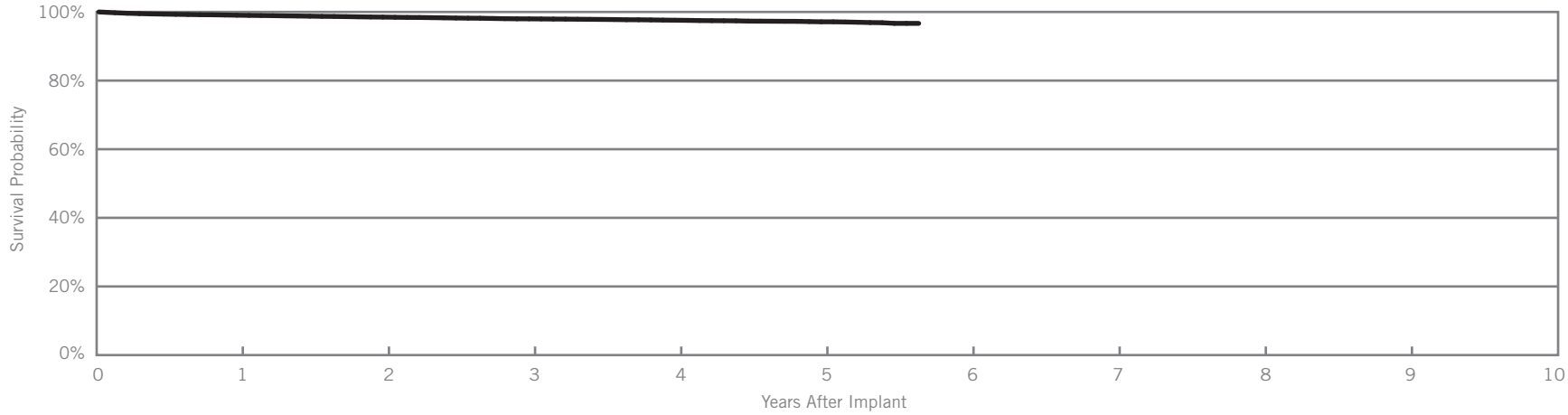
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,985
Estimated Active US Implants	19,972
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	41	0.12%	18	0.05%
Conductor Fracture	0	0.00%	32	0.09%
Lead Dislodgement	37	0.11%	39	0.11%
Failure to Capture	43	0.12%	80	0.23%
Oversensing	40	0.11%	190	0.54%
Failure to Sense	7	0.02%	20	0.06%
Insulation Breach	1	<0.01%	33	0.09%
Abnormal Pacing Impedance	8	0.02%	15	0.04%
Abnormal Defibrillation Impedance	4	0.01%	14	0.04%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	11	0.03%	30	0.09%
Total	**196**	**0.56%**	**473**	**1.35%**
Total Returned for Analysis	**81**		**209**	

Malfunctions	Qty.	Rate
Conductor Fracture	10	0.03%
Clavicular Crush	2	0.01%
In the Pocket	2	0.01%
Intravascular	6	0.02%
Insulation Breach	93	0.27%
Lead-to-Can Contact	65	0.19%
Lead-to-Lead Contact	14	0.04%
Clavicular Crush	2	0.01%
Externalized Conductors	2	0.01%
Other	10	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	102	0.29%
Total	**206**	**0.59%**



Year	1	2	3	4	5	at 68 months				
Survival Probability	99.05%	98.50%	97.99%	97.59%	97.13%	96.67%				
± 1 standard error	0.05%	0.07%	0.08%	0.09%	0.11%	0.18%				
Sample Size	34700	29600	25600	20500	11800	600				

SCORE Registry Performance Data

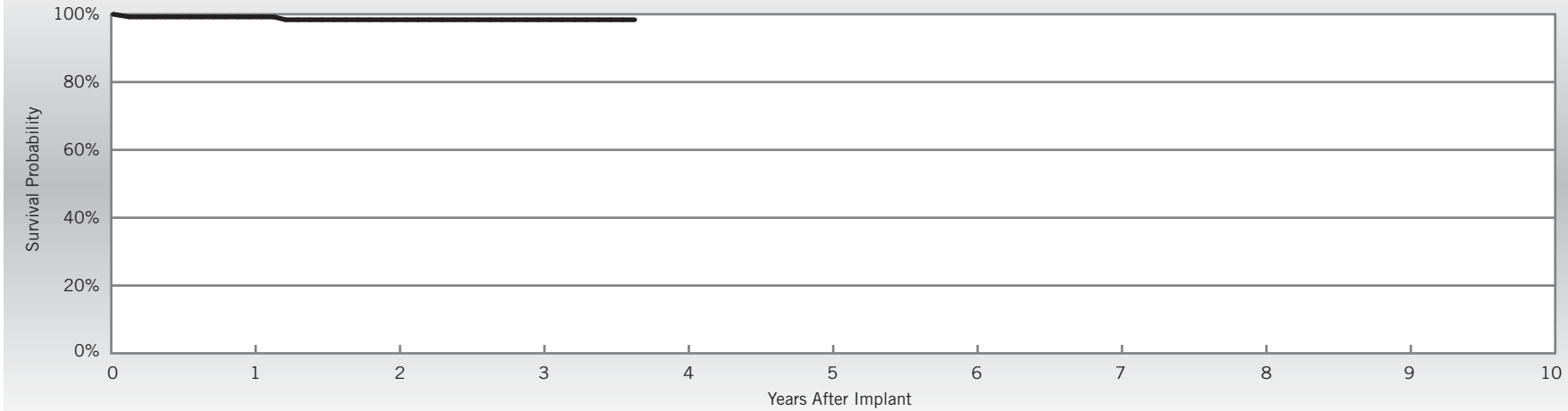
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	131
Cumulative Months of Follow-up	4,631
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	1	0.76%
Oversensing	1	0.76%

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	2.29%
Lead-to-Can Contact	1	0.76%
Lead-to-Lead Contact	1	0.76%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.76%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.76%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**4**	**3.05%**



Year	1	2	3	at 44 months						
Survival Probability	99.22%	98.38%	98.38%	98.38%						
± 1 standard error	0.78%	1.14%	1.14%	1.14%						
Sample Size	130	110	90	50						

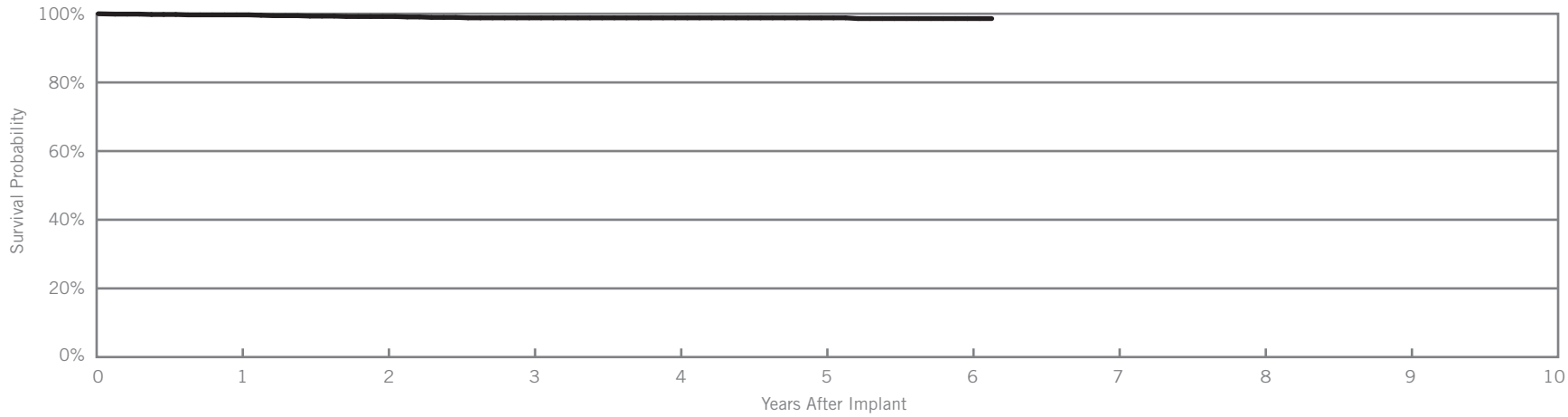
Customer Reported Performance Data

Riata® *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,008
Estimated Active US Implants	544
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	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	1	0.10%
Lead-to-Can Contact	1	0.10%
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	**1**	**0.10%**



Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.68%	99.20%	98.81%	98.81%	98.81%	98.60%	98.60%			
± 1 standard error	0.19%	0.30%	0.38%	0.38%	0.38%	0.43%	0.43%			
Sample Size	1000	900	800	700	600	400	200			

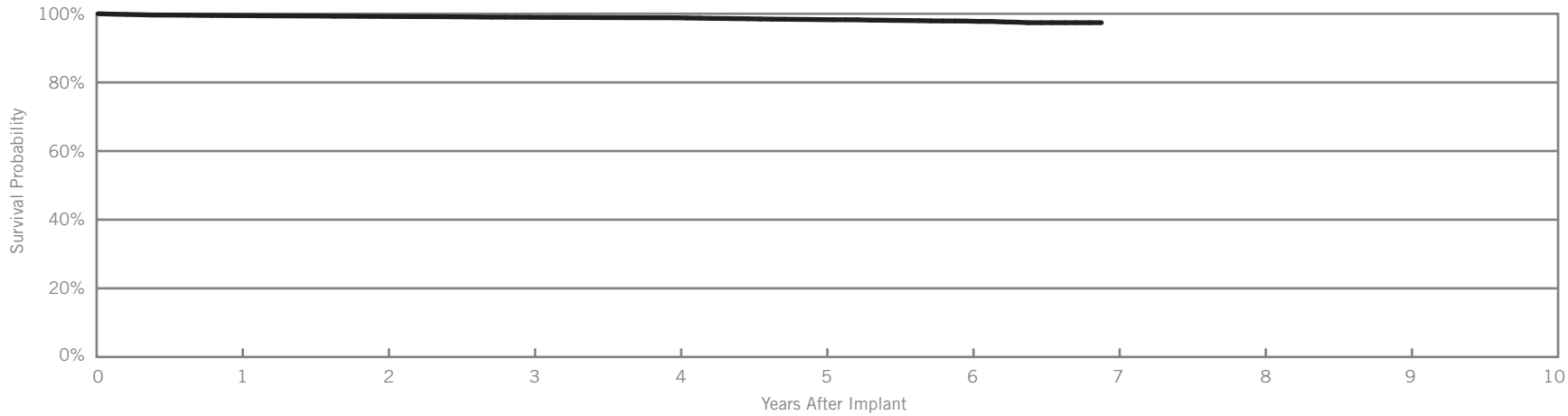
Customer Reported Performance Data

Riata® *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,763
Estimated Active US Implants	4,919
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	3	0.03%
Insulation Breach	20	0.20%
Lead-to-Can Contact	7	0.07%
Lead-to-Lead Contact	5	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.02%
Other	6	0.06%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	17	0.17%
Total	**41**	**0.42%**



Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.46%	99.23%	98.98%	98.84%	98.30%	97.86%	97.40%			
± 1 standard error	0.08%	0.09%	0.11%	0.12%	0.15%	0.19%	0.25%			
Sample Size	9600	8500	7600	6700	5600	3700	200			

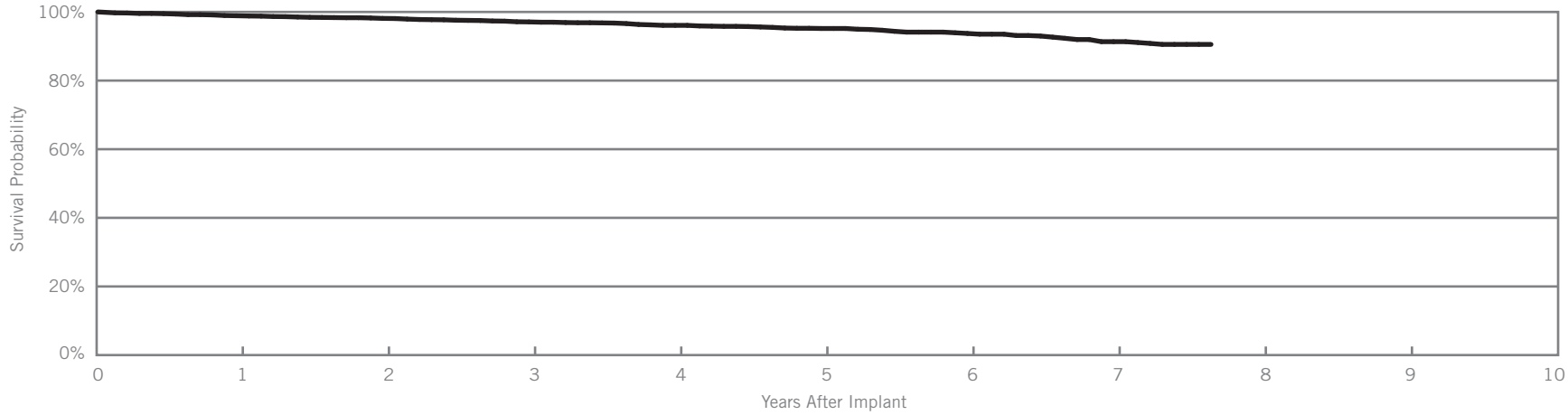
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,190
Estimated Active US Implants	1,537
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.06%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.06%
Insulation Breach	48	1.50%
Lead-to-Can Contact	25	0.78%
Lead-to-Lead Contact	5	0.16%
Clavicular Crush	1	0.03%
Externalized Conductors	5	0.16%
Other	12	0.38%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.44%
Total	**64**	**2.01%**



Year	1	2	3	4	5	6	7	at 92 months		
Survival Probability	98.89%	98.12%	97.10%	96.09%	95.18%	93.73%	91.34%	90.54%		
± 1 standard error	0.19%	0.25%	0.33%	0.40%	0.45%	0.55%	0.83%	0.95%		
Sample Size	3100	2700	2400	2100	1700	1200	700	200		

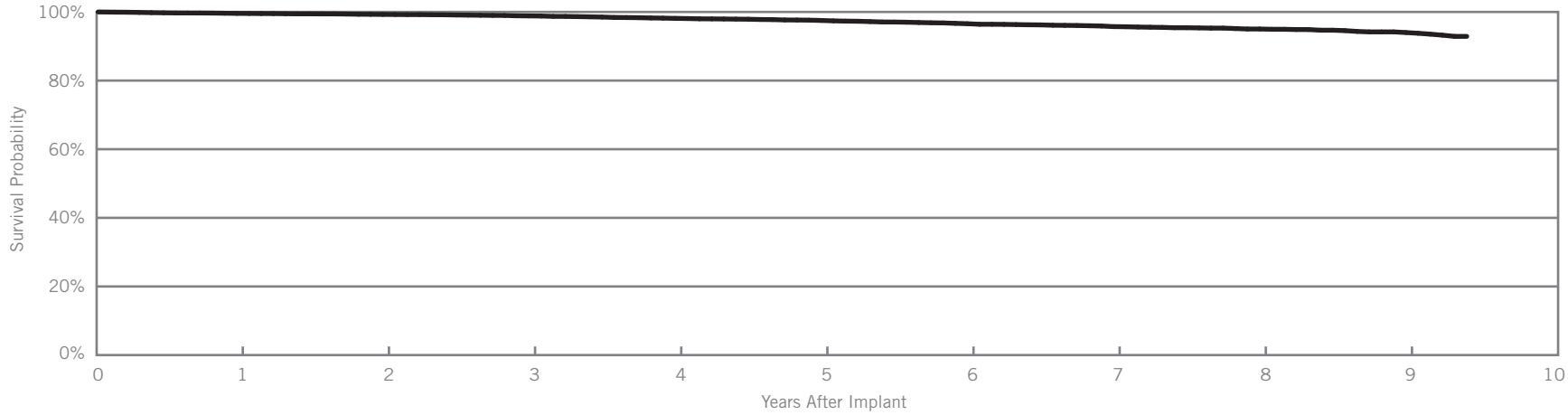
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,532
Estimated Active US Implants	4,801
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.03%
Clavicular Crush	2	0.02%
In the Pocket	1	0.01%
Intravascular	0	0.00%
Insulation Breach	45	0.43%
Lead-to-Can Contact	27	0.26%
Lead-to-Lead Contact	4	0.04%
Clavicular Crush	0	0.00%
Externalized Conductors	4	0.04%
Other	10	0.09%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	20	0.19%
Total	**68**	**0.65%**



Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.58%	99.28%	98.85%	98.13%	97.52%	96.57%	95.73%	95.03%	94.00%	92.88%
± 1 standard error	0.06%	0.09%	0.11%	0.15%	0.18%	0.23%	0.28%	0.35%	0.46%	0.75%
Sample Size	10300	9000	8100	6900	5800	4500	3100	1900	900	200

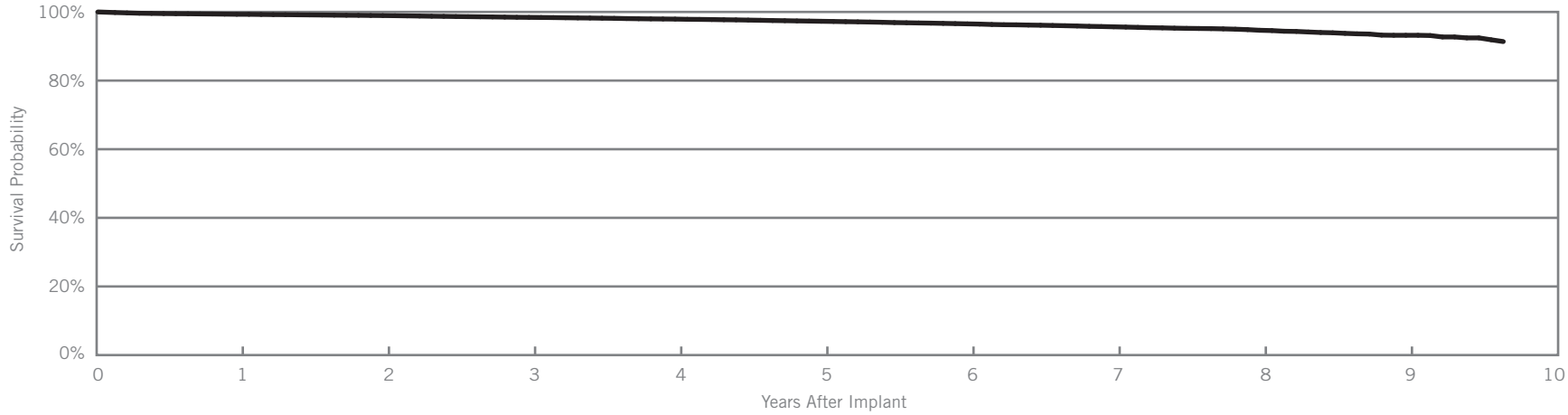
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,600
Estimated Active US Implants	32,278
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 244-256)	One

Malfunctions	Qty.	Rate
Conductor Fracture	16	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	7	0.01%
Intravascular	7	0.01%
Insulation Breach	314	0.45%
Lead-to-Can Contact	174	0.25%
Lead-to-Lead Contact	47	0.07%
Clavicular Crush	6	0.01%
Externalized Conductors	30	0.04%
Other	57	0.08%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	212	0.30%
Total	**545**	**0.78%**



Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.32%	98.95%	98.42%	97.92%	97.28%	96.53%	95.67%	94.66%	93.20%	91.37%
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.09%	0.11%	0.15%	0.26%	0.54%
Sample Size	68600	59600	53400	46600	39600	30500	18800	9200	3700	200

SCORE Registry Performance Data

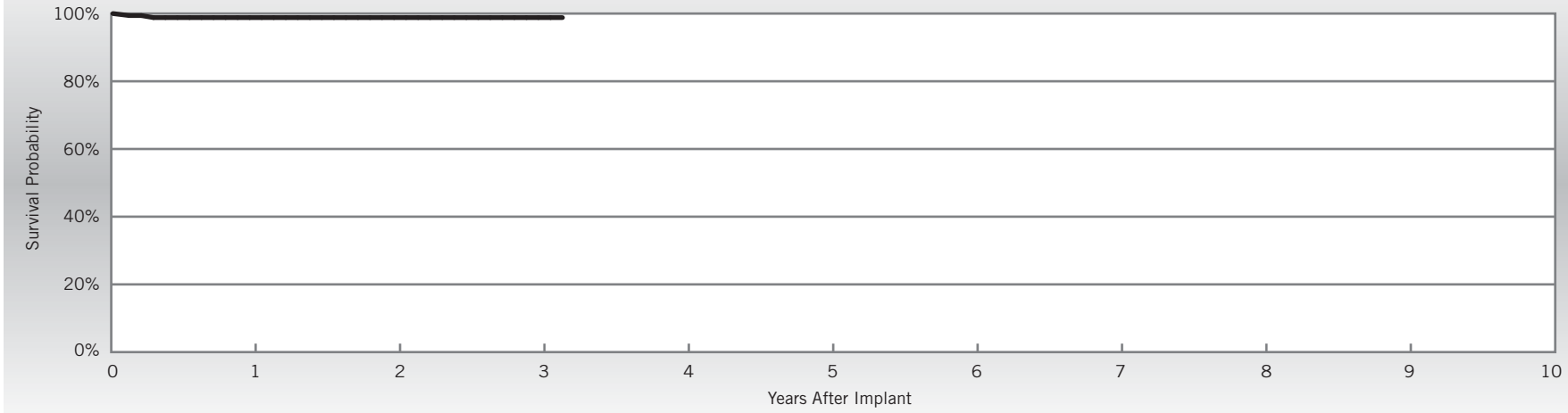
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	170
Cumulative Months of Follow-up	4,933
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	1	0.59%
Abnormal Pacing Impedance	1	0.59%

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	1.76%
Total	**3**	**1.76%**



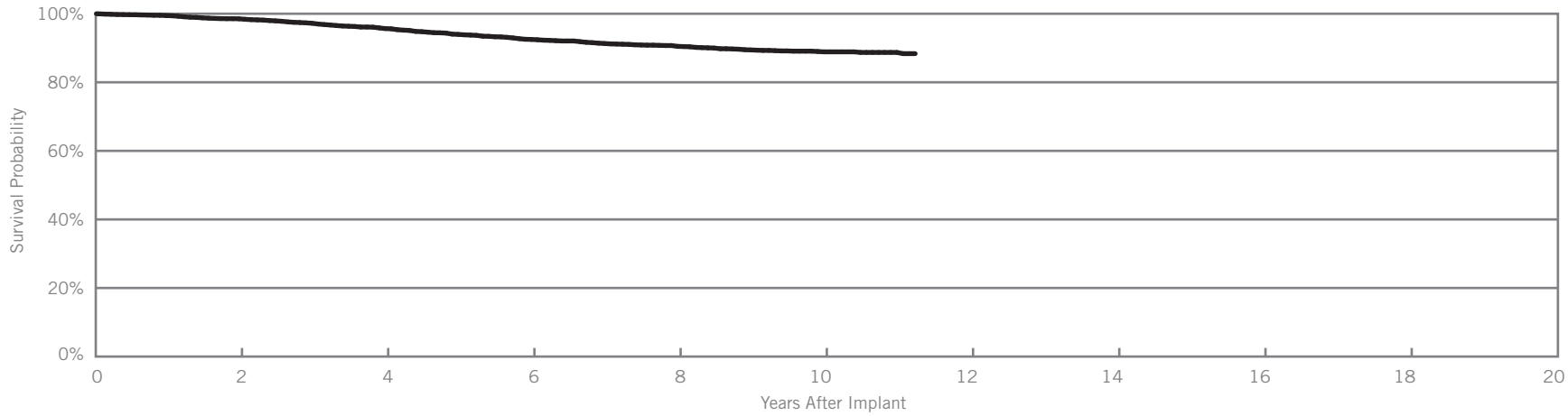
Year	1	2	3	at 38 months						
Survival Probability	98.81%	98.81%	98.81%	98.81%						
± 1 standard error	0.83%	0.83%	0.83%	0.83%						
Sample Size	160	130	80	60						

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,737
Estimated Active US Implants	1,071
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



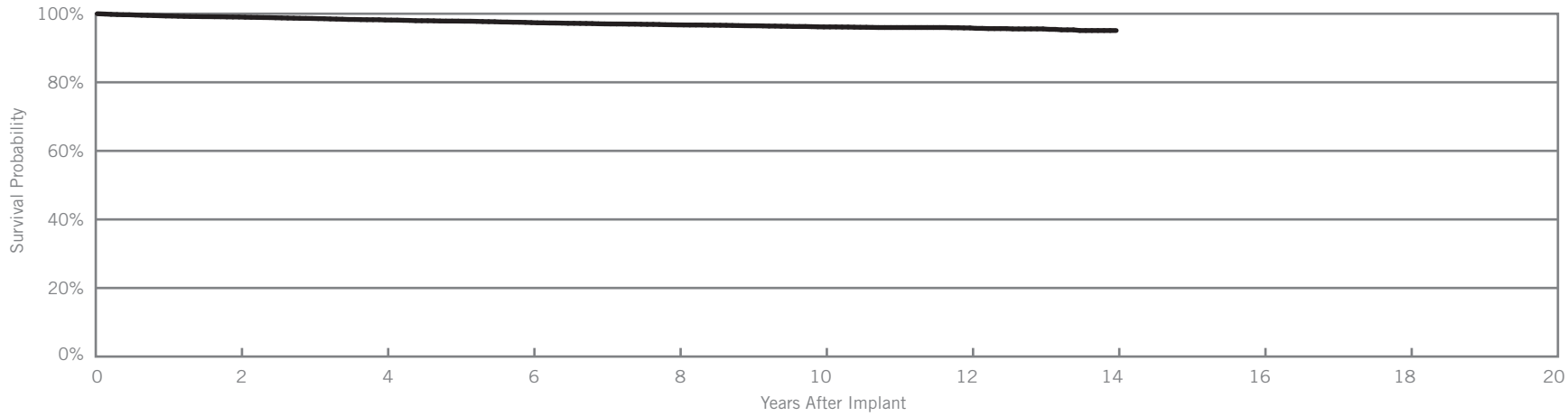
Year	2	4	6	8	10	at 135 months				
Survival Probability	98.52%	95.67%	92.50%	90.48%	88.88%	88.36%				
± 1 standard error	0.19%	0.34%	0.48%	0.56%	0.65%	0.75%				
Sample Size	3900	3100	2400	1800	1100	200				

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,642
Estimated Active US Implants	3,139
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			
Survival Probability	99.04%	98.17%	97.41%	96.75%	96.15%	95.86%	95.10%			
± 1 standard error	0.09%	0.13%	0.17%	0.20%	0.23%	0.25%	0.40%			
Sample Size	10800	8800	7100	5600	4100	2000	500			

Summary Information

Defibrillation Leads

St. Jude Medical
More control. Less risk.

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	99.10%									
7120Q/7121Q	Durata® DF4	99.35%	99.12%								
7122Q	Durata® DF4	99.30%	99.09%								
7120/7121	Durata®	99.34%	99.16%	99.02%	98.85%						
7030/7031	Riata® ST Optim®	98.96%	98.49%	98.49%	97.81%						
7122	Durata®	99.43%	99.21%	99.10%							
7070/7071	Riata® ST Optim®	99.19%	98.93%	98.67%	98.67%						
7020/7021	Riata® ST Optim®	98.64%	98.29%	98.03%	97.76%	97.34%					
7022	Riata® ST Optim®	98.74%	98.40%	98.21%	97.58%						
7010/7011	Riata® ST	99.16%	98.77%	98.45%	98.38%	98.05%					
7040/7041	Riata® ST	99.13%	98.71%	98.38%	97.48%	96.59%					
7002	Riata® ST	98.92%	98.25%	97.72%	97.35%	96.87%					
7000/7001	Riata® ST	99.05%	98.50%	97.99%	97.59%	97.13%					
1560/1561	Riata® i	99.68%	99.20%	98.81%	98.81%	98.81%	98.60%				
1590/1591	Riata® i	99.46%	99.23%	98.98%	98.84%	98.30%	97.86%				
1582	Riata®	98.89%	98.12%	97.10%	96.09%	95.18%	93.73%	91.34%			
1570/1571	Riata®	99.58%	99.28%	98.85%	98.13%	97.52%	96.57%	95.73%	95.03%	94.00%	
1580/1581	Riata®	99.32%	98.95%	98.42%	97.92%	97.28%	96.53%	95.67%	94.66%	93.20%	
1559	TVL™ ADX	99.47%	98.52%	97.22%	95.67%	93.97%	92.50%	91.31%	90.48%	89.44%	88.88%
SP01/SP02/SP03/SP04	SPL®	99.35%	99.04%	98.62%	98.17%	97.85%	97.41%	97.04%	96.75%	96.49%	96.15%

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	2267	1866	1	0.04%	0	0.00%	2	0.09%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**5**	**0.22%**	**3**
7120Q/7121Q	Jan-09	54132	45309	32	0.06%	0	0.00%	104	0.19%	39	0.07%	23	0.04%	6	0.01%	0	0.00%	2	<0.01%	2	<0.01%	2	<0.01%	5	0.01%	**215**	**0.40%**	**98**
7122Q	Jan-09	10554	9052	8	0.08%	0	0.00%	21	0.20%	11	0.10%	5	0.05%	3	0.03%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	3	0.03%	**52**	**0.49%**	**32**
7120/7121	Sep-07	55683	40309	33	0.06%	1	<0.01%	70	0.13%	18	0.03%	45	0.08%	4	0.01%	0	0.00%	1	<0.01%	17	0.03%	1	<0.01%	16	0.03%	**206**	**0.37%**	**71**
7030/7031	Jul-06	851	504	0	0.00%	0	0.00%	4	0.47%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.71%**	**3**
7122	Sep-07	9413	7200	5	0.05%	1	0.01%	9	0.10%	7	0.07%	4	0.04%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**28**	**0.30%**	**12**
7070/7071	Jul-06	3424	2450	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**	**0.55%**	**8**
7020/7021	Jul-06	15476	9363	38	0.25%	0	0.00%	34	0.22%	19	0.12%	19	0.12%	8	0.05%	0	0.00%	1	0.01%	4	0.03%	4	0.03%	0	0.00%	**127**	**0.82%**	**46**
7022	Jul-06	1485	958	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.67%**	**1**
7010/7011	Mar-06	2211	1309	3	0.14%	0	0.00%	1	0.05%	3	0.14%	2	0.09%	1	0.05%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**12**	**0.54%**	**4**
7040/7041	Mar-06	4089	2459	4	0.10%	0	0.00%	5	0.12%	1	0.02%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**16**	**0.39%**	**2**
7002	Jun-05	2415	1438	6	0.25%	0	0.00%	2	0.08%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	**20**	**0.83%**	**8**
7000/7001	Jun-05	34985	19972	41	0.12%	0	0.00%	37	0.11%	43	0.12%	40	0.11%	7	0.02%	1	<0.01%	8	0.02%	4	0.01%	4	0.01%	11	0.03%	**196**	**0.56%**	**81**

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	2267	1866	0	0.00%	0	0.00%	4	0.18%	8	0.35%	1	0.04%	0	0.00%	1	0.04%	1	0.04%	1	0.04%	0	0.00%	0	0.00%	**16**	**0.71%**	**12**
7120Q/7121Q	Jan-09	54132	45309	8	0.01%	11	0.02%	165	0.30%	62	0.11%	27	0.05%	10	0.02%	0	0.00%	2	<0.01%	12	0.02%	2	<0.01%	7	0.01%	**306**	**0.57%**	**215**
7122Q	Jan-09	10554	9052	6	0.06%	1	0.01%	25	0.24%	9	0.09%	8	0.08%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**52**	**0.49%**	**41**
7120/7121	Sep-07	55683	40309	5	0.01%	17	0.03%	122	0.22%	58	0.10%	62	0.11%	14	0.03%	5	0.01%	12	0.02%	23	0.04%	0	0.00%	11	0.02%	**329**	**0.59%**	**174**
7030/7031	Jul-06	851	504	1	0.12%	0	0.00%	0	0.00%	4	0.47%	6	0.71%	0	0.00%	1	0.12%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	**13**	**1.53%**	**2**
7122	Sep-07	9413	7200	1	0.01%	2	0.02%	14	0.15%	10	0.11%	10	0.11%	4	0.04%	4	0.04%	5	0.05%	1	0.01%	0	0.00%	2	0.02%	**53**	**0.56%**	**38**
7070/7071	Jul-06	3424	2450	2	0.06%	2	0.06%	4	0.12%	4	0.12%	6	0.18%	2	0.06%	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	**23**	**0.67%**	**7**
7020/7021	Jul-06	15476	9363	10	0.06%	11	0.07%	49	0.32%	42	0.27%	51	0.33%	11	0.07%	3	0.02%	4	0.03%	9	0.06%	2	0.01%	14	0.09%	**206**	**1.33%**	**123**
7022	Jul-06	1485	958	2	0.13%	3	0.20%	6	0.40%	1	0.07%	6	0.40%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**19**	**1.28%**	**10**
7010/7011	Mar-06	2211	1309	1	0.05%	0	0.00%	5	0.23%	2	0.09%	4	0.18%	2	0.09%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**16**	**0.72%**	**6**
7040/7041	Mar-06	4089	2459	2	0.05%	10	0.24%	3	0.07%	10	0.24%	20	0.49%	4	0.10%	1	0.02%	3	0.07%	4	0.10%	0	0.00%	0	0.00%	**57**	**1.39%**	**14**
7002	Jun-05	2415	1438	2	0.08%	3	0.12%	9	0.37%	7	0.29%	14	0.58%	0	0.00%	1	0.04%	0	0.00%	1	0.04%	0	0.00%	4	0.17%	**41**	**1.70%**	**18**
7000/7001	Jun-05	34985	19972	18	0.05%	32	0.09%	39	0.11%	80	0.23%	190	0.54%	20	0.06%	33	0.09%	15	0.04%	14	0.04%	2	0.01%	30	0.09%	**473**	**1.35%**	**209**

Definitions of observations and complications can be found on pages 8-9.

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	2267	0	0.00%	0	0.00%	1	0.04%	**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%	10	0.44%	**11**	**0.49%**
7120Q/7121Q	54132	0	0.00%	2	<0.01%	2	<0.01%	**4**	**0.01%**	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**2**	**<0.01%**	0	0.00%	6	0.01%	190	0.35%	**202**	**0.37%**
7122Q	10554	0	0.00%	2	0.02%	0	0.00%	**2**	**0.02%**	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**	0	0.00%	2	0.02%	34	0.32%	**39**	**0.37%**
7120/7121	55683	1	<0.01%	8	0.01%	2	<0.01%	**11**	**0.02%**	5	0.01%	2	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**9**	**0.02%**	1	<0.01%	3	0.01%	136	0.24%	**160**	**0.29%**
7030/7031	851	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	0.35%	**3**	**0.35%**
7122	9413	0	0.00%	3	0.03%	1	0.01%	**4**	**0.04%**	1	0.01%	2	0.02%	0	0.00%	0	0.00%	1	0.01%	**4**	**0.04%**	0	0.00%	0	0.00%	26	0.28%	**34**	**0.36%**
7070/7071	3424	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	**1**	**0.03%**	0	0.00%	0	0.00%	5	0.15%	**7**	**0.20%**
7020/7021	15476	1	0.01%	1	0.01%	3	0.02%	**5**	**0.03%**	4	0.03%	3	0.02%	1	0.01%	0	0.00%	3	0.02%	**11**	**0.07%**	0	0.00%	0	0.00%	91	0.59%	**107**	**0.69%**
7022	1485	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	8	0.54%	**9**	**0.61%**
7010/7011	2211	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.05%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.14%**	0	0.00%	0	0.00%	4	0.18%	**7**	**0.32%**
7040/7041	4089	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	6	0.15%	2	0.05%	0	0.00%	0	0.00%	2	0.05%	**10**	**0.24%**	0	0.00%	0	0.00%	7	0.17%	**19**	**0.46%**
7002	2415	0	0.00%	0	0.00%	2	0.08%	**2**	**0.08%**	5	0.21%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.25%**	0	0.00%	0	0.00%	10	0.41%	**18**	**0.75%**
7000/7001	34985	2	0.01%	2	0.01%	6	0.02%	**10**	**0.03%**	65	0.19%	14	0.04%	2	0.01%	2	0.01%	10	0.03%	**93**	**0.27%**	1	<0.01%	0	0.00%	102	0.29%	**206**	**0.59%**
1560/1561	1008	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**
1590/1591	9763	1	0.01%	0	0.00%	3	0.03%	**4**	**0.04%**	7	0.07%	5	0.05%	0	0.00%	2	0.02%	6	0.06%	**20**	**0.20%**	0	0.00%	0	0.00%	17	0.17%	**41**	**0.42%**
1582	3190	0	0.00%	0	0.00%	2	0.06%	**2**	**0.06%**	25	0.78%	5	0.16%	1	0.03%	5	0.16%	12	0.38%	**48**	**1.50%**	0	0.00%	0	0.00%	14	0.44%	**64**	**2.01%**
1570/1571	10532	2	0.02%	1	0.01%	0	0.00%	**3**	**0.03%**	27	0.26%	4	0.04%	0	0.00%	4	0.04%	10	0.09%	**45**	**0.43%**	0	0.00%	0	0.00%	20	0.19%	**68**	**0.65%**
1580/1581	69600	2	<0.01%	7	0.01%	7	0.01%	**16**	**0.02%**	174	0.25%	47	0.07%	6	0.01%	30	0.04%	57	0.08%	**314**	**0.45%**	3	<0.01%	0	0.00%	212	0.30%	**545**	**0.78%**

Definitions of malfunction categories can be found on pages 9-10.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	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	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	969	13434	0	0.00%	0	0.00%	3	0.31%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.21%	0	0.00%	0	0.00%	**6**	**0.62%**
7122Q	205	2608	0	0.00%	0	0.00%	0	0.00%	1	0.49%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.49%**
7120/7121	1501	40458	0	0.00%	2	0.13%	5	0.33%	3	0.20%	1	0.07%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	**13**	**0.87%**
7122	297	5937	0	0.00%	0	0.00%	3	1.01%	0	0.00%	1	0.34%	0	0.00%	0	0.00%	1	0.34%	0	0.00%	0	0.00%	0	0.00%	**5**	**1.68%**
7070/7071	152	4207	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%**
7020/7021	176	6353	1	0.57%	2	1.14%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	1	0.57%	0	0.00%	0	0.00%	0	0.00%	**5**	**2.84%**
7000/7001	131	4631	0	0.00%	0	0.00%	1	0.76%	0	0.00%	1	0.76%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.53%**
1580/1581	170	4933	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.18%**

Malfunctions

Models	Number of Devices Enrolled	Conductor Fracture								Insulation Breach										Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach							
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	969	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%	5	0.52%	**5**	**0.52%**
7122Q	205	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	0.49%	**1**	**0.49%**
7120/7121	1501	0	0.00%	1	0.07%	0	0.00%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	0.13%	**3**	**0.20%**
7122	297	0	0.00%	0	0.00%	1	0.34%	**1**	**0.34%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	0.67%	**3**	**1.01%**
7070/7071	152	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	0.66%	**1**	**0.66%**
7020/7021	176	0	0.00%	1	0.57%	0	0.00%	**1**	**0.57%**	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	0.57%	**2**	**1.14%**
7000/7001	131	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.76%	1	0.76%	0	0.00%	1	0.76%	0	0.00%	**3**	**2.29%**	1	0.76%	0	0.00%	0	0.00%	**4**	**3.05%**
1580/1581	170	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	1.76%	**3**	**1.76%**

Definitions of complications can be found on page 13.
Definitions of malfunction categories can be found on pages 9-10.

Pacemakers

Dual-Chamber

St. Jude Medical
More control. Less risk.

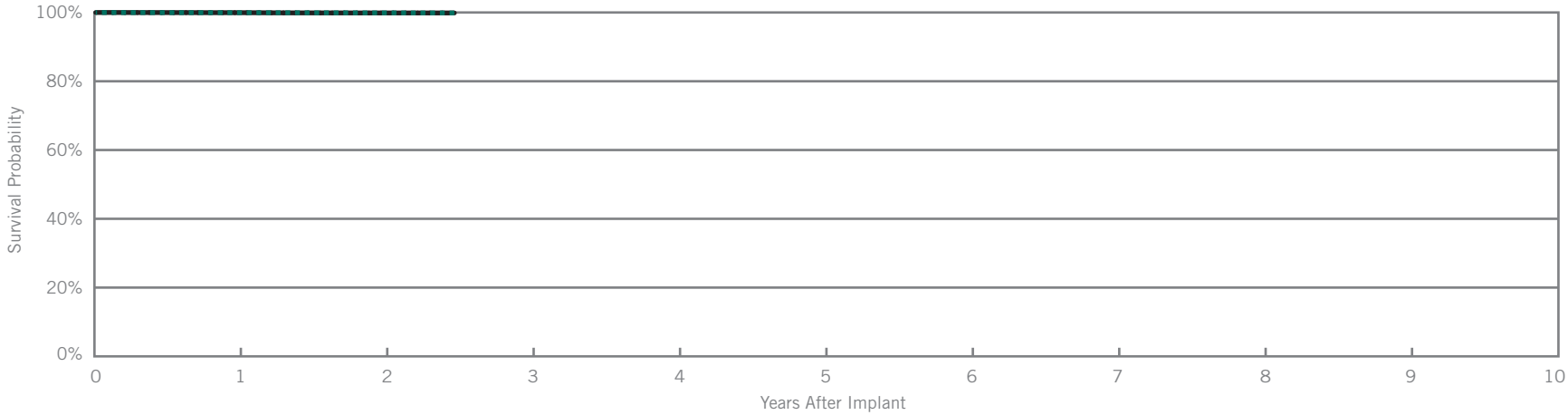
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	106,830
Estimated Active US Implants	92,726
Estimated Longevity	8 Years
Normal Battery Depletion	3
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	3	<0.01%
Electrical Interconnect	3	<0.01%	8	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	3	<0.01%	5	<0.01%
Other	1	<0.01%	2	<0.01%
Total	**8**	**0.01%**	**25**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.93%	99.85%	99.85%							
± 1 standard error	0.01%	0.02%	0.02%							
Sample Size	85600	31000	200							

Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.94%	99.86%	99.86%							
± 1 standard error	0.01%	0.02%	0.02%							

SCORE Registry Performance Data

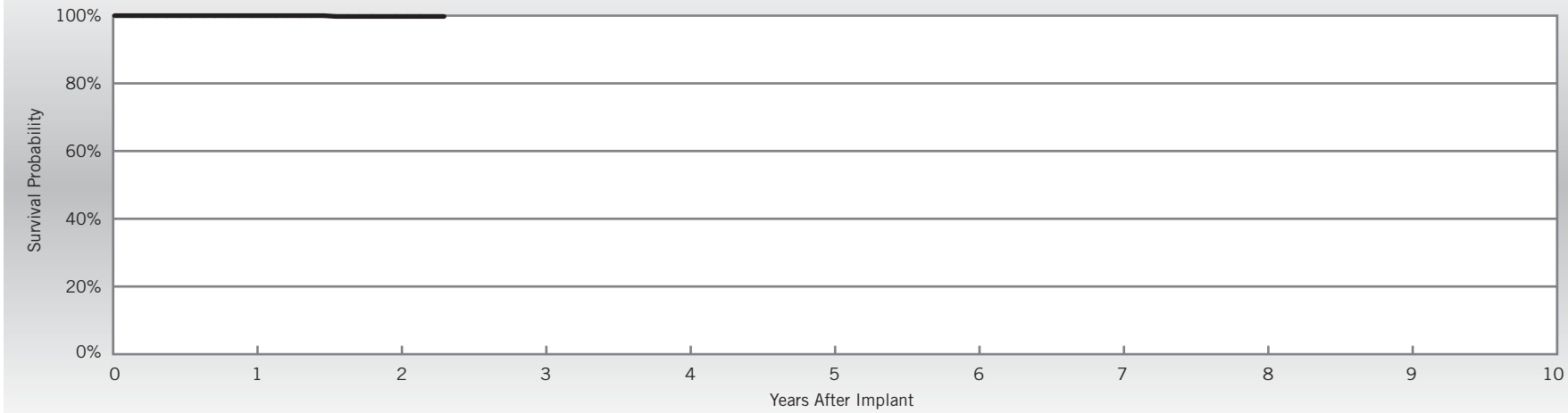
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,762
Cumulative Months of Follow-up	22,882
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	at 28 months							
Survival Probability	100.00%	99.77%	99.77%							
± 1 standard error	0.00%	0.23%	0.23%							
Sample Size	1300	510	70							

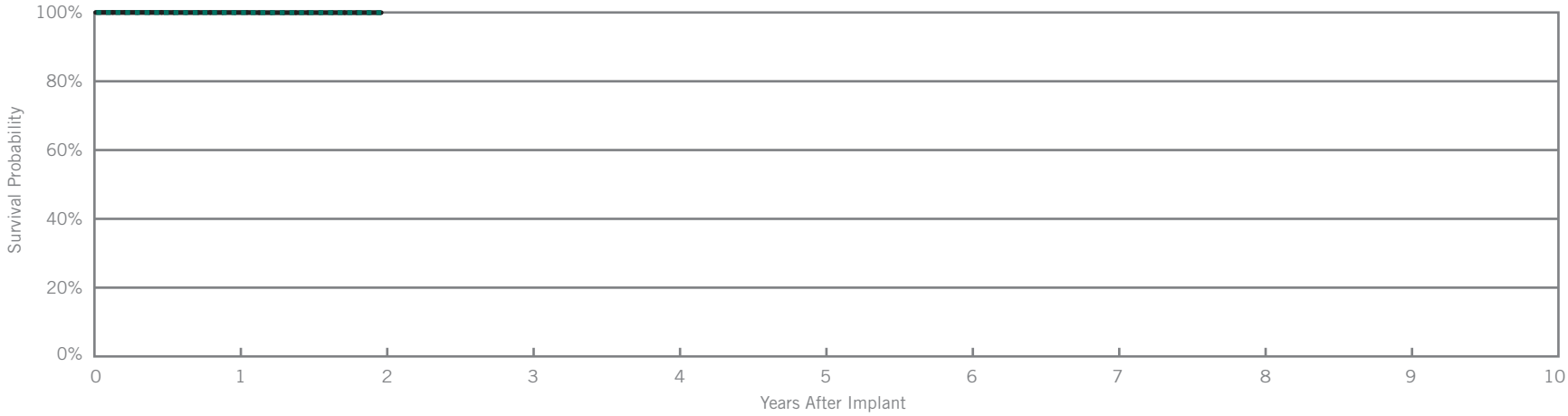
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	19,804
Estimated Active US Implants	17,698
Estimated Longevity	9.2 Years
Normal Battery Depletion	0
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	1	0.01%
Electrical Interconnect	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	**1**	**0.01%**	**1**	**0.01%**



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.98%	99.95%								
± 1 standard error	0.01%	0.03%								
Sample Size	14400	3600								

Excluding Normal Battery Depletion

Year	1	2								
Survival Probability	99.98%	99.95%								
± 1 standard error	0.01%	0.03%								

SCORE Registry Performance Data

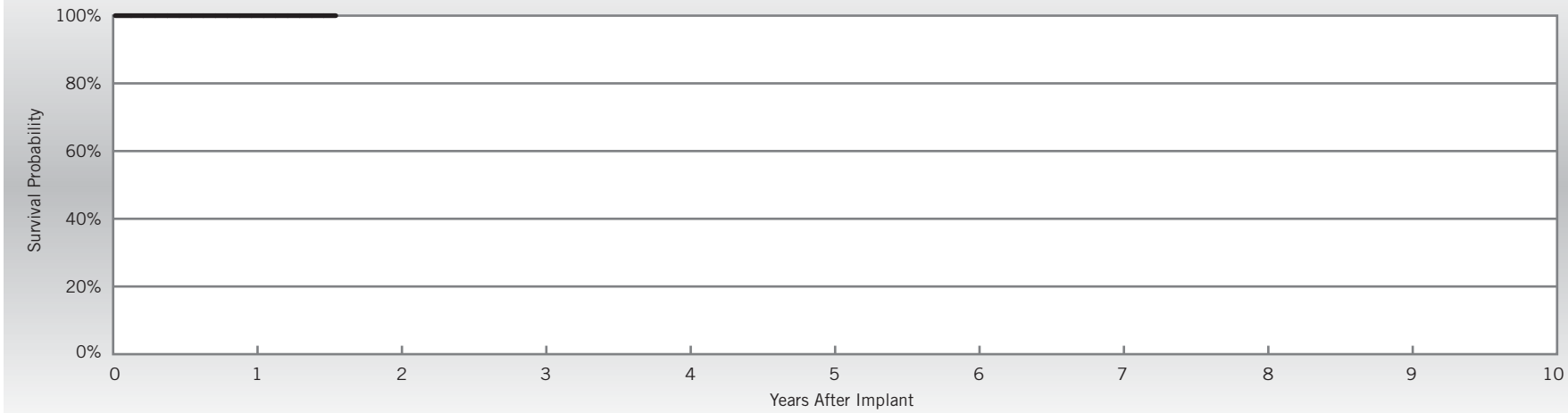
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	223
Cumulative Months of Follow-up	2,944
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	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	170	50								

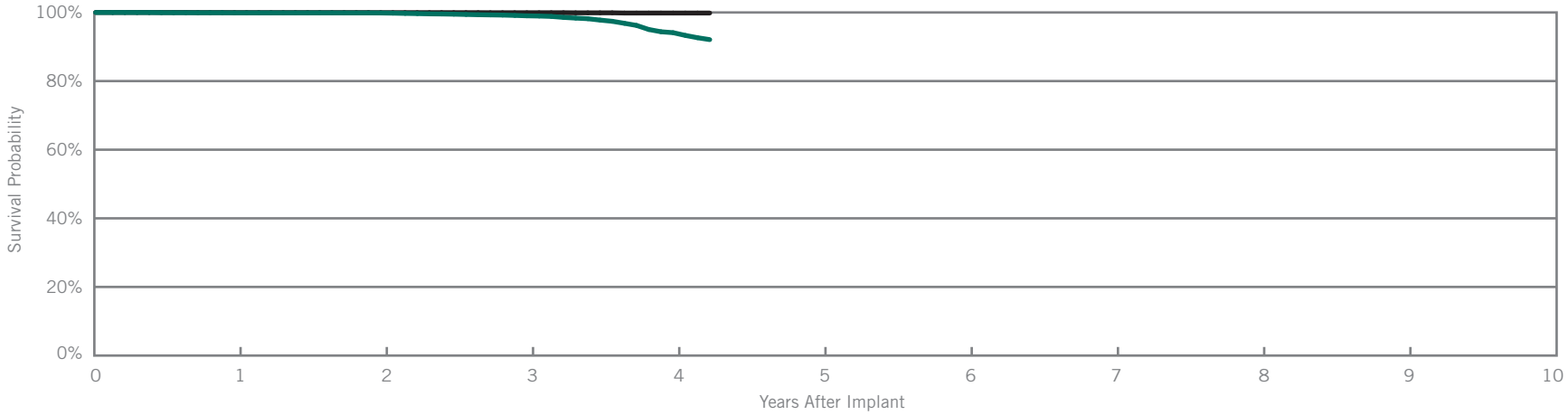
Customer Reported Performance Data

Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	38,521
Estimated Active US Implants	28,107
Estimated Longevity	6.5 Years
Normal Battery Depletion	140
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	5	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	2	0.01%
Total	**1**	**<0.01%**	**9**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.88%	99.84%	99.01%	94.10%	73.22%					
± 1 standard error	0.02%	0.02%	0.08%	0.37%	0.50%					
Sample Size	35200	23700	13900	5300	1000					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.96%	99.95%	99.92%	99.83%	99.83%					
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.05%					

SCORE Registry Performance Data

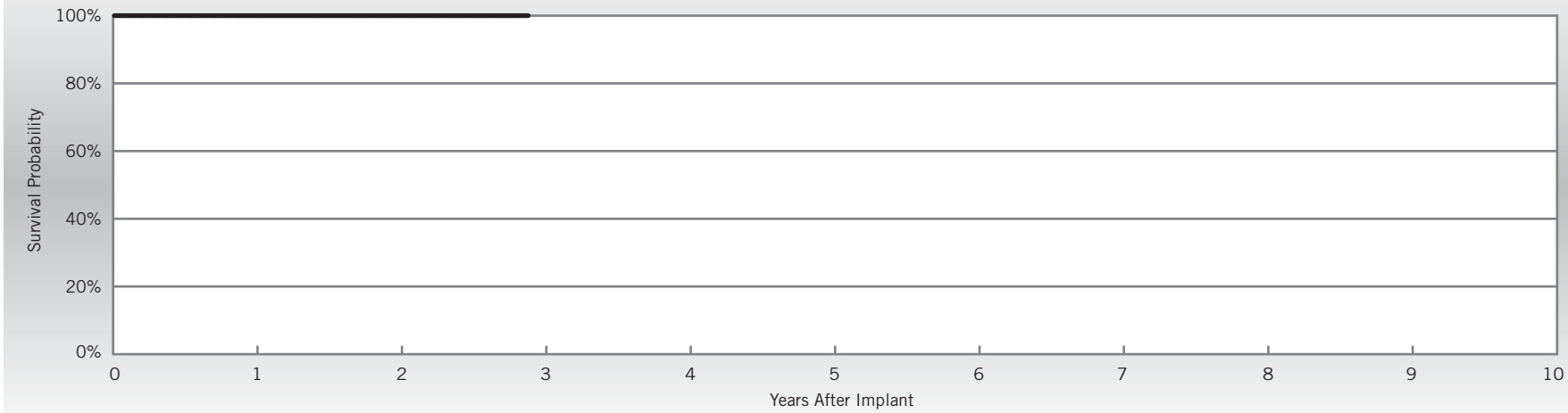
Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	283
Cumulative Months of Follow-up	6,483
Estimated Longevity	6.5 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 35 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	250	170	50							

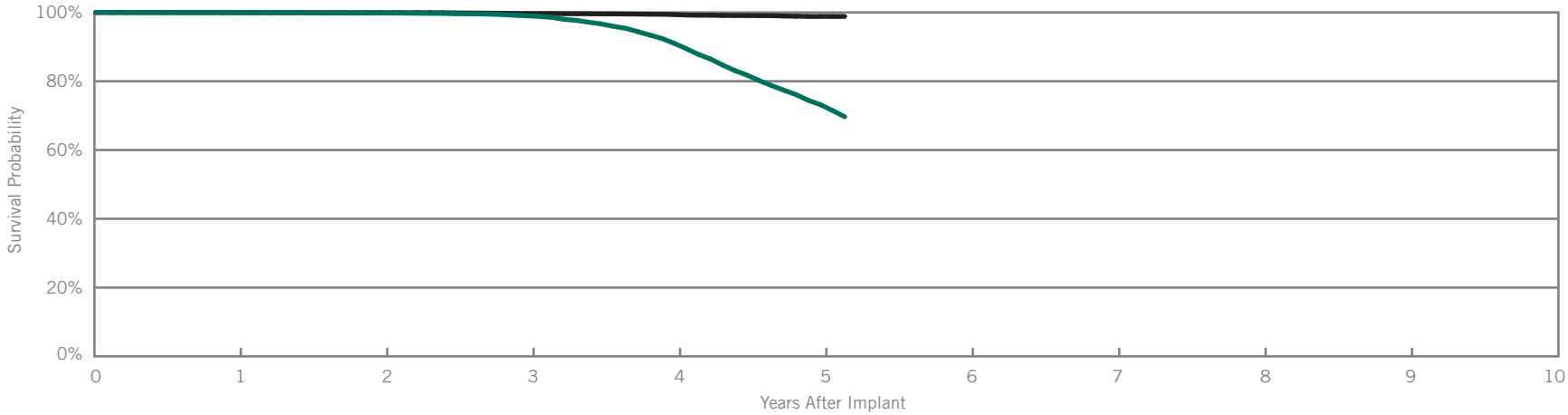
Customer Reported Performance Data

Victory® DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,317
Estimated Active US Implants	12,037
Estimated Longevity	6.5 Years
Normal Battery Depletion	1005
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	35	0.13%
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	**0**	**0.00%**	**53**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.93%	99.84%	99.02%	91.05%	73.20%	69.67%				
± 1 standard error	0.01%	0.03%	0.07%	0.23%	0.49%	0.56%				
Sample Size	26200	22200	18400	13800	7300	2100				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.98%	99.94%	99.68%	99.39%	98.85%	98.85%				
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.12%	0.12%				

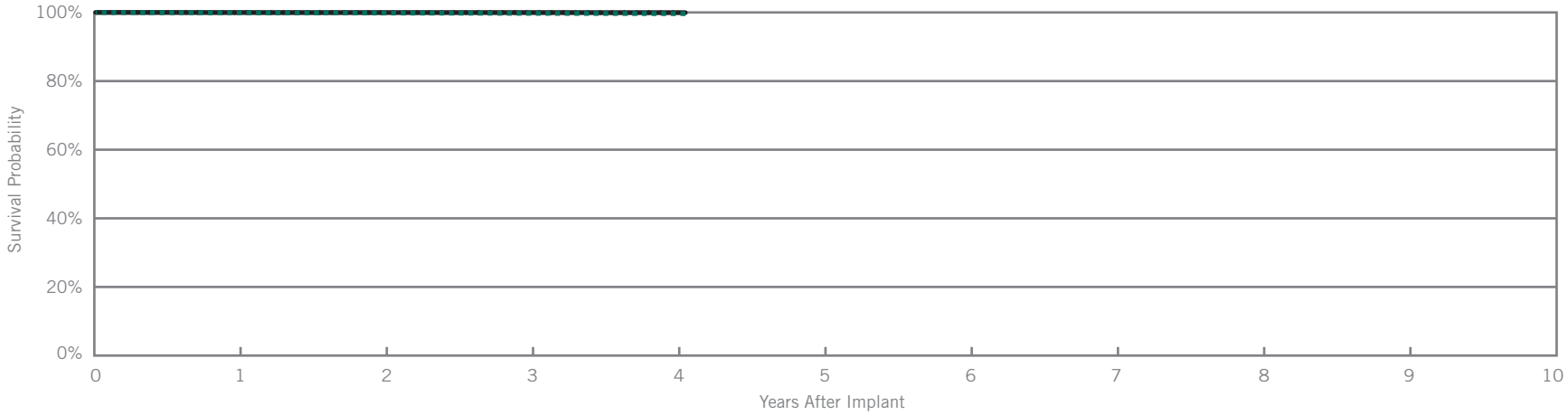
Customer Reported Performance Data

Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	103,805
Estimated Active US Implants	73,737
Estimated Longevity	11.7 Years
Normal Battery Depletion	42
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	9	0.01%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	3	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	2	<0.01%
Total	**4**	**<0.01%**	**15**	**0.01%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.94%	99.91%	99.84%	99.69%	99.65%					
± 1 standard error	0.01%	0.01%	0.01%	0.03%	0.03%					
Sample Size	101100	81100	52600	20200	6300					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.97%	99.96%	99.96%	99.94%	99.94%					
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%					

SCORE Registry Performance Data

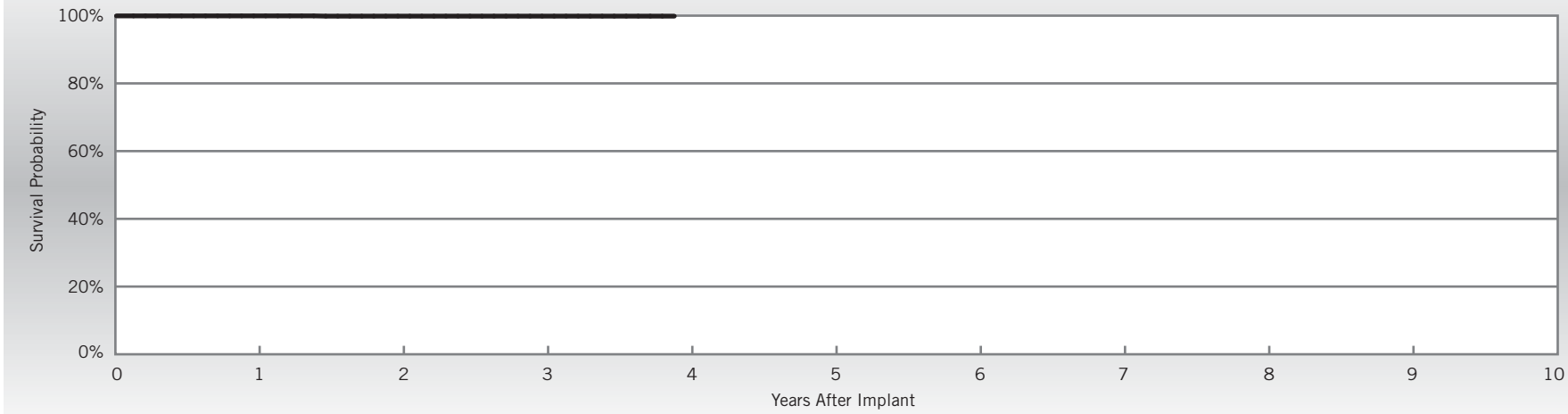
Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,517
Cumulative Months of Follow-up	46,083
Estimated Longevity	11.7 Years

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.13%

	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	at 47 months						
Survival Probability	99.93%	99.86%	99.86%	99.86%						
± 1 standard error	0.07%	0.10%	0.10%	0.10%						
Sample Size	1440	1240	830	60						

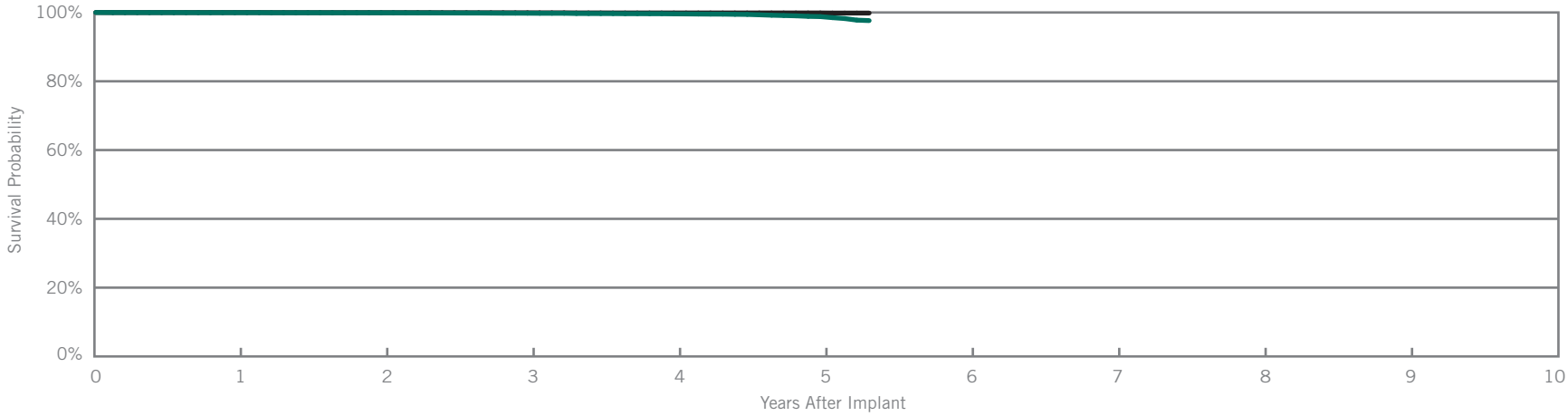
Customer Reported Performance Data

Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,285
Estimated Active US Implants	37,573
Estimated Longevity	11.7 Years
Normal Battery Depletion	114
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	12	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%	5	0.01%
Possible Early Battery Depletion	0	0.00%	4	0.01%
Other	1	<0.01%	4	0.01%
Total	**3**	**<0.01%**	**25**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.95%	99.91%	99.78%	99.59%	98.80%	97.64%				
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.08%	0.16%				
Sample Size	62100	53800	44600	33300	17300	4200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.98%	99.95%	99.91%	99.86%	99.86%	99.83%				
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%				

SCORE Registry Performance Data

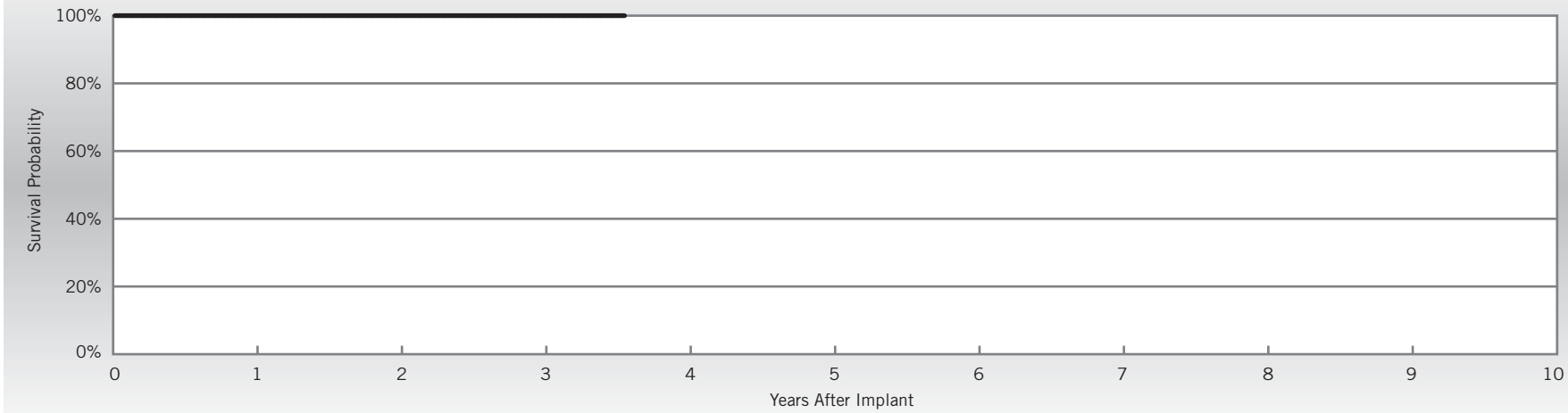
Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	333
Cumulative Months of Follow-up	10,608
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%**



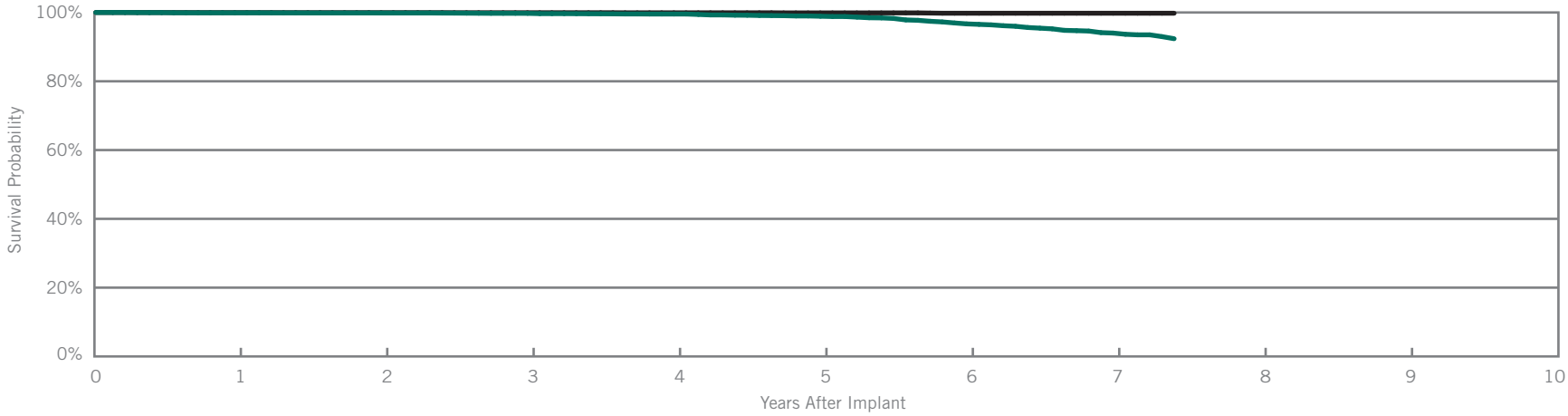
Year	1	2	3	at 43 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	280	200	60						

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	17,025
Estimated Active US Implants	7,974
Estimated Longevity	6.9 Years
Normal Battery Depletion	114
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	at 89 months		
Survival Probability	99.90%	99.84%	99.74%	99.54%	98.90%	96.68%	94.01%	92.37%		
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.11%	0.23%	0.40%	0.50%		
Sample Size	16900	14400	12700	10500	7900	5100	2700	800		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.96%	99.95%	99.93%	99.91%	99.88%	99.78%	99.78%	99.78%		
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.03%	0.06%	0.06%	0.06%		

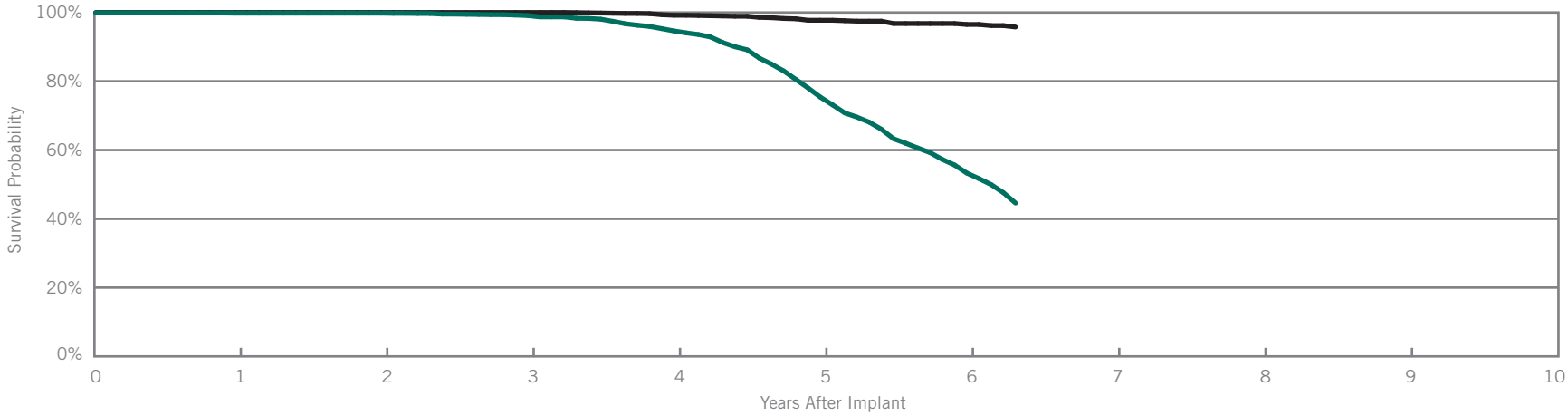
Integrity® ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,840
Estimated Active US Implants	1,133
Estimated Longevity	3.8 Years
Normal Battery Depletion	466
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%	34	0.58%
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%**	**35**	**0.60%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.80%	99.80%	99.11%	94.63%	75.39%	53.32%	44.58%			
± 1 standard error	0.05%	0.06%	0.13%	0.35%	0.79%	1.11%	1.22%			
Sample Size	5800	5000	4400	3800	2900	1500	500			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	100.00%	100.00%	100.00%	99.19%	97.74%	96.52%	95.78%			
± 1 standard error	0.00%	0.00%	0.00%	0.14%	0.30%	0.40%	0.50%			

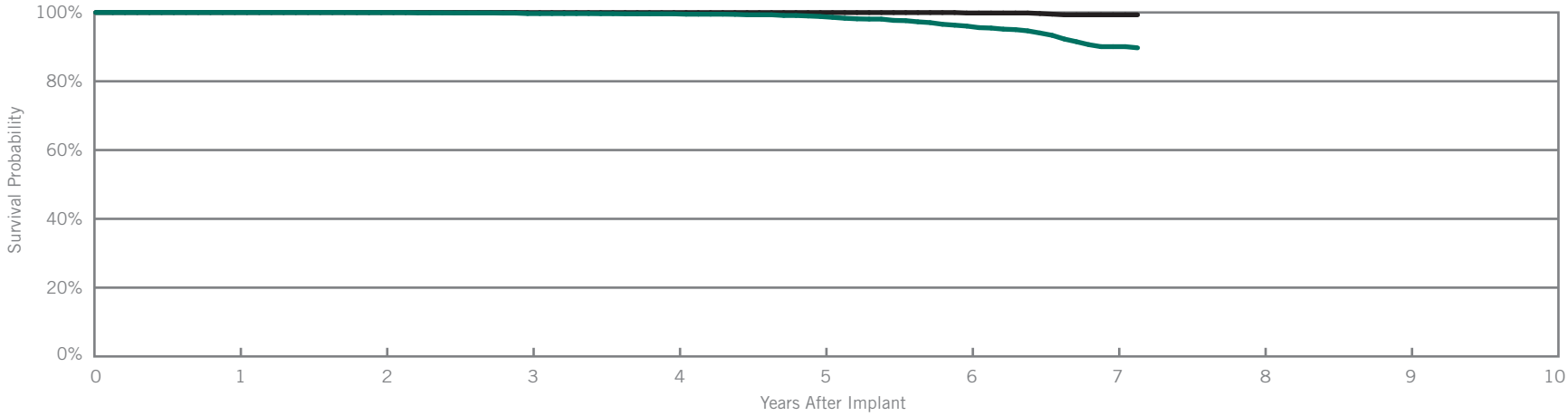
Customer Reported Performance Data

Integrity® ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,009
Estimated Active US Implants	3,999
Estimated Longevity	6.9 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%	4	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%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**5**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	100.00%	99.97%	99.68%	99.60%	98.83%	96.04%	90.06%	89.72%		
± 1 standard error	0.00%	0.02%	0.05%	0.08%	0.15%	0.36%	0.79%	0.79%		
Sample Size	8000	7100	6300	5500	4300	2700	1300	600		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	100.00%	100.00%	99.97%	99.97%	99.97%	99.85%	99.32%	99.32%		
± 1 standard error	0.00%	0.00%	0.00%	0.03%	0.03%	0.03%	0.23%	0.23%		

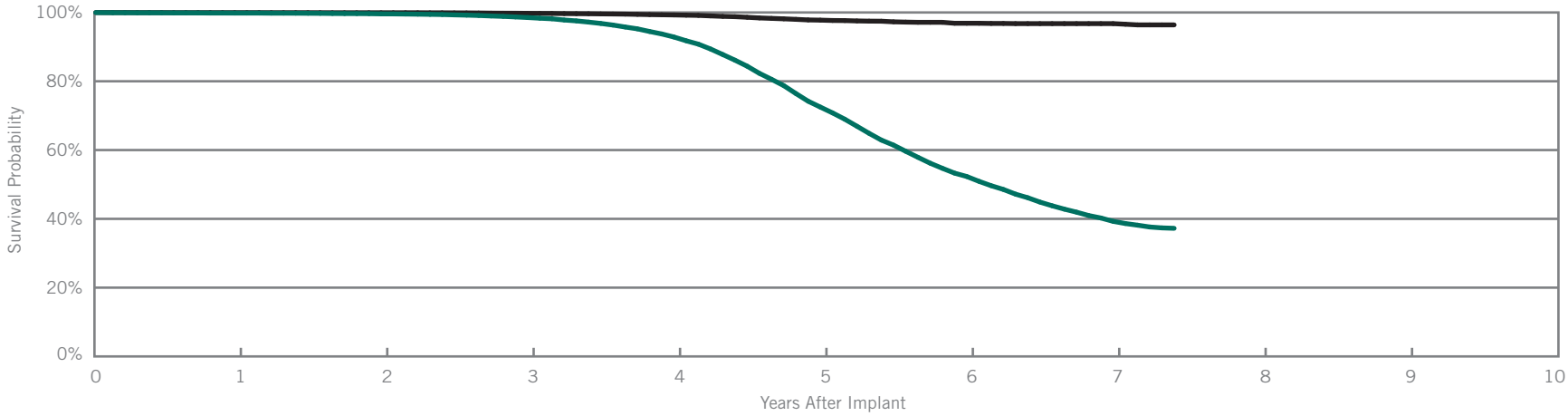
Integrity® ADx DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	53,981
Estimated Active US Implants	10,906
Estimated Longevity	3.8 Years
Normal Battery Depletion	4,335
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	4	0.01%	245	0.45%
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%**	**264**	**0.49%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.82%	99.59%	98.53%	92.86%	72.49%	52.31%	39.27%	37.25%		
± 1 standard error	0.02%	0.03%	0.06%	0.13%	0.27%	0.37%	0.50%	0.56%		
Sample Size	53700	46300	40900	34900	26400	13500	4000	700		

Excluding Normal Battery Depletion

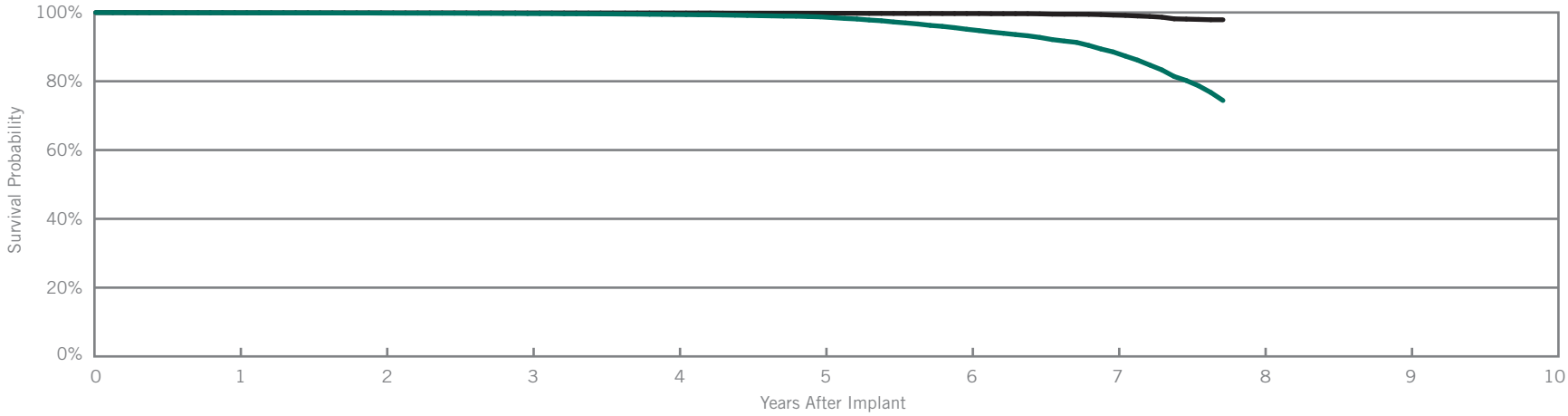
Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.96%	99.93%	99.75%	99.28%	97.77%	96.86%	96.76%	96.39%		
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.09%	0.14%	0.15%	0.24%		

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

US Regulatory Approval	March 2003
Registered US Implants	66,943
Estimated Active US Implants	32,576
Estimated Longevity	6.9 Years
Normal Battery Depletion	905
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	70	0.10%
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%	2	<0.01%
Total	**2**	**<0.01%**	**87**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.90%	99.82%	99.68%	99.41%	98.72%	95.12%	88.53%	74.41%		
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.06%	0.13%	0.27%	0.60%		
Sample Size	66400	57500	50100	41900	33000	22500	11300	1600		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.92%	99.90%	99.87%	99.85%	99.78%	99.69%	99.24%	97.88%		
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.07%	0.22%		

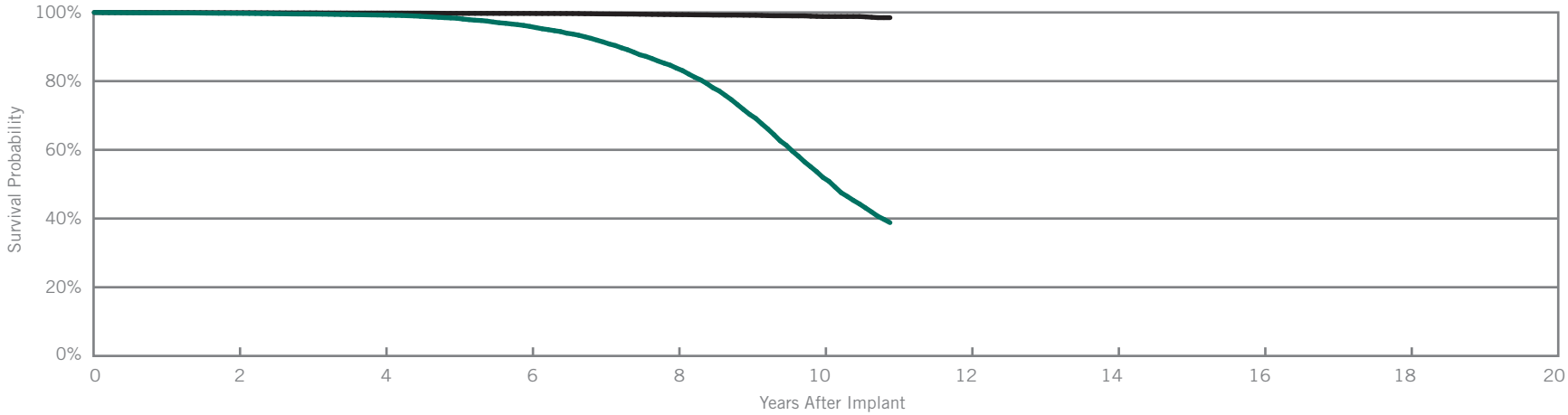
Integrity® AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,555
Estimated Active US Implants	6,358
Estimated Longevity	6.3 Years
Normal Battery Depletion	3,215
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%	82	0.17%
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%**	**88**	**0.19%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.75%	99.23%	95.92%	83.79%	51.98%	38.81%				
± 1 standard error	0.02%	0.04%	0.11%	0.25%	0.44%	0.56%				
Sample Size	42000	34900	27700	19000	8000	1200				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 131 months				
Survival Probability	99.92%	99.82%	99.71%	99.35%	98.82%	98.48%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.10%	0.17%				

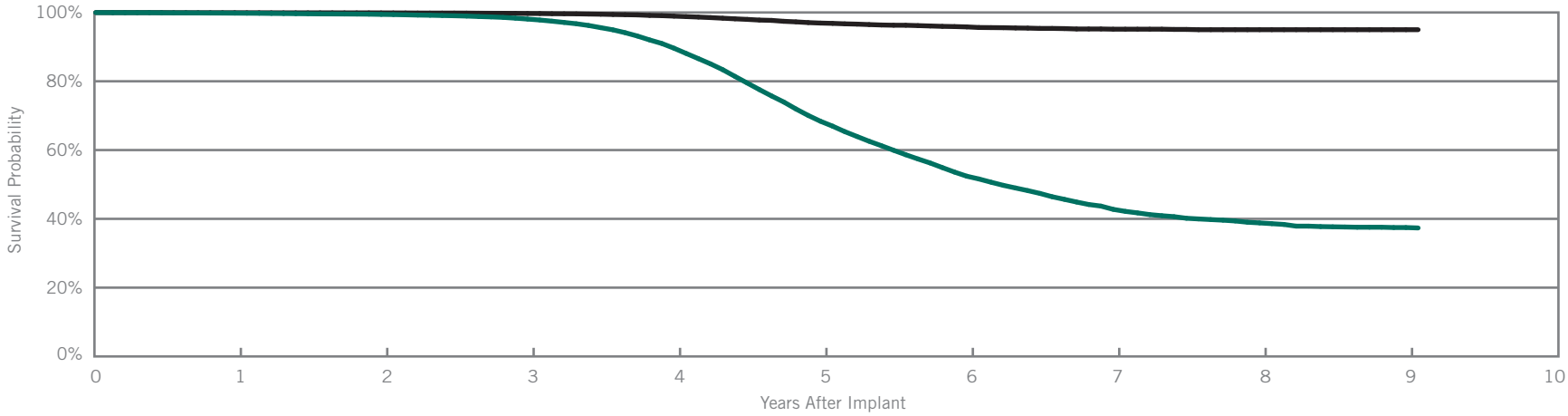
Customer Reported Performance Data

Identity®

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,454
Estimated Active US Implants	4,910
Estimated Longevity	3.8 Years
Normal Battery Depletion	5,309
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	390	0.67%
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%**	**420**	**0.72%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.80%	99.44%	98.08%	89.61%	68.39%	52.40%	42.76%	38.82%	37.47%	37.35%
± 1 standard error	0.02%	0.03%	0.06%	0.15%	0.26%	0.33%	0.39%	0.43%	0.45%	0.45%
Sample Size	58300	50700	45200	39500	30200	15800	6700	3000	1400	700

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.93%	99.88%	99.71%	98.93%	96.92%	95.80%	95.14%	94.99%	94.99%	94.99%
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.10%	0.14%	0.18%	0.20%	0.20%	0.20%

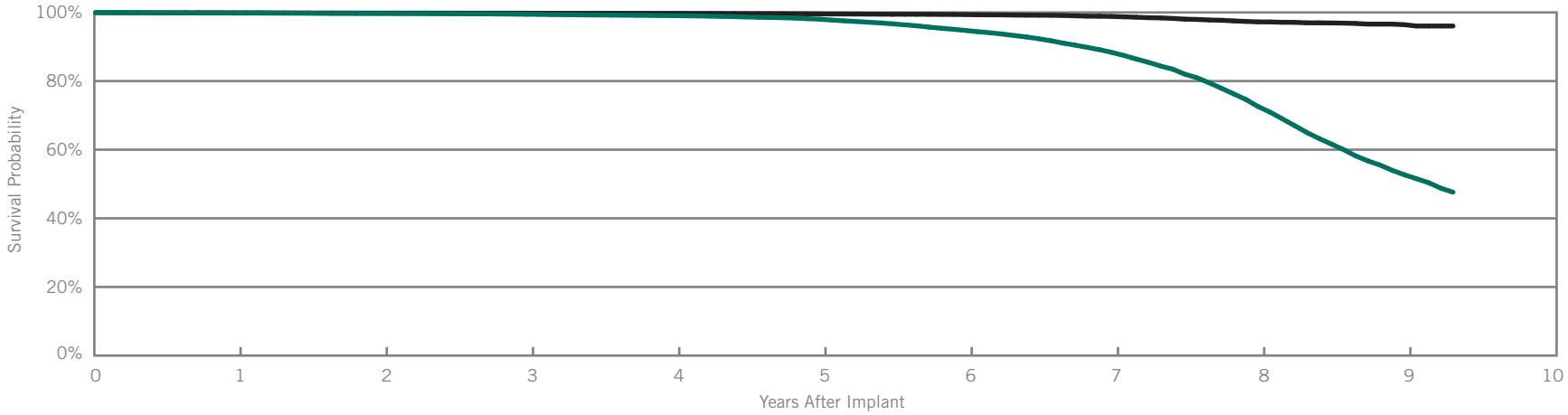
Customer Reported Performance Data

Identity® XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,498
Estimated Active US Implants	14,837
Estimated Longevity	6.9 Years
Normal Battery Depletion	2,659
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	206	0.40%
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%**	**225**	**0.44%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.81%	99.69%	99.46%	99.06%	98.03%	94.75%	88.35%	72.57%	52.70%	47.62%
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.07%	0.13%	0.20%	0.33%	0.48%	0.55%
Sample Size	51400	45900	41800	37500	32900	27300	21000	14400	7000	1600

Excluding Normal Battery Depletion

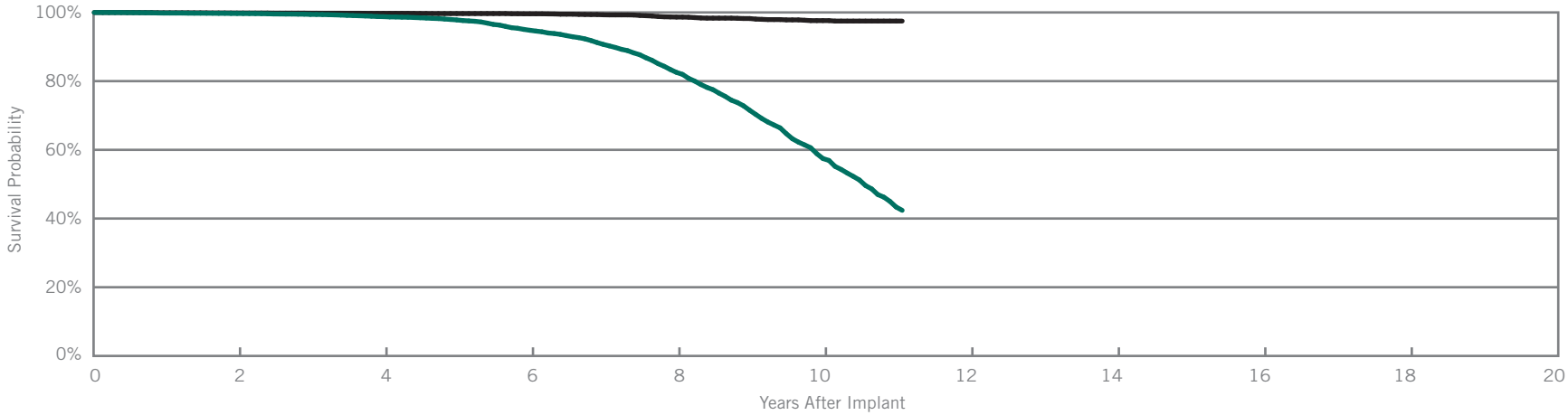
Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.90%	99.81%	99.78%	99.73%	99.57%	99.37%	98.84%	97.25%	96.43%	96.04%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.07%	0.13%	0.17%	0.22%

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,877
Estimated Active US Implants	2,067
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,099
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	63	0.29%
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%**	**67**	**0.31%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 133 months				
Survival Probability	99.69%	98.77%	94.80%	82.55%	57.47%	42.39%				
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.73%	0.95%				
Sample Size	18700	14800	11100	7100	2800	600				

Excluding Normal Battery Depletion

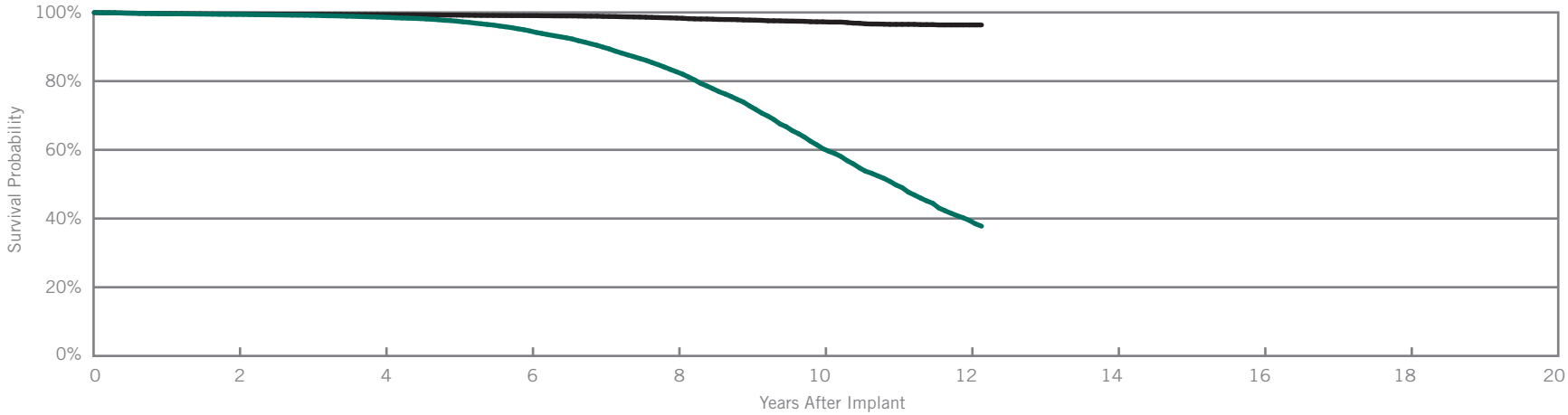
Year	2	4	6	8	10	at 133 months				
Survival Probability	99.85%	99.74%	99.60%	98.65%	97.62%	97.49%				
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.23%	0.25%				

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

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,692
Estimated Active US Implants	5,223
Estimated Longevity	6.3 Years
Normal Battery Depletion	3,659
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.01%	278	0.42%
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%**	**308**	**0.47%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 146 months			
Survival Probability	99.42%	98.60%	94.60%	82.73%	60.34%	39.45%	37.78%			
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.38%	0.55%	0.58%			
Sample Size	57500	46900	36300	23700	10400	2600	900			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 146 months			
Survival Probability	99.56%	99.35%	99.07%	98.36%	97.27%	96.36%	96.36%			
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	0.19%	0.19%			

Summary Information

Dual-Chamber Pacemakers

St. Jude Medical
More control. Less risk.

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%	99.85%								
PM2110	Accent® DR	99.98%	99.95%								
5820	Zephyr® DR	99.88%	99.84%	99.01%	94.10%						
5810	Victory® DR	99.93%	99.84%	99.02%	91.05%	73.20%					
5826	Zephyr® XL DR	99.94%	99.91%	99.84%	99.69%						
5816	Victory® XL DR	99.95%	99.91%	99.78%	99.59%	98.80%					
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	99.90%	99.84%	99.74%	99.54%	98.90%	96.68%	94.01%			
5360	Integrity® ADx DR	99.80%	99.80%	99.11%	94.63%	75.39%	53.32%				
5366	Integrity® ADx XL DR	100.00%	99.97%	99.68%	99.60%	98.83%	96.04%	90.06%			
5380	Identity® ADx DR	99.82%	99.59%	98.53%	92.86%	72.49%	52.31%	39.27%			
5386/5286	Identity® ADx XL DR/DC	99.90%	99.82%	99.68%	99.41%	98.72%	95.12%	88.53%			
5342/5346	Integrity® AFx DR	99.87%	99.75%	99.53%	99.23%	98.31%	95.92%	91.40%	83.79%	70.32%	51.98%
5370	Identity®	99.80%	99.44%	98.08%	89.61%	68.39%	52.40%	42.76%	38.82%	37.47%	
5376	Identity® XL	99.81%	99.69%	99.46%	99.06%	98.03%	94.75%	88.35%	72.57%	52.70%	
5326/5226	Entity® DR/DC	99.81%	99.69%	99.42%	98.77%	97.82%	94.80%	90.70%	82.55%	71.52%	57.47%
5330/5331/5230	Affinity® DR/DC	99.64%	99.42%	99.16%	98.60%	97.46%	94.60%	89.88%	82.73%	72.76%	60.34%

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%	99.86%								
PM2110	Accent® DR	99.98%	99.95%								
5820	Zephyr® DR	99.96%	99.95%	99.92%	99.83%						
5810	Victory® DR	99.98%	99.94%	99.68%	99.39%	98.85%					
5826	Zephyr® XL DR	99.97%	99.96%	99.96%	99.94%						
5816	Victory® XL DR	99.98%	99.95%	99.91%	99.86%	99.86%					
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	99.96%	99.95%	99.93%	99.91%	99.88%	99.78%	99.78%			
5360	Integrity® ADx DR	100.00%	100.00%	100.00%	99.19%	97.74%	96.52%				
5366	Integrity® ADx XL DR	100.00%	100.00%	99.97%	99.97%	99.97%	99.85%	99.32%			
5380	Identity® ADx DR	99.96%	99.93%	99.75%	99.28%	97.77%	96.86%	96.76%			
5386/5286	Identity® ADx XL DR/DC	99.92%	99.90%	99.87%	99.85%	99.78%	99.69%	99.24%			
5342/5346	Integrity® AFx DR	99.96%	99.92%	99.87%	99.82%	99.73%	99.71%	99.57%	99.35%	99.18%	98.82%
5370	Identity®	99.93%	99.88%	99.71%	98.93%	96.92%	95.80%	95.14%	94.99%	94.99%	
5376	Identity® XL	99.90%	99.81%	99.78%	99.73%	99.57%	99.37%	98.84%	97.25%	96.43%	
5326/5226	Entity® DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.31%	98.65%	98.23%	97.62%
5330/5331/5230	Affinity® DR/DC	99.68%	99.56%	99.46%	99.35%	99.23%	99.07%	98.85%	98.36%	97.78%	97.27%

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	106830	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	1	<0.01%	**8**	**0.01%**
PM2110	Accent® DR	19804	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5820	Zephyr® DR	38521	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5810	Victory® DR	26317	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	Zephyr® XL DR	103805	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**<0.01%**
5816	Victory® XL DR	62285	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	17025	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	5840	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	8009	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	53981	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	66943	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	47555	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®	58454	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	51498	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	21877	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	65692	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 root cause categories can be found on pages 6-7.

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	106830	3	<0.01%	8	0.01%	0	0.00%	0	0.00%	7	0.01%	5	<0.01%	2	<0.01%	**25**	**0.02%**
PM2110	Accent® DR	19804	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5820	Zephyr® DR	38521	5	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	2	0.01%	**9**	**0.02%**
5810	Victory® DR	26317	35	0.13%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	17	0.06%	0	0.00%	**53**	**0.20%**
5826	Zephyr® XL DR	103805	9	0.01%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	1	<0.01%	2	<0.01%	**15**	**0.01%**
5816	Victory® XL DR	62285	12	0.02%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	4	0.01%	4	0.01%	**25**	**0.04%**
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	17025	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	5840	34	0.58%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**35**	**0.60%**
5366	Integrity® ADx XL DR	8009	4	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**5**	**0.06%**
5380	Identity® ADx DR	53981	245	0.45%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	11	0.02%	3	0.01%	**264**	**0.49%**
5386/5286	Identity® ADx XL DR/DC	66943	70	0.10%	2	<0.01%	0	0.00%	0	0.00%	7	0.01%	6	0.01%	2	<0.01%	**87**	**0.13%**
5342/5346	Integrity® AFx DR	47555	82	0.17%	1	<0.01%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**88**	**0.19%**
5370	Identity®	58454	390	0.67%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	12	0.02%	11	0.02%	**420**	**0.72%**
5376	Identity® XL	51498	206	0.40%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	5	0.01%	7	0.01%	**225**	**0.44%**
5326/5226	Entity® DR/DC	21877	63	0.29%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**67**	**0.31%**
5330/5331/5230	Affinity® DR/DC	65692	278	0.42%	13	0.02%	6	0.01%	2	<0.01%	5	0.01%	1	<0.01%	3	<0.01%	**308**	**0.47%**

Definitions of malfunction root cause categories can be found on pages 6-7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Possible Early Battery Depletion		Backup Operation		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2110	223	2944	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	1762	22882	1	0.06%	0	0.00%	**0**	**0.00%**
5820	283	6483	0	0.00%	0	0.00%	**0**	**0.00%**
5826	1517	46083	0	0.00%	2	0.13%	**2**	**0.13%**
5816	333	10608	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
PM2110	223	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	1762	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	1517	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%**

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
PM2110	223	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	1762	0	0.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.06%**
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	1517	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%**

Definitions of complications can be found on page 13.
Definitions of malfunction root cause categories can be found on pages 6-7.

Pacemakers

Single-Chamber

St. Jude Medical™
More control. Less risk.

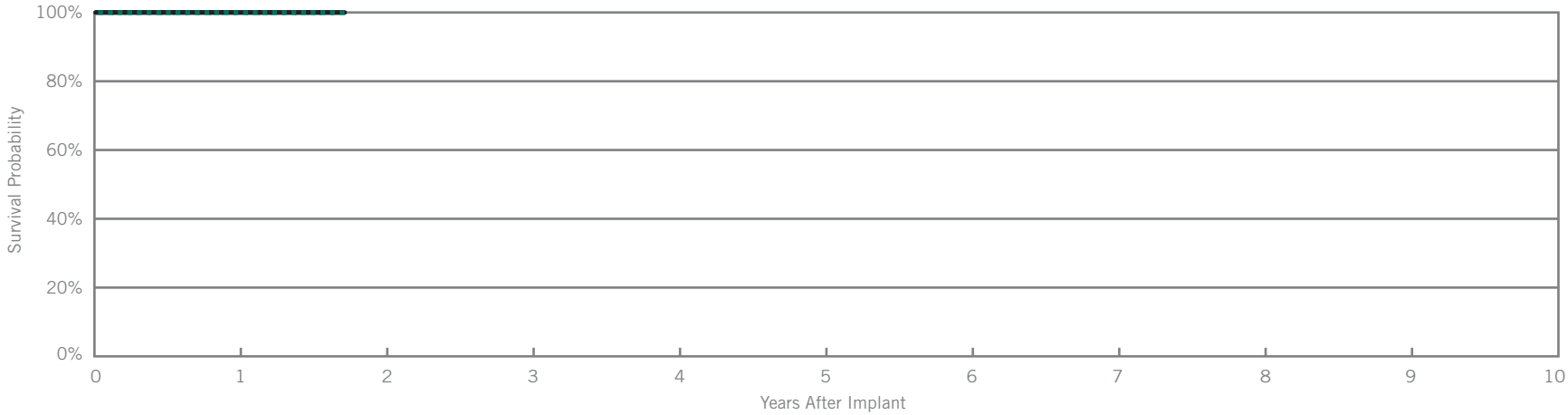
Accent® SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	4,890
Estimated Active US Implants	4,309
Estimated Longevity	12.9 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	3400	200								

Excluding Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

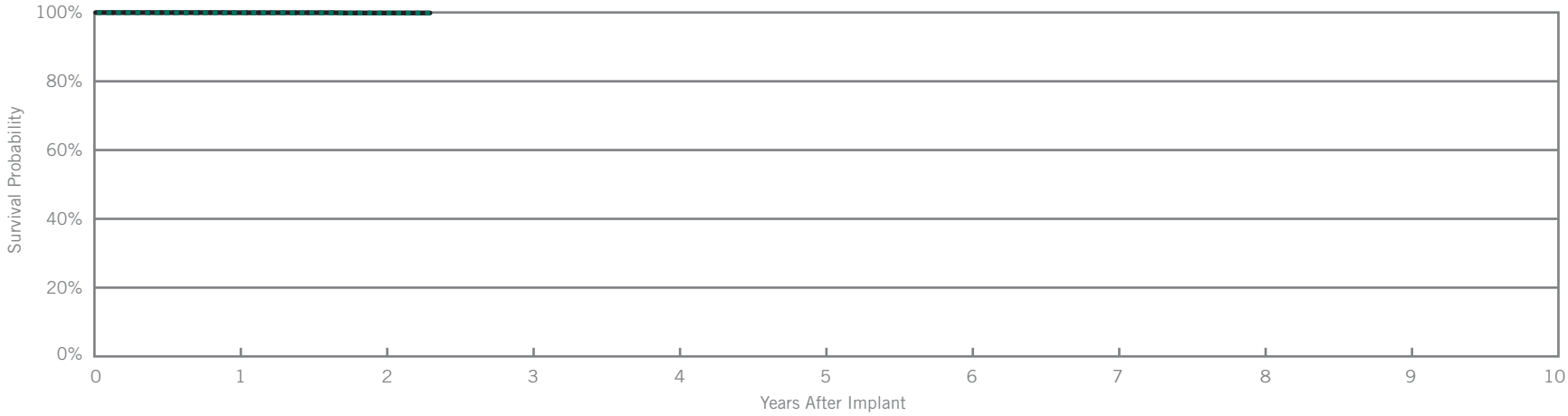
Customer Reported Performance Data

Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	16,651
Estimated Active US Implants	14,348
Estimated Longevity	10.9 Years
Normal Battery Depletion	4
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	0	0.00%	1	0.01%
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	1	0.01%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.01%**	**3**	**0.02%**



Including Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.86%	99.79%	99.79%							
± 1 standard error	0.03%	0.06%	0.06%							
Sample Size	13200	4600	400							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	99.93%	99.86%	99.86%							
± 1 standard error	0.02%	0.06%	0.06%							

SCORE Registry Performance Data

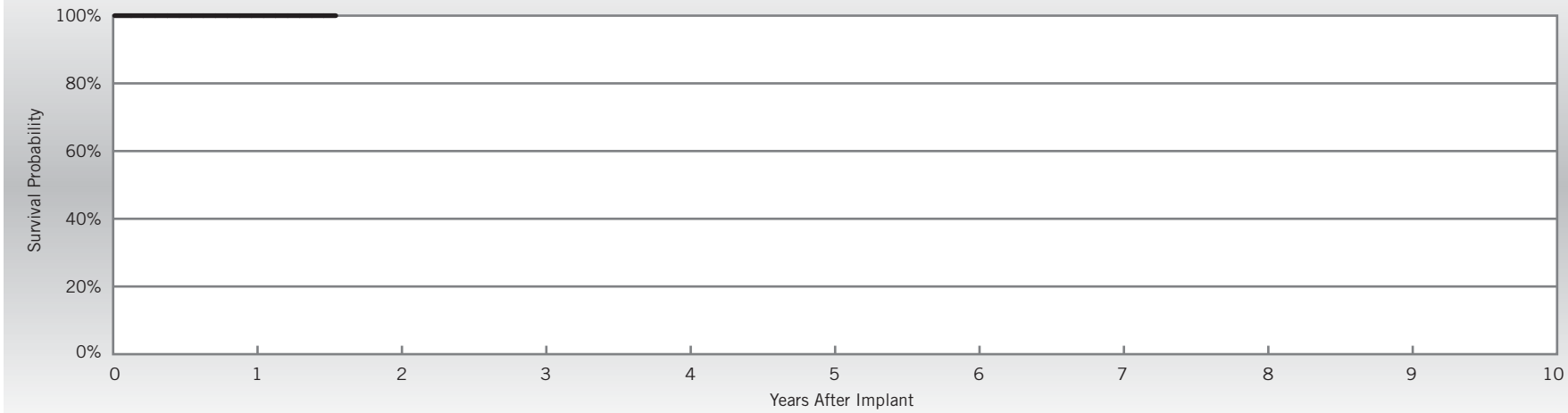
Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	220
Cumulative Months of Follow-up	2,957
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	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	170	50								

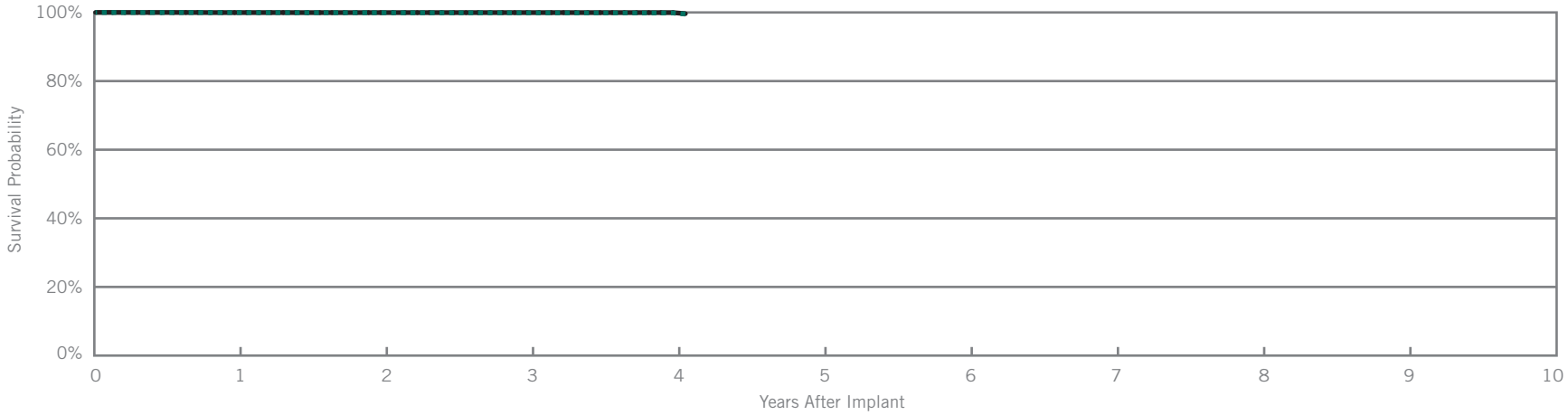
Customer Reported Performance Data

Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	18,914
Estimated Active US Implants	13,072
Estimated Longevity	15.8 Years
Normal Battery Depletion	5
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%	2	0.01%
Total	**0**	**0.00%**	**5**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.96%	99.86%	99.84%	99.84%	99.53%					
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.03%					
Sample Size	18300	13600	8200	2900	700					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.96%	99.95%	99.95%	99.95%	99.64%					
± 1 standard error	0.02%	0.02%	0.02%	0.02%	0.02%					

SCORE Registry Performance Data

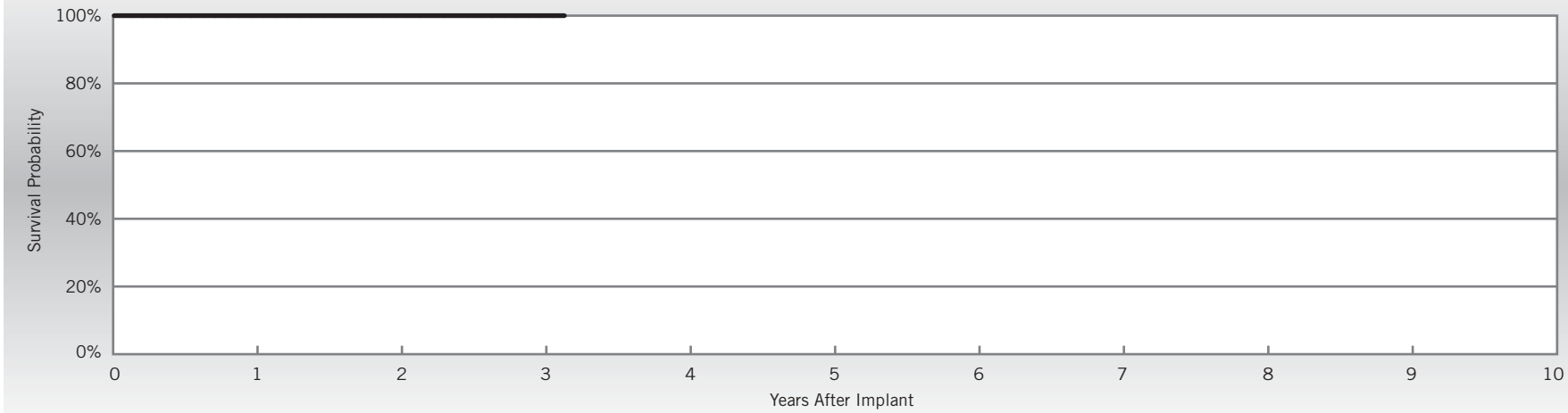
Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	230
Cumulative Months of Follow-up	6,314
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 38 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	110	50						

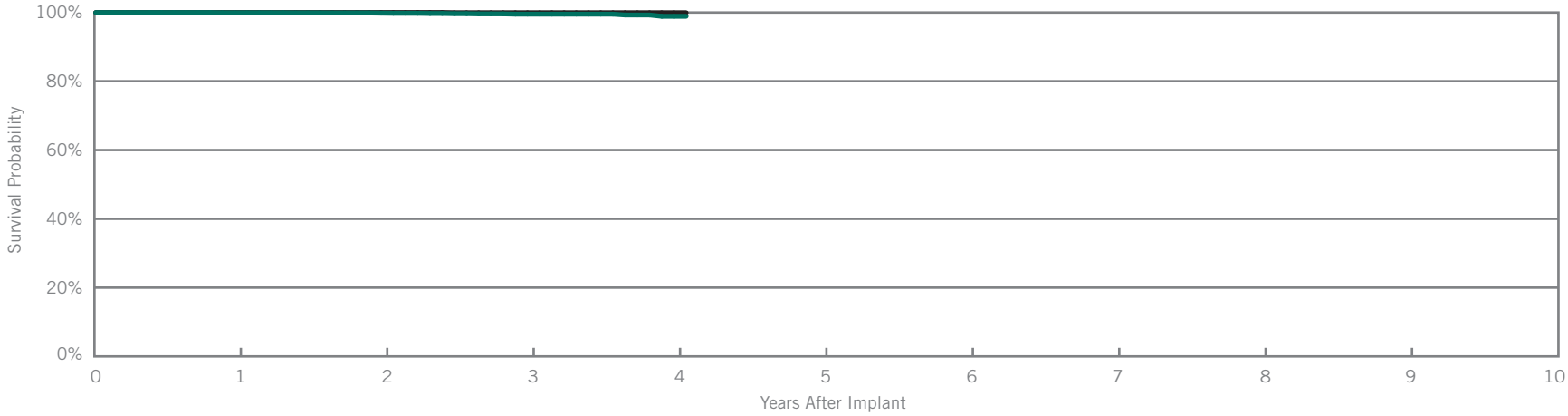
Customer Reported Performance Data

Zephyr® SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	11,857
Estimated Active US Implants	8,026
Estimated Longevity	8.8 Years
Normal Battery Depletion	13
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.92%	99.81%	99.52%	98.90%	98.90%					
± 1 standard error	0.03%	0.04%	0.11%	0.33%	0.33%					
Sample Size	10800	6700	3600	1300	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	100.00%	99.94%	99.94%	99.94%					
± 1 standard error	0.00%	0.00%	0.04%	0.04%	0.04%					

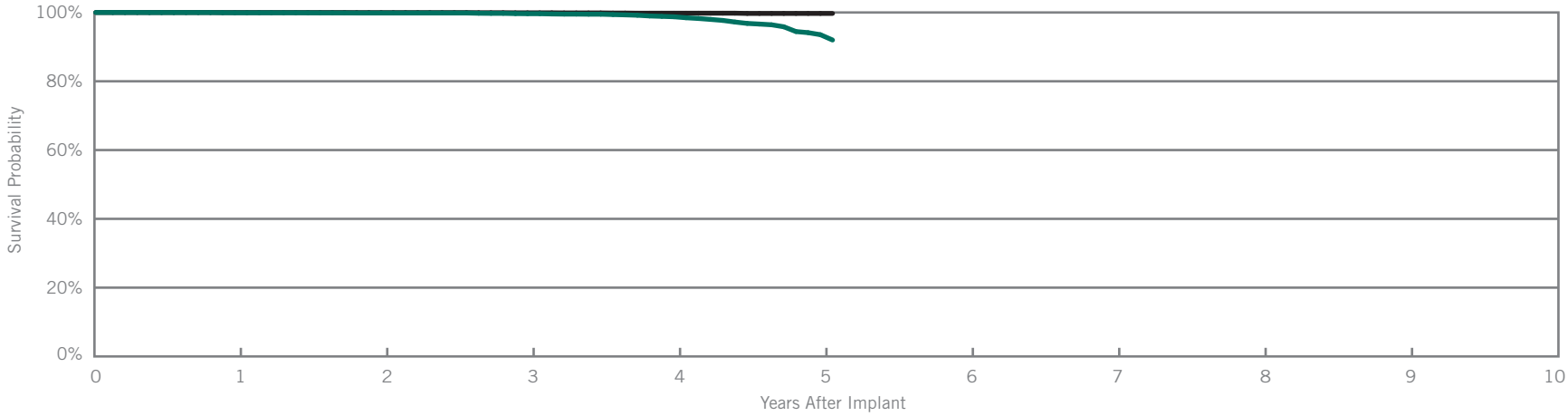
Customer Reported Performance Data

Victory® SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,591
Estimated Active US Implants	6,490
Estimated Longevity	8.8 Years
Normal Battery Depletion	105
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	6	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%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**7**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.92%	99.84%	99.64%	98.75%	93.54%	91.99%				
± 1 standard error	0.02%	0.04%	0.06%	0.14%	0.46%	0.50%				
Sample Size	13500	10600	8300	5700	2900	1200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.98%	99.96%	99.90%	99.79%	99.72%	99.72%				
± 1 standard error	0.01%	0.02%	0.03%	0.06%	0.08%	0.08%				

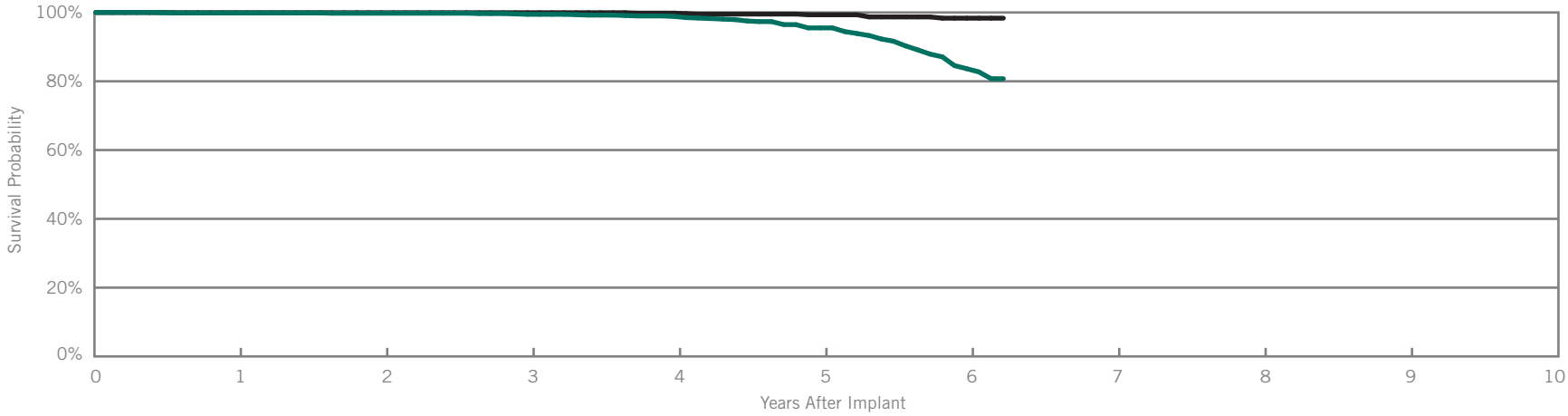
Customer Reported Performance Data

Integrity® ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,403
Estimated Active US Implants	861
Estimated Longevity	5.7 Years
Normal Battery Depletion	72
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	7	0.21%
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%**	**8**	**0.24%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.86%	99.78%	99.46%	98.85%	95.51%	83.65%	80.74%			
± 1 standard error	0.07%	0.09%	0.14%	0.23%	0.58%	1.29%	1.48%			
Sample Size	3400	2600	2200	1800	1400	800	400			

Excluding Normal Battery Depletion

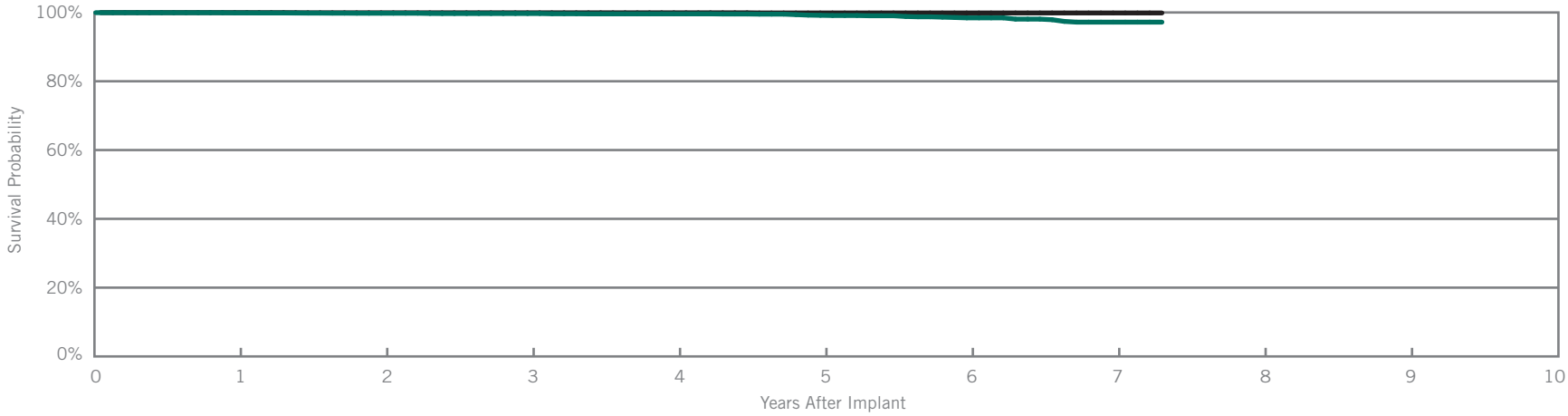
Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.93%	99.93%	99.93%	99.81%	99.33%	98.34%	98.34%			
± 1 standard error	0.05%	0.05%	0.05%	0.10%	0.17%	0.44%	0.44%			

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	14,277
Estimated Active US Implants	6,061
Estimated Longevity	10.2 Years
Normal Battery Depletion	33
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**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.87%	99.77%	99.69%	99.59%	99.17%	98.43%	97.19%	97.19%		
± 1 standard error	0.03%	0.04%	0.05%	0.07%	0.12%	0.21%	0.40%	0.40%		
Sample Size	14100	11200	9100	7000	4700	2700	1300	500		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.86%	99.86%	99.86%	99.86%		
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%		

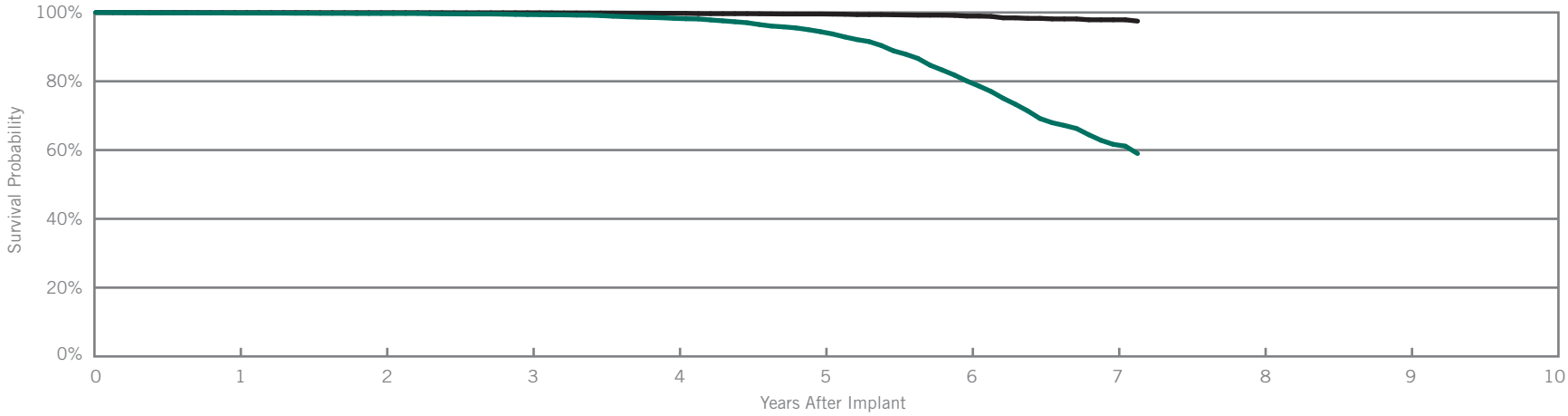
Customer Reported Performance Data

Integrity® ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,692
Estimated Active US Implants	6,186
Estimated Longevity	5.7 Years
Normal Battery Depletion	555
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	31	0.15%
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%**	**40**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.82%	99.71%	99.39%	98.29%	94.42%	80.08%	61.66%	58.99%		
± 1 standard error	0.03%	0.04%	0.06%	0.12%	0.25%	0.56%	1.01%	1.07%		
Sample Size	20500	16100	13100	10400	7700	4700	1800	500		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.96%	99.94%	99.91%	99.76%	99.56%	98.95%	97.87%	97.49%		
± 1 standard error	0.02%	0.02%	0.02%	0.05%	0.07%	0.12%	0.32%	0.32%		

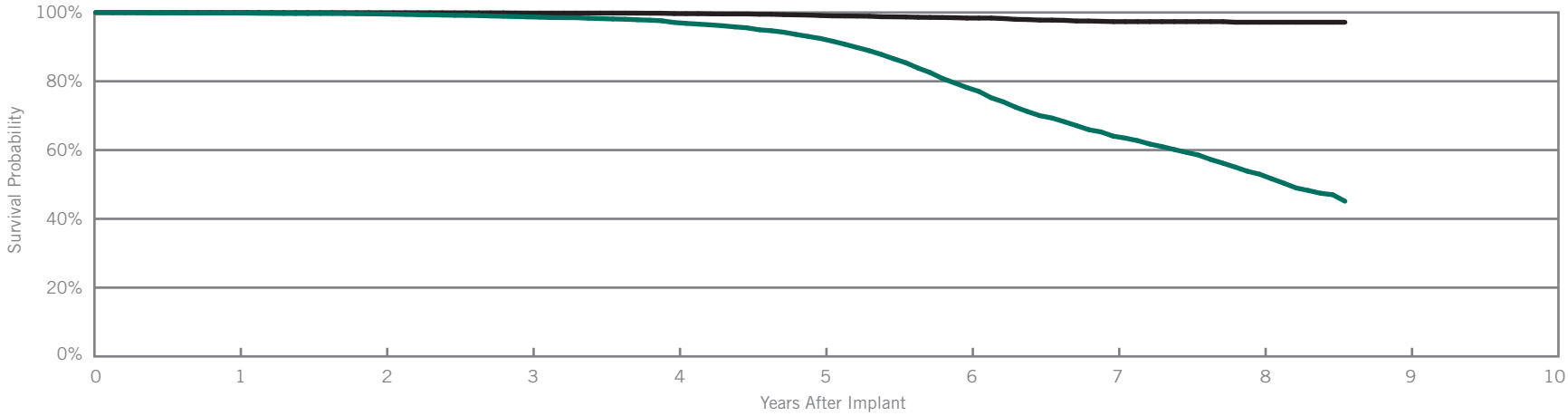
Identity® SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,935
Estimated Active US Implants	2,820
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,039
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	63	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%**	**72**	**0.33%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 103 months
Survival Probability	99.83%	99.56%	98.71%	97.10%	92.44%	78.19%	64.04%	52.98%	45.12%
± 1 standard error	0.03%	0.05%	0.09%	0.14%	0.25%	0.47%	0.65%	0.83%	0.97%
Sample Size	21900	17500	14800	12400	9900	7200	3900	1800	500

Excluding Normal Battery Depletion

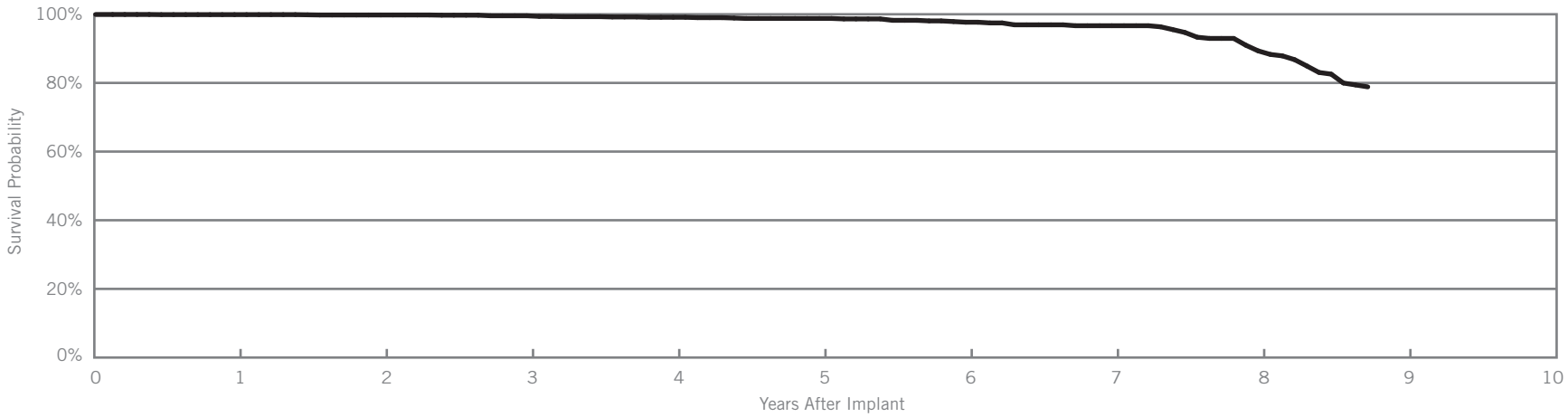
Year	1	2	3	4	5	6	7	8	at 103 months
Survival Probability	99.97%	99.92%	99.82%	99.67%	99.11%	98.37%	97.34%	97.16%	97.16%
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.09%	0.14%	0.23%	0.27%	0.27%

Customer Reported Performance Data

Microny®

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	6,991
Estimated Longevity	7.5 Years
Number of US Advisories	None



Year	1	2	3	4	5	6	7	8	at 105 months	
Survival Probability	99.89%	99.79%	99.56%	99.12%	98.78%	97.68%	96.66%	89.34%	78.85%	
± 1 standard error	0.04%	0.06%	0.11%	0.17%	0.22%	0.35%	0.50%	1.09%	1.81%	
Sample Size	6800	4600	3500	2600	1900	1300	900	600	300	

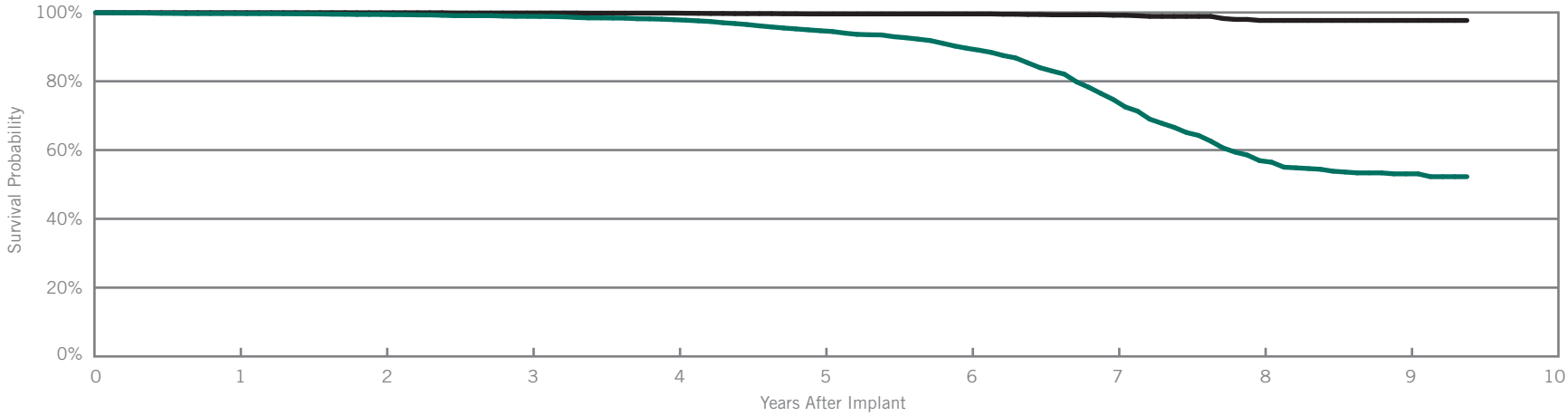
Customer Reported Performance Data

Integrity® µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	11,980
Estimated Active US Implants	725
Estimated Longevity	5.3 Years
Normal Battery Depletion	454
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	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.68%	99.42%	98.88%	97.90%	94.69%	89.59%	74.71%	56.92%	53.08%	52.26%
± 1 standard error	0.05%	0.08%	0.12%	0.16%	0.29%	0.44%	0.78%	1.13%	1.25%	1.28%
Sample Size	11900	9400	7800	6500	5300	4100	2900	1400	600	300

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 113 months
Survival Probability	99.94%	99.92%	99.85%	99.81%	99.57%	99.57%	99.19%	97.68%	97.68%	97.68%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.09%	0.09%	0.13%	0.40%	0.45%	0.45%

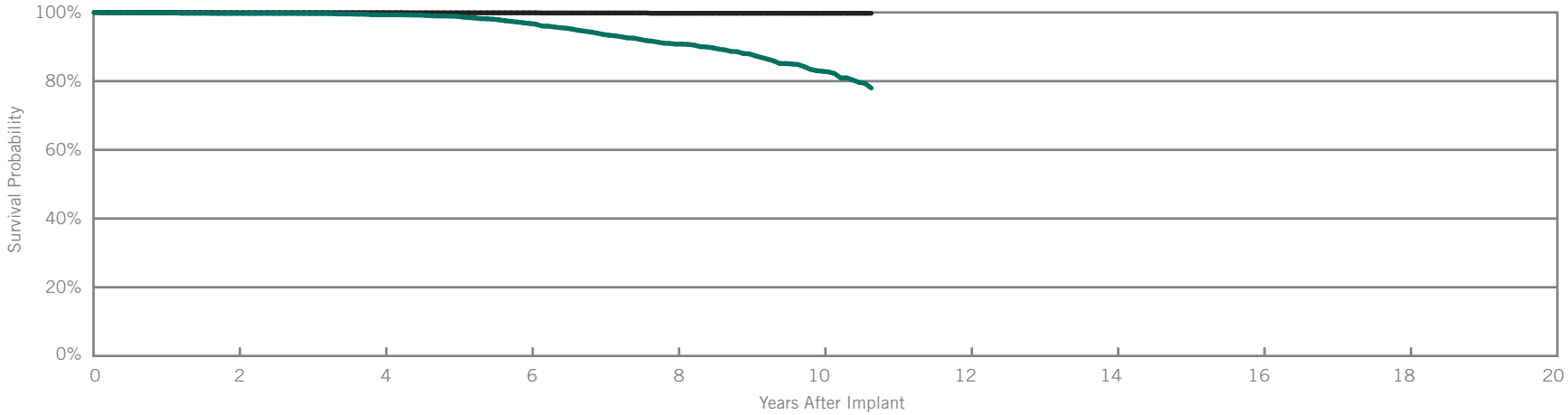
Customer Reported Performance Data

Integrity® SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,512
Estimated Active US Implants	1,682
Estimated Longevity	8.6 Years
Normal Battery Depletion	213
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.03%
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%**	**5**	**0.05%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 128 months				
Survival Probability	99.71%	99.31%	96.79%	90.77%	82.87%	77.99%				
± 1 standard error	0.06%	0.10%	0.25%	0.48%	0.80%	0.99%				
Sample Size	8600	6300	4500	2900	1400	500				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 128 months				
Survival Probability	99.93%	99.93%	99.89%	99.76%	99.76%	99.76%				
± 1 standard error	0.03%	0.03%	0.04%	0.08%	0.08%	0.08%				

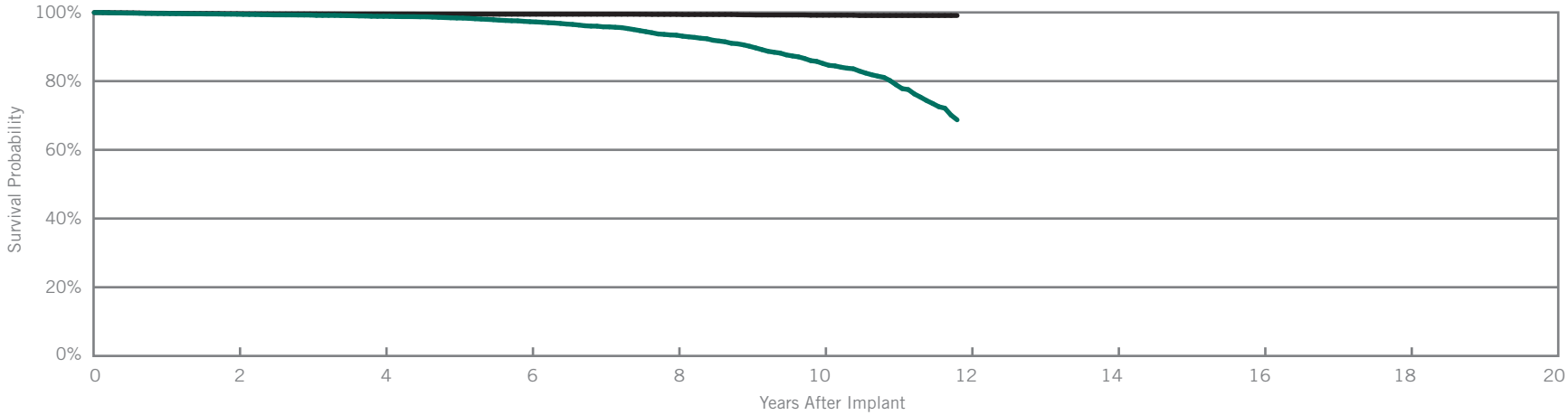
Affinity® SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,720
Estimated Active US Implants	3,181
Estimated Longevity	8.6 Years
Normal Battery Depletion	512
Number of US Advisories (see pgs. 244-256)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	43	0.15%
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%**	**52**	**0.18%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 142 months				
Survival Probability	99.48%	98.87%	97.31%	93.38%	85.14%	68.73%				
± 1 standard error	0.05%	0.08%	0.14%	0.26%	0.46%	0.96%				
Sample Size	22900	16300	11400	7600	3900	700				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 142 months				
Survival Probability	99.63%	99.53%	99.48%	99.43%	99.19%	99.10%				
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.10%	0.11%				

Summary Information

Single-Chamber Pacemakers

St. Jude Medical™
More control. Less risk.

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	100.00%									
PM1210	Accent® SR RF	99.86%	99.79%								
5626	Zephyr® XL SR	99.96%	99.86%	99.84%	99.84%						
5620	Zephyr® SR	99.92%	99.81%	99.52%	98.90%						
5610	Victory® SR	99.92%	99.84%	99.64%	98.75%	93.54%					
5160	Integrity® ADx SR	99.86%	99.78%	99.46%	98.85%	95.51%	83.65%				
5156/5157/5056	Verity® ADx XL SR/SR(M/S) / SC	99.87%	99.77%	99.69%	99.59%	99.17%	98.43%	97.19%			
5180	Integrity® ADx SR	99.82%	99.71%	99.39%	98.29%	94.42%	80.08%	61.66%			
5172	Identity® SR	99.83%	99.56%	98.71%	97.10%	92.44%	78.19%	64.04%	52.98%		
5136	Integrity® µ SR	99.68%	99.42%	98.88%	97.90%	94.69%	89.59%	74.71%	56.92%	53.08%	
5142	Integrity® SR	99.85%	99.71%	99.68%	99.31%	98.89%	96.79%	93.61%	90.77%	87.94%	82.87%
5130/5131	Affinity® SR	99.69%	99.48%	99.24%	98.87%	98.38%	97.31%	95.81%	93.38%	90.14%	85.14%

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%									
PM1210	Accent® SR RF	99.93%	99.86%								
5626	Zephyr® XL SR	99.96%	99.95%	99.95%	99.95%						
5620	Zephyr® SR	100.00%	100.00%	99.94%	99.94%						
5610	Victory® SR	99.98%	99.96%	99.90%	99.79%	99.72%					
5160	Integrity® ADx SR	99.93%	99.93%	99.93%	99.81%	99.33%	98.34%				
5156/5157/5056	Verity® ADx XL SR/SR(M/S) / SC	99.96%	99.91%	99.91%	99.91%	99.86%	99.86%	99.86%			
5180	Integrity® ADx SR	99.96%	99.94%	99.91%	99.76%	99.56%	98.95%	97.87%			
5172	Identity® SR	99.97%	99.92%	99.82%	99.67%	99.11%	98.37%	97.34%	97.16%		
5136	Integrity® µ SR	99.94%	99.92%	99.85%	99.81%	99.57%	99.57%	99.19%	97.68%	97.68%	
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%	99.63%	99.57%	99.53%	99.50%	99.48%	99.48%	99.43%	99.30%	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	4890	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	16651	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**2**	**0.01%**
5626	Zephyr® XL SR	18914	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5620	Zephyr® SR	11857	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	13591	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	3403	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	14277	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	20692	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	21935	1	<0.00%	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	11980	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	10512	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	28720	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	4890	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	16651	1	0.01%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**3**	**0.02%**
5626	Zephyr® XL SR	18914	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**5**	**0.03%**
5620	Zephyr® SR	11857	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5610	Victory® SR	13591	6	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**7**	**0.05%**
5160	Integrity® ADx SR	3403	7	0.21%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	**8**	**0.24%**
5356/5357/5256	Verity® ADx XL SR/SR(M/S) / SC	14277	3	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	**5**	**0.04%**
5180	Integrity® ADx SR	20692	31	0.15%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	8	0.04%	0	0.00%	**40**	**0.19%**
5172	Identity® SR	21935	63	0.29%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.04%	1	<0.01%	**72**	**0.33%**
5136	Integrity® µ SR	11980	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	10512	3	0.03%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	**5**	**0.05%**
5130/5131	Affinity® SR	28720	43	0.15%	2	0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	**52**	**0.18%**

Definitions of malfunction root cause categories can be found on pages 6-7.

Pacing Leads

Customer Reported Performance Data

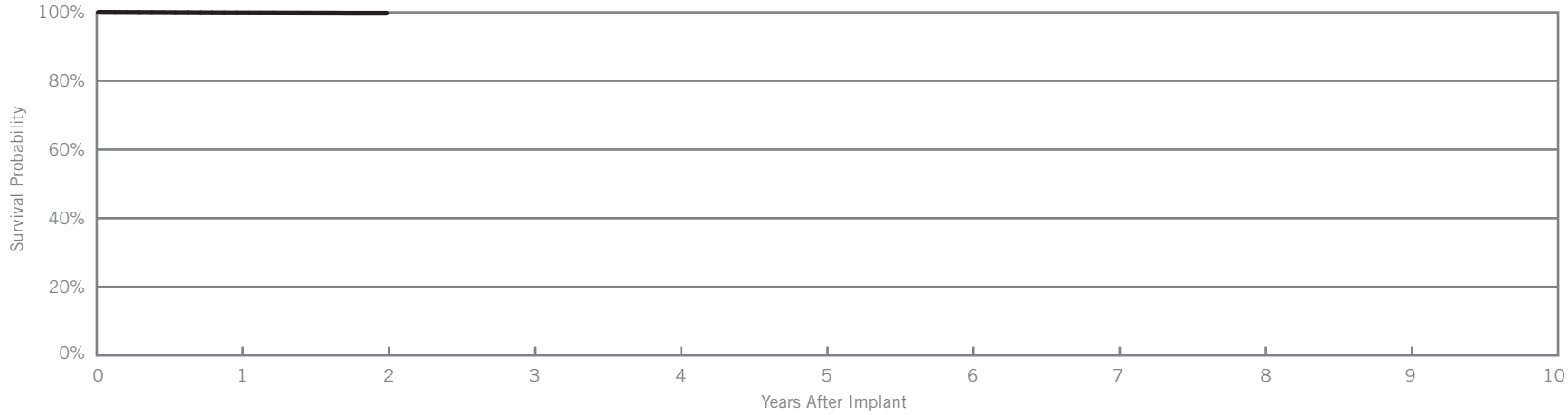
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	103,163
Estimated Active US Implants	90,620
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	16	0.02%	1	<0.01%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	60	0.06%	42	0.04%
Failure to Capture	7	0.01%	27	0.03%
Oversensing	2	<0.01%	16	0.02%
Failure to Sense	2	<0.01%	4	<0.01%
Insulation Breach	2	<0.01%	4	<0.01%
Abnormal Pacing Impedance	2	<0.01%	3	<0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	<0.01%	6	0.01%
Total	**93**	**0.09%**	**105**	**0.10%**
Total Returned for Analysis	**50**		**90**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	18	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	82	0.08%
Total	**104**	**0.10%**



Year	1	2								
Survival Probability	99.84%	99.75%								
± 1 standard error	0.02%	0.04%								
Sample Size	72400	16300								

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

SCORE Registry Performance Data

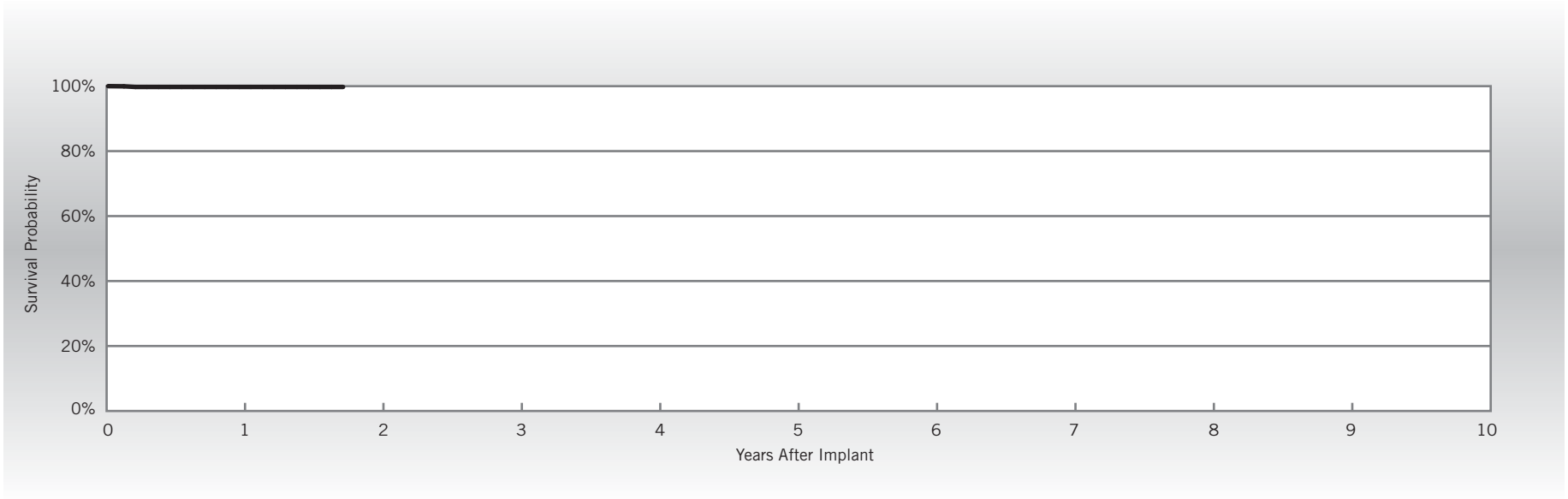
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	2,261
Cumulative Months of Follow-up	24,300
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Cardiac Perforation	1	0.04%
Lead Dislodgement	2	0.09%
Failure to Capture	1	0.04%
Abnormal Pacing Impedance	1	0.04%

Malfunctions	Qty	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	18	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	3	<0.01%
Extrinsic Factors	82	0.08%
Total	**104**	**0.10%**



Year	1	at 21 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.11%	0.11%								
Sample Size	1570	90								

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

Customer Reported Performance Data

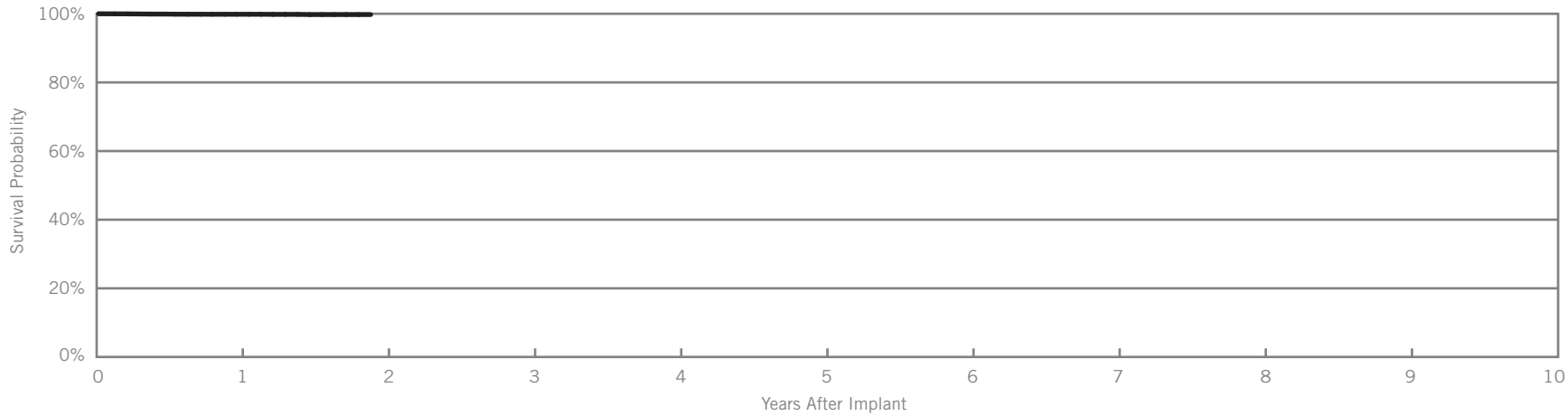
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	13,643
Estimated Active US Implants	11,870
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	7	0.05%	9	0.07%
Failure to Capture	2	0.01%	4	0.03%
Oversensing	1	0.01%	2	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**10**	**0.07%**	**16**	**0.12%**
Total Returned for Analysis	**3**		**15**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	11	0.08%
Total	**14**	**0.10%**



Year	1	at 23 months								
Survival Probability	99.85%	99.77%								
± 1 standard error	0.04%	0.07%								
Sample Size	10000	300								

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

SCORE Registry Performance Data

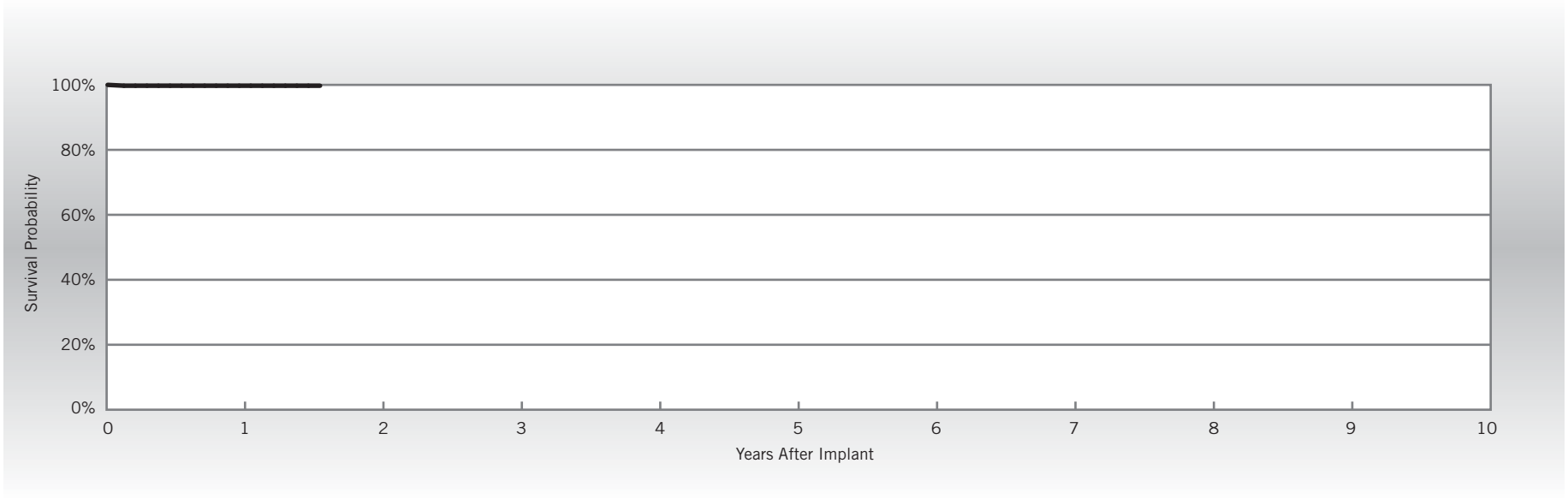
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	402
Cumulative Months of Follow-up	4,163
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	1	0.25%

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	1	0.25%
Total	**1**	**0.25%**



Year	1	at 19 months								
Survival Probability	99.74%	99.74%								
± 1 standard error	0.26%	0.26%								
Sample Size	270	60								

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

Customer Reported Performance Data

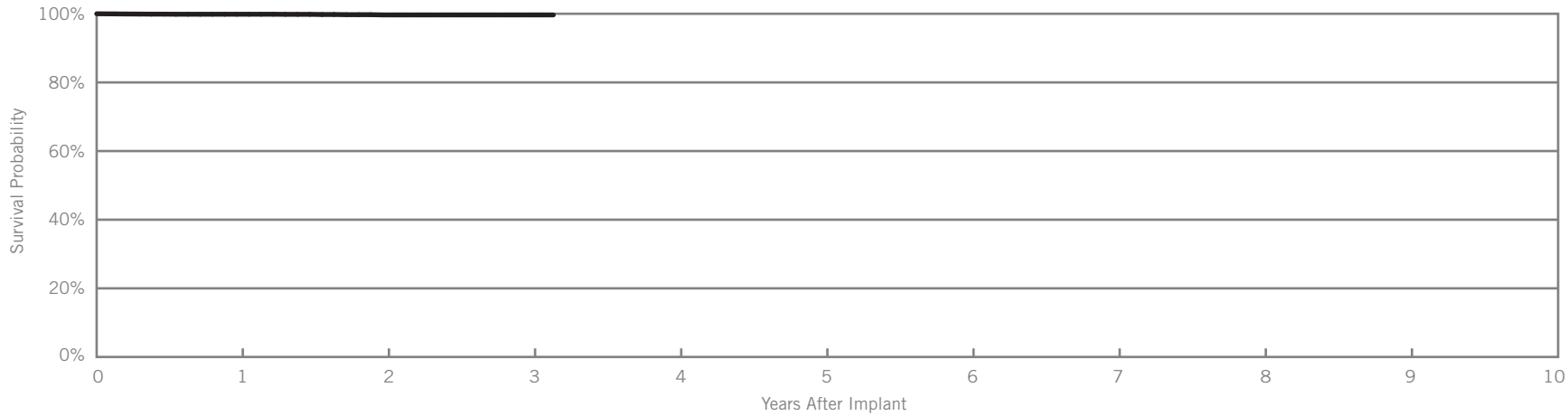
IsoFlex® Optim®

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	6,220
Estimated Active US Implants	4,831
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	14	0.23%	8	0.13%
Failure to Capture	1	0.02%	0	0.00%
Oversensing	0	0.00%	1	0.02%
Failure to Sense	2	0.03%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	1	0.02%
Total	**17**	**0.27%**	**10**	**0.16%**
Total Returned for Analysis	**10**		**5**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.08%
Total	**6**	**0.10%**



Year	1	2	3	at 38 months						
Survival Probability	99.86%	99.66%	99.66%	99.66%						
± 1 standard error	0.05%	0.09%	0.12%	0.12%						
Sample Size	5100	2500	900	200						

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

Customer Reported Performance Data

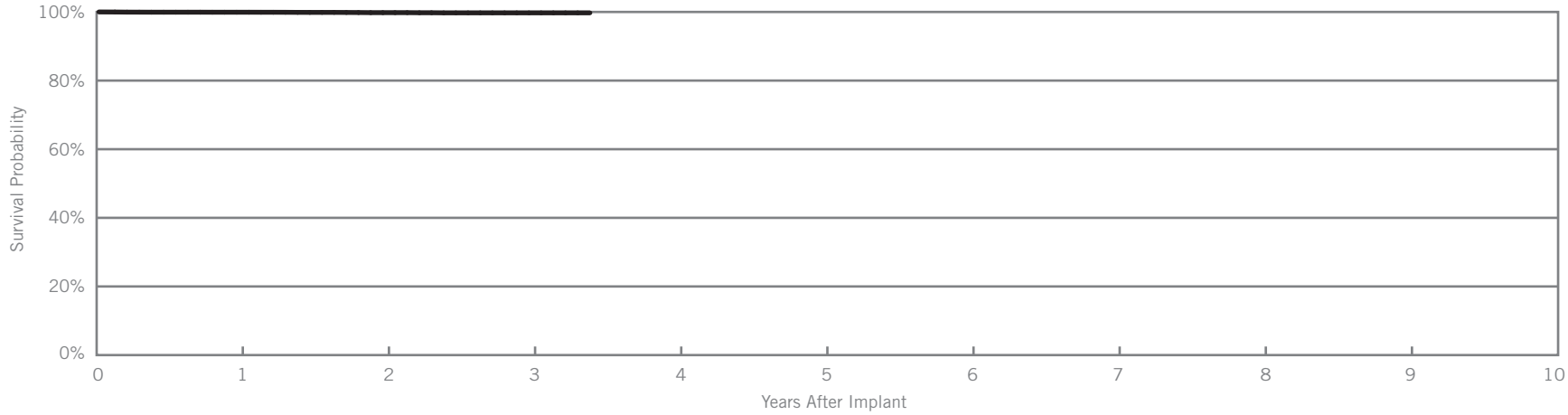
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	21,102
Estimated Active US Implants	16,927
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%	4	0.02%
Lead Dislodgement	12	0.06%	5	0.02%
Failure to Capture	4	0.02%	3	0.01%
Oversensing	0	0.00%	3	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	4	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**17**	**0.08%**	**19**	**0.09%**
Total Returned for Analysis	**12**		**9**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	5	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	8	0.04%
Total	**14**	**0.07%**



Year	1	2	3	at 41 months						
Survival Probability	99.92%	99.80%	99.74%	99.74%						
± 1 standard error	0.02%	0.05%	0.06%	0.06%						
Sample Size	17600	8600	2900	300						

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

SCORE Registry Performance Data

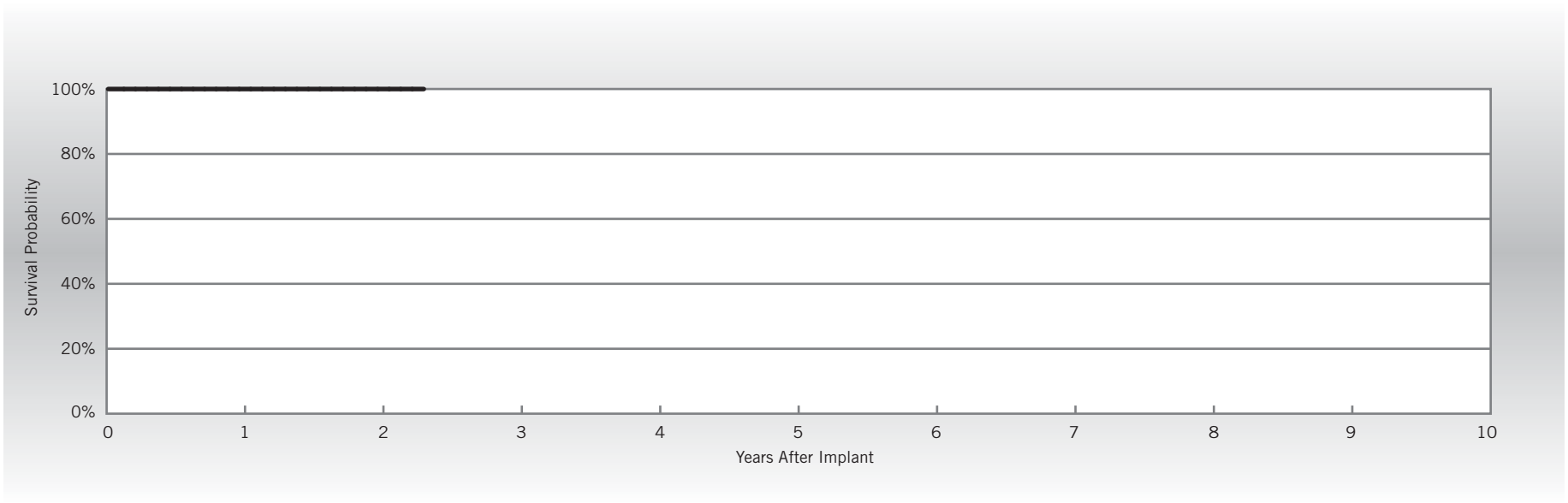
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	380
Cumulative Months of Follow-up	5,908
Insulation	Optim*
Type and/or Fixation	Passive
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	at 28 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	290	150	50							

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

Customer Reported Performance Data

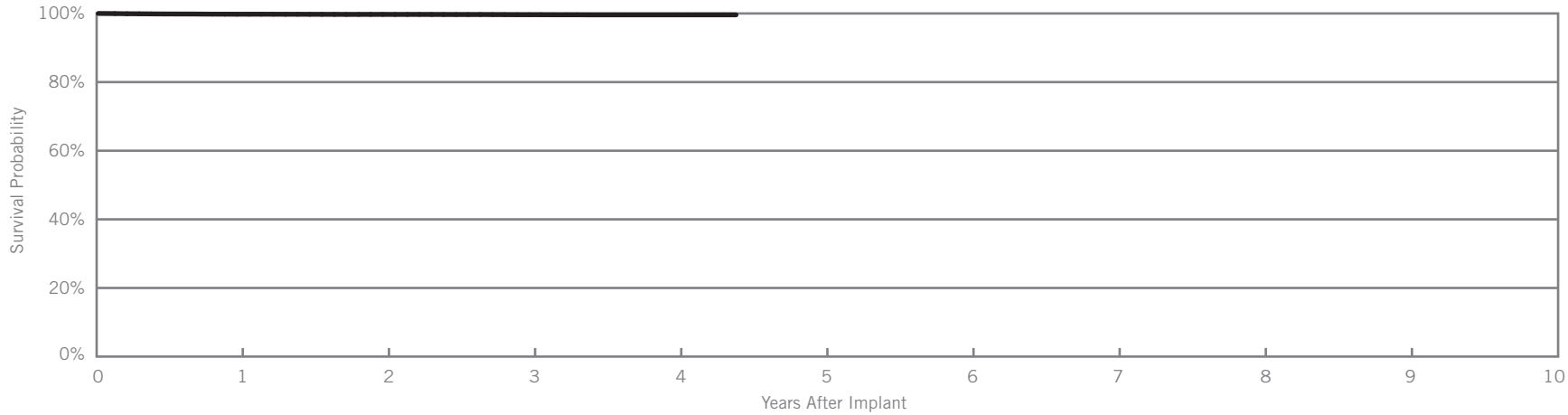
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	23,288
Estimated Active US Implants	16,399
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%	4	0.02%
Lead Dislodgement	5	0.02%	21	0.09%
Failure to Capture	3	0.01%	11	0.05%
Oversensing	2	0.01%	7	0.03%
Failure to Sense	8	0.03%	5	0.02%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	3	0.01%
Extracardiac Stimulation	0	0.00%	2	0.01%
Other	2	0.01%	0	0.00%
Total	**21**	**0.09%**	**53**	**0.23%**
Total Returned for Analysis	**16**		**37**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	6	0.03%
Insulation Breach	6	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	28	0.12%
Total	**40**	**0.17%**



Year	1	2	3	4	at 53 months					
Survival Probability	99.78%	99.72%	99.63%	99.59%	99.59%					
± 1 standard error	0.03%	0.04%	0.05%	0.05%	0.05%					
Sample Size	22800	18000	11500	4400	200					

SCORE Registry Performance Data

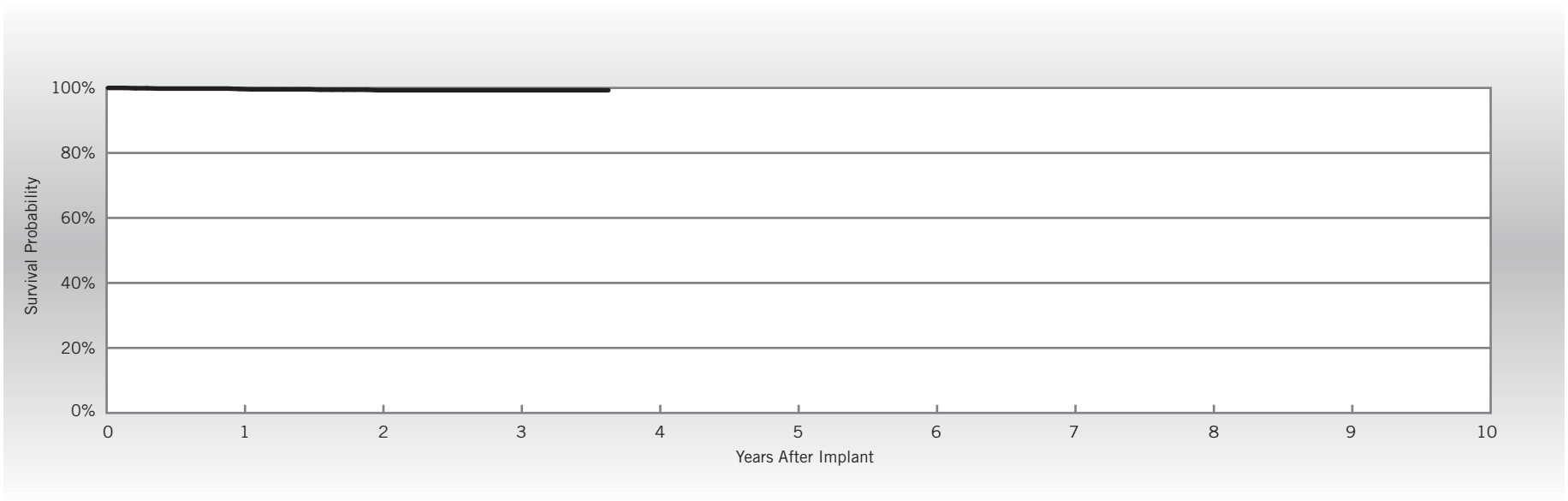
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,004
Cumulative Months of Follow-up	28,661
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	2	0.20%
Failure to Capture	2	0.20%
Abnormal Pacing Impedance	2	0.20%

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	1	0.10%
Total	**1**	**0.10%**



Year	1	2	3	at 44 months						
Survival Probability	99.57%	99.29%	99.29%	99.29%						
± 1 standard error	0.18%	0.29%	0.29%	0.29%						
Sample Size	940	760	480	70						

Customer Reported Performance Data

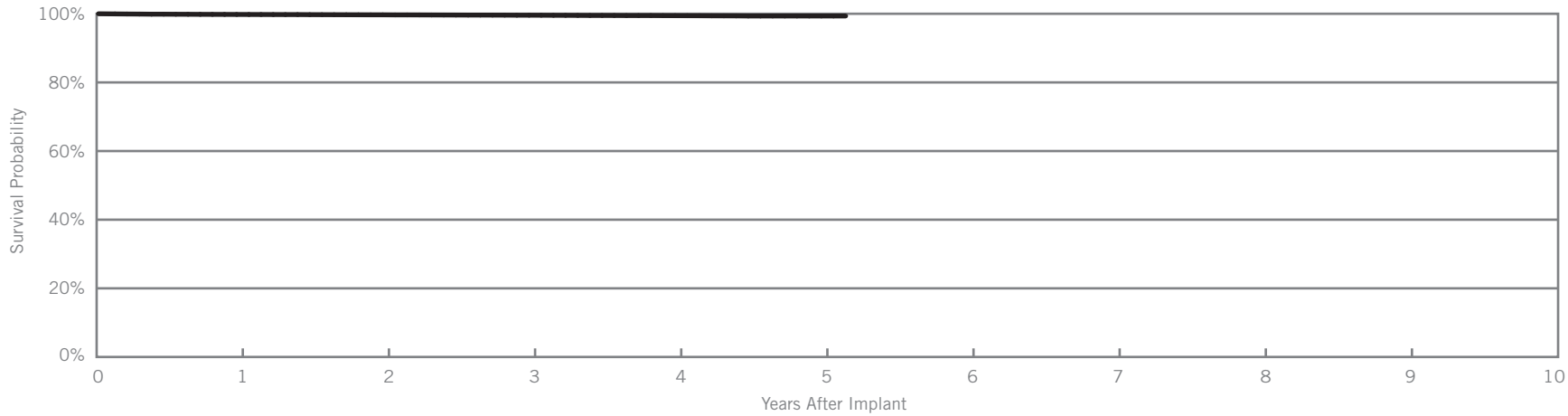
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	235,147
Estimated Active US Implants	170,735
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	28	0.01%	20	0.01%
Conductor Fracture	5	<0.01%	30	0.01%
Lead Dislodgement	101	0.04%	190	0.08%
Failure to Capture	66	0.03%	123	0.05%
Oversensing	10	<0.01%	96	0.04%
Failure to Sense	8	<0.01%	15	0.01%
Insulation Breach	3	<0.01%	28	0.01%
Abnormal Pacing Impedance	6	<0.01%	24	0.01%
Extracardiac Stimulation	3	<0.01%	10	<0.01%
Other	17	0.01%	31	0.01%
Total	**247**	**0.11%**	**567**	**0.24%**
Total Returned for Analysis	**111**		**363**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	13	0.01%
Insulation Breach	113	0.05%
Crimps, Welds & Bonds	1	<0.01%
Other	3	<0.01%
Extrinsic Factors	285	0.12%
Total	**415**	**0.18%**



Year	1	2	3	4	5	at 62 months				
Survival Probability	99.80%	99.69%	99.58%	99.44%	99.35%	99.35%				
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%	0.04%				
Sample Size	219400	149700	86000	36000	8600	200				

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

SCORE Registry Performance Data

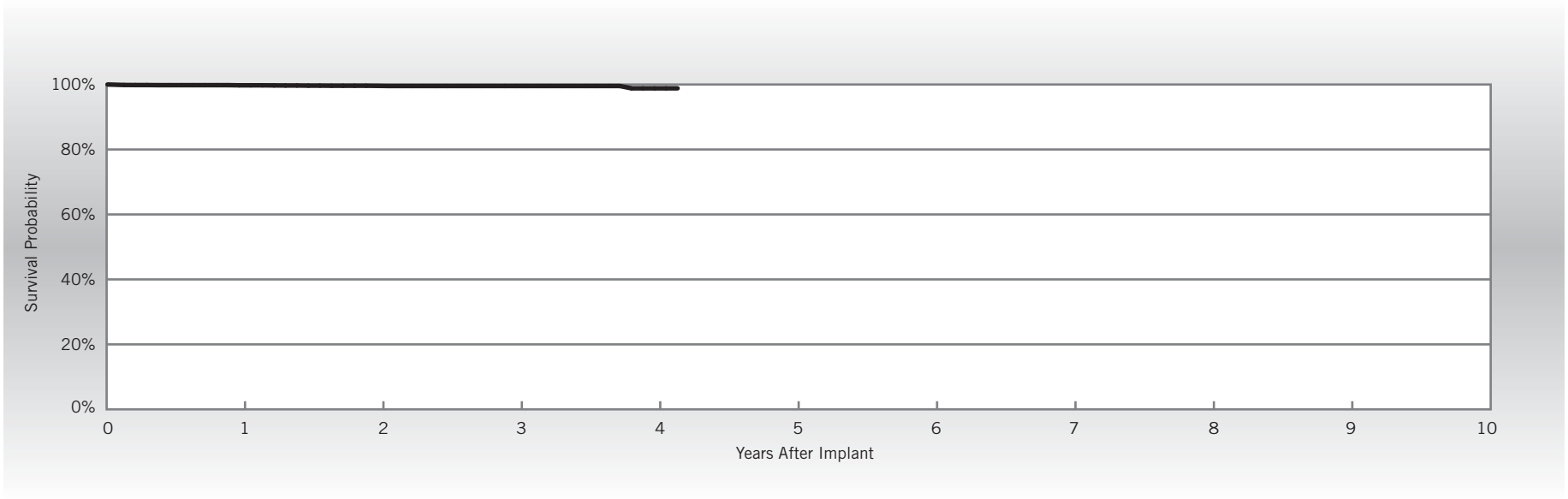
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	4,139
Cumulative Months of Follow-up	110,800
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Conductor Fracture	1	0.02%
Lead Dislodgement	9	0.22%
Failure to Capture	2	0.05%
Oversensing	1	0.02%
Abnormal Pacing Impedance	3	0.07%
Extracardiac Stimulation	1	0.02%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.02%
Insulation Breach	4	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	6	0.14%
Total	**12**	**0.29%**



Year	1	2	3	4	at 50 months					
Survival Probability	99.75%	99.58%	99.54%	98.83%	98.83%					
± 1 standard error	0.07%	0.10%	0.12%	0.72%	0.72%					
Sample Size	3810	2970	1750	550	60					

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

Customer Reported Performance Data

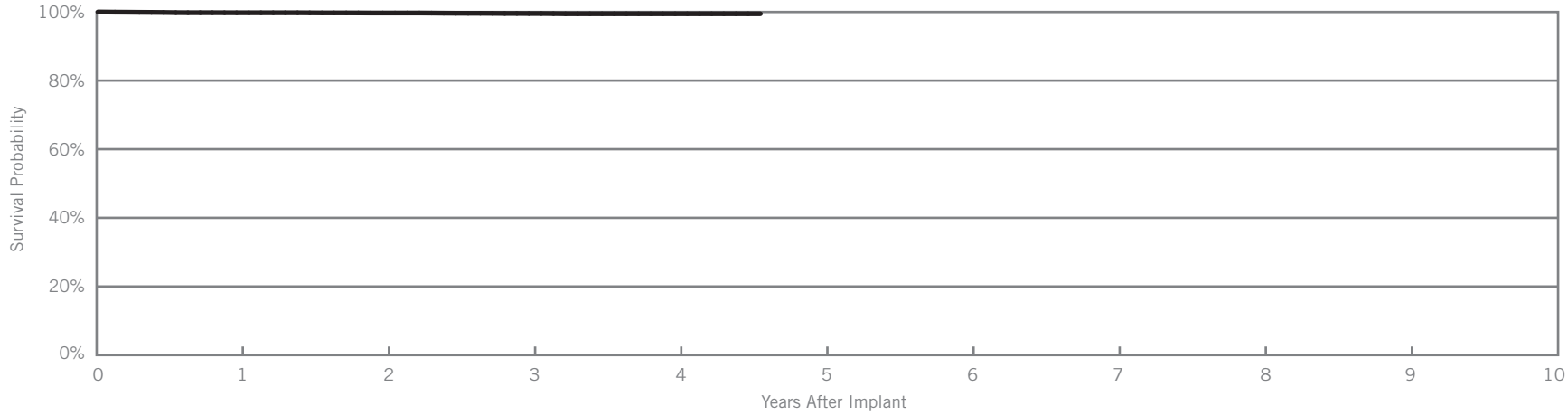
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	22,533
Estimated Active US Implants	17,171
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	2	0.01%	0	0.00%
Conductor Fracture	0	0.00%	2	0.01%
Lead Dislodgement	14	0.06%	22	0.10%
Failure to Capture	5	0.02%	13	0.06%
Oversensing	2	0.01%	6	0.03%
Failure to Sense	4	0.02%	2	0.01%
Insulation Breach	0	0.00%	3	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	0.01%	5	0.02%
Total	**29**	**0.13%**	**53**	**0.24%**
Total Returned for Analysis	**11**		**38**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	8	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.01%
Extrinsic Factors	28	0.12%
Total	**39**	**0.17%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.76%	99.69%	99.54%	99.47%	99.47%					
± 1 standard error	0.04%	0.05%	0.07%	0.08%	0.08%					
Sample Size	19700	11700	6200	2400	200					

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

SCORE Registry Performance Data

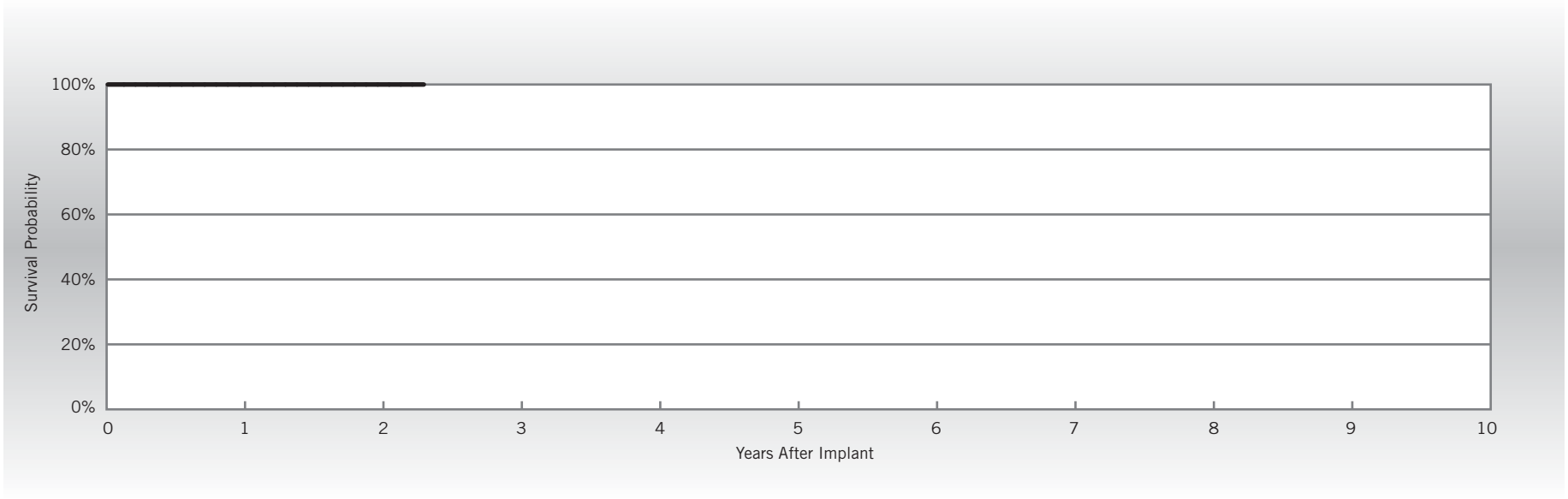
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	197
Cumulative Months of Follow-up	3,865
Insulation	Optim*
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	1	0.51%
Total	**1**	**0.51%**



Year	1	2	at 28 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	170	110	50							

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

Customer Reported Performance Data

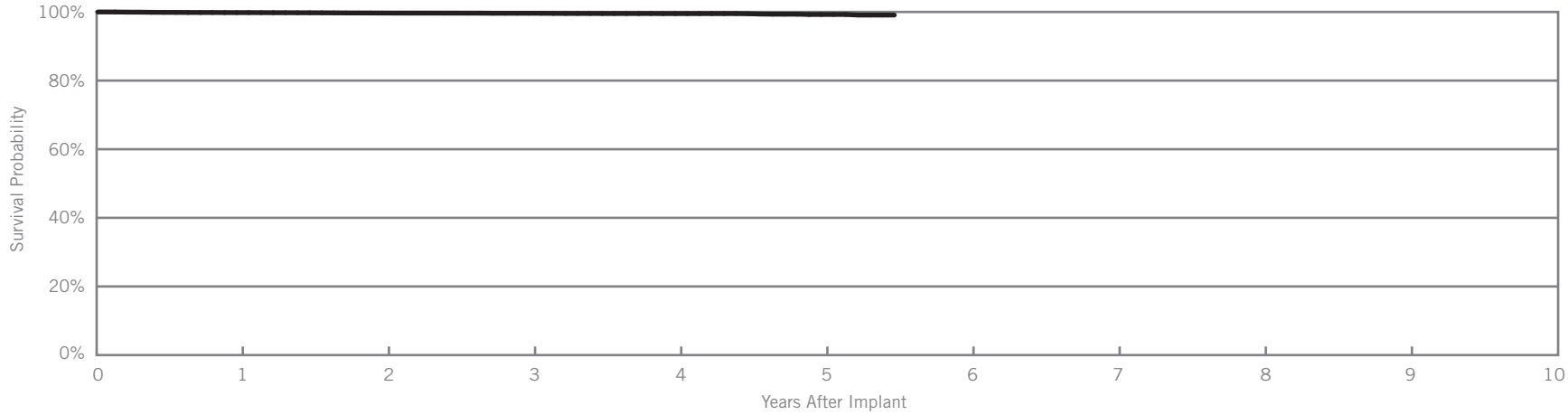
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,009
Estimated Active US Implants	10,679
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%	21	0.13%
Failure to Capture	5	0.03%	14	0.09%
Oversensing	0	0.00%	3	0.02%
Failure to Sense	0	0.00%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	2	0.01%
Extracardiac Stimulation	1	0.01%	1	0.01%
Other	2	0.01%	1	0.01%
Total	**29**	**0.18%**	**45**	**0.28%**
Total Returned for Analysis	**16**		**31**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	4	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	24	0.15%
Total	**29**	**0.18%**



Year	1	2	3	4	5	at 66 months				
Survival Probability	99.81%	99.68%	99.62%	99.52%	99.27%	99.10%				
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.14%	0.22%				
Sample Size	15300	11800	8700	5700	2600	200				

SCORE Registry Performance Data

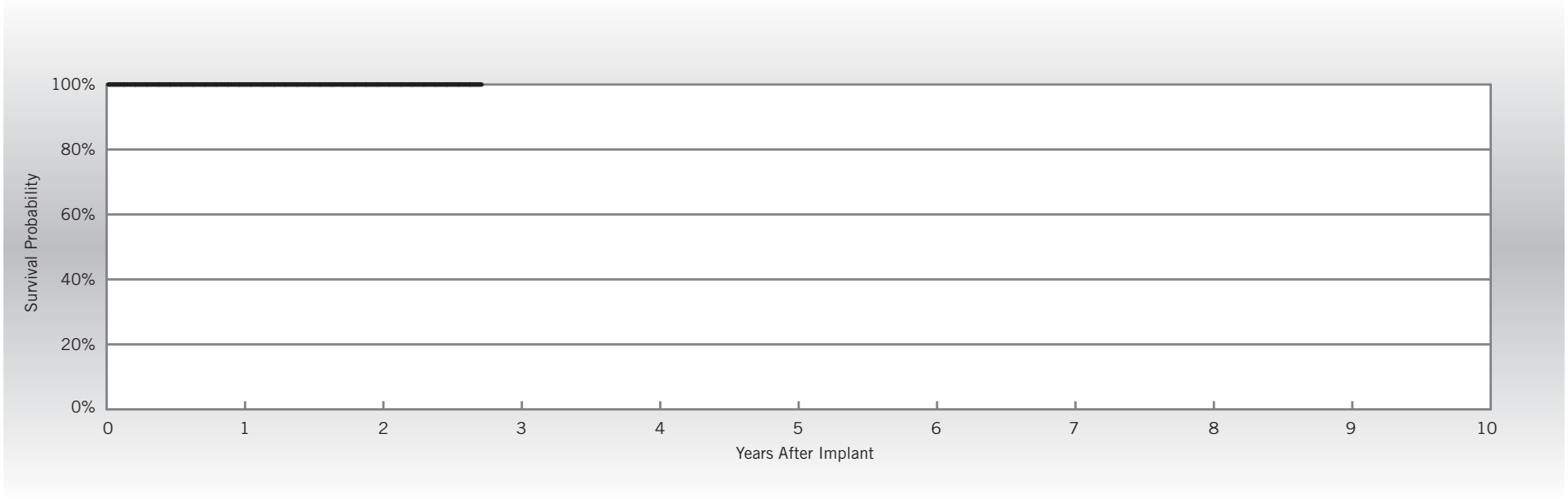
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	154
Cumulative Months of Follow-up	4,023
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	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	140	100	50							

Customer Reported Performance Data

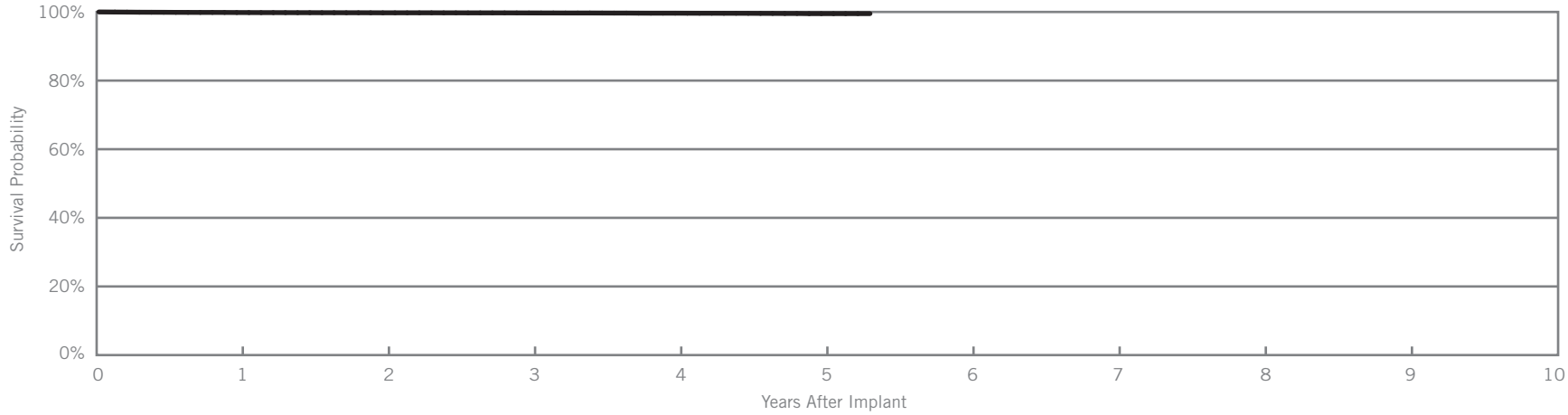
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,568
Estimated Active US Implants	41,631
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%	2	<0.01%
Conductor Fracture	1	<0.01%	4	0.01%
Lead Dislodgement	30	0.05%	34	0.05%
Failure to Capture	30	0.05%	40	0.06%
Oversensing	2	<0.01%	22	0.03%
Failure to Sense	2	<0.01%	1	<0.01%
Insulation Breach	1	<0.01%	2	<0.01%
Abnormal Pacing Impedance	9	0.01%	11	0.02%
Extracardiac Stimulation	2	<0.01%	1	<0.01%
Other	20	0.03%	8	0.01%
Total	**109**	**0.17%**	**125**	**0.19%**
Total Returned for Analysis	**42**		**84**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	30	0.05%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	55	0.08%
Total	**90**	**0.14%**



Year	1	2	3	4	5	at 64 months				
Survival Probability	99.83%	99.75%	99.71%	99.64%	99.51%	99.51%				
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%				
Sample Size	64300	53200	43100	30300	13800	700				

SCORE Registry Performance Data

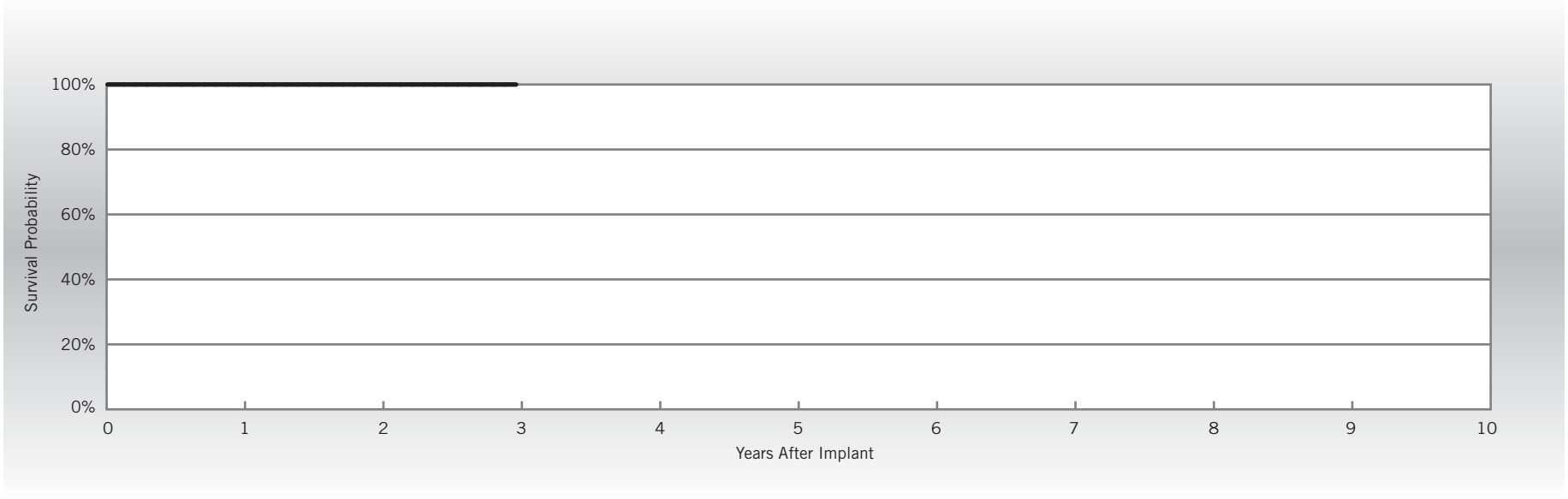
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	259
Cumulative Months of Follow-up	6,110
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							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	220	160	90							

Customer Reported Performance Data

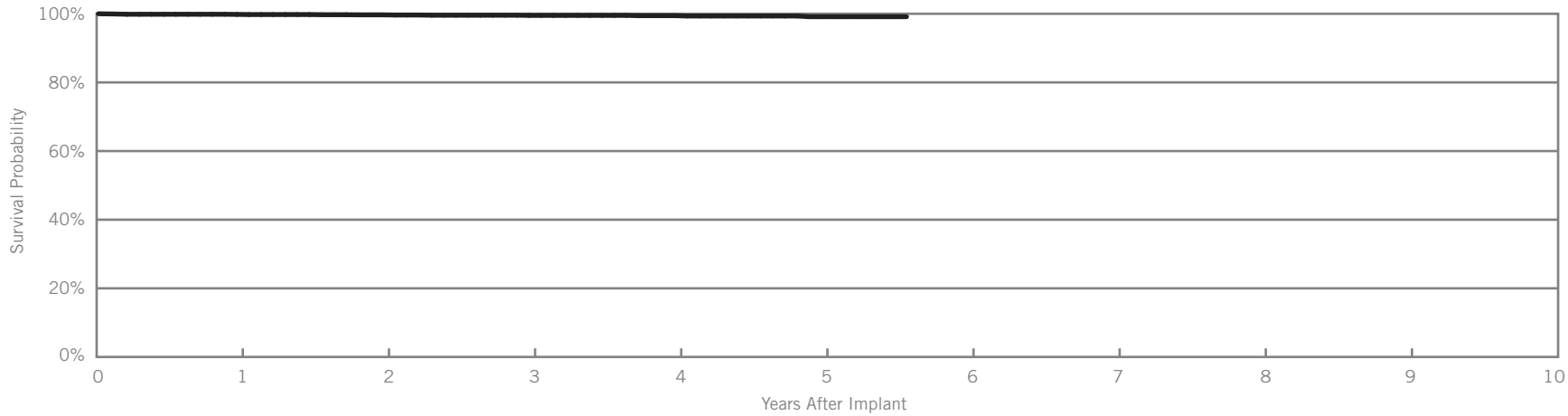
IsoFlex® P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,841
Estimated Active US Implants	1,449
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%	0	0.00%
Lead Dislodgement	2	0.07%	1	0.04%
Failure to Capture	2	0.07%	2	0.07%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	0.04%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
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%**	**9**	**0.32%**
Total Returned for Analysis	**1**		**5**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	3	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.07%
Extrinsic Factors	2	0.07%
Total	**7**	**0.25%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	99.81%	99.68%	99.52%	99.44%	99.14%	99.14%				
± 1 standard error	0.07%	0.12%	0.14%	0.17%	0.28%	0.28%				
Sample Size	2800	2400	2000	1400	800	200				

Customer Reported Performance Data

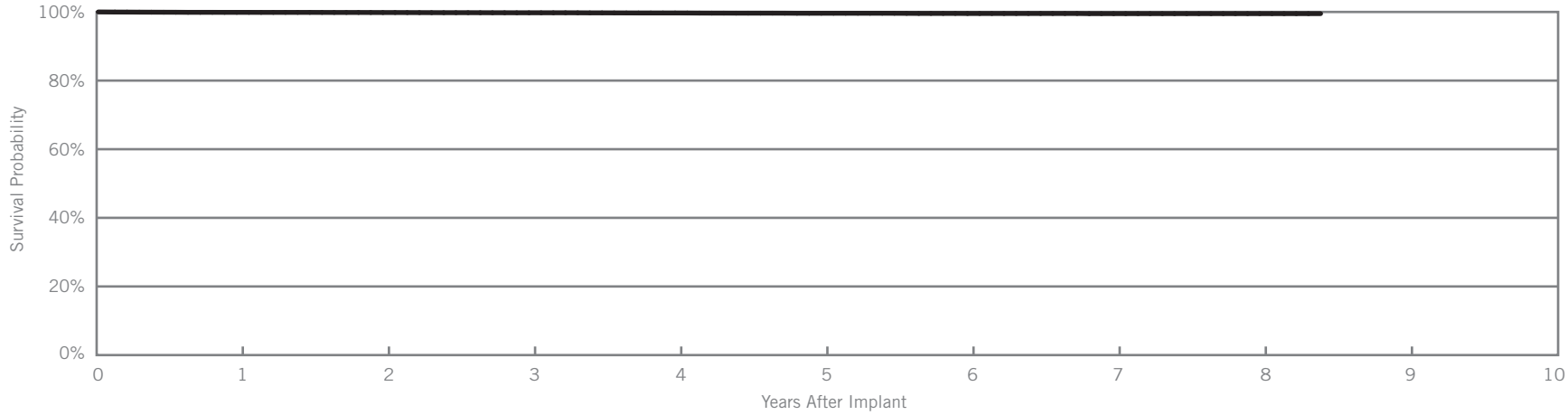
IsoFlex® S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	26,659
Estimated Active US Implants	15,695
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	48	0.18%	21	0.08%
Failure to Capture	5	0.02%	16	0.06%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	3	0.01%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
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	**60**	**0.23%**	**45**	**0.17%**
Total Returned for Analysis	**36**		**16**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	3	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	2	0.01%
Extrinsic Factors	13	0.05%
Total	**19**	**0.07%**



Year	1	2	3	4	5	6	7	8	at 101 months	
Survival Probability	99.88%	99.83%	99.76%	99.70%	99.62%	99.55%	99.51%	99.51%	99.51%	
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.08%	0.08%	0.08%	
Sample Size	25800	21000	17100	13100	9300	6000	3400	1400	200	

Customer Reported Performance Data

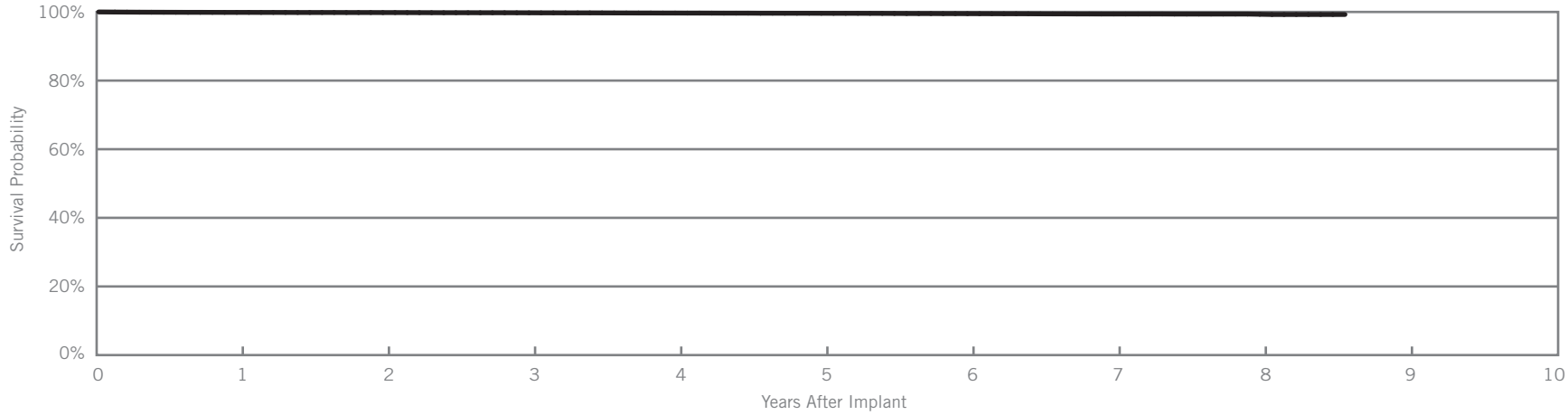
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	88,476
Estimated Active US Implants	51,282
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	3	<0.01%	1	<0.01%
Conductor Fracture	2	<0.01%	28	0.03%
Lead Dislodgement	35	0.04%	23	0.03%
Failure to Capture	32	0.04%	82	0.09%
Oversensing	0	0.00%	12	0.01%
Failure to Sense	2	<0.01%	2	<0.01%
Insulation Breach	2	<0.01%	1	<0.01%
Abnormal Pacing Impedance	6	0.01%	26	0.03%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	<0.01%	11	0.01%
Total	**84**	**0.09%**	**187**	**0.21%**
Total Returned for Analysis	**36**		**47**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	12	0.01%
Insulation Breach	11	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	6	0.01%
Extrinsic Factors	35	0.04%
Total	**64**	**0.07%**



Year	1	2	3	4	5	6	7	8	at 103 months	
Survival Probability	99.87%	99.82%	99.75%	99.68%	99.61%	99.50%	99.40%	99.32%	99.26%	
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%	0.06%	0.10%	
Sample Size	85700	68600	55100	41600	29100	18400	10100	4100	200	

SCORE Registry Performance Data

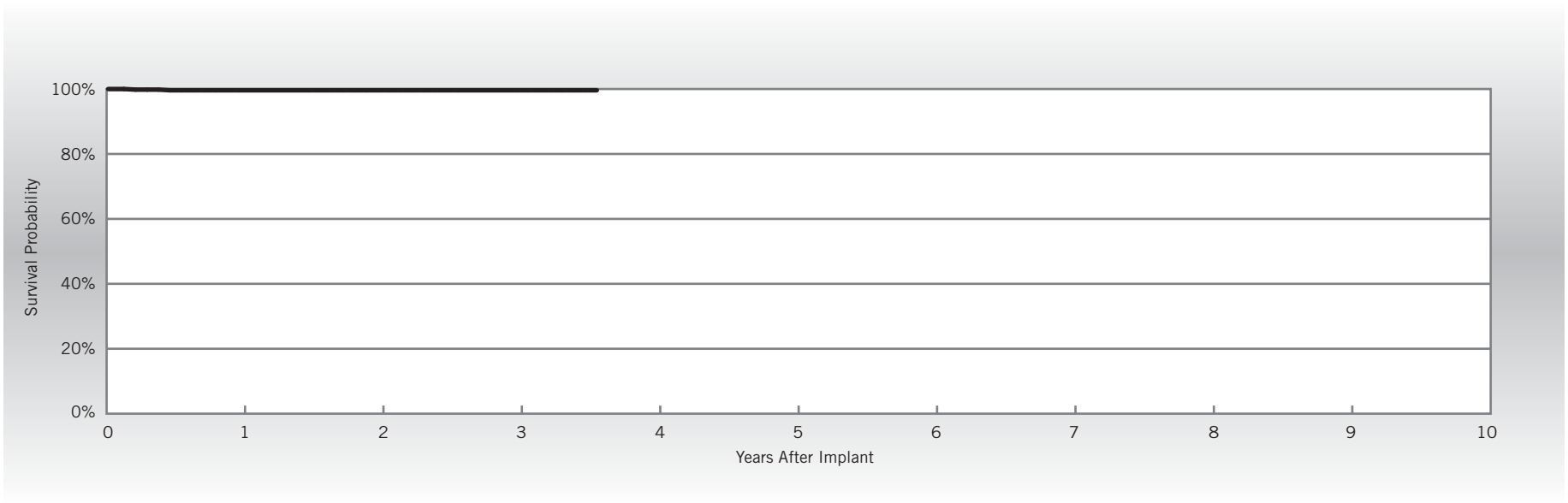
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	574
Cumulative Months of Follow-up	14,048
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	1	0.17%
Failure to Capture	1	0.17%

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	99.62%	99.62%	99.62%	99.62%						
± 1 standard error	0.27%	0.27%	0.27%	0.27%						
Sample Size	500	360	220	50						

Customer Reported Performance Data

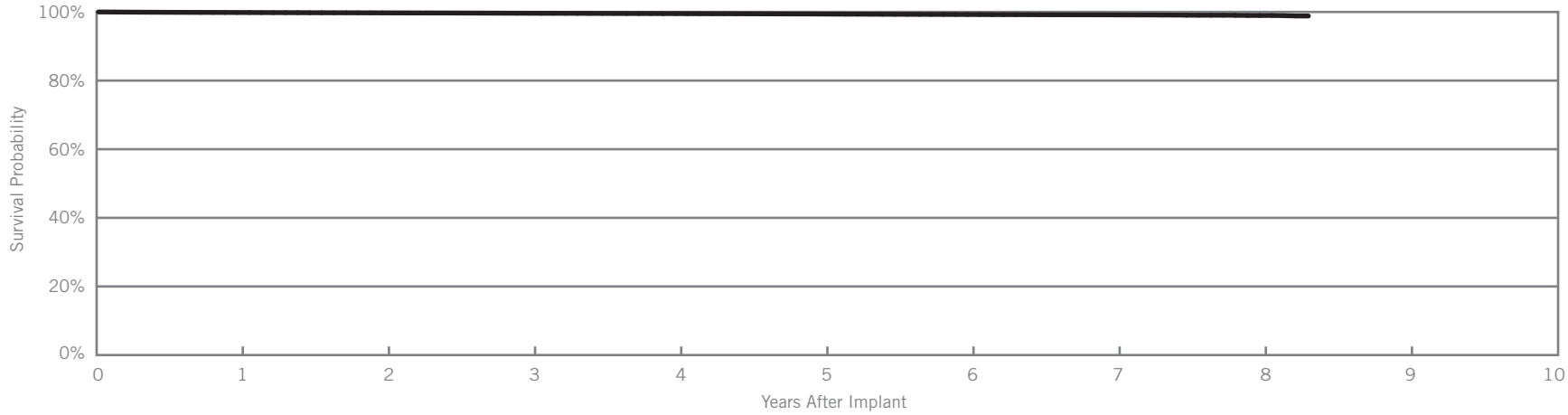
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	383,476
Estimated Active US Implants	227,823
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	43	0.01%	10	<0.01%
Conductor Fracture	4	<0.01%	99	0.03%
Lead Dislodgement	180	0.05%	219	0.06%
Failure to Capture	125	0.03%	359	0.09%
Oversensing	10	<0.01%	193	0.05%
Failure to Sense	22	0.01%	18	<0.01%
Insulation Breach	5	<0.01%	33	0.01%
Abnormal Pacing Impedance	25	0.01%	161	0.04%
Extracardiac Stimulation	4	<0.01%	10	<0.01%
Other	28	0.01%	65	0.02%
Total	**446**	**0.12%**	**1167**	**0.30%**
Total Returned for Analysis	**189**		**549**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	113	0.03%
Insulation Breach	183	0.05%
Crimps, Welds & Bonds	2	<0.01%
Other	3	<0.01%
Extrinsic Factors	325	0.08%
Total	**626**	**0.16%**



Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.84%	99.73%	99.62%	99.52%	99.39%	99.26%	99.15%	98.98%	98.83%	
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.06%	0.12%	
Sample Size	368300	292800	236200	184600	137100	86600	41100	12400	700	

SCORE Registry Performance Data

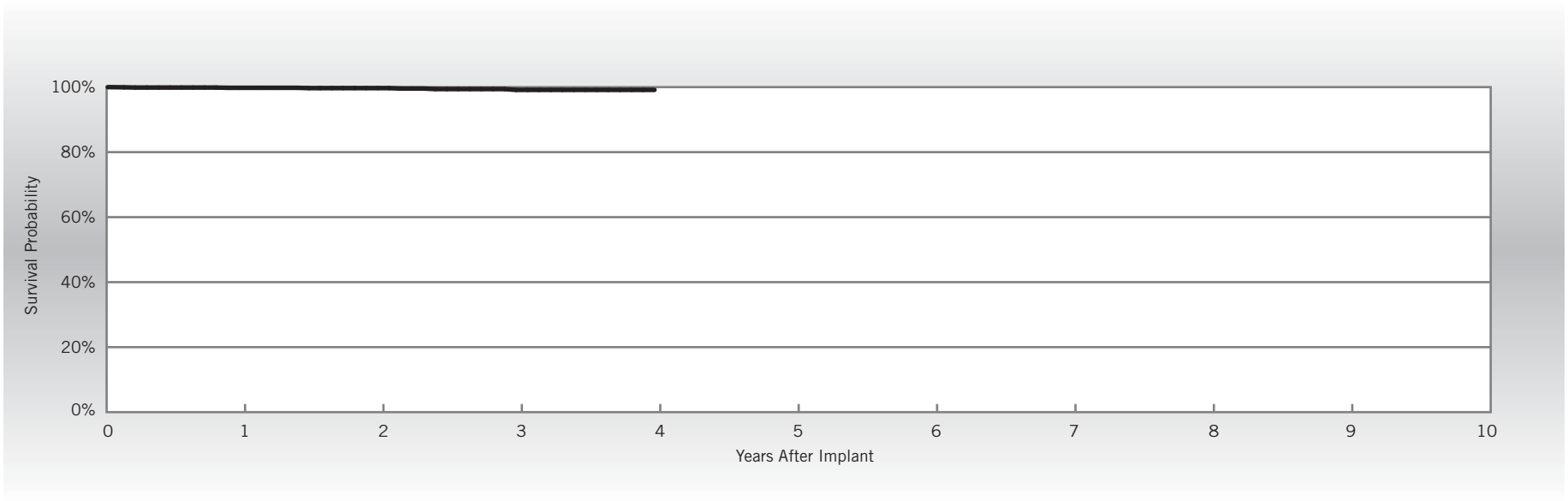
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	1,623
Cumulative Months of Follow-up	38,910
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Cardiac Perforation	1	0.06%
Lead Dilslodgement	1	0.06%
Failure to Capture	2	0.12%
Abnormal Pacing Impedance	1	0.06%
Extracardiac Stimulation	1	0.06%
Other	1	0.06%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.06%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.12%
Total	**3**	**0.18%**



Year	1	2	3	4						
Survival Probability	99.79%	99.69%	99.15%	99.15%						
± 1 standard error	0.12%	0.16%	0.26%	0.36%						
Sample Size	1400	980	590	210						

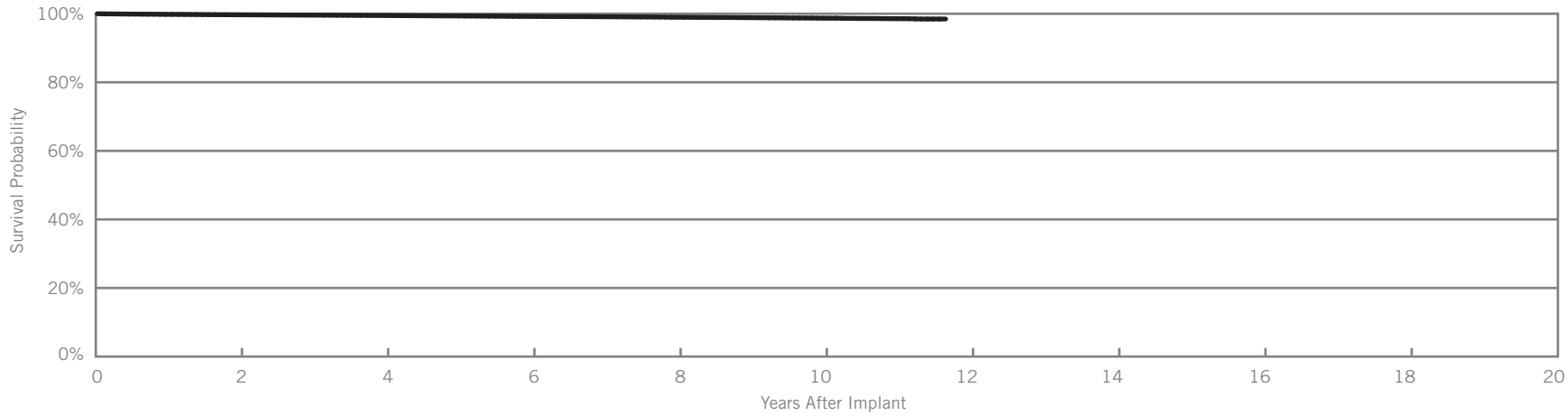
Customer Reported Performance Data

Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	273,906
Estimated Active US Implants	99,061
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	132	0.05%
Insulation Breach	94	0.03%
Crimps, Welds & Bonds	5	<0.01%
Other	0	0.00%
Extrinsic Factors	256	0.09%
Total	**487**	**0.18%**



Year	2	4	6	8	10	at 140 months				
Survival Probability	99.69%	99.48%	99.22%	98.99%	98.71%	98.46%				
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.08%				
Sample Size	234300	189800	142600	88200	30500	500				

SCORE Registry Performance Data

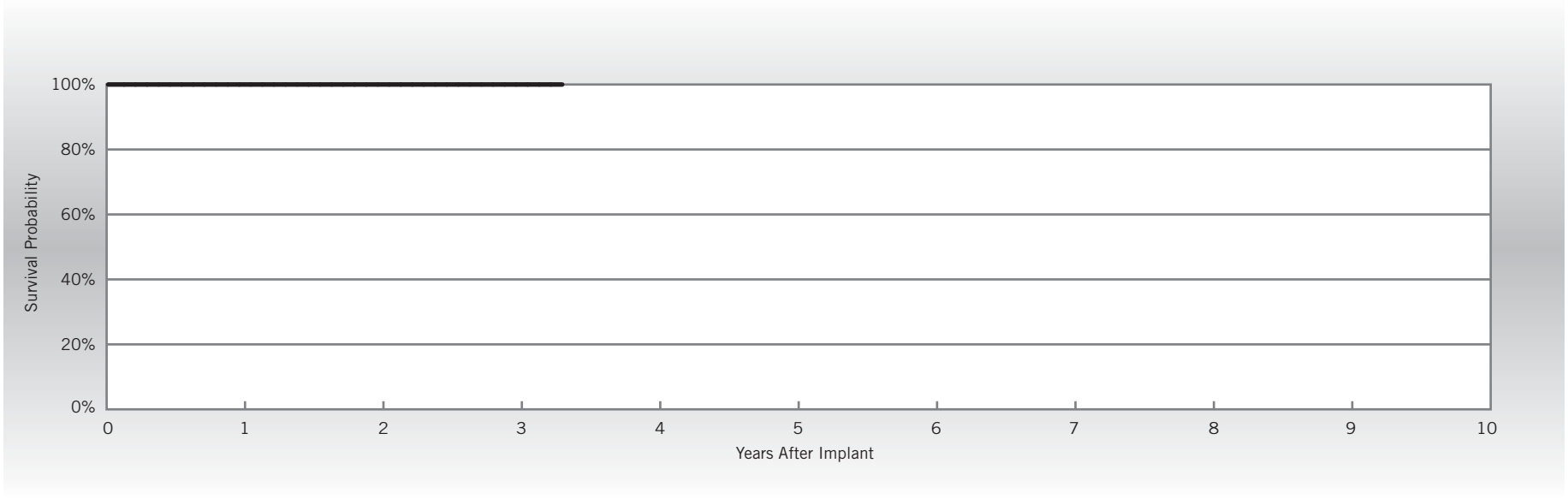
Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	146
Cumulative Months of Follow-up	4,545
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%**



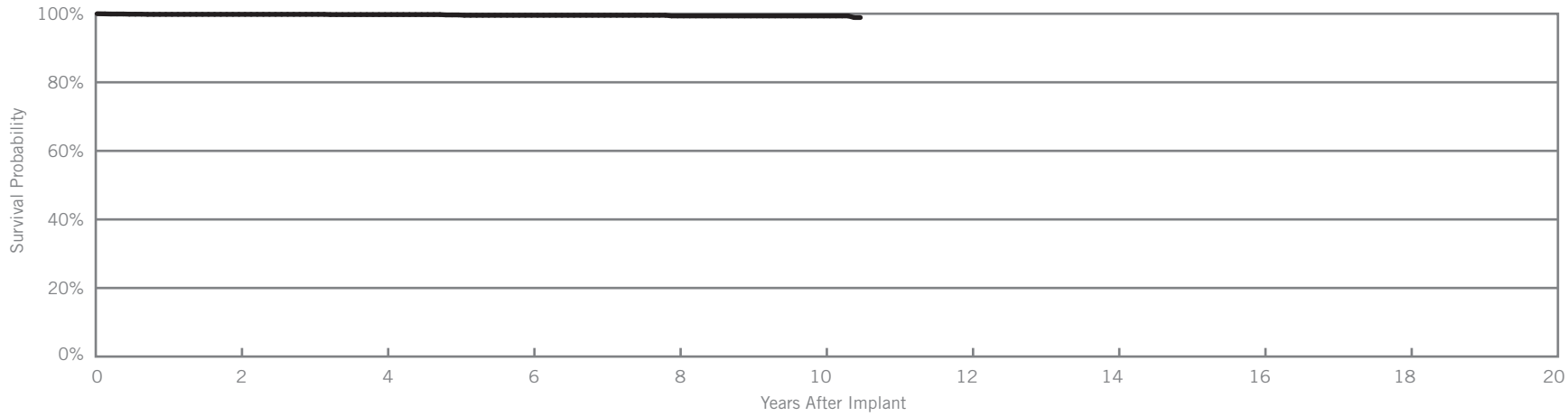
Year	1	2	3	at 40 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	130	110	80	60						

Customer Reported Performance Data

AV Plus® DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,577
Estimated Active US Implants	686
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



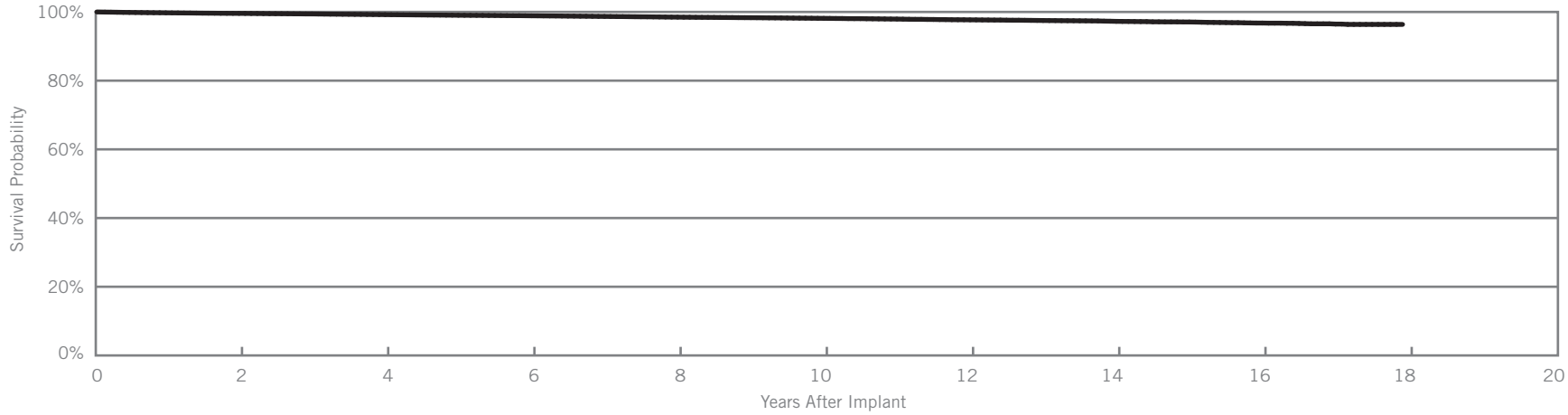
Year	2	4	6	8	10	at 126 months				
Survival Probability	99.82%	99.75%	99.55%	99.36%	99.36%	98.89%				
± 1 standard error	0.09%	0.11%	0.18%	0.26%	0.26%	0.53%				
Sample Size	2000	1400	900	600	300	200				

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	326,814
Estimated Active US Implants	80,468
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	at 215 months	
Survival Probability	99.58%	99.22%	98.88%	98.49%	98.14%	97.70%	97.26%	96.77%	96.37%	
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.05%	0.07%	0.12%	0.20%	
Sample Size	277700	223600	169900	120500	77600	43000	15700	4600	200	

Customer Reported Performance Data

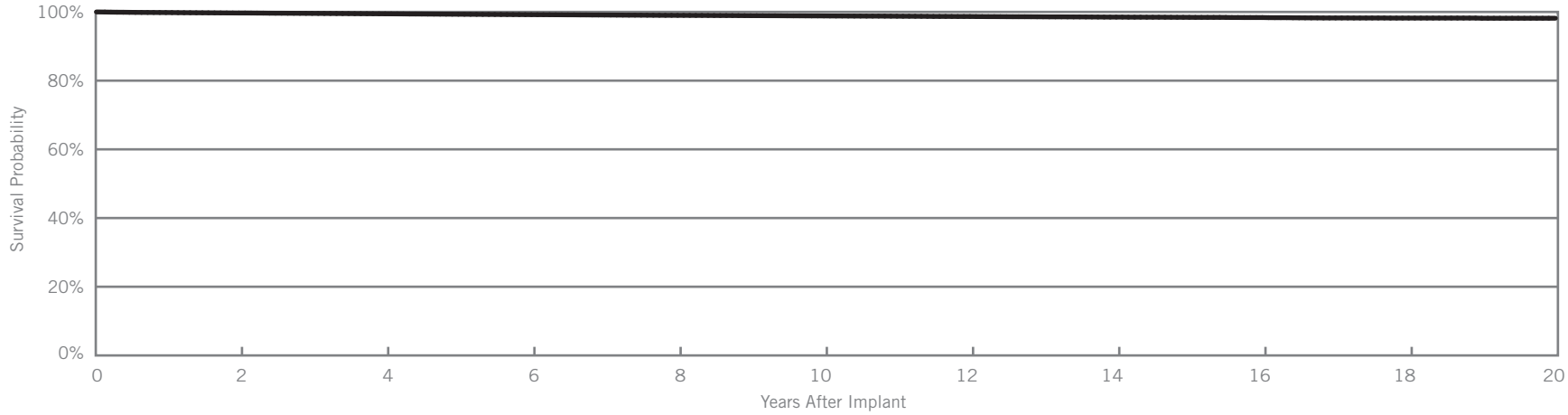
Passive Plus®

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	374,097
Estimated Active US Implants	71,209
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	2	4	6	8	10	12	14	16	18	20
Survival Probability	99.69%	99.45%	99.21%	99.01%	98.84%	98.68%	98.50%	98.37%	98.22%	98.17%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%	0.06%	0.08%
Sample Size	316400	253300	196700	146600	98300	59200	31900	15200	5700	1400

Summary Information

Pacing Leads

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%	99.75%								
1999	OptiSense® Optim®	99.85%									
1944	IsoFlex® Optim®	99.86%	99.66%	99.66%							
1948	IsoFlex® Optim®	99.92%	99.80%	99.74%							
1699T/TC	OptiSense®	99.78%	99.72%	99.63%	99.59%						
1888T/TC	Tendril® ST Optim®	99.80%	99.69%	99.58%	99.44%	99.35%					
1882T/TC	Tendril® ST Optim®	99.76%	99.69%	99.54%	99.47%						
1782T/TC	Tendril®	99.81%	99.68%	99.62%	99.52%	99.27%					
1788T/TC	Tendril®	99.83%	99.75%	99.71%	99.64%	99.51%					
1648T	IsoFlex® P	99.81%	99.68%	99.52%	99.44%	99.14%					
1642T	IsoFlex® S	99.88%	99.83%	99.76%	99.70%	99.62%	99.55%	99.51%	99.51%		
1646T	IsoFlex® S	99.87%	99.82%	99.75%	99.68%	99.61%	99.50%	99.40%	99.32%		
1688T/TC	Tendril® SDX	99.84%	99.73%	99.62%	99.52%	99.39%	99.26%	99.15%	98.98%		
1488T/TC	Tendril® SDX	99.82%	99.69%	99.60%	99.48%	99.36%	99.22%	99.12%	98.99%	98.86%	98.71%

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	103163	90620	16	0.02%	0	0.00%	60	0.06%	7	0.01%	2	<0.01%	2	<0.01%	2	<0.01%	2	<0.01%	0	0.00%	2	<0.01%	**93**	**0.09%**	**50**
1999	May-07	13643	11870	0	0.00%	0	0.00%	7	0.05%	2	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.07%**	**3**
1944	Mar-08	6220	4831	0	0.00%	0	0.00%	14	0.23%	1	0.02%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**17**	**0.27%**	**10**
1948	Mar-08	21102	16927	0	0.00%	0	0.00%	12	0.06%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**17**	**0.08%**	**12**
1699T/TC	May-07	23288	16399	1	<0.01%	0	0.00%	5	0.02%	3	0.01%	2	0.01%	8	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**21**	**0.09%**	**16**
1888T/TC	Jun-06	235147	170735	28	0.01%	5	<0.01%	101	0.04%	66	0.03%	10	<0.01%	8	<0.01%	3	<0.01%	6	<0.01%	3	<0.01%	17	0.01%	**247**	**0.11%**	**111**
1882T/TC	Jun-06	22533	17171	2	0.01%	0	0.00%	14	0.06%	5	0.02%	2	0.01%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**29**	**0.13%**	**11**
1782T/TC	Jun-06	16009	10679	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	65568	41631	12	0.02%	1	<0.01%	30	0.05%	30	0.05%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**109**	**0.17%**	**42**
1648T	Apr-05	2841	1449	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	26659	15695	0	0.00%	0	0.00%	48	0.18%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**60**	**0.23%**	**36**
1646T	May-02	88476	51282	3	<0.01%	2	<0.01%	35	0.04%	32	0.04%	0	0.00%	2	<0.01%	2	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**84**	**0.09%**	**36**
1688T/TC	Jun-03	383476	227823	43	0.01%	4	<0.01%	180	0.05%	125	0.03%	10	<0.01%	22	0.01%	5	<0.01%	25	0.01%	4	<0.01%	28	0.01%	**446**	**0.12%**	**189**

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	103163	90620	1	<0.01%	1	<0.01%	42	0.04%	27	0.03%	16	0.02%	4	<0.01%	4	<0.01%	3	<0.01%	1	<0.01%	6	0.01%	**105**	**0.10%**	**90**
1999	May-07	13643	11870	0	0.00%	0	0.00%	9	0.07%	4	0.03%	2	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**16**	**0.12%**	**15**
1944	Mar-08	6220	4831	0	0.00%	0	0.00%	8	0.13%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**10**	**0.16%**	**5**
1948	Mar-08	21102	16927	0	0.00%	4	0.02%	5	0.02%	3	0.01%	3	0.01%	0	0.00%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	**19**	**0.09%**	**9**
1699T/TC	May-07	23288	16399	0	0.00%	4	0.02%	21	0.09%	11	0.05%	7	0.03%	5	0.02%	0	0.00%	3	0.01%	2	0.01%	0	0.00%	**53**	**0.23%**	**37**
1888T/TC	Jun-06	235147	170735	20	0.01%	30	0.01%	190	0.08%	123	0.05%	96	0.04%	15	0.01%	28	0.01%	24	0.01%	10	<0.01%	31	0.01%	**567**	**0.24%**	**363**
1882T/TC	Jun-06	22533	17171	0	0.00%	2	0.01%	22	0.10%	13	0.06%	6	0.03%	2	0.01%	3	0.01%	0	0.00%	0	0.00%	5	0.02%	**53**	**0.24%**	**38**
1782T/TC	Jun-06	16009	10679	0	0.00%	1	0.01%	21	0.13%	14	0.09%	3	0.02%	2	0.01%	0	0.00%	2	0.01%	1	0.01%	1	0.01%	**45**	**0.28%**	**31**
1788T/TC	Feb-06	65568	41631	2	<0.01%	4	0.01%	34	0.05%	40	0.06%	22	0.03%	1	<0.01%	2	<0.01%	11	0.02%	1	<0.01%	8	0.01%	**125**	**0.19%**	**84**
1648T	Apr-05	2841	1449	0	0.00%	0	0.00%	1	0.04%	2	0.07%	0	0.00%	0	0.00%	1	0.04%	3	0.11%	0	0.00%	2	0.07%	**9**	**0.32%**	**5**
1642T	May-02	26659	15695	0	0.00%	3	0.01%	21	0.08%	16	0.06%	0	0.00%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	**45**	**0.17%**	**16**
1646T	May-02	88476	51282	1	<0.01%	28	0.03%	23	0.03%	82	0.09%	12	0.01%	2	<0.01%	1	<0.01%	26	0.03%	1	<0.01%	11	0.01%	**187**	**0.21%**	**47**
1688T/TC	Jun-03	383476	227823	10	<0.01%	99	0.03%	219	0.06%	359	0.09%	193	0.05%	18	<0.01%	33	0.01%	161	0.04%	10	<0.01%	65	0.02%	**1167**	**0.30%**	**549**

Definitions of observations and complications can be found on pages 8-9.

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	103163	1	<0.01%	18	0.02%	0	0.00%	3	<0.01%	82	0.08%	**104**	**0.10%**
1999	13643	1	0.01%	2	0.01%	0	0.00%	0	0.00%	11	0.08%	**14**	**0.10%**
1944	6220	0	0.00%	1	0.02%	0	0.00%	0	0.00%	5	0.08%	**6**	**0.10%**
1948	21102	0	0.00%	5	0.02%	0	0.00%	1	<0.01%	8	0.04%	**14**	**0.07%**
1699T/TC	23288	6	0.03%	6	0.03%	0	0.00%	0	0.00%	28	0.12%	**40**	**0.17%**
1888T/TC	235147	13	0.01%	113	0.05%	1	<0.01%	3	<0.01%	285	0.12%	**415**	**0.18%**
1882T/TC	22533	1	<0.01%	8	0.04%	0	0.00%	2	0.01%	28	0.12%	**39**	**0.17%**
1782T/TC	16009	1	0.01%	4	0.02%	0	0.00%	0	0.00%	24	0.15%	**29**	**0.18%**
1788T/TC	65568	3	<0.01%	30	0.05%	1	<0.01%	1	<0.01%	55	0.08%	**90**	**0.14%**
1648T	2841	0	0.00%	3	0.11%	0	0.00%	2	0.07%	2	0.07%	**7**	**0.25%**
1642T	26659	0	0.00%	3	0.01%	1	<0.01%	2	0.01%	13	0.05%	**19**	**0.07%**
1646T	88476	12	0.01%	11	0.01%	0	0.00%	6	0.01%	35	0.04%	**64**	**0.07%**
1688T/TC	383476	113	0.03%	183	0.05%	2	<0.01%	3	<0.01%	325	0.08%	**626**	**0.16%**
1488T/TC	273906	132	0.05%	94	0.03%	5	<0.01%	0	0.00%	256	0.09%	**487**	**0.18%**

Definitions of malfunction categories can be found on pages 9-10.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088TC	2261	24300	1	0.04%	0	0.00%	2	0.09%	1	0.04%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	**5**	**0.22%**
1999	402	4163	0	0.00%	0	0.00%	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.25%**
1948	380	5908	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%**
1699T/TC	1004	28661	0	0.00%	0	0.00%	2	0.20%	2	0.20%	0	0.00%	2	0.20%	0	0.00%	0	0.00%	**6**	**0.60%**
1888T/TC	4139	110800	0	0.00%	1	0.02%	9	0.22%	2	0.05%	1	0.02%	3	0.07%	1	0.02%	0	0.00%	**17**	**0.41%**
1882T/TC	197	3865	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%**
1782T/TC	154	4023	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	259	6110	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%**
1646T	574	14048	0	0.00%	0	0.00%	1	0.17%	1	0.17%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.35%**
1688T/TC	1623	38910	1	0.06%	0	0.00%	1	0.06%	2	0.12%	0	0.00%	1	0.06%	1	0.06%	1	0.06%	**7**	**0.43%**
1488T/TC	146	4545	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

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
2088TC	2261	0	0.00%	1	0.04%	0	0.00%	0	0.00%	1	0.04%	**2**	**0.09%**
1999	402	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.25%	**1**	**0.25%**
1948	380	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	1004	0	0.00%	1	0.10%	0	0.00%	0	0.00%	1	0.10%	**2**	**0.20%**
1888T/TC	4139	1	0.02%	4	0.10%	0	0.00%	1	0.02%	6	0.14%	**12**	**0.29%**
1882T/TC	197	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.51%	**1**	**0.51%**
1782T/TC	154	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	259	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	574	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	1623	1	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.12%	**3**	**0.18%**
1488T/TC	146	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Definitions of complications can be found on page 13.
Definitions of malfunction categories can be found on pages 9-10.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical™
More control. Less risk.

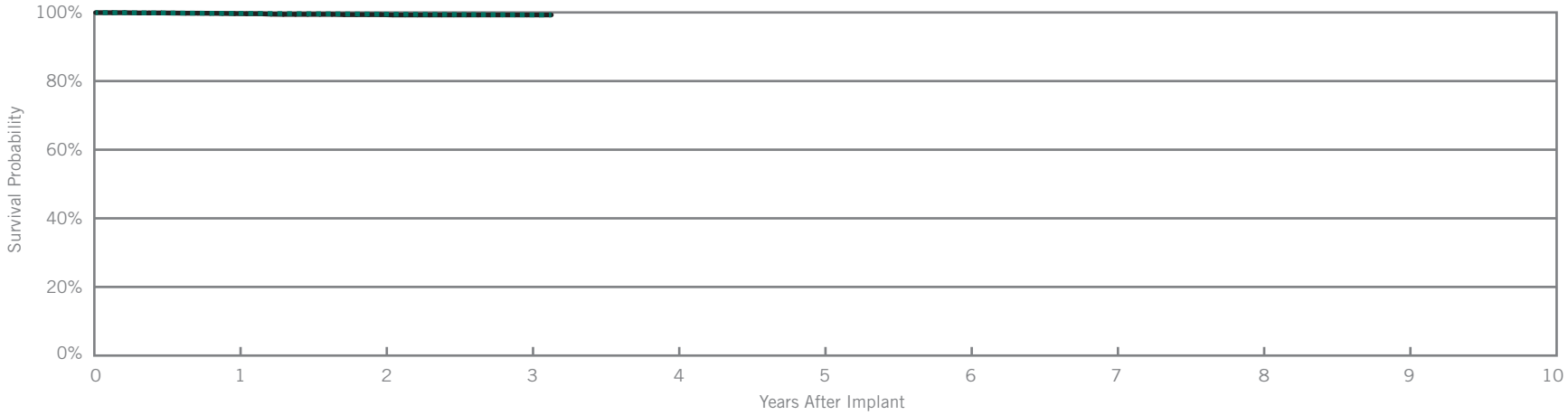
Customer Reported Performance Data

SJM Confirm®

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	9,140
Estimated Active US Implants	6,221
Estimated Longevity	3 Years*
Normal Battery Depletion	0
Number of US Advisories (see pgs. 244-256)	One

	Malfunctions	
	Qty	**Rate**
Electrical Component	1	0.01%
Electrical Interconnect	0	0.00%
Battery	5	0.05%
Software/Firmware	7	0.08%
Mechanical	0	0.00%
Possible Early Battery Depletion	0	0.00%
Other	3	0.03%
Total	**16**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	at 38 months						
Survival Probability	99.66%	99.36%	99.27%	99.27%						
± 1 standard error	0.07%	0.12%	0.14%	0.14%						
Sample Size	7900	3600	1300	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 38 months						
Survival Probability	99.66%	99.36%	99.27%	99.27%						
± 1 standard error	0.07%	0.12%	0.14%	0.14%						

**After 12 month shelf-life.*

Summary Information

Implantable Cardiac Monitors (ICMs)

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
DM2100	SJM Confirm®	99.66%	99.36%	99.27%							

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®	99.66%	99.36%	99.27%							

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®	9140	1	0.01%	0	0.00%	5	0.05%	7	0.08%	0	0.00%	0	0.00%	3	0.03%	16	0.18%

Definitions of malfunction root cause categories can be found on pages 6-7.

Focus on Clinical Performance

Update on Riata® Lead Performance

As of February 29, 2012, there were 671 confirmed cases of externalized conductors reported to St. Jude Medical worldwide on Riata® (8F) and Riata® ST (7F) silicone defibrillation leads, equating to a 0.30% incidence rate (671 out of 226,973). Of these 671 leads, 500 were not returned and 171 were returned for analysis. The majority of the increase since issuance of the Medical Device Advisory on November 28, 2011 is from non-returned leads identified during fluoroscopic screening. The incidence rate observed for Riata 8F is 0.37% and for Riata ST is 0.13%.

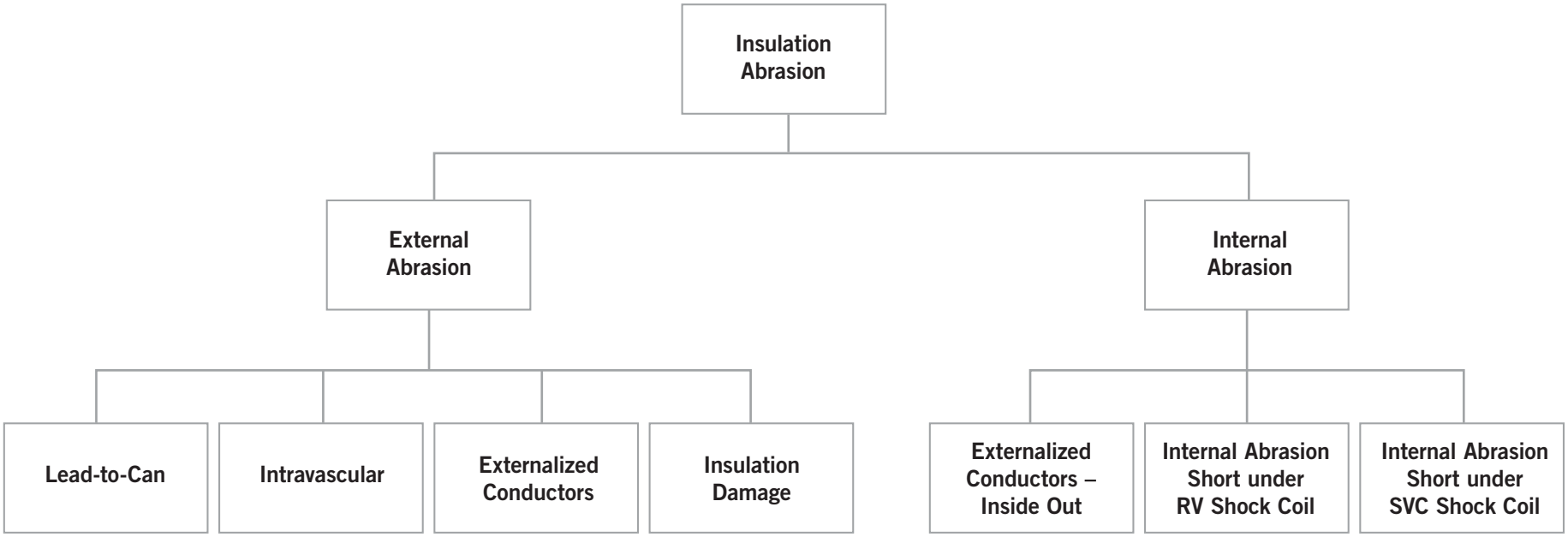
St. Jude Medical understands that the passive complaint reporting system results in under-reporting and hence underestimates the true failure rate associated with any given failure mechanism. This is especially true for externalized conductors since most manifest as visual anomalies only with normal electrical performance. There have been a number of peer reviewed publications on this subject indicating that the incidence rate of externalized conductors observed on Riata and Riata ST leads is substantially higher than the 0.30% derived from passive complaint reporting, a summary of which is available on the Riata Communication website at www.RiataCommunication.com.

As with any lead, there are other failure mechanisms associated with insulation abrasion. Historically, the rate of 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 we have referred to as inside-out abrasion, where the conductor cables become visible outside the insulation body. Approximately 85% of confirmed externalized conductors from product returns analysis are caused by inside-out abrasion, while 15% 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. Definitions are:

- **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 a full thickness outer insulation breach.
- **Internal Abrasion:** Abrasion between a lead conductor and its surrounding insulation that results in a full thickness insulation breach.
- **Lead-to-Can Abrasion:** Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) that results in a full thickness outer insulation breach.
- **Intravascular External 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 a full thickness outer insulation breach. The nature of the breach does not result in the conductors becoming visible outside the lead body.
- **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 a full thickness outer insulation breach, resulting in the normally contained conductors becoming visible outside the lead body.
- **Insulation Damage:** Insulation breaches that result from non-abrasion mechanisms, such as clavicular crush and damage at or around the suture sleeve tie down.
- **Externalized Conductors – Inside-Out:** Outward abrasion of the conductors that results in an outer insulation breach within the vascular system or heart, resulting in the normally contained conductors becoming visible outside the lead body.
- **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.
- **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.

Flow Diagram of Insulation Abrasion Types and Mechanisms



The table below summarizes the insulation failure mechanisms observed on Riata® and Riata® ST leads (out of a total of approximately 7,200 Riata and Riata ST returned leads). 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 Failure Mechanisms from Complaints and Returns

Insulation Failure Mechanism	Abrasion Type	Riata (8F) Worldwide (WW) Incidence Rate (WW Sales = 156,308)	Riata ST (7F) Worldwide (WW) Incidence Rate (WW Sales = 70,665)
Lead-to-Can Abrasion	External Abrasion	0.36%	0.29%
Intravascular External Abrasion (e.g., Lead-to-Lead, Lead-to-Anatomical Structure)	External Abrasion	0.12%	0.08%
Externalized Conductors – External Source of Abrasion	External Abrasion	0.06%	0.02%
Insulation Damage (e.g., Clavicular Crush, Suture Sleeve Tie Down)	External Abrasion	0.02%	0.03%
Externalized Conductors – Inside-Out	Internal Abrasion	0.31%	0.11%
Internal Abrasion Short under RV shock coil	Internal Abrasion	0.05%	0.01%
Internal Abrasion Short under SVC shock coil	Internal Abrasion	0.03%	0.003%

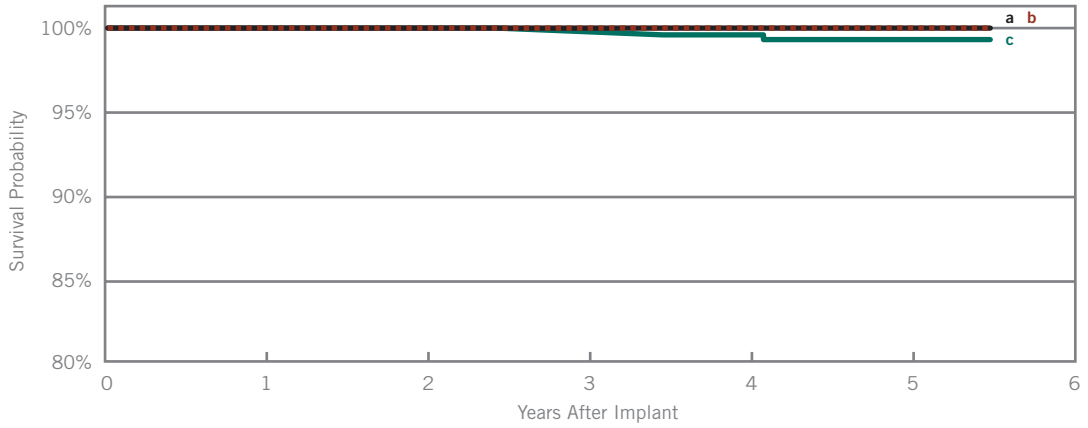
Prospective, monitored registries continue to provide the best data to support clinical decision making. St. Jude Medical is conducting the Riata Lead Evaluation Study, which will enroll approximately 700 patients from the U.S., Canada, and Japan to provide information that will assist clinicians in the management of their patients. The study began in December 2011 and continues to enroll patients. Current enrollment is over 600 patients and fluoroscopic images are being adjudicated by independent physicians; we expect to have the initial results reporting on the incidence of externalized conductors compiled and communicated by the end of June 2012. The study will continue to follow patients to evaluate the performance of leads that have externalized conductors over the next 2 years.

Durata® Lead Performance

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.

The three studies enrolling either Durata or Riata® ST Optim® leads are the OPTIMUM registry, SCORE registry, and the SJ4 Post Approval Study (PAS). These are prospective, outcome-oriented, actively monitored registries. Currently, a total of 10,950 Optim-insulated leads (8,075 Durata and 2,875 Riata ST Optim leads) are enrolled in these studies at 292 sites. These leads have been followed for over five years with a total of 27,477 patient-years of follow-up. The survival curves and table represent data collected as of March 31, 2012. These prospective studies to date have not included fluoroscopic imaging of the Optim-insulated defibrillation leads; however St. Jude Medical is currently in the process of implementing plans to collect fluoroscopic images of these leads going forward.

Performance of Optim-insulated defibrillation leads



	1	2	3	4	5
Freedom from Externalized Conductors (a)	100%	100%	100%	100%	100%
Freedom from All-Cause Insulation Abrasion (b)	100%	100%	100%	99.9%	99.9%
Freedom from Mechanical Failures (includes Insulation Abrasion, Conductor Fractures, and failures of crimps, welds and bonds) (c)	100%	99.9%	99.8%	99.7%	99.6%

Durata® and Riata® ST Optim® Failure Categories from Active Registries

Failure Category	Incidence Rate
Externalized Conductors	0.0%
All-Cause Insulation Abrasion	0.04%
All-Cause Mechanical Failures	0.16%

The table below summarizes different insulation failure mechanisms observed out of approximately 6,700 Durata and Riata ST Optim leads that have been returned for analysis through February 29, 2012. The incidence rates demonstrate the effectiveness of the lead design changes in improving insulation related failures compared to the Riata®/Riata ST silicone leads (see page 231). The incidence of total Durata insulation failures from returns analysis is approximately 0.02%, which is consistent with the incidence rate of all-cause insulation abrasion (0.04%) from our actively monitored registries.

Durata (WW Sales = 276,021) and Riata ST Optim (WW Sales =33,030) Insulation Failure Mechanisms from Complaints and Returns

Insulation Failure Mechanism	Abrasion Type	Optim Defib Lead Worldwide (WW) Incidence Rate (WW Sales = 309,051)
Lead-to-Can Abrasion	External Abrasion	0.013%
Intravascular External Abrasion (e.g., Lead-to-Lead, Lead-to-Anatomical Structure)	External Abrasion	0.006%
Externalized Conductors – External Source of Abrasion	External Abrasion	0.0%
Insulation Damage (e.g., Clavicular Crush, Suture Sleeve Tie Down)	External Abrasion	0.008%
Externalized Conductors – Inside-Out	Internal Abrasion	0.0%
Internal Abrasion Short under RV shock coil	Internal Abrasion	0.001%
Internal Abrasion Short under SVC shock coil	Internal Abrasion	0.001%

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 >1.3 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. Conductor externalization, a possible result of internal or external abrasion, has not been observed in leads where Optim lead insulation is present.

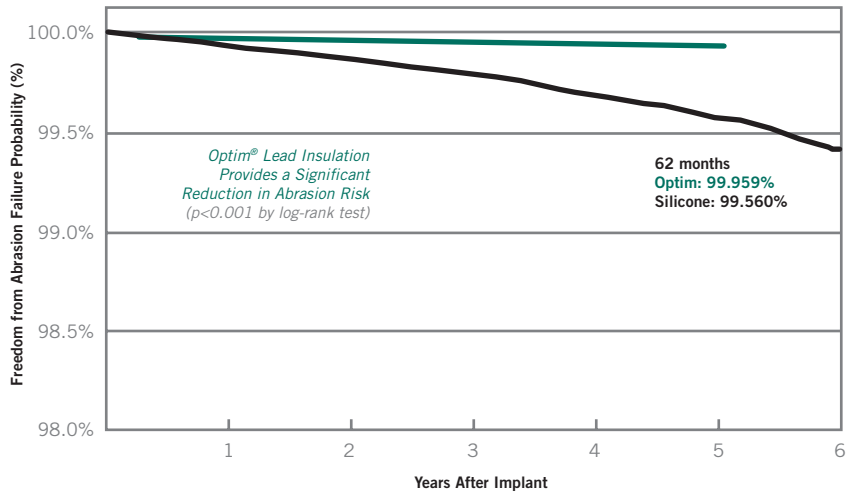
This product performance report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on St. Jude Medical tachycardia leads. A Kaplan-Meier analysis including all U.S. data through December 31, 2011 was performed on two groups of leads: (1) tachycardia leads with silicone insulation [Riata and Riata ST lead families], and (2) tachycardia leads with Optim lead insulation [Riata ST Optim and Durata lead families]. For both 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 62 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 62 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 62 months by 91%, which was confirmed to be statistically significant (p<0.001) by a log-rank test. The abrasion resistance of Optim lead insulation has decreased by a factor of ten the probability of abrasion malfunction in the St. Jude Medical's Riata® ST Optim and Durata® lead families when compared to the Riata® and Riata® ST lead families.

Optim® Lead Insulation Effects on SJM Tachycardia Lead Abrasion

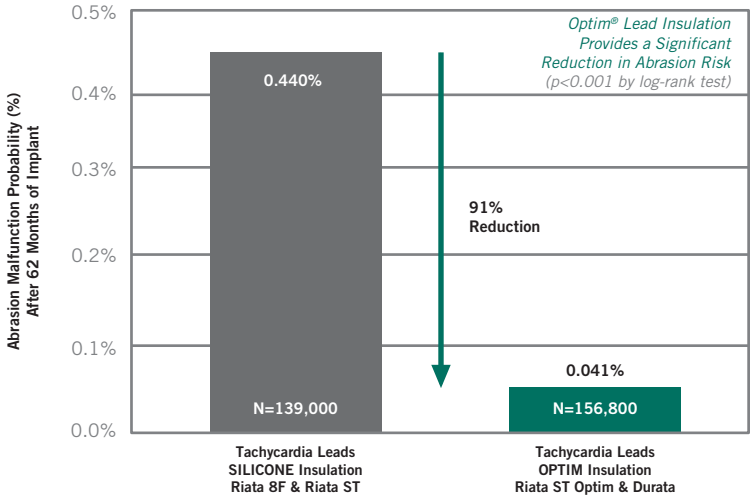
Kaplan-Meier Analysis of US Returns Analysis Data

Freedom from Abrasion Failure (%)



Sample Size	1	2	3	4	5
Optim	129,696	82,201	44,598	17,923	3,723
Silicone	129,122	115,360	103,224	88,354	68,291

Abrasion Malfunction Probability after 62 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).

High Voltage DF4 Connector System

Background

In June 2009 St. Jude Medical announced the first implant of the SJ4 connector system. This four-pole system featured a single connection between the implantable cardioverter defibrillator (ICD) and the defibrillation lead and simplified the implant procedure. This innovative connector reduced system pocket bulk by eliminating the lead yoke and reducing the header size. The fewer number of ports on the ICD lowered the likelihood of lead insertion in the incorrect port and reduced the number of setscrews necessary to secure the leads within the header. In June 2010 St. Jude Medical received FDA approval to update its label designation to DF4 in recognition of compliance with the international standard ISO 27186:2010, "Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements". The DF4 connector represents state-of-the-art medical device technology for implanted systems with benefits for both implanter and patient.

The ISO 27186:2010 international standard is the result of nearly a decade of industry-wide cooperation. During the process of standard creation and product development, the DF4 connector system underwent an exhaustive battery of tests intended to simulate acute and chronic conditions beyond worst case clinical scenarios. With these rigorous testing methods St. Jude Medical was able to ensure the quality and reliability of this new connector system. Demand for the DF4 connector system remains high, currently representing more than 60% of all U.S. ICD and CRT-D implants. Today's DF4 implants consist primarily of Durata® Q defibrillation leads, Fortify® ICDs, and Unify® CRT-Ds.

As of the December 31, 2011 data cutoff for this Product Performance Report, the DF4 connector system has been in clinical use for 30 months and represents over 67,000 U.S. implants. St. Jude Medical is continuously monitoring the DF4 connector system performance with customer reported complaints and returns data as well as a post-approval registry study currently underway. Customer Reported and SCORE Registry Performance Data for many DF4 models can be found in this report.

Analysis

St. Jude Medical completed an updated statistical comparison of the complaints and malfunctions related to the DF4 and IS-1/DF-1 connector systems. All connector-related system complaints were found to be assigned to the ICD/CRT-D, therefore a separate lead-based analysis was not undertaken. Due diligence was applied to ensure a direct and unbiased comparison. Devices included in the analysis were implanted on or after August 1, 2009, which represents the first month with at least 100 DF4 system implants, and no later than December 31, 2011, which is the data cutoff for this Product Performance Report. Complaints included in the analysis represent events occurring within this same period. All malfunction data included in this comparative analysis were generated between August 1, 2009 and December 31, 2011. Because complaints may occur during implant or during an attempted implant, no restriction related to implant duration was applied. A non-biased comparison was ensured by including only those defibrillation lead and ICD/CRT-D models which were offered with both DF4 and IS-1/DF-1 connector systems (see Table 1).

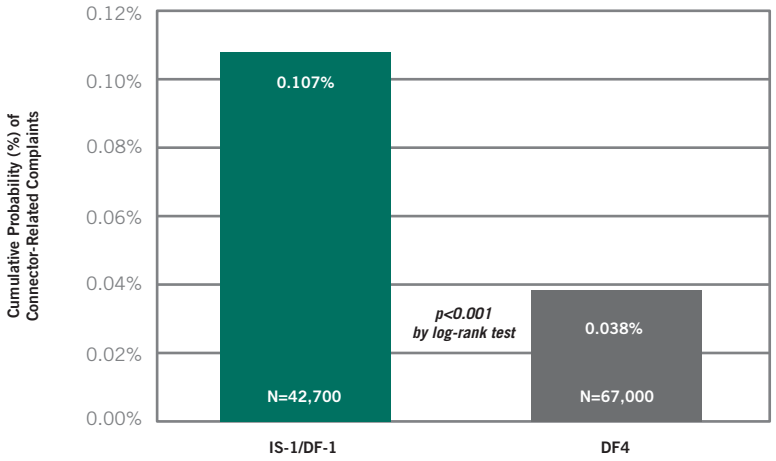
Table 1. Models Included in Analysis

	Traditional (IS-1/DF-1)	DF4
Sample Size	~42,700	~67,100
Defibrillation Lead Models	7120, 7121, 7122, 7070, 7071	7120Q, 7121Q, 7122Q, 7170Q, 7171Q
ICD/CRT-D Models	CD1211-36, CD1215-36, CD1231-40, CD2211-36, CD2215-36, CD2231-40, CD3211-36, CD3215-36, CD3231-40	CD1211-36Q, CD1215-36Q, CD1231-40Q, CD2211-36Q, CD2215-36Q, CD2231-40Q, CD3211-36Q, CD3215-36Q, CD3231-40Q

It is important to note that complaints represent direct feedback from the field and are logged as reported with no validation or analysis by St. Jude Medical. Complaints may be the result of true product performance issues, patient/environmental factors unrelated to the product, or problems associated with off-label product use. In contrast, malfunction data, which is generated from laboratory analysis of returned products, represent a thorough assessment of device performance and field information, resulting in the most accurate understanding of product failure modes.

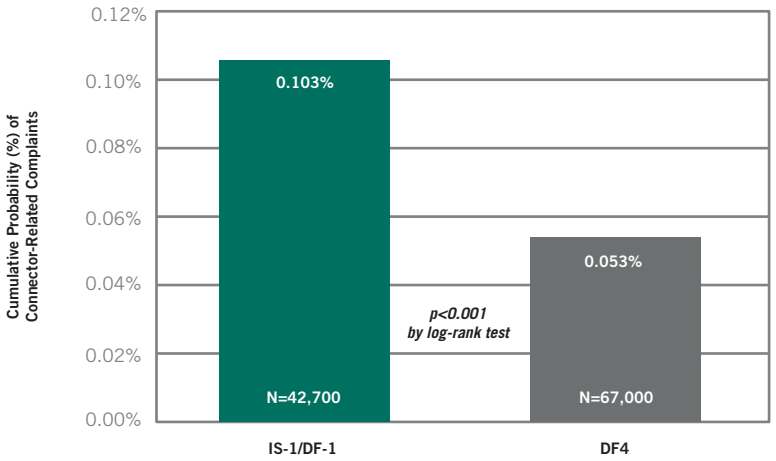
A Kaplan-Meier analysis of event-free survival was performed for ICD/CRT-D connector-related complaint comparing the DF4 to the IS-1/DF-1 family of devices. This was followed by a log-rank comparison of the Kaplan-Meier cumulative probability curves. Figure 1 presents the resulting cumulative probability of connector-related complaints at the end of the analysis period, December 31, 2011. The probability of a connector related complaint for either group was less than 0.11%. The probability of a connector-related ICD/CRT-D complaint in a DF4 system is 64% less than the probability observed in an IS-1/DF-1 system. This difference proved to be highly statistically significant ($p<0.001$). The majority of complaints referenced problems with setscrew function or generic connection issues.

Figure 1. ICD/CRT-D Connector Related Complaints
Represents Events between Aug 1, 2009 and December 31, 2011



A similar statistical treatment was applied to the ICD connector-related malfunction data. Typical malfunctions included problems with the setscrew or difficulty inserting the lead into the ICD/CRT-D header. The resulting cumulative probability of connector-related malfunctions at the end of the analysis period, December 31, 2011, is shown below in Figure 2. The probability of an ICD/CRT-D malfunction in a DF4 system is approximately 49% less than in an IS-1/DF-1 system. This reduction in malfunction was also found to be statistically significant ($p<0.001$).

Figure 2. ICD/CRT-D Connector Related Malfunctions
Represents Malfunctions Analyzed between Aug 1, 2009 and December 31, 2011



The vast majority of complaints and malfunctions for the ICDs and CRT-Ds in this analysis were related to operation of the setscrew. The St. Jude Medical DF4 connector port design requires only one setscrew. This reduces the total quantity of setscrews in a CRT-D system implant from 8 in a traditional IS-1/DF-1 connector system to only 3 in a DF4 connector system. This DF4 design advantage accounts for a majority of the reduction in complaints and malfunctions identified by this analysis.

Conclusions

This updated analysis of DF4 connector system field performance data has demonstrated the excellent field performance of the four-pole connector system, with a statistically significantly lower rate of both complaints and malfunctions when compared to the traditional IS-1/DF-1 connector system.

Low Frequency Attenuation Filter: Reduce T-Wave Oversensing (TWOS)

Background

When starting the design of its new High Voltage Device platform several years ago, St. Jude Medical focused on three main goals: retain the clinically successful portfolio of features existing in the Current® and Promote® product families, meet St. Jude Medical's tradition of high product quality, and incorporate new features and capabilities that would meet the current and future needs of our patients and customers. Literature has shown that approximately one third of all ICD Shocks are inappropriate,[1] leading to a reduced quality-of-life for those patients affected.[2, 3] With that in mind, St. Jude Medical made the reduction of shocks (appropriate and inappropriate) a priority in the design of its new High Voltage platform.

In May 2010, St. Jude Medical launched this new technology platform with three new devices: Unify® CRT-D, Fortify® DR, and Fortify® VR. This new design and technology allows St. Jude Medical to bring to our customer a smaller device without compromising on performance and safety. It retains the quality and features that were designed in our previous platforms and also brings forward new capabilities. A primary example of these new capabilities is the addition of a novel Low Frequency Attenuation filter. This enhanced filter increases the R to T-wave amplitude ratio by a factor of 2x to 3x, effectively enhancing sensing performance and reducing the possibility of oversensing T-waves which can lead to inappropriate therapy.[4] Statistical analysis has shown that the enhanced filter has no adverse effect on the detection of Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF) rhythms.[5]

Analysis

St. Jude Medical performed a statistical analysis of the inquiries received by our U.S. technical services department related to T-wave oversensing for the Unify/Fortify family of devices and the Current/Promote family of devices (see Table 1). While underreporting of T-wave oversensing may exist, inquiries to technical services regarding T-wave oversensing represents a metric by which relative comparisons can be made between families or models. Note that most inquiries regarding T-wave oversensing represent acute issues that are solved by programming changes and have no chronic performance implications. These inquiries represent direct feedback from the field and are logged as reported with no validation by St. Jude Medical. All inquiries included in this analysis occurred between product launch to the cutoff date of this report which is December 31, 2011.

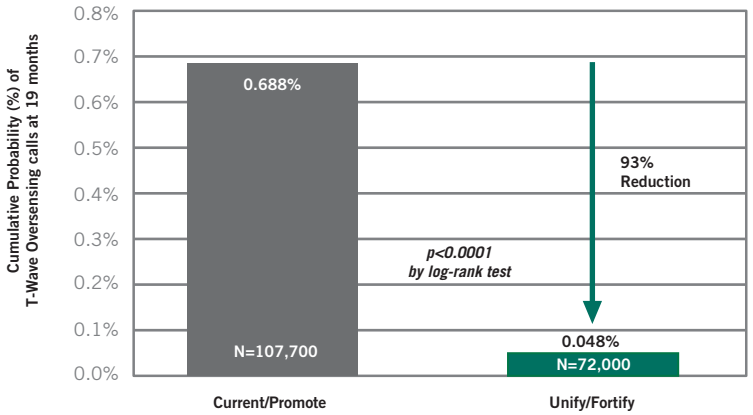
Table 1: Models included in this analysis

	Promote®/Current® Family of devices	Unify®/Fortify® Family of devices
Sample Size	~107,700	~72,000
Models	1107-30, 1207-30, 1207-36 2107-36, 2207-30, 2207-36 3107-36, 3207-30, 3207-36 CD1211-36/Q, CD1215-36/Q CD2211-36/Q, CD2215-36/Q CD3211-36/Q, CD3215-36/Q	CD1231-40/Q CD2231-40/Q CD3231-40/Q

The Unify/Fortify device family was most recently market released, having a maximum implant duration of 19 months as of December 31, 2011. A Kaplan-Meier analysis of event-free survival was performed for each family out to 19 months of implant duration. An event was defined as a T-wave oversensing inquiry. This analysis required the U.S. registration and tracking data of all patients implanted with the above device families as well as data from all T-wave oversensing inquiries. A log-rank comparison of the Kaplan-Meier cumulative probability curves of both families was also performed.

The resulting cumulative probability of a T-wave oversensing inquiry by 19 months of implant time is presented in Figure 1. The probability of a T-wave oversensing inquiry in the Unify/Fortify family of devices is 93% lower than the probability observed in the Current/Promote family of devices. The log-rank result ($p<0.001$) confirmed this difference to be statistically significant.

Figure 1: T-wave Oversensing for the Unify®/Fortify® and Current®/Promote® device families



Conclusions

The field performance data represented in Figure 1 indicates that the Unify/Fortify device family of ICDs and CRT-Ds has a significantly lower rate of T-wave oversensing than its predecessor family, Current/Promote devices. St. Jude Medical attributes this performance improvement to the implementation of a novel Low Frequency Attenuation filter in the Unify/Fortify family.

[1] Daubert, J.P. et al. Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II: Frequency, Mechanisms, Predictors, and Survival Impact. *JACC*. 2008;51(14):1357-1365.
[2] Carroll DL, et al. Quality of life in implanted cardioverter defibrillator recipients: the impact of a device shock. *Heart Lung*, 2005, 34, pp. 169-178.
[3] Irvine J, et al. Quality of life in the Canadian Implantable Defibrillator Study (CIDS). *Am Heart J*, 2002, 144, pp. 282-289.
[4] Rauwolf T, et al. Ventricular oversensing in 518 patients with implanted cardiac defibrillators: incidence, complications, and solutions. *Europace* 2007,9, pp 1041-1047.
[5] Data on file with the FDA, file ETR 60029255

Advisories & Safety Alerts

St. Jude Medical™
More control. Less risk.

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
Convert®+ (Model V-195)	5/6/2010 Outside US only A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin® Patient Care System (PCS) programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful.	If a patient's device is already programmed to a two zone configuration with a Merlin® PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below: A permanent correction is available in the new release of the Merlin® PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin® programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (December 31, 2011):** 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, 2011, there have been no additional reports associated with this advisory.

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 (December 31, 2011):** 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, 2011 there have been no additional devices confirmed to have this issue since the time of the advisory.

ICD and CRT-D Devices

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 (December 31, 2011):** 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, 2011 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 (December 31, 2011):** 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 (V-338), Epic®+ HF (V-350), Atlas®+ (V-193, V-243), Atlas®+ HF (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 (December 31, 2011):** 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® 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 (December 31, 2011):** 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 (December 31, 2011):** 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, 2011 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 programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or Autocapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program Autocapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (December 31, 2011):** 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 Not yet classified by the FDA 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.

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, innappropriate 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 228-231 of this Product Performance Report.	St. Jude Medical and its Medical Advisory Board 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 (December 31, 2011):** 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 December 31, 2011, there have been additional reports. The world-wide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 0.74% and 0.17%, respectively. 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 228-231 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 (December 31, 2011):** At the time of the advisory there was a world-wide reported insulation abrasion rate of 0.47% for Riata silicone leads. As of December 31, 2011, there have been additional reports and the world-wide reported insulation abrasion rate is 0.74%.

[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 (December 31, 2011):** 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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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.

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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

Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

St. Jude Medical AB
Veddestavägen 19
175 84 Järfälla
Sweden
+46 8 474 40 00
+46 8 760 95 42 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

SJMprofessional.com

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