Cardiac Rhythm Management Division
Product Performance Report
November 2011

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

November 2011

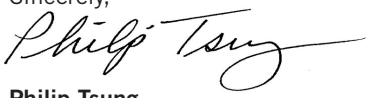
As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, St. Jude Medical continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose 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), implantable pacemakers, and implantable pacing and defibrillation leads. St. Jude Medical recognizes that such performance data must be transparent and consistent. In order to meet these goals we continue our commitment to the reporting methods described in the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", which set new standards for lead performance reporting and specifically addressed the reporting of active registry performance data. Determined to provide the highest level of transparency, St. Jude Medical has once again enhanced our performance reporting methods and will now identify the root cause of each pacemaker, ICD, and ICM laboratory-confirmed malfunction.

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

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

Sincerely,



Philip Tsung
Vice President, Quality Assurance

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Serving Our Mission

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

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

- Compliance with U.S. and international quality system standards, such as the U.S. FDA Quality Systems Regulation (21 CFR Part 820) and ISO 13485 (an international standard for the Quality Management System for medical devices)
- Thorough evaluation of product design, including extensive design verification and validation, as well as product qualification testing
- Rigorous control of the design and manufacturing processes
- Inspection and qualification of externally supplied components and materials
- Timely analysis of returned products, including extensive malfunction investigation
- Extensive internal auditing
- Post market surveillance
- Continuous improvement programs
- Ensuring 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 June 30, 2011, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - For the more recent products, the quantity, rate, and type of product malfunctions are detailed
  - For the more recent lead models, the quantity, rate, and type of customer complaints (acute observations and chronic complications) are detailed
- Summary tables of performance data, organized by product type and model
- For all ICD, pacemaker, ICM, and lead models that meet SCORE Registry inclusion criteria, St. Jude Medical provides active registry performance data, collected through June 30, 2011, 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, DF4 connector system performance, and a novel Low Frequency Attenuation Filter from St. Jude Medical
- An updated summary of advisories on all implantable devices since 2003
- An index by product type and model name
- An index of phased-out models by product type and model name

What's New in This Report

Enhanced Pacemaker, ICD, and CRT-D Malfunction Details

St. Jude Medical Product Performance Reports have previously followed Advamed reporting guidelines and provided the quantity and rate of all returned pacemakers, ICDs, CRT-Ds, and ICMs with a malfunction identified by laboratory analysis. These malfunctions were grouped into two categories: those that resulted in compromised therapy and those that did not result in compromised therapy. Beginning with the November 2011 Product Performance Report, St. Jude Medical will be providing additional detail. The root cause of all pacemaker, ICD, CRT-D, and ICM laboratory-confirmed malfunctions will now be classified into one of eight categories: Electrical Component, Electrical Interconnect, Battery, High Voltage Capacitor (ICDs and CRT-Ds only), Software/Firmware, Mechanical, Possible Premature Battery Depletion, or Other. St. Jude Medical believes that this enhancement will provide our customers and patients with additional understanding and, ultimately, confidence in our product performance and reliability. For details see the "ICD, Pacemaker, and ICM Malfunction Reporting" section of the Introduction.

Benefits of a Low Frequency Attenuation Filter in Unify® ICDs and Fortify® CRT-Ds

Our latest defibrillation devices, Unify® ICDs and Fortify® CRT-Ds, are the first to contain an advanced Low Frequency Attenuation Filter designed to reduce the oversensing of T-waves and the potential clinical complications that may follow. In this Product Performance Report we provide a statistical comparison of the field performance of ~48,000 Unify/Fortify and ~106,000 Current®/Promote® devices. The data demonstrates that the Low Frequency Attenuation Filter in the Unify/Fortify family has significantly reduced reports of T-wave oversensing.

Index of Phased Out Models

The Advamed Industry Guidance for Uniform Reporting of Clinical Performance of CRM Pulse Generators and Leads indicates that models with greater than 20 years of reporting or fewer than 500 implants estimated to be active may be phased out of the Product Performance Report. Accordingly, St. Jude Medical has phased out several early generation lead, pacemaker, and ICD models from our Product Performance Report over the last several years. To ensure that our customers can access product performance data for all current and past SJM products, a separate index has been added to the November 2011 Product Performance Report which identifies the edition of the Product Performance Report containing the final and most complete performance data for each phased out model. This index of phased out models will be maintained in future editions of the Product Performance Report. Previous editions of the St. Jude Medical Product Performance Report can always be viewed at www.SJMprofessional.com.

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 pacemaker model PM2110 is 9.2 years. Actual performance can vary considerably, depending on the actual programmed settings and operations.

Normal Battery Depletion - The condition where a returned device met its electrical specification and reached its elective replacement indicator voltage (1) with an implant duration meeting or exceeding the nominal predicted longevity at default shipped settings, or (2) with an implant duration exceeding 75% of its estimated longevity, based on longevity calculations using information from device usage and the actual device settings. 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.

St. Jude Medical is constantly working to improve the accuracy and utility of the data within this Product Performance Report. An example implemented in this report is the use of an enhanced method to compensate for the underreporting of patient mortality. This enhancement has resulted in a reduced number of Estimated Active U.S. Implants for many models which has a minor impact on certain survival probabilities.

Because of the large size of the U.S. data pool, and because the same products are generally used both in the U.S. and internationally, we consider the data in this report to be accurately representative of each device's performance, regardless of where in the world it was implanted.

ICD, Pacemaker, and ICM Survival Analysis

The data used for the analysis of ICDs, pacemakers, and ICMs includes up-to-date device registration information and the laboratory analysis of all domestically implanted devices returned to St. Jude Medical. The analysis measures device performance to specification, and does not reflect medical complications, such as infection, erosion, muscle stimulation or inhibition, or units implanted for fewer than 24 hours.

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

Survival data are presented in a single table and graph. The survival data is separated into "Including Normal Battery Depletion" and "Excluding Normal Battery Depletion" categories. For the purposes of this data, non-returned devices removed from service for battery depletion with no associated complaint are considered as normal battery depletions. The "Including Normal Battery Depletion" data reflects the frequency of device removal due to normal battery depletion and malfunction of any type. The "Excluding Normal Battery Depletion" category reflects the frequency of device removal due to malfunctions only.

ICD, Pacemaker, and ICM Malfunction Reporting

The quantity and rate of malfunctions recorded for each ICD, pacemaker, and ICM model are presented in a tabular format on both the Customer Reported Performance Data and SCORE Registry Performance Data pages. Beginning with this November 2011 Product Performance Report, the root cause of all laboratory-confirmed malfunctions will now be classified into one of eight categories: Electrical Component, Electrical Interconnect, Battery, High Voltage Capacitor (ICDs and CRT-Ds only), Software/Firmware, Mechanical, Possible Premature Battery Depletion, or Other. Note that in the rare cases where multiple malfunctions are identified in a single device, a single malfunction category will be selected with priority given in the order of the list above. Consistent with previous performance reports, all malfunctions are further classified as with or without compromised therapy.

Malfunction Definitions

Malfunction - Having characteristics that are outside the performance limits established by the manufacturer while implanted and in service, as confirmed by laboratory analysis, except changes to characteristics due to normal battery depletion or induced malfunction. Device damage caused after or during explant is not considered a malfunction. Note that lead-related malfunctions of a pacemaker or ICD system are assigned to the lead.

Malfunction with Compromised Therapy - The condition when a device is found to have "malfunctioned," as defined above, in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if no therapy is available or critical patient-protective pacing or defibrillation therapy is not available.

A malfunction with compromised therapy does not imply that a patient has actually experienced a serious complication or death as a result of the malfunction although it does imply that the potential for a serious complication or death did exist during the period of the malfunction.

Malfunction without Compromised Therapy - The condition when a device is found to have "malfunctioned," as defined above, in a manner that did not compromise pacing or defibrillation therapy while implanted and in service, as confirmed by laboratory analysis. Therapy is not compromised as long as the critical patient-protective pacing and defibrillation therapies are available. Changes in device settings that occur as intended by the design (for example, reversion to a designed Safe Mode) that do not result in loss of critical patient-protective therapies but are the reported reasons for explant shall be categorized as a Malfunction without Compromised Therapy.

Malfunction Root Cause Category Definitions

Electrical Component - Findings linked to electrical components such as integrated circuits, resistors, low voltage capacitors, diodes, etc.. Does not include high voltage capacitors.

Electrical Interconnect - Findings linked to the connections between electrical components such as wires, solder joints, wire bonds, feedthroughs, etc.

Battery - Findings linked to the battery and its components.

High Voltage Capacitor - Findings linked to the high voltage capacitor and its components.

Software/Firmware - Findings linked to software or firmware function.

Mechanical - Findings linked to mechanical components such as headers, setscrews, fluid seals, internal supports, the hermetic case, etc.

Possible Early Battery Depletion - Findings where the actual reported implant time is less than 75% of the expected longevity calculated using the available device setting information and no root cause was able to be identified. Additionally, in the absence of a specific root cause finding, returned devices with insufficient device setting information to determine conclusively if battery depletion was normal or premature are conservatively classified as Possible Early Battery Depletion malfunctions.

Other - Findings linked to other components such as packaging and accessories, and findings where analysis is inconclusive.

Leads Survival Analysis

Implanted cardiac leads are subjected to constant, complex flexural and torsional forces, interactions with other leads and/or the pulse generator device, plus other forces associated with cardiac contractions, patient physical activity, posture, and anatomy. Therefore, the functional lifetime of cardiac leads is limited and cannot be predicted with a high degree of confidence. Understanding these limitations, survival estimates are provided for all leads included in this report.

The data used for the survival analysis of leads includes up-to-date device registration information, chronic complications (>30 days) reported by the field, and the laboratory analysis of all domestically implanted leads returned to St. Jude Medical. Complaints reported within 30 days of implant (acute observations), are considered to be related to factors other than lead malfunction, such as patient specific characteristics or implant technique, and are, therefore, excluded from the survival calculations, consistent with industry practice. If there is laboratory data that determines the lead to have exhibited 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 $< 200\ \Omega$ or $> 2000\ \Omega$ (based on lead model and measurement range of the device).

Abnormal Defibrillation Impedance: Defibrillation impedance is typically considered abnormal if a measurement is $< 20\ \Omega$ or $> 200\ \Omega$ (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 are also provided. The definitions of these subcategories are provided below:

Clavicular Crush: Conductor fracture due to strong compression and bending at the approximation of the first rib and clavicle.

In the Pocket: Conductor fracture not within the vascular or cardiac systems, typically within the subcutaneous pocket or associated with the suture sleeve, excluding the mechanism of clavicular crush.

Intravascular: Conductor fracture within the vascular or cardiac systems.

Insulation Breach: Any lead insulation breach, such as: 1) proximal abrasion associated with lead-to-lead or lead-to-can contact in the pocket, 2) mid-lead insulation damage caused by clavicular crush or insulation wear in the region of vein insertion, 3) distal abrasion due to lead-to-lead interactions or contact with anatomic structures, and 4) externalized conductors in the distal region.

Subcategories of insulation breach are also provided. The definitions of these subcategories are provided below:

Lead-to-Can Contact: Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) combined with repetitive skeletal movement caused abrasion that resulted in a full thickness outer insulation breach.

Lead-to-Lead Contact: Repetitive contact between two leads caused abrasion that resulted in a full thickness outer insulation 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.[1,2,3,4,5,6,7,8,9] 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 lead models is summarized on pages 137-138 of this Product Performance Report. Externalized conductors were referenced in a December 2010 communication regarding all-cause insulation abrasion failures on silicone Riata and Riata ST lead families (summary on page 244)

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.

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[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).
[7] Kodoth V, Cromie N, Lau E, McEneaney D, Wilson C, Roberts MJ. Riata lead failure; A report from Northern Ireland Riata lead screening programme. European Heart Journal (2011) 32 (Abstract Supplement) 310.
[8] Chan C-W, Chiang C-S. An ICD Lead with Failure of Outer Insulation Goes Undetected by Regular Measurements. PACE On-Line July 2011.
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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 8,500 patients enrolled as of June 30, 2011. Using a common protocol, these sites are individually monitoring and reporting on the performance of all St. Jude Medical cardiac rhythm management products used at their site. The SCORE registry is designed to include new products as they become available.

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 June 30, 2011, with the latest interval to be reported having a minimum of 50 devices which have been followed for at least six months. Five model families meet the inclusion criteria for the first time in this report. Below is a complete list of all forty-two models which will report SCORE performance data:

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

Pacemakers
Anthem® RF (Model PM3210)*
Accent® DR (Model PM2110)
Accent® SR RF (Model PM1210)
Accent® DR RF (Model PM2210)
Zephyr® DR (Model 5820)
Zephyr® DR (Model 5826)
Zephyr® SR (Model 5626)
Victory® XL DR (Model 5816)

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

*New for November 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

Lead Dislodgement
Lead Conductor Fracture
Insulation Breach
Phrenic Nerve/Diaphragmatic Stimulation
Elevated Pacing Thresholds
Failure to Capture
Failure to Sense
Abnormal Pacing Impedance
Abnormal Defibrillation Impedance
Skin Erosion
Cardiac Perforation
Pericardial Effusion
Oversensing
Premature Battery Depletion
Inappropriate Shock
Loss of Telemetry

Qualifying Clinical Action

Lead Surgically Repositioned
Lead Surgically Abandoned/Capped
Lead Electrically Abandoned/Capped
Lead/Generator Explanted
Lead/Generator Replaced
Lead Polarity Changed
Generator Pacing Mode Changed

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.

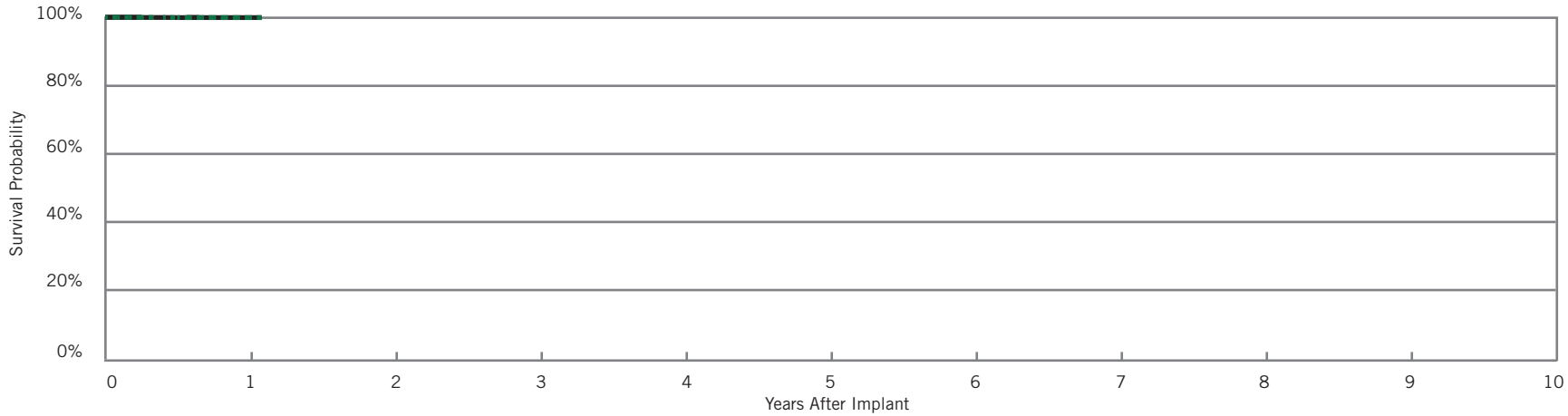
Customer Reported Performance Data

Unify®

Model CD3231-40Q

US Regulatory Approval	May 2010
Registered US Implants	11,458
Estimated Active US Implants	10,638
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.04%	0.04%								
Sample Size	6400	600								

Excluding Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.91%	99.91%								
± 1 standard error	0.04%	0.04%								

SCORE Registry Performance Data

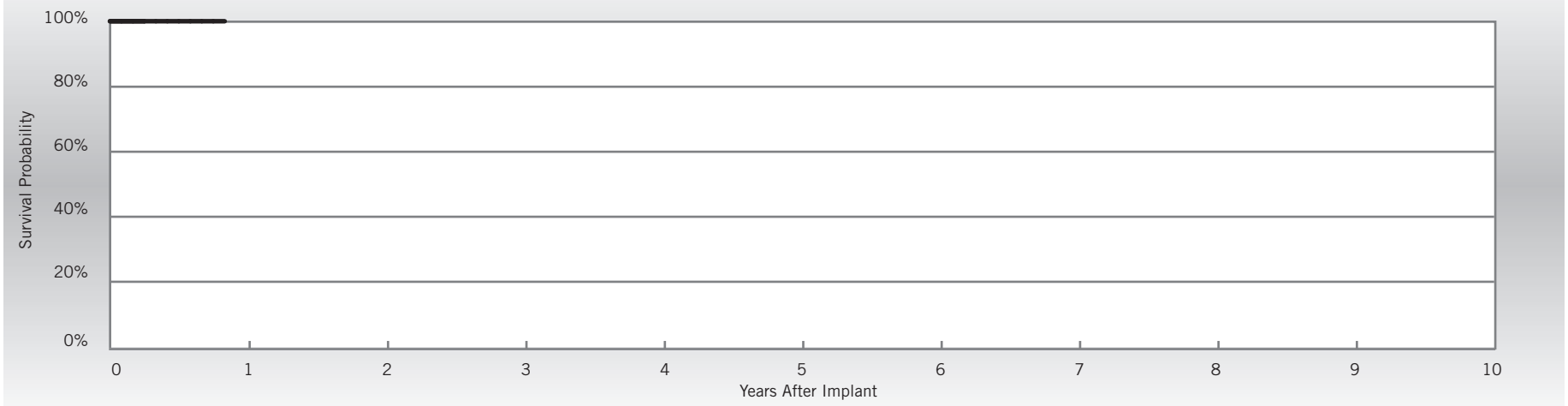
Unify® CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	232
Cumulative Months of Follow-up	1,598
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	at 10 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

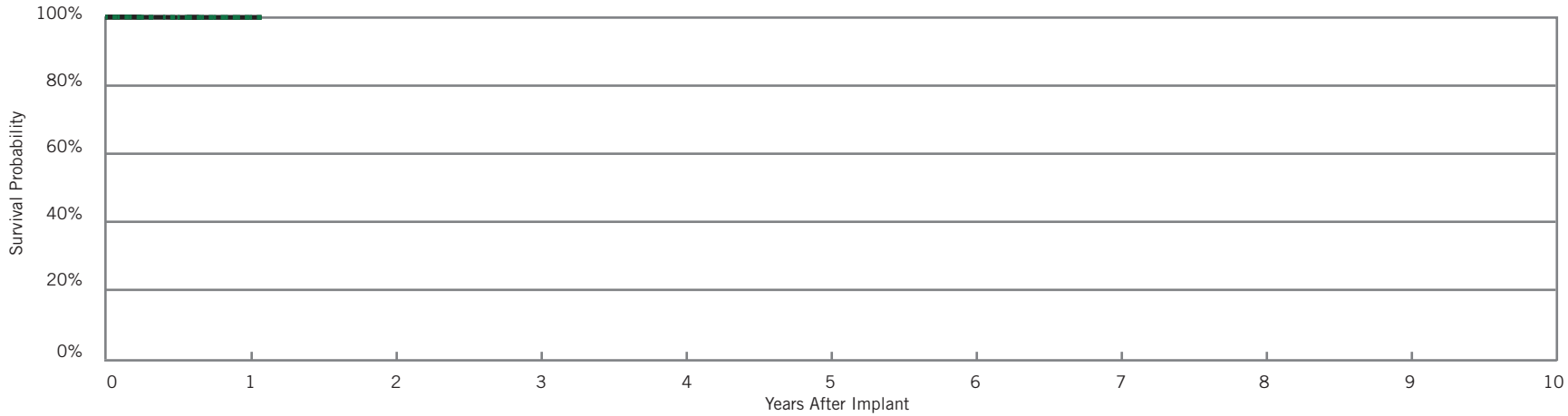
Customer Reported Performance Data

Unify®

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	9,479
Estimated Active US Implants	8,861
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.04%	0.04%								
Sample Size	5200	400								

Excluding Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.04%	0.04%								

SCORE Registry Performance Data

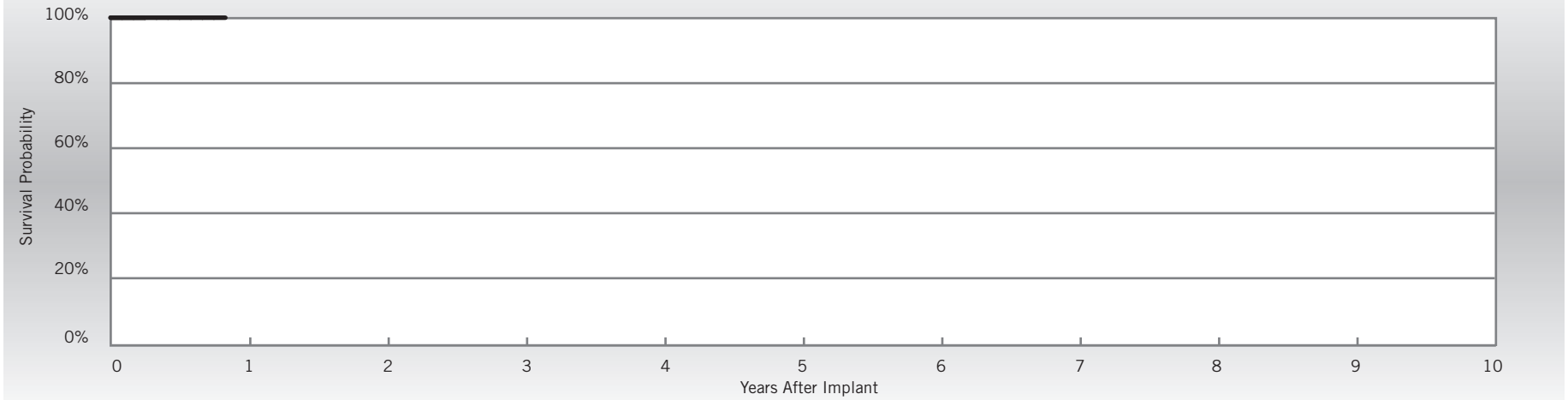
Unify® CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	239
Cumulative Months of Follow-up	1,655
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	at 10 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	60									

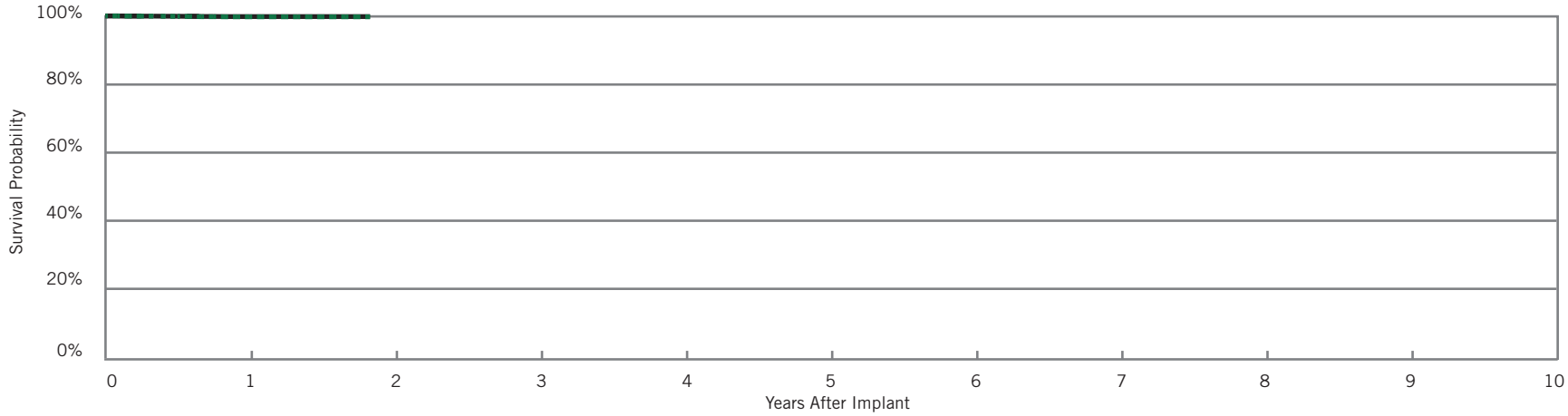
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	7,316
Estimated Active US Implants	6,269
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.73%	99.73%								
± 1 standard error	0.06%	0.06%								
Sample Size	7100	400								

Excluding Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.81%	99.81%								
± 1 standard error	0.05%	0.05%								

SCORE Registry Performance Data

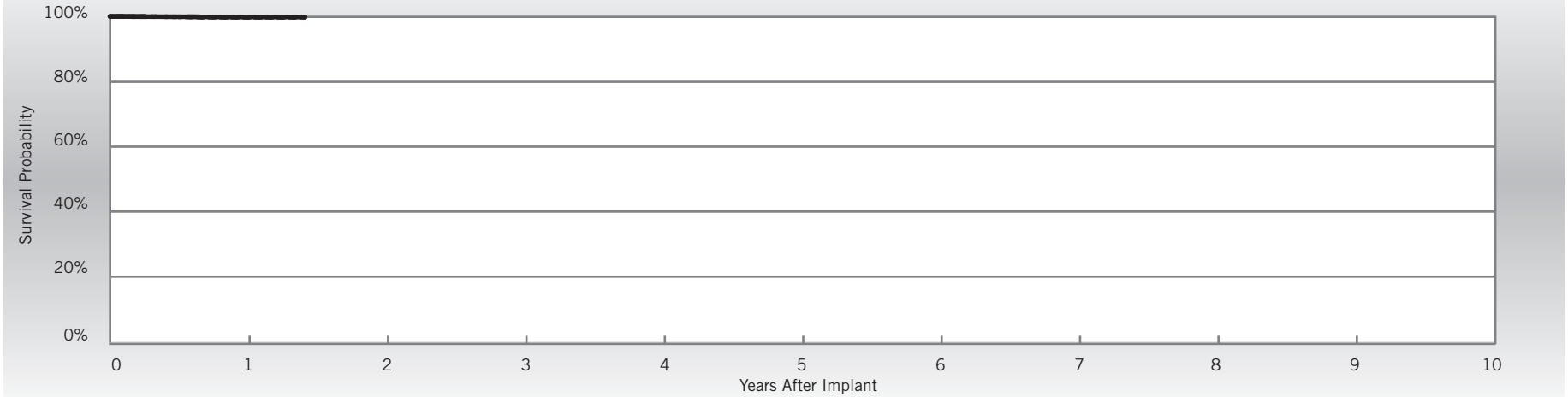
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	127
Cumulative Months of Follow-up	1,976
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Inappropriate Shock	1	0.79%

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



Year	1	at 17 months								
Survival Probability	100.00%	98.41%								
± 1 standard error	0.00%	1.34%								
Sample Size	120	50								

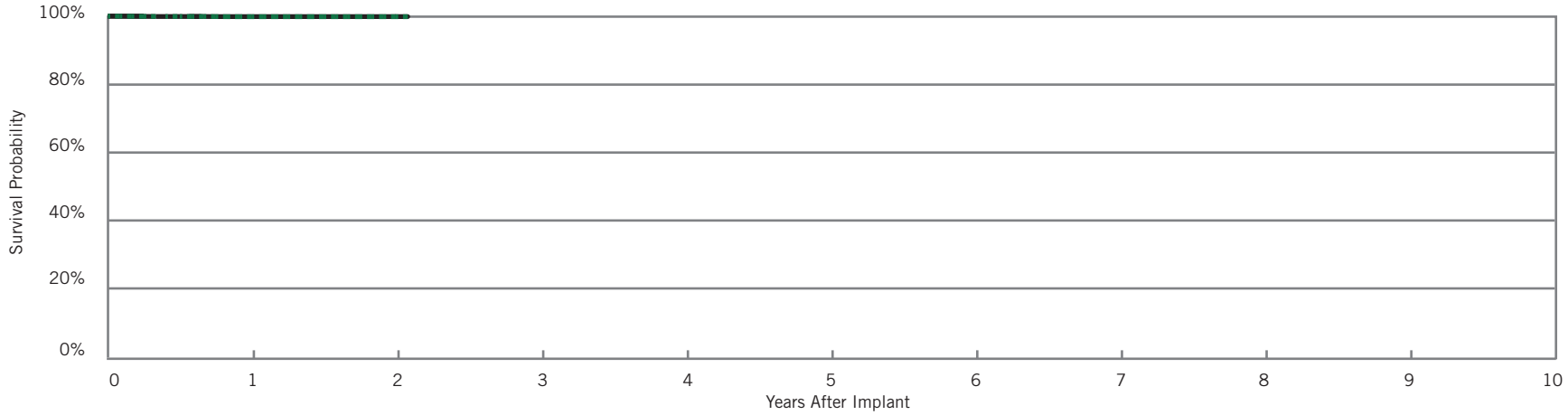
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,261
Estimated Active US Implants	6,894
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.84%	99.84%	99.84%							
± 1 standard error	0.05%	0.05%	0.05%							
Sample Size	7900	3600	500							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.87%	99.87%	99.87%							
± 1 standard error	0.04%	0.04%	0.04%							

SCORE Registry Performance Data

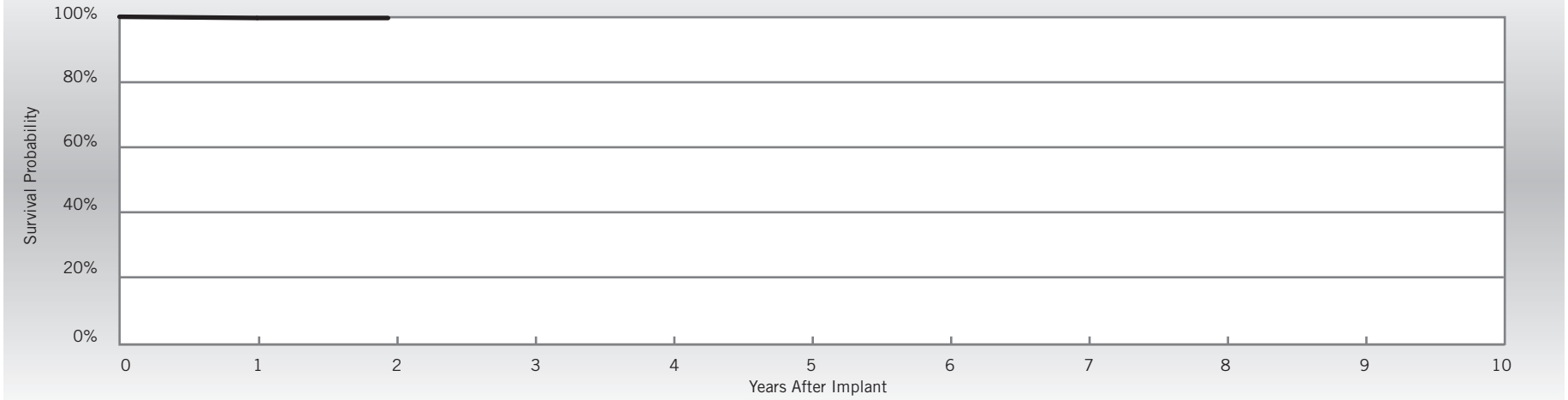
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	259
Cumulative Months of Follow-up	4,569
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	1	0.39%

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



Year	1	at 23 months								
Survival Probability	99.61%	99.61%								
± 1 standard error	0.39%	0.39%								
Sample Size	240	50								

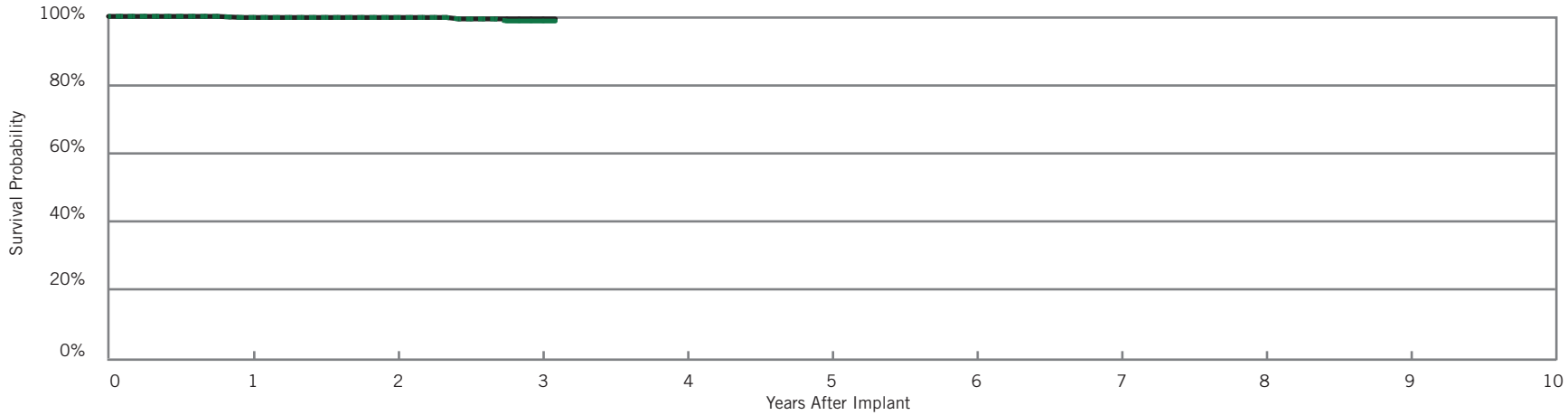
Customer Reported Performance Data

Promote® RF

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,410
Estimated Active US Implants	1,041
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	1
Max. Delivered Energy	30 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	1	0.07%
Battery	0	0.00%	1	0.07%
High Voltage Capacitor	1	0.07%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.07%**	**2**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.67%	99.67%	98.64%	98.64%						
± 1 standard error	0.17%	0.17%	0.55%	0.55%						
Sample Size	1400	1000	500	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.67%	99.67%	99.25%	99.25%						
± 1 standard error	0.17%	0.17%	0.34%	0.34%						

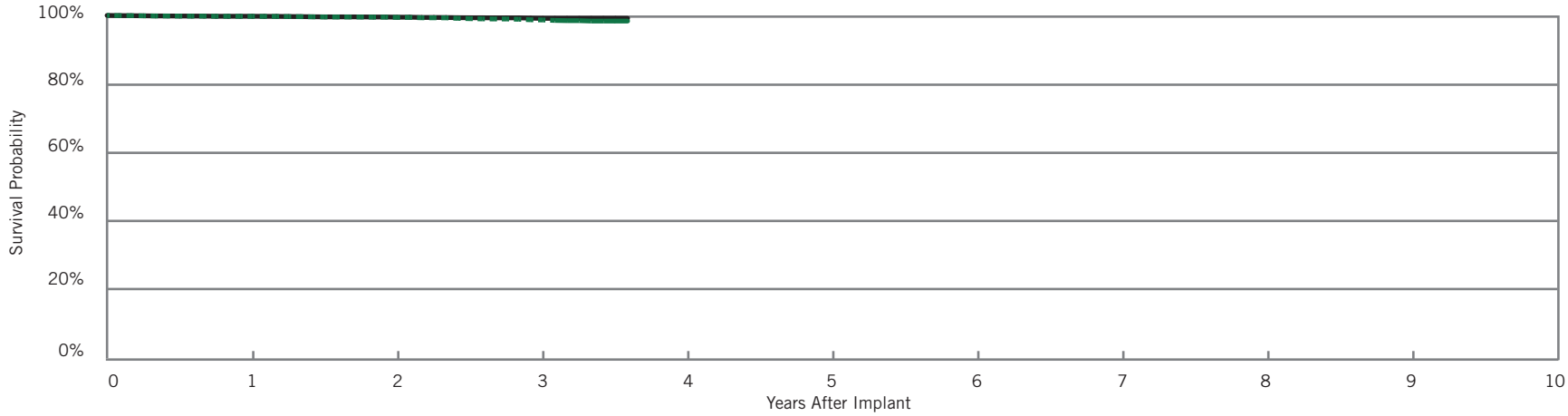
Customer Reported Performance Data

Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,779
Estimated Active US Implants	17,371
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	22
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	5	0.02%
Electrical Interconnect	4	0.02%	0	0.00%
Battery	6	0.03%	6	0.03%
High Voltage Capacitor	5	0.02%	1	<0.01%
Software/Firmware	0	0.00%	5	0.02%
Mechanical	2	0.01%	1	<0.01%
Possible Early Battery Depletion	3	0.01%	2	0.01%
Other	3	0.01%	6	0.03%
Total	**23**	**0.10%**	**26**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.74%	99.42%	98.68%	98.36%						
± 1 standard error	0.03%	0.05%	0.11%	0.16%						
Sample Size	23700	18200	9500	500						

Excluding Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.76%	99.49%	99.15%	99.15%						
± 1 standard error	0.03%	0.05%	0.08%	0.09%						

SCORE Registry Performance Data

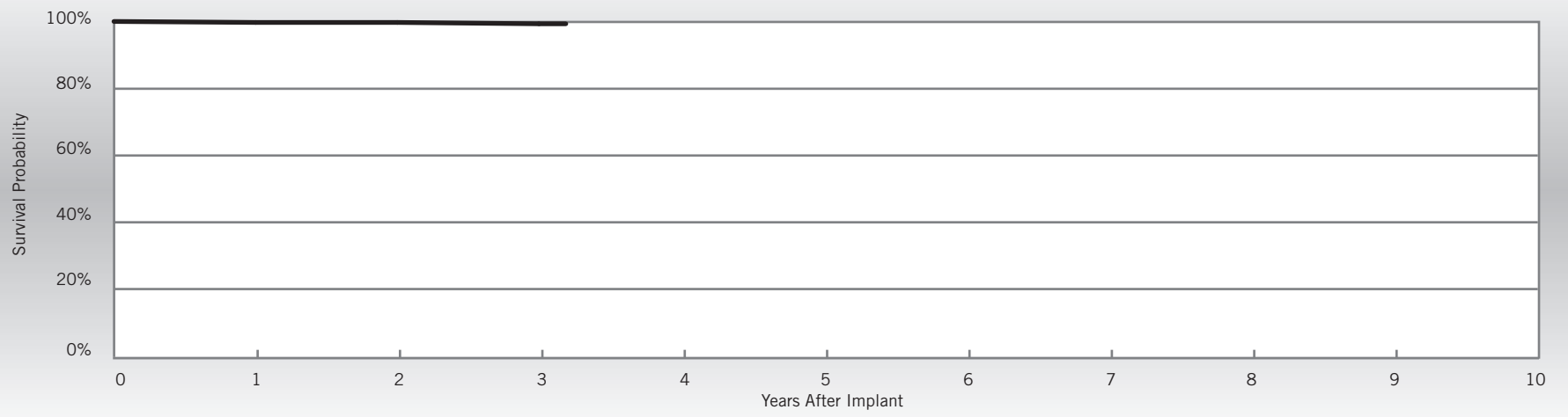
Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	674
Cumulative Months of Follow-up	17,530
Estimated Longevity	(see table on page 33)
Max. Delivered Energy	36 joules

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

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



Year	1	2	3	at 38 months						
Survival Probability	99.70%	99.70%	99.29%	99.29%						
± 1 standard error	0.21%	0.21%	0.45%	0.45%						
Sample Size	630	510	270	70						

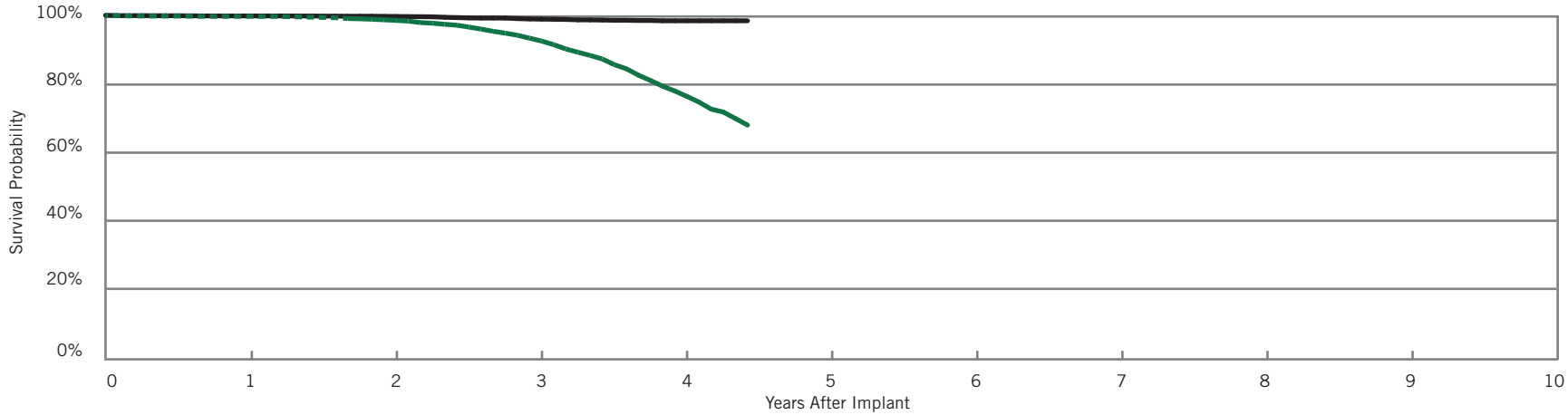
Customer Reported Performance Data

Atlas® II HF

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	7,997
Estimated Active US Implants	3,589
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	403
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	1	0.01%
Electrical Interconnect	2	0.03%	0	0.00%
Battery	13	0.16%	3	0.04%
High Voltage Capacitor	2	0.03%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	3	0.04%	3	0.04%
Other	4	0.05%	4	0.05%
Total	**25**	**0.31%**	**11**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.70%	98.50%	92.47%	76.29%	67.92%					
± 1 standard error	0.06%	0.14%	0.33%	0.66%	0.95%					
Sample Size	8000	6800	5700	3600	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.82%	99.66%	98.88%	98.40%	98.40%					
± 1 standard error	0.05%	0.07%	0.14%	0.18%	0.18%					

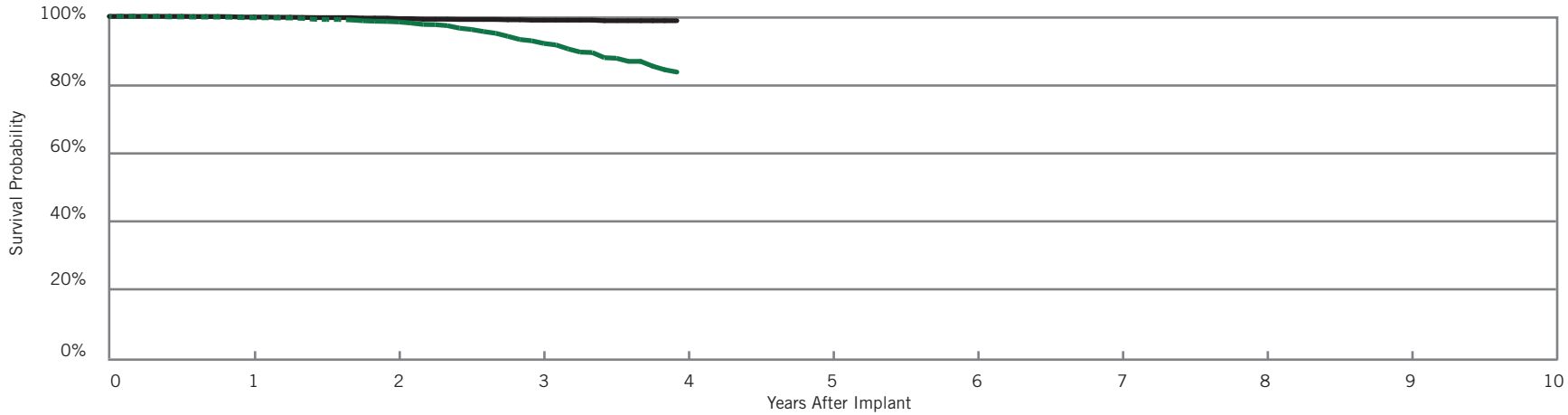
Customer Reported Performance Data

Atlas® II + HF

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	4,889
Estimated Active US Implants	2,877
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	108
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.06%	1	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.04%	3	0.06%
Other	4	0.08%	1	0.02%
Total	**9**	**0.18%**	**8**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.59%	98.36%	92.06%	83.69%						
± 1 standard error	0.09%	0.20%	0.50%	0.99%						
Sample Size	4900	3900	2700	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.79%	99.33%	98.89%	98.73%						
± 1 standard error	0.07%	0.11%	0.19%	0.22%						

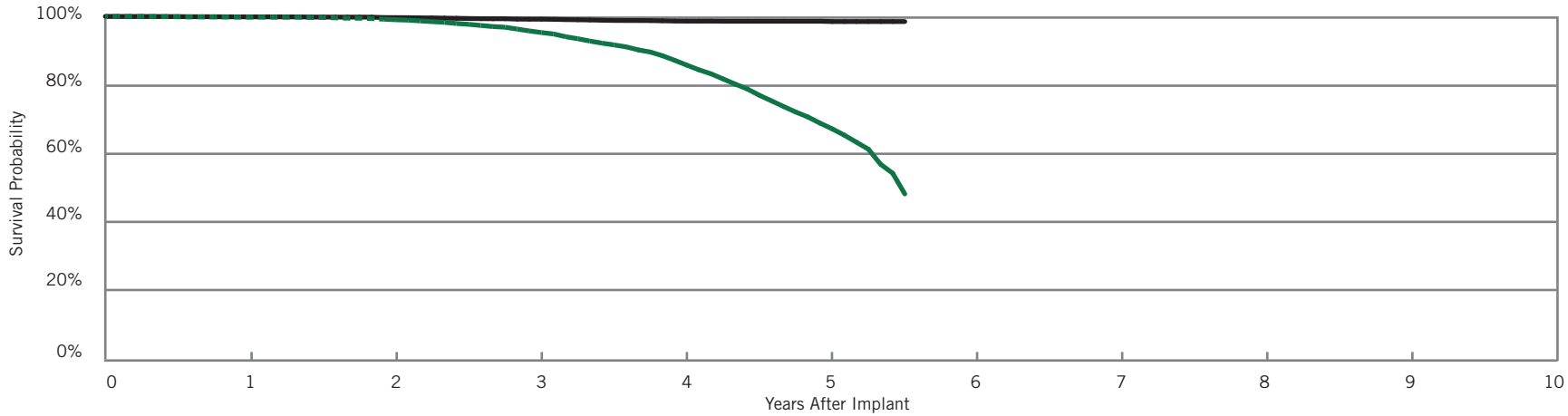
Customer Reported Performance Data

Atlas® + HF

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	17,635
Estimated Active US Implants	5,579
Estimated Longevity	(see table on page 33)
Normal Battery Depletion	1,041
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	2	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	33	0.19%	2	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	5	0.03%	10	0.06%
Other	8	0.05%	3	0.02%
Total	**49**	**0.28%**	**19**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.78%	99.02%	95.28%	85.77%	67.16%	48.13%				
± 1 standard error	0.04%	0.08%	0.18%	0.33%	0.58%	1.08%				
Sample Size	17600	15000	12900	10000	5700	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.87%	99.64%	99.19%	98.62%	98.50%	98.50%				
± 1 standard error	0.03%	0.05%	0.08%	0.11%	0.11%	0.13%				

Battery Longevity Summary

CRT ICDs

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-343	Atlas® + HF	7.9	7.1	6.4	5.4

**Battery longevity calculated with one EGM storage.*
Pacing parameters: DDD-BiV, RV 2.5V, LV 2.5V, A 2.5V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.
***Three maximum charges per year. Battery voltage range: 3.20-2.59.*

Summary Information

CRT ICDs

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3231-40Q	Unify®	99.91%									
CD3231-40	Unify®	99.92%									
CD3211-36Q	Promote® + CRT-D	99.73%									
CD3211-36	Promote® + CRT-D	99.84%	99.84%								
3207-30	Promote® RF	99.67%	99.67%	98.64%							
3207-36	Promote® RF	99.74%	99.42%	98.68%							
V-365	Atlas® II HF	99.70%	98.50%	92.47%	76.29%						
V-366	Atlas® II + HF	99.59%	98.36%	92.06%							
V-343	Atlas® + HF	99.78%	99.02%	95.28%	85.77%	67.16%					

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®	99.91%									
CD3231-40	Unify®	99.92%									
CD3211-36Q	Promote® + CRT-D	99.81%									
CD3211-36	Promote® + CRT-D	99.87%	99.87%								
3207-30	Promote® RF	99.67%	99.67%	99.25%							
3207-36	Promote® RF	99.76%	99.49%	99.15%							
V-365	Atlas® II HF	99.82%	99.66%	98.88%	98.40%						
V-366	Atlas® II + HF	99.79%	99.33%	98.89%							
V-343	Atlas® + HF	99.87%	99.64%	99.19%	98.62%	98.50%					

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	11458	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
CD3231-40	Unify®	9479	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**
CD3211-36Q	Promote® + CRT-D	7316	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	**4**	**0.05%**
CD3211-36	Promote® + CRT-D	8261	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.02%**
3207-30	Promote® RF	1410	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
3207-36	Promote® RF	23779	0	0.00%	4	0.02%	6	0.03%	5	0.02%	0	0.00%	2	0.01%	3	0.01%	3	0.01%	**23**	**0.10%**
V-365	Atlas® II HF	7997	1	0.01%	2	0.03%	13	0.16%	2	0.03%	0	0.00%	0	0.00%	3	0.04%	4	0.05%	**25**	**0.31%**
V-366	Atlas® II + HF	4889	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	4	0.08%	**9**	**0.18%**
V-343	Atlas® + HF	17635	3	0.02%	0	0.00%	33	0.19%	0	0.00%	0	0.00%	0	0.00%	5	0.03%	8	0.05%	**49**	**0.28%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	11458	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**2**	**0.02%**
CD3231-40	Unify®	9479	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	Promote® + CRT-D	7316	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**2**	**0.03%**
CD3211-36	Promote® + CRT-D	8261	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	**3**	**0.04%**
3207-30	Promote® RF	1410	0	0.00%	1	0.07%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.14%**
3207-36	Promote® RF	23779	5	0.02%	0	0.00%	6	0.03%	1	<0.01%	5	0.02%	1	<0.01%	2	0.01%	6	0.03%	**26**	**0.11%**
V-365	Atlas® II HF	7997	1	0.01%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	4	0.05%	**11**	**0.14%**
V-366	Atlas® II + HF	4889	3	0.06%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	3	0.06%	1	0.02%	**8**	**0.16%**
V-343	Atlas® + HF	17635	2	0.01%	0	0.00%	2	0.01%	0	0.00%	1	0.01%	1	0.01%	10	0.06%	3	0.02%	**19**	**0.11%**

Definitions of malfunction root cause categories can be found on page 7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Extracardiac Stimulation		Inappropriate Shock		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	232	1598	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	239	1655	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	127	1976	0	0.00%	0	0.00%	1	0.79%	1	0.79%	**2**	**1.57%**
CD3211-36	259	4569	0	0.00%	1	0.39%	0	0.00%	0	0.00%	**1**	**0.39%**
3207-36	674	17530	2	0.30%	0	0.00%	0	0.00%	1	0.15%	**3**	**0.45%**

Malfunctions

Models	Family	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	232	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	Unify®	239	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	Promote® + CRT-D	127	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36	Promote® + CRT-D	259	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote® RF	674	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	**1**	**0.15%**

Models	Family	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	232	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	Unify®	239	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	Promote® + CRT-D	127	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36	Promote® + CRT-D	259	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote® RF	674	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.15%	0	0.00%	**2**	**0.30%**

Definitions of complications can be found on page 14.
Definitions of malfunction root cause categories can be found on page 7.

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical
More control. Less risk.

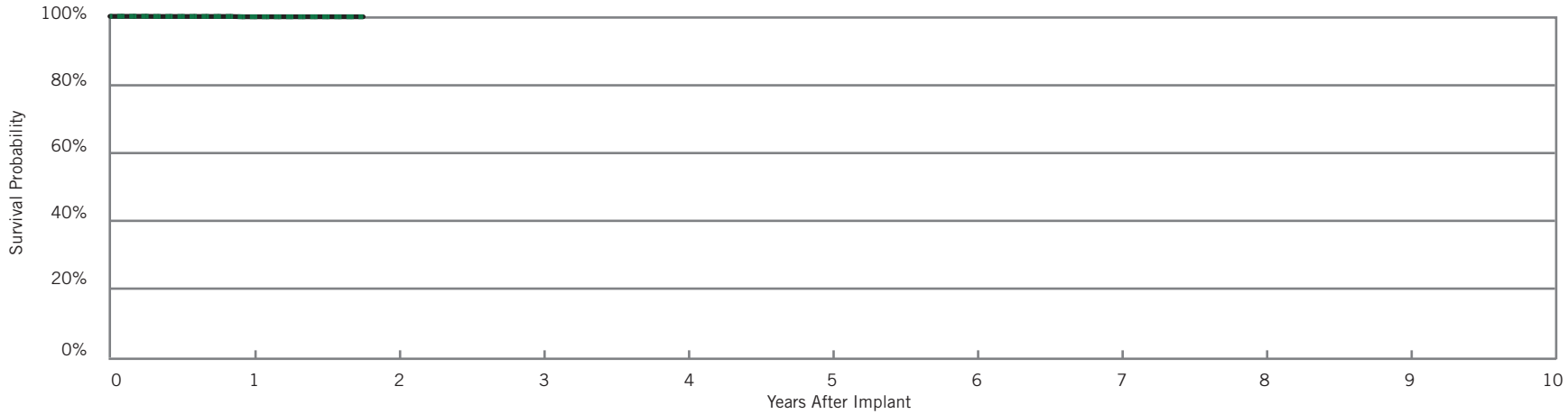
Customer Reported Performance Data

Anthem® RF

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	6,695
Estimated Active US Implants	5,686
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories (see pgs. 234-245)	One

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



Including Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.07%	0.07%								
Sample Size	4600	300								

Excluding Normal Battery Depletion

Year	1	at 21 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.07%	0.07%								

SCORE Registry Performance Data

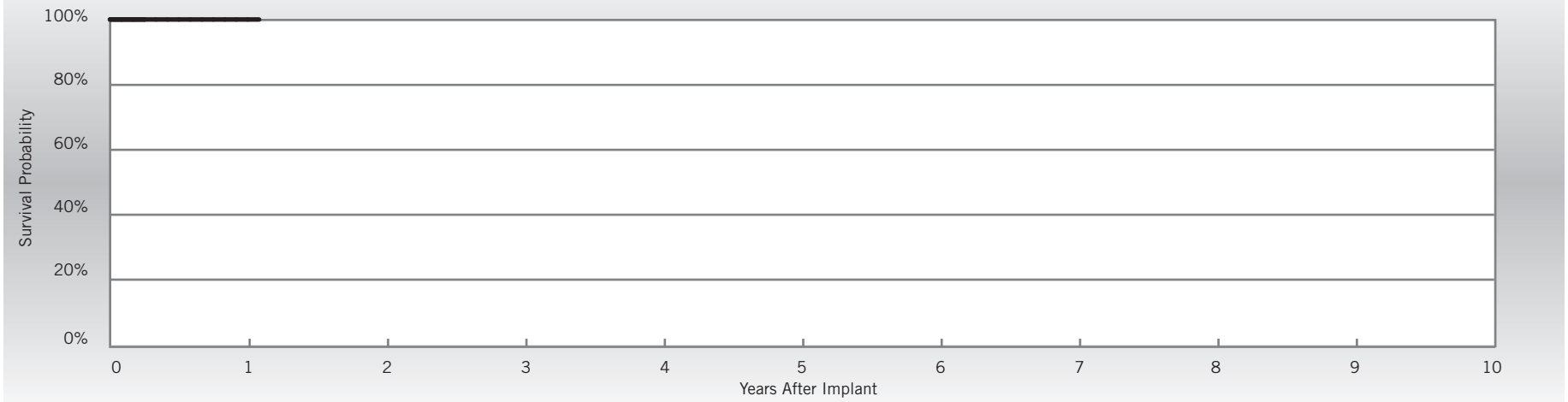
Anthem®

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	141
Cumulative Months of Follow-up	1,503
Estimated Longevity	8 Years

Qualifying Complications
None Reported

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



Year	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	100	60								

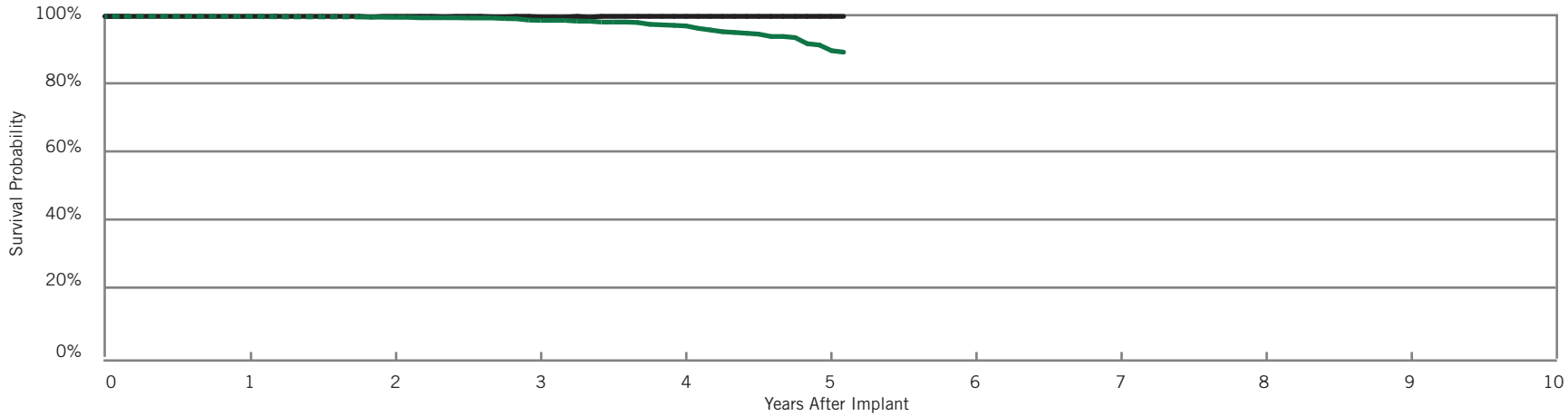
Customer Reported Performance Data

Frontier® II

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,715
Estimated Active US Implants	3,515
Estimated Longevity	6.5 Years
Normal Battery Depletion	50
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	4	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	7	0.10%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**11**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.90%	99.73%	98.84%	97.21%	89.99%	89.55%				
± 1 standard error	0.04%	0.07%	0.18%	0.35%	0.93%	1.08%				
Sample Size	6700	5200	3600	2000	900	400				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.93%	99.88%	99.69%	99.30%	98.47%	98.47%				
± 1 standard error	0.04%	0.04%	0.10%	0.19%	0.35%	0.35%				

Summary Information

CRT Pacemakers

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

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®	99.84%									
5586	Frontier® II	99.90%	99.73%	98.84%	97.21%	89.99%					

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®	99.84%									
5586	Frontier® II	99.93%	99.88%	99.69%	99.30%	98.47%					

Customer Reported Performance Data

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem®	6695	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%
5586	Frontier® II	6715	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%

Models	Family	Registered US Implants	Malfunctions w//o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem®	6695	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.03%
5586	Frontier® II	6715	4	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	0	0.00%	11	0.16%

Definitions of malfunction root cause categories can be found on page 7.

Left-Heart Leads

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

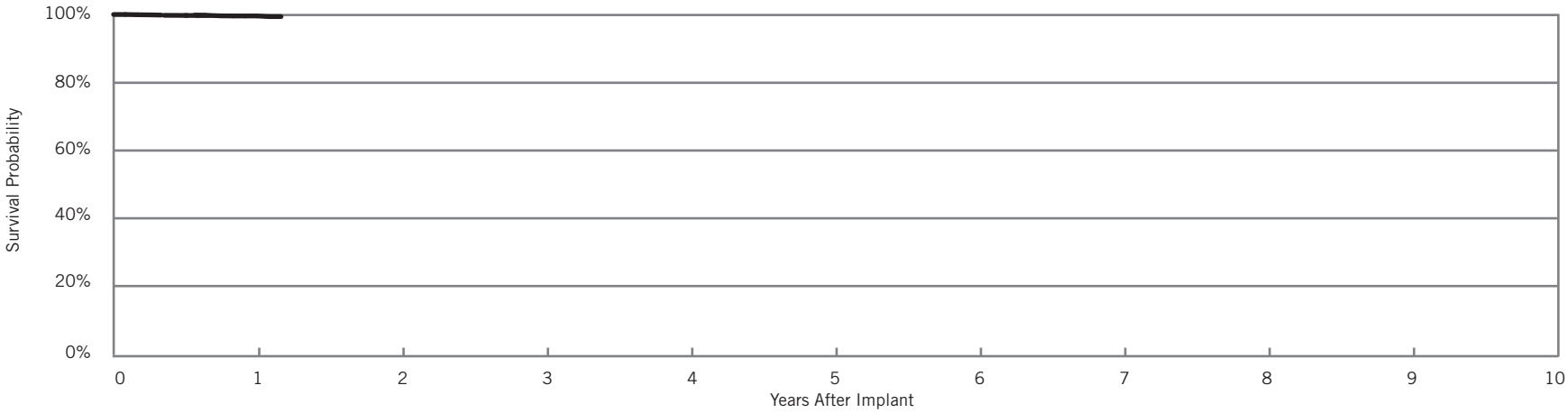
QuickFlex® µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	14,479
Estimated Active US Implants	12,726
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	12	0.08%	16	0.11%
Failure to Capture	7	0.05%	3	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	11	0.08%	4	0.03%
Other	2	0.01%	1	0.01%
Total	**32**	**0.22%**	**24**	**0.17%**
Total Returned for Analysis	**17**		**16**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.10%
Total	**14**	**0.10%**



Year	1	at 14 months								
Survival Probability	99.61%	99.41%								
± 1 standard error	0.09%	0.21%								
Sample Size	7800	300								

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

SCORE Registry Performance Data

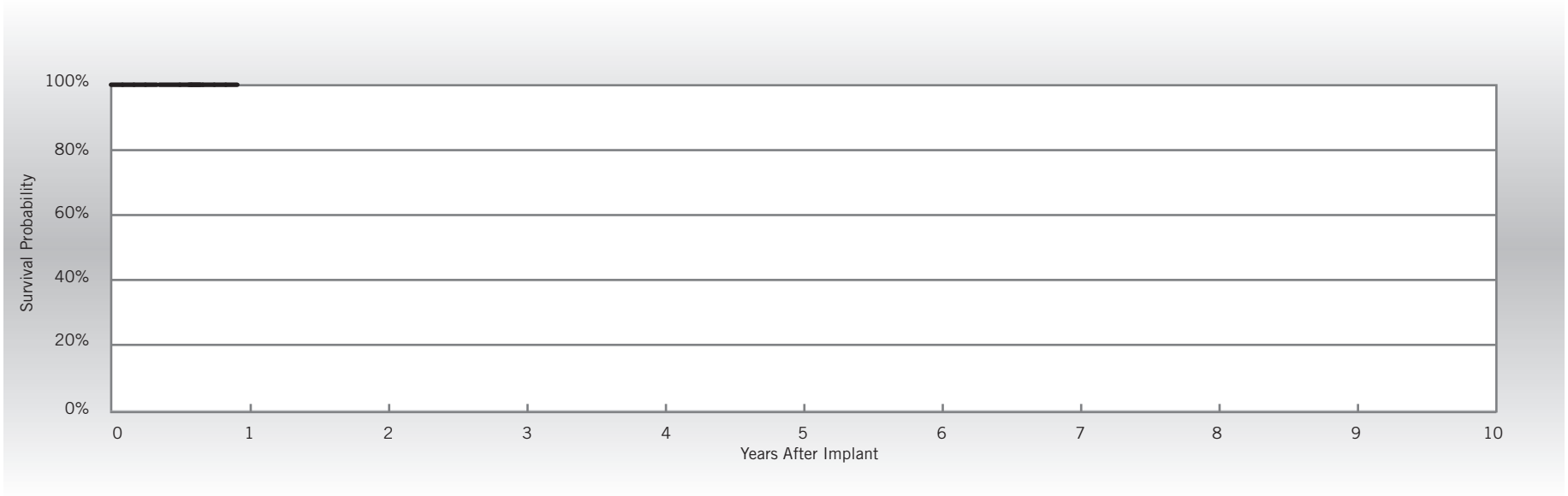
QuickFlex® µ

Model 1258T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	330
Cumulative Months of Follow-up	2,348
Insulation	Optim®*
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	0.30%
Total	**1**	**0.30%**



Year	at 11 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

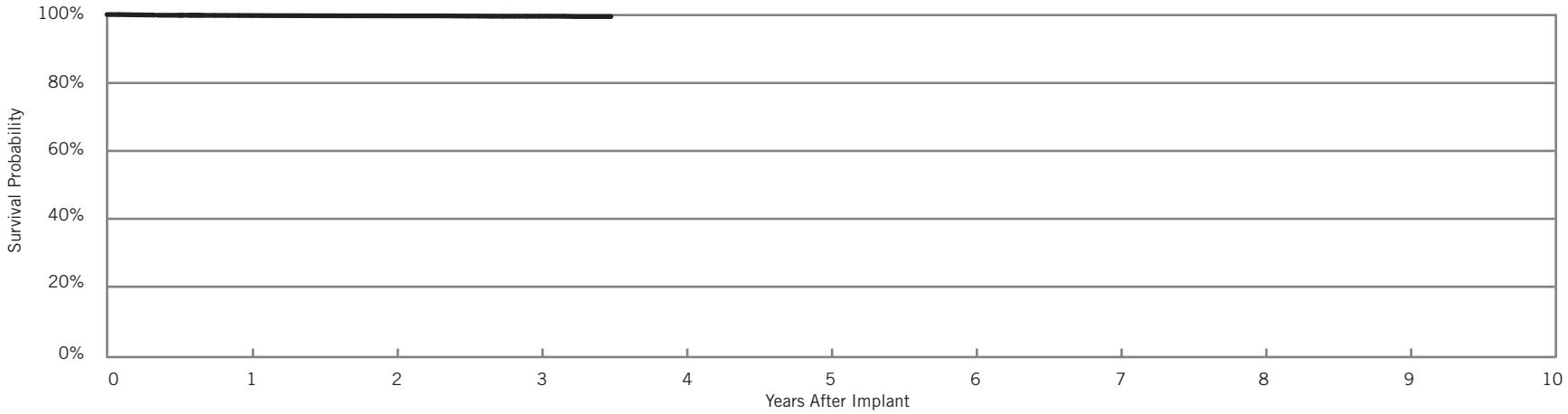
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	26,245
Estimated Active US Implants	19,926
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	12	0.05%	33	0.13%
Failure to Capture	6	0.02%	17	0.06%
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%	18	0.07%
Other	9	0.03%	2	0.01%
Total	**43**	**0.16%**	**78**	**0.30%**
Total Returned for Analysis	**16**		**58**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Insulation Breach	6	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	34	0.13%
Total	**42**	**0.16%**



Year	1	2	3	at 42 months						
Survival Probability	99.71%	99.60%	99.49%	99.38%						
± 1 standard error	0.04%	0.04%	0.07%	0.13%						
Sample Size	23400	13500	5100	200						

SCORE Registry Performance Data

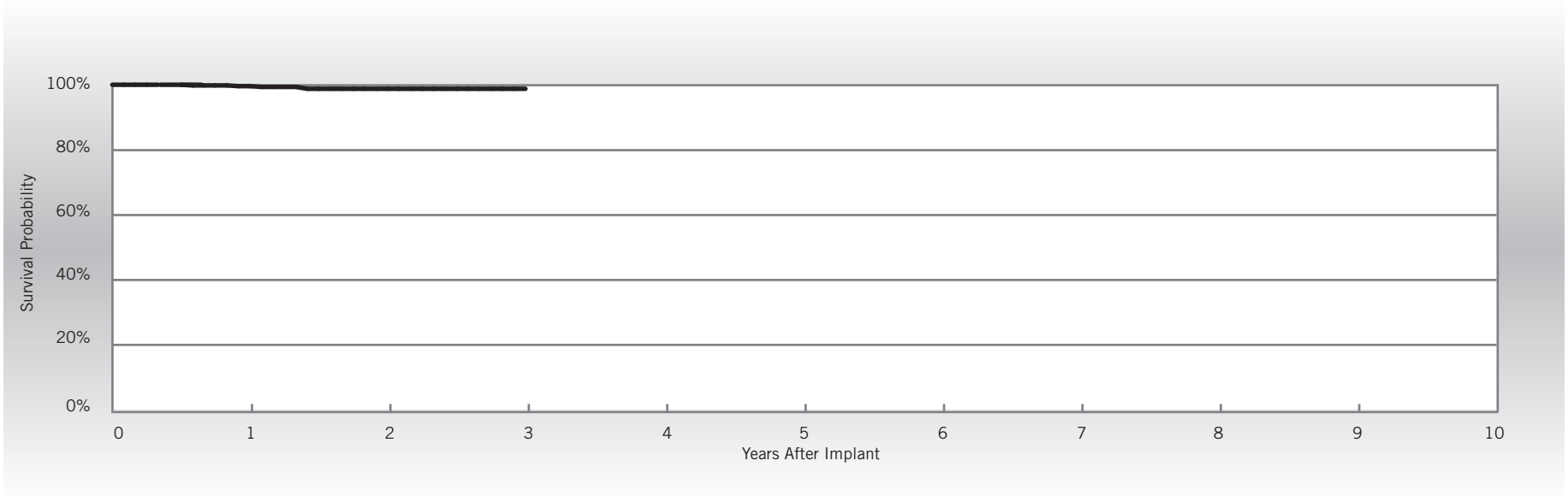
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	556
Cumulative Months of Follow-up	11,277
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	2	0.36%
Failure To Capture	2	0.36%
Lead Dislodgement	1	0.18%

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	0.18%
Total	**1**	**0.18%**



Year	1	2	3							
Survival Probability	99.56%	98.73%	98.73%							
± 1 standard error	0.30%	0.56%	0.56%							
Sample Size	490	310	120							

Customer Reported Performance Data

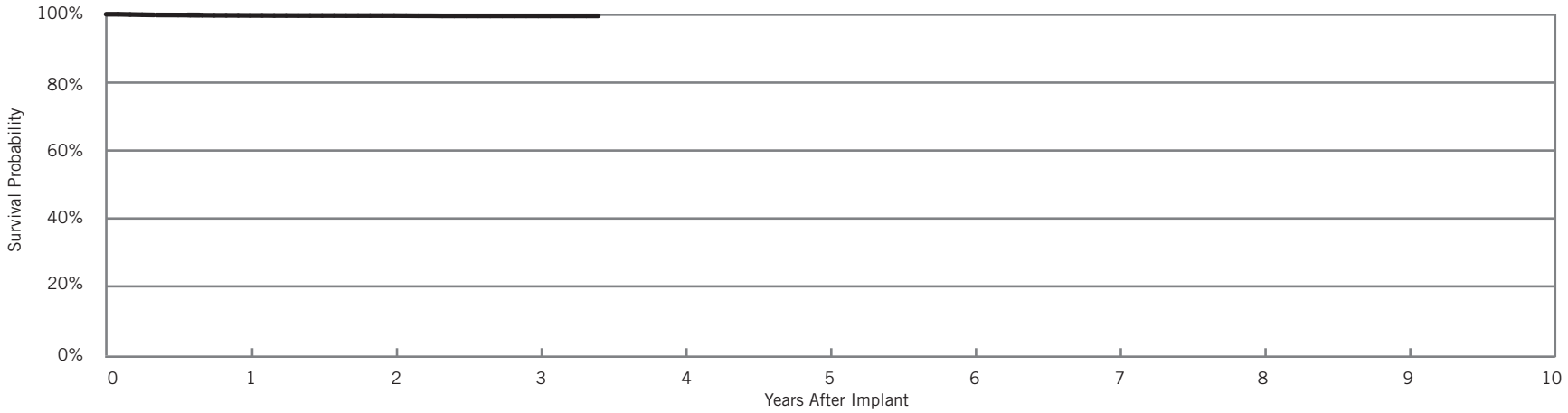
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	14,200
Estimated Active US Implants	10,652
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	7	0.05%	27	0.19%
Failure to Capture	1	0.01%	6	0.04%
Oversensing	1	0.01%	0	0.00%
Failure to Sense	0	0.00%	1	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	2	0.01%
Extracardiac Stimulation	6	0.04%	6	0.04%
Other	6	0.04%	1	0.01%
Total	**23**	**0.16%**	**43**	**0.30%**
Total Returned for Analysis	**15**		**31**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	24	0.17%
Total	**28**	**0.20%**



Year	1	2	3	at 41 months						
Survival Probability	99.64%	99.59%	99.51%	99.51%						
± 1 standard error	0.05%	0.06%	0.08%	0.08%						
Sample Size	12500	7200	2900	300						

SCORE Registry Performance Data

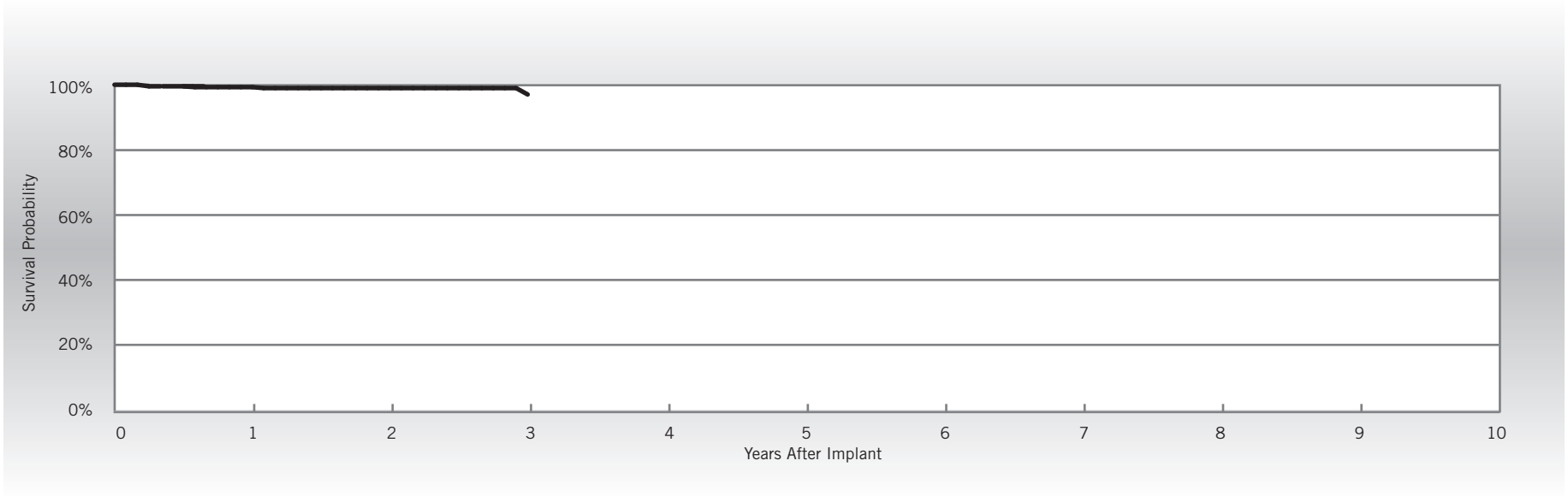
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	432
Cumulative Months of Follow-up	8,796
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	2	0.46%
Failure To Capture	2	0.46%
Lead Dislodgement	1	0.23%

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	0.69%
Total	**3**	**0.69%**



Year	1	2	3							
Survival Probability	99.25%	98.95%	96.95%							
± 1 standard error	0.43%	0.52%	1.92%							
Sample Size	430	330	170							

Customer Reported Performance Data

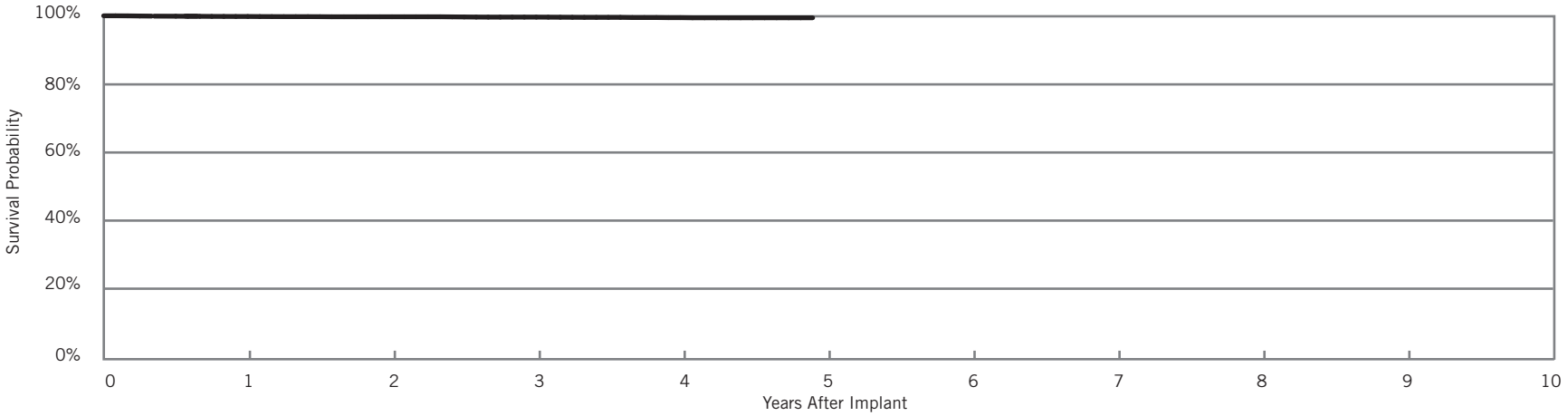
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,392
Estimated Active US Implants	6,220
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	10	0.10%	11	0.11%
Failure to Capture	3	0.03%	18	0.17%
Oversensing	1	0.01%	1	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	2	0.02%
Extracardiac Stimulation	9	0.09%	5	0.05%
Other	2	0.02%	1	0.01%
Total	**27**	**0.26%**	**39**	**0.38%**
Total Returned for Analysis	**10**		**16**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	3	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	11	0.11%
Total	**16**	**0.15%**



Year	1	2	3	4	at 59 months					
Survival Probability	99.79%	99.71%	99.60%	99.44%	99.40%					
± 1 standard error	0.05%	0.06%	0.07%	0.09%	0.10%					
Sample Size	10000	8200	6700	4300	200					

Customer Reported Performance Data

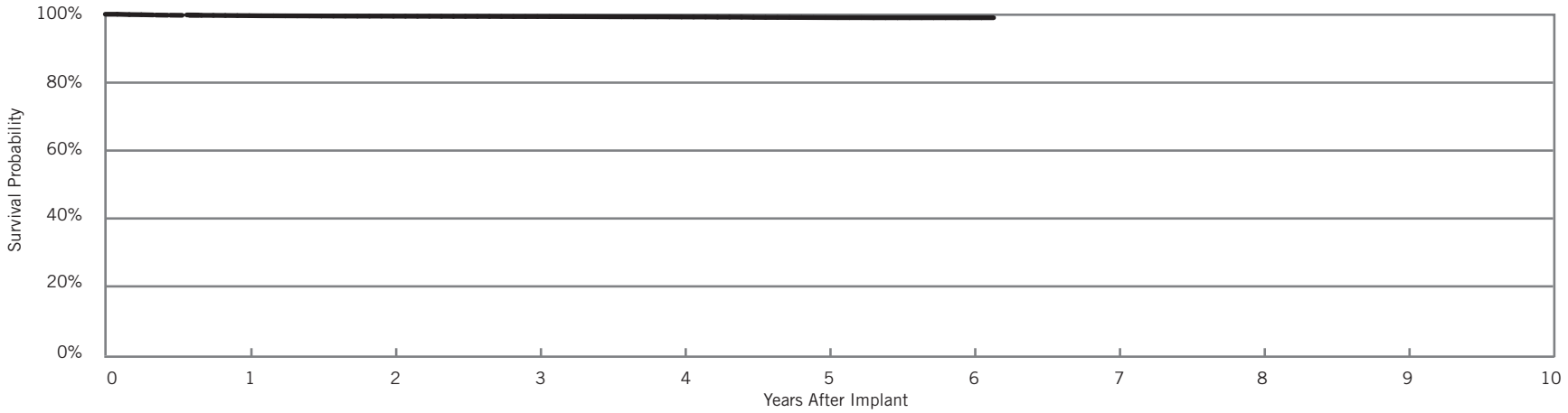
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	34,152
Estimated Active US Implants	17,957
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	29	0.08%	83	0.24%
Failure to Capture	14	0.04%	75	0.22%
Oversensing	1	<0.01%	4	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	1	<0.01%
Abnormal Pacing Impedance	3	0.01%	3	0.01%
Extracardiac Stimulation	23	0.07%	43	0.13%
Other	9	0.03%	8	0.02%
Total	**80**	**0.23%**	**221**	**0.65%**
Total Returned for Analysis	**33**		**112**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Insulation Breach	11	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	84	0.25%
Total	**98**	**0.29%**



Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.58%	99.42%	99.32%	99.19%	98.99%	98.96%	98.96%			
± 1 standard error	0.04%	0.04%	0.05%	0.06%	0.07%	0.08%	0.08%			
Sample Size	32100	26400	22200	16900	10200	3700	400			

SCORE Registry Performance Data

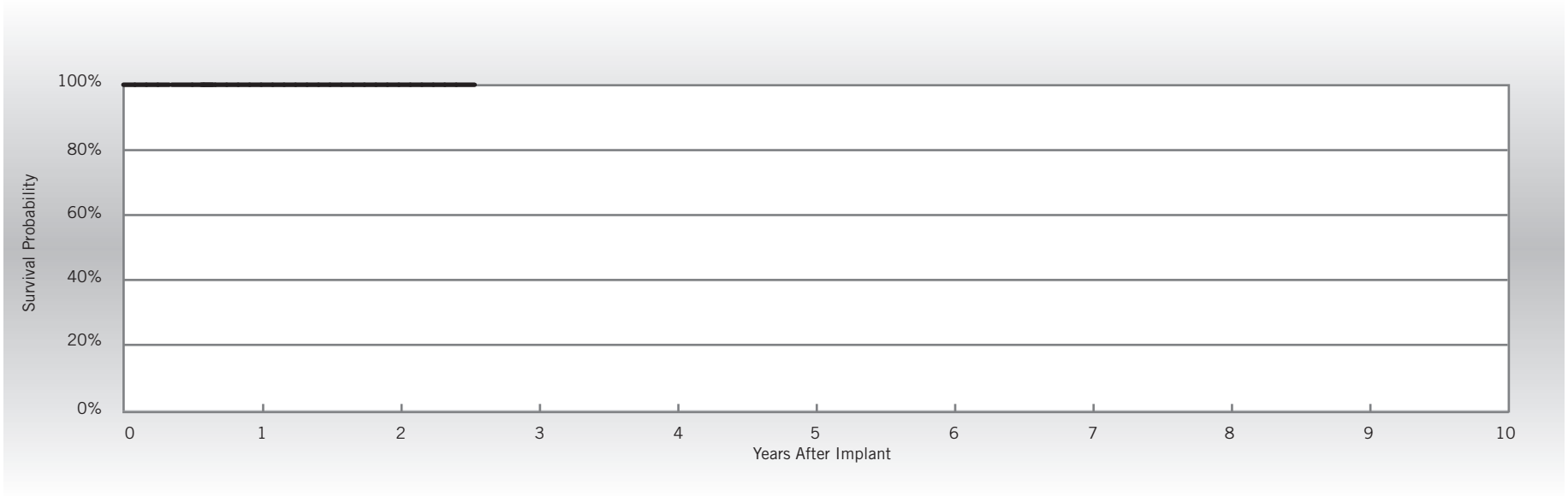
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	140
Cumulative Months of Follow-up	3,651
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	0	0.00%
Total	**0**	**0.00%**



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

Customer Reported Performance Data

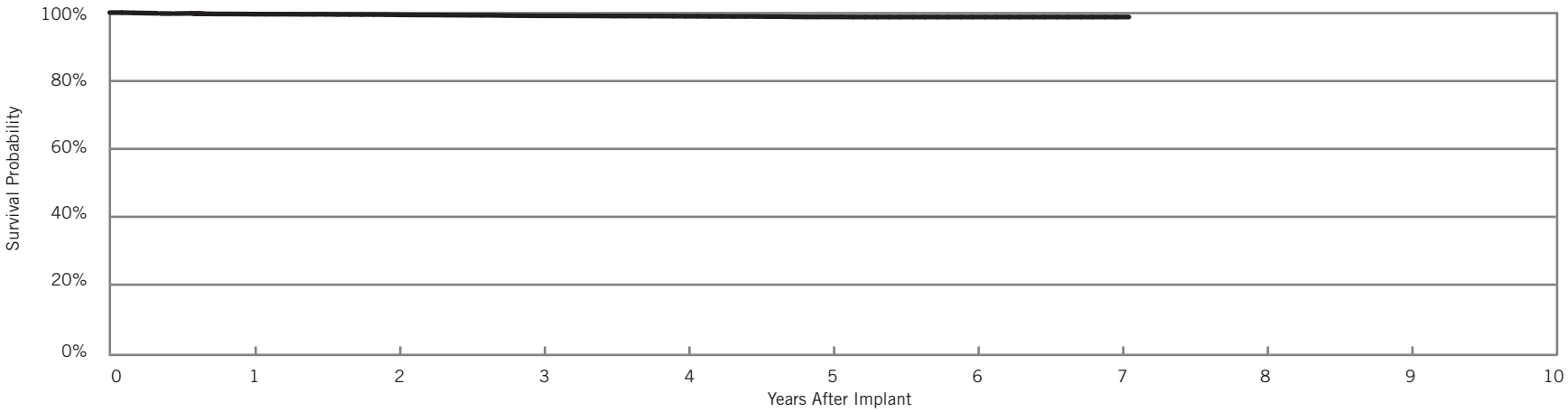
QuickSite®

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	8,805
Estimated Active US Implants	3,013
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.11%	26	0.30%
Failure to Capture	3	0.03%	28	0.32%
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%**	**76**	**0.86%**
Total Returned for Analysis	**18**		**39**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.02%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	25	0.28%
Total	**27**	**0.31%**



Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.54%	99.34%	99.04%	98.90%	98.71%	98.67%	98.67%	98.67%		
± 1 standard error	0.08%	0.09%	0.12%	0.13%	0.15%	0.16%	0.16%	0.16%		
Sample Size	7900	6600	5700	4800	3800	3000	1400	200		

Summary Information

Left-Heart Leads

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
1258T	QuickFlex® µ	99.61%									
1156T	QuickFlex®	99.71%	99.60%	99.49%							
1158T	QuickFlex® XL	99.64%	99.59%	99.51%							
1058T	QuickSite® XL	99.79%	99.71%	99.60%	99.44%						
1056T	QuickSite®	99.58%	99.42%	99.32%	99.19%	98.99%	98.96%				
1056K	QuickSite®	99.54%	99.34%	99.04%	98.90%	98.71%	98.67%	98.67%			

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	14479	12726	0	0.00%	0	0.00%	12	0.08%	7	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	11	0.08%	2	0.01%	**32**	**0.22%**	**17**
1156T	Jul-07	26245	19926	0	0.00%	0	0.00%	12	0.05%	6	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.06%	9	0.03%	**43**	**0.16%**	**16**
1158T	Jul-07	14200	10652	0	0.00%	0	0.00%	7	0.05%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	2	0.01%	6	0.04%	6	0.04%	**23**	**0.16%**	**15**
1058T	Feb-06	10392	6220	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%**	**10**
1056T	Apr-05	34152	17957	0	0.00%	0	0.00%	29	0.08%	14	0.04%	1	<0.01%	0	0.00%	1	<0.01%	3	0.01%	23	0.07%	9	0.03%	**80**	**0.23%**	**33**
1056K	Jun-04	8805	3013	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%**	**18**

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	14479	12726	0	0.00%	0	0.00%	16	0.11%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.03%	1	0.01%	**24**	**0.17%**	**16**
1156T	Jul-07	26245	19926	0	0.00%	1	<0.01%	33	0.13%	17	0.06%	3	0.01%	0	0.00%	0	0.00%	4	0.02%	18	0.07%	2	0.01%	**78**	**0.30%**	**58**
1158T	Jul-07	14200	10652	0	0.00%	0	0.00%	27	0.19%	6	0.04%	0	0.00%	1	0.01%	0	0.00%	2	0.01%	6	0.04%	1	0.01%	**43**	**0.30%**	**31**
1058T	Feb-06	10392	6220	0	0.00%	1	0.01%	11	0.11%	18	0.17%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	5	0.05%	1	0.01%	**39**	**0.38%**	**16**
1056T	Apr-05	34152	17957	0	0.00%	3	0.01%	83	0.24%	75	0.22%	4	0.01%	1	<0.01%	1	<0.01%	3	0.01%	43	0.13%	8	0.02%	**221**	**0.65%**	**112**
1056K	Jun-04	8805	3013	0	0.00%	0	0.00%	26	0.30%	28	0.32%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	12	0.14%	8	0.09%	**76**	**0.86%**	**39**

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

Malfunction Summary

Models	US Regulatory Approval	Registered US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1258T	May-10	14479	0	0.00%	0	0.00%	0	0.00%	0	0.00%	14	0.10%	**14**	**0.10%**
1156T	Jul-07	26245	2	0.01%	6	0.02%	0	0.00%	0	0.00%	34	0.13%	**42**	**0.16%**
1158T	Jul-07	14200	1	0.01%	2	0.01%	1	0.01%	0	0.00%	24	0.17%	**28**	**0.20%**
1058T	Feb-06	10392	1	0.01%	3	0.03%	0	0.00%	1	0.01%	11	0.11%	**16**	**0.15%**
1056T	Apr-05	34152	2	0.01%	11	0.03%	0	0.00%	1	<0.01%	84	0.25%	**98**	**0.29%**
1056K	Jun-04	8805	2	0.02%	0	0.00%	0	0.00%	0	0.00%	25	0.28%	**27**	**0.31%**

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

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1258T	330	2348	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1156T	556	11277	0	0.00%	0	0.00%	1	0.18%	2	0.36%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.36%	0	0.00%	**5**	**0.90%**
1158T	432	8796	0	0.00%	0	0.00%	1	0.23%	2	0.46%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.46%	0	0.00%	**5**	**1.16%**
1056T	140	3651	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	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
1258T	330	2348	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.30%	**1**	**0.30%**
1156T	556	11277	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.18%	**1**	**0.18%**
1158T	432	8796	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.69%	**3**	**0.69%**
1056T	140	3651	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Definitions of complications can be found on page 14.
Definitions of malfunction categories can be found on pages 10 and 11.

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical
More control. Less risk.

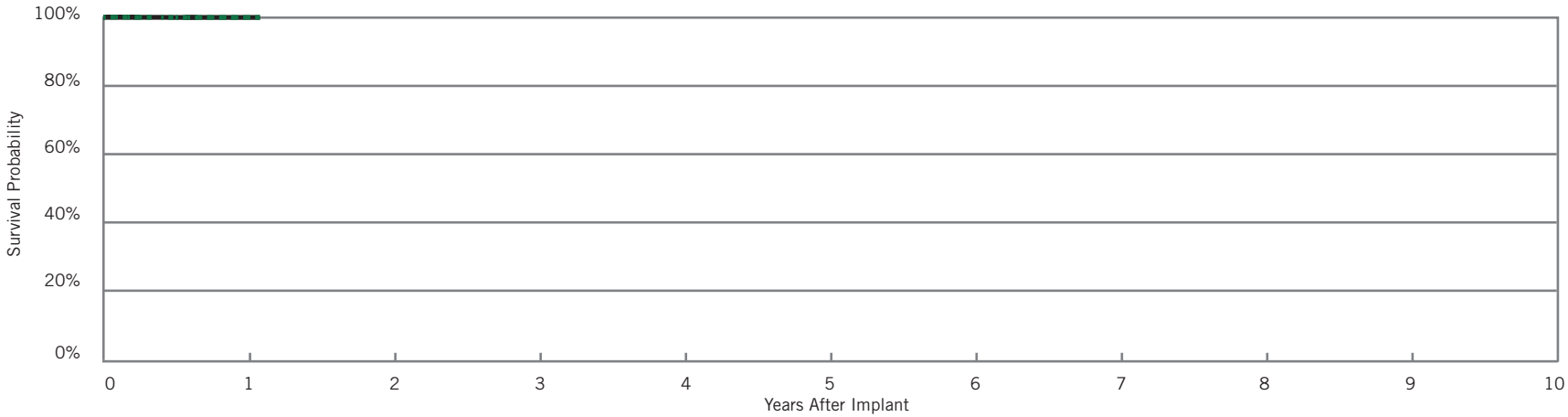
Customer Reported Performance Data

Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	12,463
Estimated Active US Implants	11,620
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.93%	99.93%								
± 1 standard error	0.03%	0.03%								
Sample Size	7000	600								

Excluding Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.93%	99.93%								
± 1 standard error	0.03%	0.03%								

SCORE Registry Performance Data

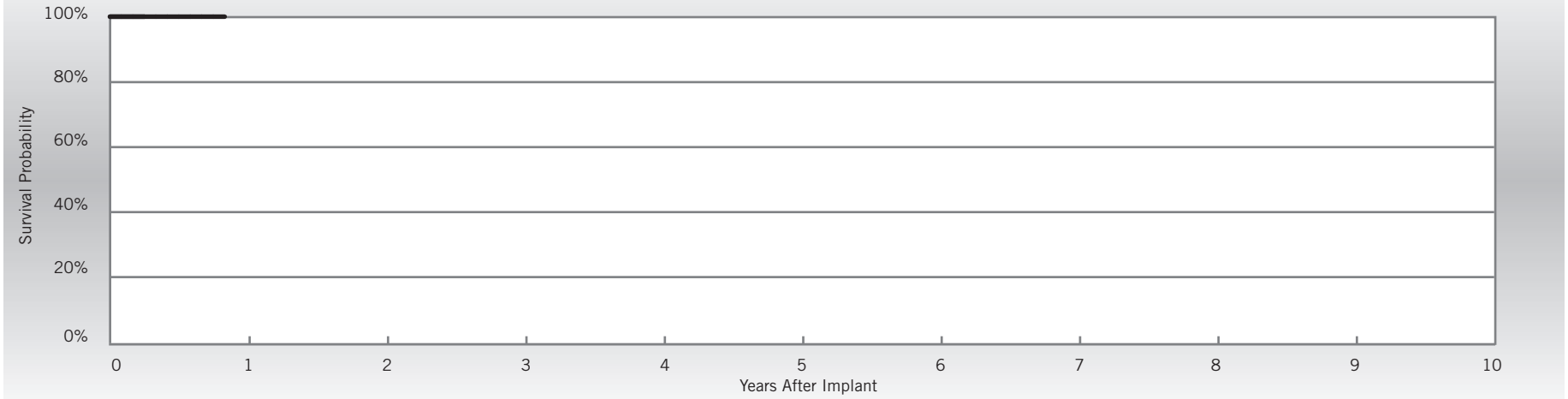
Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	244
Cumulative Months of Follow-up	1,660
Estimated Longevity	(see table on page 80)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	at 10 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	50									

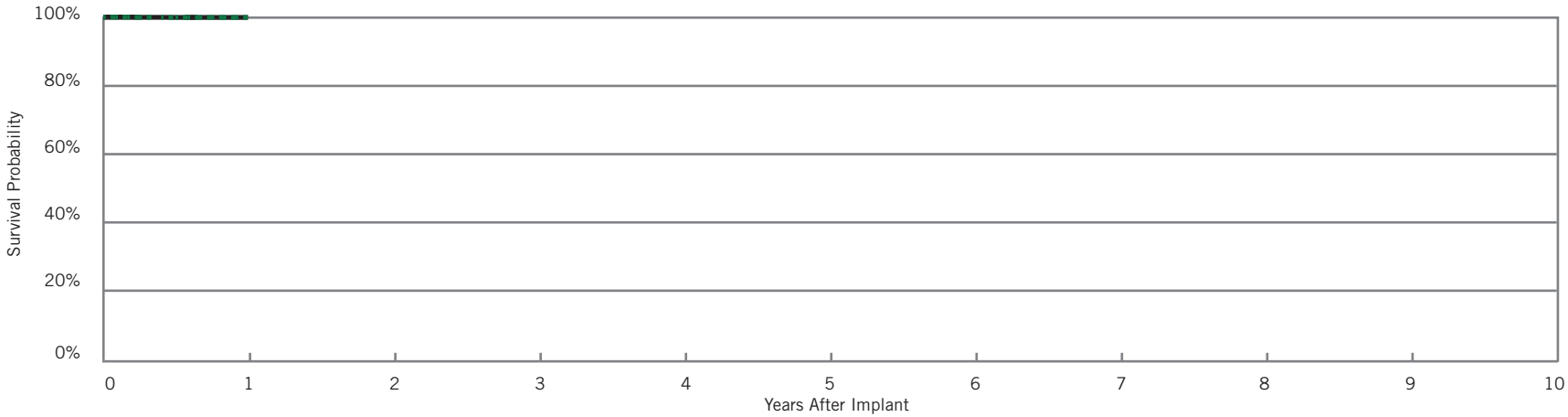
Customer Reported Performance Data

Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	5,046
Estimated Active US Implants	4,713
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	2800									

Excluding Normal Battery Depletion

Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									

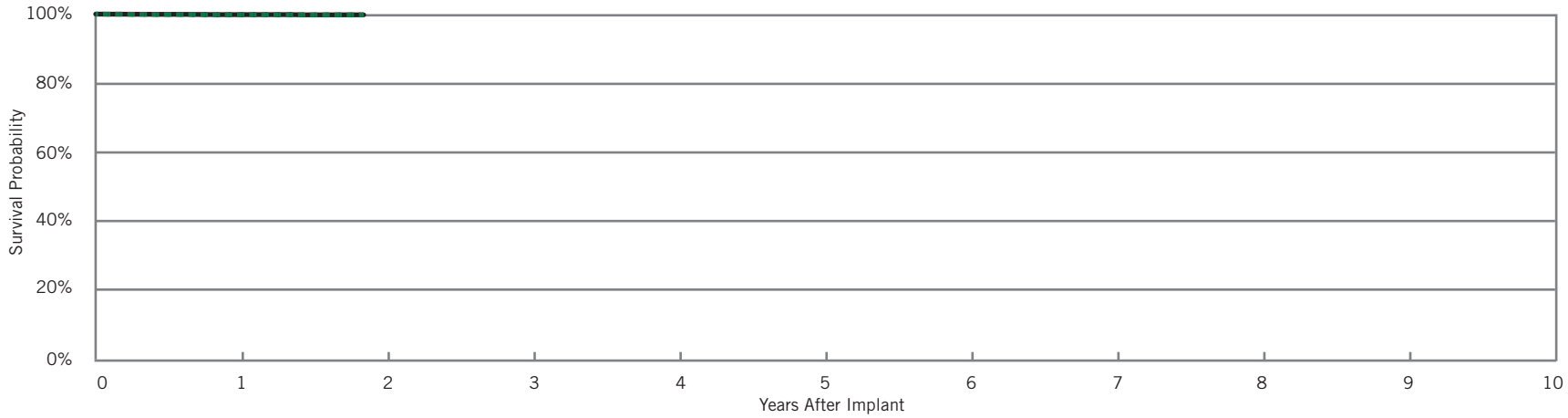
Customer Reported Performance Data

Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	8,444
Estimated Active US Implants	7,129
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.84%	99.78%								
± 1 standard error	0.05%	0.06%								
Sample Size	8100	500								

Excluding Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.84%	99.78%								
± 1 standard error	0.05%	0.06%								

SCORE Registry Performance Data

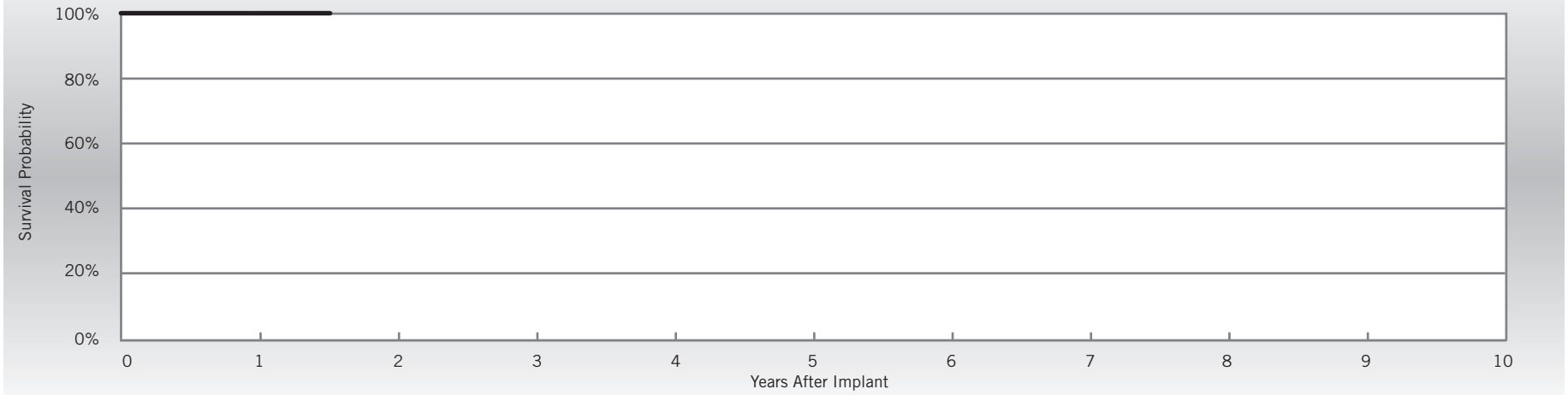
Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	154
Cumulative Months of Follow-up	2,482
Estimated Longevity	(see table on page 80)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	at 18 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	140	60								

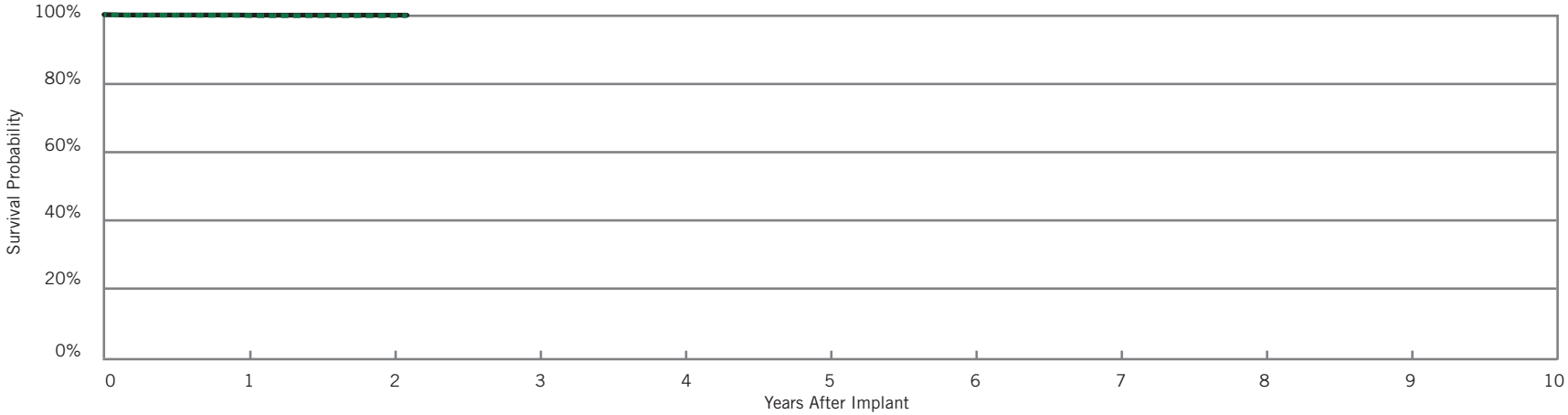
Customer Reported Performance Data

Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	5,773
Estimated Active US Implants	4,819
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	1	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.02%
Total	**2**	**0.03%**	**2**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.74%	99.70%	99.70%							
± 1 standard error	0.06%	0.08%	0.08%							
Sample Size	5500	2500	300							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.83%	99.83%	99.83%							
± 1 standard error	0.05%	0.06%	0.06%							

SCORE Registry Performance Data

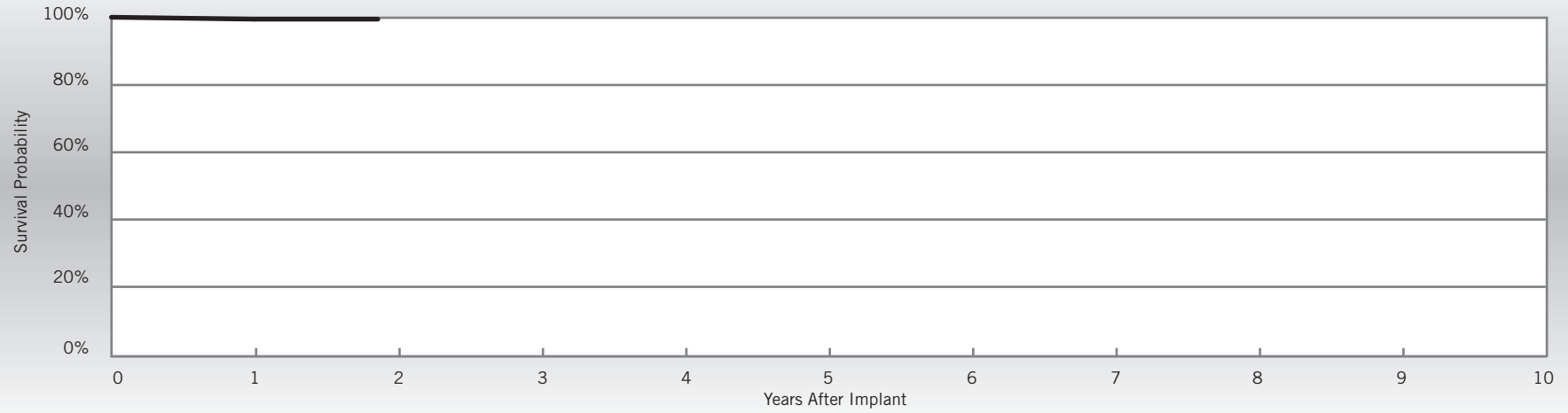
Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	185
Cumulative Months of Follow-up	3,300
Estimated Longevity	(see table on page 80)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Premature Battery Depletion	1	0.54%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.54%
Total	**0**	**0.00%**	**1**	**0.54%**



Year	1	at 22 months								
Survival Probability	99.42%	99.42%								
± 1 standard error	0.58%	0.58%								
Sample Size	170	60								

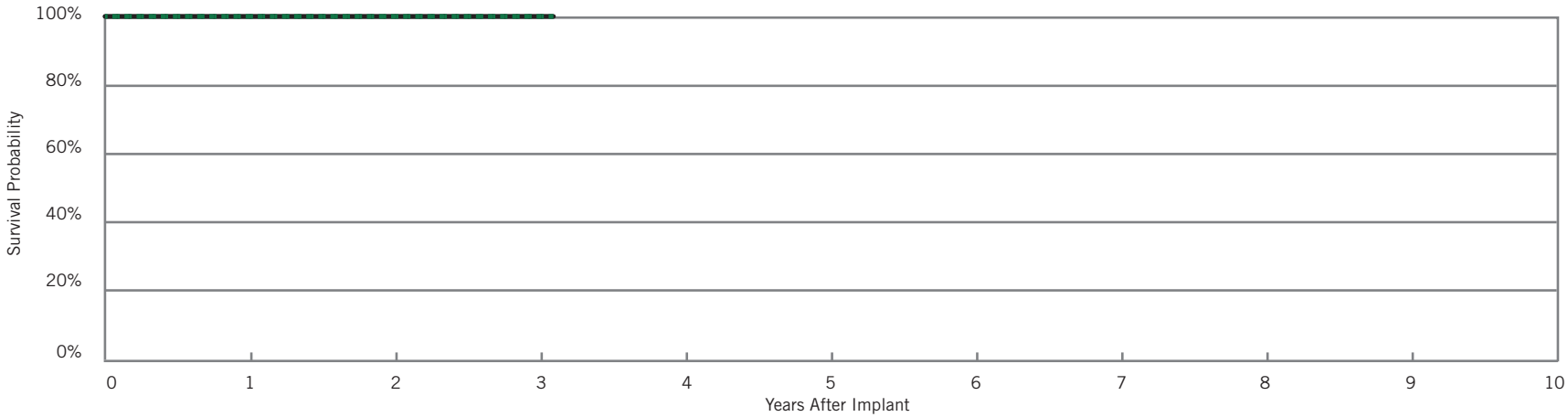
Customer Reported Performance Data

Current® DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,558
Estimated Active US Implants	1,164
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	1600	1200	600	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						

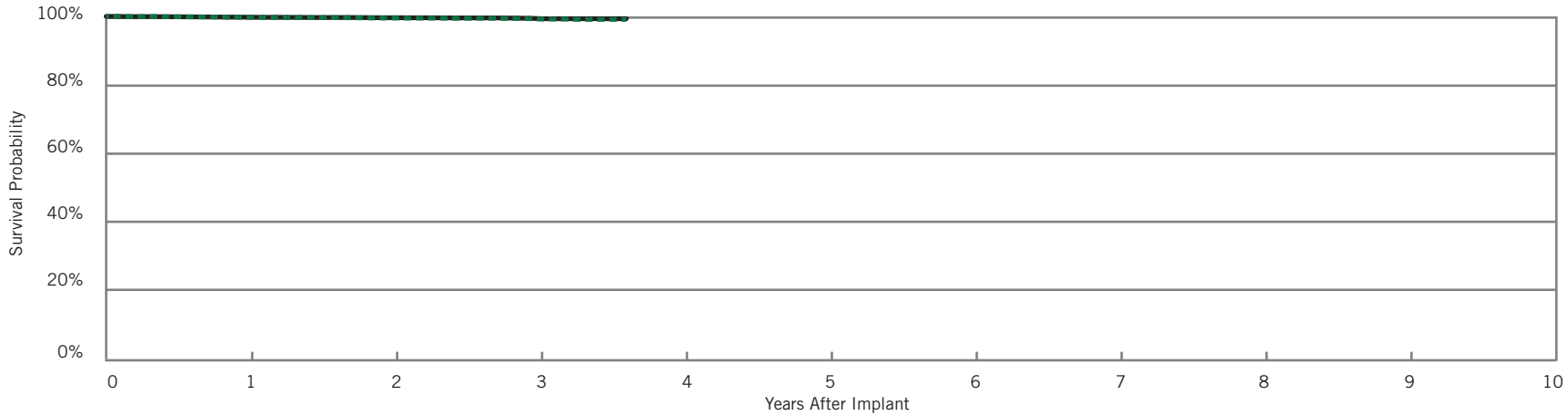
Customer Reported Performance Data

Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,284
Estimated Active US Implants	16,282
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	8
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	5	0.02%
Electrical Interconnect	3	0.01%	1	<0.01%
Battery	1	<0.01%	2	0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	4	0.02%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	7	0.03%	3	0.01%
Other	5	0.02%	2	0.01%
Total	**20**	**0.09%**	**18**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.73%	99.50%	99.21%	99.11%						
± 1 standard error	0.03%	0.05%	0.07%	0.11%						
Sample Size	22200	17300	9000	400						

Excluding Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.75%	99.61%	99.32%	99.32%						
± 1 standard error	0.03%	0.05%	0.07%	0.09%						

SCORE Registry Performance Data

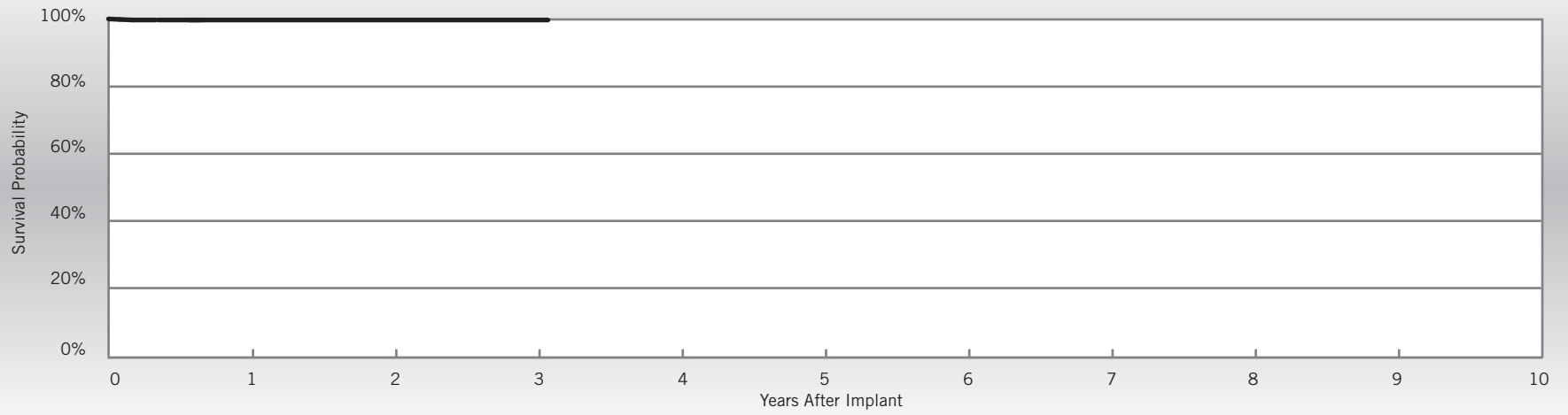
Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	631
Cumulative Months of Follow-up	16,686
Estimated Longevity	(see table on page 80)
Max. Delivered Energy	36 joules

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

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



Year	1	2	3	at 37 months						
Survival Probability	99.68%	99.68%	99.68%	99.68%						
± 1 standard error	0.23%	0.23%	0.23%	0.23%						
Sample Size	600	490	240	70						

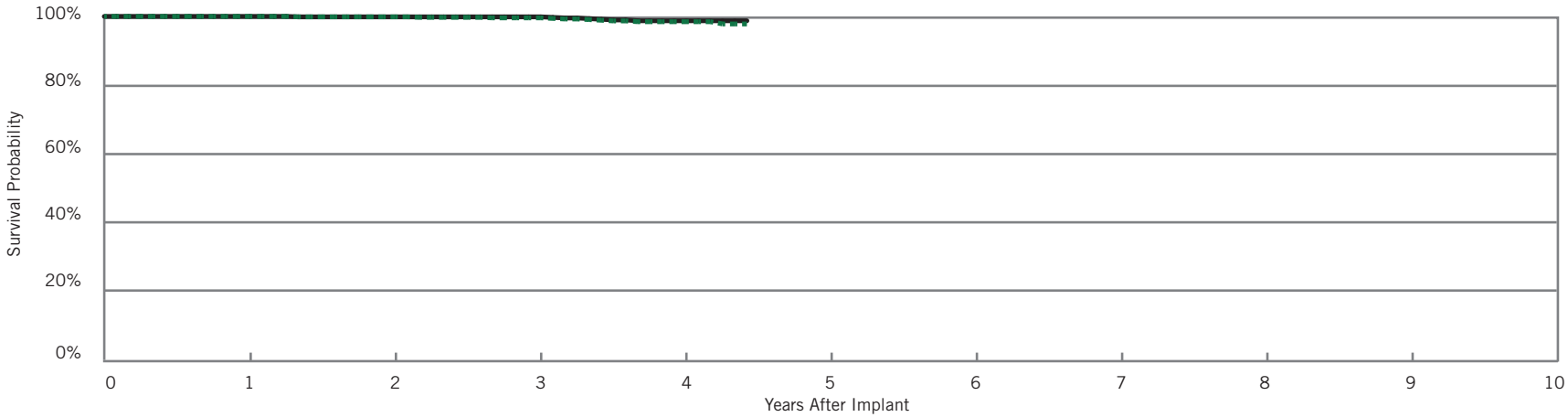
Customer Reported Performance Data

Atlas® II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,876
Estimated Active US Implants	1,179
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	3
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.16%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.11%	2	0.11%
Other	0	0.00%	0	0.00%
Total	**5**	**0.27%**	**2**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	100.00%	99.87%	99.58%	98.46%	97.81%					
± 1 standard error	0.00%	0.09%	0.17%	0.37%	0.58%					
Sample Size	1900	1600	1400	900	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	100.00%	99.87%	99.87%	98.74%	98.74%					
± 1 standard error	0.00%	0.09%	0.09%	0.34%	0.34%					

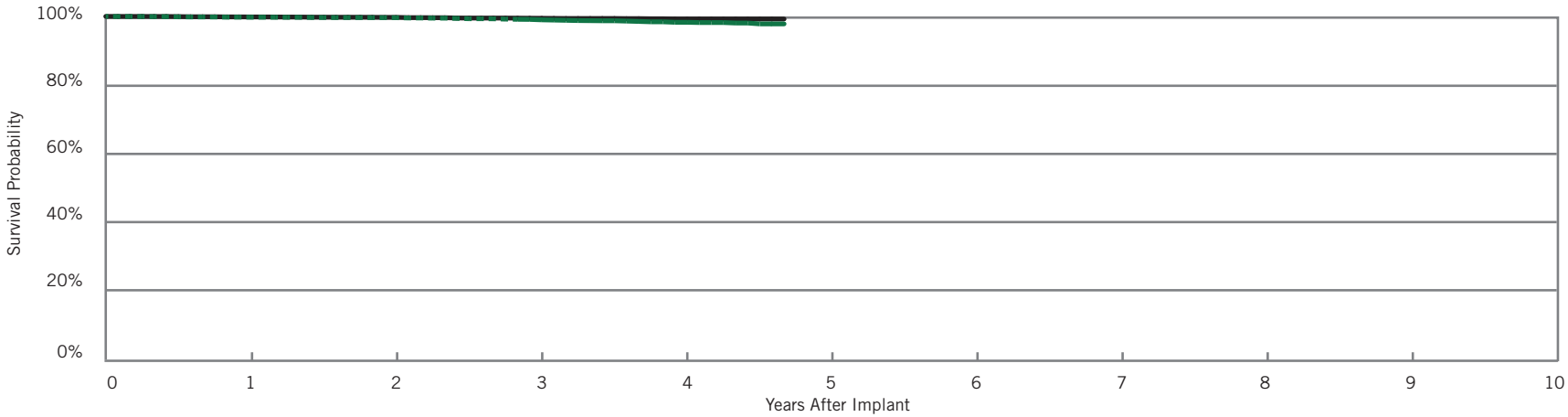
Customer Reported Performance Data

Atlas® II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,714
Estimated Active US Implants	9,319
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	30
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	4	0.03%	2	0.01%
Electrical Interconnect	4	0.03%	0	0.00%
Battery	5	0.03%	2	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	6	0.04%	6	0.04%
Other	2	0.01%	0	0.00%
Total	**21**	**0.14%**	**10**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.77%	99.62%	99.00%	98.28%	97.82%					
± 1 standard error	0.04%	0.05%	0.09%	0.15%	0.26%					
Sample Size	14700	12300	9700	5500	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.84%	99.72%	99.44%	99.25%	99.25%					
± 1 standard error	0.03%	0.05%	0.07%	0.10%	0.10%					

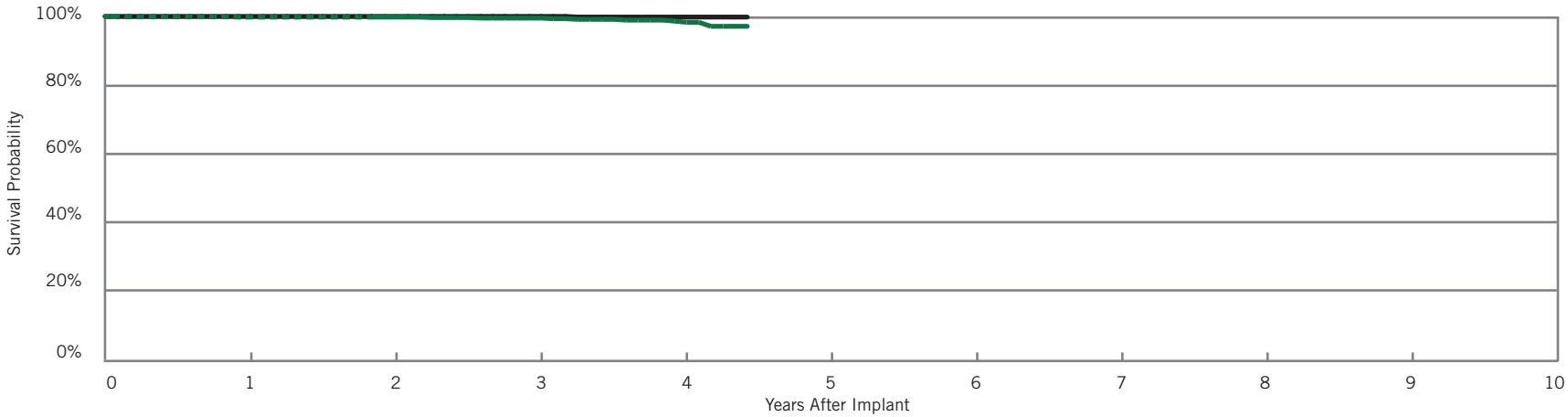
Customer Reported Performance Data

Epic® II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,086
Estimated Active US Implants	1,278
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	10
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 234-245)	One

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



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.79%	99.79%	99.50%	98.29%	97.11%					
± 1 standard error	0.10%	0.10%	0.18%	0.37%	0.68%					
Sample Size	2100	1800	1400	900	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	100.00%	100.00%	100.00%	99.81%	99.81%					
± 1 standard error	0.00%	0.00%	0.00%	0.13%	0.13%					

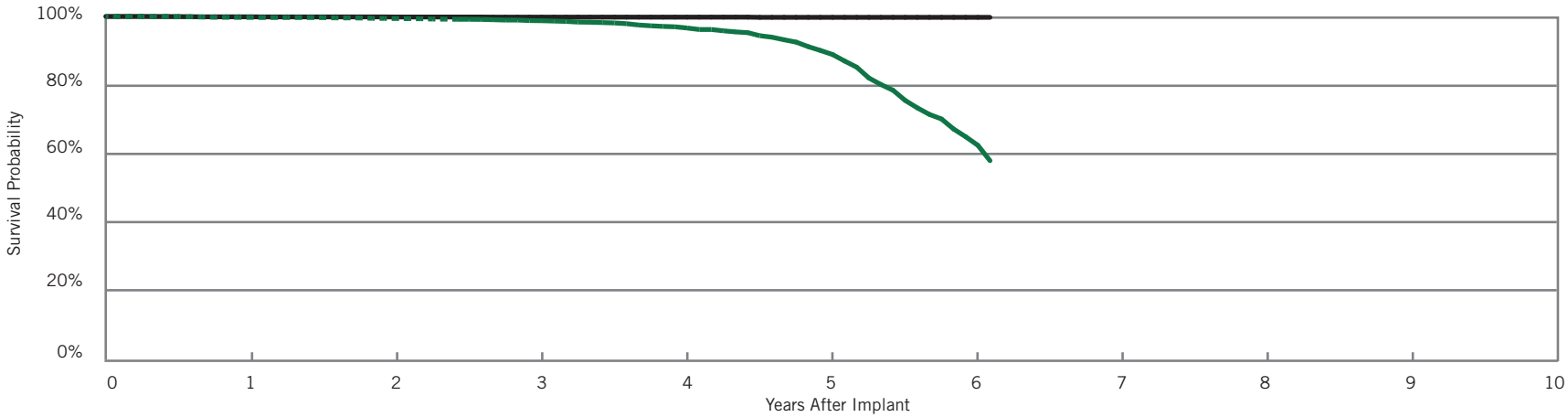
Customer Reported Performance Data

Epic® + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,482
Estimated Active US Implants	2,396
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	362
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 234-245)	Two

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.71%	99.38%	98.74%	96.61%	88.88%	62.37%	57.90%			
± 1 standard error	0.06%	0.09%	0.14%	0.24%	0.49%	1.21%	1.32%			
Sample Size	7400	6600	5800	5000	3700	1800	300			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.89%	99.82%	99.79%	99.79%	99.73%	99.73%	99.73%			
± 1 standard error	0.04%	0.05%	0.06%	0.06%	0.07%	0.07%	0.07%			

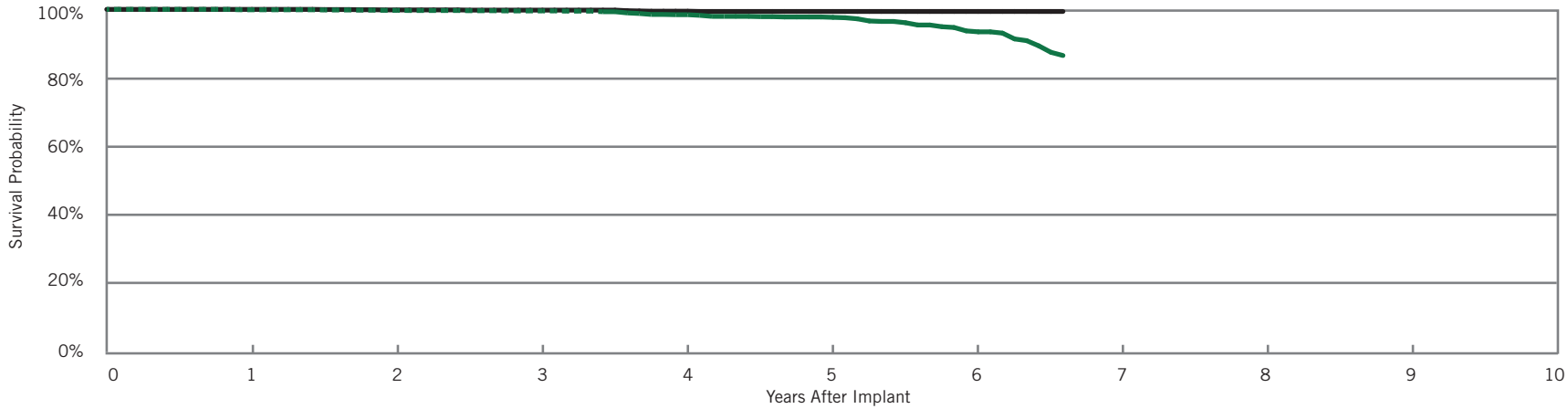
Customer Reported Performance Data

Atlas® DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,596
Estimated Active US Implants	2,099
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	51
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	4	0.09%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	0.02%	0	0.00%
Other	2	0.04%	0	0.00%
Total	**8**	**0.17%**	**1**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.88%	99.72%	99.54%	98.44%	97.67%	93.43%	86.52%			
± 1 standard error	0.05%	0.09%	0.11%	0.22%	0.27%	0.65%	1.42%			
Sample Size	4600	4000	3600	3100	2400	1300	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	100.00%	99.84%	99.78%	99.47%	99.39%	99.39%	99.39%			
± 1 standard error	0.00%	0.07%	0.08%	0.13%	0.14%	0.14%	0.14%			

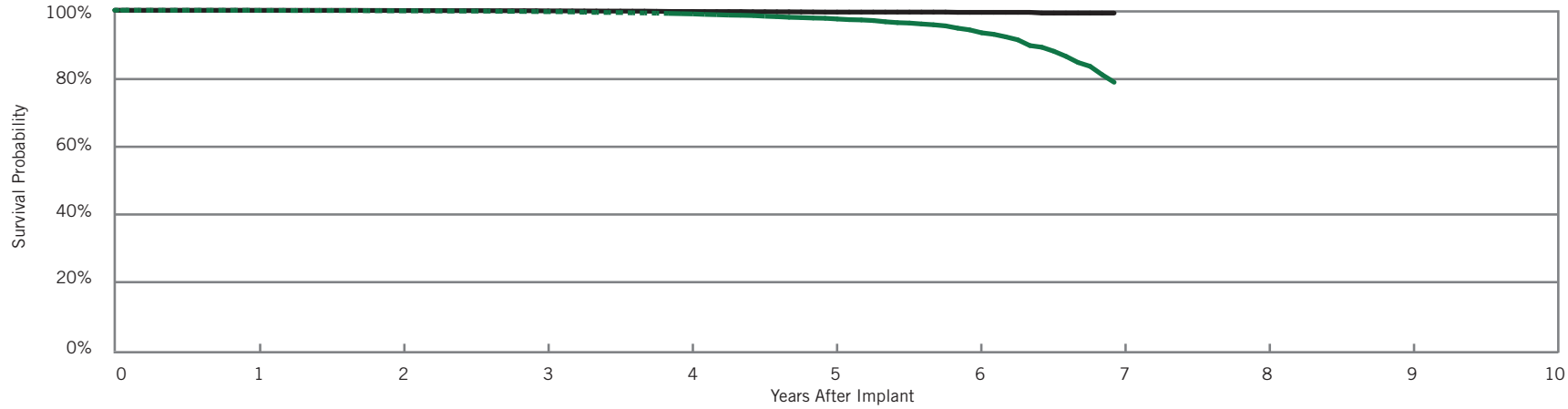
Customer Reported Performance Data

Atlas® + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	20,813
Estimated Active US Implants	9,535
Estimated Longevity	(see table on page 80)
Normal Battery Depletion	178
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	3	0.01%	2	0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	9	0.04%	3	0.01%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	6	0.03%	1	<0.01%
Other	5	0.02%	1	<0.01%
Total	**25**	**0.12%**	**8**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.93%	99.81%	99.56%	98.91%	97.42%	93.36%	78.83%			
± 1 standard error	0.01%	0.03%	0.05%	0.09%	0.15%	0.34%	1.40%			
Sample Size	20800	18200	15900	13300	9400	4500	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.97%	99.90%	99.80%	99.62%	99.45%	99.38%	99.16%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.07%	0.09%	0.17%			

Battery Longevity Summary

Dual-Chamber ICDs

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD2231-40Q	Fortify® DR**	10.2	9.4	8.7	7.6
CD2231-40	Fortify® DR**	10.2	9.4	8.7	7.6
CD2211-36Q	Current® + DR	8.2	7.5	7.0	6.1
CD2211-36	Current® + DR	8.2	7.5	7.0	6.1
2207-30	Current® DR RF	6.5	5.9	5.4	4.6
2207-36	Current® DR RF	8.2	7.5	7.0	6.1
V-265	Atlas® II DR	8.2	7.5	7.0	6.1
V-268	Atlas® II + DR	8.2	7.5	7.0	6.1
V-258	Epic® II + DR	6.5	5.9	5.4	4.6
V-239	Epic® + DR	6.4	6.0	5.6	4.5
V-242	Atlas® DR	7.9	7.3	6.9	6.1
V-243	Atlas® + DR	7.9	7.3	6.9	6.1

**Battery longevity calculated with one EGM storage.*
Pacing parameters: DDD-BiV, RV 2.5V, LV 2.5V, A 2.5V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.
***Three maximum charges per year. Battery voltage range: 3.20-2.59.*

Summary Information

Dual-Chamber ICDs

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR	99.93%									
CD2231-40	Fortify® DR	100.00%									
CD2211-36Q	Current® + DR	99.84%									
CD2211-36	Current® + DR	99.74%	99.70%								
2207-30	Current® DR RF	100.00%	100.00%	100.00%							
2207-36	Current® DR RF	99.73%	99.50%	99.21%							
V-265	Atlas® II DR	100.00%	99.87%	99.58%	98.46%						
V-268	Atlas® II + DR	99.77%	99.62%	99.00%	98.28%						
V-258	Epic® II + DR	99.79%	99.79%	99.50%	98.29%						
V-239	Epic® + DR	99.71%	99.38%	98.74%	96.61%	88.88%	62.37%				
V-242	Atlas® DR	99.88%	99.72%	99.54%	98.44%	97.67%	93.43%				
V-243	Atlas® + DR	99.93%	99.81%	99.56%	98.91%	97.42%	93.36%				

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR	99.93%									
CD2231-40	Fortify® DR	100.00%									
CD2211-36Q	Current® + DR	99.84%									
CD2211-36	Current® + DR	99.83%	99.83%								
2207-30	Current® DR RF	100.00%	100.00%	100.00%							
2207-36	Current® DR RF	99.75%	99.61%	99.32%							
V-265	Atlas® II DR	100.00%	99.87%	99.87%	98.74%						
V-268	Atlas® II + DR	99.84%	99.72%	99.44%	99.25%						
V-258	Epic® II + DR	100.00%	100.00%	100.00%	99.81%						
V-239	Epic® + DR	99.89%	99.82%	99.79%	99.79%	99.73%	99.73%				
V-242	Atlas® DR	100.00%	99.84%	99.78%	99.47%	99.39%	99.39%				
V-243	Atlas® + DR	99.97%	99.90%	99.80%	99.62%	99.45%	99.38%				

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	12463	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
CD2231-40	Fortify® DR	5046	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current® + DR	8444	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
CD2211-36	Current® + DR	5773	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**
2207-30	Current® DR RF	1558	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
2207-36	Current® DR RF	22284	3	0.01%	3	0.01%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	7	0.03%	5	0.02%	**20**	**0.09%**
V-265	Atlas® II DR	1876	0	0.00%	0	0.00%	3	0.16%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**5**	**0.27%**
V-268	Atlas® II + DR	14714	4	0.03%	4	0.03%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	2	0.01%	**21**	**0.14%**
V-258	Epic® II + DR	2086	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
V-239	Epic® + DR	7482	0	0.00%	2	0.03%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**5**	**0.07%**
V-242	Atlas® DR	4596	0	0.00%	1	0.02%	4	0.09%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	2	0.04%	**8**	**0.17%**
V-243	Atlas® + DR	20813	3	0.01%	1	<0.01%	9	0.04%	1	<0.01%	0	0.00%	0	0.00%	6	0.03%	5	0.02%	**25**	**0.12%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	12463	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.02%**
CD2231-40	Fortify® DR	5046	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current® + DR	8444	0	0.00%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	2	0.02%	0	0.00%	**6**	**0.07%**
CD2211-36	Current® + DR	5773	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**2**	**0.03%**
2207-30	Current® DR RF	1558	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
2207-36	Current® DR RF	22284	5	0.02%	1	<0.01%	2	0.01%	0	0.00%	4	0.02%	1	<0.01%	3	0.01%	2	0.01%	**18**	**0.08%**
V-265	Atlas® II DR	1876	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**2**	**0.11%**
V-268	Atlas® II + DR	14714	2	0.01%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	0	0.00%	**10**	**0.07%**
V-258	Epic® II + DR	2086	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**
V-239	Epic® + DR	7482	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	**3**	**0.04%**
V-242	Atlas® DR	4596	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.02%**
V-243	Atlas® + DR	20813	2	0.01%	0	0.00%	3	0.01%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	1	<0.01%	**8**	**0.04%**

Definitions of malfunction root cause categories can be found on page 7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Failure to Sense		Inappropriate Shock		Premature Battery Depletion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	244	1660	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	154	2482	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36	185	3300	0	0.00%	0	0.00%	1	0.54%	**1**	**0.54%**
2207-36	631	16686	1	0.16%	1	0.16%	0	0.00%	**2**	**0.32%**

Malfunctions

Models	Family	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	244	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current® + DR	154	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36	Current® + DR	185	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
2207-36	Current® DR RF	631	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Models	Family	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	244	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current® + DR	154	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36	Current® + DR	185	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.54%	**1**	**0.54%**
2207-36	Current® DR RF	631	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Definitions of complications can be found on page 14.
Definitions of malfunction root cause categories can be found on page 7.

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical
More control. Less risk.

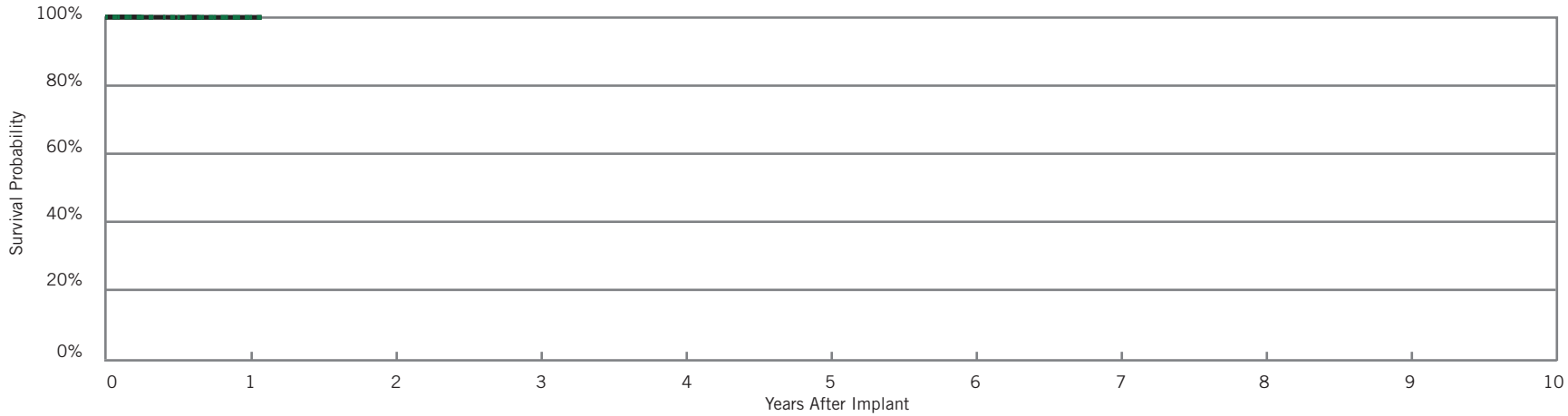
Customer Reported Performance Data

Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Registered US Implants	6,823
Estimated Active US Implants	6,341
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.02%	0.02%								
Sample Size	3800	300								

Excluding Normal Battery Depletion

Year	1	at 13 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.02%	0.02%								

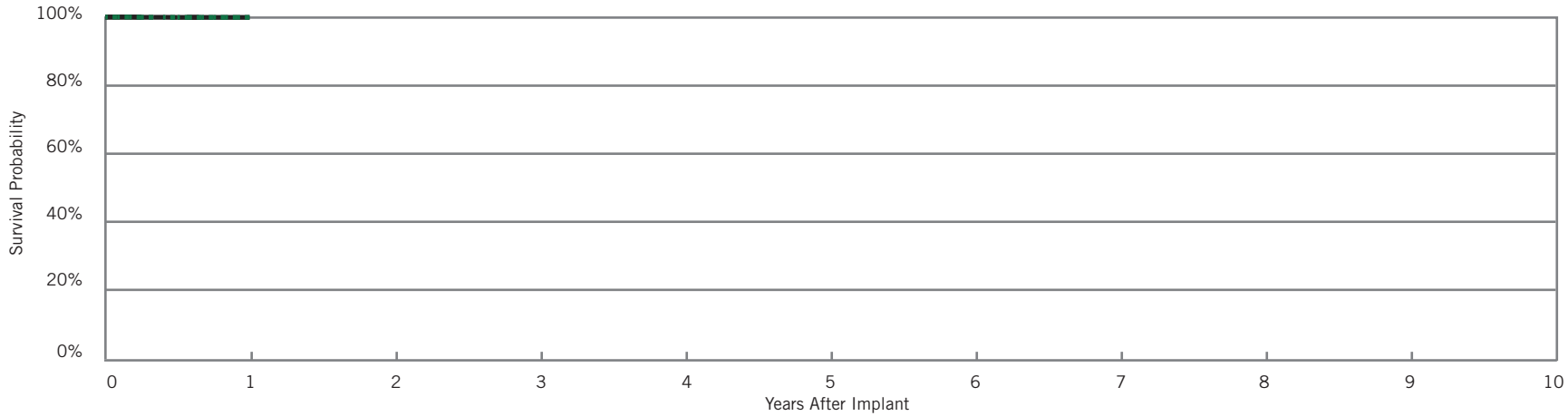
Customer Reported Performance Data

Fortify® VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	2,840
Estimated Active US Implants	2,644
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	1600									

Excluding Normal Battery Depletion

Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									

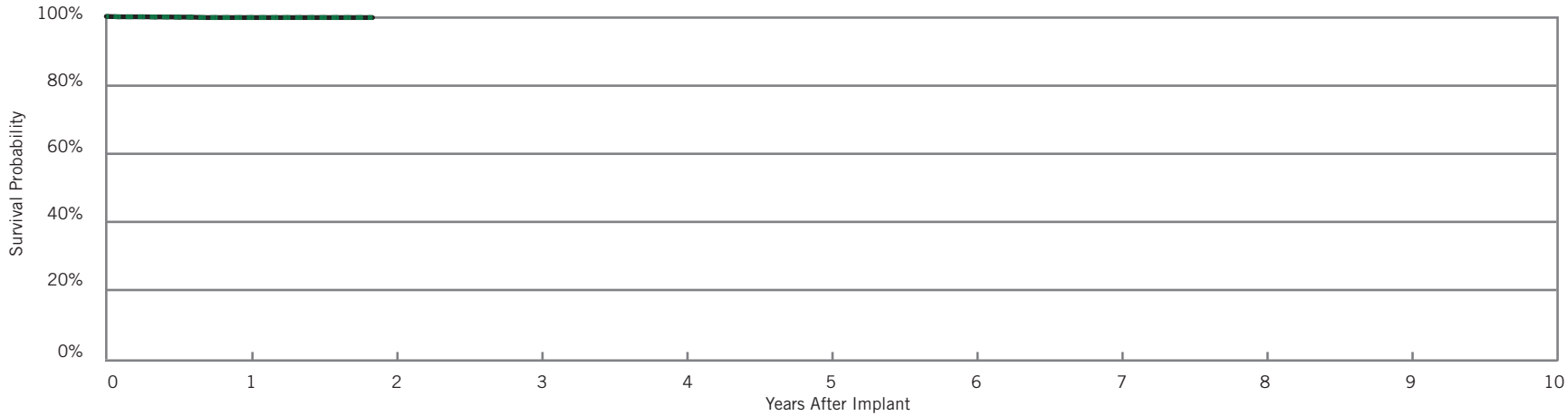
Customer Reported Performance Data

Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	4,431
Estimated Active US Implants	3,739
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.02%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.02%	1	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.02%
Other	0	0.00%	0	0.00%
Total	**2**	**0.05%**	**4**	**0.09%**



Including Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.66%	99.66%								
± 1 standard error	0.09%	0.09%								
Sample Size	4200	200								

Excluding Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.66%	99.66%								
± 1 standard error	0.09%	0.09%								

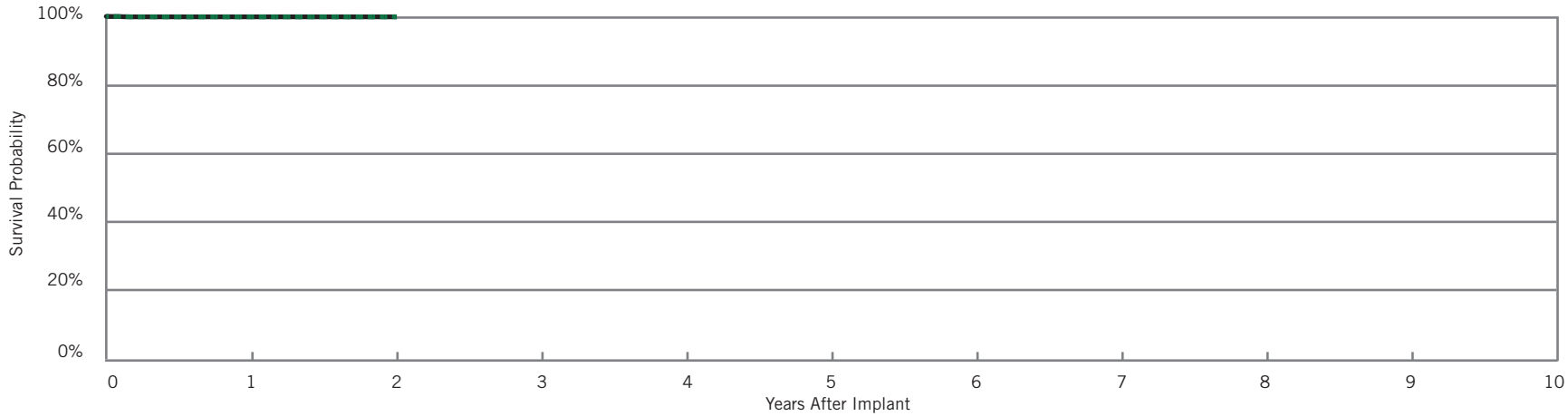
Customer Reported Performance Data

Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,237
Estimated Active US Implants	2,711
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.06%	0.06%								
Sample Size	3100	1400								

Excluding Normal Battery Depletion

Year	1	2								
Survival Probability	99.87%	99.87%								
± 1 standard error	0.06%	0.06%								

SCORE Registry Performance Data

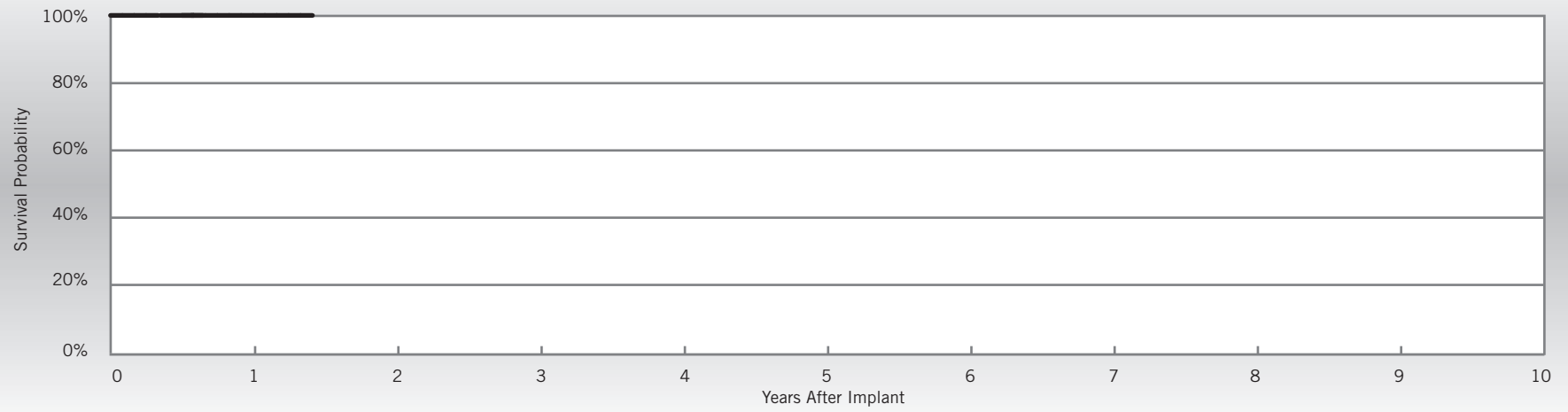
Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	108
Cumulative Months of Follow-up	1853
Estimated Longevity	(see table on page 100)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	at 17 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	100	60								

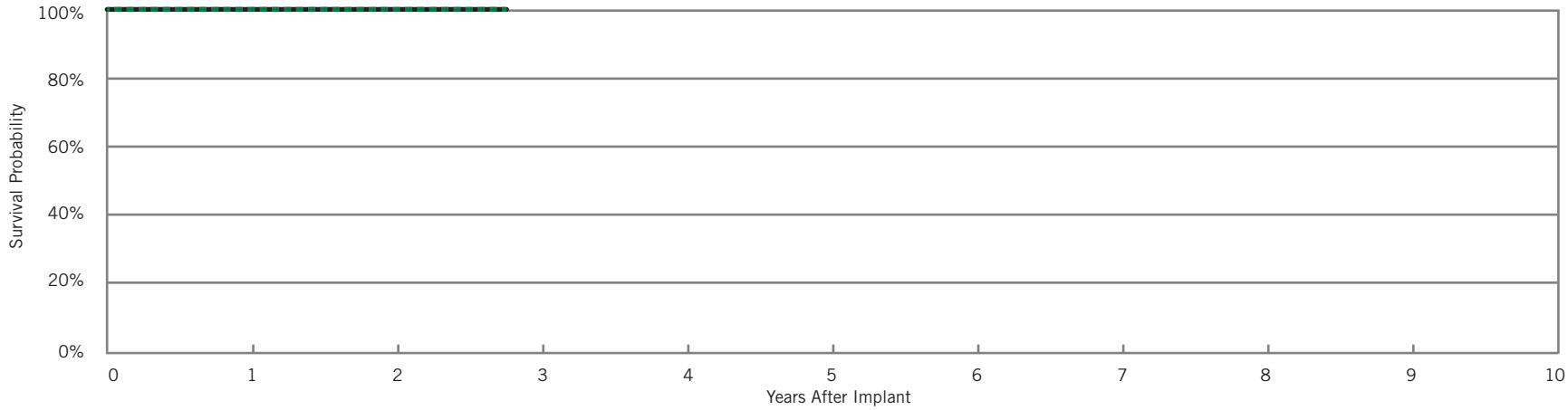
Customer Reported Performance Data

Current® VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	875
Estimated Active US Implants	667
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	900	700	200							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

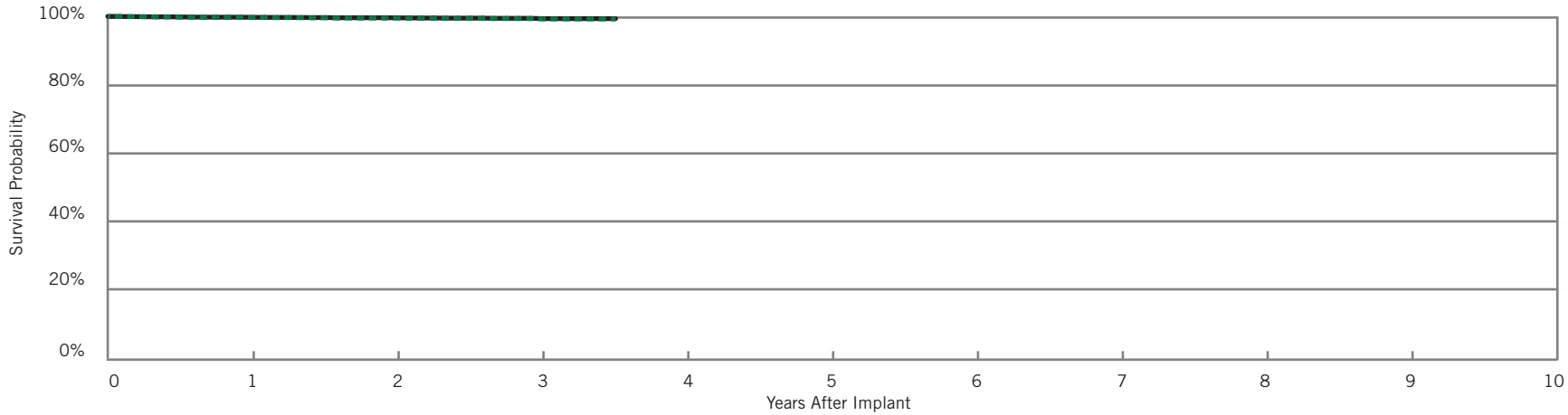
Customer Reported Performance Data

Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,157
Estimated Active US Implants	9,686
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	4
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.04%	2	0.02%
Electrical Interconnect	4	0.03%	0	0.00%
Battery	1	0.01%	3	0.02%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	3	0.02%
Other	3	0.02%	2	0.02%
Total	**14**	**0.11%**	**11**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.66%	99.48%	99.24%	99.24%						
± 1 standard error	0.05%	0.07%	0.09%	0.11%						
Sample Size	13100	10000	5000	400						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.71%	99.57%	99.33%	99.33%						
± 1 standard error	0.04%	0.06%	0.08%	0.11%						

SCORE Registry Performance Data

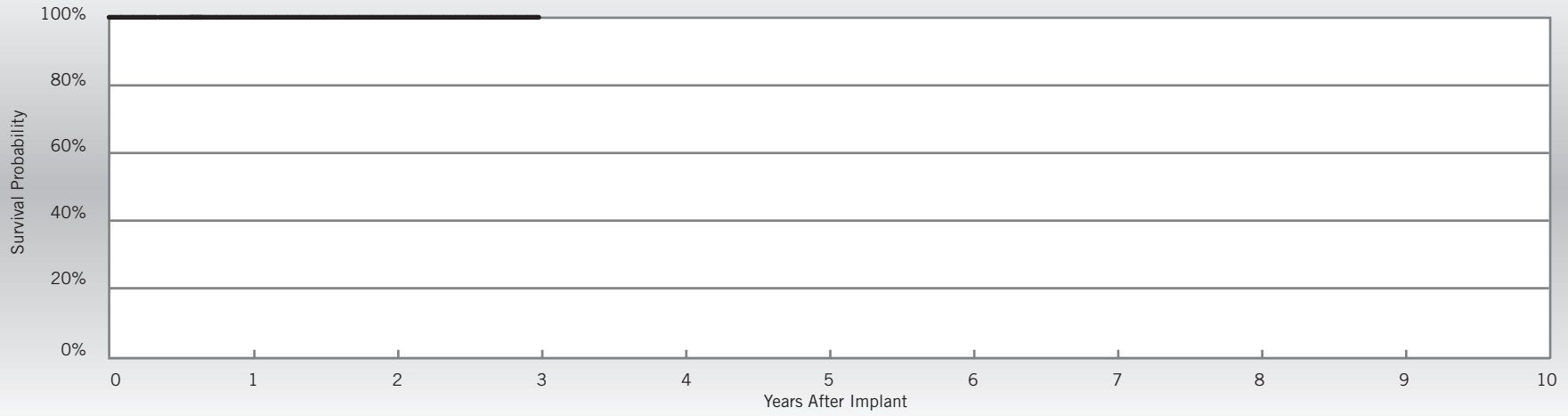
Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	10,726
Estimated Longevity	(see table on page 100)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	2	3							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	380	320	160							

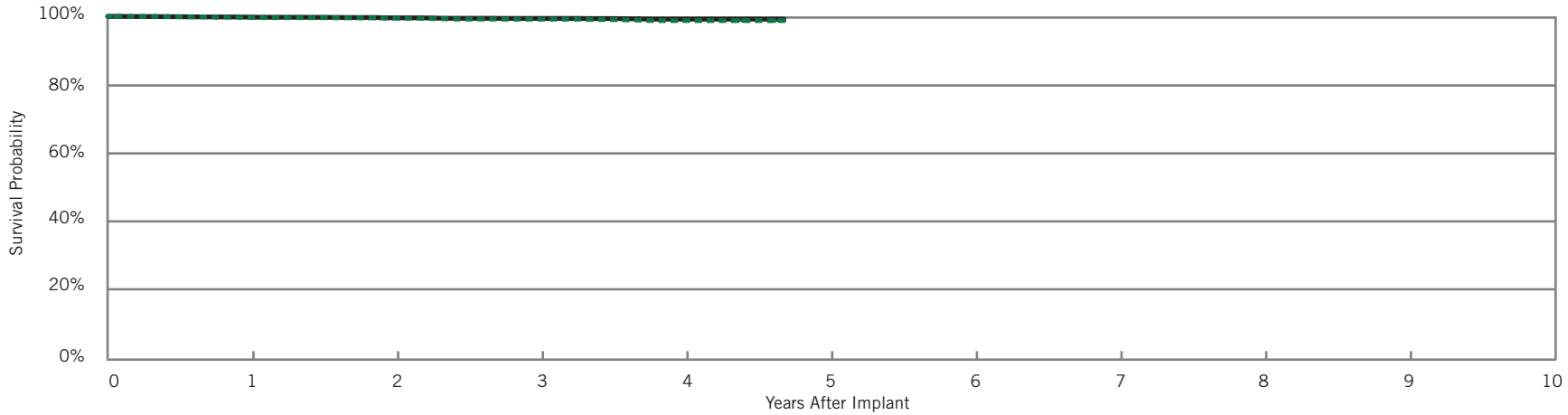
Customer Reported Performance Data

Atlas® II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,490
Estimated Active US Implants	6,780
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	10
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	2	0.02%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	5	0.05%	1	0.01%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	6	0.06%	2	0.02%
Other	5	0.05%	2	0.02%
Total	**20**	**0.19%**	**7**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.66%	99.45%	99.18%	98.76%	98.76%					
± 1 standard error	0.05%	0.08%	0.10%	0.15%	0.15%					
Sample Size	10500	8900	7000	4000	300					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.75%	99.57%	99.40%	99.18%	99.18%					
± 1 standard error	0.04%	0.07%	0.09%	0.12%	0.12%					

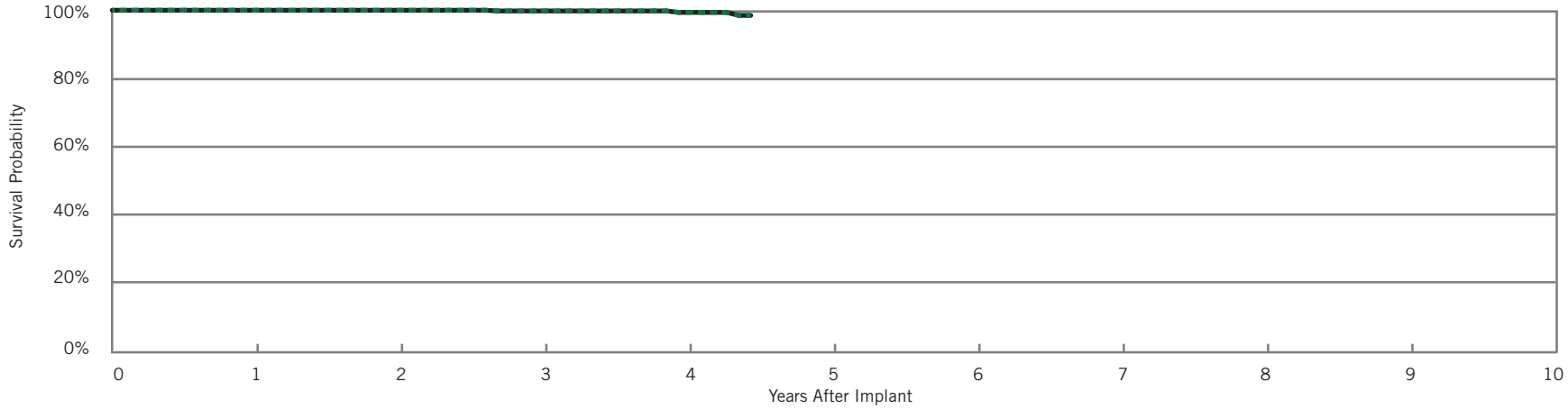
Customer Reported Performance Data

Epic® II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,572
Estimated Active US Implants	986
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	1	0.06%
Battery	0	0.00%	2	0.13%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**3**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	100.00%	100.00%	99.80%	99.38%	98.50%					
± 1 standard error	0.00%	0.00%	0.14%	0.33%	0.70%					
Sample Size	1600	1300	1100	700	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	100.00%	100.00%	99.80%	99.38%	98.50%					
± 1 standard error	0.00%	0.00%	0.14%	0.33%	0.70%					

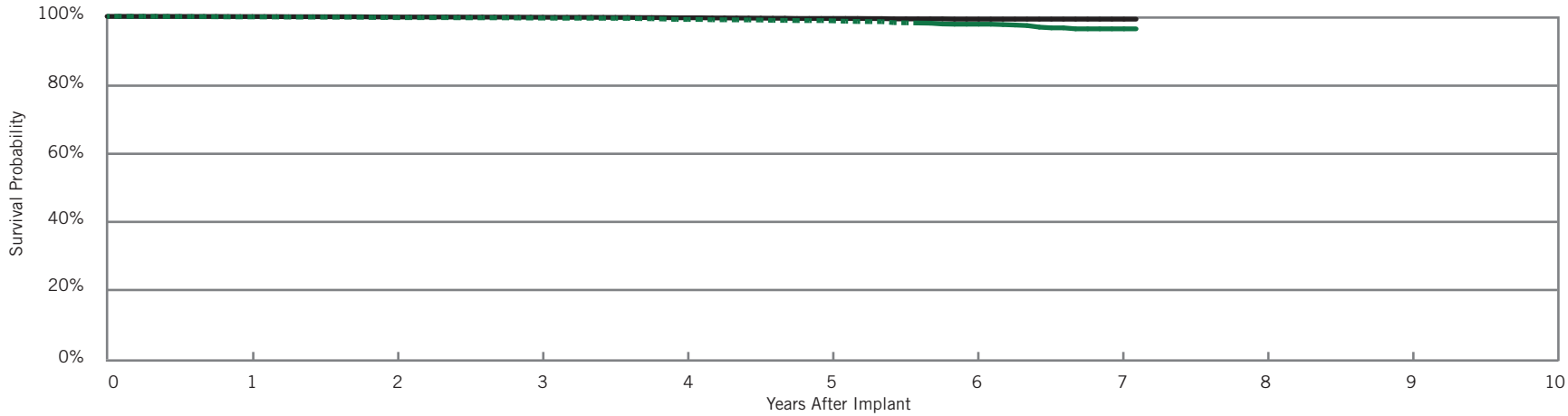
Customer Reported Performance Data

Atlas® + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,480
Estimated Active US Implants	9,955
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	56
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 234-245)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	1	<0.01%	1	<0.01%
Electrical Interconnect	4	0.02%	1	<0.01%
Battery	3	0.01%	1	<0.01%
High Voltage Capacitor	2	0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	15	0.07%	3	0.01%
Other	5	0.02%	1	<0.01%
Total	**30**	**0.15%**	**9**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.84%	99.63%	99.50%	99.10%	98.69%	97.72%	96.36%	96.36%		
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.10%	0.18%	0.40%	0.40%		
Sample Size	20500	17900	15700	12900	9300	4700	1300	300		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.95%	99.81%	99.74%	99.59%	99.39%	99.19%	99.19%	99.19%		
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.07%	0.10%	0.10%	0.10%		

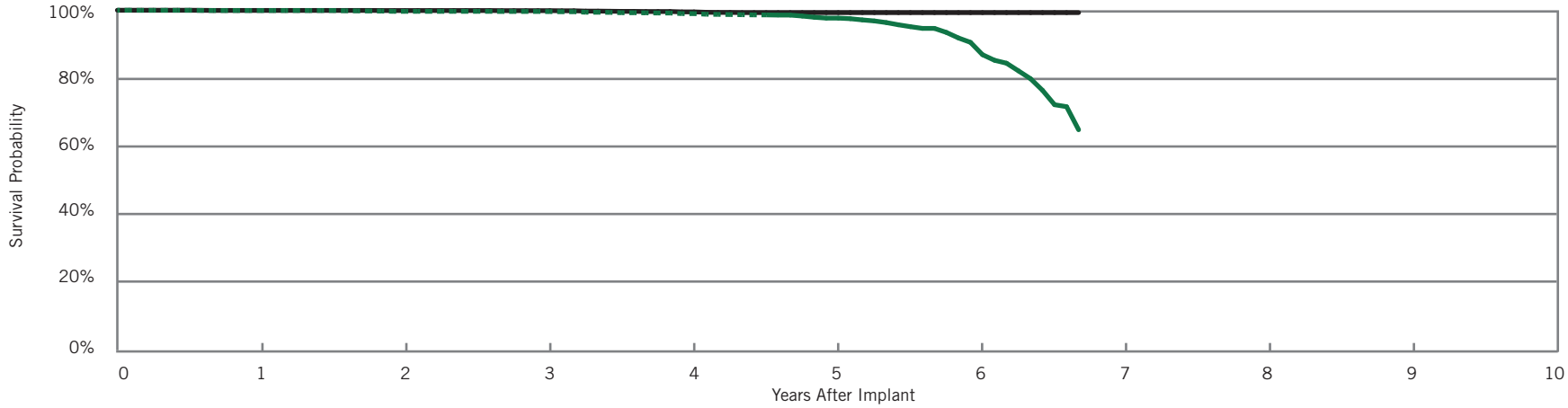
Customer Reported Performance Data

Epic® + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,805
Estimated Active US Implants	2,877
Estimated Longevity	(see table on page 100)
Normal Battery Depletion	161
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 234-245)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	12	0.15%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	0.01%	0	0.00%
Other	2	0.03%	0	0.00%
Total	**4**	**0.05%**	**12**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.92%	99.67%	99.59%	99.00%	97.68%	86.91%	64.79%			
± 1 standard error	0.03%	0.07%	0.08%	0.14%	0.23%	0.65%	1.66%			
Sample Size	7800	6900	6100	5200	4000	2300	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.95%	99.91%	99.88%	99.51%	99.30%	99.30%	99.30%			
± 1 standard error	0.03%	0.04%	0.04%	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
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
CD1231-40Q	Fortify® VR	99.97%									
CD1231-40	Fortify® VR	100.00%									
CD1211-36Q	Current® + VR	99.66%									
CD1211-36	Current® + VR	99.87%	99.87%								
1207-30	Current® VR RF	100.00%	100.00%								
1207-36	Current® VR RF	99.66%	99.48%	99.24%							
V-168	Atlas® II VR	99.66%	99.45%	99.18%	98.76%						
V-158	Epic® II VR	100.00%	100.00%	99.80%	99.38%						
V-193	Atlas® + VR	99.84%	99.63%	99.50%	99.10%	98.69%	97.72%	96.36%			
V-196	Epic® + VR	99.92%	99.67%	99.59%	99.00%	97.68%	86.91%				

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1231-40Q	Fortify® VR	99.97%									
CD1231-40	Fortify® VR	100.00%									
CD1211-36Q	Current® + VR	99.66%									
CD1211-36	Current® + VR	99.87%	99.87%								
1207-30	Current® VR RF	100.00%	100.00%								
1207-36	Current® VR RF	99.71%	99.57%	99.33%							
V-168	Atlas® II VR	99.75%	99.57%	99.40%	99.18%						
V-158	Epic® II VR	100.00%	100.00%	99.80%	99.37%						
V-193	Atlas® + VR	99.95%	99.81%	99.74%	99.59%	99.39%	99.19%	99.19%			
V-196	Epic® + VR	99.95%	99.91%	99.88%	99.51%	99.30%	99.30%				

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify® VR	6823	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
CD1231-40	Fortify® VR	2840	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	Current® + VR	4431	1	0.02%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.05%**
CD1211-36	Current® + VR	3237	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.03%**
1207-30	Current® VR RF	875	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current® VR RF	13157	5	0.04%	4	0.03%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	**14**	**0.11%**
V-168	Atlas® II VR	10490	1	0.01%	1	0.01%	5	0.05%	1	0.01%	0	0.00%	1	0.01%	6	0.06%	5	0.05%	**20**	**0.19%**
V-158	Epic® II VR	1572	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
V-193	Atlas® + VR	20480	1	<0.01%	4	0.02%	3	0.01%	2	0.01%	0	0.00%	0	0.00%	15	0.07%	5	0.02%	**30**	**0.15%**
V-196	Epic® + VR	7805	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	**4**	**0.05%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify® VR	6823	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1231-40	Fortify® VR	2840	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	Current® + VR	4431	2	0.05%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**4**	**0.09%**
CD1211-36	Current® + VR	3237	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.03%**
1207-30	Current® VR RF	875	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current® VR RF	13157	2	0.02%	0	0.00%	3	0.02%	0	0.00%	1	0.01%	0	0.00%	3	0.02%	2	0.02%	**11**	**0.08%**
V-168	Atlas® II VR	10490	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	2	0.02%	**7**	**0.07%**
V-158	Epic® II VR	1572	0	0.00%	1	0.06%	2	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.19%**
V-193	Atlas® + VR	20480	1	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	1	<0.01%	0	0.00%	3	0.01%	1	<0.01%	**9**	**0.04%**
V-196	Epic® + VR	7805	0	0.00%	0	0.00%	12	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**12**	**0.15%**

Definitions of malfunction root cause categories can be found on page 7.

Defibrillation Leads

St. Jude Medical™
More control. Less risk.

Customer Reported Performance Data

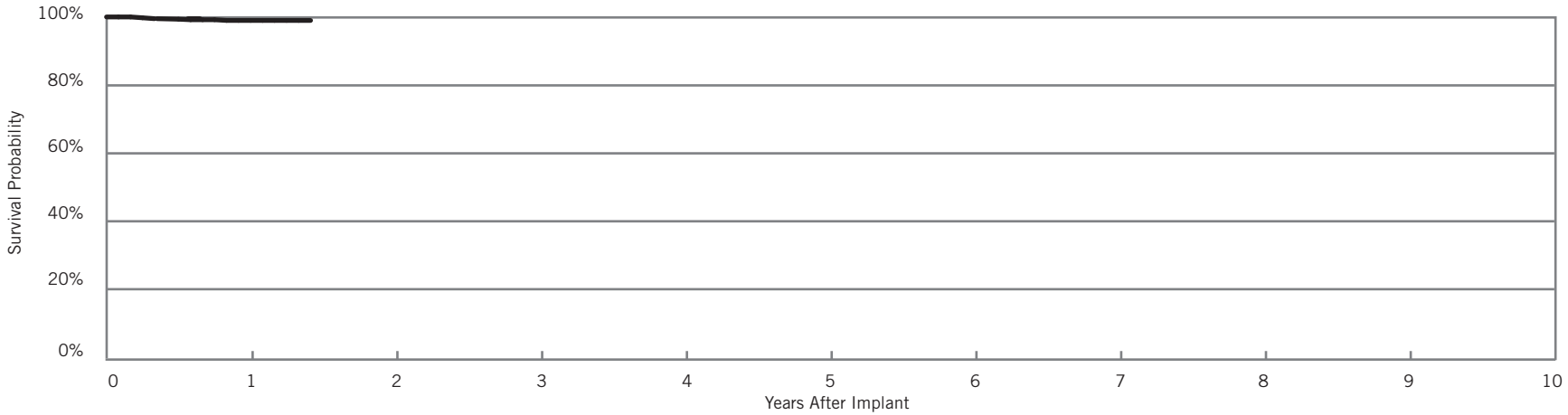
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	1,740
Estimated Active US Implants	1,538
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	0.06%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.11%	2	0.11%
Failure to Capture	1	0.06%	6	0.34%
Oversensing	0	0.00%	1	0.06%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	1	0.06%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.23%**	**10**	**0.57%**
Total Returned for Analysis	**3**		**6**	

Lead 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 Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.34%
Total	**6**	**0.34%**



Year	1	at 17 months								
Survival Probability	98.95%	98.95%								
± 1 standard error	0.28%	0.28%								
Sample Size	700	200								

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

Customer Reported Performance Data

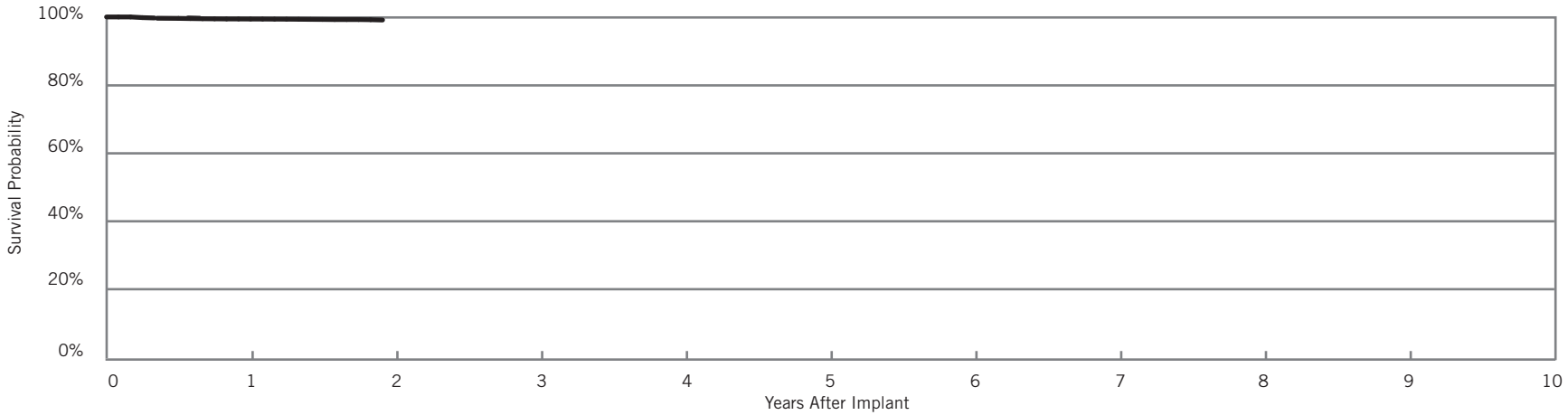
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	42,871
Estimated Active US Implants	37,926
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	23	0.05%	7	0.02%
Conductor Fracture	0	0.00%	6	0.01%
Lead Dislodgement	70	0.16%	112	0.26%
Failure to Capture	34	0.08%	41	0.10%
Oversensing	21	0.05%	20	0.05%
Failure to Sense	6	0.01%	5	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	<0.01%	1	<0.01%
Abnormal Defibrillation Impedance	1	<0.01%	6	0.01%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	4	0.01%	4	0.01%
Total	**162**	**0.38%**	**203**	**0.47%**
Total Returned for Analysis	**90**		**171**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	4	0.01%
Clavicular Crush	0	0.00%
In the Pocket	2	<0.01%
Intravascular	2	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Others	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.01%
Extrinsic Factors	122	0.28%
Total	**131**	**0.31%**



Year	1	at 23 months								
Survival Probability	99.37%	99.08%								
± 1 standard error	0.04%	0.12%								
Sample Size	30700	600								

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

SCORE Registry Performance Data

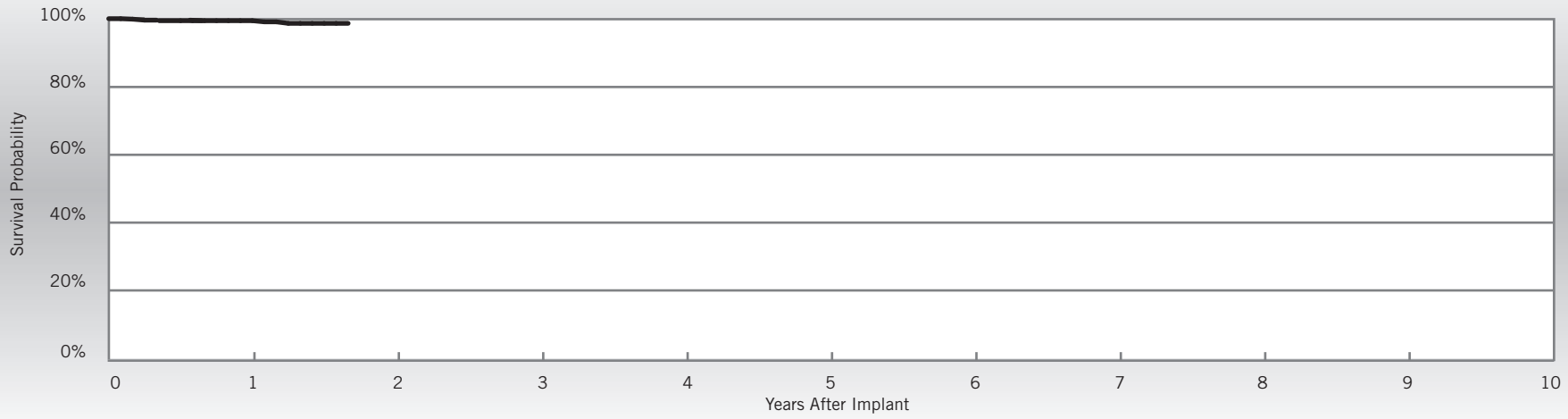
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	736
Cumulative Months of Follow-up	8,043
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	2	0.27%
Failure to Capture	1	0.14%
Lead Dislodgement	3	0.41%

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	0.68%
Total	**5**	**0.68%**



Year	1	at 20 months								
Survival Probability	99.40%	98.60%								
± 1 standard error	0.29%	0.60%								
Sample Size	520	70								

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

Customer Reported Performance Data

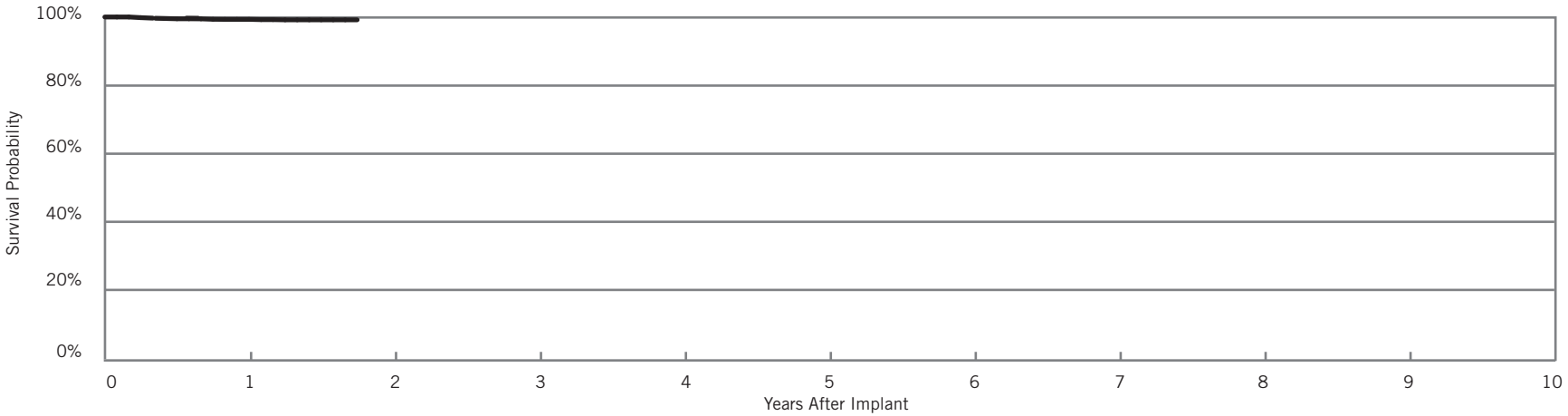
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	7,403
Estimated Active US Implants	6,602
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.08%	4	0.05%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	11	0.15%	19	0.26%
Failure to Capture	11	0.15%	5	0.07%
Oversensing	4	0.05%	6	0.08%
Failure to Sense	3	0.04%	2	0.03%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	1	0.01%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.04%	0	0.00%
Total	**39**	**0.53%**	**37**	**0.50%**
Total Returned for Analysis	**28**		**32**	

Lead 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	0	0.00%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	25	0.34%
Total	**27**	**0.36%**



Year	1	at 21 months								
Survival Probability	99.21%	99.15%								
± 1 standard error	0.12%	0.14%								
Sample Size	5000	300								

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

SCORE Registry Performance Data

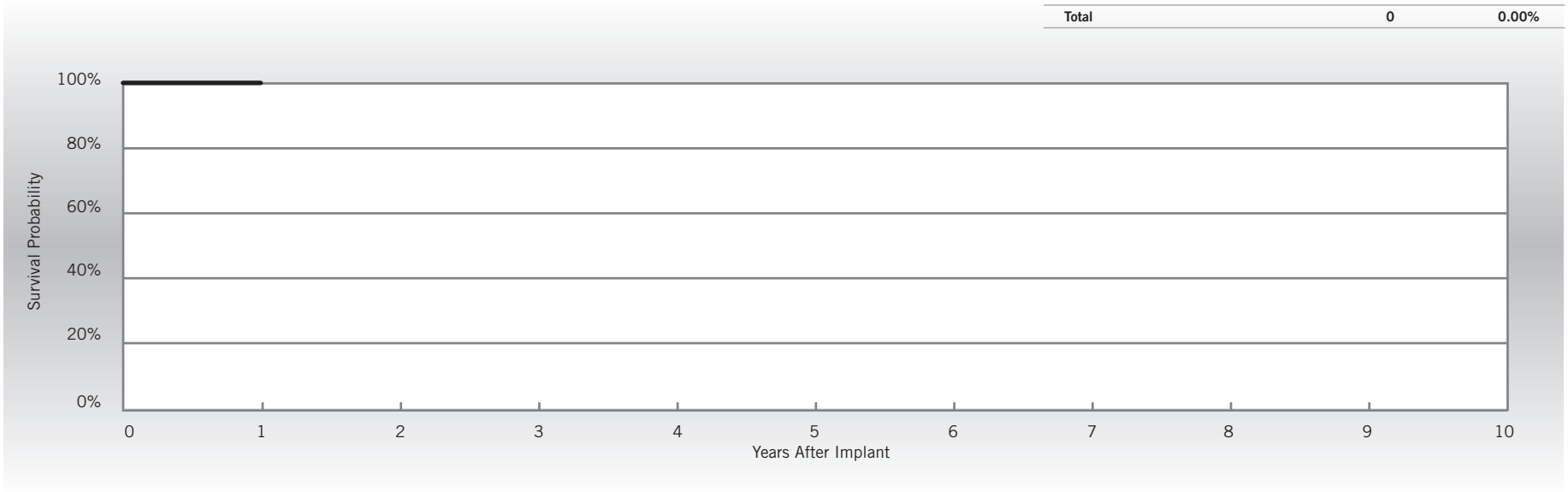
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	145
Cumulative Months of Follow-up	1,526
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	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	100									

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

Customer Reported Performance Data

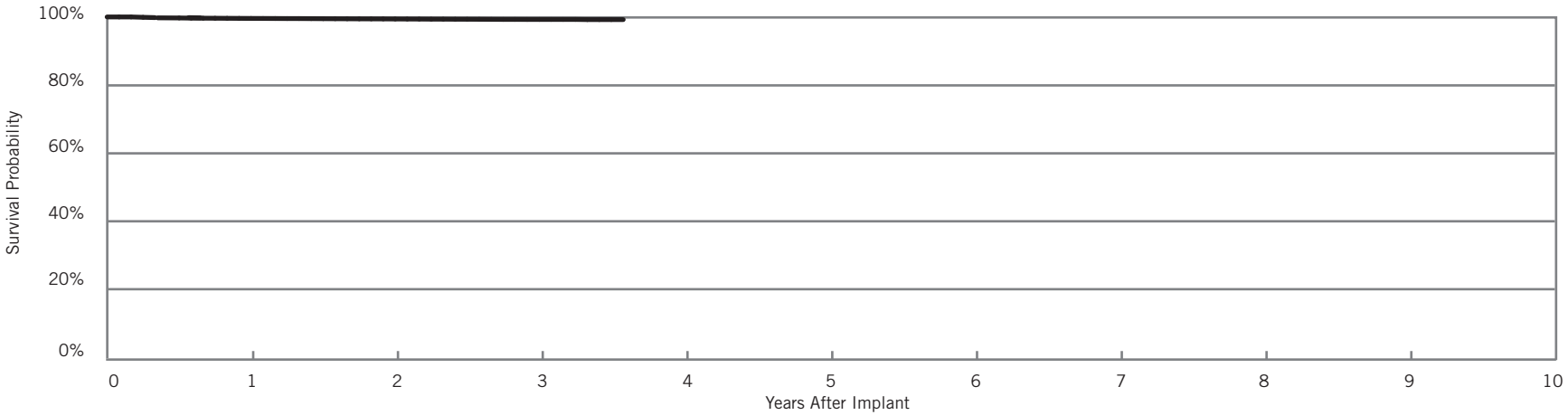
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	53,161
Estimated Active US Implants	41,241
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	31	0.06%	4	0.01%
Conductor Fracture	1	<0.01%	9	0.02%
Lead Dislodgement	66	0.12%	113	0.21%
Failure to Capture	17	0.03%	50	0.09%
Oversensing	44	0.08%	55	0.10%
Failure to Sense	4	0.01%	11	0.02%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	1	<0.01%	10	0.02%
Abnormal Defibrillation Impedance	17	0.03%	16	0.03%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	15	0.03%	11	0.02%
Total	**197**	**0.37%**	**280**	**0.53%**
Total Returned for Analysis	**81**		**197**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	9	0.02%
Clavicular Crush	0	0.00%
In the Pocket	7	0.01%
Intravascular	2	<0.01%
Insulation Breach	6	0.01%
Lead-to-Can Contacts	2	<0.01%
Lead-to-Lead Contacts	2	<0.01%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Others	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	2	<0.01%
Extrinsic Factors	120	0.23%
Total	**138**	**0.26%**



Year	1	2	3	at 43 months						
Survival Probability	99.55%	99.38%	99.25%	99.21%						
± 1 standard error	0.03%	0.04%	0.05%	0.06%						
Sample Size	49600	35300	16500	300						

SCORE Registry Performance Data

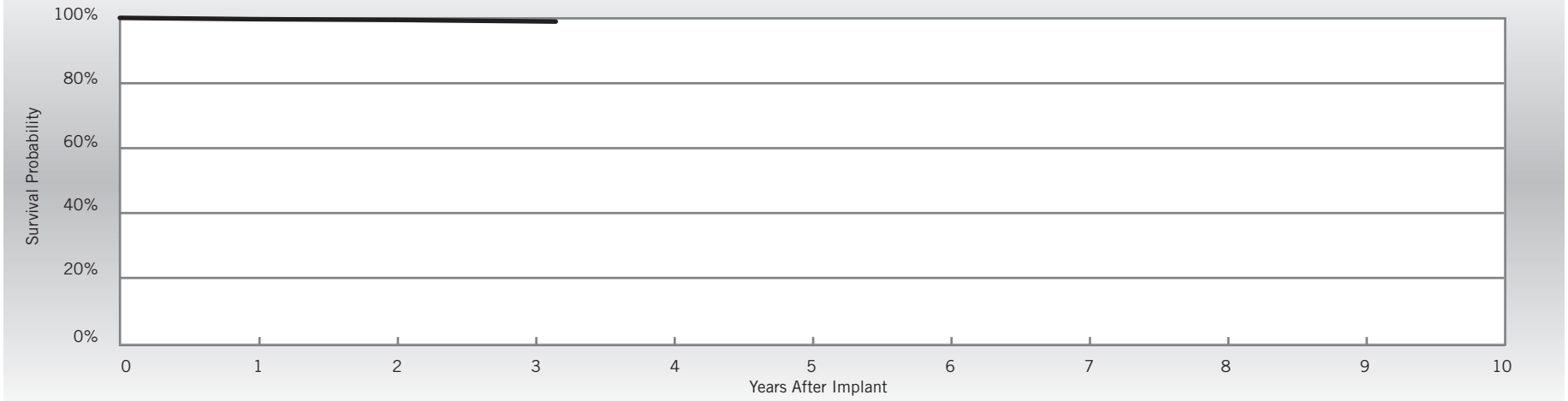
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,490
Cumulative Months of Follow-up	33,880
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	2	0.13%
Extracardiac Stimulation	1	0.07%
Failure to Capture	2	0.13%
Lead Dislodgement	5	0.34%
Oversensing	1	0.07%

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



Year	1	2	3	at 38 months						
Survival Probability	99.58%	99.36%	98.84%	98.84%						
± 1 standard error	0.17%	0.23%	0.37%	0.37%						
Sample Size	1330	950	430	70						

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

Customer Reported Performance Data

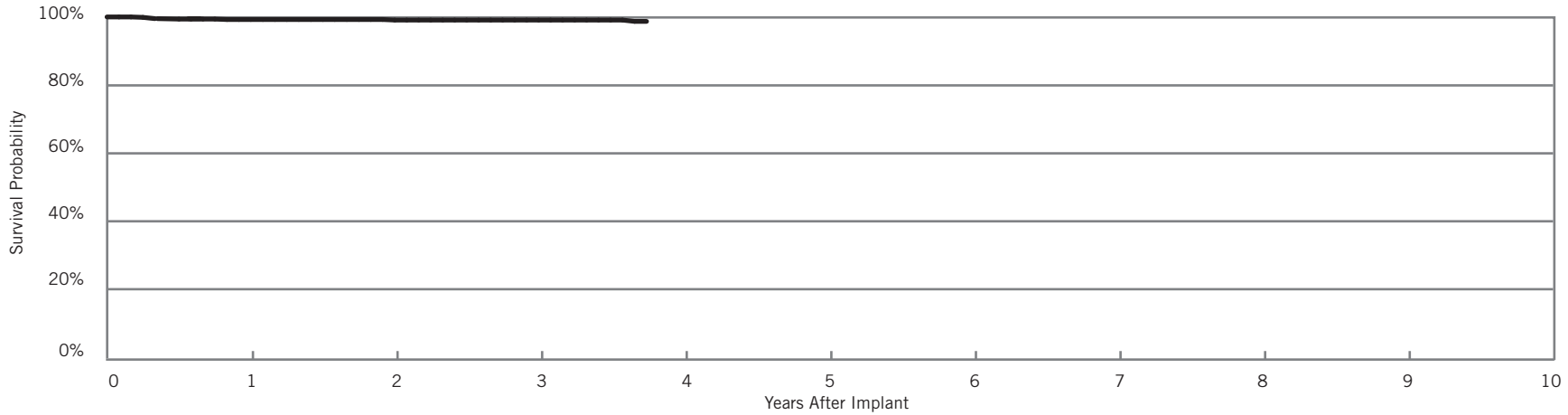
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	851
Estimated Active US Implants	547
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	1	0.12%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	5	0.59%	0	0.00%
Failure to Capture	0	0.00%	4	0.47%
Oversensing	2	0.24%	6	0.71%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	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	**7**	**0.82%**	**12**	**1.41%**
Total Returned for Analysis	**3**		**2**	

Lead 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 Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	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 45 months						
Survival Probability	99.23%	99.07%	99.07%	98.67%						
± 1 standard error	0.31%	0.35%	0.35%	0.53%						
Sample Size	800	700	500	200						

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

Customer Reported Performance Data

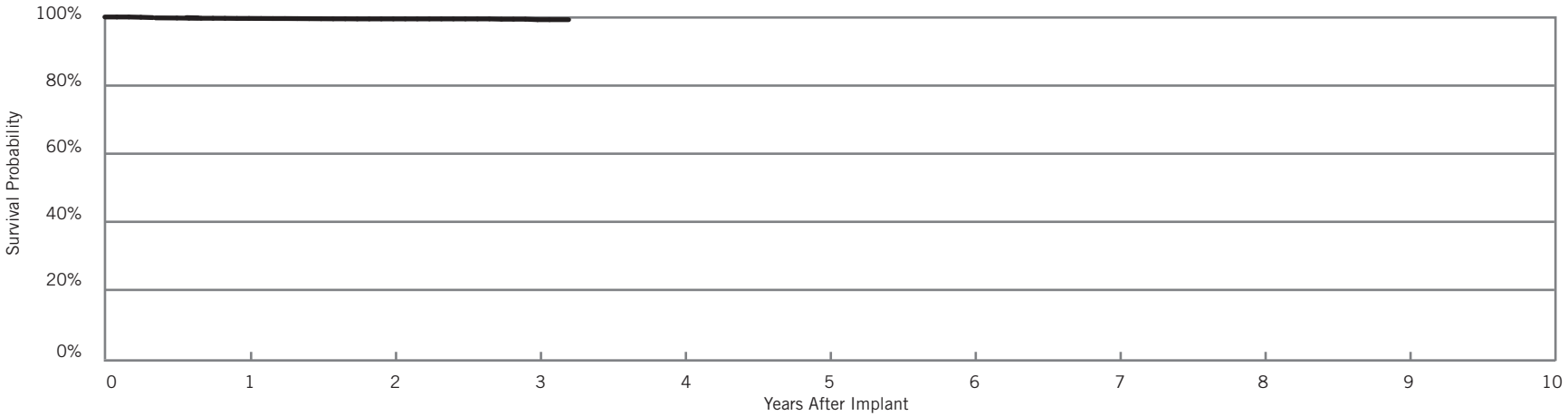
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	8,362
Estimated Active US Implants	6,779
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.05%	1	0.01%
Conductor Fracture	1	0.01%	2	0.02%
Lead Dislodgement	8	0.10%	13	0.16%
Failure to Capture	6	0.07%	10	0.12%
Oversensing	3	0.04%	6	0.07%
Failure to Sense	0	0.00%	3	0.04%
Insulation Breach	0	0.00%	2	0.02%
Abnormal Pacing Impedance	1	0.01%	4	0.05%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	**24**	**0.29%**	**44**	**0.53%**
Total Returned for Analysis	**12**		**40**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	0.04%
Clavicular Crush	0	0.00%
In the Pocket	2	0.02%
Intravascular	1	0.01%
Insulation Breach	3	0.04%
Lead-to-Can Contacts	1	0.01%
Lead-to-Lead Contacts	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	24	0.29%
Total	**30**	**0.36%**



Year	1	2	3	at 38 months						
Survival Probability	99.56%	99.43%	99.34%	99.19%						
± 1 standard error	0.08%	0.09%	0.20%	0.20%						
Sample Size	7200	4300	600	300						

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

SCORE Registry Performance Data

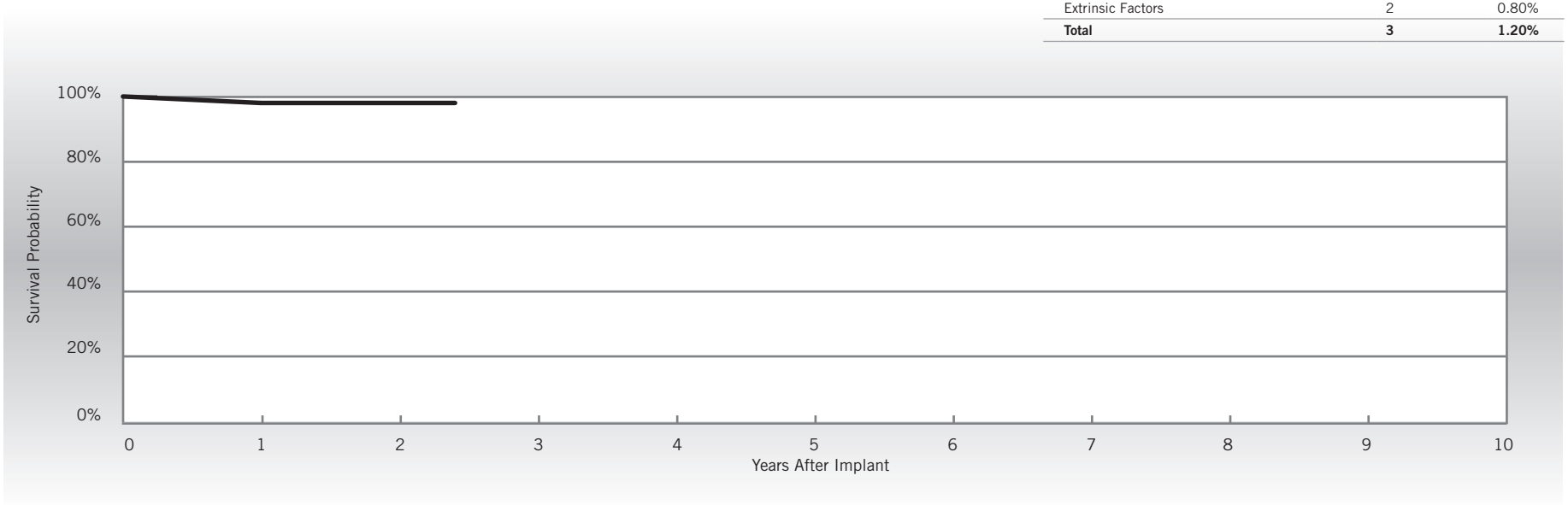
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	251
Cumulative Months of Follow-up	4,509
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.40%
Lead Dislodgement	3	1.20%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.40%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.40%
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	0.80%
Total	**3**	**1.20%**



Year	1	2	at 28 months							
Survival Probability	97.96%	97.96%	97.96%							
± 1 standard error	1.00%	1.00%	1.00%							
Sample Size	210	120	60							

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

Customer Reported Performance Data

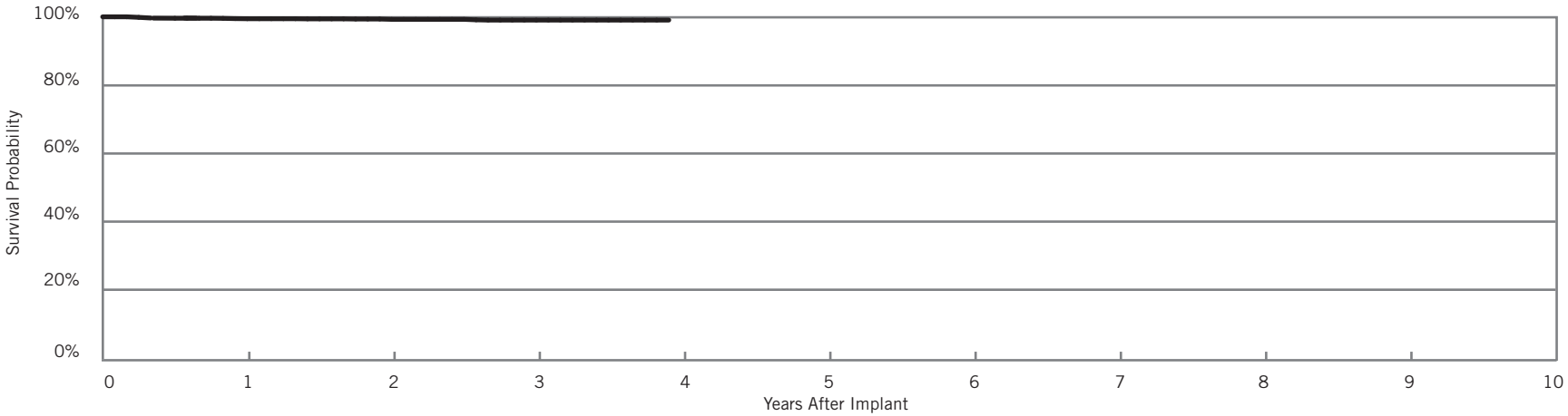
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,296
Estimated Active US Implants	2,423
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	2	0.06%	2	0.06%
Conductor Fracture	1	0.03%	2	0.06%
Lead Dislodgement	3	0.09%	4	0.12%
Failure to Capture	5	0.15%	4	0.12%
Oversensing	4	0.12%	6	0.18%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.06%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**18**	**0.55%**	**23**	**0.70%**
Total Returned for Analysis	**8**		**8**	

Lead 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 Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	1	0.03%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.15%
Total	**7**	**0.21%**



Year	1	2	3	at 47 months						
Survival Probability	99.42%	99.24%	99.02%	99.02%						
± 1 standard error	0.14%	0.17%	0.21%	0.21%						
Sample Size	3100	2300	1400	200						

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

SCORE Registry Performance Data

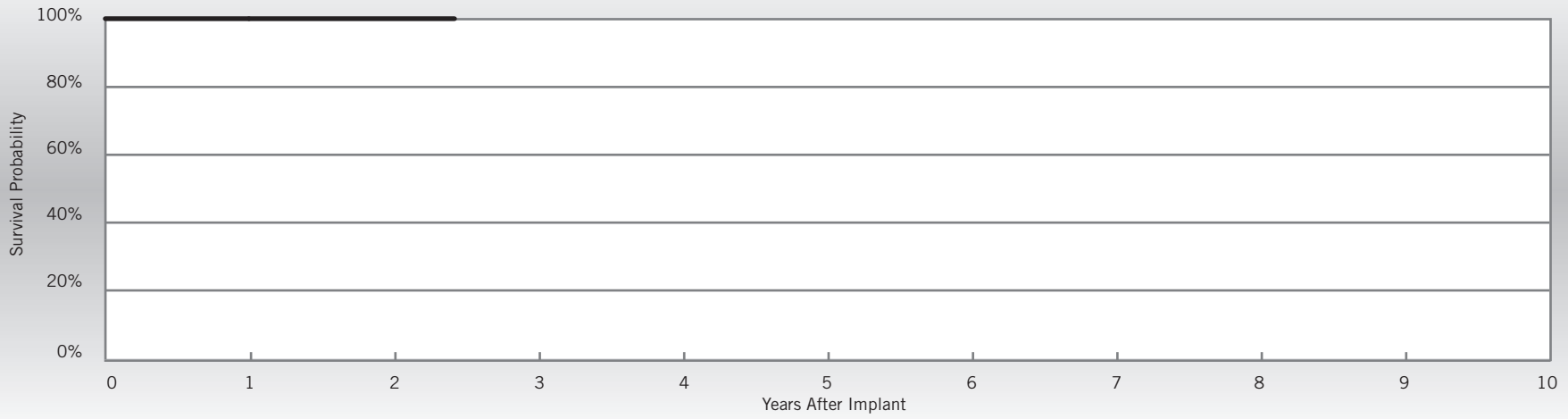
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	150
Cumulative Months of Follow-up	3511
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	0.67%
Total	**1**	**0.67%**



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	140	100	60							

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

Customer Reported Performance Data

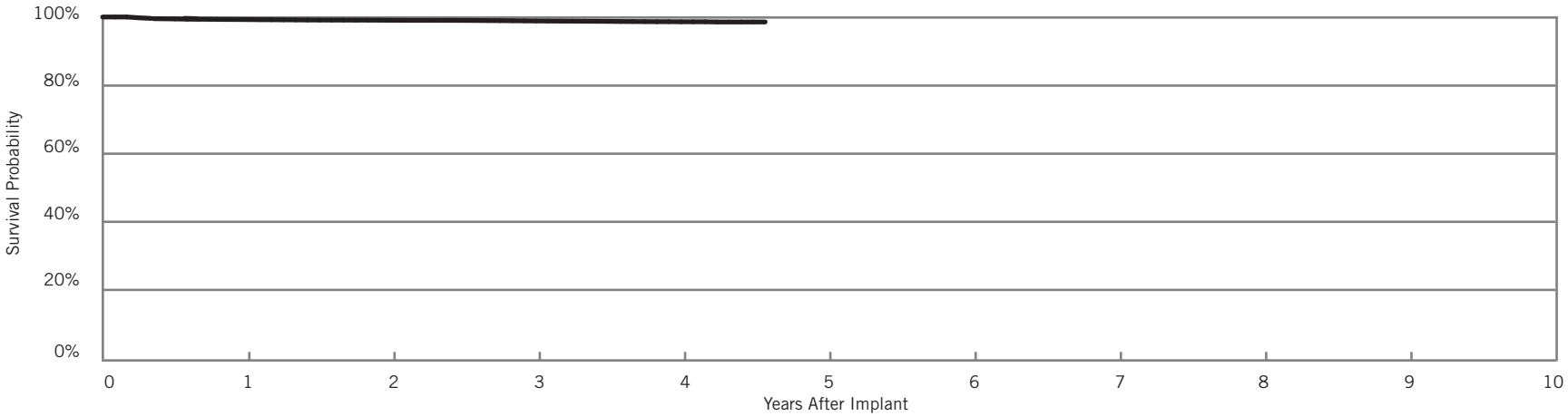
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,461
Estimated Active US Implants	10,148
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	38	0.25%	10	0.06%
Conductor Fracture	0	0.00%	4	0.03%
Lead Dislodgement	34	0.22%	47	0.30%
Failure to Capture	19	0.12%	39	0.25%
Oversensing	19	0.12%	46	0.30%
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%	7	0.05%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	13	0.08%
Total	**127**	**0.82%**	**184**	**1.19%**
Total Returned for Analysis	**62**		**132**	

Lead 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	10	0.06%
Lead-to-Can Contacts	3	0.02%
Lead-to-Lead Contacts	3	0.02%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Others	3	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	87	0.56%
Total	**102**	**0.66%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.19%	99.00%	98.79%	98.57%	98.51%					
± 1 standard error	0.07%	0.08%	0.09%	0.11%	0.13%					
Sample Size	15100	13000	10900	6100	200					

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

SCORE Registry Performance Data

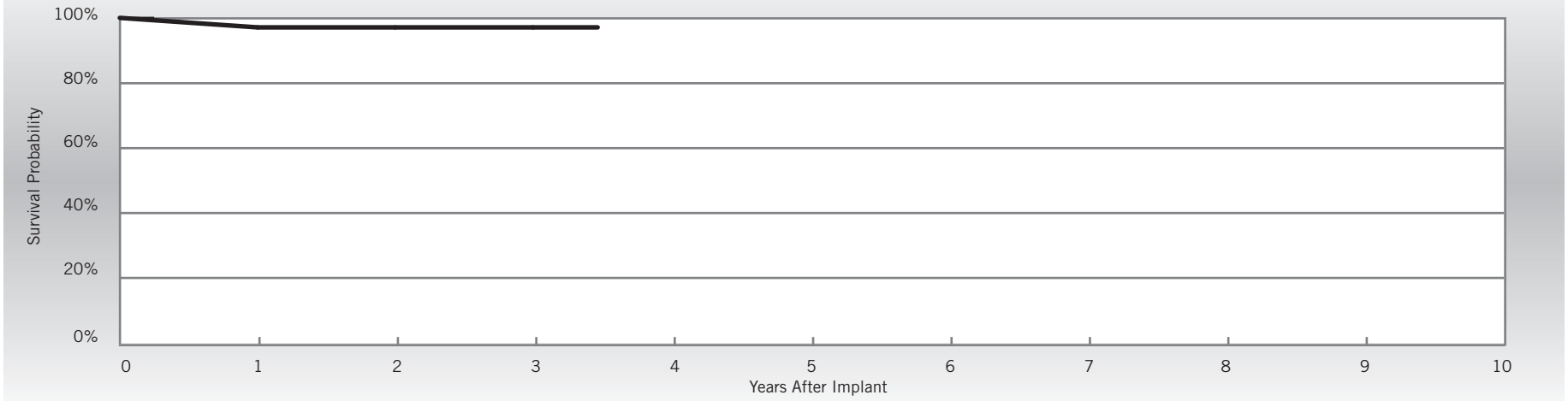
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	176
Cumulative Months of Follow-up	5,628
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

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

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.57%
Clavicular Crush	0	0.00%
In the Pocket	1	0.57%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.57%
Total	**2**	**1.14%**



Year	1	2	3	at 41 months						
Survival Probability	97.01%	97.01%	97.01%	97.01%						
± 1 standard error	1.31%	1.31%	1.31%	1.31%						
Sample Size	170	140	110	70						

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

Customer Reported Performance Data

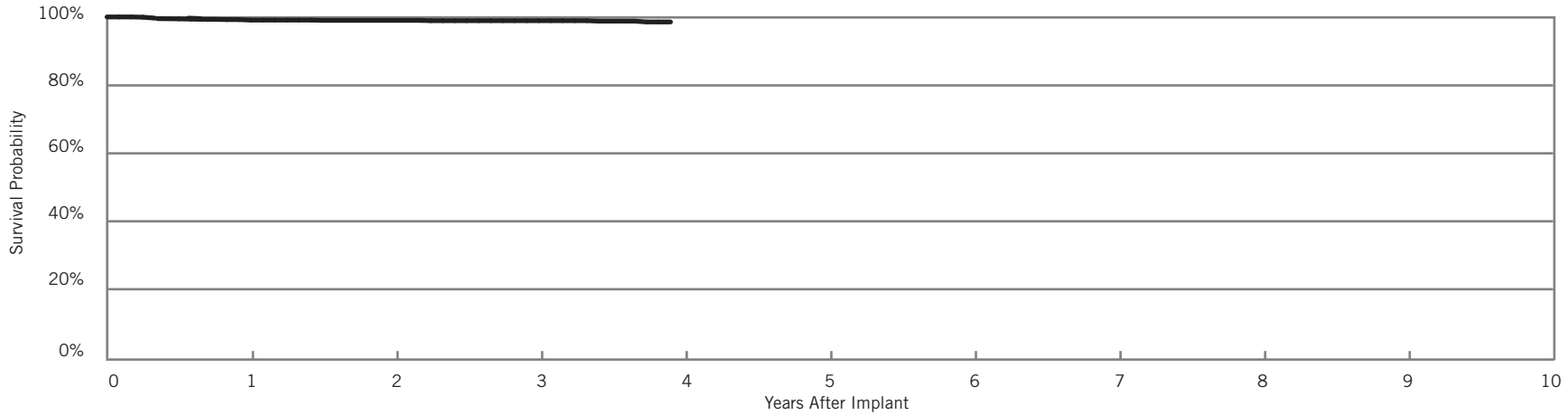
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,483
Estimated Active US Implants	975
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	5	0.34%	3	0.20%
Conductor Fracture	0	0.00%	3	0.20%
Lead Dislodgement	3	0.20%	6	0.40%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	5	0.34%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.13%	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	**11**	**0.74%**	**18**	**1.21%**
Total Returned for Analysis	**4**		**13**	

Lead 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 Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.54%
Total	**9**	**0.61%**



Year	1	2	3	at 47 months						
Survival Probability	99.06%	98.98%	98.89%	97.97%						
± 1 standard error	0.26%	0.27%	0.29%	0.40%						
Sample Size	1400	1300	1000	200						

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

Customer Reported Performance Data

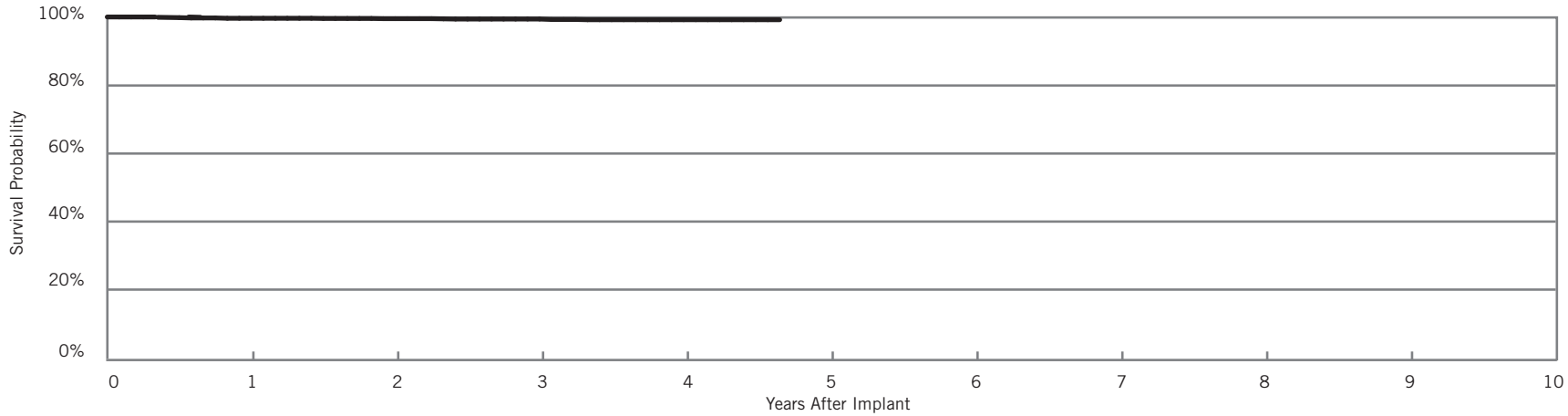
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,208
Estimated Active US Implants	1,355
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) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.05%	5	0.23%
Failure to Capture	3	0.14%	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%**	**14**	**0.63%**
Total Returned for Analysis	**5**		**9**	

Lead 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	0.09%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	2	0.09%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.18%
Total	**6**	**0.27%**



Year	1	2	3	4	at 56 months					
Survival Probability	99.61%	99.50%	99.38%	99.17%	99.17%					
± 1 standard error	0.14%	0.16%	0.18%	0.22%	0.22%					
Sample Size	2200	1900	1700	1200	200					

Customer Reported Performance Data

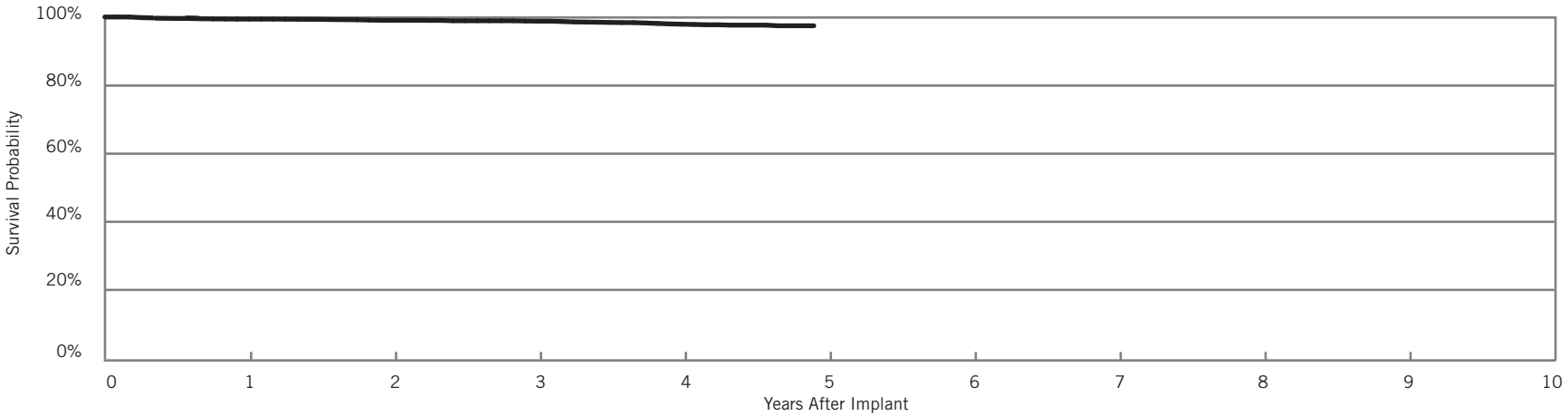
Riata® ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,088
Estimated Active US Implants	2,618
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	6	0.15%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	1	0.02%	9	0.22%
Oversensing	3	0.07%	19	0.46%
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%**	**50**	**1.22%**
Total Returned for Analysis	**4**		**20**	

Lead 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	8	0.20%
Lead-to-Can Contacts	5	0.12%
Lead-to-Lead Contacts	2	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	1	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.15%
Total	**16**	**0.39%**



Year	1	2	3	4	at 59 months					
Survival Probability	99.37%	99.01%	98.75%	97.76%	97.37%					
± 1 standard error	0.13%	0.16%	0.19%	0.30%	0.39%					
Sample Size	4000	3400	2800	1800	200					

Customer Reported Performance Data

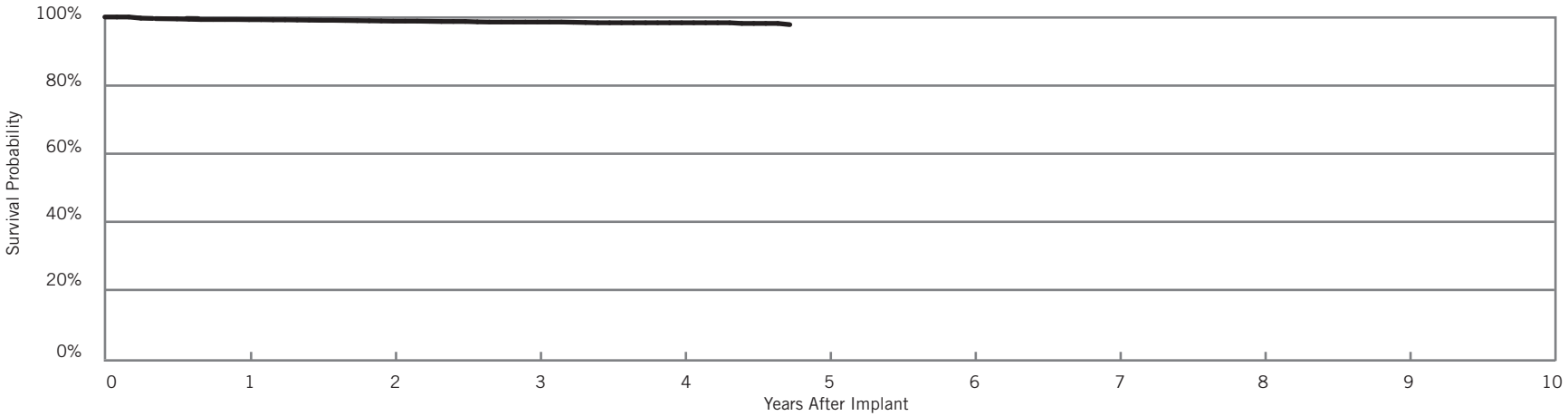
Riata® ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,413
Estimated Active US Implants	1,508
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.25%	2	0.08%
Conductor Fracture	0	0.00%	3	0.12%
Lead Dislodgement	3	0.12%	9	0.37%
Failure to Capture	4	0.17%	7	0.29%
Oversensing	4	0.17%	11	0.46%
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%	3	0.12%
Total	**21**	**0.87%**	**36**	**1.49%**
Total Returned for Analysis	**10**		**18**	

Lead 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 Contacts	2	0.08%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	10	0.41%
Total	**14**	**0.58%**



Year	1	2	3	4	at 57 months					
Survival Probability	99.21%	98.76%	98.49%	98.28%	97.71%					
± 1 standard error	0.19%	0.24%	0.27%	0.29%	0.51%					
Sample Size	2400	2100	1800	1100	200					

Customer Reported Performance Data

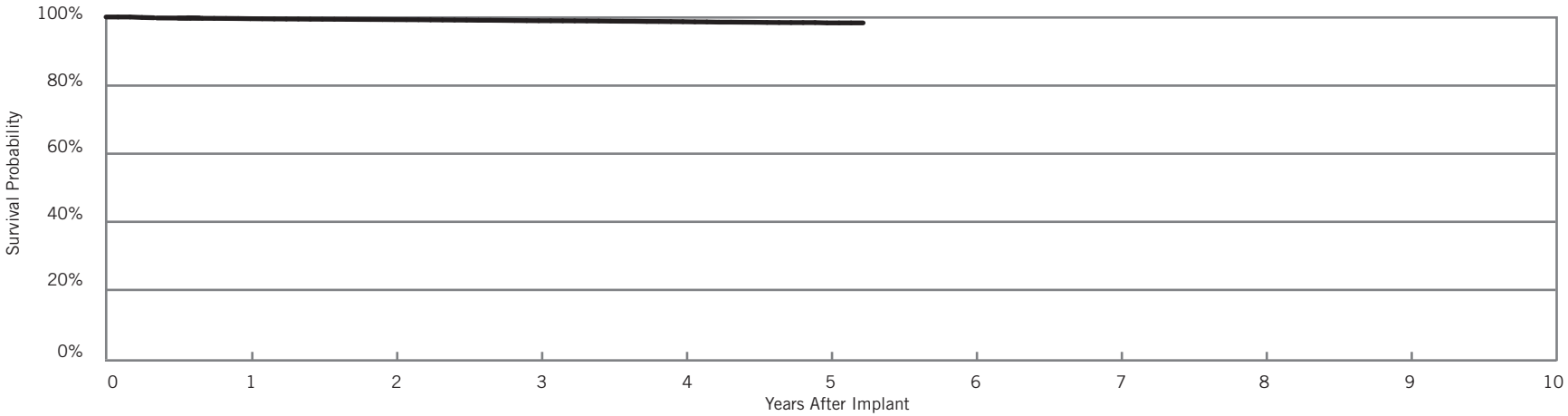
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,925
Estimated Active US Implants	21,523
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	41	0.12%	18	0.05%
Conductor Fracture	0	0.00%	23	0.07%
Lead Dislodgement	37	0.11%	39	0.11%
Failure to Capture	43	0.12%	72	0.21%
Oversensing	40	0.11%	171	0.49%
Failure to Sense	7	0.02%	19	0.05%
Insulation Breach	1	<0.01%	9	0.03%
Abnormal Pacing Impedance	8	0.02%	11	0.03%
Abnormal Defibrillation Impedance	4	0.01%	12	0.03%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	11	0.03%	29	0.08%
Total	**196**	**0.56%**	**405**	**1.16%**
Total Returned for Analysis	**103**		**233**	

Lead 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	80	0.23%
Lead-to-Can Contacts	58	0.17%
Lead-to-Lead Contacts	11	0.03%
Clavicular Crush	2	0.01%
Externalized Conductors	1	<0.01%
Others	8	0.02%
Crimps, Welds & Bonds	1	0.00%
Other	0	0.00%
Extrinsic Factors	94	0.27%
Total	**185**	**0.53%**



Year	1	2	3	4	5	at 63 months				
Survival Probability	99.47%	99.20%	98.88%	98.55%	98.23%	98.23%				
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.10%	0.10%				
Sample Size	34300	30100	26100	19200	2700	500				

SCORE Registry Performance Data

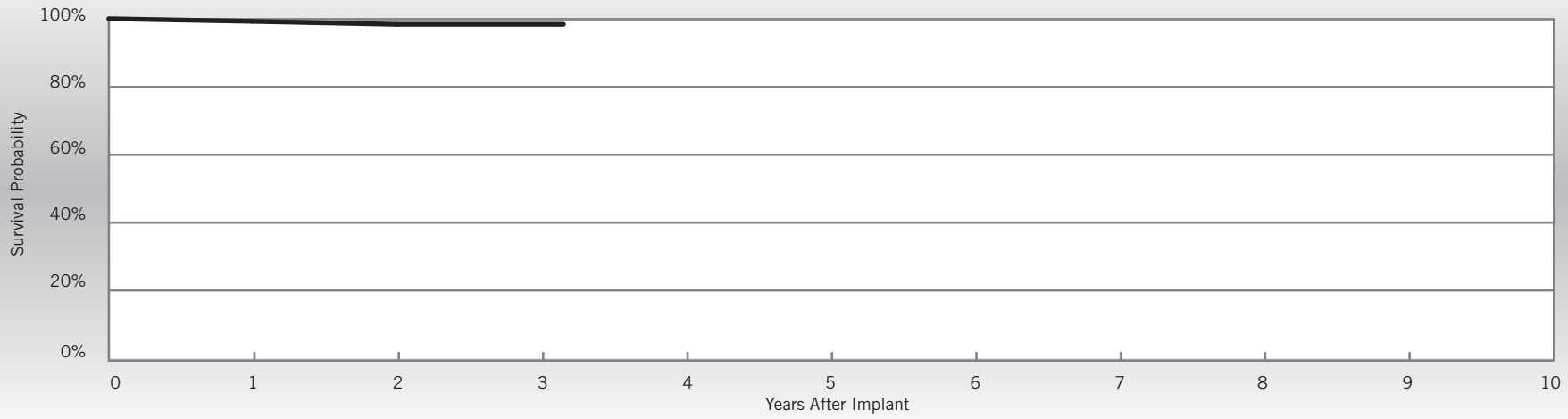
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	128
Cumulative Months of Follow-up	3,946
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.78%
Oversensing	1	0.78%

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	1.56%
Lead-to-Can Contact	1	0.78%
Lead-to-Lead Contact	1	0.78%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.78%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**3**	**2.34%**



Year	1	2	3	at 38 months						
Survival Probability	99.20%	98.32%	98.32%	98.32%						
± 1 standard error	0.79%	1.17%	1.17%	1.17%						
Sample Size	120	100	70	50						

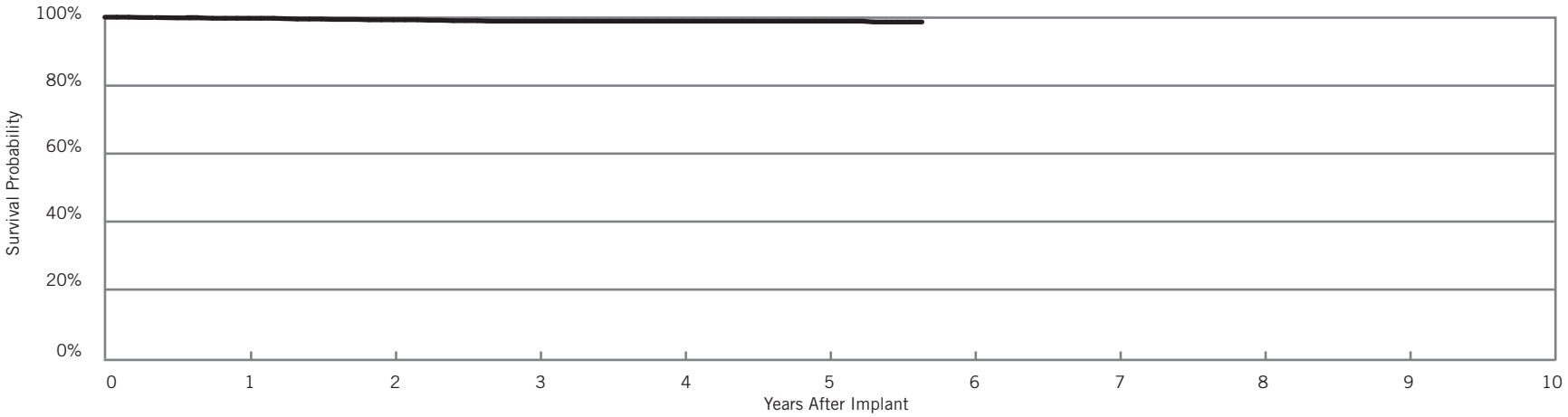
Customer Reported Performance Data

Riata® *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,008
Estimated Active US Implants	503
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

Lead 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 Contacts	1	0.10%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	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 68 months				
Survival Probability	99.68%	99.20%	98.81%	98.81%	98.81%	98.55%				
± 1 standard error	0.19%	0.30%	0.38%	0.38%	0.38%	0.45%				
Sample Size	1000	900	800	700	600	200				

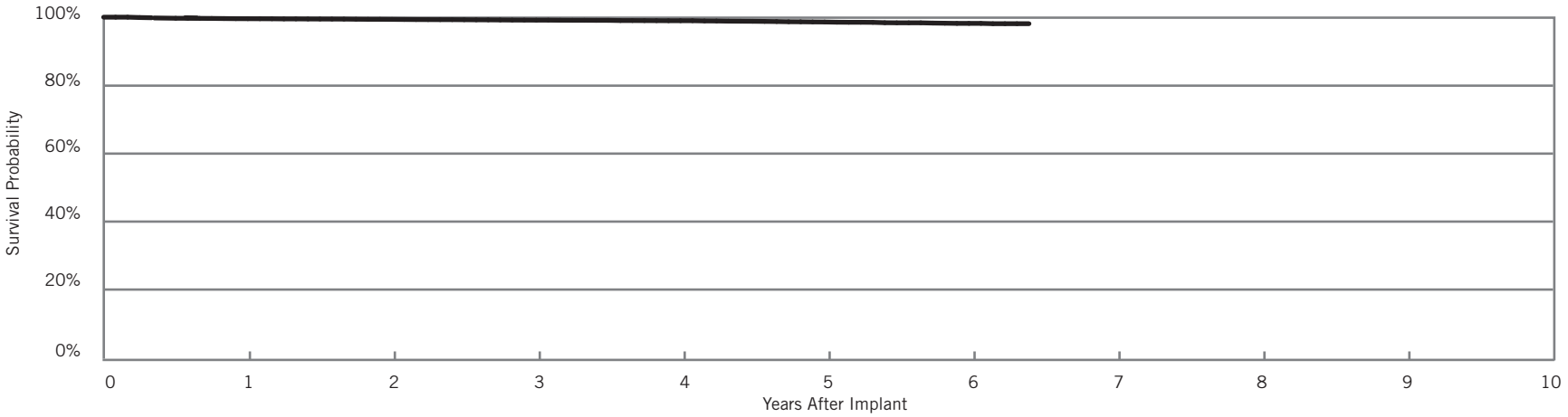
Customer Reported Performance Data

Riata® *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,753
Estimated Active US Implants	5,104
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	3	0.03%
Insulation Breach	14	0.14%
Lead-to-Can Contacts	7	0.07%
Lead-to-Lead Contacts	3	0.03%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	4	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	16	0.16%
Total	**34**	**0.35%**



Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.53%	99.31%	99.11%	98.94%	98.49%	98.04%	97.62%			
± 1 standard error	0.07%	0.09%	0.10%	0.11%	0.14%	0.21%	0.21%			
Sample Size	9600	8500	7700	6700	5500	900	300			

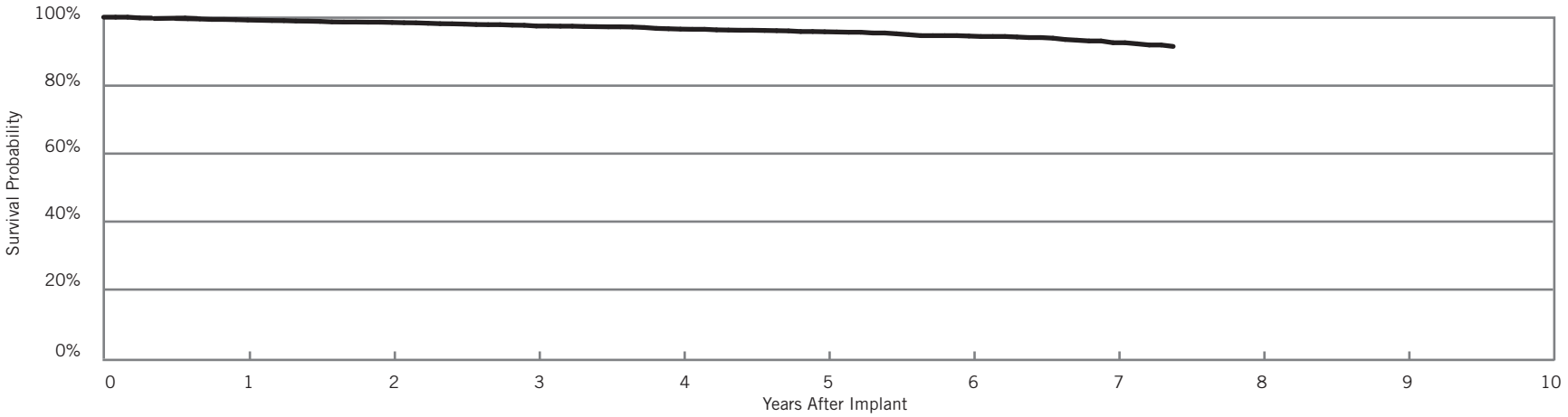
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,189
Estimated Active US Implants	1,480
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead 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	44	1.38%
Lead-to-Can Contacts	24	0.75%
Lead-to-Lead Contacts	4	0.13%
Clavicular Crush	1	0.03%
Externalized Conductors	5	0.16%
Others	10	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.44%
Total	**60**	**1.88%**



Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.07%	98.34%	97.34%	96.36%	95.55%	94.20%	92.32%	91.21%		
± 1 standard error	0.17%	0.24%	0.32%	0.38%	0.44%	0.55%	0.84%	1.05%		
Sample Size	3100	2700	2400	2000	1600	1100	300	200		

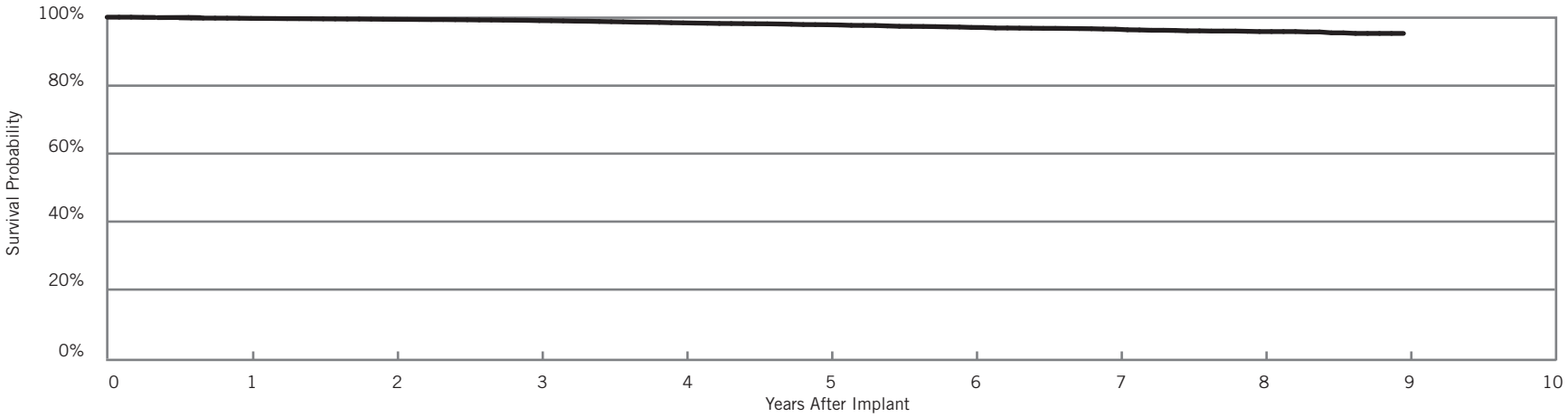
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,529
Estimated Active US Implants	4,795
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead 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	32	0.30%
Lead-to-Can Contacts	20	0.19%
Lead-to-Lead Contacts	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.03%
Others	7	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	19	0.18%
Total	**54**	**0.51%**



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.62%	99.33%	98.94%	98.23%	97.67%	96.89%	96.21%	95.67%	95.12%	
± 1 standard error	0.06%	0.08%	0.11%	0.15%	0.18%	0.22%	0.26%	0.33%	0.43%	
Sample Size	10200	9000	8000	6900	5700	4300	2800	1600	200	

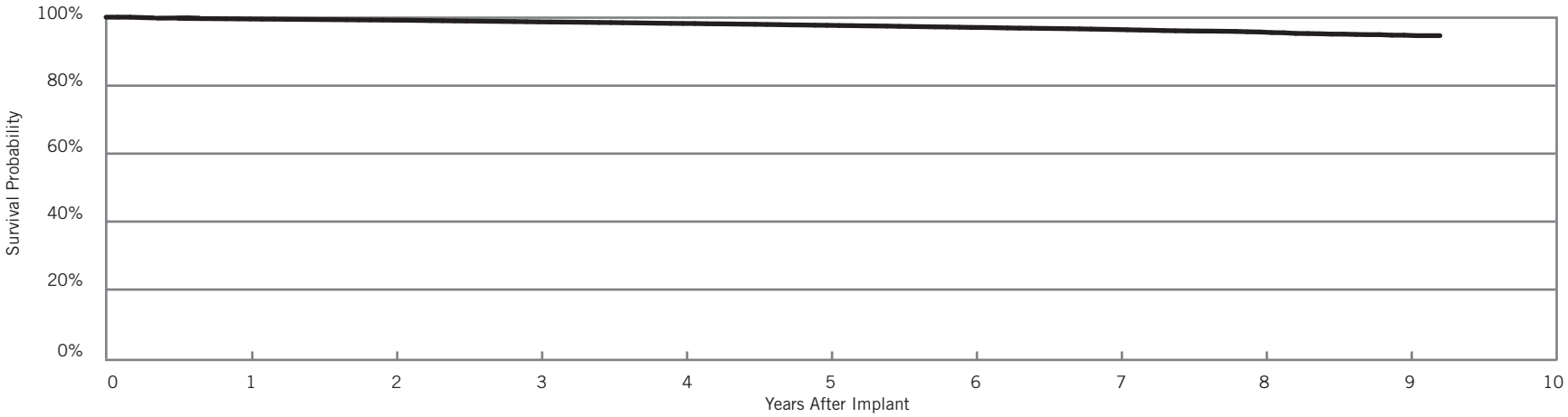
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,242
Estimated Active US Implants	33,066
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	14	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	5	0.01%
Intravascular	7	0.01%
Insulation Breach	267	0.39%
Lead-to-Can Contacts	157	0.23%
Lead-to-Lead Contacts	35	0.05%
Clavicular Crush	6	0.01%
Externalized Conductors	24	0.03%
Others	45	0.06%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	207	0.30%
Total	**491**	**0.71%**



Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.42%	99.08%	98.56%	98.09%	97.50%	96.90%	96.21%	95.37%	94.45%	94.45%
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.08%	0.11%	0.15%	0.25%	0.28%
Sample Size	68100	60000	53700	46900	39600	28300	15500	7100	800	200

SCORE Registry Performance Data

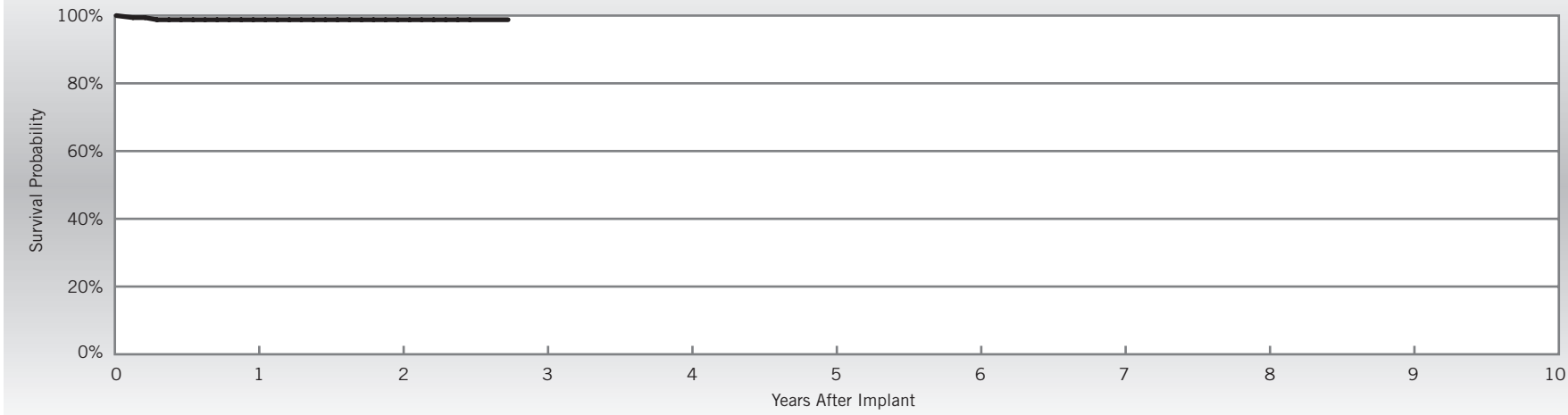
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	170
Cumulative Months of Follow-up	4,241
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

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

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	1.76%
Total	**3**	**1.76%**



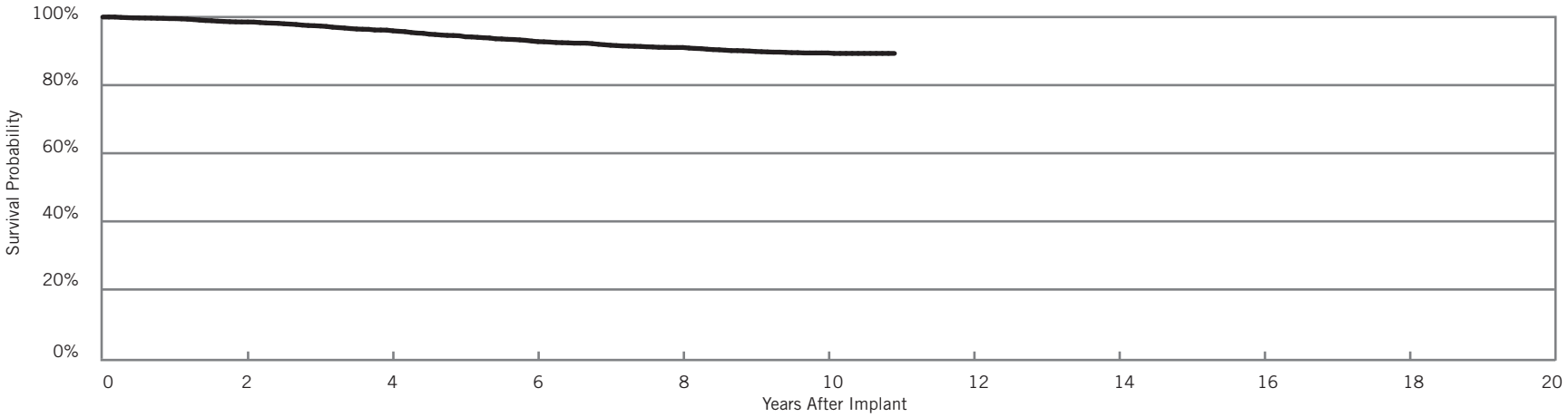
Year	1	2	at 33 months							
Survival Probability	98.81%	98.81%	98.81%							
± 1 standard error	0.83%	0.83%	0.83%							
Sample Size	160	120	50							

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,736
Estimated Active US Implants	1,041
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



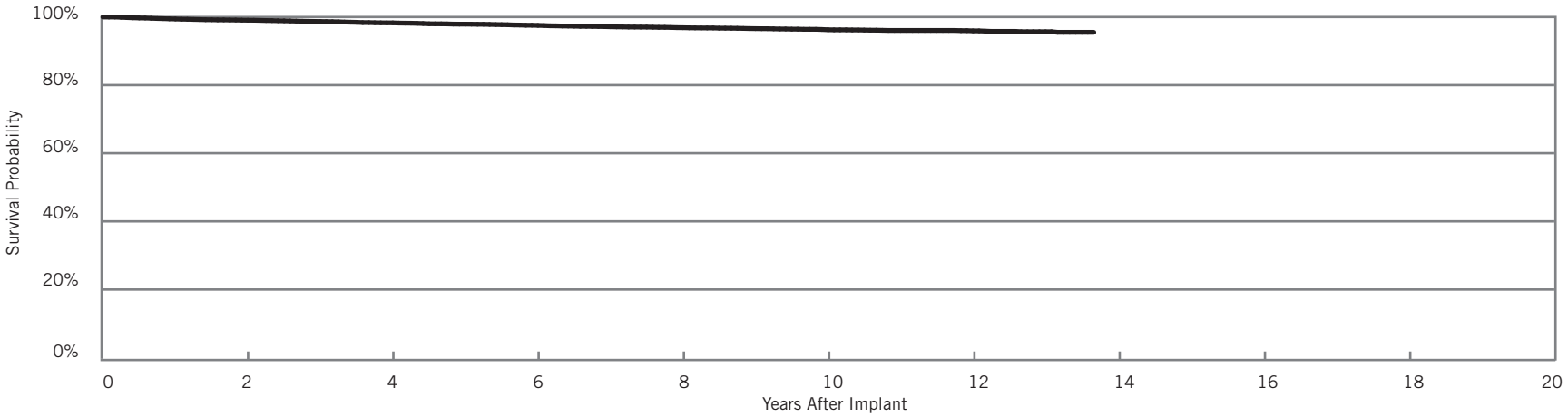
Year	2	4	6	8	10	at 131 months				
Survival Probability	98.51%	95.80%	92.70%	90.86%	89.28%	89.28%				
± 1 standard error	0.19%	0.34%	0.47%	0.54%	0.62%	0.63%				
Sample Size	3900	3100	2400	1900	1100	200				

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,642
Estimated Active US Implants	2,940
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 164 months			
Survival Probability	99.05%	98.22%	97.49%	96.82%	96.22%	95.92%	95.50%			
± 1 standard error	0.09%	0.13%	0.16%	0.19%	0.22%	0.25%	0.34%			
Sample Size	11000	9000	7300	5800	4200	1900	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	98.95%									
7120Q/7121Q	Durata® DF4	99.37%									
7122Q	Durata® DF4	99.21%									
7120/7121	Durata®	99.55%	99.38%	99.25%							
7122	Durata®	99.56%	99.43%	99.34%							
7030/7031	Riata® ST Optim®	99.23%	99.07%	99.07%							
7022	Riata® ST Optim®	99.06%	98.98%	98.89%							
7070/7071	Riata® ST Optim®	99.42%	99.24%	99.02%							
7020/7021	Riata® ST Optim®	99.19%	99.00%	98.79%	98.57%						
7010/7011	Riata® ST	99.61%	99.50%	99.38%	99.17%						
7040/7041	Riata® ST	99.37%	99.01%	98.75%	97.76%						
7002	Riata® ST	99.21%	98.76%	98.49%	98.28%						
7000/7001	Riata® ST	99.47%	99.20%	98.88%	98.55%	98.23%					
1560/1561	Riata® i	99.68%	99.20%	98.81%	98.81%	98.81%					
1590/1591	Riata® i	99.53%	99.31%	99.11%	98.94%	98.49%	98.04%				
1582	Riata®	99.07%	98.34%	97.34%	96.36%	95.55%	94.20%	92.32%			
1570/1571	Riata®	99.62%	99.33%	98.94%	98.23%	97.67%	96.89%	96.21%	95.67%	95.12%	
1580/1581	Riata®	99.42%	99.08%	98.56%	98.09%	97.50%	96.90%	96.21%	95.37%	94.45%	
1559	TVL™ ADX	99.45%	98.51%	97.22%	95.80%	94.14%	92.70%	91.58%	90.86%	89.79%	89.28%
SP01/SP02/SP03/SP04	SPL®	99.36%	99.05%	98.65%	98.22%	97.89%	97.49%	97.10%	96.82%	96.56%	96.22%

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	1740	1538	1	0.06%	0	0.00%	2	0.11%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.23%**	**3**
7120Q/7121Q	Jan-09	42871	37926	23	0.05%	0	0.00%	70	0.16%	34	0.08%	21	0.05%	6	0.01%	0	0.00%	2	<0.01%	1	<0.01%	1	<0.01%	4	0.01%	**162**	**0.38%**	**90**
7122Q	Jan-09	7403	6602	6	0.08%	0	0.00%	11	0.15%	11	0.15%	4	0.05%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	3	0.04%	**39**	**0.53%**	**28**
7120/7121	Sep-07	53161	41241	31	0.06%	1	<0.01%	66	0.12%	17	0.03%	44	0.08%	4	0.01%	0	0.00%	1	<0.01%	17	0.03%	1	<0.01%	15	0.03%	**197**	**0.37%**	**81**
7122	Sep-07	8362	6779	4	0.05%	1	0.01%	8	0.10%	6	0.07%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**24**	**0.29%**	**12**
7030/7031	Jul-06	851	547	0	0.00%	0	0.00%	5	0.59%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.82%**	**3**
7022	Jul-06	1483	975	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	2	0.13%	0	0.00%	0	0.00%	0	0.00%	**11**	**0.74%**	**4**
7070/7071	Jul-06	3296	2423	2	0.06%	1	0.03%	3	0.09%	5	0.15%	4	0.12%	3	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**18**	**0.55%**	**8**
7020/7021	Jul-06	15461	10148	38	0.25%	0	0.00%	34	0.22%	19	0.12%	19	0.12%	8	0.05%	0	0.00%	1	0.01%	4	0.03%	4	0.03%	0	0.00%	**127**	**0.82%**	**62**
7010/7011	Mar-06	2208	1355	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%**	**5**
7040/7041	Mar-06	4088	2618	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%**	**4**
7002	Jun-05	2413	1508	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%**	**10**
7000/7001	Jun-05	34925	21523	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%**	**103**

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	1740	1538	0	0.00%	0	0.00%	2	0.11%	6	0.34%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	**10**	**0.57%**	**8**
7120Q/7121Q	Jan-09	42871	37926	7	0.02%	6	0.01%	112	0.26%	41	0.10%	20	0.05%	5	0.01%	0	0.00%	1	<0.01%	6	0.01%	1	<0.01%	4	0.01%	**203**	**0.47%**	**171**
7122Q	Jan-09	7403	6602	4	0.05%	1	0.01%	19	0.26%	5	0.07%	6	0.08%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**37**	**0.50%**	**32**
7120/7121	Sep-07	53161	41241	4	0.01%	9	0.02%	113	0.21%	50	0.09%	55	0.10%	11	0.02%	1	<0.01%	10	0.02%	16	0.03%	0	0.00%	11	0.02%	**280**	**0.53%**	**197**
7122	Sep-07	8362	6779	1	0.01%	2	0.02%	13	0.16%	10	0.12%	6	0.07%	3	0.04%	2	0.02%	4	0.05%	1	0.01%	0	0.00%	2	0.02%	**44**	**0.53%**	**40**
7030/7031	Jul-06	851	547	1	0.12%	0	0.00%	0	0.00%	4	0.47%	6	0.71%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	**12**	**1.41%**	**2**
7022	Jul-06	1483	975	3	0.20%	3	0.20%	6	0.40%	1	0.07%	5	0.34%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**18**	**1.21%**	**13**
7070/7071	Jul-06	3296	2423	2	0.06%	2	0.06%	4	0.12%	4	0.12%	6	0.18%	2	0.06%	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	**23**	**0.70%**	**8**
7020/7021	Jul-06	15461	10148	10	0.06%	4	0.03%	47	0.30%	39	0.25%	46	0.30%	10	0.06%	2	0.01%	4	0.03%	7	0.05%	2	0.01%	13	0.08%	**184**	**1.19%**	**132**
7010/7011	Mar-06	2208	1355	1	0.05%	0	0.00%	5	0.23%	0	0.00%	4	0.18%	2	0.09%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**14**	**0.63%**	**9**
7040/7041	Mar-06	4088	2618	2	0.05%	6	0.15%	3	0.07%	9	0.22%	19	0.46%	4	0.10%	1	0.02%	3	0.07%	3	0.07%	0	0.00%	0	0.00%	**50**	**1.22%**	**20**
7002	Jun-05	2413	1508	2	0.08%	3	0.12%	9	0.37%	7	0.29%	11	0.46%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	3	0.12%	**36**	**1.49%**	**18**
7000/7001	Jun-05	34925	21523	18	0.05%	23	0.07%	39	0.11%	72	0.21%	171	0.49%	19	0.05%	9	0.03%	11	0.03%	12	0.03%	2	0.01%	29	0.08%	**405**	**1.16%**	**233**

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

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	1740	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	6	0.34%	**6**	**0.34%**
7120Q/7121Q	42871	0	0.00%	2	<0.01%	2	<0.01%	**4**	**0.01%**	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**2**	**<0.01%**	0	0.00%	3	0.01%	122	0.28%	**131**	**0.31%**
7122Q	7403	0	0.00%	2	0.03%	0	0.00%	**2**	**0.03%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	25	0.34%	**27**	**0.36%**
7120/7121	53161	0	0.00%	7	0.01%	2	<0.01%	**9**	**0.02%**	2	<0.01%	2	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	**6**	**0.01%**	1	<0.01%	2	<0.01%	120	0.23%	**138**	**0.26%**
7122	8362	0	0.00%	2	0.02%	1	0.01%	**3**	**0.04%**	1	0.01%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.04%**	0	0.00%	0	0.00%	24	0.29%	**30**	**0.36%**
7030/7031	851	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	3	0.35%	**3**	**0.35%**
7022	1483	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	8	0.54%	**9**	**0.61%**
7070/7071	3296	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	**1**	**0.03%**	0	0.00%	0	0.00%	5	0.15%	**7**	**0.21%**
7020/7021	15461	1	0.01%	1	0.01%	3	0.02%	**5**	**0.03%**	3	0.02%	3	0.02%	1	0.01%	0	0.00%	3	0.02%	**10**	**0.06%**	0	0.00%	0	0.00%	87	0.56%	**102**	**0.66%**
7010/7011	2208	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.09%**	0	0.00%	0	0.00%	4	0.18%	**6**	**0.27%**
7040/7041	4088	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	5	0.12%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**8**	**0.20%**	0	0.00%	0	0.00%	6	0.15%	**16**	**0.39%**
7002	2413	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%	10	0.41%	**14**	**0.58%**
7000/7001	34925	2	0.01%	2	0.01%	6	0.02%	**10**	**0.03%**	58	0.17%	11	0.03%	2	0.01%	1	<0.01%	8	0.02%	**80**	**0.23%**	1	<0.01%	0	0.00%	94	0.27%	**185**	**0.53%**
1560/1561	1008	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**
1590/1591	9753	1	0.01%	0	0.00%	3	0.03%	**4**	**0.04%**	7	0.07%	3	0.03%	0	0.00%	0	0.00%	4	0.04%	**14**	**0.14%**	0	0.00%	0	0.00%	16	0.16%	**34**	**0.35%**
1582	3189	0	0.00%	0	0.00%	2	0.06%	**2**	**0.06%**	24	0.75%	4	0.13%	1	0.03%	5	0.16%	10	0.31%	**44**	**1.38%**	0	0.00%	0	0.00%	14	0.44%	**60**	**1.88%**
1570/1571	10529	2	0.02%	1	0.01%	0	0.00%	**3**	**0.03%**	20	0.19%	2	0.02%	0	0.00%	3	0.03%	7	0.07%	**32**	**0.30%**	0	0.00%	0	0.00%	19	0.18%	**54**	**0.51%**
1580/1581	69242	2	<0.01%	5	0.01%	7	0.01%	**14**	**0.02%**	157	0.23%	35	0.05%	6	0.01%	24	0.03%	45	0.06%	**267**	**0.39%**	3	<0.01%	0	0.00%	207	0.30%	**491**	**0.71%**

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

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	736	8043	0	0.00%	0	0.00%	3	0.41%	1	0.14%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.27%	0	0.00%	0	0.00%	**6**	**0.82%**
7122Q	145	1526	0	0.00%	0	0.00%	0	0.00%	0	0.00%	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	1490	33880	0	0.00%	2	0.13%	5	0.34%	2	0.13%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	**11**	**0.74%**
7122	251	4509	0	0.00%	0	0.00%	3	1.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.40%	0	0.00%	0	0.00%	0	0.00%	**4**	**1.59%**
7070/7071	150	3511	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
7020/7021	176	5628	1	0.57%	2	1.14%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	1	0.57%	0	0.00%	0	0.00%	0	0.00%	**5**	**2.84%**
7000/7001	128	3946	0	0.00%	0	0.00%	1	0.78%	0	0.00%	1	0.78%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.56%**
1580/1581	170	4241	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.18%**

Malfunctions

		Conductor Fracture								Insulation Breach																	
Models	Number of Devices Enrolled	Clavicular Crush		Extravascular		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	
				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	736	0	0.00%	0	0.00%	0	0.00%	0	0.00%	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	0.68%	**5**	**0.68%**
7122Q	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%	0	0.00%	**0**	**0.00%**
7120/7121	1490	0	0.00%	1	0.07%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.13%	**3**	**0.20%**
7122	251	0	0.00%	0	0.00%	1	0.40%	1	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.80%	**3**	**1.20%**
7070/7071	150	0	0.00%	0	0.00%	0	0.00%	0	0.00%	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	0.67%	**1**	**0.67%**
7020/7021	176	0	0.00%	1	0.57%	0	0.00%	1	0.57%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	**2**	**1.14%**
7000/7001	128	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.78%	1	0.78%	0	0.00%	0	0.00%	0	0.00%	2	1.56%	1	0.78%	0	0.00%	0	0.00%	**3**	**2.34%**
1580/1581	170	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	1.76%	**3**	**1.76%**

Definitions of complications can be found on page 14.
Definitions of malfunction categories can be found on pages 10 and 11.

Pacemakers

Dual-Chamber

St. Jude Medical
More control. Less risk.

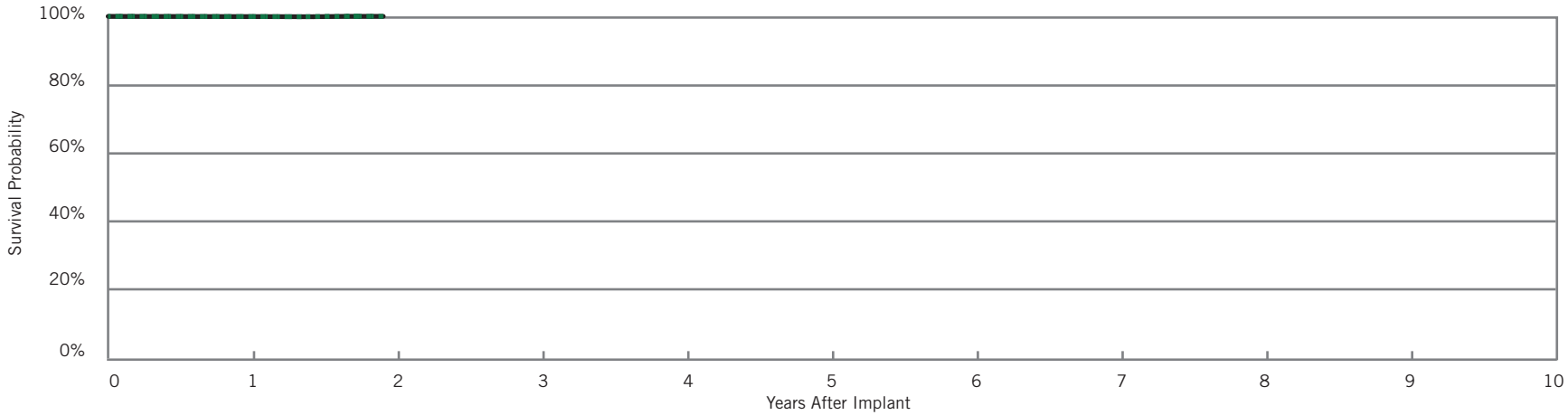
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	81,975
Estimated Active US Implants	72,956
Estimated Longevity	8 Years
Normal Battery Depletion	2
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	<0.01%
Electrical Interconnect	2	<0.01%	3	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	7	0.01%
Possible Early Battery Depletion	3	<0.01%	2	<0.01%
Other	0	0.00%	2	<0.01%
Total	**5**	**0.01%**	**15**	**0.02%**



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.93%	99.89%								
± 1 standard error	0.01%	0.02%								
Sample Size	59400	1200								

Excluding Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	99.94%	99.90%								
± 1 standard error	0.01%	0.02%								

SCORE Registry Performance Data

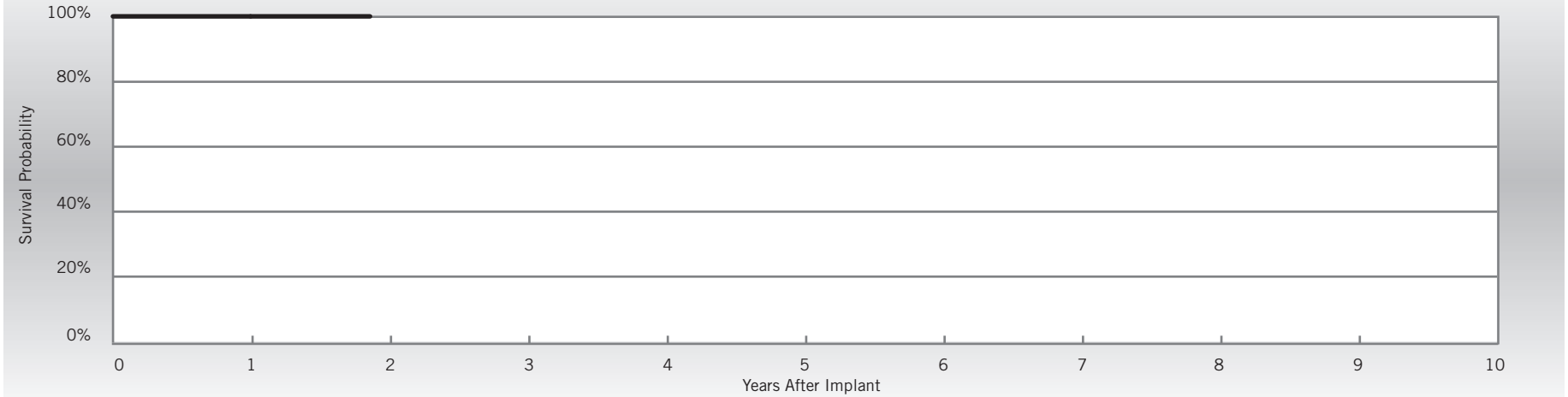
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,294
Cumulative Months of Follow-up	13,693
Estimated Longevity	8 Years

Qualifying Complications
None Reported

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



Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	890	70								

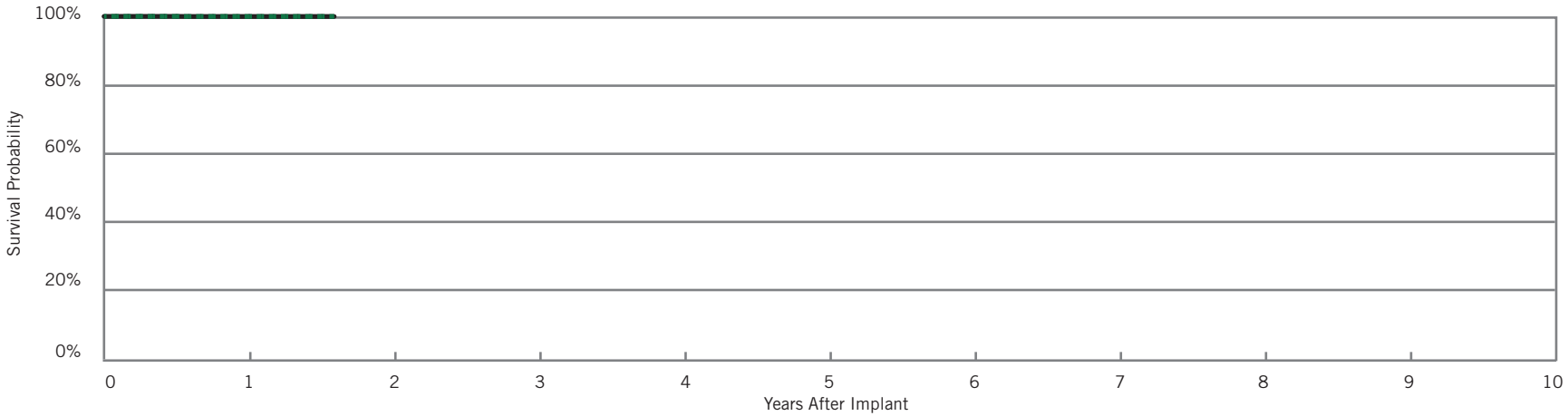
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	13,607
Estimated Active US Implants	12,287
Estimated Longevity	9.2 Years
Normal Battery Depletion	0
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.02%	0.02%								
Sample Size	8500	200								

Excluding Normal Battery Depletion

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

SCORE Registry Performance Data

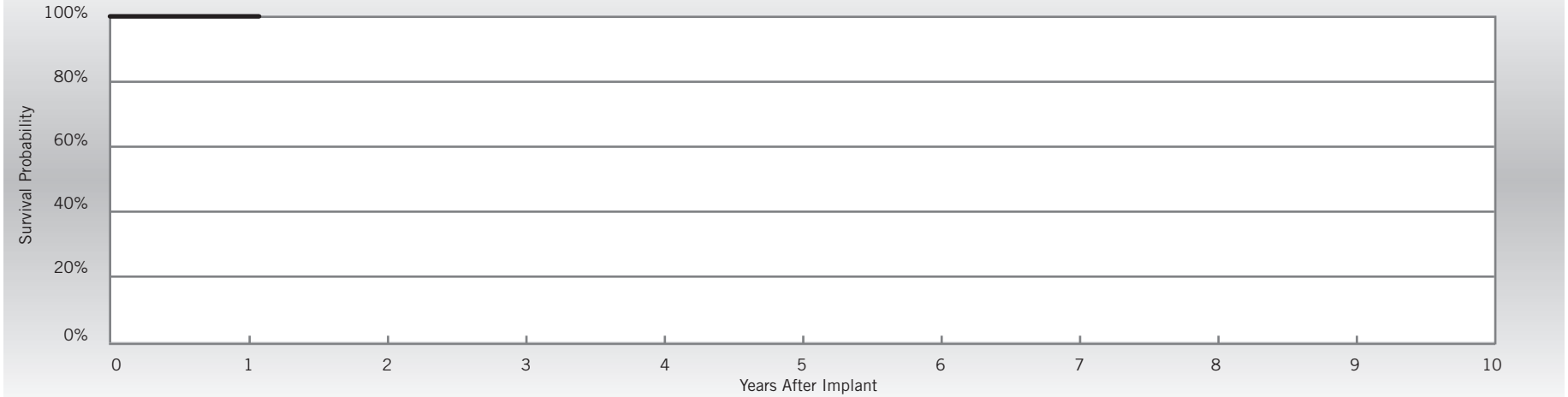
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	179
Cumulative Months of Follow-up	1,719
Estimated Longevity	9.2 Years

Qualifying Complications
None Reported

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



Year	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	120	60								

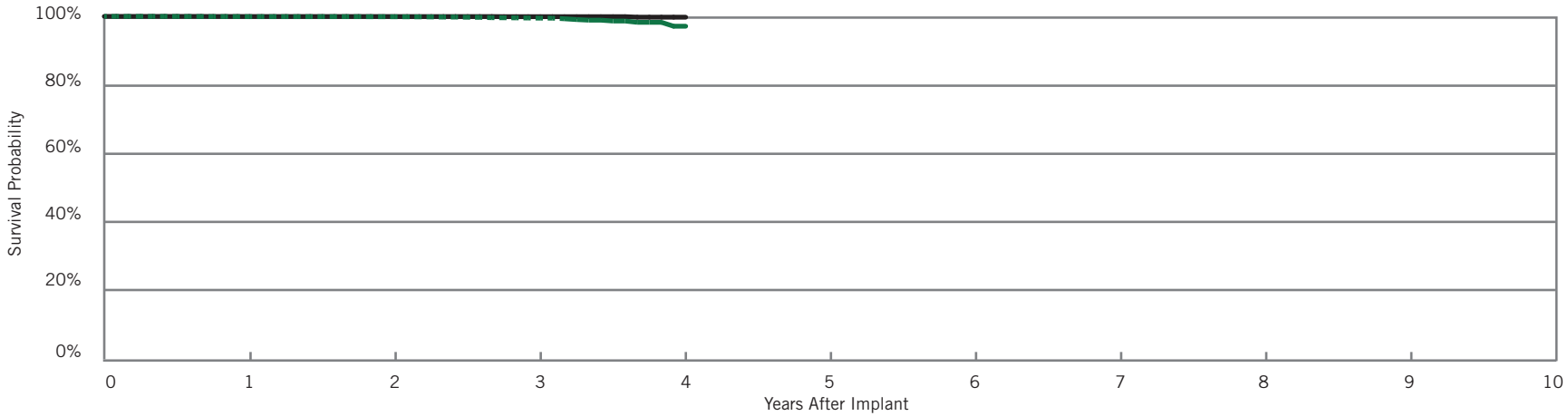
Customer Reported Performance Data

Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	35,298
Estimated Active US Implants	27,109
Estimated Longevity	6.5 Years
Normal Battery Depletion	33
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.92%	99.89%	99.49%	97.13%						
± 1 standard error	0.02%	0.02%	0.07%	0.57%						
Sample Size	31900	20100	10100	2700						

Excluding Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.96%	99.95%	99.92%	99.77%						
± 1 standard error	0.01%	0.01%	0.02%	0.11%						

SCORE Registry Performance Data

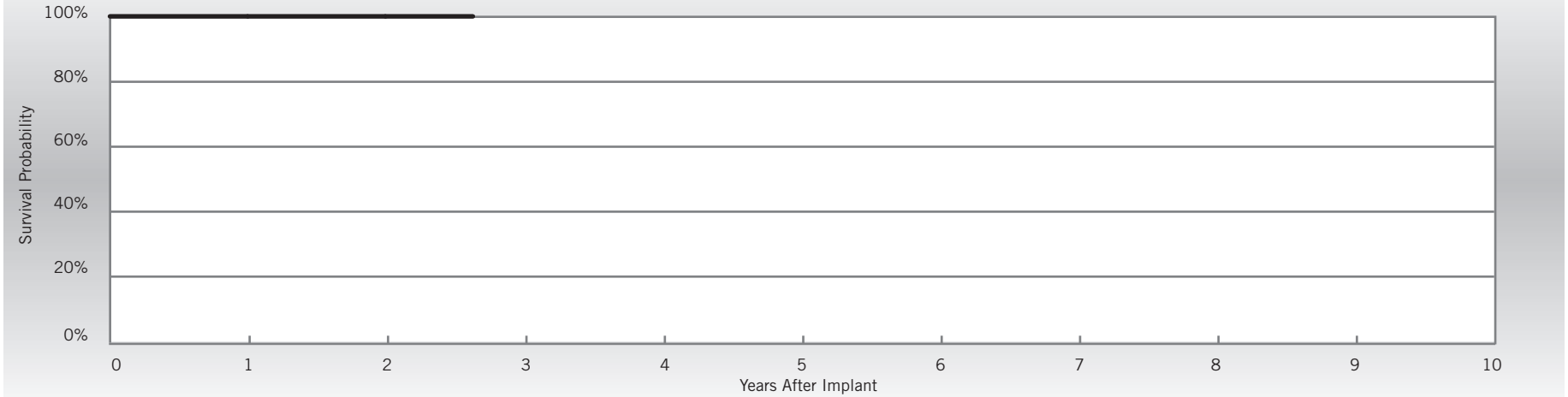
Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	267
Cumulative Months of Follow-up	5,303
Estimated Longevity	6.5 Years

Qualifying Complications
None Reported

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



Year	1	2	at 32 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	230	140	50							

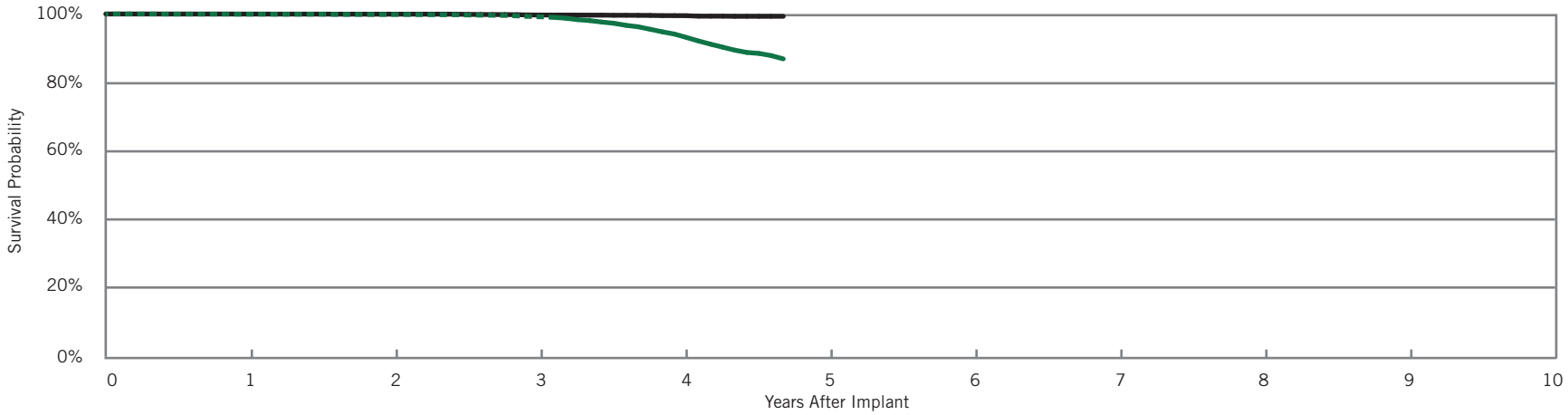
Customer Reported Performance Data

Victory® DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,277
Estimated Active US Implants	14,133
Estimated Longevity	6.5 Years
Normal Battery Depletion	431
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	21	0.08%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	15	0.06%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**37**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.95%	99.86%	99.16%	93.13%	84.92%					
± 1 standard error	0.01%	0.03%	0.07%	0.22%	0.38%					
Sample Size	26000	21700	17300	11900	2800					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.98%	99.95%	99.69%	99.50%	99.22%					
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.08%					

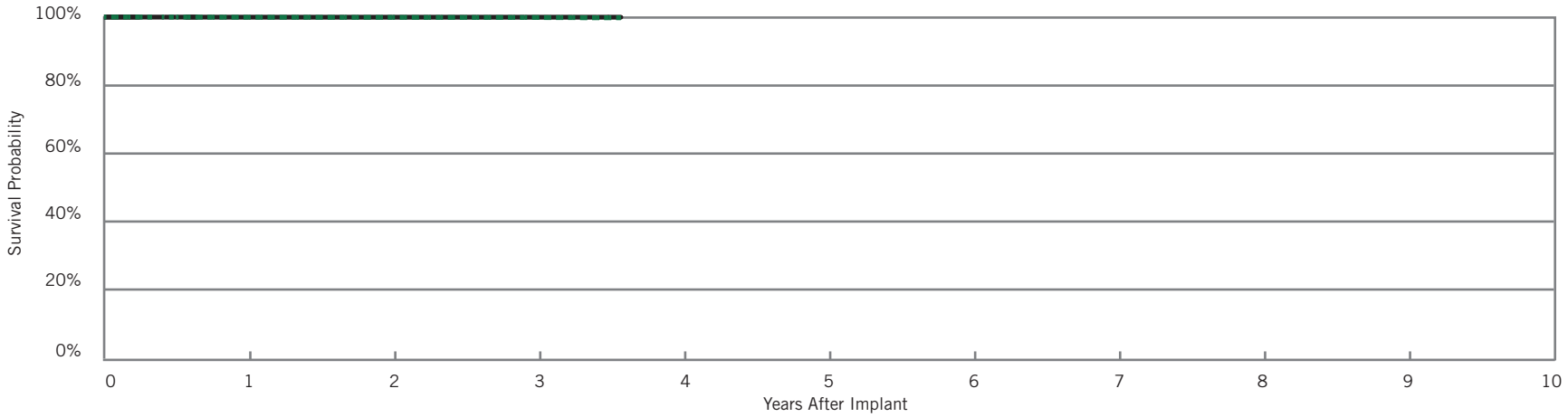
Customer Reported Performance Data

Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	101,360
Estimated Active US Implants	76,793
Estimated Longevity	11.7 Years
Normal Battery Depletion	27
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	7	0.01%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	3	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	2	<0.01%
Total	**4**	**<0.01%**	**12**	**0.01%**



Including Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.94%	99.91%	99.87%	99.79%						
± 1 standard error	0.01%	0.01%	0.01%	0.03%						
Sample Size	98000	72500	38600	6700						

Excluding Normal Battery Depletion

Year	1	2	3	at 43 months						
Survival Probability	99.97%	99.96%	99.96%	99.96%						
± 1 standard error	0.01%	0.01%	0.01%	0.01%						

SCORE Registry Performance Data

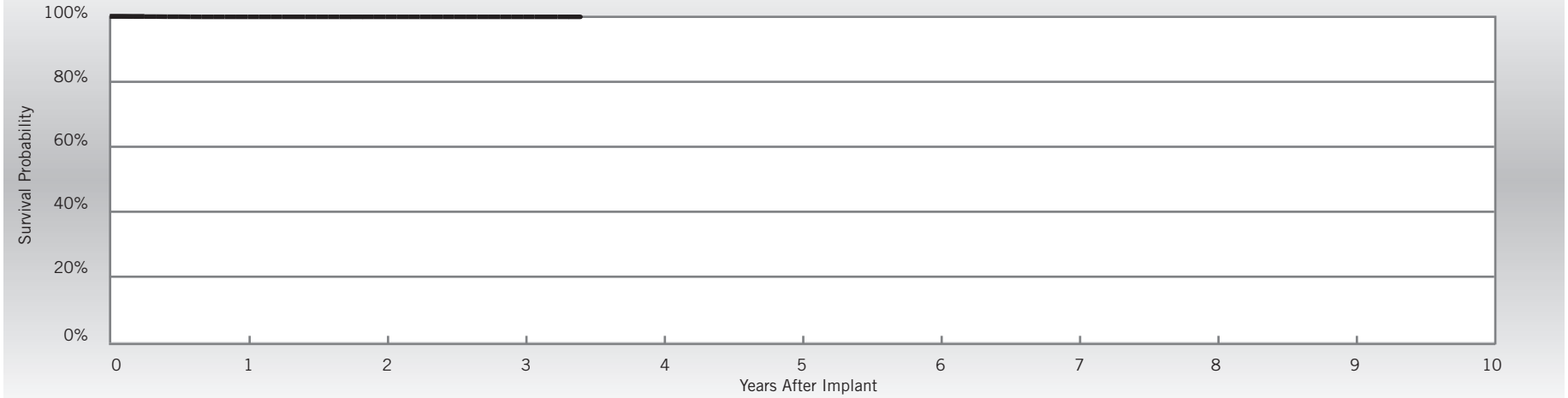
Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1505
Cumulative Months of Follow-up	39,524
Estimated Longevity	11.7 Years

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.13%

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



Year	1	2	3	at 41 months						
Survival Probability	99.93%	99.85%	99.85%	99.85%						
± 1 standard error	0.07%	0.11%	0.11%	0.11%						
Sample Size	1420	1150	590	70						

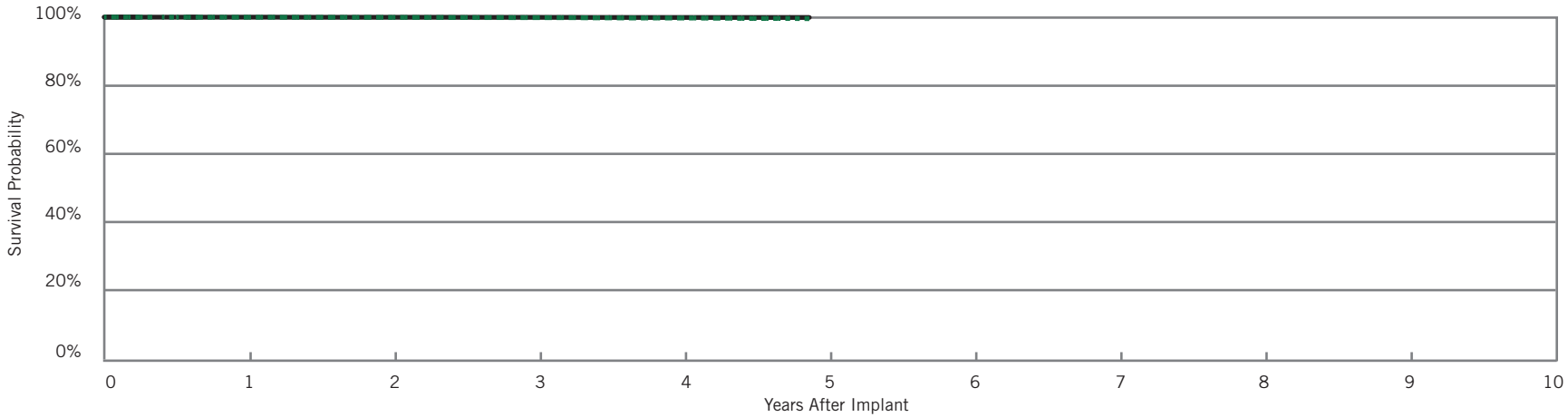
Customer Reported Performance Data

Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,265
Estimated Active US Implants	40,340
Estimated Longevity	11.7 Years
Normal Battery Depletion	34
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	8	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	3	<0.01%
Other	0	0.00%	3	<0.01%
Total	**2**	**<0.01%**	**19**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.95%	99.91%	99.84%	99.72%	99.53%					
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%					
Sample Size	61800	52300	41700	27600	4500					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.98%	99.95%	99.93%	99.89%	99.89%					
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%					

SCORE Registry Performance Data

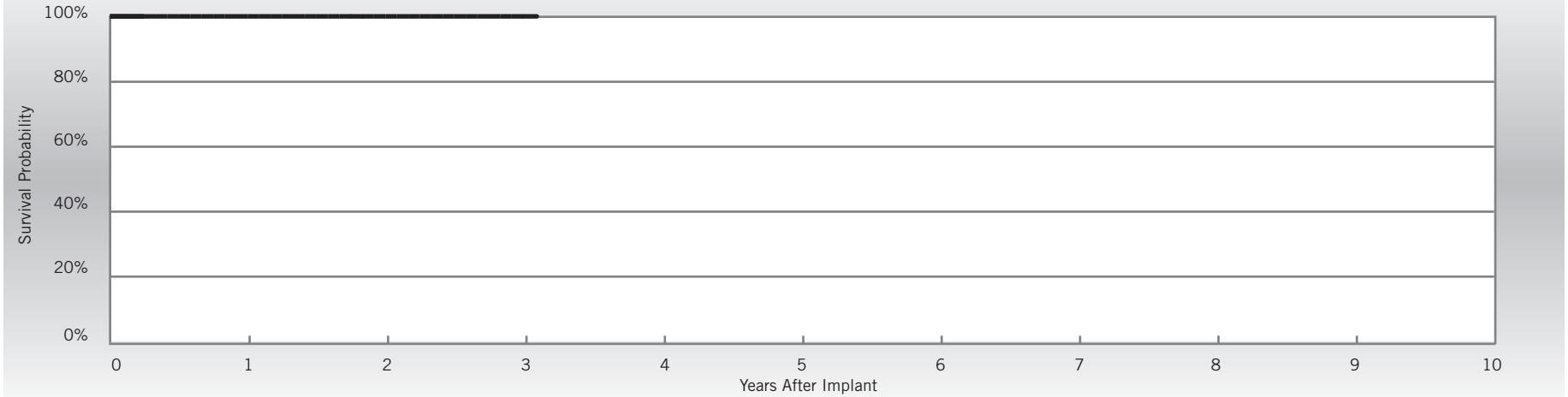
Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	333
Cumulative Months of Follow-up	9,415
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

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



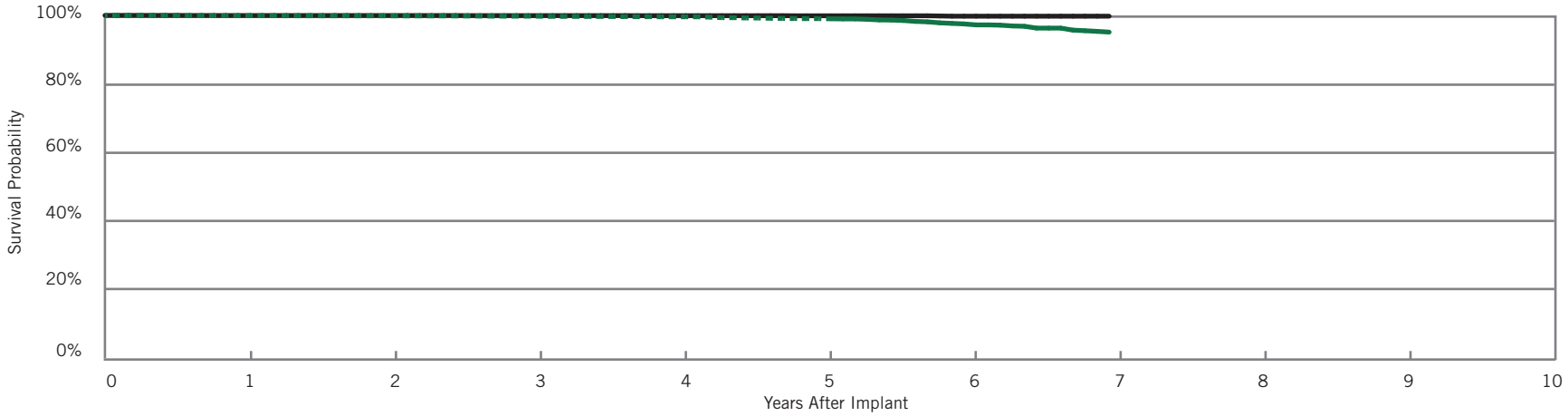
Year	1	2	3	at 37 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	270	150	60						

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

US Regulatory Approval	May 2003
Registered US Implants	16,939
Estimated Active US Implants	8,439
Estimated Longevity	6.9 Years
Normal Battery Depletion	74
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	6	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**8**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.90%	99.85%	99.75%	99.59%	99.01%	97.23%	95.12%			
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.11%	0.23%	0.42%			
Sample Size	16800	14300	12500	10000	7000	4200	900			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.96%	99.96%	99.94%	99.92%	99.89%	99.77%	99.77%			
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.03%	0.07%	0.07%			

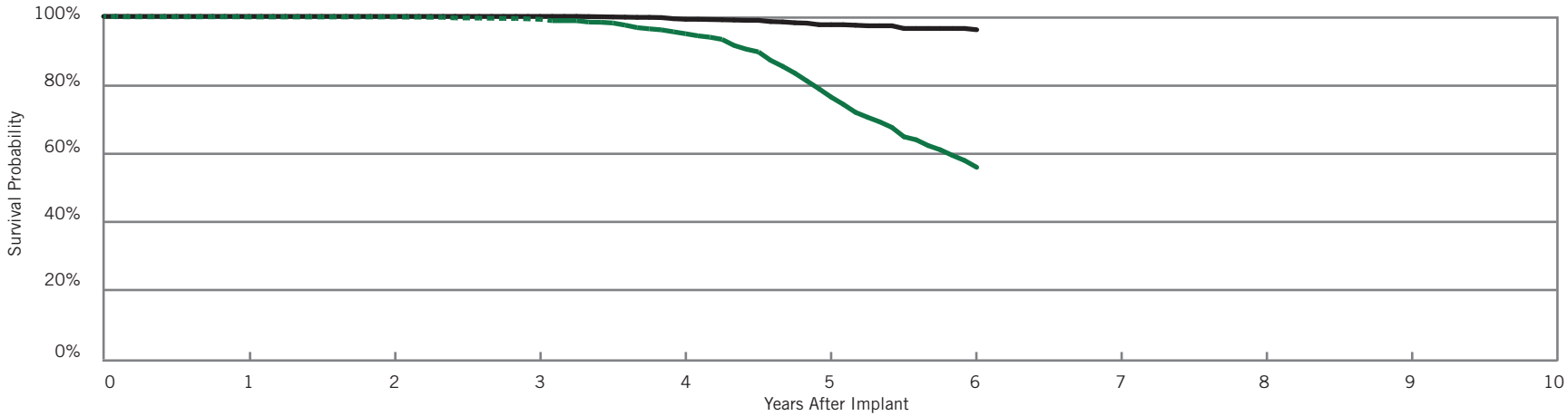
Integrity® ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,837
Estimated Active US Implants	1,336
Estimated Longevity	3.8 Years
Normal Battery Depletion	353
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	33	0.57%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.02%
Total	**0**	**0.00%**	**34**	**0.58%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	99.84%	99.84%	99.15%	94.93%	76.41%	55.91%				
± 1 standard error	0.05%	0.05%	0.13%	0.35%	0.81%	1.20%				
Sample Size	5800	5000	4400	3700	2700	1300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6				
Survival Probability	100.00%	100.00%	100.00%	99.16%	97.57%	96.10%				
± 1 standard error	0.00%	0.00%	0.00%	0.14%	0.32%	0.45%				

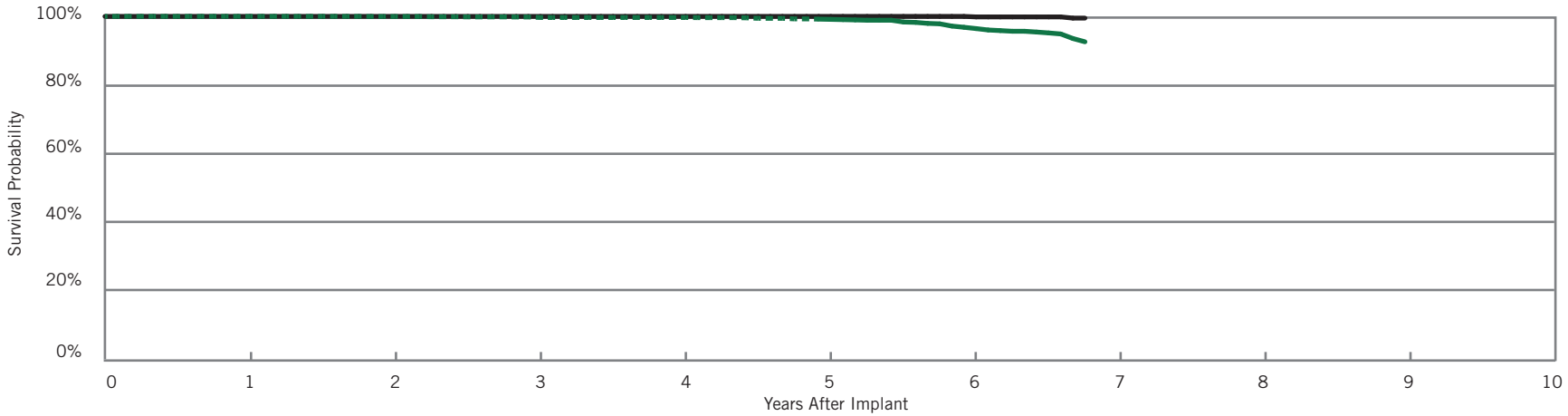
Customer Reported Performance Data

Integrity® ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,008
Estimated Active US Implants	4,113
Estimated Longevity	6.9 Years
Normal Battery Depletion	49
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	100.00%	99.97%	99.67%	99.67%	99.13%	96.44%	92.58%			
± 1 standard error	0.00%	0.02%	0.05%	0.07%	0.14%	0.39%	0.75%			
Sample Size	8000	7100	6300	5200	3700	2000	500			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%	99.85%	99.50%			
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%	0.11%	0.27%			

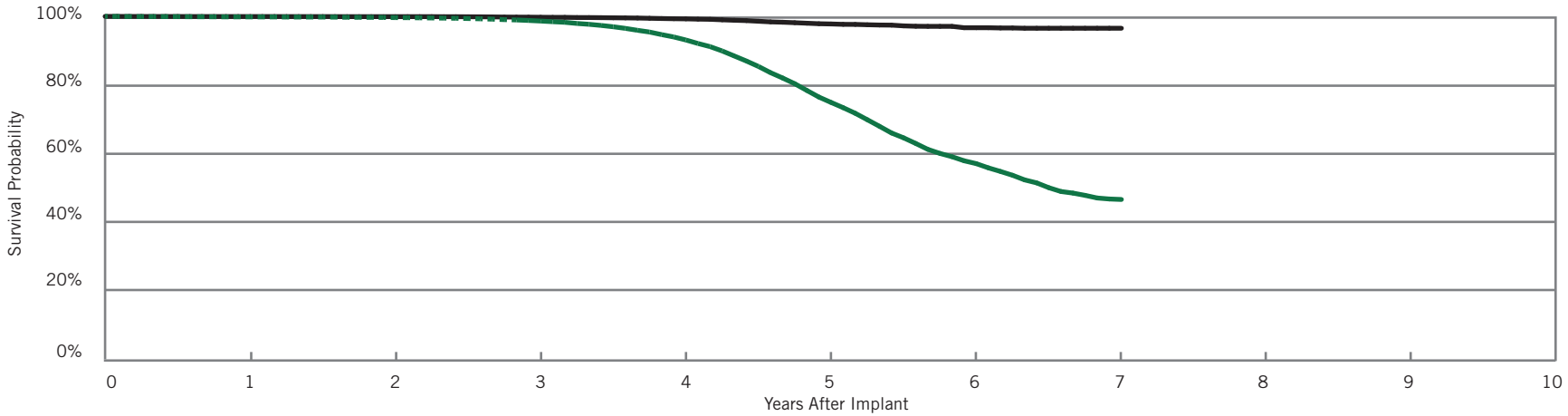
Integrity® ADx DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	53,839
Estimated Active US Implants	13,479
Estimated Longevity	3.8 Years
Normal Battery Depletion	3,361
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	3	0.01%	232	0.43%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	11	0.02%
Other	0	0.00%	3	0.01%
Total	**4**	**0.01%**	**251**	**0.47%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.85%	99.64%	98.64%	93.11%	74.87%	56.99%	46.52%			
± 1 standard error	0.02%	0.03%	0.05%	0.13%	0.27%	0.40%	0.61%			
Sample Size	53500	46000	40400	34000	24800	11200	2600			

Excluding Normal Battery Depletion

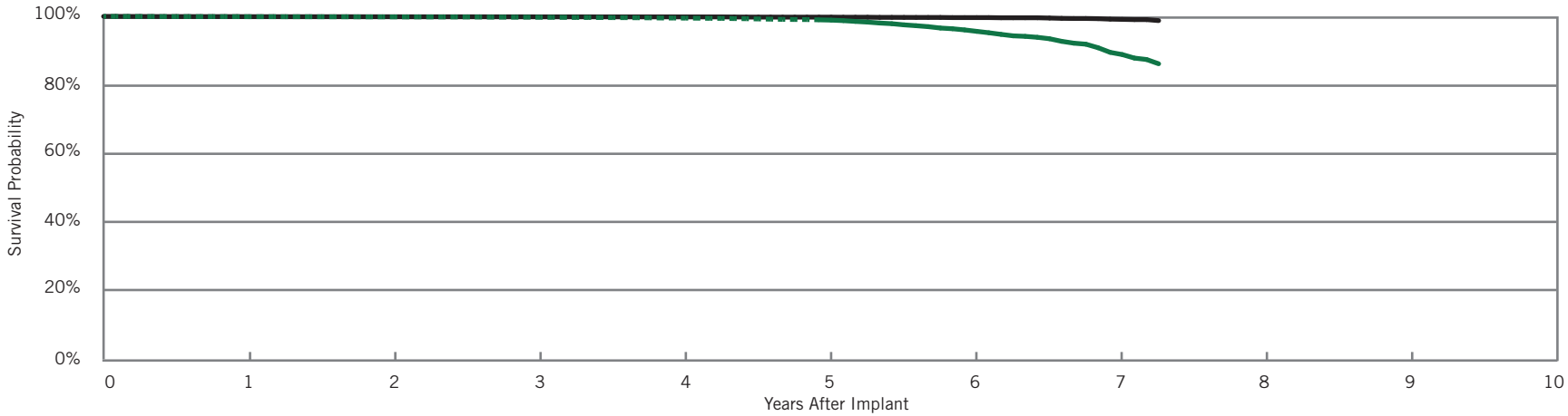
Year	1	2	3	4	5	6	7			
Survival Probability	99.96%	99.93%	99.75%	99.28%	97.79%	96.69%	96.54%			
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.10%	0.16%	0.18%			

Customer Reported Performance Data

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

US Regulatory Approval	March 2003
Registered US Implants	66,581
Estimated Active US Implants	34,759
Estimated Longevity	6.9 Years
Normal Battery Depletion	511
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	52	0.08%
Electrical Interconnect	0	0.00%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	6	0.01%
Possible Early Battery Depletion	0	0.00%	6	0.01%
Other	0	0.00%	2	<0.01%
Total	**2**	**<0.01%**	**68**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.91%	99.85%	99.73%	99.49%	98.91%	95.63%	88.85%	86.16%		
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.05%	0.14%	0.36%	0.44%		
Sample Size	65900	56400	48500	39600	29800	17800	7100	1900		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.92%	99.90%	99.87%	99.85%	99.78%	99.65%	99.13%	98.77%		
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.04%	0.10%	0.13%		

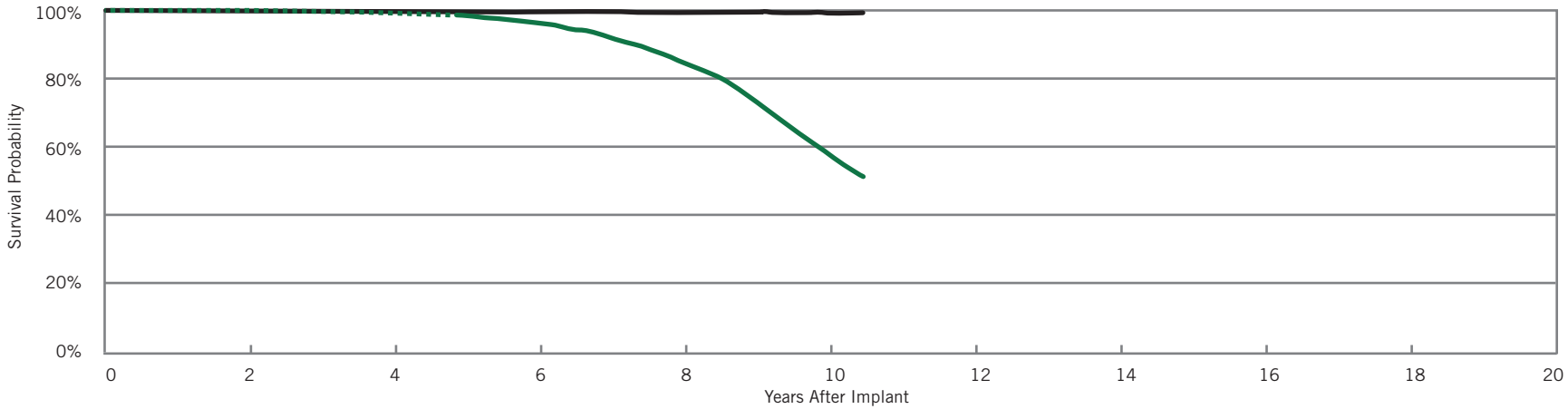
Integrity® AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,548
Estimated Active US Implants	7,727
Estimated Longevity	6.3 Years
Normal Battery Depletion	2,622
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	78	0.16%
Electrical Interconnect	3	0.01%	1	<0.01%
Battery	0	0.00%	2	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**6**	**0.01%**	**84**	**0.18%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 125 months				
Survival Probability	99.77%	99.26%	95.99%	84.03%	56.00%	50.53%				
± 1 standard error	0.02%	0.04%	0.11%	0.25%	0.47%	0.56%				
Sample Size	41900	34800	27500	18500	6600	1600				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 125 months				
Survival Probability	99.92%	99.82%	99.71%	99.36%	98.77%	98.77%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.11%	0.12%				

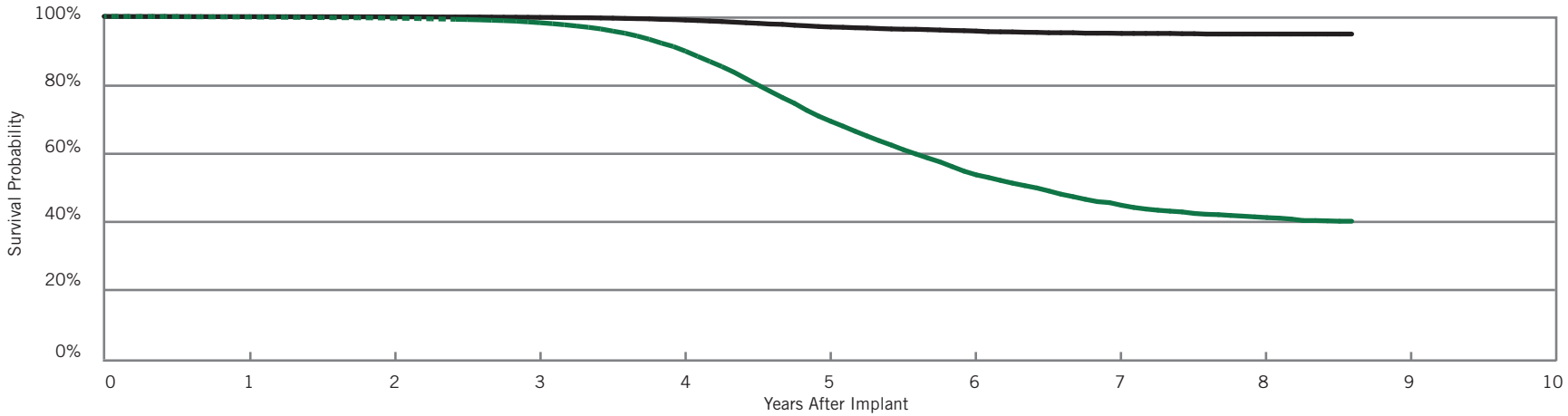
Customer Reported Performance Data

Identity®

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,439
Estimated Active US Implants	5,897
Estimated Longevity	3.8 Years
Normal Battery Depletion	4899
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	385	0.66%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	6	0.01%
Possible Early Battery Depletion	0	0.00%	11	0.02%
Other	0	0.00%	11	0.02%
Total	**5**	**0.01%**	**415**	**0.71%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 103 months
Survival Probability	99.82%	99.48%	98.15%	89.84%	69.35%	53.71%	44.82%	41.22%	40.17%
± 1 standard error	0.02%	0.03%	0.06%	0.15%	0.26%	0.34%	0.40%	0.45%	0.49%
Sample Size	58300	50600	45200	39400	29700	15100	6000	2500	700

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 103 months
Survival Probability	99.93%	99.88%	99.71%	98.93%	96.90%	95.72%	95.03%	94.85%	94.85%
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.10%	0.15%	0.19%	0.21%	0.21%

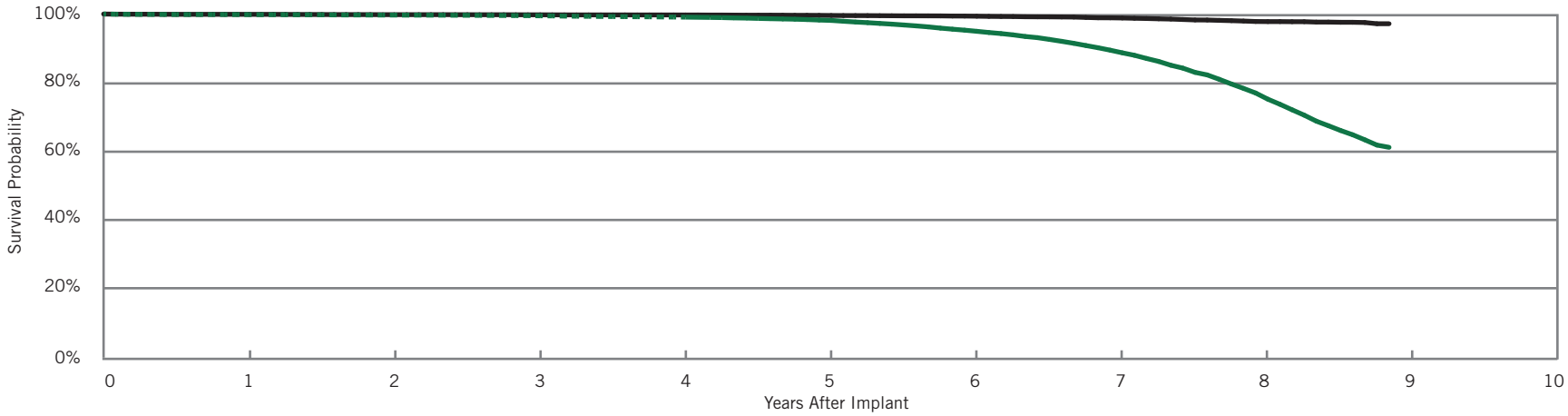
Identity® XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,482
Estimated Active US Implants	17,051
Estimated Longevity	6.9 Years
Normal Battery Depletion	1,866
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	2	<0.01%	157	0.30%
Electrical Interconnect	4	0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	<0.01%	5	0.01%
Possible Early Battery Depletion	0	0.00%	4	0.01%
Other	0	0.00%	7	0.01%
Total	**8**	**0.02%**	**175**	**0.34%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.82%	99.69%	99.47%	99.08%	98.13%	94.96%	88.69%	75.18%	61.14%
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.07%	0.13%	0.21%	0.35%	0.55%
Sample Size	51300	45700	41600	37100	32000	25800	19100	12000	2100

Excluding Normal Battery Depletion

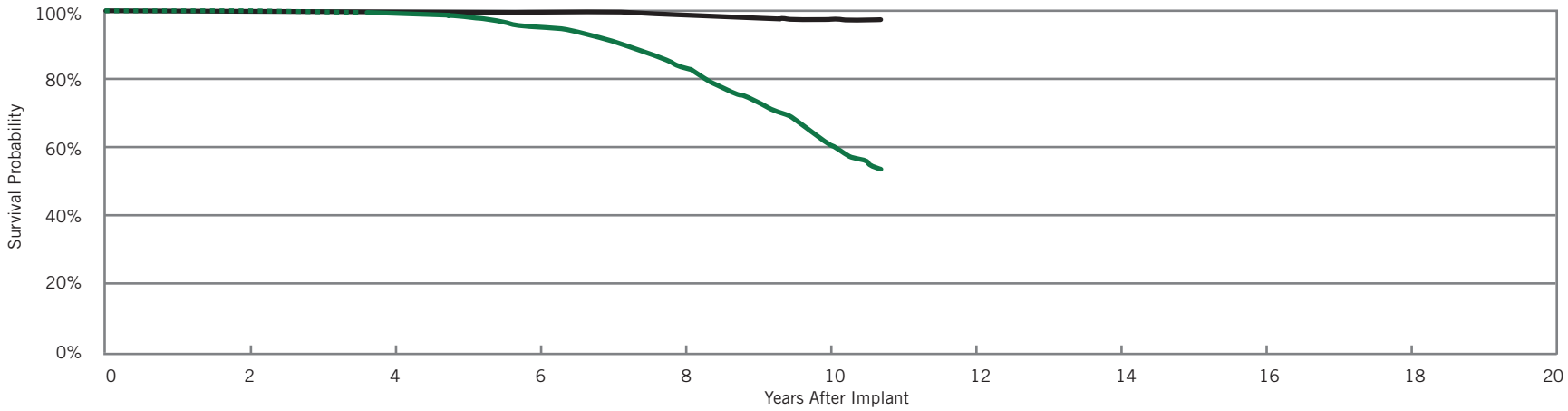
Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.90%	99.81%	99.77%	99.72%	99.57%	99.36%	98.84%	97.79%	97.17%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.07%	0.12%	0.19%

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,872
Estimated Active US Implants	2,401
Estimated Longevity	6.3 Years
Normal Battery Depletion	919
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	1	<0.01%	61	0.28%
Electrical Interconnect	2	0.01%	2	0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**3**	**0.01%**	**65**	**0.30%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 128 months				
Survival Probability	99.69%	98.78%	94.84%	83.02%	60.88%	53.17%				
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.75%	0.94%				
Sample Size	18700	14800	11100	6900	2400	700				

Excluding Normal Battery Depletion

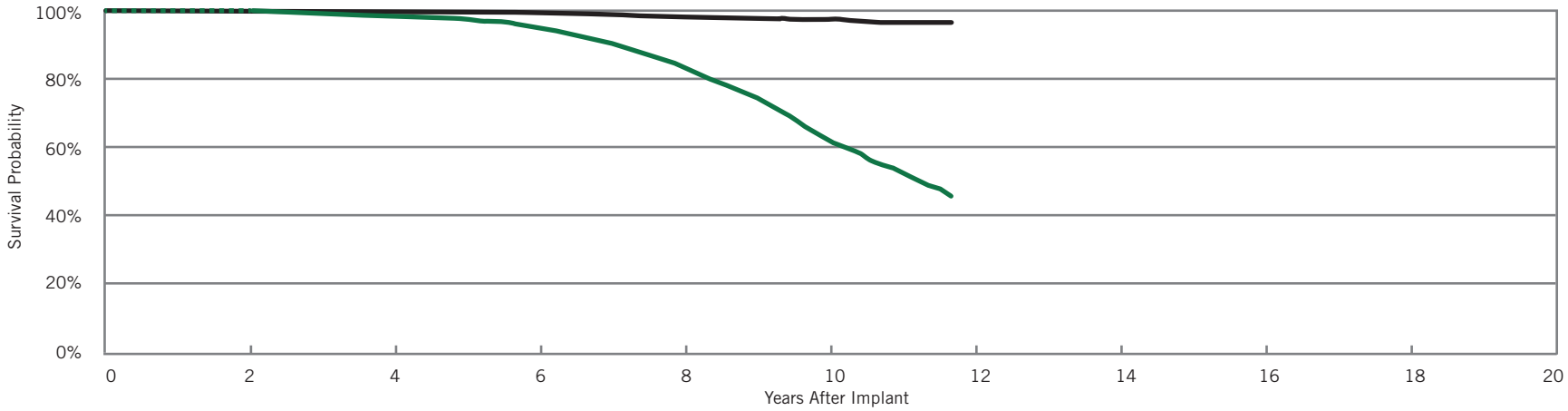
Year	2	4	6	8	10	at 128 months				
Survival Probability	99.85%	99.74%	99.60%	98.66%	97.59%	97.42%				
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.24%	0.27%				

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	65,687
Estimated Active US Implants	6,213
Estimated Longevity	6.3 Years
Normal Battery Depletion	3,297
Number of US Advisories (see pgs. 234-245)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	5	0.01%	272	0.41%
Electrical Interconnect	9	0.01%	13	0.02%
Battery	0	0.00%	6	0.01%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	3	<0.01%
Total	**15**	**0.02%**	**302**	**0.46%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 140 months				
Survival Probability	99.43%	98.61%	94.65%	82.93%	61.43%	45.51%				
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.38%	0.57%				
Sample Size	57400	46800	36200	23400	9700	1100				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 140 months				
Survival Probability	99.56%	99.35%	99.07%	98.38%	97.30%	96.40%				
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	0.20%				

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	99.97%									
5820	Zephyr® DR	99.92%	99.89%	99.49%	97.13%						
5810	Victory® DR	99.95%	99.86%	99.16%	93.13%						
5826	Zephyr® XL DR	99.94%	99.91%	99.87%							
5816	Victory® XL DR	99.95%	99.91%	99.84%	99.72%						
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	99.90%	99.85%	99.75%	99.59%	99.01%	97.23%				
5360	Integrity® ADx DR	99.84%	99.84%	99.15%	94.93%	76.41%	55.91%				
5366	Integrity® ADx XL DR	100.00%	99.97%	99.67%	99.67%	99.13%	96.44%				
5380	Identity ADx® DR	99.85%	99.64%	98.64%	93.11%	74.87%	56.99%	46.52%			
5386/5286	Identity ADx® XL DR/DC	99.91%	99.85%	99.73%	99.49%	98.91%	95.63%	88.85%			
5342/5346	Integrity® AFx DR	99.89%	99.77%	99.55%	99.26%	98.37%	95.99%	91.50%	84.03%	71.33%	56.00%
5370	Identity®	99.82%	99.48%	98.15%	89.84%	69.35%	53.71%	44.82%	41.22%		
5376	Identity® XL	99.82%	99.69%	99.47%	99.08%	98.13%	94.96%	88.69%	75.18%		
5326/5226	Entity® DR/DC	99.81%	99.69%	99.44%	98.78%	97.84%	94.84%	90.81%	83.02%	72.85%	60.88%
5330/5331/5230	Affinity® DR/DC	99.64%	99.43%	99.17%	98.61%	97.50%	94.65%	89.97%	82.93%	73.35%	61.43%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2210	Accent® DR RF	99.94%									
PM2110	Accent® DR	99.97%									
5820	Zephyr® DR	99.96%	99.95%	99.92%	99.77%						
5810	Victory® DR	99.98%	99.95%	99.69%	99.50%						
5826	Zephyr® XL DR	99.97%	99.96%	99.96%							
5816	Victory® XL DR	99.98%	99.95%	99.93%	99.89%						
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	99.96%	99.96%	99.94%	99.92%	99.89%	99.77%				
5360	Integrity® ADx DR	100.00%	100.00%	100.00%	99.16%	97.57%	96.10%				
5366	Integrity® ADx XL DR	100.00%	100.00%	100.00%	100.00%	100.00%	99.85%				
5380	Identity ADx® DR	99.96%	99.93%	99.75%	99.28%	97.79%	96.69%	96.54%			
5386/5286	Identity ADx® XL DR/DC	99.92%	99.90%	99.87%	99.85%	99.78%	99.65%	99.13%			
5342/5346	Integrity® AFx DR	99.96%	99.92%	99.87%	99.82%	99.73%	99.71%	99.57%	99.36%	99.18%	98.77%
5370	Identity®	99.93%	99.88%	99.71%	98.93%	96.90%	95.72%	95.03%	94.85%		
5376	Identity® XL	99.90%	99.81%	99.77%	99.72%	99.57%	99.36%	98.84%	97.79%		
5326/5226	Entity® DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.34%	98.66%	98.27%	97.59%
5330/5331/5230	Affinity® DR/DC	99.68%	99.56%	99.46%	99.35%	99.23%	99.07%	98.86%	98.38%	97.78%	97.30%

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent® DR RF	81975	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	0	0.00%	**5**	**0.01%**
PM2110	Accent® DR	13607	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5820	Zephyr® DR	35298	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5810	Victory® DR	26277	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	Zephyr® XL DR	101360	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**<0.01%**
5816	Victory® XL DR	62265	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	16939	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5360	Integrity® ADx DR	5837	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5366	Integrity® ADx XL DR	8008	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5380	Identity ADx® DR	53839	3	0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.01%**
5386/5286	Identity ADx® XL DR/DC	66581	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5342/5346	Integrity® AFx DR	47548	2	<0.01%	3	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**6**	**0.01%**
5370	Identity®	58439	3	0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.01%**
5376	Identity® XL	51482	2	<0.01%	4	0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**8**	**0.02%**
5326/5226	Entity® DR/DC	21872	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.01%**
5330/5331/5230	Affinity® DR/DC	65687	5	0.01%	9	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**15**	**0.02%**

Definitions of malfunction root cause categories can be found on page 7.

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent® DR RF	81975	1	<0.01%	3	<0.01%	0	0.00%	0	0.00%	7	0.01%	2	<0.01%	2	<0.01%	**15**	**0.02%**
PM2110	Accent® DR	13607	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	Zephyr® DR	35298	4	0.01%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	**7**	**0.02%**
5810	Victory® DR	26277	21	0.08%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	15	0.06%	0	0.00%	**37**	**0.14%**
5826	Zephyr® XL DR	101360	7	0.01%	0	0.00%	0	0.00%	0	0.00%	3	<0.01%	0	0.00%	2	<0.01%	**12**	**0.01%**
5816	Victory® XL DR	62265	8	0.01%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	3	<0.01%	3	<0.01%	**19**	**0.03%**
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	16939	6	0.04%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**8**	**0.05%**
5360	Integrity® ADx DR	5837	33	0.57%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**34**	**0.58%**
5366	Integrity® ADx XL DR	8008	2	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.02%**
5380	Identity ADx® DR	53839	232	0.43%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	11	0.02%	3	0.01%	**251**	**0.47%**
5386/5286	Identity ADx® XL DR/DC	66581	52	0.08%	2	<0.01%	0	0.00%	0	0.00%	6	0.01%	6	0.01%	2	<0.01%	**68**	**0.10%**
5342/5346	Integrity® AFx DR	47548	78	0.16%	1	<0.01%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**84**	**0.18%**
5370	Identity®	58439	385	0.66%	2	<0.01%	0	0.00%	0	0.00%	6	0.01%	11	0.02%	11	0.02%	**415**	**0.71%**
5376	Identity® XL	51482	157	0.30%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	4	0.01%	7	0.01%	**175**	**0.34%**
5326/5226	Entity® DR/DC	21872	61	0.28%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**65**	**0.30%**
5330/5331/5230	Affinity® DR/DC	65687	272	0.41%	13	0.02%	6	0.01%	2	<0.01%	5	0.01%	1	<0.01%	3	<0.01%	**302**	**0.46%**

Definitions of malfunction root cause categories can be found on page 7.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Total	
			Qty.	Rate	Qty.	Rate
PM2110	179	1719	0	0.00%	**0**	**0.00%**
PM2210	1294	13693	0	0.00%	**0**	**0.00%**
5820	267	5303	0	0.00%	**0**	**0.00%**
5826	1505	39524	2	0.13%	**2**	**0.13%**
5816	333	9415	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy															
		Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2110	179	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	1294	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	267	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	1505	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	333	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Models	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy															
		Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2110	179	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2210	1294	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	267	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	1505	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
5816	333	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Definitions of complications can be found on page 14.
Definitions of malfunction root cause categories can be found on page 7.

Pacemakers

Single-Chamber

St. Jude Medical
More control. Less risk.

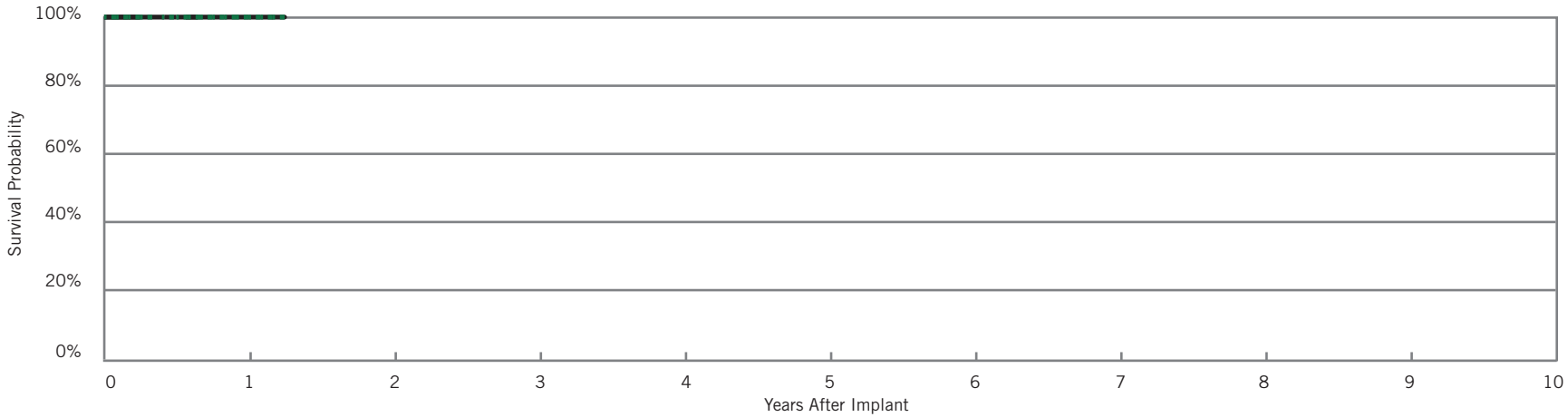
Accent® SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	3,224
Estimated Active US Implants	2,796
Estimated Longevity	12.9 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	at 15 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	2000	200								

Excluding Normal Battery Depletion

Year	1	at 15 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

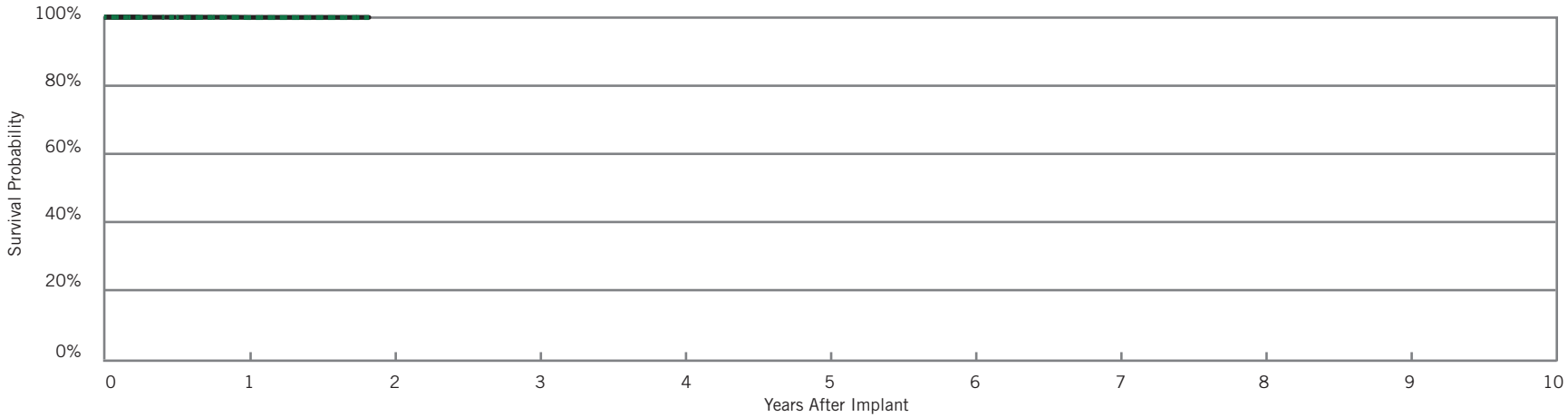
Customer Reported Performance Data

Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	12,640
Estimated Active US Implants	11,000
Estimated Longevity	10.9 Years
Normal Battery Depletion	3
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.85%	99.85%								
± 1 standard error	0.03%	0.04%								
Sample Size	9100	400								

Excluding Normal Battery Depletion

Year	1	at 22 months								
Survival Probability	99.92%	99.92%								
± 1 standard error	0.02%	0.04%								

SCORE Registry Performance Data

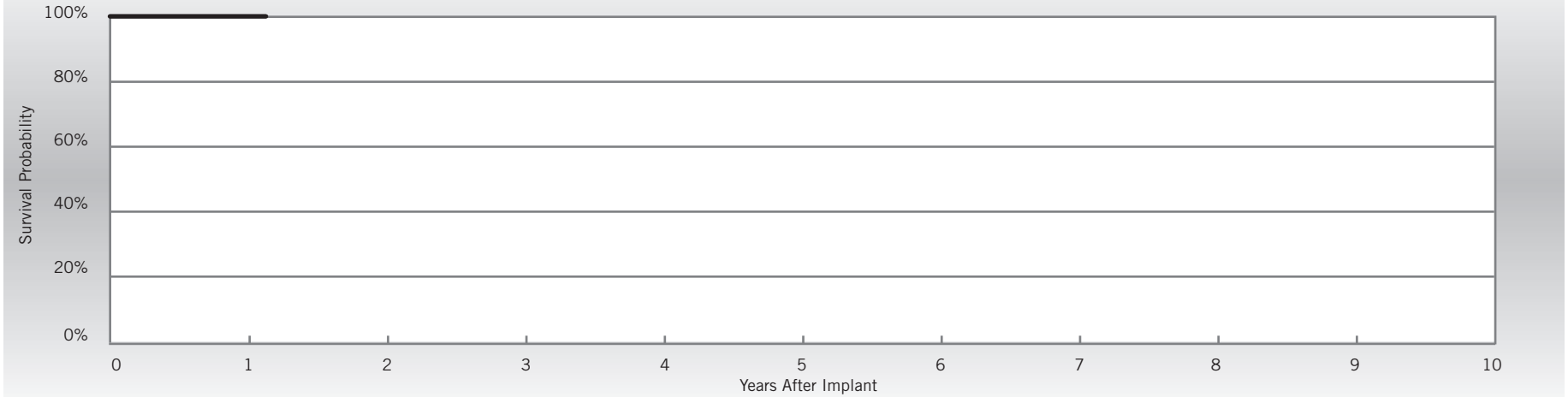
Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	189
Cumulative Months of Follow-up	1,827
Estimated Longevity	10.9 Years

Qualifying Complications
None Reported

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



Year	1	at 14 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	120	50								

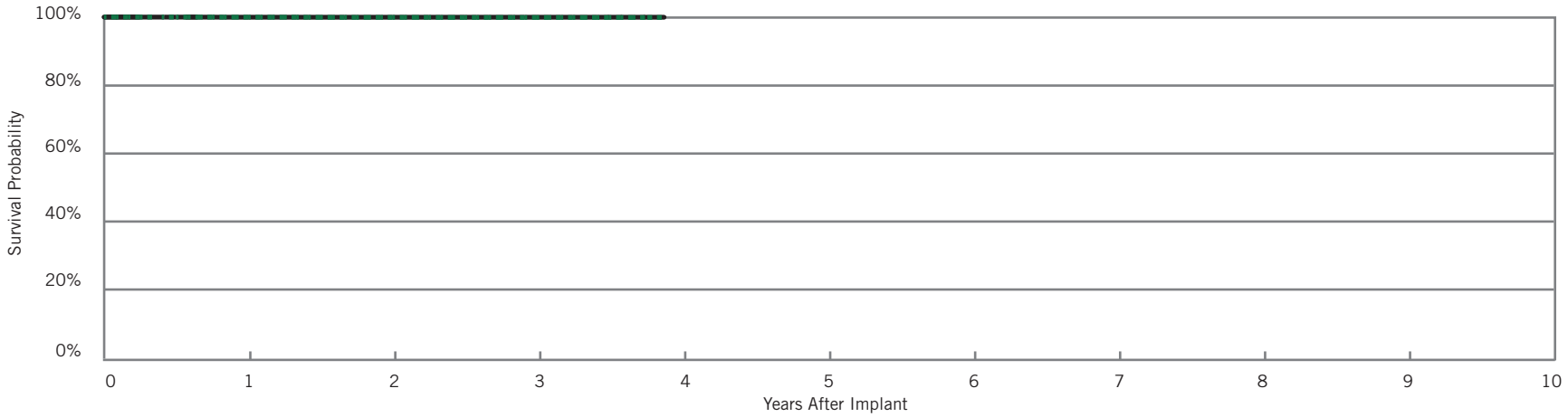
Customer Reported Performance Data

Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	18,410
Estimated Active US Implants	13,619
Estimated Longevity	15.8 Years
Normal Battery Depletion	4
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.96%	99.90%	99.87%	99.87%						
± 1 standard error	0.02%	0.03%	0.04%	0.04%						
Sample Size	17500	11900	5900	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.96%	99.95%	99.95%	99.95%						
± 1 standard error	0.02%	0.02%	0.02%	0.02%						

SCORE Registry Performance Data

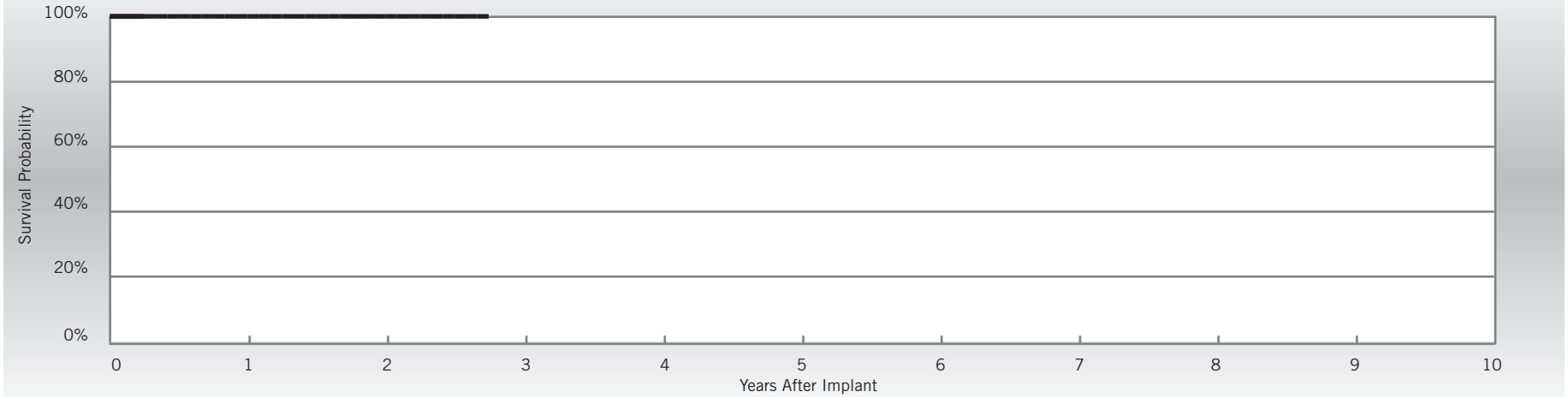
Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	228
Cumulative Months of Follow-up	5,461
Estimated Longevity	15.8 Years

Qualifying Complications
None Reported

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



Year	1	2	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	210	160	50							

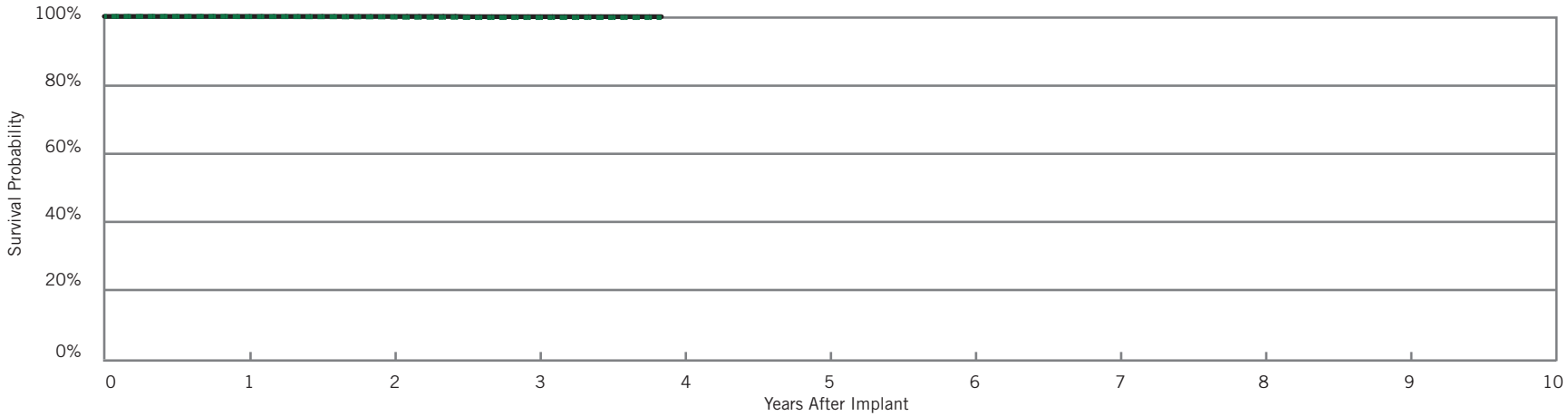
Customer Reported Performance Data

Zephyr® SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	10,801
Estimated Active US Implants	7,677
Estimated Longevity	8.8 Years
Normal Battery Depletion	7
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	99.91%	99.78%	99.65%	99.65%						
± 1 standard error	0.03%	0.05%	0.09%	0.09%						
Sample Size	9700	5700	2600	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 46 months						
Survival Probability	100.00%	100.00%	99.92%	99.92%						
± 1 standard error	0.00%	0.00%	0.06%	0.06%						

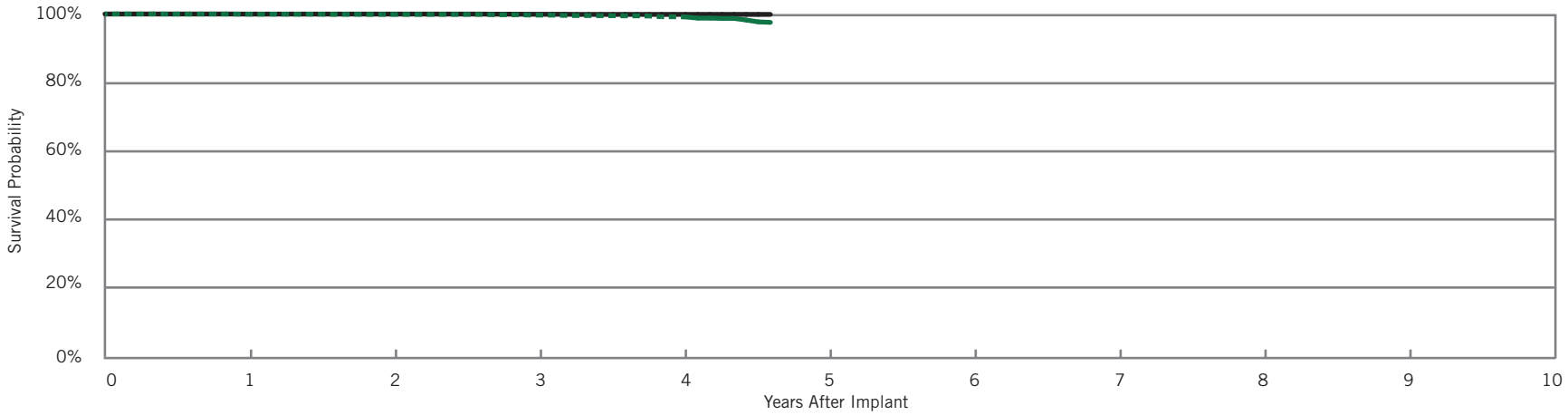
Customer Reported Performance Data

Victory® SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,567
Estimated Active US Implants	7,300
Estimated Longevity	8.8 Years
Normal Battery Depletion	32
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.95%	99.88%	99.67%	99.13%	96.91%					
± 1 standard error	0.02%	0.03%	0.06%	0.12%	0.31%					
Sample Size	13400	10300	7700	4700	1400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.98%	99.98%	99.92%	99.88%	99.88%					
± 1 standard error	0.01%	0.01%	0.03%	0.04%	0.04%					

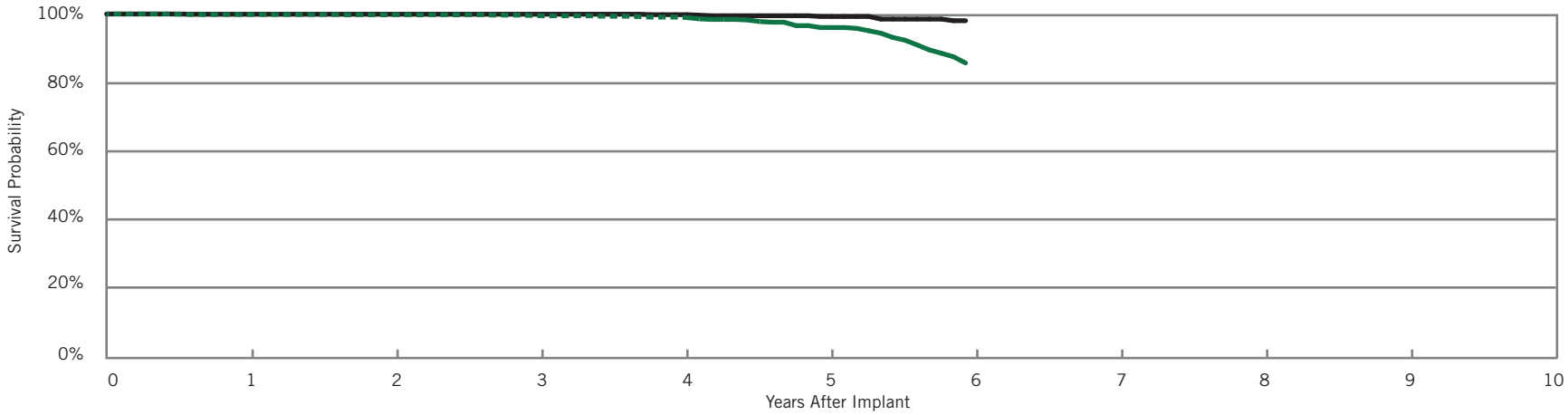
Integrity® ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,401
Estimated Active US Implants	864
Estimated Longevity	5.7 Years
Normal Battery Depletion	47
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	7	0.21%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.03%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**8**	**0.24%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.86%	99.78%	99.46%	98.94%	96.04%	84.46%				
± 1 standard error	0.07%	0.09%	0.14%	0.22%	0.57%	1.27%				
Sample Size	3400	2600	2200	1700	1200	400				

Excluding Normal Battery Depletion

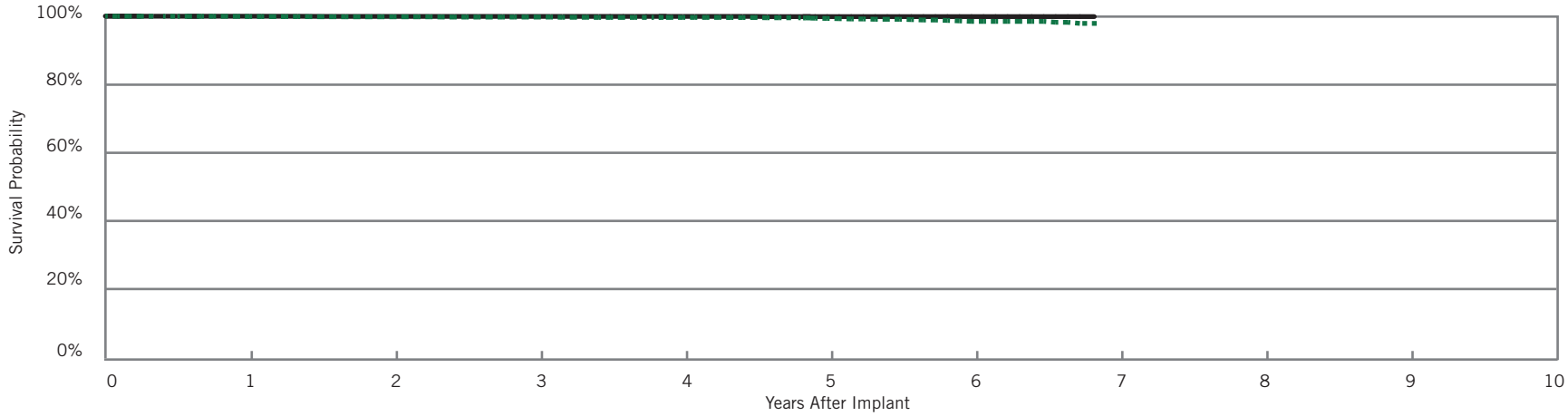
Year	1	2	3	4	5	at 71 months				
Survival Probability	99.93%	99.93%	99.93%	99.80%	99.27%	98.04%				
± 1 standard error	0.05%	0.05%	0.05%	0.11%	0.25%	0.53%				

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

US Regulatory Approval	May 2003
Registered US Implants	14,223
Estimated Active US Implants	6,427
Estimated Longevity	10.2 Years
Normal Battery Depletion	26
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.87%	99.79%	99.71%	99.60%	99.30%	98.41%	97.81%			
± 1 standard error	0.03%	0.04%	0.05%	0.07%	0.11%	0.23%	0.40%			
Sample Size	14100	11000	8800	6500	4000	2100	500			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.85%	99.85%	99.85%			
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.05%	0.05%	0.05%			

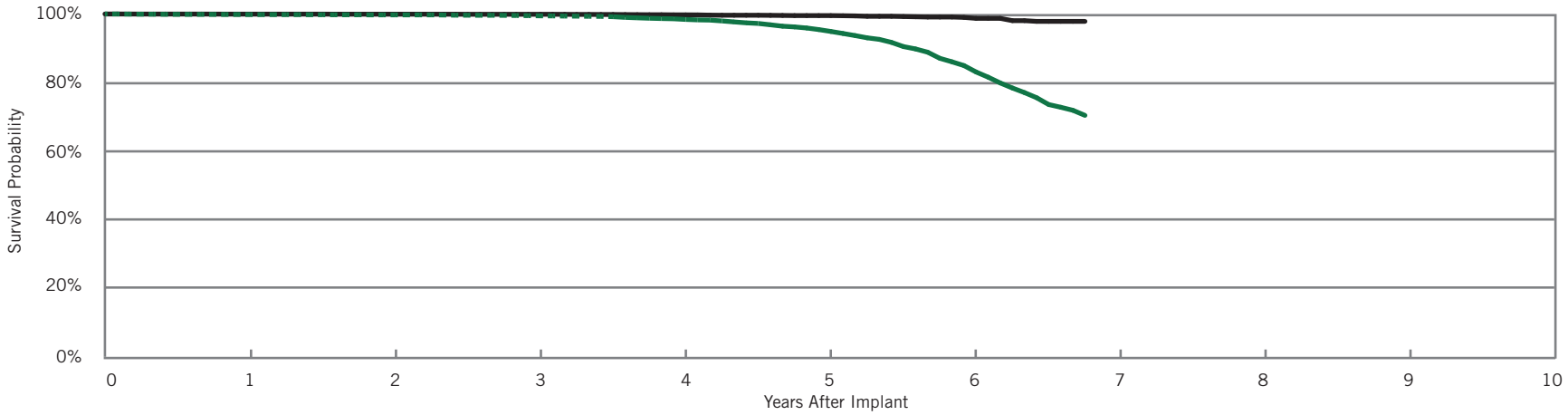
Integrity® ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,550
Estimated Active US Implants	7,108
Estimated Longevity	5.7 Years
Normal Battery Depletion	342
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	27	0.13%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**36**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.82%	99.73%	99.45%	98.40%	94.89%	83.05%	70.37%			
± 1 standard error	0.03%	0.04%	0.06%	0.12%	0.25%	0.59%	1.04%			
Sample Size	20300	15800	12800	9900	6900	3700	600			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 81 months			
Survival Probability	99.96%	99.94%	99.91%	99.75%	99.53%	98.72%	97.84%			
± 1 standard error	0.02%	0.02%	0.02%	0.05%	0.08%	0.15%	0.34%			

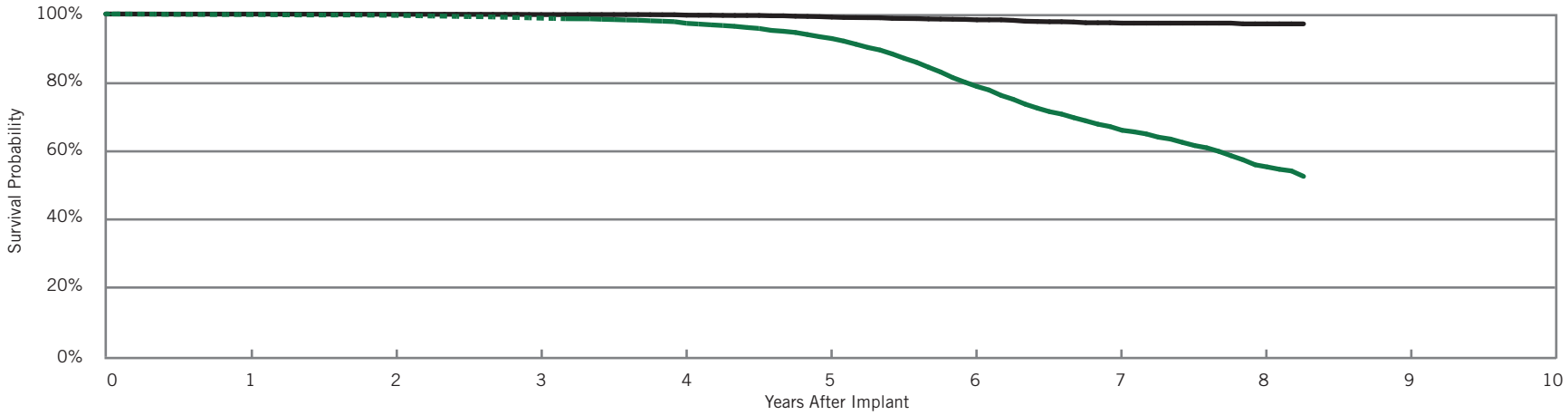
Identity® SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,931
Estimated Active US Implants	3,368
Estimated Longevity	7.8 Years
Normal Battery Depletion	859
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	1	<0.01%	60	0.27%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	1	<0.01%
Total	**1**	**<0.01%**	**69**	**0.31%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.84%	99.59%	98.77%	97.27%	92.83%	78.82%	66.02%	55.30%	52.55%
± 1 standard error	0.03%	0.05%	0.09%	0.13%	0.25%	0.48%	0.67%	0.91%	0.96%
Sample Size	21900	17500	14700	12200	9700	6800	3400	1500	500

Excluding Normal Battery Depletion

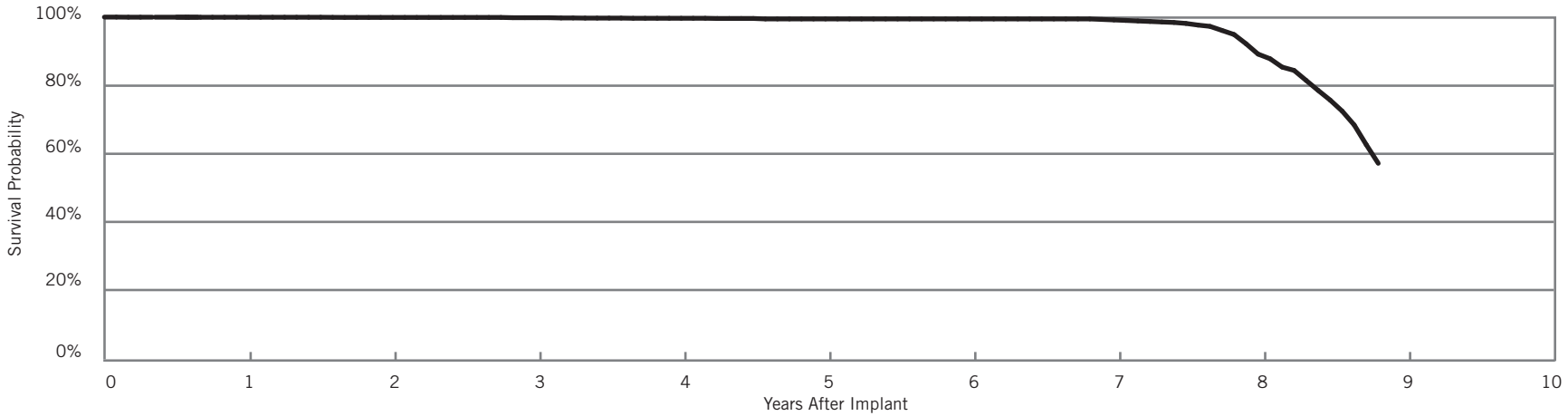
Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.97%	99.92%	99.82%	99.66%	99.09%	98.29%	97.33%	97.11%	97.11%
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.09%	0.15%	0.23%	0.29%	0.29%

Customer Reported Performance Data

Microny®

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	6,882
Estimated Longevity	7.5 Years
Number of US Advisories	None



Year	1	2	3	4	5	6	7	8	at 106 months
Survival Probability	99.95%	99.90%	99.82%	99.61%	99.45%	99.41%	98.98%	88.69%	56.13%
± 1 standard error	0.03%	0.05%	0.07%	0.11%	0.17%	0.17%	0.21%	0.38%	0.41%
Sample Size	6500	4400	3300	2400	1700	1200	800	500	300

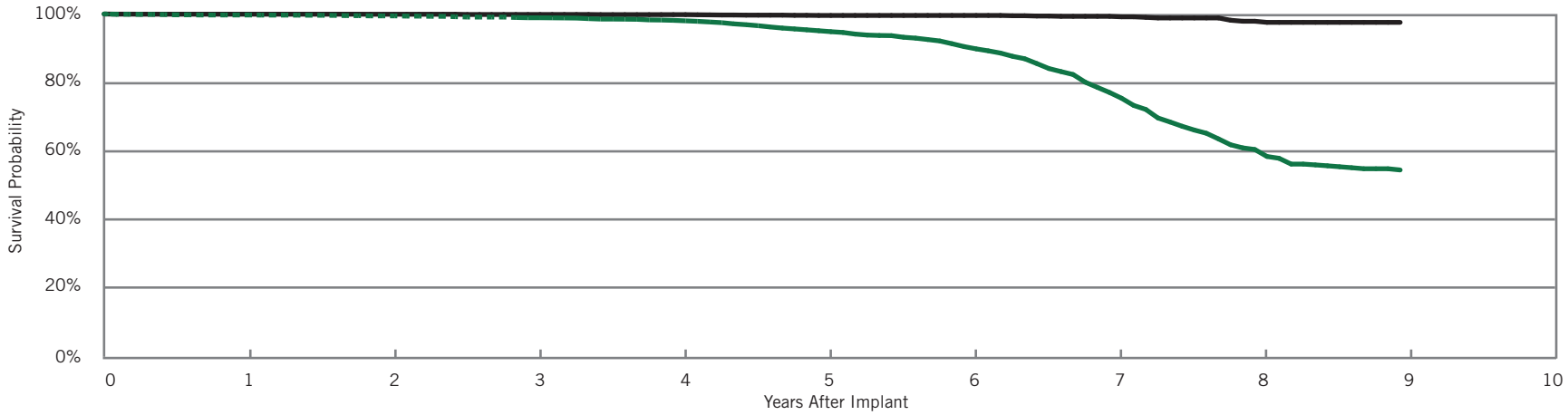
Integrity® µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	11,978
Estimated Active US Implants	659
Estimated Longevity	5.3 Years
Normal Battery Depletion	420
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	0	0.00%	22	0.18%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**0**	**0.00%**	**23**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	99.70%	99.44%	98.90%	98.00%	94.83%	89.80%	75.38%	58.37%	54.42%
± 1 standard error	0.05%	0.08%	0.12%	0.16%	0.29%	0.44%	0.78%	1.14%	1.29%
Sample Size	11900	9400	7800	6500	5300	4100	2800	1300	300

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 107 months
Survival Probability	99.94%	99.92%	99.85%	99.81%	99.57%	99.57%	99.17%	97.55%	97.55%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.09%	0.09%	0.14%	0.43%	0.49%

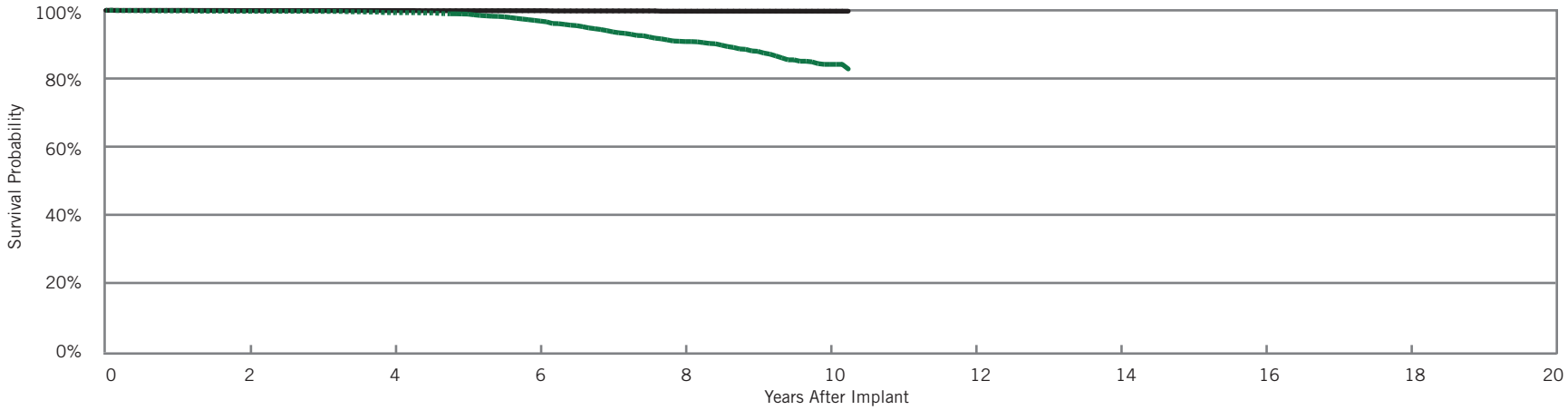
Integrity® SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,511
Estimated Active US Implants	1,810
Estimated Longevity	8.6 Years
Normal Battery Depletion	180
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	0	0.00%	3	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**5**	**0.05%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 123 months				
Survival Probability	99.71%	99.31%	96.83%	90.80%	84.09%	82.74%				
± 1 standard error	0.06%	0.10%	0.25%	0.49%	0.79%	0.79%				
Sample Size	8600	6300	4400	2800	1200	500				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 123 months				
Survival Probability	99.93%	99.93%	99.89%	99.75%	99.75%	99.75%				
± 1 standard error	0.03%	0.03%	0.04%	0.08%	0.08%	0.08%				

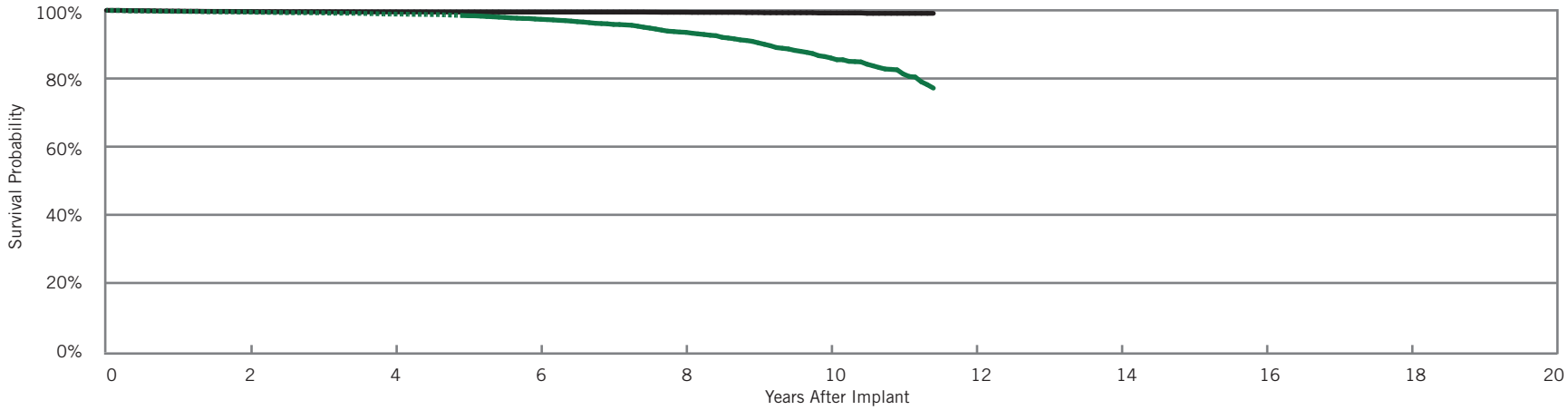
Affinity® SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,717
Estimated Active US Implants	3,512
Estimated Longevity	8.6 Years
Normal Battery Depletion	415
Number of US Advisories (see pgs. 234-245)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	43	0.15%
Electrical Interconnect	3	0.01%	2	0.01%
Battery	0	0.00%	3	0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	2	0.01%
Total	**4**	**0.01%**	**51**	**0.18%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.48%	98.90%	97.35%	93.52%	85.98%	77.10%				
± 1 standard error	0.05%	0.08%	0.14%	0.26%	0.47%	0.83%				
Sample Size	22900	16300	11300	7400	3600	700				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.63%	99.53%	99.48%	99.42%	99.22%	99.11%				
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.09%	0.12%				

Summary Information

Single-Chamber Pacemakers

St. Jude Medical™
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1110	Accent® SR	100.00%									
PM1210	Accent® SR RF	99.85%									
5626	Zephyr® XL SR	99.96%	99.90%	99.87%							
5620	Zephyr® SR	99.91%	99.78%	99.65%							
5610	Victory® SR	99.95%	99.88%	99.67%	99.13%						
5160	Integrity® ADx SR	99.86%	99.78%	99.46%	98.94%	96.04%					
5156/5157/5056	Verity ADx® XL SR/SR(M/S) / SC	99.87%	99.79%	99.71%	99.60%	99.30%	98.41%				
5180	Integrity® ADx SR	99.82%	99.73%	99.45%	98.40%	94.89%	83.05%				
5172	Identity® SR	99.84%	99.59%	98.77%	97.27%	92.83%	78.82%	66.02%	55.30%		
5136	Integrity® µ SR	99.70%	99.44%	98.90%	98.00%	94.83%	89.80%	75.38%	58.37%		
5142	Integrity® SR	99.85%	99.71%	99.68%	99.31%	98.89%	96.83%	93.65%	90.80%	87.93%	84.09%
5130/5131	Affinity® SR	99.69%	99.48%	99.25%	98.90%	98.40%	97.35%	95.84%	93.52%	90.42%	85.98%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1110	Accent® SR	100.00%									
PM1210	Accent® SR RF	99.92%									
5626	Zephyr® XL SR	99.96%	99.95%	99.95%							
5620	Zephyr® SR	100.00%	100.00%	99.92%							
5610	Victory® SR	99.98%	99.98%	99.92%	99.88%						
5160	Integrity® ADx SR	99.93%	99.93%	99.93%	99.80%	99.27%					
5156/5157/5056	Verity ADx® XL SR/SR(M/S) / SC	99.96%	99.91%	99.91%	99.91%	99.85%	99.85%				
5180	Integrity® ADx SR	99.96%	99.94%	99.91%	99.75%	99.53%	98.72%				
5172	Identity® SR	99.97%	99.92%	99.82%	99.66%	99.09%	98.29%	97.33%	97.11%		
5136	Integrity® µ SR	99.94%	99.92%	99.85%	99.81%	99.57%	99.57%	99.17%	97.55%		
5142	Integrity® SR	99.98%	99.93%	99.93%	99.93%	99.89%	99.89%	99.83%	99.75%	99.75%	99.75%
5130/5131	Affinity® SR	99.78%	99.63%	99.57%	99.53%	99.50%	99.48%	99.48%	99.42%	99.34%	99.22%

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1110	Accent® SR	3224	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent® SR RF	12640	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**2**	**0.02%**
5626	Zephyr® XL SR	18410	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5620	Zephyr® SR	10801	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5610	Victory® SR	13567	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
5160	Integrity® ADx SR	3401	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5356/5357/5256	Verity ADx® XL SR/SR(M/S) / SC	14223	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5180	Integrity® ADx SR	20550	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5172	Identity® SR	21931	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5136	Integrity® µ SR	11978	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5142	Integrity® SR	10511	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
5130/5131	Affinity® SR	28717	0	0.00%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**0.01%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1110	Accent® SR	3224	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent® SR RF	12640	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**1**	**0.01%**
5626	Zephyr® XL SR	18410	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**4**	**0.02%**
5620	Zephyr® SR	10801	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5610	Victory® SR	13567	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.02%**
5160	Integrity® ADx SR	3401	7	0.21%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	**8**	**0.24%**
5356/5357/5256	Verity ADx® XL SR/SR(M/S) / SC	14223	3	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	**5**	**0.04%**
5180	Integrity® ADx SR	20550	27	0.13%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	8	0.04%	0	0.00%	**36**	**0.18%**
5172	Identity® SR	21931	60	0.27%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.04%	1	<0.01%	**69**	**0.31%**
5136	Integrity® µ SR	11978	22	0.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**23**	**0.19%**
5142	Integrity® SR	10511	3	0.03%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	**5**	**0.05%**
5130/5131	Affinity® SR	28717	43	0.15%	2	0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	2	0.01%	**51**	**0.18%**

Definitions of malfunction root cause categories can be found on page 7.

Pacing Leads

Customer Reported Performance Data

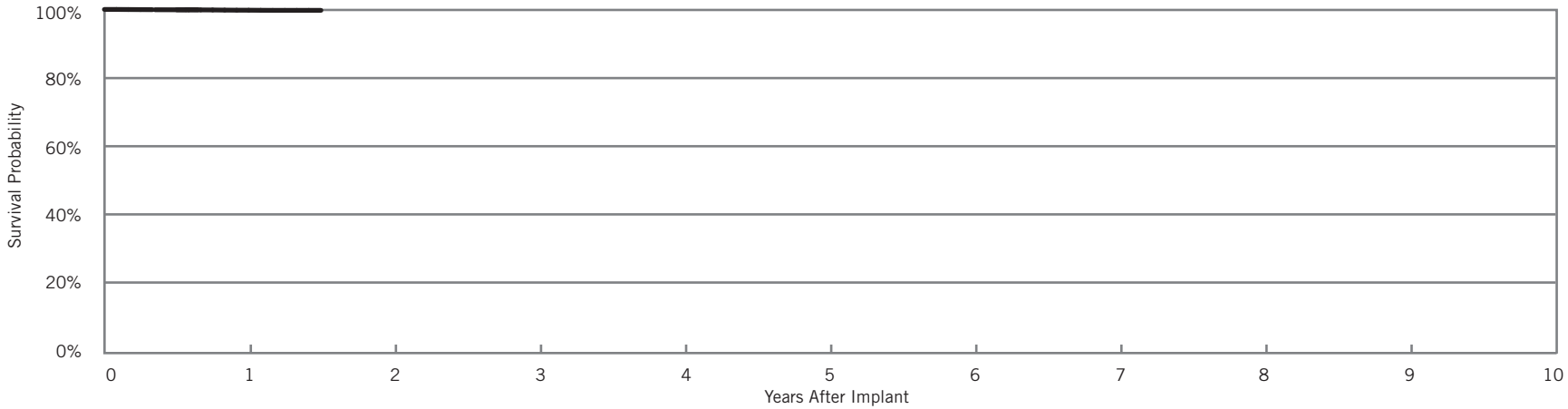
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	70,068
Estimated Active US Implants	61,983
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	11	0.02%	1	<0.01%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	35	0.05%	16	0.02%
Failure to Capture	6	0.01%	15	0.02%
Oversensing	2	<0.01%	9	0.01%
Failure to Sense	1	<0.01%	1	<0.01%
Insulation Breach	1	<0.01%	4	0.01%
Abnormal Pacing Impedance	2	<0.01%	2	<0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	2	<0.01%
Total	**59**	**0.08%**	**50**	**0.07%**
Total Returned for Analysis	**29**		**44**	

Lead 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	0.01%
Total	**10**	**0.01%**



Year	1	at 18 months								
Survival Probability	99.77%	99.73%								
± 1 standard error	0.03%	0.04%								
Sample Size	42100	500								

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

SCORE Registry Performance Data

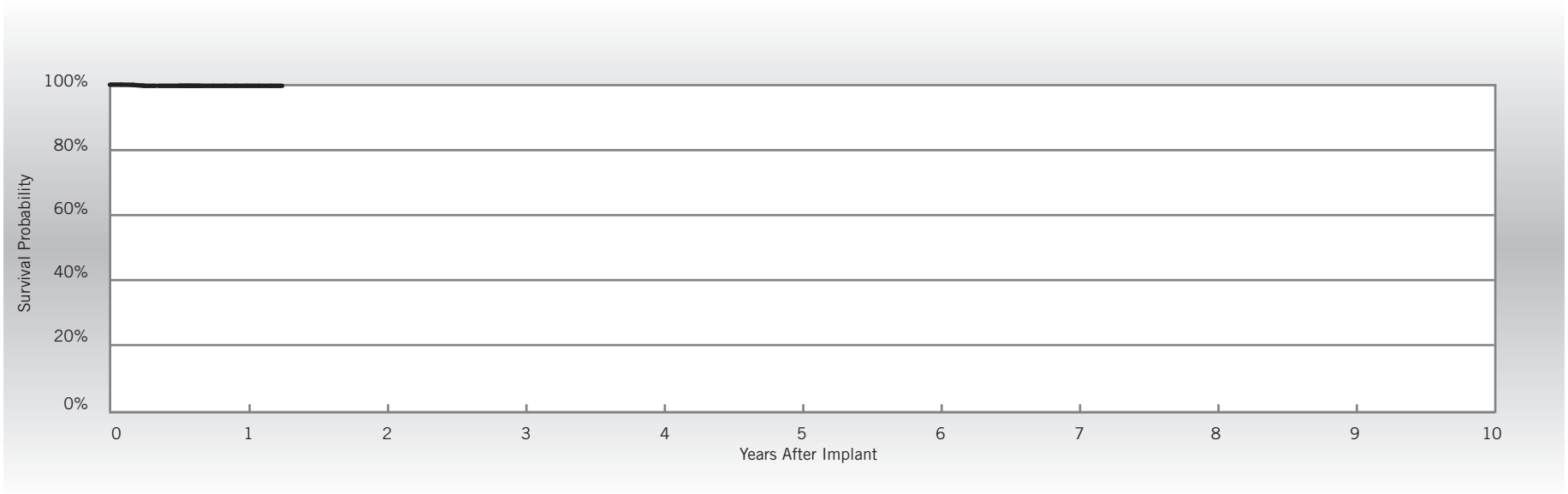
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	1,572
Cumulative Months of Follow-up	12,366
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.06%
Cardiac Perforation	1	0.06%
Failure to Capture	1	0.06%
Lead Dislodgement	2	0.13%

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 15 months								
Survival Probability	99.64%	99.64%								
± 1 standard error	0.15%	0.15%								
Sample Size	920	100								

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

Customer Reported Performance Data

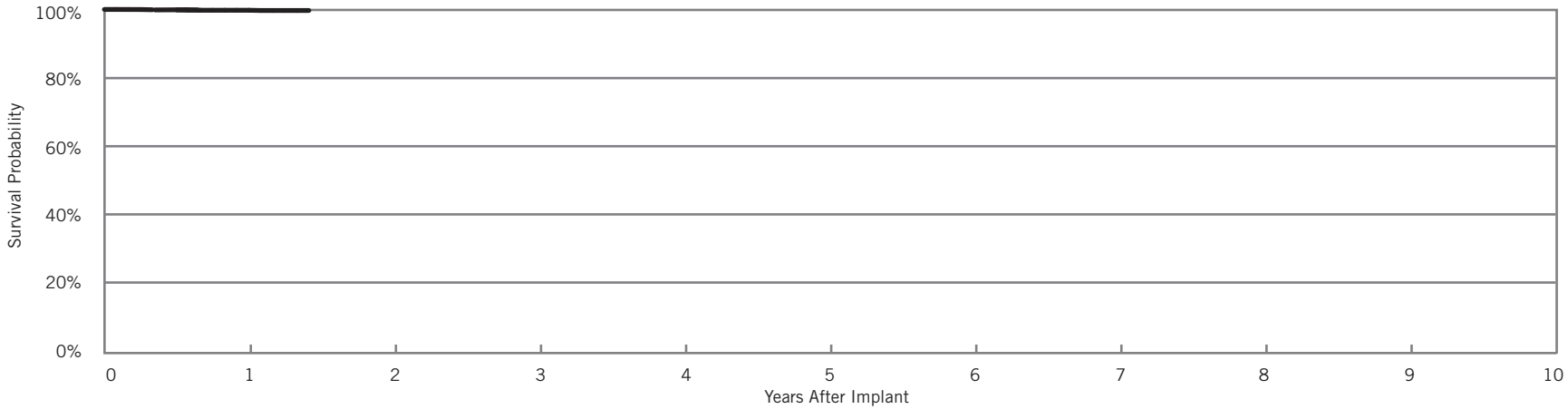
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	10,082
Estimated Active US Implants	8,844
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	6	0.06%	7	0.07%
Failure to Capture	1	0.01%	3	0.03%
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	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**8**	**0.08%**	**11**	**0.11%**
Total Returned for Analysis	**2**		**11**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.01%
Total	**2**	**0.02%**



Year	1	at 17 months								
Survival Probability	99.76%	99.69%								
± 1 standard error	0.06%	0.09%								
Sample Size	6200	300								

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

SCORE Registry Performance Data

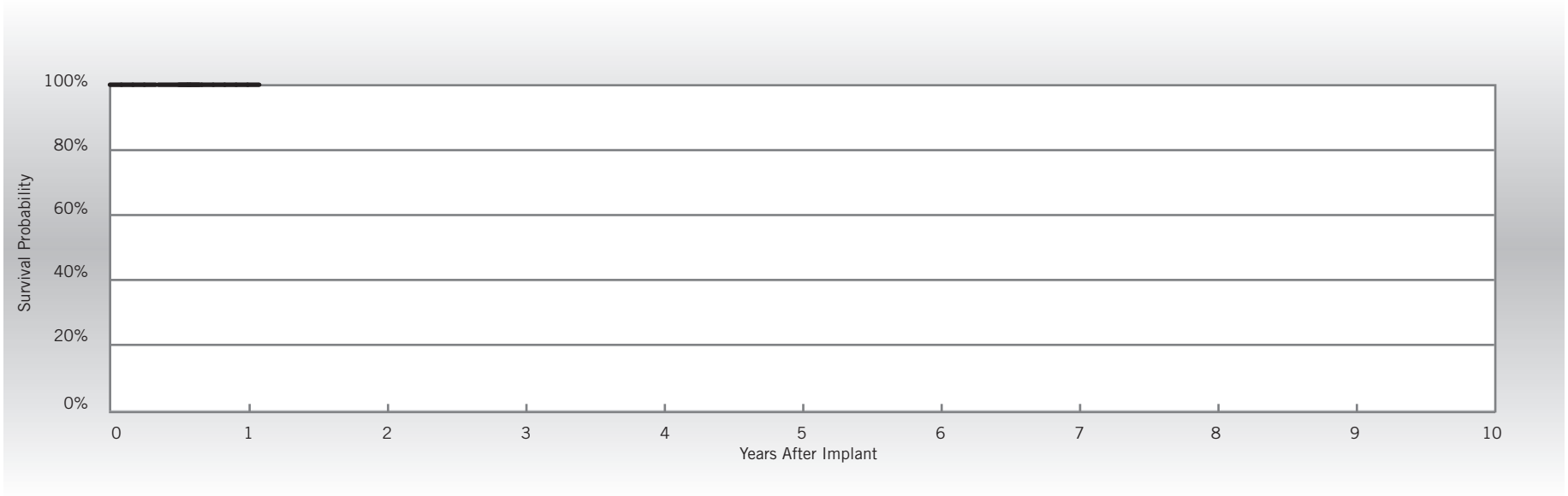
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	241
Cumulative Months of Follow-up	2030
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	1	at 13 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	150	60								

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

Customer Reported Performance Data

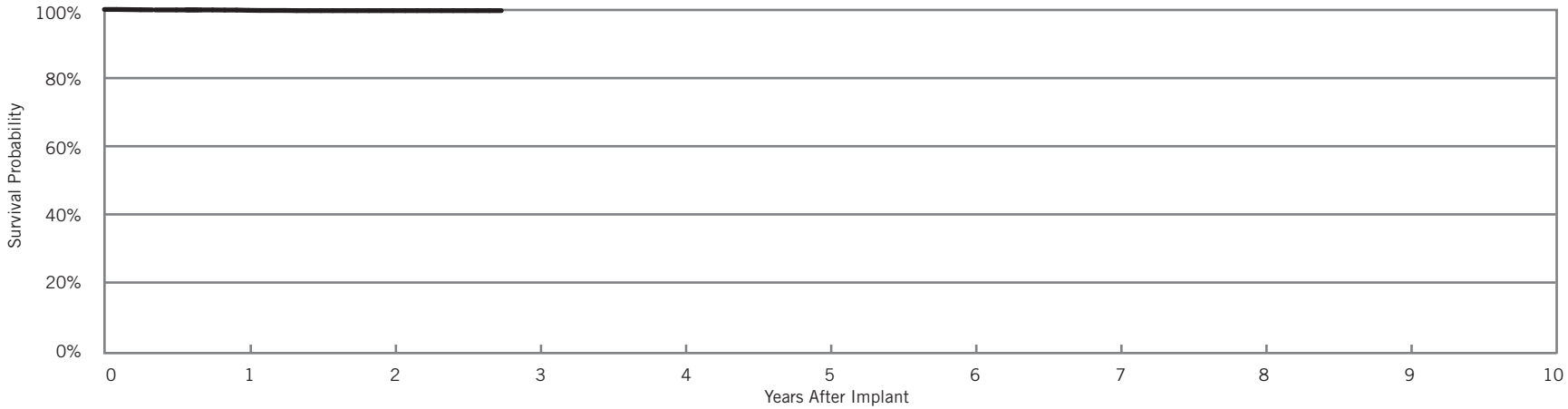
IsoFlex® Optim®

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	5,114
Estimated Active US Implants	4,077
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	12	0.23%	4	0.08%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	1	0.02%
Failure to Sense	2	0.04%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	1	0.02%
Total	**14**	**0.27%**	**6**	**0.12%**
Total Returned for Analysis	**8**		**3**	

Lead 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	0.04%
Total	**2**	**0.04%**



Year	1	2	at 33 months							
Survival Probability	99.74%	99.65%	99.65%							
± 1 standard error	0.07%	0.11%	0.11%							
Sample Size	4000	1700	200							

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

Customer Reported Performance Data

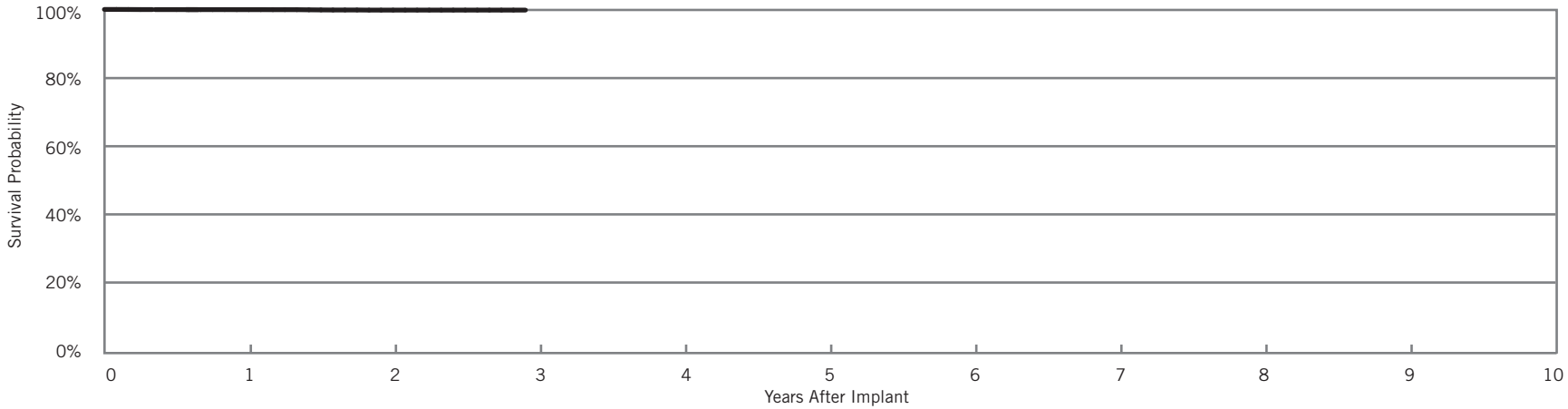
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	17,666
Estimated Active US Implants	14,389
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	8	0.05%	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	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.01%	0	0.00%
Total	**12**	**0.07%**	**10**	**0.06%**
Total Returned for Analysis	**9**		**7**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	5	0.03%
Total	**7**	**0.04%**



Year	1	2	at 35 months							
Survival Probability	99.94%	99.81%	99.81%							
± 1 standard error	0.02%	0.05%	0.05%							
Sample Size	13900	5800	300							

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

SCORE Registry Performance Data

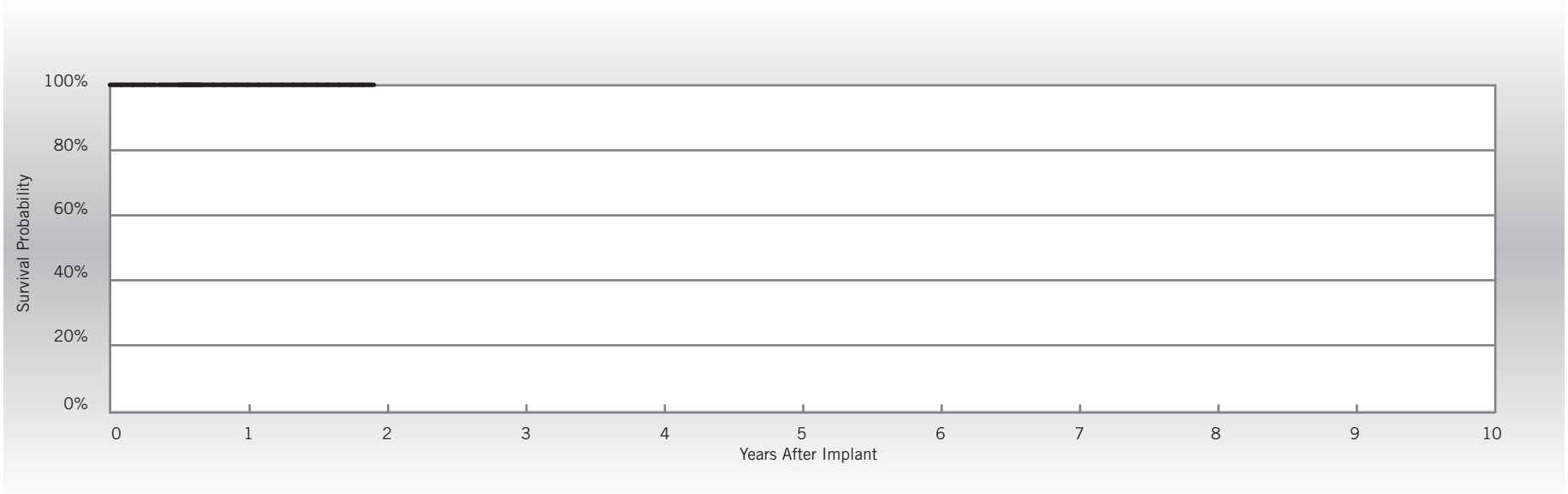
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	292
Cumulative Months of Follow-up	3952
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 23 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	220	50								

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

Customer Reported Performance Data

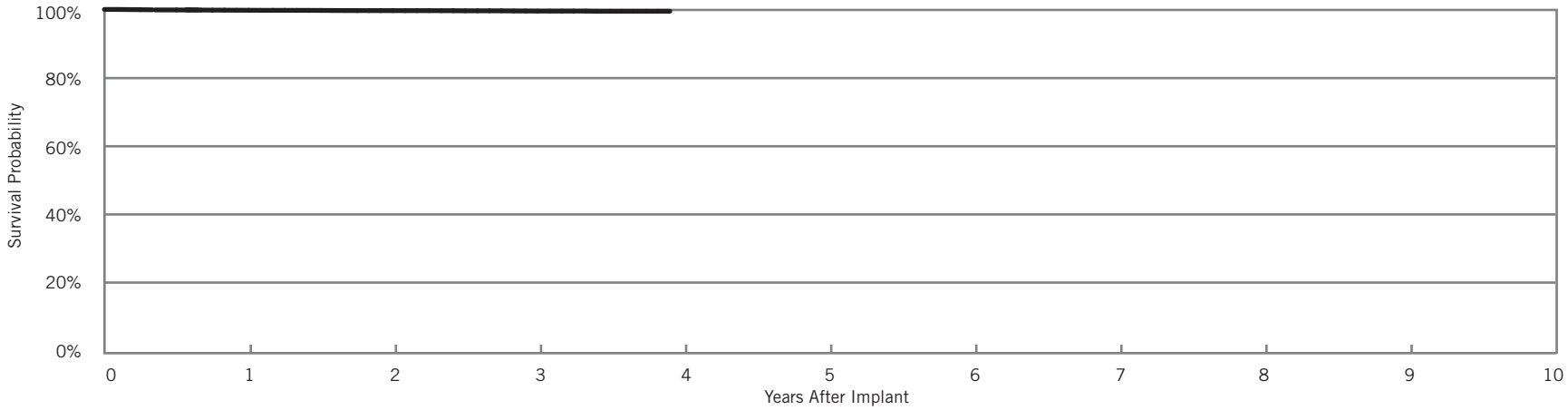
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	23,837
Estimated Active US Implants	17,346
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	5	0.02%	20	0.08%
Failure to Capture	3	0.01%	12	0.05%
Oversensing	2	0.01%	5	0.02%
Failure to Sense	8	0.03%	5	0.02%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	3	0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	0.01%	0	0.00%
Total	**21**	**0.09%**	**49**	**0.21%**
Total Returned for Analysis	**16**		**35**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	0.01%
Insulation Breach	3	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	27	0.11%
Total	**33**	**0.14%**



Year	1	2	3	at 47 months						
Survival Probability	99.76%	99.65%	99.51%	99.46%						
± 1 standard error	0.03%	0.04%	0.06%	0.08%						
Sample Size	22300	15800	8300	300						

SCORE Registry Performance Data

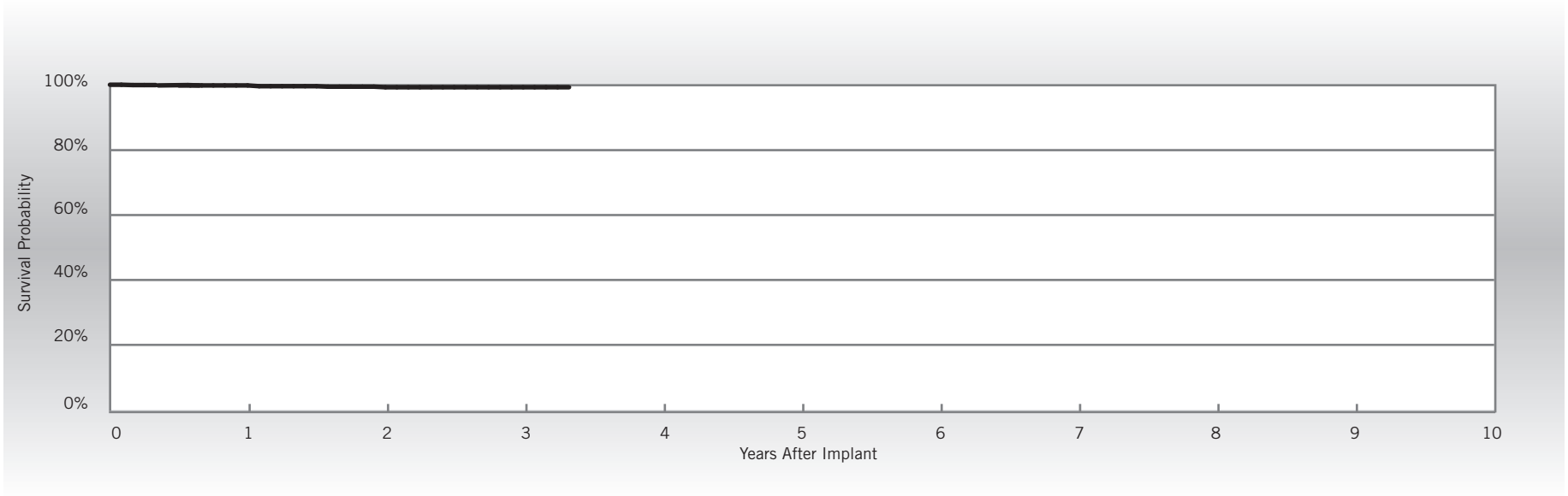
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	998
Cumulative Months of Follow-up	24,180
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

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

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.10%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.10%
Total	**2**	**0.20%**



Year	1	2	3	at 40 months						
Survival Probability	99.79%	99.22%	99.22%	99.22%						
± 1 standard error	0.15%	0.32%	0.32%	0.32%						
Sample Size	910	680	340	50						

Customer Reported Performance Data

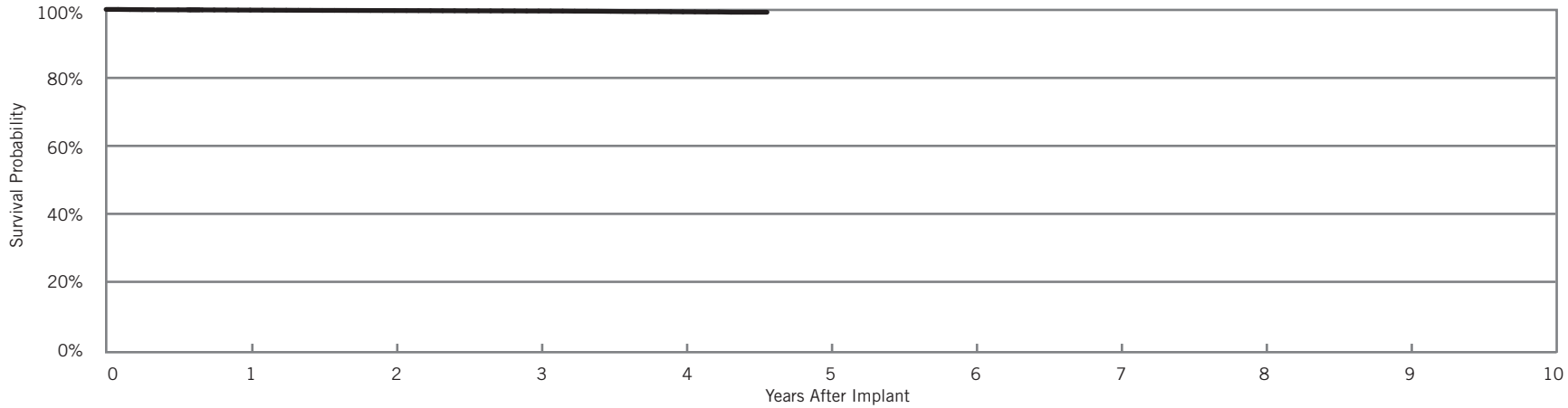
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	223,988
Estimated Active US Implants	167,283
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	26	0.01%	18	0.01%
Conductor Fracture	5	<0.01%	20	0.01%
Lead Dislodgement	97	0.04%	158	0.07%
Failure to Capture	67	0.03%	96	0.04%
Oversensing	10	<0.01%	65	0.03%
Failure to Sense	8	<0.01%	11	<0.01%
Insulation Breach	3	<0.01%	25	0.01%
Abnormal Pacing Impedance	6	<0.01%	19	0.01%
Extracardiac Stimulation	3	<0.01%	7	<0.01%
Other	17	0.01%	27	0.01%
Total	**242**	**0.11%**	**446**	**0.20%**
Total Returned for Analysis	**105**		**285**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	7	<0.01%
Insulation Breach	74	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	3	<0.01%
Extrinsic Factors	221	0.10%
Total	**306**	**0.14%**



Year	1	2	3	4	at 55 months					
Survival Probability	99.80%	99.66%	99.53%	99.28%	99.16%					
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.09%					
Sample Size	201200	124600	61600	20600	300					

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

SCORE Registry Performance Data

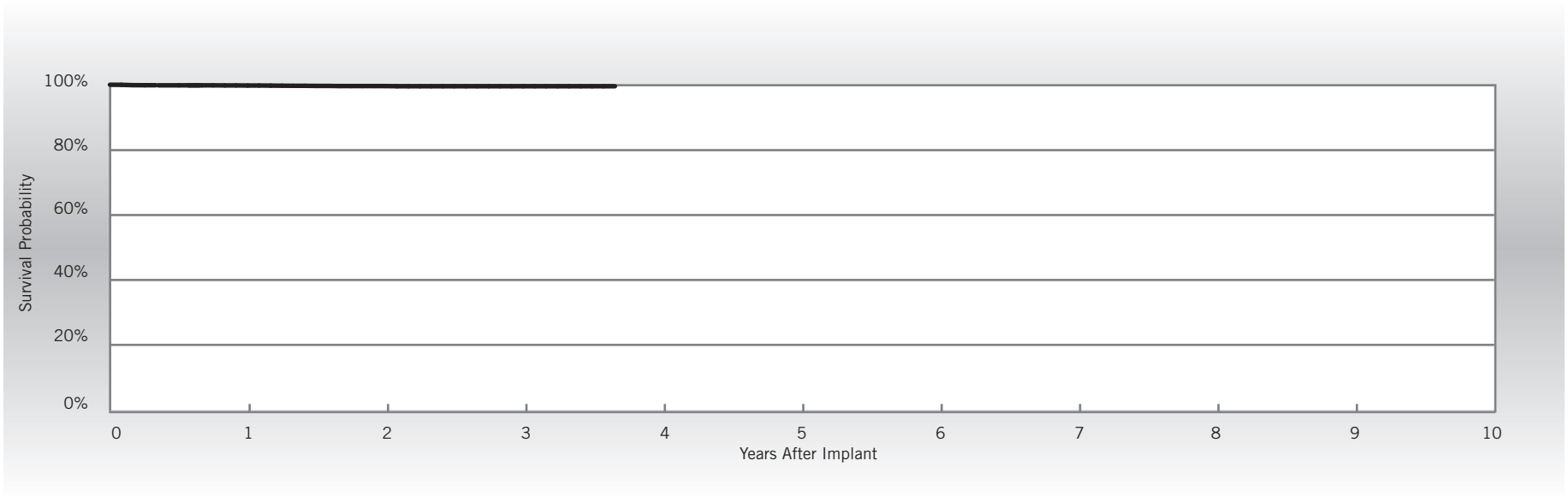
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	4,029
Cumulative Months of Follow-up	92,332
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

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

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.02%
Insulation Breach	2	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	5	0.12%
Total	**9**	**0.22%**



Year	1	2	3	at 44 months						
Survival Probability	99.76%	99.59%	99.53%	99.53%						
± 1 standard error	0.08%	0.11%	0.12%	0.12%						
Sample Size	3660	2570	1130	60						

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

Customer Reported Performance Data

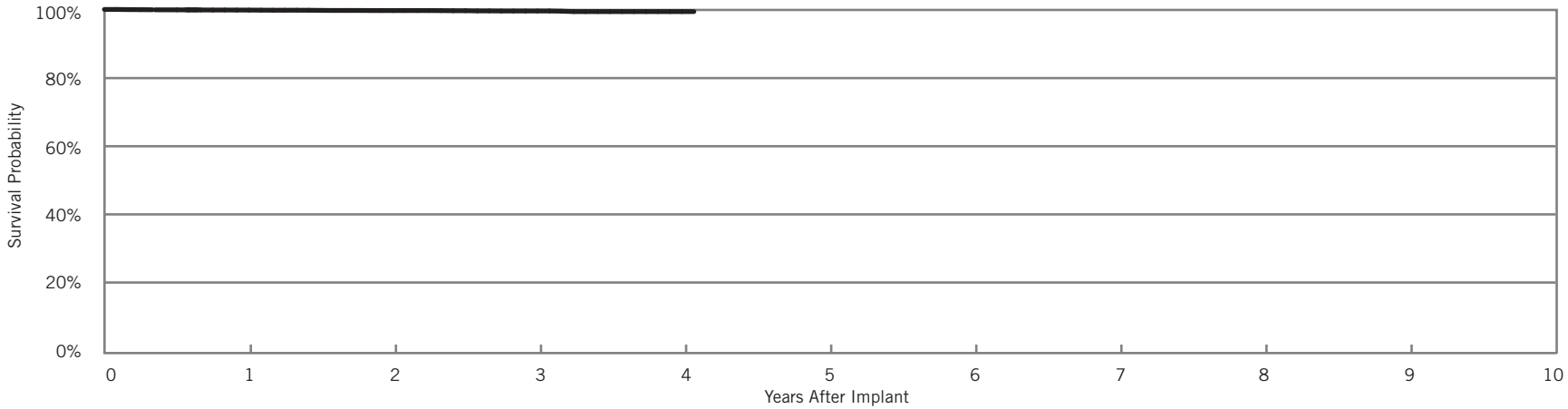
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	19,757
Estimated Active US Implants	15,436
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	2	0.01%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	14	0.07%	14	0.07%
Failure to Capture	5	0.03%	8	0.04%
Oversensing	2	0.01%	4	0.02%
Failure to Sense	3	0.02%	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%	5	0.03%
Total	**28**	**0.14%**	**36**	**0.18%**
Total Returned for Analysis	**9**		**27**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	4	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	21	0.11%
Total	**26**	**0.13%**



Year	1	2	3	4	at 49 months					
Survival Probability	99.81%	99.67%	99.54%	99.36%	99.36%					
± 1 standard error	0.03%	0.05%	0.08%	0.13%	0.13%					
Sample Size	16800	9400	4400	1300	200					

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

SCORE Registry Performance Data

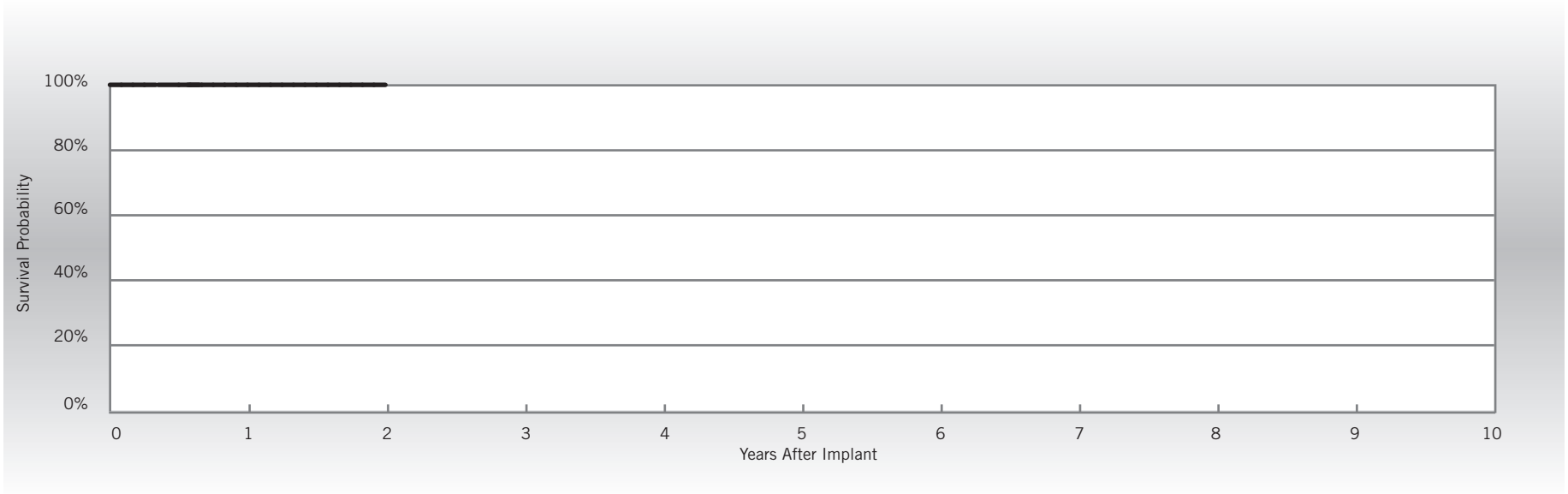
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	172
Cumulative Months of Follow-up	2,960
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	0.58%
Total	**1**	**0.58%**



Year	1	2								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	140	80								

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

Customer Reported Performance Data

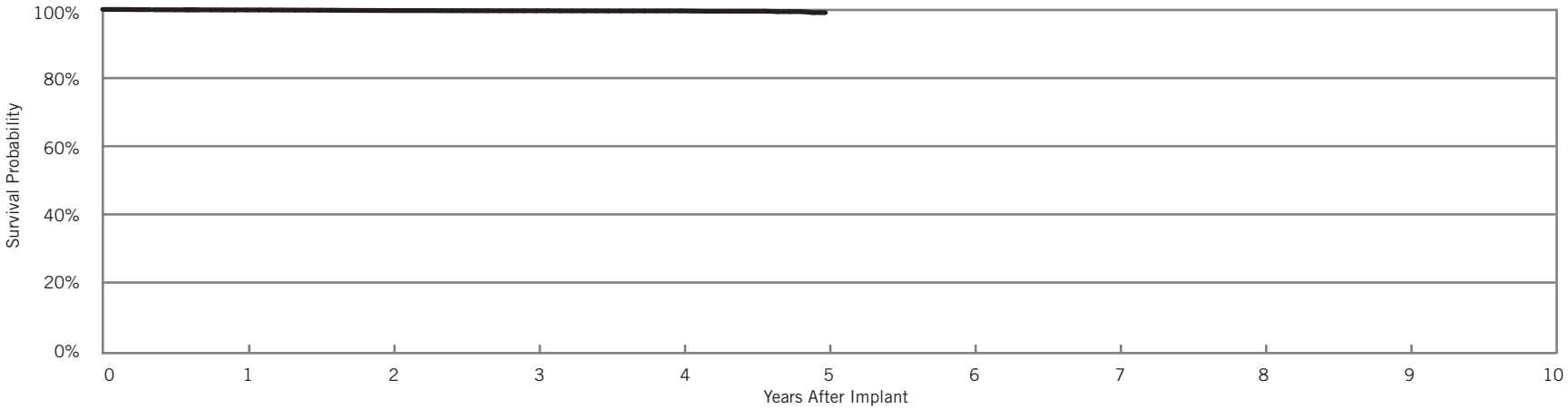
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	15,622
Estimated Active US Implants	10,882
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	11	0.07%	17	0.11%
Failure to Capture	5	0.03%	12	0.08%
Oversensing	0	0.00%	3	0.02%
Failure to Sense	0	0.00%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	2	0.01%
Extracardiac Stimulation	1	0.01%	0	0.00%
Other	2	0.01%	1	0.01%
Total	**26**	**0.17%**	**38**	**0.24%**
Total Returned for Analysis	**14**		**28**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	22	0.14%
Total	**25**	**0.16%**



Year	1	2	3	4	5					
Survival Probability	99.85%	99.67%	99.60%	99.56%	99.05%					
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.34%					
Sample Size	14600	10900	7600	4400	1400					

SCORE Registry Performance Data

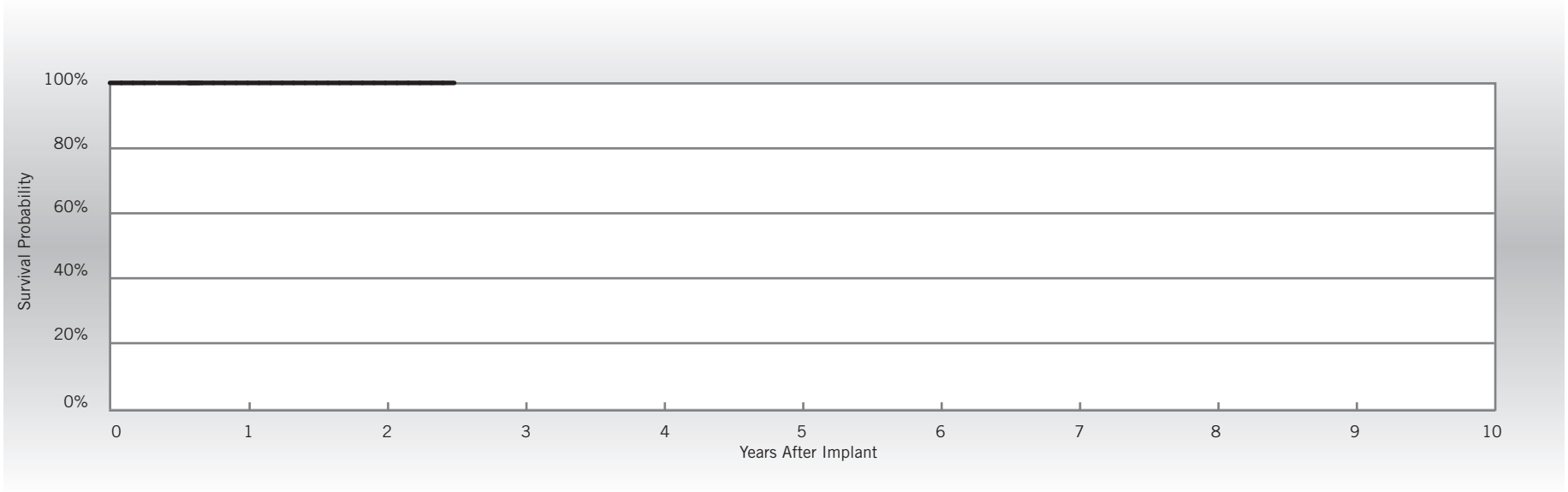
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	146
Cumulative Months of Follow-up	3,242
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 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	130	80	50							

Customer Reported Performance Data

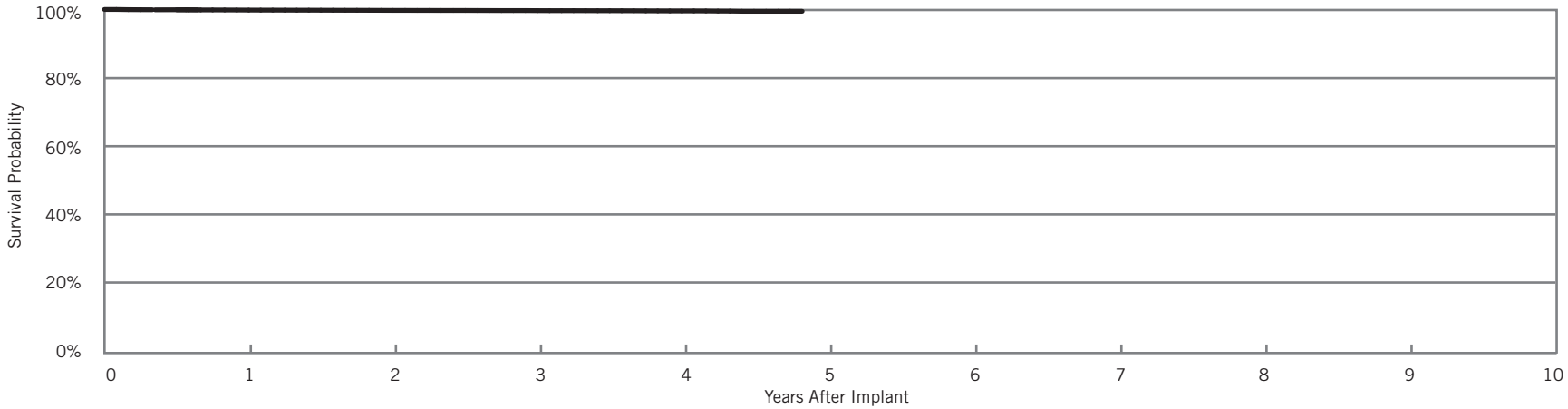
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,435
Estimated Active US Implants	44,067
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	11	0.02%	2	<0.01%
Conductor Fracture	1	<0.01%	2	<0.01%
Lead Dislodgement	31	0.05%	29	0.04%
Failure to Capture	29	0.04%	38	0.06%
Oversensing	2	<0.01%	21	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	**108**	**0.17%**	**111**	**0.17%**
Total Returned for Analysis	**41**		**80**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	27	0.04%
Crimps, Welds & Bonds	1	<0.01%
Other	1	0.00%
Extrinsic Factors	51	0.08%
Total	**83**	**0.13%**



Year	1	2	3	4	at 58 months					
Survival Probability	99.82%	99.73%	99.66%	99.57%	99.47%					
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.05%					
Sample Size	63500	50900	38900	24100	800					

SCORE Registry Performance Data

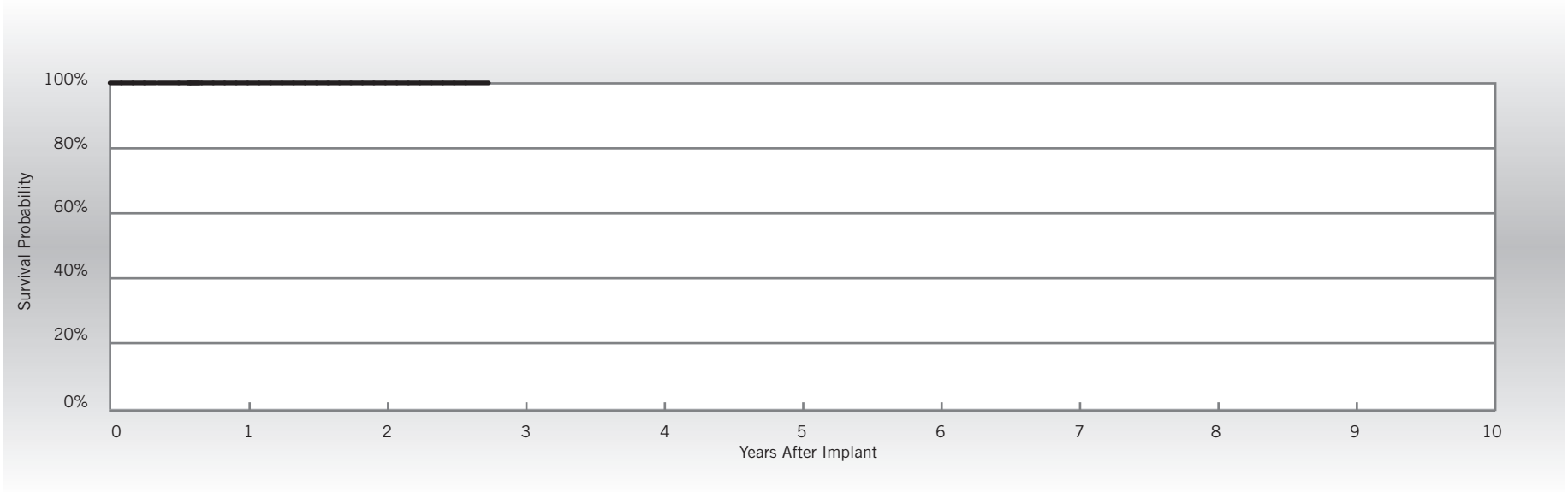
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	243
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	210	150	50							

Customer Reported Performance Data

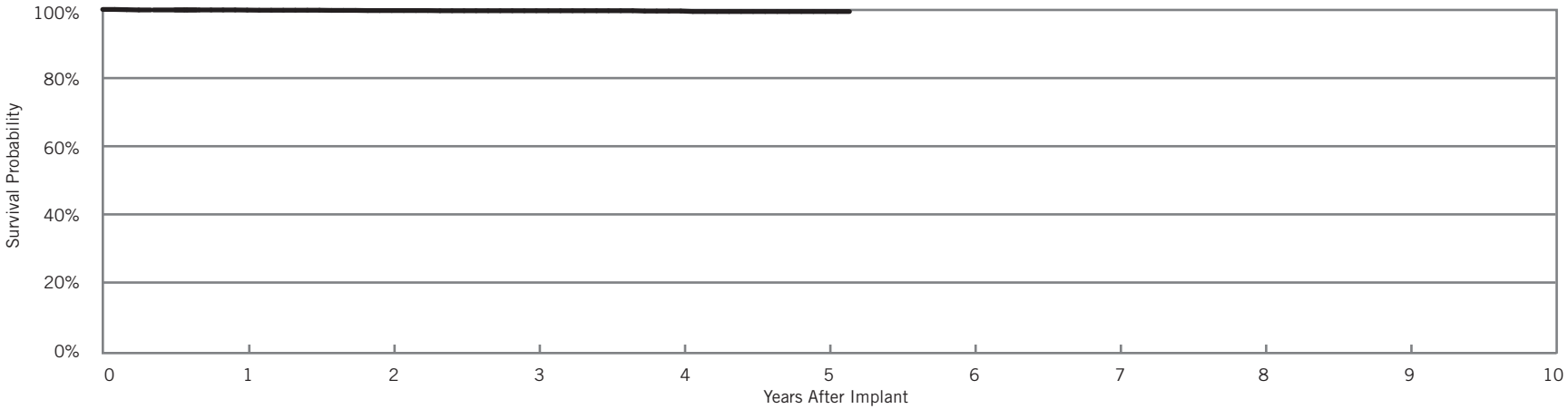
IsoFlex® P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,840
Estimated Active US Implants	1,587
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**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	3	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.04%
Extrinsic Factors	2	0.07%
Total	**6**	**0.21%**



Year	1	2	3	4	5	at 62 months				
Survival Probability	99.81%	99.67%	99.62%	99.52%	99.38%	99.38%				
± 1 standard error	0.07%	0.12%	0.13%	0.16%	0.21%	0.21%				
Sample Size	2800	2300	1900	1200	500	200				

Customer Reported Performance Data

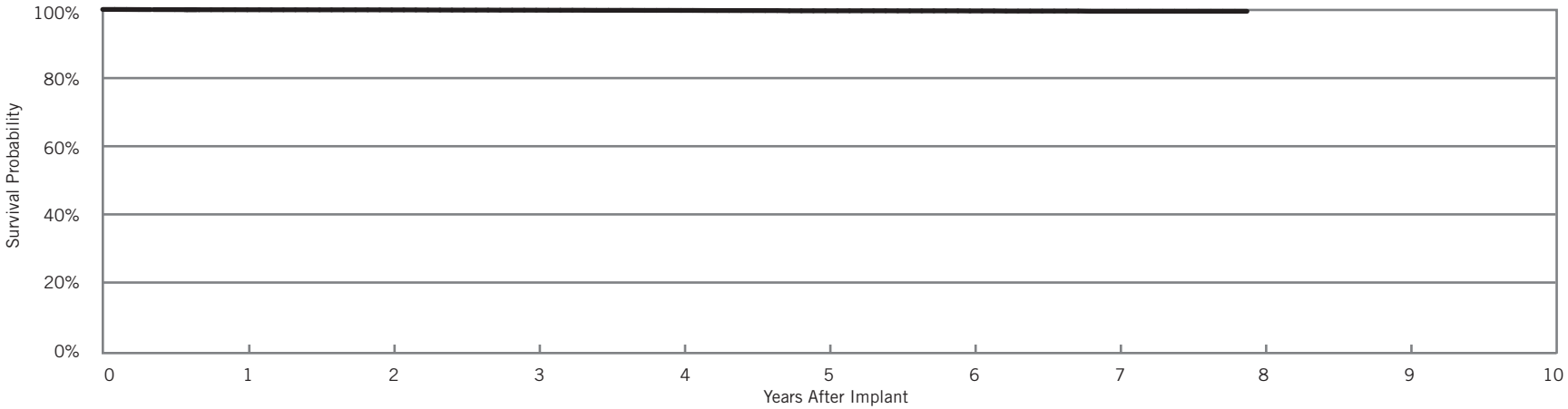
IsoFlex® S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	26,181
Estimated Active US Implants	16,171
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	48	0.18%	20	0.08%
Failure to Capture	5	0.02%	16	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%	2	0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**60**	**0.23%**	**43**	**0.16%**
Total Returned for Analysis	**36**		**16**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	2	0.01%
Extrinsic Factors	12	0.05%
Total	**17**	**0.06%**



Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.91%	99.87%	99.78%	99.71%	99.60%	99.55%	99.45%	99.45%		
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.06%	0.06%	0.10%	0.10%		
Sample Size	25200	20100	15900	11800	8000	4900	2400	300		

Customer Reported Performance Data

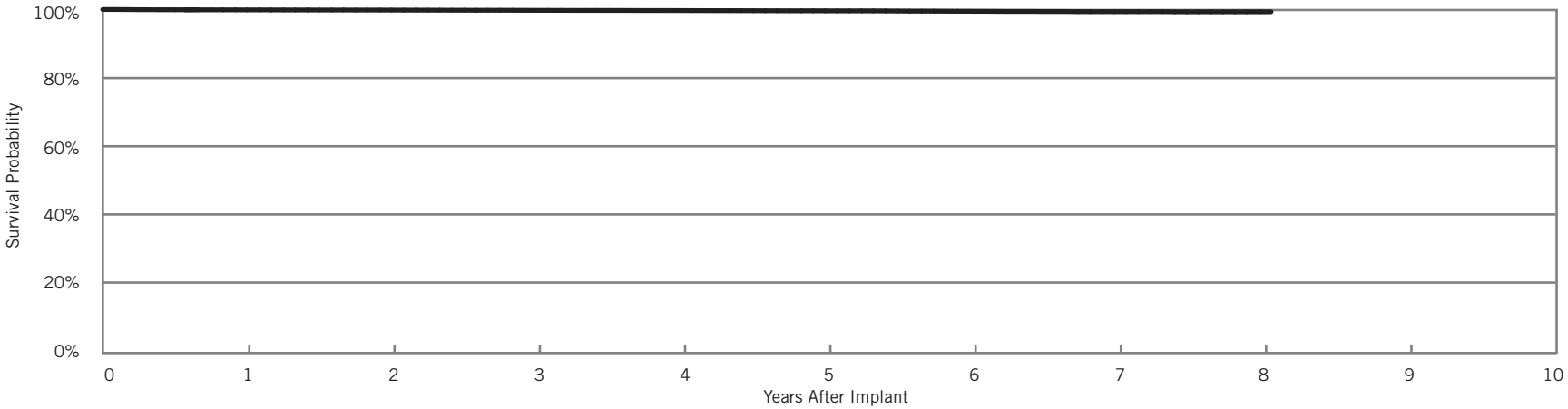
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	87,005
Estimated Active US Implants	53,391
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	<0.01%	1	<0.01%
Conductor Fracture	2	<0.01%	20	0.02%
Lead Dislodgement	35	0.04%	23	0.03%
Failure to Capture	31	0.04%	70	0.08%
Oversensing	0	0.00%	10	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%	24	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	<0.01%	9	0.01%
Total	**84**	**0.10%**	**160**	**0.18%**
Total Returned for Analysis	**35**		**45**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	11	0.01%
Insulation Breach	10	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	6	0.01%
Extrinsic Factors	27	0.03%
Total	**54**	**0.06%**



Year	1	2	3	4	5	6	7	8	at 97 months	
Survival Probability	99.88%	99.83%	99.75%	99.69%	99.60%	99.47%	99.36%	99.32%	99.32%	
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.06%	0.07%	0.07%	
Sample Size	83300	65900	51600	37500	25100	14900	7400	2200	300	

SCORE Registry Performance Data

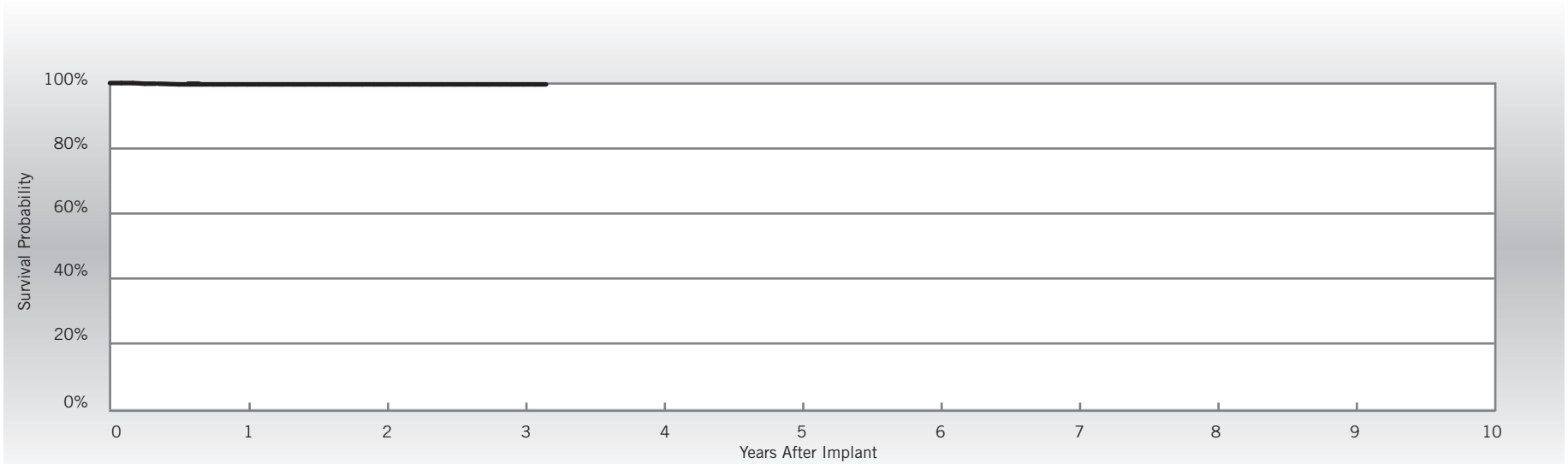
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	521
Cumulative Months of Follow-up	11,416
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	1	0.19%
Lead Dislodgement	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	0	0.00%
Total	**0**	**0.00%**



Year	1	2	3	at 38 months						
Survival Probability	99.59%	99.59%	99.59%	99.59%						
± 1 standard error	0.29%	0.29%	0.29%	0.29%						
Sample Size	450	310	150	50						

Customer Reported Performance Data

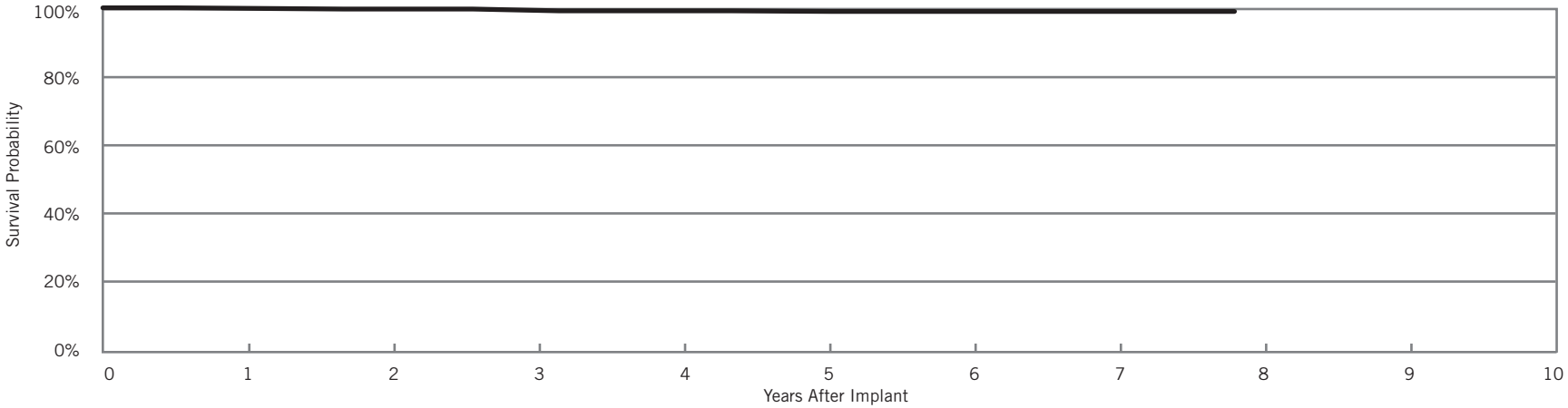
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	372,255
Estimated Active US Implants	229,308
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	40	0.01%	9	<0.01%
Conductor Fracture	4	<0.01%	81	0.02%
Lead Dislodgement	169	0.05%	202	0.05%
Failure to Capture	123	0.03%	308	0.08%
Oversensing	10	<0.01%	163	0.04%
Failure to Sense	22	0.01%	17	<0.01%
Insulation Breach	5	<0.01%	27	0.01%
Abnormal Pacing Impedance	25	0.01%	145	0.04%
Extracardiac Stimulation	3	<0.01%	10	<0.01%
Other	29	0.01%	64	0.02%
Total	**430**	**0.12%**	**1026**	**0.28%**
Total Returned for Analysis	**175**		**495**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	102	0.03%
Insulation Breach	144	0.04%
Crimps, Welds & Bonds	2	<0.01%
Other	1	<0.01%
Extrinsic Factors	296	0.08%
Total	**545**	**0.15%**



Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.85%	99.74%	99.61%	99.49%	99.35%	99.20%	99.02%	98.92%		
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.04%	0.06%		
Sample Size	354300	279500	222200	169800	117200	65500	25900	700		

SCORE Registry Performance Data

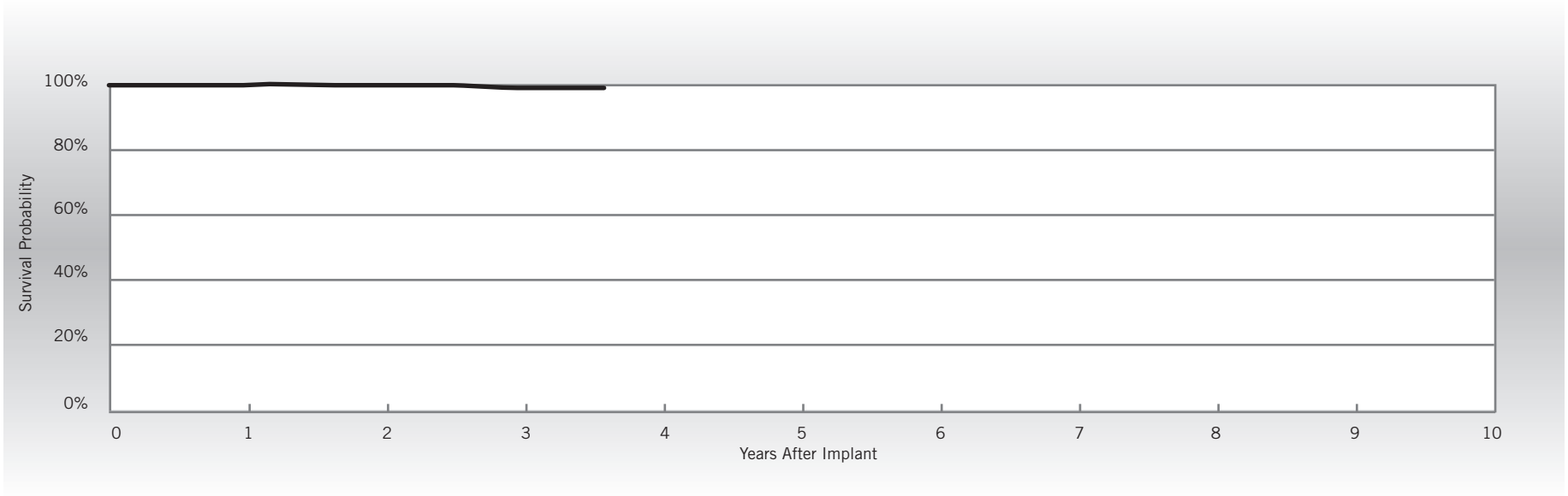
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	1,477
Cumulative Months of Follow-up	31,445
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.07%
Cardiac Perforation	1	0.07%
Extracardiac Stimulation	1	0.07%
Failure to Capture	1	0.07%
Other	1	0.07%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Insulation Breach	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	3	at 43 months						
Survival Probability	99.76%	99.76%	99.38%	99.38%						
± 1 standard error	0.14%	0.14%	0.29%	0.29%						
Sample Size	1250	840	410	50						

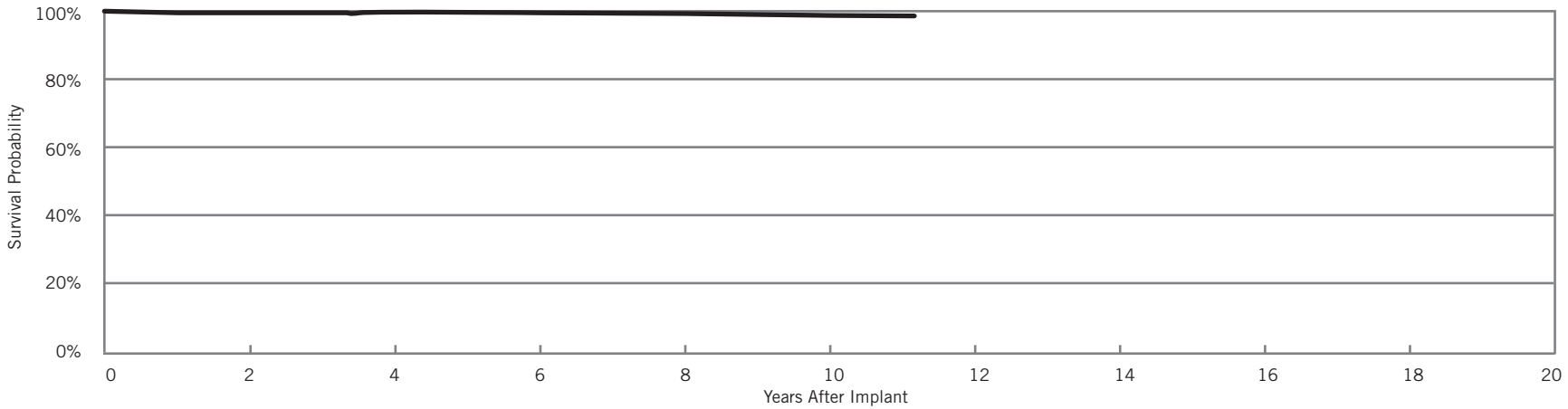
Customer Reported Performance Data

Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	274,067
Estimated Active US Implants	106,178
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	129	0.05%
Insulation Breach	88	0.03%
Crimps, Welds & Bonds	5	<0.01%
Other	0	0.00%
Extrinsic Factors	247	0.09%
Total	**469**	**0.17%**



Year	2	4	6	8	10	at 134 months				
Survival Probability	99.70%	99.48%	99.23%	99.02%	98.74%	98.53%				
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.09%				
Sample Size	235500	190200	138800	78800	21000	500				

SCORE Registry Performance Data

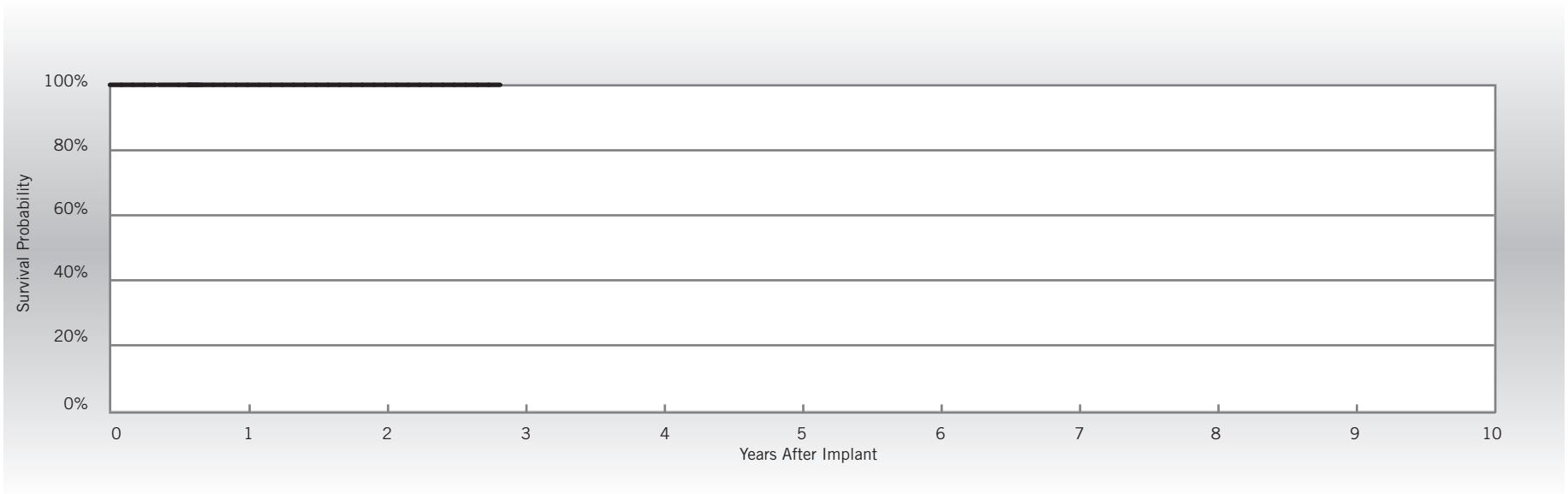
Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	141
Cumulative Months of Follow-up	3,843
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%**



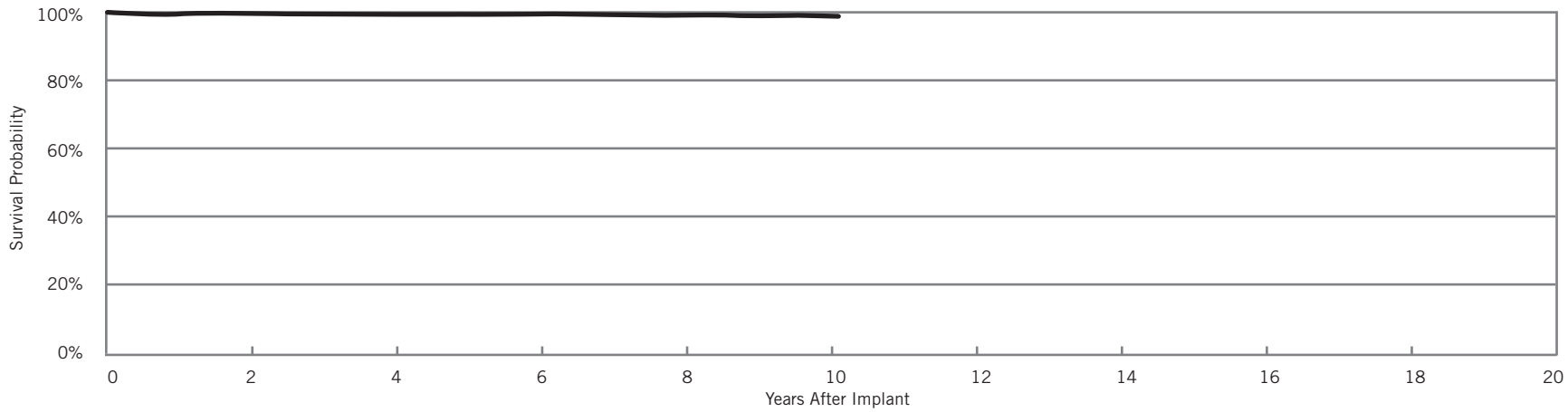
Year	1	2	at 34 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	130	110	60							

Customer Reported Performance Data

AV Plus® DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,546
Estimated Active US Implants	728
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



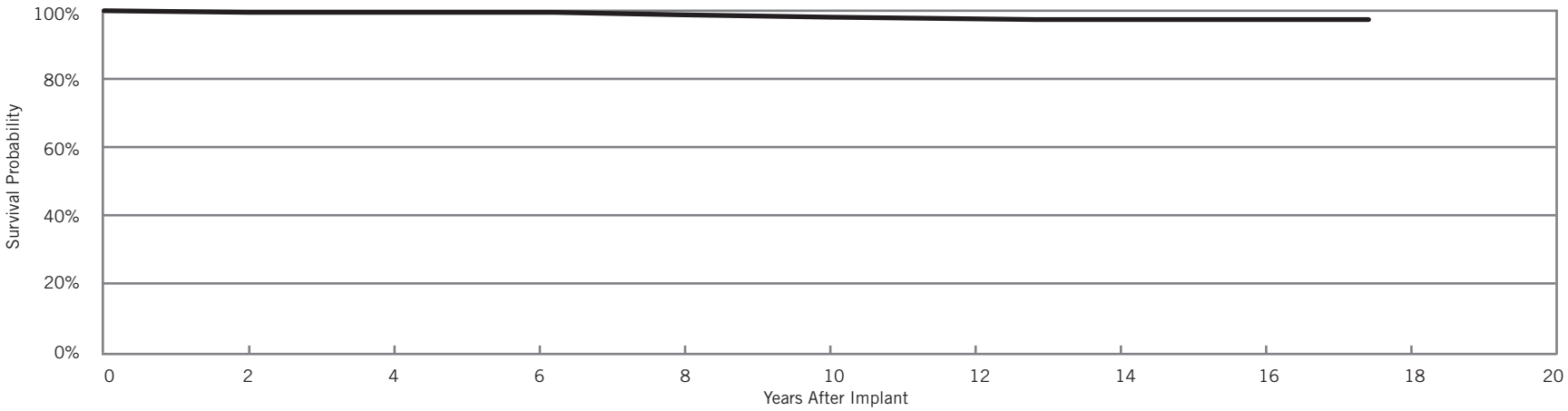
Year	2	4	6	8	10	at 121 months				
Survival Probability	99.82%	99.75%	99.55%	99.55%	99.55%	99.55%				
± 1 standard error	0.09%	0.12%	0.18%	0.18%	0.18%	0.18%				
Sample Size	2000	1400	900	600	300	200				

Customer Reported Performance Data

Tendril®
Models 1148T & 1188T

Tendril® DX
Models 1388T & 1388TC

US Regulatory Approval	(1148) June 1993; (1188T) June 1994; (1388T) June 1997
Registered US Implants	326,704
Estimated Active US Implants	86,629
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 209 months	
Survival Probability	99.58%	99.22%	98.90%	98.53%	98.21%	97.86%	97.48%	97.15%	97.06%	
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.04%	0.07%	0.12%	0.15%	
Sample Size	280300	225300	169900	119400	75000	38500	12900	3500	200	

Customer Reported Performance Data

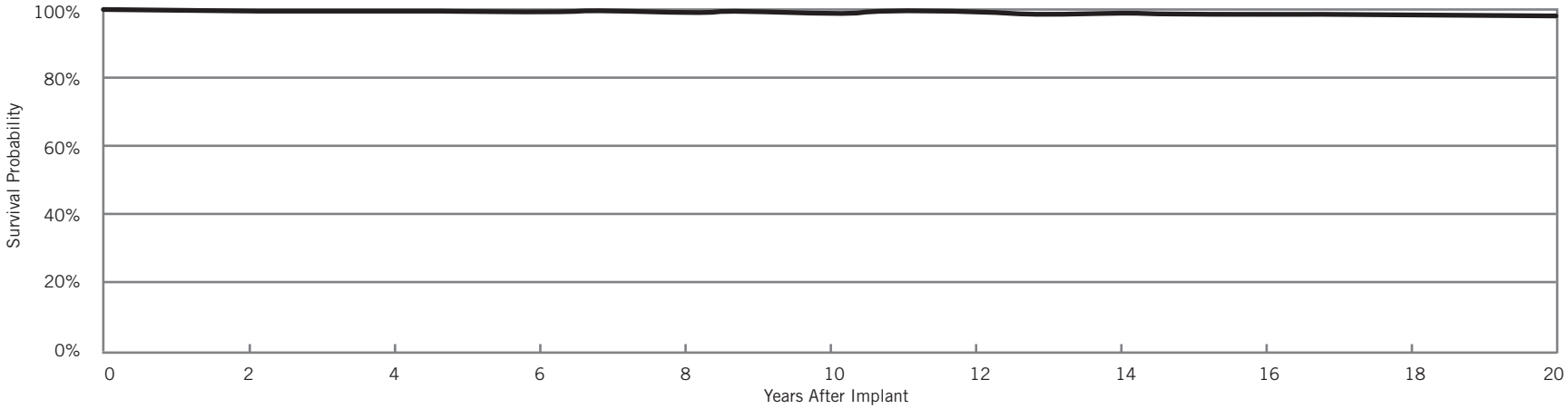
Passive Plus®

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

Passive Plus® DX

Models 1336T, 1342T & 1346T

US Regulatory Approval	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990
Registered US Implants	374,044
Estimated Active US Implants	76,883
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	20
Survival Probability	99.70%	99.45%	99.22%	99.03%	98.88%	98.74%	98.57%	98.48%	98.38%	98.38%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.04%	0.06%	0.06%
Sample Size	318500	255900	199100	147200	96200	57000	30400	13700	4600	1000

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
2088	Tendril® STS	99.77%									
1999	OptiSense® Optim®	99.76%									
1944	IsoFlex® Optim®	99.74%	99.65%								
1948	IsoFlex® Optim®	99.94%	99.81%								
1699T/TC	OptiSense®	99.76%	99.65%	99.51%							
1888T/TC	Tendril® ST Optim®	99.80%	99.66%	99.53%	99.28%						
1882T/TC	Tendril® ST Optim®	99.81%	99.67%	99.54%	99.36%						
1782T/TC	Tendril®	99.85%	99.67%	99.60%	99.56%	99.05%					
1788T/TC	Tendril®	99.82%	99.73%	99.66%	99.57%						
1648T	IsoFlex® P	99.81%	99.67%	99.62%	99.52%	99.38%					
1642T	IsoFlex® S	99.91%	99.87%	99.78%	99.71%	99.60%	99.55%	99.45%			
1646T	IsoFlex® S	99.88%	99.83%	99.75%	99.69%	99.60%	99.47%	99.36%	99.32%		
1688T/TC	Tendril® SDX	99.85%	99.74%	99.61%	99.49%	99.35%	99.20%	99.02%			
1488T/TC	Tendril® SDX	99.82%	99.70%	99.60%	99.48%	99.36%	99.23%	99.14%	99.02%	98.88%	98.74%

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	70068	61983	11	0.02%	0	0.00%	35	0.05%	6	0.01%	2	<0.01%	1	<0.01%	1	<0.01%	2	<0.01%	0	0.00%	1	<0.01%	**59**	**0.08%**	**29**
1999	May-07	10082	8844	0	0.00%	0	0.00%	6	0.06%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.08%**	**2**
1944	Mar-08	5114	4077	0	0.00%	0	0.00%	12	0.23%	0	0.00%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**14**	**0.27%**	**8**
1948	Mar-08	17666	14389	0	0.00%	0	0.00%	8	0.05%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**12**	**0.07%**	**9**
1699T/TC	May-07	23837	17346	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	223988	167283	26	0.01%	5	<0.01%	97	0.04%	67	0.03%	10	<0.01%	8	<0.01%	3	<0.01%	6	<0.01%	3	<0.01%	17	0.01%	**242**	**0.11%**	**105**
1882T/TC	Jun-06	19757	15436	2	0.01%	0	0.00%	14	0.07%	5	0.03%	2	0.01%	3	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**28**	**0.14%**	**9**
1782T/TC	Jun-06	15622	10882	5	0.03%	0	0.00%	11	0.07%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	0.01%	2	0.01%	**26**	**0.17%**	**14**
1788T/TC	Feb-06	65435	44067	11	0.02%	1	<0.01%	31	0.05%	29	0.04%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**108**	**0.17%**	**41**
1648T	Apr-05	2840	1587	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	26181	16171	0	0.00%	0	0.00%	48	0.18%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**60**	**0.23%**	**36**
1646T	May-02	87005	53391	3	<0.01%	2	<0.01%	35	0.04%	31	0.04%	0	0.00%	3	<0.01%	2	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**84**	**0.10%**	**35**
1688T/TC	Jun-03	372255	229308	40	0.01%	4	<0.01%	169	0.05%	123	0.03%	10	<0.01%	22	0.01%	5	<0.01%	25	0.01%	3	<0.01%	29	0.01%	**430**	**0.12%**	**175**

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	
2088	May-09	70068	61983	1	<0.01%	0	0.00%	16	0.02%	15	0.02%	9	0.01%	1	<0.01%	4	0.01%	2	<0.01%	0	0.00%	2	<0.01%	**50**	**0.07%**	**44**
1999	May-07	10082	8844	0	0.00%	0	0.00%	7	0.07%	3	0.03%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**11**	**0.11%**	**11**
1944	Mar-08	5114	4077	0	0.00%	0	0.00%	4	0.08%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**6**	**0.12%**	**3**
1948	Mar-08	17666	14389	0	0.00%	1	0.01%	3	0.02%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	**10**	**0.06%**	**7**
1699T/TC	May-07	23837	17346	0	0.00%	3	0.01%	20	0.08%	12	0.05%	5	0.02%	5	0.02%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**49**	**0.21%**	**35**
1888T/TC	Jun-06	223988	167283	18	0.01%	20	0.01%	158	0.07%	96	0.04%	65	0.03%	11	<0.01%	25	0.01%	19	0.01%	7	<0.01%	27	0.01%	**446**	**0.20%**	**285**
1882T/TC	Jun-06	19757	15436	0	0.00%	1	0.01%	14	0.07%	8	0.04%	4	0.02%	2	0.01%	2	0.01%	0	0.00%	0	0.00%	5	0.03%	**36**	**0.18%**	**27**
1782T/TC	Jun-06	15622	10882	0	0.00%	1	0.01%	17	0.11%	12	0.08%	3	0.02%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	1	0.01%	**38**	**0.24%**	**28**
1788T/TC	Feb-06	65435	44067	2	<0.01%	2	<0.01%	29	0.04%	38	0.06%	21	0.03%	1	<0.01%	2	<0.01%	10	0.02%	1	<0.01%	5	0.01%	**111**	**0.17%**	**80**
1648T	Apr-05	2840	1587	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	26181	16171	0	0.00%	1	<0.01%	20	0.08%	16	0.06%	0	0.00%	3	0.01%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	**43**	**0.16%**	**16**
1646T	May-02	87005	53391	1	<0.01%	20	0.02%	23	0.03%	70	0.08%	10	0.01%	2	<0.01%	1	<0.01%	24	0.03%	0	0.00%	9	0.01%	**160**	**0.18%**	**45**
1688T/TC	Jun-03	372255	229308	9	<0.01%	81	0.02%	202	0.05%	308	0.08%	163	0.04%	17	<0.01%	27	0.01%	145	0.04%	10	<0.01%	64	0.02%	**1026**	**0.28%**	**495**

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

Malfunction Summary

Models	Registered US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088TC	70068	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	8	0.01%	**10**	**0.01%**
1999	10082	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**2**	**0.02%**
1944	5114	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	**2**	**0.04%**
1948	17666	0	0.00%	1	0.01%	0	0.00%	1	0.01%	5	0.03%	**7**	**0.04%**
1699T/TC	23837	3	0.01%	3	0.01%	0	0.00%	0	0.00%	27	0.11%	**33**	**0.14%**
1888T/TC	223988	7	<0.01%	74	0.03%	1	<0.01%	3	<0.01%	221	0.10%	**306**	**0.14%**
1882T/TC	19757	0	0.00%	4	0.02%	0	0.00%	1	0.01%	21	0.11%	**26**	**0.13%**
1782T/TC	15622	1	0.01%	2	0.01%	0	0.00%	0	0.00%	22	0.14%	**25**	**0.16%**
1788T/TC	65435	3	<0.01%	27	0.04%	1	<0.01%	1	<0.01%	51	0.08%	**83**	**0.13%**
1648T	2840	0	0.00%	3	0.11%	0	0.00%	1	0.04%	2	0.07%	**6**	**0.21%**
1642T	26181	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	12	0.05%	**17**	**0.06%**
1646T	87005	11	0.01%	10	0.01%	0	0.00%	6	0.01%	27	0.03%	**54**	**0.06%**
1688T/TC	372255	102	0.03%	144	0.04%	2	<0.01%	1	<0.01%	296	0.08%	**545**	**0.15%**
1488T/TC	274067	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 10 and 11.

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Lead Dislodgement		Failure to Capture		Oversensing		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	1572	12366	1	0.06%	2	0.13%	1	0.06%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	**5**	**0.32%**
1999	241	2030	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	292	3952	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	998	24180	0	0.00%	2	0.20%	2	0.20%	0	0.00%	2	0.20%	0	0.00%	0	0.00%	**6**	**0.60%**
1888T/TC	4029	92332	0	0.00%	9	0.22%	1	0.02%	1	0.02%	3	0.07%	1	0.02%	0	0.00%	**15**	**0.37%**
1882T/TC	172	2960	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1782T/TC	146	3242	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	243	5691	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	521	11416	0	0.00%	1	0.19%	1	0.19%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.38%**
1688T/TC	1477	31445	1	0.07%	0	0.00%	1	0.07%	0	0.00%	1	0.07%	1	0.07%	1	0.07%	**5**	**0.34%**
1488T/TC	141	3843	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	1572	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1999	241	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	292	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	998	0	0.00%	1	0.10%	0	0.00%	0	0.00%	1	0.10%	**2**	**0.20%**
1888T/TC	4029	1	0.02%	2	0.05%	0	0.00%	1	0.02%	5	0.12%	**9**	**0.22%**
1882T/TC	172	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.58%	**1**	**0.58%**
1782T/TC	146	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	243	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	521	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	1477	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**2**	**0.14%**
1488T/TC	141	0	0.00%	1	0.71%	0	0.00%	0	0.00%	2	1.42%	**3**	**2.13%**

Definitions of complications can be found on page 14.
Definitions of malfunction categories can be found on pages 10 and 11.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical™
More control. Less risk.

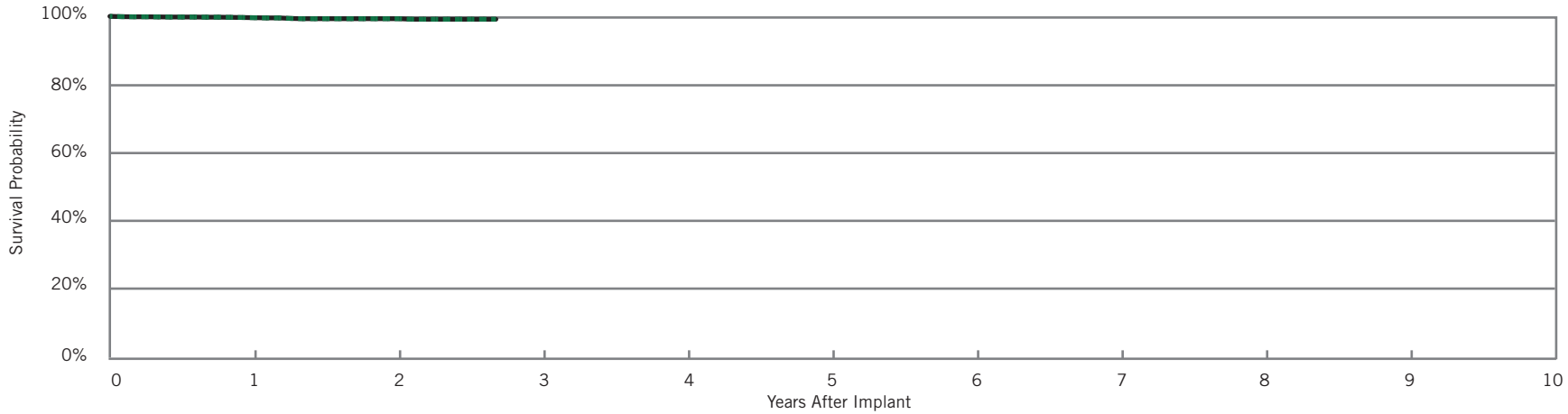
Customer Reported Performance Data

SJM Confirm®

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	7,572
Estimated Active US Implants	5,420
Estimated Longevity	3 Years*
Normal Battery Depletion	0
Number of US Advisories	None

	Malfunctions	
	Qty	**Rate**
Electrical Component	1	0.01%
Electrical Interconnect	0	0.00%
Battery	4	0.05%
Software/Firmware	7	0.09%
Mechanical	0	0.00%
Possible Early Battery Depletion	0	0.00%
Other	1	0.01%
Total	**13**	**0.17%**



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.59%	99.30%	99.14%							
± 1 standard error	0.08%	0.13%	0.17%							
Sample Size	6400	2600	300							

Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.59%	99.30%	99.14%							
± 1 standard error	0.08%	0.13%	0.17%							

**After 12 month shelf-life.*

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
DM2100	Confirm	7572	1	0.01%	0	0.00%	4	0.05%	7	0.09%	0	0.00%	0	0.00%	1	0.01%	13	0.17%

Definitions of malfunction root cause categories can be found on page 7.

Focus on Clinical Performance

St. Jude Medical™
More control. Less risk.

Optim® Lead Insulation

In 2006 St. Jude Medical brought to the cardiac rhythm management (CRM) market the first novel insulation technology in over 20 years: a silicone-polyurethane co-polymer known as Optim® lead insulation, now featured in IsoFlex® Optim®, Tendril® STS, OptiSense®, QuickFlex® µ, and Durata® lead families. Optim lead insulation consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone.
The polyurethane content of Optim lead insulation imparts lubricity, strength, and abrasion resistance while the nearly 50% silicone content imparts flexibility and biostability.[1,2] The clinical performance of >1.3 million Optim-insulated pacing and tachycardia leads implanted worldwide continues to be excellent.

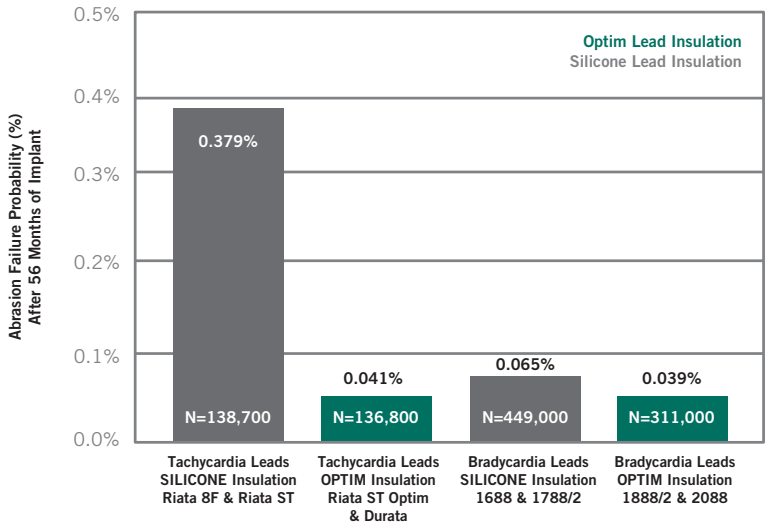
All aspects of Optim lead insulation performance can be appreciated by referring to the Acute Observation, Chronic Complication, Lead Malfunction, and Survival Probability data found in this Product Performance Report. One noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[3] Insulation abrasion can occur as a result of lead motion and contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. 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 Product Performance Report, St. Jude Medical has regularly presented a Kaplan-Meier statistical comparison of confirmed abrasion malfunctions on leads with Optim insulation and silicone insulation. The latest update to this statistical analysis now includes data through June 30, 2011. Four model groups were again considered for this analysis: (1) bradycardia leads with silicone insulation [models 1688, 1788, 1782], (2) bradycardia leads with Optim lead insulation [models 1888, 1882, 2088], (3) tachycardia leads with silicone insulation [Riata, Riata ST lead families], and (4) tachycardia leads with Optim lead insulation [Riata ST Optim and Durata lead families]. For each model group, the U.S. registration and tracking data was combined with data from all U.S. confirmed abrasion malfunctions in a Kaplan-Meier analysis. The longest implant duration that is common to all four model groups was 56 months.
To provide a direct comparison of all four model groups, the probability of an abrasion malfunction by 56 months of implant time is presented in graphical format below.

The graphical data shows that the presence of Optim® lead insulation dramatically reduces the probability of abrasion malfunction at 56 months by 89% on tachycardia leads, which was confirmed to be statistically significant ($p<0.0001$) by a log-rank test. The 56 month comparison data for silicone-insulated leads demonstrates that abrasion failures of bradycardia leads occur at a rate ~6X lower than tachycardia leads. This disparity is believed to be the result of many factors, including a smaller device size and fewer leads in bradycardia systems. The addition of Optim lead insulation to bradycardia leads has reduced the already low probability of abrasion malfunction by 40% at 56 months. The impressive abrasion resistance of Optim lead insulation has reduced the probability of abrasion malfunction for all lead types, bringing tachycardia lead insulation abrasion probability in line with the traditionally low probability associated with bradycardia leads.

Optim® Lead Insulation Effects on SJM 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] T. Kleemann, T. Becker, K. Doenges, M. Vater, J. Senges, S. Schneider, W. Saggau, U. Weisse, and K. Seidl, "Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years," Circulation, 115, 2474-2480 (2007).

High Voltage DF4 Connector System

Background

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

The ISO 27186:2010 international standard is the result of nearly a decade of industry-wide cooperation. During the process of standard creation and product development, the DF4 connector system underwent an exhaustive battery of tests intended to simulate acute and chronic conditions beyond worst case clinical scenarios. With these rigorous testing methods St. Jude Medical was able to ensure the quality and reliability of this new connector system. Demand for the DF4 connector system remains high, currently representing more than 60% of 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 June 30, 2011 data cutoff for this Product Performance Report, the DF4 connector system has been in clinical use for 24 months and represents over 51,000 U.S. implants. St. Jude Medical is continuously monitoring the DF4 connector system performance with customer reported complaints and returns data as well as a post-approval registry study currently underway. Customer Reported and SCORE Registry Performance Data for many DF4 models can be found in this report.

Analysis

St. Jude Medical completed an updated statistical comparison of the complaints and malfunctions related to the DF4 and IS-1/DF-1 connector systems. All connector-related system complaints were found to be assigned to the ICD/CRT-D, therefore a separate lead-based analysis was not undertaken. Due diligence was applied to ensure a direct and unbiased comparison. Devices included in the analysis were implanted on or after August 1, 2009, which represents the first month with at least 100 DF4 system implants, and no later than June 30, 2011, which is the data cutoff for this Product Performance Report. Complaints included in the analysis represent events occurring within this same period. All malfunction data included in this comparative analysis were generated between August 1, 2009 and June 30, 2011. Because complaints may occur during implant or during an attempted implant, no restriction related to implant duration was applied. A non-biased comparison was ensured by including only those defibrillation lead and ICD/CRT-D models which were offered with both DF4 and IS-1/DF-1 connector systems (see Table 1).

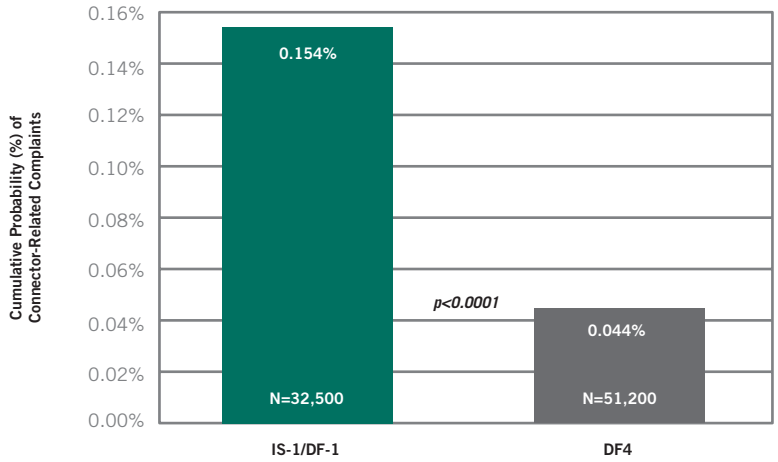
Table 1. Models Included in Analysis

	Traditional (IS-1/DF-1)	DF4
Sample Size	~32,500	~51,200
Defibrillation Lead Models	7120, 7121, 7122, 7070, 7071	7120Q, 7121Q, 7122Q, 7170Q, 7171Q
ICD/CRT-D Models	CD1211-36, CD1215-36, CD1231-40, CD2211-36, CD2215-36, CD2231-40, CD3211-36, CD3215-36, CD3231-40	CD1211-36Q, CD1215-36Q, CD1231-40Q, CD2211-36Q, CD2215-36Q, CD2231-40Q, CD3211-36Q, CD3215-36Q, CD3231-40Q

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

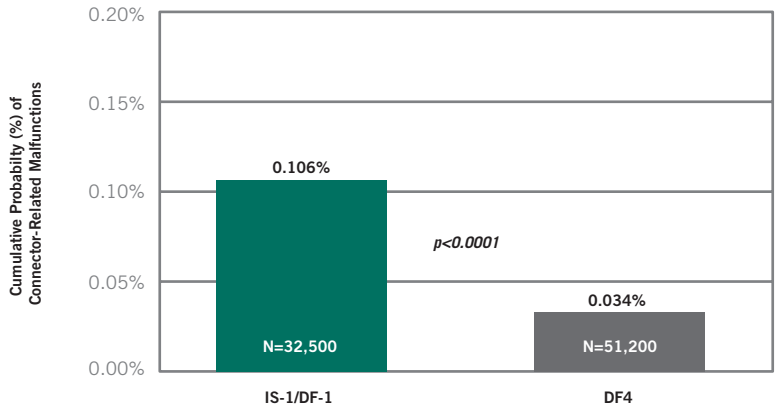
The statistical treatment of ICD/CRT-D connector-related complaint data included a comparison of cumulative incidence functions adjusted for the competing risk of explant without complaint. This was followed by the use of Gray's method[1] to assess any difference in the cumulative incidence rates and calculate a p-value. Figure 1 presents the resulting cumulative probability of connector-related complaints at the end of the analysis period, June 30, 2011. The probability of a connector-related complaint for either group was less than 0.2%. The probability of a connector-related ICD/CRT-D complaint in a DF4 system is 72% less than the probability observed in an IS-1/DF-1 system. This difference proved to be highly statistically significant ($p<0.0001$). The majority of complaints referenced problems with setscrew function or generic connection issues.

Figure 1. ICD/CRT-D Connector-Related Complaints
Represents Events Between Aug 1, 2009 and June 30th, 2011



A similar statistical treatment was applied to the ICD connector-related malfunction data. Typical malfunctions included problems with the set screw or difficulty inserting the lead into the ICD/CRT-D header. The resulting cumulative probability of connector-related malfunctions at the end of the analysis period, June 30, 2011, is shown below in figure 2. The probability of an ICD/CRT-D malfunction in a DF4 system is approximately 68% less than in an IS-1/DF-1 system. This reduction in malfunction was also found to be statistically significant ($p<0.0001$).

Figure 2. ICD/CRT-D Connector-Related Malfunctions
Represents Malfunctions Analyzed Between Aug 1, 2009 and June 30, 2011



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

Conclusions:

This updated analysis of DF4 connector system field performance data has demonstrated the excellent field performance of the four-pole connector system, with a statistically significantly lower rate of approximately 70% for both complaints and malfunctions when compared to the traditional IS-1/DF-1 connector system.

[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.

Low Frequency Attenuation Filter

Background

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

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

Analysis

St. Jude Medical performed a statistical analysis of the inquiries received by our U.S.Technical Services department related to T-wave oversensing for the Unify/Fortify family of devices and the Current/Promote family of devices (see Table 1). While underreporting of T-wave oversensing may exist, inquiries to technical services regarding T-wave oversensing represents a metric by which relative comparisons can be made between families or models. Note that most inquiries regarding T-wave oversensing represent acute issues that are solved by programming changes and have no chronic performance implications. These inquiries represent direct feedback from the field and are logged as reported with no validation by St. Jude Medical. All inquiries included in this analysis occurred between product launch to the cutoff date of this report which is June 30, 2011.

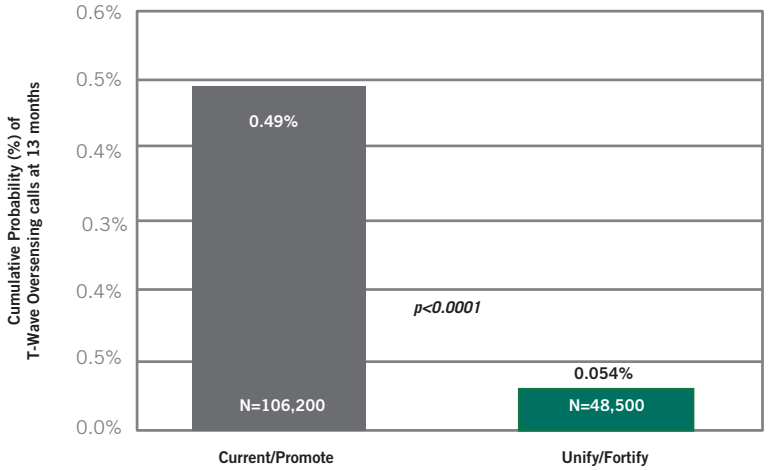
Table 1. Models Included in Analysis

	Promote®/Current® Family of devices	Unify®/Fortify® Family of devices
Sample Size	~106,000	~48,000
Models	1107-30, 1207-30, 1207-36 2107-36, 2207-30, 2207-36 3107-36, 3207-30, 3207-36 CD1211-36/Q, CD1215-36/Q CD2211-36/Q, CD2215-36/Q CD3211-36/Q, CD3215-36/Q	CD1231-40/Q CD2231-40/Q CD3231-40/Q

The Unify/Fortify family of devices was most recently market released, having a maximum implant duration of 13 months as of June 30, 2011. A Kaplan-Meier analysis of event-free survival was performed for each family out to 13 months of implant duration. An event was defined as a T-wave oversensing inquiry. This analysis required the U.S. registration and tracking data of all patients implanted with the above device families as well as data from all T-wave oversensing inquiries. A log-rank comparison of the Kaplan-Meier cumulative probability curves of both families was also performed.

The resulting cumulative probability of a T-wave oversensing inquiry by 13 months of implant time is presented in Figure 1. The probability of a T-wave oversensing inquiry in the Unify/Fortify family of devices is 89% lower than the probability observed in the Current/Promote family of devices. The log-rank result ($p<0.0001$) confirmed this difference to be statistically significant.

Figure 1. T-Wave Oversensing for the Unify®/Fortify® and Current®/Promote® family of devices



Conclusions:

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

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

Advisories & Safety Alerts

St. Jude Medical
More control. Less risk.

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

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Convert®+ (Model V-195)	5/6/2010 Outside US only A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin® Patient Care System programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful.	If a patient's device is already programmed to a two zone configuration with a Merlin® PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below: A permanent correction is available in the new release of the Merlin® PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin® programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (June 30, 2011):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of June 30, 2011, there have been no additional reports associated with this advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic® + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic® II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas® + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas® II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	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 (June 30, 2011):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2011 there have been no additional devices confirmed to have this issue since the time of the advisory.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Photon™ DR (V-230HV) (certain serial numbers), Photon™ Micro VR/DR (Models V-194/V-232), Atlas® VR/DR (Models V-199/V-240)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (June 30, 2011):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2011 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue. This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/ V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/ V-340/V-341/V-343).	6/13/05 Class II Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to St. Jude Medical. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. St. Jude Medical has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (June 30, 2011):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® (V-197, V-235), Epic®+ (V-196, V-236), Epic® HF (V-338), Epic®+ HF (V-350), Atlas®+ (V-193, V-243), Atlas®+ HF (V-340), or Atlas® (model V-242) ICDs	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (June 30, 2011):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Profile™ V-186	7/13/01 Class II Failure of a ceramic capacitor could lead to sensing anomalies/ early battery depletion	This Advisory applies to a well-defined group of Profile™ MD (Model V-186HV3) implantable cardioverter-defibrillators (ICDs) which have been observed to exhibit decreased reliability. These devices had specific modules (subcircuits) manufactured during a five-month period during the first half of 1999. **Those potentially affected devices that have not exhibited any anomalous behavior within 24 months of manufacture are not at increased risk of failure at a later date.** These failures were caused by a component anomaly that is limited to a specific, traceable lot (group) of capacitors. If these capacitors fail, two different clinical manifestations may be observed, depending on the location of the failed capacitors: **Low Voltage Module:** The devices may exhibit sudden loss of sensing or oversensing of internally generated interference (noise) resulting in aborted or delivered shocks. Due to the potential for sudden loss of sensing, which would prevent the ICD from detecting ventricular tachyarrhythmias, device replacement should be considered for patients with devices incorporating the suspect capacitors in this location. In making this decision, you should weigh the likelihood that your patient will have one of the few additional devices expected to fail against the risk associated with the replacement procedure. For patients who do not have their devices replaced, St. Jude Medical recommends monthly monitoring for the remaining months during which additional failures are expected to occur and every three months thereafter. **High-Voltage Module:** The devices may exhibit premature battery depletion with no other clinical manifestations. While the battery voltage may drop rapidly to a value near or below the device's ERI, it stabilizes for several months at a value at which the device continues to detect arrhythmias and deliver therapy appropriately. In addition, some of these devices may exhibit oversensing of internally generated electrical interference (noise), which may result in false detection of tachyarrhythmias. However, during charging, the interference abates, and the therapy is usually aborted without the delivery of inappropriate shocks to the patient. Because these devices generally continue to respond appropriately to spontaneous tachyarrhythmias, and because the battery voltage stabilizes for several months at a level that does not compromise device function, St. Jude Medical recommends that patients with devices incorporating suspect capacitors in this location be monitored monthly for the remaining months during which additional failures are expected to occur and every three months thereafter.

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Accent® DR (Models PM2110, PM2112, PM2210 and PM2212) and Anthem® CRT-P (Models PM3110, PM3112, PM3210 and PM3212)	9/22/11 A small amount of electrical charge may accumulate within an internal capacitor which results in a low or varying pacing lead impedance (PLI) value during the automatic daily measurements. An out of range lead impedance measurement may result in a patient notifier alert, a remote monitoring Merlin.net® Patient Care Network alert, or a prior alert message to be displayed on the programmer screen at the next in-clinic follow-up.	In order to prevent a false reading, a new Merlin® Patient Care System programmer software version is available. When used to interrogate an Accent DR or Anthem CRT-P pacemaker this software will eliminate the potential for this anomaly to occur. With the new software, the programmer will automatically activate circuitry in the pacemaker during the interrogation process to ensure that any residual charge on the capacitor is discharged prior to performing the daily PLI measurement. The onetime upgrade is performed automatically on affected devices and will not change the operation of the implanted device. Your St. Jude Medical Sales Representative will assist you in loading the new programmer software onto your Merlin programmer. If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, St. Jude Medical makes the following recommendations, which are consistent with standard best practices: ■ Ensure that the new programmer software version is loaded on your programmers as soon as practical. ■ Continue to follow patients on their standard follow-up schedule. Since the likelihood of the low lead impedance measurement is low, the device interrogation can be performed at the patient's next regular scheduled follow-up visit. ■ In the event that a patient receives a low lead impedance alert before the new programmer software has been loaded, we suggest that you evaluate the device as you normally would for any such instance. If the daily pacing lead impedance value is out-of range, re-interrogate the device's measured data and look at the lead impedance values. This "in-clinic" measurement is not affected by the aforementioned capacitor charge build-up and will provide an accurate lead impedance measurement. **Current Status (September 30, 2011):** World-wide, 13 Accent DR (<0.01%) and 225 Anthem CRT-P (1.6%) devices have exhibited this diagnostic anomaly

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity® SR (5172) Identity® DR (5370) Identity® XL DR (5376)	10/12/06 Class II A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in St. Jude Medical Identity® pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the St. Jude Medical Identity® family of pacemakers when programmed by the St. Jude Medical APS™ III Model 3500/3510 or Merlin® Patient Care System Model 3650 programmers.	No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process. **Current Status (June 30, 2011):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2011 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity ADx® DR Models 5286, 5380, 5386 and 5480	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 (June 30, 2011):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Tempo™ 2102 and Meta™ 1256D	11/04/02 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	Decreased reliability has been observed in a group of these devices. The devices in the advisory population were manufactured at the Telectronics' manufacturing facility between the second quarter of 1996 and the second quarter of 1997. Premature battery depletion resulting from bridging between adjacent connectors has resulted in no output or no telemetry in 1% of this population of devices to date. The following recommendations are made: Physicians are advised to review patients who have 1256D/2102 pacemakers at an early date to evaluate pacemaker function. **For patients who are pacemaker dependent,** the physician should give consideration to explantation and replacement as soon as practicable. **For patients who are not considered pacemaker dependent,** the physician should consider replacement only if any abnormal function is identified (such as no output, telemetry loss, telemetry abnormality or premature end of life indication). All remaining non-pacemaker dependent patients with 1256D/2102 pacemakers should subsequently be reviewed at least every six months.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Tempo™ 1102, 1902, 2102, 2902 and Meta™ 1256D	11/04/02 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	This Advisory applies to a well-defined group of Tempo™ and Meta™ 1256D pacemakers which have been observed to exhibit premature battery depletion. This is an extension of a previous Tempo™/Meta™ advisory dated 6/6/00. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Meta™ DDDR 1256	6/6/00 Class II Integrated circuit failure due to electrostatic discharge during manufacturing resulting in no output or sensing anomalies.	This Advisory applies to a well-defined group of Meta™ 1256 pacemakers, which have been observed to exhibit decreased reliability. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.

Pacemaker and CRT-P Devices

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

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Trilogy™ 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	3/10/00 Class II Risk of malfunction due to an anomaly of the pacemaker's microprocessor. Typical manifestations of this anomaly are dashes observed on the programmer screen, unexpected rate variation, abnormally high battery current drain, and mode change.	Continued monitoring of Trilogy™ devices affected by an Advisory issued in July 1999 has revealed an additional low level of adverse events. A sub-population of the above models, principally those manufactured before January 1999, is potentially affected by a risk of malfunction due to an anomaly of the pacemaker's microprocessor. To date this has been reported in only 0.11% of the implanted population. Typical manifestations of this anomaly are: Interrogation/programming difficulties, including the presence of dashes (—) on the programmer screen for some parameter values after interrogation Unexpected rate variations Abnormally high battery current drain Mode change The presence of dashes on the programmer screen is typically caused by partial programming of one or more of the programmed parameters and may be corrected by reprogramming. In the event that observed dashes (—-) cannot be resolved by reprogramming, please contact your St. Jude Medical representative, as it may be possible to resolve the situation non-invasively via special programming and may not be indicative of a microprocessor anomaly. Considering the low level of incidence of this anomaly, the following steps are recommended: 1. Assess the patient population, relative to the potential for an inappropriate mode change to single-chamber atrial pacing, to determine which patients are pacemaker-dependent and have an inadequate ventricular escape rhythm. 2. Replacement of a device always remains a matter of clinical judgement, including balancing the clinical risk associated with pacemaker replacement against the risk of device malfunction. 3. Almost all microprocessor malfunctions described in this notification were found during routine follow-up. This reinforces the importance that pacemaker patients should be followed regularly in accordance with best prevailing medical practices.

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Affinity® 5130L, 5130R, 5330L, 5330R, 5230L, 5230R	2/14/00 Class II An unsecured resistor connection to the hybrid circuit might cause abnormal measured data, false RRT indication, backup VVI mode, or intermittent loss of output.	This advisory applies to a very specific, well-defined group of Affinity devices that have been implanted worldwide. The device may exhibit any or all of the following output anomalies: Abnormal measured battery data, A false recommended replacement (RRT) indication, Reversion to back-up VVI mode, Intermittent loss of output. One marker of an affected device that may be apparent during a routine follow-up interrogation is an abnormally high reading for battery current (taking into consideration the device's programmed output parameters). If this or an early indication of RRT or reversion to back-up VVI mode is observed, please contact your local St. Jude Medical representative or Technical Services. Although the time course is variable, these behavioral anomalies will occur before there is any affect on device output.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Trilogy™ 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	7/19/99 Class II Premature battery depletion caused by a current leakage path that could be created during the laser welding process to attach the battery to the device hybrid	Analysis of the clinical data associated with the failed devices has shown that an early increase in battery impedance could be observed at one or more previous routine follow-up visits prior to reaching RRT. The observed rise in battery impedance is an earlier and more reliable indicator than the reported battery voltage. The battery depletion, although accelerated, does not occur abruptly and patients can be monitored using the measured data telemetry in the pacemaker. The following follow-up schedule and device monitoring is advised. 1. For patients who have had a follow-up visit at least 12 months after their device was implanted, check the measured data printout from the last follow-up evaluation. If a battery impedance of "< 1 kOhm" was recorded, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every 6 months is not your routine schedule, then an additional visit at 18 months should be performed. 2. For patients who have not yet had a follow-up visit at least 12 months after their device was implanted, the following is recommended: If the patient has had their device implanted for less than two months or has not had a device interrogation with measured data within the last three months, an evaluation of the battery impedance is recommended as soon as possible. This should be printed and a copy retained in the patient's pacemaker or office chart. Otherwise, if the battery impedance from the most recent evaluation is "< 1 kOhm," begin an every 3-month follow-up schedule with respect to measured data telemetry until that value has been recorded at least 12 months post-implant. Thereafter, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every six months is not your routine schedule, then an additional visit at 18 months should be performed. If the battery impedance reading is 1 kOhm or higher and the pacemaker has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services.

Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Riata® Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582) Riata® i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata® ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)	12/15/2010 Outside US Only Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10%. After more than 9 years of clinical use and approximately 227,000 implants, silicone-insulated Riata®, Riata® i, and Riata® ST defibrillation leads have exhibited an insulation abrasion rate of 0.47% (inclusive of confirmed returns and complaints/observations with no associated return). There are several factors that can contribute to lead abrasion in implanted pacing and defibrillation systems, including physiological stresses placed on the lead due to patient anatomy, implant orientation, and mechanical stresses applied from concomitant devices in the body. The main types of insulation abrasion are: lead-to-can abrasion, lead-to-lead abrasion, clavicular crush, and externalized conductors. (These abrasion types are defined on pages 10-11 within this Product Performance Report.) The incidence rate of U.S. abrasion malfunctions for Riata models is summarized on pages 137-138 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 pre the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedure in particular looking for significant changes from the patient's previous follow-up visits. If there is evidence of a lead electrical failure, manage the patient per standard practice[1]. This may include x-ray or flouroscopy. Additional testing if necessary could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem if one exists. Consider remote monitoring and advise your patients of the importance of contacting you if they expereince any adverse events. The company and its Medical Advisory Board (MAB) currently do not recommend x-ray or fluoroscopic screening for potential externalized conductors in Riata silicone leads that do not have electrical abnormalities. In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended. Based on input from the MAB, St. Jude Medical is conducting a prospective study to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities. **Current Status (June 30, 2011):** At the time of the advisory there was a world-wide reported insulation abrasion rate of 0.47% for Riata silicone leads. As of June 30, 2011, there have been additional reports and the world-wide reported insulation abrasion rate is 0.58%.

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

ICM Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
SJM Confirm® ICM (Models DM2100 and DM2102)	3/11/2011 Class II US and Germany A product firmware upgrade using the Merlin® Patient Care System programmer running software versions 10.1.1.3, 10.1.1.2, or 11.2.2 leaves the implantable cardiac monitor device in a state which results in increased current usage. If not corrected this state could result in premature battery depletion.	If you are following any patients implanted with the SJM Confirm Models DM2100 or DM2102 and their device was upgraded using the Merlin programmer with the above mentioned software versions it is recommended to determine the patient's clinical reason for the implant and their continued need for the device: ■ If the device has previously been used to record and assist in the diagnosis of an arrhythmia and is no longer needed, no further action is required. The device will exhaust its battery capacity prior to the 3 year expected longevity. ■ If the unit is still indicated for diagnosing a potential clinical arrhythmia, contact your Field Clinical Engineer and he/she will assist in calculating the projected remaining longevity. If appropriate, the microprocessor operation can be reset to the nominal current drain. ■ If the device is no longer indicated it can be left implanted until such time that a routine explant is desired. If the device is determined to be necessary and is experiencing increased current usage as described above, it can be corrected with assistance from your Sales Representative or St. Jude Medical Technical Services. St. Jude Medical is in the process of developing new Merlin PCS programmer software that will properly upgrade SJM Confirm devices. **Current Status (September 30, 2011):** At the time of the advisory, 83 implanted devices world-wide were identified as having undergone the problematic firmware upgrade. All of these devices have been corrected using the Merlin PCS programmer or were determined by the clinician to not require further action because the device had already provided the necessary diagnostic information and was no longer required. There have been no additional implanted devices confirmed to have been affected by this issue. Updated Merlin PCS programmer software has been implemented which prevents this issue from occurring in the future.

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Index of Phased-out Models as of November 2011

St. Jude Medical
More control. Less risk.

Phased-out Models

As stated in the introduction of this Product Performance Report, product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report. As such, models that no longer meet the criteria for inclusion have been phased-out of the Product Performance Report over time. In order to provide our customers with information on these phased-out models, an index including the final edition for each phased-out model has been included. Previous Product Performance Reports can be viewed on the web at www.SJMprofessional.com.

CRT Devices	Final Edition
Atlas® + HF (V-340)	Apr 2011
Epic® HF (V-337)	Apr 2011
Epic® HF (V-338)	May 2010
Epic® II HF (V-355)	Apr 2011
Frontier® (5508)	May 2010
Promote® (3107-36)	Nov 2010

ICDs	Final Edition
Atlas® DR (V-240)	May 2010
Atlas® VR (V-199)	Nov 2010
Contour™ II (V-185, V-185AC, V-185B, V-185C, V-185D)	May 2008
Contour™ MD (V-175, V-175AC, V-175B, V-175C, V-175D)	May 2010
Current® DR (2107-36)	Nov 2010
Current® VR (1107-36)	May 2010
Epic® + DR (V-236)	May 2010
Epic® DR (V-233)	Apr 2011
Epic® DR (V-235)	Nov 2010
Epic® II DR (V-255)	May 2010
Epic® VR (V-197)	Nov 2010
Photon™ DR (V-230HV)	Oct 2007
Photon™ µ DR (V-232)	Oct 2009
Photon™ µ VR (V-194)	May 2010
Profile™ (V-186F, V-186HV3)	Oct 2007

Defibrillation Leads	Final Edition
TVL™ RV (RV01, RV02, RV03, RV06, RV07)	May 2010
TVL™ SVC (SV01, SV02, SV03)	May 2010

Pacemakers	Final Edition
AddVent™ (2060)	May 2010
Affinity® VDR (5430)	May 2010
Integrity® µ DR (5336)	Nov 2010
Meta™ DDDR (1256)	Oct 2008

Pacemakers	Final Edition
Meta™ DDDR (1256D)	Oct 2008
Paragon™ (2010, 2011, 2012)	Nov 2010
Paragon™ II (2016)	Nov 2010
Paragon™ III (2304, 2314, 2315)	May 2010
Phoenix™ III (2204, 2205)	Apr 2009
Phoenix™ II (2005, 2008, 2009)	Nov 2010
Regency® SC+ (2400L, 2402L)	May 2010
Solus® (2002, 2003)	Nov 2010
Solus® II (2006, 2007)	Nov 2010
Synchrony™ II (2022, 2023)	Oct 2009
Synchrony™ III (2028, 2029)	May 2010
Tempo™ D (2902)	Oct 2008
Tempo™ DR (2102)	Oct 2008
Tempo™ V (1102)	May 2010
Tempo™ VR (1902)	May 2010
Trilogy™ DC (2308)	Oct 2006
Trilogy™ DC+ (2318)	Oct 2009
Trilogy™ DR (2350)	Apr 2007
Trilogy™ SR (2250)	Oct 2009
Trilogy™ DR+ (2360, 2364)	May 2010
Trilogy™ SR+ (2260, 2264)	Nov 2010

Pacing Leads	Final Edition
ACE™ (1015M, 1025M)	Oct 2009
Fast-Pass® (1018T, 1028T)	Oct 2009
IsoFlex® P (1644T)	Apr 2011
Passive Plus® (1135K, 1143K, 1145K,1235K, 1243K, 1245K)	May 2010
Passive Plus® DX (1343K, 1345K)	May 2010
Permathane™ ACE (1035M)	May 2010
Permathane™ ACE (1036T, 1038T)	May 2010
Tendril® (1188K)	May 2010
Tendril® DX (1388K)	May 2010
Unipolar Lead (Model 1007)	May 2010

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

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