Product Performance Report

Cardiac Rhythm Management

October 2009

St. Jude Medical™

More control. Less risk.

Letter from St. Jude Medical

October 2009

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

In keeping with this commitment, we publish a product performance report semi-annually to ensure that the healthcare community and the patients it serves are informed about the overall performance of our cardiac devices, which include implantable cardiac monitors, implantable cardioverter defibrillators (ICDs), pacemakers and implantable pacing and defibrillation leads.

This is the third report to include data from St. Jude Medical Product Longevity and Performance Registry (SCORE). SCORE is an active, ongoing source of information on the reliability and performance of St. Jude Medical cardiac rhythm management products. Unlike other active registries, SCORE tracks information on multiple product families, including leads as well as ICD and pacemaker models, making it the most comprehensive registry in the industry. This prospective, non-randomized, multi-center registry complements the data gathered from returned product analysis. In addition to helping determine and report survival probabilities, the data from this registry may also be used to support design and development of new cardiac rhythm management products. SCORE started enrolling patients in June 2007. The registry will actively monitor indefinitely the performance of implanted St. Jude Medical products at participating sites and is thus designed to include new products as they become available. SCORE is just one example of how we are working to reduce risk and set new standards for quality and performance.

St. Jude Medical also recognizes the value of the industry working together to provide transparent and consistent information on the performance of cardiac rhythm management products. Following the 2005 Policy Conference on Pacemaker and ICD Device Performance, cardiac device companies have worked through AdvaMed to establish uniform guidelines for product performance reporting. The most recent output of this AdvaMed effort was the August 2009 revision of the industry guidance document entitled "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads". St. Jude Medical has now adopted these updated AdvaMed guidelines, which set forth the definitions and requirements for product performance reports and seek to provide physicians and their patients with a level of device performance information that is consistent across manufacturers. Starting with this report, leads reporting for the recently released lead models has been enhanced, as per the AdvaMed guidelines, to provide detail on specific lead observations and complications. Additionally, laboratory analysis results for leads are now categorized into five distinct classifications of malfunction.

As we continually strive to provide unbiased and reliable information on the performance of our products, we are pleased to release this product performance report with the latest performance information on our ICDs, pacemakers and lead systems.

Sincerely,

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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Serving our mission

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

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

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

What you'll find in this report

For all ICDs starting with the Photon™ Micro device and for all pacemakers starting with the Affinity® device, you will find the analysis of data, according to the AdvaMed guidelines, collected through June 30, 2009, including:

- A graph of survival probability that reflects reasons for device removal (including normal battery depletion, malfunction with compromised therapy, and malfunction without compromised therapy). It includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions as well as a method to adjust for under-reporting;
- A graph of survival probability that excludes normal battery depletion in the Analysis;
- A longevity bar representing the range of longevities for each model as referred to in the User's Manual;
- A table that accompanies and summarizes the data in each graph; and
- An update to Advisories on implantable devices starting in 2003.

Introduction and Overview

Additional data summary tables for ICDs starting with the Photon™ Micro device and pacemakers starting with the Affinity® device can be found for Cardiac Resynchronization Therapy (CRT) ICDs on page 29, for CRT-Pulse Generators on page 39, for ICDs on pages 75 and 95 and for Pulse Generators on pages 155 and 181.

For ICDs prior to the Photon™ Micro device and pacemakers prior to the Affinity® device, you will find analysis of the data collected through June 30, 2009, consistent with previous product performance reports. These device models include:

ICDs

Contour™ MD V-175, V-175AC, V-175B, V-175C, V-175D

Pulse Generators (Pacemakers)

Trilogy™ DC+ 2318
Trilogy™ DR+ 2360, 2364
Paragon™ III 2304, 2314, 2315
Paragon™ II 2016
Paragon™ 2010, 2011, 2012
Synchrony™ III 2028, 2029
Synchrony™ II 2022, 2023
AddVent™ 2060
Microny® 2425T, 2525T, 2535K
Regency® SC+ 2400L, 2402L
Tempo™ V 1102
Tempo™ VR 1902
Trilogy™ SR+ 2260, 2264
Trilogy™ SR 2250
Solus® II 2006, 2007
Solus® 2002, 2003
Phoenix™ II 2005, 2008, 2009

Older lead models for which survival charts are presented consistent with previous product performance reports include:

Defibrillation Leads

TVL™ ADX 1559
SPL® SP01, SP02, SP03, SP04
TVL™ RV RV01, RV02, RV03, RV06, RV07
TVL™ SVC SV01, SV02, SV03

Pacing Leads

Tendril® 1148, 1188T
Tendril® DX 1388T/TC
Models 1018T, 1028T Bipolar Leads
Passive Plus® 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T
Passive Plus® DX 1336T, 1342T, 1346T
Permathane™ ACE 1036T, 1038T
Tendril® 1188K
Tendril® DX 1388K
Fast-Pass® 1007
Passive Plus® 1135K, 1143K, 1145K, 1235K, 1243K, 1245K
Passive Plus® DX 1343K, 1345K
Permathane™ ACE 1035M
AV Plus® 1368
ACE™ 1015M, 1025M, 1026T, 1016T

We have also included a summary of the methods used for measuring product performance and a summary of the definitions for key terms used in preparing the report. Additionally, the survival charts include a summary description section, as identified below:

ICDs and Pulse Generators (Pacemakers)

US Market Release Date

Registered Number of US Implants

Estimated Number of Active US Implants

Estimated Longevity in years

Number of Normal Battery Depletions

Number of Malfunctions (including returns related to advisories)

Number of Advisories

Maximum Delivered Energy – in joules (ICDs only)

Leads

US Market Release Date

Registered Number of US Implants

Estimated Number of Active US Implants

Insulation Material

Lead Type and/or Fixation

Polarity

Steroid

Number of Advisories

Observations, Complications, and Lead Malfunctions for the recently released models

Introduction and Overview

What's new in this report

SCORE Registry Data:

St. Jude Medical is pleased to again provide results from the SCORE (St. Jude Medical Product Longevity and Performance) Registry. SCORE is an active, ongoing source of reliability and performance information of St. Jude Medical market-released cardiac rhythm management products – including multiple product families of leads as well as ICD and pacemaker models. SCORE Registry data complements the data collected from returned product analysis, further enhancing St. Jude Medical's performance reporting.

To ensure a sufficiently large and appropriately representative source of data, 45 clinical sites are participating in the SCORE Registry with over 4,100 patients enrolled as of June 30, 2009. Using a common protocol, these sites are individually monitoring and reporting on the performance of St. Jude Medical cardiac rhythm management products used at their site.

In order for a device model to be included in this report, a minimum of 100 devices are required to have been enrolled, with the latest interval to be reported having a minimum of 50 devices which have been followed for at least six months. Consistent with industry practice, lead complications are included in the survival calculations for events with implant duration greater than 30 days.

The registry will actively monitor indefinitely the performance of implanted St. Jude Medical products at participating sites and is thus designed to include new products as they become available. In this report, the following device models have data from the SCORE Registry included:

ICDs

Promote® RF (Model 3207-36)
Current® DR RF (Model 2207-36)
Current® VR RF (Model 1207-36)

Defibrillation Leads

Durata® (Models 7120/7121)
Riata® ST Optim® (Models 7020/7021)
Riata® ST (Models 7000/7001)
Riata® (Models 1580/1581)

Pacemakers

Zephyr® DR (Model 5826)
Zephyr® SR (Model 5626)
Victory® XL DR (Model 5816)

Pacing Leads	CRT Leads
Tendril® ST Optim® (Model 1888)	QuickFlex® XL (Model 1158T)
Tendril® (Model 1788)	QuickFlex® (Model 1156T)
Tendril® SDX (Model 1688)	
Tendril® SDX (Model 1488)	
Optisense® (Model 1699)	
Isoflex® S (Model 1646)	

Additional device models will be included in future reports once a sufficient sample size is reached.

Initiation of Lead Observation and Complication Reporting

St. Jude Medical continues to work with other cardiac device companies through AdvaMed to develop a uniform approach to reporting clinical performance of devices and leads. Starting with this report, leads reporting for the recently released lead models has been enhanced as per the AdvaMed guidelines to provide 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. The categories for reporting of chronic complications and acute observations are summarized 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, and tamponade.

Conductor Fracture: A mechanical break within a lead conductor (includes connectors, coils 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.

Introduction and Overview

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

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

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

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

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

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

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

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

Also in accordance with AdvaMed guidelines, laboratory analysis results of returned leads are now categorized into one of the following five categories of malfunctions:

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

Insulation Breach: Any lead insulation breach. Examples include: 1) proximal abrasions associated with lead-on-lead or lead-on-PG contact in the pocket, 2) mid-lead insulation damage caused by clavicle flex-fatigue or crush, suture or suture sleeve, or insulation wear in the region of vein insertion, and 3) distal region wear due to lead-on-lead (intracardiac), lead-on-heart valve or lead-on-other anatomy contact.

Crimps, Welds, and Bonds: Any interruption in the conductor or lead body associated with a point of connection. Typically demonstrated by high or low shocking/pacing impedance, undersensing or oversensing.

Other: Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, seal rings or the IS-4 connector, as well as other analysis results not included in the other categories. (Note that this AdvaMed definition of "Other" confirmed malfunctions is not identical to the "Other" category of lab analysis previously reported in St. Jude Medical performance reports.)

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

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.

Methodology

For devices that are implanted in the body and have a service life of several years, measuring performance presents a number of considerations for medical device manufacturers. St. Jude Medical encourages that all products, once they are taken out of a patient for any reason, be returned for analysis. There are some situations where those devices are not always returned. These include, for example, pacing and defibrillation leads that are not routinely explanted due to potential risk to patients from explanting these devices.

Industry Standards

The industry standard method of evaluating product performance is survival analysis, which estimates the probability that a device will not malfunction during a specified period of time. This statistical method best represents device performance in general over a specified period of time.

How St. Jude Medical measures product performance

For cardiac monitors, ICDs, pacemakers 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." 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 time period of 200 devices. The data for the analysis covers all documented implants in the United States, and includes the analysis of all domestically implanted pulse generators 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.

"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 devices within each model family are included in the calculations.

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

St. Jude Medical lead analysis includes all leads returned to the company, as well as those registered as complaints but not returned. This method is used to ensure a conservative failure estimate for lead performance. The method to calculate leads survival includes lead complications (returns and complaints not returned) with implant duration greater than 30 days. Lead complications under 30 days 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 a lead is known to have been implanted for more than 30 days, it is subject to evaluation for survival characteristics. If there is laboratory data that determines the lead to have exhibited an electrical malfunction, the lead is counted as a non-survivor. If a lead was not returned for analysis, the status of the lead is examined. If by examination of this status the lead is identified with certain codes as a complaint, is no longer in service as a result of the complaint, and was implanted for more than 30 days, then the lead is counted as a non-survivor. This condition is also followed for partial lead returns. These complaint codes for non-returned leads and partial lead returns include, but are not limited to, reports of sensing, pacing, capture anomalies, perforation, and dislodgement.

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 and patient physical activity, posture, and anatomical influences. As such, cardiac leads' functional lifetimes are therefore limited and indeed, their functional longevity can not be predicted with a high degree of confidence. As a supplement to the survival estimates, the categorization of lead malfunctions emphasize the root cause of malfunction rather than functional longevity prediction.

Medical Advisory Board Review

St. Jude Medical has established separate and independent device and leads Medical Advisory Boards (MABs) to review 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:

Devices

Dr. Steven Bailin, Des Moines, Iowa
Dr. Jim Baker, Nashville, Tennessee
Dr. Anne Curtis, Tampa, Florida
Dr. Steve Greenberg, Roslyn, New York
Dr. Thomas Mattioni, Phoenix, Arizona
Dr. Gery Tomassoni, Lexington, Kentucky

Leads

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

Introduction and Overview

Returning Devices to St. Jude Medical

To maintain the continued accuracy of our performance reporting, we encourage physicians to notify our Patient Records department each time a device is removed from service as a result of device replacement or patient death. Our Patient Records department can be reached at 888-SJM-CRMD or 818-362-6822.

All explanted devices should be returned for evaluation. St. Jude Medical will provide upon request a Returned Products Kit comprised of a postage paid explant box with a shipping address label, a Removed Device Information (RDI) form, a biohazard bag, and biohazard labels to seal the explant box. This kit, order #N0004, can be ordered at no charge through St. Jude Medical Customer Service by any of the following means:

Call St. Jude Medical Cardiac Rhythm Management Customer Service at 800-681-9293

Fax St. Jude Medical Cardiac Rhythm Management Customer Service at 800-918-8111

In addition, we are always ready to respond to questions, comments or suggestions. You can reach us by phone at 888-SJM-CRMD, or on the web at www.sjm.com.

Definitions

The following definitions have been used in preparing this report. Where applicable, the asterisk denotes definitions taken verbatim or based on AdvaMed guidance definitions.

Estimated Active Implants - The total number of registered implants of a device, adjusted to reduce the bias attributable to the potential under reporting of:

- Devices removed from service due to malfunction;
- Devices removed from service while in specification, such as devices removed due to changes in patient condition;
- Devices removed from service due to patient death; and
- Devices removed from service due to normal battery depletion.

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 user's manual. The estimate is based on battery life approximations, and is affected by many factors such as programmed parameters, percentage of time paced, internal impedance, use of AutoCapture™ Pacing System, etc. For example, the estimated longevity for Affinity®, Identity®, and ADx® pacemakers is based on the mean longevity (or 50%) value in our manuals corresponding to a pacing output setting of 3.5 V, 500 ohm lead impedance, 100% DDD pacing, AutoCapture™ Off, and Stored EGMs Off (e.g. estimated longevity of 6.9 years for Identity pacemaker model 5386). Since all Victory® and Zephyr® pacemakers have a shipped setting of 2.5 V for pacing output, longevities for these two models of our newest pacemakers are calculated at 2.5 V output. However, actual performance would vary considerably, depending on the actual programmed settings and operations. We estimate that due to differences in actual programmed settings and operations, including use of AutoCapture™ Pacing System by physicians, approximately 85% of pacemakers could survive up to the estimated mean longevity value.

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

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

*"Industry Guidance for Uniformed Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", AdvaMed 2009.

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 setting that occur as intended by the design (for example, reversion to a designed Safe Mode or Power-On Reset [POR]) that do not result in loss of critical patient protective therapies but are the reported reasons for explant shall be categorized as a Malfunction without Compromised Therapy.*

Normal Battery Depletion - The condition where a returned device met its electrical specification and reached its elective replacement indicator voltage:

- with implant duration meeting or exceeding the nominal predicted longevity at default shipped settings,*

  or

- with an implant duration exceeding 75% of its estimated longevity, based on the longevity calculation tool using information from device usage and the actual device settings.* A device that does not exceed 75% of its estimated longevity would be considered a premature battery depletion malfunction (either with or without compromised therapy), provided that actual device setting information is available.

The quantity of normal battery depletions reported is determined directly from laboratory analysis and does not represent any adjustment to account for under reporting.

*"Industry Guidance for Uniformed Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads", AdvaMed 2009.

Cardiac Resynchronization Therapy

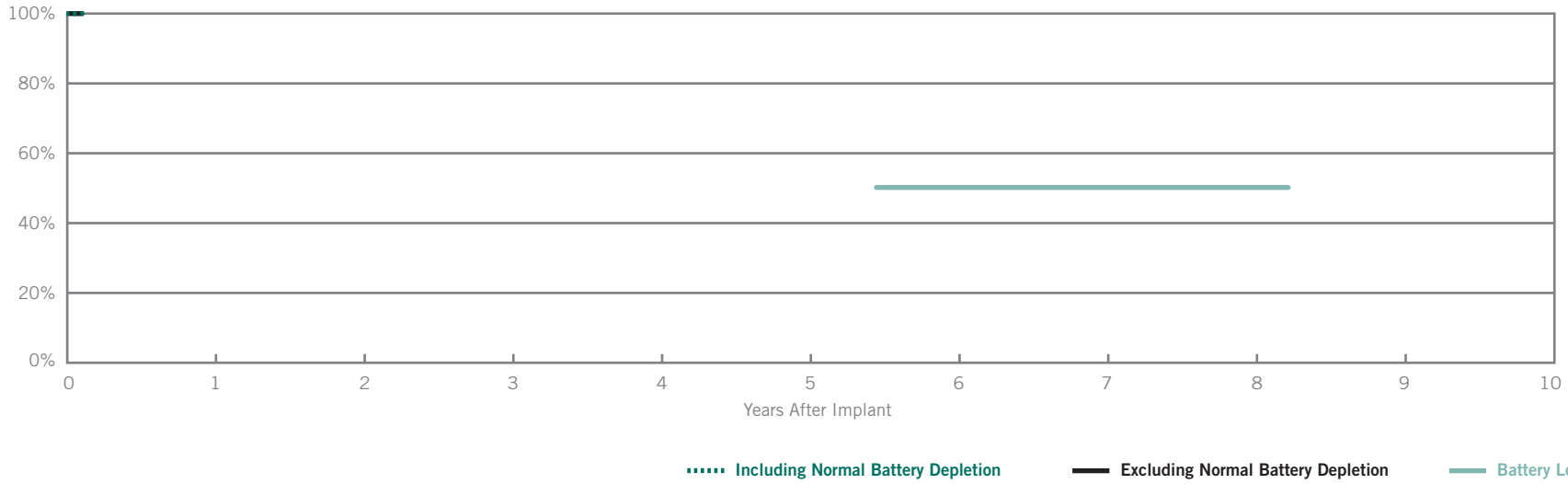
CRT ICDs

St. Jude Medical
More control. Less risk.

Promote® + CRT-D (Model CD3211-36)

US Market Release	February 2009	Normal Battery Depletion	0
Registered US Implants	612	Malfunctions	0
Estimated Active US Implants	605	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

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

Excluding Normal Battery Depletion

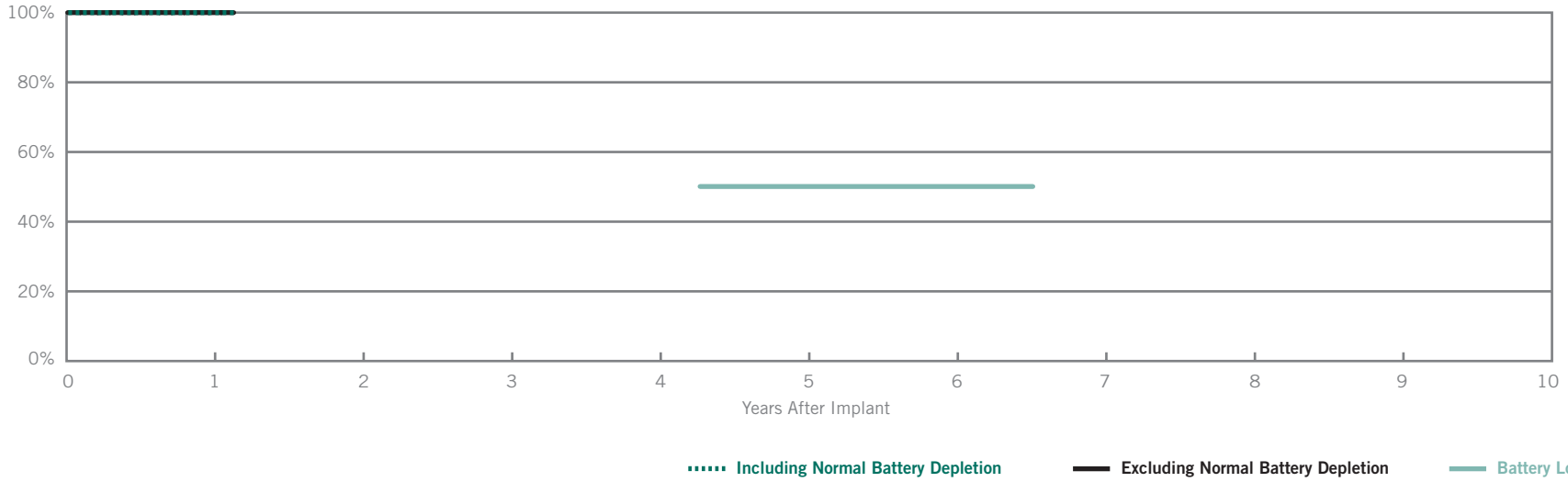
Year	at 1 month									
Survival Probability	100.00%									
± 1 standard error	0.00%									

Cardiac Resynchronization Therapy

Promote® RF (Model 3207-30)

US Market Release	September 2007	Normal Battery Depletion	0
Registered US Implants	935	Malfunctions	0
Estimated Active US Implants	830	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 14 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	700	200								

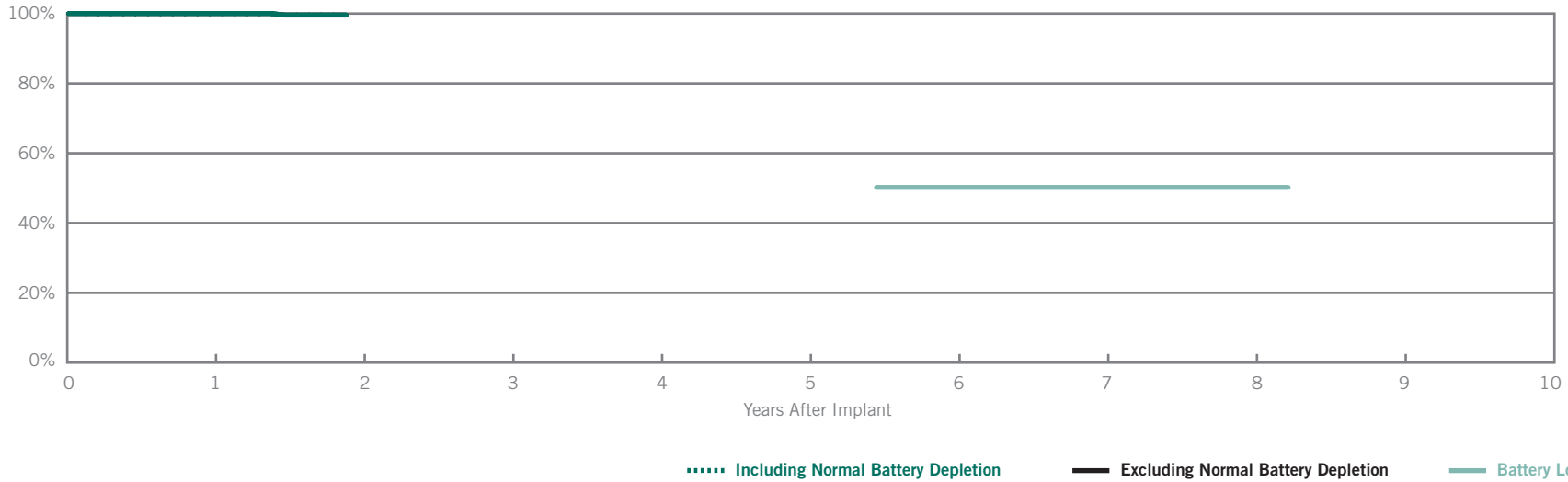
Excluding Normal Battery Depletion

Year	1	at 14 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

Promote® (Model 3107-36)

US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	691	Malfunctions	1
Estimated Active US Implants	535	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	100.00%	99.57%								
± 1 standard error	0.00%	0.30%								
Sample Size	700	400								

Excluding Normal Battery Depletion

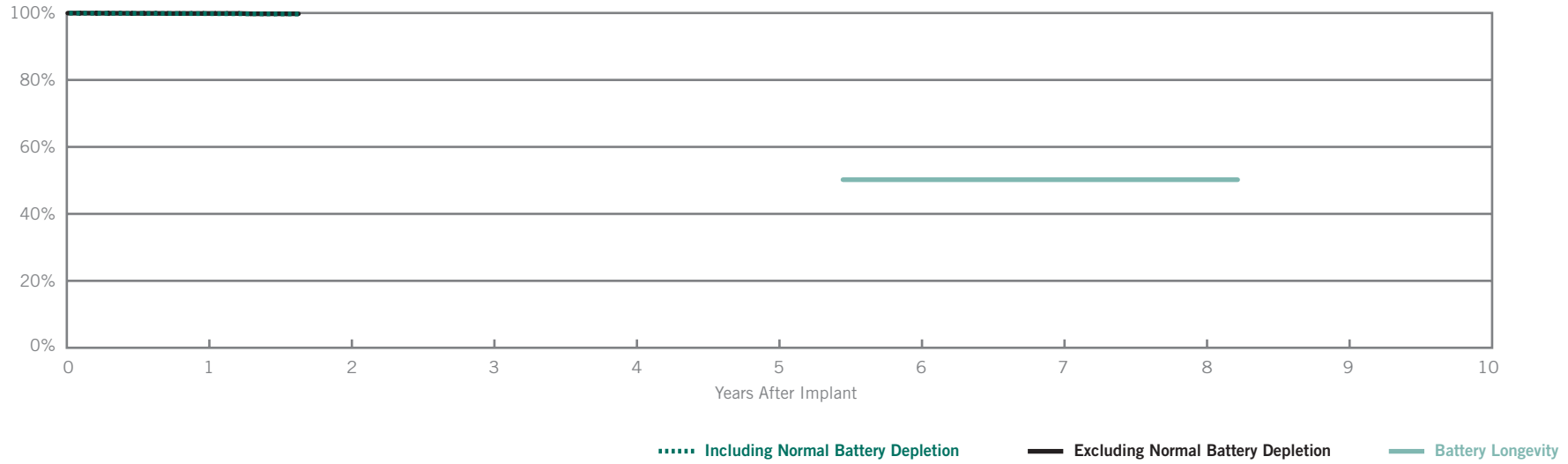
Year	1	at 23 months								
Survival Probability	100.00%	99.57%								
± 1 standard error	0.00%	0.30%								

Cardiac Resynchronization Therapy

Promote® RF (Model 3207-36)

US Market Release	September 2007	Normal Battery Depletion	2
Registered US Implants	19,118	Malfunctions	14
Estimated Active US Implants	17,052	Malfunctions w/ Compromised Therapy	5
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy	9
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 20 months								
Survival Probability	99.80%	99.71%								
± 1 standard error	0.04%	0.08%								
Sample Size	13400	2700								

Excluding Normal Battery Depletion

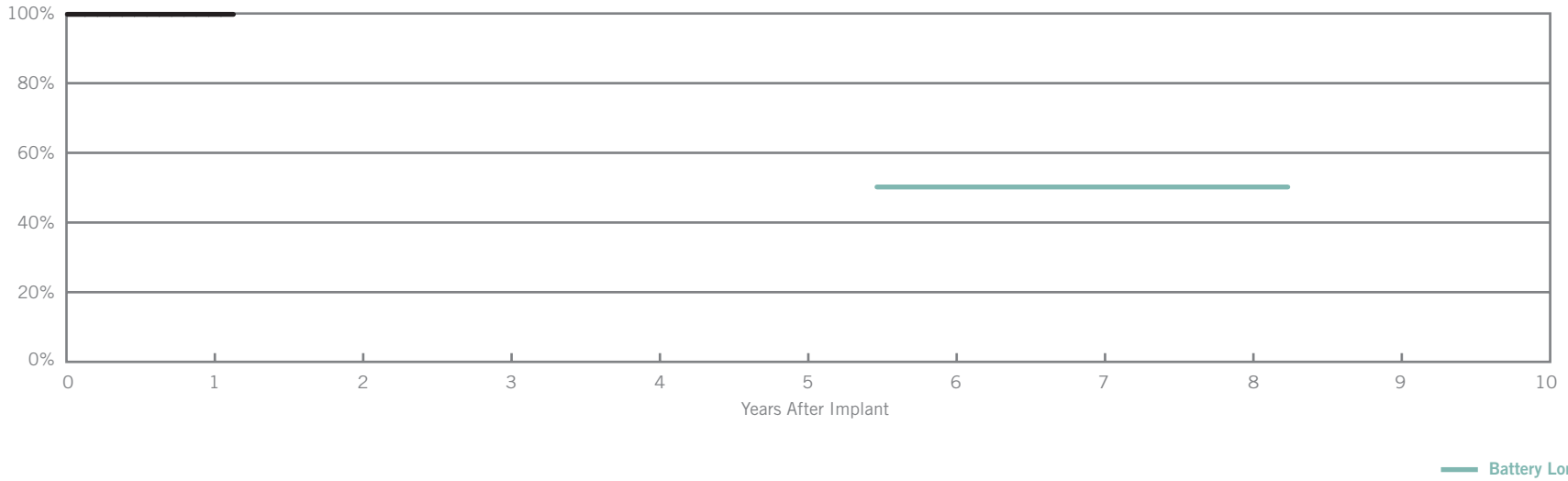
Year	1	at 20 months								
Survival Probability	99.86%	99.77%								
± 1 standard error	0.03%	0.07%								

Promote® RF (Model 3207-36)	
US Market Release	September 2007

SCORE Enrollment	
Number of Devices Enrolled in Study	486
Cumulative Months of Follow-up	3,791

Qualifying Complications		
Type	**Qty.**	**Rate**
Backup Operation	1	0.21%

Survival from SCORE Registry



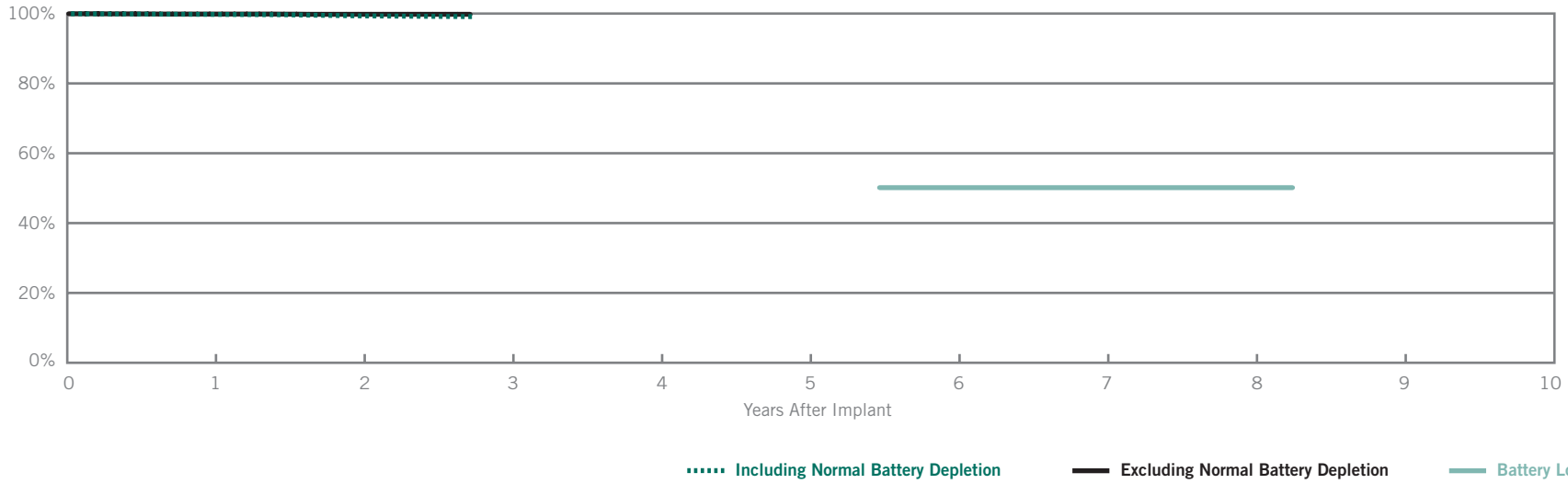
Year	1	at 14 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.24%	0.24%								
Sample Size	129	60								

Cardiac Resynchronization Therapy

Atlas® II HF (Model V-365)

US Market Release	July 2006	Normal Battery Depletion	17
Registered US Implants	8,362	Malfunctions	8
Estimated Active US Implants	6,126	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.86%	99.34%	99.13%							
± 1 standard error	0.04%	0.10%	0.14%							
Sample Size	8200	5700	1900							

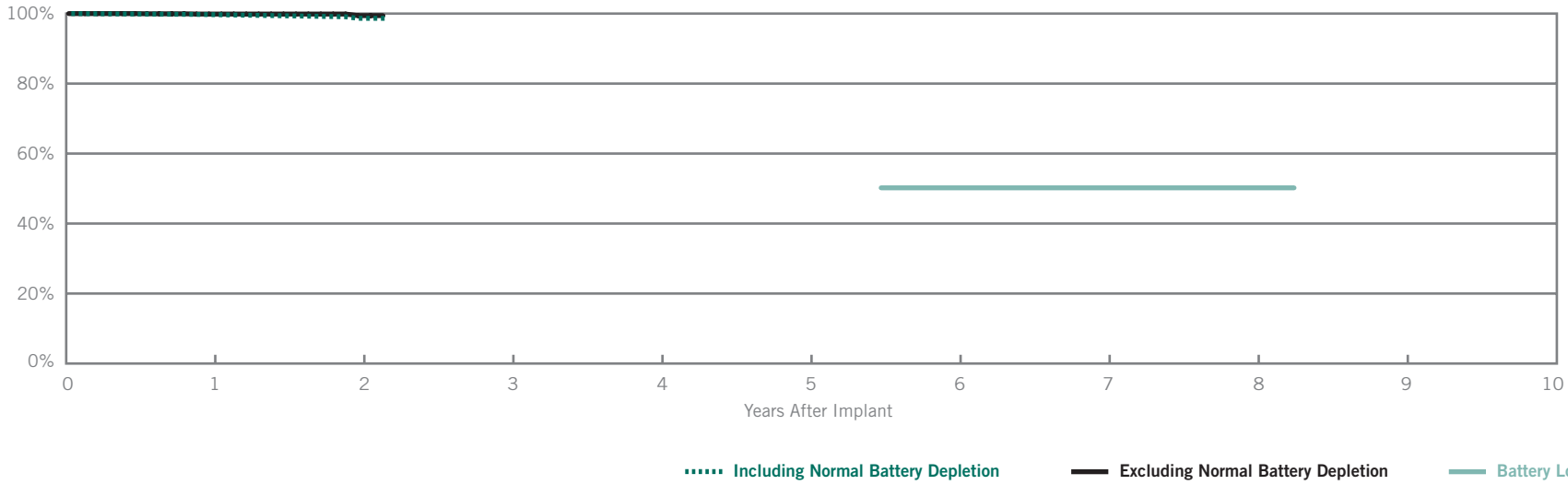
Excluding Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.86%	99.79%	99.79%							
± 1 standard error	0.04%	0.06%	0.06%							

Atlas® II + HF (Model V-366)

US Market Release	February 2007	Normal Battery Depletion	6
Registered US Implants	4,420	Malfunctions	3
Estimated Active US Implants	3,580	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	2
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 26 months							
Survival Probability	99.69%	98.65%	98.65%							
± 1 standard error	0.08%	0.28%	0.43%							
Sample Size	3800	1700	200							

Excluding Normal Battery Depletion

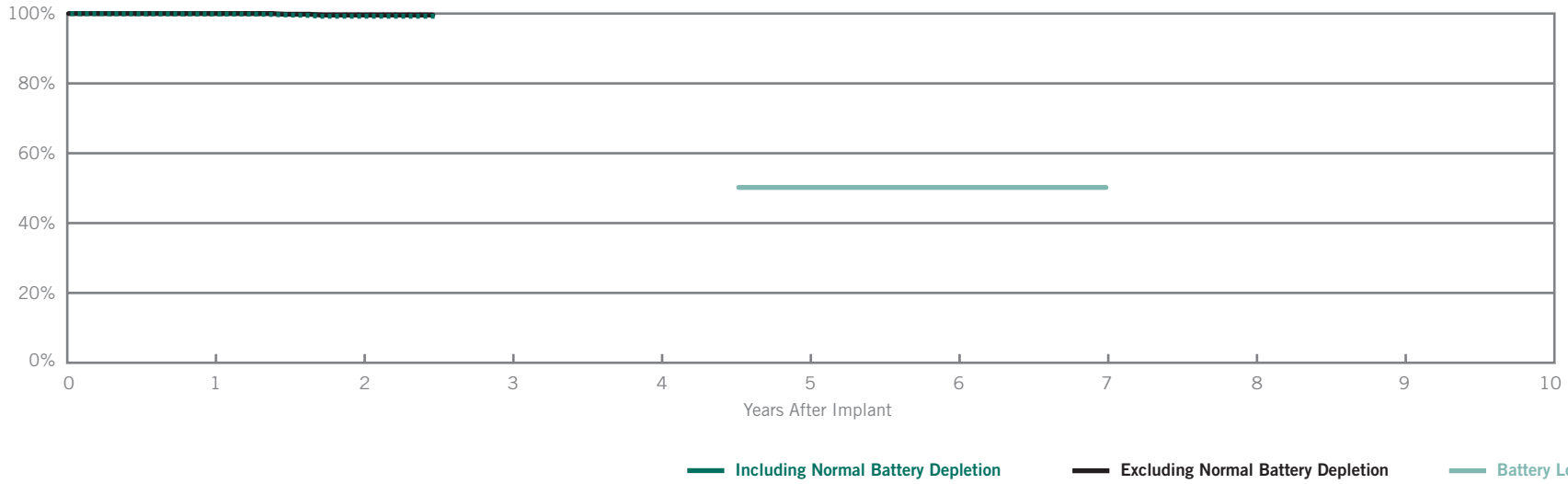
Year	1	2	at 26 months							
Survival Probability	99.87%	99.42%	99.42%							
± 1 standard error	0.06%	0.06%	0.33%							

Cardiac Resynchronization Therapy

Epic® II HF (Model V-355)

US Market Release	March 2006	Normal Battery Depletion	2
Registered US Implants	1,658	Malfunctions	2
Estimated Active US Implants	1,178	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	2
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	100.00%	99.23%	99.23%							
± 1 standard error	0.00%	0.27%	0.27%							
Sample Size	1600	1100	400							

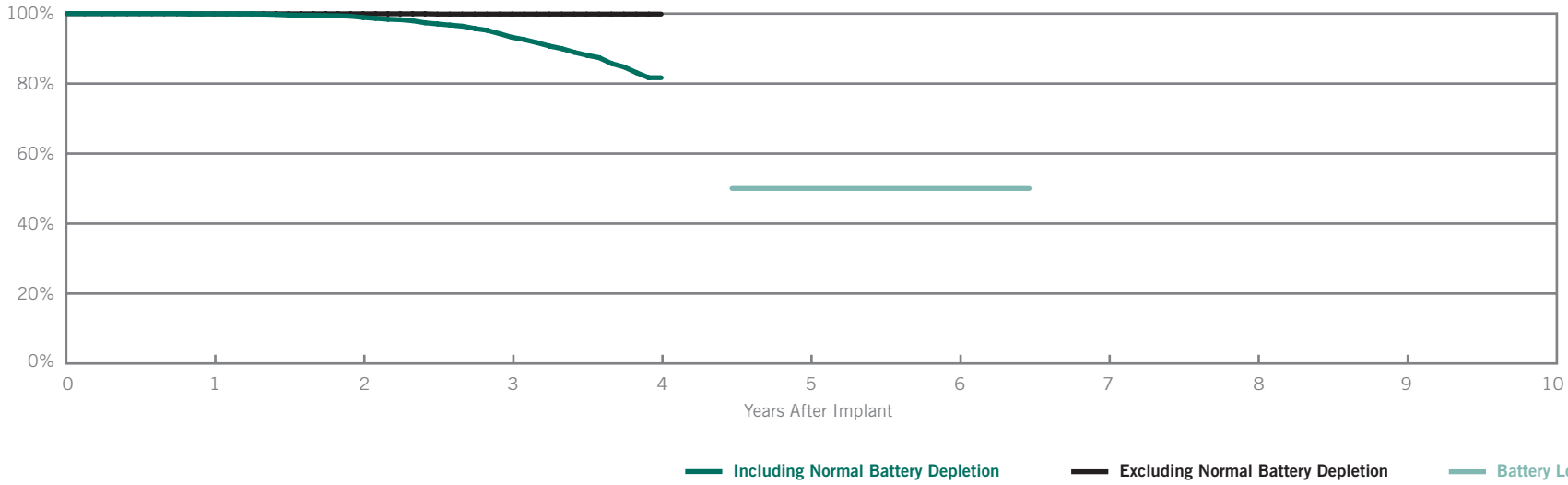
Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	100.00%	99.59%	99.59%							
± 1 standard error	0.00%	0.21%	0.21%							

Epic® HF (Model V-337)

US Market Release	November 2004	Normal Battery Depletion	143
Registered US Implants	3,959	Malfunctions	2
Estimated Active US Implants	1,795	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4						
Survival Probability	99.94%	98.89%	93.21%	81.69%						
± 1 standard error	0.04%	0.16%	0.49%	1.37%						
Sample Size	4000	3300	2400	1000						

Excluding Normal Battery Depletion

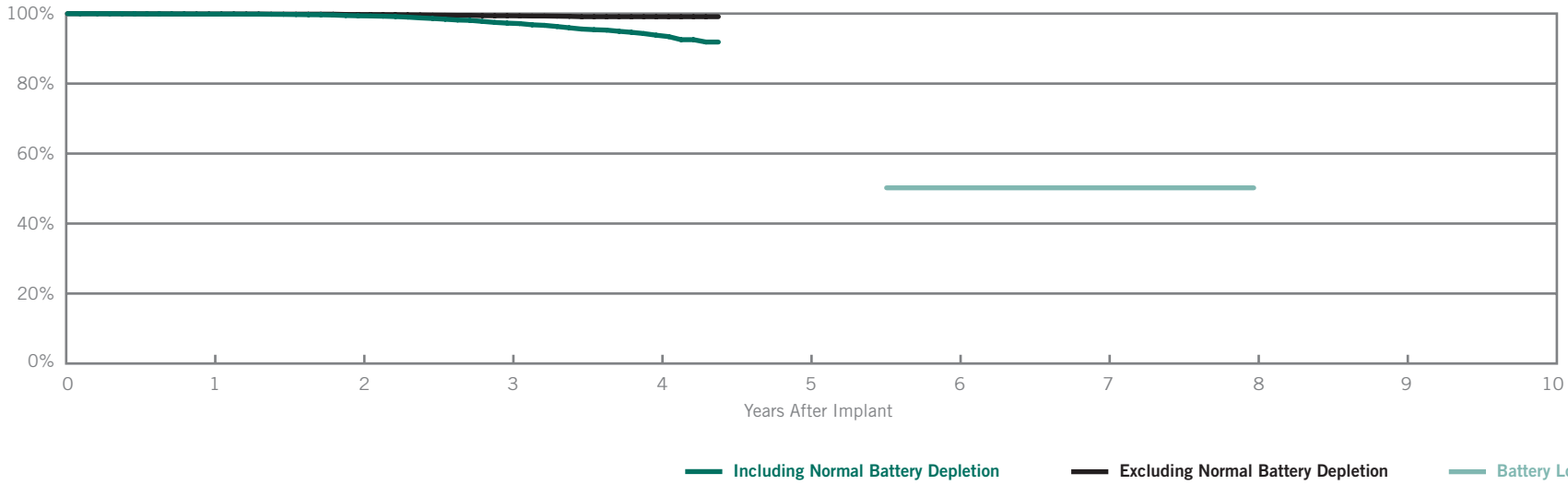
Year	1	2	3	4						
Survival Probability	99.94%	99.94%	99.86%	99.86%						
± 1 standard error	0.04%	0.04%	0.07%	0.07%						

Cardiac Resynchronization Therapy

Atlas® + HF (Model V-343)

US Market Release	November 2004	Normal Battery Depletion	184
Registered US Implants	18,551	Malfunctions	48
Estimated Active US Implants	10,771	Malfunctions w/ Compromised Therapy (1 related to Advisory)	34
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	14
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.85%	99.37%	97.27%	93.82%	91.87%					
± 1 standard error	0.03%	0.06%	0.16%	0.36%	0.77%					
Sample Size	18500	15000	10400	4100	500					

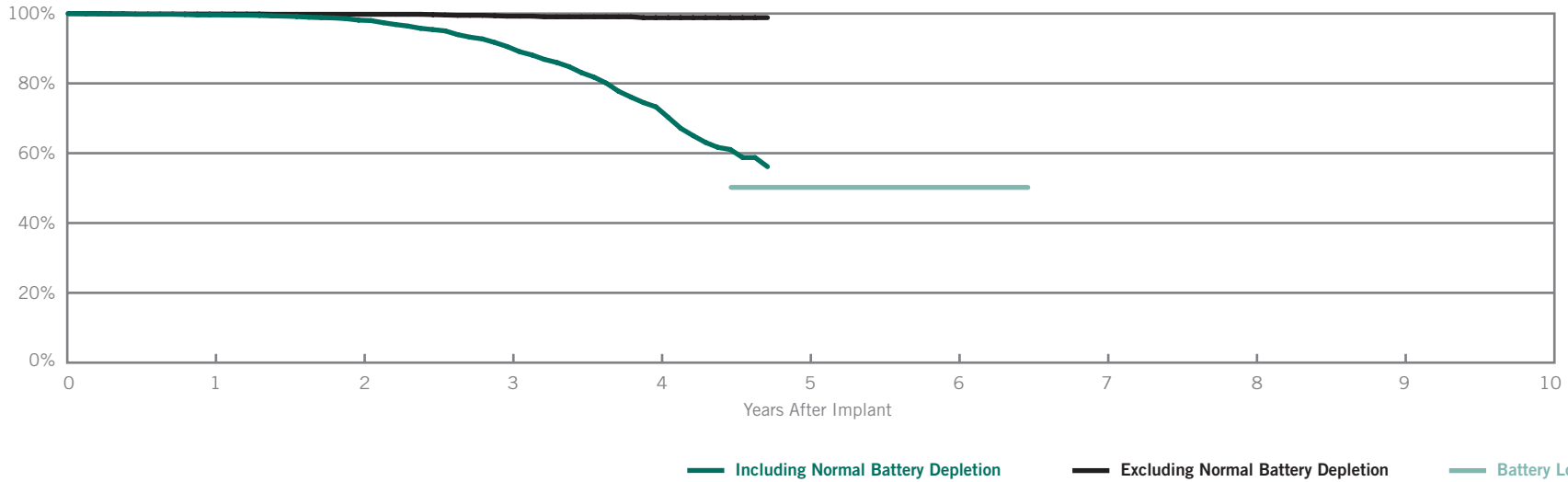
Excluding Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.89%	99.73%	99.38%	99.11%	99.11%					
± 1 standard error	0.03%	0.04%	0.07%	0.11%	0.11%					

Epic® HF (Model V-338)

US Market Release	June 2004	Normal Battery Depletion	317
Registered US Implants	3.096	Malfunctions	11
Estimated Active US Implants	515	Malfunctions w/ Compromised Therapy (0 related to Advisory)	3
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	8
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 57 months					
Survival Probability	99.61%	98.12%	90.54%	73.27%	56.14%					
± 1 standard error	0.12%	0.24%	0.59%	1.09%	1.64%					
Sample Size	3100	2700	2300	1600	600					

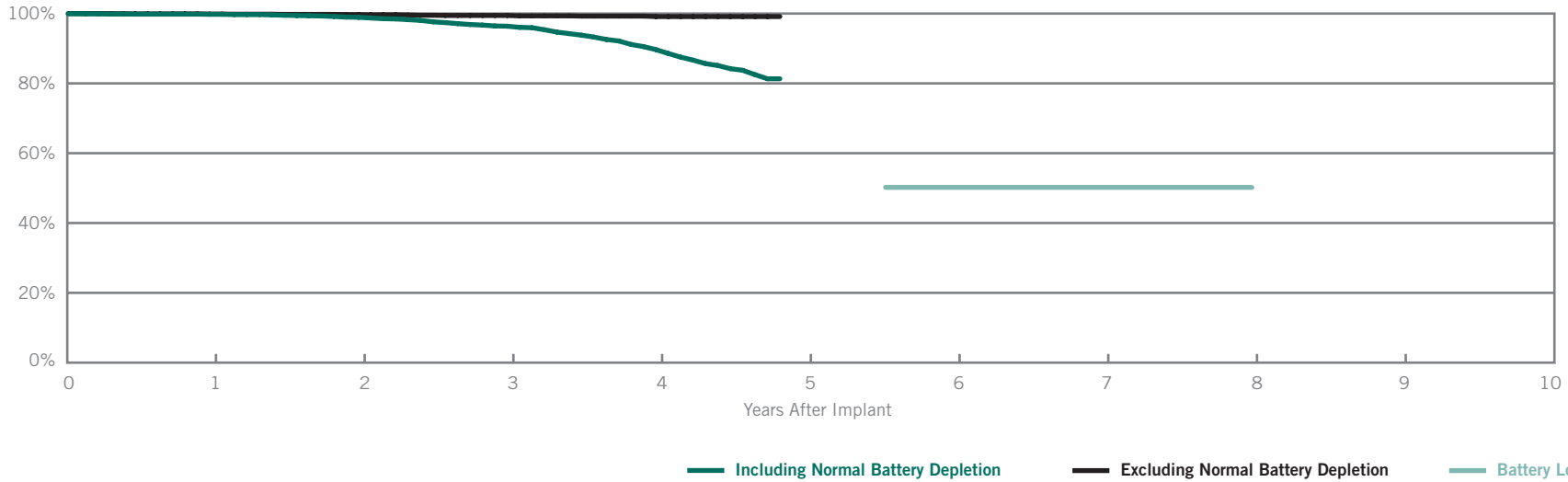
Excluding Normal Battery Depletion

Year	1	2	3	4	at 57 months					
Survival Probability	99.86%	99.79%	99.26%	98.83%	98.83%					
± 1 standard error	0.07%	0.09%	0.17%	0.28%	0.28%					

Atlas® + HF (Model V-340)

US Market Release	June 2004	Normal Battery Depletion	202
Registered US Implants	4,914	Malfunctions	15
Estimated Active US Implants	1,600	Malfunctions w/ Compromised Therapy (1 related to Advisory)	9
Estimated Longevity	(see table on page 28)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	6
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.78%	98.92%	96.38%	89.67%	81.32%					
± 1 standard error	0.06%	0.16%	0.31%	0.56%	1.13%					
Sample Size	4900	4200	3600	2700	1100					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.86%	99.71%	99.45%	99.14%	99.14%					
± 1 standard error	0.04%	0.08%	0.12%	0.15%	0.17%					

Summary & Longevity Information

Cardiac Resynchronization Therapy

CRT ICDs

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Cardiac Resynchronization Therapy

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
CD3211-36	Promote® + CRT-D	8.2	7.2	6.5	5.4
3207-30	Promote® RF	6.5	5.7	5.1	4.2
3107-36	Promote®	8.2	7.2	6.5	5.4
3207-36	Promote® RF	8.2	7.2	6.5	5.4
V-365	Atlas® II HF	8.2	7.2	6.5	5.4
V-366	Atlas® II + HF	8.2	7.2	6.5	5.4
V-355	Epic® II HF	7.0	6.1	5.5	4.5
V-337, V-338	Epic® HF, Serial Numbers <13000	6.4	5.7	5.2	4.4
V-337, V-338	Epic® HF, Serial Numbers >13000	6.5	5.8	5.2	4.4
V-343	Atlas® + HF	7.9	7.1	6.4	5.4
V-340	Atlas® + HF	7.9	7.1	6.4	5.4

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

Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/ Compromised Therapy (under advisory)	Malfunctions w/ Compromised Therapy (premature battery depletion)	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
CD3211-36	Promote® + CRT-D	Feb-07	612	605	0	0	0	0	0	0	0
3207-30	Promote® RF	Sep-07	935	830	0	0	0	0	0	0	0
3107-36	Promote®	May-07	691	535	1	0	0	0	0	1	0
3207-36	Promote® RF	Sep-07	19118	17052	4	0	1	7	2	14	2
V-365	Atlas® II HF	Jul-06	8362	6126	3	0	1	2	2	8	17
V-366	Atlas® II + HF	Feb-07	4420	3580	0	0	1	1	1	3	6
V-355	Epic® II HF	Mar-06	1658	1178	0	0	0	0	2	2	2
V-337	Epic® HF	Nov-04	3959	1795	0	0	1	1	0	2	143
V-343	Atlas® + HF	Nov-04	18551	10771	1	1	32	6	8	48	184
V-338	Epic® HF	Jun-04	3096	515	2	0	1	1	7	11	317
V-340	Atlas® + HF	Jun-04	4914	1600	3	1	5	0	6	15	202

Cardiac Resynchronization Therapy

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3211-36	Promote® + CRT-D*										
3207-30	Promote® RF	100.00%									
3107-36	Promote®	100.00%									
3207-36	Promote® RF	99.80%									
V-365	Atlas® II HF	99.86%	99.34%								
V-366	Atlas® II + HF	99.69%	98.65%								
V-355	Epic® II HF	100.00%	99.23%								
V-337	Epic® HF	99.94%	98.89%	93.21%	81.69%						
V-343	Atlas® + HF	99.85%	99.37%	97.27%	93.82%						
V-338	Epic® HF	99.61%	98.12%	90.54%	73.27%						
V-340	Atlas® + HF	99.78%	98.92%	96.38%	89.67%						

**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.*

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
CD3211-36	Promote® + CRT-D*										
3207-30	Promote® RF	100.00%									
3107-36	Promote®	100.00%									
3207-36	Promote® RF	99.86%									
V-365	Atlas® II HF	99.86%	99.79%								
V-366	Atlas® II + HF	99.87%	99.42%								
V-355	Epic® II HF	100.00%	99.59%								
V-337	Epic® HF	99.94%	99.94%	99.86%	99.86%						
V-343	Atlas® + HF	99.89%	99.73%	99.38%	99.11%						
V-338	Epic® HF	99.86%	99.79%	99.26%	98.83%						
V-340	Atlas® + HF	99.86%	99.71%	99.45%	99.14%						

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

Cardiac Resynchronization Therapy

CRT Pulse Generators

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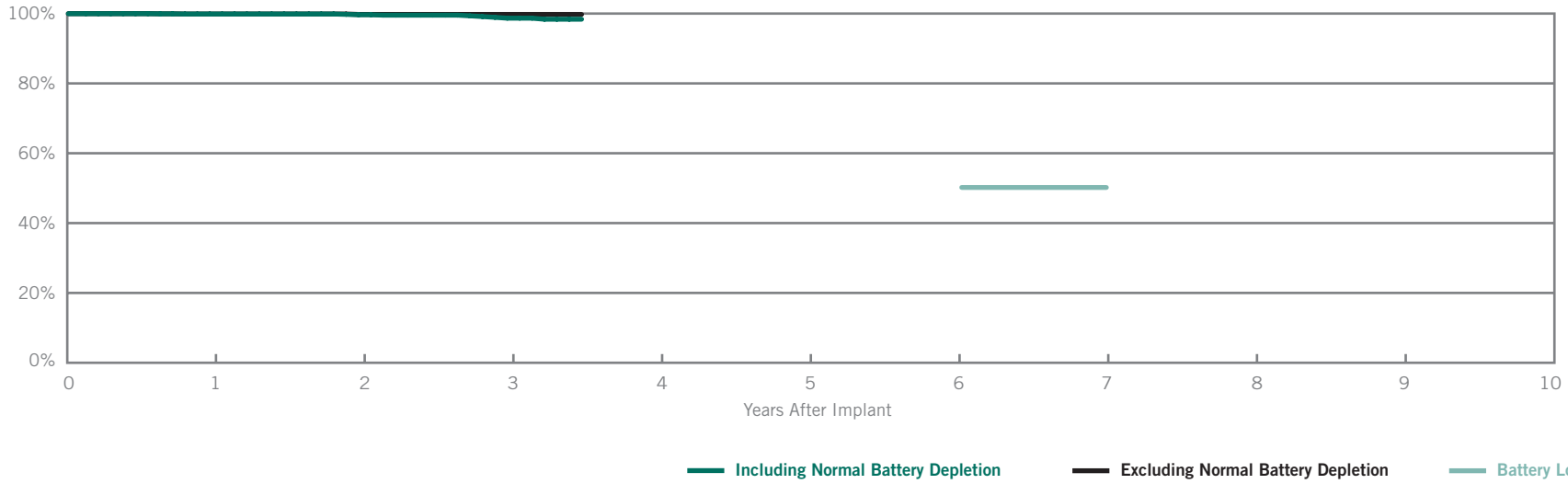
Cardiac Resynchronization Therapy

Frontier® II (Model 5586)

US Market Release	August 2004	Normal Battery Depletion	8
Registered US Implants	6,040	Malfunctions	4
Estimated Active US Implants	4,884	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.87%	99.66%	98.68%	98.38%						
± 1 standard error	0.05%	0.09%	0.29%	0.40%						
Sample Size	5100	2800	1400	900						

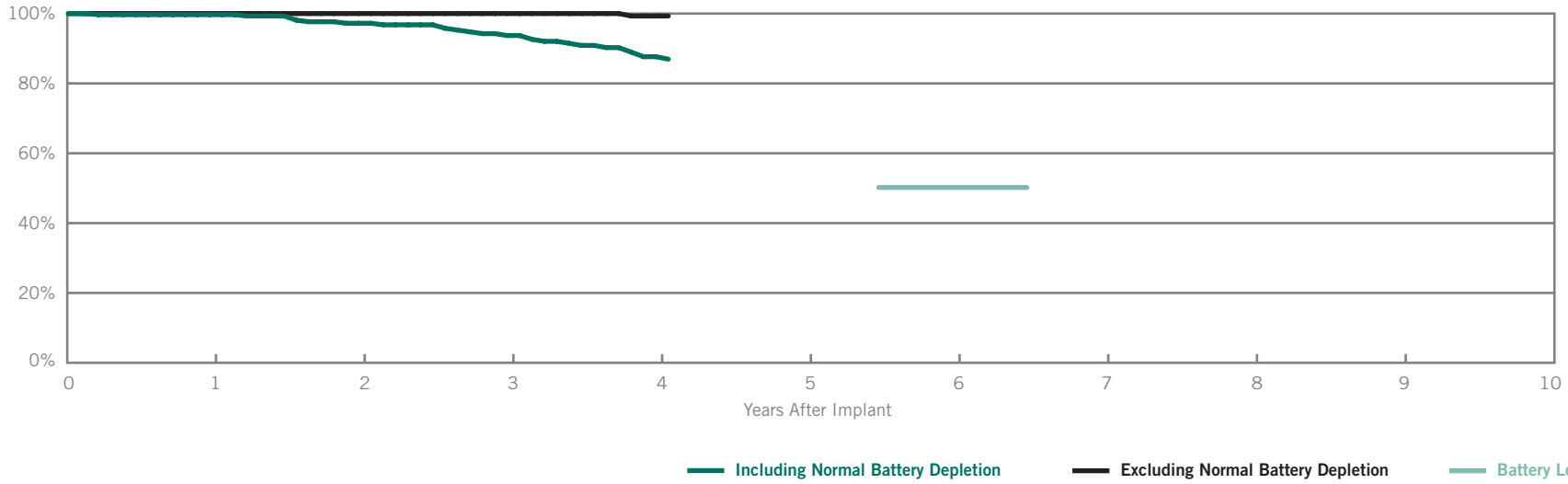
Excluding Normal Battery Depletion

Year	1	2	3	at 42 months						
Survival Probability	99.87%	99.76%	99.76%	99.76%						
± 1 standard error	0.05%	0.05%	0.09%	0.09%						

Frontier® (Model 5508)

US Market Release	May 2004	Normal Battery Depletion	36
Registered US Implants	671	Malfunctions	2
Estimated Active US Implants	188	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.9 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	99.68%	97.22%	93.71%	87.64%	86.95%					
± 1 standard error	0.22%	0.74%	1.11%	1.71%	1.71%					
Sample Size	700	500	400	300	300					

Excluding Normal Battery Depletion

Year	1	2	3	4	at 49 months					
Survival Probability	100.00%	100.00%	100.00%	99.30%	99.30%					
± 1 standard error	0.00%	0.00%	0.00%	0.49%	0.49%					

Summary & Longevity Information

Cardiac Resynchronization Therapy

CRT Pulse Generators

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Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (under advisory)	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
5586	Frontier® II	Aug-04	6040	4884	1	3	0	0	4	8
5508	Frontier®	May-04	671	188	0	1	0	1	2	36

Cardiac Resynchronization Therapy

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability							
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year
5586	Frontier® II	99.87%	99.66%	98.68%					
5508	Frontier®	99.68%	97.22%	93.71%	87.64%				

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability							
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year
5586	Frontier® II	99.87%	99.76%	99.76%					
5508	Frontier®	100.00%	100.00%	100.00%	99.30%				

Left-Heart Leads

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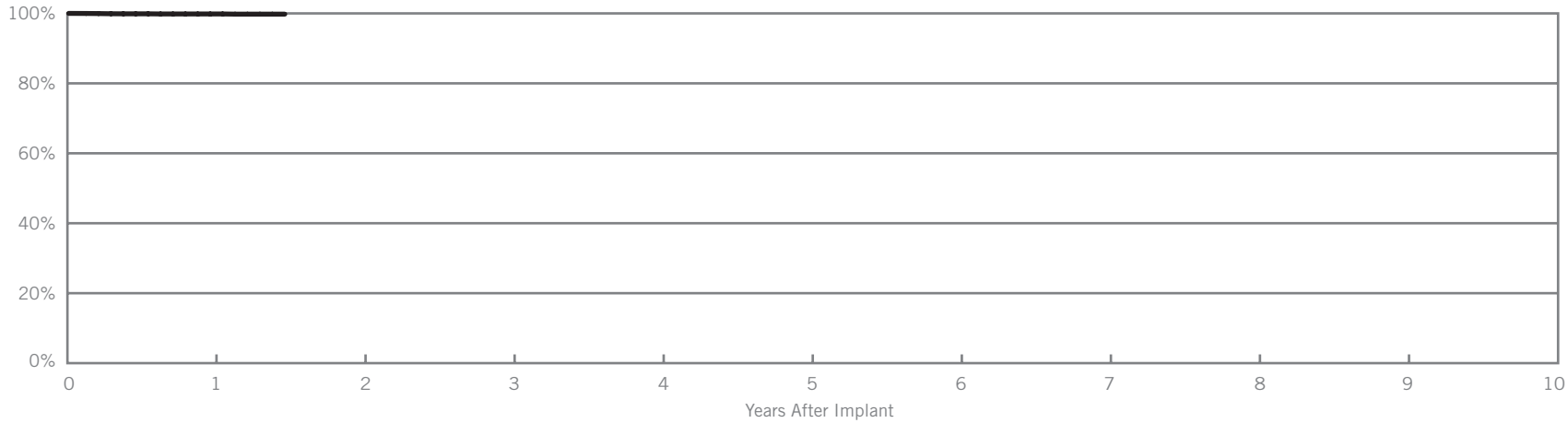
Left-Heart Leads

QuickFlex® (Model 1156T)	
US Market Release	July 2007
Registered US Implants	11,374
Estimated Active US Implants	10,557
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	6	0.05%	7	0.06%
Failure to Capture	3	0.03%	2	0.02%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.01%
Extracardiac Stimulation	7	0.06%	2	0.02%
Other	4	0.04%	1	0.01%
Total	**20**	**0.18%**	**13**	**0.11%**
Total Returned for Analysis	**7**		**6**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.01%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	1	0.01%
Other	0	0.00%
Extrinsic Factors	7	0.06%
Total	**9**	**0.08%**

Survival from Returns and Complaints



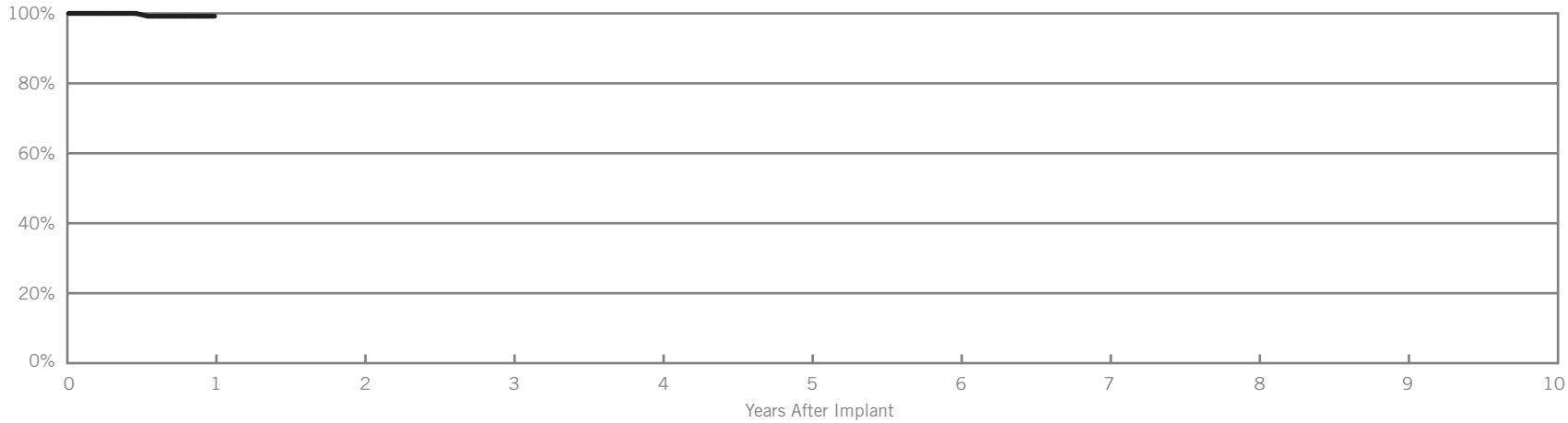
Year	1	at 18 months								
Survival Probability	99.84%	99.79%								
± 1 standard error	0.05%	0.07%								
Sample Size	6900	200								

QuickFlex® (Model 1156T)	
US Market Release	July 2007
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	219
Cumulative Months of Follow-up	1,740

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.46%

Survival from SCORE Registry



Year	1									
Survival Probability	99.21%									
± 1 standard error	0.79%									
Sample Size	62									

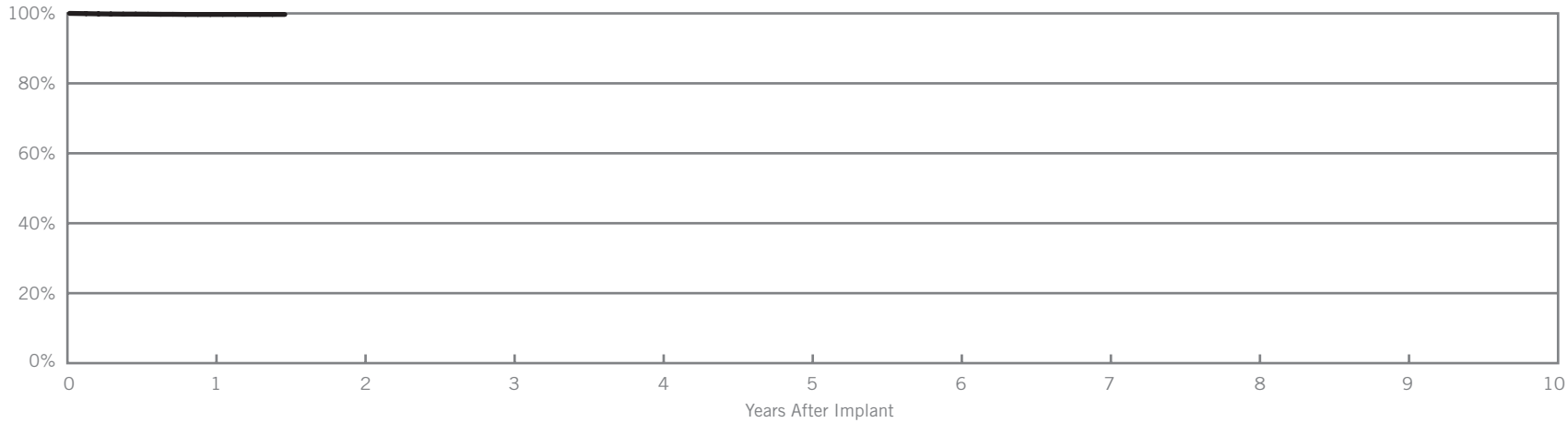
Left-Heart Leads

QuickFlex® XL (Model 1158T)	
US Market Release	July 2007
Registered US Implants	6,368
Estimated Active US Implants	5,913
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	4	0.06%	6	0.09%
Failure to Capture	1	0.02%	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	2	0.03%	0	0.00%
Extracardiac Stimulation	1	0.02%	2	0.03%
Other	5	0.08%	0	0.00%
Total	**13**	**0.20%**	**9**	**0.14%**
Total Returned for Analysis	**5**		**3**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.02%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.08%
Total	**6**	**0.09%**

Survival from Returns and Complaints



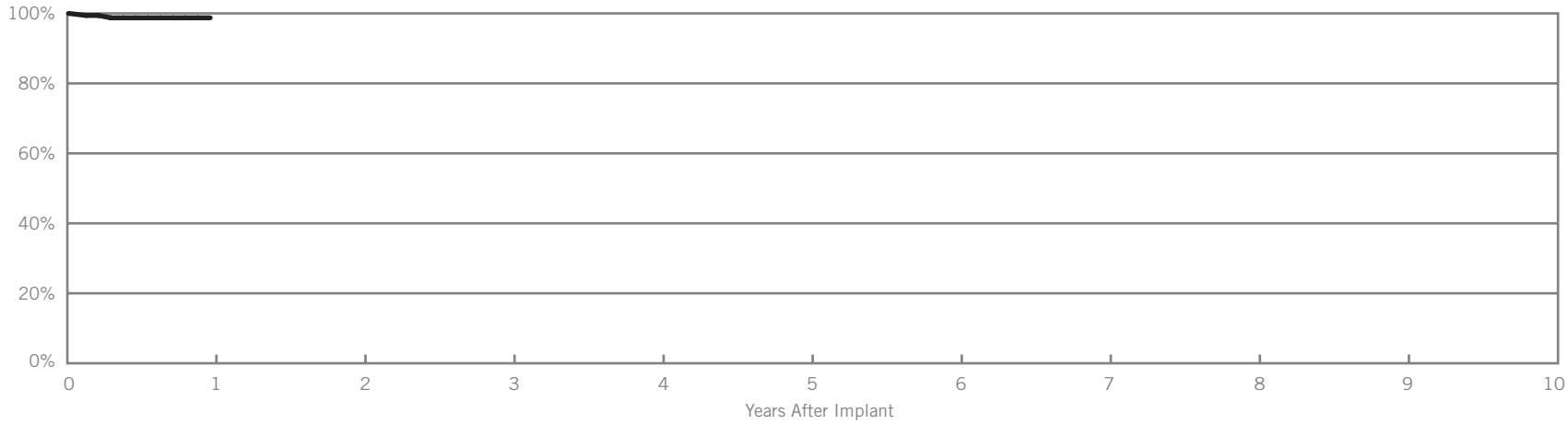
Year	1	at 18 months								
Survival Probability	99.70%	99.70%								
± 1 standard error	0.08%	0.08%								
Sample Size	4000	100								

QuickFlex® XL (Model 1158T)	
US Market Release	July 2007
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	179
Cumulative Months of Follow-up	1,602

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.56%
Failure to Capture	1	0.56%

Survival from SCORE Registry



Year	1									
Survival Probability	98.74%									
± 1 standard error	0.89%									
Sample Size	61									

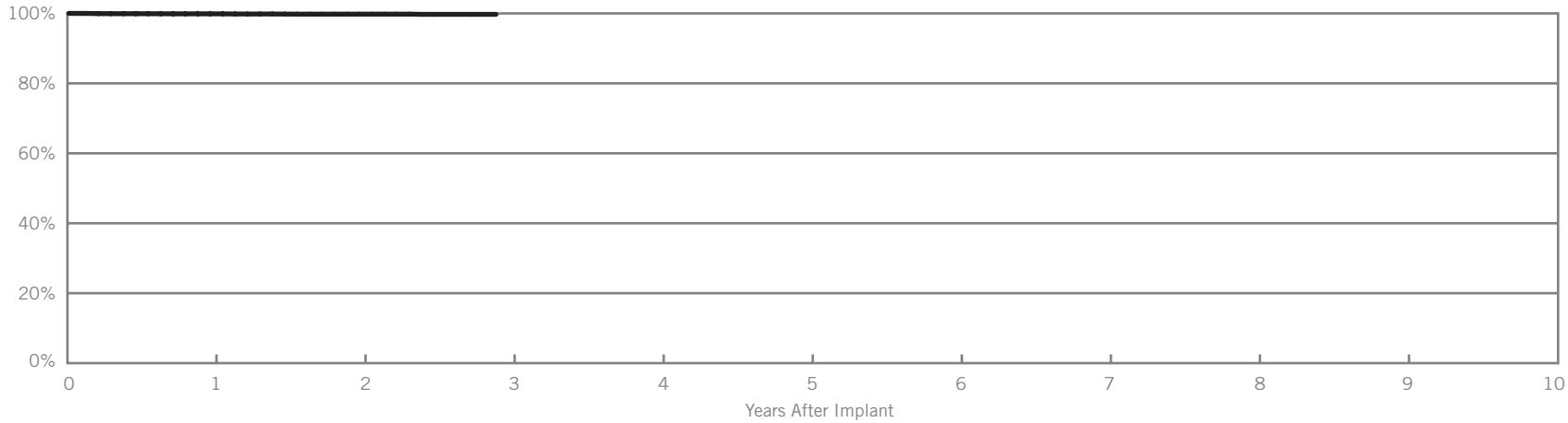
Left-Heart Leads

QuickSite® XL (Model 1058T)	
US Market Release	February 2006
Registered US Implants	9,600
Estimated Active US Implants	7,827
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	8	0.08%	9	0.09%
Failure to Capture	3	0.03%	5	0.05%
Oversensing	1	0.01%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	1	0.01%
Extracardiac Stimulation	6	0.06%	1	0.01%
Other	2	0.02%	1	0.01%
Total	**22**	**0.23%**	**18**	**0.19%**
Total Returned for Analysis	**9**		**7**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.03%
Extrinsic Factors	6	0.06%
Total	**9**	**0.09%**

Survival from Returns and Complaints



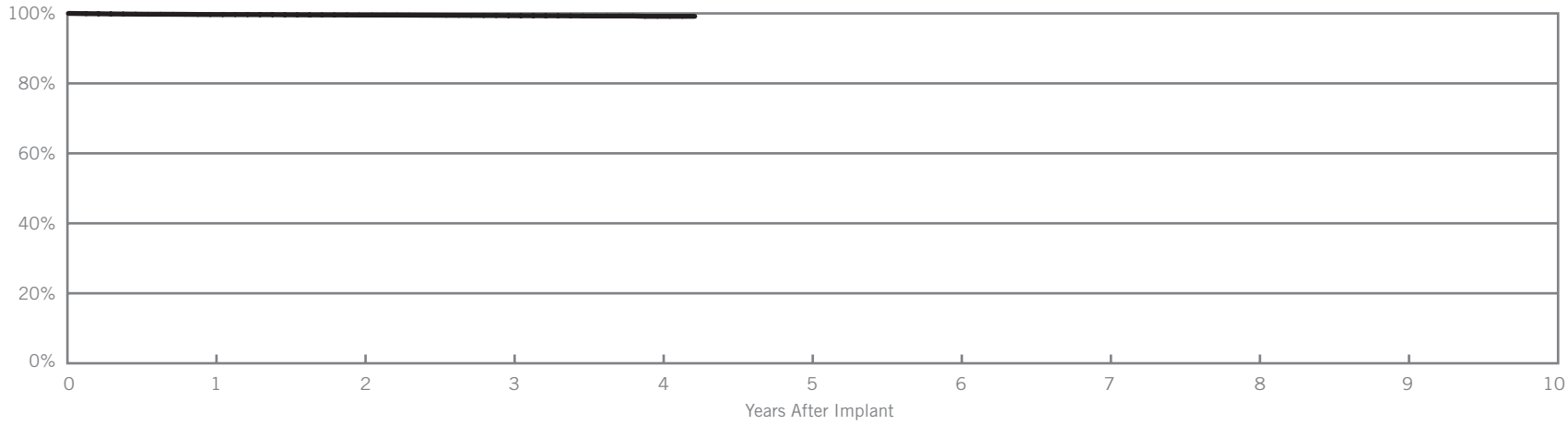
Year	1	2	at 35 months							
Survival Probability	99.88%	99.79%	99.73%							
± 1 standard error	0.04%	0.05%	0.08%							
Sample Size	8700	5500	200							

QuickSite® (Model 1056T)	
US Market Release	April 2005
Registered US Implants	32,461
Estimated Active US Implants	23,578
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	2	0.01%
Lead Dislodgement	26	0.08%	60	0.18%
Failure to Capture	13	0.04%	52	0.16%
Oversensing	1	<0.01%	3	0.01%
Failure to Sense	0	0.00%	1	<0.01%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	2	0.01%	3	0.01%
Extracardiac Stimulation	17	0.05%	28	0.09%
Other	8	0.02%	7	0.02%
Total	**68**	**0.21%**	**156**	**0.48%**
Total Returned for Analysis	**30**		**66**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	<0.01%
Insulation Breach	3	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	1	<0.01%
Extrinsic Factors	56	0.17%
Total	**62**	**0.19%**

Survival from Returns and Complaints



Year	1	2	3	4	at 51 months					
Survival Probability	99.68%	99.53%	99.37%	99.17%	99.17%					
± 1 standard error	0.03%	0.04%	0.05%	0.10%	0.10%					
Sample Size	29400	22100	13900	5400	100					

Left-Heart Leads

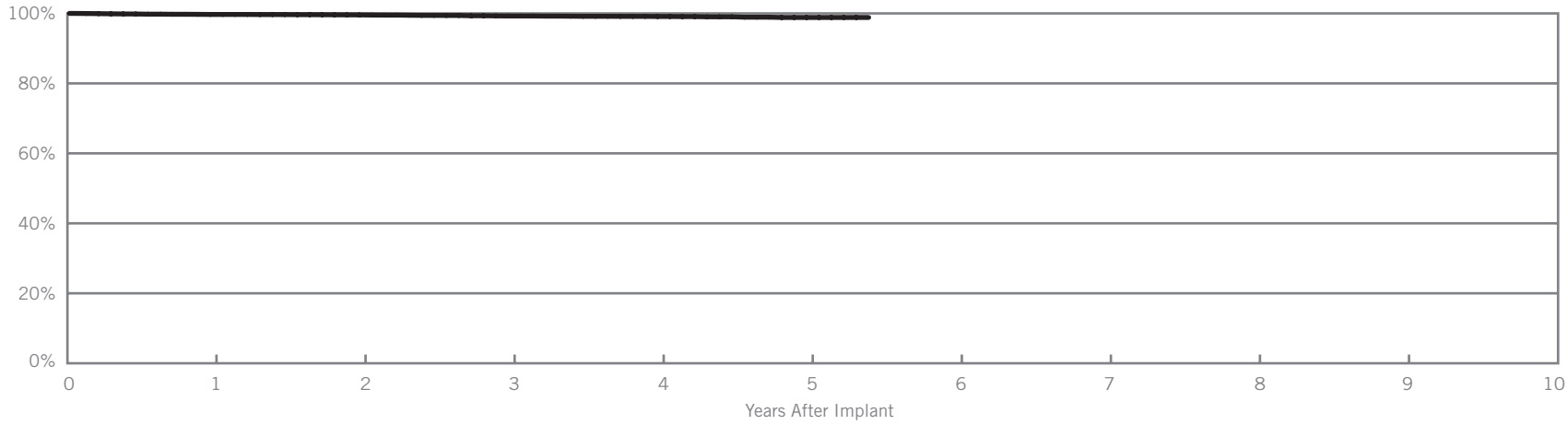
Unipolar

QuickSite® (Model 1056K)	
US Market Release	June 2004
Registered US Implants	8,689
Estimated Active US Implants	4,729
Insulation	Polyurethane/Silicone
Type and/or Fixation	S-Curve
Polarity	Unipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	10	0.12%	24	0.28%
Failure to Capture	3	0.03%	23	0.26%
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	9	0.10%	11	0.13%
Other	2	0.02%	8	0.09%
Total	**24**	**0.28%**	**68**	**0.78%**
Total Returned for Analysis	**18**		**34**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	2	0.02%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	2	0.02%
Other	0	0.00%
Extrinsic Factors	21	0.24%
Total	**25**	**0.29%**

Survival from Returns and Complaints



Year	1	2	3	4	5	at 65 months				
Survival Probability	99.70%	99.57%	99.26%	99.12%	98.84%	98.84%				
± 1 standard error	0.06%	0.08%	0.11%	0.12%	0.18%	0.18%				
Sample Size	7700	6300	5300	4400	3760	100				

Observations, Complications, and Malfunctions

Left-Heart Leads

St. Jude Medical™
More control. Less risk.

Left-Heart Leads

Acute Observations (Post Implant, ≤30 days)

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1156T	Jul-07	11374	10557	0	0.00%	0	0.00%	6	0.05%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.06%	4	0.04%	**20**	**0.18%**	**7**
1158T	Jul-07	6368	5913	0	0.00%	0	0.00%	4	0.06%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	1	0.02%	5	0.08%	**13**	**0.20%**	**5**
1058T	Feb-06	9600	7827	0	0.00%	0	0.00%	8	0.08%	3	0.03%	1	0.01%	0	0.00%	0	0.00%	2	0.02%	6	0.06%	2	0.02%	**22**	**0.23%**	**9**
1056T	Apr-05	32461	23578	0	0.00%	0	0.00%	26	0.08%	13	0.04%	1	<0.01%	0	0.00%	1	<0.01%	2	0.01%	17	0.05%	8	0.02%	**68**	**0.21%**	**30**
1056K	Jun-04	8689	4729	0	0.00%	0	0.00%	10	0.12%	3	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	9	0.10%	2	0.02%	**24**	**0.28%**	**18**

Chronic Complications (>30 days)

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1156T	Jul-07	11374	10557	0	0.00%	0	0.00%	7	0.06%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	2	0.02%	1	0.01%	**13**	**0.11%**	**6**
1158T	Jul-07	6368	5913	0	0.00%	0	0.00%	6	0.09%	1	0.02%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.03%	0	0.00%	**9**	**0.14%**	**3**
1058T	Feb-06	9600	7827	0	0.00%	1	0.01%	9	0.09%	5	0.05%	0	0.00%	0	0.01%	0	0.00%	1	0.01%	1	0.01%	1	0.01%	**18**	**0.19%**	**7**
1056T	Apr-05	32461	23578	0	0.00%	2	0.01%	60	0.18%	52	0.16%	3	0.01%	1	<0.01%	0	0.00%	3	0.01%	28	0.09%	7	0.02%	**156**	**0.48%**	**66**
1056K	Jun-04	8689	4729	0	0.00%	0	0.00%	24	0.28%	23	0.26%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	11	0.13%	8	0.09%	**68**	**0.78%**	**34**

Definitions of observations and complications can be found on pages 5 and 6.

Lead Malfunctions

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1156T	Jul-07	11374	10557	1	0.01%	0	0.00%	1	0.01%	0	0.00%	7	0.06%	**9**	**0.08%**
1158T	Jul-07	6368	5913	1	0.02%	0	0.00%	0	0.00%	0	0.00%	5	0.08%	**6**	**0.09%**
1058T	Feb-06	9600	7827	0	0.00%	0	0.00%	0	0.00%	3	0.03%	6	0.06%	**9**	**0.09%**
1056T	Apr-05	32461	23578	1	<0.01%	3	0.01%	1	<0.01%	1	<0.01%	56	0.17%	**62**	**0.19%**
1056K	Jun-04	8689	4729	2	0.02%	0	0.00%	2	0.02%	0	0.00%	21	0.24%	**25**	**0.29%**

Definitions of malfunction categories can be found on page 7.

ICDs

Dual-Chamber

ST. JUDE MEDICAL™

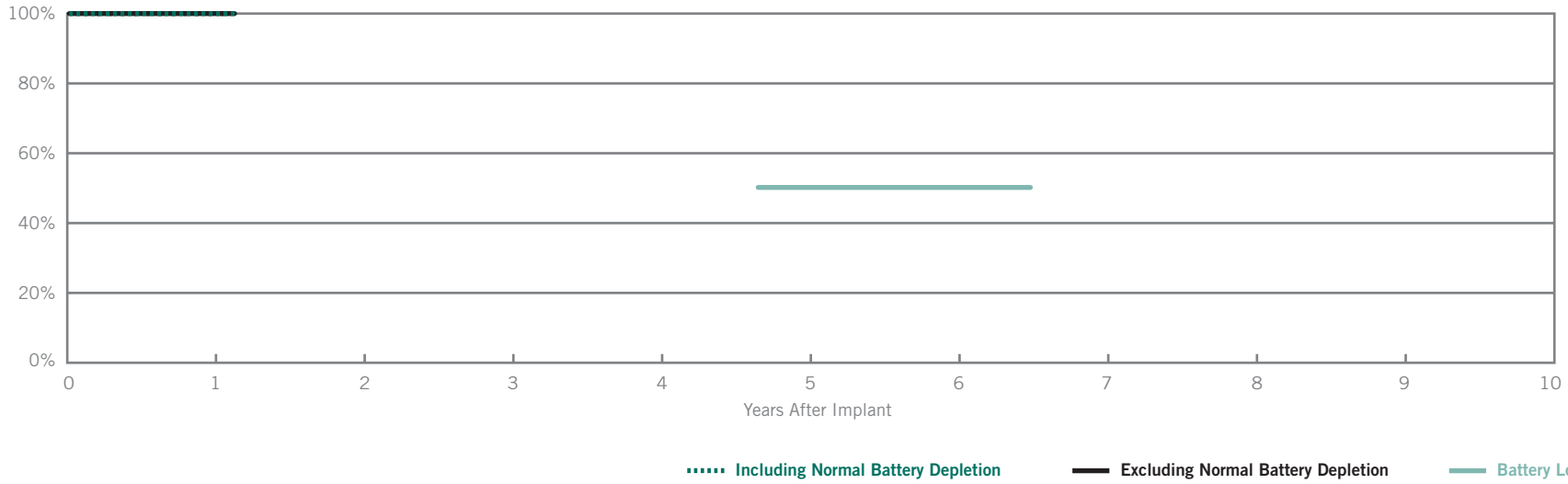
MORE CONTROL. LESS RISK.

ICDs

Current® DR RF (Model 2207-30)

US Market Release	September 2007	Normal Battery Depletion	0
Registered US Implants	1,181	Malfunctions	0
Estimated Active US Implants	1,085	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 14 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	800	200								

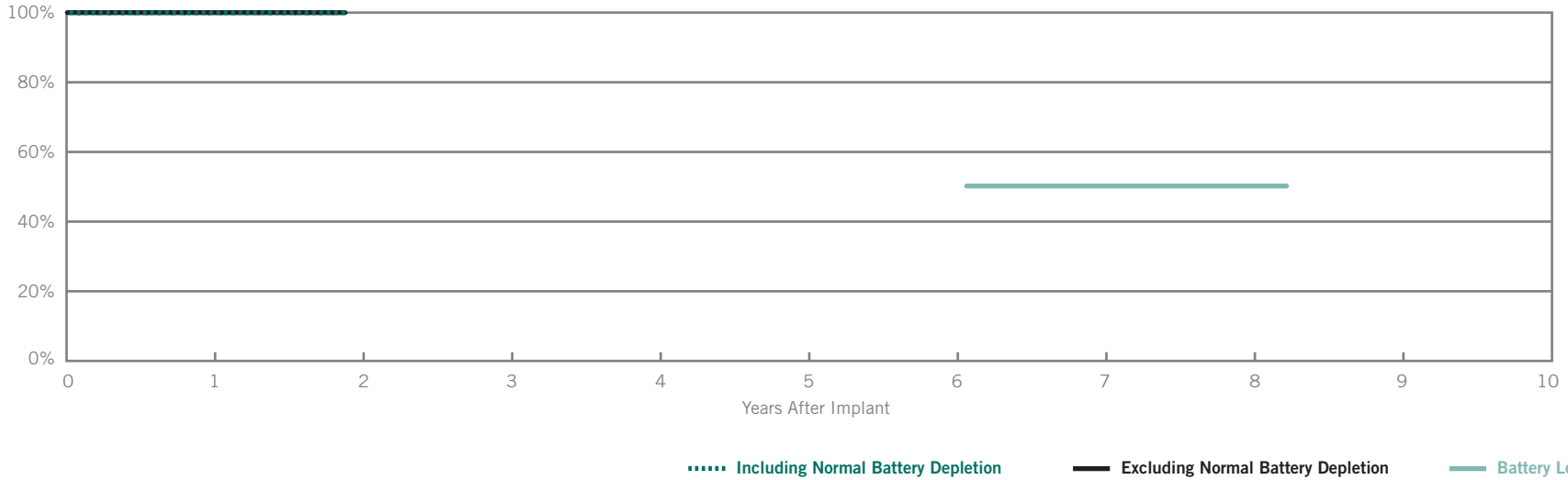
Excluding Normal Battery Depletion

Year	1	at 14 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

Current® DR (Model 2107-36)

US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	621	Malfunctions	0
Estimated Active US Implants	511	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	600	400								

Excluding Normal Battery Depletion

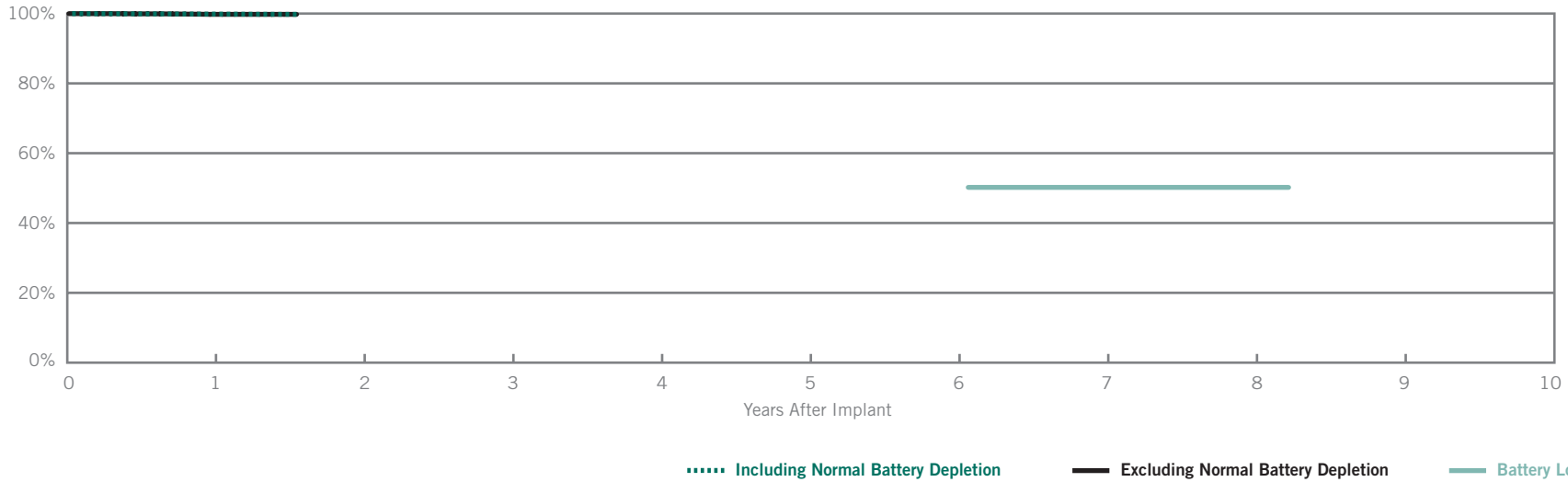
Year	1	at 23 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

ICDs

Current® DR RF (Model 2207-36)

US Market Release	September 2007	Normal Battery Depletion	0
Registered US Implants	17,910	Malfunctions	11
Estimated Active US Implants	16,465	Malfunctions w/ Compromised Therapy	4
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	7
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.79%	99.79%								
± 1 standard error	0.05%	0.05%								
Sample Size	12400	2600								

Excluding Normal Battery Depletion

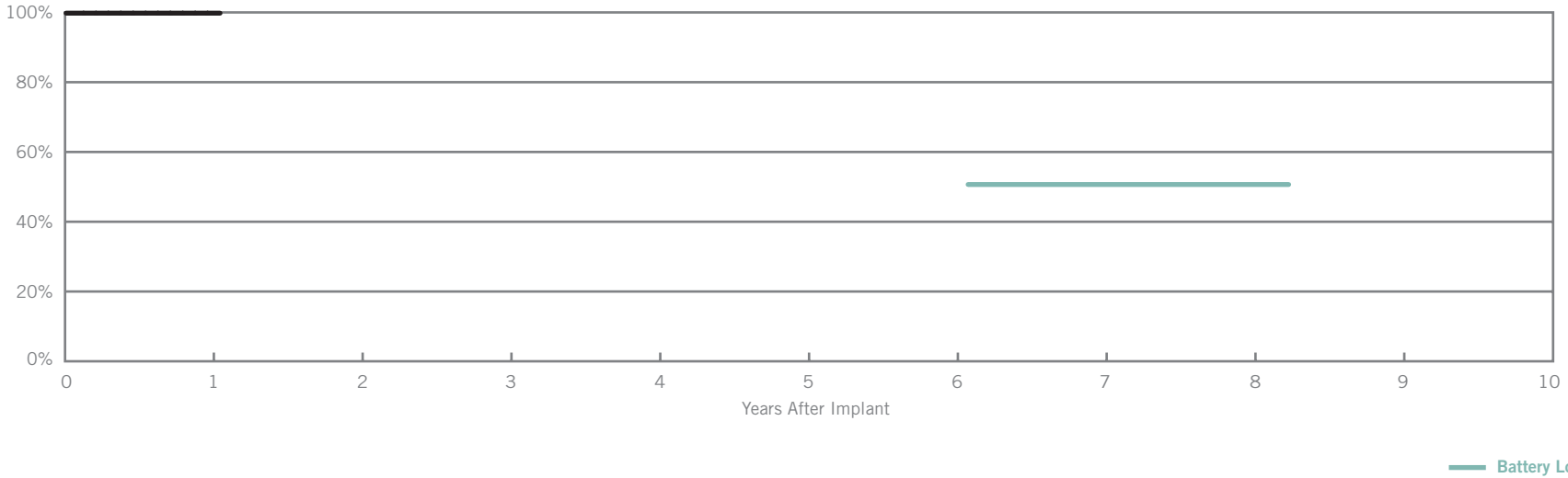
Year	1	at 19 months								
Survival Probability	99.79%	99.79%								
± 1 standard error	0.05%	0.05%								

Current® DR RF (Model 2207-36)	
US Market Release	September 2007

SCORE Enrollment	
Number of Devices Enrolled in Study	475
Cumulative Months of Follow-up	3,726

Qualifying Complications		
Type	**Qty.**	**Rate**
Failure to Sense	1	0.21%

Survival from SCORE Registry

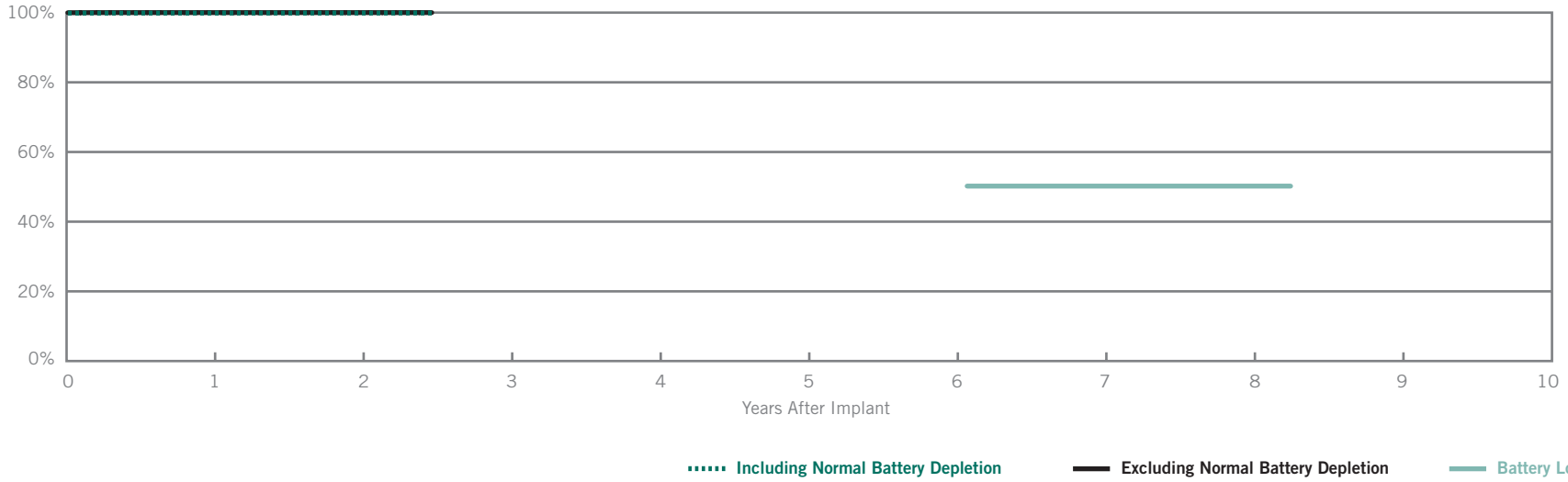


Year	1	at 13 months								
Survival Probability	99.79%	99.79%								
± 1 standard error	0.21%	0.21%								
Sample Size	96	67								

Atlas® II DR (Model V-265)

US Market Release	July 2006	Normal Battery Depletion	0
Registered US Implants	1,876	Malfunctions	0
Estimated Active US Implants	1,499	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	99.89%	99.89%	99.89%							
± 1 standard error	0.08%	0.08%	0.08%							
Sample Size	1900	1200	400							

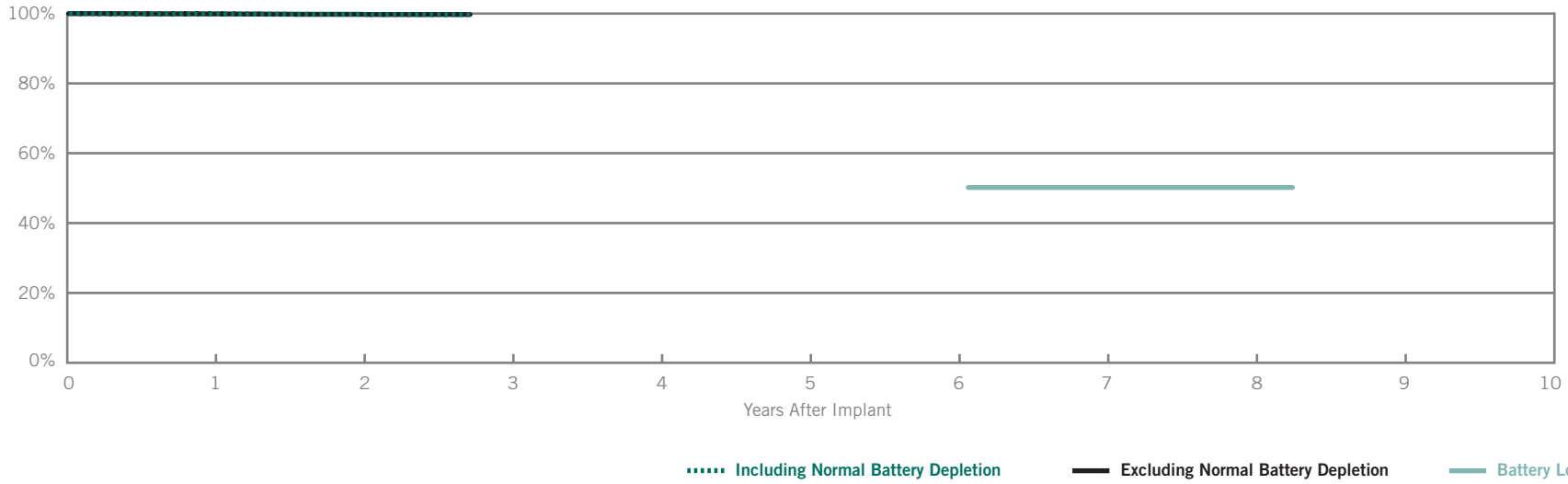
Excluding Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

Atlas® II + DR (Model V-268)

US Market Release	July 2006	Normal Battery Depletion	3
Registered US Implants	13,987	Malfunctions	13
Estimated Active US Implants	11,446	Malfunctions w/ Compromised Therapy (0 related to Advisory)	10
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	3
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 33 months							
Survival Probability	99.89%	99.75%	99.70%							
± 1 standard error	0.03%	0.05%	0.06%							
Sample Size	13000	7600	3100							

Excluding Normal Battery Depletion

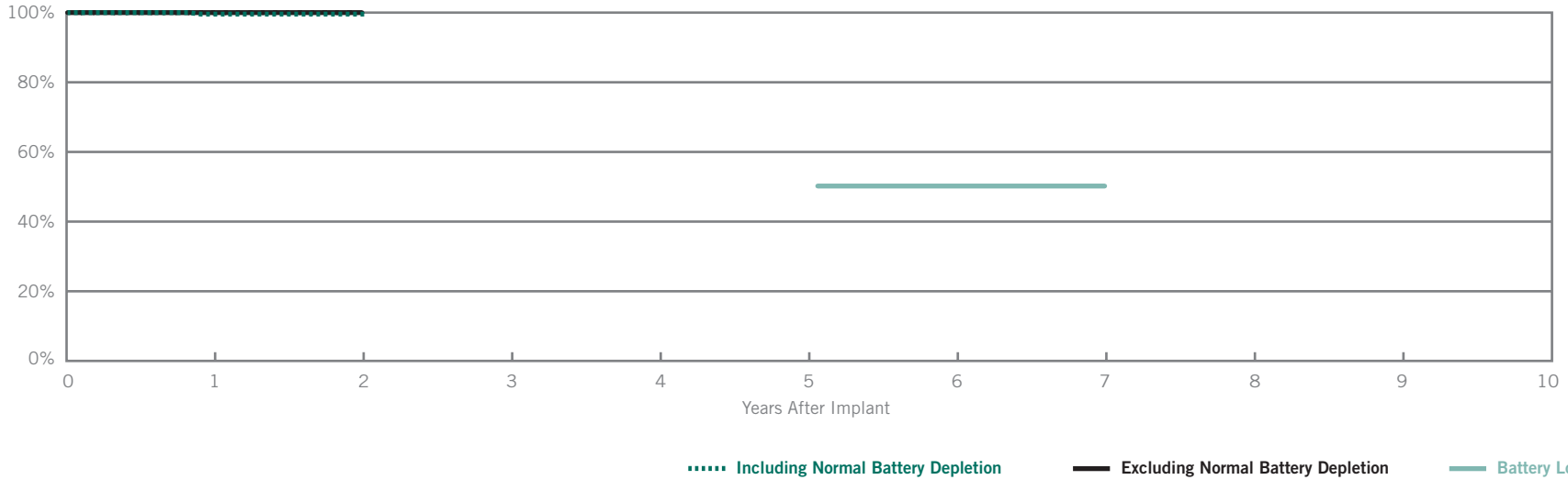
Year	1	2	at 33 months							
Survival Probability	99.90%	99.79%	99.74%							
± 1 standard error	0.03%	0.05%	0.06%							

ICDs

Epic® II DR (Model V-255)

US Market Release	March 2006	Normal Battery Depletion	1
Registered US Implants	543	Malfunctions	0
Estimated Active US Implants	417	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.57%	99.57%								
± 1 standard error	0.30%	0.30%								
Sample Size	500	300								

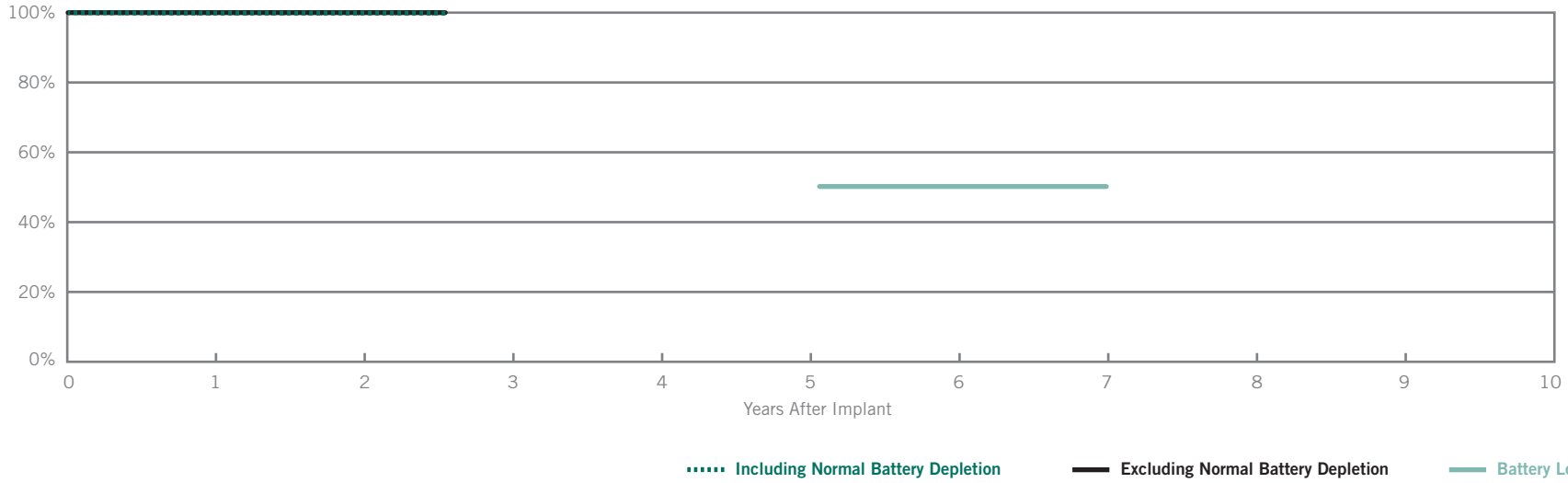
Excluding Normal Battery Depletion

Year	1	2								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

Epic® II + DR (Model V-258)

US Market Release	March 2006	Normal Battery Depletion	1
Registered US Implants	1,973	Malfunctions	0
Estimated Active US Implants	1,564	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 31 months							
Survival Probability	99.87%	99.87%	99.87%							
± 1 standard error	0.09%	0.09%	0.09%							
Sample Size	1900	1200	500							

Excluding Normal Battery Depletion

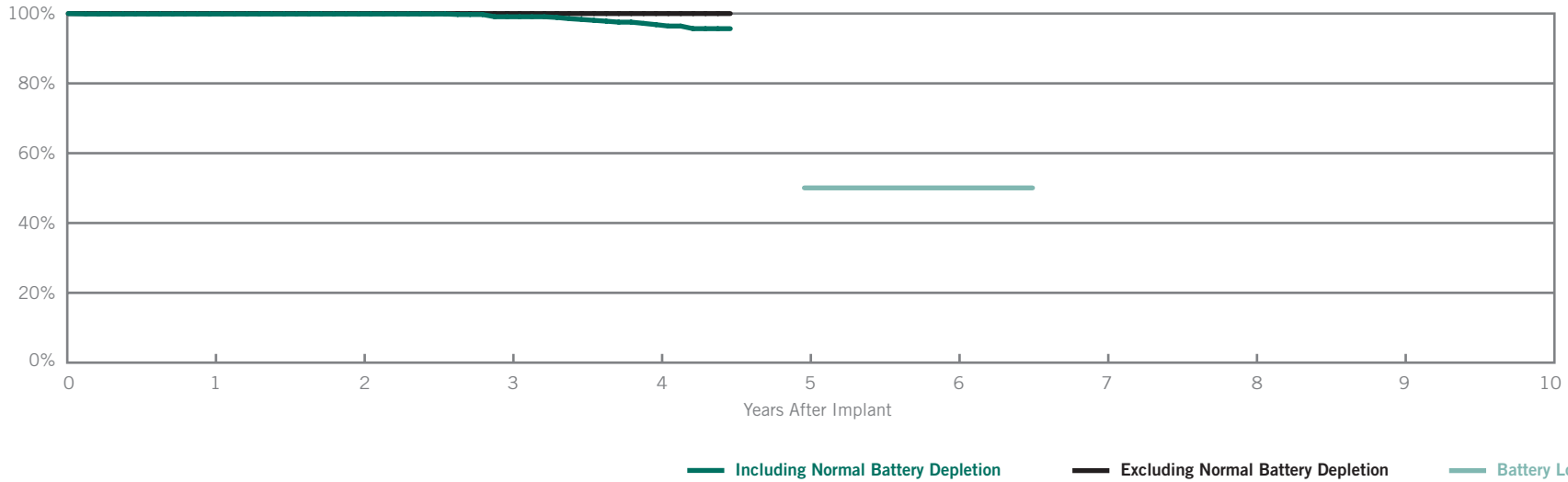
Year	1	2	at 31 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

ICDs

Epic® DR (Model V-233)

US Market Release	October 2003	Normal Battery Depletion	19
Registered US Implants	1,823	Malfunctions	0
Estimated Active US Implants	1,062	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.89%	99.89%	99.09%	96.82%	95.67%					
± 1 standard error	0.08%	0.08%	0.28%	0.56%	0.80%					
Sample Size	1800	1600	1300	900	400					

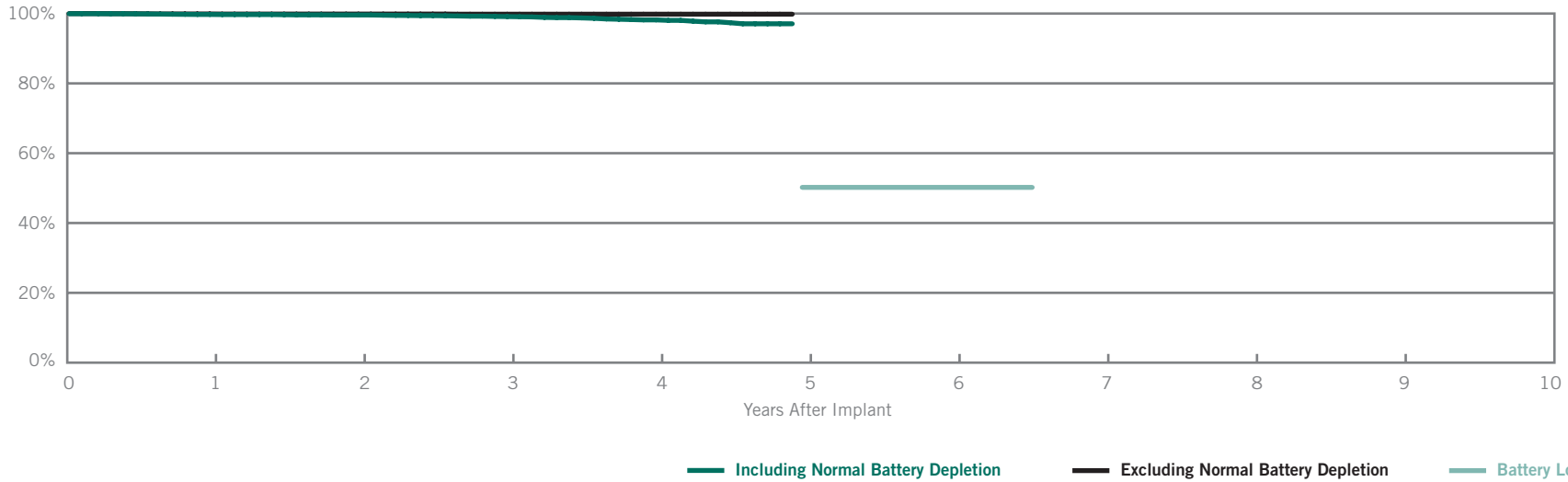
Excluding Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%					
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%					

Epic® + DR (Model V-239)

US Market Release	October 2003	Normal Battery Depletion	42
Registered US Implants	7,815	Malfunctions	6
Estimated Active US Implants	4,702	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	2
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 59 months					
Survival Probability	99.74%	99.59%	99.14%	98.18%	97.07%					
± 1 standard error	0.06%	0.08%	0.12%	0.22%	0.41%					
Sample Size	7800	6900	5500	3300	1000					

Excluding Normal Battery Depletion

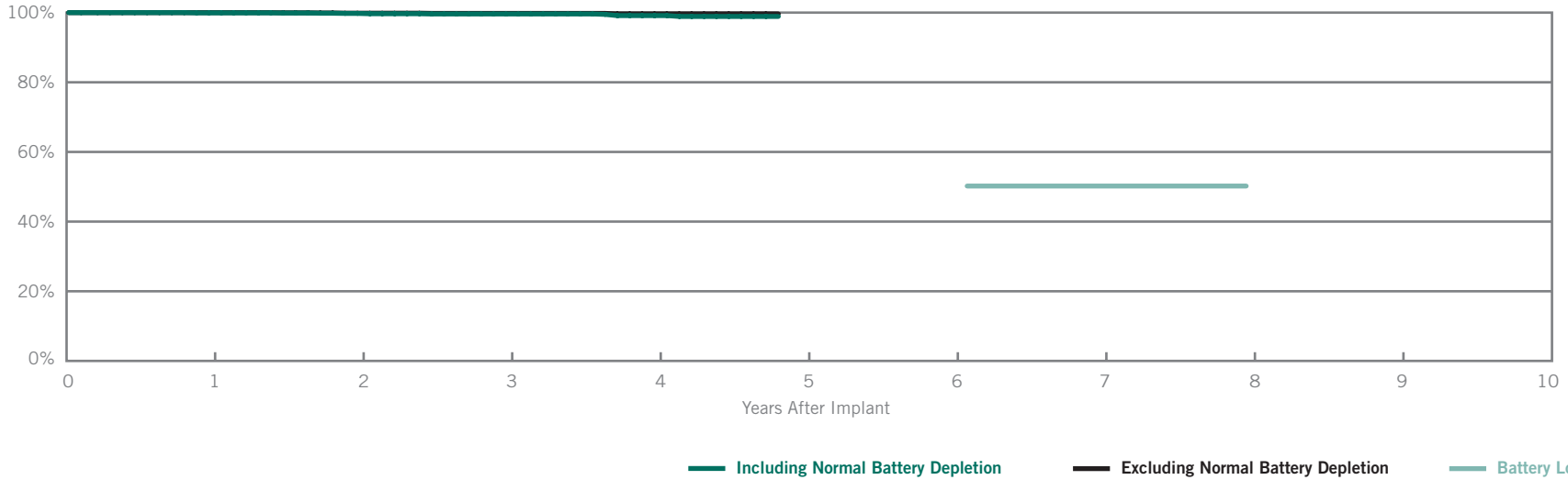
Year	1	2	3	4	at 59 months					
Survival Probability	99.89%	99.86%	99.82%	99.82%	99.82%					
± 1 standard error	0.04%	0.04%	0.05%	0.05%	0.05%					

ICDs

Atlas® DR (Model V-242)

US Market Release	October 2003	Normal Battery Depletion	7
Registered US Implants	4,639	Malfunctions	5
Estimated Active US Implants	2,931	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.93%	99.77%	99.62%	99.14%	98.90%					
± 1 standard error	0.04%	0.08%	0.10%	0.21%	0.27%					
Sample Size	4600	4100	3300	1900	800					

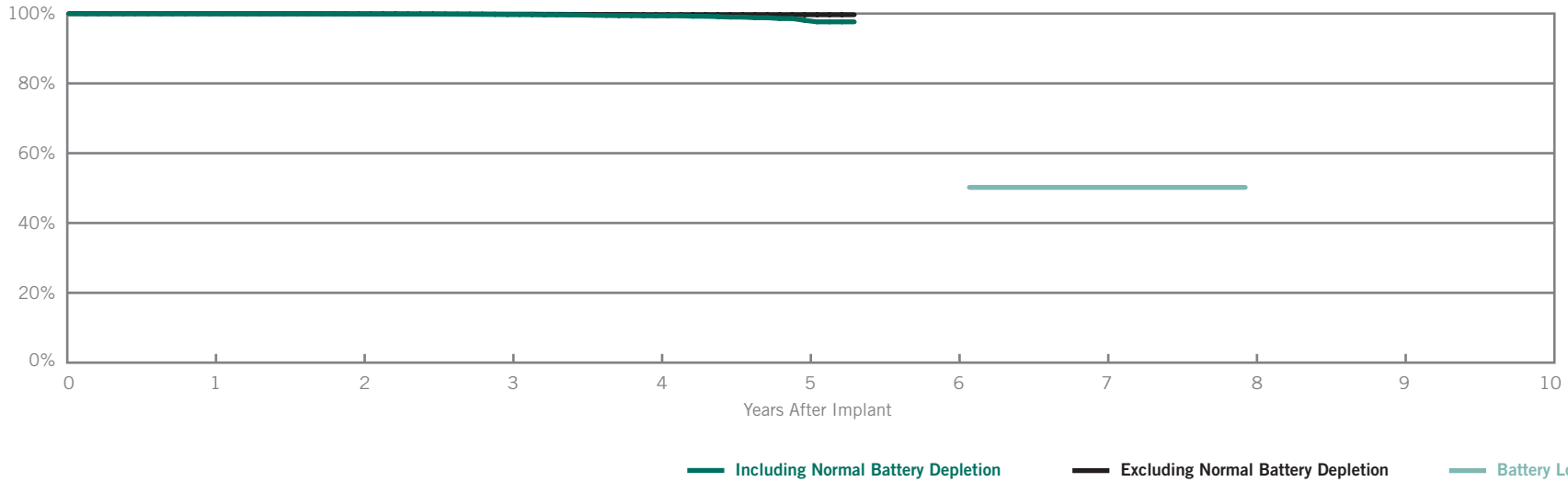
Excluding Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	100.00%	99.84%	99.78%	99.64%	99.64%					
± 1 standard error	0.00%	0.07%	0.08%	0.13%	0.13%					

Atlas® + DR (Model V-243)

US Market Release	October 2003	Normal Battery Depletion	25
Registered US Implants	20,894	Malfunctions	17
Estimated Active US Implants	13,511	Malfunctions w/ Compromised Therapy (0 related to Advisory)	13
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.95%	99.89%	99.72%	99.36%	98.05%	97.63%				
± 1 standard error	0.01%	0.02%	0.04%	0.09%	0.27%	0.50%				
Sample Size	20900	17800	13100	6800	2000	300				

Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.97%	99.92%	99.82%	99.67%	99.67%	99.67%				
± 1 standard error	0.01%	0.02%	0.03%	0.07%	0.07%	0.07%				

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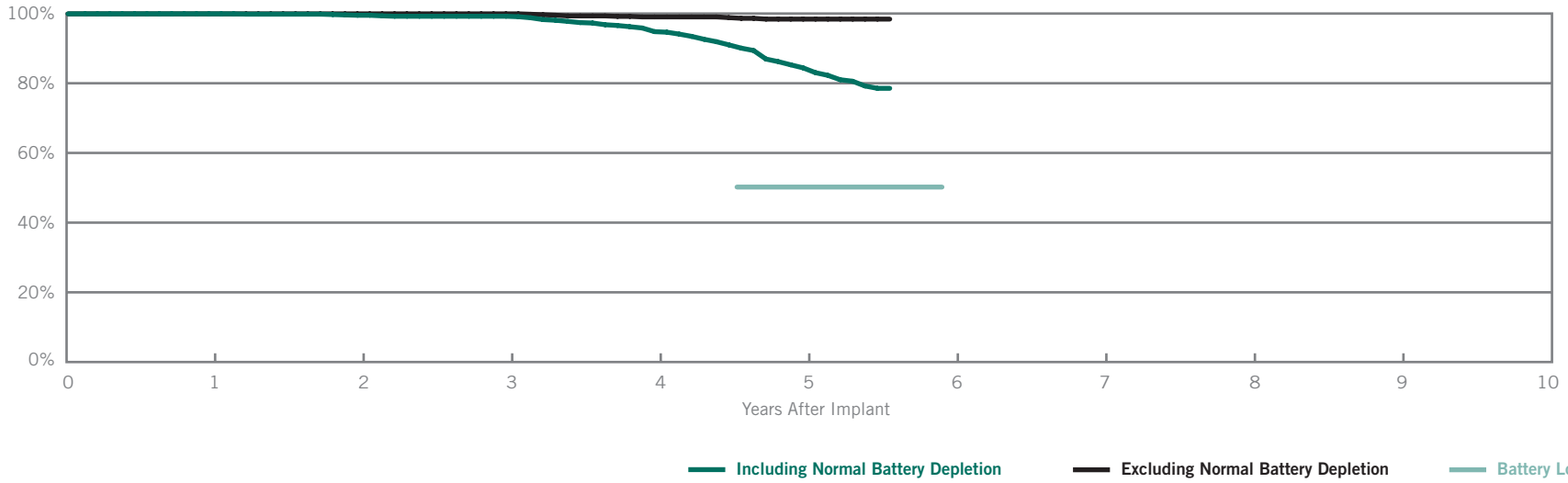
Epic® + DR (Model V-236)

US Market Release	April 2003	Normal Battery Depletion	116
Registered US Implants	2,344	Malfunctions	11
Estimated Active US Implants	466	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	10
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.91%	99.50%	99.22%	94.80%	84.41%	78.54%				
± 1 standard error	0.06%	0.14%	0.20%	0.51%	1.04%	1.47%				
Sample Size	2300	2100	1800	1600	1200	500				

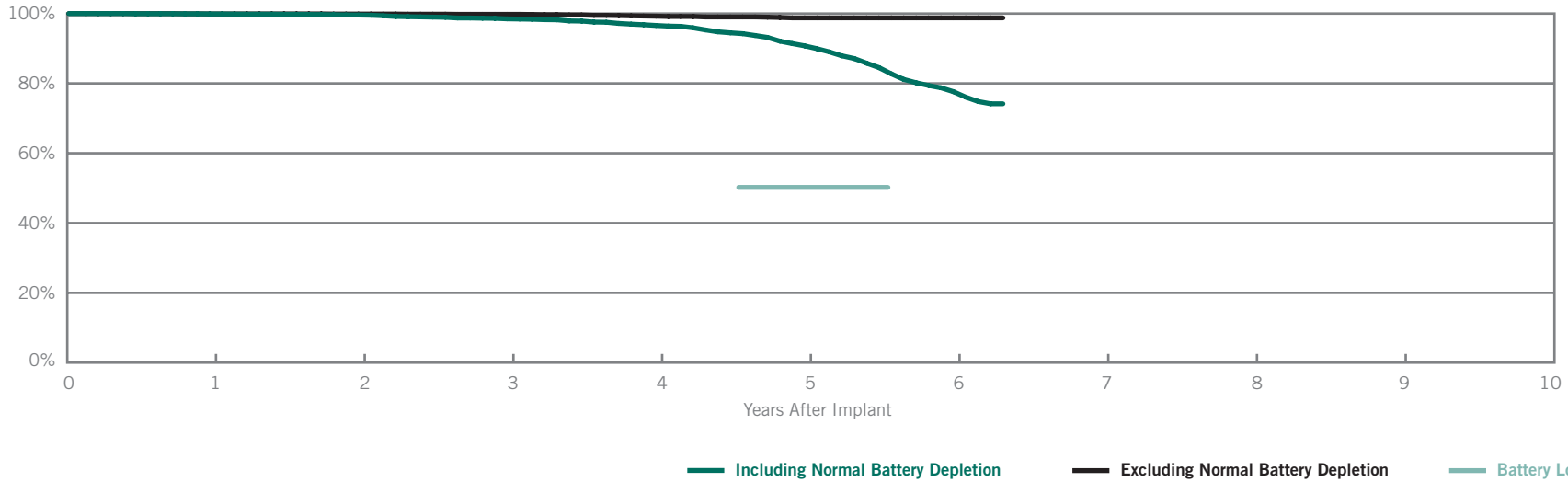
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.91%	99.91%	99.91%	99.03%	98.40%	98.40%				
± 1 standard error	0.06%	0.06%	0.06%	0.25%	0.36%	0.36%				

Epic® DR (Model V-235)

US Market Release	July 2002	Normal Battery Depletion	269
Registered US Implants	6,590	Malfunctions	28
Estimated Active US Implants	1,432	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	24
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.88%	99.58%	98.48%	96.59%	90.75%	77.63%	74.16%			
± 1 standard error	0.04%	0.08%	0.16%	0.26%	0.47%	0.98%	1.34%			
Sample Size	6600	5900	5300	4600	3600	1900	300			

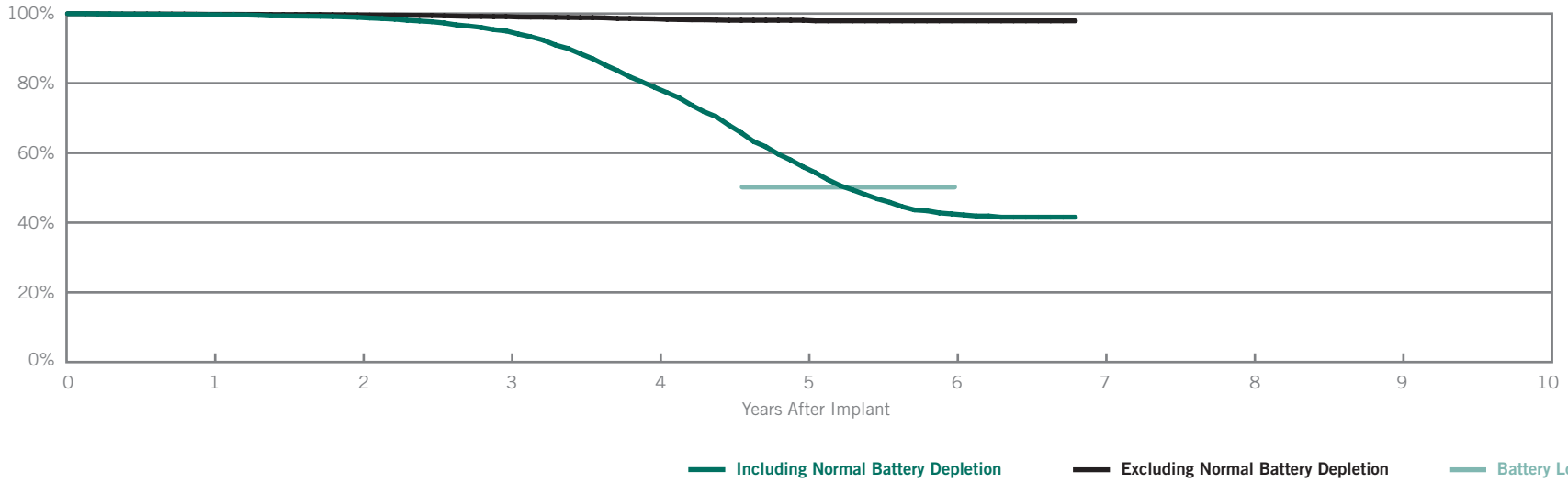
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.90%	99.86%	99.78%	99.25%	98.77%	98.77%	98.77%			
± 1 standard error	0.03%	0.05%	0.06%	0.12%	0.18%	0.18%	0.18%			

Atlas® DR (Model V-240)

US Market Release	December 2001	Normal Battery Depletion	1001
Registered US Implants	8,841	Malfunctions	60
Estimated Active US Implants	572	Malfunctions w/ Compromised Therapy (21 related to Advisory)	31
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	29
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.66%	98.93%	95.01%	78.82%	56.01%	42.50%	41.55%			
± 1 standard error	0.06%	0.11%	0.26%	0.54%	0.78%	1.00%	1.03%			
Sample Size	8800	7700	6700	5500	3600	1300	300			

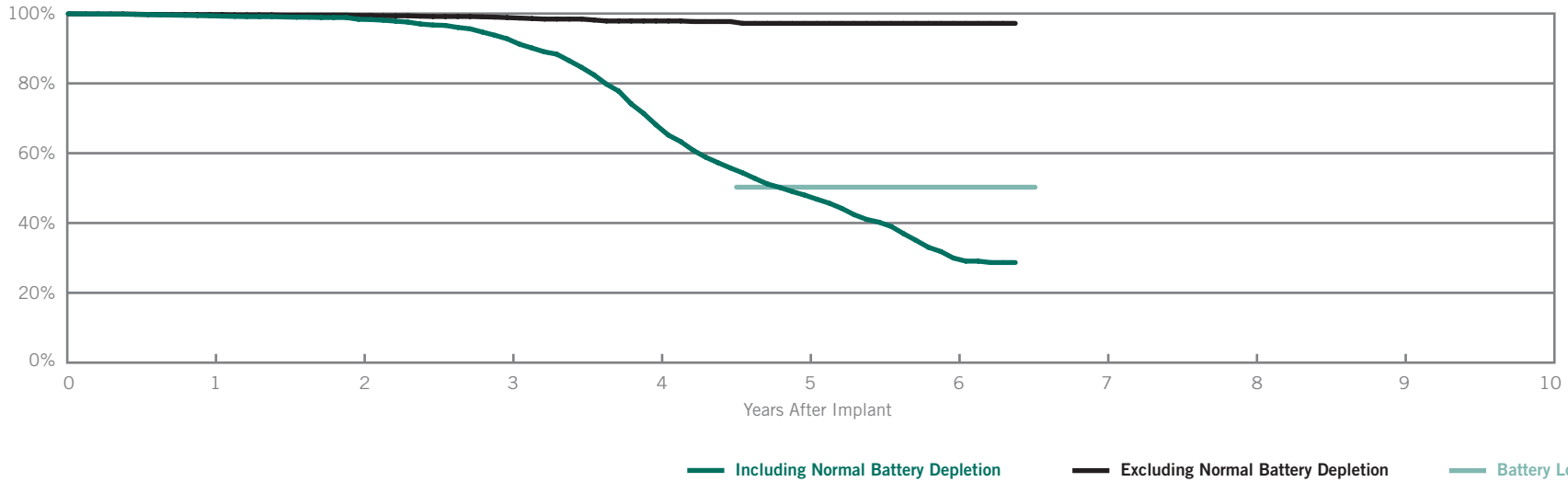
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.79%	99.60%	99.14%	98.48%	98.07%	97.91%	97.91%			
± 1 standard error	0.05%	0.07%	0.11%	0.16%	0.20%	0.23%	0.23%			

Photon™ µ DR (Model V-232)

US Market Release	June 2001	Normal Battery Depletion	440
Registered US Implants	3,402	Malfunctions	33
Estimated Active US Implants	147	Malfunctions w/ Compromised Therapy (10 related to Advisory)	16
Estimated Longevity	(see table on page 74)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	17
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.36%	98.35%	92.76%	68.14%	47.99%	29.96%	28.68%			
± 1 standard error	0.13%	0.19%	0.48%	0.96%	1.14%	1.30%	1.32%			
Sample Size	3400	3000	2600	2200	1400	600	200			

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.69%	99.44%	98.85%	97.87%	97.19%	97.19%	97.19%			
± 1 standard error	0.10%	0.12%	0.19%	0.31%	0.40%	0.40%	0.40%			

Summary & Longevity Information

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Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
2207-30	Current® DR RF	6.5	5.9	5.4	4.6
2107-36	Current® DR	8.2	7.5	7.0	6.1
2207-36	Current® DR RF	8.2	7.5	7.0	6.1
V-265	Atlas® II DR	8.2	7.5	7.0	6.1
V-268	Atlas® II + DR	8.2	7.5	7.0	6.1
V-255	Epic® II DR	7.0	6.4	5.9	5.1
V-258	Epic® II + DR	6.5	5.9	5.4	4.6
V-233	Epic® DR	6.4	6.0	5.6	4.9
V-239	Epic® + DR	6.4	6.0	5.6	4.5
V-242	Atlas® DR	7.9	7.3	6.9	6.1
V-243	Atlas® + DR	7.9	7.3	6.9	6.1
V-236	Epic® + DR	5.8	5.4	5.1	4.5
V-235	Epic® DR	5.6	5.3	4.9	4.4
V-240	Atlas® DR	6.0	5.6	5.2	4.6
V-232	Photon™µ DR <42000	6.1	5.7	5.3	4.6
V-232	Photon™µ DR >42000	6.6	6.1	5.6	4.9

**Battery longevity calculated with one EGM storage.*
Pacing parameters: DDD, 2.5V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the batteries mid-life voltage range.
(Four maximum charges per year for models V-232 and V-240).

Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/ Compromised Therapy (under advisory)	Malfunctions w/ Compromised Therapy (premature battery depletion)	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
2207-30	Current® DR RF	Sep-07	1181	1085	0	0	0	0	0	0	0
2107-36	Current® DR	May-07	621	511	0	0	0	0	0	0	0
2207-36	Current® DR RF	Sep-07	17910	16465	1	0	3	6	1	11	0
V-265	Atlas® II DR	Jul-06	1876	1499	0	0	0	0	0	0	0
V-268	Atlas® II + DR	Jul-06	13987	11446	4	0	6	1	2	13	3
V-255	Epic® II DR	Mar-06	543	417	0	0	0	0	0	0	1
V-258	Epic® II + DR	Mar-06	1973	1564	0	0	0	0	0	0	1
V-233	Epic® DR	Oct-03	1823	1062	0	0	0	0	0	0	19
V-239	Epic® + DR	Oct-03	7815	4702	4	0	0	2	0	6	42
V-242	Atlas® DR	Oct-03	4639	2931	2	0	2	1	0	5	7
V-243	Atlas® + DR	Oct-03	20894	13511	2	0	11	3	1	17	25
V-236	Epic® + DR	Apr-03	2344	466	0	0	1	8	2	11	116
V-235	Epic® DR	Jul-02	6590	1432	2	0	2	22	2	28	269
V-240	Atlas® DR	Dec-01	8841	572	5	21	5	12	17	60	1001
V-232	Photon™ µ DR	Jun-01	3402	147	4	10	2	5	12	33	440

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
2207-30	Current® DR RF	100.00%									
2107-36	Current® DR	100.00%									
2207-36	Current® DR RF	99.79%									
V-265	Atlas® II DR	99.89%	99.89%								
V-268	Atlas® II + DR	99.89%	99.75%								
V-255	Epic® II DR	99.57%	99.57%								
V-258	Epic® II + DR	99.87%	99.87%								
V-233	Epic® DR	99.89%	99.89%	99.09%	96.82%						
V-239	Epic® + DR	99.74%	99.59%	99.14%	98.18%						
V-242	Atlas® DR	99.93%	99.77%	99.62%	99.14%						
V-243	Atlas® + DR	99.95%	99.89%	99.72%	99.36%	98.05%					
V-236	Epic® + DR	99.91%	99.50%	99.22%	94.80%	84.41%					
V-235	Epic® DR	99.88%	99.58%	98.48%	96.59%	90.75%	77.63%				
V-240	Atlas® DR	99.66%	98.93%	95.01%	78.82%	56.01%	42.50%				
V-232	Photon™ µ DR	99.36%	98.35%	92.76%	68.14%	47.99%	29..96%				

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
2207-30	Current® DR RF	100.00%									
2107-36	Current® DR	100.00%									
2207-36	Current® DR RF	99.79%									
V-265	Atlas® II DR	100.00%	100.00%								
V-268	Atlas® II + DR	99.90%	99.79%								
V-255	Epic® II DR	100.00%	100.00%								
V-258	Epic® II + DR	100.00%	100.00%								
V-233	Epic® DR	100.00%	100.00%	100.00%	100.00%						
V-239	Epic® + DR	99.89%	99.86%	99.82%	99.82%						
V-242	Atlas® DR	100.00%	99.84%	99.78%	99.64%						
V-243	Atlas® + DR	99.97%	99.92%	99.82%	99.67%	99.67%					
V-236	Epic® + DR	99.91%	99.91%	99.91%	99.03%	98.40%					
V-235	Epic® DR	99.90%	99.86%	99.78%	99.25%	98.77%	98.77%				
V-240	Atlas® DR	99.79%	99.60%	99.14%	98.48%	98.07%	97.91%				
V-232	Photon™ µ DR	99.69%	99.44%	98.85%	97.87%	97.19%	97.19%				

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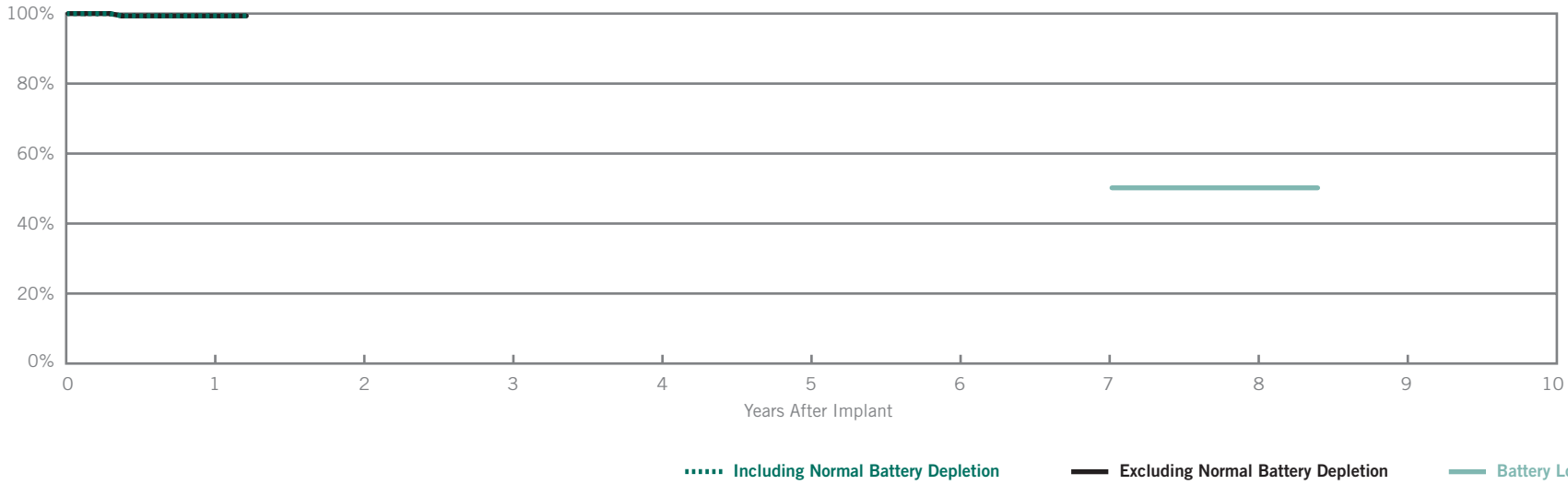
Current® VR (Model 1107-36)

US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	329	Malfunctions	1
Estimated Active US Implants	269	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 15 months								
Survival Probability	99.34%	99.34%								
± 1 standard error	0.47%	0.47%								
Sample Size	300	200								

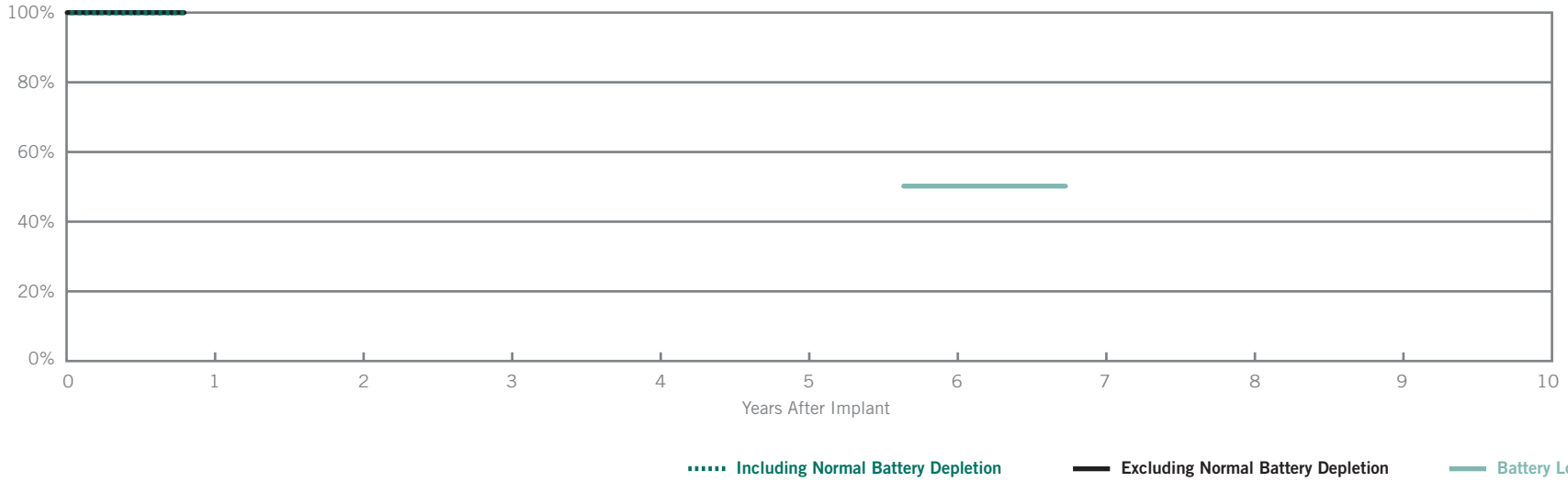
Excluding Normal Battery Depletion

Year	1	at 15 months								
Survival Probability	99.34%	99.34%								
± 1 standard error	0.47%	0.47%								

Current® VR RF (Model 1207-30)

US Market Release	September 2007	Normal Battery Depletion	0
Registered US Implants	606	Malfunctions	0
Estimated Active US Implants	570	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

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

Excluding Normal Battery Depletion

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

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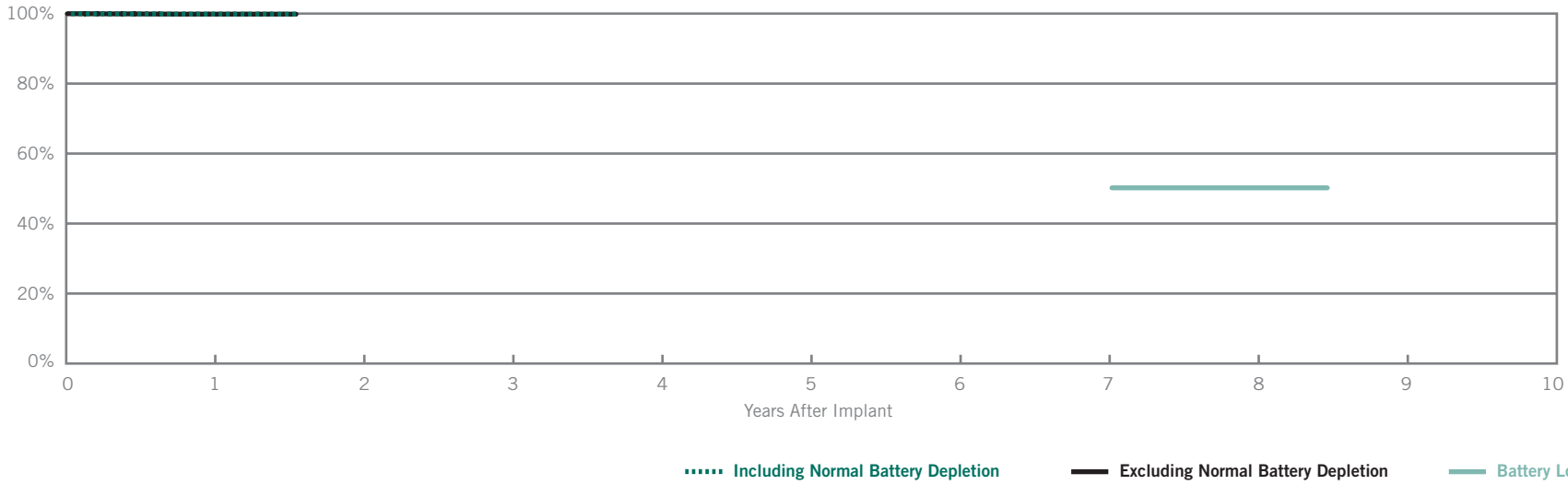
Current® VR RF (Model 1207-36)

US Market Release	September 2007	Normal Battery Depletion	0
Registered US Implants	10,112	Malfunctions	6
Estimated Active US Implants	9,320	Malfunctions w/ Compromised Therapy	3
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy	3
Max. Delivered Energy	36 joules	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 19 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.05%	0.05%								
Sample Size	6900	1300								

Excluding Normal Battery Depletion

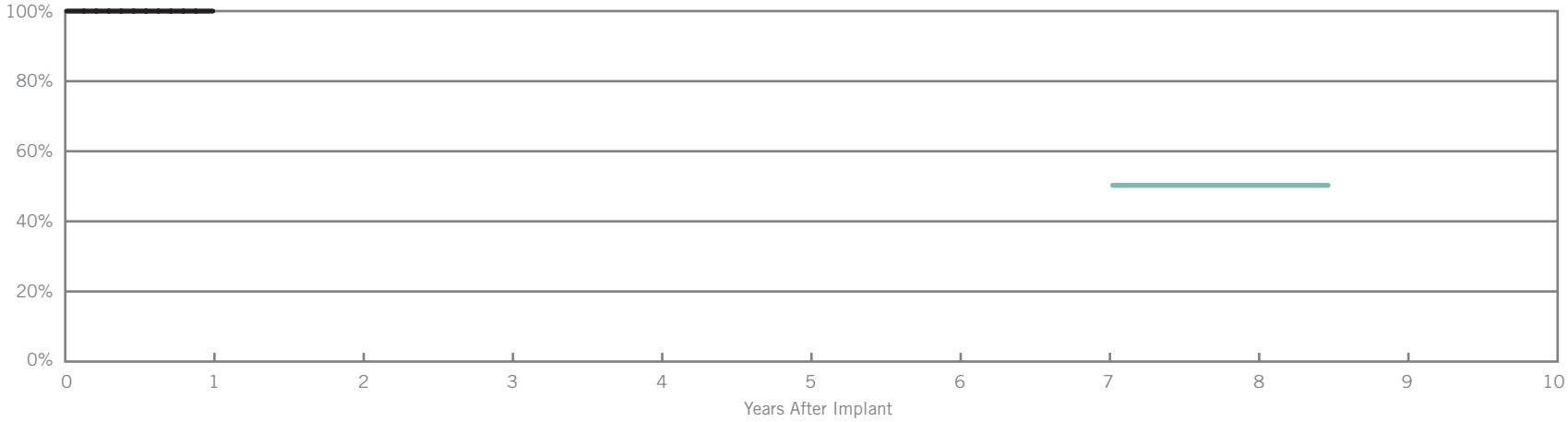
Year	1	at 19 months								
Survival Probability	99.84%	99.84%								
± 1 standard error	0.05%	0.05%								

Current® VR RF (Model 1207-36)	
US Market Release	September 2007

SCORE Enrollment	
Number of Devices Enrolled in Study	311
Cumulative Months of Follow-up	2,374

Qualifying Complications
None Reported

Survival from SCORE Registry



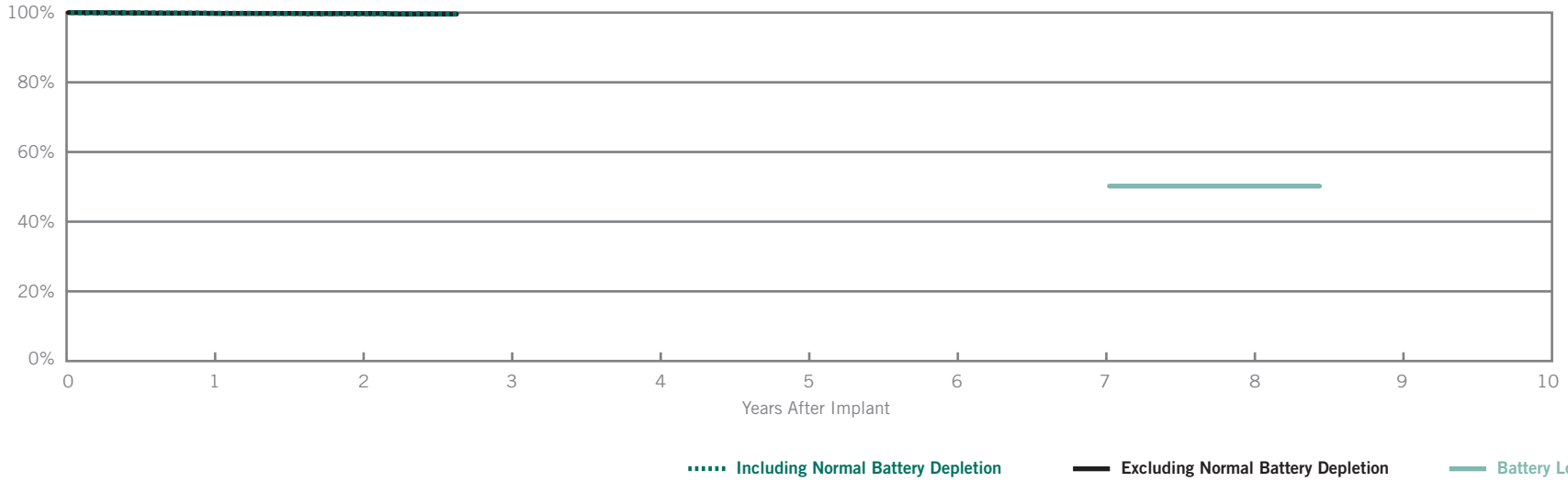
Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	59									

ICDs

Atlas® II VR (Model V-168)

US Market Release	July 2006	Normal Battery Depletion	2
Registered US Implants	9,901	Malfunctions	13
Estimated Active US Implants	8,224	Malfunctions w/ Compromised Therapy (0 related to Advisory)	9
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.78%	99.69%	99.57%							
± 1 standard error	0.05%	0.06%	0.11%							
Sample Size	9200	5400	1500							

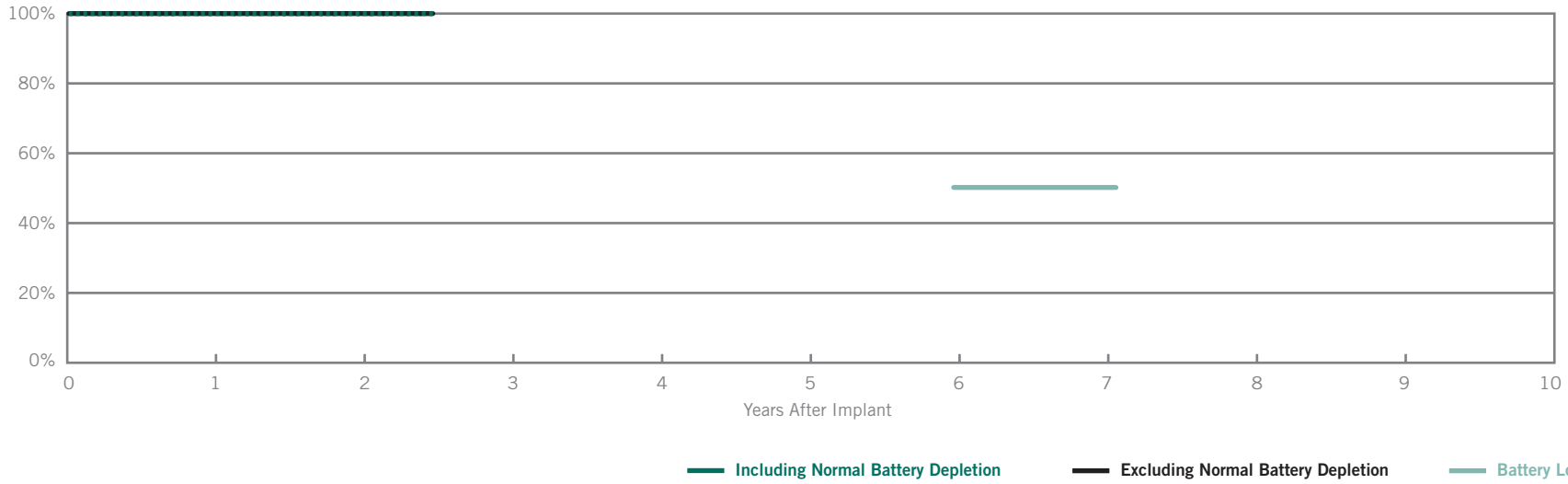
Excluding Normal Battery Depletion

Year	1	2	at 32 months							
Survival Probability	99.79%	99.72%	99.58%							
± 1 standard error	0.04%	0.06%	0.11%							

Epic® II VR (Model V-158)

US Market Release	March 2006	Normal Battery Depletion	0
Registered US Implants	1,485	Malfunctions	0
Estimated Active US Implants	1,171	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	at 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	1400	900	400							

Excluding Normal Battery Depletion

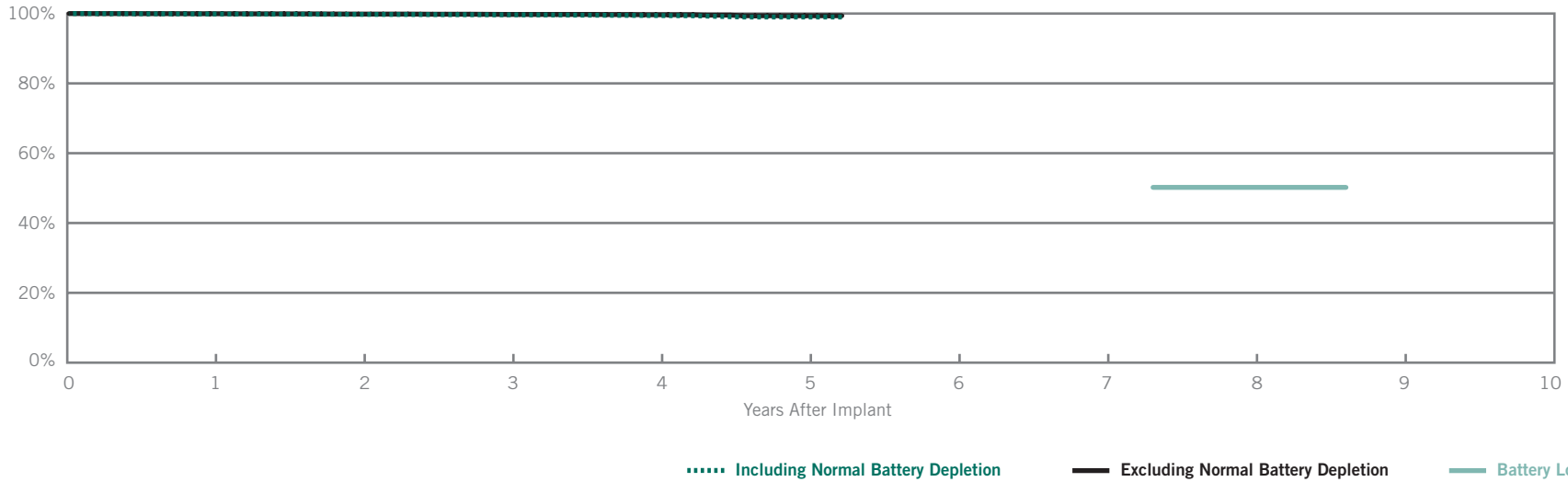
Year	1	2	at 30 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							

ICDs

Atlas® + VR (Model V-193)

US Market Release	October 2003	Normal Battery Depletion	18
Registered US Implants	20,361	Malfunctions	24
Estimated Active US Implants	13,332	Malfunctions w/ Compromised Therapy (0 related to Advisory)	15
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	9
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 63 months				
Survival Probability	99.88%	99.73%	99.63%	99.45%	99.01%	99.01%				
± 1 standard error	0.02%	0.04%	0.05%	0.08%	0.19%	0.19%				
Sample Size	20400	17300	13000	6900	2000	300				

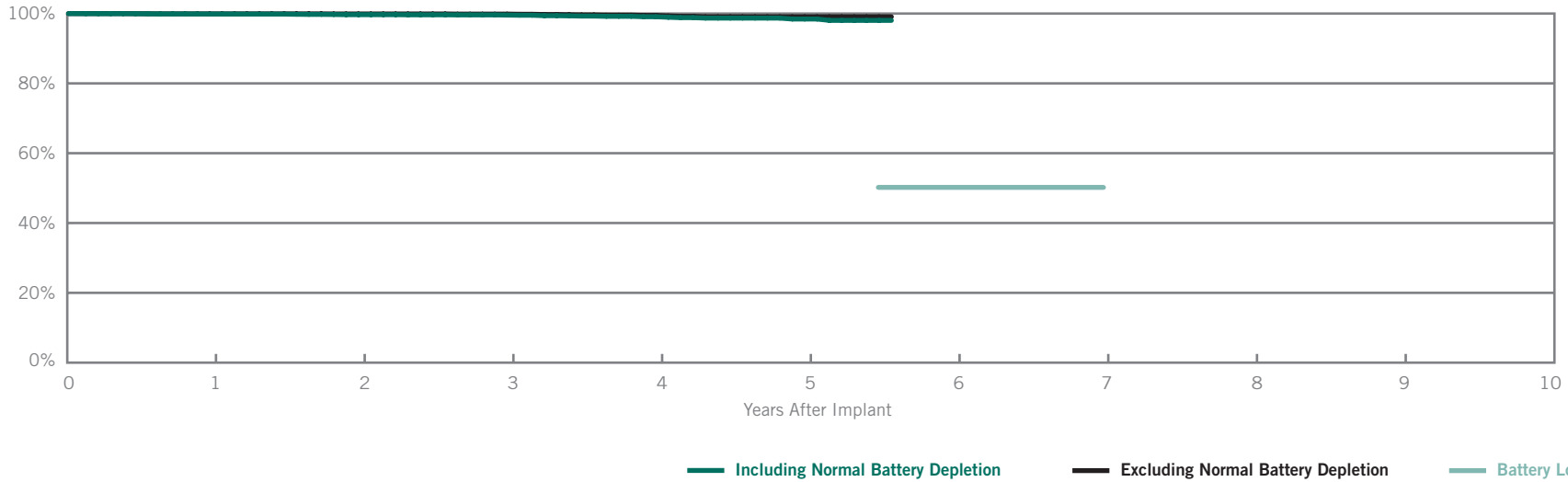
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 63 months				
Survival Probability	99.95%	99.85%	99.75%	99.66%	99.38%	99.38%				
± 1 standard error	0.02%	0.03%	0.04%	0.06%	0.16%	0.16%				

Epic® + VR (Model V-196)

US Market Release	April 2003	Normal Battery Depletion	12
Registered US Implants	7,938	Malfunctions	16
Estimated Active US Implants	4,686	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	11
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Three

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.86%	99.68%	99.56%	99.09%	98.43%	98.04%				
± 1 standard error	0.04%	0.07%	0.08%	0.15%	0.28%	0.39%				
Sample Size	7900	7000	5700	3700	1500	400				

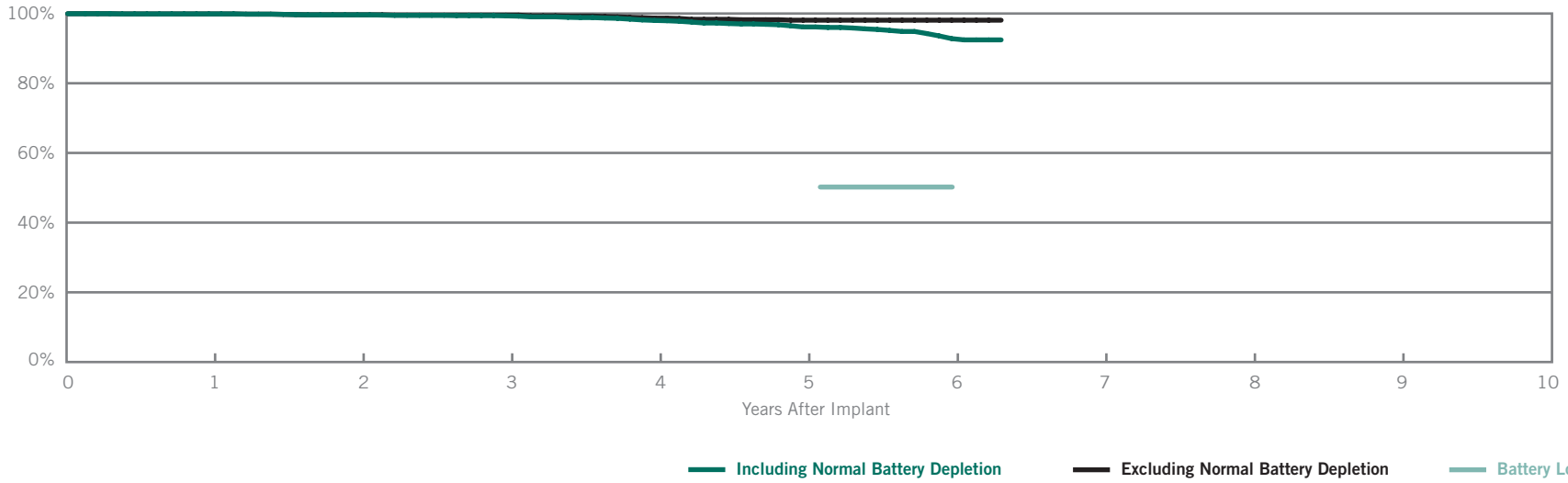
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.92%	99.89%	99.85%	99.47%	99.08%	99.08%				
± 1 standard error	0.03%	0.04%	0.05%	0.12%	0.19%	0.19%				

Epic® VR (Model V-197)

US Market Release	July 2002	Normal Battery Depletion	40
Registered US Implants	3,649	Malfunctions	25
Estimated Active US Implants	1,194	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	20
Max. Delivered Energy	30 joules	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.89%	99.62%	99.33%	98.02%	96.15%	92.80%	92.44%			
± 1 standard error	0.06%	0.11%	0.14%	0.27%	0.40%	0.66%	0.78%			
Sample Size	3600	3200	2800	2500	2000	1200	400			

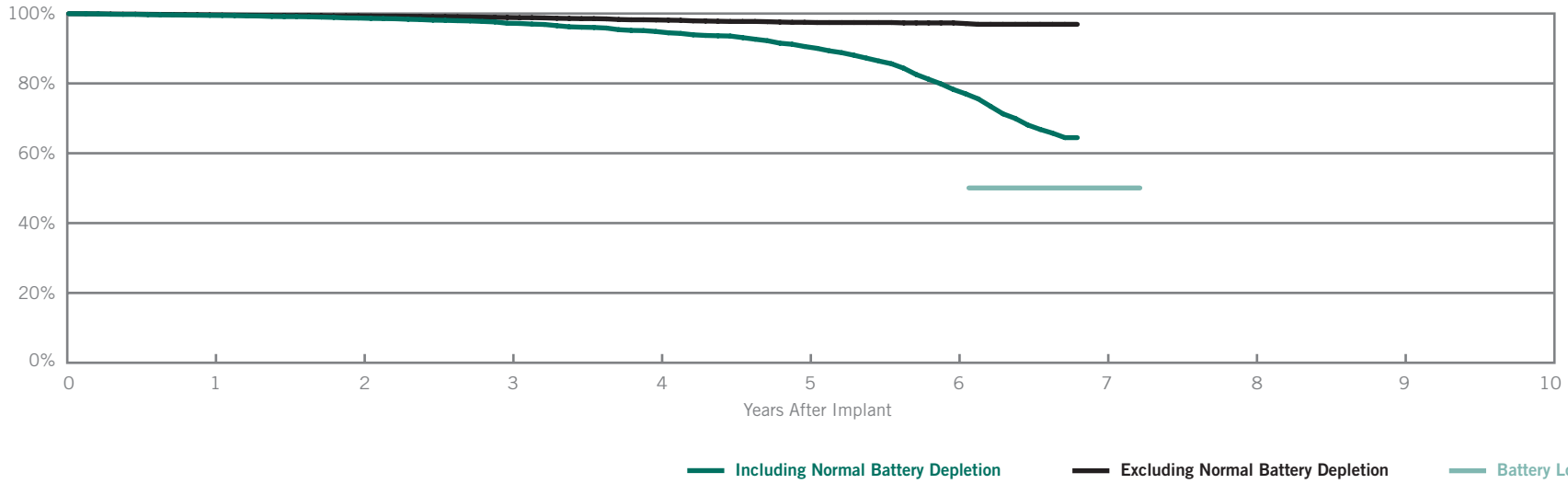
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 76 months			
Survival Probability	99.89%	99.62%	99.55%	98.68%	98.09%	98.09%	98.09%			
± 1 standard error	0.06%	0.11%	0.12%	0.21%	0.29%	0.29%	0.29%			

Atlas® VR (Model V-199)

US Market Release	December 2001	Normal Battery Depletion	338
Registered US Implants	7,086	Malfunctions	69
Estimated Active US Implants	1,188	Malfunctions w/ Compromised Therapy (22 related to Advisory)	34
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	35
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.48%	98.72%	97.23%	94.86%	90.56%	78.26%	64.47%			
± 1 standard error	0.08%	0.14%	0.21%	0.31%	0.45%	0.79%	1.46%			
Sample Size	7100	6200	5300	4500	3600	2500	900			

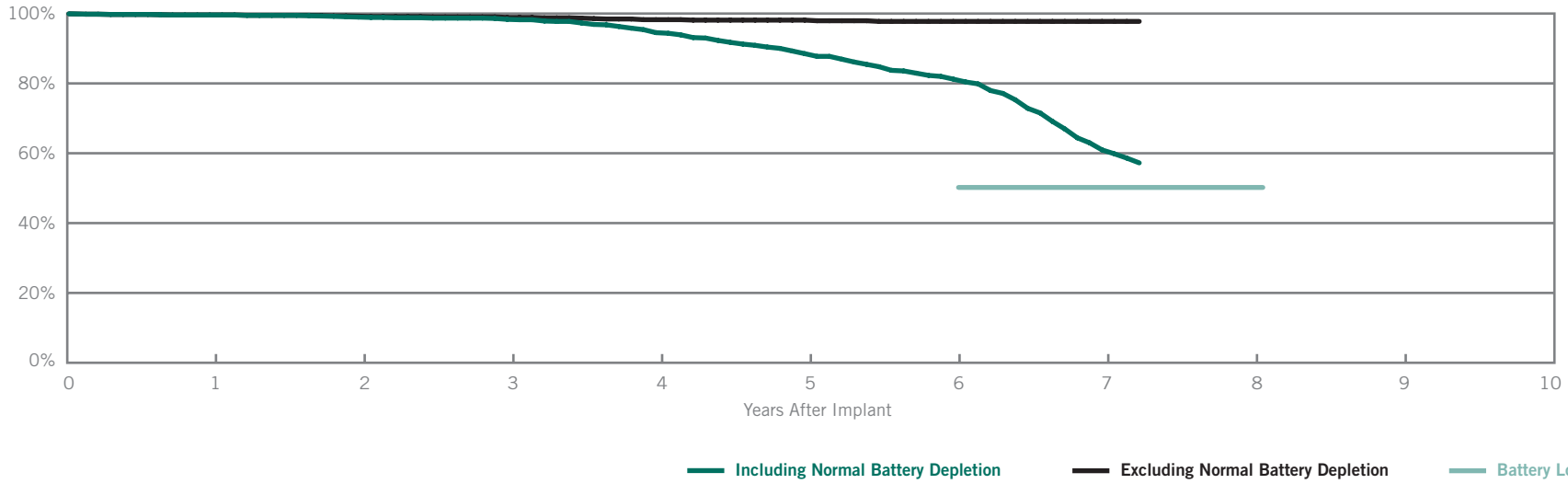
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.62%	99.35%	98.88%	98.17%	97.50%	97.32%	96.92%			
± 1 standard error	0.07%	0.10%	0.14%	0.19%	0.24%	0.26%	0.32%			

Photon™ µ VR (Model V-194)

US Market Release	June 2001	Normal Battery Depletion	193
Registered US Implants	2,838	Malfunctions	23
Estimated Active US Implants	222	Malfunctions w/ Compromised Therapy (5 related to Advisory)	12
Estimated Longevity	(see table on page 94)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	11
Max. Delivered Energy	36 joules	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

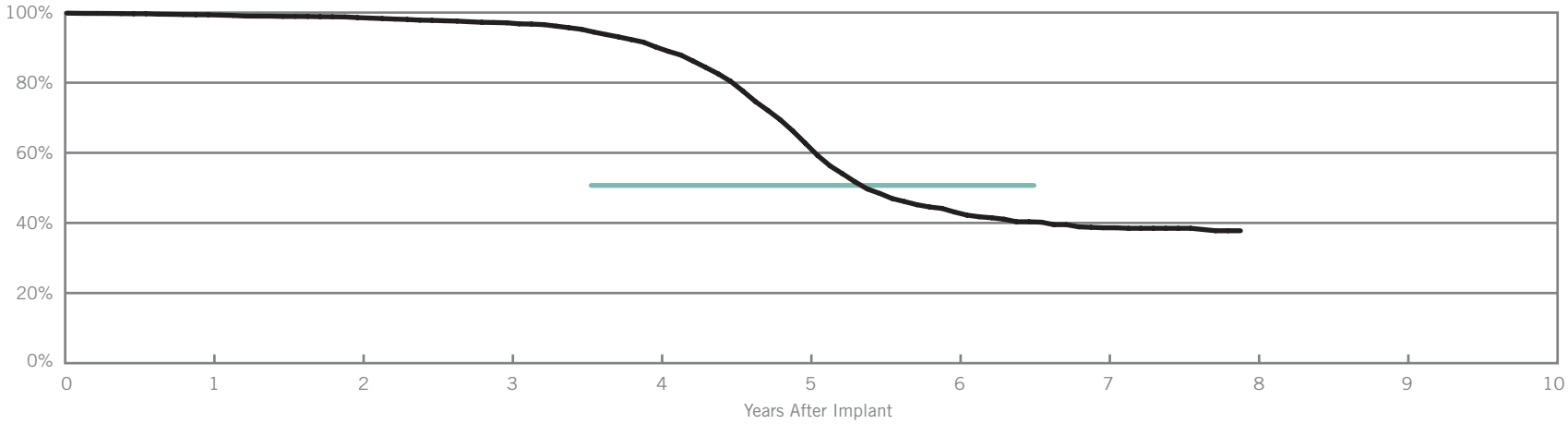
Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.59%	98.99%	98.34%	94.53%	88.52%	81.21%	60.95%	57.24%		
± 1 standard error	0.12%	0.19%	0.24%	0.48%	0.77%	1.03%	1.64%	1.80%		
Sample Size	2800	2500	2200	1900	1500	1200	800	300		

Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.59%	99.25%	98.90%	98.25%	98.12%	97.75%	97.75%	97.75%		
± 1 standard error	0.12%	0.16%	0.20%	0.29%	0.31%	0.36%	0.36%	0.36%		

Contour™ MD (Models V-175, V-175AC, V-175B, V-175C & V-175D)	
US Market Release	October 1998
Registered US Implants	4,923
Estimated Active US Implants	232
Estimated Longevity	(see table on page 94)
Number of Advisories	None

Survival from Returns and Complaints



Year	1	2	3	4	5	6	7	at 95 months		
Survival Probability	99.37%	98.57%	97.08%	90.16%	62.77%	43.11%	38.61%	37.77%		
± 1 standard error	0.11%	0.17%	0.27%	0.50%	0.98%	1.16%	1.24%	1.27%		
Sample Size	4900	4200	3600	2900	2200	1100	400	300		

Summary & Longevity Information

ICDs

Single-Chamber

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ICDs

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
1107-36	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	Curren®t VR RF	8.4	8.0	7.6	5.6
V-168	Atlas® II VR	8.4	8.0	7.6	7.0
V-158	Epic® II VR	6.7	6.4	6.1	5.6
V-193	Atlas® + VR	8.6	8.2	7.9	7.3
V-196	Epic® + VR <115000	6.3	6	5.8	5.4
V-196	Epic® + VR >115000	6.9	6.6	6.4	5.9
V-197	Epic® VR	5.9	5.7	5.5	5.1
V-199	Atlas® VR	7.2	6.9	6.6	6.1
V-194	Photon™µ VR<42000	7.1	6.8	6.5	6.0
V-194	Photon™µ VR>42000	8.1	7.7	7.4	6.8

**Battery longevity calculated with one EGM storage.*
Pacing parameters: VVI, 2.5V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.45; Battery condition: Normal
Four maximum charges per year as well as monthly charging during the batteries mid-life voltage range. (Four maximum charges per year for models V-194 and V-199).

Models	Family	4 Max charges/Yr. No Pacing	1 Maximum High-Voltage Charge/Month†		
			No Pacing	15% Pacing	100% Pacing
V-175, V-175AC, V-175B, V-175C, V-175D	Contour™ MD	6.5 yr.	4.8 yr.	4.4 yr.	3.5 yr.

†Pacing parameters: 5.0V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.55

Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/ Compromised Therapy (under advisory)	Malfunctions w/ Compromised Therapy (premature battery depletion)	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
1107-36	Current® VR	May-07	329	269	1	0	0	0	0	1	0
1207-30	Current® VR RF	Sep-07	606	570	0	0	0	0	0	0	0
1207-36	Current® VR RF	Sep-07	10112	9320	2	0	1	2	1	6	0
V-168	Atlas® II VR	Jul-06	9901	8224	4	0	5	0	4	13	2
V-158	Epic® II VR	Mar-06	1485	1171	0	0	0	0	0	0	0
V-193	Atlas® + VR	Oct-03	20361	13332	7	0	8	2	7	24	18
V-196	Epic® + VR	Apr-03	7938	4686	3	0	2	11	0	16	12
V-197	Epic® VR	Jul-02	3649	1194	4	0	1	18	2	25	40
V-199	Atlas® VR	Dec-01	7086	1188	6	22	6	32	3	69	338
V-194	Photon™ µ VR	Jun-01	2838	222	3	5	4	10	1	23	193

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
1107-36	Current® VR	99.34%									
1207-30	Current® VR RF	100.00%									
1207-36	Current® VR RF	99.84%									
V-168	Atlas® II VR	99.78%	99.69%								
V-158	Epic® II VR	100.00%	100.00%								
V-193	Atlas® + VR	99.88%	99.73%	99.63%	99.45%	99.01%					
V-196	Epic® + VR	99.86%	99.68%	99.56%	99.09%	98.43%					
V-197	Epic® VR	99.89%	99.62%	99.33%	98.02%	96.15%	92.80%				
V-199	Atlas® VR	99.48%	98.72%	97.23%	94.86%	90.56%	78.26%				
V-194	Photon™ µ VR	99.59%	98.99%	98.34%	94.53%	88.52%	81.21%	60.95%			

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
1107-36	Current® VR	99.34%									
1207-30	Current® VR RF	100.00%									
1207-36	Current® VR RF	99.84%									
V-168	Atlas® II VR	99.79%	99.72%								
V-158	Epic® II VR	100.00%	100.00%								
V-193	Atlas® + VR	99.95%	99.85%	99.75%	99.66%	99.38%					
V-196	Epic® + VR	99.92%	99.89%	99.85%	99.47%	99.08%					
V-197	Epic® VR	99.89%	99.62%	99.55%	98.68%	98.09%	98.09%				
V-199	Atlas® VR	99.62%	99.35%	98.88%	98.17%	97.50%	97.32%				
V-194	Photon™ µ VR	99.59%	99.25%	98.90%	98.25%	98.12%	97.75%	97.75%			

Defibrillation Leads

St. Jude Medical™

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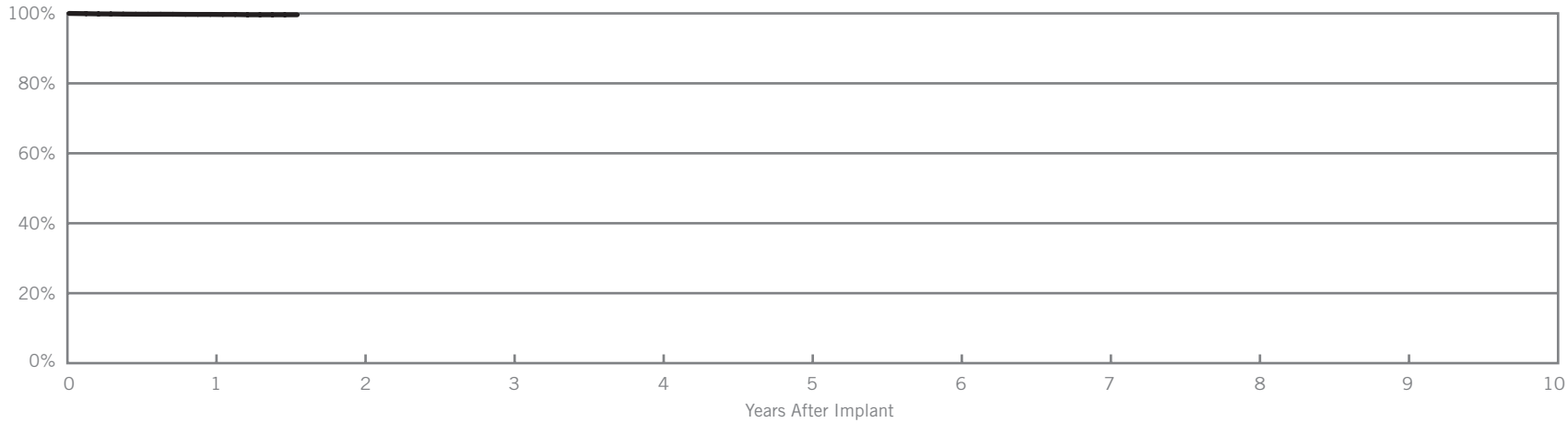
Defibrillation Leads

Durata® (Models 7120 & 7121)	
US Market Release	September 2007
Registered US Implants	31,689
Estimated Active US Implants	30,546
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	11	0.03%	4	0.01%
Conductor Fracture	1	<0.01%	1	<0.01%
Lead Dislodgement	12	0.04%	41	0.13%
Failure to Capture	6	0.02%	21	0.07%
Oversensing	7	0.02%	11	0.03%
Failure to Sense	0	0.00%	4	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	<0.01%	2	0.01%
Abnormal Defibrillation Impedance	0	0.00%	4	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	<0.01%	11	0.03%
Total	**39**	**0.12%**	**99**	**0.31%**
Total Returned for Analysis	**24**		**47**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	1	<0.01%
Other	2	0.01%
Extrinsic Factors	14	0.04%
Total	**17**	**0.05%**

Survival from Returns and Complaints



Year	1	at 19 months								
Survival Probability	99.71%	99.61%								
± 1 standard error	0.04%	0.07%								
Sample Size	19300	200								

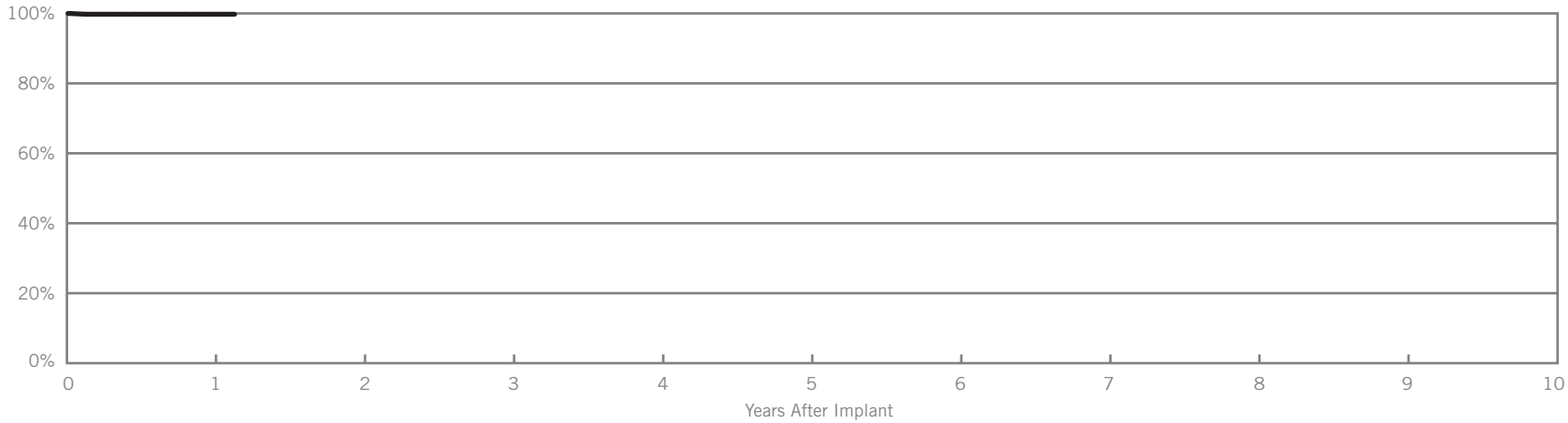
**Optim® insulation is a copolymer of silicone and polyurethane.*

Durata® (Models 7120 & 7121)	
US Market Release	September 2007
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	932
Cumulative Months of Follow-up	7294

Qualifying Complications		
Type	**Qty.**	**Rate**
Failure to Capture	1	0.11%
Extracardiac Stimulation	1	0.11%

Survival from SCORE Registry



Year	1	at 14 months								
Survival Probability	99.76%	99.76%								
± 1 standard error	0.17%	0.17%								
Sample Size	239	95								

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

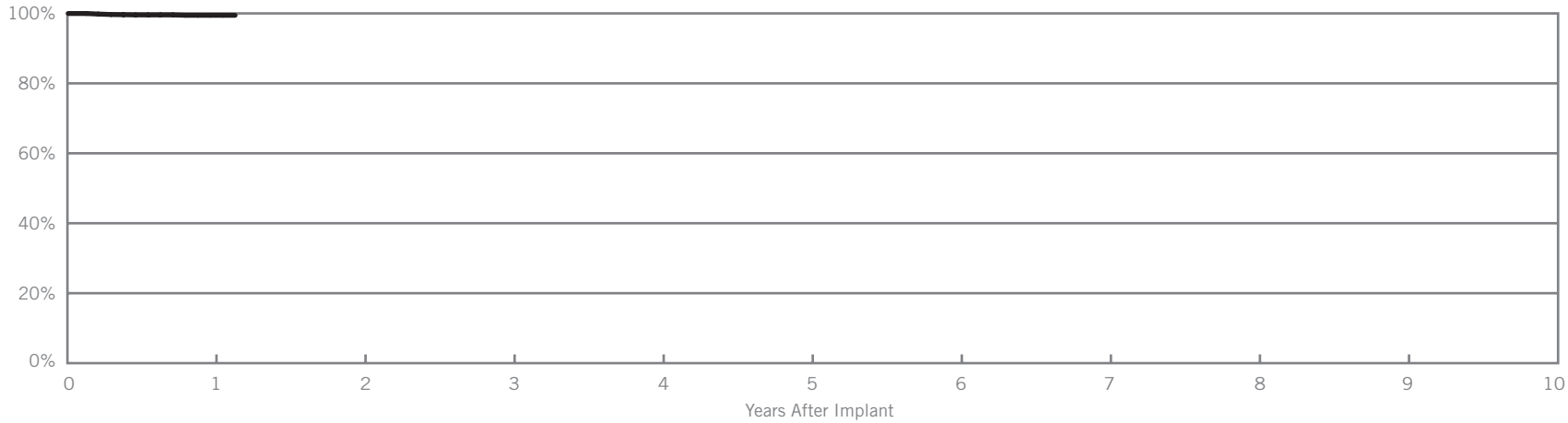
Defibrillation Leads

Durata® (Model 7122)	
US Market Release	September 2007
Registered US Implants	3,265
Estimated Active US Implants	3,138
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	2	0.06%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.06%	8	0.25%
Failure to Capture	2	0.06%	3	0.09%
Oversensing	0	0.00%	2	0.06%
Failure to Sense	0	0.00%	1	0.03%
Insulation Breach	0	0.00%	1	0.03%
Abnormal Pacing Impedance	0	0.00%	3	0.09%
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**	**0.18%**	**18**	**0.55%**
Total Returned for Analysis	**4**		**13**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.03%
Insulation Breach	1	0.03%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.12%
Total	**6**	**0.18%**

Survival from Returns and Complaints



Year	1	at 14 months								
Survival Probability	99.46%	99.46%								
± 1 standard error	0.17%	0.17%								
Sample Size	1900	200								

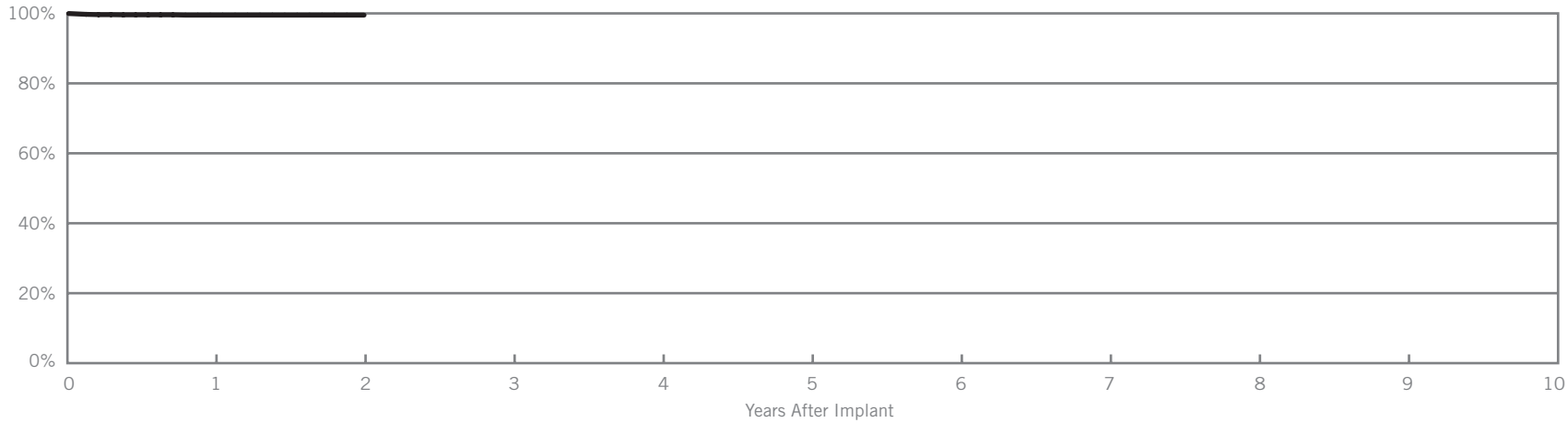
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST Optim® (Models 7070 & 7071)	
US Market Release	July 2006
Registered US Implants	2,437
Estimated Active US Implants	2,255
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	1	0.04%	1	0.04%
Conductor Fracture	1	0.04%	0	0.00%
Lead Dislodgement	1	0.04%	2	0.08%
Failure to Capture	3	0.12%	3	0.12%
Oversensing	0	0.00%	2	0.08%
Failure to Sense	1	0.04%	2	0.08%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**7**	**0.29%**	**10**	**0.41%**
Total Returned for Analysis	**4**		**5**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.04%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	1	0.04%
Other	1	0.04%
Extrinsic Factors	4	0.16%
Total	**7**	**0.29%**

Survival from Returns and Complaints



Year	1	at 24 months								
Survival Probability	99.51%	99.51%								
± 1 standard error	0.16%	0.16%								
Sample Size	1800	100								

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

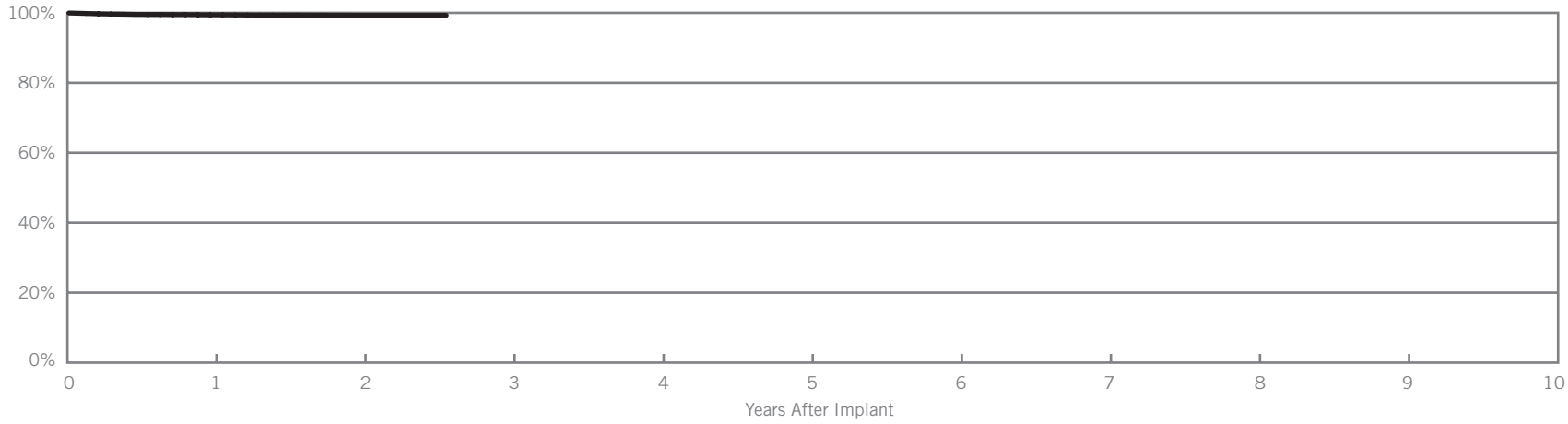
Defibrillation Leads

Riata® ST Optim® (Models 7020 & 7021)	
US Market Release	July 2006
Registered US Implants	14,587
Estimated Active US Implants	12,975
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	18	0.12%	10	0.07%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	19	0.13%	41	0.28%
Failure to Capture	13	0.09%	25	0.17%
Oversensing	9	0.06%	25	0.17%
Failure to Sense	1	0.01%	10	0.07%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	0	0.00%	2	0.01%
Abnormal Defibrillation Impedance	0	0.00%	3	0.02%
Extracardiac Stimulation	2	0.01%	0	0.00%
Other	2	0.01%	9	0.06%
Total	**64**	**0.44%**	**127**	**0.87%**
Total Returned for Analysis	**52**		**89**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	3	0.02%
Insulation Breach	4	0.03%
Crimps, Welds & Bonds	1	0.01%
Other	1	0.01%
Extrinsic Factors	37	0.25%
Total	**46**	**0.32%**

Survival from Returns and Complaints



Year	1	2	at 31 months							
Survival Probability	99.44%	99.29%	99.29%							
± 1 standard error	0.06%	0.08%	0.08%							
Sample Size	13300	7200	100							

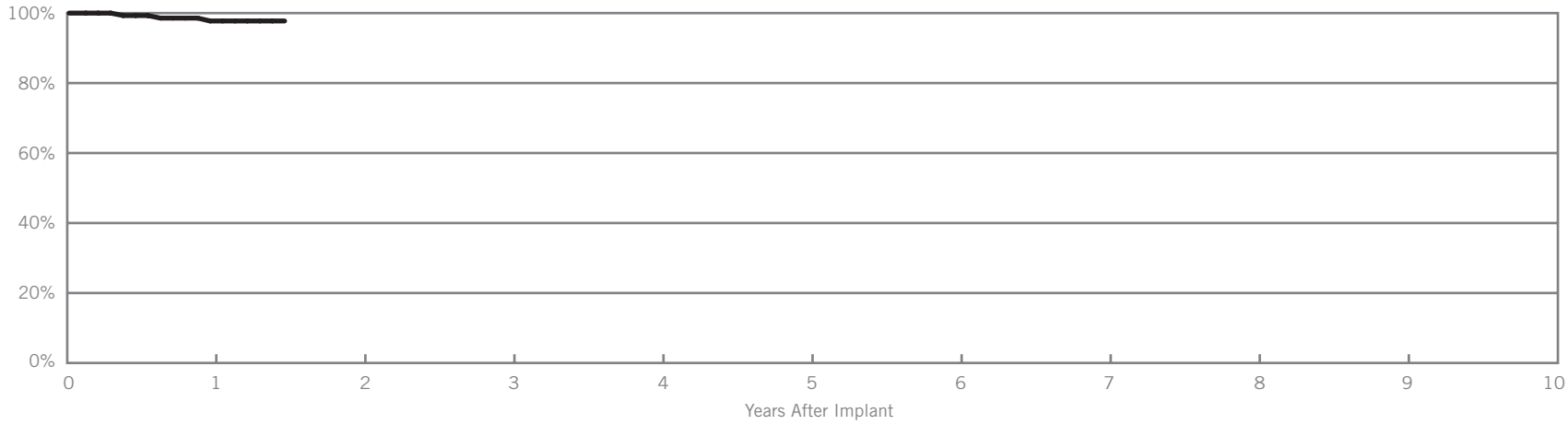
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST Optim® (Models 7020 & 7021)	
US Market Release	July 2006
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	163
Cumulative Months of Follow-up	2256

Qualifying Complications		
Type	**Qty.**	**Rate**
Cardiac Perforation	1	0.61%
Conductor Fracture	1	0.61%
Failure to Sense	1	0.61%

Survival from SCORE Registry



Year	1	at 18 months								
Survival Probability	97.75%	97.75%								
± 1 standard error	1.00%	1.29%								
Sample Size	120	51								

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

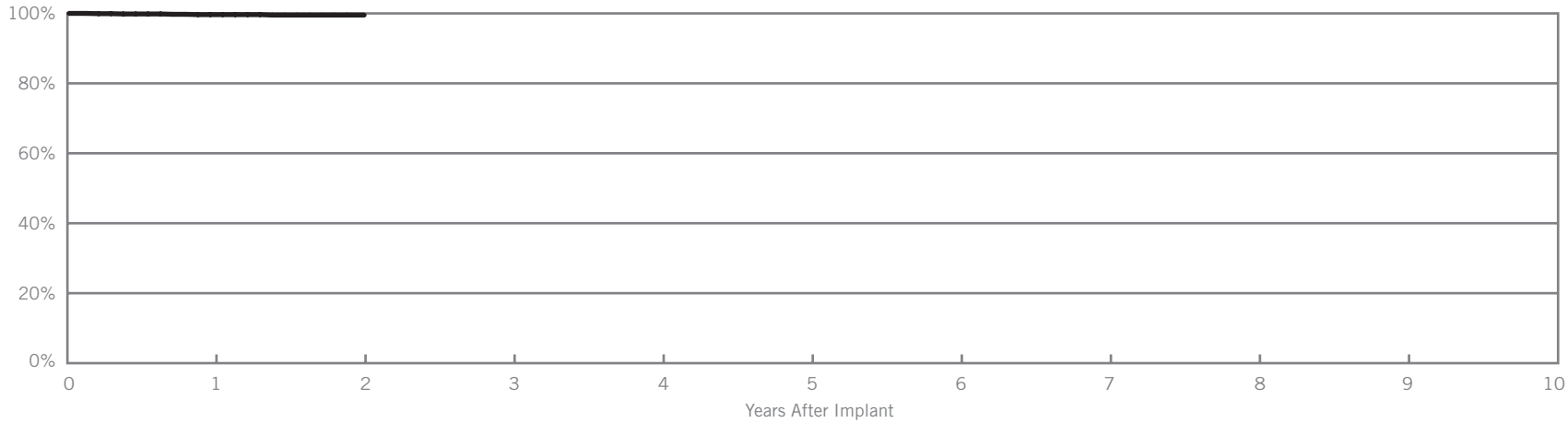
Defibrillation Leads

Riata® ST Optim® (Model 7022)	
US Market Release	July 2006
Registered US Implants	1,356
Estimated Active US Implants	1,237
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	2	0.15%	1	0.07%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.15%	5	0.37%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	2	0.15%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**4**	**0.29%**	**8**	**0.59%**
Total Returned for Analysis	**3**		**4**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.07%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	1	0.07%
Extrinsic Factors	0	0.00%
Total	**2**	**0.15%**

Survival from Returns and Complaints



Year	1	2								
Survival Probability	99.65%	99.52%								
± 1 standard error	0.18%	0.22%								
Sample Size	1200	100								

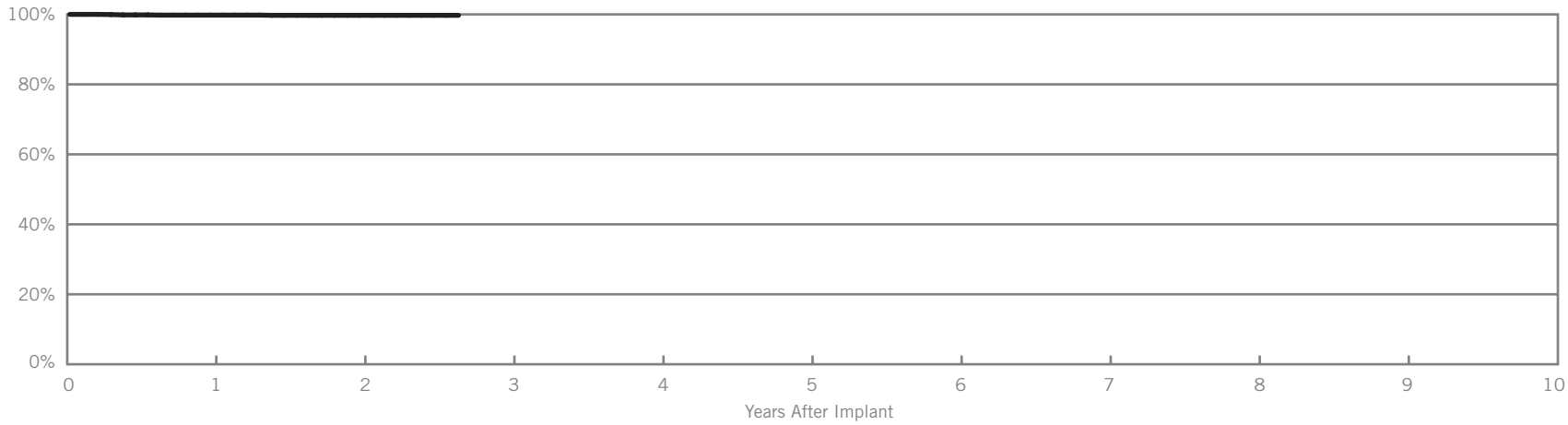
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST (Models 7010 & 7011)	
US Market Release	March 2006
Registered US Implants	2,147
Estimated Active US Implants	1,871
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	1	0.05%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	0	0.00%	4	0.19%
Failure to Capture	3	0.14%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	1	0.05%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.05%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	1	0.05%
Total	**5**	**0.23%**	**8**	**0.37%**
Total Returned for Analysis	**4**		**4**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	1	0.05%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	**1**	**0.05%**

Survival from Returns and Complaints



Year	1	2	at 32 months							
Survival Probability	99.79%	99.73%	99.73%							
± 1 standard error	0.10%	0.12%	0.12%							
Sample Size	2000	1400	100							

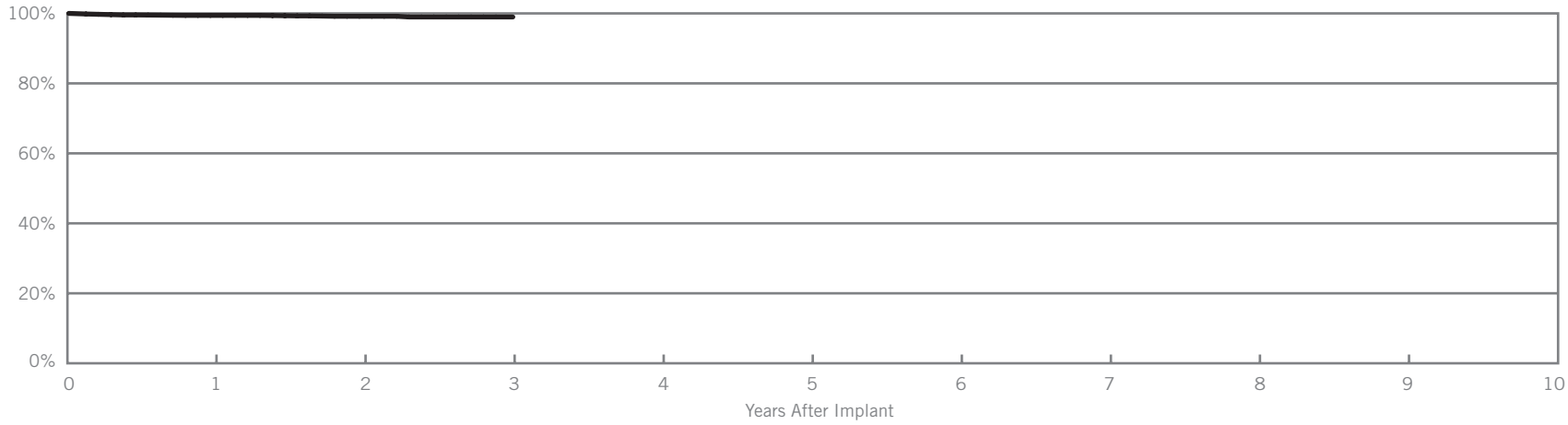
Defibrillation Leads

Riata® ST (Models 7040 & 7041)	
US Market Release	March 2006
Registered US Implants	3,741
Estimated Active US Implants	3,310
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	4	0.11%	1	0.03%
Conductor Fracture	0	0.00%	2	0.05%
Lead Dislodgement	2	0.05%	3	0.08%
Failure to Capture	0	0.00%	4	0.11%
Oversensing	0	0.00%	8	0.21%
Failure to Sense	0	0.00%	2	0.05%
Insulation Breach	0	0.00%	1	0.03%
Abnormal Pacing Impedance	0	0.00%	3	0.08%
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	**6**	**0.16%**	**25**	**0.67%**
Total Returned for Analysis	**2**		**8**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.03%
Insulation Breach	3	0.08%
Crimps, Welds & Bonds	0	0.00%
Other	2	0.05%
Extrinsic Factors	5	0.13%
Total	**11**	**0.29%**

Survival from Returns and Complaints



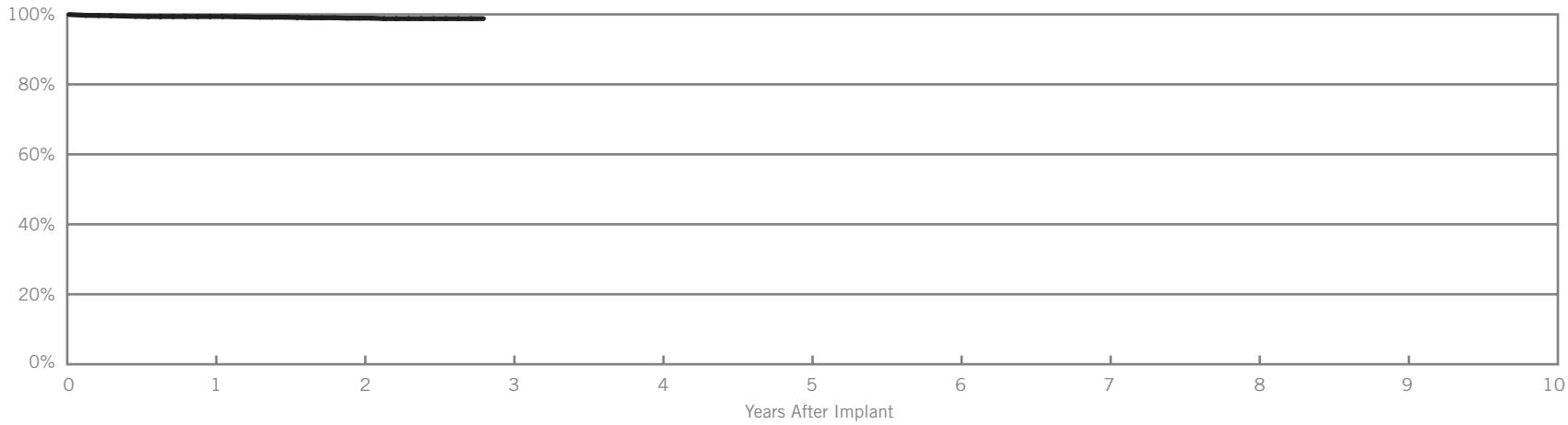
Year	1	2	3							
Survival Probability	99.43%	99.18%	98.98%							
± 1 standard error	0.13%	0.17%	0.22%							
Sample Size	3300	2100	800							

Riata® ST (Model 7002)	
US Market Release	June 2005
Registered US Implants	2,298
Estimated Active US Implants	2,034
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	3	0.13%	3	0.13%
Conductor Fracture	0	0.00%	1	0.04%
Lead Dislodgement	1	0.04%	7	0.30%
Failure to Capture	2	0.09%	4	0.17%
Oversensing	0	0.00%	8	0.35%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.04%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	1	0.04%
Total	**8**	**0.35%**	**24**	**1.04%**
Total Returned for Analysis	**4**		**11**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	2	0.09%
Insulation Breach	1	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.17%
Total	**7**	**0.30%**

Survival from Returns and Complaints



Year	1	2	at 34 months							
Survival Probability	99.39%	98.93%	98.79%							
± 1 standard error	0.17%	0.25%	0.29%							
Sample Size	2100	1300	100							

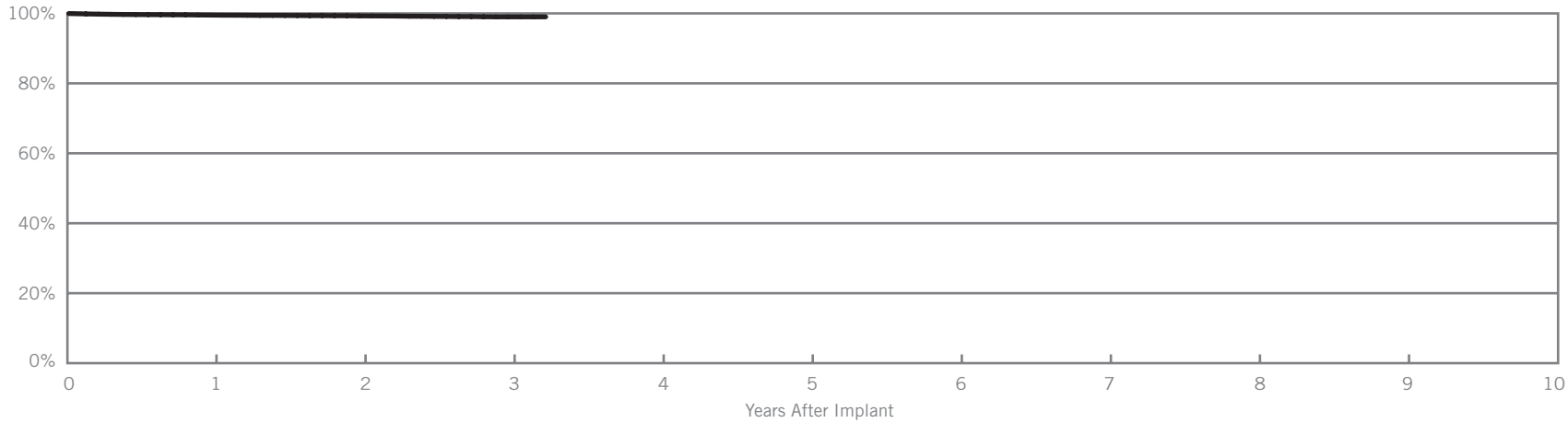
Defibrillation Leads

Riata® ST (Models 7000 & 7001)	
US Market Release	June 2005
Registered US Implants	33,861
Estimated Active US Implants	28,937
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	19	0.06%	20	0.06%
Conductor Fracture	0	0.00%	8	0.02%
Lead Dislodgement	27	0.08%	36	0.11%
Failure to Capture	34	0.10%	50	0.15%
Oversensing	8	0.02%	97	0.29%
Failure to Sense	2	0.01%	12	0.04%
Insulation Breach	0	0.00%	7	0.02%
Abnormal Pacing Impedance	2	0.01%	8	0.02%
Abnormal Defibrillation Impedance	1	<0.01%	8	0.02%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	6	0.02%	20	0.06%
Total	**103**	**0.30%**	**268**	**0.79%**
Total Returned for Analysis	**88**		**147**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	7	0.02%
Insulation Breach	41	0.12%
Crimps, Welds & Bonds	4	0.01%
Other	0	0.00%
Extrinsic Factors	54	0.16%
Total	**106**	**0.31%**

Survival from Returns and Complaints



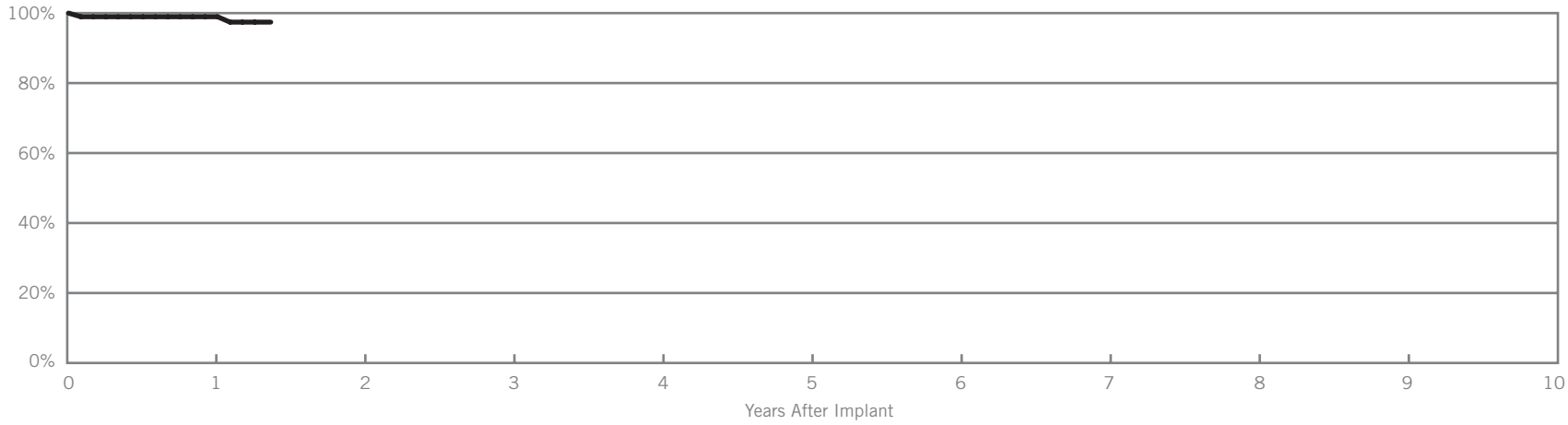
Year	1	2	3	at 39 months						
Survival Probability	99.52%	99.30%	99.02%	99.02%						
± 1 standard error	0.04%	0.05%	0.08%	0.08%						
Sample Size	31700	23100	10000	300						

Riata® ST (Models 7000 & 7001)	
US Market Release	June 2005
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	109
Cumulative Months of Follow-up	1474

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.92%
Oversensing	1	0.92%

Survival from SCORE Registry



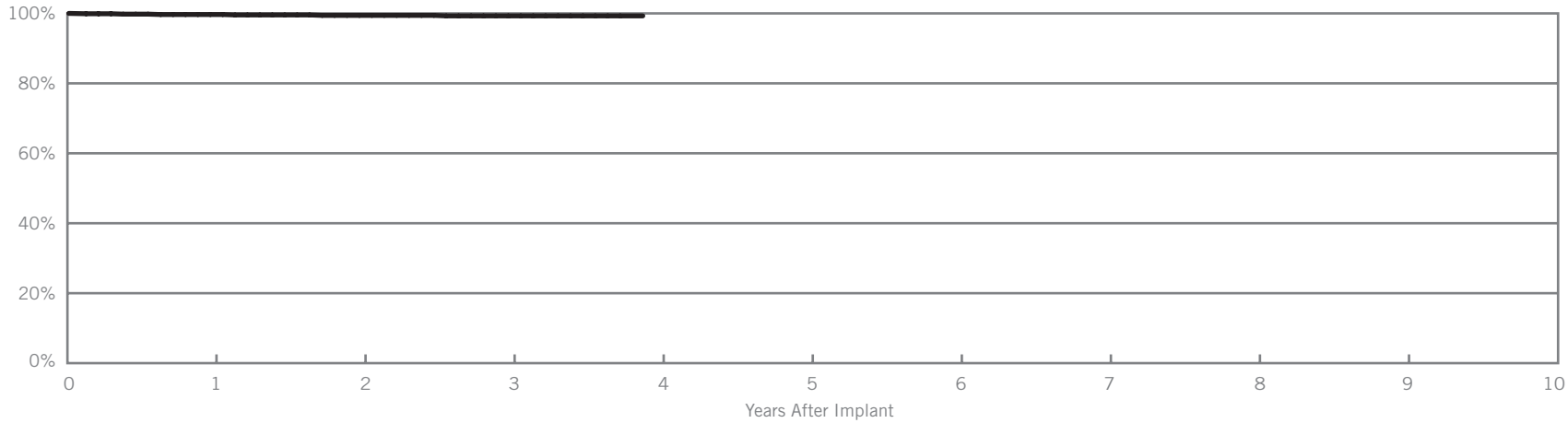
Year	1	at 17 months								
Survival Probability	98.96%	97.42%								
± 1 standard error	1.04%	1.83%								
Sample Size	77	50								

Defibrillation Leads

Riata® *i* (Models 1560 & 1561)	
US Market Release	April 2004
Registered US Implants	1,001
Estimated Active US Implants	758
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of Advisories	None

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

Survival from Returns and Complaints

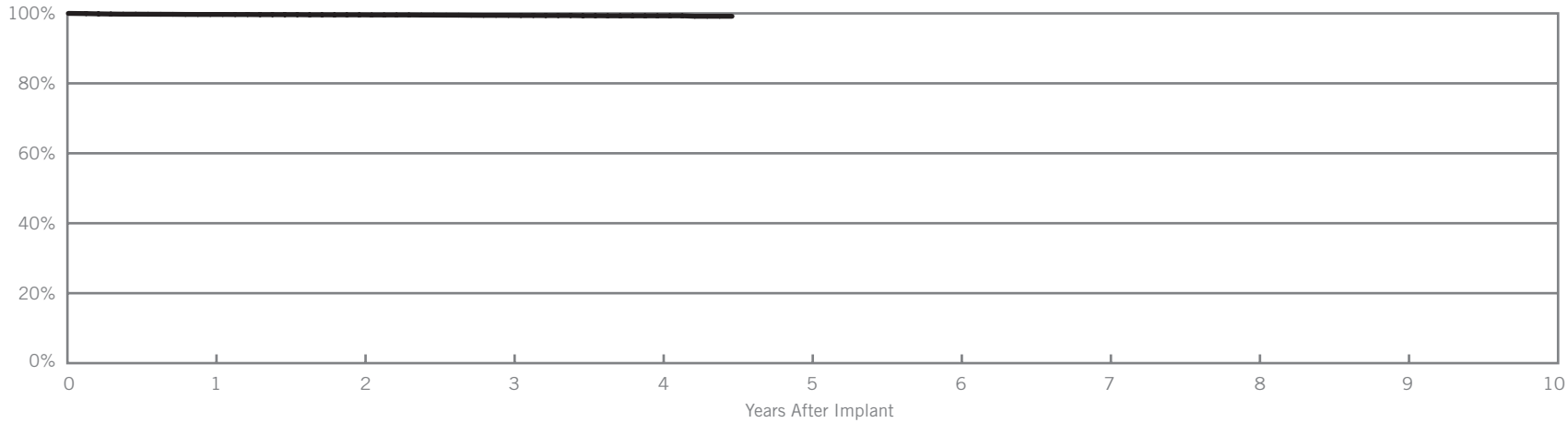


Year	1	2	3	at 46 months						
Survival Probability	99.68%	99.43%	99.29%	99.29%						
± 1 standard error	0.19%	0.25%	0.29%	0.29%						
Sample Size	1000	900	700	100						

Riata® *i* (Models 1590 & 1591)	
US Market Release	April 2004
Registered US Implants	9,667
Estimated Active US Implants	7,351
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of Advisories	None

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	3	0.03%
Insulation Breach	6	0.06%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	11	0.11%
Total	**20**	**0.21%**

Survival from Returns and Complaints



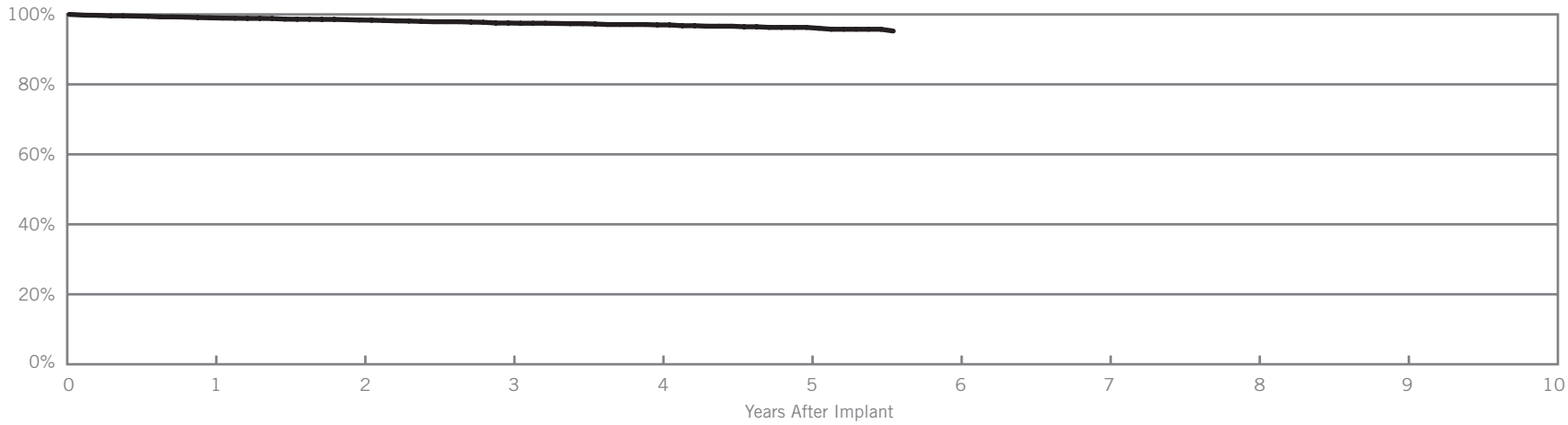
Year	1	2	3	4	at 54 months					
Survival Probability	99.70%	99.59%	99.43%	99.31%	99.18%					
± 1 standard error	0.06%	0.07%	0.08%	0.10%	0.17%					
Sample Size	9500	8200	6800	3800	100					

Defibrillation Leads

Riata® (Model 1582)	
US Market Release	March 2003
Registered US Implants	3,084
Estimated Active US Implants	2,192
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	2	0.06%
Insulation Breach	23	0.75%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	11	0.36%
Total	**36**	**1.17%**

Survival from Returns and Complaints

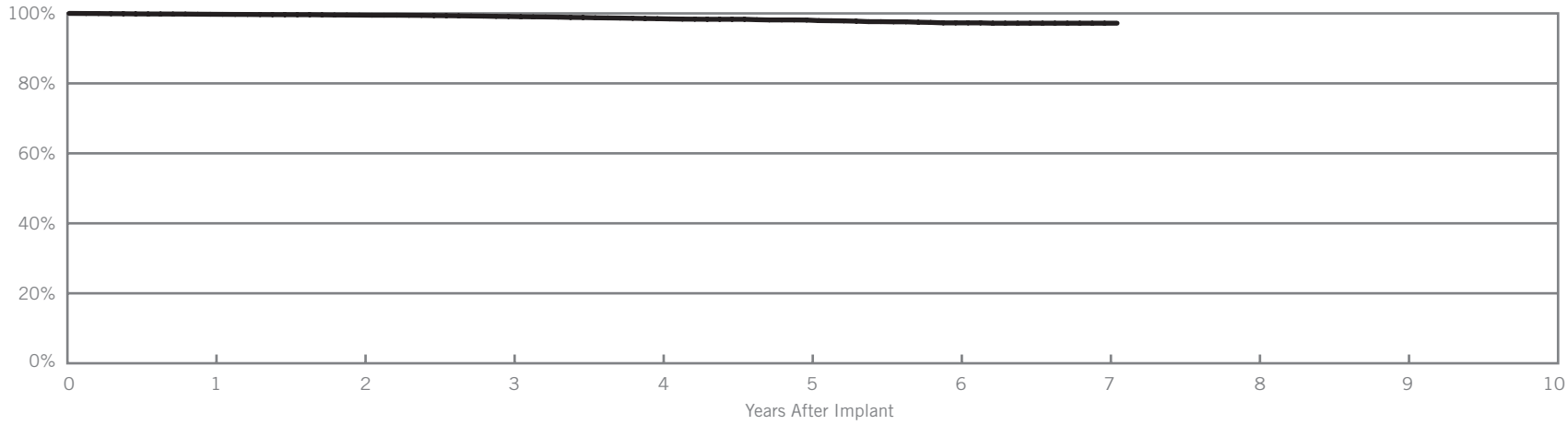


Year	1	2	3	4	5	at 67 months				
Survival Probability	99.02%	98.39%	97.53%	96.99%	96.28%	95.24%				
± 1 standard error	0.18%	0.24%	0.32%	0.37%	0.50%	0.62%				
Sample Size	2900	2400	2000	1400	700	100				

Riata® (Models 1570 & 1571)	
US Market Release	March 2002
Registered US Implants	10,206
Estimated Active US Implants	7,047
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	3	0.03%
Insulation Breach	16	0.16%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.14%
Total	**33**	**0.32%**

Survival from Returns and Complaints



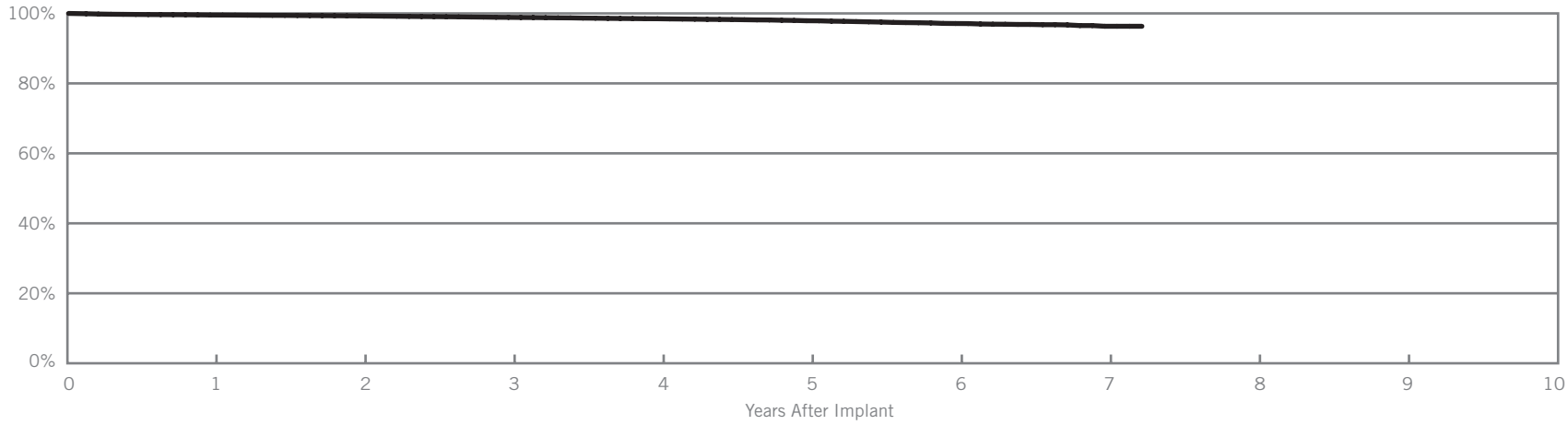
Year	1	2	3	4	5	6	7	at 85 months		
Survival Probability	99.75%	99.51%	99.12%	98.49%	98.10%	97.29%	97.20%	97.20%		
± 1 standard error	0.05%	0.07%	0.11%	0.15%	0.18%	0.27%	0.28%	0.28%		
Sample Size	9700	8300	7000	5400	3600	2100	800	100		

Defibrillation Leads

Riata® (Models 1580 & 1581)	
US Market Release	March 2002
Registered US Implants	68,256
Estimated Active US Implants	47,872
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	11	0.02%
Insulation Breach	165	0.24%
Crimps, Welds & Bonds	4	0.01%
Other	3	<0.01%
Extrinsic Factors	155	0.23%
Total	**338**	**0.50%**

Survival from Returns and Complaints



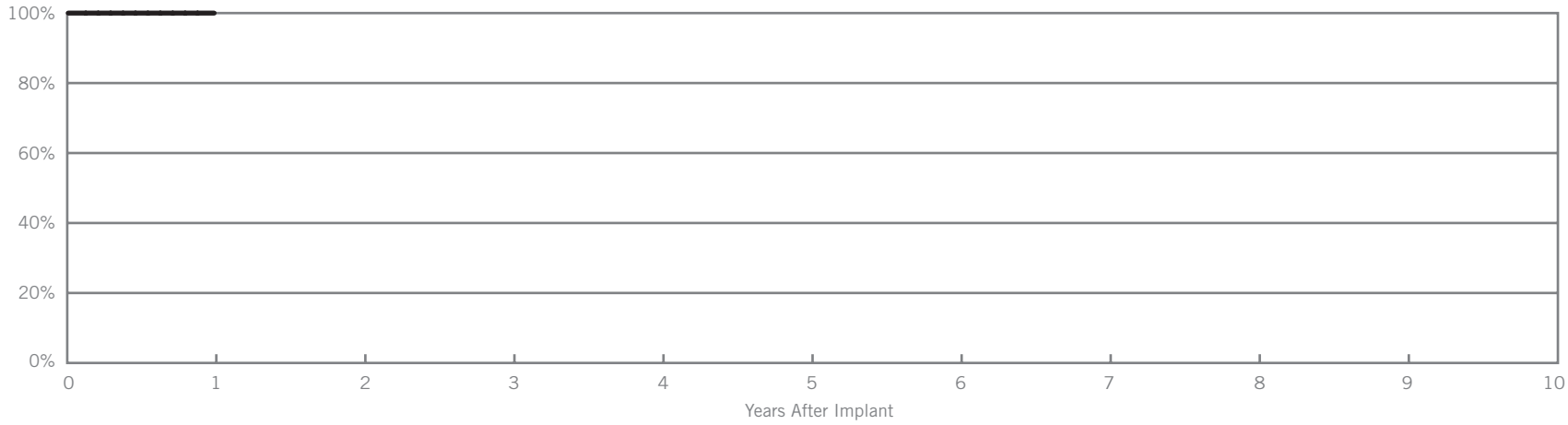
Year	1	2	3	4	5	6	7	at 87 months		
Survival Probability	99.54%	99.29%	98.87%	98.47%	97.90%	97.11%	96.32%	96.32%		
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.08%	0.12%	0.20%	0.25%		
Sample Size	66200	56800	48700	35500	19800	9300	3200	100		

Riata® (Models 1580 & 1581)	
US Market Release	March 2002
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	114
Cumulative Months of Follow-up	1175

Qualifying Complications
None Reported

Survival from SCORE Registry

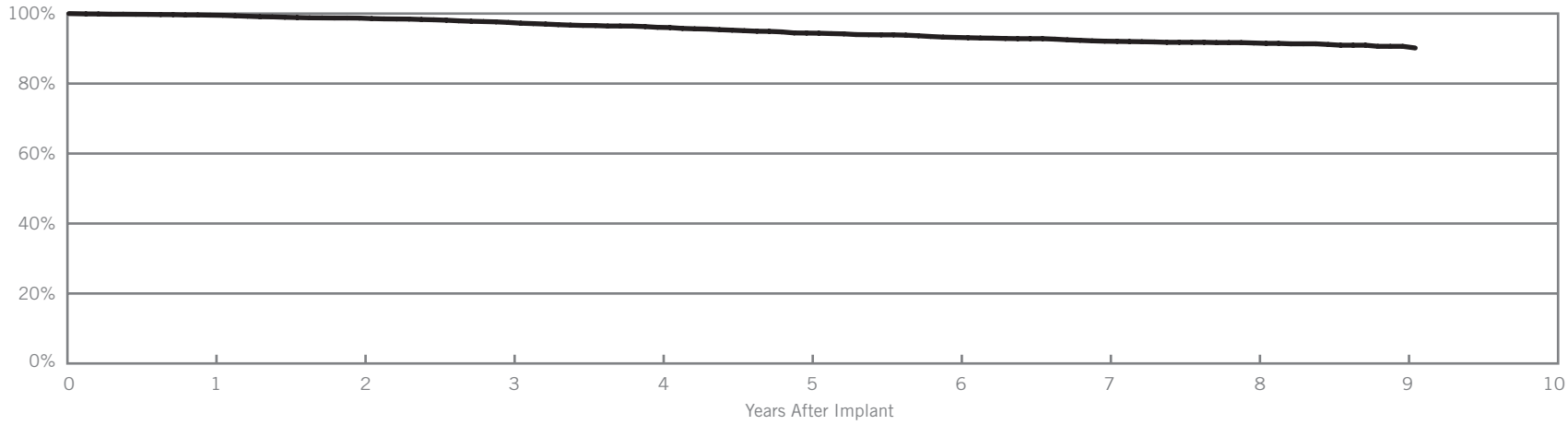


Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	52									

Defibrillation Leads

TVL™ ADX (Model 1559)	
US Market Release	November 1999
Registered US Implants	4,728
Estimated Active US Implants	1,861
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

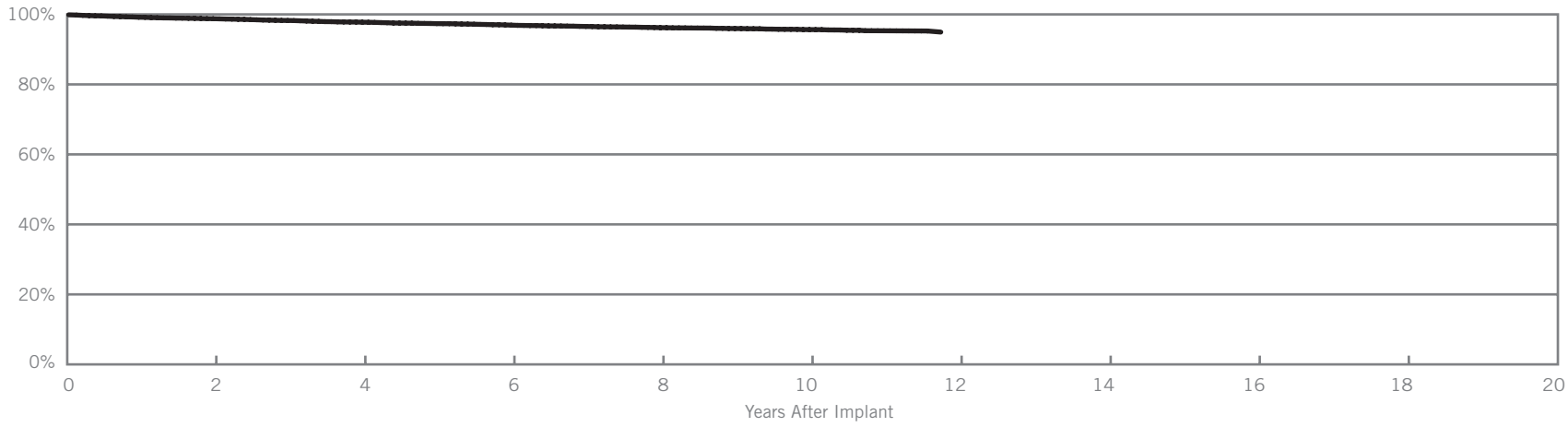
Survival from Returns and Complaints



Year	1	2	3	4	5	6	7	8	9	at 109 months
Survival Probability	99.55%	98.71%	97.47%	96.07%	94.43%	93.19%	92.11%	91.60%	90.64%	90.17%
± 1 standard error	0.09%	0.18%	0.25%	0.32%	0.41%	0.46%	0.50%	0.53%	0.70%	0.70%
Sample Size	4500	4000	3600	3100	2800	2400	2100	1400	500	100

SPL® (Models SP01, SP02, SP03 & SP04)	
US Market Release	September 1997
Registered US Implants	12,899
Estimated Active US Implants	5,031
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Survival from Returns and Complaints



Year	2	4	6	8	10	at 141 months				
Survival Probability	99.09%	98.28%	97.64%	97.11%	96.76%	96.03%				
± 1 standard error	0.09%	0.13%	0.16%	0.18%	0.22%	0.26%				
Sample Size	10900	9000	7200	5200	2400	100				

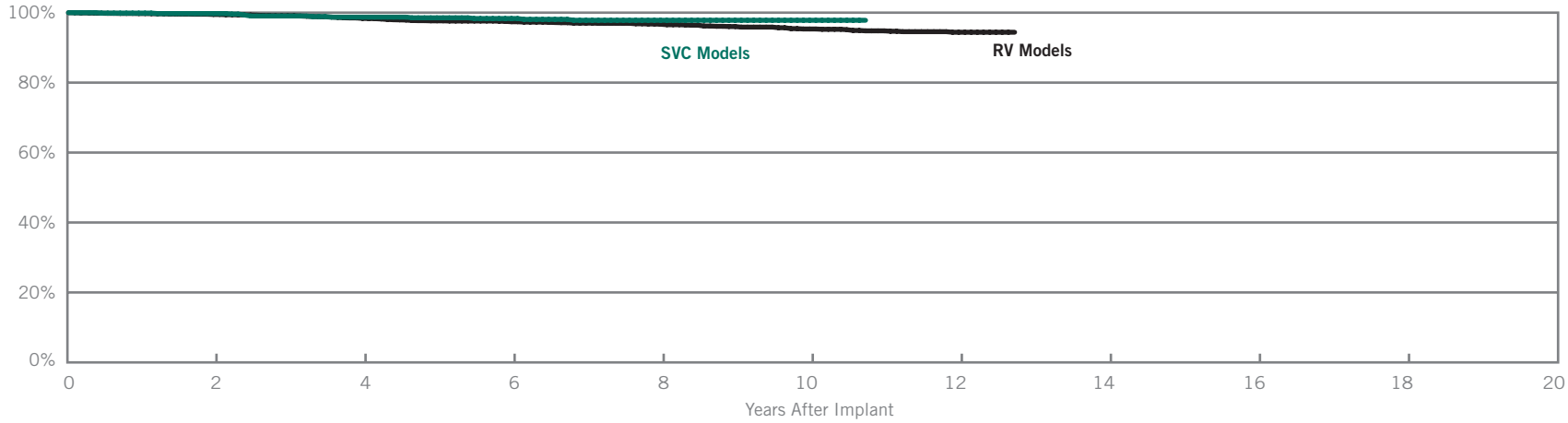
TVL™ RV (Models RV01, RV02, RV03, RV06 & RV07)
TVL™ SVC (Models SV01, SV02 & SV03)

US Market Release	
RV01, RV02, SV01, SV02, SV03	May 1996
RV03	April 1997
RV06, RV07	July 2000

Registered US Implants		Estimated Active US Implants	
RV	3,709	RV	1,069
SVC	977	SVC	255

Insulation	Silicone
Type and/or Fixation	Single Coil, Passive
Polarity	Bipolar
Steroid	No
Number of Advisories	None

Survival from Returns and Complaints



RV Models

Year	2	4	6	8	10	12	at 153 months			
Survival Probability	99.48%	98.36%	97.40%	96.69%	95.33%	94.40%	94.40%			
± 1 standard error	0.12%	0.23%	0.31%	0.37%	0.50%	0.59%	0.59%			
Sample Size	3200	2600	2100	1600	1200	700	100			

SVC Models

Year	2	4	6	8	10	at 129 months				
Survival Probability	99.75%	98.72%	98.32%	97.82%	97.82%	97.82%				
± 1 standard error	0.18%	0.43%	0.51%	0.62%	0.62%	0.62%				
Sample Size	800	600	500	400	200	100				

Observations, Complications, and Malfunctions

Defibrillation Leads

St. Jude Medical™

More control. Less risk.

Defibrillation Leads

Acute Observations (Post Implant, ≤30 days)

Models	US Market Release Date	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	
7120/7121	Sep-07	31689	30546	11	0.03%	1	<0.01%	12	0.04%	6	0.02%	7	0.02%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	0	0.00%	1	<0.01%	**39**	**0.12%**	**24**
7122	Sep-07	3265	3138	2	0.06%	0	0.00%	2	0.06%	2	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**6**	**0.18%**	**4**
7070/7071	Jul-06	2437	2255	1	0.04%	1	0.04%	1	0.04%	3	0.12%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**7**	**0.29%**	**4**
7020/7021	Jul-06	14587	12975	18	0.12%	0	0.00%	19	0.13%	13	0.09%	9	0.06%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	2	0.01%	**64**	**0.44%**	**52**
7022	Jul-06	1356	1237	2	0.15%	0	0.00%	2	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.29%**	**3**
7010/7011	Mar-06	2147	1871	1	0.05%	0	0.00%	0	0.00%	3	0.14%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.05%	**5**	**0.23%**	**4**
7040/7041	Mar-06	3741	3310	4	0.11%	0	0.00%	2	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%	**6**	**0.16%**	**2**
7002	Jun-05	2298	2034	3	0.13%	0	0.00%	1	0.04%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	1	0.04%	**8**	**0.35%**	**4**
7000/7001	Jun-05	33861	28937	19	0.06%	0	0.00%	27	0.08%	34	0.10%	8	0.02%	2	0.01%	0	0.00%	2	0.01%	1	<0.01%	4	0.01%	6	0.02%	**103**	**0.30%**	**88**

Chronic Complications (>30 days)

Models	US Market Release Date	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	
7120/7121	Sep-07	31689	30546	4	0.01%	1	<0.01%	41	0.13%	21	0.07%	11	0.03%	4	0.01%	0	0.00%	2	0.01%	4	0.01%	0	0.00%	11	0.03%	**99**	**0.31%**	**47**
7122	Sep-07	3265	3138	0	0.00%	0	0.00%	8	0.25%	3	0.09%	2	0.06%	1	0.03%	1	0.03%	3	0.09%	0	0.00%	0	0.00%	0	0.00%	**18**	**0.55%**	**13**
7070/7071	Jul-06	2437	2255	1	0.04%	0	0.00%	2	0.08%	3	0.12%	2	0.08%	2	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.41%**	**5**
7020/7021	Jul-06	14587	12975	10	0.07%	0	0.00%	41	0.28%	25	0.17%	25	0.17%	10	0.07%	2	0.01%	2	0.01%	3	0.02%	0	0.00%	9	0.06%	**127**	**0.87%**	**89**
7022	Jul-06	1356	1237	1	0.07%	0	0.00%	5	0.37%	0	0.00%	2	0.15%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**8**	**0.59%**	**4**
7010/7011	Mar-06	2147	1871	1	0.05%	0	0.00%	4	0.19%	0	0.00%	0	0.00%	1	0.05%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	**8**	**0.37%**	**4**
7040/7041	Mar-06	3741	3310	1	0.03%	2	0.05%	3	0.08%	4	0.11%	8	0.21%	2	0.05%	1	0.03%	3	0.08%	1	0.03%	0	0.00%	0	0.00%	**25**	**0.67%**	**8**
7002	Jun-05	2298	2034	3	0.13%	1	0.04%	7	0.30%	4	0.17%	8	0.35%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	**24**	**1.04%**	**11**
7000/7001	Jun-05	33861	28937	20	0.06%	8	0.02%	36	0.11%	50	0.15%	97	0.29%	12	0.04%	7	0.02%	8	0.02%	8	0.02%	2	0.01%	20	0.06%	**268**	**0.79%**	**147**

Definitions of observations and complications can be found on pages 5 and 6.

Lead Malfunctions

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120/7121	Sep-07	31689	30546	0	0.00%	0	0.00%	1	<0.01%	2	0.01%	14	0.04%	**17**	**0.05%**
7122	Sep-07	3265	3138	1	0.03%	1	0.03%	0	0.00%	0	0.00%	4	0.12%	**6**	**0.18%**
7070/7071	Jul-06	2437	2255	1	0.04%	0	0.00%	1	0.04%	1	0.04%	4	0.16%	**7**	**0.29%**
7020/7021	Jul-06	14587	12975	3	0.02%	4	0.03%	1	0.01%	1	0.01%	37	0.25%	**46**	**0.32%**
7022	Jul-06	1356	1237	1	0.07%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	**2**	**0.15%**
7010/7011	Mar-06	2147	1871	0	0.00%	1	0.05%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.05%**
7040/7041	Mar-06	3741	3310	1	0.03%	3	0.08%	0	0.00%	2	0.05%	5	0.13%	**11**	**0.29%**
7002	Jun-05	2298	2034	2	0.09%	1	0.04%	0	0.00%	0	0.00%	4	0.17%	**7**	**0.30%**
7000/7001	Jun-05	33861	28937	7	0.02%	41	0.12%	4	0.01%	0	0.00%	54	0.16%	**106**	**0.31%**
1560/1561	Apr-04	1001	758	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**
1590/1591	Apr-04	9667	7351	3	0.03%	6	0.06%	0	0.00%	0	0.00%	11	0.11%	**20**	**0.21%**
1582	Mar-03	3084	2192	2	0.06%	23	0.75%	0	0.00%	0	0.00%	11	0.36%	**36**	**1.17%**
1570/1571	Mar-02	10206	7047	3	0.03%	16	0.16%	0	0.00%	0	0.00%	14	0.14%	**33**	**0.32%**
1580/1581	Mar-02	68256	47872	11	0.02%	165	0.24%	4	0.01%	3	<0.01%	155	0.23%	**338**	**0.50%**

Definitions of malfunction categories can be found on page 7.

Pulse Generators

Dual-Chamber

St. Jude Medical

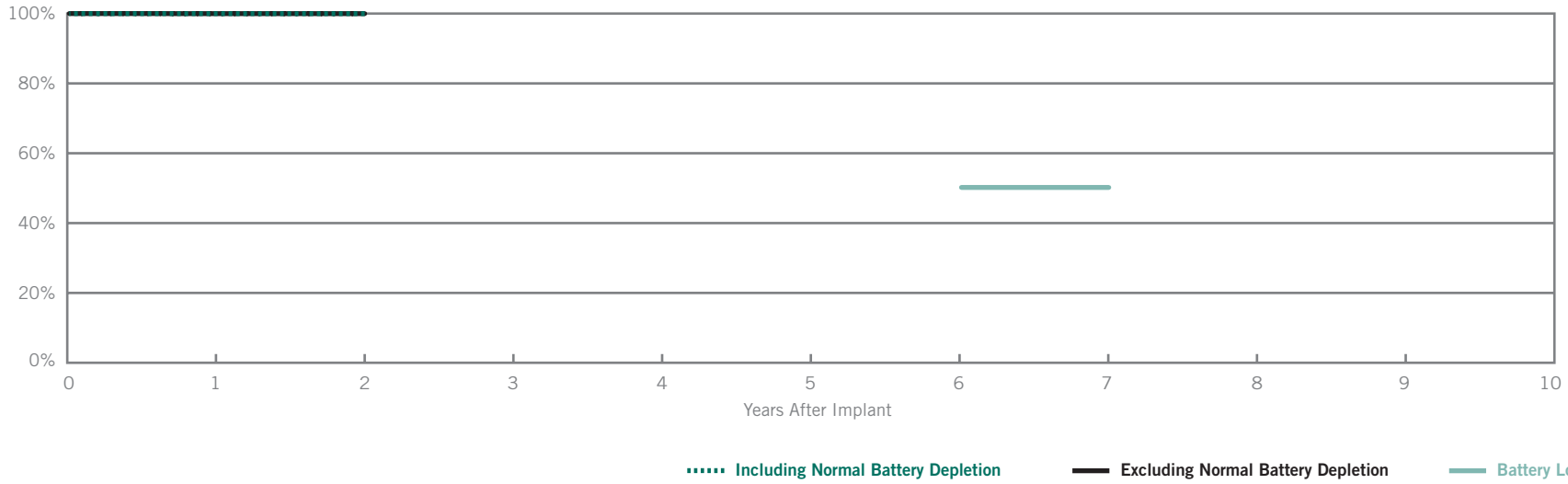
More control. Less risk.

Pulse Generators

Zephyr® DR (Model 5820)

US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	19,268	Malfunctions	1
Estimated Active US Implants	18,317	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2								
Survival Probability	99.98%	99.98%								
± 1 standard error	0.01%	0.01%								
Sample Size	13400	3600								

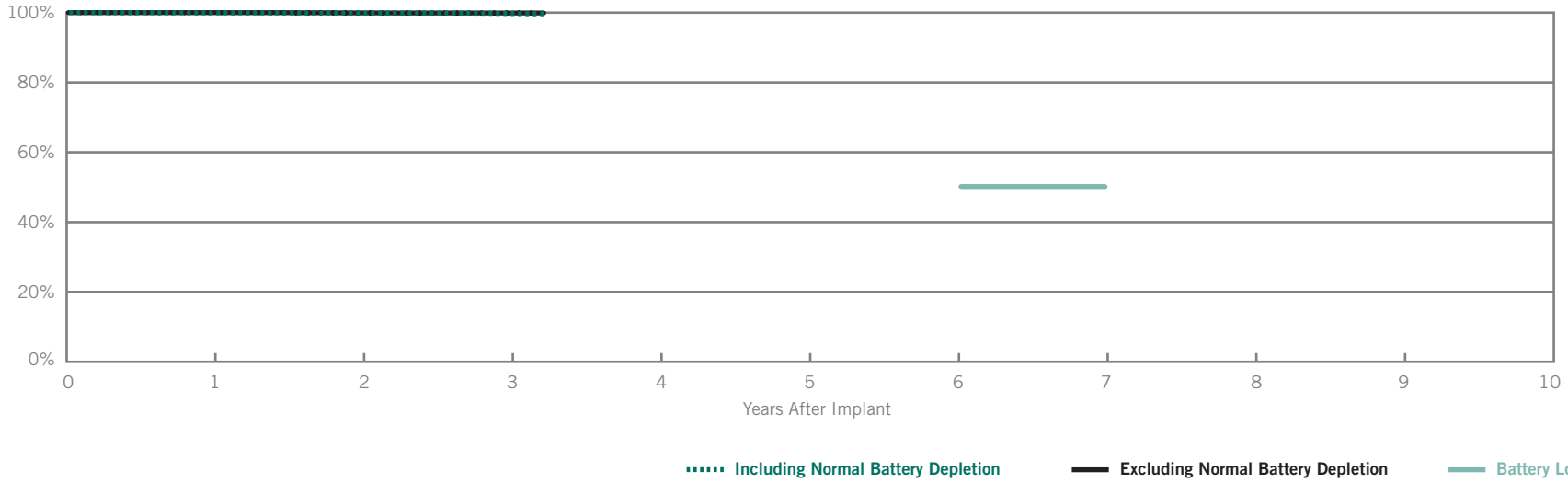
Excluding Normal Battery Depletion

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

Victory® DR (Model 5810)

US Market Release	December 2005	Normal Battery Depletion	5
Registered US Implants	24,334	Malfunctions	7
Estimated Active US Implants	20,732	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	7
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	at 39 months						
Survival Probability	100.00%	99.92%	99.66%	99.66%						
± 1 standard error	0.00%	0.02%	0.06%	0.10%						
Sample Size	22600	15700	6800	4800						

Excluding Normal Battery Depletion

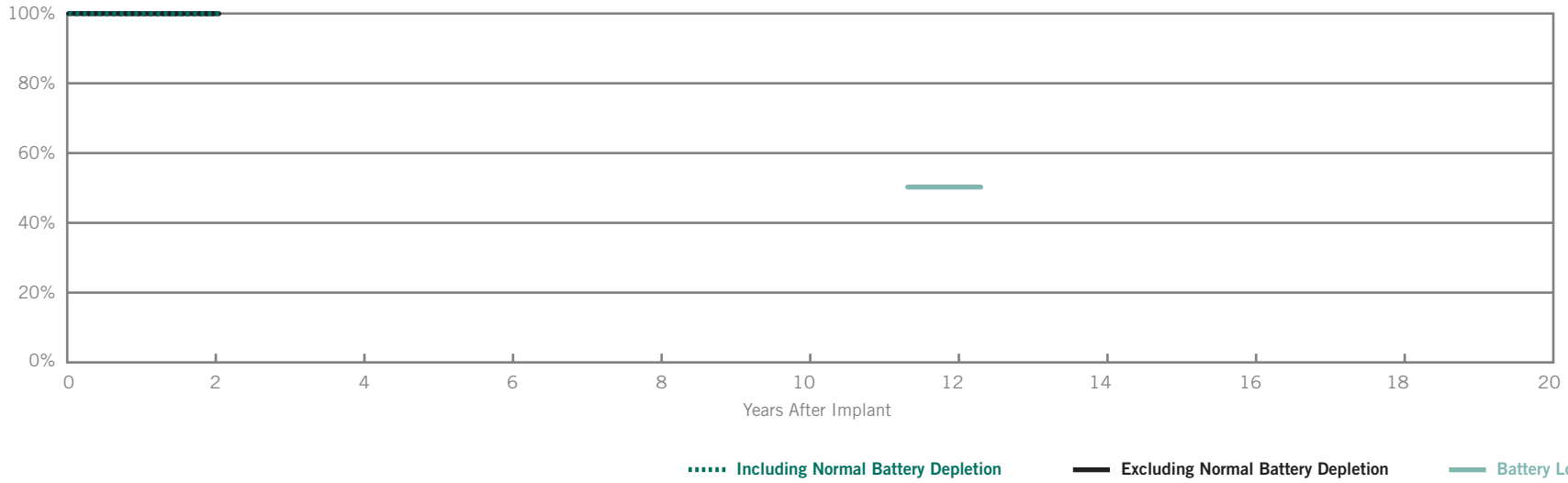
Year	1	2	3	at 39 months						
Survival Probability	100.00%	99.92%	99.90%	99.90%						
± 1 standard error	0.00%	0.02%	0.03%	0.03%						

Pulse Generators

Zephyr® XL DR (Model 5826)

US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	70,593	Malfunctions	7
Estimated Active US Implants	68,321	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	11.7 Years	Malfunctions w/o Compromised Therapy	6
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	2	at 25 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.01%	0.01%								
Sample Size	12700	11000								

Excluding Normal Battery Depletion

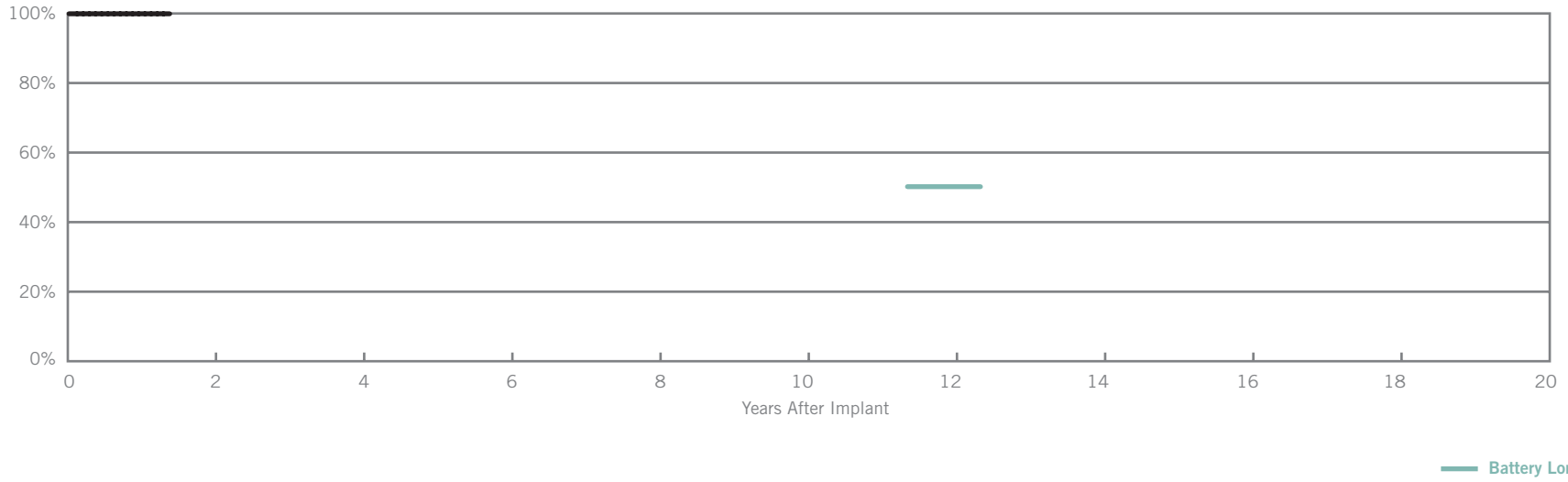
Year	2	at 25 months								
Survival Probability	99.97%	99.97%								
± 1 standard error	0.01%	0.01%								

Zephyr® XL DR (Model 5826)	
US Market Release	March 2007

SCORE Enrollment	
Number of Devices Enrolled in Study	1,163
Cumulative Months of Follow-up	9,990

Qualifying Complications		
Type	**Qty.**	**Rate**
Backup Operation	1	0.09%

Survival from SCORE Registry

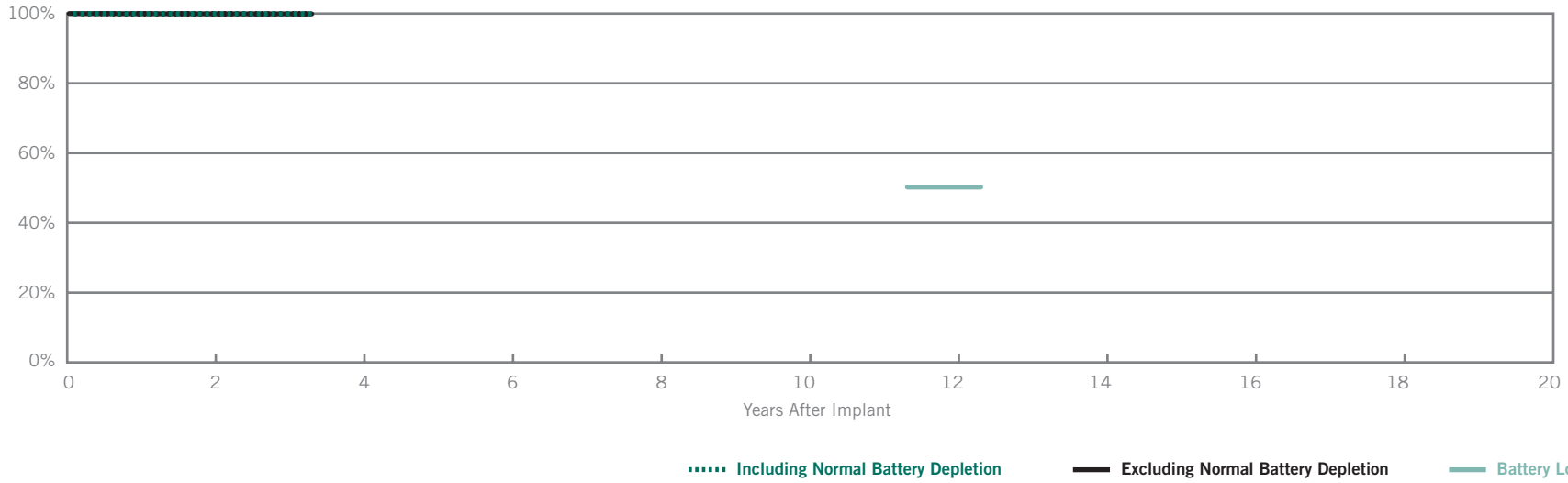


Year	at 17 months									
Survival Probability	99.91%									
± 1 standard error	0.09%									
Sample Size	89									

Victory® XL DR (Model 5816)

US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	57,811	Malfunctions	18
Estimated Active US Implants	51,890	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	11.7 Years	Malfunctions w/o Compromised Therapy	18
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	2	at 40 months								
Survival Probability	99.92%	99.91%								
± 1 standard error	0.01%	0.02%								
Sample Size	36200	8000								

Excluding Normal Battery Depletion

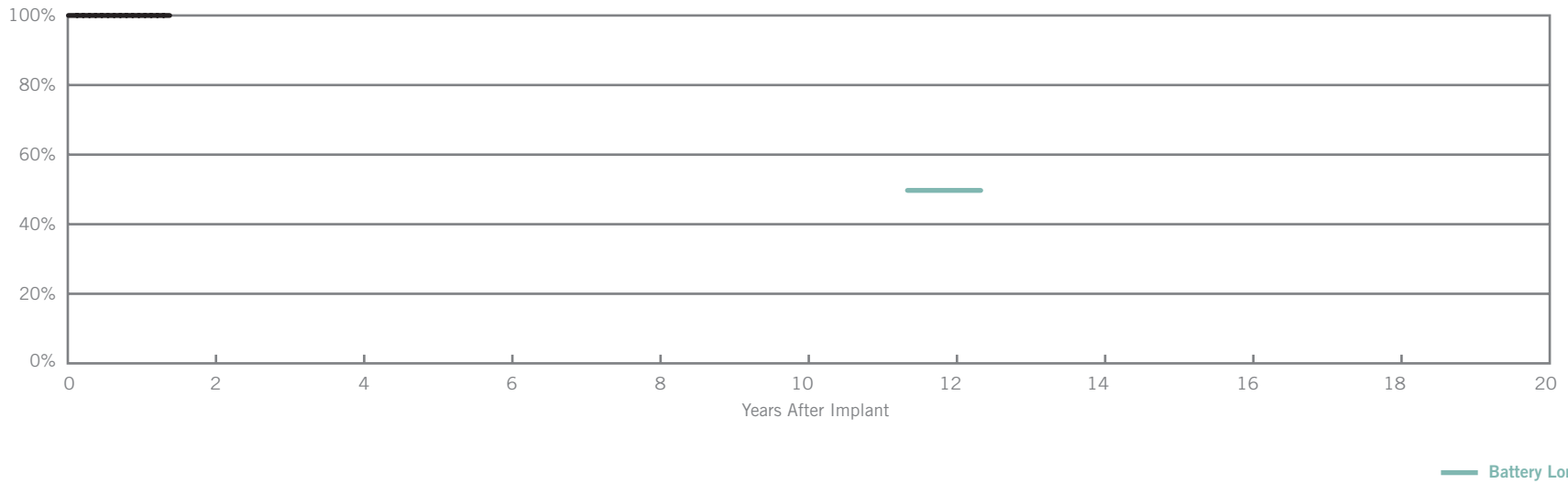
Year	2	at 40 months								
Survival Probability	99.92%	99.91%								
± 1 standard error	0.01%	0.02%								

Victory® XL DR (Model 5816)	
US Market Release	December 2005

SCORE Enrollment	
Number of Devices Enrolled in Study	290
Cumulative Months of Follow-up	3,119

Qualifying Complications
None Reported

Survival from SCORE Registry



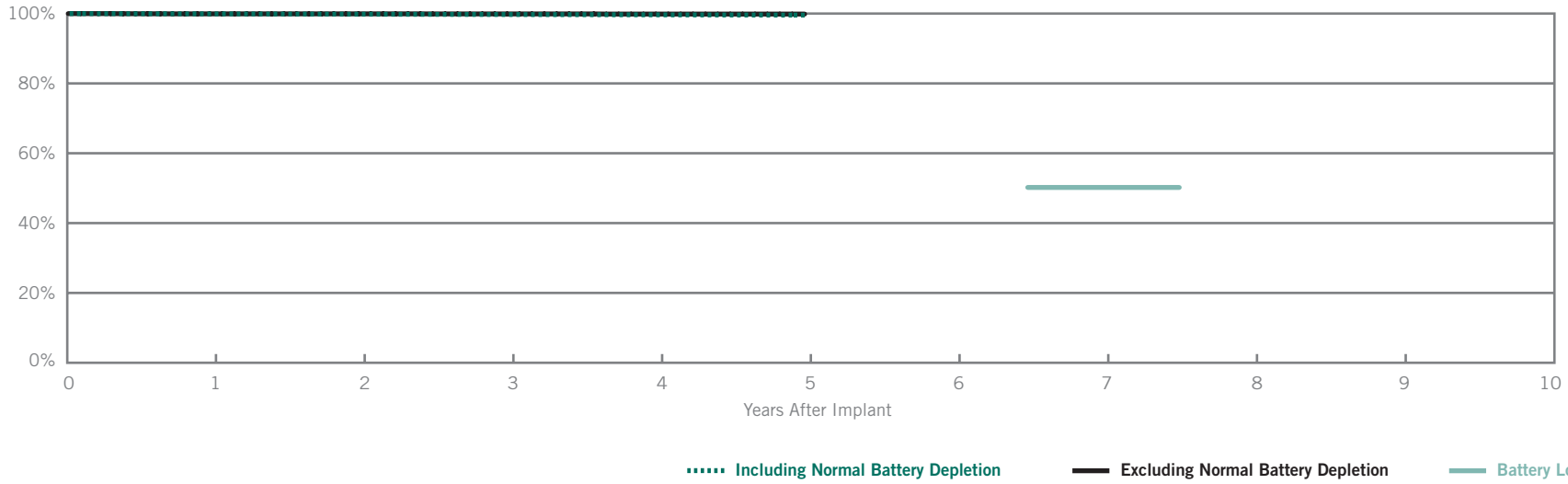
Year	at 17 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	51									

Pulse Generators

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

US Market Release	May 2003	Normal Battery Depletion	8
Registered US Implants	16,546	Malfunctions	7
Estimated Active US Implants	12,213	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	7
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	99.92%	99.92%	99.83%	99.69%	99.56%					
± 1 standard error	0.02%	0.02%	0.04%	0.06%	0.09%					
Sample Size	16200	13100	9600	6000	2700					

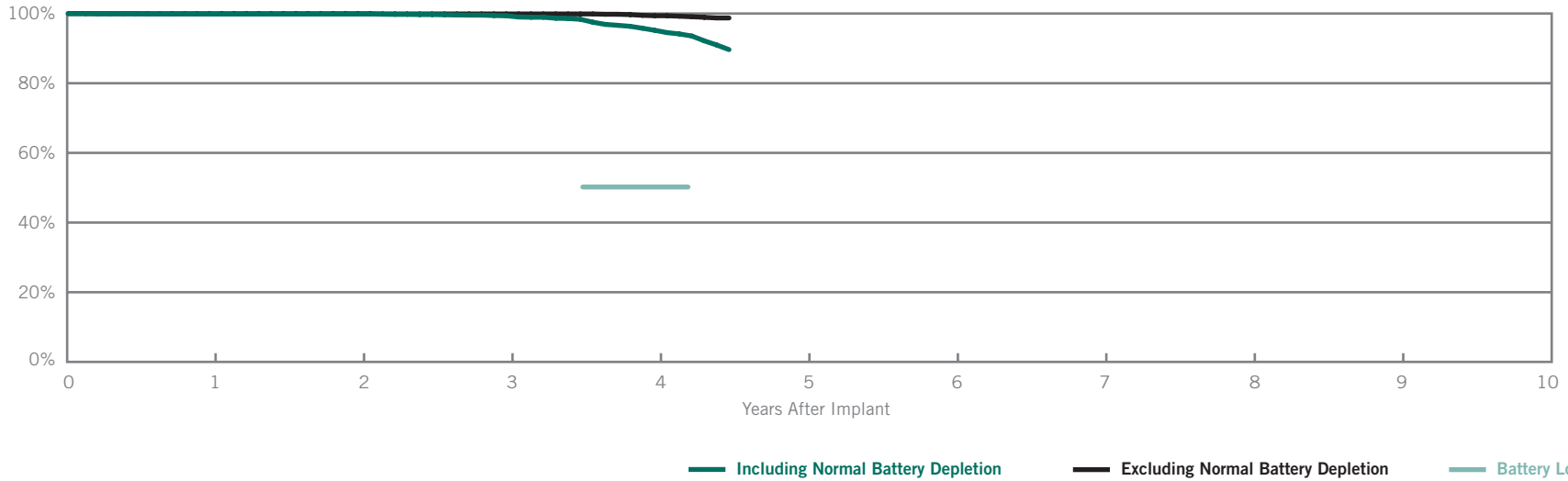
Excluding Normal Battery Depletion

Year	1	2	3	4	5					
Survival Probability	99.92%	99.92%	99.90%	99.86%	99.86%					
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.04%					

Integrity® ADx DR (Model 5360)

US Market Release	May 2003	Normal Battery Depletion	115
Registered US Implants	5,807	Malfunctions	15
Estimated Active US Implants	3,508	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy	15
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 54 months					
Survival Probability	99.85%	99.85%	99.35%	95.18%	89.64%					
± 1 standard error	0.04%	0.05%	0.12%	0.40%	0.07%					
Sample Size	5800	4900	3900	2600	1900					

Excluding Normal Battery Depletion

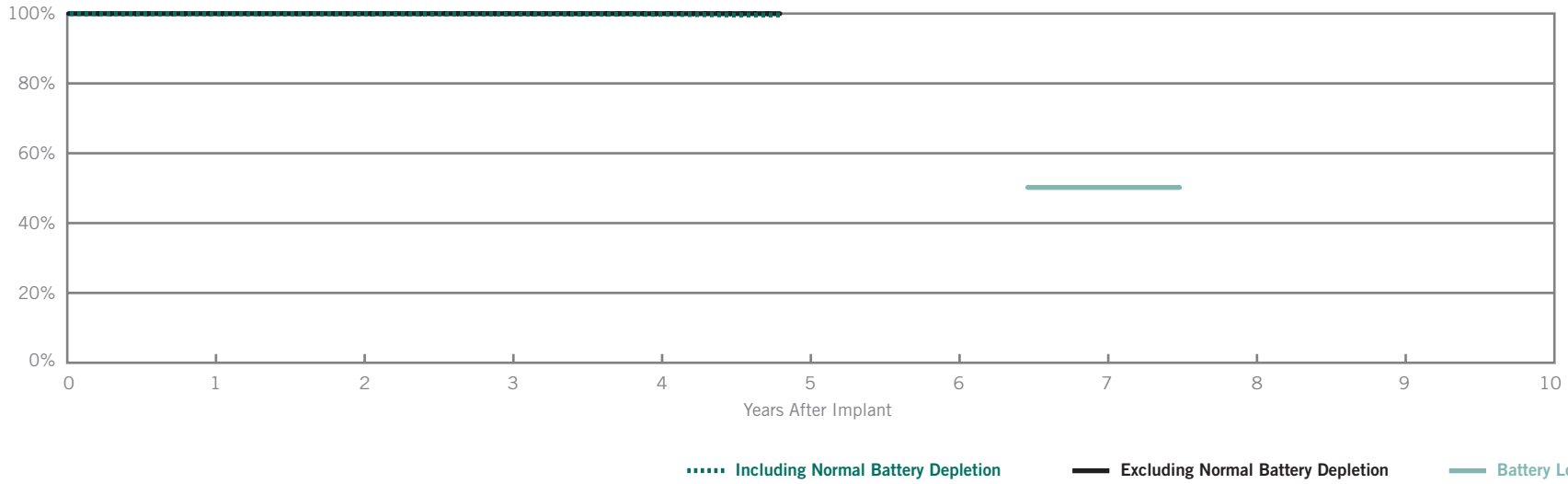
Year	1	2	3	4	at 54 months					
Survival Probability	99.93%	99.93%	99.88%	99.37%	98.73%					
± 1 standard error	0.04%	0.04%	0.05%	0.15%	0.28%					

Pulse Generators

Integrity® ADx DR (Model 5366)

US Market Release	May 2003	Normal Battery Depletion	4
Registered US Implants	7,991	Malfunctions	1
Estimated Active US Implants	6,223	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 58 months					
Survival Probability	99.98%	99.98%	99.90%	99.90%	99.61%					
± 1 standard error	0.02%	0.02%	0.04%	0.04%	0.16%					
Sample Size	8000	6700	4900	2800	1200					

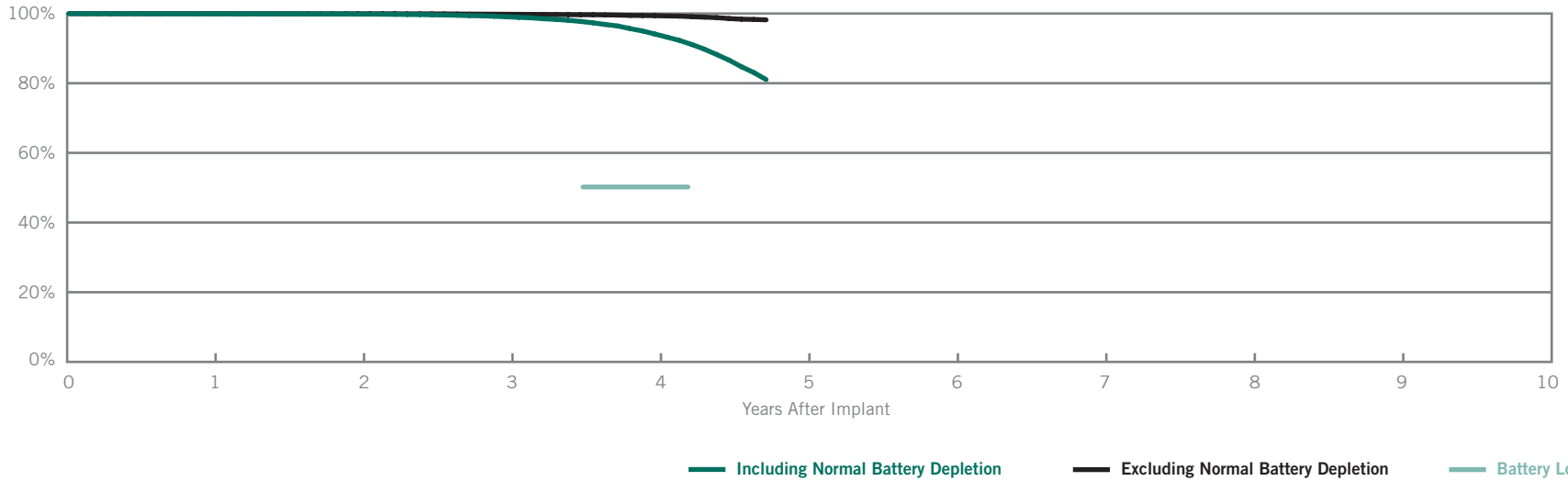
Excluding Normal Battery Depletion

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

Identity® ADx DR (Model 5380)

US Market Release	March 2003	Normal Battery Depletion	1162
Registered US Implants	52,671	Malfunctions	135
Estimated Active US Implants	31,202	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	131
		Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 57 months					
Survival Probability	99.93%	99.82%	99.06%	94.12%	81.04%					
± 1 standard error	0.01%	0.02%	0.05%	0.15%	0.38%					
Sample Size	51900	44100	36200	24000	13100					

Excluding Normal Battery Depletion

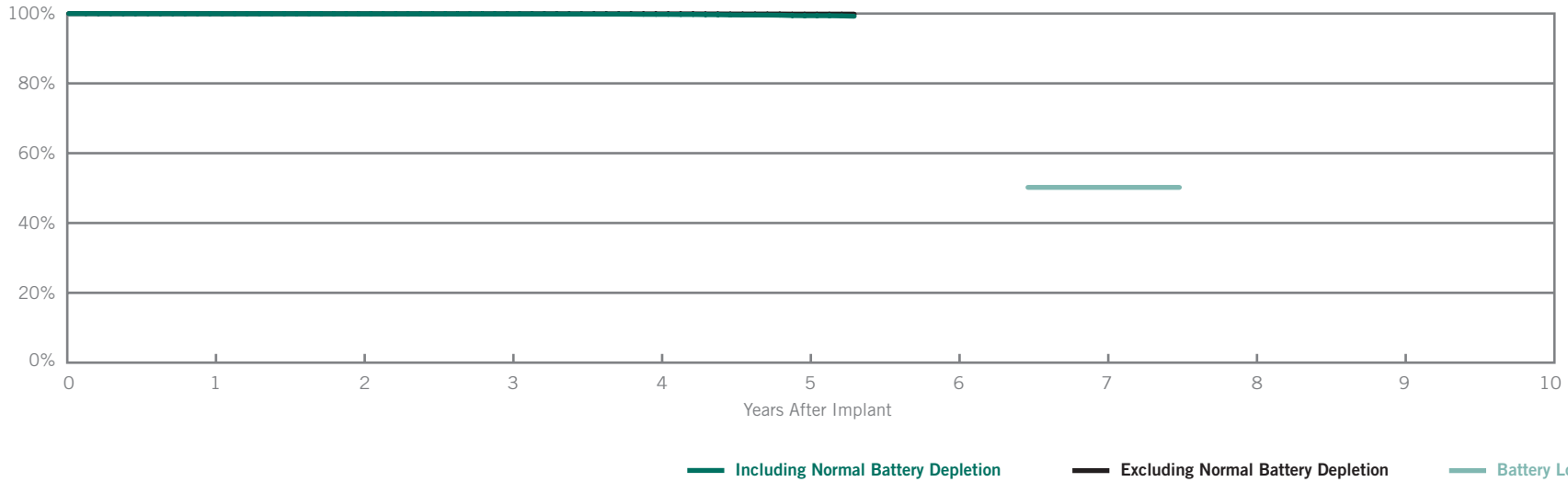
Year	1	2	3	4	at 57 months					
Survival Probability	99.96%	99.93%	99.79%	99.39%	98.19%					
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.12%					

Pulse Generators

Identity® ADx XL DR (Model 5386) Identity® ADx XL DC (Model 5286)

US Market Release	March 2003	Normal Battery Depletion	37
Registered US Implants	63,303	Malfunctions	27
Estimated Active US Implants	50,177	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	26
		Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.96%	99.92%	99.89%	99.77%	99.39%	99.24%				
± 1 standard error	0.01%	0.01%	0.01%	0.03%	0.07%	0.09%				
Sample Size	61300	51300	40500	25300	10600	6900				

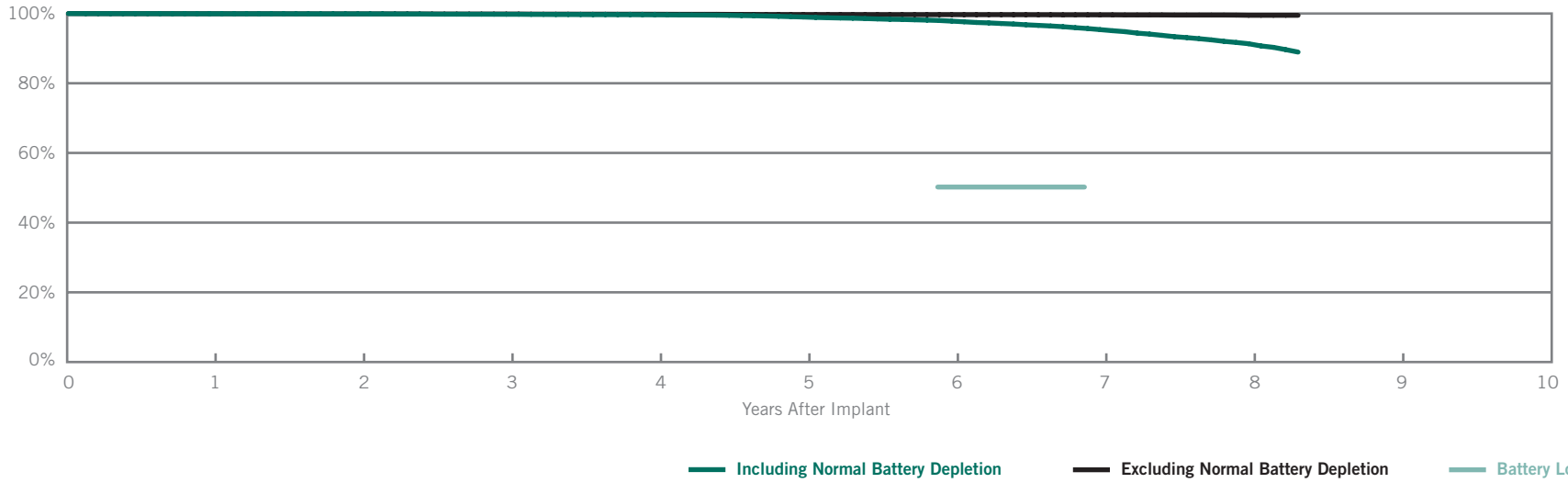
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 64 months				
Survival Probability	99.96%	99.94%	99.93%	99.91%	99.84%	99.84%				
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.03%	0.03%				

Integrity® AFx DR (Models 5342 & 5346)

US Market Release	(5342) April 2000	Normal Battery Depletion	832
	(5346) July 2001	Malfunctions	70
Registered US Implants	47,463	Malfunctions w/ Compromised Therapy	6
Estimated Active US Implants	19,420	Malfunctions w/o Compromised Therapy	64
Estimated Longevity	6.3 Years	Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.94%	99.90%	99.78%	99.64%	99.00%	97.82%	95.38%	91.33%	88.94%	
± 1 standard error	0.01%	0.02%	0.02%	0.03%	0.05%	0.08%	0.13%	0.21%	0.28%	
Sample Size	47200	42200	38700	35100	31400	27000	21600	12900	10000	

Excluding Normal Battery Depletion

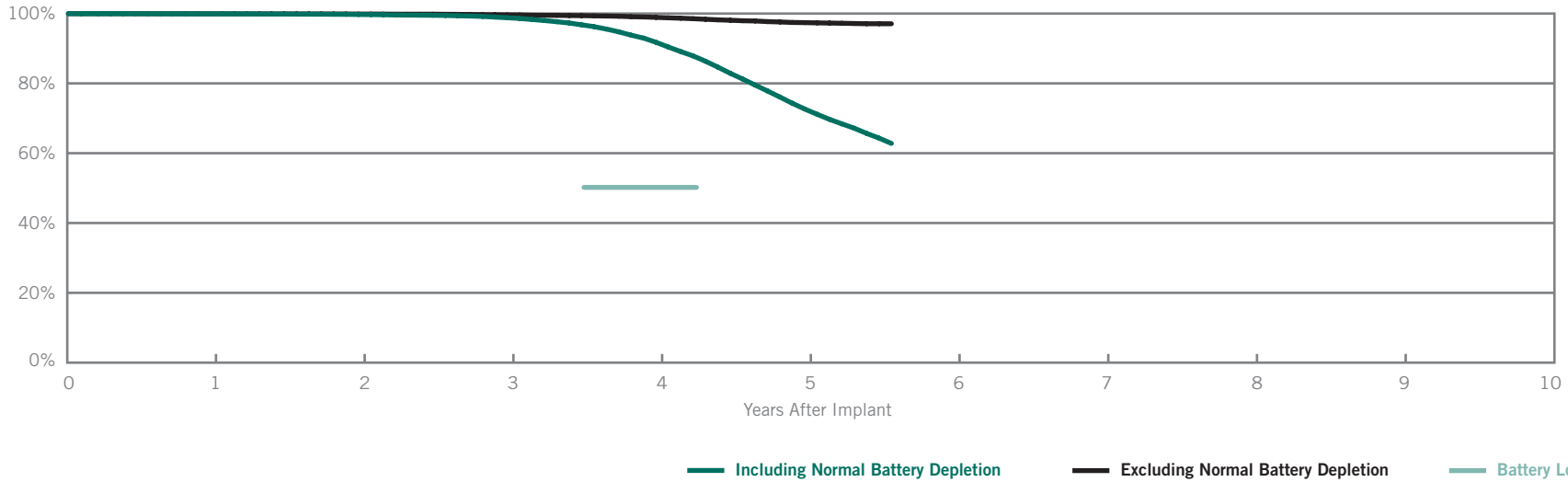
Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.94%	99.90%	99.86%	99.80%	99.70%	99.68%	99.62%	99.49%	99.49%	
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.03%	0.03%	0.04%	0.05%	

Pulse Generators

Identity® (Model 5370)

US Market Release	November 2001	Normal Battery Depletion	3,403
Registered US Implants	58,306	Malfunctions	334
Estimated Active US Implants	16,846	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (20 related to Advisory)	329
		Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.91%	99.73%	98.80%	91.78%	72.66%	62.80%				
± 1 standard error	0.01%	0.02%	0.05%	0.14%	0.30%	0.41%				
Sample Size	58100	50700	44500	36600	23700	13300				

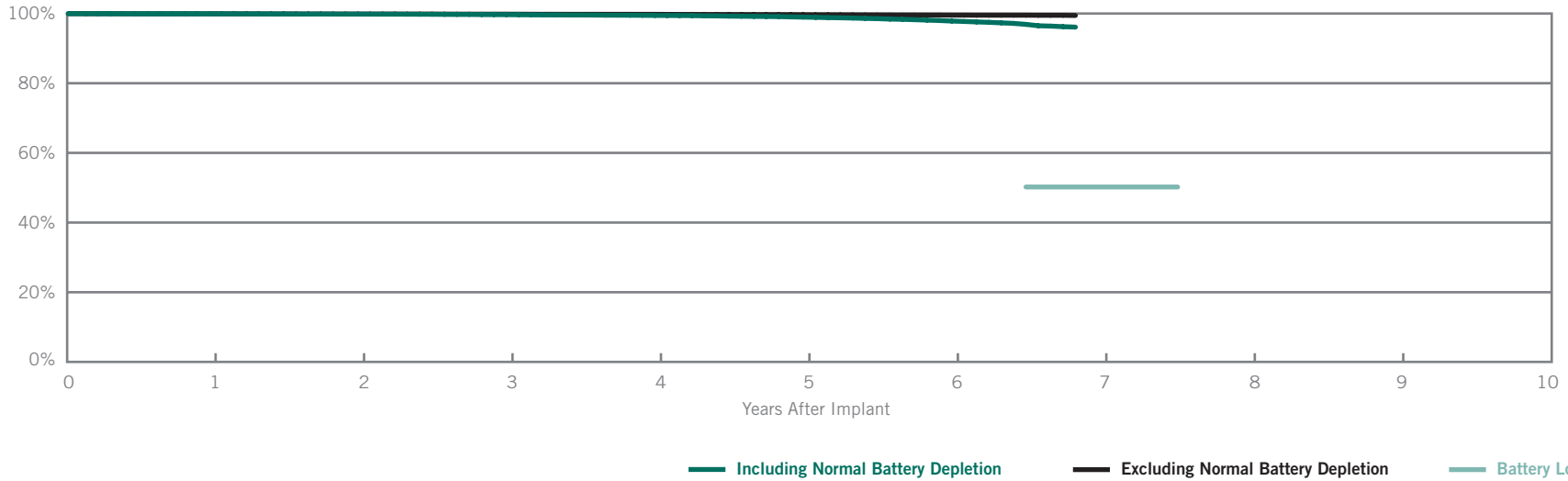
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 67 months				
Survival Probability	99.93%	99.86%	99.62%	98.91%	97.40%	97.08%				
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.11%	0.12%				

Identity® XL (Model 5376)

US Market Release	November 2001	Normal Battery Depletion	257
Registered US Implants	51,366	Malfunctions	81
Estimated Active US Implants	32,459	Malfunctions w/ Compromised Therapy (0 related to Advisory)	8
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (7 related to Advisory)	73
		Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.92%	99.83%	99.69%	99.45%	98.97%	97.84%	96.10%			
± 1 standard error	0.01%	0.02%	0.03%	0.04%	0.06%	0.09%	0.17%			
Sample Size	51200	46200	41300	34900	27300	18400	9700			

Excluding Normal Battery Depletion

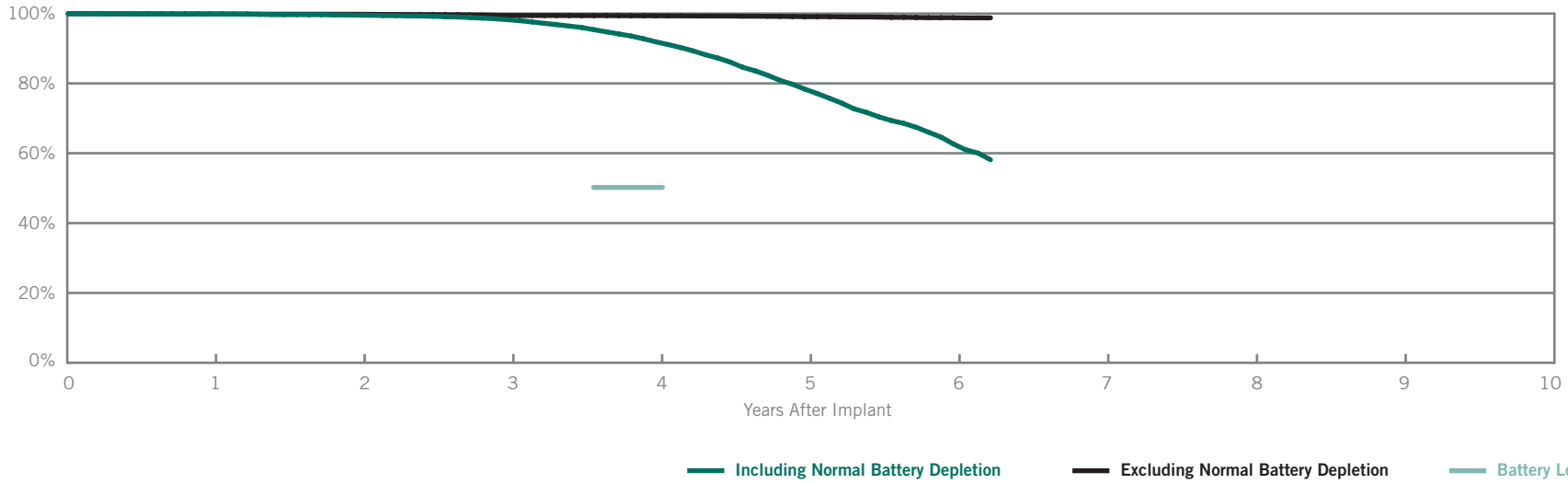
Year	1	2	3	4	5	6	at 82 months			
Survival Probability	99.93%	99.86%	99.82%	99.77%	99.65%	99.53%	99.44%			
± 1 standard error	0.01%	0.02%	0.02%	0.02%	0.03%	0.04%	0.05%			

Pulse Generators

Integrity® µ DR (Model 5336)

US Market Release	December 2000	Normal Battery Depletion	1,972
Registered US Implants	29,344	Malfunctions	82
Estimated Active US Implants	4,486	Malfunctions w/ Compromised Therapy	8
Estimated Longevity	4.0 Years	Malfunctions w/o Compromised Therapy	74
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.87%	99.54%	98.26%	91.90%	78.38%	62.65%	58.13%			
± 1 standard error	0.02%	0.04%	0.08%	0.19%	0.35%	0.55%	0.64%			
Sample Size	29300	25300	22500	19200	13900	6500	4800			

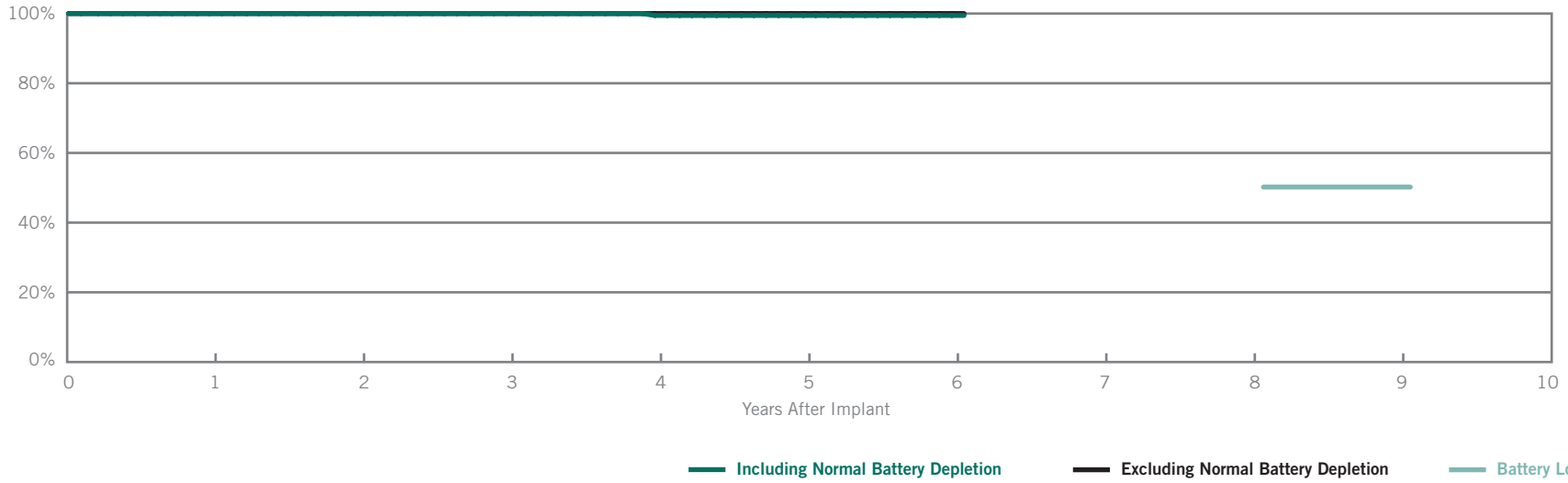
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.89%	99.80%	99.44%	99.37%	99.12%	98.83%	98.78%			
± 1 standard error	0.02%	0.03%	0.05%	0.06%	0.07%	0.10%	0.11%			

Affinity® VDR (Model 5430)

US Market Release	April 2000	Normal Battery Depletion	3
Registered US Implants	654	Malfunctions	0
Estimated Active US Implants	227	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 73 months			
Survival Probability	100.00%	100.00%	100.00%	99.44%	99.44%	99.44%	99.44%			
± 1 standard error	0.00%	0.00%	0.00%	0.39%	0.39%	0.39%	0.39%			
Sample Size	600	500	500	400	400	300	300			

Excluding Normal Battery Depletion

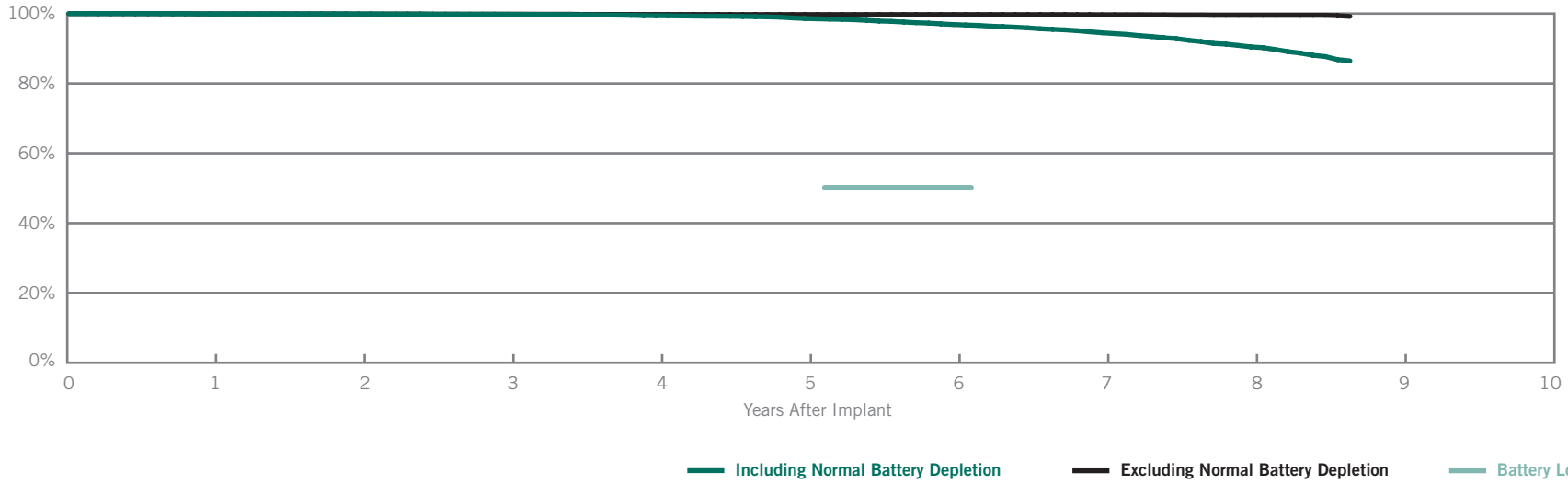
Year	1	2	3	4	5	6	at 73 months			
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%			
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%			

Pulse Generators

Entity™ DR (Model 5326) Entity™ DC (Model 5226)

US Market Release	June 1999	Normal Battery Depletion	385
Registered US Implants	21,838	Malfunctions	33
Estimated Active US Implants	6,784	Malfunctions w/ Compromised Therapy	3
Estimated Longevity	6.3 Years	Malfunctions w/o Compromised Therapy	30
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 104 months	
Survival Probability	99.92%	99.88%	99.80%	99.39%	98.59%	96.86%	94.49%	90.46%	86.46%	
± 1 standard error	0.02%	0.02%	0.03%	0.06%	0.10%	0.16%	0.23%	0.35%	0.52%	
Sample Size	21800	18800	16900	15100	13200	11100	8300	5300	3200	

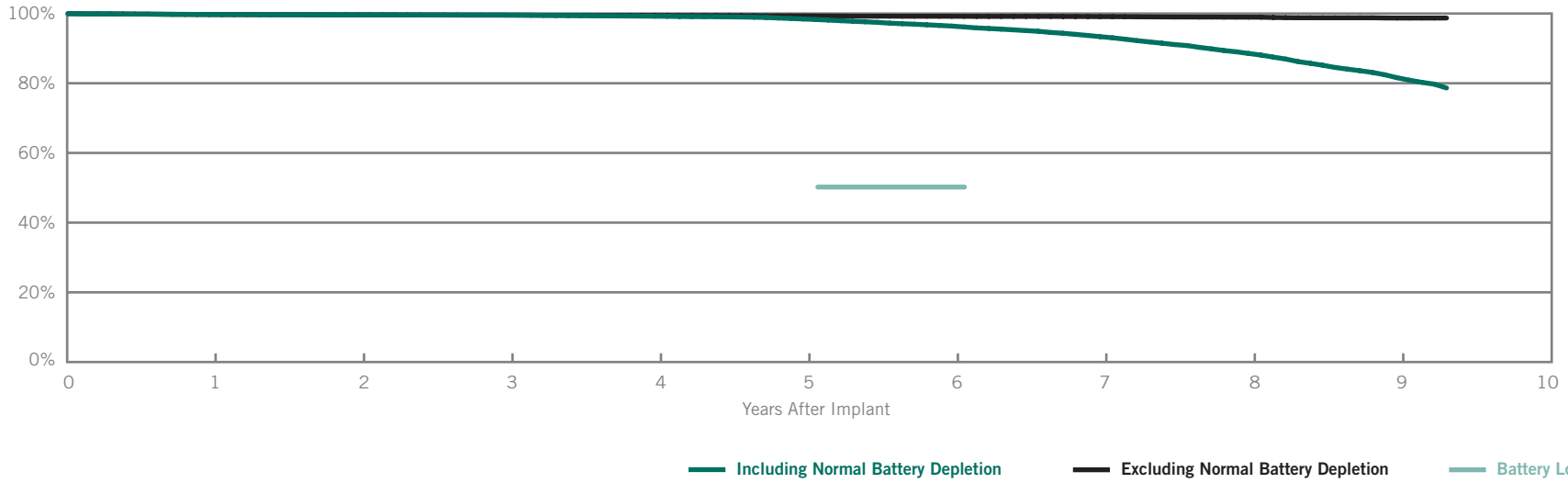
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 104 months	
Survival Probability	99.92%	99.88%	99.81%	99.72%	99.70%	99.70%	99.62%	99.50%	99.19%	
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.04%	0.04%	0.05%	0.07%	0.10%	

Affinity® DR (Models 5330 & 5331) Affinity® DC (Model 5230)

US Market Release	(5330) January 1999	Normal Battery Depletion	1,815
	(5230/5331) June 1999	Malfunctions	228
Registered US Implants	65,595	Malfunctions w/ Compromised Therapy (0 related to Advisory)	15
Estimated Active US Implants	17,065	Malfunctions w/o Compromised Therapy (65 related to Advisory)	213
Estimated Longevity	6.3 Years	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.73%	99.63%	99.55%	99.23%	98.43%	96.40%	93.36%	88.54%	81.58%	78.64%
± 1 standard error	0.02%	0.02%	0.03%	0.04%	0.06%	0.09%	0.14%	0.20%	0.29%	0.35%
Sample Size	65400	57800	52500	47500	42300	36400	28800	20400	11700	8500

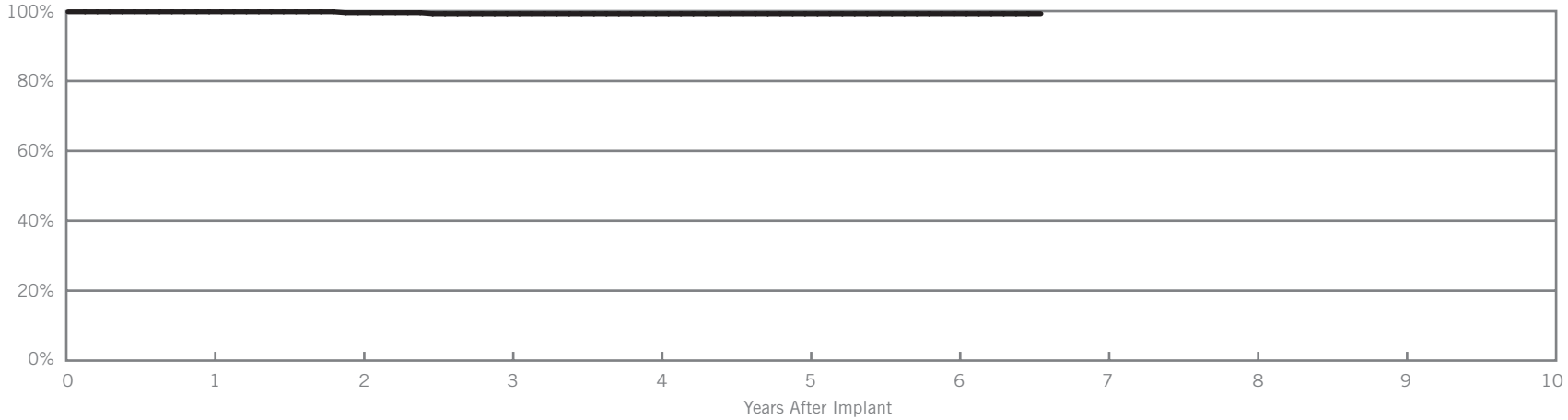
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 112 months
Survival Probability	99.73%	99.62%	99.54%	99.43%	99.33%	99.21%	99.11%	98.96%	98.71%	98.71%
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.04%	0.04%	0.04%	0.05%	0.07%	0.07%

Pulse Generators

AddVent™ (Model 2060)	
US Market Release	May 1999
Registered US Implants	536
Estimated Longevity	9.3 Years
Number of Advisories	None

Survival from Returns and Complaints

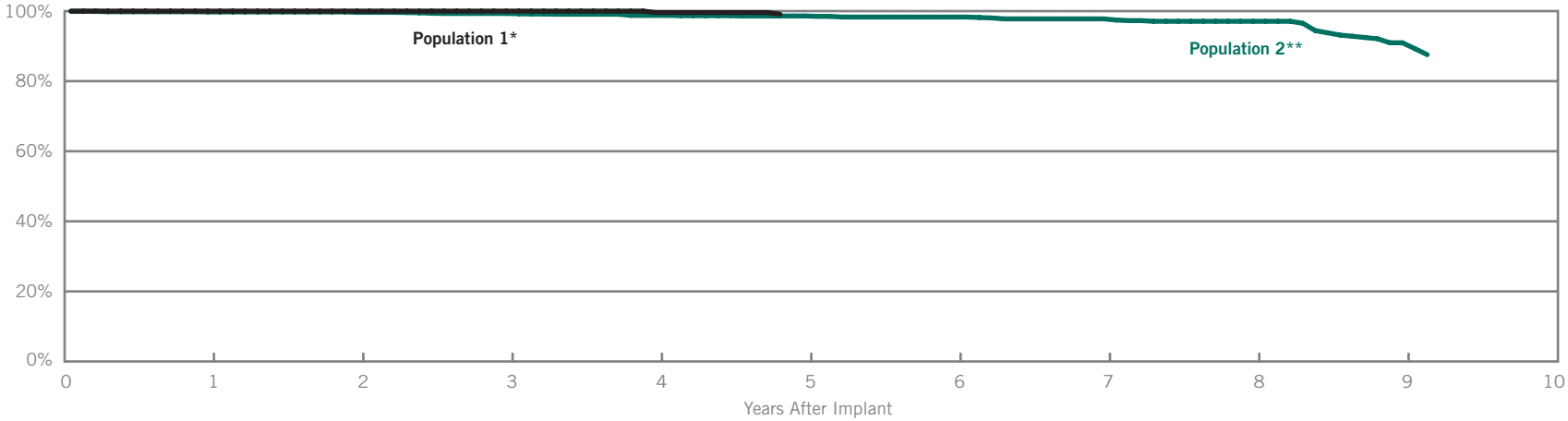


Year	1	2	3	4	5	6	at 79 months			
Survival Probability	99.81%	99.55%	99.27%	99.27%	99.27%	99.27%	99.27%			
± 1 standard error	0.19%	0.32%	0.42%	0.42%	0.42%	0.42%	0.42%			
Sample Size	400	400	300	300	200	200	200			

Trilogy™ DC+ (Model 2318)

Population 1*		Population 2**	
US Market Release	January 1997	US Market Release	January 1997
Registered US Implants	439	Registered US Implants	2,301
Estimated Longevity	5.0 Years	Estimated Longevity	5.0 Years
Number of Advisories	None	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Population 1*

Year	1	2	3	4	at 58 months					
Survival Probability	100.00%	100.00%	100.00%	99.59%	99.10%					
± 1 standard error	0.00%	0.00%	0.00%	0.41%	0.41%					
Sample Size	400	300	300	300	200					

Population 2**

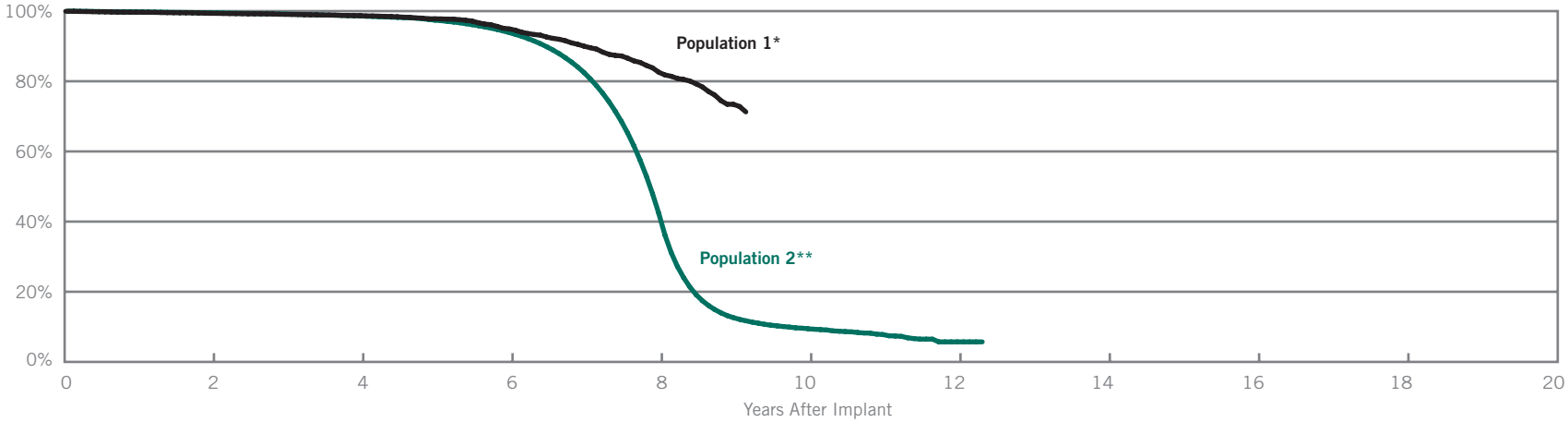
Year	1	2	3	4	5	6	7	8	9	at 110 months
Survival Probability	99.76%	99.64%	99.32%	98.77%	98.60%	98.30%	97.78%	97.09%	90.96%	87.56%
± 1 standard error	0.09%	0.11%	0.20%	0.29%	0.31%	0.35%	0.44%	0.55%	1.47%	1.66%
Sample Size	2000	1800	1500	1300	1100	900	700	500	300	200

Pulse Generators

Trilogy™ DR+ (Model 2360 & 2364)

Population 1*		Population 2**	
US Market Release	September 1996	US Market Release	September 1996
Registered US Implants	6,479	Registered US Implants	63,822
Estimated Longevity	5.0 Years	Estimated Longevity	5.0 Years
Number of Advisories	None	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Population 1*

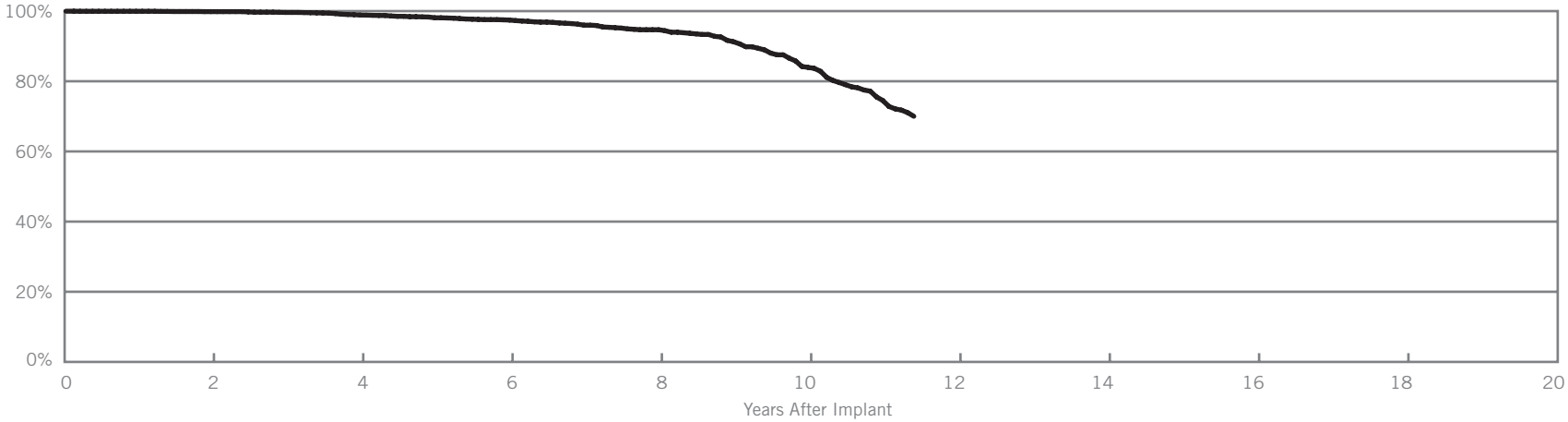
Year	2	4	6	8	at 110 months					
Survival Probability	99.36%	98.72%	94.92%	82.57%	71.27%					
± 1 standard error	0.10%	0.16%	0.38%	0.89%	1.55%					
Sample Size	4900	3700	2300	800	200					

Population 2**

Year	2	4	6	8	10	12	at 148 months			
Survival Probability	99.51%	98.62%	93.86%	42.36%	9.46%	5.72%	5.72%			
± 1 standard error	0.03%	0.05%	0.08%	0.14%	0.72%	4.42%	4.42%			
Sample Size	50400	38600	25000	9200	1000	100	100			

Paragon™ III (Models 2304, 2314, 2315)	
US Market Release	October 1994
Registered US Implants	3,824
Estimated Longevity	6.3 Years
Number of Advisories	None

Survival from Returns and Complaints

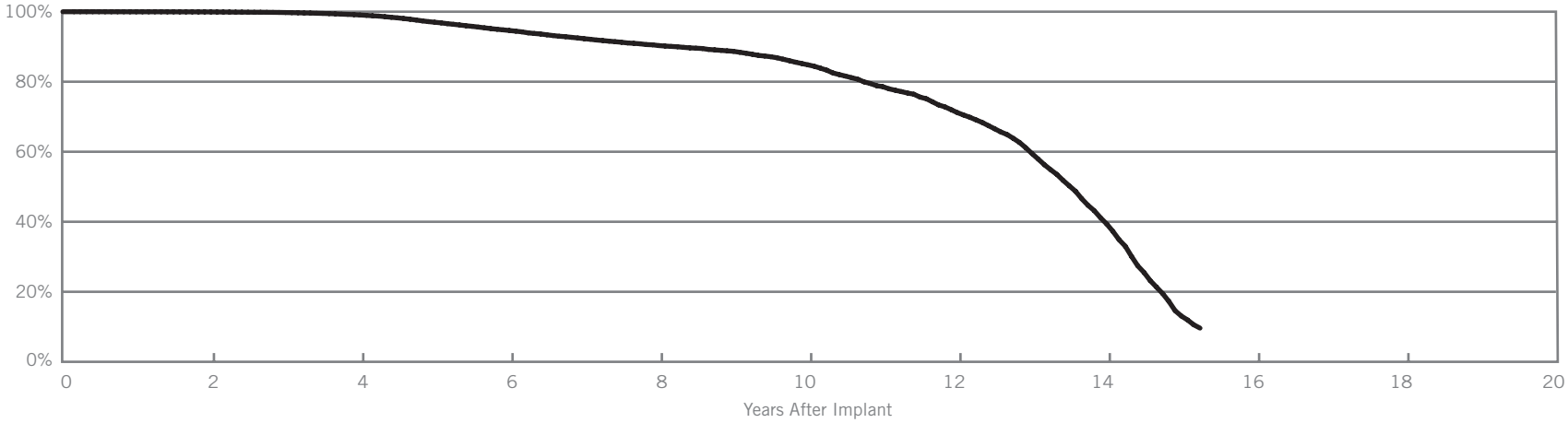


Year	2	4	6	8	10	at 137 months				
Survival Probability	99.85%	98.89%	97.44%	94.69%	83.95%	70.02%				
± 1 standard error	0.07%	0.20%	0.34%	0.61%	1.52%	2.28%				
Sample Size	2900	2200	1500	700	300	200				

Pulse Generators

Synchrony™ III (Models 2028 & 2029)	
US Market Release	February 1993
Registered US Implants	43,324
Estimated Longevity	5.5 Years
Number of Advisories	None

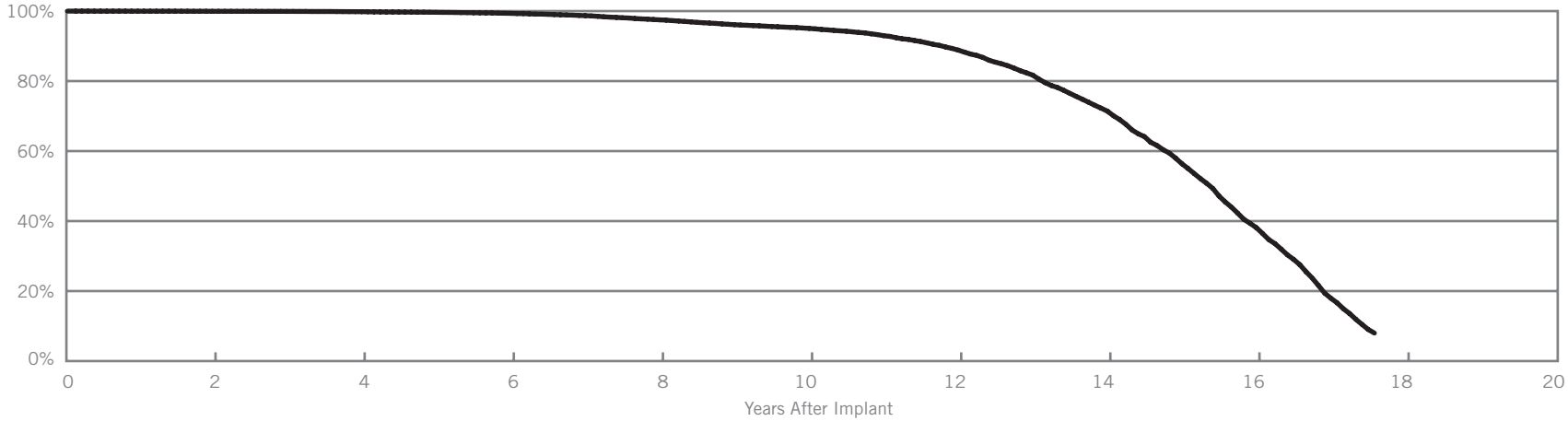
Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	at 183 months		
Survival Probability	99.93%	99.06%	94.63%	90.32%	84.81%	71.17%	39.38%	9.63%		
± 1 standard error	0.01%	0.05%	0.14%	0.24%	0.41%	0.72%	0.98%	0.67%		
Sample Size	35400	28100	16800	6300	2900	1800	900	200		

Synchrony™ II (Models 2022 & 2023)	
US Market Release	June 1990
Registered US Implants	47,160
Estimated Longevity	8.0 Years
Number of Advisories	None

Survival from Returns and Complaints

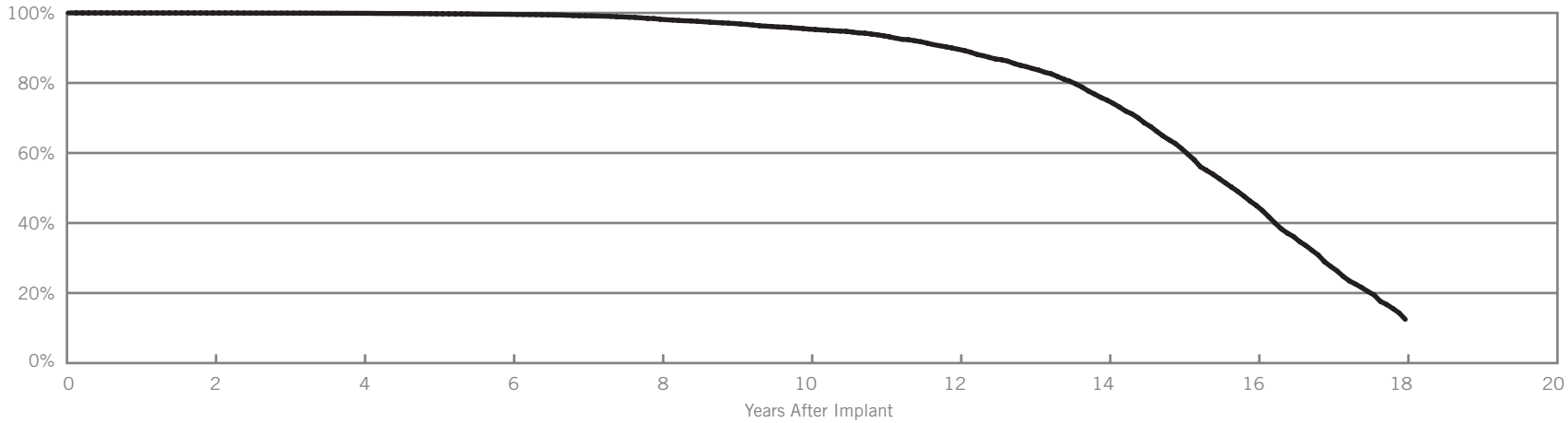


Year	2	4	6	8	10	12	14	16	at 211 months	
Survival Probability	99.94%	99.82%	99.35%	97.49%	95.05%	88.86%	71.43%	38.11%	8.00%	
± 1 standard error	0.01%	0.02%	0.04%	0.10%	0.16%	0.31%	0.61%	0.84%	0.56%	
Sample Size	40500	34000	26800	19500	11900	6200	3000	1300	200	

Pulse Generators

Paragon™ II (Model 2016)	
US Market Release	April 1989
Registered US Implants	29,069
Estimated Longevity	7.7 Years
Number of Advisories	None

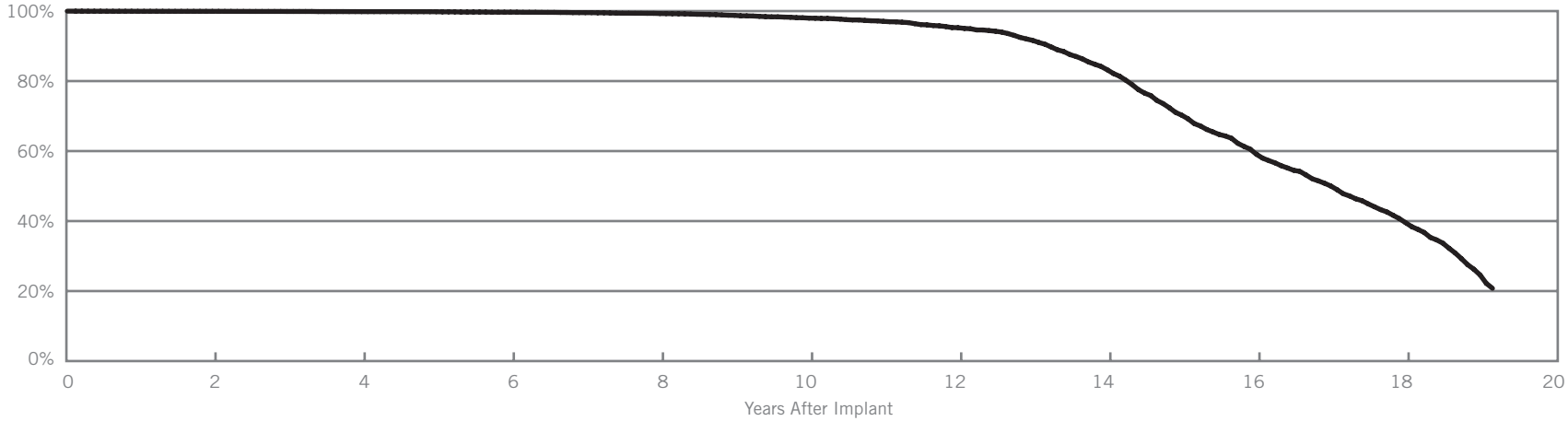
Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	16	18	
Survival Probability	99.98%	99.89%	99.59%	98.19%	95.36%	89.62%	75.07%	45.00%	12.47%	
± 1 standard error	0.01%	0.02%	0.05%	0.12%	0.23%	0.41%	0.75%	1.07%	0.87%	
Sample Size	22700	17900	13600	9200	5500	3100	1800	800	200	

Paragon™ (Models 2010, 2011 & 2012)	
US Market Release	September 1988
Registered US Implants	16,679
Estimated Longevity	7.2 Years
Number of Advisories	None

Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	16	18	at 230 months
Survival Probability	99.93%	99.84%	99.69%	99.29%	97.98%	95.25%	83.23%	59.09%	39.56%	20.78%
± 1 standard error	0.02%	0.04%	0.06%	0.10%	0.20%	0.37%	0.79%	1.21%	1.36%	1.27%
Sample Size	11300	9100	7000	5100	3500	2300	1400	800	400	200

Summary & Longevity Information

Pulse Generators

Dual-Chamber

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Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (under advisory)	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
5820	Zephyr® DR	Mar-07	19268	18317	1	0	0	0	1	0
5810	Victory® DR	Dec-05	24334	20732	0	6	0	1	7	5
5826	Zephyr® XL DR	Mar-07	70593	68321	1	6	0	0	7	0
5816	Victory® XL DR	Dec-05	57811	51890	0	18	0	0	18	0
5356/5357/5256	Verity® ADX XL DR/ DR(M/S)/DC	May-03	16546	12213	0	6	0	1	7	8
5360	Integrity® ADx DR	May-03	5807	3508	0	15	0	0	15	115
5366	Integrity® ADx XL DR	May-03	7991	6223	0	1	0	0	1	4
5380	Identity® ADx DR	Mar-03	52671	31202	4	123	0	8	135	1162
5386/5286	Identity® ADx XL DR/DC	Mar-03	63303	50177	1	26	0	0	27	37
5342/5346	Integrity® AFx DR	Apr-00/Jul-01	47463	19420	6	64	0	0	70	832
5370	Identity®	Nov-01	58306	16846	5	299	20	10	334	3403
5376	Identity® XL	Nov-01	51366	32459	8	65	7	1	81	257
5336	Integrity® µ DR	Dec-00	29344	4486	8	73	0	1	82	1972
5430	Affinity® VDR	Apr-00	654	227	0	0	0	0	0	3
5326/5226	Entity™ DR/DC	Jun-99	21838	6784	3	29	0	1	33	385
5330/5331/5230	Affinity® DR/DC	Jan-99/Jun-99	65595	17065	15	148	65	0	228	1815

Pulse Generators

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
5820	Zephyr® DR	99.98%	99.98%								
5810	Victory® DR	100.00%	99.92%	99.66%							
5826	Zephyr® XL DR	99.97%	99.97%								
5816	Victory® XL DR	99.95%	99.92%	99.91%							
5356/5357/5256	Verity® ADX XL DR/ DR(M/S)/DC	99.92%	99.92%	99.83%	99.69%	99.56%					
5360	Integrity® ADx DR	99.85%	99.85%	99.35%	95.18%						
5366	Integrity® ADx XL DR	99.98%	99.98%	99.90%	99.90%						
5380	Identity® ADx DR	99.93%	99.82%	99.06%	94.12%						
5386/5286	Identity® ADx XL DR/DC	99.96%	99.92%	99.89%	99.77%	99.39%					
5342/5346	Integrity® AFx DR	99.94%	99.90%	99.78%	99.64%	99.00%	97.82%	95.38%	91.33%		
5370	Identity®	99.91%	99.73%	98.80%	91.78%	72.66%					
5376	Identity® XL	99.92%	99.83%	99.69%	99.45%	98.97%	97.84%				
5336	Integrity® µ DR	99.87%	99.54%	98.26%	91.90%	78.38%	62.65%				
5430	Affinity® VDR	100.00%	100.00%	100.00%	99.44%	99.44%	99.44%				
5326/5226	Entity™ DR/DC	99.92%	99.88%	99.80%	99.39%	98.59%	96.86%	94.49%	90.46%		
5330/5331/5230	Affinity® DR/DC	99.73%	99.63%	99.55%	99.23%	98.43%	96.40%	93.36%	88.54%	81.58%	

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
5820	Zephyr® DR	99.98%	99.98%								
5810	Victory® DR	100.00%	99.92%	99.90%							
5826	Zephyr® XL DR	99.97%	99.97%								
5816	Victory® XL DR	99.95%	99.92%	99.91%							
5356/5357/5256	Verity® ADX XL DR/ DR(M/S)/DC	99.92%	99.92%	99.90%	99.86%	99.86%					
5360	Integrity® ADx DR	99.93%	99.93%	99.88%	99.37%						
5366	Integrity® ADx XL DR	99.98%	99.98%	99.98%	99.98%						
5380	Identity® ADx DR	99.96%	99.93%	99.79%	99.39%						
5386/5286	Identity® ADx XL DR/DC	99.96%	99.94%	99.93%	99.91%	99.84%					
5342/5346	Integrity® AFx DR	99.94%	99.90%	99.86%	99.80%	99.70%	99.68%	99.62%	99.49%		
5370	Identity®	99.93%	99.86%	99.62%	98.91%	97.40%					
5376	Identity® XL	99.93%	99.86%	99.82%	99.77%	99.65%	99.53%				
5336	Integrity® µ DR	99.89%	99.80%	99.44%	99.37%	99.12%	98.83%				
5430	Affinity® VDR	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%				
5326/5226	Entity™ DR/DC	99.92%	99.88%	99.81%	99.72%	99.70%	99.70%	99.62%	99.50%		
5330/5331/5230	Affinity® DR/DC	99.73%	99.62%	99.54%	99.43%	99.33%	99.21%	99.11%	98.96%	98.71%	

Pulse Generators

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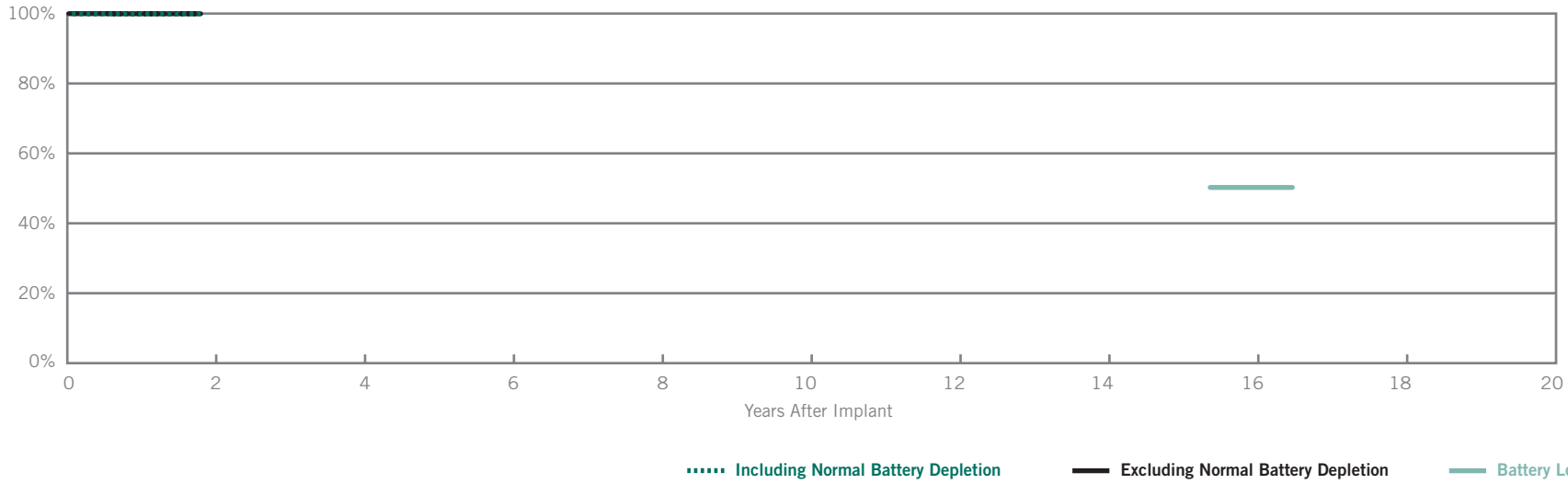
Zephyr® XL SR (Model 5626)

US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	11,840	Malfunctions	2
Estimated Active US Implants	11,270	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	15.8 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	at 22 months									
Survival Probability	99.95%									
± 1 standard error	0.03%									
Sample Size	2600									

Excluding Normal Battery Depletion

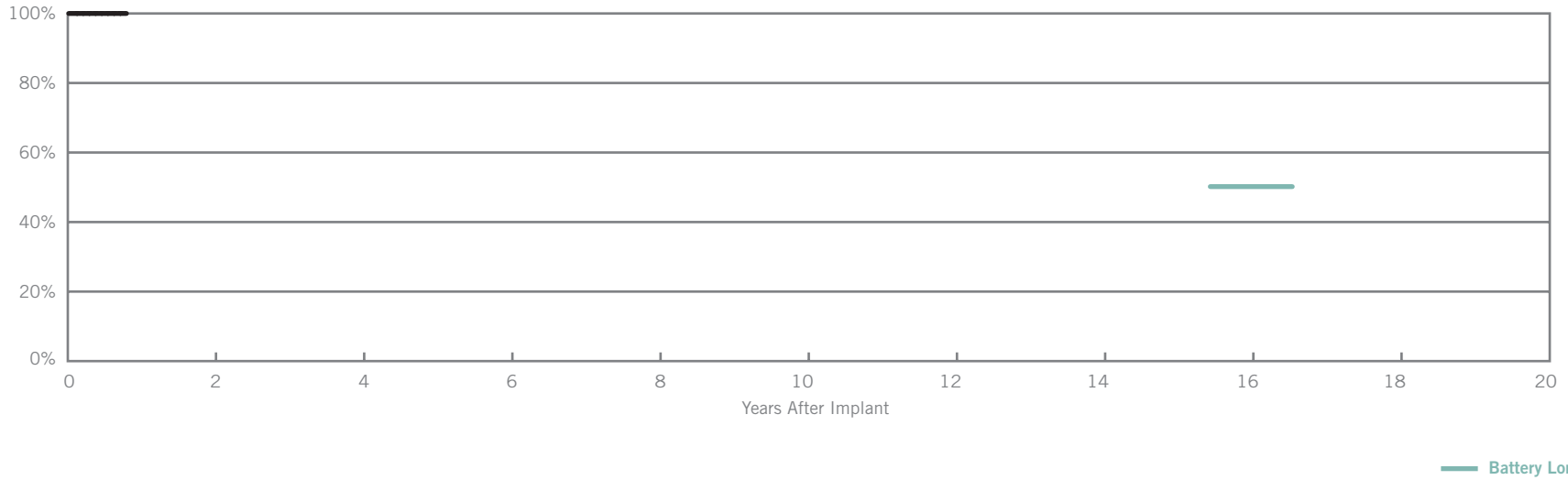
Year	at 22 months									
Survival Probability	99.95%									
± 1 standard error	0.03%									

Zephyr® XL SR (Model 5626)	
US Market Release	May 2007

SCORE Enrollment	
Number of Devices Enrolled in Study	159
Cumulative Months of Follow-up	1268

Qualifying Complications
None Reported

Survival from SCORE Registry



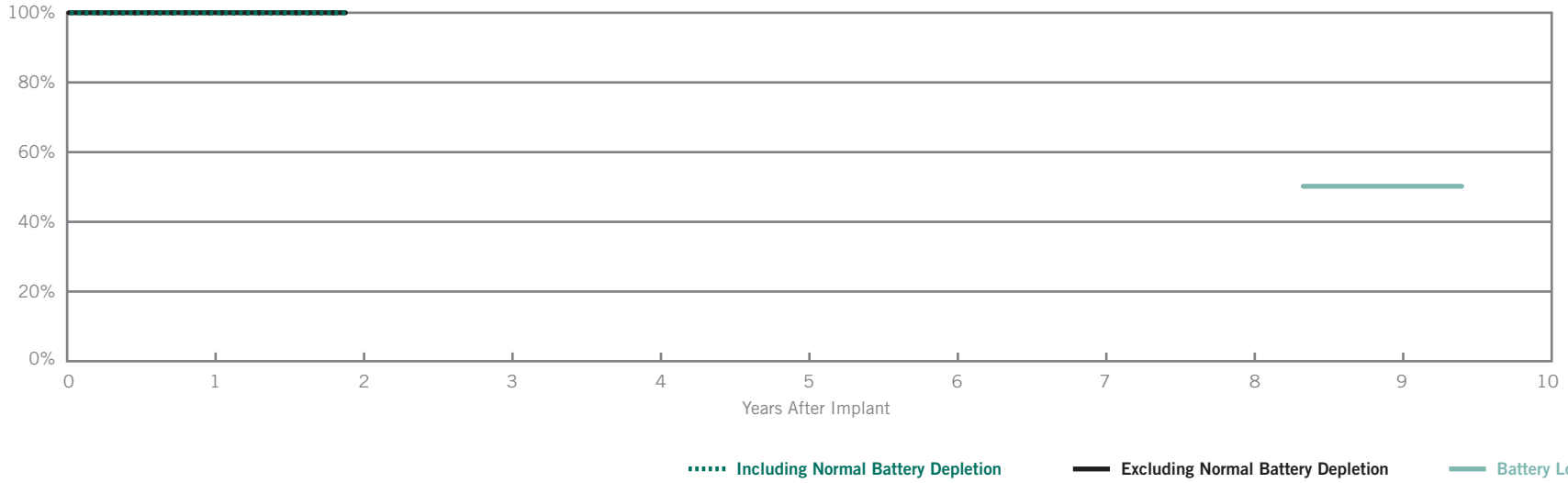
Year	at 10 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	55									

Pulse Generators

Zephyr® SR (Model 5620)

US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	5,728	Malfunctions	0
Estimated Active US Implants	5,360	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.8 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								
Sample Size	4000	1200								

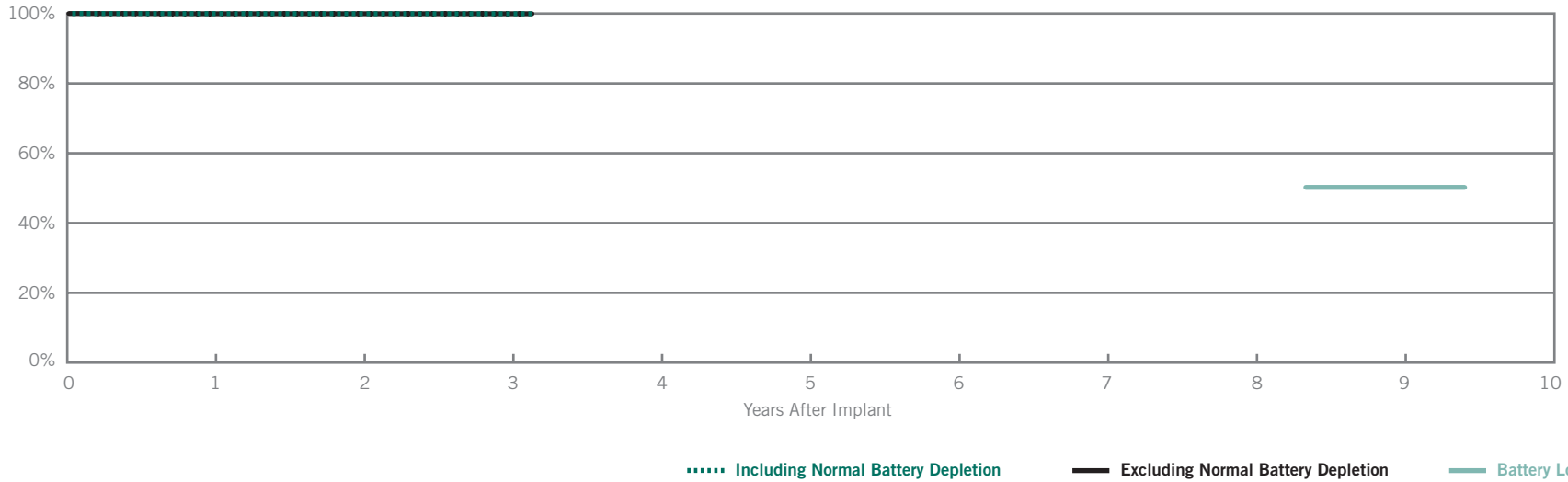
Excluding Normal Battery Depletion

Year	1	at 23 months								
Survival Probability	100.00%	100.00%								
± 1 standard error	0.00%	0.00%								

Victory® SR (Model 5610)

US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	12,342	Malfunctions	2
Estimated Active US Implants	10,153	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.8 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	at 38 months						
Survival Probability	99.94%	99.94%	99.94%	99.94%						
± 1 standard error	0.02%	0.02%	0.02%	0.02%						
Sample Size	11300	7000	2600	2000						

Excluding Normal Battery Depletion

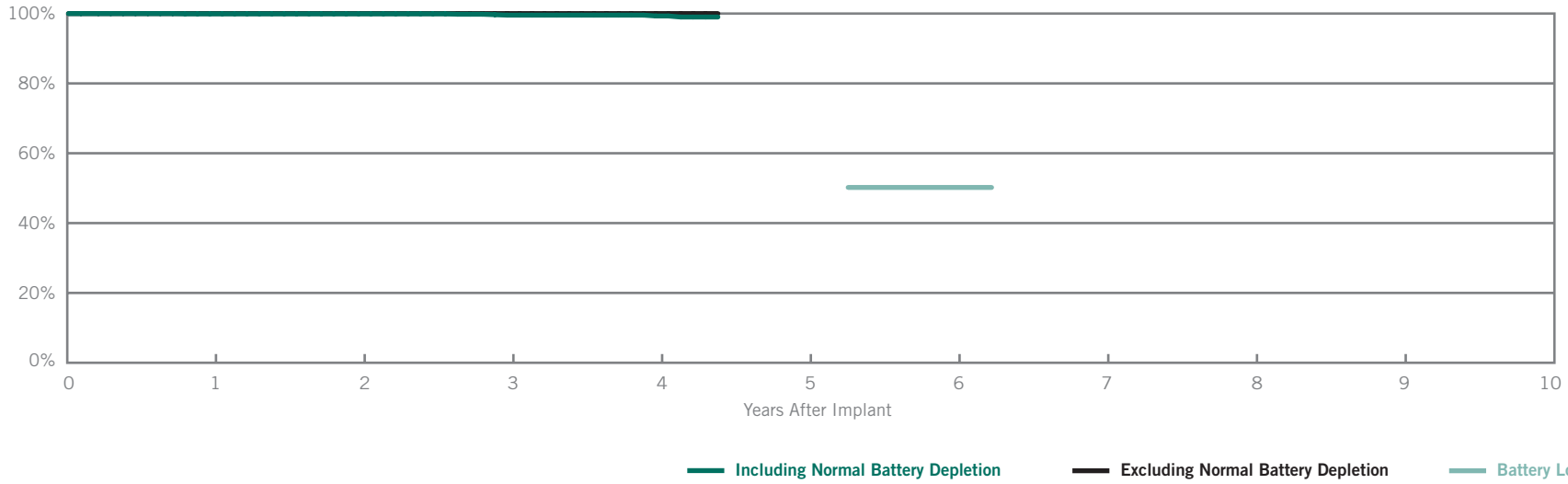
Year	1	2	3	at 38 months						
Survival Probability	99.94%	99.94%	99.94%	99.94%						
± 1 standard error	0.02%	0.02%	0.02%	0.02%						

Pulse Generators

Integrity® ADx SR (Model 5160)

US Market Release	May 2003	Normal Battery Depletion	9
Registered US Implants	3,395	Malfunctions	0
Estimated Active US Implants	2,019	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	at 53 months					
Survival Probability	99.93%	99.93%	99.55%	99.31%	98.53%					
± 1 standard error	0.05%	0.05%	0.13%	0.16%	0.51%					
Sample Size	3400	2600	1900	1200	100					

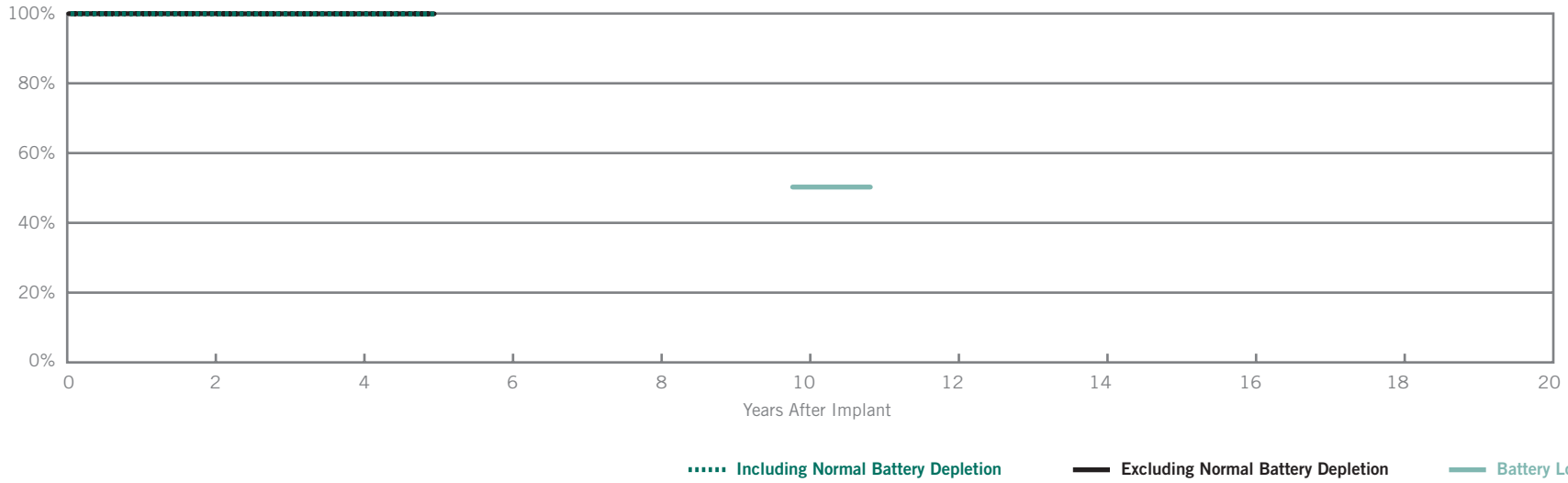
Excluding Normal Battery Depletion

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

Verity® ADx XL SR (Model 5156); Verity® ADx XL SR M/S (Model 5157M/S); Verity® ADx XL SC (Model 5056)

US Market Release	May 2003	Normal Battery Depletion	3
Registered US Implants	13,464	Malfunctions	4
Estimated Active US Implants	9,477	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	10.2 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	2	4	at 60 months							
Survival Probability	99.94%	99.87%	99.87%							
± 1 standard error	0.02%	0.04%	0.04%							
Sample Size	9300	3400	1400							

Excluding Normal Battery Depletion

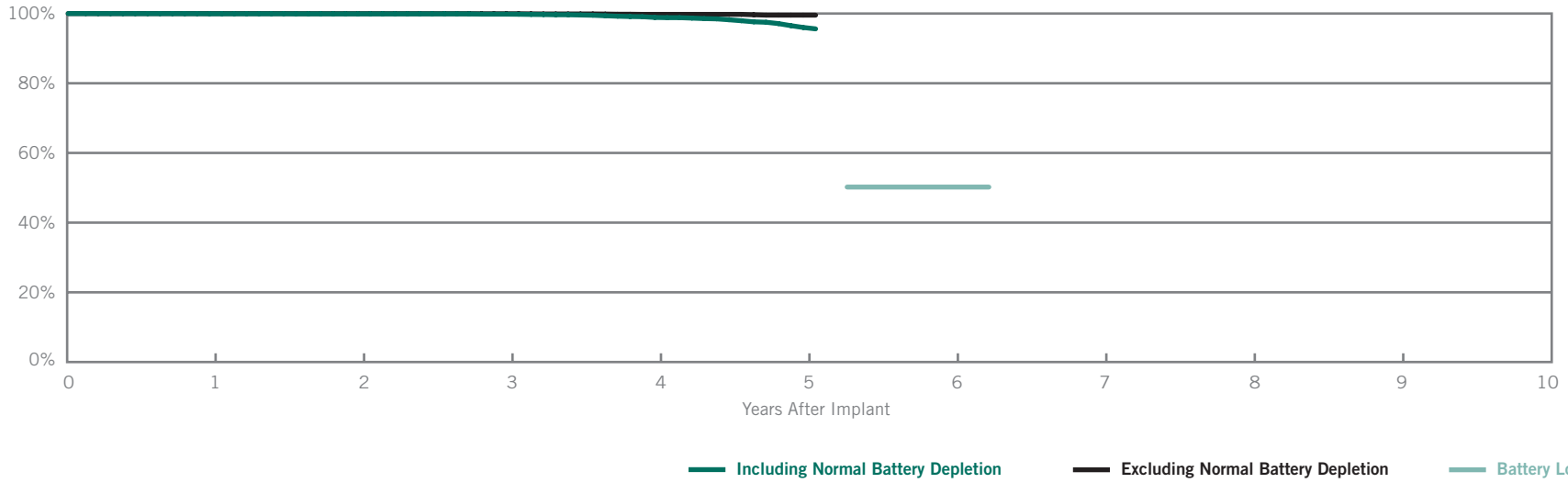
Year	2	4	at 60 months							
Survival Probability	99.96%	99.93%	99.93%							
± 1 standard error	0.02%	0.03%	0.03%							

Pulse Generators

Identity® ADx SR (Model 5180)

US Market Release	May 2003	Normal Battery Depletion	65
Registered US Implants	19.515	Malfunctions	11
Estimated Active US Implants	12,120	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	11
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.94%	99.91%	99.82%	98.88%	96.00%	95.60%				
± 1 standard error	0.01%	0.03%	0.04%	0.12%	0.39%	0.44%				
Sample Size	18900	14300	10500	6100	2500	2200				

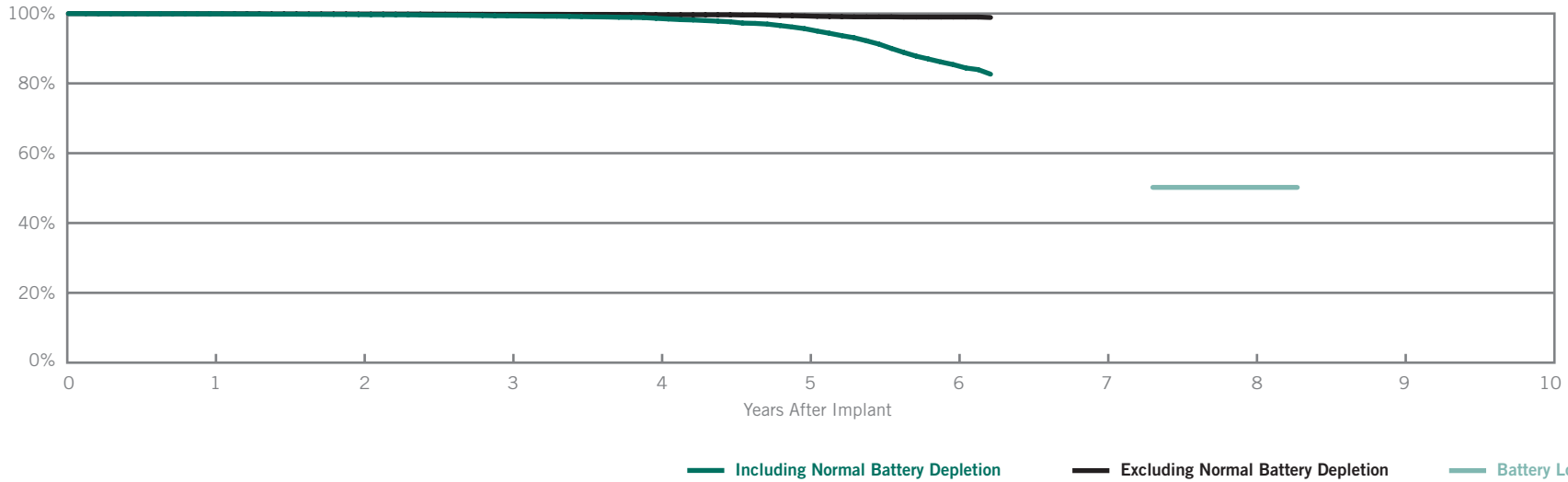
Excluding Normal Battery Depletion

Year	1	2	3	4	5	at 61 months				
Survival Probability	99.98%	99.96%	99.94%	99.76%	99.54%	99.54%				
± 1 standard error	0.01%	0.02%	0.02%	0.06%	0.13%	0.13%				

Identity® SR (Model 5172)

US Market Release	November 2001	Normal Battery Depletion	361
Registered US Implants	21,878	Malfunctions	43
Estimated Active US Implants	8,844	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	7.8 Years	Malfunctions w/o Compromised Therapy (1 related to Advisory)	42
		Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.92%	99.71%	99.36%	98.64%	95.67%	85.37%	82.64%			
± 1 standard error	0.02%	0.04%	0.07%	0.10%	0.22%	0.54%	0.62%			
Sample Size	21800	17500	14300	11000	7600	4200	3300			

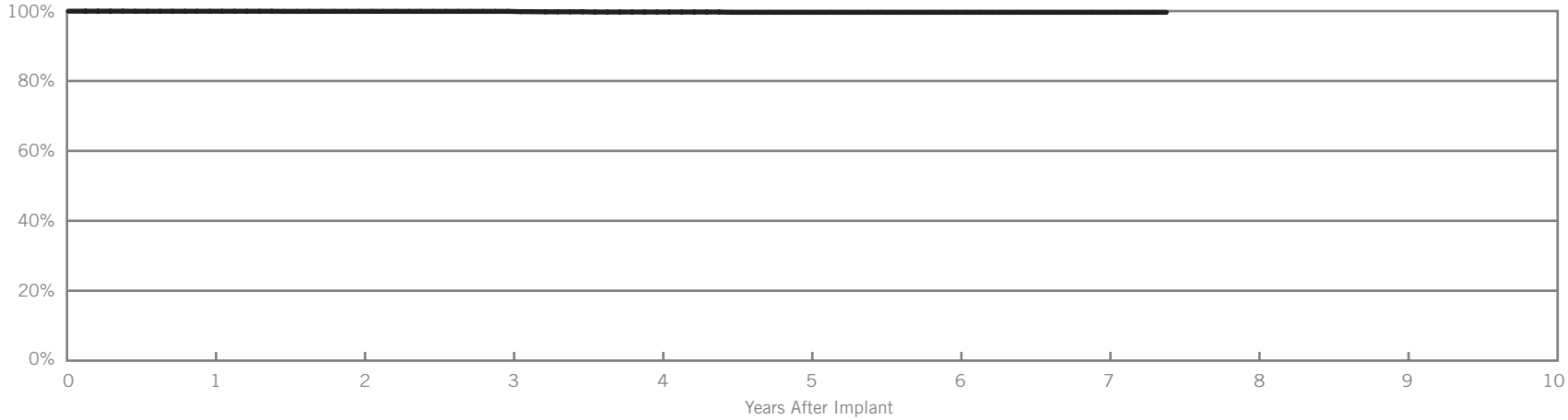
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	at 75 months			
Survival Probability	99.95%	99.87%	99.78%	99.67%	99.31%	99.00%	98.88%			
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.08%	0.13%	0.13%			

Pulse Generators

Microny® (Models 2425T, 2525T & 2535K)	
US Market Release	April 2001
Registered US Implants	6,266
Estimated Longevity	7.5 Years
Number of Advisories	None

Survival from Returns and Complaints

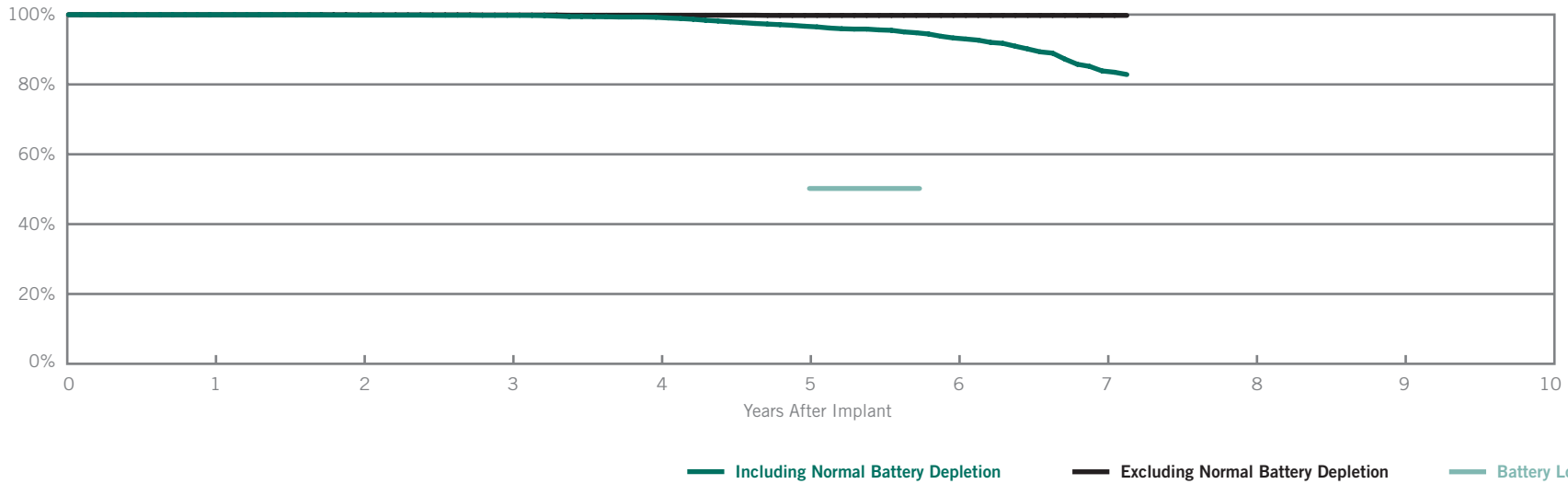


Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.95%	99.92%	99.92%	99.72%	99.64%	99.64%	99.64%	99.64%		
± 1 standard error	0.03%	0.04%	0.04%	0.11%	0.13%	0.13%	0.13%	0.13%		
Sample Size	4000	2900	2100	1400	900	500	200	100		

Integrity® µ SR (Model 5136)

US Market Release	December 2000	Normal Battery Depletion	236
Registered US Implants	11,963	Malfunctions	8
Estimated Active US Implants	2,859	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.3 Years	Malfunctions w/o Compromised Therapy	8
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.97%	99.85%	99.79%	99.23%	96.67%	93.31%	83.87%	82.84%		
± 1 standard error	0.02%	0.04%	0.05%	0.10%	0.24%	0.38%	0.76%	0.83%		
Sample Size	11900	9500	8000	6600	5200	3700	2100	1900		

Excluding Normal Battery Depletion

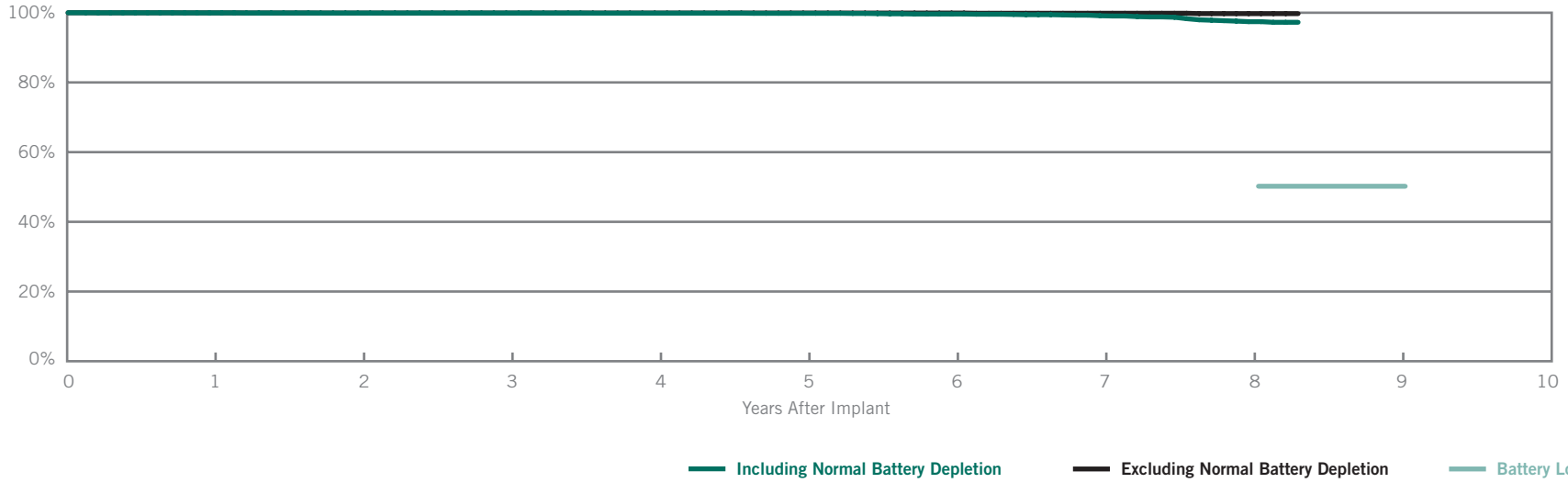
Year	1	2	3	4	5	6	7	at 86 months		
Survival Probability	99.96%	99.91%	99.88%	99.82%	99.77%	99.77%	99.77%	99.77%		
± 1 standard error	0.02%	0.03%	0.04%	0.05%	0.06%	0.06%	0.06%	0.06%		

Pulse Generators

Integrity® SR (Model 5142)

US Market Release	April 2000	Normal Battery Depletion	29
Registered US Implants	10,492	Malfunctions	6
Estimated Active US Implants	3,636	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	5
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.96%	99.91%	99.91%	99.87%	99.83%	99.63%	99.14%	97.44%	97.26%	
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.09%	0.14%	0.33%	0.36%	
Sample Size	10500	8700	7500	6400	5300	4300	3200	2000	1600	

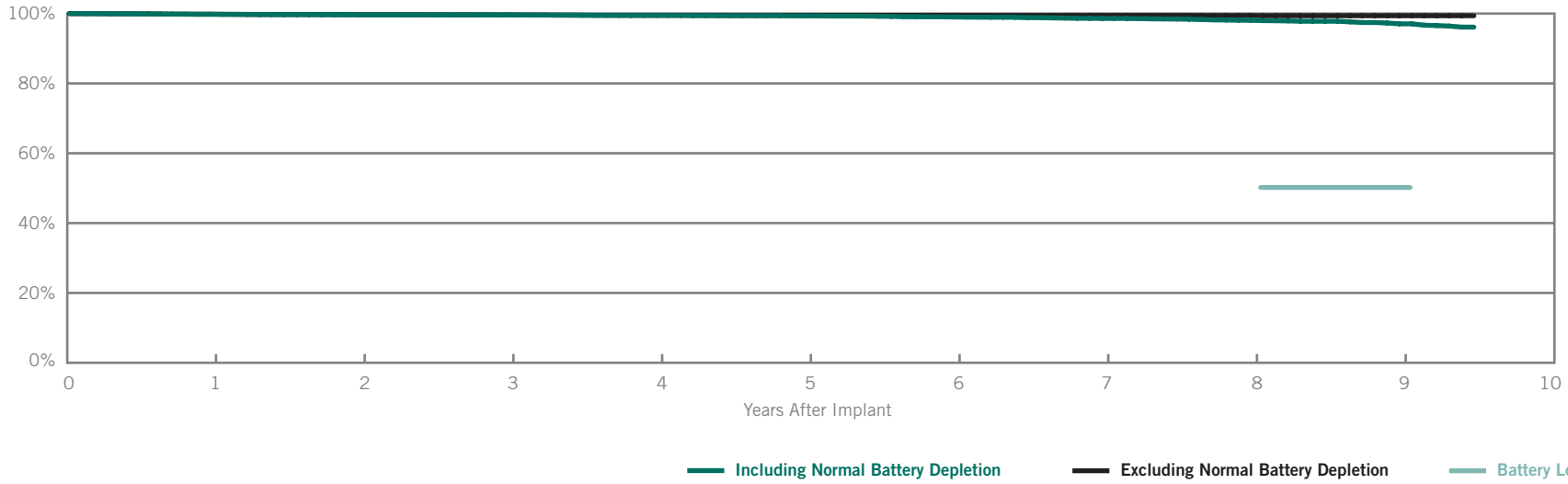
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	at 100 months	
Survival Probability	99.96%	99.91%	99.91%	99.91%	99.91%	99.91%	99.85%	99.74%	99.74%	
± 1 standard error	0.02%	0.03%	0.03%	0.03%	0.03%	0.03%	0.05%	0.09%	0.09%	

Affinity® SR (Models 5130 & 5131)

US Market Release	(5130) January 1999	Normal Battery Depletion	93
	(5131) June 1999	Malfunctions	59
Registered US Implants	28,668	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Active US Implants	7,923	Malfunctions w/o Compromised Therapy (17 related to Advisory)	55
Estimated Longevity	8.6 Years	Number of Advisories (see pages 230-235)	One

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.81%	99.68%	99.61%	99.46%	99.34%	99.02%	98.60%	98.06%	97.06%	96.12%
± 1 standard error	0.03%	0.04%	0.04%	0.05%	0.06%	0.08%	0.11%	0.14%	0.21%	0.33%
Sample Size	28600	23100	19700	16700	14100	11700	9100	6500	3800	2400

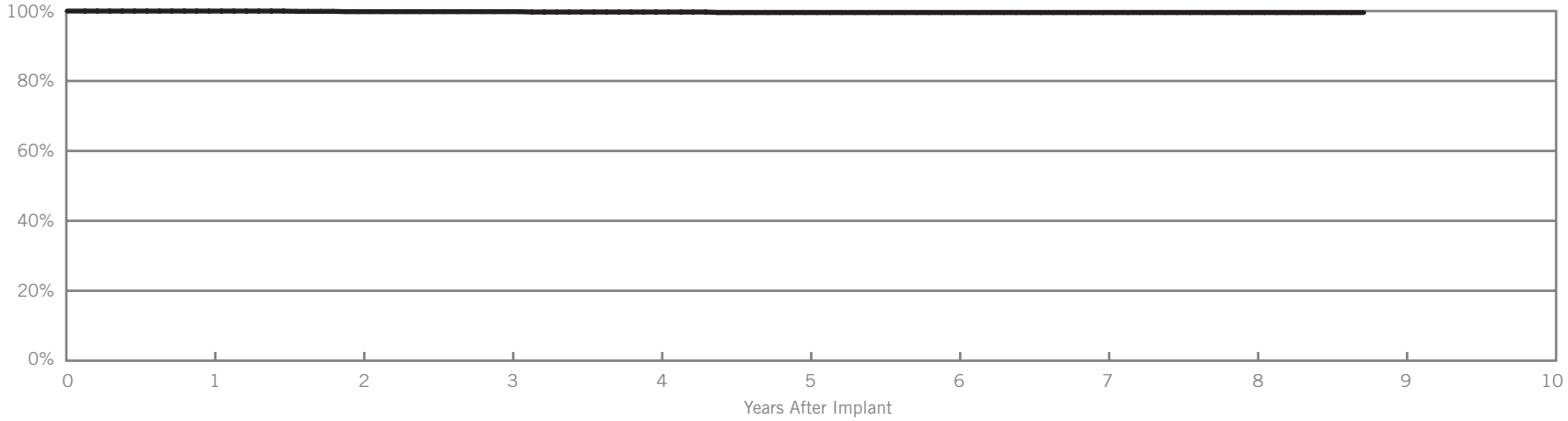
Excluding Normal Battery Depletion

Year	1	2	3	4	5	6	7	8	9	at 114 months
Survival Probability	99.81%	99.68%	99.61%	99.52%	99.49%	99.48%	99.45%	99.42%	99.38%	99.38%
± 1 standard error	0.03%	0.04%	0.04%	0.05%	0.05%	0.05%	0.05%	0.06%	0.07%	0.07%

Pulse Generators

Regency® SC+ (Models 2400L & 2402L)	
US Market Release	May 1998
Registered US Implants	2,062
Estimated Longevity	9.1 Years
Number of Advisories	None

Survival from Returns and Complaints

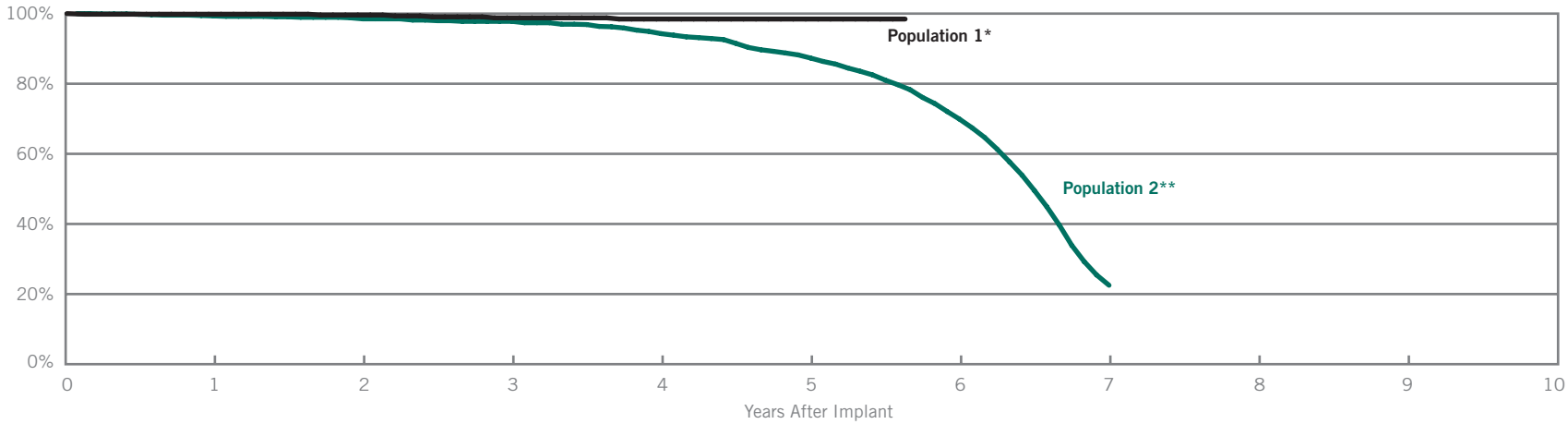


Year	1	2	3	4	5	6	7	8	at 105 months	
Survival Probability	100.00%	99.83%	99.83%	99.72%	99.57%	99.57%	99.57%	99.57%	99.57%	
± 1 standard error	0.00%	0.12%	0.12%	0.16%	0.22%	0.22%	0.22%	0.22%	0.22%	
Sample Size	1500	1100	900	700	600	500	400	300	200	

Tempo™ V (Model 1102); Tempo™ VR (Model 1902)

Population 1*		Population 2**	
US Market Release	August 1997	US Market Release	August 1997
Registered US Implants	604	Registered US Implants	1,061
Estimated Longevity	5.3 Years	Estimated Longevity	5.3 Years
Number of Advisories	None	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Population 1*

Year	1	2	3	4	5	at 68 months				
Survival Probability	99.83%	99.60%	98.79%	98.45%	98.45%	98.45%				
± 1 standard error	0.17%	0.29%	0.55%	0.64%	0.64%	0.64%				
Sample Size	500	400	400	300	200	200				

Population 2**

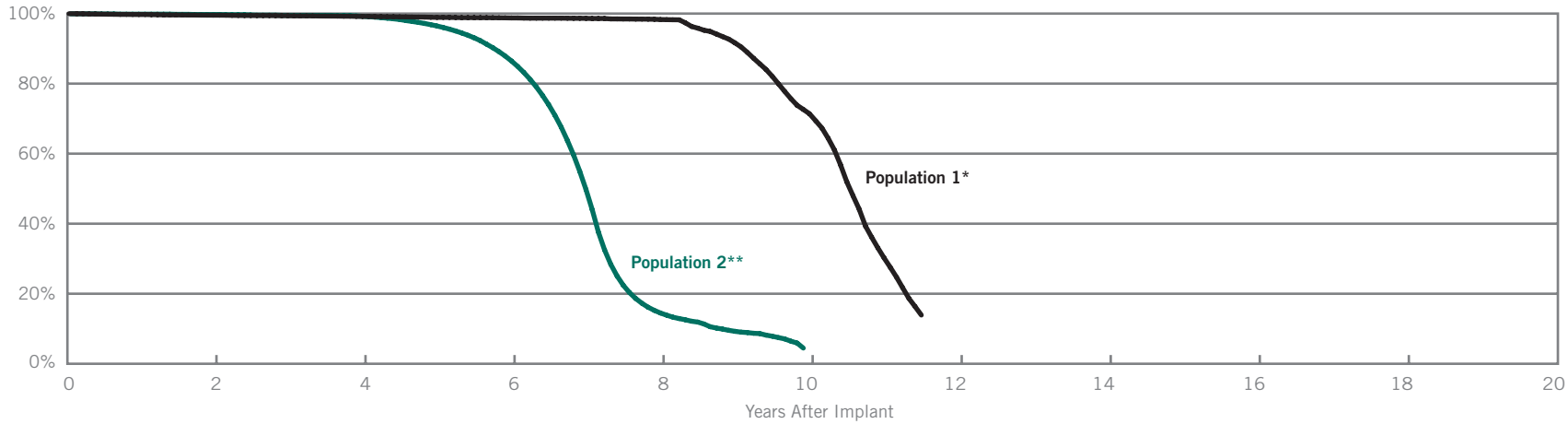
Year	1	2	3	4	5	6	7			
Survival Probability	99.34%	98.50%	97.79%	94.27%	87.32%	69.84%	22.51%			
± 1 standard error	0.25%	0.38%	0.56%	0.87%	1.20%	1.46%	1.65%			
Sample Size	900	700	500	400	300	200	200			

Pulse Generators

Trilogy™ SR+ (Models 2260 & 2264)

Population 1*		Population 2**	
US Market Release	March 1997	US Market Release	March 1997
Registered US Implants	16,082	Registered US Implants	2,779
Estimated Longevity	7.7 Years	Estimated Longevity	7.7 Years
Number of Advisories	None	Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints



Population 1*

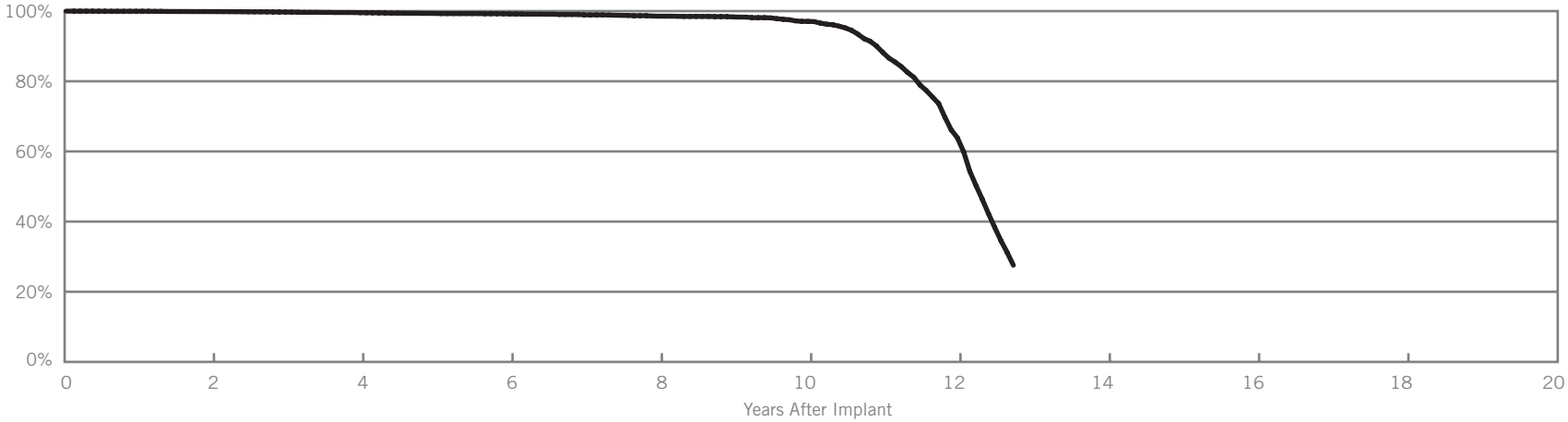
Year	2	4	6	8	10	at 138 months				
Survival Probability	99.54%	99.19%	98.76%	98.30%	71.38%	13.91%				
± 1 standard error	0.06%	0.08%	0.11%	0.15%	0.86%	0.91%				
Sample Size	11200	7900	5500	3700	1600	200				

Population 2**

Year	2	4	6	8	at 119 months					
Survival Probability	99.74%	99.23%	86.47%	14.49%	4.48%					
± 1 standard error	0.11%	0.18%	0.23%	0.49%	2.34%					
Sample Size	1800	1300	900	600	200					

Trilogy™ SR (Model 2250)	
US Market Release	June 1995
Registered US Implants	12,414
Estimated Longevity	7.7 Years
Number of Advisories (see pages 230-235)	Two

Survival from Returns and Complaints

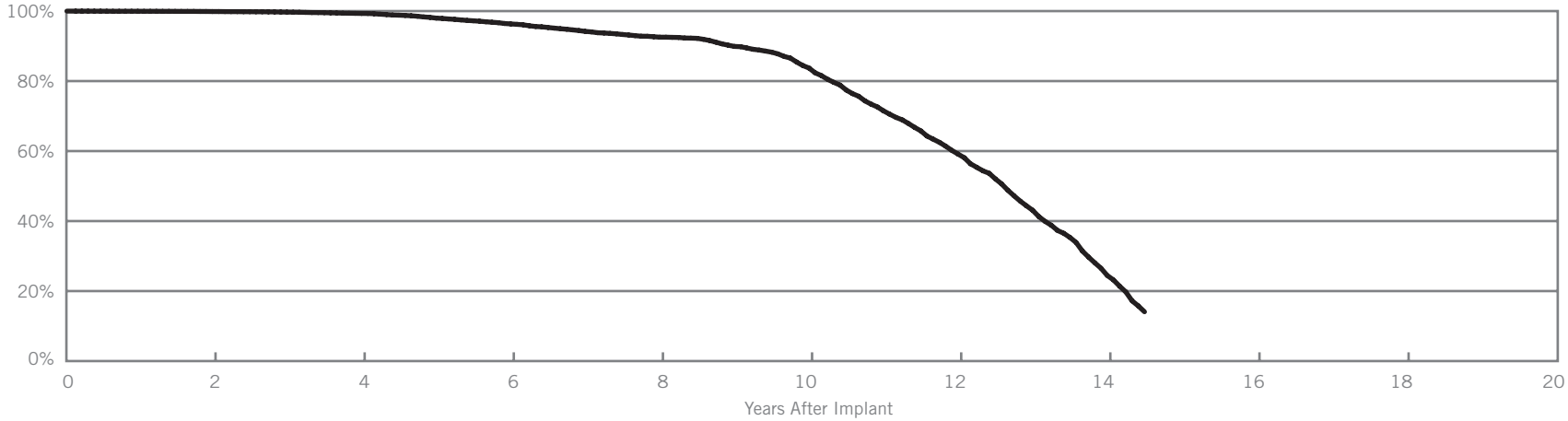


Year	2	4	6	8	10	12	at 153 months			
Survival Probability	99.86%	99.54%	99.20%	98.56%	97.07%	63.90%	27.56%			
± 1 standard error	0.04%	0.07%	0.11%	0.17%	0.34%	1.58%	1.73%			
Sample Size	8900	6400	4300	2800	1400	500	200			

Pulse Generators

Solus® II (Models 2006 & 2007)	
US Market Release	February 1993
Registered US Implants	32,331
Estimated Longevity	6.0 Years
Number of Advisories	None

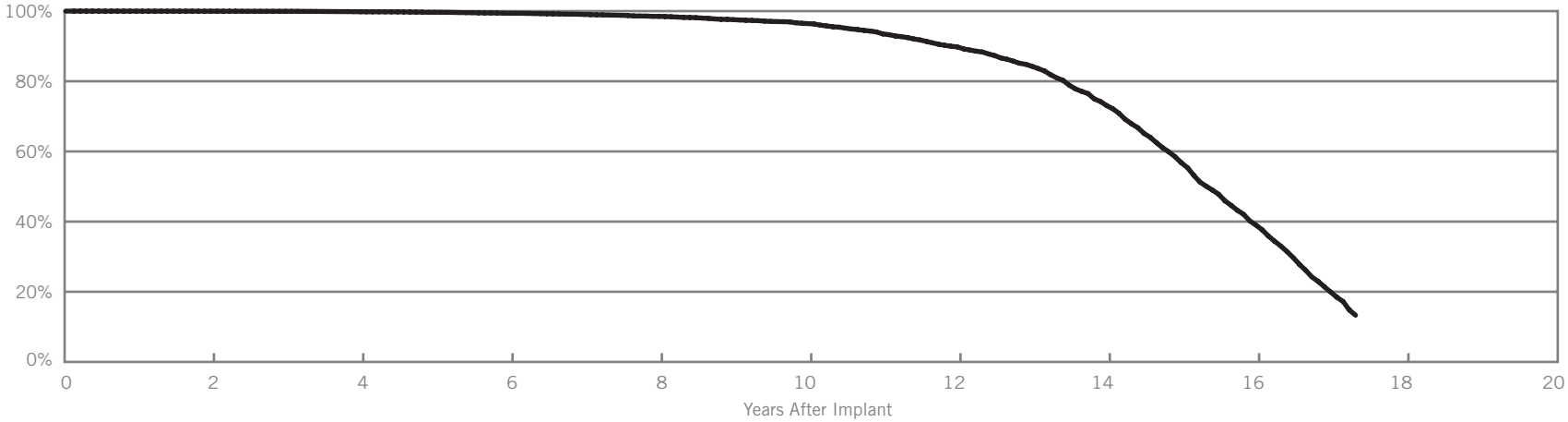
Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	at 174 months		
Survival Probability	99.87%	99.32%	96.33%	92.54%	83.73%	59.14%	24.46%	14.08%		
± 1 standard error	0.02%	0.06%	0.16%	0.28%	0.62%	1.08%	1.11%	0.95%		
Sample Size	23200	16600	9800	3600	1800	1000	400	200		

Phoenix™ II (Models 2005, 2008 & 2009)	
US Market Release	July 1990
Registered US Implants	26,790
Estimated Longevity	8.3 Years
Number of Advisories	None

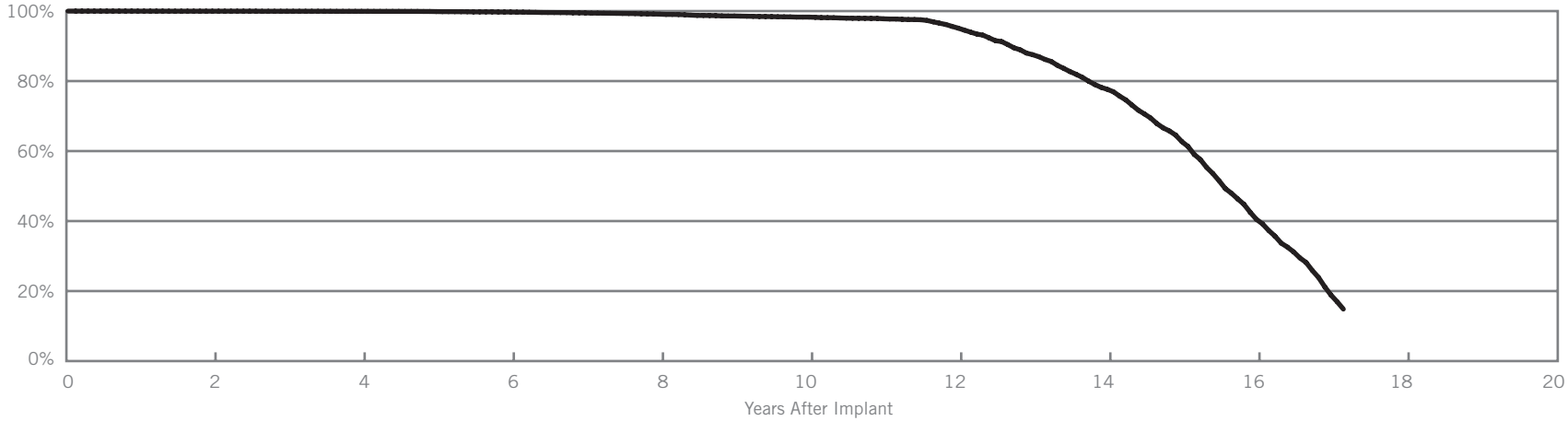
Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	16	at 208 months	
Survival Probability	99.97%	99.81%	99.38%	98.49%	96.44%	89.79%	73.07%	38.99%	13.31%	
± 1 standard error	0.01%	0.03%	0.07%	0.14%	0.26%	0.53%	0.93%	1.20%	0.93%	
Sample Size	17800	12300	8300	5400	3300	2100	1300	600	200	

Solus® (Models 2002 & 2003)	
US Market Release	June 1990
Registered US Implants	23,867
Estimated Longevity	8.3 Years
Number of Advisories	None

Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	16	at 206 months	
Survival Probability	99.97%	99.93%	99.73%	99.11%	98.28%	95.13%	77.65%	40.51%	14.85%	
± 1 standard error	0.01%	0.02%	0.05%	0.09%	0.15%	0.33%	0.87%	1.27%	1.05%	
Sample Size	17900	13600	9900	7100	4600	2600	1400	500	200	

Summary & Longevity Information

Pulse Generators

Single-Chamber

St. Jude Medical™

More control. Less risk.

Malfunction and Normal Battery Depletion Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Malfunctions w/ Compromised Therapy	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (under advisory)	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion
5626	Zephyr® XL SR	May-07	11840	11270	0	2	0	0	2	0
5620	Zephyr® SR	Mar-07	5728	5360	0	0	0	0	0	0
5610	Victory® SR	Dec-05	12342	10153	0	2	0	0	2	0
5160	Integrity® Adx SR	May-03	3395	2019	0	0	0	0	0	9
5156/5157/5056	Verity® Adx XL SR/ SR(M/S)/SC	May-03	13464	9477	1	3	0	0	4	3
5180	Identity® Adx SR	May-03	19515	12120	0	9	0	2	11	65
5172	Identity® SR	Nov-01	21878	8844	1	37	1	4	43	361
5136	Integrity® µ SR	Dec-00	11963	2859	0	8	0	0	8	236
5142	Integrity® SR	Apr-00	10492	3636	1	5	0	0	6	29
5130/5131	Affinity® SR	Jan-99/Jun-99	28668	7923	4	38	17	0	59	93

Pulse Generators

Including Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
5626	Zephyr® XL SR	99.95%									
5620	Zephyr® SR	100.00%									
5610	Victory® SR	99.94%	99.94%	99.94%							
5160	Integrity® Adx SR	99.93%	99.93%	99.55%	99.31%						
5156/5157/5056	Verity® Adx XL SR/ SR(M/S)/SC	99.96%	99.94%	99.87%	99.87%	99.87%					
5180	Identity® Adx SR	99.94%	99.91%	99.82%	98.88%	96.00%					
5172	Identity® SR	99.92%	99.71%	99.36%	98.64%	95.67%	85.37%				
5136	Integrity® µ SR	99.97%	99.85%	99.79%	99.23%	96.67%	93.31%	83.87%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.87%	99.83%	99.63%	99.14%	97.44%		
5130/5131	Affinity® SR	99.81%	99.68%	99.61%	99.46%	99.34%	99.02%	98.60%	98.06%	97.06%	

Excluding Normal Battery Depletion Summary Information

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
5626	Zephyr® XL SR	99.95%									
5620	Zephyr® SR	100.00%									
5610	Victory® SR	99.94%	99.94%	99.94%							
5160	Integrity® Adx SR	100.00%	100.00%	100.00%	100.00%						
5156/5157/5056	Verity® Adx XL SR/ SR(M/S)/SC	99.96%	99.96%	99.93%	99.93%	99.93%					
5180	Identity® Adx SR	99.98%	99.96%	99.94%	99.76%	99.54%					
5172	Identity® SR	99.95%	99.87%	99.78%	99.67%	99.31%	99.00%				
5136	Integrity® µ SR	99.96%	99.91%	99.88%	99.82%	99.77%	99.77%	99.77%			
5142	Integrity® SR	99.96%	99.91%	99.91%	99.91%	99.91%	99.91%	99.85%	99.74%		
5130/5131	Affinity® SR	99.81%	99.68%	99.61%	99.52%	99.49%	99.48%	99.45%	99.42%	99.38%	

Pacing Leads

Bipolar & Unipolar

Active & Passive Fixation

St. Jude Medical™

More control. Less risk.

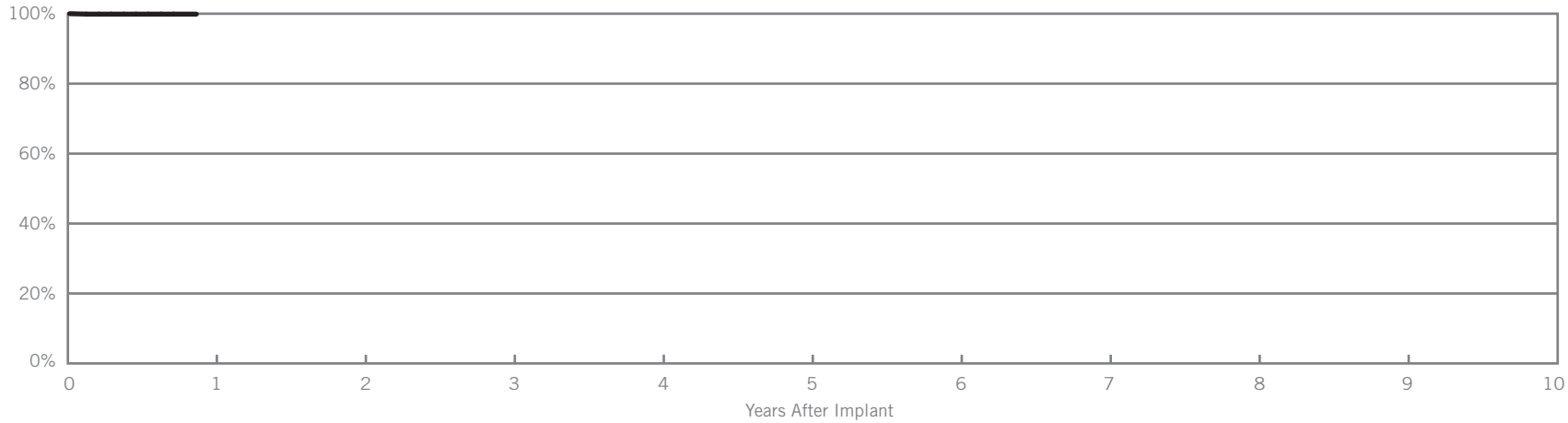
Pacing Leads

IsoFlex® Optim® (Model 1944)	
US Market Release	March 2008
Registered US Implants	1,012
Estimated Active US Implants	970
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	3	0.30%	1	0.10%
Failure to Capture	0	0.00%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	0.10%	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	**4**	**0.40%**	**1**	**0.10%**
Total Returned for Analysis	**1**		**0**	

Lead Malfunctions		
Type	**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%**

Survival from Returns and Complaints



Year	at 10 months										
Survival Probability	99.88%										
± 1 standard error	0.13%										
Sample Size	100										

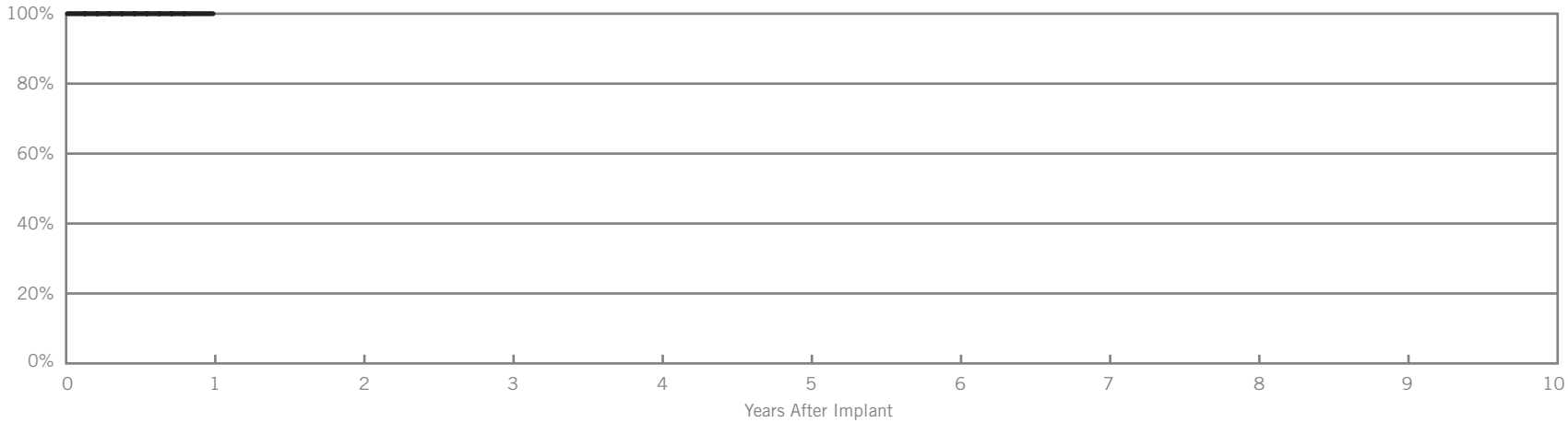
**Optim® insulation is a copolymer of silicone and polyurethane.*

IsoFlex® Optim® (Model 1948)	
US Market Release	March 2008
Registered US Implants	3,508
Estimated Active US Implants	3,440
Insulation	Optim*
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.03%	0	0.00%
Failure to Capture	1	0.03%	0	0.00%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	**2**	**0.06%**	**0**	**0.00%**
Total Returned for Analysis	**1**		**0**	

Lead Malfunctions		
Type	**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%**

Survival from Returns and Complaints



Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	1800									

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

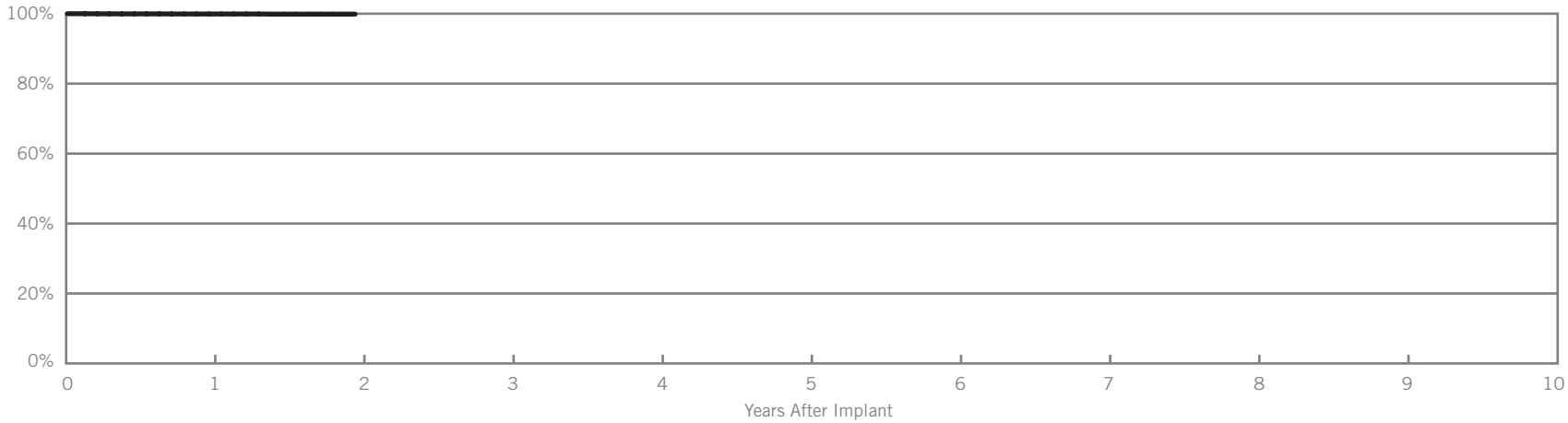
Pacing Leads

OptiSense® (Models 1699T & 1699TC)	
US Market Release	May 2007
Registered US Implants	14,852
Estimated Active US Implants	14,161
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	3	0.02%	4	0.03%
Failure to Capture	3	0.02%	3	0.02%
Oversensing	2	0.01%	1	0.01%
Failure to Sense	6	0.04%	1	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	**0.01%**	0	0.00%
Total	**15**	**0.10%**	**10**	**0.07%**
Total Returned for Analysis	**9**		**4**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.01%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.01%
Total	**3**	**0.02%**

Survival from Returns and Complaints



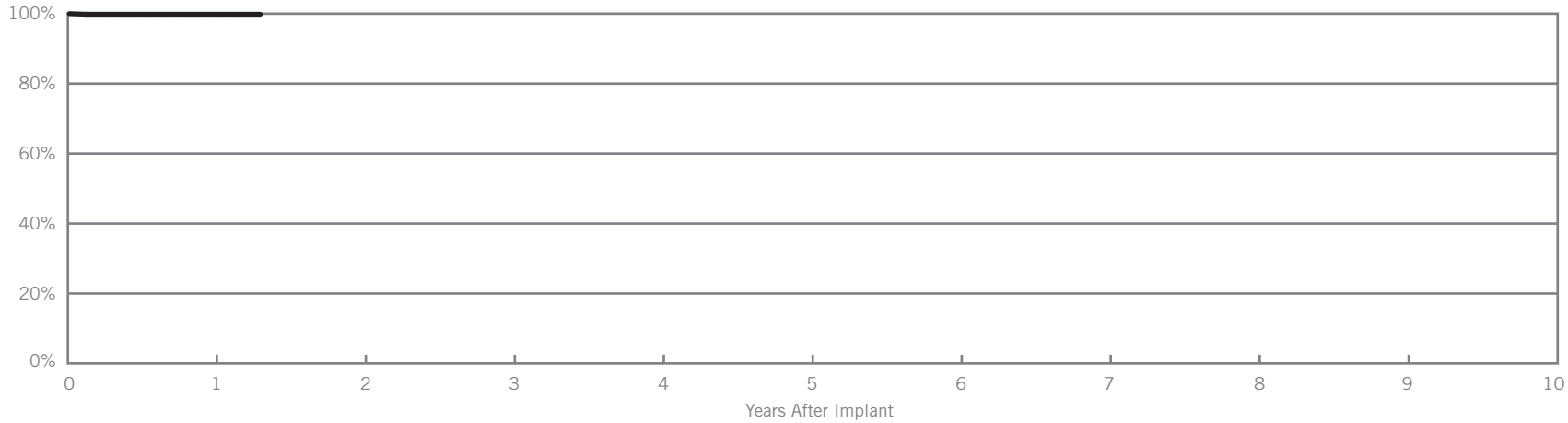
Year	1	at 23 months								
Survival Probability	99.92%	99.88%								
± 1 standard error	0.03%	0.05%								
Sample Size	10600	300								

OptiSense® (Models 1699T & 1699TC)	
US Market Release	May 2007
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	642
Cumulative Months of Follow-up	5733

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.16%

Survival from SCORE Registry



Year	1	at 16 months								
Survival Probability	99.83%	99.83%								
± 1 standard error	0.17%	0.17%								
Sample Size	400	61								

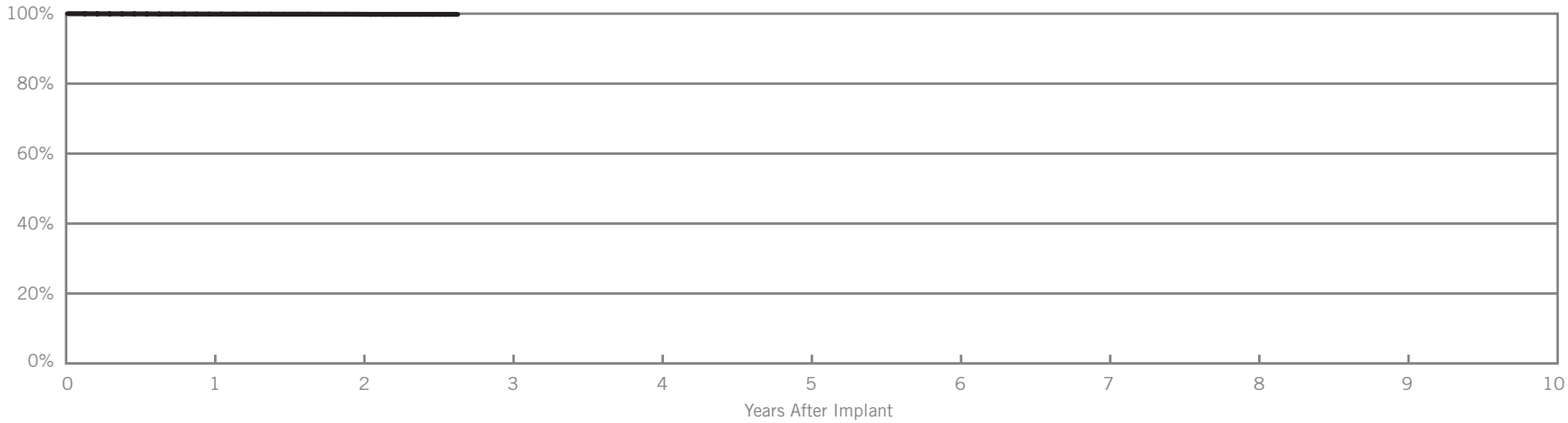
Pacing Leads

Tendril® ST Optim® (Models 1888T & 1888TC)	
US Market Release	June 2006
Registered US Implants	110,409
Estimated Active US Implants	104,550
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	18	0.02%	10	0.01%
Conductor Fracture	4	<0.01%	3	<0.01%
Lead Dislodgement	57	0.05%	52	0.05%
Failure to Capture	45	0.04%	24	0.02%
Oversensing	6	0.01%	13	0.01%
Failure to Sense	5	<0.01%	2	<0.01%
Insulation Breach	3	<0.01%	5	<0.01%
Abnormal Pacing Impedance	5	<0.01%	6	0.01%
Extracardiac Stimulation	3	<0.01%	2	<0.01%
Other	11	0.01%	9	0.01%
Total	**157**	**0.14%**	**126**	**0.11%**
Total Returned for Analysis	**42**		**71**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	3	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	40	0.04%
Total	**43**	**0.04%**

Survival from Returns and Complaints



Year	1	2	at 32 months							
Survival Probability	99.89%	99.84%	99.81%							
± 1 standard error	0.01%	0.02%	0.03%							
Sample Size	79700	26100	200							

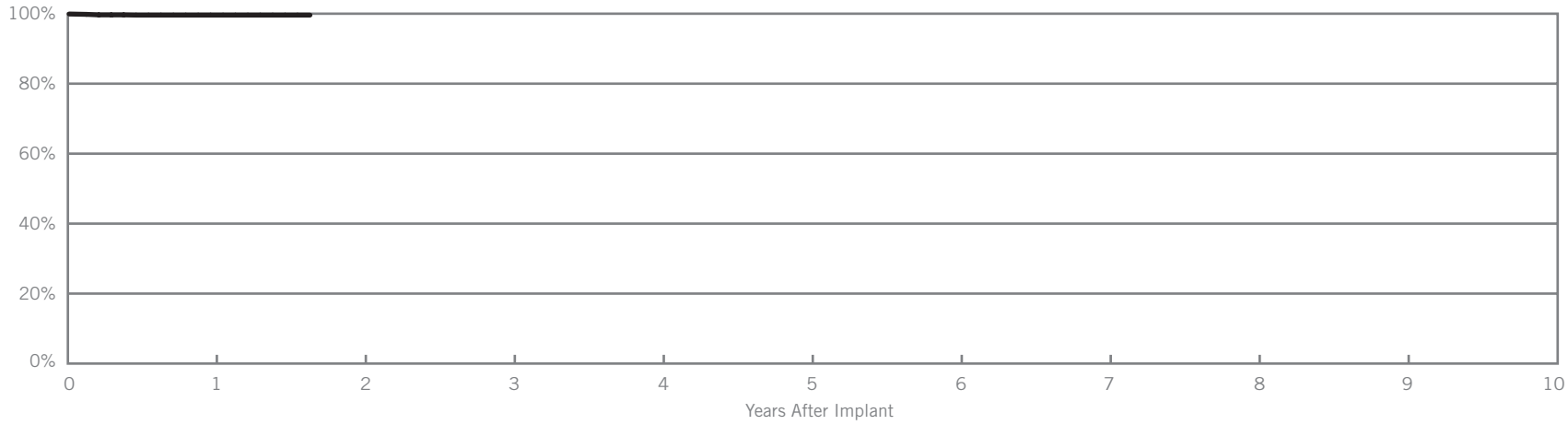
**Optim® insulation is a copolymer of silicone and polyurethane.*

Tendril® ST Optim® (Models 1888T & 1888TC)	
US Market Release	June 2006
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	2231
Cumulative Months of Follow-up	19553

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	6	0.27%
Abnormal Pacing Impedance	1	0.04%
Extracardiac Stimulation	1	0.04%

Survival from SCORE Registry



Year	1	at 20 months								
Survival Probability	99.60%	99.60%								
± 1 standard error	0.14%	0.14%								
Sample Size	1400	63								

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

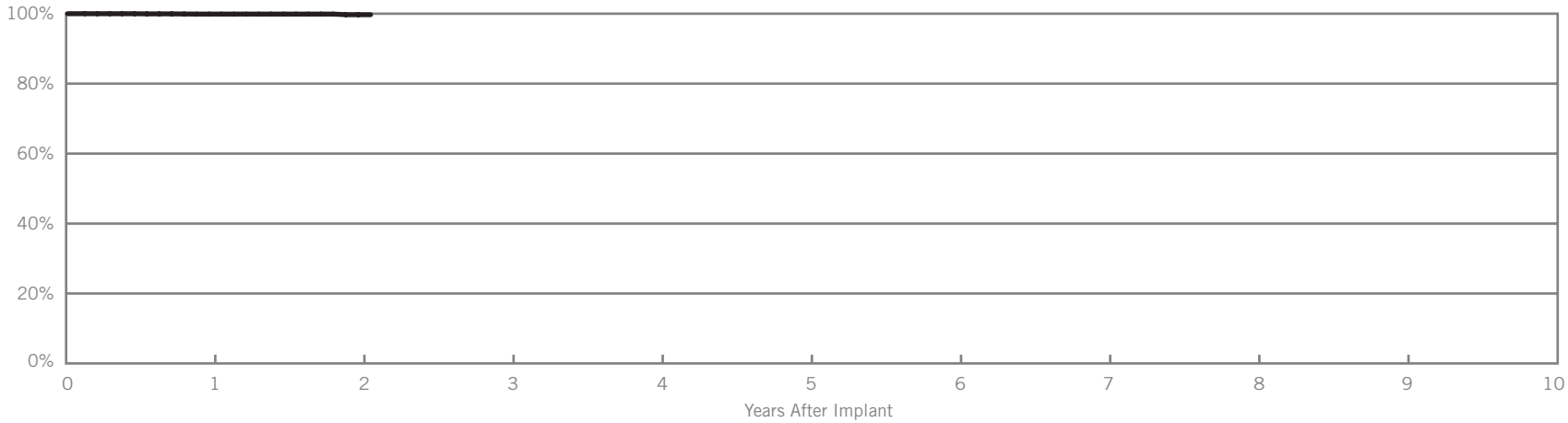
Pacing Leads

Tendril® ST Optim® (Models 1882T & 1882TC)	
US Market Release	June 2006
Registered US Implants	8,094
Estimated Active US Implants	7,715
Insulation	Optim*
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	1	0.01%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	9	0.11%	4	0.05%
Failure to Capture	4	0.05%	0	0.00%
Oversensing	2	0.02%	1	0.01%
Failure to Sense	1	0.01%	1	0.01%
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	2	0.02%	1	0.01%
Total	**19**	**0.23%**	**7**	**0.09%**
Total Returned for Analysis	**4**		**4**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.05%
Total	**4**	**0.05%**

Survival from Returns and Complaints



Year	1	2	at 25 months							
Survival Probability	99.89%	99.71%	99.71%							
± 1 standard error	0.05%	0.18%	0.18%							
Sample Size	5600	1700	200							

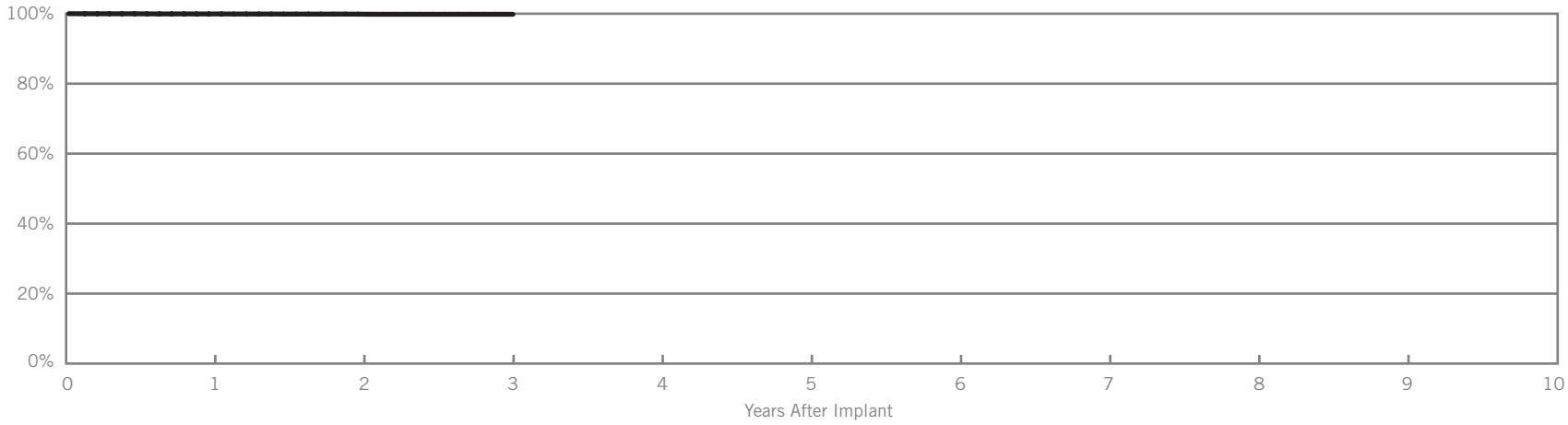
**Optim® insulation is a copolymer of silicone and polyurethane.*

Tendril® (Models 1782T & 1782TC)	
US Market Release	February 2006
Registered US Implants	11,502
Estimated Active US Implants	10,347
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	4	0.03%	0	0.00%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	6	0.05%	8	0.07%
Failure to Capture	4	0.03%	7	0.06%
Oversensing	0	0.00%	2	0.02%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.02%	1	0.01%
Extracardiac Stimulation	1	0.01%	0	0.00%
Other	2	0.02%	0	0.00%
Total	**19**	**0.17%**	**19**	**0.17%**
Total Returned for Analysis	**7**		**18**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	1	0.01%
Insulation Breach	2	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.07%
Total	**11**	**0.10%**

Survival from Returns and Complaints



Year	1	2	3							
Survival Probability	99.93%	99.87%	99.84%							
± 1 standard error	0.03%	0.04%	0.05%							
Sample Size	9800	5600	1900							

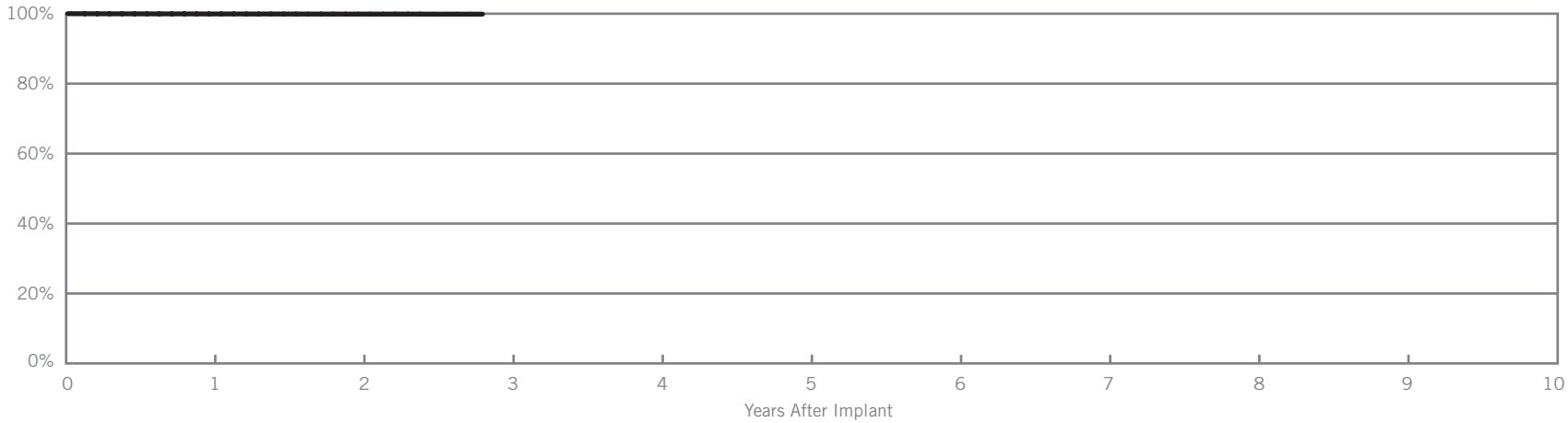
Pacing Leads

Tendril® (Models 1788T & 1788TC)	
US Market Release	February 2006
Registered US Implants	56,282
Estimated Active US Implants	49,793
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	10	0.02%	1	<0.01%
Conductor Fracture	1	<0.01%	2	<0.01%
Lead Dislodgement	31	0.06%	19	0.03%
Failure to Capture	25	0.04%	24	0.04%
Oversensing	1	<0.01%	5	0.01%
Failure to Sense	2	<0.01%	1	<0.01%
Insulation Breach	1	<0.01%	1	<0.01%
Abnormal Pacing Impedance	9	0.02%	5	0.01%
Extracardiac Stimulation	2	<0.01%	1	<0.01%
Other	20	0.04%	4	0.01%
Total	**102**	**0.18%**	**63**	**0.11%**
Total Returned for Analysis	**34**		**41**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	10	0.02%
Crimps, Welds & Bonds	1	<0.01%
Other	4	0.01%
Extrinsic Factors	13	0.02%
Total	**28**	**0.05%**

Survival from Returns and Complaints



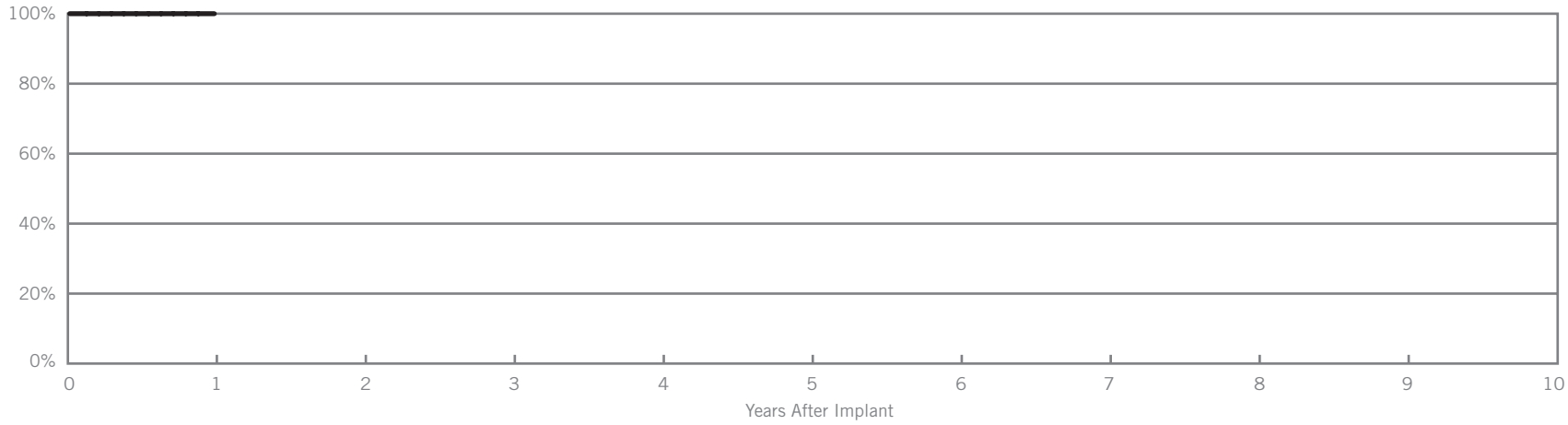
Year	1	2	at 34 months							
Survival Probability	99.93%	99.89%	99.87%							
± 1 standard error	0.01%	0.02%	0.02%							
Sample Size	49900	31200	500							

Tendril® (Models 1788T & 1788TC)	
US Market Release	February 2006
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	182
Cumulative Months of Follow-up	1575

Qualifying Complications
None Reported

Survival from SCORE Registry



Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	54									

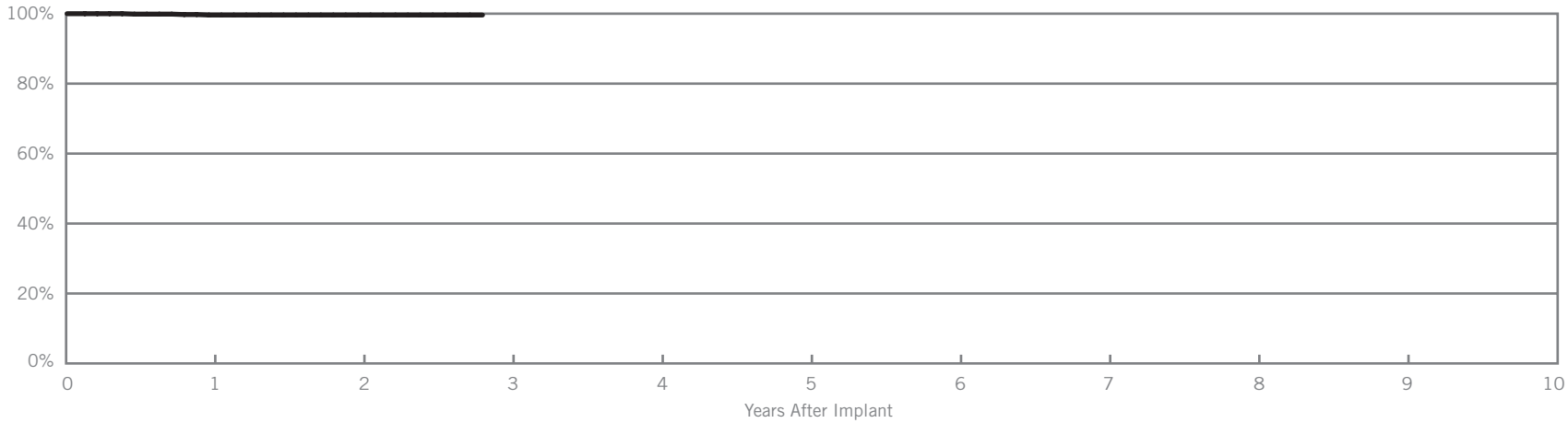
Pacing Leads

IsoFlex® P (Model 1644T)	
US Market Release	April 2005
Registered US Implants	929
Estimated Active US Implants	770
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	0.11%
Lead Dislodgement	1	0.11%	0	0.00%
Failure to Capture	0	0.00%	2	0.22%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.11%	0	0.00%
Total	**2**	**0.22%**	**3**	**0.32%**
Total Returned for Analysis	**1**		**2**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.22%
Total	**2**	**0.22%**

Survival from Returns and Complaints



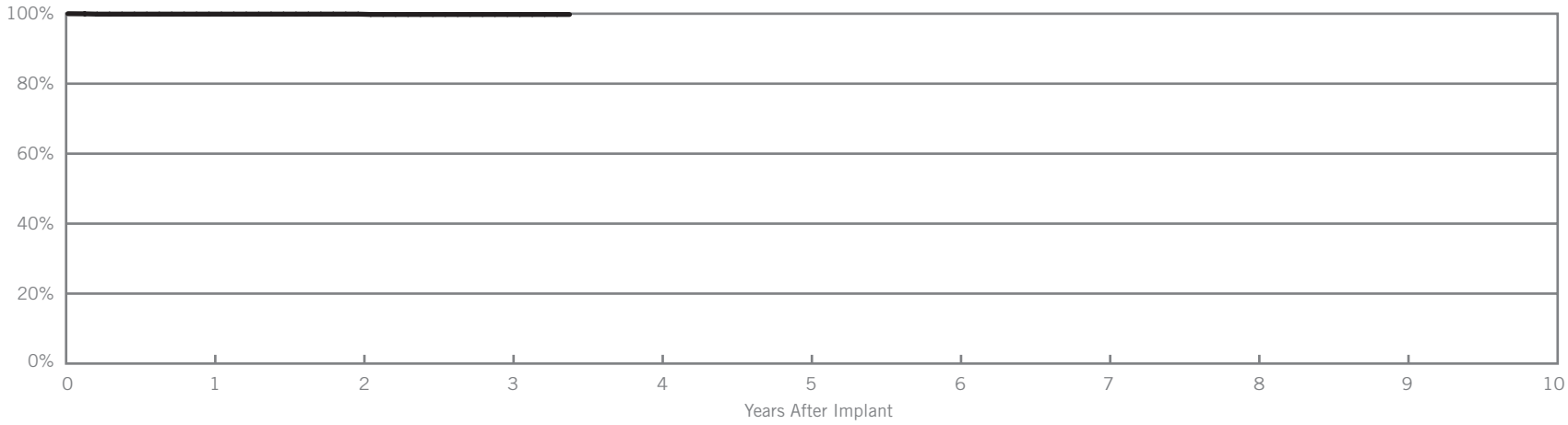
Year	1	2	at 34 months							
Survival Probability	99.62%	99.62%	99.62%							
± 1 standard error	0.17%	0.22%	0.22%							
Sample Size	900	600	100							

IsoFlex® P (Model 1648T)	
US Market Release	April 2005
Registered US Implants	2,720
Estimated Active US Implants	2,272
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.07%	0	0.00%
Failure to Capture	2	0.07%	1	0.04%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	1	0.04%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.04%
Extracardiac Stimulation	1	0.04%	0	0.00%
Other	0	0.00%	2	0.07%
Total	**6**	**0.22%**	**4**	**0.15%**
Total Returned for Analysis	**1**		**3**	

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

Survival from Returns and Complaints



Year	1	2	3	at 41 months						
Survival Probability	99.88%	99.88%	99.78%	99.78%						
± 1 standard error	0.07%	0.07%	0.12%	0.12%						
Sample Size	2500	1600	700	100						

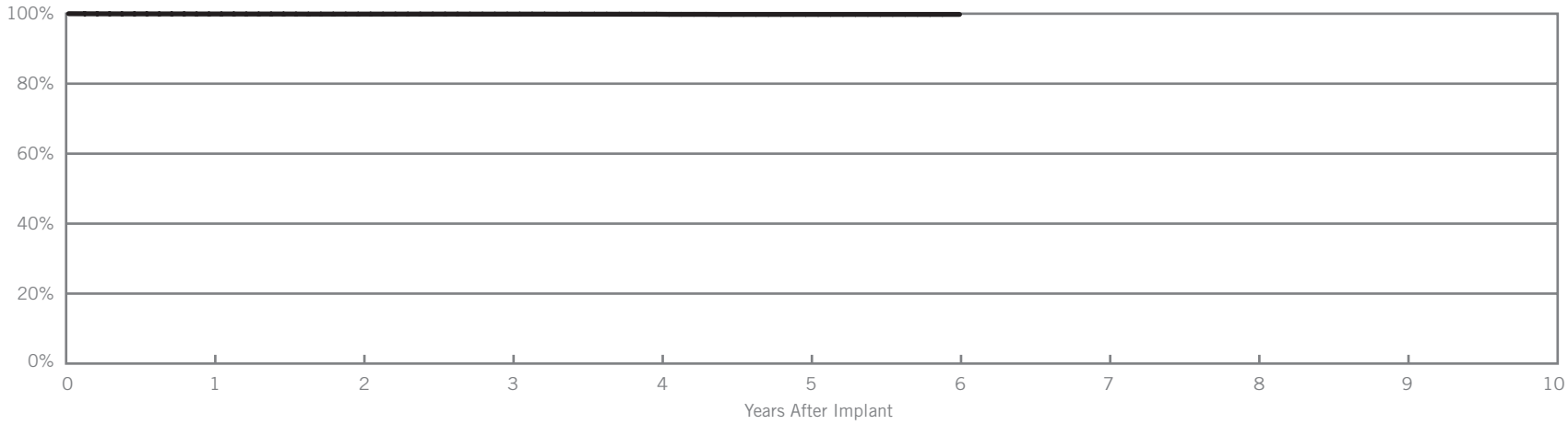
Pacing Leads

IsoFlex® S (Model 1642T)	
US Market Release	May 2002
Registered US Implants	22,082
Estimated Active US Implants	17,744
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	0	0.00%	0	0.00%
Conductor Fracture	0	0.00%	1	<0.01%
Lead Dislodgement	38	0.17%	12	0.05%
Failure to Capture	5	0.02%	7	0.03%
Oversensing	0	0.00%	0	0.00%
Failure to Sense	3	0.01%	2	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	3	0.01%	1	<0.01%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	0	0.00%	1	<0.01%
Total	**50**	0.23%	**24**	**0.11%**
Total Returned for Analysis	**27**		**8**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	0	0.00%
Insulation Breach	1	<0.01%
Crimps, Welds & Bonds	2	0.01%
Other	4	0.02%
Extrinsic Factors	**7**	0.03%
Total	**14**	**0.06%**

Survival from Returns and Complaints



Year	1	2	3	4	5	6				
Survival Probability	99.92%	99.89%	99.88%	99.85%	99.80%	99.80%				
± 1 standard error	0.02%	0.03%	0.03%	0.04%	0.05%	0.05%				
Sample Size	20100	14800	10300	6600	3400	1100				

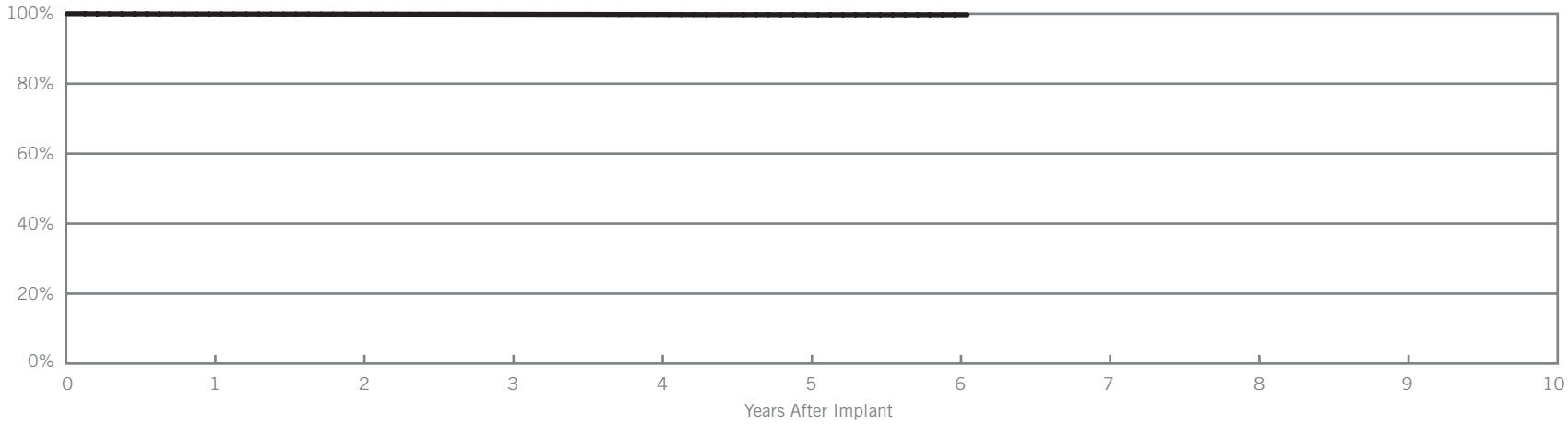
Pacing Leads

IsoFlex® S (Model 1646T)	
US Market Release	May 2002
Registered US Implants	72,975
Estimated Active US Implants	56,702
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	3	<0.01%	1	<0.01%
Conductor Fracture	1	<0.01%	7	0.01%
Lead Dislodgement	26	0.04%	13	0.02%
Failure to Capture	28	0.04%	44	0.06%
Oversensing	0	0.00%	8	0.01%
Failure to Sense	2	<0.01%	2	<0.01%
Insulation Breach	1	<0.01%	0	0.00%
Abnormal Pacing Impedance	6	0.01%	14	0.02%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	2	<0.01%	8	0.01%
Total	**69**	**0.09%**	**97**	**0.13%**
Total Returned for Analysis	**26**		**27**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	4	0.01%
Insulation Breach	5	0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	5	0.01%
Extrinsic Factors	22	0.03%
Total	**37**	**0.05%**

Survival from Returns and Complaints



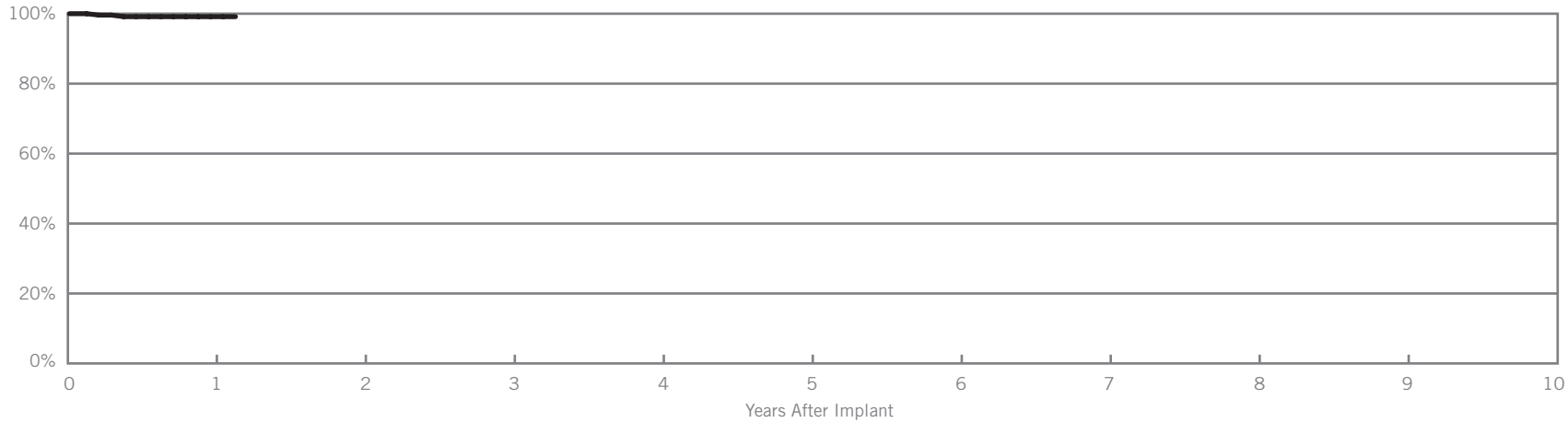
Year	1	2	3	4	5	6	at 73 months			
Survival Probability	99.92%	99.88%	99.84%	99.78%	99.71%	99.71%	99.71%			
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.03%	0.04%	0.04%			
Sample Size	66400	48100	32900	20400	10100	3000	200			

IsoFlex® S (Model 1646T)	
US Market Release	May 2002
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	287
Cumulative Months of Follow-up	2562

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.35%
Failure to Capture	1	0.35%

Survival from SCORE Registry



Year	1	at 14 months								
Survival Probability	99.15%	99.15%								
± 1 standard error	0.60%	0.60%								
Sample Size	87	55								

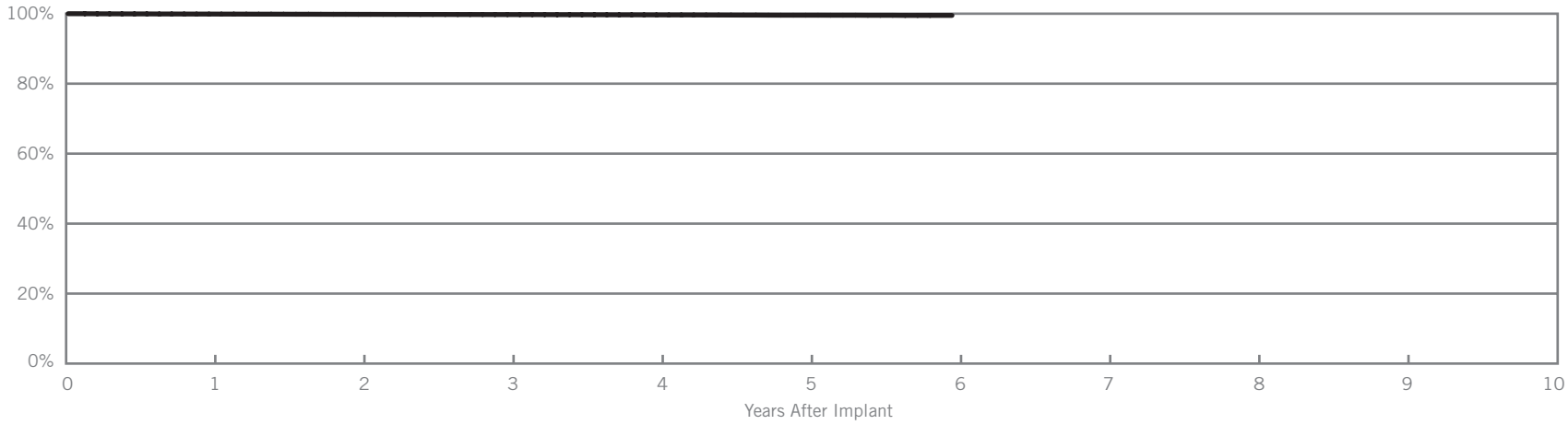
Pacing Leads

Tendril® SDX (Models 1688T & 1688TC)	
US Market Release	June 2003
Registered US Implants	303,421
Estimated Active US Implants	241,344
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
Type	**Qty.**	**Rate**	**Qty.**	**Rate**
Cardiac Perforation	32	0.01%	5	<0.01%
Conductor Fracture	3	<0.01%	44	0.01%
Lead Dislodgement	145	0.05%	149	0.05%
Failure to Capture	103	0.03%	204	0.07%
Oversensing	9	<0.01%	101	0.03%
Failure to Sense	19	0.01%	10	<0.01%
Insulation Breach	5	<0.01%	17	0.01%
Abnormal Pacing Impedance	22	0.01%	110	0.04%
Extracardiac Stimulation	3	<0.01%	3	<0.01%
Other	27	0.01%	48	0.02%
Total	**368**	**0.12%**	**691**	**0.23%**
Total Returned for Analysis	**128**		**308**	

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	69	0.02%
Insulation Breach	69	0.02%
Crimps, Welds & Bonds	16	0.01%
Other	5	<0.01%
Extrinsic Factors	136	0.04%
Total	**295**	**0.10%**

Survival from Returns and Complaints



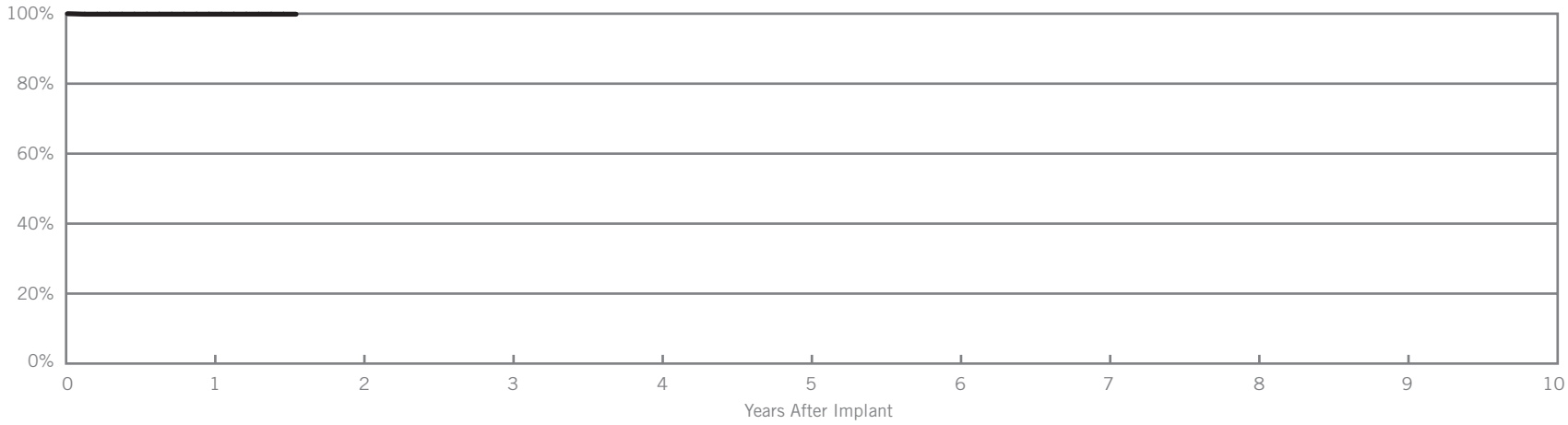
Year	1	2	3	4	5	at 71 months				
Survival Probability	99.90%	99.82%	99.75%	99.66%	99.57%	99.51%				
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.02%	0.05%				
Sample Size	280100	216600	156200	91100	35900	100				

Tendril® SDX (Models 1688T & 1688TC)	
US Market Release	June 2003
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	765
Cumulative Months of Follow-up	7313

Qualifying Complications		
Type	**Qty.**	**Rate**
Lead Dislodgement	1	0.13%

Survival from SCORE Registry



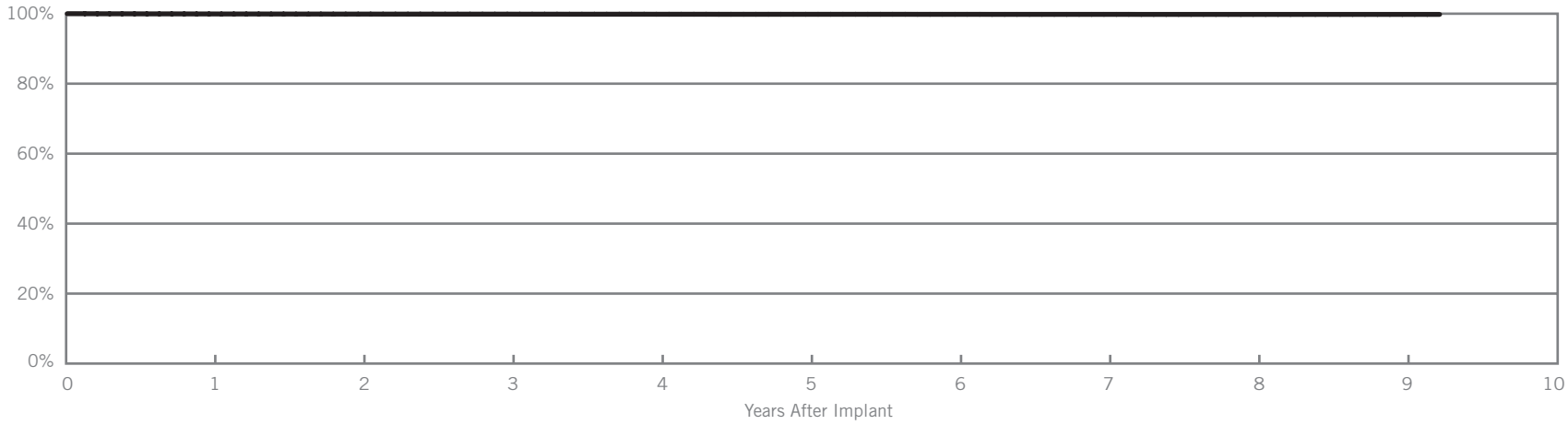
Year	1	at 19 months								
Survival Probability	99.86%	99.86%								
± 1 standard error	0.14%	0.14%								
Sample Size	280	58								

Pacing Leads

Tendril® SDX (Models 1488T & 1488TC)	
US Market Release	March 2000
Registered US Implants	272,156
Estimated Active US Implants	155,565
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

Lead Malfunctions		
Type	**Qty.**	**Rate**
Conductor Fracture	119	0.04%
Insulation Breach	73	0.03%
Crimps, Welds & Bonds	13	<0.01%
Other	2	<0.01%
Extrinsic Factors	203	0.07%
Total	**410**	**0.15%**

Survival from Returns and Complaints



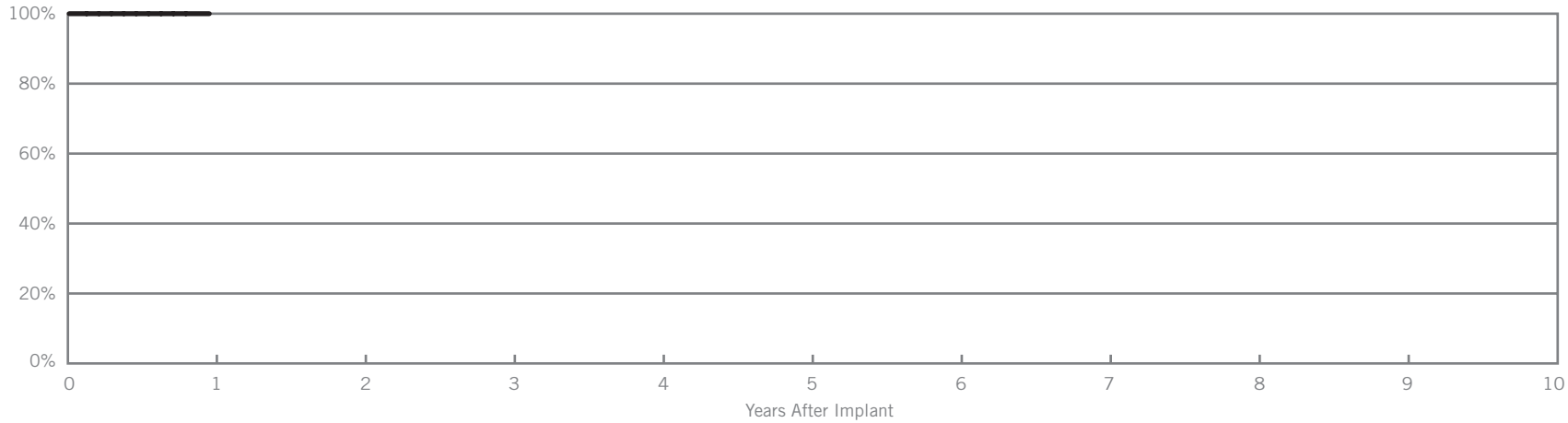
Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.93%	99.89%	99.87%	99.84%	99.83%	99.82%	99.81%	99.80%	99.80%	99.80%
± 1 standard error	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Sample Size	264700	232200	207500	178700	144600	106500	65200	30100	8600	200

Tendril® SDX (Models 1488T & 1488TC)	
US Market Release	March 2000
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

SCORE Enrollment	
Number of Devices Enrolled in Study	121
Cumulative Months of Follow-up	1201

Qualifying Complications
None Reported

Survival from SCORE Registry

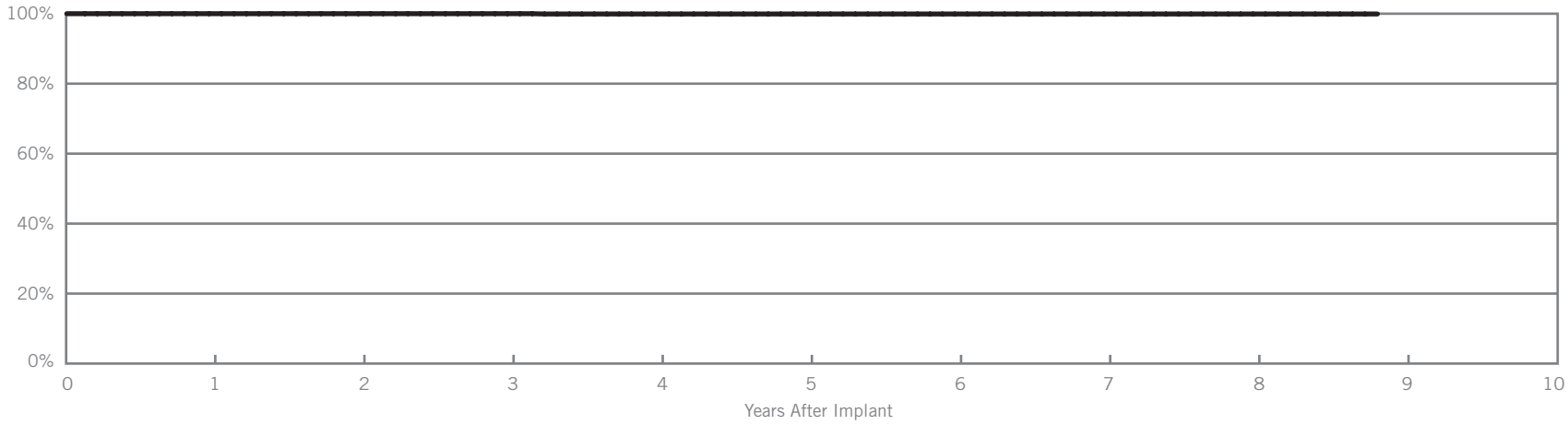


Year	at 11 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	55									

Pacing Leads

AV Plus® DX (Model 1368)	
US Market Release	May 1999
Registered US Implants	2,386
Estimated Active US Implants	1,166
Insulation	Silicone
Type and/or Fixation	Passive
Atrial Polarity	Bipolar
Ventricular Polarity	Bipolar
Steroid	Yes
Number of Advisories	None

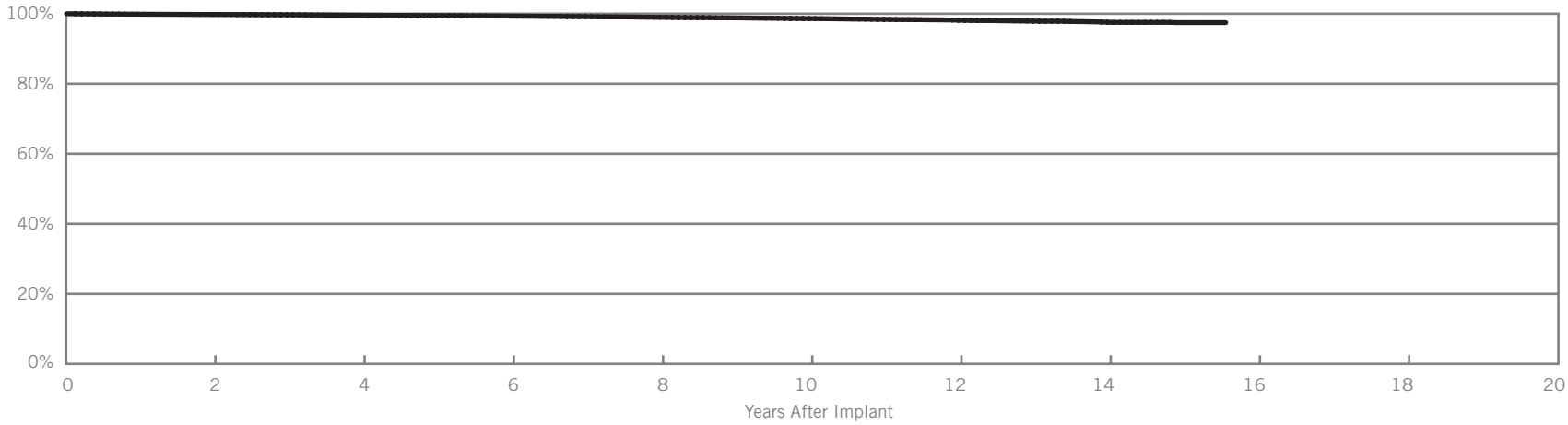
Survival from Returns and Complaints



Year	1	2	3	4	5	6	7	8	at 106 months	
Survival Probability	100.00%	100.00%	100.00%	99.92%	99.92%	99.92%	99.92%	99.92%	99.92%	
± 1 standard error	0.00%	0.00%	0.00%	0.08%	0.08%	0.08%	0.08%	0.08%	0.08%	
Sample Size	2300	1800	1500	1300	1000	800	600	400	100	

Tendril® (Models 1148 & 1188T); Tendril® DX (Models 1388T & 1388TC)	
US Market Release	(1148) June 1993; (1188T) June 1994; (1388T) June 1997
Registered US Implants	323,872
Estimated Active US Implants	132,396
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	(1148/1188) No; (1388) Yes
Number of Advisories	None

Survival from Returns and Complaints

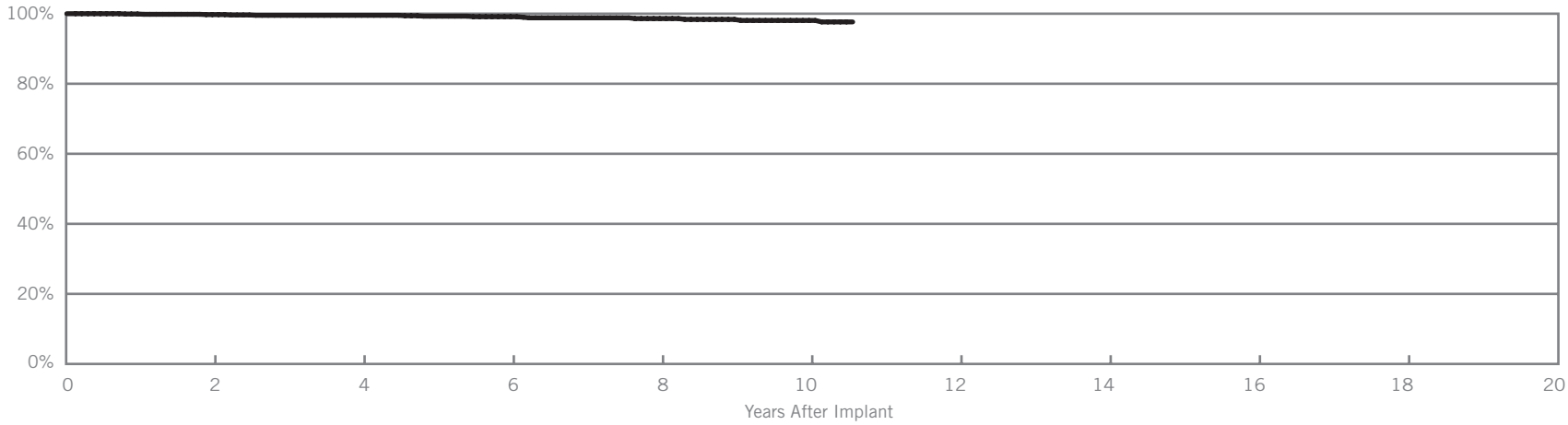


Year	2	4	6	8	10	12	14	at 187 months		
Survival Probability	99.78%	99.57%	99.32%	98.97%	98.61%	98.15%	97.57%	97.46%		
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.03%	0.05%	0.10%	0.14%		
Sample Size	273300	213800	155500	103100	54600	19200	5800	100		

Pacing Leads

Tendril® (Model 1188K) Tendril® DX (Model 1388K)	
US Market Release	(1188K) June 1995; (1388K) June 1997
Registered US Implants	1,334
Estimated Active US Implants	378
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Unipolar
Steroid	(1188K) No; (1388K) Yes
Number of Advisories	None

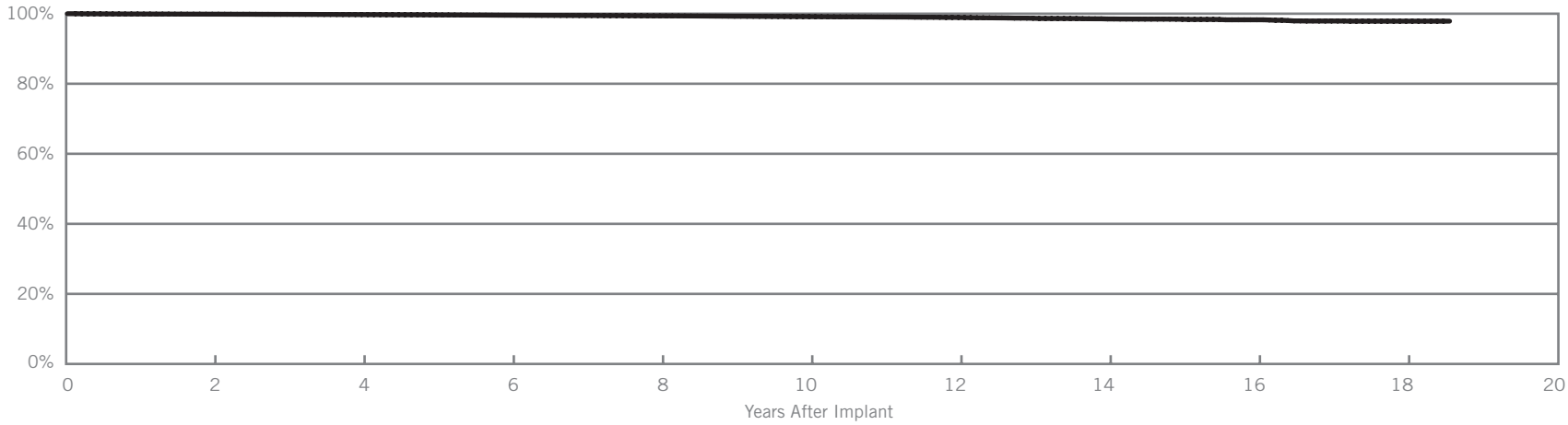
Survival from Returns and Complaints



Year	2	4	6	8	10	at 127 months				
Survival Probability	99.74%	99.54%	99.15%	98.61%	98.07%	97.65%				
± 1 standard error	0.15%	0.21%	0.31%	0.44%	0.58%	0.71%				
Sample Size	1200	1000	700	500	300	200				

Passive Plus® (Models 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T) Passive Plus® DX (Models 1336T, 1342T & 1346T)	
US Market Release	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990
Registered US Implants	373,483
Estimated Active US Implants	123,161
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Number of Advisories	None

Survival from Returns and Complaints

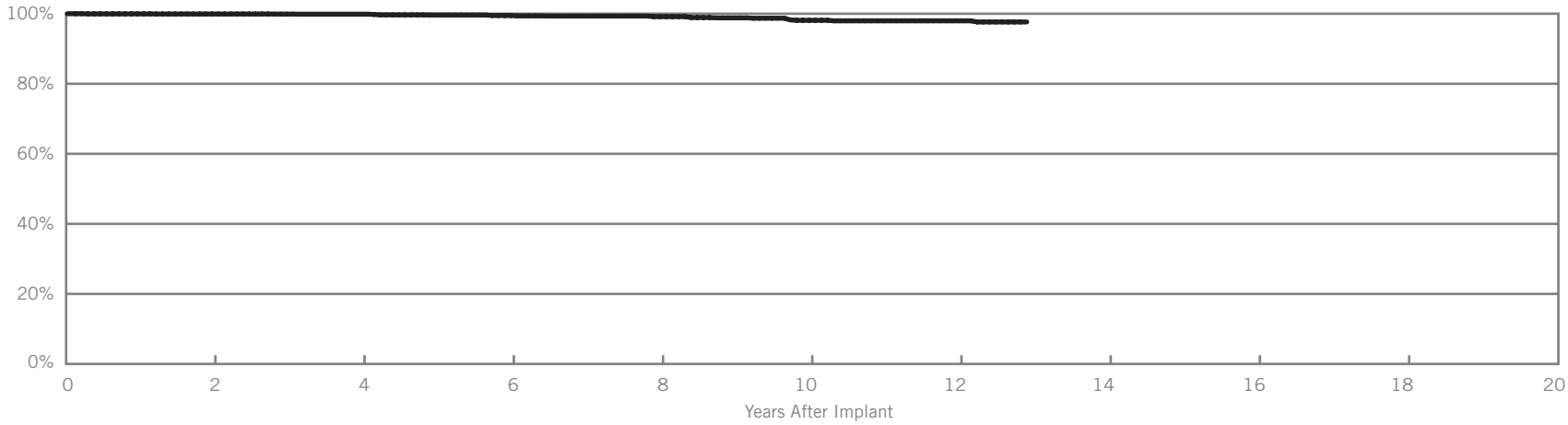


Year	2	4	6	8	10	12	14	16	18	at 223 months
Survival Probability	99.87%	99.74%	99.57%	99.39%	99.17%	98.93%	98.50%	98.26%	97.87%	97.87%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%	0.03%	0.05%	0.07%	0.13%	0.13%
Sample Size	319900	256900	195400	132100	79900	44300	20700	7600	1700	100

Pacing Leads

Passive Plus® (Models 1135K, 1143K, 1145K, 1235K, 1243K & 1245K) Passive Plus® DX (Models 1343K & 1345K)	
US Market Release	(1135K, 1143K, 1145K) July 1994; (1235K, 1243K, 1245K) August 1995; (1343K, 1345K) June 1998
Registered US Implants	4,481
Estimated Active US Implants	1,190
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Unipolar
Steroid	(1135K, 1143K, 1145K, 1235K, 1243K, 1245K) No; (1343K, 1345K) Yes
Number of Advisories	None

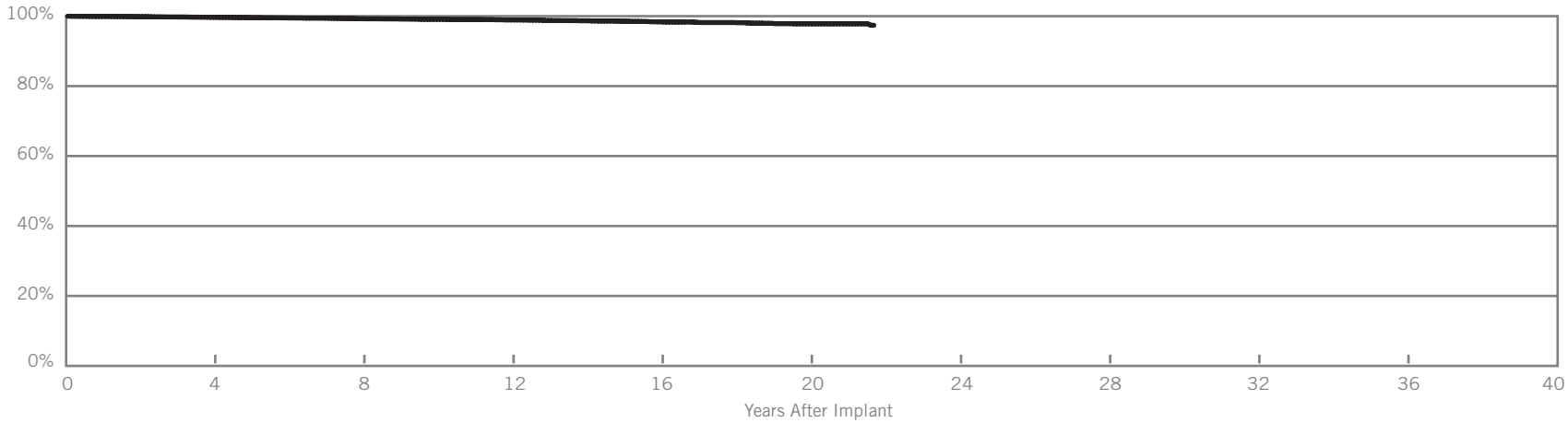
Survival from Returns and Complaints



Year	2	4	6	8	10	12	at 155 months			
Survival Probability	99.92%	99.86%	99.48%	99.17%	98.11%	97.96%	97.64%			
± 1 standard error	0.04%	0.06%	0.14%	0.20%	0.39%	0.42%	0.52%			
Sample Size	3700	3000	2300	1500	900	500	100			

ACE™ (Models 1015M & 1025M)	
US Market Release	(1025M) August 1982; (1015M) August 1991
Registered US Implants	23,874
Estimated Active US Implants	3,145
Insulation	Silicone
Type and/or Fixation	Passive
Polarity	Unipolar
Steroid	No
Number of Advisories	None

Survival from Returns and Complaints

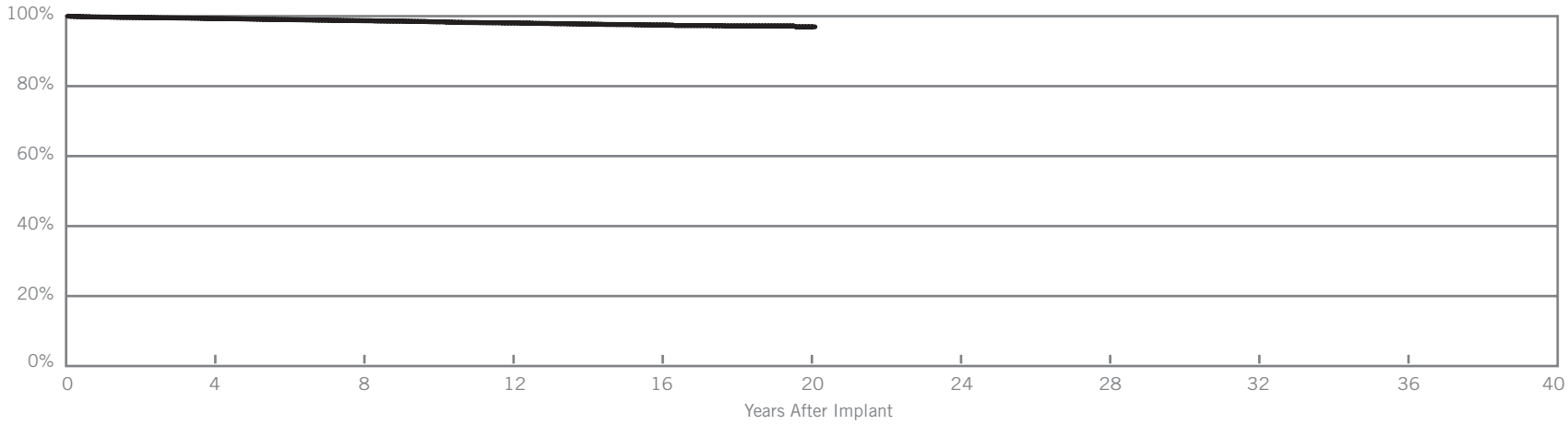


Year	4	8	12	16	20	at 262 months				
Survival Probability	99.67%	99.25%	98.91%	98.37%	97.81%	97.40%				
± 1 standard error	0.04%	0.07%	0.10%	0.15%	0.20%	0.46%				
Sample Size	16700	10500	6600	4100	2000	100				

Pacing Leads

Bipolar Leads (Models 1018T & 1028T)	
US Market Release	(1018T) February 1988; (1028T) July 1990
Registered US Implants	28,030
Estimated Active US Implants	4,360
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	No
Number of Advisories	None

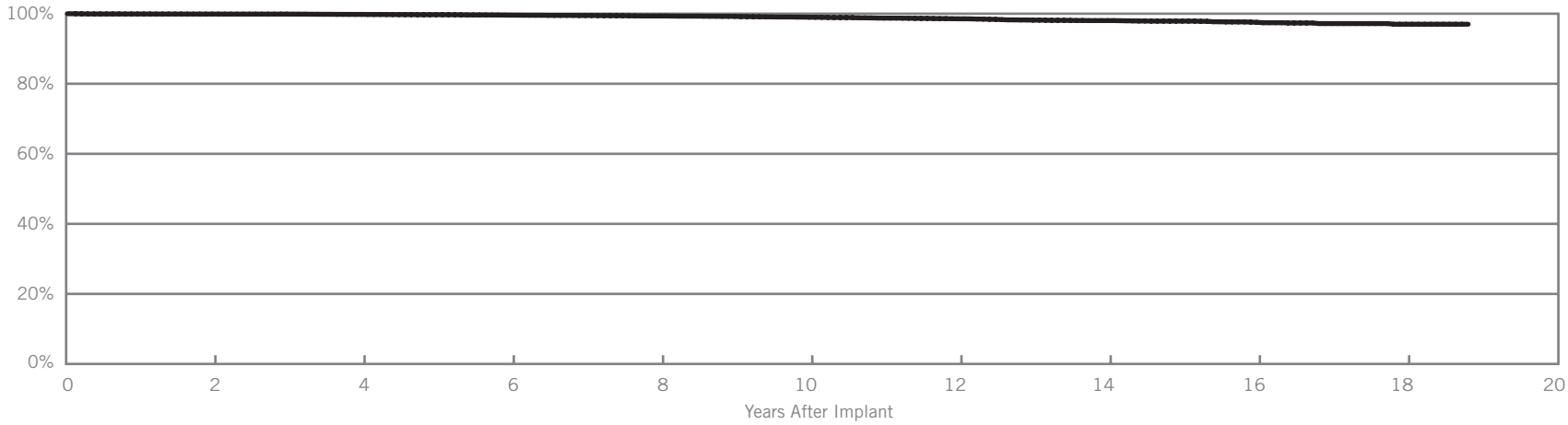
Survival from Returns and Complaints



Year	4	8	12	16	20	at 242 months				
Survival Probability	99.33%	98.70%	98.06%	97.48%	96.95%	96.95%				
± 1 standard error	0.05%	0.08%	0.12%	0.15%	0.32%	0.32%				
Sample Size	20500	13800	8500	4900	400	100				

Permathane™ ACE (Models 1036T & 1038T)	
US Market Release	June 1989
Registered US Implants	19,672
Estimated Active US Implants	2,970
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Bipolar
Steroid	No
Number of Advisories	None

Survival from Returns and Complaints

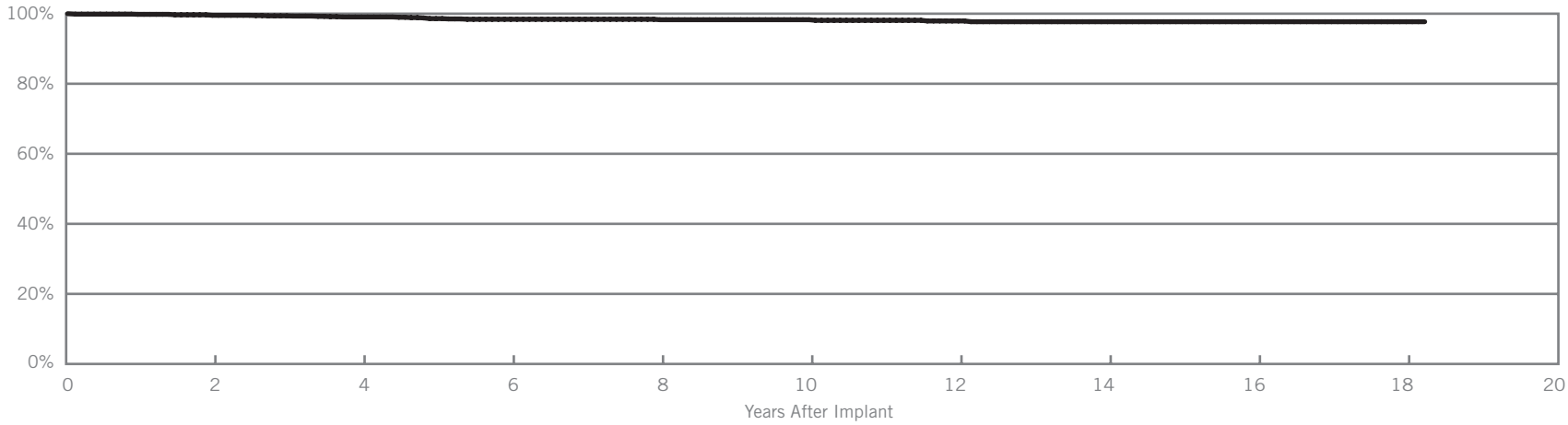


Year	2	4	6	8	10	12	14	16	18	at 226 months
Survival Probability	99.90%	99.80%	99.58%	99.35%	98.99%	98.54%	98.03%	97.54%	97.00%	97.00%
± 1 standard error	0.02%	0.04%	0.06%	0.08%	0.10%	0.14%	0.18%	0.22%	0.33%	0.33%
Sample Size	17100	13800	11100	8700	6800	5200	3900	2200	700	100

Pacing Leads

Unipolar Lead (Model 1007)	
US Market Release	June 1987
Registered US Implants	1,740
Estimated Active US Implants	235
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Unipolar
Steroid	No
Number of Advisories	None

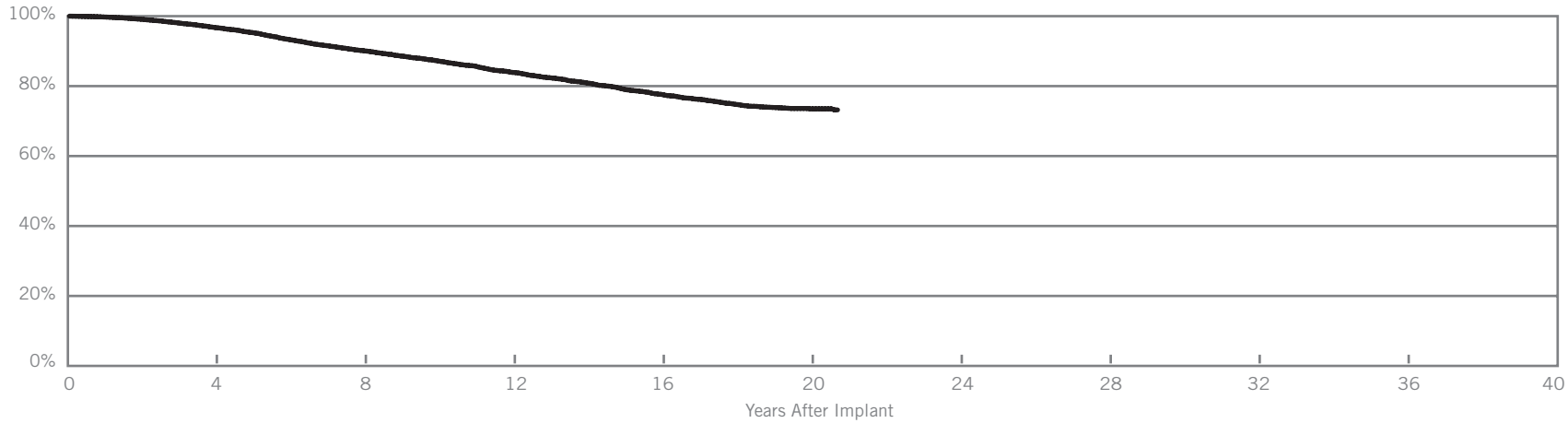
Survival from Returns and Complaints



Year	2	4	6	8	10	12	14	16	18	at 219 months
Survival Probability	99.54%	99.07%	98.41%	98.28%	98.28%	97.92%	97.71%	97.71%	97.71%	97.71%
± 1 standard error	0.14%	0.26%	0.36%	0.36%	0.38%	0.46%	0.50%	0.50%	0.50%	0.50%
Sample Size	1500	1300	1000	800	700	500	400	300	200	200

ACE™ (Models 1016T & 1026T)	
US Market Release	June 1987
Registered US Implants	24,199
Estimated Active US Implants	2,196
Insulation	Silicone
Type and/or Fixation	Active
Polarity	Bipolar
Steroid	No
Number of Advisories	One

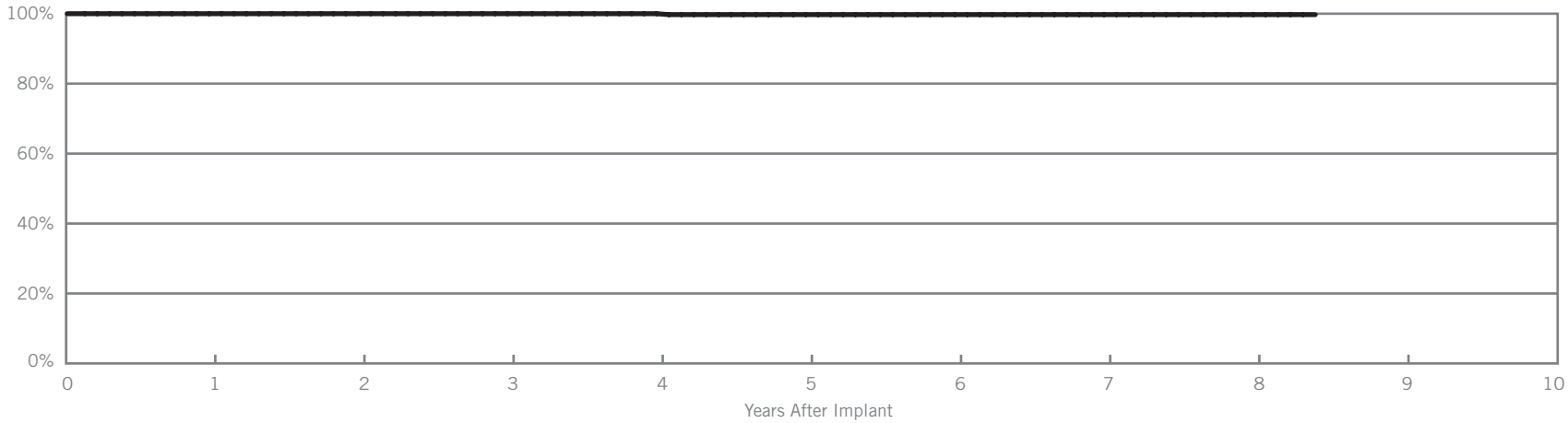
Survival from Returns and Complaints



Year	4	8	12	16	20	at 249 months				
Survival Probability	96.75%	90.11%	83.91%	77.64%	73.51%	73.20%				
± 1 standard error	0.13%	0.25%	0.36%	0.48%	0.58%	0.66%				
Sample Size	17300	10100	5900	3400	1300	100				

Permathane™ ACE (Model 1035M)	
US Market Release	March 1987
Registered US Implants	655
Estimated Active US Implants	64
Insulation	Polyurethane
Type and/or Fixation	Passive
Polarity	Unipolar
Steroid	No
Number of Advisories	None

Survival from Returns and Complaints



Year	1	2	3	4	5	6	7	8	at 101 months	
Survival Probability	100.00%	100.00%	100.00%	100.00%	99.73%	99.73%	99.73%	99.73%	99.73%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.27%	0.27%	0.27%	0.27%	0.27%	
Sample Size	600	500	500	400	400	300	300	200	200	

Observations, Complications, and Malfunctions

Pacing Leads

Bipolar & Unipolar

Active & Passive Fixation

St. Jude Medical
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Pacing Leads

Acute Observations (Post Implant, ≤30 days)

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1944	Mar-08	1012	970	0	0.00%	0	0.00%	3	0.30%	0	0.00%	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**4**	**0.40%**	**1**
1948	Mar-08	3508	3440	0	0.00%	0	0.00%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**2**	**0.06%**	**1**
1699T/TC	May-07	14852	14161	0	0.00%	0	0.00%	3	0.02%	3	0.02%	2	0.01%	6	0.04%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**15**	**0.10%**	**9**
1888T/TC	Jun-06	110409	104550	18	0.02%	4	<0.01%	57	0.05%	45	0.04%	6	0.01%	5	<0.01%	3	<0.01%	5	<0.01%	3	<0.01%	11	0.01%	**157**	**0.14%**	**42**
1882T/TC	Jun-06	8094	7715	1	0.01%	0	0.00%	9	0.11%	4	0.05%	2	0.02%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	**19**	**0.23%**	**4**
1782T/TC	Feb-06	11502	10347	4	0.03%	0	0.00%	6	0.05%	4	0.03%	0	0.00%	0	0.00%	0	0.00%	2	0.02%	1	0.01%	2	0.02%	**19**	**0.17%**	**7**
1788T/TC	Feb-06	56282	49793	10	0.02%	1	<0.01%	31	0.06%	25	0.04%	1	<0.01%	2	<0.01%	1	<0.01%	9	0.02%	2	<0.01%	20	0.04%	**102**	**0.18%**	**34**
1644T	Apr-05	929	770	0	0.00%	0	0.00%	1	0.11%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.11%	**2**	**0.22%**	**1**
1648T	Apr-05	2720	2272	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**	**0.22%**	**1**
1642T	May-02	22082	17744	0	0.00%	0	0.00%	38	0.17%	5	0.02%	0	0.00%	3	0.01%	0	0.00%	3	0.01%	1	<0.01%	0	0.00%	**50**	**0.23%**	**27**
1646T	May-02	72975	56702	3	<0.01%	1	<0.01%	26	0.04%	28	0.04%	0	0.00%	2	<0.01%	1	<0.01%	6	0.01%	0	0.00%	2	<0.01%	**69**	**0.09%**	**26**
1688T/TC	Jun-03	303421	241344	32	0.01%	3	<0.01%	145	0.05%	103	0.03%	9	<0.01%	19	0.01%	5	<0.01%	22	0.01%	3	<0.01%	27	0.01%	**368**	**0.12%**	**128**

Chronic Complications (>30 days)

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
1944	Mar-08	1012	970	0	0.00%	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**1**	**0.10%**	**0**
1948	Mar-08	3508	3440	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**	**0**
1699T/TC	May-07	14852	14161	0	0.00%	1	0.01%	4	0.03%	3	0.02%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**10**	**0.07%**	**4**
1888T/TC	Jun-06	110409	104550	10	0.01%	3	<0.01%	52	0.05%	24	0.02%	13	0.01%	2	<0.01%	5	<0.01%	6	0.01%	2	<0.01%	9	0.01%	**126**	**0.11%**	**71**
1882T/TC	Jun-06	8094	7715	0	0.00%	0	0.00%	4	0.05%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	0	0.00%	1	0.01%	**7**	**0.09%**	**4**
1782T/TC	Feb-06	11502	10347	0	0.00%	1	0.01%	8	0.07%	7	0.06%	2	0.02%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0	0.00%	**19**	**0.17%**	**18**
1788T/TC	Feb-06	56282	49793	1	<0.01%	2	<0.01%	19	0.03%	24	0.04%	5	0.01%	1	<0.01%	1	<0.01%	5	0.01%	1	<0.01%	4	0.01%	**63**	**0.11%**	**41**
1644T	Apr-05	929	770	0	0.00%	1	0.11%	0	0.00%	2	0.22%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**3**	**0.32%**	**2**
1648T	Apr-05	2720	2272	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	2	0.07%	**4**	**0.15%**	**3**
1642T	May-02	22082	17744	0	0.00%	1	<0.01%	12	0.05%	7	0.03%	0	0.00%	2	0.01%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	**24**	**0.11%**	**8**
1646T	May-02	72975	56702	1	<0.01%	7	0.01%	13	0.02%	44	0.06%	8	0.01%	2	<0.01%	0	0.00%	14	0.02%	0	0.00%	8	0.01%	**97**	**0.13%**	**27**
1688T/TC	Jun-03	303421	241344	5	<0.01%	44	0.01%	149	0.05%	204	0.07%	101	0.03%	10	<0.01%	17	0.01%	110	0.04%	3	<0.01%	48	0.02%	**691**	**0.23%**	**308**

Definitions of observations and complications can be found on pages 5 and 6.

Lead Malfunctions

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Conductor Fracture		Insulation Breach		Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
1944	Mar-08	1012	970	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1948	Mar-08	3508	3440	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	**0**	**0.00%**
1699T/TC	May-07	14852	14161	1	0.01%	0	0.00%	0	0.00%	0	0.00%	2	0.01%	**3**	**0.02%**
1888T/TC	Jun-06	110409	104550	0	0.00%	3	<0.01%	0	0.00%	0	0.00%	40	0.04%	**43**	**0.04%**
1882T/TC	Jun-06	8094	7715	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.05%	**4**	**0.05%**
1782T/TC	Feb-06	11502	10347	1	0.01%	2	0.02%	0	0.00%	0	0.00%	8	0.07%	**11**	**0.10%**
1788T/TC	Feb-06	56282	49793	0	0.00%	10	0.02%	1	<0.01%	4	0.01%	13	0.02%	**28**	**0.05%**
1644T	Apr-05	929	770	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.22%	**2**	**0.22%**
1648T	Apr-05	2720	2272	0	0.00%	0	0.00%	0	0.00%	1	0.04%	2	0.07%	**3**	**0.11%**
1642T	May-02	22082	17744	0	0.00%	1	<0.01%	2	0.01%	4	0.02%	7	0.03%	**14**	**0.06%**
1646T	May-02	72975	56702	4	0.01%	5	0.01%	1	<0.01%	5	0.01%	22	0.03%	**37**	**0.05%**
1688T/TC	Jun-03	303421	241344	69	0.02%	69	0.02%	16	0.01%	5	<0.01%	136	0.04%	**295**	**0.10%**
1488T/TC	Mar-00	272156	155565	119	0.04%	73	0.03%	13	<0.01%	2	<0.01%	203	0.07%	**410**	**0.15%**

Definitions of malfunction categories can be found on page 7.

Implantable Cardiac Monitors

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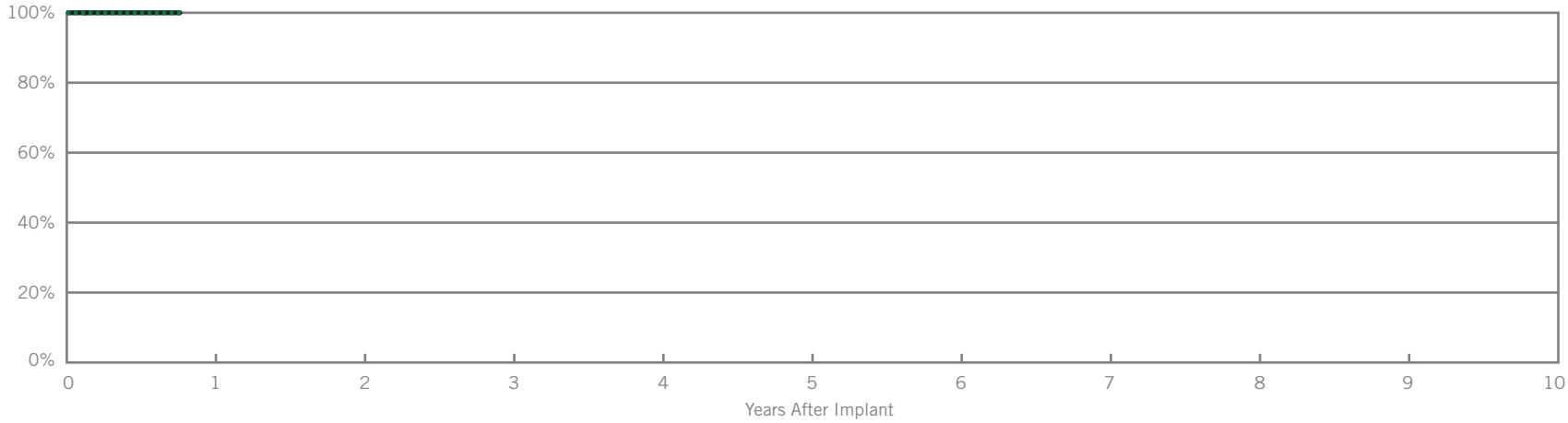
Implantable Cardiac Monitors

SJM Confirm® (Model DM2100)

US Market Release	August 2008	Normal Battery Depletion	0
Registered US Implants	1,997	Malfunctions	0
Estimated Active US Implants	1,785	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	3.0 Years*	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Survival from Returns and Complaints



Including Normal Battery Depletion

Year	at 9 months									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	1100									

Excluding Normal Battery Depletion

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

**After 12 month shelf-life.*

Summary & Longevity Information

Implantable Cardiac Monitors

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Implantable Cardiac Monitors

Malfunction Summary Information

Models	Family	US Market Release Date	Registered US Implants	Estimated Active US Implants	Confirmed Malfunctions
DM2100	SJM Confirm®	Aug-08	1,997	1,785	0

Advisories & Safety Alerts

St. Jude Medical™
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Advisories & Safety Alerts

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

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic® + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic® II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas® + ICDs (Model V-340, V-341, V-343, V-193, V-242, V-243) Atlas® II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	01/16/08 Class II A very rare condition (incidence of eight in 143,000 devices worldwide; six in the US and two outside the US) that could lead to a ventricular sensing anomaly in Epic® and Atlas® family of implantable cardioverter defibrillators (ICDs) has been identified. A loss of ventricular sensing would prevent an ICD from being able to detect an arrhythmia. The loss of ventricular sensing anomaly can only occur when the device's software writes to a particular memory location and only if there is a precise alignment of two timing parameters that normally do not coincide during routine operation of the device. The precise alignment requires the software write to occur at the exact time that a comparison is made during a specific 61 microsecond (µsec) window.	A simple programmer software/device firmware upgrade will resolve the issue and prevent a future occurrence. Patients who are followed on a routine basis with scheduled follow-up visits every three to six months should continue with their scheduled visit. Upon interrogation of one of the subject devices, the Merlin® Patient Care System and Model 3510 programmers with the newly provided software will automatically identify a device that can benefit from a firmware upgrade and will instruct the clinician that an upgrade is available. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended. **Current Status (June 30, 2009):** 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, 2009 there have been no additional devices confirmed to have this issue since the time of the 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, 2009):** 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, 2009 there were an additional 78 worldwide (65 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.
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, 2009):** 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, 2009 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.

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, 2009):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Advisories & Safety Alerts

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic® (V-197, V-235), Epic®+ (V-196, V-236), Epic® HF (V-338), Epic®+ HF (V-250), Atlas®+ (V-193, V-243), Atlas®+ HF (V-340), or Atlas® (model V-242) ICDs	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (June 30, 2009):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.
Identity® ADx DR Models 5286, 5380, 5386 and 5480	07/31/03 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. **To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval.** In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual chamber device would have to satisfy both of the following conditions: Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower Autocapture programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or Autocapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program Autocapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (June 30, 2009):** 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
Tempo™ 2102 and Meta 1256D	11/04/02 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.
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 pulse generators 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 pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator 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.
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.

Advisories & Safety Alerts

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 pulse generators, 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 pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator 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.
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 pulse generators, 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 pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator 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.
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.

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.
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 pulse generator has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services.

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

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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

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

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

U.S. Division
807 Las Cimas Parkway
Suite 400
Austin, Texas 78746
USA
+1 512 732 7400
+1 512 732 2418 Fax

SJM.com

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