# Product Performance Report

## Cardiac Rhythm Management

April 2009

St. Jude Medical

More control. Less risk.

# Letter from St. Jude Medical

## April 2009

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

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

This is the second report to include data from St. Jude Medical's Product Longevity and Performance Registry (SCORE). SCORE is an active, ongoing source of information on the reliability and performance of St. Jude Medical's cardiac rhythm management products. Unlike other active registries, SCORE tracks information on multiple product families, including leads as well as ICD and pacemaker models, making it the most comprehensive registry in the industry. This prospective, non-randomized, multi-center registry complements the data gathered from returned product analysis. In addition to helping determine and report survival probabilities, the data from this registry may also be used to support design and development of new cardiac rhythm management products.

SCORE started enrolling patients in June 2007. The registry will actively monitor indefinitely the performance of implanted St. Jude Medical products at participating sites and is thus designed to include new products as they become available. SCORE is just one example of how we are working to reduce risk, and set new standards for quality and performance.

St. Jude Medical also recognizes the value of the industry working together to provide transparent and consistent information on the performance of cardiac rhythm management products. Following the 2005 Policy Conference on Pacemaker and ICD Device Performance, cardiac device companies worked through AdvaMed to establish "Requirements for Uniform Reporting of Clinical Performance of Pulse Generators." St. Jude Medical adopted the proposal, which sets forth the definitions and requirements for product performance reports and seeks to provide physicians and their patients with a level of 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 ICDs, pacemakers and lead systems.

Sincerely,

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

St. Jude Medical™
More control. Less risk.

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## Serving our mission

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

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

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

## What you'll find in this report

For all ICDs starting with Photon® Micro device and for all pacemakers starting with Affinity® device, you will find the analysis of data, according to the AdvaMed guidelines, collected through December 31, 2008, including:

- A graph of survival probability that reflects reasons for device removal (including normal battery depletion, malfunction with compromised therapy, and malfunction without compromised therapy). It includes non-returned devices removed from service for battery depletion with no associated complaint as normal battery depletions;
- A graph of survival probability that excludes normal battery depletion in the Analysis;
- A table that accompanies and summarizes the data in each graph; and
- An update to Advisories on implantable devices starting in 2003.

# Introduction and Overview

Additional tables for ICDs starting with Photon® Micro and pacemakers starting with Affinity that aggregate and summarize the data in the report can be found for Cardiac Resynchronization Therapy (CRT) ICDs on page 25, for CRT-Pulse Generators page 35, for ICDs pages 69 and 89 and for Pulse Generators pages 147 and 173.

For ICDs prior to Photon® Micro device and pacemakers prior to Affinity® device, you will find analysis of the data collected through December 31, 2008, consistent with previous product performance reports. These device models include:

**ICDs**

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

**Pulse Generators (Pacemakers)**

Trilogy® DC+ 2318
Trilogy® DR+ 2360, 2364
Paragon™ III 2304, 2314, 2315
Paragon™ II 2016
Paragon 2010, 2011, 2012
Synchrony® III 2028, 2029
Synchrony® II 2022, 2023
AddVent® 2060
Microny® 2425T, 2525T, 2535K
Regency® SC+ 2400L, 2402L
Tempo® V 1102
Tempo® VR 1902
Trilogy® SR+ 2260, 2264
Trilogy® SR 2250
Solus® II 2006, 2007
Solus® 2002, 2003
Phoenix® III 2204, 2205
Phoenix® II 2005, 2008, 2009

For all CRT leads, defibrillation leads, and pacing leads, you will find analysis of the data collected through December 31, 2008. Laboratory analysis of the most recently released CRT leads, defibrillation leads, and pacing leads returned from the U.S. market is summarized by model. The laboratory analysis results are categorized into one of the following three categories:

- **Implant Damage -** obvious damage incurred at the time of attempted implant, including but not limited to insulation cuts and damage, helix overtorque, and stylet perforation.
- **Electrical Malfunction -** a disruption in the insulation or conductors resulting in compromised electrical performance. Electrical malfunction data are further broken down into one of the following three subcategories:
  - *Insulation Disruption -* leads exhibiting wear and abrasion that extends through the insulation and exposes the conductors.
  - *Conductor Disruption -* leads exhibiting cable and coil fractures, including those attributed to subclavian crush.
  - *Crimps, Welds, Bonds -* leads exhibiting malfunctions related to crimps, welds, and bonds.

- **Other -** includes other returns not attributed to damage incurred at the attempted implant and not resulting in compromised electrical failures. The Other category of data is further broken down into one of the following four subcategories:
  - *Explant Damage* - leads exhibiting physical damage incurred at the time of explant.
  - *Non-Electrical Workmanship* - leads exhibiting some out of specification mechanical condition, such as a bent connector pin or helix anomaly.
  - *Non-Electrical Anomaly* - leads not associated with a complaint but exhibiting some anomalous condition that did not result in an electrical malfunction. An example would be a lead exhibiting some insulation disruption that did not extend through and therefore did not compromise the function of the lead.
  - *Partial Lead* - leads with an alleged malfunction that are returned not in its entirety; as a result, it was not possible to perform a complete analysis and confirm the malfunction.

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

**Defibrillation Leads**

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

**Pacing Leads**

Tendril® 1148, 1188T
Tendril® DX 1388T/TC
Fast-Pass® 1018T, 1028T
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
ACE® 1015M, 1025M, 1026T, 1016T

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

**ICDs and Pulse Generators (Pacemakers)**

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

# Introduction and Overview

**Leads**

US Market Release Date
Registered Number of US Implants
Estimated Number of Active US Implants
Lead Type and/or Fixation
Insulation Material
Polarity
Steroid
Number of Advisories
Laboratory Analysis Results (for the most recent market released models)

## What's new in this report

### SCORE Registry Data:

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

To ensure a sufficiently large and appropriately representative source of data, 45 clinical sites are participating in the SCORE Registry with over 2,800 patients enrolled as of December 31, 2008. Using a common protocol, these sites are individually monitoring and reporting on the performance of St. Jude Medical cardiac rhythm management products used at their site.

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

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

**ICDs**

Promote RF (Model 3207-36)

Current DR RF (Model 2207-36)

Current VR RF (Model 1207-36)

**Defibrillation Leads**

Durata (Models 7120/7121)

Riata ST Optim (Models 7020/7021)

**Pacemakers**

Zephyr DR (Model 5826)

Victory XL DR (Model 5816)

**Pacing Leads**

Tendril ST Optim (Model 1888)

Tendril (Model 1788)

Tendril SDX (Model 1688)

Optisense (Model 1699)

Isoflex S (Model 1646)

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

## Adjustment Factor for Pacemakers and ICDs (including CRT Devices)

St. Jude Medical is committed to providing transparent and consistent information on product performance to our physicians and their patients. Beginning with the April 2009 Product Performance Report (PPR), we are reporting ICD and pacemaker survivability in a manner that is more consistent with new industry standards. Specifically, the company is employing a new method to adjust for bias due to under-reporting of devices. Previously, St. Jude Medical employed a method to adjust for under-reporting of pacemakers. This method, however, has been revised as the result of a joint collaboration with other cardiac device companies under the auspices of AdvaMed. It establishes uniform reporting standards for ICDs and pacemakers to ensure more consistency among device manufacturers. As a result of this change in calculation methods, you will notice:

- Somewhat lower survival probability charts for ICD models, as this is the first time ICD data has been adjusted for under-reporting
- Somewhat higher survival probability charts for pacemaker models, as the previous methodology used in 2006 to adjust for under-reporting was more conservative than the new methodology

These changes do not have any effect on longevity estimates or any impact to device performance in the field. Furthermore, this does not alter the fact that the survival charts, even with these changes, still demonstrate that St. Jude Medical device families meet or exceed the estimated longevity as stated in the User's Manuals. To help readers with this, we have combined the including and excluding battery depletion survival curves into one chart and also added a horizontal longevity estimate bar on the same chart. For ICDs, this longevity bar represents the range of longevities for each model as stated in the User's Manual, corresponding to 100% pacing to no pacing. For pacemakers, the longevity bar represents a 90% confidence range for nominal longevity. Also, to accommodate the above enhancements, the survival probability charts will be presented in landscape format starting with the April 2009 PPR.

# Introduction and Overview

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 continued support and allowing St. Jude Medical to positively impact the lives of the patients you serve on a daily basis.

## Methodology

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

## Industry Standards

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

## How St. Jude Medical measures product performance

For 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 of 20 years, with a minimum of 500 registered implants required for inclusion in the report, and a minimum sample size for each time period of 200 devices. The data for the analysis covers all documented implants in the United States, and includes the analysis of all domestically implanted pulse generators returned to St. Jude Medical. The analysis measures device performance to specification, and does not reflect medical complications such as infection, erosion, muscle stimulation or inhibition, or units implanted for fewer than 24 hours.

"Survival" refers to the proper function of the device, not the survival of the patient, and is intended to illustrate the calculated probability of device survival at a given point in time. A survival probability of 99% at five years, for example, indicates that at five years after implant, the system has a 1% risk of incurring a malfunction and/or normal battery depletion. All devices within each model family (except where noted) 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 data in this report to be accurately representative of each device's performance, regardless of where in the world it was implanted.

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

Implanted cardiac leads are subjected to constant, complex flexural and torsional forces, interactions with other leads and/or the pulse generator device, plus other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. As such, cardiac leads' functional lifetimes are therefore limited and indeed, their functional longevity can not be predicted with a high degree of confidence. As a supplement to the survival estimates, product returns analysis results emphasize 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 as a result of device replacement or patient death. Our Patient Records department can be reached at 888-SJM-CRMD or 818-362-6822.

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

- Call St. Jude Medical Cardiac Rhythm Management Customer Service at 800-681-9293
- Fax St. Jude Medical Cardiac Rhythm Management Customer Service at 866-805-3405
- Email St. Jude Medical Cardiac Rhythm Management Customer Service at lit@sjm.com

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

## Definitions

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

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

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

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

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

*AdvaMed Proposal – Requirema4ents for Uniform Reporting of Clinical Performance of Pulse Generators.

**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 or Power-On Reset [POR]) that do not result in loss of critical patient protective therapies but are the reported reasons for explant shall be categorized as a Malfunction without Compromised Therapy.*

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

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

As a result of the use of the adjustment factor to account for bias due to under-reporting, the number of normal battery depletions identified for pacemaker models has changed from previous versions of this report. Specifically, the quantity of normal battery depletions is based on the confirmed number from product return analysis.

*AdvaMed Proposal – Requirema4ents for Uniform Reporting of Clinical Performance of Pulse Generators.

# Cardiac Resynchronization Therapy

## CRT ICDs

St. Jude Medical

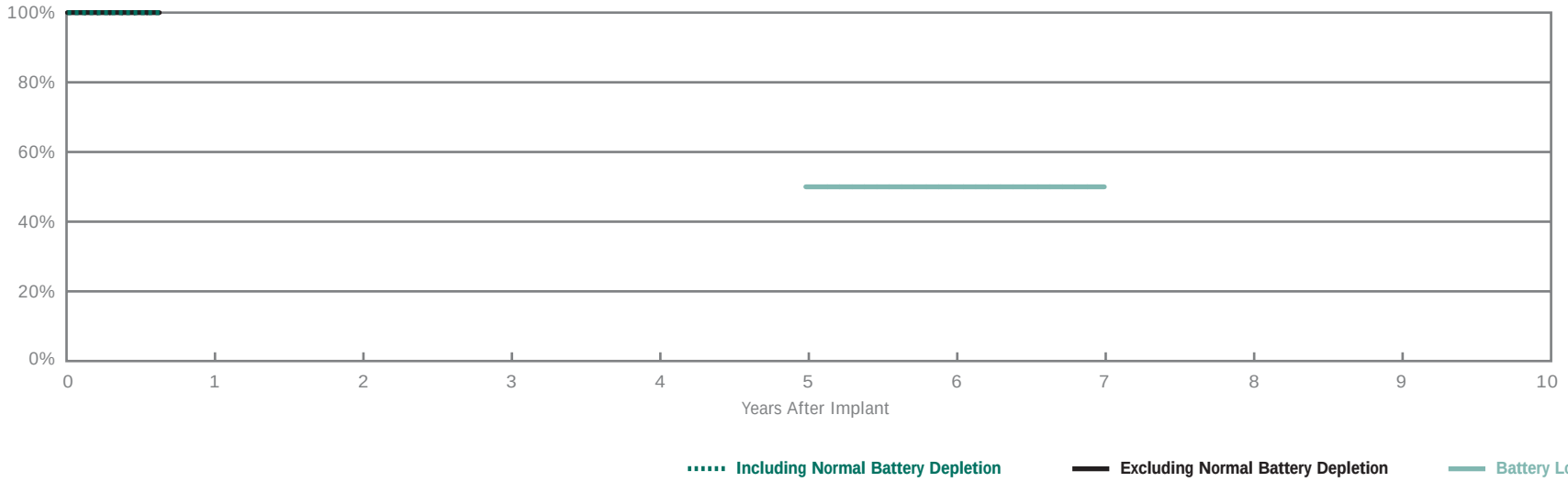
More control. Less risk.

# Cardiac Resynchronization Therapy

## Promote® RF (Model 3207-30)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 596 | Malfunctions | 0 |
| Estimated Active US Implants | 559 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 400 | | | | | | | | | |

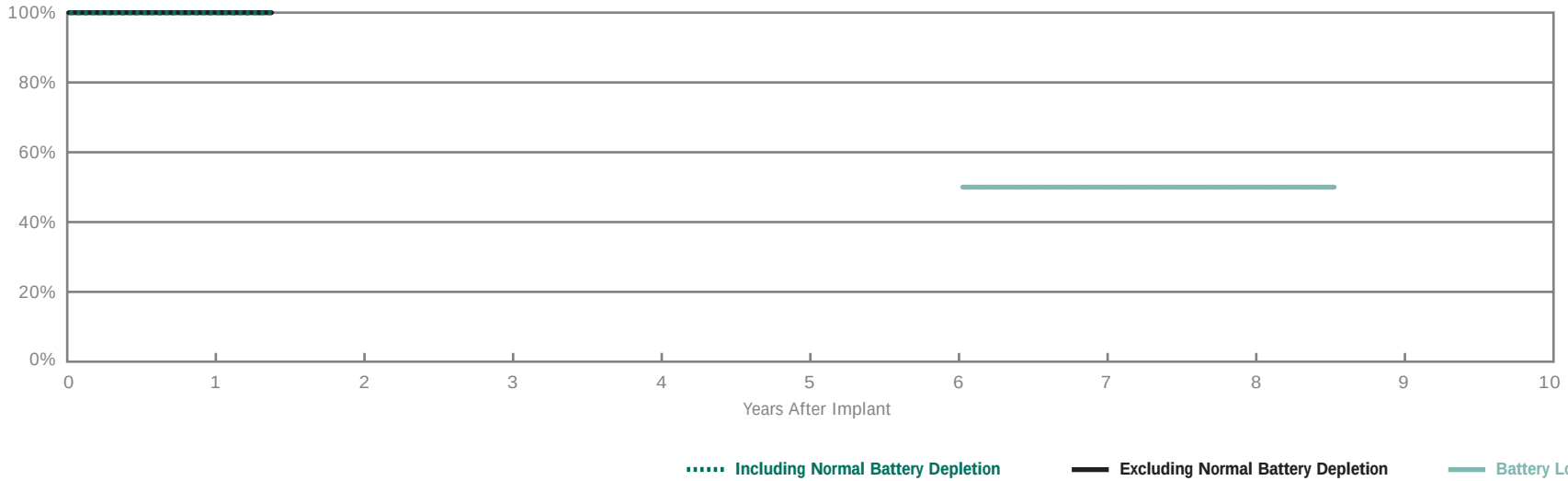
**Excluding Normal Battery Depletion**

| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

## Promote® (Model 3107-36)

| | | | |
|---|---|---|---|
| US Market Release | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 679 | Malfunctions | 0 |
| Estimated Active US Implants | 558 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | 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 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 600 | 400 | | | | | | | | |

**Excluding Normal Battery Depletion**

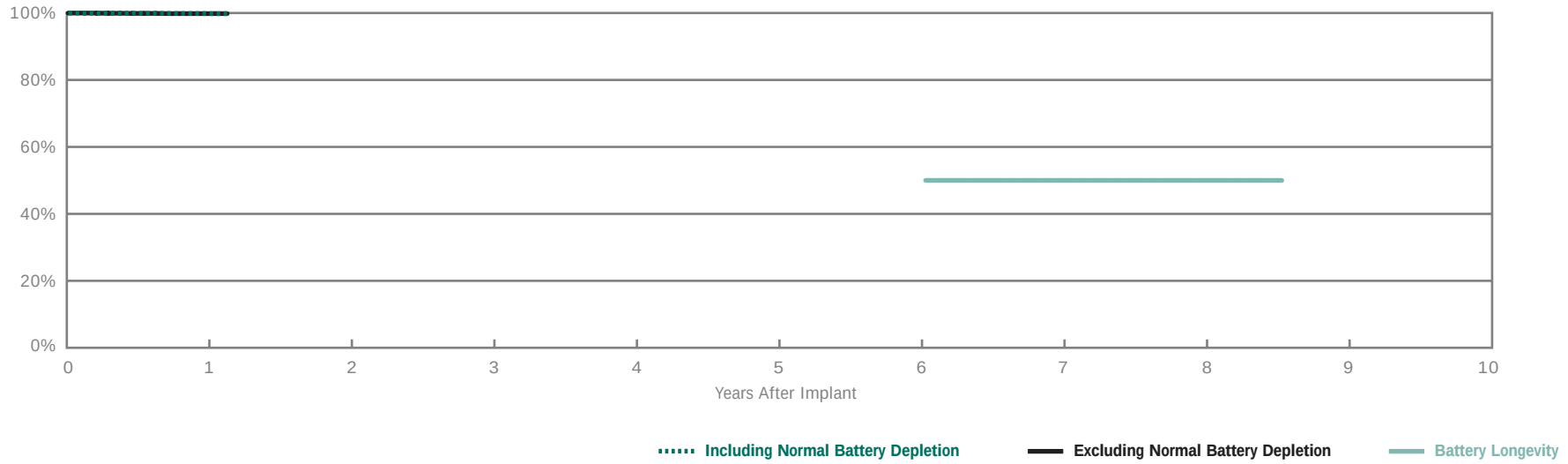
| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

# Cardiac Resynchronization Therapy

## Promote® RF (Model 3207-36)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 1 |
| Registered US Implants | 12,177 | Malfunctions | 7 |
| Estimated Active US Implants | 11,371 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy | 7 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.80% | 99.80% | | | | | | | | |
| ± 1 standard error | 0.06% | 0.06% | | | | | | | | |
| Sample Size | 6900 | 400 | | | | | | | | |

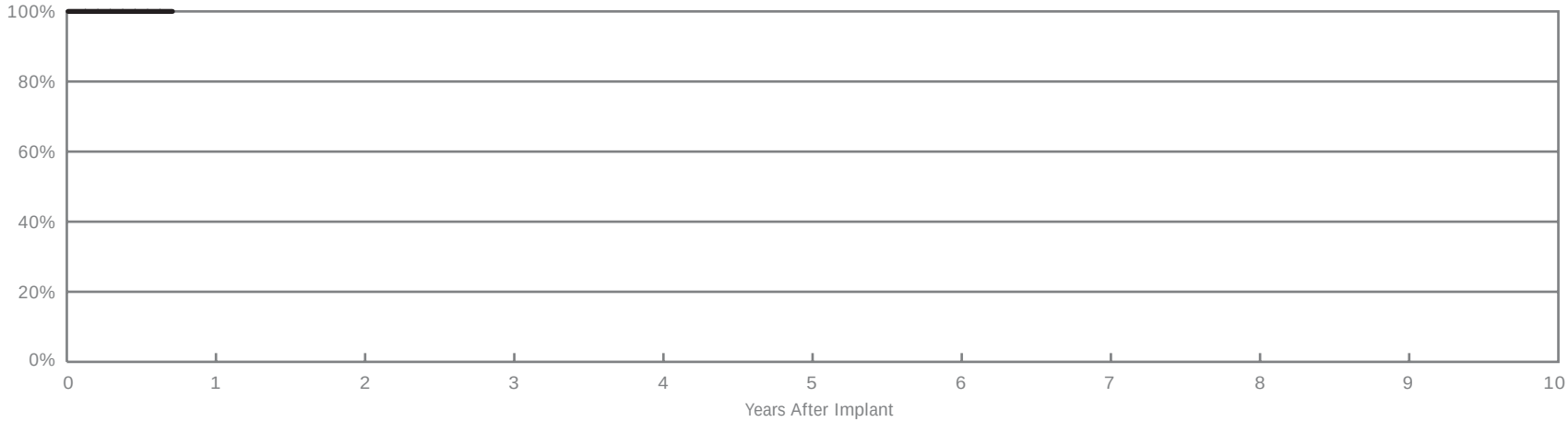
**Excluding Normal Battery Depletion**

| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.82% | 99.82% | | | | | | | | |
| ± 1 standard error | 0.06% | 0.06% | | | | | | | | |

| Promote® RF (Model 3207-36) | |
|---|---|
| **SCORE Results** | |
| Number of Devices Enrolled in Study | 215 |
| Cumulative Months of Follow-Up | 1,525 |

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

## Survival from SCORE Registry



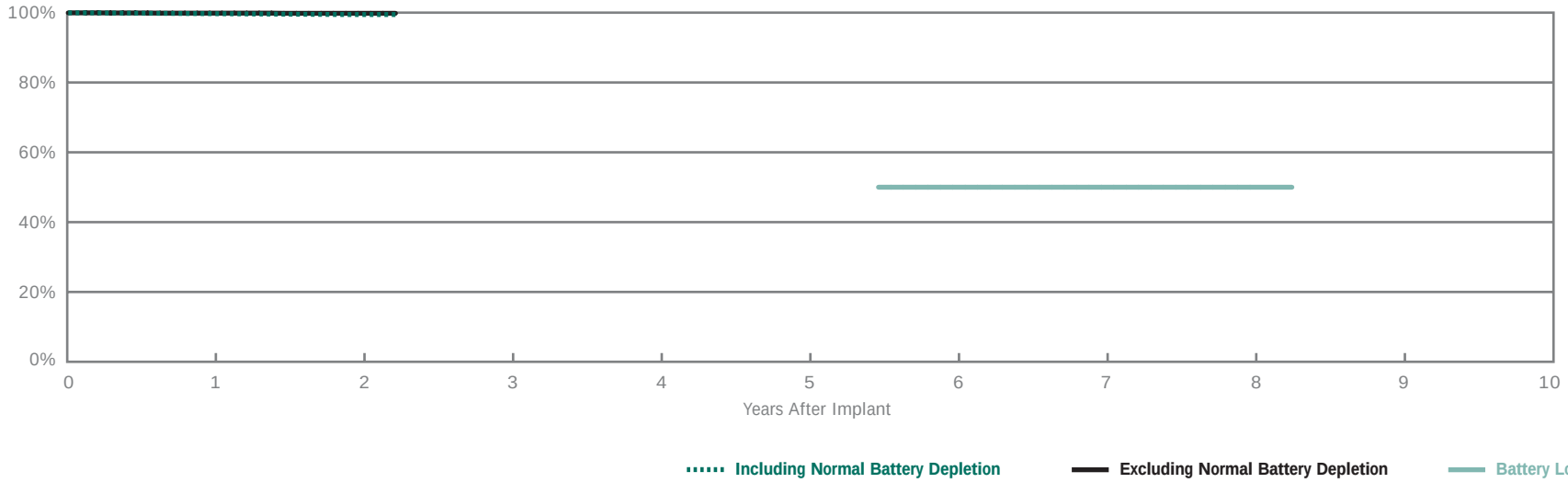

| Year | at 9 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100% | | | | | | | | | |
| **± 1 standard error** | 0.00% | | | | | | | | | |
| **Sample Size** | 60 | | | | | | | | | |

# Cardiac Resynchronization Therapy

## Atlas® II HF (Model V-365)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Normal Battery Depletion | 6 |
| Registered US Implants | 8,346 | Malfunctions | 7 |
| Estimated Active US Implants | 6,716 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 3 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 4 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.46% | 99.46% | | | | | | |
| ± 1 standard error | 0.04% | 0.13% | 0.13% | | | | | | |
| Sample Size | 7800 | 3800 | 500 | | | | | | |

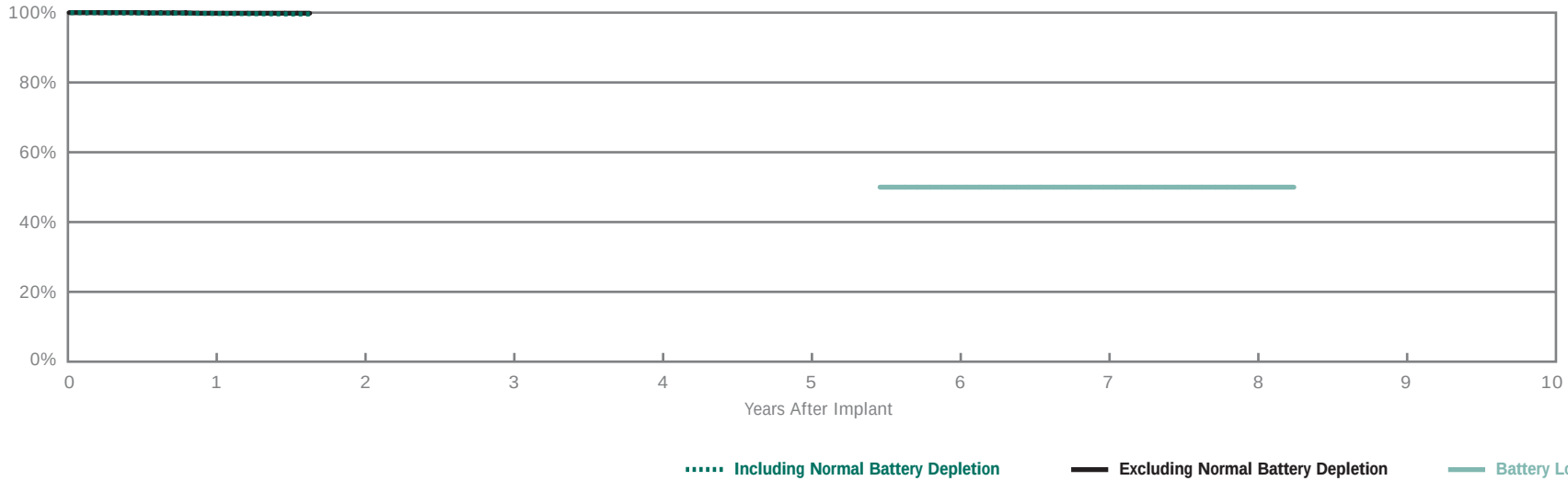
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 98.81% | 99.81% | | | | | | |
| ± 1 standard error | 0.04% | 0.06% | 0.06% | | | | | | |

## Atlas® II + HF (Model V-366)

| | | | |
|---|---|---|---|
| US Market Release | February 2007 | Normal Battery Depletion | 3 |
| Registered US Implants | 3,845 | Malfunctions | 2 |
| Estimated Active US Implants | 3,350 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy | 2 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.61% | 99.61% | | | | | | | | |
| ± 1 standard error | 0.10% | 0.13% | | | | | | | | |
| Sample Size | 3100 | 1000 | | | | | | | | |

**Excluding Normal Battery Depletion**

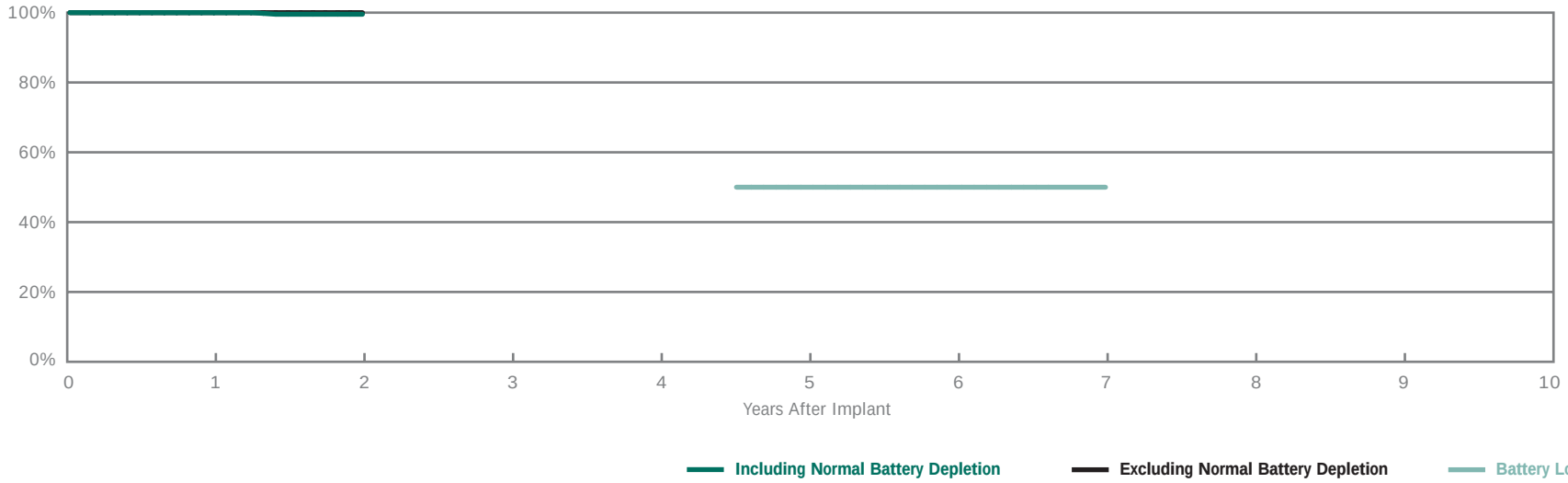
| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.83% | | | | | | | | |
| ± 1 standard error | 0.08% | 0.08% | | | | | | | | |

# Cardiac Resynchronization Therapy

## Epic® II HF (Model V-355)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Normal Battery Depletion | 2 |
| Registered US Implants | 1,604 | Malfunctions | 0 |
| Estimated Active US Implants | 1,279 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.54% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.23% | | | | | | | | |
| Sample Size | 1500 | 700 | | | | | | | | |

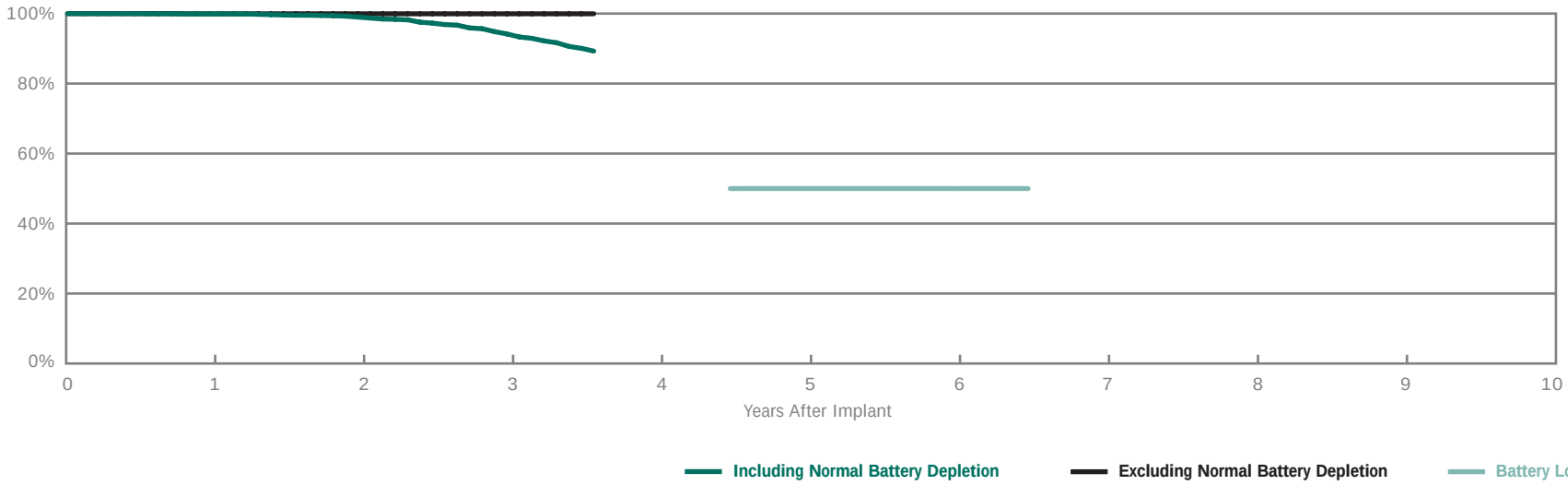
**Excluding Normal Battery Depletion**

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

## Epic® HF (Model V-337)

| | | | |
|---|---|---|---|
| US Market Release | November 2004 | Normal Battery Depletion | 78 |
| Registered US Implants | 3,952 | Malfunctions | 1 |
| Estimated Active US Implants | 2,300 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 1 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 43 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.01% | 94.18% | 89.28% | | | | | | |
| ± 1 standard error | 0.06% | 0.16% | 0.52% | 1.00% | | | | | | |
| Sample Size | 3900 | 3200 | 2000 | 600 | | | | | | |

**Excluding Normal Battery Depletion**

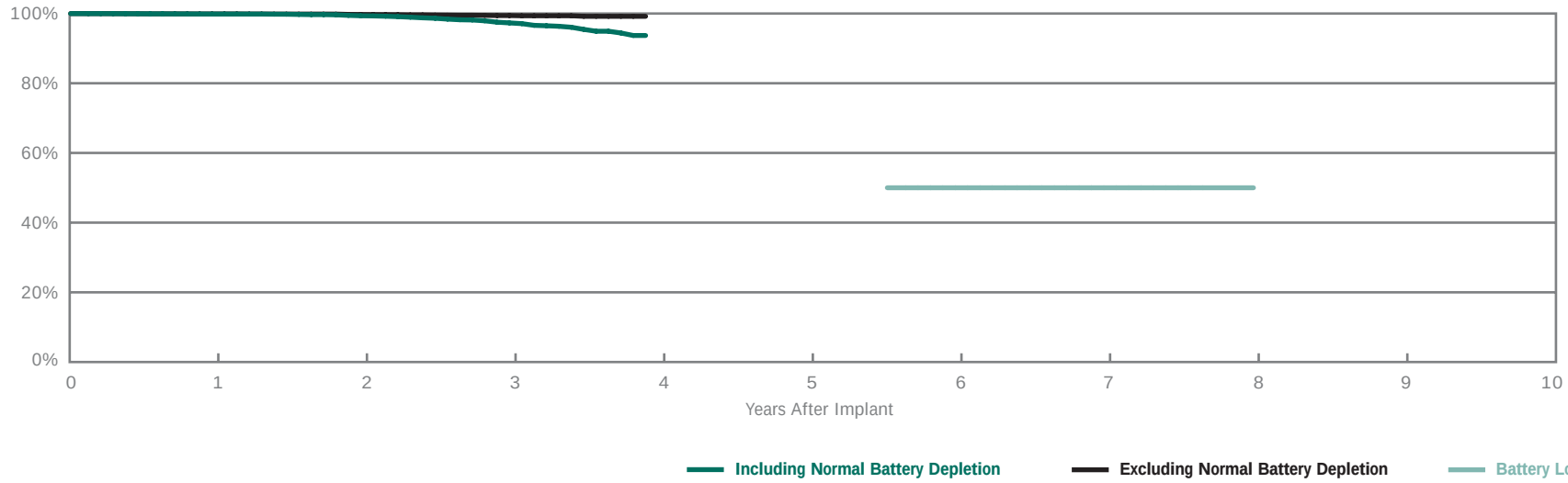
| Year | 1 | 2 | 3 | at 43 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.94% | 99.94% | 99.94% | | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.04% | 0.04% | | | | | | |

# Cardiac Resynchronization Therapy

## Atlas® + HF (Model V-343)

| | | | |
|---|---|---|---|
| US Market Release | November 2004 | Normal Battery Depletion | 117 |
| Registered US Implants | 18,245 | Malfunctions | 36 |
| Estimated Active US Implants | 12,238 | Malfunctions w/ Compromised Therapy (1 related to Advisory) | 23 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 13 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 47 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.36% | 97.31% | 93.70% | | | | | | |
| ± 1 standard error | 0.03% | 0.06% | 0.18% | 0.66% | | | | | | |
| Sample Size | 18200 | 14000 | 7800 | 2000 | | | | | | |

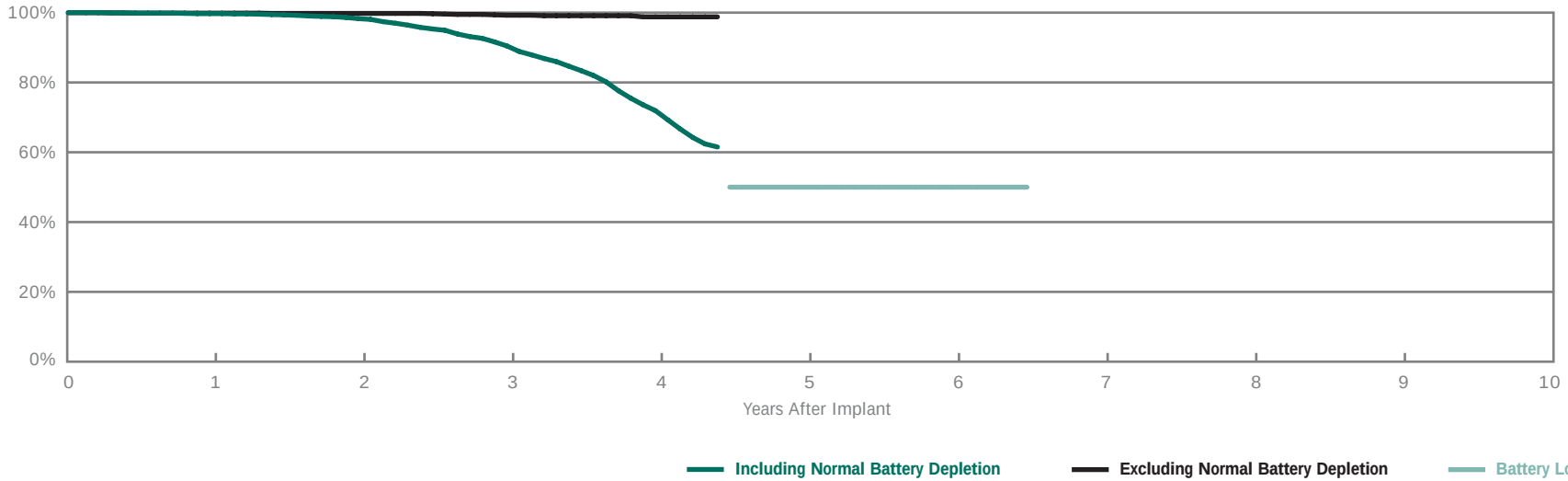
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | at 47 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.72% | 99.42% | 99.20% | | | | | | |
| ± 1 standard error | 0.03% | 0.04% | 0.08% | 0.14% | | | | | | |

## Epic® HF (Model V-338)

| | | | |
|---|---|---|---|
| US Market Release | June 2004 | Normal Battery Depletion | 267 |
| Registered US Implants | 3.095 | Malfunctions | 10 |
| Estimated Active US Implants | 811 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 2 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 8 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.71% | 98.28% | 90.45% | 71.90% | 61.51% | | | | | |
| ± 1 standard error | 0.10% | 0.23% | 0.60% | 1.23% | 1.68% | | | | | |
| Sample Size | 3100 | 2700 | 2300 | 1400 | 400 | | | | | |

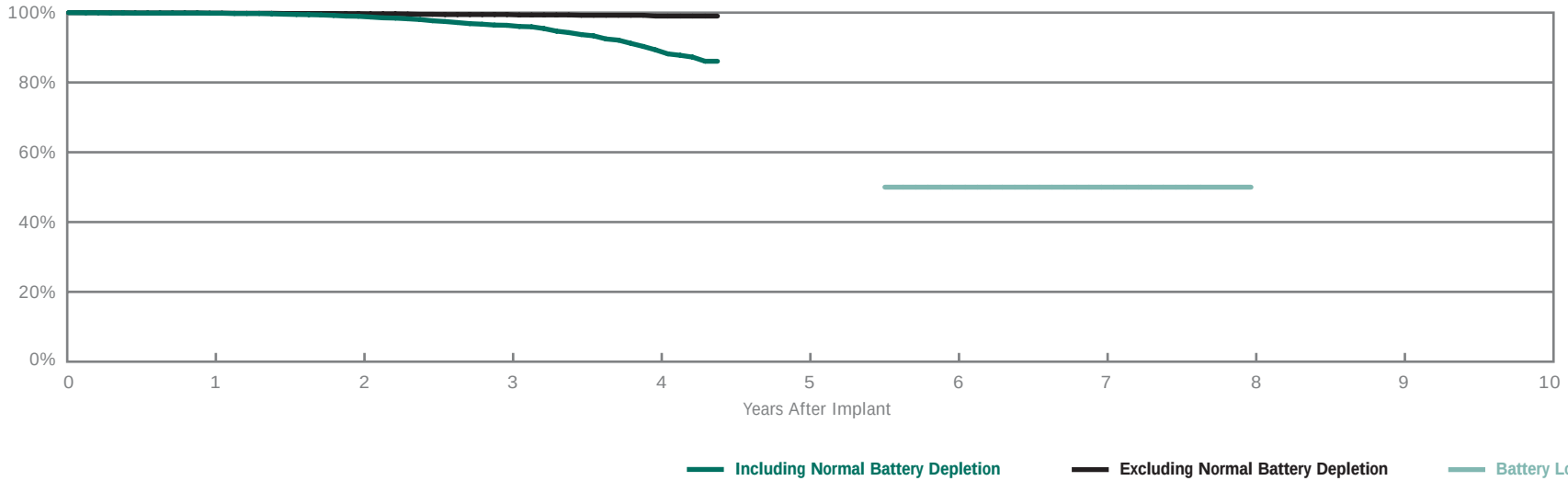
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.78% | 99.26% | 98.79% | 98.79% | | | | | |
| ± 1 standard error | 0.07% | 0.09% | 0.17% | 0.32% | 0.32% | | | | | |

## Atlas® + HF (Model V-340)

| | | | |
|---|---|---|---|
| US Market Release | June 2004 | Normal Battery Depletion | 142 |
| Registered US Implants | 4,912 | Malfunctions | 15 |
| Estimated Active US Implants | 2,174 | Malfunctions w/ Compromised Therapy (1 related to Advisory) | 9 |
| Estimated Longevity | (see table on page 24) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 6 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.82% | 98.96% | 96.37% | 89.33% | 86.07% | | | | | |
| ± 1 standard error | 0.05% | 0.16% | 0.31% | 0.65% | 1.00% | | | | | |
| Sample Size | 4900 | 4200 | 3600 | 2200 | 600 | | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.71% | 99.45% | 99.02% | 99.02% | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.12% | 0.15% | 0.22% | | | | | |

# Summary & Longevity Information

## Cardiac Resynchronization Therapy

## CRT ICDs

# Cardiac Resynchronization Therapy

## Battery Longevity

| Models | Family | Approximate Duration (years)* | | | |
|---|---|---|---|---|---|
| | | No Pacing | 25% Pacing | 50% Pacing | 100% Pacing |
| 3207-30 | Promote RF | 7.0 | 6.4 | 5.8 | 4.9 |
| 3107-36 | Promote | 8.6 | 7.8 | 7.1 | 6.1 |
| 3207-36 | Promote RF | 8.6 | 7.8 | 7.1 | 6.1 |
| 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 | 6.1 | 5.5 | 4.5 |
| V-337, V-338 | Epic HF, Serial Numbers <13000 | 6.4 | 5.7 | 5.2 | 4.4 |
| V-337, V-338 | Epic HF, Serial Numbers >13000 | 6.5 | 5.8 | 5.2 | 4.4 |
| V-343 | Atlas + HF | 7.9 | 7.1 | 6.4 | 5.4 |
| V-340 | Atlas + HF | 7.9 | 7.1 | 6.4 | 5.4 |

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

## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/ Compromised Therapy (under advisory) | Malfunctions w/ Compromised Therapy (premature battery depletion) | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 3207-30 | Promote RF | Sep-07 | 596 | 559 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3107-36 | Promote | May-07 | 679 | 558 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3207-36 | Promote RF | Sep-07 | 12177 | 11371 | 0 | 0 | 0 | 6 | 1 | 7 | 1 |
| V-365 | Atlas II HF | Jul-06 | 8346 | 6716 | 3 | 0 | 0 | 2 | 2 | 7 | 6 |
| V-366 | Atlas II + HF | Feb-07 | 3845 | 3350 | 0 | 0 | 0 | 1 | 1 | 2 | 3 |
| V-355 | Epic II HF | Mar-06 | 1604 | 1279 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| V-337 | Epic HF | Nov-04 | 3952 | 2300 | 0 | 0 | 0 | 1 | 0 | 1 | 78 |
| V-343 | Atlas + HF | Nov-04 | 18425 | 12238 | 1 | 1 | 21 | 6 | 7 | 36 | 117 |
| V-338 | Epic HF | Jun-04 | 3095 | 811 | 2 | 0 | 0 | 1 | 7 | 10 | 267 |
| V-340 | Atlas + HF | Jun-04 | 4912 | 2174 | 3 | 1 | 5 | 0 | 6 | 15 | 142 |

**Based on returned product analysis as of December 31, 2008.*

# 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 |
| 3207-30 | Promote RF** | | | | | | | | | | |
| 3107-36 | Promote | 100.00% | | | | | | | | | |
| 3207-36 | Promote RF | 99.80% | | | | | | | | | |
| V-365 | Atlas II HF | 99.86% | 99.46% | | | | | | | | |
| V-366 | Atlas II + HF | 99.61% | | | | | | | | | |
| V-355 | Epic II HF | 100.00% | 99.54% | | | | | | | | |
| V-337 | Epic HF | 99.89% | 99.01% | 94.18% | | | | | | | |
| V-343 | Atlas + HF | 99.85% | 99.36% | 97.31% | | | | | | | |
| V-338 | Epic HF | 99.71% | 98.28% | 90.45% | 71.90% | | | | | | |
| V-340 | Atlas + HF | 99.82% | 98.96% | 96.37% | 89.33% | | | | | | |

**Based on returned product analysis as of December 31, 2008.*

***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 |
| 3207-30 | Promote RF** | | | | | | | | | | |
| 3107-36 | Promote | 100.00% | | | | | | | | | |
| 3207-36 | Promote RF | 99.82% | | | | | | | | | |
| V-365 | Atlas II HF | 99.86% | 99.81% | | | | | | | | |
| V-366 | Atlas II + HF | 99.83% | | | | | | | | | |
| V-355 | Epic II HF | 100.00% | 100.00% | | | | | | | | |
| V-337 | Epic HF | 99.94% | 99.94% | 99.94% | | | | | | | |
| V-343 | Atlas + HF | 99.89% | 99.72% | 99.42% | | | | | | | |
| V-338 | Epic HF | 99.86% | 99.78% | 99.26% | 98.79% | | | | | | |
| V-340 | Atlas + HF | 99.86% | 99.71% | 99.45% | 99.02% | | | | | | |

*Based on returned product analysis as of December 31, 2008.

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

# Cardiac Resynchronization Therapy

## CRT Pulse Generators

St. Jude Medical

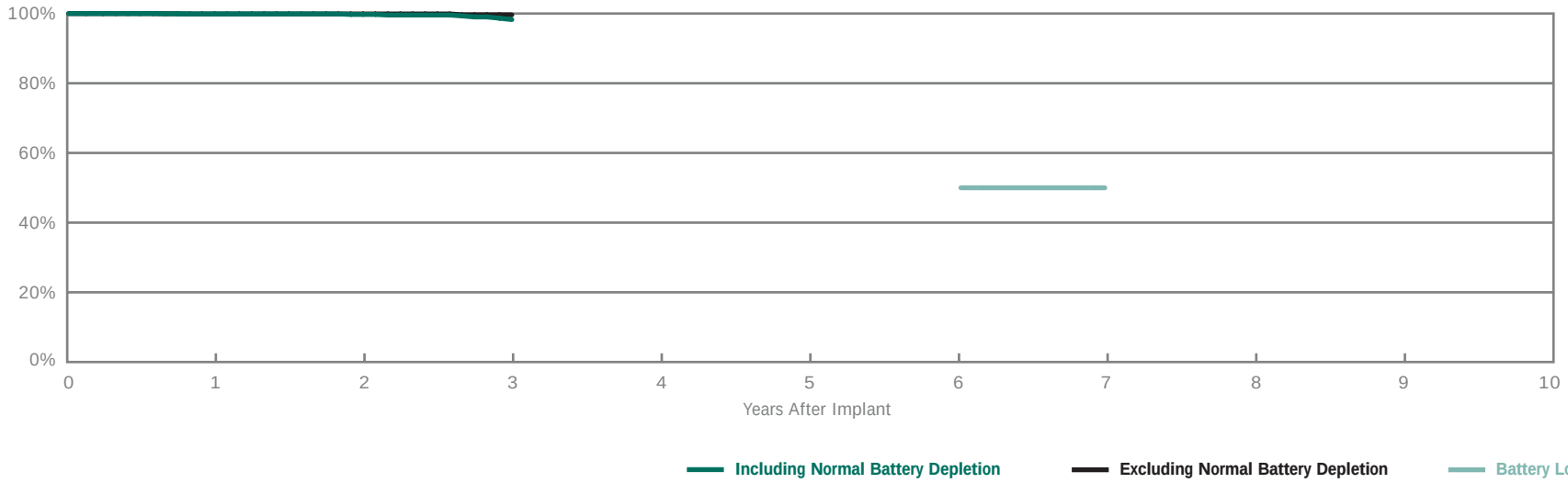
More control. Less risk.

# Cardiac Resynchronization Therapy

## Frontier® II (Model 5586)

| | | | |
|---|---|---|---|
| US Market Release | August 2004 | Normal Battery Depletion | 5 |
| Registered US Implants | 5,066 | Malfunctions | 3 |
| Estimated Active US Implants | 3,999 | 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 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.74% | 98.26% | | | | | | | |
| ± 1 standard error | 0.06% | 0.12% | 0.41% | | | | | | | |
| Sample Size | 4200 | 2100 | 900 | | | | | | | |

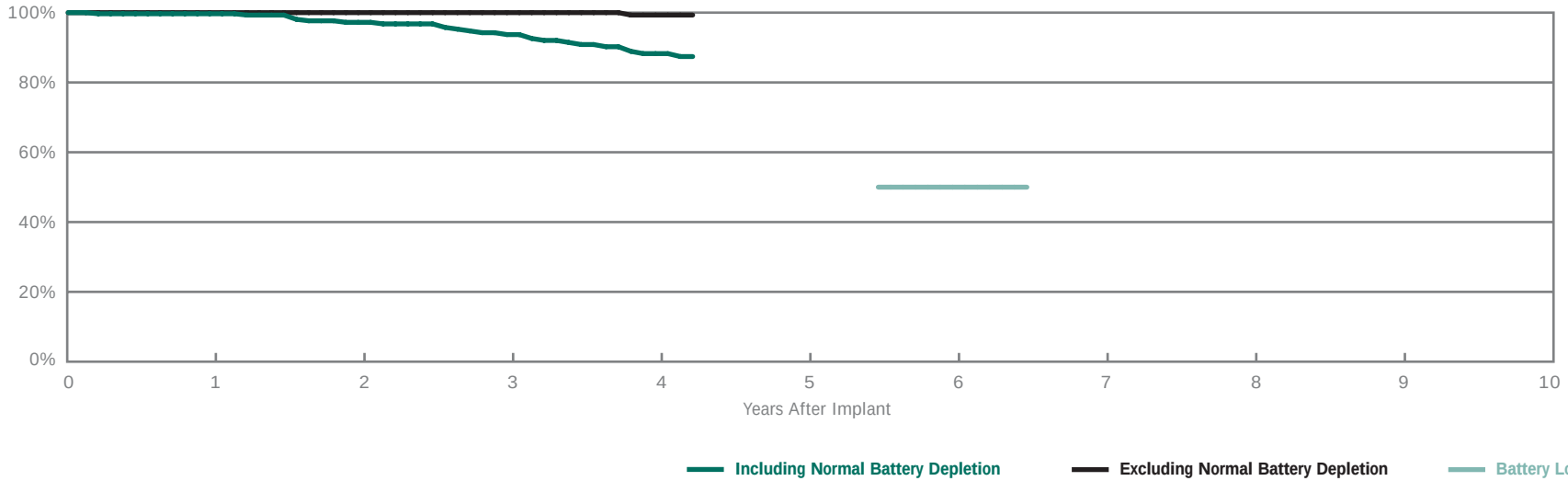
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.88% | 99.62% | | | | | | | |
| ± 1 standard error | 0.06% | 0.06% | 0.19% | | | | | | | |

## Frontier® (Model 5508)

| | | | |
|---|---|---|---|
| US Market Release | May 2004 | Normal Battery Depletion | 31 |
| Registered US Implants | 671 | Malfunctions | 2 |
| Estimated Active US Implants | 210 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.9 Years | Malfunctions w/o Compromised Therapy | 2 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 51 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.68% | 97.22% | 93.71% | 88.26% | 87.42% | | | | | |
| ± 1 standard error | 0.22% | 0.74% | 1.11% | 1.67% | 1.75% | | | | | |
| Sample Size | 700 | 500 | 400 | 300 | 200 | | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 51 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.31% | 99.31% | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.49% | 0.49% | | | | | |

# Summary & Longevity Information

## Cardiac Resynchronization Therapy

## CRT Pulse Generators

St. Jude Medical
More control. Less risk.

## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (under advisory) | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|
| 5586 | Frontier II | Aug-04 | 5066 | 3999 | 1 | 2 | 0 | 0 | 3 | 5 |
| 5508 | Frontier | May-04 | 671 | 210 | 0 | 1 | 0 | 1 | 2 | 31 |

**Based on returned product analysis as of December 31, 2008.*

# Cardiac Resynchronization Therapy

## Including Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year |
| 5586 | Frontier II | 99.88% | 99.74% | 98.26% | | | | | |
| 5508 | Frontier | 99.68% | 97.22% | 93.71% | 88.26% | | | | |

**Based on returned product analysis as of December 31, 2008.*

## Excluding Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year |
| 5586 | Frontier II | 99.88% | 99.88% | 99.62% | | | | | |
| 5508 | Frontier | 100.00% | 100.00% | 100.00% | 99.31% | | | | |

**Based on returned product analysis as of December 31, 2008.*

# Cardiac Resynchronization Therapy

## Left-Heart Leads

St. Jude Medical

More control. Less risk.

# Cardiac Resynchronization Therapy

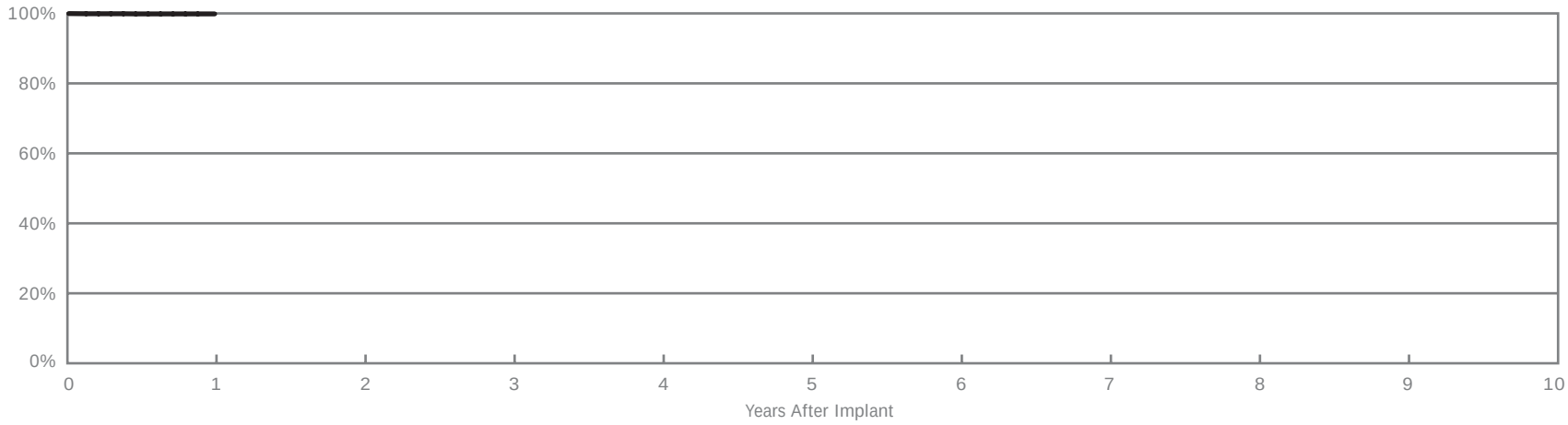
## QuickFlex® (Model 1156T)

| | | | |
|---|---|---|---|
| US Market Release | July 2007 | Type and/or Fixation | S-Curve |
| Registered US Implants | 6,694 | Polarity | Bipolar |
| Estimated Active US Implants | 6,128 | Steroid | None |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **18** | **Electrical Malfunction** | **1** | **Other** | **5** |
| | | Insulation Disruption | 0 | Explant Damage | 2 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 3 |
| | | Crimps, Welds, Bonds | 1 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.86% | | | | | | | | | |
| **± 1 standard error** | 0.05% | | | | | | | | | |
| **Sample Size** | 3400 | | | | | | | | | |

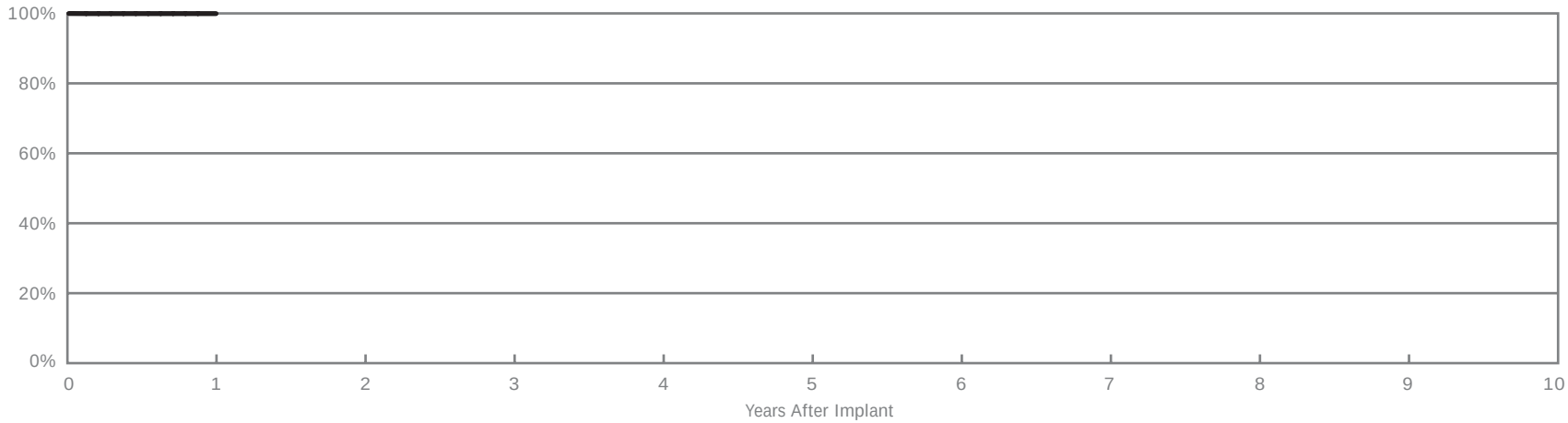
## QuickFlex® XL (Model 1158T)

| | | | |
|---|---|---|---|
| US Market Release | July 2007 | Type and/or Fixation | S-Curve |
| Registered US Implants | 3,997 | Polarity | Bipolar |
| Estimated Active US Implants | 3,623 | Steroid | None |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **18** | **Electrical Malfunction** | **0** | **Other** | **4** |
| | | Insulation Disruption | 0 | Explant Damage | 3 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 0 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.94% | | | | | | | | | |
| **± 1 standard error** | 0.04% | | | | | | | | | |
| **Sample Size** | 2000 | | | | | | | | | |

# Cardiac Resynchronization Therapy

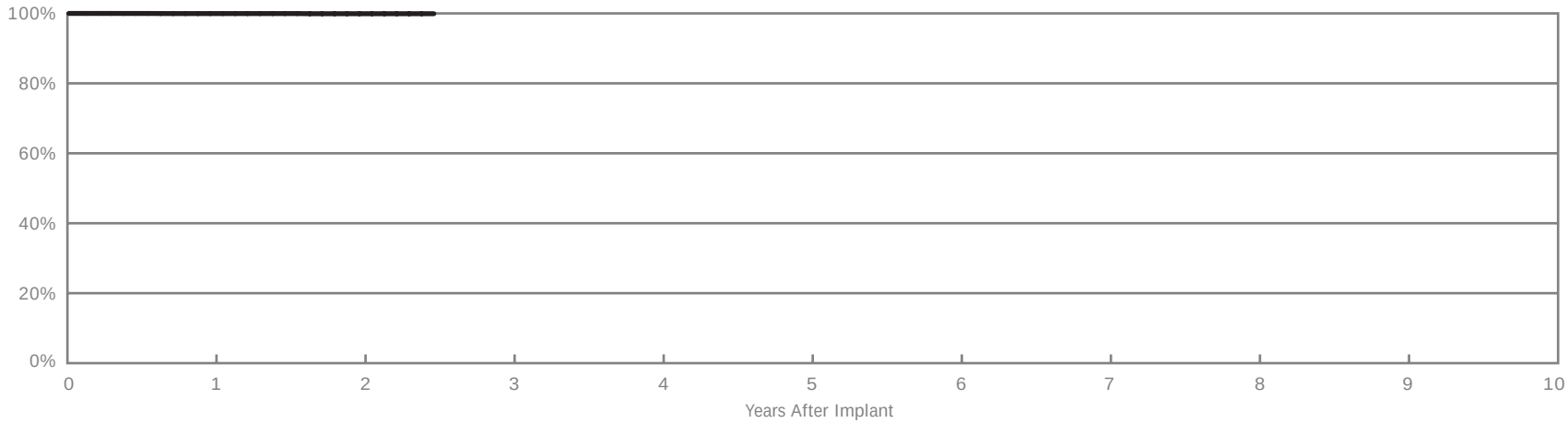
## QuickSite® XL (Model 1058T)

| | | | |
|---|---|---|---|
| US Market Release | February 2006 | Type and/or Fixation | S-Curve |
| Registered US Implants | 9,057 | Polarity | Bipolar |
| Estimated Active US Implants | 7,467 | Steroid | Yes |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **28** | **Electrical Malfunction** | **0** | **Other** | **11** |
| | | Insulation Disruption | 0 | Explant Damage | 6 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 4 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.95% | 99.91% | 99.91% | | | | | | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.04% | | | | | | | |
| **Sample Size** | 7800 | 3700 | 100 | | | | | | | |

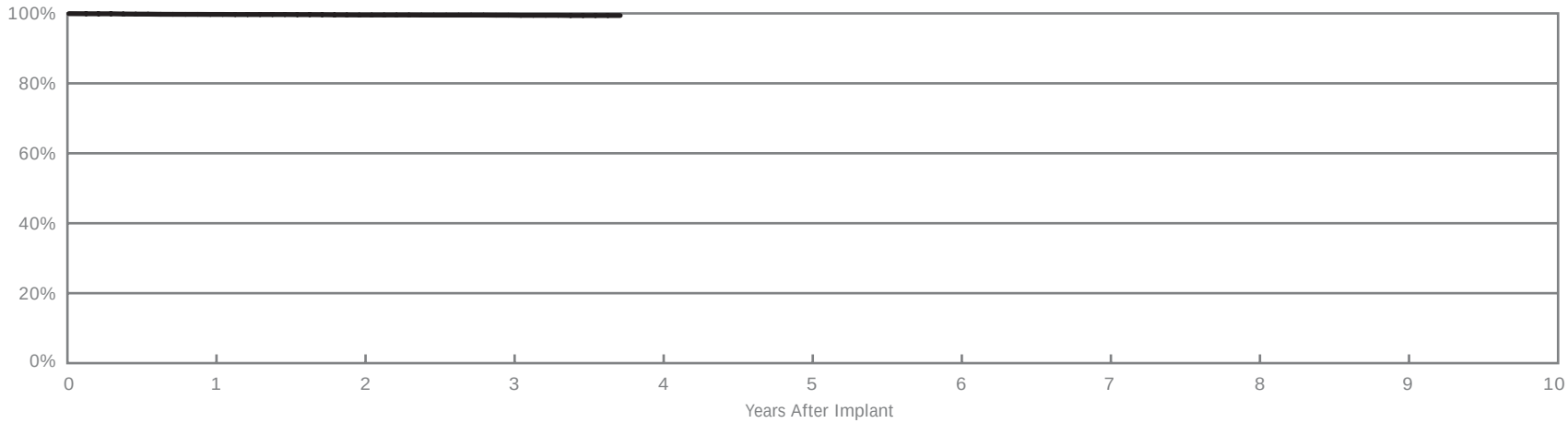
## QuickSite® (Model 1056T)

| | | | |
|---|---|---|---|
| US Market Release | April 2005 | Type and/or Fixation | S-Curve |
| Registered US Implants | 31,431 | Polarity | Bipolar |
| Estimated Active US Implants | 23,243 | Steroid | Yes |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **80** | **Electrical Malfunction** | **1** | **Other** | **145** |
| | | Insulation Disruption | 0 | Explant Damage | 135 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 5 |
| | | Crimps, Welds, Bonds | 1 | Non-Electrical Anomaly | 3 |
| | | | | Partial Lead | 2 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | at 45 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.71% | 99.55% | 99.49% | 99.40% | | | | | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.05% | 0.08% | | | | | | |
| **Sample Size** | 28400 | 19200 | 9900 | 100 | | | | | | |

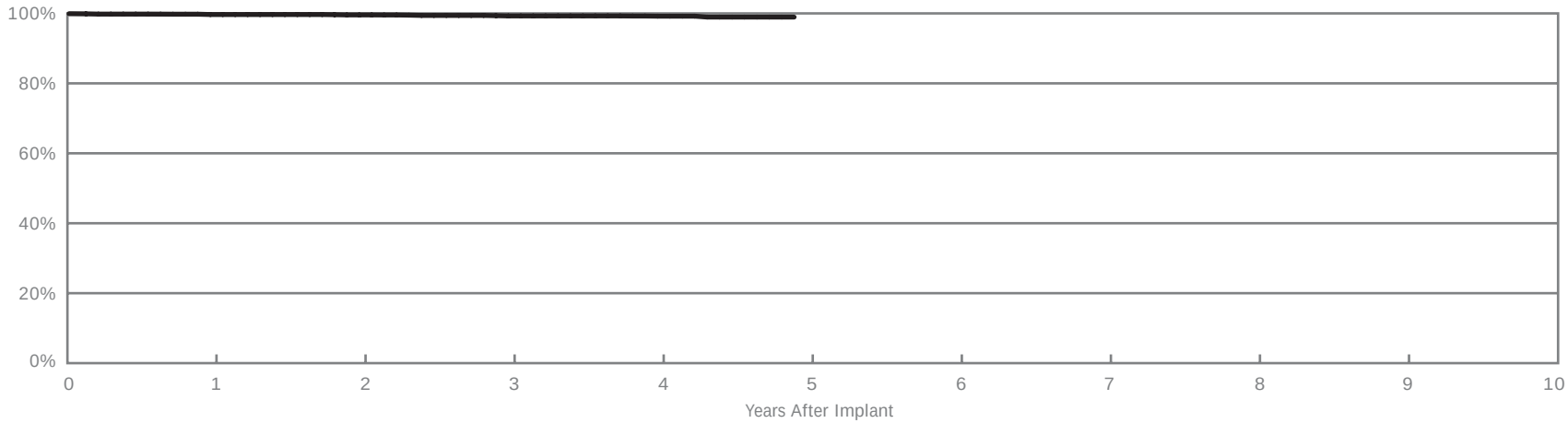
## QuickSite® (Model 1056K)

| | | | |
|---|---|---|---|
| US Market Release | June 2004 | Type and/or Fixation | S-Curve |
| Registered US Implants | 8,591 | Polarity | Unipolar |
| Estimated Active US Implants | 4,826 | Steroid | Yes |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **88** | **Electrical Malfunction** | **4** | **Other** | **71** |
| | | Insulation Disruption | 0 | Explant Damage | 55 |
| | | Conductor Disruption | 2 | Non-Electrical Workmanship | 15 |
| | | Crimps, Welds, Bonds | 2 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | at 59 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.68% | 99.57% | 99.28% | 99.21% | 98.95% | | | | | |
| **± 1 standard error** | 0.06% | 0.08% | 0.11% | 0.12% | 0.19% | | | | | |
| **Sample Size** | 7700 | 6300 | 5200 | 3500 | 100 | | | | | |

# Laboratory Analysis

## Cardiac Resynchronization Therapy

## Left-Heart Leads

St. Jude Medical

More control. Less risk.

## Laboratory Analysis*

| Models | US Market Release Date | Registered US Implants | Estimated Active US Implants | Implant Damage | Electrical Malfunctions | | | | Other | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Insulation Disruption | Conductor Disruption | Crimps, Welds, Bonds | Total Electrical Malfunctions | Explant Damage | Non-Electrical Workmanship | Non-Electrical Anomaly | Partial Lead | Total Other |
| 1156T | Jul-07 | 6694 | 6128 | 18 | 0 | 0 | 1 | 1 | 2 | 3 | 0 | 0 | 5 |
| 1158T | Jul-07 | 3997 | 3623 | 18 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 1 | 4 |
| 1058T | Feb-06 | 9057 | 7467 | 28 | 0 | 0 | 0 | 0 | 6 | 4 | 0 | 1 | 11 |
| 1056T | Apr-05 | 31431 | 23243 | 80 | 0 | 0 | 1 | 1 | 135 | 5 | 3 | 2 | 145 |
| 1056K | Jun-04 | 8591 | 4826 | 88 | 0 | 2 | 2 | 4 | 55 | 15 | 1 | 0 | 71 |

**Based on returned product analysis as of December 31, 2008.*

The laboratory analysis results are categorized into one of the following three categories:

- **Implant Damage -** obvious damage incurred at the time of attempted implant, including but not limited to insulation cuts and damage, helix overtorque, and stylet perforation.
- **Electrical Malfunction -** a disruption in the insulation or conductors resulting in compromised electrical performance. Electrical malfunction data are further broken down into one of the following three subcategories:
  - *Insulation Disruption* - leads exhibiting wear and abrasion that extends through the insulation and exposes the conductors.
  - *Conductor Disruption* - leads exhibiting cable and coil fractures, including those attributed to subclavian crush.
  - *Crimps, Welds, Bonds* - leads exhibiting malfunctions related to crimps, welds, and bonds.
- **Other -** includes other returns not attributed to damage incurred at the attempted implant and not resulting in compromised electrical failures. The Other category of data is further broken down into one of the following four subcategories:
  - *Explant Damage* - leads exhibiting physical damage incurred at the time of explant.
  - *Non-Electrical Workmanship* - leads exhibiting some out of specification mechanical condition, such as a bent connector pin or helix anomaly.
  - *Non-Electrical Anomaly* - leads not associated with a complaint but exhibiting some anomalous condition that did not result in an electrical malfunction. An example would be a lead exhibiting some insulation disruption that did not extend through and therefore did not compromise the function of the lead.
  - *Partial Lead* - leads with an alleged malfunction that are returned not in its entirety; as a result, it was not possible to perform a complete analysis and confirm the malfunction.

# ICDs

## Dual-Chamber

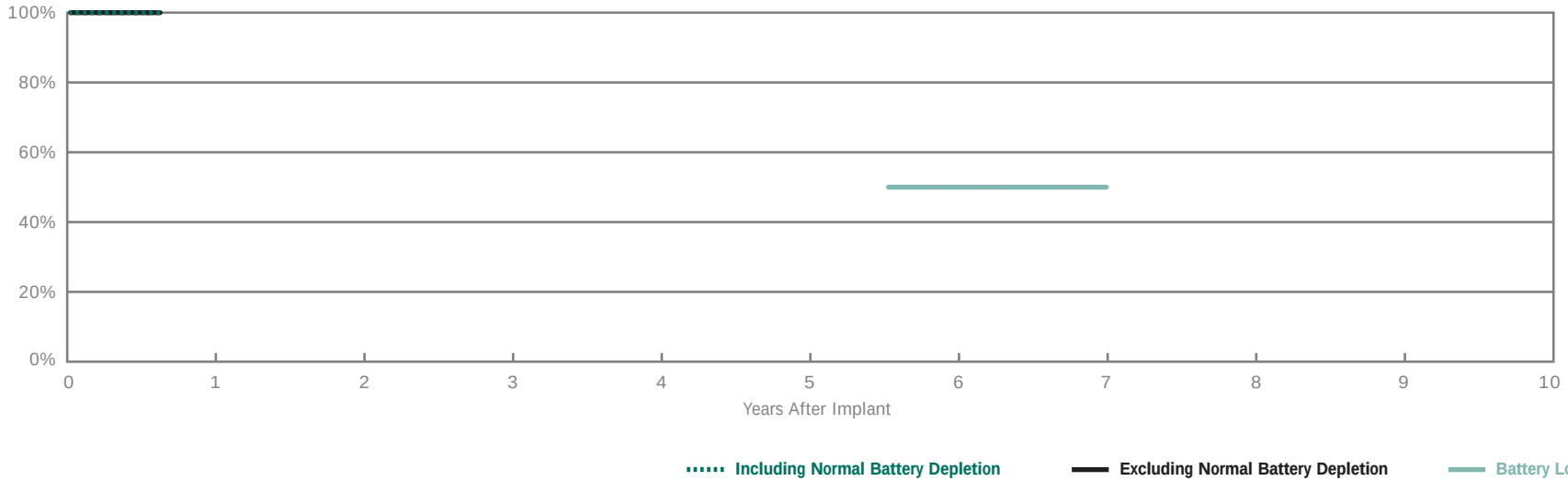
ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

## Current® DR RF (Model 2207-30)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 738 | Malfunctions | 0 |
| Estimated Active US Implants | 690 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 500 | | | | | | | | | |

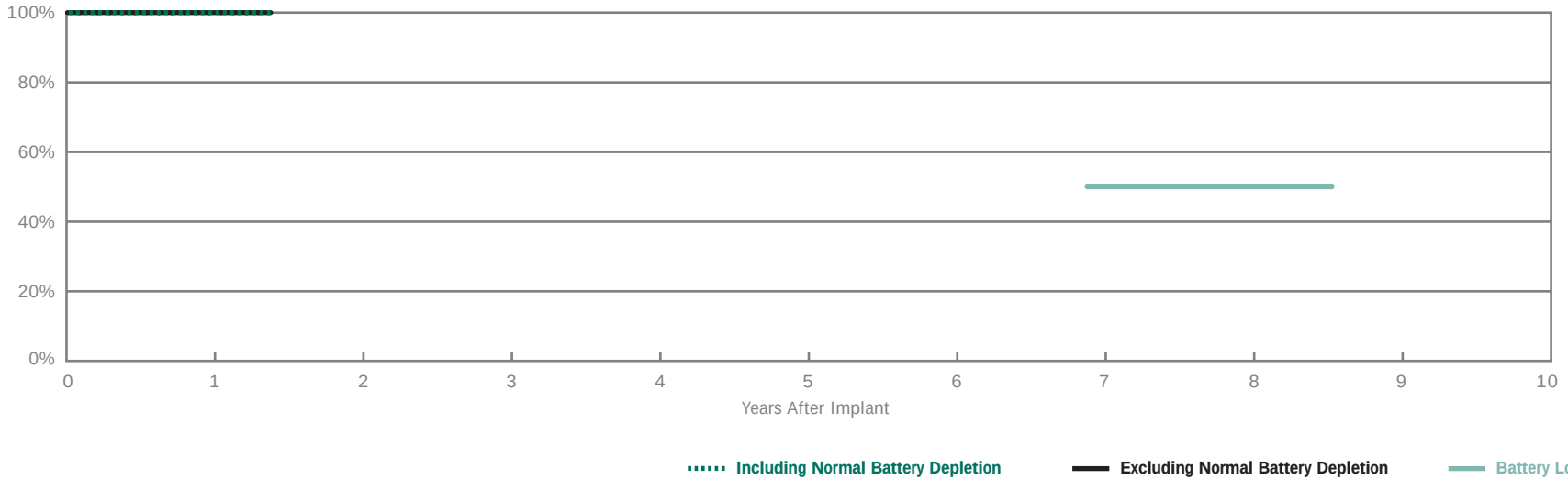
**Excluding Normal Battery Depletion**

| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |

## Current® DR (Model 2107-36)

| | | | |
|---|---|---|---|
| US Market Release | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 595 | Malfunctions | 0 |
| Estimated Active US Implants | 495 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | 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 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 600 | 300 | | | | | | | | |

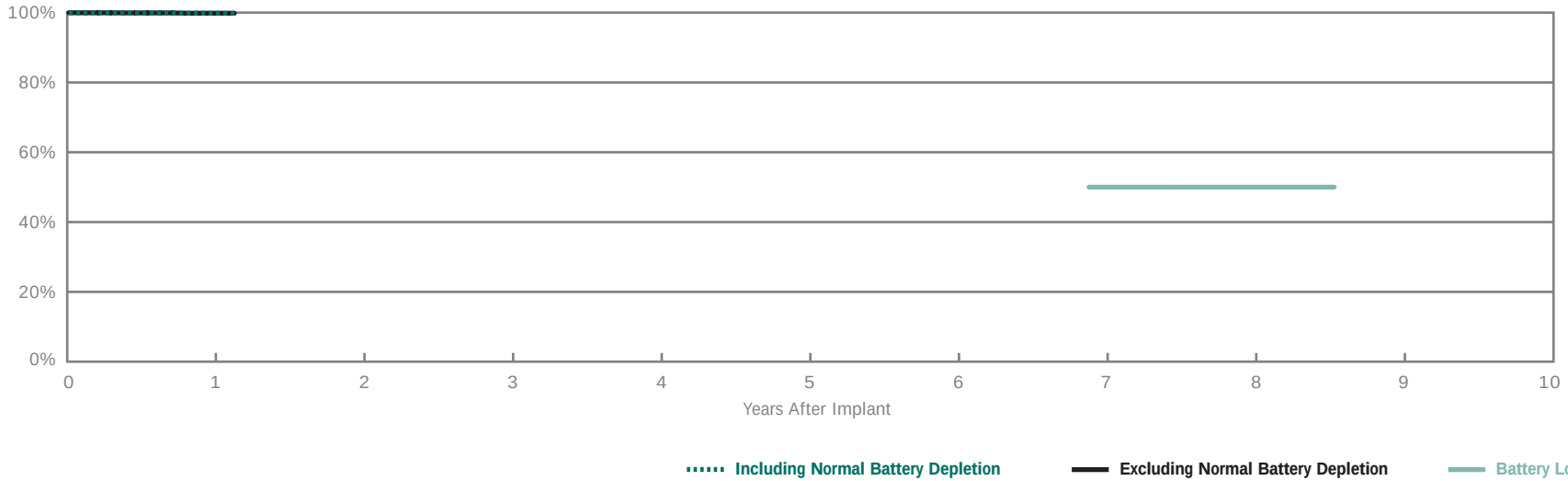
**Excluding Normal Battery Depletion**

| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

## Current® DR RF (Model 2207-36)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 11,161 | Malfunctions | 5 |
| Estimated Active US Implants | 10,422 | Malfunctions w/ Compromised Therapy | 3 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 2 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

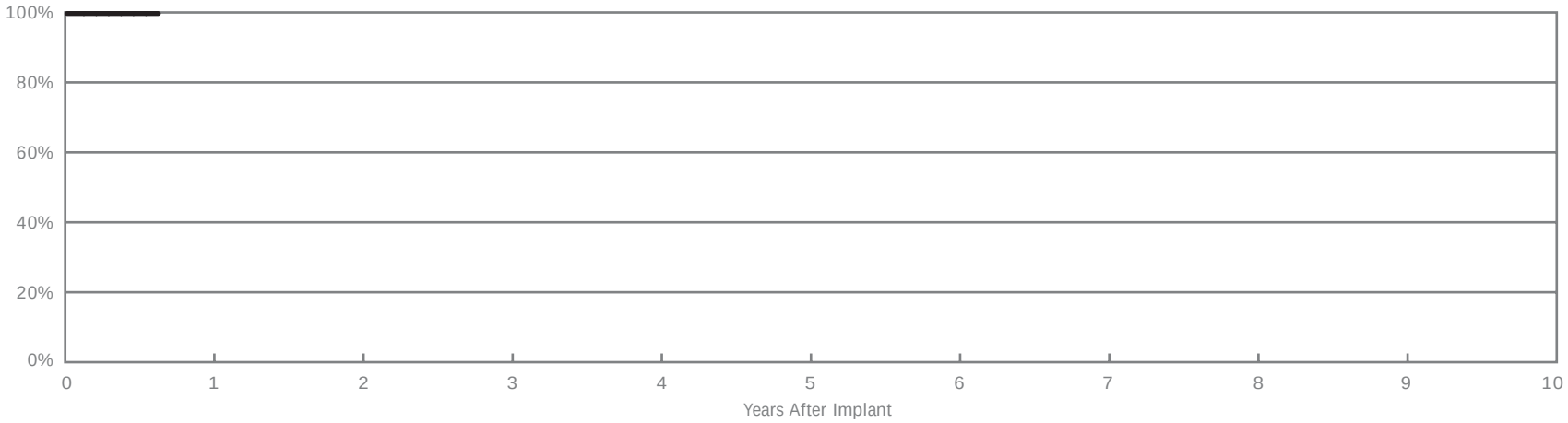
| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.83% | | | | | | | | |
| ± 1 standard error | 0.07% | 0.07% | | | | | | | | |
| Sample Size | 6300 | 300 | | | | | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.83% | | | | | | | | |
| ± 1 standard error | 0.07% | 0.07% | | | | | | | | |

| Current® DR RF (Model 2207-36) | | | |
|---|---|---|---|
| **SCORE Results** | | **Qualifying Complications** | **1** |
| Number of Devices Enrolled in Study | 327 | Failure to Sense | 1 |
| Cumulative Months of Follow-Up | 1,766 | | |

## Survival from SCORE Registry

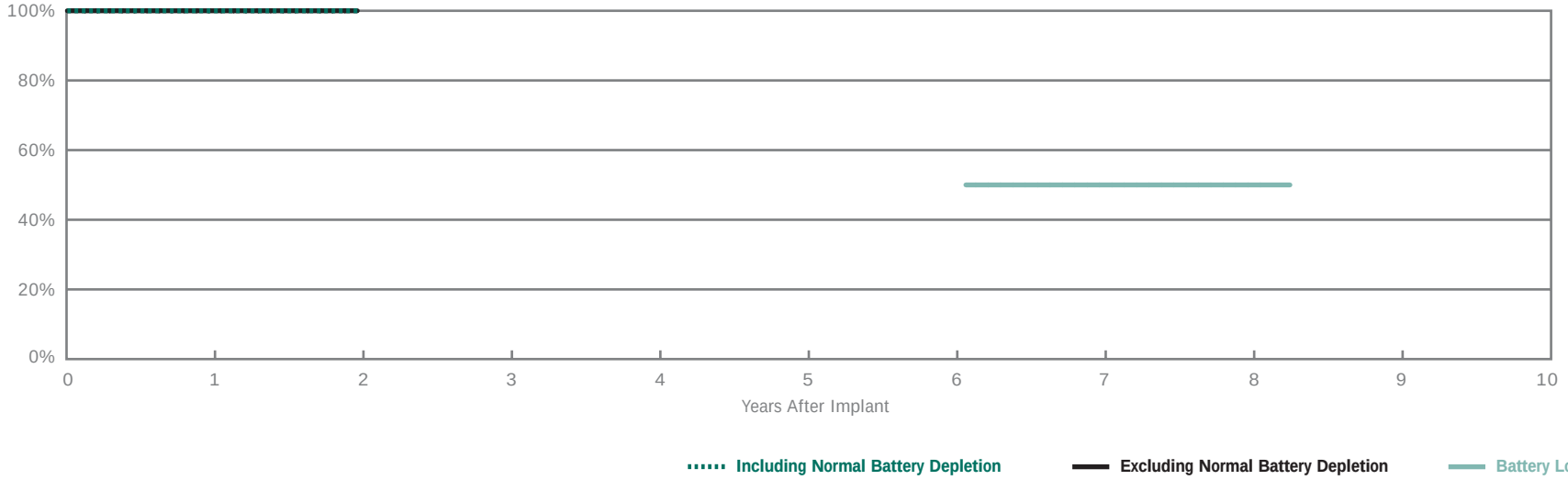



| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.69% | | | | | | | | | |
| **± 1 standard error** | 0.31% | | | | | | | | | |
| **Sample Size** | 69 | | | | | | | | | |

## Atlas® II DR (Model V-265)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,874 | Malfunctions | 0 |
| Estimated Active US Implants | 1,525 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 1700 | 800 | | | | | | | | |

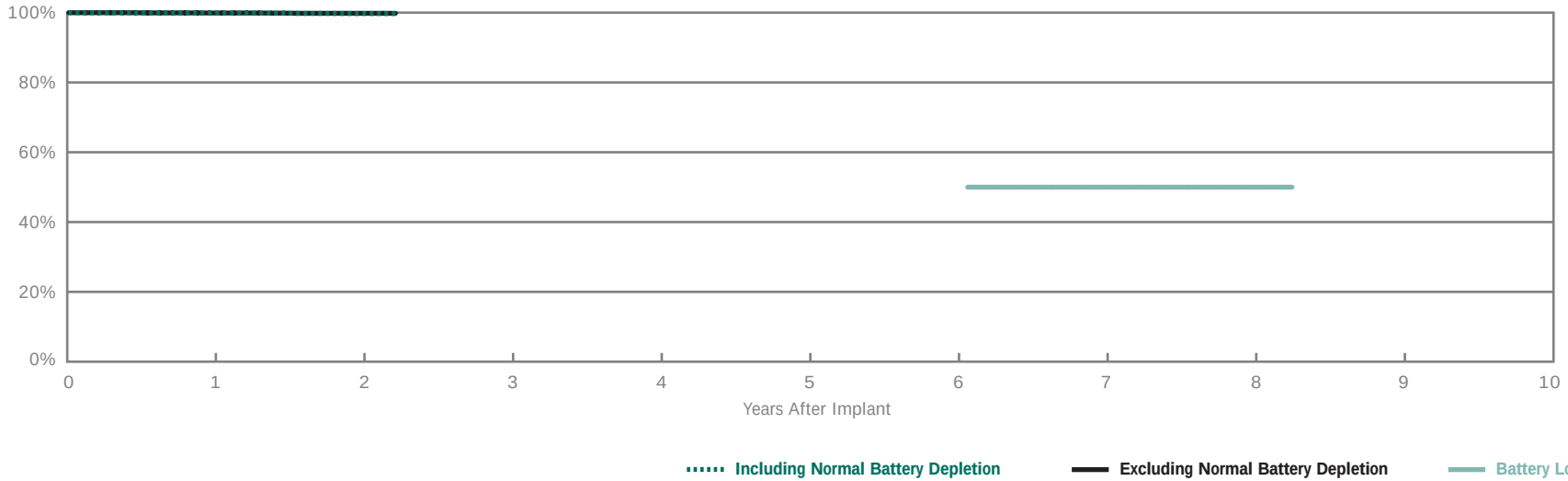
**Excluding Normal Battery Depletion**

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

## Atlas® II + DR (Model V-268)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Normal Battery Depletion | 2 |
| Registered US Implants | 12,953 | Malfunctions | 8 |
| Estimated Active US Implants | 10,812 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 6 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 2 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.74% | 99.74% | | | | | | |
| ± 1 standard error | 0.03% | 0.07% | 0.07% | | | | | | |
| Sample Size | 11200 | 4700 | 500 | | | | | | |

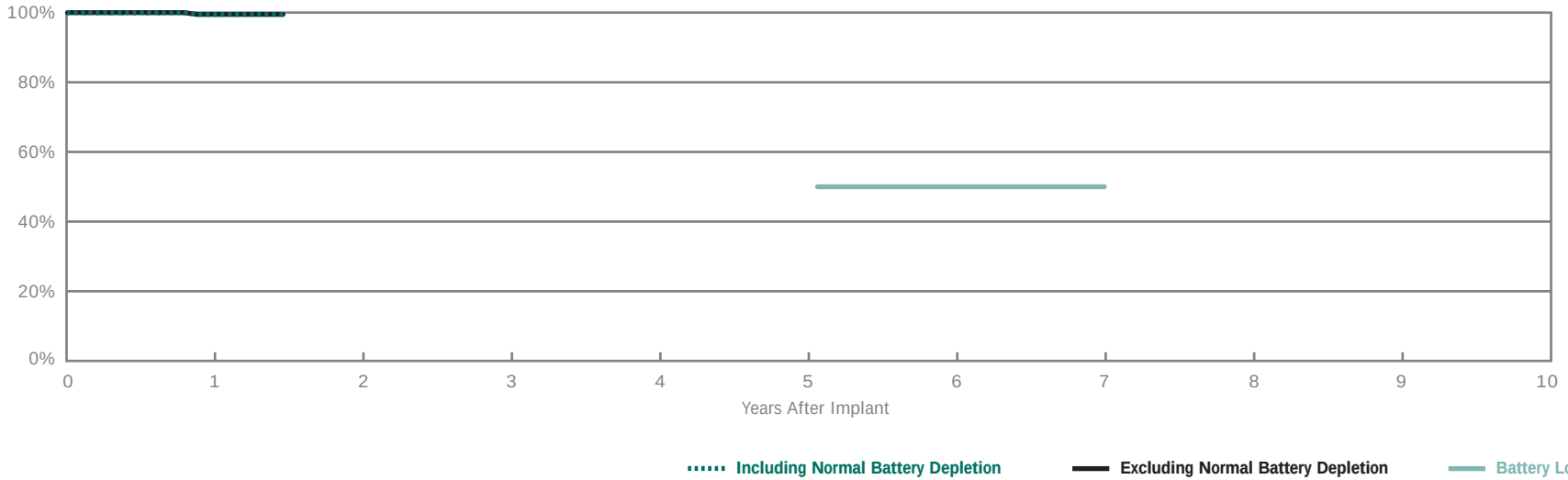
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.90% | 99.81% | 99.81% | | | | | | |
| ± 1 standard error | 0.03% | 0.06% | 0.06% | | | | | | |

## Epic® II DR (Model V-255)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Normal Battery Depletion | 1 |
| Registered US Implants | 542 | Malfunctions | 0 |
| Estimated Active US Implants | 427 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.49% | 99.49% | | | | | | | | |
| ± 1 standard error | 0.36% | 0.36% | | | | | | | | |
| Sample Size | 500 | 300 | | | | | | | | |

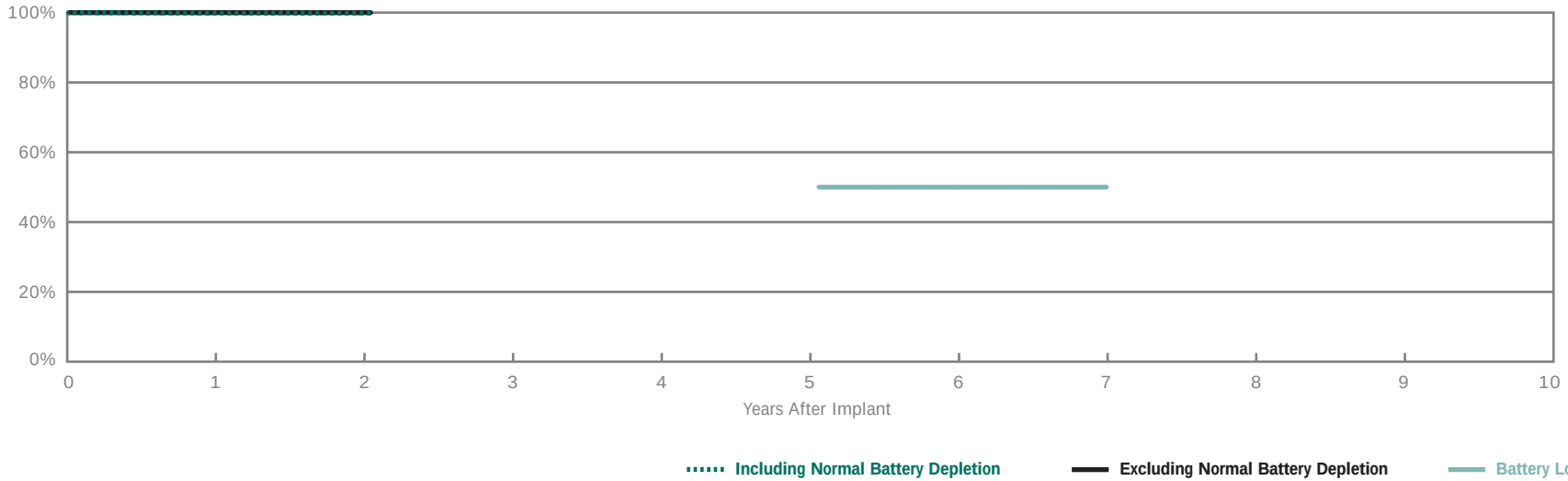
**Excluding Normal Battery Depletion**

| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.50% | 99.50% | | | | | | | | |
| ± 1 standard error | 0.35% | 0.35% | | | | | | | | |

## Epic® II + DR (Model V-258)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Normal Battery Depletion | 1 |
| Registered US Implants | 1,875 | Malfunctions | 0 |
| Estimated Active US Implants | 1,539 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.85% | 99.85% | | | | | | | |
| ± 1 standard error | 0.11% | 0.11% | 0.11% | | | | | | | |
| Sample Size | 1700 | 800 | 200 | | | | | | | |

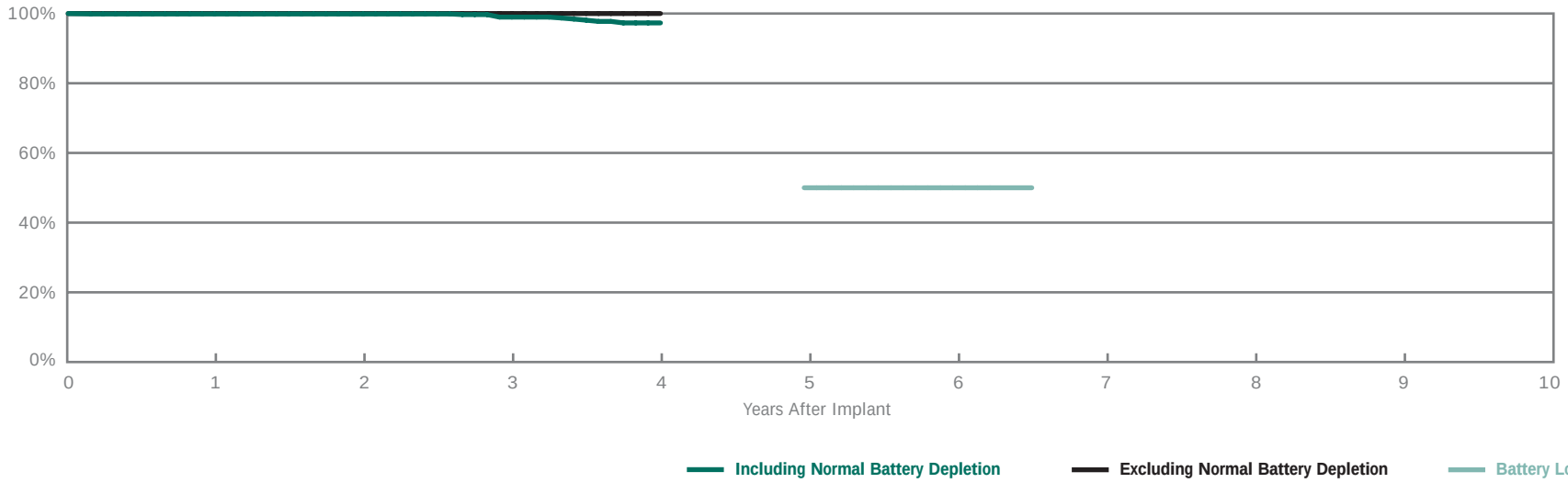
**Excluding Normal Battery Depletion**

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

## Epic® DR (Model V-233)

| | | | |
|---|---|---|---|
| US Market Release | October 2003 | Normal Battery Depletion | 13 |
| Registered US Implants | 1,823 | Malfunctions | 0 |
| Estimated Active US Implants | 1,062 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.89% | 98.98% | 97.31% | | | | | | |
| ± 1 standard error | 0.08% | 0.08% | 0.31% | 0.62% | | | | | | |
| Sample Size | 1800 | 1600 | 1300 | 600 | | | | | | |

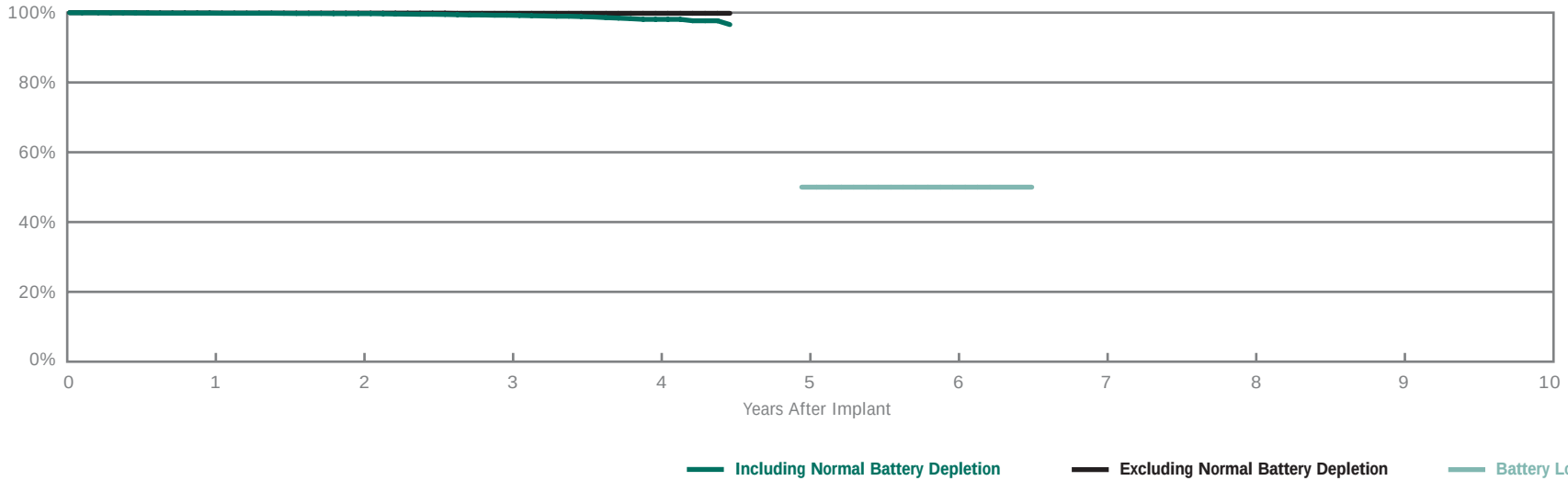
**Excluding Normal Battery Depletion**

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

## Epic® + DR (Model V-239)

| | | | |
|---|---|---|---|
| US Market Release | October 2003 | Normal Battery Depletion | 30 |
| Registered US Implants | 7,801 | Malfunctions | 6 |
| Estimated Active US Implants | 4,709 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 2 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 3 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.72% | 99.26% | 98.08% | 96.58% | | | | | |
| ± 1 standard error | 0.05% | 0.06% | 0.12% | 0.30% | 0.41% | | | | | |
| Sample Size | 7800 | 6600 | 4600 | 3300 | 1200 | | | | | |

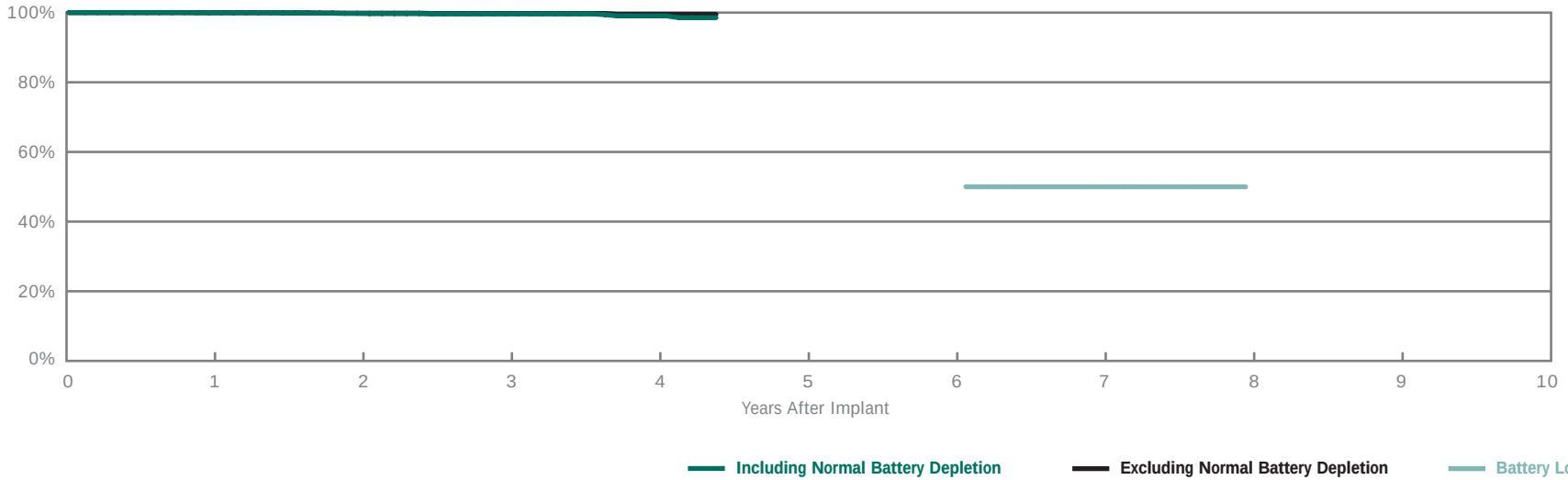
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.86% | 99.81% | 99.81% | 99.81% | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.06% | 0.06% | 0.06% | | | | | |

## Atlas® DR (Model V-242)

| | | | |
|---|---|---|---|
| US Market Release | October 2003 | Normal Battery Depletion | 6 |
| Registered US Implants | 4,361 | Malfunctions | 5 |
| Estimated Active US Implants | 2,831 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 1 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.76% | 99.63% | 99.05% | 98.54% | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.10% | 0.28% | 0.46% | | | | | |
| Sample Size | 4600 | 3900 | 2800 | 1300 | 300 | | | | | |

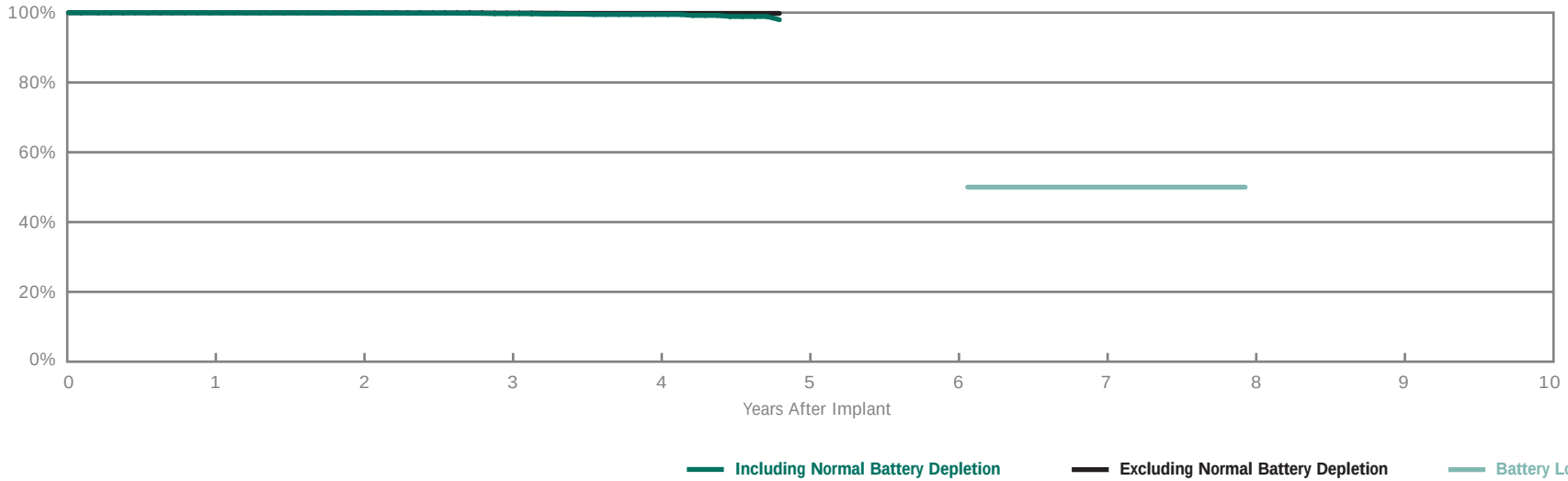
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.84% | 99.76% | 99.52% | 99.52% | | | | | |
| ± 1 standard error | 0.00% | 0.07% | 0.08% | 0.19% | 0.19% | | | | | |

## Atlas® + DR (Model V-243)

| | | | |
|---|---|---|---|
| US Market Release | October 2003 | Normal Battery Depletion | 16 |
| Registered US Implants | 20,806 | Malfunctions | 11 |
| Estimated Active US Implants | 13,328 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 8 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 3 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.89% | 99.72% | 99.47% | 97.97% | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.09% | 0.28% | | | | | |
| Sample Size | 20800 | 16800 | 10700 | 4200 | 900 | | | | | |

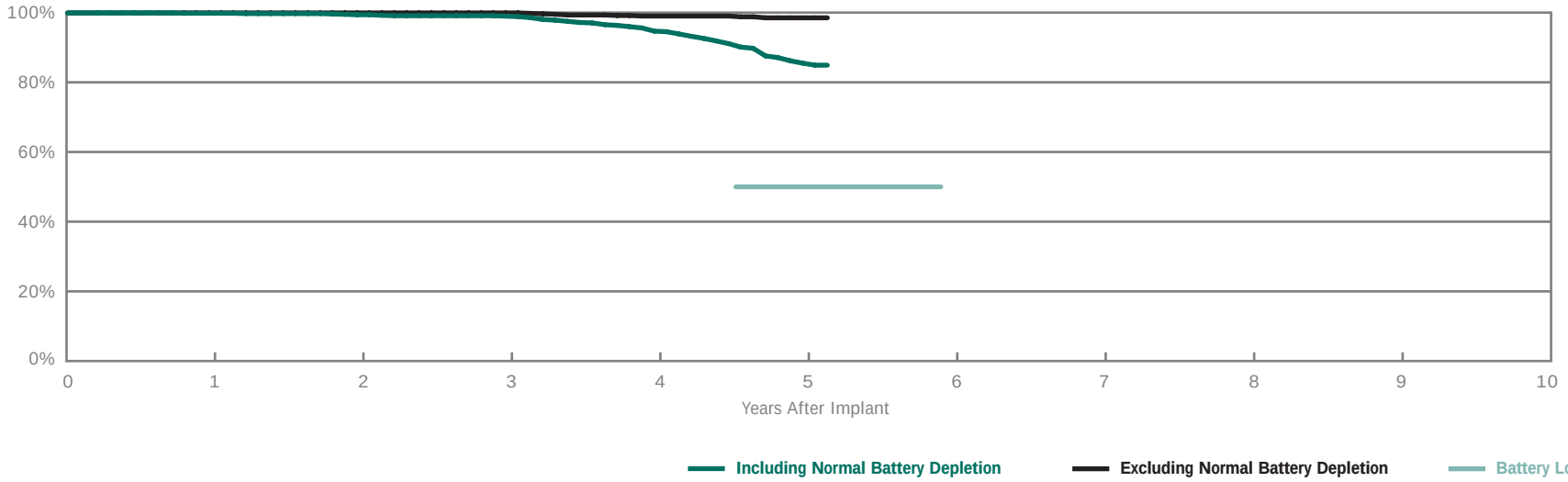
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | 99.93% | 99.87% | 99.78% | 99.78% | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.06% | 0.06% | | | | | |

## Epic® + DR (Model V-236)

| | | | |
|---|---|---|---|
| US Market Release | April 2003 | Normal Battery Depletion | 83 |
| Registered US Implants | 2,342 | Malfunctions | 10 |
| Estimated Active US Implants | 579 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 9 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 62 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.82% | 99.39% | 98.99% | 94.68% | 85.49% | 84.91% | | | | |
| ± 1 standard error | 0.09% | 0.16% | 0.22% | 0.52% | 1.09% | 1.21% | | | | |
| Sample Size | 2300 | 2000 | 1800 | 1600 | 1000 | 300 | | | | |

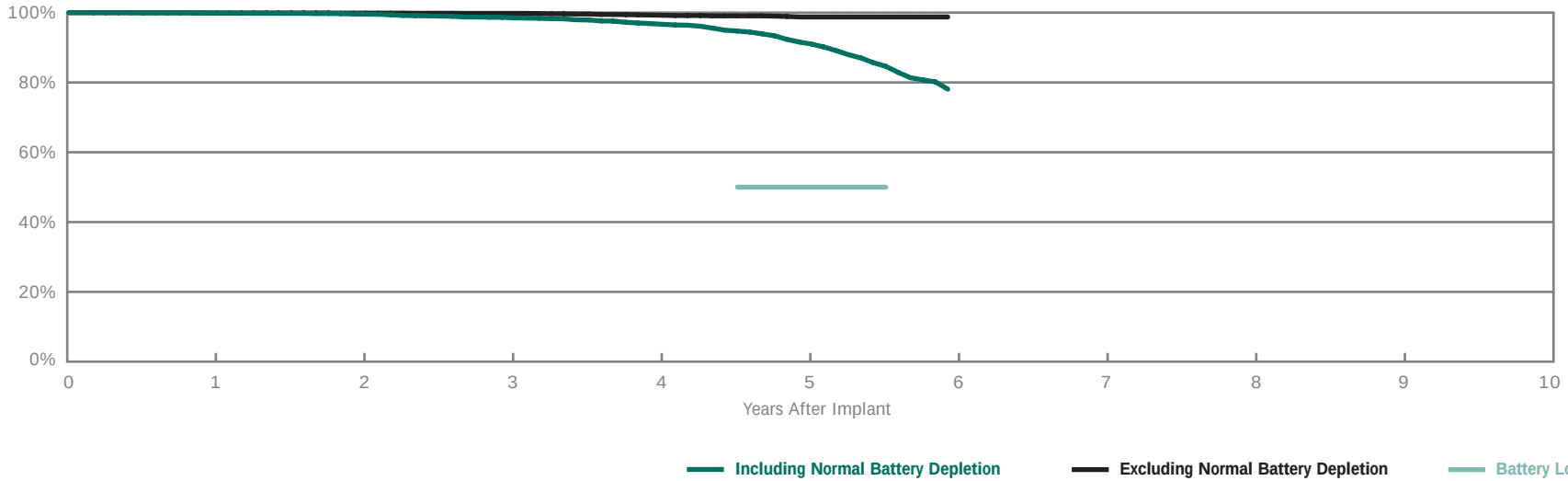
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 62 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.91% | 99.91% | 99.02% | 98.51% | 98.51% | | | | |
| ± 1 standard error | 0.06% | 0.06% | 0.06% | 0.26% | 0.36% | 0.36% | | | | |

## Epic® DR (Model V-235)

| | | | |
|---|---|---|---|
| US Market Release | July 2002 | Normal Battery Depletion | 204 |
| Registered US Implants | 6,586 | Malfunctions | 27 |
| Estimated Active US Implants | 1,619 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 23 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.57% | 98.49% | 96.65% | 90.98% | 78.07% | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.16% | 0.26% | 0.49% | 1.15% | | | | |
| Sample Size | 6600 | 5800 | 5200 | 4600 | 3300 | 1200 | | | | |

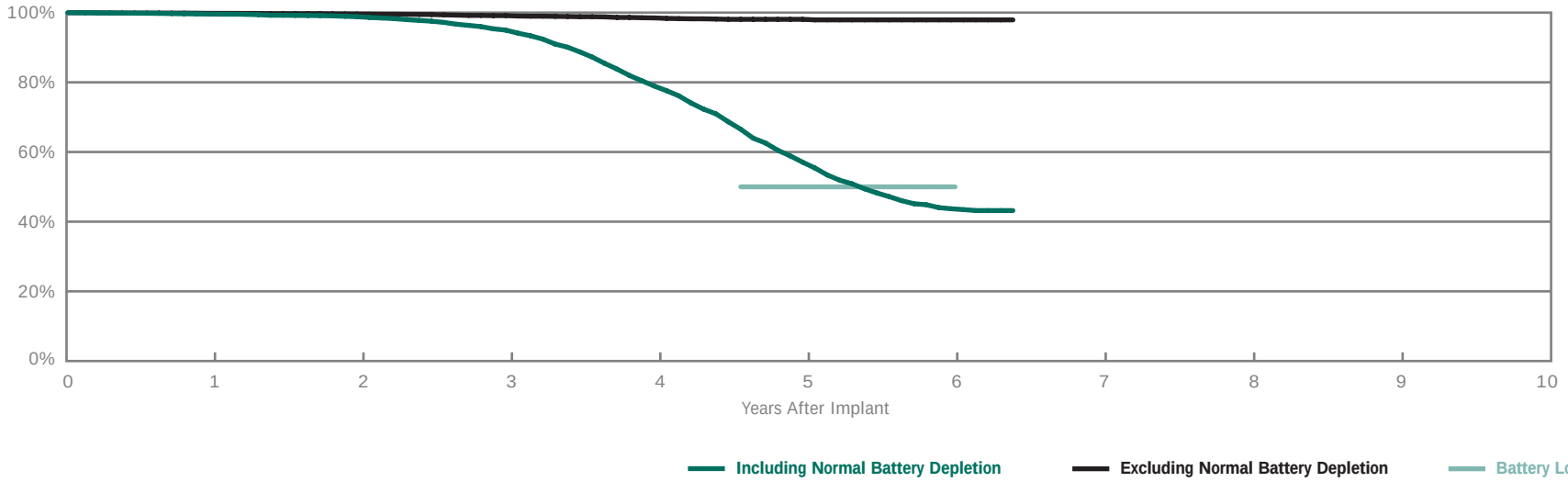
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.90% | 99.86% | 99.78% | 99.25% | 98.76% | 98.76% | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.06% | 0.12% | 0.19% | 0.19% | | | | |

## Atlas® DR (Model V-240)

| | | | |
|---|---|---|---|
| US Market Release | December 2001 | Normal Battery Depletion | 951 |
| Registered US Implants | 8,839 | Malfunctions | 60 |
| Estimated Active US Implants | 419 | Malfunctions w/ Compromised Therapy (21 related to Advisory) | 31 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 29 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 77 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.57% | 98.83% | 94.98% | 78.94% | 57.07% | 43.70% | 43.19% | | | |
| ± 1 standard error | 0.07% | 0.12% | 0.26% | 0.54% | 0.79% | 1.04% | 1.07% | | | |
| Sample Size | 8800 | 7600 | 6700 | 5500 | 3500 | 1100 | 300 | | | |

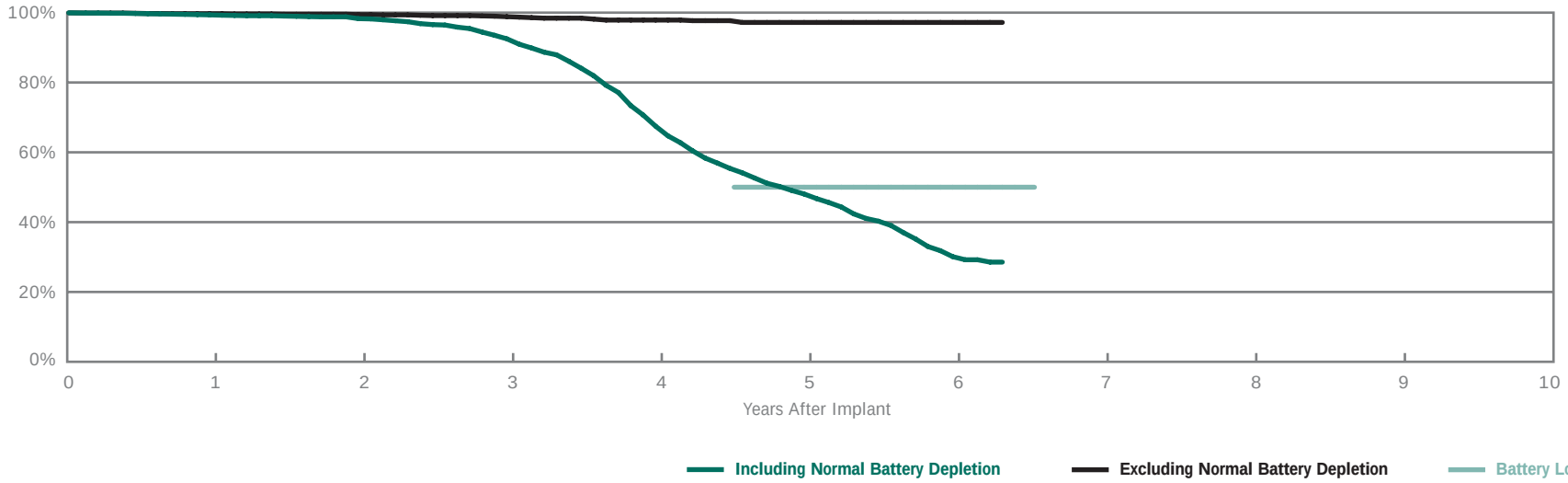
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 77 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.79% | 99.60% | 99.14% | 98.48% | 98.07% | 97.91% | 97.91% | | | |
| ± 1 standard error | 0.05% | 0.07% | 0.11% | 0.16% | 0.20% | 0.23% | 0.23% | | | |

## Photon® µ DR (Model V-232)

| | | | |
|---|---|---|---|
| US Market Release | June 2001 | Normal Battery Depletion | 437 |
| Registered US Implants | 3,403 | Malfunctions | 33 |
| Estimated Active US Implants | 13 | Malfunctions w/ Compromised Therapy (10 related to Advisory) | 16 |
| Estimated Longevity | (see table on page 68) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 17 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 76 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.36% | 98.28% | 92.49% | 67.49% | 48.05% | 30.10% | 28.55% | | | |
| ± 1 standard error | 0.13% | 0.20% | 0.49% | 0.97% | 1.13% | 1.29% | 1.31% | | | |
| Sample Size | 3400 | 3000 | 2600 | 2200 | 1400 | 600 | 200 | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 76 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.69% | 99.44% | 98.85% | 97.87% | 97.19% | 97.19% | 97.19% | | | |
| ± 1 standard error | 0.10% | 0.12% | 0.19% | 0.31% | 0.40% | 0.40% | 0.40% | | | |

# Summary & Longevity Information

## ICDs

## Dual-Chamber

# ICDs

## Battery Longevity

| Models | Family | Approximate Duration (years)* | | | |
|---|---|---|---|---|---|
| | | No Pacing | 25% Pacing | 50% Pacing | 100% Pacing |
| 2207-30 | Current DR RF | 7.0 | 6.6 | 6.2 | 5.5 |
| 2107-36 | Current DR | 8.6 | 8.0 | 7.1 | 6.8 |
| 2207-36 | Current DR RF | 8.6 | 8.0 | 7.1 | 6.8 |
| 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 | 7.0 | 6.4 | 5.9 | 5.1 |
| V-233 | Epic DR | 6.4 | 6.0 | 5.6 | 4.9 |
| V-239 | Epic + DR | 6.4 | 6.0 | 5.6 | 4.9 |
| V-242 | Atlas DR | 7.9 | 7.3 | 6.9 | 6.1 |
| V-243 | Atlas + DR | 7.9 | 7.3 | 6.9 | 6.1 |
| V-236 | Epic + DR | 5.8 | 5.4 | 5.1 | 4.5 |
| V-235 | Epic DR | 5.6 | 5.3 | 4.9 | 4.4 |
| V-240 | Atlas DR | 6.0 | 5.6 | 5.2 | 4.6 |
| V-232 | Photon µ DR <42000 | 6.1 | 5.7 | 5.3 | 4.6 |
| V-232 | Photon µ DR >42000 | 6.6 | 6.1 | 5.6 | 4.9 |

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

## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/ Compromised Therapy (under advisory) | Malfunctions w/ Compromised Therapy (premature battery depletion) | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2207-30 | Current DR RF | Sep-07 | 738 | 690 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2107-36 | Current DR | May-07 | 595 | 495 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2207-36 | Current DR RF | Sep-07 | 11161 | 10422 | 1 | 0 | 2 | 2 | 0 | 5 | 0 |
| V-265 | Atlas II DR | Jul-06 | 1874 | 1525 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| V-268 | Atlas II + DR | Jul-06 | 12953 | 10812 | 3 | 0 | 3 | 1 | 1 | 8 | 2 |
| V-255 | Epic II DR | Mar-06 | 542 | 427 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| V-258 | Epic II + DR | Mar-06 | 1875 | 1539 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| V-233 | Epic DR | Oct-03 | 1823 | 1062 | 0 | 0 | 0 | 0 | 0 | 0 | 13 |
| V-239 | Epic + DR | Oct-03 | 7801 | 4709 | 4 | 0 | 0 | 2 | 0 | 6 | 30 |
| V-242 | Atlas DR | Oct-03 | 4361 | 2831 | 2 | 0 | 2 | 1 | 0 | 5 | 6 |
| V-243 | Atlas + DR | Oct-03 | 20806 | 13328 | 2 | 0 | 6 | 3 | 0 | 11 | 16 |
| V-236 | Epic + DR | Apr-03 | 2342 | 579 | 0 | 0 | 1 | 7 | 2 | 10 | 83 |
| V-235 | Epic DR | Jul-02 | 6586 | 1619 | 2 | 0 | 2 | 22 | 1 | 27 | 204 |
| V-240 | Atlas DR | Dec-01 | 8839 | 419 | 5 | 21 | 5 | 12 | 17 | 60 | 951 |
| V-232 | Photon µ DR | Jun-01 | 3403 | 13 | 4 | 10 | 2 | 5 | 12 | 33 | 437 |

**Based on returned product analysis as of December 31, 2008.*

## Including Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year | 9 year | 10 year |
| 2207-30 | Current DR RF** | | | | | | | | | | |
| 2107-36 | Current DR | 100.00% | | | | | | | | | |
| 2207-36 | Current DR RF | 99.83% | | | | | | | | | |
| V-265 | Atlas II DR | 100.00% | 100.00% | | | | | | | | |
| V-268 | Atlas II + DR | 99.87% | 99.74% | | | | | | | | |
| V-255 | Epic II DR | 99.49% | | | | | | | | | |
| V-258 | Epic II + DR | 99.85% | 99.85% | | | | | | | | |
| V-233 | Epic DR | 99.89% | 99.89% | 98.98% | 97.31% | | | | | | |
| V-239 | Epic + DR | 99.85% | 99.72% | 99.26% | 98.08% | | | | | | |
| V-242 | Atlas DR | 99.93% | 99.76% | 99.63% | 99.05% | | | | | | |
| V-243 | Atlas + DR | 99.95% | 99.89% | 99.72% | 99.47% | | | | | | |
| V-236 | Epic + DR | 99.82% | 99.39% | 98.99% | 94.68% | 85.49% | | | | | |
| V-235 | Epic DR | 99.88% | 99.57% | 98.49% | 96.65% | 90.98% | | | | | |
| V-240 | Atlas DR | 99.57% | 98.83% | 94.98% | 78.94% | 57.07% | 43.70% | | | | |
| V-232 | Photon µ DR | 99.36% | 98..28% | 92.49% | 67.49% | 48.05% | 30.10% | | | | |

**Based on returned product analysis as of December 31, 2008.*

***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 device 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 |
| 2207-30 | Current DR RF** | | | | | | | | | | |
| 2107-36 | Current DR | 100.00% | | | | | | | | | |
| 2207-36 | Current DR RF | 99.83% | | | | | | | | | |
| V-265 | Atlas II DR | 100.00% | 100.00% | | | | | | | | |
| V-268 | Atlas II + DR | 99.90% | 99.81% | | | | | | | | |
| V-255 | Epic II DR | 99.50% | | | | | | | | | |
| V-258 | Epic II + DR | 100.00% | 100.00% | | | | | | | | |
| V-233 | Epic DR | 100.00% | 100.00% | 100.00% | 100.00% | | | | | | |
| V-239 | Epic + DR | 99.89% | 99.86% | 99.81% | 99.81% | | | | | | |
| V-242 | Atlas DR | 100.00% | 99.84% | 99.76% | 99.52% | | | | | | |
| V-243 | Atlas + DR | 99.97% | 99.93% | 99.87% | 99.78% | | | | | | |
| V-236 | Epic + DR | 99.91% | 99.91% | 99.91% | 99.02% | 98.51% | | | | | |
| V-235 | Epic DR | 99.90% | 99.86% | 99.78% | 99.25% | 98.76% | | | | | |
| V-240 | Atlas DR | 99.79% | 99.60% | 99.14% | 98.48% | 98.07% | 97.91% | | | | |
| V-232 | Photon µ DR | 99.69% | 99.44% | 98.85% | 97.87% | 97.19% | 97.19% | | | | |

# ICDs

## Single-Chamber

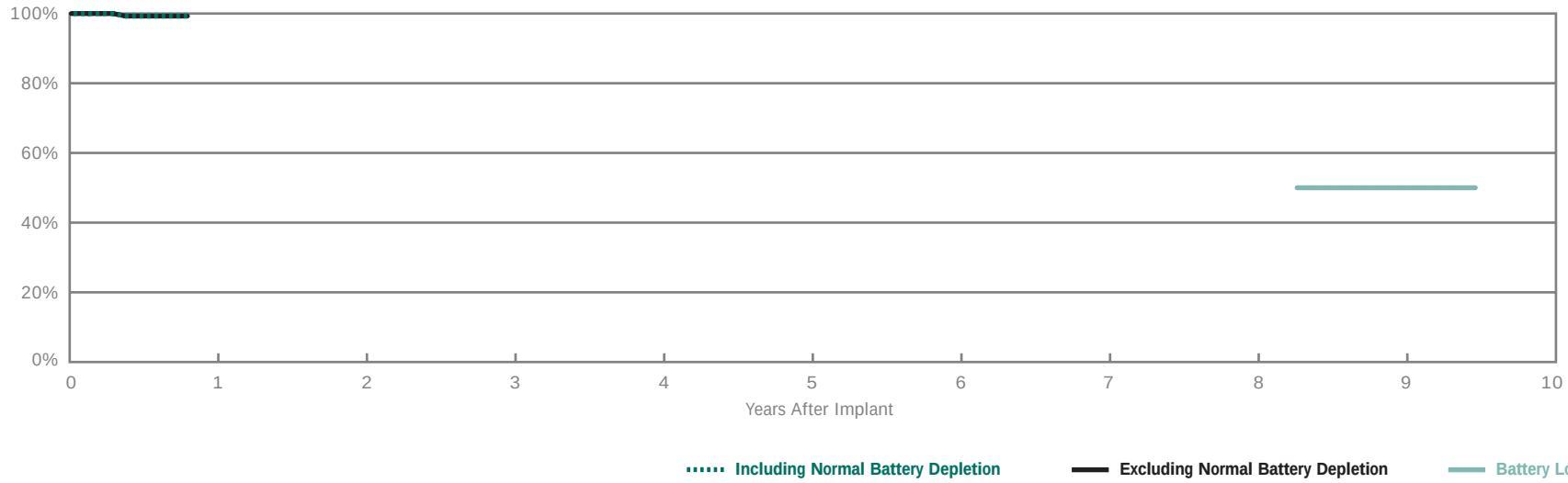
ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

## Current® VR (Model 1107-36)

| | | | |
|---|---|---|---|
| US Market Release | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 317 | Malfunctions | 1 |
| Estimated Active US Implants | 268 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | (see table on page 88) | 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 10 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.28% | | | | | | | | | |
| ± 1 standard error | 0.51% | | | | | | | | | |
| Sample Size | 300 | | | | | | | | | |

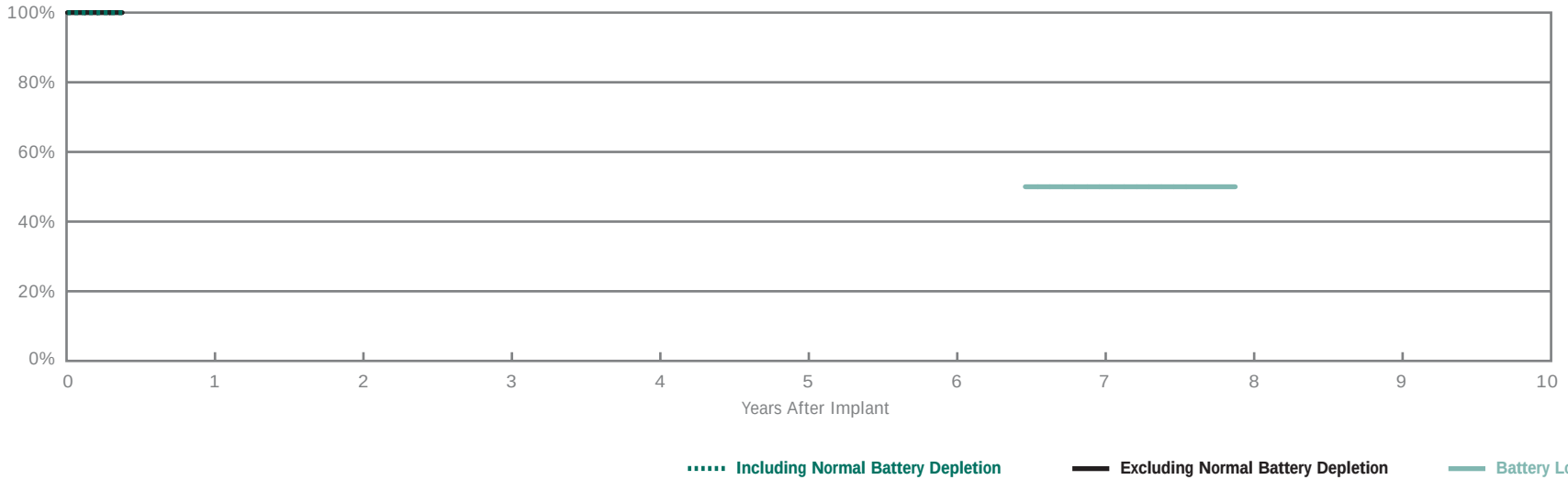
**Excluding Normal Battery Depletion**

| Year | at 10 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.28% | | | | | | | | | |
| ± 1 standard error | 0.51% | | | | | | | | | |

## Current® VR RF (Model 1207-30)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 356 | Malfunctions | 0 |
| Estimated Active US Implants | 333 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 5 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 300 | | | | | | | | | |

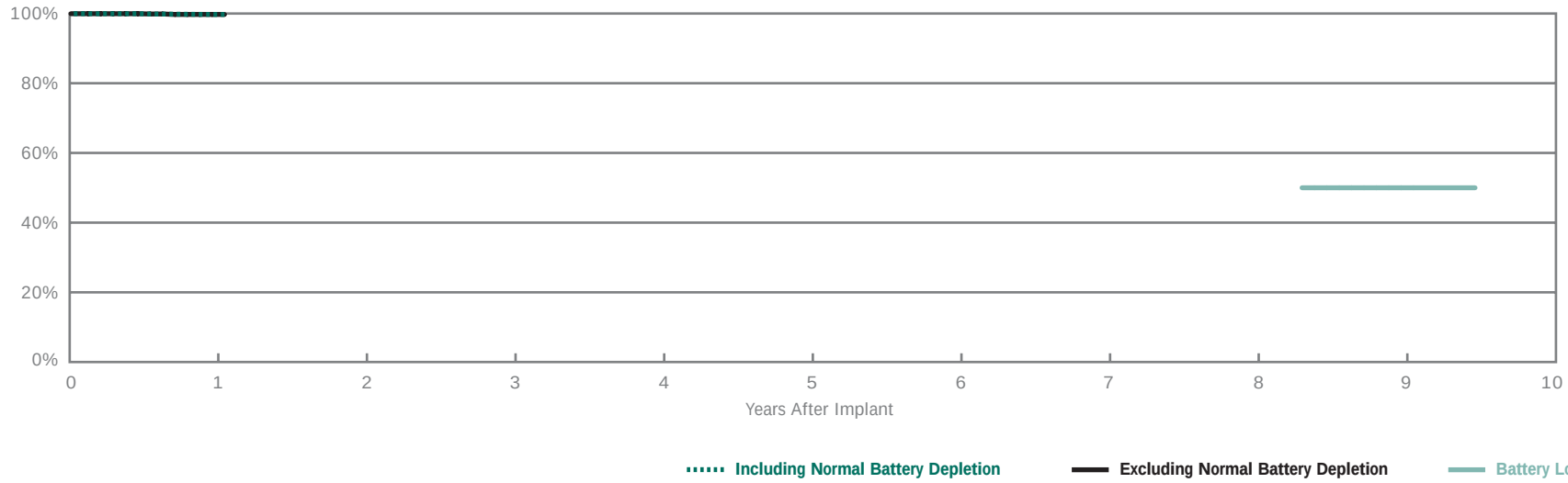
**Excluding Normal Battery Depletion**

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

## Current® VR RF (Model 1207-36)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 6,185 | Malfunctions | 4 |
| Estimated Active US Implants | 5,759 | Malfunctions w/ Compromised Therapy | 2 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy | 2 |
| Max. Delivered Energy | 36 joules | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 13 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | 99.74% | | | | | | | | |
| ± 1 standard error | 0.11% | 0.11% | | | | | | | | |
| Sample Size | 3400 | 200 | | | | | | | | |

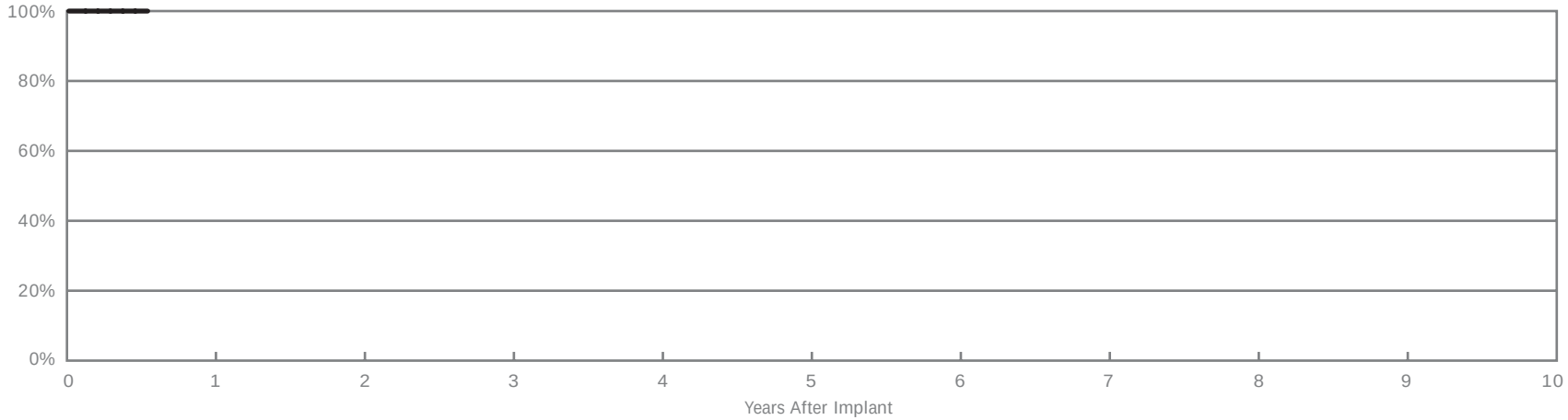
**Excluding Normal Battery Depletion**

| Year | 1 | at 13 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.74% | | | | | | | | |
| ± 1 standard error | 0.11% | 0.11% | | | | | | | | |

| Current® VR RF (Model 1207-36) | |
|---|---|
| **SCORE Results** | |
| Number of Devices Enrolled in Study | 217 |
| Cumulative Months of Follow-Up | 1,059 |

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

## Survival from SCORE Registry

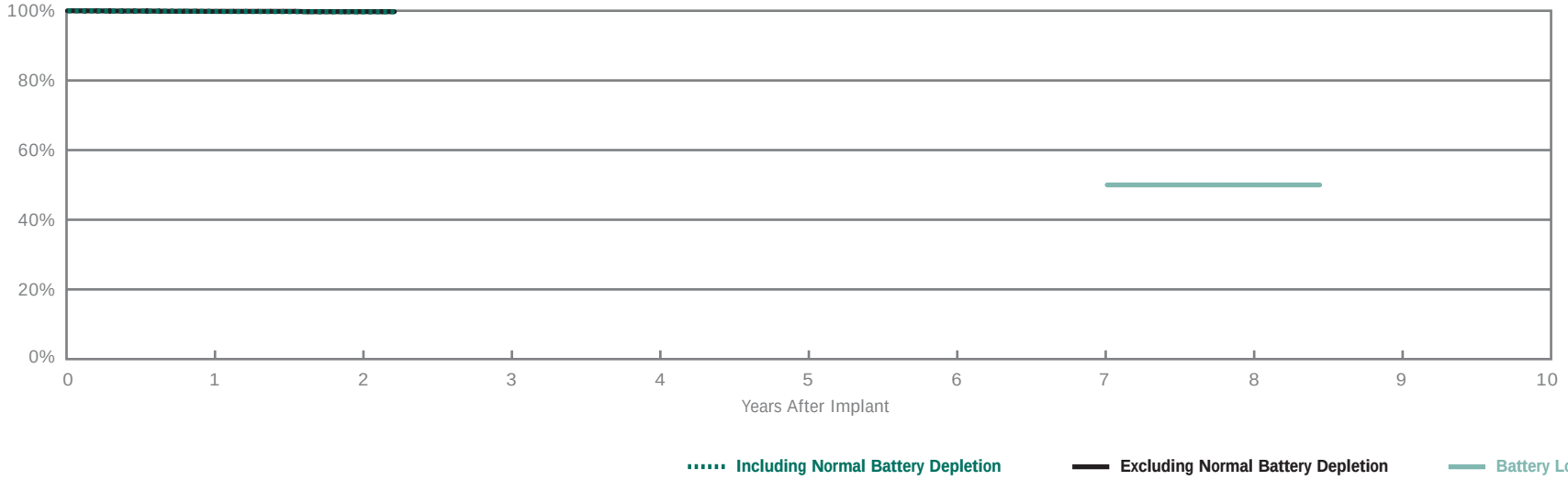



| Year | at 7 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | | | | | | | | | |
| **± 1 standard error** | 0.00% | | | | | | | | | |
| **Sample Size** | 60 | | | | | | | | | |

## Atlas® II VR (Model V-168)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Normal Battery Depletion | 1 |
| Registered US Implants | 9,166 | Malfunctions | 8 |
| Estimated Active US Implants | 7,641 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 3 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.70% | 99.70% | | | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.08% | | | | | | | |
| Sample Size | 7900 | 5800 | 300 | | | | | | | |

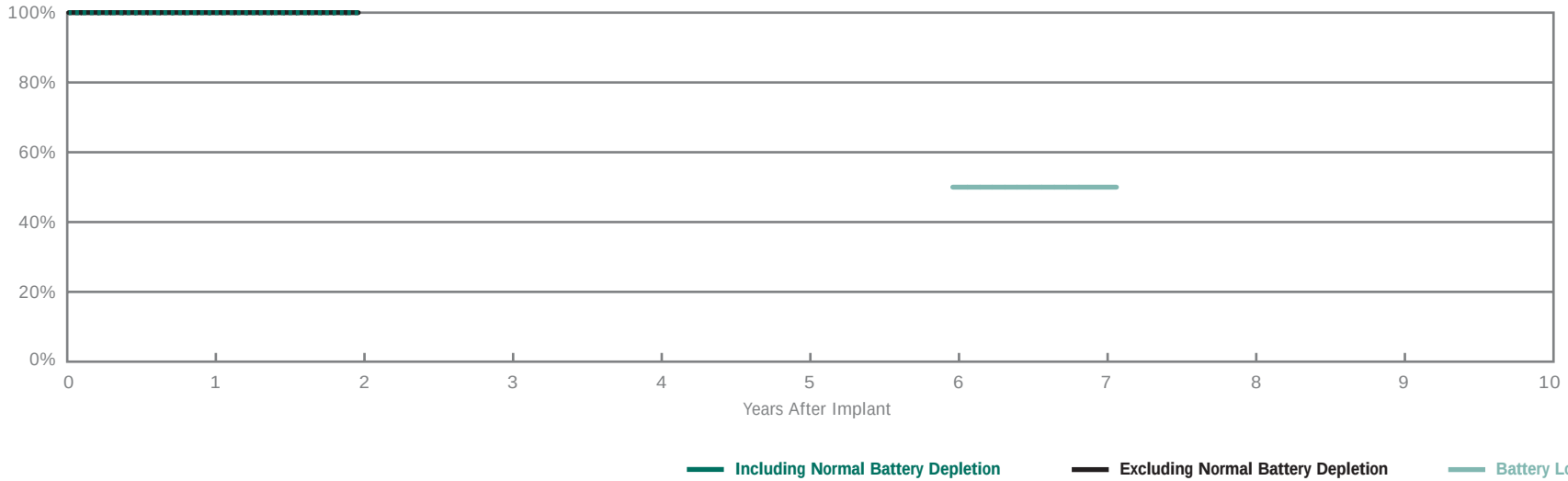
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 27 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.74% | 99.74% | | | | | | | |
| ± 1 standard error | 0.04% | 0.08% | 0.08% | | | | | | | |

## Epic® II VR (Model V-158)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Normal Battery Depletion | 0 |
| Registered US Implants | 1,418 | Malfunctions | 0 |
| Estimated Active US Implants | 1,141 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy | 0 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 1300 | 600 | | | | | | | | |

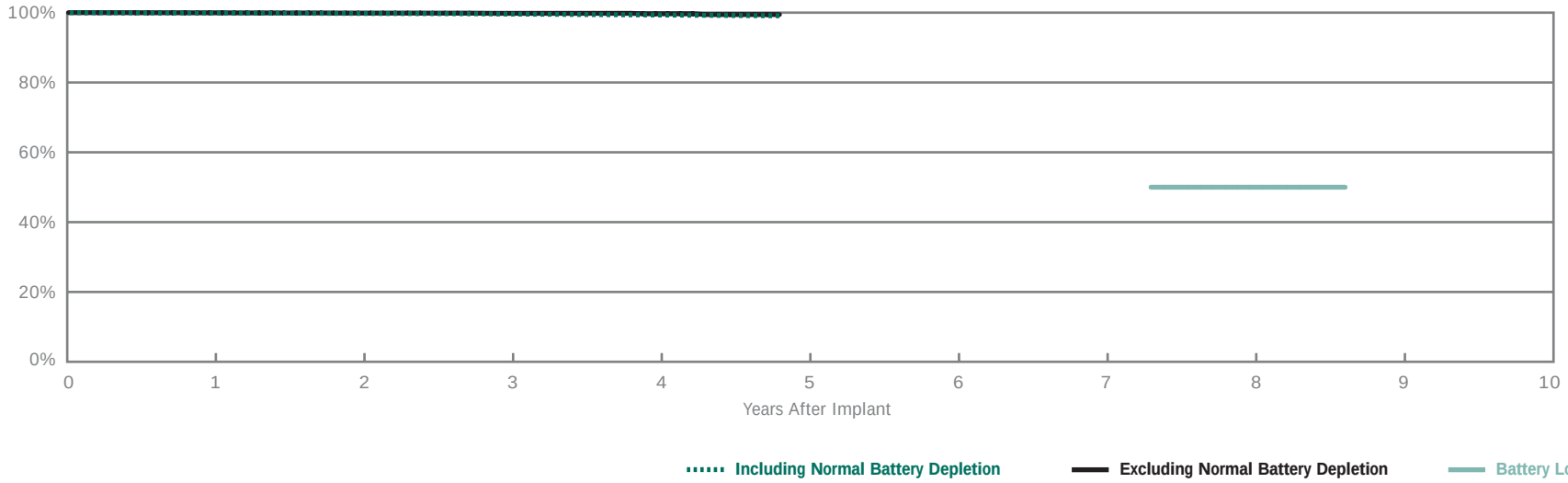
**Excluding Normal Battery Depletion**

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

## Atlas® + VR (Model V-193)

| | | | |
|---|---|---|---|
| US Market Release | October 2003 | Normal Battery Depletion | 11 |
| Registered US Implants | 20,260 | Malfunctions | 17 |
| Estimated Active US Implants | 12,940 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 9 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 8 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.75% | 99.64% | 99.53% | 99.12% | | | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.05% | 0.10% | 0.23% | | | | | |
| Sample Size | 20200 | 16400 | 10700 | 4300 | 700 | | | | | |

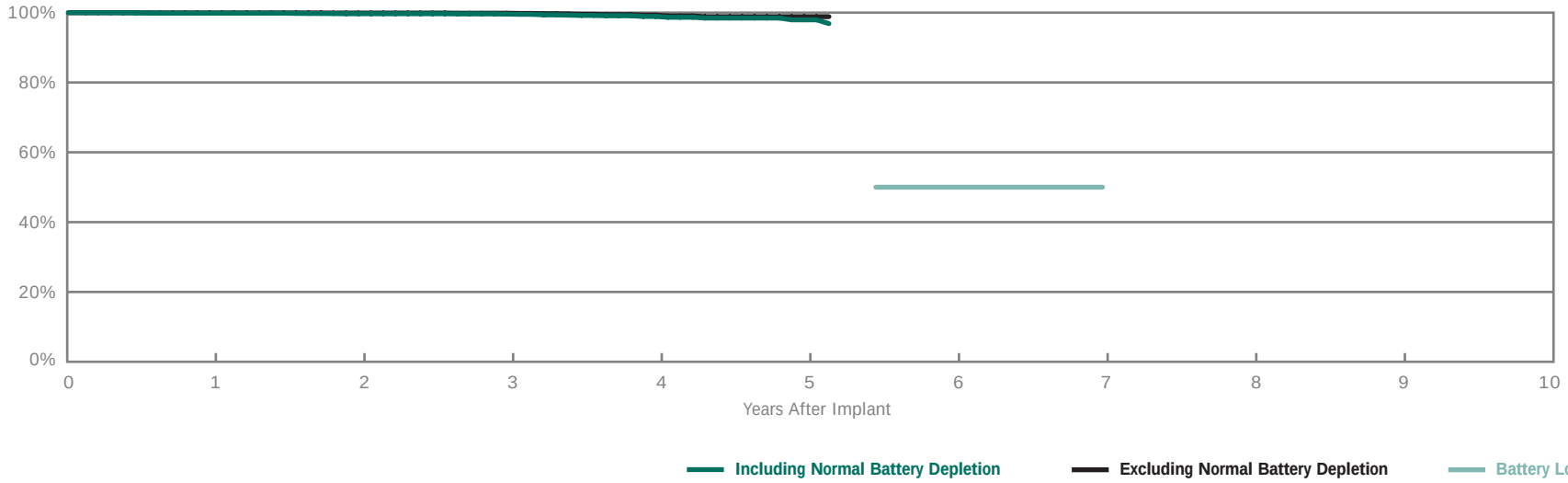
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.87% | 99.80% | 99.68% | 99.45% | | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.04% | 0.09% | 0.19% | | | | | |

## Epic® + VR (Model V-196)

| | | | |
|---|---|---|---|
| US Market Release | April 2003 | Normal Battery Depletion | 11 |
| Registered US Implants | 7,923 | Malfunctions | 15 |
| Estimated Active US Implants | 4,514 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 10 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Three |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 62 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.84% | 99.68% | 99.58% | 98.91% | 97.94% | 96.86% | | | | |
| ± 1 standard error | 0.04% | 0.07% | 0.08% | 0.19% | 0.46% | 0.46% | | | | |
| Sample Size | 7900 | 6900 | 5000 | 2700 | 900 | 200 | | | | |

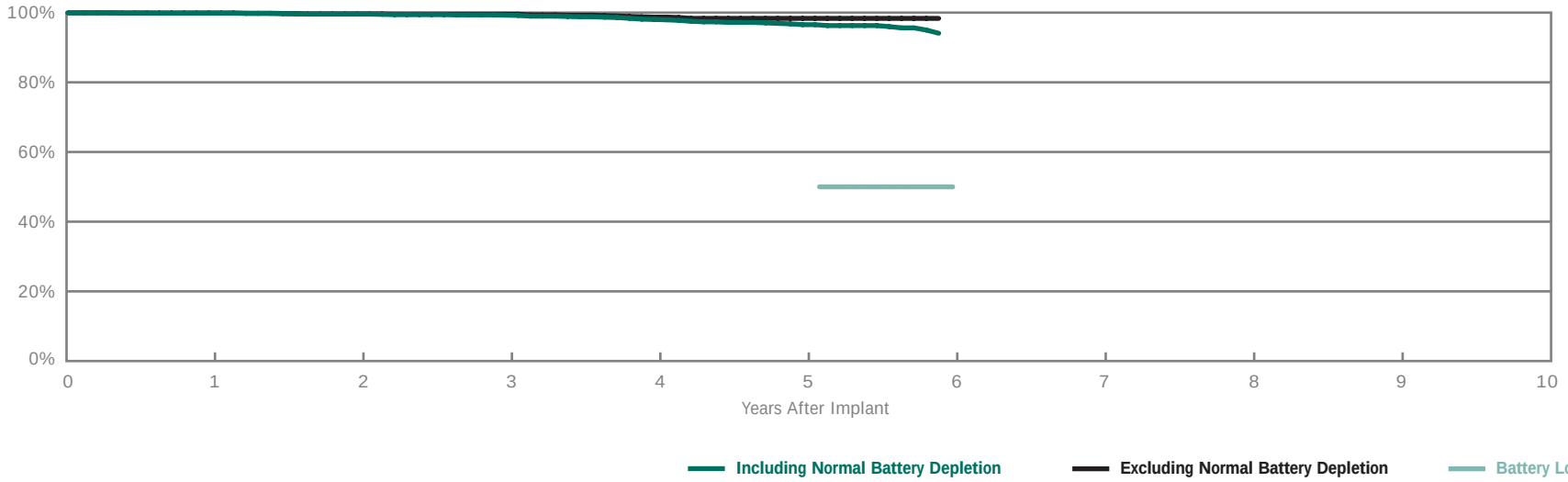
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 62 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.89% | 99.84% | 99.30% | 98.85% | 98.85% | | | | |
| ± 1 standard error | 0.03% | 0.04% | 0.05% | 0.16% | 0.26% | 0.26% | | | | |

## Epic® VR (Model V-197)

| | | | |
|---|---|---|---|
| US Market Release | July 2002 | Normal Battery Depletion | 23 |
| Registered US Implants | 3,647 | Malfunctions | 22 |
| Estimated Active US Implants | 1,189 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 17 |
| Max. Delivered Energy | 30 joules | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.83% | 99.56% | 99.26% | 98.03% | 96.54% | 94.08% | | | | |
| ± 1 standard error | 0.07% | 0.12% | 0.15% | 0.27% | 0.39% | 0.70% | | | | |
| Sample Size | 3600 | 3200 | 2800 | 2500 | 1800 | 800 | | | | |

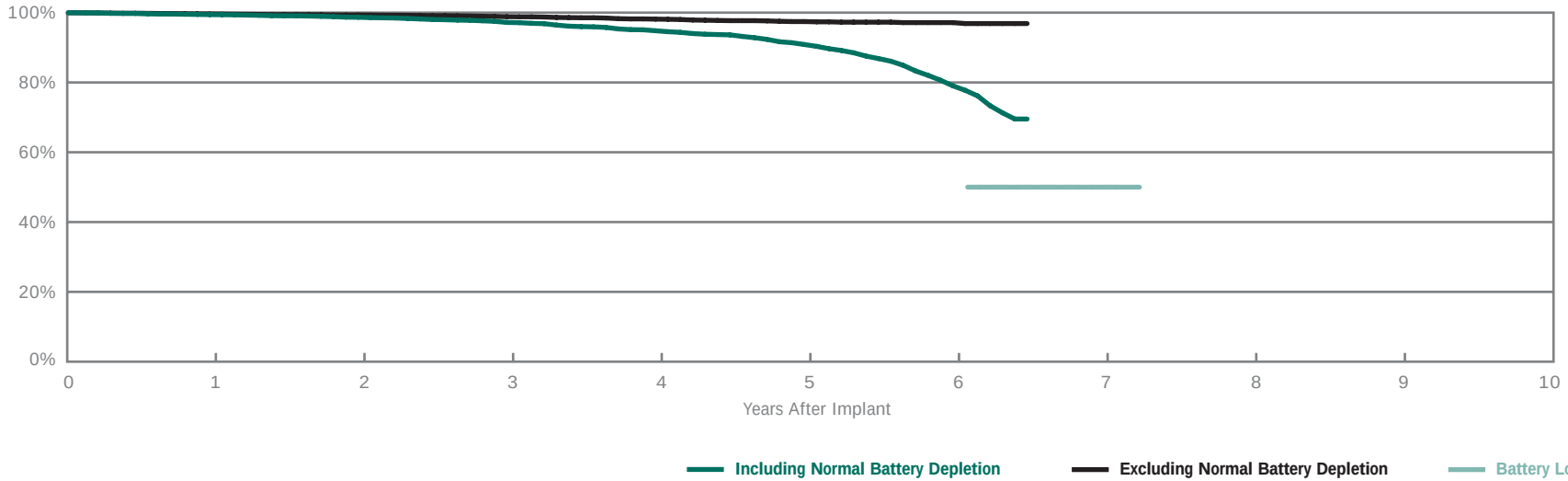
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.89% | 99.62% | 99.55% | 98.71% | 98.34% | 98.34% | | | | |
| ± 1 standard error | 0.06% | 0.11% | 0.12% | 0.22% | 0.27% | 0.27% | | | | |

## Atlas® VR (Model V-199)

| | | | |
|---|---|---|---|
| US Market Release | December 2001 | Normal Battery Depletion | 262 |
| Registered US Implants | 7,089 | Malfunctions | 70 |
| Estimated Active US Implants | 1,427 | Malfunctions w/ Compromised Therapy (22 related to Advisory) | 34 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 36 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 78 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.43% | 98.67% | 97.19% | 94.81% | 90.87% | 79.04% | 69.52% | | | |
| ± 1 standard error | 0.09% | 0.15% | 0.21% | 0.31% | 0.45% | 0.84% | 1.47% | | | |
| Sample Size | 7100 | 6100 | 5300 | 4500 | 3400 | 2100 | 400 | | | |

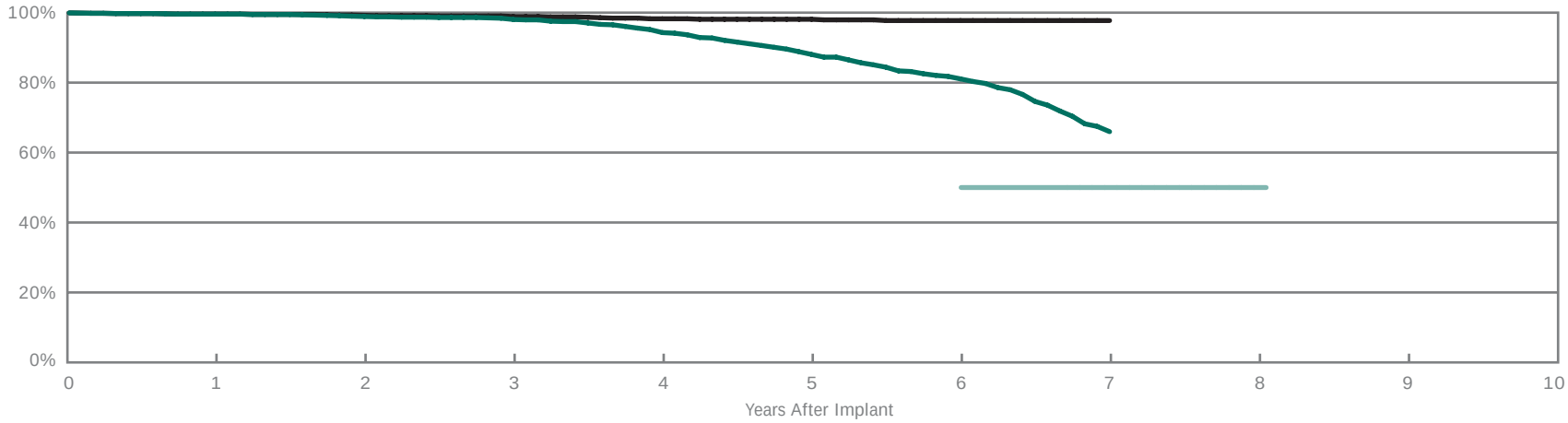
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 78 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.62% | 99.34% | 98.85% | 98.14% | 97.44% | 97.14% | 96.87% | | | |
| ± 1 standard error | 0.07% | 0.10% | 0.14% | 0.19% | 0.24% | 0.27% | 0.33% | | | |

## Photon® µ VR (Model V-194)

| | | | |
|---|---|---|---|
| US Market Release | June 2001 | Normal Battery Depletion | 148 |
| Registered US Implants | 2,837 | Malfunctions | 23 |
| Estimated Active US Implants | 236 | Malfunctions w/ Compromised Therapy (5 related to Advisory) | 12 |
| Estimated Longevity | (see table on page 88) | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 11 |
| Max. Delivered Energy | 36 joules | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

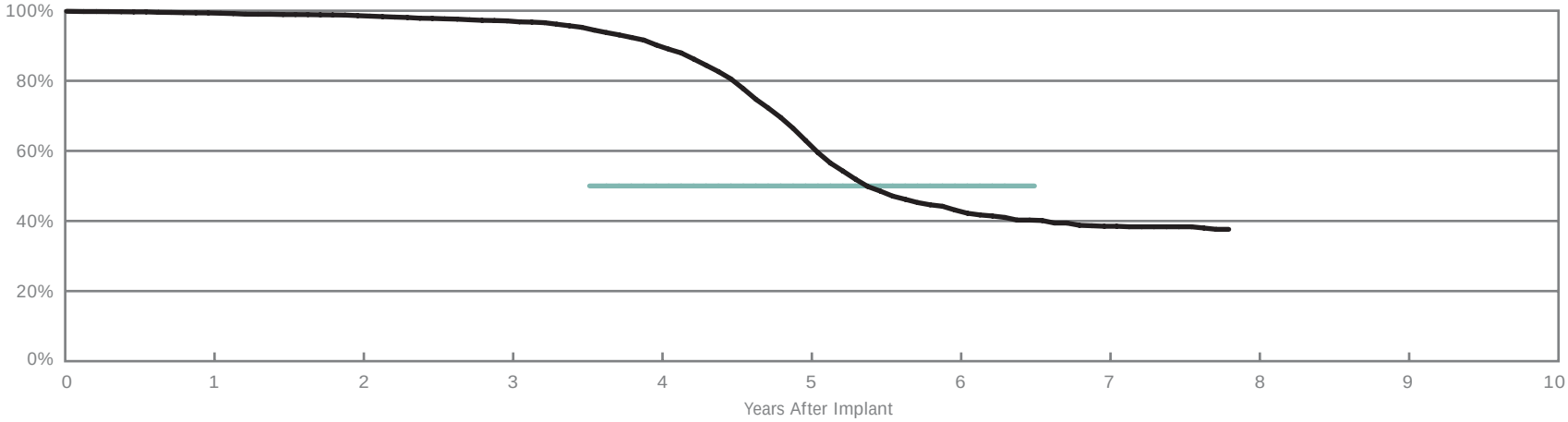
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.59% | 98.90% | 98.05% | 94.30% | 88.06% | 81.06% | 65.98% | | | |
| ± 1 standard error | 0.12% | 0.20% | 0.26% | 0.49% | 0.79% | 1.04% | 1.63% | | | |
| Sample Size | 2800 | 2500 | 2200 | 1900 | 1500 | 1100 | 700 | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.59% | 99.24% | 98.90% | 98.25% | 98.11% | 97.74% | 97.74% | | | |
| ± 1 standard error | 0.12% | 0.16% | 0.20% | 0.29% | 0.31% | 0.36% | 0.36% | | | |

| Contour® MD (Models V-175, V-175AC, V-175B, V-175C & V-175D) | |
|---|---|
| US Market Release | October 1998 |
| Registered US Implants | 4,922 |
| Estimated Active US Implants | 299 |
| Estimated Longevity | (see table on page 88) |
| Number of Advisories | None |

## Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 94 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.37% | 98.60% | 97.10% | 90.22% | 62.95% | 43.13% | 38.50% | 37.62% | | |
| **± 1 standard error** | 0.11% | 0.17% | 0.27% | 0.50% | 0.98% | 1.17% | 1.25% | 1.29% | | |
| **Sample Size** | 4900 | 4200 | 3600 | 3300 | 2200 | 1100 | 600 | 300 | | |

# Summary & Longevity Information

## ICDs

## Single-Chamber

# ICDs

## Battery Longevity

| Models | Family | Approximate Duration (years)* | | | |
|---|---|---|---|---|---|
| | | No Pacing | 25% Pacing | 50% Pacing | 100% Pacing |
| 1107-36 | Current VR | 9.5 | 9.1 | 8.8 | 8.2 |
| 1207-30 | Current VR RF | 7.8 | 7.4 | 7.1 | 6.6 |
| 1207-36 | Current VR RF | 9.5 | 9.1 | 8.8 | 8.2 |
| V-168 | Atlas II VR | 8.4 | 8.0 | 7.6 | 7.0 |
| V-158 | Epic II VR | 7.1 | 6.8 | 6.5 | 5.9 |
| V-193 | Atlas + VR | 8.6 | 8.2 | 7.9 | 7.3 |
| V-196 | Epic + VR <115000 | 6.3 | 6.0 | 5.8 | 5.4 |
| V-196 | Epic + VR >115000 | 6.9 | 6.6 | 6.4 | 5.9 |
| V-197 | Epic VR | 5.9 | 5.7 | 5.5 | 5.1 |
| V-199 | Atlas VR | 7.2 | 6.9 | 6.6 | 6.1 |
| V-194 | Photon µ VR<42000 | 7.1 | 6.8 | 6.5 | 6.0 |
| V-194 | Photon µ VR>42000 | 8.1 | 7.7 | 7.4 | 6.8 |

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

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

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

## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/ Compromised Therapy (under advisory) | Malfunctions w/ Compromised Therapy (premature battery depletion) | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1107-36 | Current VR | May-07 | 317 | 268 | 1 | 0 | 0 | 0 | 0 | 1 | 0 |
| 1207-30 | Current VR RF | Sep-07 | 356 | 333 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1207-36 | Current VR RF | Sep-07 | 6185 | 5759 | 1 | 0 | 1 | 1 | 1 | 4 | 0 |
| V-168 | Atlas II VR | Jul-06 | 9166 | 7641 | 4 | 0 | 1 | 0 | 3 | 8 | 1 |
| V-158 | Epic II VR | Mar-06 | 1418 | 1141 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| V-193 | Atlas + VR | Oct-03 | 20260 | 12940 | 7 | 0 | 2 | 3 | 5 | 17 | 11 |
| V-196 | Epic + VR | Apr-03 | 7923 | 4514 | 3 | 0 | 2 | 10 | 0 | 15 | 11 |
| V-197 | Epic VR | Jul-02 | 3647 | 1189 | 4 | 0 | 1 | 15 | 2 | 22 | 23 |
| V-199 | Atlas VR | Dec-01 | 7089 | 1427 | 6 | 22 | 6 | 33 | 3 | 70 | 262 |
| V-194 | Photon µ VR | Jun-01 | 2837 | 236 | 3 | 5 | 4 | 10 | 1 | 23 | 148 |

**Based on returned product analysis as of December 31, 2008.*

## Including Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year | 9 year | 10 year |
| 1107-36 | Current VR** | | | | | | | | | | |
| 1207-30 | Current VR RF** | | | | | | | | | | |
| 1207-36 | Current VR RF | 99.74% | | | | | | | | | |
| V-168 | Atlas II VR | 99.83% | 99.70% | | | | | | | | |
| V-158 | Epic II VR | 100.00% | 100.00% | | | | | | | | |
| V-193 | Atlas + VR | 99.89% | 99.75% | 99.64% | 99.53% | | | | | | |
| V-196 | Epic + VR | 99.84% | 99.68% | 99.58% | 98.91% | 97.94% | | | | | |
| V-197 | Epic VR | 99.83% | 99.56% | 99.26% | 98.03% | 96.54% | | | | | |
| V-199 | Atlas VR | 99.43% | 98.67% | 97.19% | 94.81% | 90.87% | 79.04% | | | | |
| V-194 | Photon µ VR | 99.59% | 98.90% | 98.05% | 94.30% | 88.06% | 81.06% | 65.98% | | | |

**Based on returned product analysis as of December 31, 2008.*

***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 device 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 |
| 1107-36 | Current VR** | | | | | | | | | | |
| 1207-30 | Current VR RF** | | | | | | | | | | |
| 1207-36 | Current VR RF | 99.74% | | | | | | | | | |
| V-168 | Atlas II VR | 99.83% | 99.74% | | | | | | | | |
| V-158 | Epic II VR | 100.00% | 100.00% | | | | | | | | |
| V-193 | Atlas + VR | 99.95% | 99.87% | 99.80% | 99.68% | | | | | | |
| V-196 | Epic + VR | 99.92% | 99.89% | 99.84% | 99.30% | 98.85% | | | | | |
| V-197 | Epic VR | 99.89% | 99.62% | 99.55% | 98.71% | 98.34% | | | | | |
| V-199 | Atlas VR | 99.62% | 99.34% | 98.85% | 98.14% | 97.44% | 97.14% | | | | |
| V-194 | Photon µ VR | 99.59% | 99.24% | 98.90% | 98.25% | 98.11% | 94.74% | 97.74% | | | |

**Based on returned product analysis as of December 31, 2008.*

***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 device graphs for data up to one year.*

# Defibrillation Leads

St. Jude Medical™

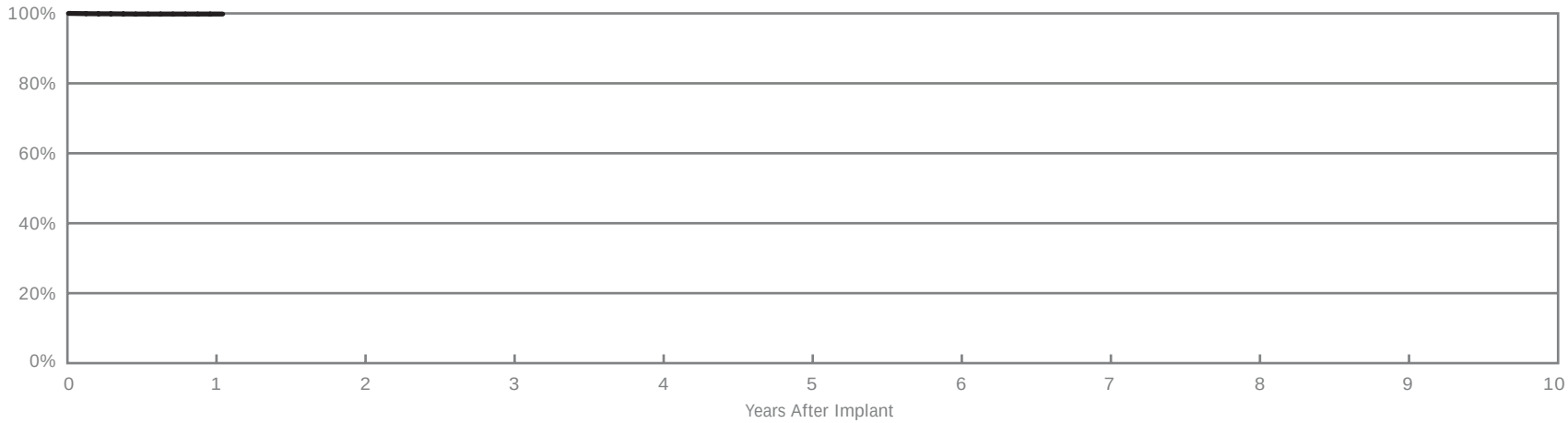
More control. Less risk.

# Defibrillation Leads

| Durata® (Models 7120 & 7121) | | | |
|---|---|---|---|
| US Market Release | September 2007 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 18,309 | Polarity | Bipolar |
| Estimated Active US Implants | 17,328 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

| Laboratory Analysis | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **15** | **Electrical Malfunction** | **1** | **Other** | **19** |
| | | Insulation Disruption | 0 | Explant Damage | 12 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 7 |
| | | Crimps, Welds, Bonds | 1 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

**Survival from Returns and Complaints**




| Year | 1 | at 13 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.82% | 99.82% | | | | | | | | |
| **± 1 standard error** | 0.04% | 0.04% | | | | | | | | |
| **Sample Size** | 9200 | 200 | | | | | | | | |

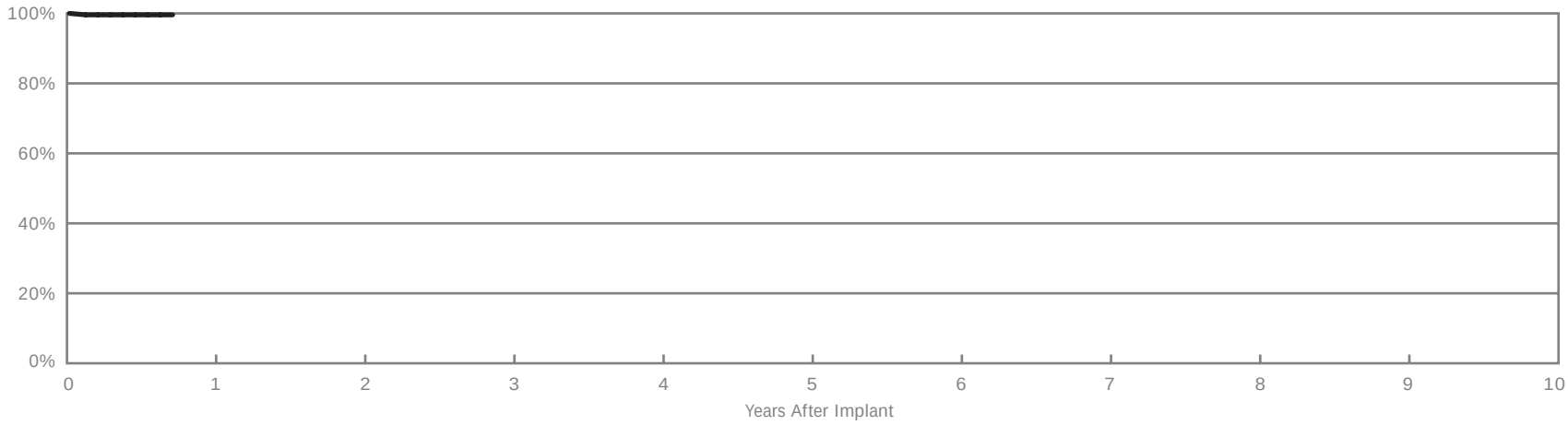
**Optim® insulation is a copolymer of silicone and polyurethane.*

## Durata® (Models 7120 & 7121)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 521 |
| Cumulative Months of Follow-Up | 2,796 |

| Qualifying Complications | 2 |
|---|---|
| Failure to Capture | 1 |
| Extracardiac Stimulation | 1 |

### Survival from SCORE Registry




| Year | at 9 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.59% | | | | | | | | | |
| ± 1 standard error | 0.29% | | | | | | | | | |
| Sample Size | 53 | | | | | | | | | |

# Defibrillation Leads

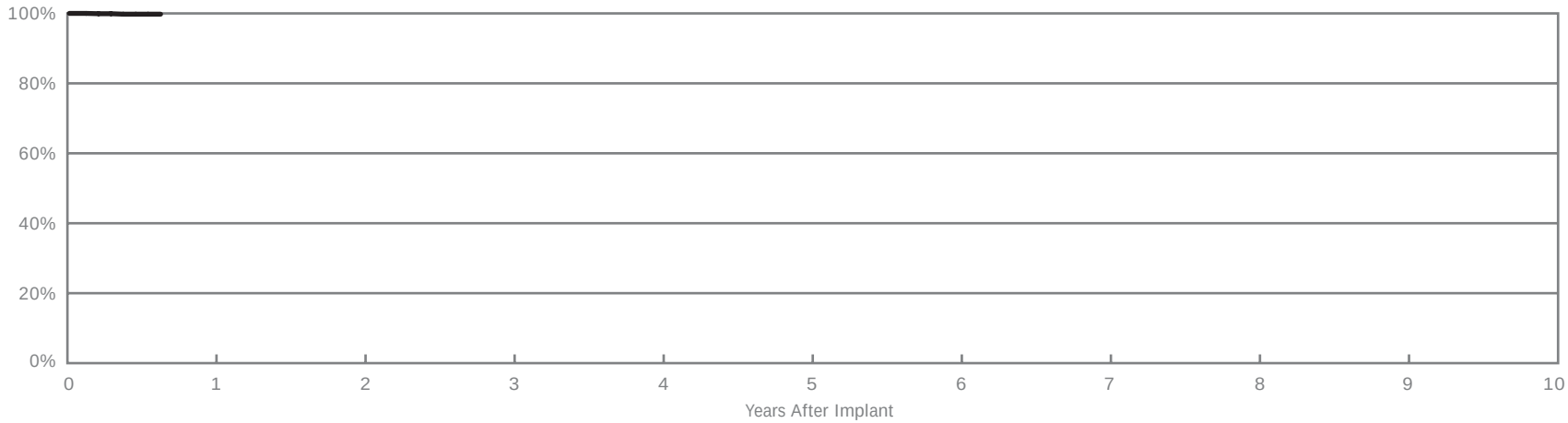
## Durata® (Model 7122)

| | | | |
|---|---|---|---|
| US Market Release | September 2007 | Type and/or Fixation | Single Coil, Active |
| Registered US Implants | 1,616 | Polarity | Bipolar |
| Estimated Active US Implants | 1,541 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **3** | **Electrical Malfunction** | **0** | **Other** | **4** |
| | | Insulation Disruption | 0 | Explant Damage | 3 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | at 8 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.78% | | | | | | | | | |
| **± 1 standard error** | 0.16% | | | | | | | | | |
| **Sample Size** | 200 | | | | | | | | | |

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

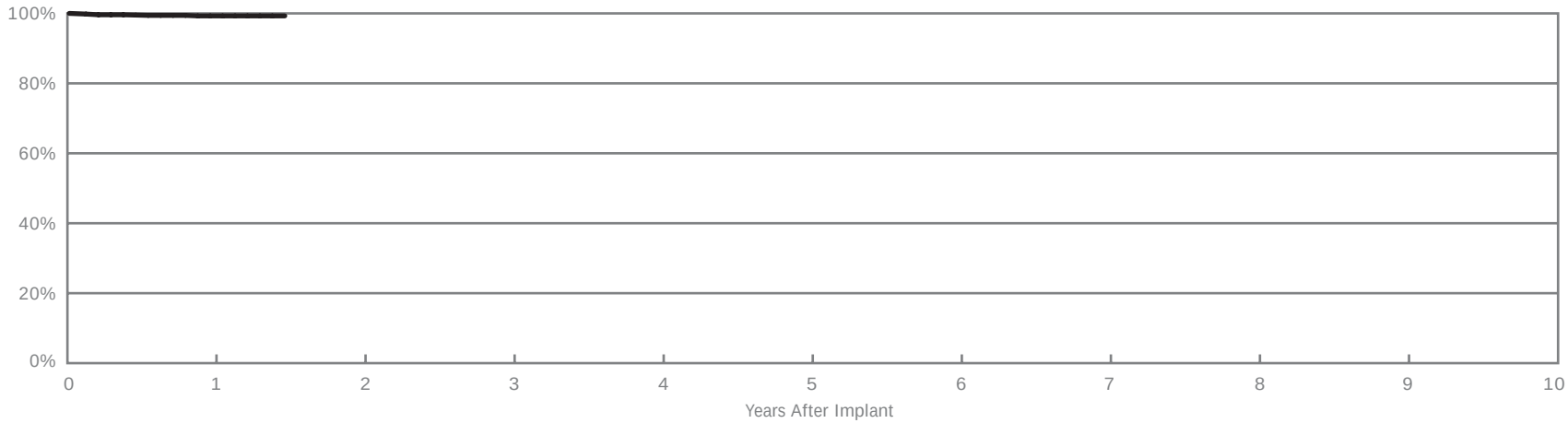
## Riata® ST Optim® (Models 7070 & 7071)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Type and/or Fixation | Dual Coil, Passive |
| Registered US Implants | 1,776 | Polarity | Bipolar |
| Estimated Active US Implants | 1,619 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| Implant Damage | 1 | Electrical Malfunction | 2 | Other | 2 |
|---|---|---|---|---|---|
| | | Insulation Disruption | 0 | Explant Damage | 1 |
| | | Conductor Disruption | 1 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 1 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.29% | 99.29% | | | | | | | | |
| ± 1 standard error | 0.24% | 0.24% | | | | | | | | |
| Sample Size | 1200 | 100 | | | | | | | | |

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

# Defibrillation Leads

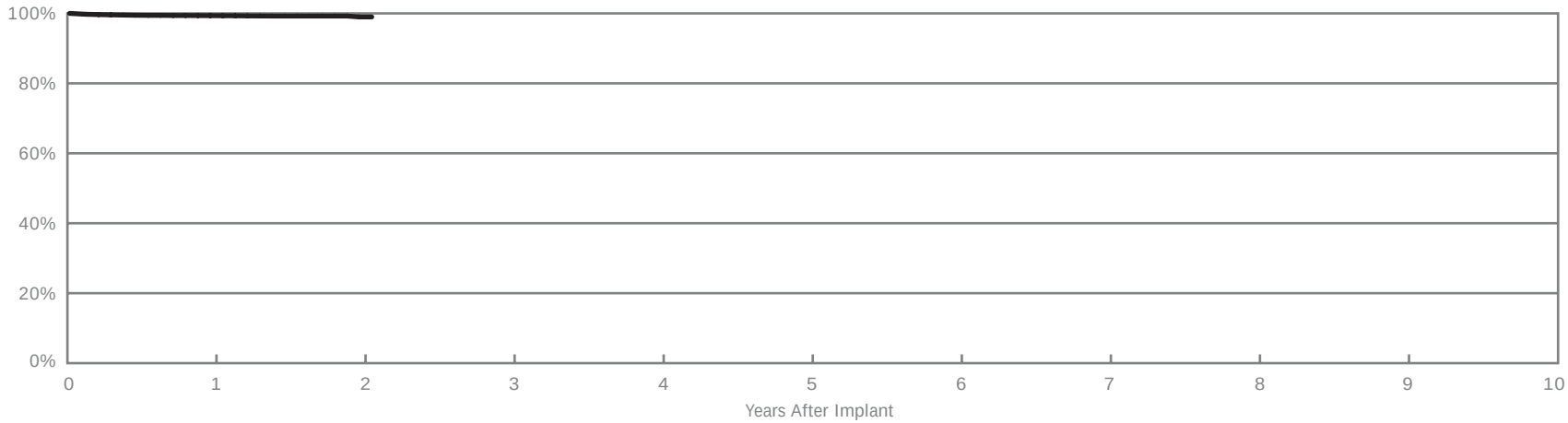
## Riata® ST Optim® (Models 7020 & 7021)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 13,861 | Polarity | Bipolar |
| Estimated Active US Implants | 12,476 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **61** | **Electrical Malfunction** | **4** | **Other** | **64** |
| | | Insulation Disruption | 1 | Explant Damage | 57 |
| | | Conductor Disruption | 3 | Non-Electrical Workmanship | 4 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 2 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 25 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.36% | 98.99% | 98.99% | | | | | | | |
| **± 1 standard error** | 0.07% | 0.08% | 0.28% | | | | | | | |
| **Sample Size** | 11300 | 4100 | 100 | | | | | | | |

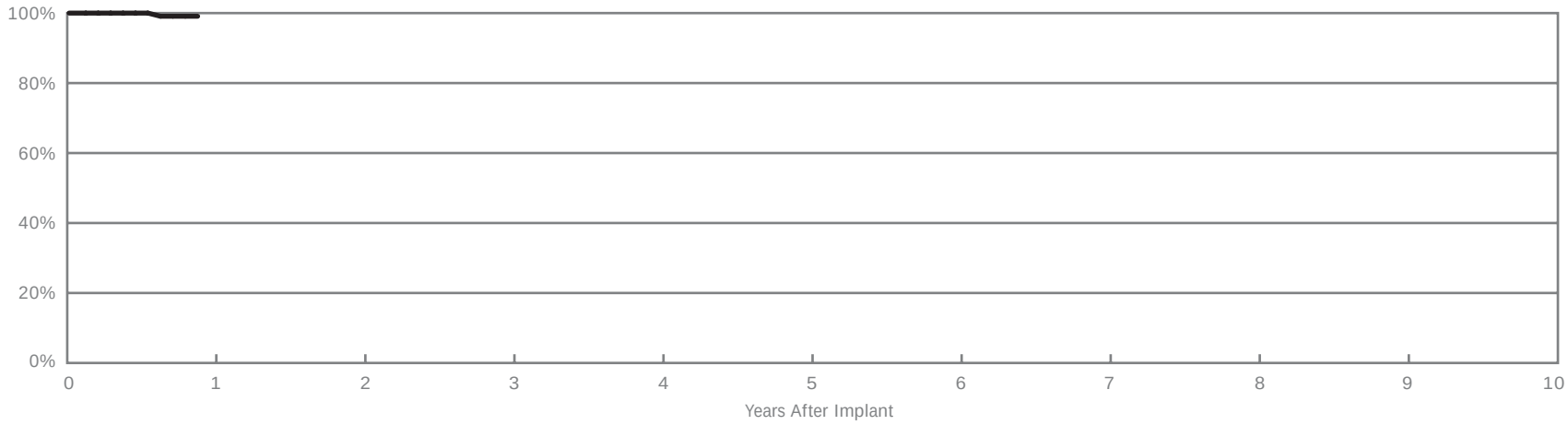
**Optim® insulation is a copolymer of silicone and polyurethane.*

## Riata® ST Optim® (Models 7020 & 7021)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 149 |
| Cumulative Months of Follow-Up | 1,347 |

| Qualifying Complications | 2 |
|---|---|
| Failure to Sense | 1 |
| Cardiac Perforation | 1 |

### Survival from SCORE Registry




| Year | at 11 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 98.21% | | | | | | | | | |
| ± 1 standard error | 0.89% | | | | | | | | | |
| Sample Size | 55 | | | | | | | | | |

# Defibrillation Leads

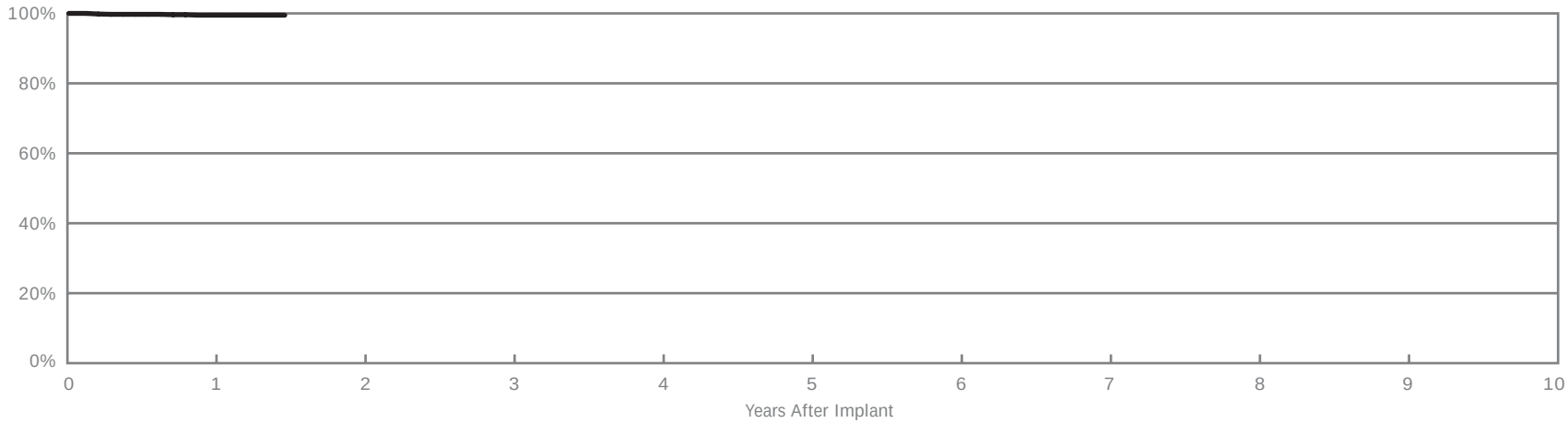
## Riata® ST Optim® (Model 7022)

| | | | |
|---|---|---|---|
| US Market Release | July 2006 | Type and/or Fixation | Single Coil, Active |
| Registered US Implants | 1,252 | Polarity | Bipolar |
| Estimated Active US Implants | 1,149 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **3** | **Electrical Malfunction** | **1** | **Other** | **5** |
| | | Insulation Disruption | 0 | Explant Damage | 4 |
| | | Conductor Disruption | 1 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.49% | 99.49% | | | | | | | | |
| **± 1 standard error** | 0.23% | 0.23% | | | | | | | | |
| **Sample Size** | 1000 | 100 | | | | | | | | |

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

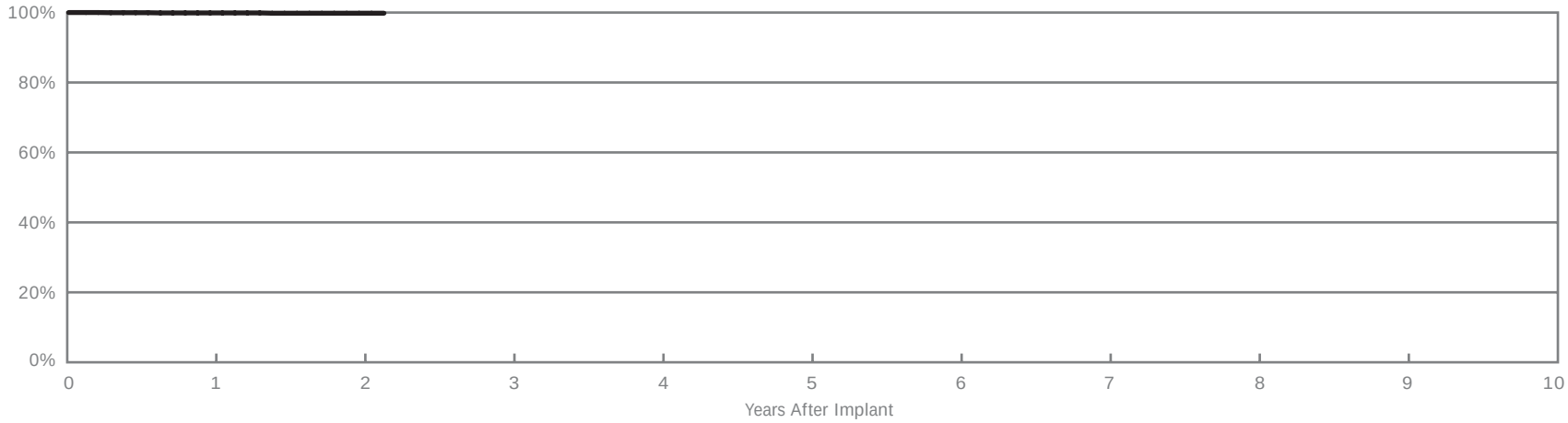
## Riata® ST (Models 7010 & 7011)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 2,079 | Polarity | Bipolar |
| Estimated Active US Implants | 1,842 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **6** | **Electrical Malfunction** | **0** | **Other** | **4** |
| | | Insulation Disruption | 0 | Explant Damage | 3 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 0 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 26 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.89% | 99.81% | 99.81% | | | | | | | |
| **± 1 standard error** | 0.08% | 0.12% | 0.12% | | | | | | | |
| **Sample Size** | 1900 | 1000 | 100 | | | | | | | |

# Defibrillation Leads

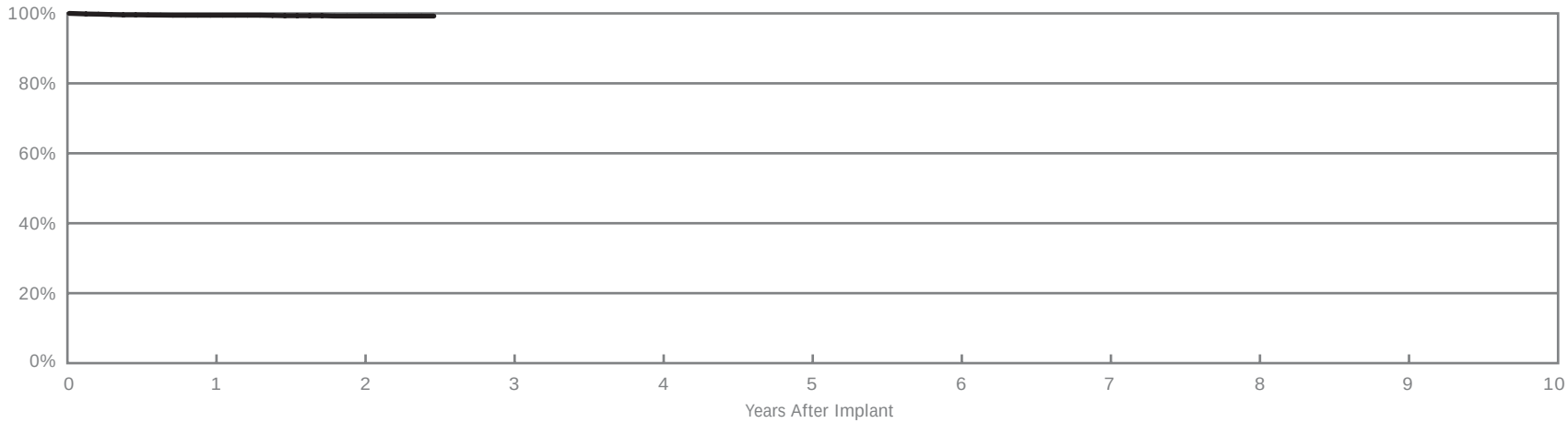
## Riata® ST (Models 7040 & 7041)

| | | | |
|---|---|---|---|
| US Market Release | March 2006 | Type and/or Fixation | Dual Coil, Passive |
| Registered US Implants | 3,373 | Polarity | Bipolar |
| Estimated Active US Implants | 2,994 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **6** | **Electrical Malfunction** | **2** | **Other** | **9** |
| | | Insulation Disruption | 1 | Explant Damage | 4 |
| | | Conductor Disruption | 1 | Non-Electrical Workmanship | 3 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 30 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.47% | 99.24% | 99.24% | | | | | | | |
| **± 1 standard error** | 0.13% | 0.19% | 0.19% | | | | | | | |
| **Sample Size** | 2900 | 1500 | 100 | | | | | | | |

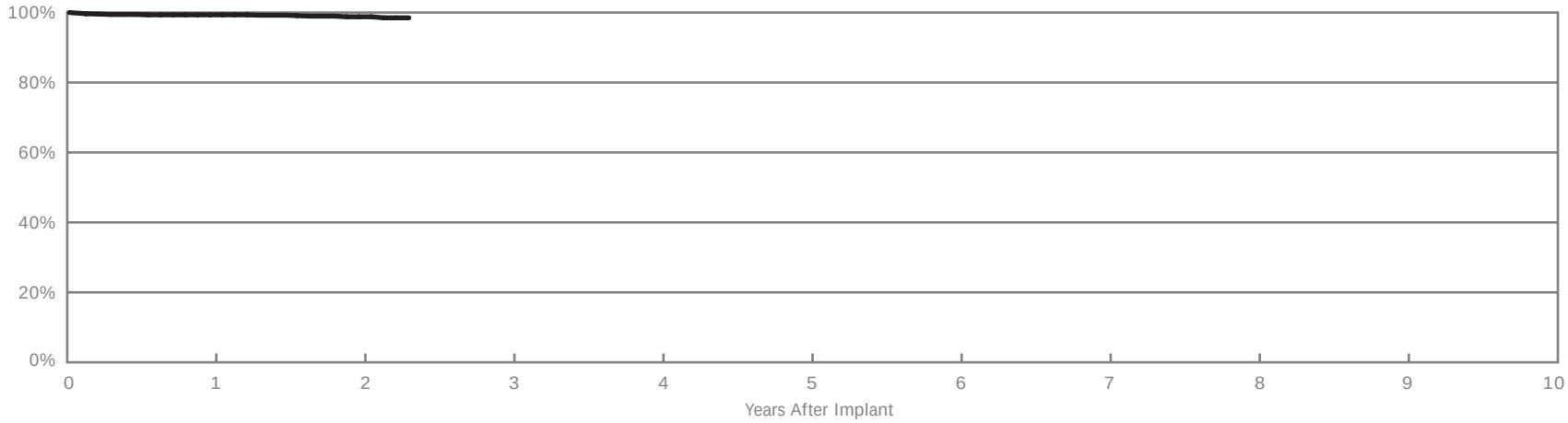
## Riata® ST (Model 7002)

| | | | |
|---|---|---|---|
| US Market Release | June 2005 | Type and/or Fixation | Single Coil, Active |
| Registered US Implants | 2,153 | Polarity | Bipolar |
| Estimated Active US Implants | 1,945 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **9** | **Electrical Malfunction** | **2** | **Other** | **8** |
| | | Insulation Disruption | 0 | Explant Damage | 7 |
| | | Conductor Disruption | 2 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 28 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.34% | 98.79% | 98.49% | | | | | | | |
| **± 1 standard error** | 0.18% | 0.34% | 0.45% | | | | | | | |
| **Sample Size** | 1800 | 900 | 100 | | | | | | | |

# Defibrillation Leads

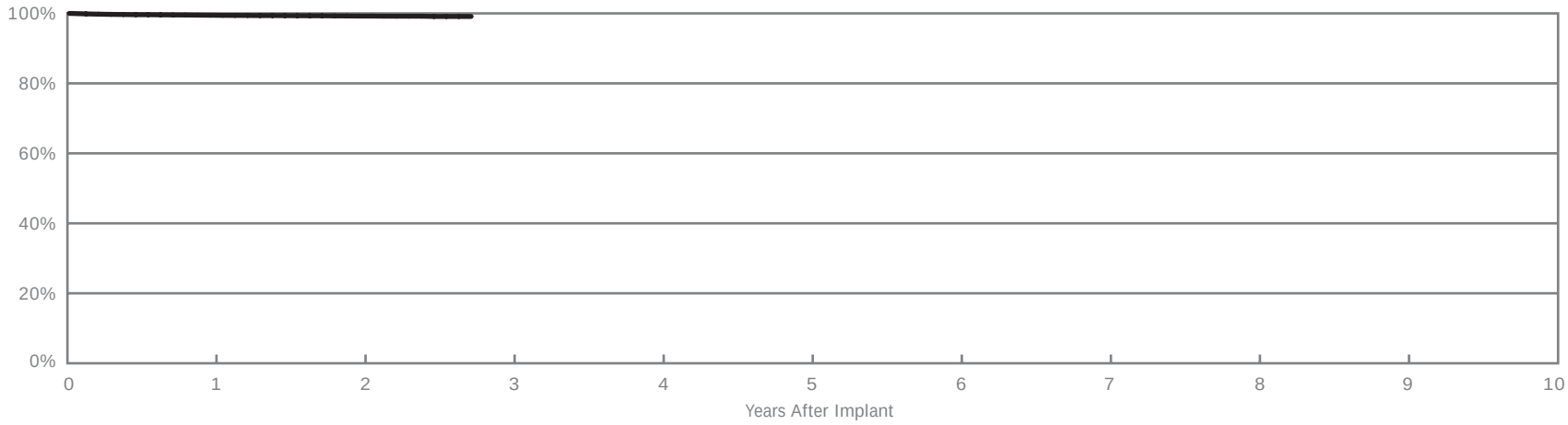
## Riata® ST (Models 7000 & 7001)

| | | | |
|---|---|---|---|
| US Market Release | June 2005 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 32,899 | Polarity | Bipolar |
| Estimated Active US Implants | 28,533 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **125** | **Electrical Malfunction** | **29** | **Other** | **110** |
| | | Insulation Disruption | 19 | Explant Damage | 87 |
| | | Conductor Disruption | 6 | Non-Electrical Workmanship | 13 |
| | | Crimps, Welds, Bonds | 4 | Non-Electrical Anomaly | 7 |
| | | | | Partial Lead | 3 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 33 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.47% | 99.24% | 99.13% | | | | | | | |
| **± 1 standard error** | 0.04% | 0.05% | 0.08% | | | | | | | |
| **Sample Size** | 29900 | 17800 | 300 | | | | | | | |

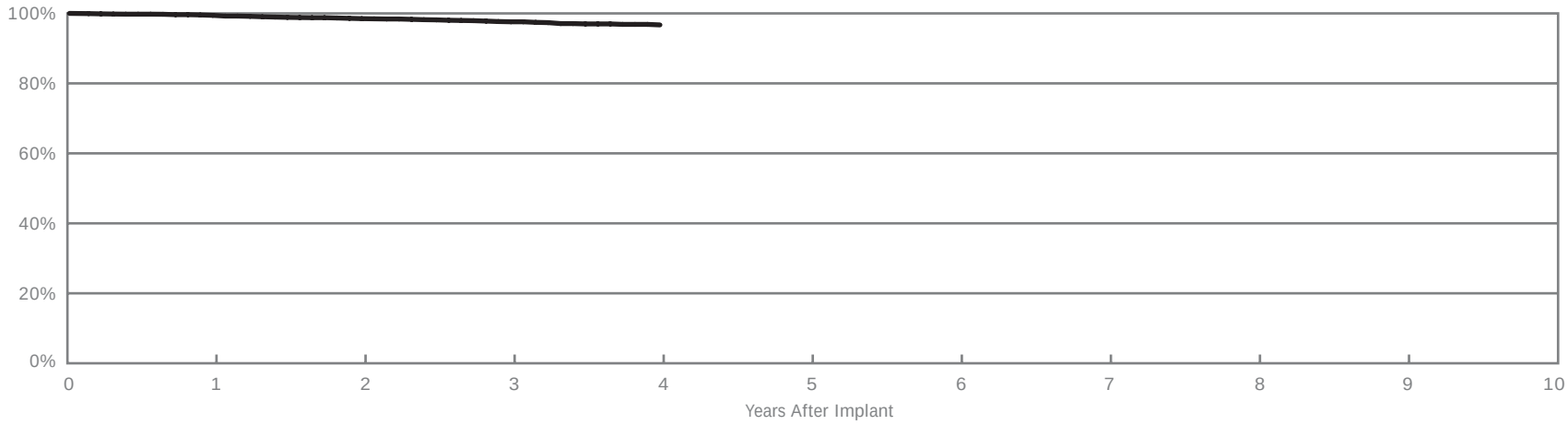
## Riata® i (Models 1590 & 1591)

| | | | |
|---|---|---|---|
| US Market Release | April 2004 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 9,586 | Polarity | Bipolar |
| Estimated Active US Implants | 7,415 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **24** | **Electrical Malfunction** | **5** | **Other** | **12** |
| | | Insulation Disruption | 2 | Explant Damage | 9 |
| | | Conductor Disruption | 3 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 98.75% | 98.20% | 97.09% | 96.71% | | | | | | |
| **± 1 standard error** | 0.06% | 0.07% | 0.10% | 0.10% | | | | | | |
| **Sample Size** | 9100 | 7400 | 4100 | 100 | | | | | | |

# Defibrillation Leads

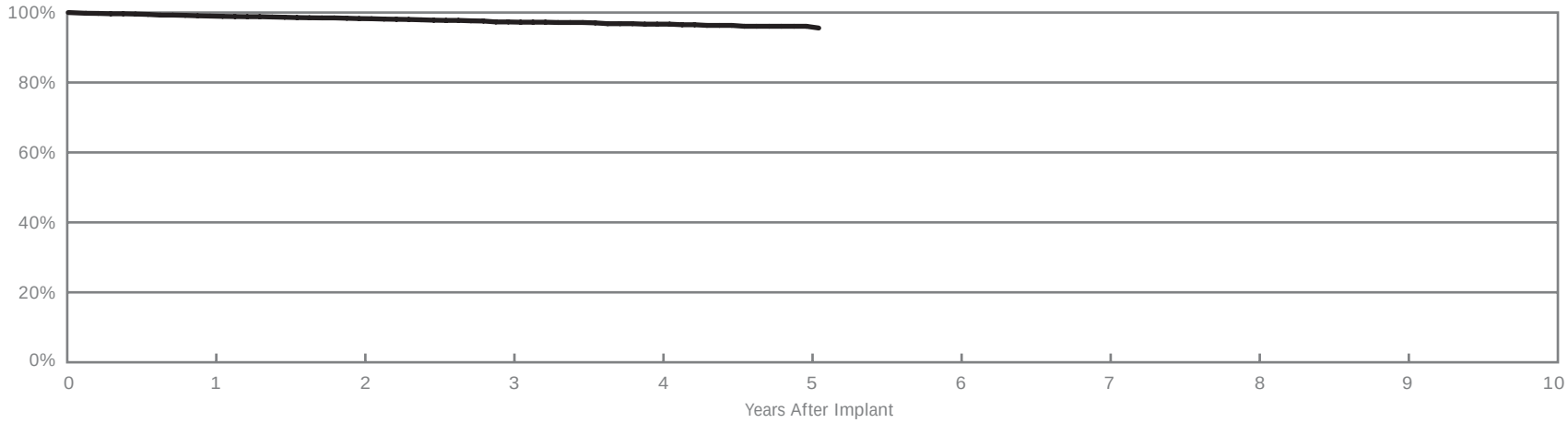
## Riata® (Model 1582)

| | | | |
|---|---|---|---|
| US Market Release | March 2003 | Type and/or Fixation | Single Coil, Active |
| Registered US Implants | 3,007 | Polarity | Bipolar |
| Estimated Active US Implants | 2,159 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **12** | **Electrical Malfunction** | **19** | **Other** | **15** |
| | | Insulation Disruption | 17 | Explant Damage | 5 |
| | | Conductor Disruption | 2 | Non-Electrical Workmanship | 3 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 6 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | at 61 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 98.99% | 98.27% | 97.31% | 96.68% | 96.07% | 95.57% | | | | |
| **± 1 standard error** | 0.19% | 0.25% | 0.35% | 0.44% | 0.56% | 0.56% | | | | |
| **Sample Size** | 2900 | 2300 | 1800 | 1000 | 400 | 100 | | | | |

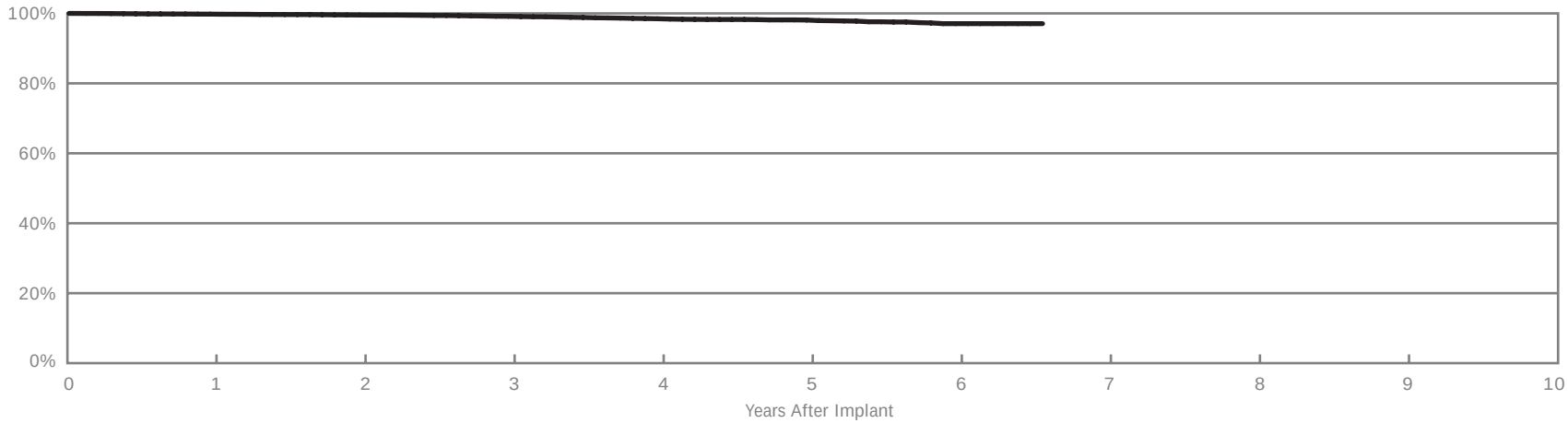
## Riata® (Models 1570 & 1571)

| | | | |
|---|---|---|---|
| US Market Release | March 2002 | Type and/or Fixation | Dual Coil, Passive |
| Registered US Implants | 10,017 | Polarity | Bipolar |
| Estimated Active US Implants | 6,939 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| **Implant Damage** | **35** | **Electrical Malfunction** | **18** | **Other** | **28** |
|---|---|---|---|---|---|
| | | Insulation Disruption | 15 | Explant Damage | 15 |
| | | Conductor Disruption | 3 | Non-Electrical Workmanship | 5 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 7 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 79 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.79% | 99.54% | 99.17% | 98.47% | 98.10% | 97.07% | 97.07% | | | |
| **± 1 standard error** | 0.05% | 0.07% | 0.11% | 0.16% | 0.20% | 0.34% | 0.34% | | | |
| **Sample Size** | 9400 | 8000 | 6500 | 4700 | 2900 | 1500 | 100 | | | |

# Defibrillation Leads

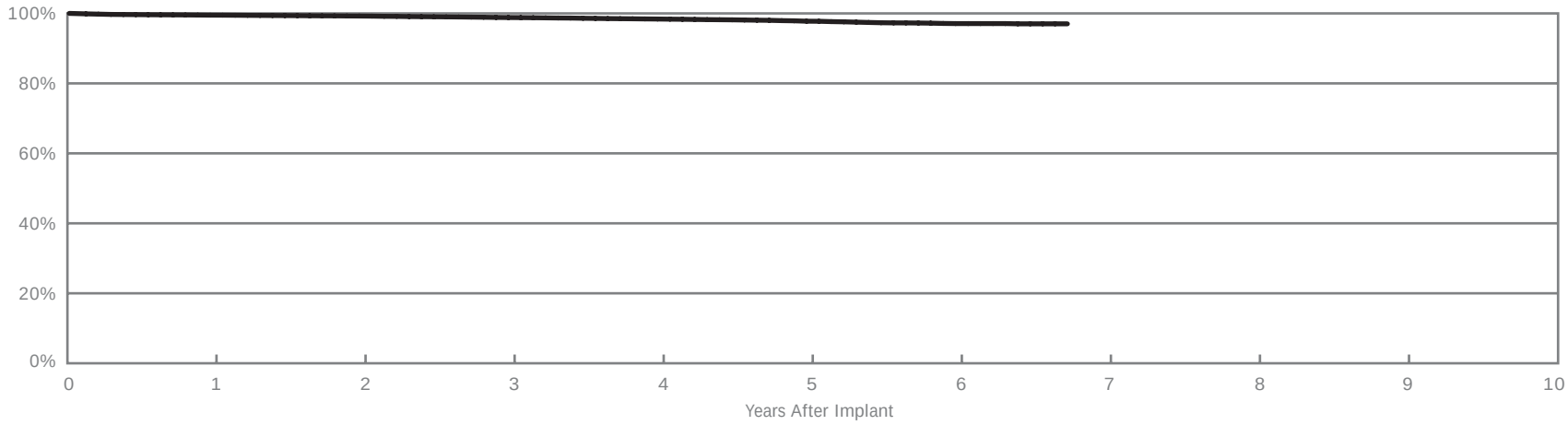
## Riata® (Models 1580 & 1581)

| | | | |
|---|---|---|---|
| US Market Release | March 2002 | Type and/or Fixation | Dual Coil, Active |
| Registered US Implants | 67,421 | Polarity | Bipolar |
| Estimated Active US Implants | 48,528 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **240** | **Electrical Malfunction** | **132** | **Other** | **238** |
| | | Insulation Disruption | 120 | Explant Damage | 145 |
| | | Conductor Disruption | 9 | Non-Electrical Workmanship | 35 |
| | | Crimps, Welds, Bonds | 3 | Non-Electrical Anomaly | 27 |
| | | | | Partial Lead | 31 |

### Survival from Returns and Complaints

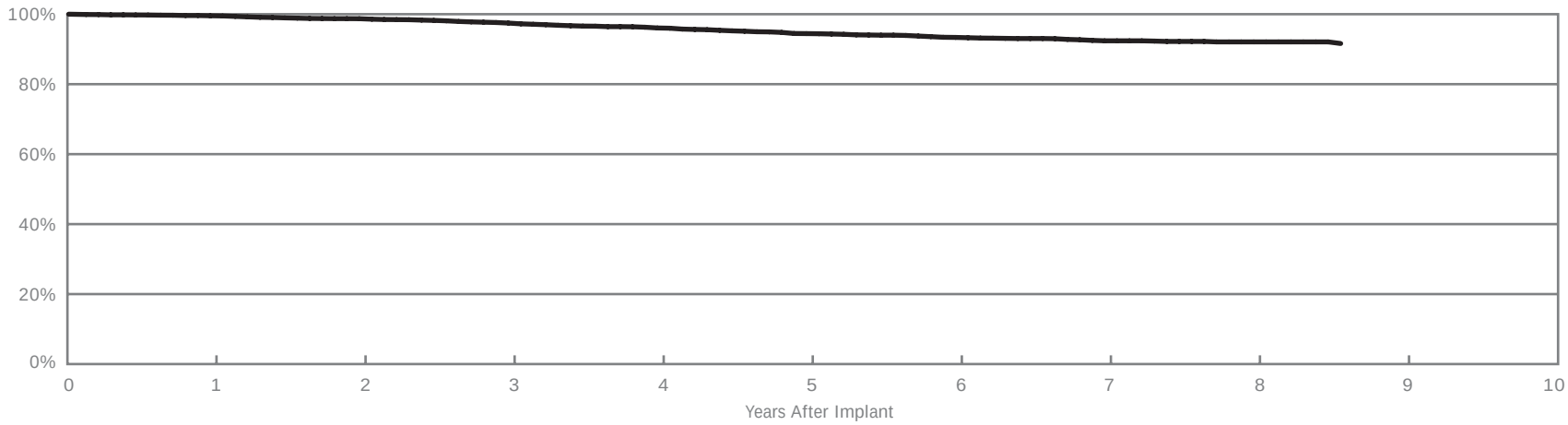



| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 81 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.50% | 99.25% | 98.82% | 98.39% | 97.77% | 97.09% | 97.02% | | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.05% | 0.06% | 0.09% | 0.14% | 0.16% | | | |
| **Sample Size** | 64300 | 55100 | 44200 | 28400 | 14400 | 6000 | 200 | | | |

## TVL® ADX (Model 1559)

| | | | |
|---|---|---|---|
| US Market Release | November 1999 | Type and/or Fixation | Single Coil, Active |
| Registered US Implants | 4,722 | Polarity | Bipolar |
| Estimated Active US Implants | 1,909 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

### Survival from Returns and Complaints

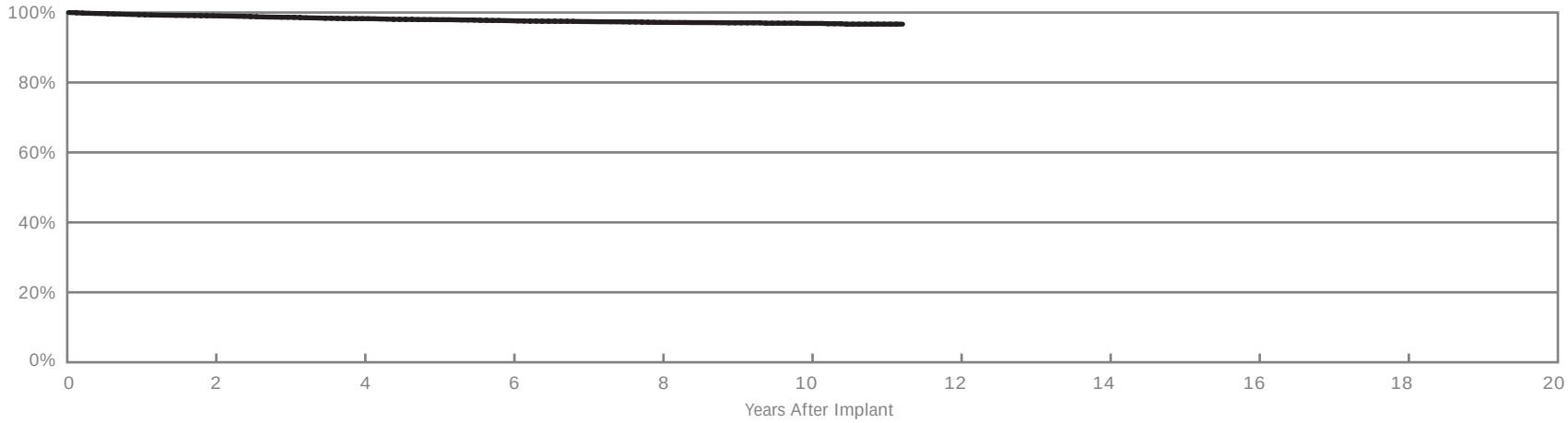



| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 103 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.55% | 98.71% | 97.46% | 96.06% | 94.45% | 93.36% | 92.39% | 92.08% | 91.62% | |
| **± 1 standard error** | 0.09% | 0.18% | 0.25% | 0.32% | 0.41% | 0.45% | 0.50% | 0.53% | 0.53% | |
| **Sample Size** | 4500 | 3900 | 3500 | 3100 | 2800 | 2400 | 1900 | 1000 | 100 | |

# Defibrillation Leads

| SPL® (Models SP01, SP02, SP03 & SP04) | | | |
|---|---|---|---|
| US Market Release | September 1997 | Type and/or Fixation | Dual Coil, Passive |
| Registered US Implants | 12,899 | Polarity | Bipolar |
| Estimated Active US Implants | 5,227 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | at 135 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.07% | 98.25% | 97.65% | 97.18% | 96.88% | 96.68% | | | | |
| ± 1 standard error | 0.09% | 0.13% | 0.16% | 0.18% | 0.22% | 0.26% | | | | |
| Sample Size | 10900 | 8900 | 7200 | 4700 | 1900 | 100 | | | | |

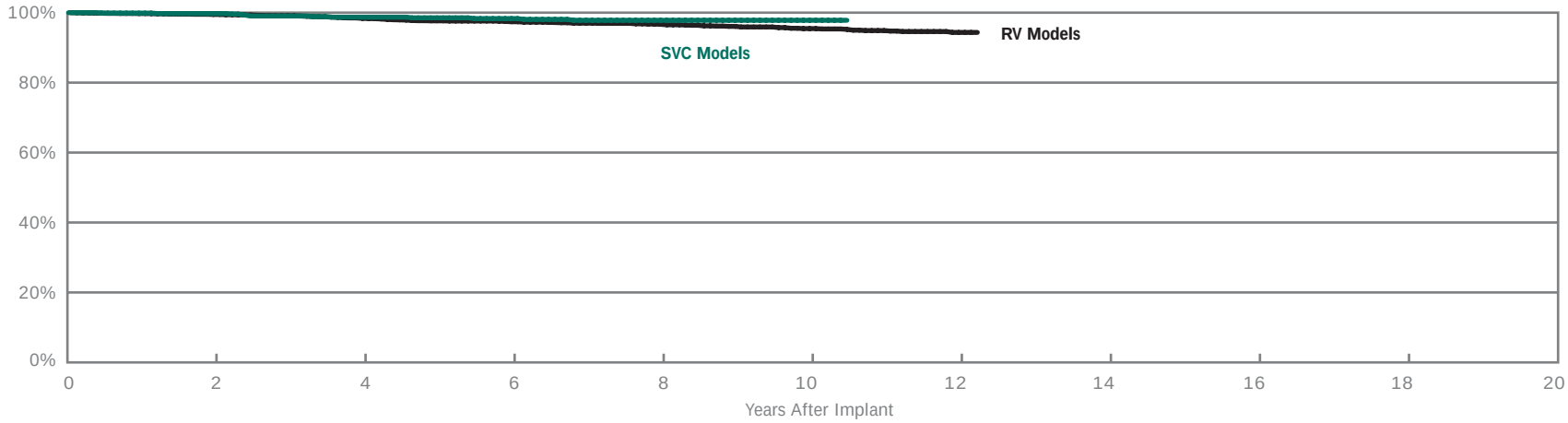
## TVL® RV (Models RV01, RV02, RV03, RV06 & RV07)
## TVL® SVC (Models SV01, SV02 & SV03)

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

| Registered US Implants | | Estimated Active US Implants | |
|---|---|---|---|
| RV | 3,656 | RV | 1,109 |
| SVC | 925 | SVC | 285 |

| | |
|---|---|
| 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 147 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.48% | 98.36% | 97.40% | 96.67% | 95.44% | 94.35% | 94.35% | | | |
| ± 1 standard error | 0.12% | 0.23% | 0.31% | 0.37% | 0.49% | 0.63% | 0.63% | | | |
| Sample Size | 3200 | 2600 | 2100 | 1600 | 1100 | 500 | 100 | | | |

**SVC Models**

| Year | 2 | 4 | 6 | 8 | 10 | at 126 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.75% | 99.25% | 98.31% | 97.82% | 97.82% | 97.82% | | | | |
| ± 1 standard error | 0.18% | 0.04% | 0.51% | 0.62% | 0.62% | 0.62% | | | | |
| Sample Size | 800 | 55100 | 400 | 300 | 200 | 100 | | | | |

# Laboratory Analysis

## Defibrillation Leads

St. Jude Medical

More control. Less risk.

## Laboratory Analysis*

| Models | US Market Release Date | Registered US Implants | Estimated Active US Implants | Implant Damage | Electrical Malfunctions | | | | Other | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Insulation Disruption | Conductor Disruption | Crimps, Welds, Bonds | Total Electrical Malfunctions | Explant Damage | Non-Electrical Workmanship | Non-Electrical Anomaly | Partial Lead | Total Other |
| 7120/7121 | Sep-07 | 18309 | 17328 | 15 | 0 | 0 | 1 | 1 | 12 | 7 | 0 | 0 | 19 |
| 7122 | Sep-07 | 1616 | 1541 | 3 | 0 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 4 |
| 7070/7071 | Jul-06 | 1776 | 1619 | 1 | 0 | 1 | 1 | 2 | 1 | 1 | 0 | 0 | 2 |
| 7020/7021 | Jul-06 | 13861 | 12476 | 61 | 1 | 3 | 0 | 4 | 57 | 4 | 1 | 2 | 64 |
| 7022 | Jul-06 | 1252 | 1149 | 3 | 0 | 1 | 0 | 1 | 4 | 1 | 0 | 0 | 5 |
| 7010/7011 | Mar-06 | 2079 | 1842 | 6 | 0 | 0 | 0 | 0 | 3 | 0 | 1 | 0 | 4 |
| 7040/7041 | Mar-06 | 3373 | 2994 | 6 | 1 | 1 | 0 | 2 | 4 | 3 | 1 | 1 | 9 |
| 7002 | Jun-05 | 2153 | 1945 | 9 | 0 | 2 | 0 | 2 | 7 | 1 | 0 | 0 | 8 |
| 7000/7001 | Jun-05 | 32899 | 28533 | 125 | 19 | 6 | 4 | 29 | 87 | 13 | 7 | 3 | 110 |
| 1590/1591 | Apr-04 | 9586 | 7415 | 24 | 2 | 3 | 0 | 5 | 9 | 1 | 1 | 1 | 12 |
| 1582 | Mar-03 | 3007 | 2159 | 12 | 17 | 2 | 0 | 19 | 5 | 3 | 6 | 1 | 15 |
| 1570/1571 | Mar-02 | 10017 | 6939 | 35 | 15 | 3 | 0 | 18 | 15 | 5 | 1 | 7 | 28 |
| 1580/1581 | Mar-02 | 67421 | 48528 | 240 | 120 | 9 | 3 | 132 | 145 | 35 | 27 | 31 | 238 |

**Based on returned product analysis as of December 31, 2008.*

The laboratory analysis results are categorized into one of the following three categories:

- **Implant Damage -** obvious damage incurred at the time of attempted implant, including but not limited to insulation cuts and damage, helix overtorque, and stylet perforation.
- **Electrical Malfunction -** a disruption in the insulation or conductors resulting in compromised electrical performance. Electrical malfunction data are further broken down into one of the following three subcategories:
  - *Insulation Disruption* - leads exhibiting wear and abrasion that extends through the insulation and exposes the conductors.
  - *Conductor Disruption* - leads exhibiting cable and coil fractures, including those attributed to subclavian crush.
  - *Crimps, Welds, Bonds* - leads exhibiting malfunctions related to crimps, welds, and bonds.
- **Other -** includes other returns not attributed to damage incurred at the attempted implant and not resulting in compromised electrical failures. The Other category of data is further broken down into one of the following four subcategories:
  - *Explant Damage* - leads exhibiting physical damage incurred at the time of explant.
  - *Non-Electrical Workmanship* - leads exhibiting some out of specification mechanical condition, such as a bent connector pin or helix anomaly.
  - *Non-Electrical Anomaly* - leads not associated with a complaint but exhibiting some anomalous condition that did not result in an electrical malfunction. An example would be a lead exhibiting some insulation disruption that did not extend through and therefore did not compromise the function of the lead.
  - *Partial Lead* - leads with an alleged malfunction that are returned not in its entirety; as a result, it was not possible to perform a complete analysis and confirm the malfunction.

# Pulse Generators

## Dual-Chamber

St. Jude Medical

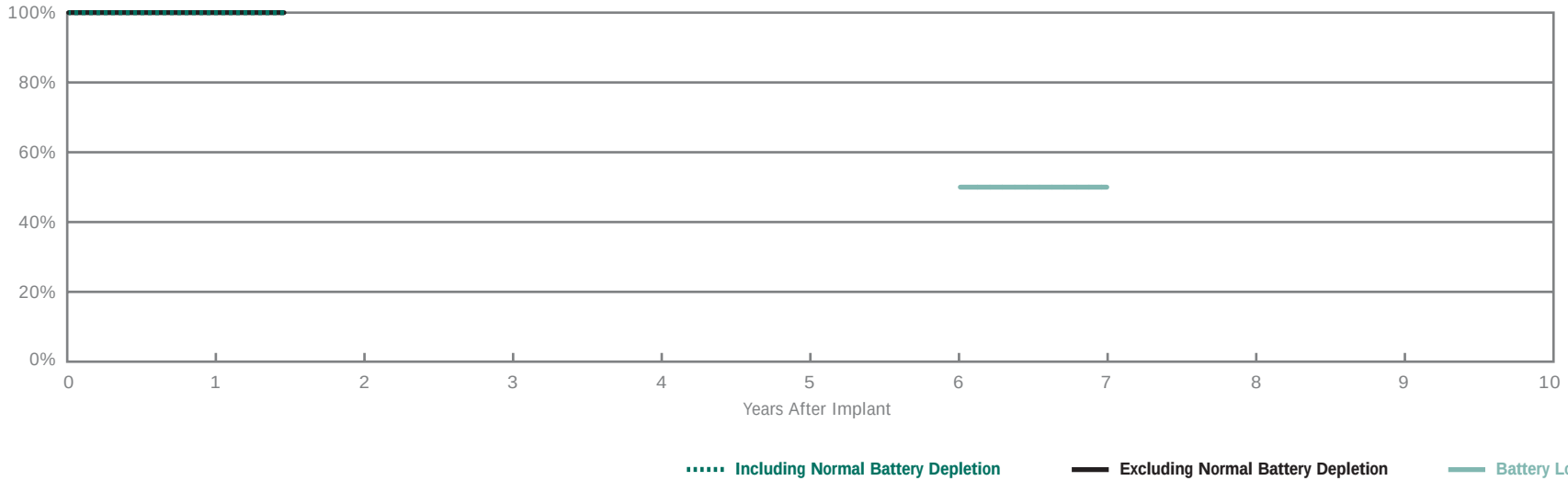
More control. Less risk.

# Pulse Generators

## Zephyr™ DR (Model 5820)

| | | | |
|---|---|---|---|
| US Market Release | March 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 13,053 | Malfunctions | 0 |
| Estimated Active US Implants | 12,219 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 6.5 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 8000 | 200 | | | | | | | | |

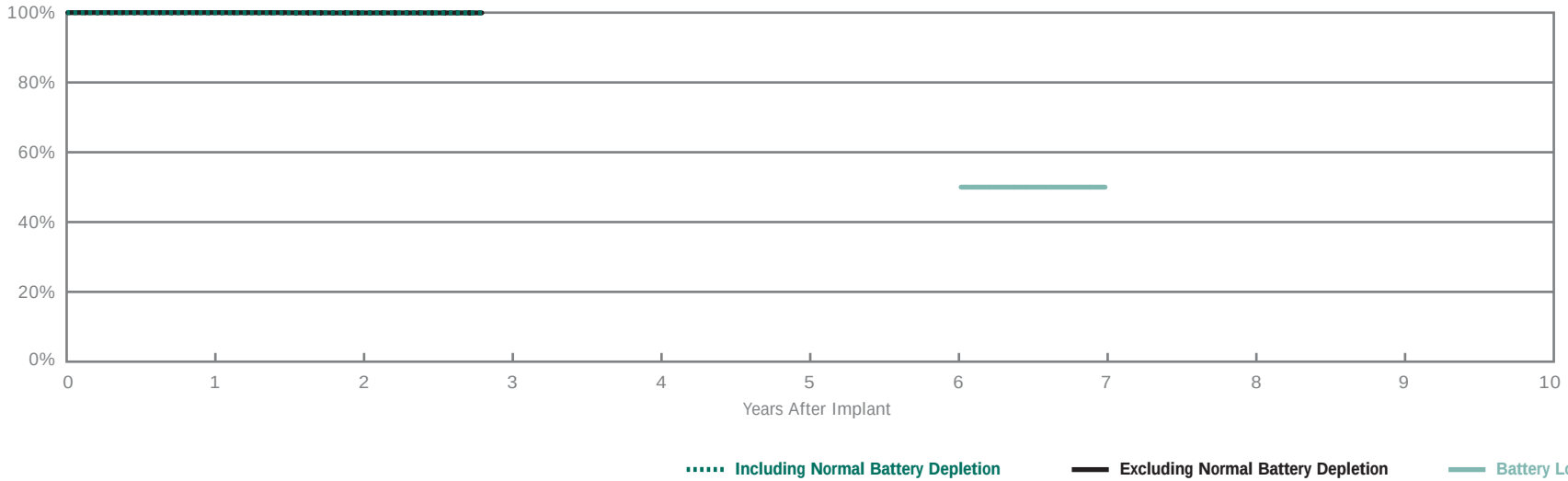
**Excluding Normal Battery Depletion**

| Year | 1 | at 18 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

## Victory® DR (Model 5810)

| | | | |
|---|---|---|---|
| US Market Release | December 2005 | Normal Battery Depletion | 0 |
| Registered US Implants | 22,733 | Malfunctions | 4 |
| Estimated Active US Implants | 19,455 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 6.5 Years | Malfunctions w/o Compromised Therapy | 4 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 34 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.93% | 99.93% | | | | | | | |
| ± 1 standard error | 0.00% | 0.03% | 0.03% | | | | | | | |
| Sample Size | 20600 | 11900 | 100 | | | | | | | |

**Excluding Normal Battery Depletion**

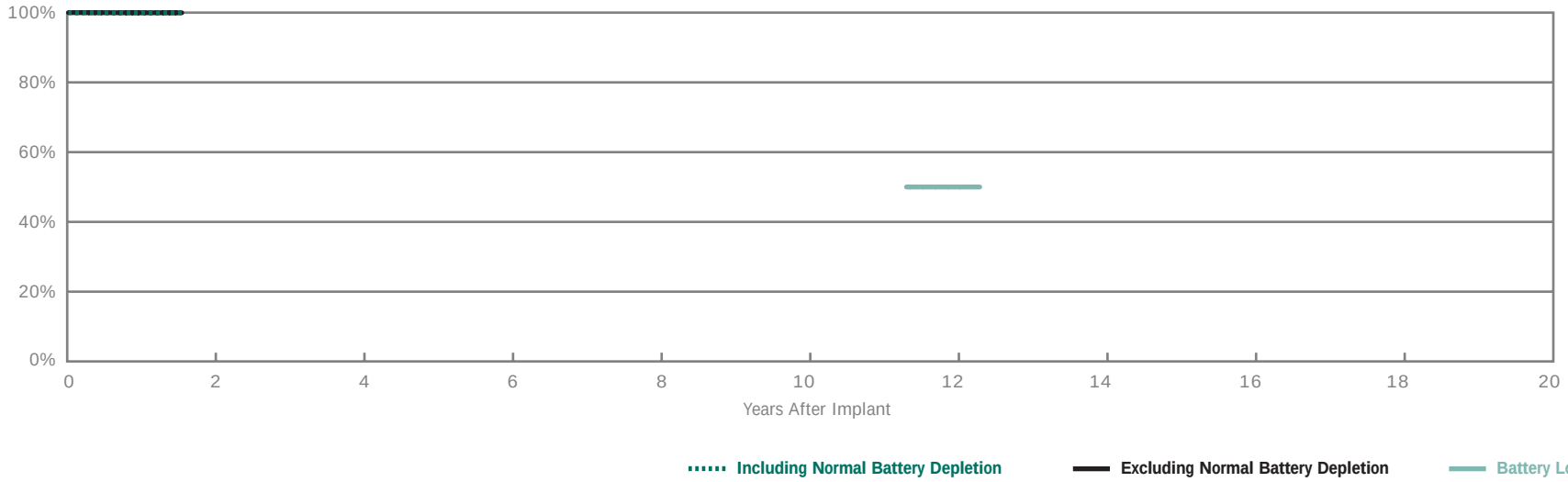
| Year | 1 | 2 | at 34 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.93% | 99.93% | | | | | | | |
| ± 1 standard error | 0.00% | 0.02% | 0.02% | | | | | | | |

# Pulse Generators

## Zephyr™ XL DR (Model 5826)

| | | | |
|---|---|---|---|
| US Market Release | March 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 47,650 | Malfunctions | 6 |
| Estimated Active US Implants | 45,240 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 11.7 Years | Malfunctions w/o Compromised Therapy | 5 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 19 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | | | | | | | | | |
| ± 1 standard error | 0.01% | | | | | | | | | |
| Sample Size | 200 | | | | | | | | | |

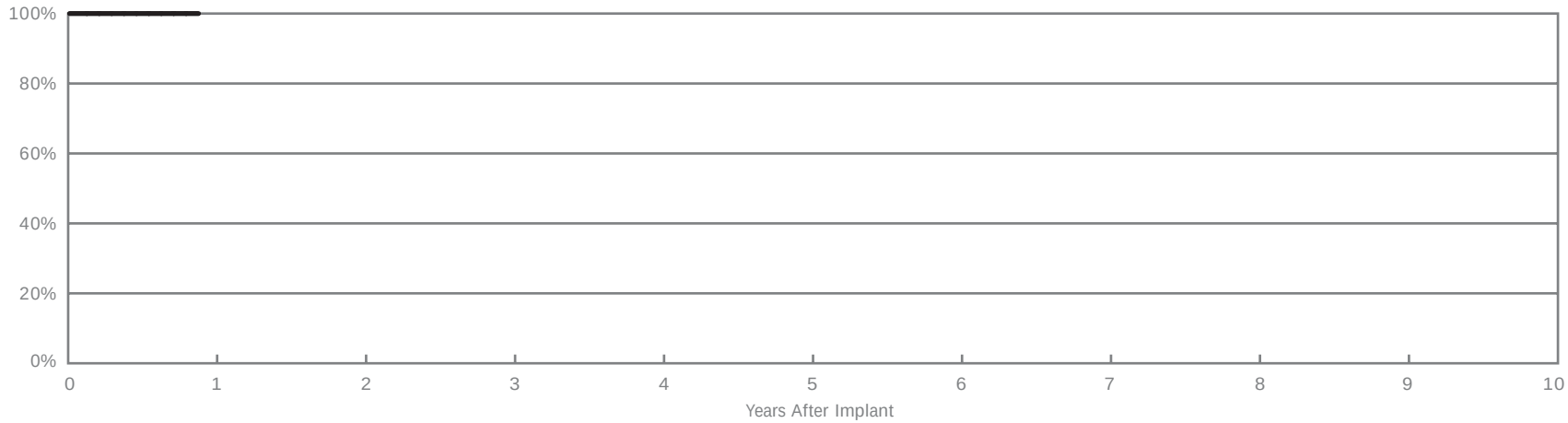
**Excluding Normal Battery Depletion**

| Year | at 19 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | | | | | | | | | |
| ± 1 standard error | 0.01% | | | | | | | | | |

| Zephyr™ XL DR (Model 5826) | |
|---|---|
| **SCORE Results** | |
| Number of Devices Enrolled in Study | 715 |
| Cumulative Months of Follow-Up | 4,152 |

| **Qualifying Complications** | **None** |
|---|---|

## Survival from SCORE Registry

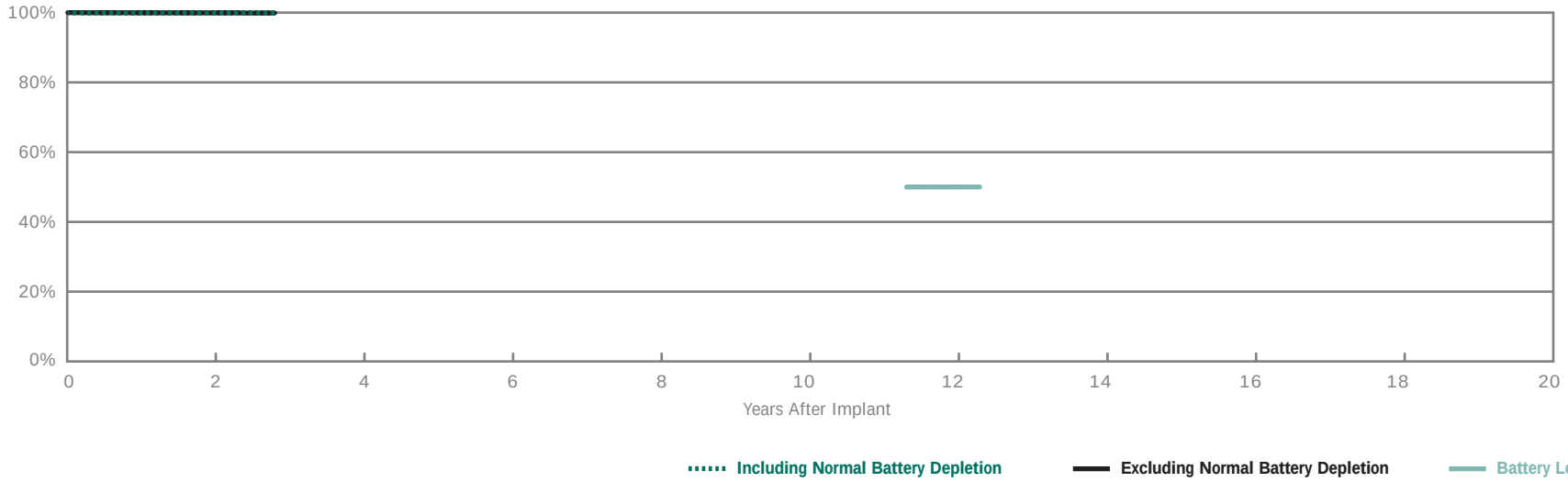



| Year | at 11 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | | | | | | | | | |
| **± 1 standard error** | 0.00% | | | | | | | | | |
| **Sample Size** | 86 | | | | | | | | | |

## Victory® XL DR (Model 5816)

| | | | |
|---|---|---|---|
| US Market Release | December 2005 | Normal Battery Depletion | 0 |
| Registered US Implants | 53,980 | Malfunctions | 15 |
| Estimated Active US Implants | 48,528 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 11.7 Years | Malfunctions w/o Compromised Therapy | 15 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | at 34 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.89% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.04% | | | | | | | | |
| Sample Size | 25600 | 100 | | | | | | | | |

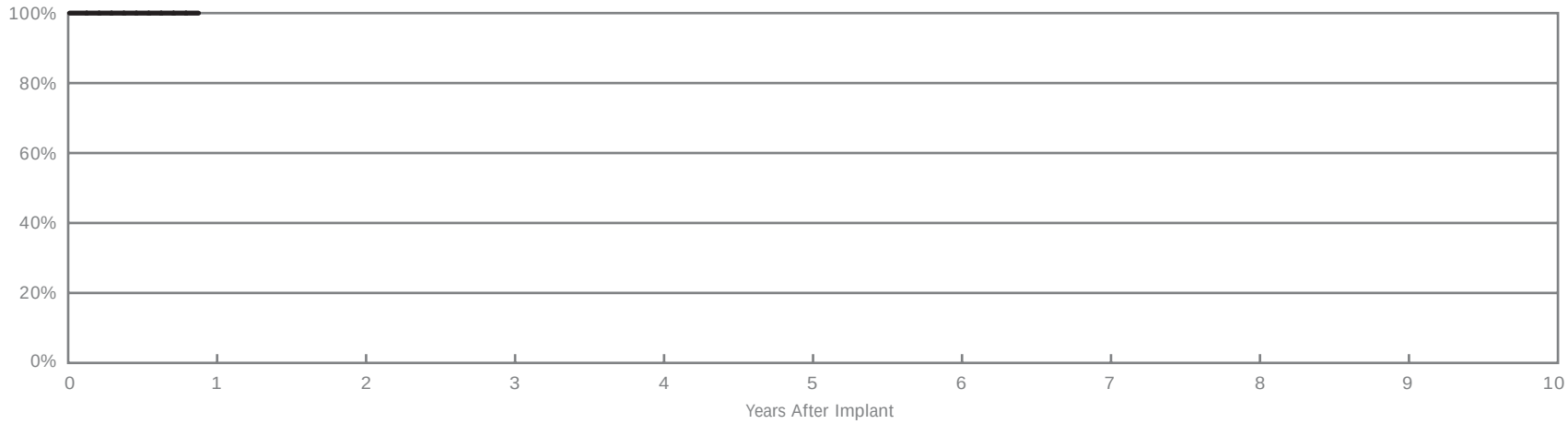
**Excluding Normal Battery Depletion**

| Year | 2 | at 34 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.89% | | | | | | | | |
| ± 1 standard error | 0.01% | 0.03% | | | | | | | | |

| Victory® XL DR (Model 5816) | |
|---|---|
| **SCORE Results** | |
| Number of Devices Enrolled in Study | 224 |
| Cumulative Months of Follow-Up | 1,605 |

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

## Survival from SCORE Registry



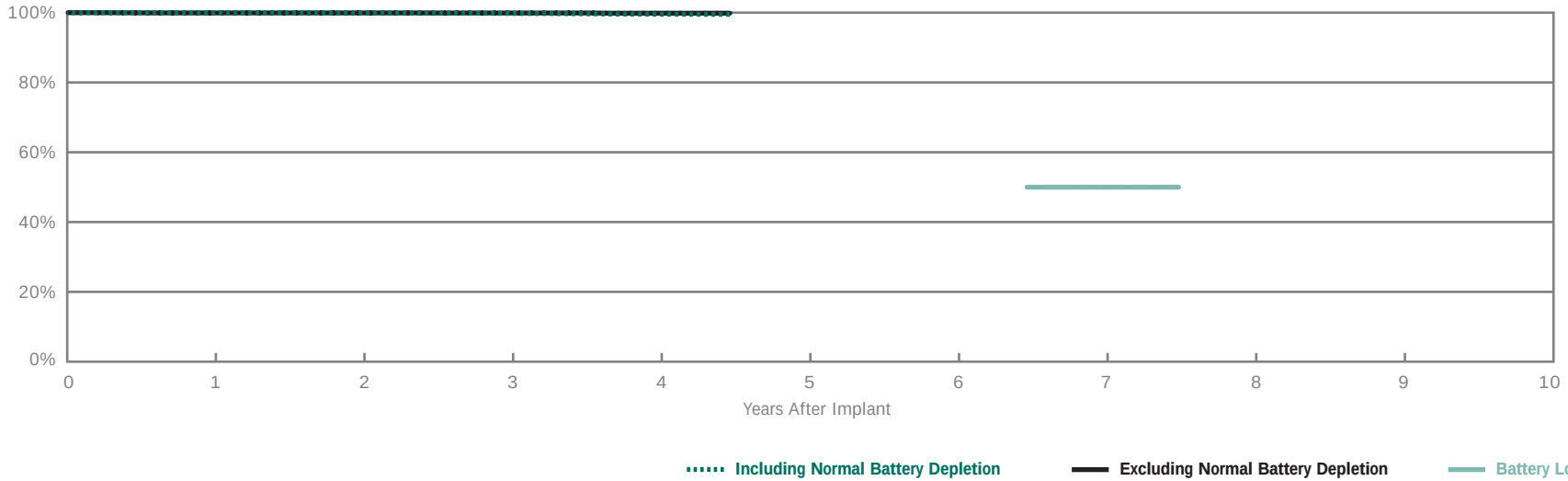

| Year | at 11 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | | | | | | | | | |
| **± 1 standard error** | 0.00% | | | | | | | | | |
| **Sample Size** | 52 | | | | | | | | | |

# Pulse Generators

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

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 7 |
| Registered US Implants | 16,361 | Malfunctions | 7 |
| Estimated Active US Implants | 12,179 | 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 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.81% | 99.61% | 99.51% | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.04% | 0.08% | 0.11% | | | | | |
| Sample Size | 15600 | 11900 | 8200 | 4500 | 700 | | | | | |

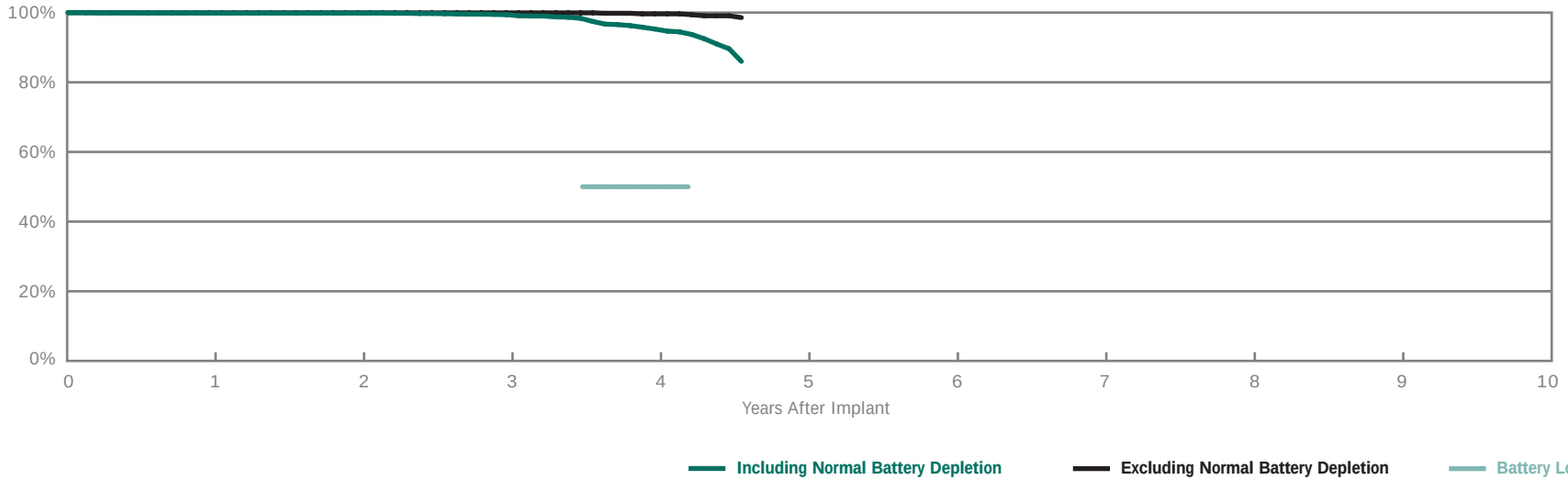
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.92% | 99.90% | 99.84% | 99.84% | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.05% | 0.05% | | | | | |

## Integrity® ADx DR (Model 5360)

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 70 |
| Registered US Implants | 5,797 | Malfunctions | 7 |
| Estimated Active US Implants | 3,788 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 3.8 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 | at 55 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 99.85% | 99.40% | 95.28% | 85.99% | | | | | |
| ± 1 standard error | 0.04% | 0.05% | 0.12% | 0.46% | 1.07% | | | | | |
| Sample Size | 5800 | 4700 | 3500 | 2000 | 200 | | | | | |

**Excluding Normal Battery Depletion**

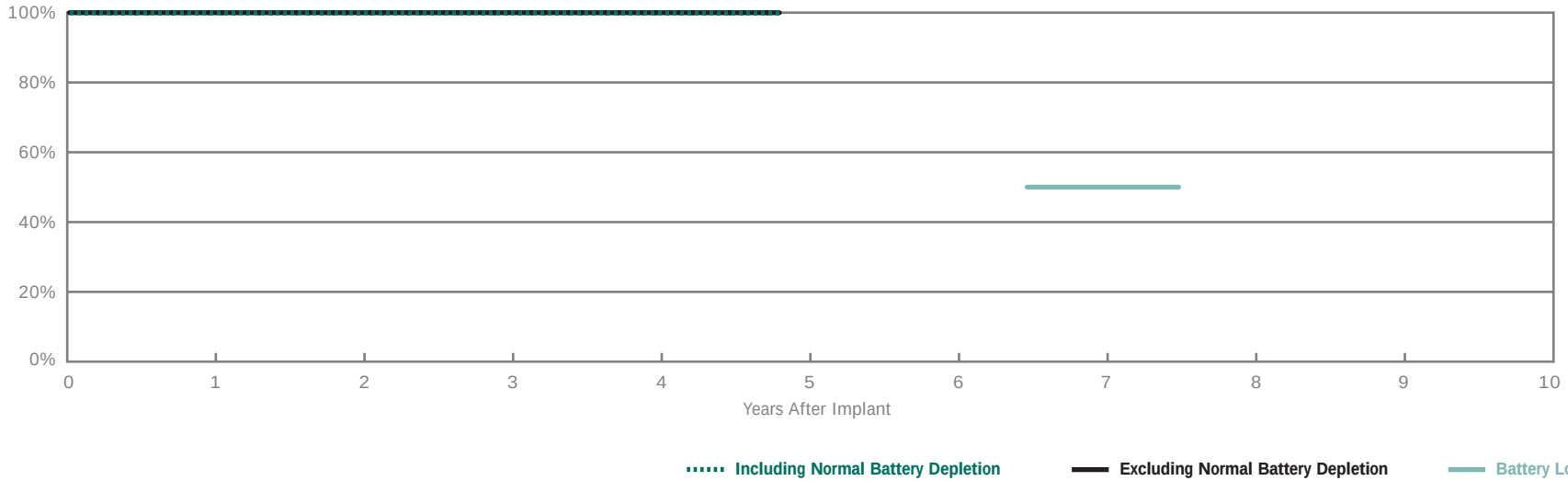
| Year | 1 | 2 | 3 | 4 | at 55 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.93% | 99.93% | 99.64% | 98.57% | | | | | |
| ± 1 standard error | 0.04% | 0.04% | 0.04% | 0.15% | 0.32% | | | | | |

# Pulse Generators

## Integrity® ADx DR (Model 5366)

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 1 |
| Registered US Implants | 7,981 | Malfunctions | 1 |
| Estimated Active US Implants | 6,294 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 6.9 Years | Malfunctions w/o Compromised Therapy | 1 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 58 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.98% | 99.93% | 99.93% | 99.93% | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.04% | 0.04% | 0.04% | | | | | |
| Sample Size | 7800 | 6200 | 3900 | 2000 | 100 | | | | | |

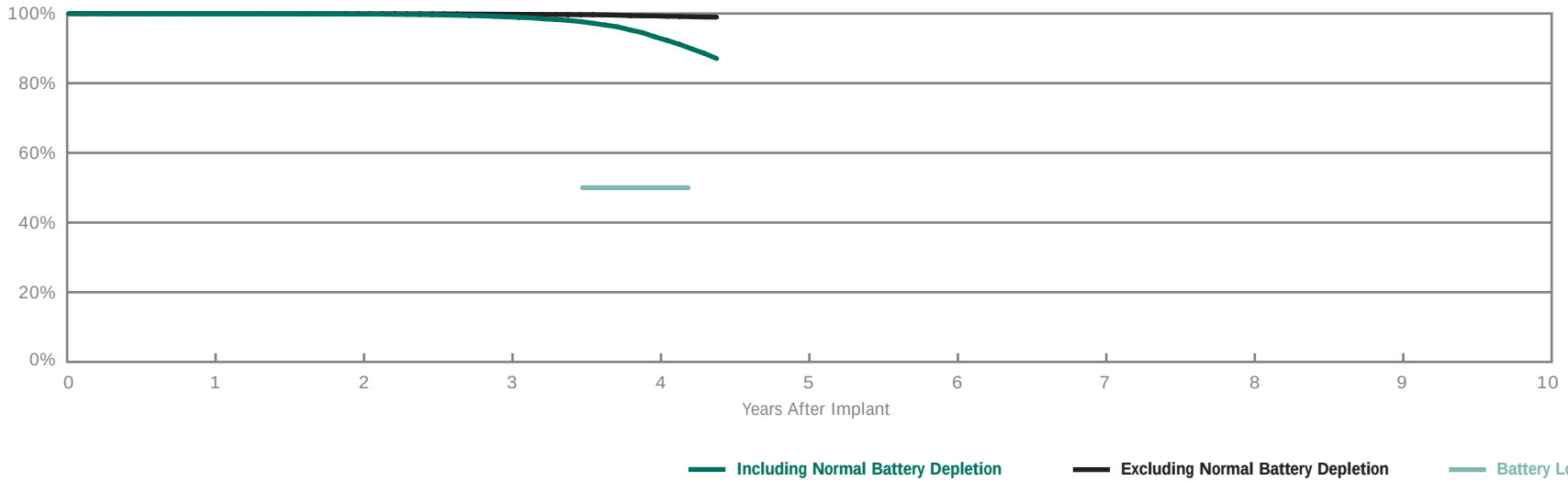
**Excluding Normal Battery Depletion**

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

## Identity® ADx DR (Model 5380)

| | | | |
|---|---|---|---|
| US Market Release | March 2003 | Normal Battery Depletion | 744 |
| Registered US Implants | 52,175 | Malfunctions | 96 |
| Estimated Active US Implants | 33,578 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Longevity | 3.8 Years | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 92 |
| | | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.83% | 99.04% | 93.30% | 87.08% | | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.18% | 0.33% | | | | | |
| Sample Size | 51200 | 42500 | 32200 | 18100 | 2700 | | | | | |

**Excluding Normal Battery Depletion**

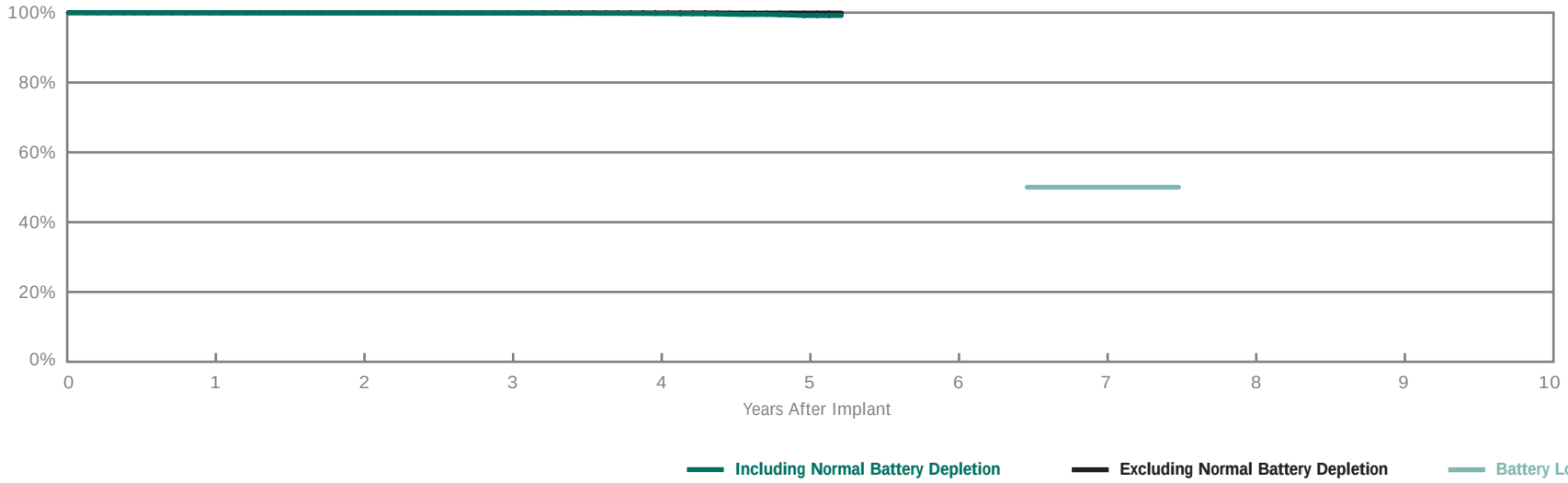
| Year | 1 | 2 | 3 | 4 | at 53 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.93% | 99.78% | 99.31% | 98.96% | | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.02% | 0.06% | 0.09% | | | | | |

# Pulse Generators

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

| | | | |
|---|---|---|---|
| US Market Release | March 2003 | Normal Battery Depletion | 25 |
| Registered US Implants | 61,657 | Malfunctions | 23 |
| Estimated Active US Implants | 49,256 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | 6.9 Years | Malfunctions w/o Compromised Therapy (0 related to Advisory) | 22 |
| | | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 63 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.92% | 99.88% | 99.75% | 99.17% | 99.17% | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.02% | 0.03% | 0.12% | 0.15% | | | | |
| Sample Size | 59100 | 47900 | 34300 | 18100 | 5700 | 300 | | | | |

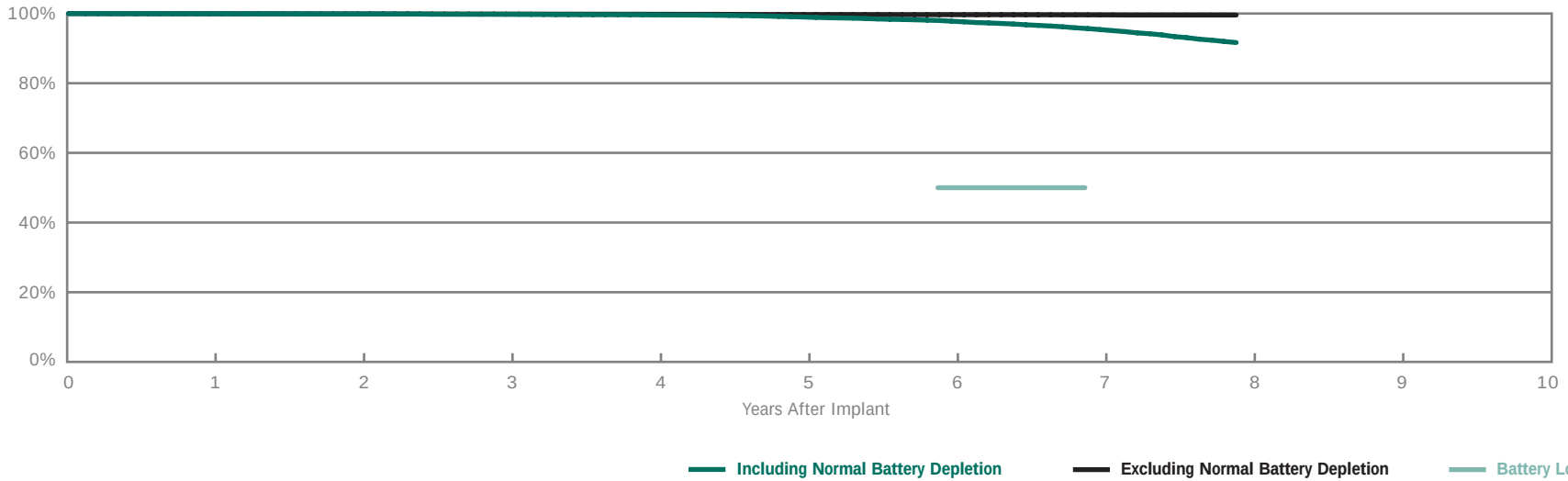
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 63 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.93% | 99.92% | 99.91% | 99.87% | 99.87% | | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.01% | 0.02% | 0.03% | 0.03% | | | | |

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

| | | | |
|---|---|---|---|
| US Market Release | (5342) April 2000 | Normal Battery Depletion | 635 |
| | (5346) July 2001 | Malfunctions | 66 |
| Registered US Implants | 47,444 | Malfunctions w/ Compromised Therapy | 6 |
| Estimated Active US Implants | 21,073 | Malfunctions w/o Compromised Therapy | 60 |
| 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 | at 95 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.88% | 99.76% | 99.61% | 99.00% | 97.80% | 95.39% | 91.67% | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.03% | 0.05% | 0.08% | 0.14% | 0.24% | | |
| Sample Size | 47300 | 42300 | 38700 | 35000 | 31100 | 26100 | 19400 | 2200 | | |

**Excluding Normal Battery Depletion**

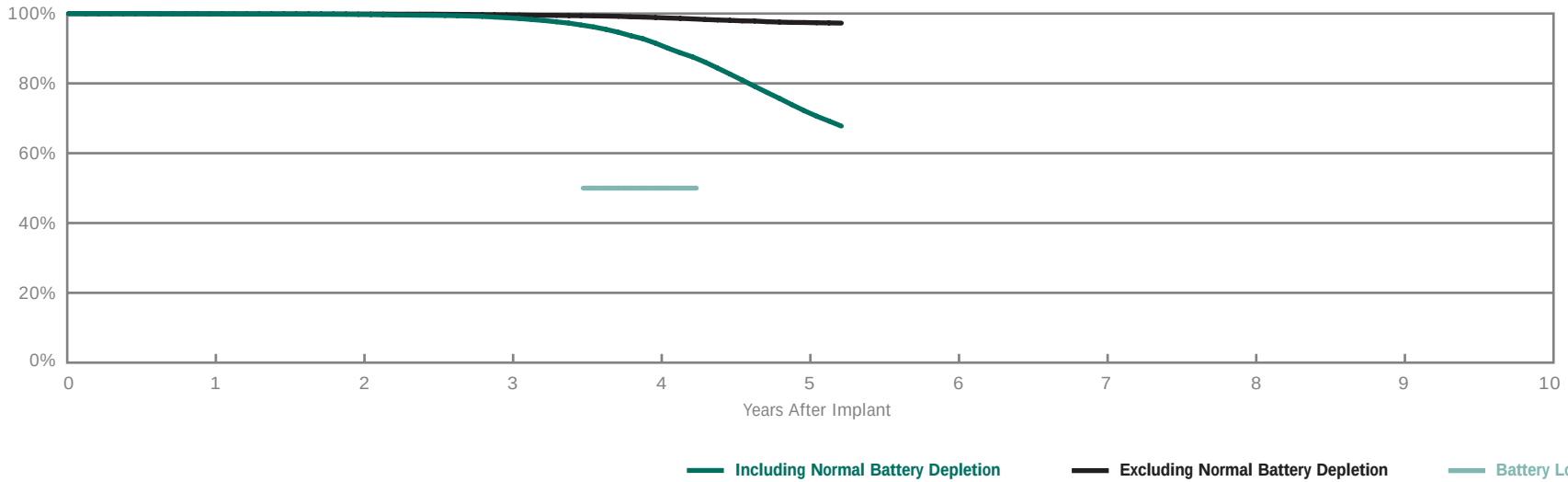
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 95 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.90% | 99.85% | 99.79% | 99.70% | 99.67% | 99.60% | 99.57% | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.02% | 0.03% | 0.03% | 0.04% | 0.04% | | |

# Pulse Generators

## Identity® (Model 5370)

| | | | |
|---|---|---|---|
| US Market Release | November 2001 | Normal Battery Depletion | 2,983 |
| Registered US Implants | 58,103 | Malfunctions | 307 |
| Estimated Active US Implants | 23,357 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 5 |
| Estimated Longevity | 3.8 Years | Malfunctions w/o Compromised Therapy (20 related to Advisory) | 302 |
| | | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 63 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.73% | 98.80% | 91.51% | 72.18% | 67.77% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.05% | 0.15% | 0.32% | 0.37% | | | | |
| Sample Size | 58100 | 50300 | 43300 | 34500 | 21100 | 3500 | | | | |

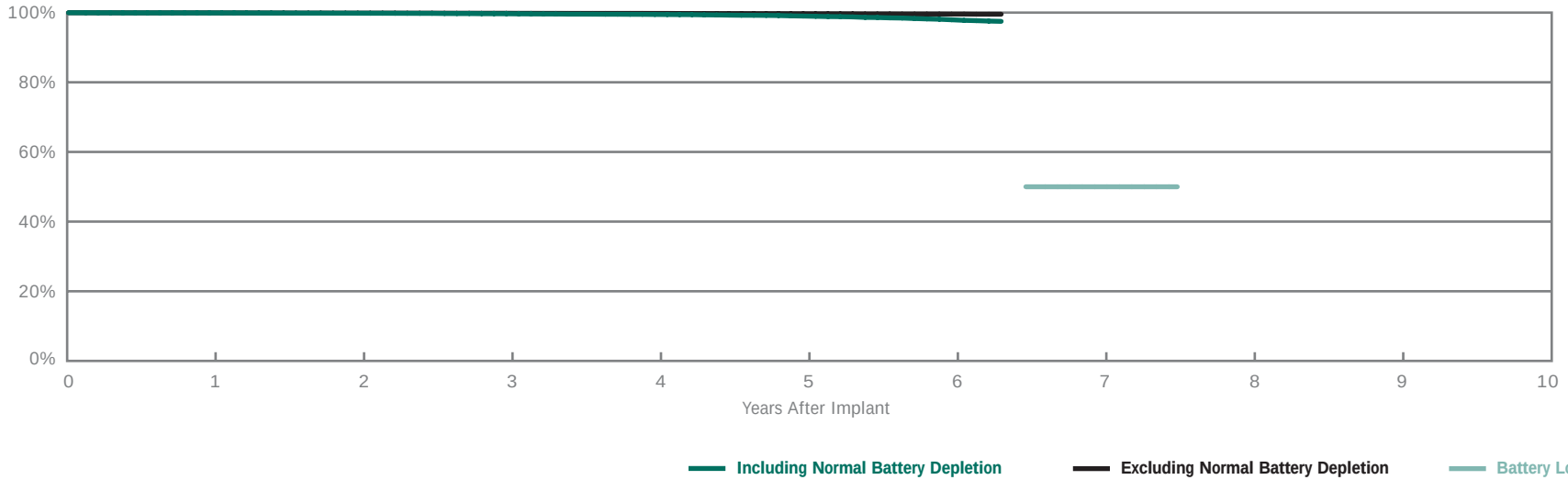
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 63 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.86% | 99.62% | 98.87% | 97.44% | 97.27% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.06% | 0.11% | 0.12% | | | | |

## Identity® XL (Model 5376)

| | | | |
|---|---|---|---|
| US Market Release | November 2001 | Normal Battery Depletion | 169 |
| Registered US Implants | 51,333 | Malfunctions | 69 |
| Estimated Active US Implants | 33,445 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 8 |
| Estimated Longevity | 6.9 Years | Malfunctions w/o Compromised Therapy (7 related to Advisory) | 61 |
| | | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 76 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.91% | 99.82% | 99.68% | 99.47% | 99.01% | 97.94% | 97.49% | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.03% | 0.04% | 0.06% | 0.10% | 0.14% | | | |
| Sample Size | 51100 | 45700 | 39900 | 32600 | 24400 | 13800 | 2300 | | | |

**Excluding Normal Battery Depletion**

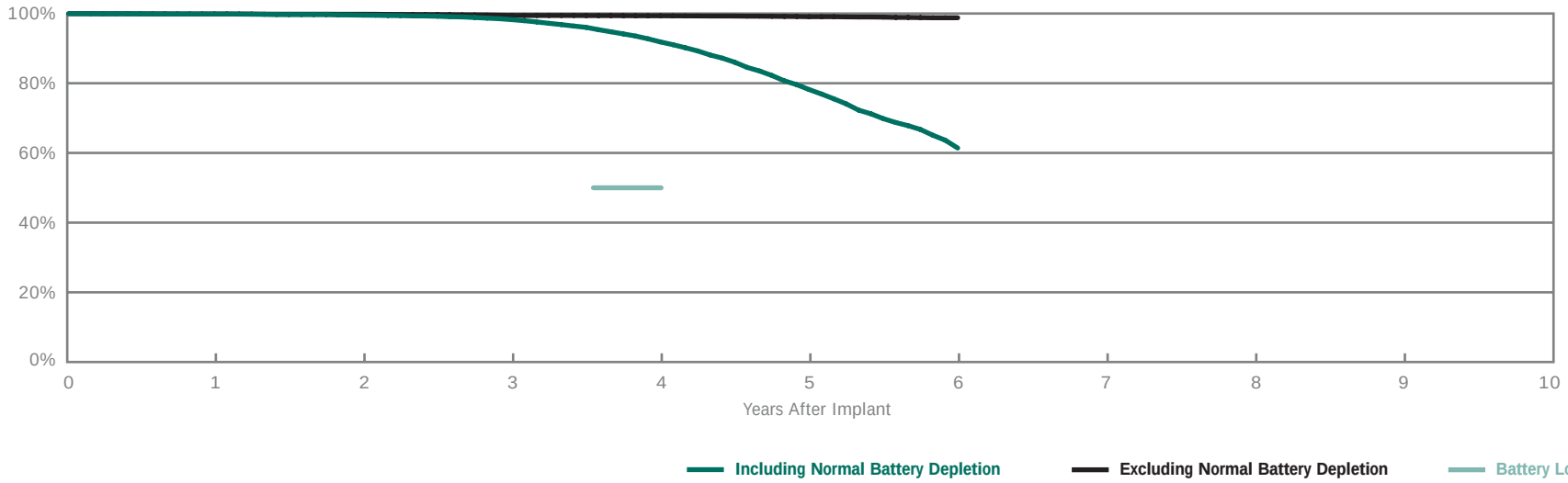
| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 76 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.86% | 99.82% | 99.77% | 99.67% | 99.57% | 99.54% | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.02% | 0.03% | 0.04% | 0.05% | | | |

# Pulse Generators

## Integrity® µ DR (Model 5336)

| | | | |
|---|---|---|---|
| US Market Release | December 2000 | Normal Battery Depletion | 1,886 |
| Registered US Implants | 29,337 | Malfunctions | 80 |
| Estimated Active US Implants | 5,196 | Malfunctions w/ Compromised Therapy | 8 |
| Estimated Longevity | 4.0 Years | Malfunctions w/o Compromised Therapy | 72 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.86% | 99.53% | 98.24% | 91.85% | 78.19% | 61.40% | | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.08% | 0.19% | 0.35% | 0.59% | | | | |
| Sample Size | 29300 | 25300 | 22400 | 19000 | 13500 | 5900 | | | | |

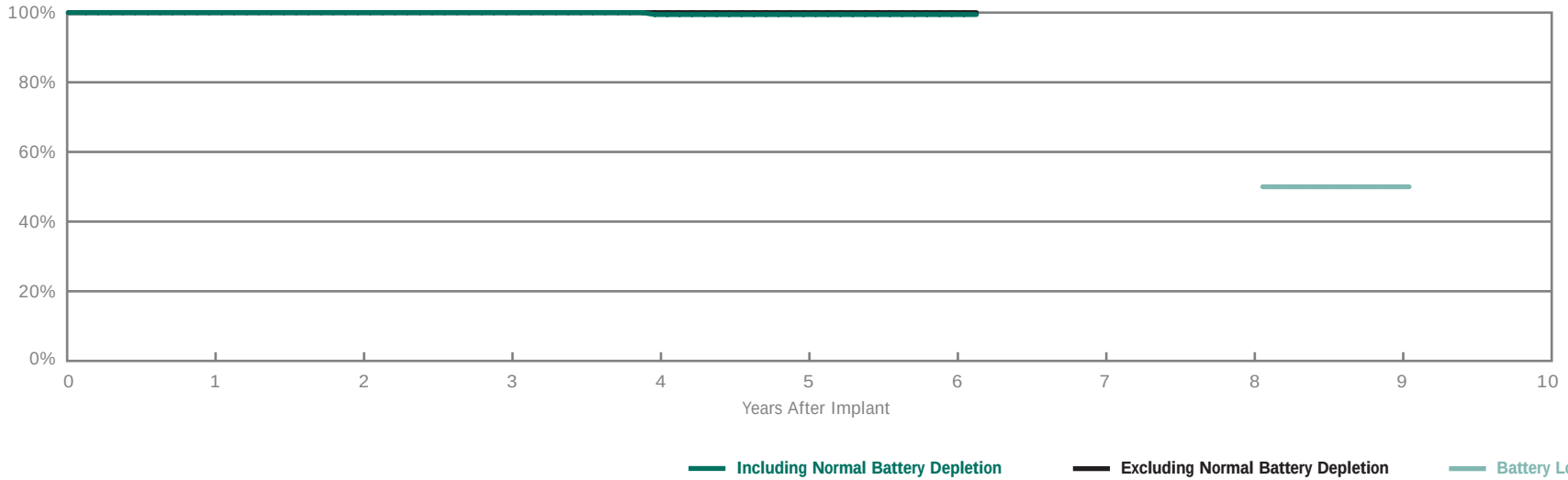
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.88% | 99.79% | 99.44% | 99.36% | 99.10% | 98.79% | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.05% | 0.06% | 0.07% | 0.11% | | | | |

## Affinity® VDR (Model 5430)

| | | | |
|---|---|---|---|
| US Market Release | April 2000 | Normal Battery Depletion | 1 |
| Registered US Implants | 654 | Malfunctions | 0 |
| Estimated Active US Implants | 231 | 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 74 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 99.44% | 99.44% | 99.44% | 99.44% | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.39% | 0.39% | 0.39% | 0.39% | | | |
| Sample Size | 600 | 500 | 500 | 400 | 400 | 300 | 200 | | | |

**Excluding Normal Battery Depletion**

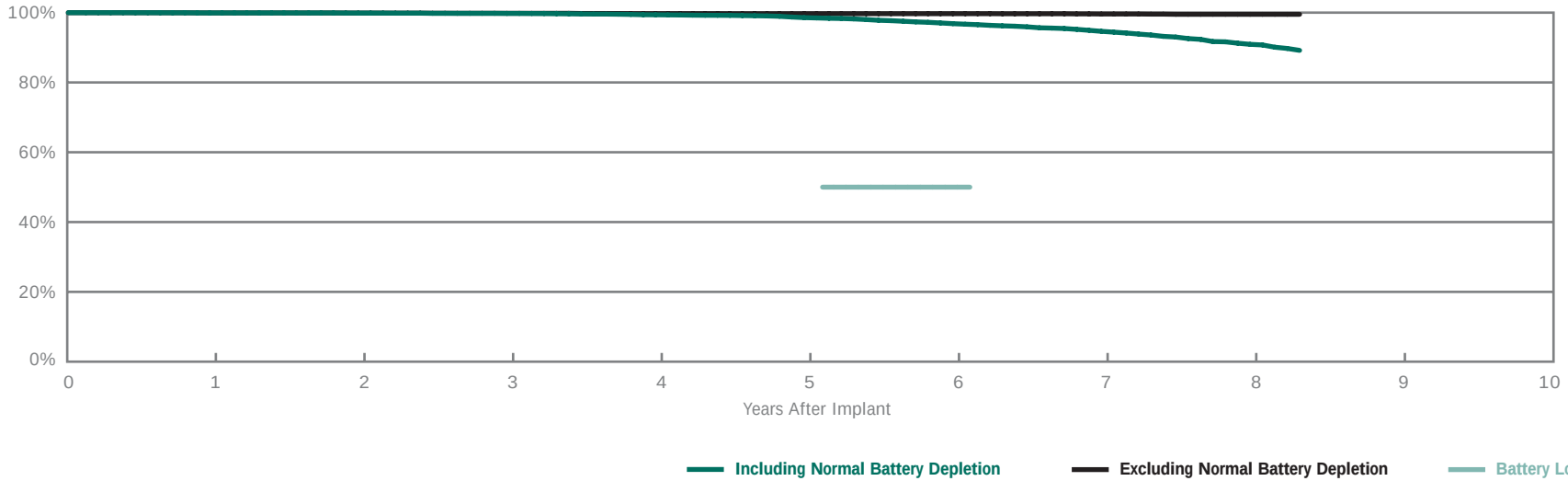
| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 74 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | | | |

# Pulse Generators

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

| | | | |
|---|---|---|---|
| US Market Release | June 1999 | Normal Battery Depletion | 307 |
| Registered US Implants | 21,830 | Malfunctions | 29 |
| Estimated Active US Implants | 7,410 | Malfunctions w/ Compromised Therapy | 3 |
| Estimated Longevity | 6.3 Years | Malfunctions w/o Compromised Therapy | 26 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 100 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.87% | 99.77% | 99.38% | 98.57% | 96.84% | 94.64% | 90.92% | 89.19% | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.06% | 0.10% | 0.16% | 0.23% | 0.37% | 0.46% | |
| Sample Size | 21800 | 18800 | 16900 | 15100 | 13100 | 10600 | 7500 | 4300 | 700 | |

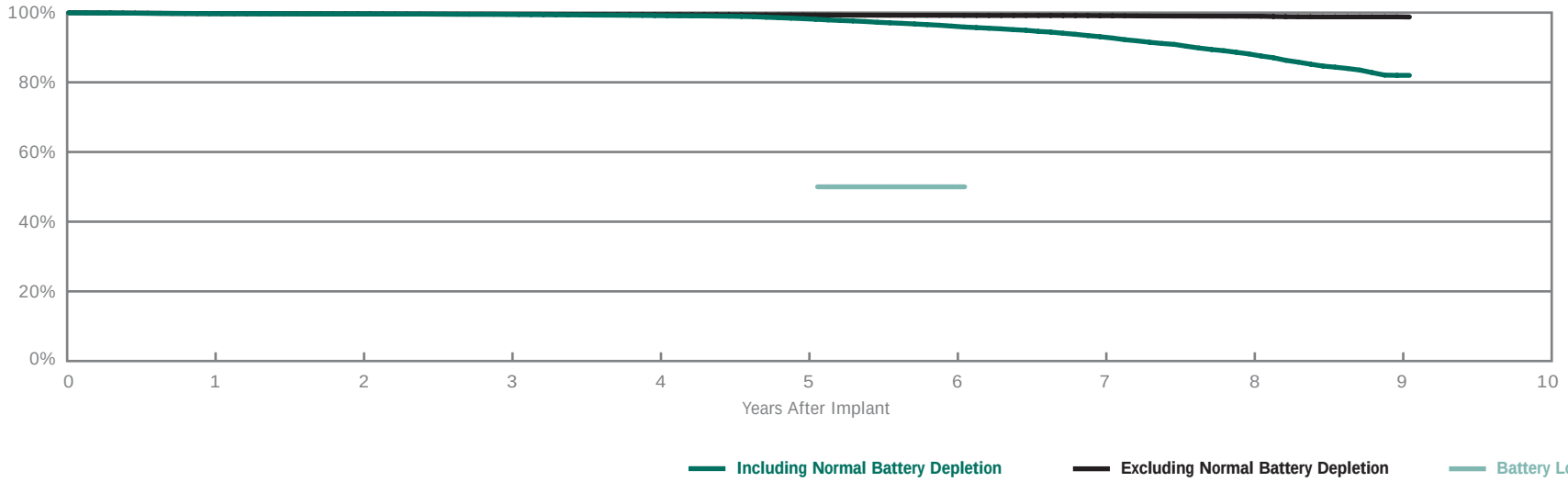
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 100 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.88% | 99.81% | 99.72% | 99.70% | 99.70% | 99.61% | 99.52% | 99.52% | |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.04% | 0.04% | 0.04% | 0.05% | 0.07% | 0.07% | |

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

| | | | |
|---|---|---|---|
| US Market Release | (5330) January 1999 | Normal Battery Depletion | 1,547 |
| | (5230/5331) June 1999 | Malfunctions | 158 |
| Registered US Implants | 65,576 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 15 |
| Estimated Active US Implants | 19,123 | Malfunctions w/o Compromised Therapy (65 related to Advisory) | 143 |
| Estimated Longevity | 6.3 Years | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.71% | 99.63% | 99.50% | 99.16% | 98.26% | 96.13% | 93.08% | 88.15% | 81.99% | 81.99% |
| ± 1 standard error | 0.02% | 0.02% | 0.03% | 0.04% | 0.06% | 0.10% | 0.14% | 0.21% | 0.35% | 0.35% |
| Sample Size | 64200 | 57400 | 52100 | 47000 | 41700 | 35000 | 26900 | 18000 | 8000 | 800 |

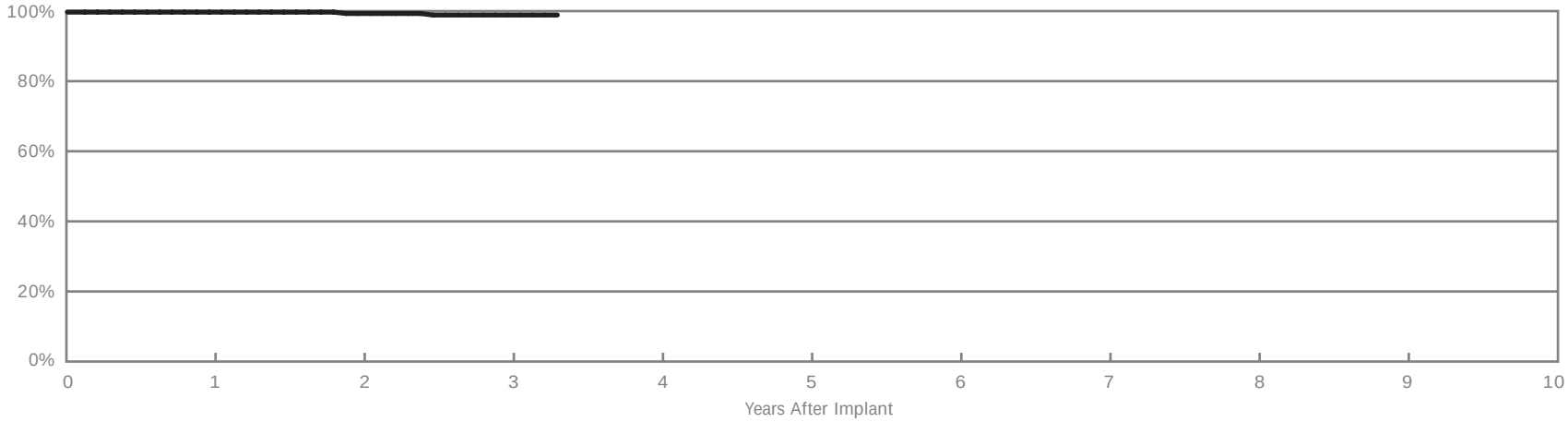
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.73% | 99.63% | 99.54% | 99.43% | 99.33% | 99.22% | 99.11% | 98.97% | 98.79% | 98.74% |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.03% | 0.04% | 0.04% | 0.04% | 0.05% | 0.07% | 0.07% |

# Pulse Generators

| AddVent® (Model 2060) | |
|---|---|
| US Market Release | May 1999 |
| Registered US Implants | 356 |
| Estimated Longevity | 9.3 Years |
| Number of Advisories | None |

**Survival from Returns and Complaints**

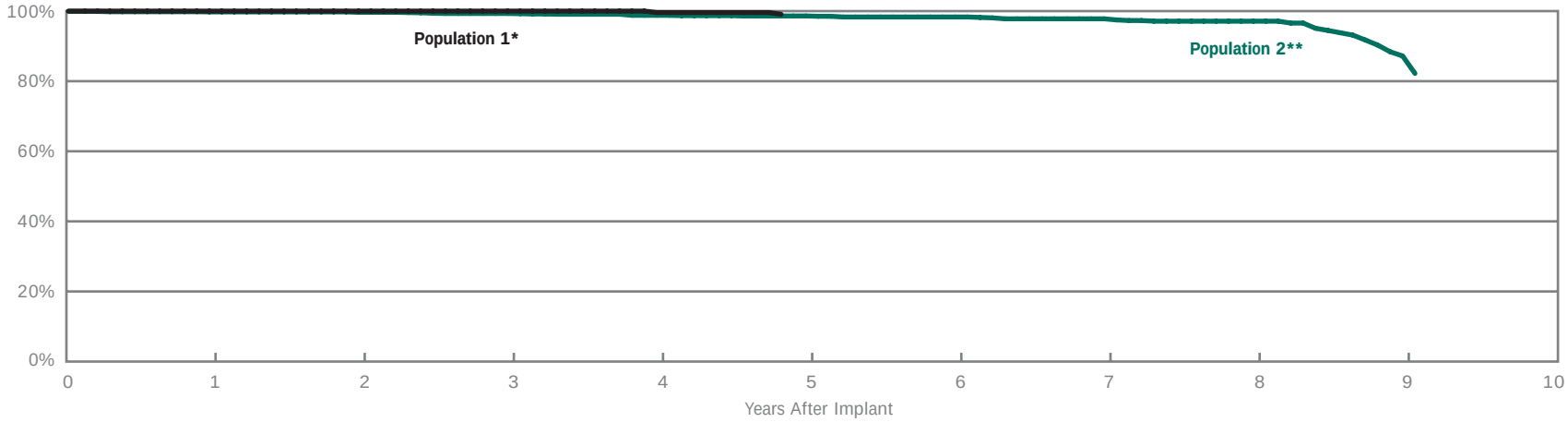



| Year | 1 | 2 | 3 | at 40 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.71% | 99.31% | 98.88% | 98.88% | | | | | | |
| ± 1 standard error | 0.29% | 0.49% | 0.65% | 0.65% | | | | | | |
| Sample Size | 300 | 300 | 200 | 200 | | | | | | |

## Trilogy® DC+ (Model 2318)

| Population 1* | | Population 2** | |
|---|---|---|---|
| (These models are no longer being manufactured) | | (These models are no longer being manufactured) | |
| US Market Release | January 1997 | US Market Release | January 1997 |
| Registered US Implants | 439 | Registered US Implants | 2,301 |
| Estimated Longevity | 5.0 Years | Estimated Longevity | 5.0 Years |
| Number of Advisories | None | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Population 1***

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

**Population 2****

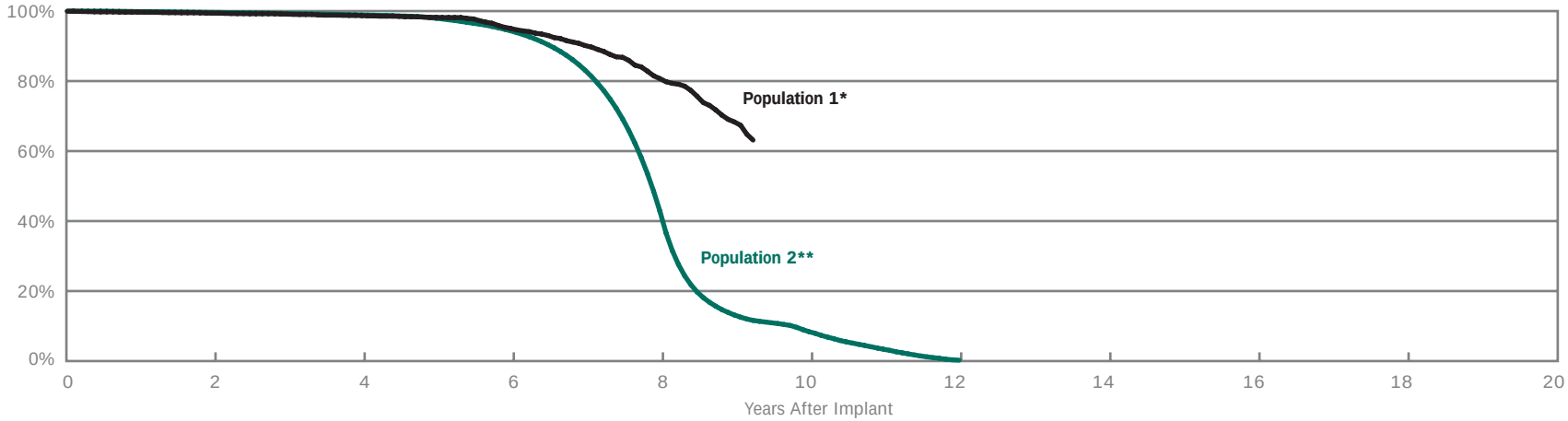
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | at 109 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.77% | 99.65% | 99.32% | 98.79% | 98.61% | 98.32% | 97.80% | 97.12% | 87.20% | 82.21% |
| ± 1 standard error | 0.09% | 0.11% | 0.20% | 0.28% | 0.31% | 0.35% | 0.43% | 0.55% | 1.72% | 1.83% |
| Sample Size | 2000 | 1800 | 1500 | 1300 | 1100 | 900 | 700 | 500 | 300 | 200 |

# Pulse Generators

## Trilogy® DR+ (Model 2360 & 2364)

| Population 1* | | Population 2** | |
|---|---|---|---|
| (These models are no longer being manufactured) | | (These models are no longer being manufactured) | |
| US Market Release | September 1996 | US Market Release | September 1996 |
| Registered US Implants | 7,029 | Registered US Implants | 56,680 |
| Estimated Longevity | 5.0 Years | Estimated Longevity | 5.0 Years |
| Number of Advisories | None | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Population 1***

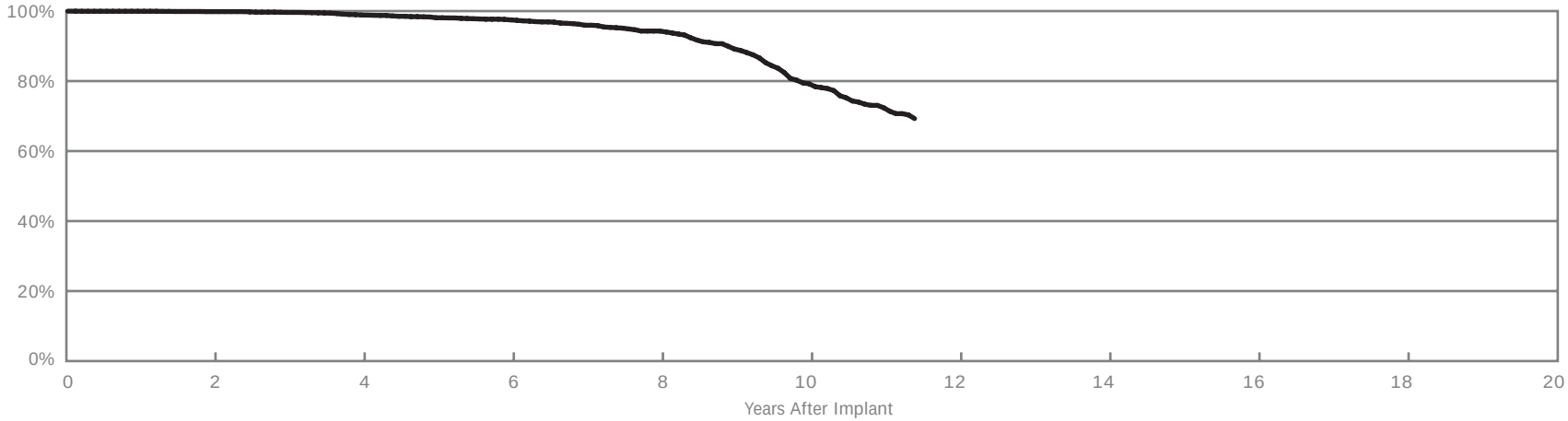
| Year | 2 | 4 | 6 | 8 | at 111 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.40% | 98.71% | 95.03% | 80.70% | 63.15% | | | | | |
| ± 1 standard error | 0.13% | 0.20% | 0.48% | 1.30% | 3.01% | | | | | |
| Sample Size | 5700 | 4600 | 3300 | 1800 | 300 | | | | | |

**Population 2****

| Year | 2 | 4 | 6 | 8 | 10 | 12 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.62% | 98.89% | 94.36% | 42.89% | 8.39% | 0.25% | | | | |
| ± 1 standard error | 0.03% | 0.05% | 0.09% | 0.14% | 0.89% | 5.07% | | | | |
| Sample Size | 46600 | 35800 | 24300 | 9900 | 1200 | 100 | | | | |

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

## Survival from Returns and Complaints

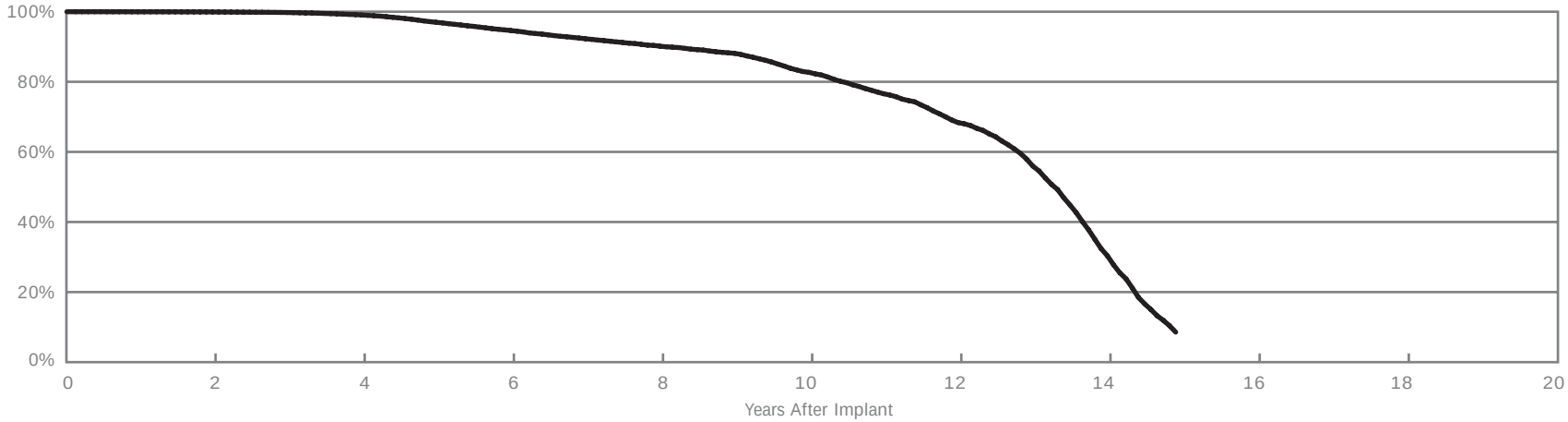



| Year | 2 | 4 | 6 | 8 | 10 | at 137 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.85% | 98.89% | 97.48% | 94.29% | 79.23% | 69.29% | | | | |
| ± 1 standard error | 0.07% | 0.20% | 0.33% | 0.64% | 1.72% | 2.20% | | | | |
| Sample Size | 3000 | 2300 | 1600 | 800 | 400 | 200 | | | | |

# Pulse Generators

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

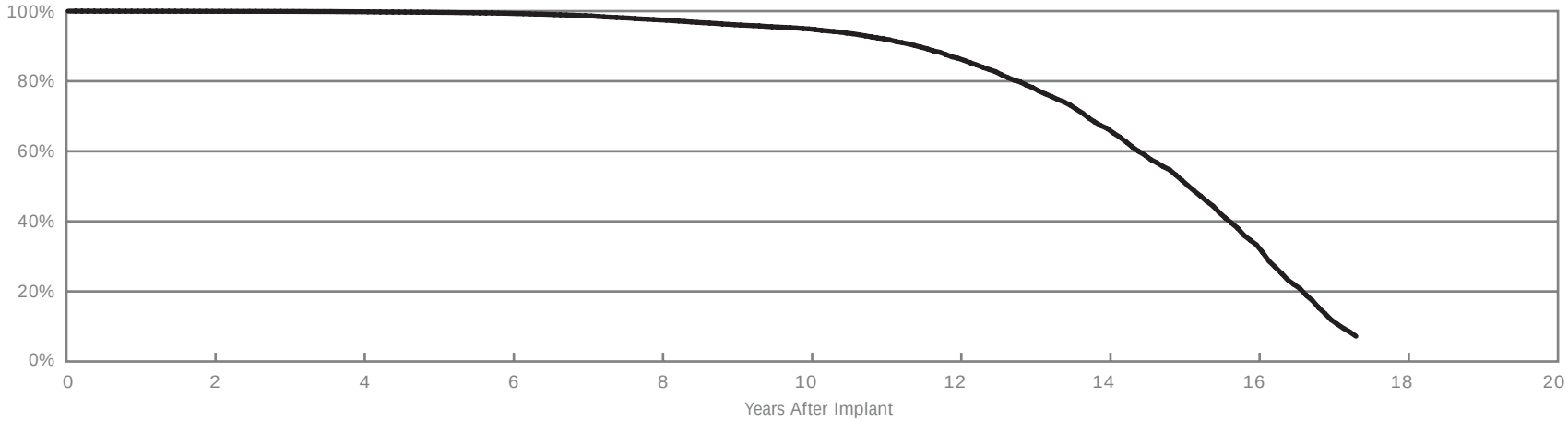
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | at 179 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.93% | 99.07% | 94.63% | 90.16% | 82.69% | 68.36% | 30.36% | 8.57% | | |
| **± 1 standard error** | 0.01% | 0.05% | 0.14% | 0.24% | 0.46% | 0.75% | 0.95% | 0.66% | | |
| **Sample Size** | 36500 | 29500 | 19000 | 7500 | 3100 | 1900 | 900 | 200 | | |

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

## Survival from Returns and Complaints

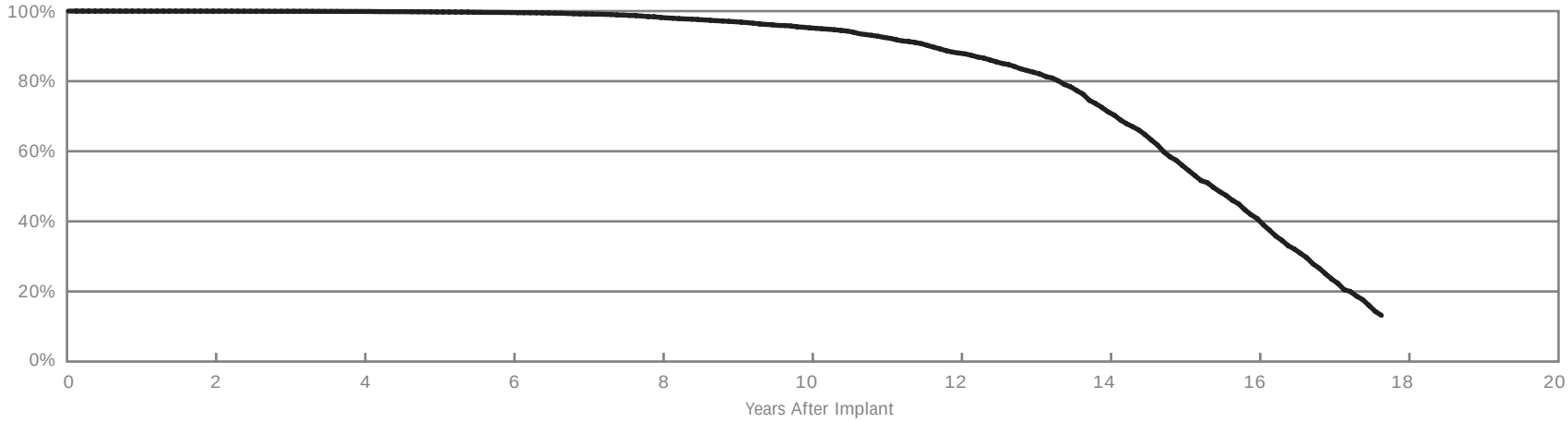



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | at 208 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.94% | 99.82% | 99.35% | 97.49% | 94.91% | 86.52% | 66.49% | 33.29% | 7.23% | |
| **± 1 standard error** | 0.01% | 0.02% | 0.04% | 0.10% | 0.16% | 0.35% | 0.64% | 0.82% | 0.54% | |
| **Sample Size** | 40500 | 34000 | 26800 | 19500 | 11900 | 6100 | 2900 | 1200 | 200 | |

# Pulse Generators

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

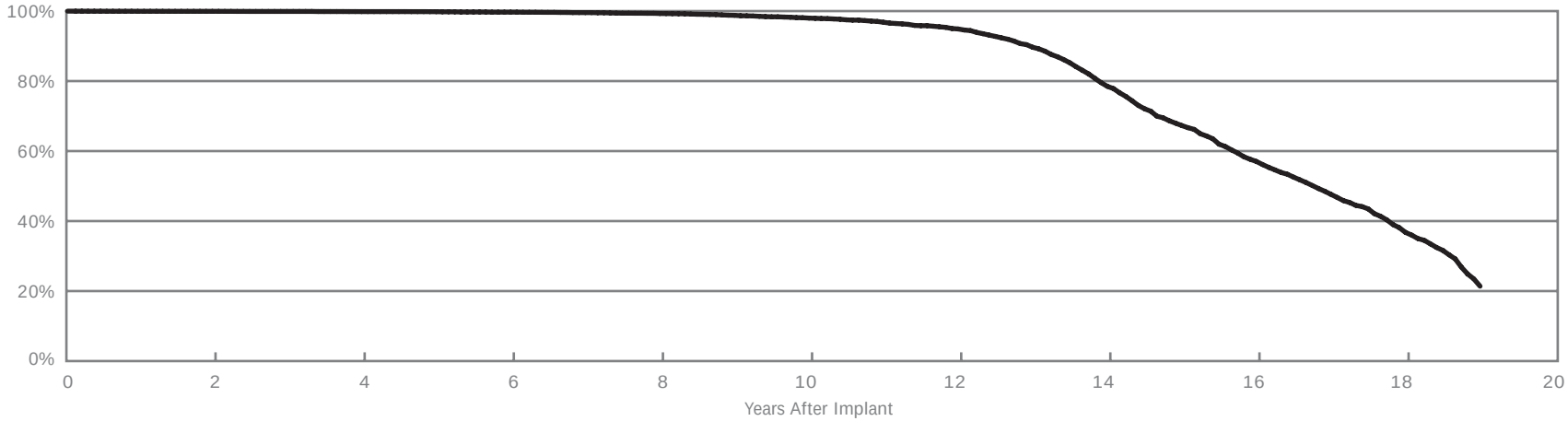
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | at 212 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.98% | 99.89% | 99.59% | 98.19% | 95.22% | 88.03% | 71.27% | 40.81% | 13.17% | |
| **± 1 standard error** | 0.01% | 0.02% | 0.05% | 0.12% | 0.23% | 0.45% | 0.79% | 1.06% | 0.86% | |
| **Sample Size** | 23500 | 18700 | 14200 | 10000 | 6000 | 3400 | 1900 | 900 | 200 | |

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

## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 228 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.85% | 99.70% | 99.30% | 97.99% | 94.89% | 78.51% | 57.03% | 36.76% | 21.39% |
| ± 1 standard error | 0.02% | 0.03% | 0.06% | 0.09% | 0.20% | 0.38% | 0.89% | 1.23% | 1.35% | 1.28% |
| Sample Size | 11600 | 9500 | 7300 | 5400 | 3700 | 2500 | 1500 | 800 | 500 | 200 |

# Summary & Longevity Information

## Pulse Generators

## Dual-Chamber

St. Jude Medical™

More control. Less risk.

## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (under advisory) | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|
| 5820 | Zephyr DR | Mar-07 | 13053 | 12219 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5810 | Victory DR | Dec-05 | 22733 | 19455 | 0 | 3 | 0 | 1 | 4 | 0 |
| 5826 | Zephyr XL DR | Mar-07 | 47650 | 45240 | 1 | 5 | 0 | 0 | 6 | 0 |
| 5816 | Victory XL DR | Dec-05 | 53980 | 48528 | 0 | 15 | 0 | 0 | 15 | 0 |
| 5356/5357/5256 | Verity ADX XL DR/ DR(M/S)/DC | May-03 | 16361 | 12179 | 0 | 6 | 0 | 1 | 7 | 7 |
| 5360 | Integrity ADx DR | May-03 | 5797 | 3788 | 0 | 7 | 0 | 0 | 7 | 70 |
| 5366 | Integrity ADx XL DR | May-03 | 7981 | 6294 | 0 | 1 | 0 | 0 | 1 | 1 |
| 5380 | Identity ADx DR | Mar-03 | 52175 | 33578 | 4 | 84 | 0 | 8 | 96 | 744 |
| 5386/5286 | Identity ADx XL DR/DC | Mar-03 | 61657 | 49256 | 1 | 22 | 0 | 0 | 23 | 25 |
| 5342/5346 | Integrity AFx DR | Apr-00/Jul-01 | 47444 | 21073 | 6 | 60 | 0 | 0 | 66 | 635 |
| 5370 | Identity | Nov-01 | 58262 | 19669 | 5 | 272 | 20 | 10 | 307 | 2983 |
| 5376 | Identity XL | Nov-01 | 51333 | 33445 | 8 | 53 | 7 | 1 | 69 | 169 |
| 5336 | Integrity µ DR | Dec-00 | 29337 | 5196 | 8 | 71 | 0 | 1 | 80 | 1886 |
| 5430 | Affinity VDR | Apr-00 | 638 | 231 | 0 | 0 | 0 | 0 | 0 | 1 |
| 5326/5226 | Entity DR/DC | Jun-99 | 21830 | 7410 | 3 | 25 | 0 | 1 | 29 | 307 |
| 5330/5331/5230 | Affinity DR/DC | Jan-99/Jun-99 | 65576 | 19123 | 15 | 78 | 65 | 0 | 158 | 1547 |

**Based on returned product analysis as of December 31, 2008.*

# Pulse Generators

## Including Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year | 9 year | 10 year |
| 5820 | Zephyr DR | 100.00% | | | | | | | | | |
| 5810 | Victory DR | 100.00% | 99.93% | | | | | | | | |
| 5826 | Zephyr XL DR | 99.96% | | | | | | | | | |
| 5816 | Victory XL DR | 99.95% | 99.93% | | | | | | | | |
| 5356/5357/5256 | Verity ADX XL DR/ DR(M/S)/DC | 99.92% | 99.92% | 99.81% | 99.61% | | | | | | |
| 5360 | Integrity ADx DR | 99.85% | 99.85% | 99.40% | 95.28% | | | | | | |
| 5366 | Integrity ADx XL DR | 99.98% | 99.98% | 99.93% | 99.93% | | | | | | |
| 5380 | Identity ADx DR | 99.93% | 99.83% | 99.04% | 93.30% | | | | | | |
| 5386/5286 | Identity ADx XL DR/DC | 99.96% | 99.92% | 99.88% | 99.75% | 99.17% | | | | | |
| 5342/5346 | Integrity AFx DR | 99.94% | 99.88% | 99.76% | 99.61% | 99.00% | 97.80% | 95.39% | | | |
| 5370 | Identity | 99.91% | 99.73% | 98.80% | 91.51% | 72.18% | | | | | |
| 5376 | Identity XL | 99.91% | 99.82% | 99.68% | 99.47% | 99.01% | 97.94% | | | | |
| 5336 | Integrity µ DR | 99.86% | 99.53% | 98.24% | 91.85% | 78.19% | 61.40% | | | | |
| 5430 | Affinity VDR | 100.00% | 100.00% | 100.00% | 99.44% | 99.44% | 99.44% | | | | |
| 5326/5226 | Entity DR/DC | 99.92% | 99.87% | 99.77% | 99.38% | 98.57% | 96.84% | 94.64% | 90.92% | | |
| 5330/5331/5230 | Affinity DR/DC | 99.71% | 99.63% | 99.50% | 99.16% | 98.26% | 96.13% | 93.08% | 88.15% | 81.99% | |

**Based on returned product analysis as of December 31, 2008.*

## Excluding Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year | 9 year | 10 year |
| 5820 | Zephyr DR | 100.00% | | | | | | | | | |
| 5810 | Victory DR | 100.00% | 99.93% | | | | | | | | |
| 5826 | Zephyr XL DR | 99.96% | | | | | | | | | |
| 5816 | Victory XL DR | 99.95% | 99.93% | | | | | | | | |
| 5356/5357/5256 | Verity ADX XL DR/ DR(M/S)/DC | 99.92% | 99.92% | 99.90% | 99.84% | | | | | | |
| 5360 | Integrity ADx DR | 99.93% | 99.93% | 99.93% | 99.64% | | | | | | |
| 5366 | Integrity ADx XL DR | 99.98% | 99.98% | 99.98% | 99.98% | | | | | | |
| 5380 | Identity ADx DR | 99.96% | 99.93% | 99.78% | 99.31% | | | | | | |
| 5386/5286 | Identity ADx XL DR/DC | 99.96% | 99.93% | 99.92% | 99.91% | 99.87% | | | | | |
| 5342/5346 | Integrity AFx DR | 99.94% | 99.90% | 99.85% | 99.79% | 99.70% | 99.67% | 99.60% | | | |
| 5370 | Identity | 99.93% | 99.86% | 99.62% | 98.87% | 97.44% | | | | | |
| 5376 | Identity XL | 99.93% | 99.86% | 99.82% | 99.77% | 99.67% | 99.57% | | | | |
| 5336 | Integrity µ DR | 99.88% | 99.79% | 99.44% | 99.36% | 99.10% | 98.79% | | | | |
| 5430 | Affinity VDR | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | | | | |
| 5326/5226 | Entity DR/DC | 99.92% | 99.88% | 99.81% | 99.72% | 99.70% | 99.70% | 99.61% | 99.52% | | |
| 5330/5331/5230 | Affinity DR/DC | 99.73% | 99.63% | 99.54% | 99.43% | 99.33% | 99.22% | 99.11% | 98.97% | 98.79% | |

**Based on returned product analysis as of December 31, 2008.*

# Pulse Generators

## Single-Chamber

St. Jude Medical

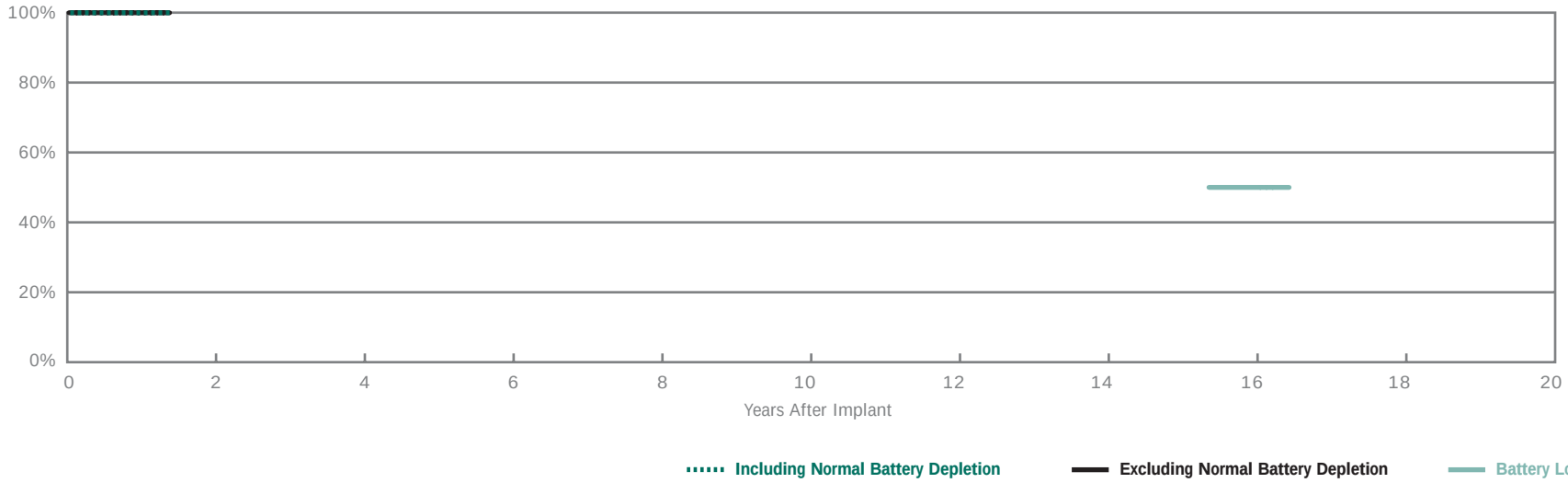
More control. Less risk.

# Pulse Generators

## Zephyr™ XL SR (Model 5626)

| | | | |
|---|---|---|---|
| US Market Release | May 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 7,689 | Malfunctions | 1 |
| Estimated Active US Implants | 7,176 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 15.8 Years | Malfunctions w/o Compromised Therapy | 1 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 17 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | | | | | | | | | |
| ± 1 standard error | 0.02% | | | | | | | | | |
| Sample Size | 100 | | | | | | | | | |

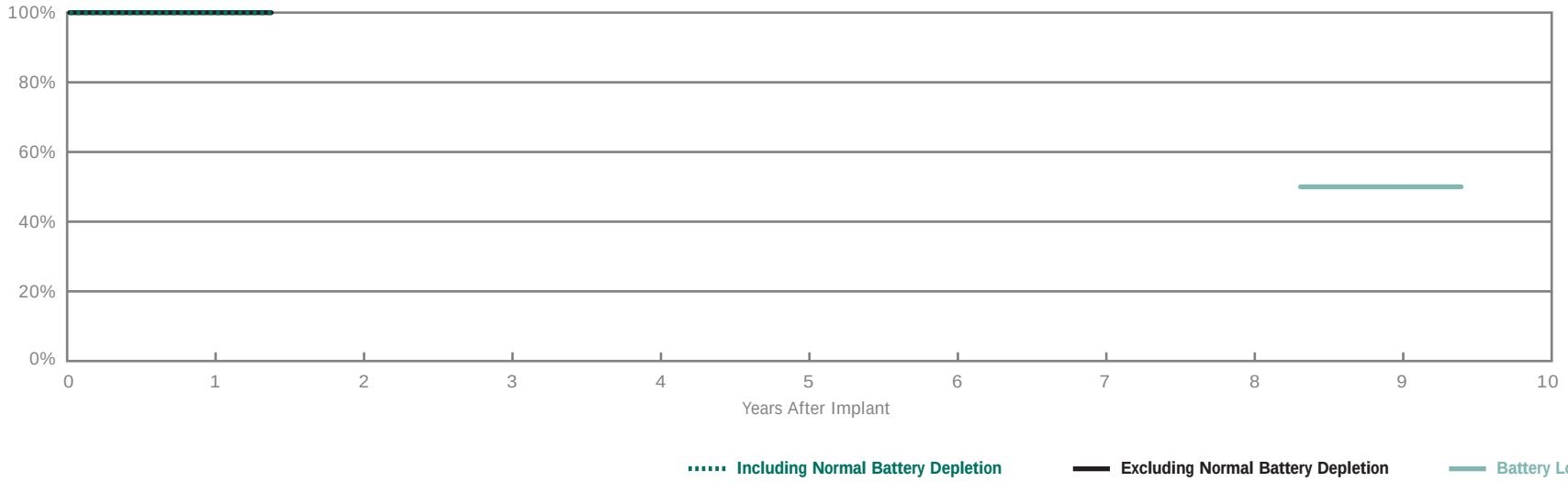
**Excluding Normal Battery Depletion**

| Year | at 17 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.97% | | | | | | | | | |
| ± 1 standard error | 0.02% | | | | | | | | | |

## Zephyr™ SR (Model 5620)

| | | | |
|---|---|---|---|
| US Market Release | March 2007 | Normal Battery Depletion | 0 |
| Registered US Implants | 3,806 | Malfunctions | 0 |
| Estimated Active US Implants | 3,500 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 8.8 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |
| Sample Size | 2400 | 100 | | | | | | | | |

**Excluding Normal Battery Depletion**

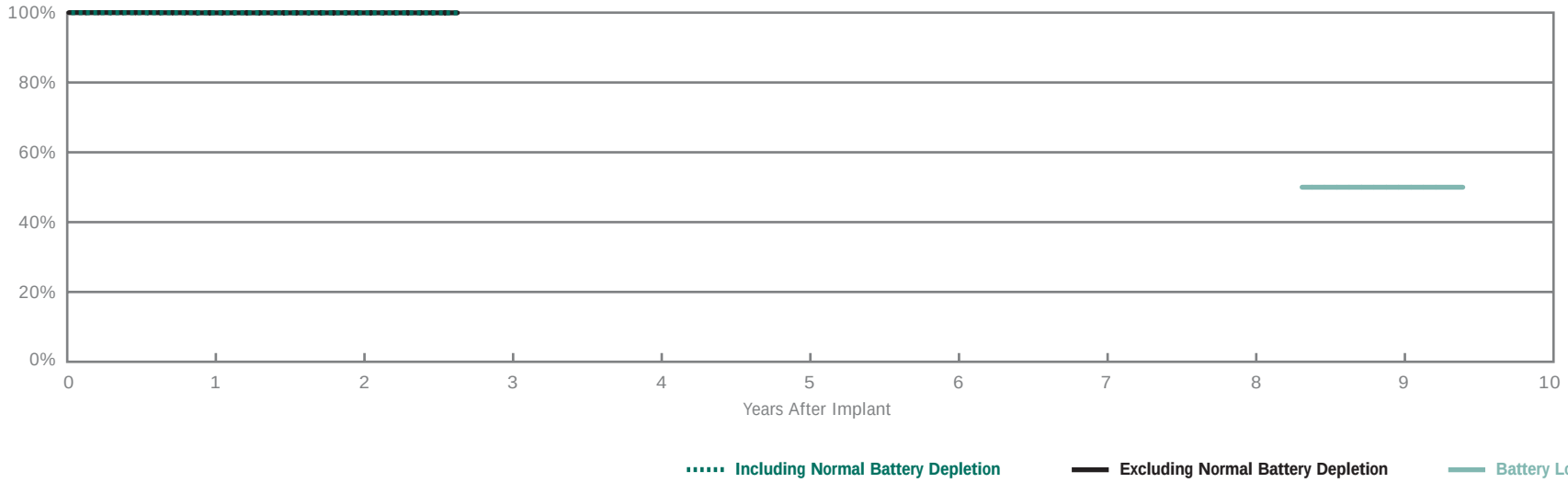
| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | | | | | | | | |
| ± 1 standard error | 0.00% | 0.00% | | | | | | | | |

# Pulse Generators

## Victory® SR (Model 5610)

| | | | |
|---|---|---|---|
| US Market Release | December 2005 | Normal Battery Depletion | 0 |
| Registered US Implants | 11,416 | Malfunctions | 1 |
| Estimated Active US Implants | 9,390 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 8.8 Years | Malfunctions w/o Compromised Therapy | 1 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | at 32 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.95% | 99.95% | | | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.02% | | | | | | | |
| Sample Size | 10000 | 5000 | 100 | | | | | | | |

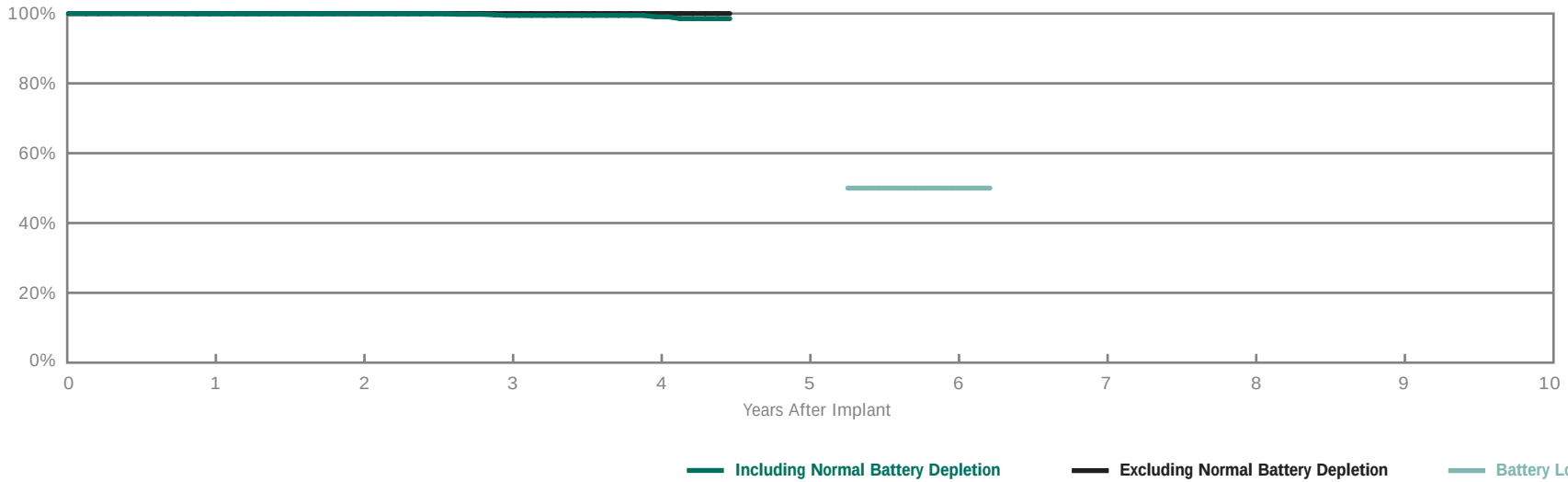
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | at 32 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.95% | 99.95% | | | | | | | |
| ± 1 standard error | 0.02% | 0.02% | 0.02% | | | | | | | |

## Integrity® ADx SR (Model 5160)

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 6 |
| Registered US Implants | 3,394 | Malfunctions | 0 |
| Estimated Active US Implants | 2,072 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.7 Years | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.93% | 99.47% | 99.07% | 98.53% | | | | | |
| ± 1 standard error | 0.05% | 0.05% | 0.16% | 0.19% | 0.51% | | | | | |
| Sample Size | 3300 | 2400 | 1600 | 900 | 100 | | | | | |

**Excluding Normal Battery Depletion**

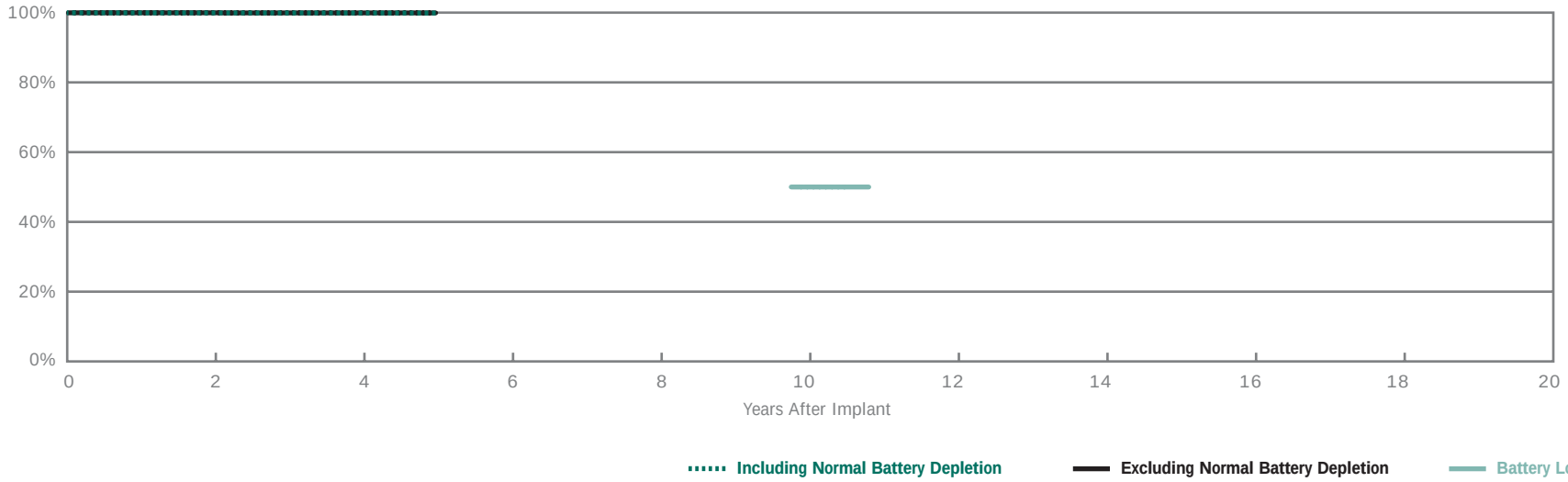
| Year | 1 | 2 | 3 | 4 | at 54 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% | | | | | |
| ± 1 standard error | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | | | | | |

# Pulse Generators

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

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 1 |
| Registered US Implants | 12,958 | Malfunctions | 4 |
| Estimated Active US Implants | 9,136 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 10.2 Years | Malfunctions w/o Compromised Therapy | 3 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 2 | 4 | at 60 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.88% | 99.88% | | | | | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.04% | | | | | | | |
| Sample Size | 8200 | 2500 | 800 | | | | | | | |

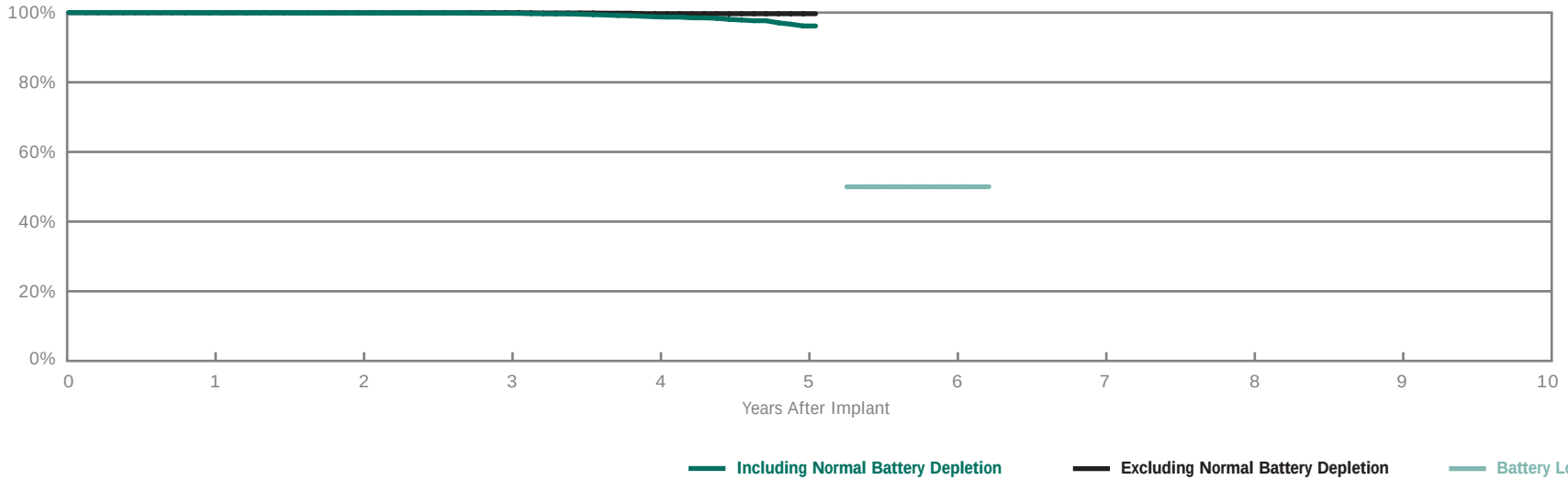
**Excluding Normal Battery Depletion**

| Year | 2 | 4 | at 60 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.92% | 99.92% | | | | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | | | | | | | |

## Identity® ADx SR (Model 5180)

| | | | |
|---|---|---|---|
| US Market Release | May 2003 | Normal Battery Depletion | 33 |
| Registered US Implants | 19.027 | Malfunctions | 8 |
| Estimated Active US Implants | 12,049 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.7 Years | Malfunctions w/o Compromised Therapy | 8 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 61 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.94% | 99.90% | 99.82% | 98.80% | 96.16% | 96.16% | | | | |
| ± 1 standard error | 0.01% | 0.03% | 0.04% | 0.16% | 0.53% | 0.64% | | | | |
| Sample Size | 18400 | 13400 | 8900 | 4500 | 1400 | 200 | | | | |

**Excluding Normal Battery Depletion**

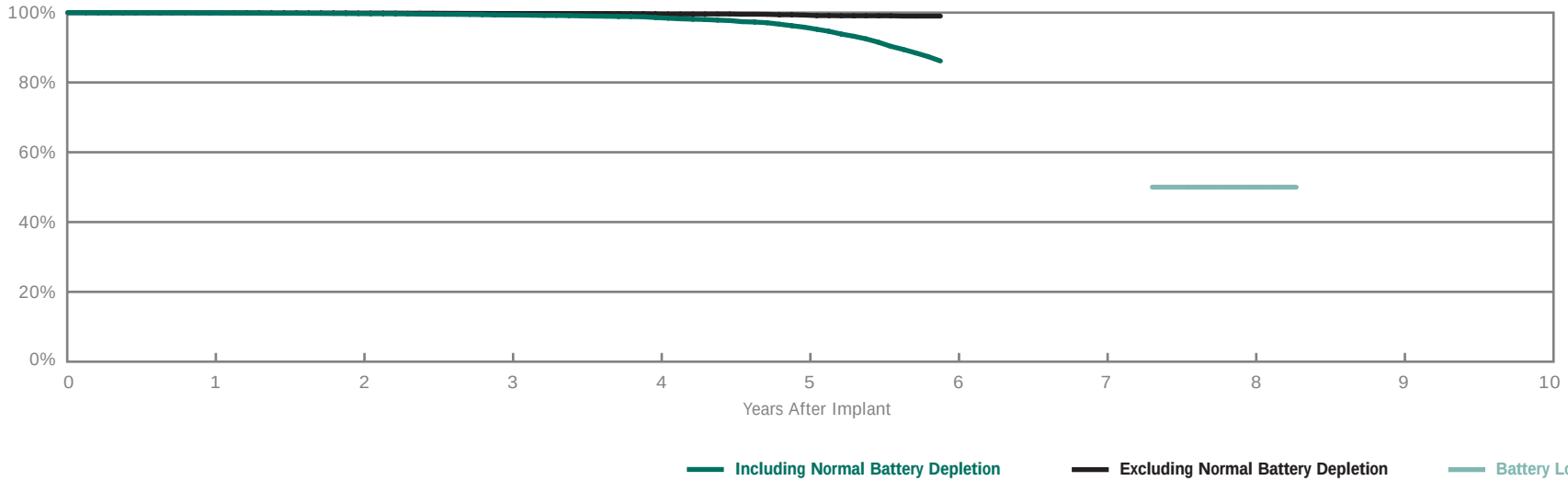
| Year | 1 | 2 | 3 | 4 | 5 | at 61 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.96% | 99.96% | 99.68% | 99.68% | 99.68% | | | | |
| ± 1 standard error | 0.01% | 0.02% | 0.02% | 0.09% | 0.09% | 0.09% | | | | |

# Pulse Generators

## Identity® SR (Model 5172)

| | | | |
|---|---|---|---|
| US Market Release | November 2001 | Normal Battery Depletion | 258 |
| Registered US Implants | 21,854 | Malfunctions | 36 |
| Estimated Active US Implants | 9,594 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 1 |
| Estimated Longevity | 7.8 Years | Malfunctions w/o Compromised Therapy (1 related to Advisory) | 35 |
| | | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

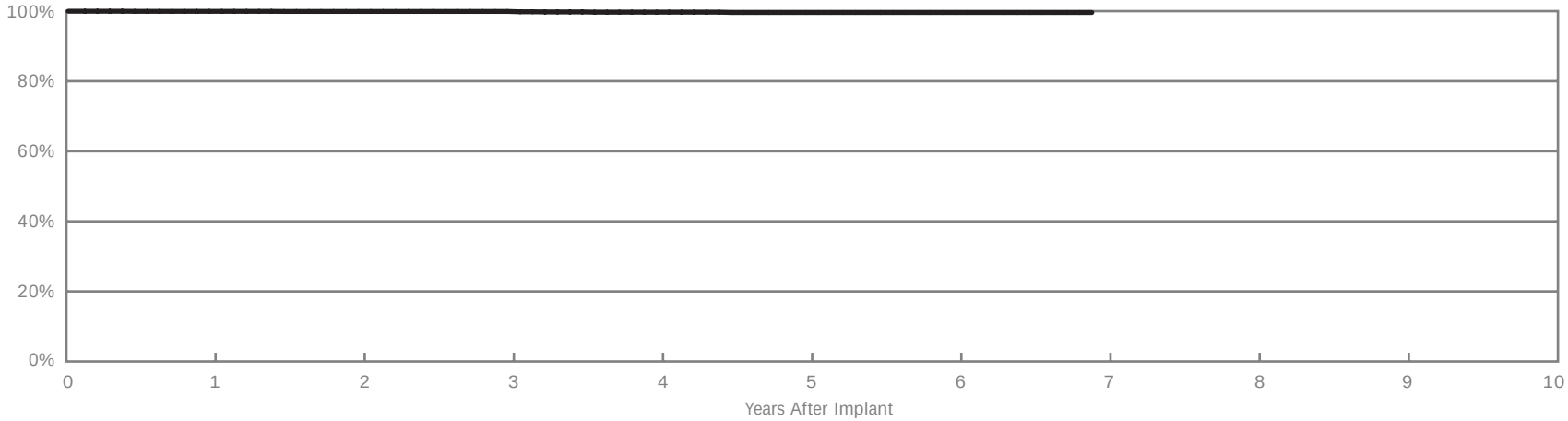
| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.93% | 99.72% | 99.33% | 98.59% | 95.83% | 86.15% | | | | |
| ± 1 standard error | 0.02% | 0.04% | 0.07% | 0.10% | 0.23% | 0.60% | | | | |
| Sample Size | 21700 | 17200 | 13600 | 10100 | 6500 | 700 | | | | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | at 71 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.95% | 99.87% | 99.76% | 99.64% | 99.30% | 99.01% | | | | |
| ± 1 standard error | 0.02% | 0.03% | 0.04% | 0.05% | 0.09% | 0.14% | | | | |

| Microny® (Models 2425T, 2525T & 2535K) | |
|---|---|
| US Market Release | April 2001 |
| Registered US Implants | 5,800 |
| Estimated Longevity | 7.5 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints



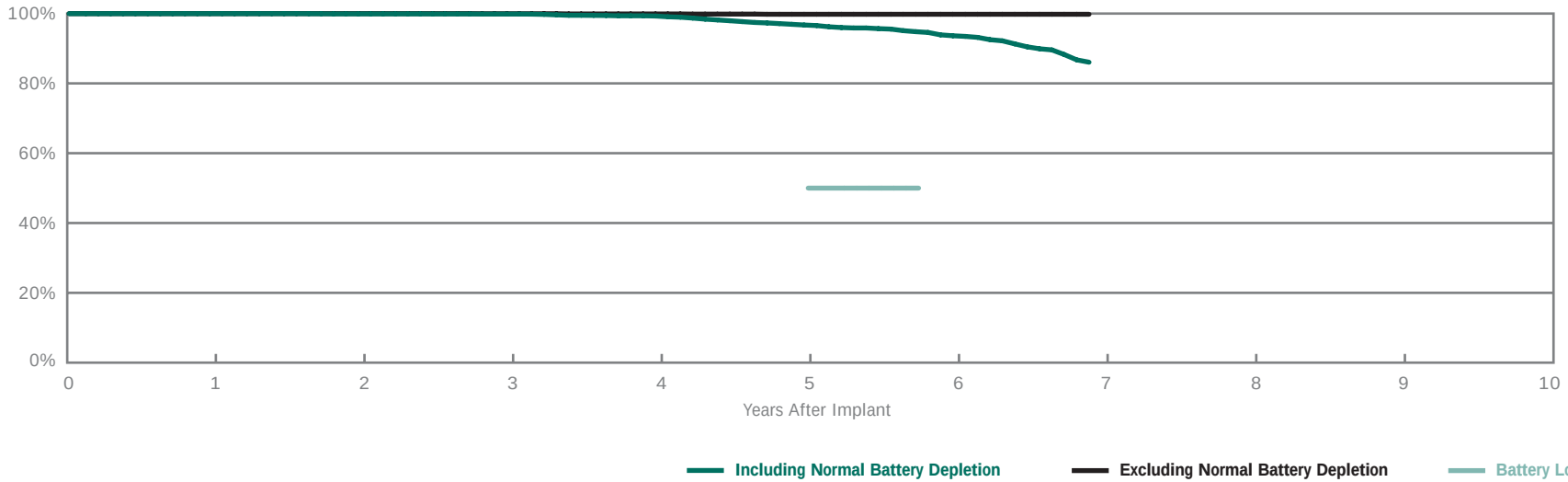

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | at 83 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.94% | 99.91% | 99.91% | 99.70% | 99.61% | 99.61% | 99.61% | 99.61% | | |
| **± 1 standard error** | 0.03% | 0.04% | 0.04% | 0.12% | 0.14% | 0.14% | 0.14% | 0.14% | | |
| **Sample Size** | 4200 | 3000 | 2200 | 1500 | 1000 | 500 | 200 | 200 | | |

# Pulse Generators

## Integrity® µ SR (Model 5136)

| | | | |
|---|---|---|---|
| US Market Release | December 2000 | Normal Battery Depletion | 188 |
| Registered US Implants | 11,959 | Malfunctions | 6 |
| Estimated Active US Implants | 3,265 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 5.3 Years | Malfunctions w/o Compromised Therapy | 6 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 83 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.91% | 99.86% | 99.29% | 96.72% | 93.64% | 86.06% | | | |
| ± 1 standard error | 0.01% | 0.03% | 0.04% | 0.10% | 0.25% | 0.39% | 0.79% | | | |
| Sample Size | 11900 | 9500 | 7900 | 6500 | 5000 | 3300 | 500 | | | |

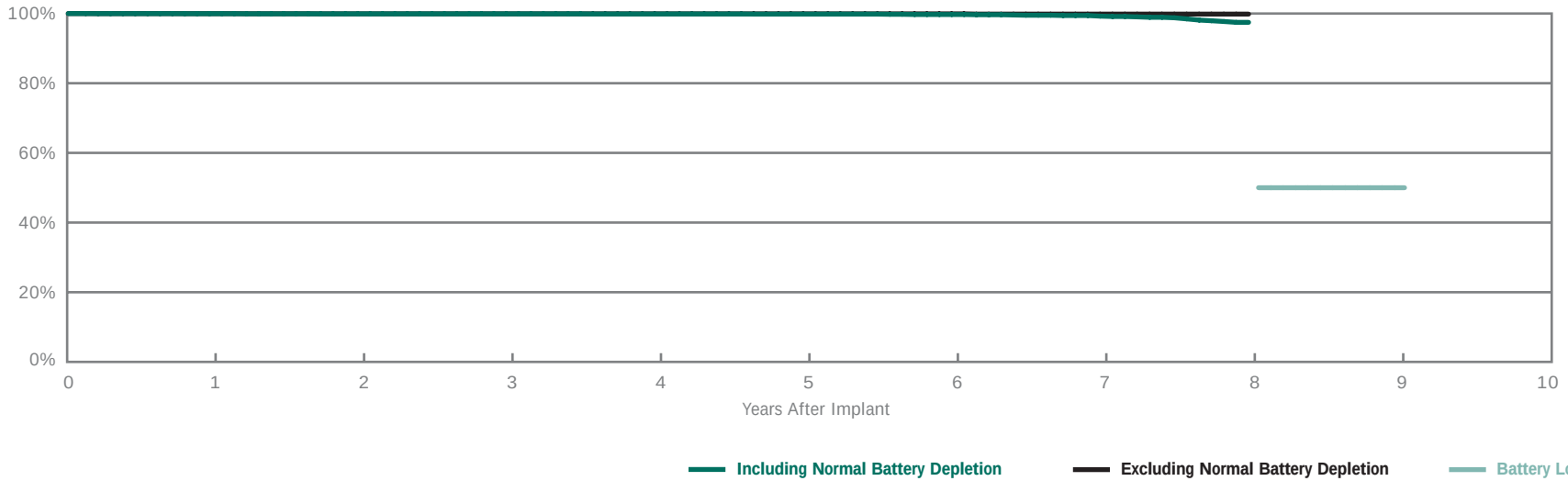
**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | at 83 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.98% | 99.98% | 99.95% | 99.89% | 99.80% | 99.80% | 99.80% | | | |
| ± 1 standard error | 0.01% | 0.01% | 0.02% | 0.04% | 0.06% | 0.06% | 0.06% | | | |

## Integrity® SR (Model 5142)

| | | | |
|---|---|---|---|
| US Market Release | April 2000 | Normal Battery Depletion | 22 |
| Registered US Implants | 10,488 | Malfunctions | 5 |
| Estimated Active US Implants | 3,728 | Malfunctions w/ Compromised Therapy | 1 |
| Estimated Longevity | 8.6 Years | Malfunctions w/o Compromised Therapy | 4 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.91% | 99.91% | 99.87% | 99.83% | 99.72% | 99.25% | 97.47% | | |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.04% | 0.05% | 0.08% | 0.13% | 0.42% | | |
| Sample Size | 10500 | 8700 | 7400 | 6300 | 5100 | 4000 | 2800 | 1500 | | |

**Excluding Normal Battery Depletion**

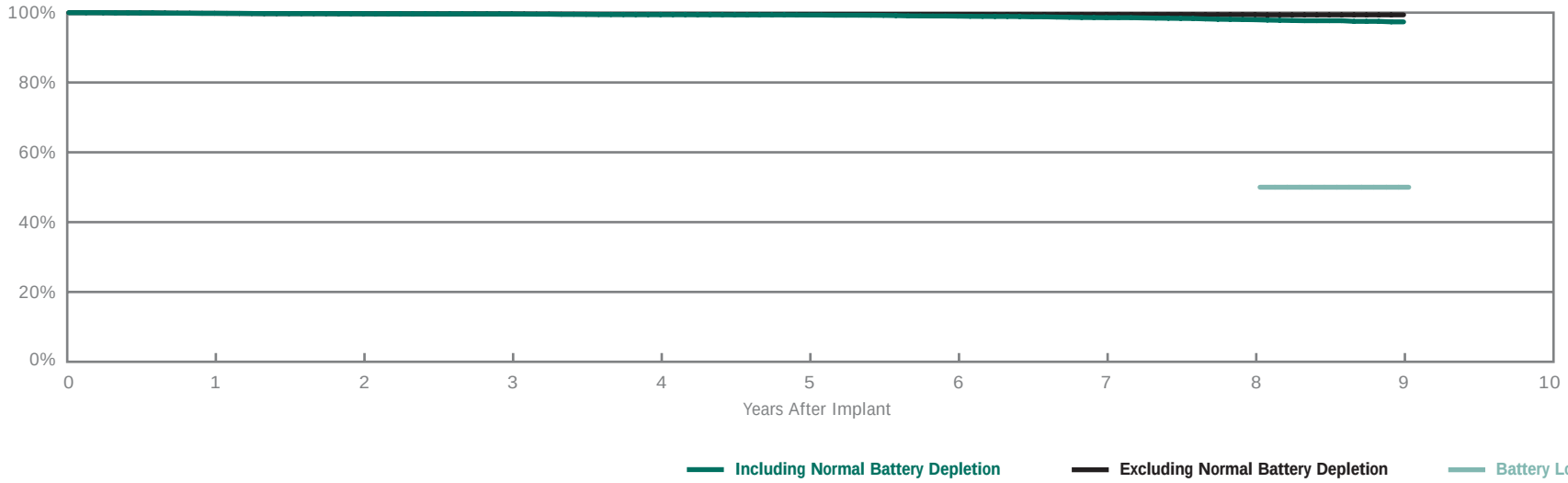
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | 99.91% | 99.84% | 99.84% | | |
| ± 1 standard error | 0.02% | 0.03% | 0.03% | 0.03% | 0.03% | 0.03% | 0.06% | 0.06% | | |

# Pulse Generators

## Affinity® SR (Models 5130 & 5131)

| | | | |
|---|---|---|---|
| US Market Release | (5130) January 1999 | Normal Battery Depletion | 73 |
| | (5131) June 1999 | Malfunctions | 57 |
| Registered US Implants | 28,657 | Malfunctions w/ Compromised Therapy (0 related to Advisory) | 4 |
| Estimated Active US Implants | 8,187 | Malfunctions w/o Compromised Therapy (17 related to Advisory) | 53 |
| Estimated Longevity | 8.6 Years | Number of Advisories (see pages 218-223) | One |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

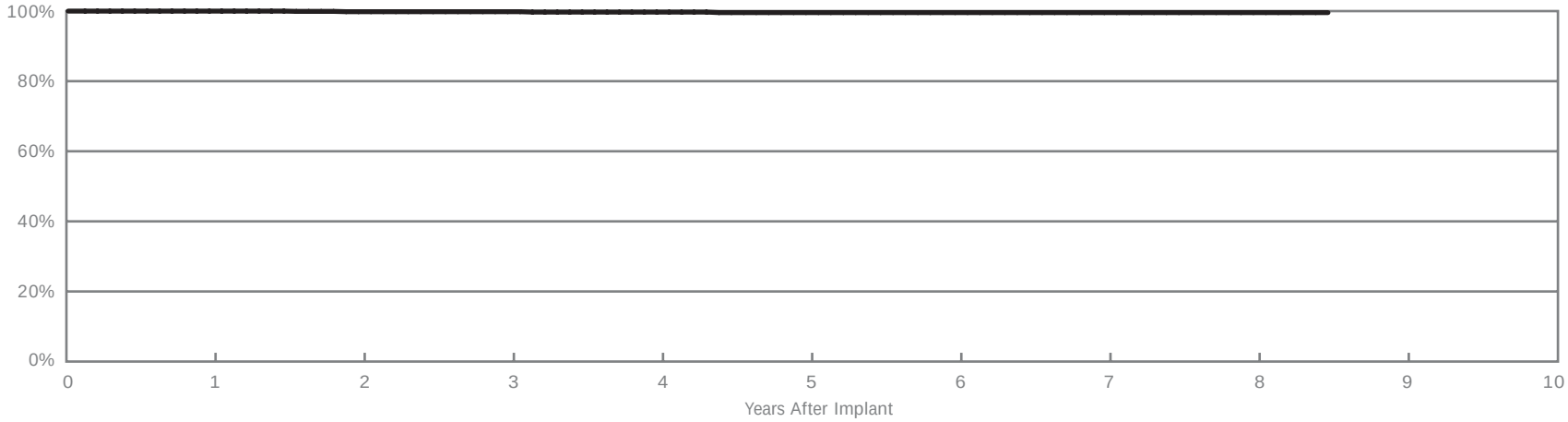
| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.81% | 99.69% | 99.61% | 99.43% | 99.32% | 99.00% | 98.56% | 97.97% | 97.36% | |
| ± 1 standard error | 0.03% | 0.04% | 0.04% | 0.05% | 0.06% | 0.08% | 0.11% | 0.15% | 0.23% | |
| Sample Size | 28600 | 23100 | 19700 | 16700 | 14000 | 11200 | 8400 | 5600 | 2600 | |

**Excluding Normal Battery Depletion**

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.81% | 99.69% | 99.62% | 99.53% | 99.50% | 99.48% | 99.46% | 99.42% | 99.37% | |
| ± 1 standard error | 0.03% | 0.04% | 0.04% | 0.05% | 0.05% | 0.05% | 0.05% | 0.06% | 0.07% | |

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

## Survival from Returns and Complaints

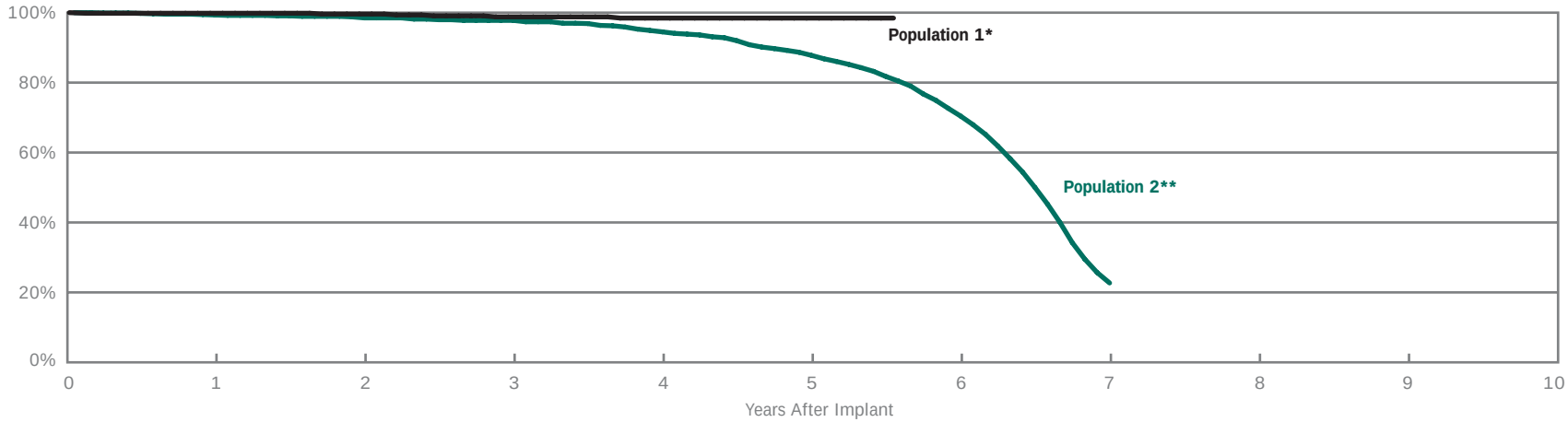



| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 102 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | 99.83% | 99.83% | 99.72% | 99.57% | 99.57% | 99.57% | 99.57% | 99.57% | |
| ± 1 standard error | 0.00% | 0.12% | 0.12% | 0.16% | 0.22% | 0.22% | 0.22% | 0.22% | 0.22% | |
| Sample Size | 1600 | 1200 | 1000 | 800 | 600 | 500 | 400 | 300 | 200 | |

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

| Population 1* | | Population 2** | |
|---|---|---|---|
| (These models are no longer being manufactured) | | (These models are no longer being manufactured) | |
| US Market Release | August 1997 | US Market Release | August 1997 |
| Registered US Implants | 604 | Registered US Implants | 1,061 |
| Estimated Longevity | 5.3 Years | Estimated Longevity | 5.3 Years |
| Number of Advisories | None | Number of Advisories (see pages 218-223) | 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% | 98.45% | 98.45% | 98.45% | | | | |
| ± 1 standard error | 0.17% | 0.29% | 0.55% | 0.64% | 0.64% | 0.64% | | | | |
| Sample Size | 500 | 400 | 400 | 300 | 200 | 200 | | | | |

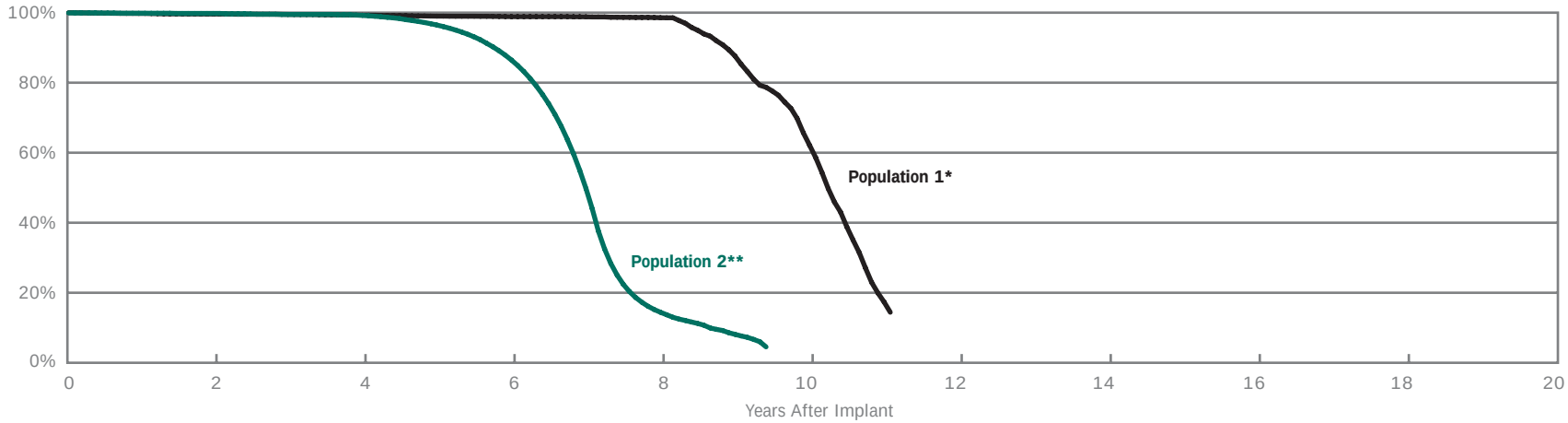
**Population 2****

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.34% | 98.50% | 97.79% | 94.50% | 87.78% | 70.44% | 22.70% | | | |
| ± 1 standard error | 0.25% | 0.38% | 0.56% | 0.87% | 1.15% | 1.40% | 1.60% | | | |
| Sample Size | 900 | 700 | 500 | 400 | 300 | 300 | 200 | | | |

## Trilogy® SR+ (Models 2260 & 2264)

| Population 1* | | Population 2** | |
|---|---|---|---|
| (These models are no longer being manufactured) | | (These models are no longer being manufactured) | |
| US Market Release | March 1997 | US Market Release | March 1997 |
| Registered US Implants | 15,323 | Registered US Implants | 2,775 |
| Estimated Longevity | 7.7 Years | Estimated Longevity | 7.7 Years |
| Number of Advisories | None | Number of Advisories (see pages 218-223) | Two |

### Survival from Returns and Complaints




**Population 1***

| Year | 2 | 4 | 6 | 8 | 10 | at 133 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.62% | 99.29% | 98.88% | 98.57% | 62.16% | 14.43% | | | | |
| ± 1 standard error | 0.06% | 0.09% | 0.12% | 0.15% | 1.00% | 0.97% | | | | |
| Sample Size | 10300 | 7200 | 5100 | 3300 | 1600 | 200 | | | | |

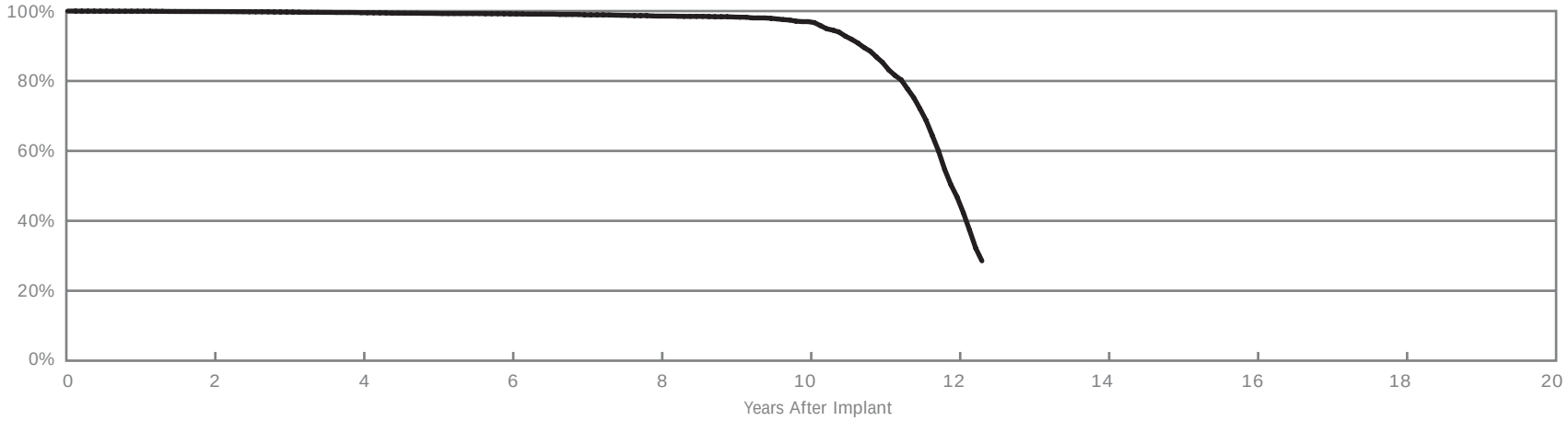
**Population 2****

| Year | 2 | 4 | 6 | 8 | at 113 months | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.79% | 99.23% | 86.47% | 14.42% | 4.54% | | | | | |
| ± 1 standard error | 0.09% | 0.18% | 0.23% | 0.53% | 2.26% | | | | | |
| Sample Size | 1900 | 1400 | 900 | 600 | 200 | | | | | |

# Pulse Generators

| Trilogy® SR (Model 2250) | |
|---|---|
| US Market Release | June 1995 |
| Registered US Implants | 12,414 |
| Estimated Longevity | 7.7 Years |
| Number of Advisories (see pages 218-223) | Two |

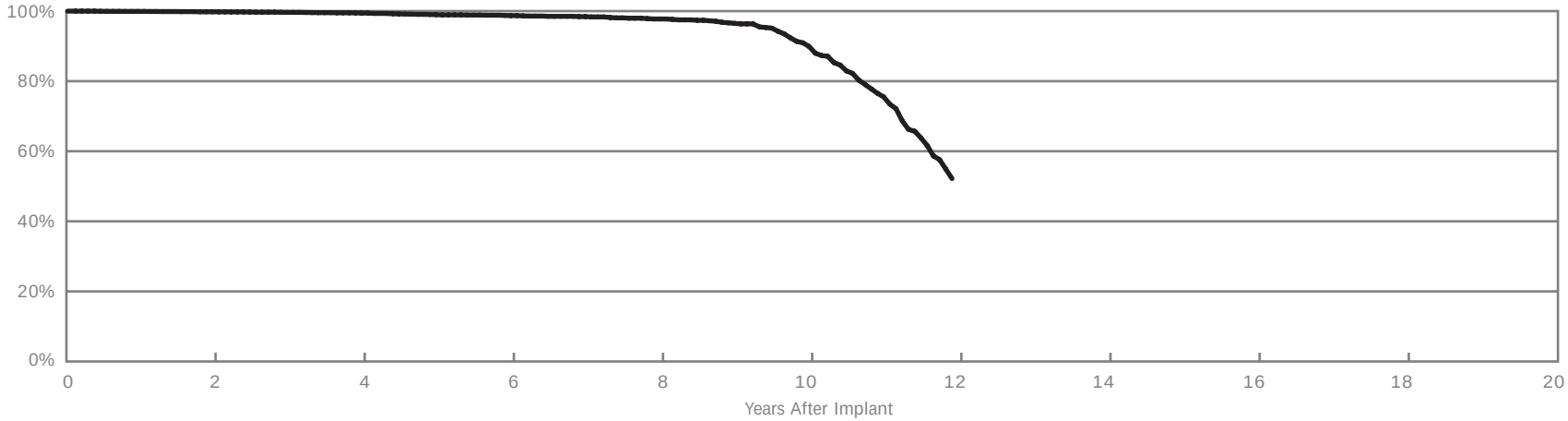
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | at 148 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.86% | 99.54% | 99.20% | 98.56% | 96.98% | 46.80% | 28.55% | | | |
| **± 1 standard error** | 0.04% | 0.07% | 0.11% | 0.17% | 0.35% | 1.70% | 1.68% | | | |
| **Sample Size** | 9400 | 6800 | 4600 | 3100 | 1600 | 600 | 200 | | | |

| Phoenix® III (Models 2204 & 2205) | |
|---|---|
| US Market Release | October 1994 |
| Registered US Implants | 6,748 |
| Estimated Longevity | 6.3 Years |
| Number of Advisories | None |

## Survival from Returns and Complaints

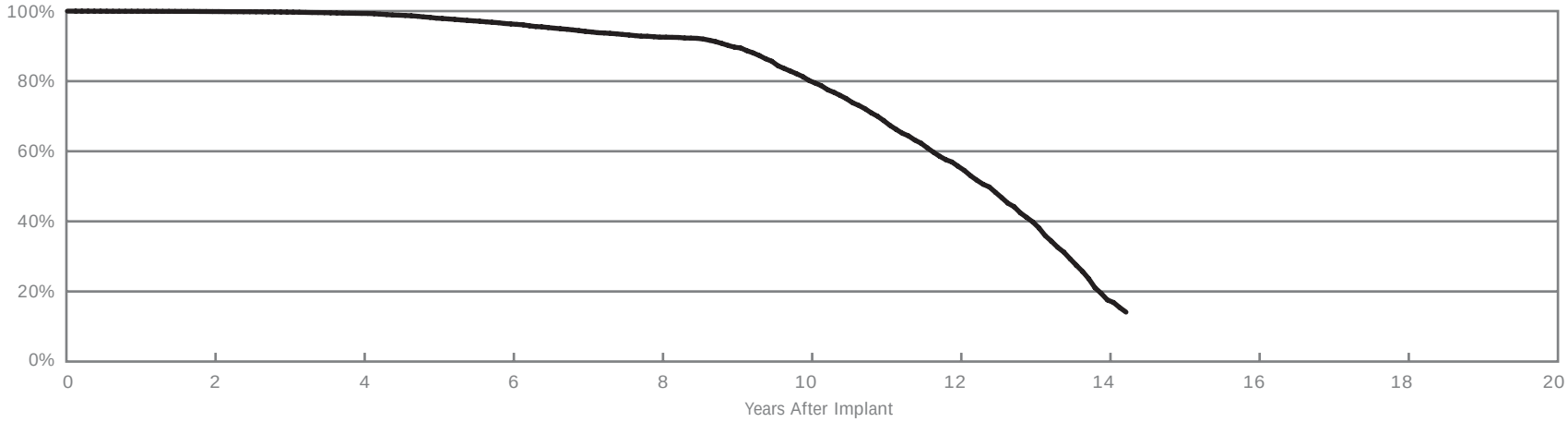



| Year | 2 | 4 | 6 | 8 | 10 | at 143 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.80% | 99.44% | 98.71% | 97.75% | 89.91% | 52.19% | | | | |
| ± 1 standard error | 0.06% | 0.12% | 0.21% | 0.37% | 1.12% | 2.47% | | | | |
| Sample Size | 4500 | 3000 | 1800 | 1000 | 500 | 200 | | | | |

# Pulse Generators

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

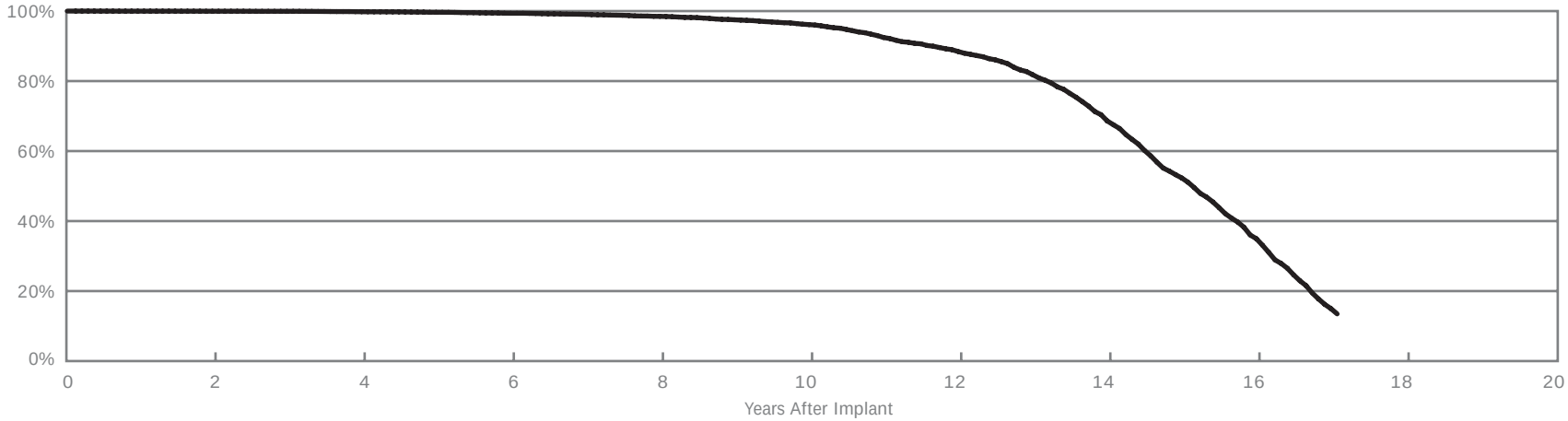
**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | at 171 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.33% | 96.34% | 92.56% | 80.19% | 55.69% | 17.58% | 14.11% | | |
| ± 1 standard error | 0.02% | 0.06% | 0.16% | 0.28% | 0.70% | 1.10% | 1.02% | 0.94% | | |
| Sample Size | 24500 | 17700 | 11100 | 4300 | 1900 | 1000 | 400 | 200 | | |

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

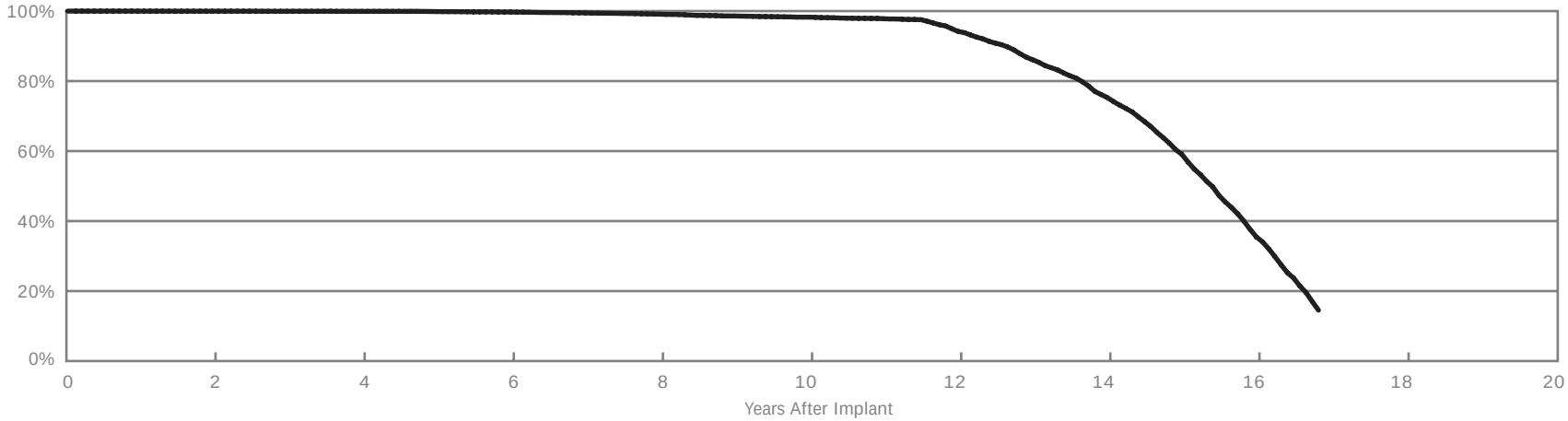
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | at 205 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.96% | 99.81% | 99.38% | 98.49% | 96.13% | 88.45% | 68.61% | 34.96% | 13.48% | |
| **± 1 standard error** | 0.01% | 0.03% | 0.07% | 0.14% | 0.27% | 0.56% | 0.98% | 1.18% | 0.93% | |
| **Sample Size** | 18900 | 13000 | 8900 | 5800 | 3600 | 2200 | 1400 | 600 | 200 | |

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

**Survival from Returns and Complaints**




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | at 202 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.97% | 99.93% | 99.73% | 99.11% | 98.27% | 94.19% | 75.29% | 35.47% | 14.54% | |
| **± 1 standard error** | 0.01% | 0.02% | 0.05% | 0.09% | 0.15% | 0.36% | 0.91% | 1.26% | 1.05% | |
| **Sample Size** | 18800 | 14300 | 10500 | 7500 | 5000 | 2900 | 1500 | 600 | 200 | |

# Summary & Longevity Information

## Pulse Generators

## Single-Chamber

ST. JUDE MEDICAL™

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## Malfunction and Normal Battery Depletion Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Malfunctions w/ Compromised Therapy | Malfunctions w/o Compromised Therapy | Malfunctions w/o Compromised Therapy (under advisory) | Malfunctions w/o Compromised Therapy (premature battery depletion) | Total Malfunctions | Total Normal Battery Depletion |
|---|---|---|---|---|---|---|---|---|---|---|
| 5626 | Zephyr XL SR | May-07 | 7689 | 7176 | 0 | 1 | 0 | 0 | 1 | 0 |
| 5620 | Zephyr SR | Mar-07 | 3806 | 3500 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5610 | Victory SR | Dec-05 | 11416 | 9390 | 0 | 1 | 0 | 0 | 1 | 0 |
| 5160 | Integrity Adx SR | May-03 | 3394 | 2072 | 0 | 0 | 0 | 0 | 0 | 6 |
| 5156/5157/5056 | Verity Adx XL SR/ SR(M/S)/SC | May-03 | 12958 | 9136 | 1 | 3 | 0 | 0 | 4 | 1 |
| 5180 | Identity Adx SR | May-03 | 19027 | 12049 | 0 | 6 | 0 | 2 | 8 | 33 |
| 5172 | Identity SR | Nov-01 | 21854 | 9594 | 1 | 30 | 1 | 4 | 36 | 258 |
| 5136 | Integrity µ SR | Dec-00 | 11959 | 3265 | 0 | 6 | 0 | 0 | 6 | 188 |
| 5142 | Integrity SR | Apr-00 | 10488 | 3728 | 1 | 4 | 0 | 0 | 5 | 22 |
| 5130/5131 | Affinity SR | Jan-99/Jun-99 | 28657 | 8187 | 4 | 36 | 17 | 0 | 57 | 73 |

**Based on returned product analysis as of December 31, 2008.*

# Pulse Generators

## Including Normal Battery Depletion Summary Information*

| Models | Family | Survival Probability | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 year | 2 year | 3 year | 4 year | 5 year | 6 year | 7 year | 8 year | 9 year | 10 year |
| 5626 | Zephyr XL SR** | 99.97% | | | | | | | | | |
| 5620 | Zephyr SR** | 100.00% | | | | | | | | | |
| 5610 | Victory SR | 99.95% | 99.95% | | | | | | | | |
| 5160 | Integrity Adx SR | 99.93% | 99.93% | 99.47% | 99.07% | | | | | | |
| 5156/5157/5056 | Verity Adx XL SR/ SR(M/S)/SC | 99.95% | 99.95% | 99.88% | 99.88% | 99.88% | | | | | |
| 5180 | Identity Adx SR | 99.94% | 99.90% | 99.82% | 98.80% | 96.16% | | | | | |
| 5172 | Identity SR | 99.93% | 99.72% | 99.33% | 98.59% | 95.83% | | | | | |
| 5136 | Integrity µ SR | 99.98% | 99.91% | 99.86% | 99.29% | 96.72% | 93.64% | | | | |
| 5142 | Integrity SR | 99.96% | 99.91% | 99.91% | 99.87% | 99.83% | 99.72% | 99.25% | 97.47% | | |
| 5130/5131 | Affinity SR | 99.81% | 99.69% | 99.61% | 99.43% | 99.32% | 99.00% | 98.56% | 97.97% | 97.36% | |

**Based on returned product analysis as of December 31, 2008.*

***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 device 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 |
| 5626 | Zephyr XL SR** | 99.97% | | | | | | | | | |
| 5620 | Zephyr SR** | 100.00% | | | | | | | | | |
| 5610 | Victory SR | 99.95% | 99.95% | | | | | | | | |
| 5160 | Integrity Adx SR | 100.00% | 100.00% | 100.00% | 100.00% | | | | | | |
| 5156/5157/5056 | Verity Adx XL SR/ SR(M/S)/SC | 99.95% | 99.95% | 99.92% | 99.92% | 99.92% | | | | | |
| 5180 | Identity Adx SR | 99.98% | 99.96% | 99.96% | 99.68% | 99.68% | | | | | |
| 5172 | Identity SR | 99.95% | 99.87% | 99.76% | 99.64% | 99.30% | | | | | |
| 5136 | Integrity µ SR | 99.98% | 99.98% | 99.95% | 99.89% | 99.80% | 99.80% | | | | |
| 5142 | Integrity SR | 99.96% | 99.91% | 99.91% | 99.91% | 99.91% | 99.91% | 99.84% | 99.84% | | |
| 5130/5131 | Affinity SR | 99.81% | 99.69% | 99.62% | 99.53% | 99.50% | 99.48% | 99.46% | 99.42% | 99.37% | |

**Based on returned product analysis as of December 31, 2008.*

***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 device graphs for data up to one year.*

# Pacing Leads

## Bipolar & Unipolar

## Active & Passive Fixation

St. Jude Medical

More control. Less risk.

# Pacing Leads

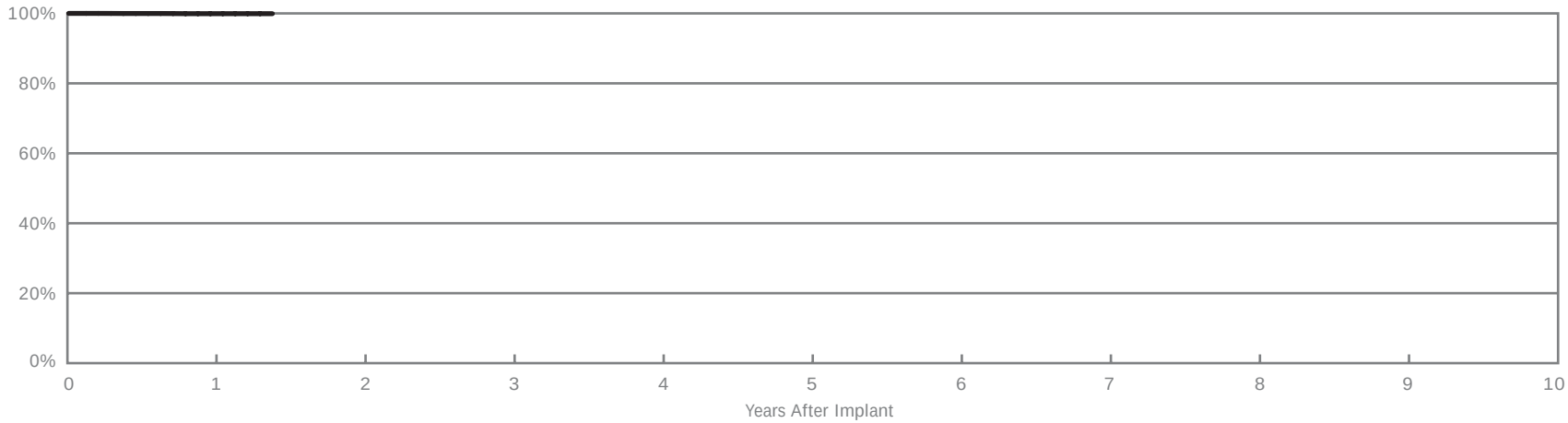
## OptiSense® (Models 1699T & 1699TC)

| | | | |
|---|---|---|---|
| US Market Release | May 2007 | Type and/or Fixation | Active |
| Registered US Implants | 10,841 | Polarity | Bipolar |
| Estimated Active US Implants | 10,155 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **15** | **Electrical Malfunction** | **0** | **Other** | **3** |
| | | Insulation Disruption | 0 | Explant Damage | 1 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 0 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 2 |

### Survival from Returns and Complaints



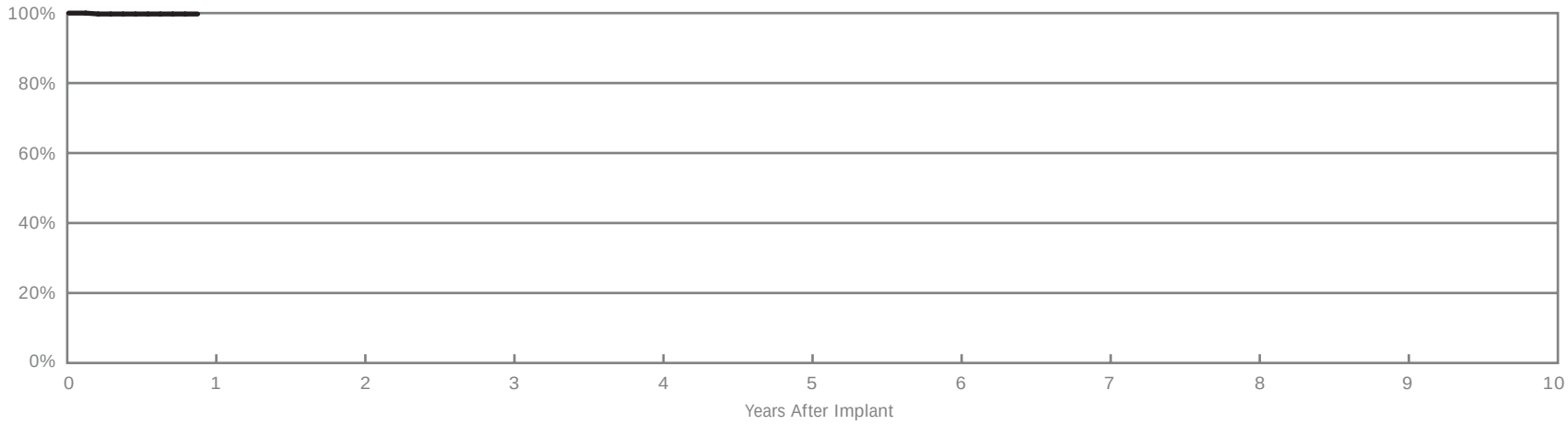

| Year | 1 | at 17 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.92% | 99.92% | | | | | | | | |
| **± 1 standard error** | 0.04% | 0.04% | | | | | | | | |
| **Sample Size** | 600 | 200 | | | | | | | | |

## OptiSense® (Models 1699T & 1699TC)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 411 |
| Cumulative Months of Follow-Up | 2,585 |

| Qualifying Complications | 1 |
|---|---|
| Lead Dislodgement | 1 |

### Survival from SCORE Registry




| Year | at 10 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.74% | | | | | | | | | |
| ± 1 standard error | 0.26% | | | | | | | | | |
| Sample Size | 64 | | | | | | | | | |

# Pacing Leads

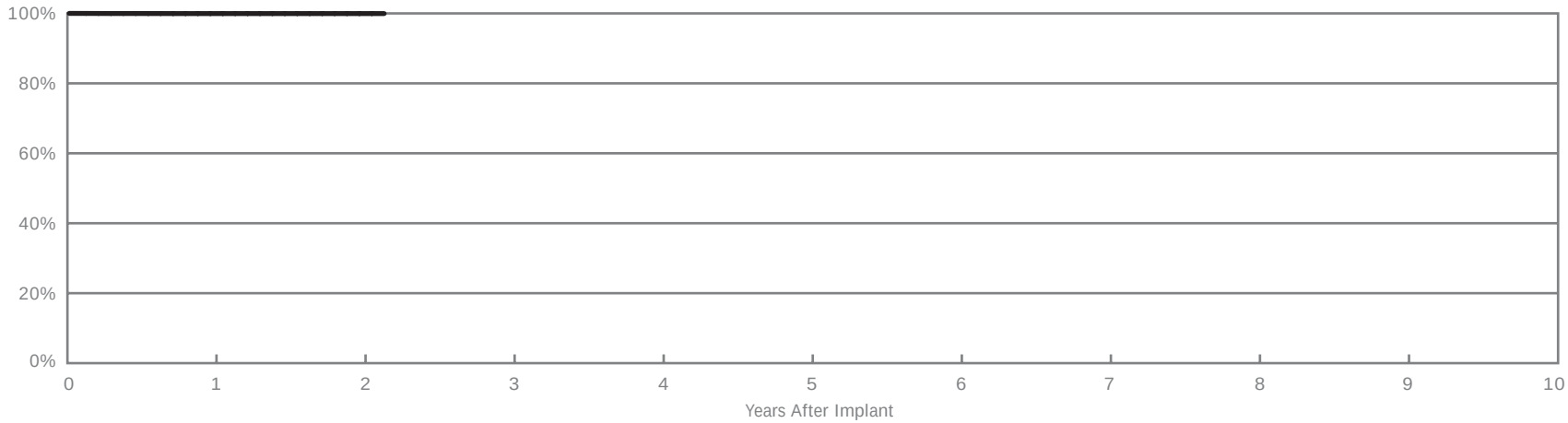
## Tendril® ST Optim® (Models 1888T & 1888TC)

| | | | |
|---|---|---|---|
| US Market Release | June 2006 | Type and/or Fixation | Active |
| Registered US Implants | 78,719 | Polarity | Bipolar |
| Estimated Active US Implants | 73,406 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **79** | **Electrical Malfunction** | **3** | **Other** | **36** |
| | | Insulation Disruption | 3 | Explant Damage | 32 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 3 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 26 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.95% | 99.95% | 99.95% | | | | | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.01% | | | | | | | |
| **Sample Size** | 52500 | 12700 | 200 | | | | | | | |

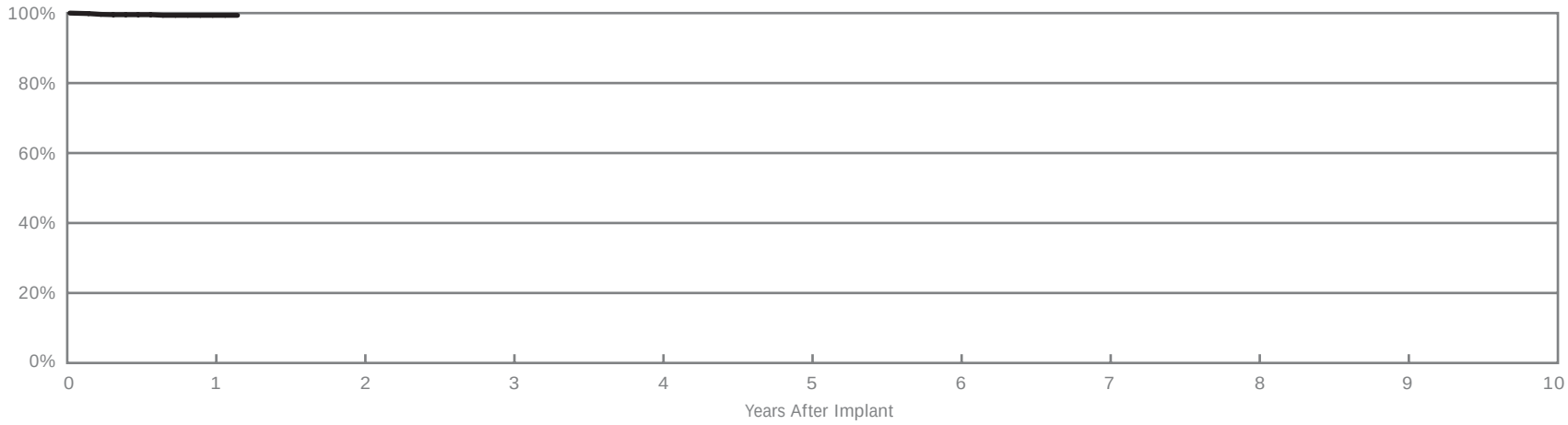
**Optim® insulation is a copolymer of silicone and polyurethane.*

## Tendril® ST Optim® (Models 1888T & 1888TC)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 1,439 |
| Cumulative Months of Follow-Up | 8,464 |

| Qualifying Complications | 7 |
|---|---|
| Lead Dislodgement | 5 |
| Extracardiac Stimulation | 1 |
| Abnormal Pacing Impedance | 1 |

### Survival from SCORE Registry




| Year | 1 | at 14 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.47% | 99.47% | | | | | | | | |
| ± 1 standard error | 0.20% | 0.20% | | | | | | | | |
| Sample Size | 147 | 65 | | | | | | | | |

# Pacing Leads

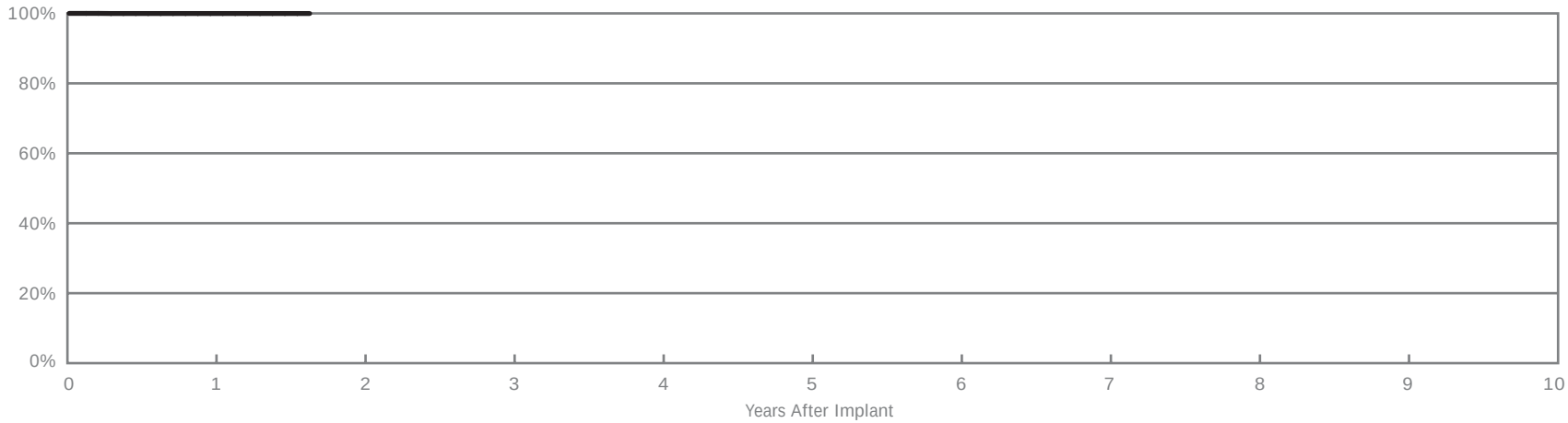
## Tendril® ST Optim® (Models 1882T & 1882TC)

| | | | |
|---|---|---|---|
| US Market Release | June 2006 | Type and/or Fixation | Active |
| Registered US Implants | 5,397 | Polarity | Bipolar |
| Estimated Active US Implants | 5,138 | Steroid | Yes |
| Insulation | Optim* | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **9** | **Electrical Malfunction** | **0** | **Other** | **6** |
| | | Insulation Disruption | 0 | Explant Damage | 5 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 1 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | at 20 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.97% | 99.97% | | | | | | | | |
| **± 1 standard error** | 0.03% | 0.03% | | | | | | | | |
| **Sample Size** | 3500 | 100 | | | | | | | | |

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

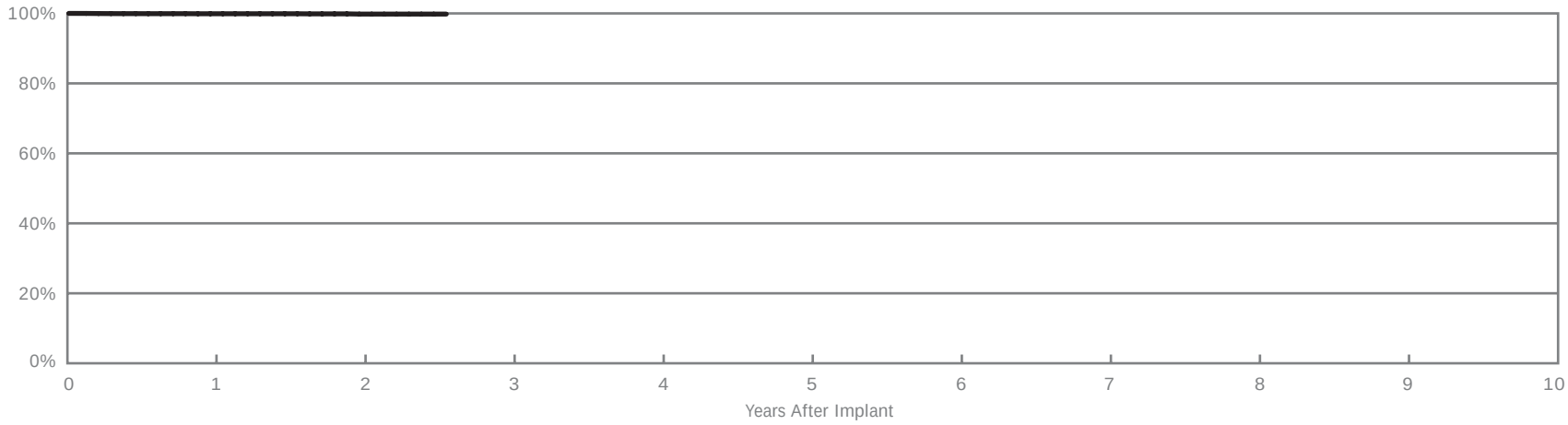
## Tendril® (Models 1782T & 1782TC)

| | | | |
|---|---|---|---|
| US Market Release | February 2006 | Type and/or Fixation | Active |
| Registered US Implants | 10,040 | Polarity | Bipolar |
| Estimated Active US Implants | 9,060 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **84** | **Electrical Malfunction** | **2** | **Other** | **13** |
| | | Insulation Disruption | 1 | Explant Damage | 9 |
| | | Conductor Disruption | 1 | Non-Electrical Workmanship | 2 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 31 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.81% | 99.81% | | | | | | | |
| **± 1 standard error** | 0.03% | 0.05% | 0.08% | | | | | | | |
| **Sample Size** | 8100 | 3700 | 100 | | | | | | | |

# Pacing Leads

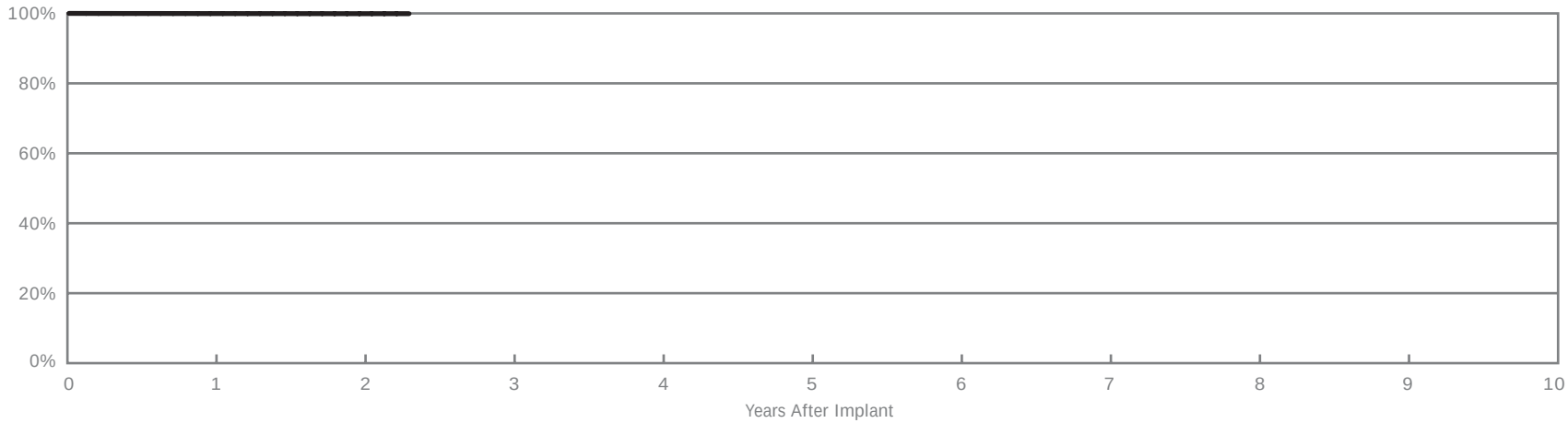
## Tendril® (Models 1788T & 1788TC)

| | | | |
|---|---|---|---|
| US Market Release | February 2006 | Type and/or Fixation | Active |
| Registered US Implants | 51,659 | Polarity | Bipolar |
| Estimated Active US Implants | 46,274 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **288** | **Electrical Malfunction** | **7** | **Other** | **53** |
| | | Insulation Disruption | 7 | Explant Damage | 33 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 17 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 2 |
| | | | | Partial Lead | 1 |

### Survival from Returns and Complaints



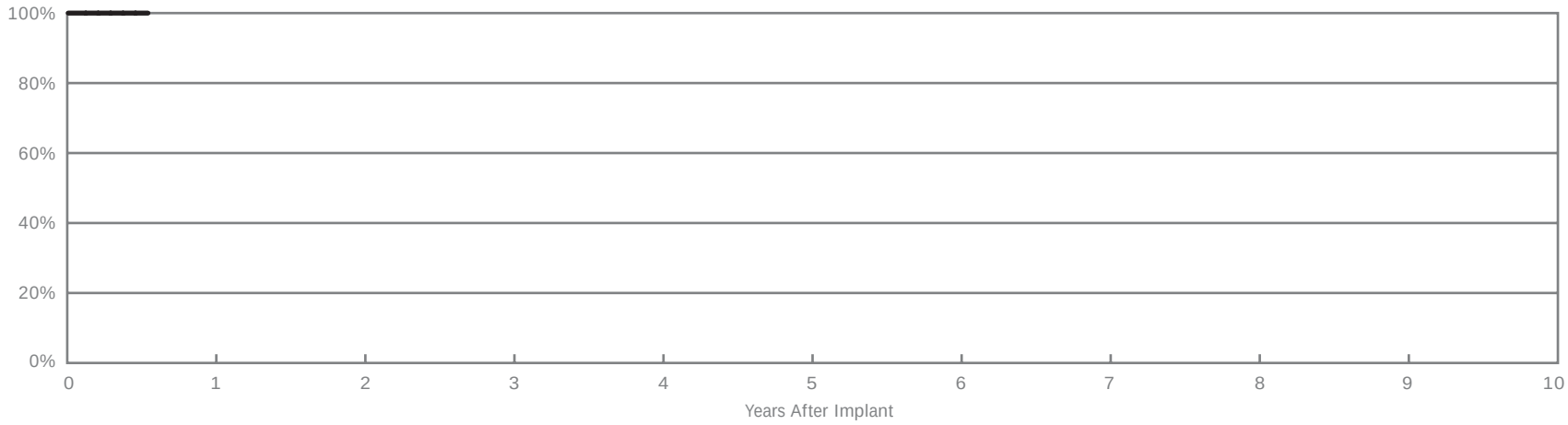

| Year | 1 | 2 | at 28 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.95% | 99.92% | 99.92% | | | | | | | |
| **± 1 standard error** | 0.01% | 0.02% | 0.02% | | | | | | | |
| **Sample Size** | 43500 | 19900 | 500 | | | | | | | |

## Tendril® (Models 1788T & 1788TC)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 109 |
| Cumulative Months of Follow-Up | 764 |

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

### Survival from SCORE Registry




| Year | at 7 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 56 | | | | | | | | | |

# Pacing Leads

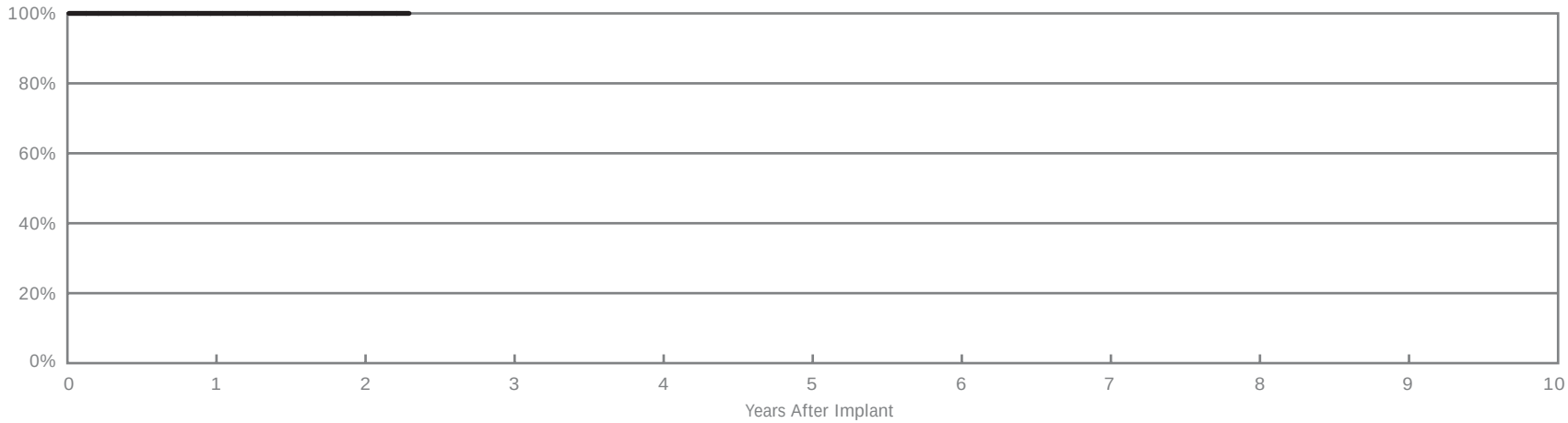
## IsoFlex® P (Model 1644T)

| | | | |
|---|---|---|---|
| US Market Release | April 2005 | Type and/or Fixation | Passive |
| Registered US Implants | 901 | Polarity | Bipolar |
| Estimated Active US Implants | 760 | Steroid | Yes |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **0** | **Electrical Malfunction** | **0** | **Other** | **1** |
| | | Insulation Disruption | 0 | Explant Damage | 1 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 0 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 28 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 100.00% | 100.00% | 100.00% | | | | | | | |
| **± 1 standard error** | 0.00% | 0.00% | 0.00% | | | | | | | |
| **Sample Size** | 800 | 500 | 100 | | | | | | | |

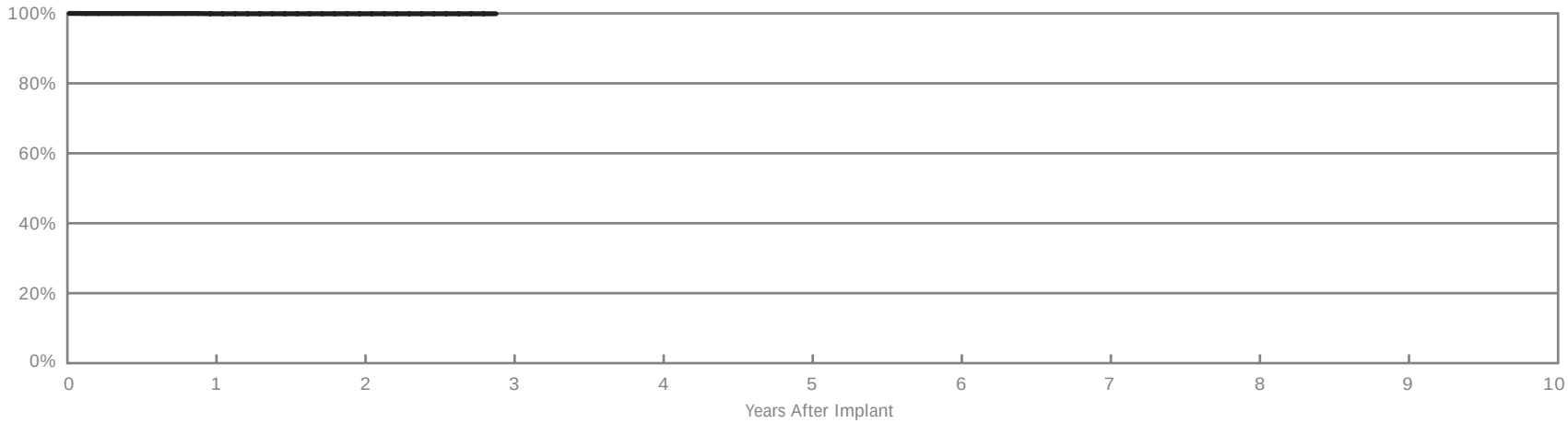
## IsoFlex® P (Model 1648T)

| | | | |
|---|---|---|---|
| US Market Release | April 2005 | Type and/or Fixation | Passive |
| Registered US Implants | 2,585 | Polarity | Bipolar |
| Estimated Active US Implants | 2,208 | Steroid | Yes |
| Insulation | Polyurethane | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **4** | **Electrical Malfunction** | **0** | **Other** | **2** |
| | | Insulation Disruption | 0 | Explant Damage | 1 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 0 |
| | | Crimps, Welds, Bonds | 0 | Non-Electrical Anomaly | 1 |
| | | | | Partial Lead | 0 |

### Survival from Returns and Complaints




| Year | 1 | 2 | at 35 months | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.90% | 99.90% | | | | | | | |
| **± 1 standard error** | 0.04% | 0.07% | 0.07% | | | | | | | |
| **Sample Size** | 2200 | 1200 | 100 | | | | | | | |

# Pacing Leads

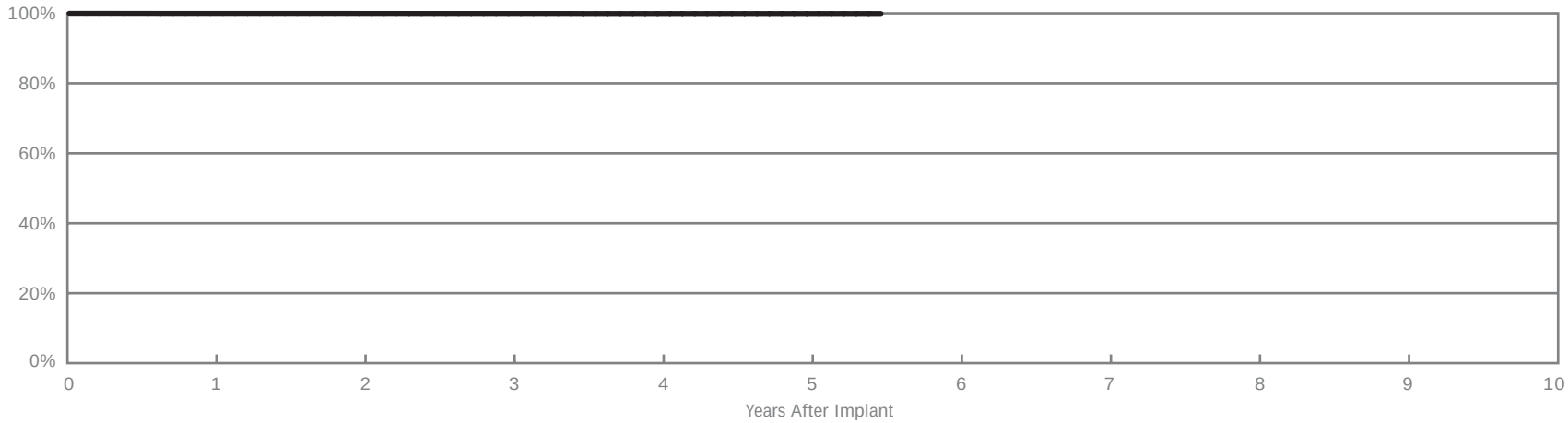
## IsoFlex® S (Model 1642T)

| | | | |
|---|---|---|---|
| US Market Release | May 2002 | Type and/or Fixation | Passive |
| Registered US Implants | 20,475 | Polarity | Bipolar |
| Estimated Active US Implants | 16,585 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **23** | **Electrical Malfunction** | **3** | **Other** | **22** |
| | | Insulation Disruption | 1 | Explant Damage | 7 |
| | | Conductor Disruption | 0 | Non-Electrical Workmanship | 13 |
| | | Crimps, Welds, Bonds | 2 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 2 |

### Survival from Returns and Complaints




| Year | 1 | 2 | 3 | 4 | 5 | at 66 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.98% | 99.97% | 99.96% | 99.94% | 99.94% | 99.94% | | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.02% | 0.03% | 0.03% | 0.03% | | | | |
| **Sample Size** | 18300 | 12900 | 8700 | 5100 | 2100 | 500 | | | | |

# Pacing Leads

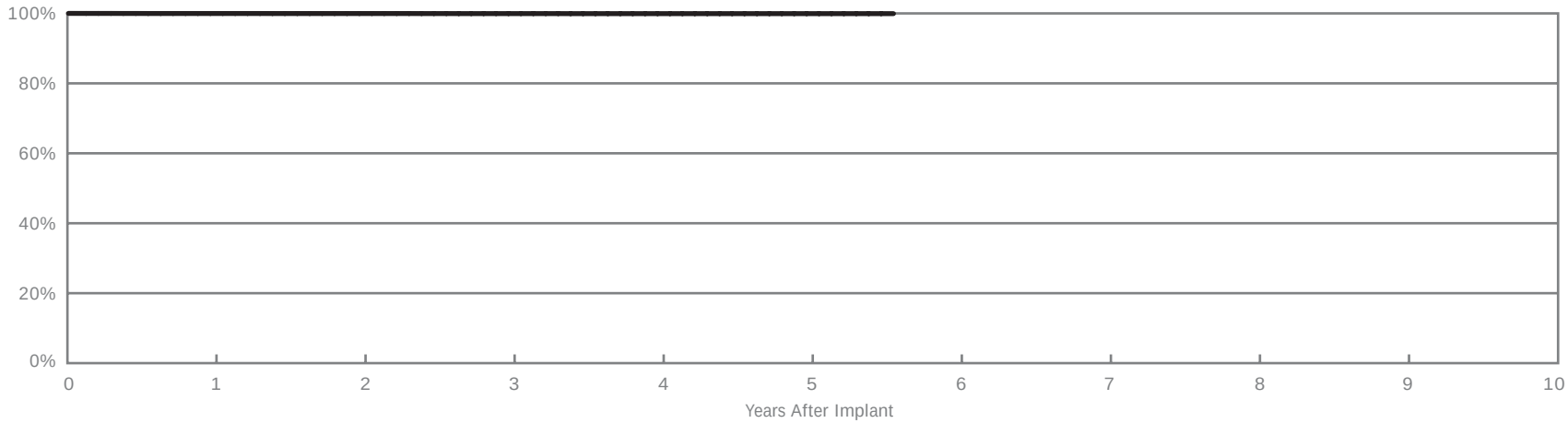
## IsoFlex® S (Model 1646T)

| | | | |
|---|---|---|---|
| US Market Release | May 2002 | Type and/or Fixation | Passive |
| Registered US Implants | 67,871 | Polarity | Bipolar |
| Estimated Active US Implants | 53,316 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **117** | **Electrical Malfunction** | **9** | **Other** | **23** |
| | | Insulation Disruption | 4 | Explant Damage | 16 |
| | | Conductor Disruption | 4 | Non-Electrical Workmanship | 4 |
| | | Crimps, Welds, Bonds | 1 | Non-Electrical Anomaly | 0 |
| | | | | Partial Lead | 3 |

### Survival from Returns and Complaints



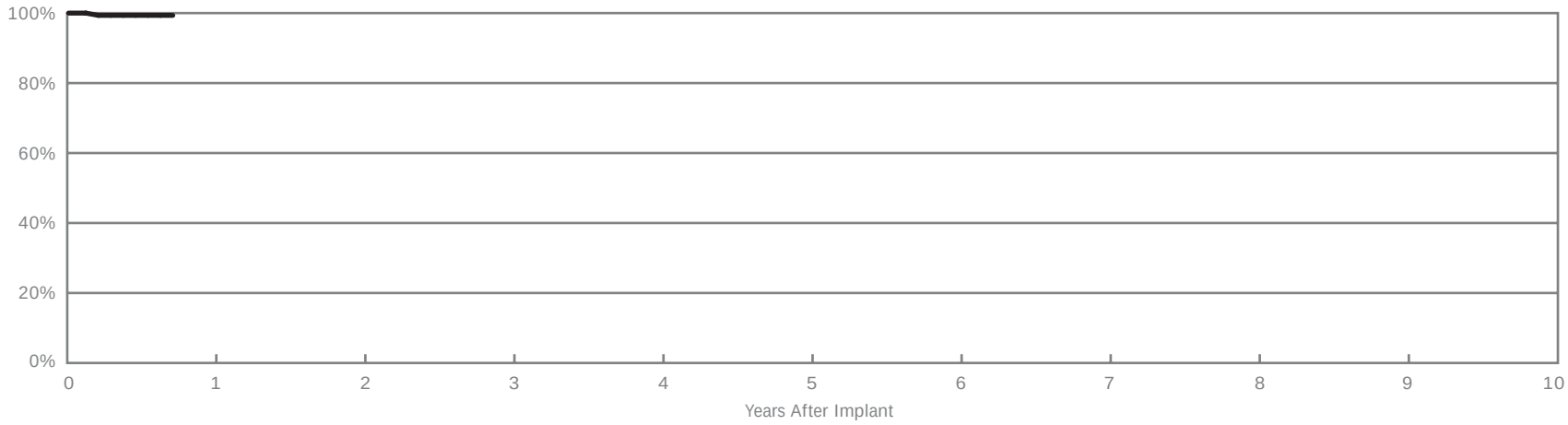

| Year | 1 | 2 | 3 | 4 | 5 | at 67 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.97% | 99.96% | 99.94% | 99.93% | 99.93% | 99.93% | | | | |
| **± 1 standard error** | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | | | | |
| **Sample Size** | 60700 | 42100 | 27500 | 15700 | 6400 | 200 | | | | |

## IsoFlex® S (Model 1646T)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 188 |
| Cumulative Months of Follow-Up | 1,136 |

| Qualifying Complications | 1 |
|---|---|
| Lead Dislodgement | 1 |

### Survival from SCORE Registry




| Year | at 9 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.35% | | | | | | | | | |
| ± 1 standard error | 0.65% | | | | | | | | | |
| Sample Size | 50 | | | | | | | | | |

# Pacing Leads

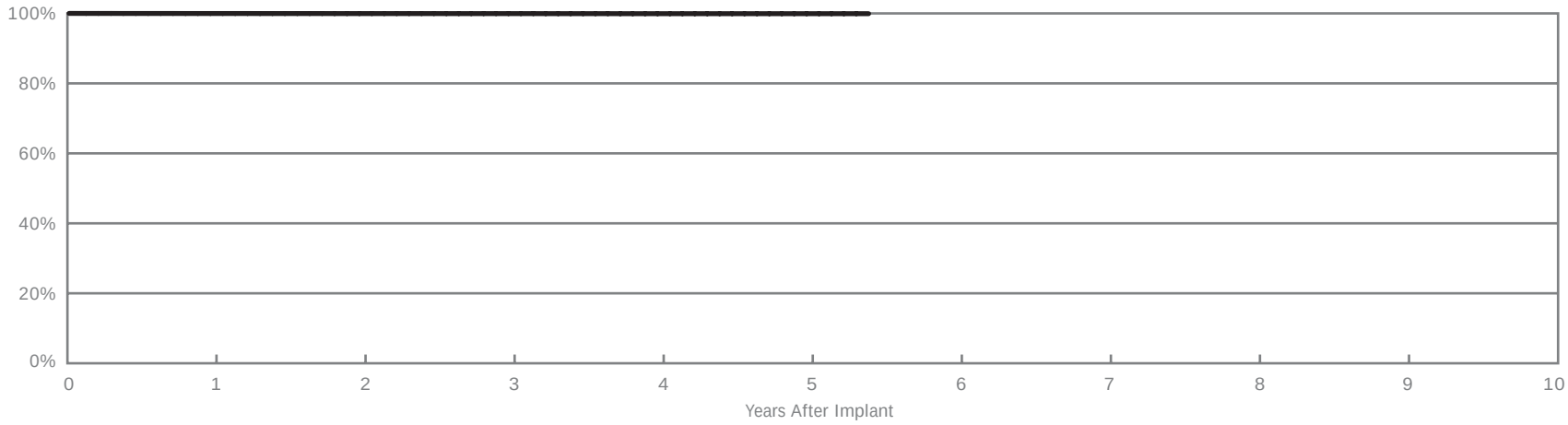
## Tendril® SDX (Models 1688T & 1688TC)

| | | | |
|---|---|---|---|
| US Market Release | June 2003 | Type and/or Fixation | Active |
| Registered US Implants | 284,331 | Polarity | Bipolar |
| Estimated Active US Implants | 228,828 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **499** | **Electrical Malfunction** | **128** | **Other** | **122** |
| | | Insulation Disruption | 51 | Explant Damage | 83 |
| | | Conductor Disruption | 62 | Non-Electrical Workmanship | 30 |
| | | Crimps, Welds, Bonds | 15 | Non-Electrical Anomaly | 2 |
| | | | | Partial Lead | 7 |

### Survival from Returns and Complaints



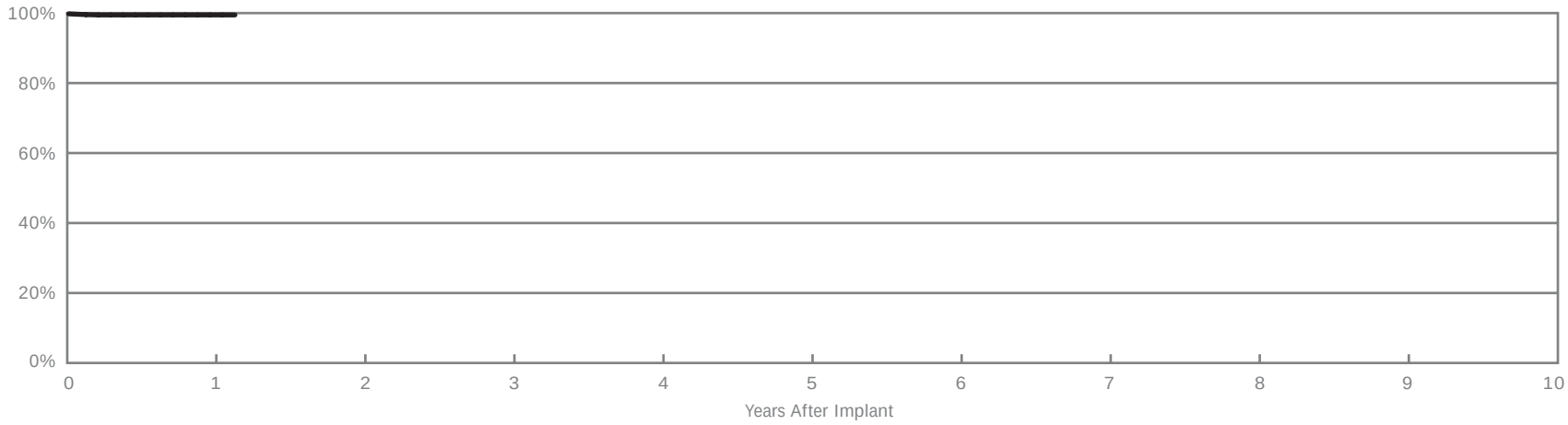

| Year | 1 | 2 | 3 | 4 | 5 | at 65 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.97% | 99.95% | 99.94% | 99.92% | 99.92% | 99.92% | | | | |
| **± 1 standard error** | 0.00% | 0.00% | 0.01% | 0.01% | 0.01% | 0.01% | | | | |
| **Sample Size** | 261000 | 196100 | 129200 | 63700 | 19300 | 100 | | | | |

## Tendril® SDX (Models 1688T & 1688TC)

| SCORE Results | |
|---|---|
| Number of Devices Enrolled in Study | 510 |
| Cumulative Months of Follow-Up | 3,444 |

| Qualifying Complications | 1 |
|---|---|
| Lead Dislodgement | 1 |

### Survival from SCORE Registry




| Year | 1 | at 13 months | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.79% | 99.79% | | | | | | | | |
| ± 1 standard error | 0.21% | 0.21% | | | | | | | | |
| Sample Size | 81 | 60 | | | | | | | | |

# Pacing Leads

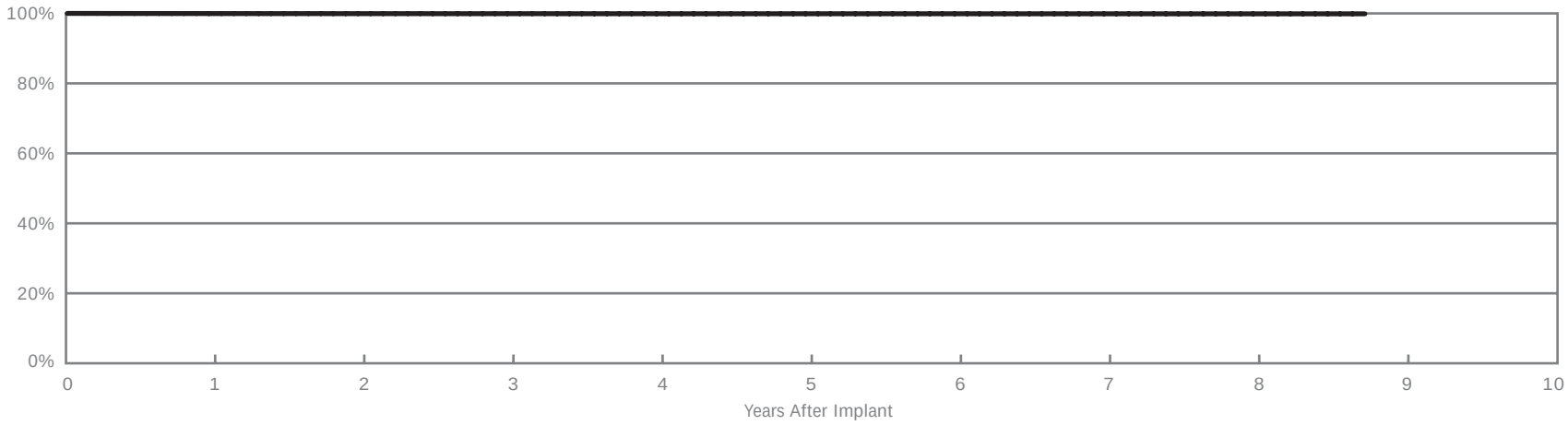
## Tendril® SDX (Models 1488T & 1488TC)

| | | | |
|---|---|---|---|
| US Market Release | March 2000 | Type and/or Fixation | Active |
| Registered US Implants | 270,983 | Polarity | Bipolar |
| Estimated Active US Implants | 160,752 | Steroid | Yes |
| Insulation | Silicone | Number of Advisories | None |

**Laboratory Analysis**

| | | | | | |
|---|---|---|---|---|---|
| **Implant Damage** | **793** | **Electrical Malfunction** | **194** | **Other** | **158** |
| | | Insulation Disruption | 66 | Explant Damage | 105 |
| | | Conductor Disruption | 119 | Non-Electrical Workmanship | 34 |
| | | Crimps, Welds, Bonds | 9 | Non-Electrical Anomaly | 3 |
| | | | | Partial Lead | 16 |

### Survival from Returns and Complaints

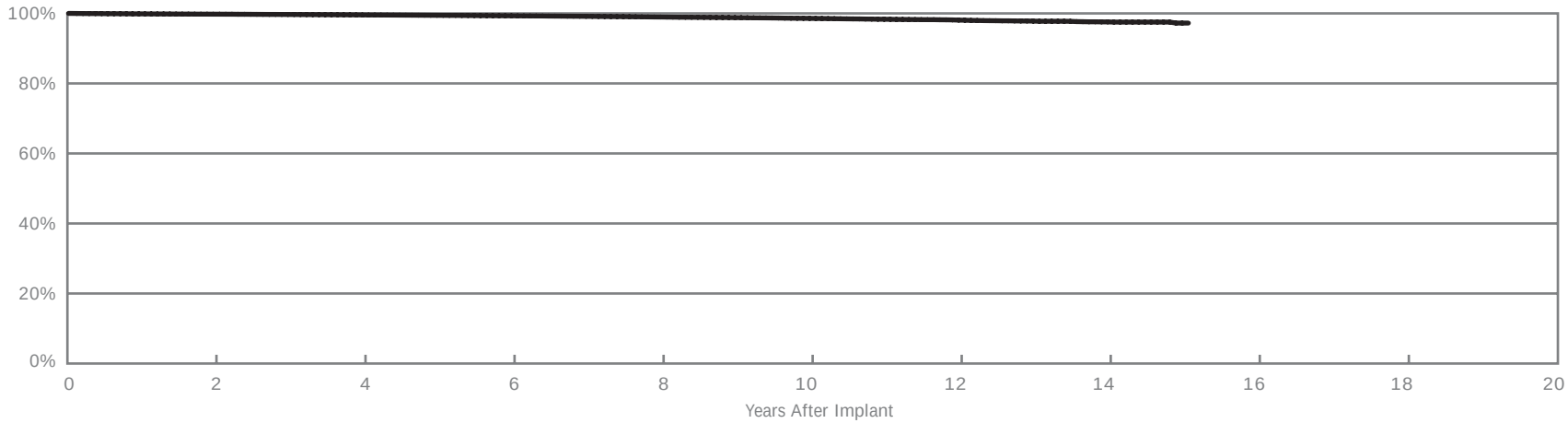



| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | at 105 months | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.95% | 99.93% | 99.92% | 99.90% | 99.90% | 99.90% | 99.89% | 99.88% | 99.88% | |
| **± 1 standard error** | 0.00% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | 0.01% | |
| **Sample Size** | 263600 | 230100 | 202000 | 169900 | 132900 | 90300 | 48300 | 18700 | 200 | |

## Tendril® (Models 1148 & 1188T); Tendril® DX (Models 1388T & 1388TC)

| | | | |
|---|---|---|---|
| US Market Release | (1148) June 1993; | Type and/or Fixation | Active |
| | (1188T) June 1994; (1388T) June 1997 | Polarity | Bipolar |
| Registered US Implants | 315,594 | Steroid | (1148/1188) No; (1388) Yes |
| Estimated Active US Implants | 140,001 | Number of Advisories | None |
| Insulation | Silicone | | |

### Survival from Returns and Complaints

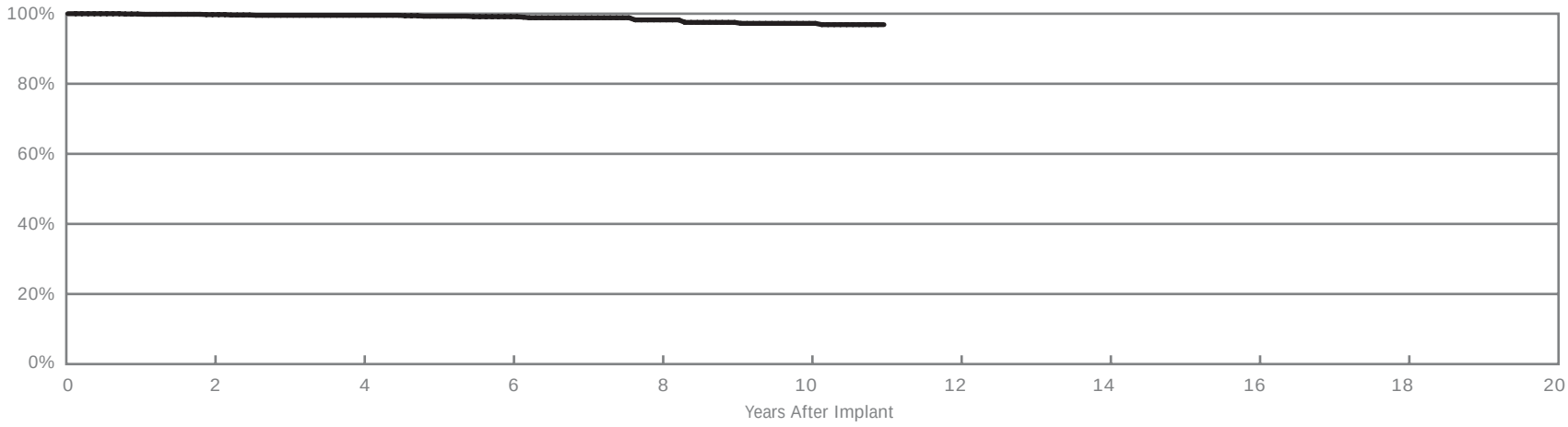



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | at 181 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.78% | 99.57% | 99.32% | 98.97% | 98.58% | 98.08% | 97.57% | 97.24% | | |
| ± 1 standard error | 0.01% | 0.01% | 0.02% | 0.03% | 0.04% | 0.06% | 0.12% | 0.31% | | |
| Sample Size | 270400 | 209000 | 149700 | 96600 | 46000 | 15500 | 4000 | 100 | | |

# Pacing Leads

| Tendril® (Model 1188K) Tendril® DX (Model 1388K) | | | |
|---|---|---|---|
| US Market Release (1188K) June 1995; (1388K) June 1997 | | Type and/or Fixation | Active |
| Registered US Implants | 1,334 | Polarity | Unipolar |
| Estimated Active US Implants | 387 | Steroid | (1188K) No; (1388K) Yes |
| Insulation | Silicone | Number of Advisories | None |

**Survival from Returns and Complaints**

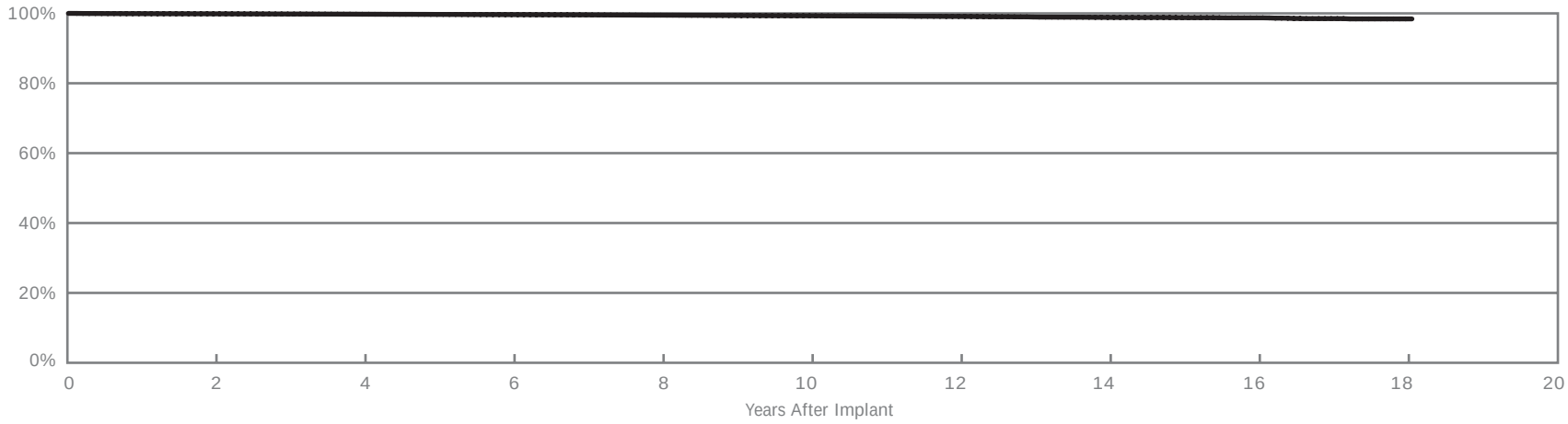



| Year | 2 | 4 | 6 | 8 | 10 | at 132 months | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.74% | 99.54% | 99.15% | 98.23% | 97.24% | 97.24% | | | | |
| **± 1 standard error** | 0.15% | 0.20% | 0.30% | 0.51% | 0.71% | 0.71% | | | | |
| **Sample Size** | 1200 | 1000 | 700 | 500 | 300 | 300 | | | | |

## Passive Plus® (Models 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T)
## Passive Plus® DX (Models 1336T, 1342T & 1346T)

| | | | |
|---|---|---|---|
| US Market Release | (1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990 | Type and/or Fixation | Passive |
| | | Polarity | Bipolar |
| Registered US Implants | 370,504 | Steroid | (1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes |
| Estimated Active US Implants | 124,393 | Number of Advisories | None |
| Insulation | Silicone | (1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T) are no longer being manufactured. | |

### Survival from Returns and Complaints



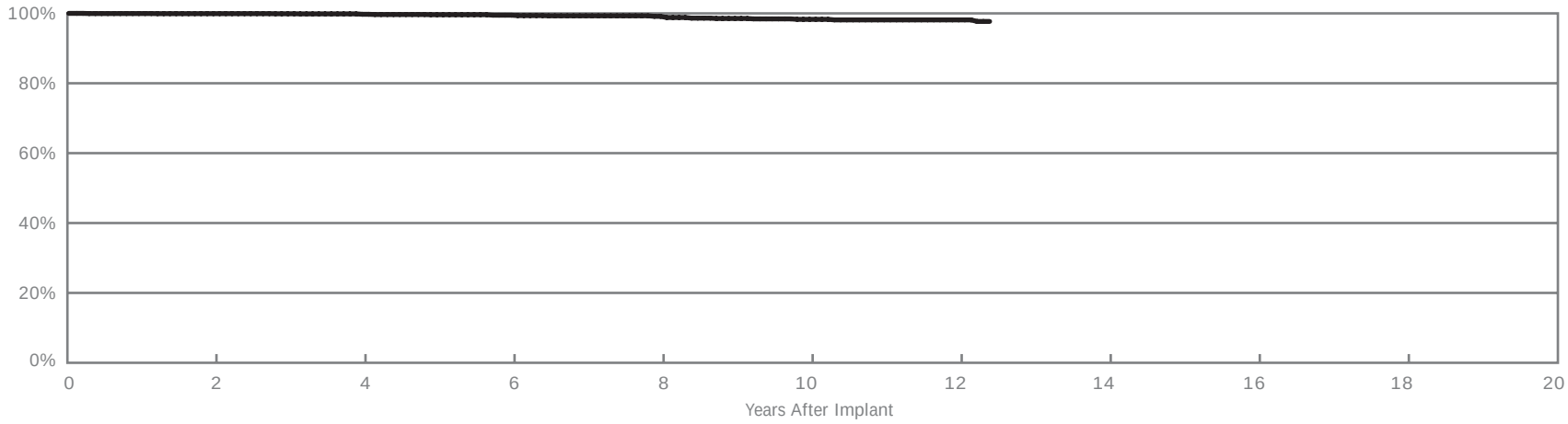

| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 217 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.87% | 99.76% | 99.64% | 99.49% | 99.32% | 99.13% | 98.85% | 98.73% | 98.42% | 98.42% |
| ± 1 standard error | 0.01% | 0.01% | 0.01% | 0.02% | 0.02% | 0.03% | 0.05% | 0.06% | 0.14% | 0.14% |
| Sample Size | 318800 | 254700 | 189700 | 124800 | 73700 | 39600 | 17300 | 6000 | 900 | 100 |

# Pacing Leads

## Passive Plus® (Models 1135K, 1143K, 1145K, 1235K, 1243K & 1245K)
## Passive Plus® DX (Models 1343K & 1345K)

| | | | |
|---|---|---|---|
| US Market Release | (1135K, 1143K, 1145K) July 1994; (1235K, 1243K, 1245K) August 1995; (1343K, 1345K) June 1998 | Type and/or Fixation | Passive |
| | | Polarity | Unipolar |
| | | Steroid | (1135K, 1143K, 1145K, 1235K, 1243K, 1245K) No; (1343K, 1345K) Yes |
| Registered US Implants | 4,481 | Number of Advisories | None |
| Estimated Active US Implants | 1,206 | (1135K, 1143K, 1145K, 1235K, 1243K & 1245K) are no longer being manufactured. | |
| Insulation | Silicone | | |

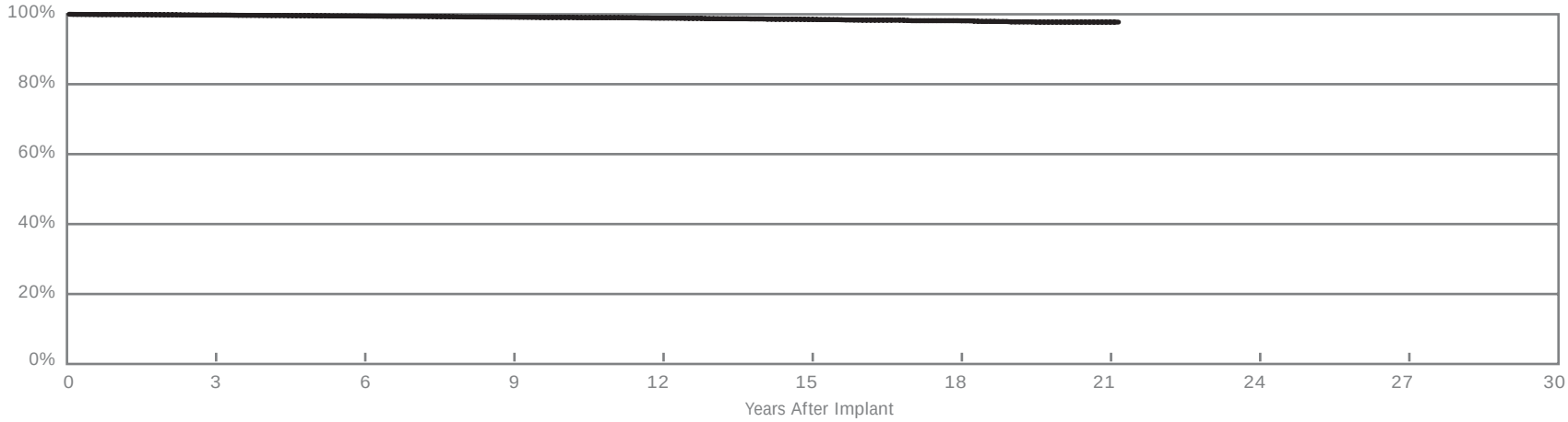
### Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | at 149 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 99.92% | 99.74% | 99.48% | 99.15% | 98.29% | 98.13% | 97.69% | | | |
| ± 1 standard error | 0.04% | 0.06% | 0.14% | 0.21% | 0.36% | 0.39% | 0.58% | | | |
| Sample Size | 3700 | 3000 | 2200 | 1500 | 900 | 400 | 100 | | | |

| ACE® (Models 1015M & 1025M) | | | |
|---|---|---|---|
| US Market Release (1025M) August 1982; (1015M) August 1991 | | Type and/or Fixation | Passive |
| Registered US Implants | 23,874 | Polarity | Unipolar |
| Estimated Active US Implants | 3,387 | Steroid | No |
| Insulation | Silicone | Number of Advisories | None |

## Survival from Returns and Complaints

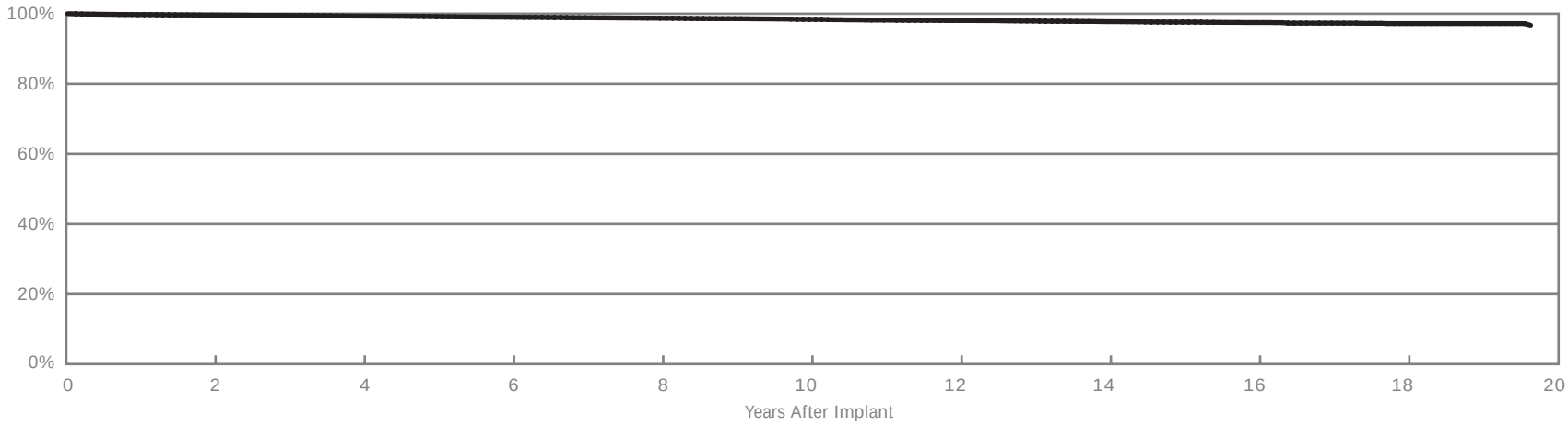



| Year | 3 | 6 | 9 | 12 | 15 | 18 | 21 | at 255 months | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.76% | 99.49% | 99.18% | 98.90% | 98.53% | 98.16% | 97.76% | 97.76% | | |
| **± 1 standard error** | 0.04% | 0.06% | 0.08% | 0.10% | 0.13% | 0.17% | 0.22% | 0.22% | | |
| **Sample Size** | 18300 | 13000 | 9200 | 6500 | 4500 | 2900 | 200 | 100 | | |

# Pacing Leads

| Fast-Pass® (Models 1018T & 1028T) | | | |
|---|---|---|---|
| US Market Release (1018T) February 1988; (1028T) July 1990 | | Type and/or Fixation | Active |
| Registered US Implants | 28,030 | Polarity | Bipolar |
| Estimated Active US Implants | 4,411 | Steroid | No |
| Insulation | Silicone | Number of Advisories | None |

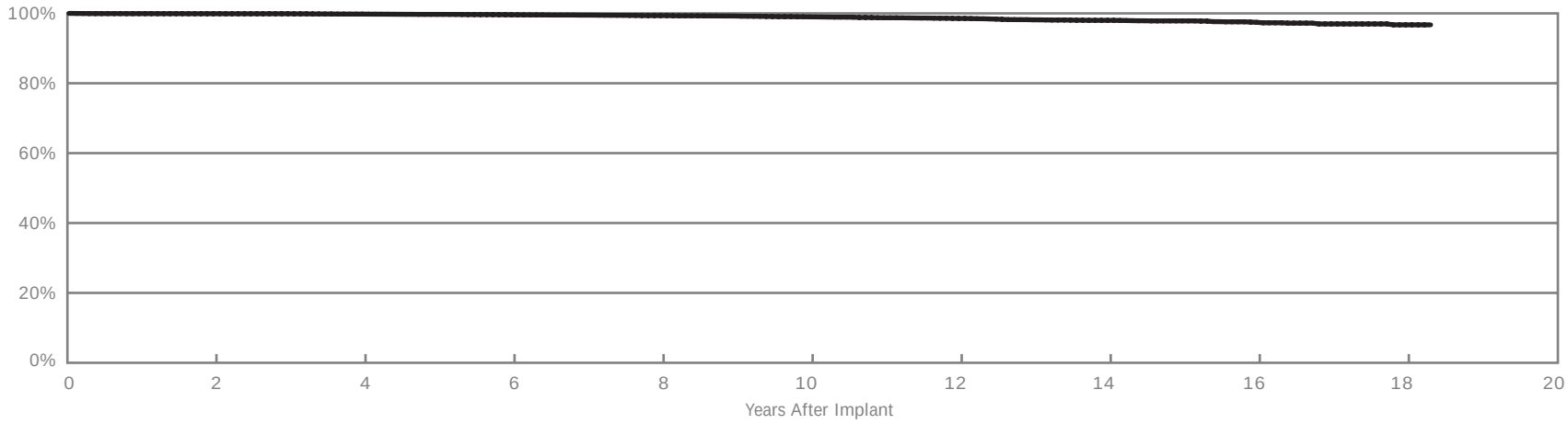
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 236 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.62% | 99.33% | 99.00% | 98.70% | 98.38% | 98.06% | 97.72% | 97.47% | 97.17% | 96.71% |
| **± 1 standard error** | 0.04% | 0.05% | 0.07% | 0.08% | 0.10% | 0.12% | 0.13% | 0.15% | 0.20% | 0.20% |
| **Sample Size** | 24600 | 20500 | 16900 | 13800 | 10900 | 8500 | 6700 | 4500 | 1500 | 100 |

| Permathane® ACE (Models 1036T & 1038T) | | | |
|---|---|---|---|
| US Market Release | June 1989 | Type and/or Fixation | Passive |
| Registered US Implants | 19,672 | Polarity | Bipolar |
| Estimated Active US Implants | 3,009 | Steroid | No |
| Insulation | Polyurethane | Number of Advisories | None |

## Survival from Returns and Complaints

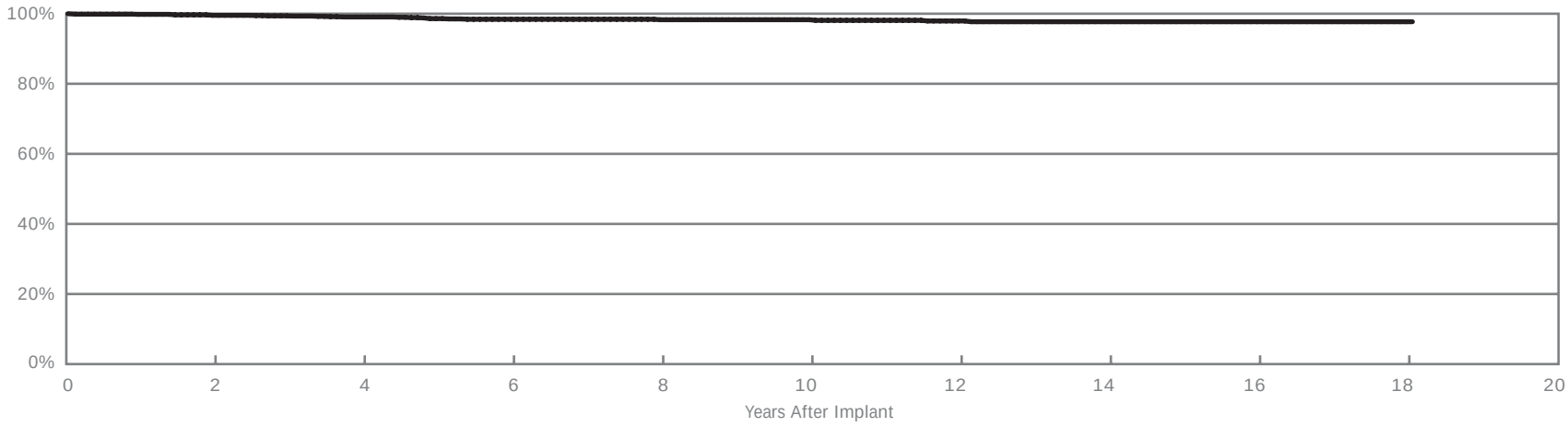



| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 220 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.90% | 99.80% | 99.59% | 99.36% | 99.00% | 98.55% | 98.01% | 97.44% | 96.72% | 96.72% |
| **± 1 standard error** | 0.02% | 0.04% | 0.05% | 0.08% | 0.10% | 0.14% | 0.18% | 0.24% | 0.41% | 0.41% |
| **Sample Size** | 17100 | 13800 | 11100 | 8700 | 6800 | 5100 | 3700 | 1800 | 500 | 100 |

# Pacing Leads

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

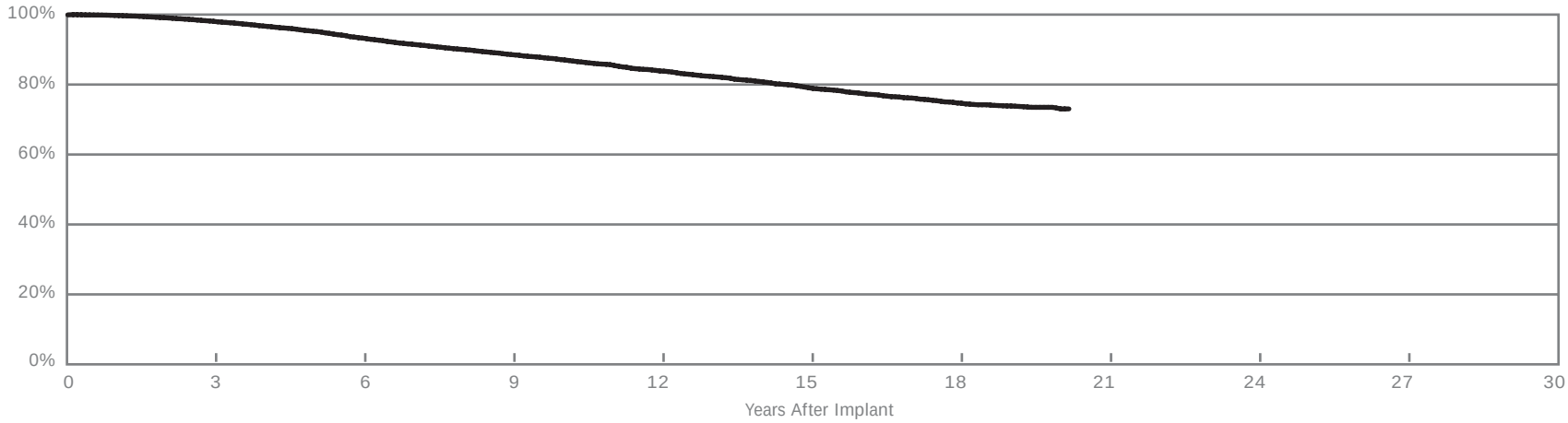
## Survival from Returns and Complaints




| Year | 2 | 4 | 6 | 8 | 10 | 12 | 14 | 16 | 18 | at 217 months |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 99.54% | 99.07% | 98.41% | 98.28% | 98.28% | 97.92% | 97.71% | 97.71% | 97.71% | 97.71% |
| **± 1 standard error** | 0.14% | 0.26% | 0.36% | 0.36% | 0.38% | 0.46% | 0.50% | 0.50% | 0.50% | 0.50% |
| **Sample Size** | 1500 | 1300 | 1000 | 800 | 700 | 500 | 400 | 300 | 200 | 200 |

| ACE® (Models 1016T & 1026T) | | | |
|---|---|---|---|
| US Market Release | June 1987 | Type and/or Fixation | Active |
| Registered US Implants | 24,199 | Polarity | Bipolar |
| Estimated Active US Implants | 2,196 | Steroid | No |
| Insulation | Silicone | Number of Advisories (see pages 218-223) | One |

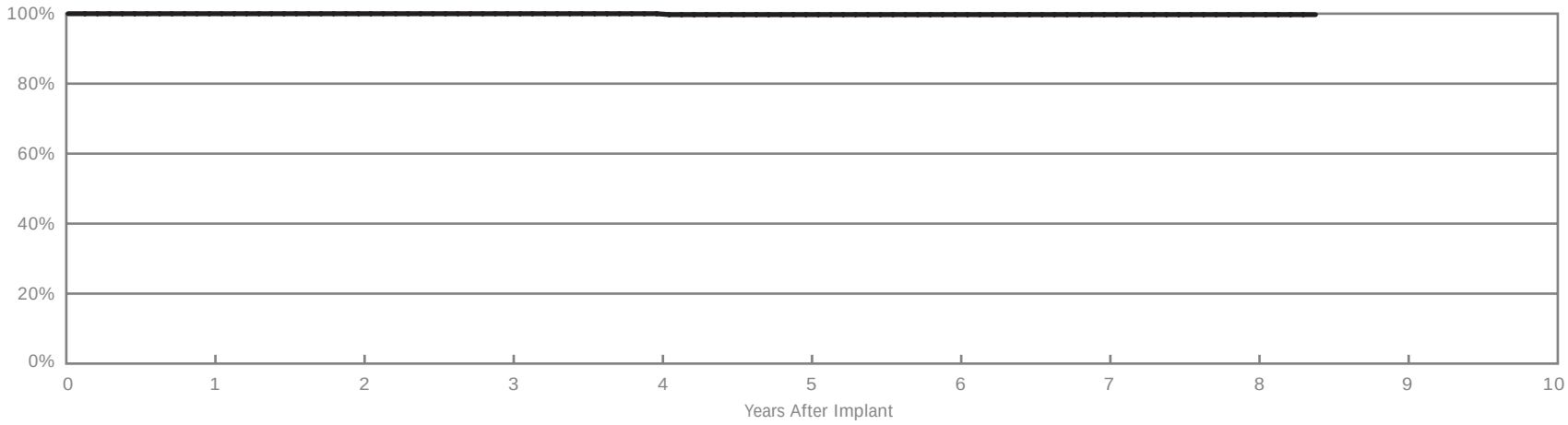
## Survival from Returns and Complaints




| Year | 3 | 6 | 9 | 12 | 15 | 18 | at 243 months | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Survival Probability** | 98.08% | 93.29% | 88.57% | 83.88% | 79.08% | 74.72% | 73.04% | | | |
| **± 1 standard error** | 0.10% | 0.20% | 0.28% | 0.36% | 0.45% | 0.54% | 0.67% | | | |
| **Sample Size** | 19300 | 13500 | 8800 | 5900 | 3900 | 2600 | 100 | | | |

| Permathane® ACE (Model 1035M) | | | |
|---|---|---|---|
| US Market Release | March 1987 | Type and/or Fixation | Passive |
| Registered US Implants | 655 | Polarity | Unipolar |
| Estimated Active US Implants | 65 | Steroid | No |
| Insulation | Polyurethane | Number of Advisories | None |

## Survival from Returns and Complaints




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

# Laboratory Analysis

Pacing Leads

Bipolar & Unipolar

Active & Passive Fixation

St. Jude Medical

More control. Less risk.

## Laboratory Analysis*

| Models | US Market Release Date | Registered US Implants | Estimated Active US Implants | Implant Damage | Electrical Malfunctions | | | | Other | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Insulation Disruption | Conductor Disruption | Crimps, Welds, Bonds | Total Electrical Malfunctions | Explant Damage | Non-Electrical Workmanship | Non-Electrical Anomaly | Partial Lead | Total Other |
| 1699T/TC | May-07 | 10841 | 10155 | 15 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 3 |
| 1888T/TC | Jun-06 | 78719 | 73406 | 79 | 3 | 0 | 0 | 3 | 32 | 3 | 0 | 1 | 36 |
| 1882T/TC | Jun-06 | 5397 | 5138 | 9 | 0 | 0 | 0 | 0 | 5 | 1 | 0 | 0 | 6 |
| 1782T/TC | Feb-06 | 10040 | 9060 | 84 | 1 | 1 | 0 | 2 | 9 | 2 | 1 | 1 | 13 |
| 1788T/TC | Feb-06 | 51659 | 46274 | 288 | 7 | 0 | 0 | 7 | 33 | 17 | 2 | 1 | 53 |
| 1644T | Apr-05 | 901 | 760 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 1648T | Apr-05 | 2585 | 2208 | 4 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 |
| 1642T | May-02 | 20475 | 16585 | 23 | 1 | 0 | 2 | 3 | 7 | 13 | 0 | 2 | 22 |
| 1646T | May-02 | 67871 | 53316 | 117 | 4 | 4 | 1 | 9 | 16 | 4 | 0 | 3 | 23 |
| 1688T/TC | Jun-03 | 284331 | 228828 | 499 | 51 | 62 | 15 | 128 | 83 | 30 | 2 | 7 | 122 |
| 1488T/TC | Mar-00 | 270983 | 160752 | 793 | 66 | 119 | 9 | 194 | 105 | 34 | 3 | 16 | 158 |

**Based on returned product analysis as of December 31, 2008.*

The laboratory analysis results are categorized into one of the following three categories:

- **Implant Damage -** obvious damage incurred at the time of attempted implant, including but not limited to insulation cuts and damage, helix overtorque, and stylet perforation.
- **Electrical Malfunction -** a disruption in the insulation or conductors resulting in compromised electrical performance. Electrical malfunction data are further broken down into one of the following three subcategories:
  - *Insulation Disruption* - leads exhibiting wear and abrasion that extends through the insulation and exposes the conductors.
  - *Conductor Disruption* - leads exhibiting cable and coil fractures, including those attributed to subclavian crush.
  - *Crimps, Welds, Bonds* - leads exhibiting malfunctions related to crimps, welds, and bonds.
- **Other -** includes other returns not attributed to damage incurred at the attempted implant and not resulting in compromised electrical failures. The Other category of data is further broken down into one of the following four subcategories:
  - *Explant Damage* - leads exhibiting physical damage incurred at the time of explant.
  - *Non-Electrical Workmanship* - leads exhibiting some out of specification mechanical condition, such as a bent connector pin or helix anomaly.
  - *Non-Electrical Anomaly* - leads not associated with a complaint but exhibiting some anomalous condition that did not result in an electrical malfunction. An example would be a lead exhibiting some insulation disruption that did not extend through and therefore did not compromise the function of the lead.
  - *Partial Lead* - leads with an alleged malfunction that are returned not in its entirety; as a result, it was not possible to perform a complete analysis and confirm the malfunction.

# Implantable Cardiac Monitors

St. Jude Medical™

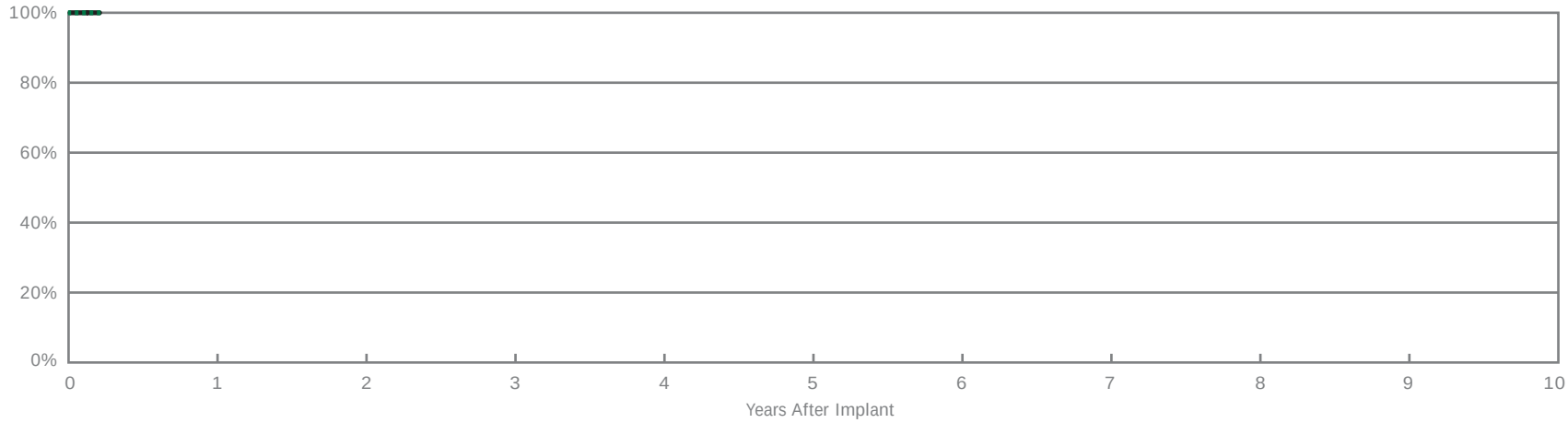
More control. Less risk.

# Implantable Cardiac Monitors

## SJM Confirm™ (Model DM2100)

| | | | |
|---|---|---|---|
| US Market Release | August 2008 | Normal Battery Depletion | 0 |
| Registered US Implants | 629 | Malfunctions | 0 |
| Estimated Active US Implants | 608 | Malfunctions w/ Compromised Therapy | 0 |
| Estimated Longevity | 3.0 Years* | Malfunctions w/o Compromised Therapy | 0 |
| | | Number of Advisories | None |

### Survival from Returns and Complaints




**Including Normal Battery Depletion**

| Year | at 3 months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Survival Probability | 100.00% | | | | | | | | | |
| ± 1 standard error | 0.00% | | | | | | | | | |
| Sample Size | 400 | | | | | | | | | |

**Excluding Normal Battery Depletion**

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

**After 12 month shelf-life.*

# Summary & Longevity Information

## Implantable Cardiac Monitors

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# Implantable Cardiac Monitors

## Malfunction Summary Information*

| Models | Family | US Market Release Date | Registered US Implants | Estimated Active US Implants | Confirmed Malfunctions |
|---|---|---|---|---|---|
| DM2100 | Confirm | Aug-08 | 629 | 608 | 0 |

**Based on returned product analysis as of December 31, 2008.*

# Advisories & Safety Alerts

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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 devices' 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 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, 2008):** 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, 2008 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 PCS 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, 2008):** 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, 2008 there were an additional 77 worldwide (64 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, 2008):** 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, 2008 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, 2008):** 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, 2008):** 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, 2008):** 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 pulse generators which have been observed to exhibit premature battery depletion. This is an extension of a previous Tempo/Meta advisory dated 6/6/00. The following recommendations are made:<br><br>For patients who are significantly pacemaker dependent. The decision as to whether or not to replace a pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated.<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 pulse generators, 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 pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated.<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 pulse generators, 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 pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated.<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 pulse generator has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services. |

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

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