# Product Performance Report

## Cardiac Rhythm Management

May 2010

St. Jude Medical™

More control. Less risk.

# Letter from St. Jude Medical

## May 2010

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

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

This is the fourth report to include data from the **S**t. Jude Medi**c**al Pr**o**duct Longevity and Perfo**r**manc**e** 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, performance and reliability.

Starting with this report, St. Jude Medical is pleased to provide survival probability and data associated with our Durata® SJ4 defibrillation leads. The Durata SJ4 employs a new in-line connector design which consolidates one IS-1 and two DF-1 connectors, thereby reducing bulk and procedure complexity. The Durata SJ4 retains the benefits of the Durata lead family, most notably the Optim® lead insulation offering increased resistance to abrasion, the soft silicone tip and slightly curved RV coil that reduces tip pressure, and the symmetrical body and centrally aligned cables that provide substantial lead body strength.

St. Jude Medical recognizes the value of the industry working together to provide transparent and consistent information about the performance of cardiac rhythm management products. Following the 2005 Policy Conference on Pacemaker and ICD Device Performance, cardiac device companies worked through an industry trade association, AdvaMed, to establish uniform guidelines for product performance reporting. The most recent output of this industry effort was the August 2009 revision of the document entitled "Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads". This revision thoroughly addresses lead performance reporting by defining the methods and categories for reporting acute observations, chronic complications and laboratory-confirmed malfunctions. Starting with the October 2009 performance report, St. Jude Medical adopted these updated AdvaMed guidelines in order to provide physicians and their patients with enhanced device performance information that is consistent across manufacturers.

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 implantable cardiac monitors, ICDs, pacemakers and lead systems.

Sincerely,

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

St. Jude Medical
More control. Less risk.

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## Serving our mission

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

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

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

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

## What you'll find in this report

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 industry guidelines, collected through December 31, 2009, including:

- A graph of survival probability that reflects the frequency of 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;

# Introduction and Overview

- 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.
- The survival charts include a summary description section, as identified below:

**ICDs and Pacemakers**

| | |
|---|---|
| US Regulatory Approval Date | Number of Normal Battery Depletions |
| Registered Number of US Implants | Number of Malfunctions (including returns related to advisories) |
| Estimated Number of Active US Implants | Number of Advisories |
| Estimated Longevity in years | Maximum Delivered Energy – in joules (ICDs only) |

**Leads**

| | |
|---|---|
| US Regulatory Approval Date | Polarity |
| Registered Number of US Implants | Steriod |
| Estimated Number of Active US Implants | Number of Advisories |
| Insulation Material | Observations, Complications, and Lead Malfunctions for the recently released models |
| Lead Type and/or Fixation | |

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-Pacemakers on page 39, for ICDs on pages 75 and 96 and for Pacemakers on pages 161 and 187.

For ICDs prior to the Photon™ Micro device and pacemakers prior to the Affinity® device, you will find analysis of the data collected through December 31, 2009, consistent with previous product performance reporting methods. These device models include:

**ICDs**

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

**Pacemakers**

Trilogy™ DR+ 2360, 2364
Paragon™ III 2304, 2314, 2315
Synchrony™ III 2028, 2029
AddVent™ 2060
Microny® 2425T, 2525T, 2535K
Regency® SC+ 2400L, 2402L
Tempo™ V 1102
Tempo™ VR 1902
Trilogy™ SR+ 2260, 2264
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 reporting methods 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
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

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.

# Introduction and Overview

## WHAT'S NEW IN THIS REPORT

### Durata® SJ4 Leads Data:

Starting with this report, St. Jude Medical is pleased to present survival probability and associated performance data on Durata® SJ4 defibrillation leads. Durata SJ4 and its single, in-line, four pole connector was introduced to the U.S. market in January 2009 with over 6,000 U.S. registered implants through December 31, 2009. Features of the Durata SJ4 include a single terminal pin connection that eliminates the yoke, minimizes bulk, and decreases the chances of lead to port mismatch. This design also uses fewer setscrews, which lessens complexity and helps to streamline procedures.

### Optim® Insulation Performance:

Now that Optim insulation has been on the market for more than 3 years, with over 250,000 leads implanted in the U.S., a thorough analysis of Optim insulation performance has been performed and is presented on p. 234 of this report. Optim insulation is a silicone-polyurethane co-polymer which consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone. The most noteworthy reliability benefit of Optim® lead insulation has been a statistically significant reduction in lead insulation abrasion as compared to silicone insulated leads.

### SCORE Registry Data:

St. Jude Medical is pleased to again provide results from the SCORE (**S**t. Jude Medi**c**al Pr**o**duct Longevity and Perfo**r**manc**e**) Registry. SCORE is an active, ongoing source of reliability and performance information for St. Jude Medical market-released cardiac rhythm management products – including multiple product families of leads, ICD models and pacemaker models. SCORE Registry data complements the data collected from returned product analysis, further enhancing performance reporting from St. Jude Medical.

To ensure a sufficiently large and appropriately representative source of data, 45 clinical sites are participating in the SCORE Registry with approximately 5,800 patients enrolled as of December 31, 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)
Durata® (Model 7122)
Riata® ST Optim® (Models 7020/7021)
Riata® ST (Models 7000/7001)
Riata® (Models 1580/1581)

### Pacemakers

Zephyr® DR (Model 5820)
Zephyr® DR (Model 5826)
Zephyr® SR (Model 5626)
Victory® XL DR (Model 5816)

### Pacing Leads

Tendril® ST Optim® (Model 1888)
Tendril® (Model 1788)
Tendril® SDX (Model 1688)
Tendril® SDX (Model 1488)
OptiSense® (Model 1699)
IsoFlex® S (Model 1646)

### CRT Leads

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

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

# Introduction and Overview

## Lead Observation and Complication Reporting

St. Jude Medical continues to work with other cardiac device companies to develop a uniform approach to reporting clinical performance of devices and leads. Leads reporting for the recently released models has been enhanced 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. In an effort to provide comprehensive performance information, the number of acute observations and chronic complications are tallied irrespective of whether the lead has been returned for analysis. 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, cables and/or electrodes) observed visually, electrically, or radiographically.

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

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

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

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

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

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

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

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

**Other:** Specific proprietary 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.

## Lead Malfunction Reporting

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 flex-fatigue or clavicular 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 clavicular crush 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, and seal rings, as well as other analysis results not included in the alternate 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 (typically including complications such as dislodgements, perforations, or failure to capture). For this particular category, malfunctions will only be included in survival probability for leads implanted greater than 30 days.

## 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 used for the analysis includes up-to-date device information and complaints for all registered implants in the United States, and the laboratory analysis of all domestically implanted devices returned to St. Jude Medical. The analysis measures device performance to specification, and does not reflect medical complications such as infection, erosion, muscle stimulation or inhibition, or units implanted for fewer than 24 hours.

"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 accurately represent the performance of each device, regardless of where in the world it was implanted.

St. Jude Medical lead survival 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 the lead is identified 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. Complaints commonly associated with non-returned leads and partial lead returns include, but are not limited to, reports of sensing, pacing, and capture anomalies, perforation, and dislodgement.

Implanted cardiac leads are subjected to constant, complex flexural and torsional forces, interactions with other leads and/or the pulse generator device, plus other forces associated with cardiac contractions, patient physical activity, posture, and anatomical influences. Therefore, the functional lifetime of cardiac leads is limited and can not be predicted with a high degree of confidence. As a supplement to the survival estimates, the categorization of lead malfunctions emphasize the root cause of malfunction rather than functional longevity prediction.

# Introduction and Overview

## 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

## 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 for any reason. Our Patient Records department can be reached at 888-SJM-CRMD or 818-362-6822.

St. Jude Medical encourages all explanted products to 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.SJMprofessional.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 Victory® and Zephyr® pacemakers is based on the mean longevity (or 50%) value in our manuals corresponding to a pacing output setting of 2.5 V, 500 ohm lead impedance, 100% DDD pacing, AutoCapture™ Off, and Stored EGMs Off (e.g. estimated longevity of 11.7 years for Zephyr® XL DR pacemaker model 5826). However, actual performance would vary considerably, depending on the actual programmed settings and operations.

**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.*

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

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

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

**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

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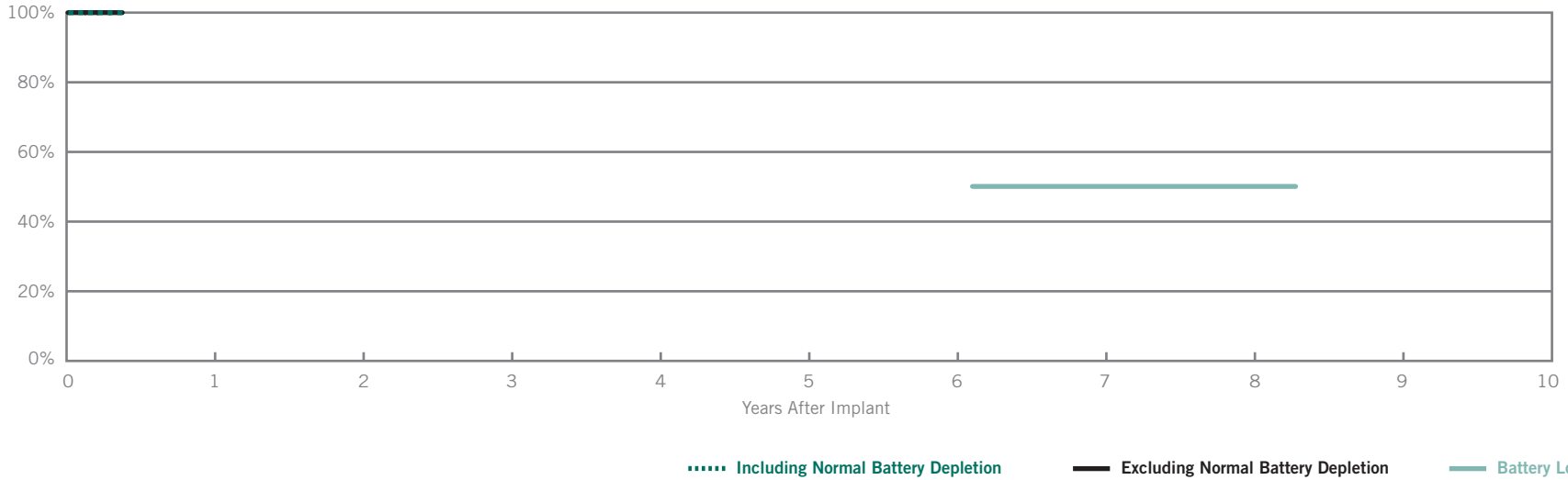
# Cardiac Resynchronization Therapy

## Promote® + CRT-D (Model CD3211-36Q)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 2,298 | Total Malfunctions | 0 |
| Estimated Active US Implants | 2,239 | 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 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

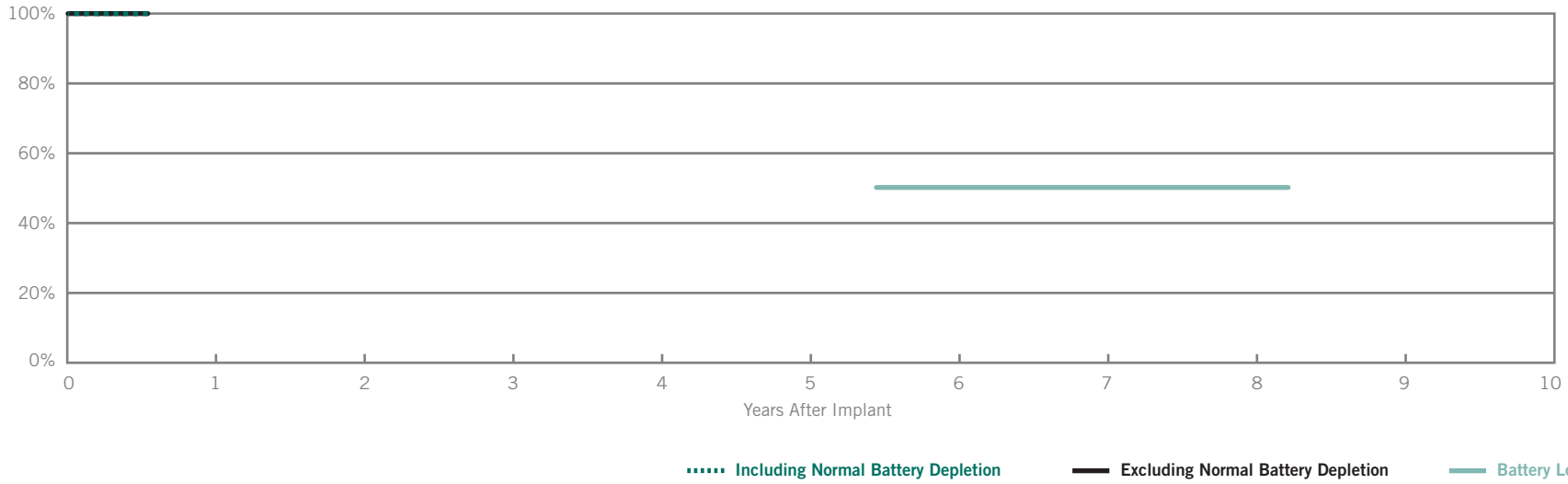
**Excluding Normal Battery Depletion**

| Year | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

## Promote® + CRT-D (Model CD3211-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 4,038 | Total Malfunctions | 0 |
| Estimated Active US Implants | 3,874 | 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 7 month | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 600 | | | | | | | | | |

**Excluding Normal Battery Depletion**

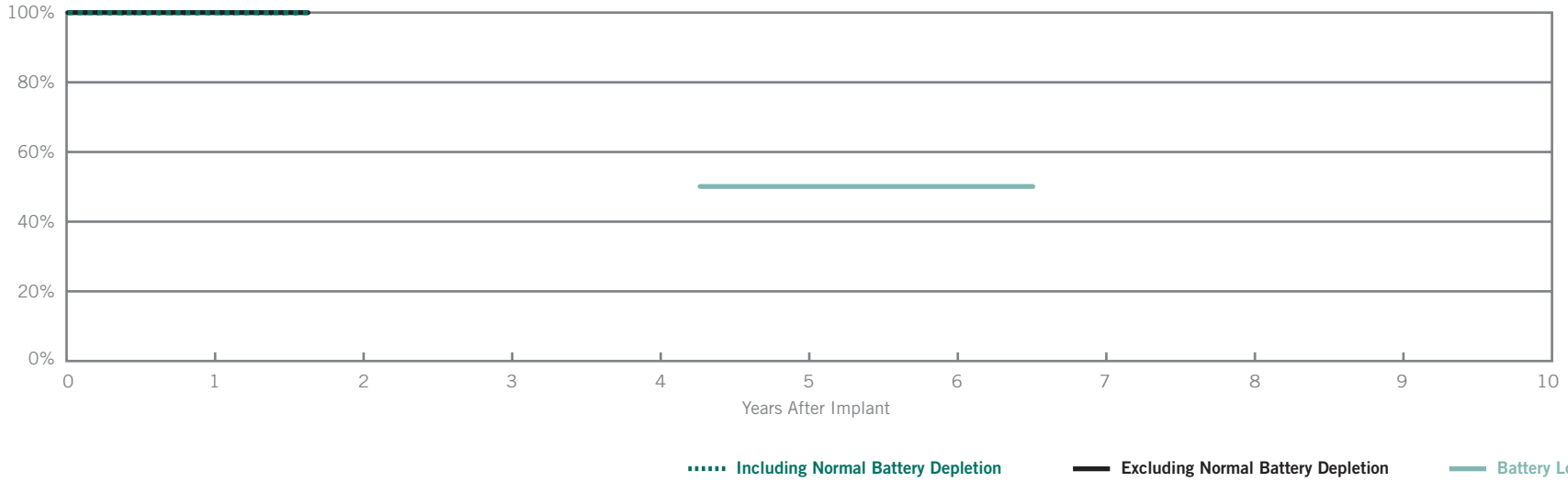
| Year | at 7 month | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

# Cardiac Resynchronization Therapy

## Promote® RF (Model 3207-30)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,212 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,043 | 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 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 900 | 200 | | | | | | | | |

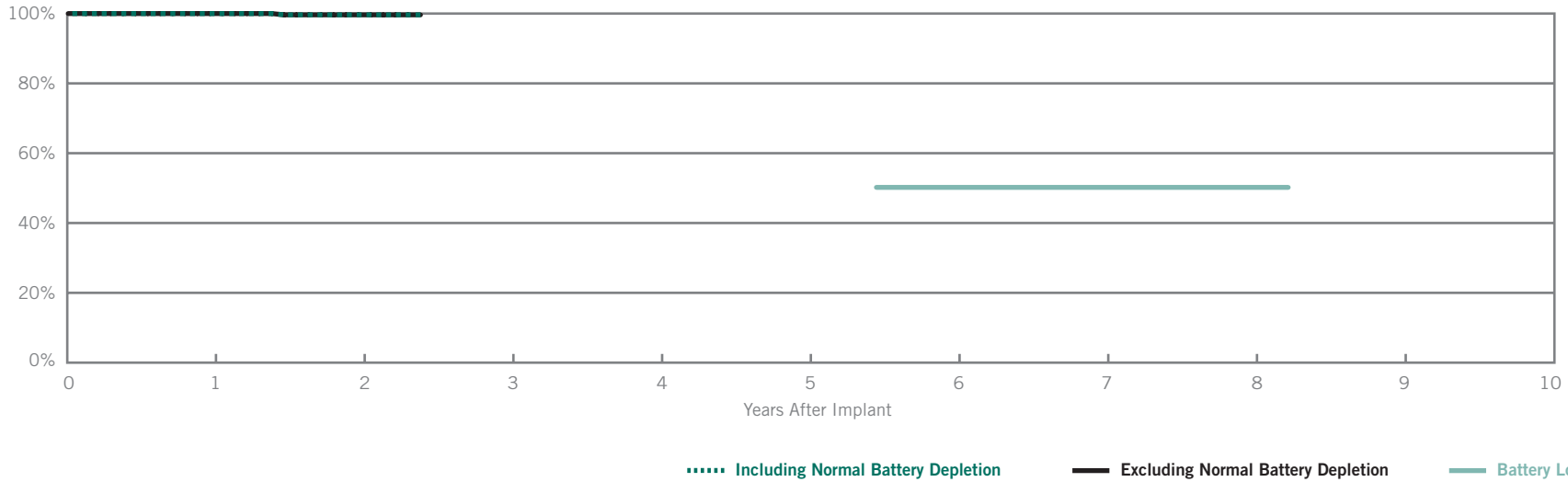
**Excluding Normal Battery Depletion**

| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

## Promote® (Model 3107-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 713 | Total Malfunctions | 1 |
| Estimated Active US Implants | 516 | 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 | 2 | at 29 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.63% | 99.63% | | | | | | | |
| ± 1 standard error | 0.00% | 0.26% | 0.26% | | | | | | | |
| Sample Size | 700 | 500 | 300 | | | | | | | |

**Excluding Normal Battery Depletion**

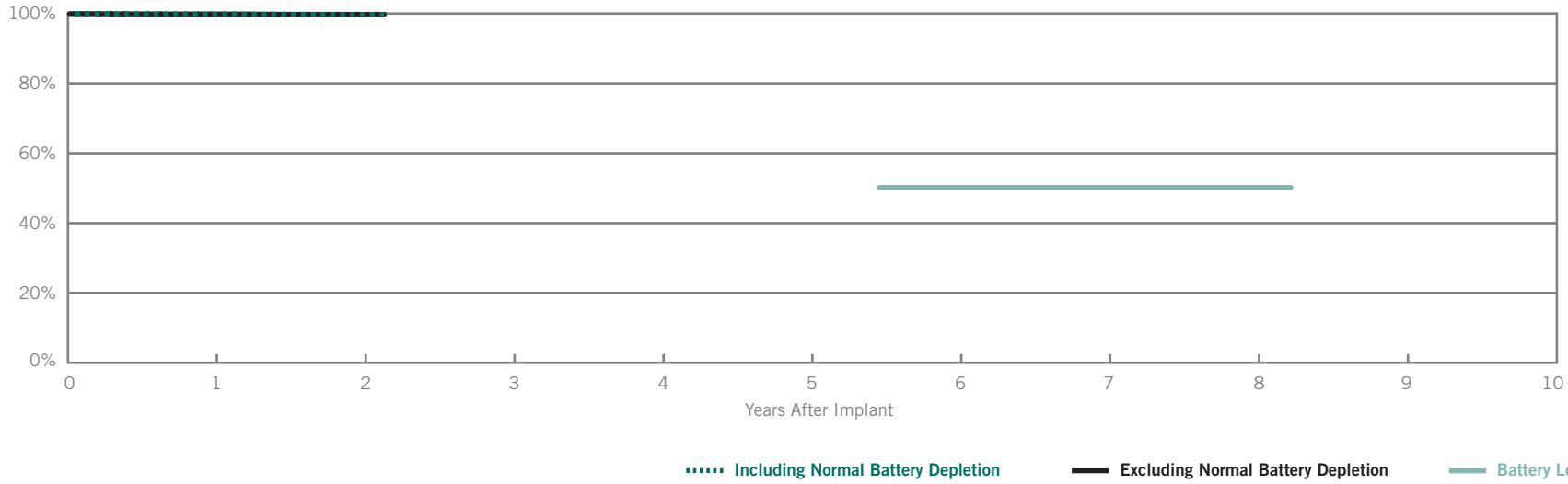
| Year | 1 | 2 | at 29 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.63% | 99.63% | | | | | | | |
| ± 1 standard error | 0.00% | 0.26% | 0.26% | | | | | | | |

# Cardiac Resynchronization Therapy

## Promote® RF (Model 3207-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 2 |
| Registered US Implants | 22,138 | Total Malfunctions | 20 |
| Estimated Active US Implants | 19,009 | Malfunctions w/ Compromised Therapy | 7 |
| Estimated Longevity | (see table on page 28) | Malfunctions w/o Compromised Therapy | 13 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 26 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.74% | 99.74% | | | | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.05% | | | | | | | |
| Sample Size | 17600 | 5900 | 300 | | | | | | | |

**Excluding Normal Battery Depletion**

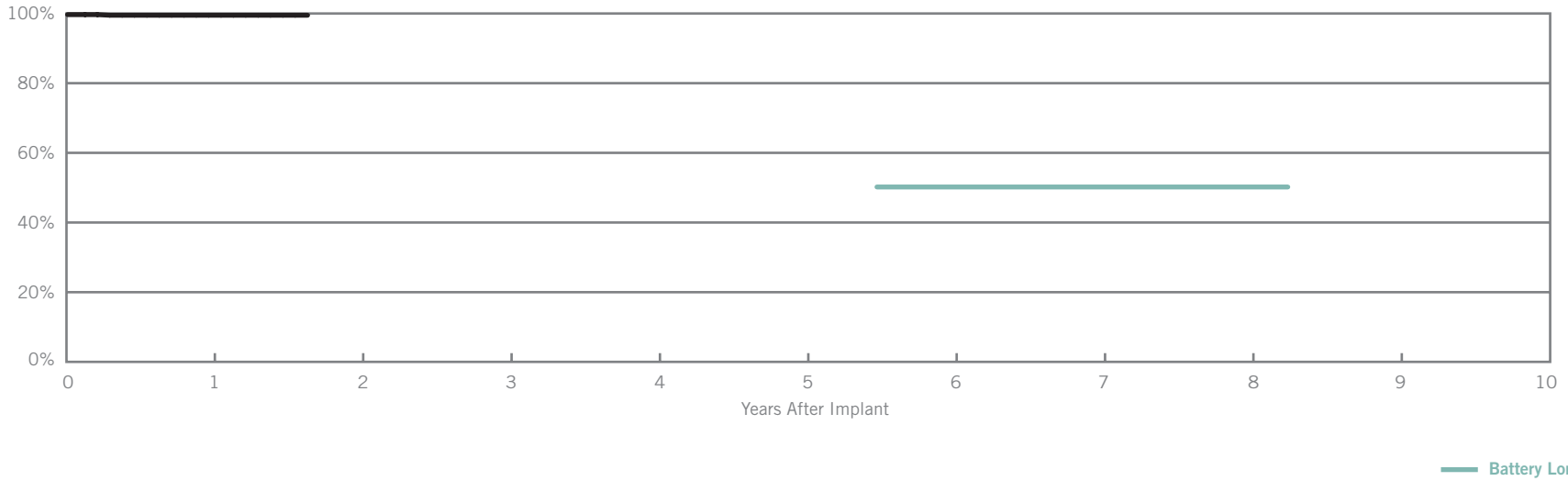
| Year | 1 | 2 | at 26 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.77% | 99.77% | | | | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.05% | | | | | | | |

| Promote® RF (Model 3207-36) | |
|---|---|
| US Regulatory Approval | September 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 621 |
| Cumulative Months of Follow-up | 7,406 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Backup Operation | 2 | 0.32% |

## Survival from SCORE Registry



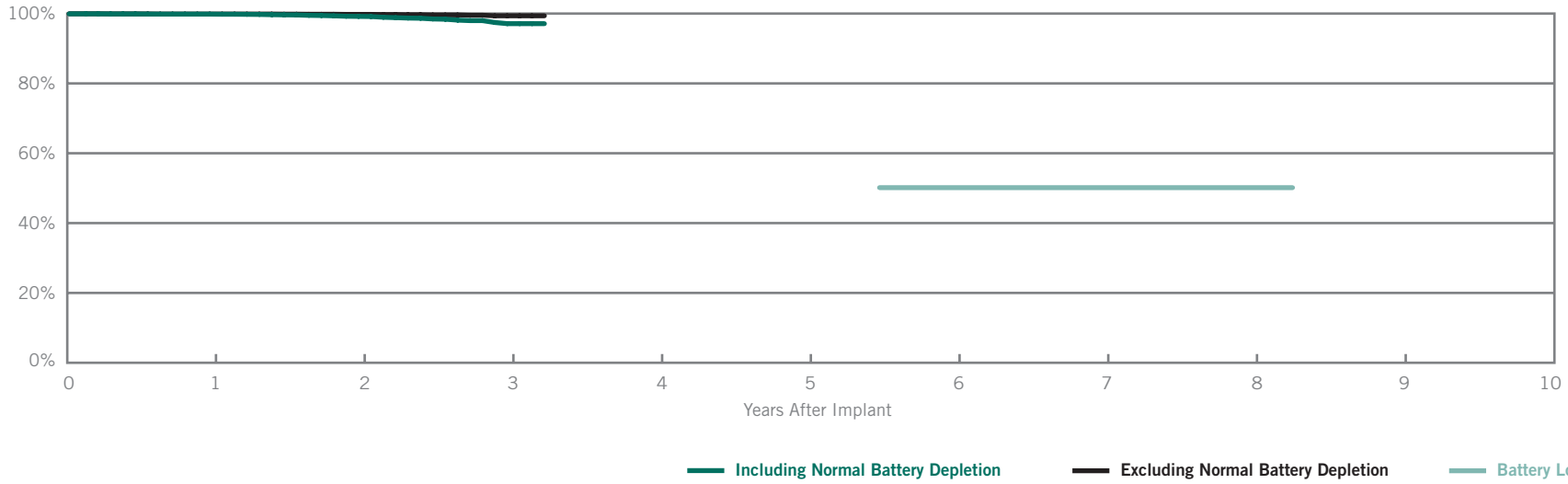

| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.50% | 99.50% | | | | | | | | |
| **± 1 standard error** | 0.29% | 0.29% | | | | | | | | |
| **Sample Size** | 320 | 53 | | | | | | | | |

# Cardiac Resynchronization Therapy

## Atlas® II HF (Model V-365)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2006 | Normal Battery Depletion | 47 |
| Registered US Implants | 8,377 | Total Malfunctions (0 related to Advisory) | 14 |
| Estimated Active US Implants | 5,662 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 10 |
| 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 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 39 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.84% | 99.19% | 97.11% | 97.11% | | | | | | |
| ± 1 standard error | 0.05% | 0.11% | 0.30% | 0.36% | | | | | | |
| Sample Size | 8400 | 6700 | 3300 | 200 | | | | | | |

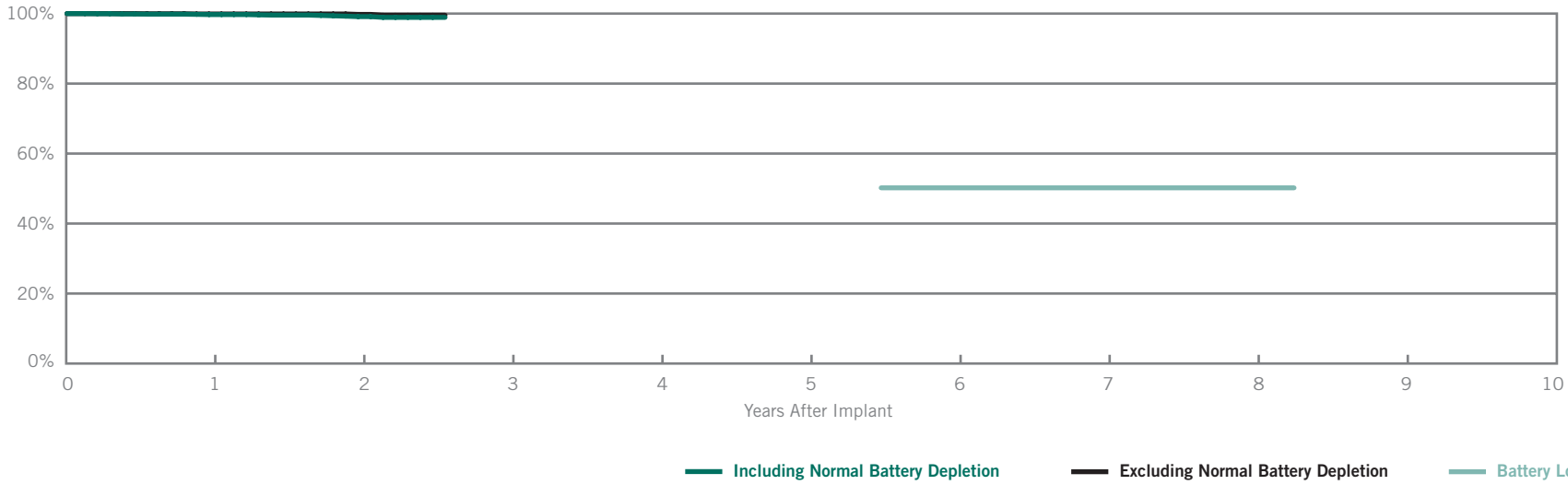
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 39 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.76% | 99.36% | 99.36% | | | | | | |
| ± 1 standard error | 0.04% | 0.06% | 0.15% | 0.15% | | | | | | |

## Atlas® II + HF (Model V-366)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2007 | Normal Battery Depletion | 9 |
| Registered US Implants | 4,756 | Total Malfunctions (0 related to Advisory) | 5 |
| Estimated Active US Implants | 3,640 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 2 |
| Estimated Longevity | (see table on page 28) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 3 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 31 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.72% | 99.14% | 98.92% | | | | | | | |
| ± 1 standard error | 0.08% | 0.17% | 0.23% | | | | | | | |
| Sample Size | 4300 | 2600 | 300 | | | | | | | |

**Excluding Normal Battery Depletion**

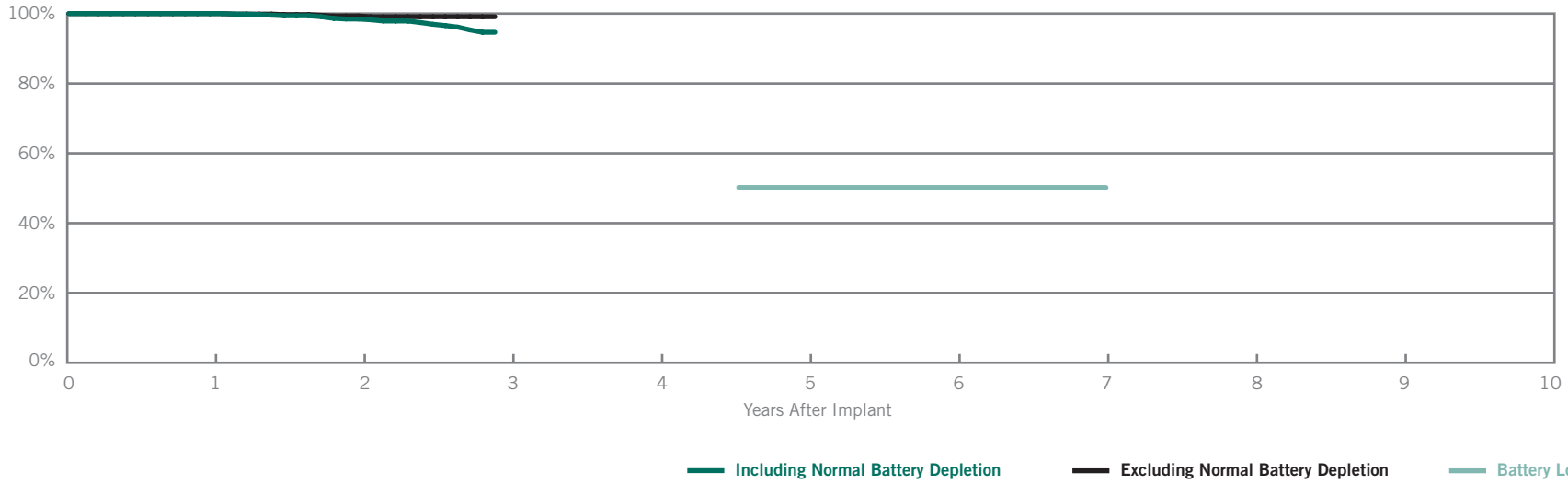
| Year | 1 | 2 | at 31 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.77% | 99.54% | | | | | | | |
| ± 1 standard error | 0.05% | 0.05% | 0.17% | | | | | | | |

# Cardiac Resynchronization Therapy

## Epic® II HF (Model V-355)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2006 | Normal Battery Depletion | 21 |
| Registered US Implants | 1,704 | Total Malfunctions (0 related to Advisory) | 5 |
| Estimated Active US Implants | 1,063 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 2 |
| Estimated Longevity | (see table on page 28) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 3 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 35 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 98.44% | 94.65% | | | | | | | |
| ± 1 standard error | 0.00% | 0.37% | 0.96% | | | | | | | |
| Sample Size | 1700 | 1300 | 200 | | | | | | | |

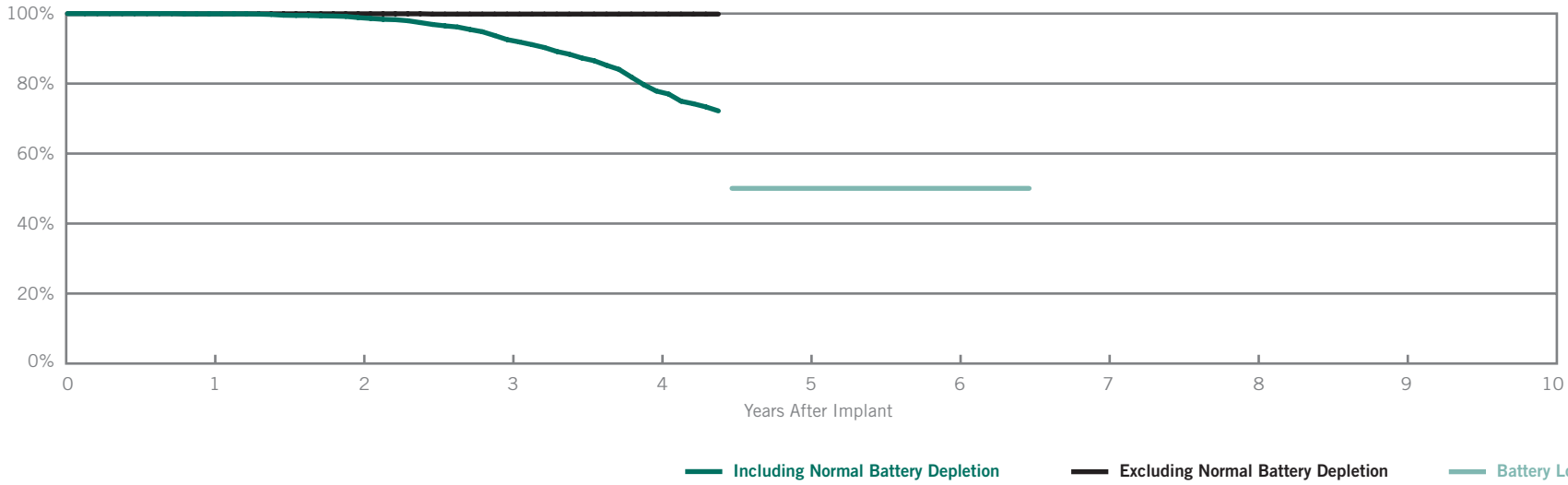
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 35 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.32% | 99.10% | | | | | | | |
| ± 1 standard error | 0.00% | 0.24% | 0.29% | | | | | | | |

## Epic® HF (Model V-337)

| | | | |
|---|---|---|---|
| US Regulatory Approval | November 2004 | Normal Battery Depletion | 231 |
| Registered US Implants | 3,966 | Total Malfunctions (0 related to Advisory) | 2 |
| Estimated Active US Implants | 1,460 | 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 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 98.86% | 92.56% | 77.87% | 72.19% | | | | | |
| ± 1 standard error | 0.04% | 0.16% | 0.48% | 1.10% | 1.49% | | | | | |
| Sample Size | 4000 | 3300 | 2700 | 1500 | 200 | | | | | |

**Excluding Normal Battery Depletion**

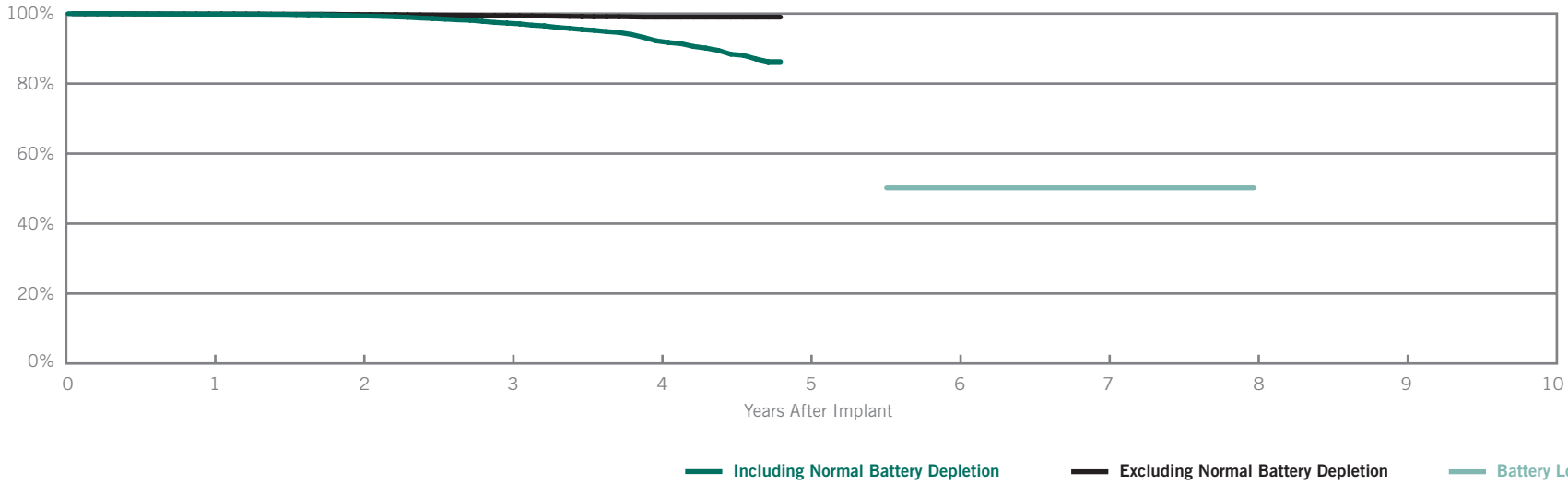
| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.94% | 99.86% | 99.86% | 99.86% | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.07% | 0.07% | 0.07% | | | | | |

# Cardiac Resynchronization Therapy

## Atlas® + HF (Model V-343)

| | | | |
|---|---|---|---|
| US Regulatory Approval | November 2004 | Normal Battery Depletion | 324 |
| Registered US Implants | 18,615 | Total Malfunctions (1 related to Advisory) | 59 |
| Estimated Active US Implants | 9,666 | Malfunctions w/ Compromised Therapy (1 related to Advisory) | 42 |
| Estimated Longevity | (see table on page 28) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 17 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.35% | 97.27% | 92.20% | 86.25% | | | | | |
| ± 1 standard error | 0.03% | 0.06% | 0.14% | 0.31% | 0.91% | | | | | |
| Sample Size | 18600 | 15600 | 12200 | 6500 | 300 | | | | | |

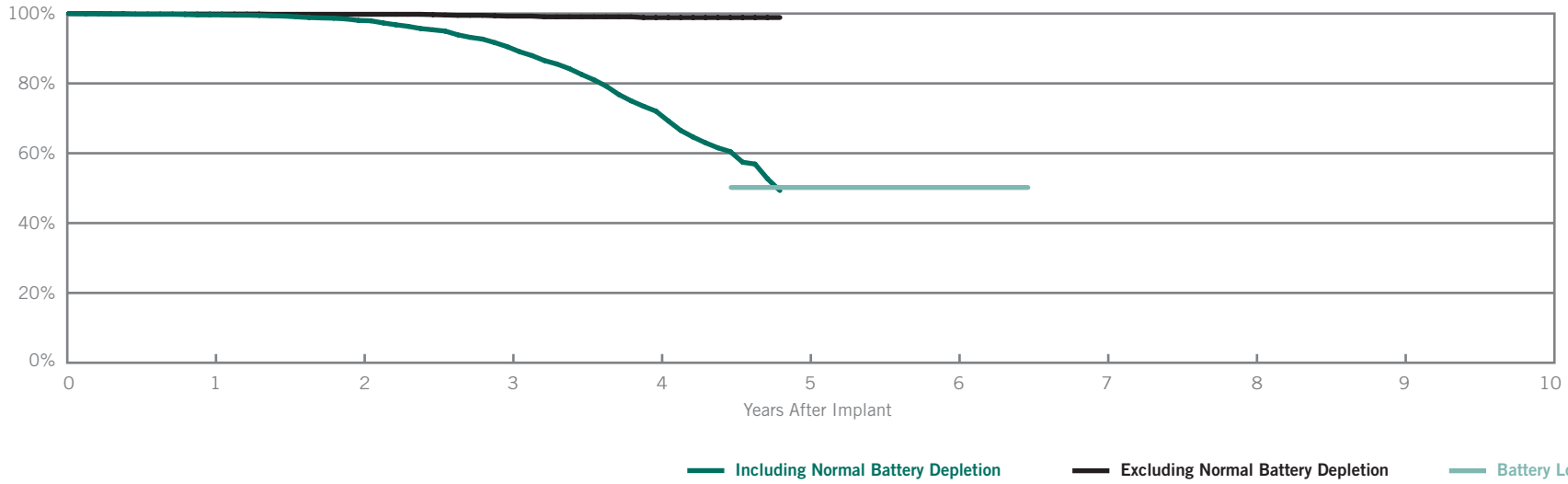
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.73% | 99.42% | 99.00% | 99.00% | | | | | |
| ± 1 standard error | 0.03% | 0.04% | 0.07% | 0.11% | 0.11% | | | | | |

## Epic® HF (Model V-338)

| | | | |
|---|---|---|---|
| US Regulatory Approval | June 2004 | Normal Battery Depletion | 381 |
| Registered US Implants | 3.101 | Total Malfunctions (0 related to Advisory) | 11 |
| Estimated Active US Implants | 337 | 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 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.62% | 98.04% | 90.52% | 72.05% | 49.32% | | | | | |
| ± 1 standard error | 0.12% | 0.24% | 0.59% | 1.08% | 1.64% | | | | | |
| Sample Size | 3100 | 2700 | 2300 | 1700 | 200 | | | | | |

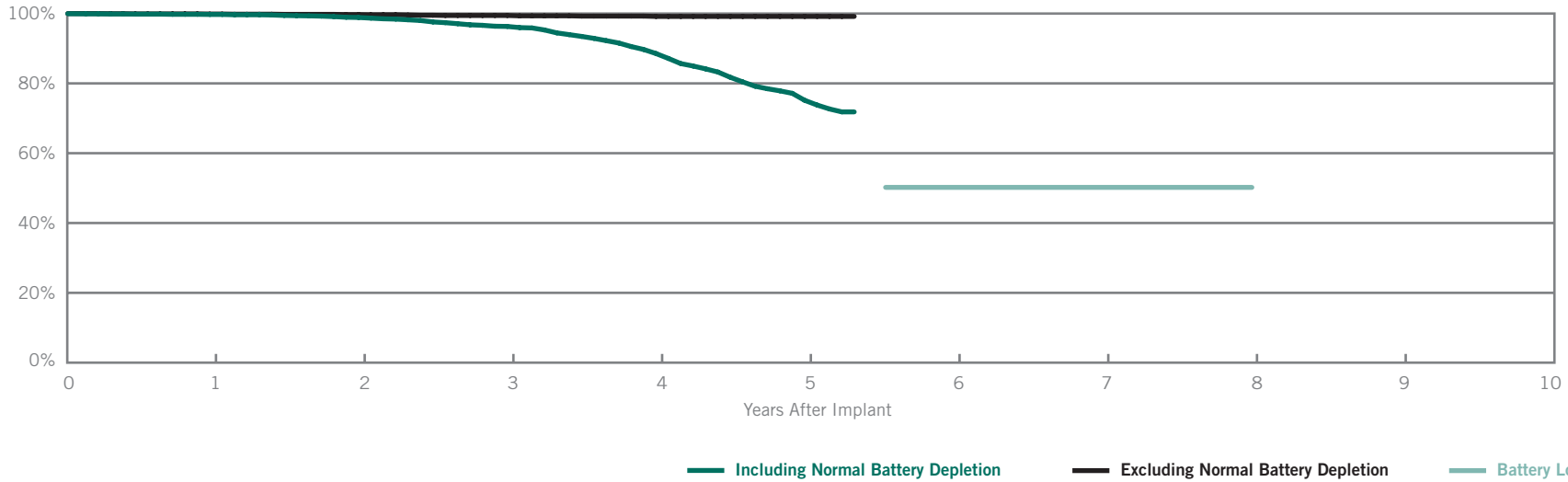
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.79% | 99.27% | 98.87% | 98.87% | | | | | |
| ± 1 standard error | 0.07% | 0.09% | 0.17% | 0.26% | 0.26% | | | | | |

## Atlas® + HF (Model V-340)

| | | | |
|---|---|---|---|
| US Regulatory Approval | June 2004 | Normal Battery Depletion | 300 |
| Registered US Implants | 4,923 | Total Malfunctions (1 related to Advisory) | 15 |
| Estimated Active US Implants | 1,248 | 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 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | 98.88% | 96.31% | 88.55% | 75.15% | 71.83% | | | | |
| ± 1 standard error | 0.07% | 0.16% | 0.31% | 0.57% | 1.01% | 1.38% | | | | |
| Sample Size | 4900 | 4200 | 3600 | 3000 | 1600 | 200 | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.71% | 99.45% | 99.18% | 99.18% | 99.18% | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.12% | 0.14% | 0.16% | 0.16% | | | | |

# Summary & Longevity Information

## CRT ICDs

ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

# Cardiac Resynchronization Therapy

## Battery Longevity

| Models | Family | Approximate Duration (years)* | | | |
|---|---|---|---|---|---|
| | | No Pacing | 25% Pacing | 50% Pacing | 100% Pacing |
| CD3211-36Q | Promote® + CRT-D | 8.2 | 7.2 | 6.5 | 5.4 |
| CD3211-36 | Promote® + CRT-D | 8.2 | 7.2 | 6.5 | 5.4 |
| 3207-30 | Promote® RF | 6.5 | 5.7 | 5.1 | 4.2 |
| 3107-36 | Promote® | 8.2 | 7.2 | 6.5 | 5.4 |
| 3207-36 | Promote® RF | 8.2 | 7.2 | 6.5 | 5.4 |
| V-365 | Atlas® II HF | 8.2 | 7.2 | 6.5 | 5.4 |
| V-366 | Atlas® II + HF | 8.2 | 7.2 | 6.5 | 5.4 |
| V-355 | Epic® II HF | 7.0 | 6.1 | 5.5 | 4.5 |
| V-337, 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 Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CD3211-36Q | Promote® + CRT-D | Feb-09 | 2298 | 2239 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CD3211-36 | Promote® + CRT-D | Feb-09 | 4038 | 3874 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3207-30 | Promote® RF | Sep-07 | 1212 | 1043 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3107-36 | Promote® | May-07 | 713 | 516 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| 3207-36 | Promote® RF | Sep-07 | 22138 | 19009 | 6 | 0 | 1 | 10 | 3 | 20 | 2 |
| V-365 | Atlas® II HF | Jul-06 | 8377 | 5662 | 5 | 0 | 5 | 2 | 2 | 14 | 47 |
| V-366 | Atlas® II + HF | Feb-07 | 4756 | 3640 | 0 | 0 | 2 | 1 | 2 | 5 | 9 |
| V-355 | Epic® II HF | Mar-06 | 1704 | 1063 | 1 | 0 | 1 | 1 | 2 | 5 | 21 |
| V-337 | Epic® HF | Nov-04 | 3966 | 1460 | 0 | 0 | 1 | 1 | 0 | 2 | 231 |
| V-343 | Atlas® + HF | Nov-04 | 18615 | 9666 | 2 | 1 | 39 | 6 | 11 | 59 | 324 |
| V-338 | Epic® HF | Jun-04 | 3101 | 337 | 2 | 0 | 1 | 1 | 7 | 11 | 381 |
| V-340 | Atlas® + HF | Jun-04 | 4923 | 1248 | 3 | 1 | 5 | 0 | 6 | 15 | 300 |

# 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 |
| CD3211-36Q | Promote® + CRT-D* | | | | | | | | | | |
| CD3211-36 | Promote® + CRT-D* | | | | | | | | | | |
| 3207-30 | Promote® RF | 100.00% | | | | | | | | | |
| 3107-36 | Promote® | 100.00% | 99.63% | | | | | | | | |
| 3207-36 | Promote® RF | 99.83% | 99.74% | | | | | | | | |
| V-365 | Atlas® II HF | 99.84% | 99.19% | 97.11% | | | | | | | |
| V-366 | Atlas® II + HF | 99.72% | 99.14% | | | | | | | | |
| V-355 | Epic® II HF | 100.00% | 98.44% | | | | | | | | |
| V-337 | Epic® HF | 99.94% | 98.86% | 92.56% | 77.87% | | | | | | |
| V-343 | Atlas® + HF | 99.85% | 99.35% | 97.27% | 92.20% | | | | | | |
| V-338 | Epic® HF | 99.62% | 98.04% | 90.52% | 72.05% | | | | | | |
| V-340 | Atlas® + HF | 99.74% | 98.88% | 96.31% | 88.55% | 75.15% | | | | | |

**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 |
| CD3211-36Q | Promote® + CRT-D* | | | | | | | | | | |
| CD3211-36 | Promote® + CRT-D* | | | | | | | | | | |
| 3207-30 | Promote® RF | 100.00% | | | | | | | | | |
| 3107-36 | Promote® | 100.00% | 99.63% | | | | | | | | |
| 3207-36 | Promote® RF | 99.86% | 99.77% | | | | | | | | |
| V-365 | Atlas® II HF | 99.86% | 99.76% | 99.36% | | | | | | | |
| V-366 | Atlas® II + HF | 99.89% | 99.77% | | | | | | | | |
| V-355 | Epic® II HF | 100.00% | 99.32% | | | | | | | | |
| V-337 | Epic® HF | 99.94% | 99.94% | 99.86% | 99.86% | | | | | | |
| V-343 | Atlas® + HF | 99.89% | 99.73% | 99.42% | 99.00% | | | | | | |
| V-338 | Epic® HF | 99.86% | 99.79% | 99.27% | 98.87% | | | | | | |
| V-340 | Atlas® + HF | 99.87% | 99.71% | 99.45% | 99.18% | 99.18% | | | | | |

**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 Pacemakers

St. Jude Medical

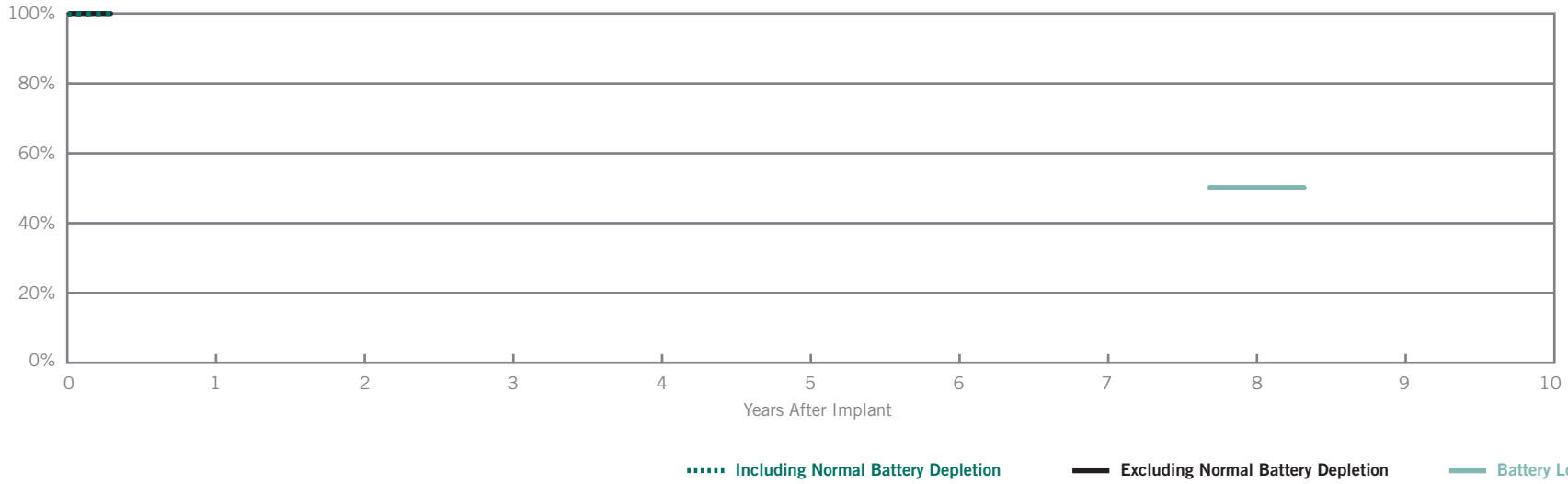
More control. Less risk.

# Cardiac Resynchronization Therapy

## Anthem® RF (Model PM3210)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 756 | Total Malfunctions | 0 |
| Estimated Active US Implants | 731 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 8 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 4 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

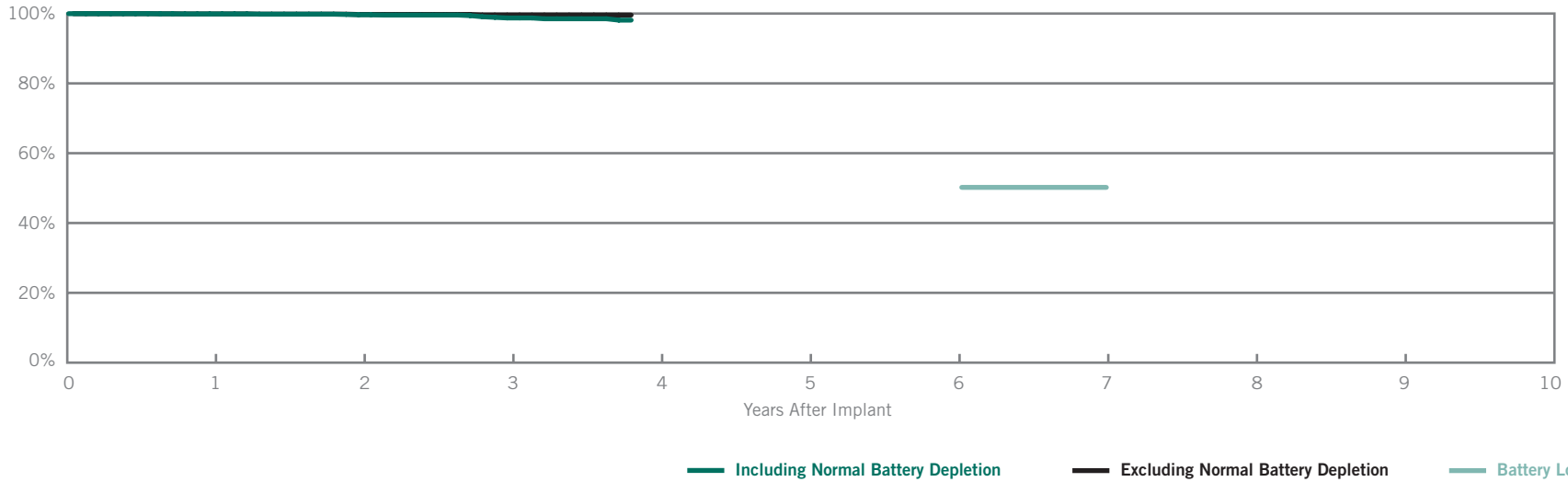
**Excluding Normal Battery Depletion**

| Year | at 4 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

## Frontier® II (Model 5586)

| | | | |
|---|---|---|---|
| US Regulatory Approval | August 2004 | Normal Battery Depletion | 8 |
| Registered US Implants | 6,549 | Total Malfunctions | 6 |
| Estimated Active US Implants | 4,518 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 6.5 Years | Malfunctions w/o Compromised Therapy | 5 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 46 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.66% | 98.74% | 98.12% | | | | | | |
| ± 1 standard error | 0.05% | 0.08% | 0.26% | 0.43% | | | | | | |
| Sample Size | 5900 | 3400 | 1800 | 200 | | | | | | |

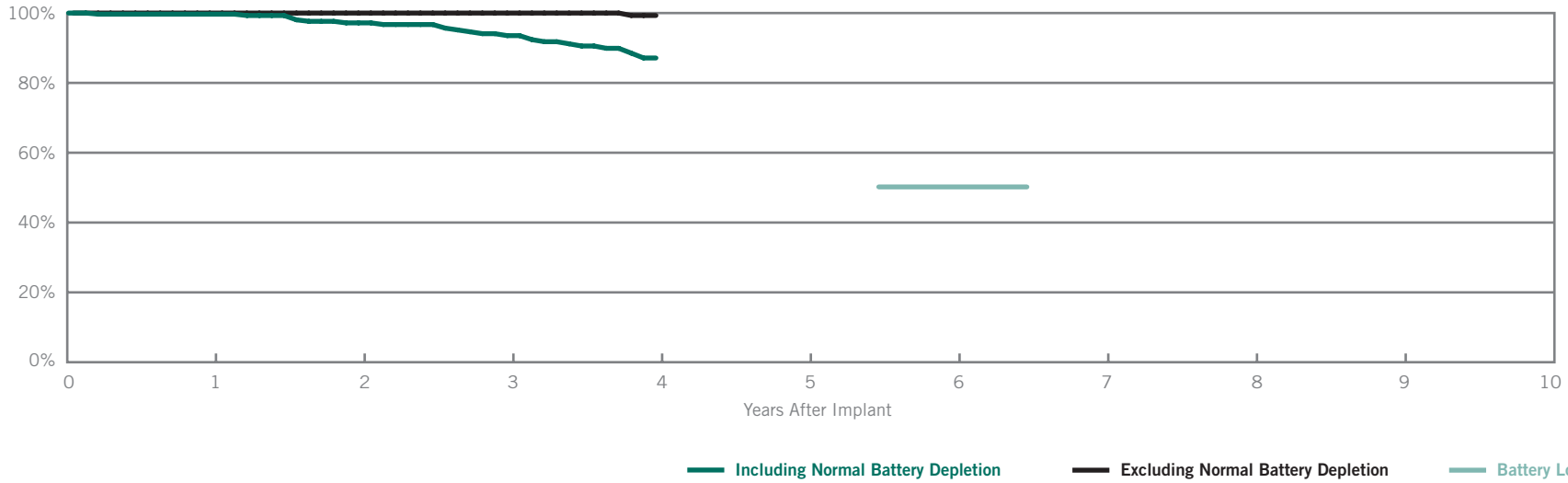
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 46 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.74% | 99.58% | 99.58% | | | | | | |
| ± 1 standard error | 0.05% | 0.06% | 0.14% | 0.14% | | | | | | |

## Frontier® (Model 5508)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2004 | Normal Battery Depletion | 40 |
| Registered US Implants | 671 | Total Malfunctions | 2 |
| Estimated Active US Implants | 128 | 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 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.68% | 97.18% | 93.53% | 87.13% | | | | | | |
| ± 1 standard error | 0.23% | 0.75% | 1.14% | 1.78% | | | | | | |
| Sample Size | 700 | 500 | 400 | 300 | | | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.30% | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.49% | | | | | | |

# Summary & Longevity Information

## CRT Pacemakers

ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

## Malfunction and Normal Battery Depletion Summary Information

| Models | Family | US Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| PM3210 | Anthem® RF | July-09 | 756 | 731 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5586 | Frontier® II | Aug-04 | 6549 | 4518 | 1 | 5 | 0 | 0 | 6 | 8 |
| 5508 | Frontier® | May-04 | 671 | 128 | 0 | 1 | 0 | 1 | 2 | 40 |

# 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 |
| PM3210 | Anthem® RF* | | | | | | | | |
| 5586 | Frontier® II | 99.89% | 99.66% | 98.74% | | | | | |
| 5508 | Frontier® | 100.00% | 97.54% | 94.02% | 87.97% | | | | |

**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 |
| PM3210 | Anthem® RF* | | | | | | | | |
| 5586 | Frontier® II | 99.89% | 99.74% | 99.58% | | | | | |
| 5508 | Frontier® | 100.00% | 100.00% | 100.00% | 99.30% | | | | |

**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.*

# Left-Heart Leads

St. Jude Medical™

More control. Less risk.

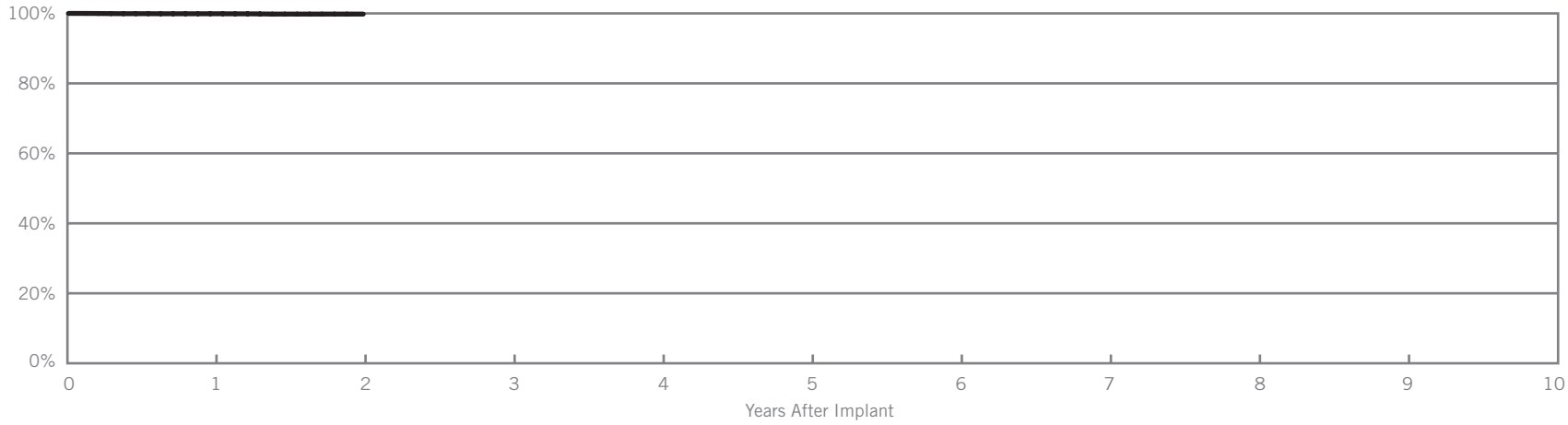
# Left-Heart Leads

| QuickFlex® (Model 1156T) | |
|---|---|
| US Regulatory Approval | July 2007 |
| Registered US Implants | 16,057 |
| Estimated Active US Implants | 13,713 |
| 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 | 12 | 0.07% | 18 | 0.11% |
| Failure to Capture | 4 | 0.02% | 4 | 0.02% |
| Oversensing | 0 | 0.00% | 2 | 0.01% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 2 | 0.01% |
| Extracardiac Stimulation | 16 | 0.10% | 13 | 0.08% |
| Other | 7 | 0.04% | 2 | 0.01% |
| **Total** | **39** | **0.24%** | **41** | **0.26%** |
| **Total Returned for Analysis** | **7** | | **13** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 1 | 0.01% |
| Insulation Breach | 0 | 0.00% |
| Crimps, Welds & Bonds | 1 | 0.01% |
| Other | 1 | 0.01% |
| Extrinsic Factors | 10 | 0.06% |
| **Total** | **13** | **0.08%** |

## Survival from Returns and Complaints



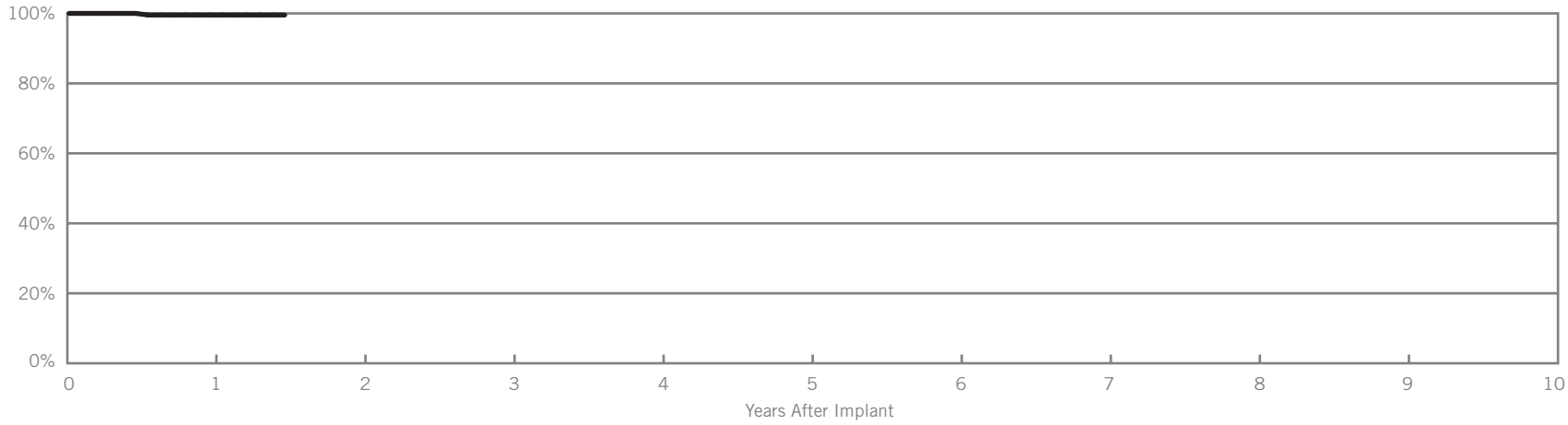

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.81% | | | | | | | | |
| **± 1 standard error** | 0.03% | 0.06% | | | | | | | | |
| **Sample Size** | 11300 | 2900 | | | | | | | | |

| QuickFlex® (Model 1156T) | |
|---|---|
| US Regulatory Approval | 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 | 319 |
| Cumulative Months of Follow-up | 3,423 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.31% |

## Survival from SCORE Registry




| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.54% | 99.54% | | | | | | | | |
| **± 1 standard error** | 0.46% | 0.46% | | | | | | | | |
| **Sample Size** | 139 | 61 | | | | | | | | |

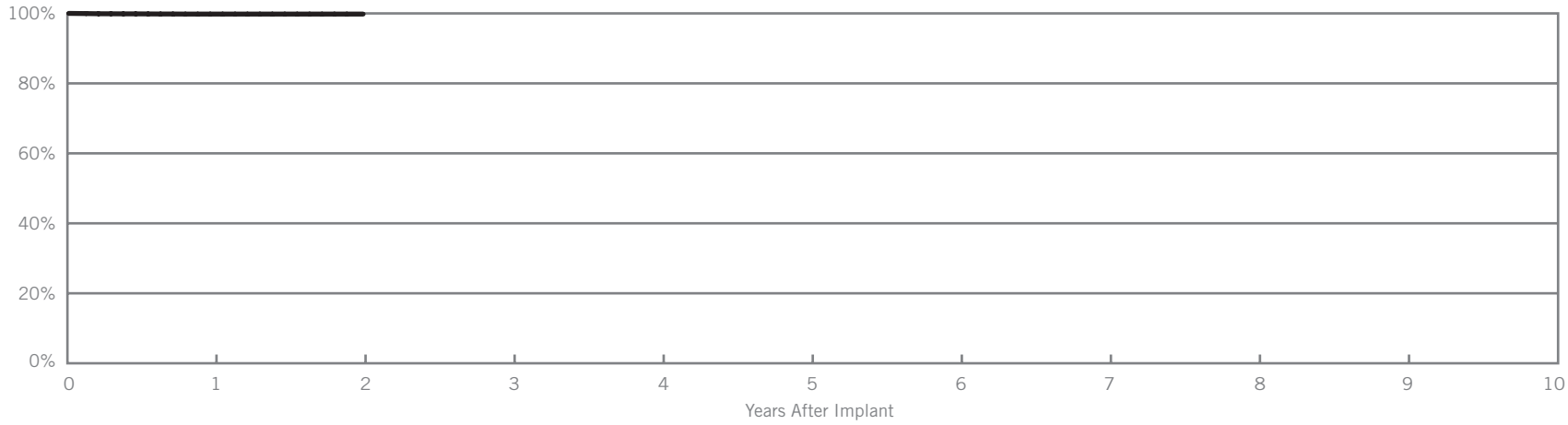
# Left-Heart Leads

| QuickFlex® XL (Model 1158T) | |
|---|---|
| US Regulatory Approval | July 2007 |
| Registered US Implants | 8,483 |
| Estimated Active US Implants | 7,210 |
| 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 | 8 | 0.09% | 9 | 0.11% |
| Failure to Capture | 2 | 0.02% | 4 | 0.05% |
| 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 | 0.02% | 2 | 0.02% |
| Extracardiac Stimulation | 5 | 0.06% | 6 | 0.07% |
| Other | 6 | 0.07% | 0 | 0.00% |
| **Total** | **23** | **0.27%** | **21** | **0.25%** |
| **Total Returned for Analysis** | **9** | | **7** | |

| 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 | 5 | 0.06% |
| **Total** | **7** | **0.08%** |

## Survival from Returns and Complaints



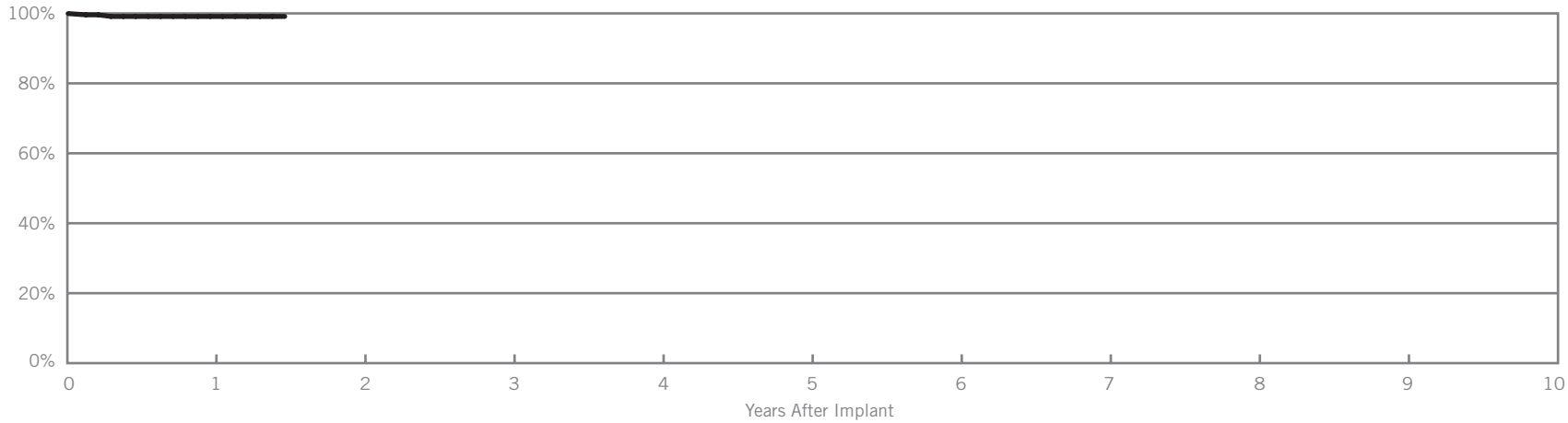

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.81% | 99.81% | | | | | | | | |
| **± 1 standard error** | 0.06% | 0.06% | | | | | | | | |
| **Sample Size** | 6100 | 1700 | | | | | | | | |

| QuickFlex® XL (Model 1158T) | |
|---|---|
| US Regulatory Approval | 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 | 250 |
| Cumulative Months of Follow-up | 2,929 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.40% |
| Failure to Capture | 1 | 0.40% |

## Survival from SCORE Registry




| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.13% | 99.13% | | | | | | | | |
| **± 1 standard error** | 0.62% | 0.62% | | | | | | | | |
| **Sample Size** | 127 | 61 | | | | | | | | |

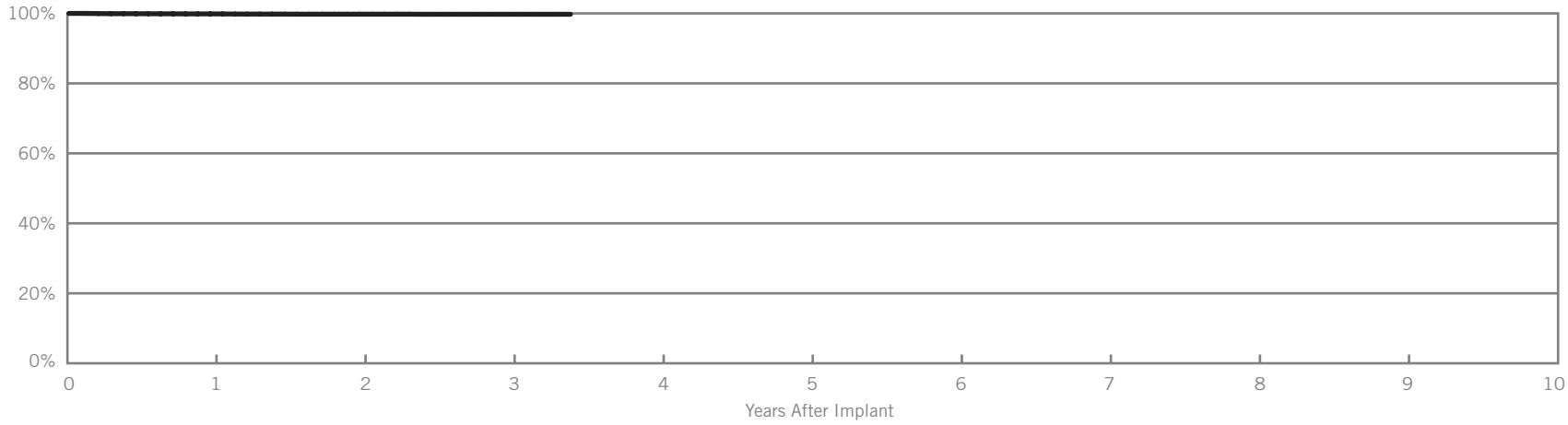
# Left-Heart Leads

| QuickSite® XL (Model 1058T) | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 10,071 |
| Estimated Active US Implants | 7,155 |
| 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% | 11 | 0.11% |
| Oversensing | 1 | 0.01% | 1 | 0.01% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 2 | 0.02% | 1 | 0.01% |
| Extracardiac Stimulation | 9 | 0.09% | 4 | 0.04% |
| Other | 2 | 0.02% | 1 | 0.01% |
| **Total** | **25** | **0.25%** | **28** | **0.28%** |
| **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 | 7 | 0.07% |
| **Total** | **10** | **0.10%** |

## Survival from Returns and Complaints



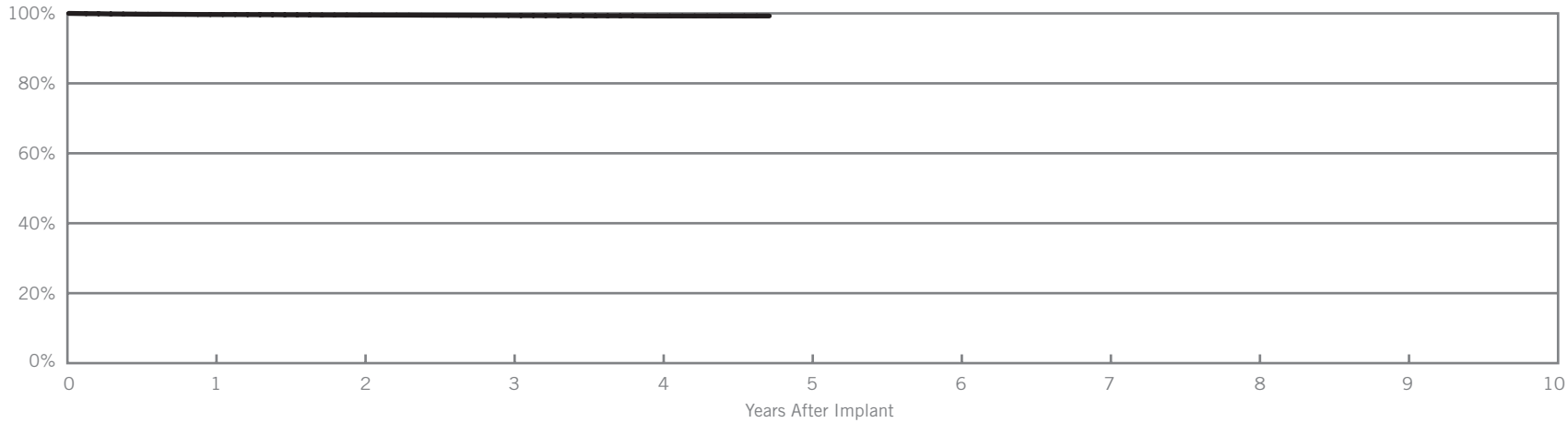

| Year | 1 | 2 | 3 | at 41 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.86% | 99.78% | 99.75% | 99.75% | | | | | | |
| **± 1 standard error** | 0.04% | 0.05% | 0.06% | 0.06% | | | | | | |
| **Sample Size** | 9300 | 6900 | 3400 | 300 | | | | | | |

| QuickSite® (Model 1056T) | |
|---|---|
| US Regulatory Approval | April 2005 |
| Registered US Implants | 33,422 |
| Estimated Active US Implants | 20,888 |
| 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 | 27 | 0.08% | 69 | 0.21% |
| Failure to Capture | 14 | 0.04% | 61 | 0.18% |
| Oversensing | 1 | <0.01% | 3 | 0.01% |
| Failure to Sense | 0 | 0.00% | 1 | <0.01% |
| Insulation Breach | 1 | <0.01% | 0 | 0.00% |
| Abnormal Pacing Impedance | 3 | 0.01% | 3 | 0.01% |
| Extracardiac Stimulation | 23 | 0.07% | 42 | 0.13% |
| Other | 9 | 0.03% | 7 | 0.02% |
| **Total** | **78** | **0.23%** | **188** | **0.56%** |
| **Total Returned for Analysis** | **30** | | **71** | |

| 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 | 65 | 0.19% |
| **Total** | **71** | **0.21%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | at 57 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.68% | 99.53% | 99.40% | 99.27% | 99.27% | | | | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.05% | 0.07% | 0.07% | | | | | |
| **Sample Size** | 30500 | 24200 | 17100 | 8700 | 200 | | | | | |

# Left-Heart Leads

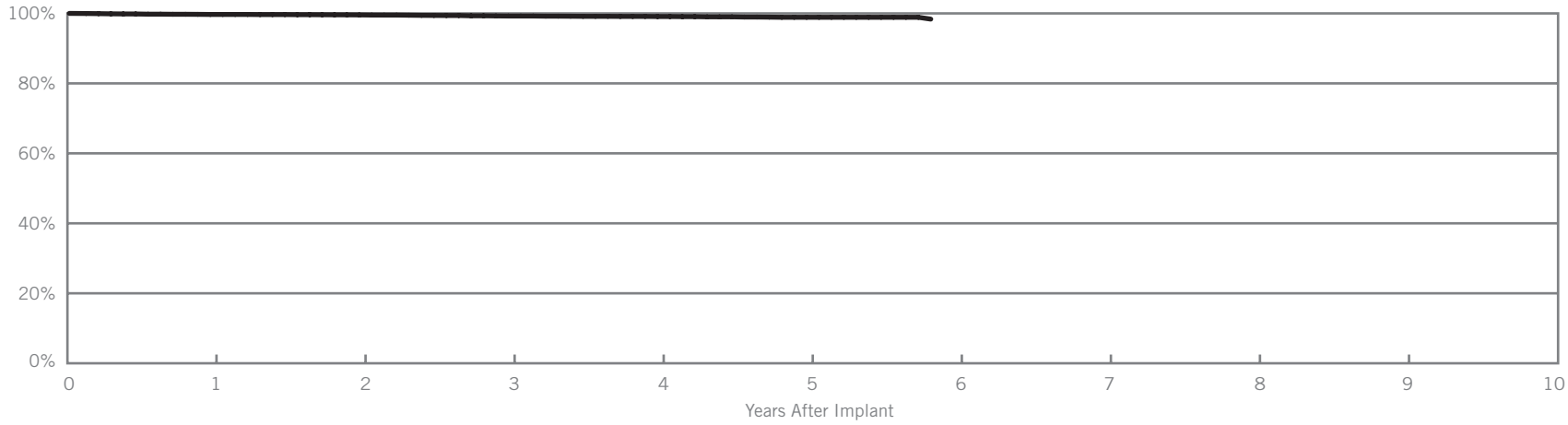
## Unipolar

| QuickSite® (Model 1056K) | |
|---|---|
| US Regulatory Approval | June 2004 |
| Registered US Implants | 8,759 |
| Estimated Active US Implants | 3,925 |
| 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 | 0.11% | 25 | 0.29% |
| Failure to Capture | 3 | 0.03% | 25 | 0.29% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 2 | 0.02% |
| Extracardiac Stimulation | 10 | 0.11% | 11 | 0.13% |
| Other | 2 | 0.02% | 8 | 0.09% |
| **Total** | **25** | **0.29%** | **71** | **0.81%** |
| **Total Returned for Analysis** | **24** | | **37** | |

| 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 | 24 | 0.27% |
| **Total** | **28** | **0.32%** |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | at 70 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.70% | 99.57% | 99.25% | 99.11% | 98.89% | 98.37% | | | | |
| **± 1 standard error** | 0.06% | 0.08% | 0.11% | 0.12% | 0.15% | 0.15% | | | | |
| **Sample Size** | 7700 | 6500 | 5400 | 4400 | 3000 | 200 | | | | |

# Observations, Complications, and Malfunctions

## Left-Heart Leads

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# Left-Heart Leads

## Acute Observations (Post Implant, ≤30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 1156T | Jul-07 | 16057 | 13713 | 0 | 0.00% | 0 | 0.00% | 12 | 0.07% | 4 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 16 | 0.10% | 7 | 0.04% | **39** | **0.24%** | **7** |
| 1158T | Jul-07 | 8483 | 7210 | 0 | 0.00% | 0 | 0.00% | 8 | 0.09% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 5 | 0.06% | 6 | 0.07% | **23** | **0.27%** | **9** |
| 1058T | Feb-06 | 10071 | 7155 | 0 | 0.00% | 0 | 0.00% | 8 | 0.08% | 3 | 0.03% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 9 | 0.09% | 2 | 0.02% | **25** | **0.25%** | **9** |
| 1056T | Apr-05 | 33422 | 20888 | 0 | 0.00% | 0 | 0.00% | 27 | 0.08% | 14 | 0.04% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | 3 | 0.01% | 23 | 0.07% | 9 | 0.03% | **78** | **0.23%** | **30** |
| 1056K | Jun-04 | 8759 | 3925 | 0 | 0.00% | 0 | 0.00% | 10 | 0.11% | 3 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 10 | 0.11% | 2 | 0.02% | **25** | **0.29%** | **24** |

## Chronic Complications (>30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 1156T | Jul-07 | 16057 | 13713 | 0 | 0.00% | 0 | 0.00% | 18 | 0.11% | 4 | 0.02% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 2 | 0.01% | 13 | 0.08% | 2 | 0.01% | **41** | **0.26%** | **13** |
| 1158T | Jul-07 | 8483 | 7210 | 0 | 0.00% | 0 | 0.00% | 9 | 0.11% | 4 | 0.05% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 6 | 0.07% | 0 | 0.00% | **21** | **0.25%** | **7** |
| 1058T | Feb-06 | 10071 | 7155 | 0 | 0.00% | 1 | 0.01% | 9 | 0.09% | 11 | 0.11% | 1 | 0.01% | 0 | 0.01% | 0 | 0.00% | 1 | 0.01% | 4 | 0.04% | 1 | 0.01% | **28** | **0.28%** | **7** |
| 1056T | Apr-05 | 33422 | 20888 | 0 | 0.00% | 2 | 0.01% | 69 | 0.21% | 61 | 0.18% | 3 | 0.01% | 1 | <0.01% | 0 | 0.00% | 3 | 0.01% | 42 | 0.13% | 7 | 0.02% | **188** | **0.56%** | **71** |
| 1056K | Jun-04 | 8759 | 3925 | 0 | 0.00% | 0 | 0.00% | 25 | 0.29% | 25 | 0.29% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 11 | 0.13% | 8 | 0.09% | **71** | **0.81%** | **37** |

*Definitions of observations and complications can be found on pages 6 and 7.*

## Lead Malfunctions

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Conductor Fracture | | Insulation Breach | | Crimps, Welds & Bonds | | Other | | Extrinsic Factors | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate |
| 1156T | Jul-07 | 16057 | 13713 | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 1 | 0.01% | 10 | 0.06% | **13** | **0.08%** |
| 1158T | Jul-07 | 8483 | 7210 | 1 | 0.01% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 5 | 0.06% | **7** | **0.08%** |
| 1058T | Feb-06 | 10071 | 7155 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 3 | 0.03% | 7 | 0.07% | **10** | **0.10%** |
| 1056T | Apr-05 | 33422 | 20888 | 1 | <0.01% | 3 | 0.01% | 1 | <0.01% | 1 | <0.01% | 65 | 0.19% | **71** | **0.21%** |
| 1056K | Jun-04 | 8759 | 3925 | 2 | 0.02% | 0 | 0.00% | 2 | 0.02% | 0 | 0.00% | 24 | 0.27% | **28** | **0.32%** |

*Definitions of malfunction categories can be found on pages 7 and 8.*

# ICDs

## Dual-Chamber

ST. JUDE MEDICAL™

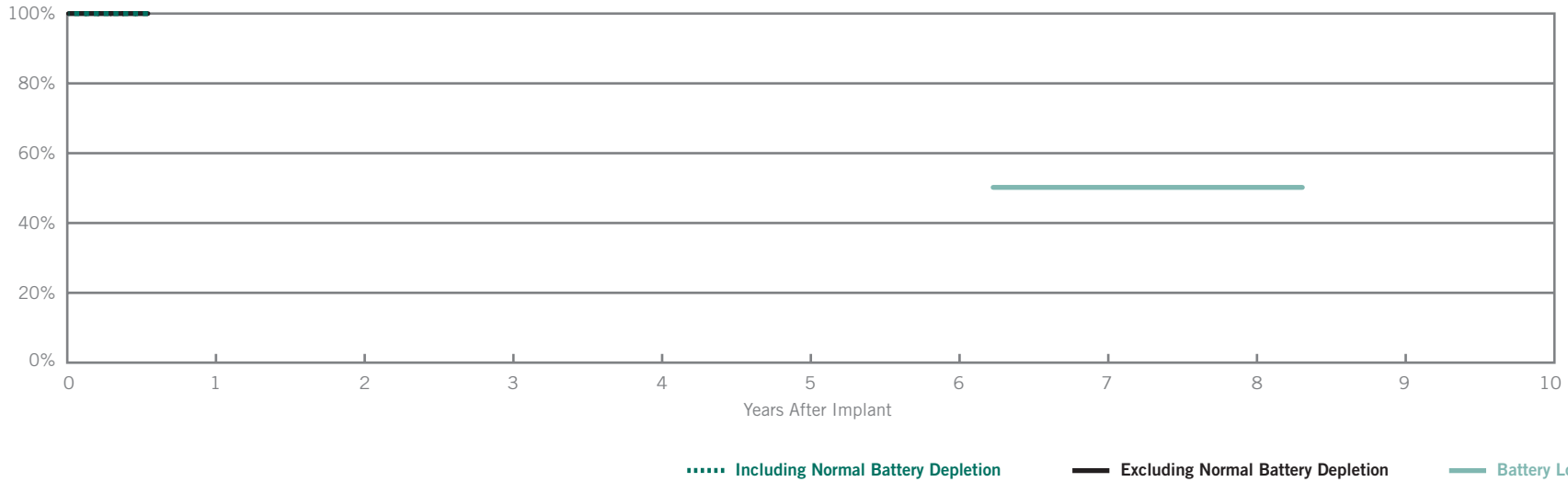
MORE CONTROL. LESS RISK.

# ICDs

## Current® + DR (Model CD2211-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 2,928 | Total Malfunctions | 0 |
| Estimated Active US Implants | 2,834 | 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 | at 7 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 500 | | | | | | | | | |

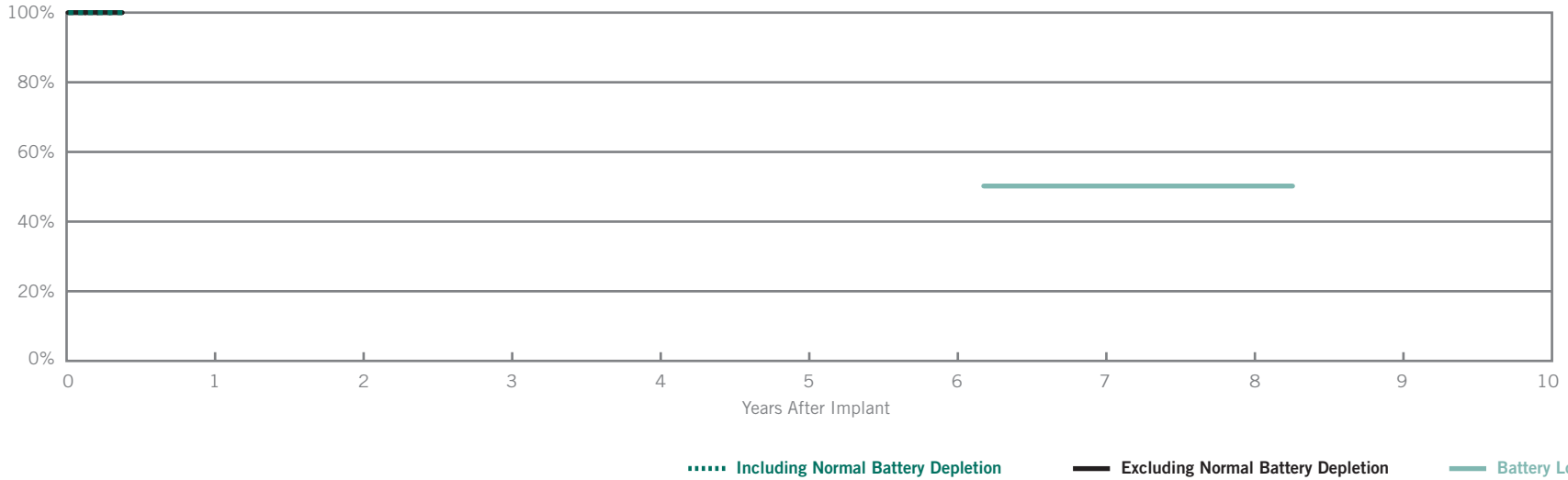
**Excluding Normal Battery Depletion**

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

## Current® + DR (Model CD2211-36Q)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 2,612 | Total Malfunctions | 0 |
| Estimated Active US Implants | 2,583 | 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 | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

**Excluding Normal Battery Depletion**

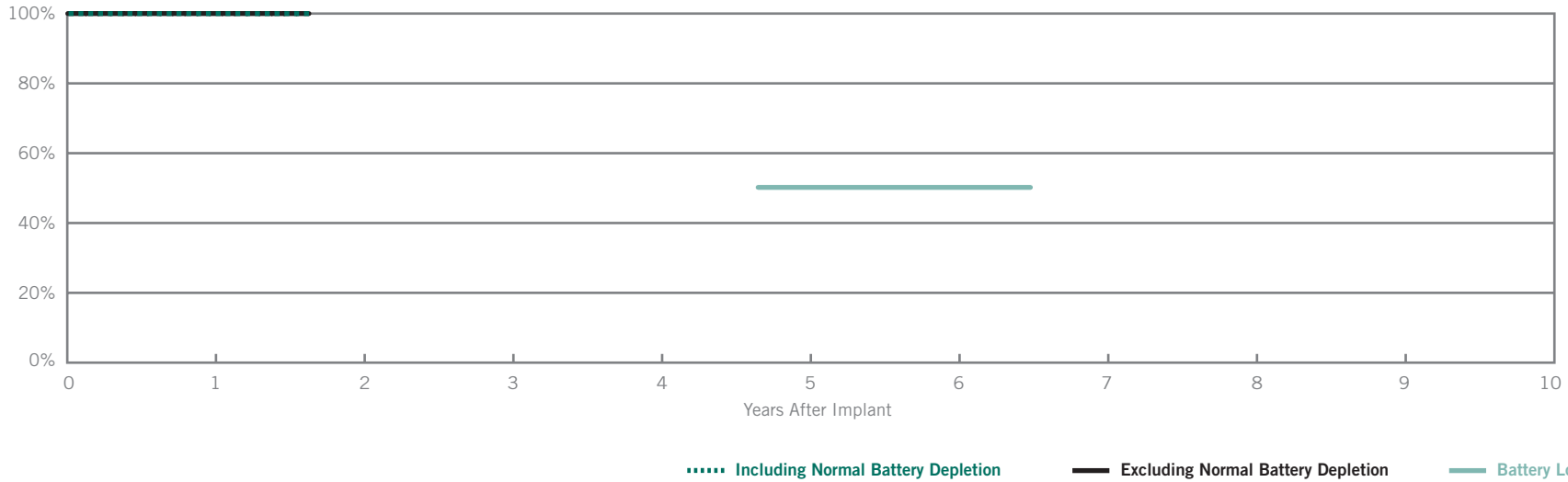
| Year | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

# ICDs

## Current® DR RF (Model 2207-30)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,434 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,274 | 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 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 1100 | 200 | | | | | | | | |

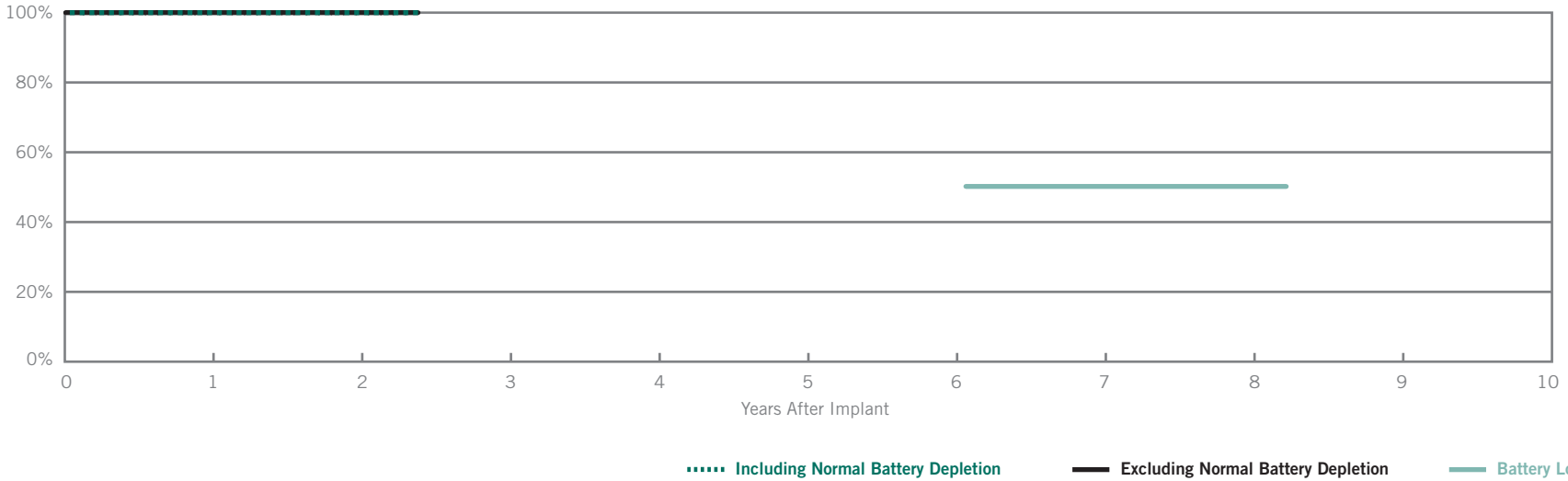
**Excluding Normal Battery Depletion**

| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

## Current® DR (Model 2107-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 651 | Total Malfunctions | 0 |
| Estimated Active US Implants | 516 | 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 | 2 | at 29 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | | | | | | |
| Sample Size | 600 | 500 | 300 | | | | | | |

**Excluding Normal Battery Depletion**

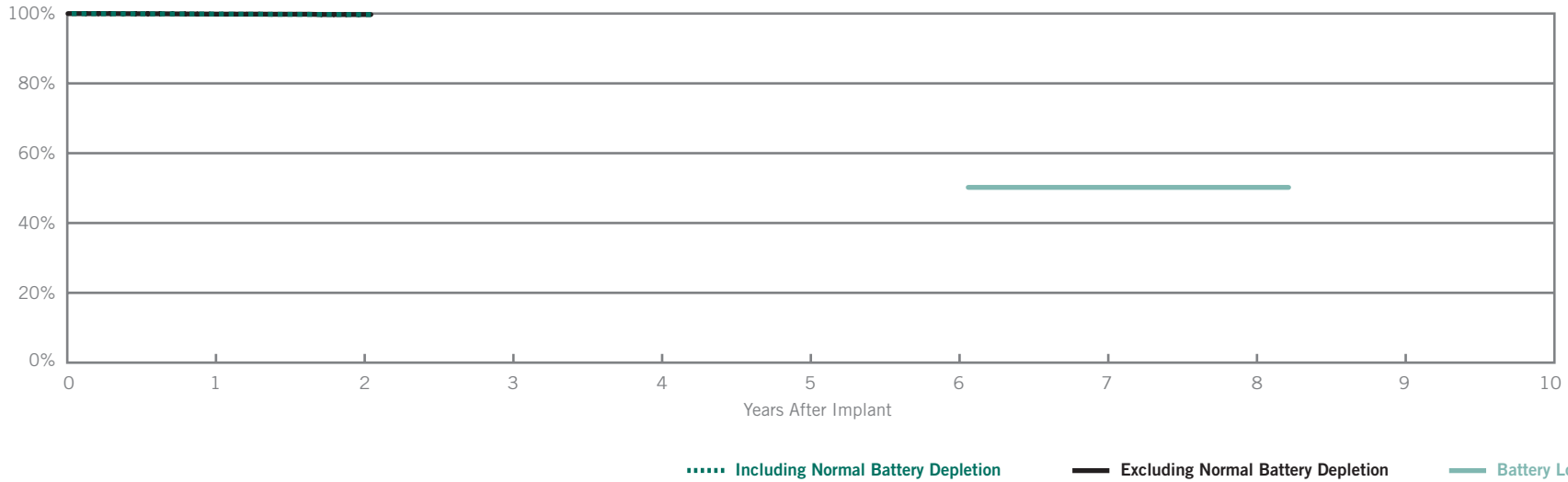
| Year | 1 | 2 | at 29 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | | | | | | |

# ICDs

## Current® DR RF (Model 2207-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 1 |
| Registered US Implants | 20,869 | Total Malfunctions | 16 |
| Estimated Active US Implants | 18,666 | Malfunctions w/ Compromised Therapy | 6 |
| Estimated Longevity | (see table on page 74) | Malfunctions w/o Compromised Therapy | 10 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.84% | 99.71% | 99.71% | | | | | | | |
| ± 1 standard error | 0.03% | 0.07% | 0.07% | | | | | | | |
| Sample Size | 16500 | 5600 | 600 | | | | | | | |

**Excluding Normal Battery Depletion**

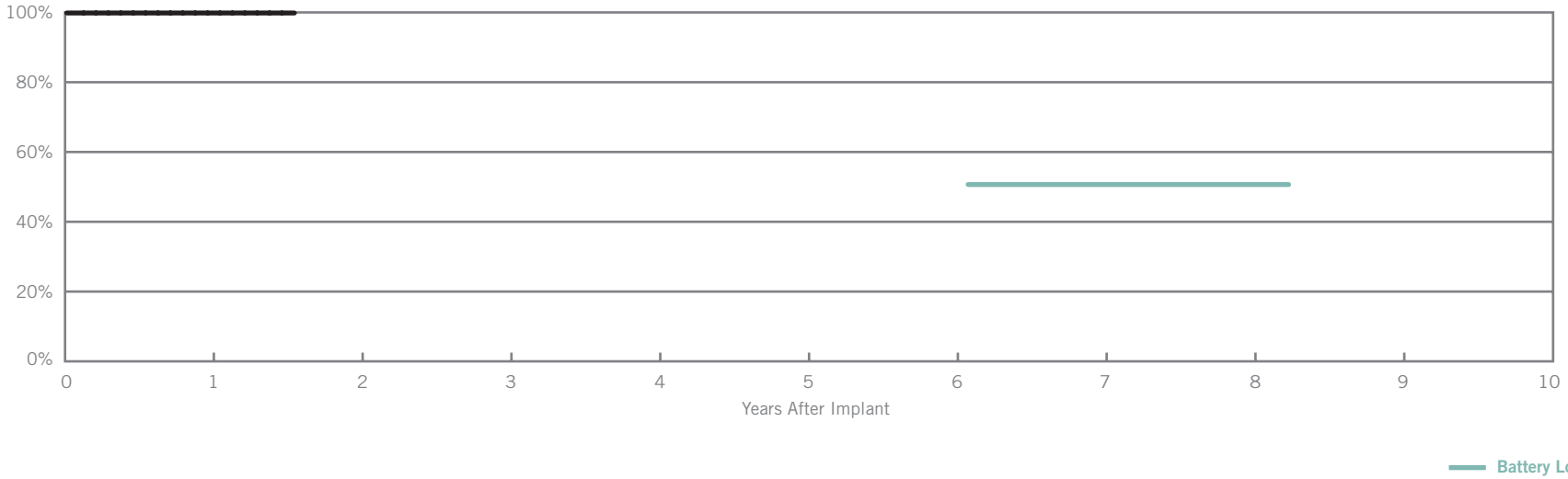
| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.72% | 99.72% | | | | | | | |
| ± 1 standard error | 0.03% | 0.07% | 0.07% | | | | | | | |

| Current® DR RF (Model 2207-36) | |
|---|---|
| US Regulatory Approval | September 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 620 |
| Cumulative Months of Follow-up | 7,418 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Failure to Sense | 1 | 0.16% |

## Survival from SCORE Registry



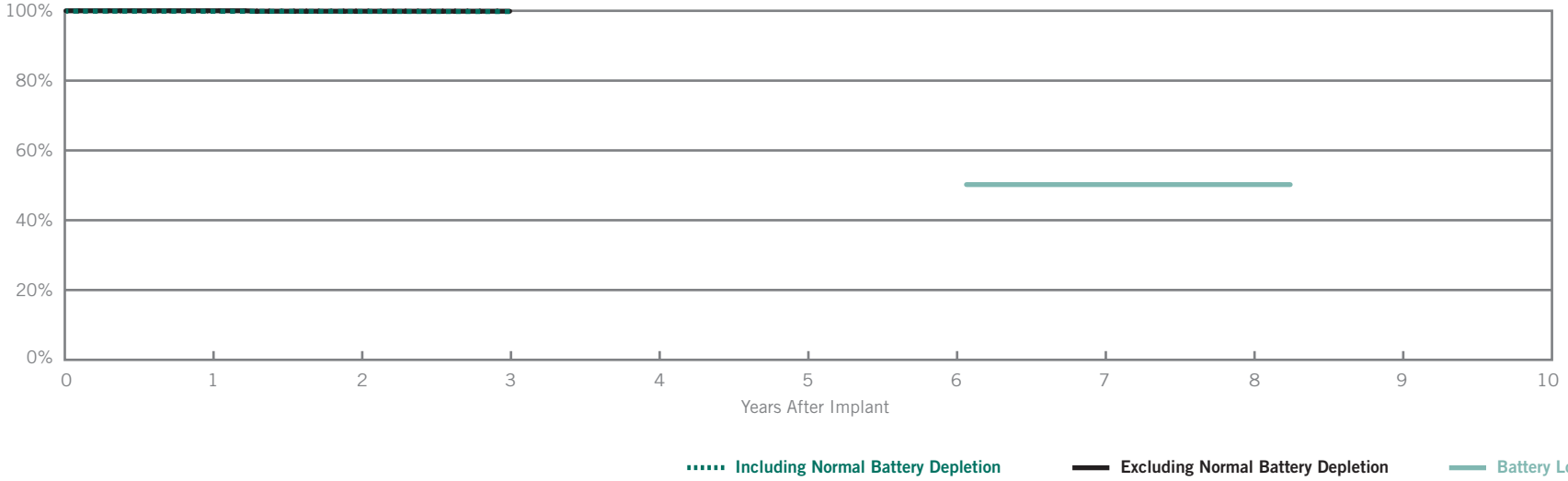

| Year | 1 | at 19 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.84% | 99.84% | | | | | | | | |
| **± 1 standard error** | 0.16% | 0.16% | | | | | | | | |
| **Sample Size** | 322 | 66 | | | | | | | | |

# ICDs

## Atlas® II DR (Model V-265)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2006 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,878 | Total Malfunctions (0 related to Advisory) | 1 |
| Estimated Active US Implants | 1,432 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | (see table on page 74) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.77% | 99.77% | | | | | | | |
| ± 1 standard error | 0.08% | 0.12% | 0.12% | | | | | | | |
| Sample Size | 1900 | 1500 | 700 | | | | | | | |

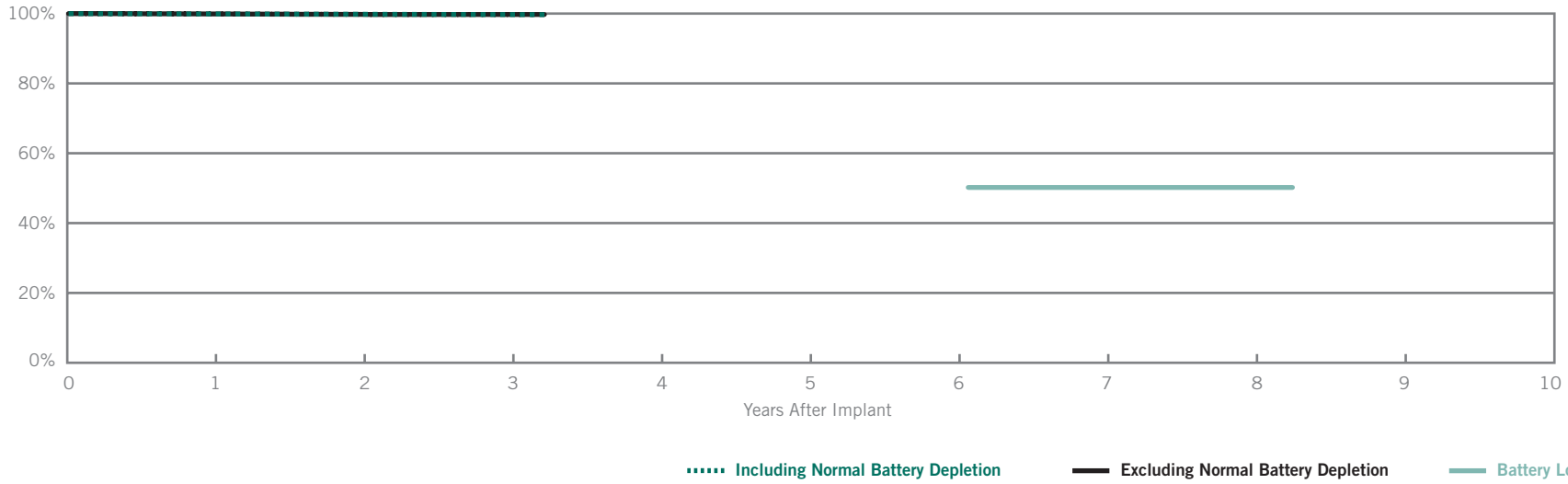
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.88% | 99.88% | | | | | | | |
| ± 1 standard error | 0.00% | 0.09% | 0.09% | | | | | | | |

## Atlas® II + DR (Model V-268)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2006 | Normal Battery Depletion | 3 |
| Registered US Implants | 14,458 | Total Malfunctions (0 related to Advisory) | 16 |
| Estimated Active US Implants | 11,416 | 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) | 6 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 39 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.74% | 99.70% | 99.70% | | | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.05% | 0.05% | | | | | | |
| Sample Size | 13900 | 9900 | 4200 | 300 | | | | | | |

**Excluding Normal Battery Depletion**

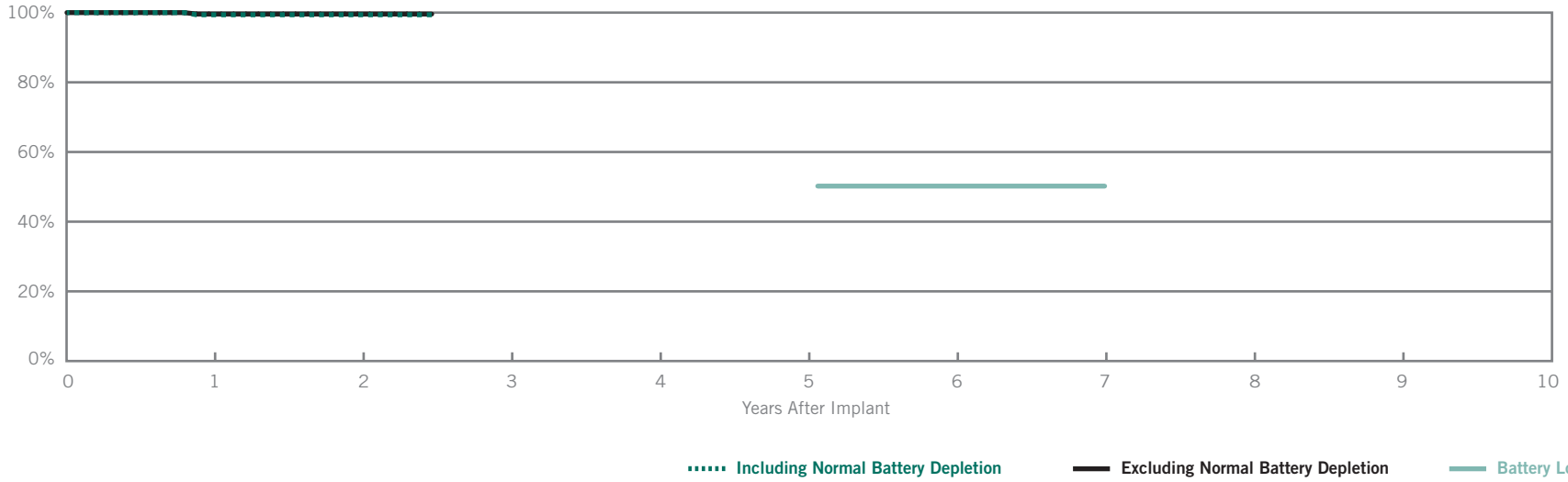
| Year | 1 | 2 | 3 | at 39 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.78% | 99.74% | 99.74% | | | | | | |
| ± 1 standard error | 0.03% | 0.04% | 0.05% | 0.05% | | | | | | |

# ICDs

## Epic® II DR (Model V-255)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2006 | Normal Battery Depletion | 1 |
| Registered US Implants | 544 | Total Malfunctions (0 related to Advisory) | 1 |
| Estimated Active US Implants | 396 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 74) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 1 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.38% | 99.38% | 99.38% | | | | | | | |
| ± 1 standard error | 0.36% | 0.36% | 0.36% | | | | | | | |
| Sample Size | 500 | 400 | 200 | | | | | | | |

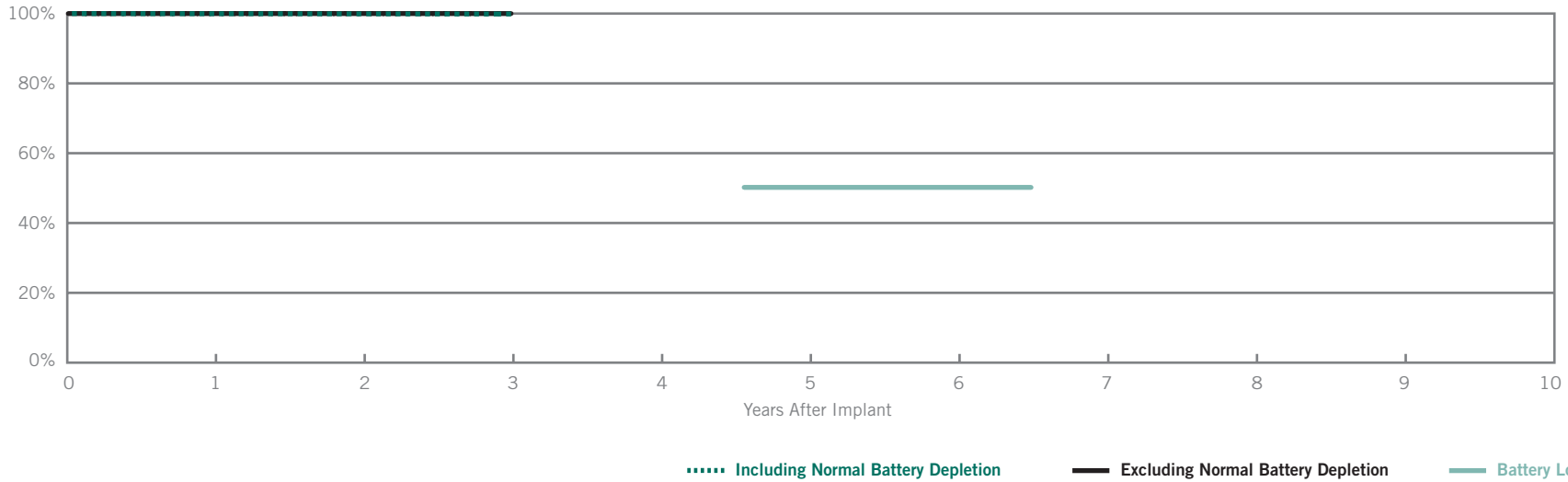
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.59% | 99.59% | 99.59% | | | | | | | |
| ± 1 standard error | 0.29% | 0.29% | 0.29% | | | | | | | |

## Epic® II + DR (Model V-258)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2006 | Normal Battery Depletion | 1 |
| Registered US Implants | 2,038 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,544 | 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 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.88% | 99.88% | | | | | | | |
| ± 1 standard error | 0.08% | 0.08% | 0.08% | | | | | | | |
| Sample Size | 2000 | 1500 | 700 | | | | | | | |

**Excluding Normal Battery Depletion**

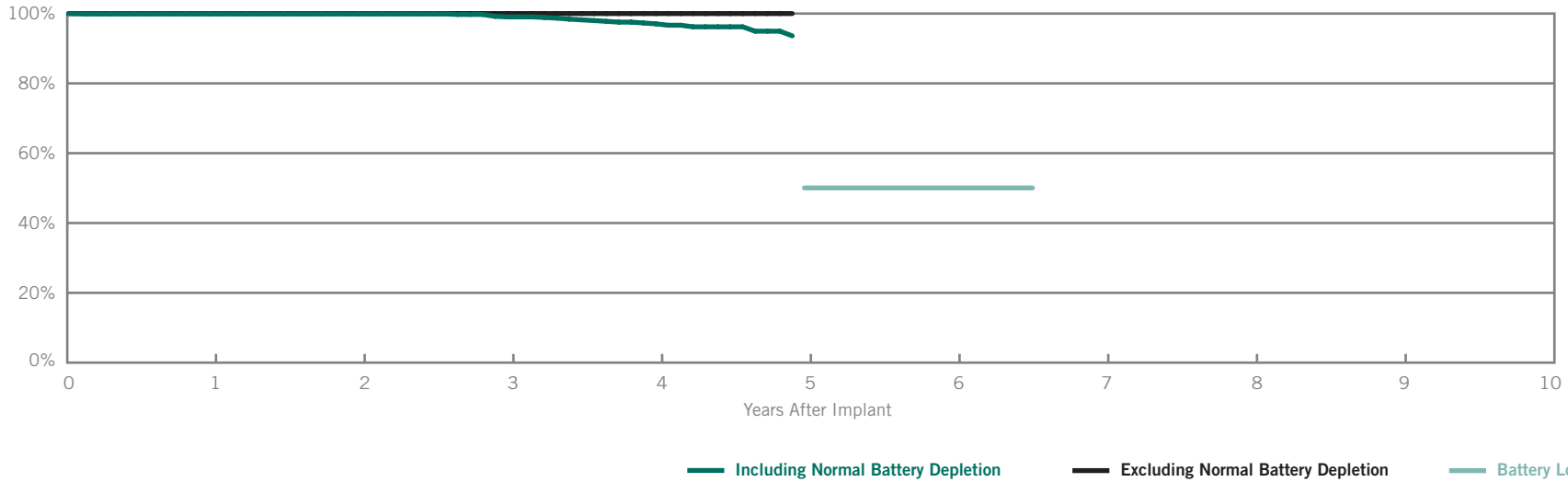
| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | | | | | | | |

# ICDs

## Epic® DR (Model V-233)

| | | | |
|---|---|---|---|
| US Regulatory Approval | October 2003 | Normal Battery Depletion | 27 |
| Registered US Implants | 1,825 | Total Malfunctions | 0 |
| Estimated Active US Implants | 963 | 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 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 59 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.89% | 99.04% | 97.05% | 96.20% | | | | | |
| ± 1 standard error | 0.08% | 0.08% | 0.24% | 0.50% | 0.62% | | | | | |
| Sample Size | 1800 | 1600 | 1400 | 1100 | 200 | | | | | |

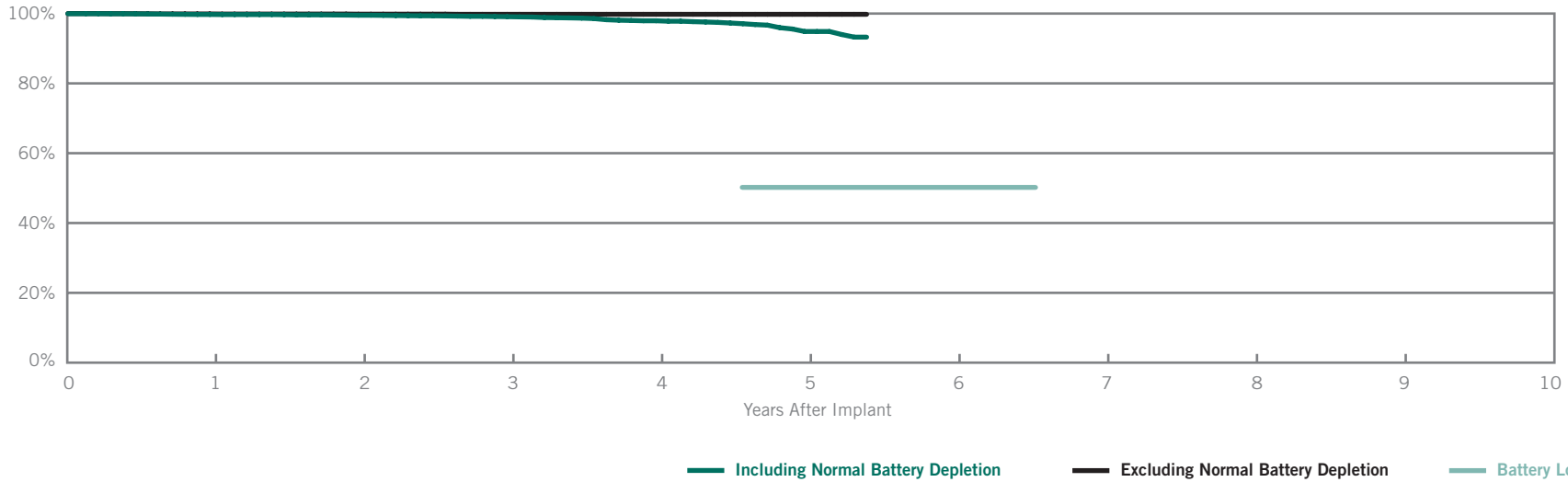
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 59 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 Regulatory Approval | October 2003 | Normal Battery Depletion | 73 |
| Registered US Implants | 7,831 | Total Malfunctions (0 related to Advisory) | 7 |
| Estimated Active US Implants | 4,275 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| 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 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 65 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | 99.52% | 99.11% | 97.93% | 94.86% | 93.25% | | | | |
| ± 1 standard error | 0.06% | 0.08% | 0.12% | 0.21% | 0.49% | 0.92% | | | | |
| Sample Size | 7800 | 6900 | 6000 | 4100 | 1900 | 200 | | | | |

**Excluding Normal Battery Depletion**

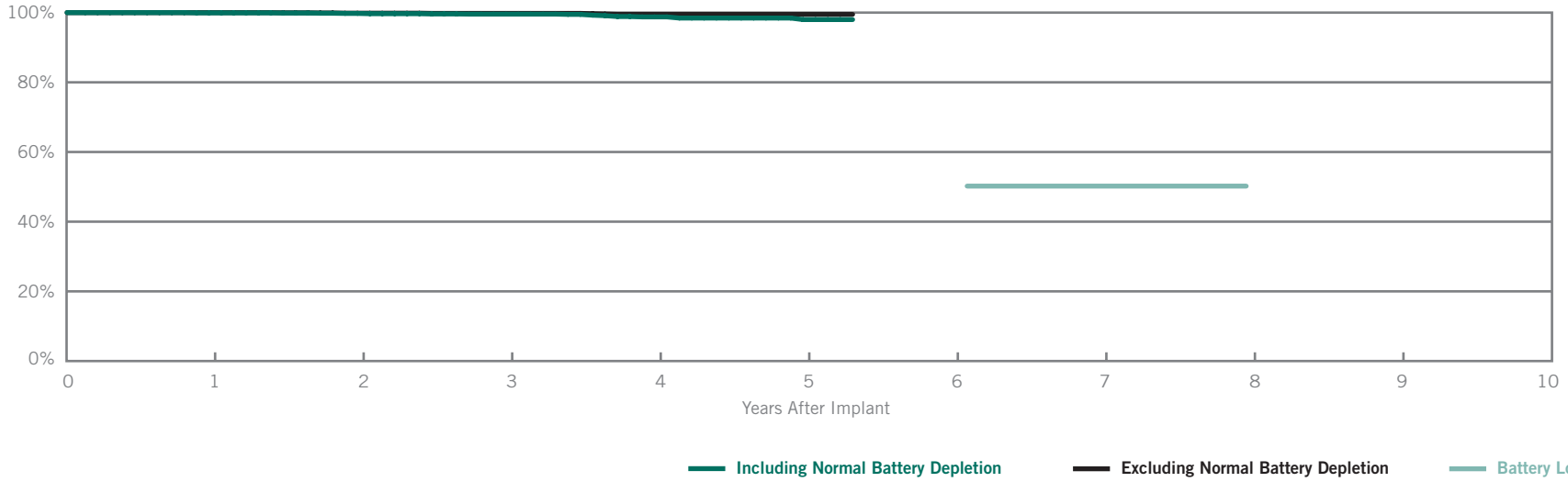
| Year | 1 | 2 | 3 | 4 | 5 | at 65 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.83% | 99.79% | 99.79% | 99.79% | 99.79% | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.06% | 0.06% | 0.06% | 0.06% | | | | |

# ICDs

## Atlas® DR (Model V-242)

| | | | |
|---|---|---|---|
| US Regulatory Approval | October 2003 | Normal Battery Depletion | 15 |
| Registered US Implants | 4,643 | Total Malfunctions (0 related to Advisory) | 7 |
| Estimated Active US Implants | 2,764 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 6 |
| 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 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.77% | 99.57% | 98.77% | 98.00% | 98.00% | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.11% | 0.22% | 0.27% | 0.41% | | | | |
| Sample Size | 4600 | 4100 | 3500 | 2500 | 1100 | 200 | | | | |

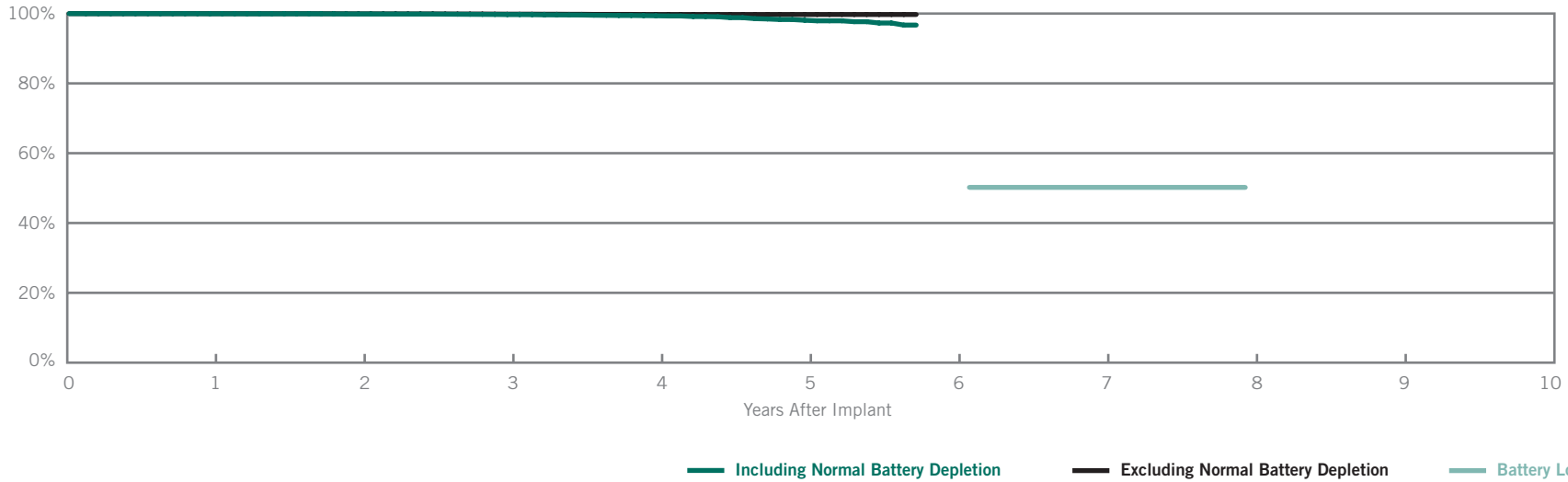
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.84% | 99.78% | 99.50% | 99.50% | 99.50% | | | | |
| ± 1 standard error | 0.00% | 0.06% | 0.08% | 0.14% | 0.14% | 0.14% | | | | |

## Atlas® + DR (Model V-243)

| | | | |
|---|---|---|---|
| US Regulatory Approval | October 2003 | Normal Battery Depletion | 49 |
| Registered US Implants | 20,946 | Total Malfunctions (0 related to Advisory) | 18 |
| Estimated Active US Implants | 12,807 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 14 |
| 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 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.88% | 99.71% | 99.37% | 98.08% | 96.70% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.04% | 0.07% | 0.21% | 0.59% | | | | |
| Sample Size | 20900 | 18300 | 14900 | 9400 | 3600 | 300 | | | | |

**Excluding Normal Battery Depletion**

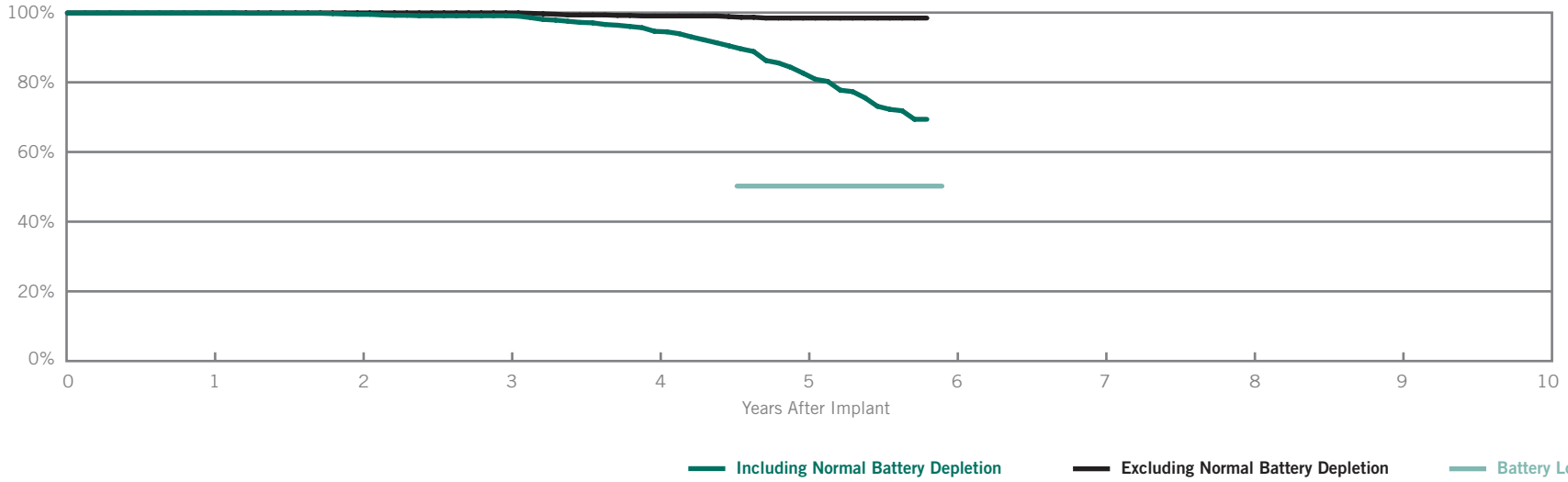
| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | 99.92% | 99.83% | 99.73% | 99.73% | 99.73% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.05% | 0.05% | 0.05% | | | | |

# ICDs

## Epic® + DR (Model V-236)

| | | | |
|---|---|---|---|
| US Regulatory Approval | April 2003 | Normal Battery Depletion | 168 |
| Registered US Implants | 2,346 | Total Malfunctions (0 related to Advisory) | 11 |
| Estimated Active US Implants | 314 | 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 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 70 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.50% | 99.11% | 94.63% | 82.63% | 69.38% | | | | |
| ± 1 standard error | 0.06% | 0.14% | 0.22% | 0.51% | 1.05% | 1.66% | | | | |
| Sample Size | 2300 | 2100 | 1800 | 1600 | 1300 | 300 | | | | |

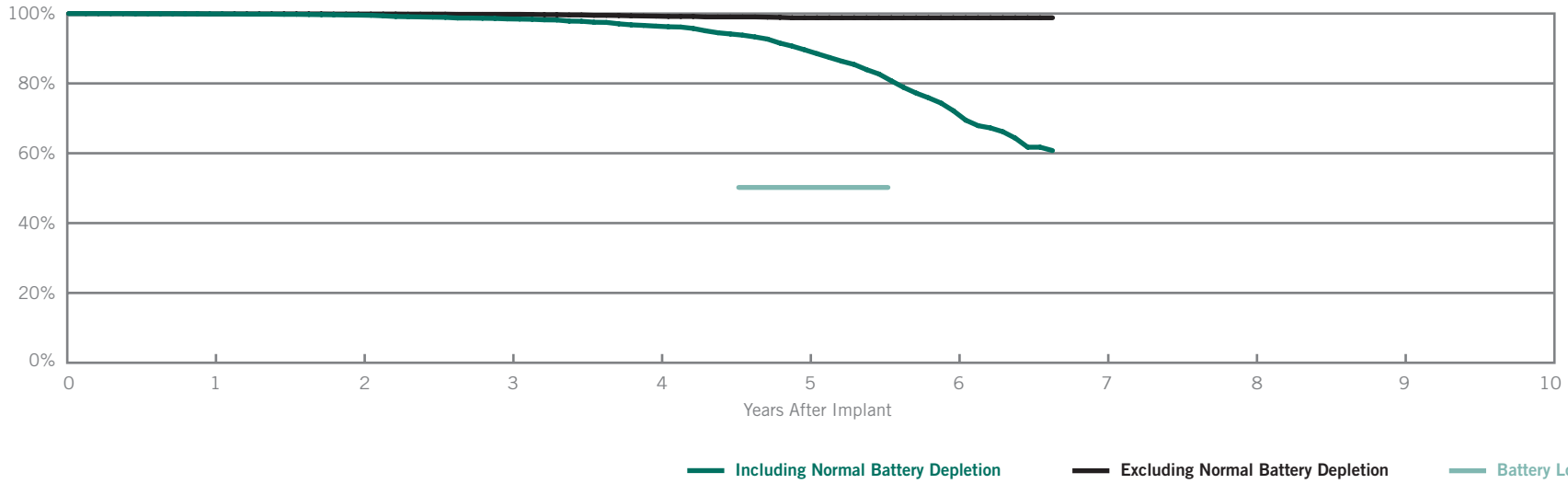
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 70 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.91% | 99.91% | 99.04% | 98.44% | 98.44% | | | | |
| ± 1 standard error | 0.06% | 0.06% | 0.06% | 0.25% | 0.35% | 0.35% | | | | |

## Epic® DR (Model V-235)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2002 | Normal Battery Depletion | 418 |
| Registered US Implants | 6,598 | Total Malfunctions (0 related to Advisory) | 28 |
| Estimated Active US Implants | 1,009 | 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 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 80 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.56% | 98.47% | 96.40% | 89.61% | 72.16% | 60.77% | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.16% | 0.27% | 0.48% | 0.94% | 1.46% | | | |
| Sample Size | 6600 | 5900 | 5300 | 4600 | 3800 | 2400 | 200 | | | |

**Excluding Normal Battery Depletion**

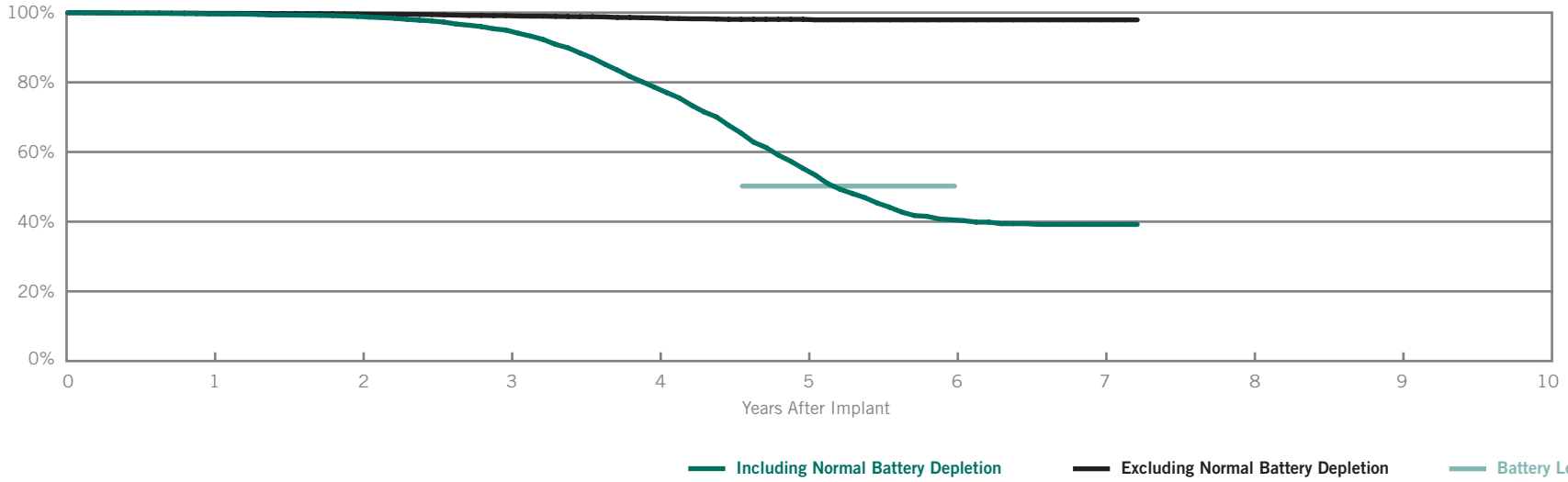
| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 80 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.90% | 99.86% | 99.78% | 99.26% | 98.80% | 98.80% | 98.80% | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.06% | 0.12% | 0.18% | 0.18% | 0.18% | | | |

# ICDs

## Atlas® DR (Model V-240)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2001 | Normal Battery Depletion | 1053 |
| Registered US Implants | 8,850 | Total Malfunctions (21 related to Advisory) | 60 |
| Estimated Active US Implants | 478 | 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 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.63% | 98.91% | 94.98% | 78.58% | 55.28% | 40.54% | 39.21% | 39.21% | | |
| ± 1 standard error | 0.06% | 0.11% | 0.26% | 0.54% | 0.78% | 0.98% | 1.01% | 1.01% | | |
| Sample Size | 8800 | 7700 | 6700 | 5500 | 3600 | 1300 | 400 | 200 | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.79% | 99.60% | 99.14% | 98.48% | 98.07% | 97.92% | 97.92% | 97.92% | | |
| ± 1 standard error | 0.05% | 0.07% | 0.11% | 0.16% | 0.20% | 0.23% | 0.23% | 0.23% | | |

# Summary & Longevity Information

## ICDs

## Dual-Chamber

St. Jude Medical
More control. Less risk.

# ICDs

## Battery Longevity

| Models | Family | Approximate Duration (years)* | | | |
|---|---|---|---|---|---|
| | | No Pacing | 25% Pacing | 50% Pacing | 100% Pacing |
| CD2211-36 | Current® + DR | 8.2 | 7.5 | 7.0 | 6.1 |
| CD2211-36Q | Current® + DR | 8.2 | 7.5 | 7.0 | 6.1 |
| 2207-30 | Current® DR RF | 6.5 | 5.9 | 5.4 | 4.6 |
| 2107-36 | Current® DR | 8.2 | 7.5 | 7.0 | 6.1 |
| 2207-36 | Current® DR RF | 8.2 | 7.5 | 7.0 | 6.1 |
| V-265 | Atlas® II DR | 8.2 | 7.5 | 7.0 | 6.1 |
| V-268 | Atlas® II + DR | 8.2 | 7.5 | 7.0 | 6.1 |
| V-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 |

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

## Malfunction and Normal Battery Depletion Summary Information

| Models | Family | US Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CD2211-36 | Current® + DR | Feb-09 | 2928 | 2834 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CD2211-36Q | Current® + DR | Feb-09 | 2612 | 2583 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2207-30 | Current® DR RF | Sep-07 | 1434 | 1274 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2107-36 | Current® DR | May-07 | 651 | 516 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2207-36 | Current® DR RF | Sep-07 | 20869 | 18666 | 2 | 0 | 4 | 7 | 3 | 16 | 1 |
| V-265 | Atlas® II DR | Jul-06 | 1878 | 1432 | 0 | 0 | 1 | 0 | 0 | 1 | 0 |
| V-268 | Atlas® II + DR | Jul-06 | 14458 | 11416 | 4 | 0 | 6 | 1 | 5 | 16 | 3 |
| V-255 | Epic® II DR | Mar-06 | 544 | 396 | 0 | 0 | 0 | 1 | 0 | 1 | 1 |
| V-258 | Epic® II + DR | Mar-06 | 2038 | 1544 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| V-233 | Epic® DR | Oct-03 | 1825 | 963 | 0 | 0 | 0 | 0 | 0 | 0 | 27 |
| V-239 | Epic® + DR | Oct-03 | 7831 | 4275 | 5 | 0 | 0 | 2 | 0 | 7 | 73 |
| V-242 | Atlas® DR | Oct-03 | 4643 | 2764 | 3 | 0 | 3 | 1 | 0 | 7 | 15 |
| V-243 | Atlas® + DR | Oct-03 | 20946 | 12807 | 2 | 0 | 12 | 3 | 1 | 18 | 49 |
| V-236 | Epic® + DR | Apr-03 | 2346 | 314 | 0 | 0 | 1 | 8 | 2 | 11 | 168 |
| V-235 | Epic® DR | Jul-02 | 6598 | 1009 | 2 | 0 | 2 | 22 | 2 | 28 | 418 |
| V-240 | Atlas® DR | Dec-01 | 8850 | 478 | 5 | 21 | 5 | 12 | 17 | 60 | 1053 |

# ICDs

## 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 |
| CD2211-36 | Current® + DR* | | | | | | | | | | |
| CD2211-36Q | Current® + DR* | | | | | | | | | | |
| 2207-30 | Current® DR RF | 100.00% | 100.00% | | | | | | | | |
| 2107-36 | Current® DR | 100.00% | 100.00% | | | | | | | | |
| 2207-36 | Current® DR RF | 99.84% | 99.71% | | | | | | | | |
| V-265 | Atlas® II DR | 99.89% | 99.77% | 99.77% | | | | | | | |
| V-268 | Atlas® II + DR | 99.88% | 99.74% | 99.70% | | | | | | | |
| V-255 | Epic® II DR | 99.38% | 99.38% | | | | | | | | |
| V-258 | Epic® II + DR | 99.88% | 99.88% | 99.88% | | | | | | | |
| V-233 | Epic® DR | 99.89% | 99.89% | 99.04% | 97.05% | | | | | | |
| V-239 | Epic® + DR | 99.74% | 99.52% | 99.11% | 97.93% | 94.86% | | | | | |
| V-242 | Atlas® DR | 99.93% | 99.77% | 99.57% | 98.77% | 98.00% | | | | | |
| V-243 | Atlas® + DR | 99.95% | 99.88% | 99.71% | 99.37% | 98.08% | | | | | |
| V-236 | Epic® + DR | 99.91% | 99.50% | 99.11% | 94.63% | 82.63% | | | | | |
| V-235 | Epic® DR | 99.89% | 99.56% | 98.47% | 96.40% | 89.61% | 72.16% | | | | |
| V-240 | Atlas® DR | 99.63% | 98.91% | 94.98% | 78.58% | 55.28% | 40.54% | 39.21% | | | |

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

## 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 |
| CD2211-36 | Current® + DR* | | | | | | | | | | |
| CD2211-36Q | Current® + DR* | | | | | | | | | | |
| 2207-30 | Current® DR RF | 100.00% | 100.00% | | | | | | | | |
| 2107-36 | Current® DR | 100.00% | 100.00% | | | | | | | | |
| 2207-36 | Current® DR RF | 99.85% | 99.72% | | | | | | | | |
| V-265 | Atlas® II DR | 100.00% | 99.88% | 99.88% | | | | | | | |
| V-268 | Atlas® II + DR | 99.89% | 99.78% | 99.74% | | | | | | | |
| V-255 | Epic® II DR | 99.59% | 99.59% | | | | | | | | |
| V-258 | Epic® II + DR | 100.00% | 100.00% | 100.00% | | | | | | | |
| V-233 | Epic® DR | 100.00% | 100.00% | 100.00% | 100.00% | | | | | | |
| V-239 | Epic® + DR | 99.89% | 99.83% | 99.79% | 99.79% | 99.79% | | | | | |
| V-242 | Atlas® DR | 100.00% | 99.84% | 99.78% | 99.50% | 99.50% | | | | | |
| V-243 | Atlas® + DR | 99.97% | 99.92% | 99.83% | 99.73% | 99.73% | | | | | |
| V-236 | Epic® + DR | 99.91% | 99.91% | 99.91% | 99.04% | 98.44% | | | | | |
| V-235 | Epic® DR | 99.90% | 99.86% | 99.78% | 99.26% | 98.80% | 98.80% | | | | |
| V-240 | Atlas® DR | 99.79% | 99.60% | 99.14% | 98.48% | 98.07% | 97.92% | 97.92% | | | |

**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.*

# ICDs

## Single-Chamber

ST. JUDE MEDICAL™

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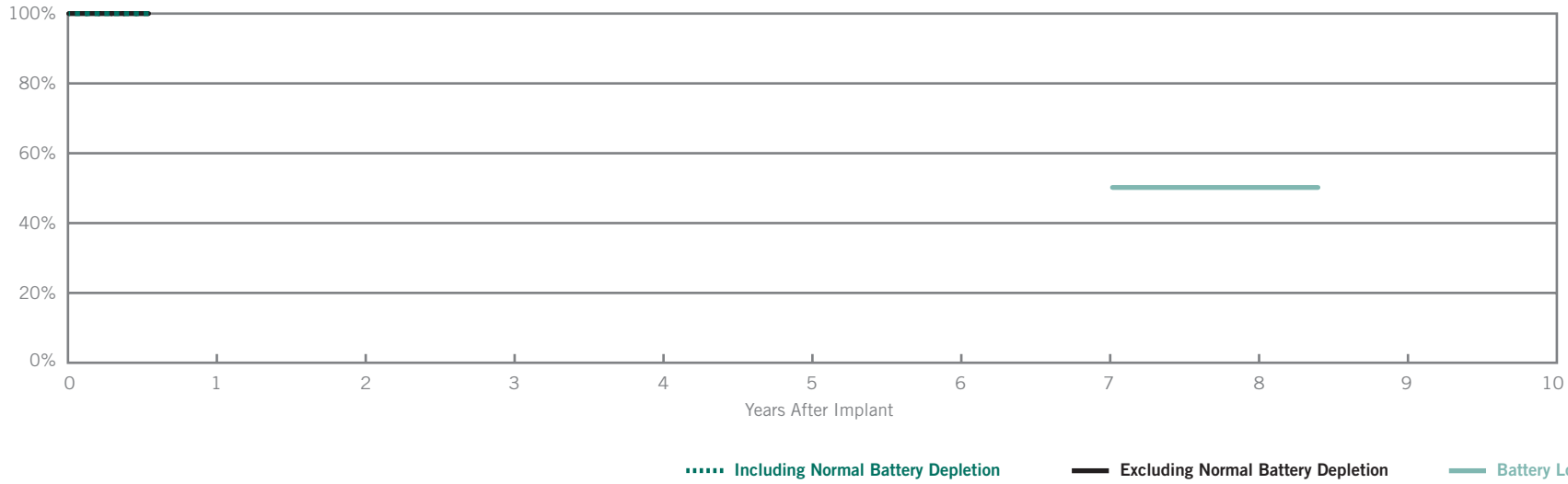
# ICDs

## Current® + VR (Model CD1211-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,575 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,526 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 96) | 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 7 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

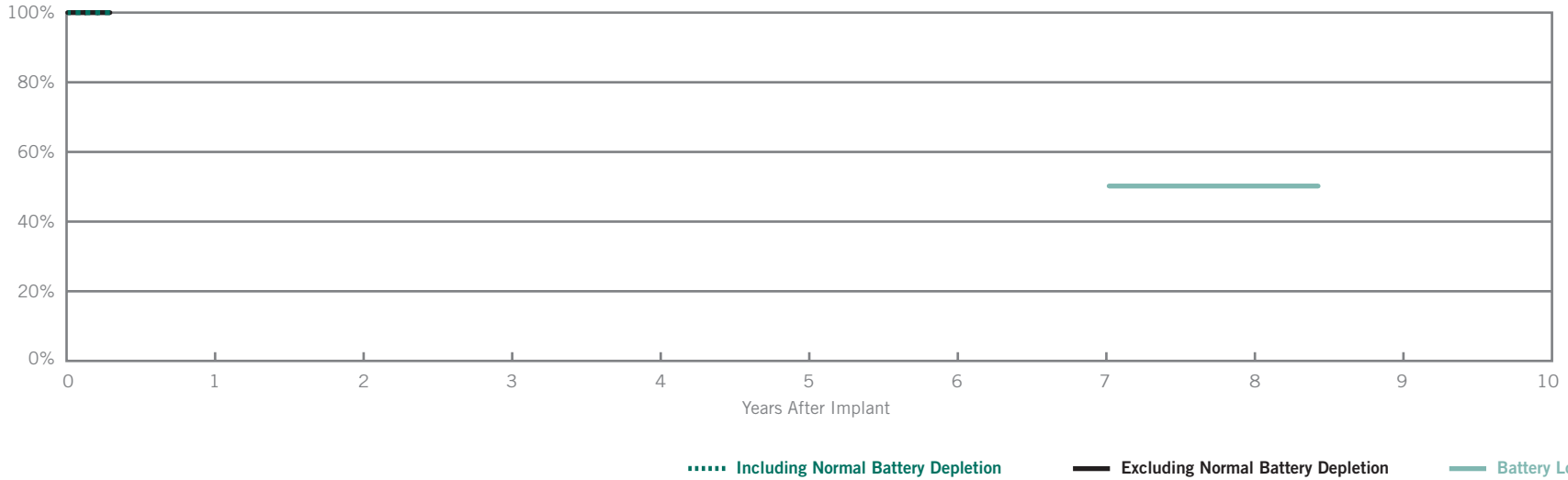
**Excluding Normal Battery Depletion**

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

## Current® + VR (Model CD1211-36Q)

| | | | |
|---|---|---|---|
| US Regulatory Approval | February 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,284 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,264 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 96) | 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 4 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 300 | | | | | | | | | |

**Excluding Normal Battery Depletion**

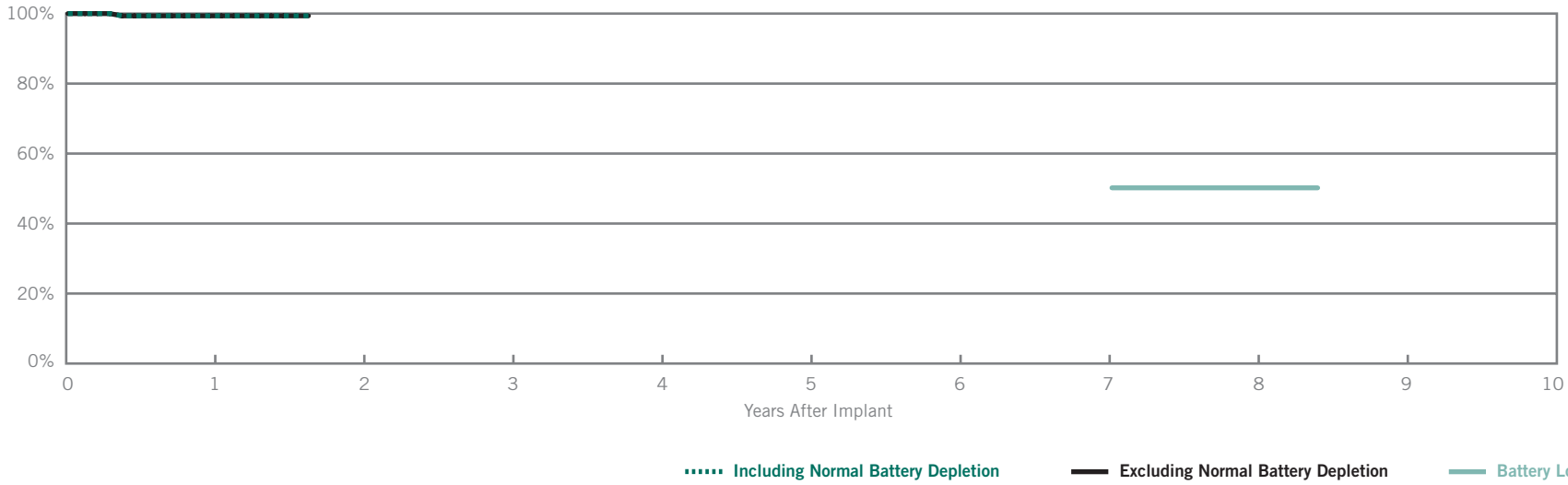
| Year | at 4 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

# ICDs

## Current® VR (Model 1107-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 339 | Total Malfunctions | 1 |
| Estimated Active US Implants | 266 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | (see table on page 96) | 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 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.36% | 99.36% | | | | | | | | |
| ± 1 standard error | 0.45% | 0.45% | | | | | | | | |
| Sample Size | 300 | 200 | | | | | | | | |

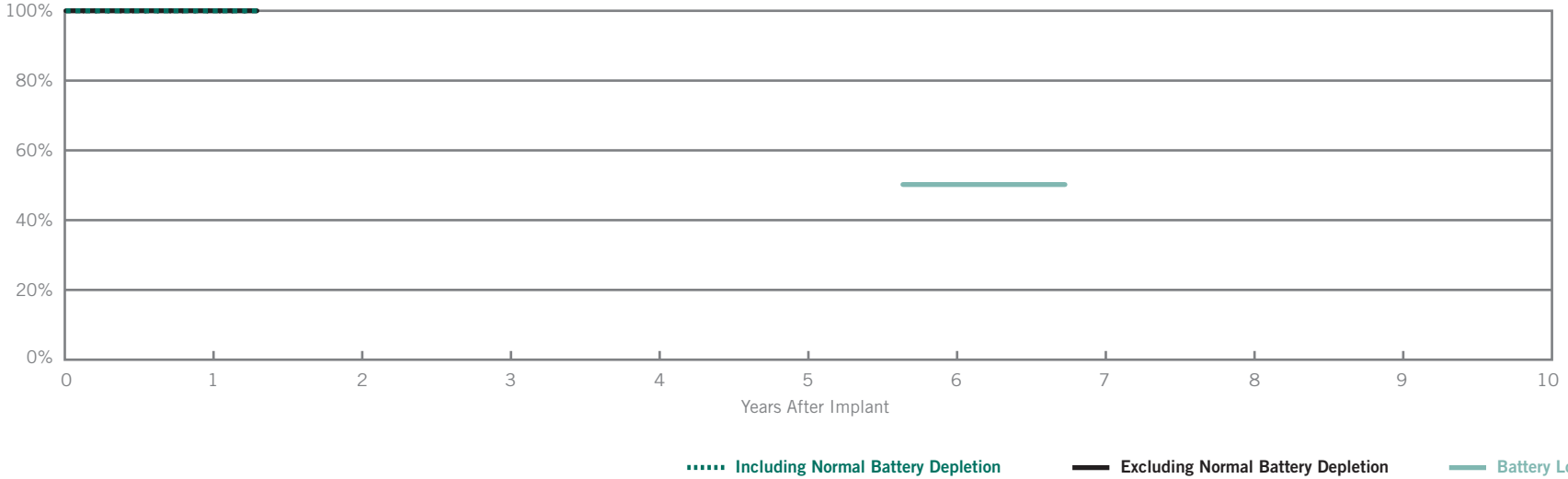
**Excluding Normal Battery Depletion**

| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.36% | 99.36% | | | | | | | | |
| ± 1 standard error | 0.45% | 0.45% | | | | | | | | |

## Current® VR RF (Model 1207-30)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 760 | Total Malfunctions | 0 |
| Estimated Active US Implants | 695 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 96) | 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 16 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 600 | 200 | | | | | | | | |

**Excluding Normal Battery Depletion**

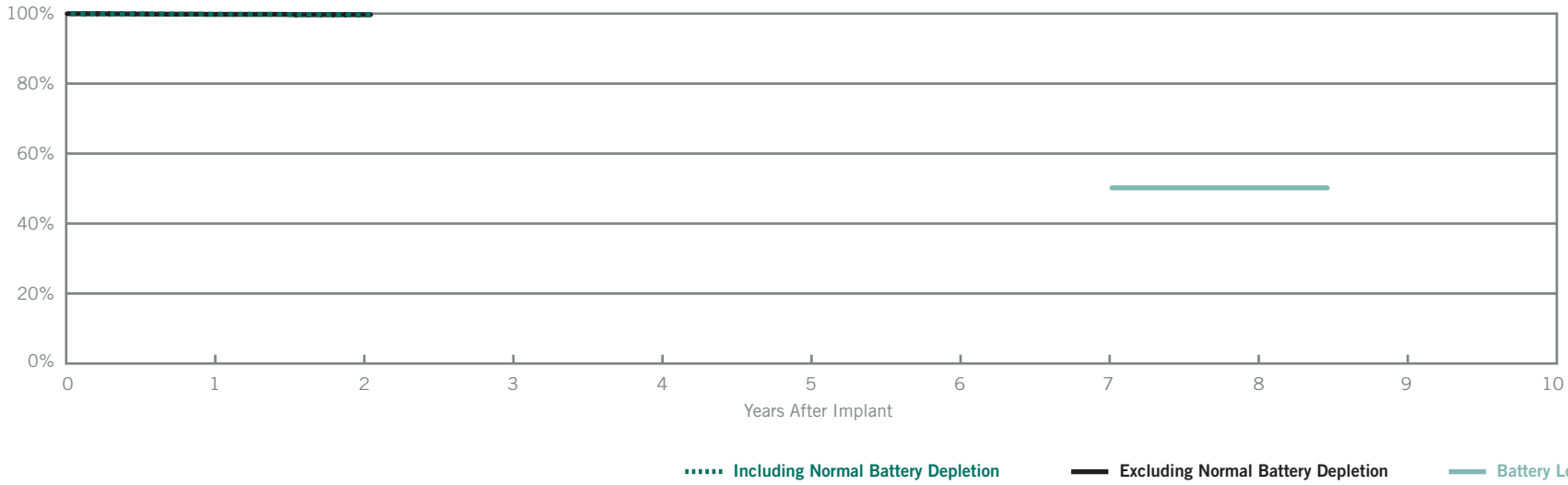
| Year | 1 | at 16 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

# ICDs

## Current® VR RF (Model 1207-36)

| | | | |
|---|---|---|---|
| US Regulatory Approval | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 10,130 | Total Malfunctions | 12 |
| Estimated Active US Implants | 8,947 | Malfunctions w/ Compromised Therapy | 6 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy | 6 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.78% | 99.69% | 99.69% | | | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.08% | | | | | | | |
| Sample Size | 8400 | 3000 | 200 | | | | | | | |

**Excluding Normal Battery Depletion**

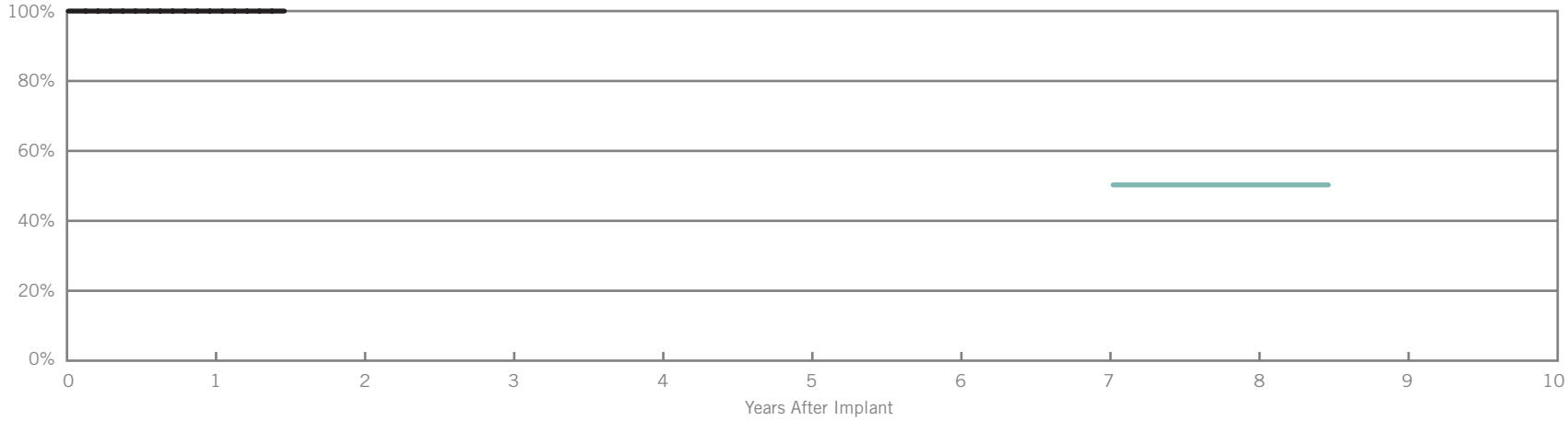
| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.78% | 99.69% | 99.69% | | | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.08% | | | | | | | |

| Current® VR RF (Model 1207-36) | |
|---|---|
| US Regulatory Approval | September 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 384 |
| Cumulative Months of Follow-up | 4,545 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry



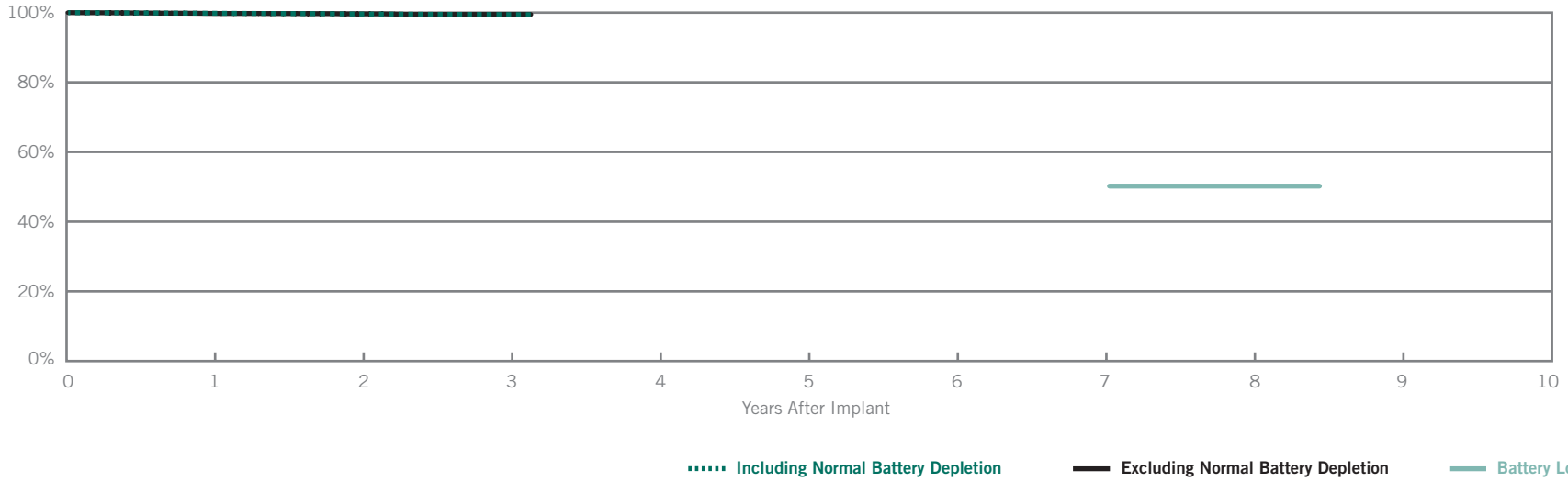

| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 204 | 58 | | | | | | | | |

# ICDs

## Atlas® II VR (Model V-168)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2006 | Normal Battery Depletion | 3 |
| Registered US Implants | 10,272 | Total Malfunctions (0 related to Advisory) | 20 |
| Estimated Active US Implants | 8,191 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 14 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 6 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 38 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.77% | 99.62% | 99.40% | 99.40% | | | | | | |
| ± 1 standard error | 0.05% | 0.07% | 0.11% | 0.11% | | | | | | |
| Sample Size | 9900 | 7100 | 3000 | 400 | | | | | | |

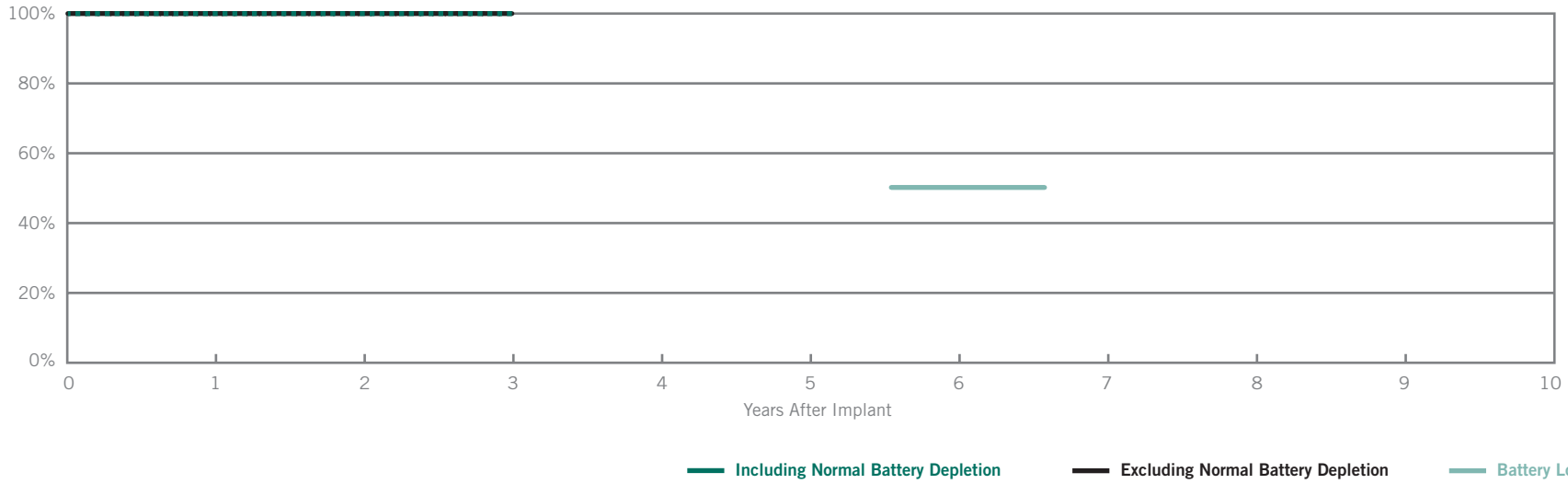
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 38 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.78% | 99.64% | 99.48% | 99.48% | | | | | | |
| ± 1 standard error | 0.04% | 0.07% | 0.09% | 0.09% | | | | | | |

## Epic® II VR (Model V-158)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2006 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,530 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,155 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | | | | | | | |
| Sample Size | 1500 | 1100 | 500 | | | | | | | |

**Excluding Normal Battery Depletion**

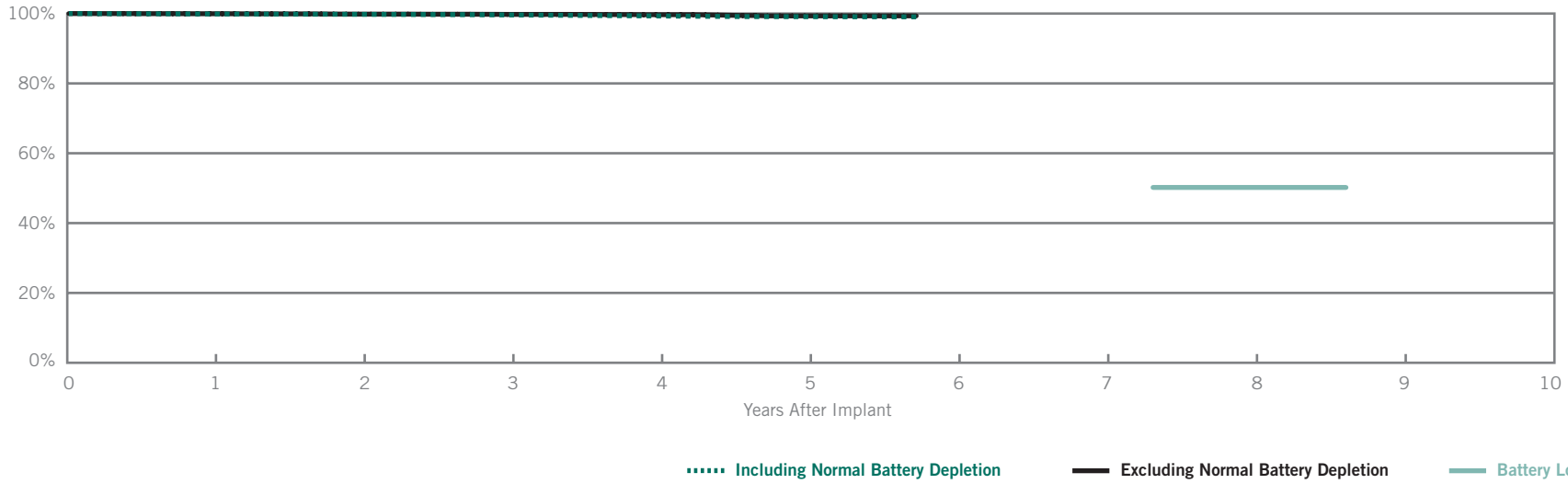
| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | | | | | | | |

# ICDs

## Atlas® + VR (Model V-193)

| | | | |
|---|---|---|---|
| US Regulatory Approval | October 2003 | Normal Battery Depletion | 21 |
| Registered US Implants | 20,431 | Total Malfunctions (0 related to Advisory) | 28 |
| Estimated Active US Implants | 12,707 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 19 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 9 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.73% | 99.64% | 99.46% | 99.05% | 99.05% | | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.05% | 0.07% | 0.14% | 0.14% | | | | |
| Sample Size | 20400 | 17900 | 14500 | 9400 | 3700 | 300 | | | | |

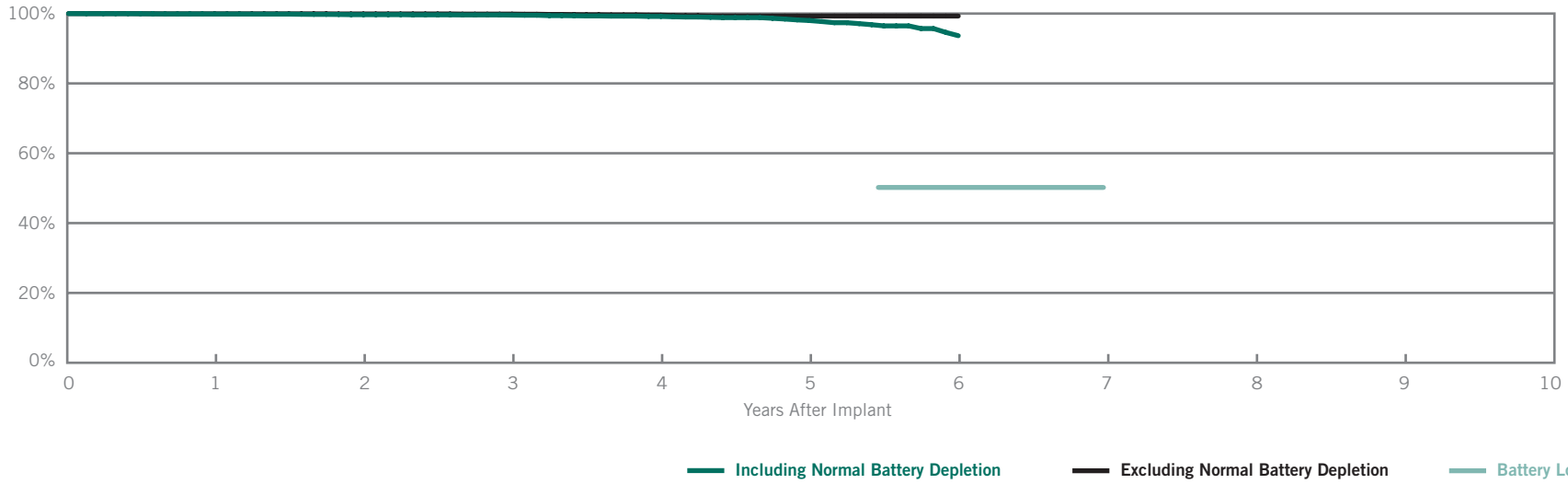
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.84% | 99.76% | 99.68% | 99.34% | 99.34% | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.04% | 0.05% | 0.12% | 0.12% | | | | |

## Epic® + VR (Model V-196)

| | | | |
|---|---|---|---|
| US Regulatory Approval | April 2003 | Normal Battery Depletion | 31 |
| Registered US Implants | 7,945 | Total Malfunctions (0 related to Advisory) | 16 |
| Estimated Active US Implants | 4,319 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 11 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 238-243) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.68% | 99.56% | 99.18% | 98.00% | 93.66% | | | | |
| ± 1 standard error | 0.04% | 0.07% | 0.08% | 0.13% | 0.28% | 0.94% | | | | |
| Sample Size | 7900 | 7000 | 6100 | 4400 | 2300 | 700 | | | | |

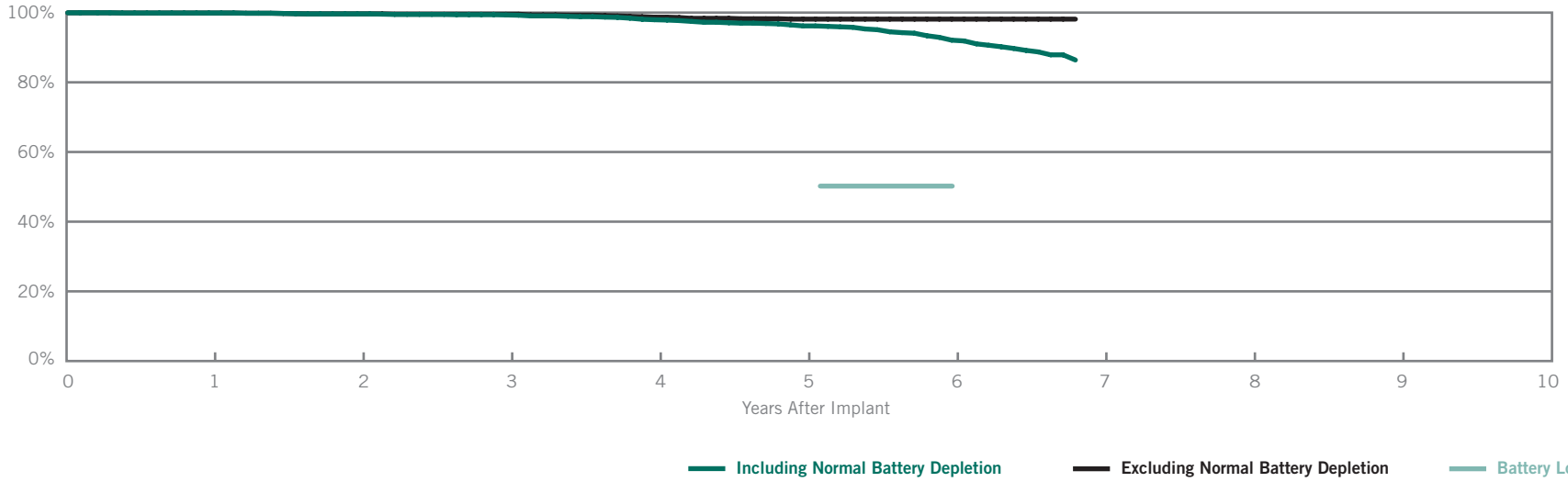
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.89% | 99.85% | 99.55% | 99.29% | 99.29% | | | | |
| ± 1 standard error | 0.03% | 0.04% | 0.05% | 0.10% | 0.14% | 0.14% | | | | |

## Epic® VR (Model V-197)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2002 | Normal Battery Depletion | 70 |
| Registered US Implants | 3,654 | Total Malfunctions (0 related to Advisory) | 25 |
| Estimated Active US Implants | 954 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 20 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 238-243) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 82 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.63% | 99.33% | 97.95% | 96.18% | 92.09% | 86.40% | | | |
| ± 1 standard error | 0.06% | 0.11% | 0.14% | 0.27% | 0.39% | 0.64% | 1.08% | | | |
| Sample Size | 3700 | 3200 | 2900 | 2500 | 2100 | 1500 | 200 | | | |

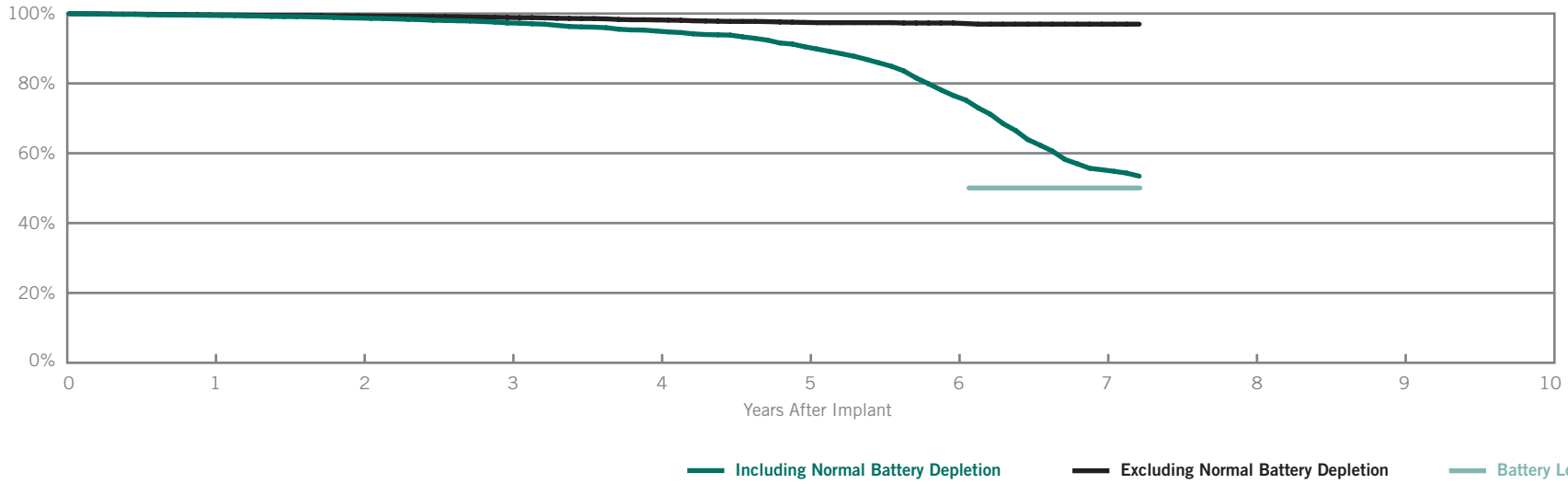
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 82 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.63% | 99.55% | 98.69% | 98.13% | 98.13% | 98.13% | | | |
| ± 1 standard error | 0.06% | 0.11% | 0.12% | 0.21% | 0.28% | 0.28% | 0.28% | | | |

## Atlas® VR (Model V-199)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2001 | Normal Battery Depletion | 459 |
| Registered US Implants | 7,095 | Total Malfunctions (22 related to Advisory) | 70 |
| Estimated Active US Implants | 864 | Malfunctions w/ Compromised Therapy (22 related to Advisory) | 34 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 36 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.49% | 98.72% | 97.32% | 95.01% | 90.50% | 76.54% | 55.27% | 53.44% | | |
| ± 1 standard error | 0.08% | 0.14% | 0.21% | 0.31% | 0.44% | 0.79% | 1.42% | 1.50% | | |
| Sample Size | 7100 | 6200 | 5400 | 4500 | 3700 | 2700 | 1200 | 200 | | |

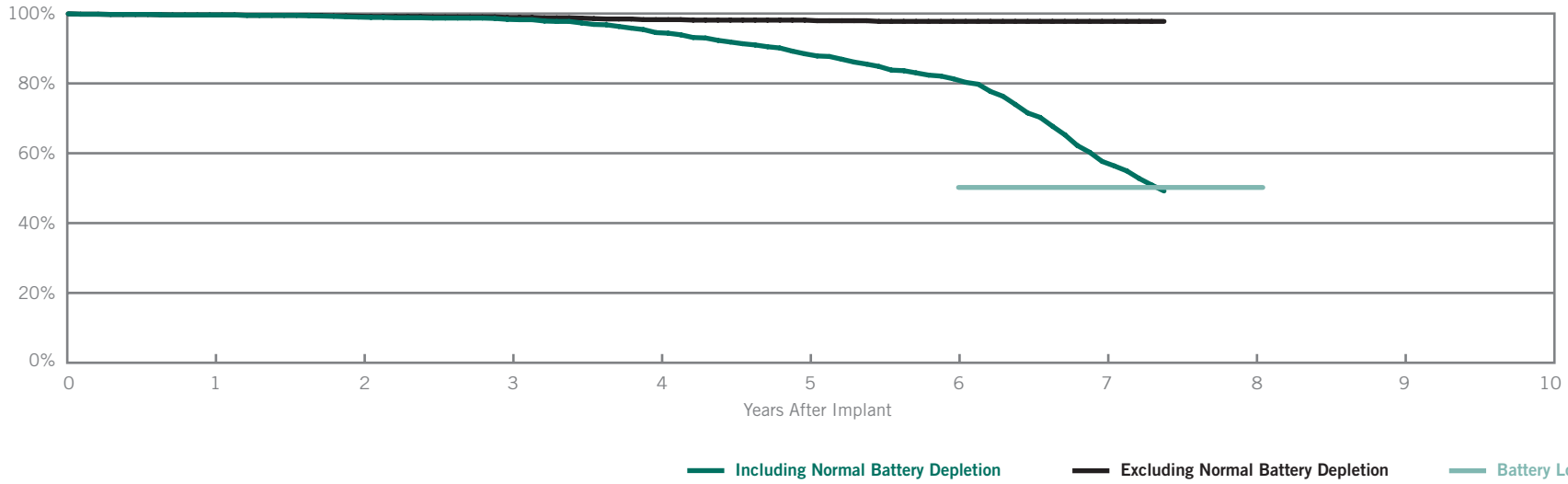
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.62% | 99.35% | 98.88% | 98.18% | 97.46% | 97.29% | 96.97% | 96.97% | | |
| ± 1 standard error | 0.07% | 0.10% | 0.14% | 0.19% | 0.24% | 0.25% | 0.30% | 0.30% | | |

## Photon™ µ VR (Model V-194)

| | | | |
|---|---|---|---|
| US Regulatory Approval | June 2001 | Normal Battery Depletion | 232 |
| Registered US Implants | 2,839 | Total Malfunctions (5 related to Advisory) | 23 |
| Estimated Active US Implants | 174 | Malfunctions w/ Compromised Therapy (5 related to Advisory) | 12 |
| Estimated Longevity | (see table on page 96) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 11 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

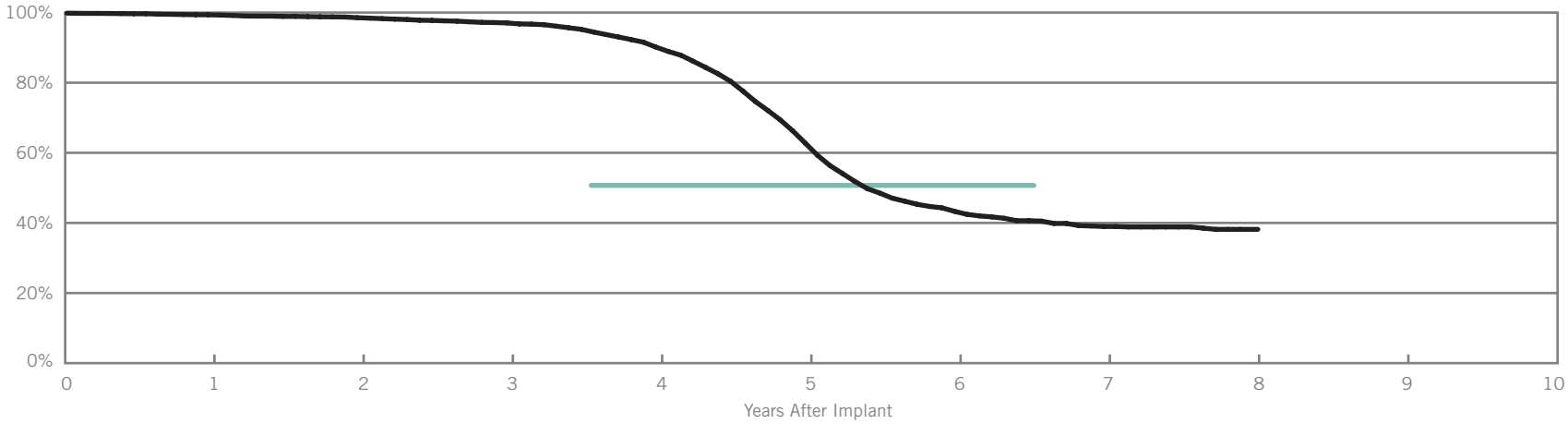
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.60% | 98.99% | 98.34% | 94.55% | 88.48% | 81.31% | 57.66% | 49.19% | | |
| ± 1 standard error | 0.12% | 0.19% | 0.24% | 0.48% | 0.77% | 1.03% | 1.64% | 1.88% | | |
| Sample Size | 2800 | 2500 | 2200 | 1900 | 1500 | 1200 | 800 | 200 | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 89 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.60% | 99.25% | 98.90% | 98.26% | 98.12% | 97.76% | 97.76% | 97.76% | | |
| ± 1 standard error | 0.12% | 0.16% | 0.20% | 0.29% | 0.31% | 0.35% | 0.35% | 0.35% | | |

| Contour™ MD (Models V-175, V-175AC, V-175B, V-175C & V-175D) | |
|---|---|
| US Regulatory Approval | October 1998 |
| Registered US Implants | 4,929 |
| Estimated Active US Implants | 204 |
| Estimated Longevity | (see table on page 96) |
| Number of Advisories | None |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.37% | 98.54% | 97.05% | 90.15% | 62.79% | 43.31% | 38.98% | 38.17% | | |
| **± 1 standard error** | 0.11% | 0.17% | 0.27% | 0.50% | 0.98% | 1.16% | 1.23% | 1.26% | | |
| **Sample Size** | 4900 | 4200 | 3600 | 3100 | 2400 | 1200 | 500 | 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 |
| CD1211-36 | Current® + VR | 8.4 | 8.0 | 7.6 | 7.0 |
| CD1211-36Q | Current® + VR | 8.4 | 8.0 | 7.6 | 7.0 |
| 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 | 7.0 |
| V-168 | Atlas® II VR | 8.4 | 8.0 | 7.6 | 7.0 |
| V-158 | Epic® II VR | 6.7 | 6.4 | 6.1 | 5.6 |
| V-193 | Atlas® + VR | 8.6 | 8.2 | 7.9 | 7.3 |
| V-196 | Epic® + VR SN <115000 | 6.3 | 6 | 5.8 | 5.4 |
| V-196 | Epic® + VR SN >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 SN <42000 | 7.1 | 6.8 | 6.5 | 6.0 |
| V-194 | Photon™µ VR SN >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 Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CD1211-36 | Current® + VR | Feb-09 | 1575 | 1526 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CD1211-36Q | Current® + VR | Feb-09 | 1284 | 1264 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1107-36 | Current® VR | May-07 | 339 | 266 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| 1207-30 | Current® VR RF | Sep-07 | 760 | 695 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1207-36 | Current® VR RF | Sep-07 | 10130 | 8947 | 3 | 0 | 3 | 3 | 3 | 12 | 0 |
| V-168 | Atlas® II VR | Jul-06 | 10272 | 8191 | 5 | 0 | 9 | 2 | 4 | 20 | 3 |
| V-158 | Epic® II VR | Mar-06 | 1530 | 1155 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| V-193 | Atlas® + VR | Oct-03 | 20431 | 12707 | 9 | 0 | 10 | 2 | 7 | 28 | 21 |
| V-196 | Epic® + VR | Apr-03 | 7945 | 4319 | 3 | 0 | 2 | 11 | 0 | 16 | 31 |
| V-197 | Epic® VR | Jul-02 | 3654 | 954 | 4 | 0 | 1 | 18 | 2 | 25 | 70 |
| V-199 | Atlas® VR | Dec-01 | 7095 | 864 | 6 | 22 | 6 | 33 | 3 | 70 | 459 |
| V-194 | Photon™ µ VR | Jun-01 | 2839 | 174 | 3 | 5 | 4 | 10 | 1 | 23 | 232 |

# ICDs

## 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 |
| CD1211-36 | Current® + VR* | | | | | | | | | | |
| CD1211-36Q | Current® + VR* | | | | | | | | | | |
| 1107-36 | Current® VR | 99.36% | | | | | | | | | |
| 1207-30 | Current® VR RF | 100.00% | | | | | | | | | |
| 1207-36 | Current® VR RF | 99.78% | 99.69% | | | | | | | | |
| V-168 | Atlas® II VR | 99.77% | 99.62% | 99.40% | | | | | | | |
| V-158 | Epic® II VR | 100.00% | 100.00% | 100.00% | | | | | | | |
| V-193 | Atlas® + VR | 99.89% | 99.73% | 99.64% | 99.46% | 99.05% | | | | | |
| V-196 | Epic® + VR | 99.87% | 99.68% | 99.56% | 99.18% | 98.00% | 93.66% | | | | |
| V-197 | Epic® VR | 99.89% | 99.63% | 99.33% | 97.95% | 96.18% | 92.09% | | | | |
| V-199 | Atlas® VR | 99.49% | 98.72% | 97.32% | 95.01% | 90.50% | 76.54% | 55.27% | | | |
| V-194 | Photon™ µ VR | 99.60% | 98.99% | 98.34% | 94.55% | 88.48% | 81.31% | 57.66% | | | |

**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 |
| CD1211-36 | Current® + VR* | | | | | | | | | | |
| CD1211-36Q | Current® + VR* | | | | | | | | | | |
| 1107-36 | Current® VR | 99.36% | | | | | | | | | |
| 1207-30 | Current® VR RF | 100.00% | | | | | | | | | |
| 1207-36 | Current® VR RF | 99.78% | 99.69% | | | | | | | | |
| V-168 | Atlas® II VR | 99.78% | 99.64% | 99.48% | | | | | | | |
| V-158 | Epic® II VR | 100.00% | 100.00% | 100.00% | | | | | | | |
| V-193 | Atlas® + VR | 99.95% | 99.84% | 99.76% | 99.68% | 99.34% | | | | | |
| V-196 | Epic® + VR | 99.92% | 99.89% | 99.85% | 99.55% | 99.29% | 99.29% | | | | |
| V-197 | Epic® VR | 99.89% | 99.63% | 99.55% | 98.69% | 98.13% | 98.13% | | | | |
| V-199 | Atlas® VR | 99.62% | 99.35% | 98.88% | 98.18% | 97.46% | 97.29% | 96.97% | | | |
| V-194 | Photon™ µ VR | 99.60% | 99.25% | 98.90% | 98.26% | 98.12% | 97.76% | 97.76% | | | |

**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.*

# Defibrillation Leads

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More control. Less risk.

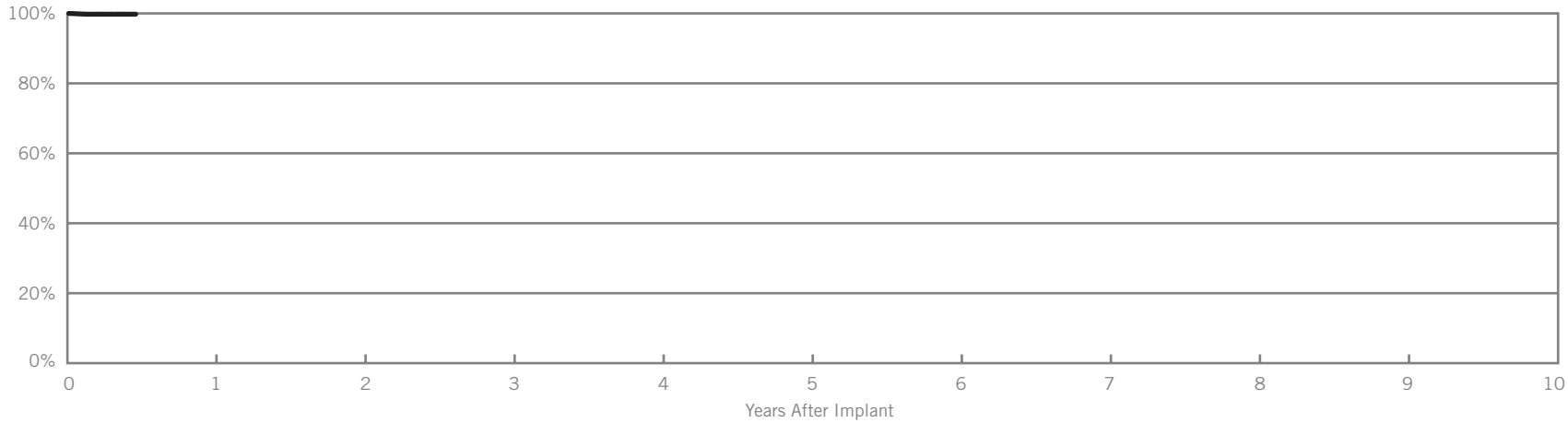
# Defibrillation Leads

| Durata® SJ4 (Model 7120Q & 7121Q) | |
|---|---|
| US Regulatory Approval | January 2009 |
| Registered US Implants | 5,527 |
| Estimated Active US Implants | 5,365 |
| 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 | 3 | 0.05% | 1 | 0.02% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 7 | 0.13% | 2 | 0.04% |
| Failure to Capture | 2 | 0.04% | 0 | 0.00% |
| Oversensing | 5 | 0.09% | 1 | 0.02% |
| Failure to Sense | 1 | 0.02% | 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** | **18** | **0.33%** | **4** | **0.07%** |
| **Total Returned for Analysis** | **8** | | **1** | |

| 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 | 0.04% |
| **Total** | **2** | **0.04%** |

## Survival from Returns and Complaints




| Year | at 6 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.77% | | | | | | | | | |
| **± 1 standard error** | 0.08% | | | | | | | | | |
| **Sample Size** | 200 | | | | | | | | | |

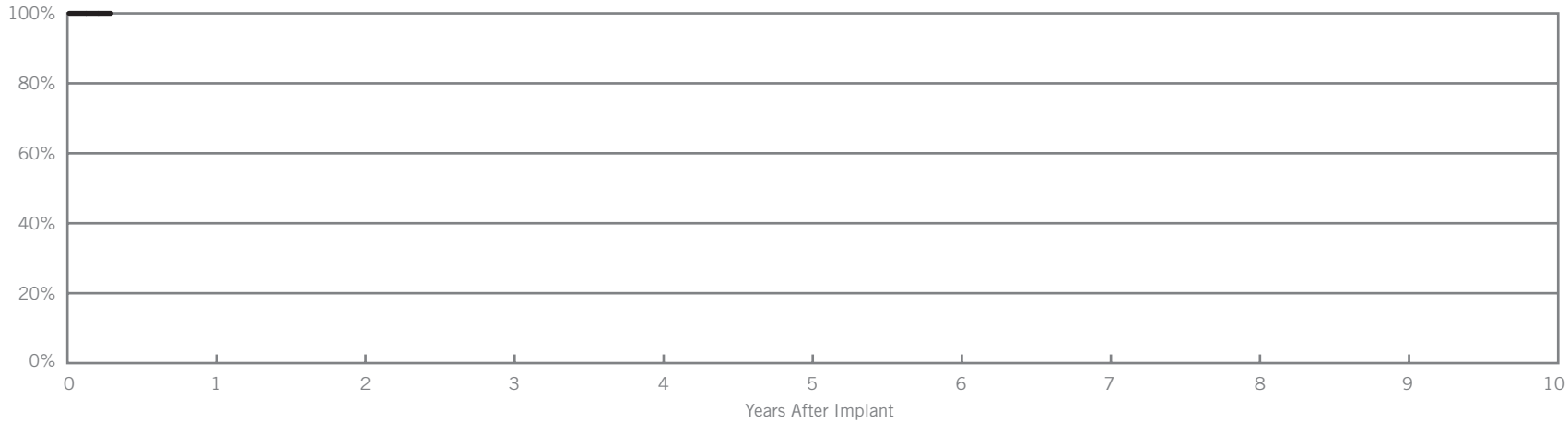
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Durata® SJ4 (Model 7122Q) | |
|---|---|
| US Regulatory Approval | January 2009 |
| Registered US Implants | 645 |
| Estimated Active US Implants | 622 |
| 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 | 0 | 0.00% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 0 | 0.00% | 0 | 0.00% |
| Failure to Capture | 1 | 0.16% | 0 | 0.00% |
| Oversensing | 1 | 0.16% | 0 | 0.00% |
| Failure to Sense | 1 | 0.16% | 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** | **3** | **0.47%** | **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 | at 4 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | | | | | | | | | |
| **± 1 standard error** | 0.00% | | | | | | | | | |
| **Sample Size** | 200 | | | | | | | | | |

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

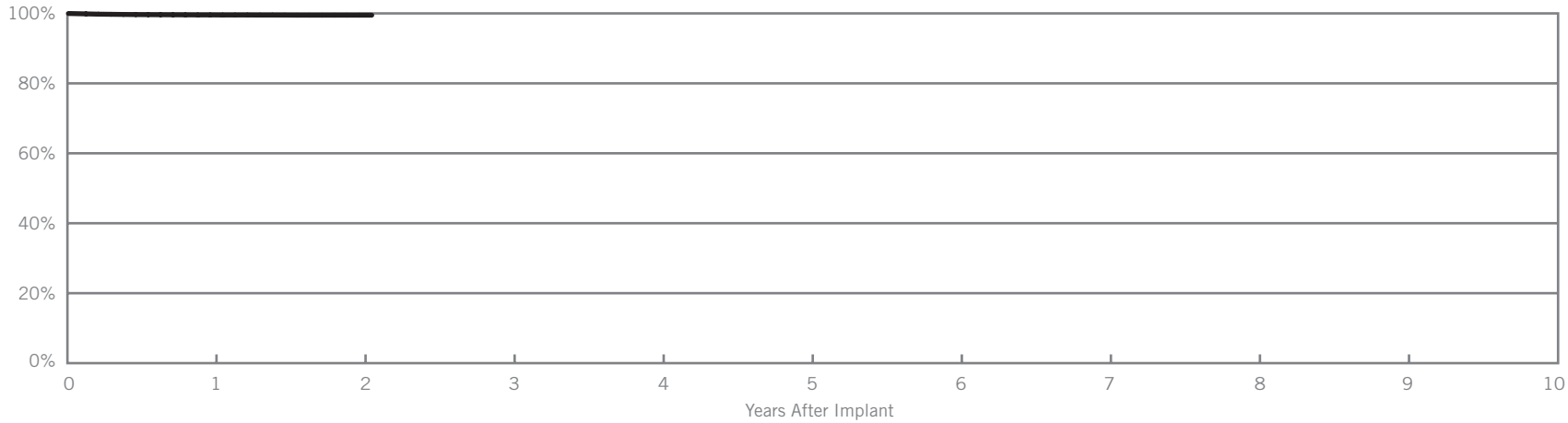
# Defibrillation Leads

| Durata® (Models 7120 & 7121) | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 42,103 |
| Estimated Active US Implants | 37,837 |
| 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 | 23 | 0.05% | 4 | 0.01% |
| Conductor Fracture | 1 | <0.01% | 1 | <0.01% |
| Lead Dislodgement | 35 | 0.08% | 68 | 0.16% |
| Failure to Capture | 11 | 0.03% | 25 | 0.06% |
| Oversensing | 35 | 0.08% | 30 | 0.07% |
| Failure to Sense | 4 | 0.01% | 7 | 0.02% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 1 | <0.01% | 7 | 0.02% |
| Abnormal Defibrillation Impedance | 14 | 0.03% | 4 | 0.01% |
| Extracardiac Stimulation | 1 | <0.01% | 0 | 0.00% |
| Other | 15 | 0.04% | 11 | 0.03% |
| **Total** | **140** | **0.33%** | **157** | **0.37%** |
| **Total Returned for Analysis** | **40** | | **71** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 1 | <0.01% |
| Insulation Breach | 1 | <0.01% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 7 | 0.02% |
| Extrinsic Factors | 56 | 0.13% |
| **Total** | **66** | **0.16%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.56% | 99.49% | 99.49% | | | | | | | |
| **± 1 standard error** | 0.04% | 0.05% | 0.05% | | | | | | | |
| **Sample Size** | 30100 | 8700 | 200 | | | | | | | |

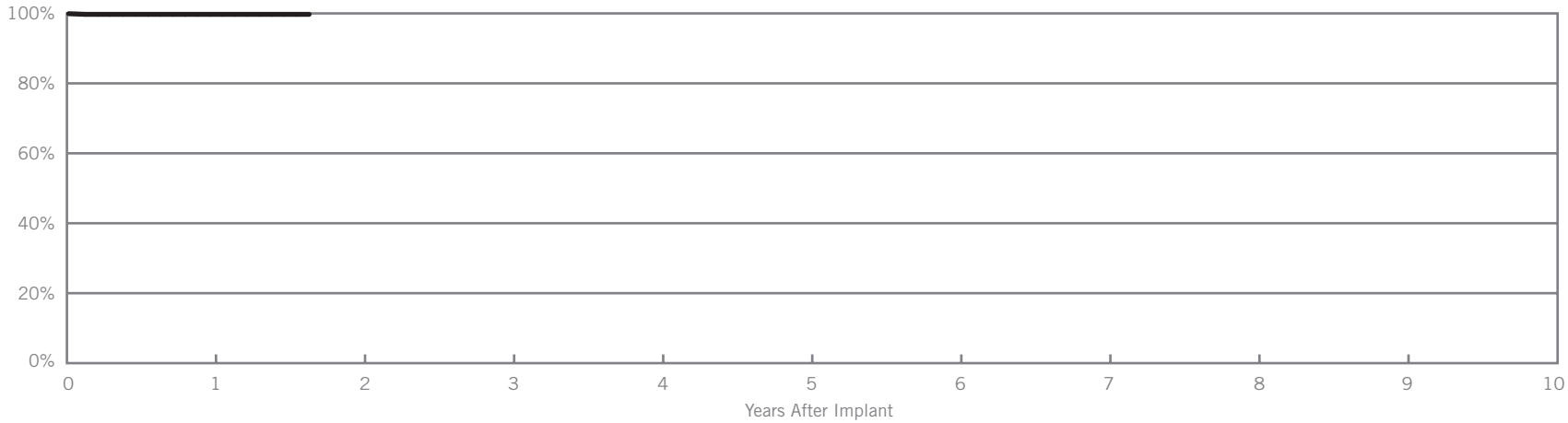
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Durata® (Models 7120 & 7121) | |
|---|---|
| US Regulatory Approval | 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 | 1,113 |
| Cumulative Months of Follow-up | 13,747 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Cardiac Perforation | 1 | 0.09% |
| Failure to Capture | 1 | 0.09% |
| Extracardiac Stimulation | 1 | 0.09% |

## Survival from SCORE Registry




| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.73% | 99.73% | | | | | | | | |
| **± 1 standard error** | 0.16% | 0.16% | | | | | | | | |
| **Sample Size** | 611 | 97 | | | | | | | | |

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

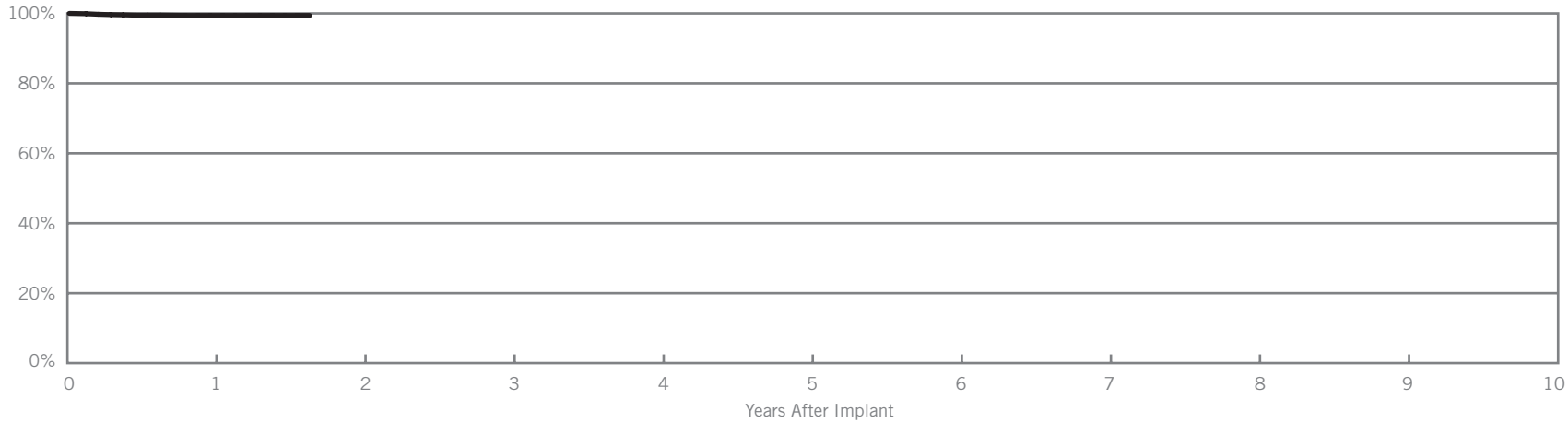
# Defibrillation Leads

| Durata® (Model 7122) | |
|---|---|
| US Regulatory Approval | September 2007 |
| Registered US Implants | 4,854 |
| Estimated Active US Implants | 4,466 |
| 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 | 3 | 0.06% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 4 | 0.08% | 9 | 0.19% |
| Failure to Capture | 2 | 0.04% | 5 | 0.10% |
| Oversensing | 2 | 0.04% | 2 | 0.04% |
| Failure to Sense | 0 | 0.00% | 1 | 0.02% |
| Insulation Breach | 0 | 0.00% | 1 | 0.02% |
| Abnormal Pacing Impedance | 0 | 0.00% | 3 | 0.06% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **11** | **0.23%** | **21** | **0.43%** |
| **Total Returned for Analysis** | **5** | | **17** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 1 | 0.02% |
| Insulation Breach | 1 | 0.02% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 1 | 0.02% |
| Extrinsic Factors | 13 | 0.27% |
| **Total** | **16** | **0.33%** |

## Survival from Returns and Complaints




| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.42% | 99.42% | | | | | | | | |
| **± 1 standard error** | 0.13% | 0.13% | | | | | | | | |
| **Sample Size** | 3300 | 200 | | | | | | | | |

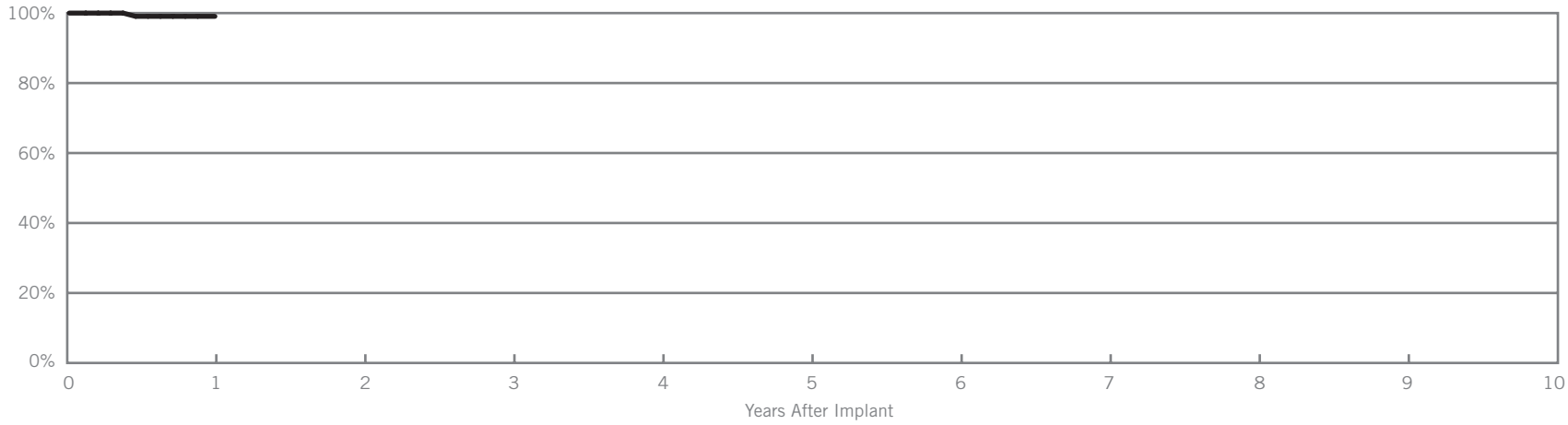
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Durata® (Model 7122) | |
|---|---|
| US Regulatory Approval | September 2007 |
| Insulation | Optim* |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of Advisories | None |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 133 |
| Cumulative Months of Follow-up | 1,425 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.09% |

## Survival from SCORE Registry




| Year | 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.07% | | | | | | | | | |
| **± 1 standard error** | 0.93% | | | | | | | | | |
| **Sample Size** | 55 | | | | | | | | | |

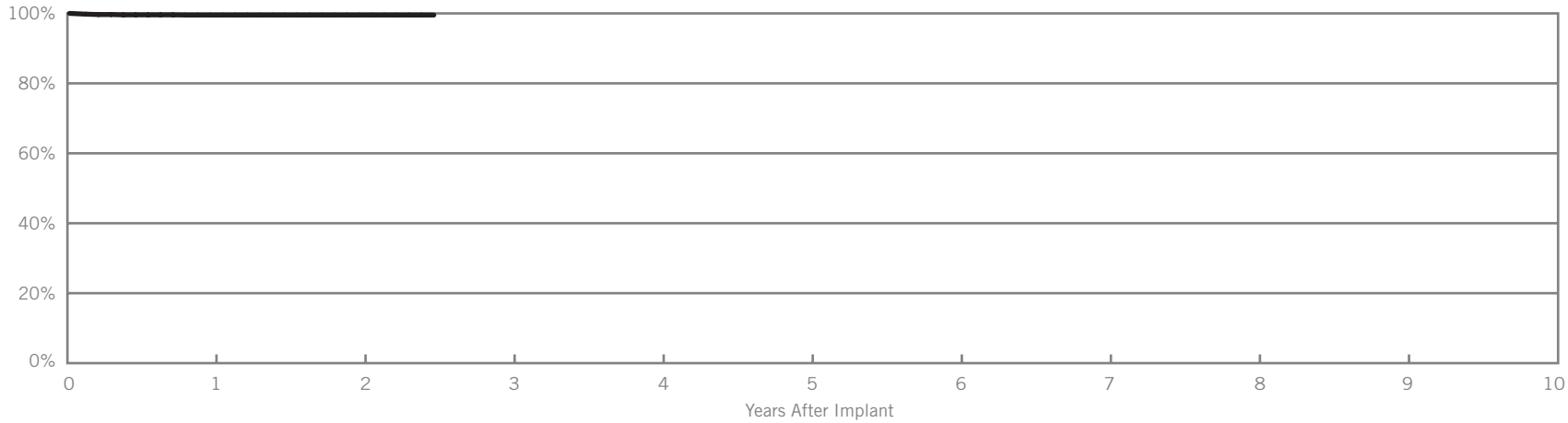
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Riata® ST Optim® (Models 7070 & 7071) | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 2,890 |
| Estimated Active US Implants | 2,462 |
| 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 | 2 | 0.07% | 1 | 0.03% |
| Conductor Fracture | 1 | 0.03% | 0 | 0.00% |
| Lead Dislodgement | 3 | 0.10% | 3 | 0.10% |
| Failure to Capture | 5 | 0.17% | 3 | 0.10% |
| Oversensing | 3 | 0.10% | 3 | 0.10% |
| Failure to Sense | 2 | 0.07% | 2 | 0.07% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 1 | 0.03% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 1 | 0.03% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **16** | **0.55%** | **14** | **0.48%** |
| **Total Returned for Analysis** | **4** | | **5** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 1 | 0.03% |
| Insulation Breach | 0 | 0.00% |
| Crimps, Welds & Bonds | 1 | 0.03% |
| Other | 1 | 0.03% |
| Extrinsic Factors | 4 | 0.14% |
| **Total** | **7** | **0.24%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.53% | 99.53% | 99.53% | | | | | | | |
| **± 1 standard error** | 0.14% | 0.14% | 0.14% | | | | | | | |
| **Sample Size** | 2300 | 1100 | 200 | | | | | | | |

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

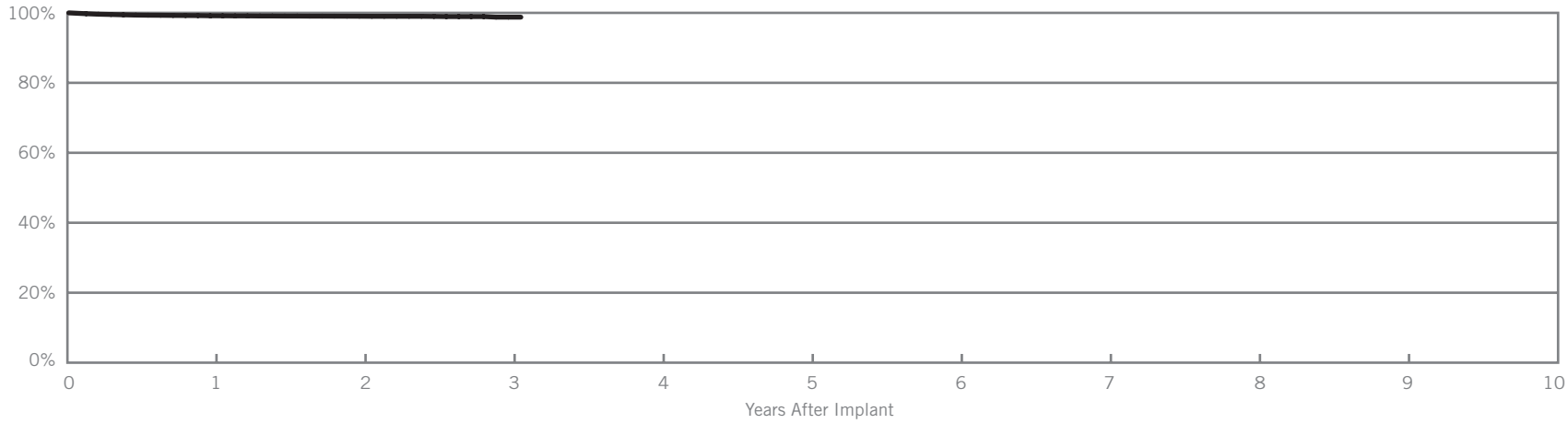
# Defibrillation Leads

| Riata® ST Optim® (Models 7020 & 7021) | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 15,272 |
| Estimated Active US Implants | 12,209 |
| 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 | 38 | 0.25% | 10 | 0.07% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 32 | 0.21% | 45 | 0.29% |
| Failure to Capture | 19 | 0.12% | 28 | 0.18% |
| Oversensing | 19 | 0.12% | 36 | 0.24% |
| Failure to Sense | 8 | 0.05% | 10 | 0.07% |
| Insulation Breach | 0 | 0.00% | 2 | 0.01% |
| Abnormal Pacing Impedance | 1 | 0.01% | 3 | 0.02% |
| Abnormal Defibrillation Impedance | 4 | 0.03% | 5 | 0.03% |
| Extracardiac Stimulation | 4 | 0.03% | 2 | 0.01% |
| Other | 2 | 0.01% | 11 | 0.07% |
| **Total** | **127** | **0.83%** | **152** | **1.00%** |
| **Total Returned for Analysis** | **55** | | **102** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 4 | 0.03% |
| Insulation Breach | 6 | 0.04% |
| Crimps, Welds & Bonds | 2 | 0.01% |
| Other | 1 | 0.01% |
| Extrinsic Factors | 73 | 0.48% |
| **Total** | **86** | **0.56%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 37 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.18% | 99.04% | 98.78% | 98.78% | | | | | | |
| **± 1 standard error** | 0.07% | 0.08% | 0.20% | 0.20% | | | | | | |
| **Sample Size** | 14200 | 10000 | 3800 | 300 | | | | | | |

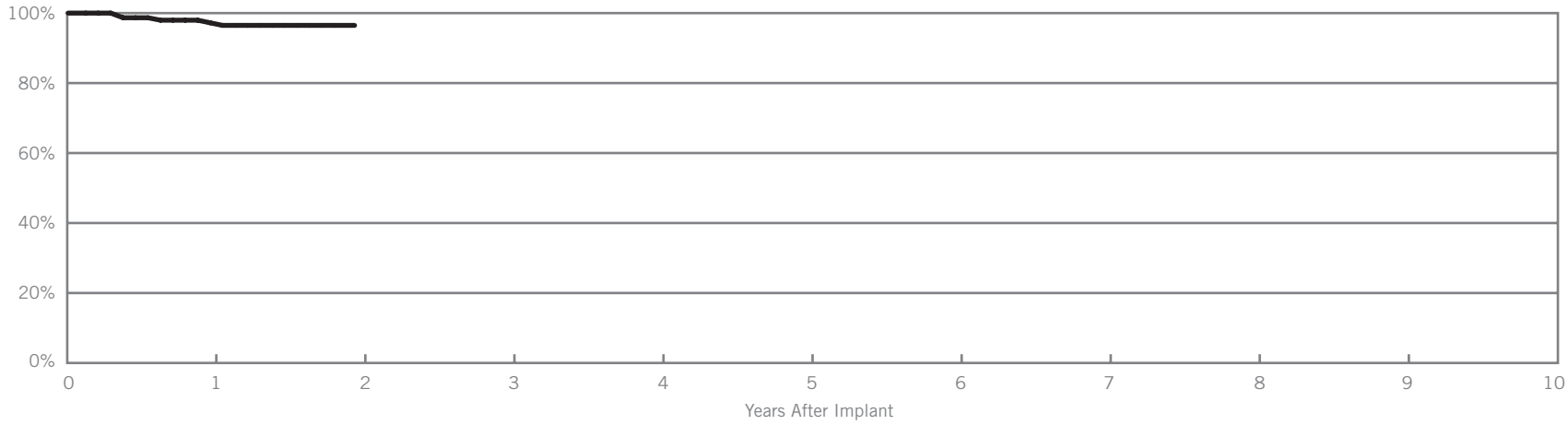
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Riata® ST Optim® (Models 7020 & 7021) | |
|---|---|
| US Regulatory Approval | 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 | 172 |
| Cumulative Months of Follow-up | 3,012 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Cardiac Perforation | 1 | 0.58% |
| Conductor Fracture | 1 | 0.58% |
| Failure to Sense | 1 | 0.58% |
| Abnormal Pacing Impedance | 1 | 0.58% |
| Abnormal Defibrillation Impedance | 1 | 0.58% |

## Survival from SCORE Registry




| Year | 1 | at 23 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 97.23% | 96.49% | | | | | | | | |
| **± 1 standard error** | 1.16% | 1.55% | | | | | | | | |
| **Sample Size** | 133 | 71 | | | | | | | | |

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

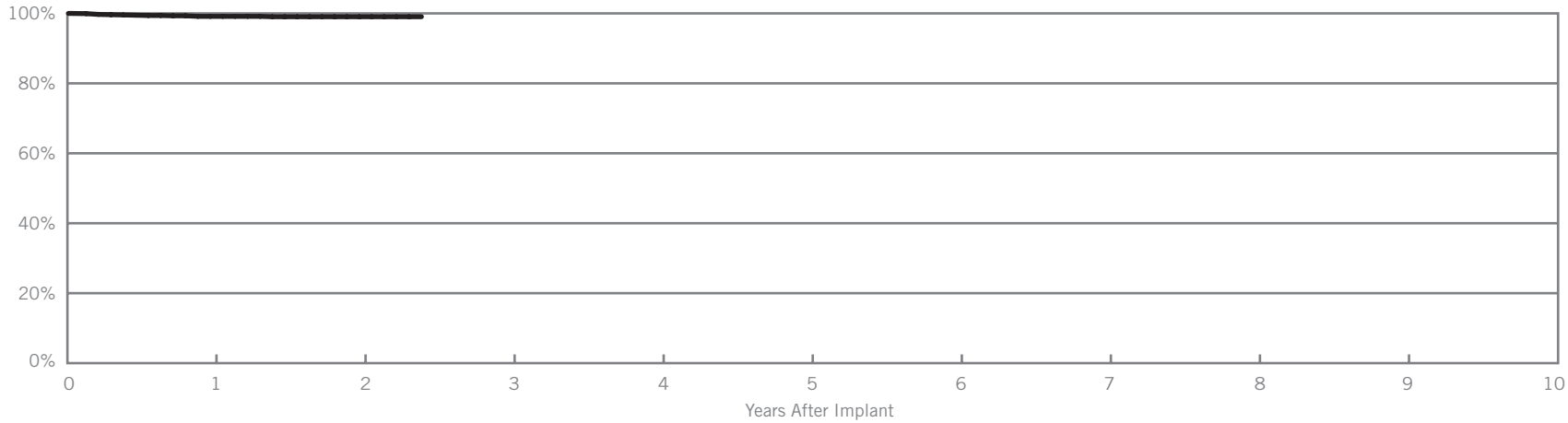
# Defibrillation Leads

| Riata® ST Optim® (Model 7022) | |
|---|---|
| US Regulatory Approval | July 2006 |
| Registered US Implants | 1,445 |
| Estimated Active US Implants | 1,214 |
| 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 | 5 | 0.35% | 2 | 0.14% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 3 | 0.21% | 6 | 0.42% |
| Failure to Capture | 1 | 0.07% | 0 | 0.00% |
| Oversensing | 0 | 0.00% | 4 | 0.28% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 1 | 0.07% | 0 | 0.00% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **10** | **0.69%** | **12** | **0.83%** |
| **Total Returned for Analysis** | **3** | | **5** | |

| 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 | 4 | 0.28% |
| **Total** | **6** | **0.42%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | at 29 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.15% | 99.05% | 99.05% | | | | | | | |
| **± 1 standard error** | 0.26% | 0.28% | 0.28% | | | | | | | |
| **Sample Size** | 1300 | 900 | 200 | | | | | | | |

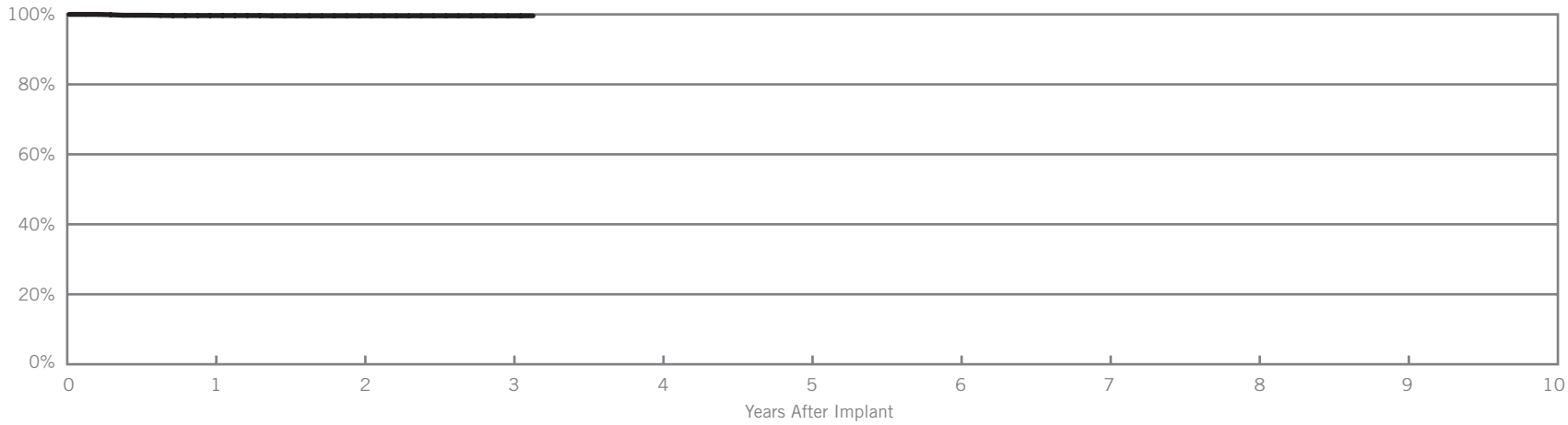
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Riata® ST (Models 7010 & 7011) | |
|---|---|
| US Regulatory Approval | March 2006 |
| Registered US Implants | 2,176 |
| Estimated Active US Implants | 1,700 |
| 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 | 3 | 0.14% | 1 | 0.05% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 1 | 0.05% | 4 | 0.18% |
| Failure to Capture | 3 | 0.14% | 0 | 0.00% |
| Oversensing | 2 | 0.09% | 1 | 0.05% |
| Failure to Sense | 1 | 0.05% | 1 | 0.05% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 1 | 0.05% | 1 | 0.05% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.05% | 1 | 0.05% |
| **Total** | **12** | **0.55%** | **9** | **0.41%** |
| **Total Returned for Analysis** | **4** | | **5** | |

| 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 | 3 | 0.14% |
| **Total** | **4** | **0.18%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 38 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.65% | 99.59% | 99.59% | 99.59% | | | | | | |
| **± 1 standard error** | 0.13% | 0.15% | 0.15% | 0.15% | | | | | | |
| **Sample Size** | 2100 | 1700 | 900 | 200 | | | | | | |

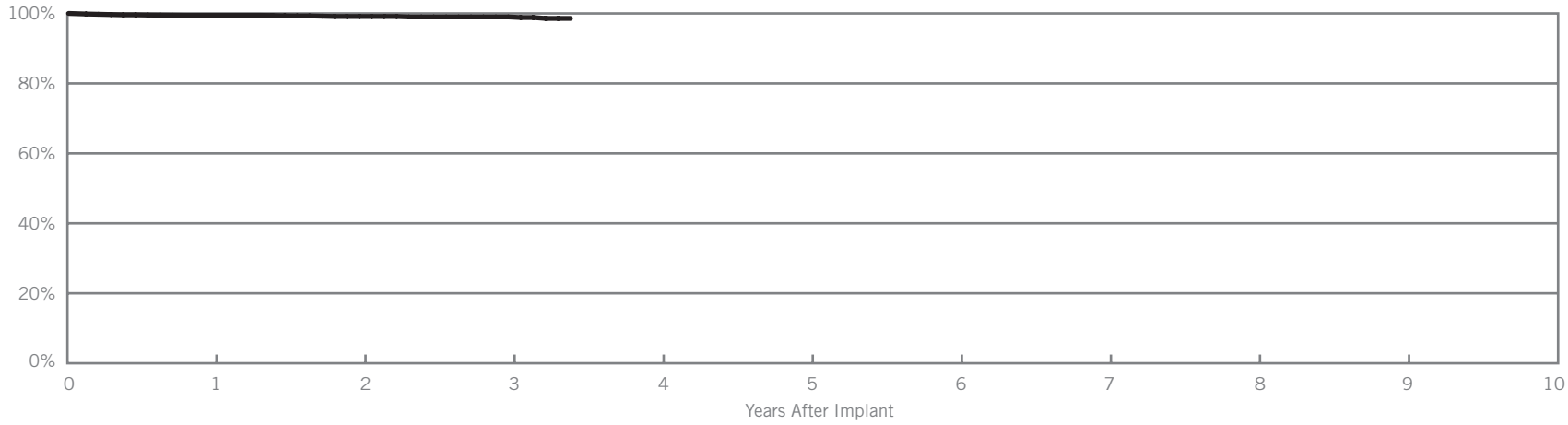
# Defibrillation Leads

| Riata® ST (Models 7040 & 7041) | |
|---|---|
| US Regulatory Approval | March 2006 |
| Registered US Implants | 3,975 |
| Estimated Active US Implants | 3,191 |
| 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 | 0.10% | 2 | 0.05% |
| Conductor Fracture | 0 | 0.00% | 2 | 0.05% |
| Lead Dislodgement | 5 | 0.13% | 3 | 0.08% |
| Failure to Capture | 1 | 0.03% | 4 | 0.10% |
| Oversensing | 3 | 0.08% | 10 | 0.25% |
| Failure to Sense | 0 | 0.00% | 3 | 0.08% |
| Insulation Breach | 0 | 0.00% | 1 | 0.03% |
| Abnormal Pacing Impedance | 2 | 0.05% | 3 | 0.08% |
| Abnormal Defibrillation Impedance | 0 | 0.00% | 2 | 0.05% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.03% | 0 | 0.00% |
| **Total** | **16** | **0.40%** | **30** | **0.75%** |
| **Total Returned for Analysis** | **3** | | **8** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 2 | 0.05% |
| Insulation Breach | 3 | 0.08% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 2 | 0.05% |
| Extrinsic Factors | 5 | 0.13% |
| **Total** | **12** | **0.30%** |

## Survival from Returns and Complaints



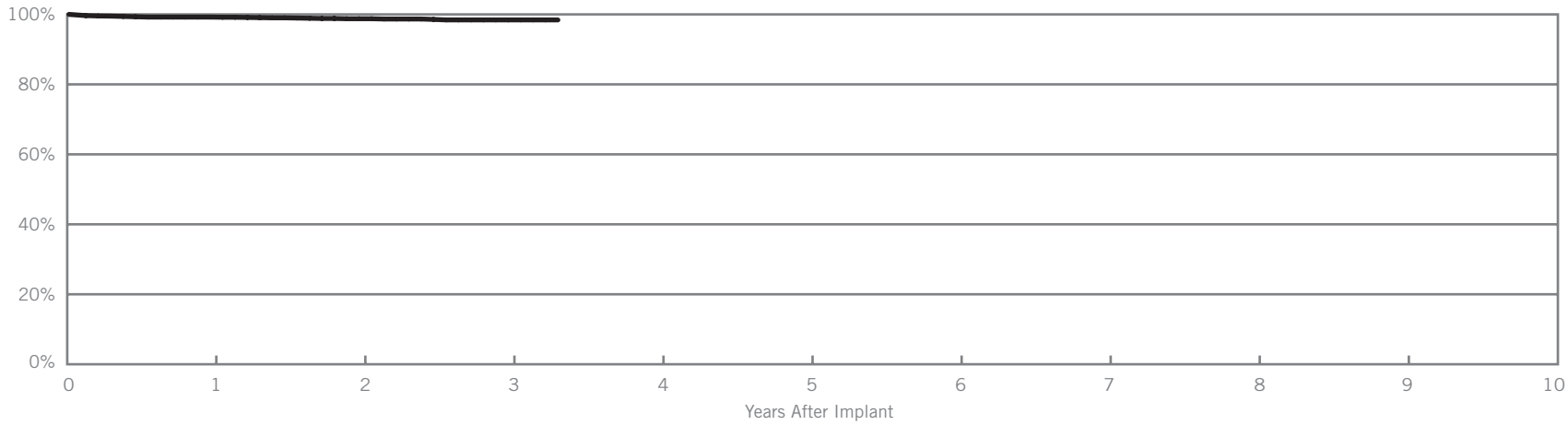

| Year | 1 | 2 | 3 | at 41 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.45% | 99.13% | 99.00% | 98.57% | | | | | | |
| **± 1 standard error** | 0.12% | 0.17% | 0.19% | 0.36% | | | | | | |
| **Sample Size** | 3600 | 2600 | 1300 | 300 | | | | | | |

| Riata® ST (Model 7002) | |
|---|---|
| US Regulatory Approval | June 2005 |
| Registered US Implants | 2,378 |
| Estimated Active US Implants | 1,913 |
| 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 | 6 | 0.25% | 3 | 0.13% |
| Conductor Fracture | 0 | 0.00% | 2 | 0.08% |
| Lead Dislodgement | 3 | 0.13% | 8 | 0.34% |
| Failure to Capture | 4 | 0.17% | 6 | 0.25% |
| Oversensing | 4 | 0.17% | 8 | 0.34% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 2 | 0.08% | 0 | 0.00% |
| Abnormal Defibrillation Impedance | 1 | 0.04% | 1 | 0.04% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.04% | 2 | 0.08% |
| **Total** | **21** | **0.88%** | **30** | **1.26%** |
| **Total Returned for Analysis** | **7** | | **14** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 2 | 0.08% |
| Insulation Breach | 2 | 0.08% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 9 | 0.38% |
| **Total** | **13** | **0.55%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 40 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.23% | 98.76% | 98.42% | 98.42% | | | | | | |
| **± 1 standard error** | 0.19% | 0.25% | 0.32% | 0.32% | | | | | | |
| **Sample Size** | 2300 | 1700 | 800 | 200 | | | | | | |

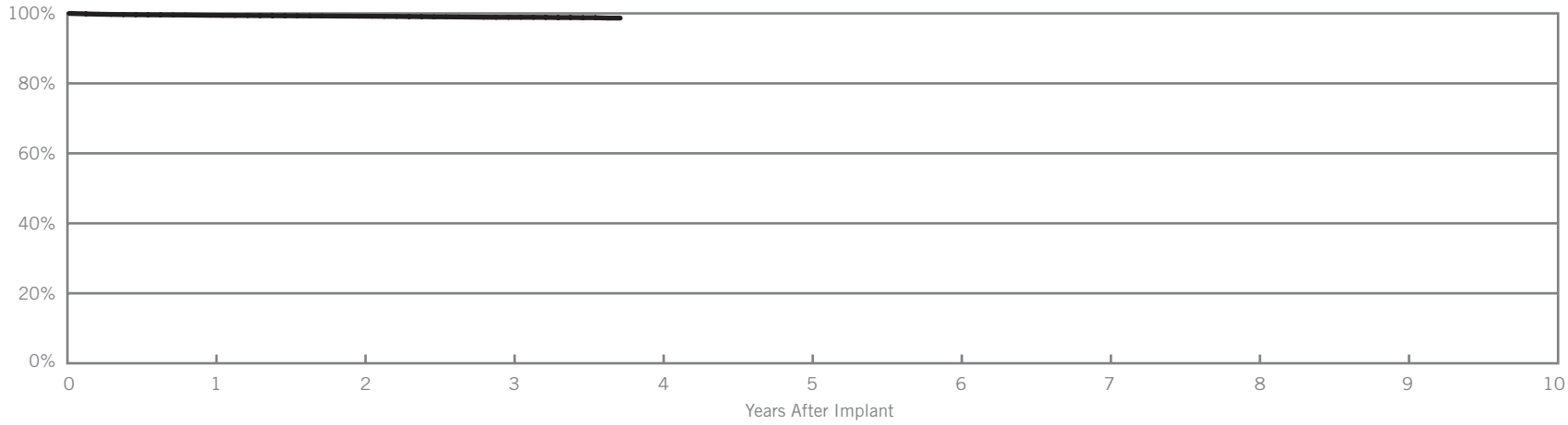
# Defibrillation Leads

| Riata® ST (Models 7000 & 7001) | |
|---|---|
| US Regulatory Approval | June 2005 |
| Registered US Implants | 34,629 |
| Estimated Active US Implants | 26,388 |
| 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 | 39 | 0.11% | 20 | 0.06% |
| Conductor Fracture | 0 | 0.00% | 10 | 0.03% |
| Lead Dislodgement | 36 | 0.10% | 36 | 0.10% |
| Failure to Capture | 42 | 0.12% | 54 | 0.16% |
| Oversensing | 40 | 0.12% | 129 | 0.37% |
| Failure to Sense | 7 | 0.02% | 14 | 0.04% |
| Insulation Breach | 1 | <0.01% | 7 | 0.02% |
| Abnormal Pacing Impedance | 8 | 0.02% | 9 | 0.03% |
| Abnormal Defibrillation Impedance | 4 | 0.01% | 9 | 0.03% |
| Extracardiac Stimulation | 4 | 0.01% | 2 | 0.01% |
| Other | 11 | 0.03% | 23 | 0.07% |
| **Total** | **192** | **0.55%** | **313** | **0.90%** |
| **Total Returned for Analysis** | **91** | | **158** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 8 | 0.02% |
| Insulation Breach | 48 | 0.14% |
| Crimps, Welds & Bonds | 4 | 0.01% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 80 | 0.23% |
| **Total** | **140** | **0.40%** |

## Survival from Returns and Complaints



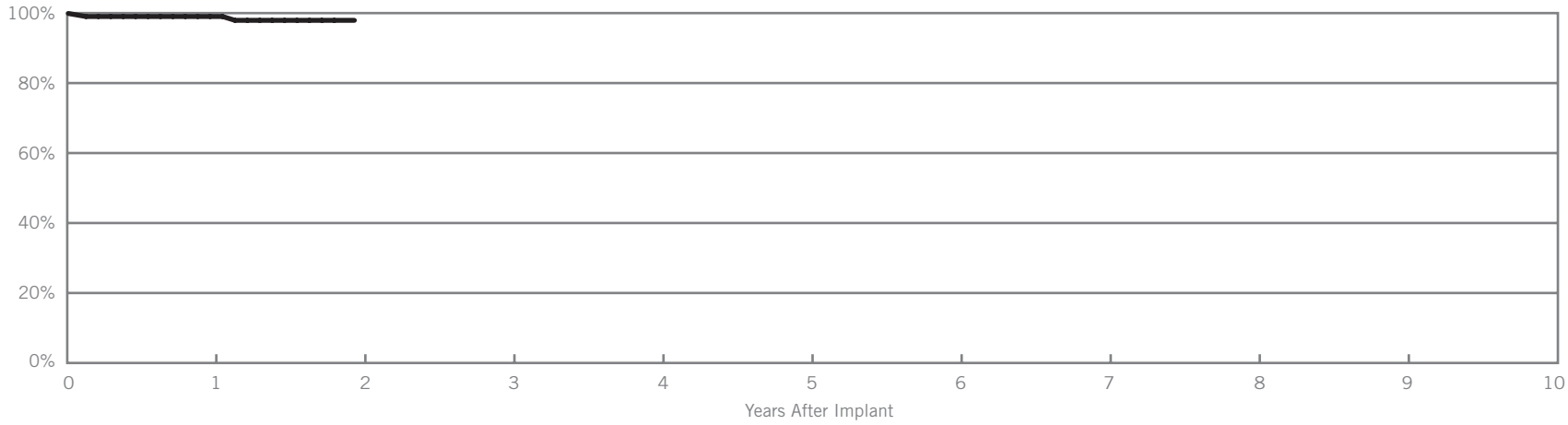

| Year | 1 | 2 | 3 | at 45 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.46% | 99.21% | 98.89% | 98.67% | | | | | | |
| **± 1 standard error** | 0.04% | 0.05% | 0.07% | 0.14% | | | | | | |
| **Sample Size** | 33100 | 26500 | 16100 | 600 | | | | | | |

| Riata® ST (Models 7000 & 7001) | |
|---|---|
| US Regulatory Approval | 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 | 117 |
| Cumulative Months of Follow-up | 2,009 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.85% |
| Oversensing | 1 | 0.85% |

## Survival from SCORE Registry



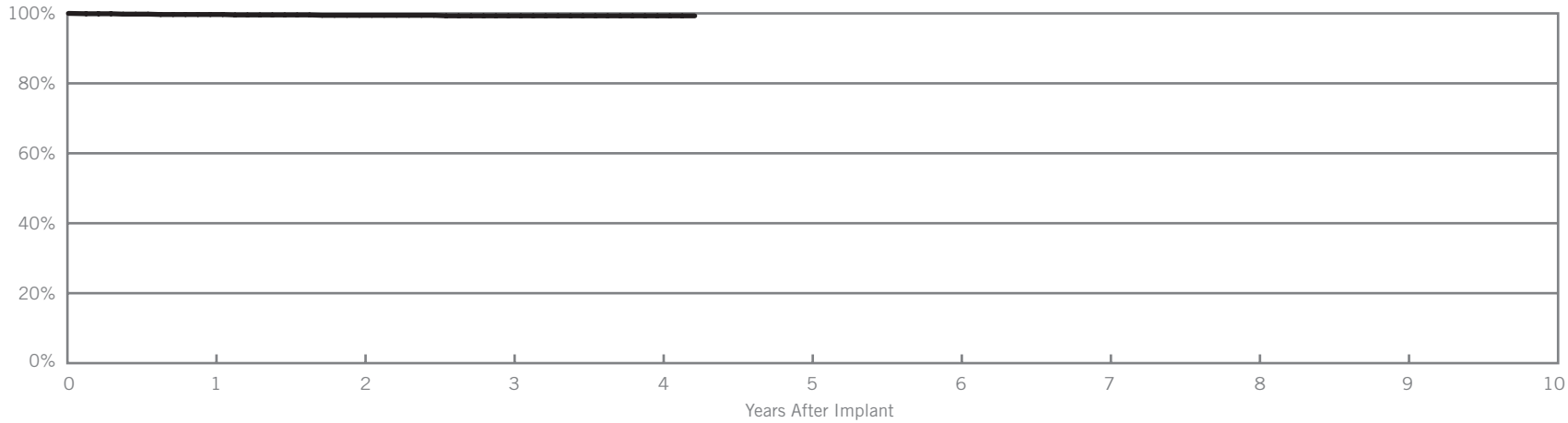

| Year | 1 | at 23 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.03% | 97.93% | | | | | | | | |
| **± 1 standard error** | 0.96% | 1.45% | | | | | | | | |
| **Sample Size** | 91 | 51 | | | | | | | | |

# Defibrillation Leads

| Riata® *i* (Models 1560 & 1561) | |
|---|---|
| US Regulatory Approval | April 2004 |
| Registered US Implants | 1,005 |
| Estimated Active US Implants | 669 |
| 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**

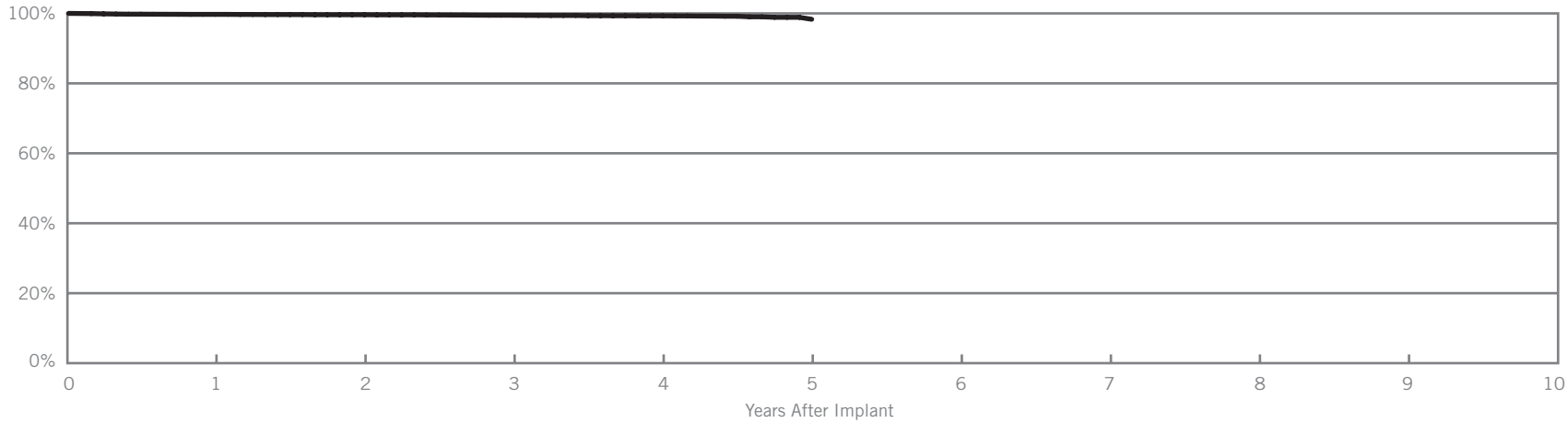



| Year | 1 | 2 | 3 | 4 | at 51 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.68% | 99.44% | 99.30% | 99.30% | 99.30% | | | | | |
| **± 1 standard error** | 0.19% | 0.25% | 0.29% | 0.29% | 0.29% | | | | | |
| **Sample Size** | 1000 | 900 | 700 | 500 | 200 | | | | | |

| Riata® *i* (Models 1590 & 1591) | |
|---|---|
| US Regulatory Approval | April 2004 |
| Registered US Implants | 9,717 |
| Estimated Active US Implants | 6,424 |
| 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 | 7 | 0.07% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 16 | 0.16% |
| **Total** | **26** | **0.27%** |

## Survival from Returns and Complaints



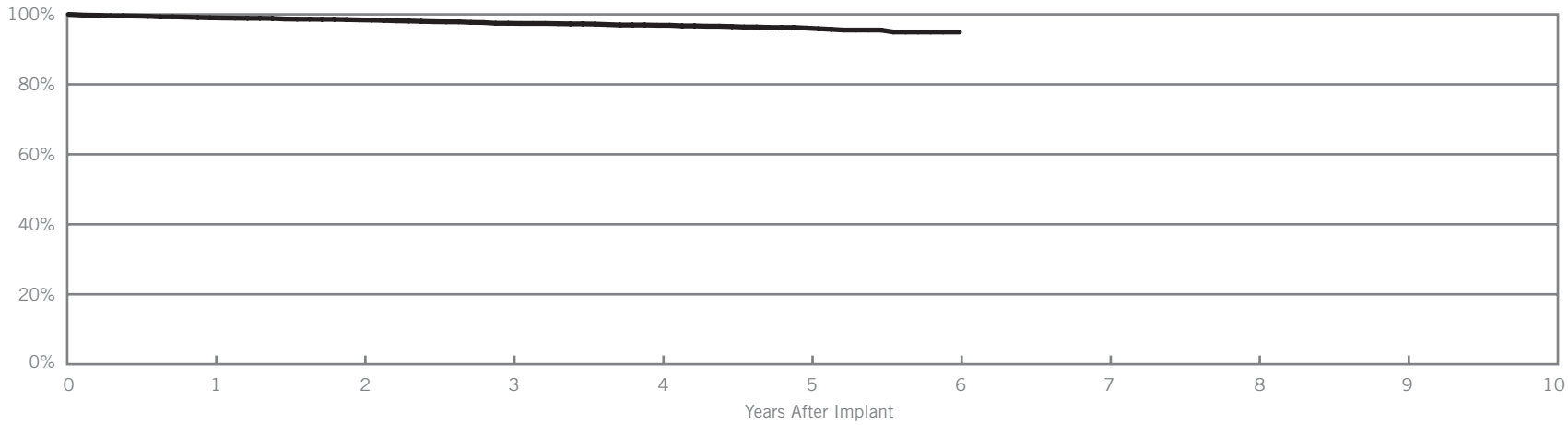

| Year | 1 | 2 | 3 | 4 | 5 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.72% | 99.62% | 99.47% | 99.31% | 98.32% | | | | | |
| **± 1 standard error** | 0.06% | 0.07% | 0.08% | 0.10% | 0.22% | | | | | |
| **Sample Size** | 9500 | 8300 | 7200 | 5100 | 1800 | | | | | |

# Defibrillation Leads

| Riata® (Model 1582) | |
|---|---|
| US Regulatory Approval | March 2003 |
| Registered US Implants | 3,132 |
| Estimated Active US Implants | 1,972 |
| 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 | 29 | 0.93% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 12 | 0.38% |
| **Total** | **43** | **1.37%** |

## Survival from Returns and Complaints

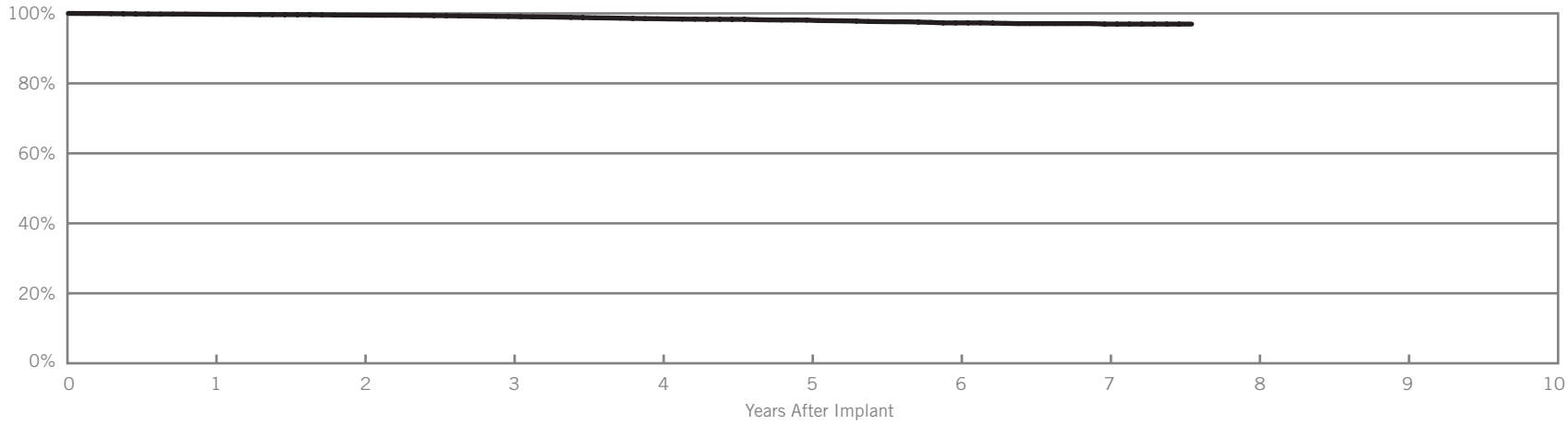



| Year | 1 | 2 | 3 | 4 | 5 | 6 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.04% | 98.43% | 97.46% | 96.89% | 96.09% | 94.98% | | | | |
| **± 1 standard error** | 0.18% | 0.23% | 0.32% | 0.37% | 0.46% | 0.69% | | | | |
| **Sample Size** | 3000 | 2500 | 2100 | 1600 | 900 | 400 | | | | |

| Riata® (Models 1570 & 1571) | |
|---|---|
| US Regulatory Approval | March 2002 |
| Registered US Implants | 10,371 |
| Estimated Active US Implants | 6,307 |
| 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 | 19 | 0.18% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 0 | 0.00% |
| Extrinsic Factors | 14 | 0.13% |
| **Total** | **36** | **0.35%** |

## Survival from Returns and Complaints



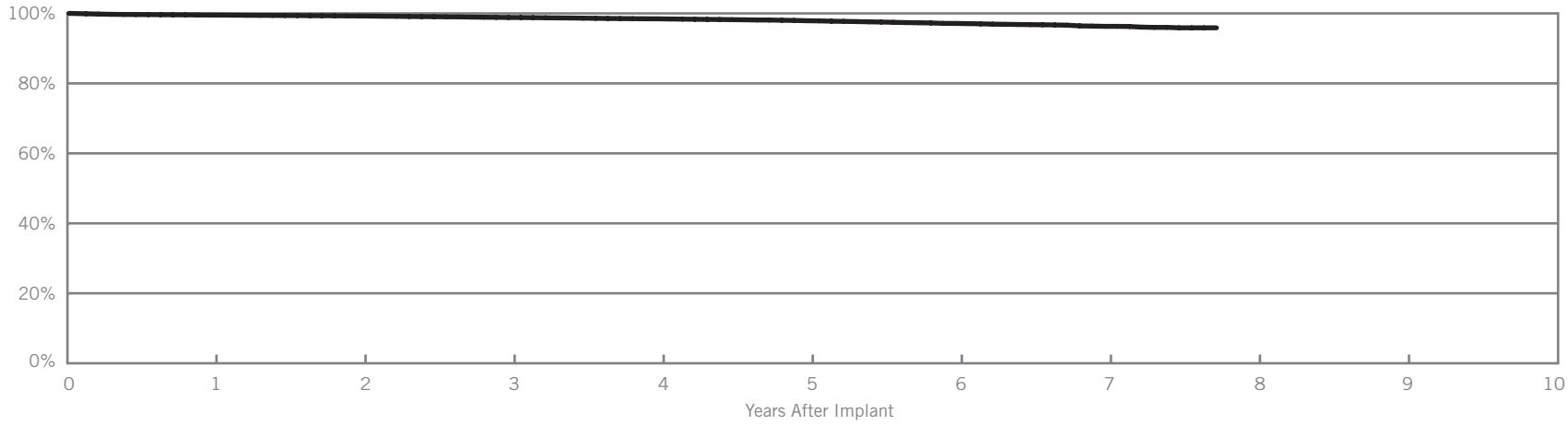

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 91 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.74% | 99.50% | 99.13% | 98.47% | 98.08% | 97.28% | 96.95% | 96.95% | | |
| **± 1 standard error** | 0.05% | 0.07% | 0.10% | 0.15% | 0.18% | 0.25% | 0.28% | 0.31% | | |
| **Sample Size** | 9900 | 8500 | 7300 | 5900 | 4200 | 2600 | 1300 | 200 | | |

# Defibrillation Leads

| Riata® (Models 1580 & 1581) | |
|---|---|
| US Regulatory Approval | March 2002 |
| Registered US Implants | 69,053 |
| Estimated Active US Implants | 42,309 |
| 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 | 186 | 0.27% |
| Crimps, Welds & Bonds | 4 | 0.01% |
| Other | 3 | <0.01% |
| Extrinsic Factors | 184 | 0.27% |
| **Total** | **388** | **0.56%** |

## Survival from Returns and Complaints



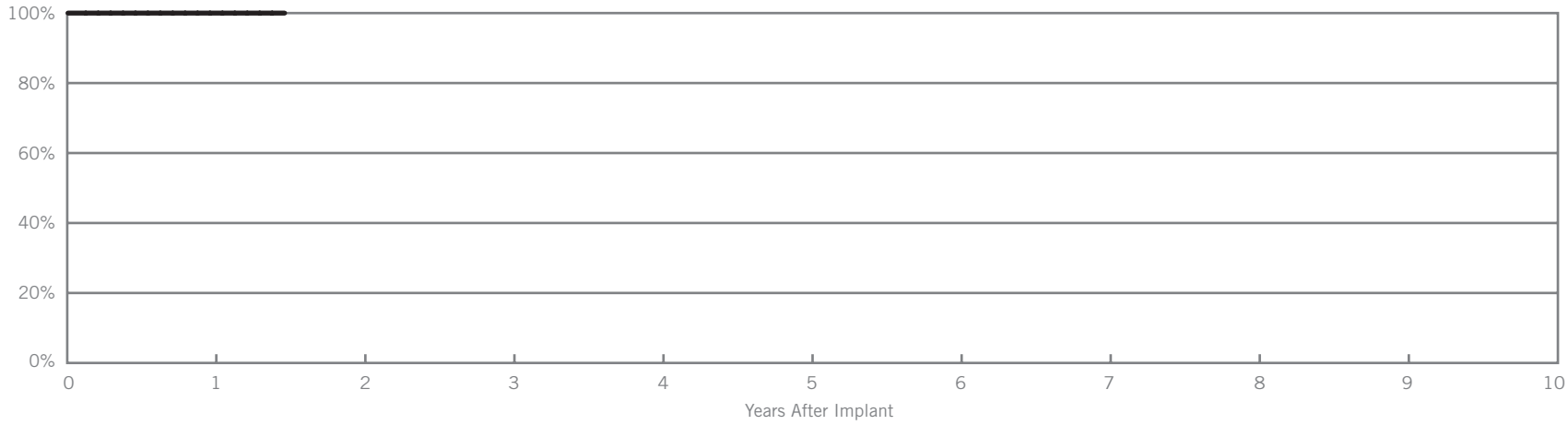

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 93 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.52% | 99.27% | 98.84% | 98.45% | 97.90% | 97.13% | 96.30% | 95.88% | | |
| **± 1 standard error** | 0.03% | 0.03% | 0.04% | 0.05% | 0.07% | 0.11% | 0.17% | 0.25% | | |
| **Sample Size** | 67100 | 57900 | 50300 | 40100 | 25600 | 12800 | 5300 | 200 | | |

| Riata® (Models 1580 & 1581) | |
|---|---|
| US Regulatory Approval | 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 | 115 |
| Cumulative Months of Follow-up | 1,837 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry

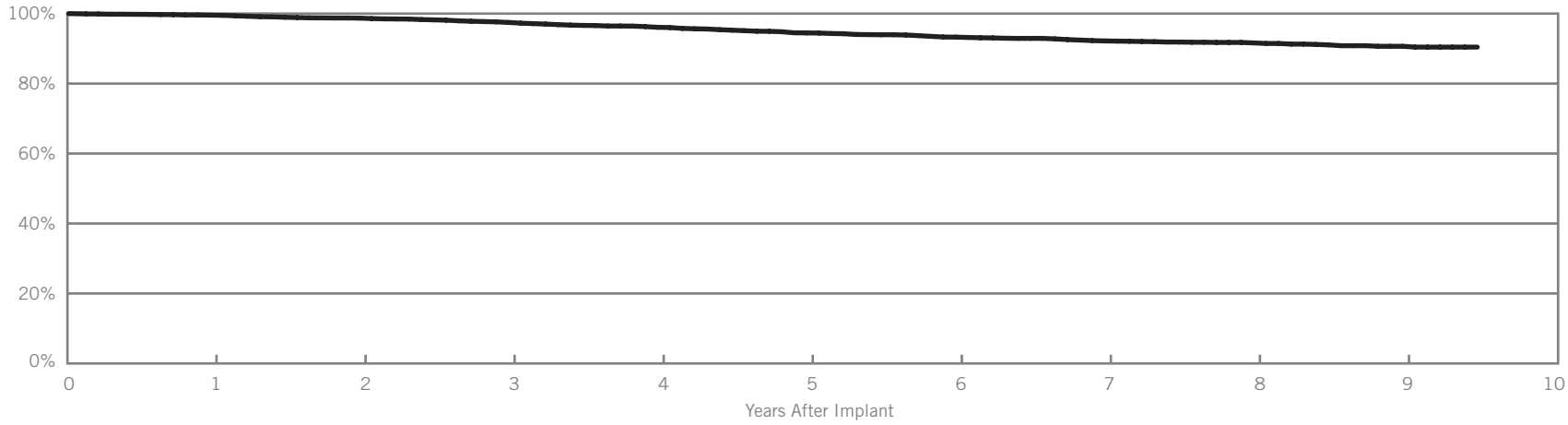



| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 87 | 52 | | | | | | | | |

# Defibrillation Leads

| TVL™ ADX (Model 1559) | |
|---|---|
| US Regulatory Approval | November 1999 |
| Registered US Implants | 4,734 |
| Estimated Active US Implants | 1,579 |
| Insulation | Silicone |
| Type and/or Fixation | Single Coil, Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of Advisories | None |

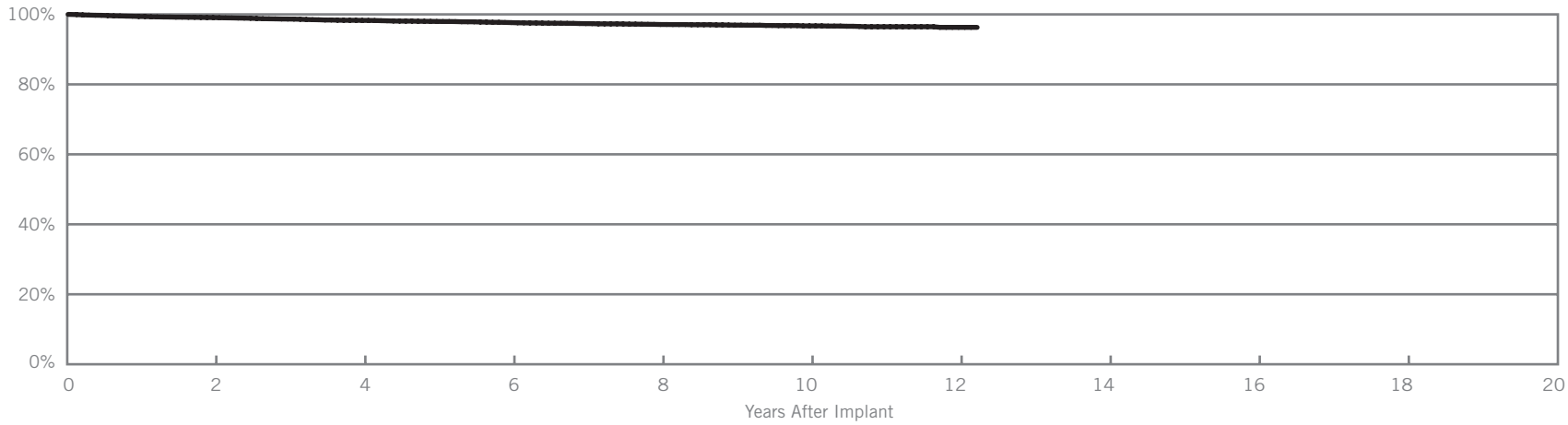
**Survival from Returns and Complaints**




| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 114 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.55% | 98.71% | 97.47% | 96.08% | 94.47% | 93.27% | 92.18% | 91.61% | 90.65% | 90.42% |
| **± 1 standard error** | 0.09% | 0.18% | 0.25% | 0.32% | 0.40% | 0.46% | 0.50% | 0.53% | 0.62% | 0.66% |
| **Sample Size** | 4500 | 4000 | 3600 | 3100 | 2800 | 2400 | 2100 | 1600 | 900 | 200 |

| SPL® (Models SP01, SP02, SP03 & SP04) | |
|---|---|
| US Regulatory Approval | September 1997 |
| Registered US Implants | 12,899 |
| Estimated Active US Implants | 4,357 |
| 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 | 12 | at 147 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.09% | 98.28% | 97.65% | 97.11% | 96.71% | 96.29% | 96.29% | | | |
| **± 1 standard error** | 0.09% | 0.13% | 0.16% | 0.18% | 0.22% | 0.31% | 0.31% | | | |
| **Sample Size** | 10900 | 9000 | 7300 | 5500 | 2800 | 700 | 200 | | | |

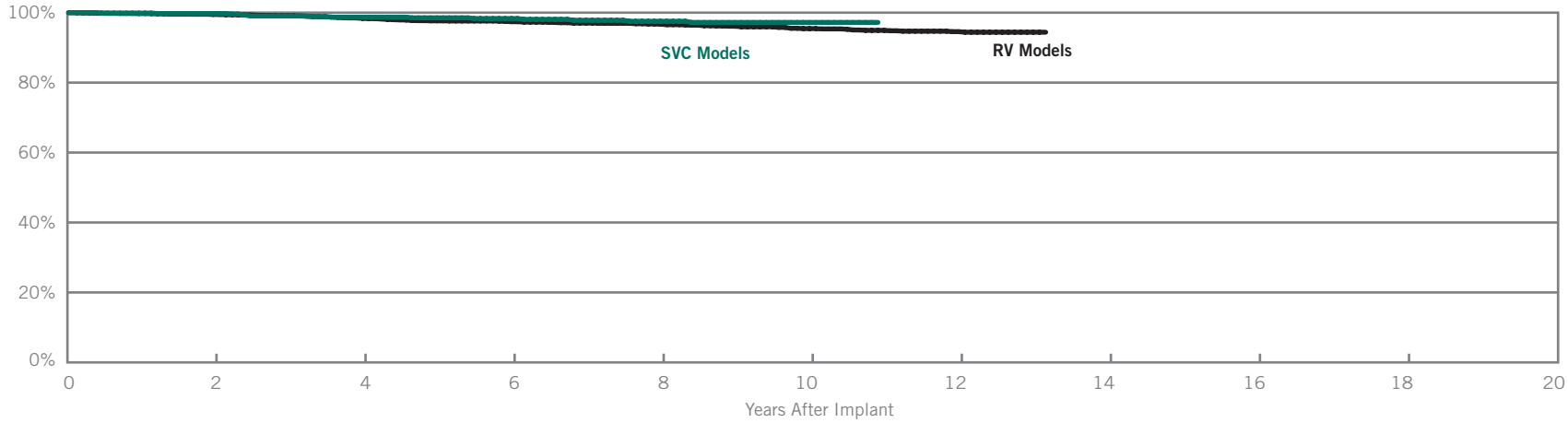
## TVL™ RV (Models RV01, RV02, RV03, RV06 & RV07)
## TVL™ SVC (Models SV01, SV02 & SV03)

| US Regulatory Approval | |
|---|---|
| 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 | 920 |
| SVC | 920 | SVC | 219 |

| | |
|---|---|
| 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 158 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.48% | 98.36% | 97.41% | 96.70% | 95.44% | 94.56% | 94.41% | | | |
| ± 1 standard error | 0.12% | 0.23% | 0.31% | 0.37% | 0.49% | 0.57% | 0.59% | | | |
| Sample Size | 3200 | 2600 | 2100 | 1600 | 1200 | 800 | 200 | | | |

**SVC Models**

| Year | 2 | 4 | 6 | 8 | 10 | at 131 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.75% | 98.72% | 98.32% | 97.54% | 97.21% | 97.21% | | | | |
| ± 1 standard error | 0.18% | 0.43% | 0.51% | 0.68% | 0.75% | 0.75% | | | | |
| Sample Size | 800 | 700 | 500 | 400 | 300 | 200 | | | | |

# Observations, Complications, and Malfunctions

## Defibrillation Leads

St. Jude Medical™

More control. Less risk.

# Defibrillation Leads

## Acute Observations (Post Implant, ≤30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Abnormal Defibrillation Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 7120Q/7121Q | Jan-09 | 5527 | 5365 | 3 | 0.05% | 0 | 0.00% | 7 | 0.13% | 2 | 0.04% | 5 | 0.09% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **18** | **0.33%** | **8** |
| 7122Q | Jan-09 | 645 | 622 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.16% | 1 | 0.16% | 1 | 0.16% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **0.47%** | **1** |
| 7120/7121 | Sep-07 | 42103 | 37837 | 23 | 0.05% | 1 | <0.01% | 35 | 0.08% | 11 | 0.03% | 35 | 0.08% | 4 | 0.01% | 0 | 0.00% | 1 | <0.01% | 14 | 0.03% | 1 | <0.01% | 15 | 0.04% | **140** | **0.33%** | **40** |
| 7122 | Sep-07 | 4854 | 4466 | 3 | 0.06% | 0 | 0.00% | 4 | 0.08% | 2 | 0.04% | 2 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **11** | **0.23%** | **5** |
| 7070/7071 | Jul-06 | 2890 | 2462 | 2 | 0.07% | 1 | 0.03% | 3 | 0.10% | 5 | 0.17% | 3 | 0.10% | 2 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **16** | **0.55%** | **4** |
| 7020/7021 | Jul-06 | 15272 | 12209 | 38 | 0.25% | 0 | 0.00% | 32 | 0.21% | 19 | 0.12% | 19 | 0.12% | 8 | 0.05% | 0 | 0.00% | 1 | 0.01% | 4 | 0.03% | 4 | 0.03% | 2 | 0.01% | **127** | **0.83%** | **55** |
| 7022 | Jul-06 | 1445 | 1214 | 5 | 0.35% | 0 | 0.00% | 3 | 0.21% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **10** | **0.69%** | **3** |
| 7010/7011 | Mar-06 | 2176 | 1700 | 3 | 0.14% | 0 | 0.00% | 1 | 0.05% | 3 | 0.14% | 2 | 0.09% | 1 | 0.05% | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 1 | 0.05% | **12** | **0.55%** | **4** |
| 7040/7041 | Mar-06 | 3975 | 3191 | 4 | 0.10% | 0 | 0.00% | 5 | 0.13% | 1 | 0.03% | 3 | 0.08% | 0 | 0.00% | 0 | 0.00% | 2 | 0.05% | 0 | 0.00% | 0 | 0.00% | 1 | 0.03% | **16** | **0.40%** | **3** |
| 7002 | Jun-05 | 2378 | 1913 | 6 | 0.25% | 0 | 0.00% | 3 | 0.13% | 4 | 0.17% | 4 | 0.17% | 0 | 0.00% | 0 | 0.00% | 2 | 0.08% | 1 | 0.04% | 0 | 0.00% | 1 | 0.04% | **21** | **0.88%** | **7** |
| 7000/7001 | Jun-05 | 34629 | 26388 | 39 | 0.11% | 0 | 0.00% | 36 | 0.10% | 42 | 0.12% | 40 | 0.12% | 7 | 0.02% | 1 | <0.01% | 8 | 0.02% | 4 | 0.01% | 4 | 0.01% | 11 | 0.03% | **192** | **0.55%** | **91** |

## Chronic Complications (>30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Abnormal Defibrillation Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 7120Q/7121Q | Jan-09 | 5527 | 5365 | 1 | 0.02% | 0 | 0.00% | 2 | 0.04% | 0 | 0.00% | 1 | 0.02% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **0.07%** | **1** |
| 7122Q | Jan-09 | 645 | 622 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** | **0** |
| 7120/7121 | Sep-07 | 42103 | 37837 | 4 | 0.01% | 1 | <0.01% | 68 | 0.16% | 25 | 0.06% | 30 | 0.07% | 7 | 0.02% | 0 | 0.00% | 7 | 0.02% | 4 | 0.01% | 0 | 0.00% | 11 | 0.03% | **157** | **0.37%** | **71** |
| 7122 | Sep-07 | 4854 | 4466 | 0 | 0.00% | 0 | 0.01% | 9 | 0.19% | 5 | 0.10% | 2 | 0.04% | 1 | 0.02% | 1 | 0.02% | 3 | 0.06% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **21** | **0.43%** | **17** |
| 7070/7071 | Jul-06 | 2890 | 2462 | 1 | 0.03% | 0 | 0.00% | 3 | 0.10% | 3 | 0.10% | 3 | 0.10% | 2 | 0.07% | 0 | 0.00% | 1 | 0.03% | 1 | 0.03% | 0 | 0.00% | 0 | 0.00% | **14** | **0.48%** | **5** |
| 7020/7021 | Jul-06 | 15272 | 12209 | 10 | 0.07% | 0 | 0.00% | 45 | 0.29% | 28 | 0.18% | 36 | 0.24% | 10 | 0.07% | 2 | 0.01% | 3 | 0.02% | 5 | 0.03% | 2 | 0.01% | 11 | 0.07% | **152** | **1.00%** | **102** |
| 7022 | Jul-06 | 1445 | 1214 | 2 | 0.14% | 0 | 0.00% | 6 | 0.42% | 0 | 0.00% | 4 | 0.28% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **12** | **0.83%** | **5** |
| 7010/7011 | Mar-06 | 2176 | 1700 | 1 | 0.05% | 0 | 0.00% | 4 | 0.18% | 0 | 0.00% | 1 | 0.05% | 1 | 0.05% | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 1 | 0.05% | **9** | **0.41%** | **5** |
| 7040/7041 | Mar-06 | 3975 | 3191 | 2 | 0.05% | 2 | 0.05% | 3 | 0.08% | 4 | 0.10% | 10 | 0.25% | 3 | 0.08% | 1 | 0.03% | 3 | 0.08% | 2 | 0.05% | 0 | 0.00% | 0 | 0.00% | **30** | **0.75%** | **8** |
| 7002 | Jun-05 | 2378 | 1913 | 3 | 0.13% | 2 | 0.08% | 8 | 0.34% | 6 | 0.25% | 8 | 0.34% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 2 | 0.08% | **30** | **1.26%** | **14** |
| 7000/7001 | Jun-05 | 34629 | 26388 | 20 | 0.06% | 10 | 0.03% | 36 | 0.10% | 54 | 0.16% | 129 | 0.37% | 14 | 0.04% | 7 | 0.02% | 9 | 0.03% | 9 | 0.03% | 2 | 0.01% | 23 | 0.07% | **313** | **0.90%** | **158** |

*Definitions of observations and complications can be found on pages 6 and 7.*

## Lead Malfunctions

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Conductor Fracture | | Insulation Breach | | Crimps, Welds & Bonds | | Other | | Extrinsic Factors | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate |
| 7120Q/7121Q | Jan-09 | 5527 | 5365 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.04% | **2** | **0.04%** |
| 7122Q | Jan-09 | 645 | 622 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 7120/7121 | Sep-07 | 42103 | 37837 | 1 | <0.01% | 1 | <0.01% | 1 | <0.01% | 7 | 0.02% | 56 | 0.13% | **66** | **0.16%** |
| 7122 | Sep-07 | 4854 | 4466 | 1 | 0.02% | 1 | 0.02% | 0 | 0.00% | 1 | 0.02% | 13 | 0.27% | **16** | **0.33%** |
| 7070/7071 | Jul-06 | 2890 | 2462 | 1 | 0.03% | 0 | 0.00% | 1 | 0.03% | 1 | 0.03% | 4 | 0.14% | **7** | **0.24%** |
| 7020/7021 | Jul-06 | 15272 | 12209 | 4 | 0.03% | 6 | 0.04% | 2 | 0.01% | 1 | 0.01% | 73 | 0.48% | **86** | **0.56%** |
| 7022 | Jul-06 | 1445 | 1214 | 1 | 0.07% | 0 | 0.00% | 0 | 0.00% | 1 | 0.07% | 4 | 0.28% | **6** | **0.42%** |
| 7010/7011 | Mar-06 | 2176 | 1700 | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 3 | 0.14% | **4** | **0.18%** |
| 7040/7041 | Mar-06 | 3975 | 3191 | 2 | 0.05% | 3 | 0.08% | 0 | 0.00% | 2 | 0.05% | 5 | 0.13% | **12** | **0.30%** |
| 7002 | Jun-05 | 2378 | 1913 | 2 | 0.08% | 2 | 0.08% | 0 | 0.00% | 0 | 0.00% | 9 | 0.38% | **13** | **0.55%** |
| 7000/7001 | Jun-05 | 34629 | 26388 | 8 | 0.02% | 48 | 0.14% | 4 | 0.01% | 0 | 0.00% | 80 | 0.23% | **140** | **0.40%** |
| 1560/1561 | Apr-04 | 1005 | 669 | 0 | 0.00% | 1 | 0.10% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.10%** |
| 1590/1591 | Apr-04 | 9717 | 6424 | 3 | 0.03% | 7 | 0.07% | 0 | 0.00% | 0 | 0.00% | 16 | 0.16% | **26** | **0.27%** |
| 1582 | Mar-03 | 3132 | 1972 | 2 | 0.06% | 29 | 0.93% | 0 | 0.00% | 0 | 0.00% | 12 | 0.38% | **43** | **1.37%** |
| 1570/1571 | Mar-02 | 10371 | 6307 | 3 | 0.03% | 19 | 0.18% | 0 | 0.00% | 0 | 0.00% | 14 | 0.13% | **36** | **0.35%** |
| 1580/1581 | Mar-02 | 69053 | 42309 | 11 | 0.02% | 186 | 0.27% | 4 | 0.01% | 3 | <0.01% | 184 | 0.27% | **388** | **0.56%** |

*Definitions of malfunction categories can be found on pages 7 and 8.*

# Pacemakers

## Dual-Chamber

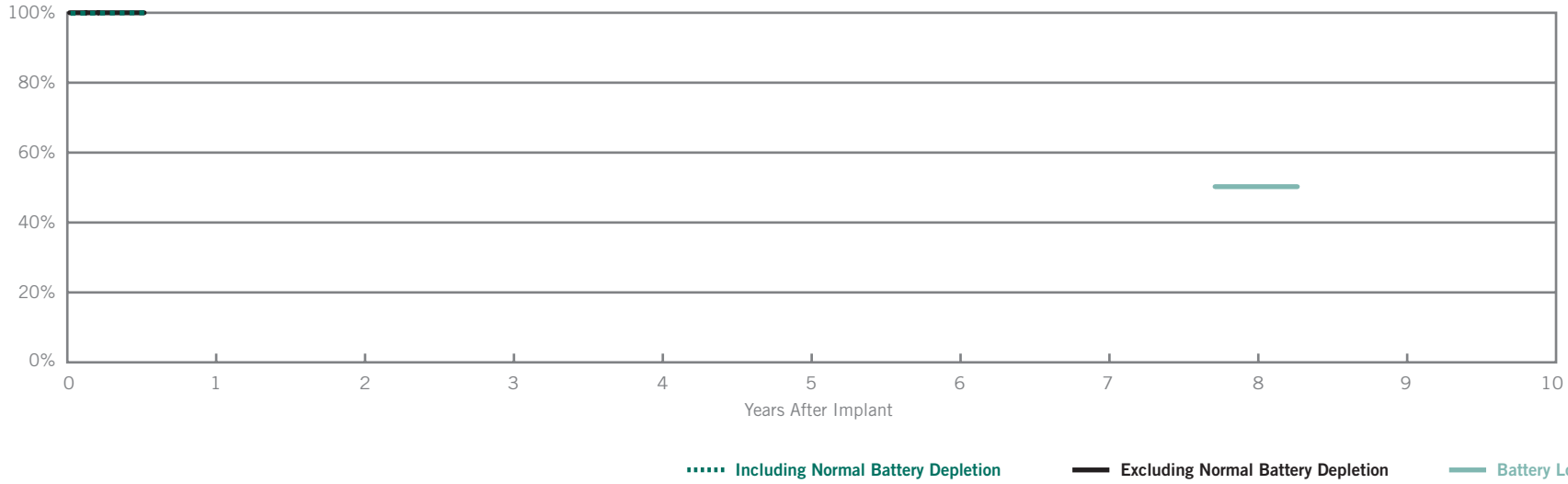
St. Jude Medical

More control. Less risk.

## Accent® DR RF (Model PM2210)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 11,896 | Total Malfunctions | 0 |
| Estimated Active US Implants | 11,697 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 8 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 6 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

**Excluding Normal Battery Depletion**

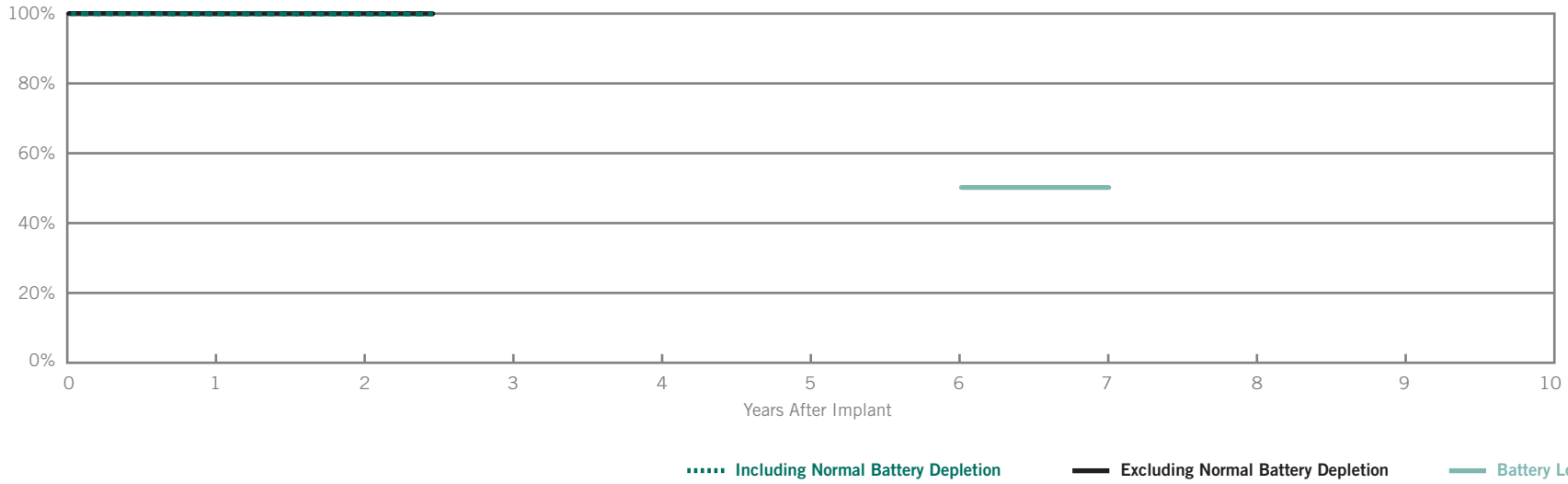
| Year | at 6 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

# Pacemakers

## Zephyr® DR (Model 5820)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2007 | Normal Battery Depletion | 1 |
| Registered US Implants | 19,268 | Total Malfunctions | 3 |
| Estimated Active US Implants | 18,317 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 6.5 Years | Malfunctions w/o Compromised Therapy | 2 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.96% | 99.86% | | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.07% | | | | | | | |
| Sample Size | 16300 | 7000 | 200 | | | | | | | |

**Excluding Normal Battery Depletion**

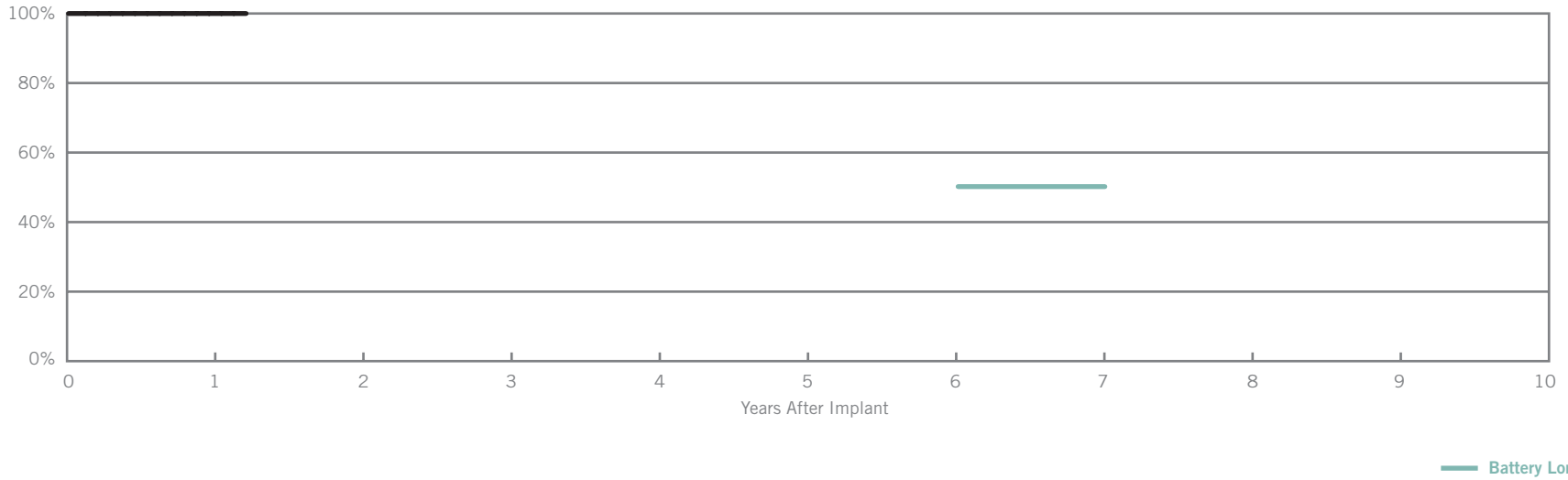
| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.96% | 99.96% | | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | | | | | | | |

| Zephyr® DR (Model 5820) | |
|---|---|
| US Regulatory Approval | March 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 178 |
| Cumulative Months of Follow-up | 1,987 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry



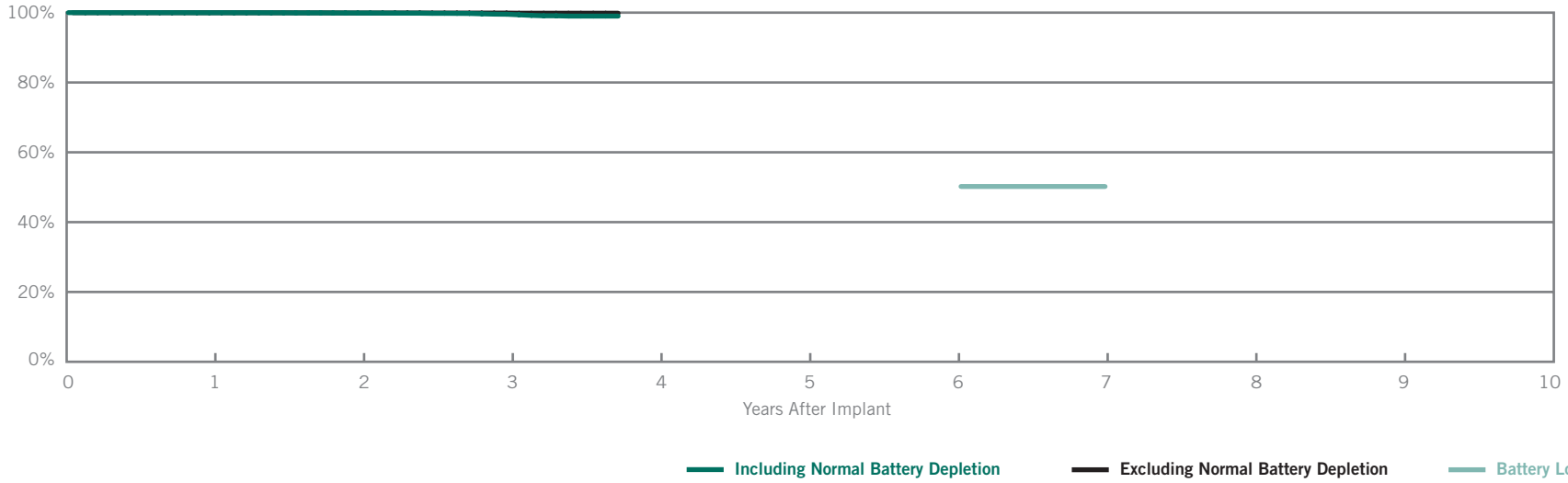

| Year | 1 | at 15 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 93 | 52 | | | | | | | | |

# Pacemakers

## Victory® DR (Model 5810)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2005 | Normal Battery Depletion | 26 |
| Registered US Implants | 25,305 | Total Malfunctions | 11 |
| Estimated Active US Implants | 18,710 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 6.5 Years | Malfunctions w/o Compromised Therapy | 11 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 45 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.89% | 99.54% | 99.01% | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.07% | 0.14% | | | | | | |
| Sample Size | 24000 | 18000 | 10600 | 200 | | | | | | |

**Excluding Normal Battery Depletion**

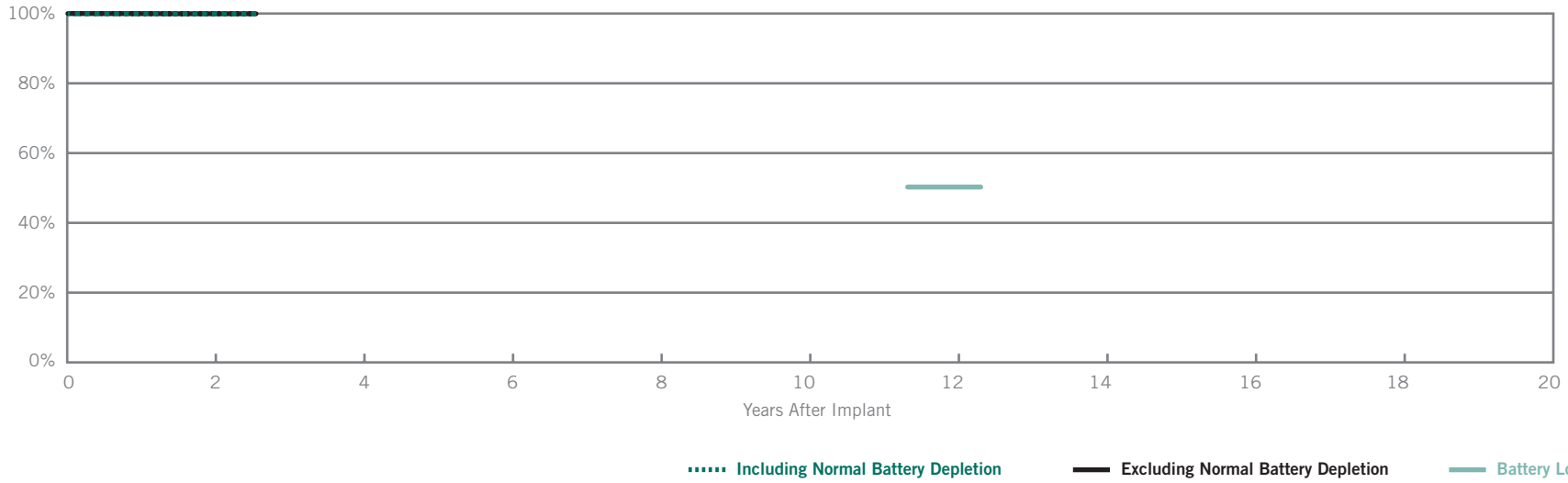
| Year | 1 | 2 | 3 | at 45 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.90% | 99.88% | 99.84% | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.04% | | | | | | |

# Pacemakers

## Zephyr® XL DR (Model 5826)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2007 | Normal Battery Depletion | 1 |
| Registered US Implants | 86,833 | Total Malfunctions | 13 |
| Estimated Active US Implants | 78,858 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 11.7 Years | Malfunctions w/o Compromised Therapy | 12 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | at 31 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | 99.94% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.01% | | | | | | | | |
| Sample Size | 67500 | 200 | | | | | | | | |

**Excluding Normal Battery Depletion**

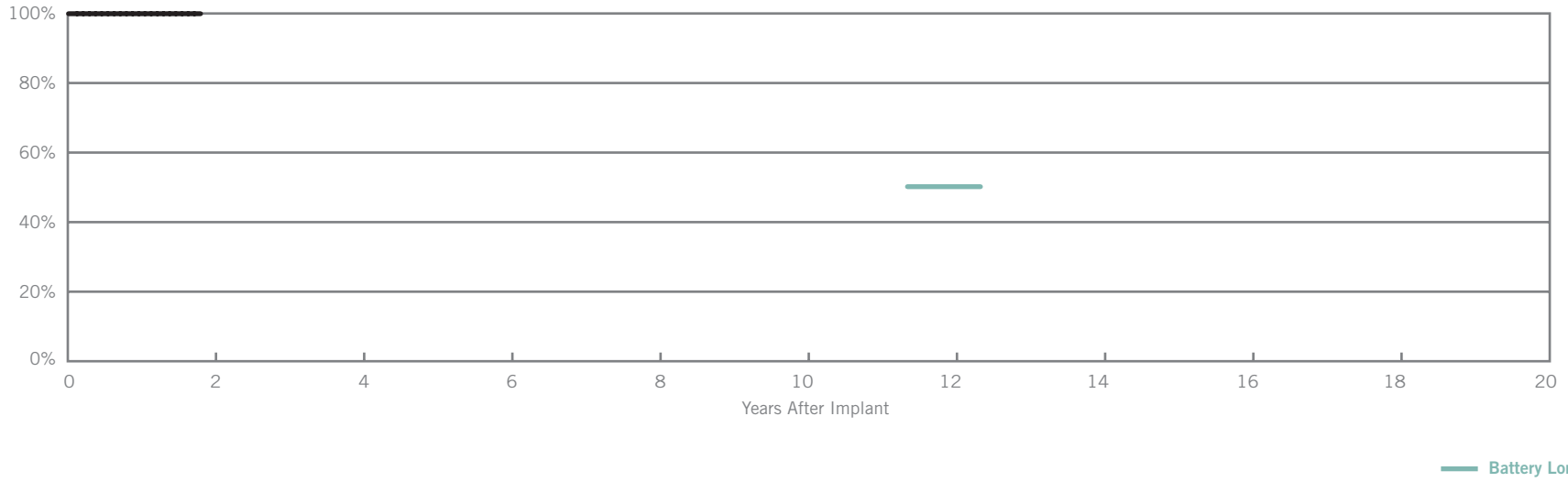
| Year | 2 | at 31 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.94% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.01% | | | | | | | | |

| Zephyr® XL DR (Model 5826) | |
|---|---|
| US Regulatory Approval | March 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 1,347 |
| Cumulative Months of Follow-up | 16,048 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Backup Operation | 1 | 0.07% |

## Survival from SCORE Registry



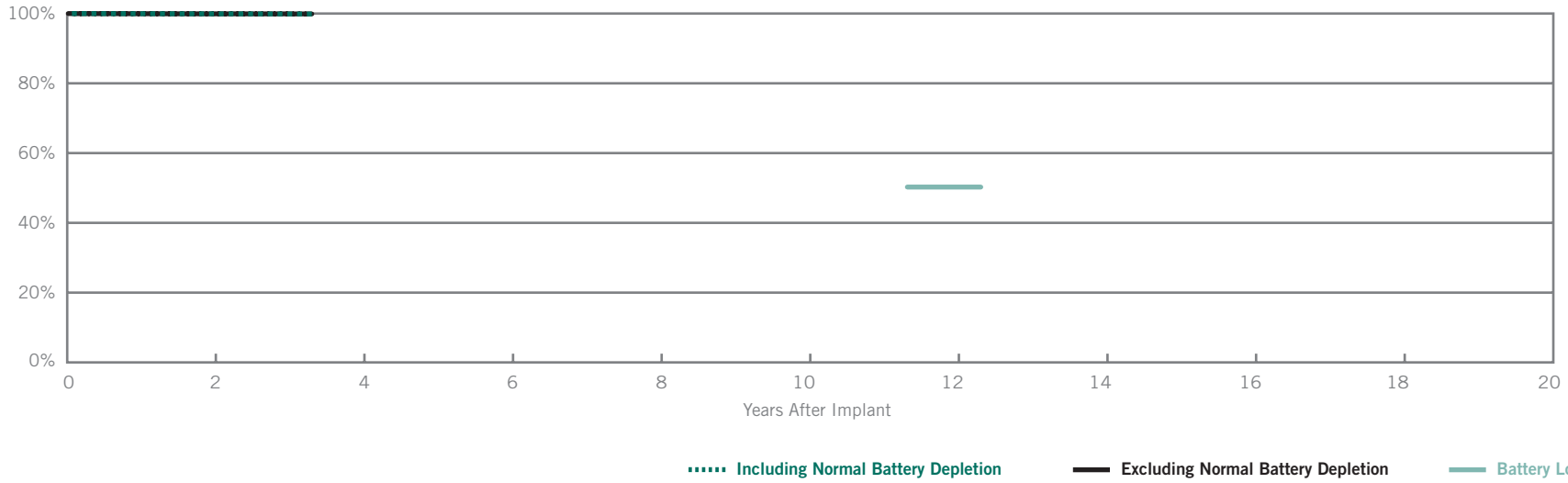

| Year | at 22 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.93% | | | | | | | | | |
| **± 1 standard error** | 0.07% | | | | | | | | | |
| **Sample Size** | 80 | | | | | | | | | |

# Pacemakers

## Victory® XL DR (Model 5816)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2005 | Normal Battery Depletion | 4 |
| Registered US Implants | 60,263 | Total Malfunctions | 23 |
| Estimated Active US Implants | 49,328 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 11.7 Years | Malfunctions w/o Compromised Therapy | 22 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | at 40 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.87% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | | | | | | | | |
| Sample Size | 43400 | 200 | | | | | | | | |

**Excluding Normal Battery Depletion**

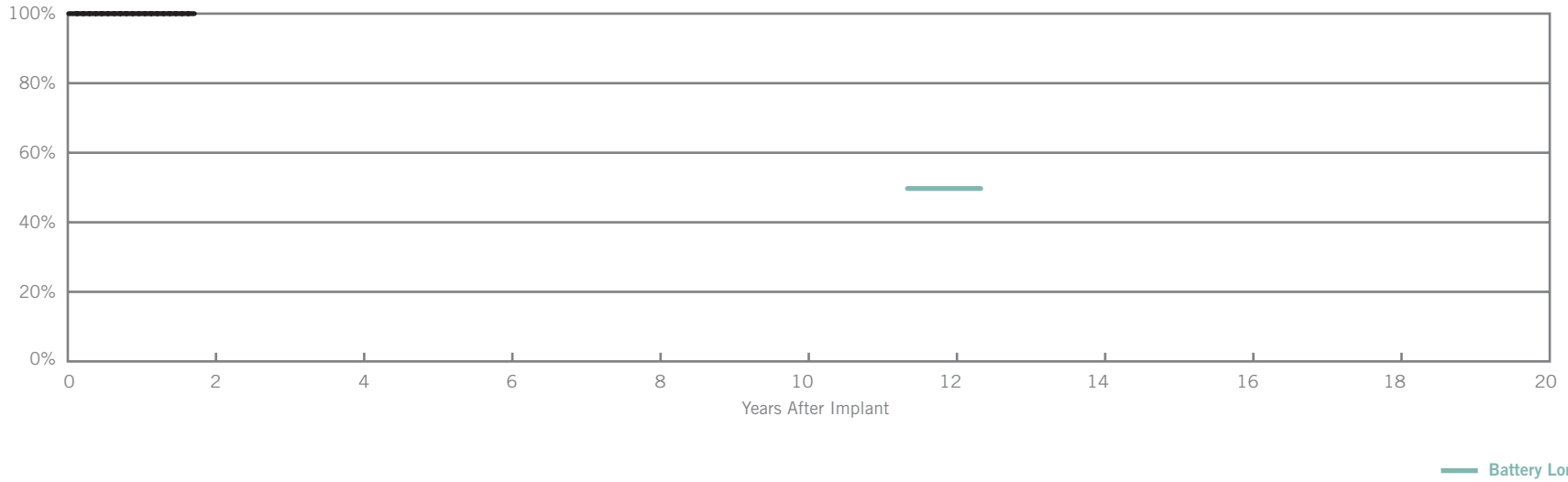
| Year | 2 | at 40 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.89% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.02% | | | | | | | | |

| Victory® XL DR (Model 5816) | |
|---|---|
| US Regulatory Approval | December 2005 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 320 |
| Cumulative Months of Follow-up | 4,605 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry



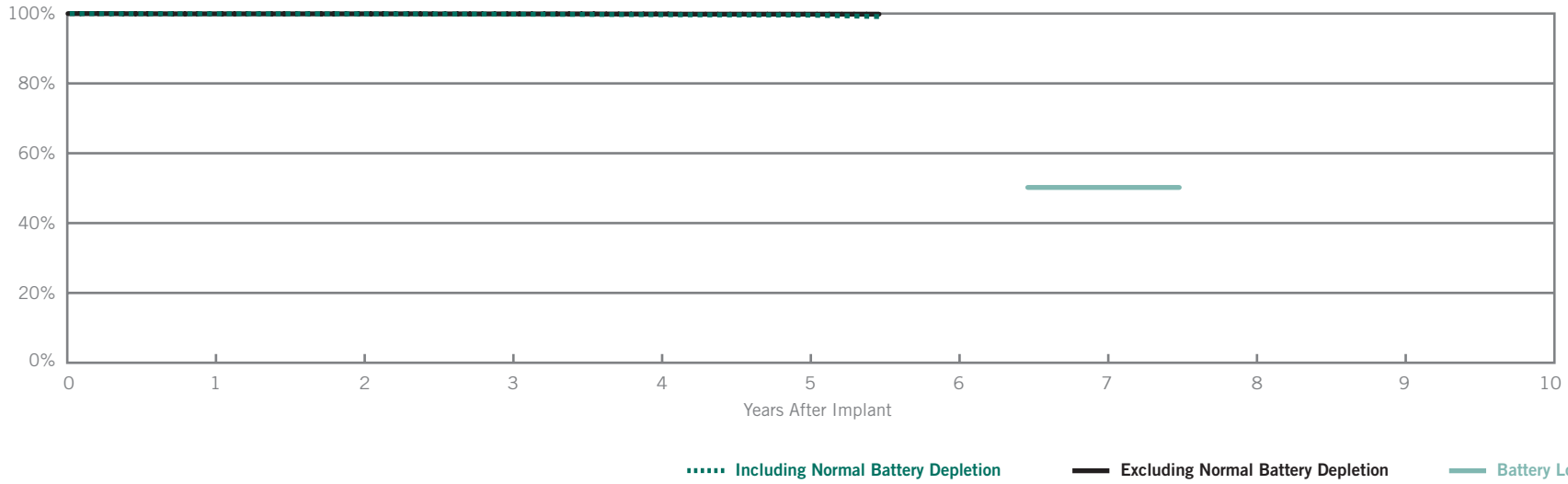

| Year | at 21 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 53 | | | | | | | | | |

# Pacemakers

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

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 11 |
| Registered US Implants | 16,663 | Total Malfunctions | 7 |
| Estimated Active US Implants | 10,596 | 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 | at 66 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.84% | 99.72% | 99.58% | 99.15% | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.06% | 0.08% | 0.15% | | | | |
| Sample Size | 16500 | 13600 | 10700 | 7300 | 3900 | 1100 | | | | |

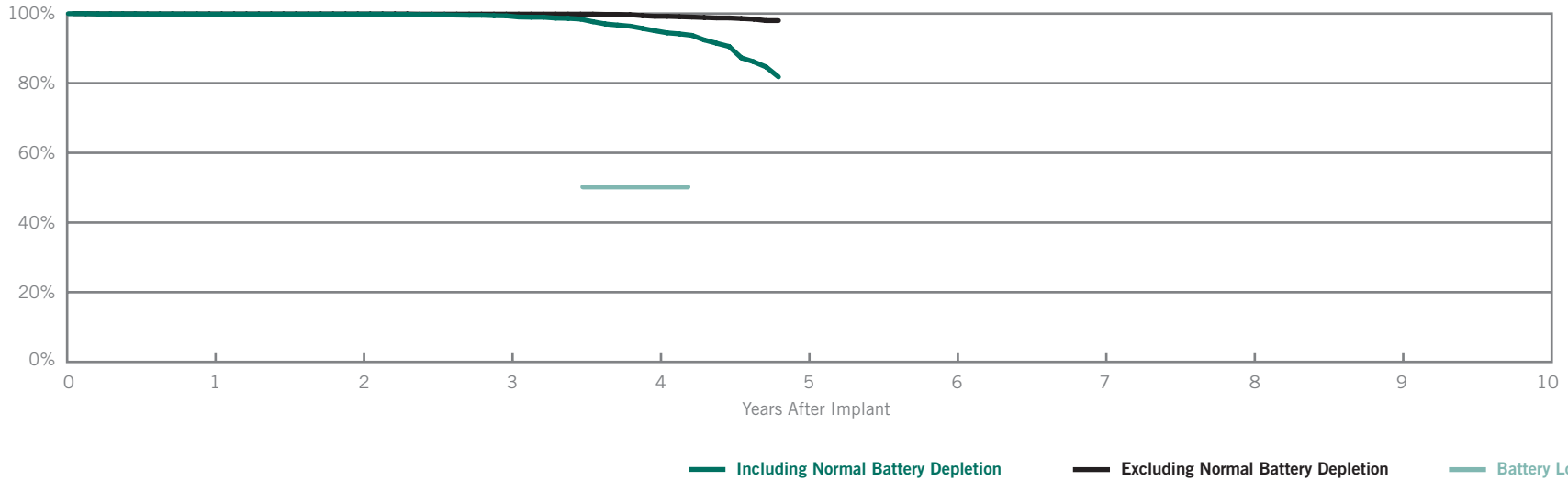
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 66 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.90% | 99.87% | 99.83% | 99.83% | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.03% | 0.05% | 0.05% | | | | |

## Integrity® ADx DR (Model 5360)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 170 |
| Registered US Implants | 5,818 | Total Malfunctions | 21 |
| Estimated Active US Implants | 2,712 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 3.8 Years | Malfunctions w/o Compromised Therapy | 21 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.82% | 99.82% | 99.34% | 95.06% | 81.81% | | | | | |
| ± 1 standard error | 0.05% | 0.06% | 0.12% | 0.38% | 0.91% | | | | | |
| Sample Size | 5800 | 5000 | 4100 | 3000 | 800 | | | | | |

**Excluding Normal Battery Depletion**

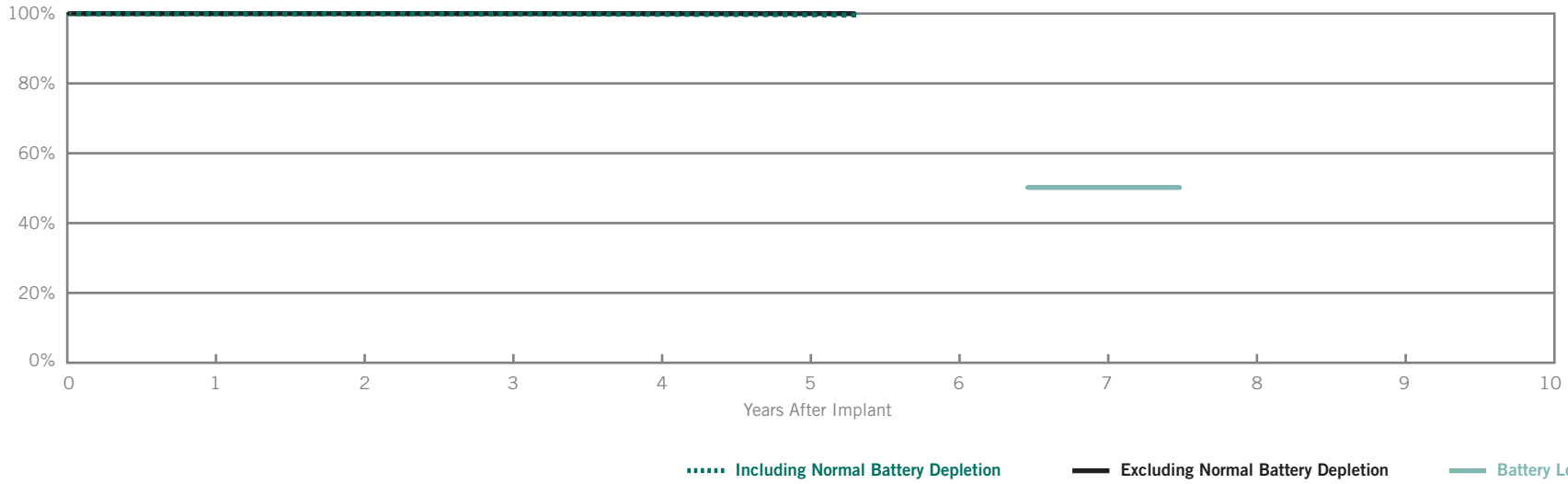
| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.89% | 99.84% | 99.21% | 97.98% | | | | | |
| ± 1 standard error | 0.05% | 0.05% | 0.06% | 0.15% | 0.36% | | | | | |

# Pacemakers

## Integrity® ADx DR (Model 5366)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 7 |
| Registered US Implants | 7,999 | Total Malfunctions | 1 |
| Estimated Active US Implants | 5,401 | 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 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.98% | 99.91% | 99.91% | 99.56% | 99.56% | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.04% | 0.04% | 0.15% | 0.15% | | | | |
| Sample Size | 8000 | 7000 | 5600 | 3500 | 1800 | 600 | | | | |

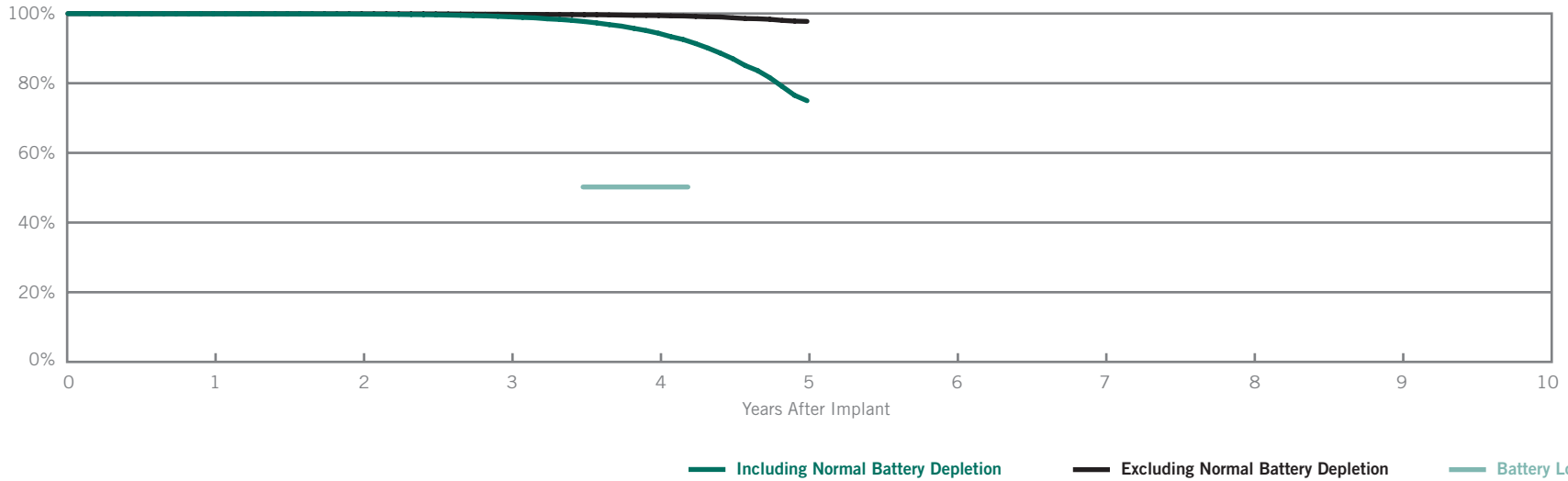
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 64 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.98% | 99.98% | 99.98% | 99.98% | 99.98% | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% | 0.02% | | | | |

## Identity® ADx DR (Model 5380)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2003 | Normal Battery Depletion | 1,600 |
| Registered US Implants | 53,095 | Total Malfunctions (0 related to Advisory) | 135 |
| Estimated Active US Implants | 24,569 | 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 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.82% | 99.05% | 94.33% | 74.97% | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.13% | 0.43% | | | | | |
| Sample Size | 52400 | 44600 | 37900 | 28000 | 200 | | | | | |

**Excluding Normal Battery Depletion**

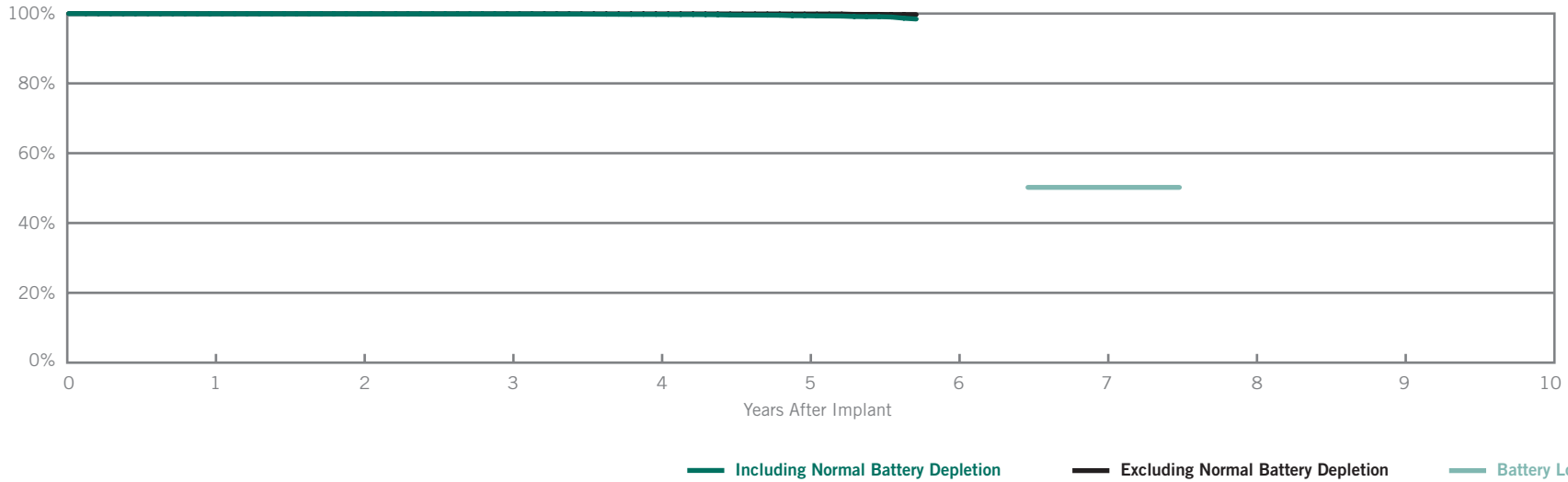
| Year | 1 | 2 | 3 | 4 | 5 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.92% | 99.78% | 99.42% | 97.74% | | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.02% | 0.04% | 0.14% | | | | | |

# Pacemakers

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

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2003 | Normal Battery Depletion | 64 |
| Registered US Implants | 64,593 | Total Malfunctions (0 related to Advisory) | 33 |
| Estimated Active US Implants | 45,831 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | 6.9 Years | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 32 |
| | | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.92% | 99.88% | 99.76% | 99.39% | 98.44% | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.01% | 0.03% | 0.06% | 0.15% | | | | |
| Sample Size | 63000 | 53500 | 44000 | 31300 | 16400 | 2900 | | | | |

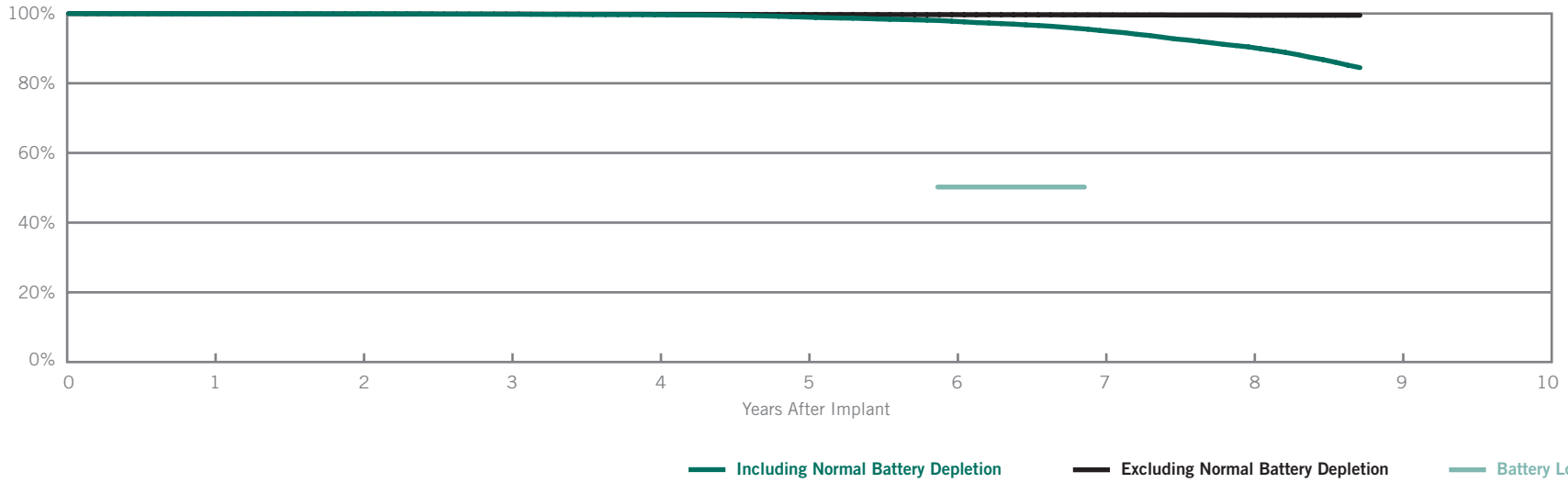
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 69 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.93% | 99.92% | 99.90% | 99.86% | 99.71% | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.01% | 0.01% | 0.02% | 0.06% | | | | |

## Integrity® AFx DR (Models 5342 & 5346)

| | | | |
|---|---|---|---|
| US Regulatory Approval | (5342) April 2000 | Normal Battery Depletion | 1,080 |
| | (5346) July 2001 | Total Malfunctions | 72 |
| Registered US Implants | 47,491 | Malfunctions w/ Compromised Therapy | 6 |
| Estimated Active US Implants | 15,345 | Malfunctions w/o Compromised Therapy | 66 |
| 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 105 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.90% | 99.80% | 99.66% | 99.00% | 97.81% | 95.13% | 90.42% | 84.47% | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.03% | 0.05% | 0.08% | 0.14% | 0.21% | 0.35% | |
| Sample Size | 47100 | 42000 | 38500 | 34900 | 31300 | 27100 | 22200 | 15500 | 3400 | |

**Excluding Normal Battery Depletion**

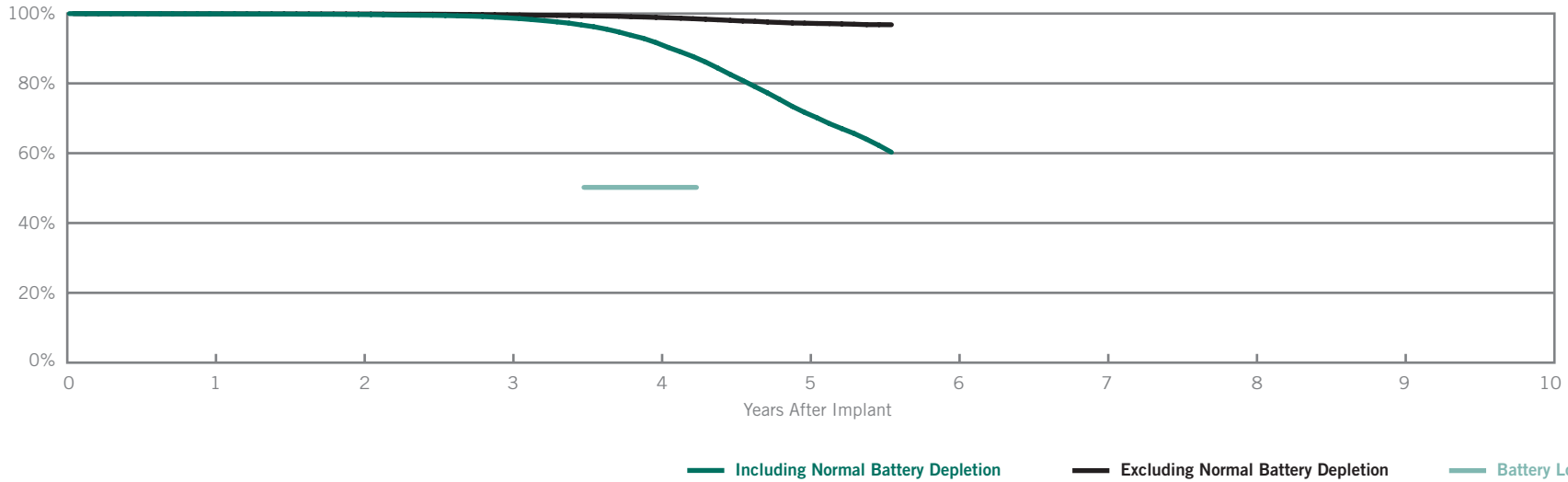
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 105 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.89% | 99.86% | 99.79% | 99.70% | 99.67% | 99.60% | 99.50% | 99.50% | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.02% | 0.03% | 0.03% | 0.04% | 0.04% | 0.05% | |

# Pacemakers

## Identity® (Model 5370)

| | | | |
|---|---|---|---|
| US Regulatory Approval | November 2001 | Normal Battery Depletion | 3,791 |
| Registered US Implants | 58,350 | Total Malfunctions (20 related to Advisory) | 359 |
| Estimated Active US Implants | 11,943 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | 3.8 Years | Malfunctions w/o Compromised Therapy (20 related to Advisory) | 354 |
| | | Number of Advisories (see pages 238-243) | 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% | 98.77% | 91.69% | 71.68% | 60.27% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.14% | 0.30% | 0.41% | | | | |
| Sample Size | 57900 | 50400 | 44600 | 37400 | 24900 | 3800 | | | | |

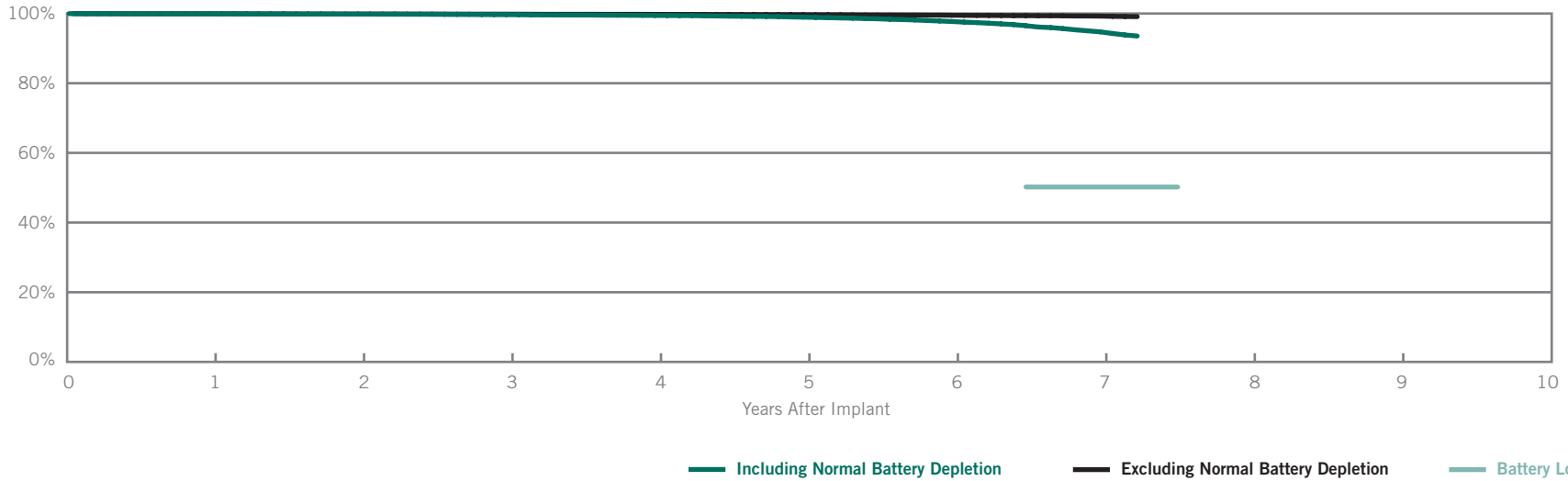
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 67 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.87% | 99.61% | 98.90% | 97.25% | 96.80% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.05% | 0.11% | 0.13% | | | | |

## Identity® XL (Model 5376)

| | | | |
|---|---|---|---|
| US Regulatory Approval | November 2001 | Normal Battery Depletion | 391 |
| Registered US Implants | 51,405 | Total Malfunctions (7 related to Advisory) | 101 |
| Estimated Active US Implants | 27,756 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 9 |
| Estimated Longevity | 6.9 Years | Malfunctions w/o Compromised Therapy (7 related to Advisory) | 92 |
| | | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.83% | 99.69% | 99.45% | 98.96% | 97.71% | 94.74% | 93.54% | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.04% | 0.05% | 0.09% | 0.18% | 0.23% | | |
| Sample Size | 51200 | 46300 | 41900 | 36200 | 29300 | 21600 | 12000 | 4300 | | |

**Excluding Normal Battery Depletion**

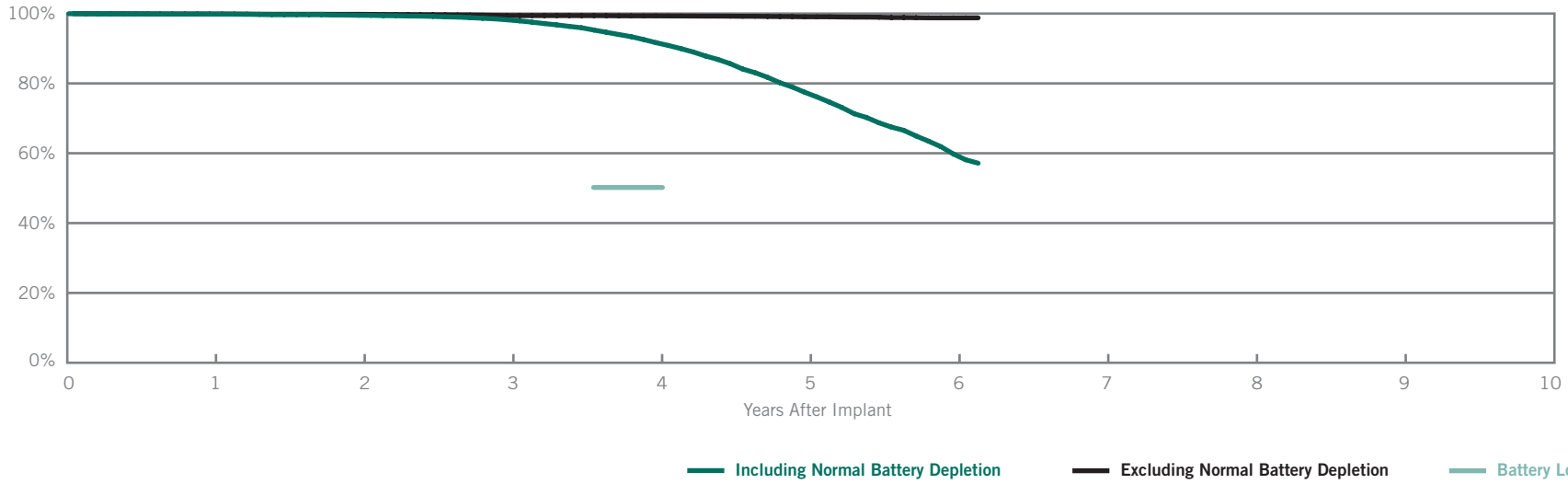
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.86% | 99.82% | 99.76% | 99.65% | 99.50% | 99.26% | 99.11% | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.02% | 0.03% | 0.04% | 0.06% | 0.08% | | |

# Pacemakers

## Integrity® µ DR (Model 5336)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2000 | Normal Battery Depletion | 2,058 |
| Registered US Implants | 29,356 | Total Malfunctions | 85 |
| Estimated Active US Implants | 3,009 | Malfunctions w/ Compromised Therapy | 8 |
| Estimated Longevity | 4.0 Years | Malfunctions w/o Compromised Therapy | 77 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 74 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.51% | 98.21% | 91.67% | 77.47% | 59.78% | 57.15% | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.08% | 0.20% | 0.36% | 0.58% | 0.65% | | | |
| Sample Size | 29200 | 25100 | 22200 | 18900 | 13700 | 6400 | 1500 | | | |

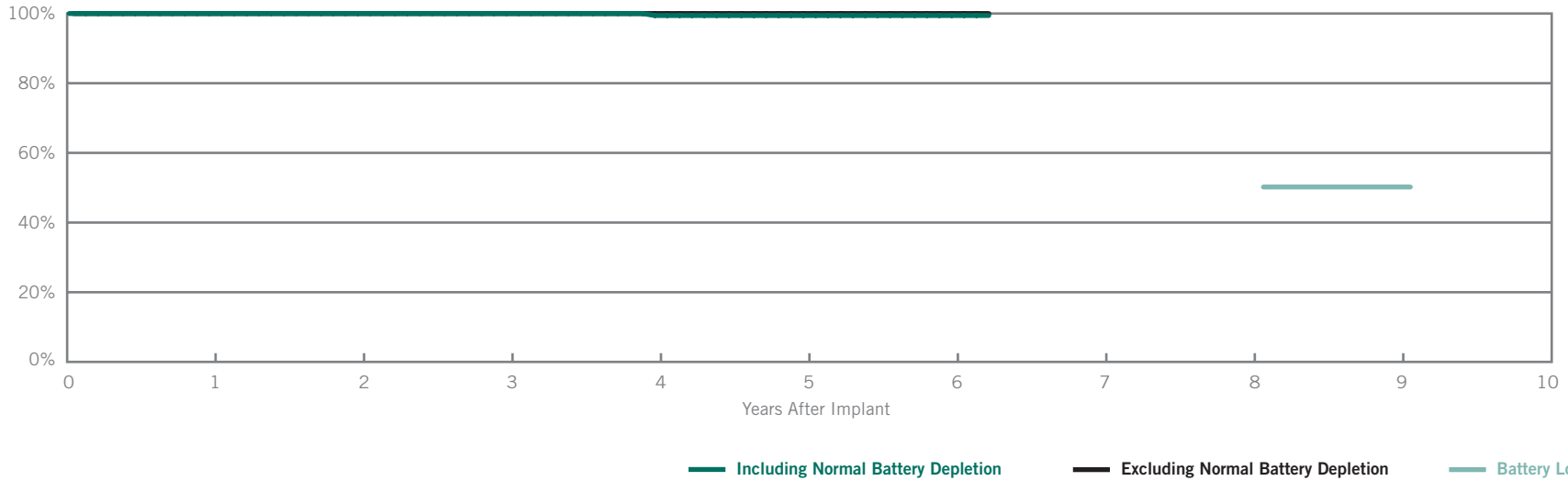
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 74 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.78% | 99.42% | 99.34% | 99.08% | 98.78% | 98.78% | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.05% | 0.06% | 0.07% | 0.11% | 0.11% | | | |

## Affinity® VDR (Model 5430)

| | | | |
|---|---|---|---|
| US Regulatory Approval | April 2000 | Normal Battery Depletion | 3 |
| Registered US Implants | 654 | Total Malfunctions | 0 |
| Estimated Active US Implants | 183 | 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 75 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.43% | 99.43% | 99.43% | 99.43% | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.00% | 0.40% | 0.40% | 0.40% | | | |
| Sample Size | 600 | 500 | 500 | 400 | 300 | 300 | 200 | | | |

**Excluding Normal Battery Depletion**

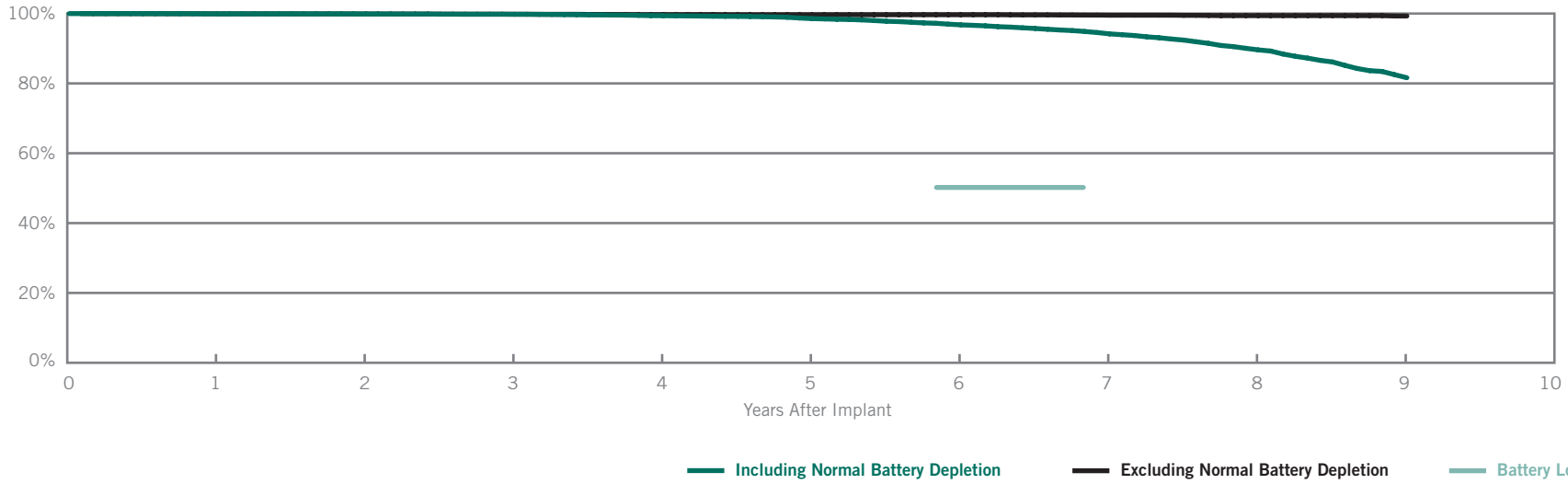
| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 75 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | | | |

# Pacemakers

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

| | | | |
|---|---|---|---|
| US Regulatory Approval | June 1999 | Normal Battery Depletion | 465 |
| Registered US Implants | 21,852 | Total Malfunctions | 36 |
| Estimated Active US Implants | 5,058 | Malfunctions w/ Compromised Therapy | 3 |
| Estimated Longevity | 6.3 Years | Malfunctions w/o Compromised Therapy | 33 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.88% | 99.81% | 99.38% | 98.55% | 96.77% | 94.18% | 89.60% | 81.62% | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.06% | 0.10% | 0.16% | 0.23% | 0.36% | 0.61% | |
| Sample Size | 21800 | 18800 | 16800 | 15000 | 13100 | 11100 | 8600 | 5800 | 200 | |

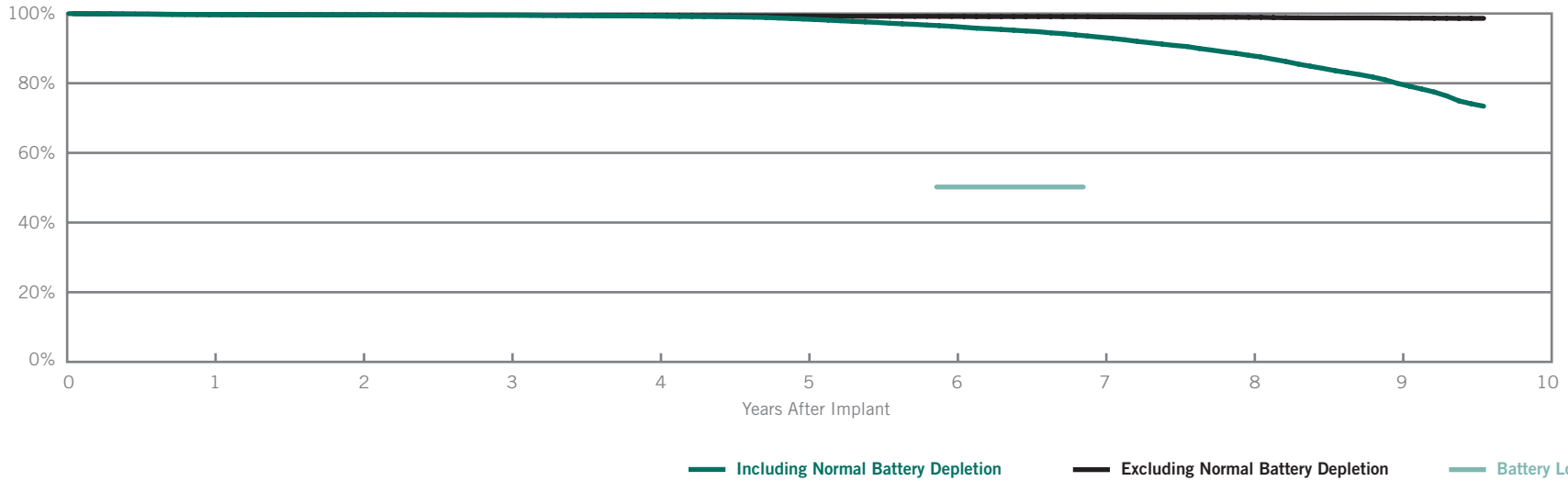
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.88% | 99.80% | 99.70% | 99.67% | 99.67% | 99.53% | 99.41% | 99.30% | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.04% | 0.05% | 0.05% | 0.06% | 0.08% | 0.11% | |

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

| | | | |
|---|---|---|---|
| US Regulatory Approval | (5330) January 1999<br>(5230/5331) June 1999 | Normal Battery Depletion | 2,126 |
| | | Total Malfunctions (65 related to Advisory) | 234 |
| Registered US Implants | 65,615 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 15 |
| Estimated Active US Implants | 12,686 | Malfunctions w/o Compromised Therapy (65 related to Advisory) | 219 |
| Estimated Longevity | 6.3 Years | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 115 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.72% | 99.63% | 99.54% | 99.26% | 98.42% | 96.32% | 93.20% | 88.01% | 79.98% | 73.40% |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.04% | 0.06% | 0.09% | 0.14% | 0.20% | 0.30% | 0.41% |
| Sample Size | 65200 | 57500 | 52100 | 47000 | 41800 | 36100 | 29000 | 20900 | 12700 | 3700 |

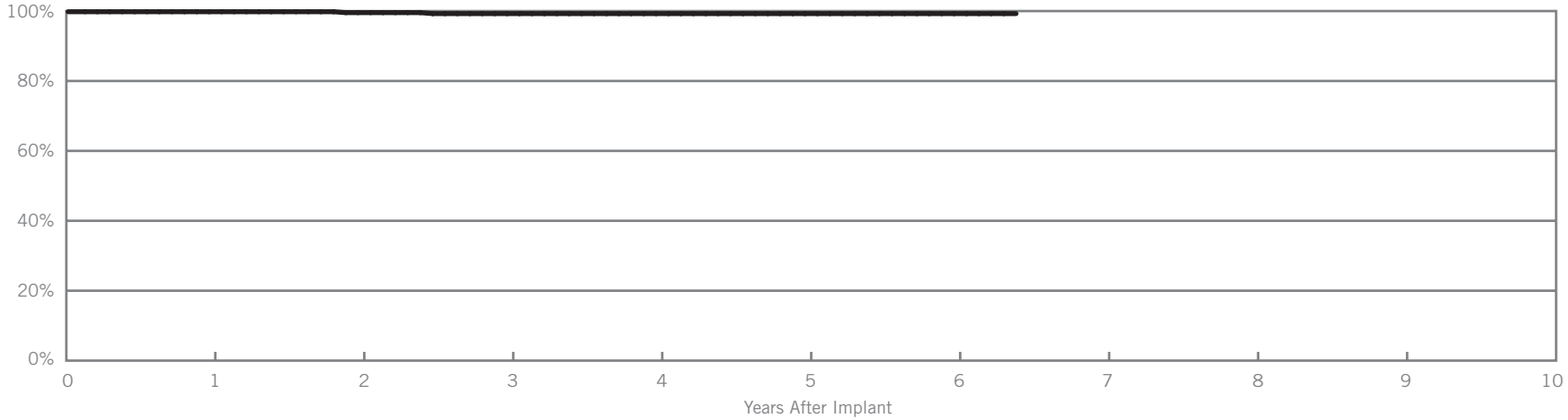
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 115 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.71% | 99.61% | 99.52% | 99.40% | 99.30% | 99.18% | 99.07% | 98.92% | 98.70% | 98.62% |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.03% | 0.04% | 0.04% | 0.05% | 0.05% | 0.07% | 0.08% |

# Pacemakers

| AddVent™ (Model 2060) | |
|---|---|
| US Regulatory Approval | May 1999 |
| Registered US Implants | 537 |
| Estimated Longevity | 9.3 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints

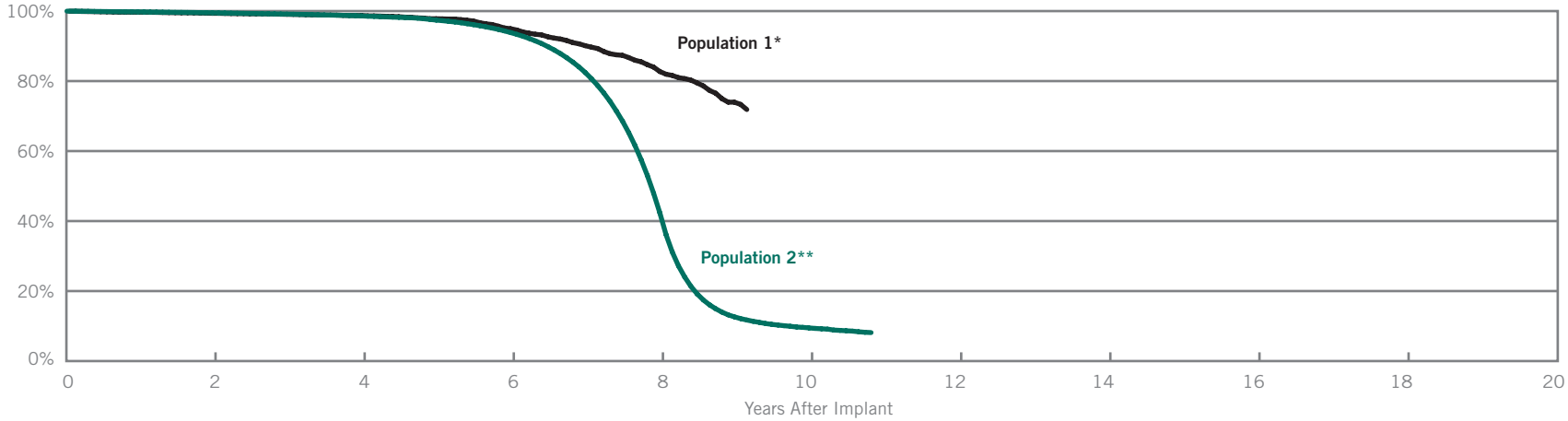



| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 77 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.81% | 99.55% | 99.27% | 99.27% | 99.27% | 99.27% | 99.27% | | | |
| ± 1 standard error | 0.19% | 0.32% | 0.43% | 0.43% | 0.43% | 0.43% | 0.43% | | | |
| Sample Size | 500 | 400 | 400 | 300 | 300 | 200 | 200 | | | |

## Trilogy™ DR+ (Model 2360 & 2364)

| Population 1* | | Population 2** | |
|---|---|---|---|
| US Regulatory Approval | September 1996 | US Regulatory Approval | 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 238-243) | Two |

### Survival from Returns and Complaints




**Population 1***

| Year | 2 | 4 | 6 | 8 | at 110 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.36% | 98.73% | 94.96% | 82.73% | 71.87% | | | | | |
| ± 1 standard error | 0.10% | 0.16% | 0.38% | 0.88% | 1.52% | | | | | |
| Sample Size | 5100 | 3900 | 2600 | 1100 | 200 | | | | | |

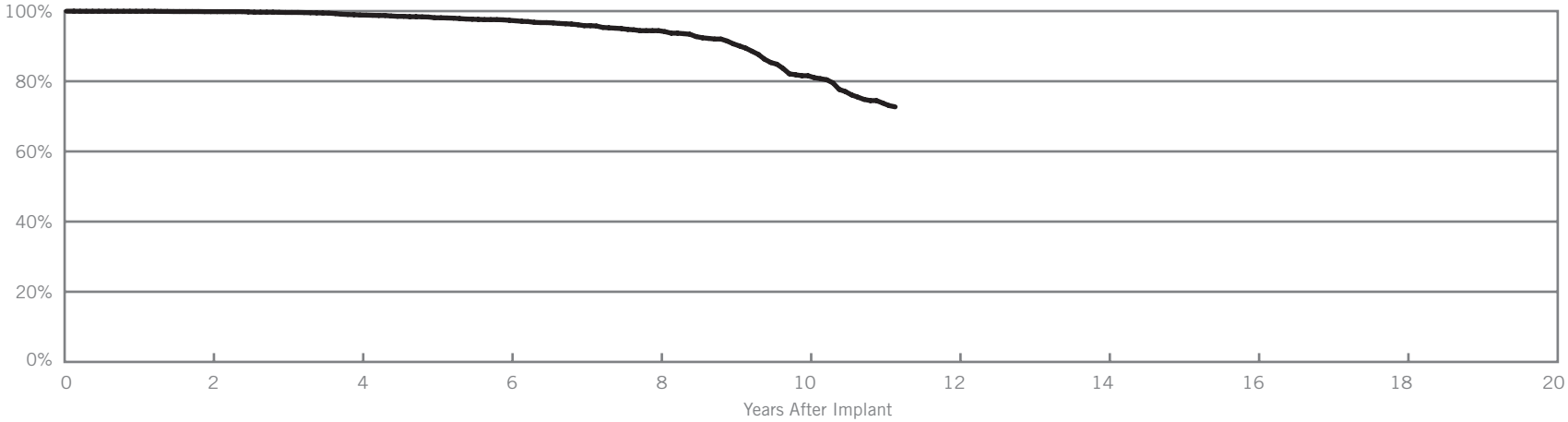
**Population 2****

| Year | 2 | 4 | 6 | 8 | 10 | at 130 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.51% | 98.62% | 93.85% | 42.36% | 9.47% | 8.14% | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.09% | 0.14% | 0.72% | 1.40% | | | | |
| Sample Size | 50400 | 38600 | 25000 | 9200 | 1000 | 300 | | | | |

# Pacemakers

| Paragon™ III (Models 2304, 2314, 2315) | |
|---|---|
| US Regulatory Approval | October 1994 |
| Registered US Implants | 3,832 |
| Estimated Longevity | 6.3 Years |
| Number of Advisories | None |

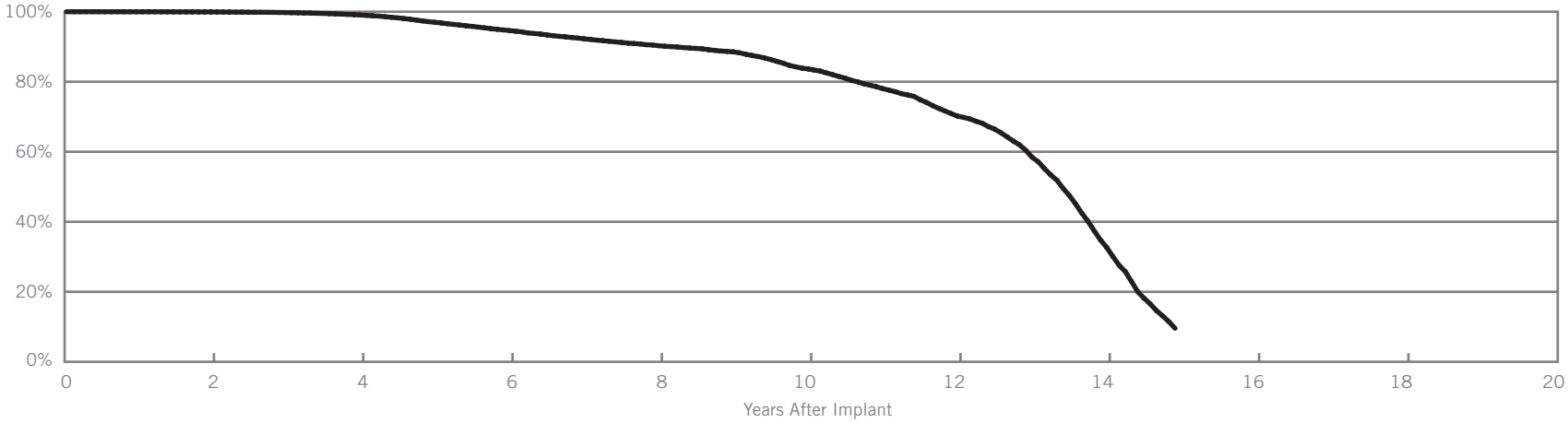
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | at 134 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 98.89% | 97.37% | 94.42% | 81.58% | 72.71% | | | | |
| ± 1 standard error | 0.07% | 0.20% | 0.34% | 0.63% | 1.65% | 2.15% | | | | |
| Sample Size | 3000 | 2300 | 1600 | 800 | 300 | 200 | | | | |

| Synchrony™ III (Models 2028 & 2029) | |
|---|---|
| US Regulatory Approval | February 1993 |
| Registered US Implants | 43,510 |
| Estimated Longevity | 5.5 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | at 179 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.93% | 99.06% | 94.61% | 90.27% | 83.65% | 70.19% | 32.67% | 9.57% | | |
| **± 1 standard error** | 0.01% | 0.05% | 0.14% | 0.24% | 0.45% | 0.74% | 0.99% | 0.72% | | |
| **Sample Size** | 36500 | 29500 | 19000 | 7500 | 3100 | 1900 | 900 | 200 | | |

# Summary & Longevity Information

## Pacemakers

## Dual-Chamber

St. Jude Medical
More control. Less risk.

## Malfunction and Normal Battery Depletion Summary Information

| Models | Family | US Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| PM2210 | Accent® DR RF | Jul-09 | 11896 | 11697 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5820 | Zephyr® DR | Mar-07 | 24153 | 20874 | 1 | 2 | 0 | 0 | 3 | 1 |
| 5810 | Victory® DR | Dec-05 | 25305 | 18710 | 0 | 10 | 0 | 1 | 11 | 26 |
| 5826 | Zephyr® XL DR | Mar-07 | 86833 | 78858 | 1 | 11 | 0 | 1 | 13 | 1 |
| 5816 | Victory® XL DR | Dec-05 | 60263 | 49328 | 1 | 22 | 0 | 0 | 23 | 4 |
| 5356/5357/5256 | Verity® ADX XL DR/ DR(M/S)/DC | May-03 | 16663 | 10596 | 0 | 6 | 0 | 1 | 7 | 11 |
| 5360 | Integrity® ADx DR | May-03 | 5818 | 2712 | 0 | 21 | 0 | 0 | 21 | 170 |
| 5366 | Integrity® ADx XL DR | May-03 | 7999 | 5401 | 0 | 1 | 0 | 0 | 1 | 7 |
| 5380 | Identity® ADx DR | Mar-03 | 53095 | 24569 | 4 | 123 | 0 | 8 | 135 | 1600 |
| 5386/5286 | Identity® ADx XL DR/DC | Mar-03 | 64593 | 45831 | 1 | 32 | 0 | 0 | 33 | 64 |
| 5342/5346 | Integrity® AFx DR | Apr-00/Jul-01 | 47491 | 15345 | 6 | 66 | 0 | 0 | 72 | 1080 |
| 5370 | Identity® | Nov-01 | 58350 | 11943 | 5 | 324 | 20 | 10 | 359 | 3791 |
| 5376 | Identity® XL | Nov-01 | 51405 | 27756 | 9 | 83 | 7 | 2 | 101 | 391 |
| 5336 | Integrity® µ DR | Dec-00 | 29356 | 3009 | 8 | 76 | 0 | 1 | 85 | 2058 |
| 5430 | Affinity® VDR | Apr-00 | 654 | 183 | 0 | 0 | 0 | 0 | 0 | 3 |
| 5326/5226 | Entity™ DR/DC | Jun-99 | 21852 | 5058 | 3 | 32 | 0 | 1 | 36 | 465 |
| 5330/5331/5230 | Affinity® DR/DC | Jan-99/Jun-99 | 65615 | 12686 | 15 | 154 | 65 | 0 | 234 | 2126 |

# Pacemakers

## 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 |
| PM2210 | Accent® DR RF* | | | | | | | | | | |
| 5820 | Zephyr® DR | 99.96% | 99.96% | | | | | | | | |
| 5810 | Victory® DR | 99.98% | 99.89% | 99.54% | | | | | | | |
| 5826 | Zephyr® XL DR | 99.97% | 99.94% | | | | | | | | |
| 5816 | Victory® XL DR | 99.95% | 99.91% | 99.89% | | | | | | | |
| 5356/5357/5256 | Verity® ADX XL DR/ DR(M/S)/DC | 99.92% | 99.92% | 99.84% | 99.72% | 99.58% | | | | | |
| 5360 | Integrity® ADx DR | 99.82% | 99.82% | 99.34% | 95.06% | | | | | | |
| 5366 | Integrity® ADx XL DR | 99.98% | 99.98% | 99.91% | 99.91% | 99.56% | | | | | |
| 5380 | Identity® ADx DR | 99.93% | 99.82% | 99.05% | 94.33% | 74.97% | | | | | |
| 5386/5286 | Identity® ADx XL DR/DC | 99.95% | 99.92% | 99.88% | 99.76% | 99.39% | | | | | |
| 5342/5346 | Integrity® AFx DR | 99.94% | 99.90% | 99.80% | 99.66% | 99.00% | 97.81% | 95.13% | 90.42% | | |
| 5370 | Identity® | 99.91% | 99.73% | 98.77% | 91.69% | 71.68% | | | | | |
| 5376 | Identity® XL | 99.92% | 99.83% | 99.69% | 99.45% | 98.96% | 97.71% | 94.74% | | | |
| 5336 | Integrity® µ DR | 99.85% | 99.51% | 98.21% | 91.67% | 77.47% | 59.78% | | | | |
| 5430 | Affinity® VDR | 100.00% | 100.00% | 100.00% | 99.43% | 99.43% | 99.43% | | | | |
| 5326/5226 | Entity™ DR/DC | 99.92% | 99.88% | 99.81% | 99.38% | 98.55% | 96.77% | 94.18% | 89.60% | 81.62% | |
| 5330/5331/5230 | Affinity® DR/DC | 99.72% | 99.63% | 99.54% | 99.26% | 98.42% | 96.32% | 93.20% | 88.01% | 79.98% | |

**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 |
| PM2210 | Accent® DR RF* | | | | | | | | | | |
| 5820 | Zephyr® DR | 99.96% | 99.96% | | | | | | | | |
| 5810 | Victory® DR | 99.98% | 99.90% | 99.88% | | | | | | | |
| 5826 | Zephyr® XL DR | 99.97% | 99.94% | | | | | | | | |
| 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% | 99.87% | 99.83% | | | | | |
| 5360 | Integrity® ADx DR | 99.89% | 99.89% | 99.84% | 99.21% | | | | | | |
| 5366 | Integrity® ADx XL DR | 99.98% | 99.98% | 99.98% | 99.98% | 99.98% | | | | | |
| 5380 | Identity® ADx DR | 99.95% | 99.92% | 99.78% | 99.42% | 97.74% | | | | | |
| 5386/5286 | Identity® ADx XL DR/DC | 99.95% | 99.93% | 99.92% | 99.90% | 99.86% | | | | | |
| 5342/5346 | Integrity® AFx DR | 99.94% | 99.89% | 99.86% | 99.79% | 99.70% | 99.67% | 99.60% | 99.50% | | |
| 5370 | Identity® | 99.93% | 99.87% | 99.61% | 98.90% | 97.57% | | | | | |
| 5376 | Identity® XL | 99.93% | 99.86% | 99.82% | 99.76% | 99.65% | 99.50% | 99.26% | | | |
| 5336 | Integrity® µ DR | 99.87% | 99.78% | 99.42% | 99.34% | 99.08% | 98.78% | | | | |
| 5430 | Affinity® VDR | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | | | | |
| 5326/5226 | Entity™ DR/DC | 99.92% | 99.88% | 99.80% | 99.70% | 99.67% | 99.67% | 99.53% | 99.41% | 99.30% | |
| 5330/5331/5230 | Affinity® DR/DC | 99.71% | 99.61% | 99.52% | 99.40% | 99.30% | 99.18% | 99.07% | 98.92% | 98.70% | |

**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.*

# Pacemakers

## Single-Chamber

St. Jude Medical™

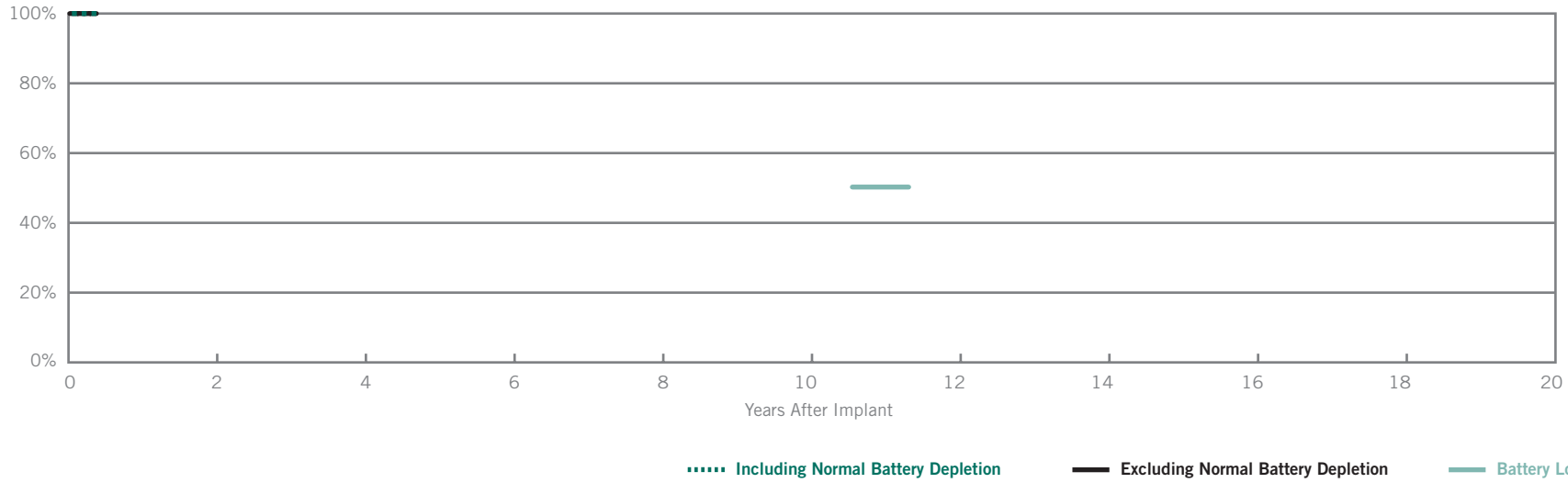
More control. Less risk.

# Pacemakers

## Accent® SR RF (Model PM1210)

| | | | |
|---|---|---|---|
| US Regulatory Approval | July 2009 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,851 | Total Malfunctions | 0 |
| Estimated Active US Implants | 1,803 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 10.9 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

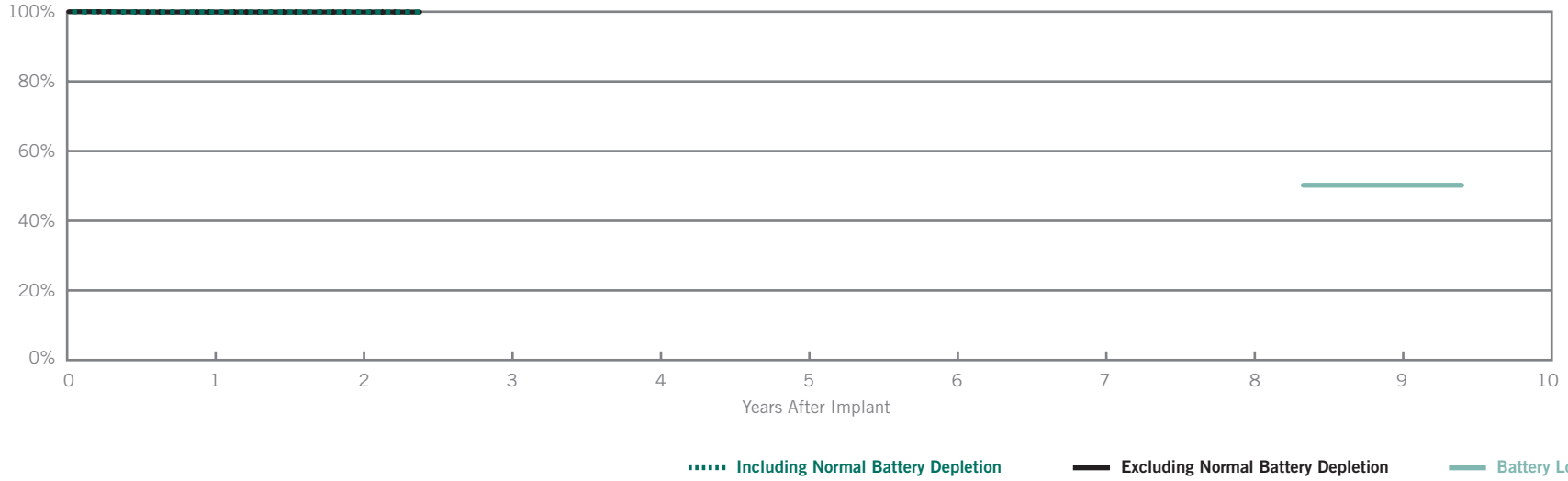
**Excluding Normal Battery Depletion**

| Year | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

## Zephyr® SR (Model 5620)

| | | | |
|---|---|---|---|
| US Regulatory Approval | March 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 7,310 | Total Malfunctions | 2 |
| Estimated Active US Implants | 5,866 | 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 | at 29 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.92% | | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.04% | | | | | | |
| Sample Size | 5700 | 1900 | 200 | | | | | | |

**Excluding Normal Battery Depletion**

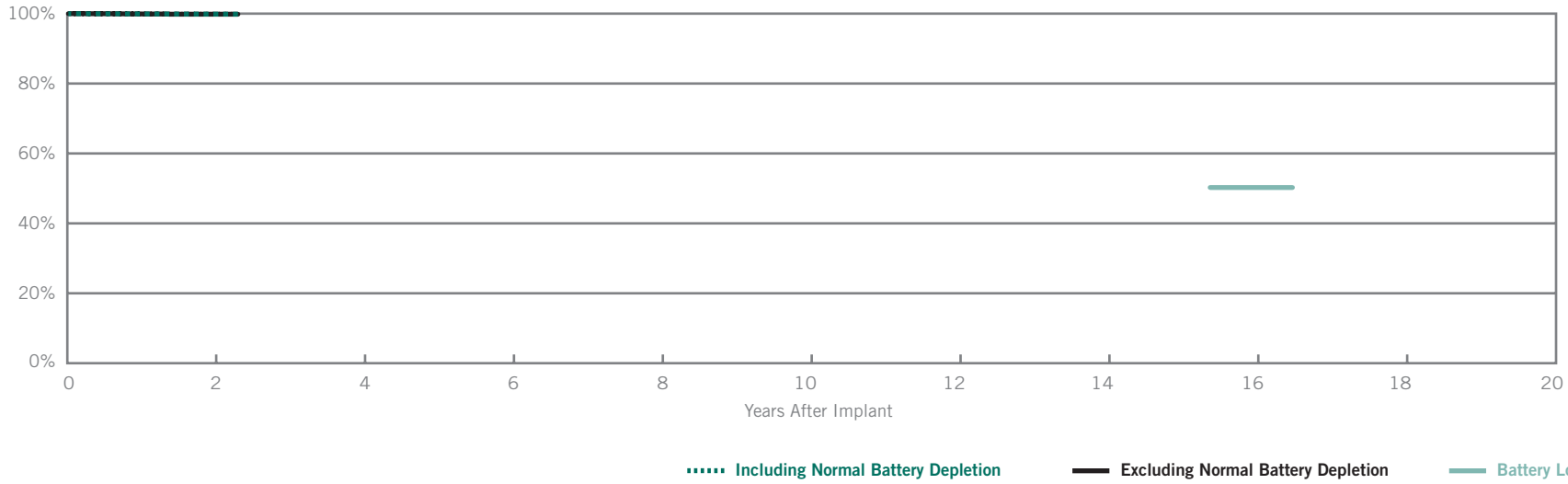
| Year | 1 | 2 | at 29 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.92% | | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.04% | | | | | | |

# Pacemakers

## Zephyr® XL SR (Model 5626)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 14,876 | Total Malfunctions | 6 |
| Estimated Active US Implants | 12,677 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 15.8 Years | Malfunctions w/o Compromised Therapy | 6 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | at 28 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.84% | 99.84% | | | | | | | | |
| ± 1 standard error | 0.05% | 0.05% | | | | | | | | |
| Sample Size | 3900 | 200 | | | | | | | | |

**Excluding Normal Battery Depletion**

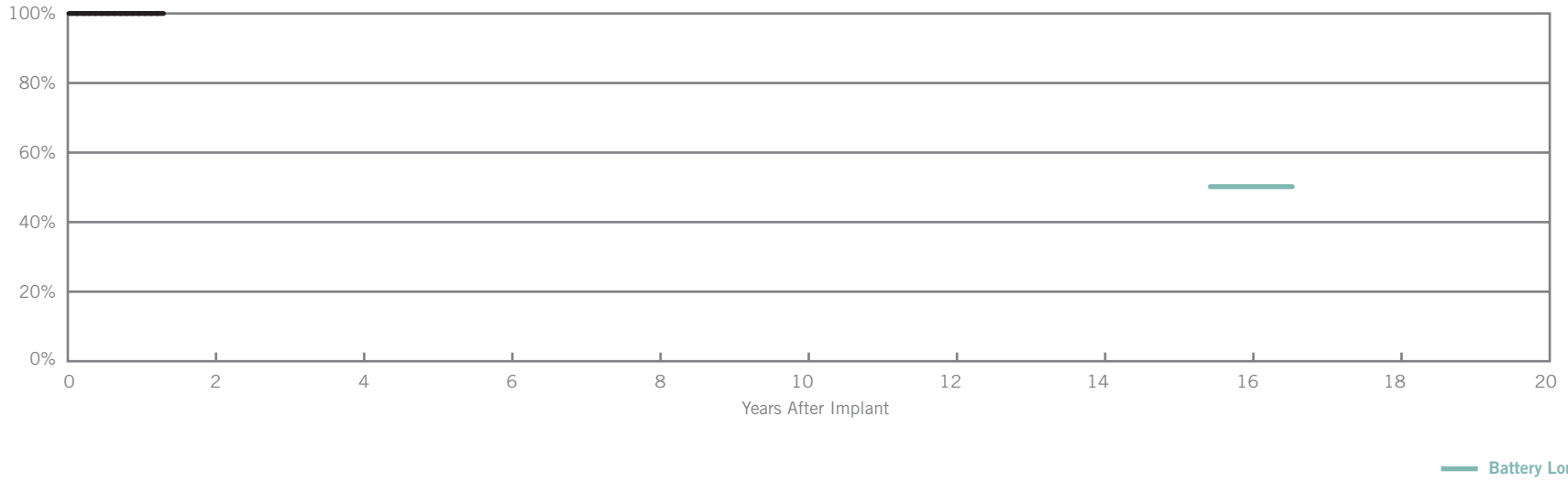
| Year | 2 | at 28 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.84% | 99.84% | | | | | | | | |
| ± 1 standard error | 0.05% | 0.05% | | | | | | | | |

| Zephyr® XL SR (Model 5626) | |
|---|---|
| US Regulatory Approval | May 2007 |

| SCORE Enrollment | |
|---|---|
| Number of Devices Enrolled in Study | 196 |
| Cumulative Months of Follow-up | 2,277 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry



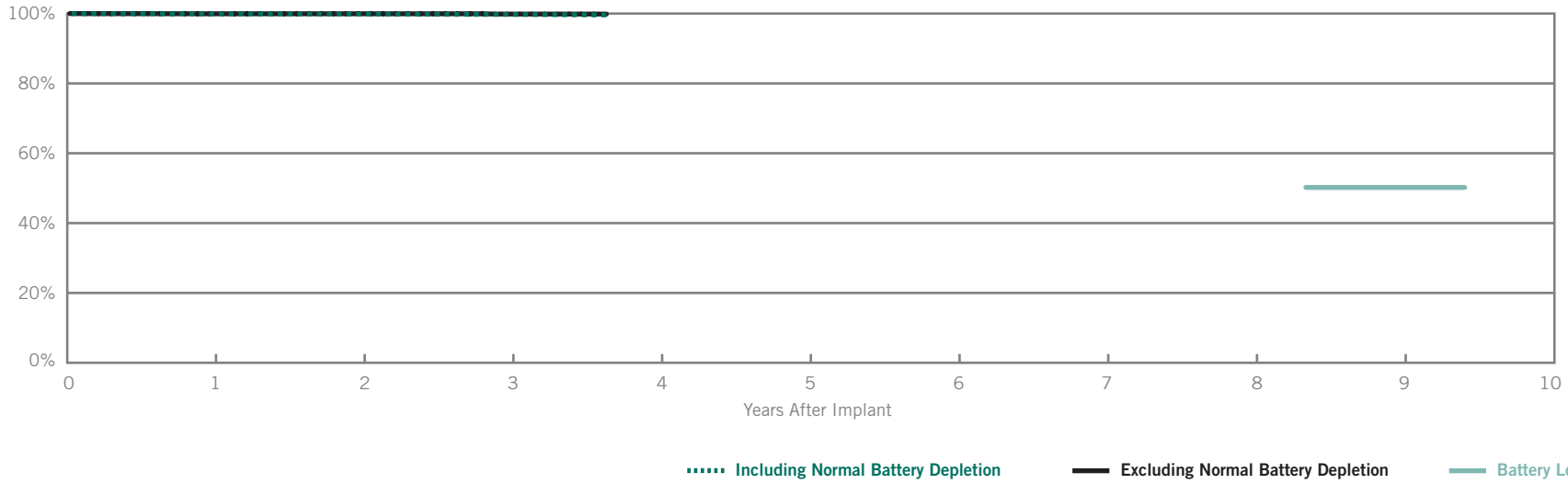

| Year | at 16 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 50 | | | | | | | | | |

# Pacemakers

## Victory® SR (Model 5610)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2005 | Normal Battery Depletion | 2 |
| Registered US Implants | 12,948 | Total Malfunctions | 3 |
| Estimated Active US Implants | 8,788 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 8.8 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 44 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.94% | 99.77% | 99.62% | | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.09% | 0.14% | | | | | | |
| Sample Size | 12200 | 8200 | 4200 | 200 | | | | | | |

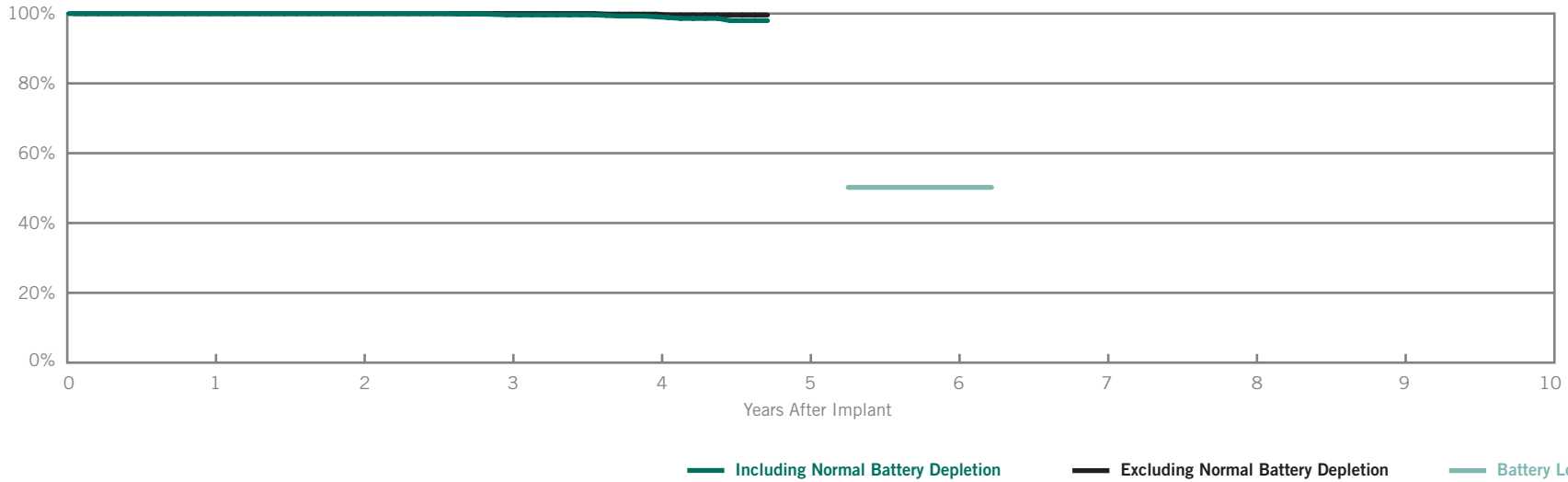
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 44 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.94% | 99.86% | 99.86% | | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.07% | 0.07% | | | | | | |

## Integrity® ADx SR (Model 5160)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 12 |
| Registered US Implants | 3,395 | Total Malfunctions | 1 |
| Estimated Active US Implants | 1,510 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.7 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 57 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 99.63% | 99.07% | 97.98% | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.12% | 0.23% | 0.47% | | | | | |
| Sample Size | 3400 | 2600 | 2000 | 1300 | 500 | | | | | |

**Excluding Normal Battery Depletion**

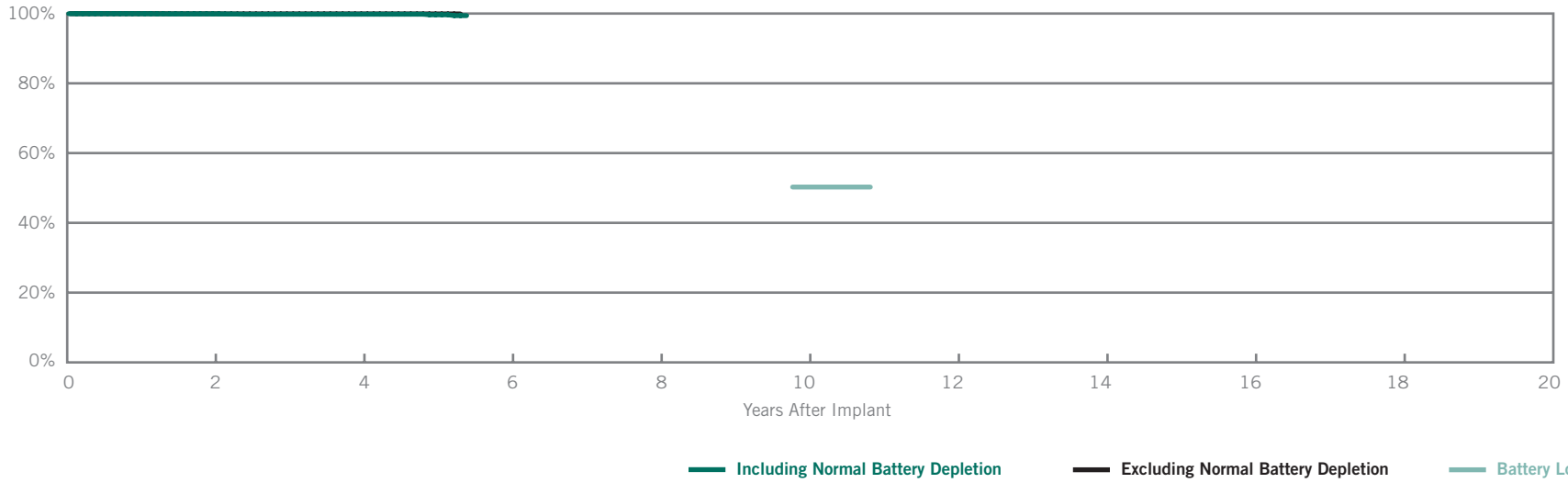
| Year | 1 | 2 | 3 | 4 | at 57 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.83% | 99.60% | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.12% | 0.20% | | | | | |

# Pacemakers

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

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 5 |
| Registered US Implants | 13,790 | Total Malfunctions | 5 |
| Estimated Active US Implants | 7,935 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 10.2 Years | Malfunctions w/o Compromised Therapy | 4 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | 4 | at 65 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.90% | 99.81% | 99.41% | | | | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.21% | | | | | | | |
| Sample Size | 9900 | 4200 | 700 | | | | | | | |

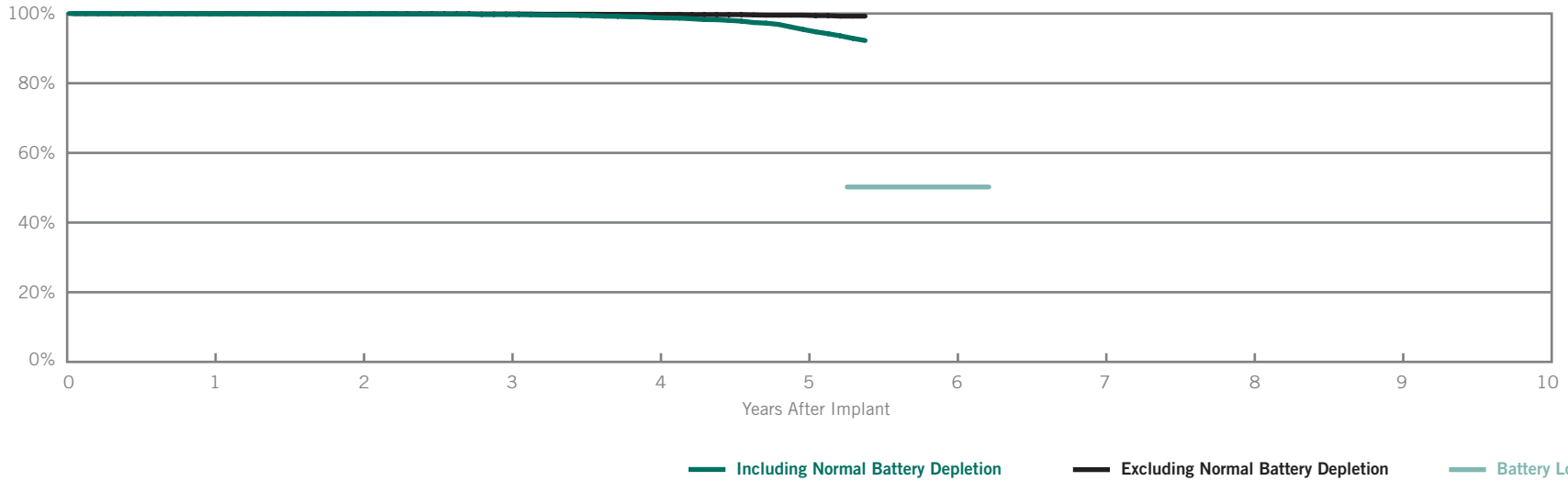
**Excluding Normal Battery Depletion**

| Year | 2 | 4 | at 65 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.89% | 99.89% | | | | | | | |
| ± 1 standard error | 0.03% | 0.03% | 0.03% | | | | | | | |

## Identity® ADx SR (Model 5180)

| | | | |
|---|---|---|---|
| US Regulatory Approval | May 2003 | Normal Battery Depletion | 104 |
| Registered US Implants | 19,913 | Total Malfunctions | 19 |
| Estimated Active US Implants | 9,851 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.7 Years | Malfunctions w/o Compromised Therapy | 19 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 65 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.88% | 99.71% | 98.81% | 95.42% | 92.25% | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.05% | 0.11% | 0.34% | 0.58% | | | | |
| Sample Size | 19500 | 14800 | 11300 | 7500 | 3600 | 1000 | | | | |

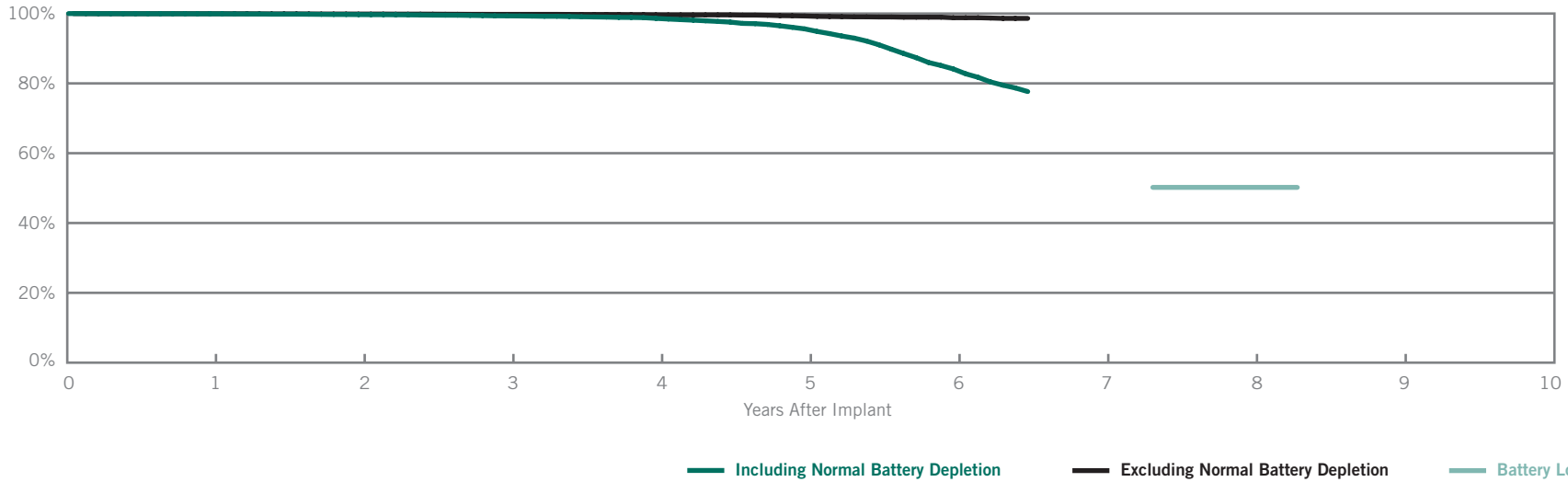
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 65 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.95% | 99.87% | 99.73% | 99.52% | 99.25% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.06% | 0.10% | 0.17% | | | | |

## Identity® SR (Model 5172)

| | | | |
|---|---|---|---|
| US Regulatory Approval | November 2001 | Normal Battery Depletion | 450 |
| Registered US Implants | 21,897 | Total Malfunctions (1 related to Advisory) | 49 |
| Estimated Active US Implants | 6,398 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | 7.8 Years | Malfunctions w/o Compromised Therapy (1 related to Advisory) | 48 |
| | | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

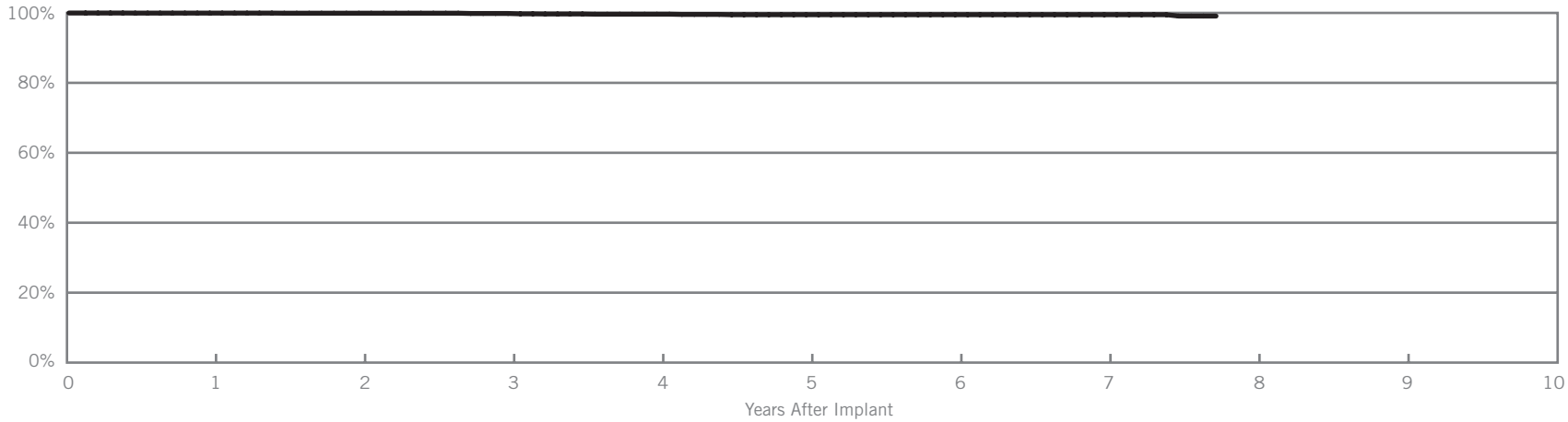
| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 78 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.70% | 99.34% | 98.62% | 95.61% | 84.12% | 77.66% | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.07% | 0.10% | 0.21% | 0.53% | 0.72% | | | |
| Sample Size | 21800 | 17500 | 14400 | 11400 | 8200 | 4900 | 1200 | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 78 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.86% | 99.77% | 99.64% | 99.30% | 98.81% | 98.62% | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.04% | 0.05% | 0.08% | 0.12% | 0.17% | | | |

| Microny® (Models 2425T, 2525T & 2535K) | |
|---|---|
| US Regulatory Approval | April 2001 |
| Registered US Implants | 6,449 |
| Estimated Longevity | 7.5 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints



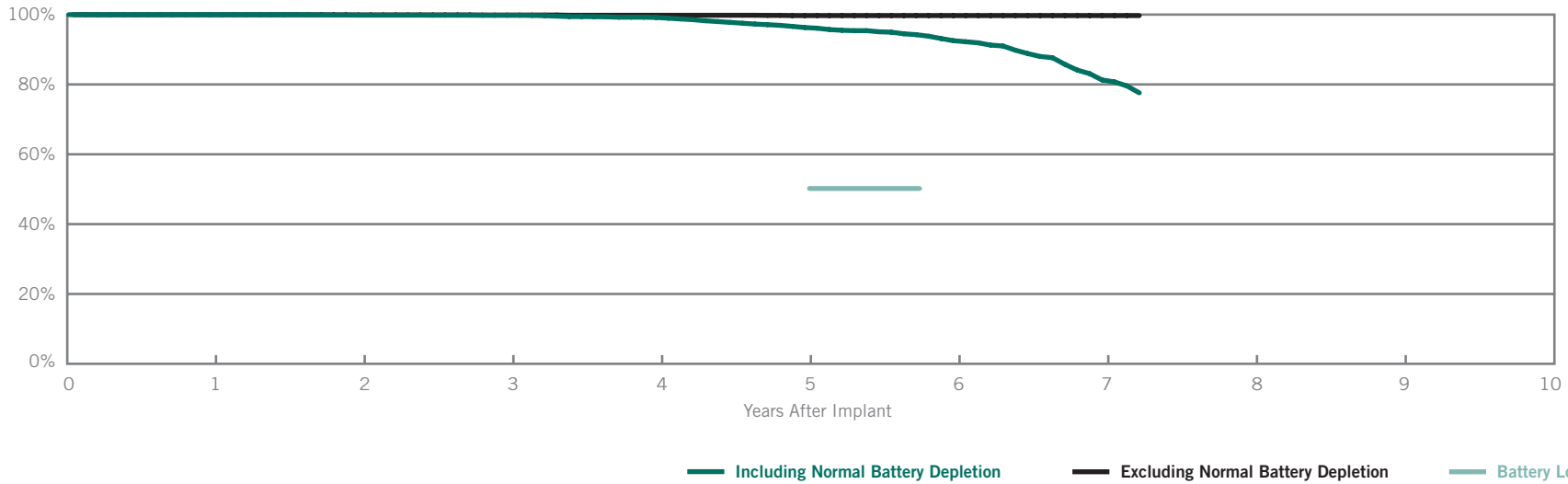

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 93 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.95% | 99.92% | 99.84% | 99.64% | 99.49% | 99.49% | 99.49% | 99.10% | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.07% | 0.12% | 0.16% | 0.16% | 0.16% | 0.42% | | |
| **Sample Size** | 4500 | 3300 | 2400 | 1700 | 1100 | 700 | 400 | 200 | | |

# Pacemakers

## Integrity® µ SR (Model 5136)

| | | | |
|---|---|---|---|
| US Regulatory Approval | December 2000 | Normal Battery Depletion | 279 |
| Registered US Implants | 11,968 | Total Malfunctions | 10 |
| Estimated Active US Implants | 1,810 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.3 Years | Malfunctions w/o Compromised Therapy | 10 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | 99.84% | 99.79% | 99.18% | 96.30% | 92.53% | 81.28% | 77.60% | | |
| ± 1 standard error | 0.02% | 0.04% | 0.05% | 0.11% | 0.26% | 0.40% | 0.81% | 0.96% | | |
| Sample Size | 11900 | 9400 | 7800 | 6500 | 5100 | 3700 | 2300 | 700 | | |

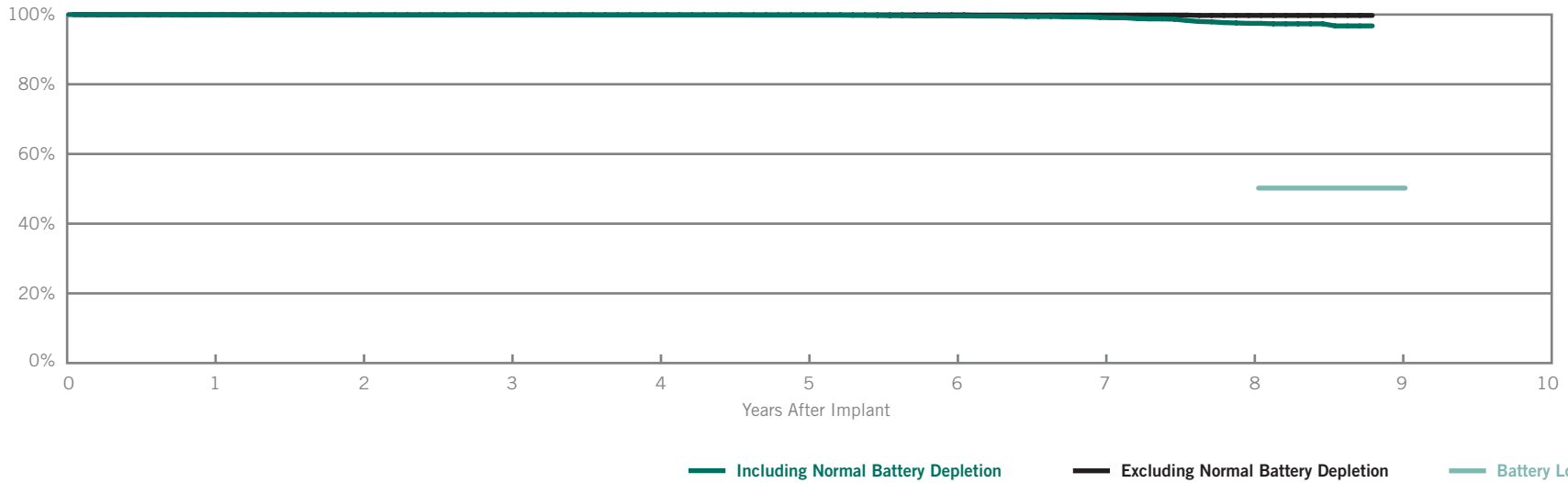
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 87 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.91% | 99.88% | 99.81% | 99.72% | 99.72% | 99.72% | 99.72% | | |
| ± 1 standard error | 0.02% | 0.03% | 0.04% | 0.05% | 0.07% | 0.07% | 0.07% | 0.07% | | |

## Integrity® SR (Model 5142)

| | | | |
|---|---|---|---|
| US Regulatory Approval | April 2000 | Normal Battery Depletion | 36 |
| Registered US Implants | 10,496 | Total Malfunctions | 6 |
| Estimated Active US Implants | 2,889 | 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 106 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.91% | 99.91% | 99.87% | 99.83% | 99.63% | 99.16% | 97.48% | 96.75% | |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.04% | 0.05% | 0.09% | 0.13% | 0.31% | 0.41% | |
| Sample Size | 10500 | 8600 | 7400 | 6300 | 5300 | 4300 | 3300 | 2300 | 700 | |

**Excluding Normal Battery Depletion**

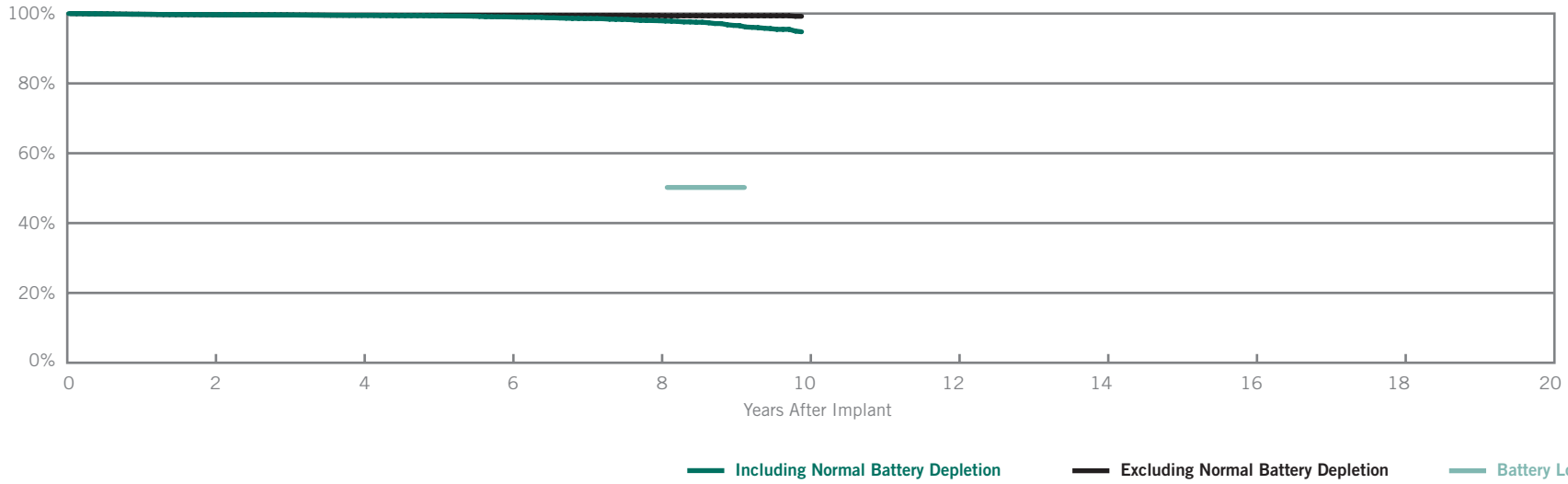
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 106 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | 99.91% | 99.85% | 99.75% | 99.75% | |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% | 0.05% | 0.09% | 0.09% | |

# Pacemakers

## Affinity® SR (Models 5130 & 5131)

| | | | |
|---|---|---|---|
| US Regulatory Approval | (5130) January 1999 | Normal Battery Depletion | 115 |
| | (5131) June 1999 | Total Malfunctions (17 related to Advisory) | 59 |
| Registered US Implants | 28,676 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Active US Implants | 5,910 | Malfunctions w/o Compromised Therapy (17 related to Advisory) | 55 |
| Estimated Longevity | 8.6 Years | Number of Advisories (see pages 238-243) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

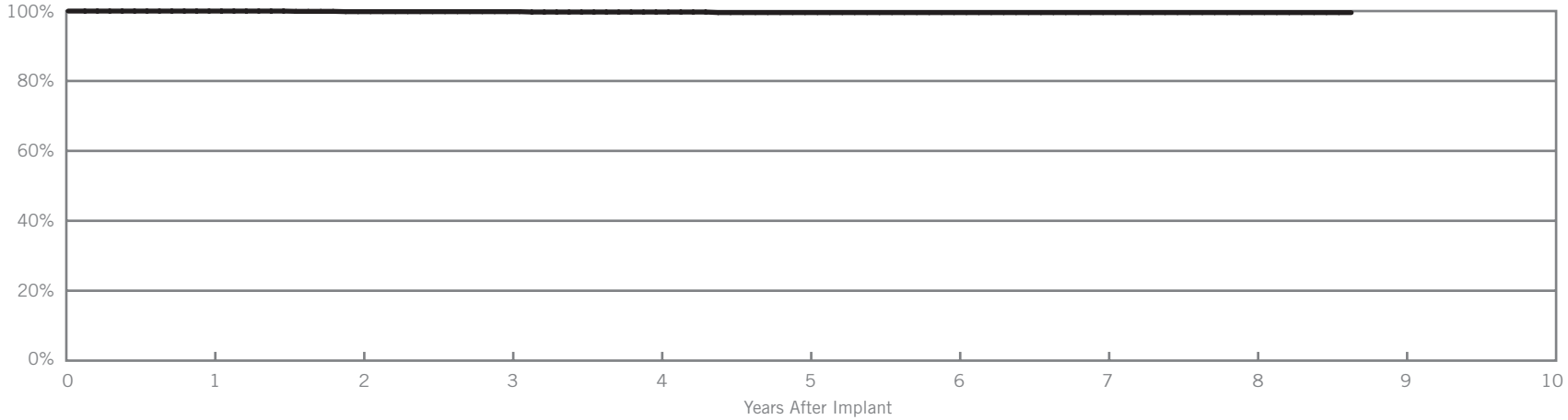
| Year | 2 | 4 | 6 | 8 | at 119 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.68% | 99.48% | 99.03% | 97.95% | 94.78% | | | | | |
| ± 1 standard error | 0.04% | 0.05% | 0.08% | 0.15% | 0.38% | | | | | |
| Sample Size | 23000 | 16500 | 11500 | 6700 | 1000 | | | | | |

**Excluding Normal Battery Depletion**

| Year | 2 | 4 | 6 | 8 | at 119 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.67% | 99.52% | 99.47% | 99.41% | 99.22% | | | | | |
| ± 1 standard error | 0.04% | 0.05% | 0.05% | 0.06% | 0.13% | | | | | |

| Regency® SC+ (Models 2400L & 2402L) | |
|---|---|
| US Regulatory Approval | May 1998 |
| Registered US Implants | 2,225 |
| Estimated Longevity | 9.1 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints

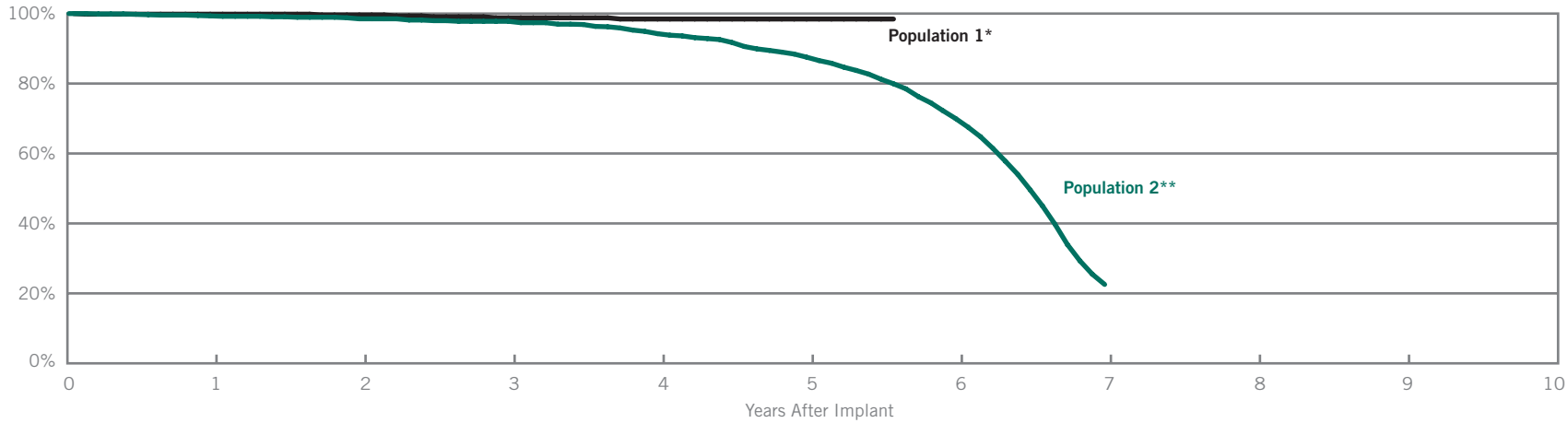



| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 104 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | 99.83% | 99.83% | 99.72% | 99.56% | 99.56% | 99.56% | 99.56% | 99.56% | |
| **± 1 standard error** | 0.00% | 0.12% | 0.12% | 0.17% | 0.23% | 0.23% | 0.23% | 0.23% | 0.23% | |
| **Sample Size** | 1600 | 1200 | 1000 | 800 | 600 | 500 | 400 | 300 | 200 | |

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

| Population 1* | | Population 2** | |
|---|---|---|---|
| US Regulatory Approval | August 1997 | US Regulatory Approval | August 1997 |
| Registered US Implants | 607 | Registered US Implants | 1,087 |
| Estimated Longevity | 5.3 Years | Estimated Longevity | 5.3 Years |
| Number of Advisories | None | Number of Advisories (see pages 238-243) | Two |

### Survival from Returns and Complaints




**Population 1***

| Year | 1 | 2 | 3 | 4 | 5 | at 67 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.60% | 98.79% | 98.44% | 98.44% | 98.44% | | | | |
| ± 1 standard error | 0.17% | 0.29% | 0.55% | 0.65% | 0.65% | 0.65% | | | | |
| Sample Size | 500 | 400 | 400 | 300 | 200 | 200 | | | | |

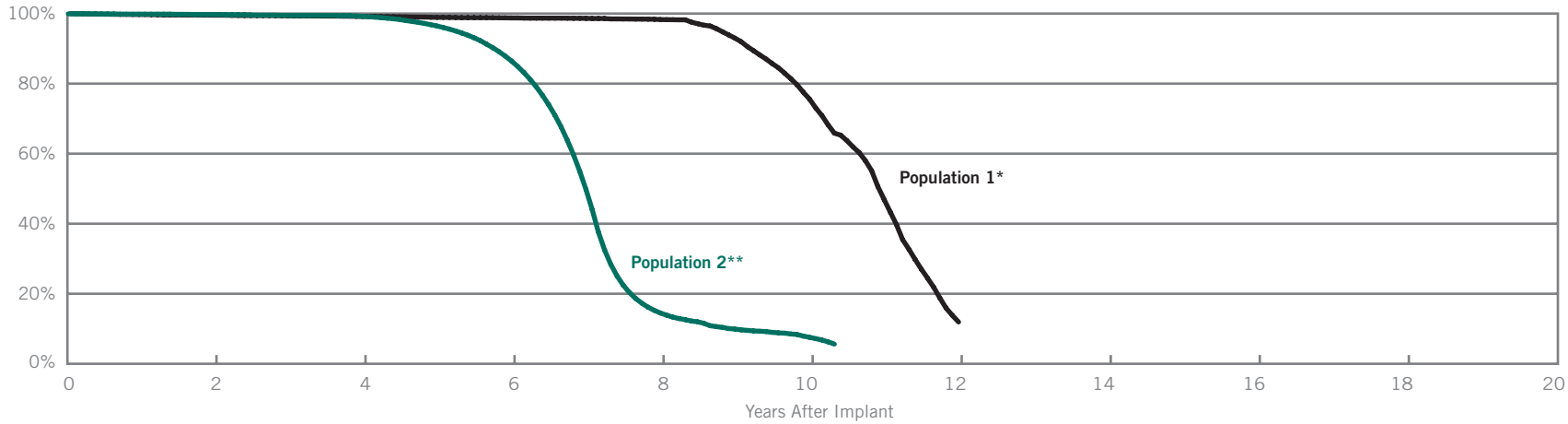
**Population 2****

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.34% | 98.50% | 97.79% | 94.25% | 87.54% | 69.99% | 22.55% | | | |
| ± 1 standard error | 0.25% | 0.38% | 0.56% | 0.88% | 1.18% | 1.46% | 1.65% | | | |
| Sample Size | 900 | 700 | 500 | 400 | 300 | 200 | 200 | | | |

## Trilogy™ SR+ (Models 2260 & 2264)

| Population 1* | | Population 2** | |
|---|---|---|---|
| US Regulatory Approval | March 1997 | US Regulatory Approval | 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 238-243) | Two |

### Survival from Returns and Complaints




**Population 1***

| Year | 2 | 4 | 6 | 8 | 10 | 12 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.54% | 99.19% | 98.76% | 98.30% | 75.59% | 11.93% | | | | |
| ± 1 standard error | 0.06% | 0.08% | 0.11% | 0.15% | 0.80% | 0.85% | | | | |
| Sample Size | 11800 | 8400 | 5900 | 4000 | 2100 | 200 | | | | |

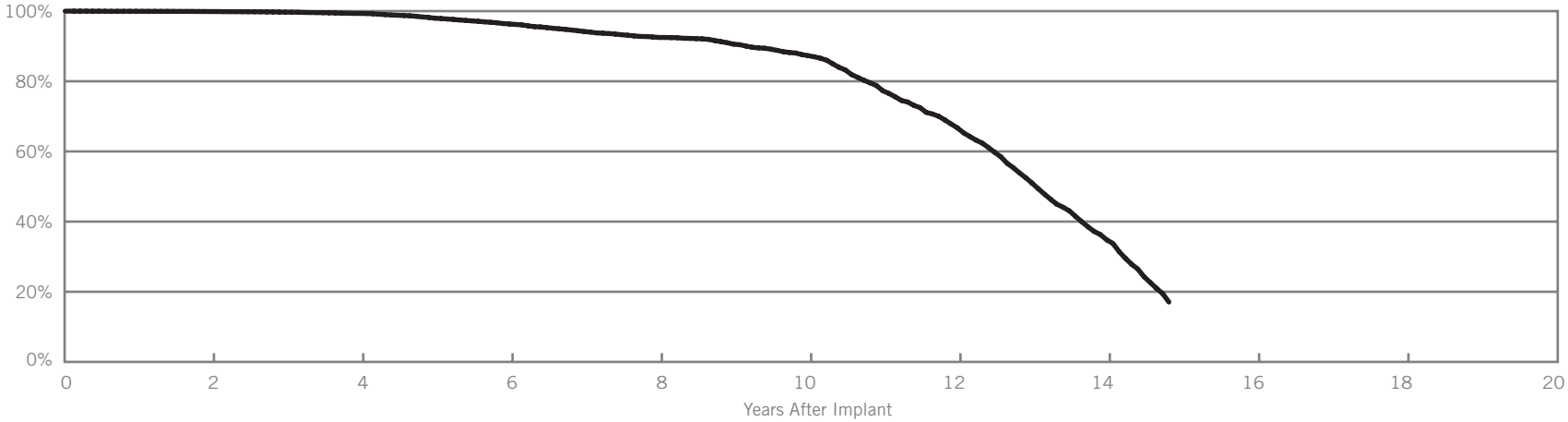
**Population 2****

| Year | 2 | 4 | 6 | 8 | at 124 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | 99.23% | 86.47% | 14.49% | 5.62% | | | | | |
| ± 1 standard error | 0.11% | 0.18% | 0.23% | 0.49% | 2.37% | | | | | |
| Sample Size | 1800 | 1300 | 900 | 600 | 200 | | | | | |

# Pacemakers

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

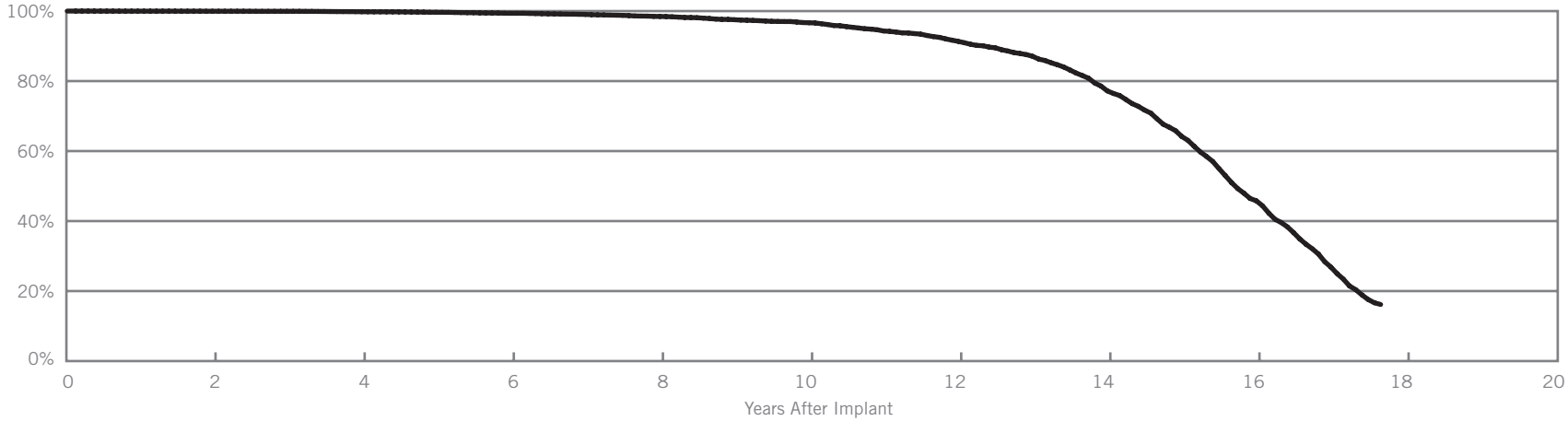
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | at 178 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.33% | 96.32% | 92.49% | 87.29% | 66.72% | 34.79% | 17.06% | | |
| ± 1 standard error | 0.02% | 0.06% | 0.16% | 0.29% | 0.52% | 1.05% | 1.27% | 1.12% | | |
| Sample Size | 24500 | 17700 | 11000 | 4300 | 1900 | 1100 | 500 | 200 | | |

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

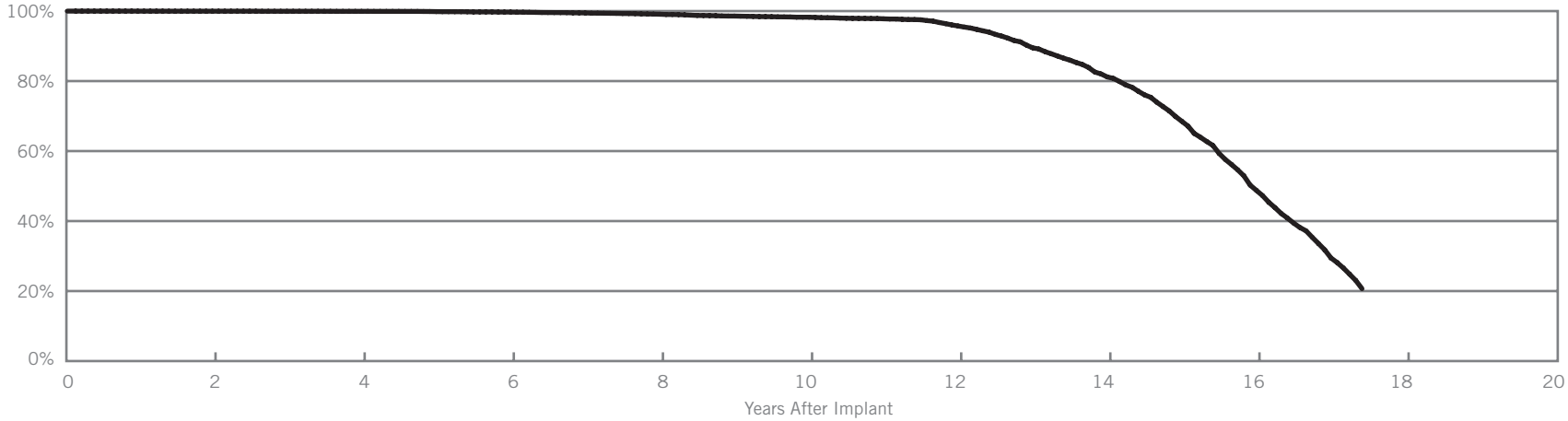
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | at 212 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.81% | 99.37% | 98.46% | 96.66% | 91.36% | 77.20% | 45.78% | 16.17% | |
| ± 1 standard error | 0.01% | 0.03% | 0.08% | 0.14% | 0.25% | 0.49% | 0.89% | 1.28% | 1.04% | |
| Sample Size | 18900 | 13000 | 8800 | 5800 | 3500 | 2200 | 1400 | 700 | 200 | |

| Solus® (Models 2002 & 2003) | |
|---|---|
| US Regulatory Approval | June 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 209 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | 99.93% | 99.72% | 99.10% | 98.25% | 95.74% | 81.18% | 48.77% | 20.68% | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.10% | 0.16% | 0.31% | 0.82% | 1.34% | 1.27% | |
| Sample Size | 18700 | 14200 | 10500 | 7400 | 4900 | 2900 | 1500 | 700 | 200 | |

# Summary & Longevity Information

## Pacemakers

## Single-Chamber

St. Jude Medical

More control. Less risk.

## Malfunction and Normal Battery Depletion Summary Information

| Models | Family | US Regulatory Approval | 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| PM1210 | Accent® SR RF | Jul-09 | 1851 | 1803 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5620 | Zephyr® SR | Mar-07 | 7310 | 5866 | 0 | 2 | 0 | 0 | 2 | 0 |
| 5626 | Zephyr® XL SR | May-07 | 14876 | 12677 | 0 | 6 | 0 | 0 | 6 | 0 |
| 5610 | Victory® SR | Dec-05 | 12948 | 8788 | 0 | 3 | 0 | 0 | 2 | 2 |
| 5160 | Integrity® Adx SR | May-03 | 3395 | 1510 | 0 | 1 | 0 | 0 | 0 | 12 |
| 5156/5157/5056 | Verity® Adx XL SR/ SR(M/S)/SC | May-03 | 13790 | 7935 | 1 | 4 | 0 | 0 | 5 | 5 |
| 5180 | Identity® Adx SR | May-03 | 19913 | 9851 | 0 | 17 | 0 | 2 | 19 | 104 |
| 5172 | Identity® SR | Nov-01 | 21897 | 6398 | 1 | 43 | 1 | 4 | 49 | 450 |
| 5136 | Integrity® µ SR | Dec-00 | 11968 | 1810 | 0 | 10 | 0 | 0 | 10 | 279 |
| 5142 | Integrity® SR | Apr-00 | 10496 | 2889 | 1 | 5 | 0 | 0 | 6 | 36 |
| 5130/5131 | Affinity® SR | Jan-99/Jun-99 | 28676 | 5910 | 4 | 38 | 17 | 0 | 59 | 115 |

# Pacemakers

## 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 |
| PM1210 | Accent® SR RF* | | | | | | | | | | |
| 5620 | Zephyr® SR | 99.92% | 99.92% | | | | | | | | |
| 5626 | Zephyr® XL SR | 99.92% | 99.84% | | | | | | | | |
| 5610 | Victory® SR | 99.94% | 99.94% | 99.77% | | | | | | | |
| 5160 | Integrity® Adx SR | 100.00% | 100.00% | 99.63% | 99.07% | | | | | | |
| 5156/5157/5056 | Verity® Adx XL SR/ SR(M/S)/SC | 99.96% | 99.90% | 99.81% | 99.81% | 99.65% | | | | | |
| 5180 | Identity® Adx SR | 99.93% | 99.88% | 99.71% | 98.81% | 95.42% | | | | | |
| 5172 | Identity® SR | 99.93% | 99.70% | 99.34% | 98.62% | 95.61% | 84.12% | | | | |
| 5136 | Integrity® µ SR | 99.97% | 99.84% | 99.79% | 99.18% | 96.30% | 92.53% | 81.28% | | | |
| 5142 | Integrity® SR | 99.96% | 99.91% | 99.91% | 99.87% | 99.83% | 99.63% | 99.16% | 97.48% | | |
| 5130/5131 | Affinity® SR | 99.81% | 99.68% | 99.61% | 99.48% | 99.36% | 99.03% | 98.57% | 97.95% | | |

**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 |
| PM1210 | Accent® SR RF* | | | | | | | | | | |
| 5620 | Zephyr® SR | 99.92% | 99.92% | | | | | | | | |
| 5626 | Zephyr® XL SR | 99.92% | 99.84% | | | | | | | | |
| 5610 | Victory® SR | 99.94% | 99.94% | 99.86% | | | | | | | |
| 5160 | Integrity® Adx SR | 100.00% | 100.00% | 100.00% | 99.83% | | | | | | |
| 5156/5157/5056 | Verity® Adx XL SR/ SR(M/S)/SC | 99.96% | 99.92% | 99.89% | 99.89% | 99.89% | | | | | |
| 5180 | Identity® Adx SR | 99.98% | 99.95% | 99.87% | 99.73% | 99.52% | | | | | |
| 5172 | Identity® SR | 99.95% | 99.86% | 99.77% | 99.64% | 99.30% | 98.81% | | | | |
| 5136 | Integrity® µ SR | 99.96% | 99.91% | 99.88% | 99.81% | 99.72% | 99.72% | 99.72% | | | |
| 5142 | Integrity® SR | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | 99.91% | 99.85% | 99.75% | | |
| 5130/5131 | Affinity® SR | 99.81% | 99.67% | 99.61% | 99.52% | 99.49% | 99.47% | 99.45% | 99.41% | | |

**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.*

# Pacing Leads

## Bipolar & Unipolar

## Active & Passive Fixation

St. Jude Medical™

More control. Less risk.

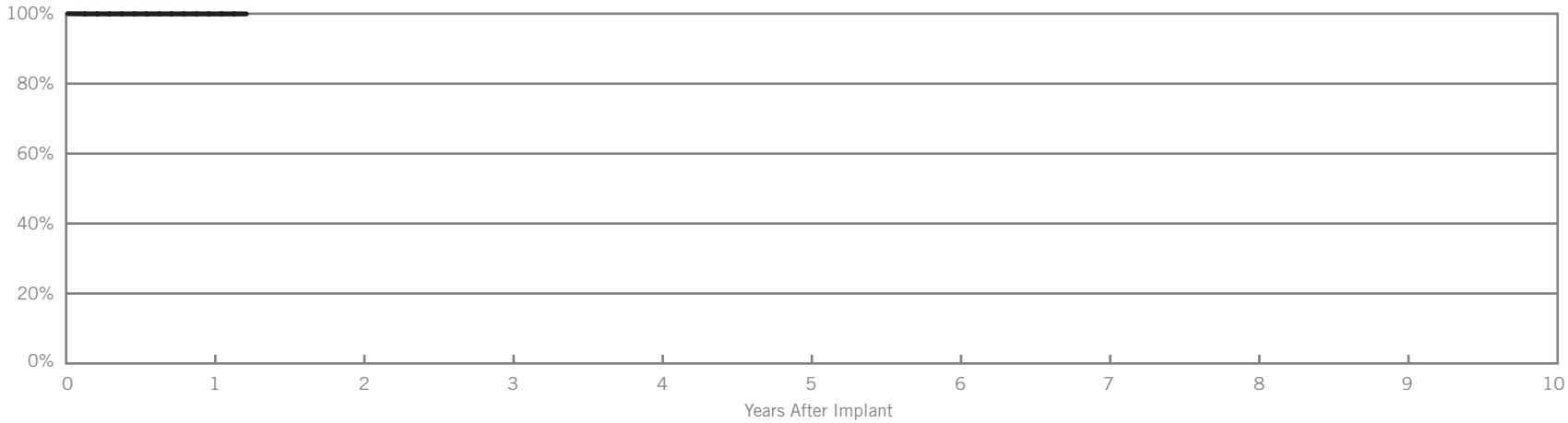
# Pacing Leads

| IsoFlex® Optim® (Model 1944) | |
|---|---|
| US Regulatory Approval | March 2008 |
| Registered US Implants | 1,906 |
| Estimated Active US Implants | 1,743 |
| 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 | 4 | 0.21% | 1 | 0.05% |
| Failure to Capture | 0 | 0.00% | 0 | 0.00% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 1 | 0.05% | 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** | **5** | **0.26%** | **1** | **0.05%** |
| **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 | at 15 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.94% | 99.94% | | | | | | | | |
| **± 1 standard error** | 0.06% | 0.06% | | | | | | | | |
| **Sample Size** | 1200 | 300 | | | | | | | | |

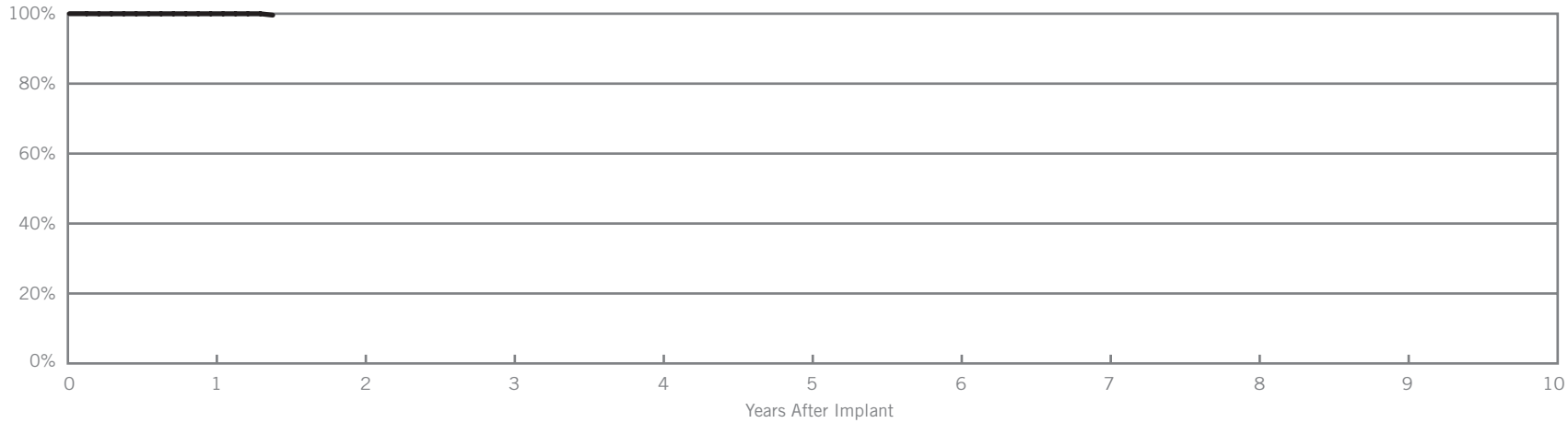
**Optim® insulation is a copolymer of silicone and polyurethane.*

| IsoFlex® Optim® (Model 1948) | |
|---|---|
| US Regulatory Approval | March 2008 |
| Registered US Implants | 6,705 |
| Estimated Active US Implants | 6,185 |
| 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 | 2 | 0.03% | 0 | 0.00% |
| Failure to Capture | 2 | 0.03% | 1 | 0.01% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 1 | 0.01% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 0 | 0.00% | 0 | 0.00% |
| **Total** | **4** | **0.06%** | **2** | **0.03%** |
| **Total Returned for Analysis** | **2** | | **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 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.98% | 99.59% | | | | | | | | |
| **± 1 standard error** | 0.02% | 0.02% | | | | | | | | |
| **Sample Size** | 4000 | 300 | | | | | | | | |

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

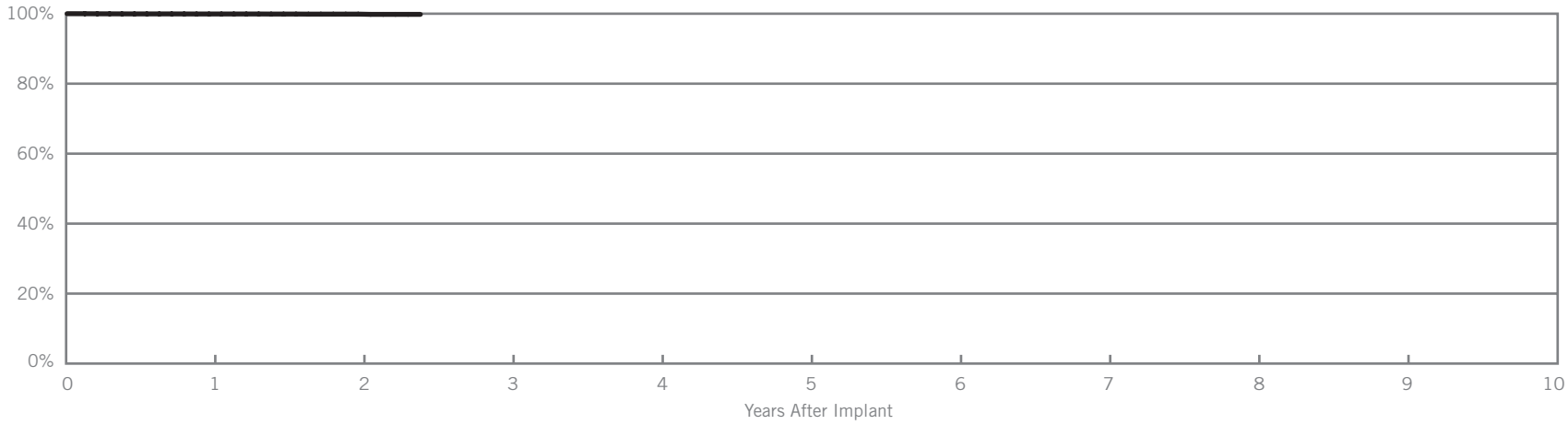
# Pacing Leads

| OptiSense® (Models 1699T & 1699TC) | |
|---|---|
| US Regulatory Approval | May 2007 |
| Registered US Implants | 19,133 |
| Estimated Active US Implants | 16,988 |
| 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 | 4 | 0.02% | 8 | 0.04% |
| Failure to Capture | 3 | 0.02% | 7 | 0.04% |
| Oversensing | 2 | 0.01% | 2 | 0.01% |
| Failure to Sense | 8 | 0.04% | 2 | 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** | **18** | **0.09%** | **20** | **0.10%** |
| **Total Returned for Analysis** | **12** | | **9** | |

| 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 | 7 | 0.04% |
| **Total** | **8** | **0.04%** |

## Survival from Returns and Complaints



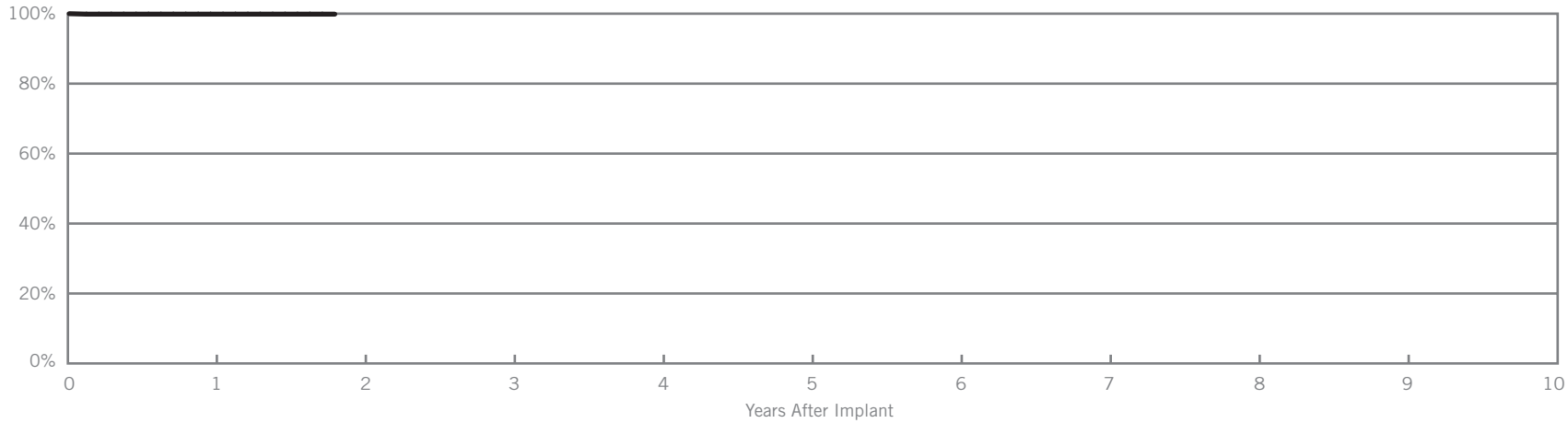

| Year | 1 | 2 | at 29 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.88% | 99.81% | | | | | | | |
| **± 1 standard error** | 0.02% | 0.04% | 0.08% | | | | | | | |
| **Sample Size** | 14800 | 5600 | 300 | | | | | | | |

| OptiSense® (Models 1699T & 1699TC) | |
|---|---|
| US Regulatory Approval | 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 | 802 |
| Cumulative Months of Follow-up | 9,996 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.12% |

## Survival from SCORE Registry




| Year | 1 | at 22 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.87% | 99.87% | | | | | | | | |
| **± 1 standard error** | 0.13% | 0.13% | | | | | | | | |
| **Sample Size** | 429 | 60 | | | | | | | | |

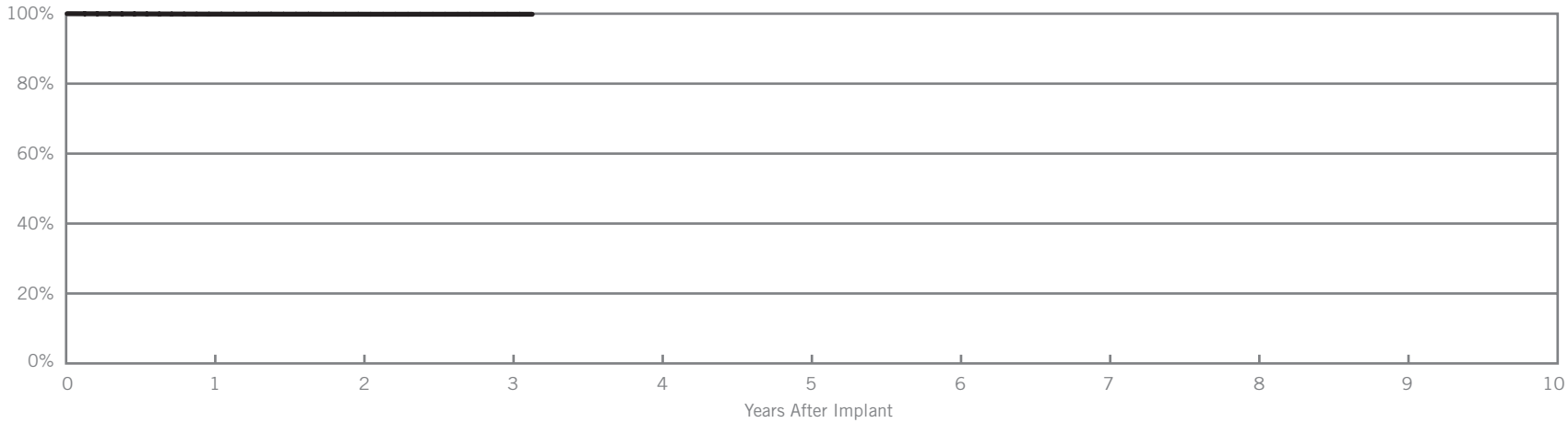
# Pacing Leads

| Tendril® ST Optim® (Models 1888T & 1888TC) | |
|---|---|
| US Regulatory Approval | June 2006 |
| Registered US Implants | 147,345 |
| Estimated Active US Implants | 130,303 |
| 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 | 19 | 0.01% | 11 | 0.01% |
| Conductor Fracture | 4 | <0.01% | 6 | <0.01% |
| Lead Dislodgement | 61 | 0.04% | 72 | 0.05% |
| Failure to Capture | 51 | 0.03% | 41 | 0.03% |
| Oversensing | 7 | <0.01% | 17 | 0.01% |
| Failure to Sense | 5 | <0.01% | 2 | <0.01% |
| Insulation Breach | 3 | <0.01% | 9 | 0.01% |
| Abnormal Pacing Impedance | 5 | <0.01% | 9 | 0.01% |
| Extracardiac Stimulation | 3 | <0.01% | 2 | <0.01% |
| Other | 13 | 0.01% | 11 | 0.01% |
| **Total** | **171** | **0.12%** | **180** | **0.12%** |
| **Total Returned for Analysis** | **55** | | **104** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 1 | <0.01% |
| Insulation Breach | 7 | <0.01% |
| Crimps, Welds & Bonds | 0 | 0.00% |
| Other | 5 | <0.01% |
| Extrinsic Factors | 87 | 0.06% |
| **Total** | **100** | **0.07%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 38 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.88% | 99.85% | 99.84% | 99.84% | | | | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.02% | 0.02% | | | | | | |
| **Sample Size** | 112700 | 46000 | 11700 | 300 | | | | | | |

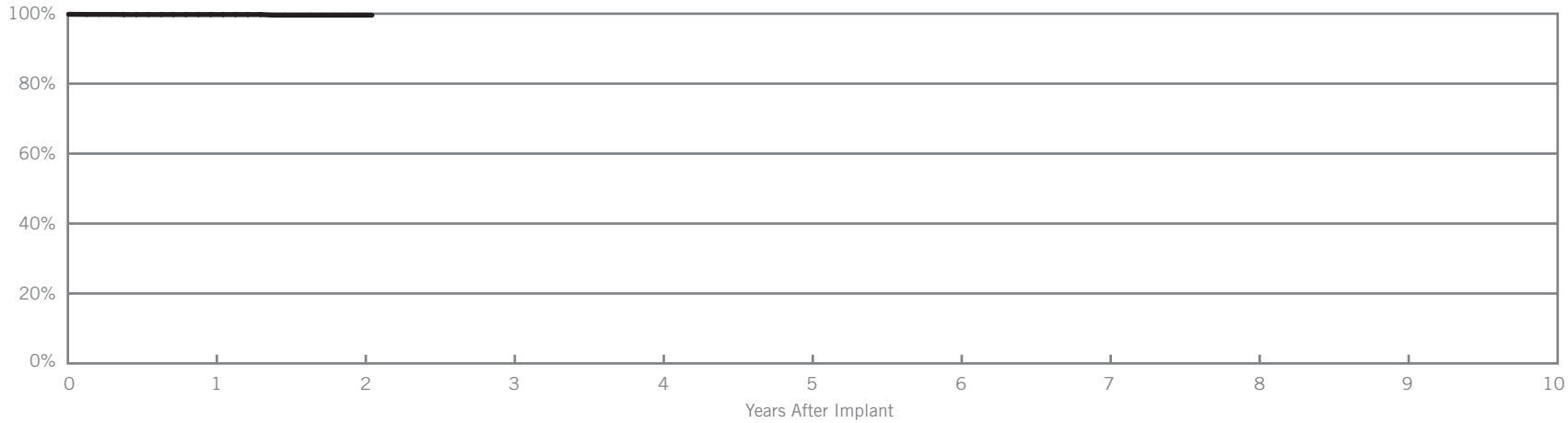
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Tendril® ST Optim® (Models 1888T & 1888TC) | |
|---|---|
| US Regulatory Approval | 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 | 2,989 |
| Cumulative Months of Follow-up | 31,572 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 7 | 0.23% |
| Abnormal Pacing Impedance | 1 | 0.03% |
| Extracardiac Stimulation | 1 | 0.03% |

## Survival from SCORE Registry




| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.75% | 99.58% | 99.58% | | | | | | | |
| **± 1 standard error** | 0.10% | 0.19% | 0.19% | | | | | | | |
| **Sample Size** | 1351 | 77 | 55 | | | | | | | |

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

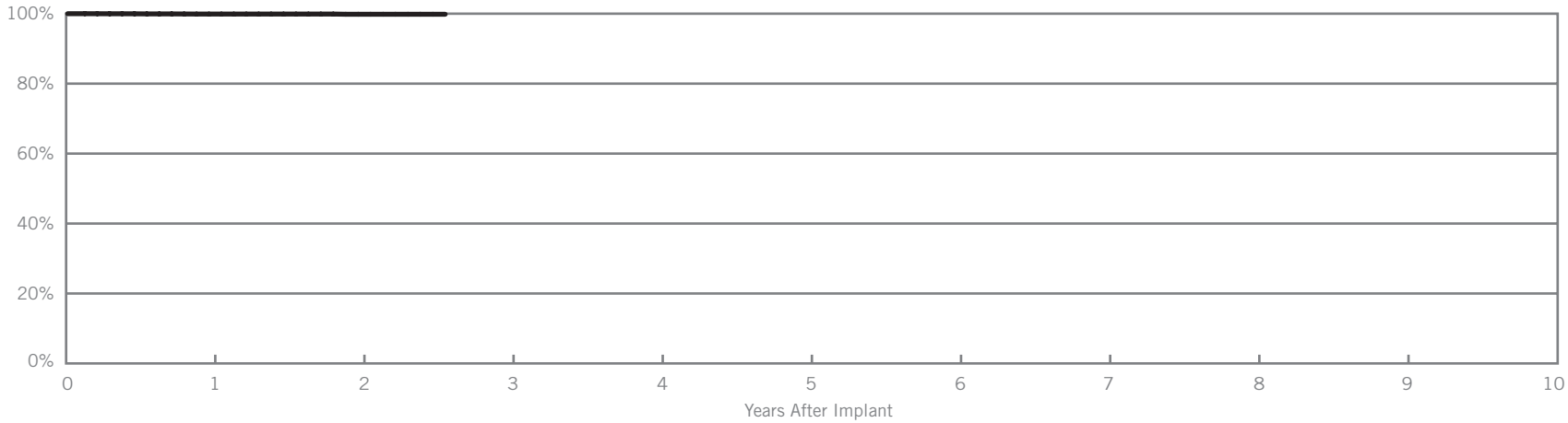
# Pacing Leads

| Tendril® ST Optim® (Models 1882T & 1882TC) | |
|---|---|
| US Regulatory Approval | June 2006 |
| Registered US Implants | 10,812 |
| Estimated Active US Implants | 9,622 |
| 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 | 2 | 0.02% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 0 | 0.00% |
| Lead Dislodgement | 9 | 0.08% | 6 | 0.06% |
| Failure to Capture | 4 | 0.04% | 1 | 0.01% |
| Oversensing | 2 | 0.02% | 2 | 0.02% |
| 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** | **20** | **0.18%** | **11** | **0.10%** |
| **Total Returned for Analysis** | **4** | | **9** | |

| 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 | 6 | 0.06% |
| **Total** | **6** | **0.06%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | at 31 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.84% | 99.84% | | | | | | | |
| **± 1 standard error** | 0.04% | 0.07% | 0.07% | | | | | | | |
| **Sample Size** | 8100 | 3100 | 300 | | | | | | | |

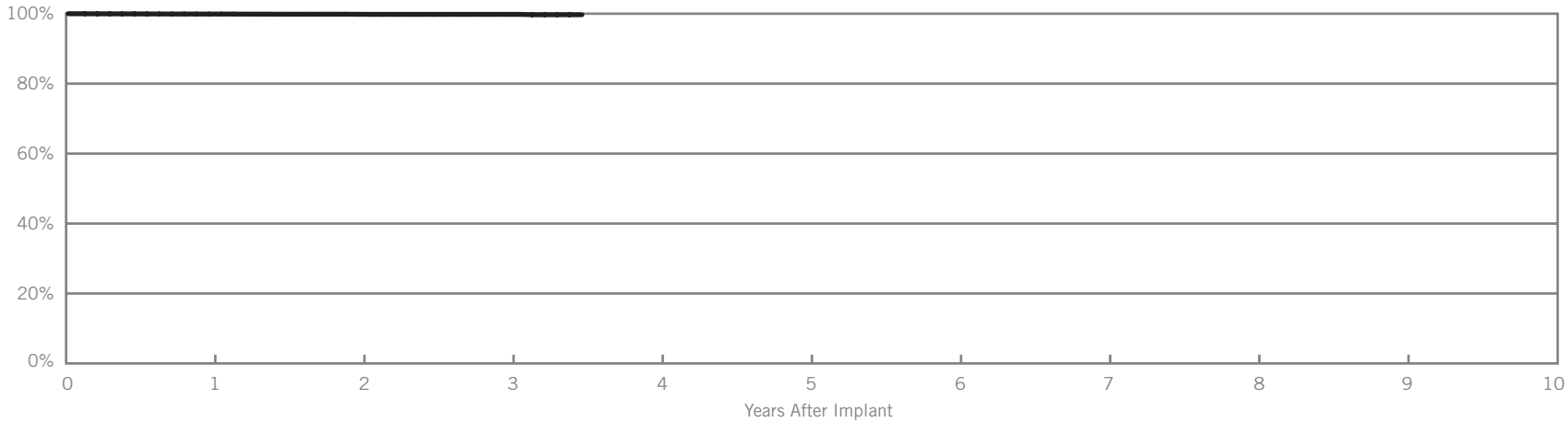
**Optim® insulation is a copolymer of silicone and polyurethane.*

| Tendril® (Models 1782T & 1782TC) | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 12,779 |
| Estimated Active US Implants | 10,515 |
| 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 | 5 | 0.04% | 0 | 0.00% |
| Conductor Fracture | 0 | 0.00% | 1 | 0.01% |
| Lead Dislodgement | 8 | 0.06% | 9 | 0.07% |
| Failure to Capture | 4 | 0.03% | 9 | 0.07% |
| 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% | 2 | 0.02% |
| Extracardiac Stimulation | 1 | 0.01% | 0 | 0.00% |
| Other | 2 | 0.02% | 0 | 0.00% |
| **Total** | **22** | **0.17%** | **23** | **0.18%** |
| **Total Returned for Analysis** | **10** | | **20** | |

| 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 | 15 | 0.12% |
| **Total** | **18** | **0.14%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 42 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.83% | 99.81% | 99.71% | | | | | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.05% | 0.11% | | | | | | |
| **Sample Size** | 11300 | 7300 | 3400 | 300 | | | | | | |

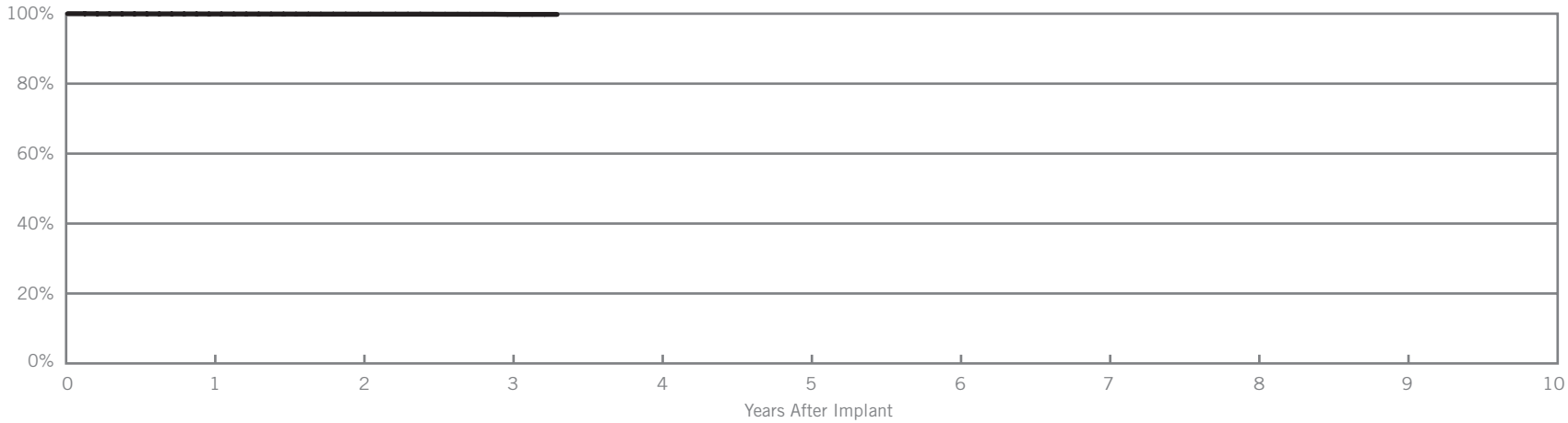
# Pacing Leads

| Tendril® (Models 1788T & 1788TC) | |
|---|---|
| US Regulatory Approval | February 2006 |
| Registered US Implants | 60,306 |
| Estimated Active US Implants | 48,259 |
| 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 | 32 | 0.05% | 22 | 0.04% |
| Failure to Capture | 26 | 0.04% | 28 | 0.05% |
| Oversensing | 2 | <0.01% | 9 | 0.01% |
| Failure to Sense | 2 | <0.01% | 1 | <0.01% |
| Insulation Breach | 1 | <0.01% | 2 | <0.01% |
| Abnormal Pacing Impedance | 9 | 0.01% | 8 | 0.01% |
| Extracardiac Stimulation | 2 | <0.01% | 1 | <0.01% |
| Other | 20 | 0.03% | 5 | 0.01% |
| **Total** | **105** | **0.17%** | **79** | **0.13%** |
| **Total Returned for Analysis** | **37** | | **59** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 17 | 0.03% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 7 | 0.01% |
| Extrinsic Factors | 37 | 0.06% |
| **Total** | **62** | **0.10%** |

## Survival from Returns and Complaints



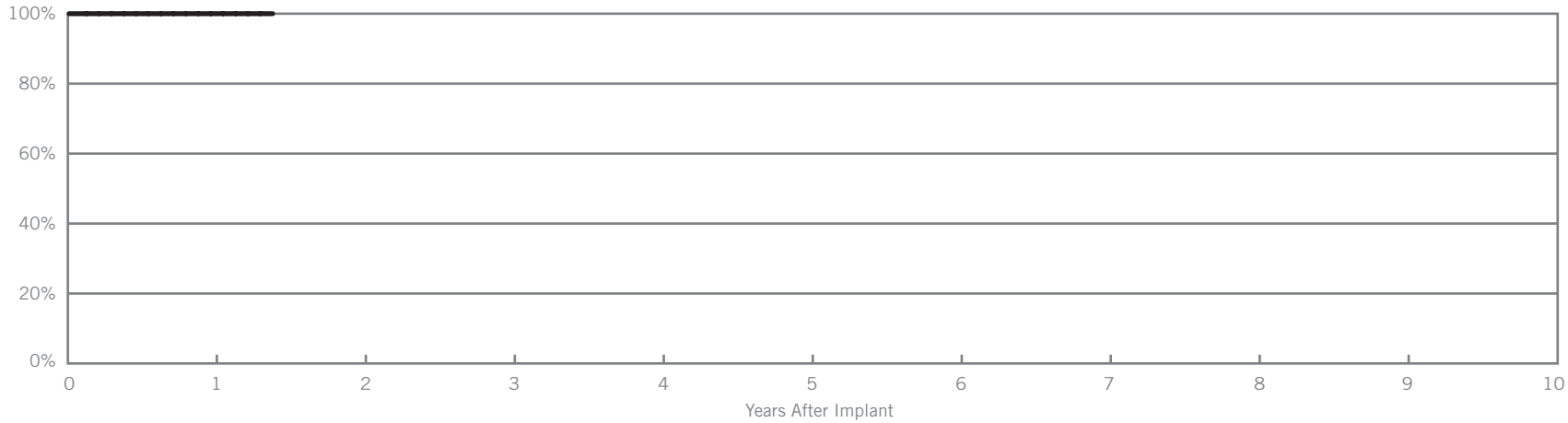

| Year | 1 | 2 | 3 | at 40 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.87% | 99.80% | 99.80% | | | | | | |
| **± 1 standard error** | 0.01% | 0.02% | 0.02% | 0.03% | | | | | | |
| **Sample Size** | 55200 | 38800 | 18300 | 900 | | | | | | |

| Tendril® (Models 1788T & 1788TC) | |
|---|---|
| US Regulatory Approval | 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 | 197 |
| Cumulative Months of Follow-up | 2,467 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry




| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 1.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 100 | 54 | | | | | | | | |

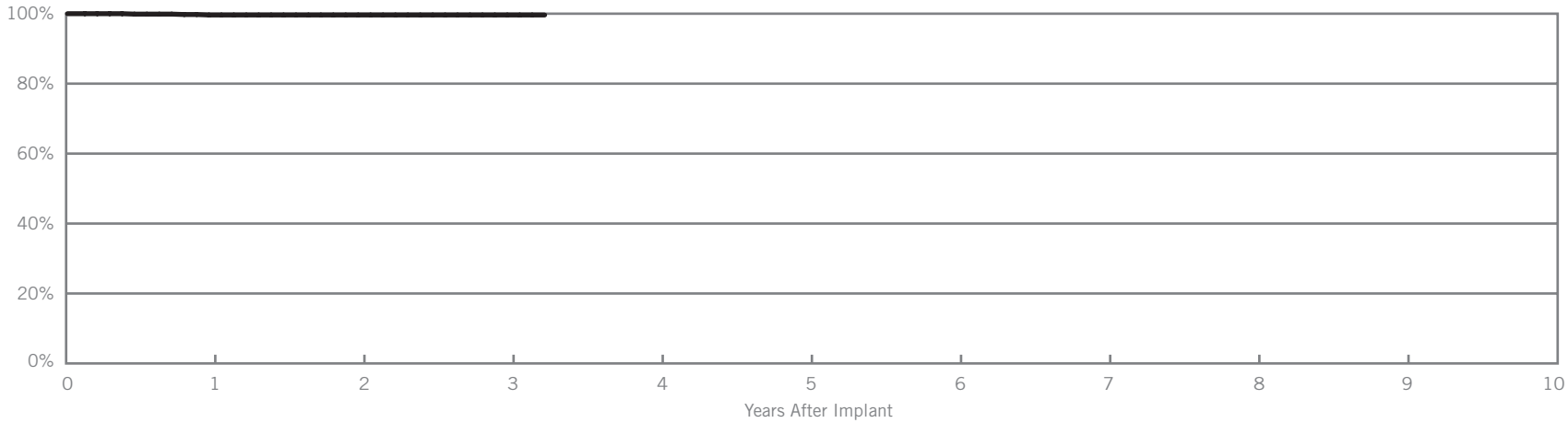
# Pacing Leads

| IsoFlex® P (Model 1644T) | |
|---|---|
| US Regulatory Approval | April 2005 |
| Registered US Implants | 941 |
| Estimated Active US Implants | 697 |
| 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 | 0.21% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 0 | 0.00% | 0 | 0.00% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 0 | 0.00% | 0 | 0.00% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 1 | 0.11% | 0 | 0.00% |
| **Total** | **2** | **0.21%** | **3** | **0.32%** |
| **Total Returned for Analysis** | **1** | | **2** | |

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

## Survival from Returns and Complaints



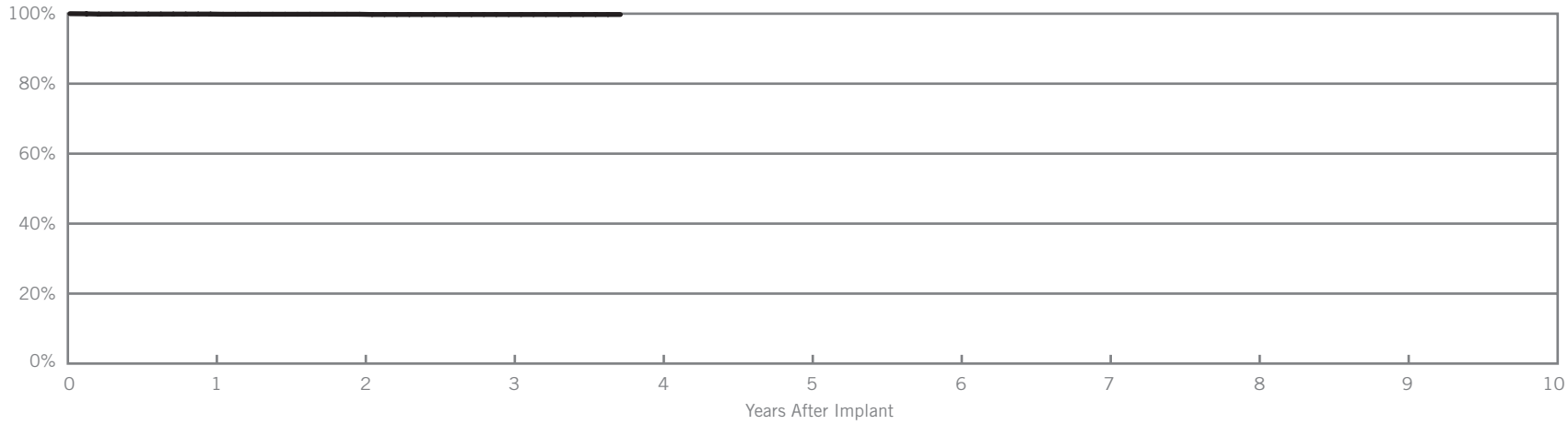

| Year | 1 | 2 | 3 | at 39 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.63% | 99.63% | 99.63% | 99.63% | | | | | | |
| **± 1 standard error** | 0.17% | 0.21% | 0.21% | 0.21% | | | | | | |
| **Sample Size** | 900 | 700 | 400 | 200 | | | | | | |

| IsoFlex® P (Model 1648T) | |
|---|---|
| US Regulatory Approval | April 2005 |
| Registered US Implants | 2,771 |
| Estimated Active US Implants | 2,035 |
| 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% | 1 | 0.04% |
| Abnormal Pacing Impedance | 0 | 0.00% | 1 | 0.04% |
| Extracardiac Stimulation | 1 | 0.04% | 0 | 0.00% |
| Other | 0 | 0.00% | 2 | 0.07% |
| **Total** | **6** | **0.22%** | **5** | **0.18%** |
| **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 45 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.89% | 99.84% | 99.77% | 99.77% | | | | | | |
| **± 1 standard error** | 0.07% | 0.08% | 0.11% | 0.11% | | | | | | |
| **Sample Size** | 2700 | 1900 | 1000 | 200 | | | | | | |

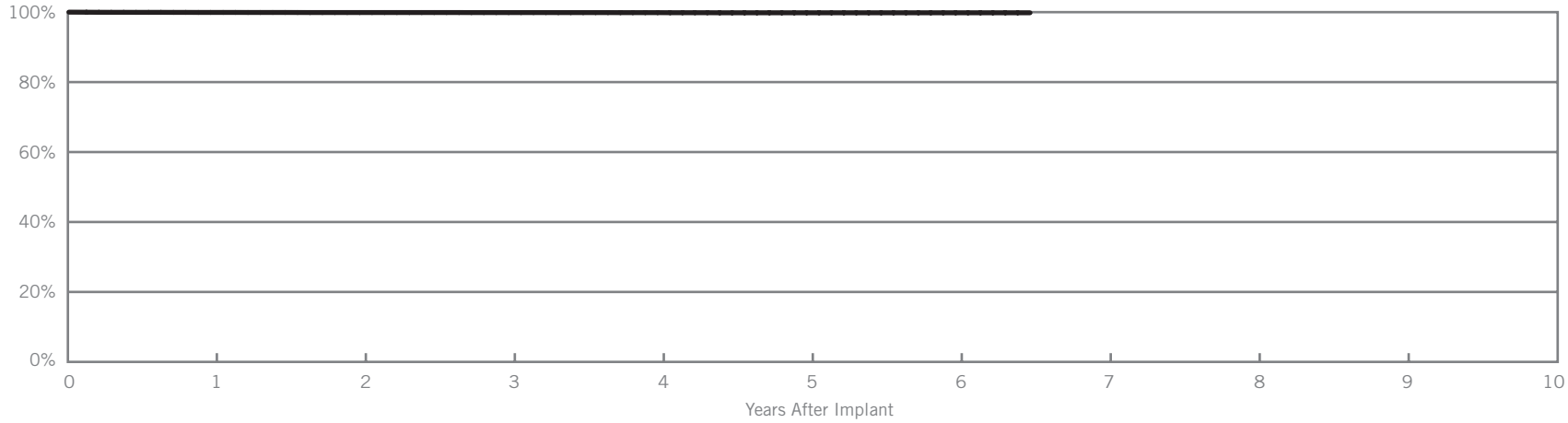
# Pacing Leads

| IsoFlex® S (Model 1642T) | |
|---|---|
| US Regulatory Approval | May 2002 |
| Registered US Implants | 23,479 |
| Estimated Active US Implants | 17,096 |
| 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 | 42 | 0.18% | 16 | 0.07% |
| Failure to Capture | 5 | 0.02% | 8 | 0.03% |
| Oversensing | 0 | 0.00% | 0 | 0.00% |
| Failure to Sense | 3 | 0.01% | 3 | 0.01% |
| Insulation Breach | 0 | 0.00% | 0 | 0.00% |
| Abnormal Pacing Impedance | 3 | 0.01% | 1 | <0.01% |
| Extracardiac Stimulation | 1 | <0.01% | 0 | 0.00% |
| Other | 0 | 0.00% | 1 | <0.01% |
| **Total** | **54** | **0.23%** | **30** | **0.13%** |
| **Total Returned for Analysis** | **31** | | **11** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 0 | 0.00% |
| Insulation Breach | 1 | <0.01% |
| Crimps, Welds & Bonds | 2 | 0.01% |
| Other | 7 | 0.03% |
| Extrinsic Factors | 9 | 0.04% |
| **Total** | **19** | **0.08%** |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 78 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.89% | 99.88% | 99.86% | 99.82% | 99.82% | 99.82% | | | |
| **± 1 standard error** | 0.02% | 0.02% | 0.03% | 0.03% | 0.04% | 0.04% | 0.04% | | | |
| **Sample Size** | 21600 | 16300 | 11900 | 8000 | 4500 | 1900 | 200 | | | |

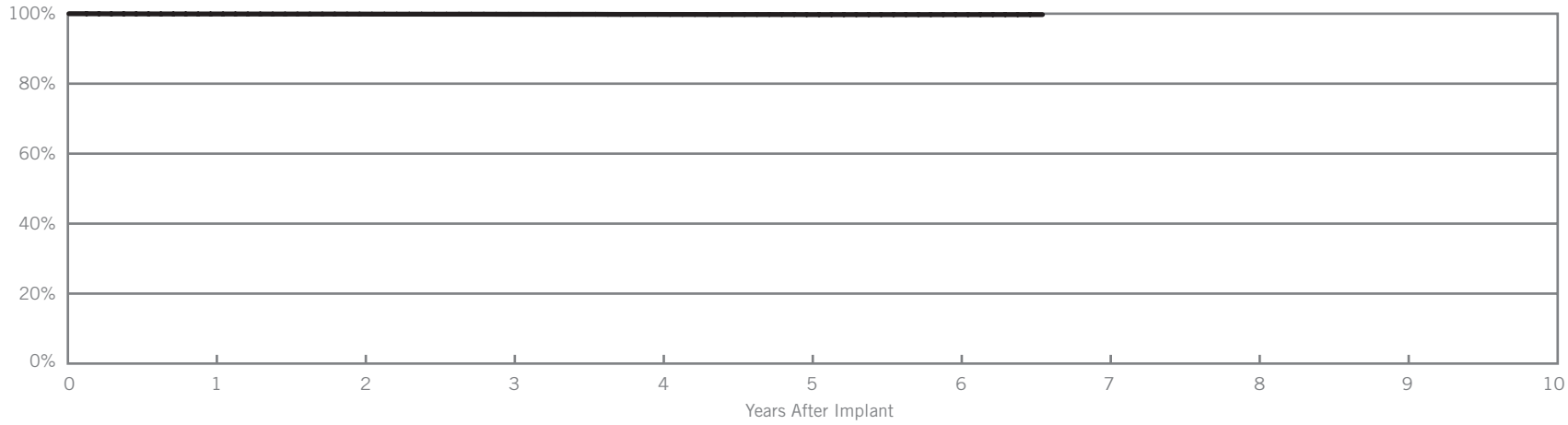
# Pacing Leads

| IsoFlex® S (Model 1646T) | |
|---|---|
| US Regulatory Approval | May 2002 |
| Registered US Implants | 77,531 |
| Estimated Active US Implants | 53,506 |
| 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 | 2 | <0.01% | 10 | 0.01% |
| Lead Dislodgement | 29 | 0.04% | 14 | 0.02% |
| Failure to Capture | 29 | 0.04% | 47 | 0.06% |
| Oversensing | 0 | 0.00% | 9 | 0.01% |
| Failure to Sense | 3 | <0.01% | 2 | <0.01% |
| Insulation Breach | 1 | <0.01% | 0 | 0.00% |
| Abnormal Pacing Impedance | 6 | 0.01% | 17 | 0.02% |
| Extracardiac Stimulation | 0 | 0.00% | 0 | 0.00% |
| Other | 2 | <0.01% | 9 | 0.01% |
| **Total** | **75** | **0.10%** | **109** | **0.14%** |
| **Total Returned for Analysis** | **29** | | **28** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 5 | 0.01% |
| Insulation Breach | 5 | 0.01% |
| Crimps, Welds & Bonds | 1 | <0.01% |
| Other | 6 | 0.01% |
| Extrinsic Factors | 22 | 0.03% |
| **Total** | **39** | **0.05%** |

## Survival from Returns and Complaints



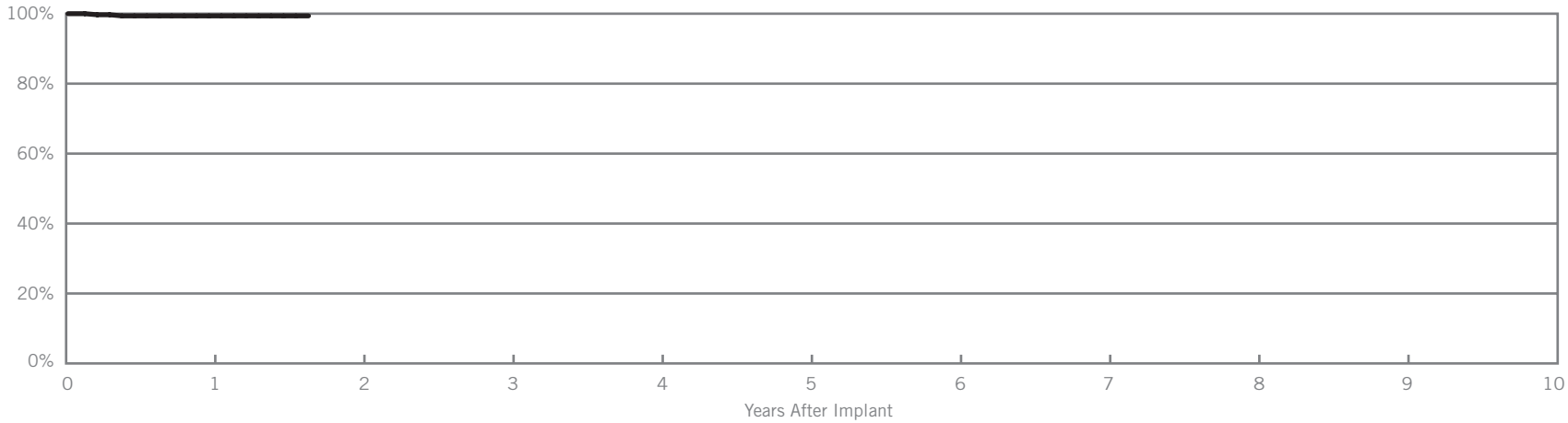

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 79 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.89% | 99.84% | 99.80% | 99.74% | 99.74% | 99.74% | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.03% | 0.03% | | | |
| **Sample Size** | 71500 | 53000 | 37800 | 24600 | 13700 | 5600 | 300 | | | |

| IsoFlex® S (Model 1646T) | |
|---|---|
| US Regulatory Approval | 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 | 350 |
| Cumulative Months of Follow-up | 4,297 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.29% |
| Failure to Capture | 1 | 0.29% |

## Survival from SCORE Registry




| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.37% | 99.37% | | | | | | | | |
| **± 1 standard error** | 0.45% | 0.45% | | | | | | | | |
| **Sample Size** | 193 | 55 | | | | | | | | |

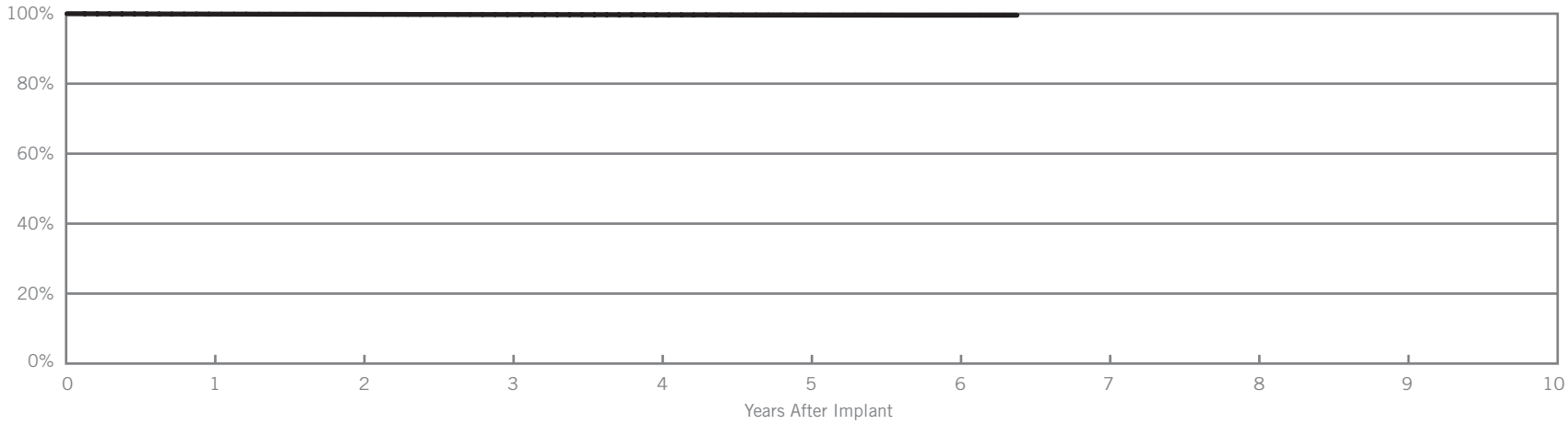
# Pacing Leads

| Tendril® SDX (Models 1688T & 1688TC) | |
|---|---|
| US Regulatory Approval | June 2003 |
| Registered US Implants | 323,486 |
| Estimated Active US Implants | 232,037 |
| 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 | 34 | 0.01% | 6 | <0.01% |
| Conductor Fracture | 3 | <0.01% | 54 | 0.02% |
| Lead Dislodgement | 148 | 0.05% | 158 | 0.05% |
| Failure to Capture | 107 | 0.03% | 223 | 0.07% |
| Oversensing | 9 | <0.01% | 109 | 0.03% |
| Failure to Sense | 19 | 0.01% | 12 | <0.01% |
| Insulation Breach | 5 | <0.01% | 17 | 0.01% |
| Abnormal Pacing Impedance | 23 | 0.01% | 119 | 0.04% |
| Extracardiac Stimulation | 3 | <0.01% | 3 | <0.01% |
| Other | 27 | 0.01% | 52 | 0.02% |
| **Total** | **378** | **0.12%** | **753** | **0.23%** |
| **Total Returned for Analysis** | **137** | | **337** | |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 76 | 0.02% |
| Insulation Breach | 74 | 0.02% |
| Crimps, Welds & Bonds | 16 | <0.01% |
| Other | 6 | <0.01% |
| Extrinsic Factors | 202 | 0.06% |
| **Total** | **374** | **0.12%** |

## Survival from Returns and Complaints



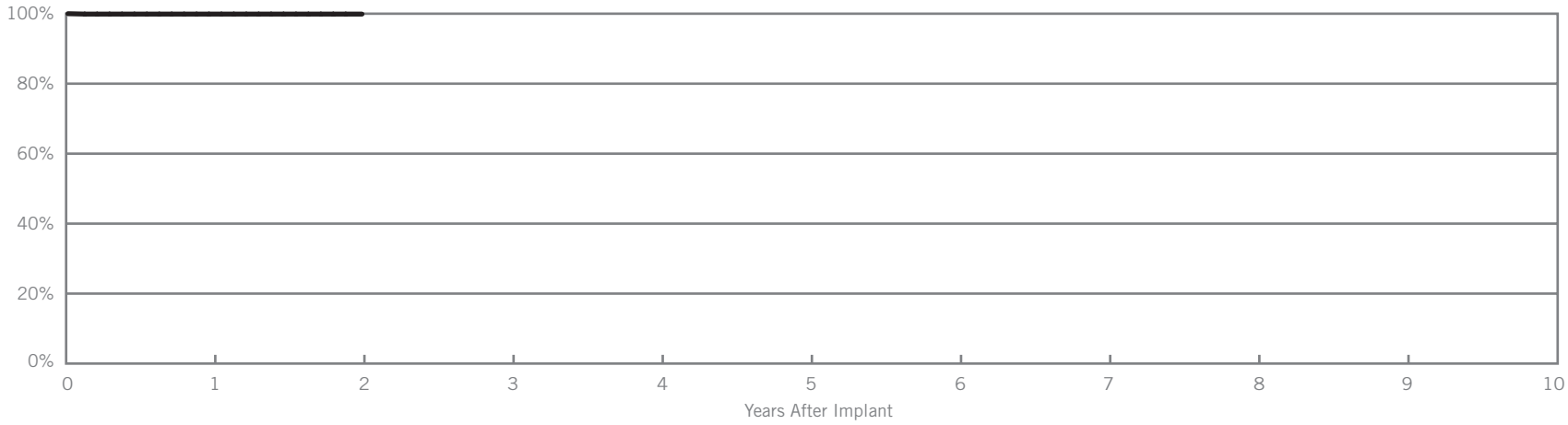

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 77 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.89% | 99.82% | 99.74% | 99.67% | 99.61% | 99.57% | 99.57% | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.01% | 0.01% | 0.02% | 0.02% | 0.02% | | | |
| **Sample Size** | 299800 | 233200 | 178900 | 117200 | 56000 | 17300 | 300 | | | |

| Tendril® SDX (Models 1688T & 1688TC) | |
|---|---|
| US Regulatory Approval | 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 | 918 |
| Cumulative Months of Follow-up | 11,458 |

| Qualifying Complications | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Lead Dislodgement | 1 | 0.11% |

## Survival from SCORE Registry



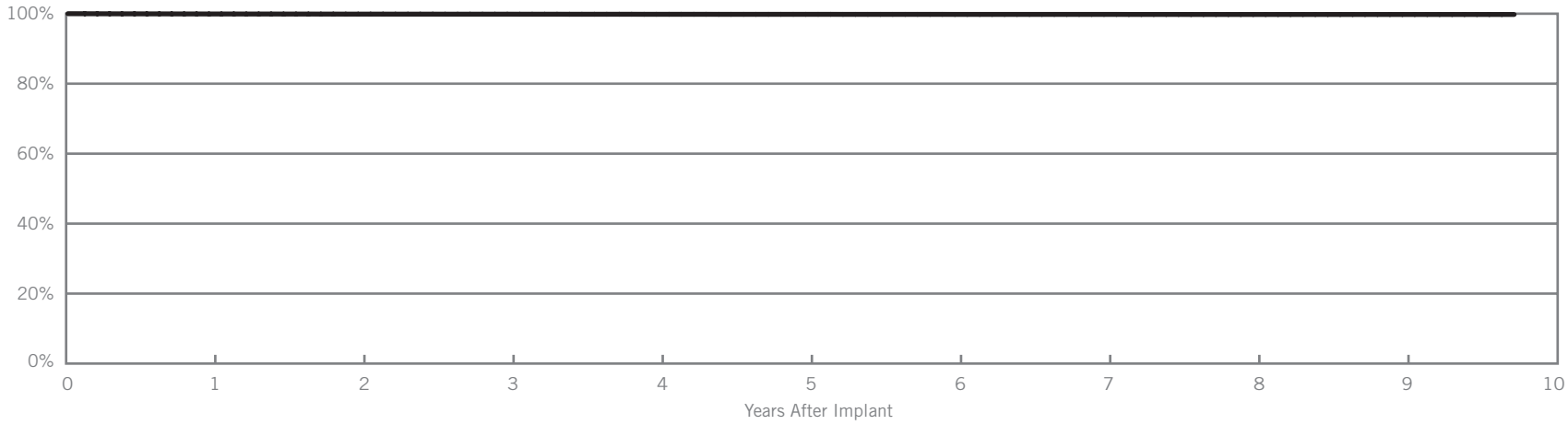

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.89% | 99.89% | | | | | | | | |
| **± 1 standard error** | 0.11% | 0.11% | | | | | | | | |
| **Sample Size** | 498 | 57 | | | | | | | | |

# Pacing Leads

| Tendril® SDX (Models 1488T & 1488TC) | |
|---|---|
| US Regulatory Approval | March 2000 |
| Registered US Implants | 273,469 |
| Estimated Active US Implants | 134,368 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | Yes |
| Number of Advisories | None |

| Lead Malfunctions | | |
|---|---|---|
| **Type** | **Qty.** | **Rate** |
| Conductor Fracture | 120 | 0.04% |
| Insulation Breach | 75 | 0.03% |
| Crimps, Welds & Bonds | 13 | <0.01% |
| Other | 2 | <0.01% |
| Extrinsic Factors | 235 | 0.09% |
| **Total** | **445** | **0.16%** |

## Survival from Returns and Complaints



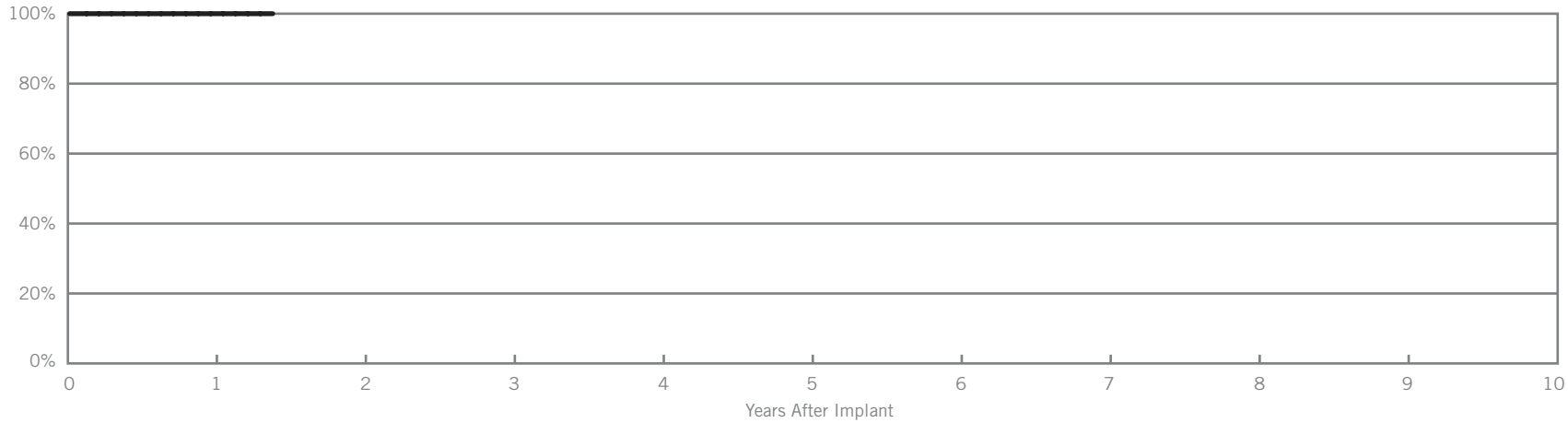

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 117 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.88% | 99.86% | 99.83% | 99.82% | 99.80% | 99.80% | 99.78% | 99.78% | 99.78% |
| **± 1 standard error** | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% |
| **Sample Size** | 266000 | 233400 | 209500 | 183600 | 152300 | 118500 | 80200 | 42600 | 16400 | 300 |

| Tendril® SDX (Models 1488T & 1488TC) | |
|---|---|
| US Regulatory Approval | 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 | 127 |
| Cumulative Months of Follow-up | 1,970 |

| Qualifying Complications |
|---|
| None Reported |

## Survival from SCORE Registry

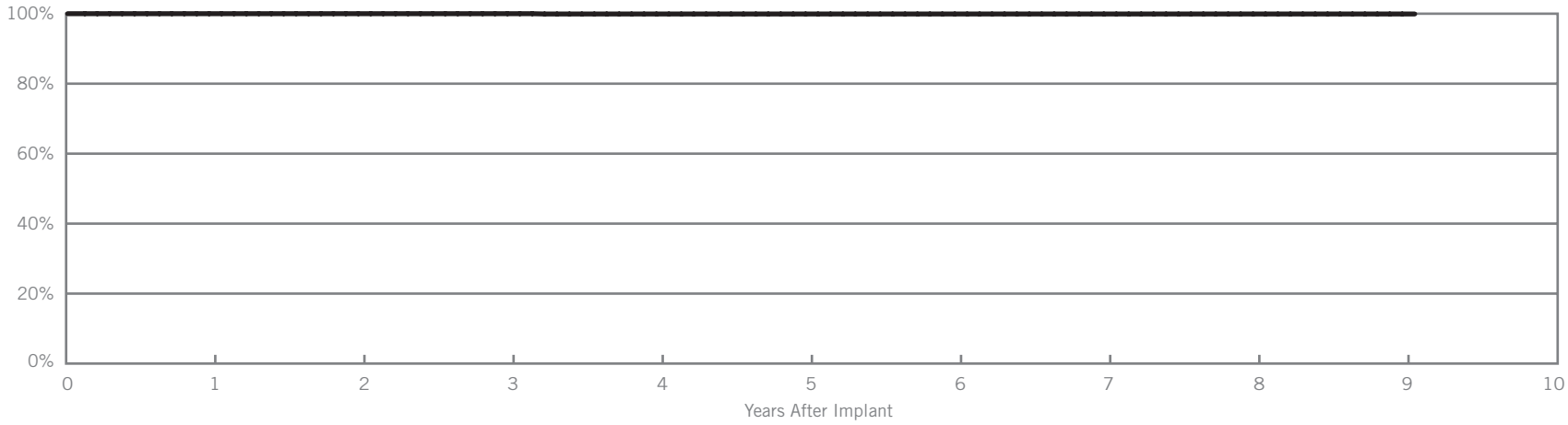



| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 86 | 51 | | | | | | | | |

# Pacing Leads

| AV Plus® DX (Model 1368) | |
|---|---|
| US Regulatory Approval | May 1999 |
| Registered US Implants | 2,432 |
| Estimated Active US Implants | 1,018 |
| Insulation | Silicone |
| Type and/or Fixation | Passive |
| Atrial Polarity | Bipolar |
| Ventricular Polarity | Bipolar |
| Steroid | Yes |
| Number of Advisories | None |

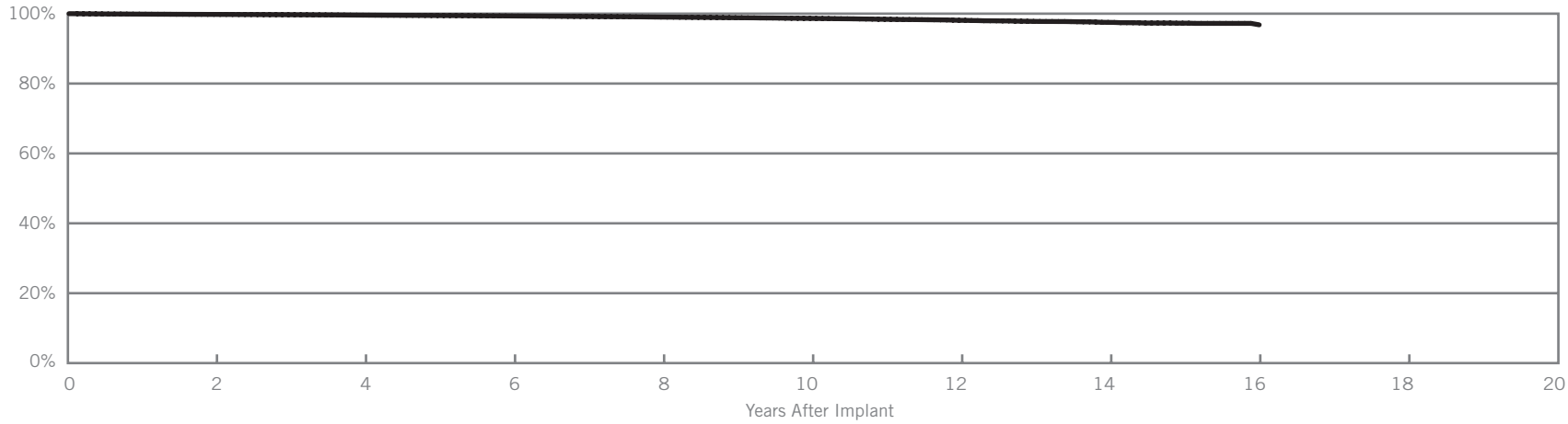
## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.92% | 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% | 0.08% |
| Sample Size | 2300 | 1900 | 1500 | 1300 | 1000 | 800 | 600 | 500 | 300 | 200 |

| Tendril® (Models 1148 & 1188T); Tendril® DX (Models 1388T & 1388TC) | |
|---|---|
| US Regulatory Approval | (1148) June 1993; (1188T) June 1994; (1388T) June 1997 |
| Registered US Implants | 323,872 |
| Estimated Active US Implants | 113,279 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Bipolar |
| Steroid | (1148/1188) No; (1388) Yes |
| Number of Advisories | None |

## Survival from Returns and Complaints

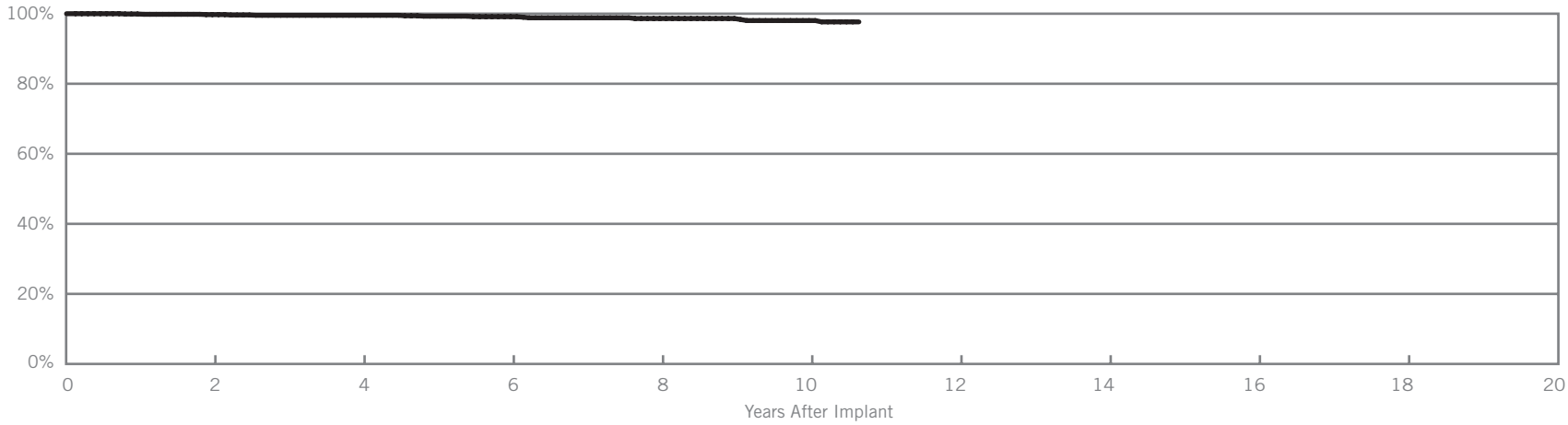



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.79% | 99.58% | 99.34% | 99.02% | 98.65% | 98.10% | 97.51% | 96.77% | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.05% | 0.10% | 0.14% | | |
| **Sample Size** | 275000 | 216600 | 159500 | 107900 | 61900 | 23500 | 7600 | 200 | | |

# Pacing Leads

| Tendril® (Model 1188K) Tendril® DX (Model 1388K) | |
|---|---|
| US Regulatory Approval | (1188K) June 1995; (1388K) June 1997 |
| Registered US Implants | 1,346 |
| Estimated Active US Implants | 303 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Unipolar |
| Steroid | (1188K) No; (1388K) Yes |
| Number of Advisories | None |

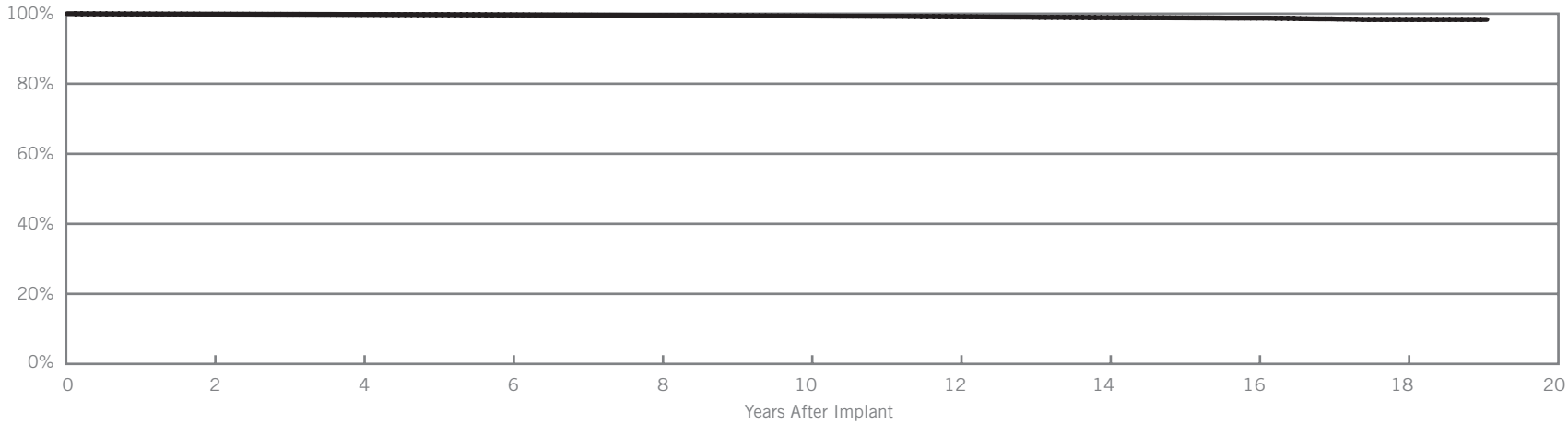
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | at 128 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | 99.54% | 99.15% | 98.62% | 98.04% | 97.65% | | | | |
| ± 1 standard error | 0.15% | 0.21% | 0.31% | 0.43% | 0.59% | 0.70% | | | | |
| Sample Size | 1200 | 900 | 700 | 500 | 300 | 200 | | | | |

| **Passive Plus® (Models 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T)<br>Passive Plus® DX (Models 1336T, 1342T & 1346T)** | |
|---|---|
| US Regulatory Approval | (1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990 |
| Registered US Implants | 373,882 |
| Estimated Active US Implants | 103,334 |
| 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

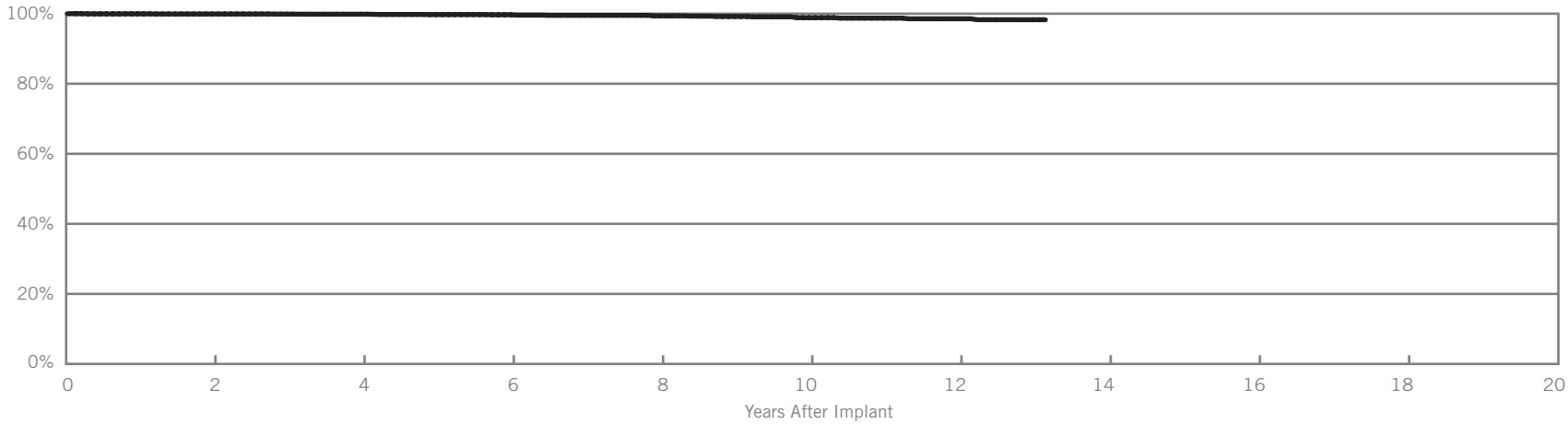



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 229 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.88% | 99.77% | 99.65% | 99.51% | 99.34% | 99.15% | 98.87% | 98.74% | 98.35% | 98.35% |
| **± 1 standard error** | 0.01% | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.04% | 0.06% | 0.11% | 0.11% |
| **Sample Size** | 319300 | 256400 | 196900 | 136900 | 84800 | 48000 | 23800 | 9300 | 2500 | 200 |

# Pacing Leads

| **Passive Plus® (Models 1135K, 1143K, 1145K, 1235K, 1243K & 1245K)<br>Passive Plus® DX (Models 1343K & 1345K)** | |
|---|---|
| US Regulatory Approval | (1135K, 1143K, 1145K) July 1994; (1235K, 1243K, 1245K) August 1995; (1343K, 1345K) June 1998 |
| Registered US Implants | 4,481 |
| Estimated Active US Implants | 854 |
| Insulation | Silicone |
| Type and/or Fixation | Passive |
| Polarity | Unipolar |
| Steroid | (1135K, 1143K, 1145K, 1235K, 1243K, 1245K) No; (1343K, 1345K) Yes |
| Number of Advisories | None |

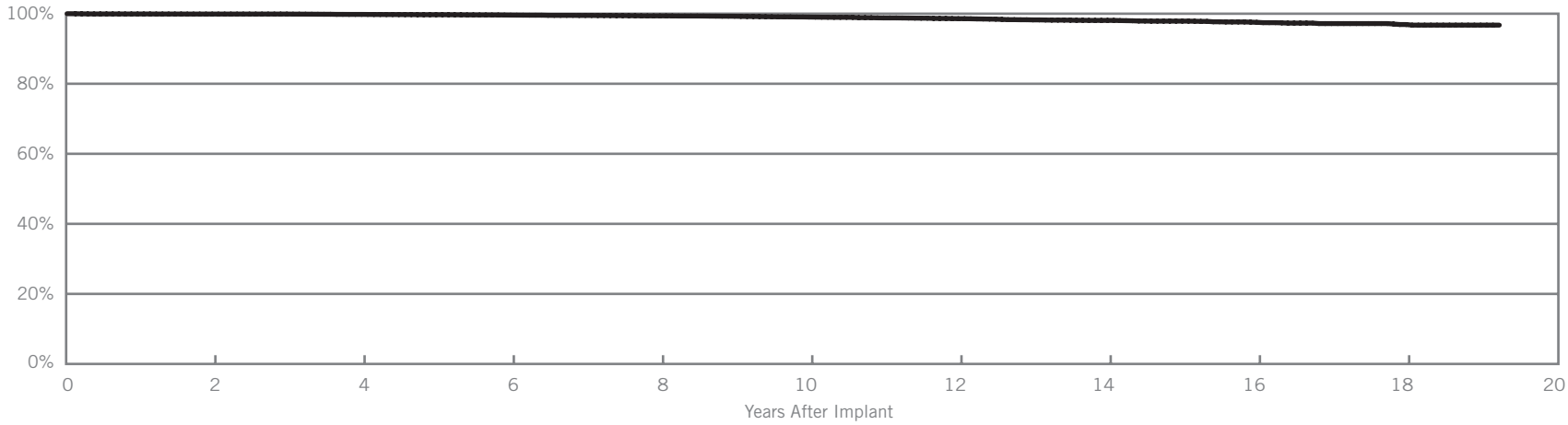
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | at 158 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.86% | 99.69% | 99.38% | 98.87% | 98.54% | 98.27% | | | |
| **± 1 standard error** | 0.04% | 0.06% | 0.11% | 0.18% | 0.29% | 0.37% | 0.46% | | | |
| **Sample Size** | 3700 | 3000 | 2300 | 1600 | 1000 | 500 | 200 | | | |

| Permathane™ ACE (Models 1036T & 1038T) | |
|---|---|
| US Regulatory Approval | June 1989 |
| Registered US Implants | 19,767 |
| Estimated Active US Implants | 2,512 |
| Insulation | Polyurethane |
| Type and/or Fixation | Passive |
| Polarity | Bipolar |
| Steroid | No |
| Number of Advisories | None |

## Survival from Returns and Complaints

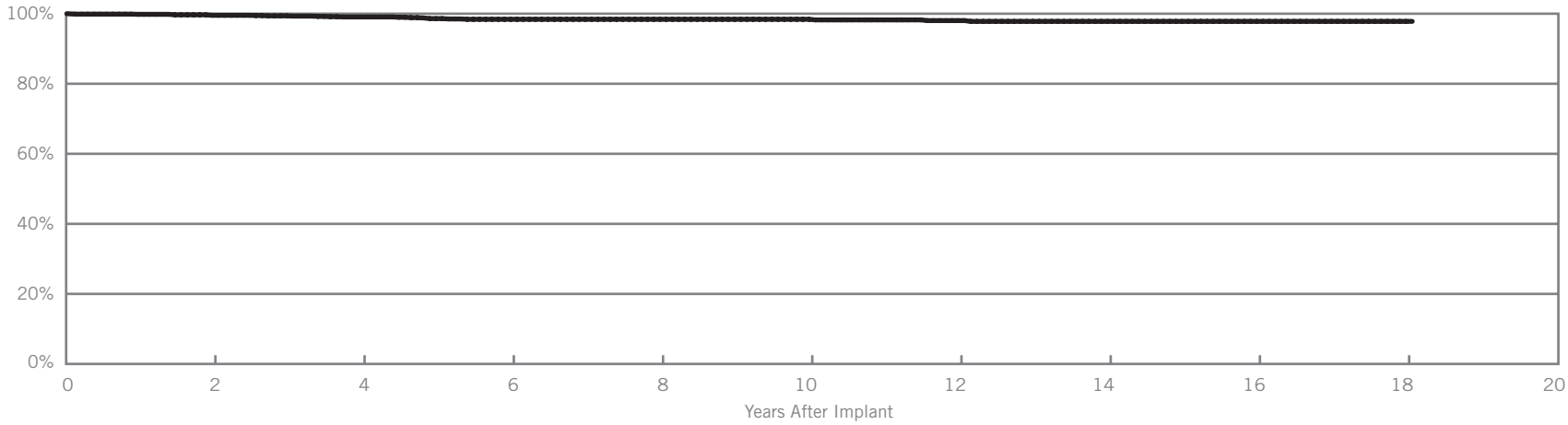



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 231 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.90% | 99.80% | 99.60% | 99.38% | 99.04% | 98.58% | 98.09% | 97.54% | 96.91% | 96.74% |
| ± 1 standard error | 0.02% | 0.04% | 0.05% | 0.08% | 0.10% | 0.14% | 0.18% | 0.22% | 0.33% | 0.37% |
| Sample Size | 17100 | 13800 | 11100 | 8700 | 6800 | 5200 | 3900 | 2400 | 900 | 200 |

# Pacing Leads

| Unipolar Lead (Model 1007) | |
|---|---|
| US Regulatory Approval | June 1987 |
| Registered US Implants | 1,748 |
| Estimated Active US Implants | 186 |
| Insulation | Silicone |
| Type and/or Fixation | Active |
| Polarity | Unipolar |
| Steroid | No |
| Number of Advisories | None |

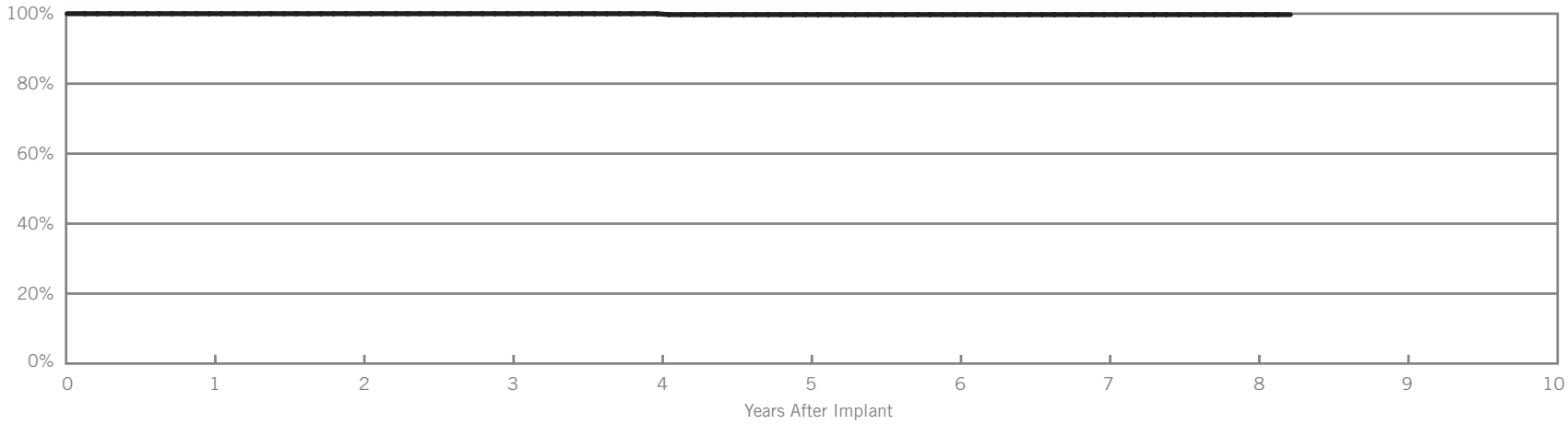
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 217 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.54% | 99.07% | 98.40% | 98.40% | 98.40% | 98.03% | 97.81% | 97.81% | 97.81% | 97.81% |
| **± 1 standard error** | 0.14% | 0.26% | 0.36% | 0.36% | 0.36% | 0.45% | 0.49% | 0.49% | 0.49% | 0.49% |
| **Sample Size** | 1500 | 1300 | 1000 | 800 | 700 | 500 | 400 | 300 | 200 | 200 |

| Permathane™ ACE (Model 1035M) | |
|---|---|
| US Regulatory Approval | March 1987 |
| Registered US Implants | 656 |
| Estimated Active US Implants | 57 |
| 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 99 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
More control. Less risk.

# Pacing Leads

## Acute Observations (Post Implant, ≤30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 1944 | Mar-08 | 1906 | 1743 | 0 | 0.00% | 0 | 0.00% | 4 | 0.21% | 0 | 0.00% | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **5** | **0.26%** | **1** |
| 1948 | Mar-08 | 6705 | 6185 | 0 | 0.00% | 0 | 0.00% | 2 | 0.03% | 2 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **4** | **0.06%** | **2** |
| 1699T/TC | May-07 | 19133 | 16988 | 0 | 0.00% | 0 | 0.00% | 4 | 0.02% | 3 | 0.02% | 2 | 0.01% | 8 | 0.04% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | **18** | **0.09%** | **12** |
| 1888T/TC | Jun-06 | 147345 | 130303 | 19 | 0.01% | 4 | <0.01% | 61 | 0.04% | 51 | 0.03% | 7 | <0.01% | 5 | <0.01% | 3 | <0.01% | 5 | <0.01% | 3 | <0.01% | 13 | 0.01% | **171** | **0.12%** | **55** |
| 1882T/TC | Jun-06 | 10812 | 9622 | 2 | 0.02% | 0 | 0.00% | 9 | 0.08% | 4 | 0.04% | 2 | 0.02% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | **20** | **0.18%** | **4** |
| 1782T/TC | Feb-06 | 12779 | 10515 | 5 | 0.04% | 0 | 0.00% | 8 | 0.06% | 4 | 0.03% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 1 | 0.01% | 2 | 0.02% | **22** | **0.17%** | **10** |
| 1788T/TC | Feb-06 | 60306 | 48259 | 10 | 0.02% | 1 | <0.01% | 32 | 0.05% | 26 | 0.04% | 2 | <0.01% | 2 | <0.01% | 1 | <0.01% | 9 | 0.01% | 2 | <0.01% | 20 | 0.03% | **105** | **0.17%** | **37** |
| 1644T | Apr-05 | 941 | 697 | 0 | 0.00% | 0 | 0.00% | 1 | 0.11% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.11% | **2** | **0.21%** | **1** |
| 1648T | Apr-05 | 2771 | 2035 | 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 | 23479 | 17096 | 0 | 0.00% | 0 | 0.00% | 42 | 0.18% | 5 | 0.02% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 3 | 0.01% | 1 | <0.01% | 0 | 0.00% | **54** | **0.23%** | **31** |
| 1646T | May-02 | 77531 | 53506 | 3 | <0.01% | 2 | <0.01% | 29 | 0.04% | 29 | 0.04% | 0 | 0.00% | 3 | <0.01% | 1 | <0.01% | 6 | 0.01% | 0 | 0.00% | 2 | <0.01% | **75** | **0.10%** | **29** |
| 1688T/TC | Jun-03 | 323486 | 232037 | 34 | 0.01% | 3 | <0.01% | 148 | 0.05% | 107 | 0.03% | 9 | <0.01% | 19 | 0.01% | 5 | <0.01% | 23 | 0.01% | 3 | <0.01% | 27 | 0.01% | **378** | **0.12%** | **137** |

## Chronic Complications (>30 days)

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Cardiac Perforation | | Conductor Fracture | | Lead Dislodgement | | Failure to Capture | | Oversensing | | Failure to Sense | | Insulation Breach | | Abnormal Pacing Impedance | | Extracardiac Stimulation | | Other | | Total | | Total Returned for Analysis |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | |
| 1944 | Mar-08 | 1906 | 1743 | 0 | 0.00% | 0 | 0.00% | 1 | 0.05% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **1** | **0.05%** | **0** |
| 1948 | Mar-08 | 6705 | 6185 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | **2** | **0.03%** | **0** |
| 1699T/TC | May-07 | 19133 | 16988 | 0 | 0.00% | 1 | 0.01% | 8 | 0.04% | 7 | 0.04% | 2 | 0.01% | 2 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **20** | **0.10%** | **9** |
| 1888T/TC | Jun-06 | 147345 | 130303 | 11 | 0.01% | 6 | <0.01% | 72 | 0.05% | 41 | 0.03% | 17 | 0.01% | 2 | <0.01% | 9 | 0.01% | 9 | 0.01% | 2 | <0.01% | 11 | 0.01% | **180** | **0.12%** | **104** |
| 1882T/TC | Jun-06 | 10812 | 9622 | 0 | 0.00% | 0 | 0.00% | 6 | 0.06% | 1 | 0.01% | 2 | 0.02% | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.01% | **11** | **0.10%** | **9** |
| 1782T/TC | Feb-06 | 12779 | 10515 | 0 | 0.00% | 1 | 0.01% | 9 | 0.07% | 9 | 0.07% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | **23** | **0.18%** | **20** |
| 1788T/TC | Feb-06 | 60306 | 48259 | 1 | <0.01% | 2 | <0.01% | 22 | 0.04% | 28 | 0.05% | 9 | 0.01% | 1 | <0.01% | 2 | <0.01% | 8 | 0.01% | 1 | <0.01% | 5 | 0.01% | **79** | **0.13%** | **59** |
| 1644T | Apr-05 | 941 | 697 | 0 | 0.00% | 1 | 0.11% | 0 | 0.00% | 2 | 0.21% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **3** | **0.32%** | **2** |
| 1648T | Apr-05 | 2771 | 2035 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 1 | 0.04% | 0 | 0.00% | 2 | 0.07% | **5** | **0.18%** | **3** |
| 1642T | May-02 | 23479 | 17096 | 0 | 0.00% | 1 | <0.01% | 16 | 0.07% | 8 | 0.03% | 0 | 0.00% | 3 | 0.01% | 0 | 0.00% | 1 | <0.01% | 0 | 0.00% | 1 | <0.01% | **30** | **0.13%** | **11** |
| 1646T | May-02 | 77531 | 53506 | 1 | <0.01% | 10 | 0.01% | 14 | 0.02% | 47 | 0.06% | 9 | 0.01% | 2 | <0.01% | 0 | 0.00% | 17 | 0.02% | 0 | 0.00% | 9 | 0.01% | **109** | **0.14%** | **28** |
| 1688T/TC | Jun-03 | 323486 | 232037 | 6 | <0.01% | 54 | 0.02% | 158 | 0.05% | 223 | 0.07% | 109 | 0.03% | 12 | <0.01% | 17 | 0.01% | 119 | 0.04% | 3 | <0.01% | 52 | 0.02% | **753** | **0.23%** | **337** |

*Definitions of observations and complications can be found on pages 6-7.*

## Lead Malfunctions

| Models | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Conductor Fracture | | Insulation Breach | | Crimps, Welds & Bonds | | Other | | Extrinsic Factors | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate | Qty. | Rate |
| 1944 | Mar-08 | 1906 | 1743 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 1948 | Mar-08 | 6705 | 6185 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | **0** | **0.00%** |
| 1699T/TC | May-07 | 19133 | 16988 | 1 | 0.01% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 7 | 0.04% | **8** | **0.04%** |
| 1888T/TC | Jun-06 | 147345 | 130303 | 1 | <0.01% | 7 | <0.01% | 0 | 0.00% | 5 | <0.01% | 87 | 0.06% | **100** | **0.07%** |
| 1882T/TC | Jun-06 | 10812 | 9622 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 6 | 0.06% | **6** | **0.06%** |
| 1782T/TC | Feb-06 | 12779 | 10515 | 1 | 0.01% | 2 | 0.02% | 0 | 0.00% | 0 | 0.00% | 15 | 0.12% | **18** | **0.14%** |
| 1788T/TC | Feb-06 | 60306 | 48259 | 0 | 0.00% | 17 | 0.03% | 1 | <0.01% | 7 | 0.01% | 37 | 0.06% | **62** | **0.10%** |
| 1644T | Apr-05 | 941 | 697 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 2 | 0.21% | **2** | **0.21%** |
| 1648T | Apr-05 | 2771 | 2035 | 0 | 0.00% | 0 | 0.00% | 0 | 0.00% | 1 | 0.04% | 2 | 0.07% | **3** | **0.11%** |
| 1642T | May-02 | 23479 | 17096 | 0 | 0.00% | 1 | <0.01% | 2 | 0.01% | 7 | 0.03% | 9 | 0.04% | **19** | **0.08%** |
| 1646T | May-02 | 77531 | 53506 | 5 | 0.01% | 5 | 0.01% | 1 | <0.01% | 6 | 0.01% | 22 | 0.03% | **39** | **0.05%** |
| 1688T/TC | Jun-03 | 323486 | 232037 | 76 | 0.02% | 74 | 0.02% | 16 | <0.01% | 6 | <0.01% | 202 | 0.06% | **374** | **0.12%** |
| 1488T/TC | Mar-00 | 273469 | 134368 | 120 | 0.04% | 75 | 0.03% | 13 | <0.01% | 2 | <0.01% | 235 | 0.09% | **445** | **0.16%** |

*Definitions of malfunction categories can be found on pages 7 and 8.*

# Implantable Cardiac Monitors

St. Jude Medical™

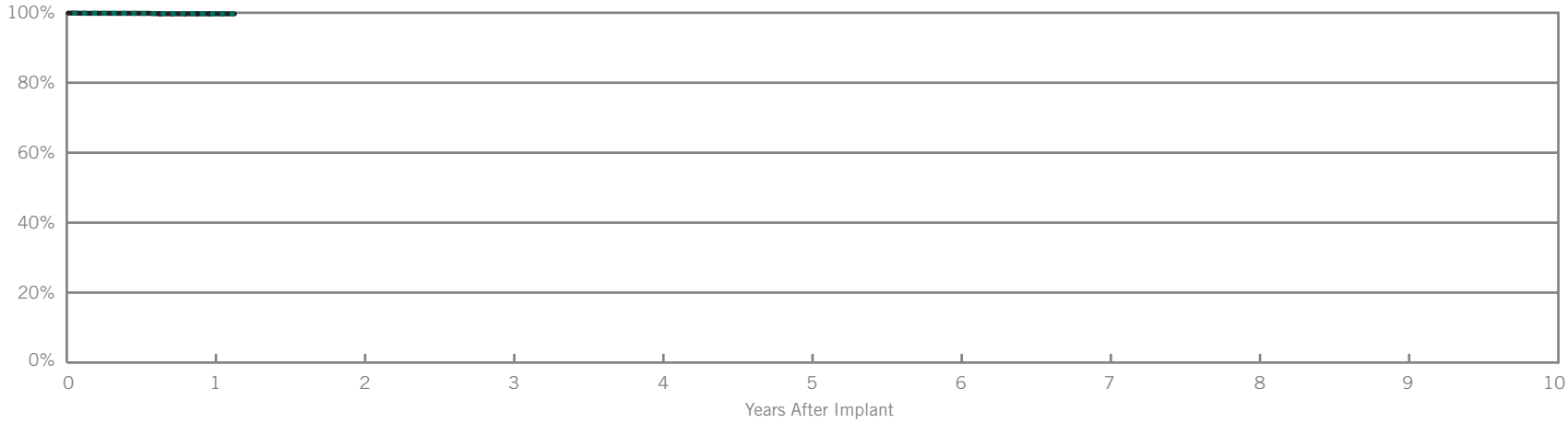
More control. Less risk.

# Implantable Cardiac Monitors

## SJM Confirm® (Model DM2100)

| | | | |
|---|---|---|---|
| US Regulatory Approval | August 2008 | Normal Battery Depletion | 0 |
| Registered US Implants | 3,289 | Total Malfunctions | 4 |
| Estimated Active US Implants | 2,912 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 3.0 Years* | Malfunctions w/o Compromised Therapy | 4 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.70% | 99.70% | | | | | | | | |
| ± 1 standard error | 0.12% | 0.12% | | | | | | | | |
| Sample Size | 2200 | 400 | | | | | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.70% | 99.70% | | | | | | | | |
| ± 1 standard error | 0.12% | 0.12% | | | | | | | | |

**After 12 month shelf-life.*

# Summary Information

## Implantable Cardiac Monitors

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# Implantable Cardiac Monitors

## Malfunction Summary Information

| Models | Family | US Regulatory Approval | Registered US Implants | Estimated Active US Implants | Confirmed Malfunctions |
|---|---|---|---|---|---|
| DM2100 | SJM Confirm® | Aug-08 | 3,289 | 2,912 | 4 |

# Focus on Clinical Performance

St. Jude Medical™

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# Focus on Clinical Performance

## Optim® Lead Insulation

In June 2006 St. Jude Medical brought to the cardiac rhythm management (CRM) market the first novel insulation technology in over 20 years: a silicone-polyurethane co-polymer known as Optim® insulation featured in Tendril® ST Optim® lead models 1888T/TC and 1882T/TC. This was rapidly followed in July 2006 by an Optim-insulated defibrillation lead, the Riata® ST Optim® lead model 7020/7021. Optim lead insulation consolidates the best characteristics of two established CRM lead insulation materials, polyurethane and silicone. The polyurethane content of Optim insulation imparts lubricity, strength, and abrasion resistance while the nearly 50% silicone content imparts flexibility and biostability.[1,2] The clinical performance of Optim insulation proved to be excellent,[3] leading to the subsequent market release of several Optim-insulated leads: IsoFlex® Optim® lead model 1944/1948 in March 2008, QuickFlex® µ lead model 1258T in March 2009*, and OptiSense® lead model 1999 in January 2010.

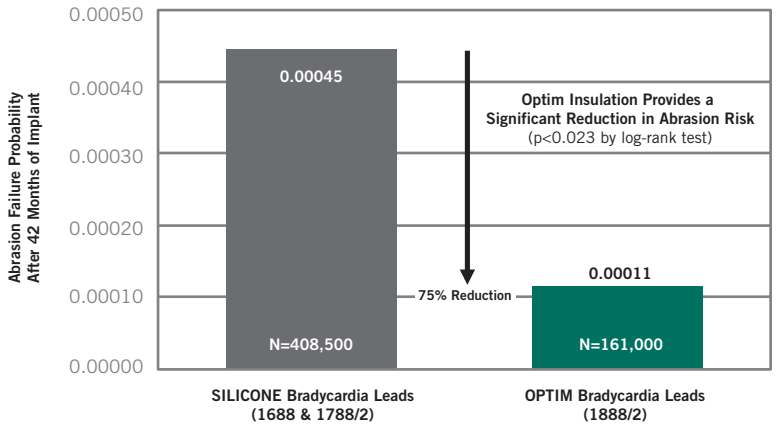
Now that Optim insulation has been on the market for more than 3 years, with over 250,000 leads implanted in the U.S., a thorough analysis of Optim insulation performance is possible. All aspects of Optim lead performance can be appreciated by referring to the Acute Observation, Chronic Complication, and Lead Malfunction tables found in this performance report. The most noteworthy reliability benefit of Optim lead insulation is a significant reduction in the most common mode of lead malfunction: insulation abrasion.[4] Insulation abrasion can occur as a result of lead contact with pacemakers, ICDs, adjacent leads, or anatomical structures and can occur in the subcutaneous, intravascular, or intracardiac areas of the lead. The clinical effects associated with abrasion malfunctions can include sensing noise and changes in both pacing and defibrillation impedances and thresholds.

In order to validate the benefits of Optim insulation in reducing insulation abrasion malfunctions, a Kaplan-Meier analysis was performed on both the Tendril and Riata®/Durata® lead families. This statistical analysis compared the clinical occurrence of insulation abrasion malfunctions found on silicone-insulated leads and Optim-insulated leads during their first three years on the market. A log-rank test was then used to verify the statistical significance of any difference in the insulation abrasion malfunction probabilities.

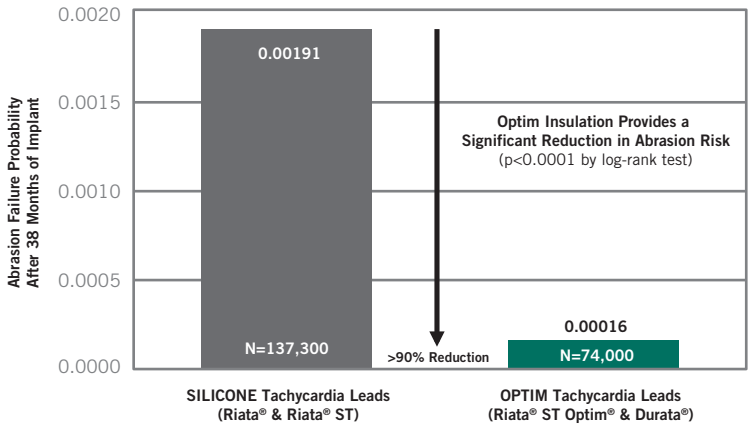
*European market release. Not market released in the U.S. at the time of this performance report publication.

The two graphs below demonstrate that the presence of Optim® insulation in CRM pacing and defibrillation leads reduces the probability of abrasion malfunction by 75-90+% after more than 3 years of implant. The time points selected for the graphs (42 months for Tendril® leads and 38 months for Riata®/Durata® leads) represent the longest duration Optim insulation data available for each model family. These dramatic reductions in abrasion malfunction probability were confirmed to be statistically significant ($p \ll 0.05$).

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




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




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

# 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<br>(Models V-197, V-235, V-337, V-338, V-339),<br>Epic® + ICDs<br>(Models V-196, V-233, V-236, V-239, V-350)<br>Epic® II ICDs<br>(Models V-158, V-255, V-258, V-355, V-356, V-357)<br>Atlas® + ICDs<br>(Model V-340, V-341, V-343, V-193, V-242, V-243)<br>Atlas® II ICDs<br>(Models V-168, V-265, V-268, V-365, V-366, V-367) | 01/16/08<br>Class II<br>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.<br><br>St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended.<br><br>**Current Status (December 31, 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 December 31, 2009 there have been no additional devices confirmed to have this issue since the time of the advisory. |
| Identity® SR (5172)<br>Identity® DR (5370)<br>Identity® XL DR (5376) | 10/12/06<br>Class II<br>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.<br><br>**Current Status (December 31, 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 December 31, 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<br>Class II<br>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.<br><br>To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends:<br>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.<br>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.<br>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.<br><br>**Current Status (December 31, 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 December 31, 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<br>Class II<br>Two anomalies have been identified:<br>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.<br>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:<br>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.<br><br>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.<br><br>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.<br><br>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.<br><br>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.<br><br>**Current Status (December 31, 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),<br>Epic®+ (V-196, V-236),<br>Epic® HF (V-338), Epic®+ HF (V-250),<br>Atlas®+ (V-193, V-243),<br>Atlas®+ HF (V-340),<br>or Atlas® (model V-242) ICDs | 3/10/05<br>Class II<br>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.<br><br>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.<br><br>**Current Status (December 31, 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<br>Class II<br>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.**<br><br>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:<br>Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower<br>Autocapture programmed ON<br>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.<br><br>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.<br><br>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.<br><br>**Current Status (December 31, 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<br>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.<br>The following recommendations are made:<br>Physicians are advised to review patients who have 1256D/2102 pacemakers at an early date to evaluate pacemaker function.<br><br>**For patients who are pacemaker dependent,** the physician should give consideration to explantation and replacement as soon as practicable.<br><br>**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<br>Class II<br>Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion. | This Advisory applies to a well-defined group of Tempo™ and Meta™ 1256D pacemakers which have been observed to exhibit premature battery depletion. This is an extension of a previous Tempo™/Meta™ advisory dated 6/6/00. The following recommendations are made:<br><br>**For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated.<br><br>**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<br>Class II<br>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.<br><br>If these capacitors fail, two different clinical manifestations may be observed, depending on the location of the failed capacitors:<br>**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.<br><br>**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<br>Class II<br>Integrated circuit failure due to electrostatic discharge during manufacturing resulting in no output or sensing anomalies. | This Advisory applies to a well-defined group of Meta™ 1256 pacemakers, which have been observed to exhibit decreased reliability. The following recommendations are made:<br><br>**For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated.<br><br>**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<br>Class II<br>Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion. | This Advisory applies to a well-defined group of Tempo™ and Meta™ 1256D pacemakers, which have been observed to exhibit premature battery depletion. The following recommendations are made:<br><br>**For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pacemaker prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pacemakers on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pacemaker replacement is medically contraindicated.<br><br>**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<br>Class II<br>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:<br>Interrogation/programming difficulties, including the presence of dashes (—) on the programmer screen for some parameter values after interrogation<br>Unexpected rate variations<br>Abnormally high battery current drain<br>Mode change<br>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.<br><br>Considering the low level of incidence of this anomaly, the following steps are recommended:<br>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.<br>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.<br>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<br>Class II<br>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:<br>Abnormal measured battery data,<br>A false recommended replacement (RRT) indication,<br>Reversion to back-up VVI mode,<br>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).<br><br>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<br>Class II<br>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.<br>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.<br>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:<br>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.<br>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.<br><br>If the battery impedance reading is 1 kOhm or higher and the pacemaker has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services. |

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

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