Implantable Electronic Systems Division
Product Performance Report
2012 Second Edition

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

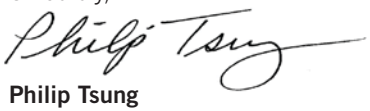
As a world leader in the development of state-of-the-art technology for cardiac rhythm management devices, St. Jude Medical continuously strives to partner with physicians in reducing risks and facilitating the best possible patient outcomes. We understand that our products are implanted in people whose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

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

With this edition of the PPR, St. Jude Medical has greatly expanded the scope of the data reported from actively monitored studies. Since 2007, the PPR has featured pacemaker, ICD, and lead data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). Post-Approval studies are now standard practice for St. Jude Medical, providing a rich source of actively collected and continuously monitored reliability and performance data for cardiac rhythm management products. This PPR now features a product performance data set which includes SCORE and three Post-Approval Studies. This combined data set encompasses more than 40,000 implants from multiple product families, including leads, ICDs and pacemakers, making it the most comprehensive, actively monitored, product performance dataset in the industry.

As we continually strive to provide unbiased and reliable information on the performance of our products, St. Jude Medical is pleased to release the second edition of the 2012 Product Performance Report containing the latest performance information on our ICMs, ICDs, pacemakers and lead systems.

Sincerely,



Philip Tsung
Vice President, Quality Assurance

St. Jude Medical
More control. Less risk.

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Serving Our Mission

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

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

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

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

What You'll Find in This Report

- Table of Contents
- A summary of the methods St. Jude Medical has used for measuring product performance, including key definitions of terms used in preparing this report
- For each ICD, pacemaker, ICM, and lead model with at least 500 active devices in service, St. Jude Medical provides product performance data, according to industry guidelines, collected through June 30, 2012, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - For the more recent products, the quantity, rate, and type of product malfunctions are detailed
  - For the more recent lead models, the quantity, rate, and type of customer complaints (acute observations and chronic complications) are detailed
- Summary tables of performance data, organized by product type and model
- For all ICD, pacemaker, ICM, and lead models that meet Actively Monitored Study Data Registry inclusion criteria, St. Jude Medical provides active registry performance data, collected through June 30, 2012, including:
  - A table of basic information about each model
  - Survival probability provided in graphical and tabular format
  - A table of all Qualifying Complications including quantity and rate
  - A table with quantity, rate, and type of product malfunctions
- A Focus on Clinical Performance section which provides product performance data on a variety of unique topics, including:
  - Riata® lead performance
  - Durata® lead performance including an independent analysis of active registry data by PHRI
  - The effect of Optim® lead insulation on HV lead abrasion
- An updated summary of advisories on all implantable devices since 2003
- An index by product type and model name
- An index of phased-out models by product type and model name

What's New in This Report

Expansion of Actively Monitored Study Data

Since 2007 the Product Performance Report has included data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). This comprehensive, monitored study provided key performance data on pacemakers, ICDs, and leads. Now that product-specific, post-market registries have become standard practice, St. Jude Medical has decided to complement the SCORE registry with data from the SJ4 Post-Approval Study, the Quickflex® µ Post-Approval Study, and the Quadripolar Pacing System Post-Approval Study. Representing >40,000 implants, this compilation of actively monitored study data will be a valuable source of product performance information.

Updates on Riata® Lead Performance

In order to provide our physician customers and patients the most up-to-date information, St. Jude Medical has included an update on Riata® lead performance in the Focus on Clinical Performance section (see pages 236-239). This section provides the latest Riata externalized conductor rates from passive complaint and returns handling and describes in considerable detail the rates of other types of Riata insulation abrasion failure mechanisms that St. Jude Medical has identified from returns analysis. New to this section is a summary of Phase I results from the St. Jude Medical Riata Lead Evaluation Study, including data from North America and Japan.

Updates on Durata® Lead Performance

Durata® lead performance continues to meet expectations by all measures. Our confidence in the Durata lead performance is based on combined data from three prospective, actively monitored registries that include 10,989 Optim® insulated defibrillation leads. Additionally, this section provides details on the very low rate of abrasion failures that have been identified on Optim insulated St. Jude Medical defibrillation leads. A statistical analysis of this registry data performed by PHRI, an independent, third-party, is presented in this special Focus on Clinical Performance section (see pages 240-243).

Customer Reported Performance Data

Product performance data derived from customer-initiated complaints and returned products is referred to as Customer Reported Performance Data. While St. Jude Medical strongly encourages the submission of any relevant complaints and product returns, this data is not proactively solicited or regularly monitored like data from the SCORE registry or Post-Approval studies. Under reporting of events within customer reported performance data is recognized throughout our industry. St. Jude Medical is constantly improving the accuracy and utility of the data within this Product Performance Report.

Summary Information

The Customer Reported Performance Data page for each model or model group includes a table of model-specific information. Several terms from this table that are relevant to performance data calculations are defined below:

Registered U.S. Implants - The total number of U.S. implanted devices for which patient and device information has been provided to St. Jude Medical. This total includes devices which have been explanted or are otherwise out of service.

Estimated Active U.S. Implants - The total number of U.S. registered implants that have not been identified to St. Jude Medical as explanted or otherwise out of service. An adjustment is made to account for the under reporting of patient mortality.

Estimated Longevity - The estimated number of years in which a device is expected to reach its Elective Replacement Indicator (ERI), as stated in the product literature. The estimate is based on battery life approximations and empirical battery performance distributions. It is strongly affected by many factors such as programmed parameters, percentage of time paced, internal impedance, etc. For example, the 9.2 year estimated longevity of an Accent® DR model PM2110 pacemaker is based on the mean longevity (or 50%) value in the product literature corresponding to a 2.5V dual-chamber output, 500 ohm lead impedance, 100% DDD pacing, and Stored EGMs On. Actual performance can vary considerably, depending on the actual programmed settings and operations.

Normal Battery Depletion - The condition where a returned device met its electrical specification and reached its elective replacement indicator voltage (1) with an implant duration meeting or exceeding the nominal predicted longevity at default shipped settings, or (2) with an implant duration exceeding 75% of its estimated longevity, based on longevity calculations using information from device usage and the actual device settings. The quantity of normal battery depletions reported is determined directly from laboratory analysis and does not represent any adjustment to account for under reporting.

Survival Calculation General Methods

For ICDs, pacemakers, ICMs, and leads, we compile cumulative survival data based on the actuarial (or life-table) method of survival analysis, consistent with ISO 5841-2:2000(E) "Reporting of Clinical Performance of Populations of Pulse Generators and Leads" and the 2009 AdvaMed document "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads". Product performance is plotted over a maximum range of 20 years, with a minimum of 500 registered implants required for inclusion in the report, and a minimum sample size for each reported time period of 200 devices. "Survival" refers to the proper function of the device, not the survival of the patient, and is intended to illustrate the calculated probability of device survival at a given point in time. A survival probability of 99% at five years, for example, indicates that at five years after implant, the system has a 1% risk of incurring a malfunction and/or normal battery depletion. All domestically implanted devices within each model family are included in the calculations.

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

ICD, Pacemaker, and ICM Survival Analysis

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

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

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

ICD, Pacemaker, and ICM Malfunction Reporting

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

Malfunction Definitions

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

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

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

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

Malfunction Root Cause Category Definitions

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

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

Battery - Findings linked to the battery and its components.

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

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

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

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

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

Leads Survival Analysis

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

The data used for the survival analysis of leads includes up-to-date device registration information, chronic complications (>30 days) reported by the field, and the laboratory analysis of all domestically implanted leads returned to St. Jude Medical. Complaints reported within 30 days of implant (acute observations), are considered to be related to factors other than lead malfunction, such as patient specific characteristics or implant technique, and are, therefore, excluded from the survival calculations, consistent with industry practice. If there is laboratory data that determines the lead to have exhibited a malfunction, and the lead is known to have been implanted, the lead is counted as a non-survivor. If a lead is the subject of a complaint (chronic complication) report, is no longer in service as a result of the complication, and was implanted for more than 30 days, then the lead is counted as a non-survivor. These criteria are also

followed for partial lead returns. This method for non-returned complications is used to ensure a conservative failure estimate for lead performance. Chronic complications commonly associated with non-returned leads and partial lead returns include, but are not limited to, reports of sensing, pacing, and capture anomalies, perforation, and dislodgement.

Leads Observation and Complication Reporting

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

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

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

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

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

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

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

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

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

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

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

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

Leads Malfunction Reporting

As a supplement to the survival estimates, the categorization of lead malfunctions emphasizes the root cause of malfunction rather than a functional longevity prediction. In accordance with AdvaMed guidelines, laboratory analysis results of returned leads are categorized into one of the following five categories of malfunctions. The quantity and rate of the each malfunction type is provided in a tabular format on the Customer Reported Performance Data and the Actively Monitored Study Data pages. Note that in the rare cases where multiple malfunctions are identified in a single lead, a single malfunction category will be selected with priority given in the order of the list below. The definition for each malfunction type is provided below:

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

In an effort to further increase customer understanding of St. Jude Medical defibrillation lead performance, subcategories of conductor fracture are also provided. The definitions of these subcategories are provided below:

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

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

Intravascular: Conductor fracture within the vascular or cardiac systems.

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

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

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

Lead-to-Lead Contact: Repetitive contact between two leads caused abrasion that resulted in a full thickness outer insulation breach.

Clavicular Crush: Damage due to strong compression between the first rib and clavicle resulted in a full thickness outer insulation breach.

Externalized Conductors: Abrasion resulted in an outer insulation breach within the vascular or cardiac systems allowing the normally contained conductors to become visible outside the lead body. Externalized conductors were described in our December 2010 and November 2011 communications regarding insulation abrasion failures on silicone Riata® and Riata® ST lead families (summary on pages 257-258). Additional information regarding externalized conductors can be found at www.RiataCommunication.com.

Other (Insulation Breach): Insulation breaches that resulted from a failure mode not represented by the other four categories. This includes a variety of failure modes, such as damage at the suture sleeve and contact with patient anatomy. Also includes insulation breaches for which analysis was unable to isolate a specific cause.

Crimps, Welds and Bonds: Any interruption in the conductor or lead body associated with a point of connection.

Other: Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, and seal rings, as well as other analysis results not included in the alternate categories.

Extrinsic Factors: The lead was removed from service and returned for analysis, however analysis was inconclusive because (1) only portions of the lead were available, or (2) the returned lead was damaged by the explantation process, or (3) lab analysis could not determine an out of specification condition (typically with complaints such as dislodgements, perforations, or failure to capture). For this particular category, malfunctions will only be included in survival calculations for leads implanted greater than 30 days.

Actively Monitored Study Data

Summary Information

Since 2007 the Product Performance Report has included data from the St. Jude Medical Product Longevity and Performance Registry (SCORE). This comprehensive study provided monitored performance data on pacemakers, ICDs, and leads. Now that product-specific, post-market registries have become standard practice, St. Jude Medical has decided to complement the SCORE registry with data from the SJ4 Post-Approval Study, the QuickFlex® µ Post-Approval Study, and the Quadripolar CRT-D Post-Approval Study. Representing >40,000 implanted devices, this actively monitored study data is a very powerful source of product performance information which complements the data collected from Customer Reported Performance Data. Actively monitored study data is not susceptible to underreporting and provides the most accurate understanding of product performance. The many sites participating in these actively monitored studies are individually providing data on the performance of St. Jude Medical cardiac rhythm management products using common definitions and criteria. In addition, each of these sites is regularly audited by St. Jude Medical personnel to ensure comprehensive reporting.

	Study Description	Study Initiated	# Sites	# Patients	Product Types/Families
SCORE (St. Jude Medical Product Longevity and Performance Registry)	Prospective, actively monitored, multicenter registry to evaluate the long-term performance of St. Jude Medical market-released cardiac rhythm management products.	September 2007	60	10959	Pacemakers, ICDs, CRT-Ds, Leads (all types)
SJ4 Post-Approval Study	Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the St. Jude Medical SJ4/DF4 connector and SJ4/DF4 defibrillation leads.	June 2009	58	1701	ICDs, CRT-Ds, Leads (all types, including Durata® Q models)
QuickFlex µ Post-Approval Study	Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the St. Jude Medical QuickFlex® µ 1258T left ventricular leads.	September 2010	76	1930	CRT-Ds, Leads (all types, including model 1258T)
Quadripolar CRT-D Post-Approval Study	Prospective, actively monitored, multicenter study to evaluate the acute and chronic performance of the St. Jude Medical Quadripolar CRT-D system.	February 2012	32	294	Unify Quadra® CRT-Ds, Leads (all types, including model 1458Q)

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

ICDs

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

Defibrillation Leads

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

CRT Leads

QuickFlex® µ (Model 1258T)
QuickFlex® XL (Model 1158T)
QuickFlex® (Model 1156T)
QuickSite® XL (Model 1058T)*
QuickSite® (Model 1056T)

Pacemakers

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

Pacing Leads

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

*New for 2012 Second Edition.

Qualifying Complications

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

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

Survival Calculation Methods

Survival calculations for actively monitored studies are made in a manner consistent with the ISO 5841-2:2000(E) method used for Customer Reported Performance Data. Any device with a Qualifying Complication is defined as a non-survivor. Consistent with industry practice, Qualifying Complications for leads are included in the survival calculations for events with an implant duration greater than 30 days. For pacemakers and ICDs, Qualifying Complications are included in the survival calculations for events with an implant duration greater than 24 hours. Medical complications unrelated to device performance are not considered as Qualified Complications. Devices included in the actively monitored studies are excluded from the Customer Reported Performance Data.

Malfunction Reporting

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

Medical Advisory Board Review

St. Jude Medical has established separate and independent device-focused and lead-focused Medical Advisory Boards (MABs). One of the important tasks assigned to the MABs is the review of the performance data contained in this report prior to its release and publication on a semi-annual basis. MAB members and their location of practice include:

Device-Focused (Pacemakers, ICDs, ICMs)

Dr. Steven Bailin, Des Moines, Iowa

Dr. Jim Baker, Nashville, Tennessee

Dr. Anne Curtis, Buffalo, New York

Dr. Steve Greenberg, Roslyn, New York

Dr. Thomas Mattioni, Phoenix, Arizona

Dr. Gery Tomassoni, Lexington, Kentucky

Lead-Focused

Dr. Roger Freedman, Salt Lake City, Utah

Dr. David Hayes, Rochester, Minnesota

Dr. Steven Kalbfleisch, Columbus, Ohio

Dr. Steven Kutalek, Philadelphia, Pennsylvania

Dr. Raymond Schaerf, Burbank, California

Dr. Bruce Wilkoff, Cleveland, Ohio

Returning Devices to St. Jude Medical

To maintain the continued accuracy of our performance reporting, St. Jude Medical strongly encourages physicians to notify our Patient Records department (888-SJM-2763) each time a device is removed from service for any reason. Additionally, all explanted products are requested to be returned to St. Jude Medical for laboratory evaluation whether or not a malfunction is suspected. To facilitate the return of explanted devices, St. Jude Medical offers a no-cost Returned Products Kit comprised of a postage paid explant box with a shipping address label, a removed device information form, a biohazard bag, and biohazard labels to seal the explant box. This kit, #N0004, can be ordered free of charge by contacting St. Jude Medical Customer Service (888-SJM-2763).

Contact Us

The St. Jude Medical team is always ready to respond to questions, comments or suggestions as well as receive product performance feedback. You can reach us by phone at 888-SJM-2763, on the web at www.SJMprofessional.com, or by contacting your local St. Jude Medical representative.

Cardiac Resynchronization Therapy (CRT) Devices

CRT ICDs

St. Jude Medical
More control. Less risk.

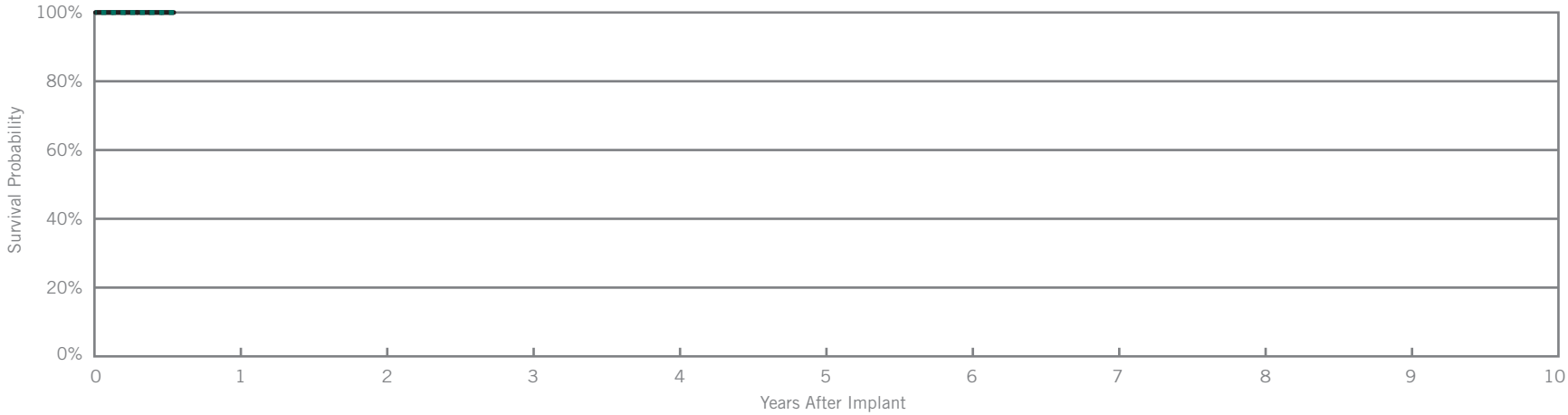
Unify Quadra® CRT-D

Model CD3249-40Q

US Regulatory Approval	Nov 2011
Registered US Implants	4,570
Estimated Active US Implants	4,402
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	at 7 months										
Survival Probability	100.00%										
± 1 standard error	0.00%										
Sample Size	300										

Excluding Normal Battery Depletion

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

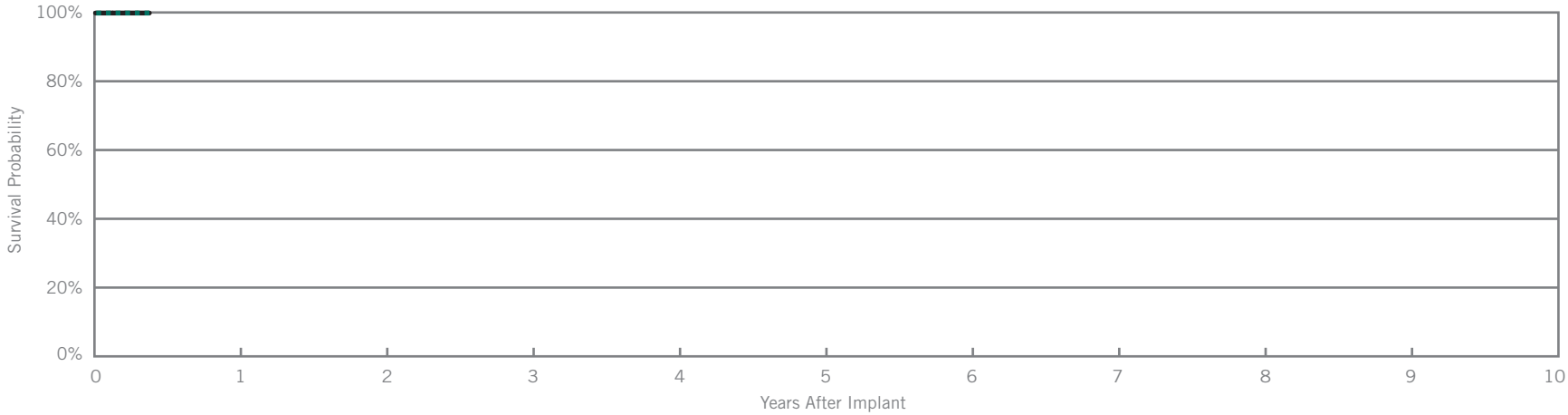
Customer Reported Performance Data

Unify Quadra® CRT-D

Model CD3249-40

US Regulatory Approval	Nov 2011
Registered US Implants	1,382
Estimated Active US Implants	1,339
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	0
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	at 5 months										
Survival Probability	99.84%										
± 1 standard error	0.11%										
Sample Size	400										

Excluding Normal Battery Depletion

Year	at 5 months										
Survival Probability	99.84%										
± 1 standard error	0.11%										

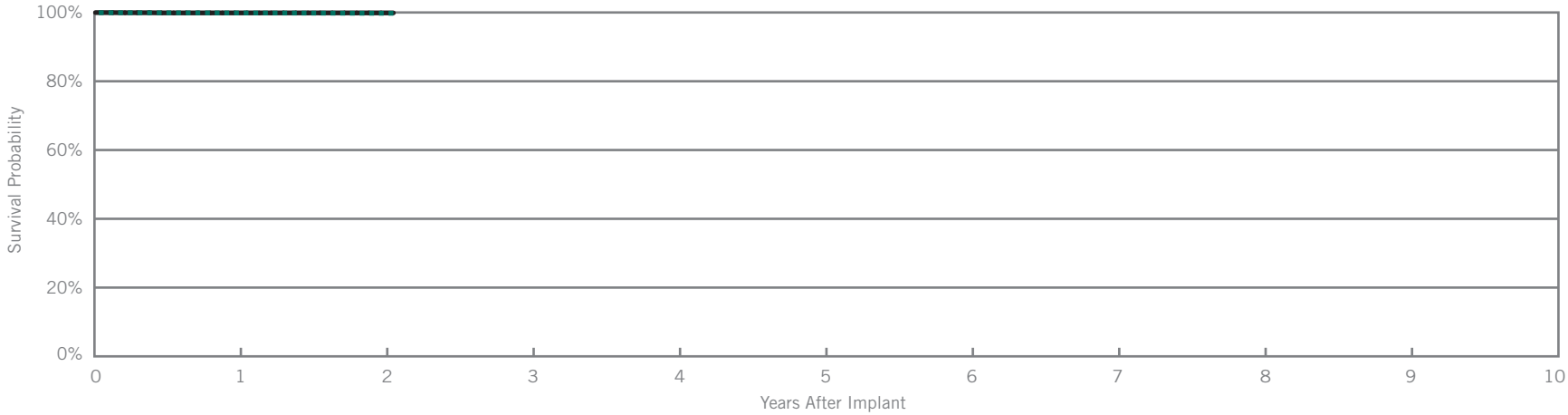
Customer Reported Performance Data

Unify® CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Registered US Implants	17,583
Estimated Active US Implants	15,145
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	7
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.77%	99.77%	99.77%							
± 1 standard error	0.04%	0.04%	0.04%							
Sample Size	14500	5100	500							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.88%	99.88%	99.88%							
± 1 standard error	0.03%	0.03%	0.03%							

Actively Monitored Study Data

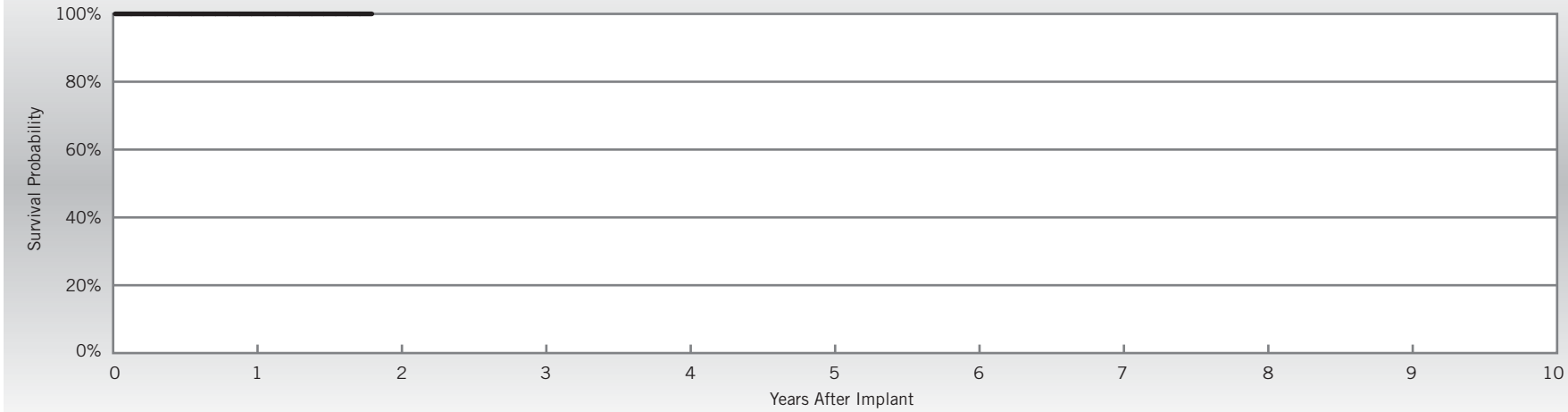
Unify® CRT-D

Model CD3231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	1,675
Cumulative Months of Follow-up	18,844
Estimated Longevity	(see table on page 34)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	1200	60								

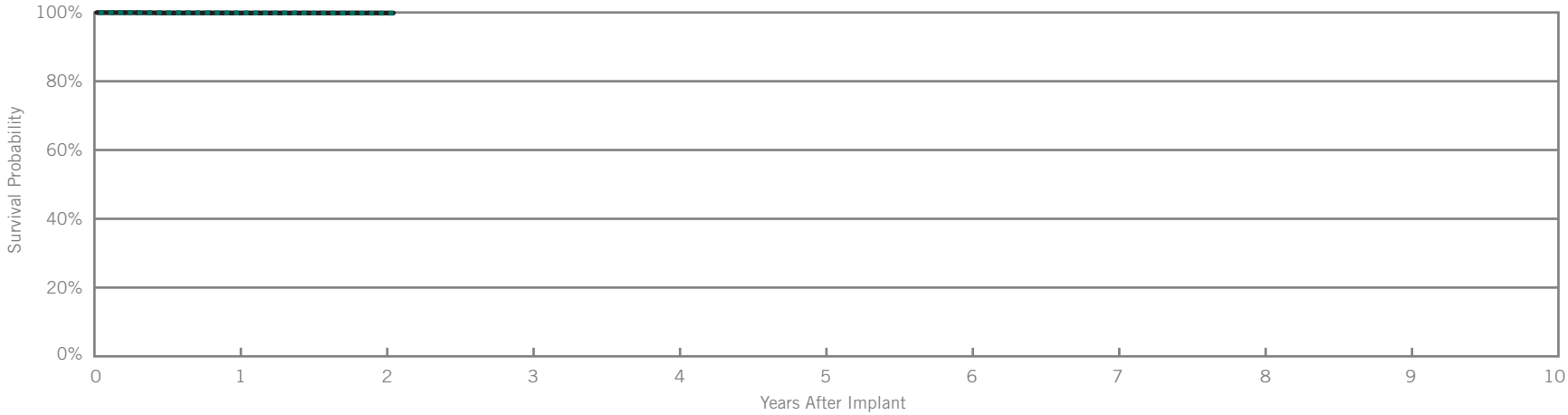
Customer Reported Performance Data

Unify® CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Registered US Implants	17,563
Estimated Active US Implants	15,317
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	3
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.81%	99.78%	99.78%							
± 1 standard error	0.03%	0.04%	0.04%							
Sample Size	13800	4300	300							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.85%	99.85%	99.85%							
± 1 standard error	0.03%	0.03%	0.03%							

Actively Monitored Study Data

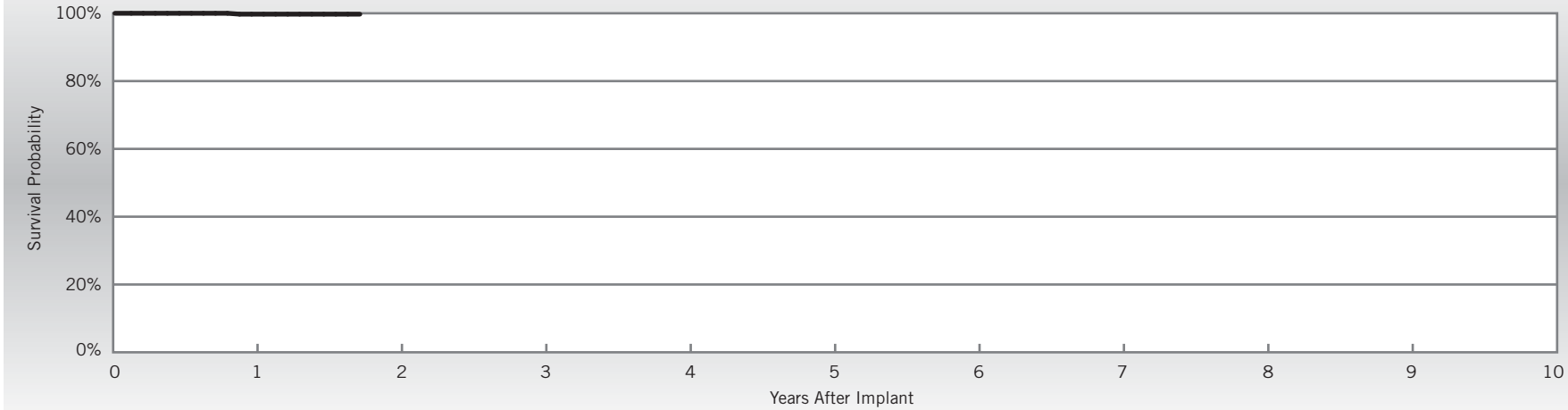
Unify® CRT-D

Model CD3231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	664
Cumulative Months of Follow-up	8,338
Estimated Longevity	(see table on page 34)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty.	Rate
Failure to Capture	1	0.15%

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



Year	1	at 21 months								
Survival Probability	99.74%	99.74%								
± 1 standard error	0.26%	0.26%								
Sample Size	500	60								

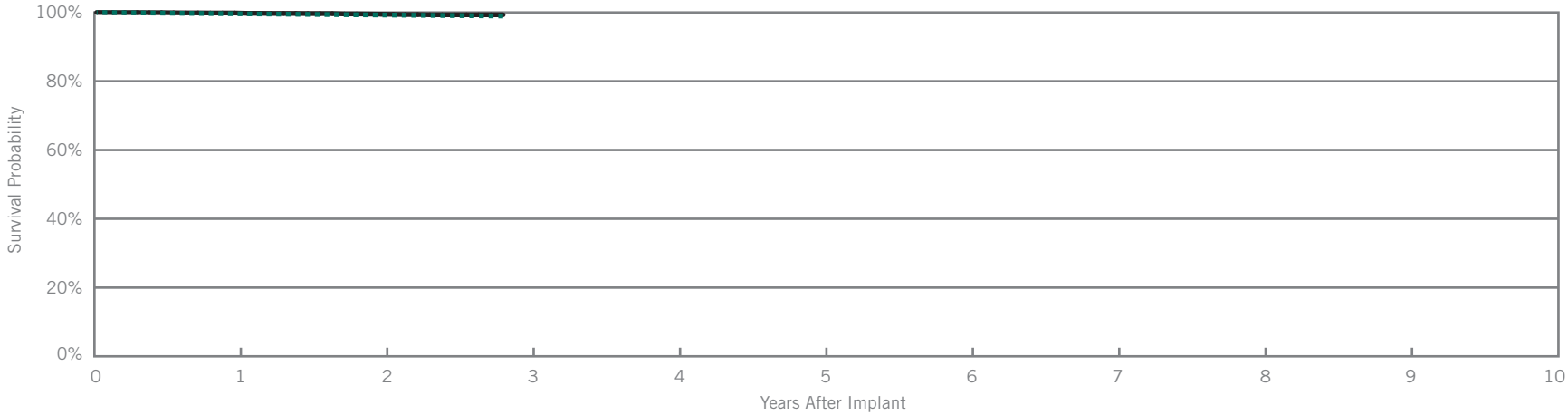
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Registered US Implants	6,714
Estimated Active US Implants	5,089
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	7
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.04%	2	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.04%	4	0.06%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	1	0.01%	0	0.00%
Other	1	0.01%	0	0.00%
Total	**10**	**0.15%**	**6**	**0.09%**



Including Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.62%	99.21%	98.98%							
± 1 standard error	0.08%	0.11%	0.14%							
Sample Size	6700	5300	300							

Excluding Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.84%	99.49%	99.32%							
± 1 standard error	0.05%	0.09%	0.12%							

Actively Monitored Study Data

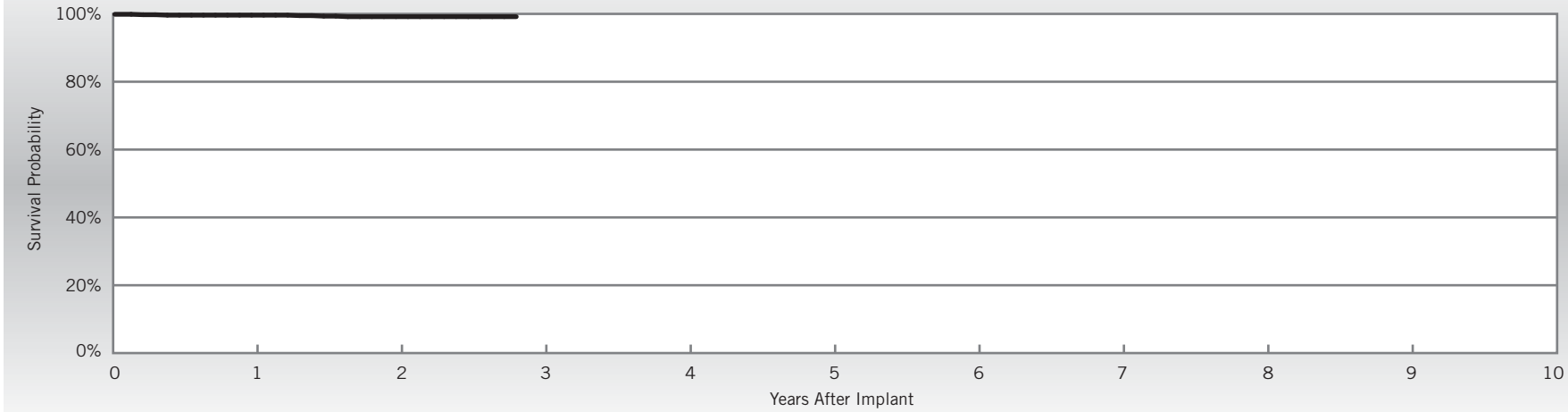
Promote® + CRT-D

Model CD3211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	854
Cumulative Months of Follow-up	20,820
Estimated Longevity	(see table on page 34)
Max. Delivered Energy	36 joules

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

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.12%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.12%	1	0.12%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.12%
Possible Early Battery Depletion	1	0.12%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**3**	**0.35%**	**2**	**0.23%**



Year	1	2	at 34 months							
Survival Probability	99.63%	99.18%	99.18%							
± 1 standard error	0.21%	0.34%	0.34%							
Sample Size	790	660	90							

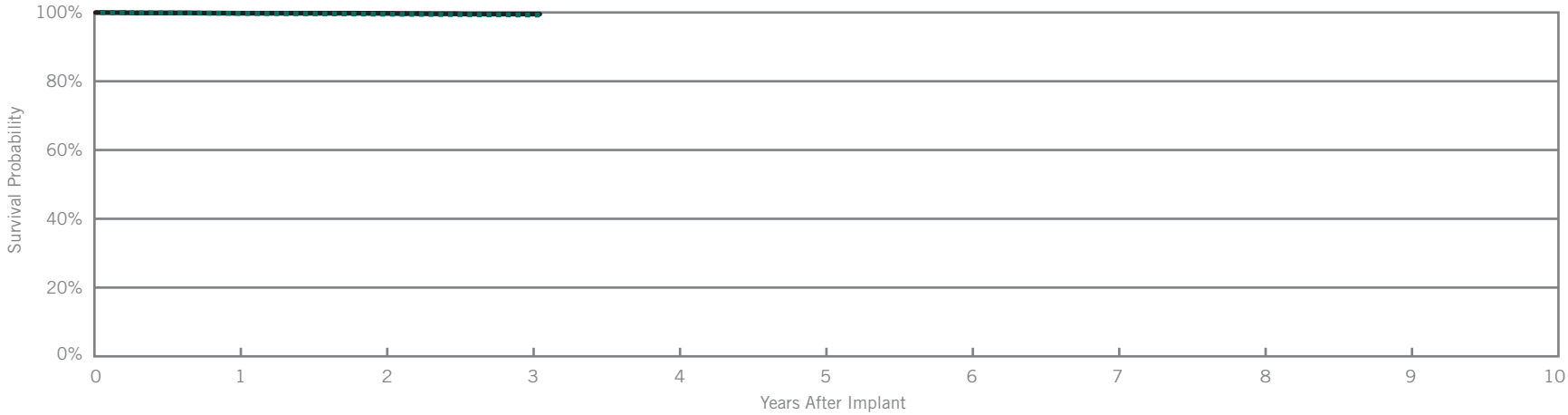
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Registered US Implants	8,487
Estimated Active US Implants	6,297
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.02%	2	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	5	0.06%	2	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	0	0.00%
Total	**7**	**0.08%**	**6**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.70%	99.64%	99.24%	99.24%						
± 1 standard error	0.06%	0.07%	0.12%	0.12%						
Sample Size	8400	6700	3100	400						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.78%	99.75%	99.54%	99.54%						
± 1 standard error	0.05%	0.06%	0.10%	0.10%						

Actively Monitored Study Data

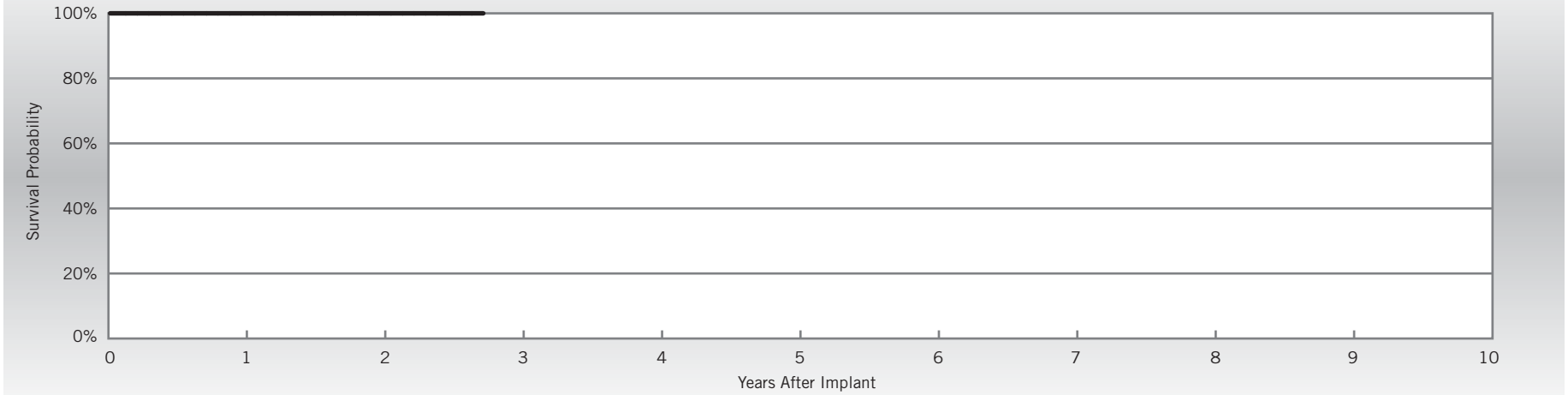
Promote® + CRT-D

Model CD3211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	226
Cumulative Months of Follow-up	5,625
Estimated Longevity	(see table on page 34)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	2	at 33 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	210	170	50							

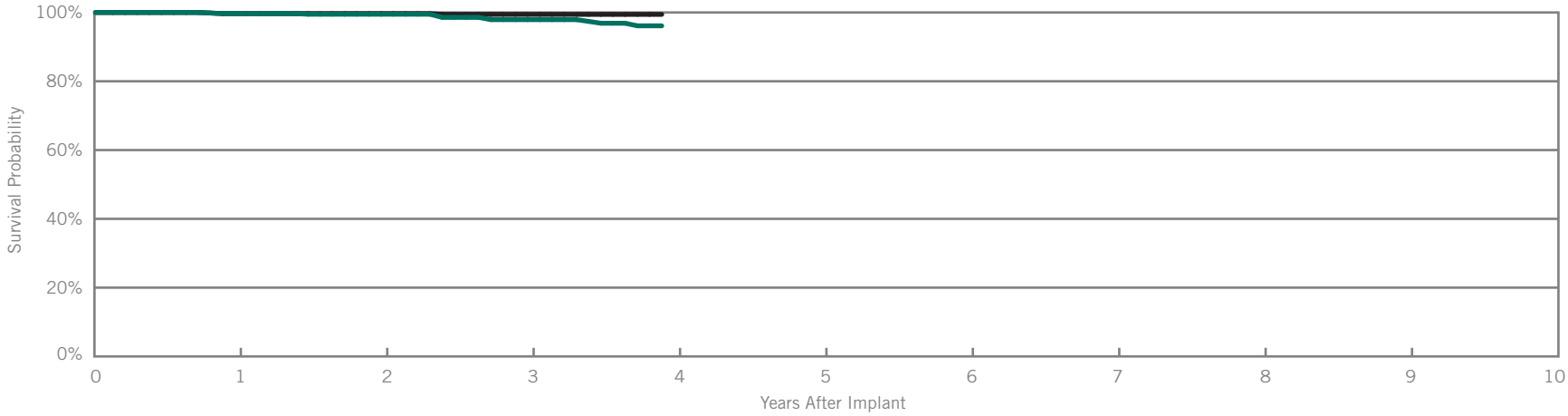
Customer Reported Performance Data

Promote® RF CRT-D

Model 3207-30

US Regulatory Approval	September 2007
Registered US Implants	1,409
Estimated Active US Implants	849
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	10
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.67%	99.49%	97.91%	96.12%						
± 1 standard error	0.16%	0.21%	0.48%	0.88%						
Sample Size	1400	1200	800	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 47 months						
Survival Probability	99.67%	99.67%	99.44%	99.44%						
± 1 standard error	0.16%	0.16%	0.23%	0.23%						

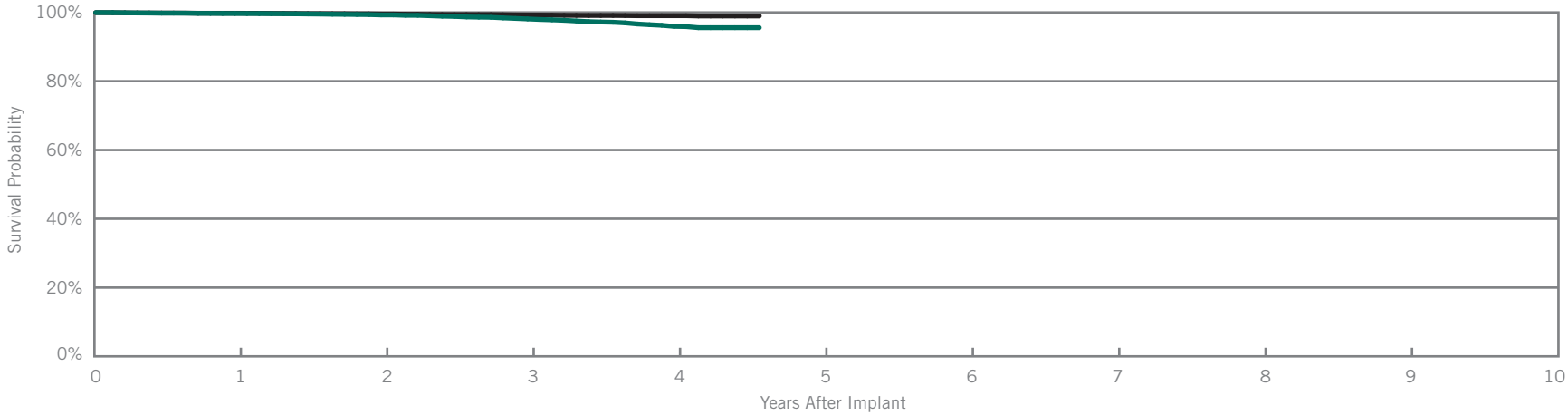
Customer Reported Performance Data

Promote® RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Registered US Implants	23,774
Estimated Active US Implants	14,642
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	127
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	5	0.02%
Electrical Interconnect	4	0.02%	0	0.00%
Battery	9	0.04%	7	0.03%
High Voltage Capacitor	5	0.02%	1	<0.01%
Software/Firmware	0	0.00%	5	0.02%
Mechanical	2	0.01%	1	<0.01%
Possible Early Battery Depletion	7	0.03%	3	0.01%
Other	5	0.02%	9	0.04%
Total	**35**	**0.15%**	**31**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.70%	99.27%	98.11%	95.95%	95.57%					
± 1 standard error	0.04%	0.06%	0.10%	0.19%	0.24%					
Sample Size	23800	20100	15800	8200	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.77%	99.53%	99.24%	99.05%	98.97%					
± 1 standard error	0.03%	0.05%	0.06%	0.08%	0.10%					

Actively Monitored Study Data

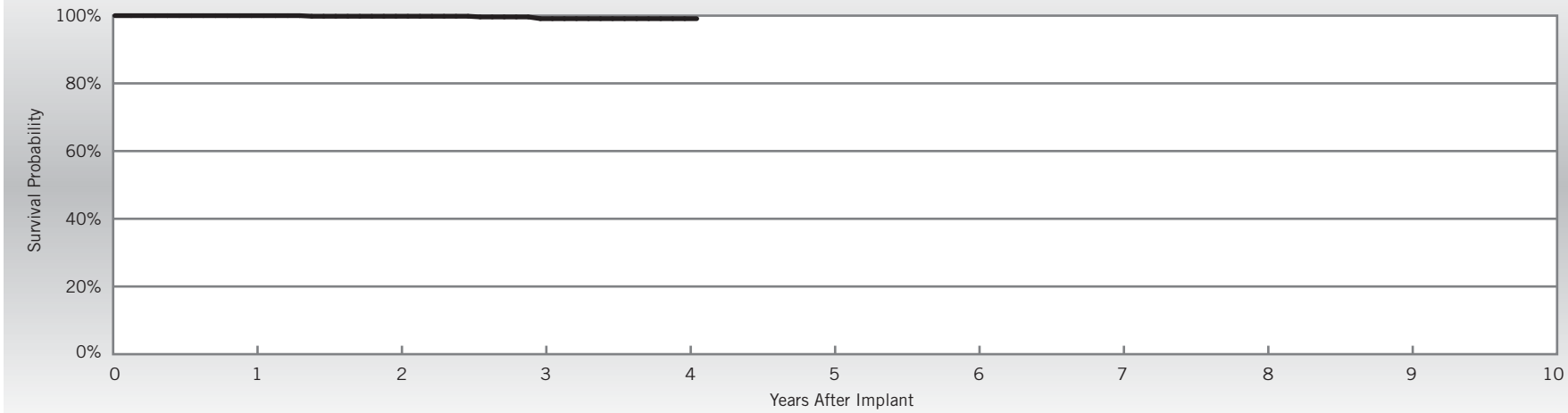
Promote® RF CRT-D

Model 3207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	717
Cumulative Months of Follow-up	24,014
Estimated Longevity	(see table on page 34)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Loss Of Telemetry	1	0.14%
Oversensing	1	0.14%
Skin Erosion	2	0.28%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.14%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	1	0.14%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.14%
Other	2	0.28%	0	0.00%
Total	**2**	**0.28%**	**3**	**0.42%**



Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	99.83%	99.11%	99.11%	99.11%					
± 1 standard error	0.00%	0.17%	0.27%	0.45%	0.45%					
Sample Size	670	590	470	220	70					

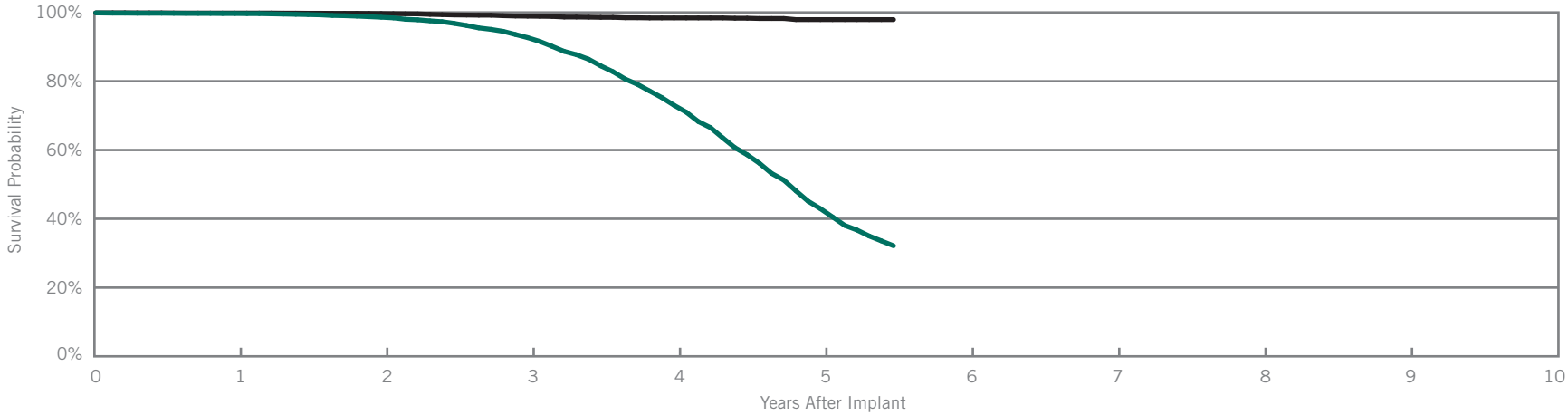
Atlas® II HF CRT-D

Model V-365

US Regulatory Approval	July 2006
Registered US Implants	8,415
Estimated Active US Implants	1,837
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	1027
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	2	0.02%
Electrical Interconnect	2	0.02%	0	0.00%
Battery	15	0.18%	3	0.04%
High Voltage Capacitor	2	0.02%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	4	0.05%	5	0.06%
Other	5	0.06%	4	0.05%
Total	**29**	**0.34%**	**14**	**0.17%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.69%	98.61%	92.69%	73.03%	42.95%	32.15%				
± 1 standard error	0.06%	0.13%	0.32%	0.60%	0.80%	0.97%				
Sample Size	8400	7200	6300	5000	2800	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.83%	99.68%	98.92%	98.41%	97.92%	97.92%				
± 1 standard error	0.05%	0.06%	0.13%	0.17%	0.24%	0.24%				

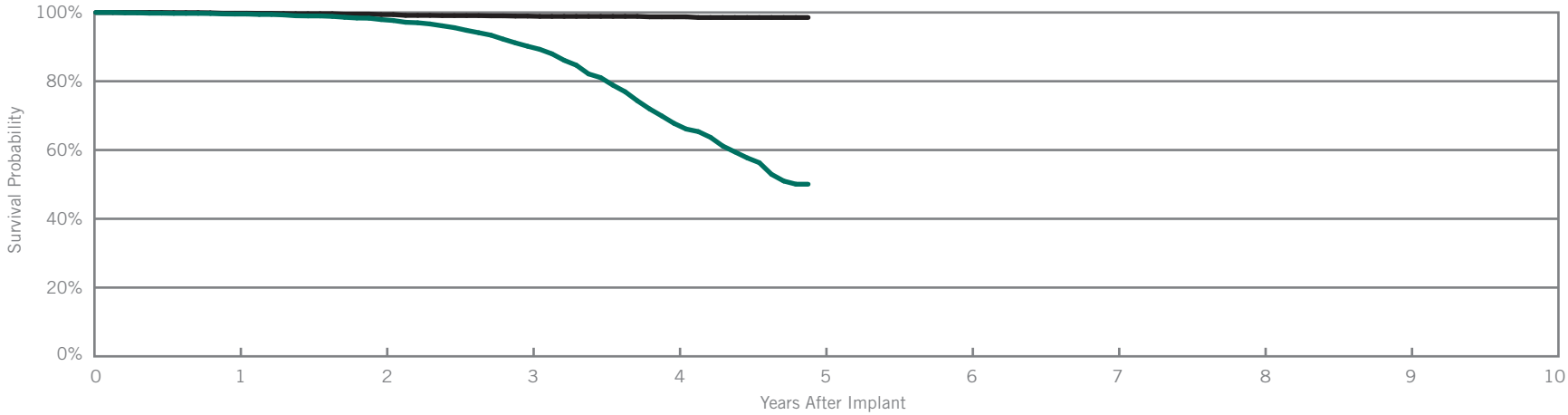
Atlas® II + HF CRT-D

Model V-366

US Regulatory Approval	February 2007
Registered US Implants	5,001
Estimated Active US Implants	1,777
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	395
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	3	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.06%	2	0.04%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.04%	4	0.08%
Other	6	0.12%	0	0.00%
Total	**11**	**0.22%**	**9**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	99.54%	97.93%	90.18%	67.76%	50.06%					
± 1 standard error	0.10%	0.20%	0.49%	0.95%	1.34%					
Sample Size	5000	4200	3400	2200	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	99.79%	99.38%	98.95%	98.73%	98.54%					
± 1 standard error	0.07%	0.11%	0.17%	0.20%	0.24%					

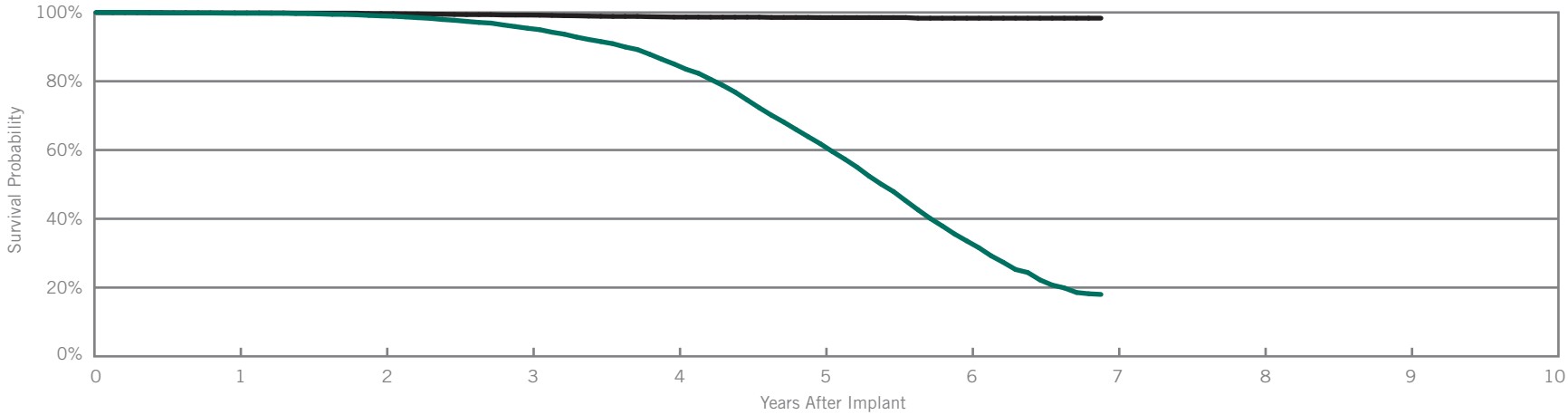
Atlas® + HF CRT-D

Model V-343

US Regulatory Approval	November 2004
Registered US Implants	18,694
Estimated Active US Implants	3,030
Estimated Longevity	(see table on page 34)
Normal Battery Depletion	2364
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	36	0.19%	4	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	5	0.03%	11	0.06%
Other	9	0.05%	4	0.02%
Total	**53**	**0.28%**	**22**	**0.12%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.78%	99.00%	95.40%	85.02%	61.81%	33.56%	18.01%			
± 1 standard error	0.03%	0.07%	0.17%	0.32%	0.49%	0.57%	0.69%			
Sample Size	18700	16000	14000	11600	8400	4200	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 83 months			
Survival Probability	99.88%	99.67%	99.25%	98.66%	98.52%	98.34%	98.34%			
± 1 standard error	0.03%	0.05%	0.07%	0.10%	0.11%	0.14%	0.14%			

Battery Longevity Summary

CRT ICDs

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3249-40Q	Unify Quadra® CRT-D	10.2	9.0	8.1	6.7
CD3249-40	Unify Quadra® CRT-D	10.2	9.0	8.1	6.7
CD3231-40Q	Unify® CRT-D**	10.2	9.0	8.1	6.7
CD3231-40	Unify® CRT-D**	10.2	9.0	8.1	6.7
CD3211-36Q	Promote® + CRT-D	8.2	7.2	6.5	5.4
CD3211-36	Promote® + CRT-D	8.2	7.2	6.5	5.4
3207-30	Promote® RF CRT-D	6.5	5.7	5.1	4.2
3207-36	Promote® RF CRT-D	8.2	7.2	6.5	5.4
V-365	Atlas® II HF CRT-D	8.2	7.2	6.5	5.4
V-366	Atlas® II HF CRT-D	8.2	7.2	6.5	5.4
V-343	Atlas® + HF CRT-D	7.9	7.1	6.4	5.4

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

Summary Information

CRT ICDs

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3249-40Q	Unify Quadra® CRT-D										
CD3249-40	Unify Quadra® CRT-D										
CD3231-40Q	Unify® CRT-D	99.77%	99.77%								
CD3231-40	Unify® CRT-D	99.81%	99.78%								
CD3211-36Q	Promote® + CRT-D	99.62%	99.21%								
CD3211-36	Promote® + CRT-D	99.70%	99.64%	99.24%							
3207-30	Promote® RF CRT-D	99.67%	99.49%	97.91%							
3207-36	Promote® RF CRT-D	99.70%	99.27%	98.11%	95.95%						
V-365	Atlas® II HF CRT-D	99.69%	98.61%	92.69%	73.03%	42.95%					
V-366	Atlas® II + HF CRT-D	99.54%	97.93%	90.18%	67.76%						
V-343	Atlas® + HF CRT-D	99.78%	99.00%	95.40%	85.02%	61.81%	33.56%				

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
CD3249-40Q	Unify Quadra® CRT-D										
CD3249-40	Unify Quadra® CRT-D										
CD3231-40Q	Unify® CRT-D	99.88%	99.88%								
CD3231-40	Unify® CRT-D	99.85%	99.85%								
CD3211-36Q	Promote® + CRT-D	99.84%	99.49%								
CD3211-36	Promote® + CRT-D	99.78%	99.75%	99.54%							
3207-30	Promote® RF CRT-D	99.67%	99.67%	99.44%							
3207-36	Promote® RF CRT-D	99.77%	99.53%	99.24%	99.05%						
V-365	Atlas® II HF CRT-D	99.83%	99.68%	98.92%	98.41%	97.92%					
V-366	Atlas® II + HF CRT-D	99.79%	99.38%	98.95%	98.73%						
V-343	Atlas® + HF CRT-D	99.88%	99.67%	99.25%	98.66%	98.52%	98.34%				

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3249-40Q	Unify Quadra® CRT-D	4570	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	Unify Quadra® CRT-D	1382	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**
CD3231-40Q	Unify® CRT-D	17583	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	**4**	**0.02%**
CD3231-40	Unify® CRT-D	17563	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	**5**	**0.03%**
CD3211-36Q	Promote® + CRT-D	6714	3	0.04%	0	0.00%	3	0.04%	1	0.01%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	**10**	**0.15%**
CD3211-36	Promote® + CRT-D	8487	2	0.02%	0	0.00%	5	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.08%**
3207-30	Promote® RF CRT-D	1409	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
3207-36	Promote® RF CRT-D	23774	3	0.01%	4	0.02%	9	0.04%	5	0.02%	0	0.00%	2	0.01%	7	0.03%	5	0.02%	**35**	**0.15%**
V-365	Atlas® II HF CRT-D	8415	1	0.01%	2	0.02%	15	0.18%	2	0.02%	0	0.00%	0	0.00%	4	0.05%	5	0.06%	**29**	**0.34%**
V-366	Atlas® II + HF CRT-D	5001	0	0.00%	0	0.00%	3	0.06%	0	0.00%	0	0.00%	0	0.00%	2	0.04%	6	0.12%	**11**	**0.22%**
V-343	Atlas® + HF CRT-D	18694	3	0.02%	0	0.00%	36	0.19%	0	0.00%	0	0.00%	0	0.00%	5	0.03%	9	0.05%	**53**	**0.28%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3249-40Q	Unify Quadra® CRT-D	4570	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3249-40	Unify Quadra® CRT-D	1382	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40Q	Unify® CRT-D	17583	3	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**4**	**0.02%**
CD3231-40	Unify® CRT-D	17563	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.02%	**4**	**0.02%**
CD3211-36Q	Promote® + CRT-D	6714	2	0.03%	0	0.00%	4	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.09%**
CD3211-36	Promote® + CRT-D	8487	2	0.02%	0	0.00%	2	0.02%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	0	0.00%	**6**	**0.07%**
3207-30	Promote® RF CRT-D	1409	0	0.00%	1	0.07%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.14%**
3207-36	Promote® RF CRT-D	23774	5	0.02%	0	0.00%	7	0.03%	1	<0.01%	5	0.02%	1	<0.01%	3	0.01%	9	0.04%	**31**	**0.13%**
V-365	Atlas® II HF CRT-D	8415	2	0.02%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	0	0.00%	5	0.06%	4	0.05%	**14**	**0.17%**
V-366	Atlas® II + HF CRT-D	5001	3	0.06%	0	0.00%	2	0.04%	0	0.00%	0	0.00%	0	0.00%	4	0.08%	0	0.00%	**9**	**0.18%**
V-343	Atlas® + HF CRT-D	18694	1	0.01%	0	0.00%	4	0.02%	0	0.00%	1	0.01%	1	0.01%	11	0.06%	4	0.02%	**22**	**0.12%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Defibrillation Impedance		Failure to Capture		Inappropriate Shock		Loss of Telemetry		Oversensing		Premature Battery Depletion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	1675	18844	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	664	8338	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.15%**
CD3211-36Q	854	20820	0	0.00%	0	0.00%	3	0.35%	0	0.00%	0	0.00%	1	0.12%	2	0.23%	**6**	**0.70%**
CD3211-36	226	5625	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	717	24014	0	0.00%	0	0.00%	0	0.00%	1	0.14%	1	0.14%	0	0.00%	2	0.28%	**4**	**0.56%**

Malfunctions

Models	Family	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify® CRT-D	1675	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3231-40	Unify® CRT-D	664	0	0.00%	1	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.15%**
CD3211-36Q	Promote® + CRT-D	854	1	0.12%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	**3**	**0.35%**
CD3211-36	Promote® + CRT-D	226	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote® RF CRT-D	717	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.28%	**2**	**0.28%**

Models	Family	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD3231-40Q	Unify® CRT-D	1675	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.06%**
CD3231-40	Unify® CRT-D	664	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD3211-36Q	Promote® + CRT-D	854	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	**2**	**0.23%**
CD3211-36	Promote® + CRT-D	226	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
3207-36	Promote® RF CRT-D	717	1	0.14%	0	0.00%	1	0.14%	0	0.00%	0	0.00%	0	0.00%	1	0.14%	0	0.00%	**3**	**0.42%**

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

Cardiac Resynchronization Therapy (CRT) Devices

CRT Pacemakers

St. Jude Medical
More control. Less risk.

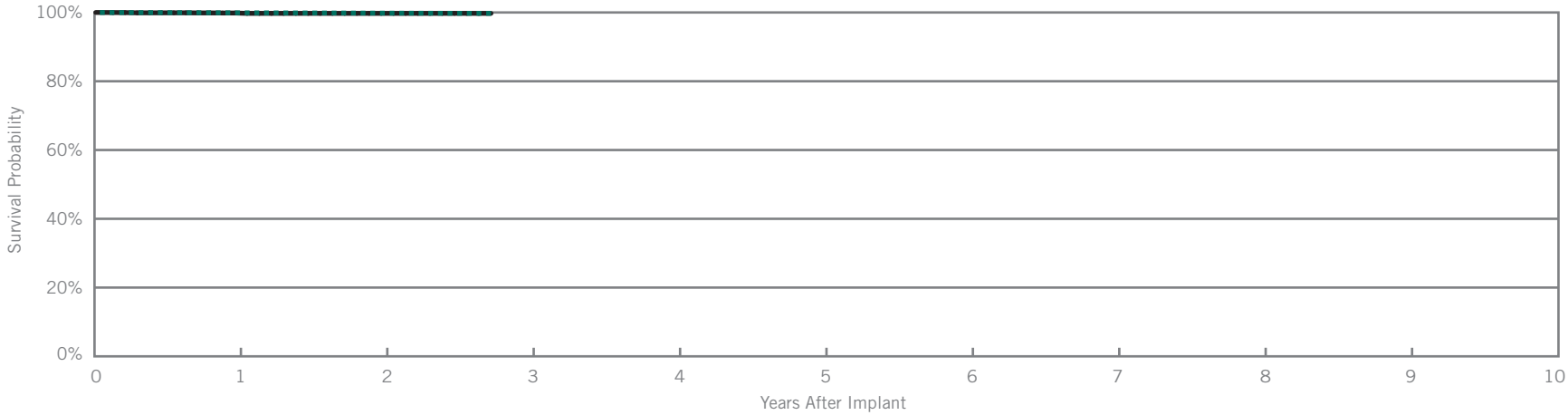
Anthem® RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Registered US Implants	10,660
Estimated Active US Implants	8,878
Estimated Longevity	8 Years
Normal Battery Depletion	0
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.84%	99.74%	99.74%							
± 1 standard error	0.05%	0.06%	0.06%							
Sample Size	8700	3700	300							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.84%	99.74%	99.74%							
± 1 standard error	0.05%	0.06%	0.06%							

Actively Monitored Study Data

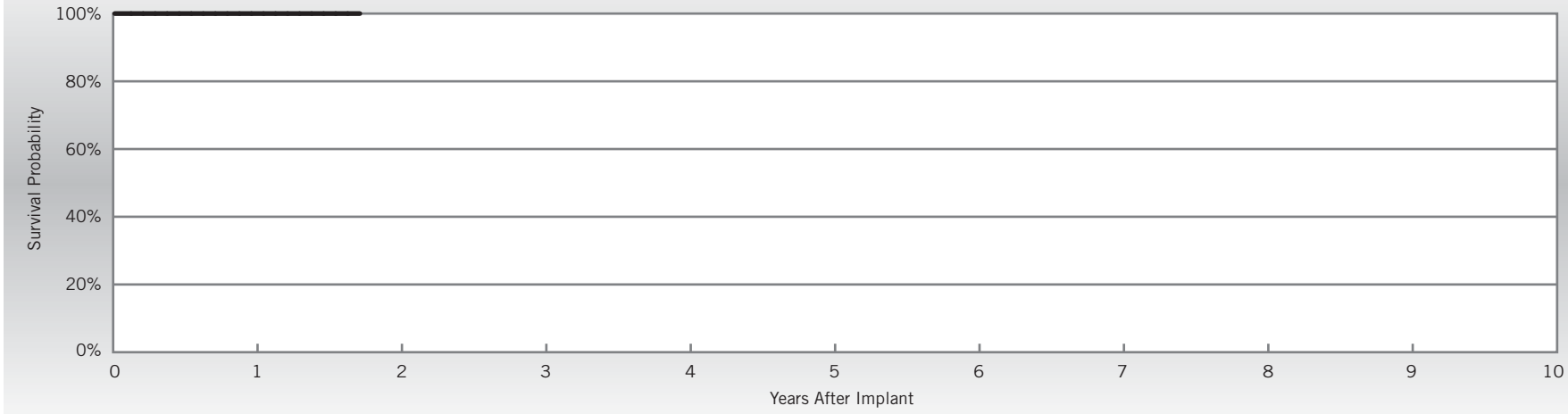
Anthem® RF CRT-P

Model PM3210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	195
Cumulative Months of Follow-up	2,948
Estimated Longevity	8 Years

Qualifying Complications
None Reported

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



Year	1	at 21 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	150	60								

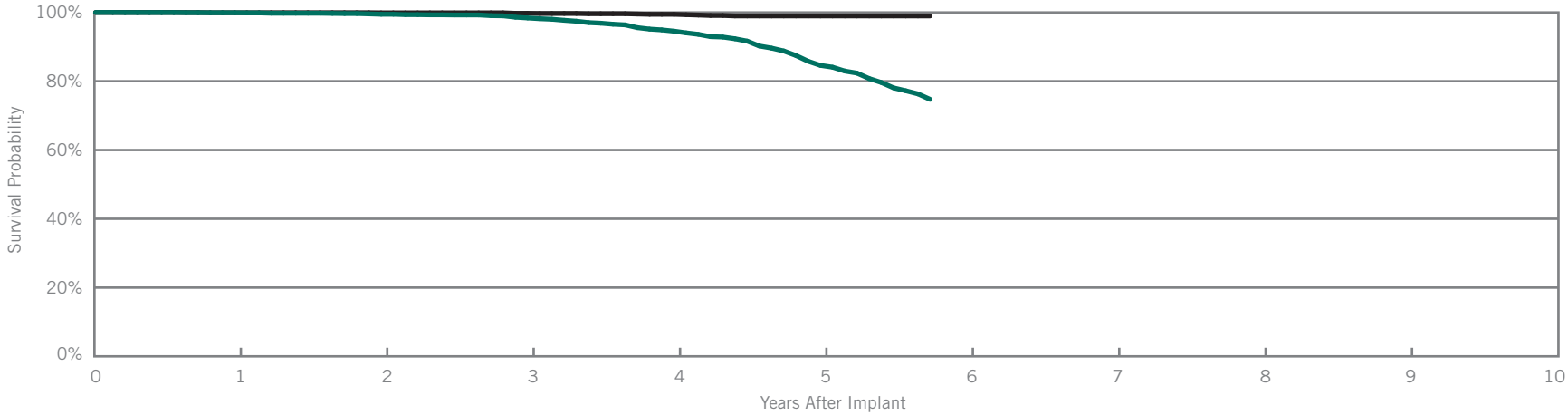
Customer Reported Performance Data

Frontier® II CRT-P

Model 5586

US Regulatory Approval	August 2004
Registered US Implants	6,717
Estimated Active US Implants	2,924
Estimated Longevity	6.5 Years
Normal Battery Depletion	178
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	5	0.07%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	7	0.10%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**12**	**0.18%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.90%	99.47%	98.40%	94.56%	84.61%	74.72%				
± 1 standard error	0.04%	0.09%	0.18%	0.40%	0.86%	1.33%				
Sample Size	6700	5400	4400	3000	1600	400				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.93%	99.89%	99.75%	99.46%	98.99%	98.99%				
± 1 standard error	0.04%	0.04%	0.08%	0.13%	0.21%	0.21%				

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® RF CRT-P	99.84%	99.74%								
5586	Frontier® II CRT-P	99.90%	99.47%	98.40%	94.56%	84.61%					

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM3210	Anthem® RF CRT-P	99.84%	99.74%								
5586	Frontier® II CRT-P	99.93%	99.89%	99.75%	99.46%	98.99%					

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem® RF CRT-P	10660	2	0.02%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	4	0.04%
5586	Frontier® II CRT-P	6717	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM3210	Anthem® RF CRT-P	10660	0	0.00%	0	0.00%	0	0.00%	3	0.03%	0	0.00%	0	0.00%	1	0.01%	4	0.04%
5586	Frontier® II CRT-P	6717	5	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.10%	0	0.00%	12	0.18%

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

Left-Heart Leads

St. Jude Medical™
More control. Less risk.

Customer Reported Performance Data

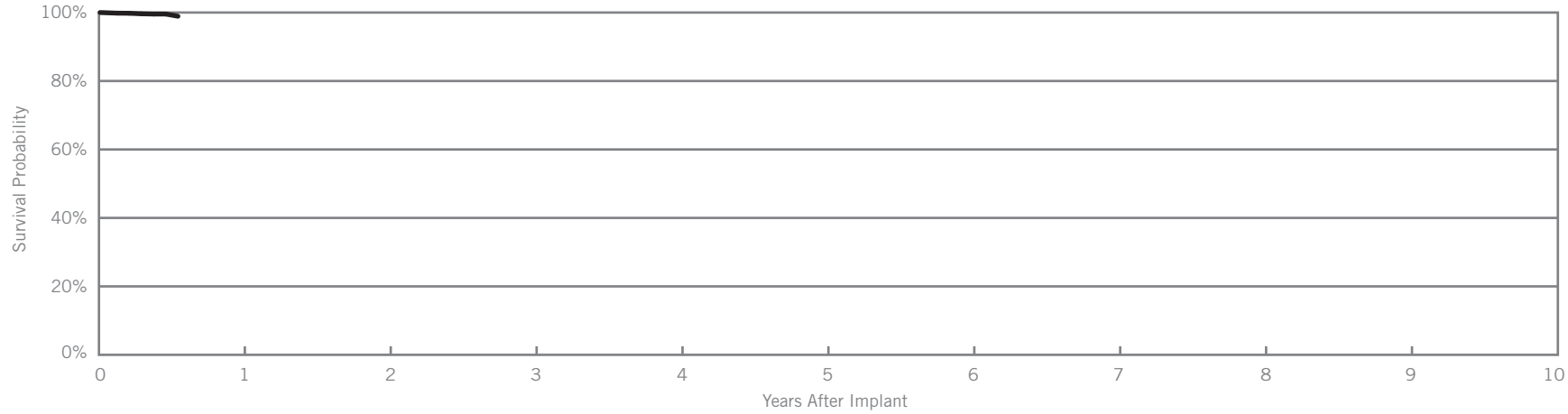
Quartet®

Model 1458Q

US Regulatory Approval	November 2011
Registered US Implants	6,665
Estimated Active US Implants	5,798
Insulation	Optim®*
Type and/or Fixation	S-Curve
Polarity	Quadpolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	5	0.08%	8	0.12%
Failure to Capture	0	0.00%	1	0.02%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	8	0.12%	0	0.00%
Other	1	0.02%	2	0.03%
Total	**14**	**0.21%**	**11**	**0.17%**
Total Returned for Analysis	**2**		**7**	

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	0.02%
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	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.06%
Total	**5**	**0.08%**



Year	**at 7 months**										
Survival Probability	98.92%										
± 1 standard error	0.13%										
Sample Size	500										

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

Customer Reported Performance Data

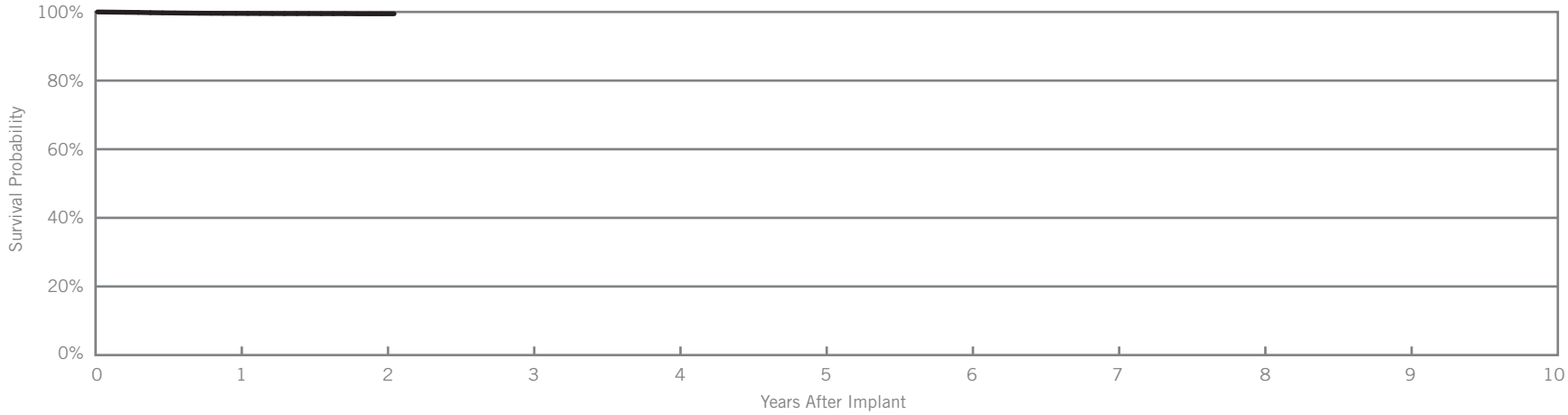
QuickFlex® µ

Model 1258T

US Regulatory Approval	May 2010
Registered US Implants	25,502
Estimated Active US Implants	20,464
Insulation	Optim®*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	19	0.07%	47	0.18%
Failure to Capture	6	0.02%	12	0.05%
Oversensing	0	0.00%	1	<0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	0	0.00%
Extracardiac Stimulation	4	0.02%	5	0.02%
Other	4	0.02%	2	0.01%
Total	**34**	**0.13%**	**67**	**0.26%**
Total Returned for Analysis	**22**		**46**	

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	0	0.00%
Extrinsic Factors	62	0.24%
Total	**63**	**0.25%**



Year	1	2	at 25 months							
Survival Probability	99.58%	99.46%	99.46%							
± 1 standard error	0.05%	0.07%	0.07%							
Sample Size	19000	6000	600							

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

Actively Monitored Study Data

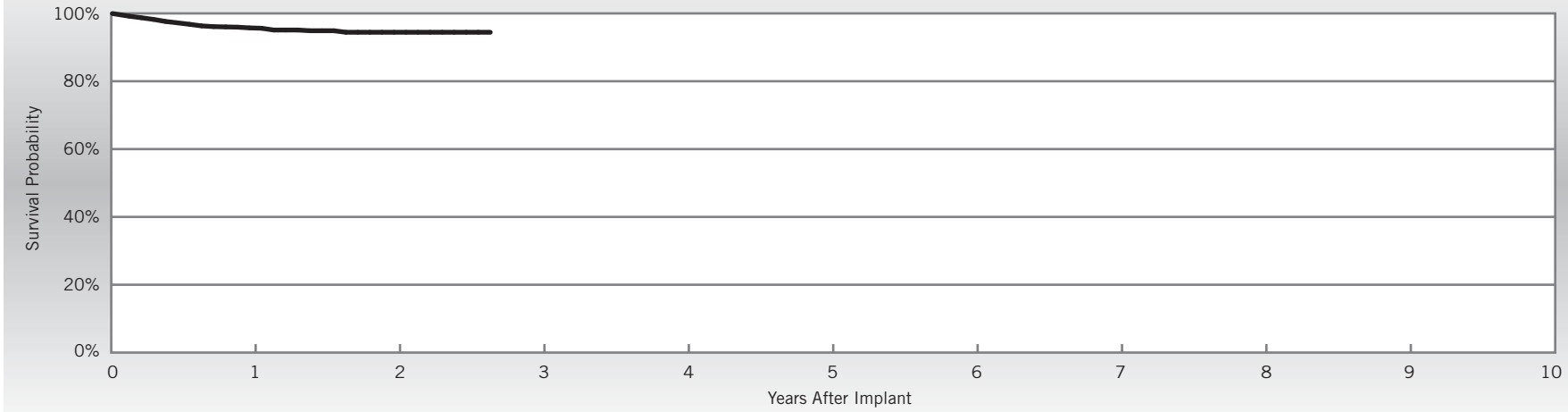
QuickFlex® µ

Model 1258T

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	2,208
Cumulative Months of Follow-up	25,441
Insulation	Optim®*
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.05%
Conductor Fracture	1	0.05%
Extracardiac Stimulation	31	1.40%
Failure to Capture	19	0.86%
Lead Dislodgement	29	1.31%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.05%
Clavicular Crush	1	0.05%
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	13	0.59%
Total	**14**	**0.63%**



Year	1	2	at 32 months							
Survival Probability	95.73%	94.44%	94.44%							
± 1 standard error	0.48%	0.75%	0.75%							
Sample Size	1590	500	50							

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

Customer Reported Performance Data

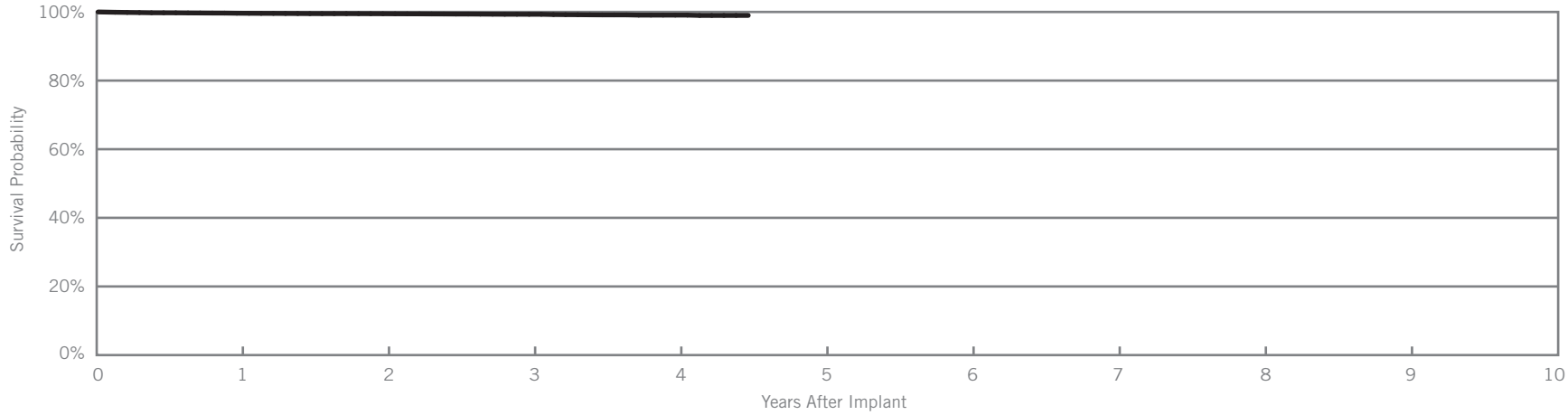
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Registered US Implants	28,185
Estimated Active US Implants	19,008
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	11	0.04%	49	0.17%
Failure to Capture	4	0.01%	32	0.11%
Oversensing	0	0.00%	3	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	0	0.00%	4	0.01%
Extracardiac Stimulation	13	0.05%	23	0.08%
Other	9	0.03%	1	<0.01%
Total	**37**	**0.13%**	**114**	**0.40%**
Total Returned for Analysis	**13**		**57**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.01%
Insulation Breach	7	0.02%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	7	0.02%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	62	0.22%
Total	**71**	**0.25%**



Year	1	2	3	4	at 54 months					
Survival Probability	99.63%	99.48%	99.32%	99.08%	98.99%					
± 1 standard error	0.04%	0.05%	0.06%	0.10%	0.13%					
Sample Size	26300	19000	11400	4400	200					

Actively Monitored Study Data

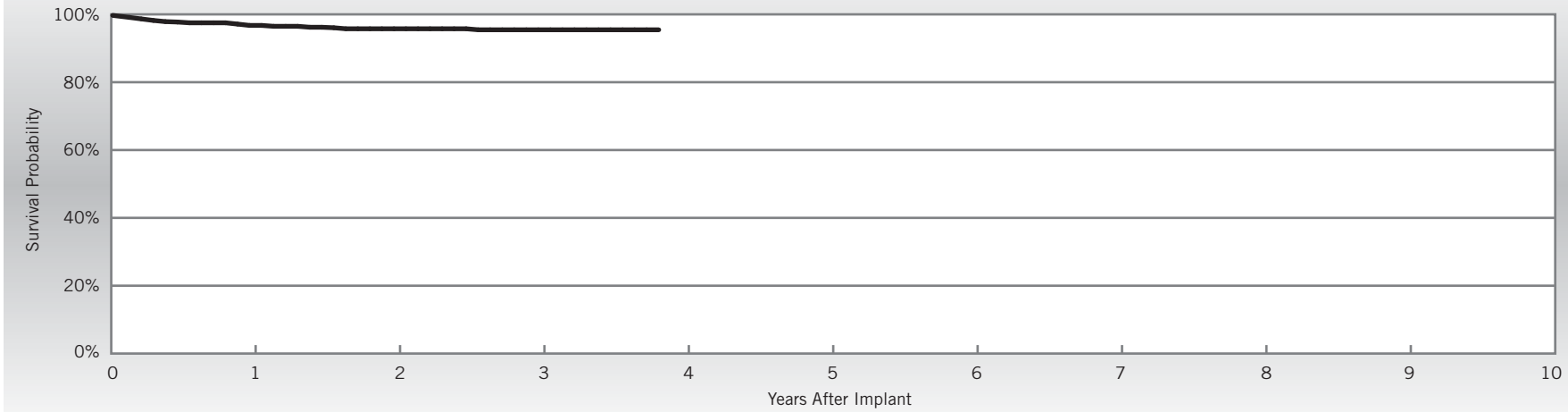
QuickFlex®

Model 1156T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	952
Cumulative Months of Follow-up	23,646
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	2	0.21%
Extracardiac Stimulation	12	1.26%
Failure to Capture	7	0.74%
Lead Dislodgement	15	1.58%

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	10	1.05%
Total	**10**	**1.05%**



Year	1	2	3	at 46 months						
Survival Probability	96.74%	95.75%	95.45%	95.45%						
± 1 standard error	0.57%	0.71%	0.77%	0.77%						
Sample Size	860	670	360	50						

Customer Reported Performance Data

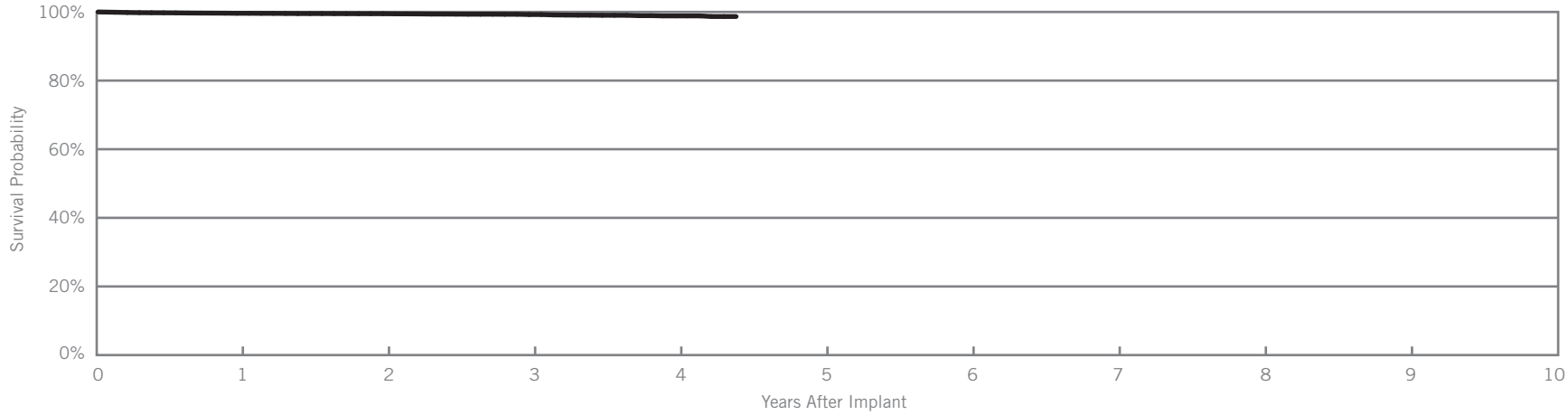
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Registered US Implants	15,806
Estimated Active US Implants	10,717
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	9	0.06%	39	0.25%
Failure to Capture	2	0.01%	18	0.11%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	0.01%
Insulation Breach	0	0.00%	1	0.01%
Abnormal Pacing Impedance	2	0.01%	1	0.01%
Extracardiac Stimulation	5	0.03%	7	0.04%
Other	6	0.04%	2	0.01%
Total	**24**	**0.15%**	**70**	**0.44%**
Total Returned for Analysis	**12**		**39**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	0.01%
Intravascular	1	0.01%
Insulation Breach	7	0.04%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	6	0.04%
Other	1	0.01%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	38	0.24%
Total	**48**	**0.30%**



Year	1	2	3	4	at 53 months					
Survival Probability	99.61%	99.49%	99.25%	98.85%	98.67%					
± 1 standard error	0.05%	0.06%	0.08%	0.16%	0.24%					
Sample Size	14500	10200	6200	2600	300					

Actively Monitored Study Data

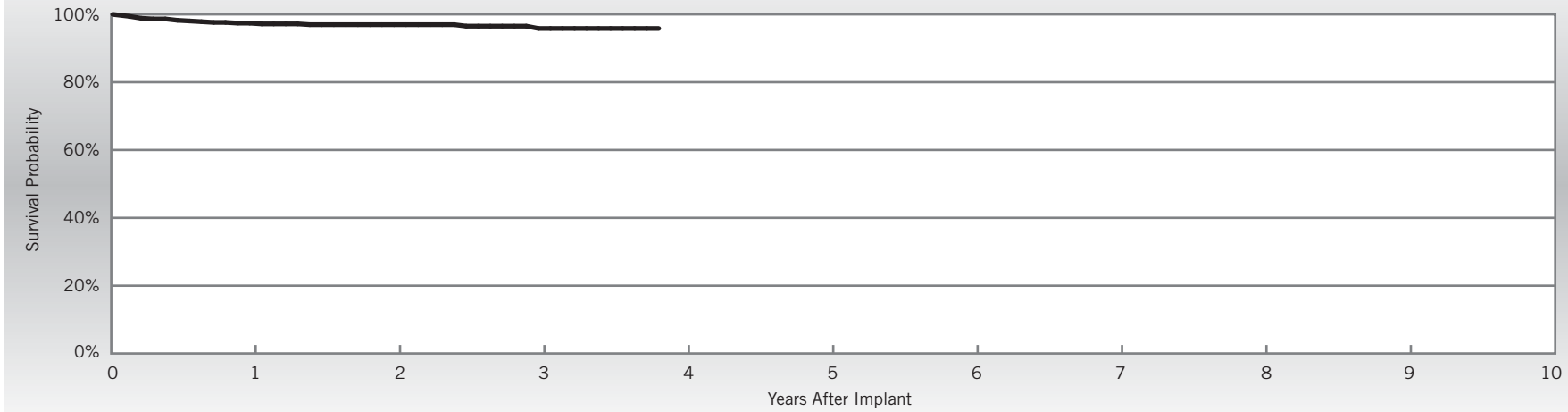
QuickFlex® XL

Model 1158T

US Regulatory Approval	July 2007
Number of Devices Enrolled in Study	552
Cumulative Months of Follow-up	14,662
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Extracardiac Stimulation	7	1.27%
Failure to Capture	6	1.09%
Lead Dislodgement	2	0.36%
Oversensing	1	0.18%
Skin Erosion	1	0.18%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	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	6	1.09%
Total	**6**	**1.09%**



Year	1	2	3	at 46 months						
Survival Probability	97.42%	96.96%	95.84%	95.84%						
± 1 standard error	0.71%	0.78%	0.88%	1.12%						
Sample Size	500	390	240	60						

Customer Reported Performance Data

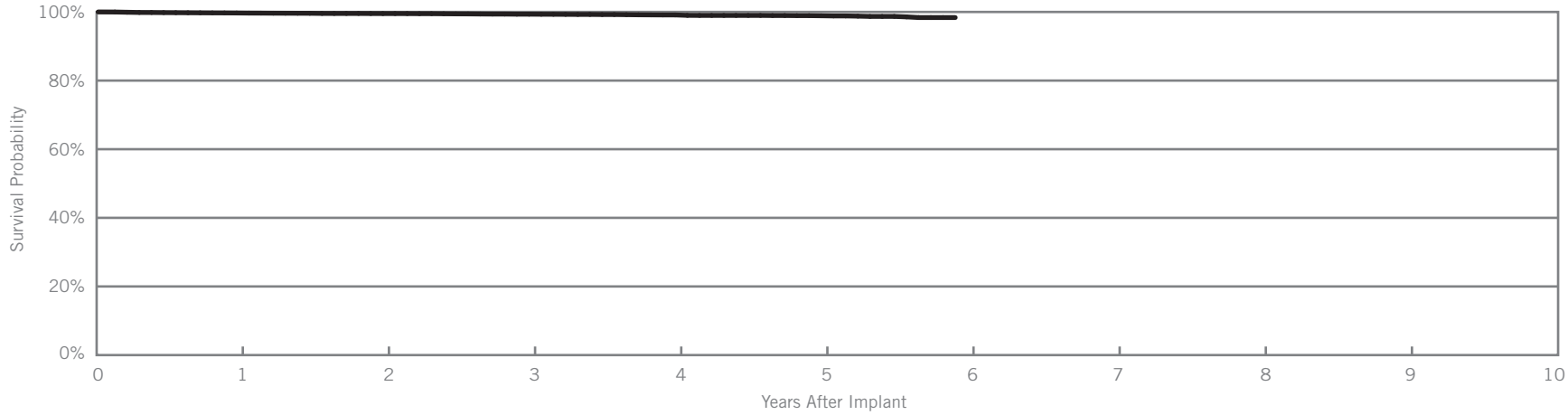
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Registered US Implants	10,331
Estimated Active US Implants	5,439
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	10	0.10%	11	0.11%
Failure to Capture	3	0.03%	29	0.28%
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%	3	0.03%
Extracardiac Stimulation	9	0.09%	6	0.06%
Other	1	0.01%	1	0.01%
Total	**26**	**0.25%**	**52**	**0.50%**
Total Returned for Analysis	**8**		**15**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.01%
Insulation Breach	4	0.04%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.03%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	13	0.13%
Total	**19**	**0.18%**



Year	1	2	3	4	5	at 71 months				
Survival Probability	99.70%	99.53%	99.35%	99.13%	98.89%	98.37%				
± 1 standard error	0.06%	0.07%	0.09%	0.11%	0.13%	0.30%				
Sample Size	9900	8400	7200	5800	3700	200				

Actively Monitored Study Data

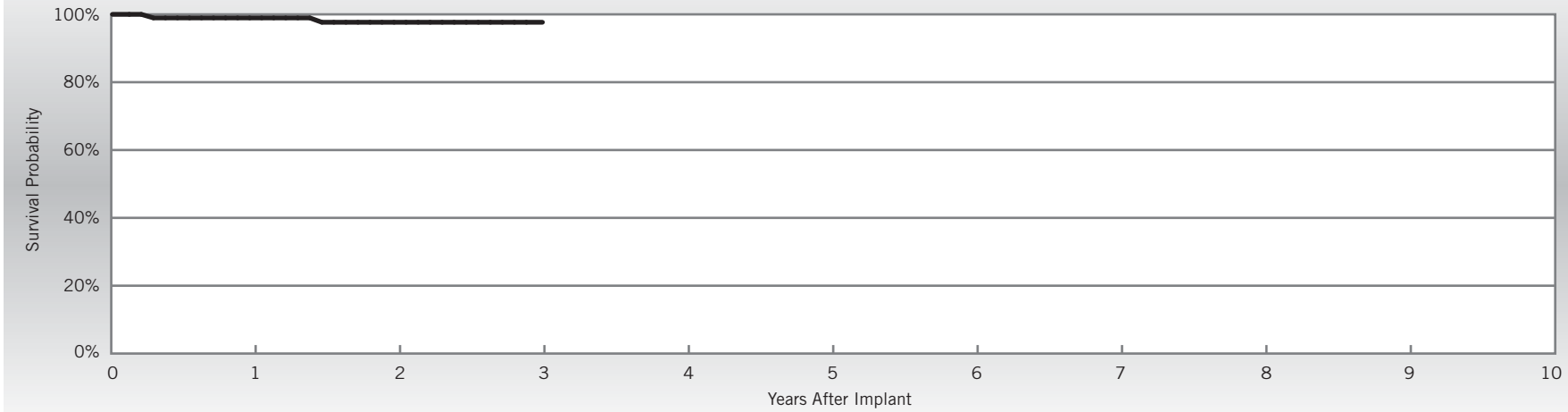
QuickSite® XL

Model 1058T

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	101
Cumulative Months of Follow-up	3,418
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	2	1.98%

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



Year	1	2	3							
Survival Probability	98.96%	97.67%	97.67%							
± 1 standard error	1.04%	1.64%	1.64%							
Sample Size	90	80	60							

Customer Reported Performance Data

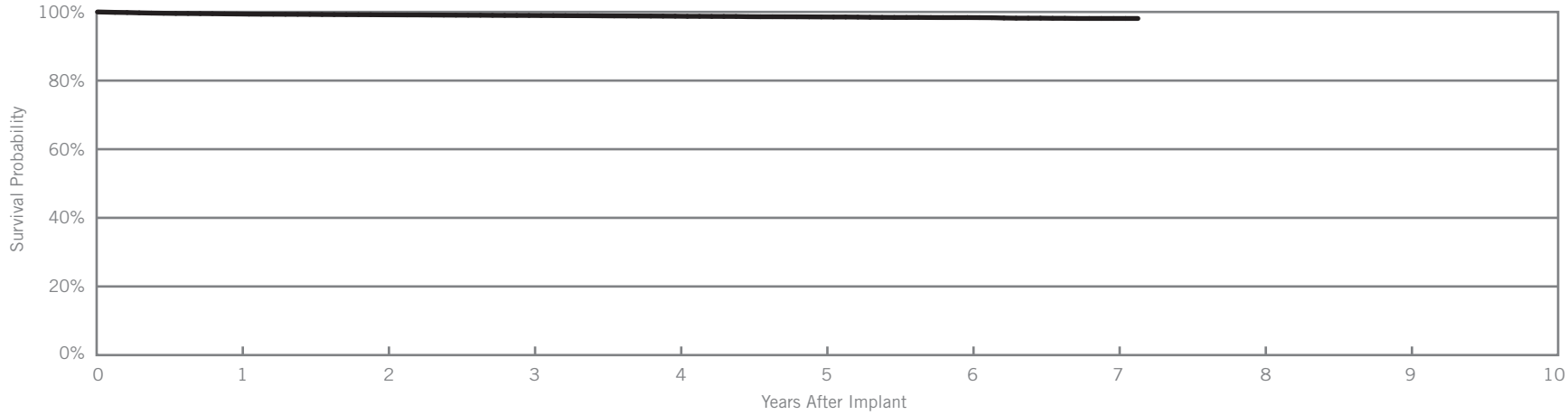
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Registered US Implants	34,233
Estimated Active US Implants	15,922
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	30	0.09%	98	0.29%
Failure to Capture	14	0.04%	86	0.25%
Oversensing	1	<0.01%	4	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	6	0.02%
Abnormal Pacing Impedance	3	0.01%	4	0.01%
Extracardiac Stimulation	22	0.06%	48	0.14%
Other	9	0.03%	8	0.02%
Total	**80**	**0.23%**	**258**	**0.75%**
Total Returned for Analysis	**26**		**107**	

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	2	0.01%
Insulation Breach	25	0.07%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	3	0.01%
Clavicular Crush	0	0.00%
Externalized Conductors	20	0.06%
Other	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	90	0.26%
Total	**119**	**0.35%**



Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.41%	99.17%	98.98%	98.77%	98.55%	98.37%	98.10%	98.10%		
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.08%	0.09%	0.13%	0.13%		
Sample Size	32100	26900	23200	19500	14700	8800	3200	300		

Actively Monitored Study Data

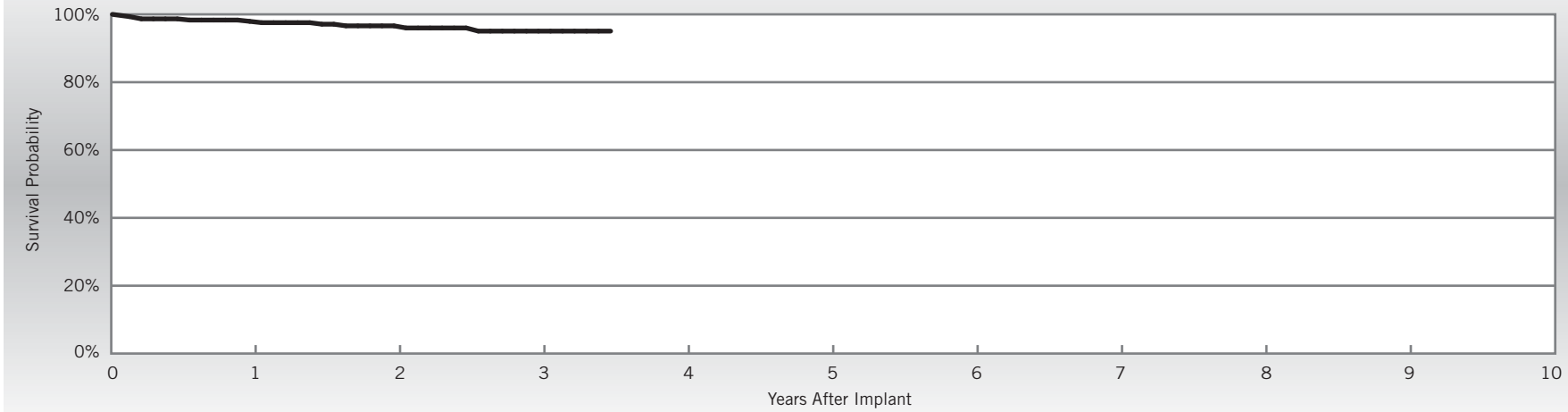
QuickSite®

Model 1056T

US Regulatory Approval	April 2005
Number of Devices Enrolled in Study	311
Cumulative Months of Follow-up	7,961
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.32%
Extracardiac Stimulation	1	0.32%
Failure to Capture	3	0.96%
Lead Dislodgement	6	1.93%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	1.29%
Total	**4**	**1.29%**



Year	1	2	3	at 42 months						
Survival Probability	97.94%	96.61%	95.06%	95.06%						
± 1 standard error	0.75%	1.13%	1.57%	1.57%						
Sample Size	290	210	110	50						

Customer Reported Performance Data

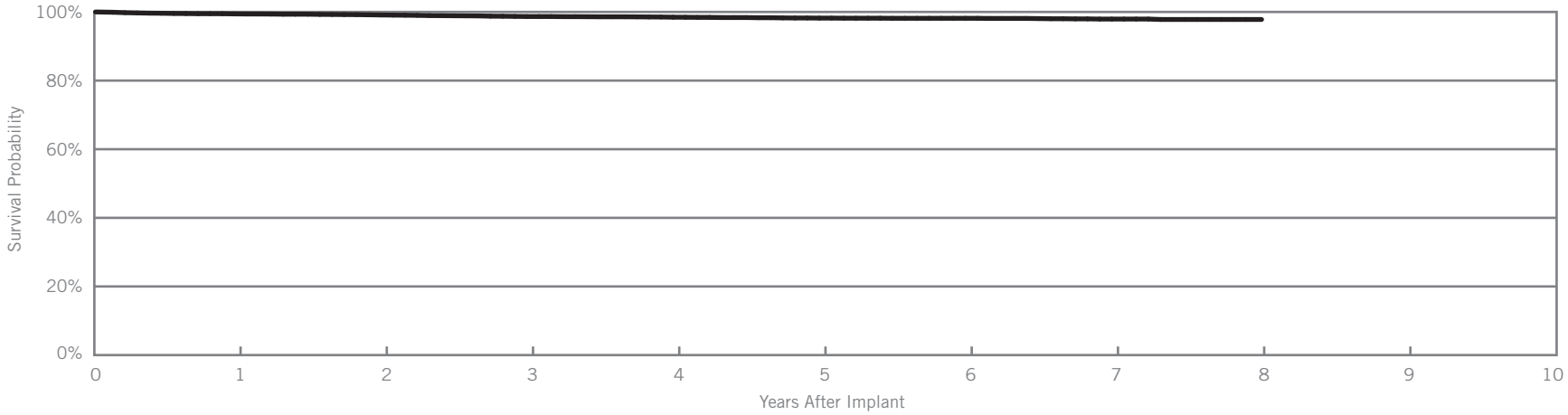
QuickSite®

Model 1056K

US Regulatory Approval	June 2004
Registered US Implants	8,826
Estimated Active US Implants	2,584
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.11%	28	0.32%
Failure to Capture	3	0.03%	35	0.40%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.02%
Extracardiac Stimulation	10	0.11%	13	0.15%
Other	2	0.02%	9	0.10%
Total	**25**	**0.28%**	**87**	**0.99%**
Total Returned for Analysis	**13**		**39**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.02%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.02%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	27	0.31%
Total	**29**	**0.33%**



Year	1	2	3	4	5	6	7	8		
Survival Probability	99.43%	99.12%	98.67%	98.47%	98.21%	98.15%	97.93%	97.81%		
± 1 standard error	0.09%	0.11%	0.14%	0.16%	0.18%	0.19%	0.21%	0.22%		
Sample Size	7900	6600	5700	4900	4000	3200	2500	1200		

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
1458Q	Quartet®*										
1258T	QuickFlex® µ	99.58%	99.46%								
1156T	QuickFlex®	99.63%	99.48%	99.32%	99.08%						
1158T	QuickFlex® XL	99.61%	99.49%	99.25%	98.85%						
1058T	QuickSite® XL	99.70%	99.53%	99.35%	99.13%	98.89%					
1056T	QuickSite®	99.41%	99.17%	98.98%	98.77%	98.55%	98.37%	98.10%			
1056K	QuickSite®	99.43%	99.12%	98.67%	98.47%	98.21%	98.15%	97.93%	97.81%		

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

Acute Observation Summary

Post Implant ≤30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1458Q	Nov-11	6665	5798	0	0.00%	0	0.00%	5	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.12%	1	0.02%	**14**	**0.21%**	**2**
1258T	May-10	25502	20464	0	0.00%	0	0.00%	19	0.07%	6	0.02%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	4	0.02%	4	0.02%	**34**	**0.13%**	**22**
1156T	Jul-07	28185	19008	0	0.00%	0	0.00%	11	0.04%	4	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	13	0.05%	9	0.03%	**37**	**0.13%**	**13**
1158T	Jul-07	15806	10717	0	0.00%	0	0.00%	9	0.06%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	5	0.03%	6	0.04%	**24**	**0.15%**	**12**
1058T	Feb-06	10331	5439	0	0.00%	0	0.00%	10	0.10%	3	0.03%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	9	0.09%	1	0.01%	**26**	**0.25%**	**8**
1056T	Apr-05	34233	15922	0	0.00%	0	0.00%	30	0.09%	14	0.04%	1	<0.01%	0	0.00%	1	<0.01%	3	0.01%	22	0.06%	9	0.03%	**80**	**0.23%**	**26**
1056K	Jun-04	8826	2584	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	
1458Q	Nov-11	6665	5798	0	0.00%	0	0.00%	8	0.12%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	**11**	**0.17%**	**7**
1258T	May-10	25502	20464	0	0.00%	0	0.00%	47	0.18%	12	0.05%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	5	0.02%	2	0.01%	**67**	**0.26%**	**46**
1156T	Jul-07	28185	19008	0	0.00%	1	<0.01%	49	0.17%	32	0.11%	3	0.01%	0	0.00%	1	<0.01%	4	0.01%	23	0.08%	1	<0.01%	**114**	**0.40%**	**57**
1158T	Jul-07	15806	10717	0	0.00%	1	0.01%	39	0.25%	18	0.11%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	7	0.04%	2	0.01%	**70**	**0.44%**	**39**
1058T	Feb-06	10331	5439	0	0.00%	1	0.01%	11	0.11%	29	0.28%	1	0.01%	0	0.00%	0	0.00%	3	0.03%	6	0.06%	1	0.01%	**52**	**0.50%**	**15**
1056T	Apr-05	34233	15922	0	0.00%	3	0.01%	98	0.29%	86	0.25%	4	0.01%	1	<0.01%	6	0.02%	4	0.01%	48	0.14%	8	0.02%	**258**	**0.75%**	**107**
1056K	Jun-04	8826	2584	0	0.00%	0	0.00%	28	0.32%	35	0.40%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	13	0.15%	9	0.10%	**87**	**0.99%**	**39**

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

Malfunction Summary

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
Models	Registered US Implants	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1458Q	6665	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	0.02%	**1**	**0.02%**	0	0.00%	0	0.00%	4	0.06%	**5**	**0.08%**
1258T	25502	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%	0	0.00%	62	0.24%	**63**	**0.25%**
1156T	28185	0	0.00%	0	0.00%	2	0.01%	**2**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	7	0.02%	0	0.00%	**7**	**0.02%**	0	0.00%	0	0.00%	62	0.22%	**71**	**0.25%**
1158T	15806	0	0.00%	1	0.01%	1	0.01%	**2**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	6	0.04%	1	0.01%	**7**	**0.04%**	1	0.01%	0	0.00%	38	0.24%	**48**	**0.30%**
1058T	10331	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**	0	0.00%	0	0.00%	0	0.00%	3	0.03%	1	0.01%	**4**	**0.04%**	0	0.00%	1	0.01%	13	0.13%	**19**	**0.18%**
1056T	34233	0	0.00%	1	<0.01%	2	0.01%	**3**	**0.01%**	0	0.00%	3	0.01%	0	0.00%	20	0.06%	2	0.01%	**25**	**0.07%**	0	0.00%	1	<0.01%	90	0.26%	**119**	**0.35%**
1056K	8826	0	0.00%	0	0.00%	2	0.02%	**2**	**0.02%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	27	0.31%	**29**	**0.33%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Defibrillation Impedance		Abnormal Pacing Impedance		Cardiac Perforation		Conductor Fracture		Extracardiac Stimulation		Failure to Capture		Failure to Sense		Inappropriate Shock		Insulation Breach		Lead Dislodgement		Oversensing		Pericardial Effusion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1258T	2208	25441	0	0.00%	1	0.05%	0	0.00%	1	0.05%	31	1.40%	19	0.86%	0	0.00%	0	0.00%	0	0.00%	29	1.31%	0	0.00%	0	0.00%	0	0.00%	81	3.67%
1156T	952	23646	0	0.00%	2	0.21%	0	0.00%	0	0.00%	12	1.26%	7	0.74%	0	0.00%	0	0.00%	0	0.00%	15	1.58%	0	0.00%	0	0.00%	0	0.00%	36	3.78%
1158T	552	14662	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	1.27%	6	1.09%	0	0.00%	0	0.00%	0	0.00%	2	0.36%	1	0.18%	0	0.00%	1	0.18%	17	3.08%
1058T	101	3418	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.98%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.98%
1056T	311	7961	0	0.00%	1	0.32%	0	0.00%	0	0.00%	1	0.32%	3	0.96%	0	0.00%	0	0.00%	0	0.00%	6	1.93%	0	0.00%	0	0.00%	0	0.00%	11	3.54%

Malfunctions

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1258T	2208	1	0.05%	0	0.00%	0	0.00%	**1**	**0.05%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	13	0.59%	**14**	**0.63%**
1156T	952	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	10	1.05%	**10**	**1.05%**
1158T	552	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	6	1.09%	**6**	**1.09%**
1058T	101	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1056T	311	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	4	1.29%	**4**	**1.29%**

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

Implantable Cardioverter Defibrillator (ICD) Devices

Dual-Chamber

St. Jude Medical
More control. Less risk.

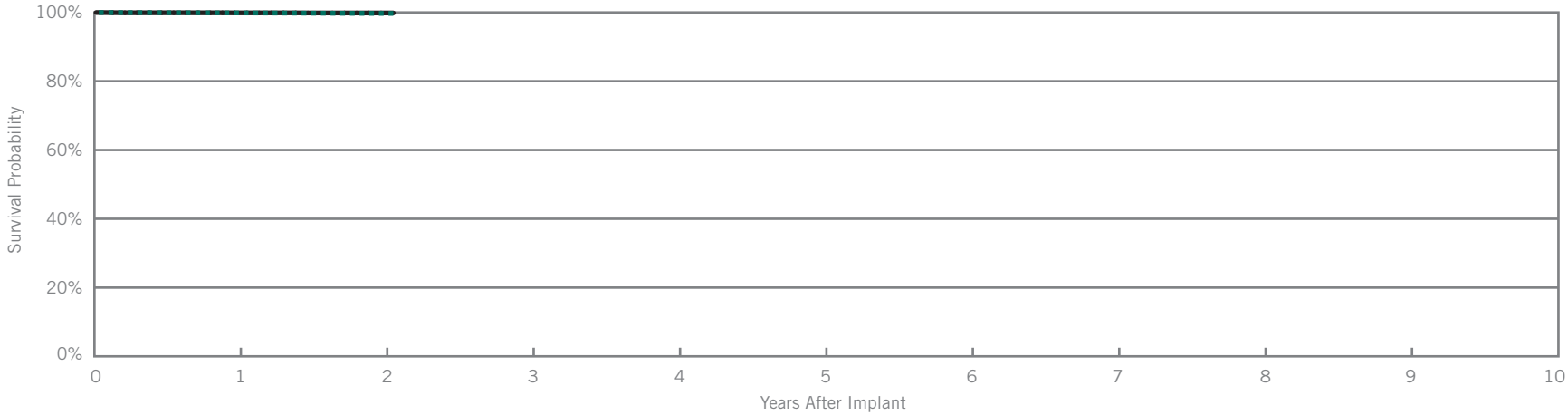
Customer Reported Performance Data

Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Registered US Implants	23,133
Estimated Active US Implants	20,150
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	9
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.76%	99.71%	99.71%							
± 1 standard error	0.03%	0.05%	0.05%							
Sample Size	18200	5900	600							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.87%	99.84%	99.84%							
± 1 standard error	0.02%	0.04%	0.04%							

Actively Monitored Study Data

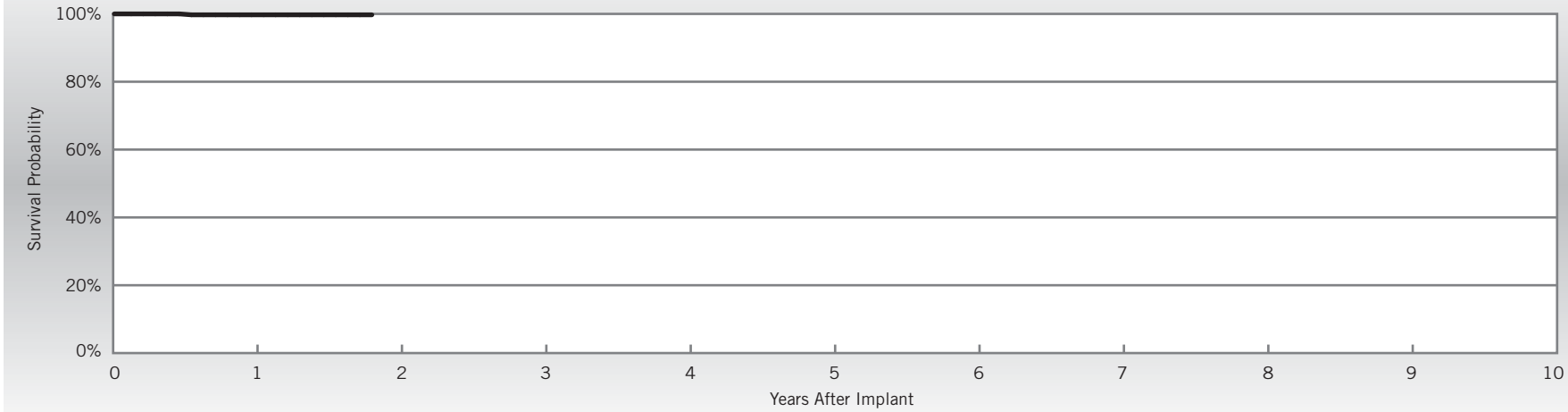
Fortify® DR

Model CD2231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	6,177
Estimated Longevity	(see table on page 84)
Max. Delivered Energy	40 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	1	0.25%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	0.25%	0	0.00%
Total	**1**	**0.25%**	**0**	**0.00%**



Year	1	at 22 months								
Survival Probability	99.73%	99.73%								
± 1 standard error	0.27%	0.27%								
Sample Size	340	60								

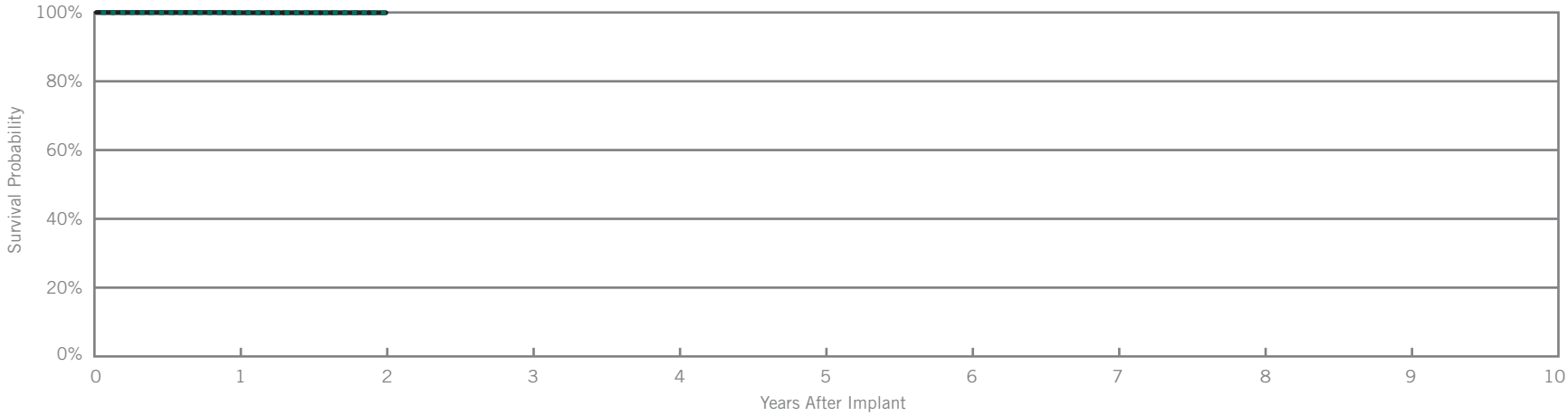
Customer Reported Performance Data

Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Registered US Implants	10,134
Estimated Active US Implants	8,885
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.88%	99.88%								
± 1 standard error	0.03%	0.04%								
Sample Size	7800	2300								

Excluding Normal Battery Depletion

Year	1	2								
Survival Probability	99.93%	99.93%								
± 1 standard error	0.02%	0.04%								

Actively Monitored Study Data

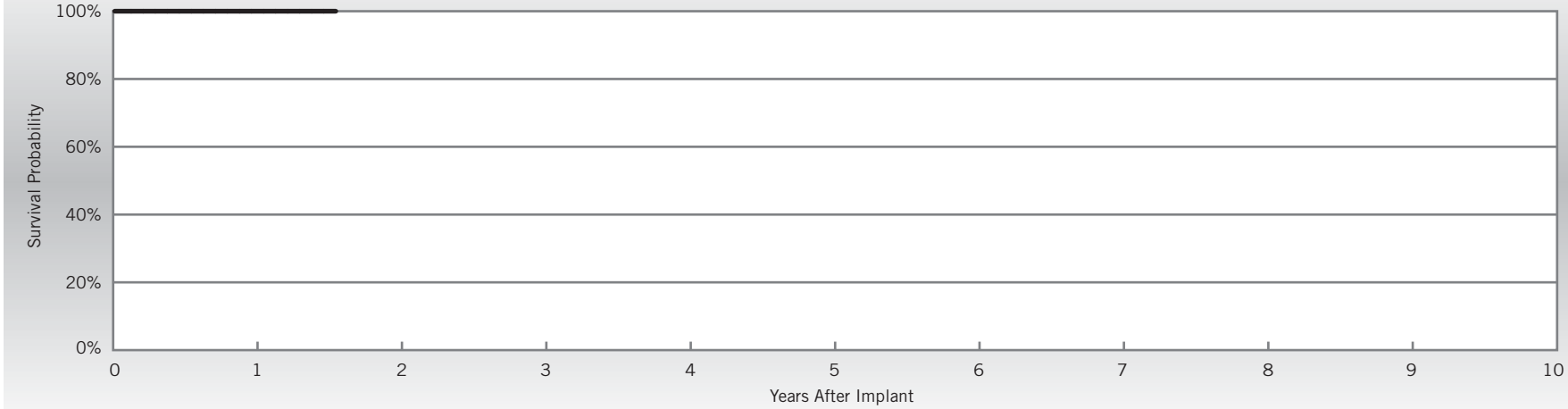
Fortify® DR

Model CD2231-40

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	177
Cumulative Months of Follow-up	2,686
Estimated Longevity	(see table on page 84)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	1	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	150	60								

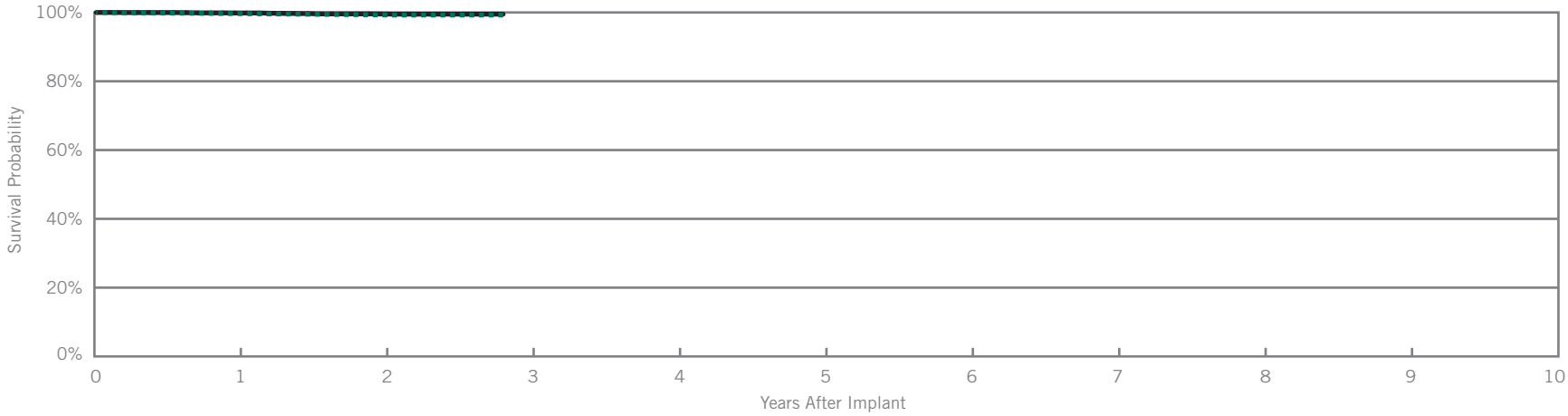
Customer Reported Performance Data

Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Registered US Implants	8,000
Estimated Active US Implants	6,036
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	6
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.04%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	3	0.04%	4	0.05%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**8**	**0.10%**	**6**	**0.08%**



Including Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.85%	99.35%	99.25%							
± 1 standard error	0.04%	0.10%	0.11%							
Sample Size	7900	6300	400							

Excluding Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.85%	99.55%	99.51%							
± 1 standard error	0.04%	0.08%	0.09%							

Actively Monitored Study Data

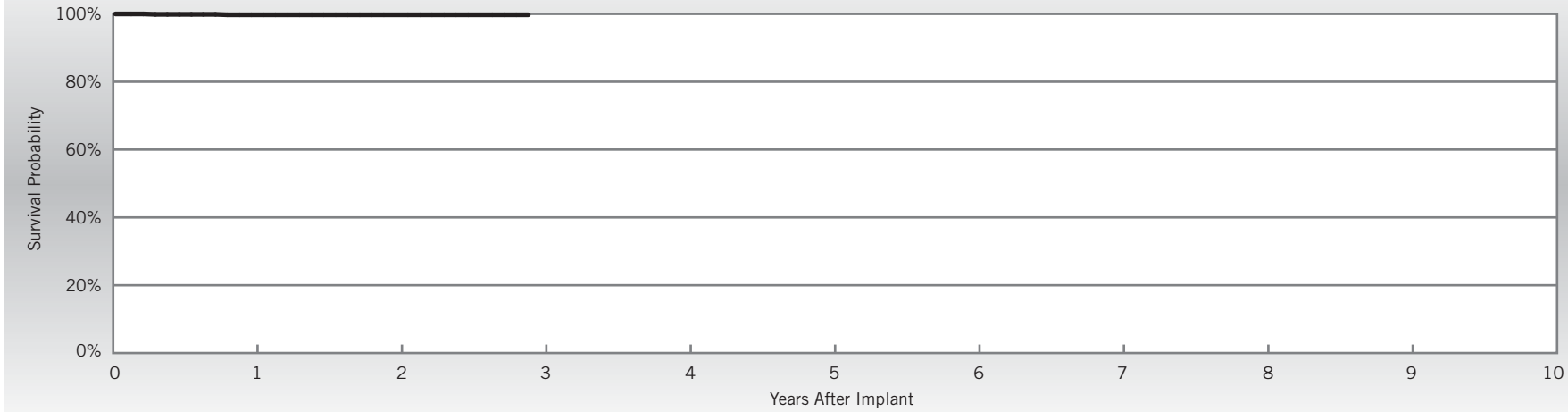
Current® + DR

Model CD2211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	836
Cumulative Months of Follow-up	22,069
Estimated Longevity	(see table on page 84)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Premature Battery Depletion	2	0.24%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	2	0.24%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.12%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**3**	**0.36%**



Year	1	2	at 35 months							
Survival Probability	99.75%	99.75%	99.75%							
± 1 standard error	0.18%	0.18%	0.18%							
Sample Size	790	710	50							

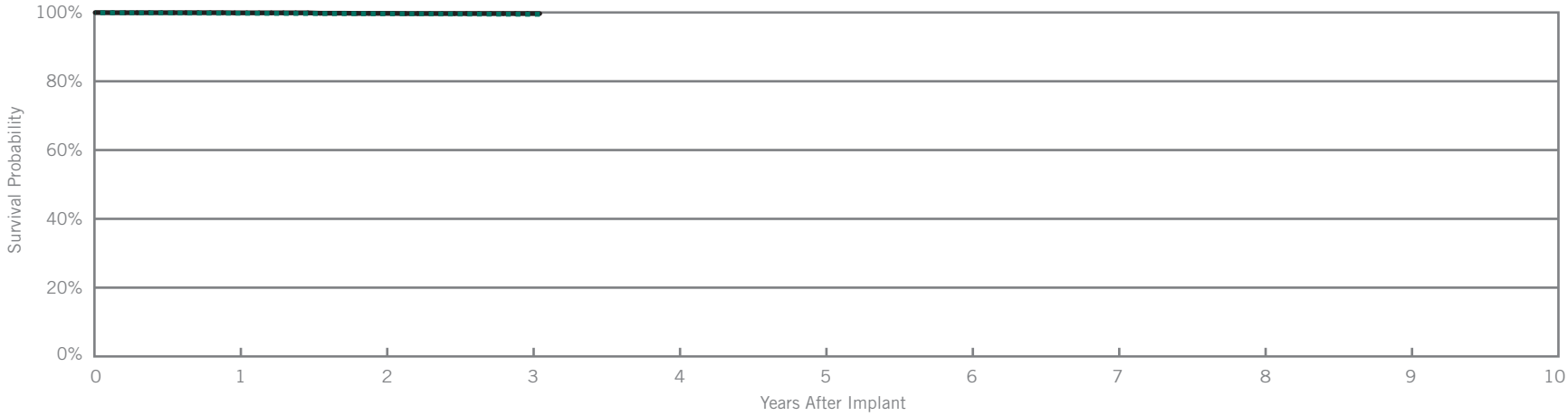
Customer Reported Performance Data

Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Registered US Implants	6,081
Estimated Active US Implants	4,546
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	5
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	1	0.02%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	1	0.02%	2	0.03%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.07%**	**3**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.77%	99.53%	99.47%	99.47%						
± 1 standard error	0.06%	0.10%	0.10%	0.10%						
Sample Size	5900	4800	2200	300						

Excluding Normal Battery Depletion

Year	1	2	3	at 37 months						
Survival Probability	99.89%	99.73%	99.68%	99.68%						
± 1 standard error	0.03%	0.07%	0.08%	0.08%						

Actively Monitored Study Data

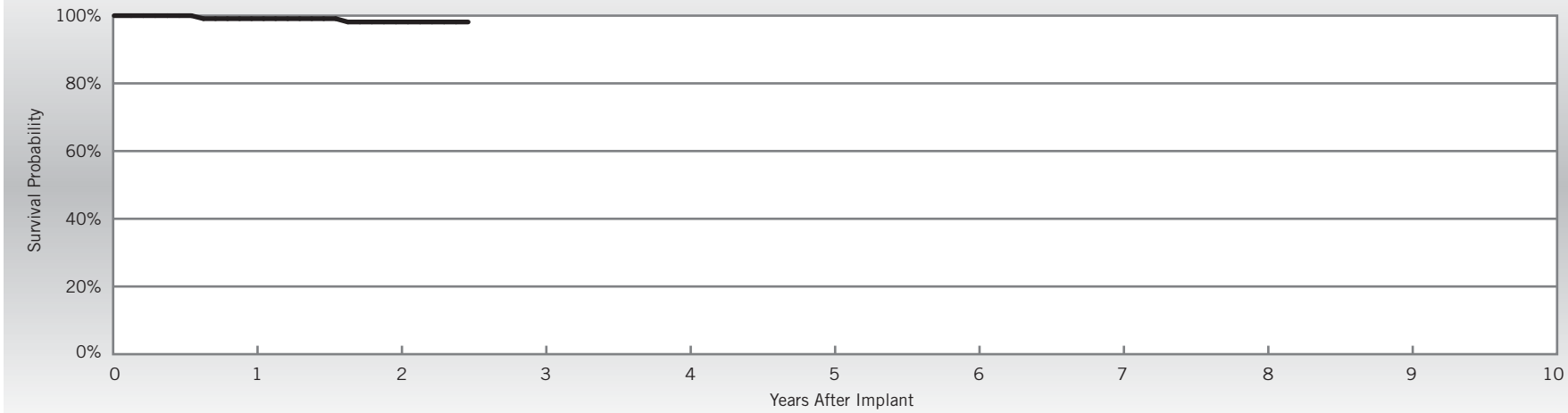
Current® + DR

Model CD2211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	118
Cumulative Months of Follow-up	3,195
Estimated Longevity	(see table on page 84)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty	Rate
Inappropriate Shock	1	0.85%
Premature Battery Depletion	1	0.85%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.85%
Total	**0**	**0.00%**	**1**	**0.85%**



Year	1	2	at 30 months							
Survival Probability	99.11%	98.13%	98.13%							
± 1 standard error	0.89%	1.32%	1.32%							
Sample Size	110	90	50							

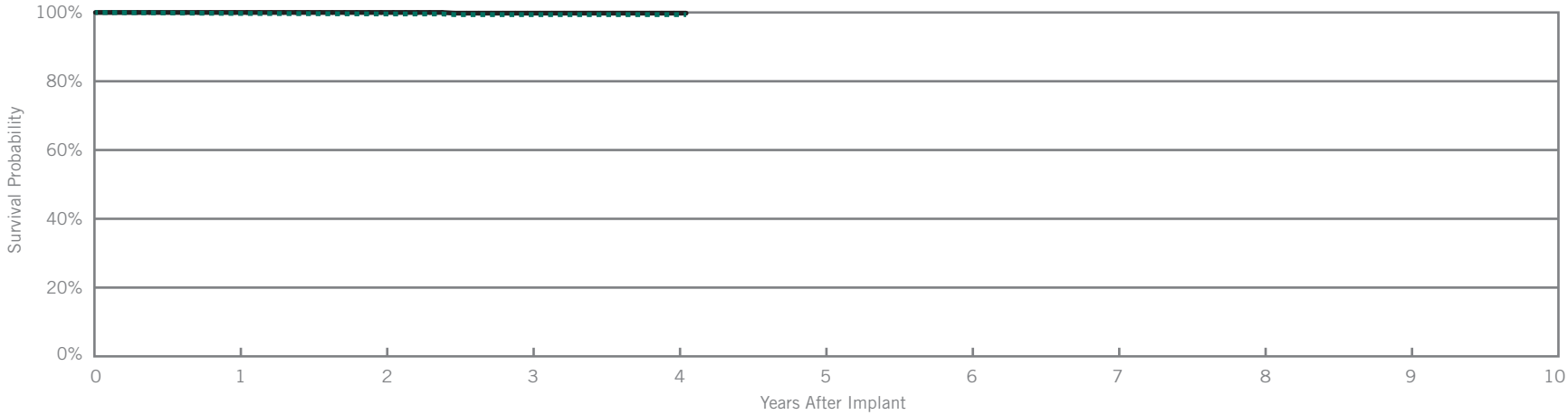
Customer Reported Performance Data

Current® DR RF

Model 2207-30

US Regulatory Approval	September 2007
Registered US Implants	1,557
Estimated Active US Implants	1,020
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	3
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.72%	99.57%	99.37%	99.37%	99.37%					
± 1 standard error	0.09%	0.18%	0.22%	0.22%	0.22%					
Sample Size	1600	1300	1000	500	200					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	100.00%	99.80%	99.80%	99.80%					
± 1 standard error	0.00%	0.00%	0.14%	0.14%	0.14%					

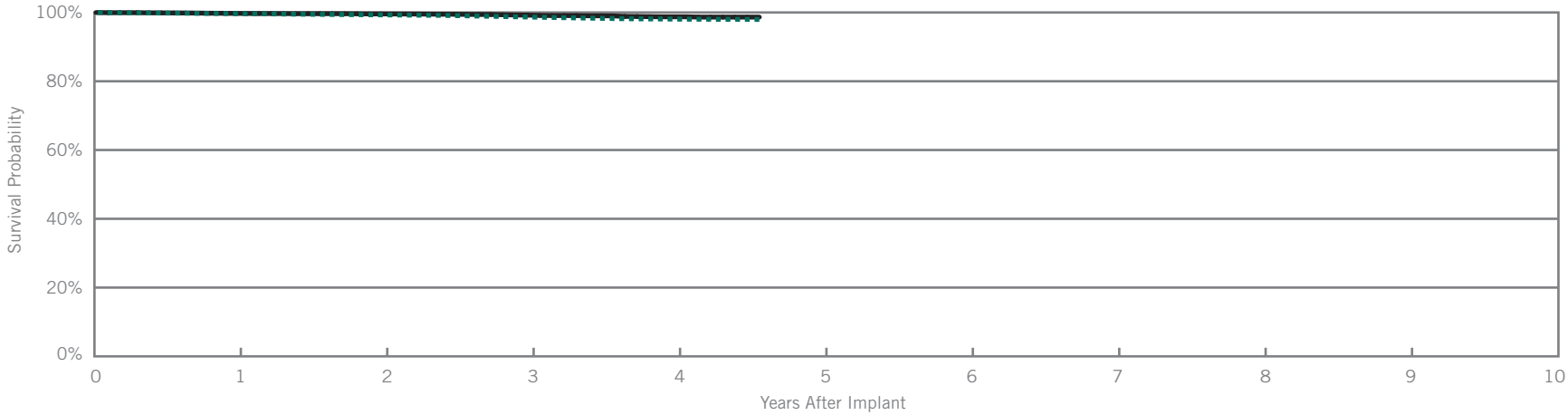
Customer Reported Performance Data

Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Registered US Implants	22,303
Estimated Active US Implants	14,190
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	37
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.02%	8	0.04%
Electrical Interconnect	4	0.02%	1	<0.01%
Battery	3	0.01%	5	0.02%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	4	0.02%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	17	0.08%	11	0.05%
Other	8	0.04%	4	0.02%
Total	**37**	**0.17%**	**34**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.69%	99.32%	98.74%	98.04%	97.96%					
± 1 standard error	0.04%	0.06%	0.08%	0.13%	0.14%					
Sample Size	22300	19100	15100	7900	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.73%	99.58%	99.22%	98.74%	98.65%					
± 1 standard error	0.03%	0.05%	0.07%	0.11%	0.12%					

Actively Monitored Study Data

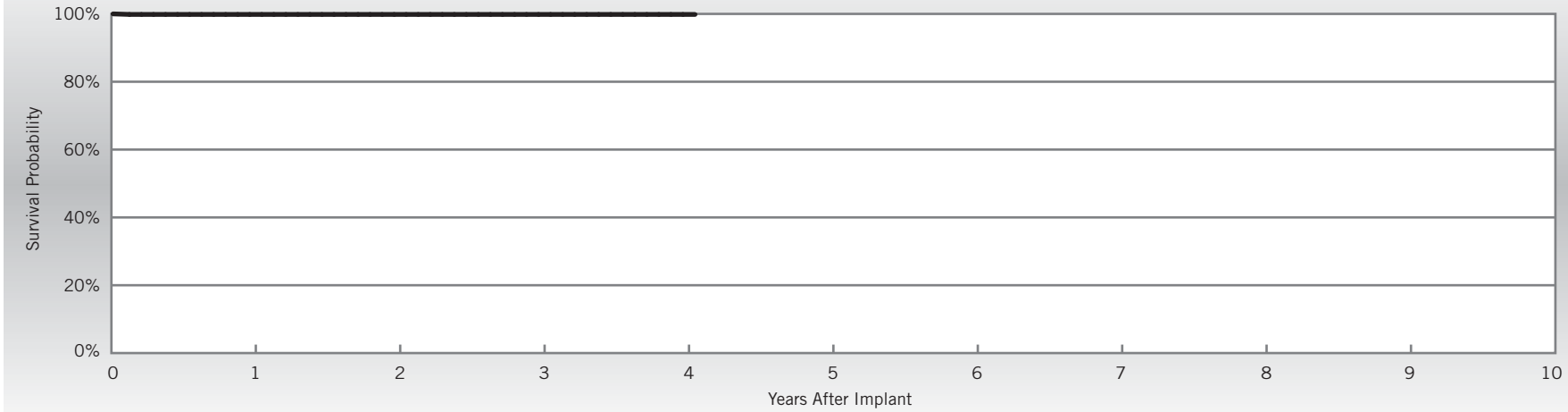
Current® DR RF

Model 2207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	627
Cumulative Months of Follow-up	21,178
Estimated Longevity	(see table on page 84)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Inappropriate Shock	1	0.16%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.16%
Electrical Interconnect	1	0.16%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.16%**	**1**	**0.16%**



Year	1	2	3	4	at 49 months					
Survival Probability	99.84%	99.84%	99.84%	99.84%	99.84%					
± 1 standard error	0.16%	0.16%	0.16%	0.16%	0.16%					
Sample Size	590	520	400	200	60					

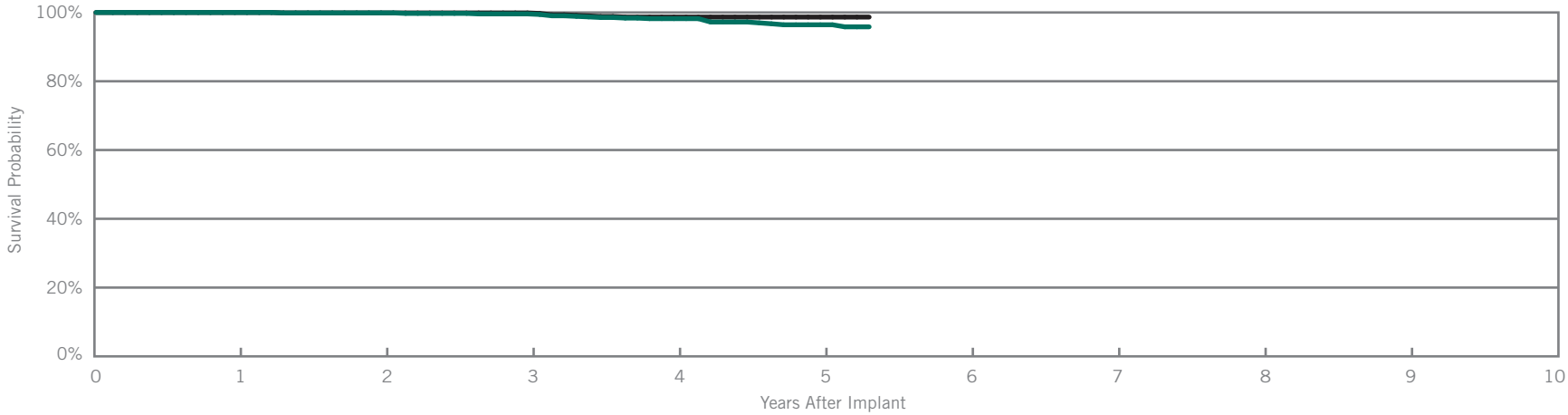
Customer Reported Performance Data

Atlas® II DR

Model V-265

US Regulatory Approval	July 2006
Registered US Implants	1,881
Estimated Active US Implants	1,006
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	11
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	4	0.21%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.11%	2	0.11%
Other	0	0.00%	0	0.00%
Total	**6**	**0.32%**	**2**	**0.11%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	99.87%	99.58%	98.20%	96.42%	95.82%				
± 1 standard error	0.00%	0.09%	0.17%	0.37%	0.58%	0.71%				
Sample Size	1900	1700	1400	1300	800	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	99.87%	99.87%	98.66%	98.66%	98.66%				
± 1 standard error	0.00%	0.09%	0.09%	0.32%	0.32%	0.32%				

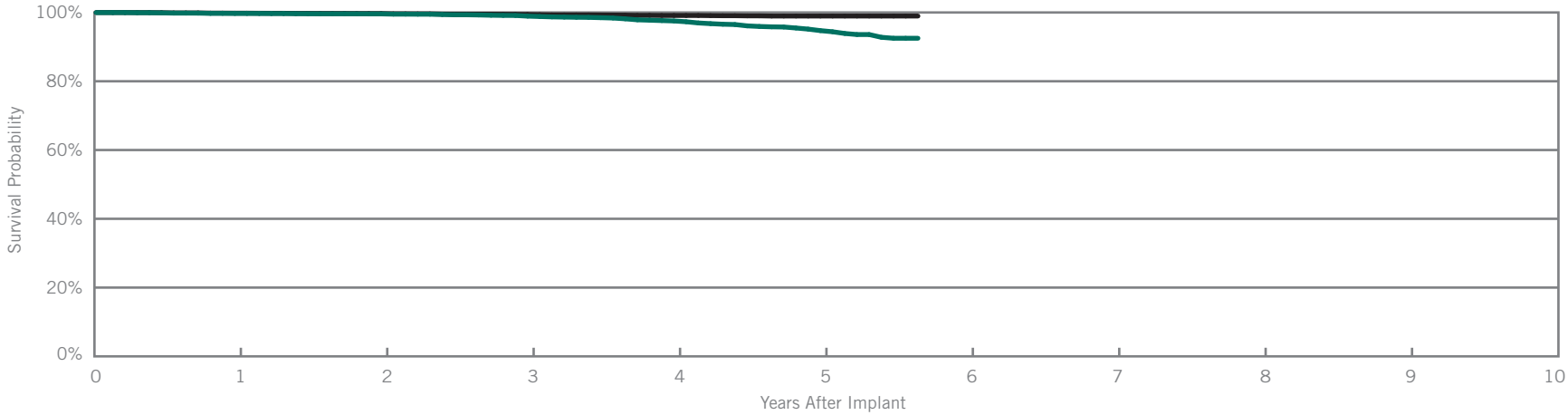
Customer Reported Performance Data

Atlas® II + DR

Model V-268

US Regulatory Approval	July 2006
Registered US Implants	14,759
Estimated Active US Implants	7,882
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	115
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.03%	2	0.01%
Electrical Interconnect	4	0.03%	0	0.00%
Battery	8	0.05%	2	0.01%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	12	0.08%	6	0.04%
Other	4	0.03%	1	0.01%
Total	**33**	**0.22%**	**11**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.72%	99.58%	98.93%	97.53%	94.72%	92.50%				
± 1 standard error	0.04%	0.06%	0.09%	0.16%	0.27%	0.51%				
Sample Size	14800	12700	11000	8500	4900	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.80%	99.68%	99.40%	99.12%	98.96%	98.96%				
± 1 standard error	0.04%	0.05%	0.07%	0.09%	0.11%	0.11%				

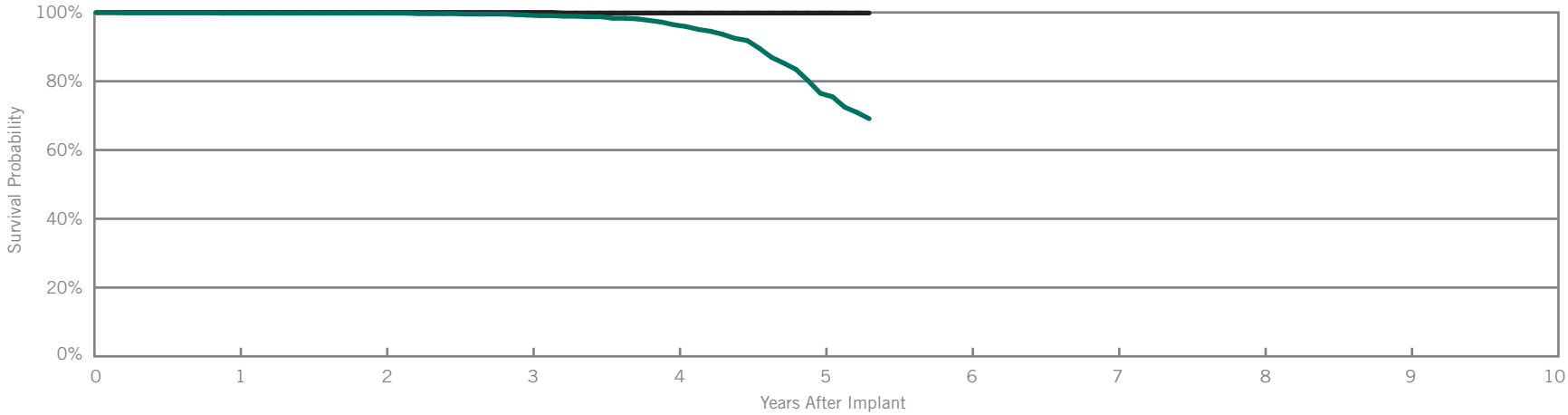
Customer Reported Performance Data

Epic® II + DR

Model V-258

US Regulatory Approval	March 2006
Registered US Implants	2,101
Estimated Active US Implants	890
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	93
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 248-260)	One

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.79%	99.79%	99.23%	96.41%	76.50%	69.12%				
± 1 standard error	0.10%	0.10%	0.20%	0.48%	1.44%	1.87%				
Sample Size	2100	1800	1600	1200	800	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	100.00%	100.00%	99.84%	99.84%	99.84%				
± 1 standard error	0.00%	0.00%	0.00%	0.11%	0.11%	0.11%				

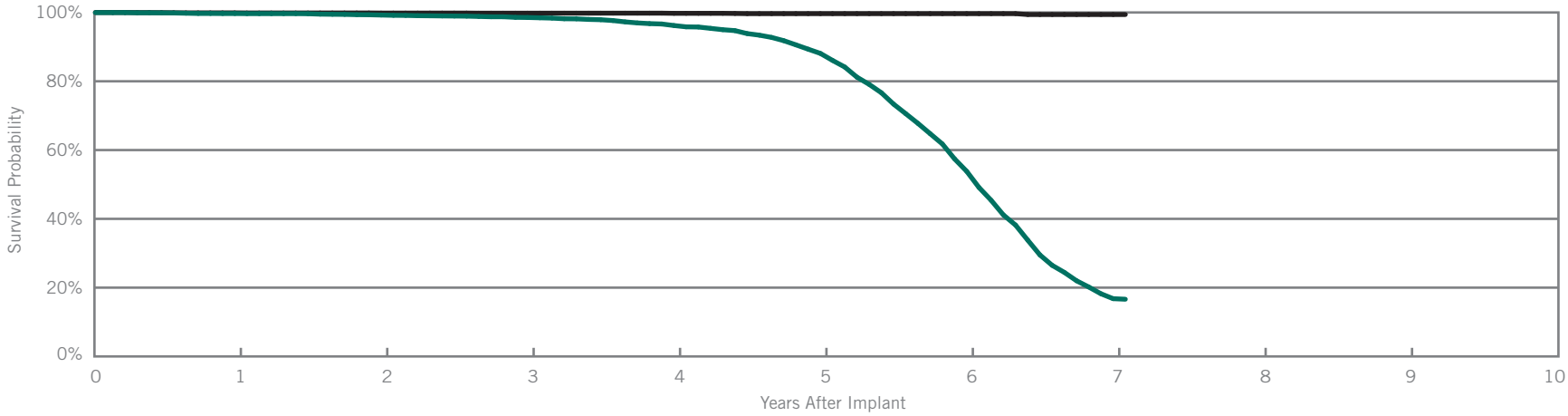
Customer Reported Performance Data

Epic® + DR

Model V-239

US Regulatory Approval	October 2003
Registered US Implants	7,857
Estimated Active US Implants	1,274
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	978
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 248-260)	Two

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.03%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	3	0.04%
High Voltage Capacitor	2	0.03%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	2	0.03%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**5**	**0.06%**	**6**	**0.08%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.69%	99.25%	98.54%	96.20%	88.10%	53.80%	16.79%	16.63%		
± 1 standard error	0.07%	0.10%	0.15%	0.24%	0.46%	0.85%	0.86%	0.85%		
Sample Size	7900	6900	6200	5500	4500	3200	1200	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.89%	99.83%	99.80%	99.75%	99.66%	99.66%	99.40%	99.40%		
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.08%	0.08%	0.20%	0.20%		

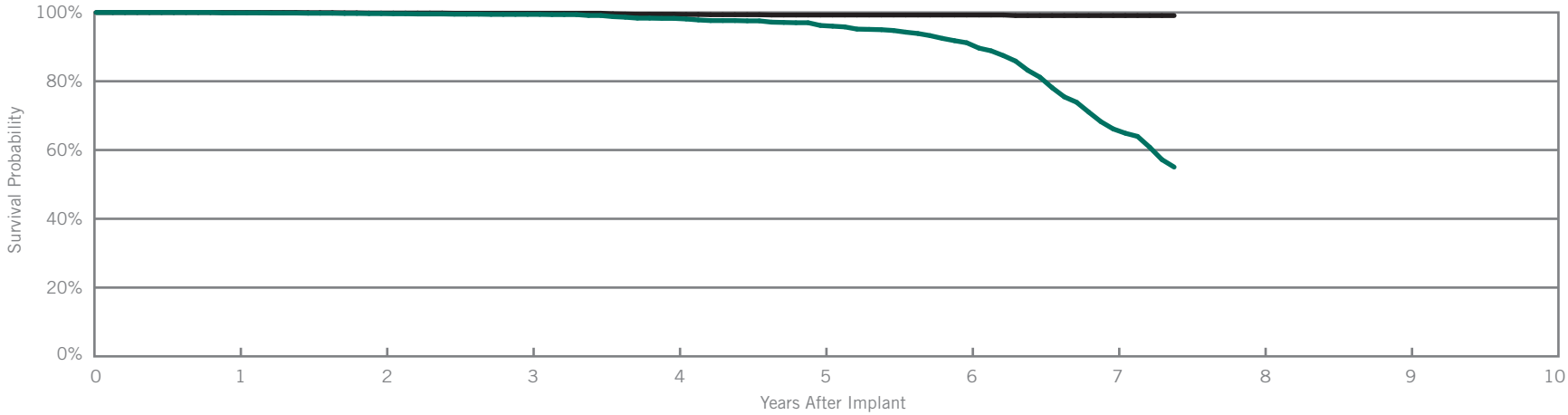
Customer Reported Performance Data

Atlas® DR

Model V-242

US Regulatory Approval	October 2003
Registered US Implants	4,647
Estimated Active US Implants	1,569
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	225
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.02%	0	0.00%
Battery	6	0.13%	1	0.02%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	1	0.02%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	0.02%	0	0.00%
Other	2	0.04%	0	0.00%
Total	**10**	**0.22%**	**2**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.88%	99.67%	99.44%	98.28%	96.22%	91.19%	66.14%	55.04%		
± 1 standard error	0.05%	0.09%	0.12%	0.23%	0.31%	0.57%	1.35%	1.77%		
Sample Size	4600	4100	3600	3200	2800	2100	1200	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	100.00%	99.84%	99.78%	99.48%	99.26%	99.26%	99.09%	99.09%		
± 1 standard error	0.00%	0.06%	0.08%	0.13%	0.16%	0.16%	0.19%	0.19%		

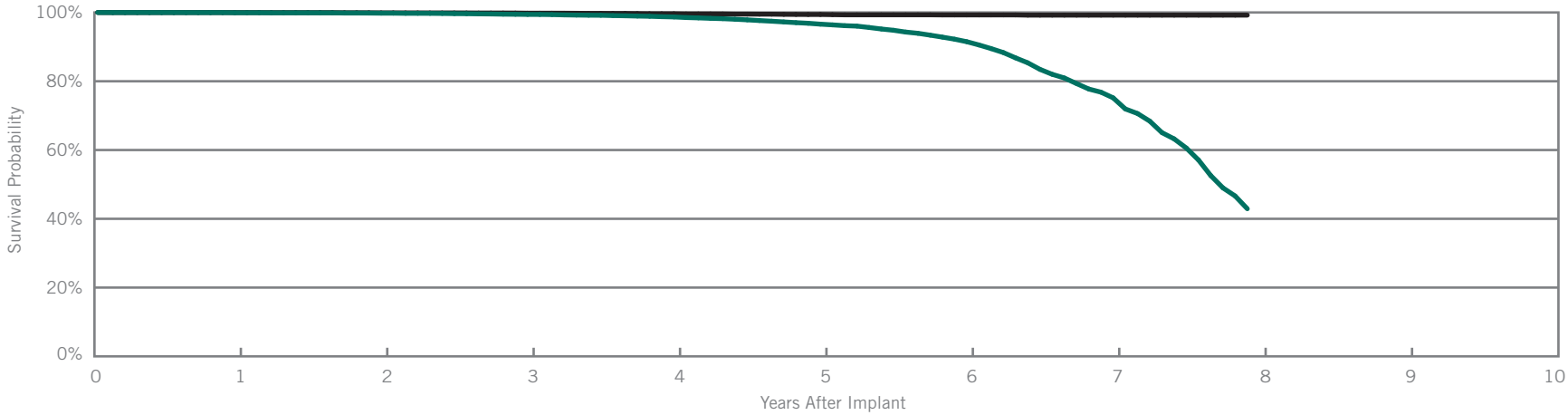
Customer Reported Performance Data

Atlas® + DR

Model V-243

US Regulatory Approval	October 2003
Registered US Implants	21,007
Estimated Active US Implants	7,516
Estimated Longevity	(see table on page 84)
Normal Battery Depletion	665
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.02%	2	0.01%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	10	0.05%	4	0.02%
High Voltage Capacitor	1	<0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	6	0.03%	2	0.01%
Other	8	0.04%	2	0.01%
Total	**30**	**0.14%**	**11**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.93%	99.79%	99.43%	98.69%	96.60%	91.50%	75.17%	42.91%		
± 1 standard error	0.01%	0.03%	0.06%	0.09%	0.16%	0.28%	0.64%	1.55%		
Sample Size	21000	18300	16100	14100	11600	8200	4000	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.97%	99.90%	99.80%	99.63%	99.41%	99.28%	99.22%	99.22%		
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.07%	0.08%	0.09%	0.09%		

Battery Longevity Summary

Dual-Chamber ICDs

St. Jude Medical™
More control. Less risk.

Battery Longevity

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

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

Summary Information

Dual-Chamber ICDs

St. Jude Medical
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Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR	99.76%	99.71%								
CD2231-40	Fortify® DR	99.88%	99.88%								
CD2211-36Q	Current® + DR	99.85%	99.35%								
CD2211-36	Current® + DR	99.77%	99.53%	99.47%							
2207-30	Current® DR RF	99.72%	99.57%	99.37%	99.37%						
2207-36	Current® DR RF	99.69%	99.32%	98.74%	98.04%						
V-265	Atlas® II DR	100.00%	99.87%	99.58%	98.20%	96.42%					
V-268	Atlas® II + DR	99.72%	99.58%	98.93%	97.53%	94.72%					
V-258	Epic® II + DR	99.79%	99.79%	99.23%	96.41%	76.50%					
V-239	Epic® + DR	99.69%	99.25%	98.54%	96.20%	88.10%	53.80%	16.79%			
V-242	Atlas® DR	99.88%	99.67%	99.44%	98.28%	96.22%	91.19%	66.14%			
V-243	Atlas® + DR	99.93%	99.79%	99.43%	98.69%	96.60%	91.50%	75.17%			

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD2231-40Q	Fortify® DR	99.87%	99.84%								
CD2231-40	Fortify® DR	99.93%	99.93%								
CD2211-36Q	Current® + DR	99.85%	99.55%								
CD2211-36	Current® + DR	99.89%	99.73%	99.68%							
2207-30	Current® DR RF	100.00%	100.00%	99.80%	99.80%						
2207-36	Current® DR RF	99.73%	99.58%	99.22%	98.74%						
V-265	Atlas® II DR	100.00%	99.87%	99.87%	98.66%	98.66%					
V-268	Atlas® II + DR	99.80%	99.68%	99.40%	99.12%	98.96%					
V-258	Epic® II + DR	100.00%	100.00%	100.00%	99.84%	99.84%					
V-239	Epic® + DR	99.89%	99.83%	99.80%	99.75%	99.66%	99.66%	99.40%			
V-242	Atlas® DR	100.00%	99.84%	99.78%	99.48%	99.26%	99.26%	99.09%			
V-243	Atlas® + DR	99.97%	99.90%	99.80%	99.63%	99.41%	99.28%	99.22%			

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	23133	1	<0.01%	0	0.00%	1	<0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**5**	**0.02%**
CD2231-40	Fortify® DR	10134	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.02%**
CD2211-36Q	Current® + DR	8000	3	0.04%	0	0.00%	3	0.04%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**8**	**0.10%**
CD2211-36	Current® + DR	6081	2	0.03%	1	0.02%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.07%**
2207-30	Current® DR RF	1557	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
2207-36	Current® DR RF	22303	4	0.02%	4	0.02%	3	0.01%	1	<0.01%	0	0.00%	0	0.00%	17	0.08%	8	0.04%	**37**	**0.17%**
V-265	Atlas® II DR	1881	0	0.00%	0	0.00%	4	0.21%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**6**	**0.32%**
V-268	Atlas® II + DR	14759	5	0.03%	4	0.03%	8	0.05%	0	0.00%	0	0.00%	0	0.00%	12	0.08%	4	0.03%	**33**	**0.22%**
V-258	Epic® II + DR	2101	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
V-239	Epic® + DR	7857	2	0.03%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**5**	**0.06%**
V-242	Atlas® DR	4647	0	0.00%	1	0.02%	6	0.13%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	2	0.04%	**10**	**0.22%**
V-243	Atlas® + DR	21007	4	0.02%	1	<0.01%	10	0.05%	1	<0.01%	0	0.00%	0	0.00%	6	0.03%	8	0.04%	**30**	**0.14%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify® DR	23133	3	0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**6**	**0.03%**
CD2231-40	Fortify® DR	10134	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current® + DR	8000	0	0.00%	0	0.00%	4	0.05%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	**6**	**0.08%**
CD2211-36	Current® + DR	6081	1	0.02%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.05%**
2207-30	Current® DR RF	1557	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.06%**
2207-36	Current® DR RF	22303	8	0.04%	1	<0.01%	5	0.02%	0	0.00%	4	0.02%	1	<0.01%	11	0.05%	4	0.02%	**34**	**0.15%**
V-265	Atlas® II DR	1881	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.11%	0	0.00%	**2**	**0.11%**
V-268	Atlas® II + DR	14759	2	0.01%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	6	0.04%	1	0.01%	**11**	**0.07%**
V-258	Epic® II + DR	2101	0	0.00%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**
V-239	Epic® + DR	7857	1	0.01%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	**6**	**0.08%**
V-242	Atlas® DR	4647	0	0.00%	0	0.00%	1	0.02%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.04%**
V-243	Atlas® + DR	21007	2	0.01%	0	0.00%	4	0.02%	0	0.00%	0	0.00%	1	<0.01%	2	0.01%	2	0.01%	**11**	**0.05%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Defibrillation Impedance		Failure to Capture		Inappropriate Shock		Loss of Telemetry		Oversensing		Premature Battery Depletion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	396	6177	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.25%	0	0.00%	**1**	**0.25%**
CD2231-40	177	2686	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	836	22069	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.24%	0	0.00%	**2**	**0.24%**
CD2211-36	118	3195	0	0.00%	0	0.00%	1	0.85%	0	0.00%	0	0.00%	1	0.85%	0	0.00%	**2**	**1.69%**
2207-36	631	21178	0	0.00%	0	0.00%	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

Malfunctions

Models	Family	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify DR	396	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.25%	**1**	**0.25%**
CD2231-40	Fortify DR	177	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current + DR	836	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36	Current + DR	118	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
2207-36	Current DR RF	631	0	0.00%	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

Models	Family	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD2231-40Q	Fortify DR	396	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2231-40	Fortify DR	177	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD2211-36Q	Current + DR	836	0	0.00%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	**3**	**0.36%**
CD2211-36	Current + DR	118	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.85%	**1**	**0.85%**
2207-36	Current DR RF	631	1	0.16%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.16%**

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

Implantable Cardioverter Defibrillator (ICD) Devices

Single-Chamber

St. Jude Medical
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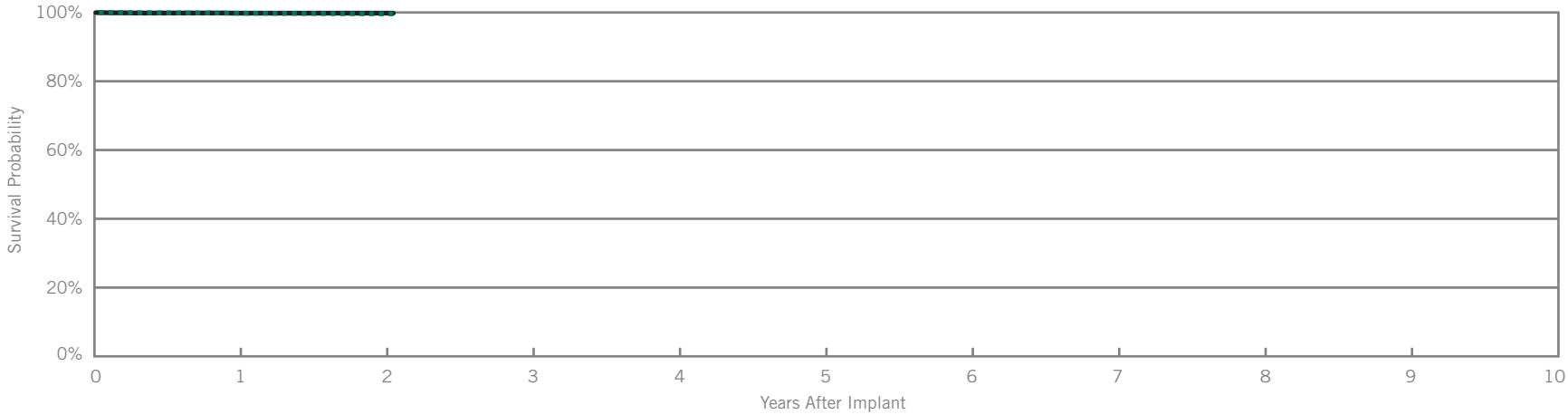
Customer Reported Performance Data

Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Registered US Implants	13,495
Estimated Active US Implants	11,714
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	7
Max. Delivered Energy	40 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.02%	1	0.01%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	3	0.02%	1	0.01%
Total	**7**	**0.05%**	**2**	**0.01%**



Including Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.70%	99.62%	99.62%							
± 1 standard error	0.05%	0.07%	0.07%							
Sample Size	10400	3200	300							

Excluding Normal Battery Depletion

Year	1	2	at 25 months							
Survival Probability	99.80%	99.80%	99.80%							
± 1 standard error	0.04%	0.04%	0.04%							

Actively Monitored Study Data

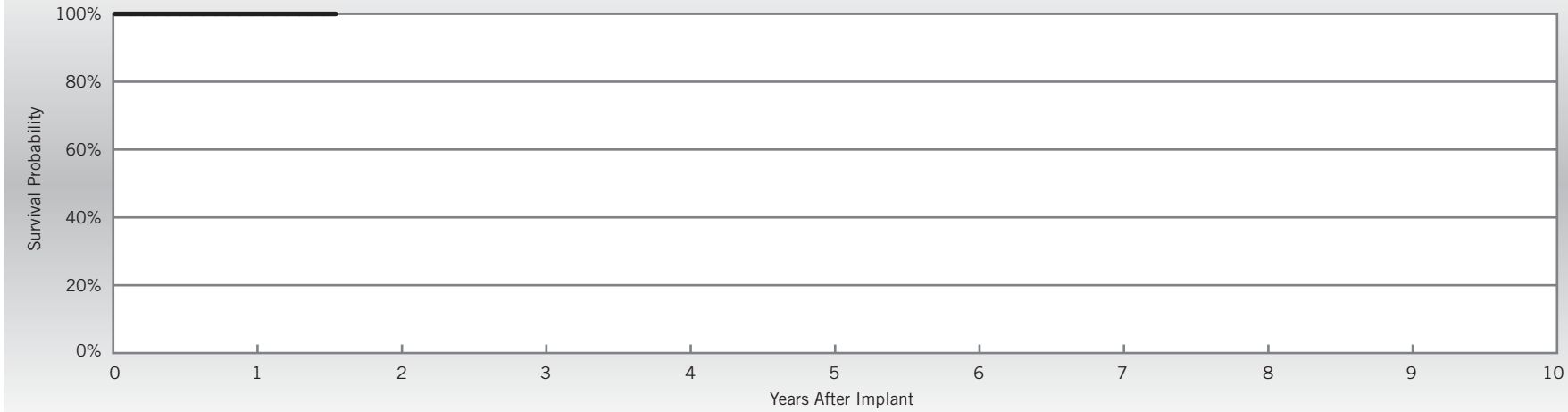
Fortify® VR

Model CD1231-40Q

US Regulatory Approval	May 2010
Number of Devices Enrolled in Study	151
Cumulative Months of Follow-up	2,354
Estimated Longevity	(see table on page 106)
Max. Delivered Energy	40 joules

Qualifying Complications
None Reported

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



Year	1	at 19 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	130	50								

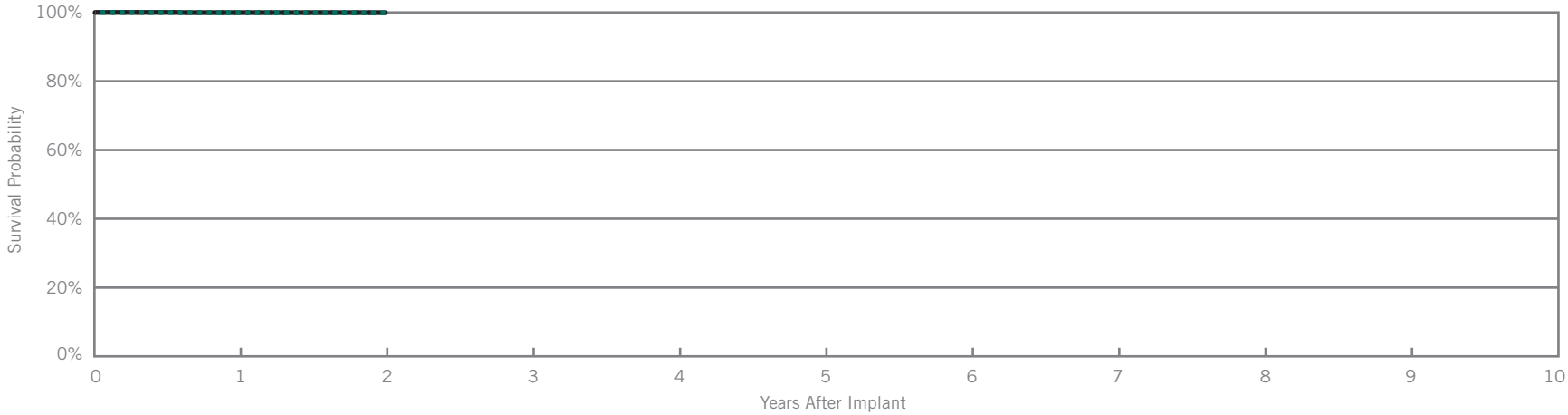
Customer Reported Performance Data

Fortify® VR

Model CD1231-40

US Regulatory Approval	May 2010
Registered US Implants	5,822
Estimated Active US Implants	5,069
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	2
Max. Delivered Energy	40 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.86%	99.86%								
± 1 standard error	0.06%	0.06%								
Sample Size	4500	1300								

Excluding Normal Battery Depletion

Year	1	2								
Survival Probability	99.94%	99.94%								
± 1 standard error	0.04%	0.04%								

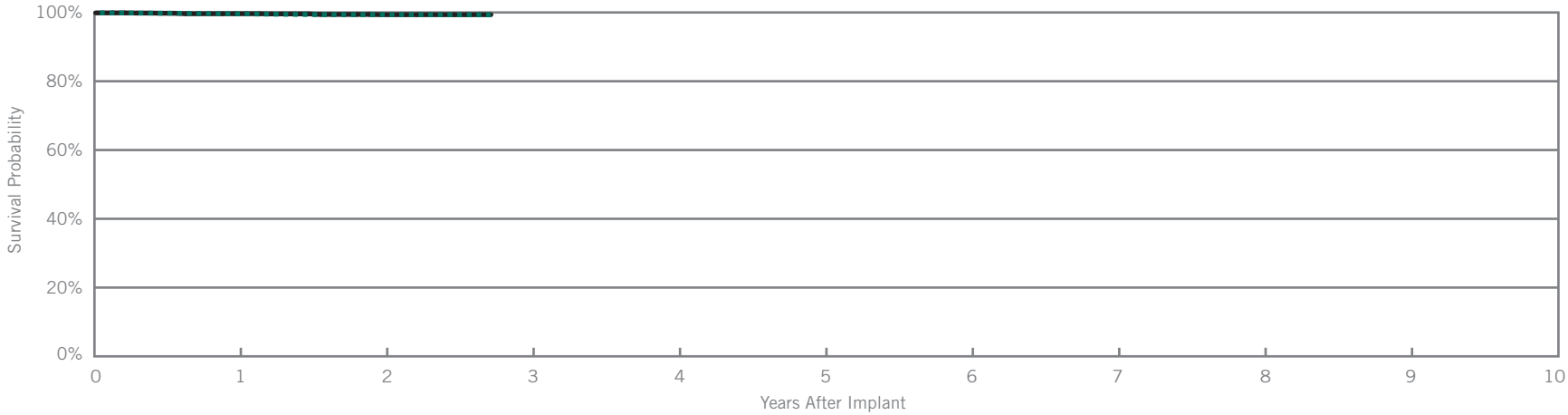
Customer Reported Performance Data

Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Registered US Implants	4,219
Estimated Active US Implants	3,182
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	1
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.05%	2	0.05%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	1	0.02%	2	0.05%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	2	0.05%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**6**	**0.14%**	**4**	**0.09%**



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.59%	99.30%	99.30%							
± 1 standard error	0.10%	0.13%	0.14%							
Sample Size	4200	3300	400							

Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.64%	99.36%	99.36%							
± 1 standard error	0.10%	0.13%	0.14%							

Actively Monitored Study Data

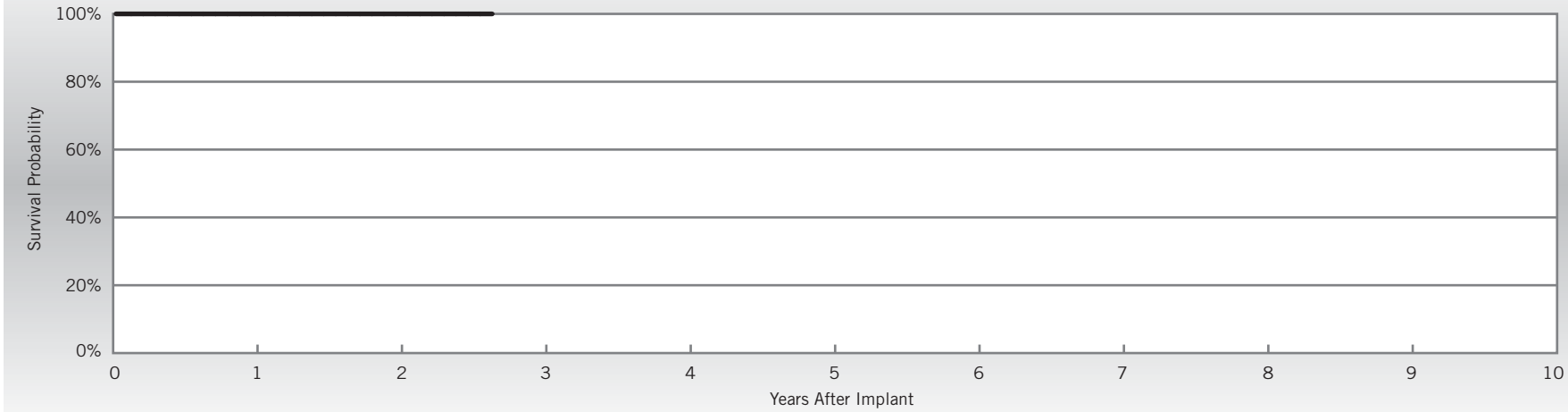
Current® + VR

Model CD1211-36Q

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	330
Cumulative Months of Follow-up	8,569
Estimated Longevity	(see table on page 106)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

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



Year	1	2	at 32 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	320	280	60							

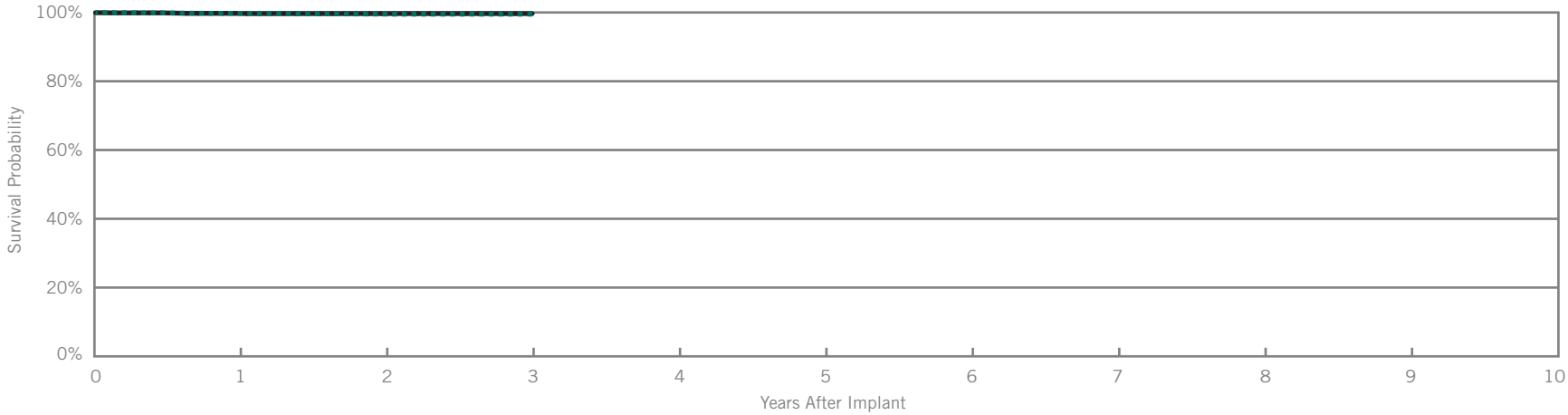
Customer Reported Performance Data

Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Registered US Implants	3,436
Estimated Active US Implants	2,565
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	2
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.06%	0	0.00%
Electrical Interconnect	1	0.03%	0	0.00%
Battery	1	0.03%	0	0.00%
High Voltage Capacitor	1	0.03%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**5**	**0.15%**	**0**	**0.00%**



Including Normal Battery Depletion

Year	1	2	3							
Survival Probability	99.75%	99.51%	99.51%							
± 1 standard error	0.09%	0.13%	0.13%							
Sample Size	3300	2600	1200							

Excluding Normal Battery Depletion

Year	1	2	3							
Survival Probability	99.75%	99.68%	99.68%							
± 1 standard error	0.09%	0.10%	0.10%							

Actively Monitored Study Data

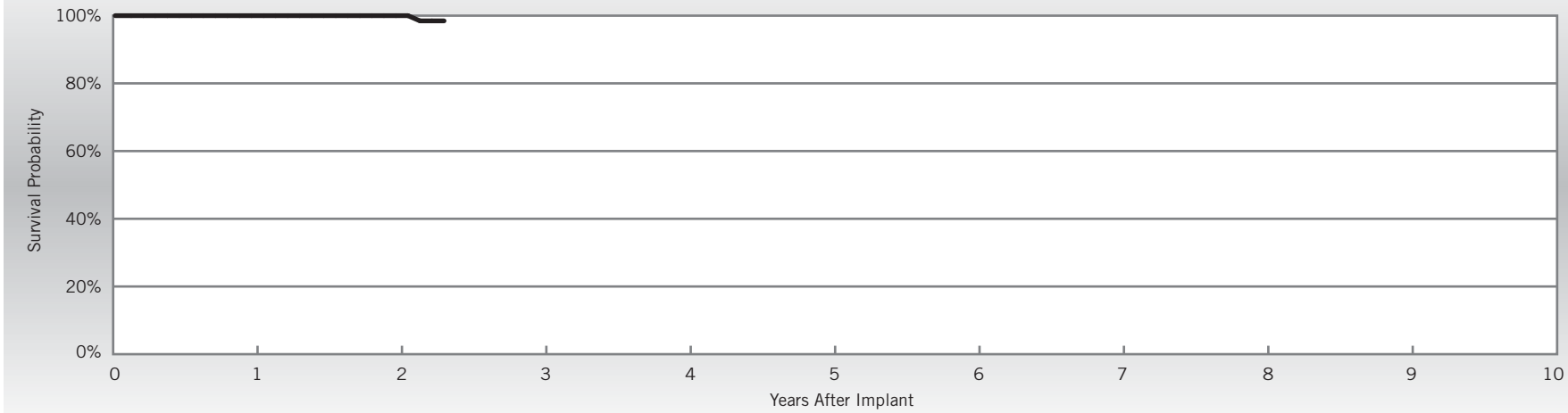
Current® + VR

Model CD1211-36

US Regulatory Approval	February 2009
Number of Devices Enrolled in Study	108
Cumulative Months of Follow-up	2,777
Estimated Longevity	(see table on page 106)
Max. Delivered Energy	36 joules

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	1	0.93%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	0	0.00%
Electrical Interconnect	1	0.93%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**1**	**0.93%**	**0**	**0.00%**



Year	1	2	at 28 months							
Survival Probability	100.00%	100.00%	98.46%							
± 1 standard error	0.00%	0.00%	1.53%							
Sample Size	100	90	50							

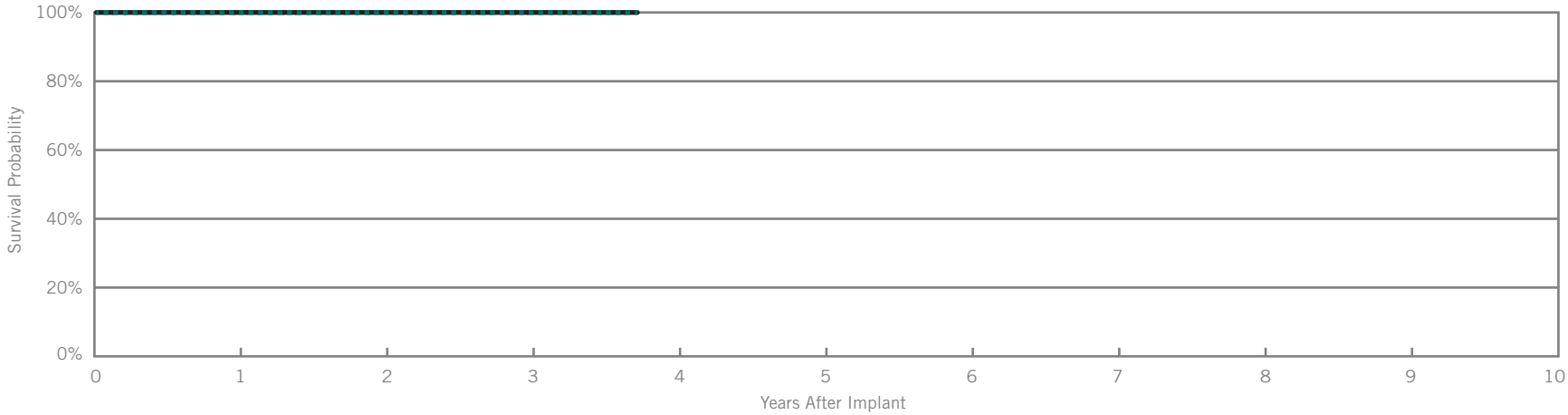
Customer Reported Performance Data

Current® VR RF

Model 1207-30

US Regulatory Approval	September 2007
Registered US Implants	875
Estimated Active US Implants	581
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	0
Max. Delivered Energy	30 joules
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	900	800	600	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						

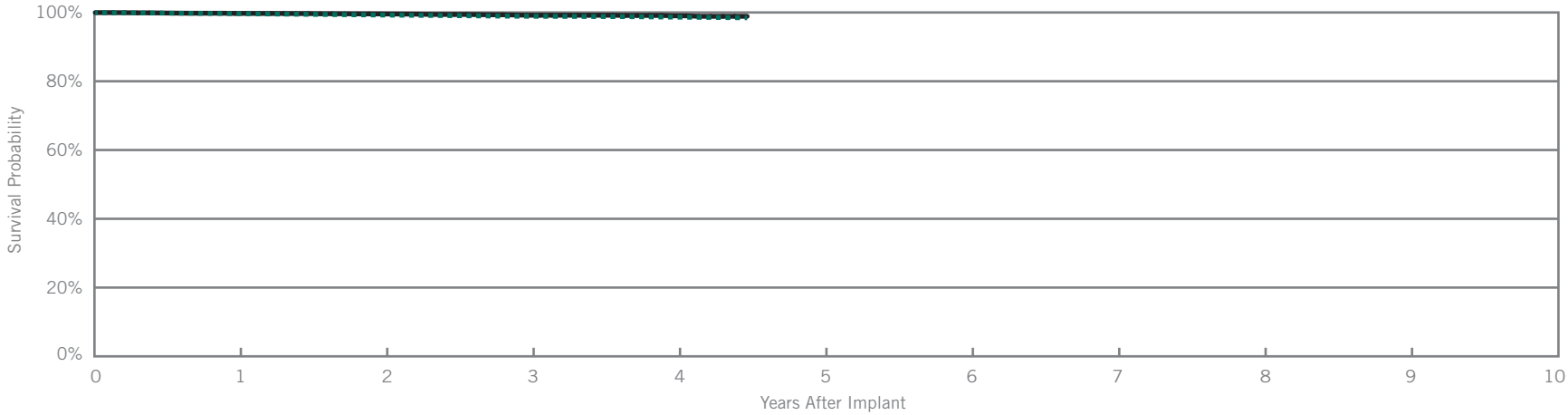
Customer Reported Performance Data

Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Registered US Implants	13,175
Estimated Active US Implants	8,537
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	15
Max. Delivered Energy	36 joules
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	6	0.05%	3	0.02%
Electrical Interconnect	7	0.05%	0	0.00%
Battery	1	0.01%	3	0.02%
High Voltage Capacitor	1	0.01%	1	0.01%
Software/Firmware	0	0.00%	1	0.01%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	2	0.02%	5	0.04%
Other	4	0.03%	3	0.02%
Total	**21**	**0.16%**	**17**	**0.13%**



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.62%	99.27%	98.84%	98.60%	98.45%					
± 1 standard error	0.05%	0.08%	0.10%	0.13%	0.18%					
Sample Size	13200	11200	8700	4400	400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.73%	99.57%	99.19%	99.03%	98.88%					
± 1 standard error	0.04%	0.06%	0.09%	0.10%	0.17%					

Actively Monitored Study Data

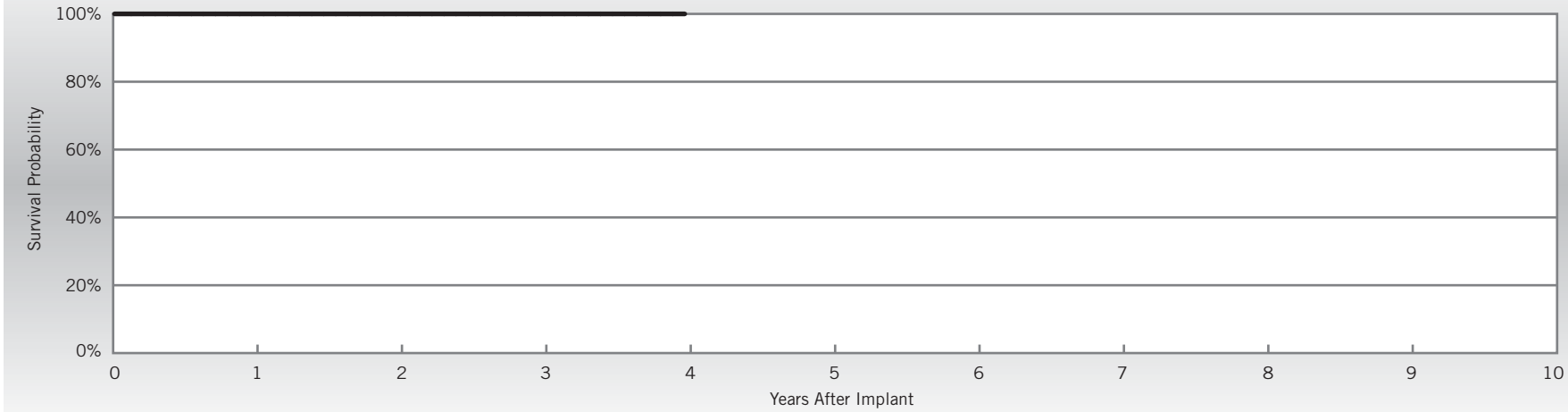
Current® VR RF

Model 1207-36

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	396
Cumulative Months of Follow-up	13,663
Estimated Longevity	(see table on page 106)
Max. Delivered Energy	36 joules

Qualifying Complications
None Reported

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.25%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
High Voltage Capacitor	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.25%**



Year	1	2	3	4						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	380	340	270	130						

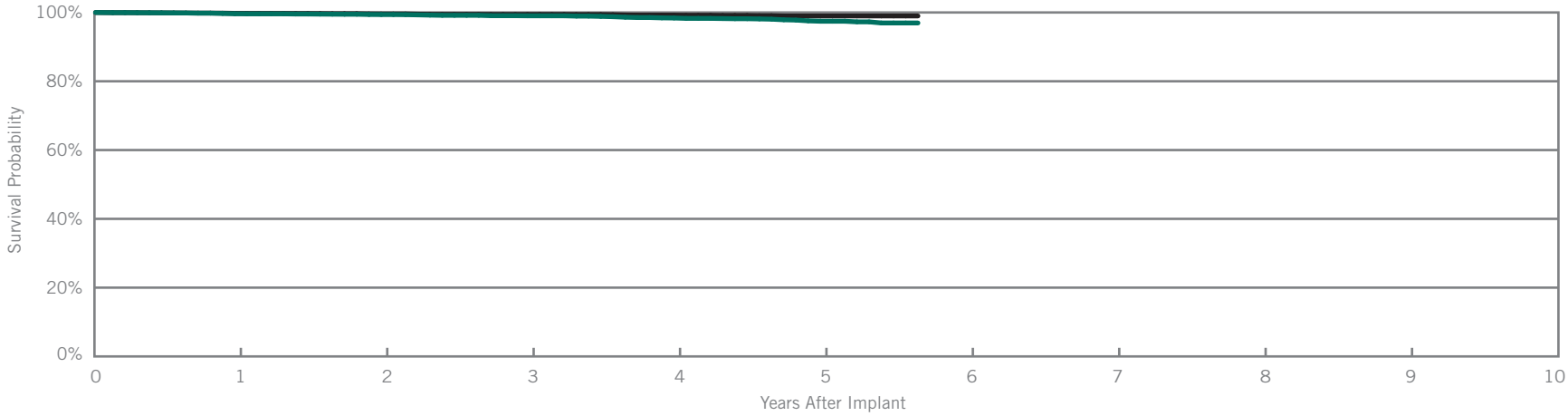
Customer Reported Performance Data

Atlas® II VR

Model V-168

US Regulatory Approval	July 2006
Registered US Implants	10,517
Estimated Active US Implants	5,844
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	31
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	0.02%	2	0.02%
Electrical Interconnect	1	0.01%	0	0.00%
Battery	6	0.06%	1	0.01%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	0.01%	0	0.00%
Possible Early Battery Depletion	6	0.06%	3	0.03%
Other	6	0.06%	3	0.03%
Total	**23**	**0.22%**	**9**	**0.09%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.63%	99.39%	99.03%	98.39%	97.45%	96.95%				
± 1 standard error	0.05%	0.08%	0.11%	0.15%	0.23%	0.35%				
Sample Size	10500	9100	7800	6000	3400	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.75%	99.58%	99.42%	99.22%	98.99%	98.99%				
± 1 standard error	0.04%	0.07%	0.08%	0.10%	0.13%	0.13%				

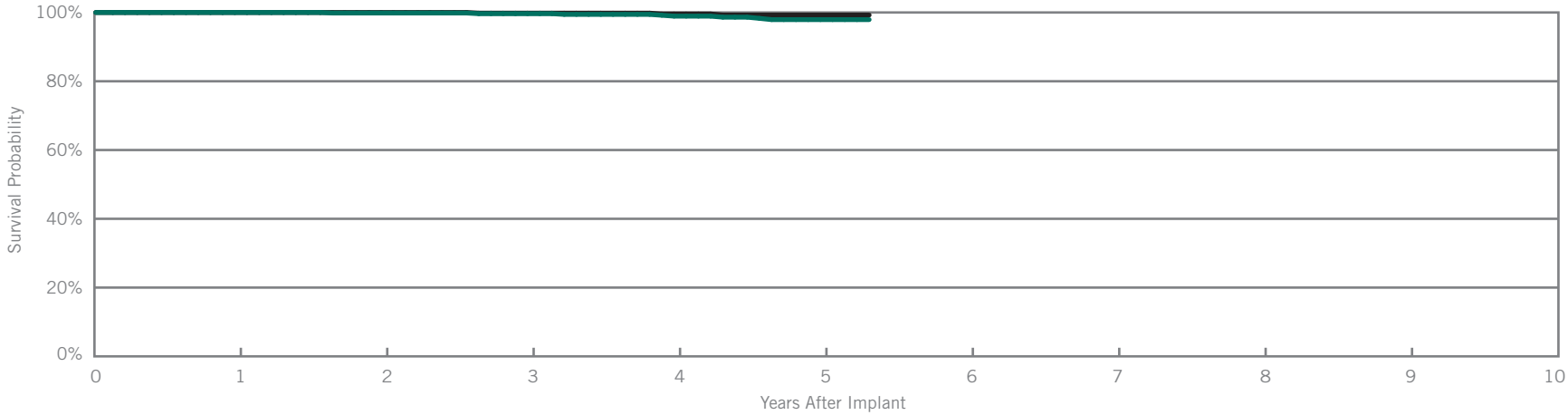
Customer Reported Performance Data

Epic® II VR

Model V-158

US Regulatory Approval	March 2006
Registered US Implants	1,574
Estimated Active US Implants	821
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	5
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	Three

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



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	99.84%	99.65%	98.93%	97.92%	97.92%				
± 1 standard error	0.00%	0.11%	0.18%	0.29%	0.53%	0.53%				
Sample Size	1600	1400	1200	900	600	200				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	100.00%	100.00%	99.81%	99.56%	99.25%	99.25%				
± 1 standard error	0.00%	0.00%	0.14%	0.22%	0.31%	0.31%				

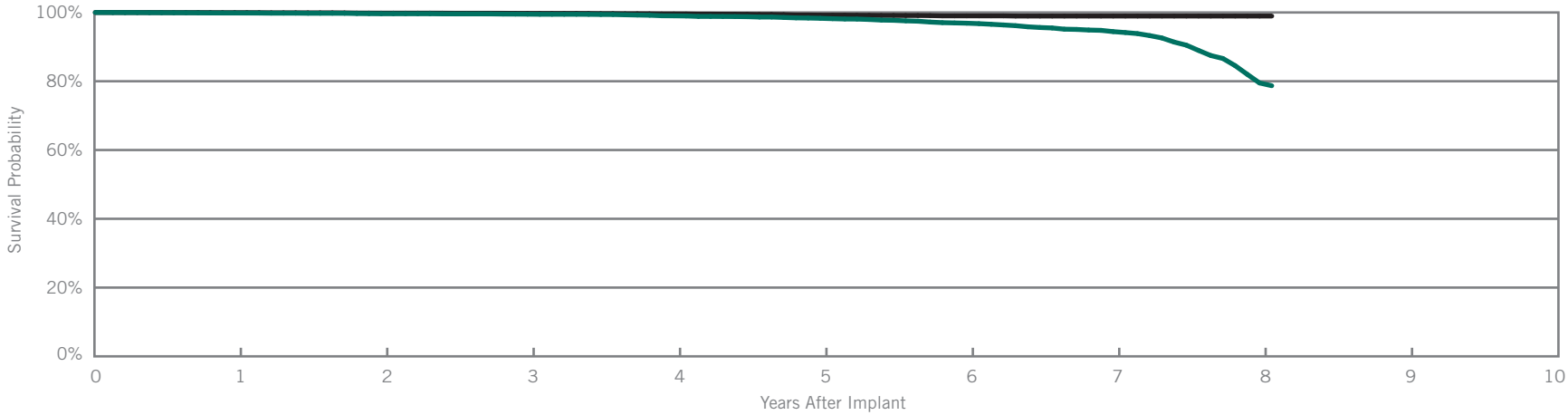
Customer Reported Performance Data

Atlas® + VR

Model V-193

US Regulatory Approval	October 2003
Registered US Implants	20,635
Estimated Active US Implants	8,509
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	164
Max. Delivered Energy	36 joules
Number of US Advisories (see pgs. 248-260)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	2	0.01%
Electrical Interconnect	4	0.02%	1	<0.01%
Battery	4	0.02%	2	0.01%
High Voltage Capacitor	2	0.01%	1	<0.01%
Software/Firmware	0	0.00%	1	<0.01%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	22	0.11%	4	0.02%
Other	6	0.03%	3	0.01%
Total	**39**	**0.19%**	**14**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 97 months
Survival Probability	99.84%	99.63%	99.50%	99.02%	98.30%	96.88%	94.43%	79.50%	78.70%
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.11%	0.17%	0.29%	1.37%	1.58%
Sample Size	20600	17900	15800	13700	11300	8100	4100	1200	200

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 97 months
Survival Probability	99.95%	99.81%	99.74%	99.57%	99.21%	99.01%	98.96%	98.96%	98.96%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.08%	0.10%	0.10%	0.10%	0.10%

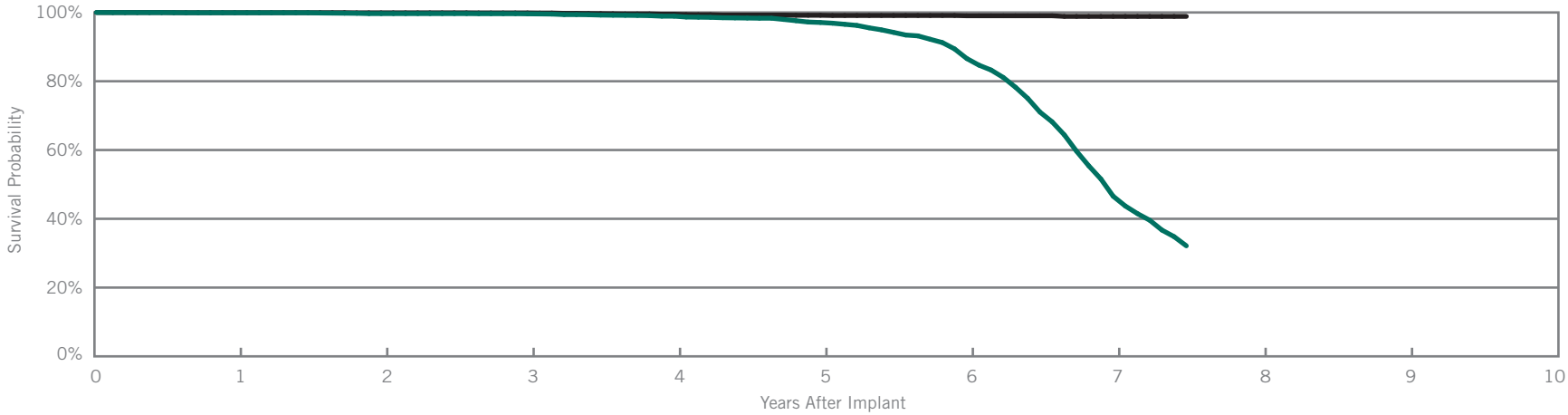
Customer Reported Performance Data

Epic® + VR

Model V-196

US Regulatory Approval	April 2003
Registered US Implants	7,970
Estimated Active US Implants	1,901
Estimated Longevity	(see table on page 106)
Normal Battery Depletion	497
Max. Delivered Energy	30 joules
Number of US Advisories (see pgs. 248-260)	Three

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	1	0.01%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	16	0.20%
High Voltage Capacitor	1	0.01%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	1	0.01%	0	0.00%
Other	2	0.03%	0	0.00%
Total	**5**	**0.06%**	**17**	**0.21%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.92%	99.67%	99.60%	98.92%	97.09%	86.61%	46.57%	32.14%		
± 1 standard error	0.03%	0.07%	0.07%	0.14%	0.24%	0.53%	1.19%	1.41%		
Sample Size	8000	7000	6200	5500	4600	3500	1900	200		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.95%	99.91%	99.88%	99.49%	99.18%	99.04%	98.86%	98.86%		
± 1 standard error	0.03%	0.04%	0.04%	0.10%	0.13%	0.13%	0.19%	0.19%		

Battery Longevity Summary

Single-Chamber ICDs

St. Jude Medical
More control. Less risk.

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD1231-40Q	Fortify® VR**	10.5	10.1	9.7	9.1
CD1231-40	Fortify® VR**	10.5	10.1	9.7	9.1
CD1211-36Q	Current® + VR	8.4	8.0	7.6	7.0
CD1211-36	Current® + VR	8.4	8.0	7.6	7.0
1207-30	Current® VR RF	6.7	6.4	6.1	5.6
1207-36	Current® VR RF	8.4	8.0	7.6	7.0
V-168	Atlas® II VR	8.4	8.0	7.6	7.0
V-158	Epic® II VR	6.7	6.4	6.1	5.6
V-193	Atlas® + VR	8.6	8.2	7.9	7.3
V-196	Epic® + VR <115000	6.3	6	5.8	5.4
V-196	Epic® + VR >115000	6.9	6.6	6.4	5.9

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

Summary Information

Single-Chamber ICDs

St. Jude Medical
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1231-40Q	Fortify® VR	99.70%	99.62%								
CD1231-40	Fortify® VR	99.86%	99.86%								
CD1211-36Q	Current® + VR	99.59%	99.30%								
CD1211-36	Current® + VR	99.75%	99.51%	99.51%							
1207-30	Current® VR RF	100.00%	100.00%	100.00%							
1207-36	Current® VR RF	99.62%	99.27%	98.84%	98.60%						
V-168	Atlas® II VR	99.63%	99.39%	99.03%	98.39%	97.45%					
V-158	Epic® II VR	100.00%	99.84%	99.65%	98.93%	97.92%					
V-193	Atlas® + VR	99.84%	99.63%	99.50%	99.02%	98.30%	96.88%	94.43%	79.50%		
V-196	Epic® + VR	99.92%	99.67%	99.60%	98.92%	97.09%	86.61%	46.57%			

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD1231-40Q	Fortify® VR	99.80%	99.80%								
CD1231-40	Fortify® VR	99.94%	99.94%								
CD1211-36Q	Current® + VR	99.64%	99.36%								
CD1211-36	Current® + VR	99.75%	99.68%	99.68%							
1207-30	Current® VR RF	100.00%	100.00%	100.00%							
1207-36	Current® VR RF	99.73%	99.57%	99.19%	99.03%						
V-168	Atlas® II VR	99.75%	99.58%	99.42%	99.22%	98.99%					
V-158	Epic® II VR	100.00%	100.00%	99.81%	99.56%	99.25%					
V-193	Atlas® + VR	99.95%	99.81%	99.74%	99.57%	99.21%	99.01%	98.96%	98.96%		
V-196	Epic® + VR	99.95%	99.91%	99.88%	99.49%	99.18%	99.04%	98.86%			

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify® VR	13495	3	0.02%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.02%	**7**	**0.05%**
CD1231-40	Fortify® VR	5822	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	Current® + VR	4219	2	0.05%	0	0.00%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.05%	1	0.02%	**6**	**0.14%**
CD1211-36	Current® + VR	3436	2	0.06%	1	0.03%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.15%**
1207-30	Current® VR RF	875	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current® VR RF	13175	6	0.05%	7	0.05%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	4	0.03%	**21**	**0.16%**
V-168	Atlas® II VR	10517	2	0.02%	1	0.01%	6	0.06%	1	0.01%	0	0.00%	1	0.01%	6	0.06%	6	0.06%	**23**	**0.22%**
V-158	Epic® II VR	1574	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
V-193	Atlas® + VR	20635	1	<0.01%	4	0.02%	4	0.02%	2	0.01%	0	0.00%	0	0.00%	22	0.11%	6	0.03%	**39**	**0.19%**
V-196	Epic® + VR	7970	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	2	0.03%	**5**	**0.06%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify® VR	13495	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**2**	**0.01%**
CD1231-40	Fortify® VR	5822	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**1**	**0.02%**
CD1211-36Q	Current® + VR	4219	2	0.05%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.09%**
CD1211-36	Current® + VR	3436	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-30	Current® VR RF	875	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current® VR RF	13175	3	0.02%	0	0.00%	3	0.02%	1	0.01%	1	0.01%	1	0.01%	5	0.04%	3	0.02%	**17**	**0.13%**
V-168	Atlas® II VR	10517	2	0.02%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	3	0.03%	3	0.03%	**9**	**0.09%**
V-158	Epic® II VR	1574	0	0.00%	1	0.06%	2	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.19%**
V-193	Atlas® + VR	20635	2	0.01%	1	<0.01%	2	0.01%	1	<0.01%	1	<0.01%	0	0.00%	4	0.02%	3	0.01%	**14**	**0.07%**
V-196	Epic® + VR	7970	1	0.01%	0	0.00%	16	0.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**17**	**0.21%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Defibrillation Impedance		Failure to Capture		Inappropriate Shock		Loss of Telemetry		Oversensing		Premature Battery Depletion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	121	2354	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36	108	2264	1	0.93%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.93%**
CD1211-36Q	330	8569	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	396	12308	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Family	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify VR	121	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36	Current + VR	108	0	0.00%	1	0.93%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.93%**
CD1211-36Q	Current + VR	330	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current VR RF	396	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Models	Family	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy																	
			Electrical Component		Electrical Interconnect		Battery		High Voltage Capacitor		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
CD1231-40Q	Fortify VR	121	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36	Current + VR	108	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
CD1211-36Q	Current + VR	330	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1207-36	Current VR RF	396	1	0.25%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.25%**

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

Defibrillation Leads

St. Jude Medical™
More control. Less risk.

Customer Reported Performance Data

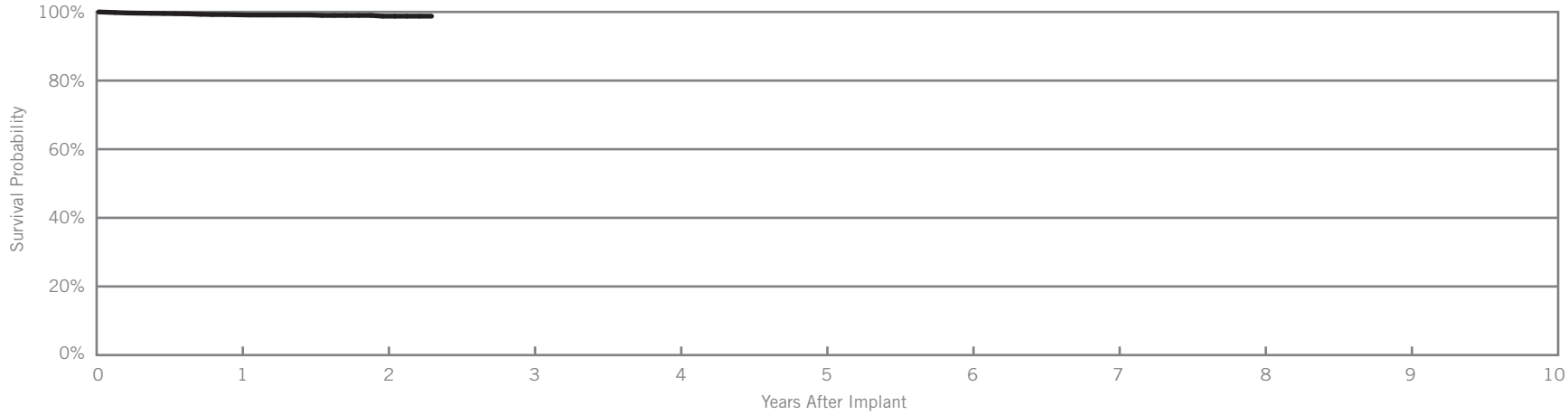
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	2,653
Estimated Active US Implants	1,992
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	0.04%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.15%	5	0.19%
Failure to Capture	2	0.08%	9	0.34%
Oversensing	1	0.04%	1	0.04%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
Abnormal Pacing Impedance	0	0.00%	1	0.04%
Abnormal Defibrillation Impedance	0	0.00%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	0	0.00%
Total	**9**	**0.34%**	**18**	**0.68%**
Total Returned for Analysis	**5**		**12**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.04%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.04%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	10	0.38%
Total	**11**	**0.41%**



Year	1	2	at 28 months							
Survival Probability	99.18%	98.77%	98.77%							
± 1 standard error	0.19%	0.25%	0.33%							
Sample Size	2200	900	200							

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

Actively Monitored Study Data

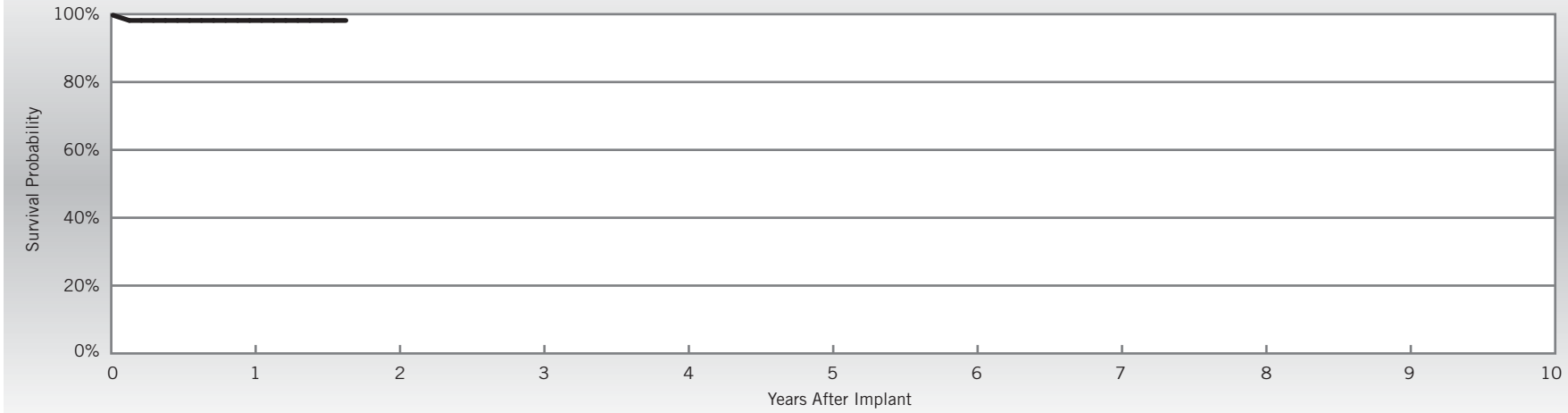
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	116
Cumulative Months of Follow-up	1,928
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Failure to Capture	2	1.72%

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	0.86%
Total	**1**	**0.86%**



Year	1	at 20 months								
Survival Probability	98.15%	98.15%								
± 1 standard error	1.30%	1.30%								
Sample Size	100	50								

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

Customer Reported Performance Data

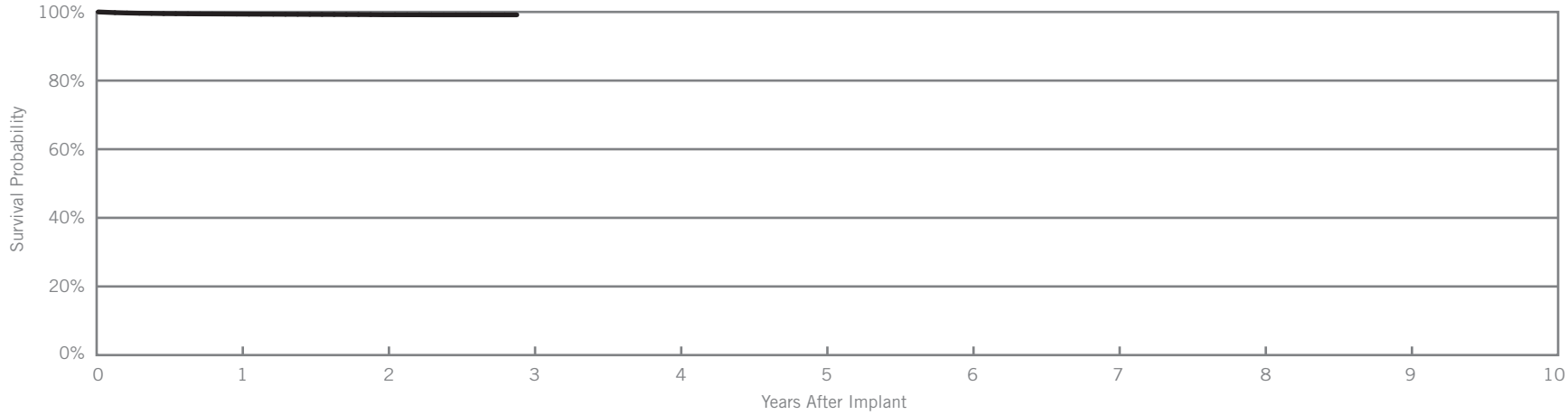
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	63,040
Estimated Active US Implants	51,656
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	34	0.05%	10	0.02%
Conductor Fracture	0	0.00%	13	0.02%
Lead Dislodgement	111	0.18%	202	0.32%
Failure to Capture	49	0.08%	80	0.13%
Oversensing	26	0.04%	37	0.06%
Failure to Sense	6	0.01%	10	0.02%
Insulation Breach	0	0.00%	4	0.01%
Abnormal Pacing Impedance	3	<0.01%	4	0.01%
Abnormal Defibrillation Impedance	4	0.01%	12	0.02%
Extracardiac Stimulation	2	<0.01%	2	<0.01%
Other	5	0.01%	9	0.01%
Total	**240**	**0.38%**	**383**	**0.61%**
Total Returned for Analysis	**115**		**268**	

Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Clavicular Crush	0	0.00%
In the Pocket	1	<0.01%
Intravascular	2	<0.01%
Insulation Breach	3	<0.01%
Lead-to-Can Contact	1	<0.01%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	13	0.02%
Extrinsic Factors	234	0.37%
Total	**253**	**0.40%**



Year	1	2	at 35 months							
Survival Probability	99.38%	99.19%	99.16%							
± 1 standard error	0.03%	0.04%	0.05%							
Sample Size	52800	24400	200							

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

Actively Monitored Study Data

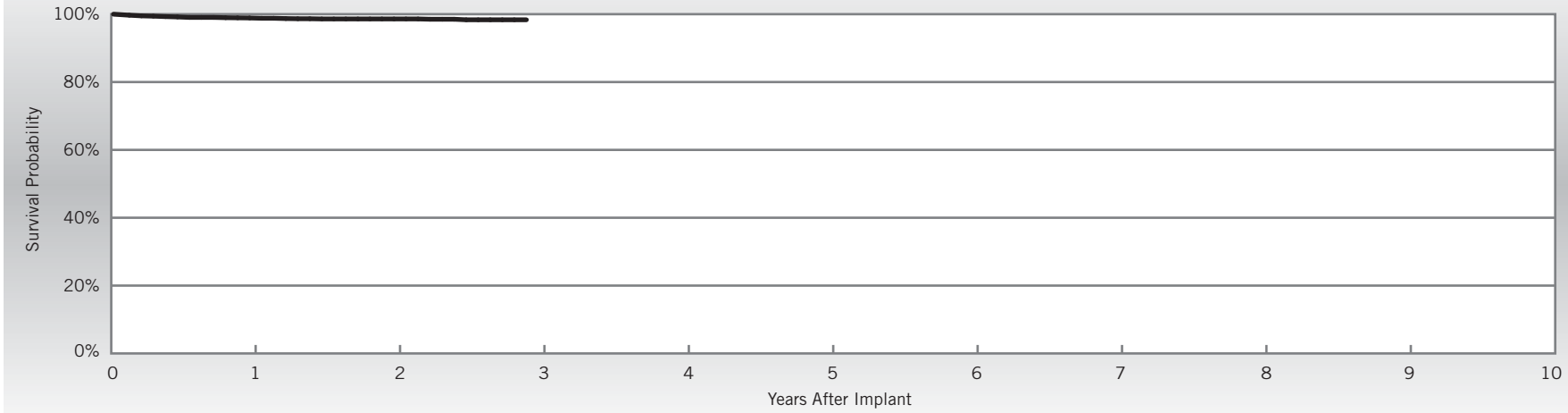
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	3,462
Cumulative Months of Follow-up	64,749
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	4	0.12%
Cardiac Perforation	1	0.03%
Conductor Fracture	2	0.06%
Failure to Capture	7	0.20%
Inappropriate Shock	1	0.03%
Lead Dislodgement	27	0.78%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.03%
Clavicular Crush	0	0.00%
In the Pocket	1	0.03%
Intravascular	0	0.00%
Insulation Breach	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	31	0.90%
Total	**32**	**0.92%**



Year	1	2	at 35 months							
Survival Probability	98.89%	98.60%	98.35%							
± 1 standard error	0.19%	0.22%	0.29%							
Sample Size	2920	1840	90							

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

Customer Reported Performance Data

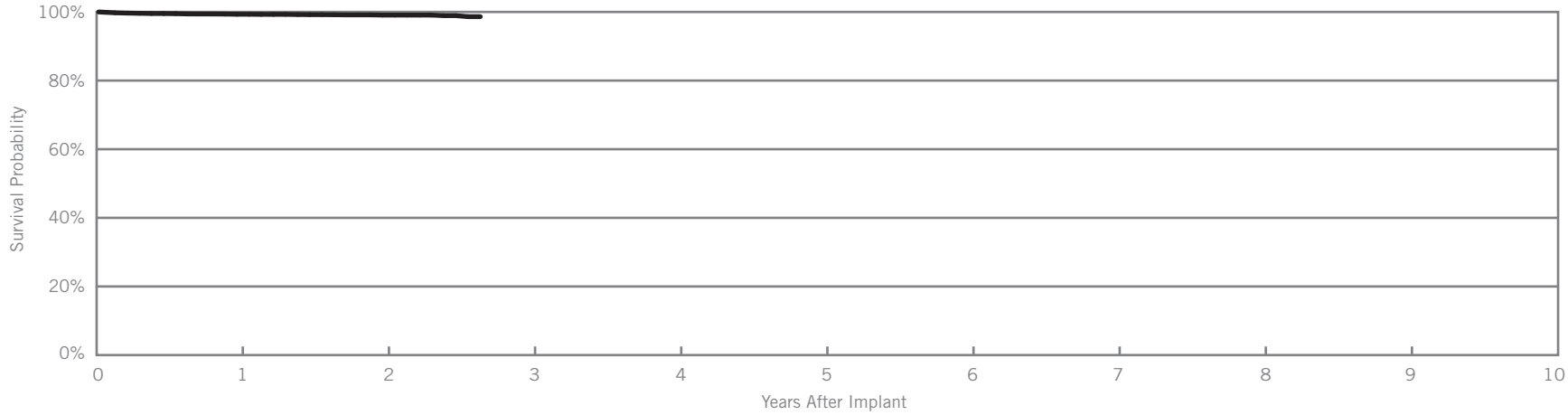
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	13,863
Estimated Active US Implants	11,460
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	9	0.06%	10	0.07%
Conductor Fracture	1	0.01%	2	0.01%
Lead Dislodgement	22	0.16%	32	0.23%
Failure to Capture	14	0.10%	13	0.09%
Oversensing	5	0.04%	12	0.09%
Failure to Sense	3	0.02%	3	0.02%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.01%
Abnormal Defibrillation Impedance	2	0.01%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.02%	0	0.00%
Total	**59**	**0.43%**	**74**	**0.53%**
Total Returned for Analysis	**33**		**54**	

Malfunctions	Qty.	Rate
Conductor Fracture	2	0.01%
Clavicular Crush	0	0.00%
In the Pocket	2	0.01%
Intravascular	0	0.00%
Insulation Breach	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	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	5	0.04%
Extrinsic Factors	44	0.32%
Total	**53**	**0.38%**



Year	1	2	at 32 months							
Survival Probability	99.33%	99.09%	98.63%							
± 1 standard error	0.08%	0.11%	0.36%							
Sample Size	10700	3900	300							

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

Actively Monitored Study Data

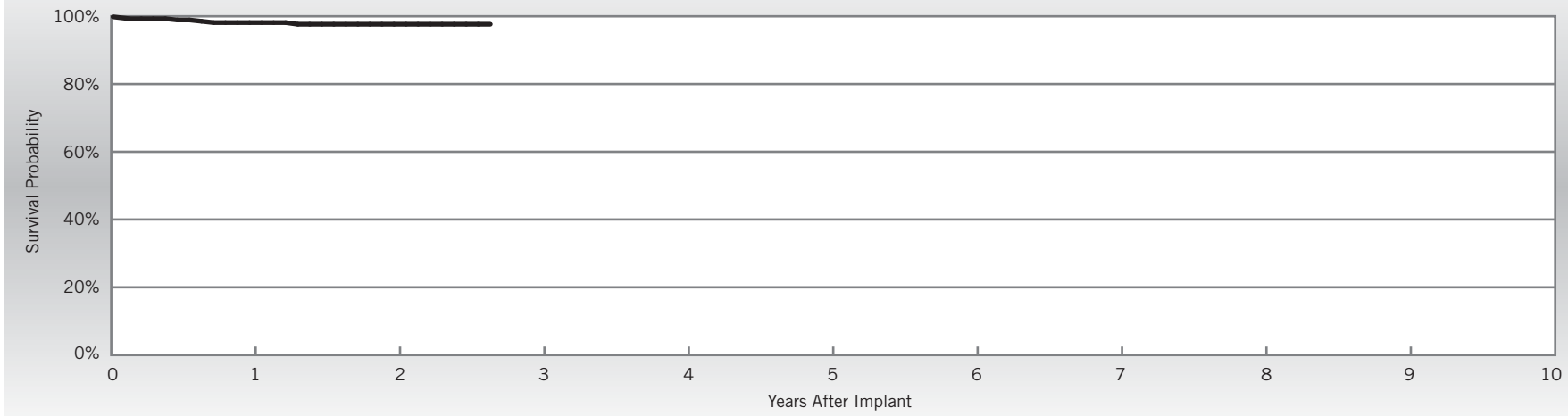
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	798
Cumulative Months of Follow-up	13,955
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	3	0.38%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	1	0.13%
Lead-to-Can Contact	1	0.13%
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	6	0.75%
Total	**7**	**0.88%**



Year	1	2	at 33 months							
Survival Probability	99.58%	99.58%	99.58%							
± 1 standard error	0.24%	0.24%	0.24%							
Sample Size	650	380	60							

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

Customer Reported Performance Data

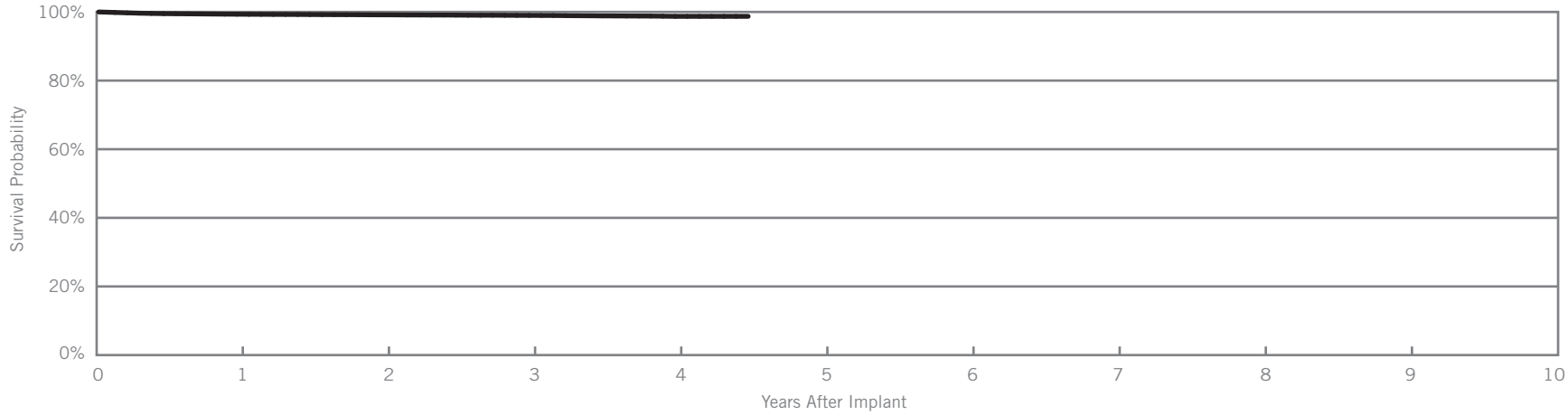
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	57,160
Estimated Active US Implants	40,010
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	34	0.06%	5	0.01%
Conductor Fracture	1	<0.01%	17	0.03%
Lead Dislodgement	70	0.12%	132	0.23%
Failure to Capture	19	0.03%	65	0.11%
Oversensing	46	0.08%	73	0.13%
Failure to Sense	4	0.01%	14	0.02%
Insulation Breach	0	0.00%	8	0.01%
Abnormal Pacing Impedance	1	<0.01%	26	0.05%
Abnormal Defibrillation Impedance	17	0.03%	26	0.05%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	17	0.03%	12	0.02%
Total	**210**	**0.37%**	**378**	**0.66%**
Total Returned for Analysis	**77**		**206**	

Malfunctions	Qty.	Rate
Conductor Fracture	17	0.03%
Clavicular Crush	1	<0.01%
In the Pocket	12	0.02%
Intravascular	4	0.01%
Insulation Breach	14	0.02%
Lead-to-Can Contact	6	0.01%
Lead-to-Lead Contact	4	0.01%
Clavicular Crush	3	0.01%
Externalized Conductors	0	0.00%
Other	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	5	0.01%
Extrinsic Factors	161	0.28%
Total	**198**	**0.35%**



Year	1	2	3	4	at 54 months					
Survival Probability	99.34%	99.16%	99.00%	98.72%	98.72%					
± 1 standard error	0.04%	0.04%	0.05%	0.07%	0.07%					
Sample Size	55000	42200	29500	13100	300					

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

Actively Monitored Study Data

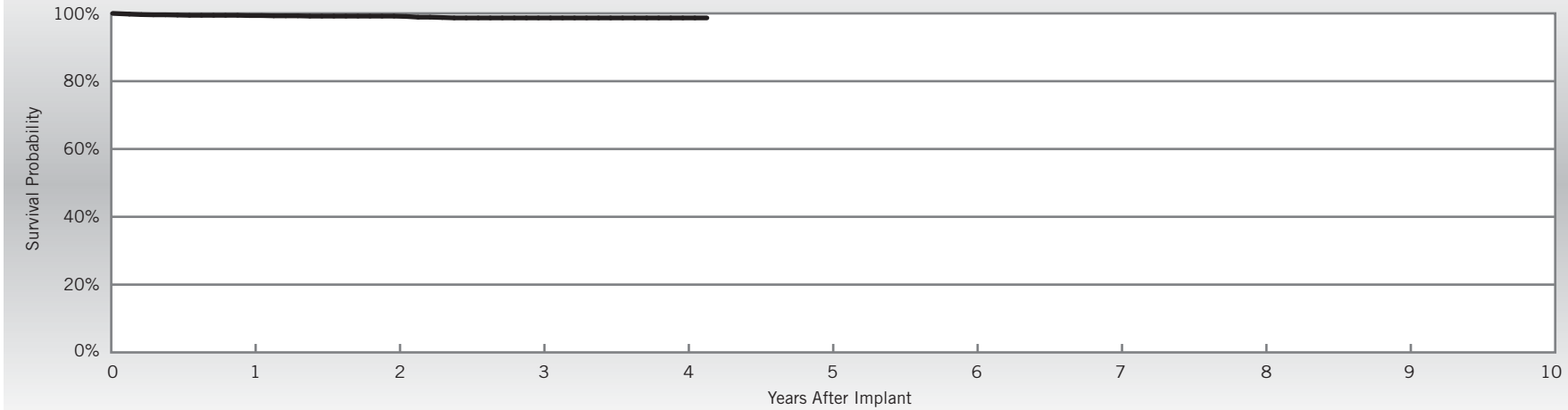
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,478
Cumulative Months of Follow-up	45,733
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	3	0.20%
Failure to Capture	3	0.20%
Failure to Sense	1	0.07%
Inappropriate Shock	1	0.07%
Insulation Breach	1	0.07%
Lead Dislodgement	6	0.41%
Oversensing	1	0.07%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	1	0.07%
Intravascular	0	0.00%
Insulation Breach	1	0.07%
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	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.14%
Total	**4**	**0.27%**



Year	1	2	3	4	at 50 months					
Survival Probability	99.36%	99.20%	98.67%	98.67%	98.67%					
± 1 standard error	0.20%	0.24%	0.34%	0.34%	0.34%					
Sample Size	1380	1130	820	380	70					

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

Customer Reported Performance Data

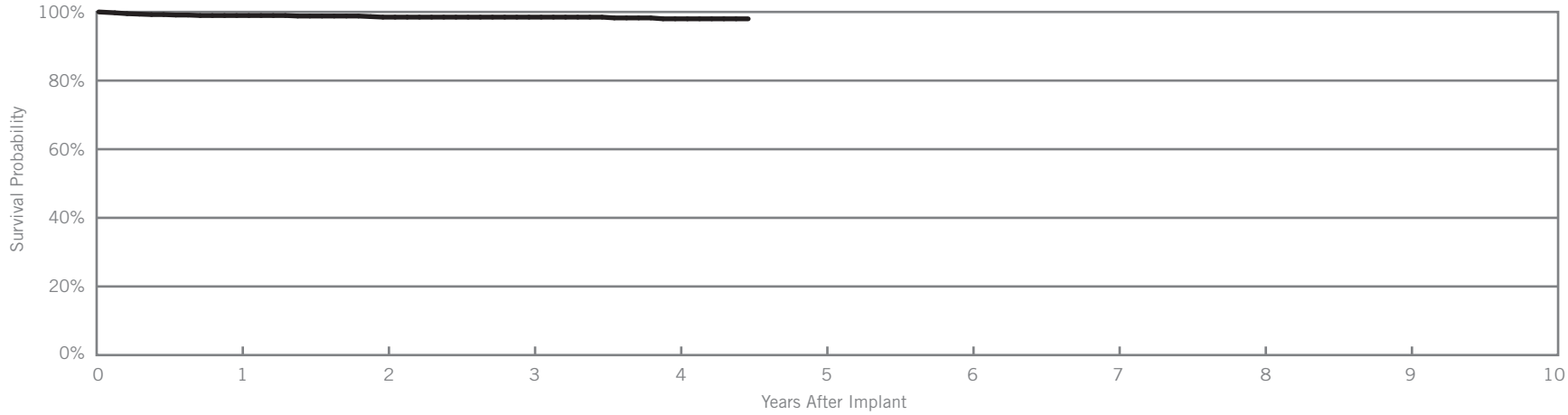
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	851
Estimated Active US Implants	295
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	1	0.12%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.47%	0	0.00%
Failure to Capture	0	0.00%	4	0.47%
Oversensing	2	0.24%	6	0.71%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.12%
Abnormal Pacing Impedance	0	0.00%	1	0.12%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**6**	**0.71%**	**13**	**1.53%**
Total Returned for Analysis	**3**		**2**	

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



Year	1	2	3	4	at 54 months					
Survival Probability	98.96%	98.49%	98.49%	98.00%	98.00%					
± 1 standard error	0.37%	0.43%	0.46%	0.57%	0.57%					
Sample Size	800	700	600	500	200					

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

Customer Reported Performance Data

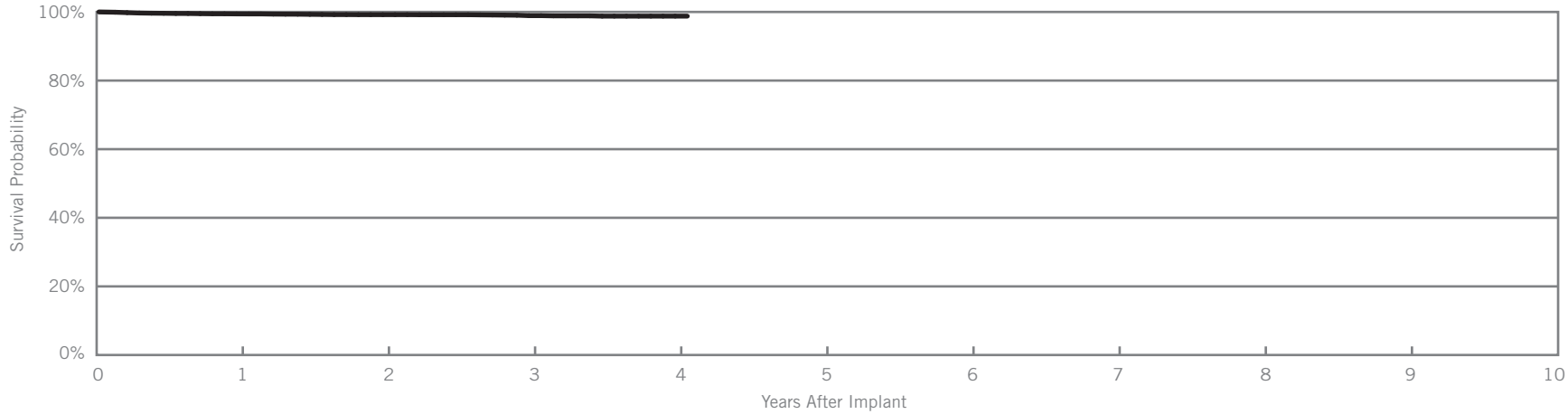
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	10,055
Estimated Active US Implants	7,292
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	5	0.05%	1	0.01%
Conductor Fracture	1	0.01%	2	0.02%
Lead Dislodgement	9	0.09%	17	0.17%
Failure to Capture	9	0.09%	14	0.14%
Oversensing	4	0.04%	11	0.11%
Failure to Sense	0	0.00%	4	0.04%
Insulation Breach	0	0.00%	5	0.05%
Abnormal Pacing Impedance	1	0.01%	10	0.10%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	**30**	**0.30%**	**67**	**0.67%**
Total Returned for Analysis	**15**		**49**	

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	0	0.00%
In the Pocket	3	0.03%
Intravascular	1	0.01%
Insulation Breach	6	0.06%
Lead-to-Can Contact	2	0.02%
Lead-to-Lead Contact	3	0.03%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	34	0.34%
Total	**45**	**0.45%**



Year	1	2	3	4	at 49 months					
Survival Probability	99.43%	99.21%	98.92%	98.78%	98.78%					
± 1 standard error	0.08%	0.10%	0.13%	0.18%	0.18%					
Sample Size	9200	6100	3500	1300	300					

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

Actively Monitored Study Data

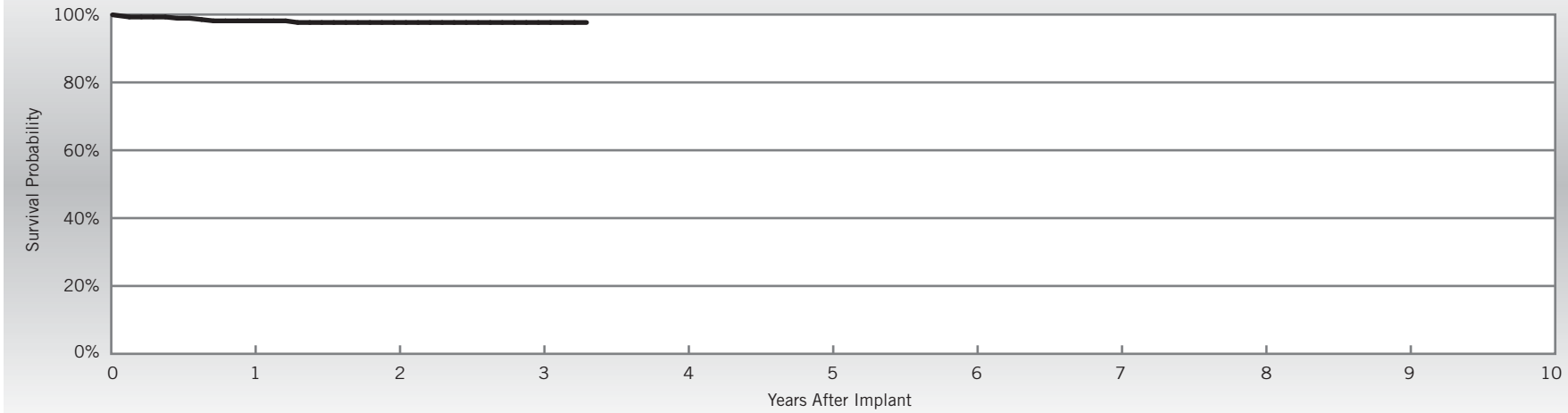
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	284
Cumulative Months of Follow-up	7,337
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	1	0.35%
Lead Dislodgement	4	1.41%
Oversensing	1	0.35%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.35%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.35%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.70%
Total	**3**	**1.06%**



Year	1	2	3	at 40 months						
Survival Probability	98.14%	97.66%	97.66%	97.66%						
± 1 standard error	0.83%	0.95%	0.95%	0.95%						
Sample Size	260	190	110	50						

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

Customer Reported Performance Data

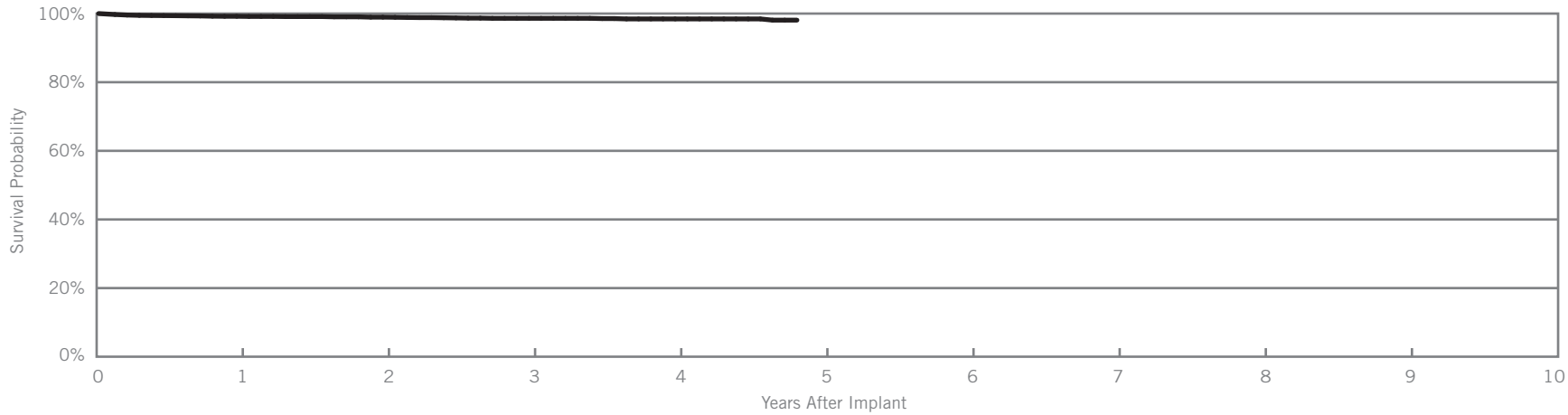
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,470
Estimated Active US Implants	2,183
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	0.09%	2	0.06%
Conductor Fracture	1	0.03%	4	0.12%
Lead Dislodgement	3	0.09%	4	0.12%
Failure to Capture	5	0.14%	4	0.12%
Oversensing	4	0.12%	7	0.20%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	1	0.03%
Abnormal Pacing Impedance	0	0.00%	1	0.03%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**19**	**0.55%**	**26**	**0.75%**
Total Returned for Analysis	**6**		**8**	

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	3	0.09%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	2	0.06%
Clavicular Crush	1	0.03%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.14%
Total	**9**	**0.26%**



Year	1	2	3	4	at 58 months					
Survival Probability	99.21%	98.96%	98.62%	98.44%	98.09%					
± 1 standard error	0.16%	0.19%	0.23%	0.26%	0.43%					
Sample Size	3400	2600	2000	1200	200					

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

Actively Monitored Study Data

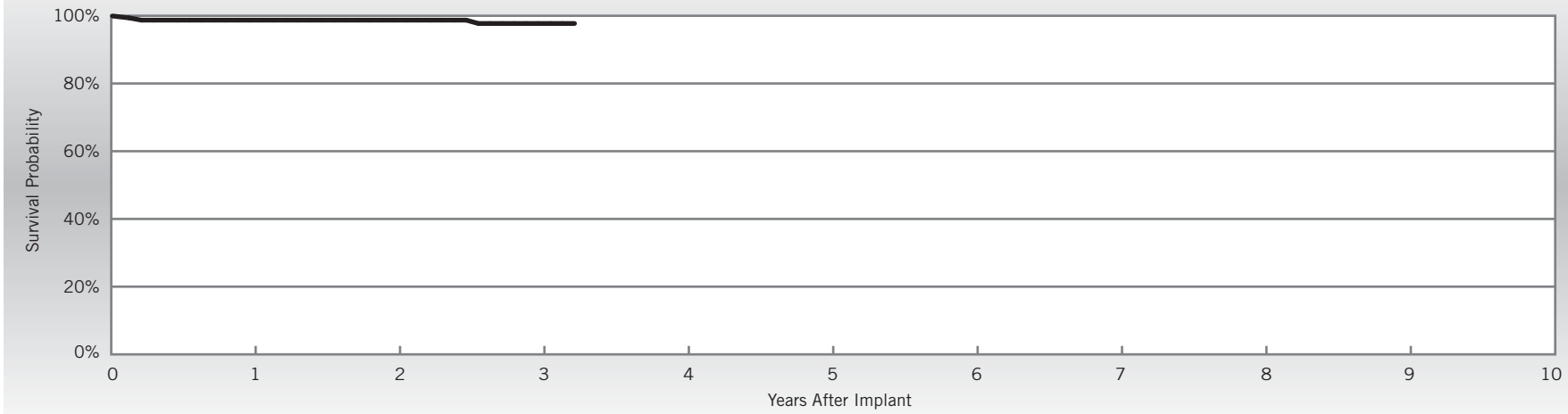
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	158
Cumulative Months of Follow-up	5,039
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	1	0.63%
Failure to Capture	1	0.63%
Lead Dislodgement	1	0.63%

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	0.63%
Total	**1**	**0.63%**



Year	1	2	3	at 39 months						
Survival Probability	98.71%	98.71%	97.72%	97.72%						
± 1 standard error	0.91%	0.91%	1.34%	1.34%						
Sample Size	150	130	90	50						

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

Customer Reported Performance Data

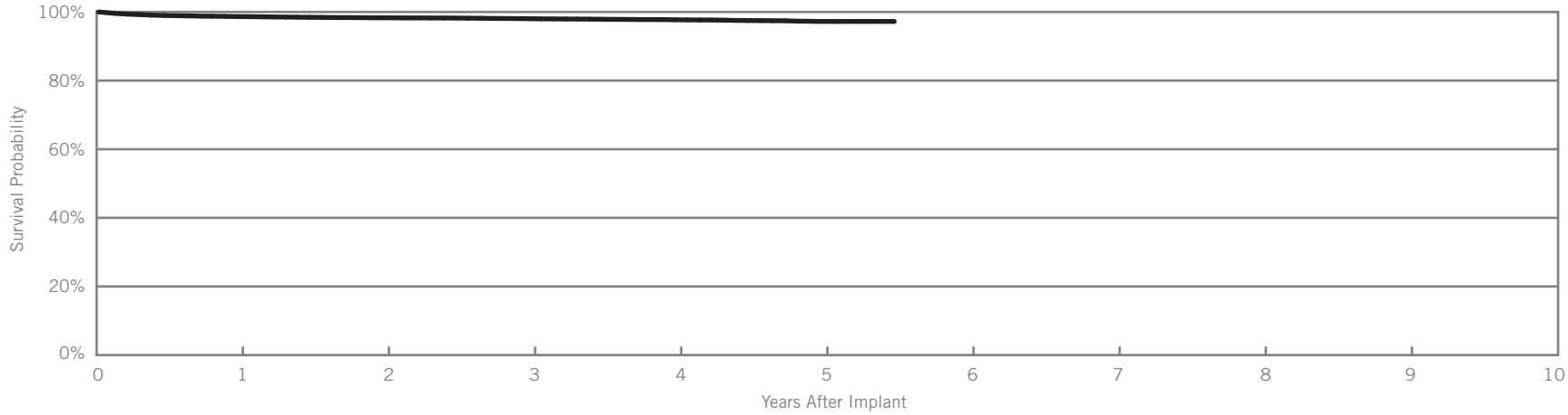
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,471
Estimated Active US Implants	8,803
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	38	0.25%	10	0.06%
Conductor Fracture	0	0.00%	16	0.10%
Lead Dislodgement	34	0.22%	52	0.34%
Failure to Capture	19	0.12%	48	0.31%
Oversensing	19	0.12%	52	0.34%
Failure to Sense	8	0.05%	11	0.07%
Insulation Breach	0	0.00%	4	0.03%
Abnormal Pacing Impedance	1	0.01%	8	0.05%
Abnormal Defibrillation Impedance	4	0.03%	10	0.06%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	14	0.09%
Total	**127**	**0.82%**	**227**	**1.47%**
Total Returned for Analysis	**58**		**132**	

Malfunctions	Qty.	Rate
Conductor Fracture	8	0.05%
Clavicular Crush	1	0.01%
In the Pocket	3	0.02%
Intravascular	4	0.03%
Insulation Breach	13	0.08%
Lead-to-Can Contact	5	0.03%
Lead-to-Lead Contact	3	0.02%
Clavicular Crush	2	0.01%
Externalized Conductors	0	0.00%
Other	3	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	97	0.63%
Total	**118**	**0.76%**



Year	1	2	3	4	5	at 66 months				
Survival Probability	98.65%	98.30%	98.03%	97.72%	97.24%	97.24%				
± 1 standard error	0.09%	0.11%	0.12%	0.13%	0.17%	0.17%				
Sample Size	15300	12800	11100	9000	4800	200				

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

Actively Monitored Study Data

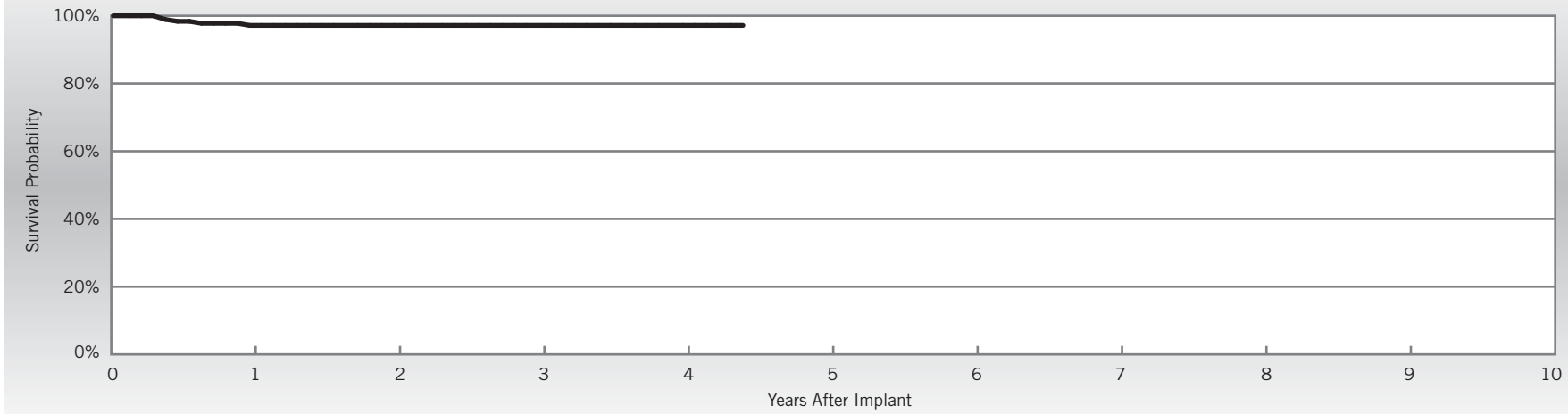
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	189
Cumulative Months of Follow-up	7,082
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	1	0.53%
Cardiac Perforation	1	0.53%
Conductor Fracture	2	1.06%
Failure to Sense	1	0.53%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.53%
Clavicular Crush	0	0.00%
In the Pocket	1	0.53%
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	0.53%
Total	**2**	**1.06%**



Year	1	2	3	4	at 53 months					
Survival Probability	97.18%	97.18%	97.18%	97.18%	97.18%					
± 1 standard error	1.10%	1.25%	1.25%	1.25%	1.25%					
Sample Size	180	150	120	100	60					

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

Customer Reported Performance Data

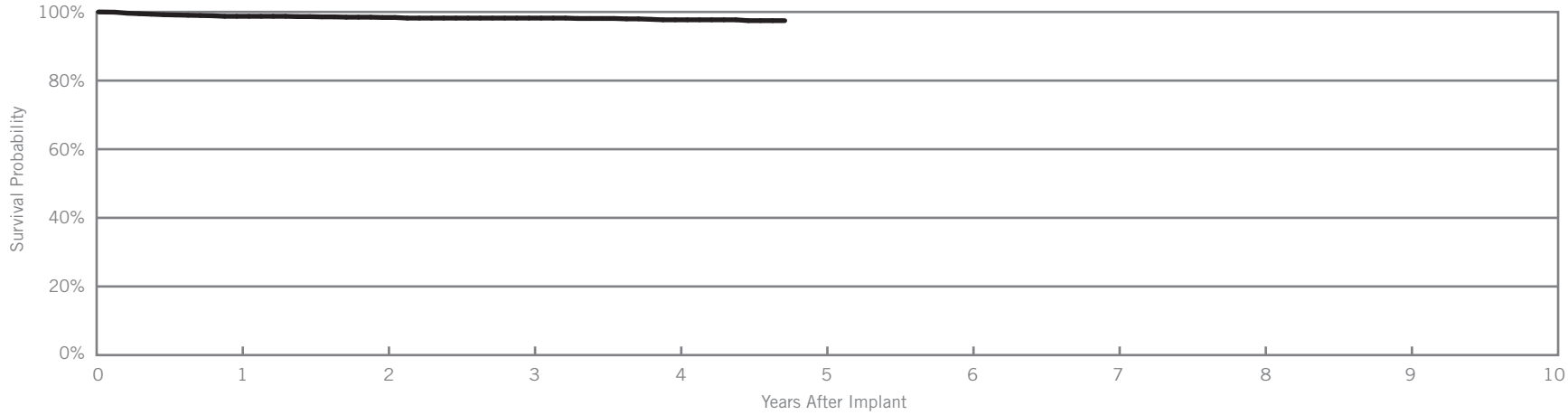
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,486
Estimated Active US Implants	723
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	5	0.34%	2	0.13%
Conductor Fracture	0	0.00%	3	0.20%
Lead Dislodgement	3	0.20%	6	0.40%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	6	0.40%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	1	0.07%
Abnormal Pacing Impedance	1	0.07%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**10**	**0.67%**	**19**	**1.28%**
Total Returned for Analysis	**3**		**10**	

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.07%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	9	0.61%
Total	**10**	**0.67%**



Year	1	2	3	4	at 57 months					
Survival Probability	98.74%	98.39%	98.21%	97.71%	97.47%					
± 1 standard error	0.31%	0.34%	0.37%	0.45%	0.51%					
Sample Size	1500	1300	1100	800	200					

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

Customer Reported Performance Data

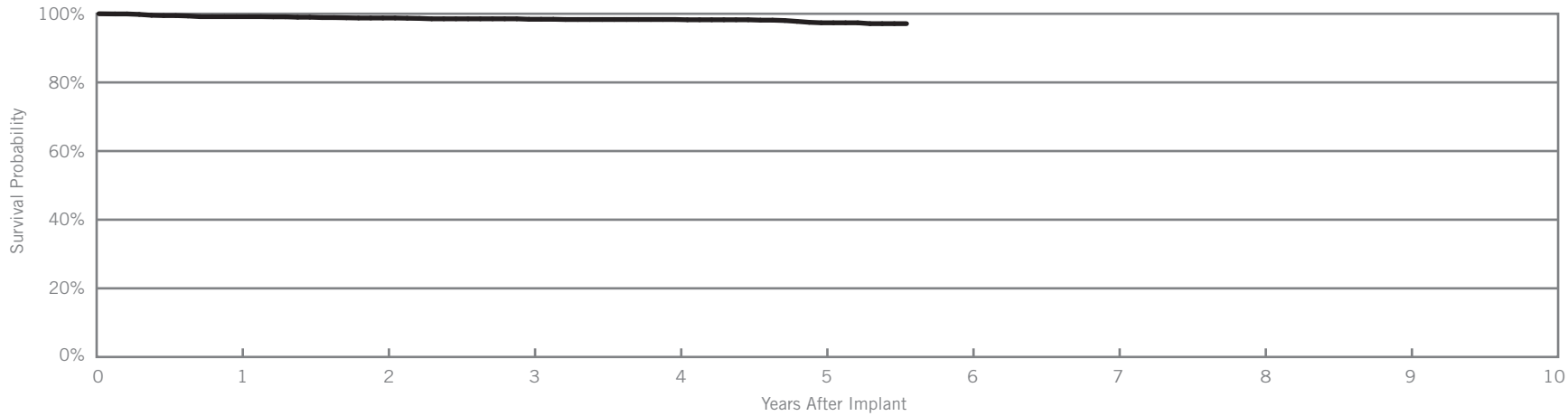
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,216
Estimated Active US Implants	1,084
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.05%	5	0.23%
Failure to Capture	2	0.09%	2	0.09%
Oversensing	2	0.09%	6	0.27%
Failure to Sense	1	0.05%	2	0.09%
Insulation Breach	0	0.00%	4	0.18%
Abnormal Pacing Impedance	1	0.05%	2	0.09%
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	**11**	**0.50%**	**23**	**1.04%**
Total Returned for Analysis	**3**		**8**	

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	5	0.23%
Lead-to-Can Contact	2	0.09%
Lead-to-Lead Contact	3	0.14%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.23%
Total	**10**	**0.45%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	99.16%	98.77%	98.40%	98.33%	97.37%	97.12%				
± 1 standard error	0.20%	0.25%	0.28%	0.30%	0.43%	0.52%				
Sample Size	2200	1900	1700	1400	1000	200				

Customer Reported Performance Data

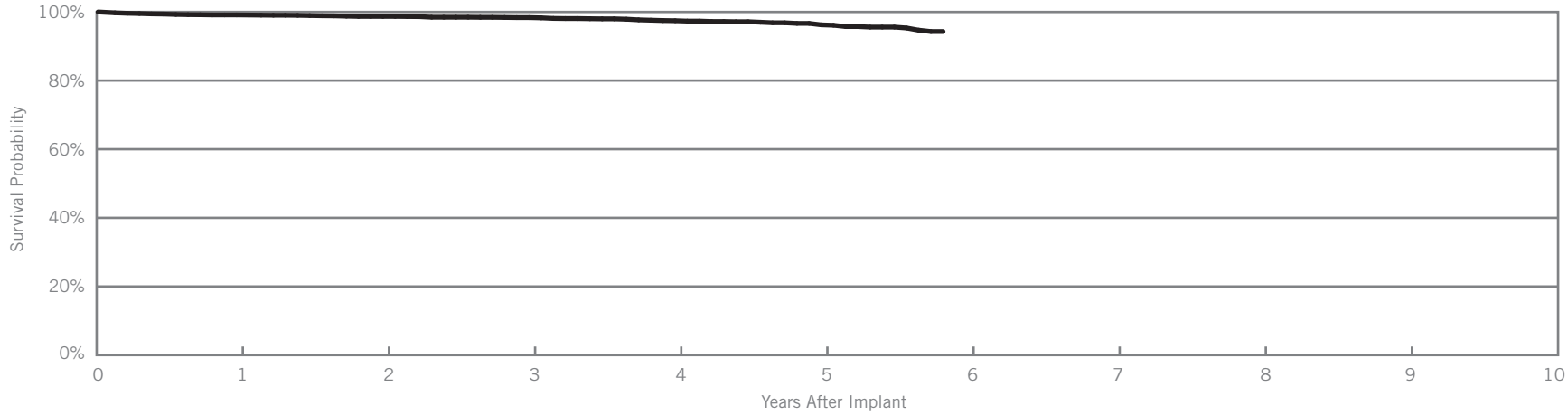
Riata® ST

Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,093
Estimated Active US Implants	2,162
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	13	0.32%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	0	0.00%	12	0.29%
Oversensing	3	0.07%	23	0.56%
Failure to Sense	0	0.00%	4	0.10%
Insulation Breach	0	0.00%	10	0.24%
Abnormal Pacing Impedance	2	0.05%	4	0.10%
Abnormal Defibrillation Impedance	0	0.00%	5	0.12%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	**15**	**0.37%**	**76**	**1.86%**
Total Returned for Analysis	**3**		**18**	

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	13	0.32%
Lead-to-Can Contact	7	0.17%
Lead-to-Lead Contact	4	0.10%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	2	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.20%
Total	**23**	**0.56%**



Year	1	2	3	4	5	at 70 months				
Survival Probability	99.13%	98.70%	98.36%	97.45%	96.25%	94.30%				
± 1 standard error	0.15%	0.19%	0.22%	0.29%	0.38%	0.83%				
Sample Size	4000	3500	3000	2300	1400	200				

Customer Reported Performance Data

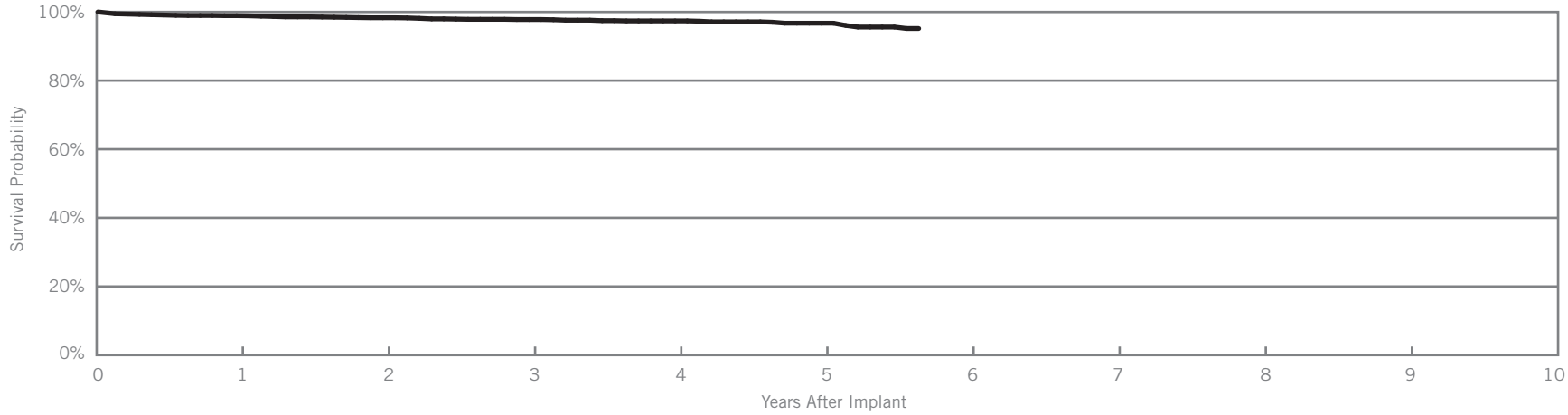
Riata® ST

Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,419
Estimated Active US Implants	1,224
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.25%	2	0.08%
Conductor Fracture	0	0.00%	4	0.17%
Lead Dislodgement	2	0.08%	9	0.37%
Failure to Capture	4	0.17%	7	0.29%
Oversensing	4	0.17%	17	0.70%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	6	0.25%
Abnormal Pacing Impedance	2	0.08%	0	0.00%
Abnormal Defibrillation Impedance	1	0.04%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	4	0.17%
Total	**20**	**0.83%**	**50**	**2.07%**
Total Returned for Analysis	**10**		**21**	

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.12%
Clavicular Crush	0	0.00%
In the Pocket	1	0.04%
Intravascular	2	0.08%
Insulation Breach	7	0.29%
Lead-to-Can Contact	5	0.21%
Lead-to-Lead Contact	1	0.04%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.04%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	10	0.41%
Total	**20**	**0.83%**



Year	1	2	3	4	5	at 68 months				
Survival Probability	98.92%	98.31%	97.80%	97.40%	96.73%	95.19%				
± 1 standard error	0.22%	0.28%	0.33%	0.36%	0.46%	0.79%				
Sample Size	2400	2000	1800	1500	900	200				

Customer Reported Performance Data

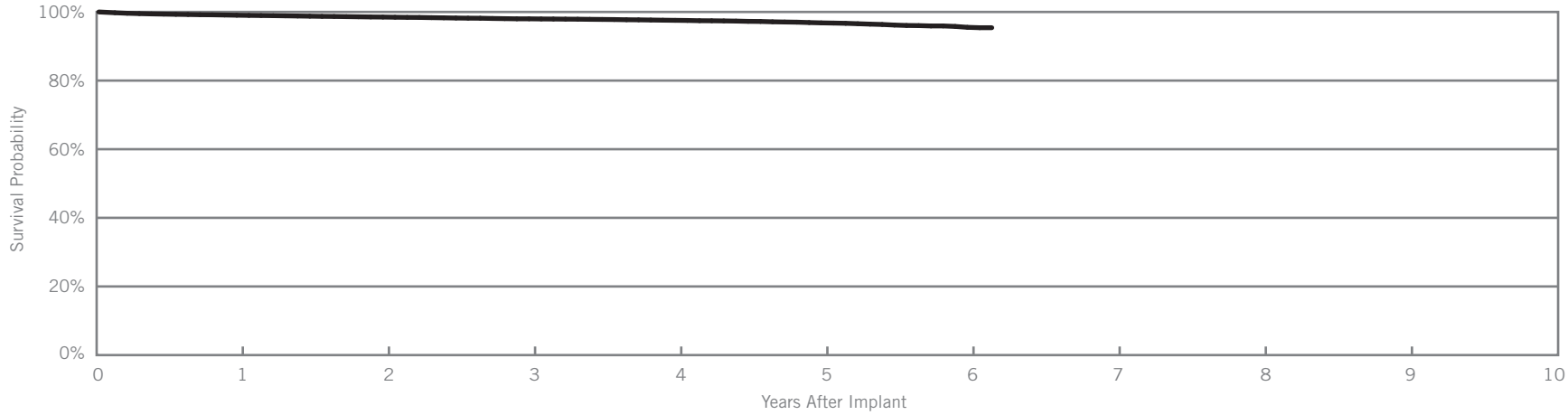
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,963
Estimated Active US Implants	18,901
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	42	0.12%	18	0.05%
Conductor Fracture	0	0.00%	40	0.11%
Lead Dislodgement	37	0.11%	43	0.12%
Failure to Capture	43	0.12%	92	0.26%
Oversensing	40	0.11%	215	0.61%
Failure to Sense	7	0.02%	20	0.06%
Insulation Breach	1	<0.01%	92	0.26%
Abnormal Pacing Impedance	8	0.02%	30	0.09%
Abnormal Defibrillation Impedance	4	0.01%	16	0.05%
Extracardiac Stimulation	3	0.01%	2	0.01%
Other	11	0.03%	31	0.09%
Total	**196**	**0.56%**	**599**	**1.71%**
Total Returned for Analysis	**93**		**236**	

Malfunctions	Qty.	Rate
Conductor Fracture	11	0.03%
Clavicular Crush	2	0.01%
In the Pocket	3	0.01%
Intravascular	6	0.02%
Insulation Breach	123	0.35%
Lead-to-Can Contact	82	0.23%
Lead-to-Lead Contact	22	0.06%
Clavicular Crush	4	0.01%
Externalized Conductors	3	0.01%
Other	12	0.03%
Crimps, Welds & Bonds	1	<0.01%
Other	0	0.00%
Extrinsic Factors	110	0.31%
Total	**245**	**0.70%**



Year	1	2	3	4	5	6	at 74 months			
Survival Probability	99.05%	98.51%	98.00%	97.56%	96.82%	95.52%	95.41%			
± 1 standard error	0.05%	0.07%	0.08%	0.09%	0.11%	0.18%	0.25%			
Sample Size	34700	29700	26000	22100	15700	6300	600			

Actively Monitored Study Data

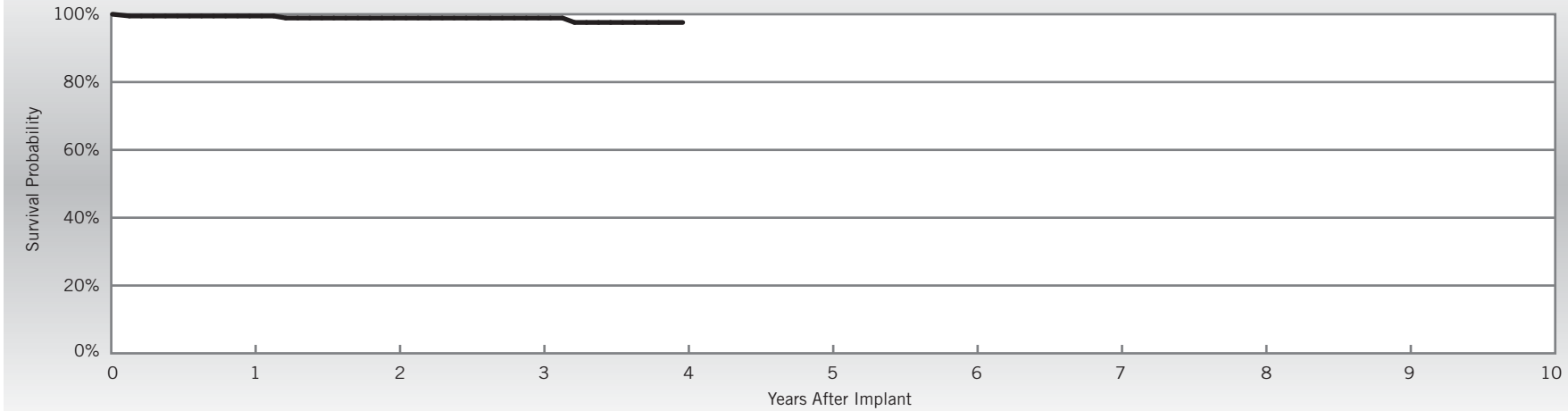
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	202
Cumulative Months of Follow-up	6,412
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Insulation Breach	1	0.50%
Lead Dislodgement	2	0.99%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	4	1.98%
Lead-to-Can Contact	2	0.99%
Lead-to-Lead Contact	1	0.50%
Clavicular Crush	0	0.00%
Externalized Conductors	1	0.50%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.50%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**5**	**2.48%**



Year	1	2	3	at 47 months						
Survival Probability	99.49%	98.89%	98.89%	97.58%						
± 1 standard error	0.51%	0.79%	0.79%	1.51%						
Sample Size	190	150	110	50						

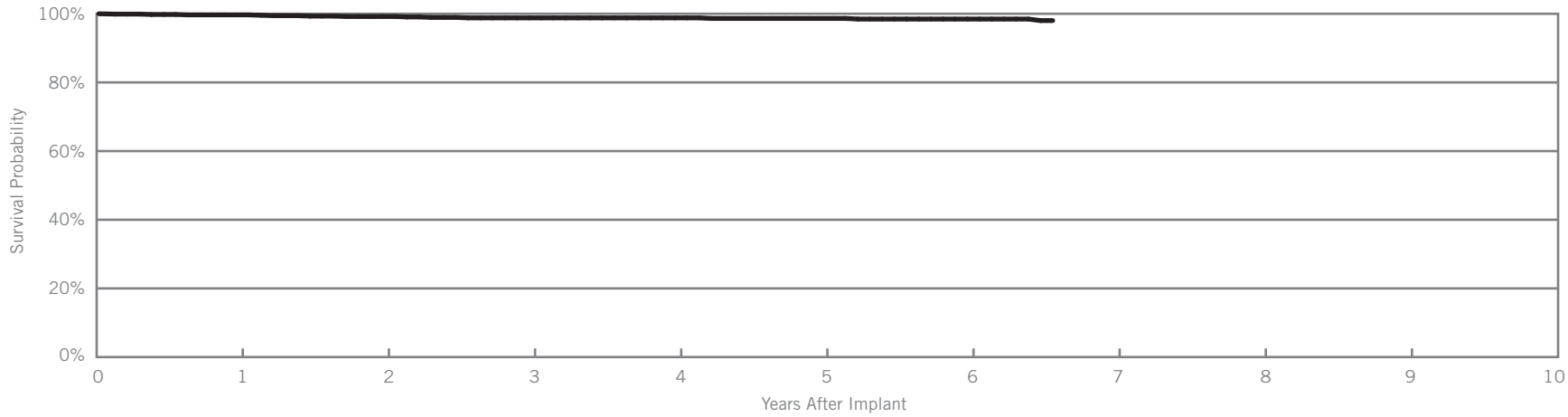
Customer Reported Performance Data

Riata® *i*

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,008
Estimated Active US Implants	340
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	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	1	0.10%
Total	**2**	**0.20%**



Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.68%	99.20%	98.80%	98.80%	98.64%	98.46%	98.02%			
± 1 standard error	0.19%	0.30%	0.38%	0.38%	0.41%	0.45%	0.62%			
Sample Size	1000	900	800	700	600	500	200			

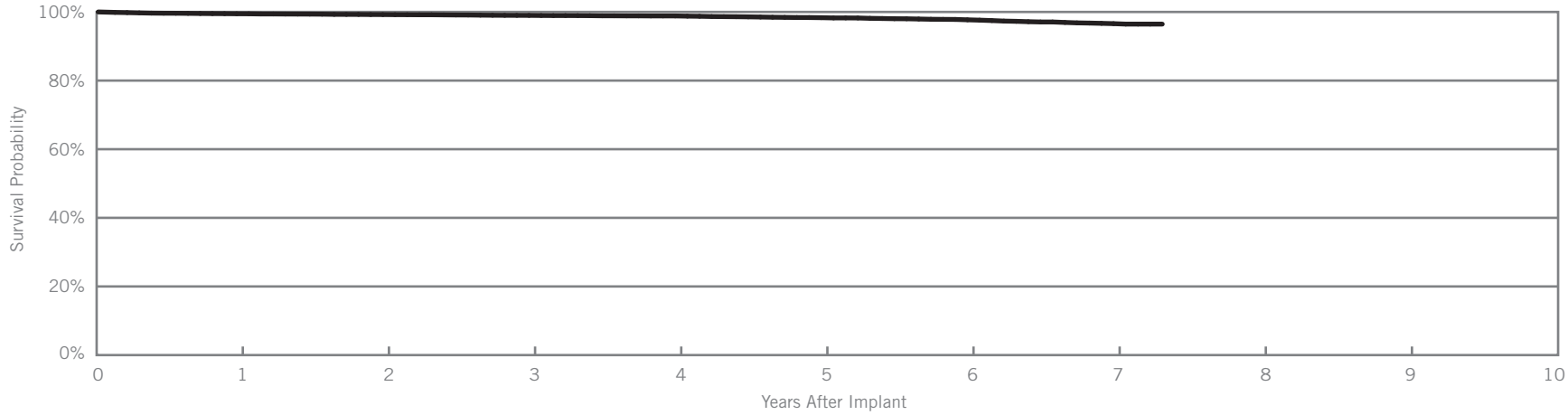
Customer Reported Performance Data

Riata® *i*

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,777
Estimated Active US Implants	4,557
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	3	0.03%
Insulation Breach	26	0.27%
Lead-to-Can Contact	10	0.10%
Lead-to-Lead Contact	7	0.07%
Clavicular Crush	0	0.00%
Externalized Conductors	2	0.02%
Other	7	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	20	0.20%
Total	**50**	**0.51%**



Year	1	2	3	4	5	6	7	at 88 months		
Survival Probability	99.47%	99.24%	99.00%	98.84%	98.33%	97.71%	96.59%	96.46%		
± 1 standard error	0.07%	0.09%	0.11%	0.12%	0.15%	0.19%	0.28%	0.32%		
Sample Size	9700	8500	7700	6800	5800	4600	2400	300		

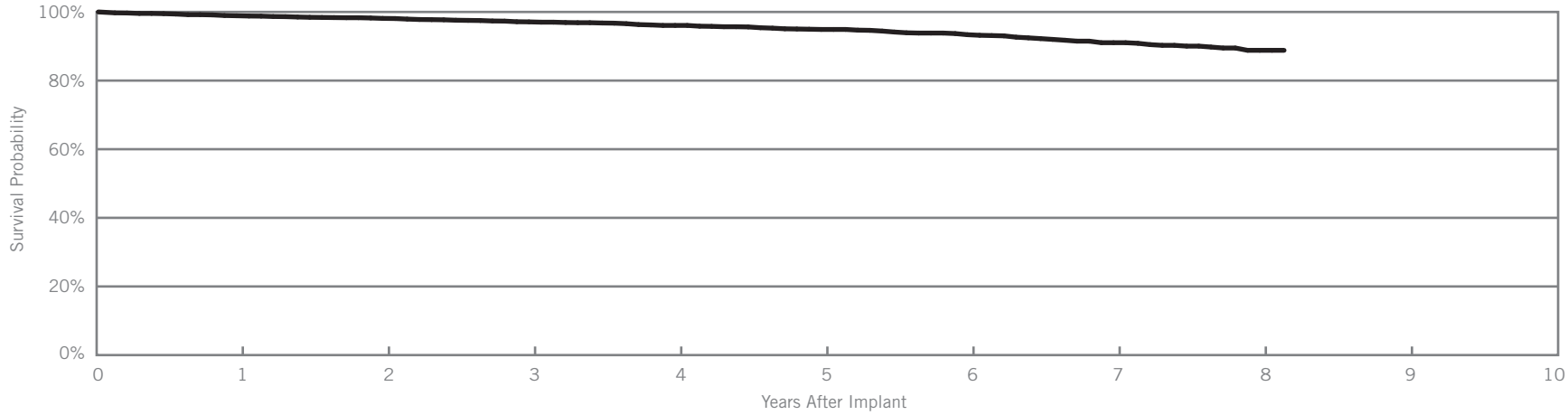
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,190
Estimated Active US Implants	1,268
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

Malfunctions	Qty.	Rate
Conductor Fracture	3	0.09%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	3	0.09%
Insulation Breach	62	1.94%
Lead-to-Can Contact	32	1.00%
Lead-to-Lead Contact	6	0.19%
Clavicular Crush	2	0.06%
Externalized Conductors	6	0.19%
Other	16	0.50%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	15	0.47%
Total	**80**	**2.51%**



Year	1	2	3	4	5	6	7	8	at 98 months	
Survival Probability	98.89%	98.12%	97.11%	96.07%	94.90%	93.37%	91.04%	88.82%	88.82%	
± 1 standard error	0.19%	0.25%	0.33%	0.40%	0.47%	0.55%	0.75%	1.05%	1.05%	
Sample Size	3100	2700	2400	2100	1800	1400	900	400	200	

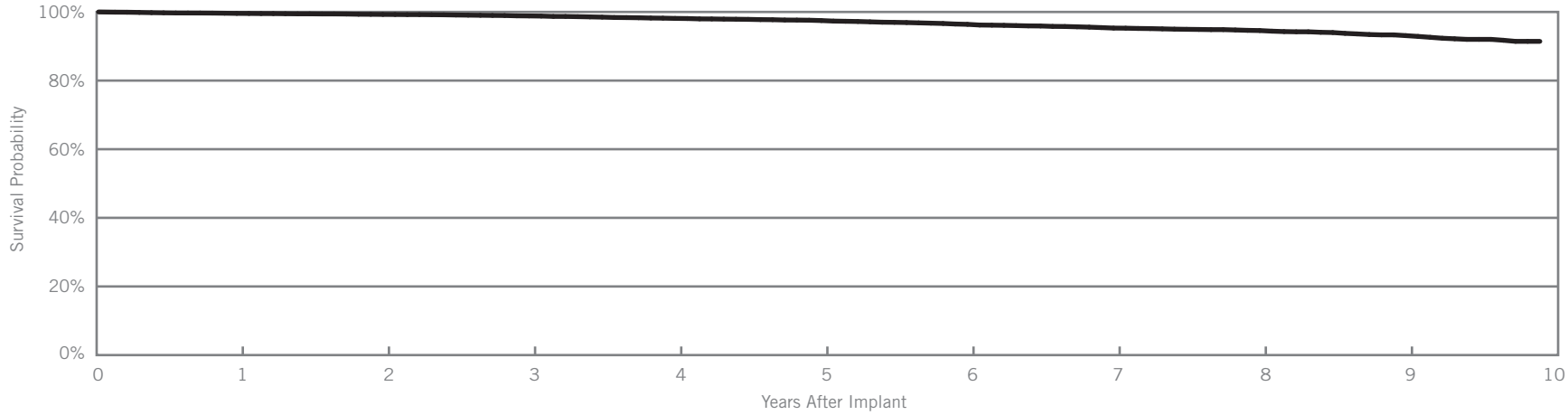
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,532
Estimated Active US Implants	4,483
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	2	0.02%
In the Pocket	2	0.02%
Intravascular	0	0.00%
Insulation Breach	53	0.50%
Lead-to-Can Contact	31	0.29%
Lead-to-Lead Contact	5	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	5	0.05%
Other	12	0.11%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	24	0.23%
Total	**81**	**0.77%**



Year	1	2	3	4	5	6	7	8	9	at 119 months
Survival Probability	99.58%	99.28%	98.84%	98.12%	97.49%	96.39%	95.30%	94.58%	93.10%	91.43%
± 1 standard error	0.06%	0.09%	0.11%	0.15%	0.18%	0.23%	0.29%	0.34%	0.46%	0.73%
Sample Size	10300	9100	8100	7100	6000	4800	3600	2300	1300	200

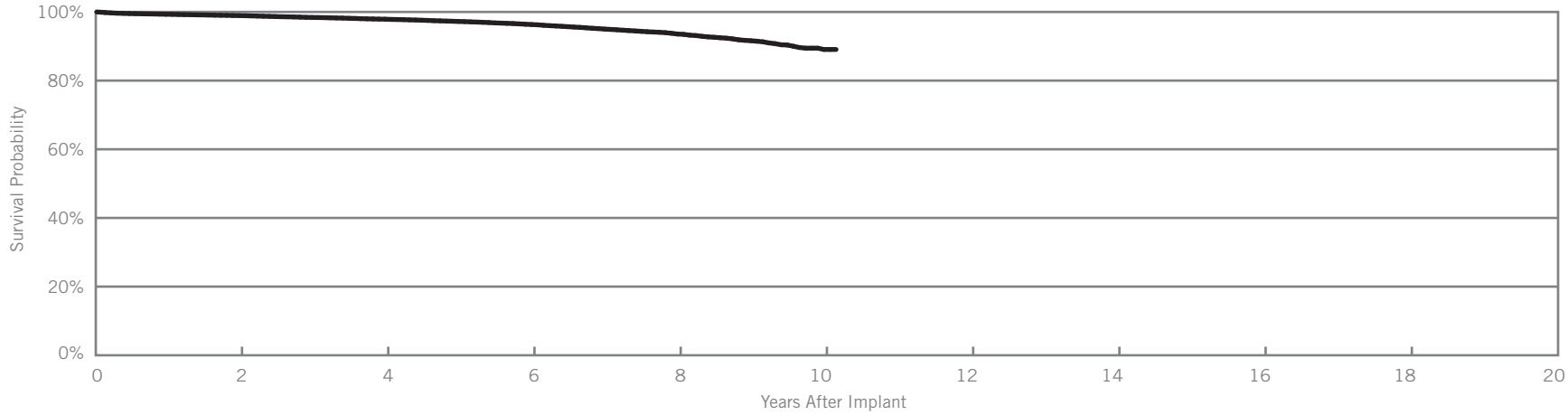
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,262
Estimated Active US Implants	29,541
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories (see pgs. 248-260)	One

Malfunctions	Qty.	Rate
Conductor Fracture	16	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	7	0.01%
Intravascular	7	0.01%
Insulation Breach	436	0.63%
Lead-to-Can Contact	225	0.32%
Lead-to-Lead Contact	80	0.12%
Clavicular Crush	7	0.01%
Externalized Conductors	51	0.07%
Other	73	0.11%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	228	0.33%
Total	**683**	**0.99%**



Year	2	4	6	8	10	at 122 months				
Survival Probability	98.94%	97.89%	96.34%	93.56%	89.07%	89.07%				
± 1 standard error	0.04%	0.06%	0.09%	0.16%	0.42%	0.50%				
Sample Size	59300	46700	32700	12100	1800	200				

Actively Monitored Study Data

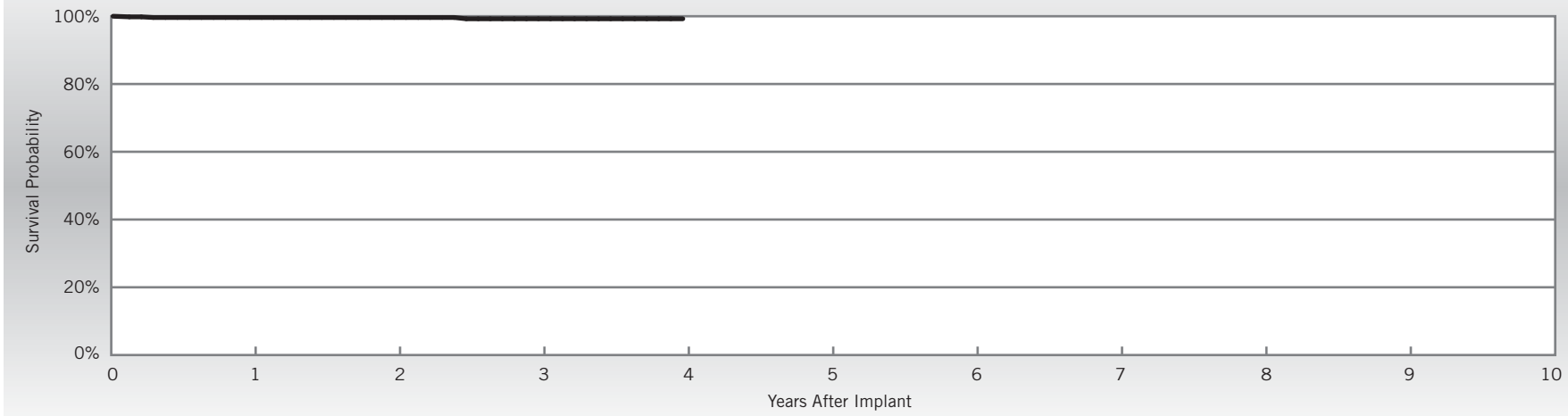
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	556
Cumulative Months of Follow-up	15,808
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Insulation Breach	1	0.18%
Lead Dislodgement	2	0.36%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.18%
Clavicular Crush	0	0.00%
In the Pocket	1	0.18%
Intravascular	0	0.00%
Insulation Breach	4	0.72%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	1	0.18%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.54%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.72%
Total	**9**	**1.62%**



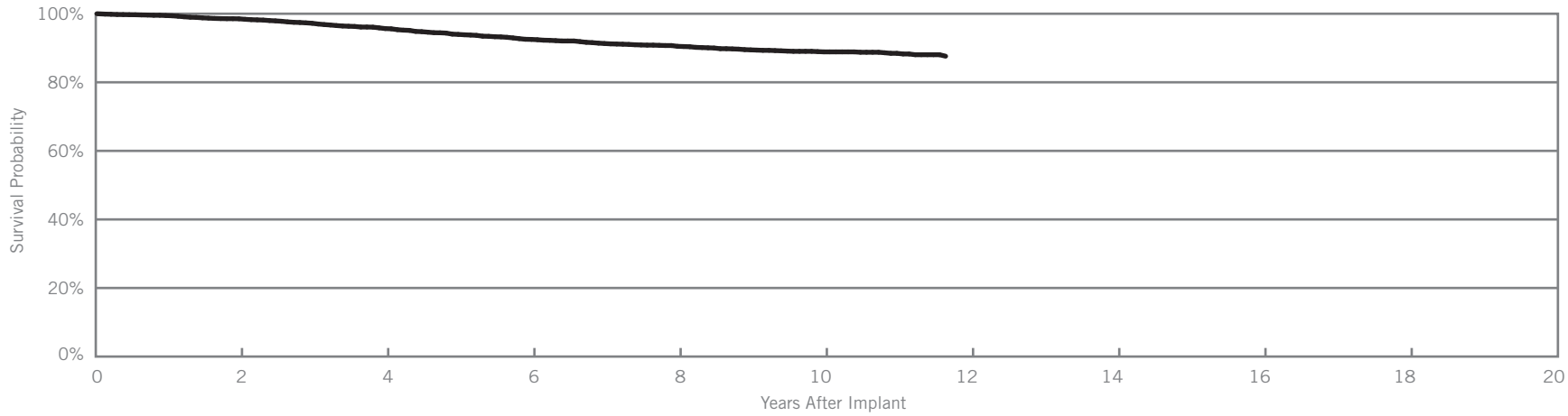
Year	1	2	3	4						
Survival Probability	99.63%	99.63%	99.25%	99.25%						
± 1 standard error	0.26%	0.26%	0.46%	0.46%						
Sample Size	510	400	260	110						

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,737
Estimated Active US Implants	860
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



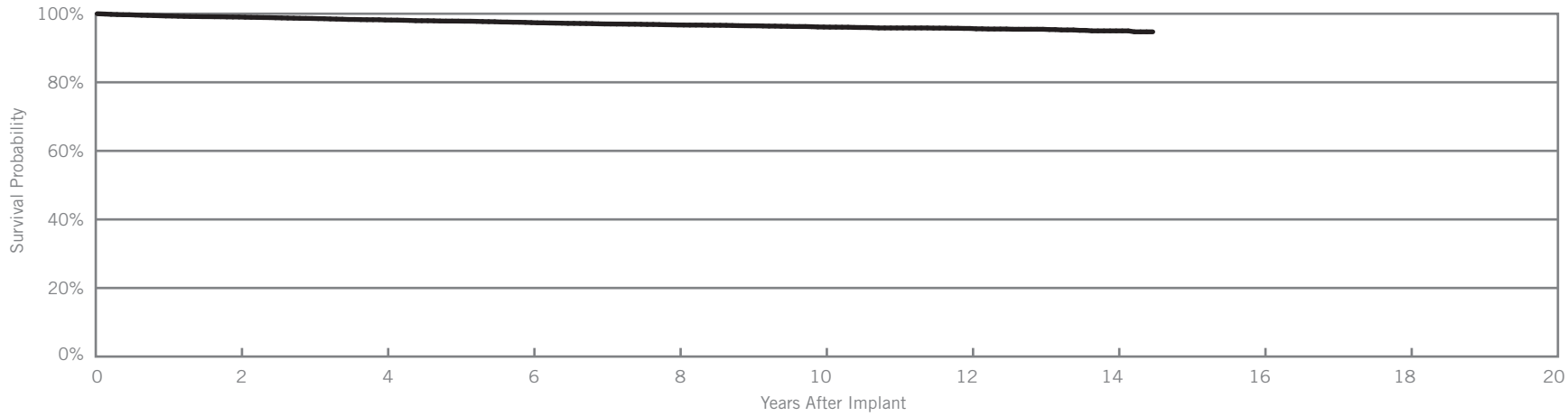
Year	2	4	6	8	10	at 140 months				
Survival Probability	98.52%	95.67%	92.51%	90.49%	88.87%	87.61%				
± 1 standard error	0.19%	0.34%	0.48%	0.56%	0.65%	0.75%				
Sample Size	3900	3100	2400	1800	1300	200				

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,642
Estimated Active US Implants	2,836
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	at 174 months		
Survival Probability	99.04%	98.17%	97.41%	96.73%	96.12%	95.71%	95.00%	94.72%		
± 1 standard error	0.09%	0.13%	0.17%	0.20%	0.23%	0.26%	0.37%	0.46%		
Sample Size	10800	8900	7100	5600	4300	2300	800	200		

Summary Information

Defibrillation Leads

St. Jude Medical
More control. Less risk.

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
7170Q/7171Q	Durata® DF4	99.18%	98.77%								
7120Q/7121Q	Durata® DF4	99.38%	99.19%								
7122Q	Durata® DF4	99.33%	99.09%								
7120/7121	Durata®	99.34%	99.16%	99.00%	98.72%						
7030/7031	Riata® ST Optim®	98.96%	98.49%	98.49%	98.00%						
7122	Durata®	99.43%	99.21%	98.92%	98.78%						
7070/7071	Riata® ST Optim®	99.21%	98.96%	98.62%	98.44%						
7020/7021	Riata® ST Optim®	98.65%	98.30%	98.03%	97.72%	97.24%					
7022	Riata® ST Optim®	98.74%	98.39%	98.21%	97.71%						
7010/7011	Riata® ST	99.16%	98.77%	98.40%	98.33%	97.37%					
7040/7041	Riata® ST	99.13%	98.70%	98.36%	97.45%	96.25%					
7002	Riata® ST	98.92%	98.31%	97.80%	97.40%	96.73%					
7000/7001	Riata® ST	99.05%	98.51%	98.00%	97.56%	96.82%	95.52%				
1560/1561	Riata® i	99.68%	99.20%	98.80%	98.80%	98.64%	98.46%				
1590/1591	Riata® i	99.47%	99.24%	99.00%	98.84%	98.33%	97.71%	96.59%			
1582	Riata®	98.89%	98.12%	97.11%	96.07%	94.90%	93.37%	91.04%	88.82%		
1570/1571	Riata®	99.58%	99.28%	98.84%	98.12%	97.49%	96.39%	95.30%	94.58%	93.10%	
1580/1581	Riata®	99.32%	98.94%	98.40%	97.89%	97.23%	96.34%	95.01%	93.56%	91.62%	89.07%
1559	TVL™ ADX	99.47%	98.52%	97.22%	95.67%	93.97%	92.51%	91.31%	90.49%	89.46%	88.87%
SP01/SP02/SP03/SP04	SPL®	99.35%	99.04%	98.62%	98.17%	97.85%	97.41%	97.02%	96.73%	96.48%	96.12%

Acute Observation Summary

Post Implant ≤30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
7170Q/7171Q	Jul-09	2653	1992	1	0.04%	0	0.00%	4	0.15%	2	0.08%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**9**	**0.34%**	**5**
7120Q/7121Q	Jan-09	63040	51656	34	0.05%	0	0.00%	111	0.18%	49	0.08%	26	0.04%	6	0.01%	0	0.00%	3	<0.01%	4	0.01%	2	<0.01%	5	0.01%	**240**	**0.38%**	**115**
7122Q	Jan-09	13863	11460	9	0.06%	1	0.01%	22	0.16%	14	0.10%	5	0.04%	3	0.02%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	3	0.02%	**59**	**0.43%**	**33**
7120/7121	Sep-07	57160	40010	34	0.06%	1	<0.01%	70	0.12%	19	0.03%	46	0.08%	4	0.01%	0	0.00%	1	<0.01%	17	0.03%	1	<0.01%	17	0.03%	**210**	**0.37%**	**77**
7030/7031	Jul-06	851	295	0	0.00%	0	0.00%	4	0.47%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.71%**	**3**
7122	Sep-07	10055	7292	5	0.05%	1	0.01%	9	0.09%	9	0.09%	4	0.04%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	**30**	**0.30%**	**15**
7070/7071	Jul-06	3470	2183	3	0.09%	1	0.03%	3	0.09%	5	0.14%	4	0.12%	3	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**19**	**0.55%**	**6**
7020/7021	Jul-06	15471	8803	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%**	**58**
7022	Jul-06	1486	723	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.67%**	**3**
7010/7011	Mar-06	2216	1084	3	0.14%	0	0.00%	1	0.05%	2	0.09%	2	0.09%	1	0.05%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**11**	**0.50%**	**3**
7040/7041	Mar-06	4093	2162	4	0.10%	0	0.00%	5	0.12%	0	0.00%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	**15**	**0.37%**	**3**
7002	Jun-05	2419	1224	6	0.25%	0	0.00%	2	0.08%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	**20**	**0.83%**	**10**
7000/7001	Jun-05	34963	18901	42	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%	3	0.01%	11	0.03%	**196**	**0.56%**	**93**

Chronic Complication Summary

>30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
7170Q/7171Q	Jul-09	2653	1992	0	0.00%	0	0.00%	5	0.19%	9	0.34%	1	0.04%	0	0.00%	1	0.04%	1	0.04%	1	0.04%	0	0.00%	0	0.00%	**18**	**0.68%**	**12**
7120Q/7121Q	Jan-09	63040	51656	10	0.02%	13	0.02%	202	0.32%	80	0.13%	37	0.06%	10	0.02%	4	0.01%	4	0.01%	12	0.02%	2	<0.01%	9	0.01%	**383**	**0.61%**	**268**
7122Q	Jan-09	13863	11460	10	0.07%	2	0.01%	32	0.23%	13	0.09%	12	0.09%	3	0.02%	0	0.00%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	**74**	**0.53%**	**54**
7120/7121	Sep-07	57160	40010	5	0.01%	17	0.03%	132	0.23%	65	0.11%	73	0.13%	14	0.02%	8	0.01%	26	0.05%	26	0.05%	0	0.00%	12	0.02%	**378**	**0.66%**	**206**
7030/7031	Jul-06	851	295	1	0.12%	0	0.00%	0	0.00%	4	0.47%	6	0.71%	0	0.00%	1	0.12%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	**13**	**1.53%**	**2**
7122	Sep-07	10055	7292	1	0.01%	2	0.02%	17	0.17%	14	0.14%	11	0.11%	4	0.04%	5	0.05%	10	0.10%	1	0.01%	0	0.00%	2	0.02%	**67**	**0.67%**	**49**
7070/7071	Jul-06	3470	2183	2	0.06%	4	0.12%	4	0.12%	4	0.12%	7	0.20%	2	0.06%	1	0.03%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	**26**	**0.75%**	**8**
7020/7021	Jul-06	15471	8803	10	0.06%	16	0.10%	52	0.34%	48	0.31%	52	0.34%	11	0.07%	4	0.03%	8	0.05%	10	0.06%	2	0.01%	14	0.09%	**227**	**1.47%**	**132**
7022	Jul-06	1486	723	2	0.13%	3	0.20%	6	0.40%	1	0.07%	6	0.40%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**19**	**1.28%**	**10**
7010/7011	Mar-06	2216	1084	1	0.05%	0	0.00%	5	0.23%	2	0.09%	6	0.27%	2	0.09%	4	0.18%	2	0.09%	0	0.00%	0	0.00%	1	0.05%	**23**	**1.04%**	**8**
7040/7041	Mar-06	4093	2162	2	0.05%	13	0.32%	3	0.07%	12	0.29%	23	0.56%	4	0.10%	10	0.24%	4	0.10%	5	0.12%	0	0.00%	0	0.00%	**76**	**1.86%**	**18**
7002	Jun-05	2419	1224	2	0.08%	4	0.17%	9	0.37%	7	0.29%	17	0.70%	0	0.00%	6	0.25%	0	0.00%	1	0.04%	0	0.00%	4	0.17%	**50**	**2.07%**	**21**
7000/7001	Jun-05	34963	18901	18	0.05%	40	0.11%	43	0.12%	92	0.26%	215	0.61%	20	0.06%	92	0.26%	30	0.09%	16	0.05%	2	0.01%	31	0.09%	**599**	**1.71%**	**236**

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

Malfunction Summary

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
Models	Registered US Implants	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7170Q/7171Q	2653	0	0.00%	0	0.00%	1	0.04%	**1**	**0.04%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	10	0.38%	**11**	**0.41%**
7120Q/7121Q	63040	0	0.00%	1	<0.01%	2	<0.01%	**3**	**<0.01%**	1	<0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**3**	**<0.01%**	0	0.00%	13	0.02%	234	0.37%	**253**	**0.40%**
7122Q	13863	0	0.00%	2	0.01%	0	0.00%	**2**	**0.01%**	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.01%**	0	0.00%	5	0.04%	44	0.32%	**53**	**0.38%**
7120/7121	57160	1	<0.01%	12	0.02%	4	0.01%	**17**	**0.03%**	6	0.01%	4	0.01%	3	0.01%	0	0.00%	1	<0.01%	**14**	**0.02%**	1	<0.01%	5	0.01%	161	0.28%	**198**	**0.35%**
7030/7031	851	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	3	0.35%	**3**	**0.35%**
7122	10055	0	0.00%	3	0.03%	1	0.01%	**4**	**0.04%**	2	0.02%	3	0.03%	0	0.00%	0	0.00%	1	0.01%	**6**	**0.06%**	0	0.00%	1	0.01%	34	0.34%	**45**	**0.45%**
7070/7071	3470	0	0.00%	0	0.00%	1	0.03%	**1**	**0.03%**	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	**3**	**0.09%**	0	0.00%	0	0.00%	5	0.14%	**9**	**0.26%**
7020/7021	15471	1	0.01%	3	0.02%	4	0.03%	**8**	**0.05%**	5	0.03%	3	0.02%	2	0.01%	0	0.00%	3	0.02%	**13**	**0.08%**	0	0.00%	0	0.00%	97	0.63%	**118**	**0.76%**
7022	1486	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	9	0.61%	**10**	**0.67%**
7010/7011	2216	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	2	0.09%	3	0.14%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.23%**	0	0.00%	0	0.00%	5	0.23%	**10**	**0.45%**
7040/7041	4093	0	0.00%	0	0.00%	2	0.05%	**2**	**0.05%**	7	0.17%	4	0.10%	0	0.00%	0	0.00%	2	0.05%	**13**	**0.32%**	0	0.00%	0	0.00%	8	0.20%	**23**	**0.56%**
7002	2419	0	0.00%	1	0.04%	2	0.08%	**3**	**0.12%**	5	0.21%	1	0.04%	0	0.00%	1	0.04%	0	0.00%	**7**	**0.29%**	0	0.00%	0	0.00%	10	0.41%	**20**	**0.83%**
7000/7001	34963	2	0.01%	3	0.01%	6	0.02%	**11**	**0.03%**	82	0.23%	22	0.06%	4	0.01%	3	0.01%	12	0.03%	**123**	**0.35%**	1	<0.01%	0	0.00%	110	0.31%	**245**	**0.70%**
1560/1561	1008	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**	0	0.00%	0	0.00%	1	0.10%	**2**	**0.20%**
1590/1591	9777	1	0.01%	0	0.00%	3	0.03%	**4**	**0.04%**	10	0.10%	7	0.07%	0	0.00%	2	0.02%	7	0.07%	**26**	**0.27%**	0	0.00%	0	0.00%	20	0.20%	**50**	**0.51%**
1582	3190	0	0.00%	0	0.00%	3	0.09%	**3**	**0.09%**	32	1.00%	6	0.19%	2	0.06%	6	0.19%	16	0.50%	**62**	**1.94%**	0	0.00%	0	0.00%	15	0.47%	**80**	**2.51%**
1570/1571	10532	2	0.02%	2	0.02%	0	0.00%	**4**	**0.04%**	31	0.29%	5	0.05%	0	0.00%	5	0.05%	12	0.11%	**53**	**0.50%**	0	0.00%	0	0.00%	24	0.23%	**81**	**0.77%**
1580/1581	69262	2	<0.01%	7	0.01%	7	0.01%	**16**	**0.02%**	225	0.32%	80	0.12%	7	0.01%	51	0.07%	73	0.11%	**436**	**0.63%**	3	<0.01%	0	0.00%	228	0.33%	**683**	**0.99%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Defibrillation Impedance		Abnormal Pacing Impedance		Cardiac Perforation		Conductor Fracture		Extracardiac Stimulation		Failure to Capture		Failure to Sense		Inappropriate Shock		Insulation Breach		Lead Dislodgement		Oversensing		Pericardial Effusion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7170Q/7171Q	116	1928	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.72%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.72%
7120Q/7121Q	3462	64749	4	0.12%	0	0.00%	1	0.03%	2	0.06%	0	0.00%	7	0.20%	0	0.00%	1	0.03%	0	0.00%	27	0.78%	0	0.00%	0	0.00%	0	0.00%	42	1.21%
7122Q	798	13955	0	0.00%	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	0.38%	0	0.00%	0	0.00%	0	0.00%	3	0.38%
7120/7121	1478	45733	0	0.00%	0	0.00%	0	0.00%	3	0.20%	0	0.00%	3	0.20%	1	0.07%	1	0.07%	1	0.07%	6	0.41%	1	0.07%	0	0.00%	0	0.00%	16	1.08%
7122	284	7337	0	0.00%	0	0.00%	0	0.00%	1	0.35%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	1.41%	1	0.35%	0	0.00%	0	0.00%	6	2.11%
7070/7071	158	5039	0	0.00%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	1	0.63%	0	0.00%	0	0.00%	0	0.00%	1	0.63%	0	0.00%	0	0.00%	0	0.00%	3	1.90%
7020/7021	189	7082	0	0.00%	1	0.53%	1	0.53%	2	1.06%	0	0.00%	0	0.00%	1	0.53%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	2.65%
7000/7001	202	6412	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	0.50%	2	0.99%	0	0.00%	0	0.00%	0	0.00%	3	1.49%
1580/1581	556	15808	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	0.18%	2	0.36%	0	0.00%	0	0.00%	0	0.00%	3	0.54%

Malfunctions

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Number of Devices Enrolled	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead-to-Can Contact		Lead-to-Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7170Q/7171Q	116	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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	0.86%	**1**	**0.86%**
7120Q/7121Q	3462	0	0.00%	1	0.03%	0	0.00%	**1**	**0.03%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	31	0.90%	**32**	**0.92%**
7122Q	798	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	1	0.13%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.13%**	0	0.00%	0	0.00%	6	0.75%	**7**	**0.88%**
7120/7121	1478	0	0.00%	1	0.07%	0	0.00%	**1**	**0.07%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	**1**	**0.07%**	0	0.00%	0	0.00%	2	0.14%	**4**	**0.27%**
7122	284	0	0.00%	0	0.00%	1	0.35%	**1**	**0.35%**	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	0	0.00%	0	0.00%	2	0.70%	**3**	**1.06%**
7070/7071	158	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	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%	**1**	**0.63%**
7020/7021	189	0	0.00%	1	0.53%	0	0.00%	**1**	**0.53%**	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	0.53%	**2**	**1.06%**
7000/7001	202	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	2	0.99%	1	0.50%	0	0.00%	1	0.50%	0	0.00%	**4**	**1.98%**	1	0.50%	0	0.00%	0	0.00%	**5**	**2.48%**
1580/1581	556	0	0.00%	1	0.18%	0	0.00%	**1**	**0.18%**	0	0.00%	1	0.18%	0	0.00%	3	0.54%	0	0.00%	**4**	**0.72%**	0	0.00%	0	0.00%	4	0.72%	**9**	**1.62%**

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

Pacemakers

Dual-Chamber

St. Jude Medical
More control. Less risk.

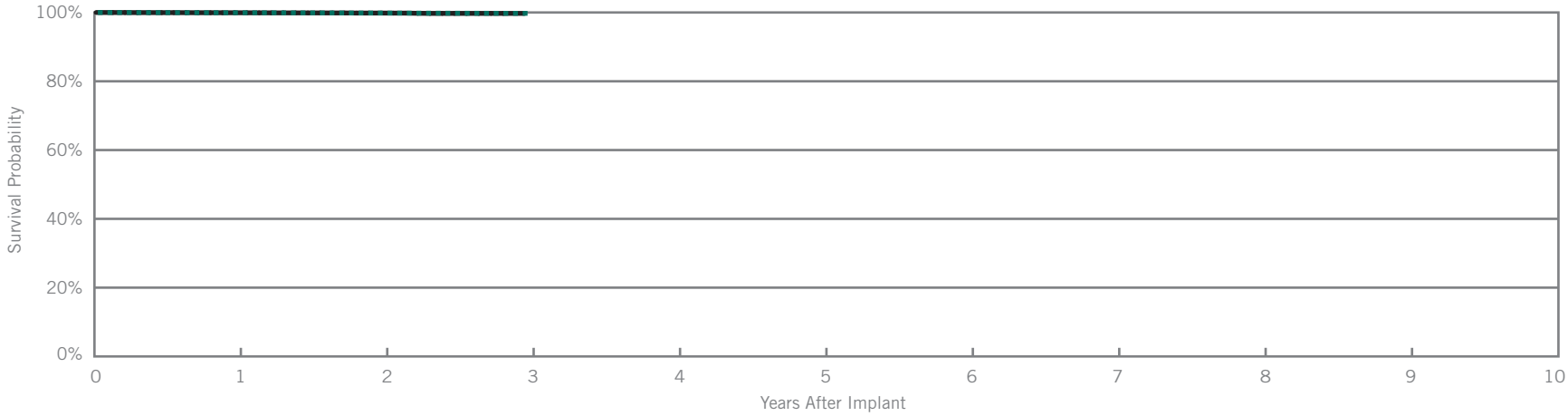
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Registered US Implants	132,555
Estimated Active US Implants	111,150
Estimated Longevity	8 Years
Normal Battery Depletion	5
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	<0.01%	7	0.01%
Electrical Interconnect	3	<0.01%	13	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	8	0.01%
Possible Early Battery Depletion	4	<0.01%	5	<0.01%
Other	2	<0.01%	6	<0.01%
Total	**14**	**0.01%**	**39**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	99.92%	99.83%	99.73%							
± 1 standard error	0.01%	0.02%	0.03%							
Sample Size	109500	50700	1100							

Excluding Normal Battery Depletion

Year	1	2	at 35 months							
Survival Probability	99.93%	99.84%	99.75%							
± 1 standard error	0.01%	0.02%	0.03%							

Actively Monitored Study Data

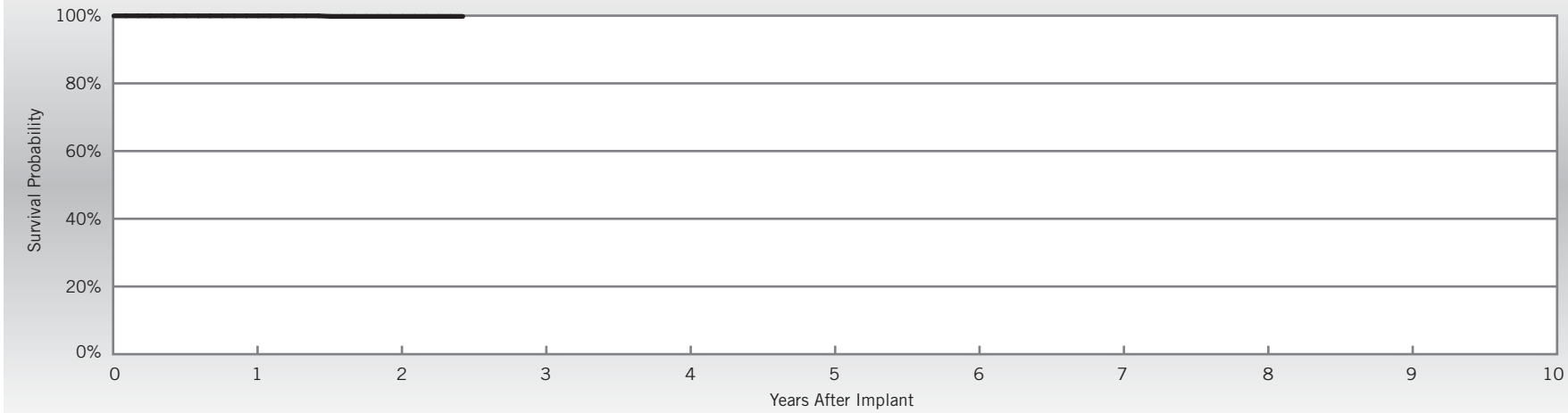
Accent® DR RF

Model PM2210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	1,764
Cumulative Months of Follow-up	28,401
Estimated Longevity	8 Years

Qualifying Complications	Qty.	Rate
Premature Battery Depletion	1	0.06%

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



Year	1	2	at 30 months							
Survival Probability	100.00%	99.84%	99.84%							
± 1 standard error	0.00%	0.16%	0.16%							
Sample Size	1450	730	60							

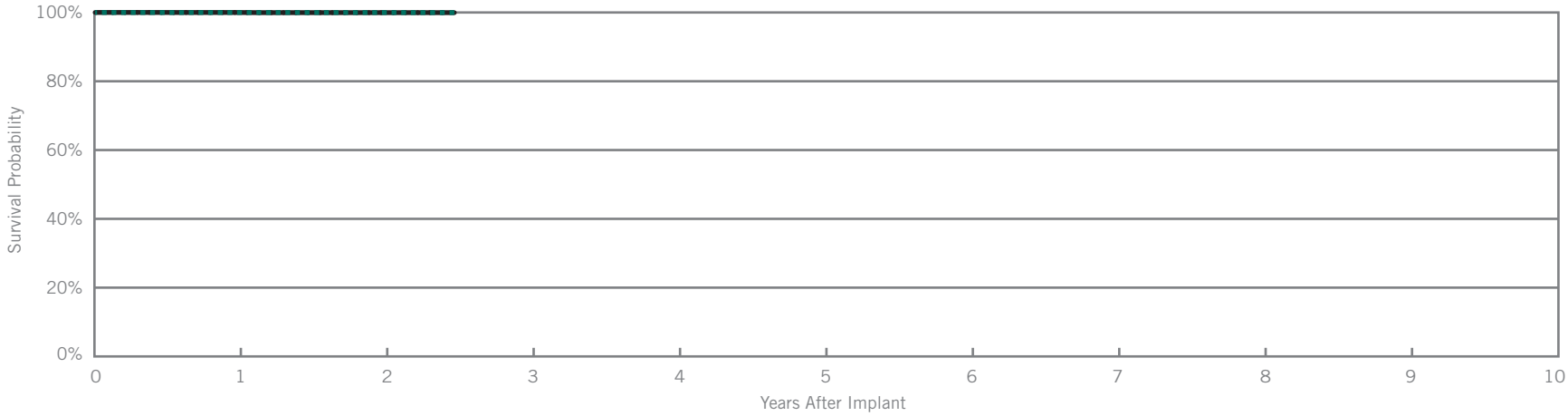
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Registered US Implants	25,758
Estimated Active US Implants	22,284
Estimated Longevity	9.2 Years
Normal Battery Depletion	1
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.99%	99.95%	99.95%							
± 1 standard error	0.01%	0.02%	0.02%							
Sample Size	20200	7200	300							

Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.99%	99.97%	99.97%							
± 1 standard error	0.01%	0.02%	0.02%							

Actively Monitored Study Data

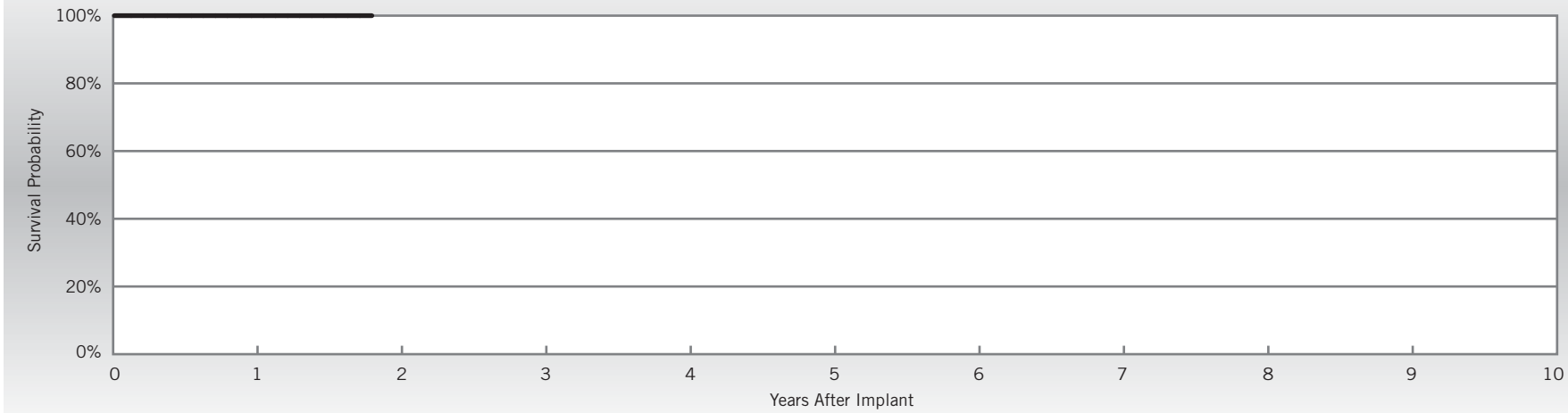
Accent® DR

Model PM2110

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	229
Cumulative Months of Follow-up	3,794
Estimated Longevity	9.2 Years

Qualifying Complications
None Reported

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



Year	1	at 22 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	200	60								

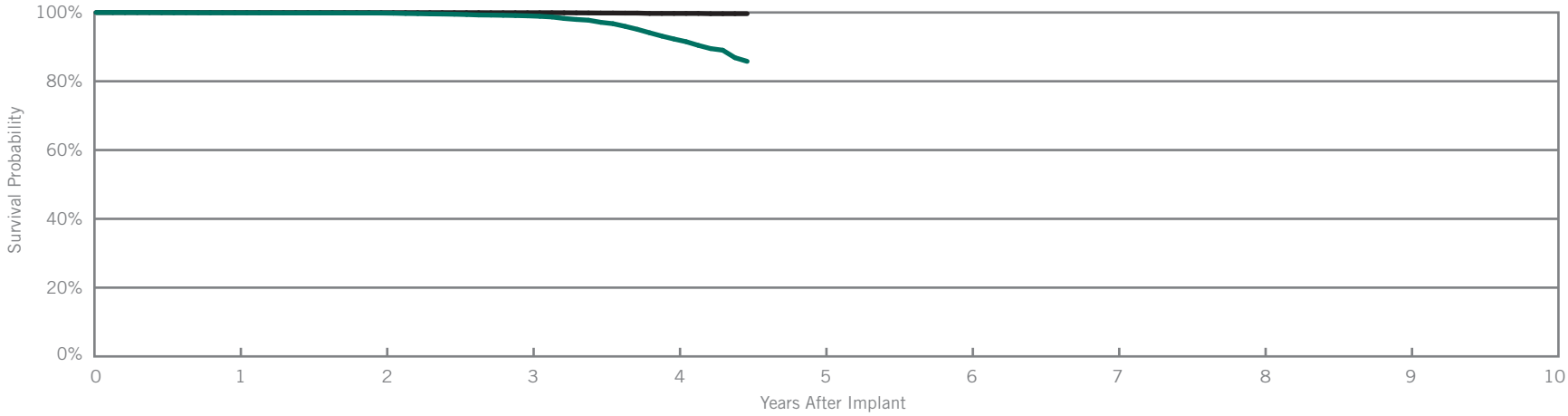
Customer Reported Performance Data

Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Registered US Implants	41,457
Estimated Active US Implants	28,797
Estimated Longevity	6.5 Years
Normal Battery Depletion	338
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	11	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	2	<0.01%
Total	**1**	**<0.01%**	**15**	**0.04%**



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.89%	99.83%	99.02%	92.28%	85.79%					
± 1 standard error	0.02%	0.02%	0.07%	0.29%	0.53%					
Sample Size	38500	26700	17400	8700	1600					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.97%	99.96%	99.93%	99.72%	99.65%					
± 1 standard error	0.01%	0.01%	0.02%	0.06%	0.08%					

Actively Monitored Study Data

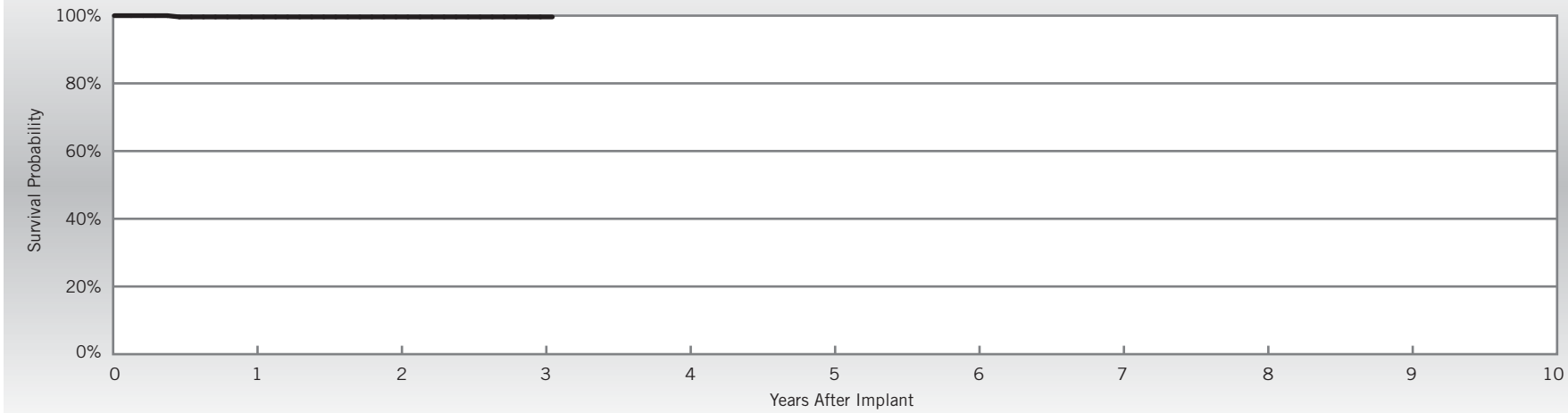
Zephyr® DR

Model 5820

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	282
Cumulative Months of Follow-up	6,933
Estimated Longevity	6.5 Years

Qualifying Complications	Qty.	Rate
Skin Erosion	1	0.35%

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	1	0.35%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**1**	**0.35%**



Year	1	2	at 37 months							
Survival Probability	99.62%	99.62%	99.62%							
± 1 standard error	0.38%	0.38%	0.38%							
Sample Size	260	190	50							

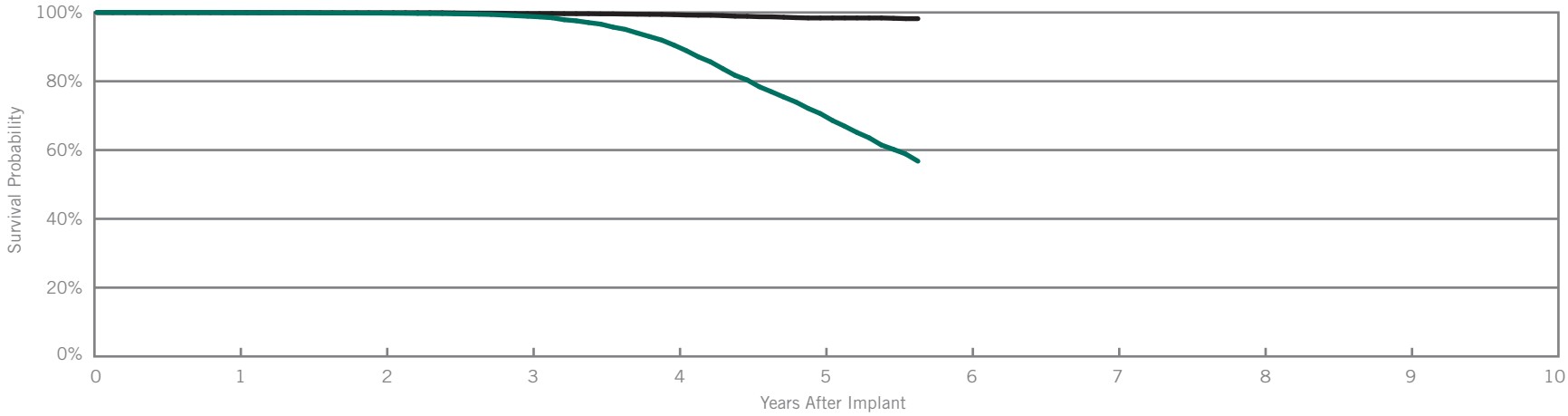
Customer Reported Performance Data

Victory® DR

Model 5810

US Regulatory Approval	December 2005
Registered US Implants	26,333
Estimated Active US Implants	10,467
Estimated Longevity	6.5 Years
Normal Battery Depletion	1,528
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	57	0.22%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	17	0.06%
Other	0	0.00%	0	0.00%
Total	**1**	**<0.01%**	**75**	**0.28%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.91%	99.82%	98.90%	90.51%	70.60%	56.76%				
± 1 standard error	0.02%	0.03%	0.07%	0.23%	0.44%	0.60%				
Sample Size	26200	22500	19100	15000	9400	1600				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.98%	99.93%	99.69%	99.36%	98.40%	97.98%				
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.13%	0.16%				

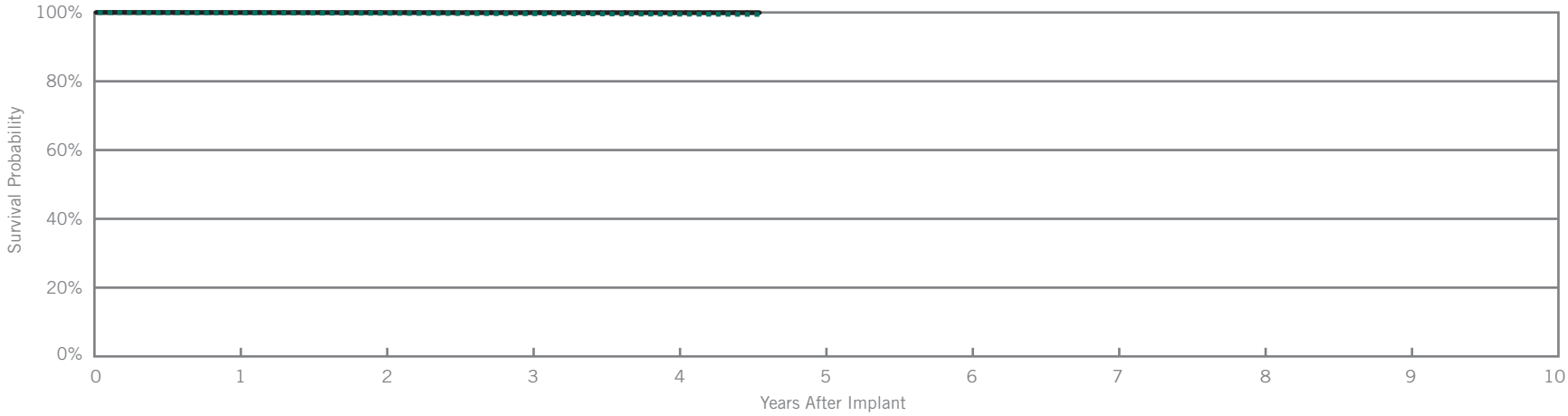
Customer Reported Performance Data

Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Registered US Implants	105,621
Estimated Active US Implants	71,524
Estimated Longevity	11.7 Years
Normal Battery Depletion	68
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	10	0.01%
Electrical Interconnect	2	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	<0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	2	<0.01%
Total	**4**	**<0.01%**	**18**	**0.02%**



Including Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.94%	99.90%	99.81%	99.63%	99.45%					
± 1 standard error	0.01%	0.01%	0.01%	0.03%	0.05%					
Sample Size	103500	85300	63900	33800	5900					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 55 months					
Survival Probability	99.97%	99.96%	99.95%	99.94%	99.94%					
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%					

Actively Monitored Study Data

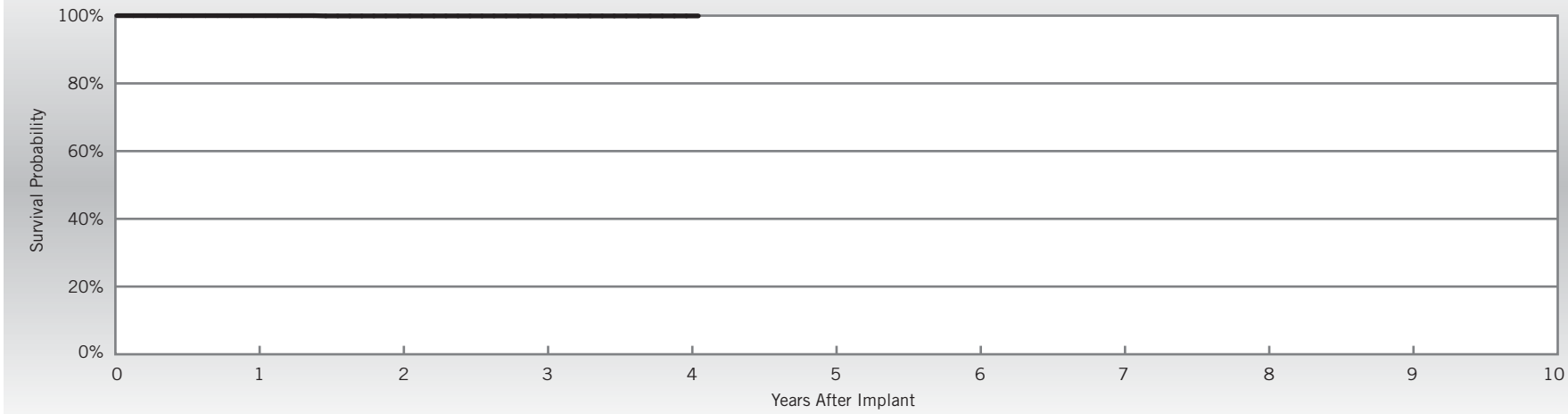
Zephyr® XL DR

Model 5826

US Regulatory Approval	March 2007
Number of Devices Enrolled in Study	1,517
Cumulative Months of Follow-up	48,131
Estimated Longevity	11.7 Years

Qualifying Complications	Qty.	Rate
Premature Battery Depletion	1	0.07%

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



Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	99.92%	99.92%	99.92%	99.92%					
± 1 standard error	0.00%	0.08%	0.08%	0.08%	0.08%					
Sample Size	1440	1250	880	340	50					

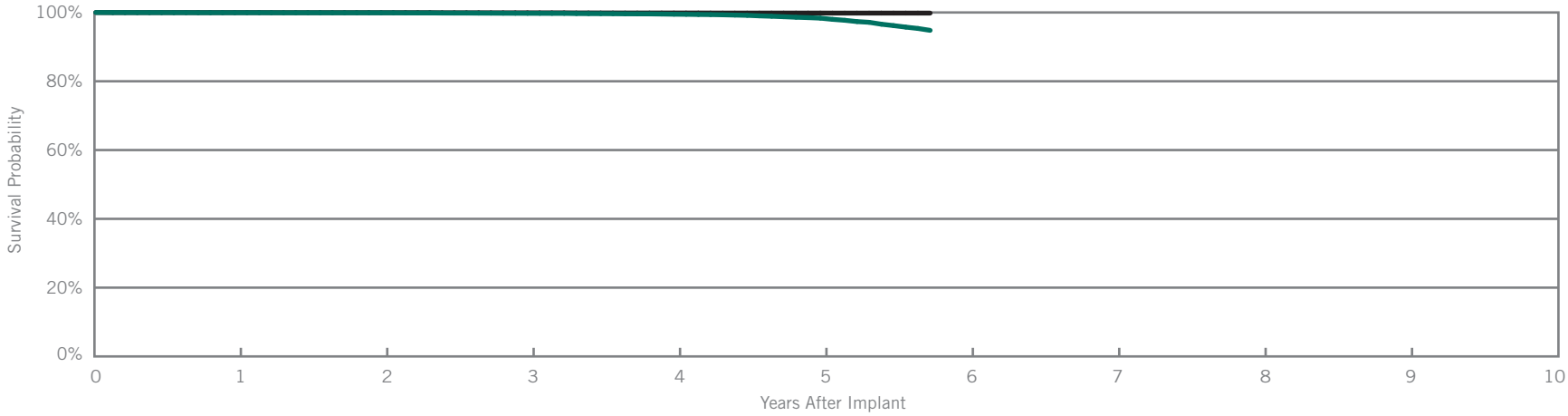
Customer Reported Performance Data

Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Registered US Implants	62,302
Estimated Active US Implants	35,443
Estimated Longevity	11.7 Years
Normal Battery Depletion	301
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	17	0.03%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	4	0.01%
Other	1	<0.01%	4	0.01%
Total	**3**	**<0.01%**	**30**	**0.05%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.94%	99.90%	99.75%	99.49%	98.35%	94.80%				
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.07%	0.20%				
Sample Size	62200	54200	46300	36800	24100	4900				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 69 months				
Survival Probability	99.97%	99.95%	99.91%	99.85%	99.83%	99.82%				
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.02%				

Actively Monitored Study Data

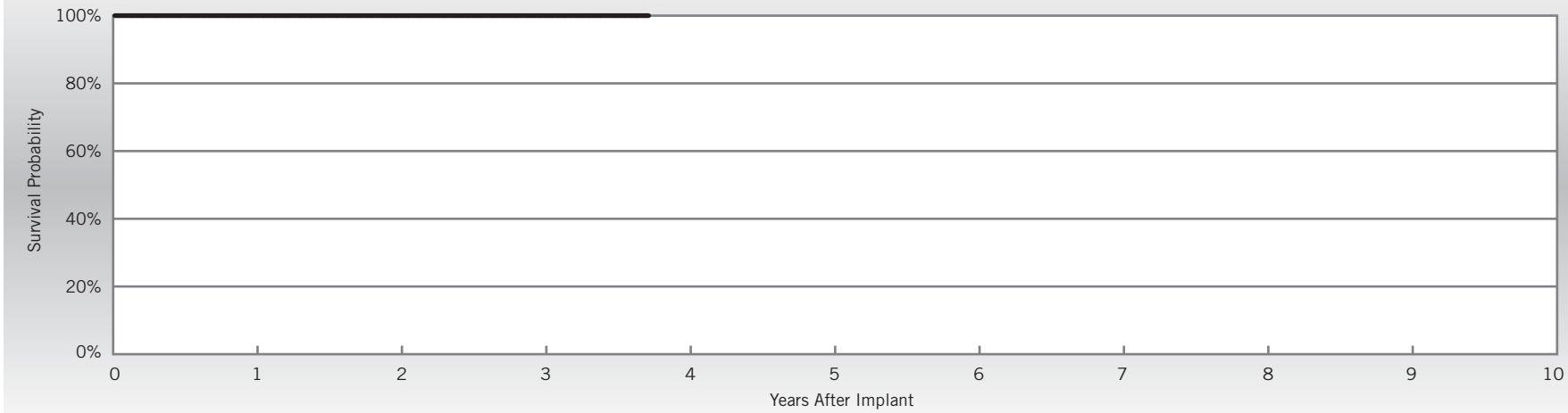
Victory® XL DR

Model 5816

US Regulatory Approval	December 2005
Number of Devices Enrolled in Study	334
Cumulative Months of Follow-up	11,037
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

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



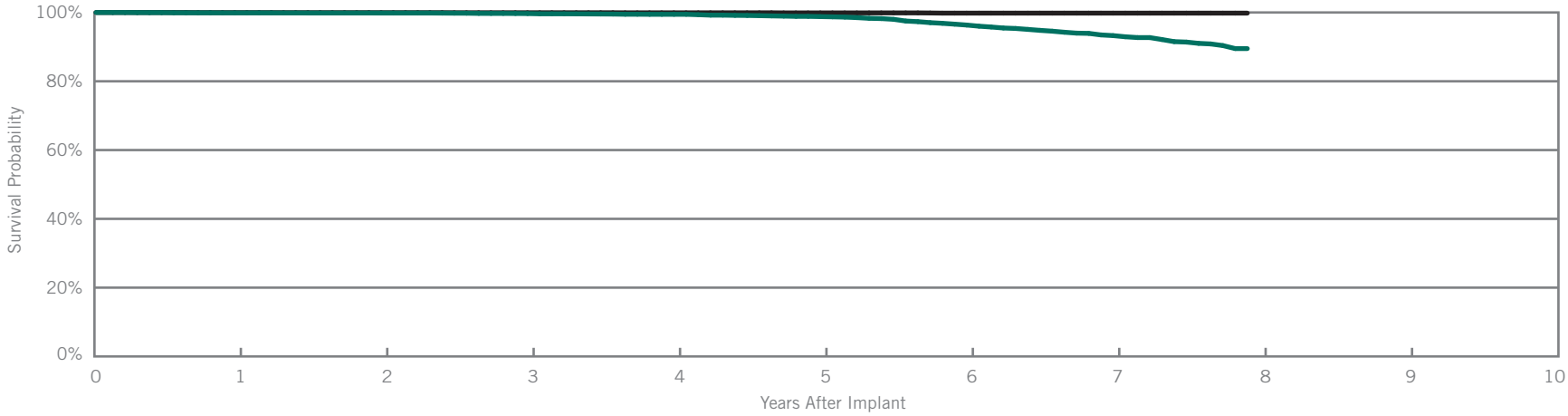
Year	1	2	3	at 45 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	320	280	210	50						

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

US Regulatory Approval	May 2003
Registered US Implants	17,099
Estimated Active US Implants	7,591
Estimated Longevity	6.9 Years
Normal Battery Depletion	169
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.88%	99.83%	99.68%	99.46%	98.80%	96.34%	93.27%	89.50%		
± 1 standard error	0.03%	0.03%	0.05%	0.07%	0.11%	0.23%	0.37%	0.64%		
Sample Size	17000	14500	12800	10900	8600	6000	3600	800		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.96%	99.95%	99.93%	99.91%	99.88%	99.81%	99.81%	99.81%		
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.03%	0.05%	0.05%	0.05%		

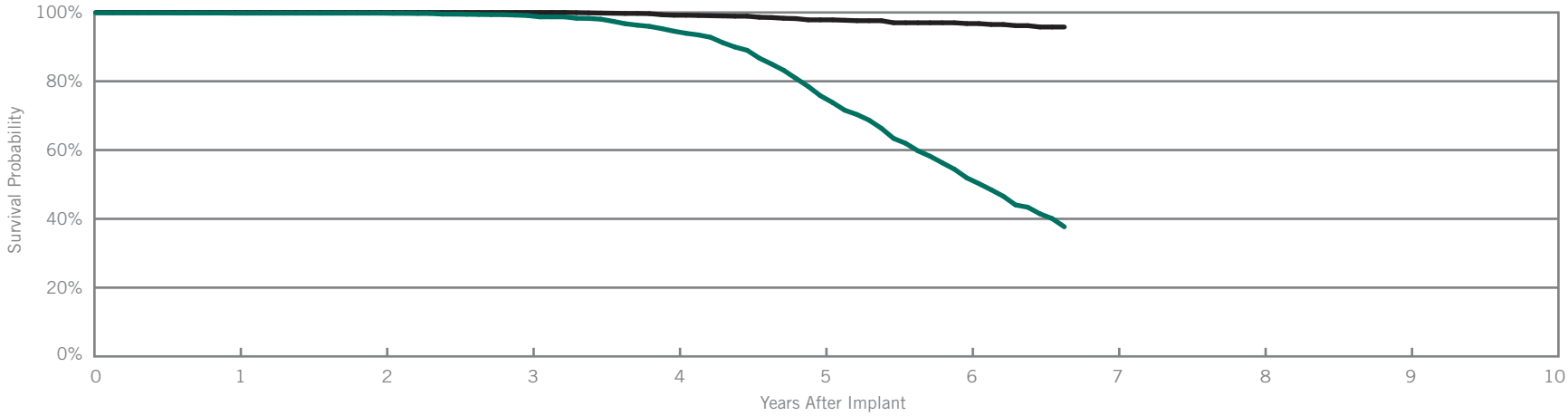
Integrity® ADx DR

Model 5360

US Regulatory Approval	May 2003
Registered US Implants	5,841
Estimated Active US Implants	913
Estimated Longevity	3.8 Years
Normal Battery Depletion	544
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	34	0.58%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.02%
Total	**0**	**0.00%**	**35**	**0.60%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	99.80%	99.80%	99.11%	94.55%	75.80%	51.92%	37.68%			
± 1 standard error	0.05%	0.06%	0.13%	0.35%	0.76%	1.06%	1.20%			
Sample Size	5800	5000	4400	3800	3100	1700	400			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 80 months			
Survival Probability	100.00%	100.00%	100.00%	99.20%	97.85%	96.77%	95.77%			
± 1 standard error	0.00%	0.00%	0.00%	0.14%	0.28%	0.37%	0.57%			

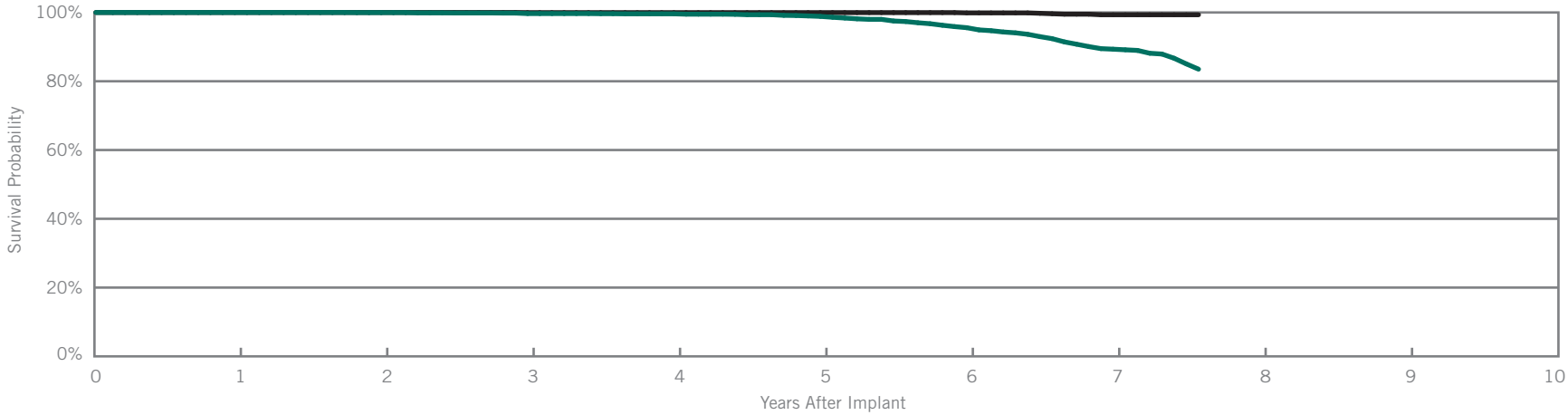
Customer Reported Performance Data

Integrity® ADx DR

Model 5366

US Regulatory Approval	May 2003
Registered US Implants	8,011
Estimated Active US Implants	3,712
Estimated Longevity	6.9 Years
Normal Battery Depletion	149
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	5	0.06%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**6**	**0.07%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	100.00%	99.97%	99.68%	99.60%	98.86%	95.57%	89.32%	83.51%		
± 1 standard error	0.00%	0.02%	0.05%	0.08%	0.14%	0.34%	0.67%	0.96%		
Sample Size	8000	7100	6300	5600	4600	3200	1800	600		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 91 months		
Survival Probability	100.00%	100.00%	99.96%	99.96%	99.96%	99.88%	99.33%	99.33%		
± 1 standard error	0.00%	0.00%	0.02%	0.03%	0.03%	0.03%	0.21%	0.21%		

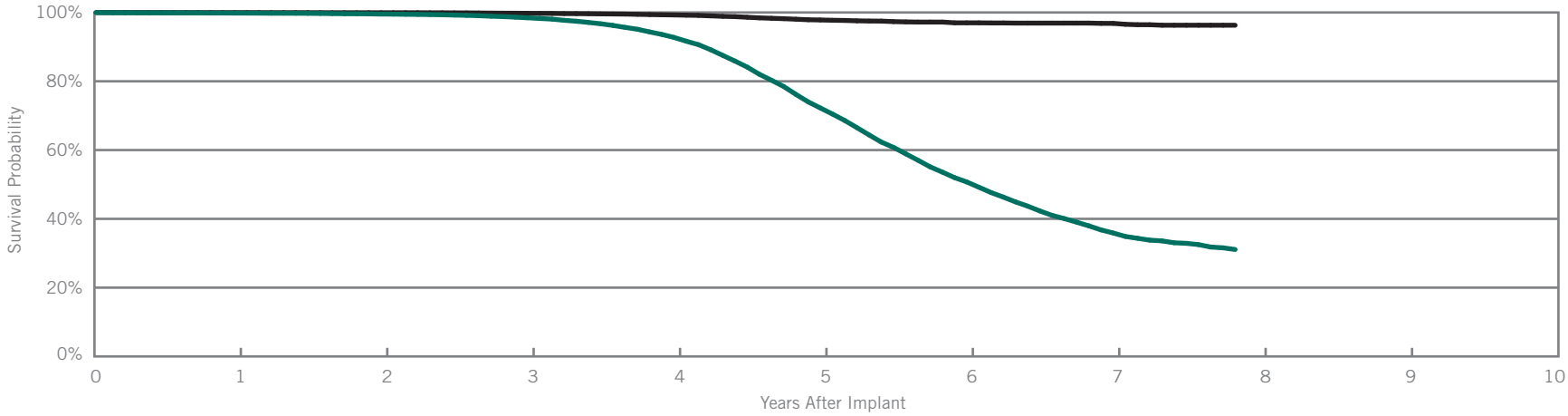
Identity ADx® DR

Model 5380

US Regulatory Approval	March 2003
Registered US Implants	54,055
Estimated Active US Implants	9,093
Estimated Longevity	3.8 Years
Normal Battery Depletion	5,065
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	4	0.01%	251	0.46%
Electrical Interconnect	1	<0.01%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	11	0.02%
Other	0	0.00%	3	0.01%
Total	**5**	**0.01%**	**270**	**0.50%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.82%	99.53%	98.45%	92.74%	72.23%	50.72%	35.89%	31.09%		
± 1 standard error	0.02%	0.03%	0.06%	0.13%	0.27%	0.35%	0.43%	0.51%		
Sample Size	53800	46500	41100	35300	27300	15100	5600	700		

Excluding Normal Battery Depletion

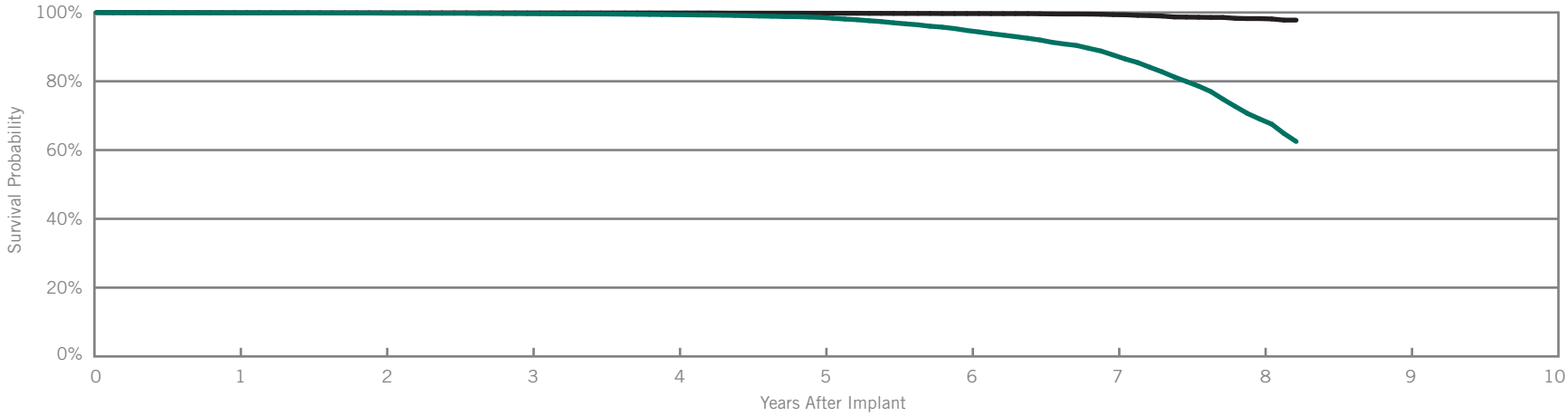
Year	1	2	3	4	5	6	7	at 94 months		
Survival Probability	99.96%	99.93%	99.75%	99.28%	97.82%	96.99%	96.83%	96.29%		
± 1 standard error	0.01%	0.01%	0.02%	0.04%	0.09%	0.13%	0.15%	0.23%		

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

US Regulatory Approval	March 2003
Registered US Implants	67,092
Estimated Active US Implants	30,103
Estimated Longevity	6.9 Years
Normal Battery Depletion	1,477
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	**Rate**	**Qty**	**Rate**
Electrical Component	2	<0.01%	80	0.12%
Electrical Interconnect	0	0.00%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	7	0.01%
Possible Early Battery Depletion	0	0.00%	6	0.01%
Other	0	0.00%	3	<0.01%
Total	**2**	**<0.01%**	**98**	**0.15%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.89%	99.81%	99.65%	99.36%	98.57%	94.77%	87.64%	69.04%	62.49%
± 1 standard error	0.01%	0.02%	0.02%	0.04%	0.06%	0.13%	0.23%	0.55%	0.69%
Sample Size	66700	57900	50800	43200	35000	26100	15500	6100	1300

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 99 months
Survival Probability	99.92%	99.90%	99.87%	99.85%	99.78%	99.68%	99.37%	98.22%	97.78%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.17%	0.24%

Actively Monitored Study Data

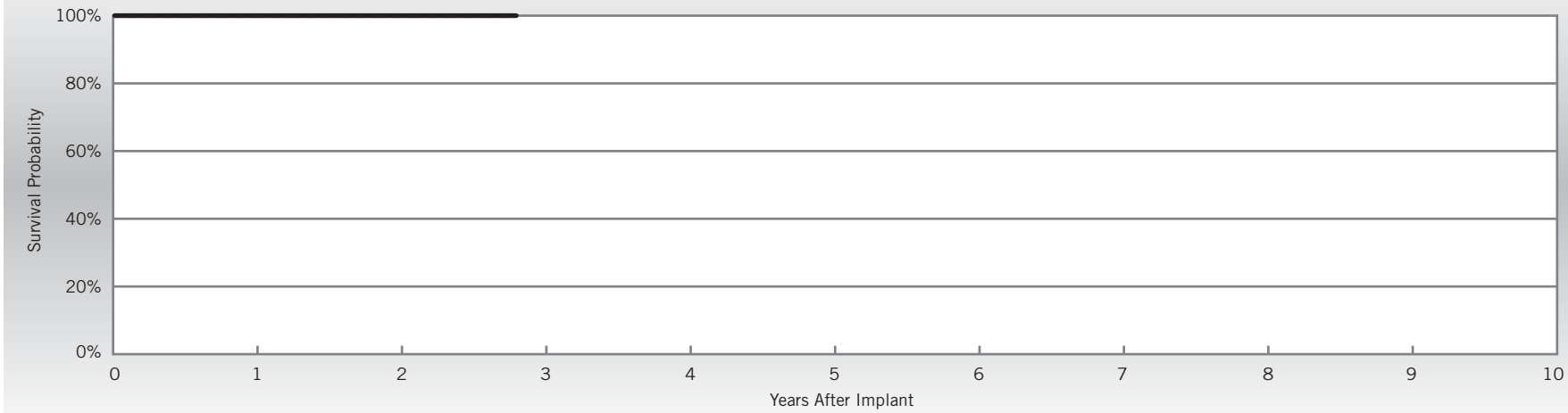
Identity ADx® XL DR

Model 5386

US Regulatory Approval	March 2003
Number of Devices Enrolled in Study	102
Cumulative Months of Follow-up	3,389
Estimated Longevity	11.7 Years

Qualifying Complications
None Reported

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



Year	1	2	at 34 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	100	80	50							

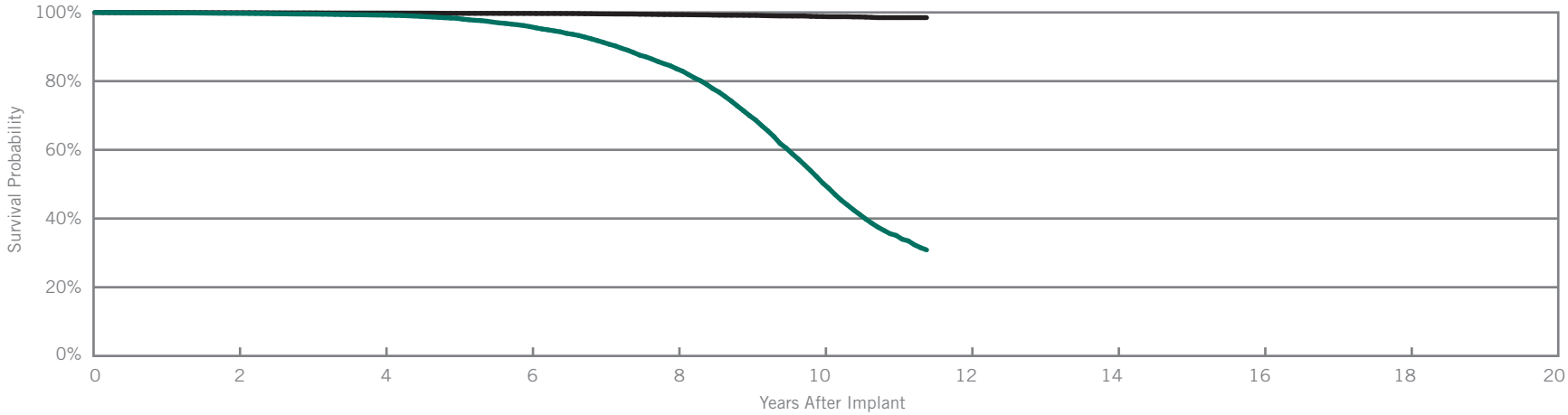
Integrity® AFx DR

Models 5342 & 5346

US Regulatory Approval	(5342) April 2000 (5346) July 2001
Registered US Implants	47,564
Estimated Active US Implants	5,226
Estimated Longevity	6.3 Years
Normal Battery Depletion	3,783
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	87	0.18%
Electrical Interconnect	3	0.01%	1	<0.01%
Battery	0	0.00%	2	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	1	<0.01%	2	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**6**	**0.01%**	**93**	**0.20%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.74%	99.22%	95.87%	83.62%	50.30%	30.86%				
± 1 standard error	0.02%	0.05%	0.11%	0.24%	0.43%	0.52%				
Sample Size	42000	34900	27700	19300	8900	1000				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 137 months				
Survival Probability	99.92%	99.82%	99.71%	99.36%	98.80%	98.49%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.09%	0.14%				

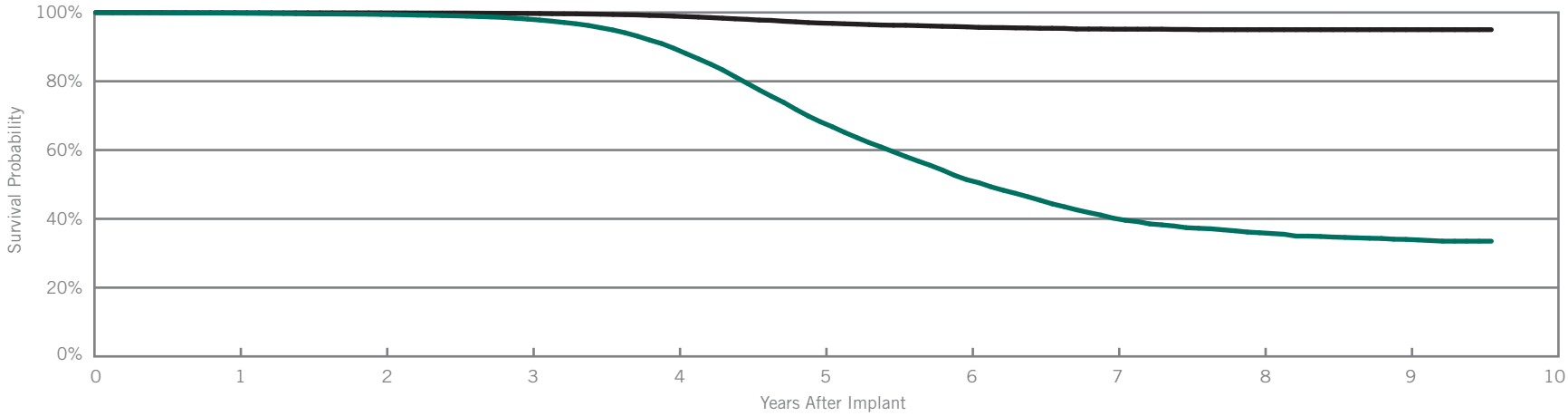
Identity®

Model 5370

US Regulatory Approval	November 2001
Registered US Implants	58,455
Estimated Active US Implants	4,151
Estimated Longevity	3.8 Years
Normal Battery Depletion	5,610
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	3	0.01%	393	0.67%
Electrical Interconnect	2	<0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	12	0.02%
Other	0	0.00%	11	0.02%
Total	**5**	**0.01%**	**423**	**0.72%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 115 months
Survival Probability	99.79%	99.43%	98.07%	89.57%	68.22%	51.38%	40.20%	35.96%	34.03%	33.51%
± 1 standard error	0.02%	0.03%	0.06%	0.15%	0.26%	0.33%	0.38%	0.41%	0.44%	0.45%
Sample Size	58300	50700	45200	39500	30400	16300	7200	3300	1700	600

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 115 months
Survival Probability	99.93%	99.88%	99.71%	98.93%	96.92%	95.81%	95.14%	95.00%	95.00%	95.00%
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.10%	0.14%	0.18%	0.19%	0.19%	0.19%

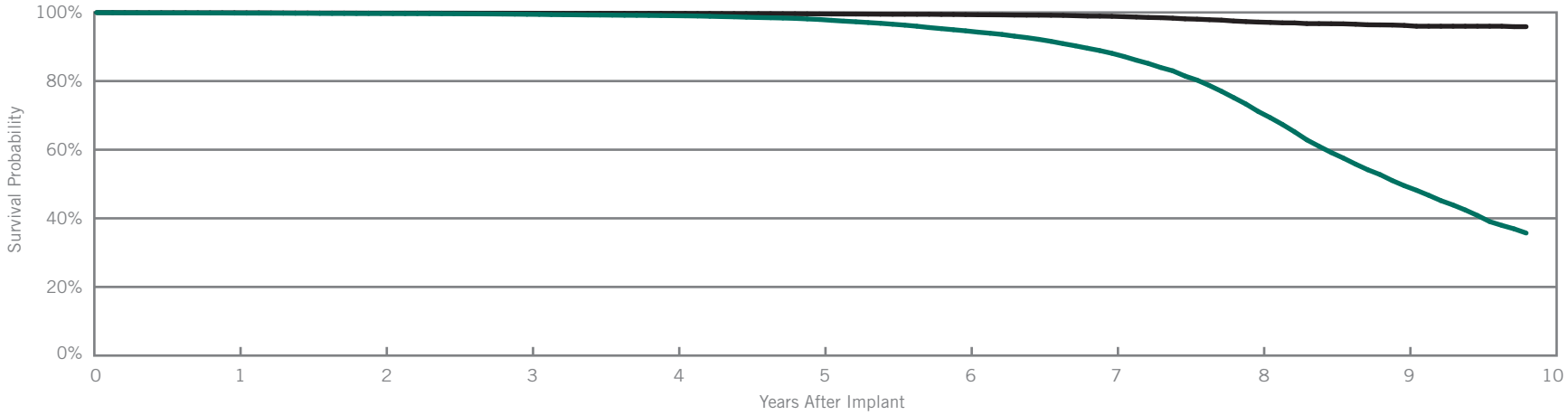
Customer Reported Performance Data

Identity® XL

Model 5376

US Regulatory Approval	November 2001
Registered US Implants	51,523
Estimated Active US Implants	12,789
Estimated Longevity	6.9 Years
Normal Battery Depletion	3,582
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	2	<0.01%	233	0.45%
Electrical Interconnect	4	0.01%	2	<0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	2	<0.01%	5	0.01%
Possible Early Battery Depletion	0	0.00%	5	0.01%
Other	0	0.00%	7	0.01%
Total	**8**	**0.02%**	**252**	**0.49%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.81%	99.69%	99.46%	99.05%	97.95%	94.64%	88.09%	71.16%	49.50%	35.71%
± 1 standard error	0.02%	0.03%	0.03%	0.05%	0.07%	0.13%	0.20%	0.32%	0.43%	0.53%
Sample Size	51400	45900	41800	37600	33200	28200	22400	16000	8900	1300

Excluding Normal Battery Depletion

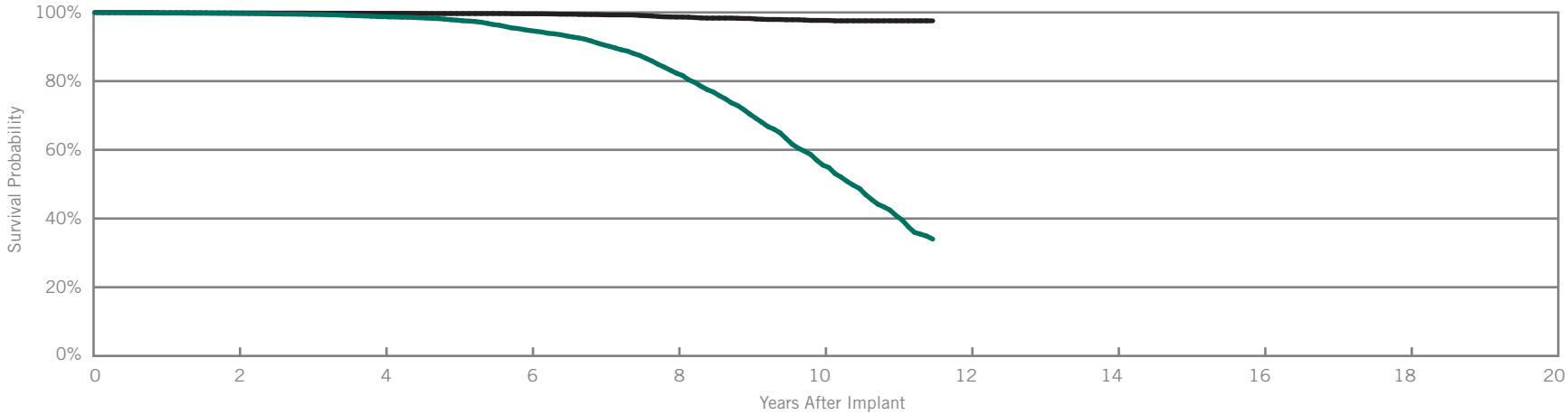
Year	1	2	3	4	5	6	7	8	9	at 118 months
Survival Probability	99.90%	99.81%	99.77%	99.72%	99.57%	99.37%	98.88%	97.19%	96.22%	95.85%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.06%	0.12%	0.17%	0.21%

Customer Reported Performance Data

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

US Regulatory Approval	June 1999
Registered US Implants	21,877
Estimated Active US Implants	1,691
Estimated Longevity	6.3 Years
Normal Battery Depletion	1,266
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	63	0.29%
Electrical Interconnect	2	0.01%	2	0.01%
Battery	0	0.00%	1	<0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	0	0.00%	0	0.00%
Total	**3**	**0.01%**	**67**	**0.31%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 138 months				
Survival Probability	99.69%	98.77%	94.74%	82.31%	55.55%	34.02%				
± 1 standard error	0.04%	0.09%	0.20%	0.41%	0.71%	0.91%				
Sample Size	18700	14800	11100	7100	3000	500				

Excluding Normal Battery Depletion

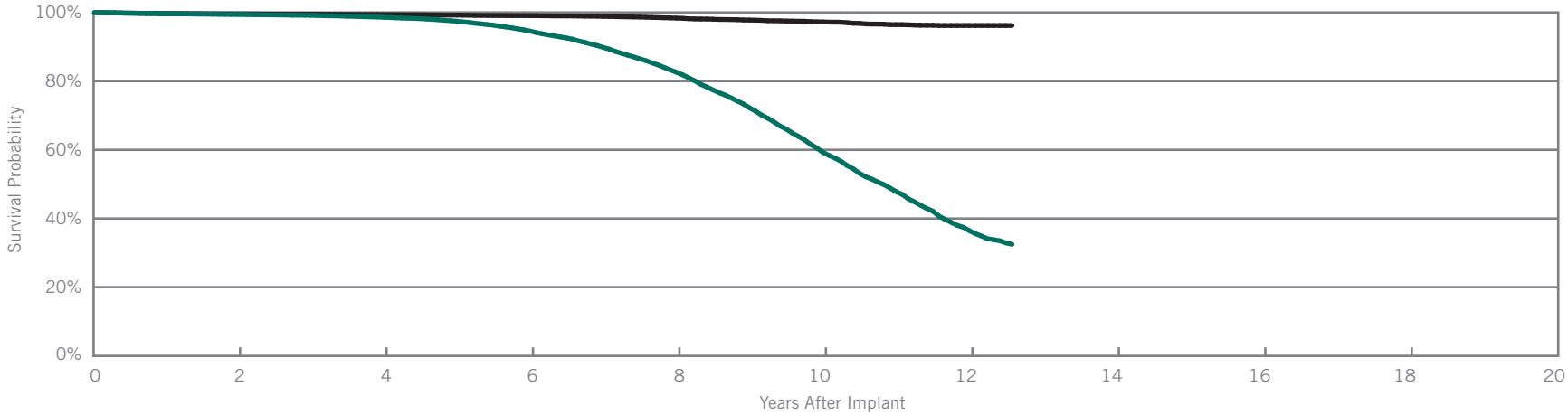
Year	2	4	6	8	10	at 138 months				
Survival Probability	99.85%	99.74%	99.60%	98.65%	97.68%	97.56%				
± 1 standard error	0.03%	0.04%	0.05%	0.13%	0.22%	0.23%				

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	65,686
Estimated Active US Implants	4,410
Estimated Longevity	6.3 Years
Normal Battery Depletion	4,013
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	5	0.01%	283	0.43%
Electrical Interconnect	9	0.01%	13	0.02%
Battery	0	0.00%	6	0.01%
Software/Firmware	0	0.00%	2	<0.01%
Mechanical	0	0.00%	5	0.01%
Possible Early Battery Depletion	0	0.00%	1	<0.01%
Other	1	<0.01%	3	<0.01%
Total	**15**	**0.02%**	**313**	**0.48%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 151 months			
Survival Probability	99.42%	98.59%	94.57%	82.58%	59.27%	36.46%	32.50%			
± 1 standard error	0.03%	0.05%	0.11%	0.22%	0.37%	0.50%	0.54%			
Sample Size	57500	46800	36200	23700	10800	3300	900			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 151 months			
Survival Probability	99.56%	99.35%	99.07%	98.36%	97.26%	96.21%	96.21%			
± 1 standard error	0.03%	0.03%	0.04%	0.07%	0.12%	0.20%	0.20%			

Summary Information

Dual-Chamber Pacemakers

St. Jude Medical
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2210	Accent® DR RF	99.92%	99.83%								
PM2110	Accent® DR	99.99%	99.95%								
5820	Zephyr® DR	99.89%	99.83%	99.02%	92.28%						
5810	Victory® DR	99.91%	99.82%	98.90%	90.51%	70.60%					
5826	Zephyr® XL DR	99.94%	99.90%	99.81%	99.63%						
5816	Victory® XL DR	99.94%	99.90%	99.75%	99.49%	98.35%					
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	99.88%	99.83%	99.68%	99.46%	98.80%	96.34%	93.27%			
5360	Integrity® ADx DR	99.80%	99.80%	99.11%	94.55%	75.80%	51.92%				
5366	Integrity® ADx XL DR	100.00%	99.97%	99.68%	99.60%	98.86%	95.57%	89.32%			
5380	Identity ADx® DR	99.82%	99.53%	98.45%	92.74%	72.23%	50.72%	35.89%			
5386/5286	Identity ADx® XL DR/DC	99.89%	99.81%	99.65%	99.36%	98.57%	94.77%	87.64%	69.04%		
5342/5346	Integrity® AFx DR	99.87%	99.74%	99.52%	99.22%	98.29%	95.87%	91.30%	83.62%	69.94%	50.30%
5370	Identity®	99.79%	99.43%	98.07%	89.57%	68.22%	51.38%	40.20%	35.96%	34.03%	
5376	Identity® XL	99.81%	99.69%	99.46%	99.05%	97.95%	94.64%	88.09%	71.16%	49.50%	
5326/5226	Entity® DR/DC	99.81%	99.69%	99.42%	98.77%	97.76%	94.74%	90.59%	82.31%	70.43%	55.55%
5330/5331/5230	Affinity® DR/DC	99.64%	99.42%	99.16%	98.59%	97.45%	94.57%	89.82%	82.58%	72.21%	59.27%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM2210	Accent® DR RF	99.93%	99.84%								
PM2110	Accent® DR	99.99%	99.97%								
5820	Zephyr® DR	99.97%	99.96%	99.93%	99.72%						
5810	Victory® DR	99.98%	99.93%	99.69%	99.36%	98.40%					
5826	Zephyr® XL DR	99.97%	99.96%	99.95%	99.94%						
5816	Victory® XL DR	99.97%	99.95%	99.91%	99.85%	99.83%					
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	99.96%	99.95%	99.93%	99.91%	99.88%	99.81%	99.81%			
5360	Integrity® ADx DR	100.00%	100.00%	100.00%	99.20%	97.85%	96.77%				
5366	Integrity® ADx XL DR	100.00%	100.00%	99.96%	99.96%	99.96%	99.88%	99.33%			
5380	Identity ADx® DR	99.96%	99.93%	99.75%	99.28%	97.82%	96.99%	96.83%			
5386/5286	Identity ADx® XL DR/DC	99.92%	99.90%	99.87%	99.85%	99.78%	99.68%	99.37%	98.22%		
5342/5346	Integrity® AFx DR	99.96%	99.92%	99.87%	99.82%	99.73%	99.71%	99.57%	99.36%	99.15%	98.80%
5370	Identity®	99.93%	99.88%	99.71%	98.93%	96.92%	95.81%	95.14%	95.00%	95.00%	
5376	Identity® XL	99.90%	99.81%	99.77%	99.72%	99.57%	99.37%	98.88%	97.19%	96.22%	
5326/5226	Entity® DR/DC	99.91%	99.85%	99.79%	99.74%	99.67%	99.60%	99.31%	98.65%	98.24%	97.68%
5330/5331/5230	Affinity® DR/DC	99.68%	99.56%	99.46%	99.35%	99.23%	99.07%	98.85%	98.36%	97.79%	97.26%

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent® DR RF	132555	5	<0.01%	3	<0.01%	0	0.00%	0	0.00%	0	0.00%	4	<0.01%	2	<0.01%	**14**	**0.01%**
PM2110	Accent® DR	25758	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**2**	**0.01%**
5820	Zephyr® DR	41457	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5810	Victory® DR	26333	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5826	Zephyr® XL DR	105621	1	<0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**<0.01%**
5816	Victory® XL DR	62302	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**3**	**<0.01%**
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	17099	0	0.00%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5360	Integrity® ADx DR	5841	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5366	Integrity® ADx XL DR	8011	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5380	Identity ADx® DR	54055	4	0.01%	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.01%**
5386/5286	Identity ADx® XL DR/DC	67092	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**<0.01%**
5342/5346	Integrity® AFx DR	47564	2	<0.01%	3	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	**6**	**0.01%**
5370	Identity®	58455	3	0.01%	2	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**5**	**0.01%**
5376	Identity® XL	51523	2	<0.01%	4	0.01%	0	0.00%	0	0.00%	2	<0.01%	0	0.00%	0	0.00%	**8**	**0.02%**
5326/5226	Entity® DR/DC	21877	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.01%**
5330/5331/5230	Affinity® DR/DC	65686	5	0.01%	9	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**15**	**0.02%**

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

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	Accent® DR RF	132555	7	0.01%	13	0.01%	0	0.00%	0	0.00%	8	0.01%	5	<0.01%	6	<0.01%	**39**	**0.03%**
PM2110	Accent® DR	25758	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	**6**	**0.02%**
5820	Zephyr® DR	41457	11	0.03%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	1	<0.01%	2	<0.01%	**15**	**0.04%**
5810	Victory® DR	26333	57	0.22%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	17	0.06%	0	0.00%	**75**	**0.28%**
5826	Zephyr® XL DR	105621	10	0.01%	0	0.00%	0	0.00%	0	0.00%	5	<0.01%	1	<0.01%	2	<0.01%	**18**	**0.02%**
5816	Victory® XL DR	62302	17	0.03%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	4	0.01%	4	0.01%	**30**	**0.05%**
5356/5357/5256	Verity® ADx XL DR/ DR(M/S) / DC	17099	6	0.04%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**8**	**0.05%**
5360	Integrity® ADx DR	5841	34	0.58%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.02%	**35**	**0.60%**
5366	Integrity® ADx XL DR	8011	5	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**6**	**0.07%**
5380	Identity ADx® DR	54055	251	0.46%	0	0.00%	0	0.00%	0	0.00%	5	0.01%	11	0.02%	3	0.01%	**270**	**0.50%**
5386/5286	Identity ADx® XL DR/DC	67092	80	0.12%	2	<0.01%	0	0.00%	0	0.00%	7	0.01%	6	0.01%	3	<0.01%	**98**	**0.15%**
5342/5346	Integrity® AFx DR	47564	87	0.18%	1	<0.01%	2	<0.01%	0	0.00%	2	<0.01%	0	0.00%	1	<0.01%	**93**	**0.20%**
5370	Identity®	58455	393	0.67%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	12	0.02%	11	0.02%	**423**	**0.72%**
5376	Identity® XL	51523	233	0.45%	2	<0.01%	0	0.00%	0	0.00%	5	0.01%	5	0.01%	7	0.01%	**252**	**0.49%**
5326/5226	Entity® DR/DC	21877	63	0.29%	2	0.01%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**67**	**0.31%**
5330/5331/5230	Affinity® DR/DC	65686	283	0.43%	13	0.02%	6	0.01%	2	<0.01%	5	0.01%	1	<0.01%	3	<0.01%	**313**	**0.48%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Premature Battery Depletion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	1764	28401	1	0.06%	0	0.00%	**1**	**0.06%**
PM2110	229	3794	0	0.00%	0	0.00%	**0**	**0.00%**
5820	282	6933	0	0.00%	1	0.35%	**1**	**0.35%**
5826	1517	48131	1	0.07%	0	0.00%	**1**	**0.07%**
5816	334	11037	0	0.00%	0	0.00%	**0**	**0.00%**
5386/5286	103	3389	0	0.00%	0	0.00%	**0**	**0.00%**

Malfunctions

Models	Number of Devices Enrolled	Malfunctions w/ Compromised Therapy															
		Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	1764	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM2110	229	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	282	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5826	1517	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5816	334	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5386/5286	102	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

Models	Number of Devices Enrolled	Malfunctions w/o Compromised Therapy															
		Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM2210	1764	0	0.00%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.06%**
PM2110	229	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5820	282	1	0.35%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.35%**
5826	1517	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.07%**
5816	334	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5386/5286	102	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**

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

Pacemakers

Single-Chamber

St. Jude Medical™
More control. Less risk.

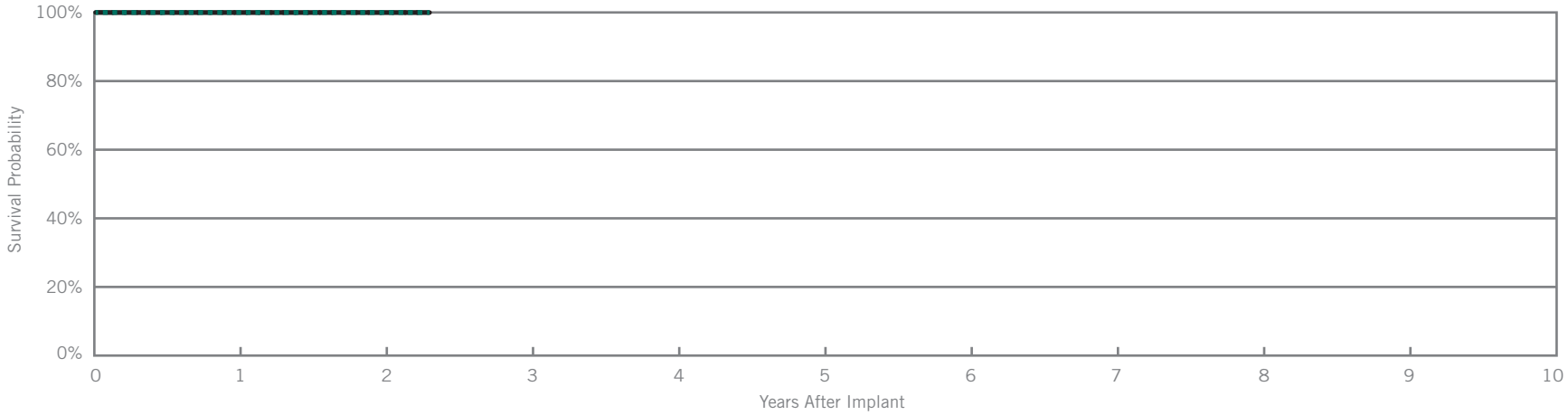
Accent® SR

Model PM1110

US Regulatory Approval	July 2009
Registered US Implants	6,633
Estimated Active US Implants	5,726
Estimated Longevity	12.9 Years
Normal Battery Depletion	0
Number of US Advisories	None

Customer Reported Performance Data

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



Including Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	5000	1600	200							

Excluding Normal Battery Depletion

Year	1	2	at 27 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

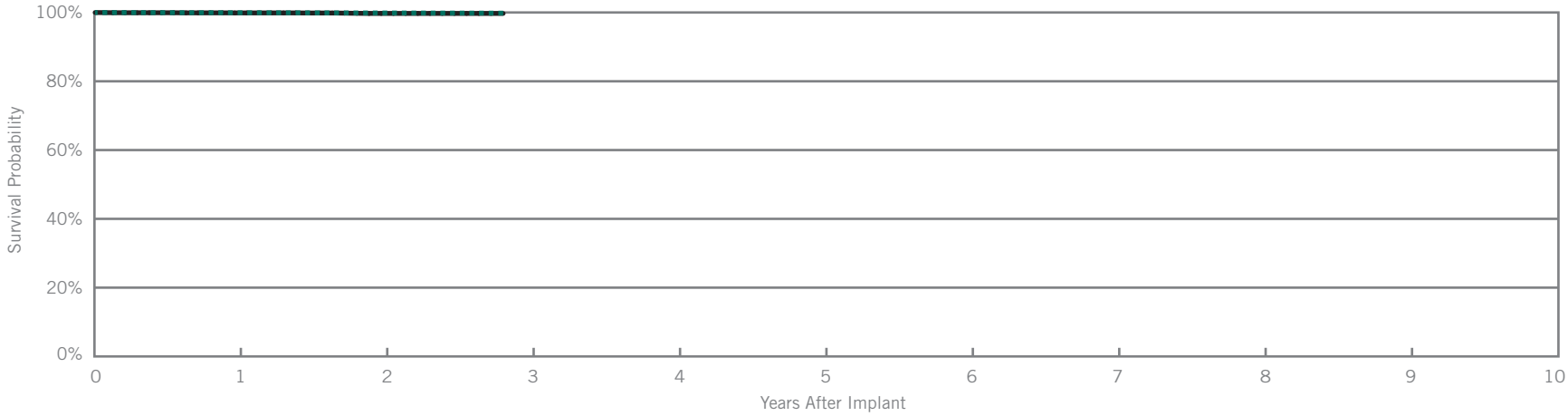
Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Registered US Implants	20,950
Estimated Active US Implants	17,394
Estimated Longevity	10.9 Years
Normal Battery Depletion	5
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	1	<0.01%
Electrical Interconnect	0	0.00%	2	0.01%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	2	0.01%
Possible Early Battery Depletion	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**2**	**0.01%**	**6**	**0.03%**



Including Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.87%	99.72%	99.72%							
± 1 standard error	0.03%	0.06%	0.06%							
Sample Size	17100	7500	400							

Excluding Normal Battery Depletion

Year	1	2	at 34 months							
Survival Probability	99.93%	99.81%	99.81%							
± 1 standard error	0.02%	0.05%	0.05%							

Actively Monitored Study Data

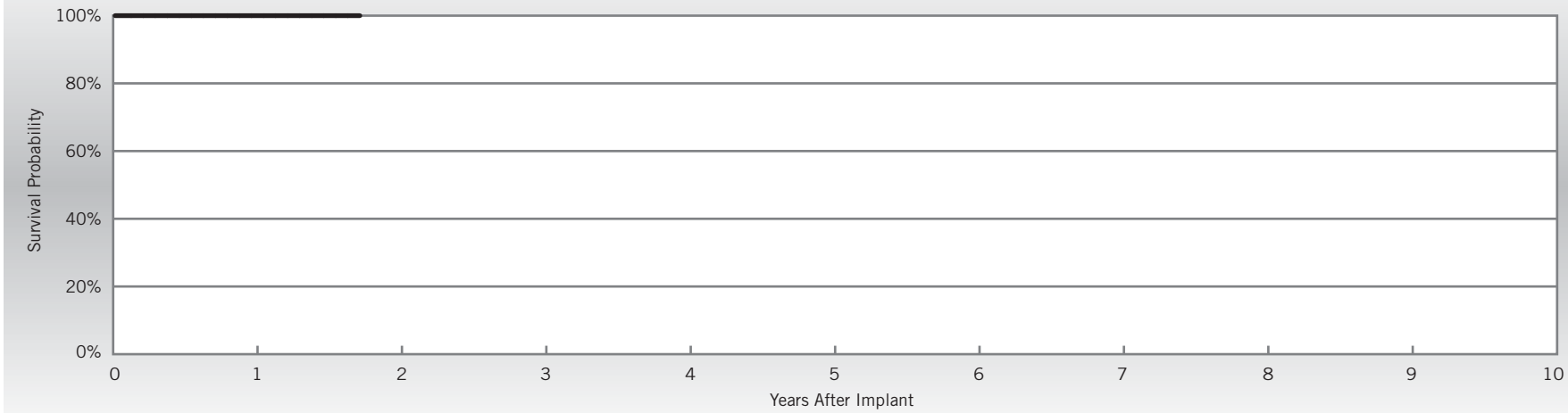
Accent® SR RF

Model PM1210

US Regulatory Approval	July 2009
Number of Devices Enrolled in Study	232
Cumulative Months of Follow-up	3,546
Estimated Longevity	10.9 Years

Qualifying Complications
None Reported

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



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

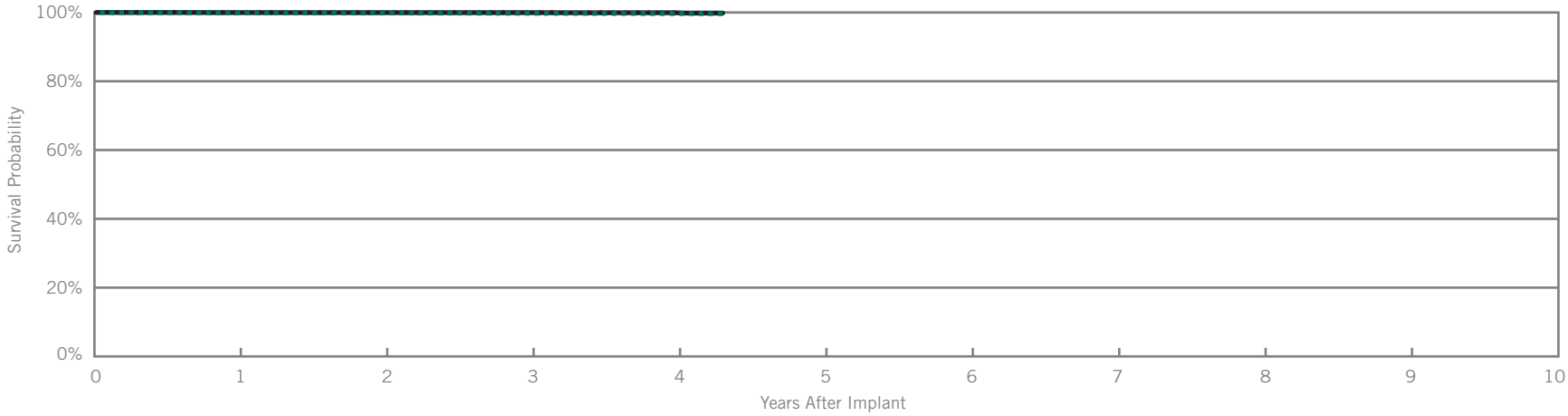
Customer Reported Performance Data

Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Registered US Implants	19,320
Estimated Active US Implants	12,809
Estimated Longevity	15.8 Years
Normal Battery Depletion	7
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	4	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	2	0.01%
Total	**0**	**0.00%**	**6**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4	at 52 months					
Survival Probability	99.96%	99.86%	99.84%	99.76%	99.67%					
± 1 standard error	0.01%	0.03%	0.03%	0.05%	0.08%					
Sample Size	18800	14500	10300	5100	1400					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 52 months					
Survival Probability	99.96%	99.95%	99.95%	99.92%	99.82%					
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.07%					

Actively Monitored Study Data

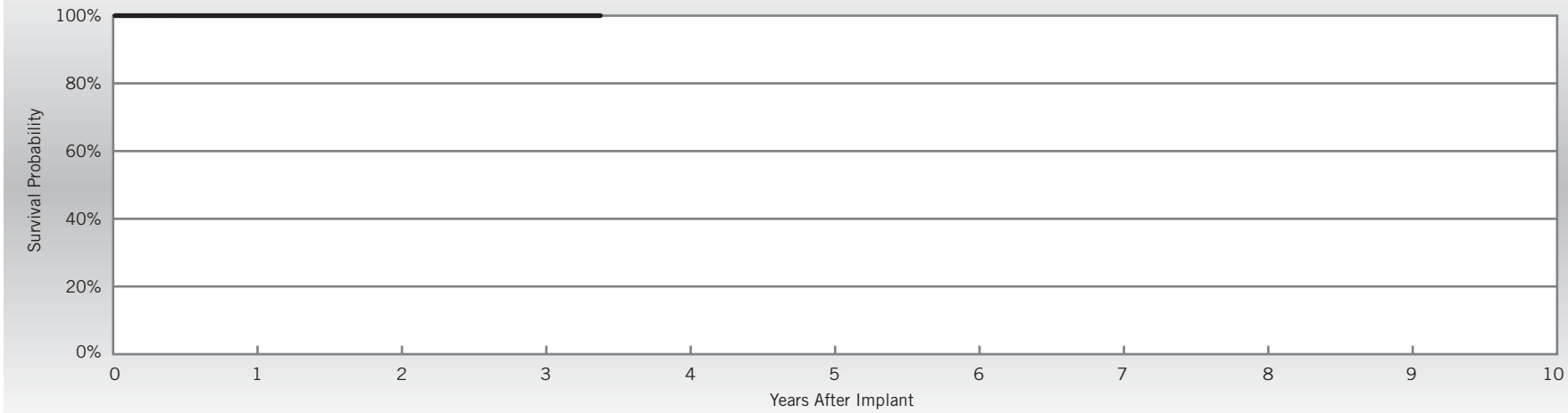
Zephyr® XL SR

Model 5626

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	234
Cumulative Months of Follow-up	6,823
Estimated Longevity	15.8 Years

Qualifying Complications
None Reported

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



Year	1	2	3	at 41 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	220	180	120	50						

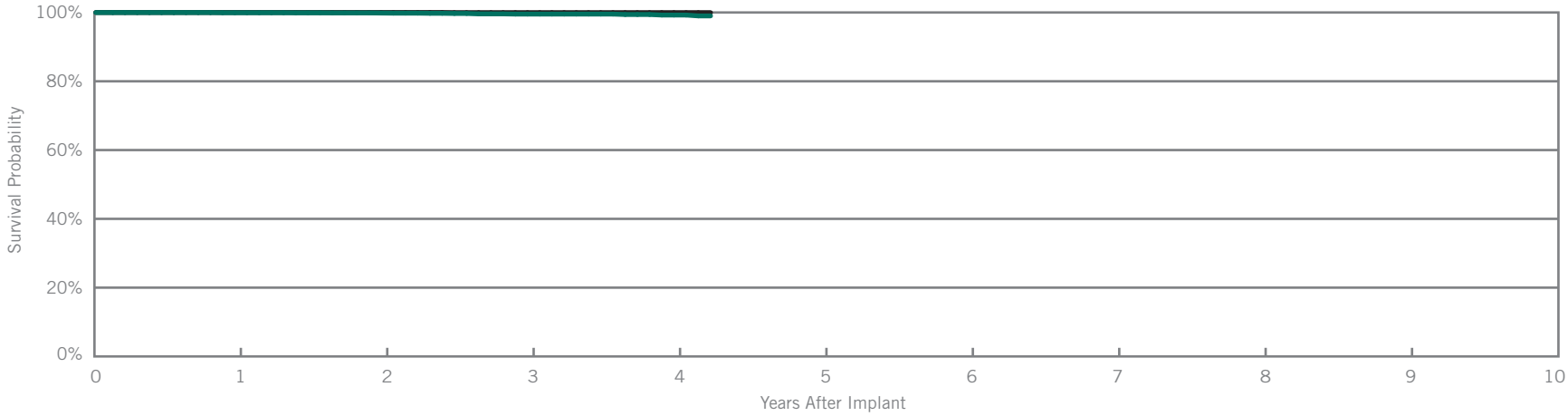
Customer Reported Performance Data

Zephyr® SR

Model 5620

US Regulatory Approval	March 2007
Registered US Implants	12,878
Estimated Active US Implants	8,558
Estimated Longevity	8.8 Years
Normal Battery Depletion	18
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	99.93%	99.83%	99.53%	99.25%	99.00%					
± 1 standard error	0.03%	0.04%	0.10%	0.17%	0.25%					
Sample Size	11800	7600	4600	2200	700					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 51 months					
Survival Probability	100.00%	100.00%	99.96%	99.96%	99.96%					
± 1 standard error	0.00%	0.00%	0.03%	0.03%	0.03%					

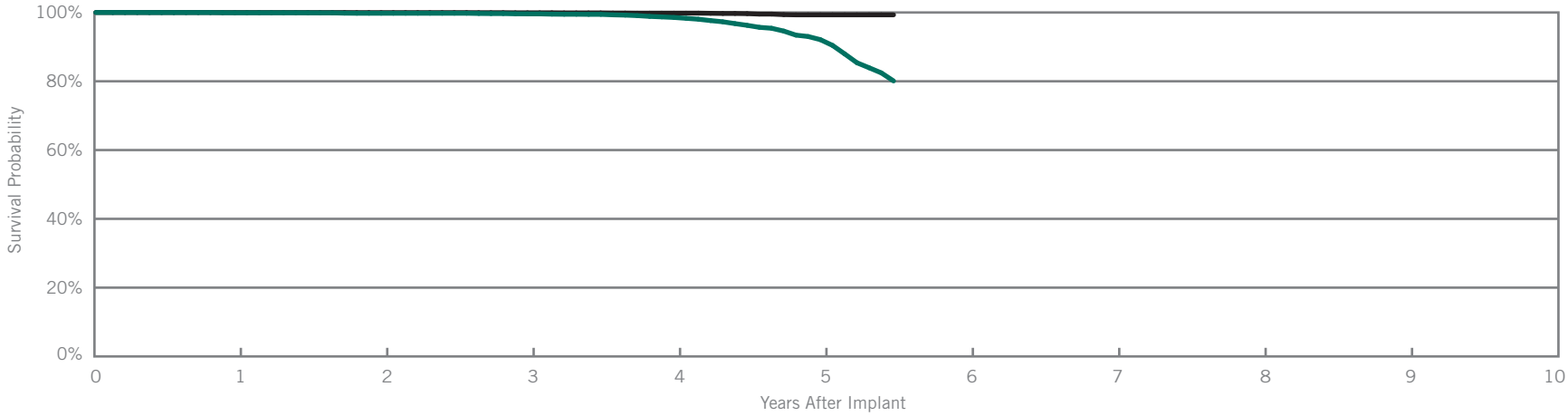
Customer Reported Performance Data

Victory® SR

Model 5610

US Regulatory Approval	December 2005
Registered US Implants	13,593
Estimated Active US Implants	5,811
Estimated Longevity	8.8 Years
Normal Battery Depletion	232
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	13	0.10%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**14**	**0.10%**



Including Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.92%	99.77%	99.59%	98.55%	92.10%	80.09%				
± 1 standard error	0.02%	0.05%	0.07%	0.14%	0.40%	0.78%				
Sample Size	13600	10700	8600	6400	4000	1100				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 66 months				
Survival Probability	99.98%	99.96%	99.91%	99.81%	99.31%	99.31%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.13%	0.13%				

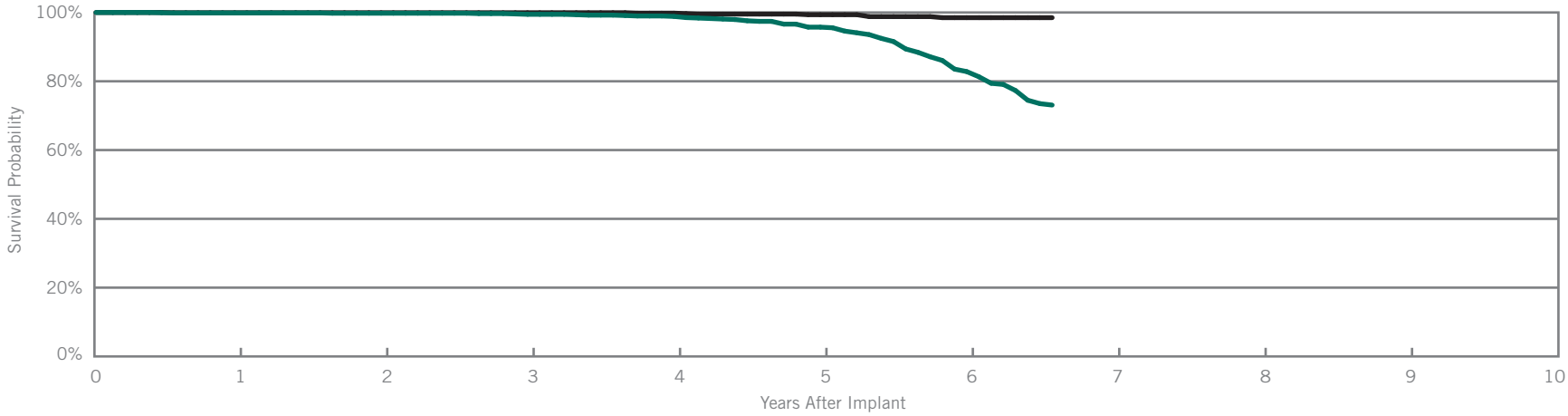
Customer Reported Performance Data

Integrity® ADx SR

Model 5160

US Regulatory Approval	May 2003
Registered US Implants	3,404
Estimated Active US Implants	725
Estimated Longevity	5.7 Years
Normal Battery Depletion	111
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.86%	99.78%	99.46%	98.85%	95.73%	82.81%	73.08%			
± 1 standard error	0.07%	0.09%	0.14%	0.23%	0.54%	1.24%	1.65%			
Sample Size	3400	2600	2200	1800	1400	900	400			

Excluding Normal Battery Depletion

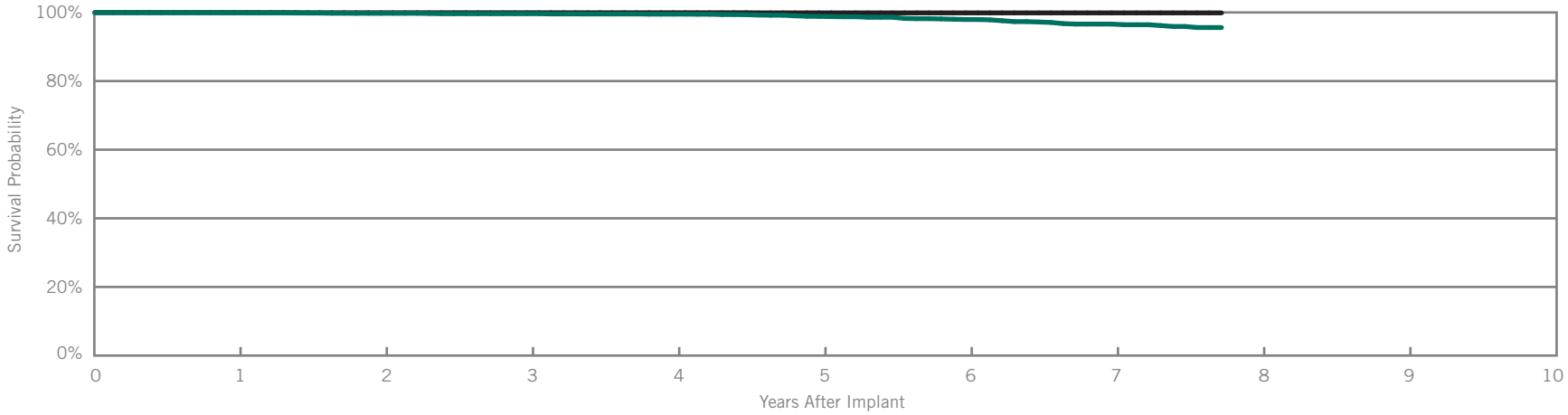
Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.93%	99.93%	99.93%	99.81%	99.35%	98.49%	98.49%			
± 1 standard error	0.05%	0.05%	0.05%	0.10%	0.17%	0.39%	0.39%			

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

US Regulatory Approval	May 2003
Registered US Implants	14,341
Estimated Active US Implants	5,707
Estimated Longevity	10.2 Years
Normal Battery Depletion	55
Number of US Advisories	None

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	0.01%	3	0.02%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	0	0.00%	1	0.01%
Total	**1**	**0.01%**	**5**	**0.03%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.87%	99.74%	99.63%	99.50%	98.84%	97.94%	96.61%	95.60%		
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.14%	0.22%	0.35%	0.50%		
Sample Size	14200	11300	9300	7400	5300	3300	1700	500		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 93 months		
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.87%	99.87%	99.87%	99.87%		
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%	0.04%		

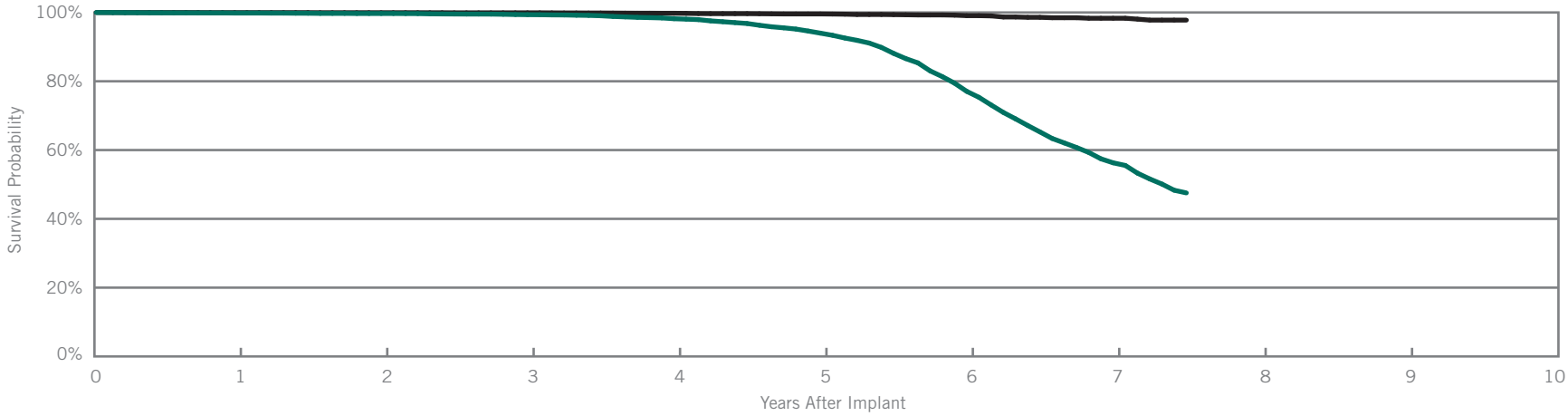
Customer Reported Performance Data

Integrity® ADx SR

Model 5180

US Regulatory Approval	May 2003
Registered US Implants	20,770
Estimated Active US Implants	5,413
Estimated Longevity	5.7 Years
Normal Battery Depletion	830
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	31	0.15%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	0	0.00%
Total	**0**	**0.00%**	**40**	**0.19%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.83%	99.70%	99.36%	98.18%	93.99%	77.06%	56.29%	47.54%		
± 1 standard error	0.03%	0.04%	0.07%	0.12%	0.25%	0.55%	0.86%	1.05%		
Sample Size	20600	16200	13300	10700	8100	5400	2500	500		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 90 months		
Survival Probability	99.96%	99.94%	99.91%	99.77%	99.57%	99.07%	98.32%	97.78%		
± 1 standard error	0.02%	0.02%	0.02%	0.05%	0.07%	0.11%	0.23%	0.35%		

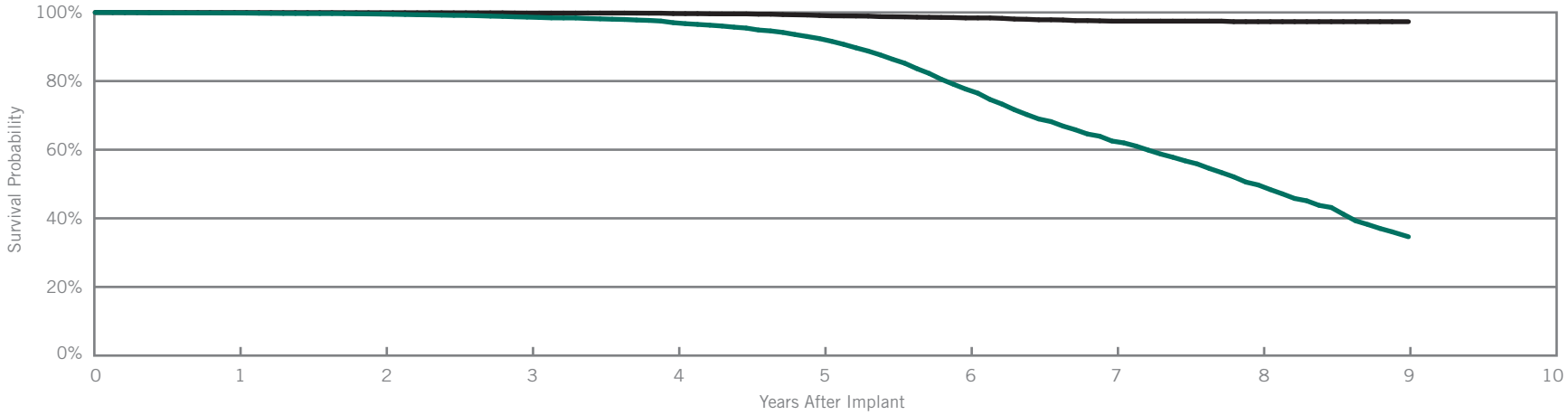
Identity® SR

Model 5172

US Regulatory Approval	November 2001
Registered US Implants	21,938
Estimated Active US Implants	2,362
Estimated Longevity	7.8 Years
Normal Battery Depletion	1,229
Number of US Advisories (see pgs. 248-260)	One

Customer Reported Performance Data

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	1	<0.01%	63	0.29%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	0	0.00%
Possible Early Battery Depletion	0	0.00%	8	0.04%
Other	0	0.00%	1	<0.01%
Total	**1**	**<0.01%**	**72**	**0.33%**



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.83%	99.53%	98.64%	97.02%	92.38%	77.67%	62.53%	49.73%	35.18%	
± 1 standard error	0.03%	0.05%	0.09%	0.14%	0.25%	0.47%	0.63%	0.79%	0.99%	
Sample Size	21900	17500	14700	12400	10000	7500	4200	2100	900	

Excluding Normal Battery Depletion

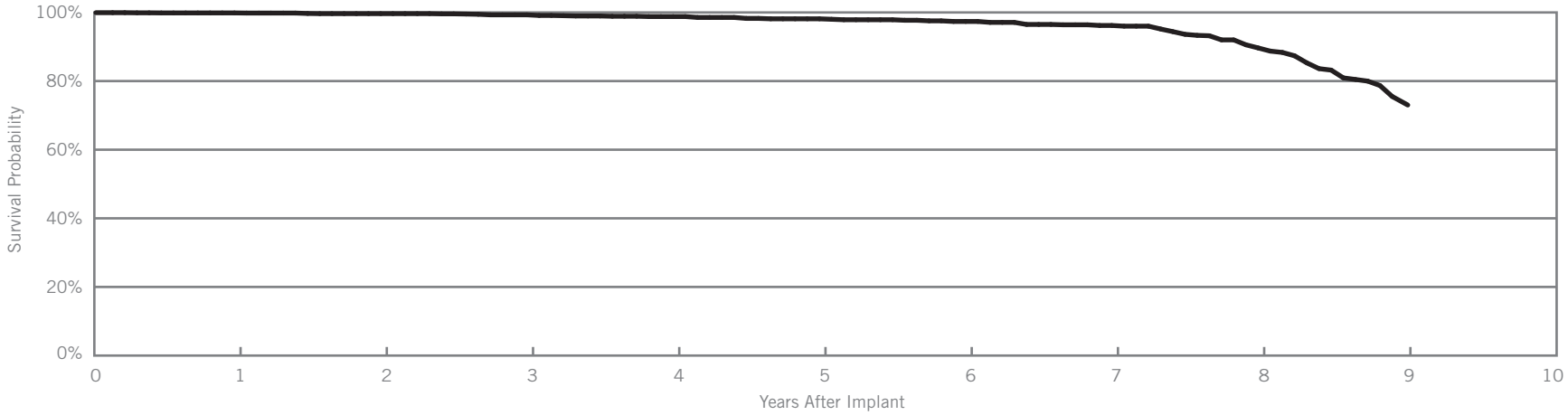
Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.97%	99.92%	99.82%	99.67%	99.12%	98.40%	97.46%	97.31%	97.31%	
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.09%	0.14%	0.22%	0.25%	0.25%	

Customer Reported Performance Data

Microny®

Models 2425T, 2525T & 2535K

US Regulatory Approval	April 2001
Registered US Implants	7,110
Estimated Longevity	7.5 Years
Number of US Advisories	None



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.86%	99.65%	99.30%	98.80%	98.14%	97.37%	96.20%	89.66%	73.35%	
± 1 standard error	0.05%	0.08%	0.13%	0.19%	0.27%	0.36%	0.56%	1.02%	1.89%	
Sample Size	6900	4700	3600	2700	2000	1400	1000	700	400	

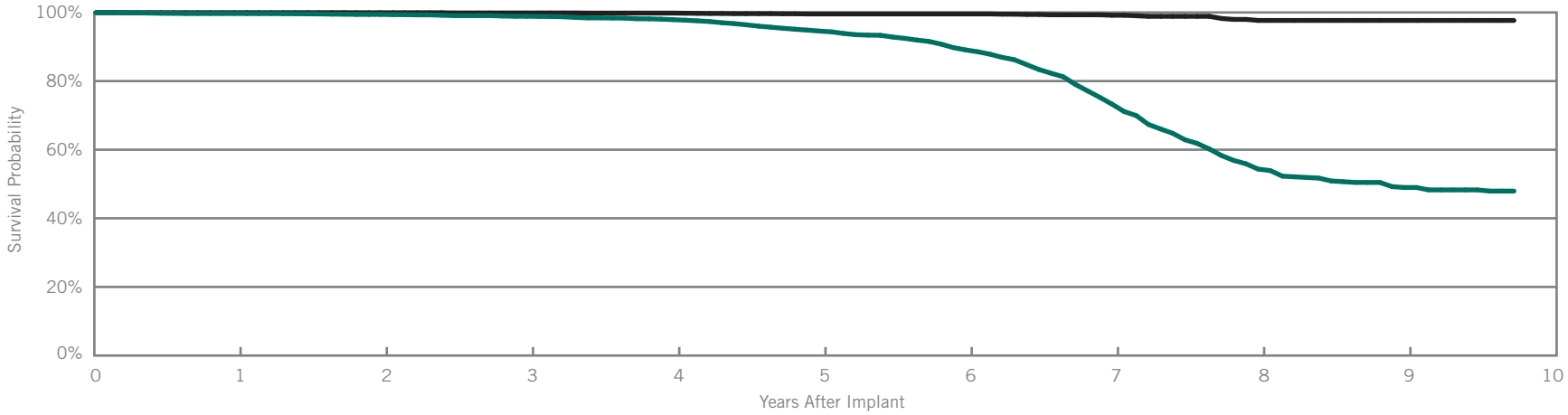
Customer Reported Performance Data

Integrity® µ SR

Model 5136

US Regulatory Approval	December 2000
Registered US Implants	11,980
Estimated Active US Implants	581
Estimated Longevity	5.3 Years
Normal Battery Depletion	489
Number of US Advisories	None

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



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.68%	99.42%	98.88%	97.89%	94.57%	89.08%	73.30%	54.35%	48.98%	47.94%
± 1 standard error	0.05%	0.08%	0.12%	0.17%	0.30%	0.46%	0.79%	1.14%	1.26%	1.30%
Sample Size	11900	9300	7800	6500	5300	4100	2900	1400	600	300

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 117 months
Survival Probability	99.94%	99.92%	99.85%	99.81%	99.56%	99.56%	99.18%	97.67%	97.67%	97.67%
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.09%	0.09%	0.13%	0.41%	0.46%	0.46%

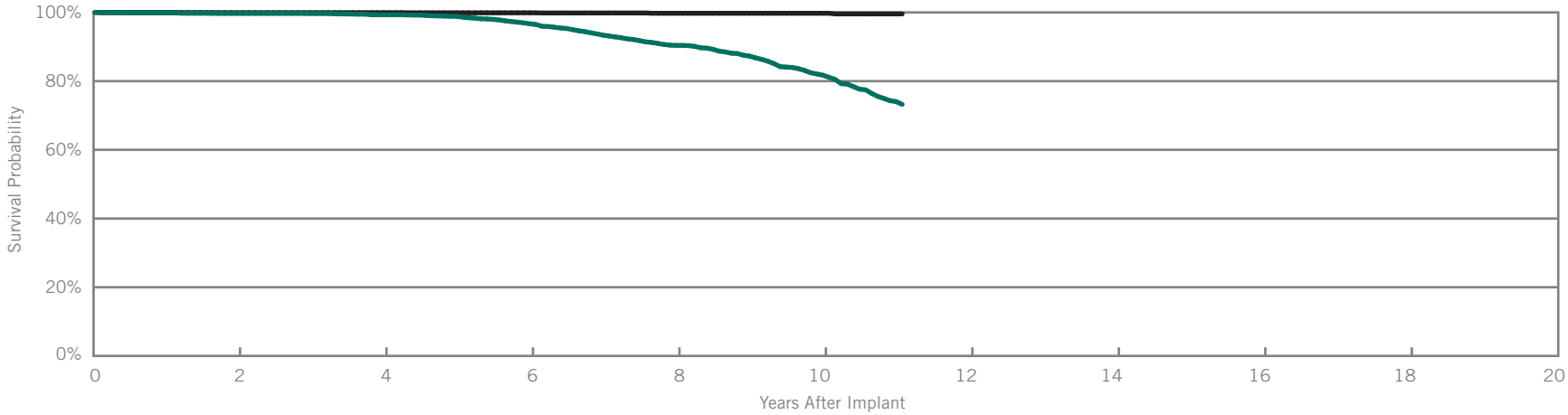
Customer Reported Performance Data

Integrity® SR

Model 5142

US Regulatory Approval	April 2000
Registered US Implants	10,512
Estimated Active US Implants	1,507
Estimated Longevity	8.6 Years
Normal Battery Depletion	258
Number of US Advisories	None

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	4	0.04%
Electrical Interconnect	0	0.00%	0	0.00%
Battery	0	0.00%	0	0.00%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	0.01%
Possible Early Battery Depletion	0	0.00%	1	0.01%
Other	1	0.01%	0	0.00%
Total	**1**	**0.01%**	**6**	**0.06%**



Including Normal Battery Depletion

Year	2	4	6	8	10	at 133 months				
Survival Probability	99.71%	99.31%	96.69%	90.40%	81.72%	73.24%				
± 1 standard error	0.06%	0.10%	0.25%	0.49%	0.79%	1.10%				
Sample Size	8600	6300	4500	3000	1600	500				

Excluding Normal Battery Depletion

Year	2	4	6	8	10	at 133 months				
Survival Probability	99.93%	99.93%	99.89%	99.76%	99.76%	99.57%				
± 1 standard error	0.03%	0.03%	0.04%	0.08%	0.08%	0.16%				

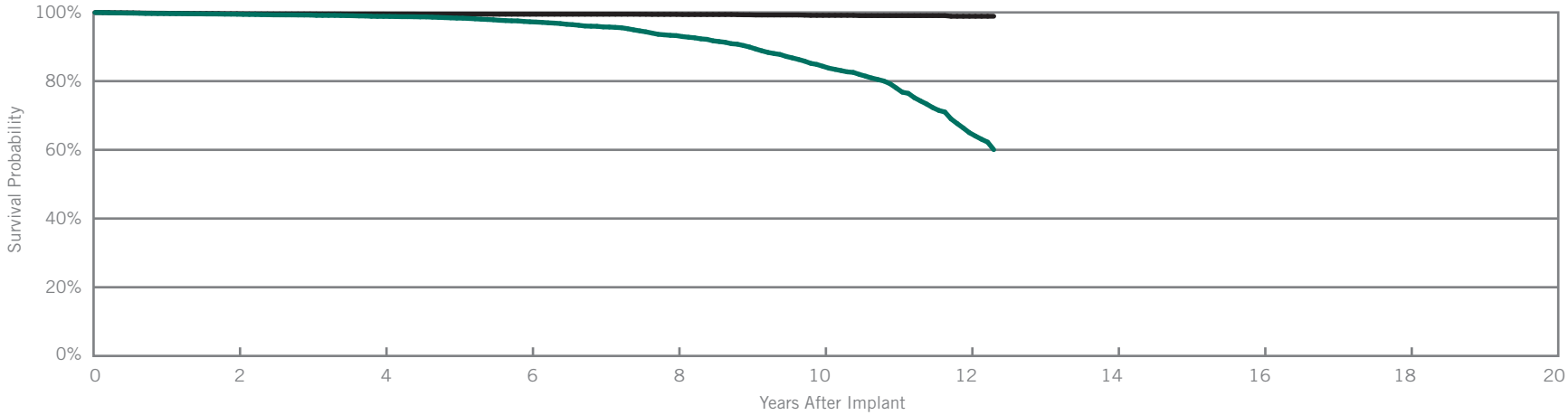
Customer Reported Performance Data

Affinity® SR

Models 5130 & 5131

US Regulatory Approval	(5130) January 1999 (5131) June 1999
Registered US Implants	28,720
Estimated Active US Implants	2,807
Estimated Longevity	8.6 Years
Normal Battery Depletion	613
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions w/ Compromised Therapy		Malfunctions w/o Compromised Therapy	
	Qty	Rate	Qty	Rate
Electrical Component	0	0.00%	45	0.16%
Electrical Interconnect	3	0.01%	2	0.01%
Battery	0	0.00%	3	0.01%
Software/Firmware	0	0.00%	0	0.00%
Mechanical	0	0.00%	1	<0.01%
Possible Early Battery Depletion	0	0.00%	0	0.00%
Other	1	<0.01%	3	0.01%
Total	**4**	**0.01%**	**54**	**0.19%**



Including Normal Battery Depletion

Year	2	4	6	8	10	12	at 148 months			
Survival Probability	99.48%	98.85%	97.28%	93.25%	84.32%	65.00%	60.05%			
± 1 standard error	0.05%	0.08%	0.14%	0.26%	0.47%	0.92%	1.04%			
Sample Size	22900	16300	11300	7600	4200	1600	600			

Excluding Normal Battery Depletion

Year	2	4	6	8	10	12	at 148 months			
Survival Probability	99.63%	99.53%	99.48%	99.43%	99.15%	98.89%	98.89%			
± 1 standard error	0.04%	0.05%	0.05%	0.06%	0.10%	0.17%	0.17%			

Summary Information

Single-Chamber Pacemakers

St. Jude Medical™
More control. Less risk.

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1110	Accent® SR	100.00%	100.00%								
PM1210	Accent® SR RF	99.87%	99.72%								
5626	Zephyr® XL SR	99.96%	99.86%	99.84%	99.76%						
5620	Zephyr® SR	99.93%	99.83%	99.53%	99.25%						
5610	Victory® SR	99.92%	99.77%	99.59%	98.55%	92.10%					
5160	Integrity® ADx SR	99.86%	99.78%	99.46%	98.85%	95.73%	82.81%				
5156/5157/5056	Verity® ADx XL SR/SR(M/S) / SC	99.87%	99.74%	99.63%	99.50%	98.84%	97.94%	96.61%			
5180	Integrity® ADx SR	99.83%	99.70%	99.36%	98.18%	93.99%	77.06%	56.29%			
5172	Identity® SR	99.83%	99.53%	98.64%	97.02%	92.38%	77.67%	62.53%	49.73%	35.18%	
5136	Integrity® µ SR	99.68%	99.42%	98.88%	97.89%	94.57%	89.08%	73.30%	54.35%	48.98%	
5142	Integrity® SR	99.85%	99.71%	99.68%	99.31%	98.85%	96.69%	93.37%	90.40%	87.28%	81.72%
5130/5131	Affinity® SR	99.69%	99.48%	99.24%	98.85%	98.35%	97.28%	95.78%	93.25%	89.92%	84.32%

Survival Summary

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
PM1110	Accent® SR	100.00%	100.00%								
PM1210	Accent® SR RF	99.93%	99.81%								
5626	Zephyr® XL SR	99.96%	99.95%	99.95%	99.92%						
5620	Zephyr® SR	100.00%	100.00%	99.96%	99.96%						
5610	Victory® SR	99.98%	99.96%	99.91%	99.81%	99.31%					
5160	Integrity® ADx SR	99.93%	99.93%	99.93%	99.81%	99.35%	98.49%				
5156/5157/5056	Verity® ADx XL SR/SR(M/S) / SC	99.96%	99.91%	99.91%	99.91%	99.87%	99.87%	99.87%			
5180	Integrity® ADx SR	99.96%	99.94%	99.91%	99.77%	99.57%	99.07%	98.32%			
5172	Identity® SR	99.97%	99.92%	99.82%	99.67%	99.12%	98.40%	97.46%	97.31%	97.31%	
5136	Integrity® µ SR	99.94%	99.92%	99.85%	99.81%	99.56%	99.56%	99.18%	97.67%	97.67%	
5142	Integrity® SR	99.98%	99.93%	99.93%	99.93%	99.89%	99.89%	99.84%	99.76%	99.76%	99.76%
5130/5131	Affinity® SR	99.78%	99.63%	99.57%	99.53%	99.50%	99.48%	99.48%	99.43%	99.31%	99.15%

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions w/ Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1110	Accent® SR	6633	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent® SR RF	20950	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	**2**	**0.01%**
5626	Zephyr® XL SR	19320	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5620	Zephyr® SR	12878	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5610	Victory® SR	13593	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
5160	Integrity® ADx SR	3404	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5356/5357/5256	Verity® ADx XL SR/SR(M/S) / SC	14341	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5180	Integrity® ADx SR	20770	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5172	Identity® SR	21938	1	<0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**<0.01%**
5136	Integrity® µ SR	11980	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
5142	Integrity® SR	10512	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**1**	**0.01%**
5130/5131	Affinity® SR	28720	0	0.00%	3	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	**4**	**0.01%**

Models	Family	Registered US Implants	Malfunctions w/o Compromised Therapy															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
PM1110	Accent® SR	6633	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
PM1210	Accent® SR RF	20950	1	<0.01%	2	0.01%	0	0.00%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	**6**	**0.03%**
5626	Zephyr® XL SR	19320	4	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**6**	**0.03%**
5620	Zephyr® SR	12878	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.01%**
5610	Victory® SR	13593	13	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	**14**	**0.10%**
5160	Integrity® ADx SR	3404	7	0.21%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	**8**	**0.24%**
5356/5357/5256	Verity® ADx XL SR/SR(M/S) / SC	14341	3	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	1	0.01%	**5**	**0.03%**
5180	Integrity® ADx SR	20770	31	0.15%	0	0.00%	0	0.00%	0	0.00%	1	<0.01%	8	0.04%	0	0.00%	**40**	**0.19%**
5172	Identity® SR	21938	63	0.29%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.04%	1	<0.01%	**72**	**0.33%**
5136	Integrity® µ SR	11980	22	0.18%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**23**	**0.19%**
5142	Integrity® SR	10512	4	0.04%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	**6**	**0.06%**
5130/5131	Affinity® SR	28720	45	0.16%	2	0.01%	3	0.01%	0	0.00%	1	<0.01%	0	0.00%	3	0.01%	**54**	**0.19%**

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

Pacing Leads

Customer Reported Performance Data

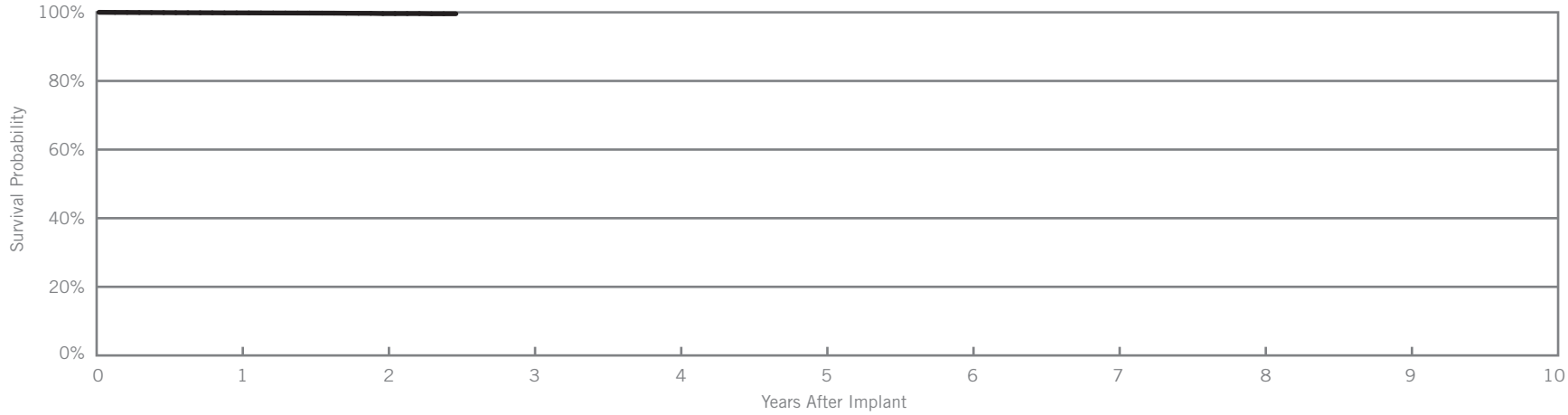
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Registered US Implants	139,828
Estimated Active US Implants	119,920
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	20	0.01%	3	<0.01%
Conductor Fracture	0	0.00%	2	<0.01%
Lead Dislodgement	91	0.07%	60	0.04%
Failure to Capture	10	0.01%	43	0.03%
Oversensing	3	<0.01%	39	0.03%
Failure to Sense	2	<0.01%	8	0.01%
Insulation Breach	2	<0.01%	9	0.01%
Abnormal Pacing Impedance	3	<0.01%	9	0.01%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	3	<0.01%	9	0.01%
Total	**134**	**0.10%**	**183**	**0.13%**
Total Returned for Analysis	**84**		**143**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	38	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	8	0.01%
Extrinsic Factors	123	0.09%
Total	**172**	**0.12%**



Year	1	2	at 30 months							
Survival Probability	99.84%	99.63%	99.58%							
± 1 standard error	0.01%	0.03%	0.06%							
Sample Size	106600	35000	500							

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

Actively Monitored Study Data

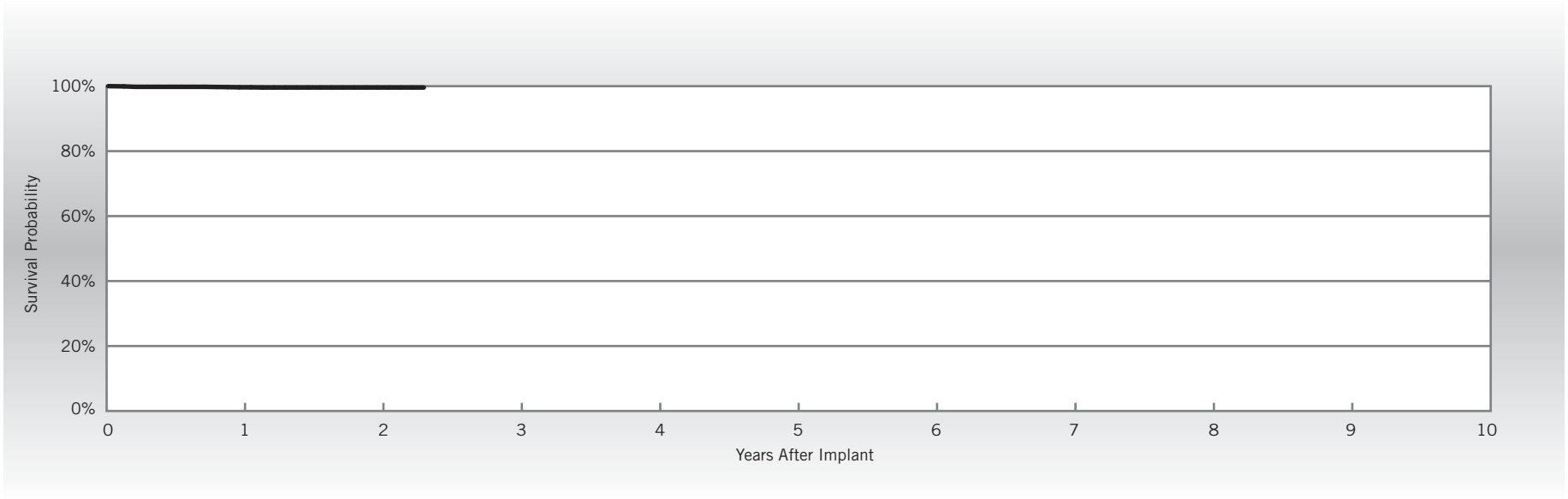
Tendril® STS

Model 2088TC

US Regulatory Approval	May 2009
Number of Devices Enrolled in Study	2,963
Cumulative Months of Follow-up	44,963
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	1	0.03%
Cardiac Perforation	1	0.03%
Failure to Capture	1	0.03%
Failure to Sense	1	0.03%
Insulation Breach	1	0.03%
Lead Dislodgement	5	0.17%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.07%
Total	**4**	**0.13%**



Year	1	2	at 28 months							
Survival Probability	99.64%	99.58%	99.58%							
± 1 standard error	0.11%	0.14%	0.14%							
Sample Size	2410	1100	60							

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

Customer Reported Performance Data

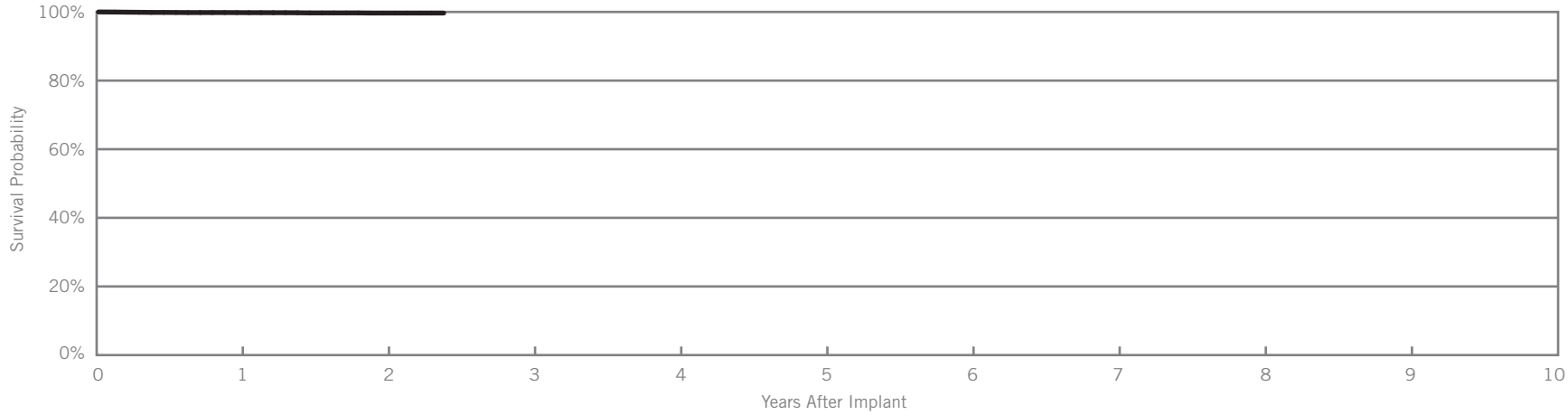
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Registered US Implants	17,063
Estimated Active US Implants	14,482
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	8	0.05%	21	0.12%
Failure to Capture	2	0.01%	8	0.05%
Oversensing	1	0.01%	2	0.01%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**11**	**0.06%**	**31**	**0.18%**
Total Returned for Analysis	**5**		**23**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	2	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.01%
Extrinsic Factors	21	0.12%
Total	**25**	**0.15%**



Year	1	2	at 29 months							
Survival Probability	99.81%	99.68%	99.68%							
± 1 standard error	0.04%	0.07%	0.07%							
Sample Size	13600	5100	200							

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

Actively Monitored Study Data

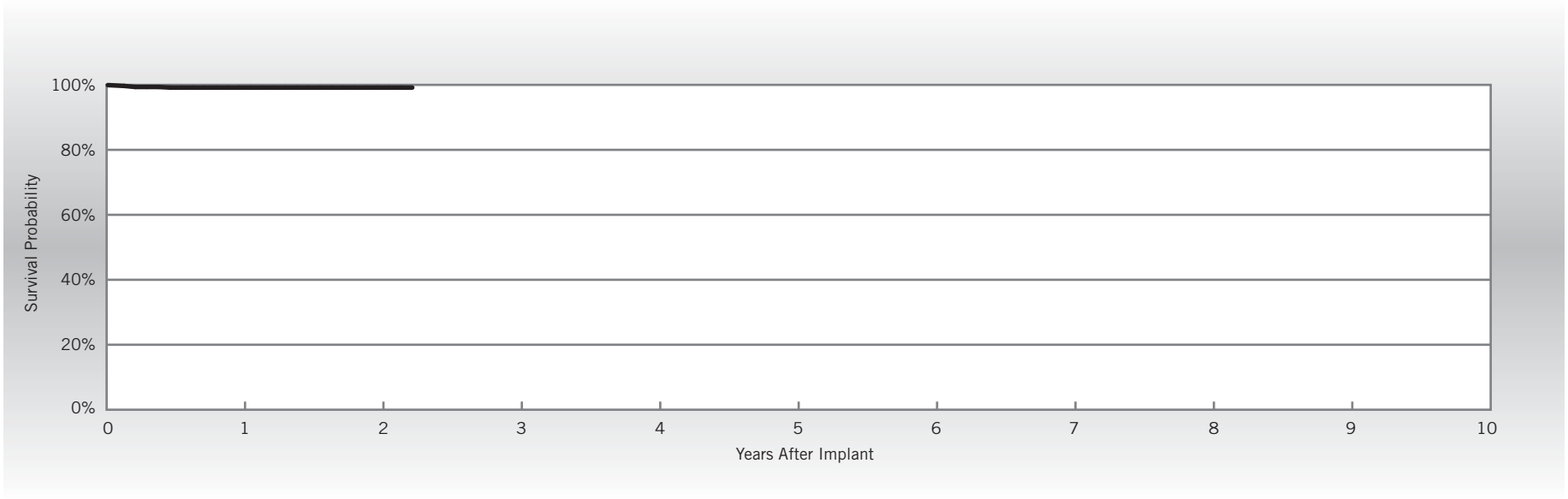
OptiSense®

Model 1999

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	643
Cumulative Months of Follow-up	9,524
Insulation	Optim®*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	5	0.78%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	0.47%
Total	**5**	**0.78%**



Year	1	2	at 27 months							
Survival Probability	99.17%	99.17%	99.17%							
± 1 standard error	0.37%	0.37%	0.37%							
Sample Size	510	230	50							

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

Customer Reported Performance Data

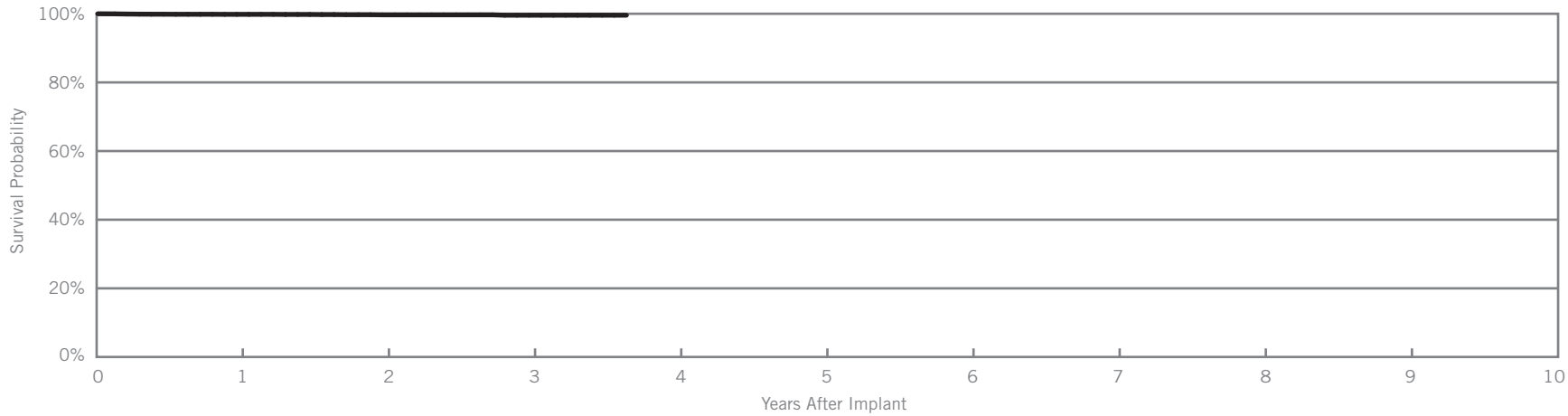
IsoFlex® Optim®

Model 1944

US Regulatory Approval	March 2008
Registered US Implants	7,365
Estimated Active US Implants	5,576
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	16	0.22%	10	0.14%
Failure to Capture	3	0.04%	1	0.01%
Oversensing	0	0.00%	1	0.01%
Failure to Sense	2	0.03%	1	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	0	0.00%	1	0.01%
Total	**21**	**0.29%**	**15**	**0.20%**
Total Returned for Analysis	**13**		**7**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.08%
Total	**7**	**0.10%**



Year	1	2	3	at 44 months						
Survival Probability	99.83%	99.69%	99.58%	99.58%						
± 1 standard error	0.05%	0.08%	0.14%	0.14%						
Sample Size	6300	3400	1500	200						

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

Customer Reported Performance Data

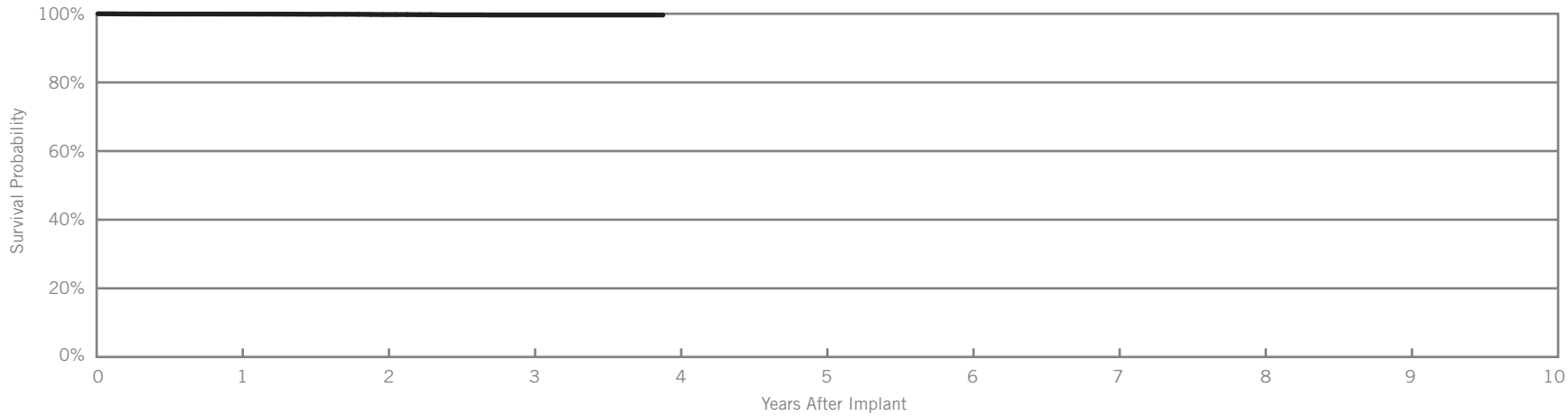
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Registered US Implants	25,204
Estimated Active US Implants	19,508
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	1	<0.01%
Conductor Fracture	0	0.00%	7	0.03%
Lead Dislodgement	15	0.06%	7	0.03%
Failure to Capture	5	0.02%	6	0.02%
Oversensing	0	0.00%	4	0.02%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	1	<0.01%	1	<0.01%
Abnormal Pacing Impedance	0	0.00%	5	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	0	0.00%
Total	**22**	**0.09%**	**31**	**0.12%**
Total Returned for Analysis	**16**		**14**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	7	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	1	<0.01%
Extrinsic Factors	13	0.05%
Total	**21**	**0.08%**



Year	1	2	3	at 47 months						
Survival Probability	99.91%	99.77%	99.64%	99.64%						
± 1 standard error	0.02%	0.04%	0.07%	0.07%						
Sample Size	21300	11600	5000	200						

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

Actively Monitored Study Data

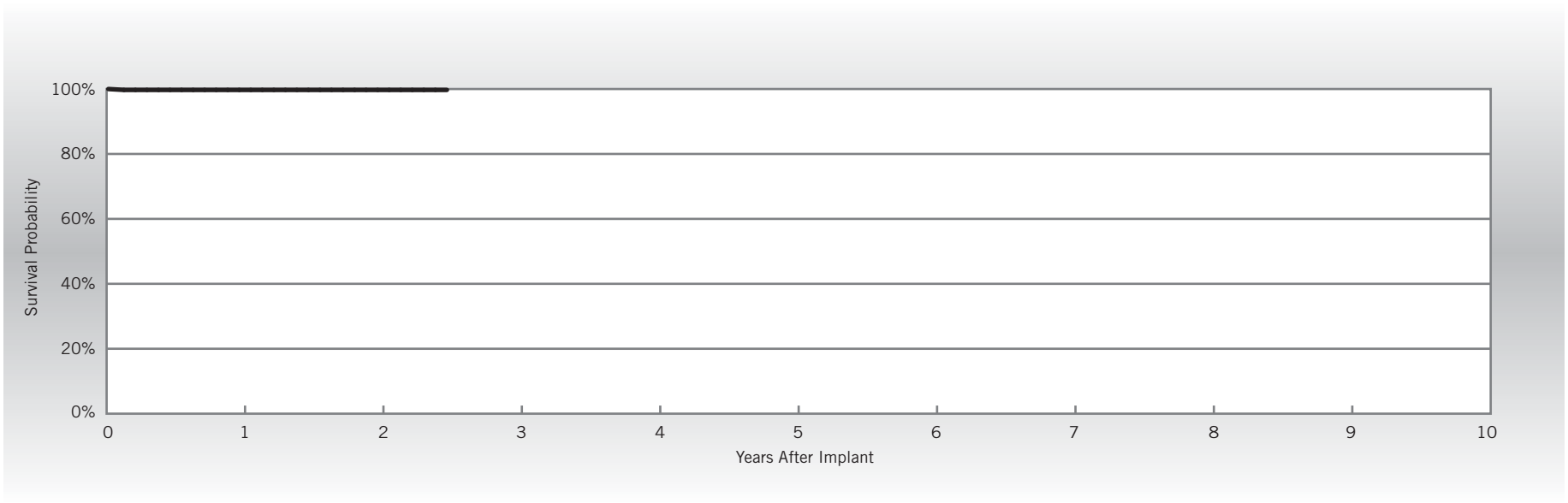
IsoFlex® Optim®

Model 1948

US Regulatory Approval	March 2008
Number of Devices Enrolled in Study	385
Cumulative Months of Follow-up	6,694
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	1	0.26%

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



Year	1	2	at 30 months							
Survival Probability	99.73%	99.73%	99.73%							
± 1 standard error	0.27%	0.27%	0.27%							
Sample Size	320	170	60							

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

Customer Reported Performance Data

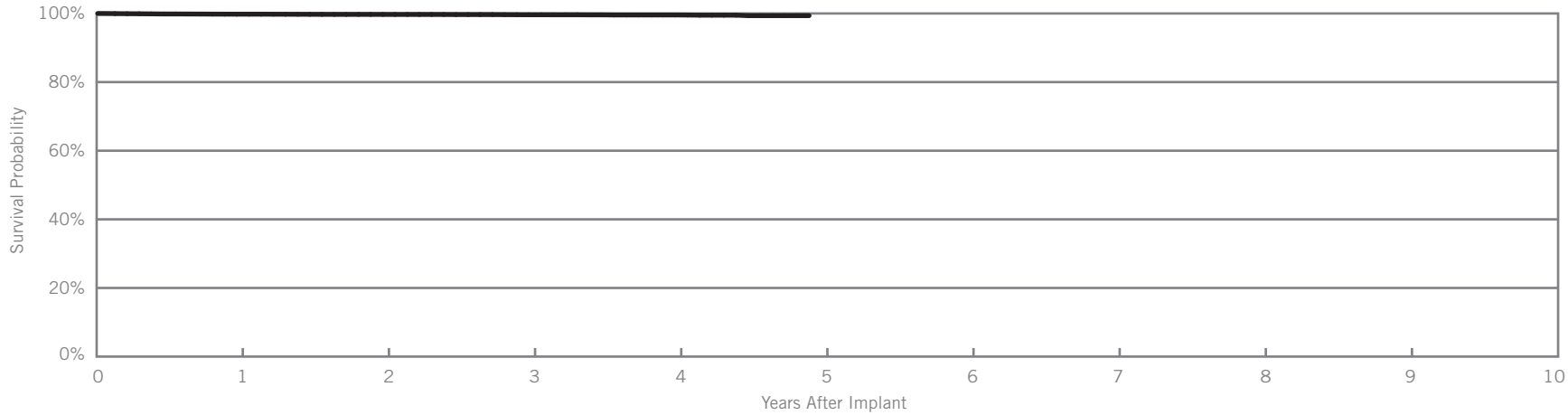
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Registered US Implants	23,262
Estimated Active US Implants	15,755
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	1	<0.01%	0	0.00%
Conductor Fracture	0	0.00%	5	0.02%
Lead Dislodgement	4	0.02%	22	0.09%
Failure to Capture	3	0.01%	12	0.05%
Oversensing	2	0.01%	8	0.03%
Failure to Sense	8	0.03%	6	0.03%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	4	0.02%
Extracardiac Stimulation	0	0.00%	2	0.01%
Other	2	0.01%	0	0.00%
Total	**20**	**0.09%**	**59**	**0.25%**
Total Returned for Analysis	**16**		**39**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	6	0.03%
Insulation Breach	7	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	33	0.14%
Total	**46**	**0.20%**



Year	1	2	3	4	at 59 months					
Survival Probability	99.79%	99.72%	99.62%	99.56%	99.36%					
± 1 standard error	0.03%	0.04%	0.05%	0.05%	0.12%					
Sample Size	22900	19100	14000	7400	200					

Actively Monitored Study Data

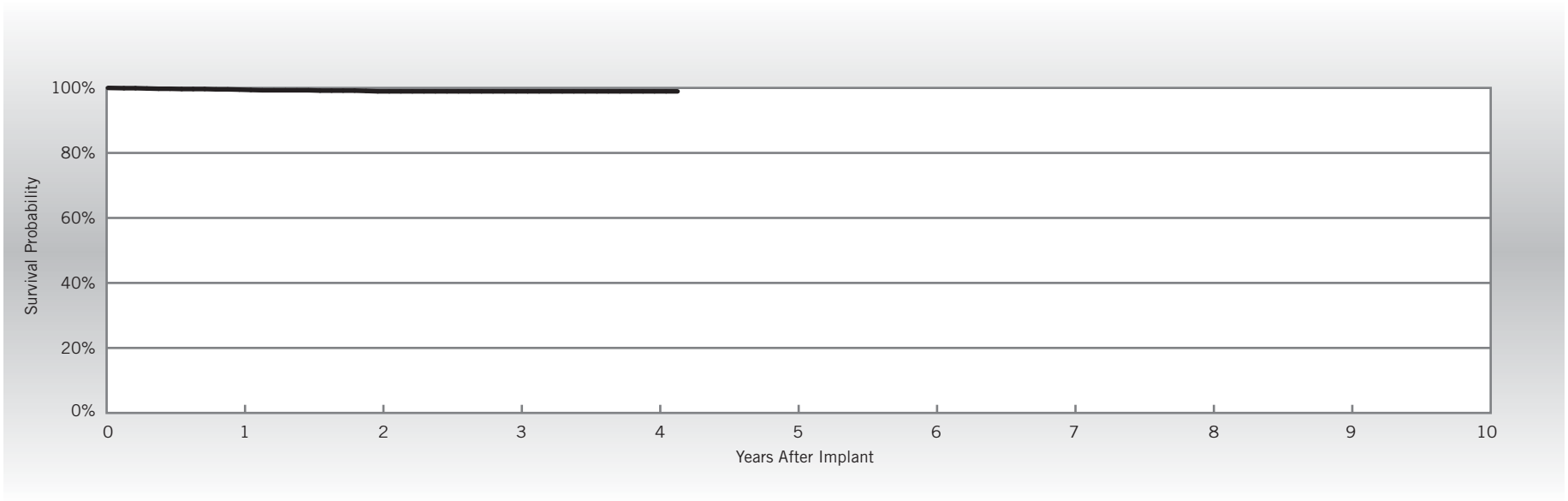
OptiSense®

Models 1699T & 1699TC

US Regulatory Approval	May 2007
Number of Devices Enrolled in Study	1,214
Cumulative Months of Follow-up	36,231
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	2	0.16%
Conductor Fracture	1	0.08%
Failure to Capture	2	0.16%
Lead Dislodgement	5	0.41%
Oversensing	1	0.08%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.33%
Total	**5**	**0.41%**



Year	1	2	3	4	at 50 months					
Survival Probability	99.47%	98.94%	98.94%	98.94%	98.94%					
± 1 standard error	0.20%	0.30%	0.32%	0.32%	0.32%					
Sample Size	1130	950	620	240	50					

Customer Reported Performance Data

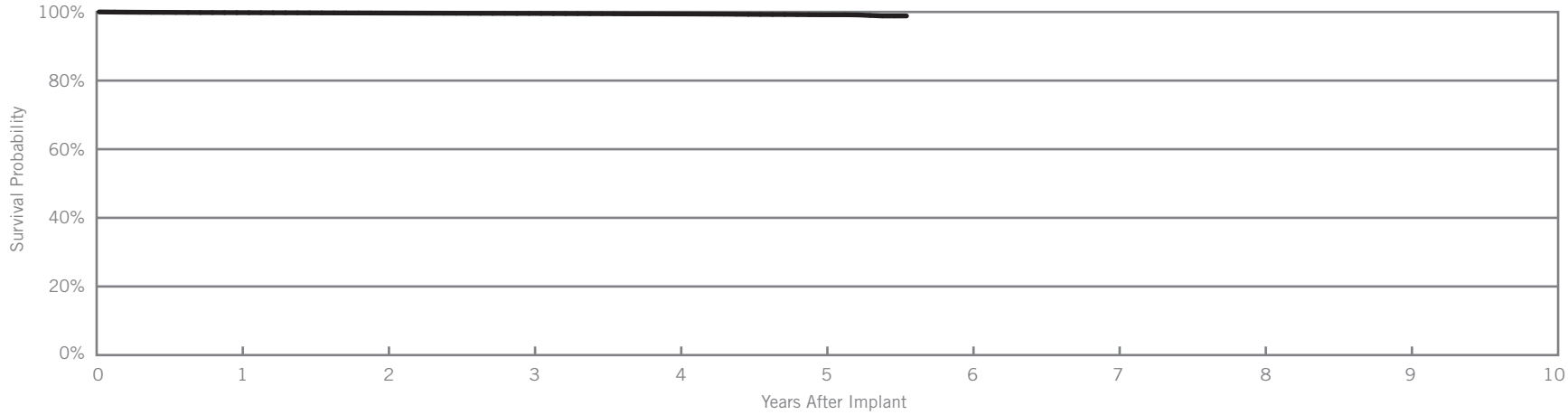
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Registered US Implants	247,362
Estimated Active US Implants	172,144
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	30	0.01%	21	0.01%
Conductor Fracture	6	<0.01%	37	0.01%
Lead Dislodgement	103	0.04%	211	0.09%
Failure to Capture	69	0.03%	150	0.06%
Oversensing	10	<0.01%	141	0.06%
Failure to Sense	8	<0.01%	17	0.01%
Insulation Breach	5	<0.01%	37	0.01%
Abnormal Pacing Impedance	6	<0.01%	26	0.01%
Extracardiac Stimulation	3	<0.01%	9	<0.01%
Other	17	0.01%	32	0.01%
Total	**257**	**0.10%**	**681**	**0.28%**
Total Returned for Analysis	**121**		**425**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	15	0.01%
Insulation Breach	153	0.06%
Crimps, Welds & Bonds	1	<0.01%
Other	5	<0.01%
Extrinsic Factors	330	0.13%
Total	**504**	**0.20%**



Year	1	2	3	4	5	at 67 months				
Survival Probability	99.80%	99.68%	99.57%	99.42%	99.19%	98.84%				
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.05%	0.20%				
Sample Size	233800	168900	109100	54000	18000	300				

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

Actively Monitored Study Data

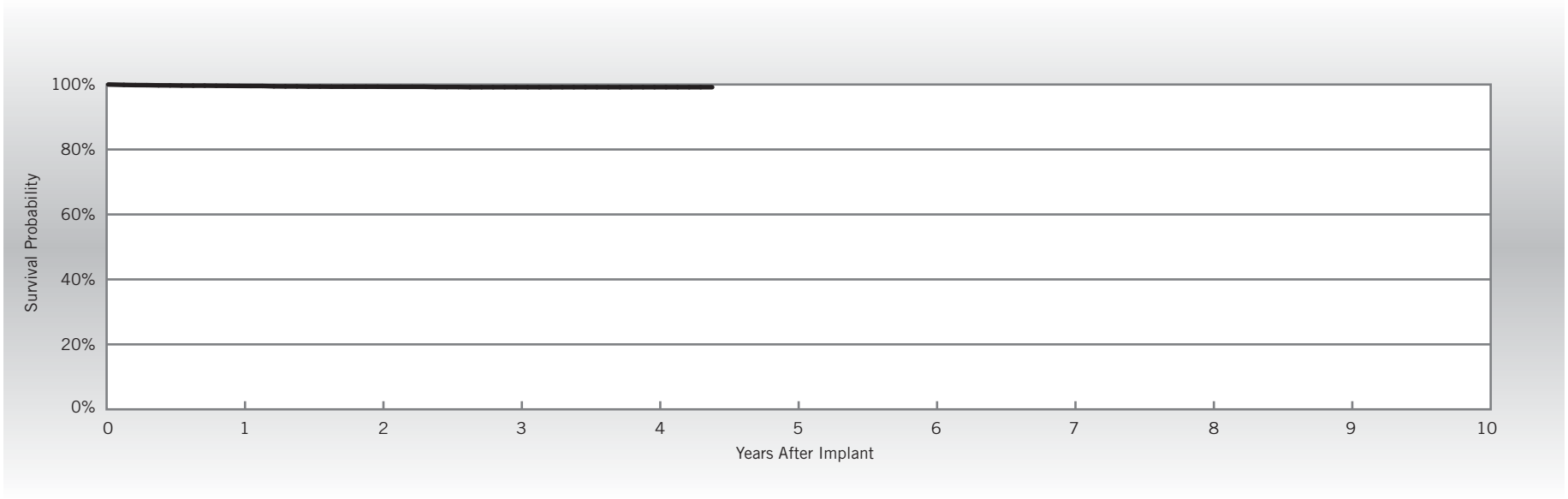
Tendril® ST Optim®

Models 1888T & 1888TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	5,137
Cumulative Months of Follow-up	138,157
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	2	0.04%
Failure to Capture	5	0.10%
Failure to Sense	1	0.02%
Insulation Breach	1	0.02%
Lead Dislodgement	20	0.39%
Oversensing	5	0.10%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.02%
Insulation Breach	4	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.02%
Extrinsic Factors	11	0.21%
Total	**17**	**0.33%**



Year	1	2	3	4	at 53 months					
Survival Probability	99.56%	99.33%	99.17%	99.17%	99.17%					
± 1 standard error	0.09%	0.12%	0.15%	0.15%	0.15%					
Sample Size	4690	3680	2200	730	60					

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

Customer Reported Performance Data

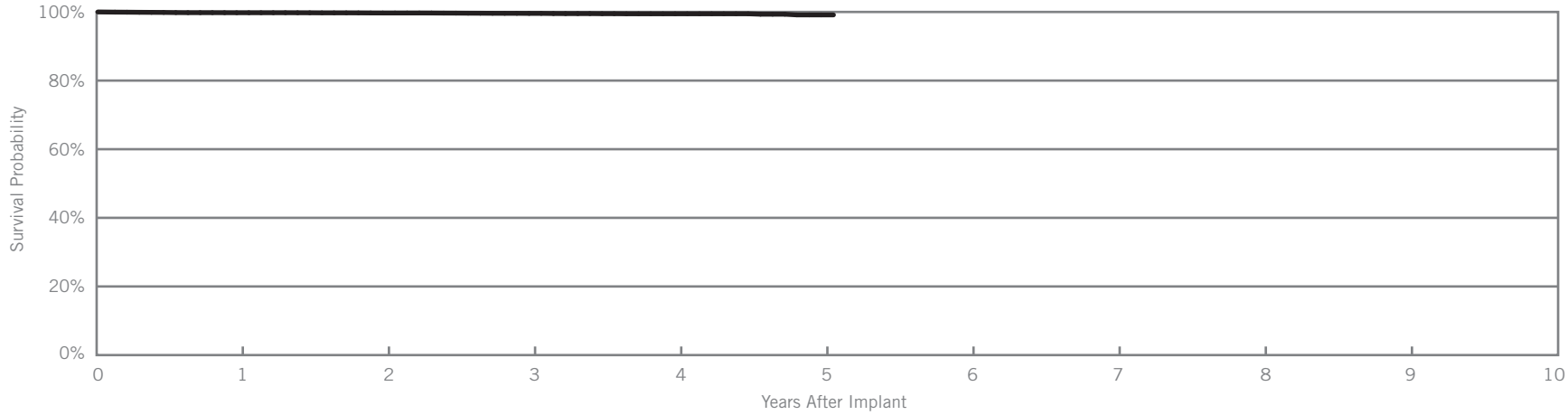
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Registered US Implants	25,700
Estimated Active US Implants	19,144
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	2	0.01%	0	0.00%
Conductor Fracture	0	0.00%	2	0.01%
Lead Dislodgement	15	0.06%	26	0.10%
Failure to Capture	5	0.02%	16	0.06%
Oversensing	2	0.01%	8	0.03%
Failure to Sense	4	0.02%	2	0.01%
Insulation Breach	0	0.00%	3	0.01%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	0.01%	6	0.02%
Total	**30**	**0.12%**	**63**	**0.25%**
Total Returned for Analysis	**12**		**43**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	<0.01%
Insulation Breach	9	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.01%
Extrinsic Factors	32	0.12%
Total	**45**	**0.18%**



Year	1	2	3	4	5	at 61 months				
Survival Probability	99.78%	99.70%	99.58%	99.46%	99.14%	99.14%				
± 1 standard error	0.03%	0.04%	0.06%	0.08%	0.25%	0.25%				
Sample Size	22800	14100	8200	3800	1100	200				

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

Actively Monitored Study Data

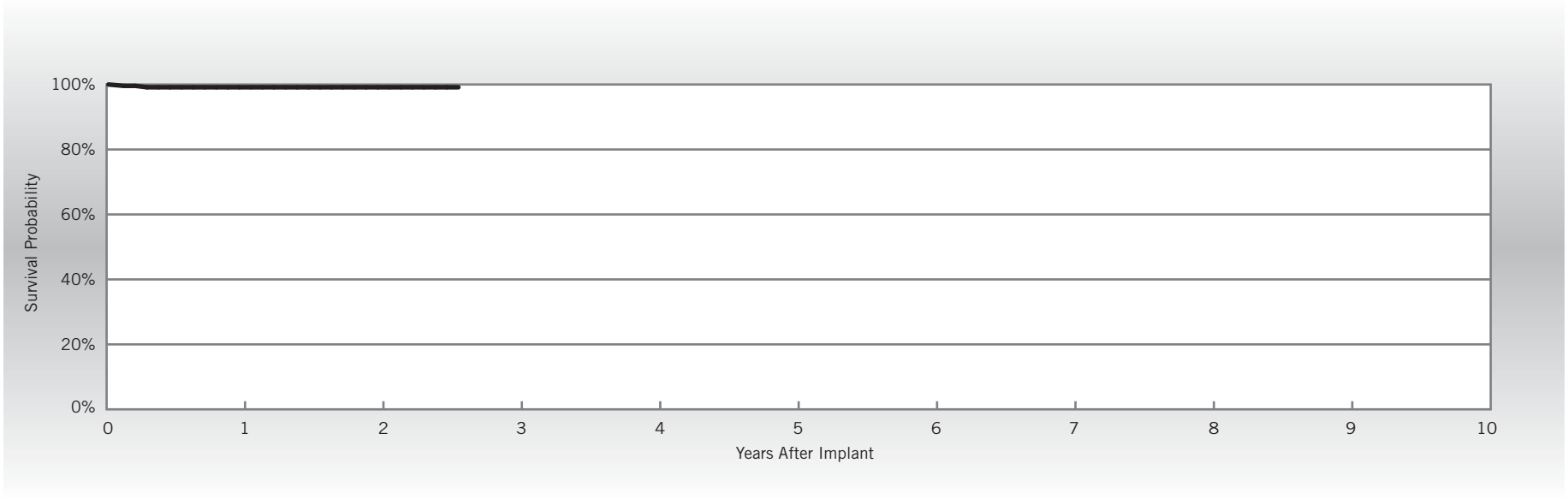
Tendril® ST Optim®

Models 1882T & 1882TC

US Regulatory Approval	June 2006
Number of Devices Enrolled in Study	250
Cumulative Months of Follow-up	5,078
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Lead Dislodgement	2	0.80%

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	1	0.40%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.40%
Total	**2**	**0.80%**



Year	1	2	at 31 months							
Survival Probability	99.15%	99.15%	99.15%							
± 1 standard error	0.60%	0.60%	0.60%							
Sample Size	210	140	50							

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

Customer Reported Performance Data

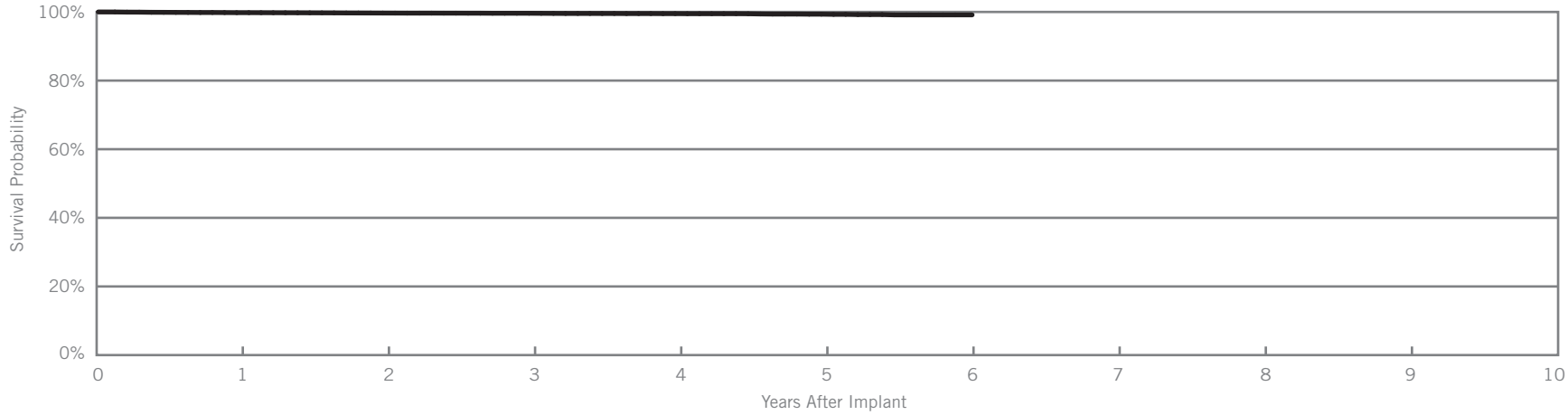
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Registered US Implants	16,351
Estimated Active US Implants	10,548
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	6	0.04%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	13	0.08%	23	0.14%
Failure to Capture	5	0.03%	15	0.09%
Oversensing	0	0.00%	4	0.02%
Failure to Sense	0	0.00%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	4	0.02%
Extracardiac Stimulation	1	0.01%	1	0.01%
Other	2	0.01%	1	0.01%
Total	**29**	**0.18%**	**51**	**0.31%**
Total Returned for Analysis	**16**		**35**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.01%
Insulation Breach	5	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	28	0.17%
Total	**34**	**0.21%**



Year	1	2	3	4	5	6				
Survival Probability	99.80%	99.68%	99.62%	99.51%	99.35%	99.15%				
± 1 standard error	0.03%	0.05%	0.06%	0.07%	0.10%	0.16%				
Sample Size	15700	12500	9700	6800	3900	1200				

Actively Monitored Study Data

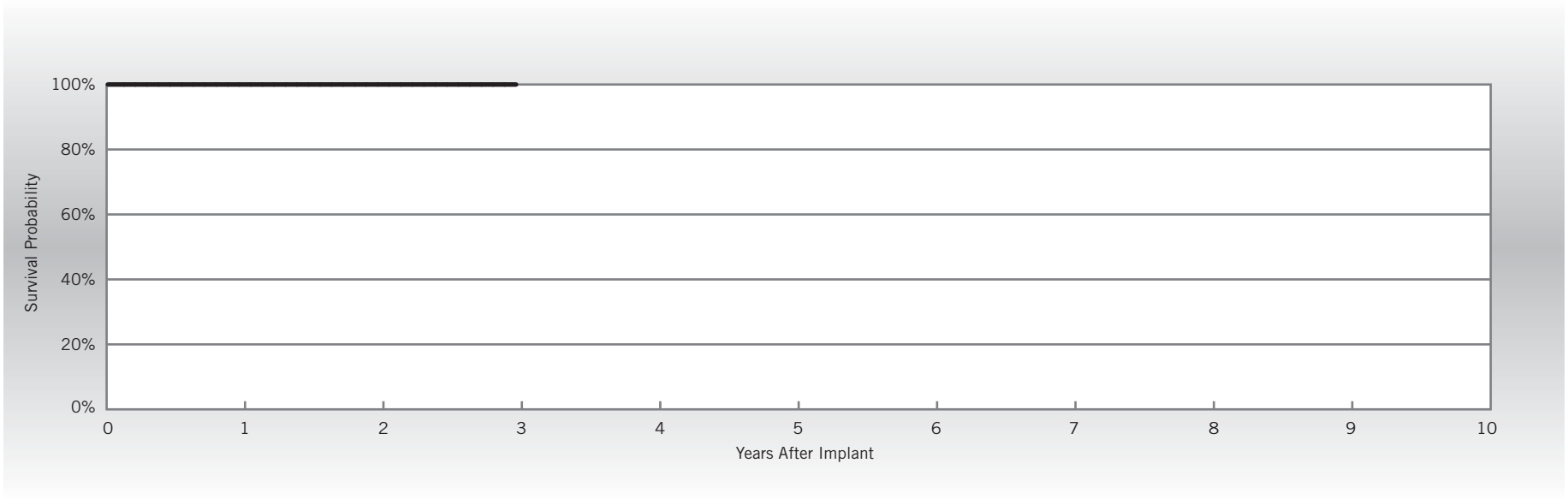
Tendril®

Models 1782T & 1782TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	169
Cumulative Months of Follow-up	4,800
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

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



Year	1	2	3							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	160	120	70							

Customer Reported Performance Data

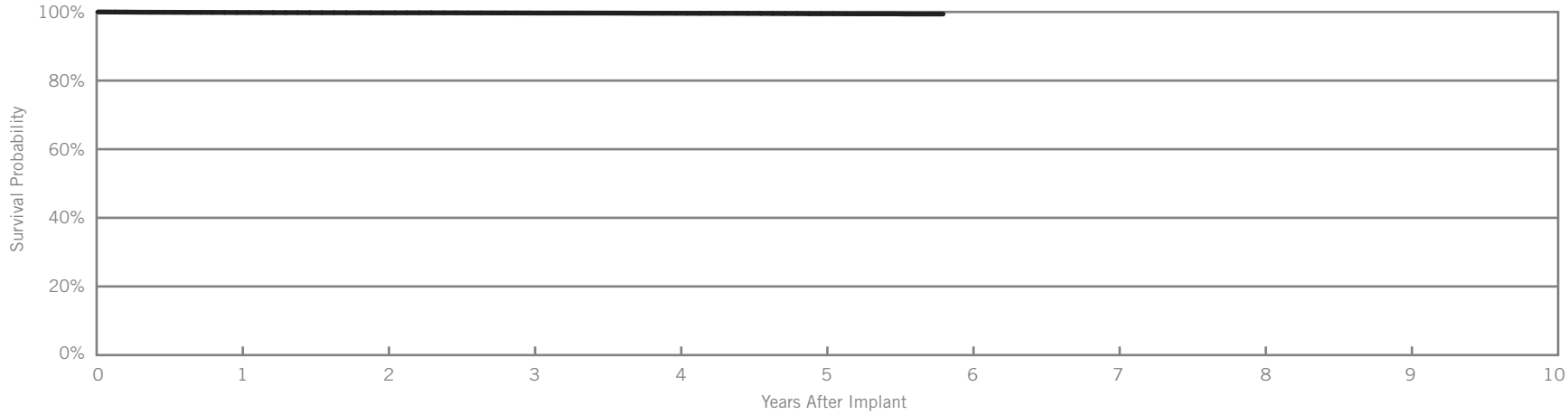
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Registered US Implants	65,617
Estimated Active US Implants	39,795
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	12	0.02%	2	<0.01%
Conductor Fracture	1	<0.01%	5	0.01%
Lead Dislodgement	31	0.05%	37	0.06%
Failure to Capture	30	0.05%	44	0.07%
Oversensing	2	<0.01%	30	0.05%
Failure to Sense	2	<0.01%	4	0.01%
Insulation Breach	1	<0.01%	4	0.01%
Abnormal Pacing Impedance	9	0.01%	12	0.02%
Extracardiac Stimulation	2	<0.01%	1	<0.01%
Other	20	0.03%	8	0.01%
Total	**110**	**0.17%**	**147**	**0.22%**
Total Returned for Analysis	**43**		**92**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	<0.01%
Insulation Breach	38	0.06%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	61	0.09%
Total	**104**	**0.16%**



Year	1	2	3	4	5	at 70 months				
Survival Probability	99.83%	99.75%	99.69%	99.61%	99.48%	99.40%				
± 1 standard error	0.02%	0.02%	0.02%	0.03%	0.04%	0.06%				
Sample Size	64700	54400	45500	34600	21400	700				

Actively Monitored Study Data

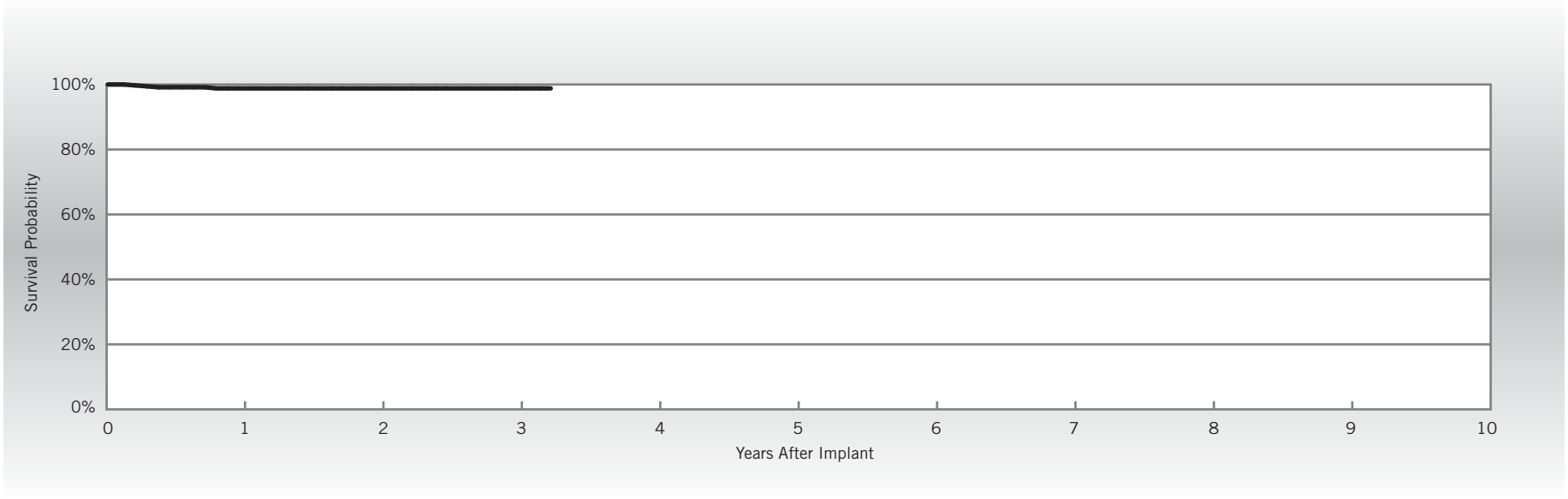
Tendril®

Models 1788T & 1788TC

US Regulatory Approval	February 2006
Number of Devices Enrolled in Study	371
Cumulative Months of Follow-up	8,931
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Extracardiac Stimulation	1	0.27%
Lead Dislodgement	3	0.81%

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



Year	1	2	3	at 39 months						
Survival Probability	98.81%	98.81%	98.81%	98.81%						
± 1 standard error	0.59%	0.59%	0.59%	0.59%						
Sample Size	320	240	140	60						

Customer Reported Performance Data

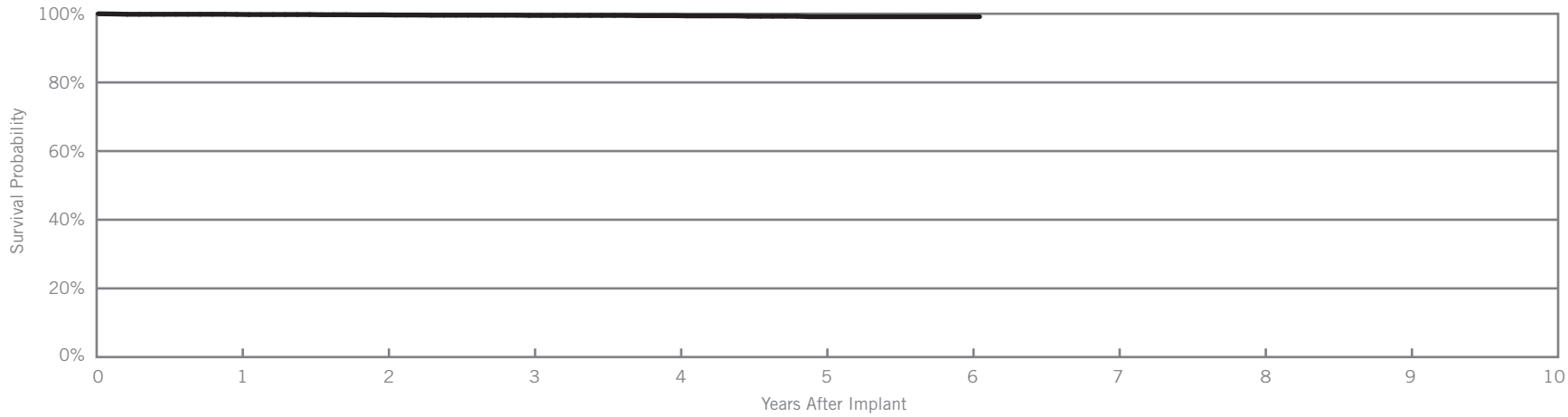
IsoFlex® P

Model 1648T

US Regulatory Approval	April 2005
Registered US Implants	2,843
Estimated Active US Implants	1,397
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.04%
Lead Dislodgement	2	0.07%	1	0.04%
Failure to Capture	2	0.07%	2	0.07%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	0.04%	0	0.00%
Insulation Breach	0	0.00%	1	0.04%
Abnormal Pacing Impedance	0	0.00%	3	0.11%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	2	0.07%
Total	**6**	**0.21%**	**10**	**0.35%**
Total Returned for Analysis	**1**		**5**	

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



Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.81%	99.68%	99.52%	99.45%	99.14%	99.14%	99.14%			
± 1 standard error	0.07%	0.12%	0.13%	0.16%	0.24%	0.24%	0.24%			
Sample Size	2800	2400	2000	1600	1100	400	200			

Customer Reported Performance Data

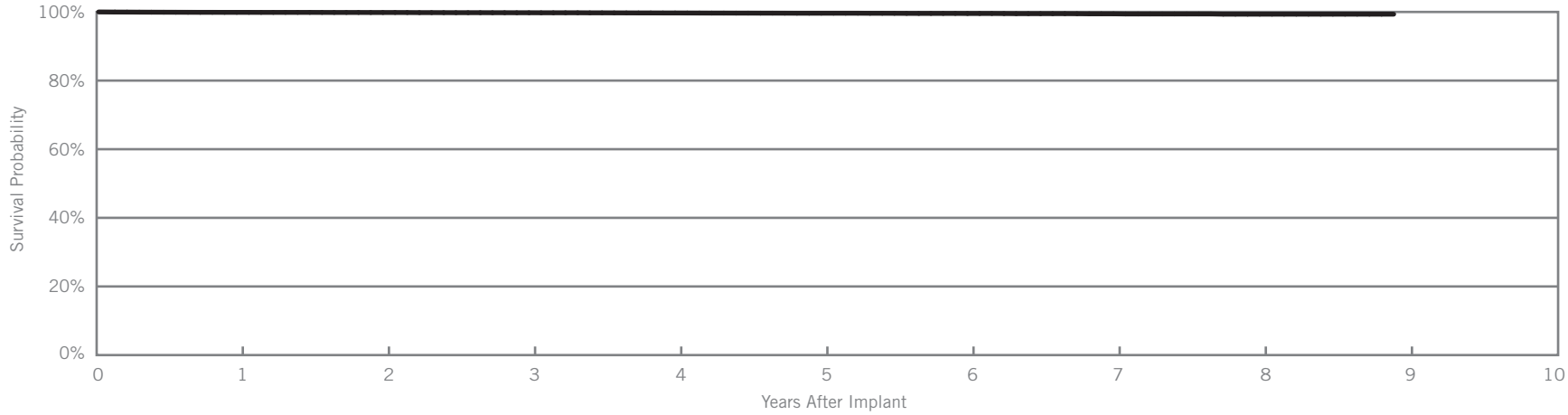
IsoFlex® S

Model 1642T

US Regulatory Approval	May 2002
Registered US Implants	26,996
Estimated Active US Implants	15,193
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	3	0.01%
Lead Dislodgement	49	0.18%	22	0.08%
Failure to Capture	6	0.02%	18	0.07%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	3	0.01%	2	0.01%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	3	0.01%	2	0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**62**	**0.23%**	**49**	**0.18%**
Total Returned for Analysis	**38**		**17**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Insulation Breach	6	0.02%
Crimps, Welds & Bonds	1	<0.01%
Other	2	0.01%
Extrinsic Factors	16	0.06%
Total	**25**	**0.09%**



Year	1	2	3	4	5	6	7	8	at 107 months	
Survival Probability	99.88%	99.84%	99.77%	99.70%	99.63%	99.55%	99.45%	99.35%	99.35%	
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.06%	0.08%	0.10%	0.10%	
Sample Size	26300	21600	18000	14200	10500	7100	4300	2100	200	

Customer Reported Performance Data

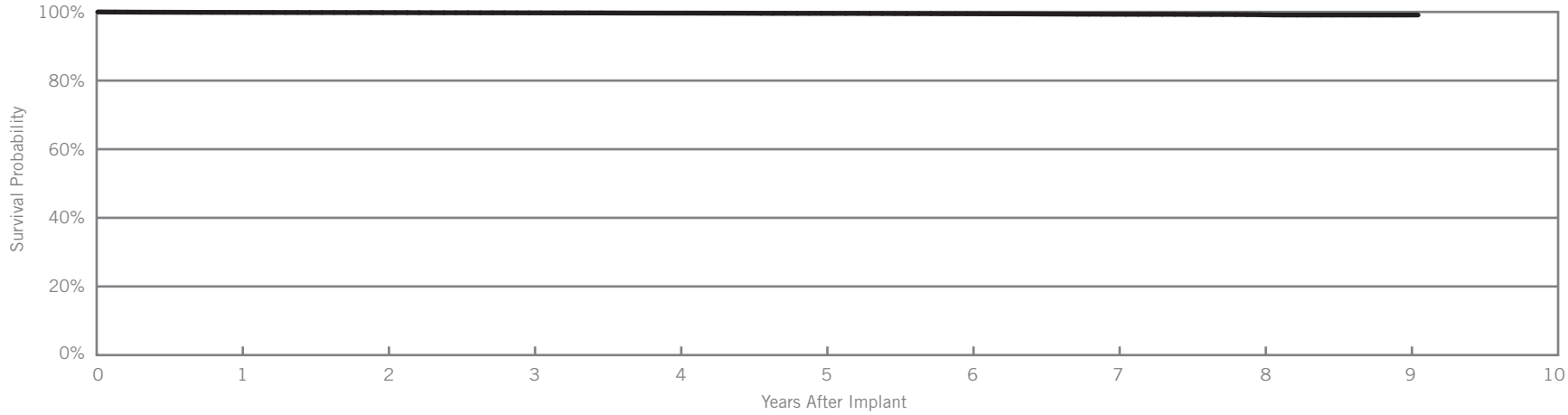
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Registered US Implants	89,836
Estimated Active US Implants	50,647
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days) Qty.	Rate	Chronic Complications (>30 days) Qty.	Rate
Cardiac Perforation	4	<0.01%	2	<0.01%
Conductor Fracture	2	<0.01%	34	0.04%
Lead Dislodgement	37	0.04%	26	0.03%
Failure to Capture	33	0.04%	97	0.11%
Oversensing	0	0.00%	18	0.02%
Failure to Sense	2	<0.01%	3	<0.01%
Insulation Breach	2	<0.01%	4	<0.01%
Abnormal Pacing Impedance	6	0.01%	31	0.03%
Extracardiac Stimulation	0	0.00%	1	<0.01%
Other	2	<0.01%	11	0.01%
Total	**88**	**0.10%**	**227**	**0.25%**
Total Returned for Analysis	**38**		**57**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	14	0.02%
Insulation Breach	14	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	6	0.01%
Extrinsic Factors	44	0.05%
Total	**78**	**0.09%**



Year	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.87%	99.81%	99.73%	99.66%	99.58%	99.47%	99.33%	99.20%	99.11%	99.11%
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%	0.07%	0.09%	0.09%
Sample Size	87400	71000	58300	45500	33000	21800	13000	6400	1900	200

Actively Monitored Study Data

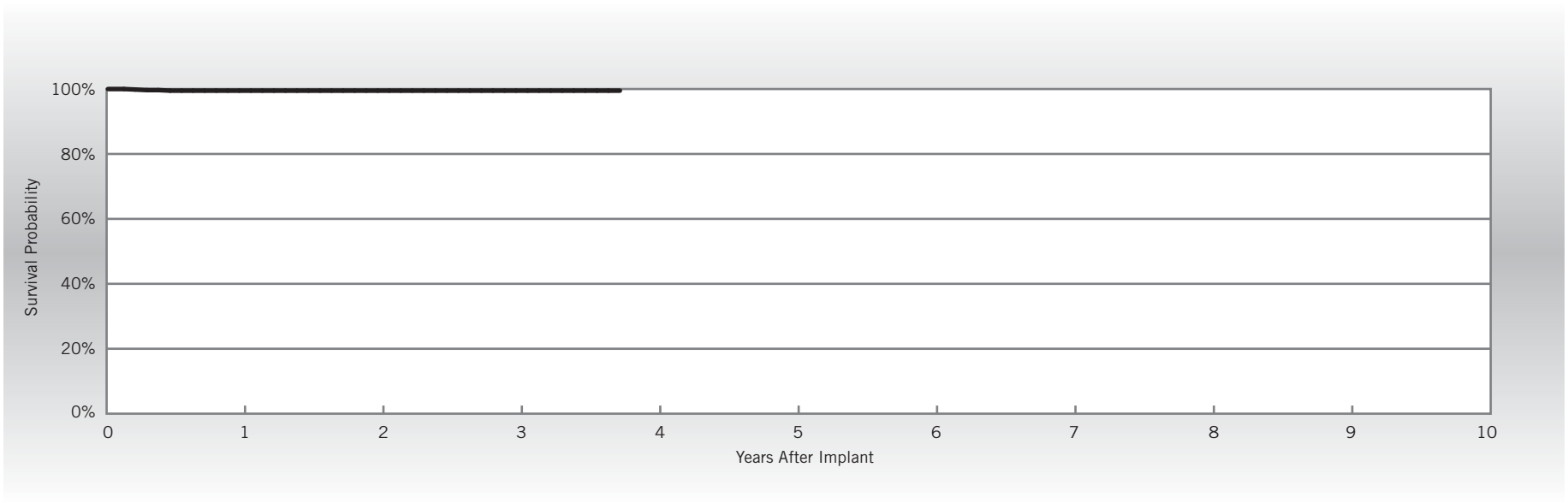
IsoFlex® S

Model 1646T

US Regulatory Approval	May 2002
Number of Devices Enrolled in Study	628
Cumulative Months of Follow-up	16,087
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Failure to Capture	2	0.32%
Lead Dislodgement	1	0.16%

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



Year	1	2	3	at 45 months						
Survival Probability	99.50%	99.50%	99.50%	99.50%						
± 1 standard error	0.29%	0.29%	0.29%	0.29%						
Sample Size	560	410	250	50						

Customer Reported Performance Data

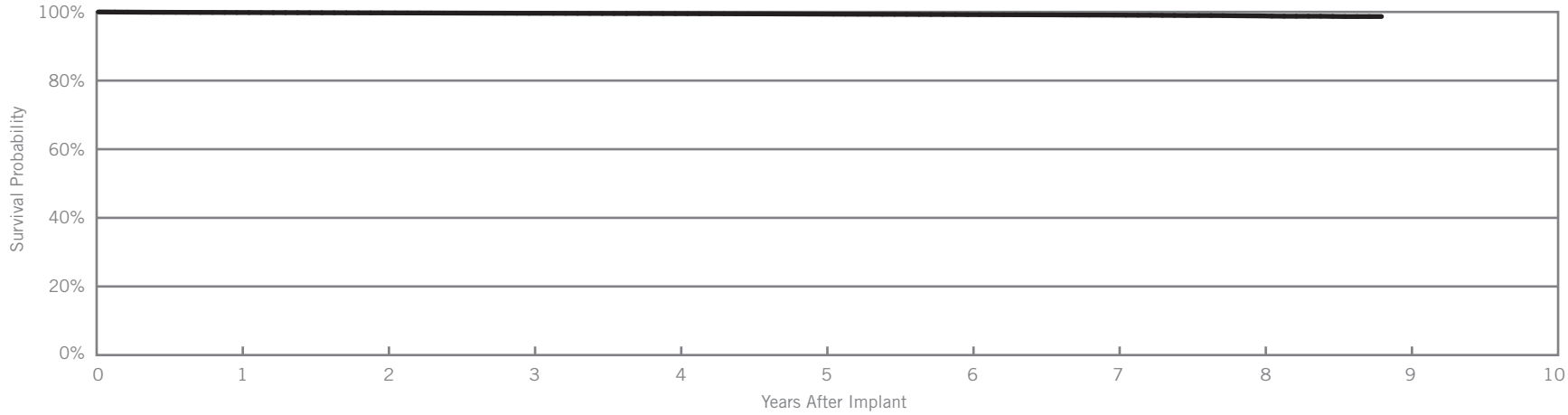
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Registered US Implants	395,246
Estimated Active US Implants	226,325
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	46	0.01%	12	<0.01%
Conductor Fracture	4	<0.01%	121	0.03%
Lead Dislodgement	189	0.05%	241	0.06%
Failure to Capture	129	0.03%	421	0.11%
Oversensing	10	<0.01%	228	0.06%
Failure to Sense	22	0.01%	23	0.01%
Insulation Breach	7	<0.01%	47	0.01%
Abnormal Pacing Impedance	25	0.01%	177	0.04%
Extracardiac Stimulation	4	<0.01%	12	<0.01%
Other	28	0.01%	71	0.02%
Total	**464**	**0.12%**	**1353**	**0.34%**
Total Returned for Analysis	**205**		**621**	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	124	0.03%
Insulation Breach	227	0.06%
Crimps, Welds & Bonds	2	<0.01%
Other	4	<0.01%
Extrinsic Factors	363	0.09%
Total	**720**	**0.18%**



Year	1	2	3	4	5	6	7	8	at 106 months	
Survival Probability	99.84%	99.73%	99.61%	99.51%	99.38%	99.23%	99.09%	98.85%	98.67%	
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.04%	0.08%	
Sample Size	380700	304200	248000	195900	149000	102600	57500	22600	700	

Actively Monitored Study Data

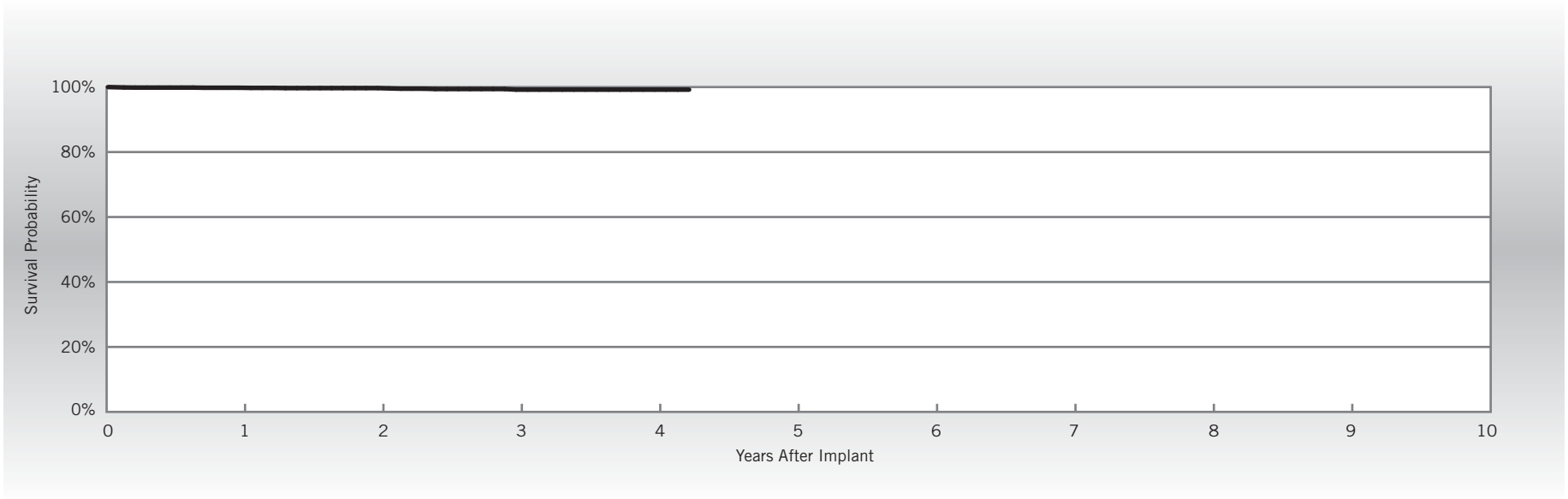
Tendril® SDX

Models 1688T & 1688TC

US Regulatory Approval	June 2003
Number of Devices Enrolled in Study	2,527
Cumulative Months of Follow-up	60,487
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Abnormal Pacing Impedance	3	0.12%
Failure to Capture	2	0.08%
Inappropriate Shock	1	0.04%
Lead Dilslodgement	3	0.12%
Oversensing	1	0.04%
Pericardial Effusion	1	0.04%

Malfunctions	Qty	Rate
Conductor Fracture	1	0.04%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.24%
Total	**7**	**0.28%**



Year	1	2	3	4	at 51 months					
Survival Probability	99.79%	99.68%	99.21%	99.21%	99.21%					
± 1 standard error	0.09%	0.12%	0.20%	0.28%	0.28%					
Sample Size	2220	1550	860	310	50					

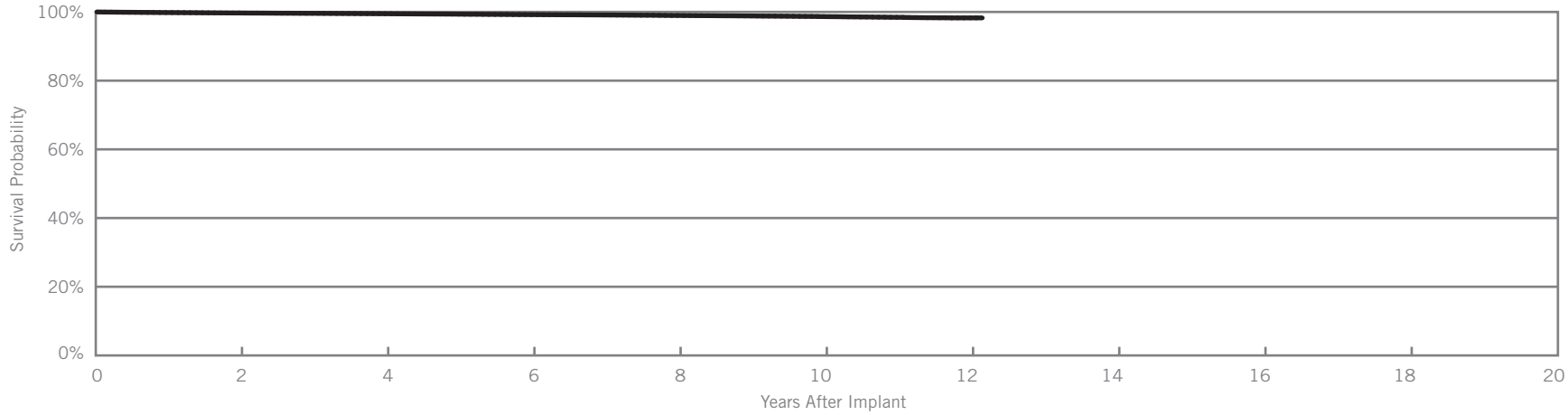
Customer Reported Performance Data

Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Registered US Implants	273,332
Estimated Active US Implants	95,406
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	139	0.05%
Insulation Breach	108	0.04%
Crimps, Welds & Bonds	5	<0.01%
Other	1	<0.01%
Extrinsic Factors	263	0.10%
Total	**516**	**0.19%**



Year	2	4	6	8	10	12	at 146 months			
Survival Probability	99.70%	99.48%	99.22%	98.98%	98.65%	98.27%	98.27%			
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.04%	0.08%	0.08%			
Sample Size	233900	189900	145400	95000	40900	5200	500			

Actively Monitored Study Data

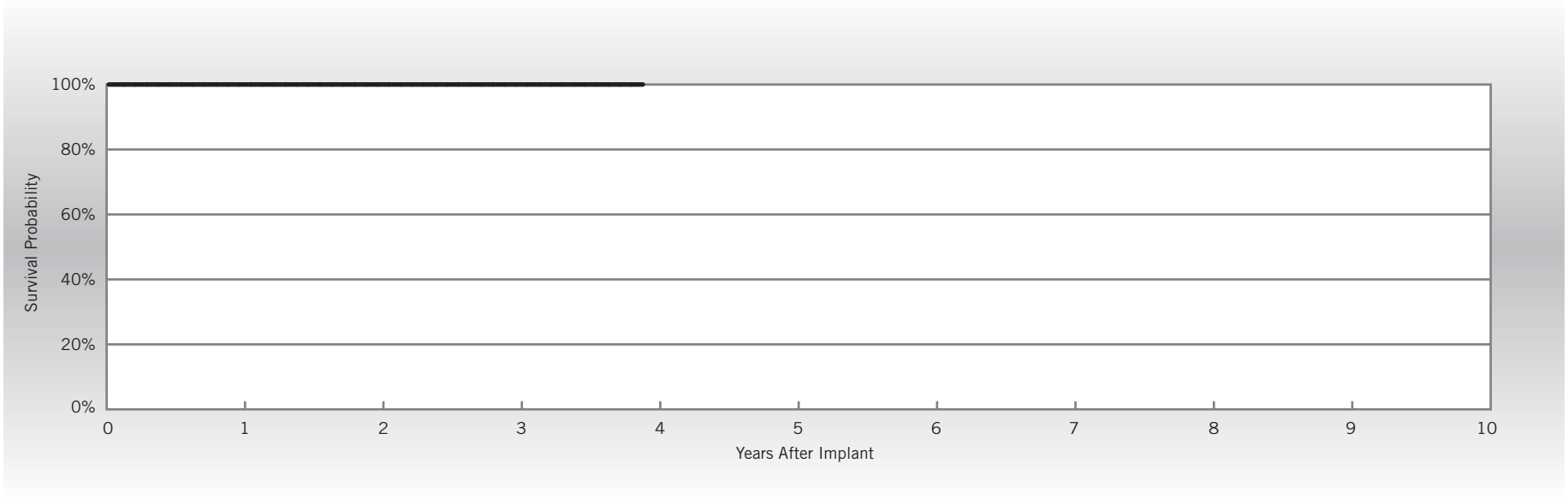
Tendril® SDX

Models 1488T & 1488TC

US Regulatory Approval	March 2000
Number of Devices Enrolled in Study	794
Cumulative Months of Follow-up	21,532
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

Malfunctions	Qty	Rate
Conductor Fracture	0	0.00%
Insulation Breach	2	0.25%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.25%
Total	**4**	**0.50%**



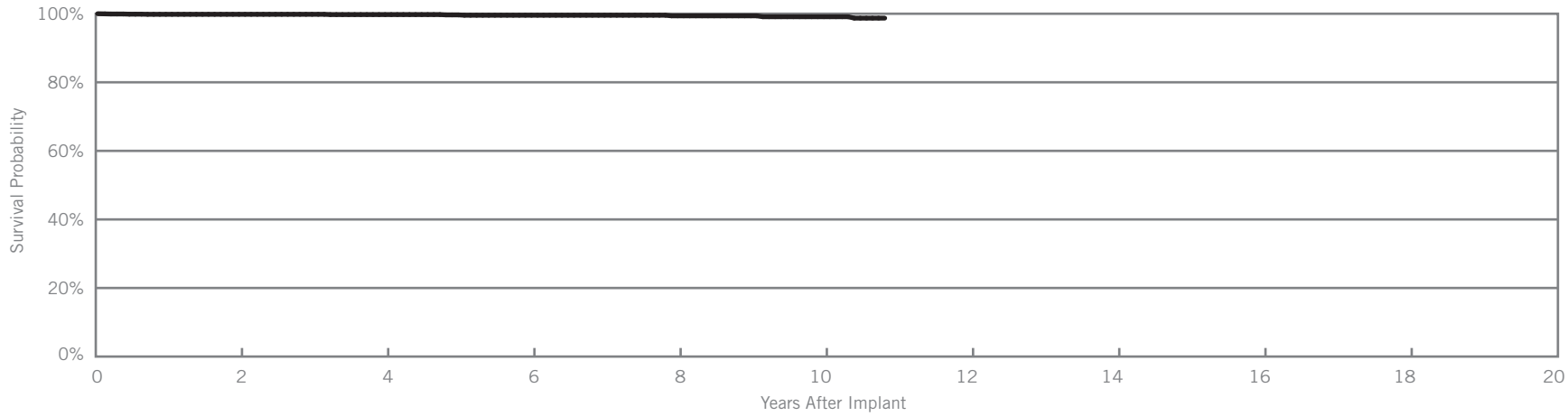
Year	1	2	3	at 47 months						
Survival Probability	100.00%	100.00%	100.00%	100.00%						
± 1 standard error	0.00%	0.00%	0.00%	0.00%						
Sample Size	720	550	350	50						

Customer Reported Performance Data

AV Plus® DX

Model 1368

US Regulatory Approval	May 1999
Registered US Implants	2,608
Estimated Active US Implants	670
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



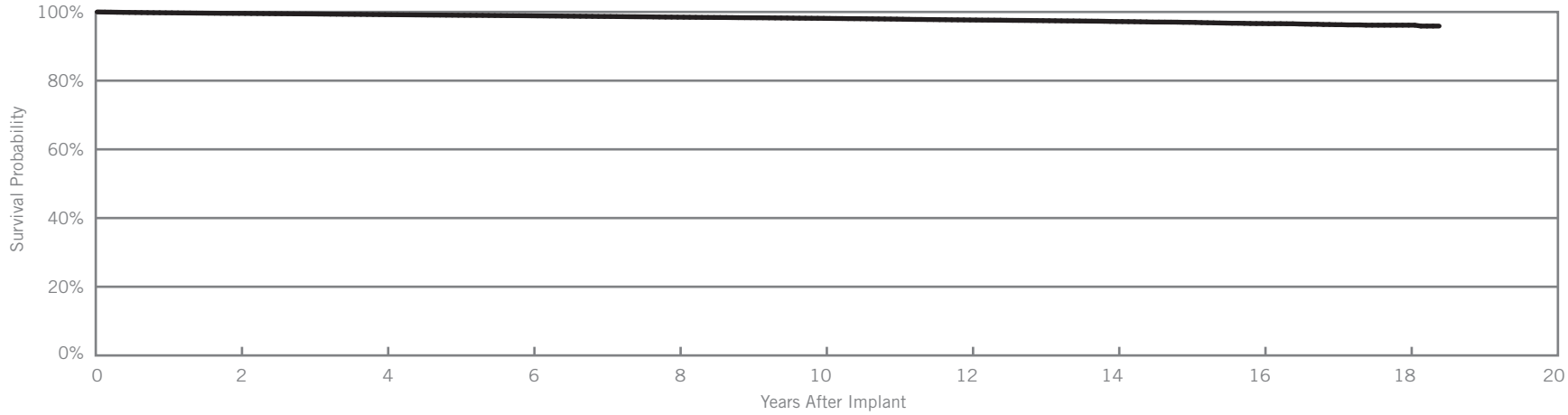
Year	2	4	6	8	10	at 130 months				
Survival Probability	99.83%	99.75%	99.56%	99.38%	99.12%	98.72%				
± 1 standard error	0.09%	0.11%	0.18%	0.25%	0.36%	0.54%				
Sample Size	2000	1400	1000	600	400	200				

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	326,814
Estimated Active US Implants	77,188
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	(1148/1188) No; (1388) Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	at 221 months
Survival Probability	99.58%	99.22%	98.88%	98.48%	98.14%	97.66%	97.21%	96.62%	96.15%	95.89%
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.03%	0.05%	0.06%	0.11%	0.19%	0.32%
Sample Size	277700	224000	172000	123200	80800	47400	19500	5800	1200	200

Actively Monitored Study Data

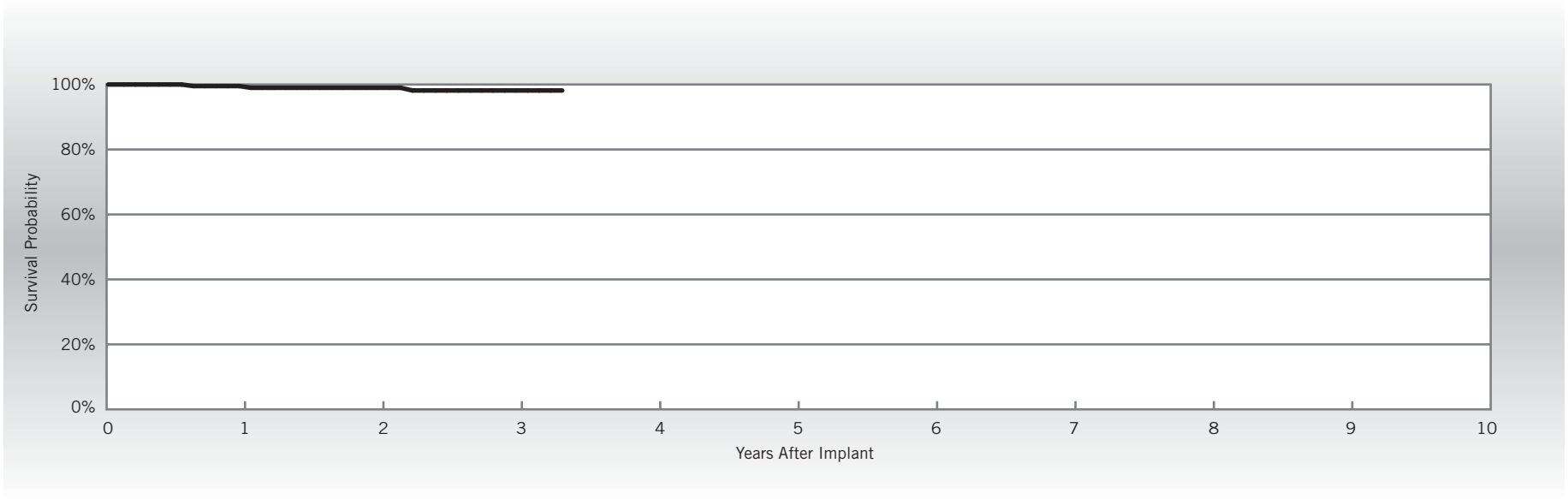
Tendril® DX

Models 1388T & 1388TC

US Regulatory Approval	June 1997
Number of Devices Enrolled in Study	234
Cumulative Months of Follow-up	6,223
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty	Rate
Conductor Fracture	1	0.43%
Failure to Capture	1	0.43%
Failure to Sense	1	0.43%

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



Year	1	2	3	at 40 months						
Survival Probability	99.52%	98.99%	98.16%	98.16%						
± 1 standard error	0.48%	0.71%	1.09%	1.09%						
Sample Size	210	160	100	60						

Customer Reported Performance Data

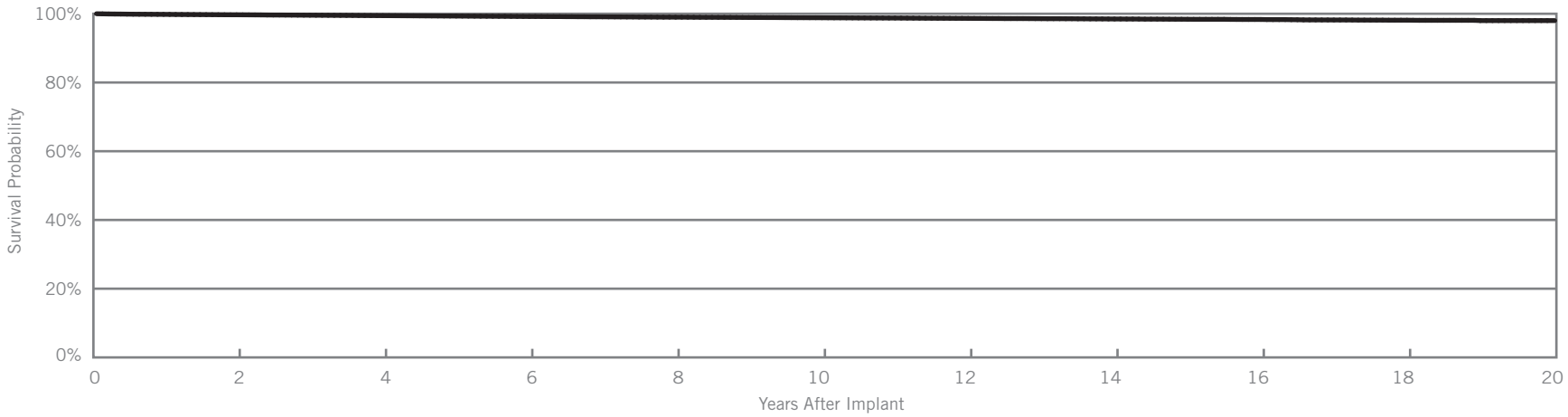
Passive Plus®

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

Passive Plus® DX

Models 1336T, 1342T & 1346T

US Regulatory Approval	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990
Registered US Implants	374,123
Estimated Active US Implants	68,416
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	14	16	18	20
Survival Probability	99.70%	99.45%	99.21%	99.01%	98.84%	98.66%	98.48%	98.34%	98.13%	98.01%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%	0.07%	0.09%
Sample Size	316500	253400	197000	148100	102300	62800	34700	17400	6900	2000

Summary Information

Pacing Leads

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
2088TC	Tendril® STS	99.84%	99.63%								
1999	OptiSense® Optim®	99.81%	99.68%								
1944	IsoFlex® Optim®	99.83%	99.69%	99.58%							
1948	IsoFlex® Optim®	99.91%	99.77%	99.64%							
1699T/TC	OptiSense®	99.79%	99.72%	99.62%	99.56%						
1888T/TC	Tendril® ST Optim®	99.80%	99.68%	99.57%	99.42%	99.19%					
1882T/TC	Tendril® ST Optim®	99.78%	99.70%	99.58%	99.46%	99.14%					
1782T/TC	Tendril®	99.80%	99.68%	99.62%	99.51%	99.35%	99.15%				
1788T/TC	Tendril®	99.83%	99.75%	99.69%	99.61%	99.48%					
1648T	IsoFlex® P	99.81%	99.68%	99.52%	99.45%	99.14%	99.14%				
1642T	IsoFlex® S	99.88%	99.84%	99.77%	99.70%	99.63%	99.55%	99.45%	99.35%		
1646T	IsoFlex® S	99.87%	99.81%	99.73%	99.66%	99.58%	99.47%	99.33%	99.20%	99.11%	
1688T/TC	Tendril® SDX	99.84%	99.73%	99.61%	99.51%	99.38%	99.23%	99.09%	98.85%		
1488T/TC	Tendril® SDX	99.82%	99.70%	99.60%	99.48%	99.36%	99.22%	99.12%	98.98%	98.84%	98.65%

Acute Observation Summary

Post Implant ≤30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
2088TC	May-09	139828	119920	20	0.01%	0	0.00%	91	0.07%	10	0.01%	3	<0.01%	2	<0.01%	2	<0.01%	3	<0.01%	0	0.00%	3	<0.01%	**134**	**0.10%**	**84**
1999	May-07	17063	14482	0	0.00%	0	0.00%	8	0.05%	2	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**11**	**0.06%**	**5**
1944	Mar-08	7365	5576	0	0.00%	0	0.00%	16	0.22%	3	0.04%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**21**	**0.29%**	**13**
1948	Mar-08	25204	19508	0	0.00%	0	0.00%	15	0.06%	5	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	**22**	**0.09%**	**16**
1699T/TC	May-07	23262	15755	1	<0.01%	0	0.00%	4	0.02%	3	0.01%	2	0.01%	8	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**20**	**0.09%**	**16**
1888T/TC	Jun-06	247362	172144	30	0.01%	6	<0.01%	103	0.04%	69	0.03%	10	<0.01%	8	<0.01%	5	<0.01%	6	<0.01%	3	<0.01%	17	0.01%	**257**	**0.10%**	**121**
1882T/TC	Jun-06	25700	19144	2	0.01%	0	0.00%	15	0.06%	5	0.02%	2	0.01%	4	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**30**	**0.12%**	**12**
1782T/TC	Jun-06	16351	10548	6	0.04%	0	0.00%	13	0.08%	5	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	1	0.01%	2	0.01%	**29**	**0.18%**	**16**
1788T/TC	Feb-06	65617	39795	12	0.02%	1	<0.01%	31	0.05%	30	0.05%	2	<0.01%	2	<0.01%	1	<0.01%	9	0.01%	2	<0.01%	20	0.03%	**110**	**0.17%**	**43**
1648T	Apr-05	2843	1397	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	26996	15193	0	0.00%	0	0.00%	49	0.18%	6	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**62**	**0.23%**	**38**
1646T	May-02	89836	50647	4	<0.01%	2	<0.01%	37	0.04%	33	0.04%	0	0.00%	2	<0.01%	2	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**88**	**0.10%**	**38**
1688T/TC	Jun-03	395246	226325	46	0.01%	4	<0.01%	189	0.05%	129	0.03%	10	<0.01%	22	0.01%	7	<0.01%	25	0.01%	4	<0.01%	28	0.01%	**464**	**0.12%**	**205**

Chronic Complication Summary

>30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
2088TC	May-09	139828	119920	3	<0.01%	2	<0.01%	60	0.04%	43	0.03%	39	0.03%	8	0.01%	9	0.01%	9	0.01%	1	<0.01%	9	0.01%	**183**	**0.13%**	**143**
1999	May-07	17063	14482	0	0.00%	0	0.00%	21	0.12%	8	0.05%	2	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**31**	**0.18%**	**23**
1944	Mar-08	7365	5576	0	0.00%	0	0.00%	10	0.14%	1	0.01%	1	0.01%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	1	0.01%	**15**	**0.20%**	**7**
1948	Mar-08	25204	19508	1	<0.01%	7	0.03%	7	0.03%	6	0.02%	4	0.02%	0	0.00%	1	<0.01%	5	0.02%	0	0.00%	0	0.00%	**31**	**0.12%**	**14**
1699T/TC	May-07	23262	15755	0	0.00%	5	0.02%	22	0.09%	12	0.05%	8	0.03%	6	0.03%	0	0.00%	4	0.02%	2	0.01%	0	0.00%	**59**	**0.25%**	**39**
1888T/TC	Jun-06	247362	172144	21	0.01%	37	0.01%	211	0.09%	150	0.06%	141	0.06%	17	0.01%	37	0.01%	26	0.01%	9	<0.01%	32	0.01%	**681**	**0.28%**	**425**
1882T/TC	Jun-06	25700	19144	0	0.00%	2	0.01%	26	0.10%	16	0.06%	8	0.03%	2	0.01%	3	0.01%	0	0.00%	0	0.00%	6	0.02%	**63**	**0.25%**	**43**
1782T/TC	Jun-06	16351	10548	0	0.00%	1	0.01%	23	0.14%	15	0.09%	4	0.02%	2	0.01%	0	0.00%	4	0.02%	1	0.01%	1	0.01%	**51**	**0.31%**	**35**
1788T/TC	Feb-06	65617	39795	2	<0.01%	5	0.01%	37	0.06%	44	0.07%	30	0.05%	4	0.01%	4	0.01%	12	0.02%	1	<0.01%	8	0.01%	**147**	**0.22%**	**92**
1648T	Apr-05	2843	1397	0	0.00%	1	0.04%	1	0.04%	2	0.07%	0	0.00%	0	0.00%	1	0.04%	3	0.11%	0	0.00%	2	0.07%	**10**	**0.35%**	**5**
1642T	May-02	26996	15193	0	0.00%	3	0.01%	22	0.08%	18	0.07%	0	0.00%	2	0.01%	1	<0.01%	2	0.01%	0	0.00%	1	<0.01%	**49**	**0.18%**	**17**
1646T	May-02	89836	50647	2	<0.01%	34	0.04%	26	0.03%	97	0.11%	18	0.02%	3	<0.01%	4	<0.01%	31	0.03%	1	<0.01%	11	0.01%	**227**	**0.25%**	**57**
1688T/TC	Jun-03	395246	226325	12	<0.01%	121	0.03%	241	0.06%	421	0.11%	228	0.06%	23	0.01%	47	0.01%	177	0.04%	12	<0.01%	71	0.02%	**1353**	**0.34%**	**621**

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

Malfunction Summary

Models	Registered US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088TC	139828	3	<0.01%	38	0.03%	0	0.00%	8	0.01%	123	0.09%	**172**	**0.12%**
1999	17063	1	0.01%	2	0.01%	0	0.00%	1	0.01%	21	0.12%	**25**	**0.15%**
1944	7365	0	0.00%	1	0.01%	0	0.00%	0	0.00%	6	0.08%	**7**	**0.10%**
1948	25204	0	0.00%	7	0.03%	0	0.00%	1	<0.01%	13	0.05%	**21**	**0.08%**
1699T/TC	23262	6	0.03%	7	0.03%	0	0.00%	0	0.00%	33	0.14%	**46**	**0.20%**
1888T/TC	247362	15	0.01%	153	0.06%	1	<0.01%	5	<0.01%	330	0.13%	**504**	**0.20%**
1882T/TC	25700	1	<0.01%	9	0.04%	0	0.00%	3	0.01%	32	0.12%	**45**	**0.18%**
1782T/TC	16351	1	0.01%	5	0.03%	0	0.00%	0	0.00%	28	0.17%	**34**	**0.21%**
1788T/TC	65617	3	<0.01%	38	0.06%	1	<0.01%	1	<0.01%	61	0.09%	**104**	**0.16%**
1648T	2843	0	0.00%	3	0.11%	0	0.00%	2	0.07%	2	0.07%	**7**	**0.25%**
1642T	26996	0	0.00%	6	0.02%	1	<0.01%	2	0.01%	16	0.06%	**25**	**0.09%**
1646T	89836	14	0.02%	14	0.02%	0	0.00%	6	0.01%	44	0.05%	**78**	**0.09%**
1688T/TC	395246	124	0.03%	227	0.06%	2	<0.01%	4	<0.01%	363	0.09%	**720**	**0.18%**
1488T/TC	273332	139	0.05%	108	0.04%	5	<0.01%	1	<0.01%	263	0.10%	**516**	**0.19%**

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

Actively Monitored Study Data Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Abnormal Pacing Impedance		Cardiac Perforation		Conductor Fracture		Extracardiac Stimulation		Failure to Capture		Failure to Sense		Inappropriate Shock		Insulation Breach		Lead Dislodgement		Oversensing		Pericardial Effusion		Skin Erosion		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088	2963	44963	1	0.03%	1	0.03%	0	0.00%	0	0.00%	1	0.03%	1	0.03%	0	0.00%	1	0.03%	5	0.17%	0	0.00%	0	0.00%	0	0.00%	10	0.34%
1999	643	9524	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.78%	0	0.00%	0	0.00%	0	0.00%	5	0.78%
1948	385	6694	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.26%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.26%
1699T/TC	1214	36231	2	0.16%	0	0.00%	1	0.08%	0	0.00%	2	0.16%	0	0.00%	0	0.00%	0	0.00%	5	0.41%	1	0.08%	0	0.00%	0	0.00%	11	0.91%
1888T/TC	5137	138157	2	0.04%	0	0.00%	0	0.00%	0	0.00%	5	0.10%	1	0.02%	0	0.00%	1	0.02%	20	0.39%	5	0.10%	0	0.00%	0	0.00%	34	0.66%
1882T/TC	250	5078	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.80%	0	0.00%	0	0.00%	0	0.00%	2	0.80%
1782T/TC	169	4800	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
1788T/TC	371	8931	0	0.00%	0	0.00%	0	0.00%	1	0.27%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.81%	0	0.00%	0	0.00%	0	0.00%	4	1.08%
1646T	628	16087	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.32%	0	0.00%	0	0.00%	0	0.00%	1	0.16%	0	0.00%	0	0.00%	0	0.00%	3	0.48%
1688T/TC	2527	60487	3	0.12%	0	0.00%	0	0.00%	0	0.00%	2	0.08%	0	0.00%	1	0.04%	0	0.00%	3	0.12%	1	0.04%	1	0.04%	0	0.00%	11	0.44%
1488T/TC	794	21532	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
1388T/TC	234	6223	0	0.00%	0	0.00%	1	0.43%	0	0.00%	1	0.43%	1	0.43%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	1.28%

Malfunctions

Models	Number of Devices Enrolled	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
2088TC	2963	0	0.00%	2	0.07%	0	0.00%	0	0.00%	2	0.07%	**4**	**0.13%**
1999	643	0	0.00%	2	0.31%	0	0.00%	0	0.00%	3	0.47%	**5**	**0.78%**
1948	385	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	1214	0	0.00%	1	0.08%	0	0.00%	0	0.00%	4	0.33%	**5**	**0.41%**
1888T/TC	5137	1	0.02%	4	0.08%	0	0.00%	1	0.02%	11	0.21%	**17**	**0.33%**
1882T/TC	250	0	0.00%	1	0.40%	0	0.00%	0	0.00%	1	0.40%	**2**	**0.80%**
1782T/TC	169	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1788T/TC	371	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1646T	628	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1688T/TC	2527	1	0.04%	0	0.00%	0	0.00%	0	0.00%	6	0.24%	**7**	**0.28%**
1488T/TC	794	0	0.00%	2	0.25%	0	0.00%	0	0.00%	2	0.25%	**4**	**0.50%**
1388T/TC	234	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 9-10.
A list of complications can be found on page 13.

Implantable Cardiac Monitors (ICMs)

St. Jude Medical™
More control. Less risk.

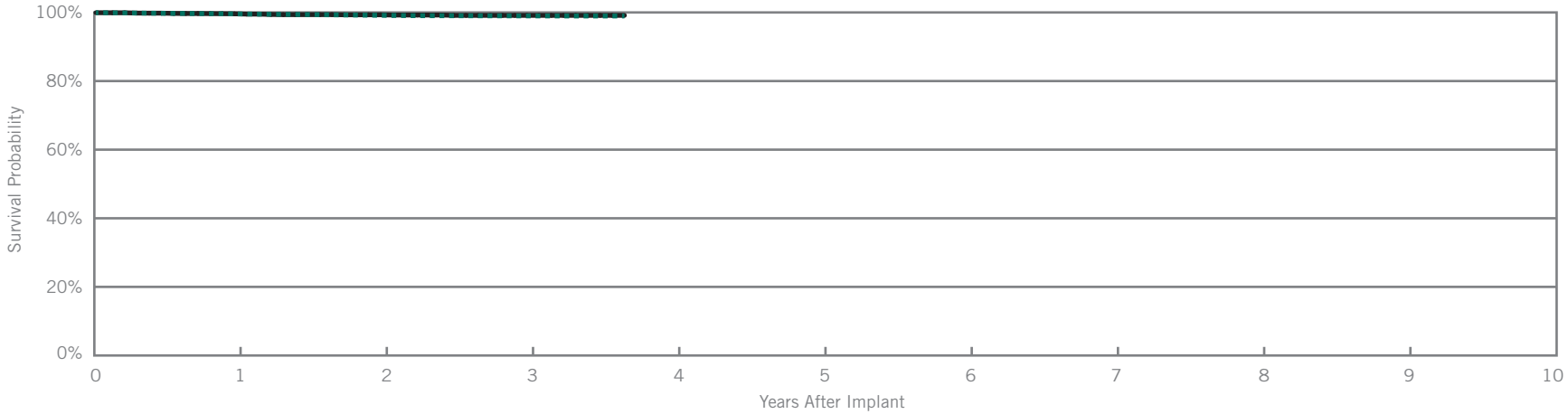
Customer Reported Performance Data

SJM Confirm®

Model DM2100

US Regulatory Approval	August 2008
Registered US Implants	10,812
Estimated Active US Implants	7,177
Estimated Longevity	3 Years*
Normal Battery Depletion	4
Number of US Advisories (see pgs. 248-260)	One

	Malfunctions	
	Qty	**Rate**
Electrical Component	2	0.02%
Electrical Interconnect	0	0.00%
Battery	5	0.05%
Software/Firmware	7	0.06%
Mechanical	0	0.00%
Possible Early Battery Depletion	1	0.01%
Other	7	0.06%
Total	**22**	**0.20%**



Including Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.52%	99.12%	98.96%	98.96%						
± 1 standard error	0.07%	0.12%	0.15%	0.15%						
Sample Size	9500	4700	2200	200						

Excluding Normal Battery Depletion

Year	1	2	3	at 44 months						
Survival Probability	99.60%	99.31%	99.14%	99.14%						
± 1 standard error	0.07%	0.11%	0.14%	0.14%						

**After 12 month shelf-life.*

Summary Information

Implantable Cardiac Monitors (ICMs)

Survival Summary

Including Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
DM2100	SJM Confirm®	99.52%	99.12%	98.96%							

Excluding Normal Battery Depletion

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
DM2100	SJM Confirm®	99.60%	99.31%	99.14%							

Malfunction Summary

Models	Family	Registered US Implants	Malfunctions															
			Electrical Component		Electrical Interconnect		Battery		Software/ Firmware		Mechanical		Possible Early Battery Depletion		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
DM2100	SJM Confirm®	10812	2	0.02%	0	0.00%	5	0.05%	7	0.06%	0	0.00%	1	0.01%	7	0.06%	22	0.20%

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

Focus on Clinical Performance

Update on Riata® Lead Performance

Prospective, monitored registries continue to provide the best data to support clinical decision making. St. Jude Medical is conducting the Riata Lead Evaluation Study, which began in December 2011 and has enrolled 782 patients from U.S., Canada and Japan. Phase I of the study involved enrollment, collection of patient information, thorough (3 angle) cinefluoroscopic imaging, and adjudication of cinefluoroscopic data by experienced, independent electrophysiologists for the presence of externalized conductors. U.S. and Canadian data from Phase I were reported by SJM in July 2012. Additional Phase I data from Japan have since been collected and are represented in this Product Performance Report. The cinefluoroscopic data from 776 patients (259 Riata® ST (7F) and 517 Riata® (8F) leads) worldwide were able to be successfully adjudicated. The prevalence of externalized conductors was significantly lower in Riata® ST (7F) leads as compared to Riata® (8F) leads (9.3% vs. 24.2%, $p<0.001$). After accounting for differences in implant durations, the prevalence of externalized conductors in Riata® ST (7F) leads remained significantly lower than that in Riata® (8F) leads implanted less than or equal to 6 years (9.4% vs. 18.9%, $p = 0.02$). It is important to note that this prevalence rate reflects a visual anomaly of externalized conductors only and not electrical failures. Phase II of the study will continue for 3 years of follow-up with a focus on the incidence of electrical malfunctions in leads with and without externalized conductors. Periodic updates on Phase II of this study will be provided by St. Jude Medical.

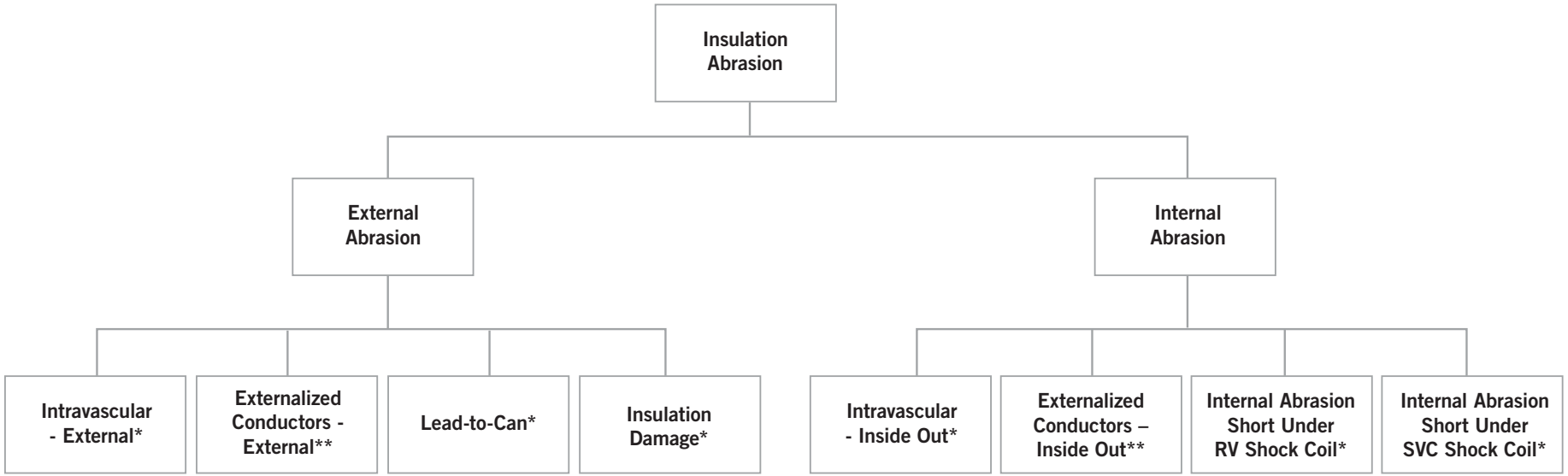
St. Jude Medical understands that the passive system of complaint reporting and returned product analysis results in under-reporting and hence underestimates the true failure rate associated with any given failure mechanism. This is especially true for externalized conductors since most manifest as visual anomalies only with normal electrical performance. While acknowledging these limitations, St. Jude Medical provides externalized conductor rates from the passive data system to maintain continuity with previously published data and to provide full disclosure of the data available to St. Jude Medical. As of August 31, 2012, there were 1929 cases of externalized conductors reported to St. Jude Medical worldwide on Riata® (8F) and Riata® ST (7F) silicone defibrillation leads, equating to a 1.04% (1620/156,100) incidence rate for Riata® (8F) and 0.44% (309/70,620) for Riata® ST (7F) leads. Of these 1929 leads, 1619 were not returned and 310 were returned for analysis.

As with any lead, there are failure mechanisms other than externalized conductors which result from insulation abrasion. Historically, the rate of all-cause insulation abrasion failures has been reported in the range of 3 to 10% (Kleemann et al., Annual Rate of Transvenous Defibrillation Lead Defects in Implantable Cardioverter Defibrillators over a Period > 10 years, Circulation 2007; 115:2474-2480). The most common form of insulation abrasion has been lead-to-can abrasion occurring in the pocket area. Externalization of conductors is another manifestation of insulation abrasion. It is most commonly caused by a mechanism

we have referred to as inside-out abrasion, where the conductor cables become visible outside the insulation body. Approximately 89% of confirmed externalized conductors from product returns analysis are caused by inside-out abrasion, while 11% result from external sources of abrasion.

A flow diagram depicting specific insulation abrasion failure mechanisms for Riata® and Riata® ST silicone leads is shown in the following figure.

Flow Diagram of Insulation Abrasion Types and Mechanisms



*Determined by returned product analysis.
**Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.

Definitions of the failure mechanisms are provided below:

- **External Abrasion:** Abrasion resulting from direct contact with an implanted device (e.g., pulse generator can, another lead), calcified anatomy, or anatomical structure that results in an outer insulation breach.
- **Internal Abrasion:** "Inside-out" abrasion between a lead conductor and the outer insulation that results in an insulation breach.
- **Intravascular Abrasion - External:** Direct contact with a foreign body (e.g., another lead), calcified anatomy, or cardiac structure within the vascular system or the heart that results in an outer insulation breach. The nature of the breach does not result in the conductors becoming visible outside the lead body. Determined by returned product analysis.
- **Externalized Conductors – External Source of Abrasion:** Direct contact with a foreign body (e.g., another lead), calcified anatomy, or cardiac structure within the vascular system or the heart that results in an outer insulation breach and the normally contained conductors becoming visible outside the lead body. Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads. For those cases not returned, the assignment of an external source of abrasion is based on the fraction of externalized conductor cases identified by returned product analysis as external.
- **Lead-to-Can Abrasion:** Direct contact between the lead and the can (i.e. pacemaker, ICD, or CRT-D) that results in an outer insulation breach. Determined by returned product analysis.
- **Insulation Damage:** Insulation breaches that result from external mechanisms, including clavicular crush and outside-in abrasion by lead conductors. Determined by returned product analysis.
- **Intravascular Abrasion – Inside Out:** "Inside-out" abrasion between a lead conductor and the outer insulation within the vascular system or the heart that results in an outer insulation breach. The nature of the breach does not result in the conductors becoming visible outside the lead body. Determined by returned product analysis.
- **Externalized Conductors – Inside-Out:** Outward abrasion of conductors that results in an outer insulation breach within the vascular system or heart and the normally contained conductors becoming visible outside the lead body. Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads. For those cases not returned, the assignment of an inside-out source of abrasion is based on the fraction of externalized conductor cases identified by returned product analysis as inside-out.

- **Internal Abrasion Short under RV Shock Coil:** Outward abrasion of the conductor cables under the RV shock coil that results in breaches of the outermost silicone insulation and the ETFE cable insulator, allowing the exposed metal surface of the conductor cables to make direct contact with, and potentially short against, the overlying RV shock coil. Determined by returned product analysis.
- **Internal Abrasion Short under SVC Shock Coil:** Outward abrasion of the conductor cables under the SVC shock coil that results in breaches of the outermost silicone insulation and the ETFE cable insulator, allowing the exposed metal surface of the conductor cables to make direct contact with, and potentially short against, the overlying SVC shock coil. Determined by returned product analysis.

Note that these definitions have been refined since the 2012 First Edition PPR. Most importantly the category of "Intravascular Abrasion – Inside Out" has been added to ensure coverage of all abrasion types.

The table below summarizes the incidence of insulation failure mechanisms observed on Riata® and Riata® ST leads (out of a total of approximately 8,400 Riata and Riata ST returned leads). Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive. Note that the rates for externalized conductors also include visual-only observations that have been reported for leads remaining implanted.

Riata (8F) and Riata ST (7F) Insulation Failure Mechanisms from Complaints and Returns

Insulation Failure Mechanism	Abrasion Type	Riata (8F) Worldwide (WW) Incidence Rate (WW Sales = 156,308)	Riata ST (7F) Worldwide (WW) Incidence Rate (WW Sales = 70,665)
Intravascular – External*	External Abrasion	0.14%	0.12%
Externalized Conductors – External**	External Abrasion	0.12%	0.05%
Lead-to-Can*	External Abrasion	0.43%	0.35%
Insulation Damage*	External Abrasion	0.04%	0.03%
Intravascular - Inside Out*	Internal Abrasion	0.17%	0.06%
Externalized Conductors - Inside Out**	Internal Abrasion	0.92%	0.39%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.05%	0.01%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.03%	0.003%

*Determined by returned product analysis.
**Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.

Durata® Lead Performance

The safety and reliability of our Durata® high voltage leads is supported by robust post-market surveillance monitoring. Data are collected on case report forms at each scheduled and unscheduled patient visit with additional information documented for any adverse event. We also employ a dedicated field monitoring organization to ensure that the data from the clinical site are accurately and completely submitted. Because of the size and scope of these actively monitored registries, they represent the true commercial experience with our current generation high voltage leads.

The three studies enrolling either Durata or Riata® ST Optim® leads are the OPTIMUM registry, SCORE registry, and the SJ4 Post Approval Study (PAS). These are prospective, outcome-oriented, actively monitored registries. Currently, a total of 10,987 Optim insulated leads (8,106 Durata and 2,881 Riata ST Optim leads) are enrolled in these studies at 293 sites.

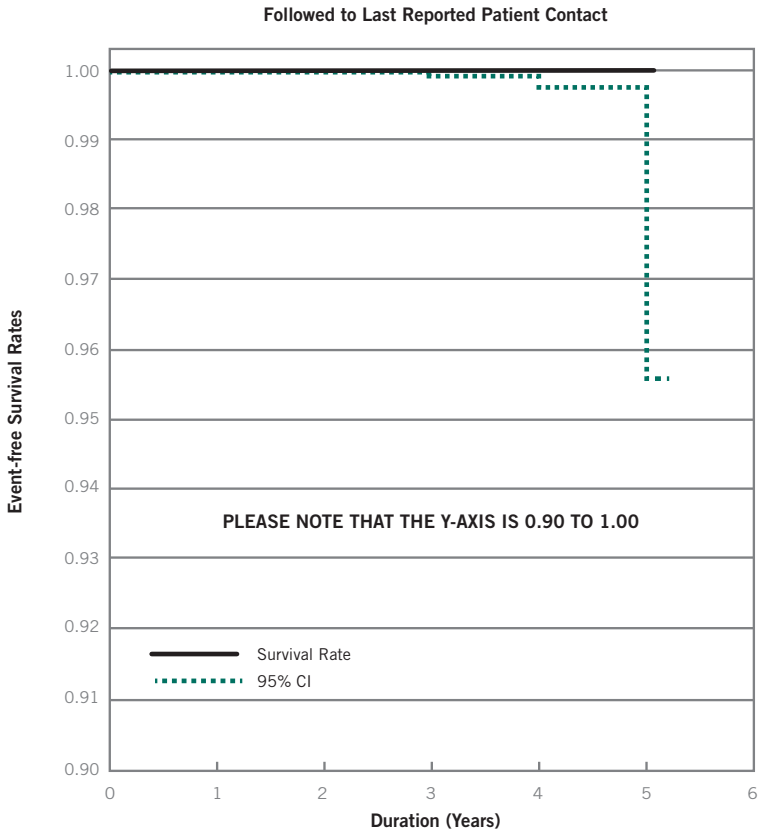
The raw data from these three registry studies, current as of August 31, 2012, was independently analyzed by the Population Health Research Institute (PHRI) of McMaster University/Hamilton Health Science. Their results quantify the performance of the Durata and Riata ST Optim leads in the categories of externalized conductors, all-cause insulation breach, and all-cause mechanical failures. An externalized conductor represents an outer insulation breach within the vascular or cardiac systems resulting in the normally contained conductors becoming visible outside the lead body. All-cause insulation breach includes all types of abrasion and other mechanical types of insulation damage, including externalized conductors. The all-cause mechanical failure category includes any insulation breach (including abrasion), conductor fracture, failure of a crimp, weld, or bond, or other mechanical failure.

An Independent Analysis of Durata and Riata ST Optim Lead Failure Rates in Active Registries by PHRI (data through August 31, 2012)

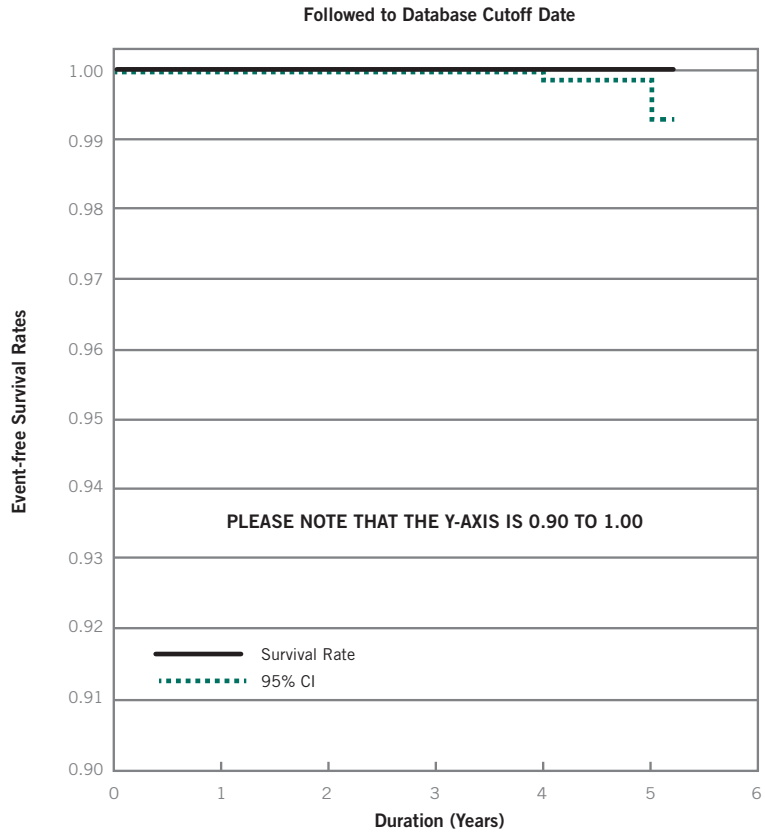
Failure Category	Durata and Riata ST Optim %	Durata and Riata ST Optim 95% CI
Externalized Conductors	0.0%	0.00% – 0.03%
All-Cause Insulation Abrasion	0.06%	0.03% - 0.12%
All-Cause Mechanical Failures	0.31%	0.21% - 0.42%

Event-Free Survival Rates for Externalized Conductors (Figure 1), All-Cause Insulation Abrasion (Figure 2), and All-Cause Mechanical Failures (Figure 3) in Optim ICD leads were calculated by PHRI. Two methodologies were utilized: follow-up duration for active leads based on last reported patient contact (left graphs) or a common database cutoff date of August 31, 2012 (right graphs). Enrollment date in the registry rather than the lead implant date is used as time zero for these survival curves. The protocols allowed patients to be enrolled up to 6 months post-implant; hence, the actual lead implant duration is longer.

Figure 1: Event Free Survival Rates for Externalized Conductors in Optim ICD Leads as Calculated by PHRI

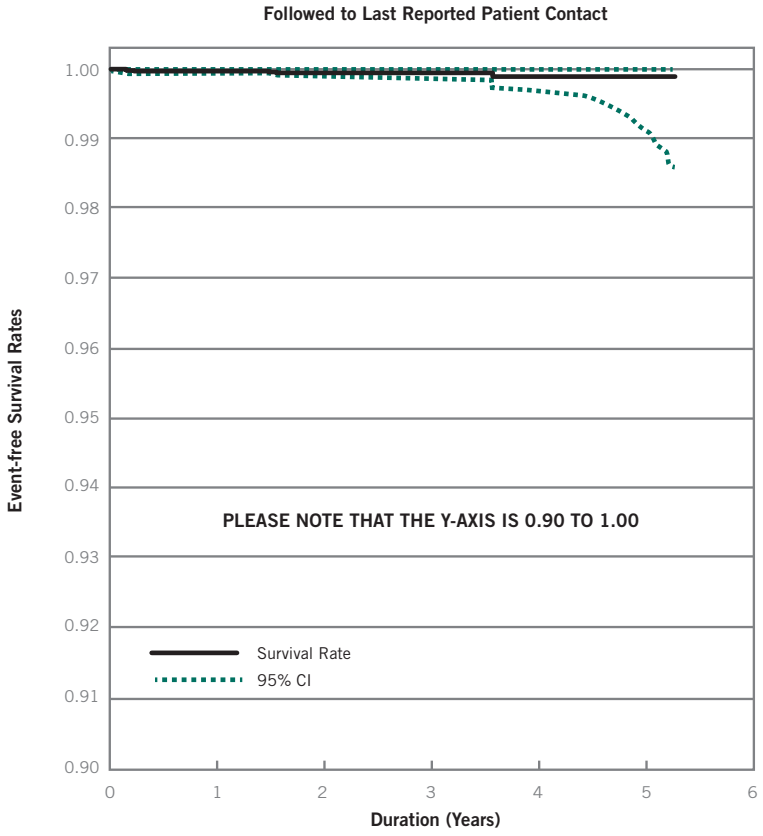


Year	0	1	2	3	4	5
Leads at Risk	10987	9280	6931	3339	1111	68

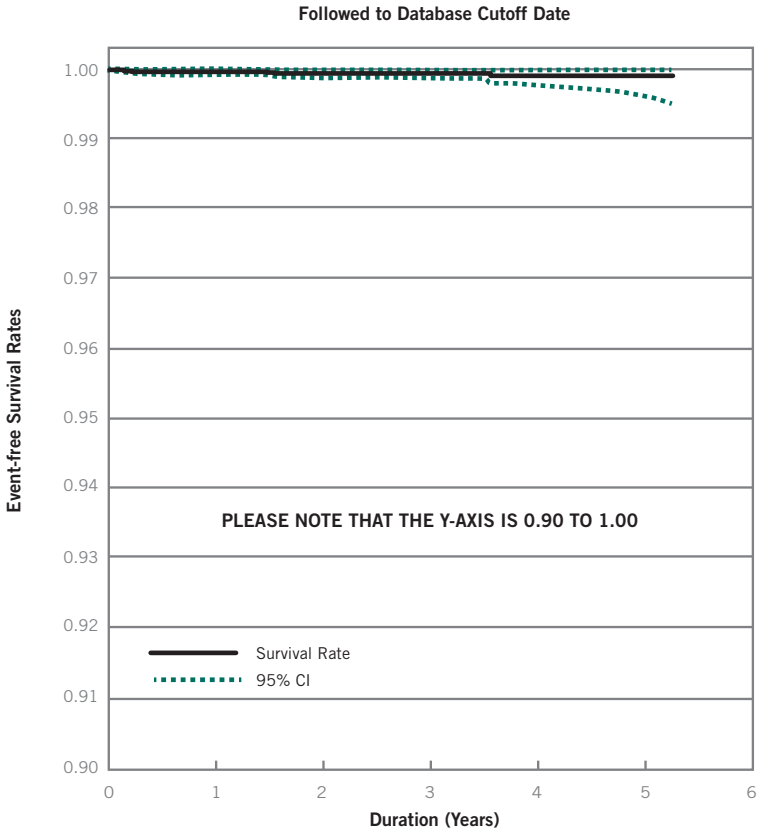


Year	0	1	2	3	4	5
Leads at Risk	10987	9677	7771	4735	1924	418

Figure 2: Event Free Survival Rates for All-Cause Insulation Abrasion in Optim ICD Leads as Calculated by PHRI

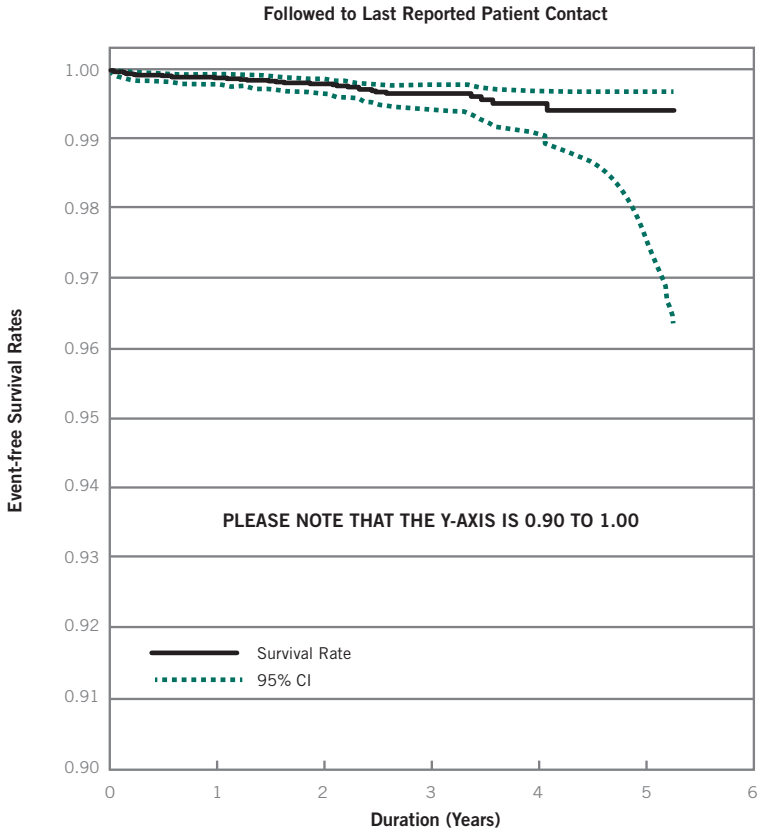


Year	0	1	2	3	4	5
Leads at Risk	10987	9276	6927	3337	1110	68

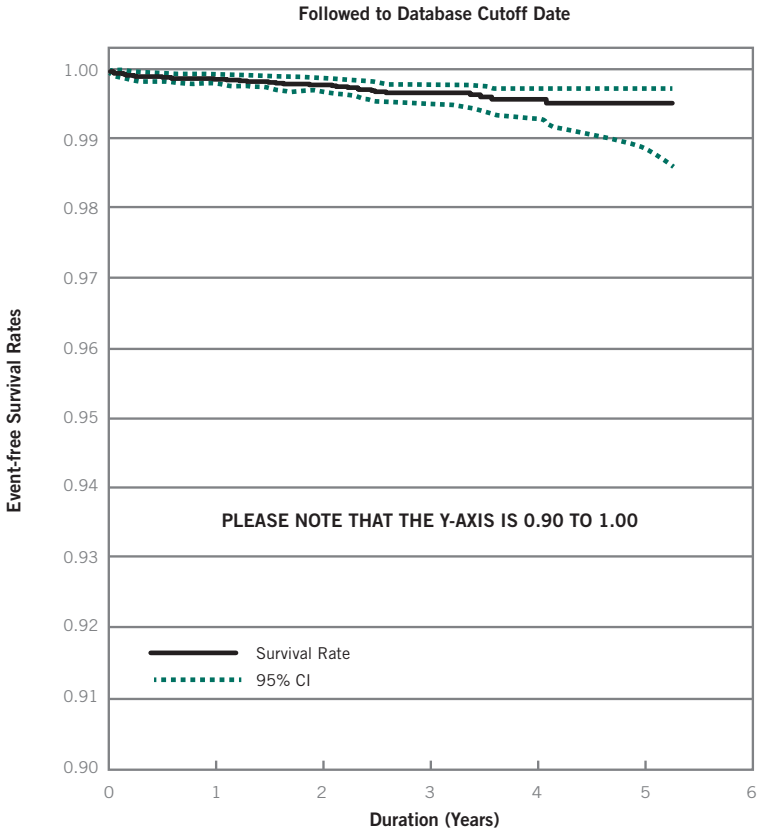


Year	0	1	2	3	4	5
Leads at Risk	10987	9676	7769	4735	1924	418

Figure 3: Event Free Survival Rates for All-Cause Mechanical Failure in Optim ICD Leads as Calculated by PHRI



Year	0	1	2	3	4	5
Leads at Risk	10987	9265	6915	3325	1109	68



Year	0	1	2	3	4	5
Leads at Risk	10987	9672	7765	4730	1923	418

While large active registry data are robust for determining the true incidence rate of failures, passively collected data from worldwide complaints and returns analysis provides an important data source for better understanding the root cause of lead failures, as well as an appropriate method for comparing relative incidence rates of failure between lead models. The table below summarizes the different insulation failure mechanisms observed out of approximately 7,900 Riata® ST Optim® and Durata® leads that have been returned for analysis worldwide through August 31, 2012. Returned leads may exhibit more than one failure mechanism; hence the incidence rates presented in the table are not mutually exclusive.

Durata® (WW Sales 315,443) and Riata® ST Optim® (WW Sales = 33,030) Leads Insulation Failure Mechanisms from Complaints and Returns Analysis

Insulation Failure Mechanism	Abrasion Type	Optim Defib Lead Worldwide (WW) Incidence Rate (WW Sales = 348,473)
Intravascular – External*	External Abrasion	0.007%
Externalized Conductors – External**	External Abrasion	0.001%
Lead-to-Can*	External Abrasion	0.018%
Insulation Damage*	External Abrasion	0.008%
Intravascular - Inside Out*	Internal Abrasion	0.000%
Externalized Conductors - Inside Out**	Internal Abrasion	0.0003%***
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.001%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.001%

*Determined by returned product analysis.
**Includes cases determined by returned product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.
***The Riata ST Optim lead design included short lengths (0.5" nominal) adjacent to the shock coils which were not covered by the Optim sheath. The 0.0003% rate reflects a single case of inside-out externalized conductors in a non-Optim region of the lead body just proximal to the RV shock coil.

These incidence rates from complaints and returns analysis demonstrate the effectiveness of the Riata ST Optim and Durata lead design changes in reducing insulation-related failures when compared to the same type of data for Riata/Riata ST silicone leads (see page 239).

Optim® Lead Insulation

In 2006 St. Jude Medical brought to the cardiac rhythm management (CRM) market the first novel insulation technology in over 20 years: a silicone-polyurethane co-polymer known as Optim® lead insulation, now featured in IsoFlex® Optim®, Tendril® STS, OptiSense®, QuickFlex® µ, Quartet®, and Durata® lead families. Optim lead insulation consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone.

The polyurethane content of Optim lead insulation imparts lubricity, strength, and abrasion resistance while the nearly 50% silicone content imparts flexibility and biostability.[1,2] The clinical performance of >1.7 million Optim insulated pacing and tachycardia leads implanted worldwide continues to be excellent.

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

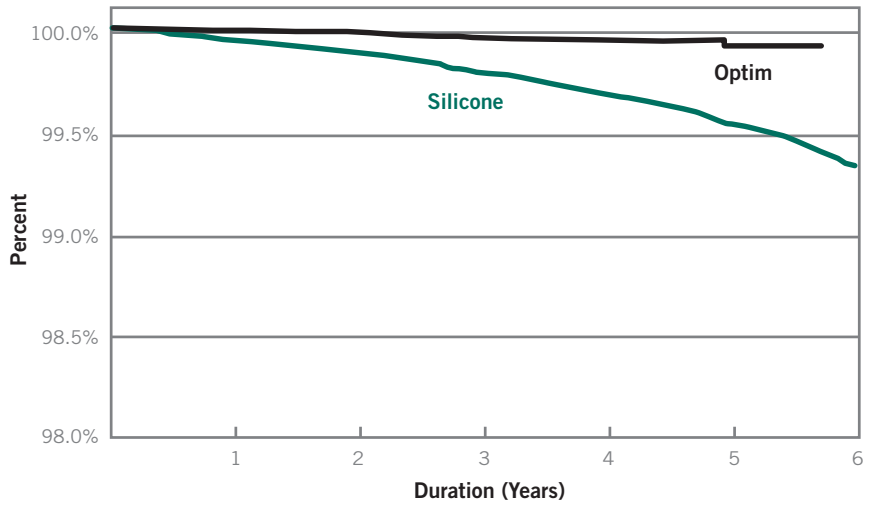
This product performance report provides an up-to-date statistical assessment of the benefits of Optim lead insulation on St. Jude Medical tachycardia leads. A Kaplan-Meier analysis including all U.S. data through June 30, 2012 was performed on two groups of leads: (1) tachycardia leads with silicone insulation [Riata and Riata ST lead families], and (2) tachycardia leads with Optim lead insulation [Riata ST Optim and Durata lead families]. For both group, the U.S. registration and tracking data was combined with data from all U.S. confirmed abrasion malfunctions. This analysis does not include data from prospective registries or non-returned complaints. A Kaplan-Meier curve representing freedom from abrasion for both groups is provided below. The longest implant duration that is common to both model groups was 68 months. To provide a direct comparison of both model groups, the probability of an abrasion malfunction by 68 months of implant time is also presented in graphical format below.

The data show that the presence of Optim® lead insulation dramatically reduces the probability of abrasion malfunction in tachycardia leads at 68 months by 83%, which was confirmed to be statistically significant ($p<0.001$) by a log-rank test. The abrasion resistance of Optim lead insulation has decreased by a factor of ten the probability of abrasion malfunction in the St. Jude Medical's Riata® ST Optim and Durata® lead families when compared to the Riata® and Riata® ST lead families.

Optim® Lead Insulation Effects on SJM Tachycardia Lead Abrasion

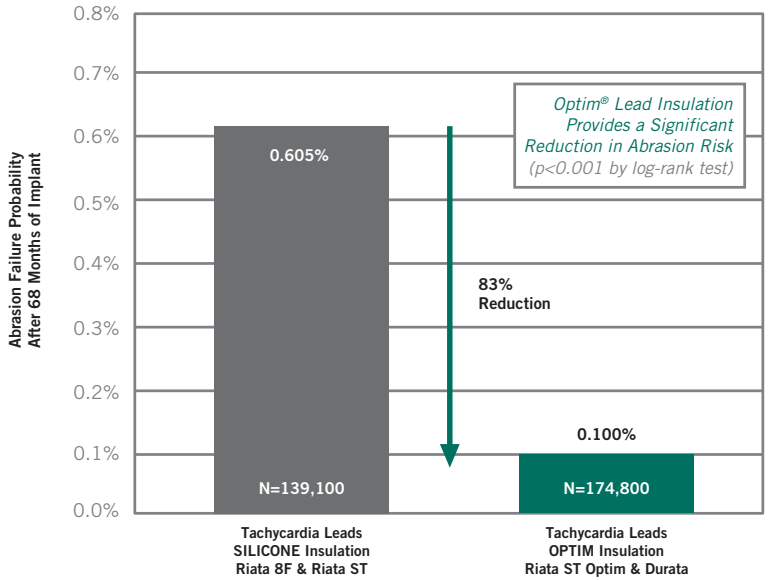
Kaplan-Meier Analysis of US Returns Analysis Data

Freedom from Abrasion Failure (%)



Year	1	2	3	4	5
Optim	147,866	100,578	60,435	28,990	9,159
Silicone	129,167	115,608	104,333	91,838	75,119

Abrasion Malfunction Probability after 68 Months of Implant



[1] C. Jenney, J. Tan, A. Karicherla, J. Burke, and J. Helland, *"A New Insulation Material for Cardiac Leads with Potential for Improved Performance,"* HRS 2005, HeartRhythm, 2, S318-S319 (2005).

[2] J. Tan and C. Jenney, *"Comparative In Vivo Biostability Study of A New Lead Insulation Material Versus Polyurethanes,"* HRS2006, Heart Rhythm, 3, S146 (2006).

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

Advisories & Safety Alerts

St. Jude Medical™
More control. Less risk.

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

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Convert®+ (Model V-195)	5/6/2010 Outside US only A condition where devices programmed to a two-zone tachy therapy configuration, using a Merlin® Patient Care System (PCS) programmer running version 7.2.1, 8.2.1 or 10.2.0 software, can result in the VT Therapy Timeout parameter being programmed OFF and HV therapy not being available if ATP therapies are unsuccessful.	If a patient's device is already programmed to a two zone configuration with a Merlin® PCS programmer running version 7.2.1, 8.2.1 or 10.2.0, a follow-up visit should be scheduled to perform the recommendations outlined below: A permanent correction is available in the new release of the Merlin® PCS programmer software version 10.2.2 which has received regulatory approval. Subsequently using a Merlin® programmer with 10.2.2 (or later) software and following the steps outlined below will ensure that the VT Therapy Timeout parameter is programmed ON. 1. Interrogate the Convert+ ICD and verify that it is programmed to a two zone configuration. 2. Program the device to a single zone, fibrillation only tachycardia mode. This action will program the VT Therapy Timeout parameter ON. 3. Re-program the device to the desired two zone configuration. (VT Therapy Timeout will remain ON). If your patient's device is programmed to a single zone (fib only) there is no need to perform any reprogramming action. As these actions fully correct the potential issue there is no need to consider any device explant. **Current Status (June 30, 2012):** 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, 2012, there have been no additional reports associated with this advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic® + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic® II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas® + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas® II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	1/16/08 Class II A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic® and Atlas® family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window.	A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin® Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (June 30, 2012):** 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, 2012 there have been no additional devices confirmed to have this issue since the time of the advisory.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Photon™ DR (V-230HV) (certain serial numbers), Photon™ Micro VR/DR (Models V-194/V-232), Atlas® VR/DR (Models V-199/V-240)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible.You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (June 30, 2012):** 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, 2012 there were an additional 42 worldwide (28 U.S.) devices confirmed with this issue. This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/ V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/ V-340/V-341/V-343).	6/13/05 Class II Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to St. Jude Medical. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic® DR/HF (V-233/V-337/V-338), Epic® Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/V-350), Atlas® DR (V-242), and Atlas® Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On," this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. St. Jude Medical has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On," devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high- voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (June 30, 2012):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

ICD and CRT-D Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® (V-197, V-235), Epic®+ (V-196, V-236), Epic® HF CRT-D (V-338), Epic®+ HF CRT-D (V-350), Atlas®+ (V-193, V-243), Atlas®+ HF CRT-D (V-340), or Atlas® (model V-242) ICDs	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (June 30, 2012):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

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

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Accent® DR (Models PM2110, PM2112, PM2210 and PM2212) and Anthem® CRT-P (Models PM3110, PM3112, PM3210 and PM3212)	9/22/11 Class II A small amount of electrical charge may accumulate within an internal capacitor which results in a low or varying pacing lead impedance (PLI) value during the automatic daily measurements. An out of range lead impedance measurement may result in a patient notifier alert, a remote monitoring Merlin.net® Patient Care Network alert, or a prior alert message to be displayed on the programmer screen at the next in-clinic follow-up.	In order to prevent a false reading, a new Merlin® Patient Care System programmer software version is available. When used to interrogate an Accent DR or Anthem CRT-P pacemaker this software will eliminate the potential for this anomaly to occur. With the new software, the programmer will automatically activate circuitry in the pacemaker during the interrogation process to ensure that any residual charge on the capacitor is discharged prior to performing the daily PLI measurement. The onetime upgrade is performed automatically on affected devices and will not change the operation of the implanted device. Your St. Jude Medical Sales Representative will assist you in loading the new programmer software onto your Merlin programmer. If you are following any patients implanted with Accent DR pacemakers or Anthem CRT-P devices, St. Jude Medical makes the following recommendations, which are consistent with standard best practices: ■ Ensure that the new programmer software version is loaded on your programmers as soon as practical. ■ Continue to follow patients on their standard follow-up schedule. Since the likelihood of the low lead impedance measurement is low, the device interrogation can be performed at the patient's next regular scheduled follow-up visit. ■ In the event that a patient receives a low lead impedance alert before the new programmer software has been loaded, we suggest that you evaluate the device as you normally would for any such instance. If the daily pacing lead impedance value is out-of range, re-interrogate the device's measured data and look at the lead impedance values. This "in-clinic" measurement is not affected by the aforementioned capacitor charge build-up and will provide an accurate lead impedance measurement. **Current Status (June 30, 2012):** World-wide, 13 Accent DR (<0.01%) and 225 Anthem CRT-P (1.6%) devices have exhibited this diagnostic anomaly

Pacemaker and CRT-P Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity® SR (5172) Identity® DR (5370) Identity® XL DR (5376)	10/12/06 Class II A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in St. Jude Medical Identity® pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the St. Jude Medical Identity® family of pacemakers when programmed by the St. Jude Medical APS™ III Model 3500/3510 or Merlin® Patient Care System Model 3650 programmers.	No follow-up is recommended at the time of advisory. Devices do not need to be replaced. A programmer software update, pending FDA and other regulatory agency approval, will mitigate this anomaly when the device is interrogated. Before the programmer software update is available, any subsequent measured data update that is performed during the session would be valid and the device operating magnet rate would be up-to-date. After the programmer software update is available, any device affected by this issue will be automatically corrected via the normal interrogation process. **Current Status (June 30, 2012):** 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, 2012 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Identity ADx® DR Models 5286, 5380, 5386 and 5480	7/31/03 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. **To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval.** In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual-chamber device would have to satisfy both of the following conditions: Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower Autocapture™ pacing system programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or Autocapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program Autocapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (June 30, 2012):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Pacemaker and CRT-P Devices

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

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

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

Pacemaker and CRT-P Devices

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

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

Pacemaker and CRT-P Devices

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

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

Left-Heart Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
QuickSite® 1056T and 1058T, QuickFlex® 1156T and 1158T	4/3/2012 Class II Abrasion of the silicone insulation in the distal portion of QuickSite and QuickFlex leads has led to visual observations of externalized conductors. There have been no reports of death or serious injury associated with the externalized conductors; likewise there have been no electrical dysfunctions attributable to the externalized conductors. The reported rate of externalized conductors in the QuickSite and QuickFlex leads is 0.023%, based on 39 confirmed cases of externalized conductors in a population of approximately 82,000 QuickSite and 89,000 QuickFlex leads sold worldwide. This issue is under-detected because these cases are visual observations without any signs of electrical dysfunction and fluoroscopic/xray imaging is not routine. Based on a review of returned leads and available fluoroscopic and x-ray images of patients with QuickSite and QuickFlex leads (1,219 leads), it is estimated that the incidence of conductor externalization on these leads may be 3% to 4%.	St. Jude Medical and its Medical Advisory Board recommend that physicians continue to monitor their patient's implanted system at regularly scheduled intervals with attention paid to diagnostic information related to LV pacing performance, in particular LV lead impedance and capture thresholds. Programming of alerts that monitor lead impedance changes outside of the nominal range and enabling the patient notifier should be considered. A special X-ray or fluoroscopic imaging is not recommended for LV CRT leads with normal electrical function. CRT pacing functionality should be evaluated during routine device checks and only leads exhibiting electrical anomalies that cannot be reprogrammed to deliver effective CRT pacing should be considered for replacement. **Current Status (June 30, 2012):** At the time of the advisory there was a world-wide reported externalized conductor rate of 0.023% in QuickSite and QuickFlex leads. As of June 30, 2012, there have been additional reports and the world-wide reported externalized conductor rate for QuickSite and QuickFlex leads was 0.051%.

Defibrillation Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Riata® Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582) Riata® i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata® ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)	11/28/2011 Class I Externalized conductors occur when an abrasion results in an outer insulation breach, allowing the normally contained conductors to become visible outside the lead body. Even though causality cannot be established, when externalized conductors are accompanied by reports of electrical malfunction, these reports typically include pacing or defibrillation impedance changes, innappropriate therapy, noise and oversensing, and pacing threshold rise. Externalized conductors have not been observed in Riata ST Optim® and Durata® models due to the presence of an abrasion resistant outer Optim lead insulation sheath. A summary of the types and incidence rates of Riata abrasion malfunctions is presented on pages 236-239 of this Product Performance Report.	St. Jude Medical and its Medical Advisory Board make the following recommendations, which are consistent with standard best practices and our December 2010 product communication. Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. St. Jude Medical remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors. Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits. If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing, if necessary, could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem associated with any source of lead electrical failure if one exists. The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time and is therefore not recommended. In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended. Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalized conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances. Based on input from the MAB, St. Jude Medical is conducting a prospective study to evaluate further the incidence of externalized conductors and the long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities. **Current Status (June 30, 2012):** At the time of the advisory there was a world-wide reported all-cause insulation abrasion rate of 0.63% for Riata silicone leads. The world-wide reported rate for the subcategory of externalized conductors in Riata silicone leads was 0.10%. As of June 30, 2012, there have been additional reports. The world-wide reported rates of all-cause abrasion and externalized conductors for Riata silicone leads was 1.37% and 0.69%, respectively. The latest information related to the silicone Riata lead advisory, including references to independent studies of Riata performance, can be obtained at www.RiataCommunication.com.

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

Defibrillation Leads

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Riata® Defibrillation Lead (Models 1570, 1571, 1572, 1580, 1581, 1582) Riata® i Defibrillation Lead (Models 1560, 1561, 1562, 1590, 1591, 1592) Riata® ST Defibrillation Lead (Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042)	12/15/2010 Outside US Only Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10%. After more than 9 years of clinical use and approximately 227,000 implants, silicone-insulated Riata®, Riata® i, and Riata® ST defibrillation leads have exhibited an insulation abrasion rate of 0.47% (inclusive of confirmed returns and complaints/observations with no associated return). There are several factors that can contribute to lead abrasion in implanted pacing and defibrillation systems, including physiological stresses placed on the lead due to patient anatomy, implant orientation, and mechanical stresses applied from concomitant devices in the body. A summary of the types and incidence rates of Riata abrasion malfunctions is presented on pages 236-239 of this Product Performance Report.	Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person or remote monitoring are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus. Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedure in particular looking for significant changes from the patient's previous follow-up visits. If there is evidence of a lead electrical failure, manage the patient per standard practice.[1] This may include x-ray or fluoroscopy. Additional testing if necessary could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem if one exists. Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events. **Current Status (June 30, 2012):** At the time of the advisory there was a world-wide reported insulation abrasion rate of 0.47% for Riata silicone leads. As of June 30, 2012, there have been additional reports and the world-wide reported insulation abrasion rate is 1.37%.

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

ICM Devices

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
SJM Confirm® ICM (Models DM2100 and DM2102)	3/11/2011 Class II US and Germany A product firmware upgrade using the Merlin® Patient Care System (PCS) programmer running software versions 10.1.1.3, 10.1.1.2, or 11.2.2 leaves the implantable cardiac monitor device in a state which results in increased current usage. If not corrected this state could result in premature battery depletion.	If you are following any patients implanted with the SJM Confirm Models DM2100 or DM2102 and their device was upgraded using the Merlin programmer with the above mentioned software versions it is recommended to determine the patient's clinical reason for the implant and their continued need for the device: ■ If the device has previously been used to record and assist in the diagnosis of an arrhythmia and is no longer needed, no further action is required. The device will exhaust its battery capacity prior to the 3 year expected longevity. ■ If the unit is still indicated for diagnosing a potential clinical arrhythmia, contact your Field Clinical Engineer and he/she will assist in calculating the projected remaining longevity. If appropriate, the microprocessor operation can be reset to the nominal current drain. ■ If the device is no longer indicated it can be left implanted until such time that a routine explant is desired. If the device is determined to be necessary and is experiencing increased current usage as described above, it can be corrected with assistance from your Sales Representative or St. Jude Medical Technical Services. St. Jude Medical is in the process of developing new Merlin PCS programmer software that will properly upgrade SJM Confirm devices. **Current Status (June 30, 2012):** At the time of the advisory, 83 implanted devices world-wide were identified as having undergone the problematic firmware upgrade. All of these devices have been corrected using the Merlin PCS programmer or were determined by the clinician to not require further action because the device had already provided the necessary diagnostic information and was no longer required. There have been no additional implanted devices confirmed to have been affected by this issue. Updated Merlin PCS programmer software has been implemented which prevents this issue from occurring in the future.

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Index of Phased-out Models

Phased-out Models

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

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

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

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

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

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

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

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

IMPLANTABLE ELECTRONIC SYSTEMS

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