Cardiac Rhythm Management Division

Product Performance Report

April 2011

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

April 2011

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), 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.

In addition to traditional performance reporting methods based on customer complaints and returns, this report includes data from the **S**t. Jude Medi**c**al Pr**o**duct Longevity and Perfo**r**manc**e** Registry (SCORE), which has now been actively collecting data on the reliability and performance of St. Jude Medical cardiac rhythm management products for over 3 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 will monitor 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.

St. Jude Medical is pleased to again provide survival probability and enhanced performance data for multiple products which incorporate our DF4 defibrillation connector system. This industry-first, in-line connector design consolidates one IS-1 and two DF-1 connectors, thereby reducing bulk and procedure complexity. The DF4 connector system includes our latest and most technologically advanced product offerings, notably the Durata® defibrillation lead, the Fortify® ICD and the Unify® CRT-D.

As we continually strive to provide unbiased and reliable information on the performance of our products, St. Jude Medical is pleased to release this report containing the latest performance information on our implantable cardiac monitors, ICDs, pacemakers and lead systems.

Sincerely,

Kathleen M. Chester
Sr. Vice President, Regulatory Affairs & Quality Assurance
Cardiac Rhythm Management

St. Jude Medical
More control. Less risk.

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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
- Committment to 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, 2010, including:
  - A table of basic information about each model
  - A graph and table describing survival probability
  - 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, 2010, including:
  - A table of basic information about each model
  - A graph and table describing survival probability
  - A table of all Qualifying Complications
  - A table with quantity, rate, and type of product malfunctions
- A Focus on Clinical Performance section which provides specialized analysis of Optim® lead insulation and DF4 connector system performance
- An updated summary of advisories on all implantable devices since 2003
- An index by product type and model name

What's New in This Report

Optim® Lead Insulation Performance

Optim lead insulation, a silicone-polyurethane co-polymer exclusive to St. Jude Medical, has been on the market for more than 4 years, with over 450,000 low voltage, defibrillation, and CRT leads implanted in the U.S.. Starting with the May 2010 Product Performance Report St. Jude Medical has provided an up-to-date analysis of Optim lead insulation performance in the Focus on Clinical Performance section. This analysis has consistently demonstrated a statistically and clinically significant reduction in Optim-insulated lead abrasion failures as compared to silicone-insulated leads. This edition of the Product Performance Report contains an updated analysis with 85,000 new Optim lead implants and up to 54 months of implant time.

DF4 Connector System Data

St. Jude Medical is pleased to update its reporting on the performance of the DF4 connector system. As of December 31, 2010, there have been over 36,000 DF4 system implants in the U.S.. The Fortify® VR model CD1231-40Q and Durata® models 7170Q and 7171Q are the latest DF4 system components to qualify for Customer Reported Performance Reporting, supplementing the previously reported Current®, Current®+, Promote®+, Fortify, Unify®, and Durata models. With over 300 SCORE registry implants, the Promote+ model CD3211-36Q and Current DR model CD2211-36Q are the first ICDs to qualify for reporting of SCORE performance data. A performance comparison between DF4 and IS-1/DF-1 connector systems in the Focus on Clinical Performance section has been updated with more than 25,000 new system implants.

Customer Reported Performance Data Incorporates New Models

As per the inclusion criteria described in the "Survival Calculation General Methods" section, Customer Reported Performance Data for the following models are present in the St. Jude Medical Product Performance Report for the first time.

Leads: QuickFlex® µ (model 1258), Durata® DF4 (models 7170Q and 7171Q), OptiSense® Optim® (Model 1999), and Tendril® STS (Model 2088)

Pacemaker: Accent® SR (Model PM1110)

ICDs/CRT-Ds: Fortify® VR (models CD1231-40 and CD1231-40Q), Fortify® DR (model CD2231-40), Unify® (model CD3231-40)

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.

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 is 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 an Accent DR 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. A device that does not exceed

75% of its estimated longevity would be considered a premature battery depletion malfunction (either with or without compromised therapy), provided that actual device setting information is available. 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 Uniformed 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.

The quantity and type of malfunctions recorded for each ICD, pacemaker, and ICM model are presented on the Customer Reported Performance Data page. The definition of each malfunction type is important to understanding the survival data.

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.

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.

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 and includes a method to adjust for under reporting. 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.

Each survival curve contains a horizontal bar labeled "Battery Longevity". For pacemakers, the center of the Battery Longevity bar represents mean longevity, as defined on page 4 of the PPR and provided in the product literature. Mean longevity is also presented in the header information of each Customer Reported Performance Data page of this Product Performance Report. The left and right bounds of the bar indicate ± 3 sigma of the predicted pacemaker longevity distribution. For ICDs, the left and right bounds of the Battery Longevity bar represent the mean longevity at 100% pacing and 0% pacing, respectively, as presented in the product literature and the Product Performance Report summary tables.

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 an electrical 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.

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 extra cardiac 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. 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 (e.g. fractured conductors). 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 have now been added to the malfunction data. 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 abrasions 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, and 3) distal region wear due to lead-to-lead (intracardiac), lead-to-heart valve or lead-to-other anatomy contact.

Subcategories of insulation breach have also been added to the malfunction data of defibrillation leads. 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 breech.

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.[1,2,3,4,5,6] This is a specific failure mechanism which we continue to actively investigate to further understand its incidence rate and clinical consequences. This failure mechanism has only been observed on our Riata® and Riata® ST silicone family of defibrillation leads and has not been seen on our Riata® ST Optim® and Durata® family of leads which employ the Optim lead insulation material. The incidence rate of U.S. abrasion malfunctions for Riata/Riata ST models is summarized on pages 135-136 of this Product Performance Report.

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.

[1]Erkapic D, Duray GZ, Bauernfeind T, De Rosa S, Hohnloser SH. Insulation Defects of Thin High-Voltage ICD Leads: An Understimated Problem?. *J. Cardiovasc Electrophysiol*, 2011, On-Line Ahead of Print.

[2]Krebsbach A, Alhumaid F. Henrikson CA, Calkins H, Berger RD, Cheng A. Premature Failure of a Riata Defibrillator Lead without Impedance Change or Inappropriate Sensing: A Case Report and Review of the Literature, *J Cardiovasc Electrophysiol*, 2011, On-Line Ahead of Print.

[3]Valk S, Luijten R, Jordaens L. Insulation Damage in a Shock Wire: An Unexpected Fluoroscopic Image. *PACE* 33, 770-772 (2010).

[4]Richards M, Warren C, Anderson M. Late failure of a single-coil Transvenous implantable cardioverter-defibrillator lead associated with conductor separation. *Europace*, 12, 1191-1192 (2010).

[5]Jalal Z, Derval N, Ploux S, Bordachar P. Unusual failure of a multilumen, small-diameter implantable cardioverter-defibrillator lead. Heart Rhythm, 8, 1166-67 (2010).

[6]Duray G, Israel C, Schmitt J, Hohnloser S. Implantable cardioverter-defibrillator lead disintegration at that level of the tricuspid valve. Heart Rhythm, 5, 1224-5 (2008).

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 50 clinical sites are participating in the SCORE Registry with approximately 8,400 patients enrolled as of December 31, 2010. 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.

Included Models

In order for a device model to report SCORE Registry data, a minimum of 100 devices must been enrolled in the registry as of December 31, 2010, with the latest interval to be reported having a minimum of 50 devices which have been followed for at least six months. Eight model families meet the inclusion criteria for the first time in this report. Below is a complete list of all thirty-six models which will report SCORE performance data:

ICDs

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)*

Pacemakers

Accent® DR RF (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)

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)

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)

CRT Leads

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

*New for April 2011 report.

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)	**Lead-Focused**
Dr. Steven Bailin, Des Moines, Iowa	Dr. Roger Freedman, Salt Lake City, Utah
Dr. Jim Baker, Nashville, Tennessee	Dr. David Hayes, Rochester, Minnesota
Dr. Anne Curtis, Buffalo, New York	Dr. Steven Kalbfleisch, Columbus, Ohio
Dr. Steve Greenberg, Roslyn, New York	Dr. Steven Kutalek, Philadelphia, Pennsylvania
Dr. Thomas Mattioni, Phoenix, Arizona	Dr. Raymond Schaerf, Burbank, California
Dr. Gery Tomassoni, Lexington, Kentucky	Dr. Bruce Wilkoff, Cleveland, Ohio

Returning Devices To St. Jude Medical

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

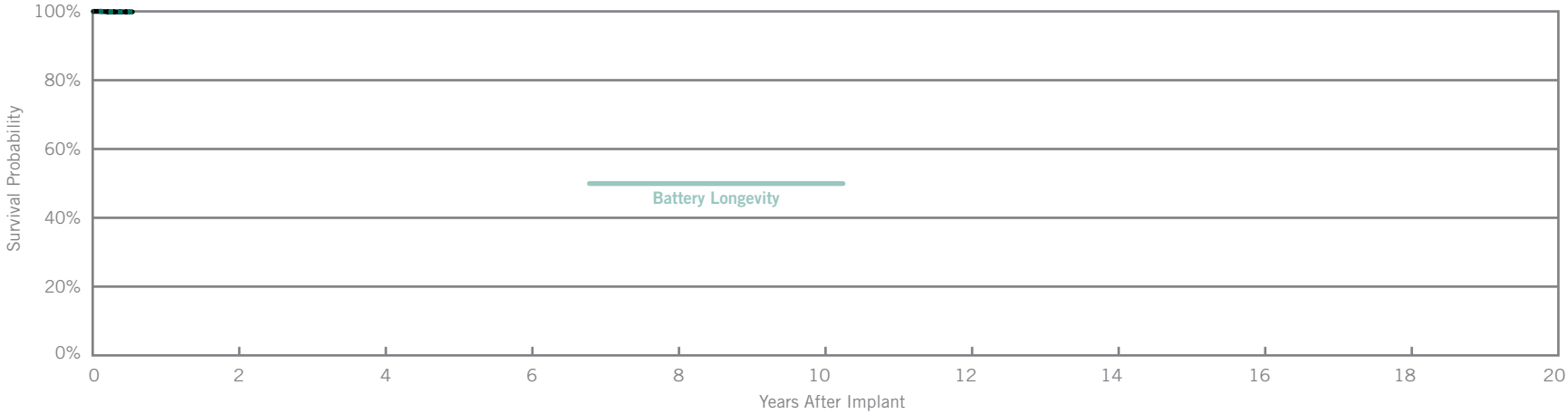
Customer Reported Performance Data

Unify®

Model CD3231-40Q

US Regulatory Approval	May 2010
Registered US Implants	5,979
Estimated Active US Implants	5,761
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.02%
Malfunctions w/o Compromised Therapy	1	0.02%
Total	**2**	**0.03%**



Including Normal Battery Depletion .....

Year	at 7 months										
Survival Probability	99.86%										
± 1 standard error	0.06%										
Sample Size	700										

Excluding Normal Battery Depletion ———

Year	at 7 months										
Survival Probability	99.86%										
± 1 standard error	0.06%										

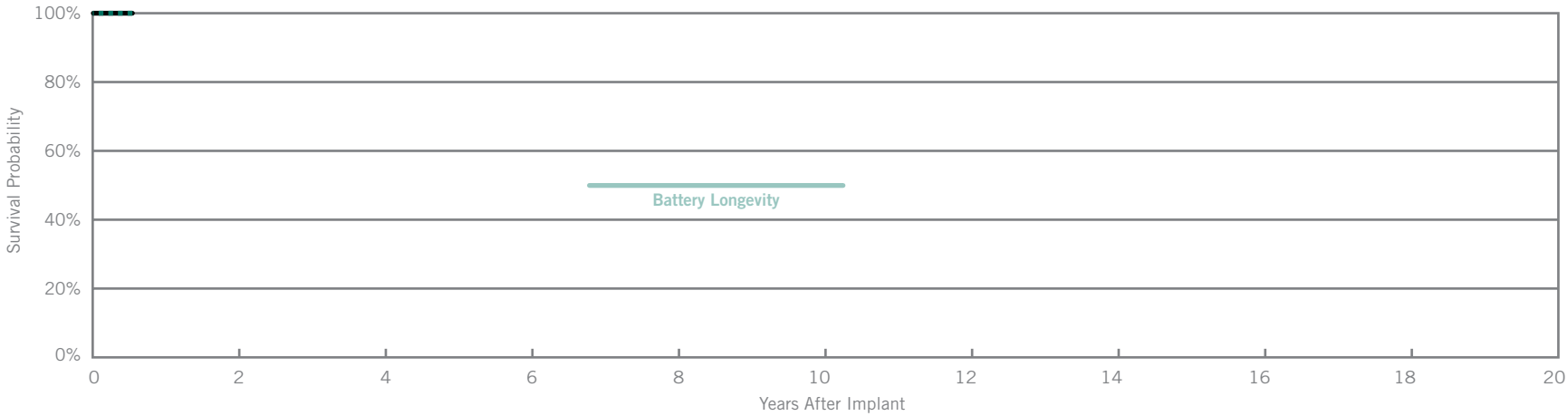
Customer Reported Performance Data

Unify®

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	4,773
Estimated Active US Implants	4,623
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion .....

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	400										

Excluding Normal Battery Depletion ———

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

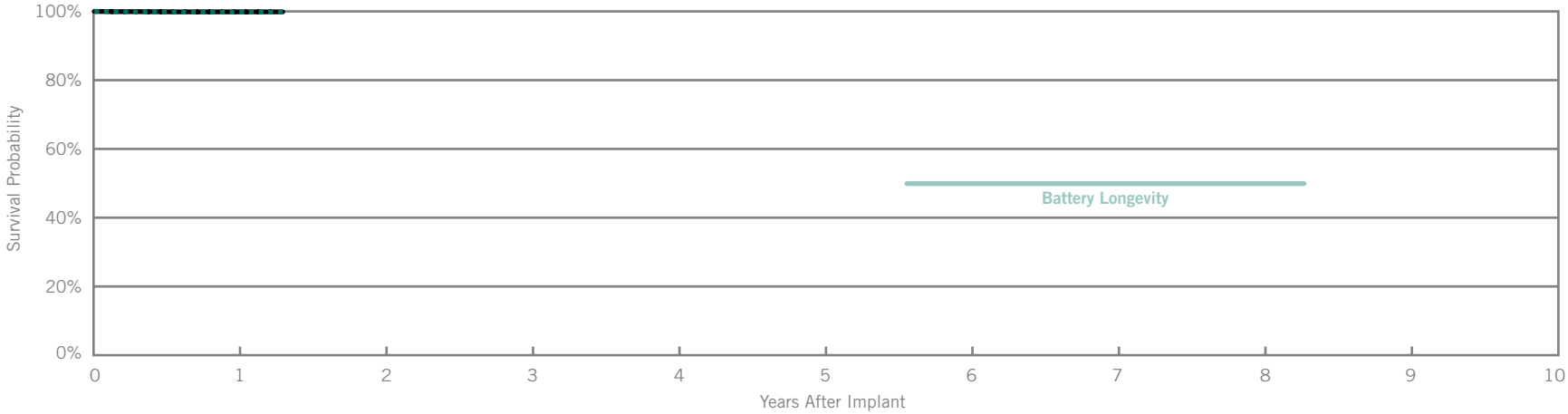
Customer Reported Performance Data

Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	7,161
Estimated Active US Implants	6,398
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	2	0.03%
Malfunctions w/o Compromised Therapy	2	0.03%
Total	**4**	**0.06%**



Including Normal Battery Depletion .....

Year	1	at 16 months								
Survival Probability	99.80%	99.80%								
± 1 standard error	0.06%	0.06%								
Sample Size	4900	500								

Excluding Normal Battery Depletion ——

Year	1	at 16 months								
Survival Probability	99.86%	99.86%								
± 1 standard error	0.05%	0.05%								

SCORE Registry Performance Data

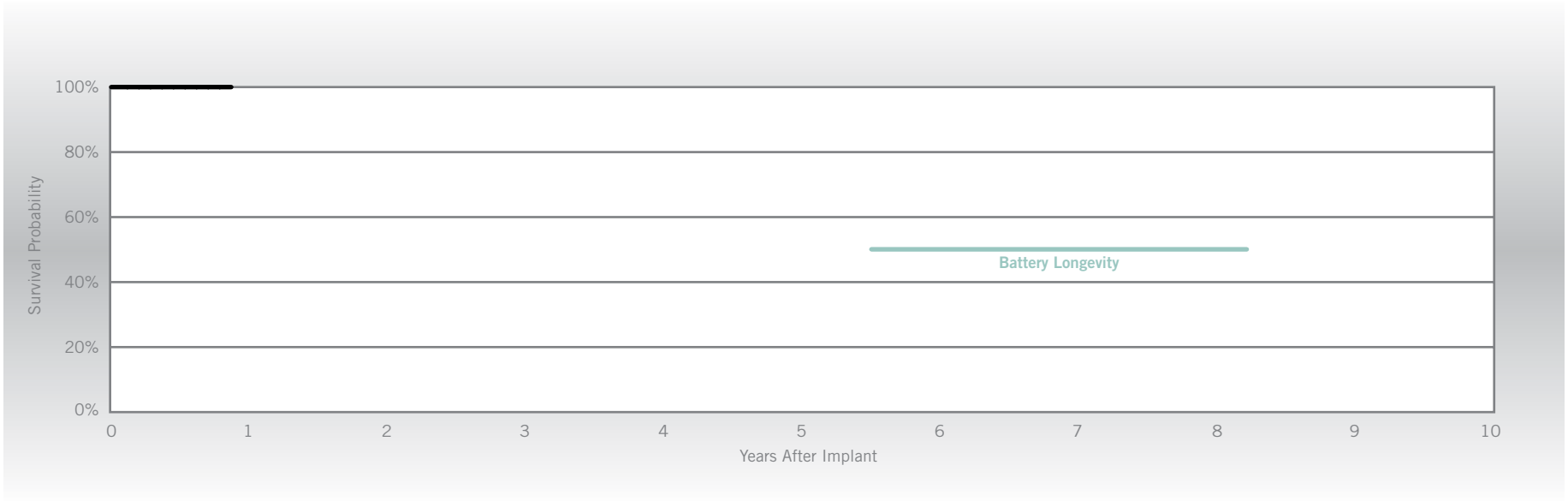
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	123
Cumulative Months of Follow-up	1,309
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	at 11 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

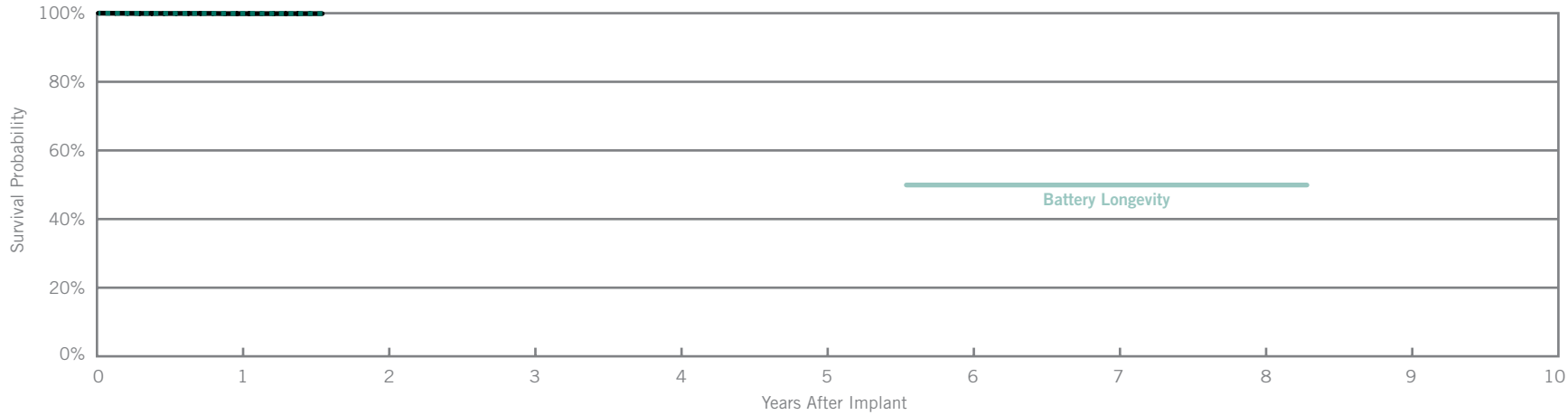
Customer Reported Performance Data

Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,050
Estimated Active US Implants	7,055
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	2	0.02%
Malfunctions w/o Compromised Therapy	2	0.02%
Total	**4**	**0.05%**



Including Normal Battery Depletion .....

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.05%	0.05%								
Sample Size	6200	500								

Excluding Normal Battery Depletion ———

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.05%	0.05%								

SCORE Registry Performance Data

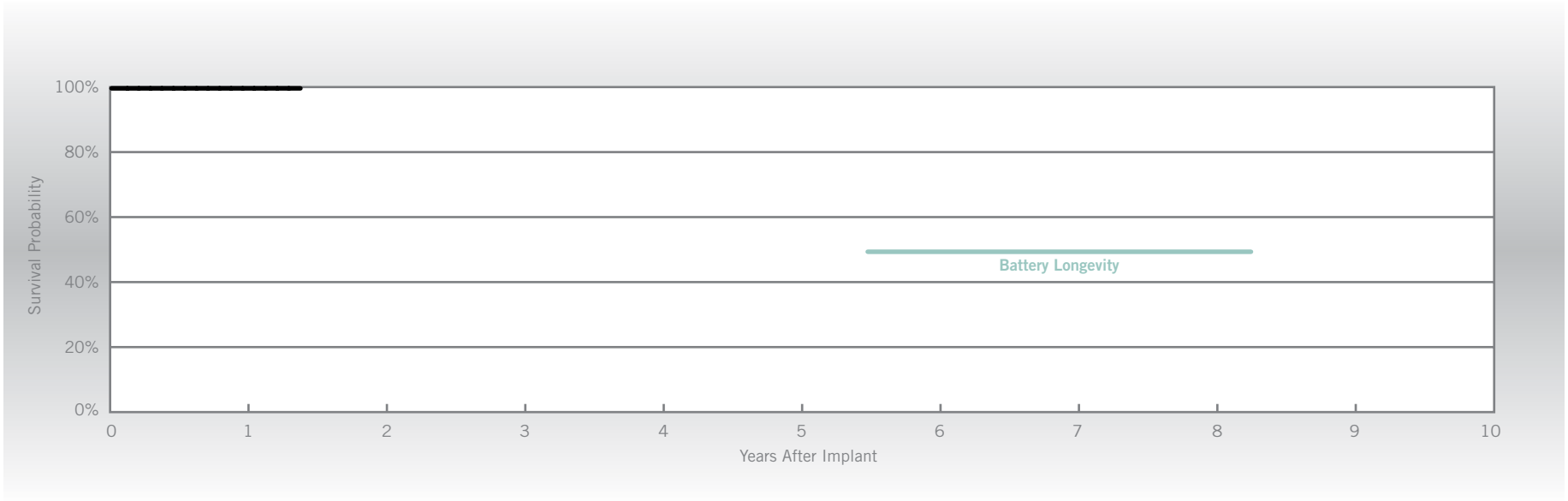
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	257
Cumulative Months of Follow-up	3,379
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	1	0.39%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1	at 17 months								
Survival Probability	99.61%	99.61%								
± 1 standard error	0.39%	0.39%								
Sample Size	200	60								

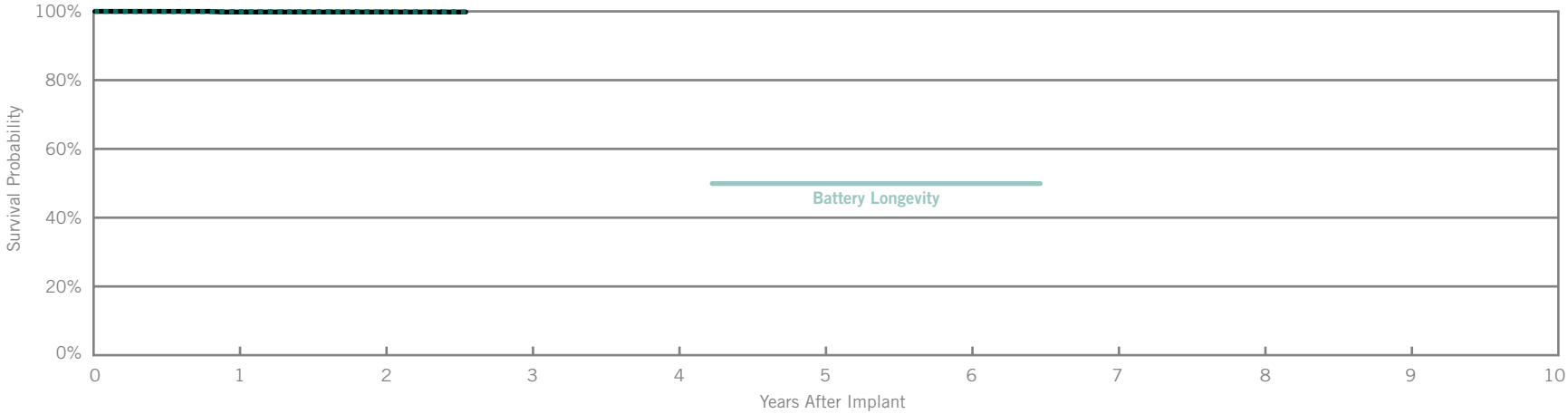
Customer Reported Performance Data

Promote® RF

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,409
Estimated Active US Implants	1,060
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.07%
Total	**1**	**0.07%**



Including Normal Battery Depletion .....

Year	1	2	at 31 months							
Survival Probability	99.82%	99.82%	99.82%							
± 1 standard error	0.13%	0.13%	0.13%							
Sample Size	1300	800	200							

Excluding Normal Battery Depletion ———

Year	1	2	at 31 months							
Survival Probability	99.82%	99.82%	99.82%							
± 1 standard error	0.13%	0.13%	0.13%							

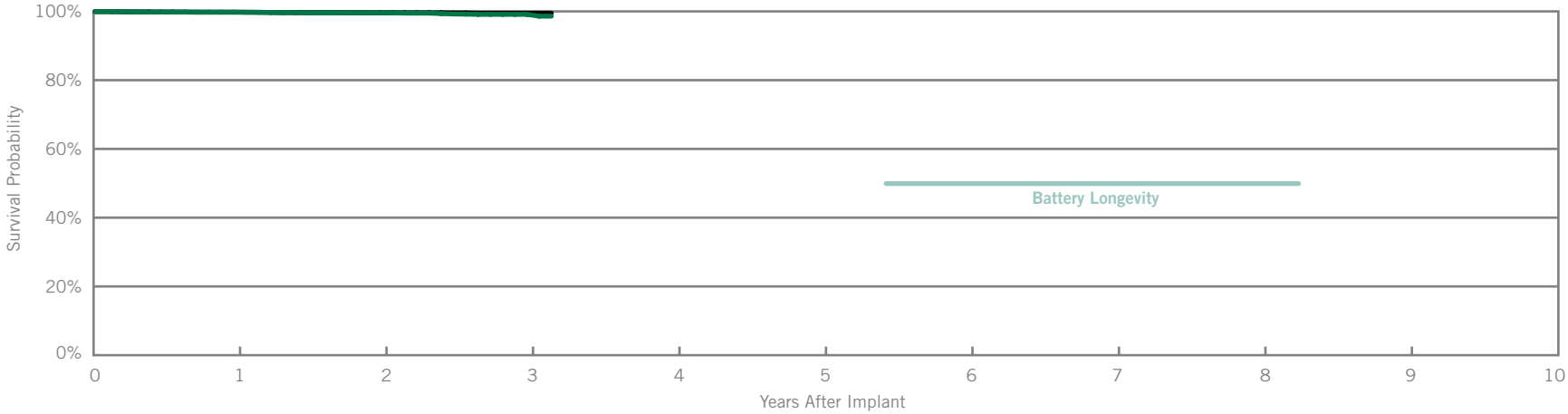
Customer Reported Performance Data

Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,730
Estimated Active US Implants	18,108
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	11
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	14	0.06%
Malfunctions w/o Compromised Therapy	21	0.09%
Total	**35**	**0.15%**



Including Normal Battery Depletion .....

Year	1	2	3	at 38 months						
Survival Probability	99.76%	99.56%	99.13%	98.61%						
± 1 standard error	0.03%	0.05%	0.11%	0.38%						
Sample Size	23000	15000	5100	200						

Excluding Normal Battery Depletion ———

Year	1	2	3	at 38 months						
Survival Probability	99.78%	99.61%	99.48%	99.48%						
± 1 standard error	0.03%	0.04%	0.07%	0.07%						

SCORE Registry Performance Data

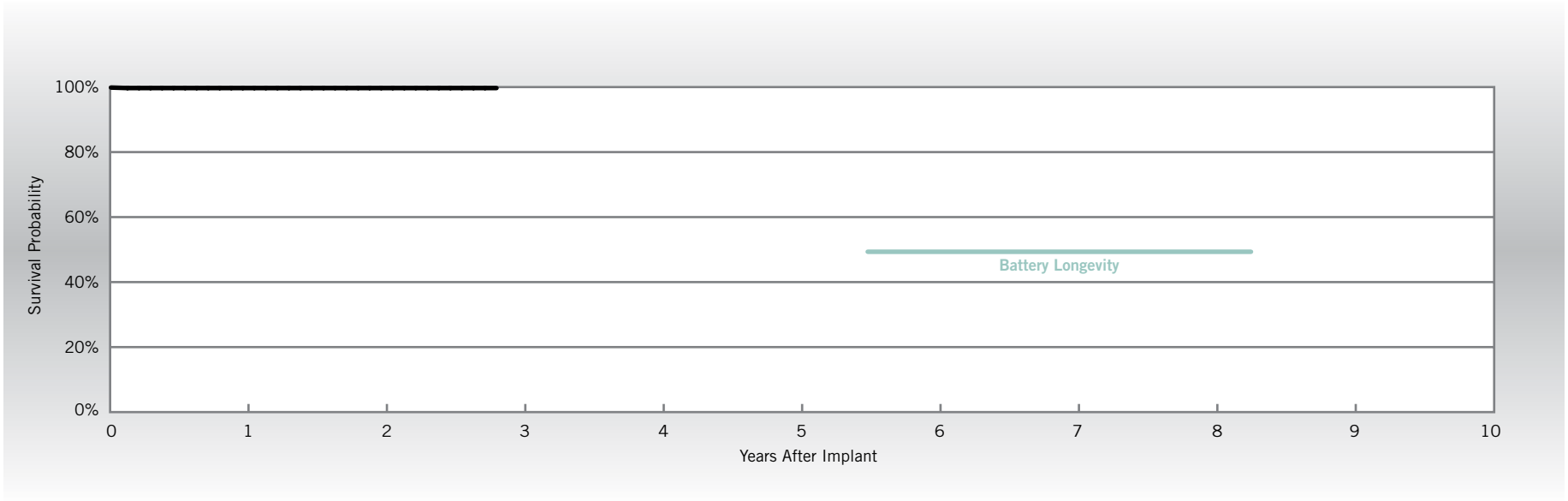
Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	669
Cumulative Months of Follow-up	16,578
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.30%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	1	0.39%
Malfunctions w/o Compromised Therapy	2	0.78%
Total	**3**	**1.17%**



Year	1	2	at 34 months							
Survival Probability	99.70%	99.70%	99.70%							
± 1 standard error	0.21%	0.21%	0.21%							
Sample Size	650	500	50							

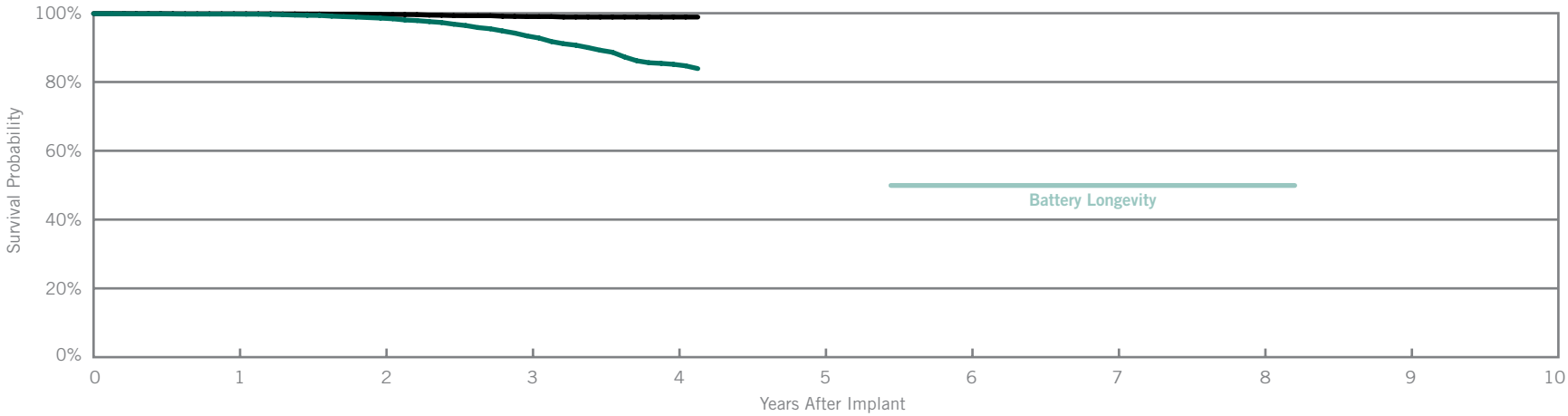
Customer Reported Performance Data

Atlas® II HF

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	8,390
Estimated Active US Implants	4,234
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	210
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	18	0.21%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	10	0.12%
Total (0 related to Advisory)	**28**	**0.33%**



Including Normal Battery Depletion

Year	1	2	3	4	at 50 months					
Survival Probability	99.75%	98.58%	93.40%	85.14%	83.90%					
± 1 standard error	0.06%	0.14%	0.31%	0.63%	0.72%					
Sample Size	8400	7200	5800	2800	100					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 50 months					
Survival Probability	99.83%	99.67%	99.02%	98.88%	98.88%					
± 1 standard error	0.05%	0.06%	0.13%	0.14%	0.14%					

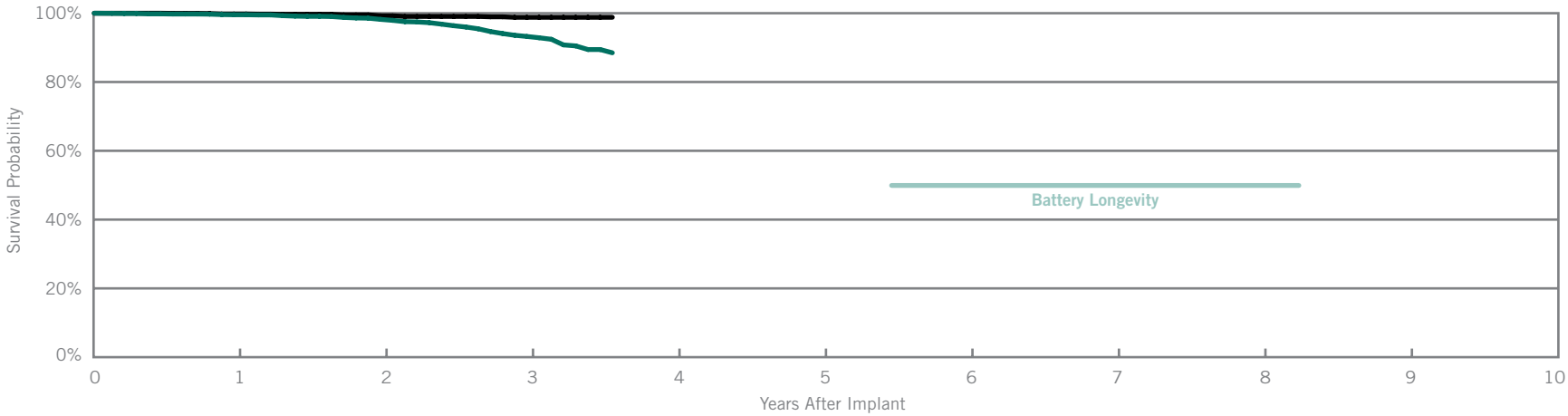
Customer Reported Performance Data

Atlas® II + HF

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	4,993
Estimated Active US Implants	3,146
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	61
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	8	0.16%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	7	0.14%
Total (0 related to Advisory)	**15**	**0.30%**



Including Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.55%	98.21%	93.24%	88.49%						
± 1 standard error	0.09%	0.20%	0.52%	0.87%						
Sample Size	4900	3700	2200	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.79%	99.25%	98.81%	98.81%						
± 1 standard error	0.07%	0.11%	0.21%	0.21%						

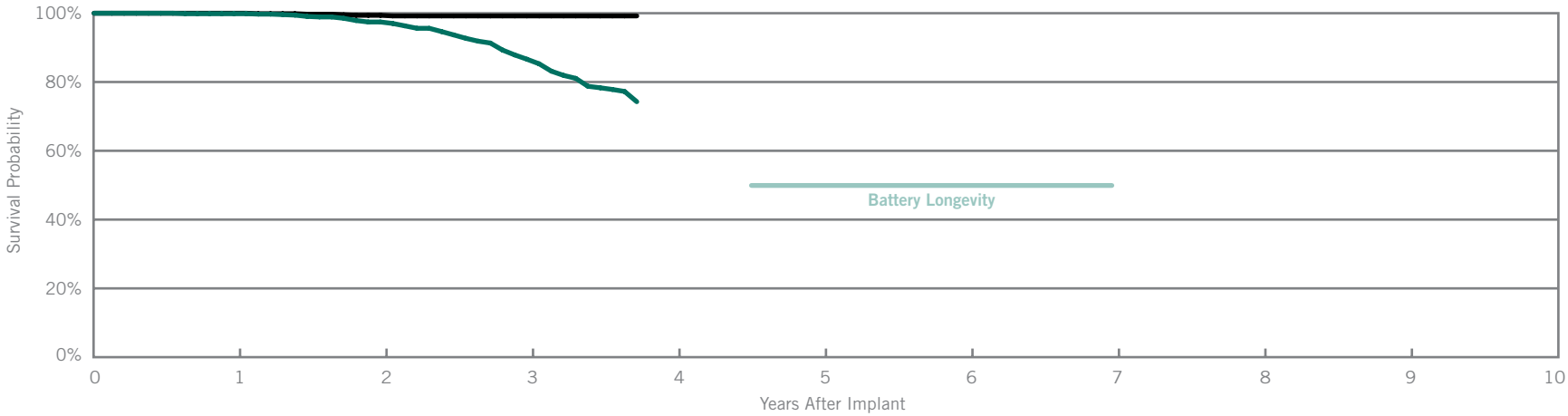
Customer Reported Performance Data

Epic® II HF

Model V-355

US Regulatory Approval	March 2006
Registered US Implants	1,743
Estimated Active US Implants	697
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	78
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	0.11%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	3	0.17%
Total (0 related to Advisory)	**5**	**0.29%**



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.87%	97.45%	86.62%	74.27%						
± 1 standard error	0.09%	0.44%	1.03%	1.56%						
Sample Size	1700	1400	1100	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	100.00%	99.39%	99.21%	99.21%						
± 1 standard error	0.00%	0.22%	0.25%	0.25%						

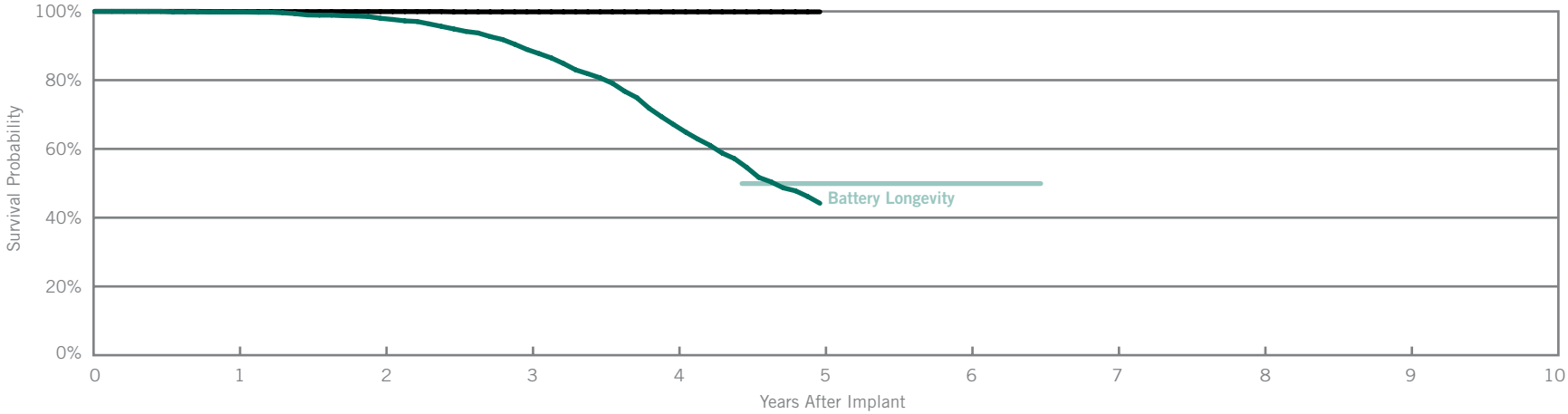
Customer Reported Performance Data

Epic® HF

Model V-337

US Regulatory Approval	November 2004
Registered US Implants	3,974
Estimated Active US Implants	681
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	389
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	1	0.03%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.03%
Total (0 related to Advisory)	**2**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	99.80%	98.00%	88.93%	67.12%	44.19%					
± 1 standard error	0.07%	0.22%	0.56%	0.99%	1.47%					
Sample Size	4000	3400	2900	2100	900					

Excluding Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	99.94%	99.94%	99.87%	99.87%	99.87%					
± 1 standard error	0.04%	0.04%	0.07%	0.07%	0.07%					

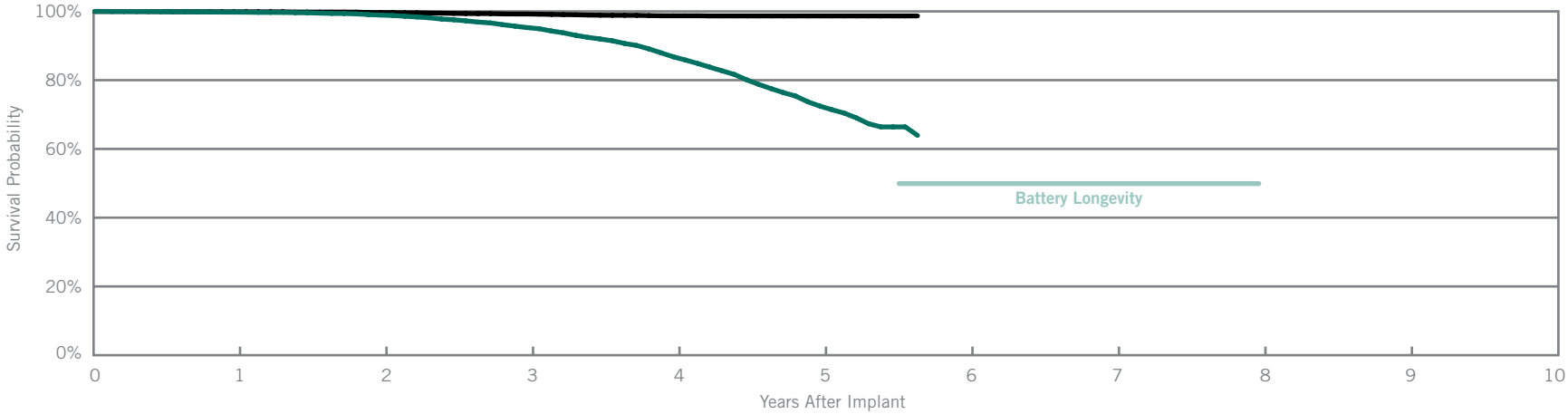
Customer Reported Performance Data

Atlas® + HF

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,655
Estimated Active US Implants	6,722
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	754
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (1 related to Advisory)	49	0.26%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	17	0.09%
Total (0 related to Advisory)	**66**	**0.35%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.78%	98.93%	95.29%	86.78%	72.45%	63.93%				
± 1 standard error	0.04%	0.08%	0.18%	0.31%	0.59%	0.62%				
Sample Size	18700	15900	13600	10300	5100	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.88%	99.66%	99.24%	98.72%	98.68%	98.68%				
± 1 standard error	0.03%	0.05%	0.07%	0.11%	0.11%	0.11%				

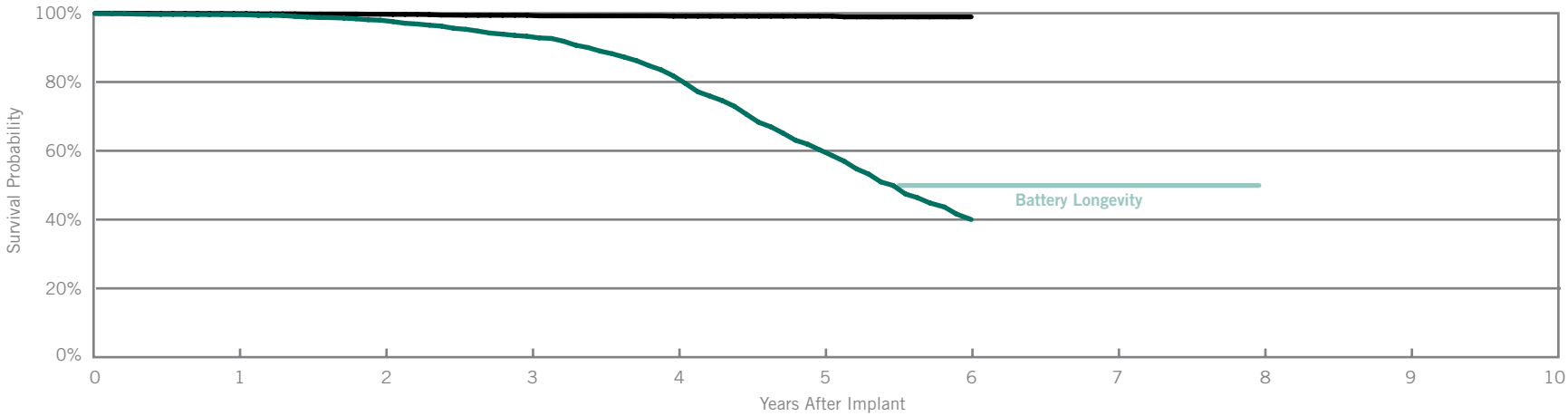
Customer Reported Performance Data

Atlas® + HF

Model V-340

US Regulatory Approval	June 2004
Registered US Implants	4,933
Estimated Active US Implants	562
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	476
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	Three

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (1 related to Advisory)	10	0.20%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	5	0.10%
Total (1 related to Advisory)	**15**	**0.30%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.57%	97.97%	93.29%	81.76%	60.25%	40.02%				
± 1 standard error	0.09%	0.21%	0.41%	0.67%	0.99%	1.35%				
Sample Size	4900	4200	3700	3000	2100	900				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.87%	99.71%	99.40%	99.14%	99.14%	98.93%				
± 1 standard error	0.04%	0.08%	0.13%	0.15%	0.16%	0.22%				

Battery Longevity Summary

CRT ICDs

St. Jude Medical™
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3231-40Q	Unify® **	10.2	9.0	8.1	6.7
CD3231-40	Unify® **	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-355	Epic® II HF	7.0	6.1	5.5	4.5
V-337	Epic® HF, Serial Numbers <13000	6.4	5.7	5.2	4.4
V-337	Epic® HF, Serial Numbers >13000	6.5	5.8	5.2	4.4
V-343	Atlas® + HF	7.9	7.1	6.4	5.4
V-340	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®*										
CD3231-40	Unify®*										
CD3211-36Q	Promote® + CRT-D	99.80%									
CD3211-36	Promote® + CRT-D	99.87%									
3207-30	Promote® RF	99.82%	99.82%								
3207-36	Promote® RF	99.76%	99.56%	99.13%							
V-365	Atlas® II HF	99.75%	98.58%	93.40%	85.14%						
V-366	Atlas® II + HF	99.55%	98.21%	93.24%							
V-355	Epic® II HF	99.87%	97.45%	86.62%							
V-337	Epic® HF	99.80%	98.00%	88.93%	67.12%	44.19%					
V-343	Atlas® + HF	99.78%	98.93%	95.29%	86.78%	72.45%					
V-340	Atlas® + HF	99.57%	97.97%	93.29%	81.76%	60.25%	40.02%				

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3231-40Q	Unify®*										
CD3231-40	Unify®*										
CD3211-36Q	Promote® + CRT-D	99.86%									
CD3211-36	Promote® + CRT-D	99.87%									
3207-30	Promote® RF	99.82%	99.82%								
3207-36	Promote® RF	99.78%	99.61%	99.48%							
V-365	Atlas® II HF	99.83%	99.67%	99.02%	98.88%						
V-366	Atlas® II + HF	99.79%	99.25%	98.81%							
V-355	Epic® II HF	100.00%	99.39%	99.21%							
V-337	Epic® HF	99.94%	99.94%	99.87%	99.87%	99.87%					
V-343	Atlas® + HF	99.88%	99.66%	99.24%	98.72%	98.68%					
V-340	Atlas® + HF	99.87%	99.71%	99.40%	99.14%	99.14%	98.93%				

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	May 10	5979	5761	1	0.02%	1	0.02%	0	0.00%	1	0.02%	2	0.03%
CD3231-40	Unify®	May 10	4773	4623	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD3211-36Q	Promote® + CRT-D	Feb 09	7161	6398	2	0.03%	2	0.03%	0	0.00%	2	0.03%	4	0.06%
CD3211-36	Promote® + CRT-D	Feb 09	8050	7055	1	0.01%	2	0.02%	1	0.01%	2	0.02%	4	0.05%
3207-30	Promote® RF	Sep-07	1409	1060	0	0.00%	0	0.00%	1	0.07%	1	0.07%	1	0.07%
3207-36	Promote® RF	Sep-07	23730	18108	2	0.01%	14	0.06%	8	0.03%	21	0.09%	35	0.15%
V-365	Atlas® II HF	Jul-06	8390	4234	11	0.13%	18	0.21%	8	0.10%	10	0.12%	28	0.33%
V-366	Atlas® II + HF	Feb-07	4993	3146	8	0.16%	8	0.16%	6	0.12%	7	0.14%	15	0.30%
V-355	Epic® II HF	Mar-06	1743	697	1	0.06%	2	0.11%	2	0.11%	3	0.17%	5	0.29%
V-337	Epic® HF	Nov-04	3974	681	1	0.03%	1	0.03%	0	0.00%	1	0.03%	2	0.05%
V-343	Atlas® + HF	Nov-04	18655	6722	45	0.24%	49	0.26%	11	0.06%	17	0.09%	66	0.35%
V-340	Atlas® + HF	Jun-04	4933	562	6	0.12%	10	0.20%	5	0.10%	5	0.10%	15	0.30%

**Totals include Premature Battery Depletion and all other confirmed malfunctions, including those related to advisories.*

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3211-36Q	123	1309	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD3211-36	257	3379	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
3207-36	669	16578	1	0.39%	1	0.39%	1	0.39%	2	0.78%	3	1.17%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Extracardiac Stimulation		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3211-36Q	123	1309	0	0.00%	0	0.00%	0	0.00%
CD3211-36	257	3379	0	0.00%	1	0.39%	1	0.39%
3207-36	669	16578	2	0.30%	0	0.00%	2	0.30%

** Totals include Premature Battery Depletion and all other confirmed malfunctions.*

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical
More control. Less risk.

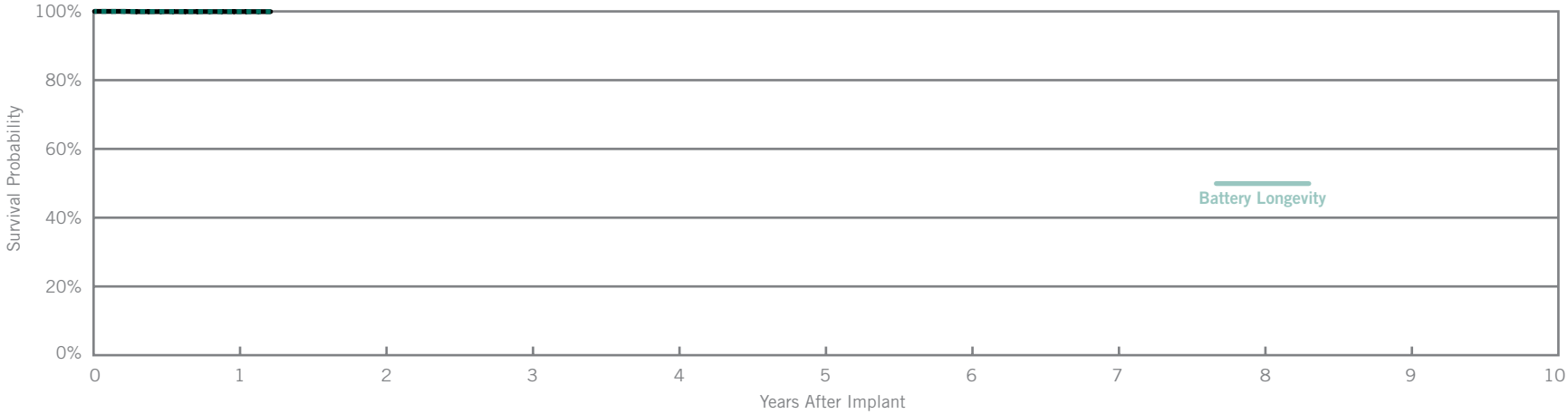
Customer Reported Performance Data

Anthem® RF

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	4,169
Estimated Active US Implants	3,763
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.02%
Total	**1**	**0.02%**



Including Normal Battery Depletion .....

Year	1	at 15 months								
Survival Probability	99.93%	99.93%								
± 1 standard error	0.05%	0.05%								
Sample Size	2600	300								

Excluding Normal Battery Depletion ———

Year	1	at 15 months								
Survival Probability	99.93%	99.93%								
± 1 standard error	0.05%	0.05%								

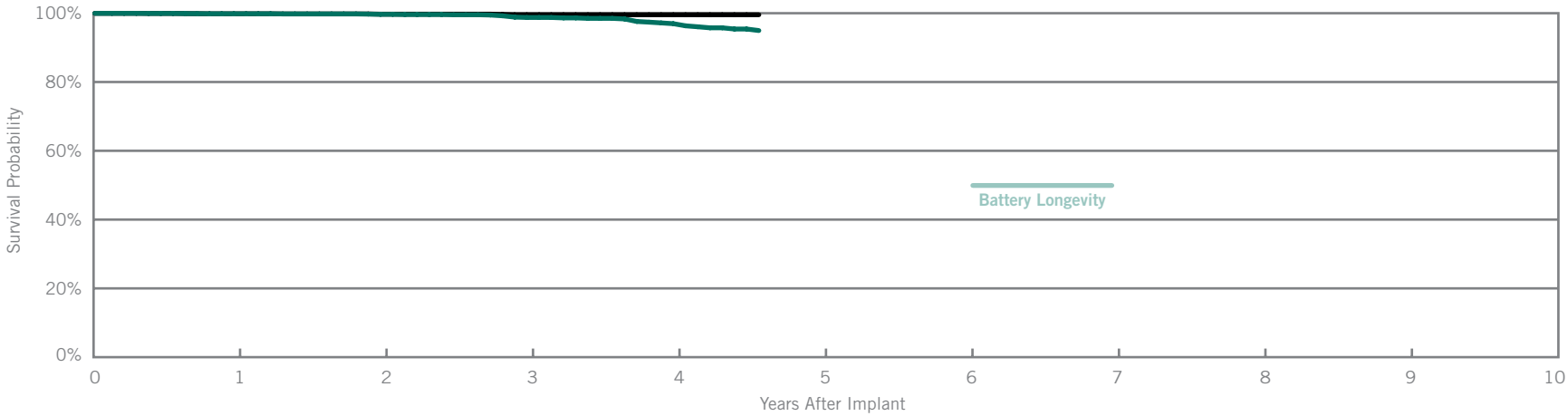
Customer Reported Performance Data

Frontier® II

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,708
Estimated Active US Implants	3,845
Estimated Longevity	6.5 Years
Normal Battery Depletion	33
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	8	0.12%
Total	**9**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.83%	99.68%	98.76%	96.95%	94.96%					
± 1 standard error	0.05%	0.07%	0.21%	0.43%	0.65%					
Sample Size	6600	4800	2900	1500	500					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.83%	99.73%	99.55%	99.55%	99.55%					
± 1 standard error	0.05%	0.06%	0.12%	0.12%	0.12%					

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®	99.93%									
5586	Frontier® II	99.83%	99.68%	98.76%	96.95%						

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®	99.93%									
5586	Frontier® II	99.83%	99.73%	99.55%	99.55%						

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem®	Jul-09	4169	3763	0	0.00%	0	0.00%	0	0.00%	1	0.02%	1	0.02%
5586	Frontier® II	Aug-04	6708	3845	0	0.00%	1	0.01%	0	0.00%	8	0.12%	9	0.13%

**Totals include Premature Battery Depletion and all other confirmed malfunctions, including those related to advisories.*

Left-Heart Leads

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

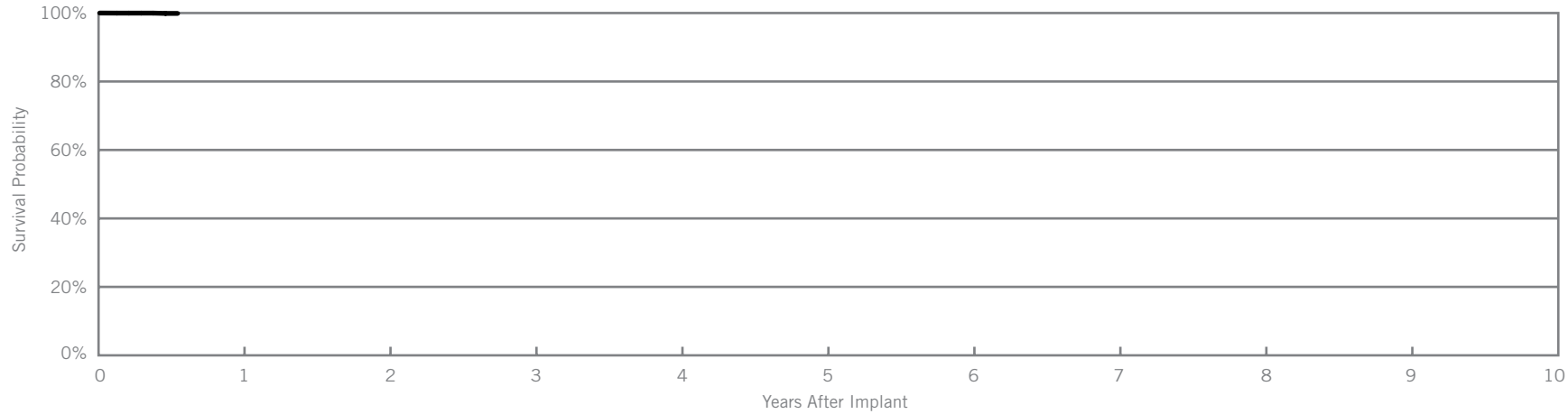
QuickFlex® µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	6,926
Estimated Active US Implants	6,281
Insulation	Optim*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	0	0.00%	1	0.01%
Failure to Capture	3	0.04%	1	0.01%
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%	0	0.00%
Extracardiac Stimulation	8	0.12%	3	0.04%
Other	1	0.01%	1	0.01%
Total	**12**	**0.17%**	**6**	**0.09%**
Total Returned for Analysis	**1**		**1**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	6	0.09%
Total	**7**	**0.10%**



Year	at 7 months										
Survival Probability	99.89%										
± 1 standard error	0.09%										
Sample Size	800										

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

Customer Reported Performance Data

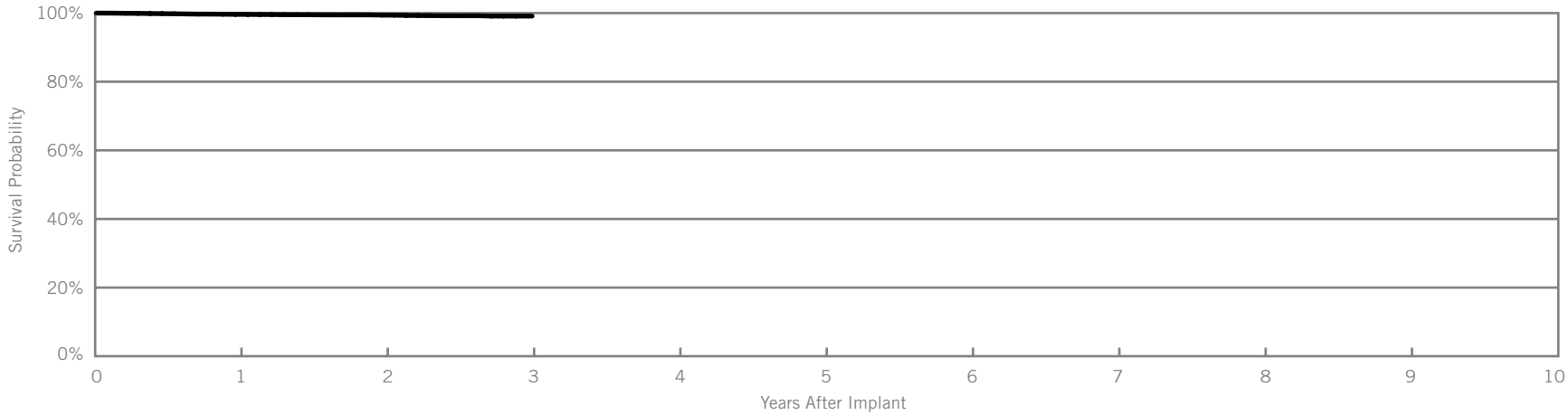
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	24,705
Estimated Active US Implants	19,478
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	10	0.04%	25	0.10%
Failure to Capture	5	0.02%	9	0.04%
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	16	0.06%	15	0.06%
Other	8	0.03%	2	0.01%
Total	**39**	**0.16%**	**59**	**0.24%**
Total Returned for Analysis	**12**		**24**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	3	0.01%
Extrinsic Factors	26	0.11%
Total	**33**	**0.13%**



Year	1	2	3							
Survival Probability	99.63%	99.41%	99.13%							
± 1 standard error	0.04%	0.06%	0.14%							
Sample Size	19700	9500	2600							

SCORE Registry Performance Data

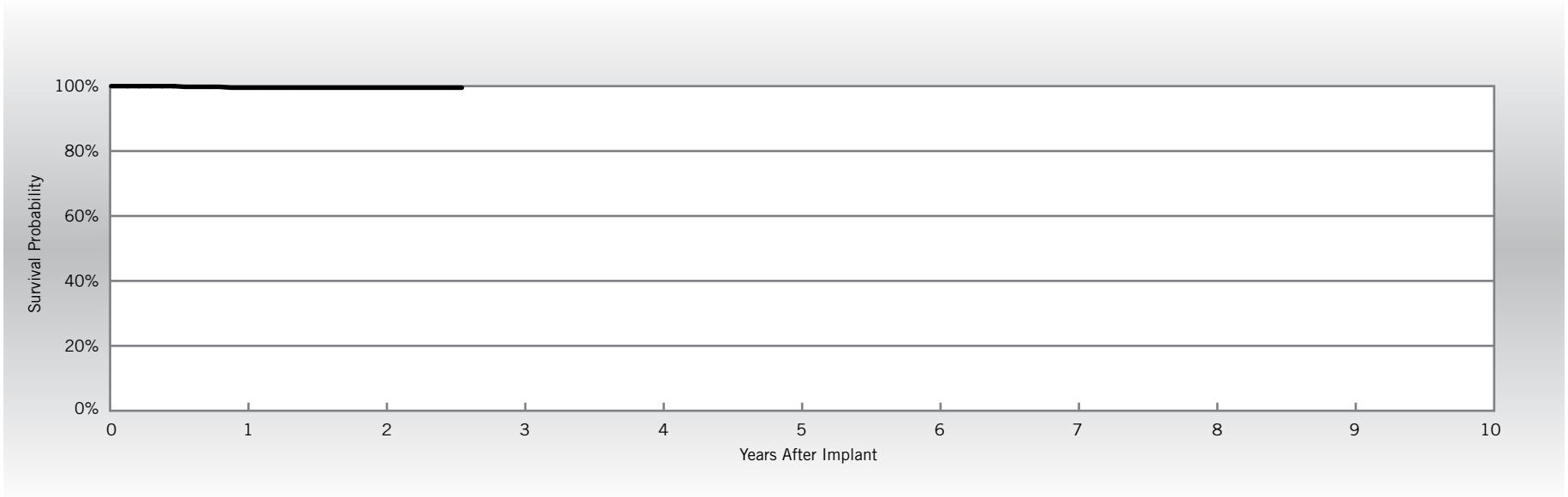
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	521
Cumulative Months of Follow-up	9,574
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.19%
Failure to Capture	1	0.19%

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	0.19%
Total	**1**	**0.19%**



Year	1	2	at 31 months							
Survival Probability	99.52%	99.52%	99.52%							
± 1 standard error	0.33%	0.33%	0.33%							
Sample Size	440	260	70							

Customer Reported Performance Data

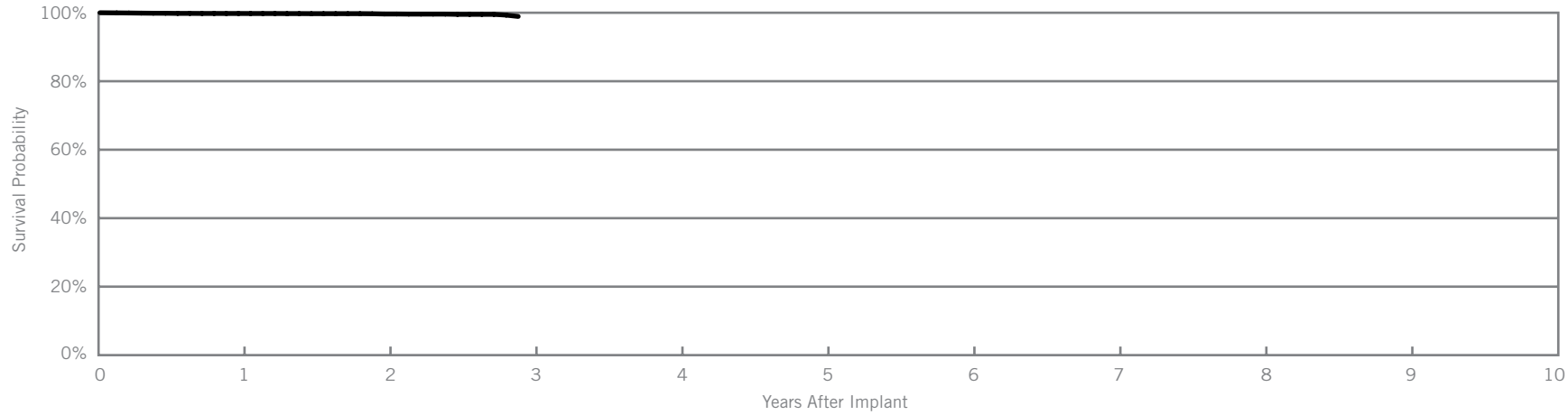
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	13,196
Estimated Active US Implants	10,234
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.03%	22	0.17%
Failure to Capture	1	0.01%	4	0.03%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	2	0.02%
Extracardiac Stimulation	5	0.04%	6	0.05%
Other	6	0.05%	1	0.01%
Total	**18**	**0.14%**	**36**	**0.27%**
Total Returned for Analysis	**6**		**16**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	18	0.14%
Total	**21**	**0.16%**



Year	1	2	at 35 months							
Survival Probability	99.78%	99.63%	98.92%							
± 1 standard error	0.05%	0.06%	0.25%							
Sample Size	10400	5200	300							

SCORE Registry Performance Data

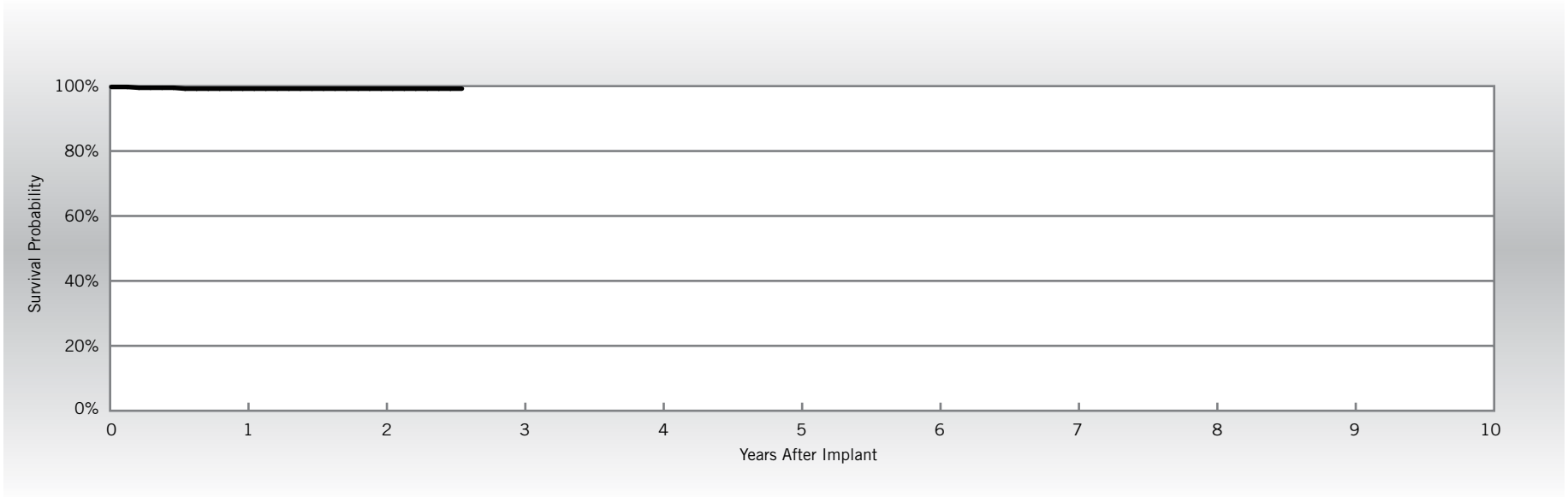
QuickFlex® XL

Model 1158T

US Regulatory Approval	JJuly 2007
Number of Devices Enrolled in Study	403
Cumulative Months of Follow-up	7,695
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	1	0.25%
Extracardiac Stimulation	2	0.50%

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	3	0.74%
Total	**3**	**0.74%**



Year	1	2	at 31 months							
Survival Probability	99.21%	99.21%	99.21%							
± 1 standard error	0.45%	0.45%	0.45%							
Sample Size	340	210	60							

Customer Reported Performance Data

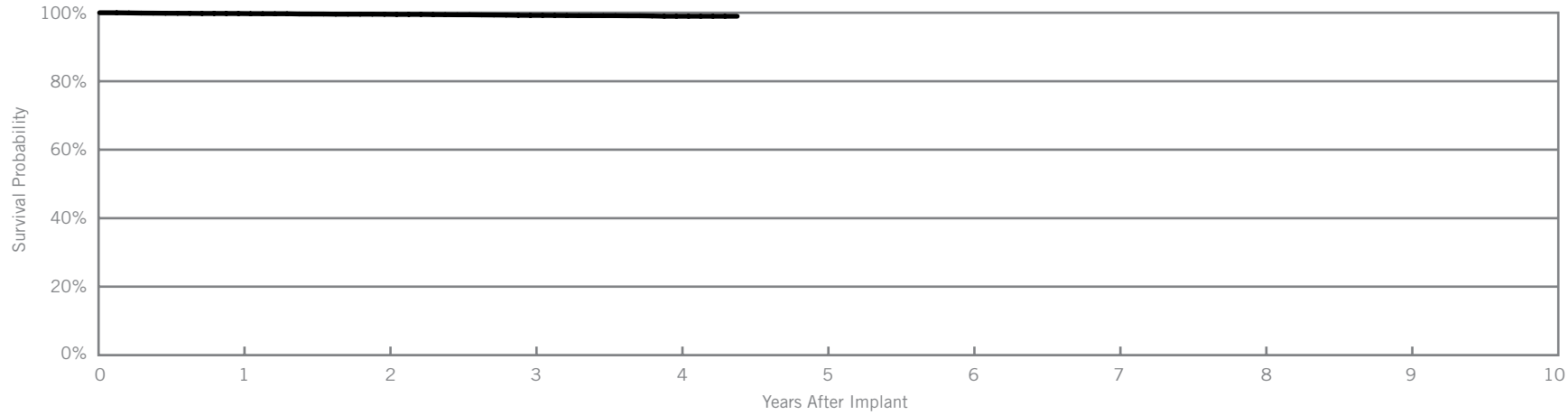
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,363
Estimated Active US Implants	6,589
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	10	0.10%	10	0.10%
Failure to Capture	3	0.03%	12	0.12%
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%	1	0.01%
Extracardiac Stimulation	9	0.09%	5	0.05%
Other	2	0.02%	1	0.01%
Total	**27**	**0.26%**	**31**	**0.30%**
Total Returned for Analysis	**8**		**9**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.03%
Extrinsic Factors	9	0.09%
Total	**14**	**0.14%**



Year	1	2	3	4	at 53 months					
Survival Probability	99.77%	99.56%	99.24%	98.98%	98.98%					
± 1 standard error	0.05%	0.07%	0.10%	0.16%	0.16%					
Sample Size	9700	8000	6200	3000	300					

Customer Reported Performance Data

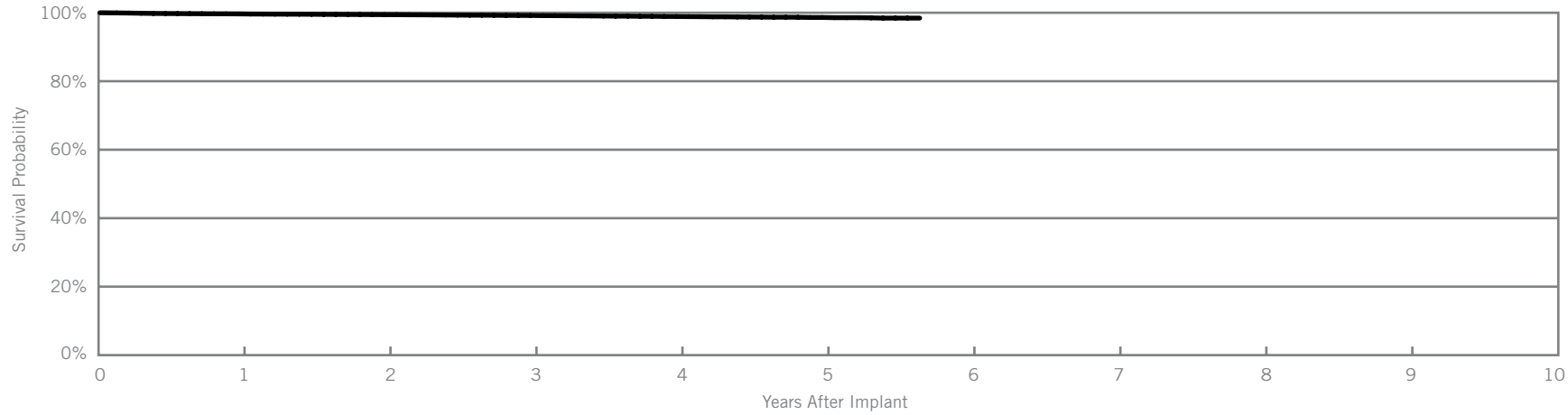
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	34,222
Estimated Active US Implants	19,241
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	28	0.08%	77	0.23%
Failure to Capture	14	0.04%	70	0.20%
Oversensing	1	<0.01%	3	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	3	0.01%	3	0.01%
Extracardiac Stimulation	22	0.06%	43	0.13%
Other	9	0.03%	7	0.02%
Total	**78**	**0.23%**	**207**	**0.60%**
Total Returned for Analysis	**24**		**85**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Insulation Breach	8	0.02%
Crimps, Welds & Bonds	1	<0.01%
Other	2	0.01%
Extrinsic Factors	77	0.23%
Total	**90**	**0.26%**



Year	1	2	3	4	5	at 68 months				
Survival Probability	99.66%	99.44%	99.20%	98.90%	98.62%	98.44%				
± 1 standard error	0.03%	0.04%	0.06%	0.07%	0.10%	0.13%				
Sample Size	31300	26000	21400	15100	7600	400				

SCORE Registry Performance Data

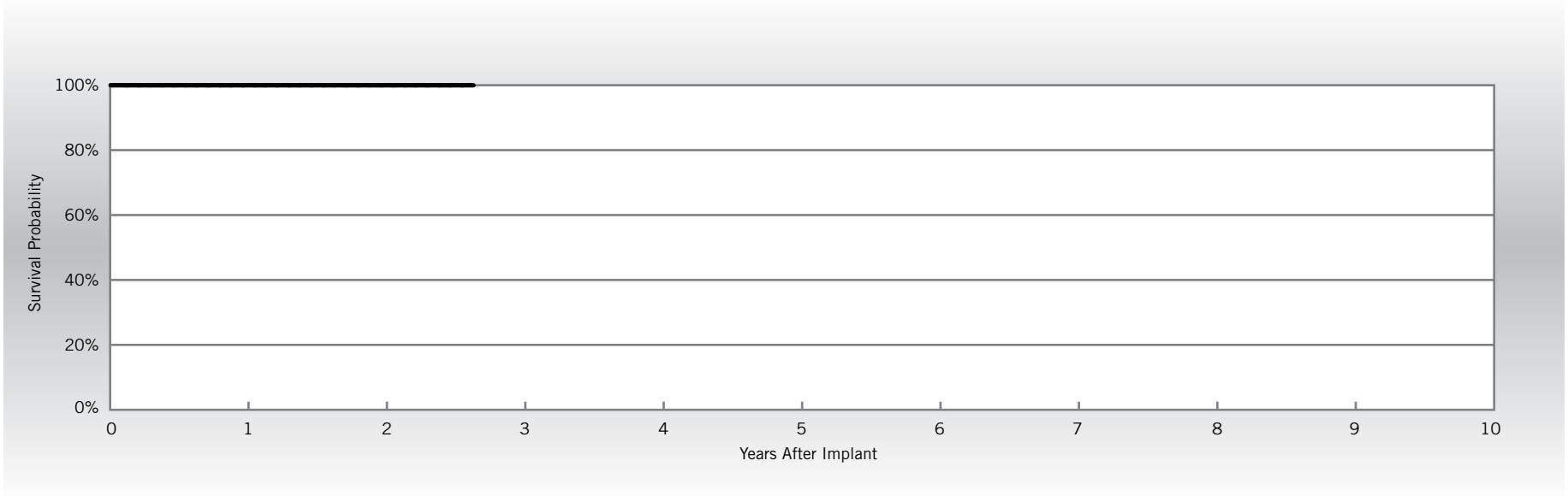
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	140
Cumulative Months of Follow-up	3,585
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%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.71%
Total	**1**	**0.71%**



Year	1	2	at 32 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	130	100	50							

Customer Reported Performance Data

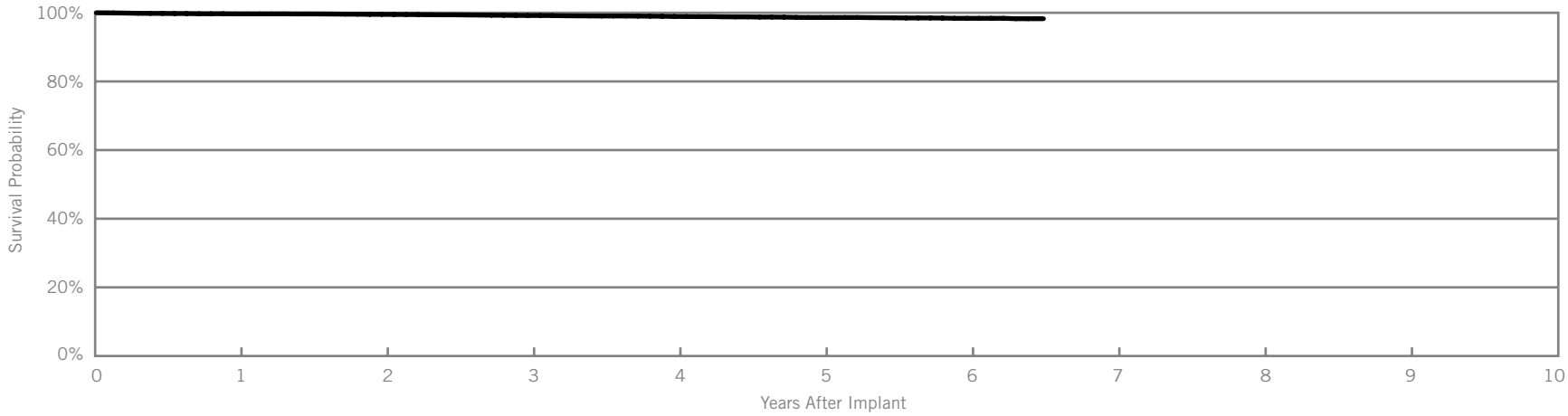
QuickSite®

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	8,805
Estimated Active US Implants	3,559
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.11%	25	0.28%
Failure to Capture	3	0.03%	26	0.30%
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%	12	0.14%
Other	2	0.02%	8	0.09%
Total	**25**	**0.28%**	**73**	**0.83%**
Total Returned for Analysis	**13**		**38**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.02%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	2	0.02%
Other	0	0.00%
Extrinsic Factors	25	0.28%
Total	**29**	**0.33%**



Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.68%	99.54%	99.21%	98.93%	98.63%	98.39%	98.27%			
± 1 standard error	0.06%	0.08%	0.11%	0.13%	0.17%	0.19%	0.23%			
Sample Size	7700	6600	5700	4700	3800	2600	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*										
1156T	QuickFlex®	99.63%	99.41%	99.13%							
1158T	QuickFlex® XL	99.78%	99.63%								
1058T	QuickSite® XL	99.77%	99.56%	99.24%	98.98%						
1056T	QuickSite®	99.66%	99.44%	99.20%	98.90%	98.62%					
1056K	QuickSite®	99.68%	99.54%	99.21%	98.93%	98.63%	98.39%				

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

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	6926	6281	0	0.00%	0	0.00%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.12%	1	0.01%	**12**	**0.17%**	**1**
1156T	Jul-07	24705	19478	0	0.00%	0	0.00%	10	0.04%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.06%	8	0.03%	**39**	**0.16%**	**12**
1158T	Jul-07	13196	10234	0	0.00%	0	0.00%	4	0.03%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	5	0.04%	6	0.05%	**18**	**0.14%**	**6**
1058T	Feb-06	10363	6589	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%	2	0.02%	**27**	**0.26%**	**8**
1056T	Apr-05	34222	19241	0	0.00%	0	0.00%	28	0.08%	14	0.04%	1	<0.01%	0	0.00%	1	<0.01%	3	0.01%	22	0.06%	9	0.03%	**78**	**0.23%**	**24**
1056K	Jun-04	8805	3559	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	6926	6281	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	1	0.01%	**6**	**0.09%**	**1**
1156T	Jul-07	24705	19478	0	0.00%	1	<0.01%	25	0.10%	9	0.04%	3	0.01%	0	0.00%	0	0.00%	4	0.02%	15	0.06%	2	0.01%	**59**	**0.24%**	**24**
1158T	Jul-07	13196	10234	0	0.00%	0	0.00%	22	0.17%	4	0.03%	0	0.00%	1	0.01%	0	0.00%	2	0.02%	6	0.05%	1	0.01%	**36**	**0.27%**	**16**
1058T	Feb-06	10363	6589	0	0.00%	1	0.01%	10	0.10%	12	0.12%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	5	0.05%	1	0.01%	**31**	**0.30%**	**9**
1056T	Apr-05	34222	19241	0	0.00%	3	0.01%	77	0.23%	70	0.20%	3	0.01%	1	<0.01%	0	0.00%	3	0.01%	43	0.13%	7	0.02%	**207**	**0.60%**	**85**
1056K	Jun-04	8805	3559	0	0.00%	0	0.00%	25	0.28%	26	0.30%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	12	0.14%	8	0.09%	**73**	**0.83%**	**38**

Definitions of observations and complications can be found on pages 7 and 8.

Malfunction Summary

Models	US Regulatory Approval	Registered US Implants	Estimated Active 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
1258T	May-10	6926	6281	0	0.00%	0	0.00%	0	0.00%	1	0.01%	6	0.09%	**7**	**0.10%**
1156T	Jul-07	24705	19478	1	<0.01%	2	0.01%	1	<0.01%	3	0.01%	26	0.11%	**33**	**0.13%**
1158T	Jul-07	13196	10234	1	0.01%	1	0.01%	1	0.01%	0	0.00%	18	0.14%	**21**	**0.16%**
1058T	Feb-06	10363	6589	0	0.00%	2	0.02%	0	0.00%	3	0.03%	9	0.09%	**14**	**0.14%**
1056T	Apr-05	34222	19241	2	0.01%	8	0.02%	1	<0.01%	2	0.01%	77	0.23%	**90**	**0.26%**
1056K	Jun-04	8805	3559	2	0.02%	0	0.00%	2	0.02%	0	0.00%	25	0.28%	**29**	**0.33%**

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1156T	521	9574	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.19%	**1**	**0.19%**
1158T	403	7695	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.74%	**3**	**0.74%**
1056T	140	3585	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.71%	**1**	**0.71%**

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
1156T	521	9574	0	0.00%	0	0.00%	1	0.19%	1	0.19%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.38%**
1158T	403	7695	0	0.00%	0	0.00%	0	0.00%	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.50%	0	0.00%	**3**	**0.74%**
1056T	140	3585	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical
More control. Less risk.

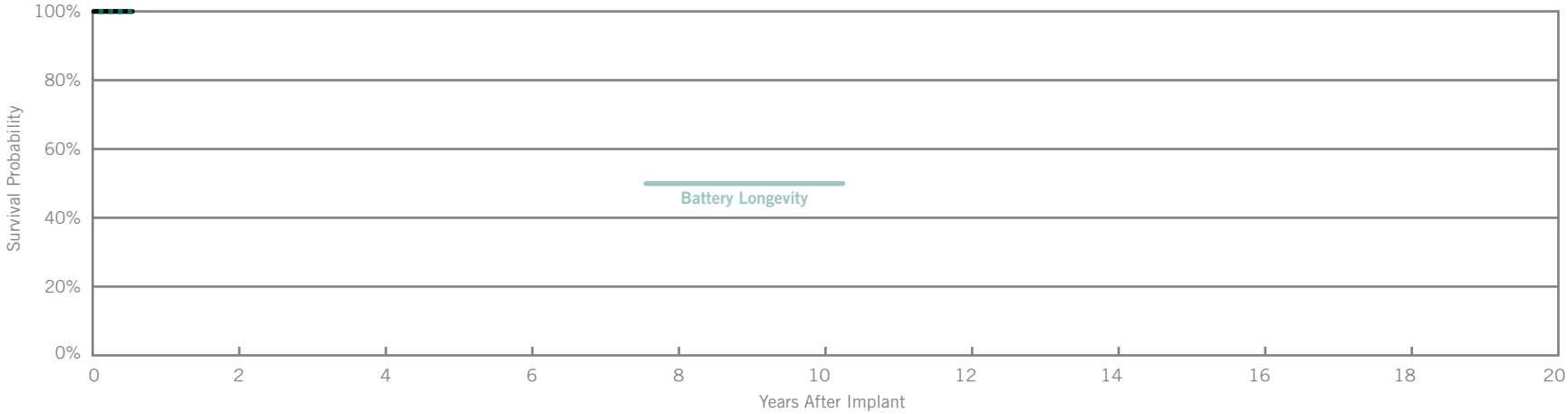
Customer Reported Performance Data

Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	6,697
Estimated Active US Implants	6,471
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 7 months										
Survival Probability	99.97%										
± 1 standard error	0.02%										
Sample Size	800										

Excluding Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

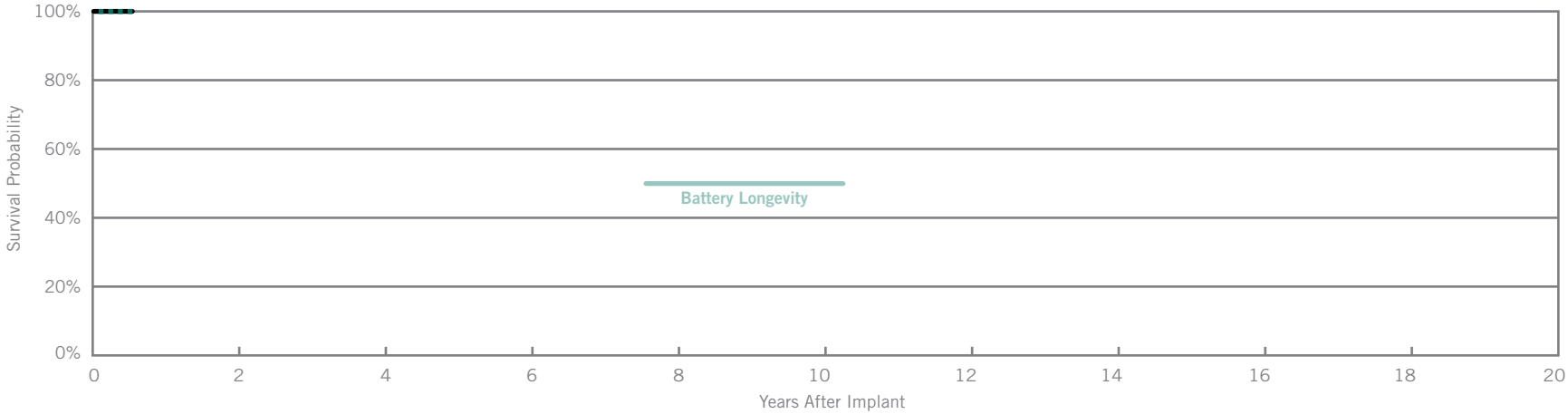
Customer Reported Performance Data

Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	2,544
Estimated Active US Implants	2,467
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	200										

Excluding Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

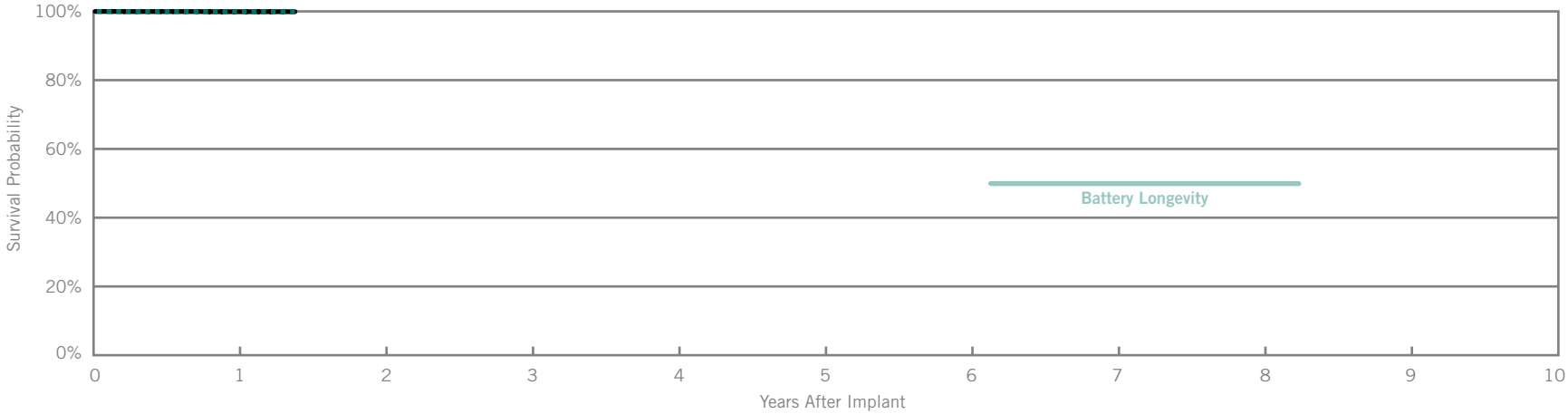
Customer Reported Performance Data

Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	8,214
Estimated Active US Implants	7,442
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	3	0.04%
Total	**3**	**0.04%**



Including Normal Battery Depletion .....

Year	1	at 17 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.04%	0.04%								
Sample Size	5600	200								

Excluding Normal Battery Depletion ——

Year	1	at 17 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.04%	0.04%								

SCORE Registry Performance Data

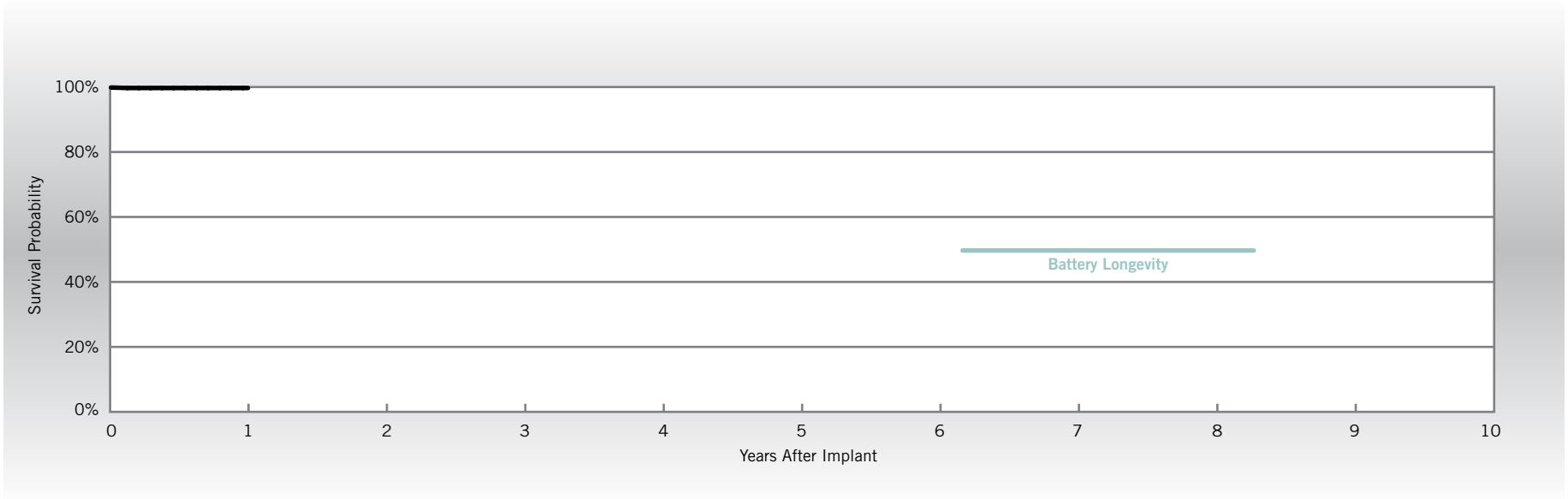
Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	152
Cumulative Months of Follow-up	1,680
Estimated Longevity	(see table on page 78)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	100									

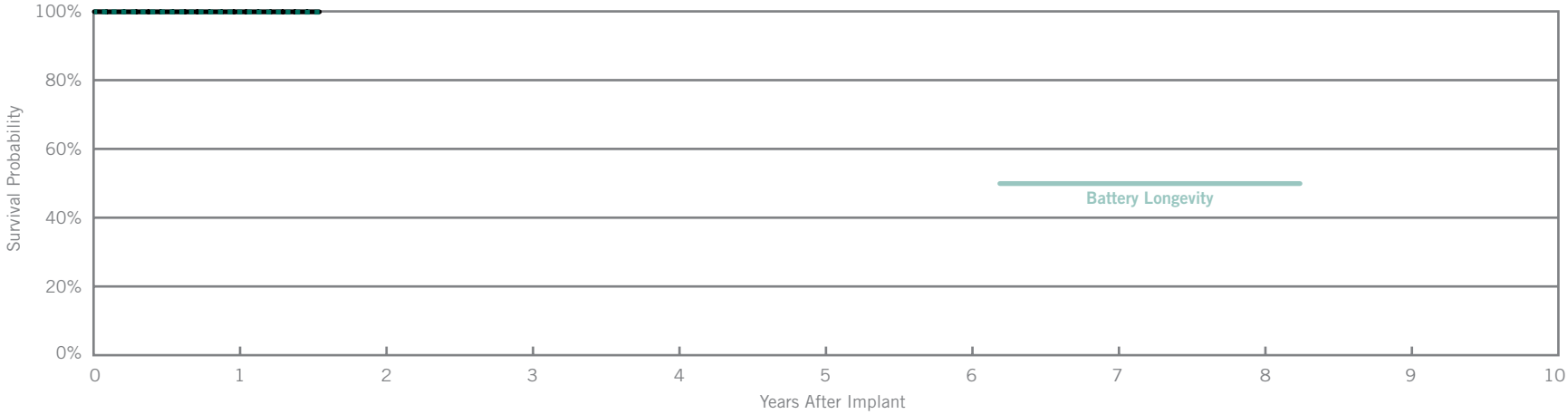
Customer Reported Performance Data

Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	5,580
Estimated Active US Implants	4,974
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.02%
Malfunctions w/o Compromised Therapy	2	0.04%
Total	**3**	**0.05%**



Including Normal Battery Depletion .....

Year	1	at 19 months								
Survival Probability	99.77%	99.77%								
± 1 standard error	0.07%	0.07%								
Sample Size	4300	400								

Excluding Normal Battery Depletion ——

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.05%	0.05%								

SCORE Registry Performance Data

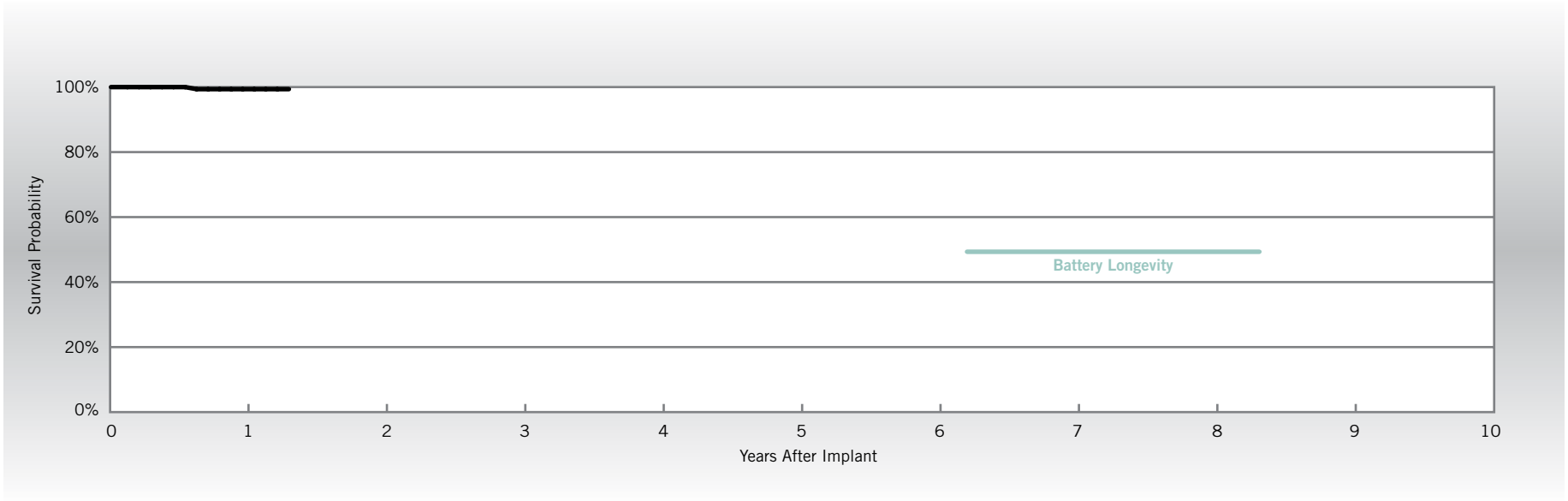
Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	180
Cumulative Months of Follow-up	2,345
Estimated Longevity	(see table on page 78)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Premature Battery Depletion	1	0.56%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.56%
Total	**1**	**0.56%**



Year	1	at 16 months								
Survival Probability	99.37%	99.37%								
± 1 standard error	0.60%	0.60%								
Sample Size	140	60								

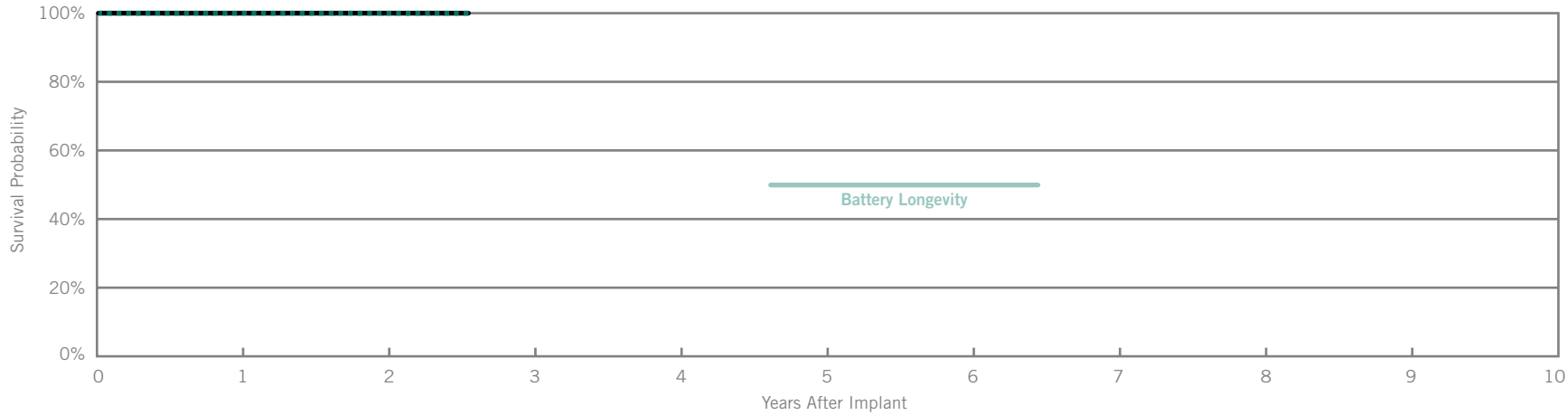
Customer Reported Performance Data

Current® DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,558
Estimated Active US Implants	1,228
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	1500	1000	200							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

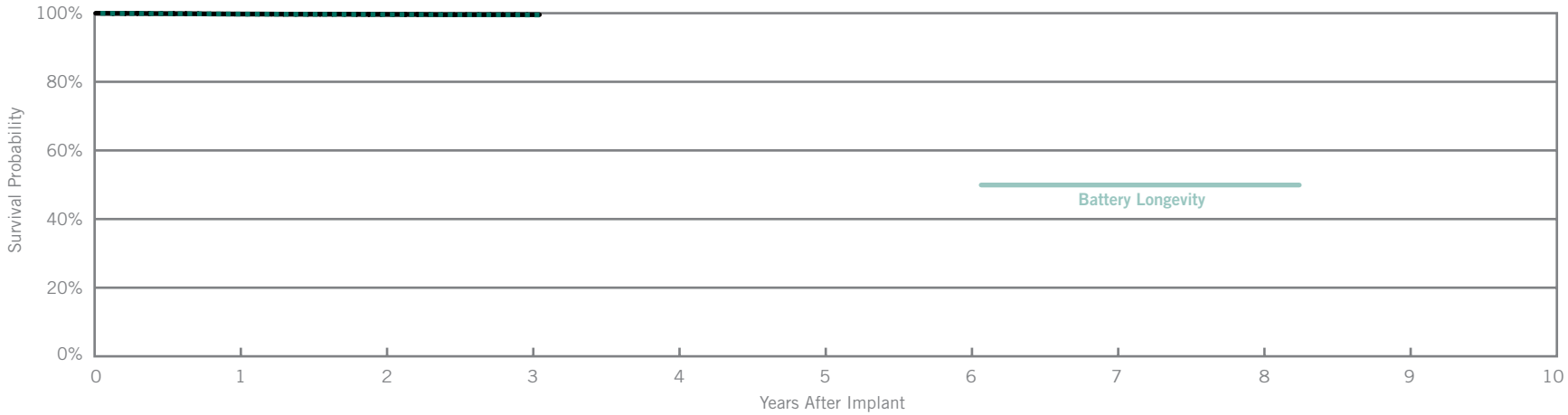
Customer Reported Performance Data

Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,250
Estimated Active US Implants	17,737
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	4
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	14	0.06%
Malfunctions w/o Compromised Therapy	17	0.08%
Total	**31**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.73%	99.58%	99.48%	99.48%						
± 1 standard error	0.03%	0.05%	0.06%	0.06%						
Sample Size	21700	14600	5000	500						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.75%	99.65%	99.56%	99.56%						
± 1 standard error	0.03%	0.04%	0.06%	0.06%						

SCORE Registry Performance Data

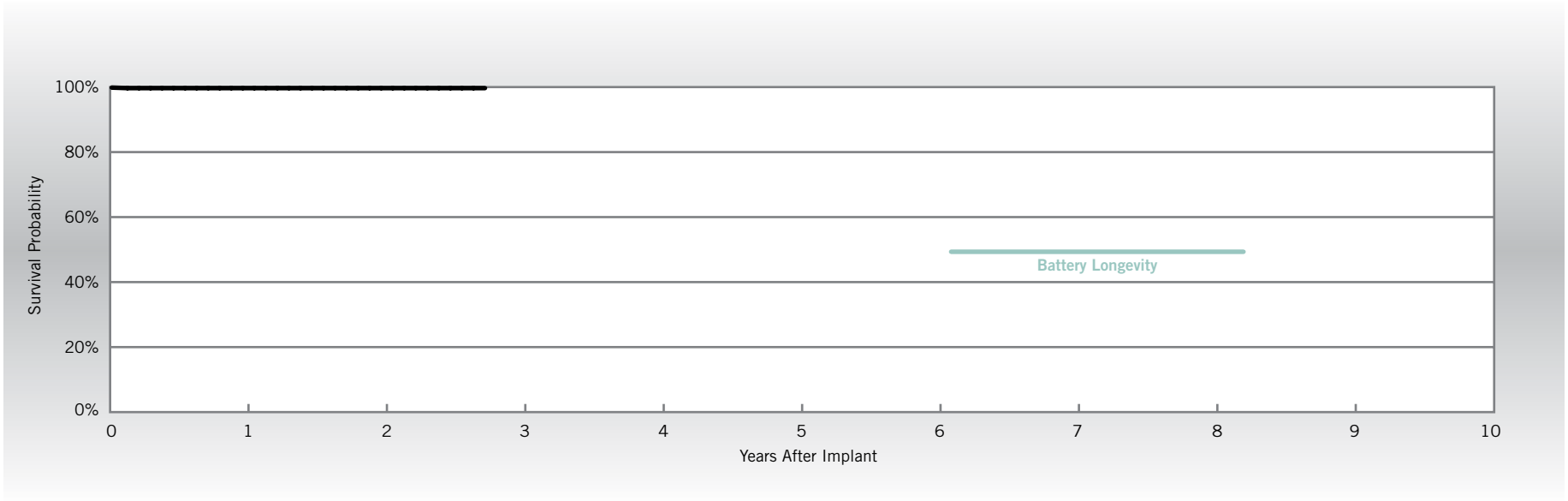
Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	630
Cumulative Months of Follow-up	15,552
Estimated Longevity	(see table on page 78)
Max. Delivered Energy	36 joules

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

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1	2	at 33 months							
Survival Probability	99.68%	99.68%	99.68%							
± 1 standard error	0.22%	0.22%	0.22%							
Sample Size	620	470	60							

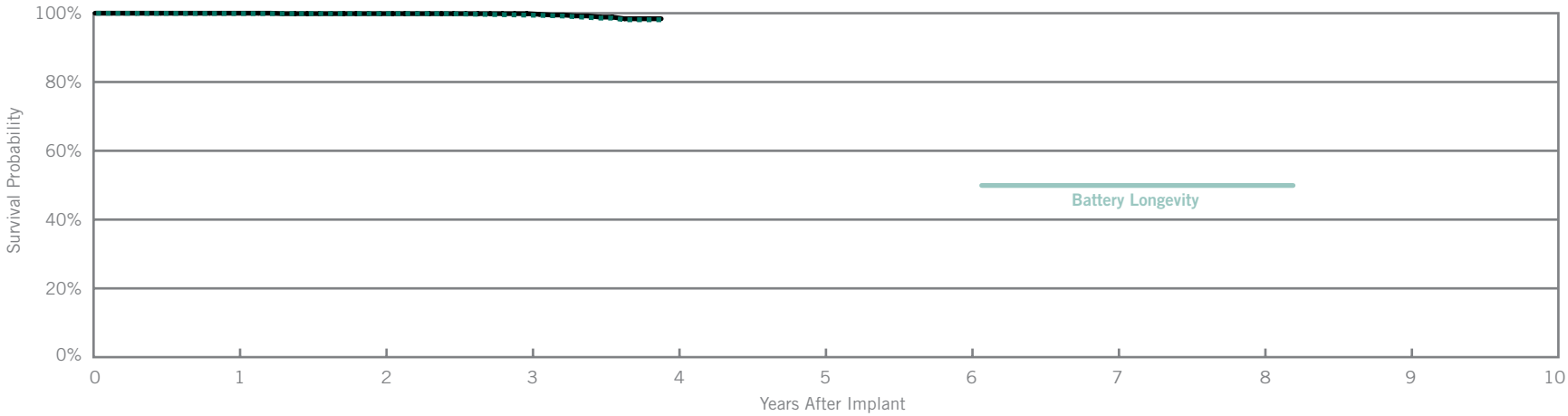
Customer Reported Performance Data

Atlas® II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,878
Estimated Active US Implants	1,261
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	4	0.21%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	2	0.11%
Total (0 related to Advisory)	**6**	**0.32%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	100.00%	99.88%	99.58%	98.10%						
± 1 standard error	0.00%	0.09%	0.17%	0.52%						
Sample Size	1900	1700	1400	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	100.00%	99.88%	99.88%	98.39%						
± 1 standard error	0.00%	0.09%	0.09%	0.50%						

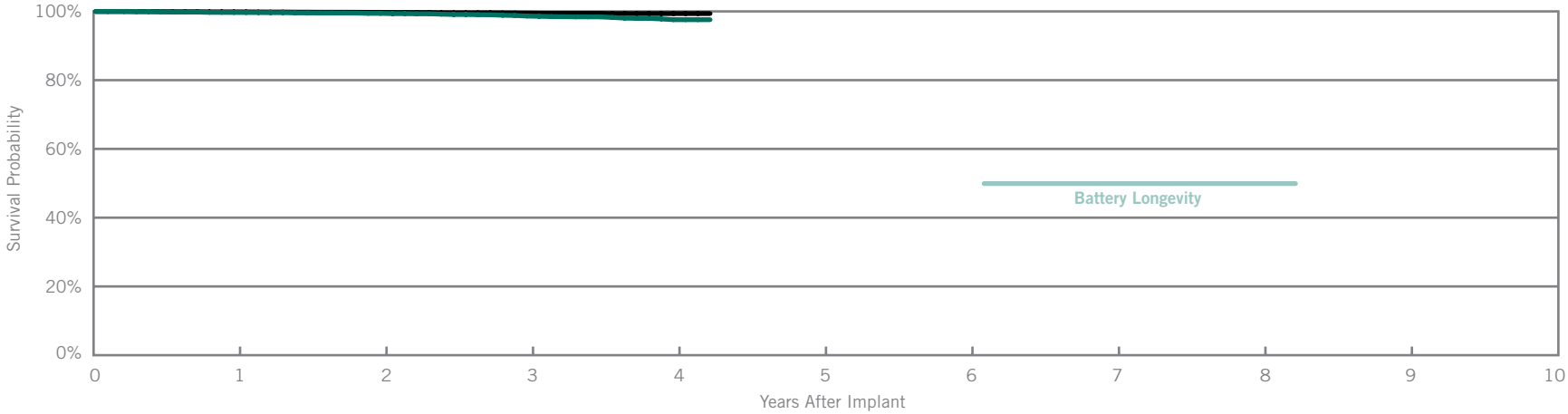
Customer Reported Performance Data

Atlas® II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,737
Estimated Active US Implants	10,200
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	23
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	19	0.13%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	9	0.06%
Total (0 related to Advisory)	**28**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.69%	99.43%	98.65%	97.59%	97.59%					
± 1 standard error	0.05%	0.07%	0.11%	0.22%	0.26%					
Sample Size	14600	12100	8800	3700	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.85%	99.72%	99.50%	99.37%	99.37%					
± 1 standard error	0.03%	0.05%	0.07%	0.09%	0.09%					

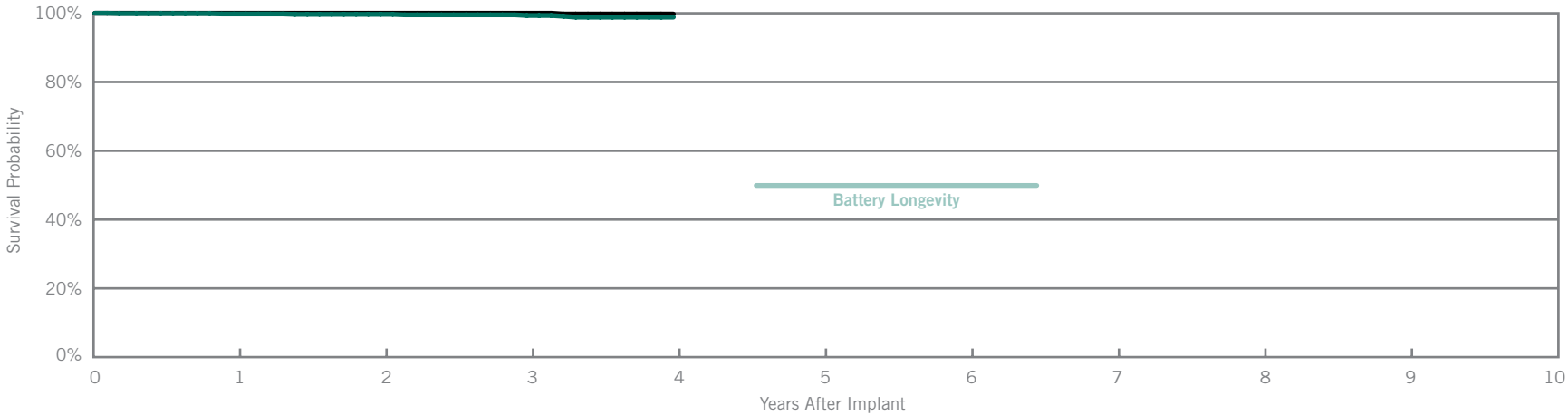
Customer Reported Performance Data

Epic® II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,094
Estimated Active US Implants	1,348
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	2
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.05%
Total (0 related to Advisory)	1	0.05%



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.79%	99.67%	99.34%	98.86%						
± 1 standard error	0.10%	0.13%	0.17%	0.32%						
Sample Size	2100	1700	1300	600						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	100.00%	100.00%	100.00%	99.77%						
± 1 standard error	0.00%	0.00%	0.00%	0.16%						

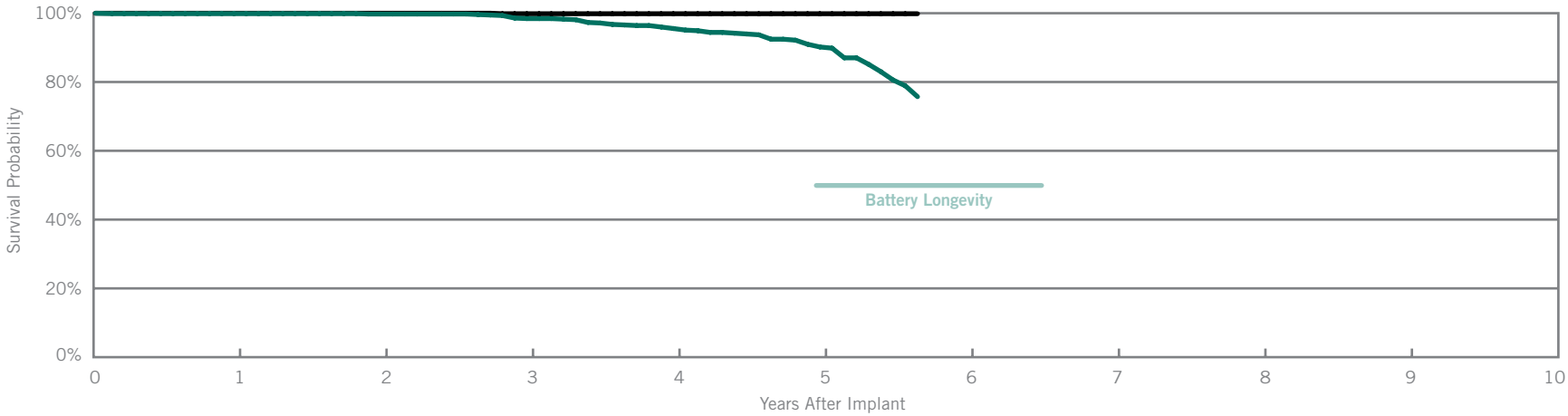
Customer Reported Performance Data

Epic® DR

Model V-233

US Regulatory Approval	October 2003
Registered US Implants	1,833
Estimated Active US Implants	585
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	59
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.05%
Total (0 related to Advisory)	**1**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.89%	99.76%	98.43%	95.54%	90.18%	75.73%				
± 1 standard error	0.08%	0.12%	0.32%	0.55%	0.92%	1.82%				
Sample Size	1800	1600	1500	1300	900	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	100.00%	100.00%	99.85%	99.85%	99.85%	99.85%				
± 1 standard error	0.00%	0.00%	0.10%	0.10%	0.10%	0.10%				

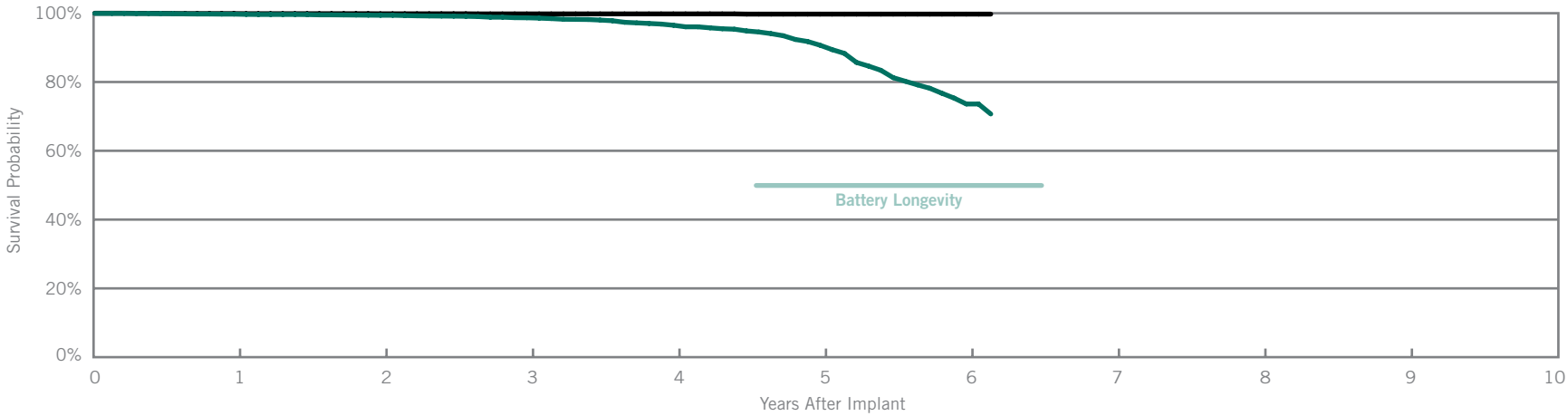
Customer Reported Performance Data

Epic® + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,843
Estimated Active US Implants	3,018
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	215
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	5	0.06%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	3	0.04%
Total (0 related to Advisory)	**8**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.73%	99.40%	98.67%	96.50%	90.71%	73.60%	70.70%			
± 1 standard error	0.06%	0.09%	0.14%	0.24%	0.45%	1.16%	1.28%			
Sample Size	7800	6900	6200	5300	3600	1500	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.89%	99.83%	99.80%	99.80%	99.74%	99.74%	99.74%			
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.07%	0.07%	0.07%			

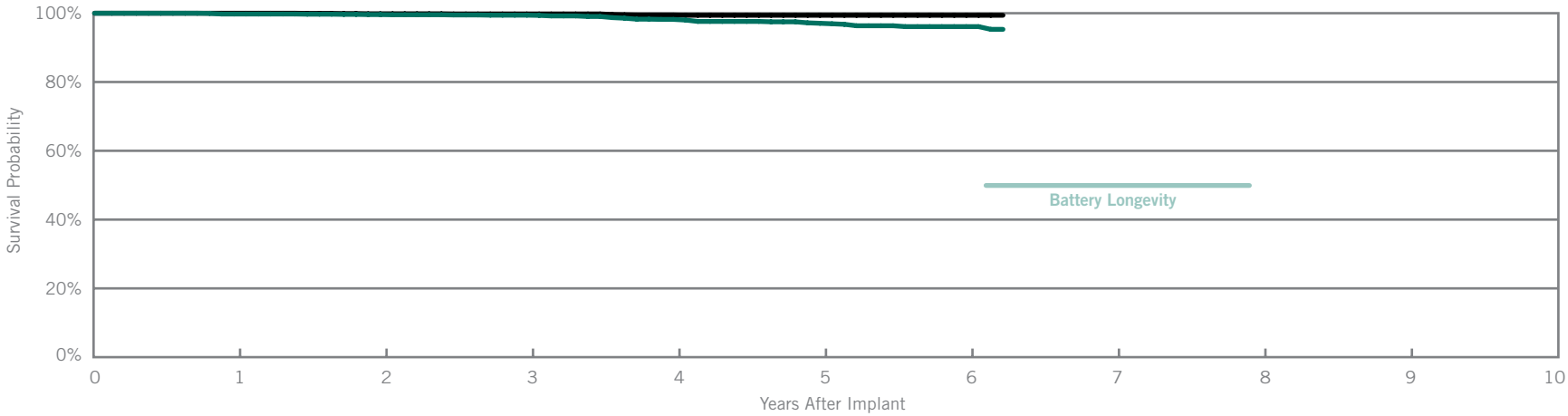
Customer Reported Performance Data

Atlas® DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,650
Estimated Active US Implants	2,298
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	26
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	Three

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	8	0.17%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.02%
Total (0 related to Advisory)	**9**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.76%	99.60%	99.43%	98.20%	97.07%	96.10%	95.31%			
± 1 standard error	0.08%	0.10%	0.12%	0.23%	0.32%	0.44%	0.71%			
Sample Size	4700	4100	3700	3100	2200	1000	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	100.00%	99.84%	99.79%	99.48%	99.40%	99.40%	99.40%			
± 1 standard error	0.00%	0.06%	0.08%	0.13%	0.14%	0.14%	0.14%			

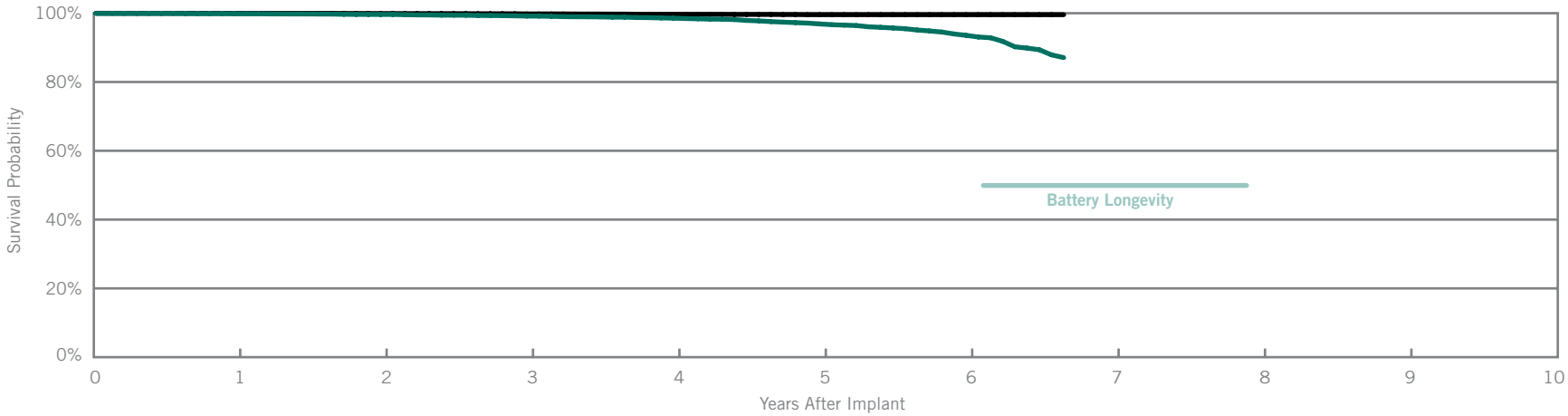
Customer Reported Performance Data

Atlas® + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	20,982
Estimated Active US Implants	10,785
Estimated Longevity	(see table on page 78)
Normal Battery Depletion	104
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	Three

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	19	0.09%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	7	0.03%
Total (0 related to Advisory)	**26**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.85%	99.63%	99.16%	98.55%	96.88%	93.56%	87.09%			
± 1 standard error	0.02%	0.04%	0.07%	0.10%	0.17%	0.40%	1.10%			
Sample Size	21000	18500	16200	13100	8200	3100	300			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.97%	99.91%	99.80%	99.67%	99.57%	99.57%	99.57%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.06%	0.06%	0.06%			

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-233	Epic® DR	6.4	6.0	5.6	4.9
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
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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
CD2231-40Q	Fortify® DR*										
CD2231-40	Fortify® DR*										
CD2211-36Q	Current® + DR	99.91%									
CD2211-36	Current® + DR	99.77%									
2207-30	Current® DR RF	100.00%	100.00%								
2207-36	Current® DR RF	99.73%	99.58%	99.48%							
V-265	Atlas® II DR	100.00%	99.88%	99.58%							
V-268	Atlas® II + DR	99.69%	99.43%	98.65%	97.59%						
V-258	Epic® II + DR	99.79%	99.67%	99.34%	98.86%						
V-233	Epic® DR	99.89%	99.76%	98.43%	95.54%	90.18%					
V-239	Epic® + DR	99.73%	99.40%	98.67%	96.50%	90.71%	73.60%				
V-242	Atlas® DR	99.76%	99.60%	99.43%	98.20%	97.07%	96.10%				
V-243	Atlas® + DR	99.85%	99.63%	99.16%	98.55%	96.88%	93.56%				

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR*										
CD2231-40	Fortify® DR*										
CD2211-36Q	Current® + DR	99.91%									
CD2211-36	Current® + DR	99.87%									
2207-30	Current® DR RF	100.00%	100.00%								
2207-36	Current® DR RF	99.75%	99.65%	99.56%							
V-265	Atlas® II DR	100.00%	99.88%	99.88%							
V-268	Atlas® II + DR	99.85%	99.72%	99.50%	99.37%						
V-258	Epic® II + DR	100.00%	100.00%	100.00%	99.77%						
V-233	Epic® DR	100.00%	100.00%	99.85%	99.85%	99.85%					
V-239	Epic® + DR	99.89%	99.83%	99.80%	99.80%	99.74%	99.74%				
V-242	Atlas® DR	100.00%	99.84%	99.79%	99.48%	99.40%	99.40%				
V-243	Atlas® + DR	99.97%	99.91%	99.80%	99.67%	99.57%	99.57%				

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	May 10	6697	6471	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2231-40	Fortify® DR*	May 10	2544	2467	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2211-36Q	Current® + DR	Feb-09	8214	7442	0	0.00%	0	0.00%	3	0.04%	3	0.04%	3	0.04%
CD2211-36	Current® + DR	Feb-09	5580	4974	1	0.02%	1	0.02%	0	0.00%	2	0.04%	3	0.05%
2207-30	Current® DR RF	Sep-07	1558	1228	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
2207-36	Current® DR RF	Sep-07	22250	17737	8	0.04%	14	0.06%	7	0.03%	17	0.08%	31	0.14%
V-265	Atlas® II DR	Jul-06	1878	1261	4	0.21%	4	0.21%	2	0.11%	2	0.11%	6	0.32%
V-268	Atlas® II + DR	Jul-06	14737	10200	14	0.09%	19	0.13%	7	0.05%	9	0.06%	28	0.19%
V-258	Epic® II + DR	Mar-06	2094	1348	0	0.00%	0	0.00%	0	0.00%	1	0.05%	1	0.05%
V-233	Epic® DR	Oct-03	1833	585	0	0.00%	0	0.00%	0	0.00%	1	0.05%	1	0.05%
V-239	Epic® + DR	Oct-03	7843	3018	0	0.00%	5	0.06%	0	0.00%	3	0.04%	8	0.10%
V-242	Atlas® DR	Oct-03	4650	2298	5	0.11%	8	0.17%	0	0.00%	1	0.02%	9	0.19%
V-243	Atlas® + DR	Oct-03	20982	10785	17	0.08%	19	0.09%	4	0.02%	7	0.03%	26	0.12%

**Totals include Premature Battery Depletion and all other confirmed malfunctions, including those related to advisories.*

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2211-36Q	152	1680	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2211-36	180	2345	0	0.00%	0	0.00%	0	0.00%	1	0.56%	1	0.56%
2207-36	630	15552	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Premature Battery Depletion		Failure to Sense		Inappropriate Shock		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2211-36Q	152	1680	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2211-36	180	2345	1	0.56%	0	0.00%	0	0.00%	1	0.56%
2207-36	630	15552	0	0.00%	1	0.16%	1	0.16%	2	0.32%

** Totals include Premature Battery Depletion and all other confirmed malfunctions.*

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical
More control. Less risk.

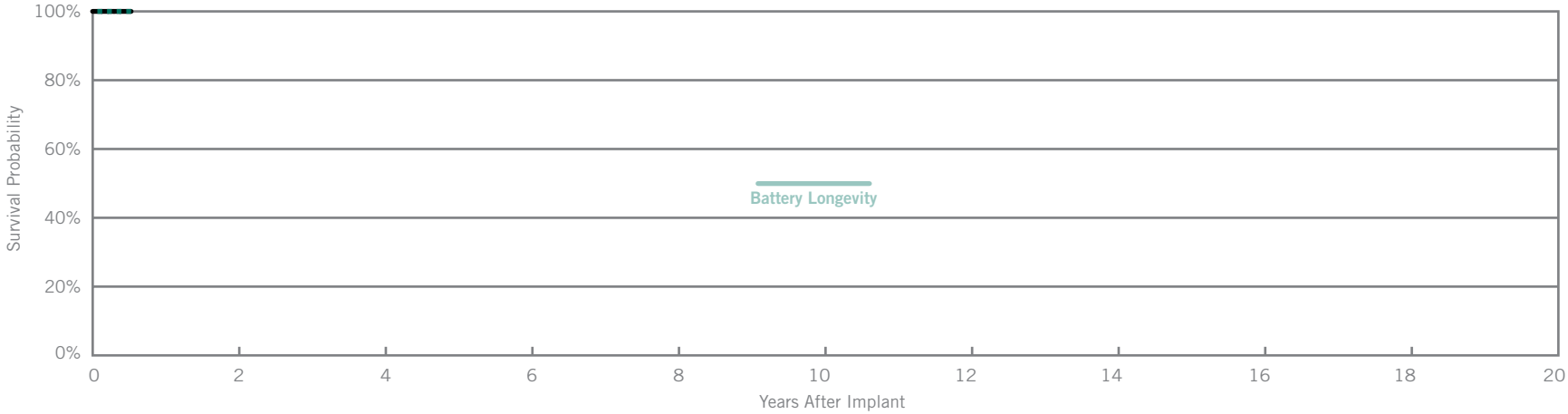
Customer Reported Performance Data

Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Registered US Implants	3,416
Estimated Active US Implants	3,311
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	400										

Excluding Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

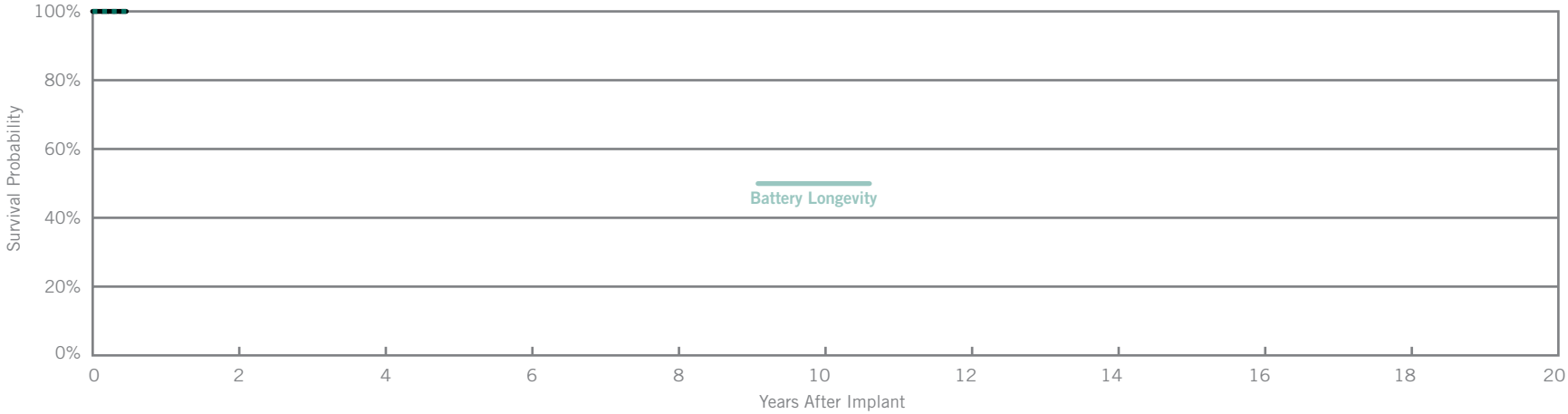
Customer Reported Performance Data

Fortify® VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	1,377
Estimated Active US Implants	1,334
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

Year	at 6 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	300										

Excluding Normal Battery Depletion

Year	at 6 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										

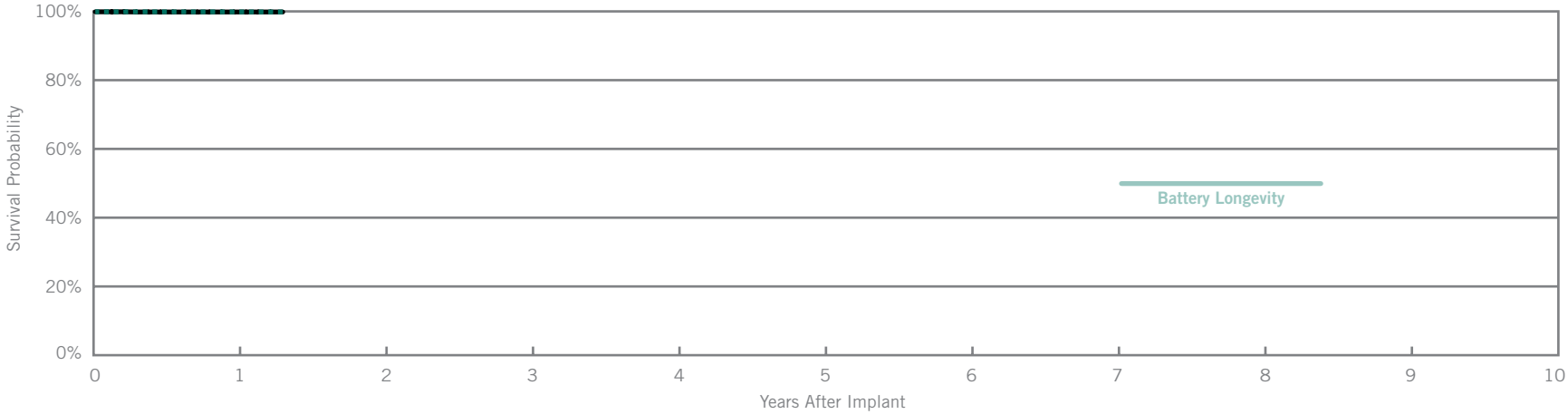
Customer Reported Performance Data

Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	4,292
Estimated Active US Implants	3,868
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.02%
Malfunctions w/o Compromised Therapy	2	0.05%
Total	**3**	**0.07%**



Including Normal Battery Depletion .....

Year	1	at 16 months								
Survival Probability	99.83%	99.83%								
± 1 standard error	0.06%	0.06%								
Sample Size	2900	300								

Excluding Normal Battery Depletion ——

Year	1	at 16 months								
Survival Probability	99.83%	99.83%								
± 1 standard error	0.06%	0.06%								

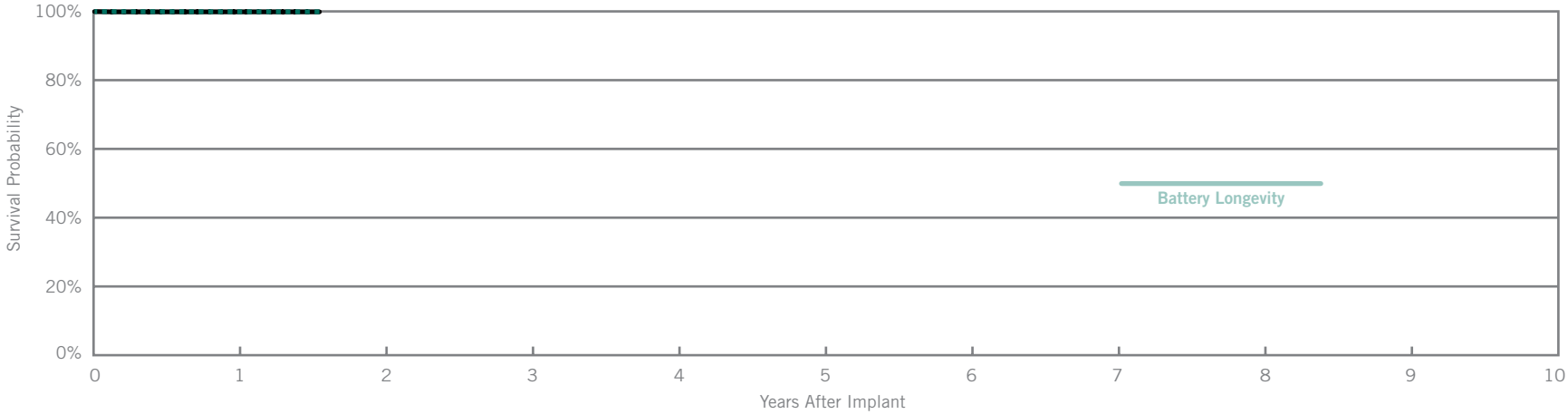
Customer Reported Performance Data

Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,101
Estimated Active US Implants	2,765
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	2	0.06%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**2**	**0.06%**



Including Normal Battery Depletion .....

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.07%	0.07%								
Sample Size	2400	200								

Excluding Normal Battery Depletion ——

Year	1	at 19 months								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.07%	0.07%								

SCORE Registry Performance Data

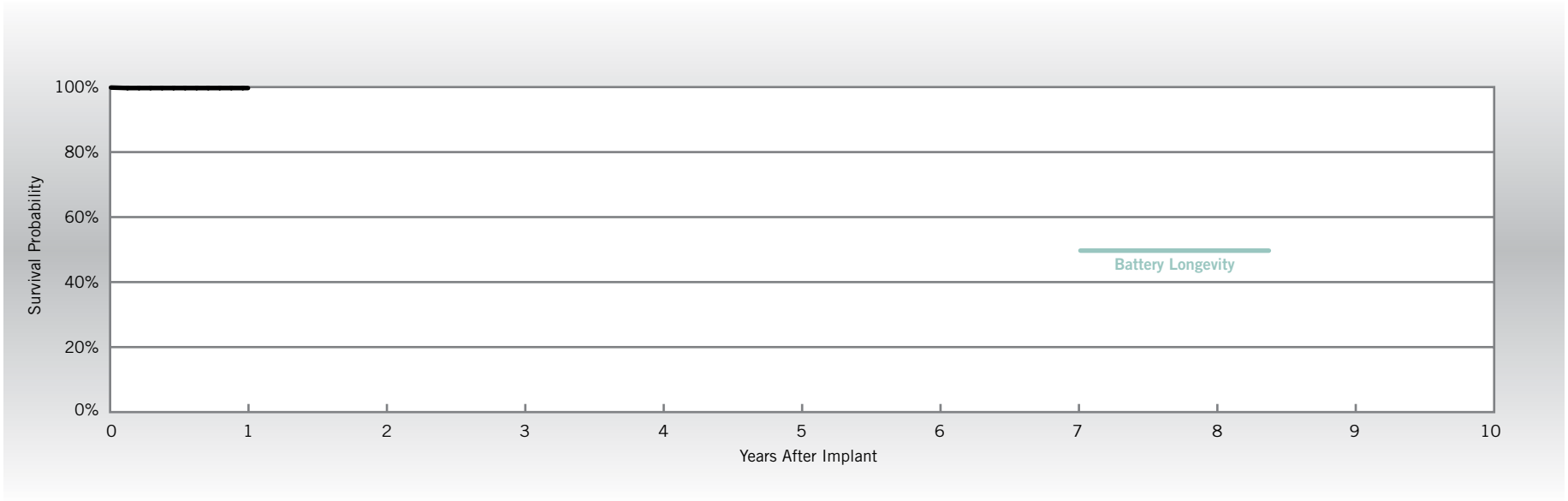
Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	105
Cumulative Months of Follow-up	1295
Estimated Longevity	(see table on page 98)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	80									

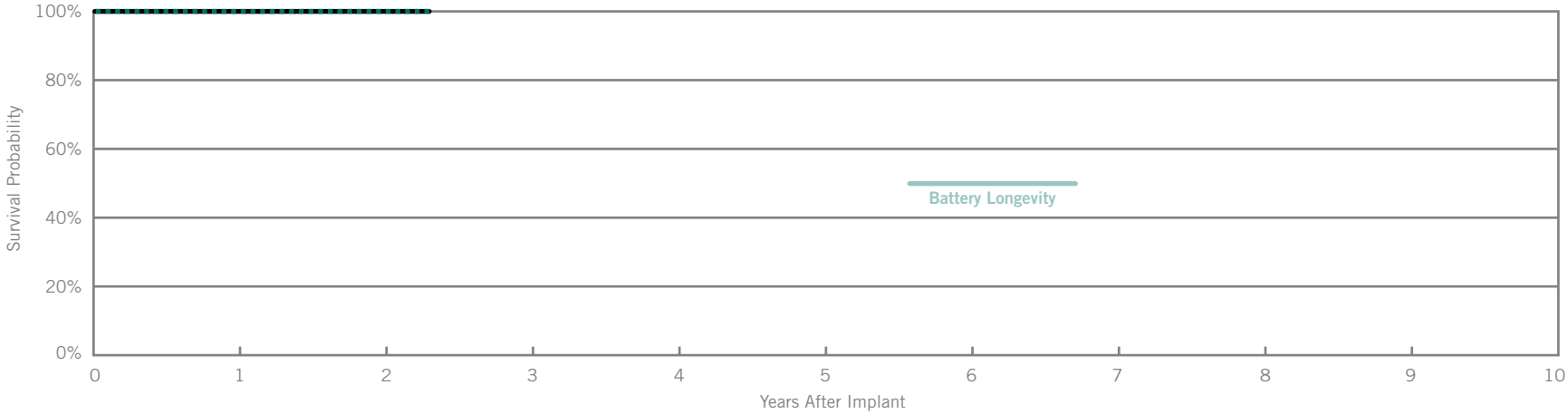
Customer Reported Performance Data

Current® VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	872
Estimated Active US Implants	709
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion

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	800	500	200							

Excluding Normal Battery Depletion

Year	1	2	at 28 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

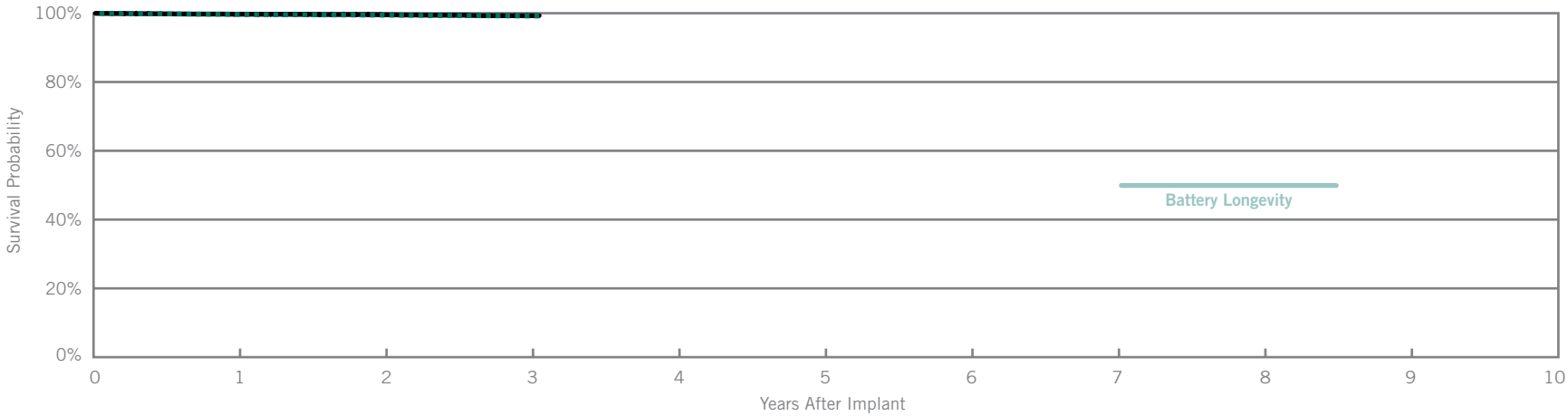
Customer Reported Performance Data

Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,134
Estimated Active US Implants	10,475
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	13	0.10%
Malfunctions w/o Compromised Therapy	11	0.08%
Total	**24**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.61%	99.45%	99.18%	99.18%						
± 1 standard error	0.05%	0.07%	0.13%	0.13%						
Sample Size	12700	8300	2700	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.71%	99.57%	99.29%	99.29%						
± 1 standard error	0.04%	0.06%	0.13%	0.13%						

SCORE Registry Performance Data

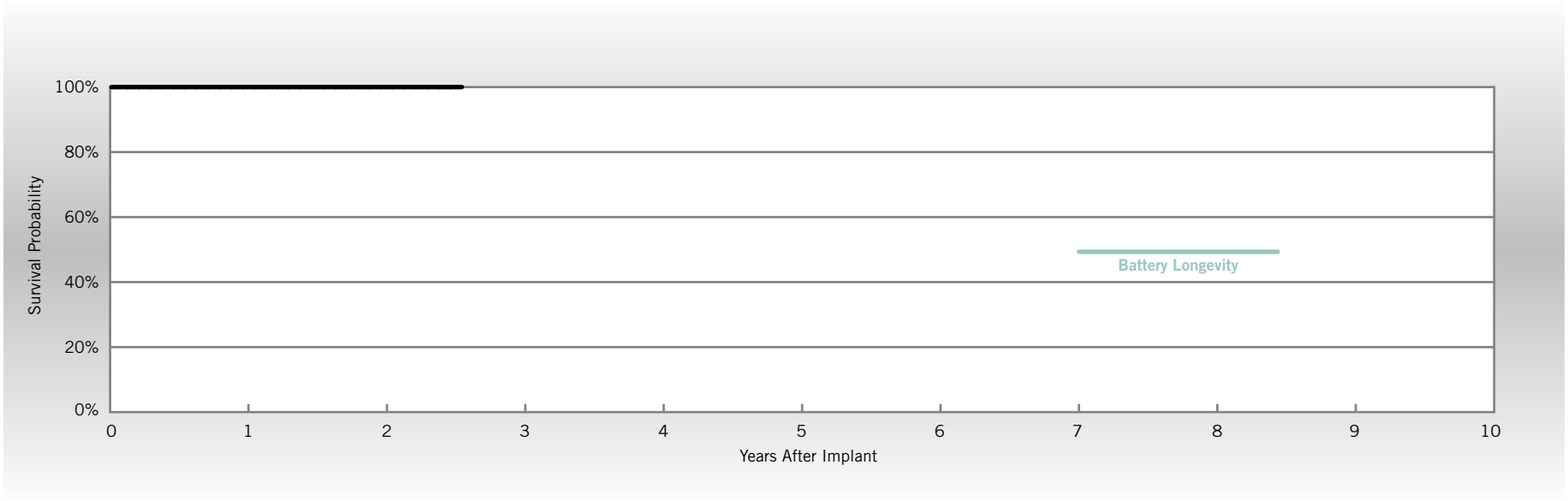
Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	9,628
Estimated Longevity	(see table on page 98)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1	2	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	390	300	60							

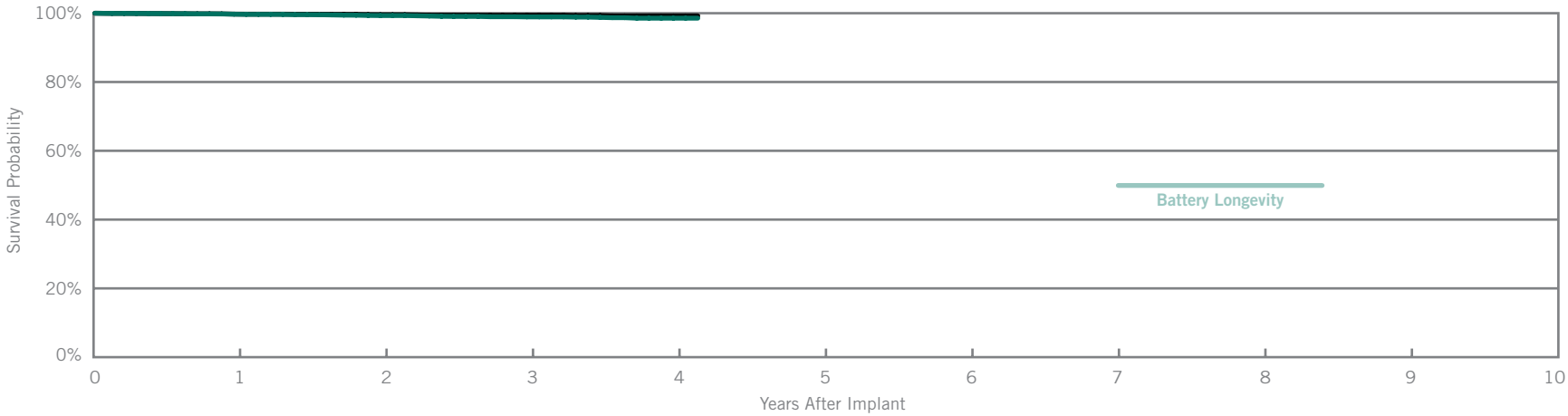
Customer Reported Performance Data

Atlas® II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,486
Estimated Active US Implants	7,315
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	19	0.18%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	6	0.06%
Total (0 related to Advisory)	**25**	**0.24%**



Including Normal Battery Depletion .....

Year	1	2	3	4	at 50 months					
Survival Probability	99.72%	99.32%	98.93%	98.56%	98.56%					
± 1 standard error	0.05%	0.09%	0.11%	0.18%	0.18%					
Sample Size	10400	8700	6300	2600	300					

Excluding Normal Battery Depletion ——

Year	1	2	3	4	at 50 months					
Survival Probability	99.75%	99.57%	99.39%	99.23%	99.23%					
± 1 standard error	0.04%	0.07%	0.09%	0.12%	0.12%					

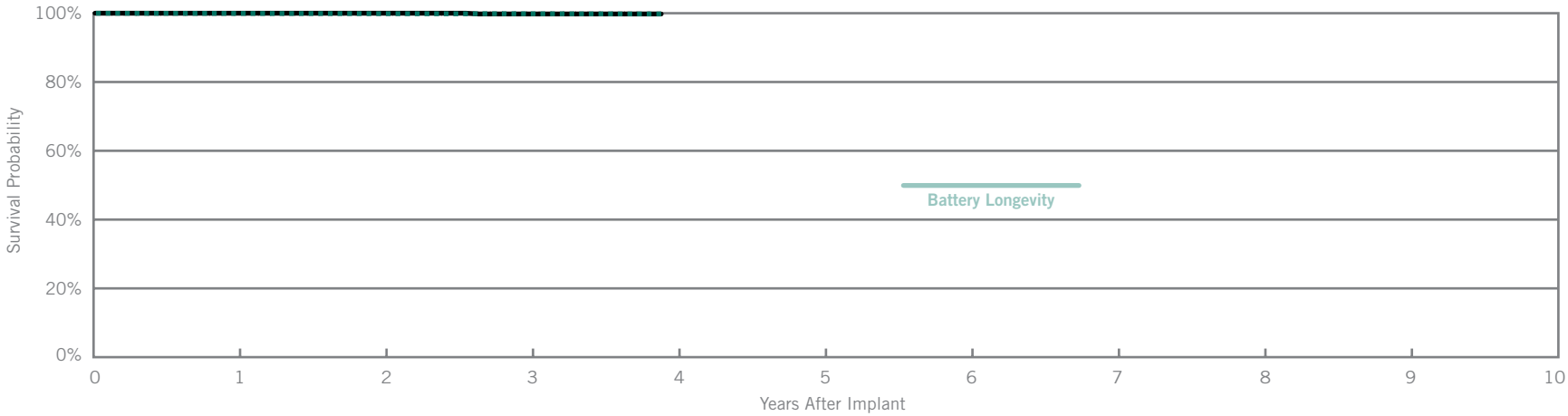
Customer Reported Performance Data

Epic® II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,569
Estimated Active US Implants	1,014
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.06%
Total (0 related to Advisory)	**1**	**0.06%**



Including Normal Battery Depletion .....

Year	1	2	3	at 47 months						
Survival Probability	100.00%	100.00%	99.78%	99.78%						
± 1 standard error	0.00%	0.00%	0.16%	0.16%						
Sample Size	1600	1300	1000	200						

Excluding Normal Battery Depletion ——

Year	1	2	3	at 47 months						
Survival Probability	100.00%	100.00%	99.78%	99.78%						
± 1 standard error	0.00%	0.00%	0.16%	0.16%						

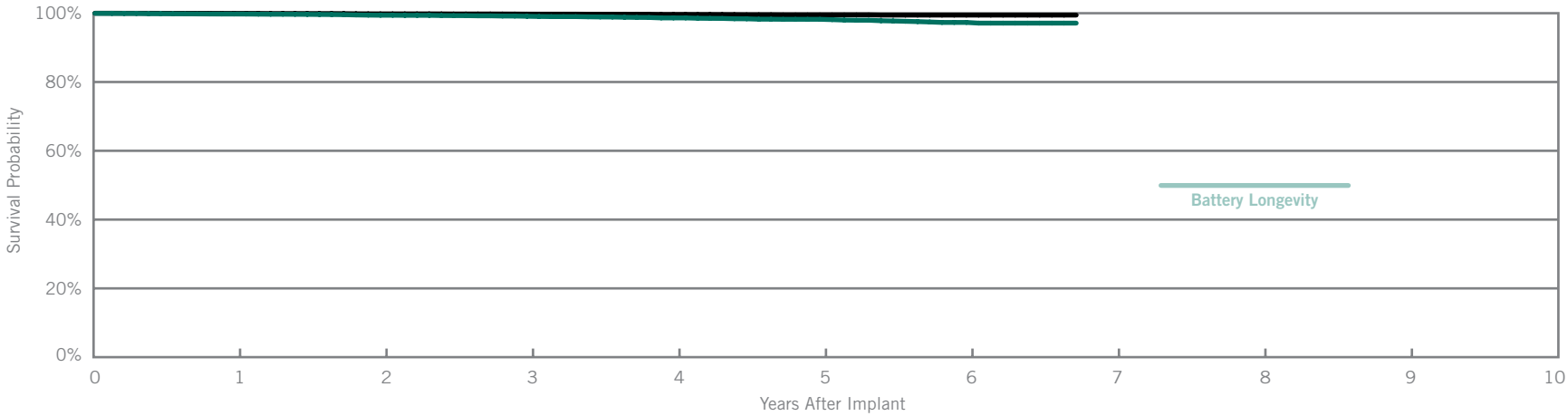
Customer Reported Performance Data

Atlas® + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,520
Estimated Active US Implants	11,021
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	38
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 229-237)	Three

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	23	0.11%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	9	0.04%
Total (0 related to Advisory)	**32**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.76%	99.41%	99.11%	98.63%	98.23%	97.32%	97.12%			
± 1 standard error	0.03%	0.06%	0.07%	0.10%	0.12%	0.22%	0.26%			
Sample Size	20500	18100	15800	12800	8200	3200	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.95%	99.81%	99.74%	99.63%	99.51%	99.45%	99.45%			
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.06%	0.08%	0.08%			

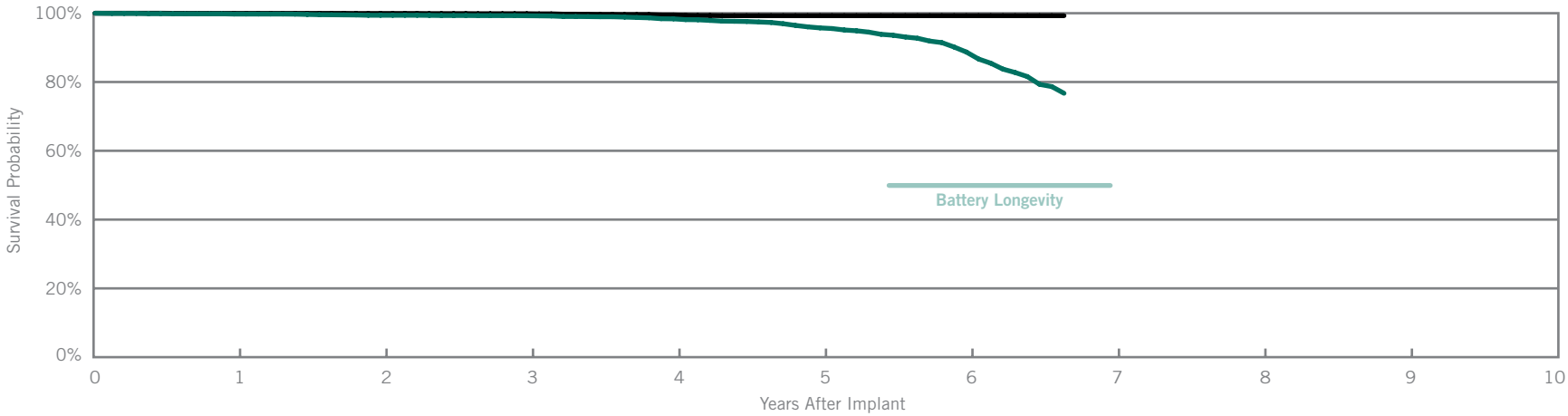
Customer Reported Performance Data

Epic® + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,962
Estimated Active US Implants	3,257
Estimated Longevity	(see table on page 98)
Normal Battery Depletion	85
Max. Delivered Energy	30 joules
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	5	0.06%
Malfunctions w/o Compromised Therapy	12	0.15%
Total	**17**	**0.21%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.75%	99.40%	99.26%	98.36%	95.73%	88.71%	76.72%			
± 1 standard error	0.05%	0.09%	0.10%	0.17%	0.31%	0.69%	1.54%			
Sample Size	8000	7100	6300	5400	3800	1900	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.95%	99.92%	99.85%	99.49%	99.28%	99.28%	99.28%			
± 1 standard error	0.03%	0.03%	0.05%	0.10%	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*										
CD1231-40	Fortify® VR*										
CD1211-36Q	Current® + VR	99.83%									
CD1211-36	Current® + VR	99.87%									
1207-30	Current® VR RF	100.00%	100.00%								
1207-36	Current® VR RF	99.61%	99.45%	99.18%							
V-168	Atlas® II VR	99.72%	99.32%	98.93%	98.56%						
V-158	Epic® II VR	100.00%	100.00%	99.78%							
V-193	Atlas® + VR	99.76%	99.41%	99.11%	98.63%	98.23%	97.32%				
V-196	Epic® + VR	99.75%	99.40%	99.26%	98.36%	95.73%	88.71%				

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1231-40Q	Fortify® VR*										
CD1231-40	Fortify® VR*										
CD1211-36Q	Current® + VR	99.83%									
CD1211-36	Current® + VR	99.87%									
1207-30	Current® VR RF	100.00%	100.00%								
1207-36	Current® VR RF	99.71%	99.57%	99.29%							
V-168	Atlas® II VR	99.75%	99.57%	99.39%	99.23%						
V-158	Epic® II VR	100.00%	100.00%	99.78%							
V-193	Atlas® + VR	99.95%	99.81%	99.74%	99.63%	99.51%	99.45%				
V-196	Epic® + VR	99.95%	99.92%	99.85%	99.49%	99.28%	99.28%				

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify® VR	May-10	3416	3311	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1231-40	Fortify® VR	May-10	1377	1334	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD1211-36Q	Current® + VR	Feb-09	4292	3868	0	0.00%	1	0.02%	0	0.00%	2	0.05%	3	0.07%
CD1211-36	Current® + VR	Feb-09	3101	2765	2	0.06%	2	0.06%	0	0.00%	0	0.00%	2	0.06%
1207-30	Current® VR RF	Sep-07	872	709	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
1207-36	Current® VR RF	Sep-07	13134	10475	4	0.03%	13	0.10%	7	0.05%	11	0.08%	24	0.18%
V-168	Atlas® II VR	Jul-06	10486	7315	13	0.12%	19	0.18%	4	0.04%	6	0.06%	25	0.24%
V-158	Epic® II VR	Mar-06	1569	1014	0	0.00%	0	0.00%	1	0.06%	1	0.06%	1	0.06%
V-193	Atlas® + VR	Oct-03	20520	11021	12	0.06%	23	0.11%	7	0.03%	9	0.04%	32	0.16%
V-196	Epic® + VR	Apr-03	7962	3257	2	0.03%	5	0.06%	0	0.00%	12	0.15%	17	0.21%

**Totals include Premature Battery Depletion and all other confirmed malfunctions, including those related to advisories.*

Defibrillation Leads

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

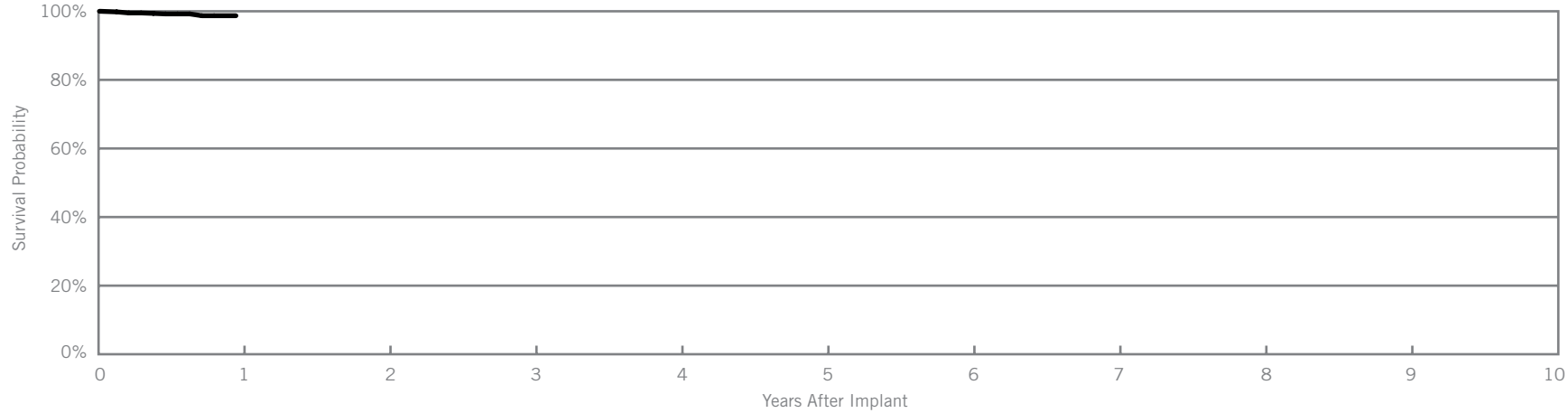
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	1,207
Estimated Active US Implants	1,102
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	1	0.08%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	0	0.00%	2	0.17%
Failure to Capture	1	0.08%	5	0.41%
Oversensing	0	0.00%	1	0.08%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.17%**	**8**	**0.66%**
Total Returned for Analysis	**0**		**1**	

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	0.41%
Total	**5**	**0.41%**



Year	at 11 months										
Survival Probability	98.70%										
± 1 standard error	0.47%										
Sample Size	200										

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

Customer Reported Performance Data

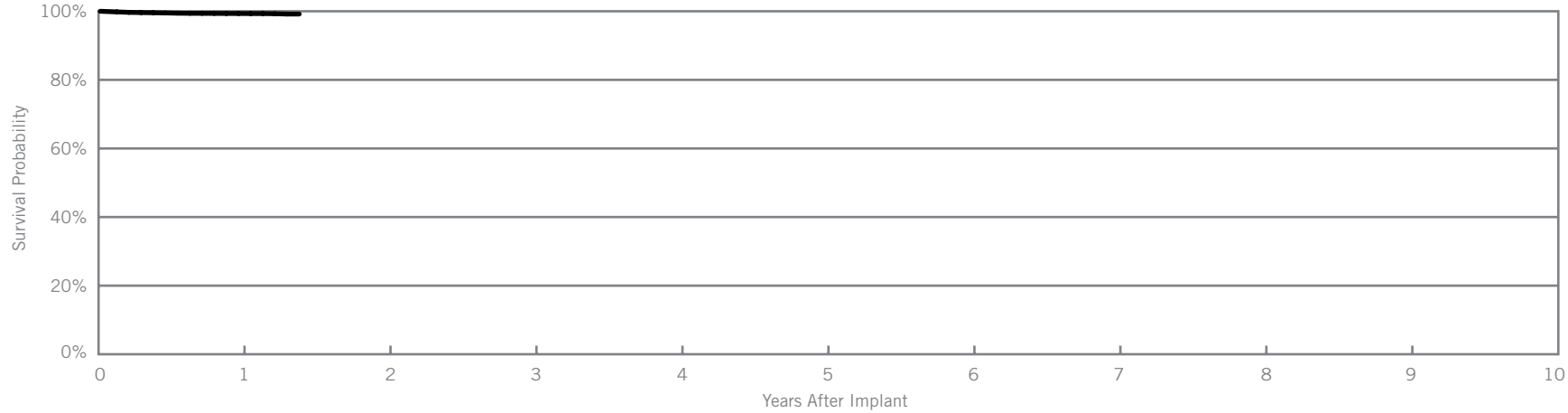
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	31,142
Estimated Active US Implants	27,788
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	16	0.05%	6	0.02%
Conductor Fracture	0	0.00%	2	0.01%
Lead Dislodgement	47	0.15%	64	0.21%
Failure to Capture	23	0.07%	25	0.08%
Oversensing	17	0.05%	15	0.05%
Failure to Sense	4	0.01%	4	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	0	0.00%
Abnormal Defibrillation Impedance	1	<0.01%	1	<0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	0.01%	1	<0.01%
Total	**111**	**0.36%**	**119**	**0.38%**
Total Returned for Analysis	**25**		**31**	

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	1	<0.01%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	64	0.21%
Total	**67**	**0.22%**



Year	1	at 17 months								
Survival Probability	99.35%	99.19%								
± 1 standard error	0.06%	0.12%								
Sample Size	18700	700								

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

SCORE Registry Performance Data

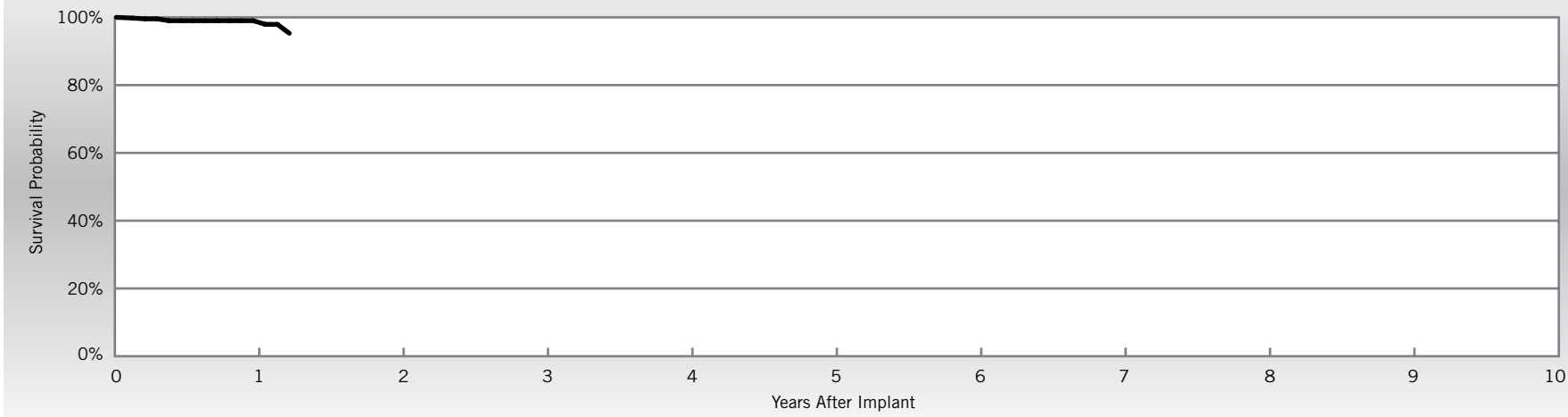
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	517
Cumulative Months of Follow-up	4,287
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	3	0.58%
Abnormal Defibrillation Impedance	2	0.39%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.77%
Total	**4**	**0.77%**



Year	1	at 15 months								
Survival Probability	99.28%	95.56%								
± 1 standard error	0.40%	2.13%								
Sample Size	310	50								

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

Customer Reported Performance Data

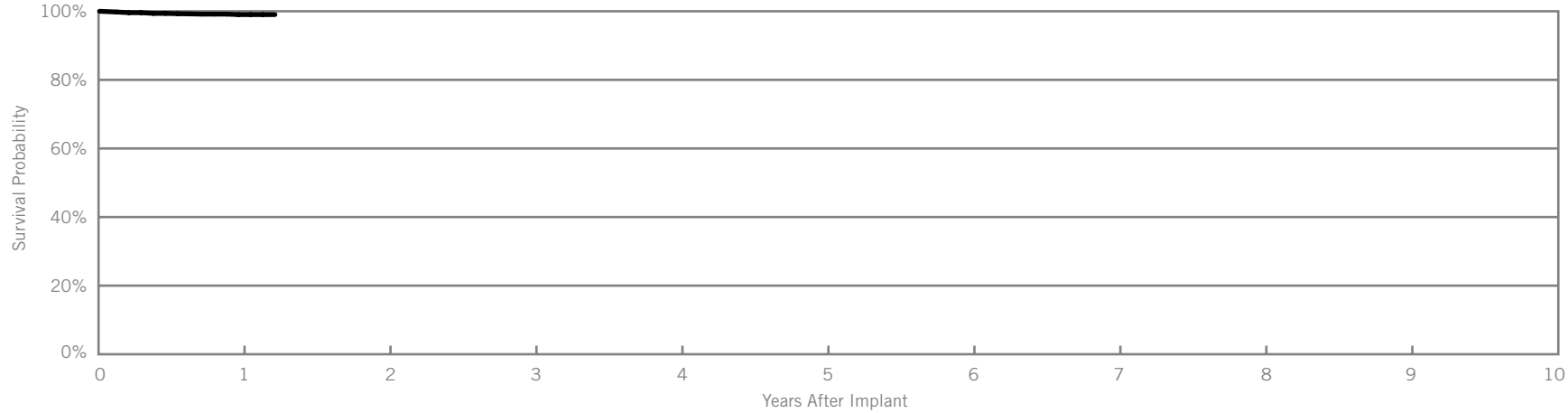
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	4,743
Estimated Active US Implants	4,210
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.06%	3	0.06%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	7	0.15%	11	0.23%
Failure to Capture	9	0.19%	4	0.08%
Oversensing	1	0.02%	3	0.06%
Failure to Sense	2	0.04%	2	0.04%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.06%	0	0.00%
Total	**25**	**0.53%**	**23**	**0.48%**
Total Returned for Analysis	**6**		**5**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.02%
Clavicular Crush	0	0.00%
In the Pocket	1	0.02%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	13	0.27%
Total	**14**	**0.30%**



Year	1	at 15 months								
Survival Probability	99.03%	99.03%								
± 1 standard error	0.17%	0.22%								
Sample Size	2700	300								

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

SCORE Registry Performance Data

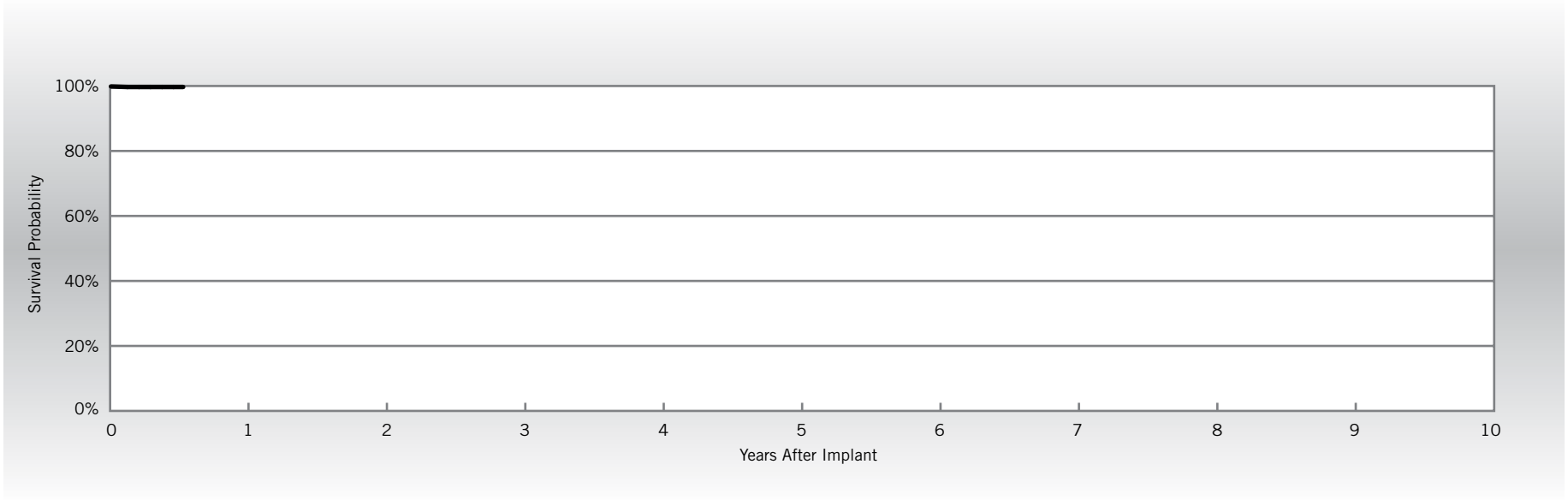
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	103
Cumulative Months of Follow-up	782
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
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	0	0.00%
Total	**0**	**0.00%**



Year	at 7 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

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

Customer Reported Performance Data

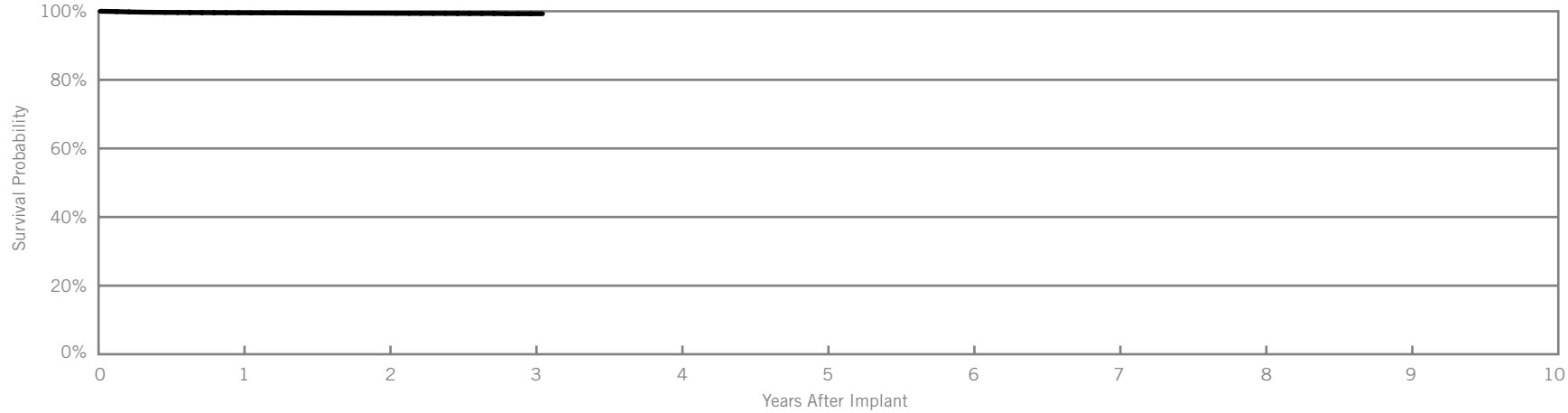
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	51,203
Estimated Active US Implants	40,504
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	29	0.06%	4	0.01%
Conductor Fracture	1	<0.01%	5	0.01%
Lead Dislodgement	57	0.11%	99	0.19%
Failure to Capture	14	0.03%	46	0.09%
Oversensing	44	0.09%	45	0.09%
Failure to Sense	4	0.01%	11	0.02%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	1	<0.01%	8	0.02%
Abnormal Defibrillation Impedance	16	0.03%	11	0.02%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	15	0.03%	11	0.02%
Total	**182**	**0.36%**	**241**	**0.47%**
Total Returned for Analysis	**52**		**105**	

Malfunctions	Qty.	Rate
Conductor Fracture	7	0.01%
Clavicular Crush	0	0.00%
In the Pocket	6	0.01%
Intravascular	1	<0.01%
Insulation Breach	3	0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	8	0.02%
Extrinsic Factors	109	0.21%
Total	**128**	**0.25%**



Year	1	2	3	at 37 months						
Survival Probability	99.56%	99.42%	99.28%	99.28%						
± 1 standard error	0.03%	0.04%	0.08%	0.08%						
Sample Size	45500	27000	7900	300						

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

SCORE Registry Performance Data

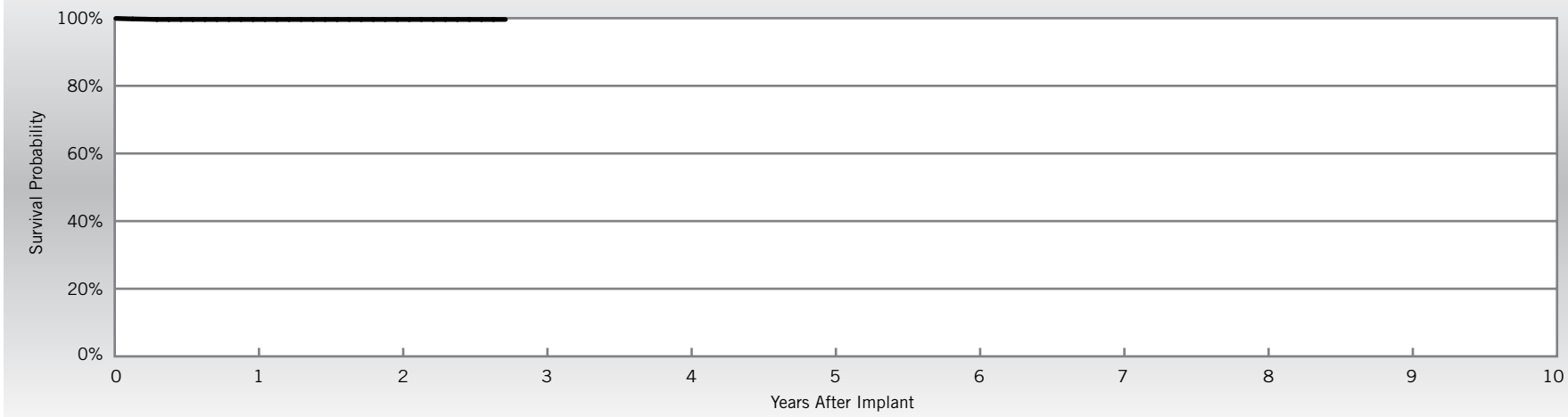
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,404
Cumulative Months of Follow-up	29,389
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	3	0.21%
Failure to Capture	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	1	0.07%
Total	**2**	**0.14%**



Year	1	2	at 33 months							
Survival Probability	99.63%	99.63%	99.63%							
± 1 standard error	0.16%	0.16%	0.16%							
Sample Size	1280	860	60							

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

Customer Reported Performance Data

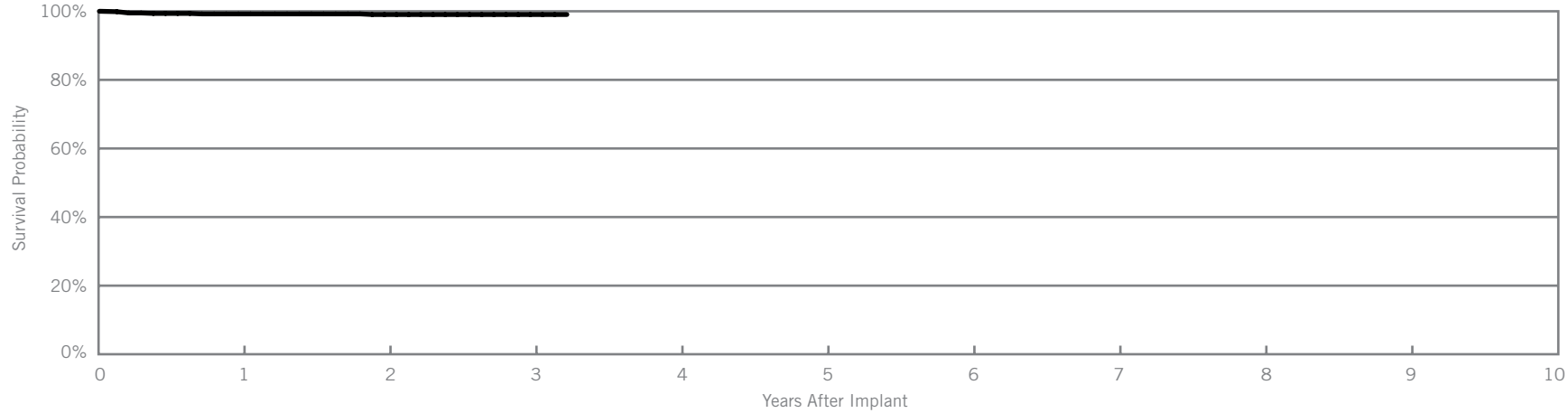
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	850
Estimated Active US Implants	575
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)		Chronic Complications (>30 days)	
	Qty.	Rate	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%	5	0.59%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.12%
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%**	**11**	**1.29%**
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	at 39 months						
Survival Probability	99.23%	99.05%	99.05%	99.05%						
± 1 standard error	0.32%	0.36%	0.36%	0.36%						
Sample Size	800	600	400	200						

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

Customer Reported Performance Data

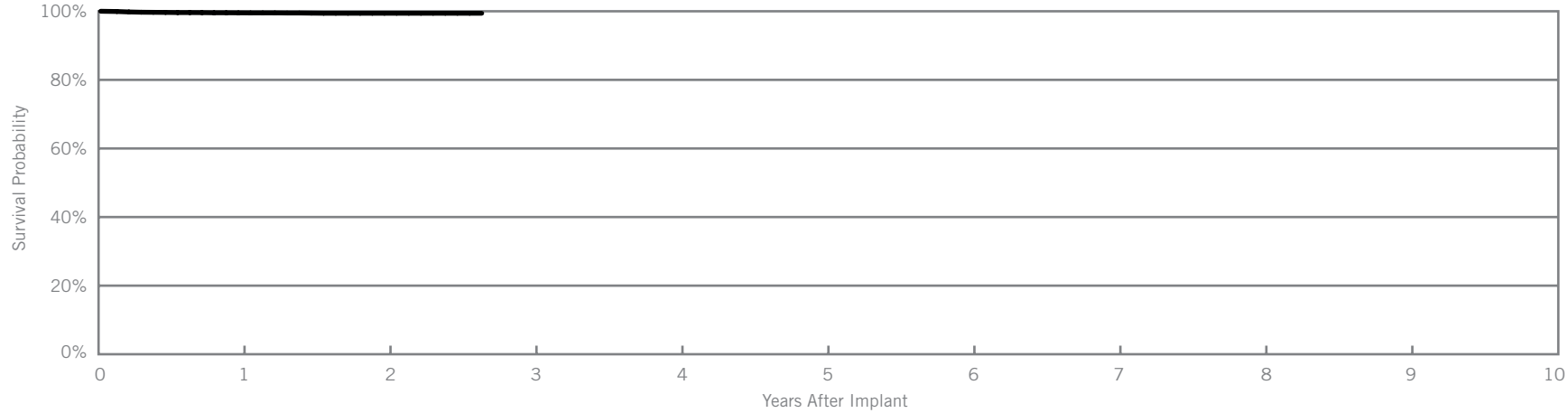
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	7,365
Estimated Active US Implants	6,009
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.04%	1	0.01%
Conductor Fracture	1	0.01%	1	0.01%
Lead Dislodgement	6	0.08%	11	0.15%
Failure to Capture	5	0.07%	6	0.08%
Oversensing	2	0.03%	4	0.05%
Failure to Sense	0	0.00%	3	0.04%
Insulation Breach	0	0.00%	2	0.03%
Abnormal Pacing Impedance	1	0.49%	4	0.05%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**19**	**0.26%**	**34**	**0.46%**
Total Returned for Analysis	**7**		**23**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.03%
Clavicular Crush	0	0.00%
In the Pocket	2	0.03%
Intravascular	0	0.00%
Insulation Breach	2	0.03%
Lead-to-Can Contact	1	0.01%
Lead-to-Lead Contact	1	0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	18	0.24%
Total	**23**	**0.31%**



Year	1	2	at 32 months							
Survival Probability	99.54%	99.42%	99.42%							
± 1 standard error	0.08%	0.11%	0.11%							
Sample Size	6000	3000	300							

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

SCORE Registry Performance Data

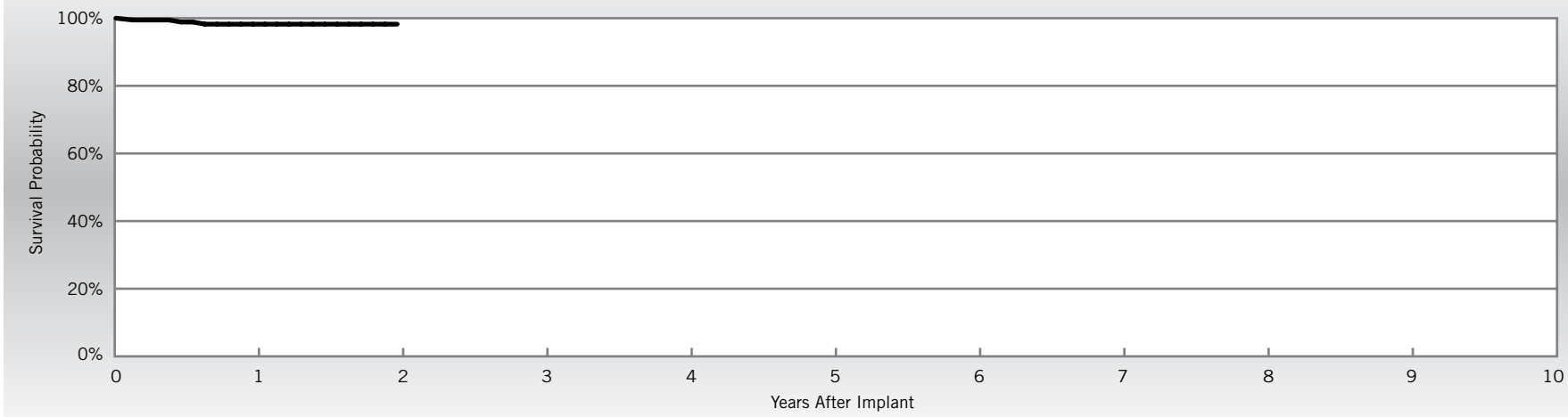
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	204
Cumulative Months of Follow-up	3,435
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	2	0.98%
Abnormal Pacing Impedance	1	0.49%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.49%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.49%
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	0.98%
Total	**3**	**1.47%**



Year	1	2								
Survival Probability	98.24%	98.24%								
± 1 standard error	0.99%	0.99%								
Sample Size	170	90								

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

Customer Reported Performance Data

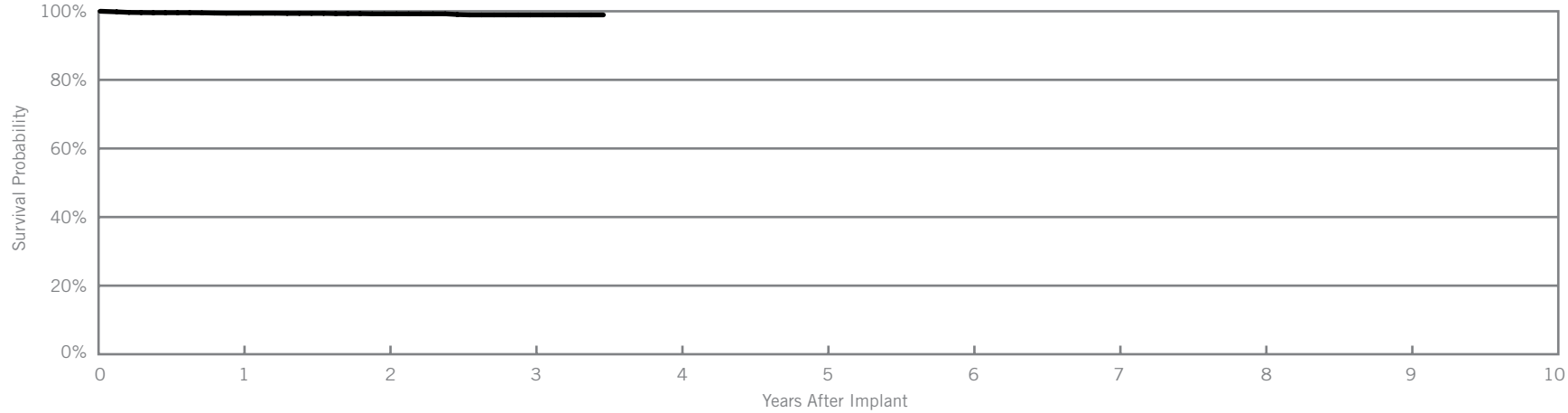
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,252
Estimated Active US Implants	2,372
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	0.06%	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%	3	0.09%
Oversensing	4	0.12%	5	0.15%
Failure to Sense	2	0.06%	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	**17**	**0.52%**	**21**	**0.65%**
Total Returned for Analysis	**4**		**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	1	0.03%
Other	1	0.03%
Extrinsic Factors	5	0.15%
Total	**9**	**0.28%**



Year	1	2	3	at 42 months						
Survival Probability	99.43%	99.26%	98.94%	98.94%						
± 1 standard error	0.14%	0.17%	0.25%	0.25%						
Sample Size	2900	2000	1000	200						

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

SCORE Registry Performance Data

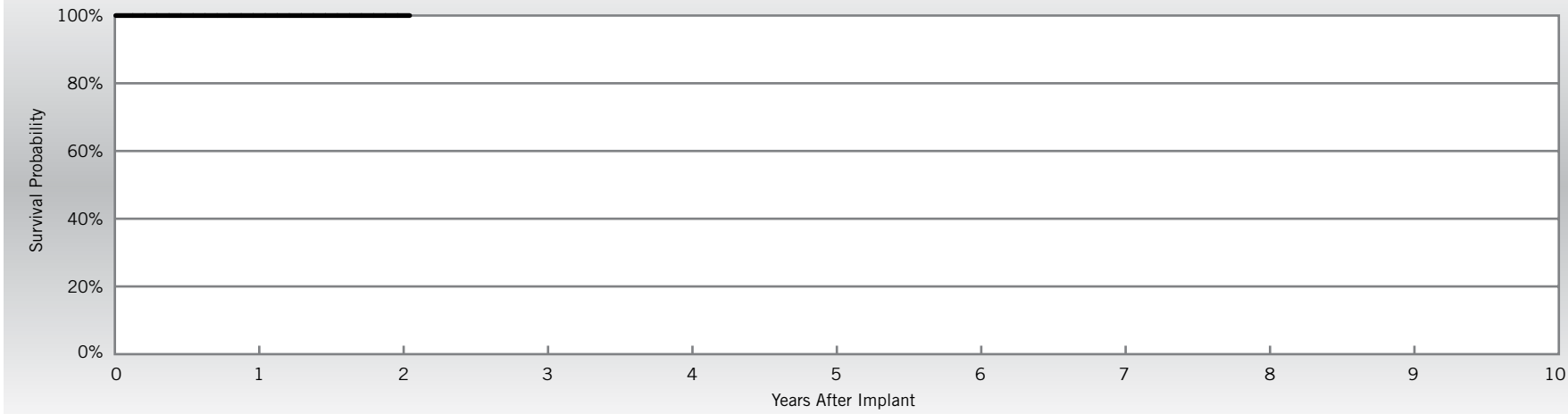
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	145
Cumulative Months of Follow-up	2,991
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	0.69%
Total	**1**	**0.69%**



Year	1	2	at 25 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	140	90	50							

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

Customer Reported Performance Data

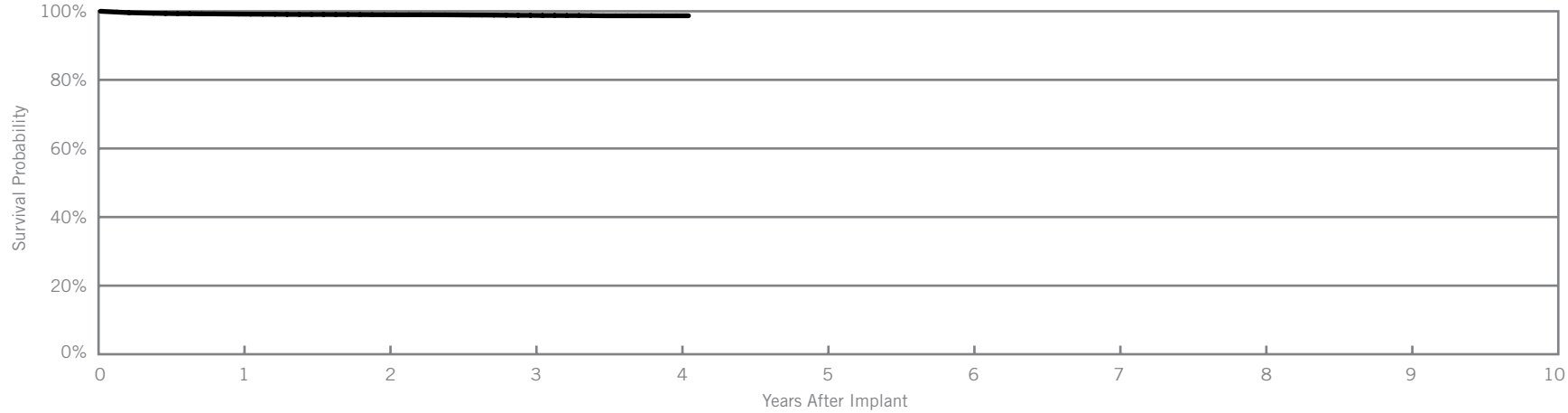
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,597
Estimated Active US Implants	10,728
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	38	0.24%	10	0.06%
Conductor Fracture	0	0.00%	3	0.02%
Lead Dislodgement	34	0.22%	47	0.30%
Failure to Capture	19	0.12%	34	0.22%
Oversensing	19	0.12%	41	0.26%
Failure to Sense	8	0.05%	10	0.06%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	1	0.01%	4	0.03%
Abnormal Defibrillation Impedance	4	0.03%	6	0.04%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	11	0.07%
Total	**127**	**0.81%**	**170**	**1.09%**
Total Returned for Analysis	**56**		**105**	

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	9	0.06%
Lead-to-Can Contact	2	0.01%
Lead-to-Lead Contact	3	0.02%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Other	3	0.02%
Crimps, Welds & Bonds	2	0.01%
Other	1	0.01%
Extrinsic Factors	84	0.54%
Total	**101**	**0.65%**



Year	1	2	3	4	at 49 months					
Survival Probability	99.18%	99.00%	98.81%	98.69%	98.69%					
± 1 standard error	0.07%	0.08%	0.10%	0.11%	0.11%					
Sample Size	15000	12600	9200	3500	200					

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

SCORE Registry Performance Data

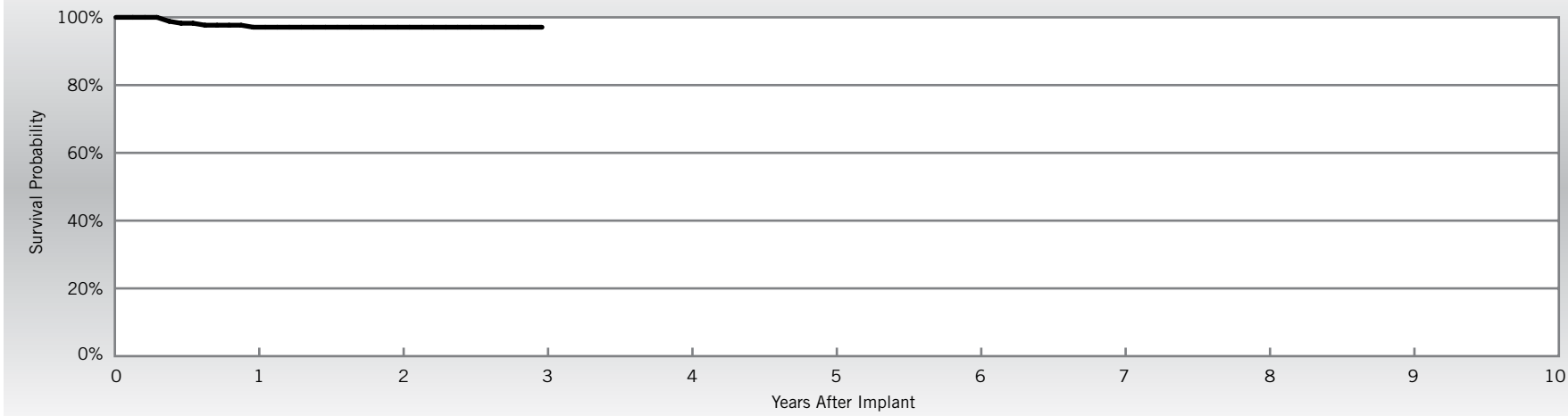
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	174
Cumulative Months of Follow-up	5,506
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	1.15%
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**	**1.15%**



Year	1	2	3							
Survival Probability	97.09%	97.09%	97.09%							
± 1 standard error	1.28%	1.28%	1.28%							
Sample Size	170	160	100							

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

Customer Reported Performance Data

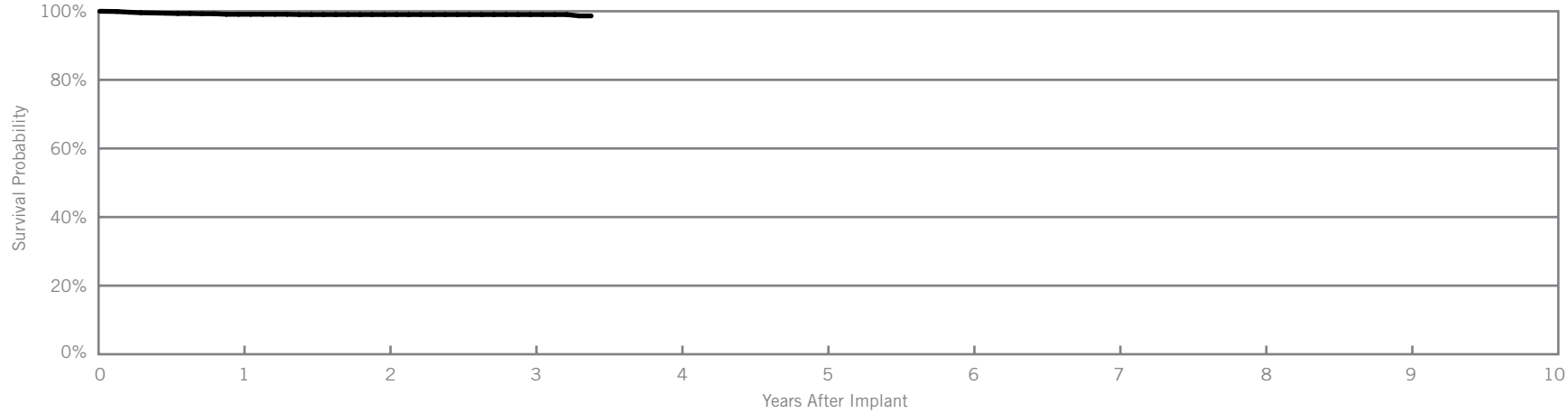
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,480
Estimated Active US Implants	1,034
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	5	0.34%	2	0.14%
Conductor Fracture	0	0.00%	1	0.07%
Lead Dislodgement	3	0.20%	6	0.41%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	5	0.34%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
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**	**0.68%**	**15**	**1.01%**
Total Returned for Analysis	**3**		**7**	

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	1	0.07%
Extrinsic Factors	7	0.47%
Total	**9**	**0.61%**



Year	1	2	3	at 41 months						
Survival Probability	99.12%	99.04%	99.04%	98.65%						
± 1 standard error	0.25%	0.27%	0.27%	0.47%						
Sample Size	1400	1200	800	200						

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

Customer Reported Performance Data

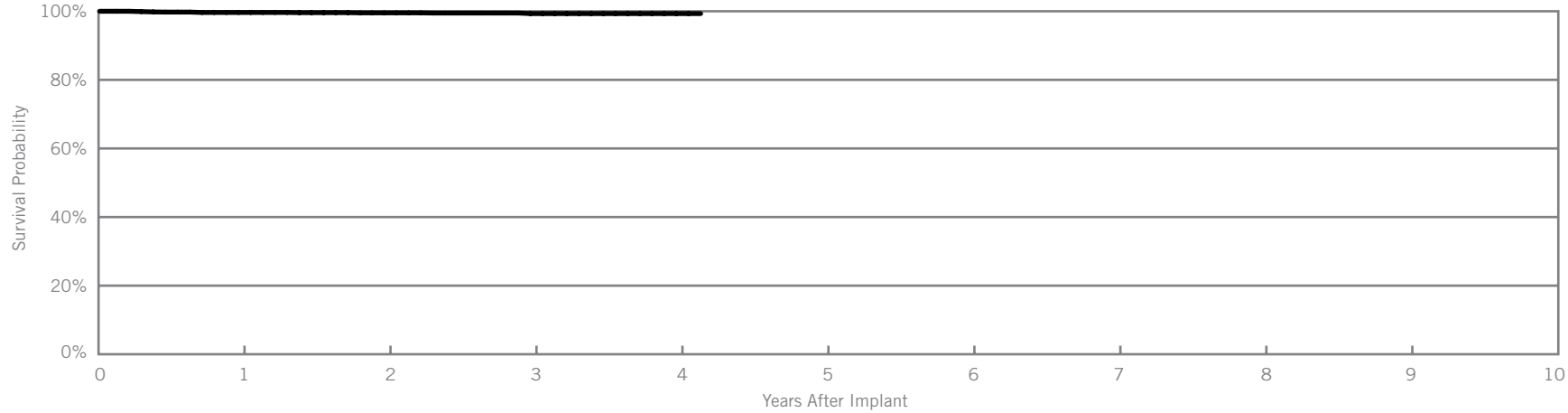
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,205
Estimated Active US Implants	1,441
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.05%	4	0.18%
Failure to Capture	3	0.14%	0	0.00%
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%**	**13**	**0.59%**
Total Returned for Analysis	**4**		**5**	

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	0.05%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	0.14%
Total	**4**	**0.18%**



Year	1	2	3	4	at 50 months					
Survival Probability	99.65%	99.54%	99.32%	99.32%	99.32%					
± 1 standard error	0.13%	0.15%	0.17%	0.20%	0.20%					
Sample Size	2200	1900	1500	800	200					

Customer Reported Performance Data

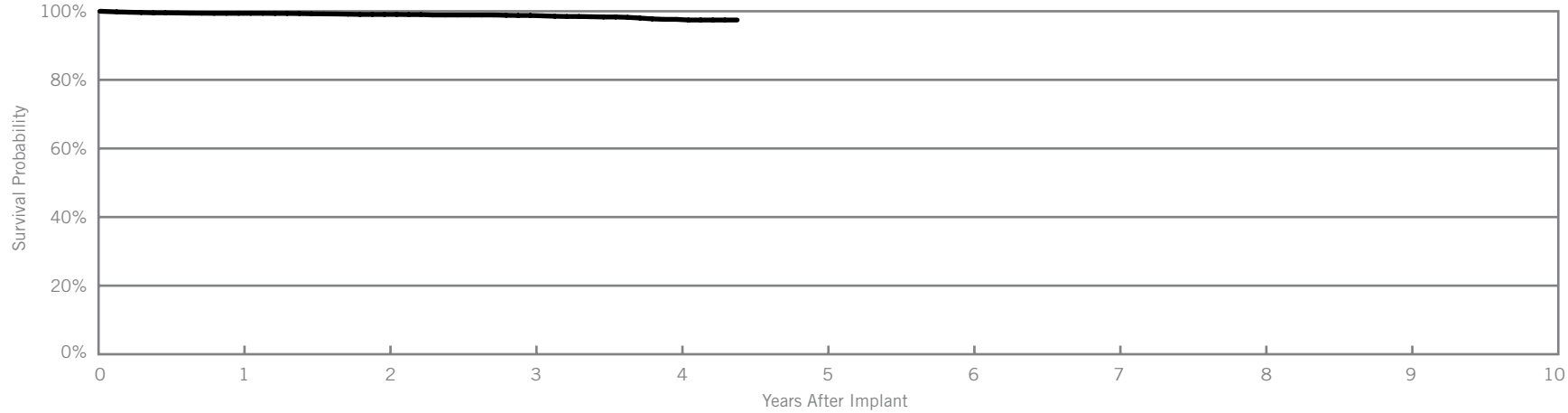
Riata® ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,086
Estimated Active US Implants	2,771
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	5	0.12%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	1	0.02%	7	0.17%
Oversensing	3	0.07%	17	0.42%
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%	3	0.07%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**16**	**0.39%**	**45**	**1.10%**
Total Returned for Analysis	**3**		**9**	

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	6	0.15%
Lead-to-Can Contact	5	0.12%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.07%
Extrinsic Factors	6	0.15%
Total	**17**	**0.42%**



Year	1	2	3	4	at 53 months					
Survival Probability	99.40%	99.08%	98.78%	97.64%	97.45%					
± 1 standard error	0.13%	0.16%	0.20%	0.38%	0.43%					
Sample Size	4000	3200	2400	1200	200					

Customer Reported Performance Data

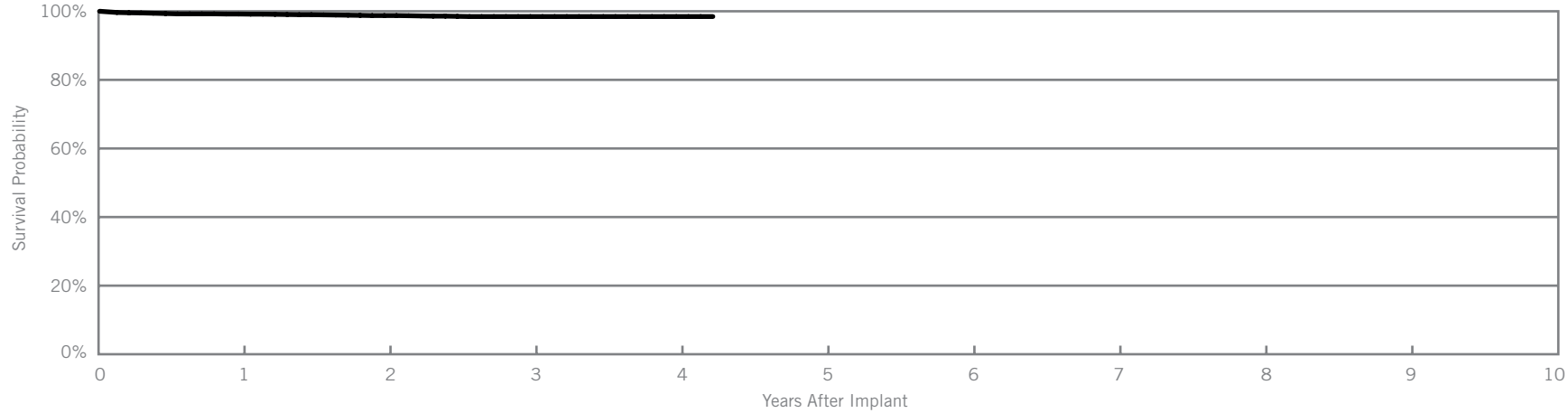
Riata® ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,411
Estimated Active US Implants	1,601
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	6	0.25%	3	0.12%
Conductor Fracture	0	0.00%	3	0.12%
Lead Dislodgement	3	0.12%	9	0.37%
Failure to Capture	4	0.17%	6	0.25%
Oversensing	4	0.17%	10	0.41%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
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%	2	0.08%
Total	**21**	**0.87%**	**34**	**1.41%**
Total Returned for Analysis	**8**		**14**	

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	2	0.08%
Lead-to-Can Contact	2	0.08%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	9	0.37%
Total	**13**	**0.54%**



Year	1	2	3	4	at 51 months					
Survival Probability	99.20%	98.75%	98.46%	98.46%	98.46%					
± 1 standard error	0.19%	0.24%	0.27%	0.27%	0.27%					
Sample Size	2400	2000	1500	800	200					

Customer Reported Performance Data

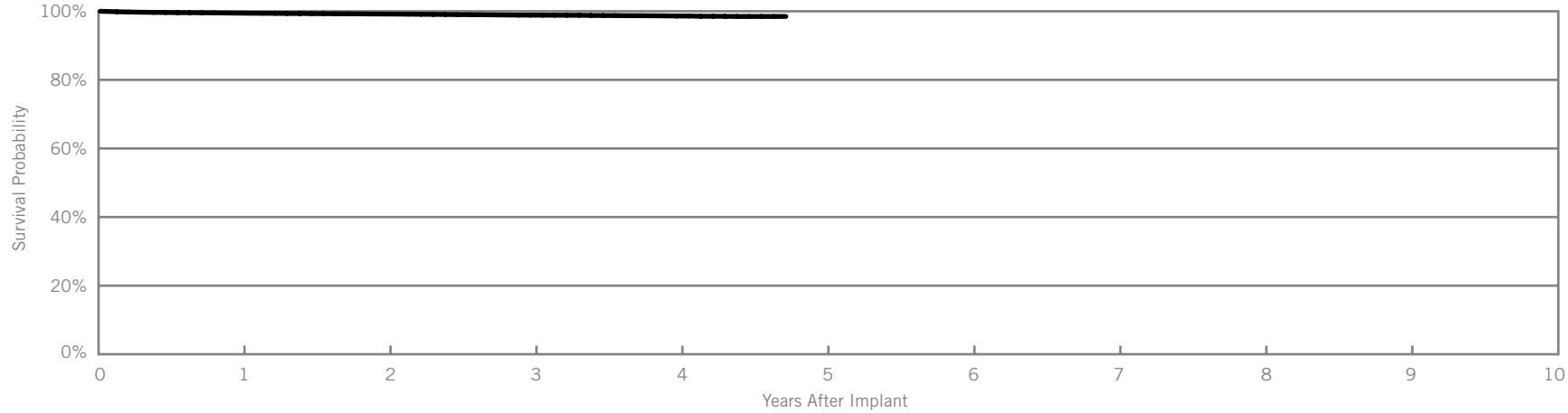
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	35,037
Estimated Active US Implants	22,858
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	41	0.12%	20	0.06%
Conductor Fracture	0	0.00%	17	0.05%
Lead Dislodgement	37	0.11%	39	0.11%
Failure to Capture	43	0.12%	67	0.19%
Oversensing	40	0.11%	158	0.45%
Failure to Sense	7	0.02%	17	0.05%
Insulation Breach	1	<0.01%	9	0.03%
Abnormal Pacing Impedance	8	0.02%	10	0.03%
Abnormal Defibrillation Impedance	4	0.01%	10	0.03%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	11	0.03%	27	0.08%
Total	**196**	**0.56%**	**376**	**1.07%**
Total Returned for Analysis	**93**		**168**	

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	66	0.19%
Lead-to-Can Contact	47	0.13%
Lead-to-Lead Contact	9	0.03%
Clavicular Crush	2	0.01%
Externalized Conductors	1	<0.01%
Other	7	0.02%
Crimps, Welds & Bonds	4	0.01%
Other	0	0.00%
Extrinsic Factors	90	0.26%
Total	**170**	**0.49%**



Year	1	2	3	4	at 57 months					
Survival Probability	99.46%	99.19%	98.87%	98.61%	98.49%					
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.09%					
Sample Size	34200	29500	24200	14700	500					

SCORE Registry Performance Data

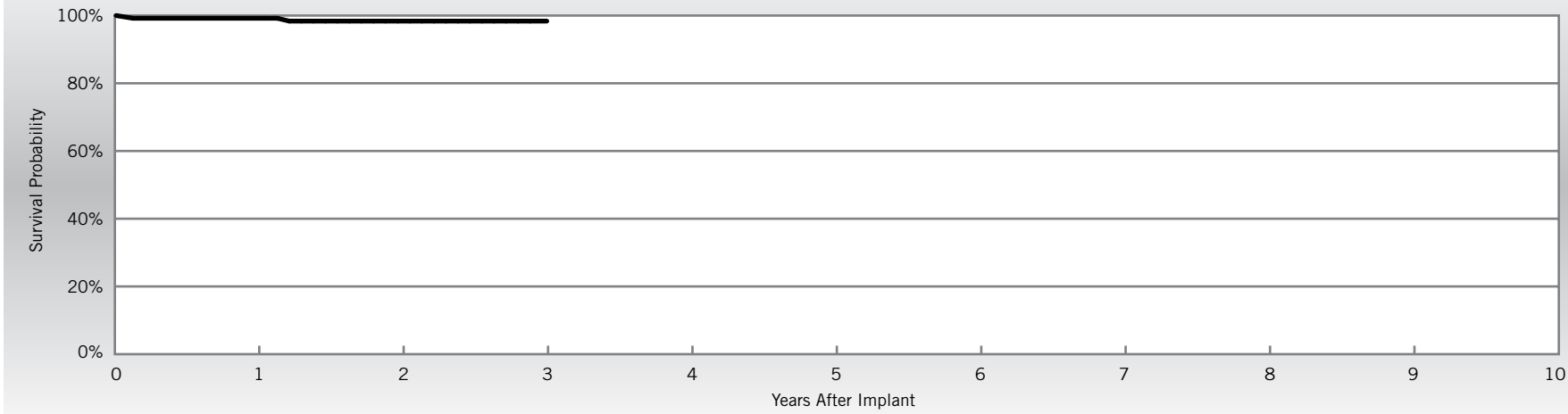
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	125
Cumulative Months of Follow-up	3,983
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.80%
Oversensing	1	0.80%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	2	1.60%
Lead-to-Can Contact	1	0.80%
Lead-to-Lead Contact	1	0.80%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.80%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**3**	**2.40%**



Year	1	2	3							
Survival Probability	99.20%	98.36%	98.36%							
± 1 standard error	0.80%	1.15%	1.15%							
Sample Size	120	110	60							

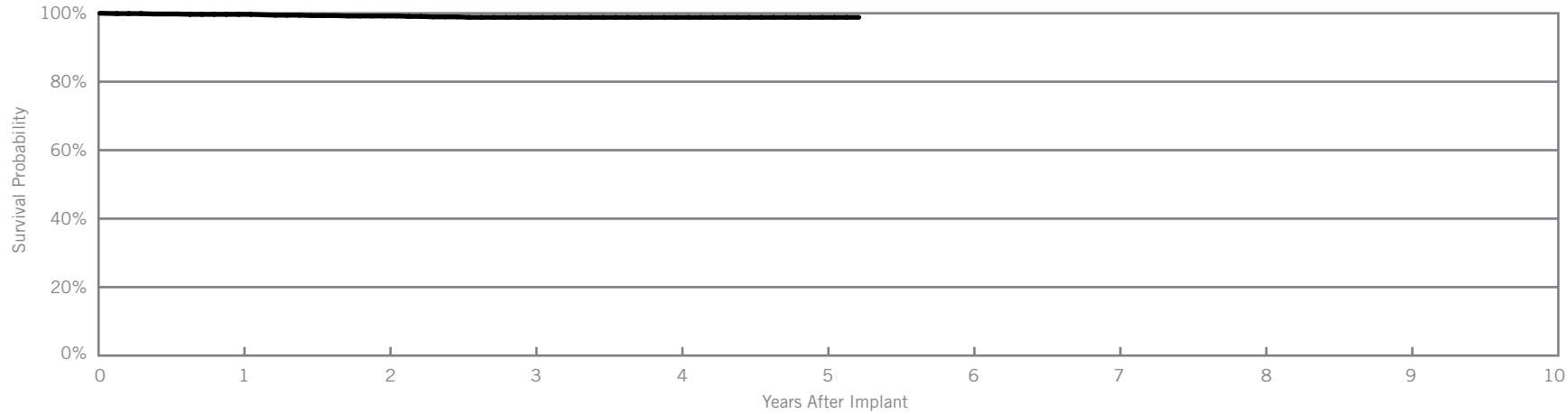
Customer Reported Performance Data

Riata® *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,007
Estimated Active US Implants	533
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

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	at 63 months				
Survival Probability	99.68%	99.20%	98.81%	98.81%	98.81%	98.81%				
± 1 standard error	0.19%	0.30%	0.38%	0.38%	0.38%	0.38%				
Sample Size	1000	900	800	700	400	200				

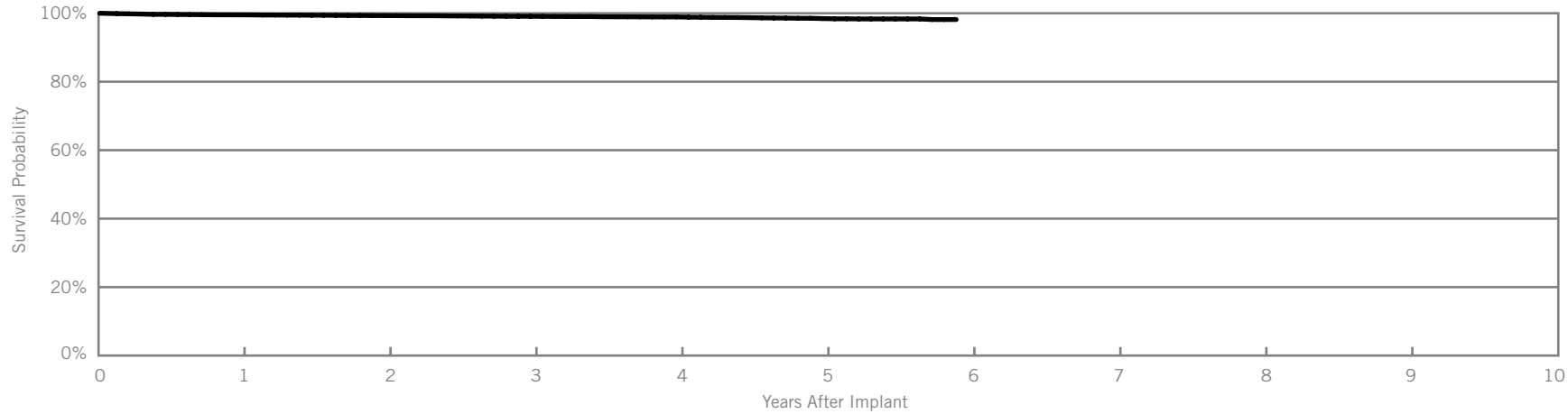
Customer Reported Performance Data

Riata® *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,747
Estimated Active US Implants	5,406
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.03%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	2	0.02%
Insulation Breach	10	0.10%
Lead-to-Can Contact	6	0.06%
Lead-to-Lead Contact	3	0.03%
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	16	0.16%
Total	**29**	**0.30%**



Year	1	2	3	4	5	at 71 months				
Survival Probability	99.53%	99.32%	99.12%	98.93%	98.45%	98.17%				
± 1 standard error	0.07%	0.09%	0.10%	0.12%	0.15%	0.24%				
Sample Size	9600	8500	7600	6500	4600	300				

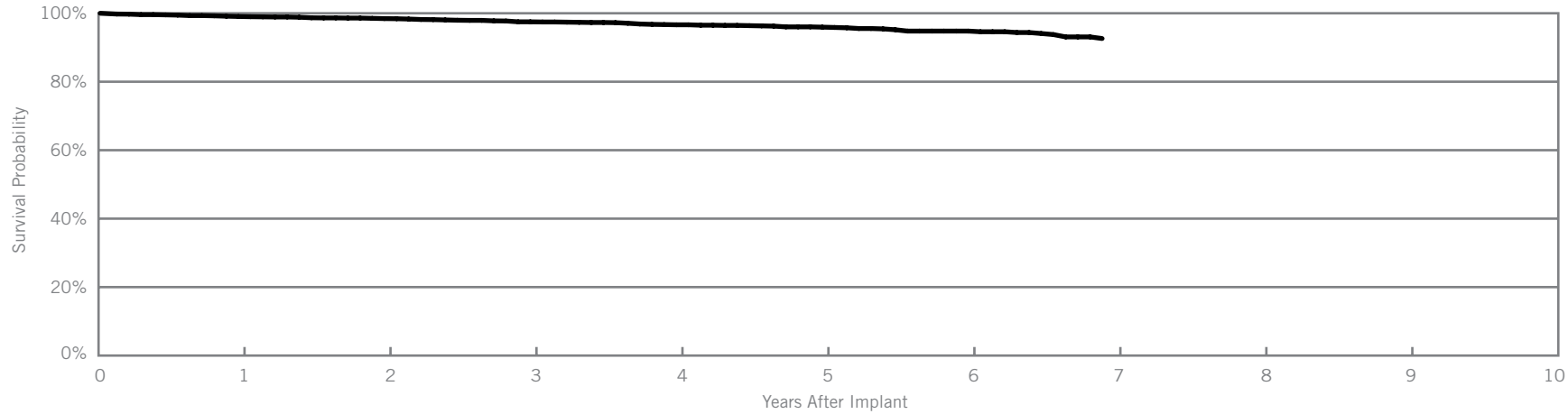
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,186
Estimated Active US Implants	1,583
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

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	37	1.16%
Lead-to-Can Contact	22	0.69%
Lead-to-Lead Contact	3	0.09%
Clavicular Crush	1	0.03%
Externalized Conductors	3	0.09%
Other	8	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.44%
Total	**53**	**1.66%**



Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.06%	98.44%	97.50%	96.63%	95.94%	94.79%	92.62%			
± 1 standard error	0.17%	0.23%	0.31%	0.37%	0.43%	0.56%	0.89%			
Sample Size	3100	2600	2300	1900	1500	800	200			

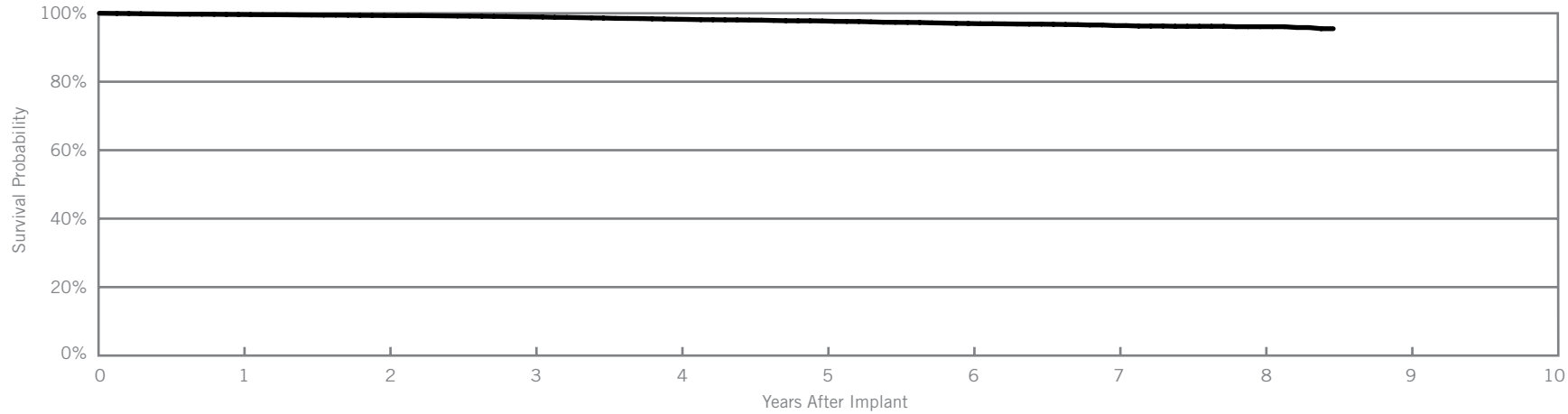
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,523
Estimated Active US Implants	5,115
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

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	28	0.27%
Lead-to-Can Contact	19	0.18%
Lead-to-Lead Contact	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.03%
Other	4	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	17	0.16%
Total	**48**	**0.46%**



Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.64%	99.34%	98.95%	98.25%	97.75%	97.01%	96.39%	96.07%	95.49%
± 1 standard error	0.06%	0.08%	0.11%	0.15%	0.18%	0.23%	0.27%	0.33%	0.53%
Sample Size	10100	8900	7800	6600	5300	3700	2300	1200	300

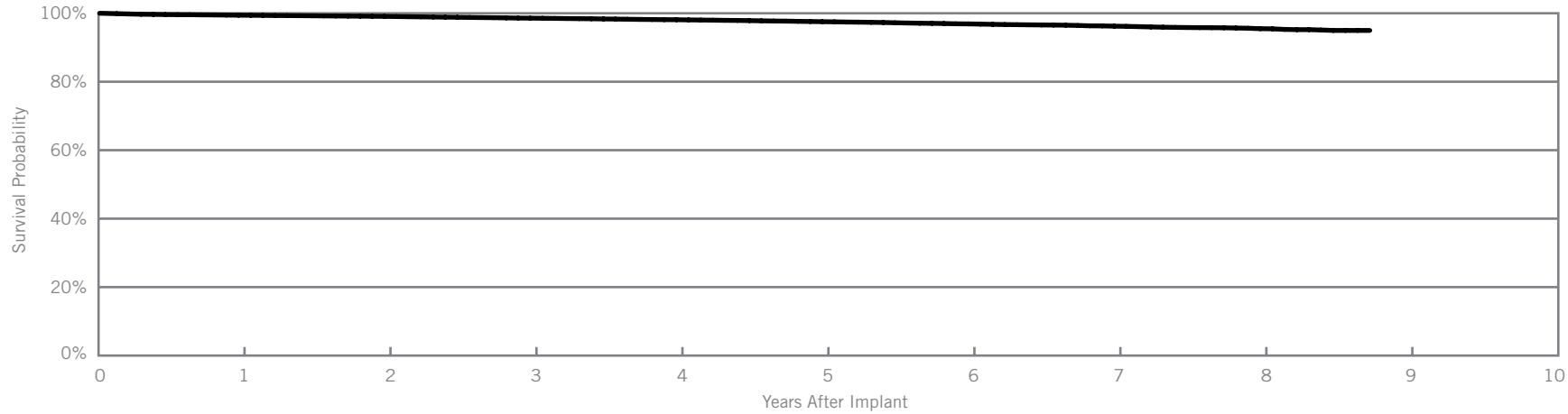
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,694
Estimated Active US Implants	35,224
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	14	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	6	0.01%
Intravascular	6	0.01%
Insulation Breach	240	0.34%
Lead-to-Can Contact	145	0.21%
Lead-to-Lead Contact	29	0.04%
Clavicular Crush	5	0.01%
Externalized Conductors	23	0.03%
Other	38	0.05%
Crimps, Welds & Bonds	4	0.01%
Other	3	<0.01%
Extrinsic Factors	200	0.29%
Total	**461**	**0.66%**



Year	1	2	3	4	5	6	7	8	at 105 months
Survival Probability	99.43%	99.09%	98.57%	98.11%	97.54%	96.89%	96.23%	95.49%	94.98%
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.09%	0.12%	0.17%	0.28%
Sample Size	67900	59500	52700	45600	36200	22800	11300	4700	200

SCORE Registry Performance Data

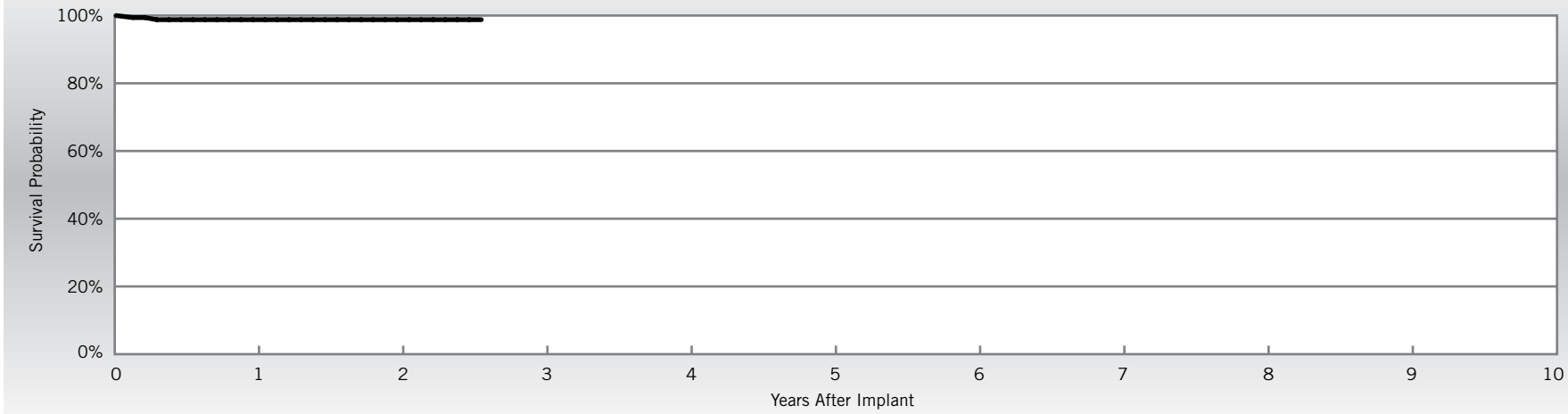
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	168
Cumulative Months of Follow-up	3,847
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.60%
Abnormal Pacing Impedance	1	0.60%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	1.79%
Total	**3**	**1.79%**



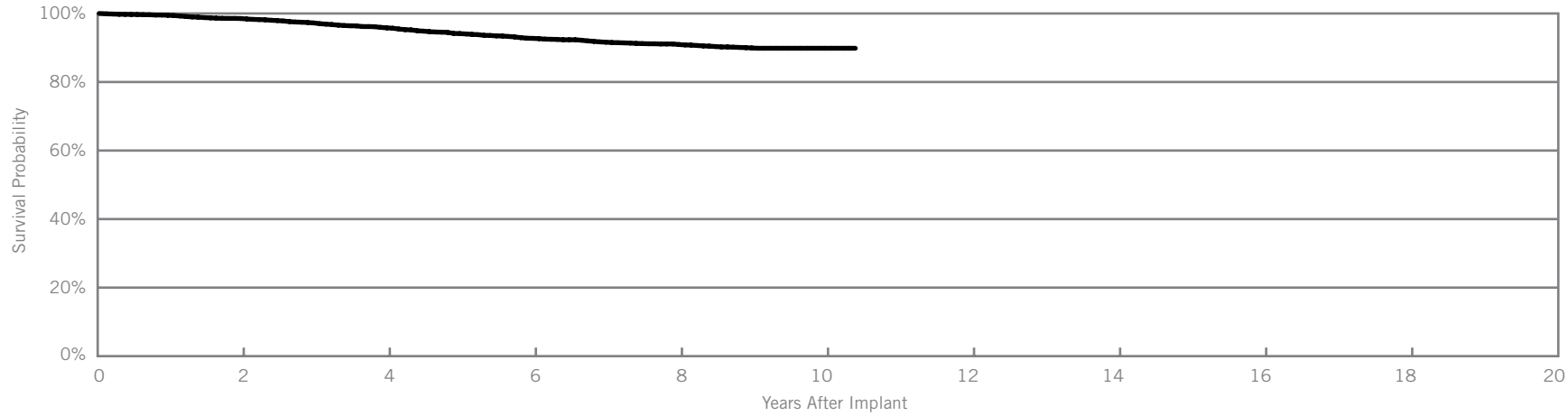
Year	1	2	at 31 months							
Survival Probability	98.78%	98.78%	98.78%							
± 1 standard error	0.85%	0.85%	0.85%							
Sample Size	150	110	50							

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,736
Estimated Active US Implants	1,109
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



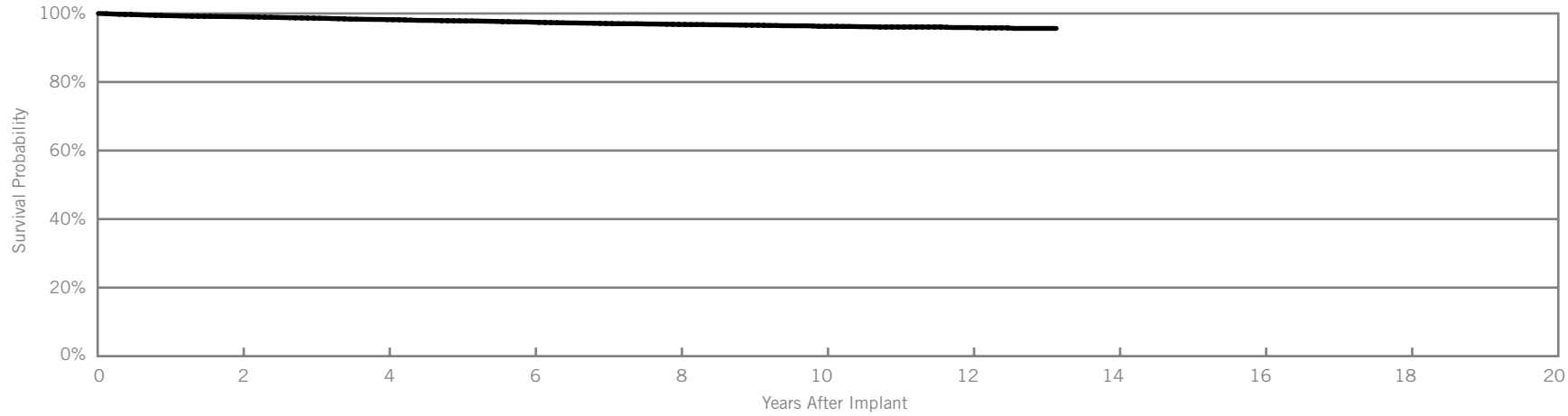
Year	2	4	6	8	10	at 125 months				
Survival Probability	98.53%	95.80%	92.74%	90.94%	89.85%	89.85%				
± 1 standard error	0.19%	0.34%	0.47%	0.54%	0.60%	0.60%				
Sample Size	3900	3100	2400	1900	800	200				

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,641
Estimated Active US Implants	3,133
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	at 158 months			
Survival Probability	99.05%	98.20%	97.46%	96.80%	96.25%	95.90%	95.64%			
± 1 standard error	0.09%	0.13%	0.16%	0.19%	0.23%	0.26%	0.33%			
Sample Size	10900	9000	7300	5800	3800	1500	200			

Summary Information

Defibrillation 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
7170Q/7171Q	Durata® DF4*										
7120Q/7121Q	Durata® DF4	99.35%									
7122Q	Durata® DF4	99.03%									
7120/7121	Durata®	99.56%	99.42%	99.28%							
7122	Durata®	99.54%	99.42%								
7030/7031	Riata® ST Optim®	99.23%	99.05%	99.05%							
7022	Riata® ST Optim®	99.12%	99.04%	99.04%							
7070/7071	Riata® ST Optim®	99.43%	99.26%	98.94%							
7020/7021	Riata® ST Optim®	99.18%	99.00%	98.81%	98.69%						
7010/7011	Riata® ST	99.65%	99.54%	99.32%	99.32%						
7040/7041	Riata® ST	99.40%	99.08%	98.78%	97.64%						
7002	Riata® ST	99.20%	98.75%	98.46%	98.46%						
7000/7001	Riata® ST	99.46%	99.19%	98.87%	98.61%						
1560/1561	Riata® i	99.68%	99.20%	98.81%	98.81%	98.81%					
1590/1591	Riata® i	99.53%	99.32%	99.12%	98.93%	98.45%					
1582	Riata®	99.06%	98.44%	97.50%	96.63%	95.94%	94.79%				
1570/1571	Riata®	99.64%	99.34%	98.95%	98.25%	97.75%	97.01%	96.39%	96.07%		
1580/1581	Riata®	99.43%	99.09%	98.57%	98.11%	97.54%	96.89%	96.23%	95.49%		
1559	TVL™ ADX	99.48%	98.53%	97.24%	95.80%	94.14%	92.74%	91.62%	90.94%	89.94%	89.85%
SP01/SP02/SP03/SP04	SPL®	99.36%	99.05%	98.64%	98.20%	97.86%	97.46%	97.07%	96.80%	96.58%	96.25%

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

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	1207	1102	1	0.08%	0	0.00%	0	0.00%	1	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.17%**	**0**
7120Q/7121Q	Jan-09	31142	27788	16	0.05%	0	0.00%	47	0.15%	23	0.07%	17	0.05%	4	0.01%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	2	0.01%	**111**	**0.36%**	**25**
7122Q	Jan-09	4743	4210	3	0.06%	0	0.00%	7	0.15%	9	0.19%	1	0.02%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.06%	**25**	**0.53%**	**6**
7120/7121	Sep-07	51203	40504	29	0.06%	1	<0.01%	57	0.11%	14	0.03%	44	0.09%	4	0.01%	0	0.00%	1	<0.01%	16	0.03%	1	<0.01%	15	0.03%	**182**	**0.36%**	**52**
7122	Sep-07	7365	6009	3	0.04%	1	0.01%	6	0.08%	5	0.07%	2	0.03%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**19**	**0.26%**	**7**
7030/7031	Jul-06	850	575	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**
7022	Jul-06	1480	1034	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.68%**	**3**
7070/7071	Jul-06	3252	2372	2	0.06%	1	0.03%	3	0.09%	5	0.15%	4	0.12%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**17**	**0.52%**	**4**
7020/7021	Jul-06	15597	10728	38	0.24%	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**	**0.81%**	**56**
7010/7011	Mar-06	2205	1441	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	4086	2771	4	0.10%	0	0.00%	5	0.12%	1	0.02%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**16**	**0.39%**	**3**
7002	Jun-05	2411	1601	6	0.25%	0	0.00%	3	0.12%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	**21**	**0.87%**	**8**
7000/7001	Jun-05	35037	22858	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%**	**93**

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	1207	1102	0	0.00%	0	0.00%	2	0.17%	5	0.41%	1	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.66%**	**1**
7120Q/7121Q	Jan-09	31142	27788	6	0.02%	2	0.01%	64	0.21%	25	0.08%	15	0.05%	4	0.01%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**119**	**0.38%**	**31**
7122Q	Jan-09	4743	4210	3	0.06%	0	0.00%	11	0.23%	4	0.08%	3	0.06%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**23**	**0.48%**	**5**
7120/7121	Sep-07	51203	40504	4	0.01%	5	0.01%	99	0.19%	46	0.09%	45	0.09%	11	0.02%	1	<0.01%	8	0.02%	11	0.02%	0	0.00%	11	0.02%	**241**	**0.47%**	**105**
7122	Sep-07	7365	6009	1	0.01%	1	0.01%	11	0.15%	6	0.08%	4	0.05%	3	0.04%	2	0.03%	4	0.05%	1	0.01%	0	0.00%	1	0.01%	**34**	**0.46%**	**23**
7030/7031	Jul-06	850	575	1	0.12%	0	0.00%	0	0.00%	4	0.47%	5	0.59%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	**11**	**1.29%**	**2**
7022	Jul-06	1480	1034	2	0.14%	1	0.07%	6	0.41%	1	0.07%	5	0.34%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**15**	**1.01%**	**7**
7070/7071	Jul-06	3252	2372	2	0.06%	2	0.06%	4	0.12%	3	0.09%	5	0.15%	2	0.06%	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	**21**	**0.65%**	**7**
7020/7021	Jul-06	15597	10728	10	0.06%	3	0.02%	47	0.30%	34	0.22%	41	0.26%	10	0.06%	2	0.01%	4	0.03%	6	0.04%	2	0.01%	11	0.07%	**170**	**1.09%**	**105**
7010/7011	Mar-06	2205	1441	1	0.05%	0	0.00%	4	0.18%	0	0.00%	4	0.18%	2	0.09%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**13**	**0.59%**	**5**
7040/7041	Mar-06	4086	2771	2	0.05%	5	0.12%	3	0.07%	7	0.17%	17	0.42%	4	0.10%	1	0.02%	3	0.07%	3	0.07%	0	0.00%	0	0.00%	**45**	**1.10%**	**9**
7002	Jun-05	2411	1601	3	0.12%	3	0.12%	9	0.37%	6	0.25%	10	0.41%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	2	0.08%	**34**	**1.41%**	**14**
7000/7001	Jun-05	35037	22858	20	0.06%	17	0.05%	39	0.11%	67	0.19%	158	0.45%	17	0.05%	9	0.03%	10	0.03%	10	0.03%	2	0.01%	27	0.08%	**376**	**1.07%**	**168**

Definitions of observations and complications can be found on pages 7 and 8.

Malfunction Summary

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7170Q/7171Q	1207	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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	0.41%	**5**	**0.41%**
7120Q/7121Q	31142	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**1**	**<0.01%**	0	0.00%	1	<0.01%	64	0.21%	**67**	**0.22%**
7122Q	4743	0	0.00%	1	0.02%	0	0.00%	**1**	**0.02%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	13	0.27%	**14**	**0.30%**
7120/7121	51203	0	0.00%	6	0.01%	1	<0.01%	**7**	**0.01%**	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	**3**	**<0.01%**	1	<0.01%	8	0.02%	109	0.21%	**128**	**0.25%**
7122	7365	0	0.00%	2	0.03%	0	0.00%	**2**	**0.03%**	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**	0	0.00%	1	0.01%	18	0.24%	**23**	**0.31%**
7030/7031	850	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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%**
7022	1480	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%	1	0.07%	7	0.47%	**9**	**0.61%**
7070/7071	3252	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%**	1	0.03%	1	0.03%	5	0.15%	**9**	**0.28%**
7020/7021	15597	1	0.01%	1	0.01%	3	0.02%	**5**	**0.03%**	2	0.01%	3	0.02%	1	0.01%	0	0.00%	3	0.02%	**9**	**0.06%**	2	0.01%	1	0.01%	84	0.54%	**101**	**0.65%**
7010/7011	2205	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**	0	0.00%	0	0.00%	3	0.14%	**4**	**0.18%**
7040/7041	4086	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	5	0.12%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**6**	**0.15%**	0	0.00%	3	0.07%	6	0.15%	**17**	**0.42%**
7002	2411	0	0.00%	0	0.00%	2	0.08%	**2**	**0.08%**	2	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.08%**	0	0.00%	0	0.00%	9	0.37%	**13**	**0.54%**
7000/7001	35037	2	0.01%	2	0.01%	6	0.02%	**10**	**0.03%**	47	0.13%	9	0.03%	2	0.01%	1	<0.01%	7	0.02%	**66**	**0.19%**	4	0.01%	0	0.00%	90	0.26%	**170**	**0.49%**
1560/1561	1007	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	9747	1	0.01%	0	0.00%	2	0.02%	**3**	**0.03%**	6	0.06%	3	0.03%	0	0.00%	0	0.00%	1	0.01%	**10**	**0.10%**	0	0.00%	0	0.00%	16	0.16%	**29**	**0.30%**
1582	3186	0	0.00%	0	0.00%	2	0.06%	**2**	**0.06%**	22	0.69%	3	0.09%	1	0.03%	3	0.09%	8	0.25%	**37**	**1.16%**	0	0.00%	0	0.00%	14	0.44%	**53**	**1.66%**
1570/1571	10523	2	0.02%	1	0.01%	0	0.00%	**3**	**0.03%**	19	0.18%	2	0.02%	0	0.00%	3	0.03%	4	0.04%	**28**	**0.27%**	0	0.00%	0	0.00%	17	0.16%	**48**	**0.46%**
1580/1581	69694	2	<0.01%	6	0.01%	6	0.01%	**14**	**0.02%**	145	0.21%	29	0.04%	5	0.01%	23	0.03%	38	0.05%	**240**	**0.34%**	4	0.01%	3	<0.01%	200	0.29%	**461**	**0.66%**

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

SCORE Summary

Malfunctions

		Conductor Fracture								Insulation Breach																	
		Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	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	517	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	4	0.77%	**4**	**0.77%**
7122Q	103	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
7120/7121	1404	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%	1	0.07%	**2**	**0.14%**
7122	204	0	0.00%	0	0.00%	1	0.49%	**1**	**0.49%**	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	0.98%	**3**	**1.47%**
7070/7071	145	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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	0.69%	**1**	**0.69%**
7020/7021	174	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**	**1.15%**
7000/7001	125	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.80%	1	0.80%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.60%**	1	0.80%	0	0.00%	0	0.00%	**3**	**2.40%**
1580/1581	168	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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	1.79%	**3**	**1.79%**

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		Inappropriate Shock		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	517	4287	0	0.00%	0	0.00%	3	0.58%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.39%	0	0.00%	0	0.00%	**5**	**0.97%**
7122Q	103	782	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
7120/7121	1404	29389	0	0.00%	0	0.00%	3	0.21%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	**5**	**0.36%**
7122	204	3435	0	0.00%	0	0.00%	2	0.98%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.49%	0	0.00%	0	0.00%	0	0.00%	**3**	**1.47%**
7070/7071	145	2991	0	0.00%	0	0.00%	0	0.00%	0	0.00%	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	174	5506	1	0.57%	2	1.15%	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**	**2.87%**
7000/7001	125	3983	0	0.00%	0	0.00%	1	0.80%	0	0.00%	1	0.80%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.60%**
1580/1581	168	3847	0	0.00%	0	0.00%	1	0.60%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.60%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.19%**

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

Pacemakers

Dual-Chamber

St. Jude Medical™
More control. Less risk.

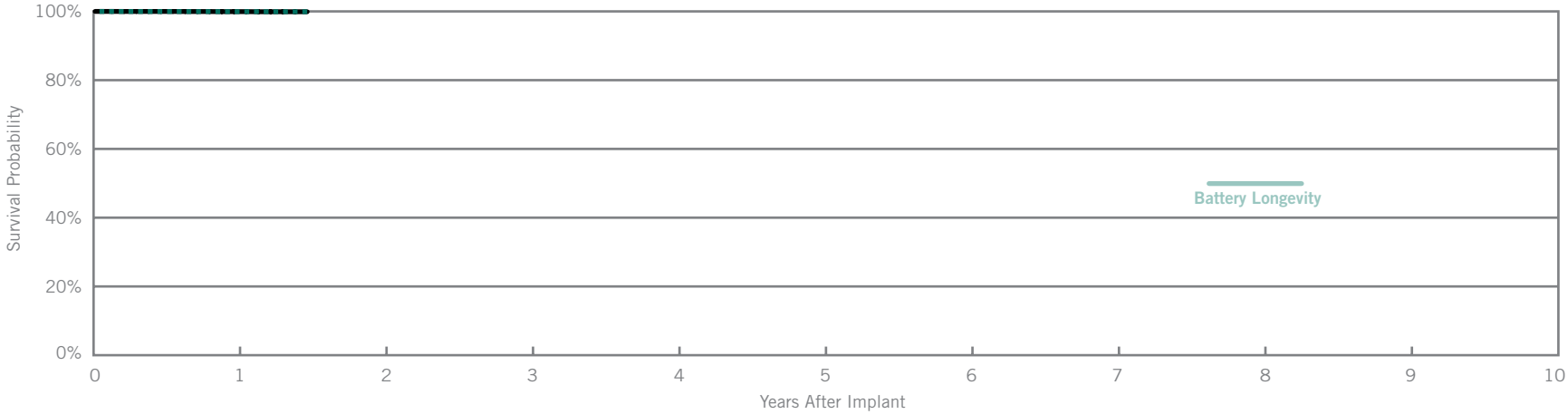
Customer Reported Performance Data

Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	58,161
Estimated Active US Implants	53,582
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	3	0.01%
Malfunctions w/o Compromised Therapy	7	0.01%
Total	**10**	**0.02%**



Including Normal Battery Depletion .....

Year	1	at 18 months								
Survival Probability	99.93%	99.90%								
± 1 standard error	0.02%	0.03%								
Sample Size	35900	200								

Excluding Normal Battery Depletion ——

Year	1	at 18 months								
Survival Probability	99.93%	99.90%								
± 1 standard error	0.02%	0.03%								

SCORE Registry Performance Data

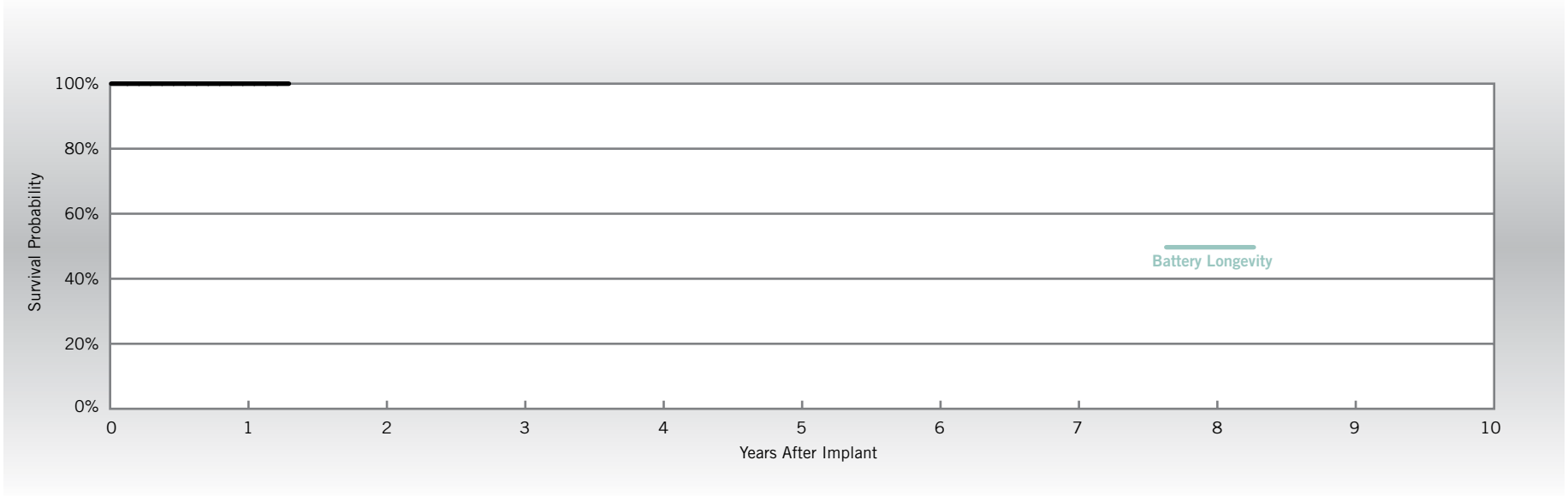
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	875
Cumulative Months of Follow-up	7,122
Estimated Longevity	8 Years

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	1	at 16 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	540	70								

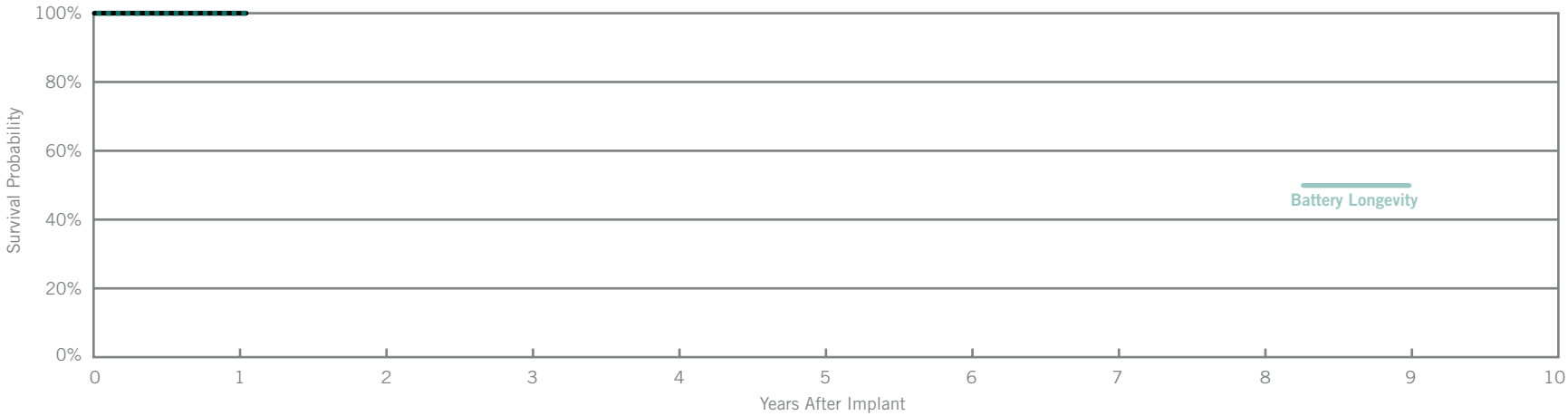
Customer Reported Performance Data

Accent® DR RF

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	7,911
Estimated Active US Implants	7,481
Estimated Longevity	8.5 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion .....

Year	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	4200	200								

Excluding Normal Battery Depletion ———

Year	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

SCORE Registry Performance Data

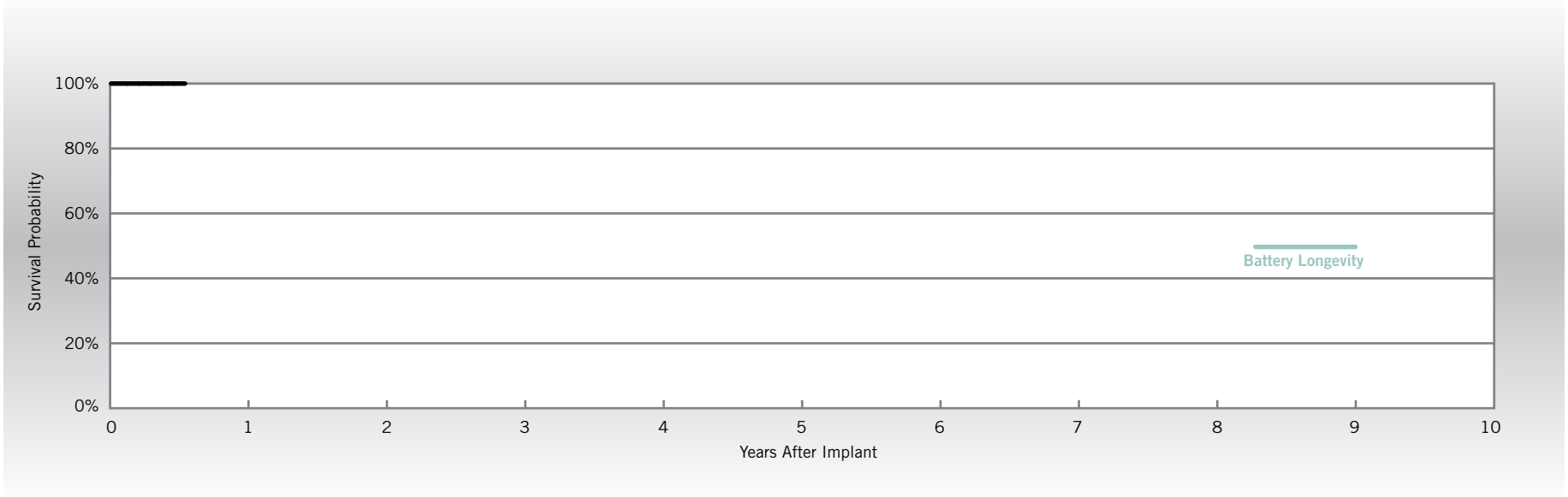
Accent® DR RF

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	875
Cumulative Months of Follow-up	7,122
Estimated Longevity	8.5 Years

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



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

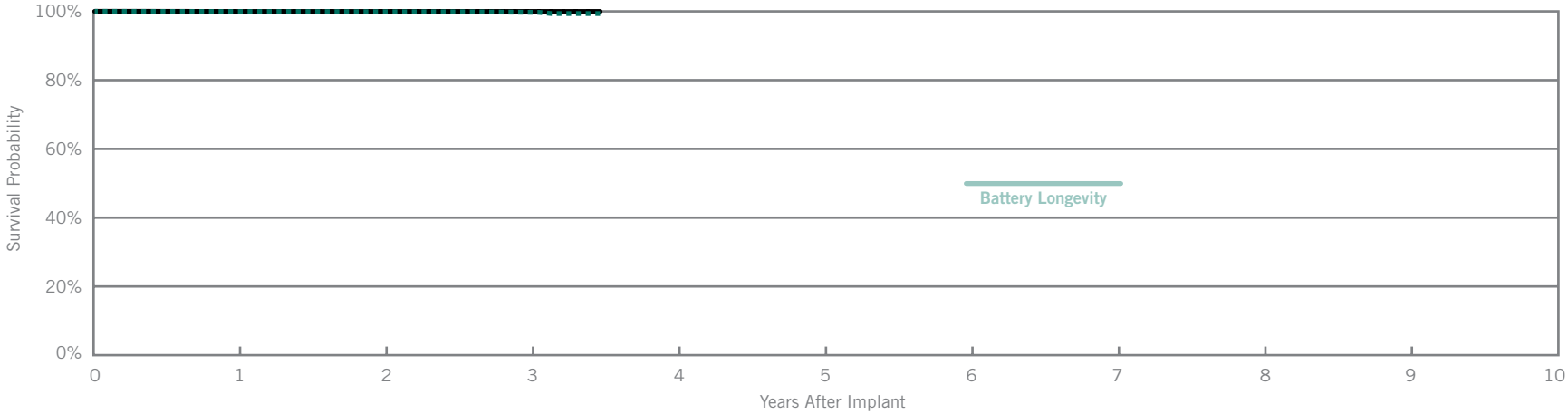
Customer Reported Performance Data

Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	31,972
Estimated Active US Implants	25,321
Estimated Longevity	6.5 Years
Normal Battery Depletion	11
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	<0.01%
Malfunctions w/o Compromised Therapy	3	0.01%
Total	**4**	**0.01%**



Including Normal Battery Depletion .....

Year	1	2	3	at 42 months						
Survival Probability	99.95%	99.95%	99.70%	99.36%						
± 1 standard error	0.01%	0.02%	0.08%	0.17%						
Sample Size	238400	16300	6300	400						

Excluding Normal Battery Depletion ———

Year	1	2	3	at 42 months						
Survival Probability	99.96%	99.96%	99.96%	99.96%						
± 1 standard error	0.01%	0.01%	0.01%	0.01%						

SCORE Registry Performance Data

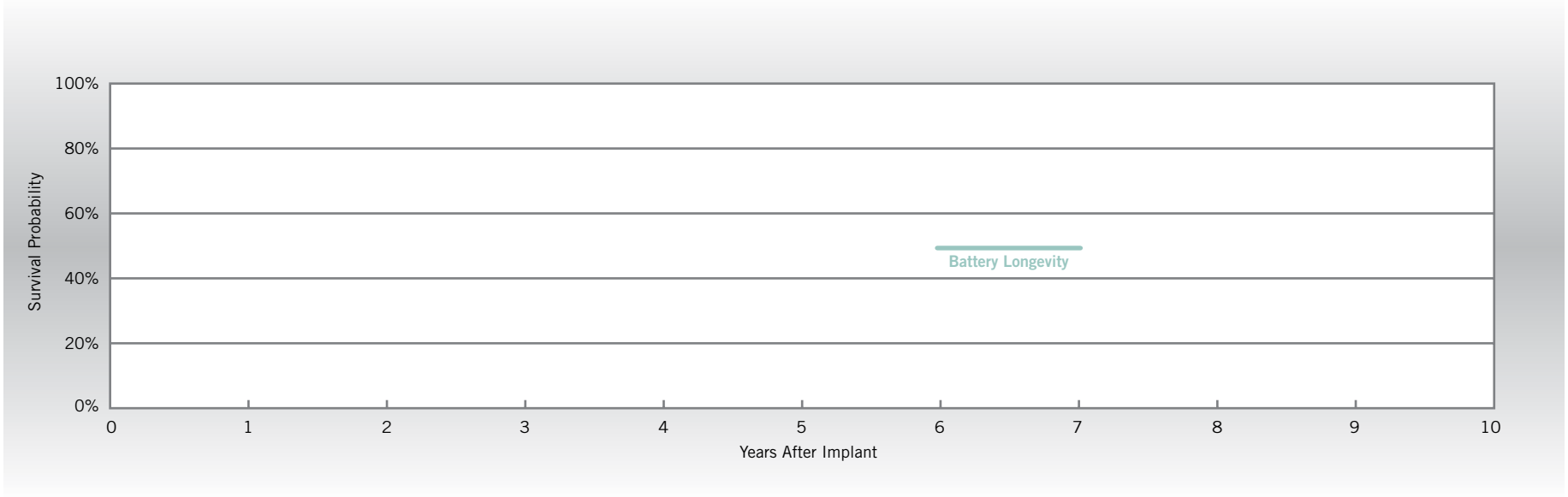
Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	245
Cumulative Months of Follow-up	4,776
Estimated Longevity	6.5 Years

Qualifying Complications
None Reported

Malfunctions	**Qty.**	**Rate**
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	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	210	140	60							

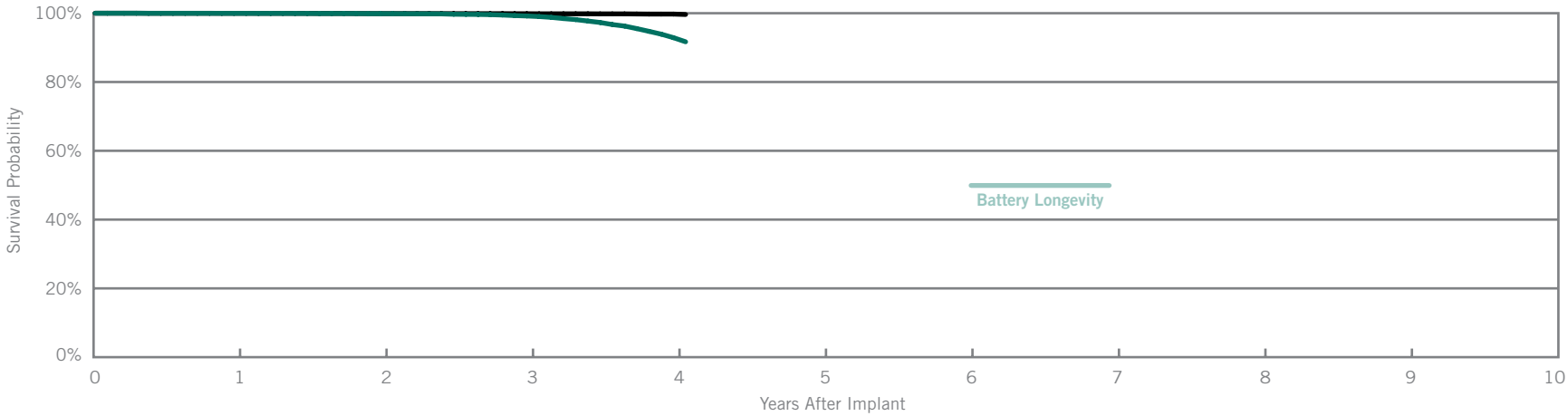
Customer Reported Performance Data

Victory® DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,162
Estimated Active US Implants	15,729
Estimated Longevity	6.5 Years
Normal Battery Depletion	275
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	19	0.07%
Total	**19**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.97%	99.87%	99.19%	92.89%	91.69%					
± 1 standard error	0.01%	0.02%	0.07%	0.27%	0.30%					
Sample Size	25700	20900	16100	9300	4100					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.97%	99.89%	99.85%	99.75%	99.63%					
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.05%					

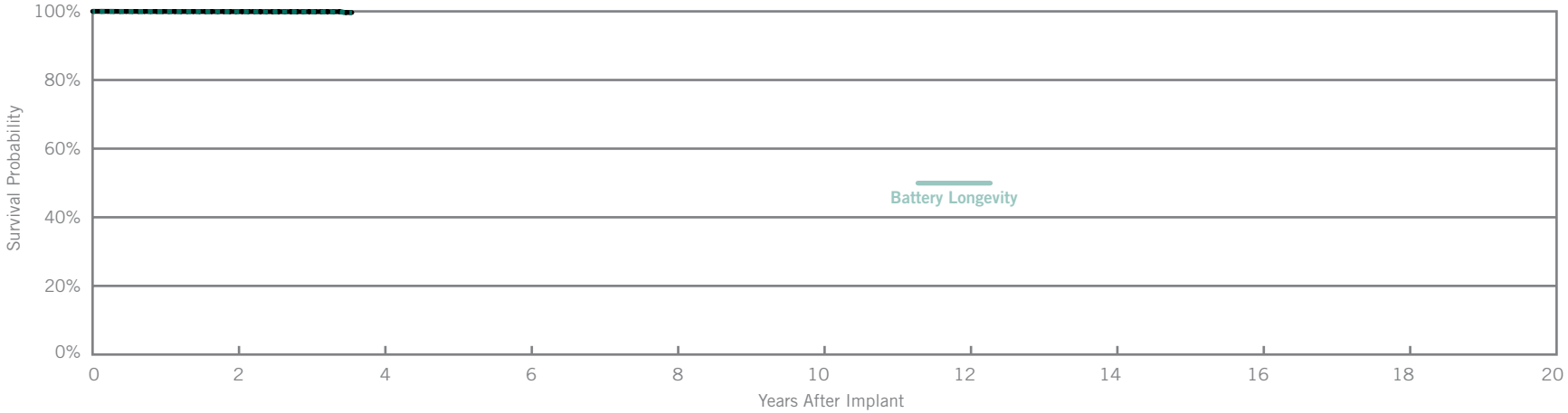
Customer Reported Performance Data

Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	99,686
Estimated Active US Implants	78,371
Estimated Longevity	11.7 Years
Normal Battery Depletion	6
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	2	<0.01%
Malfunctions w/o Compromised Therapy	23	0.02%
Total	**25**	**0.03%**



Including Normal Battery Depletion .....

Year	**2**	**at 43 months**								
Survival Probability	99.92%	99.61%								
± 1 standard error	0.01%	0.18%								
Sample Size	62500	400								

Excluding Normal Battery Depletion ———

Year	**2**	**at 43 months**								
Survival Probability	99.93%	99.67%								
± 1 standard error	0.01%	0.17%								

SCORE Registry Performance Data

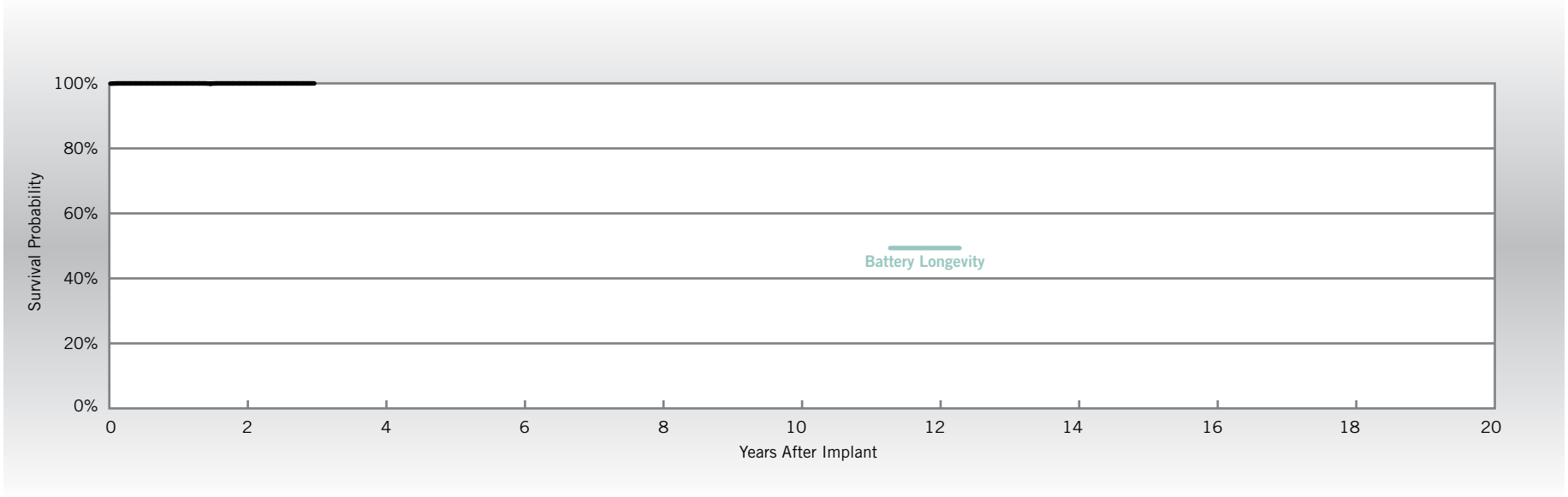
Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,486
Cumulative Months of Follow-up	35,477
Estimated Longevity	11.7 Years

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.13%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.07%
Total	**1**	**0.07%**



Year	2	at 3 years								
Survival Probability	99.85%	99.85%								
± 1 standard error	0.11%	0.11%								
Sample Size	1050	380								

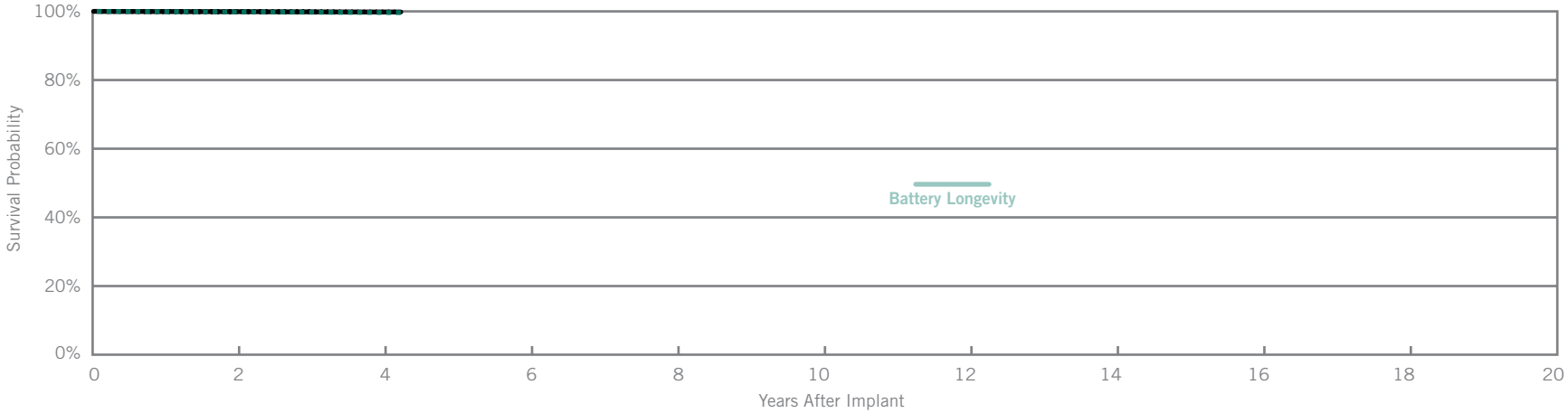
Customer Reported Performance Data

Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,451
Estimated Active US Implants	41,895
Estimated Longevity	11.7 Years
Normal Battery Depletion	15
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	2	<0.01%
Malfunctions w/o Compromised Therapy	29	0.05%
Total	**31**	**0.05%**



Including Normal Battery Depletion .....

Year	2	4	at 51 months							
Survival Probability	99.90%	99.68%	99.65%							
± 1 standard error	0.01%	0.03%	0.04%							
Sample Size	52000	21600	6600							

Excluding Normal Battery Depletion ———

Year	2	4	at 51 months							
Survival Probability	99.91%	99.82%	99.82%							
± 1 standard error	0.01%	0.02%	0.02%							

SCORE Registry Performance Data

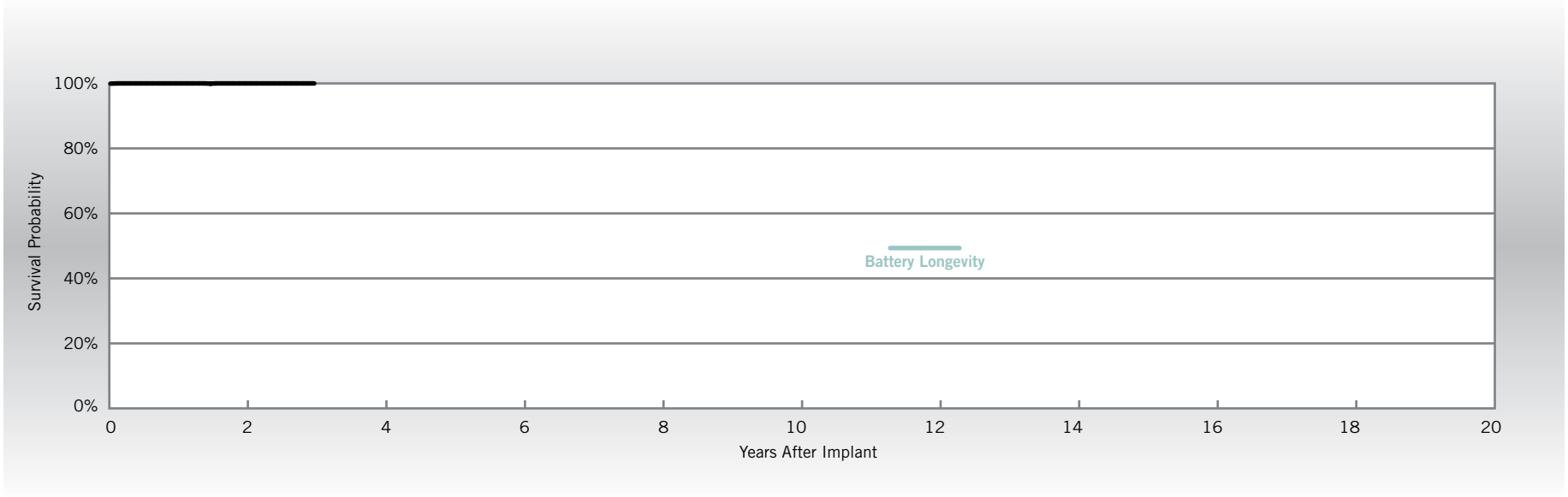
Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	333
Cumulative Months of Follow-up	9,098
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

Malfunctions	**Qty.**	**Rate**
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



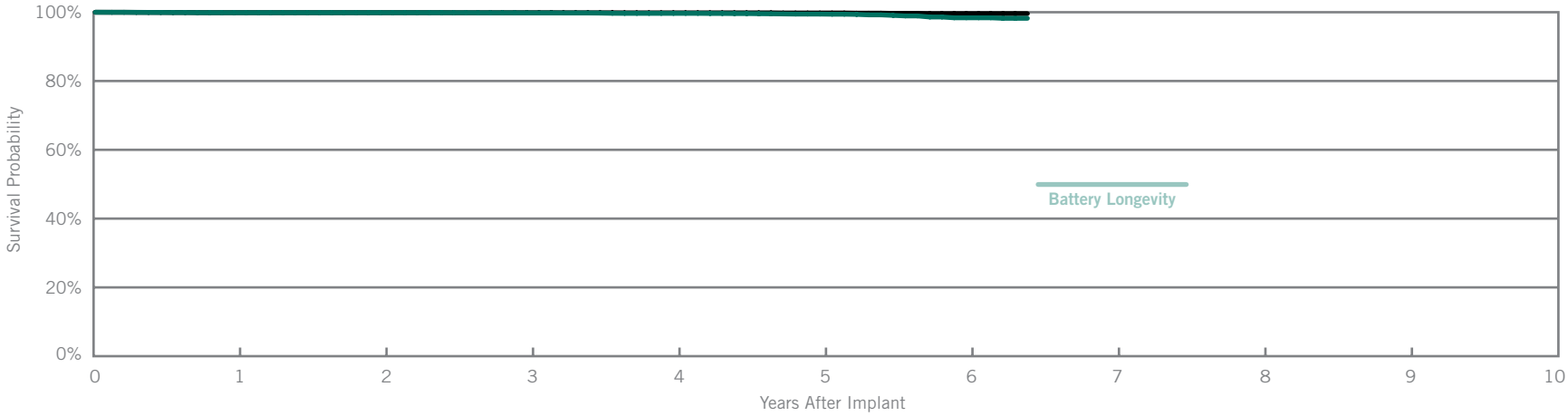
Year	**2**	**at 3 years**								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	280	50								

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

Customer Reported Performance Data

US Regulatory Approval	May 2003
Registered US Implants	16,863
Estimated Active US Implants	9,153
Estimated Longevity	6.9 Years
Normal Battery Depletion	24
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	9	0.05%
Total	**9**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.88%	99.88%	99.81%	99.67%	99.46%	98.38%	98.23%			
± 1 standard error	0.03%	0.03%	0.04%	0.05%	0.08%	0.21%	0.23%			
Sample Size	16700	14400	12300	9500	6400	3400	1100			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.88%	99.88%	99.86%	99.82%	99.78%	99.60%	99.60%			
± 1 standard error	0.03%	0.03%	0.03%	0.04%	0.05%	0.09%	0.09%			

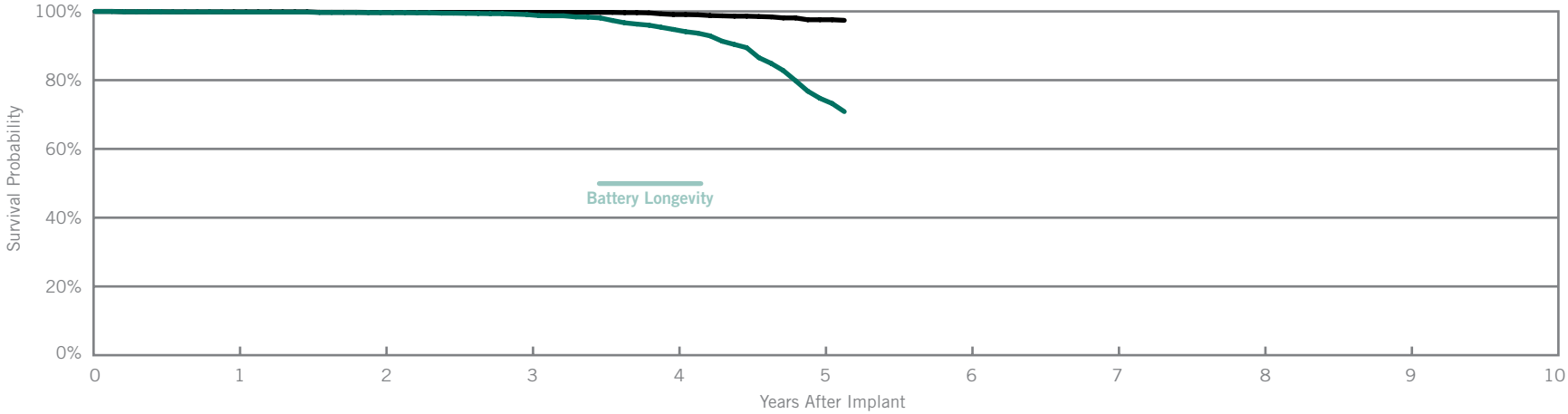
Customer Reported Performance Data

Integrity® ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,829
Estimated Active US Implants	1,537
Estimated Longevity	3.8 Years
Normal Battery Depletion	275
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	27	0.46%
Total	**27**	**0.46%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.80%	99.65%	99.08%	94.75%	74.73%	70.85%				
± 1 standard error	0.05%	0.08%	0.13%	0.36%	0.93%	1.02%				
Sample Size	5800	5000	4400	3600	2400	900				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 62 months				
Survival Probability	99.87%	99.71%	99.71%	99.09%	97.57%	97.40%				
± 1 standard error	0.05%	0.08%	0.08%	0.15%	0.34%	0.34%				

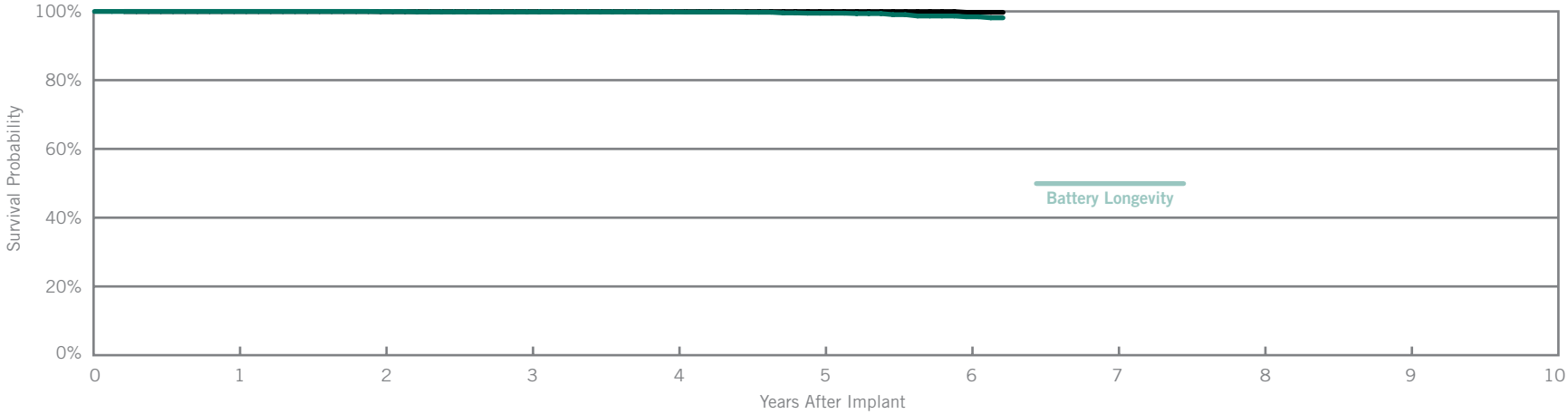
Customer Reported Performance Data

Integrity® ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,004
Estimated Active US Implants	4,367
Estimated Longevity	6.9 Years
Normal Battery Depletion	16
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	2	0.02%
Total	**2**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.98%	99.94%	99.86%	99.86%	99.48%	98.43%	98.13%			
± 1 standard error	0.02%	0.02%	0.05%	0.05%	0.13%	0.27%	0.38%			
Sample Size	8000	7100	6400	5000	3200	1600	600			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.98%	99.94%	99.94%	99.94%	99.94%	99.72%	99.72%			
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.03%	0.03%	0.16%			

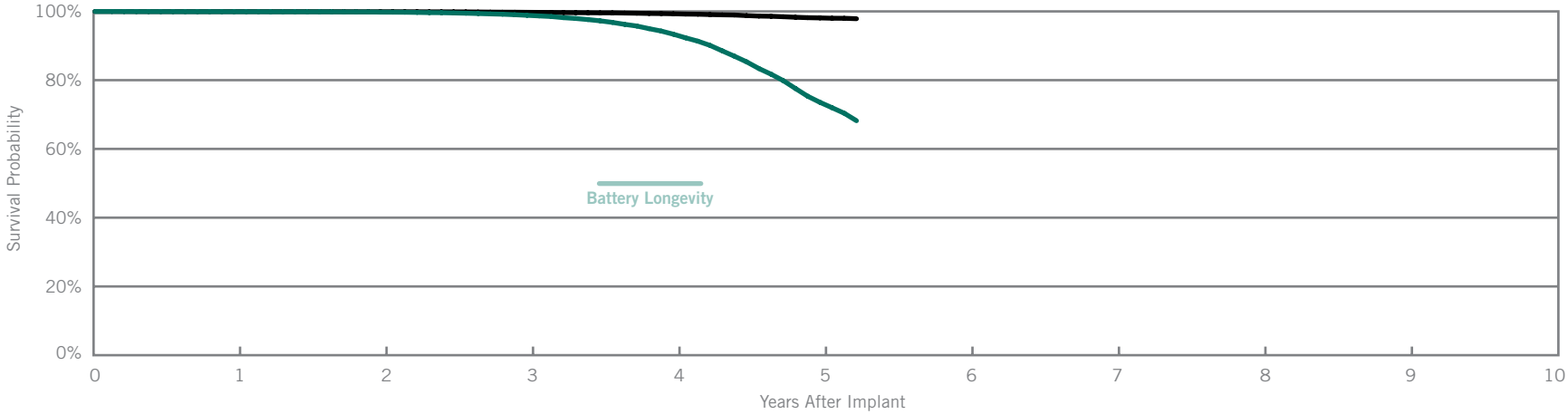
Customer Reported Performance Data

Integrity® ADx DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	53,662
Estimated Active US Implants	14,270
Estimated Longevity	3.8 Years
Normal Battery Depletion	2,539
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	5	0.01%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	181	0.34%
Total (0 related to Advisory)	**186**	**0.35%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 63 months				
Survival Probability	99.91%	99.78%	98.86%	93.36%	73.56%	68.20%				
± 1 standard error	0.01%	0.02%	0.05%	0.13%	0.31%	0.36%				
Sample Size	53000	45700	40000	33100	21700	5600				

Excluding Normal Battery Depletion

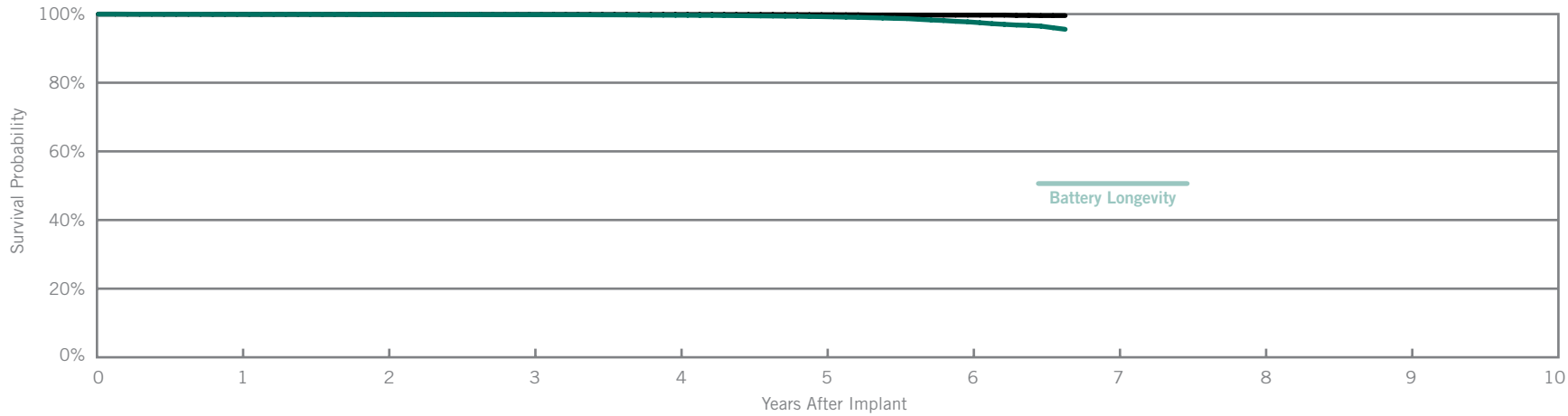
Year	1	2	3	4	5	at 63 months				
Survival Probability	99.94%	99.90%	99.73%	99.31%	98.10%	97.87%				
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.09%	0.10%				

Customer Reported Performance Data

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

US Regulatory Approval	March 2003
Registered US Implants	66,104
Estimated Active US Implants	35,252
Estimated Longevity	6.9 Years
Normal Battery Depletion	190
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	<0.01%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	46	0.07%
Total (0 related to Advisory)	**48**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.94%	99.89%	99.84%	99.67%	99.26%	97.74%	95.57%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.05%	0.12%	0.23%			
Sample Size	65200	57000	49200	40200	28600	14700	2800			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.94%	99.91%	99.88%	99.87%	99.82%	99.70%	99.56%			
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.04%	0.06%			

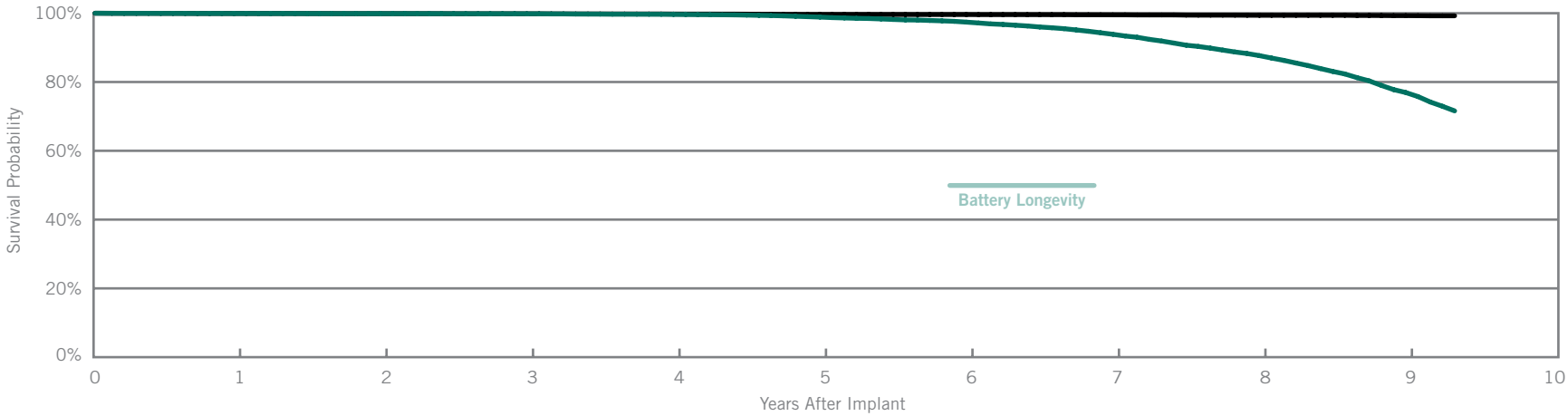
Customer Reported Performance Data

Integrity® AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,541
Estimated Active US Implants	5,422
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,666
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	6	0.01%
Malfunctions w/o Compromised Therapy	75	0.16%
Total	**81**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.93%	99.88%	99.83%	99.66%	98.87%	97.41%	93.87%	87.67%	76.93%	71.60%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.06%	0.09%	0.15%	0.23%	0.36%	0.43%
Sample Size	47200	42100	38500	35100	31500	27600	23300	18000	11200	3300

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.92%	99.88%	99.83%	99.76%	99.64%	99.62%	99.53%	99.40%	99.30%	99.25%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.07%

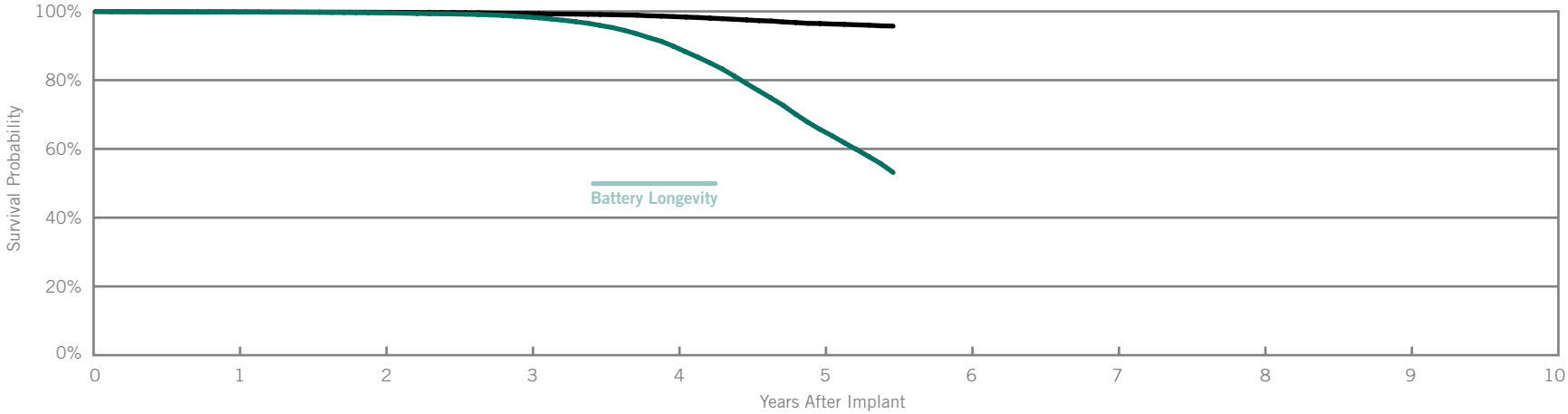
Customer Reported Performance Data

Identity®

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,419
Estimated Active US Implants	3,843
Estimated Longevity	3.8 Years
Normal Battery Depletion	4,392
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	5	0.01%
Malfunctions w/o Compromised Therapy (20 related to Advisory)	378	0.65%
Total (20 related to Advisory)	**383**	**0.66%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.82%	99.57%	98.38%	89.86%	65.69%	53.15%				
± 1 standard error	0.02%	0.03%	0.06%	0.15%	0.30%	0.38%				
Sample Size	57900	50500	44900	38700	27000	4500				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.84%	99.73%	99.38%	98.49%	96.47%	95.73%				
± 1 standard error	0.02%	0.02%	0.04%	0.06%	0.12%	0.14%				

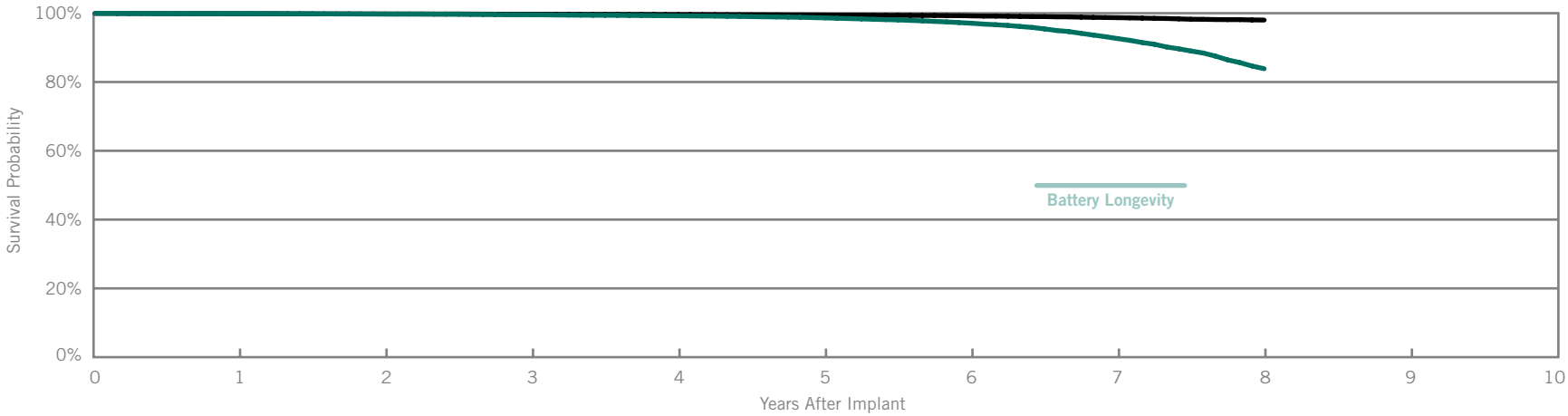
Customer Reported Performance Data

Identity® XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,458
Estimated Active US Implants	15,434
Estimated Longevity	6.9 Years
Normal Battery Depletion	878
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	10	0.02%
Malfunctions w/o Compromised Therapy (7 related to Advisory)	128	0.25%
Total (7 related to Advisory)	**138**	**0.27%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8		
Survival Probability	99.88%	99.75%	99.55%	99.24%	98.64%	97.09%	92.62%	83.86%		
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.06%	0.10%	0.18%	0.35%		
Sample Size	51200	46500	42600	38200	32700	26100	18800	9600		

Excluding Normal Battery Depletion

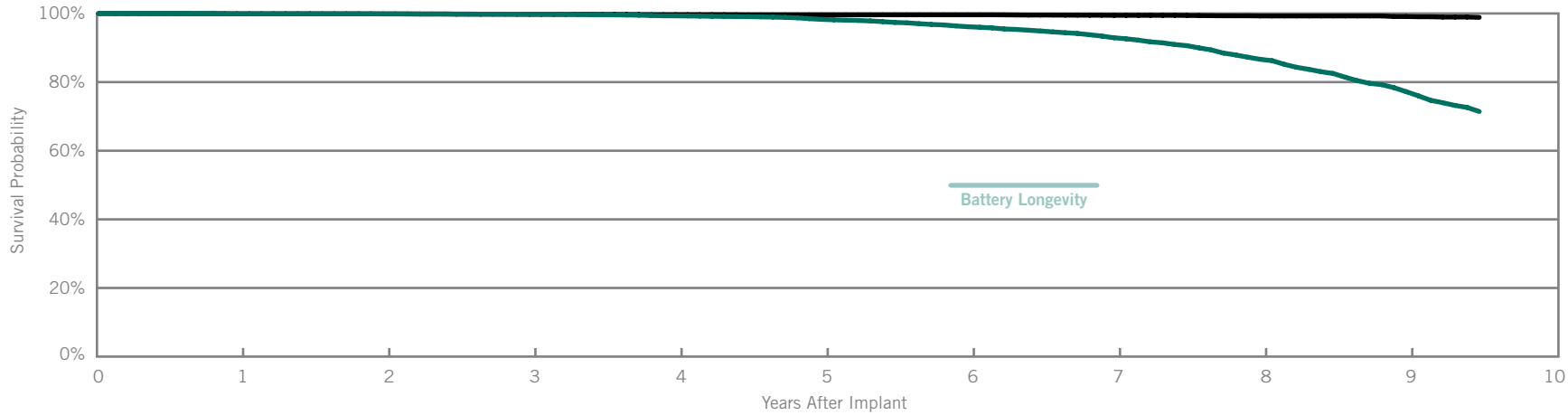
Year	1	2	3	4	5	6	7	8		
Survival Probability	99.88%	99.78%	99.69%	99.60%	99.46%	99.22%	98.70%	98.01%		
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.04%	0.05%	0.07%	0.11%		

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,869
Estimated Active US Implants	2,843
Estimated Longevity	6.3 Years
Normal Battery Depletion	639
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	3	0.01%
Malfunctions w/o Compromised Therapy	38	0.17%
Total	**41**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.91%	99.87%	99.78%	99.31%	98.28%	96.14%	92.92%	86.65%	77.20%	71.43%
± 1 standard error	0.02%	0.02%	0.03%	0.07%	0.11%	0.18%	0.25%	0.38%	0.57%	0.72%
Sample Size	21800	18800	16800	15000	13100	11200	9100	6600	3900	1200

Excluding Normal Battery Depletion

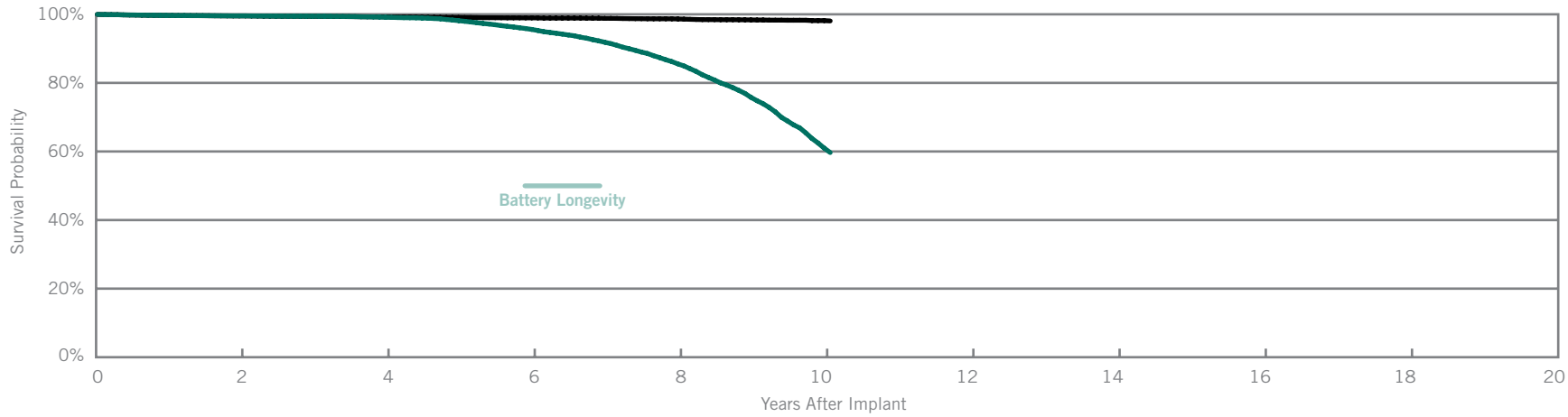
Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.90%	99.87%	99.77%	99.64%	99.61%	99.61%	99.46%	99.28%	99.11%	98.86%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.05%	0.05%	0.06%	0.08%	0.12%	0.14%

Customer Reported Performance Data

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

US Regulatory Approval	(5330) January 1999 (5230/5331) June 1999
Registered US Implants	65,679
Estimated Active US Implants	3,592
Estimated Longevity	6.3 Years
Normal Battery Depletion	2,528
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	15	0.02%
Malfunctions w/o Compromised Therapy (65 related to Advisory)	239	0.36%
Total (65 related to Advisory)	**254**	**0.39%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 121 months				
Survival Probability	99.55%	99.15%	95.59%	85.54%	60.99%	59.69%				
± 1 standard error	0.03%	0.04%	0.10%	0.21%	0.49%	0.51%				
Sample Size	57500	47000	36300	22200	7100	2400				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 121 months				
Survival Probability	99.53%	99.25%	98.96%	98.65%	98.16%	98.07%				
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.09%	0.09%				

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%									
PM2110	Accent® DR RF	100.00%									
5820	Zephyr® DR	99.95%	99.95%	99.70%							
5810	Victory® DR	99.97%	99.87%	99.19%	92.89%						
5826	Zephyr® XL DR	99.96%	99.92%	99.89%							
5816	Victory® XL DR	99.94%	99.90%	99.82%	99.68%						
5356/5357/5256	Verity® ADX XL DR/ DR(M/S) / DC	99.88%	99.88%	99.81%	99.67%	99.46%	98.38%				
5360	Integrity® ADx DR	99.80%	99.65%	99.08%	94.75%	74.73%					
5366	Integrity® ADx XL DR	99.98%	99.94%	99.86%	99.86%	99.48%	98.43%				
5380	Identity® ADx DR	99.91%	99.78%	98.86%	93.36%	73.56%					
5386/5286	Identity® ADx XL DR/DC	99.94%	99.89%	99.84%	99.67%	99.26%	97.74%				
5342/5346	Integrity® AFx DR	99.93%	99.88%	99.83%	99.66%	98.87%	97.41%	93.87%	87.67%	76.93%	
5370	Identity®	99.82%	99.57%	98.38%	89.86%	65.69%					
5376	Identity® XL	99.88%	99.75%	99.55%	99.24%	98.64%	97.09%	92.62%	83.86%		
5326/5226	Entity® DR/DC	99.91%	99.87%	99.78%	99.31%	98.28%	96.14%	92.92%	86.65%	77.20%	
5330/5331/5230	Affinity® DR/DC	99.67%	99.55%	99.44%	99.15%	98.14%	95.59%	91.85%	85.54%	75.77%	60.99%

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	99.93%									
PM2110	Accent® DR RF	100.00%									
5820	Zephyr® DR	99.96%	99.96%	99.96%							
5810	Victory® DR	99.97%	99.89%	99.85%	99.75%						
5826	Zephyr® XL DR	99.96%	99.93%	99.91%							
5816	Victory® XL DR	99.94%	99.91%	99.87%	99.82%						
5356/5357/5256	Verity® ADX XL DR/ DR(M/S) / DC	99.88%	99.88%	99.86%	99.82%	99.78%	99.60%				
5360	Integrity® ADx DR	99.87%	99.71%	99.71%	99.09%	97.57%					
5366	Integrity® ADx XL DR	99.98%	99.94%	99.94%	99.94%	99.94%	99.72%				
5380	Identity® ADx DR	99.94%	99.90%	99.73%	99.31%	98.10%					
5386/5286	Identity® ADx XL DR/DC	99.94%	99.91%	99.88%	99.87%	99.82%	99.70%				
5342/5346	Integrity® AFx DR	99.92%	99.88%	99.83%	99.76%	99.64%	99.62%	99.53%	99.40%	99.30%	
5370	Identity®	99.84%	99.73%	99.38%	98.49%	96.47%					
5376	Identity® XL	99.88%	99.78%	99.69%	99.60%	99.46%	99.22%	98.70%	98.01%		
5326/5226	Entity® DR/DC	99.90%	99.87%	99.77%	99.64%	99.61%	99.61%	99.46%	99.28%	99.11%	
5330/5331/5230	Affinity® DR/DC	99.66%	99.53%	99.41%	99.25%	99.11%	98.96%	98.83%	98.65%	98.37%	98.16%

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent® DR RF	Jul-09	58161	53582	2	<0.01%	3	0.01%	2	<0.01%	7	0.01%	10	0.02%
PM2110	Accent® DR RF	Jul-09	7911	7481	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5820	Zephyr® DR	Mar-07	31972	25321	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	4	0.01%
5810	Victory® DR	Dec-05	26162	15729	0	0.00%	0	0.00%	1	<0.01%	19	0.07%	19	0.07%
5826	Zephyr® XL DR	Mar-07	99686	78371	0	0.00%	2	<0.01%	1	<0.01%	23	0.02%	25	0.03%
5816	Victory® XL DR	Dec-05	62451	41895	0	0.00%	2	<0.01%	0	0.00%	29	0.05%	31	0.05%
5356/5357/5256	Verity® ADX XL DR/ DR(M/S) / DC	May-03	16863	9153	0	0.00%	0	0.00%	1	0.01%	9	0.05%	9	0.05%
5360	Integrity® ADx DR	May-03	5829	1537	0	0.00%	0	0.00%	0	0.00%	27	0.46%	27	0.46%
5366	Integrity® ADx XL DR	May-03	8004	4367	0	0.00%	0	0.00%	0	0.00%	2	0.02%	2	0.02%
5380	Identity® ADx DR	Mar-03	53662	14270	1	<0.01%	5	0.01%	6	0.01%	181	0.34%	186	0.35%
5386/5286	Identity® ADx XL DR/DC	Mar-03	66104	35252	0	0.00%	2	<0.01%	0	0.00%	46	0.07%	48	0.07%
5342/5346	Integrity® AFx DR	Apr-00/Jul-01	47541	5422	0	0.00%	6	0.01%	0	0.00%	75	0.16%	81	0.17%
5370	Identity®	Nov-01	58419	3843	0	0.00%	5	0.01%	9	0.02%	378	0.65%	383	0.66%
5376	Identity® XL	Nov-01	51458	15434	1	<0.01%	10	0.02%	1	<0.01%	128	0.25%	138	0.27%
5326/5226	Entity® DR/DC	Jun-99	21869	2843	0	0.00%	3	0.01%	1	<0.01%	38	0.17%	41	0.19%
5330/5331/5230	Affinity® DR/DC	Jan-99/Jun-99	65679	3592	0	0.00%	15	0.02%	0	0.00%	239	0.36%	254	0.39%

** Totals include Premature Battery Depletion and all other confirmed malfunctions.*

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	875	7122	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM2110	126	812	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5820	245	4776	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5826	1486	35477	0	0.00%	0	0.00%	0	0.00%	1	0.07%	1	0.07%
5816	333	9098	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Total	
			Qty.	Rate	Qty.	Rate
PM2210	875	7122	0	0.00%	0	0.00%
PM2110	126	812	0	0.00%	0	0.00%
5820	245	4776	0	0.00%	0	0.00%
5826	1486	35477	2	0.13%	2	0.13%
5816	333	9098	0	0.00%	0	0.00%

** Totals include Premature Battery Depletion and all other confirmed malfunctions.*

Pacemakers

Single-Chamber

St. Jude Medical™
More control. Less risk.

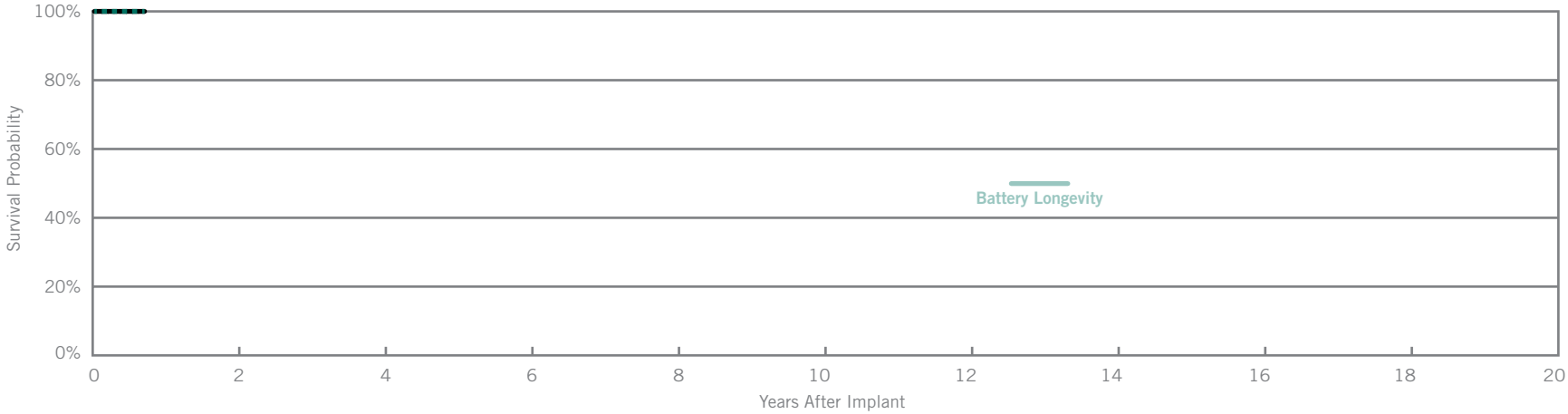
Customer Reported Performance Data

Accent® SR RF

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	1,669
Estimated Active US Implants	1,568
Estimated Longevity	12.9 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Including Normal Battery Depletion .....

Year	at 9 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	300										

Excluding Normal Battery Depletion ——

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

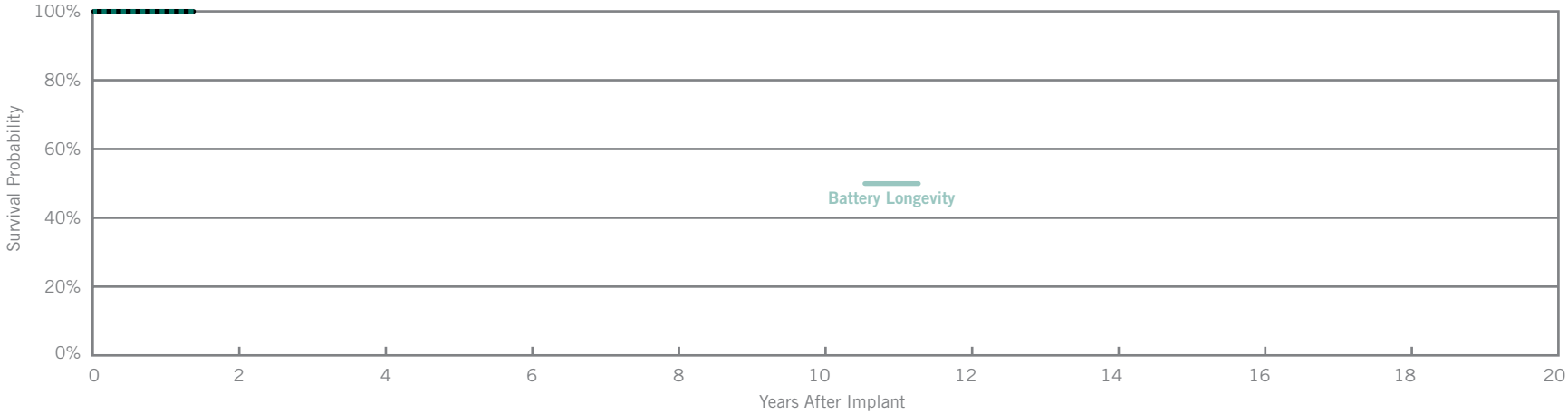
Customer Reported Performance Data

Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	8,938
Estimated Active US Implants	8,102
Estimated Longevity	10.9 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**1**	**0.01%**



Including Normal Battery Depletion .....

Year	at 17 months										
Survival Probability	99.98%										
± 1 standard error	0.02%										
Sample Size	200										

Excluding Normal Battery Depletion ———

Year	at 17 months										
Survival Probability	99.98%										
± 1 standard error	0.02%										

SCORE Registry Performance Data

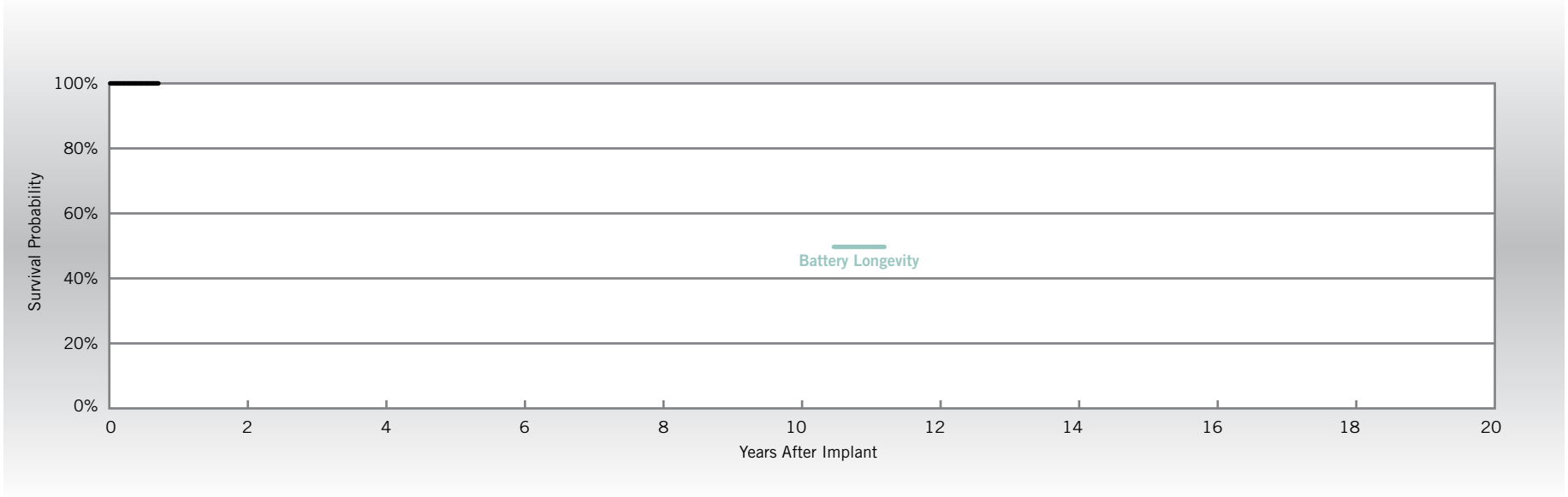
Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	128
Cumulative Months of Follow-up	937
Estimated Longevity	10.9 Years

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	at 9 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

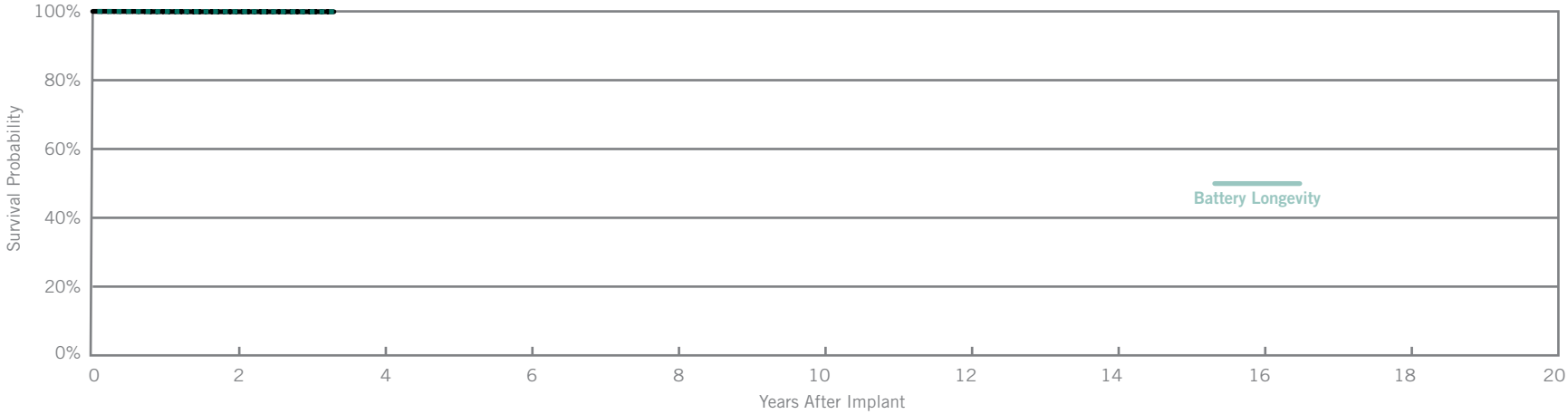
Customer Reported Performance Data

Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	17,934
Estimated Active US Implants	13,659
Estimated Longevity	15.8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	6	0.03%
Total	**6**	**0.03%**



Including Normal Battery Depletion .....

Year	2	at 40 months								
Survival Probability	99.90%	99.90%								
± 1 standard error	0.03%	0.03%								
Sample Size	9800	300								

Excluding Normal Battery Depletion ———

Year	2	at 40 months								
Survival Probability	99.90%	99.90%								
± 1 standard error	0.03%	0.03%								

SCORE Registry Performance Data

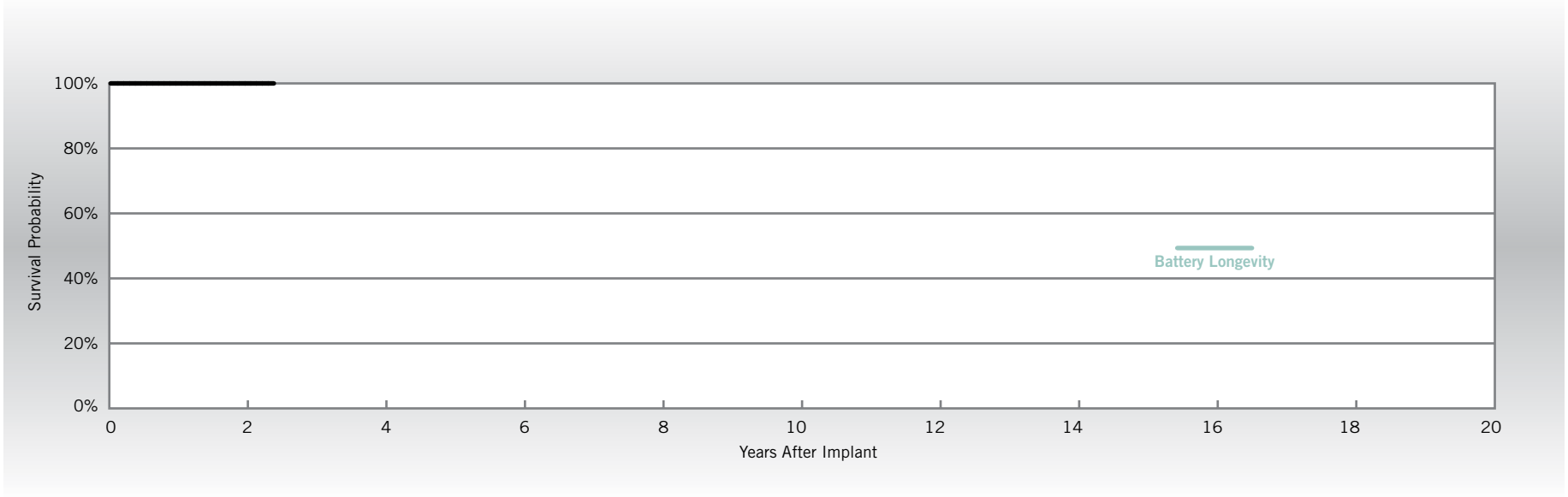
Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	224
Cumulative Months of Follow-up	5,160
Estimated Longevity	15.8 Years

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**0**	**0.00%**



Year	2	at 29 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	160	50								

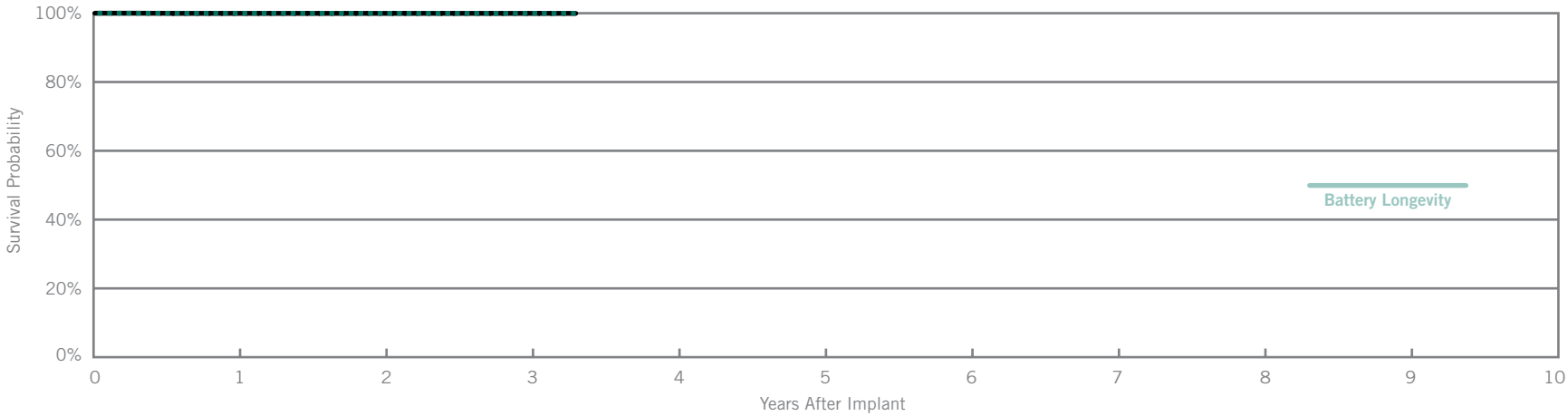
Customer Reported Performance Data

Zephyr® SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	9,740
Estimated Active US Implants	6,987
Estimated Longevity	8.8 Years
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	2	0.02%
Total	**2**	**0.02%**



Including Normal Battery Depletion .....

Year	1	2	3	at 40 months						
Survival Probability	99.95%	99.95%	99.95%	99.95%						
± 1 standard error	0.03%	0.03%	0.03%	0.03%						
Sample Size	8600	4500	1600	200						

Excluding Normal Battery Depletion ———

Year	1	2	3	at 40 months						
Survival Probability	99.95%	99.95%	99.95%	99.95%						
± 1 standard error	0.03%	0.03%	0.03%	0.03%						

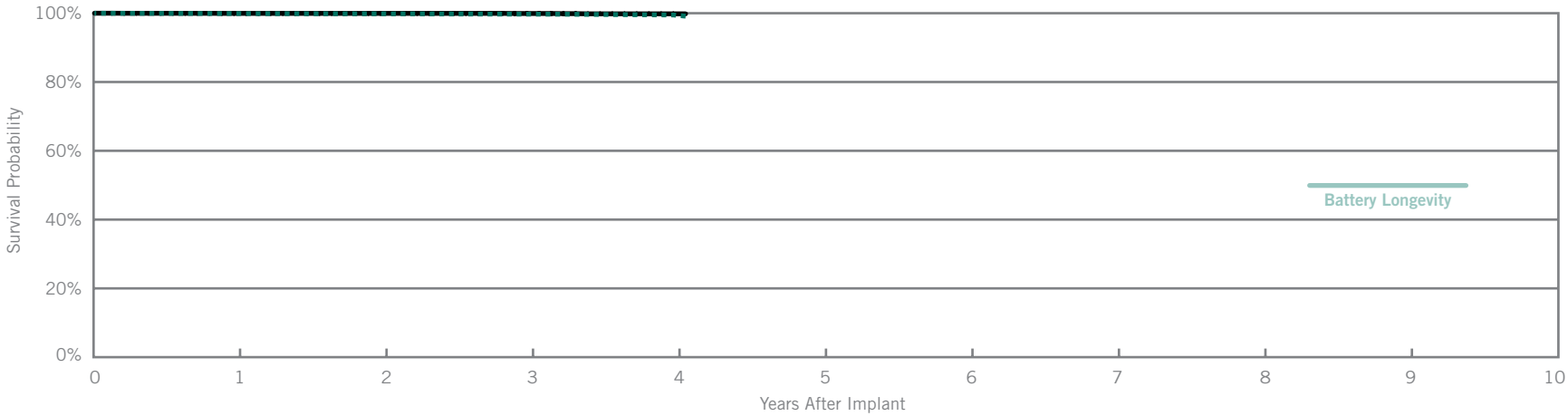
Customer Reported Performance Data

Victory® SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,478
Estimated Active US Implants	7824
Estimated Longevity	8.8 Years
Normal Battery Depletion	8
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	3	0.02%
Total	**4**	**0.03%**



Including Normal Battery Depletion .....

Year	1	2	3	4	at 49 months					
Survival Probability	99.95%	99.95%	99.86%	99.49%	99.14%					
± 1 standard error	0.02%	0.02%	0.05%	0.11%	0.11%					
Sample Size	13200	9900	7100	3600	1500					

Excluding Normal Battery Depletion ———

Year	1	2	3	4	at 49 months					
Survival Probability	99.95%	99.95%	99.91%	99.82%	99.82%					
± 1 standard error	0.02%	0.02%	0.03%	0.06%	0.06%					

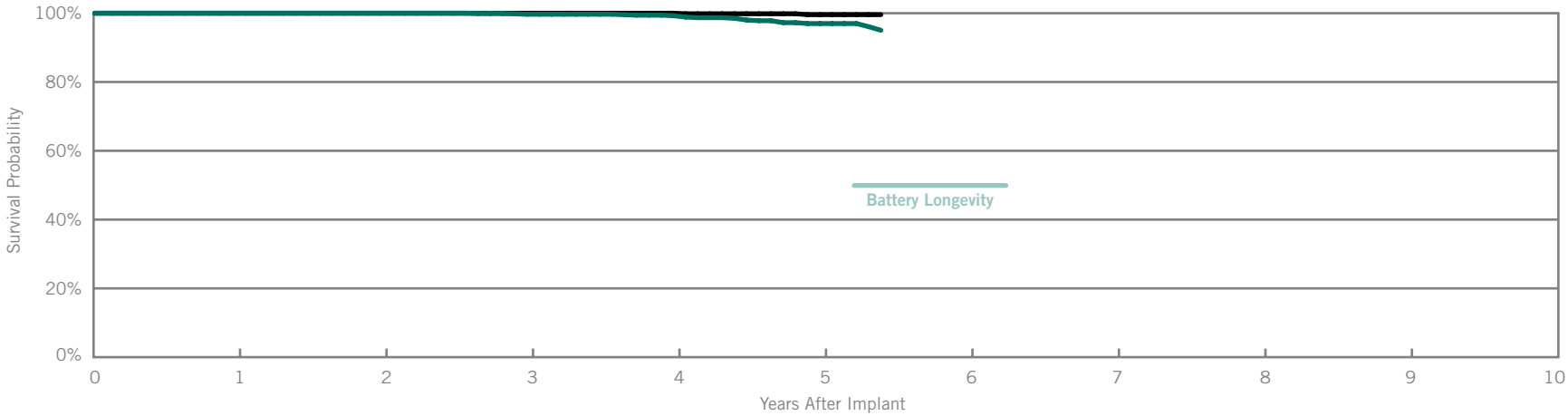
Customer Reported Performance Data

Integrity® ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,399
Estimated Active US Implants	1,145
Estimated Longevity	5.7 Years
Normal Battery Depletion	29
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	3	0.09%
Total	**3**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	100.00%	100.00%	99.69%	99.26%	96.99%	95.04%				
± 1 standard error	0.00%	0.00%	0.10%	0.19%	0.52%	0.66%				
Sample Size	3400	2600	2200	1700	1100	500				

Excluding Normal Battery Depletion

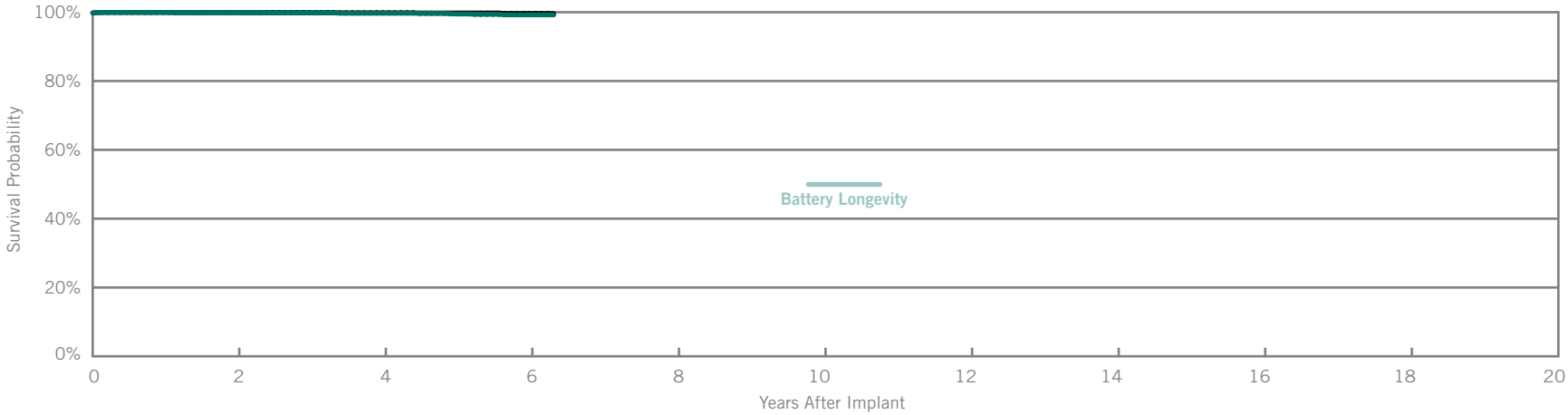
Year	1	2	3	4	5	at 65 months				
Survival Probability	100.00%	100.00%	100.00%	100.00%	99.58%	99.58%				
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.22%	0.22%				

Verity ADx® XL SR **Model 5156**
Verity ADx® XL SR M/S **Model 5157M/S**
Verity ADx® XL SC **Model 5056**

Customer Reported Performance Data

US Regulatory Approval	May 2003
Registered US Implants	14,111
Estimated Active US Implants	7,034
Estimated Longevity	10.2 Years
Normal Battery Depletion	8
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	5	0.04%
Total	**6**	**0.04%**



Including Normal Battery Depletion

Year	2	4	6	at 76 months						
Survival Probability	99.86%	99.70%	99.23%	99.23%						
± 1 standard error	0.03%	0.06%	0.17%	0.17%						
Sample Size	10900	6000	1700	600						

Excluding Normal Battery Depletion

Year	2	4	6	at 76 months						
Survival Probability	99.88%	99.82%	99.61%	99.61%						
± 1 standard error	0.03%	0.04%	0.12%	0.12%						

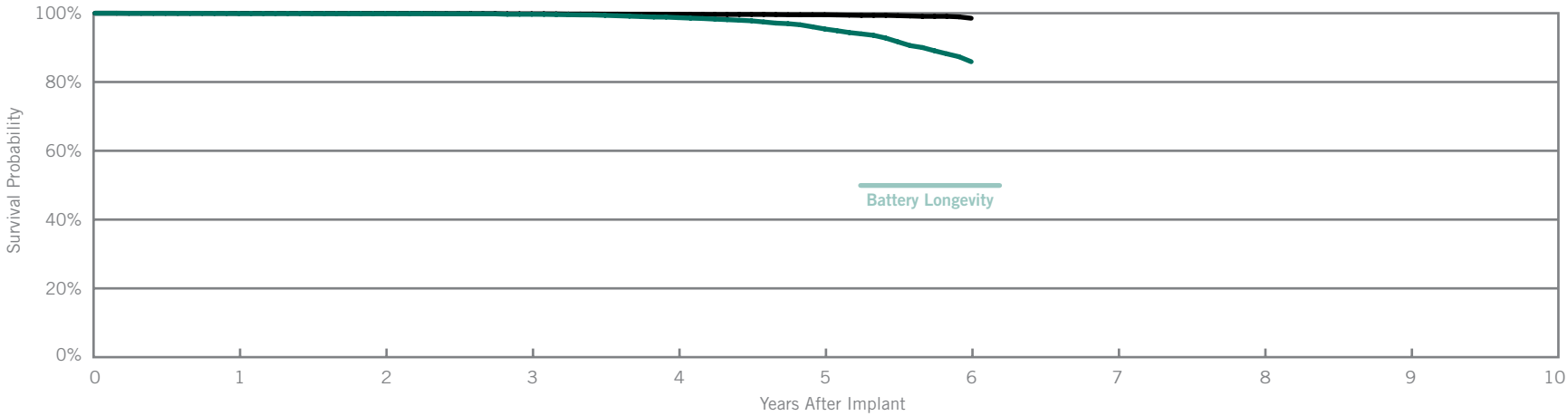
Customer Reported Performance Data

Integrity® ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,389
Estimated Active US Implants	7,919
Estimated Longevity	5.7 Years
Normal Battery Depletion	191
Number of US Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	25	0.12%
Total	**25**	**0.12%**



Including Normal Battery Depletion

Year	**1**	**2**	**3**	**4**	**5**	**6**				
Survival Probability	99.91%	99.87%	99.69%	98.71%	95.41%	85.90%				
± 1 standard error	0.02%	0.03%	0.05%	0.11%	0.25%	0.67%				
Sample Size	20100	15600	12500	9500	6100	1000				

Excluding Normal Battery Depletion

Year	**1**	**2**	**3**	**4**	**5**	**6**				
Survival Probability	99.97%	99.94%	99.84%	99.69%	99.56%	98.54%				
± 1 standard error	0.01%	0.02%	0.04%	0.05%	0.07%	0.19%				

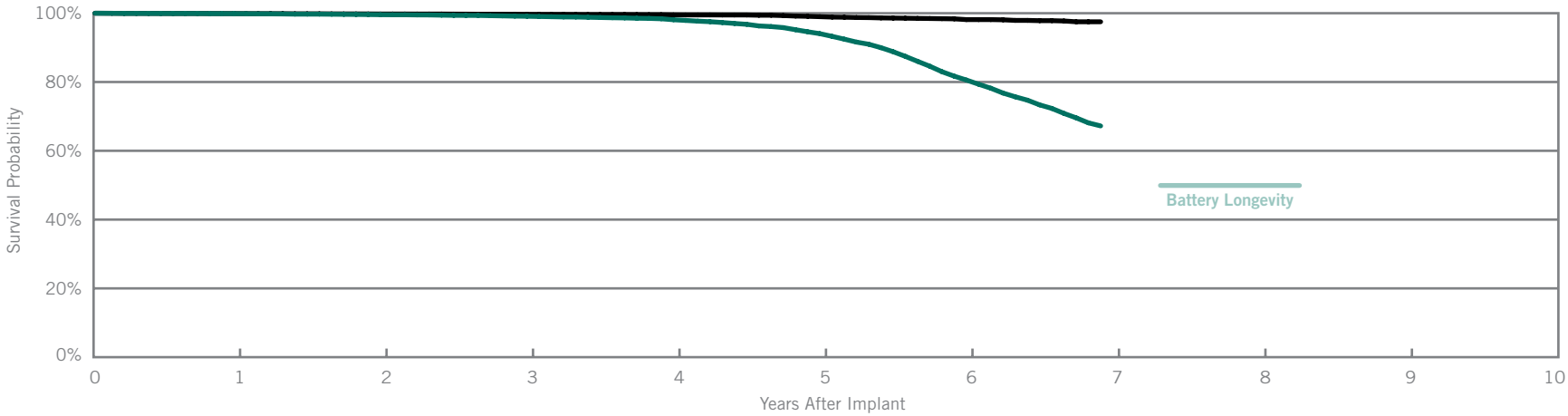
Customer Reported Performance Data

Identity® SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,926
Estimated Active US Implants	3,859
Estimated Longevity	7.8 Years
Normal Battery Depletion	617
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	0.01%
Malfunctions w/o Compromised Therapy (1 related to Advisory)	62	0.28%
Total (1 related to Advisory)	**64**	**0.29%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.88%	99.57%	99.11%	98.10%	94.05%	80.57%	67.23%			
± 1 standard error	0.02%	0.05%	0.08%	0.11%	0.23%	0.51%	0.82%			
Sample Size	21800	17600	14800	12200	9400	6200	1000			

Excluding Normal Battery Depletion

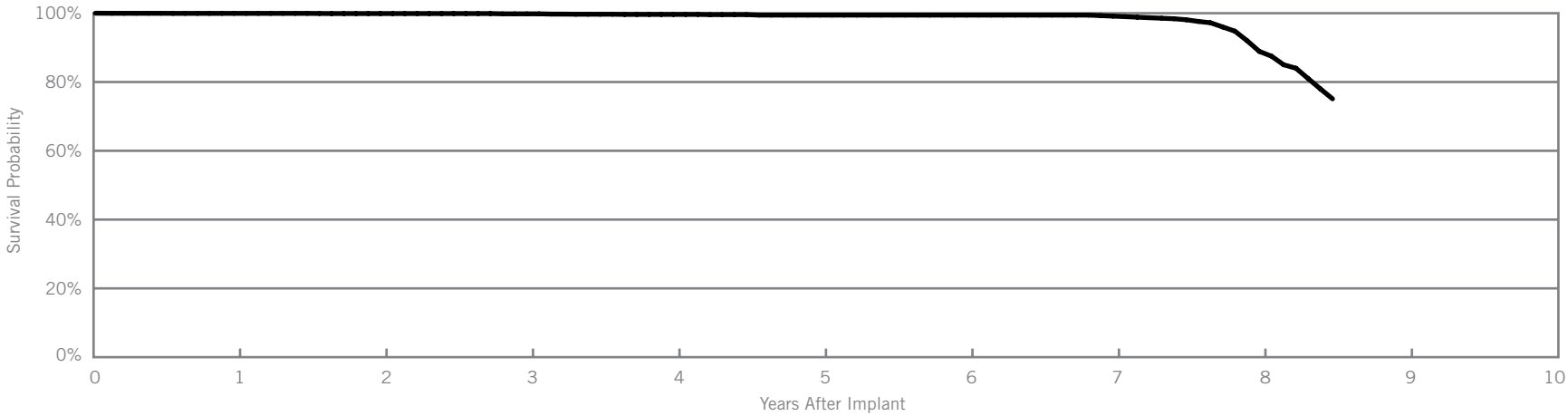
Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.90%	99.77%	99.66%	99.52%	98.99%	98.14%	97.51%			
± 1 standard error	0.02%	0.04%	0.05%	0.06%	0.09%	0.15%	0.23%			

Customer Reported Performance Data

Microny®

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	6,614
Estimated Longevity	7.5 Years
Number of US Advisories	None



Year	1	2	3	4	5	6	7	8	at 102 months
Survival Probability	99.95%	99.90%	99.82%	99.65%	99.45%	99.45%	99.15%	88.90%	75.10%
± 1 standard error	0.03%	0.05%	0.07%	0.11%	0.16%	0.16%	0.16%	0.38%	0.38%
Sample Size	6400	4300	3200	2300	1700	1100	700	400	200

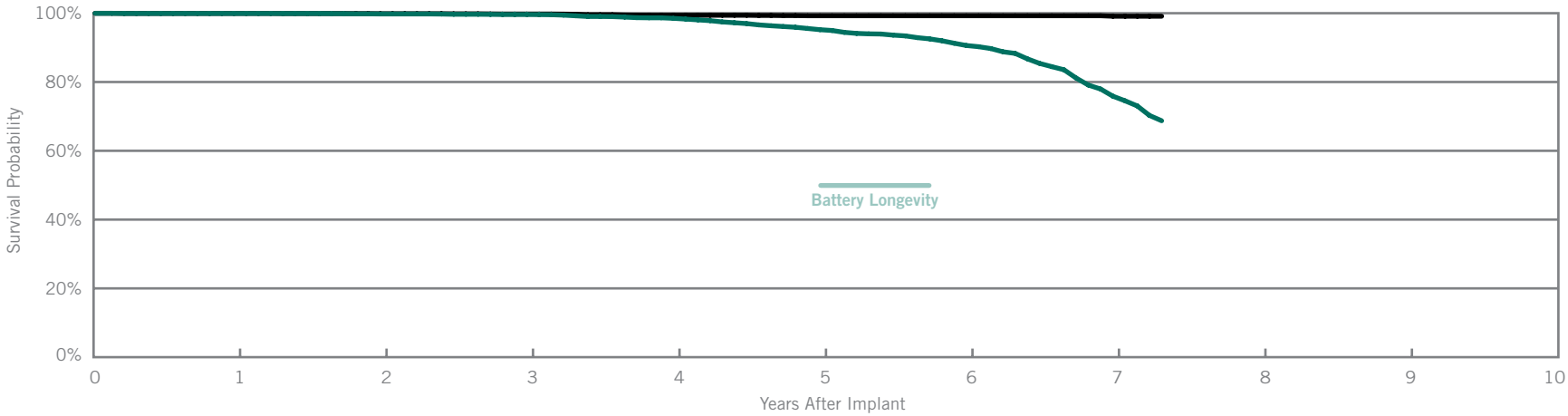
Customer Reported Performance Data

Integrity® µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	11,977
Estimated Active US Implants	787
Estimated Longevity	5.3 Years
Normal Battery Depletion	347
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	13	0.11%
Total	**13**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.94%	99.78%	99.63%	98.51%	95.21%	90.61%	75.88%	68.73%		
± 1 standard error	0.02%	0.05%	0.07%	0.14%	0.29%	0.43%	0.83%	1.06%		
Sample Size	11900	9400	7800	6500	5200	3900	2600	700		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.94%	99.86%	99.77%	99.40%	99.26%	99.26%	99.12%	99.12%		
± 1 standard error	0.02%	0.03%	0.05%	0.10%	0.11%	0.11%	0.11%	0.15%		

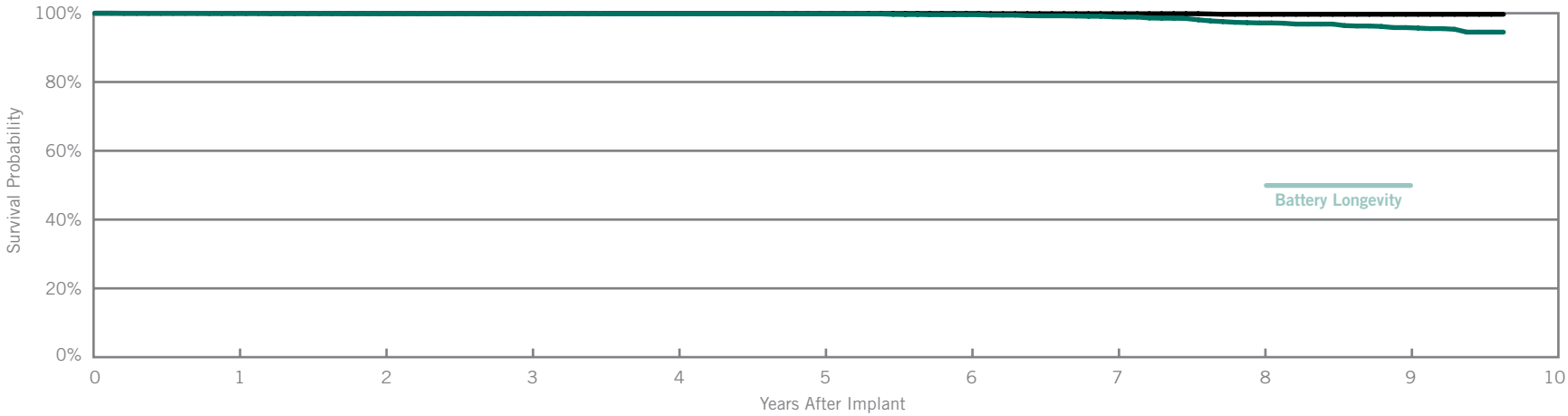
Customer Reported Performance Data

Integrity® SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,509
Estimated Active US Implants	2,359
Estimated Longevity	8.6 Years
Normal Battery Depletion	53
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	6	0.06%
Total	**7**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.96%	99.91%	99.91%	99.87%	99.83%	99.57%	98.95%	97.17%	95.82%	94.50%
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.09%	0.15%	0.30%	0.41%	0.54%
Sample Size	10500	8700	7400	6400	5400	4500	3700	2800	1900	700

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 116 months
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.91%	99.91%	99.85%	99.69%	99.69%	99.69%
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.05%	0.09%	0.09%	0.09%

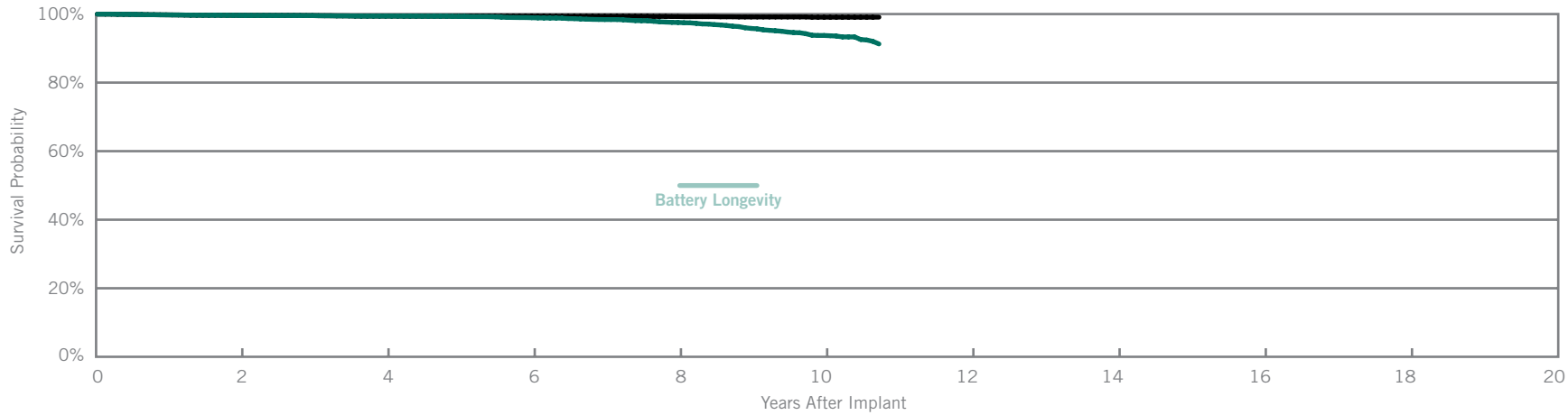
Customer Reported Performance Data

Affinity® SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,711
Estimated Active US Implants	4,569
Estimated Longevity	8.6 Years
Normal Battery Depletion	154
Number of US Advisories (see pgs. 229-237)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	4	0.01%
Malfunctions w/o Compromised Therapy (17 related to Advisory)	58	0.20%
Total (17 related to Advisory)	**62**	**0.22%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 129 months				
Survival Probability	99.62%	99.41%	98.93%	97.55%	93.75%	91.28%				
± 1 standard error	0.04%	0.05%	0.08%	0.16%	0.34%	0.47%				
Sample Size	23000	16500	11600	7600	3500	1100				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 129 months				
Survival Probability	99.62%	99.41%	99.36%	99.28%	99.09%	99.09%				
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.10%	0.10%				

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 RF*										
PM1210	Accent® SR RF	99.98%									
5626	Zephy®r XL SR	99.93%	99.90%	99.90%							
5620	Zephyr® SR	99.95%	99.95%	99.95%							
5610	Victory® SR	99.95%	99.95%	99.86%	99.49%						
5160	Integrity® ADx SR	100.00%	100.00%	99.69%	99.26%	96.99%					
5156/5157/5056	Verity® ADX XL SR/ SR(M/S)/SC	99.94%	99.86%	99.79%	99.70%	99.48%	99.23%				
5180	Integrity® ADx SR	99.91%	99.87%	99.69%	98.71%	95.41%	85.90%				
5172	Identity® SR	99.88%	99.57%	99.11%	98.10%	94.05%	80.57%				
5136	Integrity® µ SR	99.94%	99.78%	99.63%	98.51%	95.21%	90.61%	75.88%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.87%	99.83%	99.57%	98.95%	97.17%	95.82%	
5130/5131	Affinity® SR	99.77%	99.62%	99.55%	99.41%	99.32%	98.93%	98.40%	97.55%	95.81%	93.75%

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1110	Accent® SR RF*										
PM1210	Accent® SR RF	99.98%									
5626	Zephy®r XL SR	99.93%	99.90%	99.90%							
5620	Zephyr® SR	99.95%	99.95%	99.95%							
5610	Victory® SR	99.95%	99.95%	99.91%	99.82%						
5160	Integrity® ADx SR	100.00%	100.00%	100.00%	100.00%	99.58%					
5156/5157/5056	Verity® ADX XL SR/ SR(M/S)/SC	99.94%	99.88%	99.86%	99.82%	99.76%	99.61%				
5180	Integrity® ADx SR	99.97%	99.94%	99.84%	99.69%	99.56%	98.54%				
5172	Identity® SR	99.90%	99.77%	99.66%	99.52%	98.99%	98.14%				
5136	Integrity® µ SR	99.94%	99.86%	99.77%	99.40%	99.26%	99.26%	99.12%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.91%	99.91%	99.91%	99.85%	99.69%	99.69%	
5130/5131	Affinity® SR	99.77%	99.62%	99.54%	99.41%	99.38%	99.36%	99.34%	99.28%	99.16%	99.09%

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1110	Accent® SR RF*	Jul-09	1669	1568	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
PM1210	Accent® SR RF	Jul-09	8938	8102	1	0.01%	1	0.01%	0	0.00%	0	0.00%	1	0.01%
5626	Zephy®r XL SR	May-07	17934	13659	0	0.00%	0	0.00%	0	0.00%	6	0.03%	6	0.03%
5620	Zephyr® SR	Mar-07	9740	6987	0	0.00%	0	0.00%	0	0.00%	2	0.02%	2	0.02%
5610	Victory® SR	Dec-05	13478	7824	0	0.00%	1	0.01%	0	0.00%	3	0.02%	4	0.03%
5160	Integrity® ADx SR	May-03	3399	1145	0	0.00%	0	0.00%	0	0.00%	3	0.09%	3	0.09%
5156/5157/5056	Verity® ADX XL SR/ SR(M/S)/SC	May-03	14111	7034	0	0.00%	1	0.01%	0	0.00%	5	0.04%	6	0.04%
5180	Integrity® ADx SR	May-03	20389	7919	0	0.00%	0	0.00%	2	0.01%	25	0.12%	25	0.12%
5172	Identity® SR	Nov-01	21926	3859	1	<0.01%	2	0.01%	3	0.01%	62	0.28%	64	0.29%
5136	Integrity® µ SR	Dec-00	11977	787	0	0.00%	0	0.00%	0	0.00%	13	0.11%	13	0.11%
5142	Integrity® SR	Apr-00	10509	2359	0	0.00%	1	0.01%	0	0.00%	6	0.06%	7	0.07%
5130/5131	Affinity® SR	Jan-99/Jun-99	28711	4569	0	0.00%	4	0.01%	0	0.00%	58	0.20%	62	0.22%

**Totals include Premature Battery Depletion and all other confirmed malfunctions.*

Pacing Leads

Customer Reported Performance Data

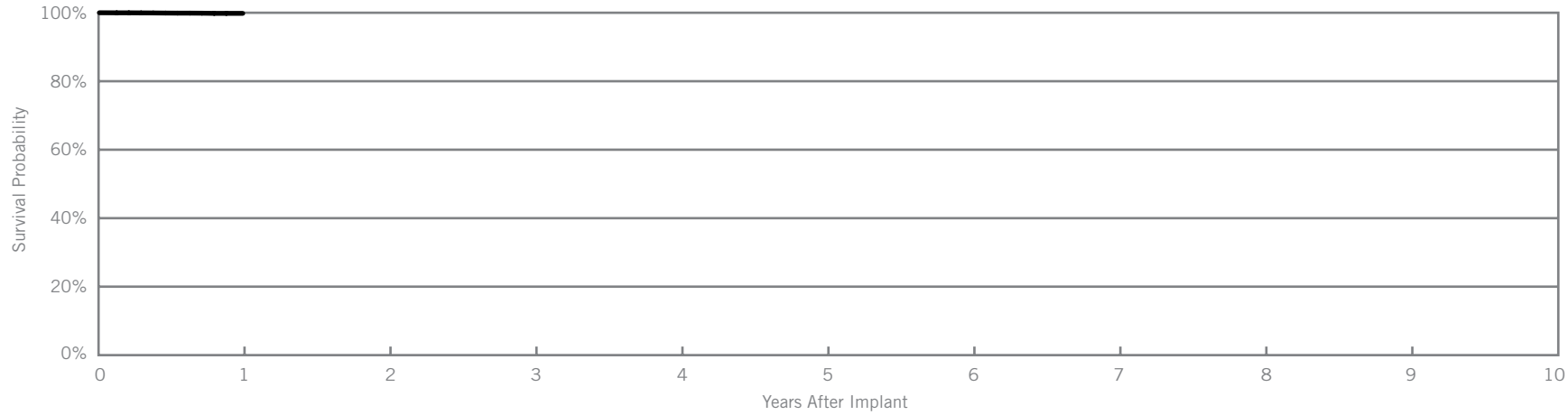
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	38,088
Estimated Active US Implants	35,180
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.01%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	9	0.02%	7	0.02%
Failure to Capture	1	<0.01%	2	0.01%
Oversensing	0	0.00%	2	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**15**	**0.04%**	**12**	**0.03%**
Total Returned for Analysis	**5**		**8**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.02%
Total	**10**	**0.03%**



Year	1									
Survival Probability	99.82%									
± 1 standard error	0.06%									
Sample Size	19100									

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

SCORE Registry Performance Data

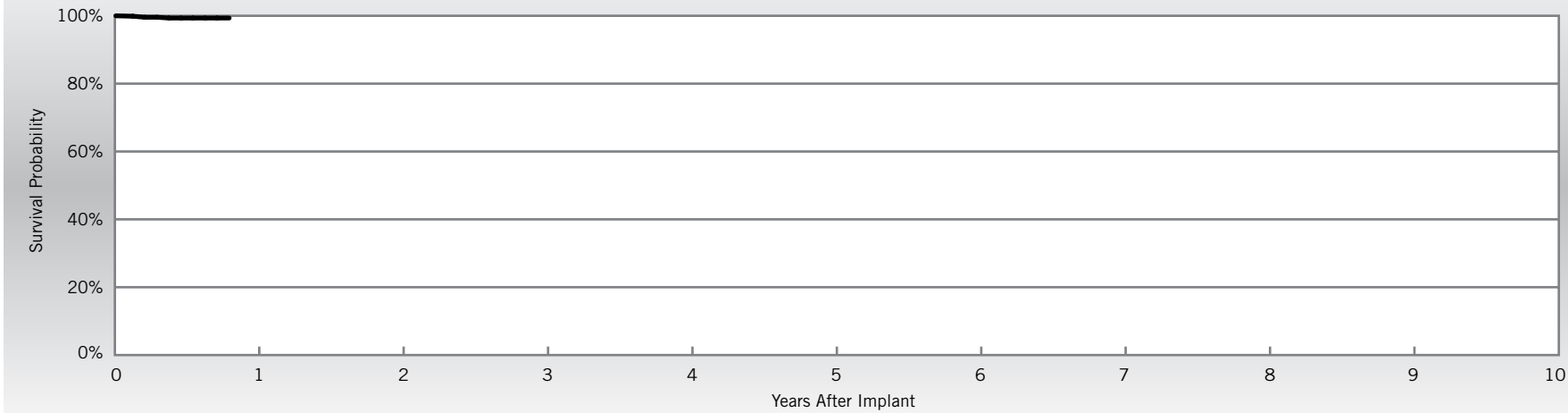
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	918
Cumulative Months of Follow-up	4,586
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Cardiac Perforation	1	0.11%
Lead Dislodgement	1	0.11%
Failure to Capture	1	0.11%
Abnormal Pacing Impedance	1	0.11%

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	at 10 months									
Survival Probability	99.34%									
± 1 standard error	0.31%									
Sample Size	50									

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

Customer Reported Performance Data

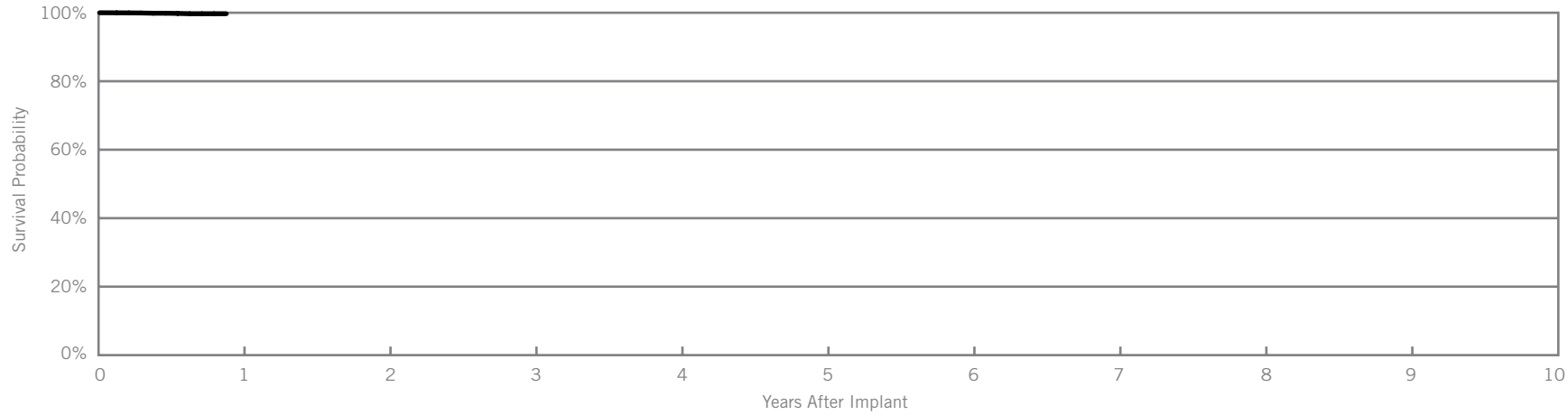
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	6,079
Estimated Active US Implants	5,618
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	0	0.00%	3	0.05%
Failure to Capture	0	0.00%	1	0.02%
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%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**4**	**0.07%**
Total Returned for Analysis	**0**		**0**	

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



Year	at 11 months										
Survival Probability	99.71%										
± 1 standard error	0.13%										
Sample Size	300										

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

SCORE Registry Performance Data

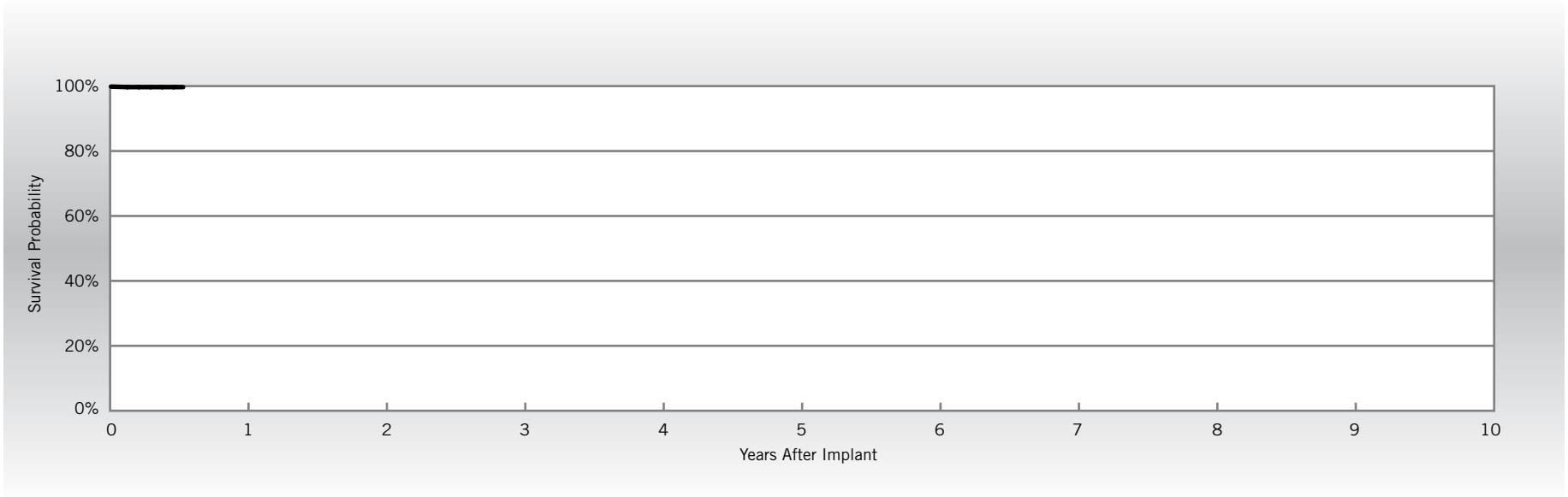
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	132
Cumulative Months of Follow-up	764
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	0	0.00%
Total	**0**	**0.00%**



Year	at 7 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	60									

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

Customer Reported Performance Data

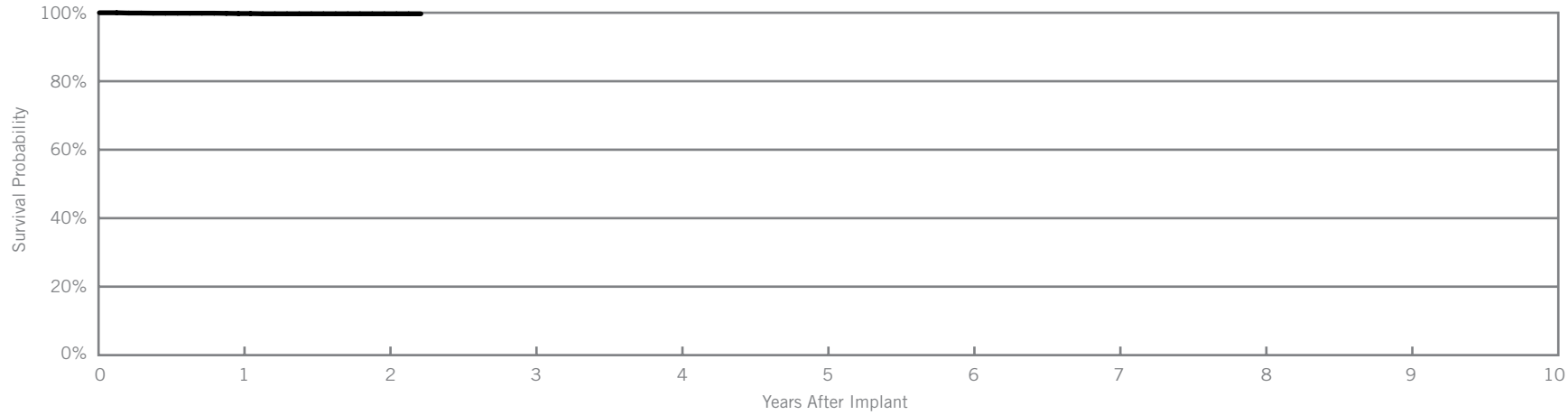
IsoFlex® Optim®

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	3,942
Estimated Active US Implants	3,452
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	6	0.15%	4	0.10%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	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	0.03%
Total	**7**	**0.18%**	**5**	**0.13%**
Total Returned for Analysis	**3**		**2**	

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	2	0.05%
Total	**2**	**0.05%**



Year	1	2	at 27 months							
Survival Probability	99.76%	99.69%	99.69%							
± 1 standard error	0.08%	0.12%	0.12%							
Sample Size	2900	1000	200							

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

Customer Reported Performance Data

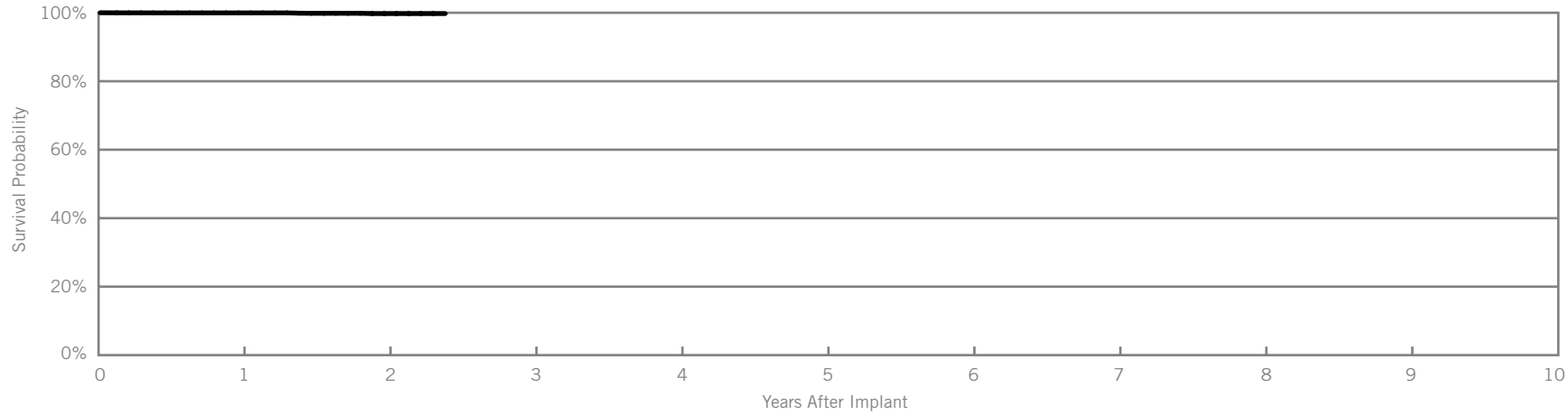
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	13,824
Estimated Active US Implants	11,961
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	6	0.04%	3	0.02%
Failure to Capture	3	0.02%	2	0.01%
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%	4	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.01%	0	0.00%
Total	**10**	**0.07%**	**9**	**0.07%**
Total Returned for Analysis	**7**		**5**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	5	0.04%
Total	**7**	**0.05%**



Year	1	2	at 29 months							
Survival Probability	99.96%	99.76%	99.76%							
± 1 standard error	0.02%	0.10%	0.10%							
Sample Size	10100	3500	300							

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

SCORE Registry Performance Data

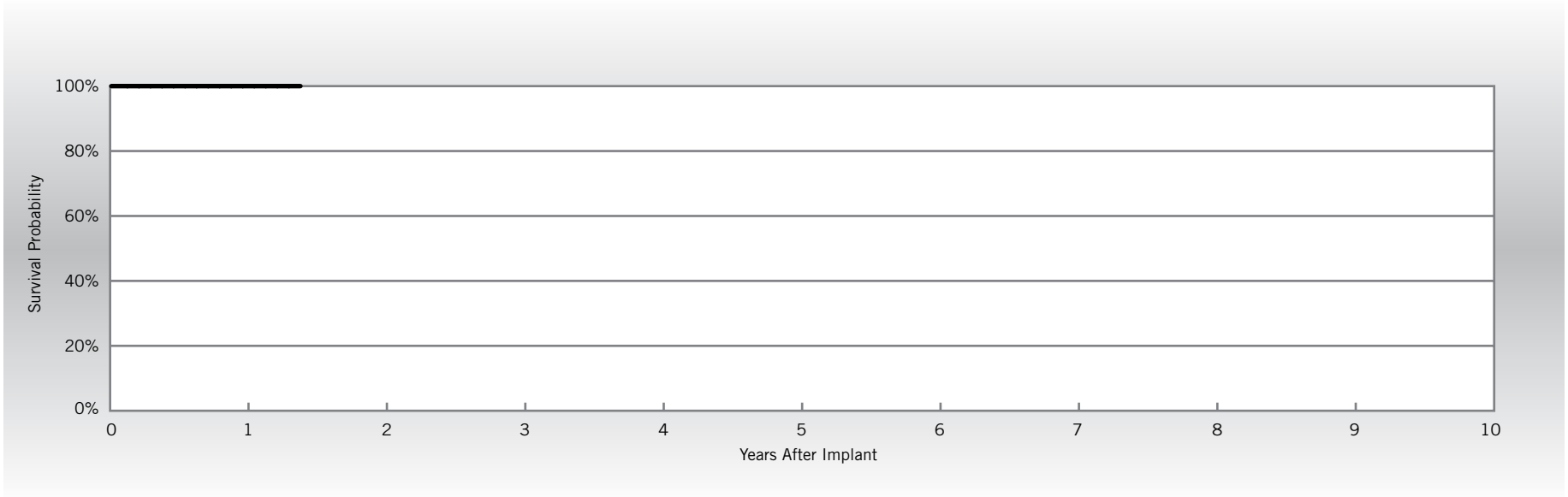
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	220
Cumulative Months of Follow-up	2,545
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	at 17 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	160	60								

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

Customer Reported Performance Data

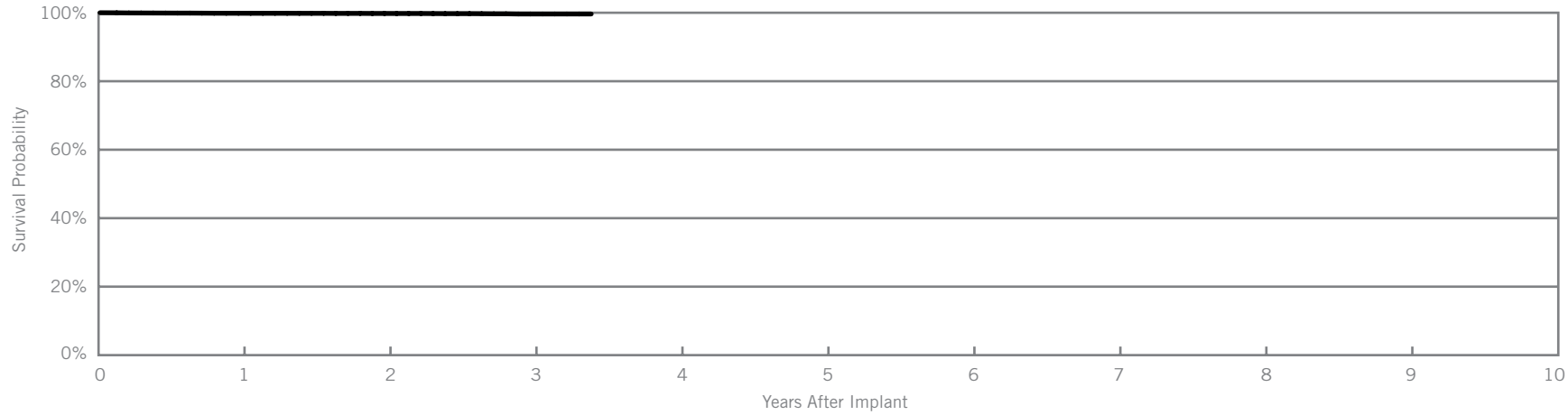
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	23,314
Estimated Active US Implants	18,007
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	5	0.02%	16	0.07%
Failure to Capture	3	0.01%	10	0.04%
Oversensing	2	0.01%	4	0.02%
Failure to Sense	8	0.03%	3	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	0.01%	0	0.00%
Total	**21**	**0.09%**	**37**	**0.16%**
Total Returned for Analysis	**16**		**23**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	19	0.08%
Total	**23**	**0.10%**



Year	1	2	3	at 41 months						
Survival Probability	99.85%	99.79%	99.64%	99.64%						
± 1 standard error	0.03%	0.04%	0.07%	0.07%						
Sample Size	20600	13300	5300	300						

SCORE Registry Performance Data

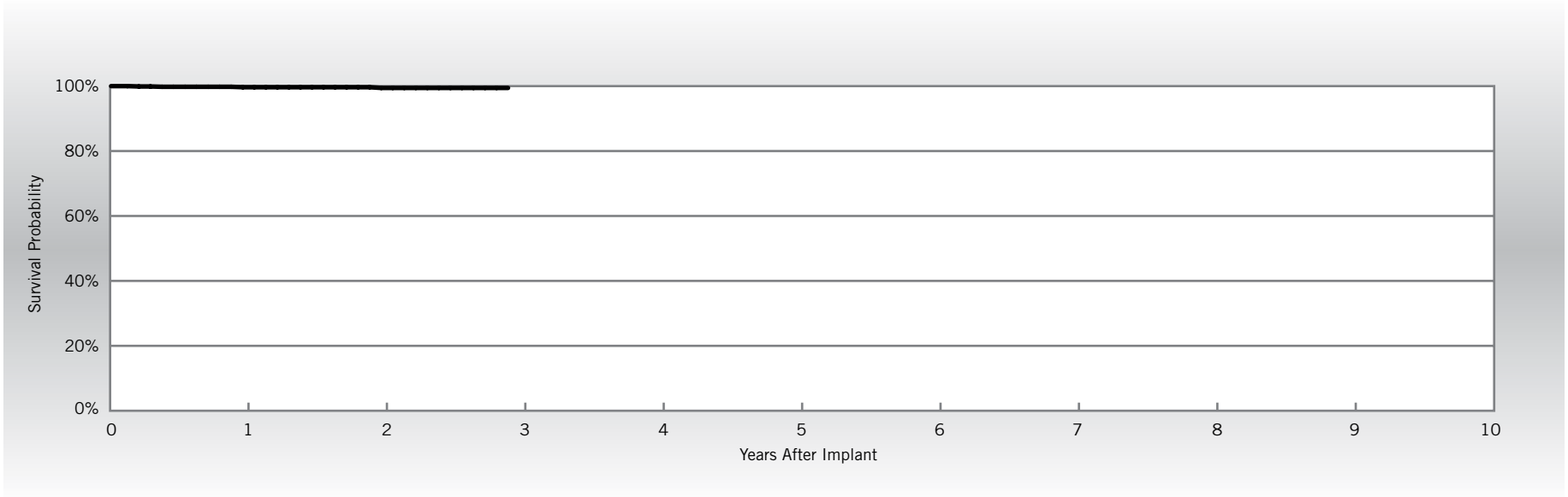
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	966
Cumulative Months of Follow-up	21,621
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

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

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	at 35 months							
Survival Probability	99.66%	99.44%	99.44%							
± 1 standard error	0.19%	0.29%	0.29%							
Sample Size	890	630	50							

Customer Reported Performance Data

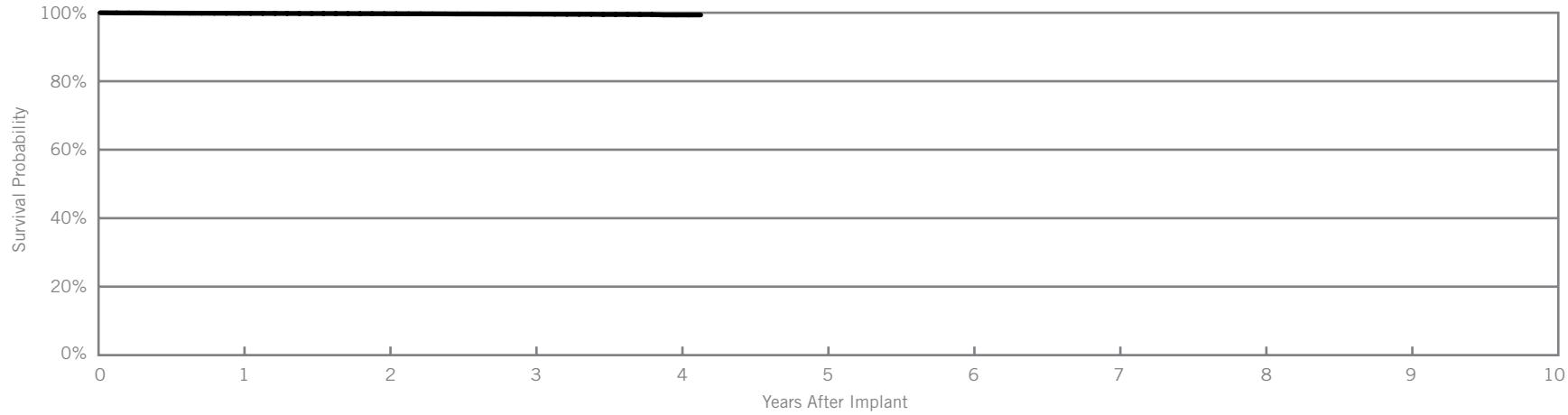
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	205,730
Estimated Active US Implants	164,352
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	26	0.01%	17	0.01%
Conductor Fracture	5	<0.01%	14	0.01%
Lead Dislodgement	82	0.04%	123	0.06%
Failure to Capture	62	0.03%	77	0.04%
Oversensing	9	<0.01%	43	0.02%
Failure to Sense	6	<0.01%	6	<0.01%
Insulation Breach	3	<0.01%	18	0.01%
Abnormal Pacing Impedance	6	<0.01%	16	0.01%
Extracardiac Stimulation	3	<0.01%	5	<0.01%
Other	16	0.01%	23	0.01%
Total	**218**	**0.11%**	**342**	**0.17%**
Total Returned for Analysis	**87**		**203**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	<0.01%
Insulation Breach	45	0.02%
Crimps, Welds & Bonds	1	<0.01%
Other	7	<0.01%
Extrinsic Factors	165	0.08%
Total	**222**	0.11%



Year	1	2	3	4	at 50 months					
Survival Probability	99.83%	99.72%	99.61%	99.36%	99.36%					
± 1 standard error	0.01%	0.01%	0.02%	0.12%	0.12%					
Sample Size	173500	100400	43300	10700	300					

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

SCORE Registry Performance Data

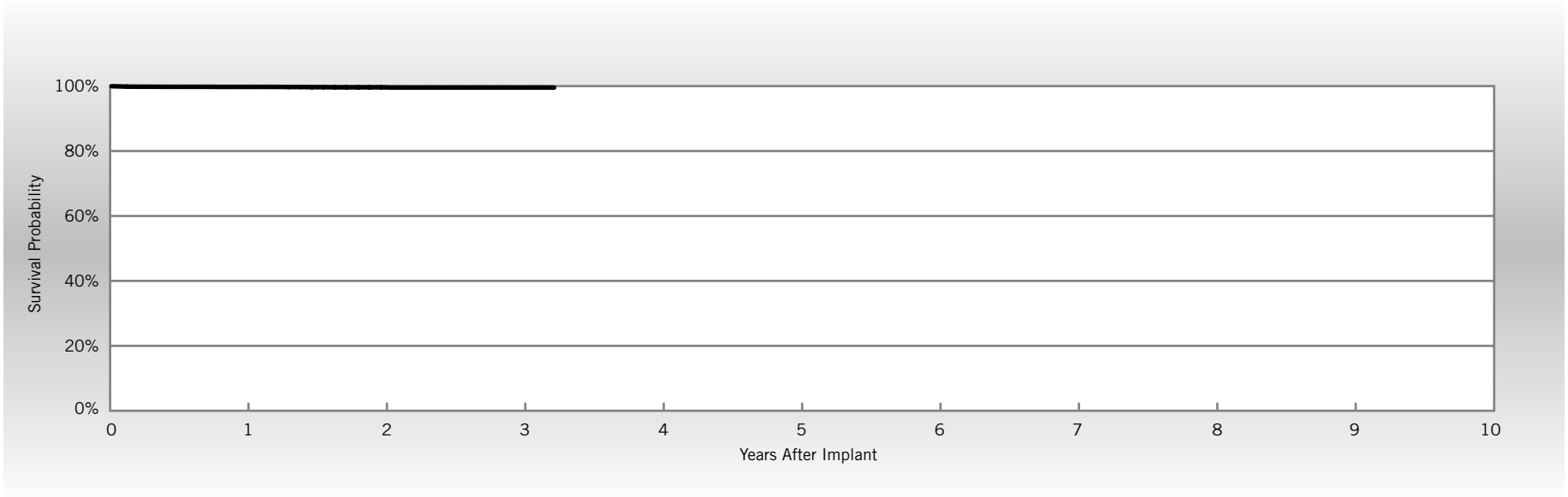
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	3,811
Cumulative Months of Follow-up	79,344
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	9	0.24%
Failure to Capture	1	0.03%
Abnormal Pacing Impedance	2	0.05%
Extracardiac Stimulation	1	0.03%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.03%
Insulation Breach	1	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.03%
Extrinsic Factors	5	0.13%
Total	**8**	**0.21%**



Year	1	2	3	at 39 months						
Survival Probability	99.76%	99.63%	99.55%	99.55%						
± 1 standard error	0.08%	0.11%	0.13%	0.13%						
Sample Size	3430	2260	790	60						

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

Customer Reported Performance Data

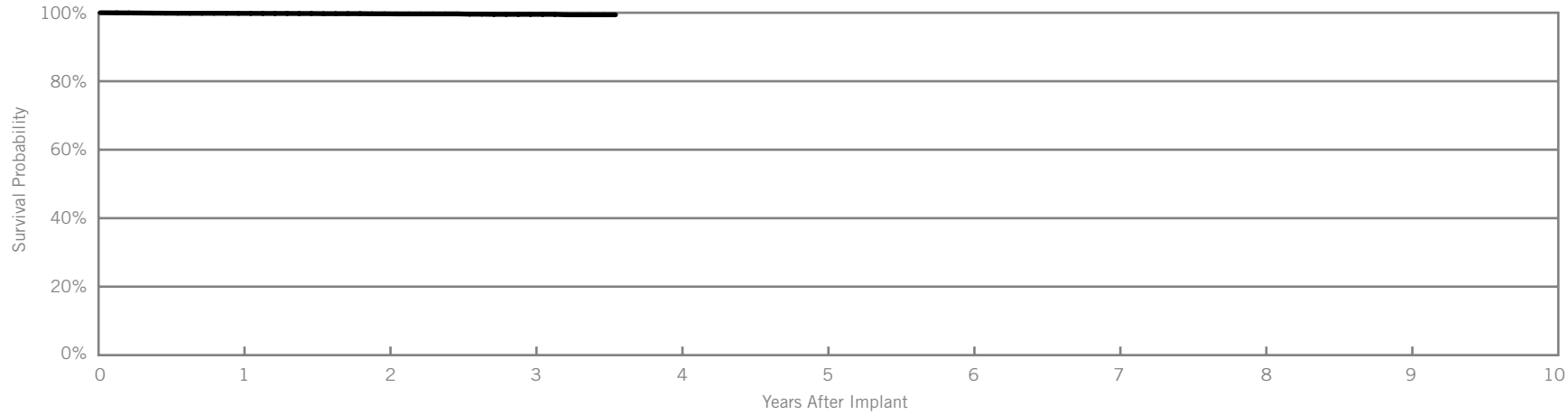
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	16,782
Estimated Active US Implants	13,856
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	0.01%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	11	0.07%	12	0.07%
Failure to Capture	4	0.02%	6	0.04%
Oversensing	2	0.01%	3	0.02%
Failure to Sense	2	0.01%	2	0.01%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	0.01%	3	0.02%
Total	**23**	**0.14%**	**28**	**0.17%**
Total Returned for Analysis	**6**		**20**	

Malfunctions	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.01%
Extrinsic Factors	16	0.10%
Total	**19**	**0.11%**



Year	1	2	3	at 43 months						
Survival Probability	99.82%	99.69%	99.53%	99.40%						
± 1 standard error	0.04%	0.06%	0.10%	0.17%						
Sample Size	13600	7200	2900	300						

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

SCORE Registry Performance Data

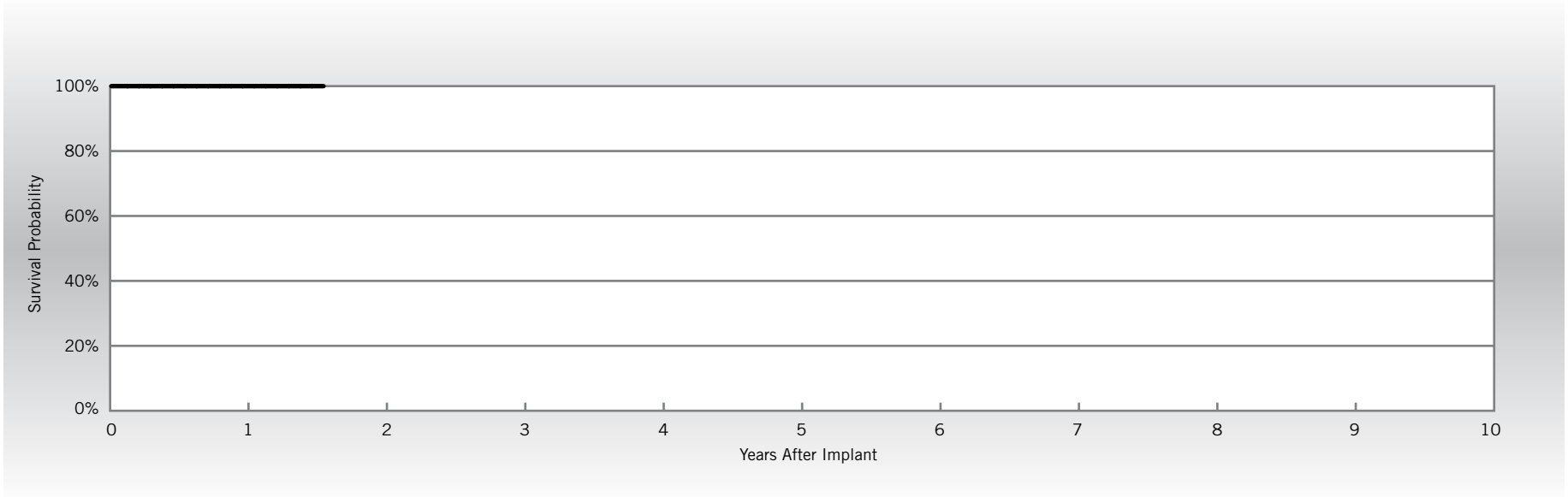
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	148
Cumulative Months of Follow-up	2,210
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	0.68%
Total	**1**	**0.68%**



Year	1	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	120	50								

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

Customer Reported Performance Data

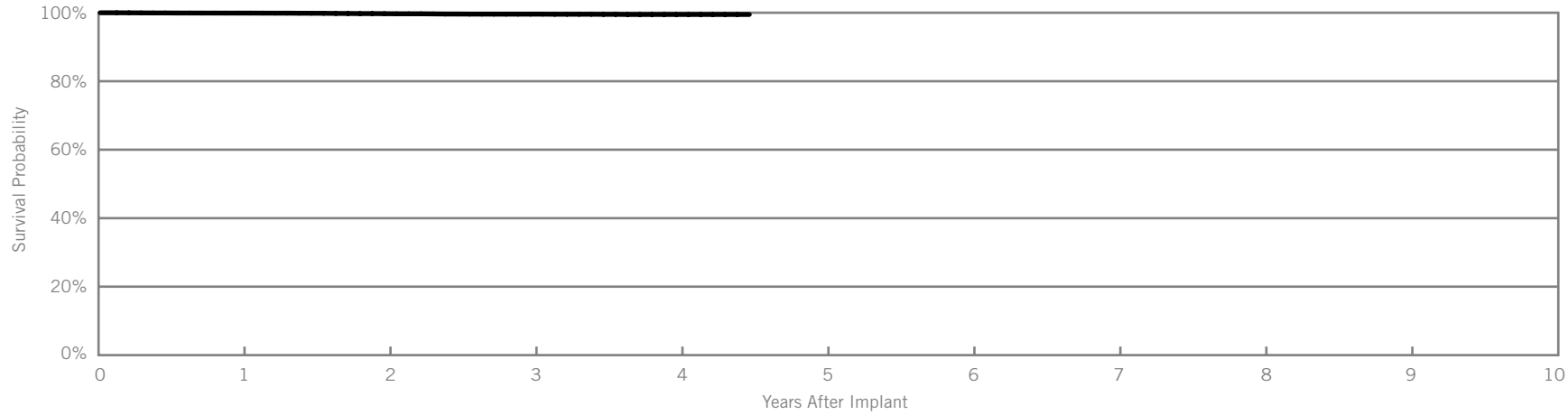
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	14,910
Estimated Active US Implants	10,938
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	5	0.03%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	9	0.06%	12	0.08%
Failure to Capture	5	0.03%	10	0.07%
Oversensing	0	0.00%	2	0.01%
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%	0	0.00%
Other	2	0.01%	1	0.01%
Total	**24**	**0.16%**	30	**0.20%**
Total Returned for Analysis	**12**		**22**	

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	18	0.12%
Total	**21**	**0.14%**



Year	1	2	3	4	at 54 months					
Survival Probability	99.90%	99.72%	99.59%	99.49%	99.49%					
± 1 standard error	0.03%	0.05%	0.07%	0.09%	0.09%					
Sample Size	13500	10000	6700	3100	300					

SCORE Registry Performance Data

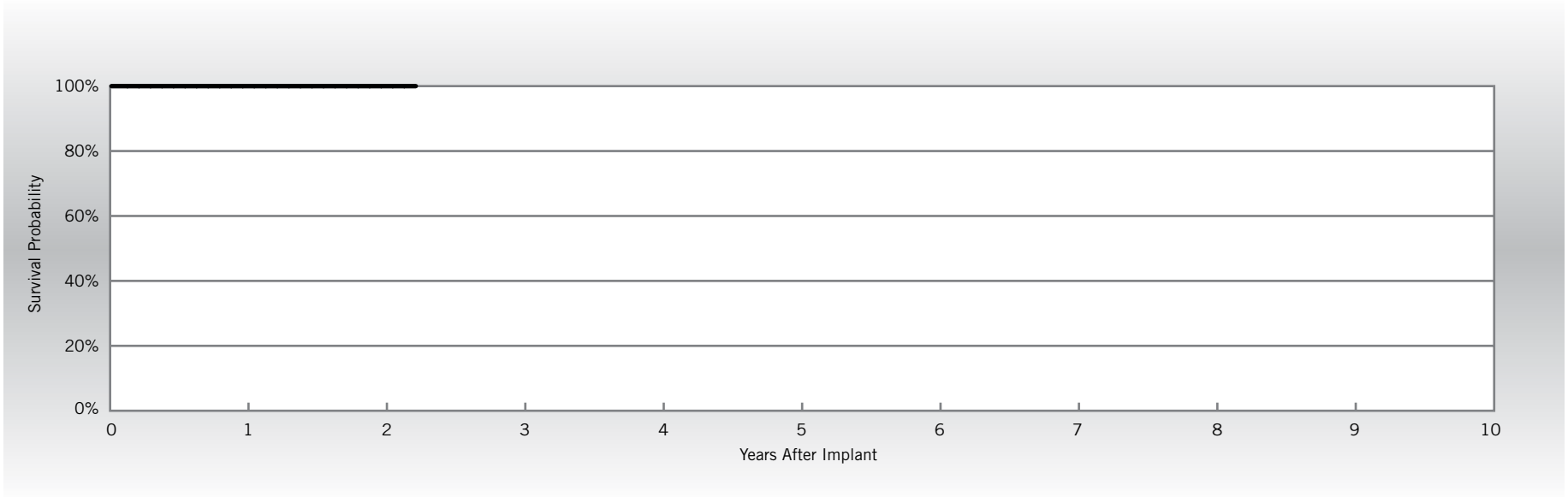
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	135
Cumulative Months of Follow-up	2,700
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 27 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	110	70	50							

Customer Reported Performance Data

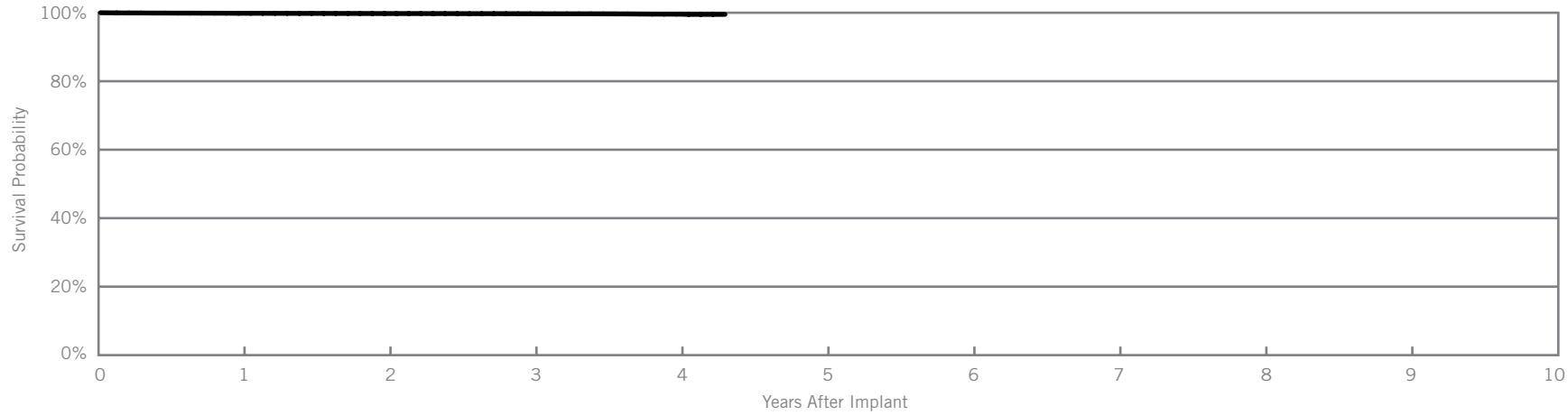
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	64,413
Estimated Active US Implants	45,376
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	11	0.02%	1	<0.01%
Conductor Fracture	1	<0.01%	2	<0.01%
Lead Dislodgement	32	0.05%	28	0.04%
Failure to Capture	29	0.05%	35	0.05%
Oversensing	2	<0.01%	17	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%	10	0.02%
Extracardiac Stimulation	2	<0.01%	1	<0.01%
Other	20	0.03%	5	0.01%
Total	**109**	**0.17%**	**102**	**0.16%**
Total Returned for Analysis	**41**		**72**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	23	0.04%
Crimps, Welds & Bonds	1	<0.01%
Other	7	0.01%
Extrinsic Factors	47	0.07%
Total	**79**	**0.12%**



Year	1	2	3	4	at 52 months					
Survival Probability	99.84%	99.76%	99.70%	99.59%	99.52%					
± 1 standard error	0.02%	0.02%	0.02%	0.04%	0.05%					
Sample Size	61000	49000	35500	16700	800					

SCORE Registry Performance Data

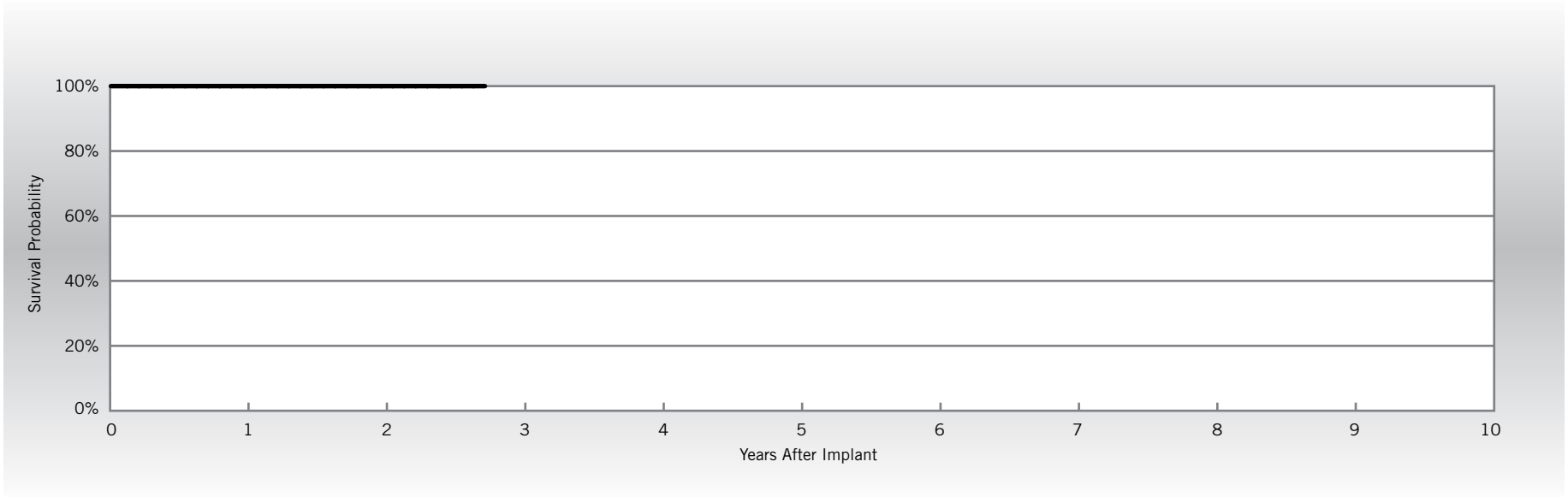
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	226
Cumulative Months of Follow-up	5,691
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	220	160	50							

Customer Reported Performance Data

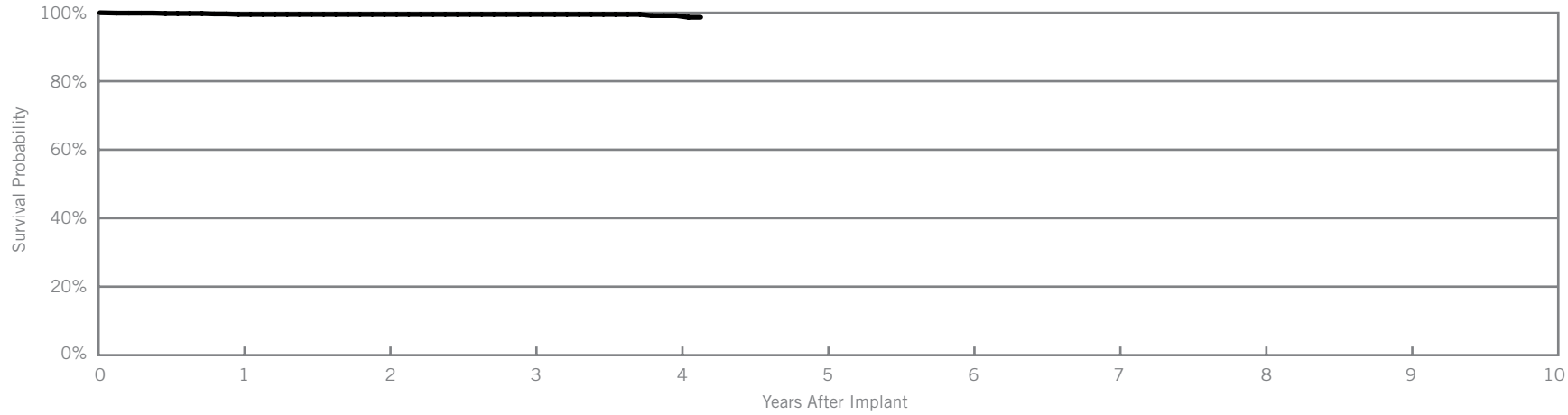
IsoFlex® P

Model 1644T

US Regulatory Approval	April 2005
Registered US Implants	955
Estimated Active US Implants	598
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%	1	0.10%
Lead Dislodgement	1	0.10%	0	0.00%
Failure to Capture	0	0.00%	3	0.31%
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%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.10%	0	0.00%
Total	**2**	**0.21%**	**4**	**0.42%**
Total Returned for Analysis	**1**		**2**	

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	2	0.21%
Total	**2**	**0.21%**



Year	1	2	3	4	at 50 months					
Survival Probability	99.53%	99.53%	99.53%	99.16%	98.69%					
± 1 standard error	0.20%	0.23%	0.23%	0.44%	0.64%					
Sample Size	900	800	600	400	200					

Customer Reported Performance Data

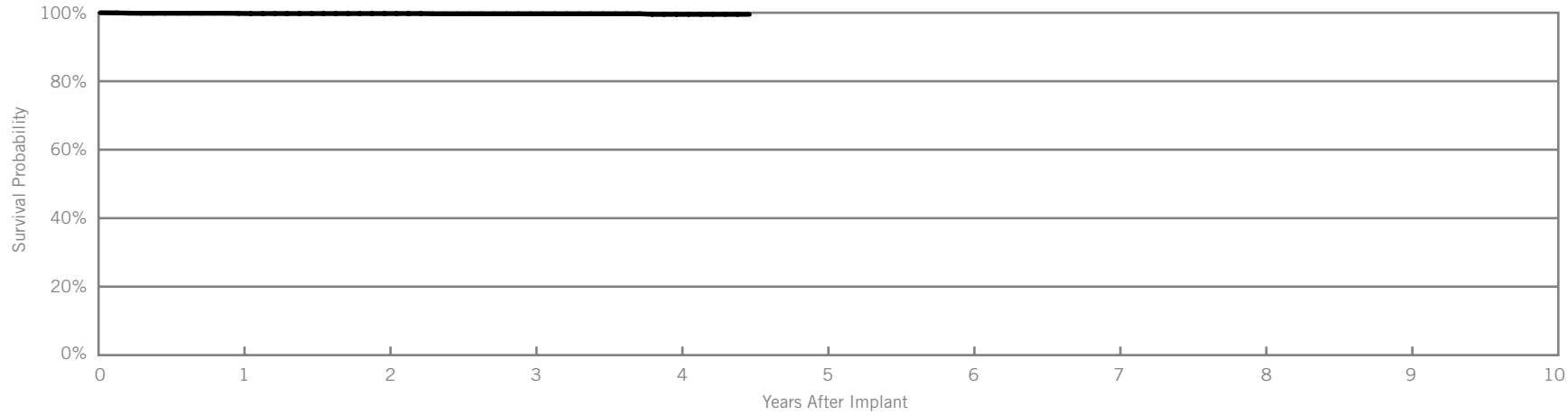
IsoFlex® P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,836
Estimated Active US Implants	1,798
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%	0	0.00%
Failure to Capture	2	0.07%	1	0.04%
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%	1	0.04%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	2	0.07%
Total	**6**	**0.21%**	**5**	**0.18%**
Total Returned for Analysis	**1**		**4**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.04%
Extrinsic Factors	2	0.07%
Total	**4**	**0.14%**



Year	1	2	3	4	at 54 months					
Survival Probability	99.80%	99.76%	99.70%	99.53%	99.53%					
± 1 standard error	0.08%	0.10%	0.12%	0.20%	0.20%					
Sample Size	2700	2200	1600	900	200					

Customer Reported Performance Data

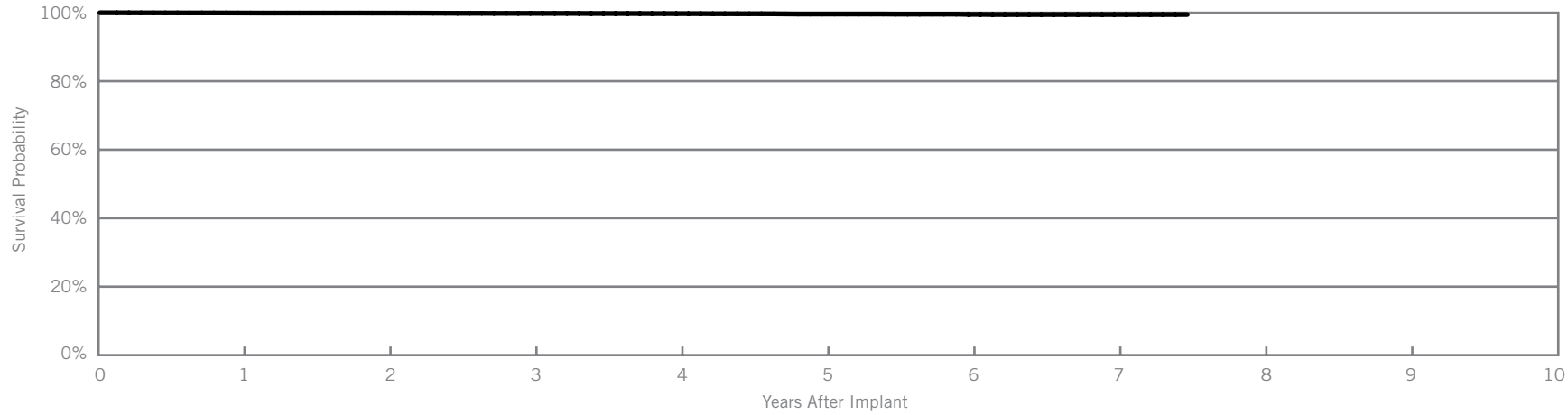
IsoFlex® S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	25,535
Estimated Active US Implants	16,431
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	46	0.18%	19	0.07%
Failure to Capture	5	0.02%	15	0.06%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	3	0.01%	3	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	3	0.01%	1	<0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**58**	**0.23%**	**40**	**0.16%**
Total Returned for Analysis	**33**		**13**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	<0.01%
Crimps, Welds & Bonds	2	0.01%
Other	8	0.03%
Extrinsic Factors	10	0.04%
Total	**21**	**0.08%**



Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.93%	99.90%	99.82%	99.74%	99.62%	99.52%	99.48%	99.48%		
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.06%	0.07%	0.09%	0.09%		
Sample Size	23900	19200	15000	10900	7300	4200	1800	200		

Customer Reported Performance Data

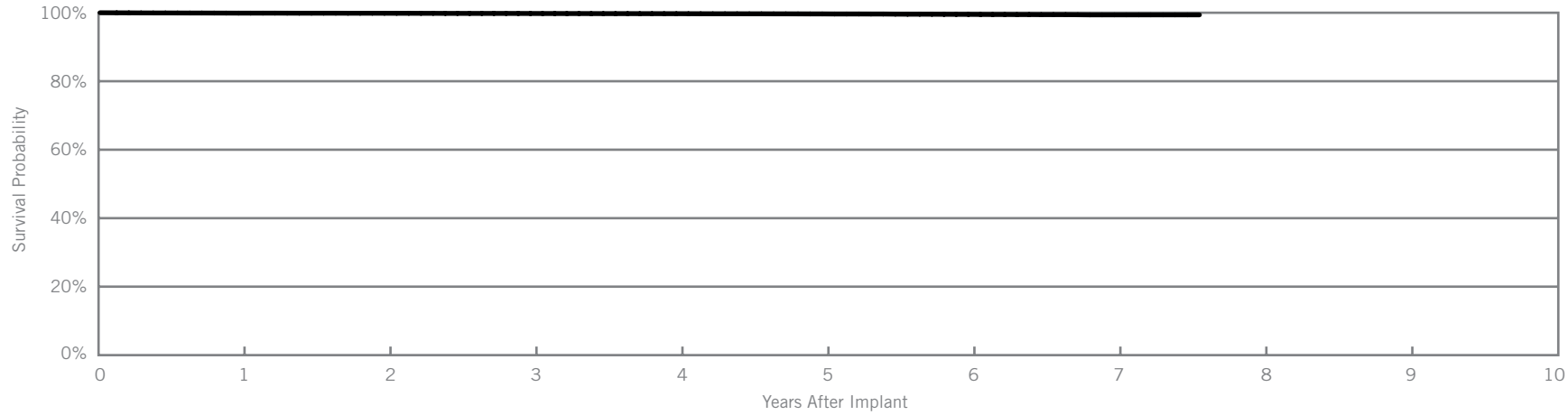
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	84,672
Estimated Active US Implants	53,954
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	<0.01%	1	<0.01%
Conductor Fracture	2	<0.01%	15	0.02%
Lead Dislodgement	32	0.04%	20	0.02%
Failure to Capture	31	0.04%	61	0.07%
Oversensing	0	0.00%	9	0.01%
Failure to Sense	3	<0.01%	2	<0.01%
Insulation Breach	2	<0.01%	1	<0.01%
Abnormal Pacing Impedance	6	0.01%	21	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	<0.01%	9	0.01%
Total	**81**	**0.10%**	**139**	**0.16%**
Total Returned for Analysis	**34**		**36**	

Malfunctions	Qty.	Rate
Conductor Fracture	9	0.01%
Insulation Breach	10	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	8	0.01%
Extrinsic Factors	27	0.03%
Total	**55**	**0.06%**



Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.89%	99.85%	99.78%	99.72%	99.65%	99.52%	99.38%	99.38%		
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.07%	0.07%		
Sample Size	79100	62400	47800	34000	22100	12300	5100	300		

SCORE Registry Performance Data

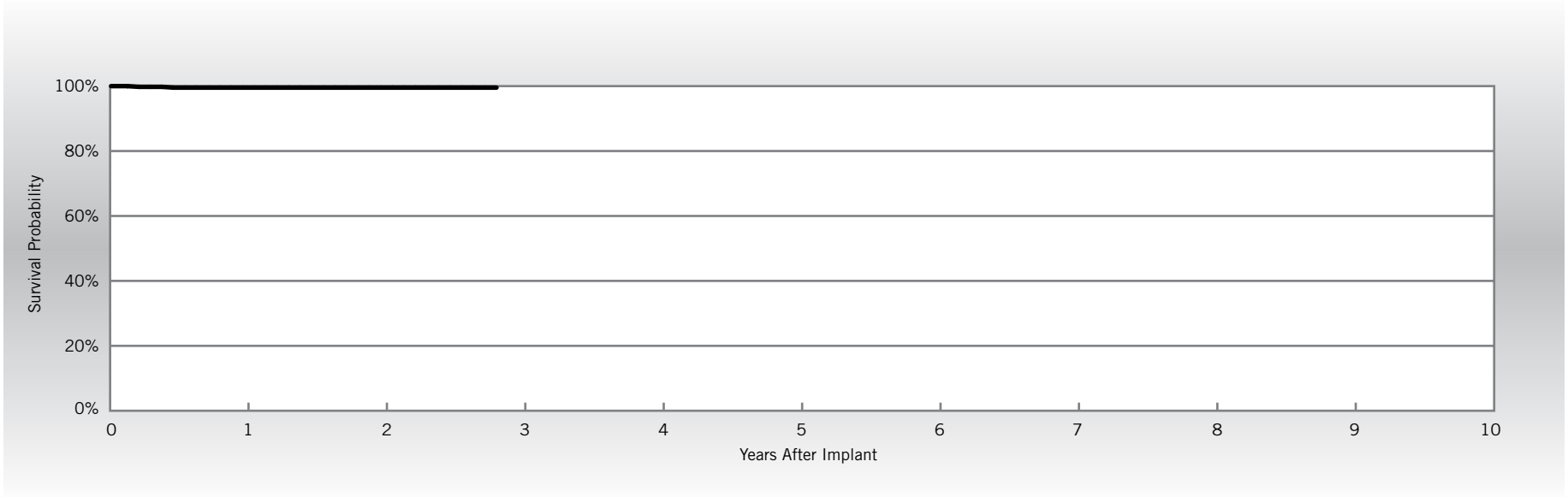
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	481
Cumulative Months of Follow-up	9,764
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.21%
Failure to Capture	1	0.21%

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 34 months							
Survival Probability	99.54%	99.54%	99.54%							
± 1 standard error	0.32%	0.32%	0.32%							
Sample Size	420	270	50							

Customer Reported Performance Data

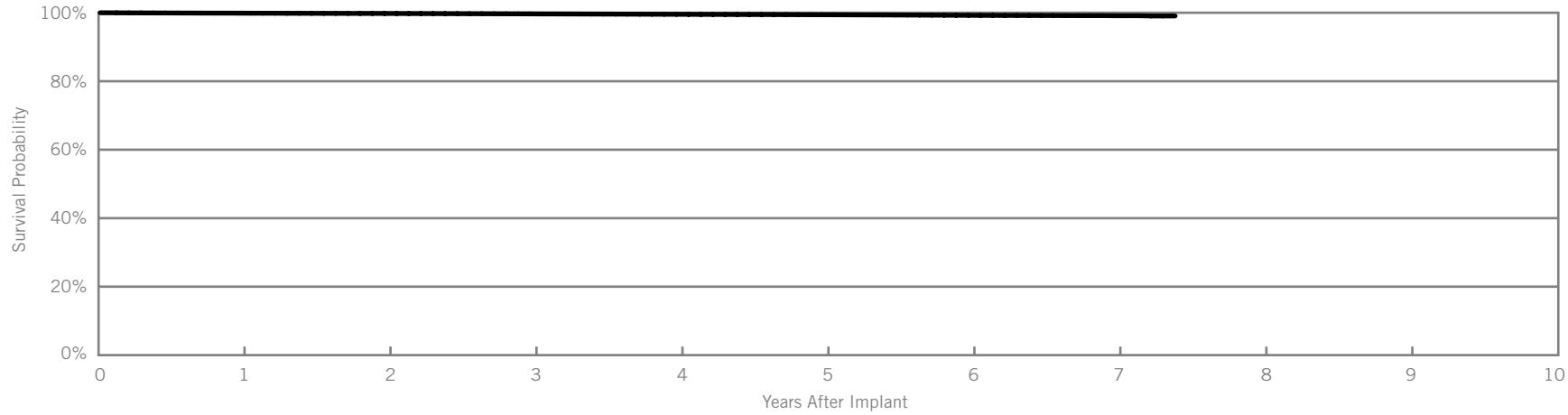
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	357,726
Estimated Active US Implants	228,093
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	37	0.01%	8	<0.01%
Conductor Fracture	3	<0.01%	66	0.02%
Lead Dislodgement	156	0.04%	186	0.05%
Failure to Capture	117	0.03%	267	0.07%
Oversensing	9	<0.01%	146	0.04%
Failure to Sense	20	0.01%	14	<0.01%
Insulation Breach	5	<0.01%	26	0.01%
Abnormal Pacing Impedance	23	0.01%	137	0.04%
Extracardiac Stimulation	3	<0.01%	7	<0.01%
Other	29	0.01%	58	0.02%
Total	**402**	**0.11%**	**915**	**0.26%**
Total Returned for Analysis	**152**		**427**	

Malfunctions	Qty.	Rate
Conductor Fracture	98	0.03%
Insulation Breach	119	0.03%
Crimps, Welds & Bonds	16	<0.01%
Other	10	<0.01%
Extrinsic Factors	251	0.07%
Total	**494**	**0.14%**



Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.88%	99.79%	99.67%	99.55%	99.42%	99.25%	99.13%	99.06%		
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.03%	0.04%	0.09%		
Sample Size	333600	266500	213000	162800	106100	51500	15900	200		

SCORE Registry Performance Data

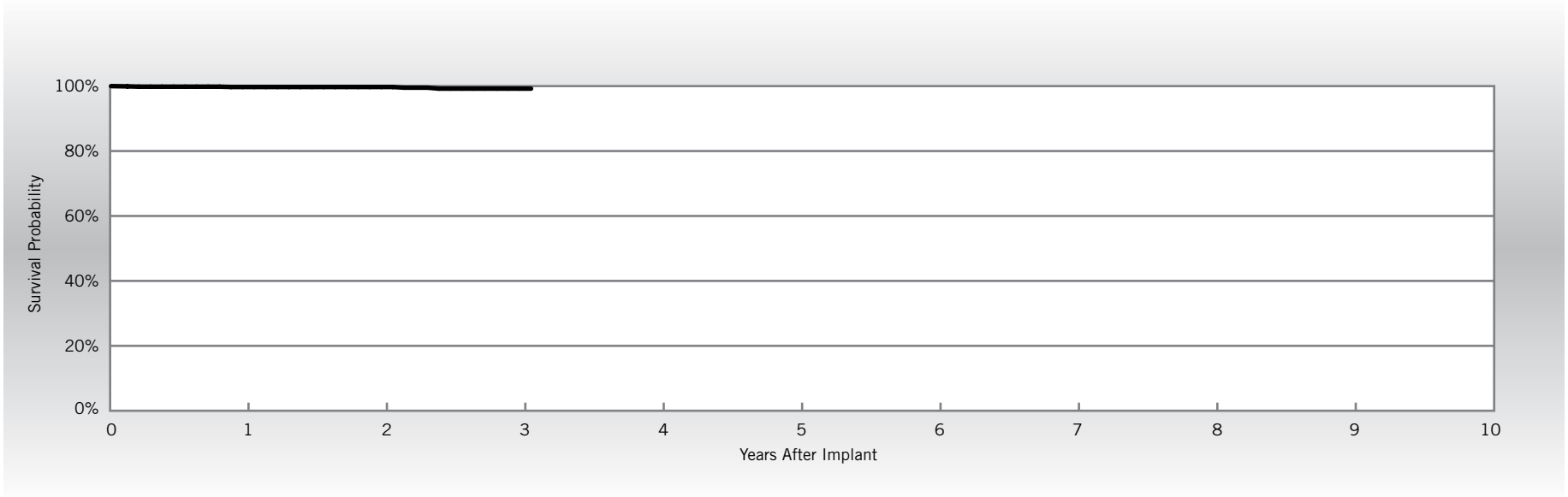
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	1,266
Cumulative Months of Follow-up	26,678
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Cardiac Perforation	1	0.08%
Failure to Capture	1	0.08%
Abnormal Pacing Impedance	1	0.08%
Extracardiac Stimulation	1	0.08%
Other	1	0.08%

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	0.08%
Total	**1**	**0.08%**



Year	1	2	3	at 37 months						
Survival Probability	99.73%	99.73%	99.23%	99.23%						
± 1 standard error	0.15%	0.15%	0.37%	0.37%						
Sample Size	1120	760	310	70						

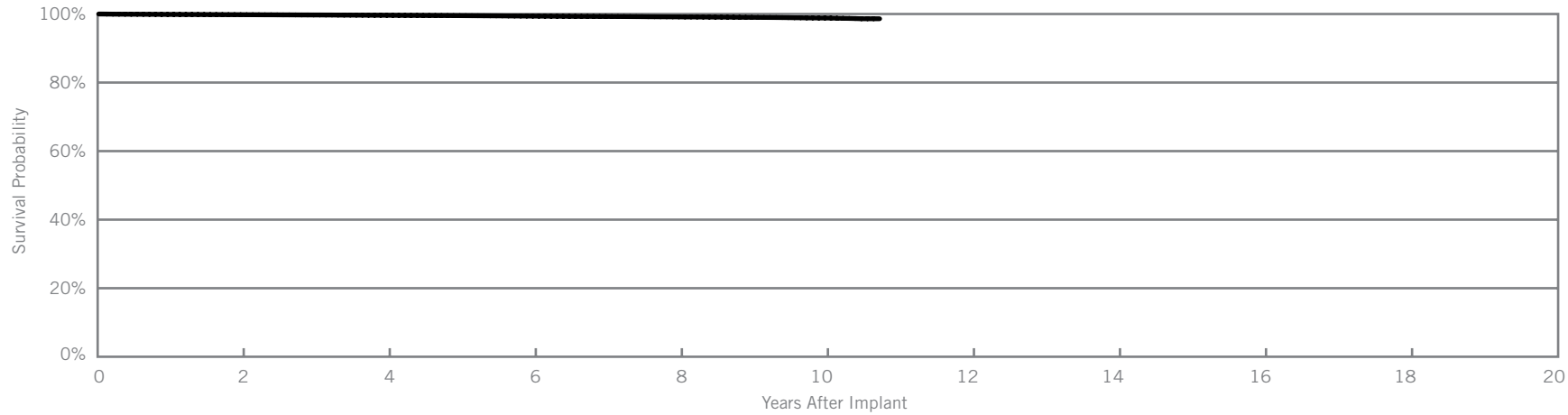
Customer Reported Performance Data

Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	273,947
Estimated Active US Implants	114,009
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	127	0.05%
Insulation Breach	83	0.03%
Crimps, Welds & Bonds	13	<0.01%
Other	2	<0.01%
Extrinsic Factors	243	0.09%
Total	**468**	**0.17%**



Year	2	4	6	8	10	at 129 months				
Survival Probability	99.80%	99.63%	99.39%	99.16%	98.84%	98.62%				
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.05%	0.10%				
Sample Size	234800	190400	137200	72600	15000	300				

SCORE Registry Performance Data

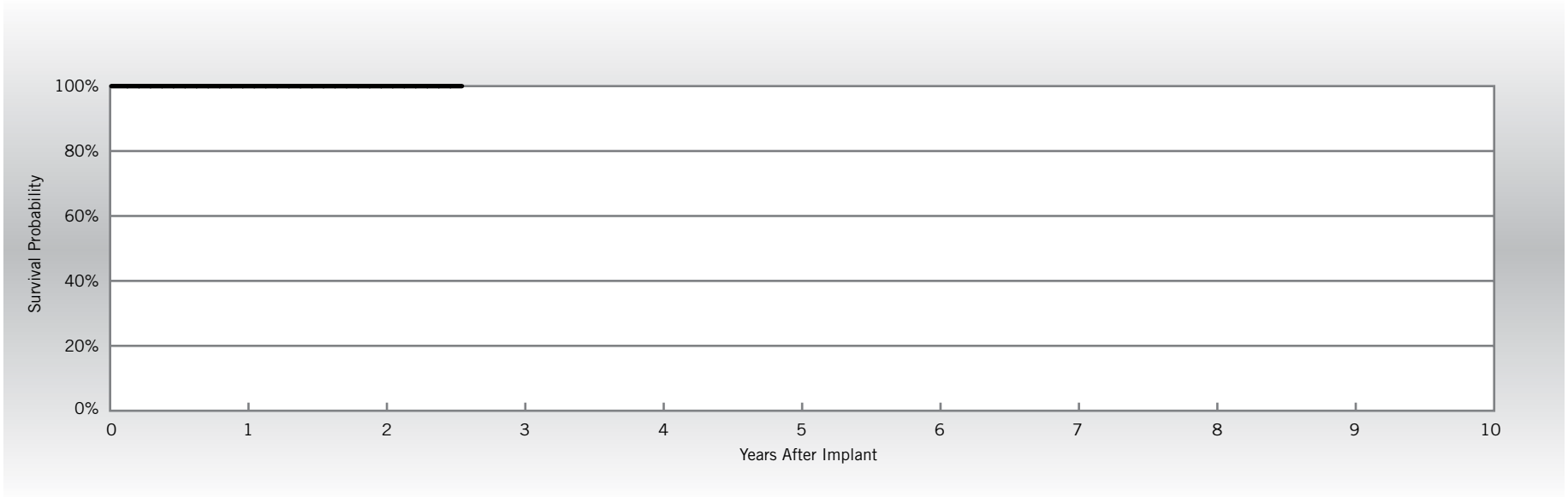
Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	138
Cumulative Months of Follow-up	3,717
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	1	0.72%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**1**	**0.72%**



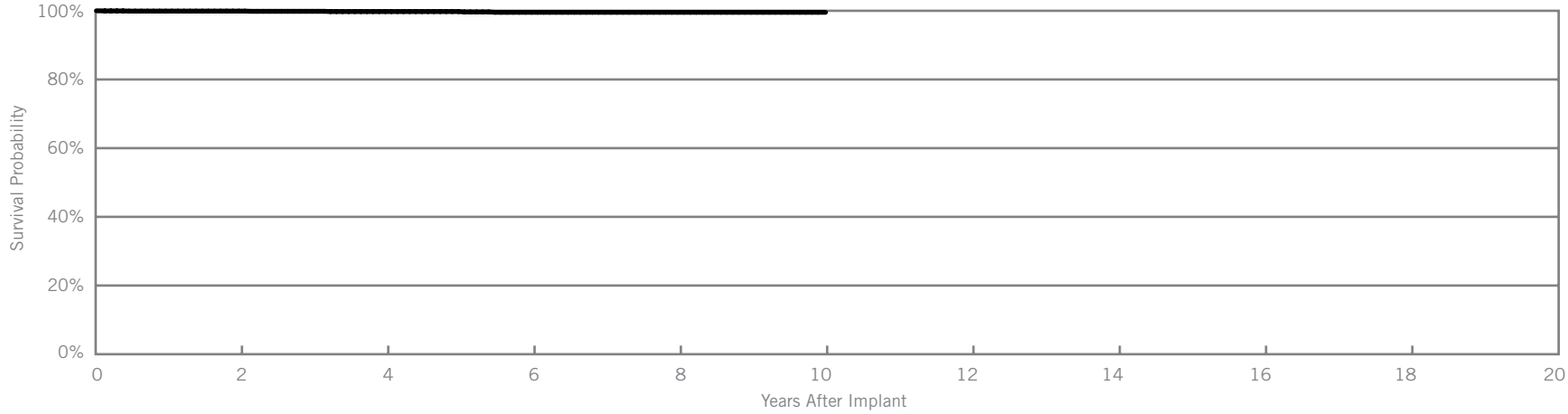
Year	1	2	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	130	110	50							

Customer Reported Performance Data

AV Plus® DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,509
Estimated Active US Implants	964
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



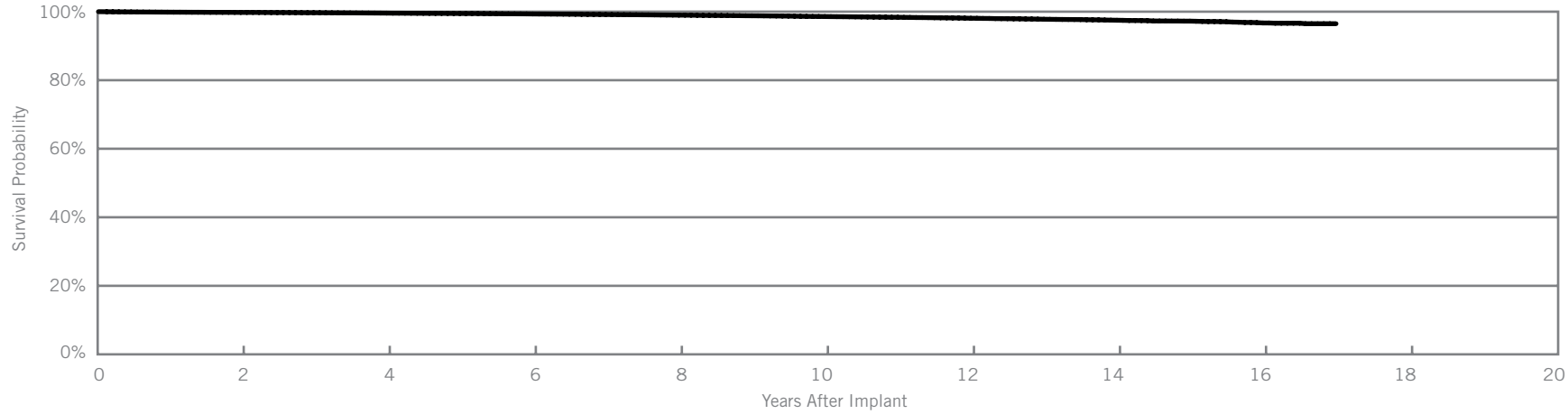
Year	2	4	6	8	10					
Survival Probability	99.91%	99.78%	99.56%	99.56%	99.56%					
± 1 standard error	0.06%	0.12%	0.19%	0.19%	0.19%					
Sample Size	1900	1400	900	600	300					

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	326,704
Estimated Active US Implants	102,114
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 17 years	
Survival Probability	99.78%	99.58%	99.33%	98.99%	98.58%	98.08%	97.50%	96.70%	96.49%	
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.08%	0.16%	0.23%	
Sample Size	280300	225600	170700	120500	76900	37300	12400	3300	1000	

Customer Reported Performance Data

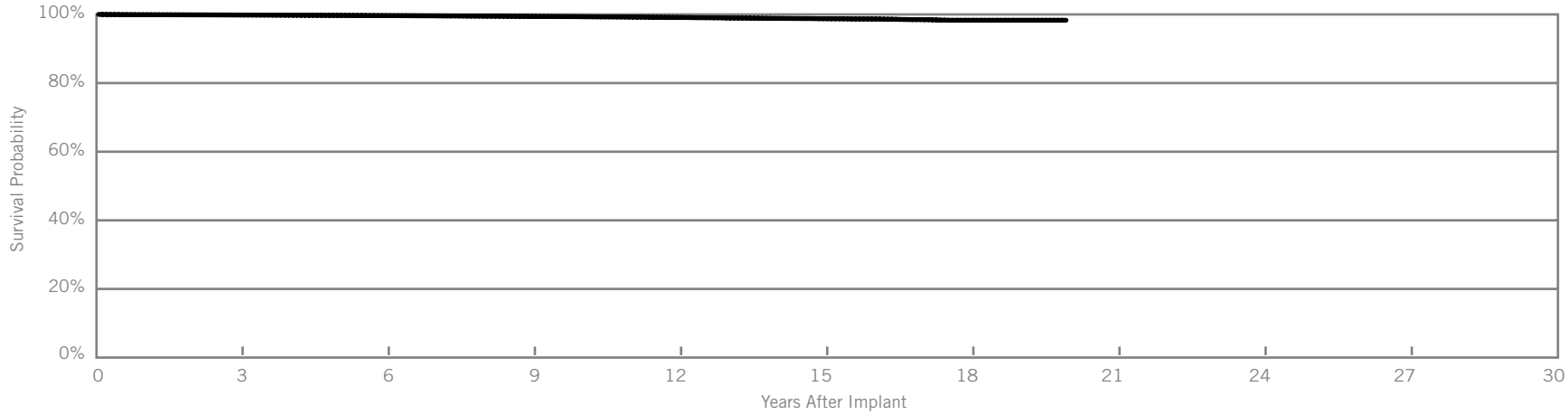
Passive Plus®

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	374,044
Estimated Active US Implants	97,857
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Number of US Advisories	None



Year	3	6	9	12	15	18	at 20 years			
Survival Probability	99.83%	99.65%	99.42%	99.13%	98.76%	98.31%	98.31%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%	0.09%	0.09%			
Sample Size	287900	201500	121400	57400	21400	4800	800			

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	99.82%									
1999	OptiSense® Optim®*										
1944	IsoFlex® Optim®	99.76%	99.69%								
1948	IsoFlex® Optim®	99.96%	99.76%								
1699T/TC	OptiSense®	99.85%	99.79%	99.64%							
1888T/TC	Tendril® ST Optim®	99.83%	99.72%	99.61%	99.36%						
1882T/TC	Tendril® ST Optim®	99.82%	99.69%	99.53%							
1782T/TC	Tendril®	99.90%	99.72%	99.59%	99.49%						
1788T/TC	Tendril®	99.84%	99.76%	99.70%	99.59%						
1644T	IsoFlex® P	99.53%	99.53%	99.53%	99.16%						
1648T	IsoFlex® P	99.80%	99.76%	99.70%	99.53%						
1642T	IsoFlex® S	99.93%	99.90%	99.82%	99.74%	99.62%	99.52%	99.48%			
1646T	IsoFlex® S	99.89%	99.85%	99.78%	99.72%	99.65%	99.52%	99.38%			
1688T/TC	Tendril® SDX	99.88%	99.79%	99.67%	99.55%	99.42%	99.25%	99.13%			
1488T/TC	Tendril® SDX	99.88%	99.80%	99.72%	99.63%	99.52%	99.39%	99.29%	99.16%	99.03%	98.84%

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	38088	35180	4	0.01%	0	0.00%	9	0.02%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	**15**	**0.04%**	**5**
1999	May-07	6079	5618	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	**0**
1944	Mar-08	3942	3452	0	0.00%	0	0.00%	6	0.15%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.18%**	**3**
1948	Mar-08	13824	11961	0	0.00%	0	0.00%	6	0.04%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**10**	**0.07%**	**7**
1699T/TC	May-07	23314	18007	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	205730	164352	26	0.01%	5	<0.01%	82	0.04%	62	0.03%	9	<0.01%	6	<0.01%	3	<0.01%	6	<0.01%	3	<0.01%	16	0.01%	**218**	**0.11%**	**87**
1882T/TC	Jun-06	16782	13856	2	0.01%	0	0.00%	11	0.07%	4	0.02%	2	0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**23**	**0.14%**	**6**
1782T/TC	Jun-06	14910	10938	5	0.03%	0	0.00%	9	0.06%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	0.01%	2	0.01%	**24**	**0.16%**	**12**
1788T/TC	Feb-06	64413	45376	11	0.02%	1	<0.01%	32	0.05%	29	0.05%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**109**	**0.17%**	**41**
1644T	Apr-05	955	598	0	0.00%	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	**2**	**0.21%**	**1**
1648T	Apr-05	2836	1798	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	25535	16431	0	0.00%	0	0.00%	46	0.18%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**58**	**0.23%**	**33**
1646T	May-02	84672	53954	3	<0.01%	2	<0.01%	32	0.04%	31	0.04%	0	0.00%	3	<0.01%	2	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**81**	**0.10%**	**34**
1688T/TC	Jun-03	357726	228093	37	0.01%	3	<0.01%	156	0.04%	117	0.03%	9	<0.01%	20	0.01%	5	<0.01%	23	0.01%	3	<0.01%	29	0.01%	**402**	**0.11%**	**152**

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	38088	35180	0	0.00%	0	0.00%	7	0.02%	2	0.01%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**12**	**0.03%**	**8**
1999	May-07	6079	5618	0	0.00%	0	0.00%	3	0.05%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.07%**	**0**
1944	Mar-08	3942	3452	0	0.00%	0	0.00%	4	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	**5**	**0.13%**	**2**
1948	Mar-08	13824	11961	0	0.00%	0	0.00%	3	0.02%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	0	0.00%	0	0.00%	**9**	**0.07%**	**5**
1699T/TC	May-07	23314	18007	0	0.00%	1	<0.01%	16	0.07%	10	0.04%	4	0.02%	3	0.01%	0	0.00%	2	0.01%	1	<0.01%	0	0.00%	**37**	**0.16%**	**23**
1888T/TC	Jun-06	205730	164352	17	0.01%	14	0.01%	123	0.06%	77	0.04%	43	0.02%	6	<0.01%	18	0.01%	16	0.01%	5	<0.01%	23	0.01%	**342**	**0.17%**	**203**
1882T/TC	Jun-06	16782	13856	0	0.00%	0	0.00%	12	0.07%	6	0.04%	3	0.02%	2	0.01%	2	0.01%	0	0.00%	0	0.00%	3	0.02%	**28**	**0.17%**	**20**
1782T/TC	Jun-06	14910	10938	0	0.00%	1	0.01%	12	0.08%	10	0.07%	2	0.01%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	1	0.01%	**30**	**0.20%**	**22**
1788T/TC	Feb-06	64413	45376	1	<0.01%	2	<0.01%	28	0.04%	35	0.05%	17	0.03%	1	<0.01%	2	<0.01%	10	0.02%	1	<0.01%	5	0.01%	**102**	**0.16%**	**72**
1644T	Apr-05	955	598	0	0.00%	1	0.10%	0	0.00%	3	0.31%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.42%**	**2**
1648T	Apr-05	2836	1798	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	1	0.04%	1	0.04%	0	0.00%	2	0.07%	**5**	**0.18%**	**4**
1642T	May-02	25535	16431	0	0.00%	1	<0.01%	19	0.07%	15	0.06%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**40**	**0.16%**	**13**
1646T	May-02	84672	53954	1	<0.01%	15	0.02%	20	0.02%	61	0.07%	9	0.01%	2	<0.01%	1	<0.01%	21	0.02%	0	0.00%	9	0.01%	**139**	**0.16%**	**36**
1688T/TC	Jun-03	357726	228093	8	<0.01%	66	0.02%	186	0.05%	267	0.07%	146	0.04%	14	<0.01%	26	0.01%	137	0.04%	7	<0.01%	58	0.02%	**915**	**0.26%**	**427**

Definitions of observations and complications can be found on pages 7 and 8.

Malfunction Summary

Models	US Regulatory Approval	Registered US Implants	Estimated Active 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	May-09	38088	35180	0	0.00%	2	0.01%	0	0.00%	0	0.00%	8	0.02%	**10**	**0.03%**
1999	May-07	6079	5618	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.02%**
1944	Mar-08	3942	3452	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**
1948	Mar-08	13824	11961	0	0.00%	1	0.01%	0	0.00%	1	0.01%	5	0.04%	**7**	**0.05%**
1699T/TC	May-07	23314	18007	2	0.01%	2	0.01%	0	0.00%	0	0.00%	19	0.08%	**23**	**0.10%**
1888T/TC	Jun-06	205730	164352	4	<0.01%	45	0.02%	1	<0.01%	7	<0.01%	165	0.08%	**222**	**0.11%**
1882T/TC	Jun-06	16782	13856	0	0.00%	1	0.01%	0	0.00%	2	0.01%	16	0.10%	**19**	**0.11%**
1782T/TC	Jun-06	14910	10938	1	0.01%	2	0.01%	0	0.00%	0	0.00%	18	0.12%	**21**	**0.14%**
1788T/TC	Feb-06	64413	45376	1	<0.01%	23	0.04%	1	<0.01%	7	0.01%	47	0.07%	**79**	**0.12%**
1644T	Apr-05	955	598	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.21%	**2**	**0.21%**
1648T	Apr-05	2836	1798	0	0.00%	1	0.04%	0	0.00%	1	0.04%	2	0.07%	**4**	**0.14%**
1642T	May-02	25535	16431	0	0.00%	1	<0.01%	2	0.01%	8	0.03%	10	0.04%	**21**	**0.08%**
1646T	May-02	84672	53954	9	0.01%	10	0.01%	1	<0.01%	8	0.01%	27	0.03%	**55**	**0.06%**
1688T/TC	Jun-03	357726	228093	98	0.03%	119	0.03%	16	<0.01%	10	<0.01%	251	0.07%	**494**	**0.14%**
1488T/TC	Mar-00	273947	114009	127	0.05%	83	0.03%	13	<0.01%	2	<0.01%	243	0.09%	**468**	**0.17%**

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	918	4586	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1999	132	764	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	220	2545	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	966	21621	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	**1**	**0.10%**
1888T/TC	3811	79344	1	0.03%	1	0.03%	0	0.00%	1	0.03%	5	0.13%	**8**	**0.21%**
1882T/TC	148	2210	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.68%	**1**	**0.68%**
1782T/TC	135	2700	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	226	5691	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	481	9764	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	1266	26678	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.08%	**1**	**0.08%**
1488T/TC	138	3717	0	0.00%	1	0.72%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.72%**

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Lead Dislodgement		Failure to Capture		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	918	4586	1	0.11%	1	0.11%	1	0.11%	1	0.11%	0	0.00%	0	0.00%	**4**	**0.44%**
1999	132	764	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	220	2545	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	966	21621	0	0.00%	1	0.10%	2	0.21%	1	0.10%	0	0.00%	0	0.00%	**4**	**0.41%**
1888T/TC	3811	79344	0	0.00%	9	0.24%	1	0.03%	2	0.05%	1	0.03%	0	0.00%	**13**	**0.34%**
1882T/TC	148	2210	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1782T/TC	135	2700	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	226	5691	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	481	9764	0	0.00%	1	0.21%	1	0.21%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.42%**
1688T/TC	1266	26678	1	0.08%	0	0.00%	1	0.08%	1	0.08%	1	0.08%	1	0.08%	**5**	**0.39%**
1488T/TC	138	3717	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Definitions of malfunction categories can be found on pages 9 and 10.
Definitions of complications can be found on pages 7 and 8.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical™
More control. Less risk.

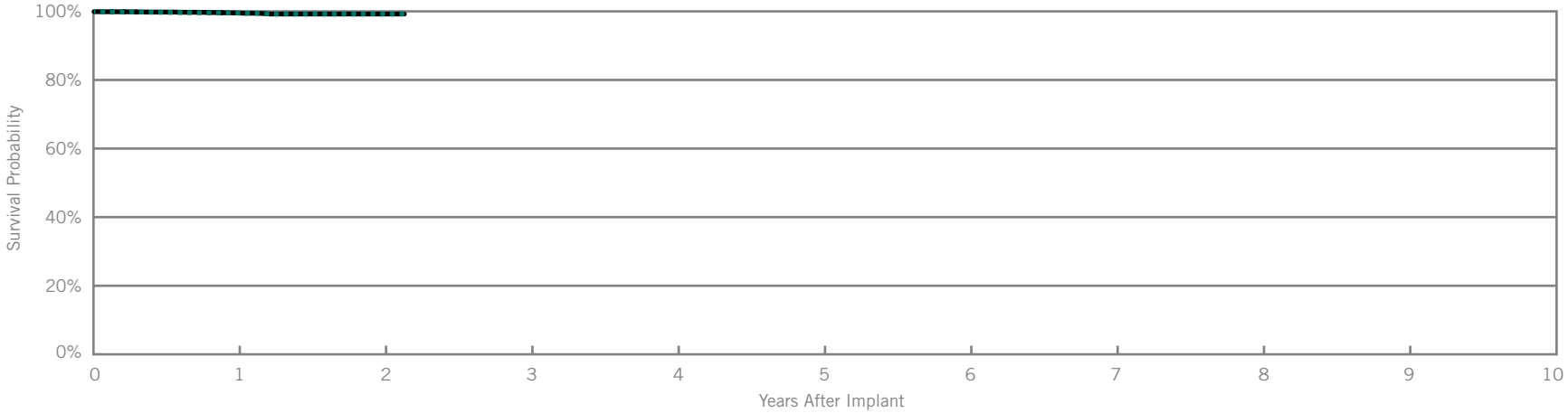
Customer Reported Performance Data

SJM Confirm®

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	5,988
Estimated Active US Implants	4,523
Estimated Longevity	3.0 Years*
Normal Battery Depletion	0
Number of US Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	12	0.20%
Total	**12**	**0.20%**



Including Normal Battery Depletion .....

Year	1	2	at 26 months							
Survival Probability	99.54%	99.23%	99.23%							
± 1 standard error	0.10%	0.16%	0.16%							
Sample Size	4900	1700	300							

Excluding Normal Battery Depletion ——

Year	1	2	at 26 months							
Survival Probability	99.54%	99.23%	99.23%							
± 1 standard error	0.10%	0.16%	0.16%							

**After 12 month shelf-life.*

Focus on Clinical Performance

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 featured in Tendril® ST Optim® bradycardia leads and Riata® ST Optim® defibrillation leads. 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 Optim lead insulation has proven to be excellent,[3] leading to the subsequent market release of Optim lead insulation across all lead families, including IsoFlex® Optim®, Tendril STS, OptiSense®, QuickFlex® µ, and Durata. Over 450,000 Optim-insulated leads have been implanted in the U.S..

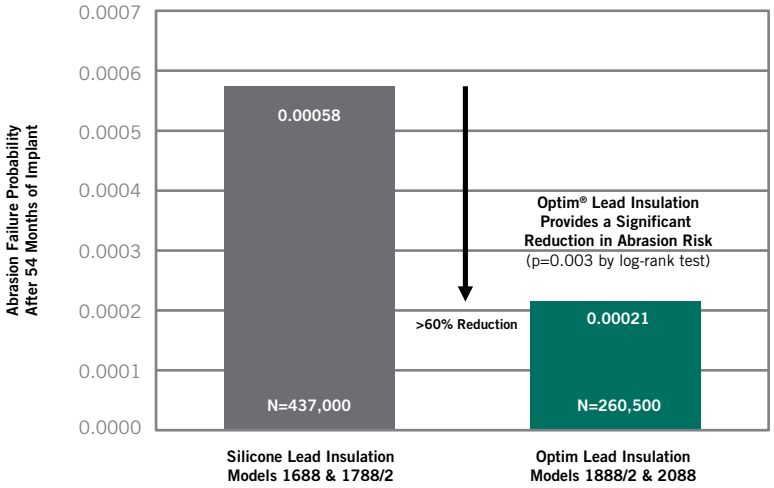
All aspects of Optim lead insulation performance can be appreciated by referring to the Acute Observation, Chronic Complication, Lead Malfunction, and Survival Probability data found in this performance report. The most noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[4] Insulation abrasion can occur as a result of lead contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. The clinical effects associated with abrasion malfunctions can include sensing noise and changes in both pacing and defibrillation impedances and thresholds.

Starting with the May 2010 Performance Report, St. Jude Medical has regularly presented a Kaplan-Meier statistical comparison of abrasion malfunctions confirmed on Optim lead insulation and silicone lead insulation. The presence of Optim lead insulation has consistently proven to dramatically reduce the probability of abrasion malfunction in implanted leads.

St. Jude Medical is proud to present the latest update to this statistical analysis, now including data through December 31, 2010. The graphs below demonstrate that the presence of Optim® lead insulation reduces the long term probability of abrasion malfunction by >60% on bradycardia leads and by 90% on tachycardia leads. The time points selected for the graphs (54 months for Tendril® leads and 50 months for Riata®/Durata® leads) represent the longest duration Optim lead insulation implants available for each model family. These dramatic reductions in abrasion malfunction probability were again confirmed to be statistically significant ($p<0.05$) by a log-rank test. The benefit of Optim lead insulation in reducing specific types of insulation breaches is also evident in the malfunction subcategory data present in this report.

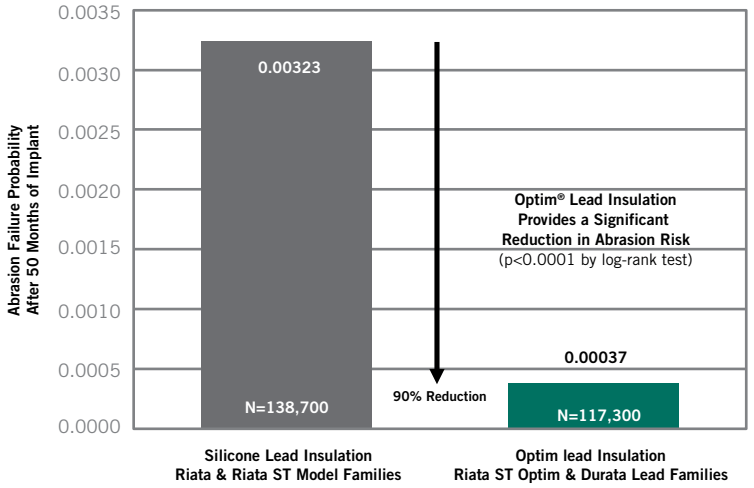
Optim® Lead Insulation Effects on St. Jude Medical Bradycardia Lead Abrasion

(Kaplan-Meier Analysis of US Data)



Optim® Lead Insulation Effects on St. Jude Medical Tachycardia Lead Abrasion

(Kaplan-Meier Analysis of US Data)



[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] F. Khairallah, F. Hamati, D. Peress, A. Schneider, J. Alonso, and M.S. Gupta, "Performance of Cardiac Leads with Optim Insulation Material: Initial Experience from the OPTIMUM Registry," HRS2009, Heart Rhythm, 6, S382 (2009).

[4] 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 set screws 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 system implants. Today's DF4 implants consist primarily of Durata® Q defibrillation leads, Fortify® ICDs, and Unify® CRT-Ds.

As of the December 31, 2010 data cutoff for this Product Performance Report, the DF4 connector system has been in clinical use for 18 months and represents over 36,000 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. 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, 2010, 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, 2010 and AdvaMed performance reporting guidelines were 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

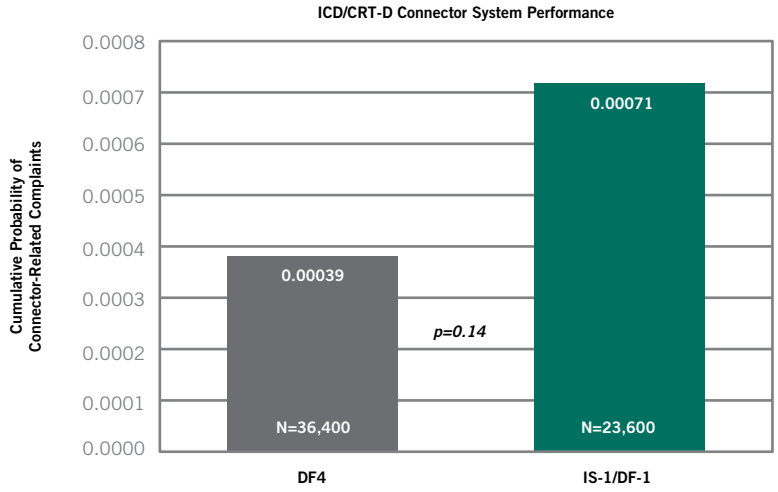
	Traditional (IS-1/DF-1)	DF4
Sample Size	~23,000	~36,000
HV Lead Models	7120, 7121, 7122, 7070, 7071	7120Q, 7121Q, 7122Q, 7170Q, 7171Q
ICD/CRT-D Models	CD1211-36, CD1215-36, CD1231-40, CD2211-36, CD2215-36, CD2231-40, CD3211-36, CD3215-36, CD3231-40	CD1211-36Q, CD1215-36Q, CD1231-40Q, CD2211-36Q, CD2215-36Q, 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.

An assessment of defibrillation lead field performance revealed no connector-related complaints and one connector-related malfunction from each of the connector types, DF4 and IS-1/DF-1. Because connector-related system complaints are typically assigned to the ICD/CRT-D, the absence of lead complaints was not unusual for an analysis of this size. Due to the absence of complaints and an extremely limited number of malfunctions, no statistical comparisons of lead performance could be performed.

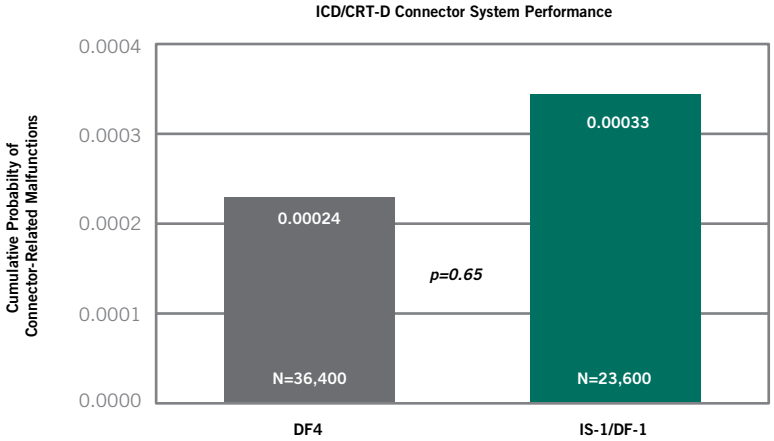
The statistical treatment of ICD/CRT-D connector-related complaint data included a comparison of cumulative incidence functions adjusted for the competing risk of explant without complaint. This was followed by the use of Gray's method1 to assess any difference in the cumulative incidence rates and calculate a p-value. Figure 1 presents the resulting cumulative probability of connector-related complaints at the end of the analysis period, December 31, 2010. The probability of a connector-related ICD/CRT-D complaint in a DF4 system is 55% the probability observed in an IS-1/DF-1 system. Due to the low number of total connector-related complaints, 12 for DF4 and 14 for IS-1/DF-1, this difference did not prove to be statistically significant (p=0.14). The majority of these complaints are related to difficulties in tightening of the setscrew. The elimination of three set screws in all DF4 ICD/CRT-D models is believed to be a factor in the trend towards reduced DF4 connector-related complaints.

Figure 1. ICD/CRT-D Connector-Related Complaints
Represents Events Between Aug 1, 2009 and Dec 31, 2010



A similar statistical treatment was applied to the ICD connector-related malfunction data. The resulting cumulative probability of connector-related malfunctions at the end of the analysis period, December 31, 2010, is shown below in figure 2. The probability of an ICD/CRT-D malfunction in a DF4 system is approximately 25% less than in an IS-1/DF-1 system. Similar to the complaint analysis, the low number of total connector-related malfunctions, 7 for DF4 and 6 for IS-1/DF-1, did not result in statistical significance (p=0.65). All of these malfunctions were confirmed to be related to improper setscrew function and/or damage to the setscrew during implant. Just as indicated in the complaints analysis, the elimination of three set screws in all DF4 ICDs/CRT-Ds models is believed to be a factor in the trend towards reduced DF4 connector-related malfunctions.

Figure 2. ICD/CRT-D Connector-Related Malfunctions
Represents Malfunctions Analyzed Between Aug 1, 2009 and Dec 31, 2010



Conclusions:

This updated analysis of DF4 connector system field performance data has demonstrated that the four-pole connector system compares favorably to the traditional IS-1/DF-1 connector system. The low quantity of connector-related complaints and malfunctions from implanted connector systems of either type has prevented the identification of statistical significance for the trends identified.

[1]Gray, R. J. (1988) A class of k-sample tests for comparing the cumulative incidence of a competing risk. Annals of Statistics 16, 1141-1154.

Advisories & Safety Alerts

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 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 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, 2010):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of December 31, 2010, 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)	01/16/08 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, 2010):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2010 there have been no additional devices confirmed to have this issue since the time of the advisory.

ICD and CRT 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, 2010):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2010 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 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, 2010):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

ICD and CRT 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-250), 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, 2010):** 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.

Pacemakers

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, 2010):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of December 31, 2010 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	07/31/03 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, 2010):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Pacemakers

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.

Pacemakers

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.

Pacemakers

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.

Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Riata® Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 5182) Riata® i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata® ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 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). The incidence rate of U.S. abrasion malfunctions for Riata models is summarized on pages 135-136 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 procedures in particular looking for significant changes from the patient's previous follow-up visits. If there is suspicion of a lead failure, consider provocative testing 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, and/or consider further evaluation of the system (e.g., x-ray or fluoroscopy). Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events. Prophylactic lead explant is not recommended.

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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.

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