Cardiac Rhythm Management Division
Product Performance Report
November 2010

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

November 2010

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.

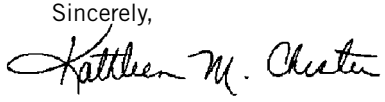
In keeping with this commitment, we publish a product performance report semi-annually to ensure that the healthcare community and the patients it serves are informed about the overall performance of our cardiac devices, which include implantable cardiac monitors, implantable cardioverter defibrillators (ICDs), pacemakers, and implantable pacing and defibrillation leads. St. Jude Medical recognizes that such performance data must be transparent and consistent. In order to meet these goals we continue our commitment to the reporting methods described in the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", which set new standards for lead performance reporting and specifically addressed the reporting of active registry performance data.

In addition to traditional performance reporting methods based on customer complaints and returns, this report includes data from the **S**t. Jude Medi**c**al Pr**o**duct Longevity and Pe**r**formanc**e** Registry (SCORE), which has now been actively collecting data on the reliability and performance of St. Jude Medical cardiac rhythm management products for 3 years. Unlike other active registries, SCORE tracks information on multiple product families, including leads as well as ICD and pacemaker models, making it the most comprehensive registry in the industry. This prospective, non-randomized, multi-center registry will monitor the performance of all implanted St. Jude Medical products at participating sites and is thus designed to include new products as they are introduced. SCORE is just one example of how we are working to reduce risk and set new standards for quality, performance and reliability.

St. Jude Medical is pleased to provide survival probability and enhanced performance data for multiple products which incorporate our SJ4/DF4 defibrillation connector system. This industry-first, in-line connector design consolidates one IS-1 and two DF-1 connectors, thereby reducing bulk and procedure complexity. The SJ4/DF4 connector system includes our latest and most technologically advanced product offerings, notably the Durata® defibrillation lead, the Fortify® ICD and the Unify® CRT-D. For the first time, St. Jude Medical will be demonstrating the reliability of the SJ4/DF4 connector system with a direct comparison of complaints and returns data for both traditional IS-1/DF-1 and SJ4/DF4 connector systems.

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

Sincerely,



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

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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

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, 2010, including:
  - A table of basic information about each model
  - A graph and table describing survival probability
  - For the more recent ICDs, pacemakers, ICMs, and leads, the quantity, rate, and type of product malfunctions are detailed
  - For the most 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, 2010, including:
  - A table of basic information about each model
  - A graph and table describing survival probability
  - A table of all Qualifying Complications
  - A table with quantity, rate, and type of product malfunctions
- A Focus on Clinical Performance section which provides specialized analysis of Optim insulation and SJ4/DF4 connector system performance.
- An updated summary of advisories on all implantable devices since 2003.
- An index by product type and model name.

What's New in This Report

SJ4/DF4 Connector System Data

St. Jude Medical is pleased to expand its reporting on the performance of the SJ4/DF4 connector system. This industry-first connector technology consolidates one IS-1 and two DF-1 connectors into a single four-pole connection, reducing pocket bulk and implant complexity. There have been over 20,000 SJ4/DF4 system implants in the U.S. through June 30, 2010. Our latest high voltage device families, Fortify and Unify, have now qualified for Customer Reported Performance Reporting, supplementing the previously reported Current, Current+, and Promote+ models. With over 300 SCORE registry implants, Durata SJ4/DF4 leads now qualify for SCORE data reporting, complementing the Customer Reported Performance Data previously provided for this lead family. To further enhance reporting on SJ4/DF4 performance, the Focus on Clinical Performance section includes a unique performance comparison of SJ4/DF4 and IS-1/DF-1 connector systems.

Optim® Insulation Performance

Optim lead insulation, a silicone-polyurethane co-polymer, has been on the market for more than 4 years, with nearly 300,000 leads implanted in the U.S.. In the May 2010 performance report St. Jude Medical provided an industry-first analysis of Optim insulation performance which clearly showed a statistically and clinically significant reduction in lead insulation abrasion failures as compared to silicone insulated leads. Page 213 within the Focus on Clinical Performance section of this report contains an updated analysis.

Additional Malfunction Information

In an effort to further increase customer understanding of St. Jude Medical lead performance, additional subcategories have been added to defibrillation lead malfunction categories. "Conductor Fracture" malfunctions will now be further identified as "Clavicular Crush", "In the Pocket" or "Intravascular". "Insulation Breach" malfunctions will now be further identified as "Lead-to-Can Contact", "Lead-to-Lead Contact", "Clavicular Crush", "Externalized Conductors" or "Other". The definitions of these new subcategories are provided in the Leads Malfunction Reporting section on page 9.

Also for the first time, malfunction data will be provided for SCORE registry devices in a manner consistent with non-SCORE devices. This is intended to allow additional comparisons between SCORE and non-SCORE data sets.

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, as would be seen in a registry. Under reporting of events is a known occurrence.

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 surface.

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, use of AutoCapture™ Pacing System, etc. For example, the estimated longevity for Victory® and Zephyr® pacemakers is based on the mean longevity (or 50%) value in the product literature corresponding to a pacing output setting of 2.5 V, 500 ohm lead impedance, 100% DDD pacing, AutoCapture™ Off, and Stored EGMs Off. Using these parameters, the estimated longevity of a Zephyr® XL DR pacemaker model 5826 is 11.7 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.

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 other within-specification out-of-service events, such as unrelated patient death or normal battery depletion.

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

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

Malfunction with Compromised Therapy - The condition when a device is found to have "malfunctioned," as defined above, in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if no therapy is available or critical patient-protective pacing or defibrillation therapy is not available. A malfunction with compromised therapy does not imply that a patient has actually experienced a serious complication or death as a result of the malfunction although it does imply that the potential for a serious complication or death did exist during the period of the malfunction.

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

ISO5841-2:2000(E) survival data are presented in a single table and graph. The survival data is separated into "Including Normal Battery Depletion" and "Excluding Normal Battery Depletion" categories and includes a method to adjust for under reporting. For the purposes of this data, non-returned devices removed from service for battery depletion with no associated complaint are considered as normal battery depletions. The "Including Normal Battery Depletion" data reflects the frequency of device removal due to normal battery depletion and malfunction of any type. The "Excluding Normal Battery Depletion" category reflects the frequency of device removal due to malfunctions only.

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 anatomical influences. Therefore, the functional lifetime of cardiac leads is limited and can not 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 reported by the field, and the laboratory analysis of all domestically implanted leads returned to St. Jude Medical. Complaints reported within 30 days of implant (acute observations), are considered to be related to factors other than lead malfunction, such as patient specific characteristics or implant technique, and are, therefore, excluded

from the survival calculations, consistent with industry practice. If there is laboratory data that determines the lead to have exhibited an electrical malfunction, and the lead is known to have been implanted for more than 30 days, the lead is counted as a non-survivor. If a lead is the subject of a complaint (chronic complication) report, is no longer in service as a result of the complication, and was implanted for more than 30 days, then the lead is counted as a non-survivor. These criteria are also followed for partial lead returns. This method for non-returned complications is used to ensure a conservative failure estimate for lead performance. Chronic complications commonly associated with non-returned leads and partial lead returns include, but are not limited to, reports of sensing, pacing, and capture anomalies, perforation, and dislodgement.

Leads Observation and Complication Reporting

Reporting for recently released lead models provides detail on specific chronic complications (more than 30 days implant), as well as acute observations (post implant to 30 days), that are reported to St. Jude Medical as complaints. Each complication and observation is categorized into one of the eleven categories below, irrespective of whether the lead has been returned for analysis. The quantity and rate of each complication and observation type is provided in a tabular format on the Customer Reported Performance Data page.

Cardiac Perforation: Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance (high thresholds), chest pain, or tamponade.

Conductor Fracture: A mechanical break within a lead conductor (includes connectors, coils, cables and/or electrodes) observed visually, electrically, or radiographically.

Lead Dislodgement: Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance.

Failure to Capture: Intermittent or complete failure to achieve cardiac stimulation (atrial or ventricular) at programmed output delivered outside of the cardiac refractory period. A sudden and significant increase in the pacing threshold value (elevated thresholds compared to previous measured value) at which 2:1 safety margin can no longer be achieved.

Oversensing: Misinterpretation of cardiac or non-cardiac events as cardiac depolarization, e.g. T-waves, skeletal muscle potentials, and extra cardiac electromagnetic interference (EMI).

Failure to Sense (undersensing): Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals (atrial or ventricular) during non-refractory periods at programmed sensitivity settings.

Insulation Breach: A disruption or break in lead insulation observed visually, electrically, or radiographically.

Abnormal Pacing Impedance: Pacing impedance is typically considered abnormal if a measurement is < 200 Ω or > 2000 Ω (based on lead model and measurement range of the device).

Abnormal Defibrillation Impedance: Defibrillation impedance is typically considered abnormal if a measurement is < 20 Ω or > 200 Ω (based on lead model and measurement range of the device).

Extracardiac Stimulation: Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle.

Other: Specific proprietary lead mechanical attributes such as lead incorporated sensors, connectors or seal rings which affect a lead's ability to perform as designed or remain in service, as well as other complications not included above.

Leads Malfunction Reporting

As a supplement to the survival estimates, the categorization of lead malfunctions emphasizes the root cause of malfunction rather than a functional longevity prediction. In accordance with AdvaMed guidelines, laboratory analysis results of returned leads are categorized into one of the following five categories of malfunctions. The quantity and rate of the each malfunction type is provided in a tabular format on the Customer Reported Performance Data and SCORE Registry Performance Data pages. The definition for each malfunction type is provided below:

Conductor Fracture: Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors). This type of malfunction includes any conductor fracture such as those associated with flex-fatigue or clavicular crush damage.

In an effort to further increase customer understanding of St. Jude Medical lead performance, subcategories of conductor fracture have now been added to the malfunction data. The definitions of these subcategories are provided below:

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

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

Intravascular: Conductor fracture within the vascular or cardiac systems.

Insulation Breach: Any lead insulation breach. Such as: 1) proximal abrasions associated with lead-to-lead or lead-to-can contact in the pocket, 2) mid-lead insulation damage caused by clavicular crush or insulation wear in the region of vein insertion, and 3) distal region wear due to lead-to-lead (intracardiac), lead-to-heart valve or lead-to-other anatomy contact.

Subcategories of insulation breach have also been added to the malfunction data. 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 previously contained conductors to become visible outside the lead body.

Other (Insulation Breach): Insulation breaches 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. Typically demonstrated by high or low shocking/pacing impedance, undersensing or oversensing.

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: Lead complication where the identified lead was removed from service and returned for analysis, where analysis was inconclusive because only portions of the lead were available or the returned lead was damaged by the explantation process, or where lab analysis could not determine an out of specification condition (including complications such as dislodgements, perforations, or failure to capture). For this particular category, malfunctions will only be included in survival probability for leads implanted greater than 30 days.

SCORE Registry Performance Data

St. Jude Medical is pleased to again provide results from the SCORE (**S**t. Jude Medi**c**al Pr**o**duct Longevity and Perfo**r**manc**e**) Registry. SCORE 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, ICD models and pacemaker models. 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, 60 clinical sites are participating in the SCORE Registry with approximately 7,000 patients enrolled as of June 30, 2010. Using a common protocol, these sites are individually monitoring and reporting on the performance of all St. Jude Medical cardiac rhythm management products used at their site. The SCORE registry is designed to include new products as they become available.

In order for a device model to be included in this report, a minimum of 100 devices must been enrolled in the registry as of June 30, 2010, with the latest interval to be reported having a minimum of 50 devices which have been followed for at least six months. Eight model families meet the inclusion criteria for the first time in this report. Below is a complete list of all twenty-eight device models which will report SCORE performance data:

ICDs
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)*

Defibrillation Leads
Durata® SJ4/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)

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

Pacing Leads
Tendril® ST Optim® (Model 1888)
Tendril® ST Optim® (Model 1882)*
Tendril® (Model 1788)
Tendril® (1782)*
Tendril® SDX (Model 1688)
Tendril® SDX (Model 1488)
OptiSense® (Model 1699)
IsoFlex® S (Model 1646)

CRT Leads
QuickFlex® XL (Model 1158T)
QuickFlex® (Model 1156T)
QuickSite® (Model 1056T)*

*New for November 2010 report.

SCORE survival calculations are made in a manner consistent with the ISO5841-2:2000(E) method used for Customer Reported Performance Data. A Qualifying Complication is defined as an adverse event reported to the SCORE registry that resulted in the device being taken out of service (explanted, abandoned, etc.). 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, such as infection, are not considered as Qualified Complications. Devices included in the SCORE survival calculations are excluded from the Customer Reported Performance Data.

For the first time, St. Jude Medical is including 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.

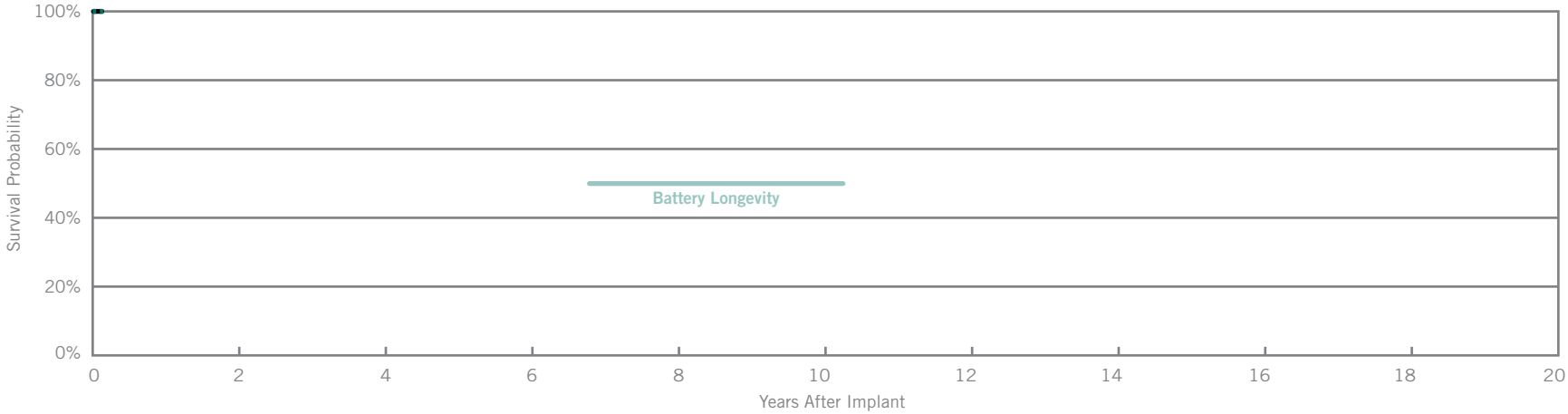
Customer Reported Performance Data

Unify®

Model CD3231-40Q

US Regulatory Approval	May 10
Registered US Implants	698
Estimated Active US Implants	697
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	at 1 month										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	700										

Excluding Normal Battery Depletion ———

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

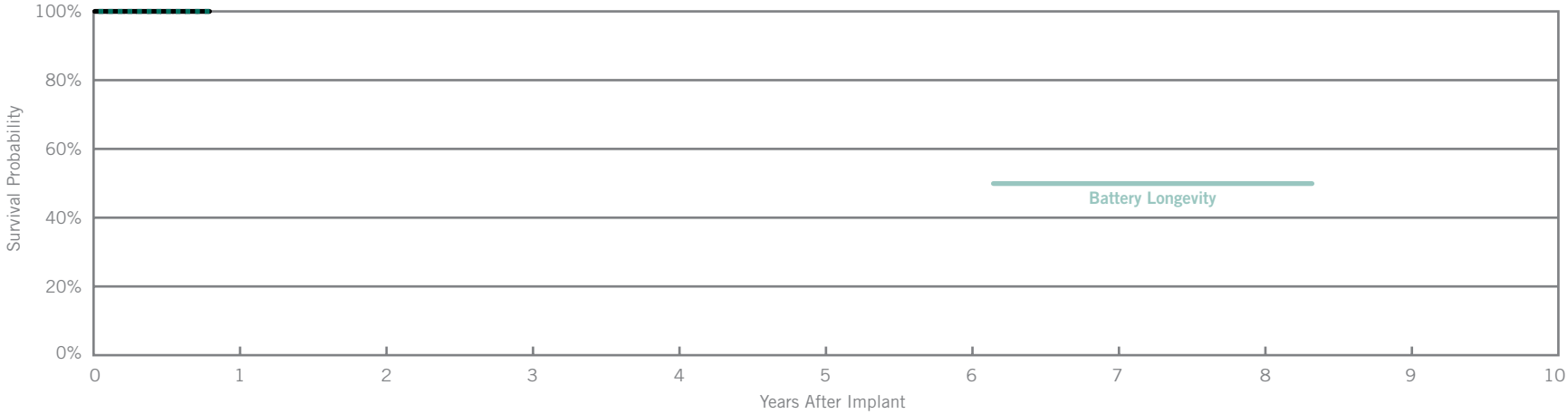
Customer Reported Performance Data

Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	6,858
Estimated Active US Implants	6,497
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	at 10 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	500										

Excluding Normal Battery Depletion ———

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

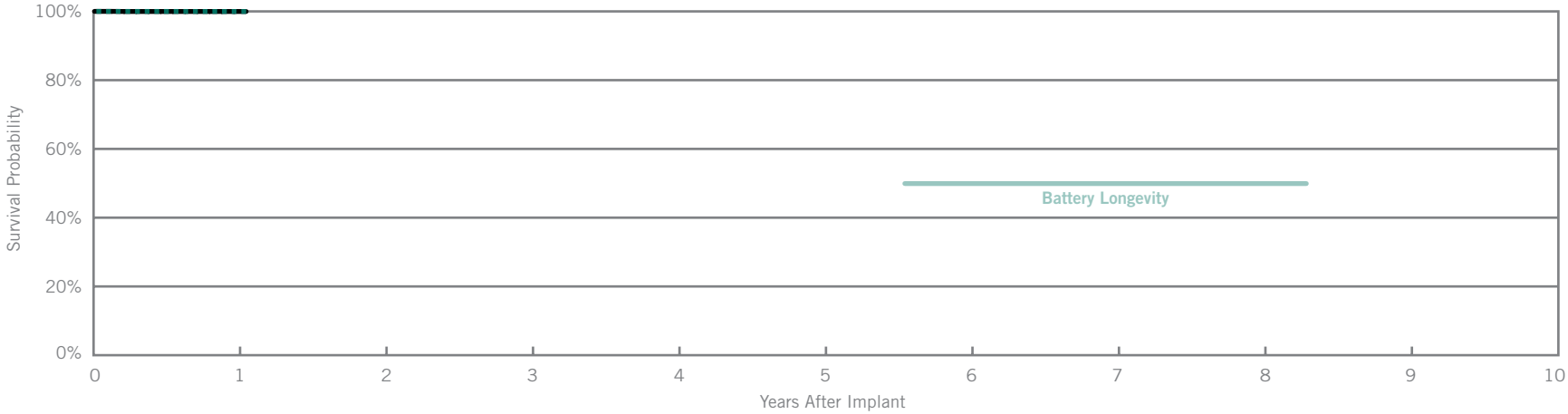
Customer Reported Performance Data

Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	7,557
Estimated Active US Implants	7,021
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	1	at 13 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.02%	0.02%								
Sample Size	4300	500								

Excluding Normal Battery Depletion ———

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

SCORE Registry Performance Data

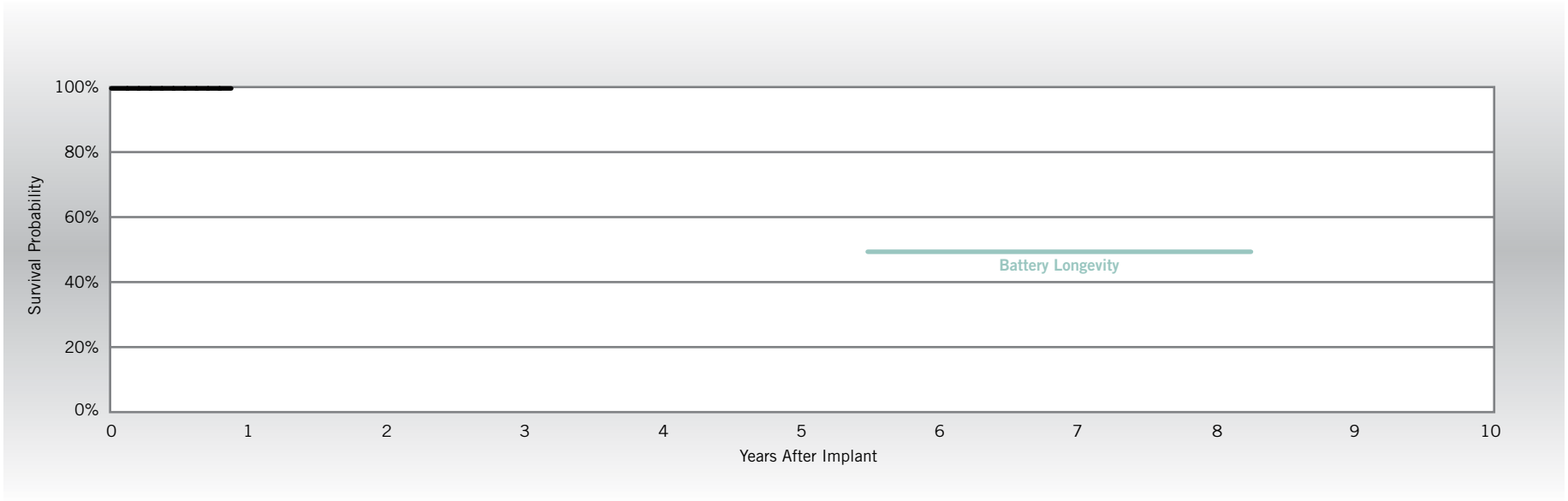
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	250
Cumulative Months of Follow-up	1,800
Estimated Longevity	(see table on page 30)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	1	0.40%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.40%
Total	**1**	**0.40%**



Year	at 11 months									
Survival Probability	99.59%									
± 1 standard error	0.41%									
Sample Size	60									

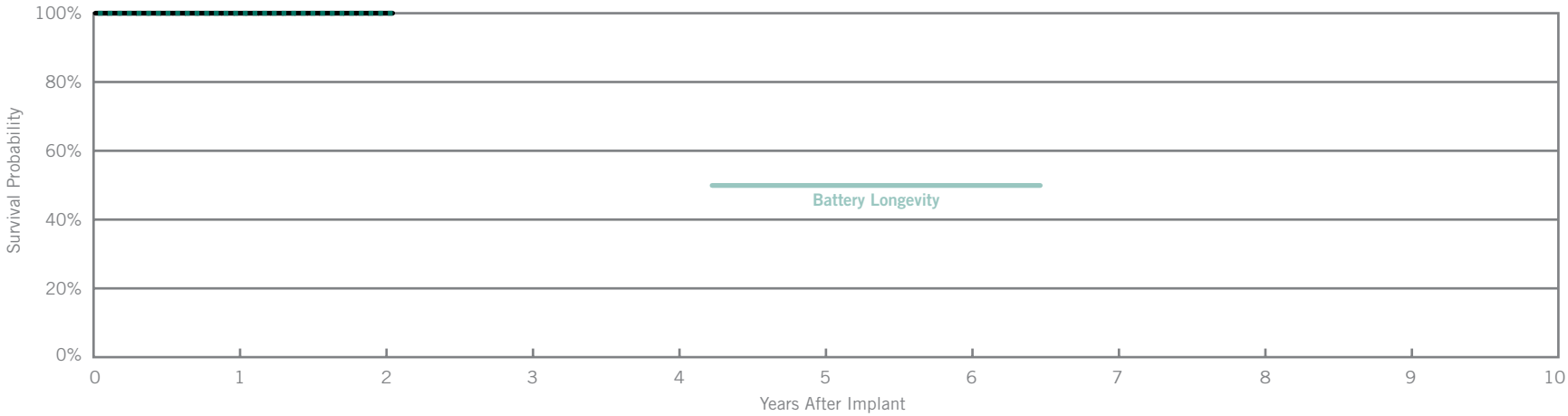
Customer Reported Performance Data

Promote® RF

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,385
Estimated Active US Implants	1,134
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	1	2	at 25 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	1200	600	200							

Excluding Normal Battery Depletion ———

Year	1	2	at 25 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

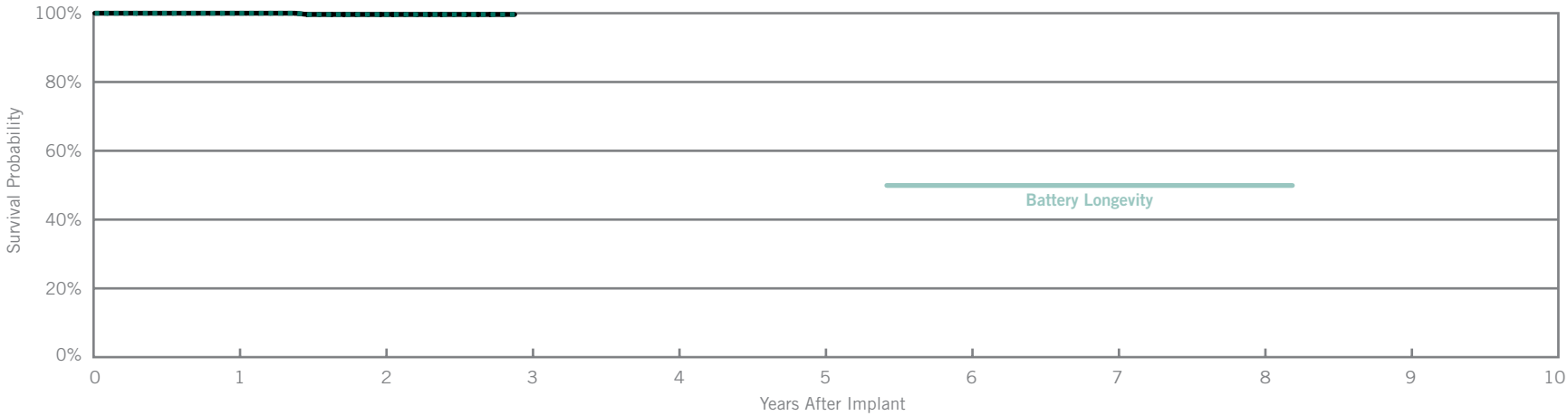
Customer Reported Performance Data

Promote®

Model 3107-36

US Regulatory Approval	May 2007
Registered US Implants	741
Estimated Active US Implants	512
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.13%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**1**	**0.13%**



Including Normal Battery Depletion .....

Year	1	2	at 35 months							
Survival Probability	100.00%	99.63%	99.63%							
± 1 standard error	0.00%	0.26%	0.26%							
Sample Size	700	600	300							

Excluding Normal Battery Depletion ———

Year	1	2	at 35 months							
Survival Probability	100.00%	99.63%	99.63%							
± 1 standard error	0.00%	0.26%	0.26%							

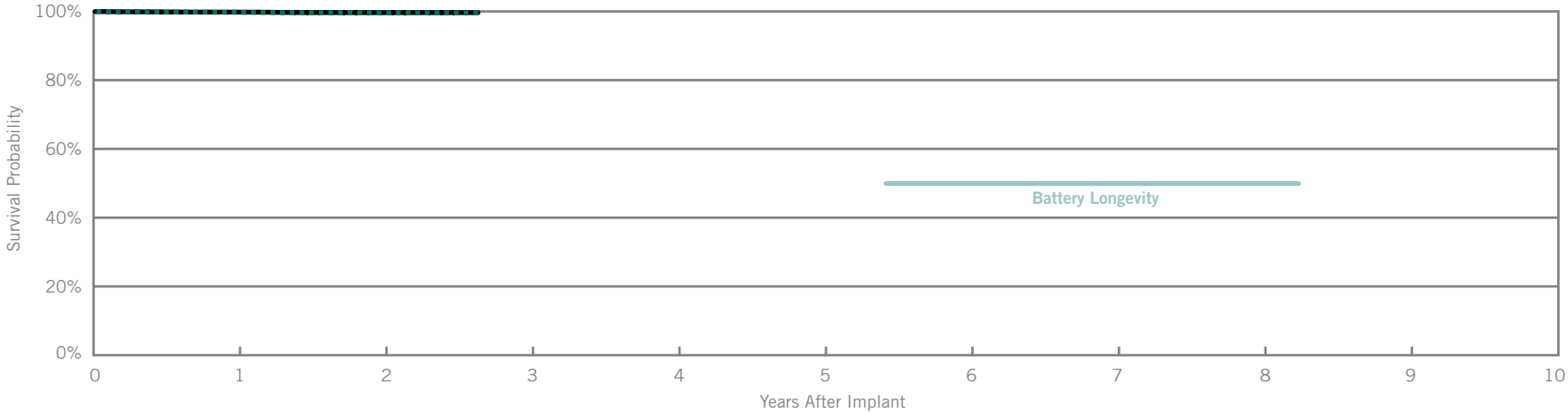
Customer Reported Performance Data

Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,540
Estimated Active US Implants	19,108
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	10	0.04%
Malfunctions w/o Compromised Therapy	17	0.07%
Total	**27**	**0.11%**



Including Normal Battery Depletion .....

Year	1	2	at 32 months							
Survival Probability	99.75%	99.60%	99.60%							
± 1 standard error	0.03%	0.05%	0.05%							
Sample Size	21500	11100	200							

Excluding Normal Battery Depletion ———

Year	1	2	at 32 months							
Survival Probability	99.79%	99.64%	99.64%							
± 1 standard error	0.03%	0.05%	0.05%							

SCORE Registry Performance Data

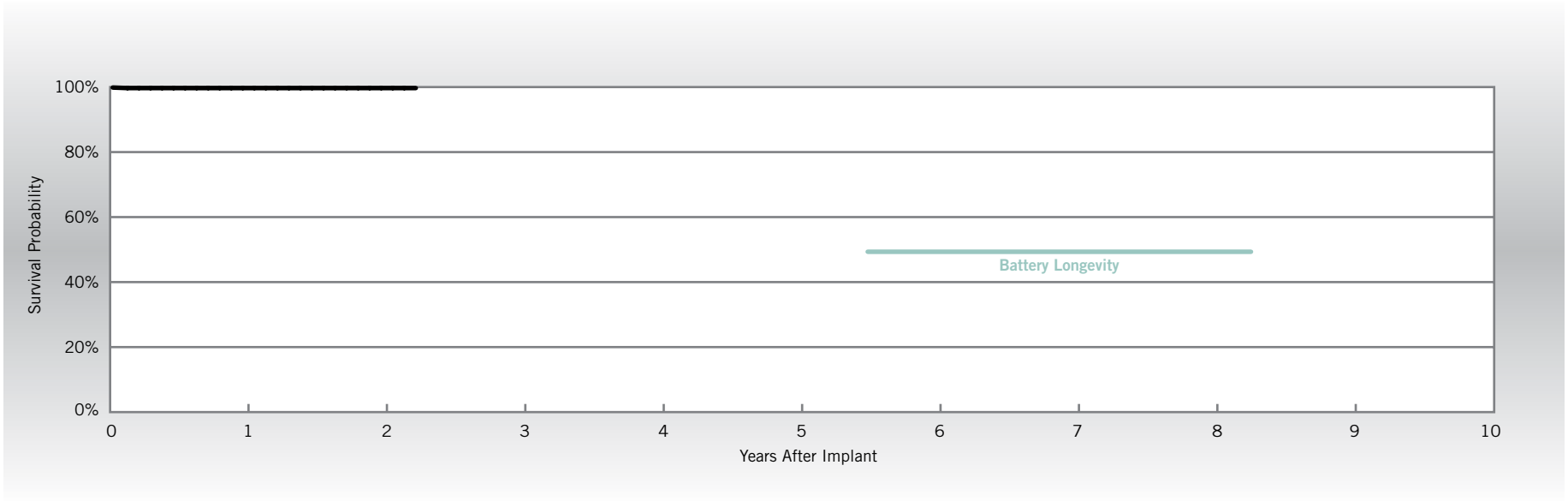
Promote® RF

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	660
Cumulative Months of Follow-up	11,240
Estimated Longevity	(see table on page 30)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Backup Operation	2	0.30%

Malfunctions	Qty.	Rate
Malfunctions w/Compromised Therapy	1	0.15%
Malfunctions w/o Compromised Therapy	2	0.30%
Total	**3**	**0.45%**



Year	1	2	at 27 months							
Survival Probability	99.69%	99.69%	99.69%							
± 1 standard error	0.22%	0.22%	0.22%							
Sample Size	580	320	50							

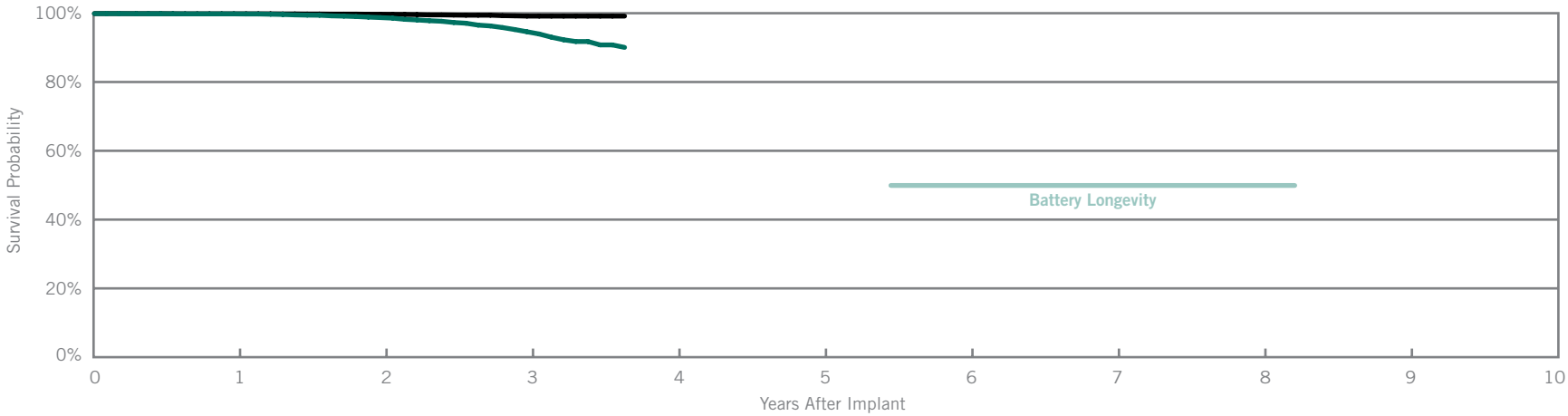
Customer Reported Performance Data

Atlas® II HF

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	8,381
Estimated Active US Implants	4,969
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	112
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	14	0.17%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	7	0.08%
Total (0 related to Advisory)	**21**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.80%	98.73%	94.61%	90.06%						
± 1 standard error	0.05%	0.13%	0.30%	0.59%						
Sample Size	8400	7100	4900	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.83%	99.70%	99.16%	99.16%						
± 1 standard error	0.05%	0.06%	0.12%	0.13%						

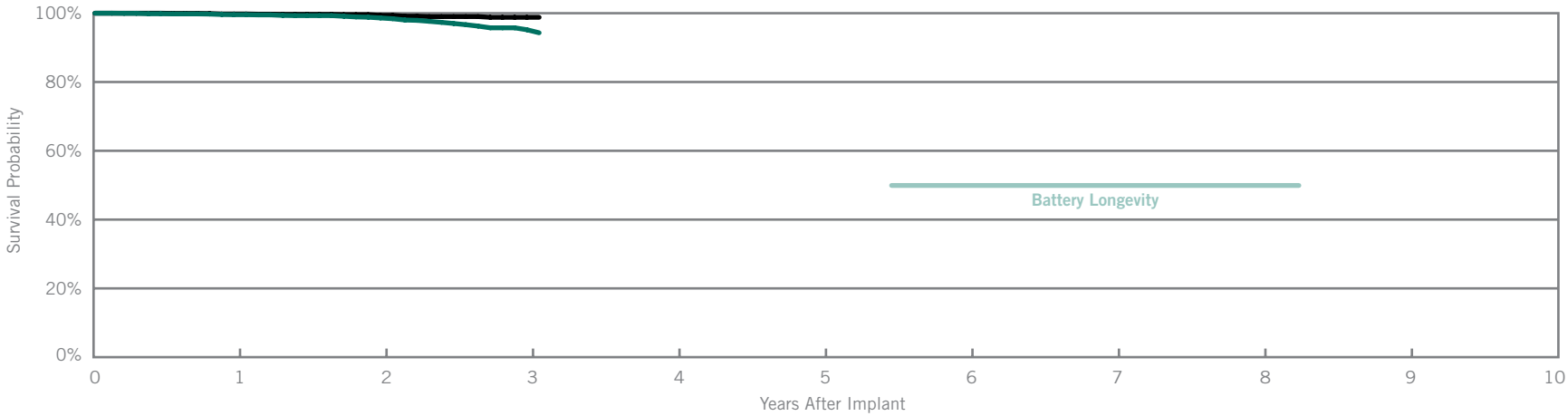
Customer Reported Performance Data

Atlas® II + HF

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	4,968
Estimated Active US Implants	3,510
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	25
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	7	0.14%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	6	0.12%
Total (0 related to Advisory)	**13**	**0.26%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.57%	98.62%	95.19%	94.31%						
± 1 standard error	0.09%	0.19%	0.48%	0.62%						
Sample Size	4700	3200	1400	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.78%	99.37%	98.81%	98.81%						
± 1 standard error	0.07%	0.11%	0.24%	0.24%						

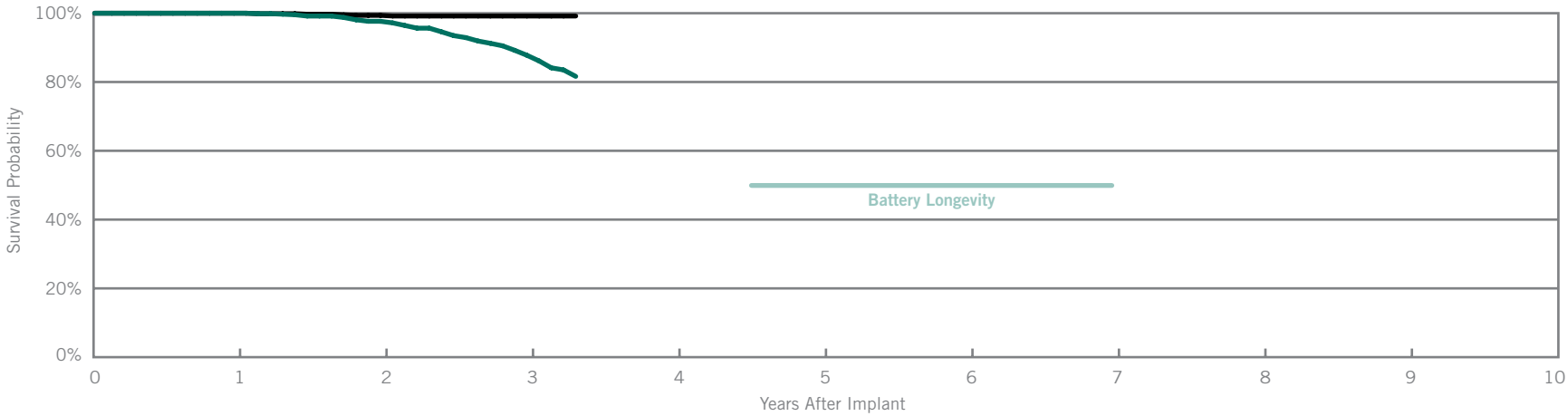
Customer Reported Performance Data

Epic® II HF

Model V-355

US Regulatory Approval	March 2006
Registered US Implants	1,739
Estimated Active US Implants	910
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	50
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	0.12%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	3	0.17%
Total (0 related to Advisory)	**5**	**0.29%**



Including Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	100.00%	97.65%	87.77%	81.63%						
± 1 standard error	0.00%	0.43%	1.05%	1.47%						
Sample Size	1700	1400	900	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 40 months						
Survival Probability	100.00%	99.37%	99.18%	99.18%						
± 1 standard error	0.00%	0.22%	0.26%	0.26%						

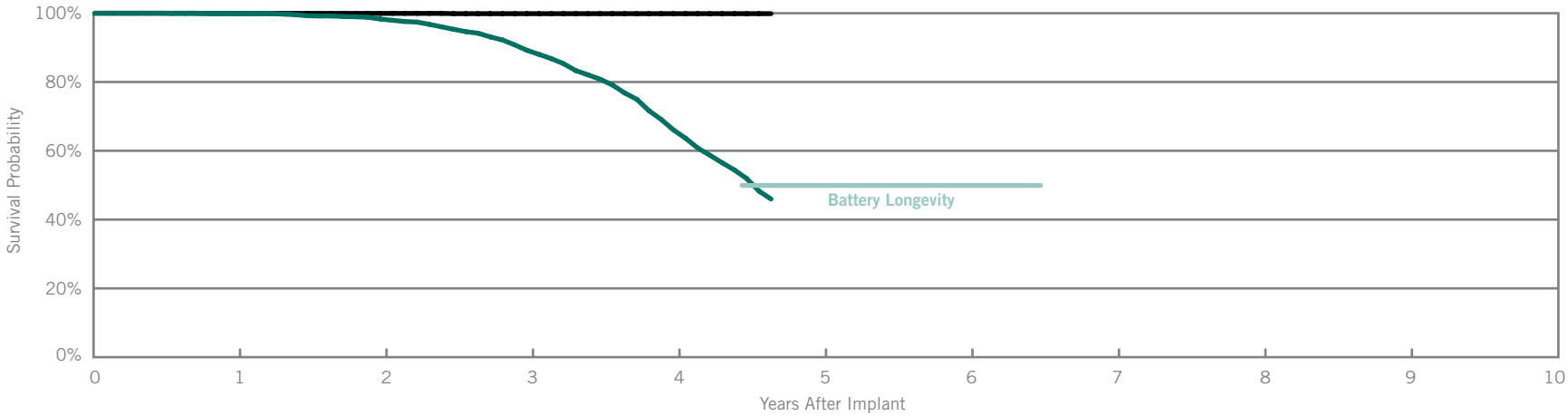
Customer Reported Performance Data

Epic® HF

Model V-337

US Regulatory Approval	November 2004
Registered US Implants	3,969
Estimated Active US Implants	1,015
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	344
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	Two

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	1	0.03%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.03%
Total (0 related to Advisory)	**2**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.89%	98.29%	89.21%	66.08%	45.97%					
± 1 standard error	0.06%	0.19%	0.56%	1.06%	1.59%					
Sample Size	4000	3400	2800	1900	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 56 months					
Survival Probability	99.94%	99.94%	99.87%	99.87%	99.87%					
± 1 standard error	0.04%	0.04%	0.07%	0.07%	0.07%					

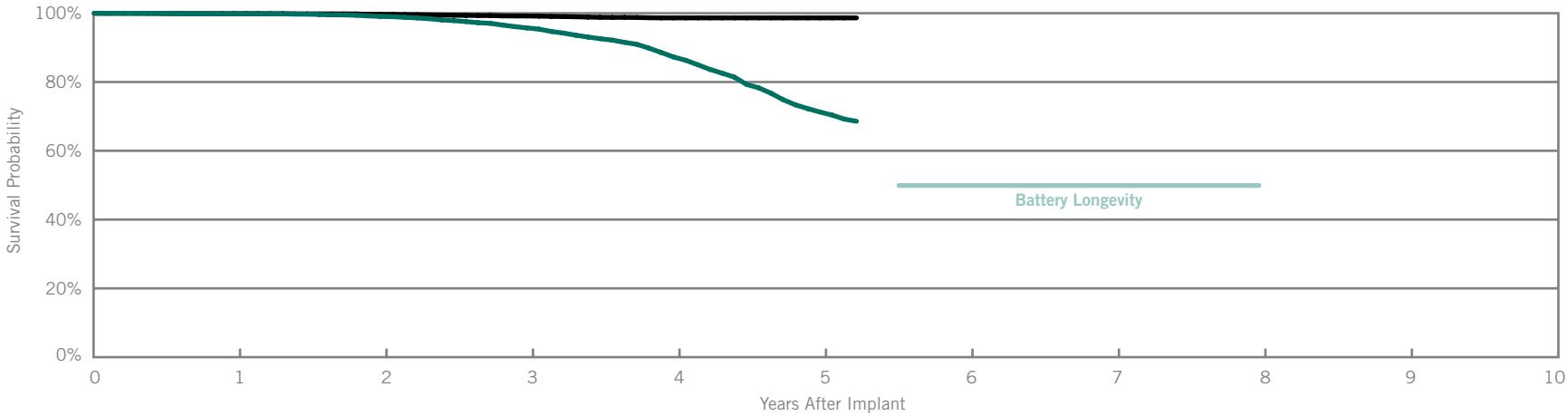
Customer Reported Performance Data

Atlas® + HF

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,630
Estimated Active US Implants	8,097
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	579
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (1 related to Advisory)	47	0.25%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	18	0.10%
Total (0 related to Advisory)	**65**	**0.35%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 63 months				
Survival Probability	99.81%	99.06%	95.72%	87.28%	71.28%	68.58%				
± 1 standard error	0.03%	0.07%	0.17%	0.33%	0.83%	1.08%				
Sample Size	18600	15800	13100	8700	3200	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 63 months				
Survival Probability	99.88%	99.66%	99.20%	98.64%	98.64%	98.64%				
± 1 standard error	0.03%	0.05%	0.08%	0.11%	0.11%	0.11%				

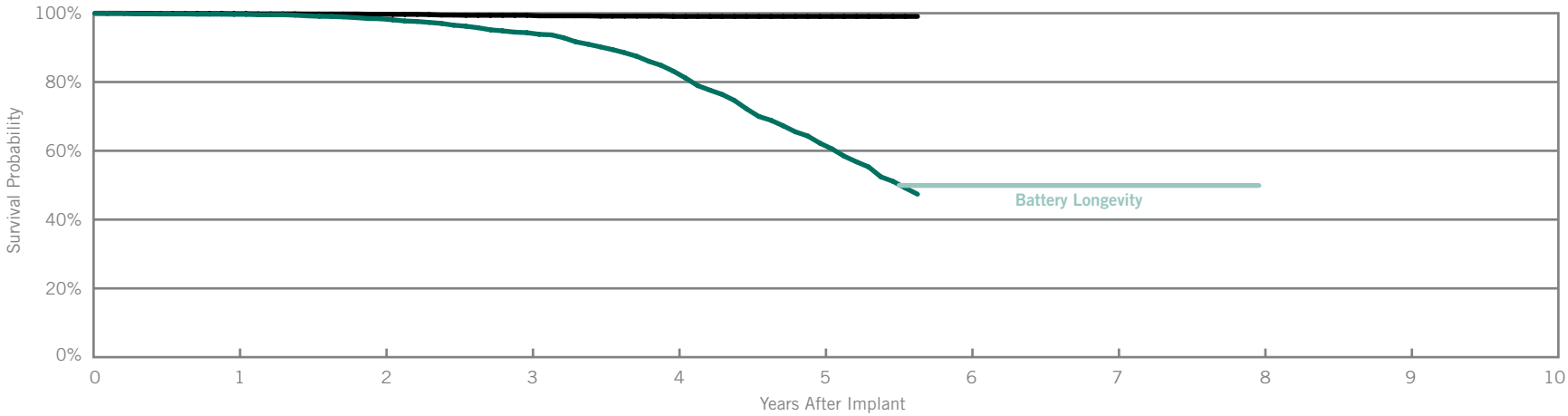
Customer Reported Performance Data

Atlas® + HF

Model V-340

US Regulatory Approval	June 2004
Registered US Implants	4,930
Estimated Active US Implants	860
Estimated Longevity	(see table on page 30)
Normal Battery Depletion	410
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	Three

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (1 related to Advisory)	9	0.18%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	6	0.12%
Total (1 related to Advisory)	**15**	**0.30%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.67%	98.39%	94.34%	83.14%	62.22%	47.38%				
± 1 standard error	0.08%	0.20%	0.38%	0.66%	1.01%	1.44%				
Sample Size	4900	4200	3600	3000	1900	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.87%	99.71%	99.39%	99.06%	99.06%	99.06%				
± 1 standard error	0.04%	0.08%	0.13%	0.16%	0.17%	0.17%				

Battery Longevity Summary

CRT ICDs

St. Jude Medical™
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3231-40Q	Unify®**	10.2	9.0	8.1	6.7
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
3107-36	Promote®	8.2	7.2	6.5	5.4
3207-36	Promote® RF	8.2	7.2	6.5	5.4
V-365	Atlas® II HF	8.2	7.2	6.5	5.4
V-366	Atlas® II + HF	8.2	7.2	6.5	5.4
V-355	Epic® II HF	7.0	6.1	5.5	4.5
V-337	Epic® HF, Serial Numbers <13000	6.4	5.7	5.2	4.4
V-337	Epic® HF, Serial Numbers >13000	6.5	5.8	5.2	4.4
V-343	Atlas® + HF	7.9	7.1	6.4	5.4
V-340	Atlas® + HF	7.9	7.1	6.4	5.4

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

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®*										
CD3211-36Q	Promote® + CRT-D*										
CD3211-36	Promote® + CRT-D	99.97%									
3207-30	Promote® RF	100.00%	100.00%								
3107-36	Promote®	100.00%	99.63%								
3207-36	Promote® RF	99.75%	99.60%								
V-365	Atlas® II HF	99.80%	98.73%	94.61%							
V-366	Atlas® II + HF	99.57%	98.62%	95.19%							
V-355	Epic® II HF	100.00%	97.65%	87.77%							
V-337	Epic® HF	99.89%	98.29%	89.21%	66.08%						
V-343	Atlas® + HF	99.81%	99.06%	95.72%	87.28%	71.28%					
V-340	Atlas® + HF	99.67%	98.39%	94.34%	83.14%	62.22%					

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3231-40Q	Unify®*										
CD3211-36Q	Promote® + CRT-D*										
CD3211-36	Promote® + CRT-D	99.97%									
3207-30	Promote® RF	100.00%	100.00%								
3107-36	Promote®	100.00%	99.63%								
3207-36	Promote® RF	99.79%	99.64%								
V-365	Atlas® II HF	99.83%	99.70%	99.16%							
V-366	Atlas® II + HF	99.78%	99.37%	98.81%							
V-355	Epic® II HF	100.00%	99.37%	99.18%							
V-337	Epic® HF	99.94%	99.94%	99.87%	99.87%						
V-343	Atlas® + HF	99.88%	99.66%	99.20%	98.64%	98.64%					
V-340	Atlas® + HF	99.87%	99.71%	99.39%	99.06%	99.06%					

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify®	May 10	698	697	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD3211-36Q	Promote® + CRT-D	Feb 09	6858	6497	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD3211-36	Promote® + CRT-D	Feb 09	7557	7021	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%
3207-30	Promote® RF	Sep-07	1385	1134	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
3107-36	Promote®	May-07	741	512	0	0.00%	1	0.13%	0	0.00%	0	0.00%	1	0.13%
3207-36	Promote® RF	Sep-07	23540	19108	1	0.00%	10	0.04%	5	0.02%	17	0.07%	27	0.11%
V-365	Atlas® II HF	Jul-06	8381	4969	7	0.08%	14	0.17%	5	0.06%	7	0.08%	21	0.25%
V-366	Atlas® II + HF	Feb-07	4968	3510	7	0.14%	7	0.14%	5	0.10%	6	0.12%	13	0.26%
V-355	Epic® II HF	Mar-06	1739	910	1	0.06%	2	0.12%	2	0.12%	3	0.17%	5	0.29%
V-337	Epic® HF	Nov-04	3969	1015	1	0.03%	1	0.03%	0	0.00%	1	0.03%	2	0.05%
V-343	Atlas® + HF	Nov-04	18630	8097	43	0.23%	47	0.25%	12	0.06%	18	0.10%	65	0.35%
V-340	Atlas® + HF	Jun-04	4930	860	5	0.10%	9	0.18%	6	0.12%	6	0.12%	15	0.30%

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3211-36	250	1800	0	0.00%	0	0.00%	0	0.00%	1	0.06%	1	0.06%
3207-36	660	11240	1	0.15%	1	0.15%	1	0.15%	2	0.30%	3	0.45%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Extracardiac Stimulation		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3211-36	250	1800	0	0.00%	1	0.40%	1	0.40%
3207-36	660	11240	2	0.30%	0	0.00%	2	0.30%

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

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical
More control. Less risk.

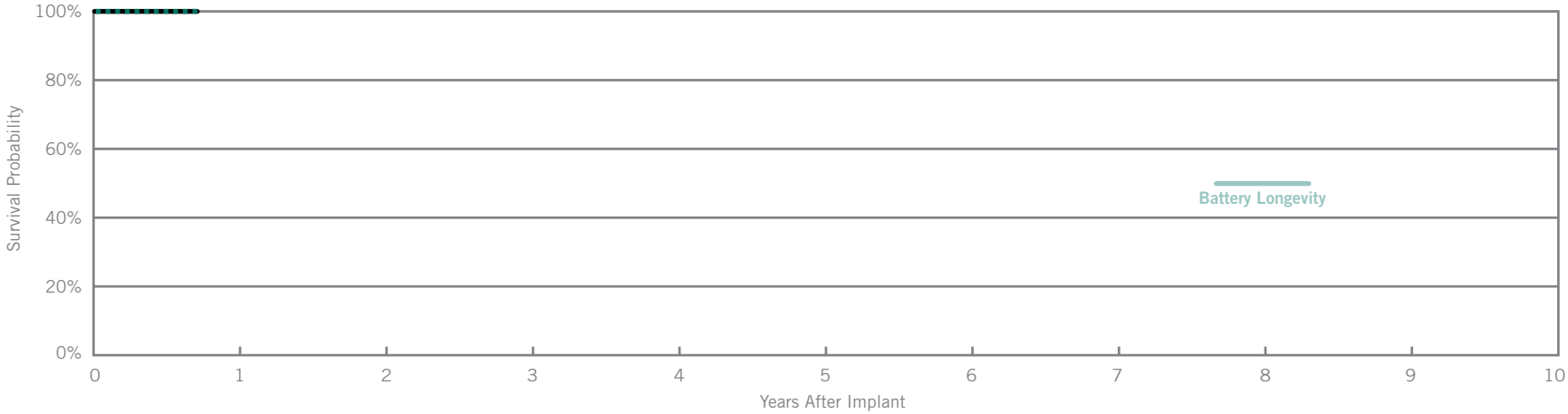
Customer Reported Performance Data

Anthem® RF

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	2,396
Estimated Active US Implants	2,292
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of Advisories	None

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



Including Normal Battery Depletion .....

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

Excluding Normal Battery Depletion ———

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

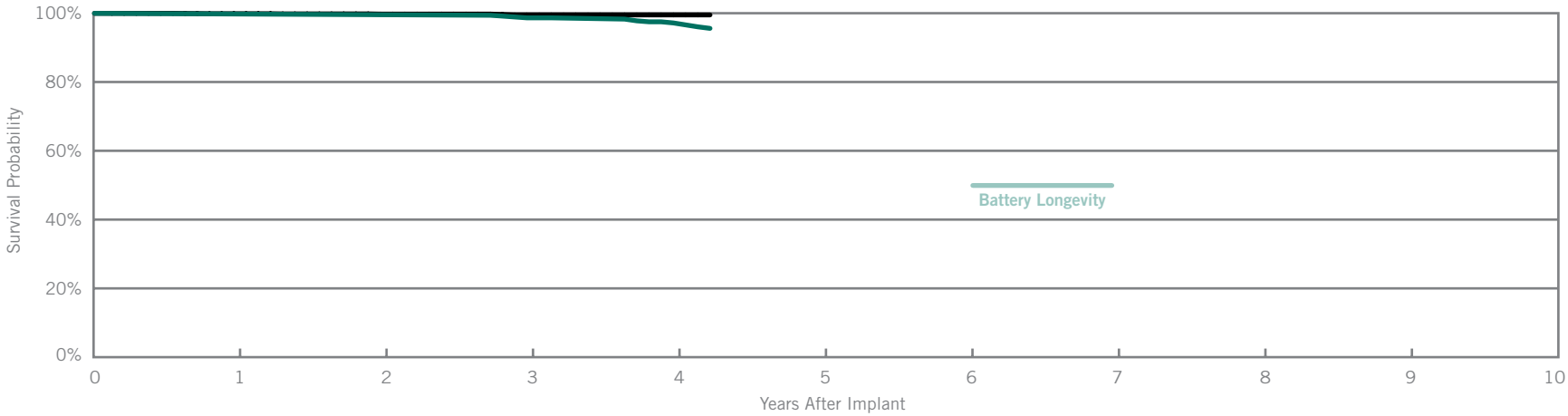
Customer Reported Performance Data

Frontier® II

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,677
Estimated Active US Implants	4,363
Estimated Longevity	6.5 Years
Normal Battery Depletion	23
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	7	0.10%
Total	**8**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.86%	99.68%	98.65%	97.17%	95.59%					
± 1 standard error	0.05%	0.08%	0.24%	0.45%	0.68%					
Sample Size	6400	4200	2300	1100	500					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.86%	99.75%	99.50%	99.50%	99.50%					
± 1 standard error	0.05%	0.06%	0.15%	0.15%	0.15%					

Summary Information

CRT Pacemakers

St. Jude Medical
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM3210	Anthem®*										
5586	Frontier® II	99.86%	99.68%	98.65%	97.17%						

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM3210	Anthem®*										
5586	Frontier® II	99.86%	99.75%	99.50%	99.50%						

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem®	Jul-09	2396	2292	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5586	Frontier® II	Aug-04	6677	4363	0	0.00%	1	0.01%	0	0.00%	7	0.10%	8	0.12%

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

Left-Heart Leads

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

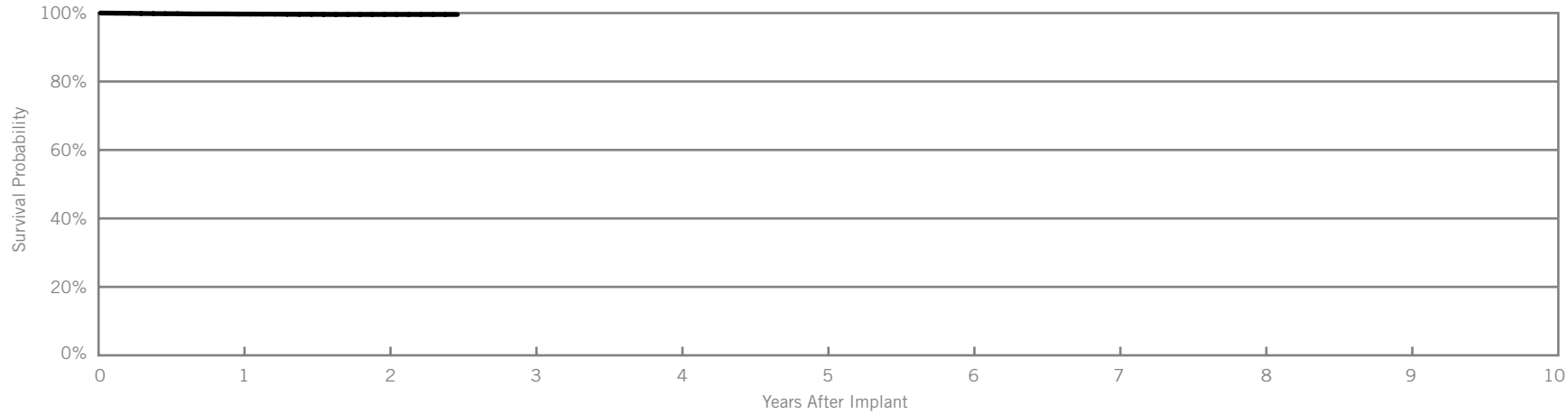
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	21,965
Estimated Active US Implants	18,317
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	10	0.05%	23	0.10%
Failure to Capture	5	0.02%	9	0.04%
Oversensing	0	0.00%	3	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	4	0.02%
Extracardiac Stimulation	16	0.07%	14	0.06%
Other	8	0.04%	2	0.01%
Total	**39**	**0.18%**	**56**	**0.25%**
Total Returned for Analysis	**10**		**19**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	3	0.01%
Extrinsic Factors	15	0.07%
Total	**21**	**0.10%**



Year	1	2	at 30 months							
Survival Probability	99.70%	99.58%	99.58%							
± 1 standard error	0.04%	0.06%	0.06%							
Sample Size	16400	6100	300							

SCORE Registry Performance Data

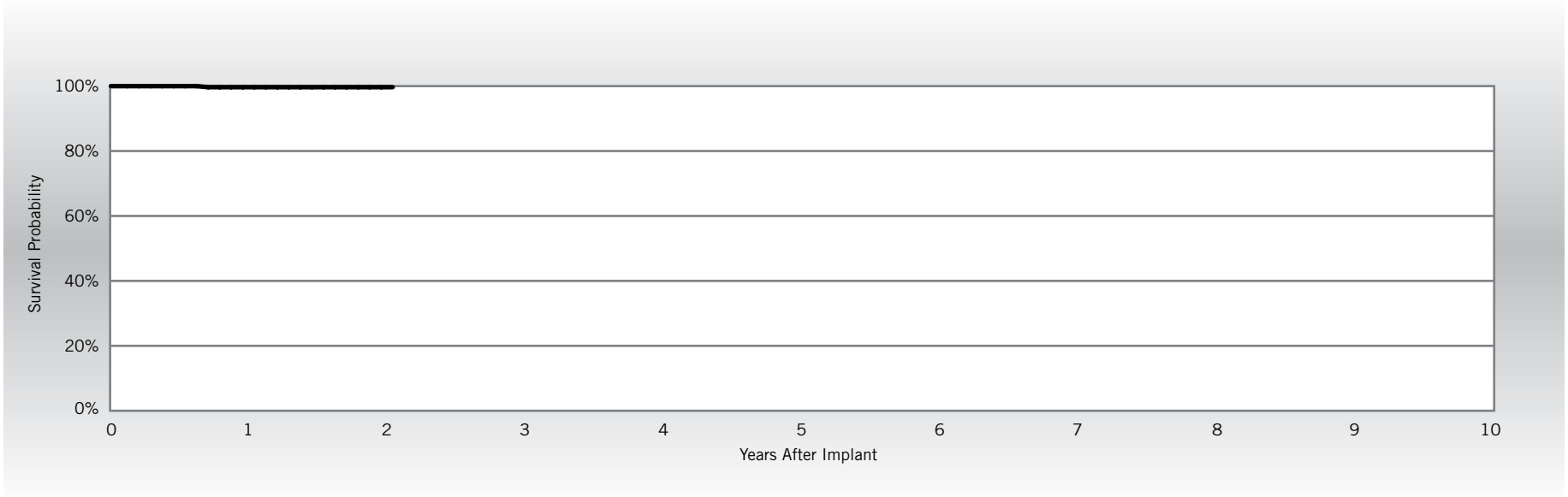
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	460
Cumulative Months of Follow-up	6,370
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.22%

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	0.22%
Total	**1**	**0.22%**



Year	1	2	at 25 months							
Survival Probability	99.68%	99.68%	99.68%							
± 1 standard error	0.31%	0.31%	0.31%							
Sample Size	350	150	60							

Customer Reported Performance Data

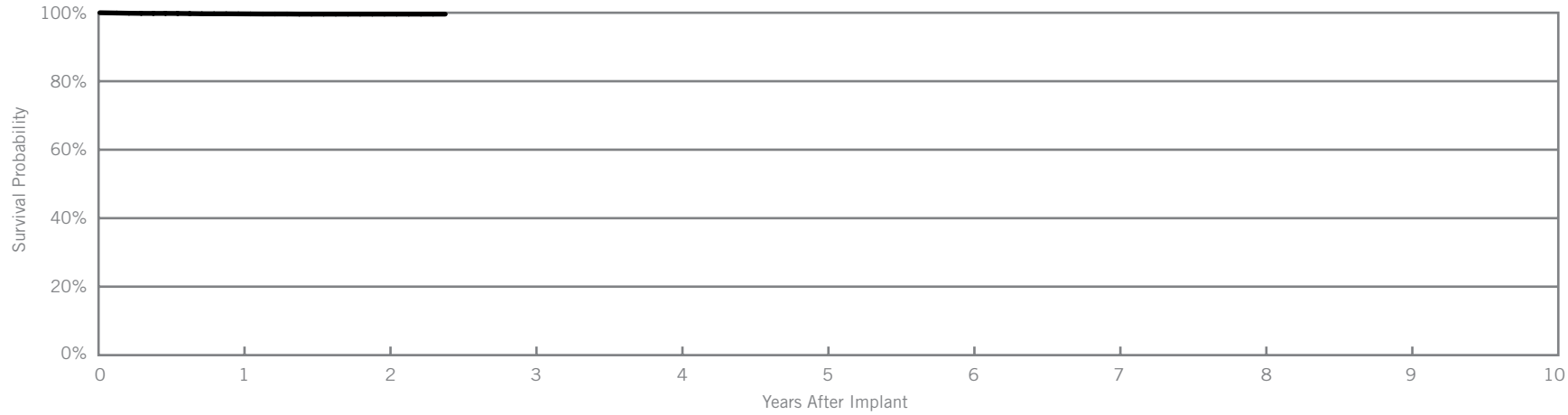
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	11,683
Estimated Active US Implants	9,703
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.03%	15	0.13%
Failure to Capture	1	0.01%	3	0.03%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	2	0.02%
Extracardiac Stimulation	5	0.04%	6	0.05%
Other	6	0.05%	1	0.01%
Total	**18**	**0.15%**	**28**	**0.24%**
Total Returned for Analysis	**6**		**10**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	8	0.07%
Total	**10**	**0.09%**



Year	1	2	at 29 months							
Survival Probability	99.67%	99.60%	99.60%							
± 1 standard error	0.06%	0.07%	0.07%							
Sample Size	8900	3500	400							

SCORE Registry Performance Data

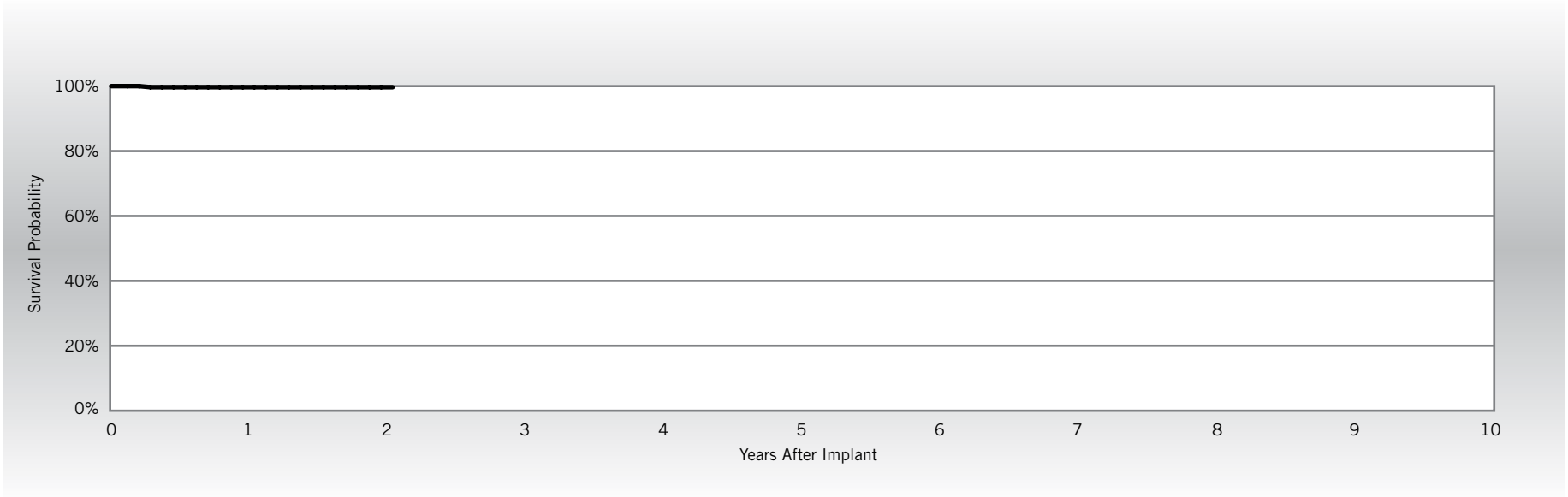
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	360
Cumulative Months of Follow-up	5,050
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	1	0.28%

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	0.83%
Total	**3**	**0.83%**



Year	1	2	at 25 months							
Survival Probability	99.67%	99.67%	99.67%							
± 1 standard error	0.32%	0.32%	0.32%							
Sample Size	280	120	50							

Customer Reported Performance Data

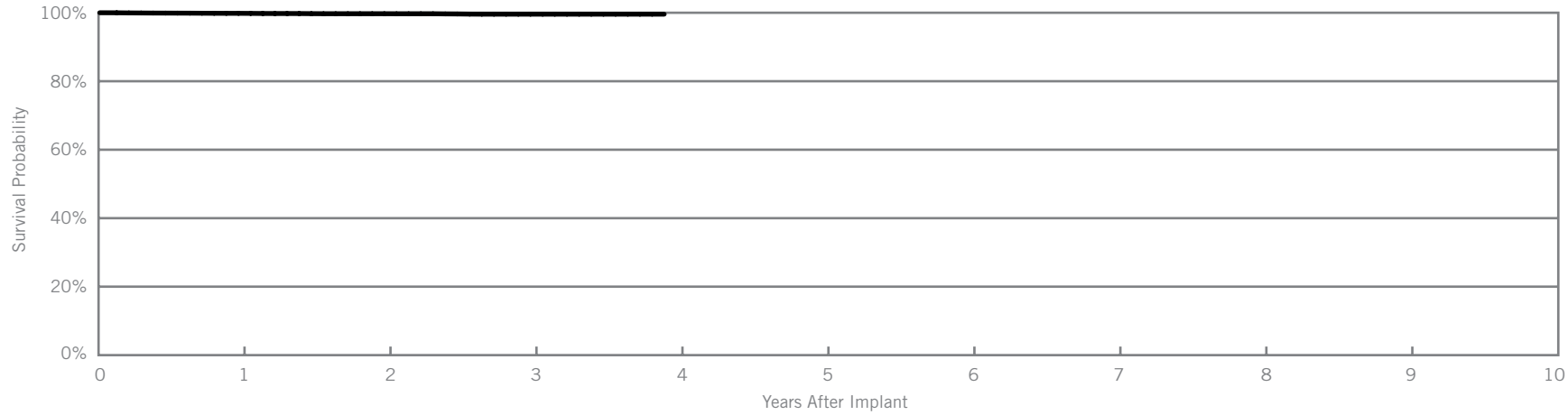
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,280
Estimated Active US Implants	6,899
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	10	0.10%	9	0.09%
Failure to Capture	3	0.03%	10	0.10%
Oversensing	1	0.01%	1	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	1	0.01%
Extracardiac Stimulation	9	0.09%	5	0.05%
Other	2	0.02%	1	0.01%
Total	**27**	**0.26%**	**28**	**0.27%**
Total Returned for Analysis	**8**		**8**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.03%
Extrinsic Factors	9	0.09%
Total	**12**	**0.12%**



Year	1	2	3	at 47 months						
Survival Probability	99.83%	99.71%	99.58%	99.58%						
± 1 standard error	0.04%	0.06%	0.08%	0.08%						
Sample Size	9600	7700	5000	300						

Customer Reported Performance Data

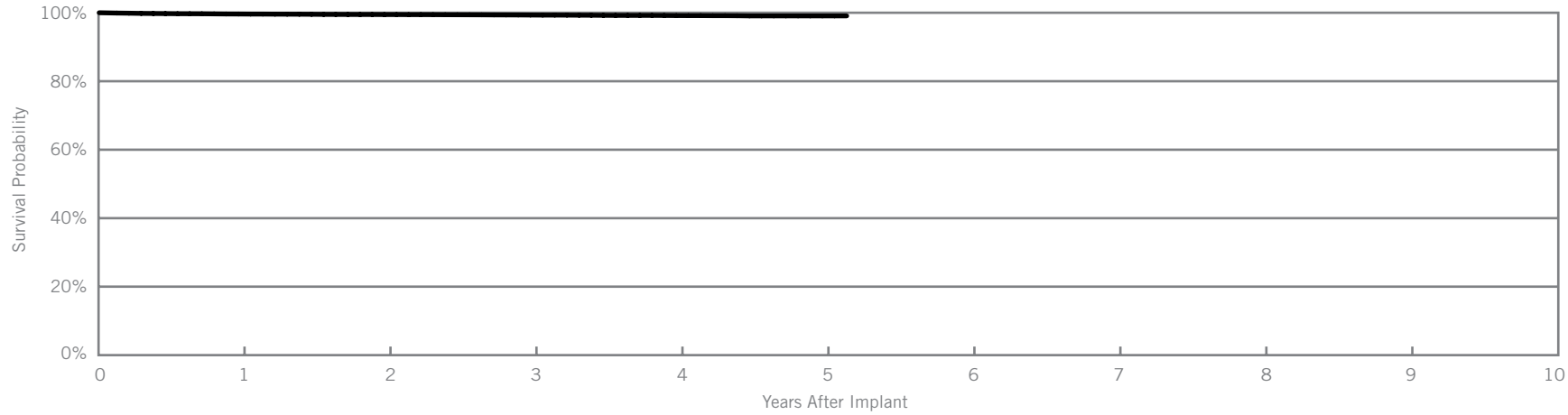
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	33,976
Estimated Active US Implants	19,977
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	28	0.08%	72	0.21%
Failure to Capture	14	0.04%	66	0.19%
Oversensing	1	<0.01%	3	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	3	0.01%	3	0.01%
Extracardiac Stimulation	22	0.06%	43	0.13%
Other	9	0.03%	7	0.02%
Total	**78**	**0.23%**	**198**	**0.58%**
Total Returned for Analysis	**24**		**79**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	5	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	71	0.21%
Total	**79**	**0.23%**



Year	1	2	3	4	5	at 62 months				
Survival Probability	99.63%	99.47%	99.33%	99.17%	99.08%	99.08%				
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.08%	0.08%				
Sample Size	31100	25400	19600	12100	4600	500				

SCORE Registry Performance Data

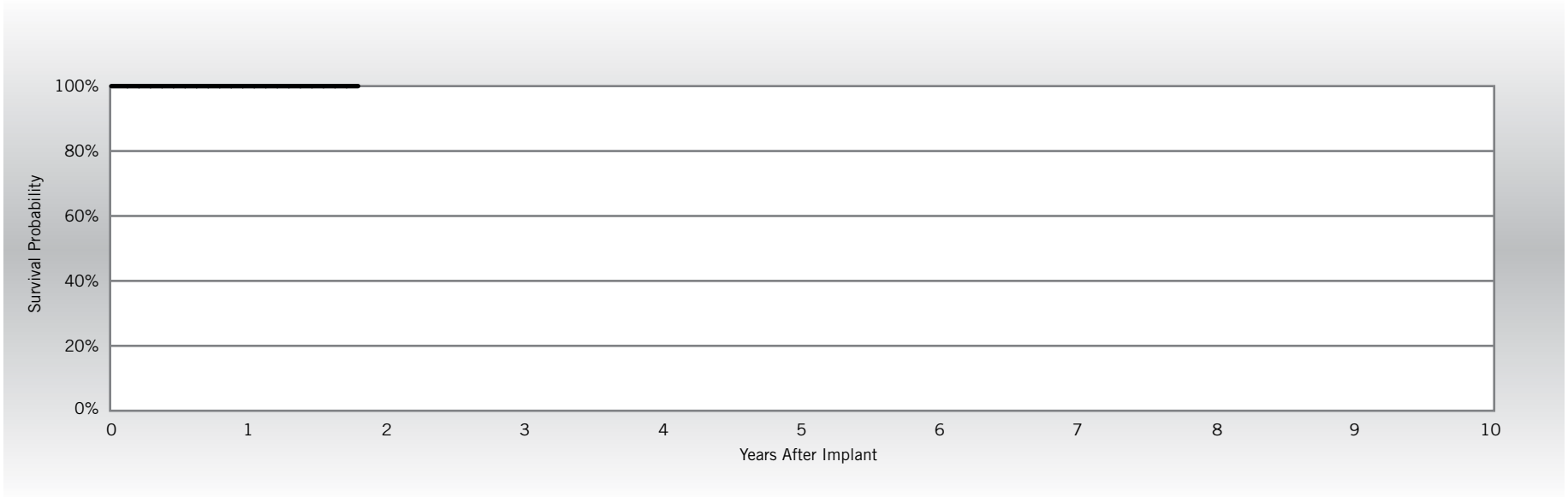
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	110
Cumulative Months of Follow-up	2,040
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	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	100	50								

Customer Reported Performance Data

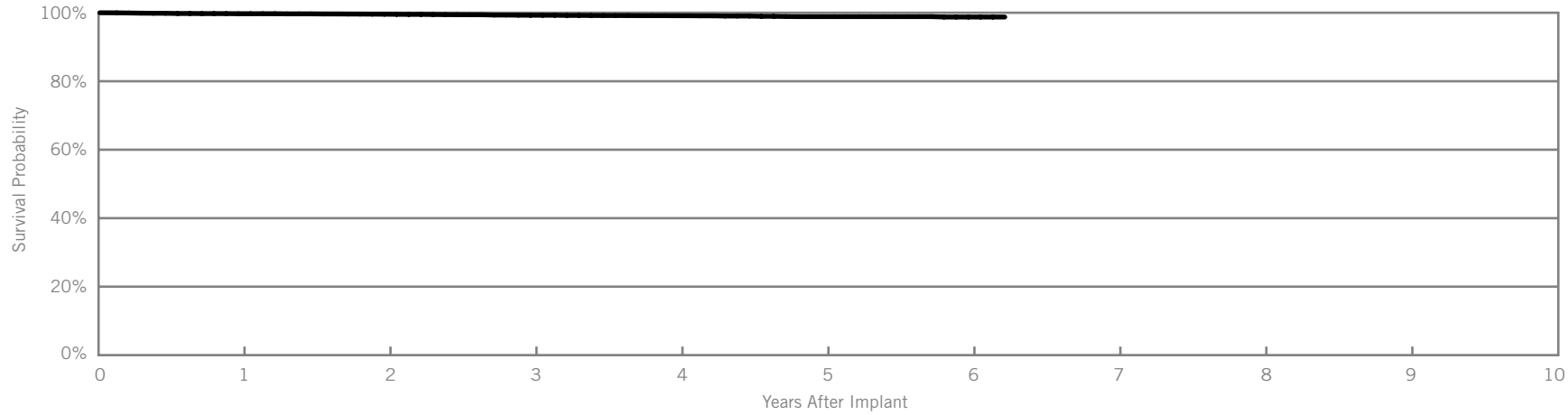
QuickSite®

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	8,759
Estimated Active US Implants	3,665
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.11%	25	0.28%
Failure to Capture	3	0.03%	26	0.30%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.02%
Extracardiac Stimulation	10	0.11%	11	0.13%
Other	2	0.02%	8	0.09%
Total	**25**	**0.28%**	**72**	**0.82%**
Total Returned for Analysis	**13**		**38**	

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



Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.71%	99.57%	99.27%	99.13%	98.87%	98.75%	98.75%			
± 1 standard error	0.06%	0.08%	0.11%	0.12%	0.15%	0.19%	0.19%			
Sample Size	7700	6500	5600	4600	3700	1800	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
1156T	QuickFlex®	99.70%	99.58%								
1158T	QuickFlex® XL	99.67%	99.60%								
1058T	QuickSite® XL	99.83%	99.71%	99.58%							
1056T	QuickSite®	99.63%	99.47%	99.33%	99.17%	99.08%					
1056K	QuickSite®	99.71%	99.57%	99.27%	99.13%	98.87%	98.75%				

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	
1156T	Jul-07	21965	18317	0	0.00%	0	0.00%	10	0.05%	5	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	16	0.07%	8	0.04%	**39**	**0.18%**	**10**
1158T	Jul-07	11683	9703	0	0.00%	0	0.00%	4	0.03%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	5	0.04%	6	0.05%	**18**	**0.15%**	**6**
1058T	Feb-06	10280	6899	0	0.00%	0	0.00%	10	0.10%	3	0.03%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	9	0.09%	2	0.02%	**27**	**0.26%**	**8**
1056T	Apr-05	33976	19977	0	0.00%	0	0.00%	28	0.08%	14	0.04%	1	<0.01%	0	0.00%	1	<0.01%	3	0.01%	22	0.06%	9	0.03%	**78**	**0.23%**	**24**
1056K	Jun-04	8789	3665	0	0.00%	0	0.00%	10	0.11%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	10	0.11%	2	0.02%	**25**	**0.28%**	**13**

Chronic Complication Summary

>30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1156T	Jul-07	21965	18317	0	0.00%	1	<0.00%	23	0.10%	9	0.04%	3	0.01%	0	0.00%	0	0.00%	4	0.02%	14	0.06%	2	0.01%	**56**	**0.25%**	**19**
1158T	Jul-07	11683	9703	0	0.00%	0	0.00%	15	0.13%	3	0.03%	0	0.00%	1	0.01%	0	0.00%	2	0.02%	6	0.05%	1	0.01%	**28**	**0.24%**	**10**
1058T	Feb-06	10280	6899	0	0.00%	1	0.01%	9	0.09%	10	0.10%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	5	0.05%	1	0.01%	**28**	**0.27%**	**8**
1056T	Apr-05	33976	19977	0	0.00%	3	0.01%	72	0.21%	66	0.19%	3	0.01%	1	<0.01%	0	0.00%	3	0.01%	43	0.13%	7	0.02%	**198**	**0.58%**	**79**
1056K	Jun-04	8789	3665	0	0.00%	0	0.00%	25	0.28%	26	0.30%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	11	0.13%	8	0.09%	**72**	**0.82%**	**38**

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

Malfunction Summary

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1156T	Jul-07	21965	18317	1	<0.01%	1	<0.01%	1	<0.01%	3	0.01%	15	0.07%	**21**	**0.10%**
1158T	Jul-07	11683	9703	1	0.01%	0	0.00%	1	0.01%	0	0.00%	8	0.07%	**10**	**0.09%**
1058T	Feb-06	10280	6899	0	0.00%	0	0.00%	0	0.00%	3	0.03%	9	0.09%	**12**	**0.12%**
1056T	Apr-05	33976	19977	1	<0.01%	5	0.01%	1	<0.01%	1	<0.01%	71	0.21%	**79**	**0.23%**
1056K	Jun-04	8789	3665	2	0.02%	0	0.00%	2	0.02%	0	0.00%	25	0.28%	**29**	**0.33%**

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1156T	460	6370	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.22%	**1**	**0.22%**
1158T	360	5050	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.83%	**3**	**0.83%**
1056T	110	2040	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1156T	460	6370	0	0.00%	0	0.00%	1	0.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.22%**
1158T	360	5050	0	0.00%	0	0.00%	0	0.00%	1	0.28%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.28%**
1056T	110	2040	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical
More control. Less risk.

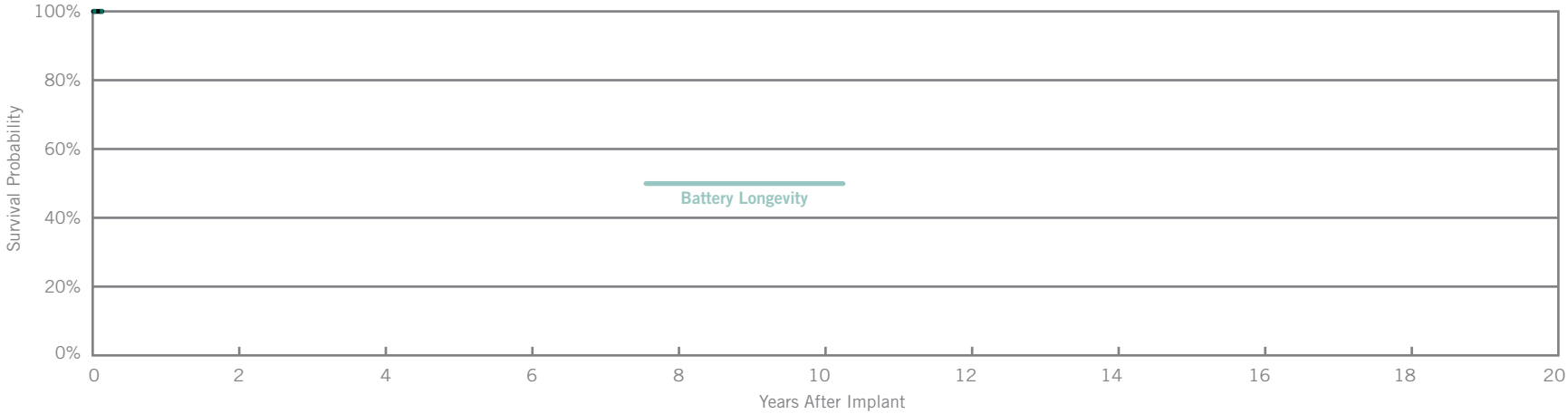
Customer Reported Performance Data

Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	748
Estimated Active US Implants	746
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of Advisories	None

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



Including Normal Battery Depletion

Year	at 1 month									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	700									

Excluding Normal Battery Depletion

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

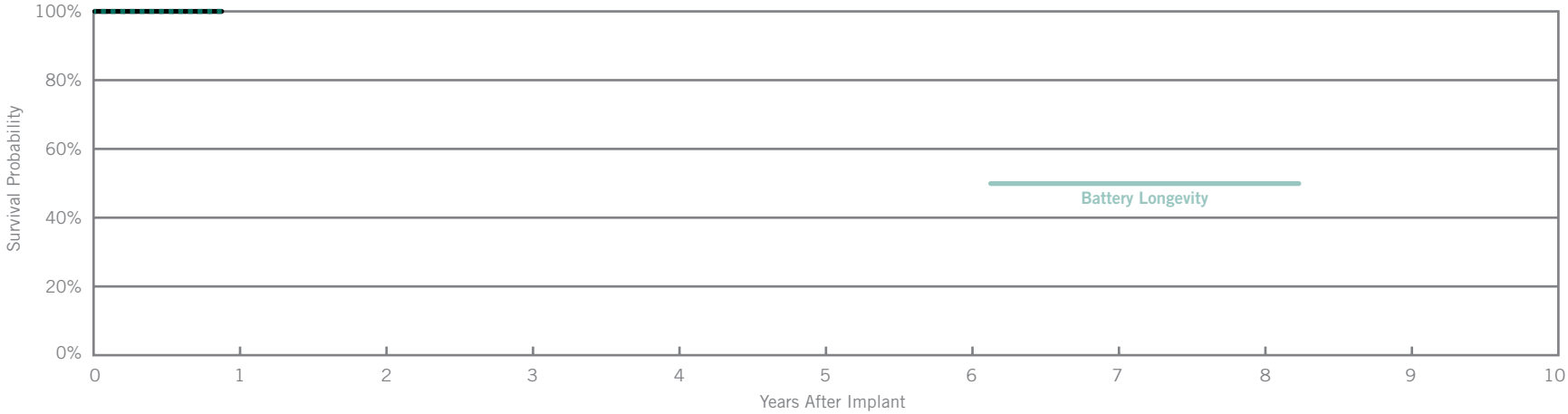
Customer Reported Performance Data

Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	7,786
Estimated Active US Implants	7,481
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	200										

Excluding Normal Battery Depletion ———

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

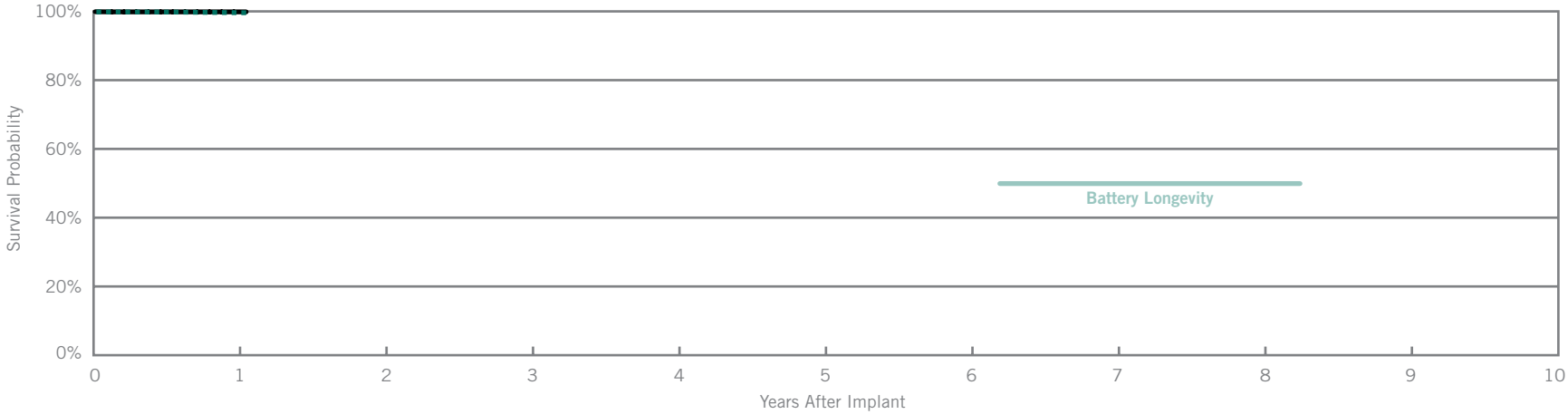
Customer Reported Performance Data

Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	5,190
Estimated Active US Implants	4,901
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.03%
Malfunctions w/o Compromised Therapy	2	0.07%
Total	**3**	**0.10%**



Including Normal Battery Depletion .....

Year	1	at 13 months								
Survival Probability	99.60%	99.60%								
± 1 standard error	0.12%	0.12%								
Sample Size	3000	400								

Excluding Normal Battery Depletion ——

Year	1	at 13 months								
Survival Probability	99.86%	99.86%								
± 1 standard error	0.05%	0.05%								

SCORE Registry Performance Data

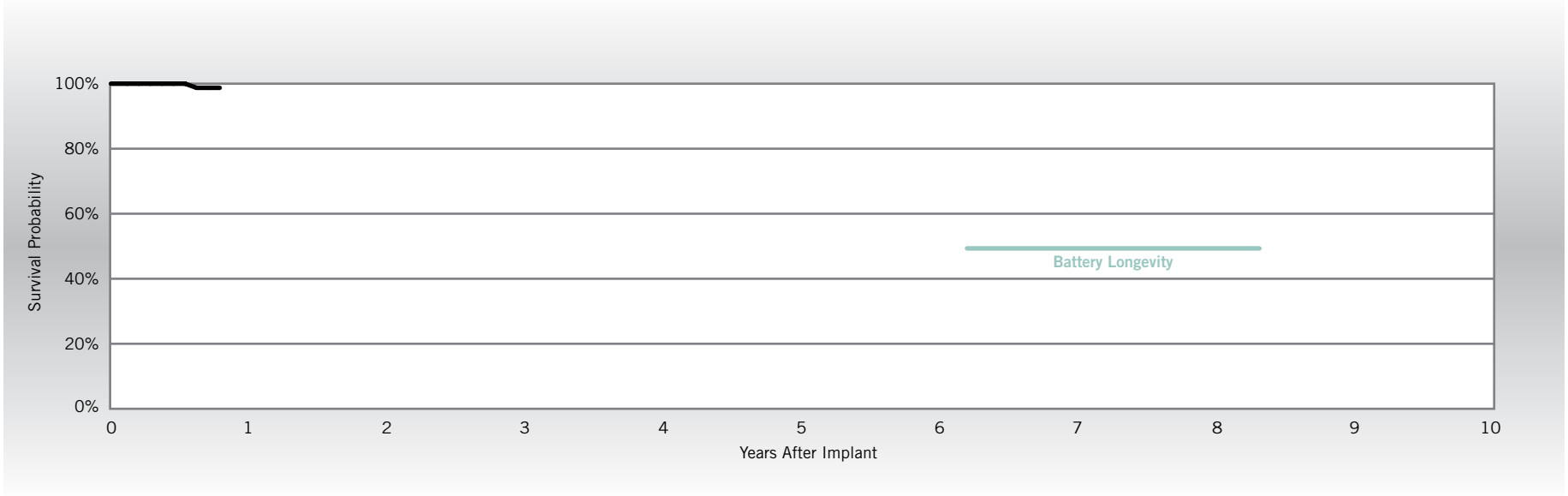
Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	170
Cumulative Months of Follow-up	1,260
Estimated Longevity	(see table on page 74)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Premature Battery Depletion	1	0.59%

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



Year	at 10 months										
Survival Probability	98.73%										
± 1 standard error	1.18%										
Sample Size	60										

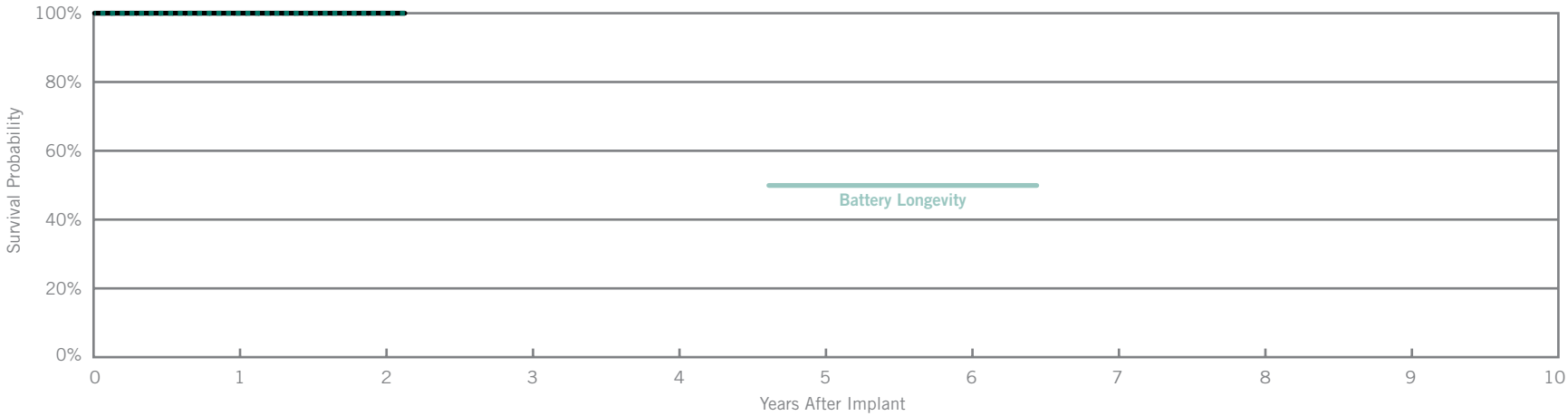
Customer Reported Performance Data

Current® DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,549
Estimated Active US Implants	1,321
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of Advisories	None

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



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	1400	700	200							

Excluding Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

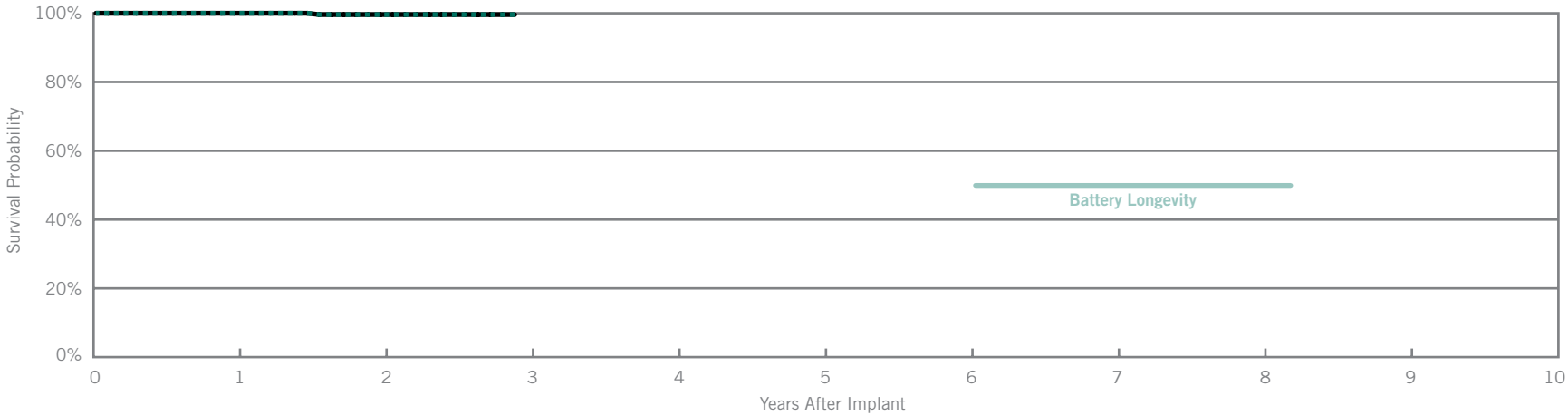
Customer Reported Performance Data

Current® DR

Model 2107-36

US Regulatory Approval	May 2007
Registered US Implants	670
Estimated Active US Implants	504
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	1	0.15%
Total	**1**	**0.15%**



Including Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	100.00%	99.60%	99.60%							
± 1 standard error	0.00%	0.28%	0.28%							
Sample Size	700	500	300							

Excluding Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	100.00%	99.60%	99.60%							
± 1 standard error	0.00%	0.28%	0.28%							

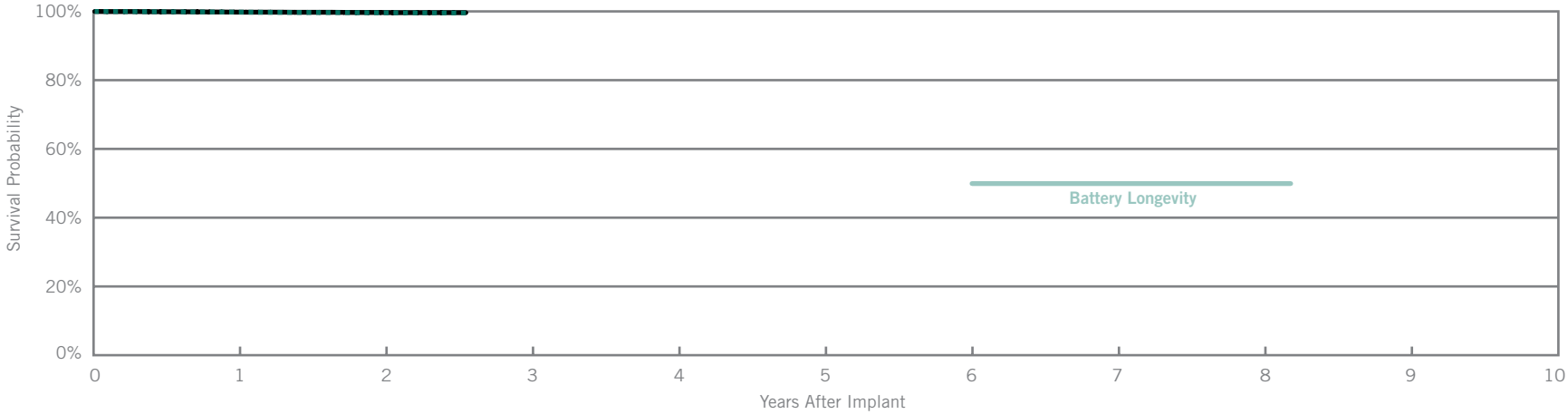
Customer Reported Performance Data

Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,020
Estimated Active US Implants	18,828
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	10	0.05%
Malfunctions w/o Compromised Therapy	13	0.06%
Total	**23**	**0.10%**



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.77%	99.64%	99.53%							
± 1 standard error	0.03%	0.05%	0.08%							
Sample Size	20300	10800	500							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.79%	99.68%	99.63%							
± 1 standard error	0.03%	0.05%	0.06%							

SCORE Registry Performance Data

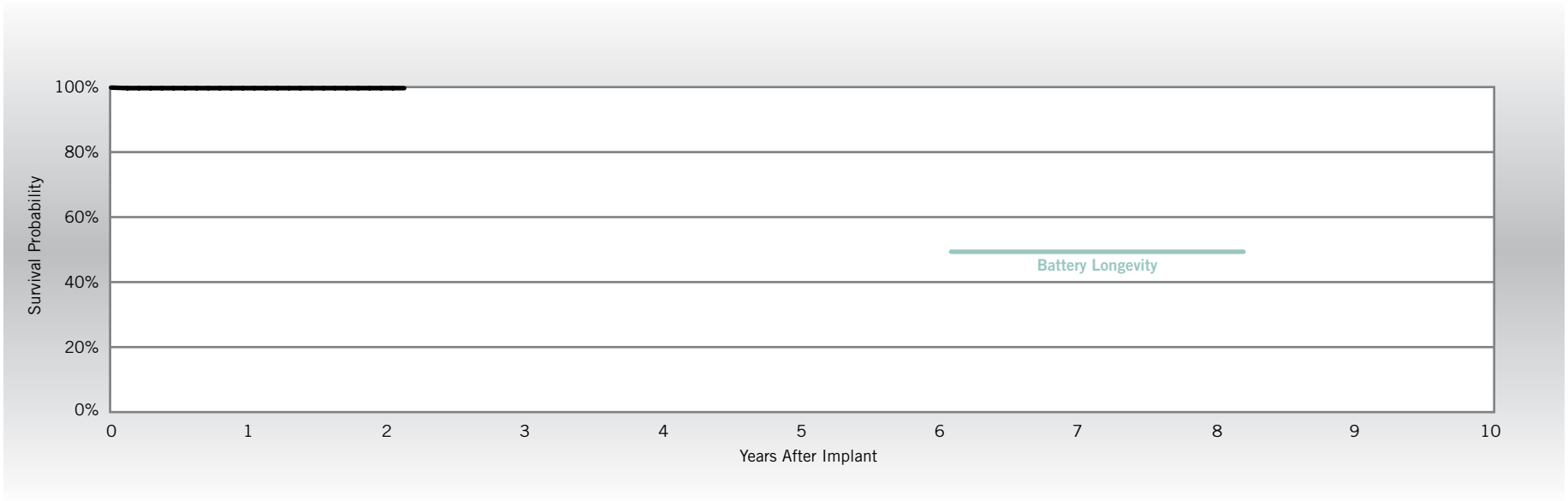
Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	620
Cumulative Months of Follow-up	10,640
Estimated Longevity	(see table on page 74)
Max. Delivered Energy	36 joules

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

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



Year	1	2	at 26 months							
Survival Probability	99.67%	99.67%	99.67%							
± 1 standard error	0.23%	0.23%	0.23%							
Sample Size	560	290	50							

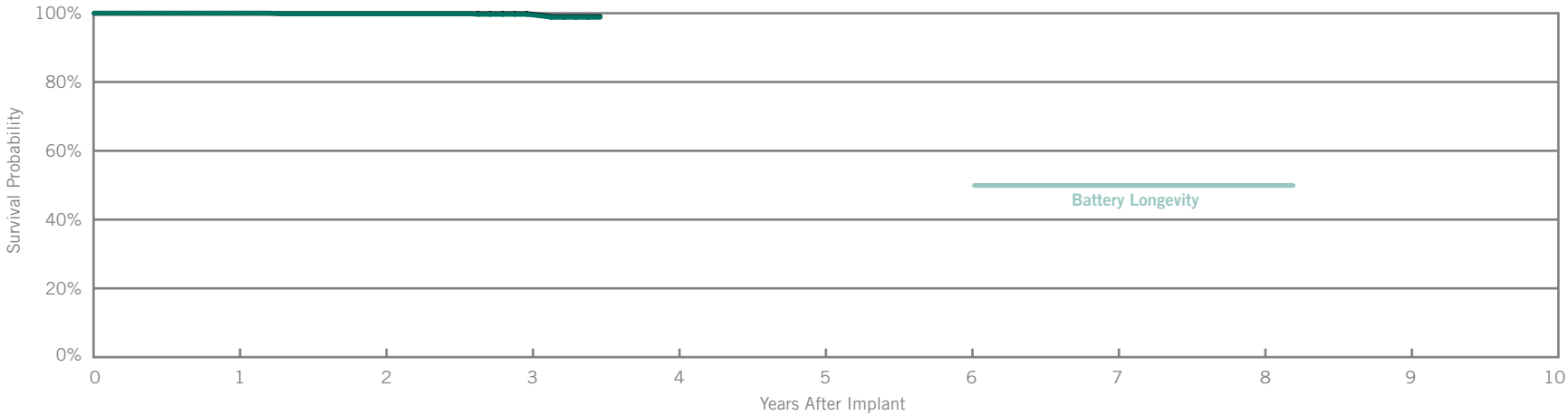
Customer Reported Performance Data

Atlas® II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,879
Estimated Active US Implants	1,366
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	0.11%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	1	0.05%
Total (0 related to Advisory)	**3**	**0.16%**



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	100.00%	99.88%	99.68%	98.83%						
± 1 standard error	0.00%	0.09%	0.17%	0.45%						
Sample Size	1900	1700	1100	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	100.00%	99.88%	99.88%	99.03%						
± 1 standard error	0.00%	0.09%	0.09%	0.43%						

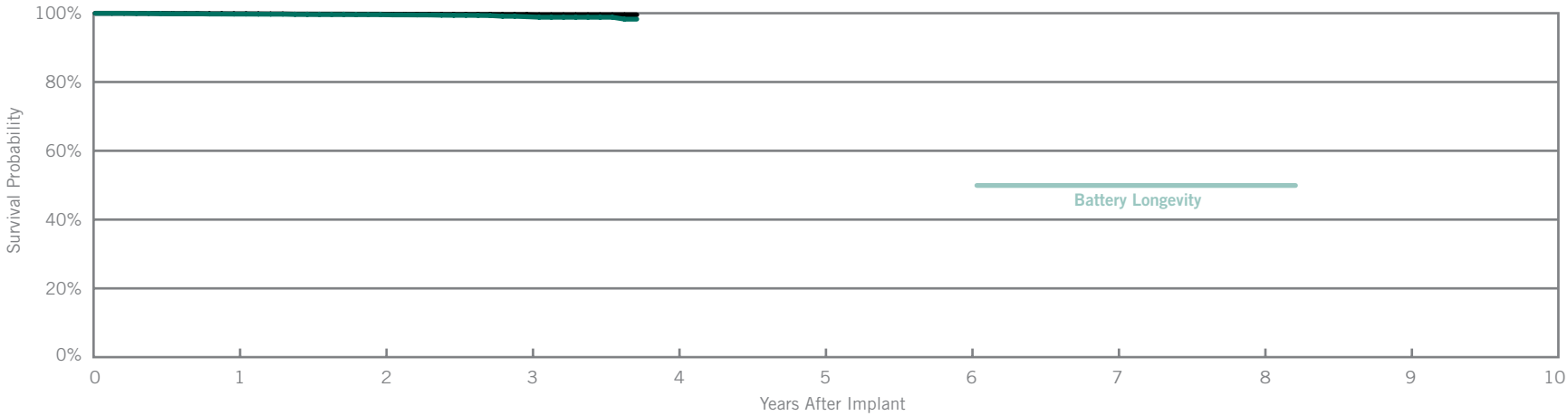
Customer Reported Performance Data

Atlas® II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,702
Estimated Active US Implants	10,984
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	14
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	13	0.09%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	7	0.05%
Total (0 related to Advisory)	**20**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.74%	99.60%	98.98%	98.27%						
± 1 standard error	0.04%	0.06%	0.11%	0.42%						
Sample Size	14500	11400	6700	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	99.84%	99.73%	99.60%	99.54%						
± 1 standard error	0.03%	0.05%	0.06%	0.08%						

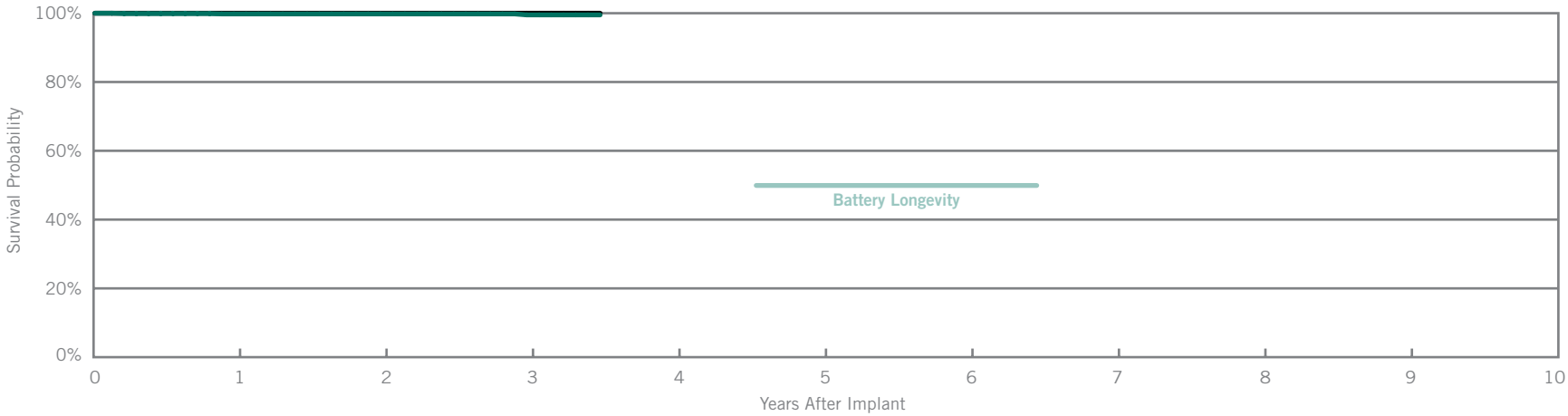
Customer Reported Performance Data

Epic® II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,087
Estimated Active US Implants	1,479
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	2
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	One

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



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.79%	99.79%	99.51%	99.51%						
± 1 standard error	0.11%	0.11%	0.11%	0.23%						
Sample Size	2000	1600	1100	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						

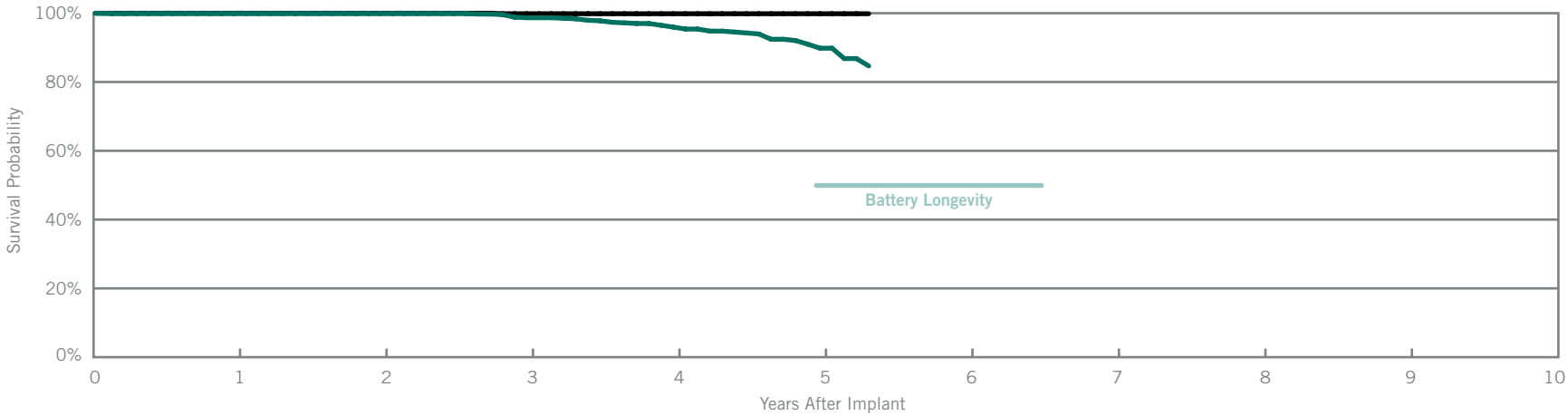
Customer Reported Performance Data

Epic® DR

Model V-233

US Regulatory Approval	October 2003
Registered US Implants	1,828
Estimated Active US Implants	791
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	48
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	Two

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.89%	99.89%	98.68%	95.95%	89.83%	84.66%				
± 1 standard error	0.08%	0.08%	0.29%	0.53%	1.02%	1.44%				
Sample Size	1800	1600	1500	1200	700	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	100.00%	99.85%	99.85%	99.85%	99.85%				
± 1 standard error	0.00%	0.00%	0.11%	0.11%	0.11%	0.11%				

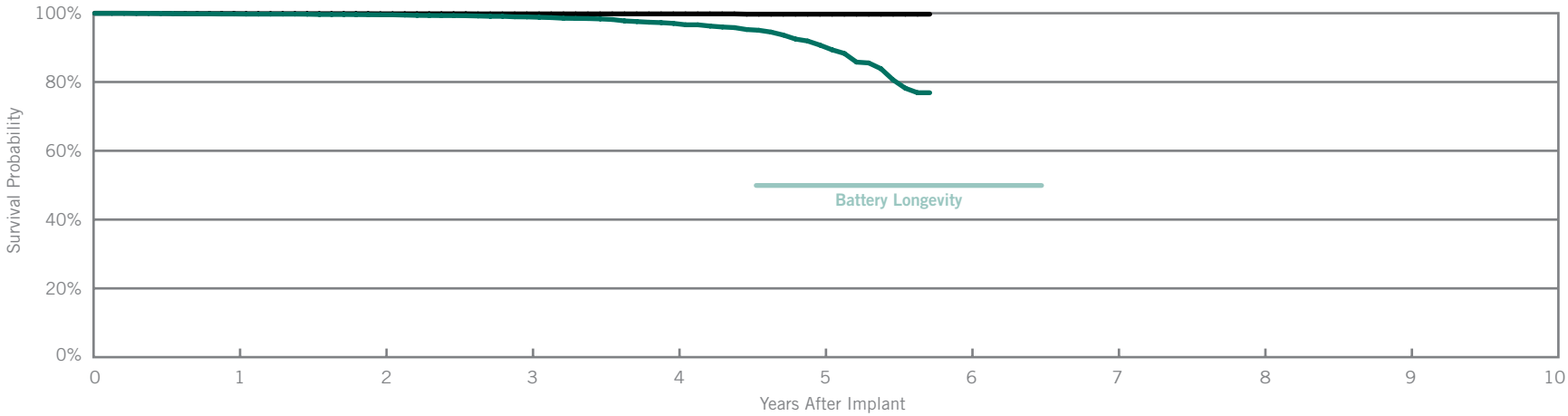
Customer Reported Performance Data

Epic® + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,839
Estimated Active US Implants	3,711
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	155
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	Two

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.77%	99.54%	98.92%	97.04%	90.73%	76.88%				
± 1 standard error	0.06%	0.08%	0.13%	0.23%	0.52%	1.44%				
Sample Size	7800	6900	6200	4800	2800	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.89%	99.83%	99.80%	99.80%	99.72%	99.72%				
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.08%	0.08%				

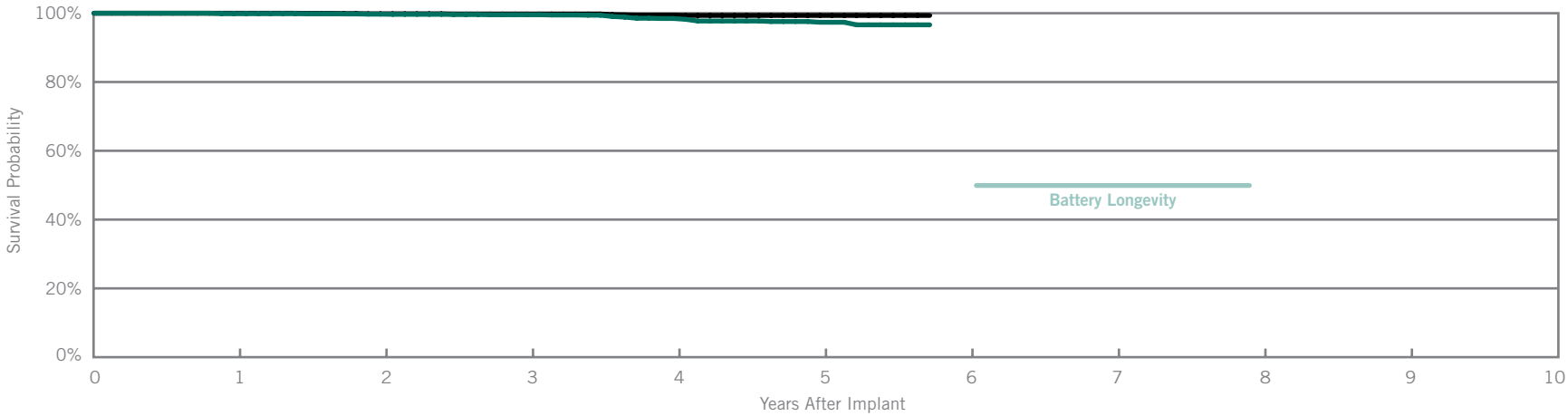
Customer Reported Performance Data

Atlas® DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,646
Estimated Active US Implants	2,552
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	21
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	Three

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.88%	99.72%	99.55%	98.46%	97.37%	96.62%				
± 1 standard error	0.05%	0.08%	0.11%	0.23%	0.31%	0.48%				
Sample Size	4600	4100	3600	2900	1600	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	100.00%	99.84%	99.78%	99.44%	99.35%	99.35%				
± 1 standard error	0.00%	0.06%	0.08%	0.14%	0.15%	0.15%				

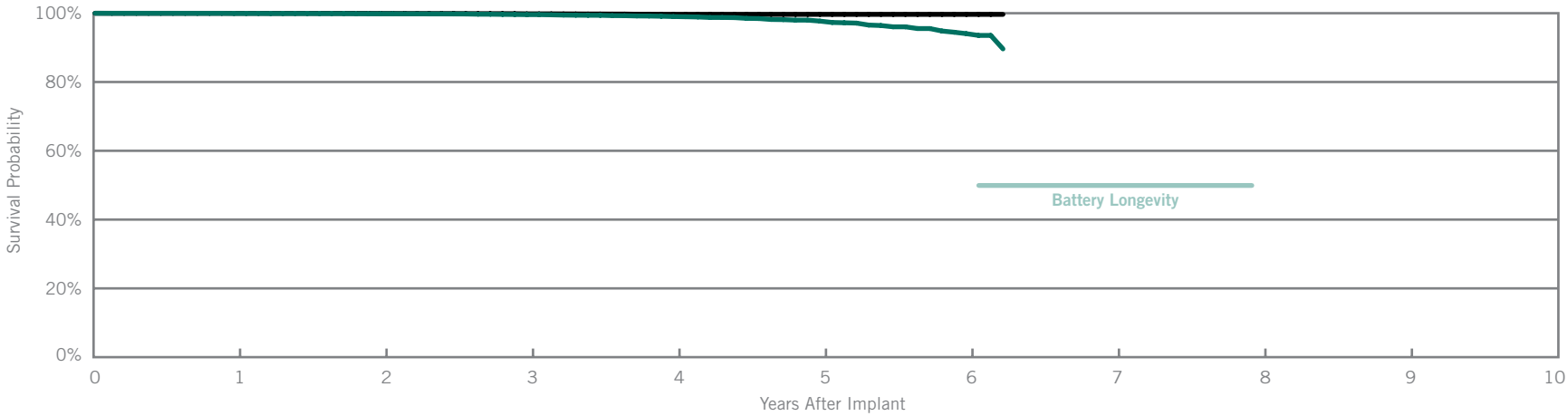
Customer Reported Performance Data

Atlas® + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	20,958
Estimated Active US Implants	11,798
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	77
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	Three

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	16	0.08%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	6	0.03%
Total (0 related to Advisory)	**22**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.94%	99.84%	99.59%	99.03%	97.71%	94.05%	89.62%			
± 1 standard error	0.01%	0.03%	0.05%	0.08%	0.17%	0.58%	0.74%			
Sample Size	21000	18400	15800	11600	5900	1700	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.97%	99.92%	99.82%	99.66%	99.66%	99.66%	99.66%			
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.05%	0.05%	0.05%			

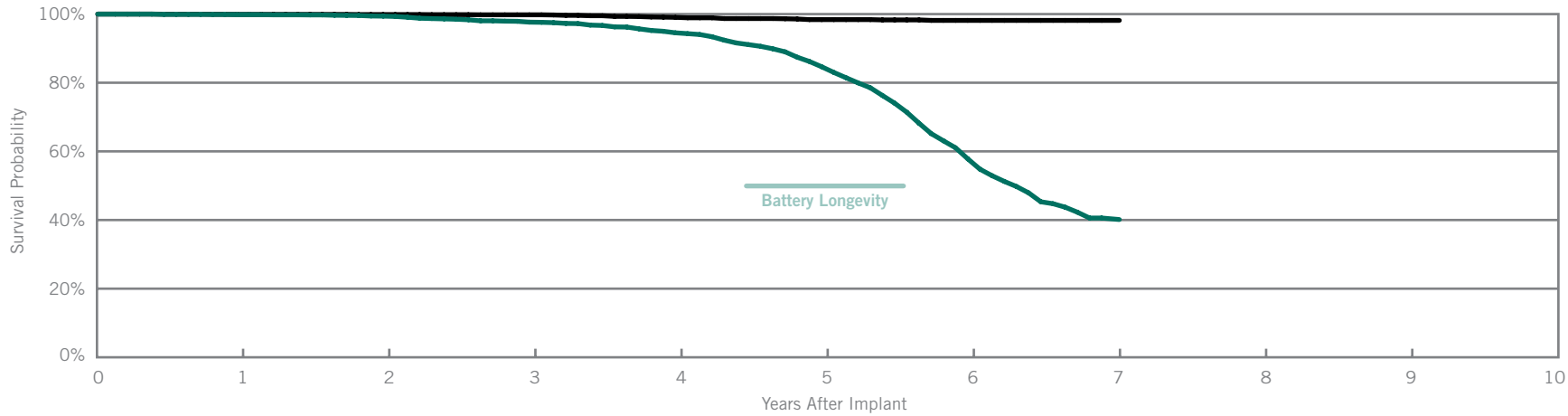
Customer Reported Performance Data

Epic® DR

Model V-235

US Regulatory Approval	July 2002
Registered US Implants	6,601
Estimated Active US Implants	604
Estimated Longevity	(see table on page 74)
Normal Battery Depletion	518
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	Two

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	4	0.06%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	26	0.39%
Total (0 related to Advisory)	**30**	**0.45%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.85%	99.40%	97.65%	94.54%	84.66%	57.83%	40.14%			
± 1 standard error	0.04%	0.10%	0.20%	0.32%	0.56%	0.96%	1.33%			
Sample Size	6600	5900	5300	4600	3800	2600	800			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7			
Survival Probability	99.90%	99.86%	99.79%	99.05%	98.39%	98.16%	98.16%			
± 1 standard error	0.03%	0.05%	0.06%	0.14%	0.20%	0.23%	0.23%			

Battery Longevity Summary

Dual-Chamber ICDs

St. Jude Medical™
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD2231-40Q	Fortify® DR**	10.2	9.4	8.7	7.6
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
2107-36	Current® DR	8.2	7.5	7.0	6.1
2207-36	Current® DR RF	8.2	7.5	7.0	6.1
V-265	Atlas® II DR	8.2	7.5	7.0	6.1
V-268	Atlas® II + DR	8.2	7.5	7.0	6.1
V-258	Epic® II + DR	6.5	5.9	5.4	4.6
V-233	Epic® DR	6.4	6.0	5.6	4.9
V-239	Epic® + DR	6.4	6.0	5.6	4.5
V-242	Atlas® DR	7.9	7.3	6.9	6.1
V-243	Atlas® + DR	7.9	7.3	6.9	6.1
V-235	Epic® DR	5.6	5.3	4.9	4.4

**Battery longevity calculated with one EGM storage.*
Pacing parameters: DDD, 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 batteries mid-life voltage range.
(Four maximum charges per year for model V-240).
***Three maximum charges per year.*

Summary Information

Dual-Chamber ICDs

St. Jude Medical
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR*										
CD2211-36Q	Current® + DR*										
CD2211-36	Current® + DR	99.60%									
2207-30	Current® DR RF	100.00%	100.00%								
2107-36	Current® DR	100.00%	99.60%								
2207-36	Current® DR RF	99.77%	99.64%								
V-265	Atlas® II DR	100.00%	99.88%	99.68%							
V-268	Atlas® II + DR	99.74%	99.60%	98.98%							
V-258	Epic® II + DR	99.79%	99.79%	99.51%							
V-233	Epic® DR	99.89%	99.89%	98.68%	95.95%	89.83%					
V-239	Epic® + DR	99.77%	99.54%	98.92%	97.04%	90.73%					
V-242	Atlas® DR	99.88%	99.72%	99.55%	98.46%	97.37%					
V-243	Atlas® + DR	99.94%	99.84%	99.59%	99.03%	97.71%	94.05%				
V-235	Epic® DR	99.85%	99.40%	97.65%	94.54%	84.66%	57.83%	40.14%			

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR*										
CD2211-36Q	Current® + DR*										
CD2211-36	Current® + DR	99.86%									
2207-30	Current® DR RF	100.00%	100.00%								
2107-36	Current® DR	100.00%	99.60%								
2207-36	Current® DR RF	99.79%	99.68%								
V-265	Atlas® II DR	100.00%	99.88%	99.88%							
V-268	Atlas® II + DR	99.84%	99.73%	99.60%							
V-258	Epic® II + DR	100.00%	100.00%	100.00%							
V-233	Epic® DR	100.00%	100.00%	99.85%	99.85%	99.85%					
V-239	Epic® + DR	99.89%	99.83%	99.80%	99.80%	99.72%					
V-242	Atlas® DR	100.00%	99.84%	99.78%	99.44%	99.35%					
V-243	Atlas® + DR	99.97%	99.92%	99.82%	99.66%	99.66%	99.66%				
V-235	Epic® DR	99.90%	99.86%	99.79%	99.05%	98.39%	98.16%	98.16%			

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	May 10	748	746	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2211-36Q	Current® + DR	Feb-09	7786	7481	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
CD2211-36	Current® + DR	Feb-09	5190	4901	1	0.03%	1	0.03%	0	0.00%	2	0.07%	3	0.10%
2207-30	Current® DR RF	Sep-07	1549	1321	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
2107-36	Current® DR	May-07	670	504	0	0.00%	0	0.00%	0	0.00%	1	0.15%	1	0.15%
2207-36	Current® DR RF	Sep-07	22020	18828	7	0.03%	10	0.05%	5	0.02%	13	0.06%	23	0.10%
V-265	Atlas® II DR	Jul-06	1879	1366	2	0.11%	2	0.11%	1	0.05%	1	0.05%	3	0.16%
V-268	Atlas® II + DR	Jul-06	14702	10984	9	0.06%	13	0.09%	6	0.04%	7	0.05%	20	0.14%
V-258	Epic® II + DR	Mar-06	2087	1479	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
V-233	Epic® DR	Oct-03	1828	791	0	0.00%	0	0.00%	0	0.00%	1	0.05%	1	0.05%
V-239	Epic® + DR	Oct-03	7839	3711	0	0.00%	5	0.06%	0	0.00%	3	0.04%	8	0.10%
V-242	Atlas® DR	Oct-03	4646	2552	5	0.11%	8	0.17%	0	0.00%	1	0.02%	9	0.19%
V-243	Atlas® + DR	Oct-03	20958	11798	14	0.07%	16	0.08%	3	0.01%	6	0.03%	22	0.10%
V-235	Epic® DR	Jul-02	6601	604	2	0.03%	4	0.06%	3	0.05%	26	0.39%	30	0.45%

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2211-36	170	1260	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
2207-36	620	10640	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Premature Battery Depletion		Failure to Sense		Inappropriate Shock		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2211-36	170	1260	1	0.59%	0	0.00%	0	0.00%	1	0.59%
2207-36	620	10640	0	0.00%	1	0.16%	1	0.16%	2	0.32%

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

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

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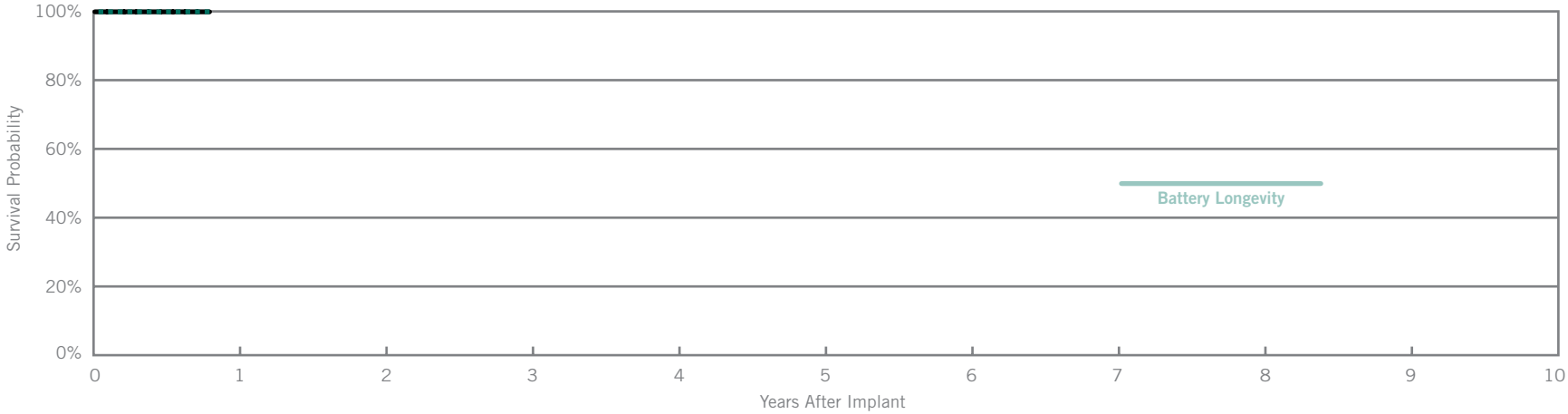
Customer Reported Performance Data

Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	3,982
Estimated Active US Implants	3,831
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	2	0.05%
Total	**2**	**0.05%**



Including Normal Battery Depletion .....

Year	at 10 months										
Survival Probability	99.87%										
± 1 standard error	0.06%										
Sample Size	200										

Excluding Normal Battery Depletion ———

Year	at 10 months										
Survival Probability	99.87%										
± 1 standard error	0.06%										

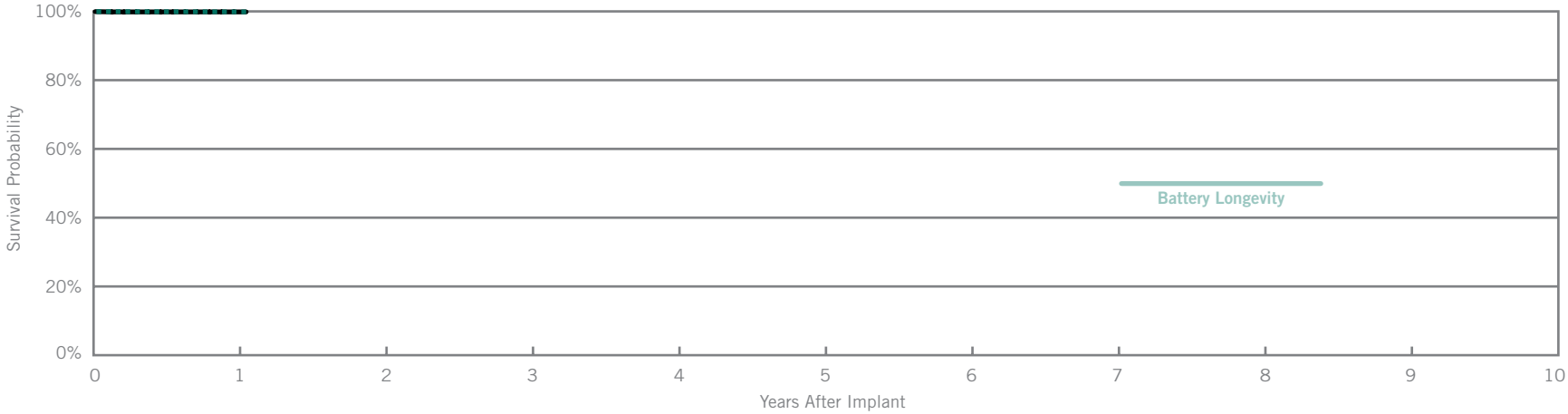
Customer Reported Performance Data

Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	2,894
Estimated Active US Implants	2,734
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	0
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	2	0.07%
Malfunctions w/o Compromised Therapy	0	0.00%
Total	**2**	**0.07%**



Including Normal Battery Depletion .....

Year	1	at 13 months								
Survival Probability	99.85%	99.85%								
± 1 standard error	0.07%	0.07%								
Sample Size	1700	200								

Excluding Normal Battery Depletion ——

Year	1	at 13 months								
Survival Probability	99.85%	99.85%								
± 1 standard error	0.07%	0.07%								

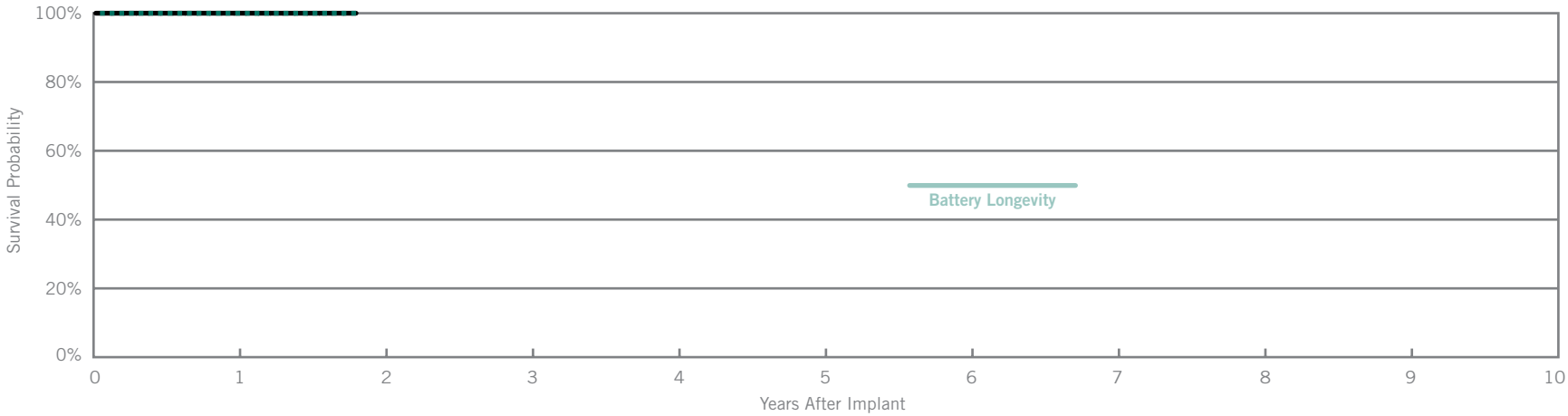
Customer Reported Performance Data

Current® VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	849
Estimated Active US Implants	754
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	700	200								

Excluding Normal Battery Depletion ——

Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

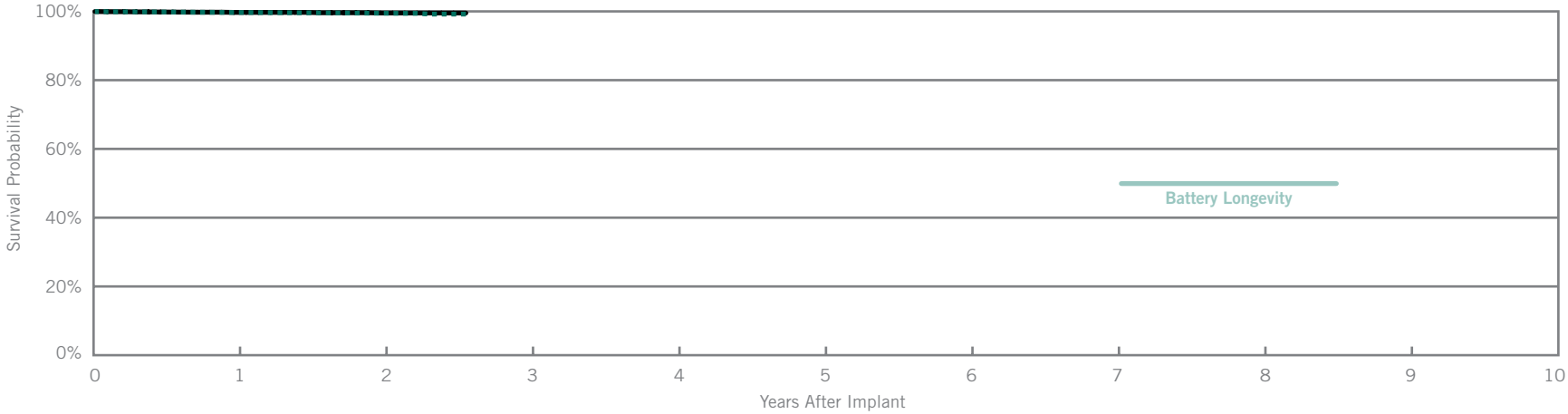
Customer Reported Performance Data

Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	12,917
Estimated Active US Implants	11,087
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	10	0.08%
Malfunctions w/o Compromised Therapy	7	0.05%
Total	**17**	**0.13%**



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.66%	99.44%	99.22%							
± 1 standard error	0.05%	0.08%	0.18%							
Sample Size	11800	6000	200							

Excluding Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.71%	99.53%	99.53%							
± 1 standard error	0.04%	0.07%	0.09%							

SCORE Registry Performance Data

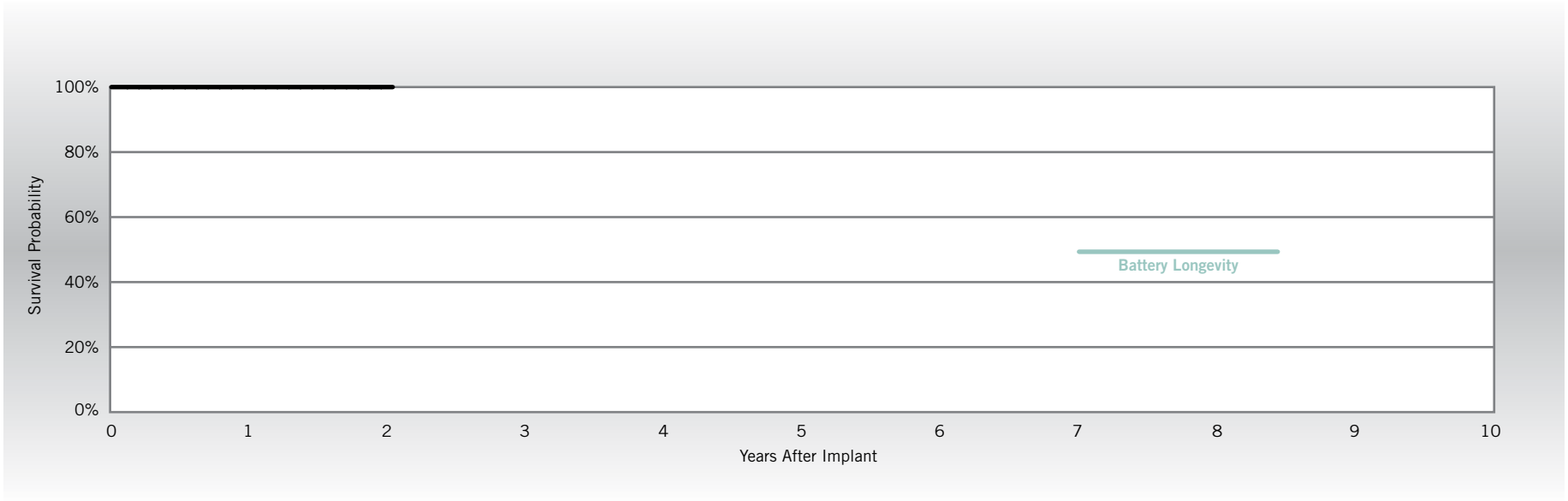
Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	390
Cumulative Months of Follow-up	6,890
Estimated Longevity	(see table on page 93)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	2	at 25 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	360	200	50							

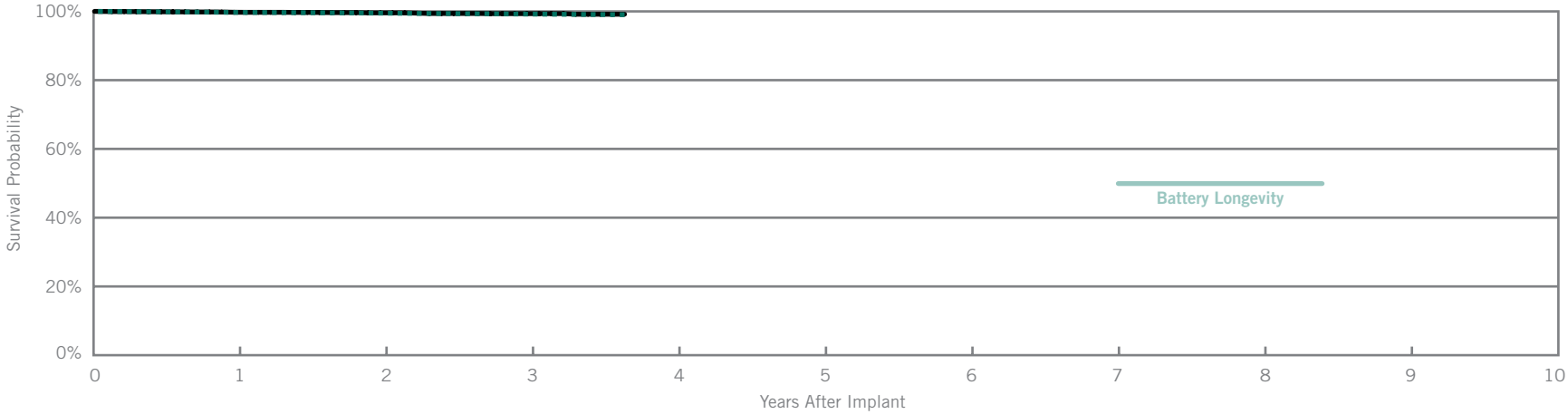
Customer Reported Performance Data

Atlas® II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,446
Estimated Active US Implants	7,925
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	5
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	17	0.16%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	6	0.06%
Total (0 related to Advisory)	**23**	**0.22%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.72%	99.48%	99.21%	99.04%						
± 1 standard error	0.05%	0.08%	0.11%	0.16%						
Sample Size	10300	8200	4800	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.75%	99.58%	99.35%	99.17%						
± 1 standard error	0.04%	0.07%	0.10%	0.16%						

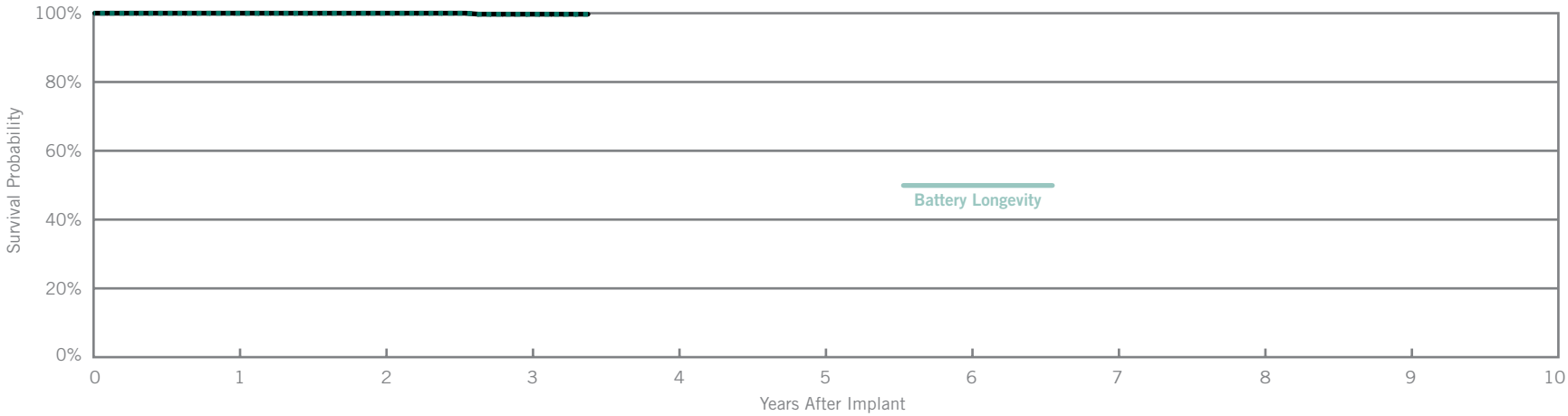
Customer Reported Performance Data

Epic® II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,565
Estimated Active US Implants	1,121
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	One

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



Including Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	100.00%	100.00%	99.72%	99.72%						
± 1 standard error	0.00%	0.00%	0.20%	0.20%						
Sample Size	1500	1200	800	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 41 months						
Survival Probability	100.00%	100.00%	99.72%	99.72%						
± 1 standard error	0.00%	0.00%	0.20%	0.20%						

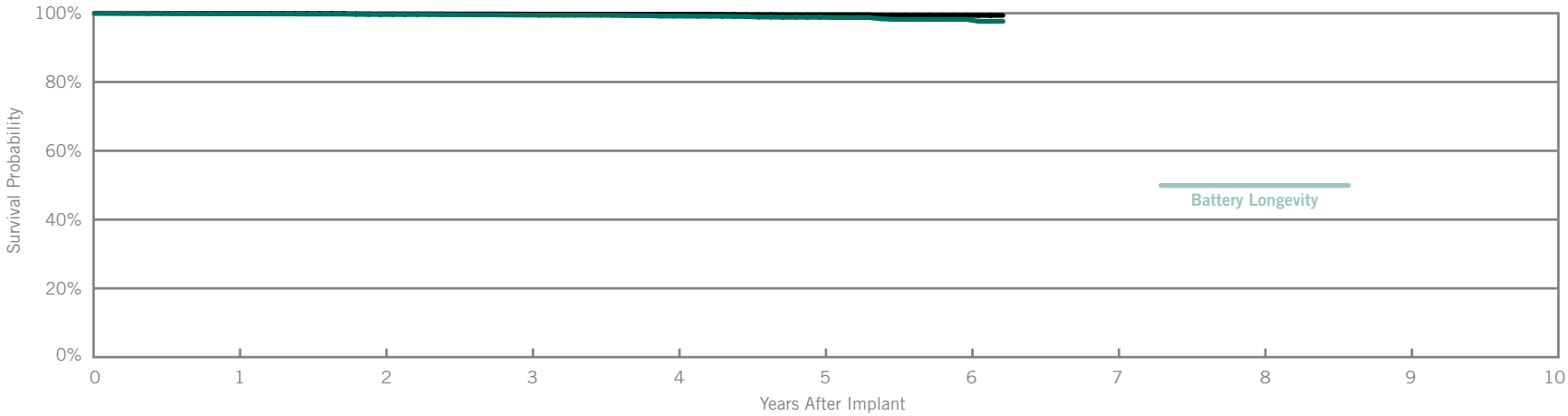
Customer Reported Performance Data

Atlas® + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,481
Estimated Active US Implants	11,930
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	31
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	Three

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	20	0.10%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	9	0.04%
Total (0 related to Advisory)	**29**	**0.14%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.85%	99.61%	99.46%	99.16%	98.83%	98.22%	97.65%			
± 1 standard error	0.03%	0.05%	0.06%	0.08%	0.11%	0.24%	0.47%			
Sample Size	20500	18000	15400	11400	6000	1700	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.95%	99.81%	99.74%	99.66%	99.52%	99.37%	99.37%			
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.07%	0.13%	0.13%			

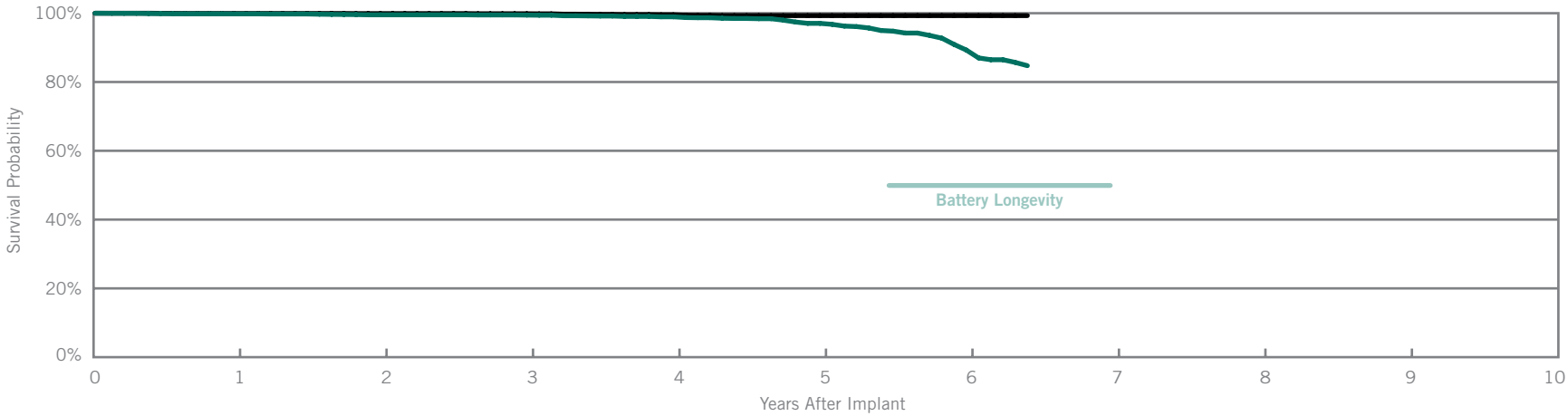
Customer Reported Performance Data

Epic® + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,954
Estimated Active US Implants	3,803
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	60
Max. Delivered Energy	30 joules
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	5	0.06%
Malfunctions w/o Compromised Therapy	11	0.14%
Total	**16**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.80%	99.53%	99.45%	98.95%	97.05%	89.28%	84.74%			
± 1 standard error	0.05%	0.08%	0.09%	0.14%	0.31%	0.92%	1.40%			
Sample Size	8000	7000	6300	5100	3100	1300	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.92%	99.89%	99.85%	99.55%	99.30%	99.30%	99.30%			
± 1 standard error	0.03%	0.04%	0.05%	0.09%	0.12%	0.12%	0.12%			

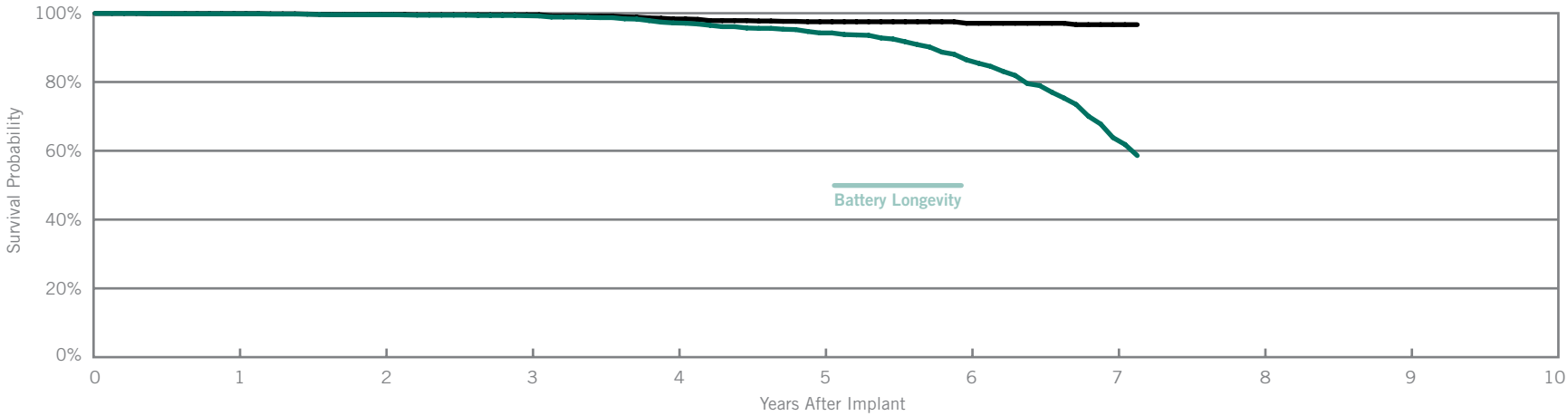
Customer Reported Performance Data

Epic® VR

Model V-197

US Regulatory Approval	July 2002
Registered US Implants	3,658
Estimated Active US Implants	634
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	142
Max. Delivered Energy	30 joules
Number of Advisories (see pages 220-227)	Two

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	7	0.19%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	22	0.60%
Total (0 related to Advisory)	**29**	**0.79%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.83%	99.57%	99.27%	97.18%	94.26%	86.45%	63.87%	58.61%		
± 1 standard error	0.07%	0.12%	0.15%	0.32%	0.48%	0.78%	1.58%	1.83%		
Sample Size	3700	3200	2900	2600	2100	1700	1100	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.89%	99.63%	99.56%	98.32%	97.52%	97.07%	96.67%	96.67%		
± 1 standard error	0.06%	0.11%	0.12%	0.24%	0.32%	0.32%	0.47%	0.47%		

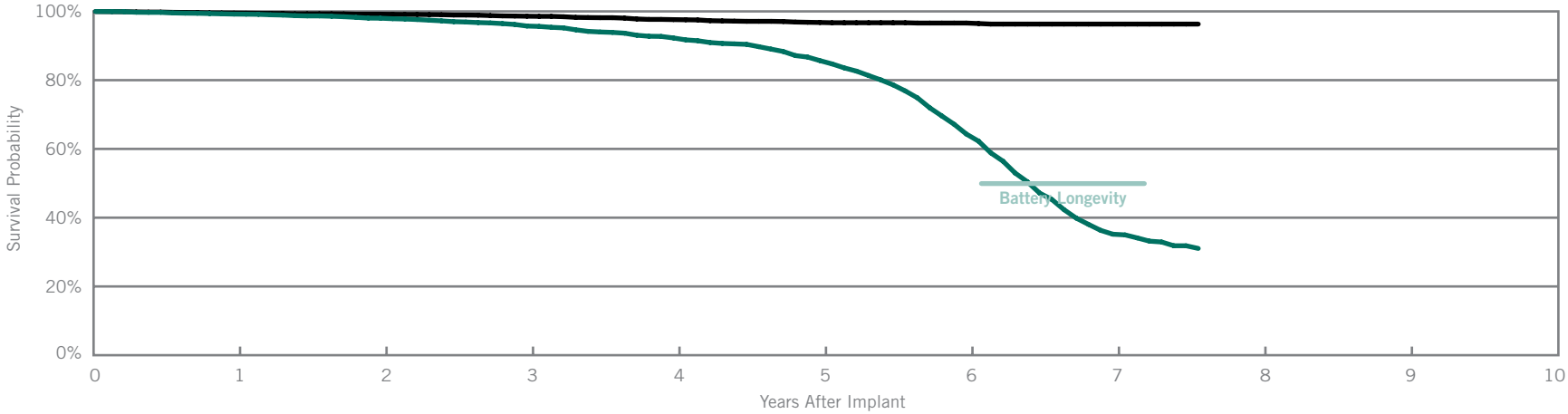
Customer Reported Performance Data

Atlas® VR

Model V-199

US Regulatory Approval	December 2001
Registered US Implants	7,101
Estimated Active US Implants	620
Estimated Longevity	(see table on page 93)
Normal Battery Depletion	566
Max. Delivered Energy	36 joules
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (22 related to Advisory)	34	0.48%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	36	0.51%
Total (22 related to Advisory)	**70**	**0.99%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.21%	98.02%	95.74%	92.27%	85.68%	64.32%	35.19%	31.05%		
± 1 standard error	0.10%	0.18%	0.26%	0.37%	0.52%	0.85%	1.15%	1.21%		
Sample Size	7100	6200	5400	4500	3700	2900	1400	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	99.53%	99.19%	98.60%	97.61%	96.77%	96.61%	96.31%	96.31%		
± 1 standard error	0.08%	0.11%	0.15%	0.22%	0.26%	0.28%	0.32%	0.32%		

Battery Longevity Summary

Single-Chamber ICDs

St. Jude Medical™
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Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
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
V-197	Epic® VR	5.9	5.7	5.5	5.1
V-199	Atlas® VR	7.2	6.9	6.6	6.1

**Battery longevity calculated with one EGM storage.*
Pacing parameters: VVI, 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 batteries mid-life voltage range.
(Four maximum charges per year for models V-194 and V-199).

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
CD1211-36Q	Current® + VR*										
CD1211-36	Current® + VR	99.85%									
1207-30	Current® VR RF	100.00%									
1207-36	Current® VR RF	99.66%	99.44%								
V-168	Atlas® II VR	99.72%	99.48%	99.21%							
V-158	Epic® II VR	100.00%	100.00%	99.72%							
V-193	Atlas® + VR	99.85%	99.61%	99.46%	99.16%	98.83%	98.22%				
V-196	Epic® + VR	99.80%	99.53%	99.45%	98.95%	97.05%	89.28%				
V-197	Epic® VR	99.83%	99.57%	99.27%	97.18%	94.26%	86.45%	63.87%			
V-199	Atlas® VR	99.21%	98.02%	95.74%	92.27%	85.68%	64.32%	35.19%			

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1211-36Q	Current® + VR*										
CD1211-36	Current® + VR	99.85%									
1207-30	Current® VR RF	100.00%									
1207-36	Current® VR RF	99.71%	99.53%								
V-168	Atlas® II VR	99.75%	99.58%	99.35%							
V-158	Epic® II VR	100.00%	100.00%	99.72%							
V-193	Atlas® + VR	99.95%	99.81%	99.74%	99.66%	99.52%	99.37%				
V-196	Epic® + VR	99.92%	99.89%	99.85%	99.55%	99.30%	99.30%				
V-197	Epic® VR	99.89%	99.63%	99.56%	98.32%	97.52%	97.07%	96.67%			
V-199	Atlas® VR	99.53%	99.19%	98.60%	97.61%	96.77%	96.61%	96.31%			

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1211-36Q	Current + VR	Feb-09	3982	3831	0	0.00%	0	0.00%	0	0.00%	2	0.05%	2	0.05%
CD1211-36	Current + VR	Feb-09	2894	2734	2	0.07%	2	0.07%	0	0.00%	0	0.00%	2	0.07%
1207-30	Current VR RF	Sep-07	849	754	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
1207-36	Current VR RF	Sep-07	12917	11087	4	0.03%	10	0.08%	3	0.02%	7	0.05%	17	0.13%
V-168	Atlas II VR	Jul-06	10446	7925	11	0.11%	17	0.16%	4	0.04%	6	0.06%	23	0.22%
V-158	Epic II VR	Mar-06	1565	1121	0	0.00%	0	0.00%	1	0.06%	1	0.06%	1	0.06%
V-193	Atlas + VR	Oct-03	20481	11930	10	0.05%	20	0.10%	7	0.03%	9	0.04%	29	0.14%
V-196	Epic + VR	Apr-03	7954	3803	2	0.03%	5	0.06%	0	0.00%	11	0.14%	16	0.20%
V-197	Epic VR	Jul-02	3658	634	3	0.08%	7	0.19%	2	0.05%	22	0.60%	29	0.79%
V-199	Atlas VR	Dec-01	7101	620	6	0.08%	34	0.48%	3	0.04%	36	0.51%	70	0.99%

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

Defibrillation Leads

St. Jude Medical
More control. Less risk.

Customer Reported Performance Data

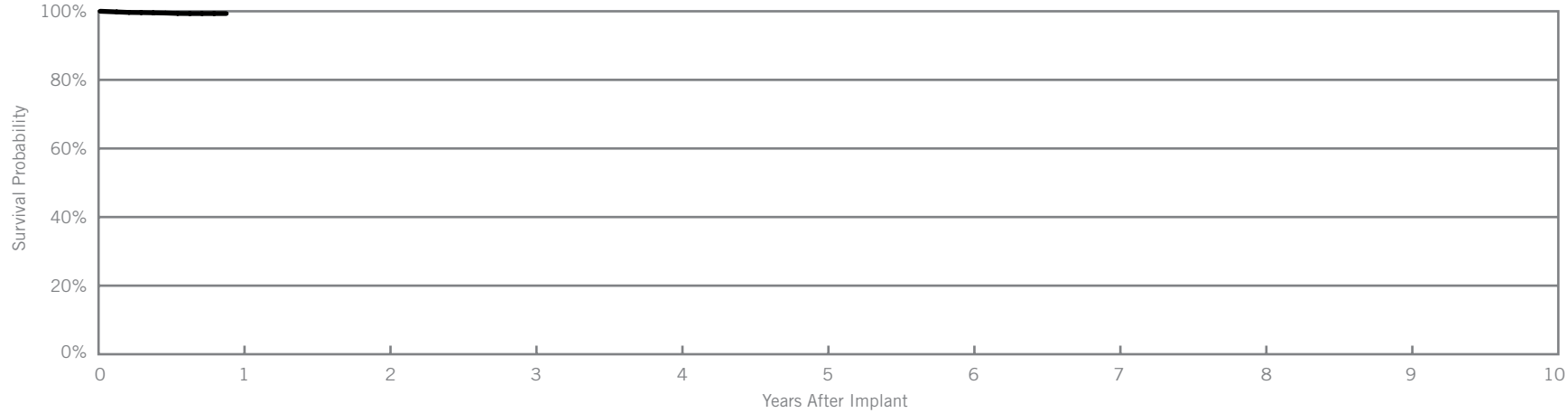
Durata® SJ4/DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	17,910
Estimated Active US Implants	17,202
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	10	0.06%	4	0.02%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	30	0.17%	25	0.14%
Failure to Capture	14	0.08%	12	0.07%
Oversensing	12	0.07%	5	0.03%
Failure to Sense	2	0.01%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.01%	0	0.00%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.01%	0	0.00%
Total	**71**	**0.40%**	**49**	**0.27%**
Total Returned for Analysis	**25**		**30**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	1	0.01%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	32	0.18%
Total	**34**	**0.19%**



Year	at 11 months										
Survival Probability	99.34%										
± 1 standard error	0.09%										
Sample Size	700										

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

SCORE Registry Performance Data

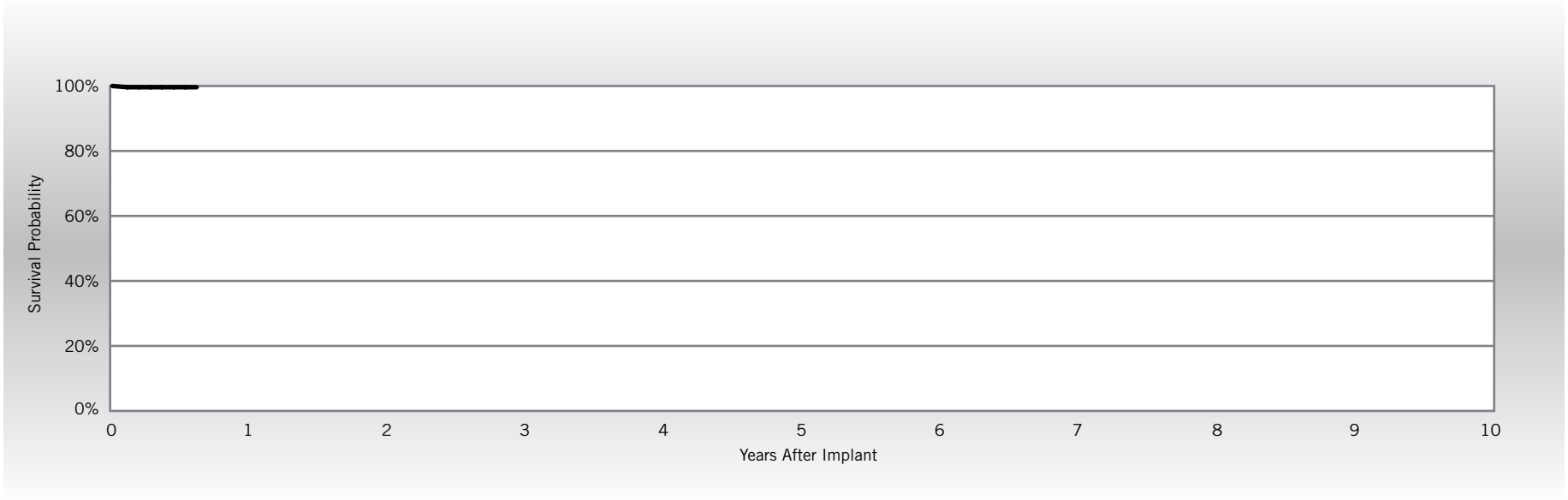
Durata® SJ4/DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	320
Cumulative Months of Follow-up	1,630
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Inappropriate Shock	1	0.31%

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	0.31%
Total	**1**	**0.31%**



Year	at 8 months									
Survival Probability	99.63%									
± 1 standard error	0.34%									
Sample Size	70									

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

Customer Reported Performance Data

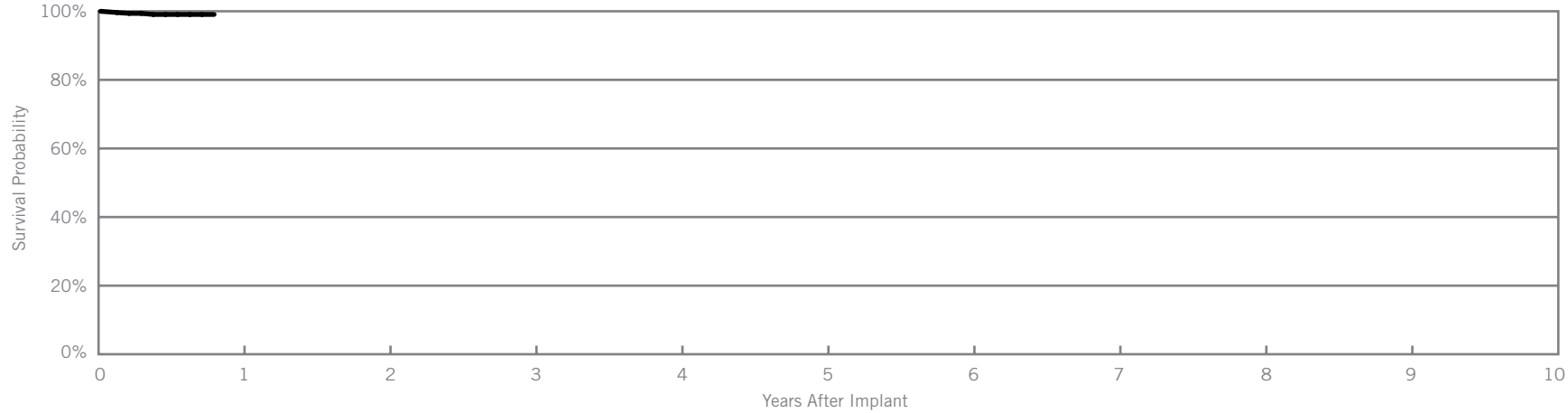
Durata® SJ4/DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	2,403
Estimated Active US Implants	2,209
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	2	0.08%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.04%	4	0.17%
Failure to Capture	5	0.21%	1	0.04%
Oversensing	1	0.04%	1	0.04%
Failure to Sense	1	0.04%	1	0.04%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.12%	0	0.00%
Total	**11**	**0.46%**	**9**	**0.37%**
Total Returned for Analysis	**6**		**5**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	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	7	0.29%
Total	**7**	**0.29%**



Year	at 10 months										
Survival Probability	99.07%										
± 1 standard error	0.26%										
Sample Size	200										

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

Customer Reported Performance Data

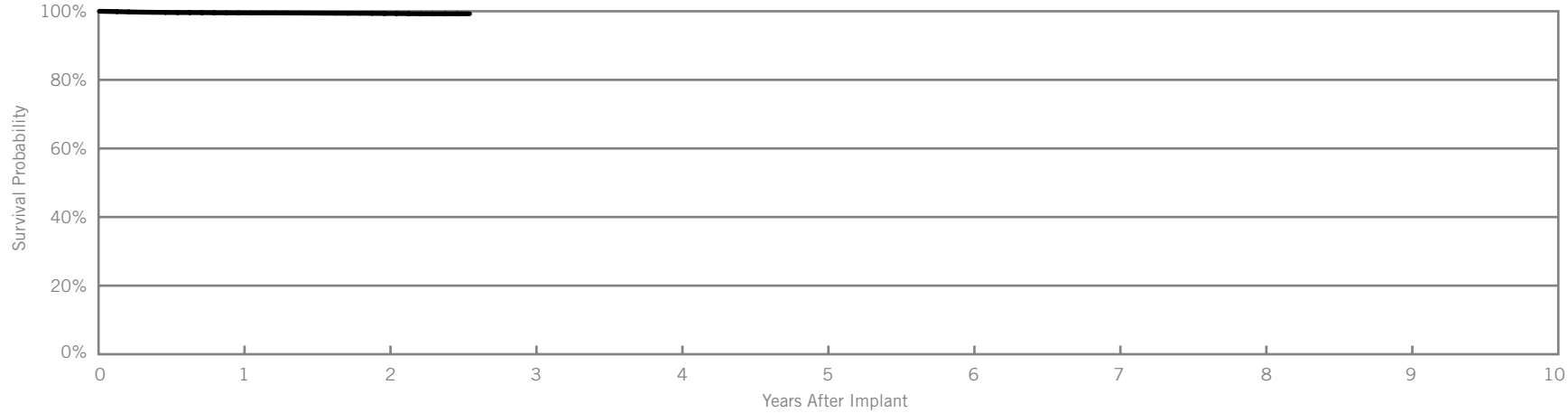
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	47,577
Estimated Active US Implants	42,095
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	27	0.06%	4	0.01%
Conductor Fracture	1	<0.01%	3	<0.01%
Lead Dislodgement	52	0.11%	82	0.17%
Failure to Capture	13	0.03%	33	0.07%
Oversensing	44	0.09%	39	0.08%
Failure to Sense	4	0.01%	8	0.02%
Insulation Breach	0	0.00%	1	<0.00%
Abnormal Pacing Impedance	1	<0.01%	8	0.02%
Abnormal Defibrillation Impedance	16	0.03%	11	0.02%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	15	0.03%	11	0.02%
Total	**174**	**0.37%**	**200**	**0.42%**
Total Returned for Analysis	**52**		**102**	

Malfunctions	Qty.	Rate
Conductor Fracture	6	0.01%
Clavicular Crush	0	0.00%
In the Pocket	5	0.01%
Intravascular	1	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	1	<0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	8	0.02%
Extrinsic Factors	87	0.18%
Total	**104**	**0.22%**



Year	1	2	at 31 months							
Survival Probability	99.54%	99.36%	99.27%							
± 1 standard error	0.03%	0.05%	0.07%							
Sample Size	39700	17900	300							

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

SCORE Registry Performance Data

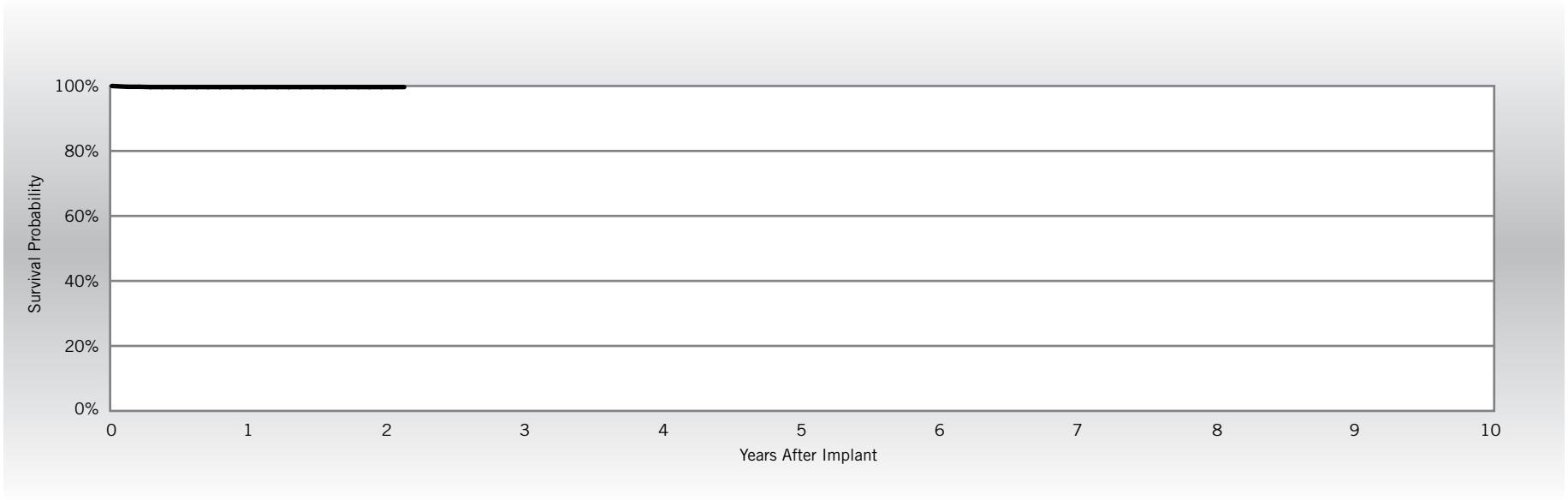
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,260
Cumulative Months of Follow-up	19,510
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	2	0.16%
Failure to Capture	1	0.08%
Extracardiac Stimulation	1	0.08%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.08%
Clavicular Crush	0	0.00%
In the Pocket	1	0.08%
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	0.08%
Total	**2**	**0.16%**



Year	1	2	at 26 months							
Survival Probability	99.67%	99.67%	99.67%							
± 1 standard error	0.16%	0.16%	0.16%							
Sample Size	1080	500	80							

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

Customer Reported Performance Data

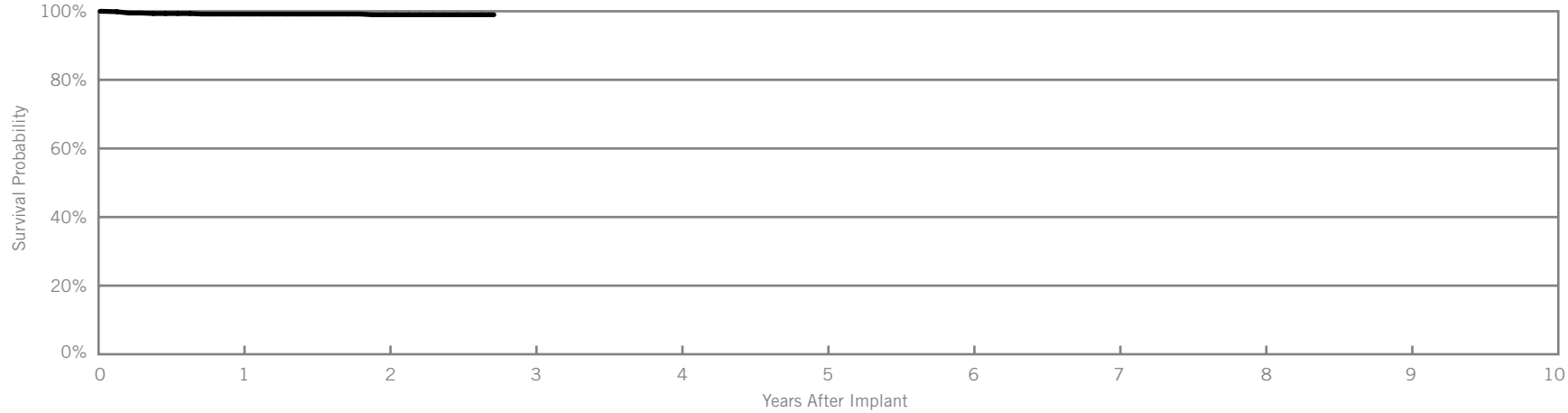
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	850
Estimated Active US Implants	642
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	1	0.12%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.47%	0	0.00%
Failure to Capture	0	0.00%	4	0.47%
Oversensing	2	0.24%	5	0.59%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.12%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**6**	**0.71%**	**11**	**1.29%**
Total Returned for Analysis	**3**		**2**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	0.35%
Total	**3**	**0.35%**



Year	1	2	at 33 months							
Survival Probability	99.19%	98.98%	98.98%							
± 1 standard error	0.33%	0.39%	0.39%							
Sample Size	800	600	200							

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

Customer Reported Performance Data

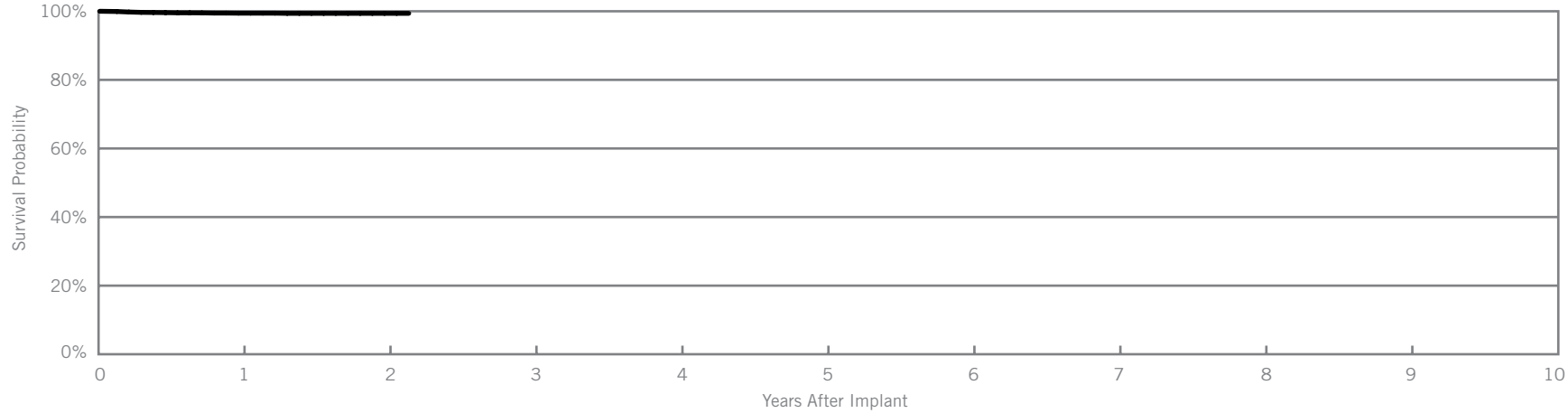
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	6,179
Estimated Active US Implants	5,651
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.05%	1	0.02%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	6	0.10%	11	0.18%
Failure to Capture	3	0.05%	5	0.08%
Oversensing	2	0.03%	3	0.05%
Failure to Sense	0	0.00%	2	0.03%
Insulation Breach	0	0.00%	2	0.03%
Abnormal Pacing Impedance	0	0.00%	3	0.05%
Abnormal Defibrillation Impedance	1	0.02%	1	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**15**	**0.24%**	**28**	**0.45%**
Total Returned for Analysis	**7**		**23**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.03%
Clavicular Crush	0	0.00%
In the Pocket	2	0.03%
Intravascular	0	0.00%
Insulation Breach	2	0.03%
Lead-to-Can Contact	1	0.02%
Lead-to-Lead Contact	1	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	17	0.28%
Total	**22**	**0.36%**



Year	1	2	at 26 months							
Survival Probability	99.44%	99.39%	99.39%							
± 1 standard error	0.10%	0.12%	0.12%							
Sample Size	4700	1800	300							

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

SCORE Registry Performance Data

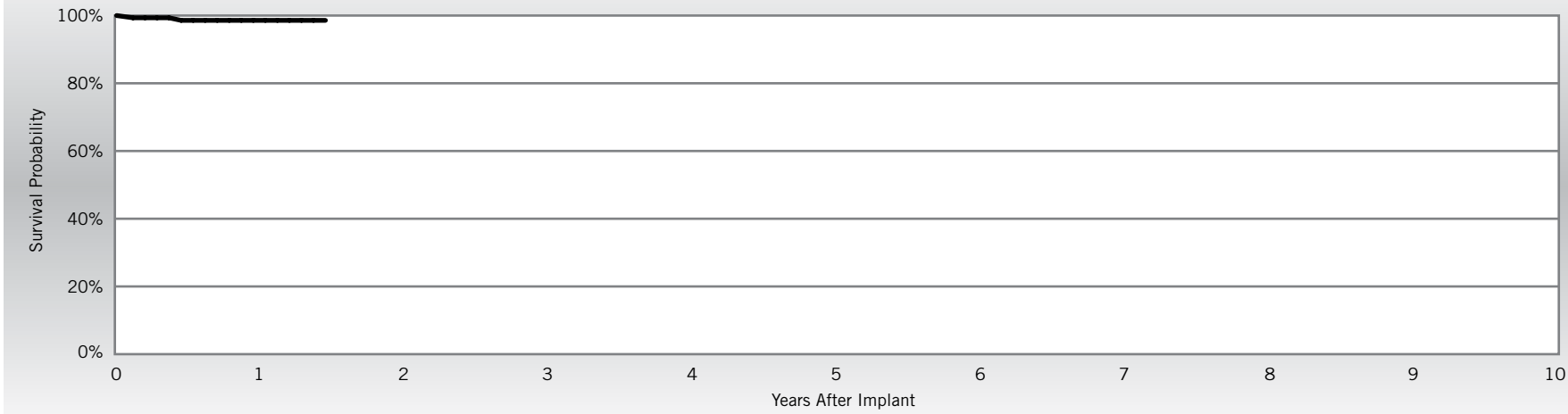
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	160
Cumulative Months of Follow-up	2,200
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.63%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.63%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.63%
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	0.63%
Total	**2**	**1.25%**



Year	1	at 18 months								
Survival Probability	98.58%	98.58%								
± 1 standard error	0.99%	0.99%								
Sample Size	130	50								

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

Customer Reported Performance Data

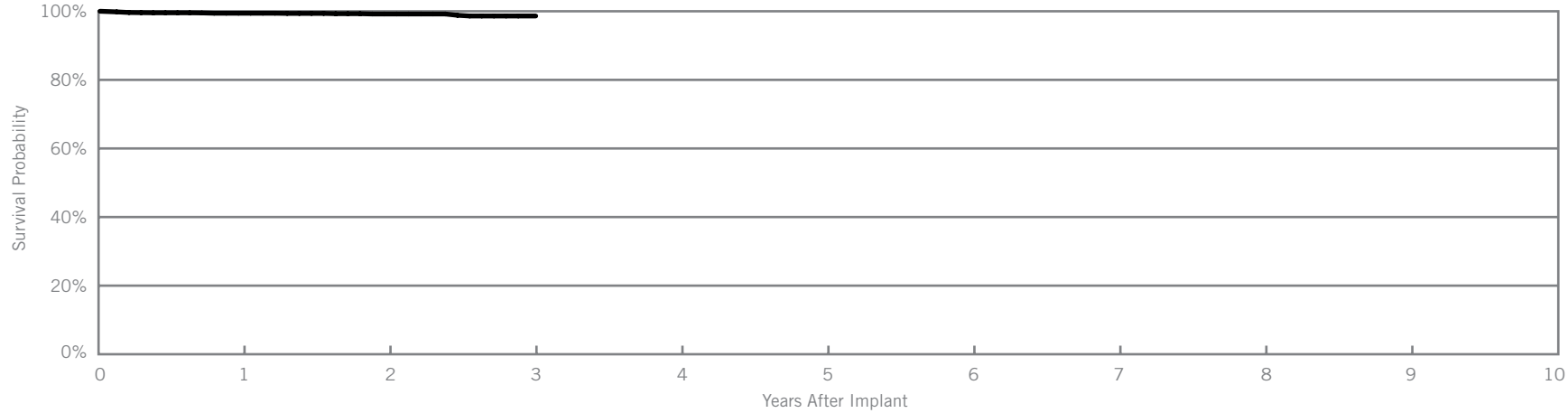
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,091
Estimated Active US Implants	2,562
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	0.06%	2	0.06%
Conductor Fracture	1	0.03%	1	0.03%
Lead Dislodgement	3	0.10%	3	0.10%
Failure to Capture	5	0.16%	3	0.10%
Oversensing	4	0.13%	5	0.16%
Failure to Sense	2	0.06%	2	0.06%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.06%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**17**	**0.55%**	**19**	**0.61%**
Total Returned for Analysis	**4**		**7**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.03%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.03%
Insulation Breach	1	0.03%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	0.03%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.03%
Other	1	0.03%
Extrinsic Factors	5	0.16%
Total	**9**	**0.29%**



Year	1	2	3							
Survival Probability	99.43%	99.21%	98.62%							
± 1 standard error	0.15%	0.20%	0.39%							
Sample Size	2600	1600	600							

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

SCORE Registry Performance Data

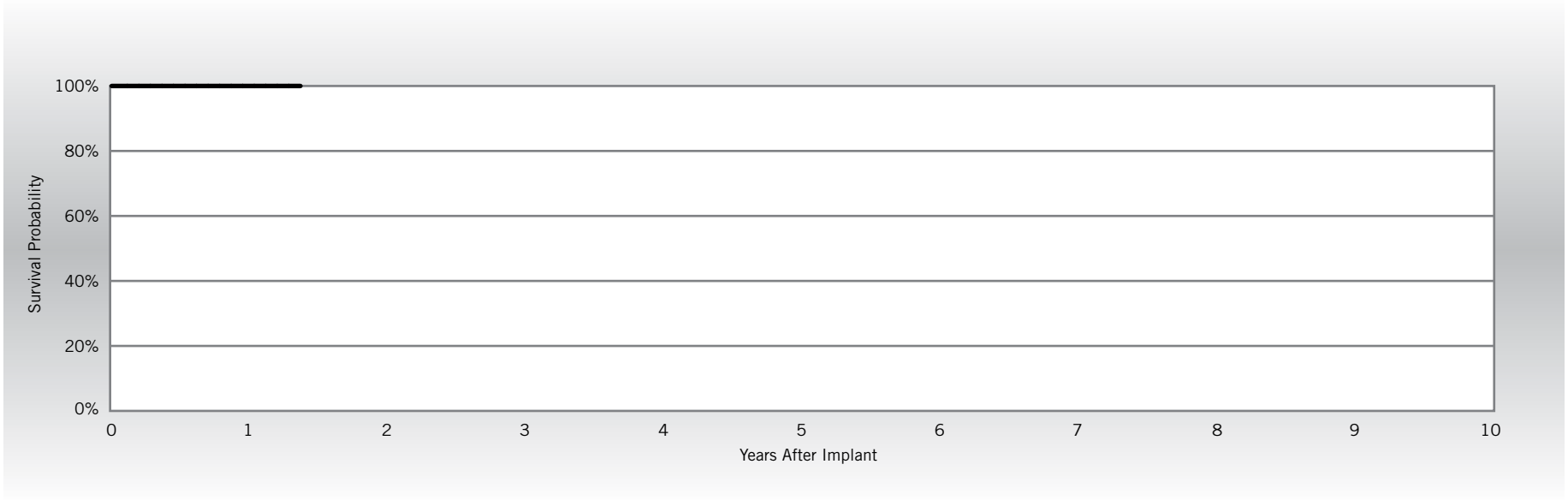
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	140
Cumulative Months of Follow-up	1,940
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	0.71%
Total	**1**	**0.71%**



Year	1	at 17 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	110	50								

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

Customer Reported Performance Data

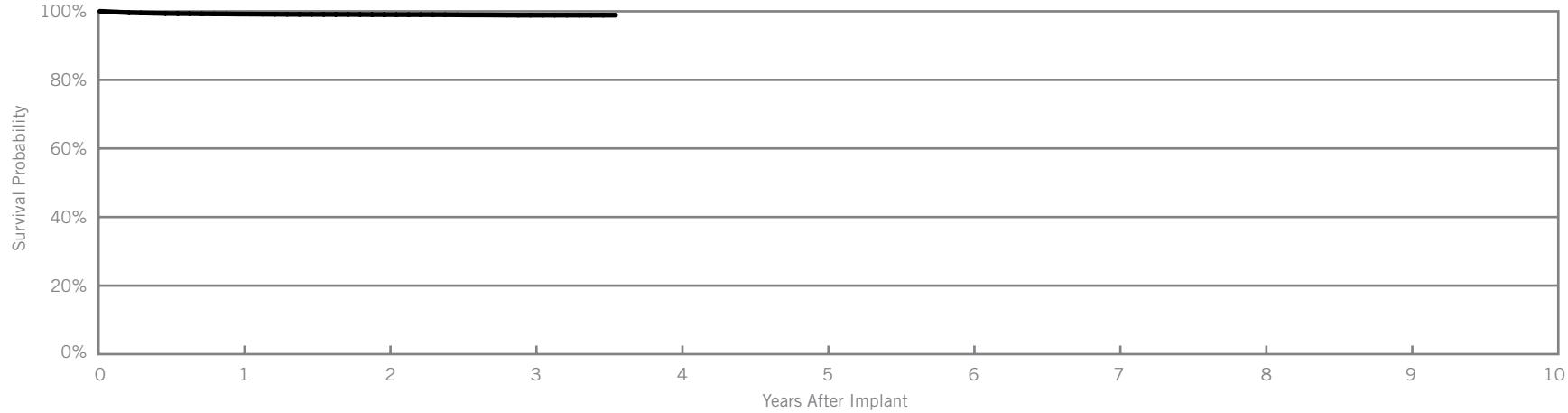
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,499
Estimated Active US Implants	12,081
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	38	0.25%	10	0.06%
Conductor Fracture	0	0.00%	2	0.01%
Lead Dislodgement	34	0.22%	47	0.30%
Failure to Capture	19	0.12%	28	0.18%
Oversensing	19	0.12%	37	0.24%
Failure to Sense	8	0.05%	10	0.06%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	1	0.01%	4	0.03%
Abnormal Defibrillation Impedance	4	0.03%	6	0.04%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	11	0.07%
Total	**127**	**0.82%**	**159**	**1.03%**
Total Returned for Analysis	**55**		**102**	

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	8	0.05%
Lead-to-Can Contact	2	0.01%
Lead-to-Lead Contact	2	0.01%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Other	3	0.02%
Crimps, Welds & Bonds	2	0.01%
Other	1	0.01%
Extrinsic Factors	76	0.49%
Total	**92**	**0.59%**



Year	1	2	3	at 43 months						
Survival Probability	99.20%	99.04%	98.88%	98.88%						
± 1 standard error	0.07%	0.08%	0.10%	0.10%						
Sample Size	14800	11900	6700	200						

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

SCORE Registry Performance Data

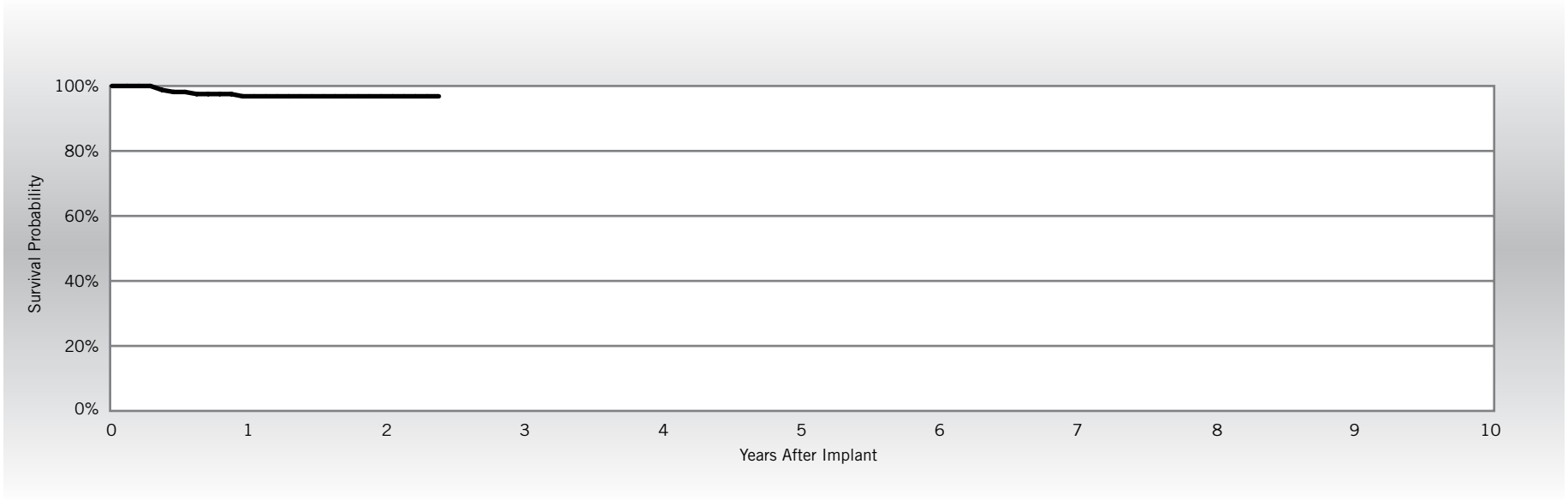
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	170
Cumulative Months of Follow-up	3,930
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Cardiac Perforation	1	0.59%
Conductor Fracture	2	1.18%
Failure to Sense	1	0.59%
Abnormal Pacing Impedance	1	0.59%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.59%
Clavicular Crush	0	0.00%
In the Pocket	1	0.59%
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	0.59%
Total	**2**	**1.18%**



Year	1	2	at 29 months							
Survival Probability	96.83%	96.83%	96.83%							
± 1 standard error	1.39%	1.39%	1.39%							
Sample Size	160	120	70							

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

Customer Reported Performance Data

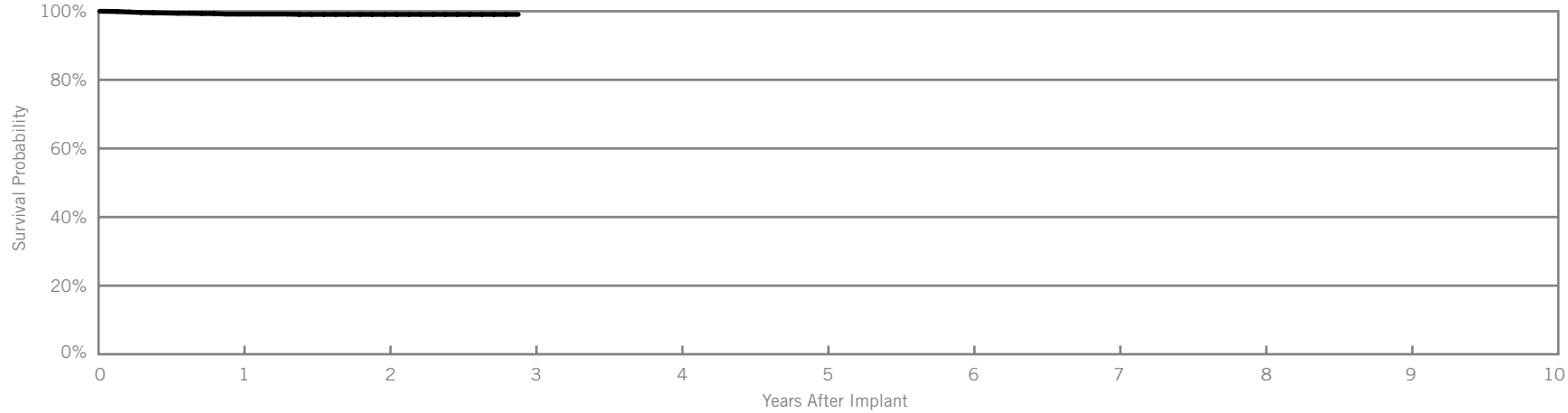
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,471
Estimated Active US Implants	1,204
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	5	0.34%	2	0.14%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	3	0.20%	6	0.41%
Failure to Capture	1	0.07%	0	0.00%
Oversensing	0	0.00%	4	0.27%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.07%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	**0.00%**
Total	**10**	**0.68%**	**12**	**0.82%**
Total Returned for Analysis	**3**		**7**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.07%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.07%
Extrinsic Factors	6	0.41%
Total	**8**	**0.54%**



Year	1	2	at 35 months							
Survival Probability	99.17%	99.08%	99.08%							
± 1 standard error	0.25%	0.26%	0.26%							
Sample Size	1400	1100	200							

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

Customer Reported Performance Data

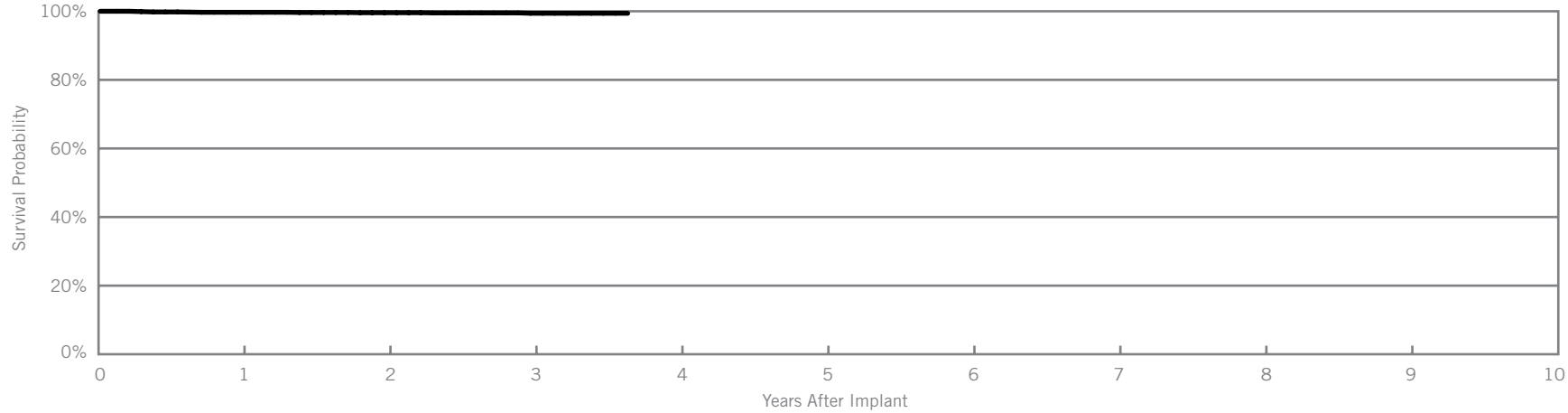
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,196
Estimated Active US Implants	1,670
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.05%	4	0.18%
Failure to Capture	3	0.14%	0	0.00%
Oversensing	2	0.09%	3	0.14%
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**	**0.55%**	**12**	**0.55%**
Total Returned for Analysis	**4**		**5**	

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



Year	1	2	3	at 44 months						
Survival Probability	99.70%	99.58%	99.41%	99.41%						
± 1 standard error	0.12%	0.15%	0.16%	0.20%						
Sample Size	2100	1800	1300	200						

Customer Reported Performance Data

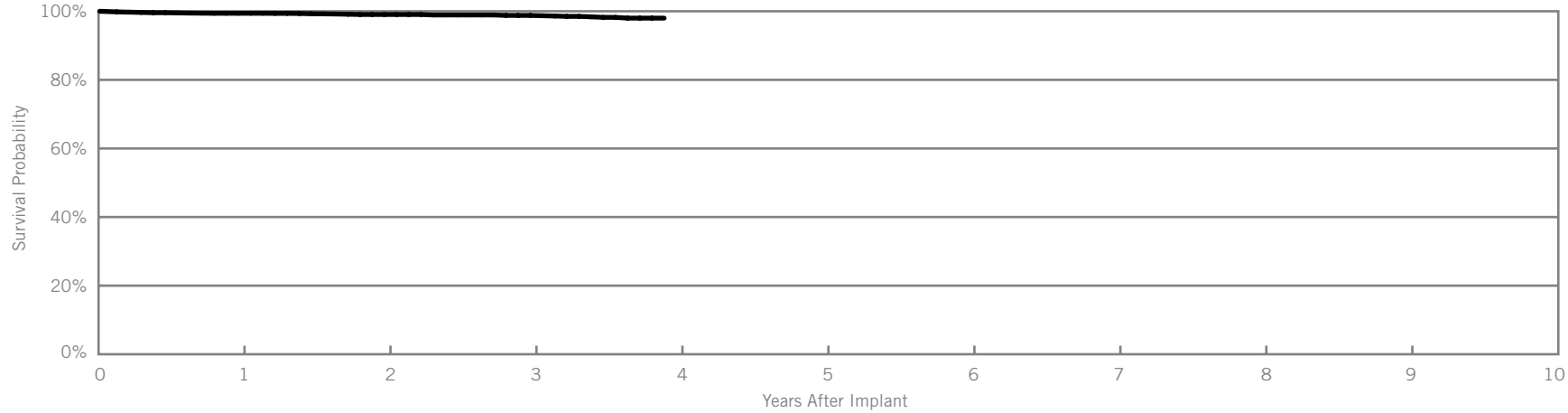
Riata® ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,046
Estimated Active US Implants	3,148
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	2	0.05%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	1	0.02%	4	0.10%
Oversensing	3	0.07%	12	0.30%
Failure to Sense	0	0.00%	3	0.07%
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**	**0.40%**	**33**	**0.82%**
Total Returned for Analysis	**3**		**9**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.05%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.05%
Insulation Breach	4	0.10%
Lead-to-Can Contact	4	0.10%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.07%
Extrinsic Factors	6	0.15%
Total	**15**	**0.37%**



Year	1	2	3	at 47 months						
Survival Probability	99.41%	99.06%	98.79%	98.00%						
± 1 standard error	0.13%	0.17%	0.21%	0.40%						
Sample Size	3800	3000	2000	300						

Customer Reported Performance Data

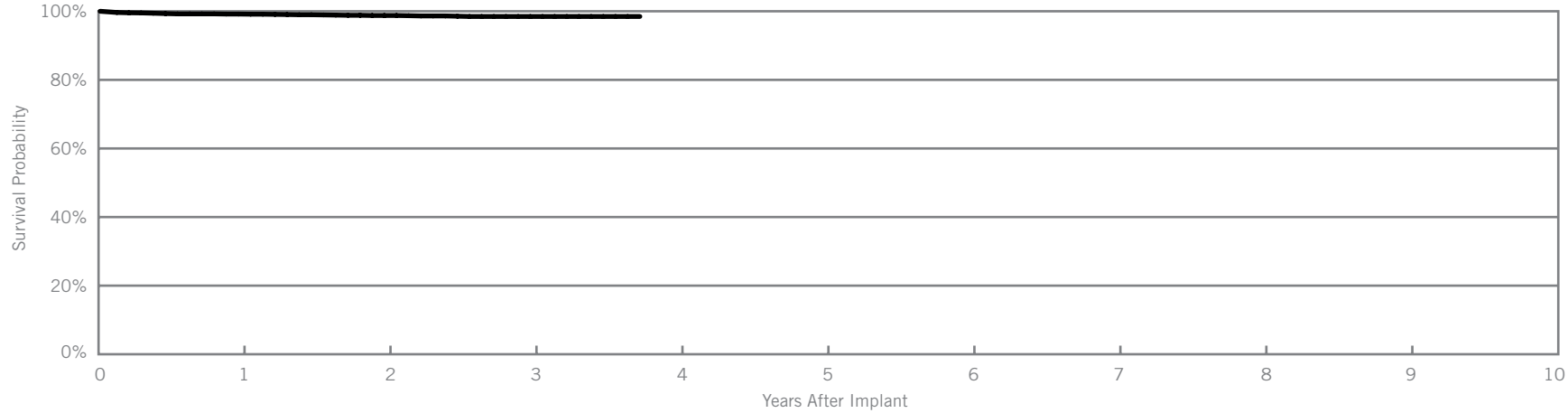
Riata® ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,395
Estimated Active US Implants	1,886
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	6	0.25%	3	0.13%
Conductor Fracture	0	0.00%	2	0.08%
Lead Dislodgement	3	0.13%	8	0.33%
Failure to Capture	4	0.17%	6	0.25%
Oversensing	4	0.17%	9	0.38%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.08%	0	0.00%
Abnormal Defibrillation Impedance	1	0.04%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	2	0.08%
Total	**21**	**0.88%**	**31**	**1.29%**
Total Returned for Analysis	**8**		**14**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.08%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.08%
Insulation Breach	2	0.08%
Lead-to-Can Contact	2	0.08%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	9	0.38%
Total	**13**	**0.54%**



Year	1	2	3	at 45 months						
Survival Probability	99.19%	98.77%	98.48%	98.48%						
± 1 standard error	0.19%	0.24%	0.28%	0.28%						
Sample Size	2300	1900	1200	300						

Customer Reported Performance Data

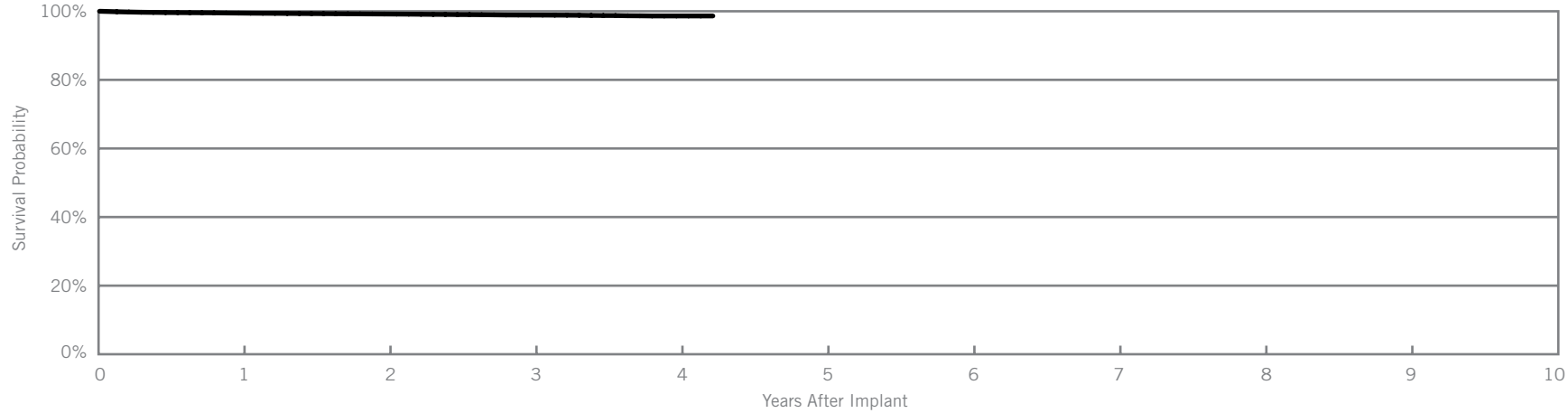
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,905
Estimated Active US Implants	25,900
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	41	0.12%	20	0.06%
Conductor Fracture	0	0.00%	12	0.03%
Lead Dislodgement	37	0.11%	38	0.11%
Failure to Capture	43	0.12%	60	0.17%
Oversensing	40	0.11%	145	0.42%
Failure to Sense	7	0.02%	15	0.04%
Insulation Breach	1	<0.01%	9	0.03%
Abnormal Pacing Impedance	8	0.02%	10	0.03%
Abnormal Defibrillation Impedance	4	0.01%	10	0.03%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	11	0.03%	26	0.07%
Total	**196**	**0.56%**	**347**	**0.99%**
Total Returned for Analysis	**92**		**167**	

Malfunctions	Qty.	Rate
Conductor Fracture	9	0.03%
Clavicular Crush	1	<0.01%
In the Pocket	2	0.01%
Intravascular	6	0.02%
Insulation Breach	57	0.16%
Lead-to-Can Contact	41	0.12%
Lead-to-Lead Contact	8	0.02%
Clavicular Crush	2	0.01%
Externalized Conductors	0	0.00%
Other	6	0.02%
Crimps, Welds & Bonds	4	0.01%
Other	0	0.00%
Extrinsic Factors	86	0.25%
Total	**156**	**0.45%**



Year	1	2	3	4	at 51 months					
Survival Probability	99.47%	99.20%	98.90%	98.63%	98.63%					
± 1 standard error	0.04%	0.05%	0.06%	0.09%	0.09%					
Sample Size	33900	28700	21200	9000	500					

SCORE Registry Performance Data

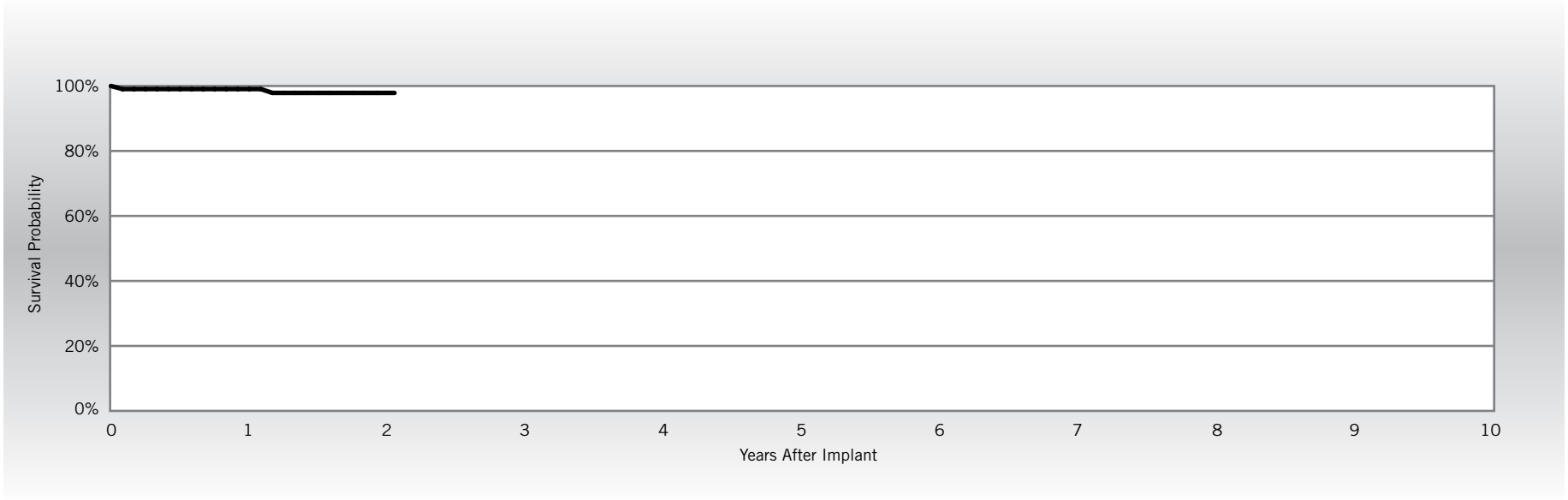
Riata® ST

Models 7000 & 7001

US Regulatory Approval	July 2005
Number of Devices Enrolled in Study	110
Cumulative Months of Follow-up	2,410
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.91%
Oversensing	1	0.91%

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	1.82%
Lead-to-Can Contact	1	0.91%
Lead-to-Lead Contact	1	0.91%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.91%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**3**	**2.73%**



Year	1	2	at 25 months							
Survival Probability	99.06%	97.87%	97.87%							
± 1 standard error	0.93%	1.49%	1.49%							
Sample Size	100	80	50							

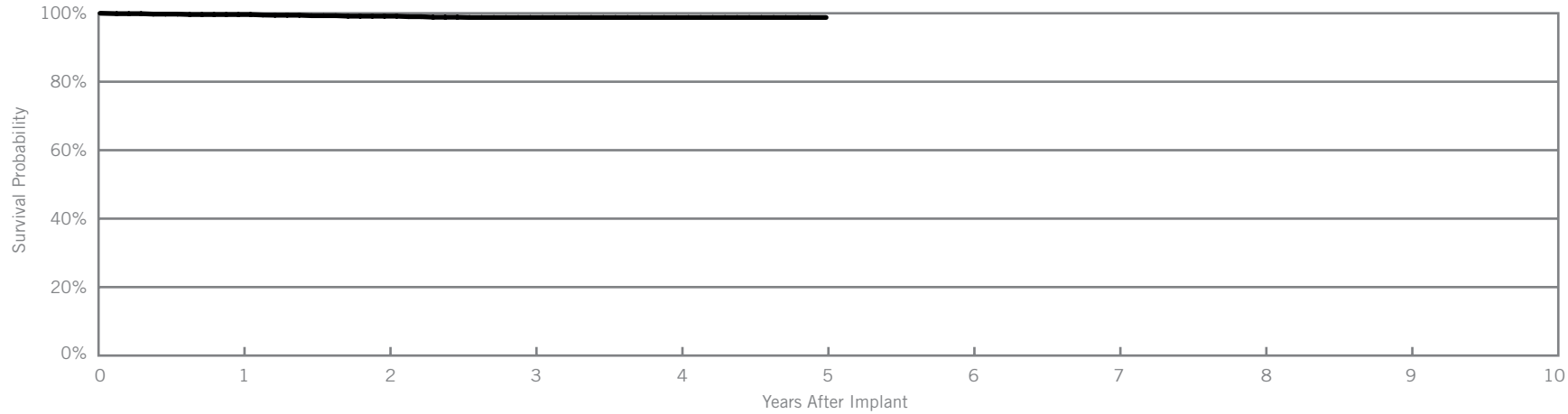
Customer Reported Performance Data

Riata® *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,006
Estimated Active US Implants	651
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	1	0.10%
Lead-to-Can Contact	1	0.10%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**1**	**0.10%**



Year	1	2	3	4	5					
Survival Probability	99.63%	99.15%	98.77%	98.77%	98.77%					
± 1 standard error	0.15%	0.24%	0.29%	0.29%	0.29%					
Sample Size	1700	1500	1300	1100	600					

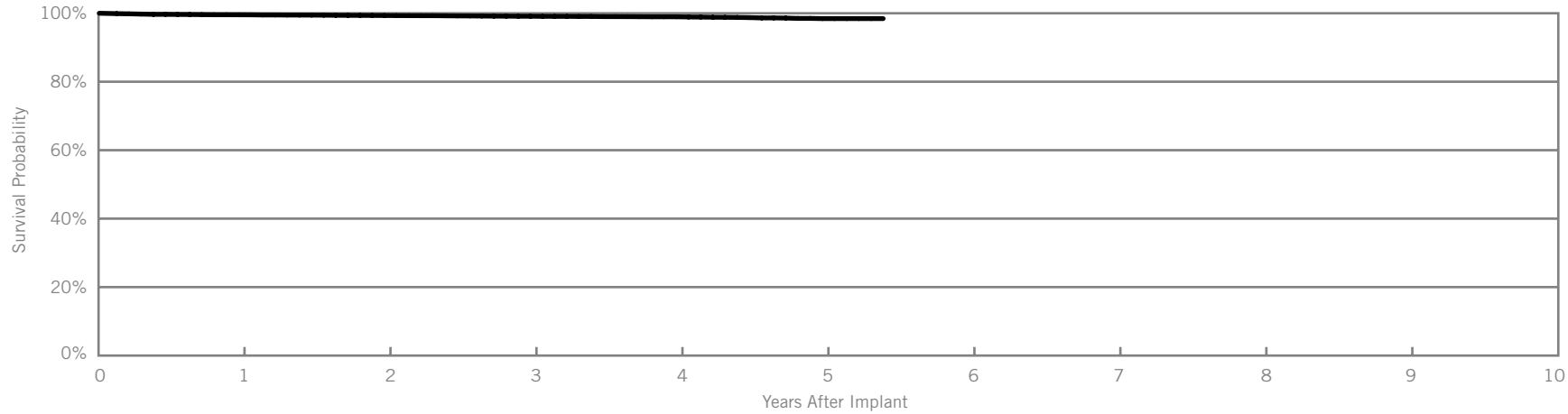
Customer Reported Performance Data

Riata® *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,732
Estimated Active US Implants	6,228
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.03%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	2	0.02%
Insulation Breach	7	0.07%
Lead-to-Can Contact	5	0.05%
Lead-to-Lead Contact	1	0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	16	0.16%
Total	**26**	**0.27%**



Year	1	2	3	4	5	at 65 months				
Survival Probability	99.55%	99.34%	99.13%	98.97%	98.44%	98.44%				
± 1 standard error	0.07%	0.09%	0.10%	0.11%	0.17%	0.18%				
Sample Size	9600	8400	7400	6100	3300	300				

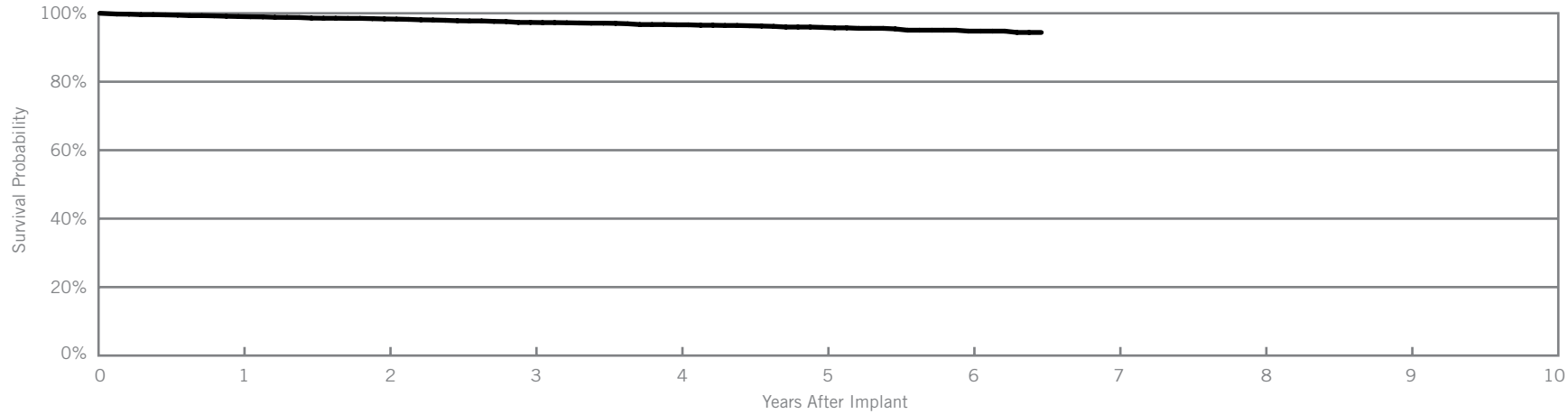
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,154
Estimated Active US Implants	1,922
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.06%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.06%
Insulation Breach	30	0.95%
Lead-to-Can Contact	20	0.63%
Lead-to-Lead Contact	2	0.06%
Clavicular Crush	1	0.03%
Externalized Conductors	2	0.06%
Other	5	0.16%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	12	0.38%
Total	**44**	**1.40%**



Year	1	2	3	4	5	6	at 78 months			
Survival Probability	99.05%	98.34%	97.32%	96.63%	95.86%	94.78%	94.39%			
± 1 standard error	0.17%	0.24%	0.33%	0.37%	0.44%	0.58%	0.75%			
Sample Size	3000	2600	2200	1800	1200	600	200			

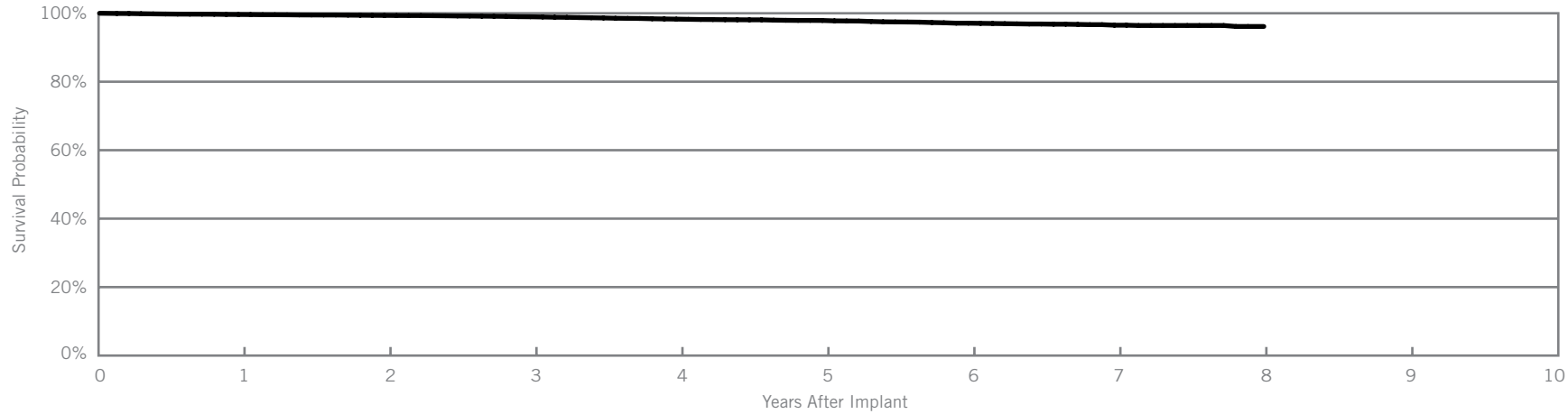
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,473
Estimated Active US Implants	6,186
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.03%
Clavicular Crush	2	0.02%
In the Pocket	1	0.01%
Intravascular	0	0.00%
Insulation Breach	23	0.22%
Lead-to-Can Contact	16	0.15%
Lead-to-Lead Contact	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.02%
Other	3	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	16	0.15%
Total	**42**	**0.40%**



Year	1	2	3	4	5	6	7	8		
Survival Probability	99.64%	99.37%	98.97%	98.29%	97.89%	97.10%	96.51%	96.14%		
± 1 standard error	0.06%	0.08%	0.11%	0.15%	0.18%	0.24%	0.28%	0.42%		
Sample Size	10000	8700	7500	6300	4800	3100	1800	700		

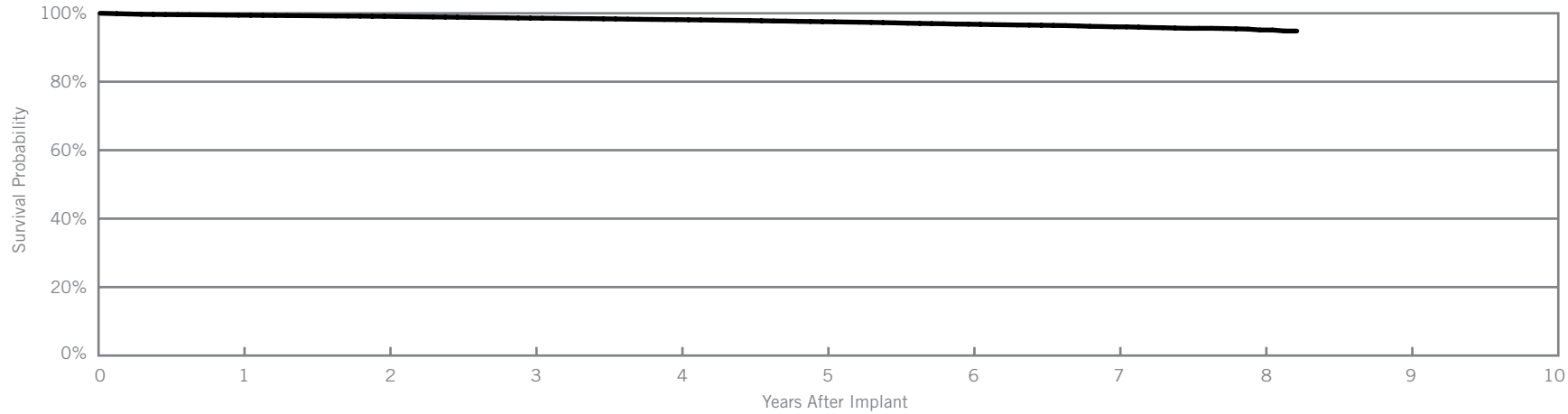
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,390
Estimated Active US Implants	41,101
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	14	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	6	0.01%
Intravascular	6	0.01%
Insulation Breach	205	0.30%
Lead-to-Can Contact	127	0.18%
Lead-to-Lead Contact	23	0.03%
Clavicular Crush	5	0.01%
Externalized Conductors	18	0.03%
Other	32	0.05%
Crimps, Welds & Bonds	4	0.01%
Other	3	<0.01%
Extrinsic Factors	189	0.27%
Total	**415**	**0.60%**



Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.44%	99.11%	98.59%	98.14%	97.54%	96.81%	96.04%	95.11%	94.81%
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.10%	0.14%	0.23%	0.42%
Sample Size	67600	58900	51600	43800	31700	17400	8100	2700	200

SCORE Registry Performance Data

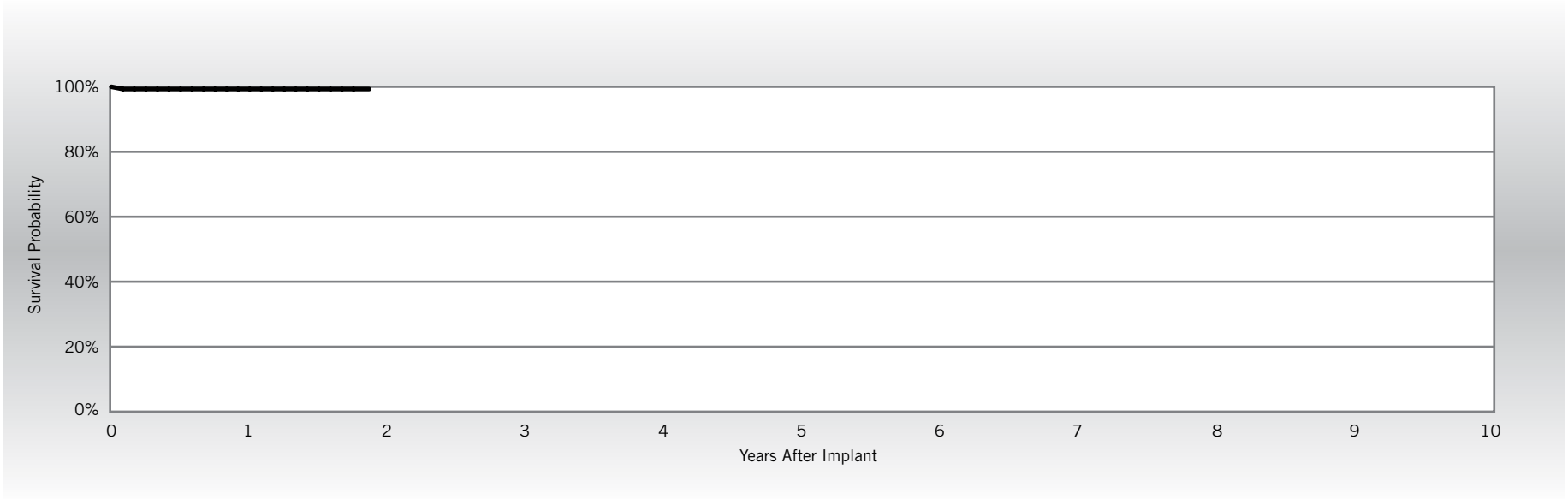
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	150
Cumulative Months of Follow-up	2,540
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.67%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	1.33%
Total	**2**	**1.33%**



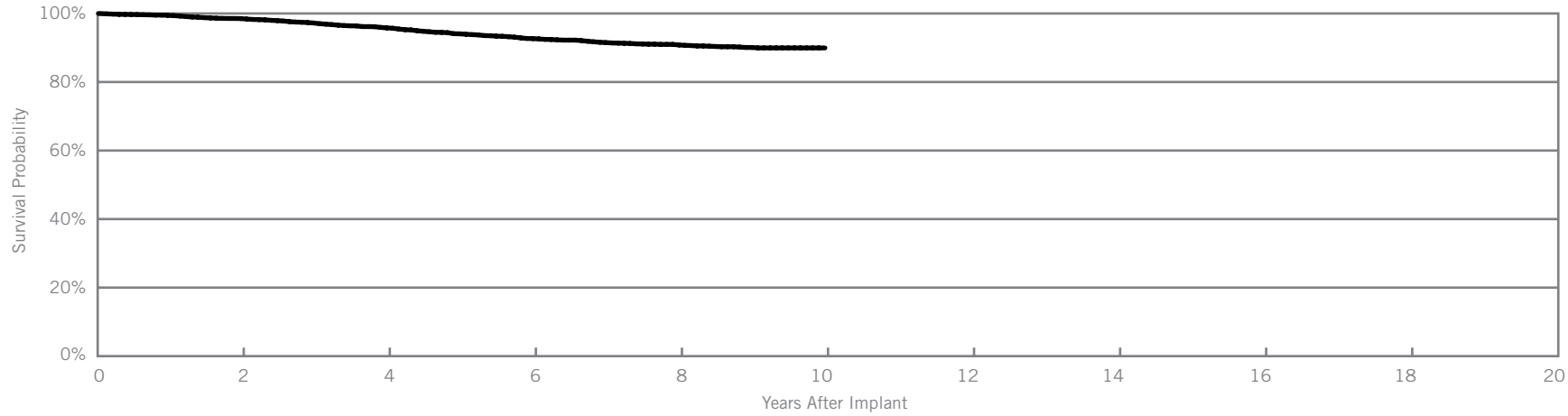
Year	1	at 23 months								
Survival Probability	99.31%	99.31%								
± 1 standard error	0.67%	0.67%								
Sample Size	130	50								

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,736
Estimated Active US Implants	1,518
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None



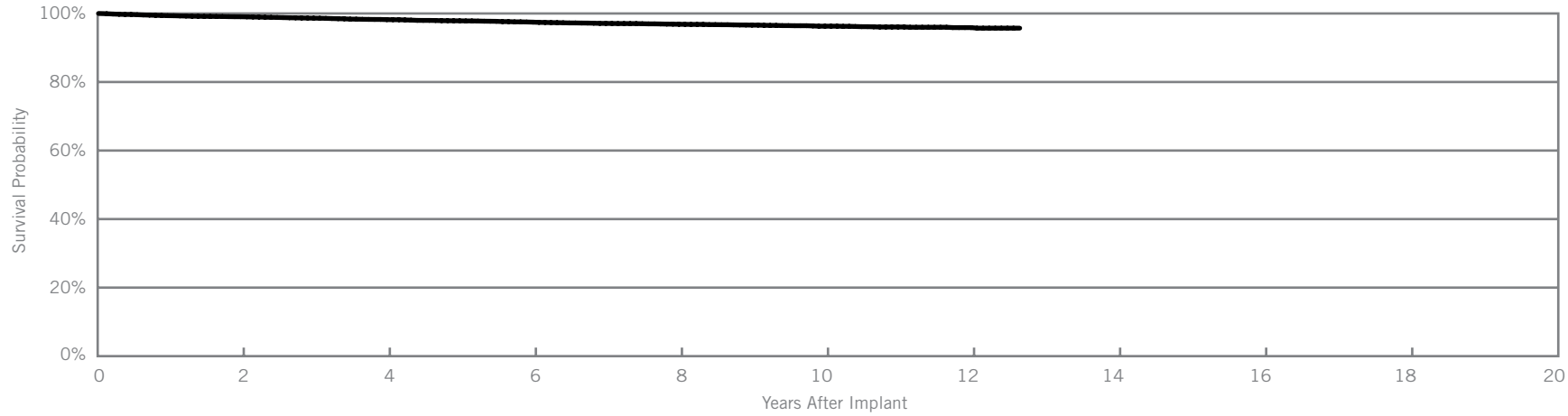
Year	2	4	6	8	10					
Survival Probability	98.51%	95.79%	92.66%	90.81%	89.95%					
± 1 standard error	0.19%	0.34%	0.47%	0.55%	0.61%					
Sample Size	3900	3100	2400	1800	500					

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,640
Estimated Active US Implants	4,207
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None



Year	2	4	6	8	10	12	at 152 months			
Survival Probability	99.05%	98.20%	97.47%	96.85%	96.29%	95.88%	95.72%			
± 1 standard error	0.09%	0.13%	0.16%	0.19%	0.23%	0.28%	0.32%			
Sample Size	10900	9000	7300	5800	3300	1100	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
7120Q/7121Q	Durata® SJ4/DF4*										
7122Q	Durata® SJ4/DF4*										
7120/7121	Durata®	99.54%	99.36%								
7122	Durata®	99.44%	99.39%								
7030/7031	Riata® ST Optim®	99.19%	98.98%								
7022	Riata® ST Optim®	99.17%	99.08%								
7070/7071	Riata® ST Optim®	99.43%	99.21%	98.62%							
7020/7021	Riata® ST Optim®	99.20%	99.04%	98.88%							
7010/7011	Riata® ST	99.70%	99.58%	99.41%							
7040/7041	Riata® ST	99.41%	99.06%	98.79%							
7002	Riata® ST	99.19%	98.77%	98.48%							
7000/7001	Riata® ST	99.47%	99.20%	98.90%	98.63%						
1560/1561	Riata® *i*	99.63%	99.15%	98.77%	98.77%	98.77%					
1590/1591	Riata® *i*	99.55%	99.34%	99.13%	98.97%	98.44%					
1582	Riata®	99.05%	98.34%	97.32%	96.63%	95.86%	94.78%				
1570/1571	Riata®	99.64%	99.37%	98.97%	98.29%	97.89%	97.10%	96.51%	96.14%		
1580/1581	Riata®	99.44%	99.11%	98.59%	98.14%	97.54%	96.81%	96.04%	95.11%		
1559	TVL™ ADX	99.45%	98.51%	97.22%	95.79%	94.06%	92.66%	91.50%	90.81%	90.08%	89.95%
SP01/SP02/SP03/SP04	SPL®	99.36%	99.05%	98.64%	98.20%	97.86%	97.47%	97.10%	96.85%	96.60%	96.29%

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

Acute Observation Summary

Post Implant <30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
7120Q/7121Q	Jan-09	17910	17202	10	0.06%	0	0.00%	30	0.17%	14	0.08%	12	0.07%	2	0.01%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	1	0.01%	**71**	**0.40%**	**25**
7122Q	Jan-09	2403	2289	0	0.00%	0	0.00%	1	0.04%	5	0.21%	1	0.04%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.12%	**11**	**0.46%**	**6**
7120/7121	Sep-07	47577	42095	27	0.06%	1	<0.01%	52	0.11%	13	0.03%	44	0.09%	4	0.01%	0	0.00%	1	<0.01%	16	0.03%	1	<0.01%	15	0.03%	**174**	**0.37%**	**52**
7122	Sep-07	6179	5651	3	0.05%	0	0.00%	6	0.10%	3	0.05%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	**15**	**0.24%**	**7**
7030/7031	Jul-06	850	642	0	0.00%	0	0.00%	4	0.47%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.71%**	**3**
7022	Jul-06	1471	1204	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.68%**	**3**
7070/7071	Jul-06	3091	2562	2	0.06%	1	0.03%	3	0.10%	5	0.16%	4	0.13%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**17**	**0.55%**	**4**
7020/7021	Jul-06	15499	12081	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%**	**55**
7010/7011	Mar-06	2196	1670	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**	**0.55%**	**4**
7040/7041	Mar-06	4046	3148	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**	**0.40%**	**3**
7002	Jun-05	2395	1886	6	0.25%	0	0.00%	3	0.13%	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**	**0.88%**	**8**
7000/7001	Jun-05	34905	25900	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%**	**92**

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	
7120Q/7121Q	Jan-09	17910	17202	4	0.02%	0	0.00%	25	0.14%	12	0.07%	5	0.03%	2	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**49**	**0.27%**	**30**
7122Q	Jan-09	2403	2289	2	0.08%	0	0.00%	4	0.17%	1	0.04%	1	0.04%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**9**	**0.37%**	**5**
7120/7121	Sep-07	47577	42095	4	0.01%	3	0.01%	82	0.17%	33	0.07%	39	0.08%	8	0.02%	1	<0.01%	8	0.02%	11	0.02%	0	0.00%	11	0.02%	**200**	**0.42%**	**102**
7122	Sep-07	6179	5651	1	0.02%	0	0.00%	11	0.18%	5	0.08%	3	0.05%	2	0.03%	2	0.03%	3	0.05%	1	0.02%	0	0.00%	0	0.00%	**28**	**0.45%**	**23**
7030/7031	Jul-06	850	642	1	0.12%	0	0.00%	0	0.00%	4	0.47%	5	0.59%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	**11**	**1.29%**	**2**
7022	Jul-06	1471	1204	2	0.14%	0	0.00%	6	0.41%	0	0.00%	4	0.27%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**12**	**0.82%**	**7**
7070/7071	Jul-06	3091	2562	2	0.06%	1	0.03%	3	0.10%	3	0.10%	5	0.16%	2	0.06%	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	**19**	**0.61%**	**7**
7020/7021	Jul-06	15499	12081	10	0.06%	2	0.01%	47	0.30%	28	0.18%	37	0.24%	10	0.06%	2	0.01%	4	0.03%	6	0.04%	2	0.01%	11	0.07%	**159**	**1.03%**	**102**
7010/7011	Mar-06	2196	1670	1	0.05%	0	0.00%	4	0.18%	0	0.00%	3	0.14%	2	0.09%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**12**	**0.55%**	**5**
7040/7041	Mar-06	4046	3148	2	0.05%	2	0.05%	3	0.07%	4	0.10%	12	0.30%	3	0.07%	1	0.02%	3	0.07%	3	0.07%	0	0.00%	0	0.00%	**33**	**0.82%**	**9**
7002	Jun-05	2395	1886	3	0.13%	2	0.08%	8	0.33%	6	0.25%	9	0.38%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	2	0.08%	**31**	**1.29%**	**14**
7000/7001	Jun-05	34905	25900	20	0.06%	12	0.03%	38	0.11%	60	0.17%	145	0.42%	15	0.04%	9	0.03%	10	0.03%	10	0.03%	2	0.01%	26	0.07%	**347**	**0.99%**	**167**

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

Malfunction Summary

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	17910	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**	0	0.00%	1	0.01%	32	0.18%	**34**	**0.19%**
7122Q	2403	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	7	0.29%	**7**	**0.29%**
7120/7121	47577	0	0.00%	5	0.01%	1	<0.01%	**6**	**0.01%**	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**	1	<0.01%	8	0.02%	87	0.18%	**104**	**0.22%**
7122	6179	0	0.00%	2	0.03%	0	0.00%	**2**	**0.03%**	1	0.02%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.03%**	0	0.00%	1	0.02%	17	0.28%	**22**	**0.36%**
7030/7031	850	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	3	0.35%	**3**	**0.35%**
7022	1471	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	1	0.07%	6	0.41%	**8**	**0.54%**
7070/7071	3091	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	**1**	**0.03%**	1	0.03%	1	0.03%	5	0.16%	**9**	**0.29%**
7020/7021	15499	1	0.01%	1	0.01%	3	0.02%	**5**	**0.03%**	2	0.01%	2	0.01%	1	0.01%	0	0.00%	3	0.02%	**8**	**0.05%**	2	0.01%	1	0.01%	76	0.49%	**92**	**0.59%**
7010/7011	2196	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**	0	0.00%	0	0.00%	3	0.14%	**4**	**0.18%**
7040/7041	4046	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	4	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.10%**	0	0.00%	3	0.07%	6	0.15%	**15**	**0.37%**
7002	2395	0	0.00%	0	0.00%	2	0.08%	**2**	**0.08%**	2	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.08%**	0	0.00%	0	0.00%	9	0.38%	**13**	**0.54%**
7000/7001	34905	1	<0.01%	2	0.01%	6	0.02%	**9**	**0.03%**	41	0.12%	8	0.02%	2	0.01%	0	0.00%	6	0.02%	**57**	**0.16%**	4	0.01%	0	0.00%	86	0.25%	**156**	**0.45%**
1560/1561	1006	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	9732	1	0.01%	0	0.00%	2	0.02%	**3**	**0.03%**	5	0.05%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	**7**	**0.07%**	0	0.00%	0	0.00%	16	0.16%	**26**	**0.27%**
1582	3154	0	0.00%	0	0.00%	2	0.06%	**2**	**0.06%**	20	0.63%	2	0.06%	1	0.03%	2	0.06%	5	0.16%	**30**	**0.95%**	0	0.00%	0	0.00%	12	0.38%	**44**	**1.40%**
1570/1571	10473	2	0.02%	1	0.01%	0	0.00%	**3**	**0.03%**	16	0.15%	2	0.02%	0	0.00%	2	0.02%	3	0.03%	**23**	**0.22%**	0	0.00%	0	0.00%	16	0.15%	**42**	**0.40%**
1580/1581	69390	2	<0.01%	6	0.01%	6	0.01%	**14**	**0.02%**	127	0.18%	23	0.03%	5	0.01%	18	0.03%	32	0.05%	**205**	**0.30%**	4	0.01%	3	<0.01%	189	0.27%	**415**	**0.60%**

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

SCORE Summary

Malfunctions

		Conductor Fracture								Insulation Breach																			
		Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	320	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	1	0.31%	**1**	**0.31%**
7120/7121	1260	0	0.00%	1	0.08%	0	0.00%	**1**	**0.08%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	1	0.08%	**2**	**0.16%**
7122	160	0	0.00%	0	0.00%	1	0.63%	**1**	**0.63%**	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	0.63%	**2**	**1.25%**
7070/7071	140	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	1	0.71%	**1**	**0.71%**
7020/7021	170	0	0.00%	1	0.59%	0	0.00%	**1**	**0.59%**	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	0.59%	**2**	**1.18%**
7000/7001	110	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.91%	1	0.91%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.82%**	1	0.91%	0	0.00%	0	0.00%	**3**	**2.73%**
1580/1581	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%	2	1.33%	**2**	**1.33%**

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Inappropriate Shock		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	320	1630	0	0.00%	0	0.00%	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	0.31%	**1**	**0.31%**
7120/7121	1260	19510	0	0.00%	0	0.00%	2	0.16%	1	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.08%	0	0.00%	**4**	**0.32%**
7122	160	2200	0	0.00%	0	0.00%	2	1.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.25%**
7070/7071	140	1940	0	0.00%	0	0.00%	0	0.00%	0	0.00%	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	170	3930	1	0.59%	2	1.18%	0	0.00%	0	0.00%	0	0.00%	1	0.59%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	**5**	**2.94%**
7000/7001	110	2410	0	0.00%	0	0.00%	1	0.91%	0	0.00%	1	0.91%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**1.82%**
1580/1581	150	2540	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.67%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.67%**

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

Pacemakers

Dual-Chamber

St. Jude Medical™
More control. Less risk.

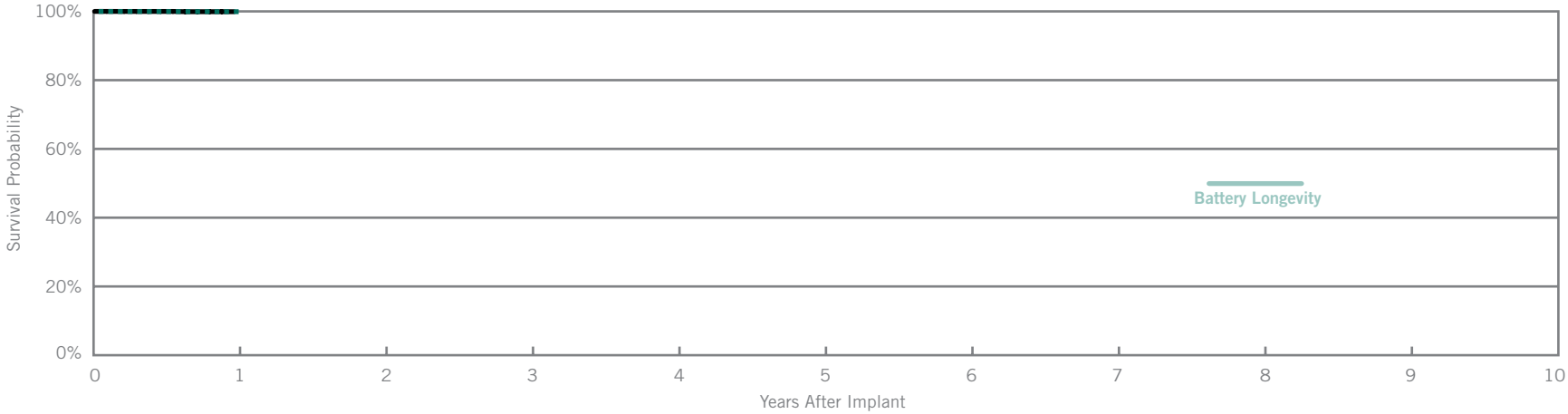
Customer Reported Performance Data

Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	33,883
Estimated Active US Implants	33,085
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	<0.01%
Malfunctions w/o Compromised Therapy	4	0.01%
Total	**5**	**0.01%**



Including Normal Battery Depletion .....

Year	1									
Survival Probability	99.91%									
± 1 standard error	0.03%									
Sample Size	17200									

Excluding Normal Battery Depletion ——

Year	1									
Survival Probability	99.91%									
± 1 standard error	0.03%									

SCORE Registry Performance Data

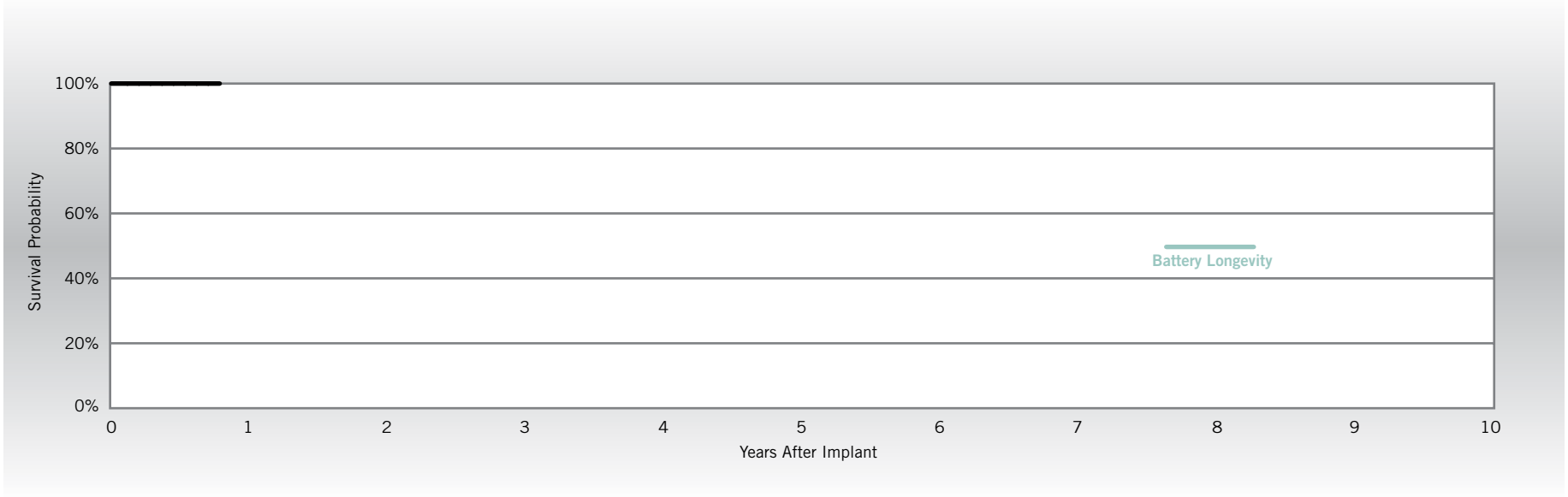
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	490
Cumulative Months of Follow-up	2,830
Estimated Longevity	8 Years

Qualifying Complications
None Reported

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



Year	at 10 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	70									

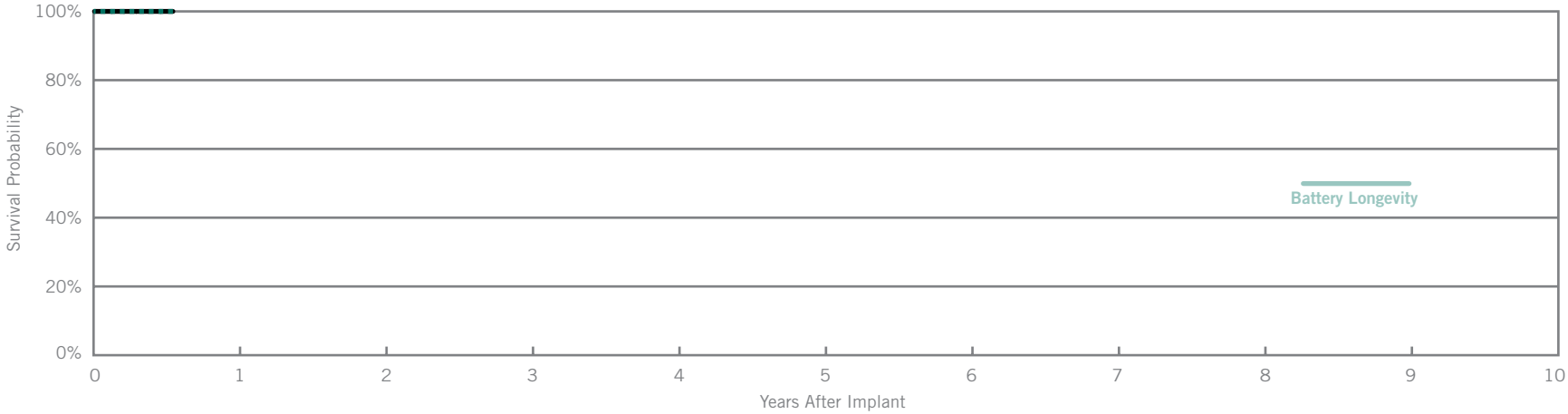
Customer Reported Performance Data

Accent® DR RF

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	2,739
Estimated Active US Implants	2704
Estimated Longevity	8.5 Years
Normal Battery Depletion	0
Number of Advisories	None

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



Including Normal Battery Depletion .....

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

Excluding Normal Battery Depletion ——

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

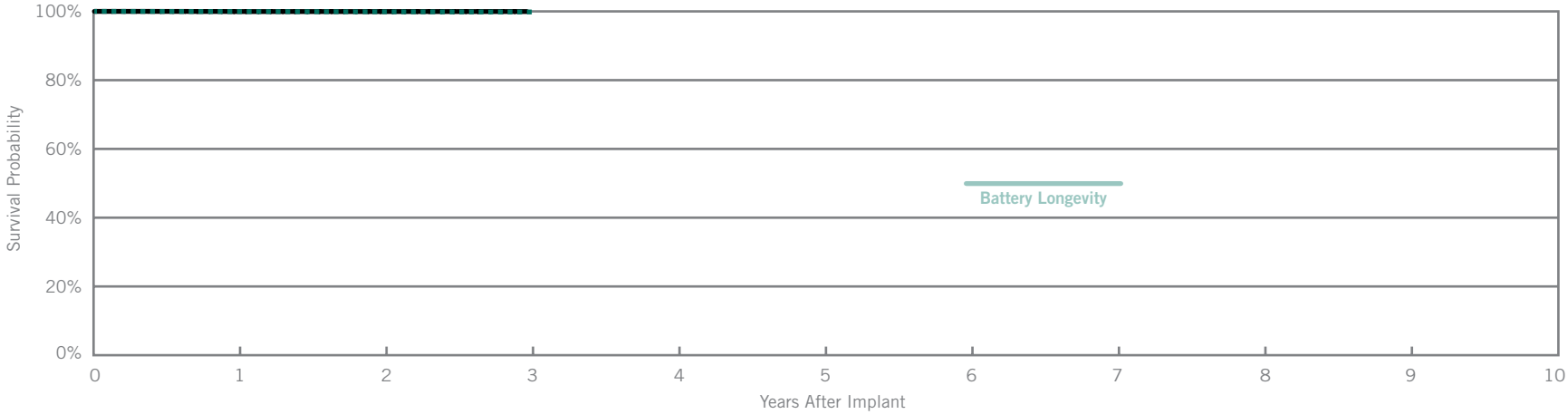
Customer Reported Performance Data

Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	28,382
Estimated Active US Implants	24,204
Estimated Longevity	6.5 Years
Normal Battery Depletion	4
Number of Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	1	<0.00%
Malfunctions w/o Compromised Therapy	3	0.01%
Total	**4**	**0.01%**



Including Normal Battery Depletion .....

Year	**1**	**2**	**3**							
Survival Probability	99.95%	99.95%	99.83%							
± 1 standard error	0.01%	0.02%	0.06%							
Sample Size	23900	11700	3100							

Excluding Normal Battery Depletion ———

Year	**1**	**2**	**3**							
Survival Probability	99.95%	99.95%	99.95%							
± 1 standard error	0.01%	0.02%	0.02%							

SCORE Registry Performance Data

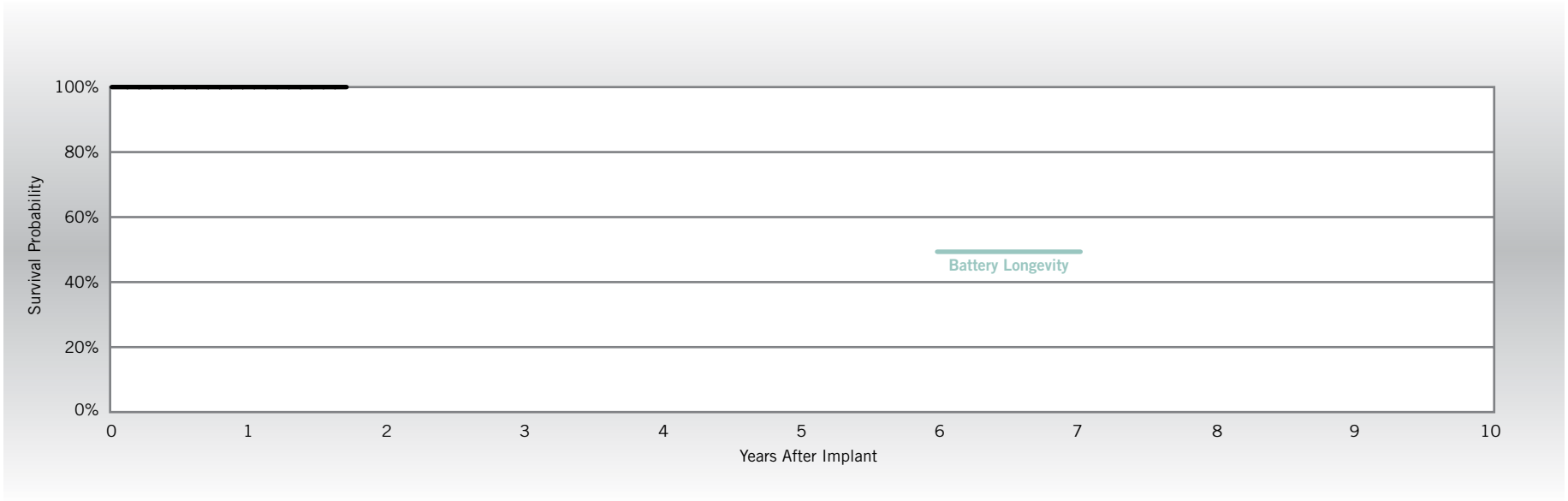
Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	220
Cumulative Months of Follow-up	3,040
Estimated Longevity	6.5 Years

Qualifying Complications
None Reported

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



Year	**1**	**at 21 months**								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	170	60								

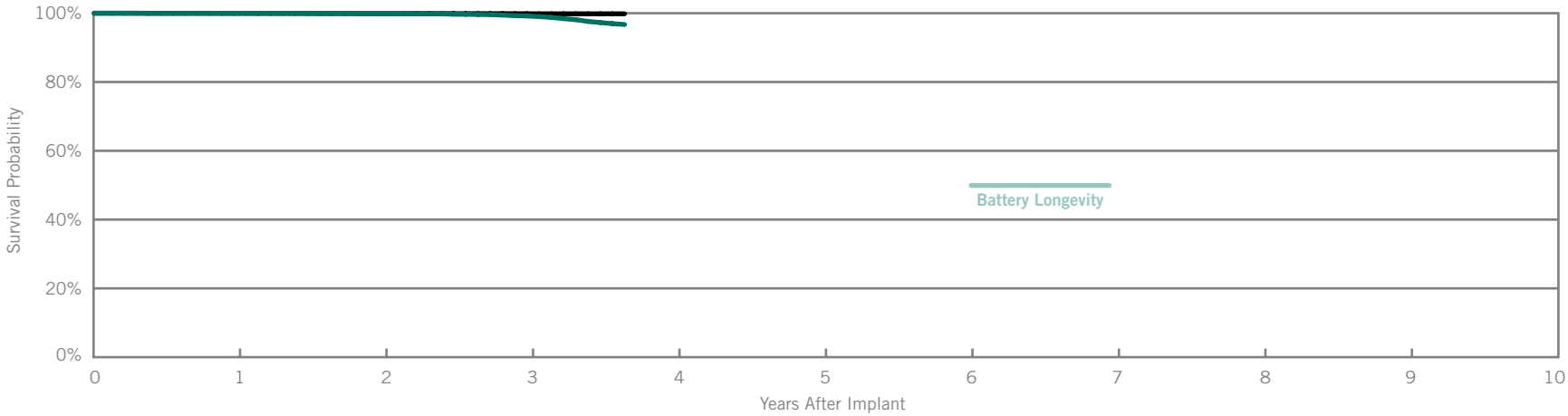
Customer Reported Performance Data

Victory® DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	25,873
Estimated Active US Implants	18,025
Estimated Longevity	6.5 Years
Normal Battery Depletion	26
Number of Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	14	0.05%
Total	**14**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.97%	99.88%	99.20%	96.71%						
± 1 standard error	0.01%	0.02%	0.07%	0.20%						
Sample Size	25100	19700	13900	4200						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.97%	99.89%	99.85%	99.77%						
± 1 standard error	0.01%	0.02%	0.03%	0.03%						

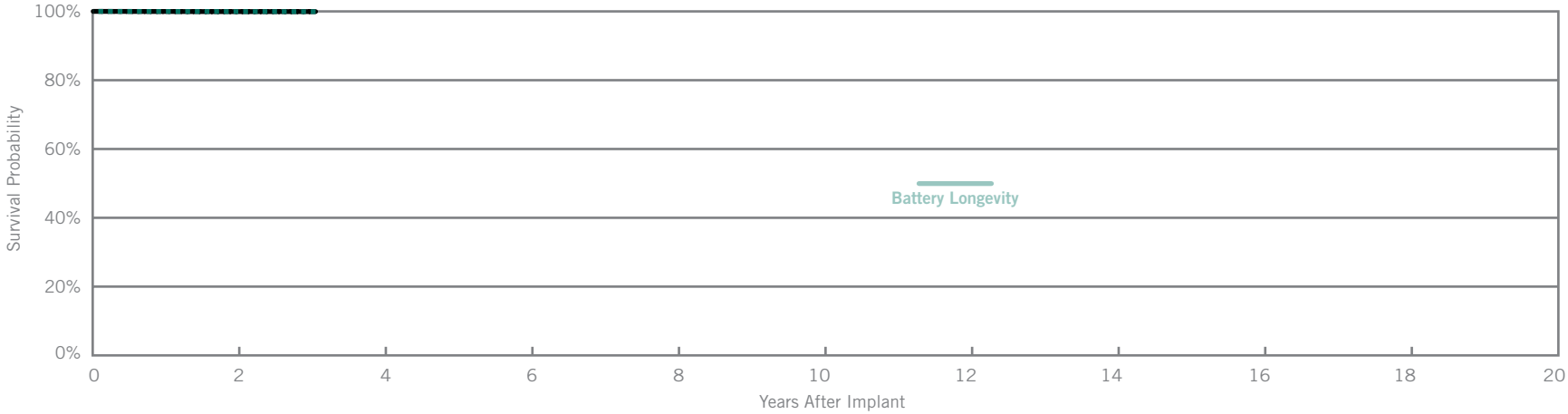
Customer Reported Performance Data

Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	95,600
Estimated Active US Implants	85,292
Estimated Longevity	11.7 Years
Normal Battery Depletion	3
Number of Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	2	<0.00%
Malfunctions w/o Compromised Therapy	17	0.02%
Total	**19**	**0.02%**



Including Normal Battery Depletion .....

Year	**2**	**at 37 months**								
Survival Probability	99.93%	99.92%								
± 1 standard error	0.01%	0.01%								
Sample Size	44600	300								

Excluding Normal Battery Depletion ———

Year	**2**	**at 37 months**								
Survival Probability	99.94%	99.94%								
± 1 standard error	0.01%	0.01%								

SCORE Registry Performance Data

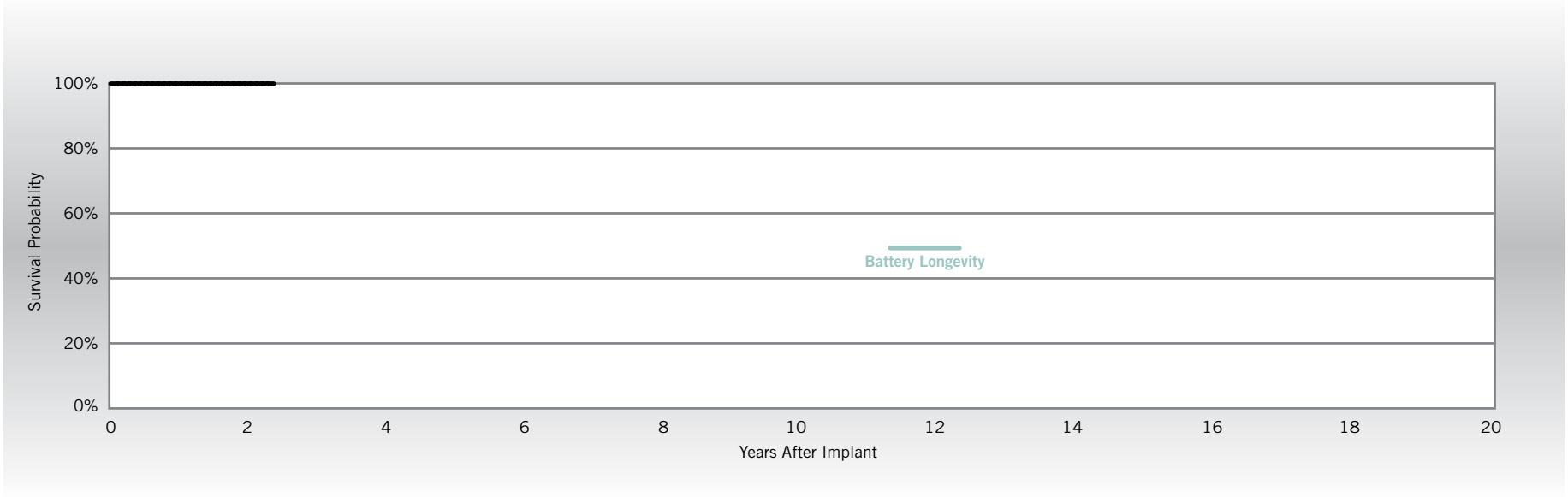
Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,440
Cumulative Months of Follow-up	24,830
Estimated Longevity	11.7 Years

Qualifying Complications	Qty.	Rate
Backup Operation	1	0.07%

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



Year	1	2	at 29 months							
Survival Probability	99.93%	99.93%	99.93%							
± 1 standard error	0.07%	0.07%	0.07%							
Sample Size	1290	700	80							

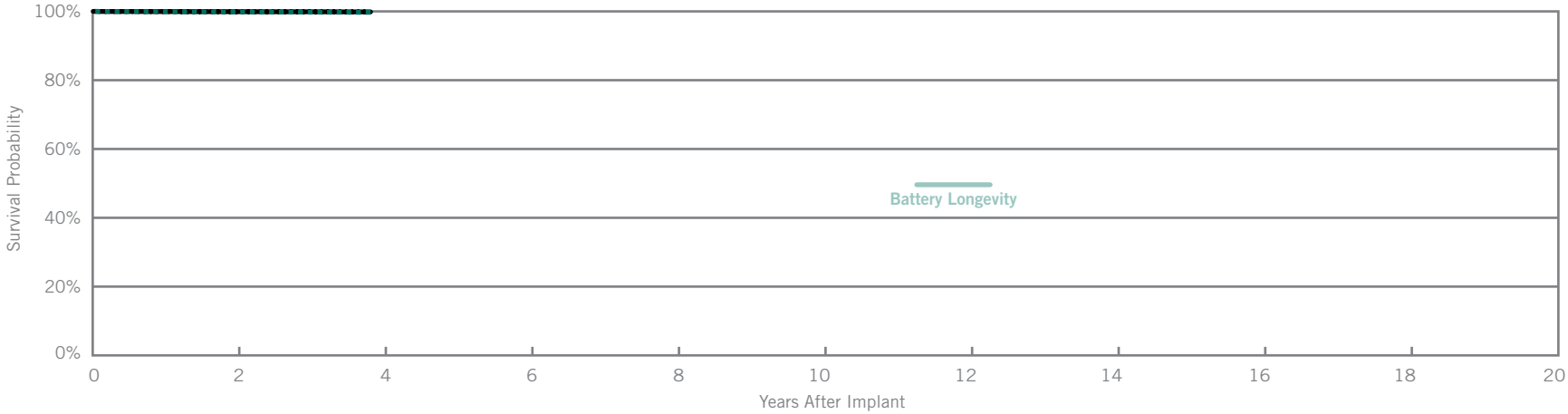
Customer Reported Performance Data

Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	61,805
Estimated Active US Implants	49,378
Estimated Longevity	11.7 Years
Normal Battery Depletion	10
Number of Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	1	<0.01%
Malfunctions w/o Compromised Therapy	25	0.04%
Total	**26**	**0.04%**



Including Normal Battery Depletion .....

Year	**2**	**at 46 months**								
Survival Probability	99.90%	99.73%								
± 1 standard error	0.01%	0.04%								
Sample Size	48400	5500								

Excluding Normal Battery Depletion ———

Year	**2**	**at 46 months**								
Survival Probability	99.91%	99.86%								
± 1 standard error	0.01%	0.02%								

SCORE Registry Performance Data

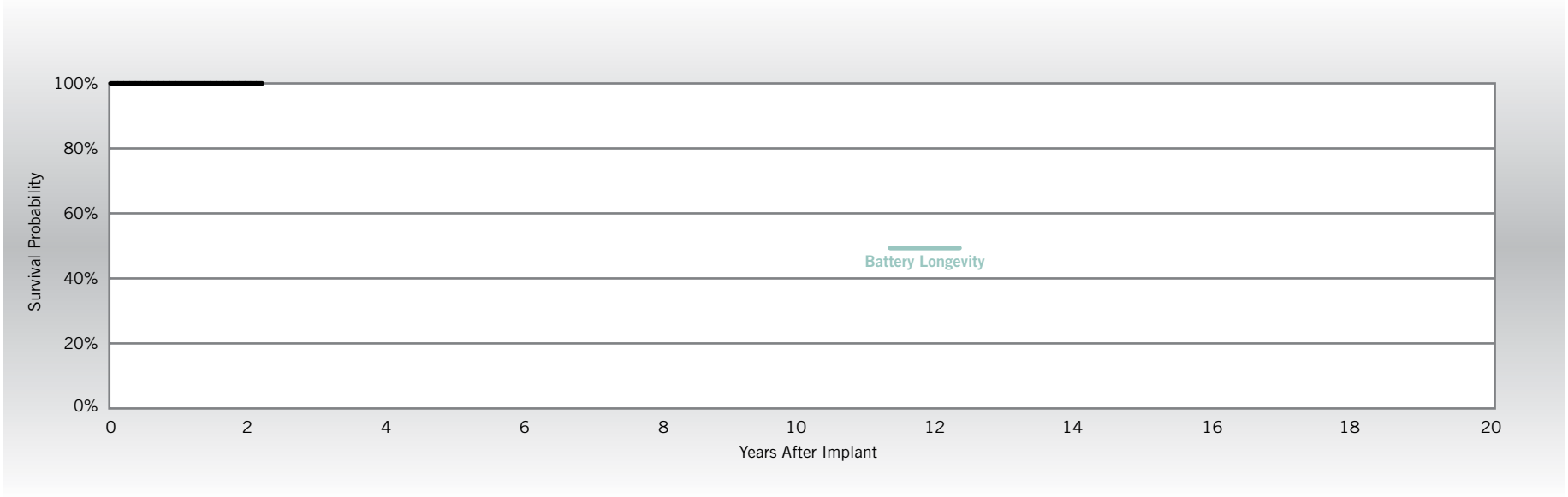
Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	330
Cumulative Months of Follow-up	6,480
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

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



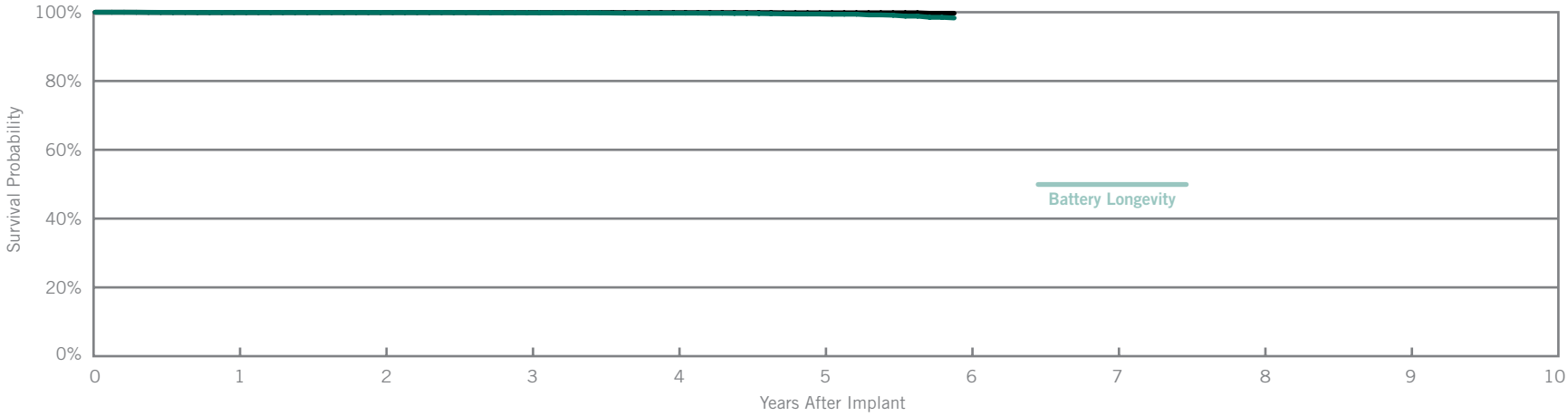
Year	**1**	**2**	**at 27 months**							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	300	190	50							

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

Customer Reported Performance Data

US Regulatory Approval	May 2003
Registered US Implants	16,770
Estimated Active US Implants	10,263
Estimated Longevity	6.9 Years
Normal Battery Depletion	20
Number of Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.92%	99.92%	99.85%	99.73%	99.48%	98.33%				
± 1 standard error	0.02%	0.02%	0.03%	0.05%	0.09%	0.24%				
Sample Size	16600	14200	11700	8500	5200	1200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.92%	99.92%	99.91%	99.88%	99.83%	99.70%				
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.05%	0.10%				

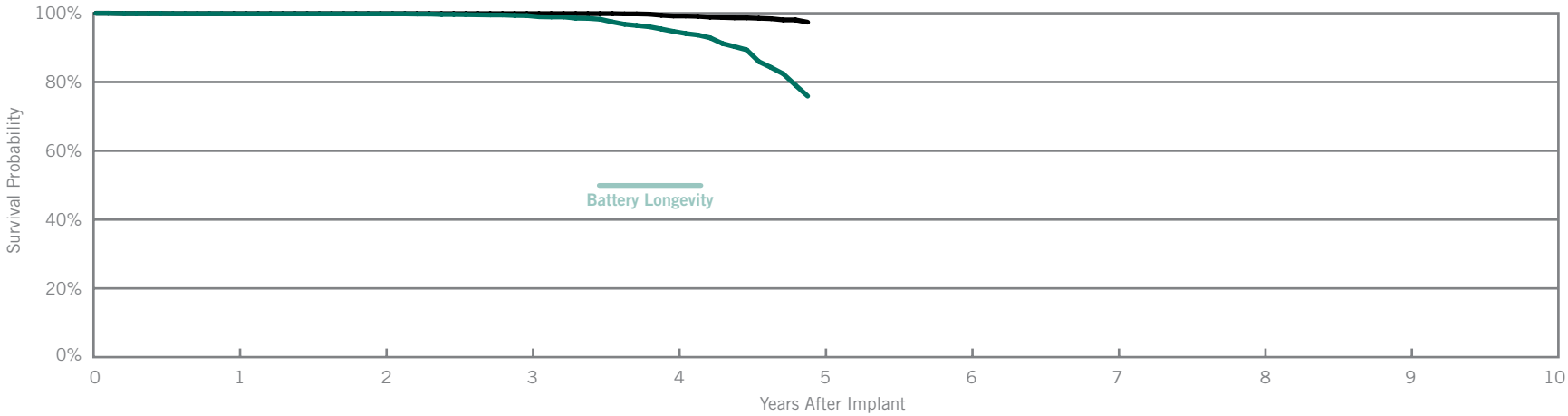
Customer Reported Performance Data

Integrity® ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,825
Estimated Active US Implants	2,346
Estimated Longevity	3.8 Years
Normal Battery Depletion	221
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	26	0.45%
Total	**26**	**0.45%**



Including Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	99.80%	99.80%	99.30%	94.70%	75.91%					
± 1 standard error	0.05%	0.06%	0.12%	0.37%	0.95%					
Sample Size	5800	5000	4300	3300	1000					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	99.87%	99.87%	99.87%	99.19%	97.38%					
± 1 standard error	0.05%	0.05%	0.05%	0.14%	0.31%					

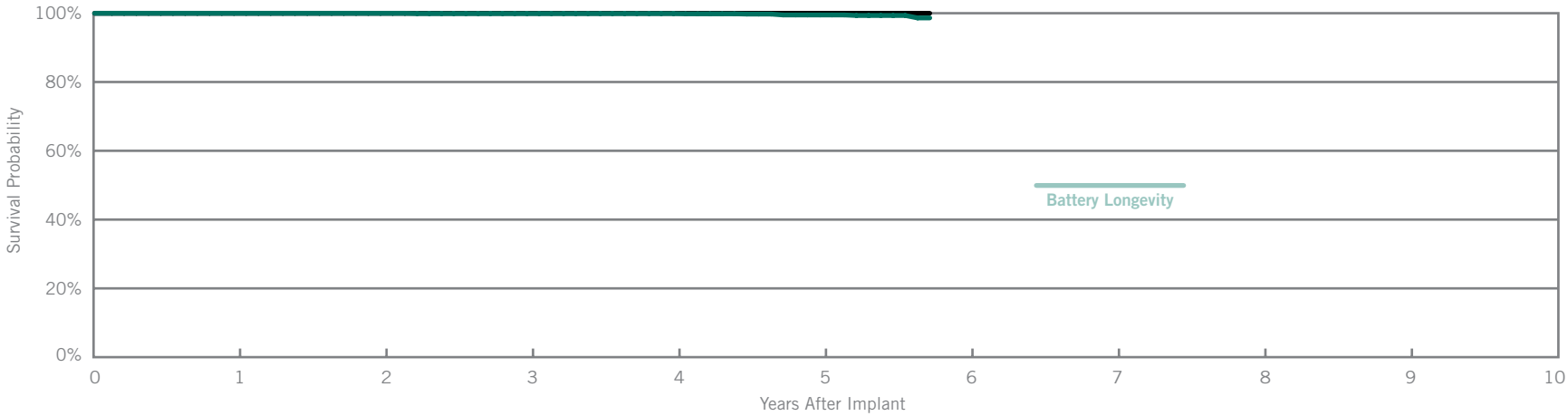
Customer Reported Performance Data

Integrity® ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,003
Estimated Active US Implants	5,201
Estimated Longevity	6.9 Years
Normal Battery Depletion	10
Number of Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.98%	99.98%	99.90%	99.90%	99.49%	98.63%				
± 1 standard error	0.02%	0.02%	0.04%	0.04%	0.14%	0.36%				
Sample Size	8000	7100	6000	4300	2500	700				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.98%	99.98%	99.98%	99.98%	99.98%	99.98%				
± 1 standard error	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%				

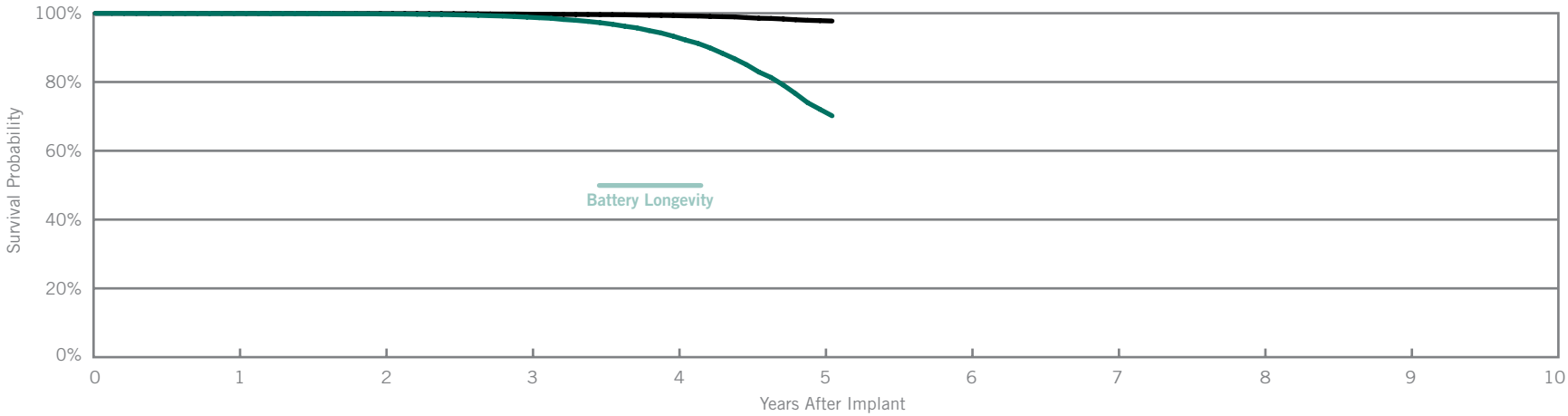
Customer Reported Performance Data

Integrity® ADx DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	53,405
Estimated Active US Implants	21,291
Estimated Longevity	3.8 Years
Normal Battery Depletion	2,075
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	5	0.01%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	174	0.33%
Total (0 related to Advisory)	**179**	**0.34%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.92%	99.78%	98.86%	93.30%	72.07%	70.17%				
± 1 standard error	0.01%	0.02%	0.05%	0.14%	0.36%	0.39%				
Sample Size	52700	45200	39100	31300	18100	4800				

Excluding Normal Battery Depletion

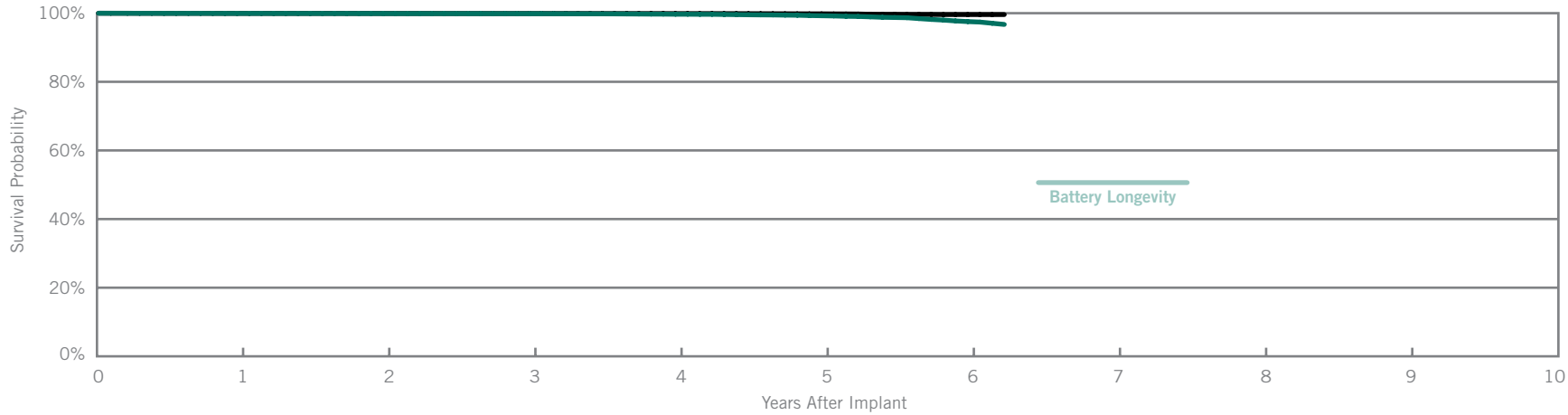
Year	1	2	3	4	5	at 61 months				
Survival Probability	99.94%	99.90%	99.72%	99.32%	97.84%	97.73%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.11%	0.12%				

Customer Reported Performance Data

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

US Regulatory Approval	March 2003
Registered US Implants	65,462
Estimated Active US Implants	45,016
Estimated Longevity	6.9 Years
Normal Battery Depletion	107
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	<0.01%
Malfunctions w/o Compromised Therapy (0 related to Advisory)	41	0.06%
Total (0 related to Advisory)	**43**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.94%	99.90%	99.86%	99.69%	99.25%	97.55%	96.72%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.05%	0.16%	0.21%			
Sample Size	64300	55400	46900	36700	22700	9200	2500			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.94%	99.91%	99.90%	99.88%	99.81%	99.60%	99.60%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.05%	0.05%			

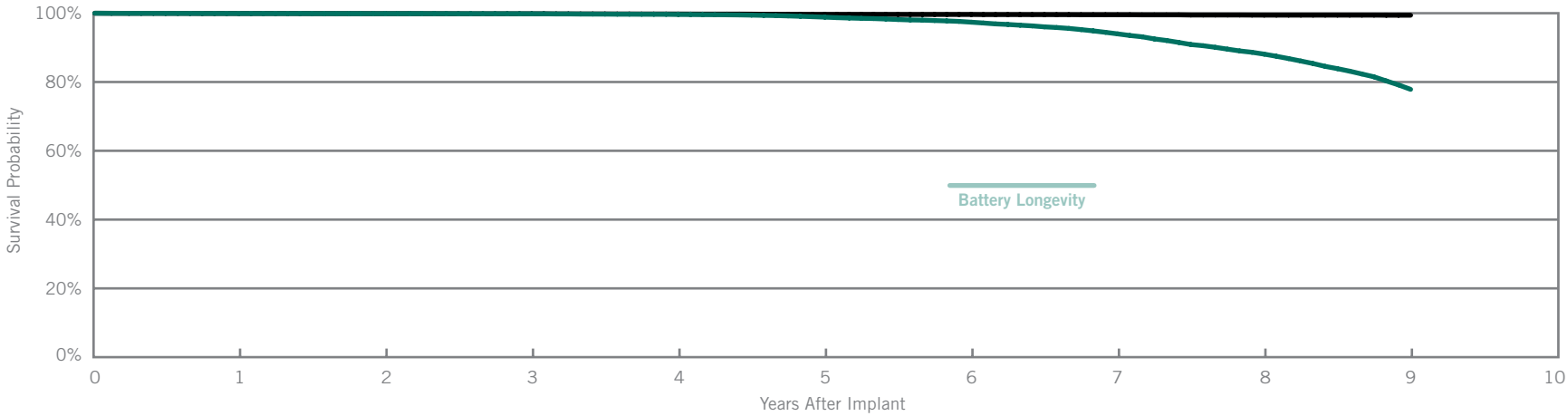
Customer Reported Performance Data

Integrity® AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,531
Estimated Active US Implants	13,361
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,354
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	6	0.01%
Malfunctions w/o Compromised Therapy	67	0.14%
Total	**73**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9
Survival Probability	99.93%	99.88%	99.82%	99.64%	98.85%	97.39%	93.99%	88.10%	77.86%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.06%	0.09%	0.15%	0.23%	0.39%
Sample Size	47100	42000	38500	35000	31400	27400	22800	17000	8900

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9
Survival Probability	99.92%	99.88%	99.84%	99.77%	99.65%	99.63%	99.55%	99.44%	99.41%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.03%	0.04%	0.05%	0.05%

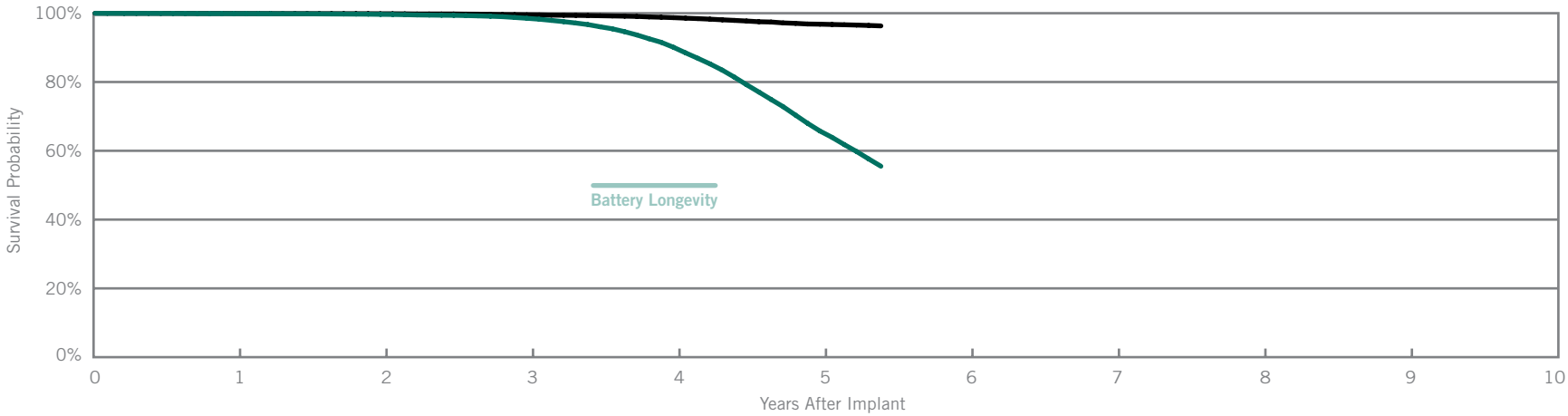
Customer Reported Performance Data

Identity®

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,399
Estimated Active US Implants	10,053
Estimated Longevity	3.8 Years
Normal Battery Depletion	4,131
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	5	0.01%
Malfunctions w/o Compromised Therapy (20 related to Advisory)	363	0.62%
Total (20 related to Advisory)	**368**	**0.63%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.88%	99.66%	98.52%	90.10%	65.76%	55.51%				
± 1 standard error	0.01%	0.02%	0.05%	0.15%	0.31%	0.39%				
Sample Size	57900	50500	44900	38300	25900	4600				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 65 months				
Survival Probability	99.91%	99.84%	99.54%	98.71%	96.81%	96.31%				
± 1 standard error	0.01%	0.02%	0.03%	0.06%	0.11%	0.13%				

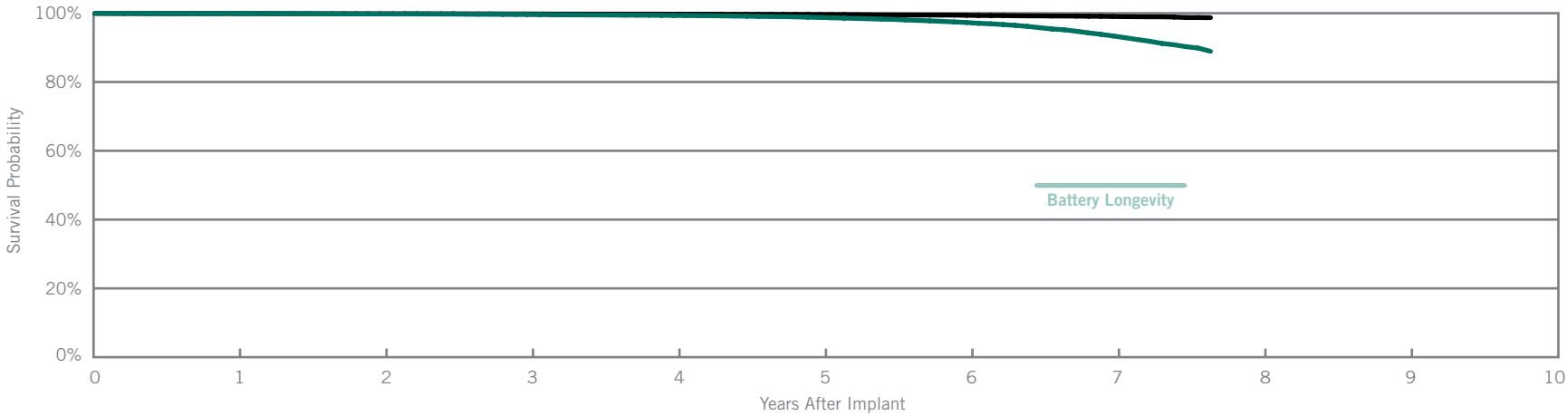
Customer Reported Performance Data

Identity® XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,438
Estimated Active US Implants	25,777
Estimated Longevity	6.9 Years
Normal Battery Depletion	582
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	10	0.02%
Malfunctions w/o Compromised Therapy (7 related to Advisory)	108	0.21%
Total (7 related to Advisory)	**118**	**0.23%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 92 months		
Survival Probability	99.91%	99.79%	99.63%	99.35%	98.77%	97.30%	93.39%	88.92%		
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.06%	0.10%	0.18%	0.29%		
Sample Size	51200	46400	42300	37400	31200	24000	15700	4000		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 92 months		
Survival Probability	99.91%	99.83%	99.78%	99.71%	99.59%	99.40%	99.05%	98.71%		
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.04%	0.06%	0.09%		

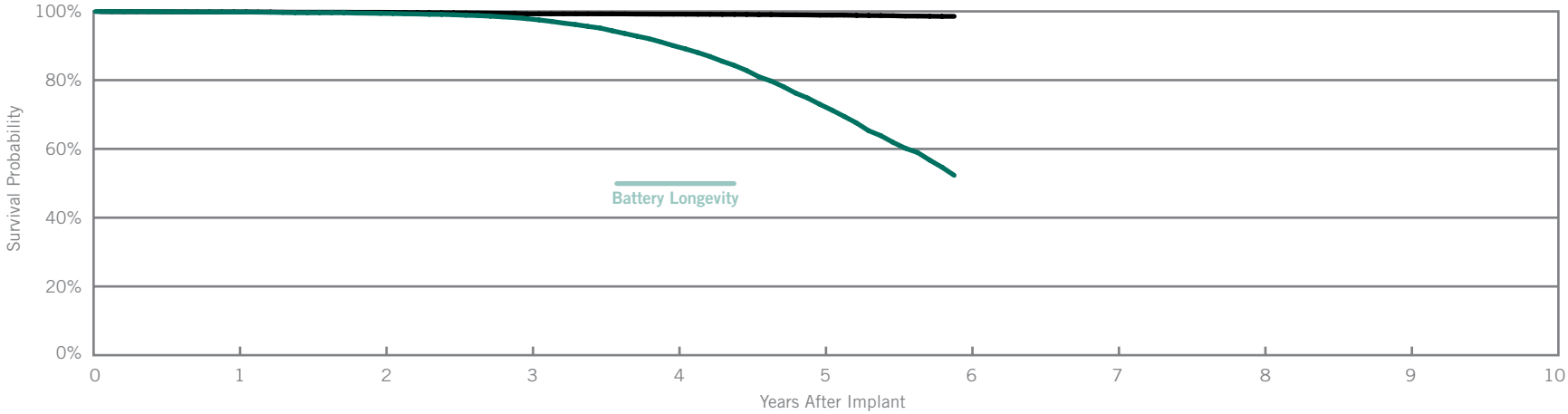
Customer Reported Performance Data

Integrity® µ DR

Model 5336

US Regulatory Approval	December 2000
Registered US Implants	29,377
Estimated Active US Implants	2,639
Estimated Longevity	4.0 Years
Normal Battery Depletion	2,102
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	8	0.03%
Malfunctions w/o Compromised Therapy	78	0.27%
Total	**86**	**0.29%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 71 months				
Survival Probability	99.82%	99.42%	97.88%	90.02%	72.96%	52.32%				
± 1 standard error	0.02%	0.05%	0.09%	0.21%	0.38%	0.61%				
Sample Size	29200	25100	22200	18900	13500	1600				

Excluding Normal Battery Depletion

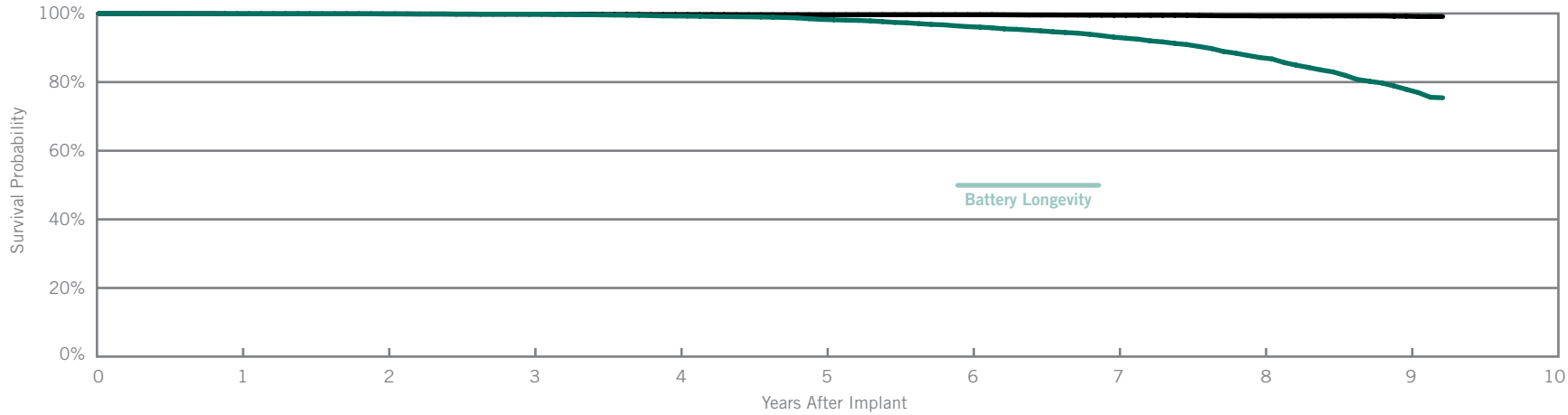
Year	1	2	3	4	5	at 71 months				
Survival Probability	99.85%	99.73%	99.29%	99.20%	98.92%	98.56%				
± 1 standard error	0.02%	0.03%	0.05%	0.06%	0.08%	0.12%				

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,865
Estimated Active US Implants	4,417
Estimated Longevity	6.3 Years
Normal Battery Depletion	536
Number of Advisories	None

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy	3	0.01%
Malfunctions w/o Compromised Therapy	37	0.17%
Total	**40**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.91%	99.87%	99.79%	99.27%	98.26%	96.17%	93.10%	87.15%	77.90%	75.43%
± 1 standard error	0.02%	0.02%	0.03%	0.07%	0.11%	0.17%	0.25%	0.39%	0.61%	0.72%
Sample Size	21800	18800	16800	15000	13100	11100	8900	6200	3400	1100

Excluding Normal Battery Depletion

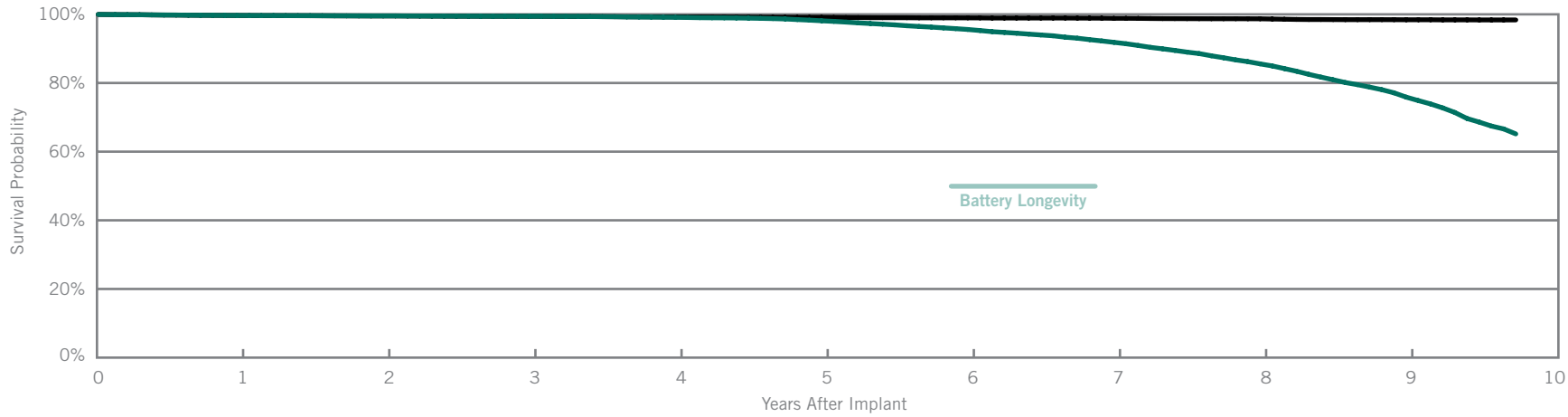
Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.91%	99.87%	99.79%	99.66%	99.63%	99.63%	99.47%	99.28%	99.20%	99.11%
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.05%	0.05%	0.06%	0.08%	0.11%	0.12%

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	65,665
Estimated Active US Implants	11,026
Estimated Longevity	6.3 Years
Normal Battery Depletion	2,326
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	15	0.02%
Malfunctions w/o Compromised Therapy (65 related to Advisory)	228	0.35%
Total (65 related to Advisory)	**243**	**0.37%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.67%	99.55%	99.44%	99.13%	98.12%	95.59%	91.84%	85.57%	75.88%	65.17%
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.06%	0.10%	0.15%	0.22%	0.32%	0.45%
Sample Size	65200	57500	52100	47000	41800	36200	29400	21400	13200	3200

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.66%	99.53%	99.42%	99.27%	99.14%	98.97%	98.85%	98.70%	98.42%	98.37%
± 1 standard error	0.02%	0.03%	0.04%	0.04%	0.04%	0.05%	0.05%	0.06%	0.07%	0.08%

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®	99.91%									
PM2110	Accent®*										
5820	Zephyr® DR	99.95%	99.95%	99.83%							
5810	Victory® DR	99.97%	99.88%	99.20%							
5826	Zephyr® XL DR	99.96%	99.93%	99.92%							
5816	Victory® XL DR	99.95%	99.90%	99.85%							
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	99.92%	99.92%	99.85%	99.73%	99.48%					
5360	Integrity® ADx DR	99.80%	99.80%	99.30%	94.70%						
5366	Integrity® ADx XL DR	99.98%	99.98%	99.90%	99.90%	99.49%					
5380	Identity ADx® DR	99.92%	99.78%	98.86%	93.30%	72.07%					
5386/5286	Identity ADx® XL DR/DC	99.94%	99.90%	99.86%	99.69%	99.25%	97.55%				
5342/5346	Integrity® AFx DR	99.93%	99.88%	99.82%	99.64%	98.85%	97.39%	93.99%	88.10%	77.86%	
5370	Identity®	99.88%	99.66%	98.52%	90.10%	65.76%					
5376	Identity® XL	99.91%	99.79%	99.63%	99.35%	98.77%	97.30%	93.39%			
5336	Integrity® µ DR	99.82%	99.42%	97.88%	90.02%	72.96%					
5326/5226	Entity™ DR/DC	99.91%	99.87%	99.79%	99.27%	98.26%	96.17%	93.10%	87.15%	77.90%	
5330/5331/5230	Affinity® DR/DC	99.67%	99.55%	99.44%	99.13%	98.12%	95.59%	91.84%	85.57%	75.88%	

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

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2210	Accent®	99.91%									
PM2110	Accent®*										
5820	Zephyr® DR	99.95%	99.95%	99.95%							
5810	Victory® DR	99.97%	99.89%	99.85%							
5826	Zephyr® XL DR	99.97%	99.94%	99.94%							
5816	Victory® XL DR	99.95%	99.91%	99.89%							
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	99.92%	99.92%	99.91%	99.88%	99.83%					
5360	Integrity® ADx DR	99.87%	99.87%	99.87%	99.19%						
5366	Integrity® ADx XL DR	99.98%	99.98%	99.98%	99.98%	99.98%					
5380	Identity ADx® DR	99.94%	99.90%	99.72%	99.32%	97.84%					
5386/5286	Identity ADx® XL DR/DC	99.94%	99.91%	99.90%	99.88%	99.81%	99.60%				
5342/5346	Integrity® AFx DR	99.92%	99.88%	99.84%	99.77%	99.65%	99.63%	99.55%	99.44%	99.41%	
5370	Identity®	99.91%	99.84%	99.54%	98.71%	96.81%					
5376	Identity® XL	99.91%	99.83%	99.78%	99.71%	99.59%	99.40%	99.05%			
5336	Integrity® µ DR	99.85%	99.73%	99.29%	99.20%	98.92%					
5326/5226	Entity™ DR/DC	99.91%	99.87%	99.79%	99.66%	99.63%	99.63%	99.47%	99.28%	99.20%	
5330/5331/5230	Affinity® DR/DC	99.66%	99.53%	99.42%	99.27%	99.14%	98.97%	98.85%	98.70%	98.42%	

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent®	Jul-09	33883	33085	1	<0.01%	1	<0.01%	0	0.00%	4	0.01%	5	0.01%
PM2110	Accent®	Jul-09	2739	2704	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5820	Zephyr® DR	Mar-07	28382	24204	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	4	0.01%
5810	Victory® DR	Dec-05	25873	18025	0	0.00%	0	0.00%	1	<0.01%	14	0.05%	14	0.05%
5826	Zephyr® XL DR	Mar-07	95600	85292	0	0.00%	2	<0.01%	1	<0.01%	17	0.02%	19	0.02%
5816	Victory® XL DR	Dec-05	61805	49378	0	0.00%	1	<0.01%	0	0.00%	25	0.04%	26	0.04%
5356/5357/5256	Verity ADx® XL DR/ DR(M/S) / DC	May-03	16770	10263	0	0.00%	0	0.00%	1	0.01%	9	0.05%	9	0.05%
5360	Integrity® ADx DR	May-03	5825	2346	0	0.00%	0	0.00%	0	0.00%	26	0.45%	26	0.45%
5366	Integrity® ADx XL DR	May-03	8003	5201	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%
5380	Identity ADx® DR	Mar-03	53405	21291	1	<0.01%	5	0.01%	6	0.01%	174	0.33%	179	0.34%
5386/5286	Identity ADx® XL DR/DC	Mar-03	65462	45016	0	0.00%	2	<0.01%	0	0.00%	41	0.06%	43	0.07%
5342/5346	Integrity® AFx DR	Apr-00/Jul-01	47531	13361	0	0.00%	6	0.01%	0	0.00%	67	0.14%	73	0.15%
5370	Identity®	Nov-01	58399	10053	0	0.00%	5	0.01%	9	0.02%	363	0.62%	368	0.63%
5376	Identity® XL	Nov-01	51438	25777	1	<0.01%	10	0.02%	1	<0.01%	108	0.21%	118	0.23%
5336	Integrity® µ DR	Dec-00	29377	2639	0	0.00%	8	0.03%	1	<0.01%	78	0.27%	86	0.29%
5326/5226	Entity™ DR/DC	Jun-99	21865	4417	0	0.00%	3	0.01%	1	<0.01%	37	0.17%	40	0.18%
5330/5331/5230	Affinity® DR/DC	Jan-99/Jun-99	65665	11026	0	0.00%	15	0.02%	0	0.00%	228	0.35%	243	0.37%

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy					
			Premature Battery Depletion		Total*		Premature Battery Depletion		Total*		Total Malfunctions*	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	490	2830	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5820	220	3040	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5826	1440	24830	0	0.00%	0	0.00%	0	0.00%	1	0.07%	1	0.07%
5816	330	6480	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Backup Operation		Total	
			Qty.	Rate	Qty.	Rate
PM2210	490	2830	0	0.00%	0	0.00%
5820	220	3040	0	0.00%	0	0.00%
5826	1440	24830	1	0.07%	1	0.07%
5816	330	6480	0	0.00%	0	0.00%

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

Pacemakers

Single-Chamber

St. Jude Medical™
More control. Less risk.

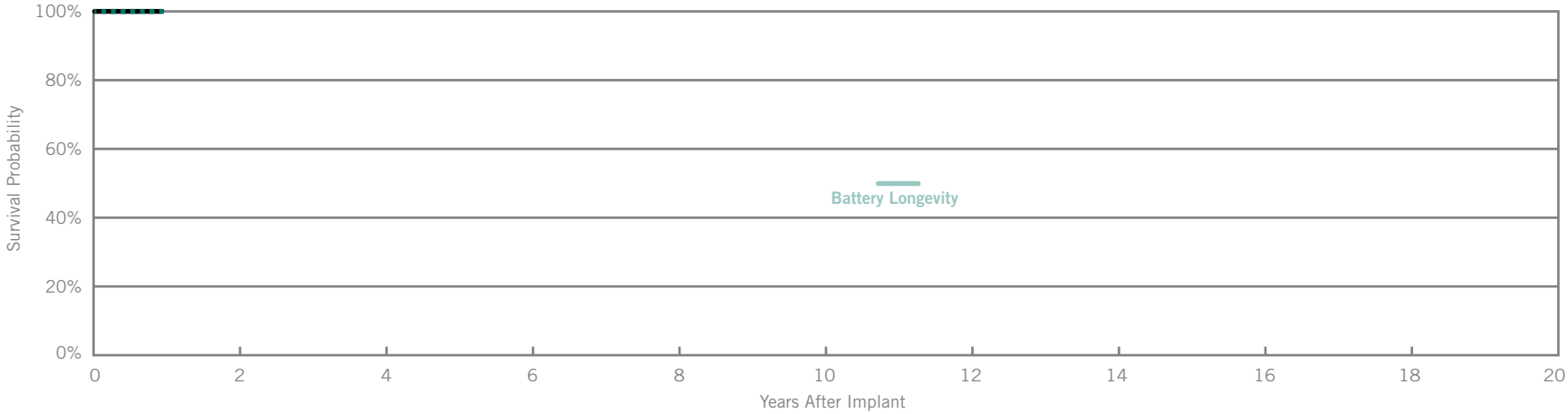
Customer Reported Performance Data

Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	5,207
Estimated Active US Implants	4,987
Estimated Longevity	10.9 Years
Normal Battery Depletion	0
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	at 11 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	200										

Excluding Normal Battery Depletion ———

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

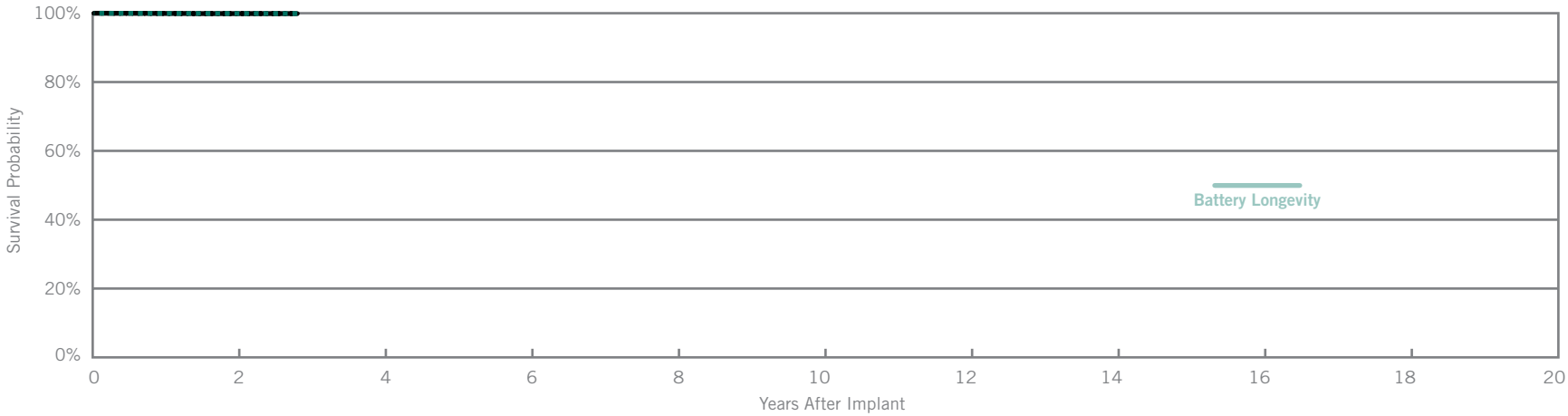
Customer Reported Performance Data

Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	16,862
Estimated Active US Implants	14,031
Estimated Longevity	15.8 Years
Normal Battery Depletion	0
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	6	0.04%
Total	**6**	**0.04%**



Including Normal Battery Depletion .....

Year	2	at 34 months								
Survival Probability	99.89%	99.89%								
± 1 standard error	0.03%	0.03%								
Sample Size	6900	300								

Excluding Normal Battery Depletion ———

Year	2	at 34 months								
Survival Probability	99.89%	99.89%								
± 1 standard error	0.03%	0.03%								

SCORE Registry Performance Data

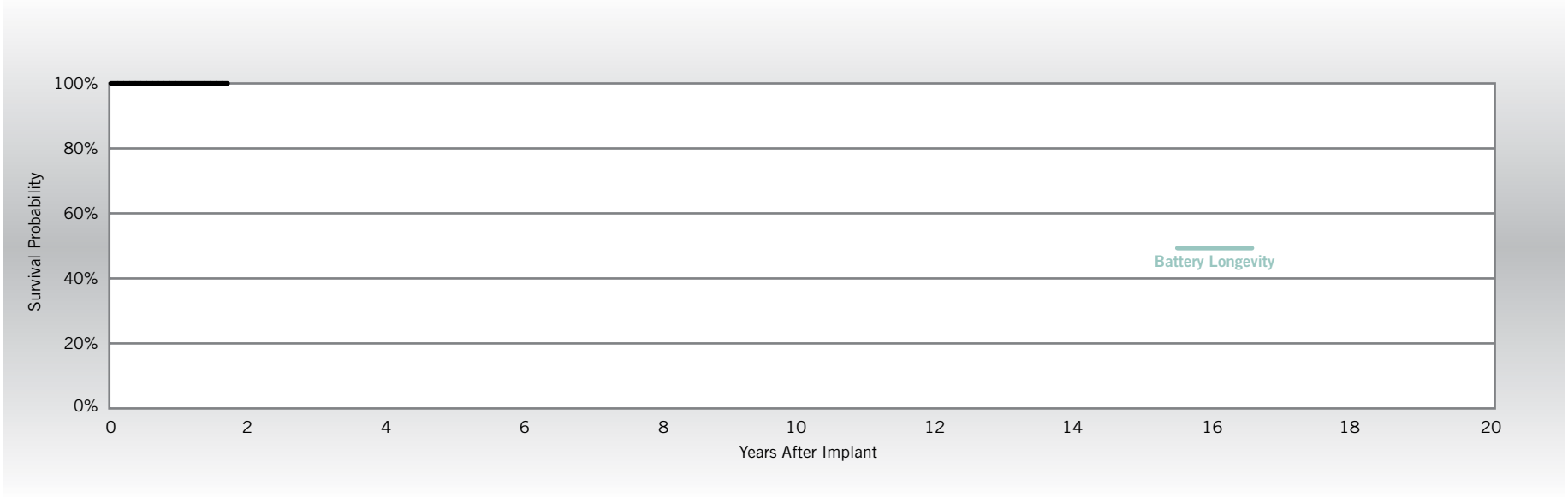
Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	210
Cumulative Months of Follow-up	3,420
Estimated Longevity	15.8 Years

Qualifying Complications
None Reported

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



Year	**1**	**at 21 months**								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	190	60								

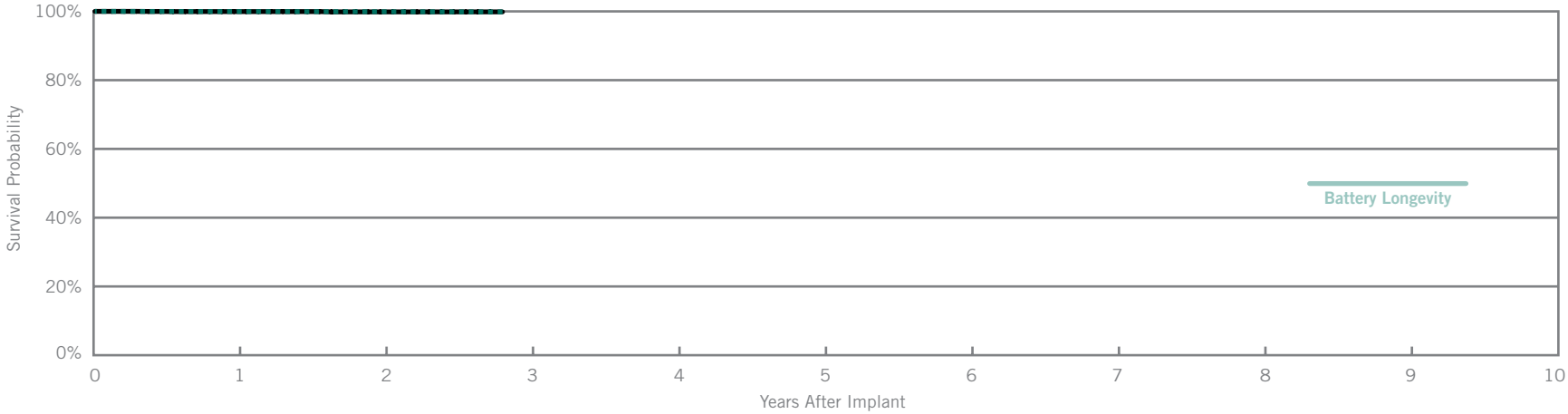
Customer Reported Performance Data

Zephyr® SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	8,613
Estimated Active US Implants	6,786
Estimated Longevity	8.8 Years
Normal Battery Depletion	0
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	1	2	at 34 months							
Survival Probability	99.94%	99.86%	99.86%							
± 1 standard error	0.03%	0.07%	0.07%							
Sample Size	7300	3200	300							

Excluding Normal Battery Depletion ———

Year	1	2	at 34 months							
Survival Probability	99.94%	99.86%	99.86%							
± 1 standard error	0.03%	0.07%	0.07%							

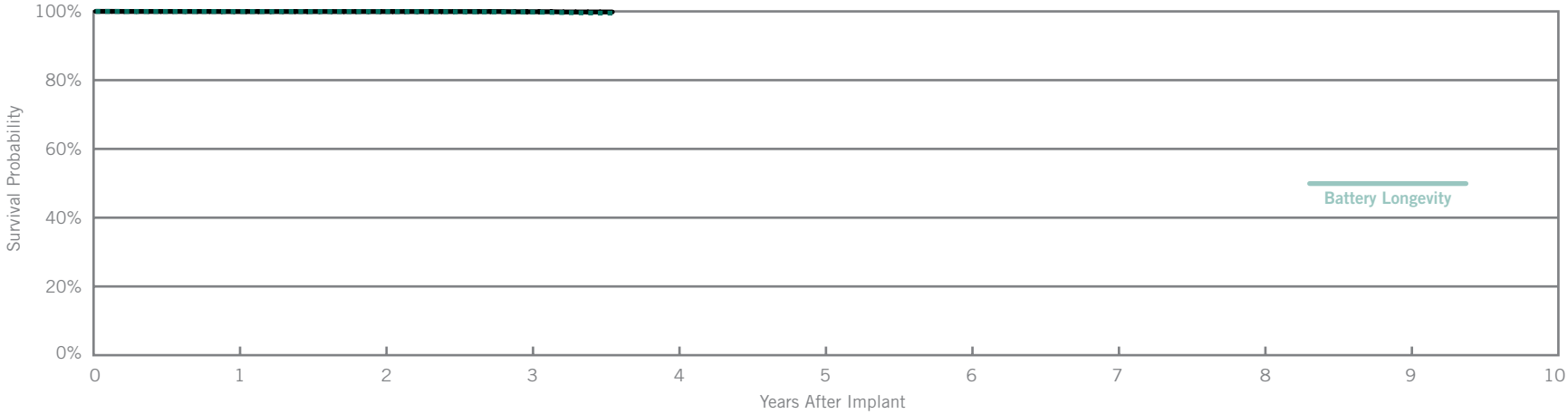
Customer Reported Performance Data

Victory® SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,323
Estimated Active US Implants	8,693
Estimated Longevity	8.8 Years
Normal Battery Depletion	4
Number of Advisories	None

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



Including Normal Battery Depletion .....

Year	1	2	3	at 43 months						
Survival Probability	99.95%	99.95%	99.83%	99.50%						
± 1 standard error	0.02%	0.02%	0.06%	0.13%						
Sample Size	12900	9200	5800	1600						

Excluding Normal Battery Depletion ———

Year	1	2	3	at 43 months						
Survival Probability	99.95%	99.95%	99.90%	99.83%						
± 1 standard error	0.02%	0.02%	0.04%	0.07%						

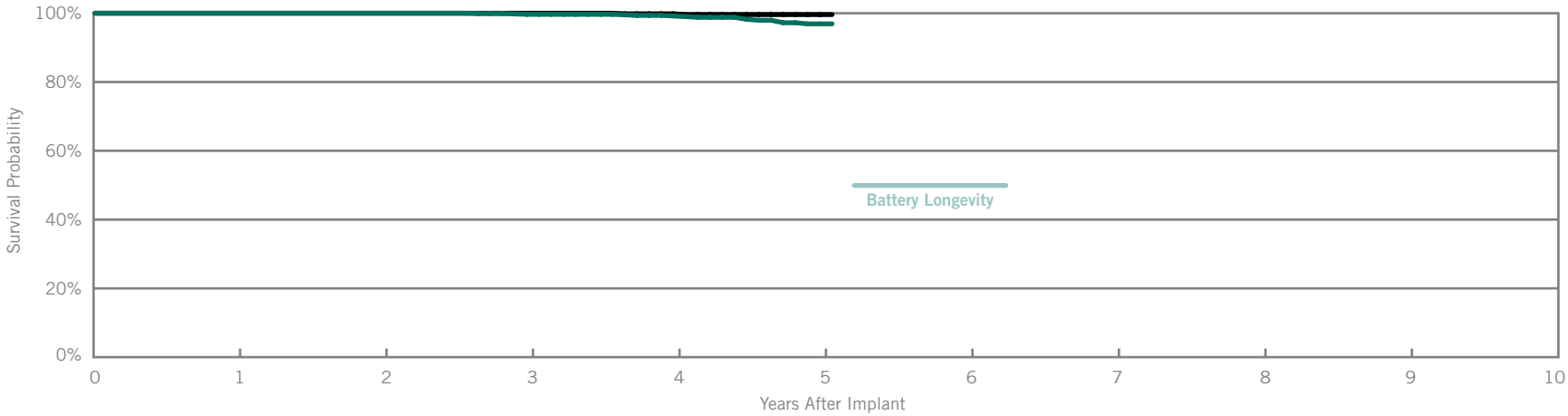
Customer Reported Performance Data

Integrity® ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,397
Estimated Active US Implants	1,381
Estimated Longevity	5.7 Years
Normal Battery Depletion	21
Number of Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	100.00%	100.00%	99.67%	99.19%	96.90%	96.90%				
± 1 standard error	0.00%	0.00%	0.11%	0.20%	0.59%	0.59%				
Sample Size	3400	2600	2100	1500	900	500				

Excluding Normal Battery Depletion

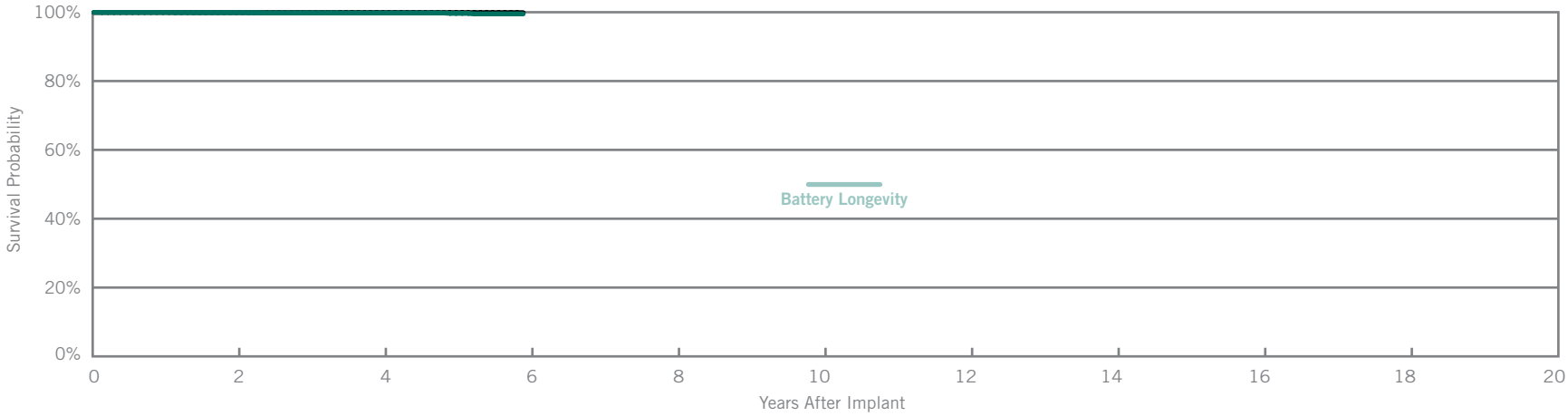
Year	1	2	3	4	5	at 61 months				
Survival Probability	100.00%	100.00%	100.00%	99.83%	99.60%	99.60%				
± 1 standard error	0.00%	0.00%	0.00%	0.12%	0.20%	0.20%				

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

Customer Reported Performance Data

US Regulatory Approval	May 2003
Registered US Implants	13,979
Estimated Active US Implants	7,711
Estimated Longevity	10.2 Years
Normal Battery Depletion	6
Number of Advisories	None

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



Including Normal Battery Depletion

Year	2	4	at 71 months							
Survival Probability	99.89%	99.77%	99.51%							
± 1 standard error	0.03%	0.05%	0.14%							
Sample Size	10500	5100	600							

Excluding Normal Battery Depletion

Year	2	4	at 71 months							
Survival Probability	99.90%	99.88%	99.88%							
± 1 standard error	0.03%	0.03%	0.03%							

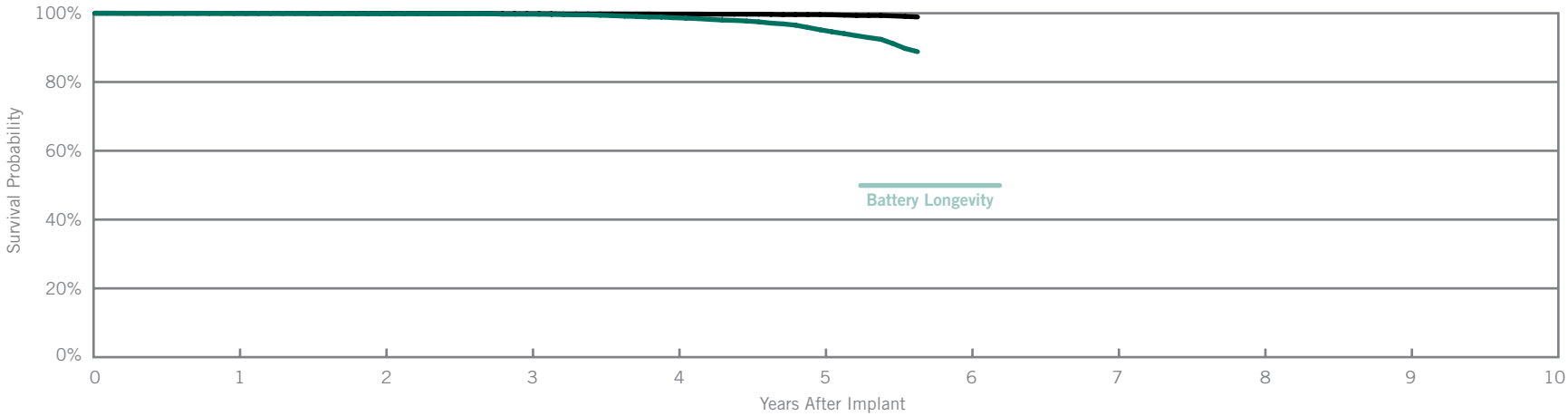
Customer Reported Performance Data

Integrity® ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,200
Estimated Active US Implants	9,309
Estimated Longevity	5.7 Years
Normal Battery Depletion	139
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	23	0.11%
Total	**23**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.92%	99.87%	99.72%	98.69%	95.20%	88.82%				
± 1 standard error	0.02%	0.03%	0.05%	0.11%	0.29%	0.65%				
Sample Size	19800	15300	12000	8700	4900	1100				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.98%	99.95%	99.88%	99.75%	99.60%	98.91%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.08%	0.19%				

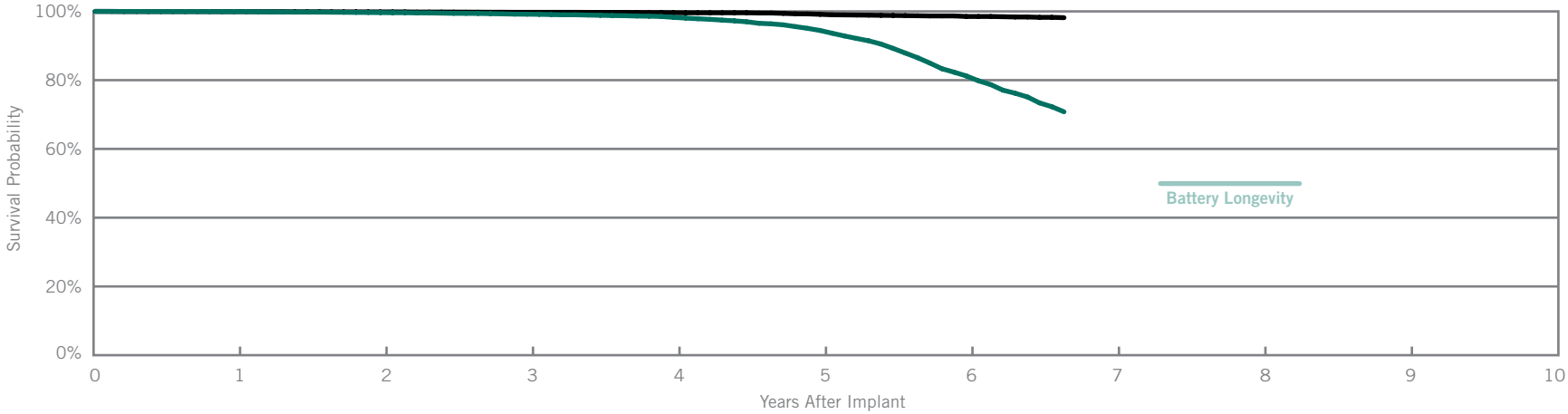
Customer Reported Performance Data

Identity® SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,917
Estimated Active US Implants	5,590
Estimated Longevity	7.8 Years
Normal Battery Depletion	530
Number of Advisories (see pages 220-227)	One

Malfunctions	**Qty.**	**Rate**
Malfunctions w/ Compromised Therapy (0 related to Advisory)	2	0.01%
Malfunctions w/o Compromised Therapy (1 related to Advisory)	53	0.24%
Total (1 related to Advisory)	**55**	**0.25%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.92%	99.65%	99.18%	98.26%	94.46%	81.22%	70.79%			
± 1 standard error	0.02%	0.04%	0.07%	0.11%	0.23%	0.53%	0.78%			
Sample Size	21800	17500	14600	11900	8900	5600	1100			

Excluding Normal Battery Depletion

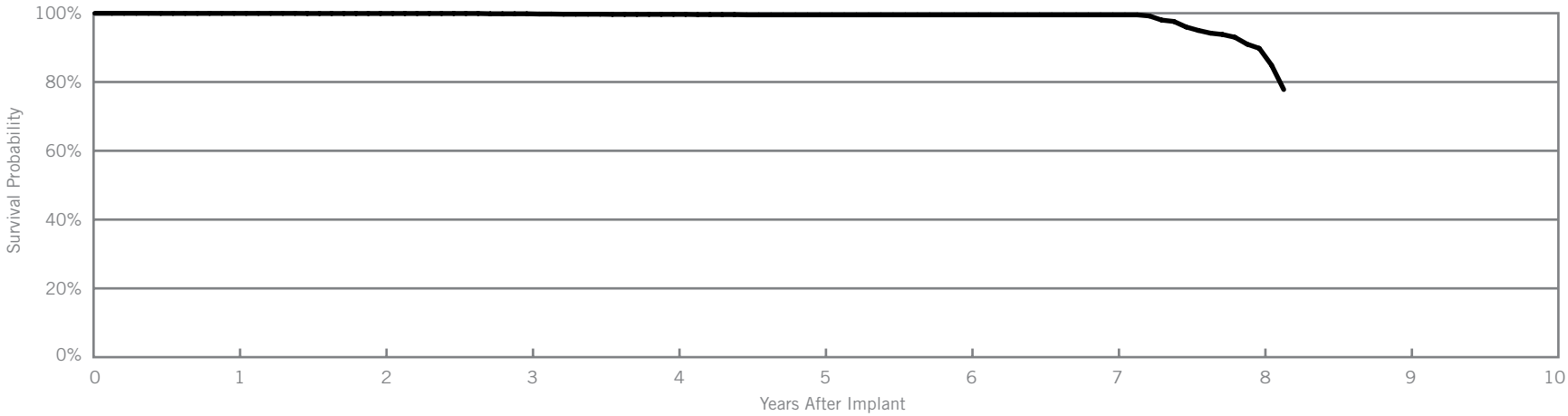
Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.94%	99.85%	99.73%	99.62%	99.15%	98.52%	98.17%			
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.09%	0.14%	0.19%			

Customer Reported Performance Data

Microny®

Models 2425T, 2525T & 2535K

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



Year	1	2	3	4	5	6	7	8	at 98 months	
Survival Probability	99.95%	99.92%	99.84%	99.66%	99.52%	99.52%	99.52%	89.78%	77.81%	
± 1 standard error	0.03%	0.04%	0.07%	0.12%	0.15%	0.15%	0.15%	1.36%	2.23%	
Sample Size	6300	4100	3100	2200	1500	1000	700	400	200	

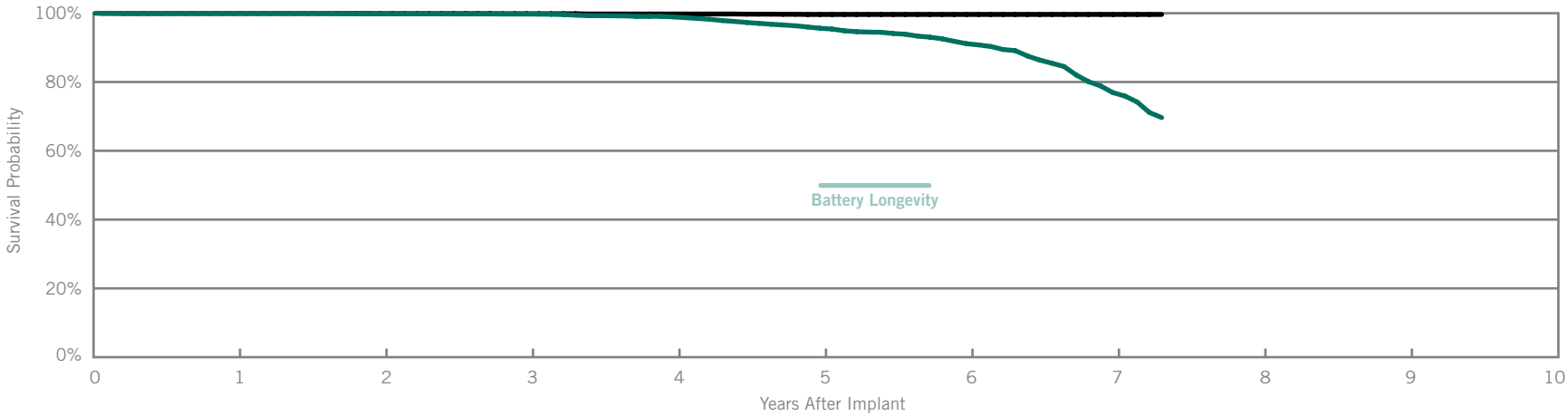
Customer Reported Performance Data

Integrity® µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	11,976
Estimated Active US Implants	1,528
Estimated Longevity	5.3 Years
Normal Battery Depletion	314
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	11	0.09%
Total	**11**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.94%	99.80%	99.75%	98.92%	95.63%	91.14%	76.92%	69.65%		
± 1 standard error	0.02%	0.04%	0.05%	0.12%	0.28%	0.43%	0.86%	1.12%		
Sample Size	11900	9400	7800	6500	5200	3800	2400	600		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.94%	99.88%	99.85%	99.77%	99.63%	99.63%	99.63%	99.63%		
± 1 standard error	0.02%	0.03%	0.04%	0.06%	0.08%	0.08%	0.08%	0.08%		

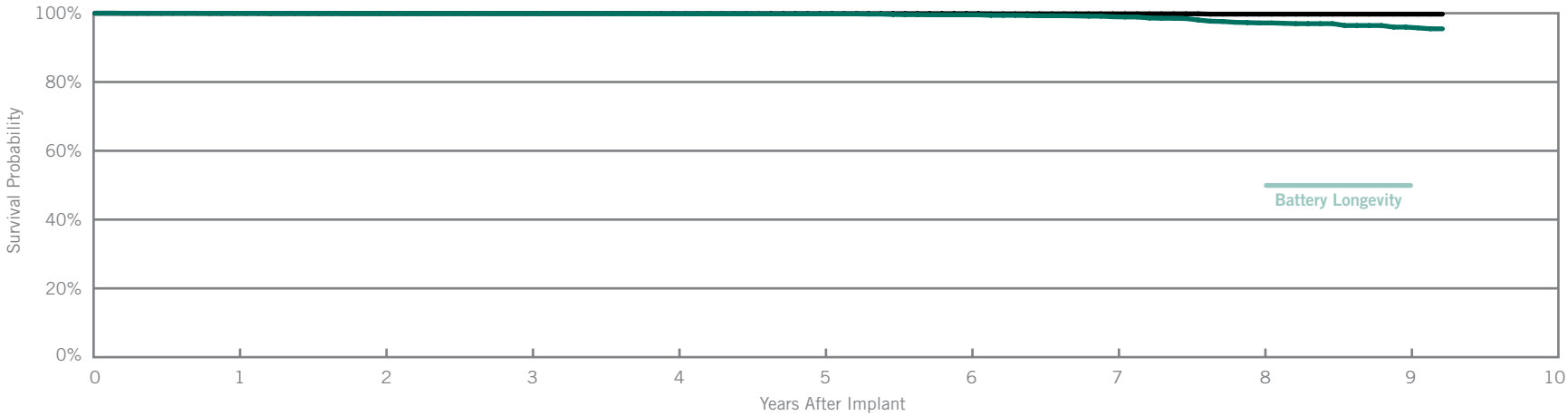
Customer Reported Performance Data

Integrity® SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,509
Estimated Active US Implants	2,740
Estimated Longevity	8.6 Years
Normal Battery Depletion	42
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	1	0.01%
Malfunctions w/o Compromised Therapy	5	0.05%
Total	**6**	**0.06%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.96%	99.91%	99.91%	99.84%	99.80%	99.53%	98.97%	97.17%	95.96%	95.47%
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.06%	0.10%	0.15%	0.13%	0.43%	0.50%
Sample Size	10500	8600	7400	6400	5300	4400	3500	2600	1600	700

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.96%	99.91%	99.91%	99.87%	99.87%	99.87%	99.82%	99.73%	99.73%	99.73%
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.04%	0.04%	0.06%	0.08%	0.08%	0.08%

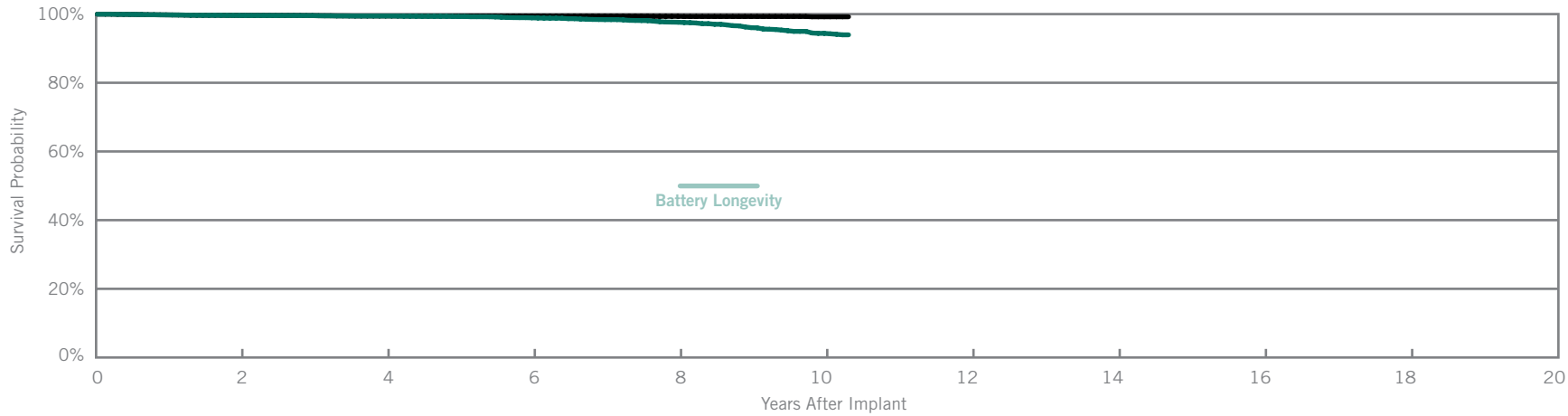
Customer Reported Performance Data

Affinity® SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,708
Estimated Active US Implants	5,504
Estimated Longevity	8.6 Years
Normal Battery Depletion	127
Number of Advisories (see pages 220-227)	One

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy (0 related to Advisory)	4	0.01%
Malfunctions w/o Compromised Therapy (17 related to Advisory)	55	0.19%
Total (17 related to Advisory)	**59**	**0.21%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 124 months				
Survival Probability	99.62%	99.45%	98.91%	97.63%	94.39%	93.96%				
± 1 standard error	0.04%	0.05%	0.08%	0.16%	0.35%	0.39%				
Sample Size	23000	16500	11600	7200	2800	1100				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 124 months				
Survival Probability	99.62%	99.44%	99.39%	99.34%	99.21%	99.21%				
± 1 standard error	0.04%	0.05%	0.06%	0.06%	0.09%	0.09%				

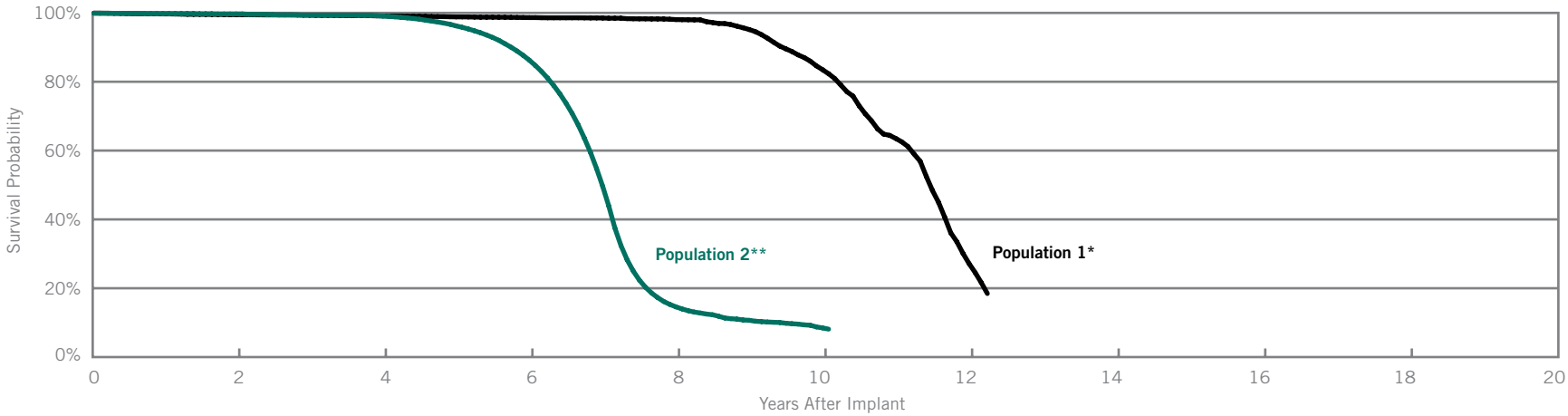
Customer Reported Performance Data

Trilogy™ SR+

Models 2260 & 2264

Population 1*	
US Regulatory Approval	March 1997
Registered US Implants	16,092
Estimated Longevity	7.7 Years
Number of Advisories	None

Population 2**	
US Regulatory Approval	March 1997
Registered US Implants	2,779
Estimated Longevity	7.7 Years
Number of Advisories (see pages 220-227)	Two



Population 1* ——

Year	2	4	6	8	10	12	at 147 months			
Survival Probability	99.49%	99.12%	98.64%	98.06%	83.51%	27.17%	18.46%			
± 1 standard error	0.06%	0.09%	0.12%	0.16%	0.71%	1.31%	1.21%			
Sample Size	13100	9300	6500	4400	2600	800	200			

Population 2** ——

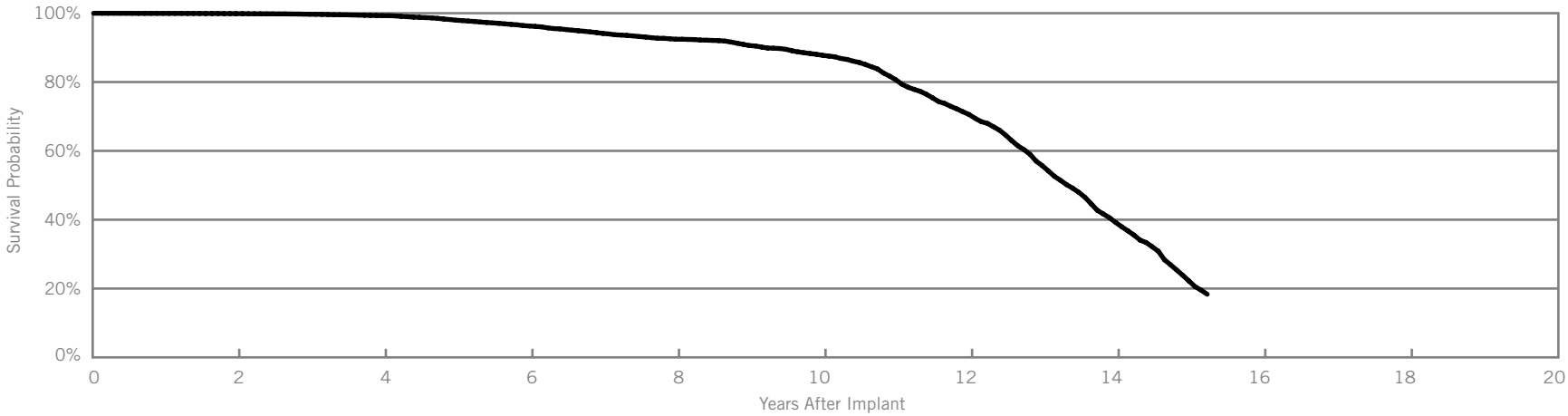
Year	2	4	6	8	10	at 121 months				
Survival Probability	99.71%	99.09%	86.26%	14.59%	8.48%	8.12%				
± 1 standard error	0.11%	0.20%	0.26%	0.41%	2.24%	2.33%				
Sample Size	2200	1500	1000	700	400	200				

Customer Reported Performance Data

Solus® II

Models 2006 & 2007

US Regulatory Approval	February 1993
Registered US Implants	32,403
Estimated Longevity	6.0 Years
Number of Advisories	None



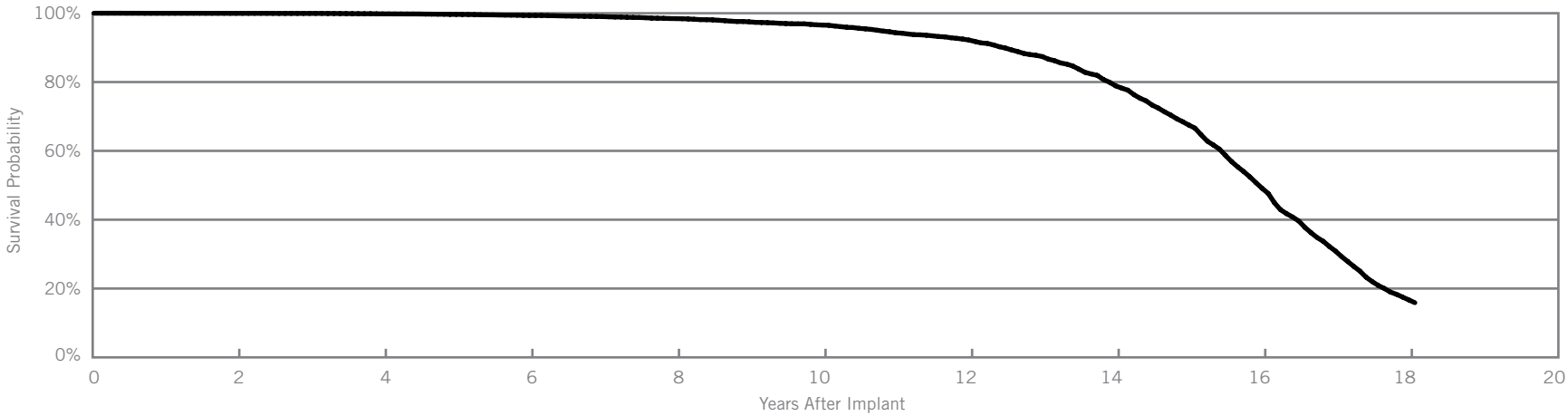
Year	2	4	6	8	10	12	14	at 183 months		
Survival Probability	99.91%	99.40%	96.76%	92.72%	88.51%	72.93%	42.72%	18.33%		
± 1 standard error	0.02%	0.05%	0.14%	0.27%	0.47%	0.95%	1.30%	1.14%		
Sample Size	26700	19500	13100	5800	2200	1300	700	200		

Customer Reported Performance Data

Phoenix™ II

Models 2005, 2008 & 2009

US Regulatory Approval	July 1990
Registered US Implants	26,833
Estimated Longevity	8.3 Years
Number of Advisories	None



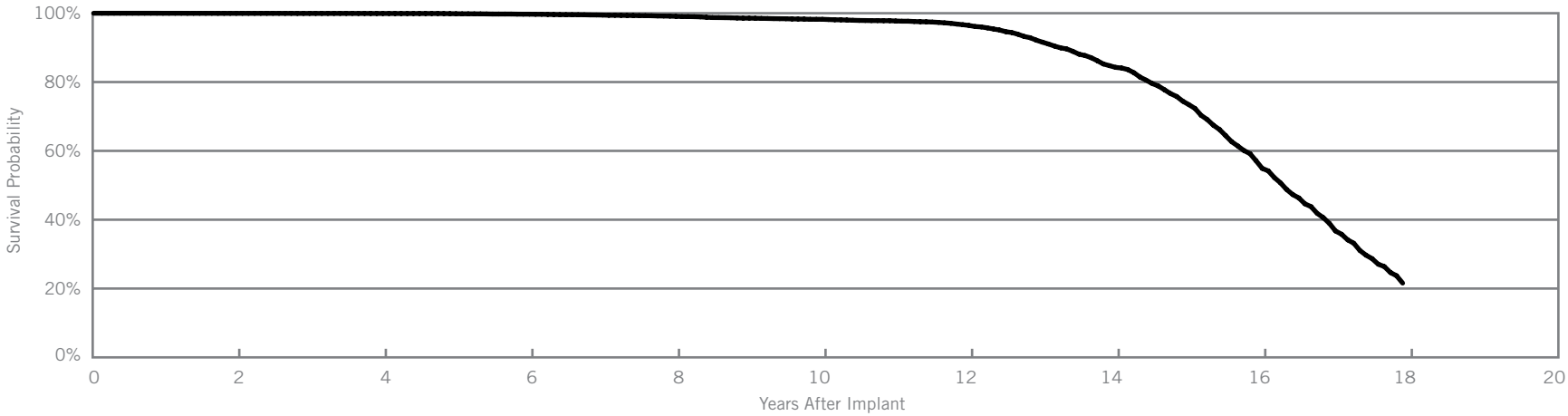
Year	2	4	6	8	10	12	14	16	18	at 217 months
Survival Probability	99.97%	99.85%	99.44%	98.54%	96.91%	92.87%	81.93%	53.95%	18.97%	15.89%
± 1 standard error	0.01%	0.03%	0.07%	0.13%	0.23%	0.42%	0.80%	1.24%	1.10%	1.03%
Sample Size	21000	14600	9900	6600	4100	2500	1600	1000	400	200

Customer Reported Performance Data

Solus®

Models 2002 & 2003

US Regulatory Approval	June 1990
Registered US Implants	23,937
Estimated Longevity	8.3 Years
Number of Advisories	None



Year	2	4	6	8	10	12	14	16	at 215 months
Survival Probability	99.96%	99.92%	99.72%	99.09%	98.23%	96.44%	84.26%	54.92%	21.58%
± 1 standard error	0.01%	0.02%	0.05%	0.10%	0.16%	0.27%	0.77%	1.33%	1.34%
Sample Size	20300	15400	11500	8300	5600	3400	1900	900	200

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
PM1210	Accent®*										
5626	Zephyr® XL SR	99.94%	99.89%								
5620	Zephyr® SR	99.94%	99.86%								
5610	Victory® SR	99.95%	99.95%	99.83%							
5160	Integrity® ADx SR	100.00%	100.00%	99.67%	99.19%	96.90%					
5156/5157/5056	Enti ADx® XL SR/ SR(M/S)/SC	99.94%	99.89%	99.81%	99.77%	99.66%					
5180	Integrity® ADx SR	99.92%	99.87%	99.72%	98.69%	95.20%					
5172	Identity® SR	99.92%	99.65%	99.18%	98.26%	94.46%	81.22%				
5136	Integrity® µ SR	99.94%	99.80%	99.75%	98.92%	95.63%	91.14%	76.92%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.84%	99.80%	99.53%	98.97%	97.17%	95.96%	
5130/5131	Affinity® SR	99.77%	99.62%	99.55%	99.45%	99.30%	98.91%	98.39%	97.63%	96.05%	94.39%

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

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
PM1210	Accent®*										
5626	Zephyr® XL SR	99.94%	99.89%								
5620	Zephyr® SR	99.94%	99.86%								
5610	Victory® SR	99.95%	99.95%	99.90%							
5160	Integrity® ADx SR	100.00%	100.00%	100.00%	99.83%	99.60%					
5156/5157/5056	Verity ADx® XL SR/ SR(M/S)/SC	99.94%	99.90%	99.88%	99.88%	99.88%					
5180	Integrity® ADx SR	99.98%	99.95%	99.88%	99.75%	99.60%					
5172	Identity® SR	99.94%	99.85%	99.73%	99.62%	99.15%	98.52%				
5136	Integrity® µ SR	99.94%	99.88%	99.85%	99.77%	99.63%	99.63%	99.63%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.87%	99.87%	99.87%	99.82%	99.73%	99.73%	
5130/5131	Affinity® SR	99.77%	99.62%	99.54%	99.44%	99.41%	99.39%	99.37%	99.34%	99.30%	99.21%

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

Malfunction Summary

Models	Family	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy				Malfunctions w/o Compromised Therapy				Total Malfunctions*	
					Premature Battery Depletion		Total*		Premature Battery Depletion		Total*			
					Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1210	Accent®	Jul-09	5207	4987	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
5626	Zephyr® XL SR	May-07	16862	14031	0	0.00%	0	0.00%	0	0.00%	6	0.04%	6	0.04%
5620	Zephyr® SR	Mar-07	8613	6786	0	0.00%	0	0.00%	0	0.00%	2	0.02%	2	0.02%
5610	Victory® SR	Dec-05	13323	8693	0	0.00%	1	0.01%	0	0.00%	3	0.02%	4	0.03%
5160	Integrity® ADx SR	May-03	3397	1381	0	0.00%	0	0.00%	0	0.00%	3	0.09%	3	0.09%
5156/5157/5056	Verity ADx® XL SR/ SR(M/S)/SC	May-03	13979	7711	0	0.00%	1	0.01%	0	0.00%	5	0.04%	6	0.04%
5180	Integrity® ADx SR	May-03	20200	9309	0	0.00%	0	0.00%	2	0.01%	23	0.11%	23	0.11%
5172	Identity® SR	Nov-01	21917	5590	1	<0.01%	2	0.01%	3	0.01%	53	0.24%	55	0.25%
5136	Integrity® µ SR	Dec-00	11976	1528	0	0.00%	0	0.00%	0	0.00%	11	0.09%	11	0.09%
5142	Integrity® SR	Apr-00	10509	2740	0	0.00%	1	0.01%	0	0.00%	5	0.05%	6	0.06%
5130/5131	Affinity® SR	Jan-99/Jun-99	28708	5504	0	0.00%	4	0.01%	0	0.00%	55	0.19%	59	0.21%

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

Pacing Leads

Customer Reported Performance Data

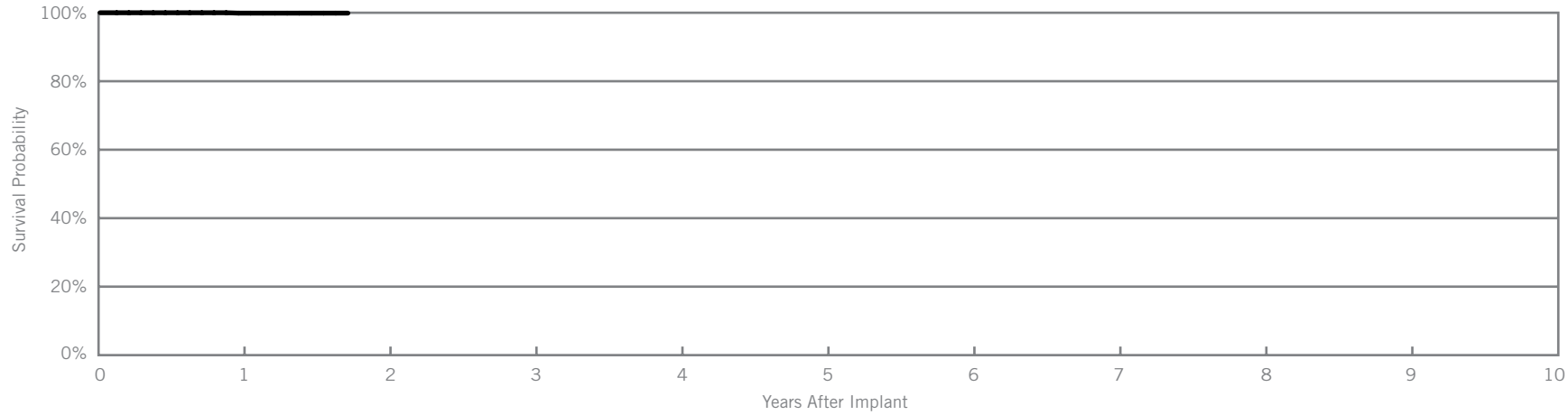
IsoFlex® Optim®

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	2,851
Estimated Active US Implants	2,604
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of 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	5	0.18%	1	0.04%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	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%	0	0.00%
Total	**6**	**0.21%**	**1**	**0.04%**
Total Returned for Analysis	**1**		**0**	

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	0.04%
Total	**1**	**0.04%**



Year	1	at 21 months								
Survival Probability	99.89%	99.89%								
± 1 standard error	0.11%	0.11%								
Sample Size	1900	200								

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

Customer Reported Performance Data

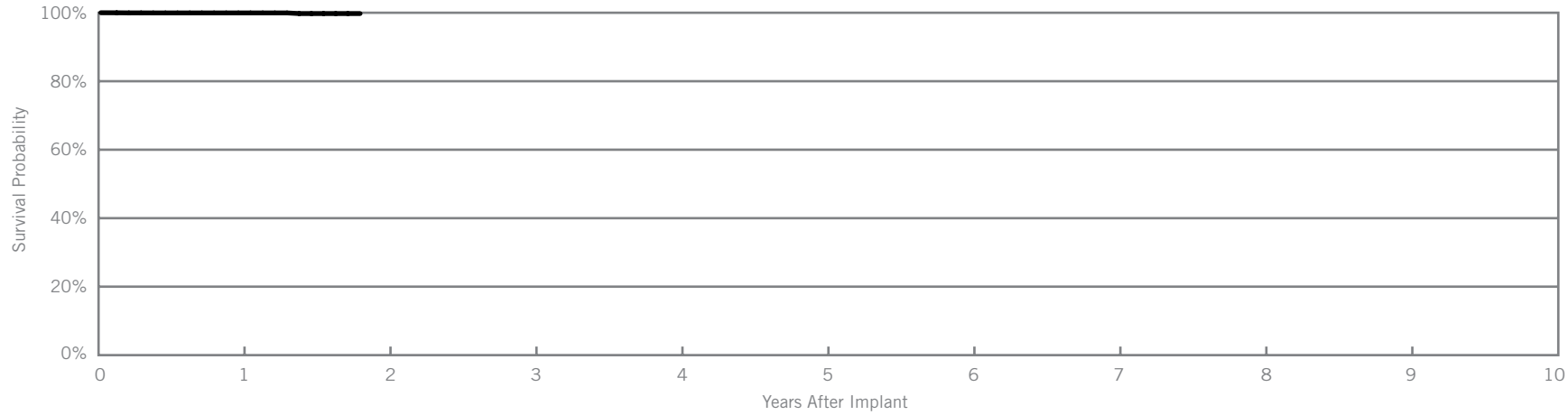
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	10,104
Estimated Active US Implants	9,284
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

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

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



Year	1	at 22 months								
Survival Probability	99.95%	99.76%								
± 1 standard error	0.03%	0.13%								
Sample Size	6400	300								

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

SCORE Registry Performance Data

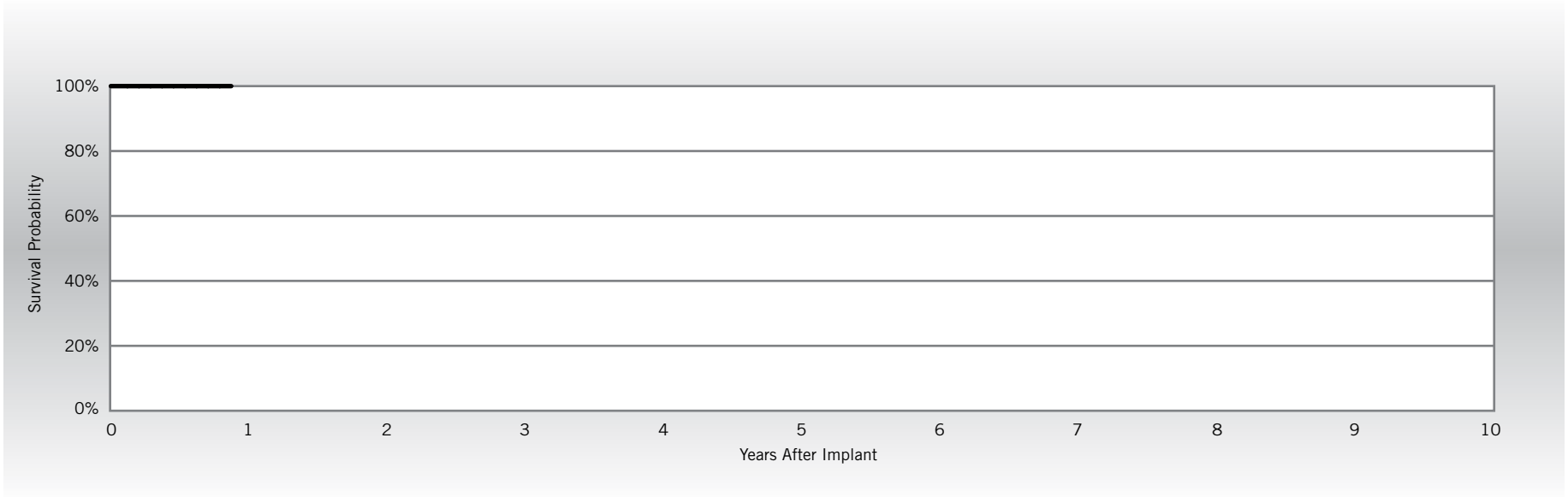
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	150
Cumulative Months of Follow-up	1,340
Insulation	Optim*
Type and/or Fixation	Pasive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

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



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

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

Customer Reported Performance Data

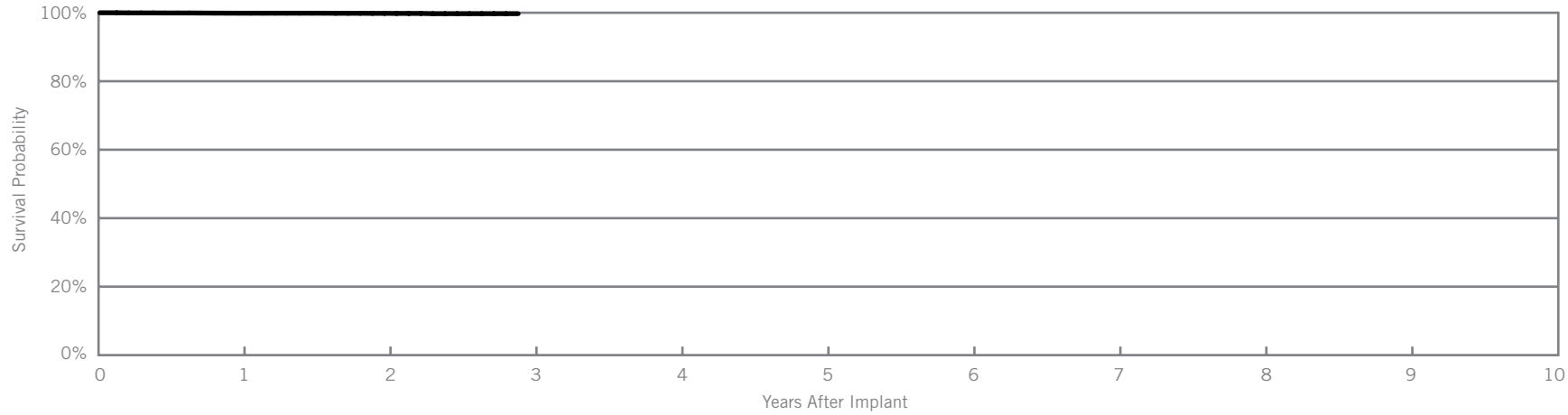
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	22,324
Estimated Active US Implants	19,606
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	4	0.02%	11	0.05%
Failure to Capture	3	0.01%	8	0.04%
Oversensing	2	0.01%	2	0.01%
Failure to Sense	8	0.04%	3	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	0.01%	0	0.00%
Total	**20**	**0.09%**	**28**	**0.13%**
Total Returned for Analysis	**15**		**19**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	15	0.07%
Total	**19**	**0.09%**



Year	1	2	at 35 months							
Survival Probability	99.87%	99.82%	99.73%							
± 1 standard error	0.03%	0.04%	0.07%							
Sample Size	18000	9500	200							

SCORE Registry Performance Data

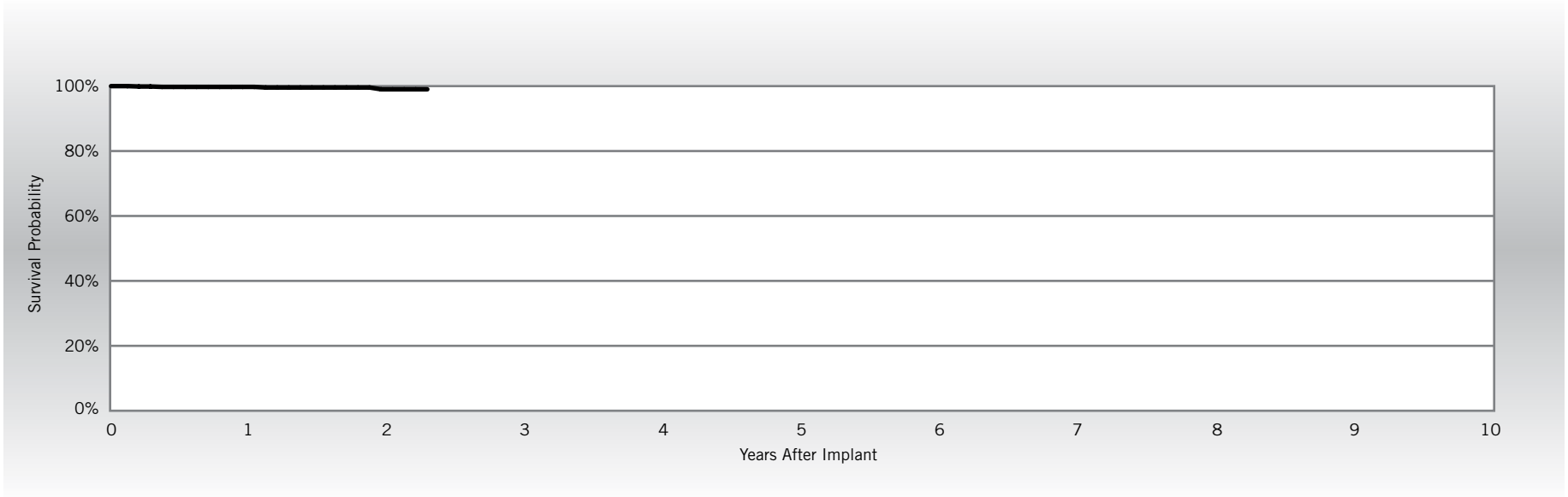
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	890
Cumulative Months of Follow-up	14,440
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.11%
Failure to Capture	2	0.22%
Abnormal Pacing Impedance	1	0.11%

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



Year	1	2	at 28 months							
Survival Probability	99.76%	99.02%	99.02%							
± 1 standard error	0.17%	0.56%	0.56%							
Sample Size	740	370	50							

Customer Reported Performance Data

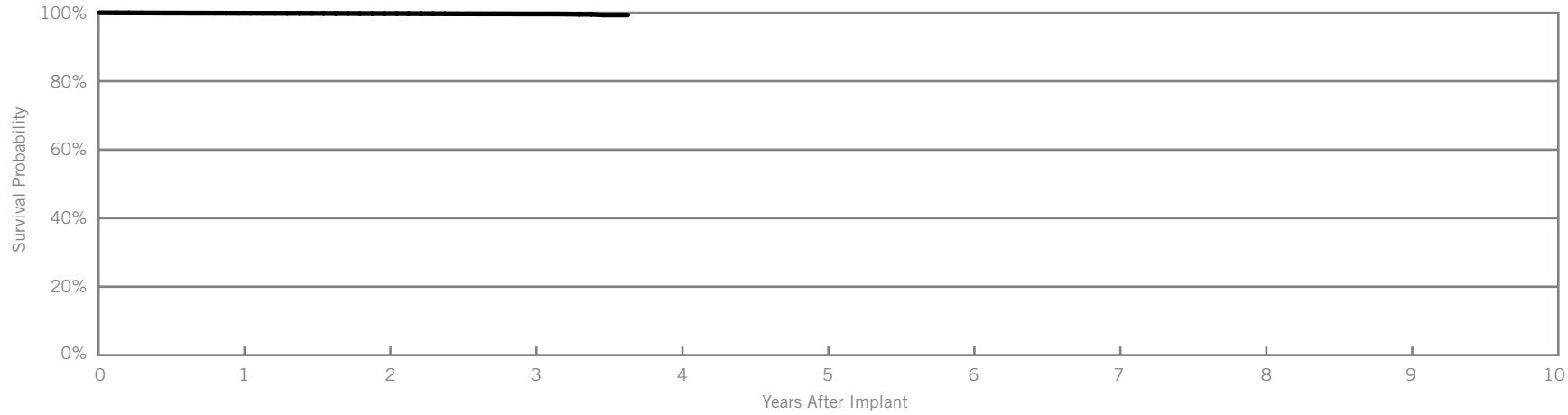
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	183,006
Estimated Active US Implants	161,324
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	23	0.01%	15	0.01%
Conductor Fracture	4	<0.01%	10	<0.01%
Lead Dislodgement	71	0.04%	88	0.05%
Failure to Capture	59	0.03%	59	0.03%
Oversensing	8	<0.01%	30	0.02%
Failure to Sense	6	<0.01%	4	<0.01%
Insulation Breach	3	<0.01%	14	0.01%
Abnormal Pacing Impedance	5	<0.01%	14	0.01%
Extracardiac Stimulation	3	<0.01%	4	<0.01%
Other	14	0.01%	14	0.01%
Total	**196**	**0.11%**	**252**	**0.14%**
Total Returned for Analysis	**71**		**148**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	<0.01%
Insulation Breach	12	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	6	<0.01%
Extrinsic Factors	121	0.07%
Total	**144**	**0.08%**



Year	1	2	3	at 44 months						
Survival Probability	99.86%	99.76%	99.64%	99.36%						
± 1 standard error	0.01%	0.02%	0.03%	0.20%						
Sample Size	144900	71600	24600	200						

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

SCORE Registry Performance Data

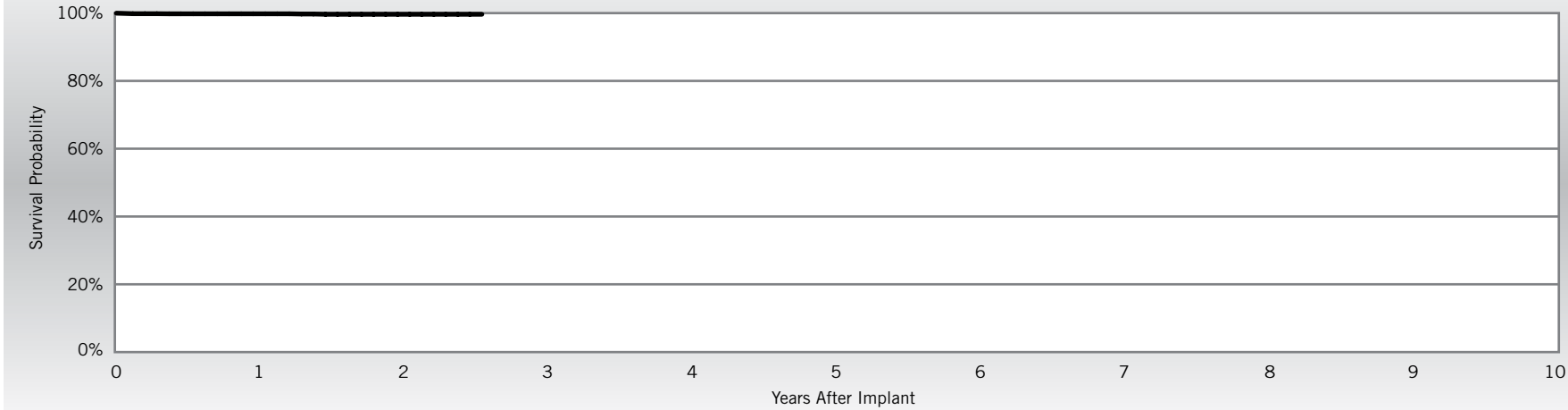
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	3,490
Cumulative Months of Follow-up	52,280
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	7	0.20%
Abnormal Pacing Impedance	1	0.03%
Extracardiac Stimulation	1	0.03%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.03%
Insulation Breach	1	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.03%
Extrinsic Factors	2	0.06%
Total	**5**	0.14%



Year	1	2	at 31 months							
Survival Probability	99.79%	99.65%	99.65%							
± 1 standard error	0.08%	0.12%	0.12%							
Sample Size	2850	1310	60							

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

Customer Reported Performance Data

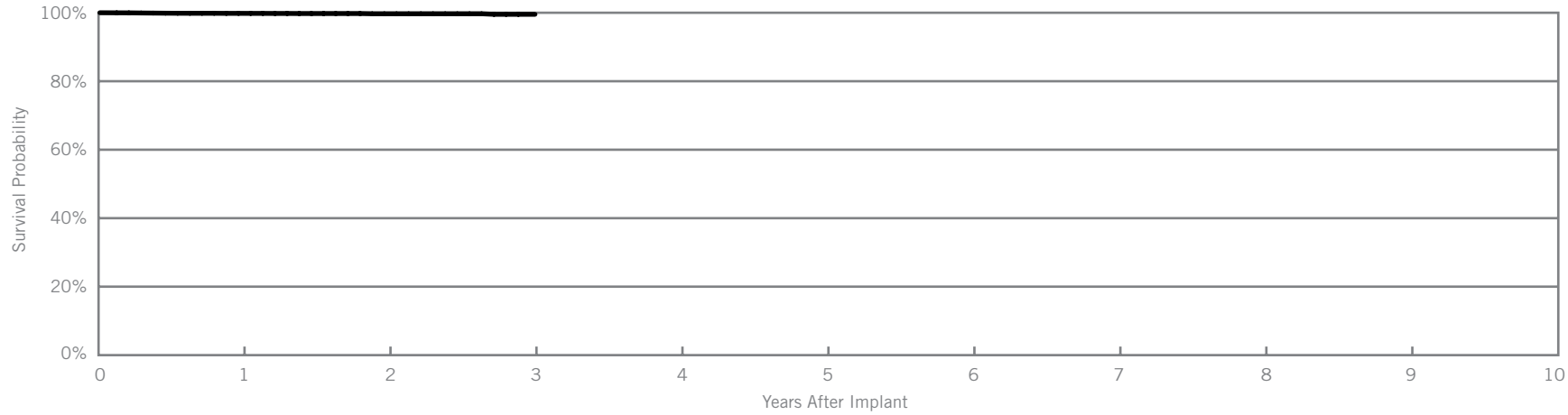
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	13,777
Estimated Active US Implants	12,250
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	0.01%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.07%	8	0.06%
Failure to Capture	4	0.03%	4	0.03%
Oversensing	2	0.01%	2	0.01%
Failure to Sense	2	0.01%	2	0.01%
Insulation Breach	0	0.00%	1	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	0.01%	1	0.01%
Total	**22**	**0.16%**	18	**0.13%**
Total Returned for Analysis	**5**		**15**	

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



Year	1	2	3							
Survival Probability	99.82%	99.70%	99.54%							
± 1 standard error	0.04%	0.07%	0.17%							
Sample Size	10400	4700	1300							

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

SCORE Registry Performance Data

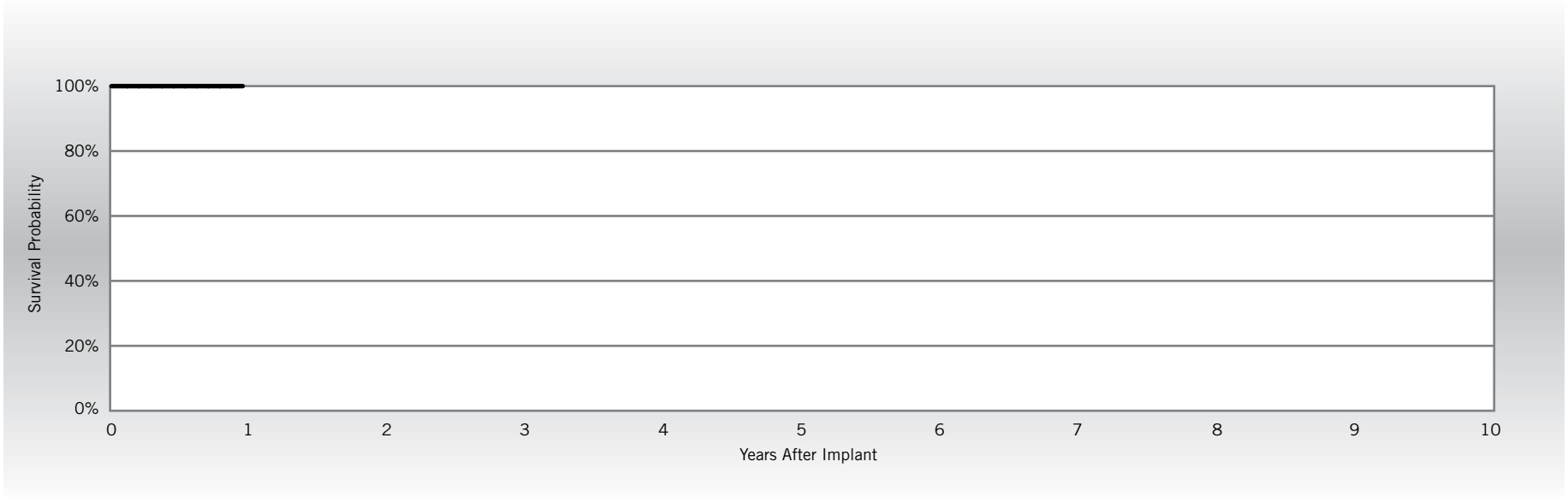
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	110
Cumulative Months of Follow-up	1,230
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	0.91%
Total	**1**	**0.91%**



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

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

Customer Reported Performance Data

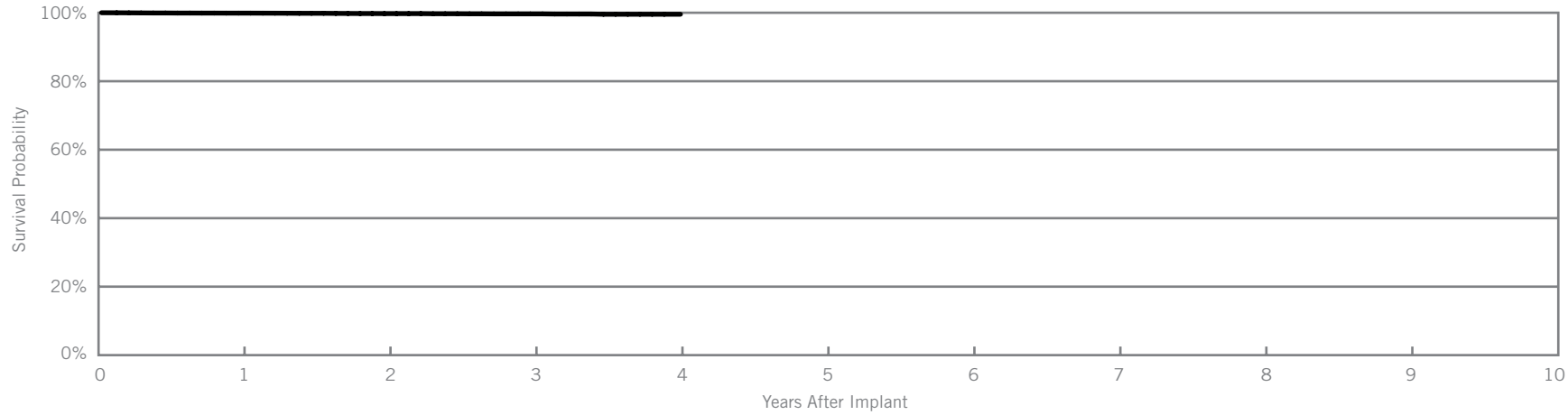
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	13,995
Estimated Active US Implants	11,377
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	5	0.04%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	9	0.06%	11	0.08%
Failure to Capture	4	0.03%	9	0.06%
Oversensing	0	0.00%	2	0.01%
Failure to Sense	0	0.00%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	2	0.01%
Extracardiac Stimulation	1	0.01%	0	0.00%
Other	2	0.01%	1	0.01%
Total	**23**	**0.16%**	**28**	**0.20%**
Total Returned for Analysis	**12**		**21**	

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	16	0.11%
Total	**19**	**0.14%**



Year	1	2	3	4						
Survival Probability	99.89%	99.75%	99.67%	99.56%						
± 1 standard error	0.03%	0.05%	0.07%	0.10%						
Sample Size	12600	8700	5100	1700						

SCORE Registry Performance Data

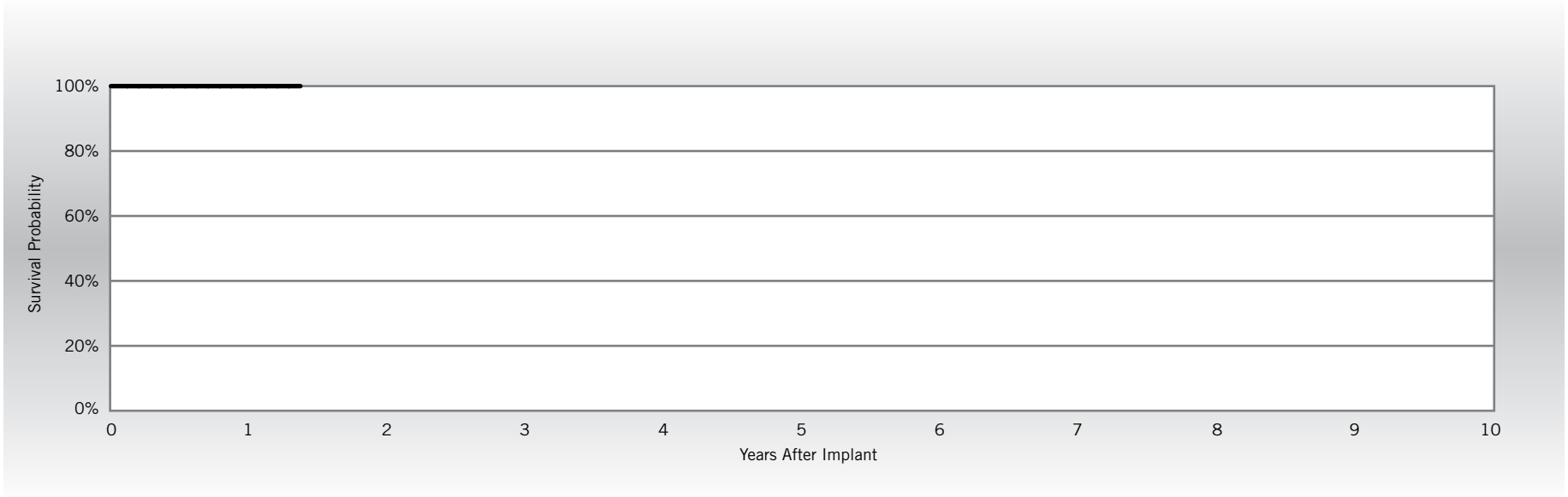
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	100
Cumulative Months of Follow-up	1,680
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	at 17 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	80	50								

Customer Reported Performance Data

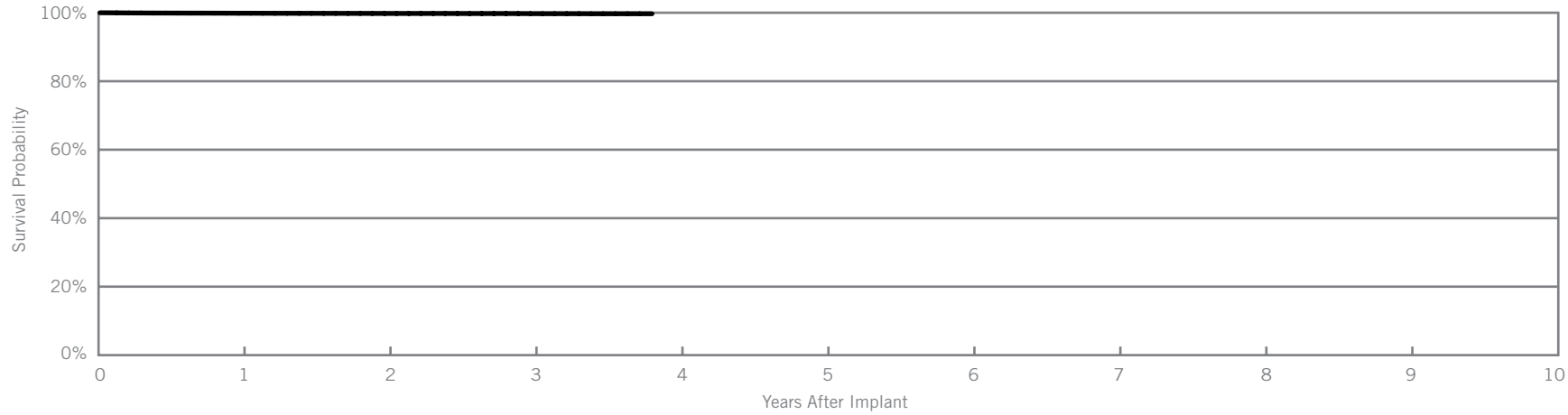
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	62,935
Estimated Active US Implants	49,408
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	11	0.02%	1	<0.01%
Conductor Fracture	1	<0.01%	2	<0.01%
Lead Dislodgement	32	0.05%	25	0.04%
Failure to Capture	29	0.05%	31	0.05%
Oversensing	2	<0.01%	11	0.02%
Failure to Sense	2	<0.01%	1	<0.01%
Insulation Breach	1	<0.01%	2	<0.01%
Abnormal Pacing Impedance	9	0.01%	9	0.01%
Extracardiac Stimulation	2	<0.01%	1	<0.01%
Other	20	0.03%	5	0.01%
Total	**109**	**0.17%**	**88**	**0.14%**
Total Returned for Analysis	**40**		**66**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	22	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	7	0.01%
Extrinsic Factors	41	0.07%
Total	**72**	**0.11%**



Year	1	2	3	at 46 months						
Survival Probability	99.86%	99.79%	99.74%	99.71%						
± 1 standard error	0.02%	0.02%	0.02%	0.03%						
Sample Size	58400	44500	28200	900						

SCORE Registry Performance Data

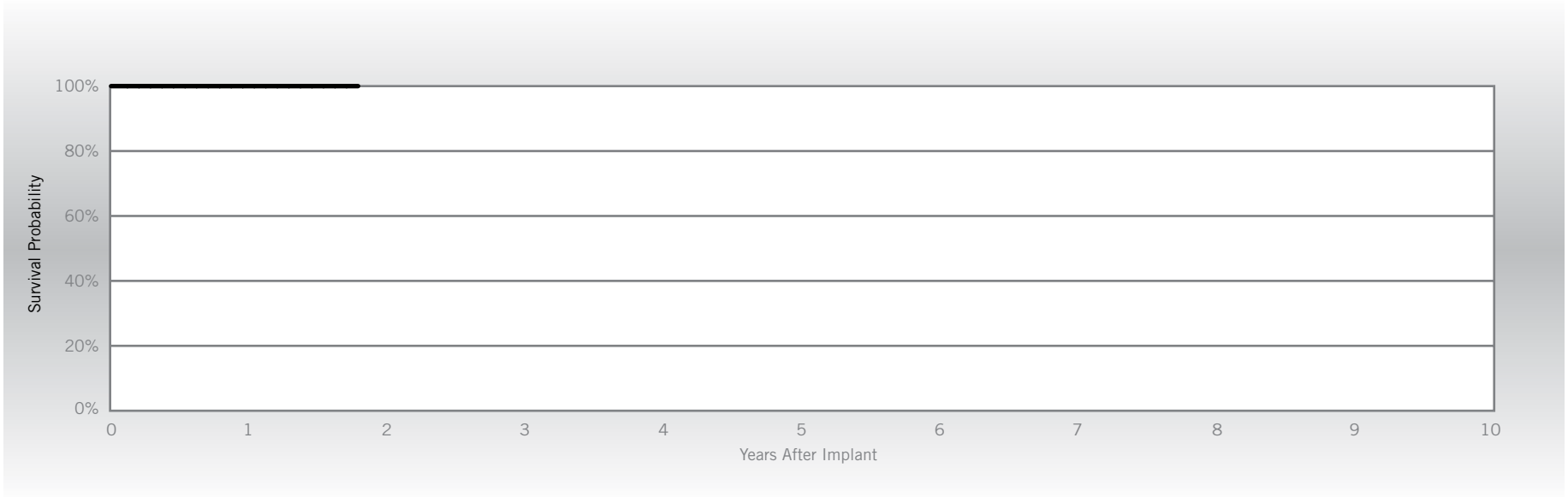
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	210
Cumulative Months of Follow-up	3,390
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	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	180	50								

Customer Reported Performance Data

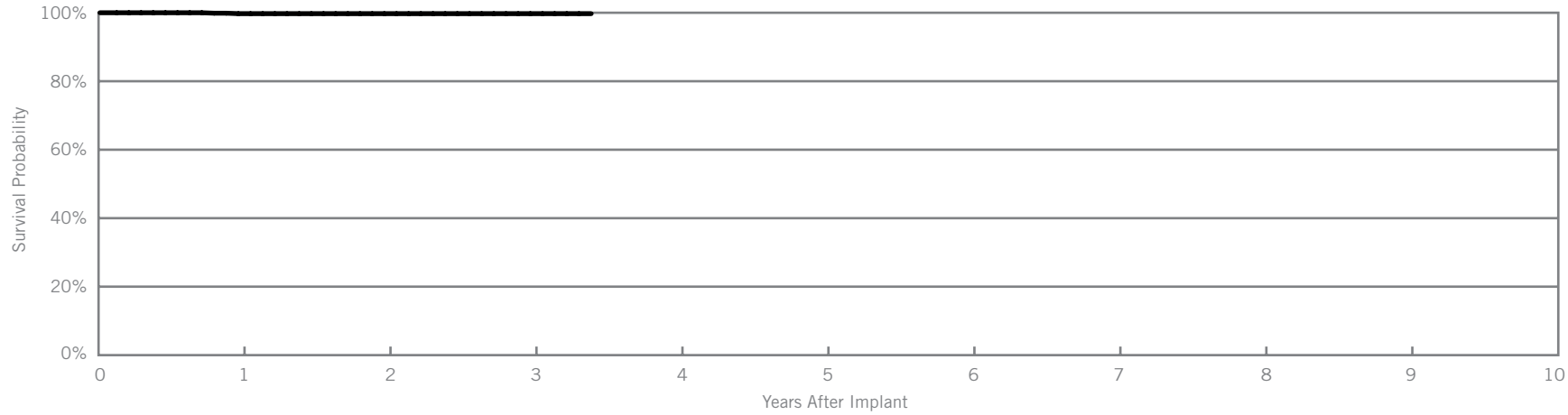
IsoFlex® P

Model 1644T

US Regulatory Approval	April 2005
Registered US Implants	948
Estimated Active US Implants	681
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of 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	0.11%
Lead Dislodgement	1	0.11%	0	0.00%
Failure to Capture	0	0.00%	2	0.21%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.11%	0	0.00%
Total	**2**	**0.21%**	**3**	**0.32%**
Total Returned for Analysis	**1**		**2**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.21%
Total	**2**	**0.21%**



Year	1	2	3	at 41 months						
Survival Probability	99.73%	99.73%	99.73%	99.73%						
± 1 standard error	0.13%	0.19%	0.19%	0.19%						
Sample Size	900	700	500	200						

Customer Reported Performance Data

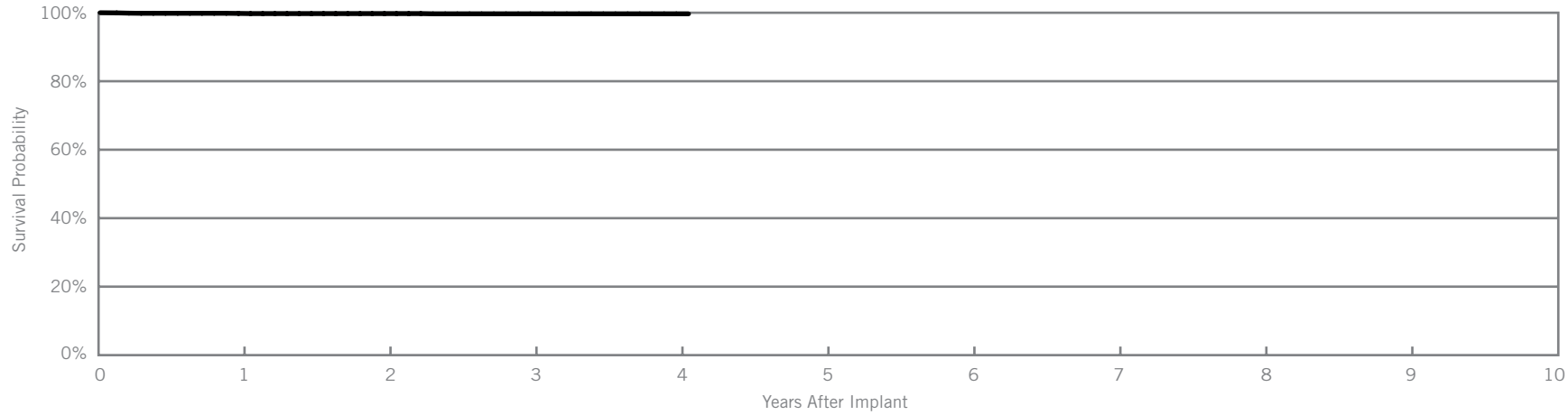
IsoFlex® P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,820
Estimated Active US Implants	2,014
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.07%	0	0.00%
Failure to Capture	2	0.07%	1	0.04%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	0.04%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
Abnormal Pacing Impedance	0	0.00%	1	0.04%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	2	0.07%
Total	**6**	**0.21%**	**5**	**0.18%**
Total Returned for Analysis	**1**		**4**	

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



Year	1	2	3	4	at 49 months					
Survival Probability	99.80%	99.75%	99.68%	99.68%	99.68%					
± 1 standard error	0.08%	0.10%	0.12%	0.12%	0.12%					
Sample Size	2600	2100	1300	500	200					

Customer Reported Performance Data

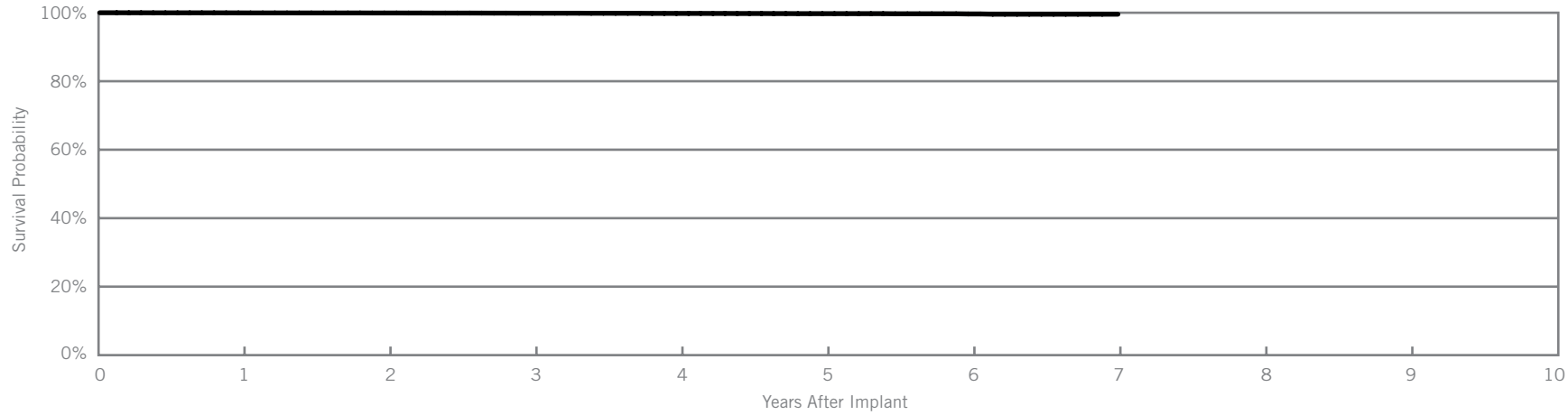
IsoFlex® S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	24,663
Estimated Active US Implants	17,742
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	44	0.18%	17	0.07%
Failure to Capture	5	0.02%	9	0.04%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	3	0.01%	3	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	3	0.01%	1	<0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**56**	**0.23%**	**32**	**0.13%**
Total Returned for Analysis	**33**		**12**	

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	<0.01%
Crimps, Welds & Bonds	2	0.01%
Other	7	0.03%
Extrinsic Factors	10	0.04%
Total	**20**	**0.08%**



Year	1	2	3	4	5	6	7			
Survival Probability	99.96%	99.93%	99.88%	99.80%	99.73%	99.64%	99.57%			
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.05%	0.07%	0.11%			
Sample Size	22900	17900	13500	9400	5900	3000	1000			

Customer Reported Performance Data

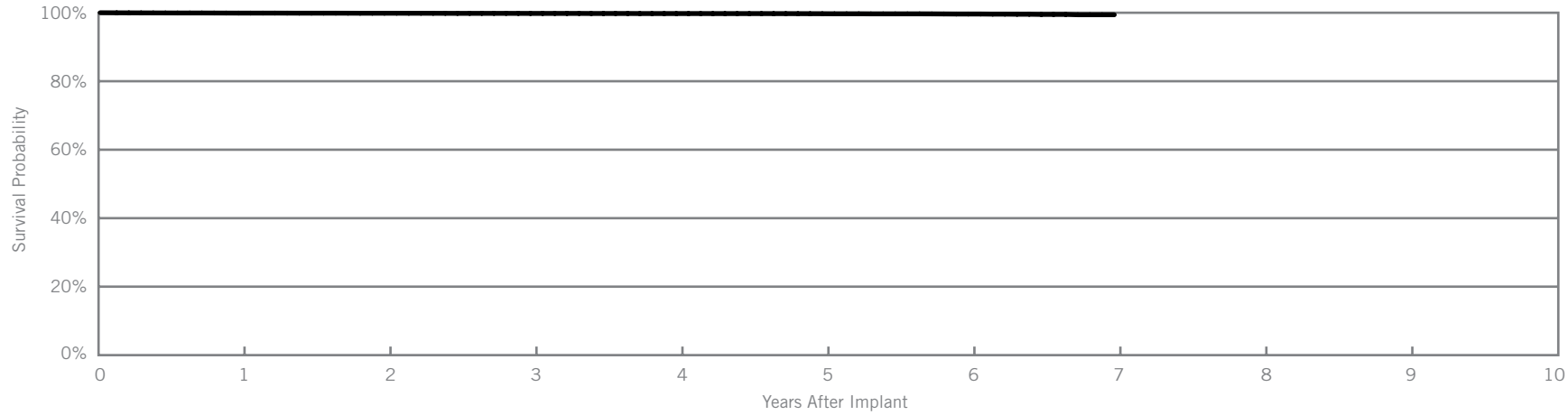
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	81,690
Estimated Active US Implants	55,668
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	<0.01%	1	<0.01%
Conductor Fracture	2	<0.01%	12	0.01%
Lead Dislodgement	32	0.04%	18	0.02%
Failure to Capture	31	0.04%	48	0.06%
Oversensing	0	0.00%	9	0.01%
Failure to Sense	3	<0.01%	2	<0.01%
Insulation Breach	2	<0.01%	0	0.00%
Abnormal Pacing Impedance	6	0.01%	18	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	<0.01%	9	0.01%
Total	**81**	**0.10%**	**117**	**0.14%**
Total Returned for Analysis	**33**		**30**	

Malfunctions	Qty.	Rate
Conductor Fracture	7	0.01%
Insulation Breach	7	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	8	0.01%
Extrinsic Factors	23	0.03%
Total	**46**	**0.06%**



Year	1	2	3	4	5	6	7			
Survival Probability	99.90%	99.86%	99.80%	99.76%	99.71%	99.62%	99.41%			
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.13%			
Sample Size	74900	57200	42000	28500	17300	8400	2400			

SCORE Registry Performance Data

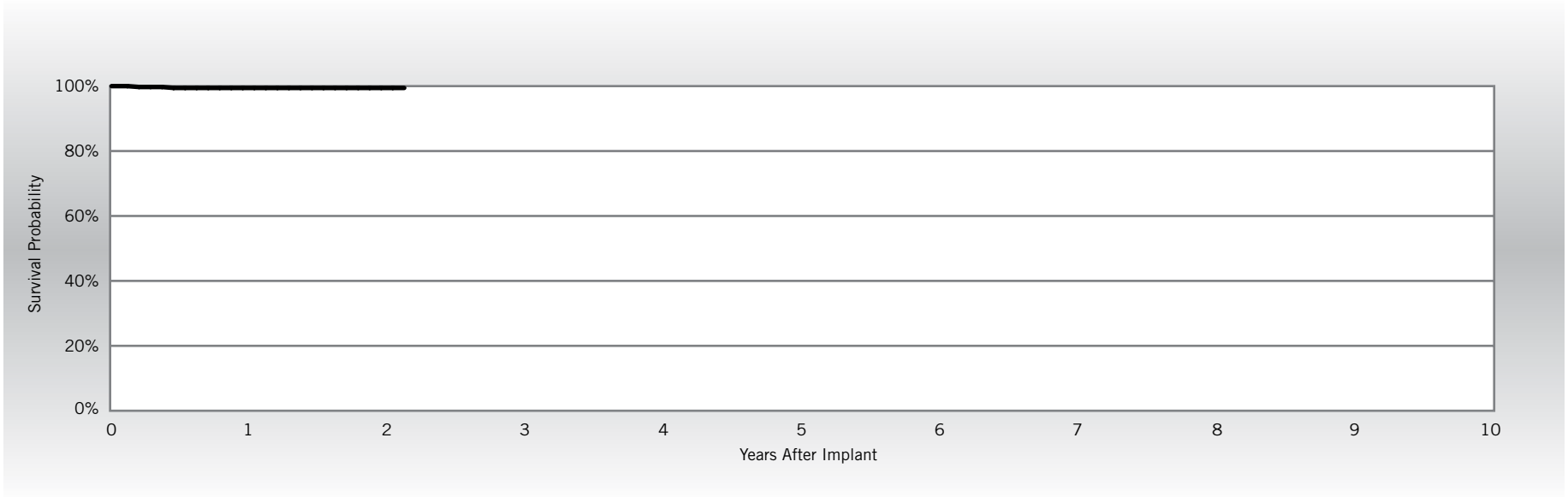
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	410
Cumulative Months of Follow-up	6,350
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.24%
Failure to Capture	1	0.24%

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 26 months							
Survival Probability	99.44%	99.44%	99.44%							
± 1 standard error	0.39%	0.39%	0.39%							
Sample Size	340	160	60							

Customer Reported Performance Data

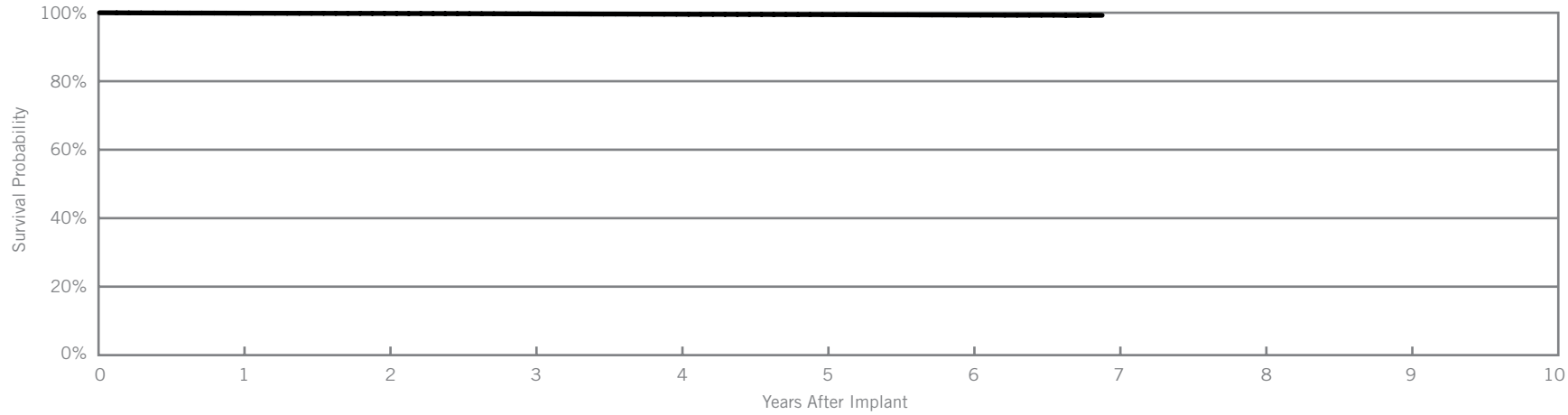
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	341,705
Estimated Active US Implants	242,512
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	37	0.01%	7	<0.01%
Conductor Fracture	3	<0.01%	60	0.02%
Lead Dislodgement	152	0.04%	173	0.05%
Failure to Capture	111	0.03%	245	0.07%
Oversensing	9	<0.01%	125	0.04%
Failure to Sense	19	0.01%	12	<0.01%
Insulation Breach	5	<0.01%	21	0.01%
Abnormal Pacing Impedance	23	0.01%	125	0.04%
Extracardiac Stimulation	3	<0.01%	4	<0.01%
Other	28	0.01%	56	0.02%
Total	**390**	**0.11%**	**828**	**0.24%**
Total Returned for Analysis	**144**		**390**	

Malfunctions	Qty.	Rate
Conductor Fracture	94	0.03%
Insulation Breach	94	0.03%
Crimps, Welds & Bonds	16	<0.01%
Other	10	<0.01%
Extrinsic Factors	225	0.07%
Total	**439**	0.13%



Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.88%	99.80%	99.68%	99.57%	99.46%	99.33%	99.25%			
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.03%	0.06%			
Sample Size	316600	249500	196300	140500	80900	32500	200			

SCORE Registry Performance Data

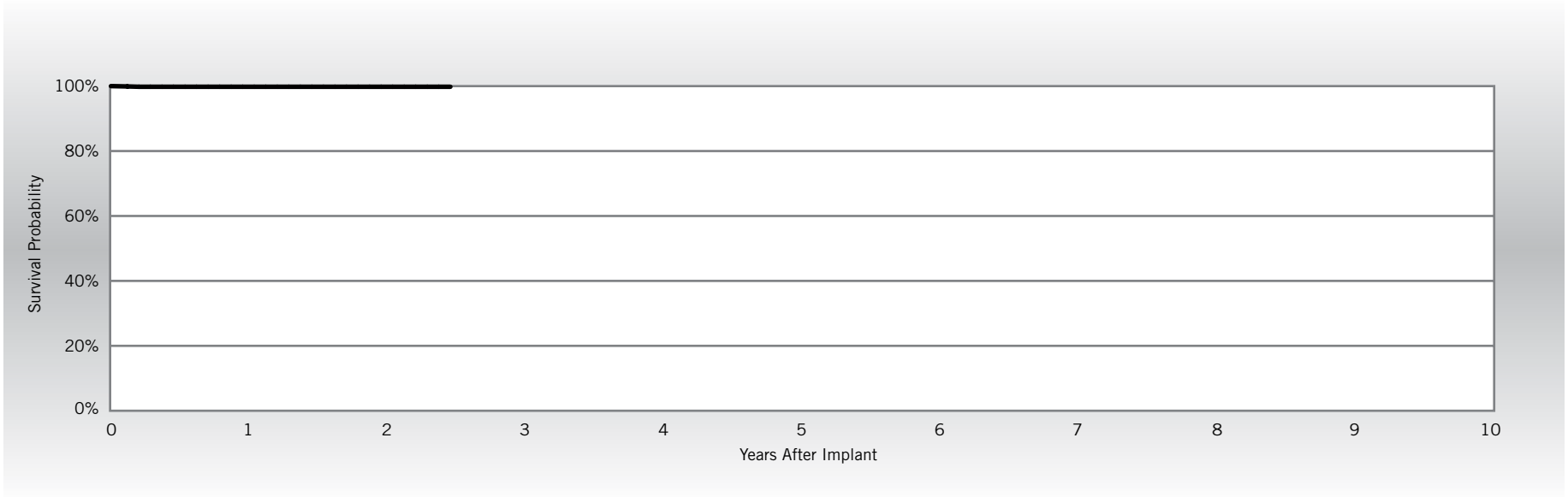
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	1,060
Cumulative Months of Follow-up	17,430
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Cardiac Perforation	1	0.09%
Abnormal Pacing Impedance	1	0.09%

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	0.09%
Total	**1**	**0.09%**



Year	1	2	at 30 months							
Survival Probability	99.80%	99.80%	99.80%							
± 1 standard error	0.14%	0.14%	0.14%							
Sample Size	880	450	70							

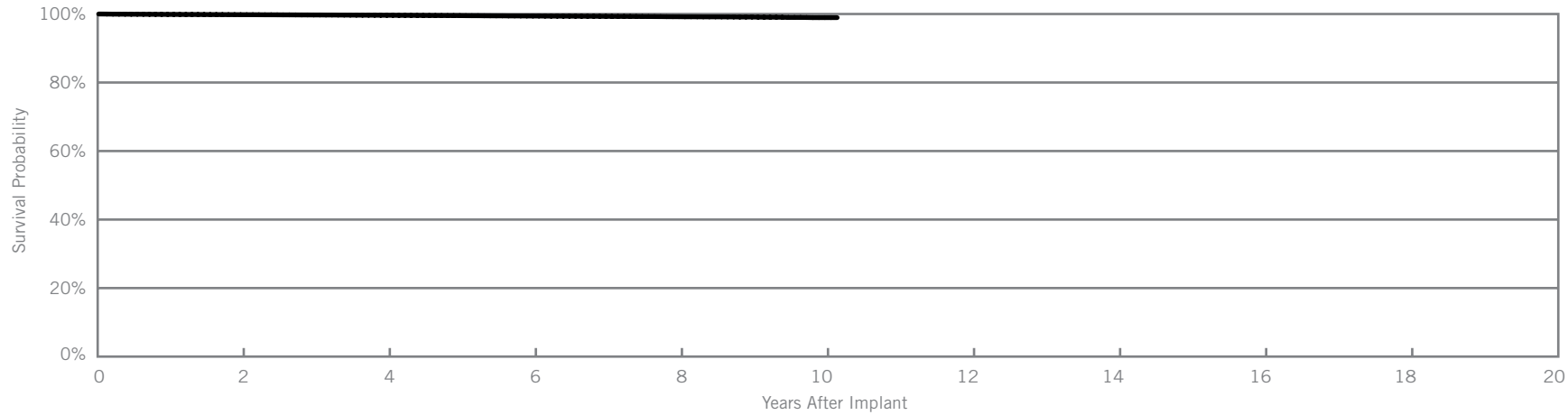
Customer Reported Performance Data

Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	273,784
Estimated Active US Implants	129,822
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Malfunctions	Qty.	Rate
Conductor Fracture	124	0.05%
Insulation Breach	78	0.03%
Crimps, Welds & Bonds	13	<0.01%
Other	2	<0.01%
Extrinsic Factors	240	0.09%
Total	**457**	**0.17%**



Year	2	4	6	8	10	at 122 months				
Survival Probability	99.82%	99.66%	99.44%	99.24%	98.98%	98.95%				
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.05%	0.06%				
Sample Size	234000	187800	129000	58000	6237	600				

SCORE Registry Performance Data

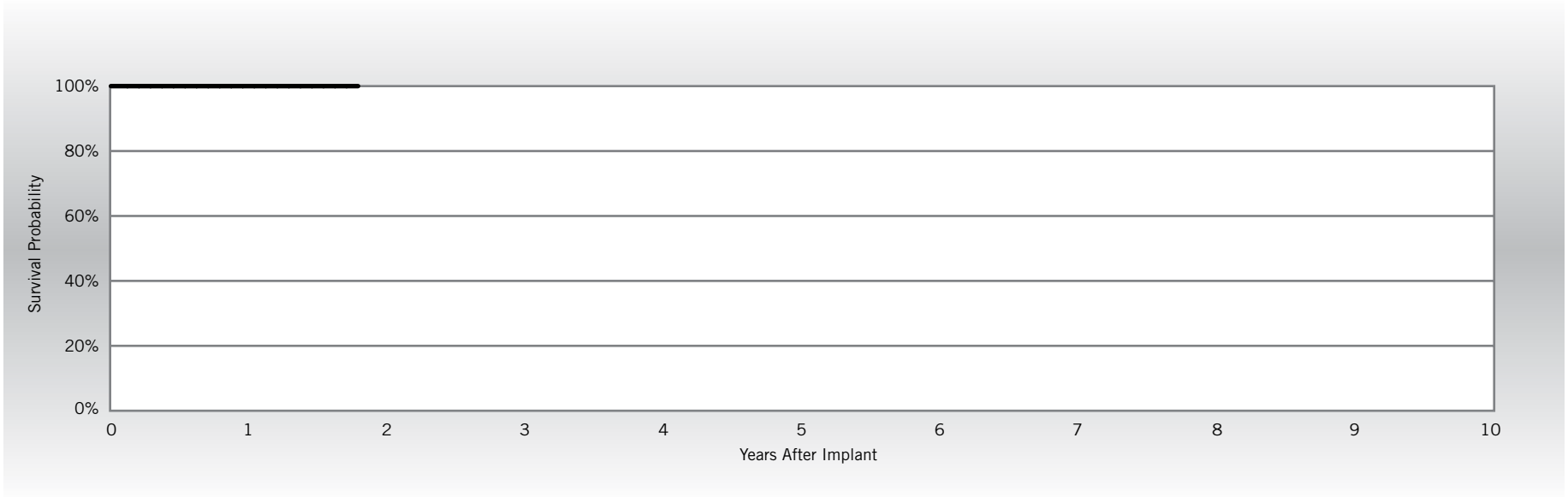
Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	130
Cumulative Months of Follow-up	2,470
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%**



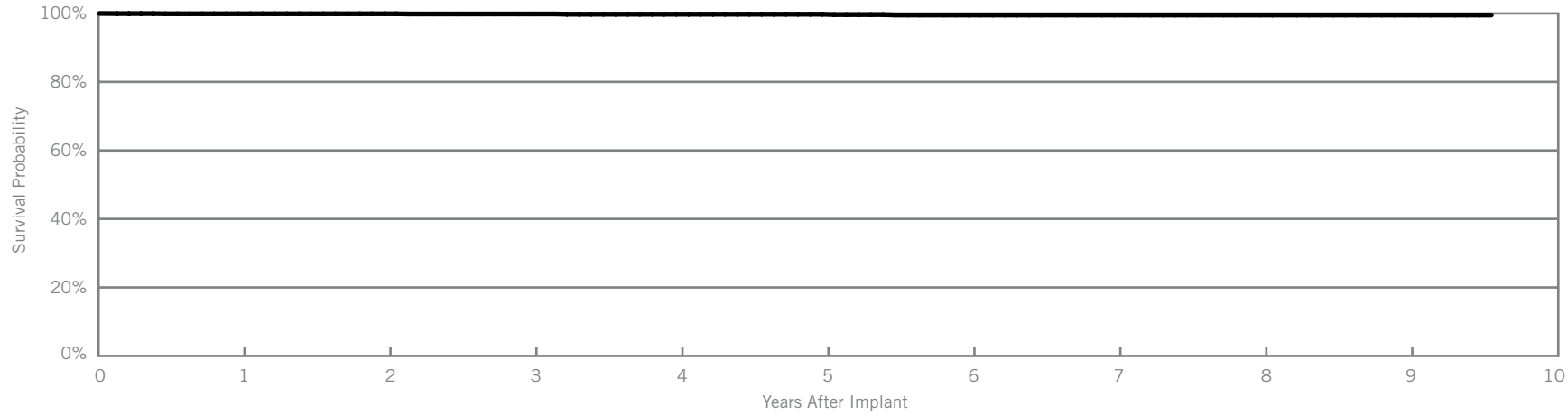
Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	120	60								

Customer Reported Performance Data

AV Plus® DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,474
Estimated Active US Implants	1,025
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of Advisories	None



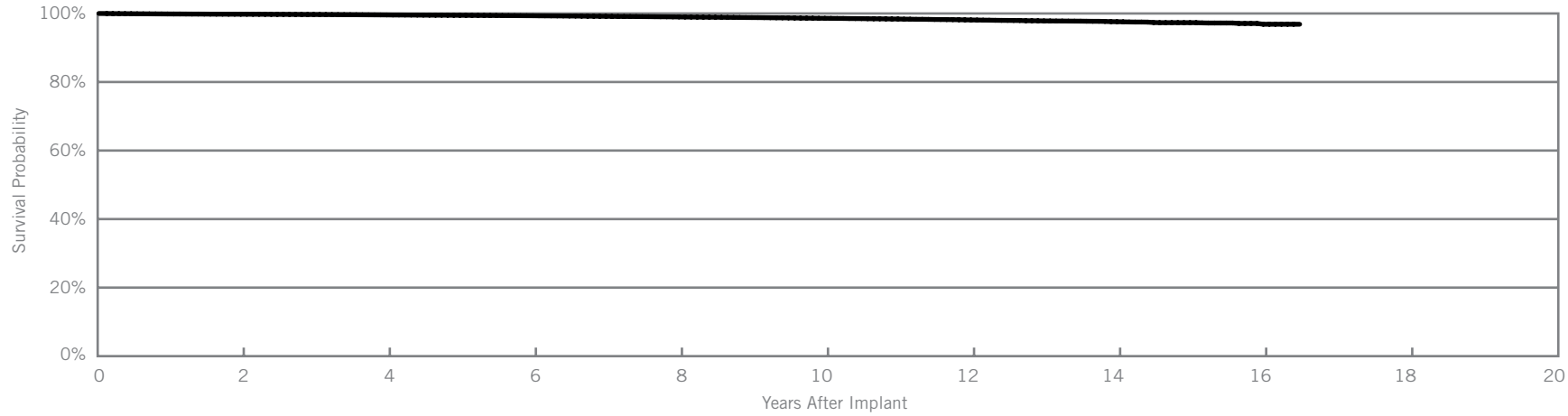
Year	1	2	3	4	5	6	7	8	9	at 115 months
Survival Probability	99.91%	99.91%	99.85%	99.77%	99.77%	99.54%	99.54%	99.54%	99.54%	99.54%
± 1 standard error	0.06%	0.06%	0.09%	0.12%	0.12%	0.20%	0.20%	0.20%	0.20%	0.20%
Sample Size	2300	1900	1600	1300	1100	900	700	500	400	200

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	326,471
Estimated Active US Implants	109,433
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	(1148/1188) No; (1388) Yes
Number of Advisories	None



Year	2	4	6	8	10	12	14	16	at 198 months	
Survival Probability	99.78%	99.58%	99.34%	98.99%	98.60%	98.11%	97.60%	96.86%	96.86%	
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.08%	0.16%	0.22%	
Sample Size	279800	222900	166700	115600	71000	30600	9700	2100	200	

Customer Reported Performance Data

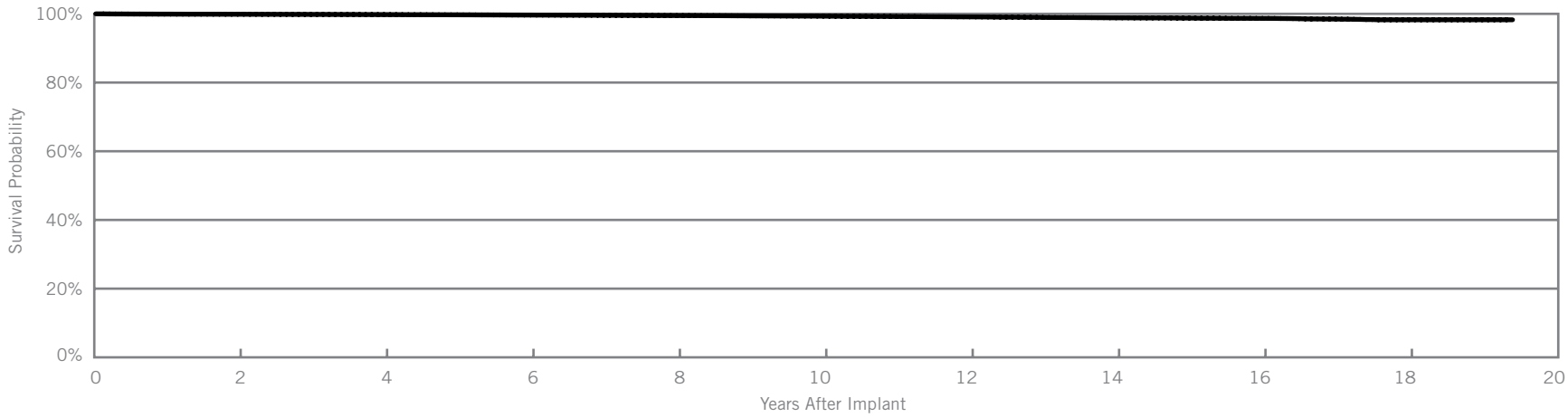
Passive Plus®

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	374,012
Estimated Active US Implants	91,568
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 Advisories	None



Year	2	4	6	8	10	12	14	16	18	at 233 months
Survival Probability	99.88%	99.78%	99.65%	99.50%	99.33%	99.12%	98.84%	98.68%	98.27%	98.27%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.05%	0.11%	0.11%
Sample Size	319400	257000	199300	142600	90000	52000	27000	11100	3400	300

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
1944	IsoFlex® Optim®	99.89%									
1948	IsoFlex® Optim®	99.95%									
1699T/TC	OptiSense®	99.87%	99.82%								
1888T/TC	Tendril® ST Optim®	99.86%	99.76%	99.64%							
1882T/TC	Tendril® ST Optim®	99.82%	99.70%	99.54%							
1782T/TC	Tendril®	99.89%	99.75%	99.67%	99.56%						
1788T/TC	Tendril®	99.86%	99.79%	99.74%							
1644T	IsoFlex® P	99.73%	99.73%	99.73%							
1648T	IsoFlex® P	99.80%	99.75%	99.68%	99.68%						
1642T	IsoFlex® S	99.96%	99.93%	99.88%	99.80%	99.73%	99.64%	99.57%			
1646T	IsoFlex® S	99.90%	99.86%	99.80%	99.76%	99.71%	99.62%	99.41%			
1688T/TC	Tendril® SDX	99.88%	99.80%	99.68%	99.57%	99.46%	99.33%				
1488T/TC	Tendril® SDX	99.91%	99.82%	99.74%	99.66%	99.55%	99.44%	99.34%	99.24%	99.14%	98.98%

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	
1944	Mar-08	2851	2604	0	0.00%	0	0.00%	5	0.18%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.21%**	**1**
1948	Mar-08	10104	9284	0	0.00%	0	0.00%	4	0.04%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**7**	**0.07%**	**5**
1699T/TC	May-07	22324	19606	1	<0.01%	0	0.00%	4	0.02%	3	0.01%	2	0.01%	8	0.04%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**20**	**0.09%**	**15**
1888T/TC	Jun-06	183006	161324	23	0.01%	4	<0.01%	71	0.04%	59	0.03%	8	<0.01%	6	<0.01%	3	<0.01%	5	<0.01%	3	<0.01%	14	0.01%	**196**	**0.11%**	**71**
1882T/TC	Jun-06	13777	12250	2	0.01%	0	0.00%	10	0.07%	4	0.03%	2	0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**22**	**0.16%**	**5**
1782T/TC	Jun-06	13995	11377	5	0.04%	0	0.00%	9	0.06%	4	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	0.01%	2	0.01%	**23**	**0.16%**	**12**
1788T/TC	Feb-06	62935	49408	11	0.02%	1	<0.01%	32	0.05%	29	0.05%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**109**	**0.17%**	**40**
1644T	Apr-05	948	681	0	0.00%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.11%	**2**	**0.21%**	**1**
1648T	Apr-05	2820	2014	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	24663	17742	0	0.00%	0	0.00%	44	0.18%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**56**	**0.23%**	**33**
1646T	May-02	81690	55668	3	<0.01%	2	<0.01%	32	0.04%	31	0.04%	0	0.00%	3	<0.01%	2	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**81**	**0.10%**	**33**
1688T/TC	Jun-03	341705	242512	37	0.01%	3	<0.01%	152	0.04%	111	0.03%	9	<0.01%	19	0.01%	5	<0.01%	23	0.01%	3	<0.01%	28	0.01%	**390**	**0.11%**	**144**

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	
1944	Mar-08	2851	2604	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.04%**	**1**
1948	Mar-08	10104	9284	0	0.00%	0	0.00%	1	0.01%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**4**	**0.04%**	**2**
1699T/TC	May-07	22324	19606	0	0.00%	1	<0.01%	11	0.05%	8	0.04%	2	0.01%	3	0.01%	0	0.00%	2	0.01%	1	<0.01%	0	0.00%	**28**	**0.13%**	**19**
1888T/TC	Jun-06	183006	161324	15	0.01%	10	0.01%	88	0.05%	59	0.03%	30	0.02%	4	<0.01%	14	0.01%	14	0.01%	4	<0.01%	14	0.01%	**252**	**0.14%**	**148**
1882T/TC	Jun-06	13777	12250	0	0.00%	0	0.00%	8	0.06%	4	0.03%	2	0.01%	2	0.01%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	**18**	**0.13%**	**15**
1782T/TC	Jun-06	13995	11377	0	0.00%	1	0.01%	11	0.08%	9	0.06%	2	0.01%	2	0.01%	0	0.00%	2	0.01%	0	0.00%	1	0.01%	**28**	**0.20%**	**21**
1788T/TC	Feb-06	62935	49408	1	<0.01%	2	<0.01%	25	0.04%	31	0.05%	11	0.02%	1	<0.01%	2	<0.01%	9	0.01%	1	<0.01%	5	0.01%	**88**	**0.14%**	**66**
1644T	Apr-05	948	681	0	0.00%	1	0.11%	0	0.00%	2	0.21%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.32%**	**2**
1648T	Apr-05	2820	2014	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	24663	17742	0	0.00%	1	<0.01%	17	0.07%	9	0.04%	0	0.00%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**32**	**0.13%**	**12**
1646T	May-02	81690	55668	1	<0.01%	12	0.01%	18	0.02%	48	0.06%	9	0.01%	2	<0.01%	0	0.00%	18	0.02%	0	0.00%	9	0.01%	**117**	**0.14%**	**30**
1688T/TC	Jun-03	341705	242512	7	<0.01%	60	0.02%	173	0.05%	245	0.07%	125	0.04%	12	<0.01%	21	0.01%	125	0.04%	4	<0.01%	56	0.02%	**828**	**0.24%**	**390**

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

Malfunction Summary

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1944	Mar-08	2851	2604	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**1**	**0.04%**
1948	Mar-08	10104	9284	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**
1699T/TC	May-07	22324	19606	2	0.01%	2	0.01%	0	0.00%	0	0.00%	15	0.07%	**19**	**0.09%**
1888T/TC	Jun-06	183006	161324	4	<0.01%	12	0.01%	1	<0.01%	6	<0.01%	121	0.07%	**144**	**0.08%**
1882T/TC	Jun-06	13777	12250	0	0.00%	1	0.01%	0	0.00%	2	0.01%	11	0.08%	**14**	**0.10%**
1782T/TC	Jun-06	13995	11377	1	0.01%	2	0.01%	0	0.00%	0	0.00%	16	0.11%	**19**	**0.14%**
1788T/TC	Feb-06	62935	49408	1	<0.01%	22	0.03%	1	<0.01%	7	0.01%	41	0.07%	**72**	**0.11%**
1644T	Apr-05	948	681	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.21%	**2**	**0.21%**
1648T	Apr-05	2820	2014	0	0.00%	1	0.04%	0	0.00%	1	0.04%	2	0.07%	**4**	**0.14%**
1642T	May-02	24663	17742	0	0.00%	1	<0.01%	2	0.01%	7	0.03%	10	0.04%	**20**	**0.08%**
1646T	May-02	81690	55668	7	0.01%	7	0.01%	1	<0.01%	8	0.01%	23	0.03%	**46**	**0.06%**
1688T/TC	Jun-03	341705	242512	94	0.03%	94	0.03%	16	<0.01%	10	<0.01%	225	0.07%	**439**	**0.13%**
1488T/TC	Mar-00	273784	129822	124	0.05%	78	0.03%	13	<0.01%	2	<0.01%	240	0.09%	**457**	**0.17%**

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

SCORE Summary

Malfunctions

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1948	150	1340	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	890	14440	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1888T/TC	3490	52280	1	0.03%	1	0.03%	0	0.00%	1	0.03%	2	0.06%	**5**	**0.04%**
1882T/TC	110	1230	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.91%	**1**	**0.91%**
1782T/TC	100	1680	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	210	3390	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	410	6350	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	1060	17430	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.09%	**1**	**0.09%**
1488T/TC	130	2470	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Lead Dislodgement		Failure to Capture		Abnormal Pacing Impedance		Extracardiac Stimulation		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1948	150	1340	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	890	14440	0	0.00%	1	0.11%	2	0.22%	1	0.11%	0	0.00%	**4**	**0.45%**
1888T/TC	3490	52280	0	0.00%	7	0.20%	0	0.00%	1	0.03%	1	0.03%	**9**	**0.26%**
1882T/TC	110	1230	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1782T/TC	100	1680	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	210	3390	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	410	6350	0	0.00%	1	0.24%	1	0.24%	0	0.00%	0	0.00%	**2**	**0.49%**
1688T/TC	1060	17430	1	0.09%	0	0.00%	0	0.00%	1	0.09%	0	0.00%	**2**	**0.19%**
1488T/TC	130	2470	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Implantable Cardiac Monitors (ICM)

St. Jude Medical™
More control. Less risk.

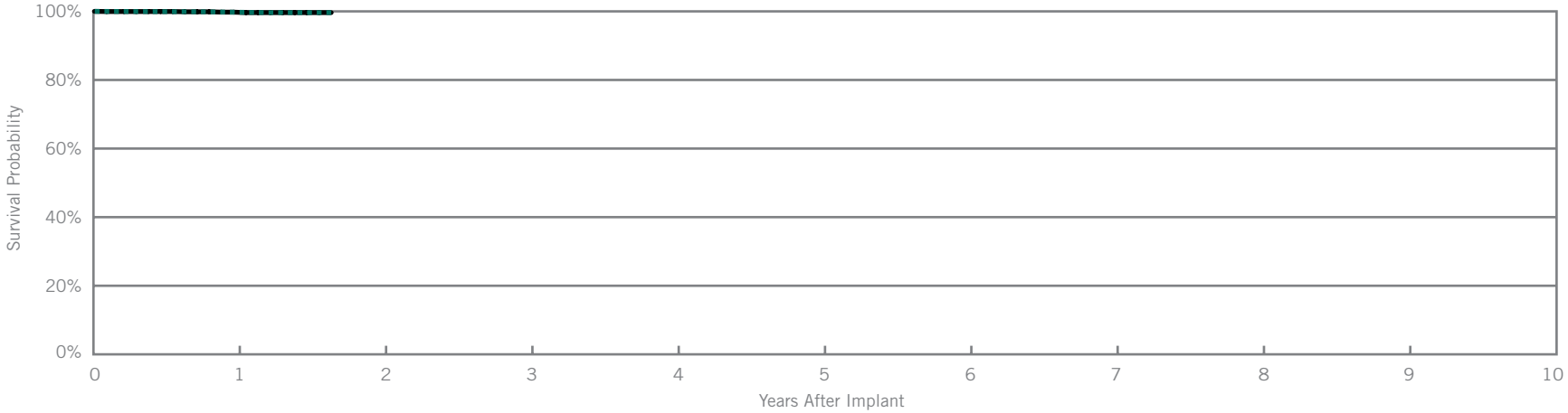
Customer Reported Performance Data

SJM Confirm®

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	4,625
Estimated Active US Implants	3,907
Estimated Longevity	3.0 Years*
Normal Battery Depletion	0
Number of Advisories	None

Malfunctions	Qty.	Rate
Malfunctions w/ Compromised Therapy	0	0.00%
Malfunctions w/o Compromised Therapy	4	0.09%
Total	**4**	**0.09%**



Including Normal Battery Depletion .....

Year	1	at 20 months								
Survival Probability	99.77%	99.64%								
± 1 standard error	0.10%	0.13%								
Sample Size	3600	300								

Excluding Normal Battery Depletion ——

Year	1	at 20 months								
Survival Probability	99.77%	99.64%								
± 1 standard error	0.10%	0.13%								

**After 12 month shelf-life.*

Focus on Clinical Performance

Optim® Lead Insulation

In June 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® insulation featured in Tendril® ST Optim® lead models 1888T/TC and 1882T/TC. This was rapidly followed in July 2006 by an Optim-insulated defibrillation lead, the Riata® ST Optim® lead model 7020/7021. Optim lead insulation consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone. The polyurethane content of Optim® insulation imparts lubricity, strength, and abrasion resistance while the nearly 50% silicone content imparts flexibility and biostability.[1,2] The clinical performance of Optim insulation proved to be excellent,[3] leading to the subsequent market release of several Optim-insulated leads: IsoFlex® Optim® lead model 1944/1948 in March 2008, QuickFlex® µ lead model 1258T in March 2009, and OptiSense® lead model 1999 in January 2010.

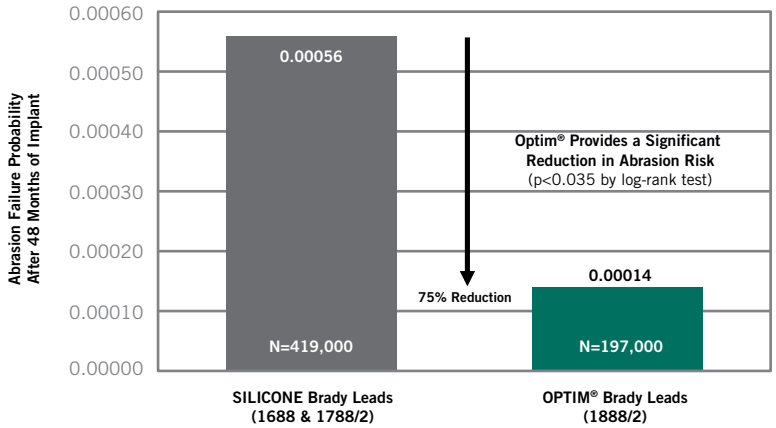
Optim insulation has been on the market for 4 years, with over 300,000 leads implanted in the U.S.. All aspects of Optim lead performance can be appreciated by referring to the Acute Observation, Chronic Complication, and Lead Malfunction tables, and Survival Charts found in this performance report. The most noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[4] Insulation abrasion can occur as a result of lead contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. The clinical effects associated with abrasion malfunctions can include sensing noise and changes in both pacing and defibrillation impedances and thresholds.

For the May 2010 Performance Report, a Kaplan-Meier analysis was performed on both the Tendril and Riata®/Durata® lead families, comparing the clinical occurrence of insulation abrasion malfunctions found on silicone-insulated leads and Optim-insulated leads during their first three years on the market. The presence of Optim insulation proved to dramatically reduce the probability of abrasion malfunction. A log-rank test verified the statistical significance of the Optim benefit.

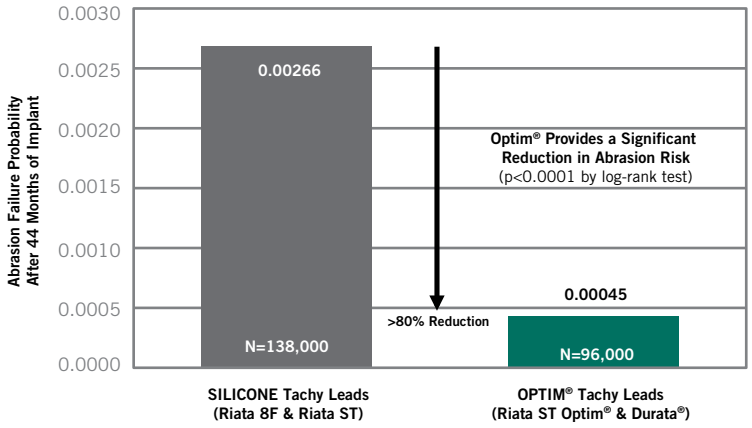
St. Jude Medical is proud to present the results of an updated statistical analysis in this Performance Report, now including data through June 30, 2010. The graphs below demonstrate that the presence of Optim® insulation in CRM pacing and defibrillation leads reduces the probability of abrasion malfunction by at least 75% after more than 3.5 years of implant. The time points selected for the graphs (48 months for Tendril® leads and 44 months for Riata®/Durata® leads) represent the longest duration Optim insulation implants available for each model family. These dramatic reductions in abrasion malfunction probability were again confirmed to be statistically significant ($p << 0.05$) by a log-rank test.

This analysis demonstrates the strong benefit of Optim insulation in reducing the probability of all-cause abrasion malfunctions. The benefit of Optim in reducing specific types of insulation breaches is also evident in the malfunction subcategory data present in this report.

Optim® Insulation Effects on St. Jude Medical Bradycardia Lead Abrasion
(Kaplan-Meier Analysis of US Data)



Optim® Insulation Effects on St. Jude Medical Tachycardia Lead Abrasion
(Kaplan-Meier Analysis of US Data)



[1] C. Jenney, J. Tan, A. Karicherla, J. Burke, and J. Helland, "A New Insulation Material for Cardiac Leads with Potential for Improved Performance," HRS 2005, HeartRhythm, 2, S318-S319 (2005).
[2] J. Tan and C. Jenney, "Comparative In Vivo Biostability Study of A New Lead Insulation Material Versus Polyurethanes," HRS2006, Heart Rhythm, 3, S146 (2006).
[3] F. Khairallah, F. Hamati, D. Peress, A. Schneider, J. Alonso, and M.S. Gupta, "Performance of Cardiac Leads with Optim Insulation Material: Initial Experience from the OPTIMUM Registry," HRS2009, Heart Rhythm, 6, S382 (2009).
[4] T. Kleemann, T. Becker, K. Doenges, M. Vater, J. Senges, S. Schneider, W. Saggau, U. Weisse, and K. Seidl, "Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter-Defibrillators Over a Period of >10 Years," Circulation, 115, 2474-2480 (2007).

High Voltage DF4 Connector System

Background

In June 2009 St. Jude Medical announced the first implant of the SJ4 connector system. This four-pole connector system featured a single connection between the implantable cardioverter defibrillator (ICD) and the defibrillation lead and simplified the implant procedure. The SJ4 connector reduced system pocket bulk by eliminating the lead yoke and reducing the header size. The fewer number of ports on the ICD lowered the likelihood of lead insertion in the incorrect port and reduced the number of set screws necessary to secure the leads within the header. The DF4 connector represents state-of-the-art medical device technology for implanted systems with benefits for both implanter and patient.

Since its initial release, the SJ4 design complied with the DF4 connector requirements in the recently published international standard ISO 27186:2010, "Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements". In recognition of this compliance, St. Jude Medical received FDA approval in June 2010 to update its SJ4 system label designation to DF4. For this analysis, all four-pole defibrillation connectors will be identified as DF4. 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 50% of all U.S. ICD and CRT-D system implants. Initial DF4 implants consisted of Durata® Q defibrillation leads, Current® ICDs, and Promote® CRT-Ds. In May 2010 St. Jude Medical received approval for the Fortify® ICD and Unify® CRT-D families featuring the DF4 connector system and 40J delivered energy, which now represent the majority of defibrillator devices sold in the U.S..

As of the June 30, 2010 data cutoff for this Product Performance Report, the DF4 connector system has been in clinical use for 12 months and represents over 20,000 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

The number of DF4 systems implanted, combined with a significant duration in the field, allowed a first assessment of chronic field performance. St. Jude Medical completed a statistical comparison of the complaints and malfunctions related to the DF4 and IS-1/DF-1 connector systems. Due diligence was applied to ensure a direct and unbiased comparison. Devices included in the analysis were implanted on or after August 1, 2009, which represents the first month with at least 100 DF4 system implants, and no later than June 30, 2010, which is the data cutoff for this Product Performance Report. Complaints included in the analysis represent events occurring within this same period. In order to capture as much of the clinical performance information as possible, no restrictions were made on implant duration for complaint data. All malfunction data included in this comparative analysis were generated between August 1, 2009 and June 30, 2010 and AdvaMed performance reporting guidelines were applied. A non-biased comparison was ensured by including only those 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	~15,000	~20,000
HV Lead Models	7120, 7121, 7122, 7070, 7071	7120Q, 7121Q, 7122Q, 7170Q, 7171Q
ICD/CRT-D Models	CD1211-36, CD1215-36, CD1231-40, CD2211-36, CD2215-36, CD2231-40, CD3211-36, CD3215-36, CD3231-40	CD1211-36Q, CD1215-36Q, CD1231-40Q, CD2211-36Q, CD2215-36Q, CD2231-40Q, CD3211-36Q, CD3215-36Q, CD3231-40Q

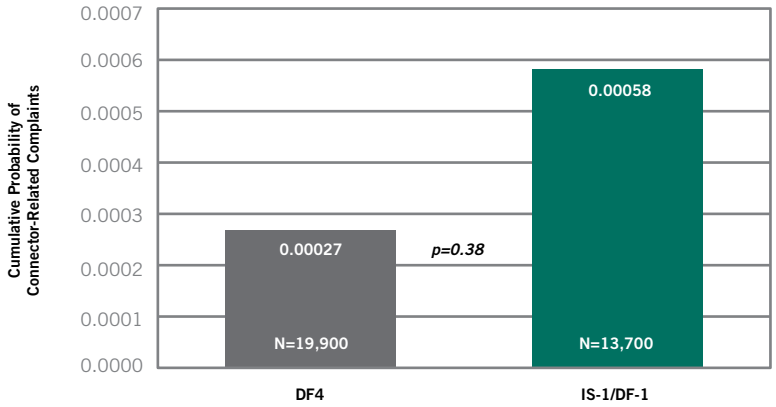
Note that lead models 7070/7071 and 7170Q/7171Q were considered equivalent in design, except for the connector.

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 publication of ICD/CRT-D complaint data analysis at this level of detail is a first for St. Jude Medical cardiac rhythm management performance reporting.

An assessment of lead field performance revealed no connector-related complaints or connector-related malfunctions recorded for either DF4 or IS-1/DF-1 defibrillation leads. Because connector-related system complaints are typically assigned to the ICD/CRT-D, the absence of lead complaints was not unusual for an analysis of this size. Due to the absence of complaints and malfunctions, no statistical comparisons of lead performance could be performed.

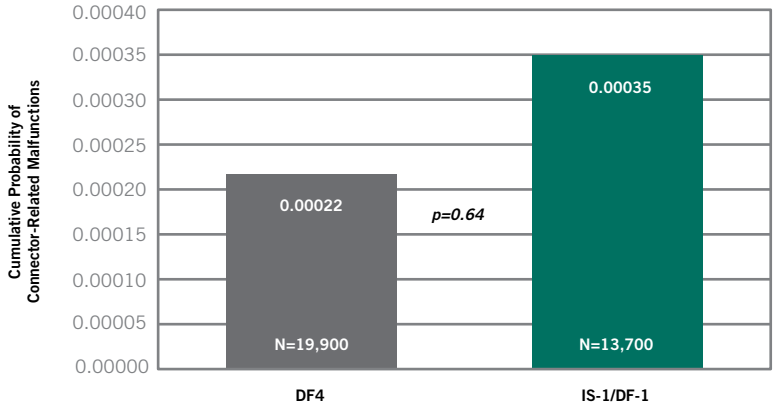
The statistical treatment of ICD/CRT-D connector-related complaint data included a comparison of cumulative incidence functions adjusted for the competing risk of explant without complaint. This was followed by the use of Gray's method[1] to assess any difference in the cumulative incidence rates and calculate a p-value. Figure 1 presents the resulting cumulative probability of connector-related complaints at the end of the analysis period, June 30, 2010. The probability of a connector-related ICD/CRT-D complaint in a DF4 system is one-half the probability observed in an IS-1/DF-1 system. Due to the low number of total connector-related complaints, 5 for DF4 and 7 for IS-1/DF-1, this difference did not prove to be statistically significant (p=0.38). Reports of difficult IS-1 connector insertion account for 3 of these malfunctions while the remaining 9 are the result of reported difficulties in tightening of the setscrew. The elimination of three set screws in all DF4 ICD/CRT-D models is believed to be a factor in the trend towards reduced DF4 connector-related complaints.

Figure 1. ICD/CRT-D Connector-Related Complaints
Represents Events Between Aug 1, 2009 and June 30, 2010



A similar statistical treatment was applied to the ICD connector-related malfunction data. The resulting cumulative probability of connector-related malfunctions at the end of the analysis period, June 30, 2010, is shown below in figure 2. The probability of an ICD/CRT-D malfunction in a DF4 system is approximately 35% less than in an IS-1/DF-1 system. Similar to the complaint analysis, the low number of total connector-related malfunctions, 4 for DF4 and 4 for IS-1/DF-1, did not result in statistical significance (p=0.64). All of these malfunctions were confirmed to be related to improper setscrew function and/or damage to the setscrew during implant. Just as indicated in the complaints analysis, the elimination of three set screws in all DF4 ICDs/CRT-Ds models is believed to be a factor in the trend towards reduced DF4 connector-related malfunctions.

Figure 2. ICD/CRT-D Connector-Related Malfunctions
Represents Malfunctions Analyzed Between Aug 1, 2009 and June 30, 2010



Conclusions:

This first analysis of early DF4 connector system field performance data has demonstrated that the four-pole connector system compares favorably to the traditional IS-1/DF-1 connector system. The relatively short duration that DF4 has been on the market has limited the time period of this analysis and prevented the identification of statistical significance for the trends identified. Continued tracking of DF4 field performance may allow us to confirm these early trends.

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

Advisories & Safety Alerts

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 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, 2010):** At the time of the advisory there was one report of this issue out of approximately 330 Convert+ Model V-195 ICDs distributed in Europe and Asia. As of June 30, 2010, there have been no additional reports associated with this advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic® + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic® II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas® + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas® II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	01/16/08 Class II A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic® and Atlas® family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window.	A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin® Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (June 30, 2010):** At the time of the advisory, there were 8 worldwide (6 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2010 there have been no additional devices confirmed to have this issue since the time of the advisory.

ICD and CRT Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Photon™ DR (V-230HV) (certain serial numbers), Photon™ Micro VR/DR (Models V-194/V-232), Atlas® VR/DR (Models V-199/V-240)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (June 30, 2010):** At the time of the advisory, there were 60 worldwide (38 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2010 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue. This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death.

ICD and CRT Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/ V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/ V-340/V-341/V-343).	6/13/05 Class II Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to St. Jude Medical. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. St. Jude Medical has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (June 30, 2010):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

ICD and CRT Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® (V-197, V-235), Epic®+ (V-196, V-236), Epic® HF (V-338), Epic®+ HF (V-250), Atlas®+ (V-193, V-243), Atlas®+ HF (V-340), or Atlas® (model V-242) ICDs	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (June 30, 2010):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

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

Pacemakers

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity® SR (5172) Identity® DR (5370) Identity® XL DR (5376)	10/12/06 Class II A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in St. Jude Medical Identity® pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the St. Jude Medical Identity® family of pacemakers when programmed by the St. Jude Medical APS™ III Model 3500/3510 or Merlin® Patient Care System Model 3650 programmers.	No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process. **Current Status (June 30, 2010):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of June 30, 2010 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity ADx® DR Models 5286, 5380, 5386 and 5480	07/31/03 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. **To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval.** In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual chamber device would have to satisfy both of the following conditions: Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower Autocapture programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or Autocapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program Autocapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (June 30, 2010):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Pacemakers

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

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

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

Pacemakers

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

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

Pacemakers

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

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

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

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