PRODUCT PERFORMANCE REPORT

Cardiac Rhythm Management

May 2008

ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

MAY 2008

As world leaders in the development of state-of-the-art technology for cardiac rhythm management (CRM) devices, St. Jude Medical continuously strives to partner with physicians in order to share their commitment to 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 reducing risks by ensuring product quality and patient safety. In keeping with this commitment, we publish a product performance report semi-annually to ensure the healthcare community and the patients it serves are informed of the overall performance of our cardiac devices, which include implantable cardioverter defibrillators (ICDs), pacemakers and implantable pacing and defibrillation leads.

St. Jude Medical also recognizes the value of the industry working together to provide transparent and consistent information on the performance of CRM products. Following the 2005 Policy Conference on Pacemaker and ICD Device Performance, cardiac device companies worked together 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
Vice President, Regulatory Affairs & Quality Assurance
Cardiac Rhythm Management

ST. JUDE MEDICAL
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Serving our mission

St. Jude Medical's 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 and for all pacemakers starting with Affinity, you will find the analysis of data, according to the AdvaMed guidelines, collected through December 31, 2007, 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 on pages 24 for Cardiac Resynchronization Therapy (CRT) ICDs, for CRT-Pulse Generators page 32, for ICDs pages 60 and 74 and for Pulse Generators pages 122 and 144.

For ICDs prior to Photon Micro and pacemakers prior to Affinity, you will find analysis of the data collected through December 31, 2007, 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)

Meta DDDR 1256D
Tempo D 2902
Tempo DR 2102
Meta DDDR 1256
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 2 2005, 2008, 2009

For all CRT leads, defibrillation leads, and pacing leads, you will find analysis of the data collected through December 31, 2007. 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)

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)

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 were 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.

St. Jude Medical has initiated the SCORE (St. Jude Medical Product Longevity and Performance) registry to serve as an active ongoing source of updated information on the long-term reliability and performance of SJM market-released CRM products. SCORE is designed to encompass new products as they become commercially available. To ensure a sufficiently large and appropriately representative source of data, a number of clinical sites are participating in the SCORE Registry. To date, over 500 patients have been enrolled. Using a common protocol, these sites are individually monitoring and reporting on the performance of SJM CRM products used at their site. The data from the SCORE Registry will be reflected in future Product Performance Reports issued by St. Jude Medical once a sufficient sample size for each model or model family is available.

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. Christopher Fellows, Seattle, Washington
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 SJM CRM Customer Service at 800-681-9293
- Fax SJM CRM Customer Service at 866-805-3405
- Email SJM CRM 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.

In St. Jude Medical's product performance reports, additional adjustments have been made to account for potential underreporting of patient deaths and devices removed from service due to battery depletion. For underreporting of devices removed from service due to battery depletion, in addition to returned product, we have also included product that has not been returned in the total count of normal battery depletion. By doing this, we see a steeper decline in the all cause survival probabilities in the latter years of the device life 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, 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.*

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.

*AdvaMed Proposal - Requirements for Uniform Reporting of Clinical Performance of Pulse Generators.

Cardiac Resynchronization Therapy

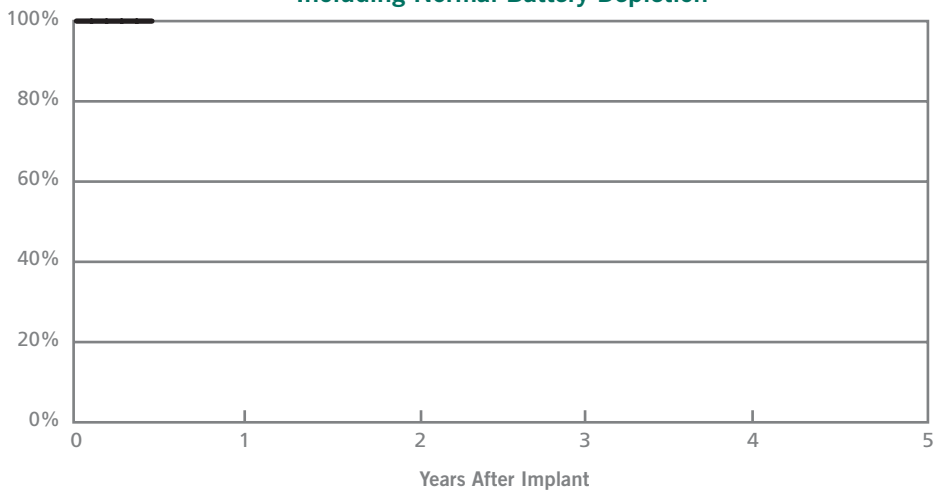
CRT ICDs

Cardiac Resynchronization Therapy

Promote® HE (Model 3107-36)

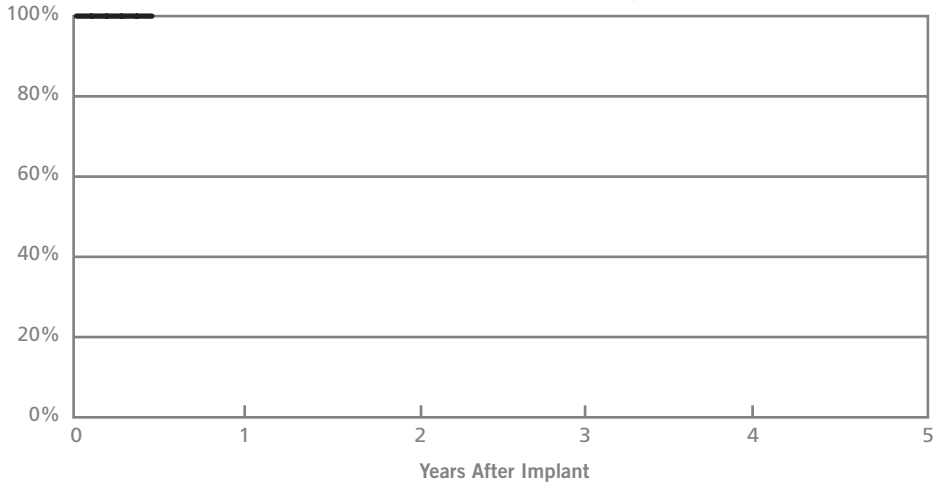
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	572	Malfunctions	0
Estimated Active US Implants	542	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 6 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	300				

Excluding Normal Battery Depletion

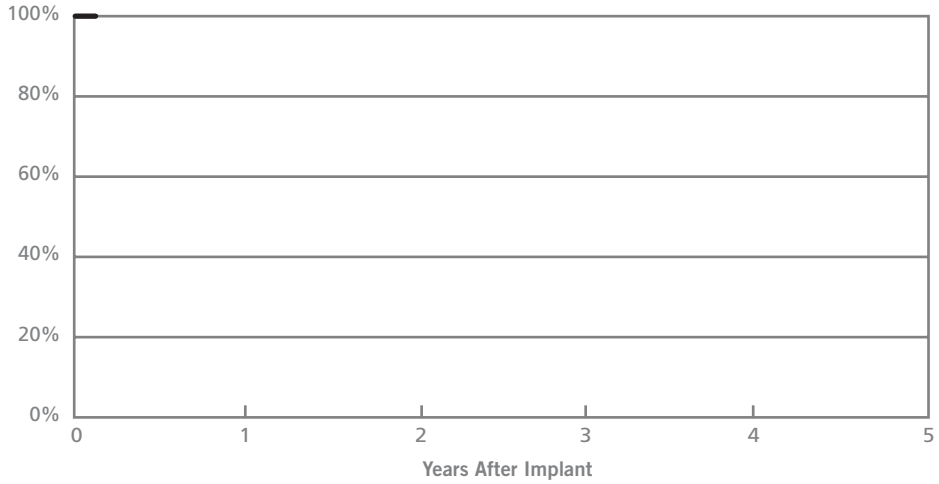


Year	at 6 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Promote® RF HE (Model 3207-36)

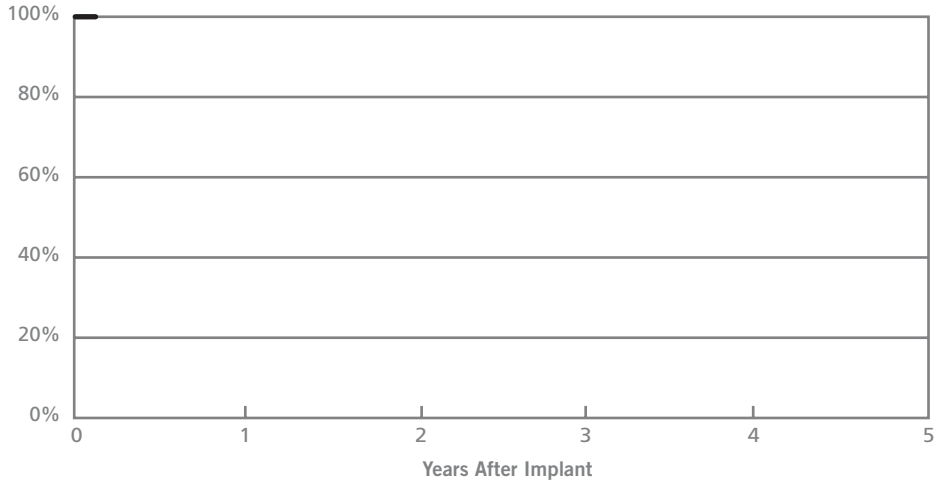
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	847	Malfunctions	0
Estimated Active US Implants	829	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

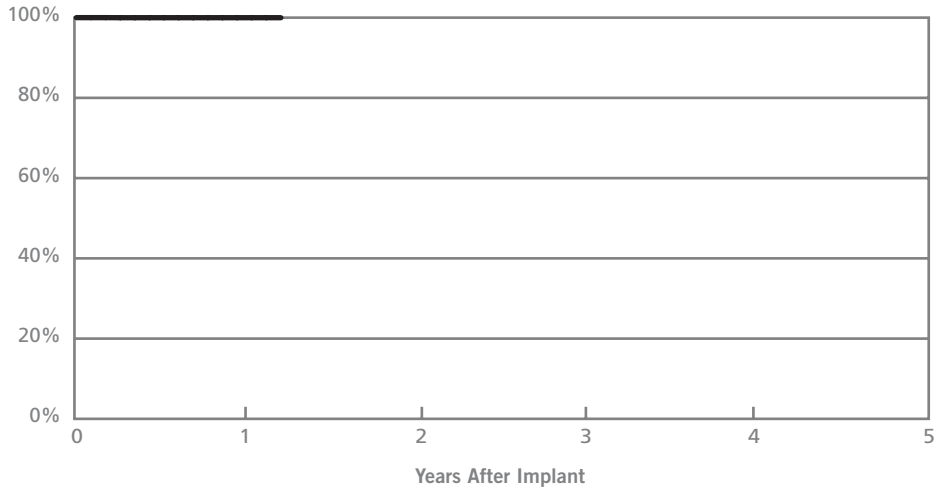


Year	at 2 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® II HF (Model V-365)

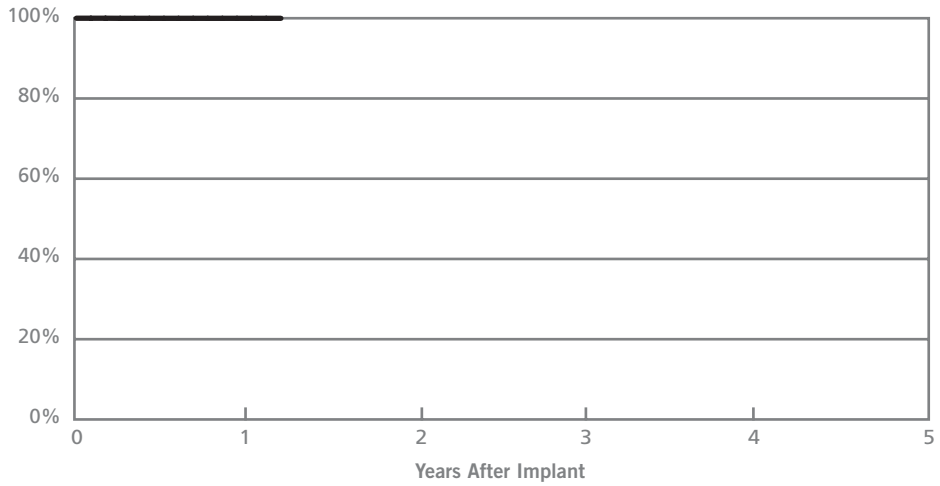
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	7,009	Malfunctions	1
Estimated Active US Implants	6,348	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 15 months			
Survival Probability	99.98%	99.98%			
± 1 standard error	0.02%	0.02%			
Sample Size	4300	600			

Excluding Normal Battery Depletion

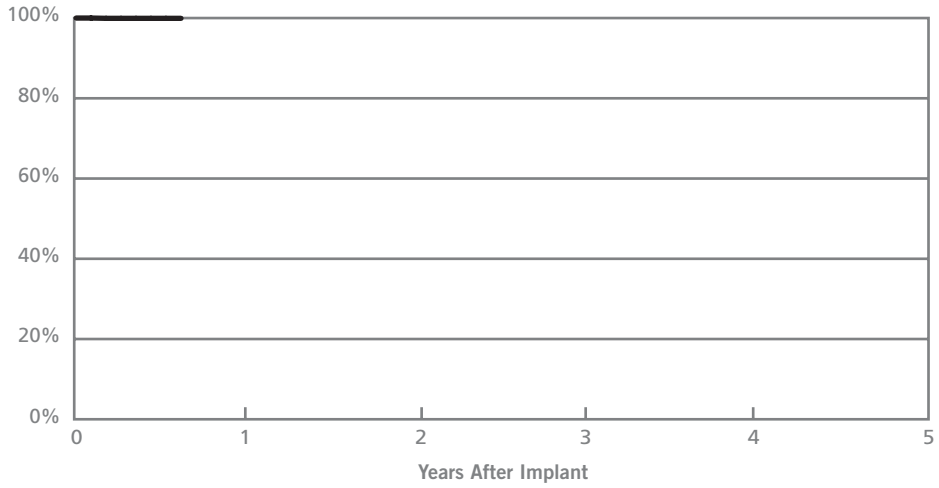


Year	1	at 15 months			
Survival Probability	99.98%	99.98%			
± 1 standard error	0.02%	0.02%			

Atlas® II + HF (Model V-366)

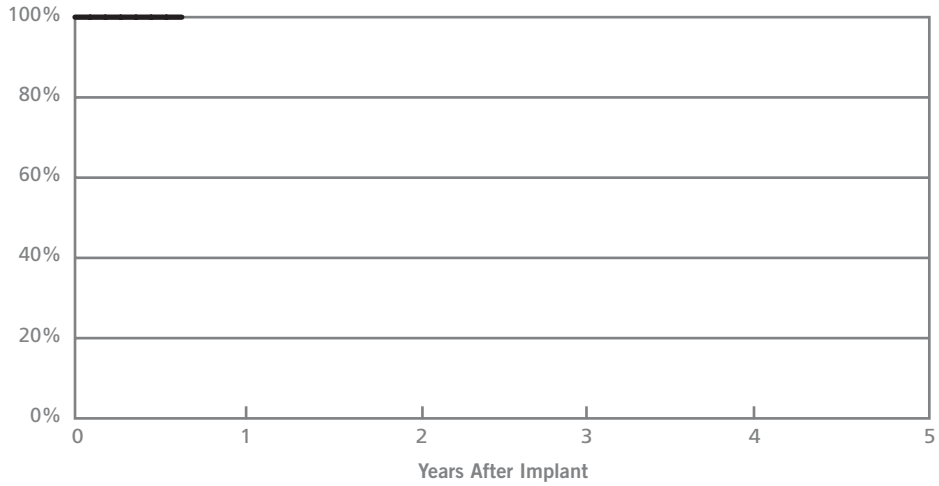
US Market Release	August 2006	Normal Battery Depletion	1
Registered US Implants	2,129	Malfunctions	0
Estimated Active US Implants	2,007	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 8 months				
Survival Probability	99.93%				
± 1 standard error	0.07%				
Sample Size	1200				

Excluding Normal Battery Depletion

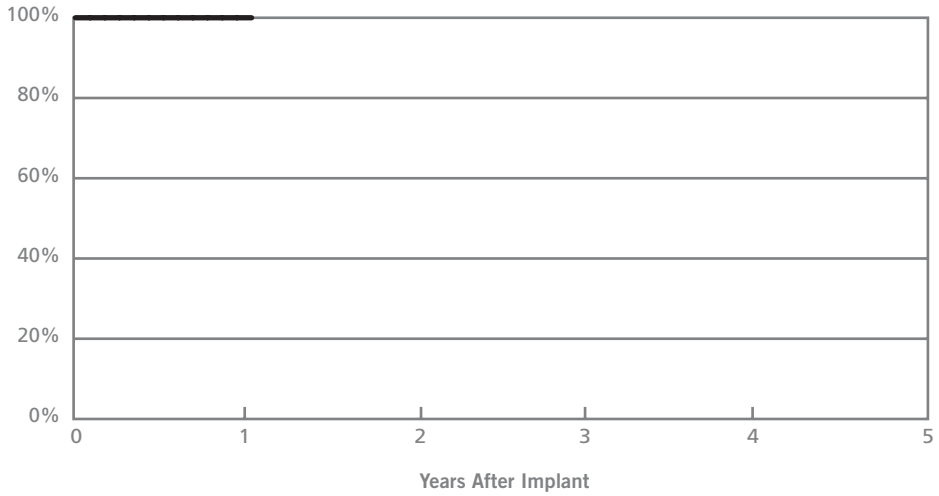


Year	at 8 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Epic® II HF (Model V-355)

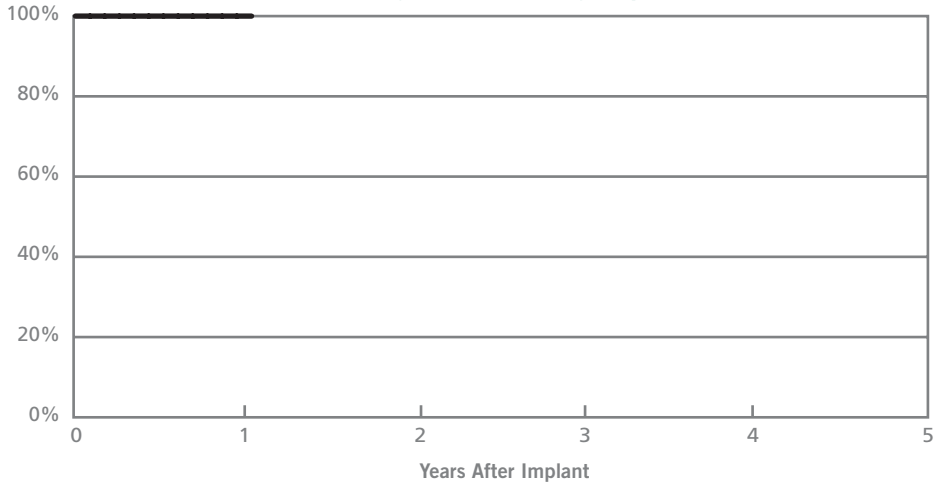
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	1,288	Malfunctions	0
Estimated Active US Implants	1,168	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	800	200			

Excluding Normal Battery Depletion

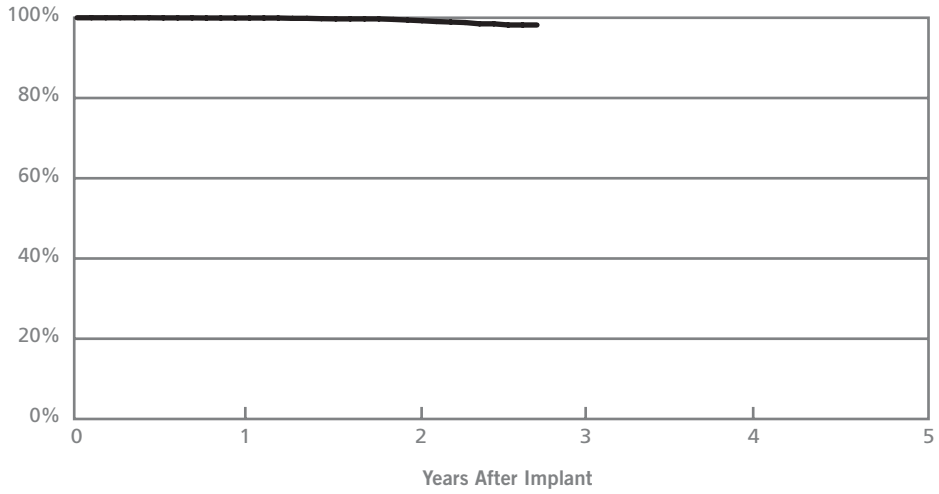


Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Epic® HF (Model V-337)

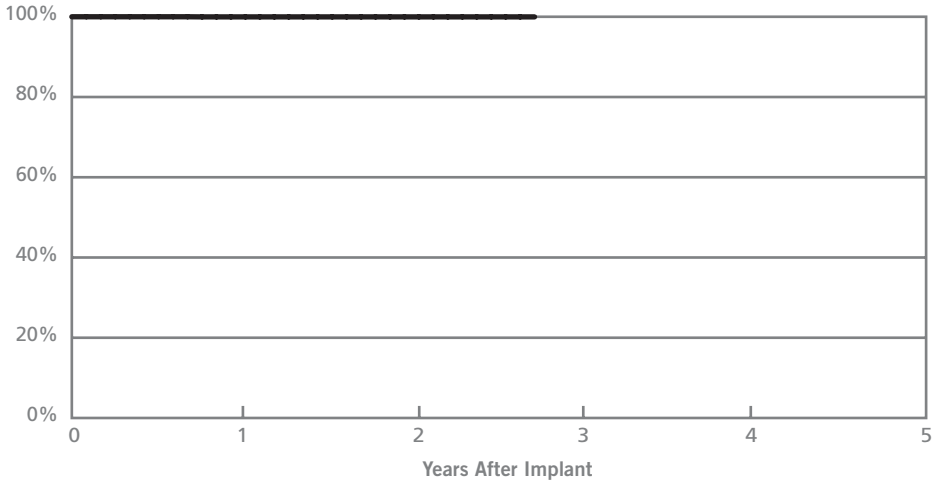
US Market Release	November 2004	Normal Battery Depletion	19
Registered US Implants	3,919	Malfunctions	1
Estimated Active US Implants	2,962	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	at 33 months		
Survival Probability	99.94%	99.43%	98.20%		
± 1 standard error	0.04%	0.14%	0.48%		
Sample Size	3700	2300	800		

Excluding Normal Battery Depletion

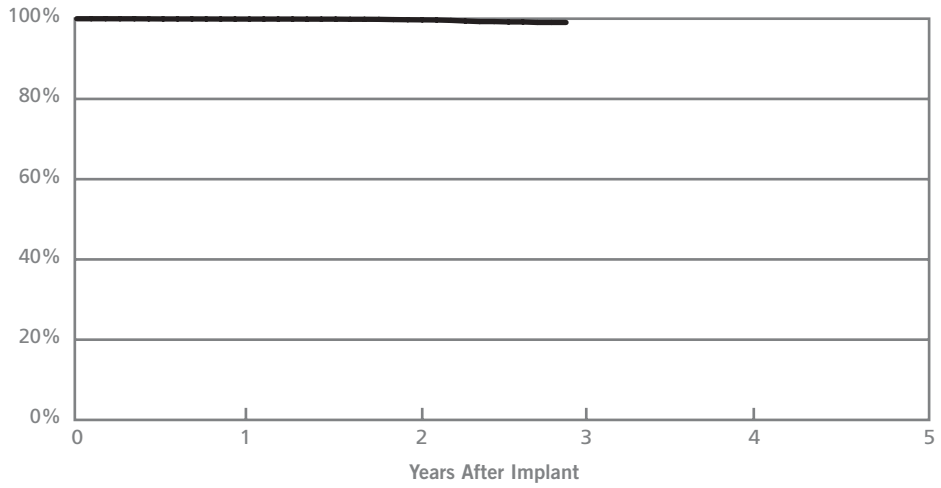


Year	1	2	at 33 months		
Survival Probability	99.97%	99.97%	99.97%		
± 1 standard error	0.03%	0.03%	0.03%		

Atlas® + HF (Model V-343)

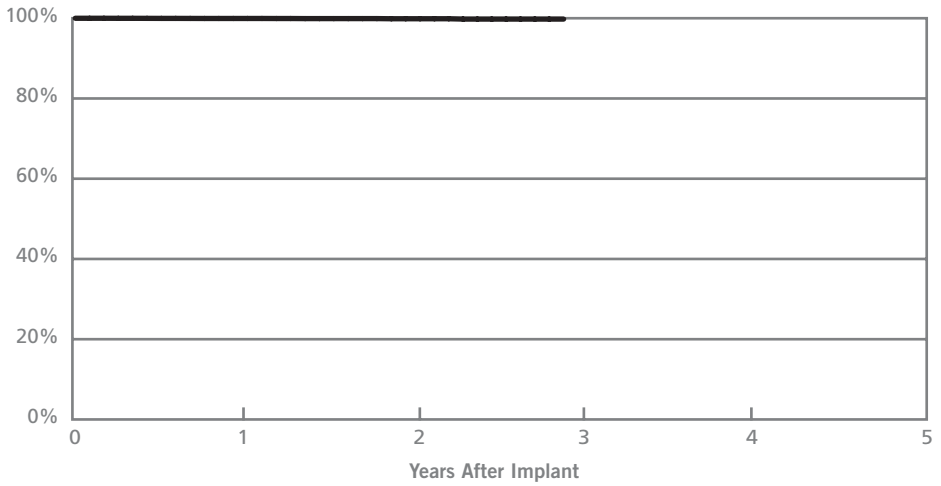
US Market Release	November 2004	Normal Battery Depletion	21
Registered US Implants	17,963	Malfunctions	17
Estimated Active US Implants	14,005	Malfunctions w/ Compromised Therapy (0 related to Advisory)	11
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	6
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	at 35 months		
Survival Probability	99.91%	99.74%	99.06%		
± 1 standard error	0.02%	0.05%	0.22%		
Sample Size	16500	9000	2300		

Excluding Normal Battery Depletion

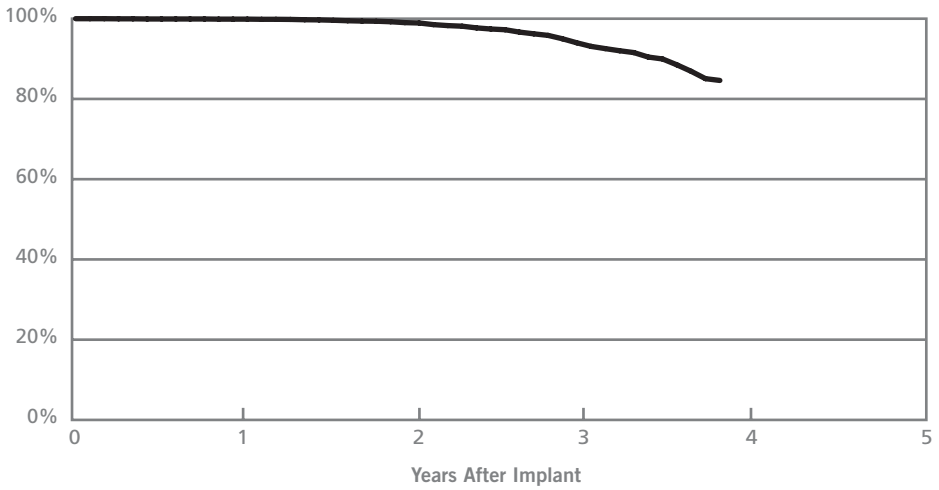


Year	1	2	at 35 months		
Survival Probability	99.94%	99.87%	99.79%		
± 1 standard error	0.02%	0.04%	0.07%		

Epic® HF (Model V-338)

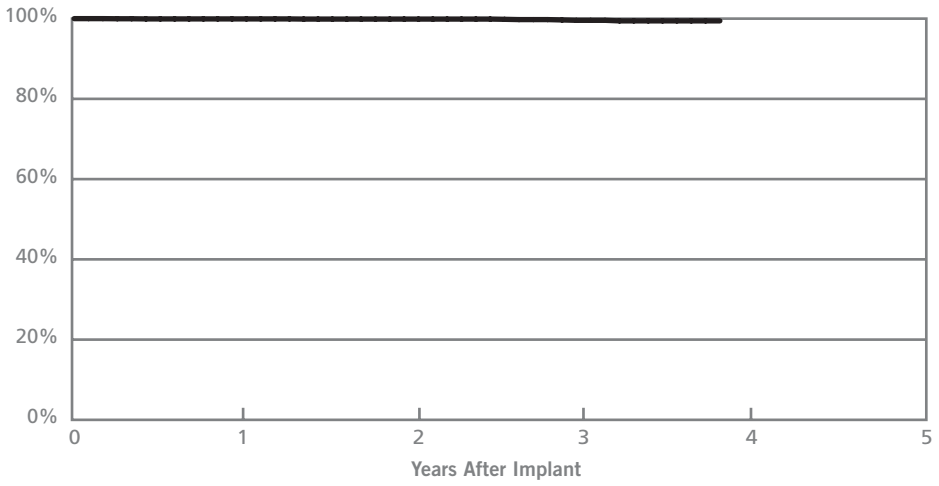
US Market Release	June 2004	Normal Battery Depletion	156
Registered US Implants	3.091	Malfunctions	9
Estimated Active US Implants	1,474	Malfunctions w/ Compromised Therapy (0 related to Advisory)	2
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	7
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	at 46 months	
Survival Probability	99.89%	99.02%	94.00%	84.61%	
± 1 standard error	0.06%	0.18%	0.54%	1.54%	
Sample Size	3100	2600	1900	700	

Excluding Normal Battery Depletion

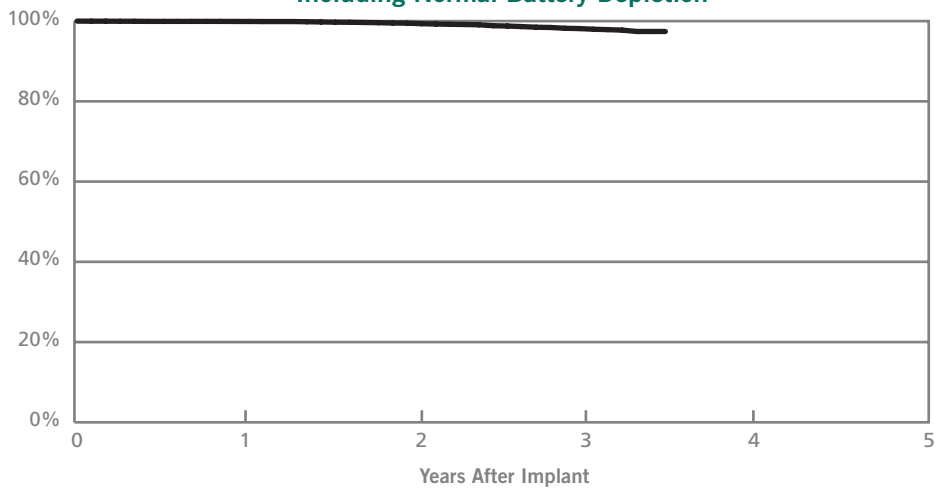


Year	1	2	3	at 46 months	
Survival Probability	99.93%	99.89%	99.58%	99.44%	
± 1 standard error	0.05%	0.06%	0.14%	0.22%	

Atlas® + HF (Model V-340)

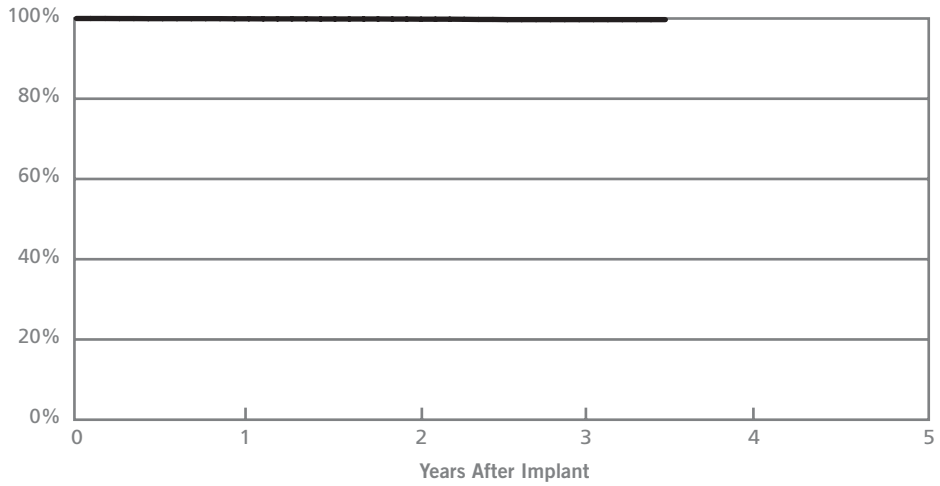
US Market Release	June 2004	Normal Battery Depletion	50
Registered US Implants	4,909	Malfunctions	10
Estimated Active US Implants	2,969	Malfunctions w/ Compromised Therapy (0 related to Advisory)	7
Estimated Longevity	(see table on page 25)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	3
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	at 42 months	
Survival Probability	99.91%	99.49%	98.14%	97.41%	
± 1 standard error	0.04%	0.11%	0.26%	0.41%	
Sample Size	4900	4100	2700	700	

Excluding Normal Battery Depletion



Year	1	2	3	at 42 months	
Survival Probability	99.93%	99.86%	99.72%	99.72%	
± 1 standard error	0.03%	0.06%	0.09%	0.09%	

SUMMARY & LONGEVITY INFORMATION

Cardiac Resynchronization Therapy
CRT ICDs

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Cardiac Resynchronization Therapy

Including 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
3107-36	Promote HE	May-07	572	542	0	0	0	0	0	0	0
3207-36	Promote RF HE	May-07	847	829	0	0	0	0	0	0	0
V-365	Atlas II HF	Aug-06	7009	6348	1	0	0	0	0	1	0
V-366	Atlas II + HF	Aug-06	2129	2007	0	0	0	0	0	0	1
V-355	Epic II HF	May-06	1288	1168	0	0	0	0	0	0	0
V-337	Epic HF	Nov-04	3919	2962	0	0	0	1	0	1	19
V-343	Atlas + HF	Nov-04	17963	14005	2	0	9	5	1	17	21
V-338	Epic HF	Jun-04	3091	1474	2	0	0	1	6	9	156
V-340	Atlas + HF	Jun-04	4909	2969	3	0	4	0	3	10	50

Excluding 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
3107-36	Promote HE	May-07	572	542	0	0	0	0	0	0
3207-36	Promote RF HE	May-07	847	829	0	0	0	0	0	0
V-365	Atlas II HF	Aug-06	7009	6348	1	0	0	0	0	1
V-366	Atlas II + HF	Aug-06	2129	2007	0	0	0	0	0	0
V-355	Epic II HF	May-06	1288	1168	0	0	0	0	0	0
V-337	Epic HF	Nov-04	3919	2962	0	0	0	1	0	1
V-343	Atlas + HF	Nov-04	17963	14005	2	0	9	5	1	17
V-338	Epic HF	Jun-04	3091	1474	2	0	0	1	6	9
V-340	Atlas + HF	Jun-04	4909	2969	3	0	4	0	3	10

**Based on returned product analysis as of December 31, 2007.*

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
3107-36	Promote HE**										
3207-36	Promote RF HE**										
V-365	Atlas II HF	99.98%									
V-366	Atlas II + HF**										
V-355	Epic II HF	100.00%									
V-337	Epic HF	99.94%	99.43%								
V-343	Atlas + HF	99.91%	99.74%								
V-338	Epic HF	99.89%	99.02%	94.00%							
V-340	Atlas + HF	99.91%	99.49%	98.14%							

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
3107-36	Promote HE**										
3207-36	Promote RF HE**										
V-365	Atlas II HF	99.98%									
V-366	Atlas II + HF**										
V-355	Epic II HF	100.00%									
V-337	Epic HF	99.97%	99.97%								
V-343	Atlas + HF	99.94%	99.87%								
V-338	Epic HF	99.93%	99.89%	99.58%							
V-340	Atlas + HF	99.93%	99.86%	99.72%							

Battery Longevity

Models	Family	Approximate Duration (years)†			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
3107-36	Promote HE	8.6	7.8	7.1	6.1
3207-36	Promote RF HE	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

**Based on returned product analysis as of December 31, 2007.*

***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.*

† 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.

CARDIAC RESYNCHRONIZATION THERAPY

CRT Pulse Generators

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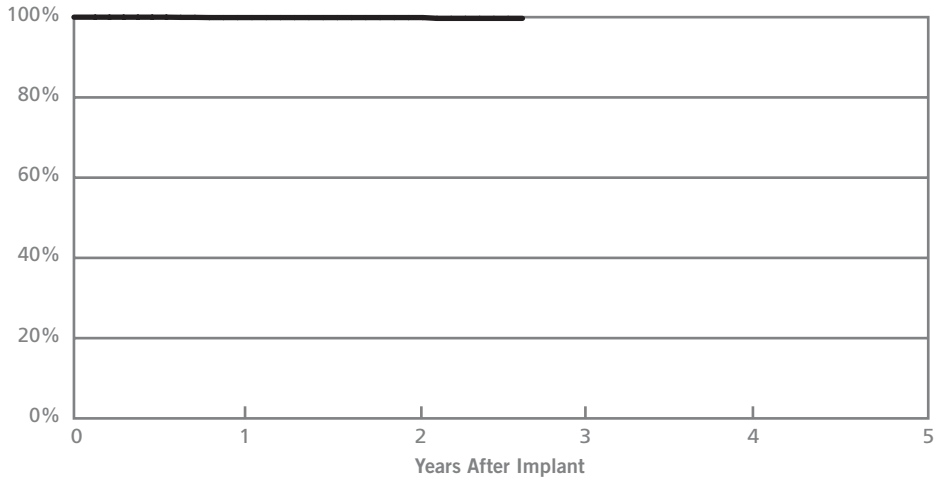
Cardiac Resynchronization Therapy

Frontier® II (Model 5586)

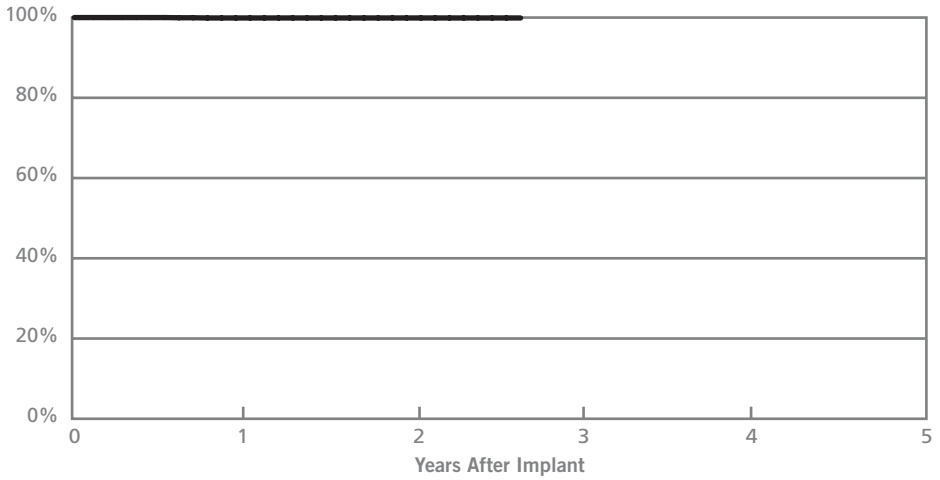
US Market Release	August 2004	Normal Battery Depletion	1
Registered US Implants	3,349	Malfunctions	2
Estimated Active US Implants	2,880	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	at 32 months		
Survival Probability	99.90%	99.90%	99.70%		
± 1 standard error	0.07%	0.07%	0.21%		
Sample Size	2600	1100	100		

Excluding Normal Battery Depletion

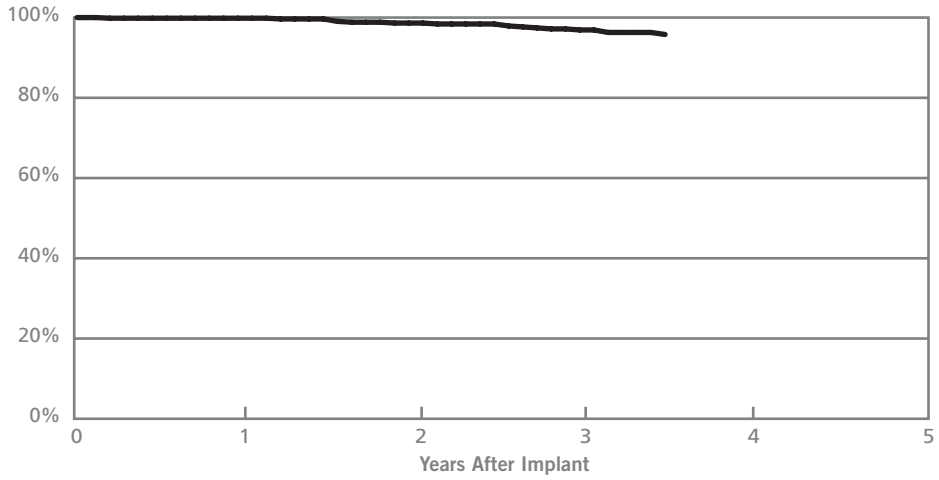


Year	1	2	at 32 months		
Survival Probability	99.90%	99.90%	99.90%		
± 1 standard error	0.07%	0.07%	0.07%		

Frontier® (Model 5508)

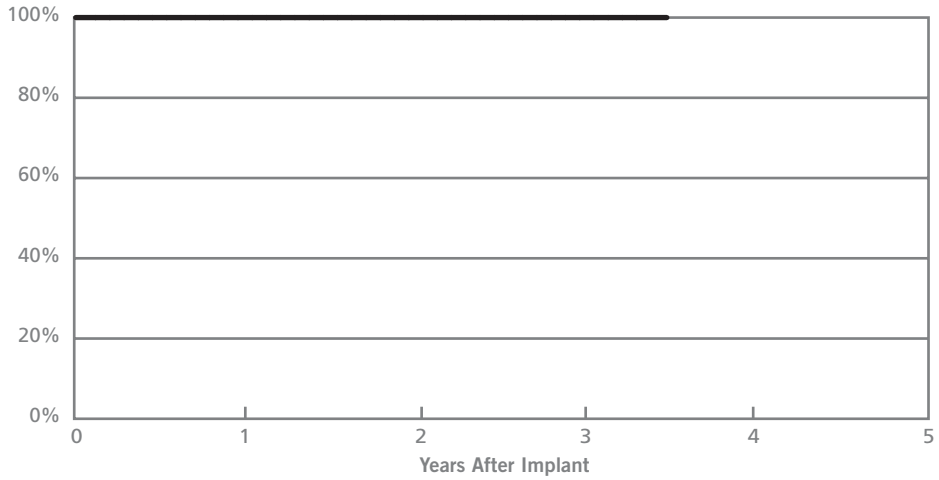
US Market Release	May 2004	Normal Battery Depletion	27
Registered US Implants	671	Malfunctions	1
Estimated Active US Implants	281	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.9 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 41 months	
Survival Probability	99.84%	98.63%	96.91%	95.78%	
± 1 standard error	0.16%	0.52%	0.78%	0.93%	
Sample Size	600	600	400	200	

Excluding Normal Battery Depletion



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

SUMMARY INFORMATION

Cardiac Resynchronization Therapy
CRT Pulse Generators

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Cardiac Resynchronization Therapy

Including 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	3349	2880	1	1	0	0	2	1
5508	Frontier	May-04	671	281	0	1	0	0	1	27

Excluding 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
5586	Frontier II	Aug-04	3349	2880	1	1	0	0	2
5508	Frontier	May-04	671	281	0	1	0	0	1

**Based on returned product analysis as of December 31, 2007.*

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	99.90%	99.90%						
5508	Frontier	99.84%	98.63%	96.91%					

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	99.90%	99.90%						
5508	Frontier	100.00%	100.00%	100.00%					

**Based on returned product analysis as of December 31, 2007.*

CARDIAC RESYNCHRONIZATION THERAPY

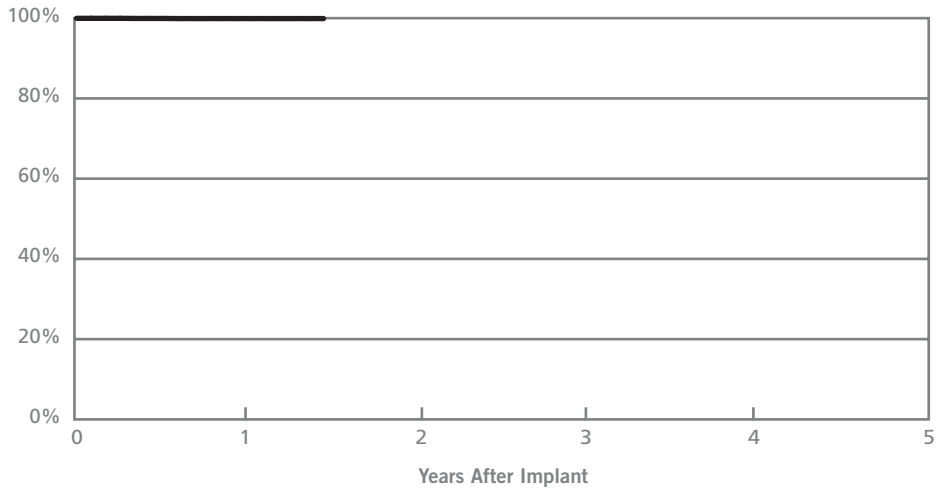
Left-Heart Leads

QuickSite® XL (Model 1058T)

US Market Release	February 2006	Type and/or Fixation	S-Curve
Registered US Implants	6,906	Polarity	Bipolar
Estimated Active US Implants	6,580	Steroid	Yes
Insulation	Polyurethane	Number of Advisories	None

Laboratory Analysis

Implant Damage	**22**	**Electrical Malfunction**	**0**	**Other**	**9**
		Insulation Disruption	0	Explant Damage	6
		Conductor Disruption	0	Non-Electrical Workmanship	3
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	0
				Partial Lead	0



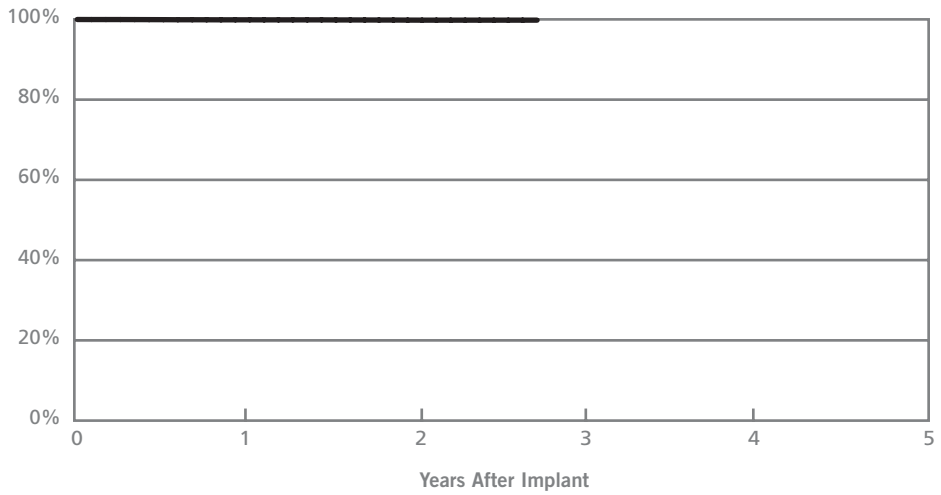
Year	1	at 18 months			
Survival Probability	99.90%	99.90%			
± 1 standard error	0.05%	0.05%			
Sample Size	4300	100			

QuickSite® (Model 1056T)

US Market Release	April 2005	Type and/or Fixation	S-Curve
Registered US Implants	26,396	Polarity	Bipolar
Estimated Active US Implants	23,307	Steroid	Yes
Insulation	Polyurethane	Number of Advisories	None

Laboratory Analysis

Implant Damage	**73**	**Electrical Malfunction**	**1**	**Other**	**139**
		Insulation Disruption	0	Explant Damage	132
		Conductor Disruption	0	Non-Electrical Workmanship	4
		Crimps, Welds, Bonds	1	Non-Electrical Anomaly	2
				Partial Lead	1



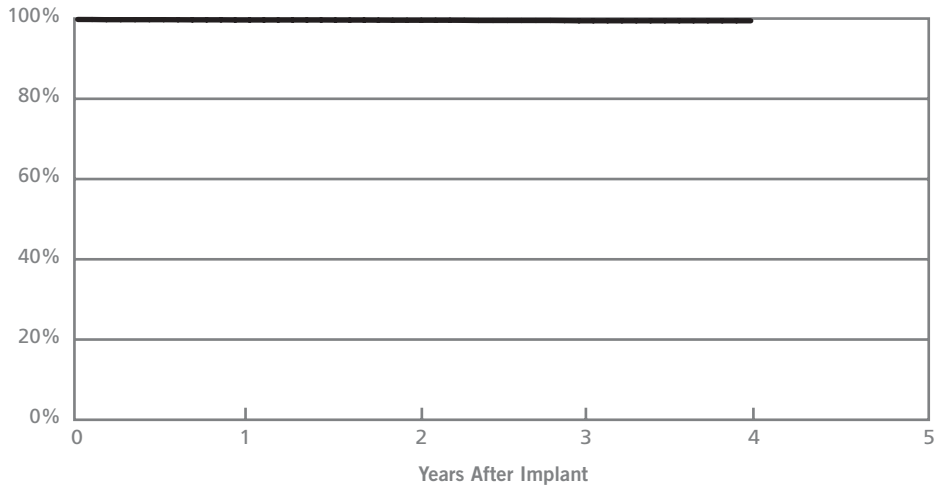
Year	1	2	at 33 months		
Survival Probability	99.89%	99.82%	99.81%		
± 1 standard error	0.02%	0.03%	0.04%		
Sample Size	22200	11100	200		

QuickSite® (Model 1056K)

US Market Release	June 2004	Type and/or Fixation	S-Curve
Registered US Implants	7,506	Polarity	Unipolar
Estimated Active US Implants	5,535	Steroid	Yes
Insulation	Polyurethane	Number of Advisories	None

Laboratory Analysis

Implant Damage	**88**	**Electrical Malfunction**	**3**	**Other**	**68**
		Insulation Disruption	0	Explant Damage	53
		Conductor Disruption	1	Non-Electrical Workmanship	14
		Crimps, Welds, Bonds	2	Non-Electrical Anomaly	1
				Partial Lead	0



Year	1	2	3	4	
Survival Probability	99.81%	99.75%	99.62%	99.62%	
± 1 standard error	0.05%	0.06%	0.08%	0.09%	
Sample Size	7200	5800	4000	1400	

LABORATORY ANALYSIS

Cardiac Resynchronization Therapy
Left-Heart Leads

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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
1058T	Feb-06	6906	6580	22	0	0	0	0	6	3	0	0	9
1056T	Apr-05	26396	23307	73	0	0	1	1	132	4	2	1	139
1056K	Jun-04	7506	5535	88	0	1	2	3	53	14	1	0	68

**Based on returned product analysis as of December 31, 2007.*

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

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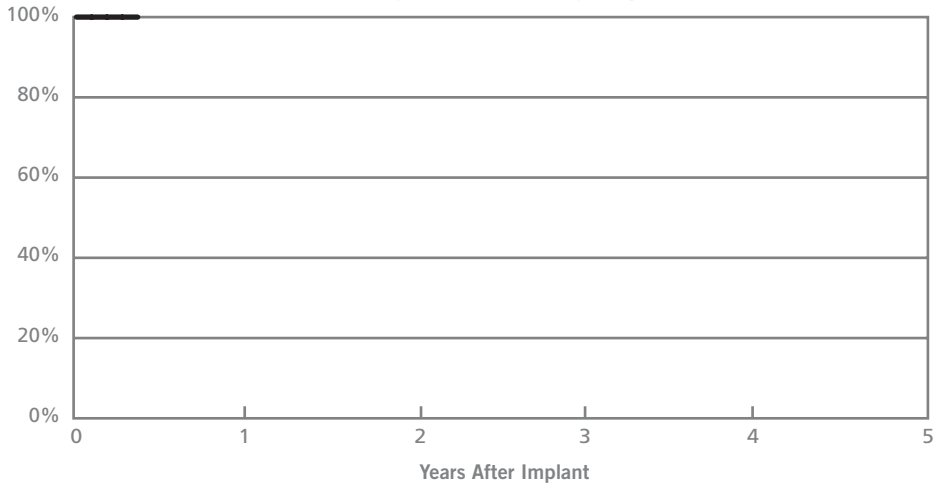
Current® DR HE (Model 2107-36)

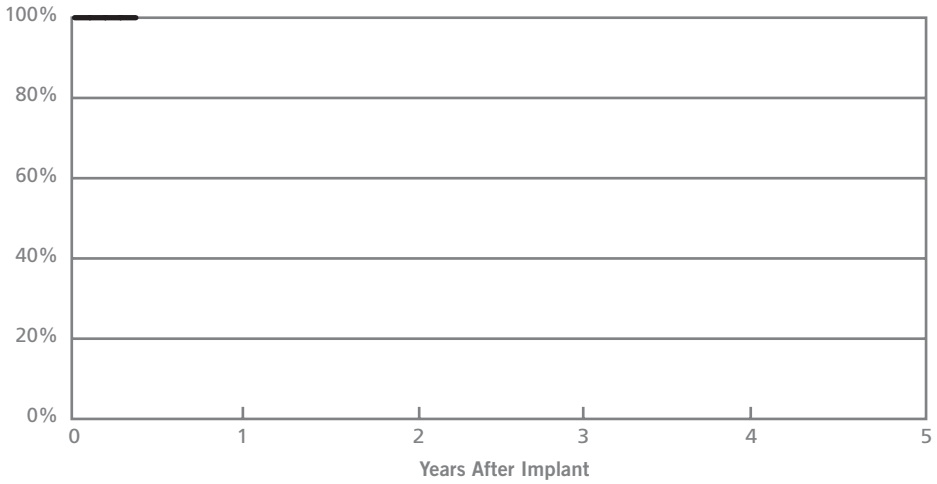
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	472	Malfunctions	0
Estimated Active US Implants	447	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

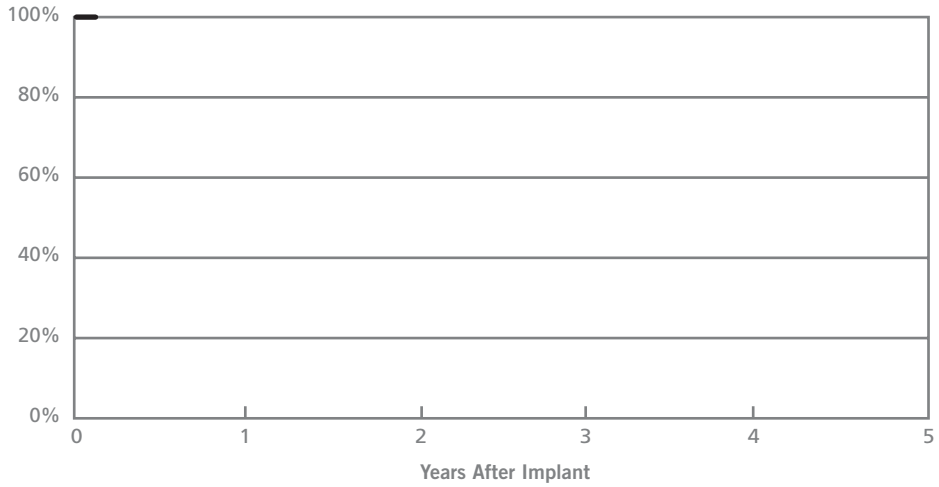


Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Current® RF DR HE (Model 2207-36)

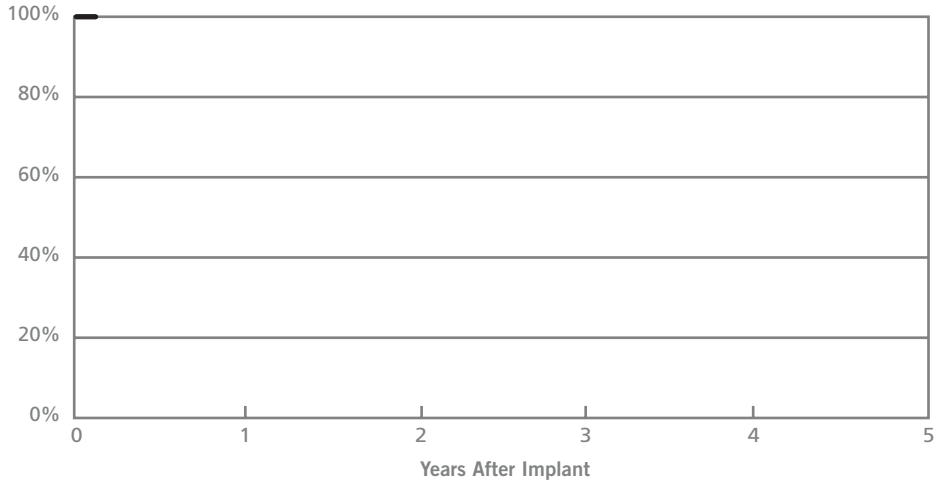
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	693	Malfunctions	0
Estimated Active US Implants	680	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

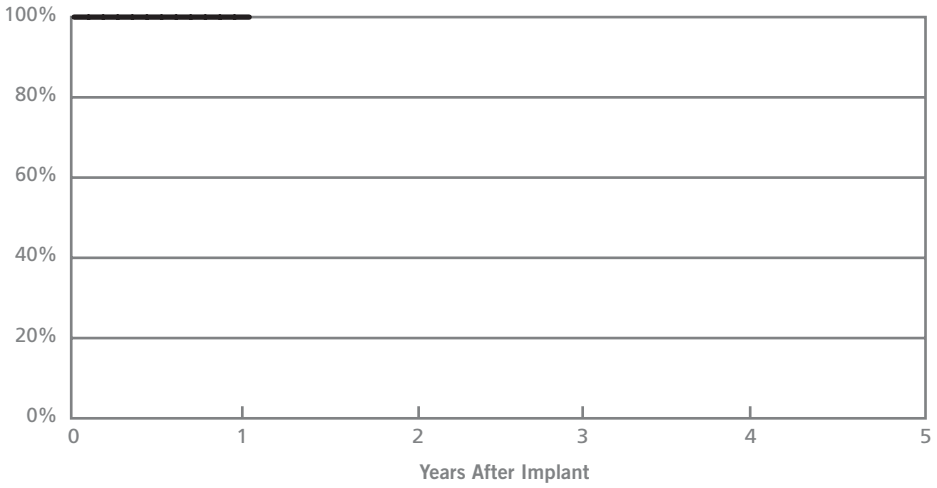


Year	at 2 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® II DR (Model V-265)

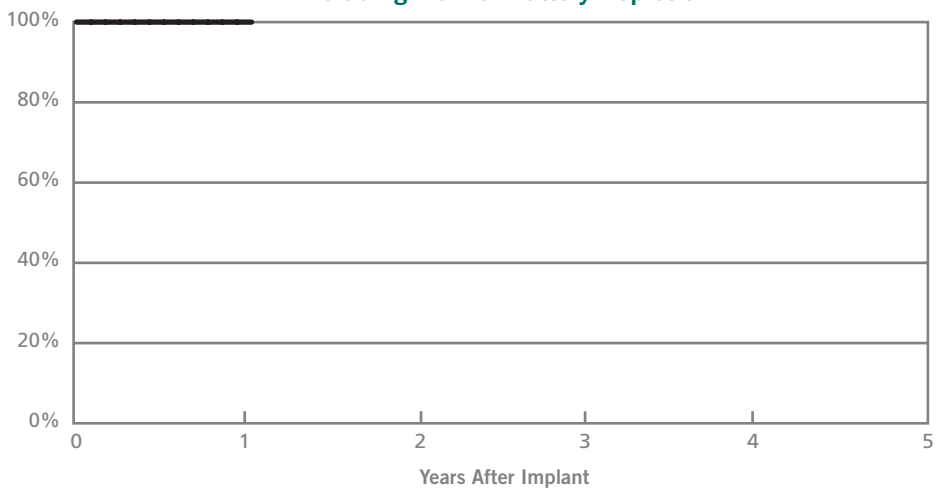
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	1,480	Malfunctions	0
Estimated Active US Implants	1,358	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	900	200			

Excluding Normal Battery Depletion

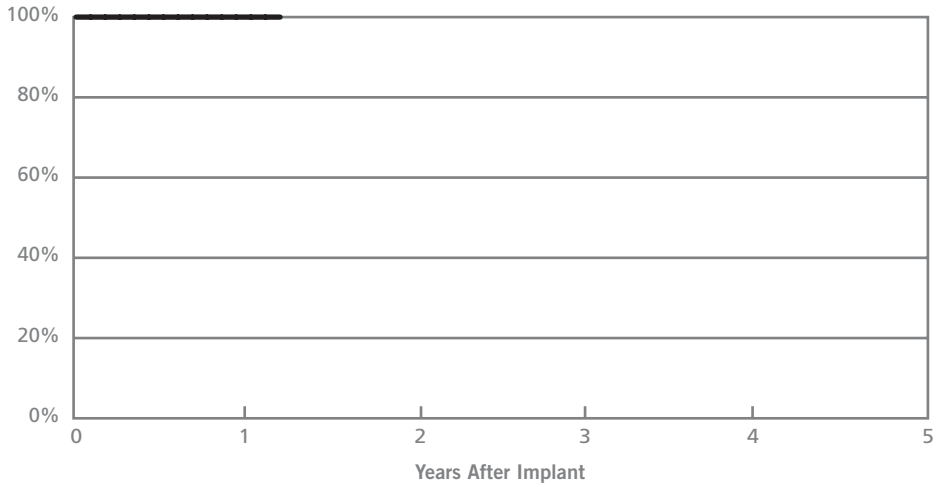


Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Atlas® II + DR (Model V-268)

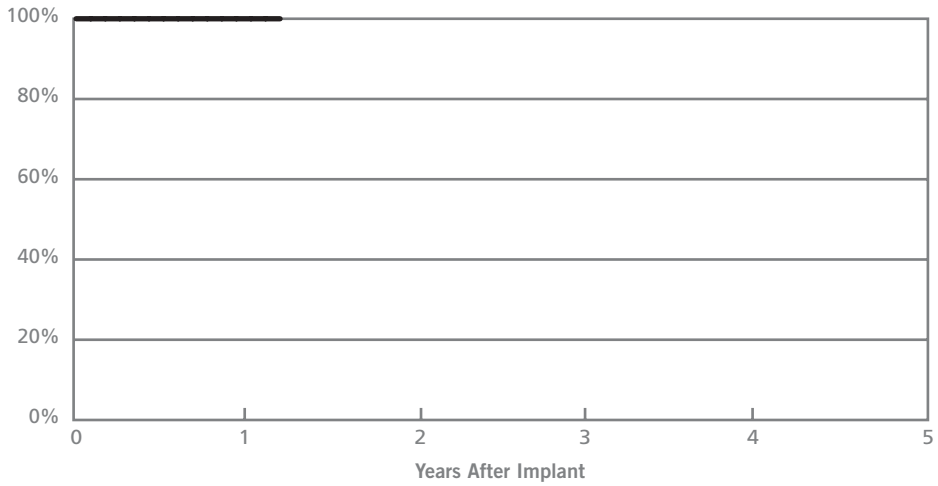
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	8,800	Malfunctions	0
Estimated Active US Implants	8,087	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 15 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	5300	600			

Excluding Normal Battery Depletion

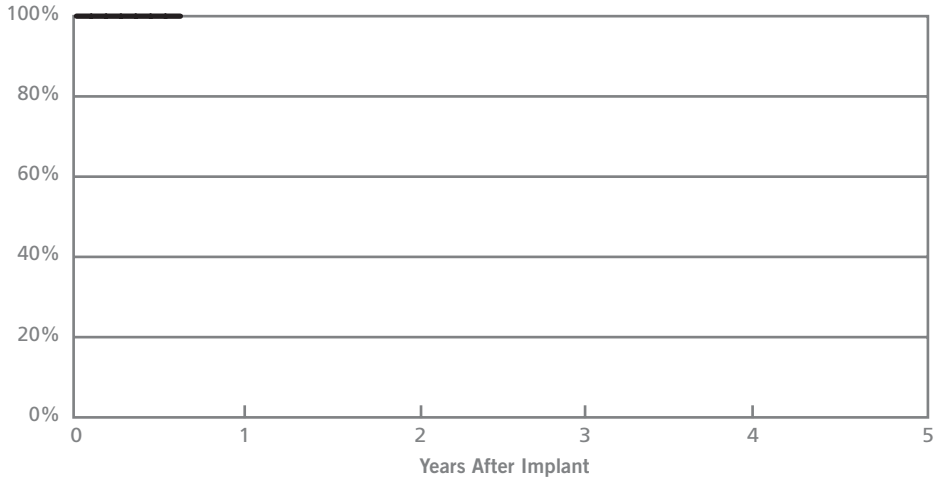


Year	1	at 15 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Epic® II DR (Model V-255)

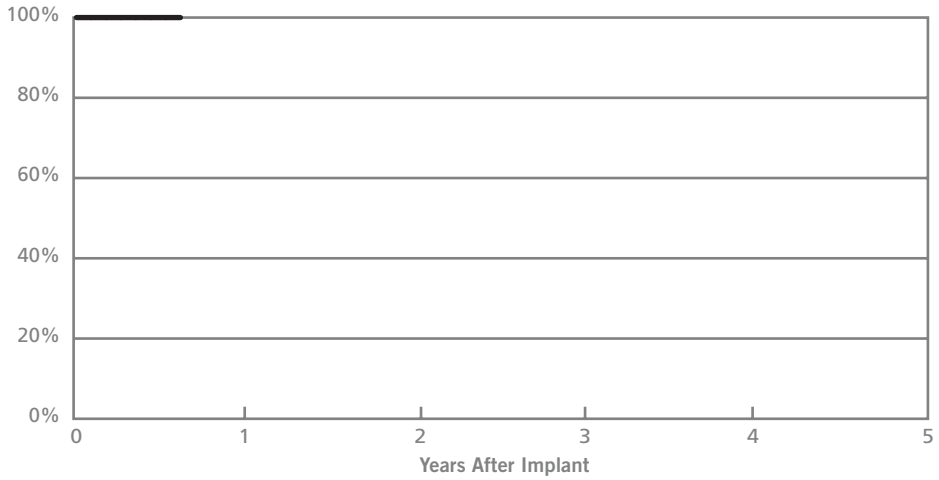
US Market Release	May 2006	Normal Battery Depletion	1
Registered US Implants	413	Malfunctions	0
Estimated Active US Implants	368	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 8 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	300				

Excluding Normal Battery Depletion

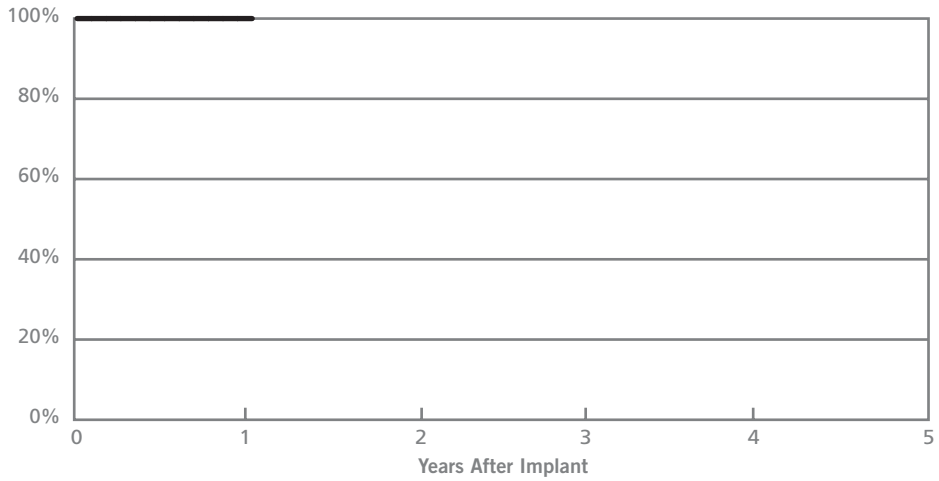


Year	at 8 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Epic® II + DR (Model V-258)

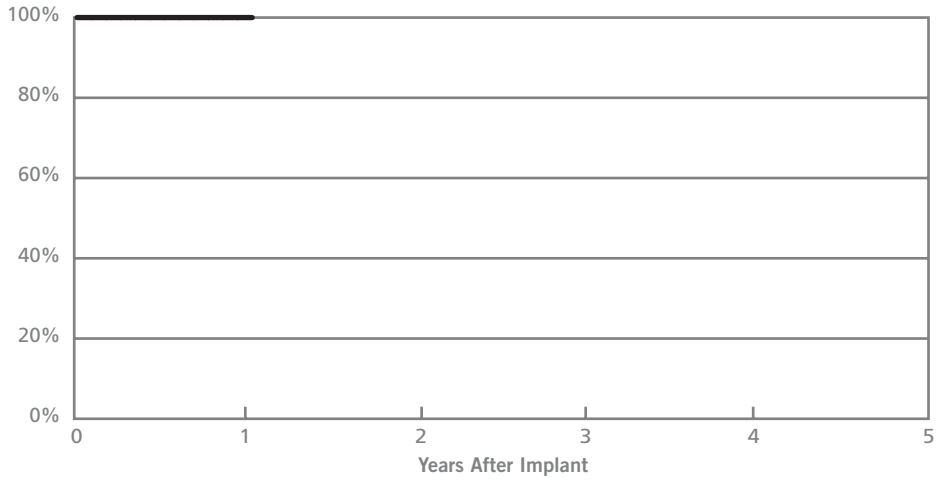
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	1,435	Malfunctions	0
Estimated Active US Implants	1,293	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	900	200			

Excluding Normal Battery Depletion

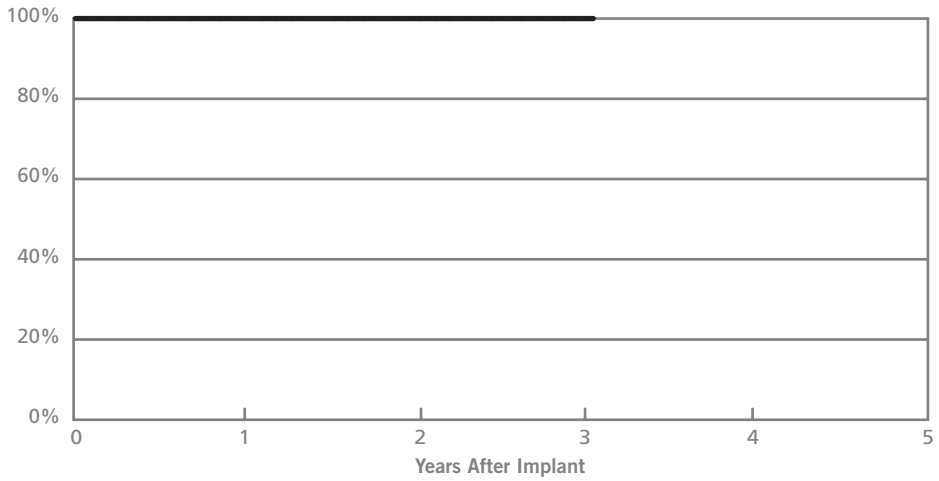


Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Epic® DR (Model V-233)

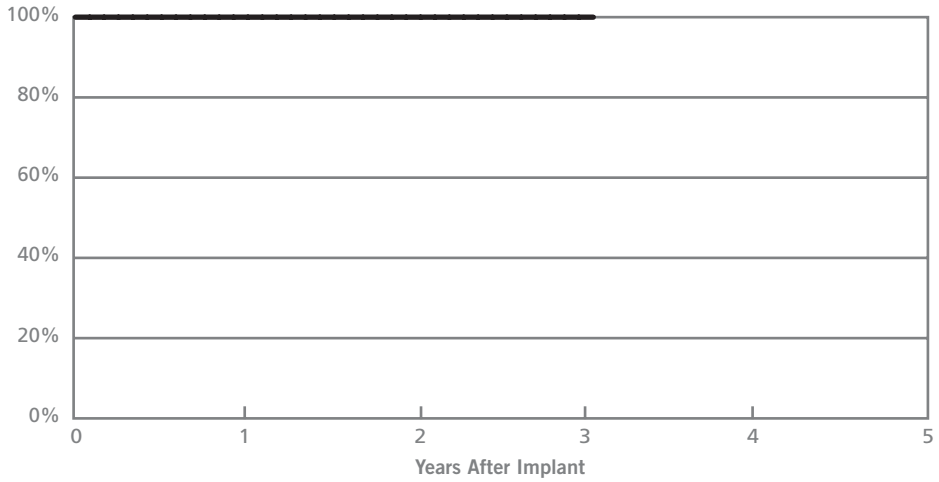
US Market Release	October 2003	Normal Battery Depletion	0
Registered US Implants	1,818	Malfunctions	0
Estimated Active US Implants	1,304	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	at 37 months	
Survival Probability	100.00%	100.00%	100.00%	100.00%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	
Sample Size	1800	1400	700	200	

Excluding Normal Battery Depletion

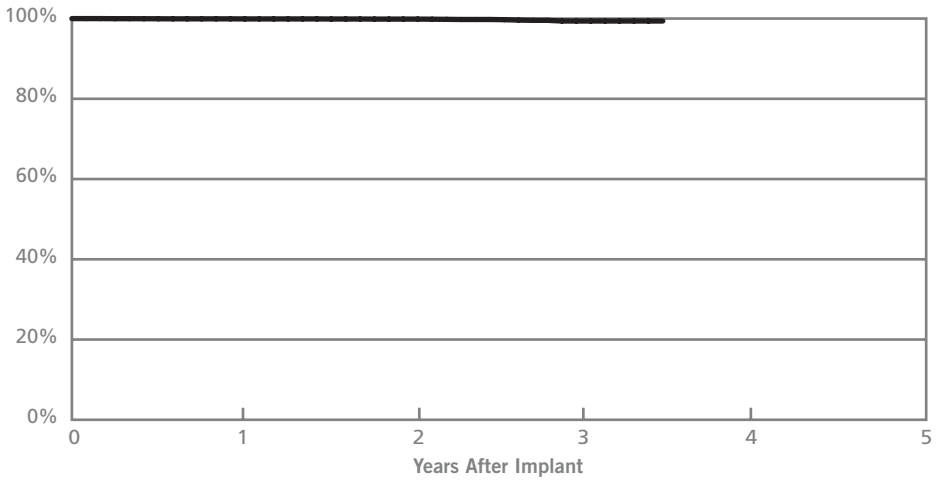


Year	1	2	3	at 37 months	
Survival Probability	100.00%	100.00%	100.00%	100.00%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	

Epic® + DR (Model V-239)

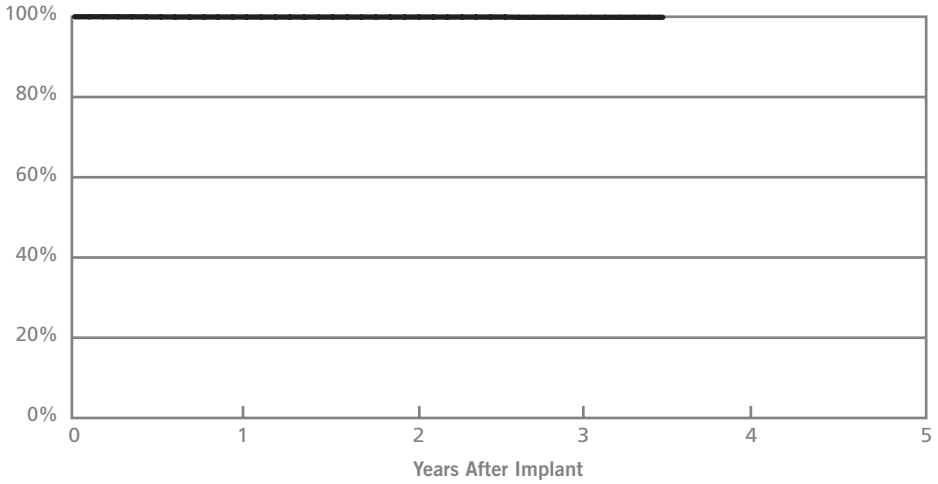
US Market Release	October 2003	Normal Battery Depletion	11
Registered US Implants	7,786	Malfunctions	6
Estimated Active US Implants	5,580	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	2
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	at 42 months	
Survival Probability	99.93%	99.87%	99.39%	99.39%	
± 1 standard error	0.03%	0.05%	0.17%	0.17%	
Sample Size	7500	5300	2500	600	

Excluding Normal Battery Depletion

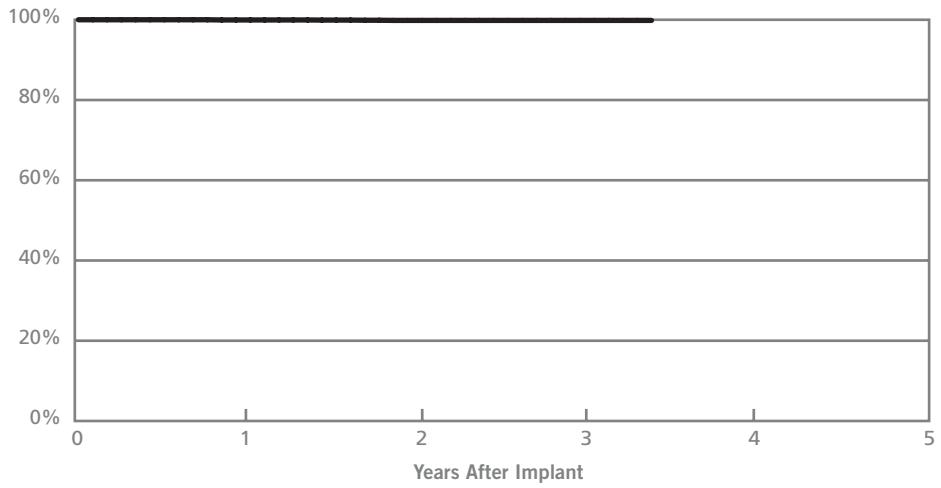


Year	1	2	3	at 42 months	
Survival Probability	99.94%	99.93%	99.87%	99.87%	
± 1 standard error	0.03%	0.03%	0.06%	0.06%	

Atlas® DR (Model V-242)

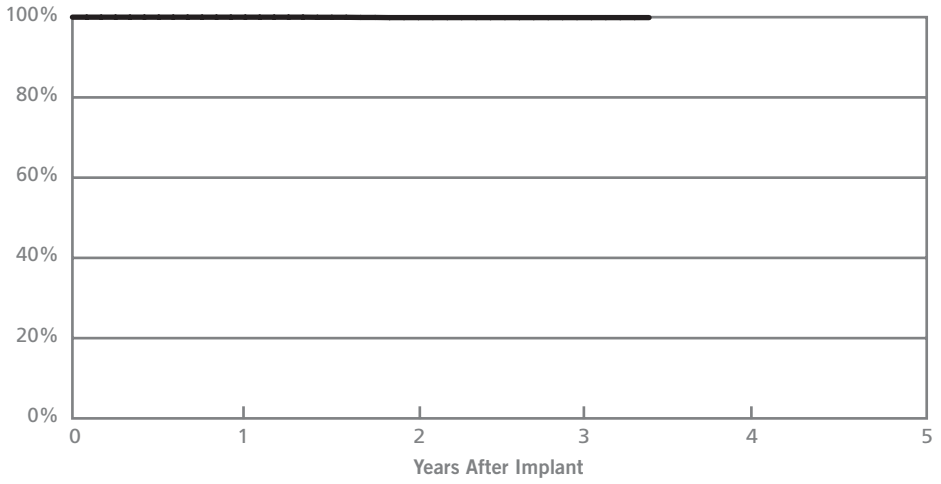
US Market Release	October 2003	Normal Battery Depletion	2
Registered US Implants	4,629	Malfunctions	3
Estimated Active US Implants	3,309	Malfunctions w/ Compromised Therapy (0 related to Advisory)	2
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	at 41 months	
Survival Probability	99.95%	99.84%	99.84%	99.84%	
± 1 standard error	0.04%	0.07%	0.07%	0.07%	
Sample Size	4500	3200	1500	400	

Excluding Normal Battery Depletion

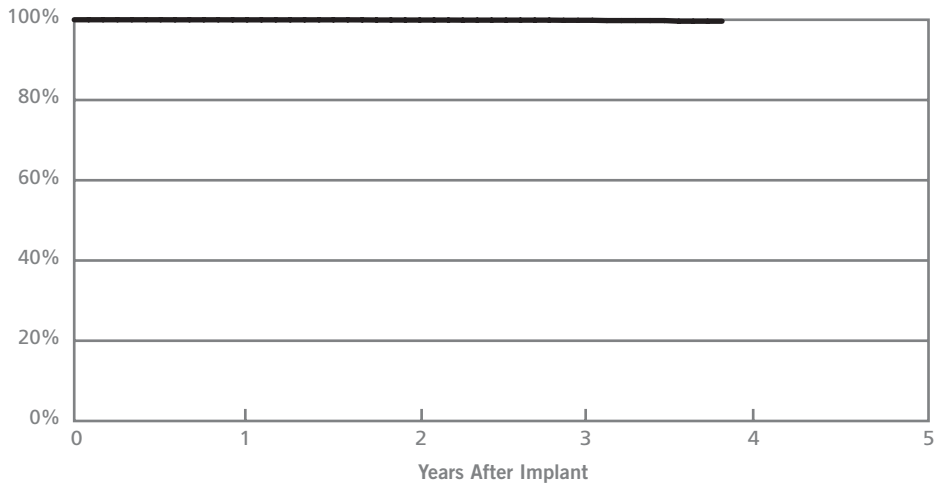


Year	1	2	3	at 41 months	
Survival Probability	100.00%	99.89%	99.89%	99.89%	
± 1 standard error	0.00%	0.06%	0.06%	0.06%	

Atlas® + DR (Model V-243)

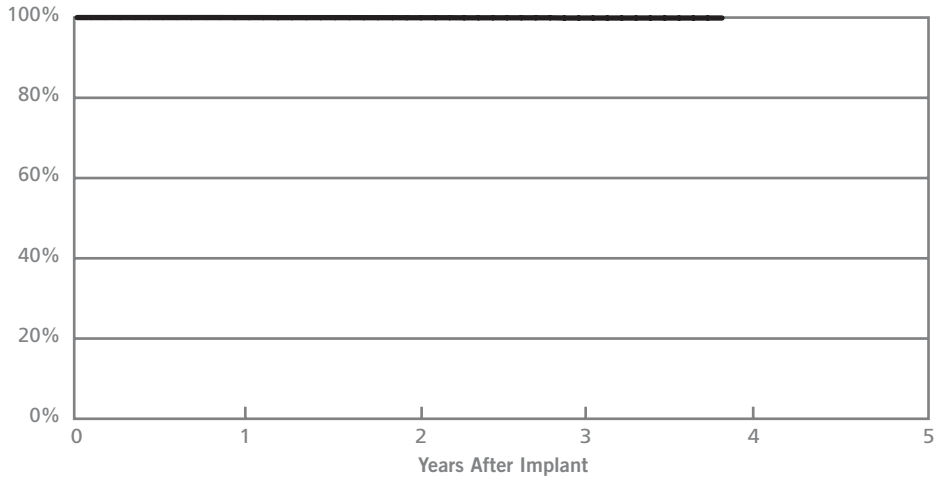
US Market Release	October 2003	Normal Battery Depletion	5
Registered US Implants	20,207	Malfunctions	7
Estimated Active US Implants	14,916	Malfunctions w/ Compromised Therapy (0 related to Advisory)	6
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	at 46 months	
Survival Probability	99.98%	99.93%	99.87%	99.64%	
± 1 standard error	0.01%	0.02%	0.06%	0.18%	
Sample Size	19100	12100	4800	1100	

Excluding Normal Battery Depletion

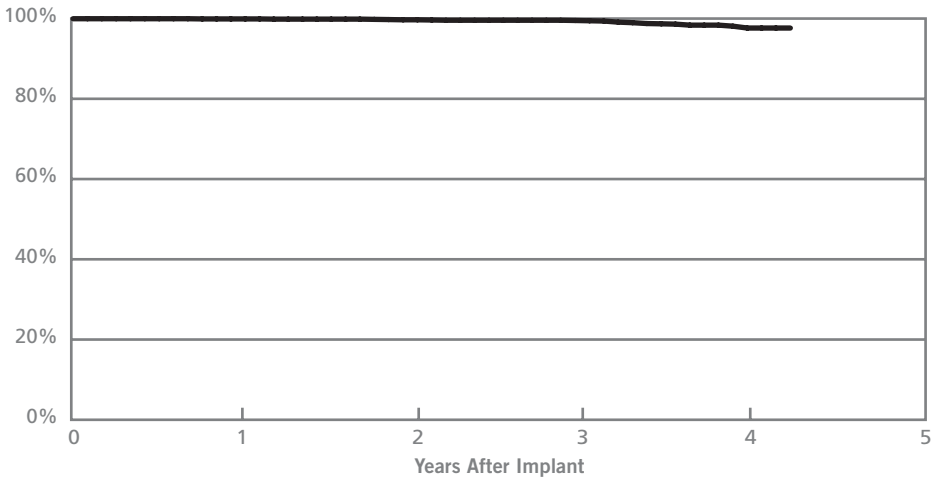


Year	1	2	3	at 46 months	
Survival Probability	99.99%	99.96%	99.89%	99.89%	
± 1 standard error	0.01%	0.02%	0.05%	0.05%	

Epic® + DR (Model V-236)

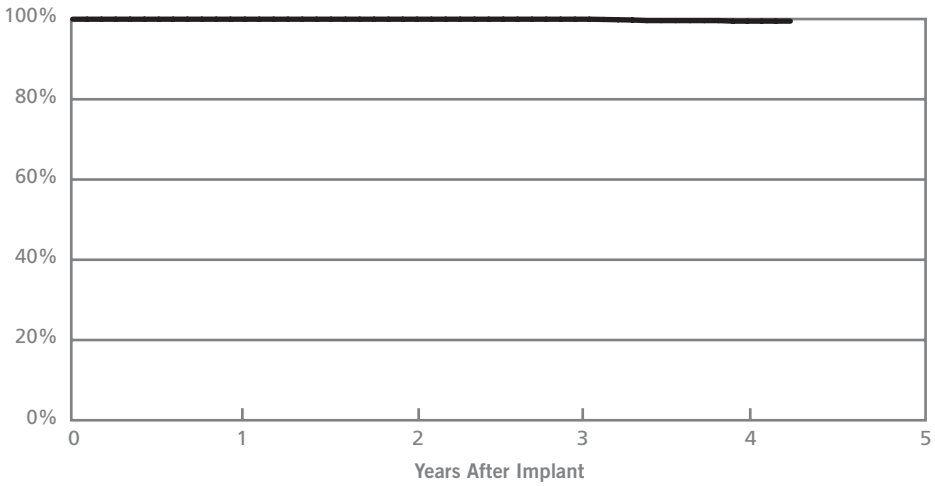
US Market Release	April 2003	Normal Battery Depletion	22
Registered US Implants	2,343	Malfunctions	7
Estimated Active US Implants	1,059	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	7
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	4	at 51 months
Survival Probability	99.91%	99.69%	99.52%	97.64%	97.64%
± 1 standard error	0.07%	0.11%	0.15%	0.38%	0.46%
Sample Size	2300	2000	1800	1200	400

Excluding Normal Battery Depletion

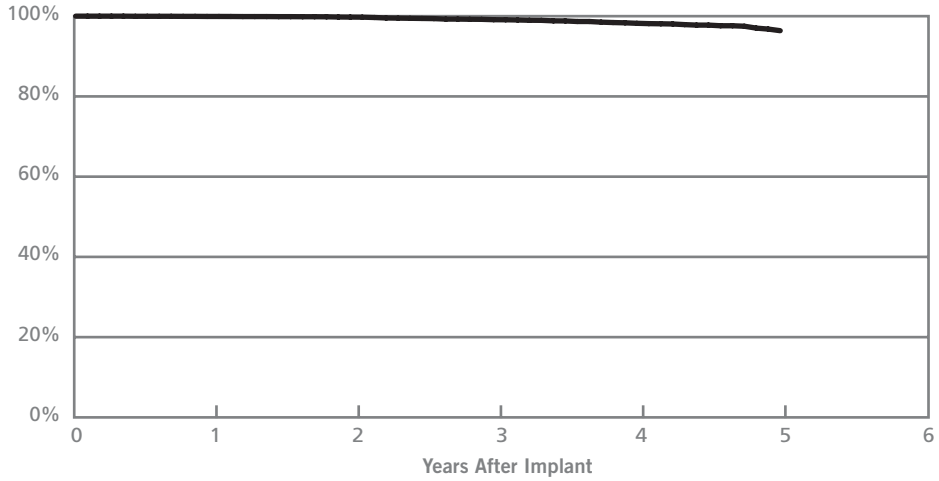


Year	1	2	3	4	at 51 months
Survival Probability	99.96%	99.96%	99.96%	99.48%	99.48%
± 1 standard error	0.04%	0.04%	0.04%	0.21%	0.21%

Epic® DR (Model V-235)

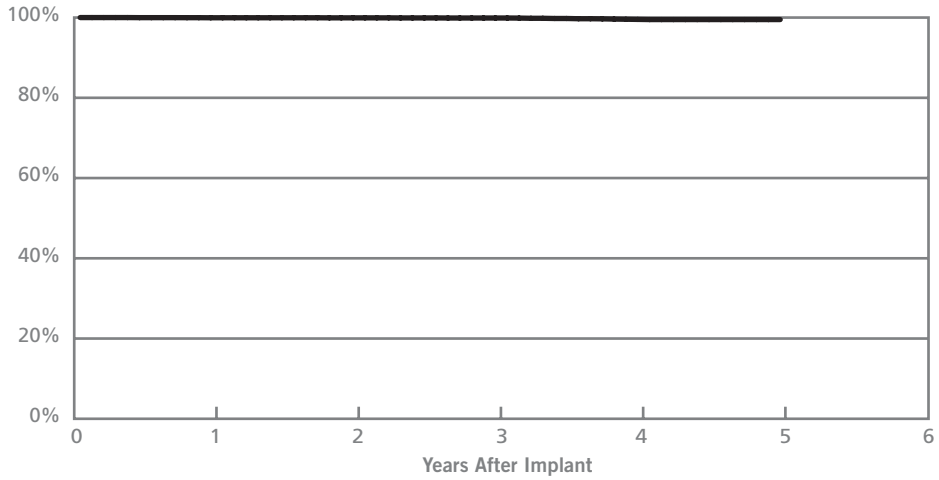
US Market Release	July 2002	Normal Battery Depletion	74
Registered US Implants	6,582	Malfunctions	19
Estimated Active US Implants	2,883	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	15
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	
Survival Probability	99.93%	99.77%	99.12%	98.22%	96.38%	
± 1 standard error	0.03%	0.06%	0.12%	0.20%	0.47%	
Sample Size	6600	5800	5200	3900	1500	

Excluding Normal Battery Depletion

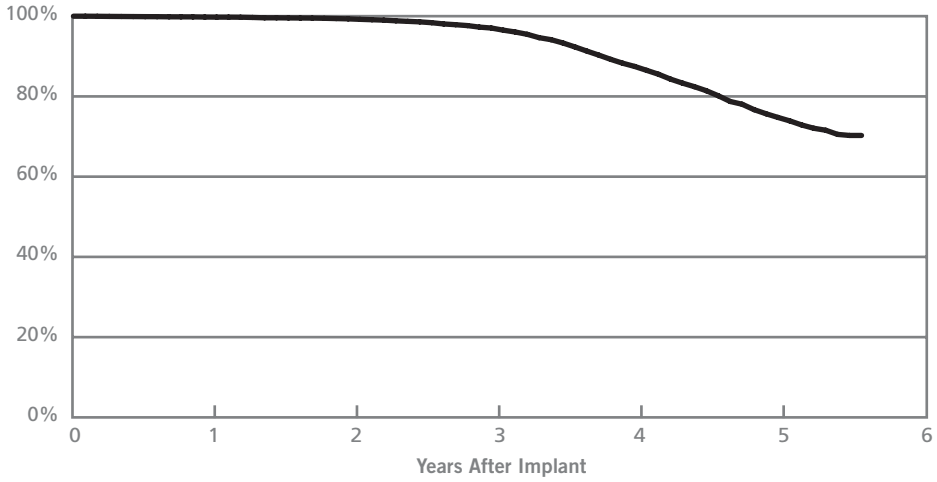


Year	1	2	3	4	5	
Survival Probability	99.95%	99.93%	99.89%	99.54%	99.50%	
± 1 standard error	0.02%	0.03%	0.04%	0.11%	0.12%	

Atlas® DR (Model V-240)

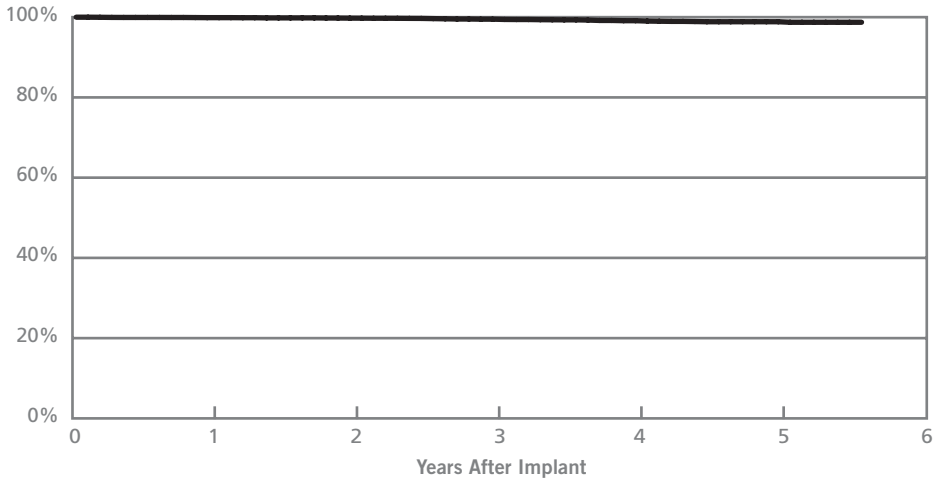
US Market Release	December 2001	Normal Battery Depletion	902
Registered US Implants	8,838	Malfunctions	59
Estimated Active US Implants	1,440	Malfunctions w/ Compromised Therapy (21 related to Advisory)	31
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	28
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 67 months
Survival Probability	99.78%	99.33%	97.04%	87.47%	74.76%	70.27%
± 1 standard error	0.05%	0.09%	0.20%	0.46%	0.81%	1.13%
Sample Size	8800	7600	6700	5300	2800	600

Excluding Normal Battery Depletion

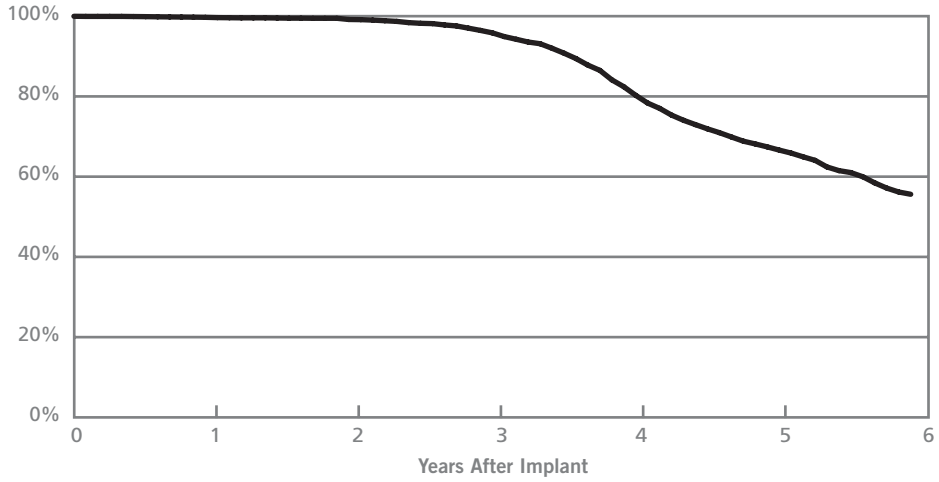


Year	1	2	3	4	5	at 67 months
Survival Probability	99.88%	99.76%	99.50%	99.12%	98.86%	98.73%
± 1 standard error	0.03%	0.05%	0.09%	0.13%	0.16%	0.21%

Photon® µ DR (Model V-232)

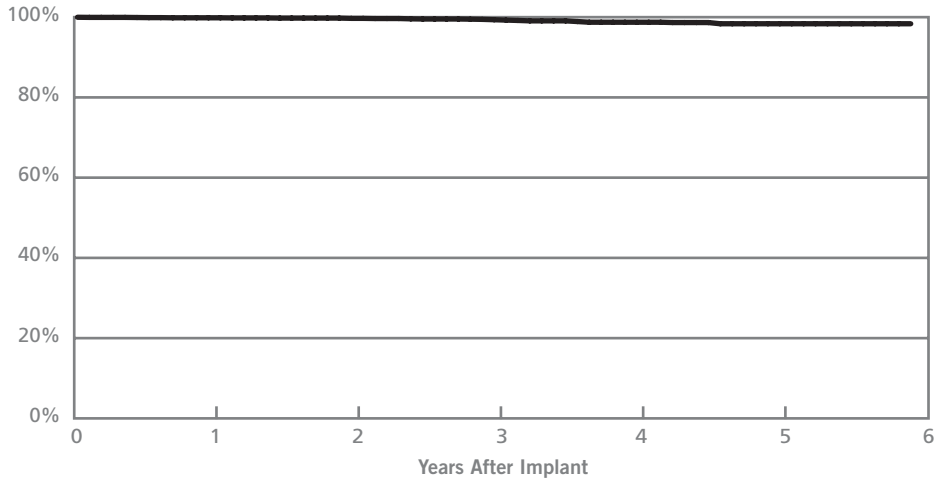
US Market Release	June 2001	Normal Battery Depletion	648
Registered US Implants	3,403	Malfunctions	33
Estimated Active US Implants	154	Malfunctions w/ Compromised Therapy (10 related to Advisory)	16
Estimated Longevity	(see table on page 62)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	17
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 71 months
Survival Probability	99.71%	99.17%	95.84%	80.26%	66.62%	55.61%
± 1 standard error	0.09%	0.13%	0.37%	0.84%	1.15%	1.57%
Sample Size	3400	3000	2600	2200	1400	600

Excluding Normal Battery Depletion



Year	1	2	3	4	5	at 71 months
Survival Probability	99.84%	99.70%	99.36%	98.74%	98.36%	98.36%
± 1 standard error	0.07%	0.09%	0.14%	0.24%	0.30%	0.30%

SUMMARY & LONGEVITY INFORMATION

ICDs
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Including 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
2107-36	Current DR HE	May-07	472	447	0	0	0	0	0	0	0
2207-36	Current RF DR HE	May-07	693	680	0	0	0	0	0	0	0
V-265	Atlas II DR	Aug-06	1480	1358	0	0	0	0	0	0	0
V-268	Atlas II + DR	Aug-06	8800	8087	0	0	0	0	0	0	0
V-255	Epic II DR	May-06	413	368	0	0	0	0	0	0	1
V-258	Epic II + DR	May-06	1435	1293	0	0	0	0	0	0	0
V-233	Epic DR	Oct-03	1818	1304	0	0	0	0	0	0	0
V-239	Epic + DR	Oct-03	7786	5580	4	0	0	2	0	6	11
V-242	Atlas DR	Oct-03	4629	3309	1	0	1	1	0	3	2
V-243	Atlas + DR	Oct-03	20207	14916	2	0	4	1	0	7	5
V-236	Epic + DR	Apr-03	2343	1059	0	0	0	5	2	7	22
V-235	Epic DR	Jul-02	6582	2883	2	0	2	14	1	19	74
V-240	Atlas DR	Dec-01	8838	1440	5	21	5	12	16	59	902
V-232	Photon µ DR	Jun-01	3403	154	4	10	2	5	12	33	648

Excluding 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
2107-36	Current DR HE	May-07	472	447	0	0	0	0	0	0
2207-36	Current RF DR HE	May-07	693	680	0	0	0	0	0	0
V-265	Atlas II DR	Aug-06	1480	1358	0	0	0	0	0	0
V-268	Atlas II + DR	Aug-06	8800	8087	0	0	0	0	0	0
V-255	Epic II DR	May-06	413	368	0	0	0	0	0	0
V-258	Epic II + DR	May-06	1435	1293	0	0	0	0	0	0
V-233	Epic DR	Oct-03	1818	1304	0	0	0	0	0	0
V-239	Epic + DR	Oct-03	7786	5580	4	0	0	2	0	6
V-242	Atlas DR	Oct-03	4629	3309	1	0	1	1	0	3
V-243	Atlas + DR	Oct-03	20207	14916	2	0	4	1	0	7
V-236	Epic + DR	Apr-03	2343	1059	0	0	0	5	2	7
V-235	Epic DR	Jul-02	6582	2883	2	0	2	14	1	19
V-240	Atlas DR	Dec-01	8838	1440	5	21	5	12	16	59
V-232	Photon µ DR	Jun-01	3403	154	4	10	2	5	12	33

**Based on returned product analysis as of December 31, 2007.*

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
2107-36	Current DR HE**										
2207-36	Current RF DR HE**										
V-265	Atlas II DR	100.00%									
V-268	Atlas II + DR	100.00%									
V-255	Epic II DR**										
V-258	Epic II + DR	100.00%									
V-233	Epic DR	100.00%	100.00%	100.00%							
V-239	Epic + DR	99.93%	99.87%	99.39%							
V-242	Atlas DR	99.95%	99.84%	99.84%							
V-243	Atlas + DR	99.98%	99.93%	99.87%							
V-236	Epic + DR	99.91%	99.69%	99.52%	97.64%						
V-235	Epic DR	99.93%	99.77%	99.12%	98.22%	96.38%					
V-240	Atlas DR	99.78%	99.33%	97.04%	87.47%	74.76%					
V-232	Photon µ DR	99.71%	99.17%	95.84%	80.26%	66.62%					

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
2107-36	Current DR HE**										
2207-36	Current RF DR HE**										
V-265	Atlas II DR	100.00%									
V-268	Atlas II + DR	100.00%									
V-255	Epic II DR**										
V-258	Epic II + DR	100.00%									
V-233	Epic DR	100.00%	100.00%	100.00%							
V-239	Epic + DR	99.94%	99.93%	99.87%							
V-242	Atlas DR	100.00%	99.89%	99.89%							
V-243	Atlas + DR	99.99%	99.96%	99.89%							
V-236	Epic + DR	99.96%	99.96%	99.96%	99.48%						
V-235	Epic DR	99.95%	99.93%	99.89%	99.54%	99.50%					
V-240	Atlas DR	99.88%	99.76%	99.50%	99.12%	98.86%					
V-232	Photon µ DR	99.84%	99.70%	99.36%	98.74%	98.36%					

**Based on returned product analysis as of December 31, 2007.*

***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.*

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
2107-36	Current DR HE	8.6	8.0	7.1	6.8
2207-36	Current RF DR HE	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).

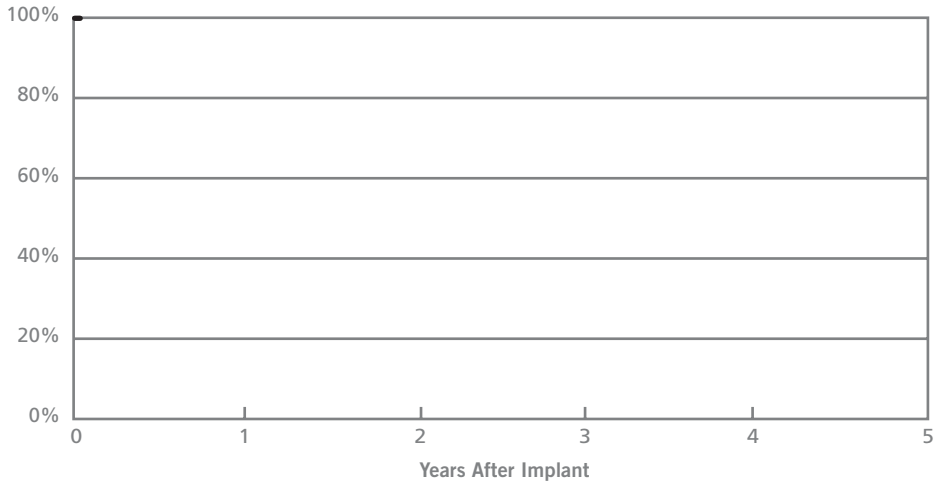
ICDs

Single-Chamber

Current® VR HE (Model 1207-36)

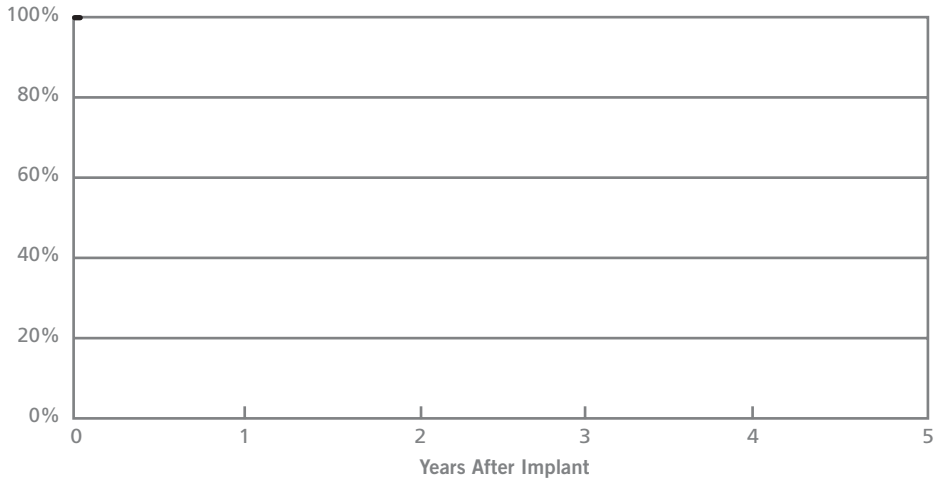
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	290	Malfunctions	0
Estimated Active US Implants	283	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 1 month				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	100				

Excluding Normal Battery Depletion

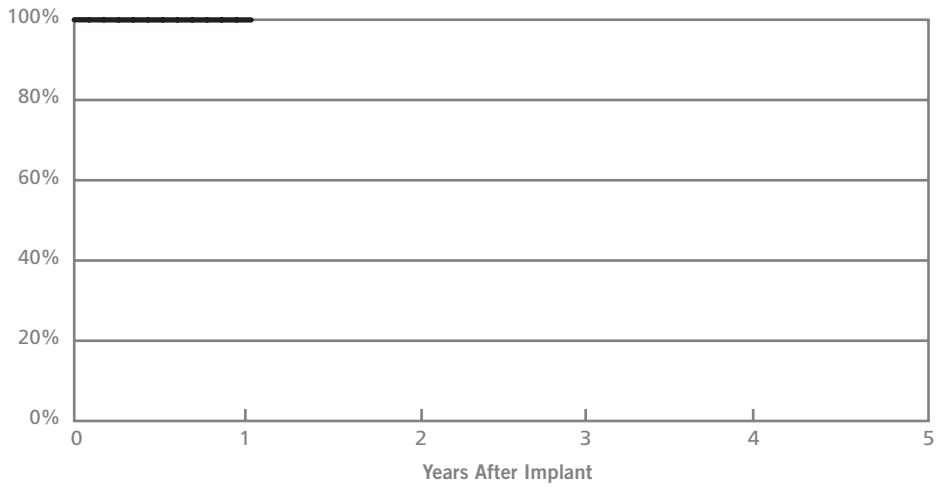


Year	at 1 month				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® II VR (Model V-168)

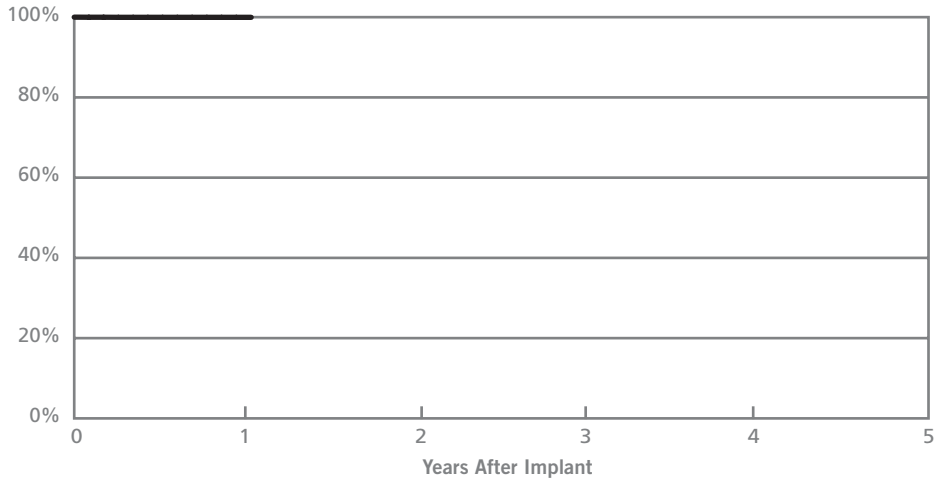
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	6,172	Malfunctions	2
Estimated Active US Implants	5,639	Malfunctions w/ Compromised Therapy	2
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 13 months			
Survival Probability	99.96%	99.96%			
± 1 standard error	0.03%	0.03%			
Sample Size	3700	200			

Excluding Normal Battery Depletion

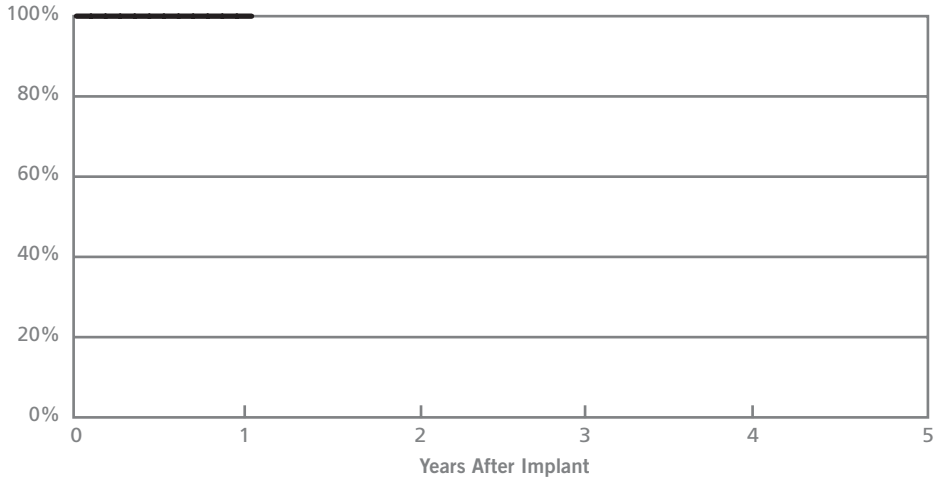


Year	1	at 13 months			
Survival Probability	99.96%	99.96%			
± 1 standard error	0.03%	0.03%			

Epic® II VR (Model V-158)

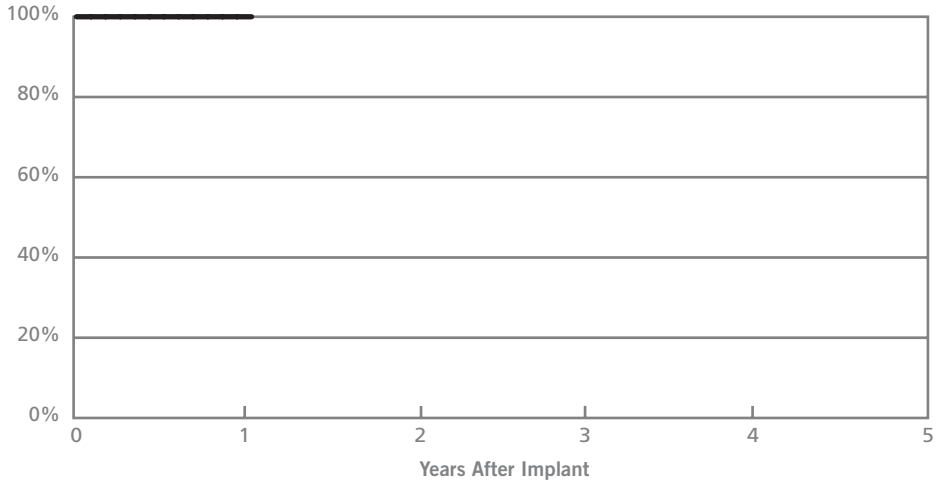
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	1,086	Malfunctions	0
Estimated Active US Implants	980	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	700	200			

Excluding Normal Battery Depletion

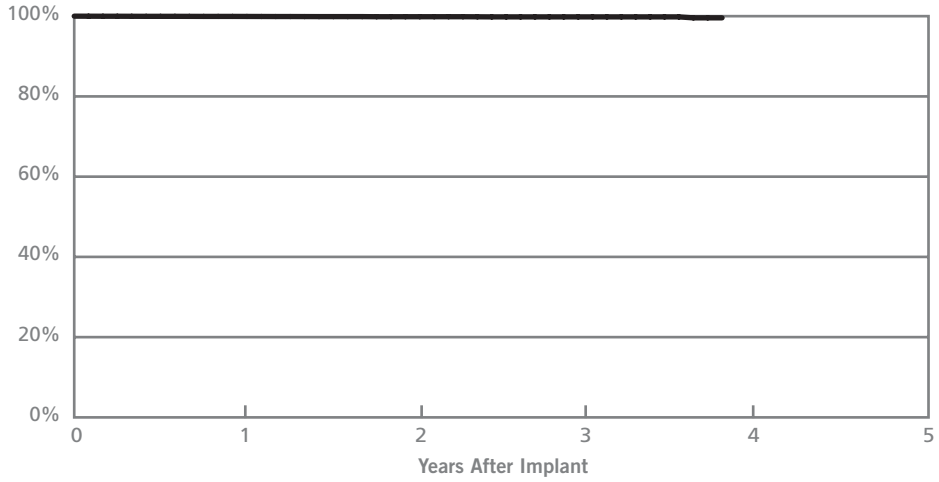


Year	1	at 13 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Atlas® + VR (Model V-193)

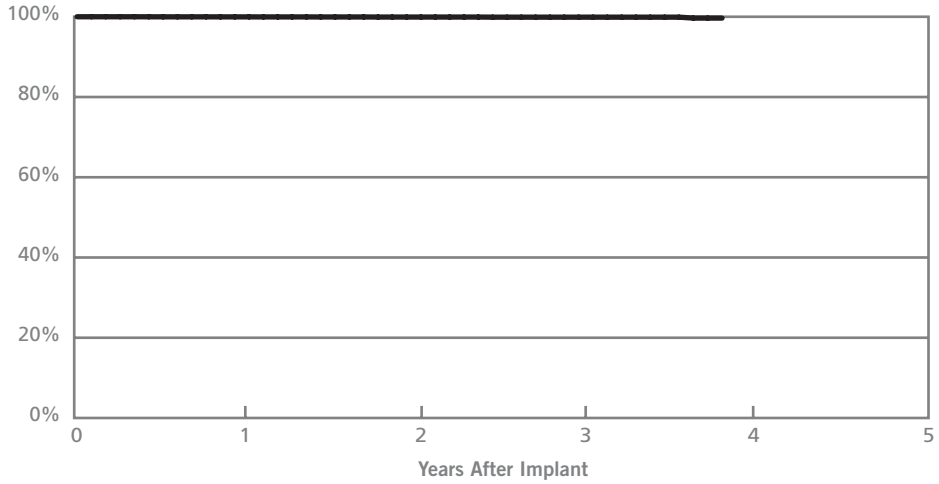
US Market Release	October 2003	Normal Battery Depletion	11
Registered US Implants	19,587	Malfunctions	12
Estimated Active US Implants	14,422	Malfunctions w/ Compromised Therapy (0 related to Advisory)	8
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	at 46 months	
Survival Probability	99.94%	99.86%	99.82%	99.58%	
± 1 standard error	0.02%	0.03%	0.05%	0.24%	
Sample Size	18600	12100	4900	1000	

Excluding Normal Battery Depletion

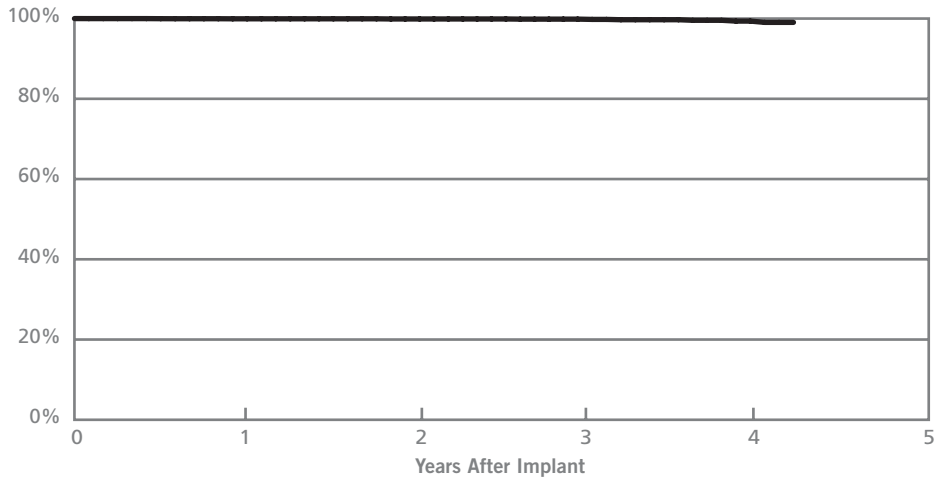


Year	1	2	3	at 46 months	
Survival Probability	99.97%	99.93%	99.90%	99.67%	
± 1 standard error	0.01%	0.02%	0.03%	0.24%	

Epic® + VR (Model V-196)

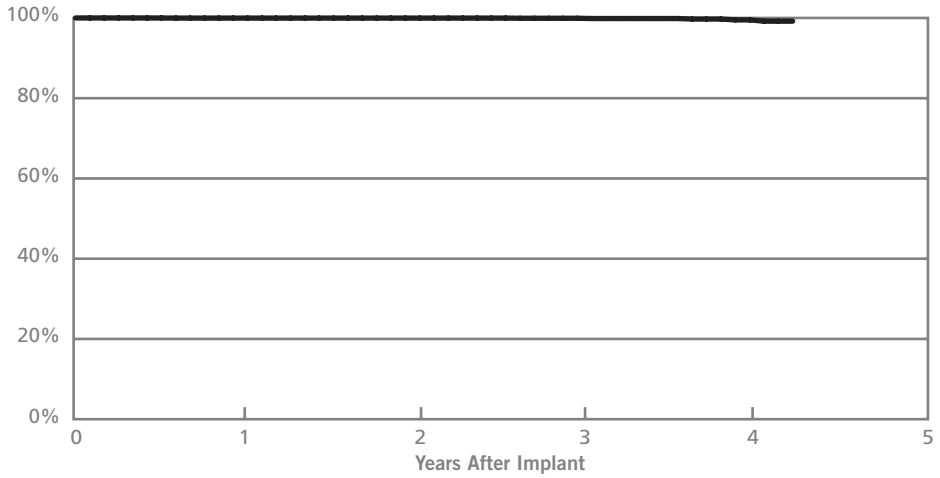
US Market Release	April 2003	Normal Battery Depletion	5
Registered US Implants	7,841	Malfunctions	7
Estimated Active US Implants	5,333	Malfunctions w/ Compromised Therapy (0 related to Advisory)	3
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	Two

Including Normal Battery Depletion



Year	1	2	3	4	at 51 months
Survival Probability	99.94%	99.90%	99.86%	99.37%	99.05%
± 1 standard error	0.02%	0.04%	0.06%	0.27%	0.42%
Sample Size	7700	5600	3000	500	300

Excluding Normal Battery Depletion

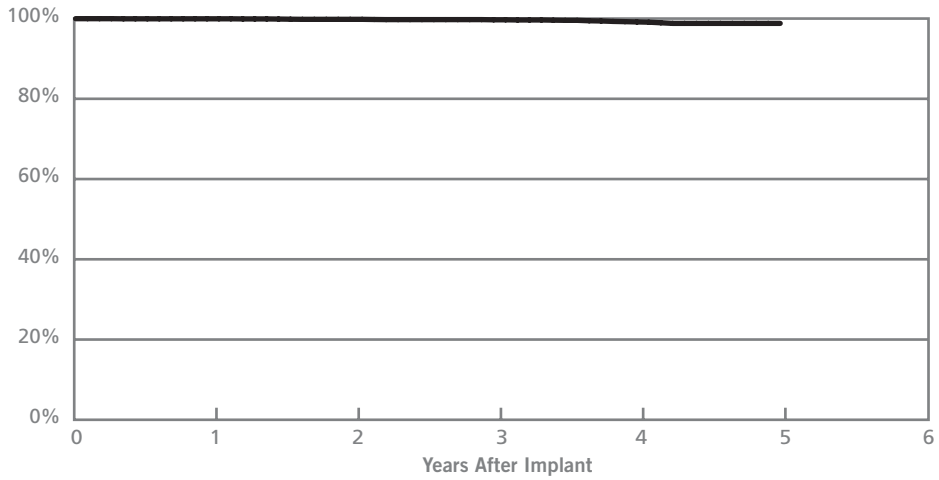


Year	1	2	3	4	at 51 months
Survival Probability	99.97%	99.97%	99.93%	99.52%	99.20%
± 1 standard error	0.02%	0.02%	0.05%	0.26%	0.41%

Epic® VR (Model V-197)

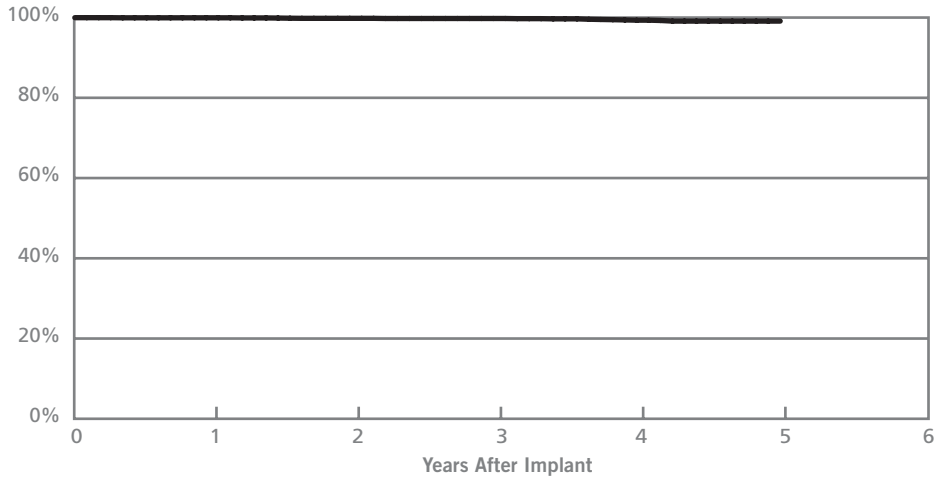
US Market Release	July 2002	Normal Battery Depletion	6
Registered US Implants	3,646	Malfunctions	18
Estimated Active US Implants	1,640	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	13
Max. Delivered Energy	30 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	
Survival Probability	99.94%	99.81%	99.69%	99.16%	98.80%	
± 1 standard error	0.04%	0.08%	0.09%	0.19%	0.26%	
Sample Size	3600	3100	2800	2200	900	

Excluding Normal Battery Depletion

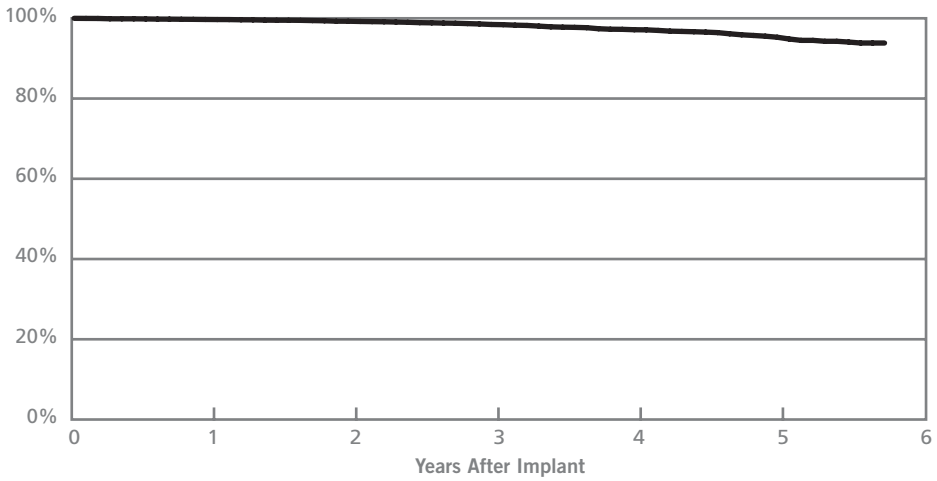


Year	1	2	3	4	5	
Survival Probability	99.94%	99.81%	99.77%	99.35%	99.12%	
± 1 standard error	0.04%	0.08%	0.09%	0.16%	0.22%	

Atlas® VR (Model V-199)

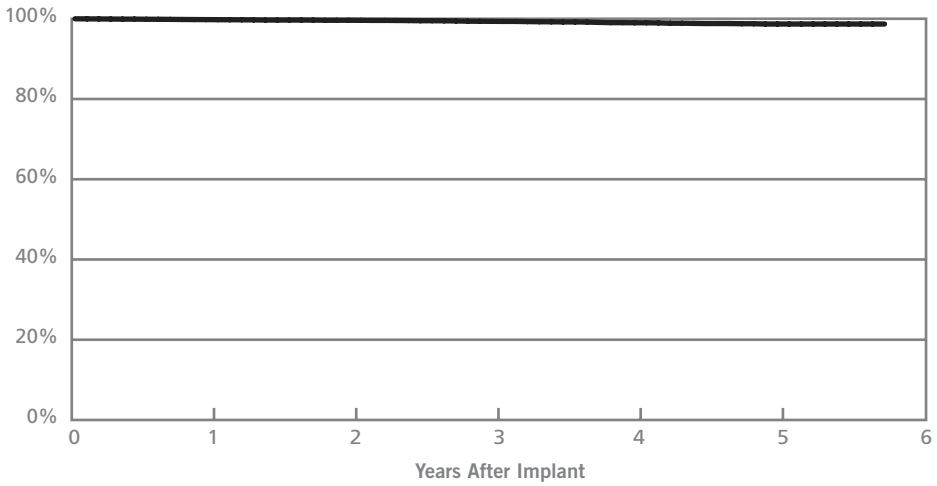
US Market Release	December 2001	Normal Battery Depletion	131
Registered US Implants	7,087	Malfunctions	56
Estimated Active US Implants	2,571	Malfunctions w/ Compromised Therapy (22 related to Advisory)	32
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	24
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 69 months
Survival Probability	99.71%	99.27%	98.46%	97.15%	95.28%	93.84%
± 1 standard error	0.06%	0.11%	0.16%	0.24%	0.37%	0.57%
Sample Size	7100	6100	5200	4100	2500	900

Excluding Normal Battery Depletion

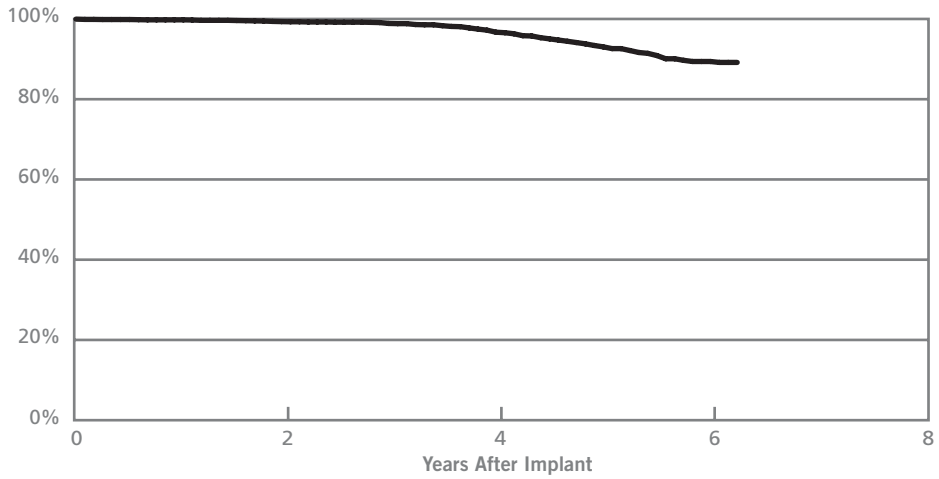


Year	1	2	3	4	5	at 69 months
Survival Probability	99.79%	99.63%	99.36%	99.00%	98.69%	98.69%
± 1 standard error	0.06%	0.08%	0.11%	0.14%	0.19%	0.19%

Photon® µ VR (Model V-194)

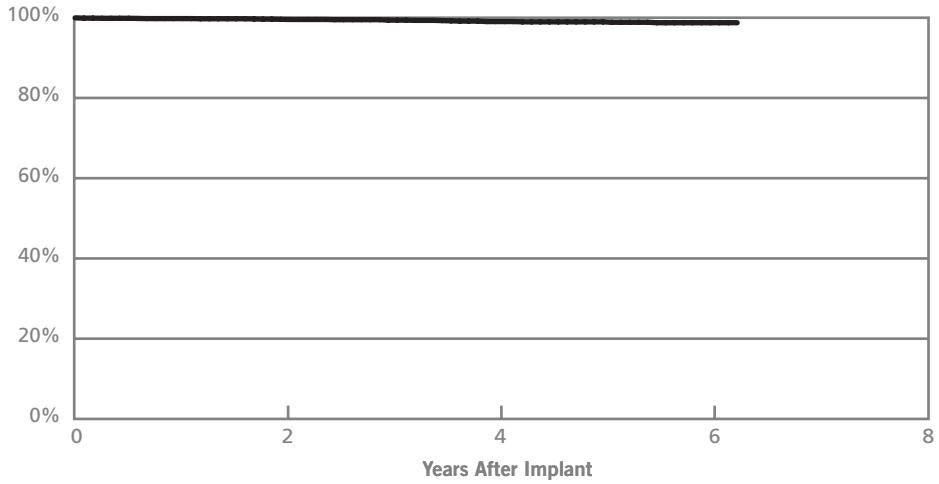
US Market Release	June 2001	Normal Battery Depletion	122
Registered US Implants	2,833	Malfunctions	23
Estimated Active US Implants	660	Malfunctions w/ Compromised Therapy (5 related to Advisory)	12
Estimated Longevity	(see table on page 76)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	11
Max. Delivered Energy	36 joules	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



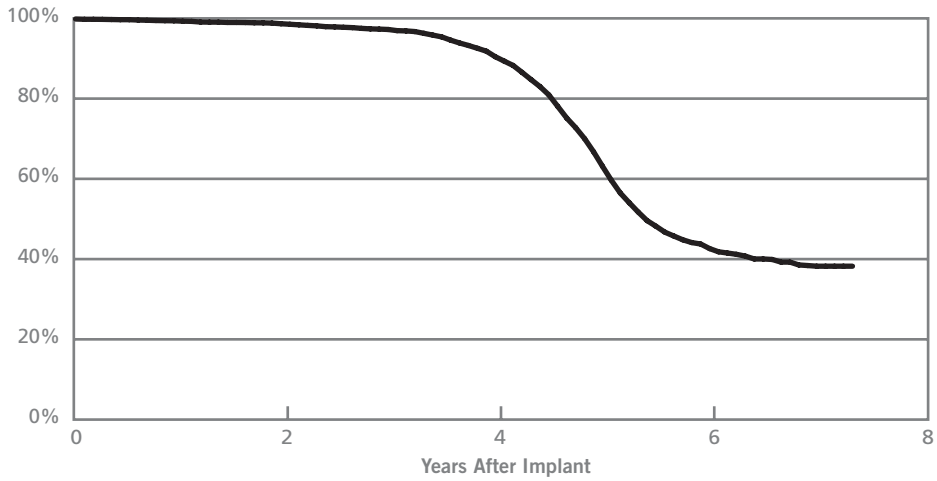
Year	2	4	6	at 75 months
Survival Probability	99.34%	96.70%	89.40%	89.17%
± 1 standard error	0.16%	0.38%	0.88%	0.91%
Sample Size	2500	1800	900	300

Excluding Normal Battery Depletion



Year	2	4	6	at 75 months
Survival Probability	99.60%	99.04%	98.75%	98.75%
± 1 standard error	0.12%	0.22%	0.28%	0.28%

Contour® MD (Models V-175, V-175AC, V-175B, V-175C & V-175D)	
US Market Release	October 1998
Registered US Implants	4,920
Estimated Active US Implants	471
Estimated Longevity	(see table on page 76)
Number of Advisories	None



Year	2	4	6	at 88 months
Survival Probability	98.66%	90.44%	42.62%	38.23%
± 1 standard error	0.16%	0.50%	1.21%	1.30%
Sample Size	4200	3000	1100	200

SUMMARY & LONGEVITY INFORMATION

ICDs
Single-Chamber

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Including 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
1207-36	Current VR HE	May-07	290	283	0	0	0	0	0	0	0
V-168	Atlas II VR	Aug-06	6172	5639	2	0	0	0	0	2	0
V-158	Epic II VR	May-06	1086	980	0	0	0	0	0	0	0
V-193	Atlas + VR	Oct-03	19587	14422	6	0	2	2	2	12	11
V-196	Epic + VR	Apr-03	7841	5333	1	0	2	4	0	7	5
V-197	Epic VR	Jul-02	3646	1640	4	0	1	11	2	18	6
V-199	Atlas VR	Dec-01	7087	2571	4	22	6	22	2	56	131
V-194	Photon µ VR	Jun-01	2833	660	3	5	4	10	1	23	122

Excluding 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
1207-36	Current VR HE	May-07	290	283	0	0	0	0	0	0
V-168	Atlas II VR	Aug-06	6172	5639	2	0	0	0	0	2
V-158	Epic II VR	May-06	1086	980	0	0	0	0	0	0
V-193	Atlas + VR	Oct-03	19587	14422	6	0	2	2	2	12
V-196	Epic + VR	Apr-03	7841	5333	1	0	2	4	0	7
V-197	Epic VR	Jul-02	3646	1640	4	0	1	11	2	18
V-199	Atlas VR	Dec-01	7087	2571	4	22	6	22	2	56
V-194	Photon µ VR	Jun-01	2833	660	3	5	4	10	1	23

**Based on returned product analysis as of December 31, 2007.*

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
1207-36	Current VR HE**										
V-168	Atlas II VR	99.96%									
V-158	Epic II VR	100.00%									
V-193	Atlas + VR	99.94%	99.86%	99.82%							
V-196	Epic + VR	99.94%	99.90%	99.86%	99.37%						
V-197	Epic VR	99.94%	99.81%	99.69%	99.16%	98.80%					
V-199	Atlas VR	99.71%	99.27%	98.46%	97.15%	95.28%					
V-194	Photon µ VR	99.78%	99.34%	98.88%	96.70%	93.05%	89.40%				

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
1207-36	Current VR HE**										
V-168	Atlas II VR	99.96%									
V-158	Epic II VR	100.00%									
V-193	Atlas + VR	99.97%	99.93%	99.90%							
V-196	Epic + VR	99.97%	99.97%	99.93%	99.52%						
V-197	Epic VR	99.94%	99.81%	99.77%	99.35%	99.12%					
V-199	Atlas VR	99.79%	99.63%	99.36%	99.00%	98.69%					
V-194	Photon µ VR	99.78%	99.60%	99.40%	99.04%	98.97%	98.75%				

**Based on returned product analysis as of December 31, 2007.*

***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.*

Battery Longevity

Models	Family	Approximate Duration (years)*			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
1207-36	Current VR HE	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

DEFIBRILLATION LEADS

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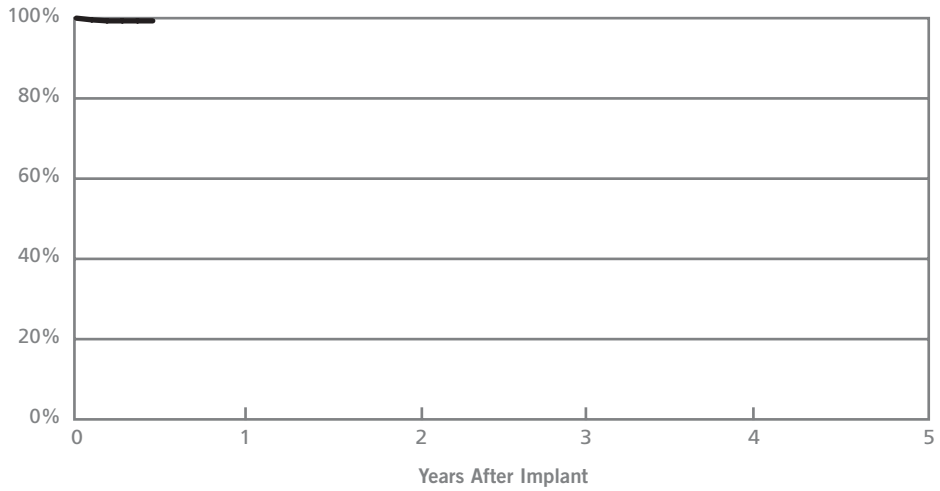
Riata® ST Optim™ (Models 7070 & 7071)

US Market Release	July 2006	Type and/or Fixation	Dual Coil, Passive
Registered US Implants	621	Polarity	Bipolar
Estimated Active US Implants	609	Steroid	Yes
Insulation	Optim*	Number of Advisories	None

Laboratory Analysis

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



Year	at 6 months				
Survival Probability	99.33%				
± 1 standard error	0.38%				
Sample Size	100				

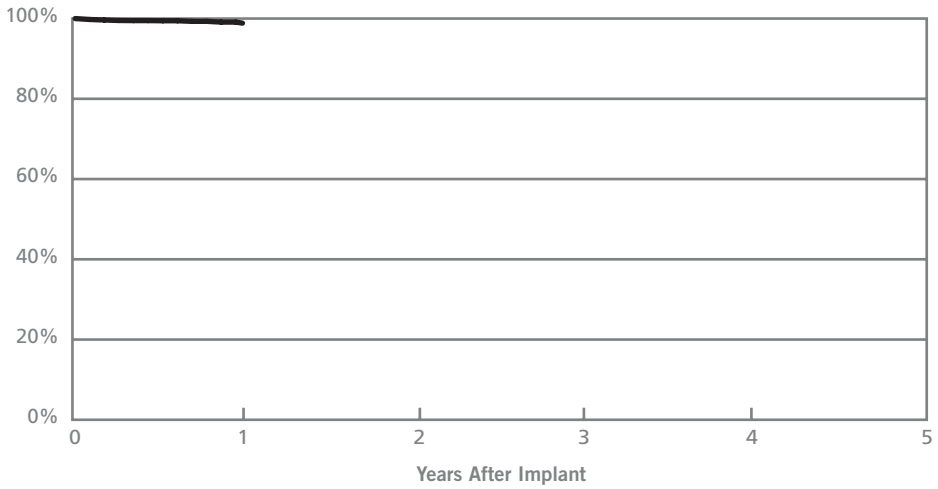
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST Optim™ (Models 7020 & 7021)

US Market Release	July 2006	Type and/or Fixation	Dual Coil, Active
Registered US Implants	8,470	Polarity	Bipolar
Estimated Active US Implants	8,288	Steroid	Yes
Insulation	Optim*	Number of Advisories	None

Laboratory Analysis

Implant Damage	25	Electrical Malfunction	1	Other	25
		Insulation Disruption	1	Explant Damage	21
		Conductor Disruption	0	Non-Electrical Workmanship	3
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	0
				Partial Lead	1



Year	1				
Survival Probability	99.12%				
± 1 standard error	0.24%				
Sample Size	4400				

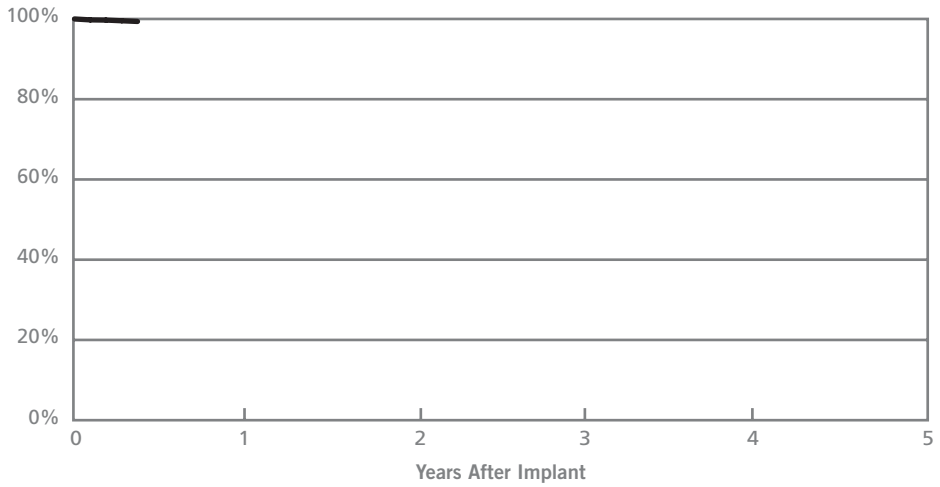
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST Optim™ (Model 7022)

US Market Release	July 2006	Type and/or Fixation	Single Coil, Active
Registered US Implants	617	Polarity	Bipolar
Estimated Active US Implants	606	Steroid	Yes
Insulation	Optim*	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



Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	100				

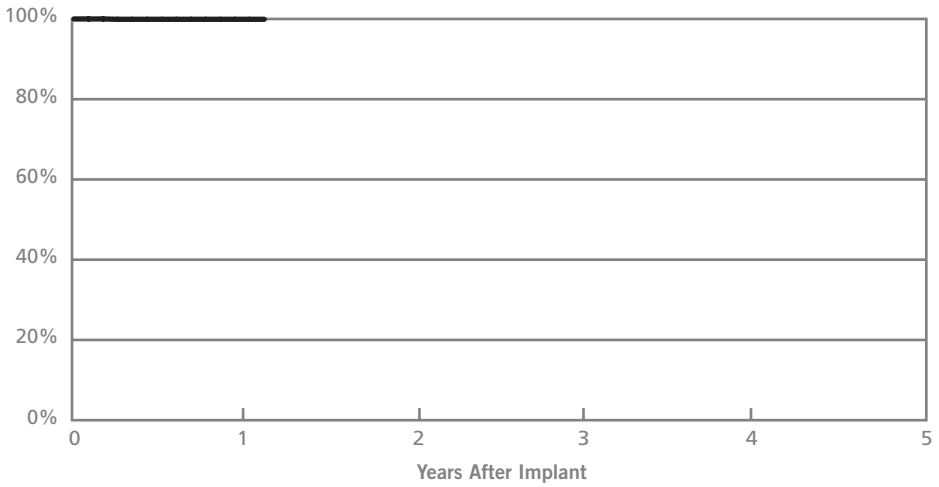
**Optim® insulation is a copolymer of silicone and polyurethane.*

Riata® ST (Models 7010 & 7011)

US Market Release	March 2006	Type and/or Fixation	Dual Coil, Active
Registered US Implants	1,678	Polarity	Bipolar
Estimated Active US Implants	1,624	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**5**	**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



Year	1	at 14 months			
Survival Probability	99.92%	99.92%			
± 1 standard error	0.08%	0.08%			
Sample Size	1000	100			

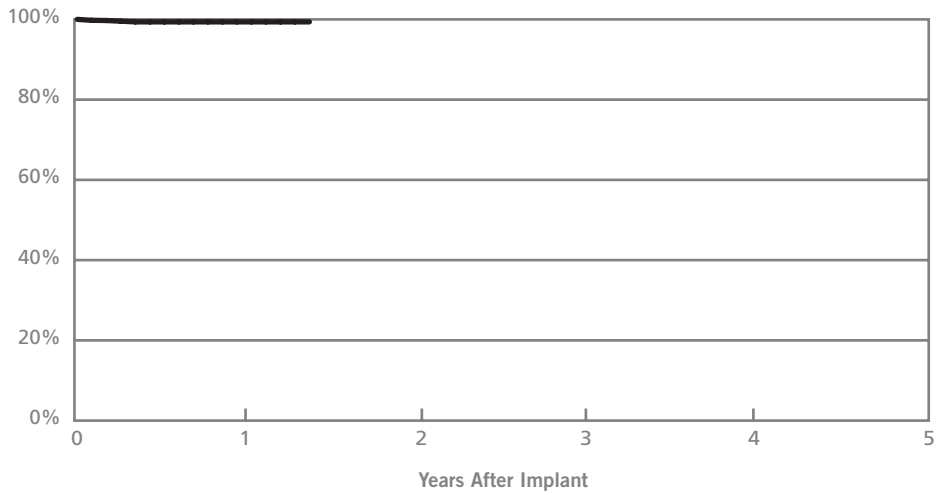
Defibrillation Leads

Riata® ST (Models 7040 & 7041)

US Market Release	March 2006	Type and/or Fixation	Dual Coil, Passive
Registered US Implants	2,366	Polarity	Bipolar
Estimated Active US Implants	2,293	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

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



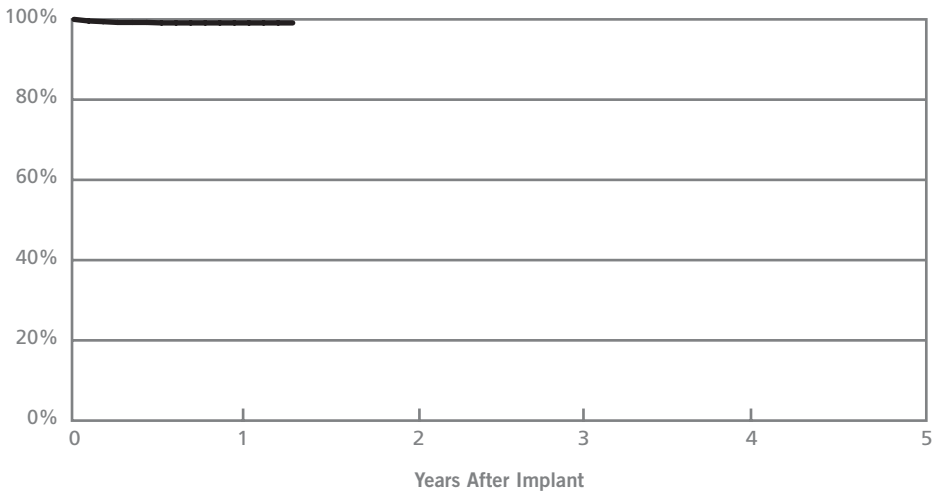
Year	1	at 17 months			
Survival Probability	99.38%	99.38%			
± 1 standard error	0.18%	0.18%			
Sample Size	1600	100			

Riata® ST (Model 7002)

US Market Release	March 2006	Type and/or Fixation	Single Coil, Active
Registered US Implants	1,435	Polarity	Bipolar
Estimated Active US Implants	1,385	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

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



Year	1	at 16 months			
Survival Probability	99.12%	99.12%			
± 1 standard error	0.28%	0.28%			
Sample Size	900	100			

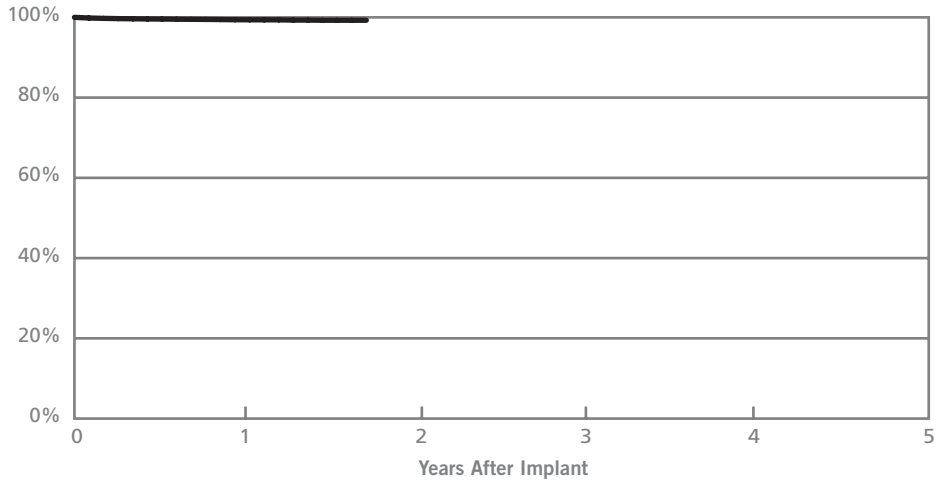
Defibrillation Leads

Riata® ST (Models 7000 & 7001)

US Market Release	June 2005	Type and/or Fixation	Dual Coil, Active
Registered US Implants	26,986	Polarity	Bipolar
Estimated Active US Implants	25,757	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**108**	**Electrical Malfunction**	**7**	**Other**	**76**
		Insulation Disruption	3	Explant Damage	61
		Conductor Disruption	2	Non-Electrical Workmanship	9
		Crimps, Welds, Bonds	2	Non-Electrical Anomaly	3
				Partial Lead	3



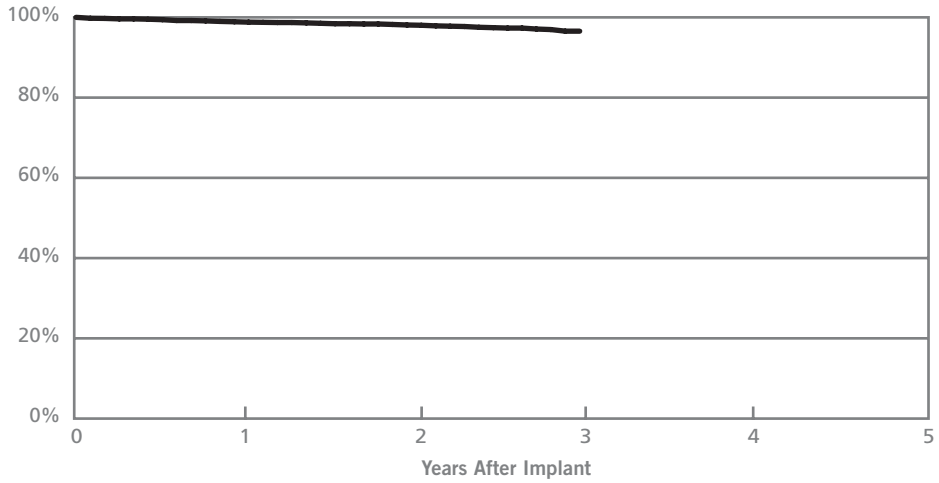
Year	1	at 21 months			
Survival Probability	99.41%	99.28%			
± 1 standard error	0.05%	0.08%			
Sample Size	19300	200			

Riata® *i* (Models 1590 & 1591)

US Market Release	August 2004	Type and/or Fixation	Dual Coil, Active
Registered US Implants	9,283	Polarity	Bipolar
Estimated Active US Implants	8,095	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**23**	**Electrical Malfunction**	**4**	**Other**	**4**
		Insulation Disruption	1	Explant Damage	2
		Conductor Disruption	3	Non-Electrical Workmanship	0
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	1
				Partial Lead	1



Year	1	2	3		
Survival Probability	98.90%	98.10%	96.56%		
± 1 standard error	0.20%	0.28%	0.50%		
Sample Size	8800	6000	2100		

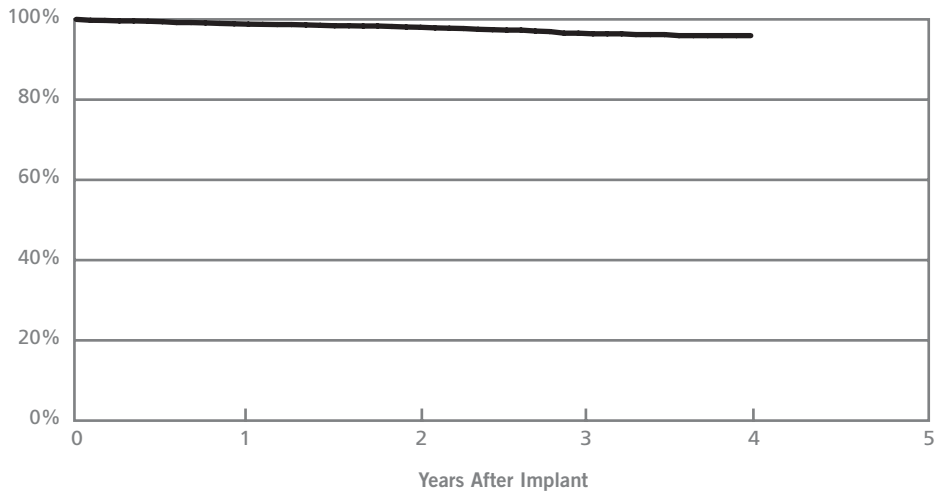
Defibrillation Leads

Riata® (Model 1582)

US Market Release	March 2003	Type and/or Fixation	Single Coil, Active
Registered US Implants	2,791	Polarity	Bipolar
Estimated Active US Implants	2,274	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**12**	**Electrical Malfunction**	**16**	**Other**	**10**
		Insulation Disruption	14	Explant Damage	4
		Conductor Disruption	2	Non-Electrical Workmanship	3
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	2
				Partial Lead	1



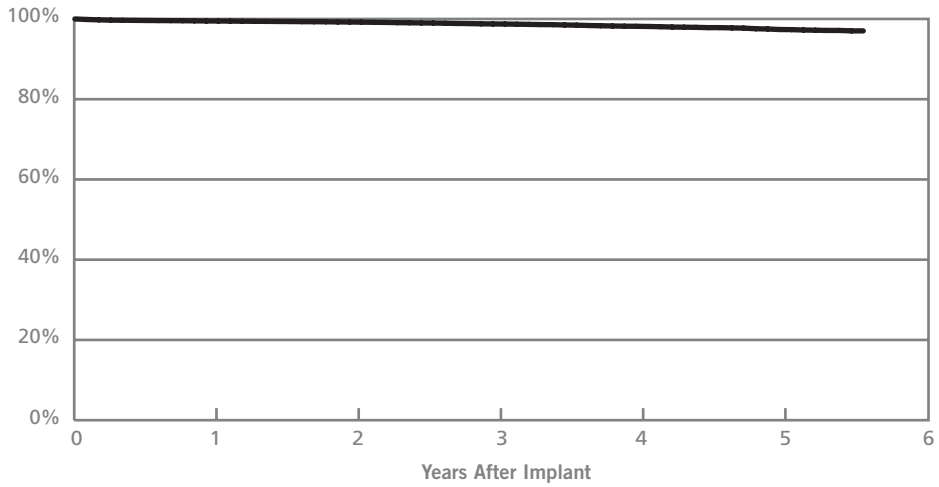
Year	1	2	3	4	
Survival Probability	98.90%	98.10%	96.56%	95.95%	
± 1 standard error	0.20%	0.28%	0.50%	0.61%	
Sample Size	2600	1900	1100	400	

Riata® (Models 1570 & 1571)

US Market Release	March 2002	Type and/or Fixation	Dual Coil, Passive
Registered US Implants	9,199	Polarity	Bipolar
Estimated Active US Implants	7,245	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**33**	**Electrical Malfunction**	**14**	**Other**	**25**
		Insulation Disruption	12	Explant Damage	14
		Conductor Disruption	2	Non-Electrical Workmanship	5
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	1
				Partial Lead	5



Year	1	2	3	4	5	at 67 months
Survival Probability	99.50%	99.24%	98.76%	98.17%	97.37%	97.03%
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.14%	0.22%
Sample Size	8800	7000	5000	3100	100	100

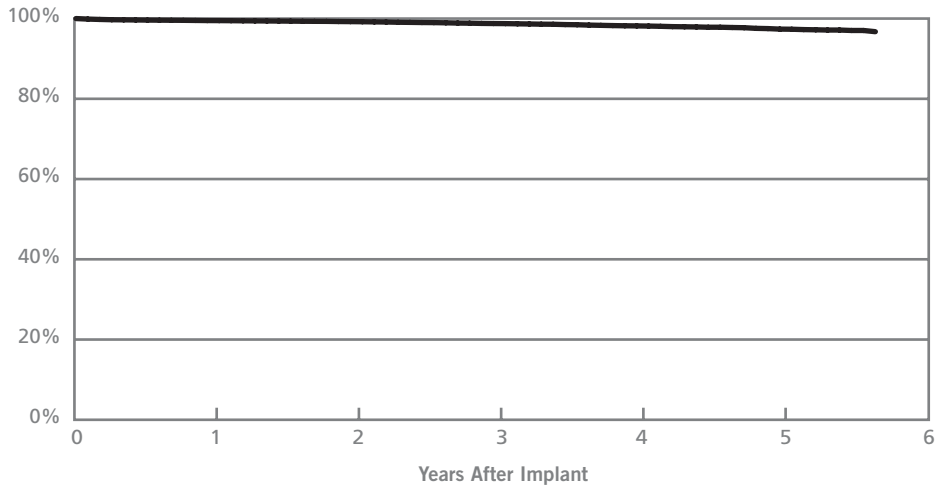
Defibrillation Leads

Riata® (Models 1580 & 1581)

US Market Release	March 2002	Type and/or Fixation	Dual Coil, Active
Registered US Implants	63,832	Polarity	Bipolar
Estimated Active US Implants	51,191	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

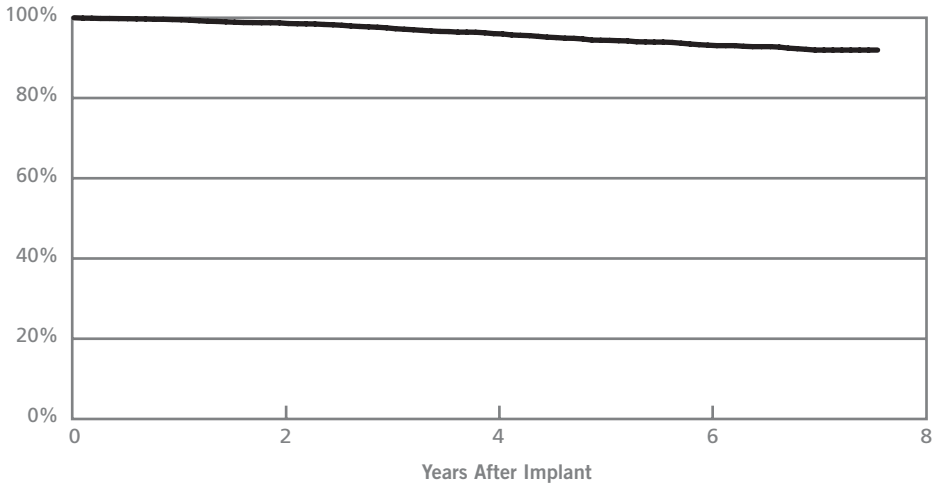
Implant Damage	**235**	**Electrical Malfunction**	**98**	**Other**	**190**
		Insulation Disruption	87	Explant Damage	124
		Conductor Disruption	8	Non-Electrical Workmanship	33
		Crimps, Welds, Bonds	3	Non-Electrical Anomaly	11
				Partial Lead	22



Year	1	2	3	4	5	at 68 months
Survival Probability	99.50%	99.24%	98.76%	98.17%	97.37%	96.73%
± 1 standard error	0.03%	0.04%	0.05%	0.08%	0.14%	0.22%
Sample Size	61400	47400	30000	15000	500	200

TVL® ADX (Model 1559)

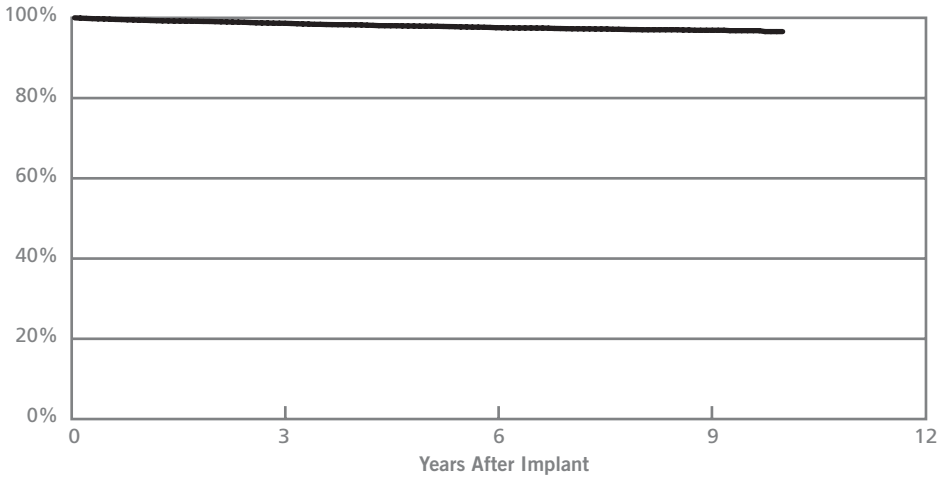
US Market Release	November 1999	Type and/or Fixation	Single Coil, Active
Registered US Implants	4,575	Polarity	Bipolar
Estimated Active US Implants	2,246	Steroid	Yes
Insulation	Silicone	Number of Advisories	None



Year	2	4	6	at 91 months
Survival Probability	98.73%	96.04%	93.17%	91.95%
± 1 standard error	0.18%	0.33%	0.47%	0.61%
Sample Size	3900	3100	2700	100

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	6,076	Steroid	Yes
Insulation	Silicone	Number of Advisories	None



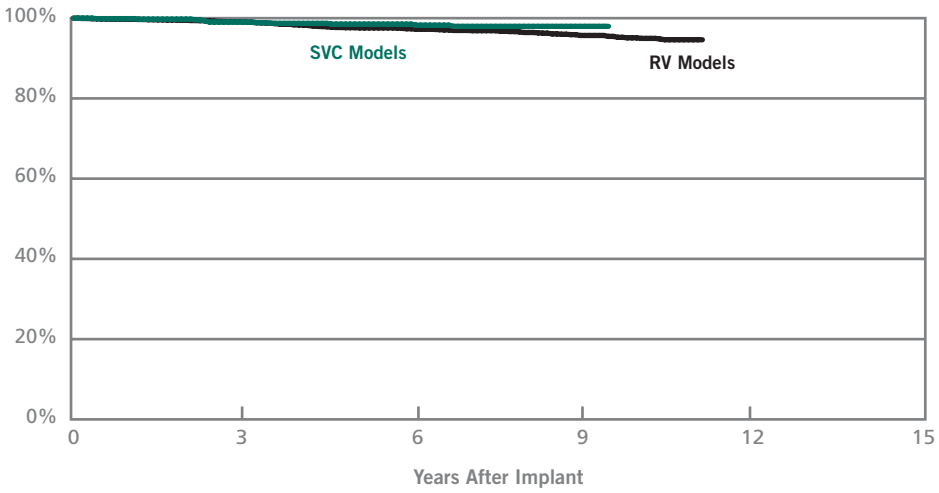
Year	3	6	9	at 122 months
Survival Probability	98.66%	97.61%	96.90%	96.57%
± 1 standard error	0.11%	0.16%	0.22%	0.25%
Sample Size	9900	6700	2000	800

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	3,647	RV	1,309
SVC	917	SVC	330

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



RV Models

Year	3	6	9	at 135 months	
Survival Probability	99.12%	97.36%	95.89%	94.62%	
± 1 standard error	0.17%	0.31%	0.46%	0.61%	
Sample Size	2900	2000	1200	100	

SVC Models

Year	3	6	9	at 115 months	
Survival Probability	99.03%	98.51%	97.96%	97.96%	
± 1 standard error	0.37%	0.47%	0.61%	0.61%	
Sample Size	700	500	200	200	

LABORATORY ANALYSIS

Defibrillation Leads

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
7070/7071	Jul-06	621	609	0	0	0	0	0	1	1	0	0	2
7020/7021	Jul-06	8470	8288	25	1	0	0	1	21	3	0	1	25
7022	Jul-06	617	606	0	0	0	0	0	1	0	0	0	1
7010/7011	Mar-06	1678	1624	5	0	0	0	0	1	0	1	0	2
7040/7041	Mar-06	2366	2293	6	1	0	0	1	2	2	1	1	6
7002	Mar-06	1435	1385	6	0	0	0	0	4	0	0	0	4
7000/7001	Jun-05	26986	25757	108	3	2	2	7	61	9	3	3	76
1590/1591	Apr-04	9283	8095	23	1	3	0	4	2	0	1	1	4
1582	Mar-03	2791	2274	12	14	2	0	16	4	3	2	1	10
1570/1571	Mar-02	9199	7245	33	12	2	0	14	14	5	1	5	25
1580/1581	Mar-02	63835	51191	235	87	8	3	98	124	33	11	22	190

**Based on returned product analysis as of December 31, 2007.*

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

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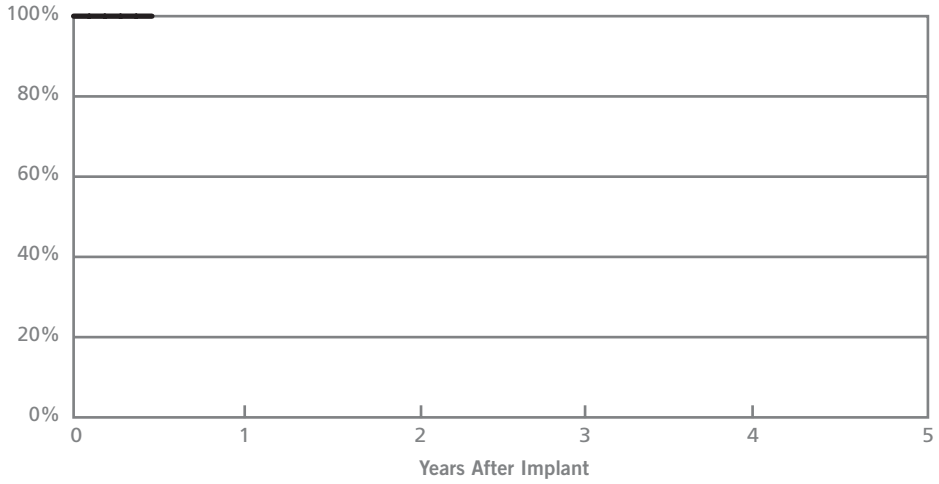
Zephyr™ DR (Model 5820)

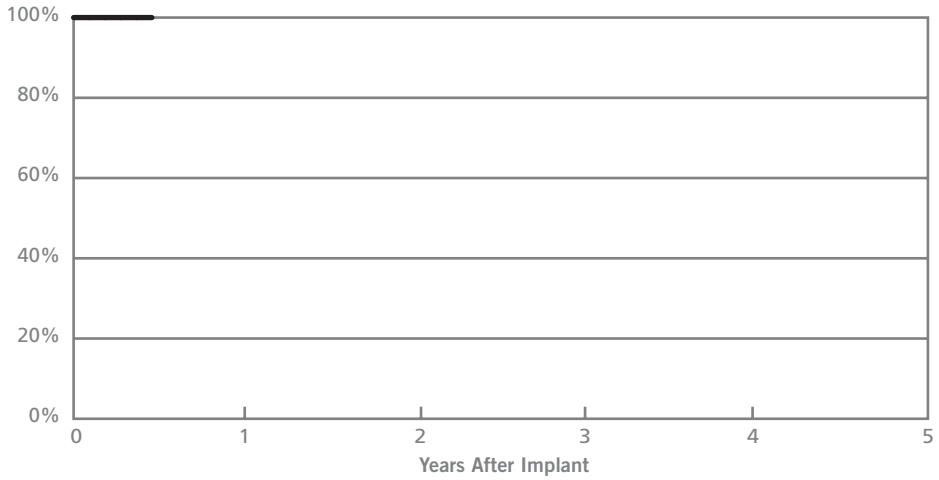
US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	2,875	Malfunctions	0
Estimated Active US Implants	2,847	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

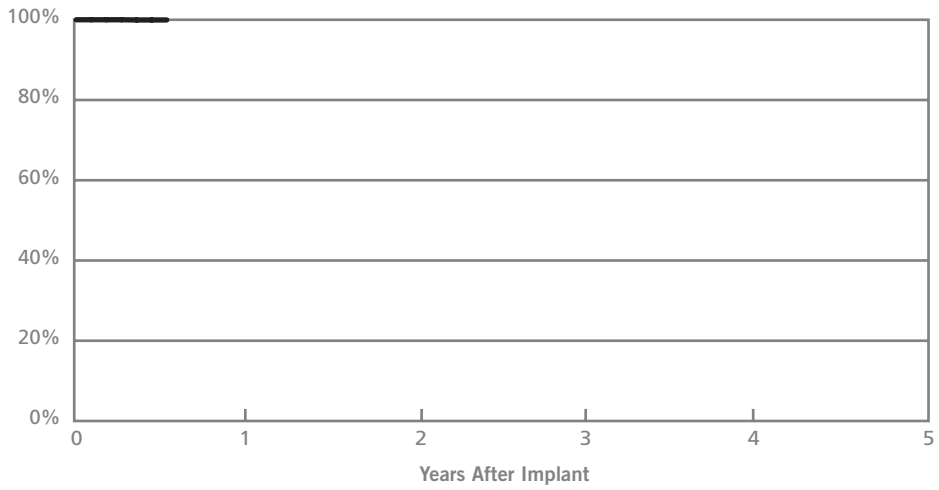


Year	at 6 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Zephyr™ XL DR (Model 5826)

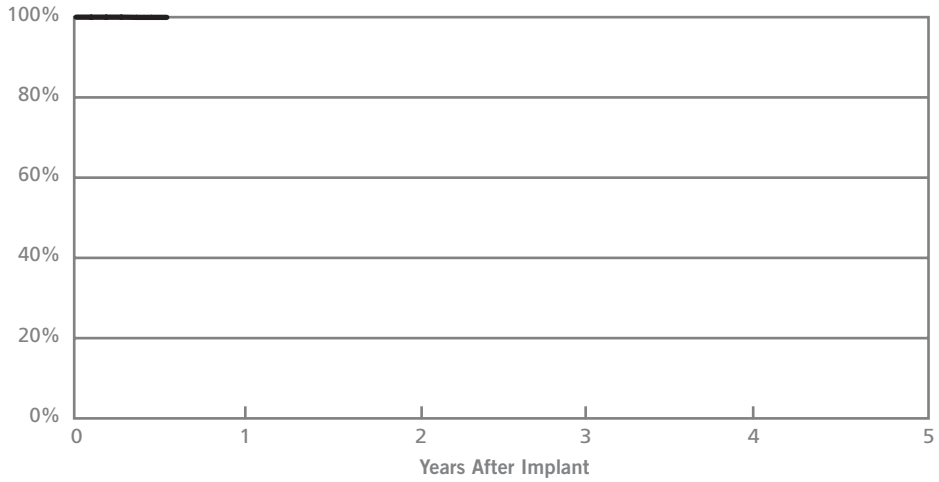
US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	9,837	Malfunctions	0
Estimated Active US Implants	9,776	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	11.7 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

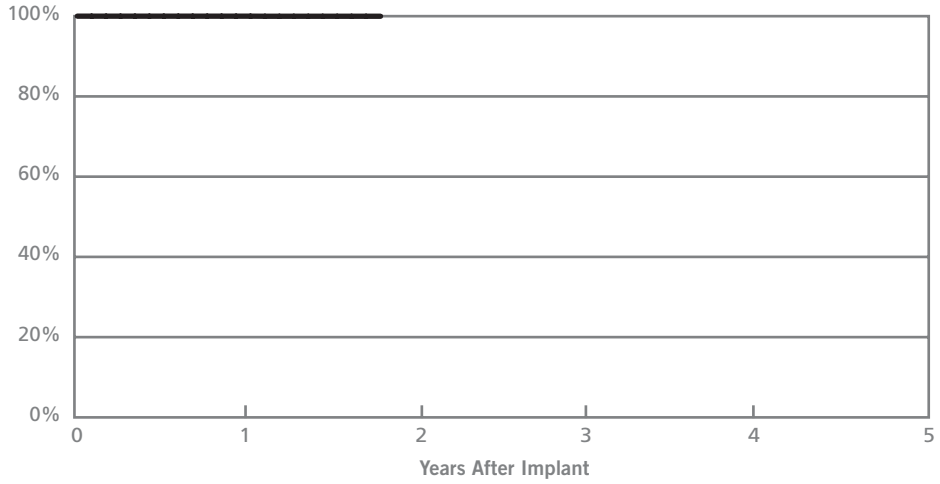


Year	at 7 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Victory® DR (Model 5810)

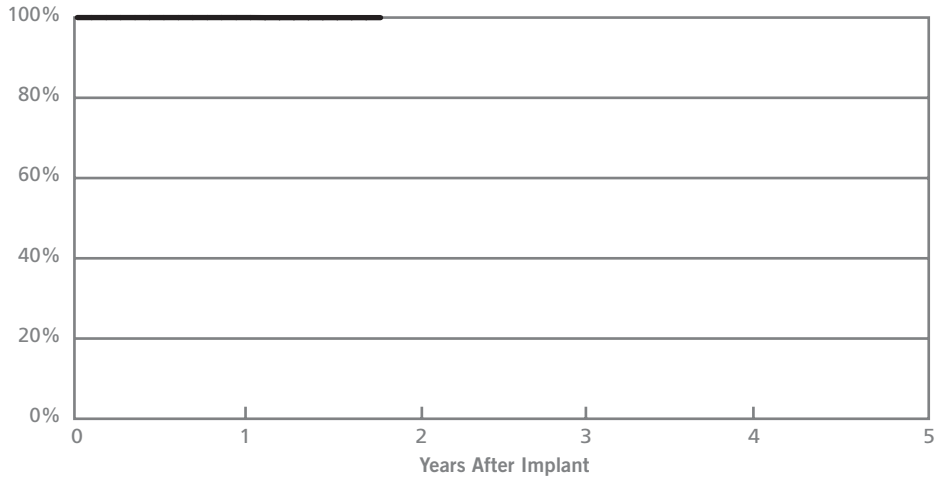
US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	18,326	Malfunctions	0
Estimated Active US Implants	17,404	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 22 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	13400	100			

Excluding Normal Battery Depletion

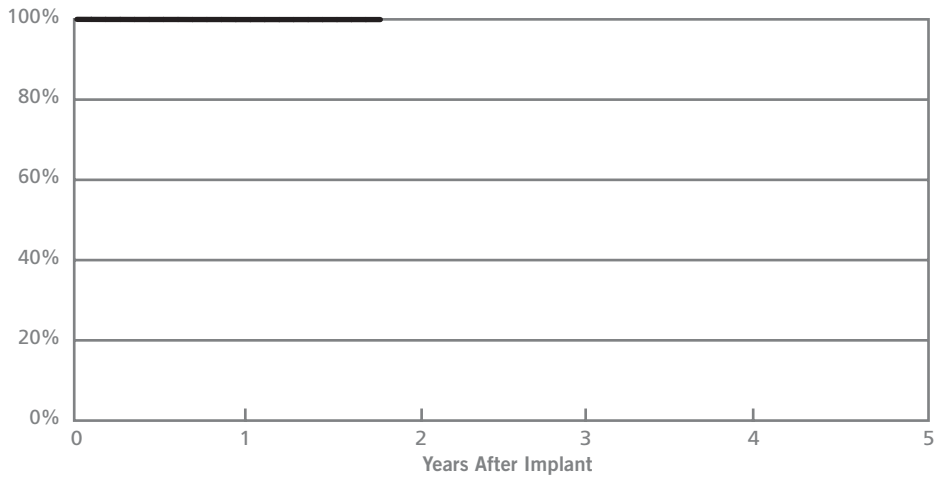


Year	1	at 22 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Victory® XL (Model 5816)

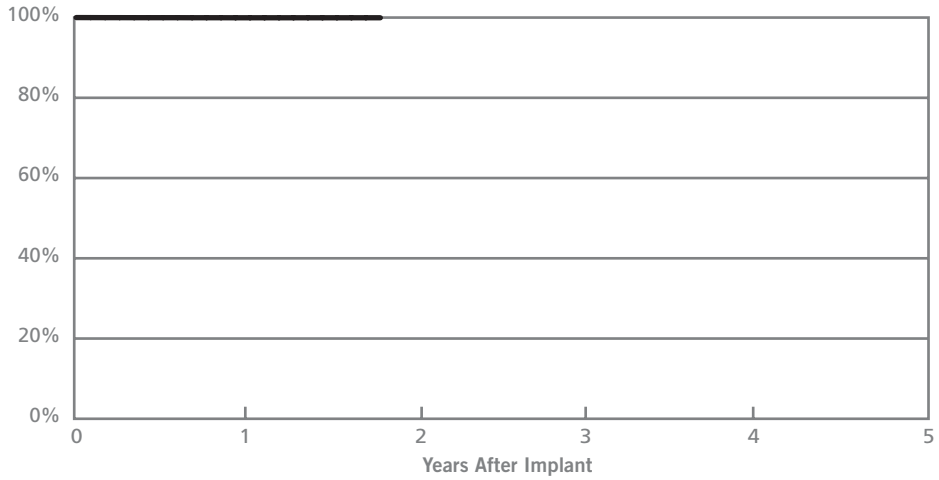
US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	41,419	Malfunctions	11
Estimated Active US Implants	40,101	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	11.7 Years	Malfunctions w/o Compromised Therapy	11
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 22 months			
Survival Probability	99.95%	99.95%			
± 1 standard error	0.01%	0.01%			
Sample Size	27700	200			

Excluding Normal Battery Depletion

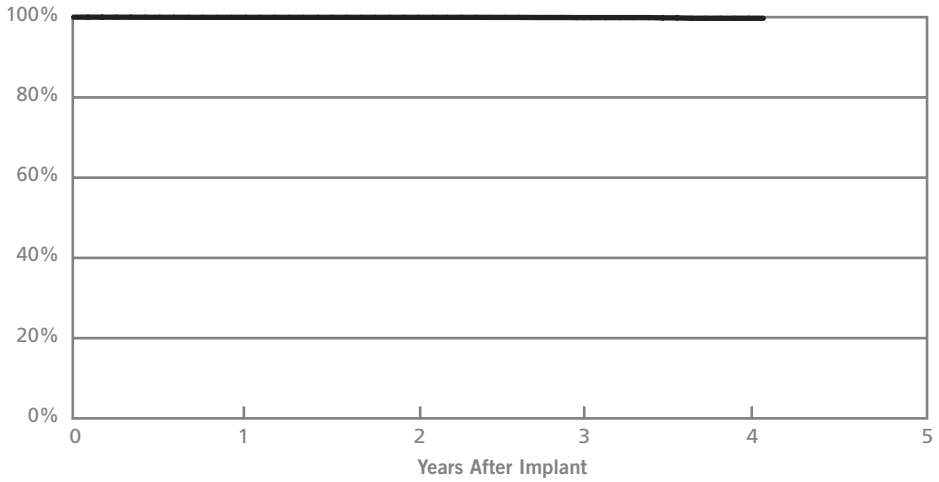


Year	1	at 22 months			
Survival Probability	99.95%	99.95%			
± 1 standard error	0.01%	0.01%			

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

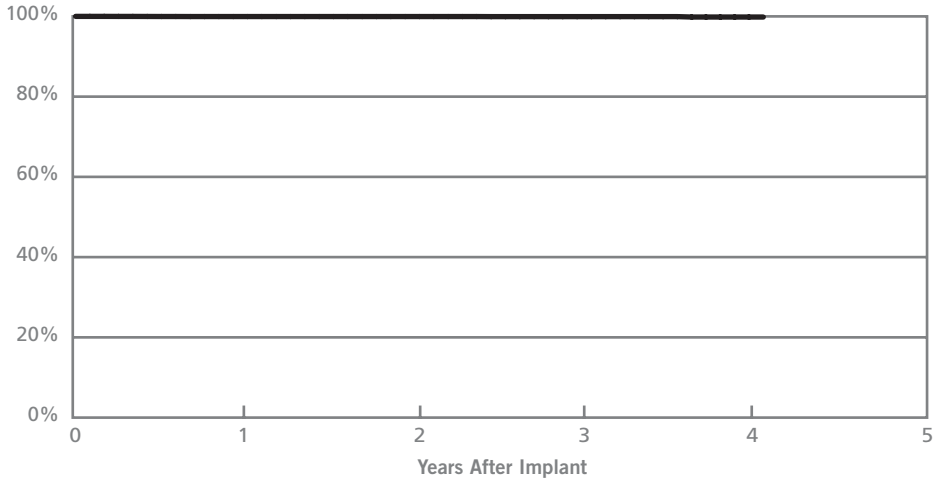
US Market Release	May 2003	Normal Battery Depletion	3
Registered US Implants	14,915	Malfunctions	7
Estimated Active US Implants	12,429	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	7
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	at 49 months
Survival Probability	99.96%	99.96%	99.89%	99.72%	99.72%
± 1 standard error	0.02%	0.02%	0.04%	0.13%	0.13%
Sample Size	13600	9100	5000	1700	100

Excluding Normal Battery Depletion

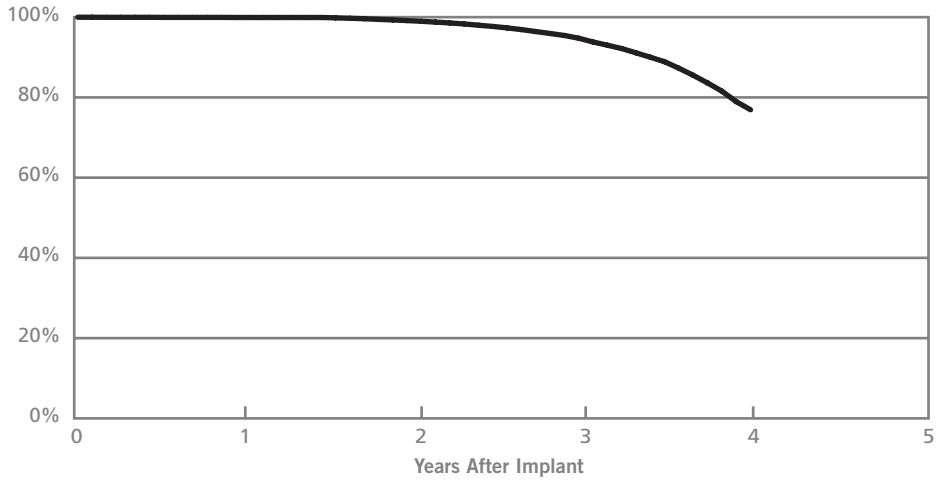


Year	1	2	3	4	at 49 months
Survival Probability	99.96%	99.96%	99.94%	99.84%	99.84%
± 1 standard error	0.02%	0.02%	0.03%	0.10%	0.10%

Integrity® ADx DR (Model 5360)

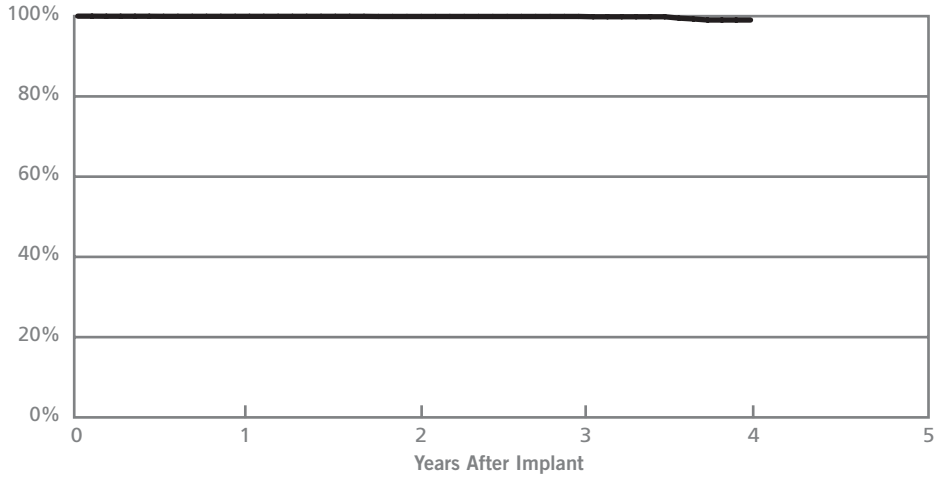
US Market Release	May 2003	Normal Battery Depletion	697
Registered US Implants	5,726	Malfunctions	2
Estimated Active US Implants	4,561	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	
Survival Probability	99.92%	99.15%	94.75%	76.92%	
± 1 standard error	0.03%	0.05%	0.10%	0.86%	
Sample Size	5400	3900	2300	1400	

Excluding Normal Battery Depletion

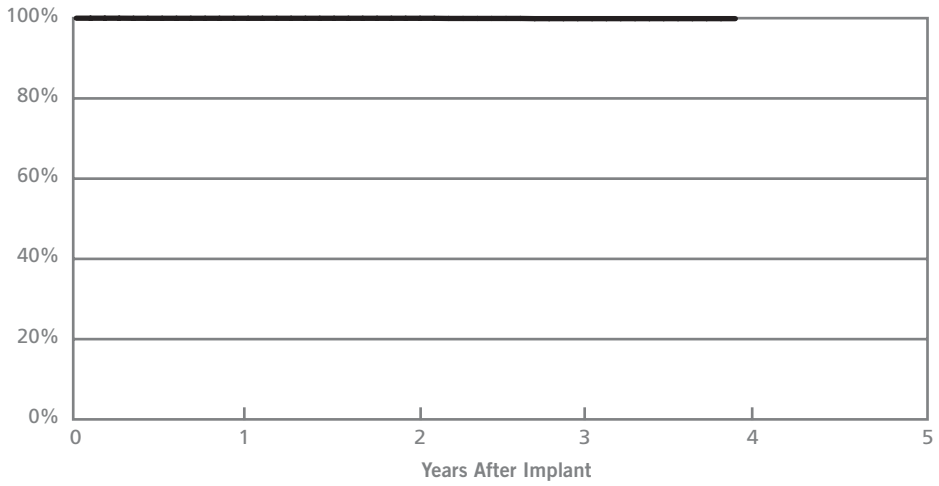


Year	1	2	3	4	
Survival Probability	99.96%	99.93%	99.93%	99.04%	
± 1 standard error	0.03%	0.04%	0.04%	0.42%	

Integrity® ADx XL DR (Model 5366)

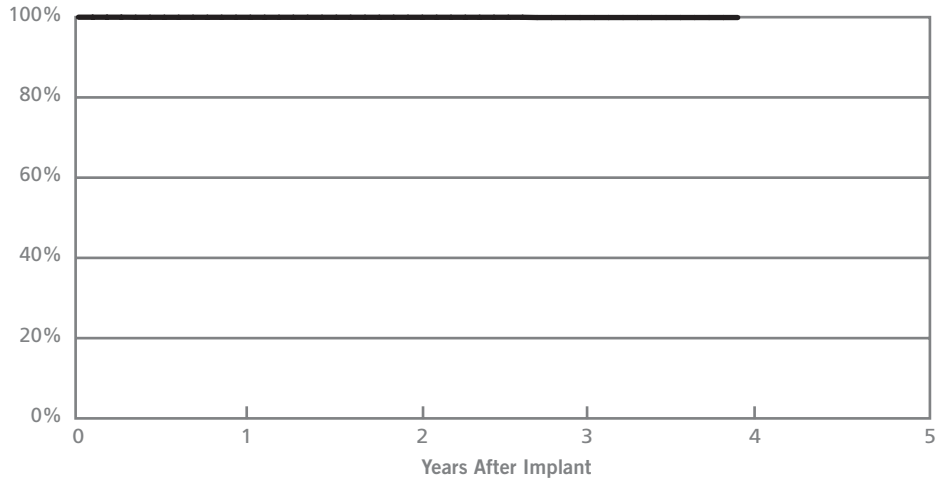
US Market Release	May 2003	Normal Battery Depletion	1
Registered US Implants	7,727	Malfunctions	1
Estimated Active US Implants	6,770	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 47 months	
Survival Probability	99.97%	99.97%	99.88%	99.88%	
± 1 standard error	0.02%	0.02%	0.07%	0.07%	
Sample Size	6800	4300	2200	100	

Excluding Normal Battery Depletion

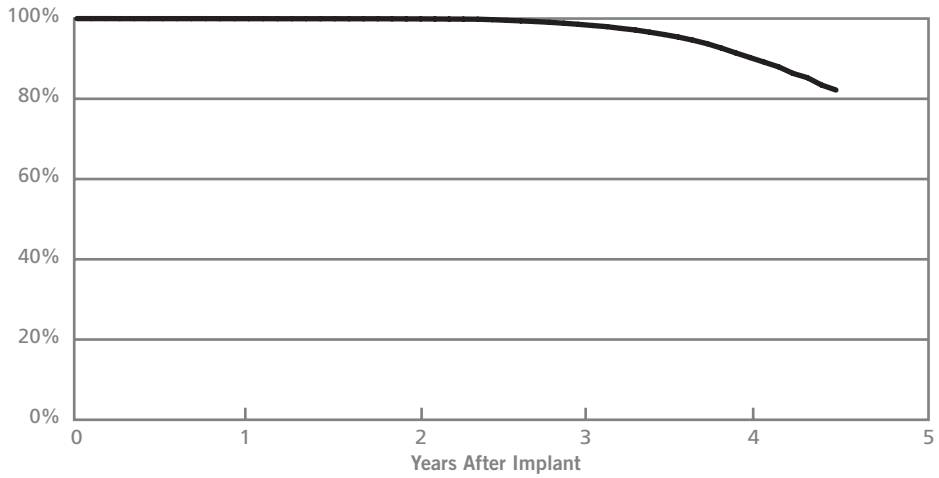


Year	1	2	3	at 47 months	
Survival Probability	99.97%	99.97%	99.91%	99.91%	
± 1 standard error	0.02%	0.02%	0.06%	0.06%	

Identity® ADx DR (Model 5380)

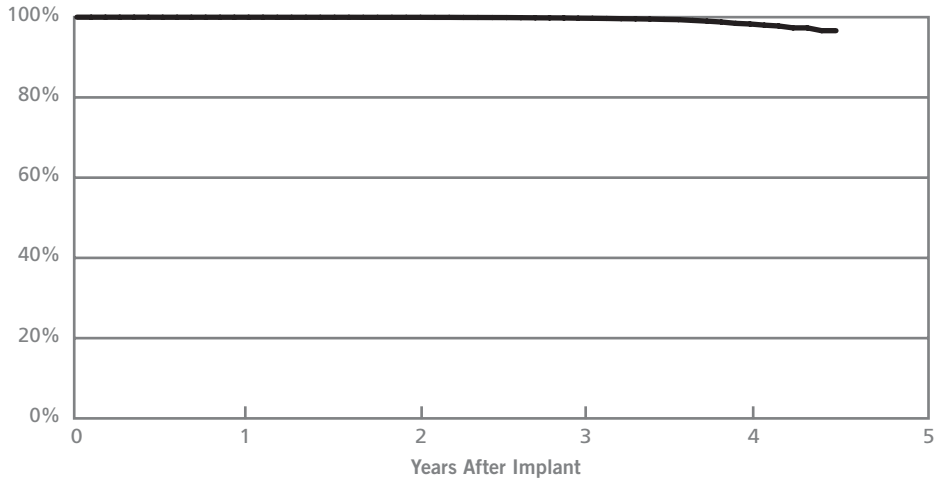
US Market Release	March 2003	Normal Battery Depletion	2,716
Registered US Implants	50,261	Malfunctions	49
Estimated Active US Implants	39,742	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	48
		Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 54 months
Survival Probability	99.97%	99.92%	98.57%	90.28%	82.19%
± 1 standard error	0.01%	0.01%	0.05%	0.28%	0.79%
Sample Size	48300	35700	20600	7800	300

Excluding Normal Battery Depletion

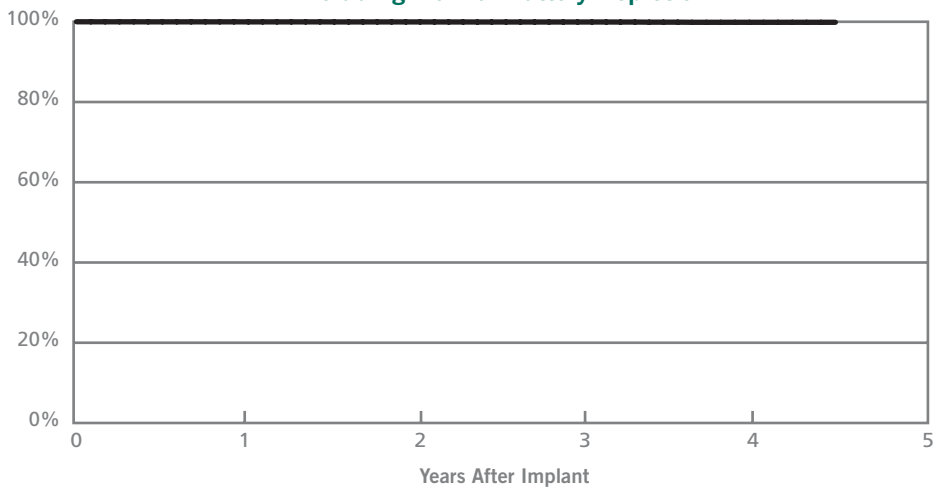


Year	1	2	3	4	at 54 months
Survival Probability	99.98%	99.96%	99.75%	98.30%	96.63%
± 1 standard error	0.01%	0.01%	0.03%	0.19%	0.64%

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

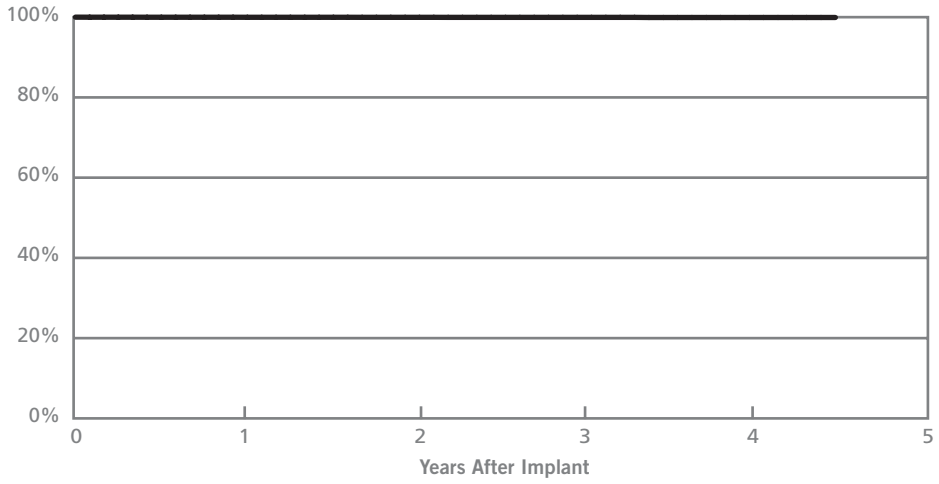
US Market Release	March 2003	Normal Battery Depletion	4
Registered US Implants	56,668	Malfunctions	21
Estimated Active US Implants	49,435	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	20
		Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 54 months
Survival Probability	99.98%	99.96%	99.94%	99.87%	99.87%
± 1 standard error	0.01%	0.01%	0.01%	0.04%	0.04%
Sample Size	52700	37200	19800	6400	200

Excluding Normal Battery Depletion

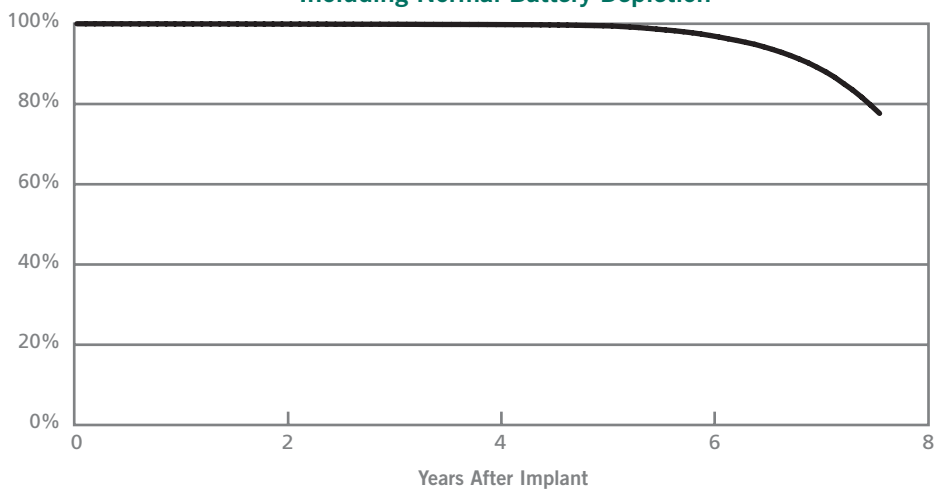


Year	1	2	3	4	at 54 months
Survival Probability	99.98%	99.96%	99.95%	99.92%	99.92%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%

Integrity® AFx DR (Models 5342 & 5346)

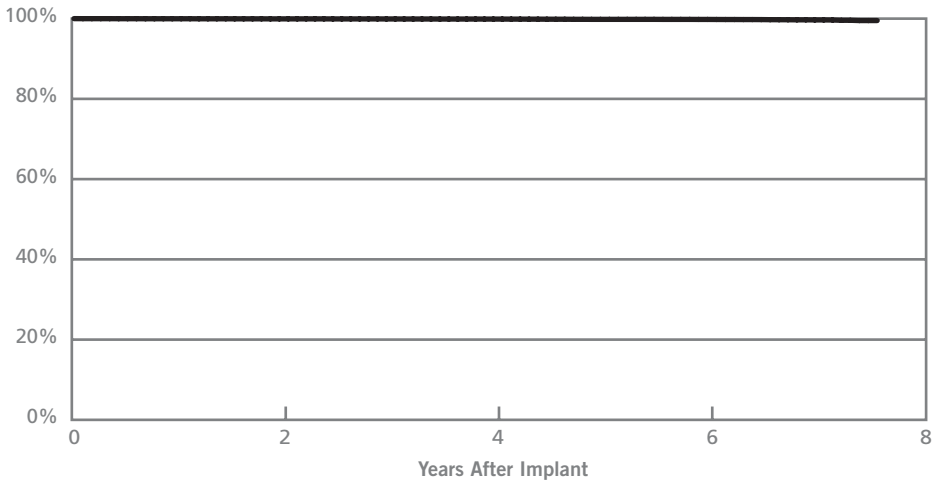
US Market Release	(5342) April 2000 (5346) July 2001	Normal Battery Depletion	9,849
		Malfunctions	60
Registered US Implants	47,339	Malfunctions w/ Compromised Therapy	6
Estimated Active US Implants	25,931	Malfunctions w/o Compromised Therapy	54
Estimated Longevity	6.3 Years	Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 91 months
Survival Probability	99.93%	99.80%	97.08%	77.66%
± 1 standard error	0.01%	0.02%	0.06%	0.18%
Sample Size	42200	34400	22400	500

Excluding Normal Battery Depletion

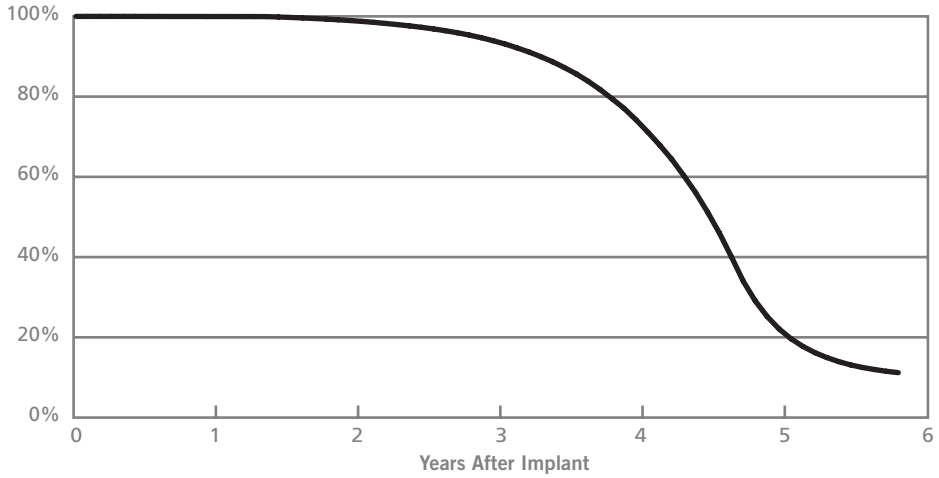


Year	2	4	6	at 91 months
Survival Probability	99.94%	99.89%	99.80%	99.52%
± 1 standard error	0.01%	0.02%	0.03%	0.10%

Identity® (Model 5370)

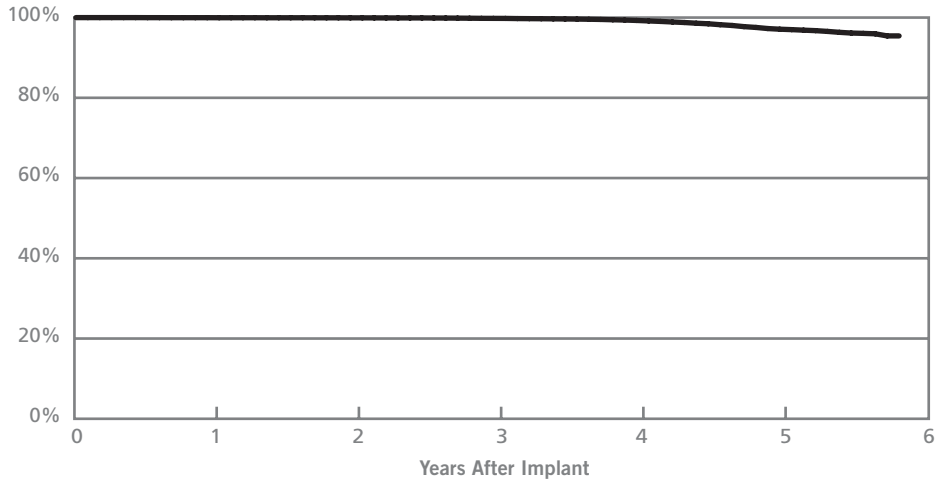
US Market Release	November 2001	Normal Battery Depletion	16,404
Registered US Implants	57,917	Malfunctions	223
Estimated Active US Implants	29,212	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (19 related to Advisory)	218
		Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 70 months
Survival Probability	99.96%	98.96%	93.94%	74.20%	22.09%	11.20%
± 1 standard error	0.01%	0.01%	0.04%	0.11%	0.28%	0.54%
Sample Size	57500	49400	42000	32600	19300	400

Excluding Normal Battery Depletion

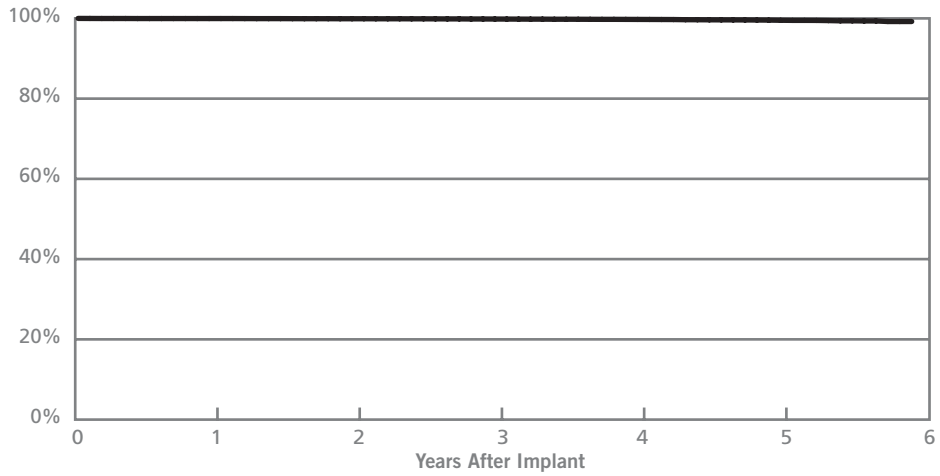


Year	1	2	3	4	5	at 70 months
Survival Probability	99.97%	99.93%	99.80%	99.28%	97.10%	95.43%
± 1 standard error	0.01%	0.01%	0.02%	0.05%	0.16%	0.42%

Identity® XL (Model 5376)

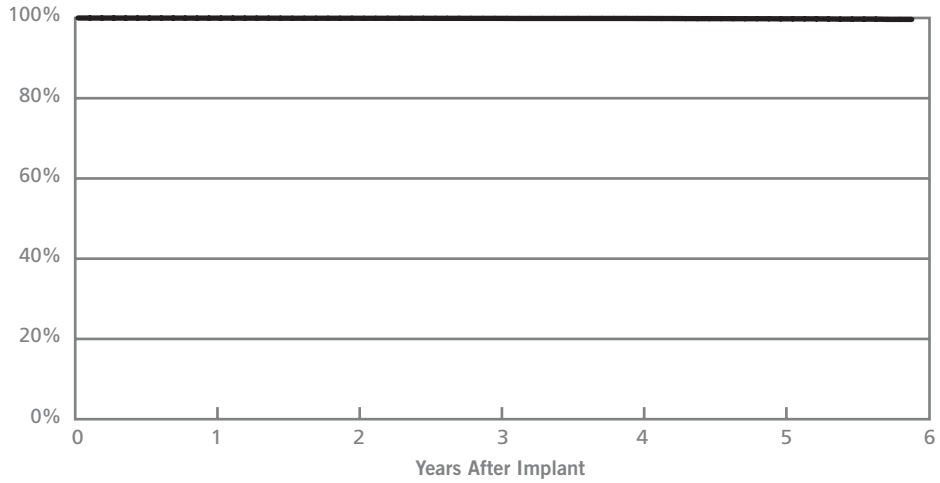
US Market Release	November 2001	Normal Battery Depletion	63
Registered US Implants	50,948	Malfunctions	58
Estimated Active US Implants	37,811	Malfunctions w/ Compromised Therapy (0 related to Advisory)	6
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (5 related to Advisory)	52
		Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 71 months
Survival Probability	99.96%	99.91%	99.84%	99.74%	99.53%	99.22%
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%	0.12%
Sample Size	50300	43300	35700	27000	15600	200

Excluding Normal Battery Depletion

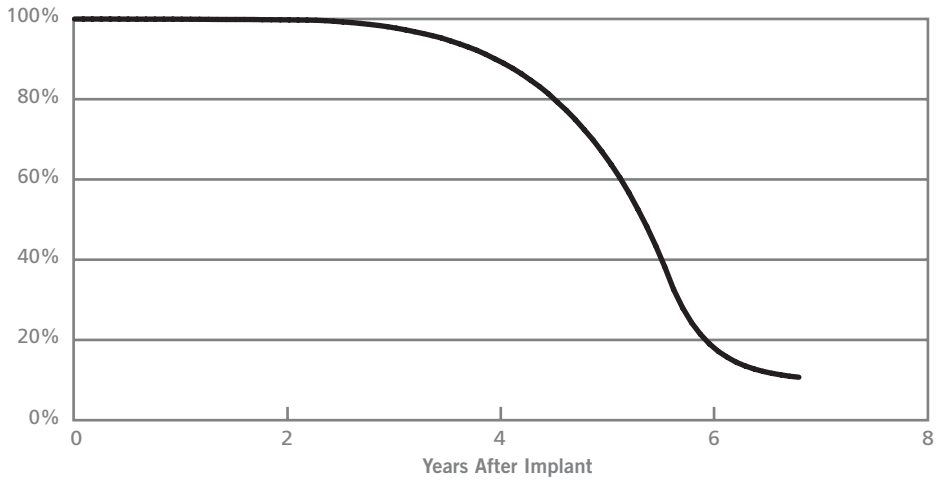


Year	1	2	3	4	5	at 71 months
Survival Probability	99.96%	99.93%	99.90%	99.87%	99.78%	99.64%
± 1 standard error	0.01%	0.01%	0.02%	0.02%	0.03%	0.08%

Integrity® µ DR (Model 5336)

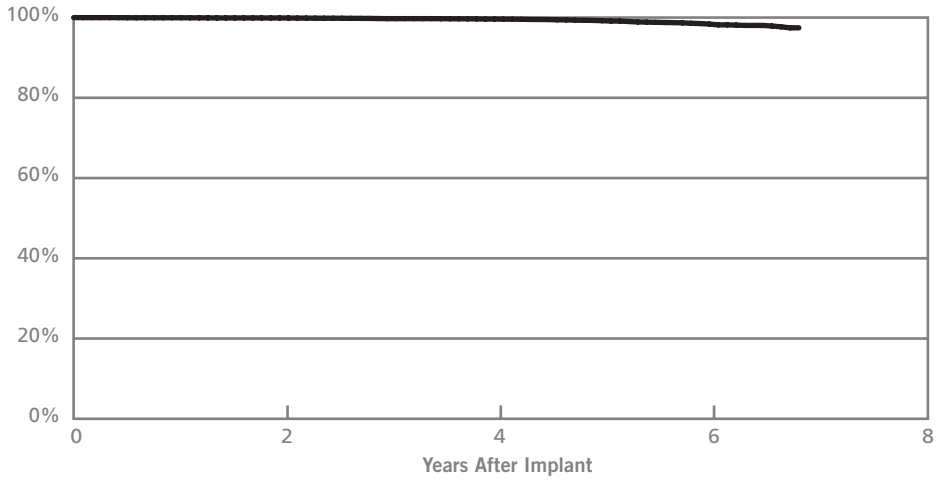
US Market Release	December 2000	Normal Battery Depletion	7,828
Registered US Implants	29,318	Malfunctions	73
Estimated Active US Implants	1,725	Malfunctions w/ Compromised Therapy	7
Estimated Longevity	4.0 Years	Malfunctions w/o Compromised Therapy	66
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 82 months
Survival Probability	99.79%	90.06%	19.02%	10.71%
± 1 standard error	0.03%	0.14%	0.42%	0.66%
Sample Size	25300	18600	6700	200

Excluding Normal Battery Depletion

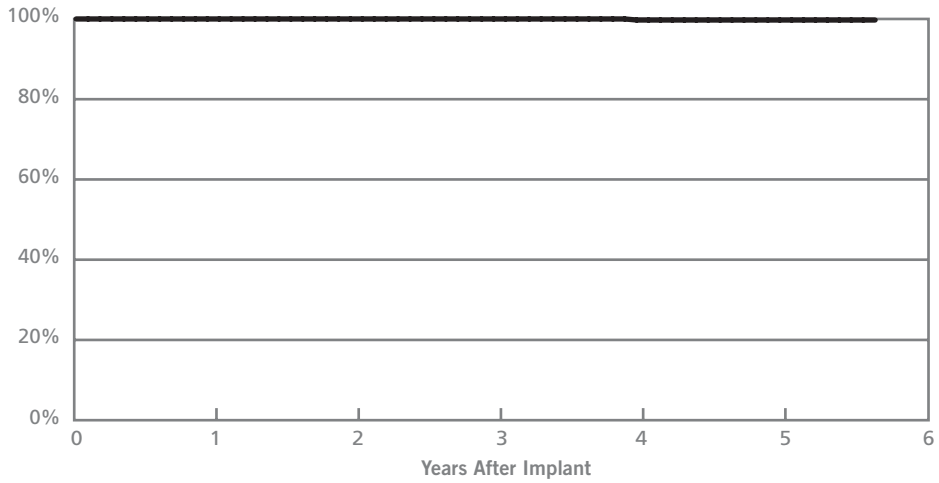


Year	2	4	6	at 82 months
Survival Probability	99.90%	99.63%	98.38%	97.44%
± 1 standard error	0.02%	0.04%	0.16%	0.42%

Affinity® VDR (Model 5430)

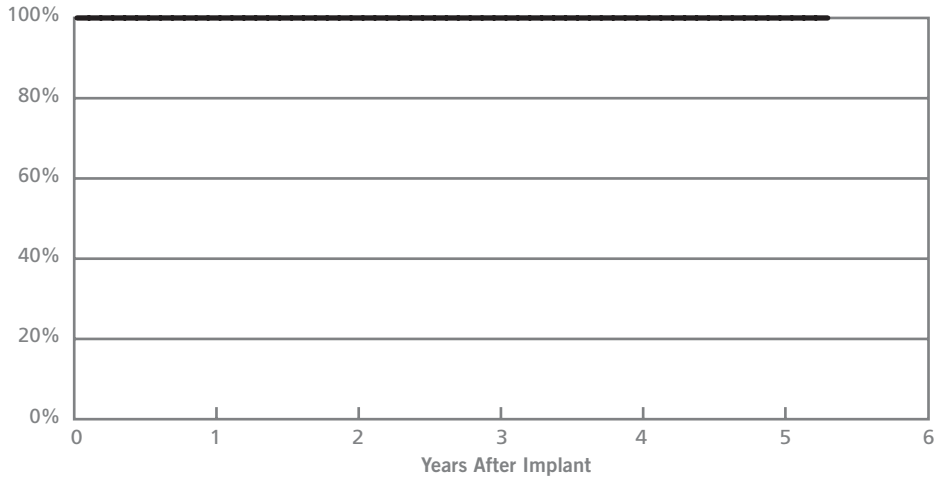
US Market Release	April 2000	Normal Battery Depletion	2
Registered US Implants	665	Malfunctions	0
Estimated Active US Implants	307	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	5	at 68 months
Survival Probability	100.00%	100.00%	100.00%	99.74%	99.74%	99.74%
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.26%	0.26%
Sample Size	700	600	500	400	300	200

Excluding Normal Battery Depletion

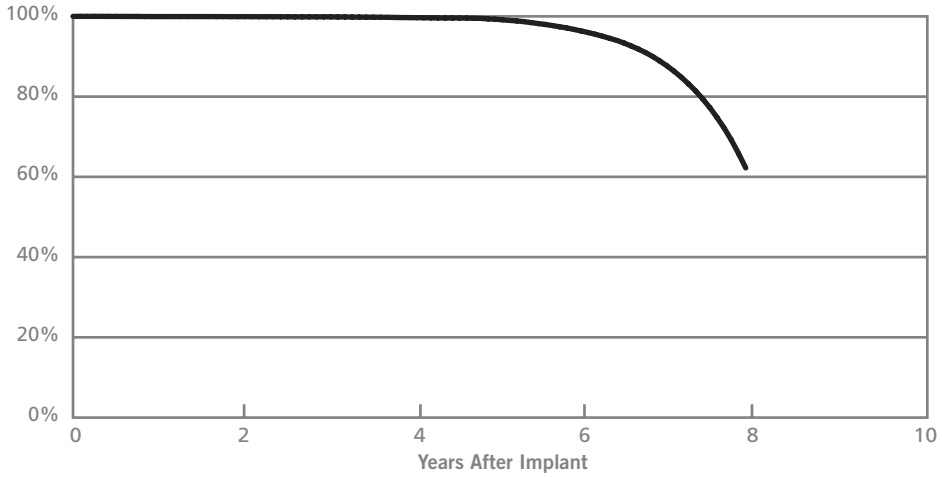


Year	1	2	3	4	5	at 68 months
Survival Probability	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
± 1 standard error	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

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

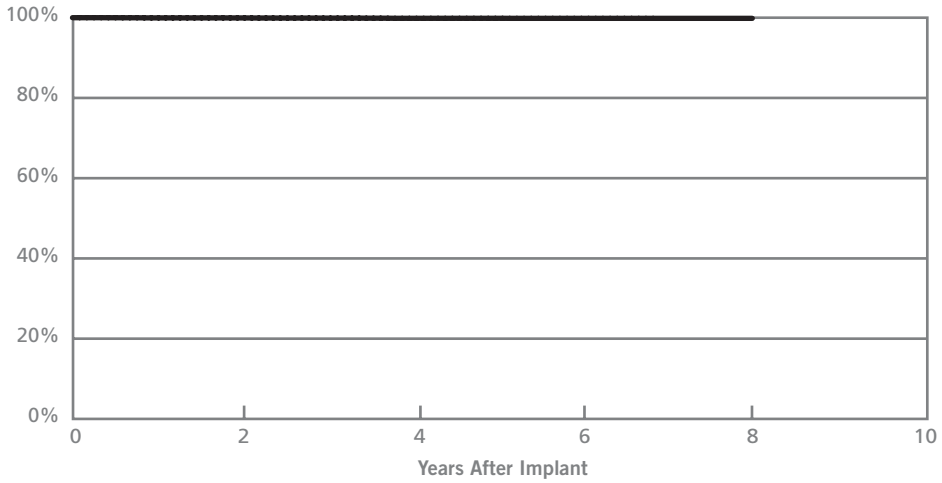
US Market Release	June 1999	Normal Battery Depletion	7,801
Registered US Implants	21,782	Malfunctions	25
Estimated Active US Implants	9,527	Malfunctions w/ Compromised Therapy	3
Estimated Longevity	6.3 Years	Malfunctions w/o Compromised Therapy	22
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	8	
Survival Probability	99.93%	99.69%	96.36%	58.25%	
± 1 standard error	0.02%	0.04%	0.12%	0.27%	
Sample Size	18900	14600	10000	100	

Excluding Normal Battery Depletion

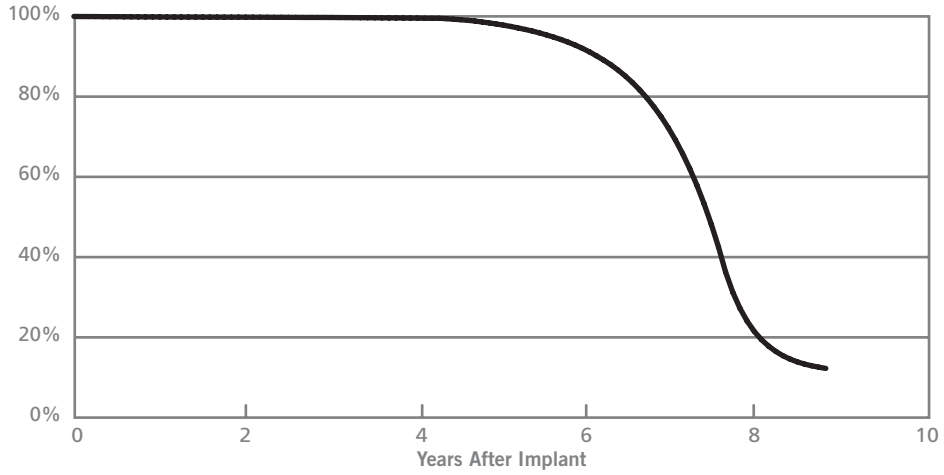


Year	2	4	6	8	
Survival Probability	99.94%	99.85%	99.84%	99.84%	
± 1 standard error	0.02%	0.03%	0.03%	0.03%	

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

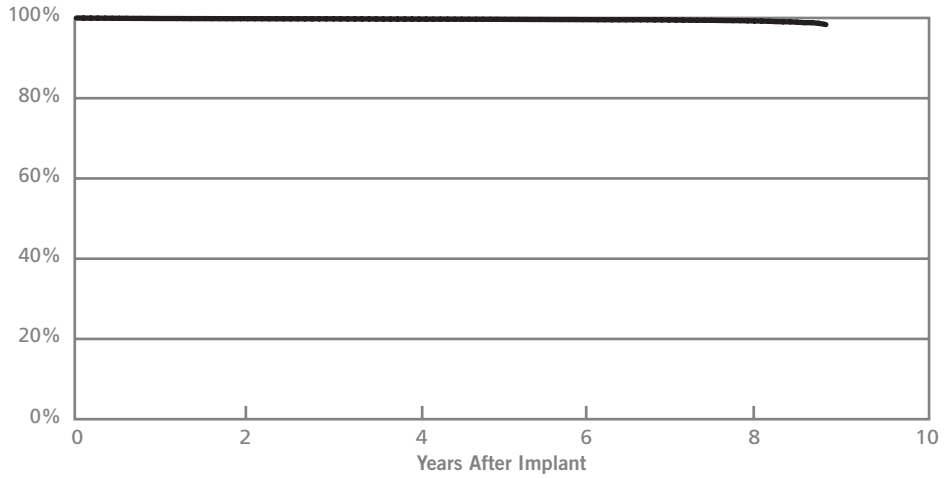
US Market Release	(5330) January 1999 (5230/5331) June 1999	Normal Battery Depletion	19,544
		Malfunctions	207
Registered US Implants	65,495	Malfunctions w/ Compromised Therapy (0 related to Advisory)	15
Estimated Active US Implants	25,708	Malfunctions w/o Compromised Therapy (64 related to Advisory)	192
Estimated Longevity	6.3 Years	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



Year	2	4	6	8	at 106 months
Survival Probability	99.81%	99.58%	92.04%	21.50%	12.26%
± 1 standard error	0.02%	0.03%	0.07%	0.16%	0.32%
Sample Size	57900	46900	33100	18000	500

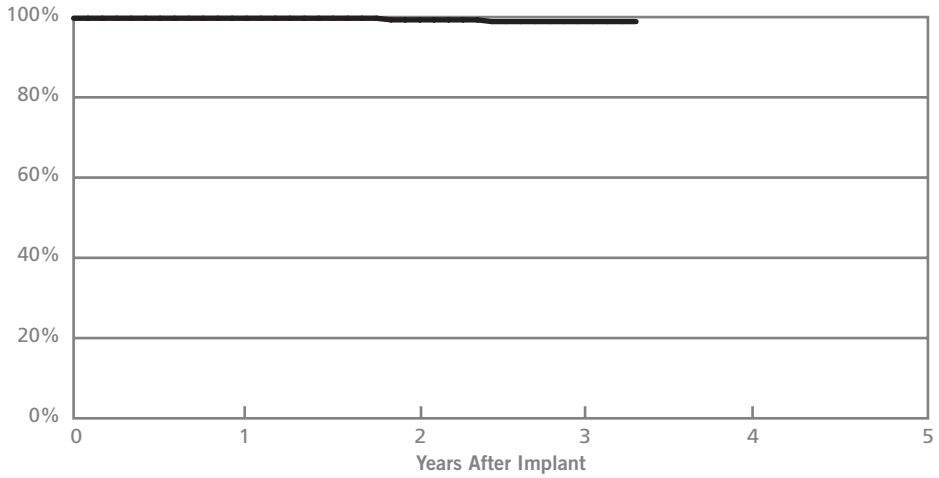
Excluding Normal Battery Depletion



Year	2	4	6	8	at 106 months
Survival Probability	99.82%	99.72%	99.58%	99.26%	98.36%
± 1 standard error	0.02%	0.02%	0.03%	0.06%	0.21%

Pulse Generators

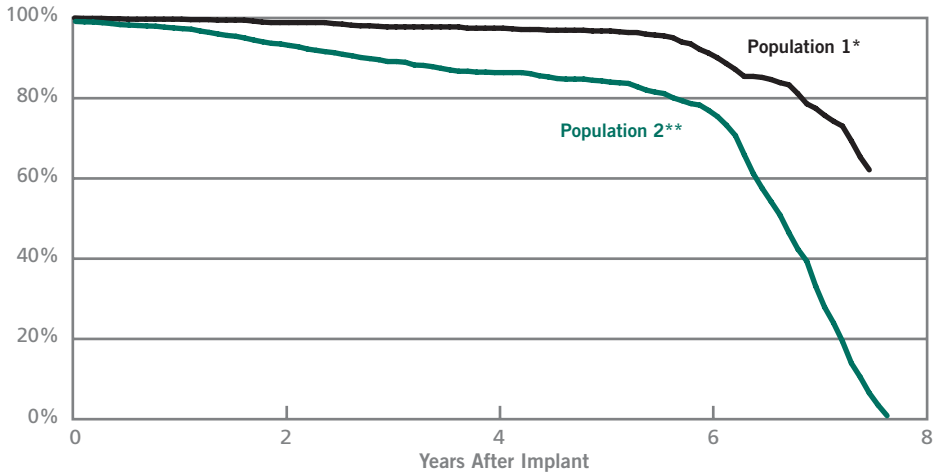
AddVent® (Model 2060)	
US Market Release	May 1999
Registered US Implants	353
Estimated Longevity	9.3 Years
Number of Advisories	None



Year	1	2	3	at 40 months	
Survival Probability	99.71%	99.31%	98.88%	98.88%	
± 1 standard error	0.29%	0.49%	0.66%	0.66%	
Sample Size	400	300	200	200	

Meta™ DDDR (Model 1256D)
Tempo® D (Model 2902); Tempo® DR (Model 2102)

Population 1*		Population 2**	
(These models are no longer being manufactured)		(These models are no longer being manufactured)	
US Market Release	(1256D) April 1997 (2902/2102) August 1997	US Market Release	(1256D) April 1997 (2902/2102) August 1997
Registered US Implants	1,036	Registered US Implants	2,578
Estimated Longevity	(1256D) 5.0 Years (2902/2102) 5.5 Years	Estimated Longevity	(1256D) 5.0 Years (2902/2102) 5.5 Years
Number of Advisories	None	Number of Advisories (see pages 168-173)	(1256D/2102) Three (2902) Two



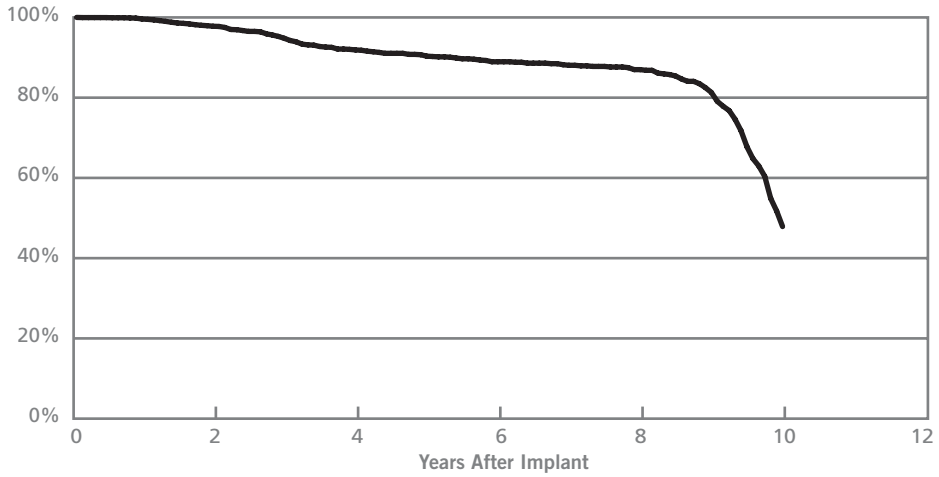
Population 1*

Year	2	4	6	at 90 months
Survival Probability	98.85%	97.45%	91.25%	62.15%
± 1 standard error	0.36%	0.57%	1.16%	2.47%
Sample Size	900	700	500	500

Population 2**

Year	2	4	6	at 93 months
Survival Probability	93.52%	86.38%	76.95%	0.00%
± 1 standard error	0.26%	0.72%	1.01%	0.00%
Sample Size	2200	1400	800	100

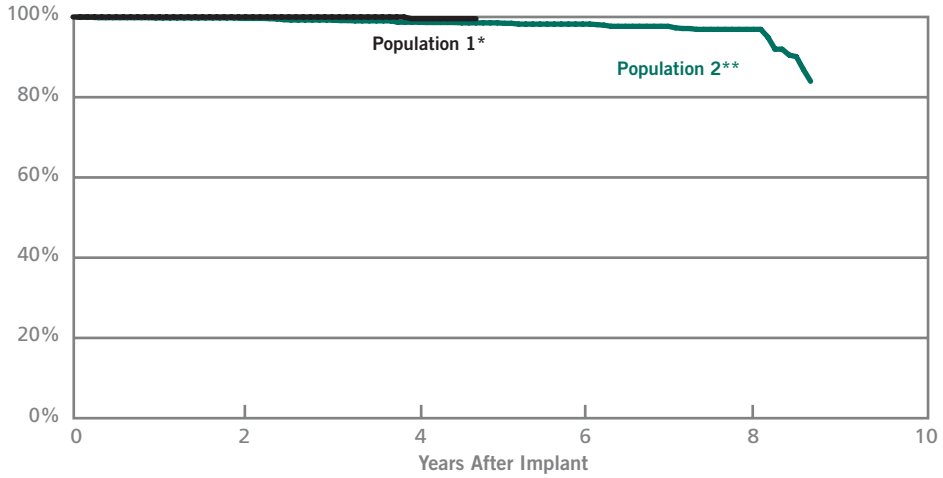
Meta™ DDDR (Model 1256)	
US Market Release	April 1997
Registered US Implants	2,579
Estimated Longevity	6.6 Years
Number of Advisories (see pages 168-173)	One



Year	2	4	6	8	10	
Survival Probability	97.80%	91.90%	88.95%	86.99%	47.88%	
± 1 standard error	0.30%	0.64%	0.81%	0.95%	2.25%	
Sample Size	2200	1600	1000	600	400	

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	436	Registered US Implants	2,291
Estimated Longevity	5.0 Years	Estimated Longevity	5.0 Years
Number of Advisories	None	Number of Advisories (see pages 168-173)	Two



Population 1*

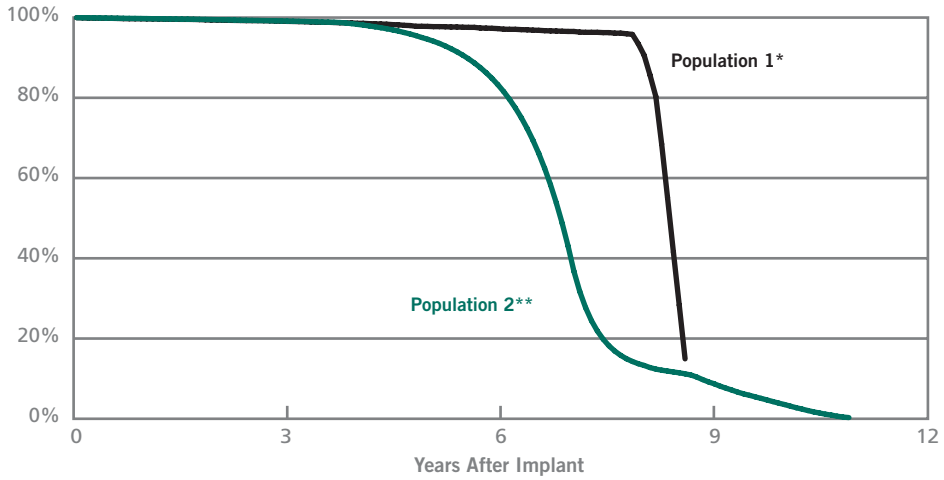
Year	2	4	at 58 months		
Survival Probability	100.00%	99.58%	99.07%		
± 1 standard error	0.00%	0.00%	0.42%		
Sample Size	400	300	200		

Population 2**

Year	2	4	6	8	at 104 months
Survival Probability	99.64%	98.70%	98.22%	96.91%	83.97%
± 1 standard error	0.11%	0.29%	0.37%	0.59%	1.89%
Sample Size	1900	1400	1000	400	200

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	58,754
Estimated Longevity	5.0 Years	Estimated Longevity	5.0 Years
Number of Advisories	None	Number of Advisories (see pages 168-173)	Two



Population 1*

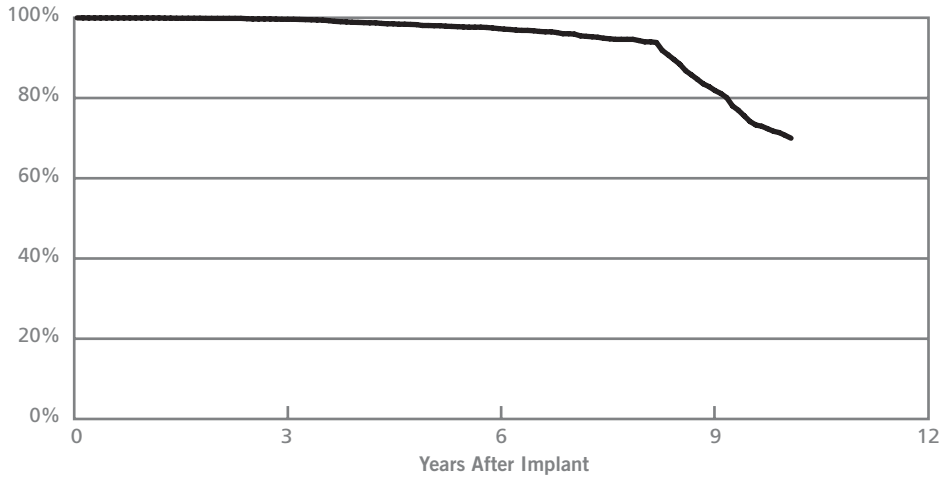
Year	3	6	at 105 months	
Survival Probability	99.09%	97.32%	14.94%	
± 1 standard error	0.12%	0.24%	1.44%	
Sample Size	5500	3600	1000	

Population 2**

Year	3	6	9	at 133 months
Survival Probability	99.16%	84.85%	9.77%	0.30%
± 1 standard error	0.04%	0.08%	0.35%	0.24%
Sample Size	47300	32200	8000	1200

Paragon™ III (Models 2304, 2314, 2315)

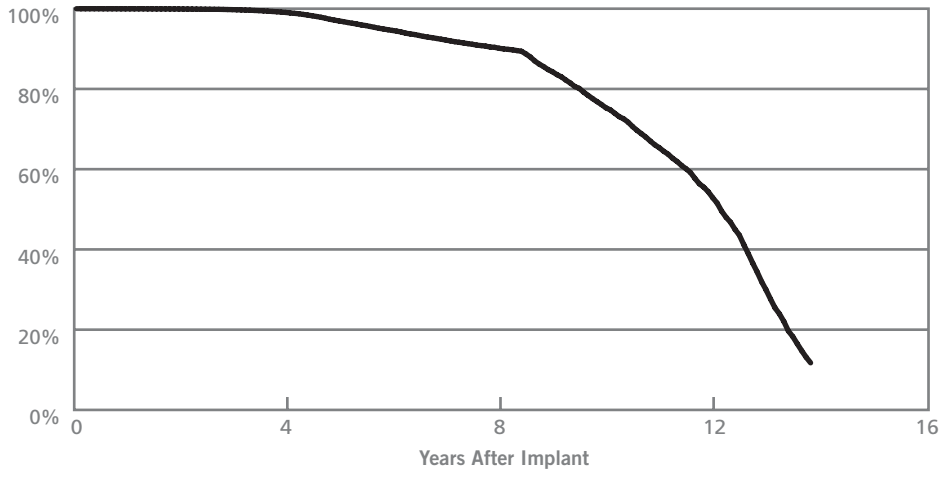
US Market Release	October 1994
Registered US Implants	3,821
Estimated Longevity	6.3 Years
Number of Advisories	None



Year	3	6	9	at 123 months
Survival Probability	99.62%	97.45%	83.53%	69.99%
± 1 standard error	0.11%	0.35%	1.43%	2.15%
Sample Size	2800	1800	600	300

Synchrony® III (Models 2028 & 2029)

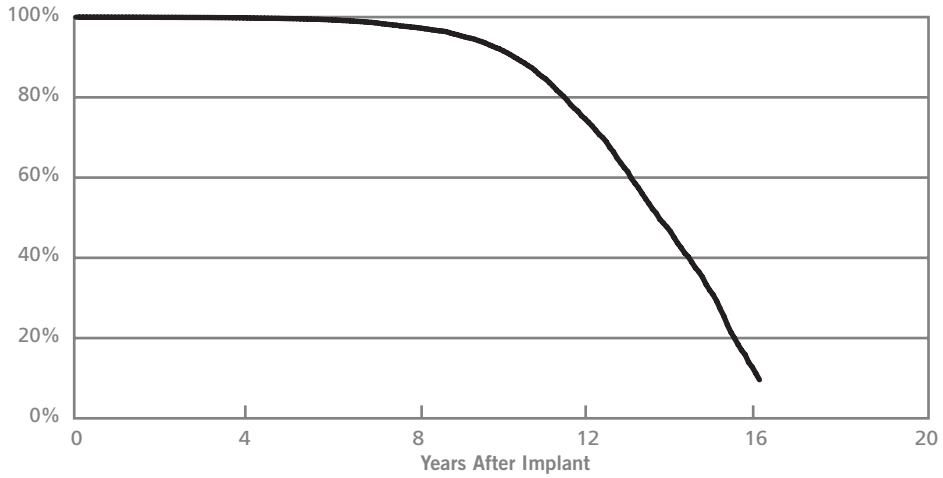
US Market Release	February 1993
Registered US Implants	43,429
Estimated Longevity	5.5 Years
Number of Advisories	None



Year	4	8	12	at 166 months
Survival Probability	99.07%	90.13%	52.89%	11.74%
± 1 standard error	0.05%	0.24%	0.95%	0.80%
Sample Size	31600	9600	1500	300

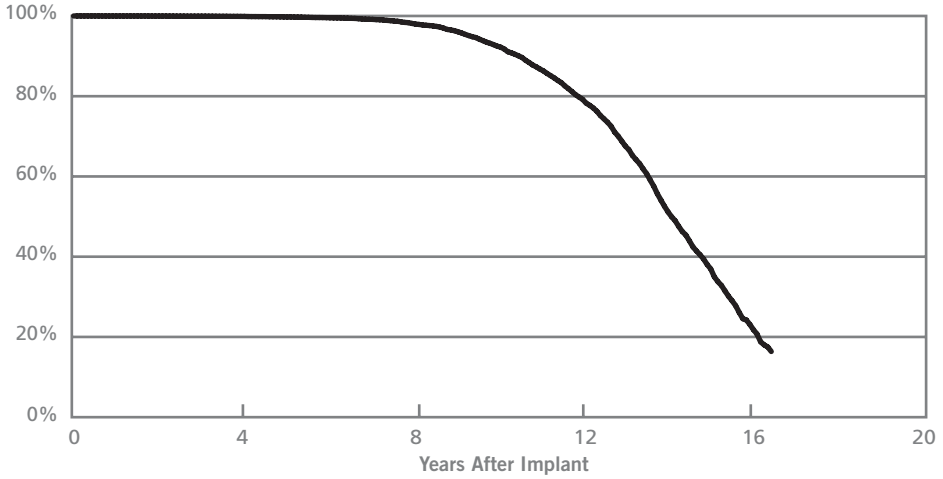
Pulse Generators

Synchrony® II (Models 2022 & 2023)	
US Market Release	June 1990
Registered US Implants	47,277
Estimated Longevity	8.0 Years
Number of Advisories	None



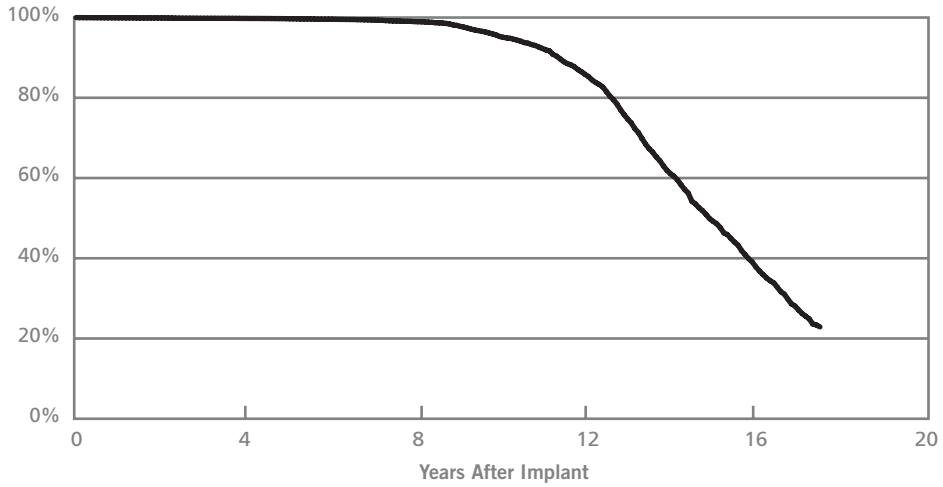
Year	4	8	12	16	at 193 months
Survival Probability	99.81%	97.45%	74.66%	11.17%	9.62%
± 1 standard error	0.02%	0.10%	0.48%	0.68%	0.65%
Sample Size	35800	21100	6300	500	200

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



Year	4	8	12	16	at 197 months
Survival Probability	99.89%	98.14%	79.21%	21.79%	16.37%
± 1 standard error	0.02%	0.12%	0.61%	1.06%	1.00%
Sample Size	20000	10800	3300	400	200

Paragon™ (Models 2010, 2011 & 2012)	
US Market Release	September 1988
Registered US Implants	16,677
Estimated Longevity	7.2 Years
Number of Advisories	None



Year	4	8	12	16	at 210 months
Survival Probability	99.78%	98.99%	85.85%	37.86%	22.91%
± 1 standard error	0.04%	0.11%	0.59%	1.25%	1.25%
Sample Size	11800	6700	2800	600	200

SUMMARY INFORMATION

Pulse Generators
Dual-Chamber

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Pulse Generators

Including 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	2875	2847	0	0	0	0	0	0
5826	Zephyr XL DR	Mar-07	9837	9776	0	0	0	0	0	0
5810	Victory DR	Dec-05	18326	17404	0	0	0	0	0	0
5816	Victory XL	Dec-05	41419	40101	0	11	0	0	11	0
5366	Integrity ADx XL DR	May-03	7727	6770	0	1	0	0	1	1
5356/5357/5256	Verity ADx XL DR/ DR(M/S)/DC	May-03	14915	12429	0	6	0	1	7	3
5360	Integrity ADx DR	May-03	5726	4561	0	2	0	0	2	697
5380	Identity ADx DR	Mar-03	50261	39742	1	40	0	8	49	2716
5386/5286	Identity ADx XL DR/DC	Mar-03	56668	49435	1	20	0	0	21	4
5370	Identity	Nov-01	57917	29212	5	190	19	9	223	16404
5376	Identity XL	Nov-01	50948	37811	6	46	5	1	58	63
5336	Integrity µ DR	Dec-00	29318	1725	7	66	0	0	73	7828
5342/5346	Integrity AFx DR	Apr-00/Jul-01	47339	25931	6	54	0	0	60	9849
5430	Affinity VDR	Apr-00	665	307	0	0	0	0	0	2
5326/5226	Entity DR/DC	Jun-99	21782	9527	3	21	0	1	25	7801
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65495	25708	15	128	64	0	207	19544

Excluding 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
5820	Zephyr DR	Mar-07	2875	2847	0	0	0	0	0
5826	Zephyr XL DR	Mar-07	9837	9776	0	0	0	0	0
5810	Victory DR	Dec-05	18326	17404	0	0	0	0	0
5816	Victory XL	Dec-05	41419	40101	0	11	0	0	11
5366	Integrity ADx XL DR	May-03	7727	6770	0	1	0	0	1
5356/5357/5256	Verity ADx XL DR/ DR(M/S)/DC	May-03	14915	12429	0	6	0	1	7
5360	Integrity ADx DR	May-03	5726	4561	0	2	0	0	2
5380	Identity ADx DR	Mar-03	50261	39742	1	40	0	8	49
5386/5286	Identity ADx XL DR/DC	Mar-03	56668	49435	1	20	0	0	21
5370	Identity	Nov-01	57917	29212	5	190	19	9	223
5376	Identity XL	Nov-01	50948	37811	6	46	5	1	58
5336	Integrity µ DR	Dec-00	29318	1725	7	66	0	0	73
5342/5346	Integrity AFx DR	Apr-00/Jul-01	47339	25931	6	54	0	0	60
5430	Affinity VDR	Apr-00	665	307	0	0	0	0	0
5326/5226	Entity DR/DC	Jun-99	21782	9527	3	21	0	1	25
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65495	25708	15	128	64	0	207

**Based on returned product analysis as of December 31, 2007.*

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
5820	Zephyr DR**								
5826	Zephyr XL DR**								
5810	Victory DR	100.00%							
5816	Victory XL	99.95%							
5366	Integrity ADx XL DR	99.97%	99.97%	99.88%					
5356/5357/5256	Verity ADx XL DR/ DR(M/S)/DC	99.96%	99.96%	99.89%	99.72%				
5360	Integrity ADx DR	99.92%	99.15%	94.75%	76.92%				
5380	Identity ADx DR	99.97%	99.92%	98.57%	90.28%				
5386/5286	Identity ADx XL DR/DC	99.98%	99.96%	99.94%	99.87%				
5370	Identity	99.96%	98.96%	93.94%	74.20%	22.09%			
5376	Identity XL	99.96%	99.91%	99.84%	99.74%	99.53%			
5336	Integrity µ DR	99.95%	99.79%	98.07%	90.06%	66.87%	19.02%		
5342/5346	Integrity AFx DR	99.96%	99.93%	99.87%	99.80%	99.50%	97.08%	89.14%	
5430	Affinity VDR	100.00%	100.00%	100.00%	99.74%	99.74%			
5326/5226	Entity DR/DC	99.95%	99.93%	99.88%	99.69%	99.29%	96.36%	87.65%	58.25%
5330/5331/5230	Affinity DR/DC	99.87%	99.81%	99.73%	99.58%	98.10%	92.04%	72.23%	21.50%

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
5820	Zephyr DR**								
5826	Zephyr XL DR**								
5810	Victory DR	100.00%							
5816	Victory XL	99.95%							
5366	Integrity ADx XL DR	99.97%	99.97%	99.91%					
5356/5357/5256	Verity ADx XL DR/ DR(M/S)/DC	99.96%	99.96%	99.94%	99.84%				
5360	Integrity ADx DR	99.96%	99.93%	99.93%	99.04%				
5380	Identity ADx DR	99.98%	99.96%	99.75%	98.30%				
5386/5286	Identity ADx XL DR/DC	99.98%	99.96%	99.95%	99.92%				
5370	Identity	99.97%	99.93%	99.80%	99.28%	97.10%			
5376	Identity XL	99.96%	99.93%	99.90%	99.87%	99.78%			
5336	Integrity µ DR	99.95%	99.90%	99.73%	99.63%	99.21%	98.38%		
5342/5346	Integrity AFx DR	99.97%	99.94%	99.92%	99.89%	99.82%	99.80%	99.68%	
5430	Affinity VDR	100.00%	100.00%	100.00%	100.00%	100.00%			
5326/5226	Entity DR/DC	99.95%	99.94%	99.90%	99.85%	99.85%	99.84%	99.84%	99.84%
5330/5331/5230	Affinity DR/DC	99.87%	99.82%	99.78%	99.72%	99.66%	99.58%	99.51%	99.26%

*Based on returned product analysis as of December 31, 2007.

**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.

PULSE GENERATORS

Single-Chamber

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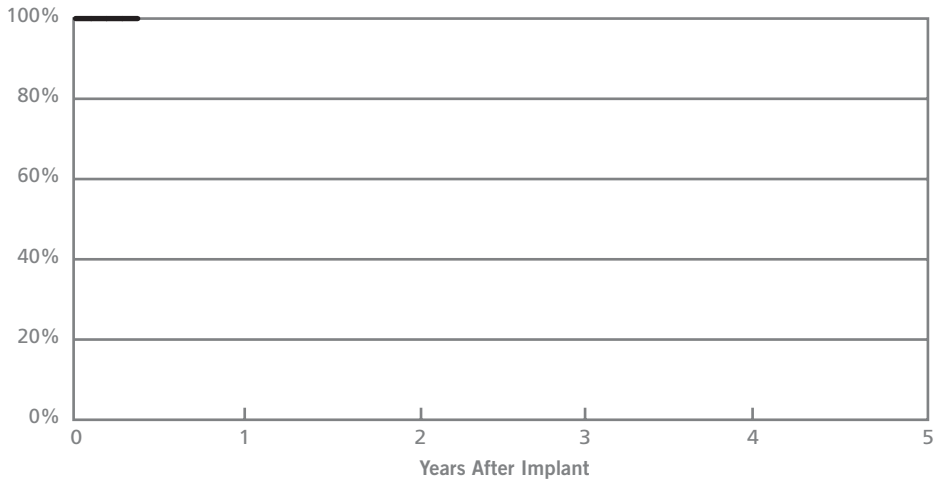
Zephyr™ XL SR (Model 5626)

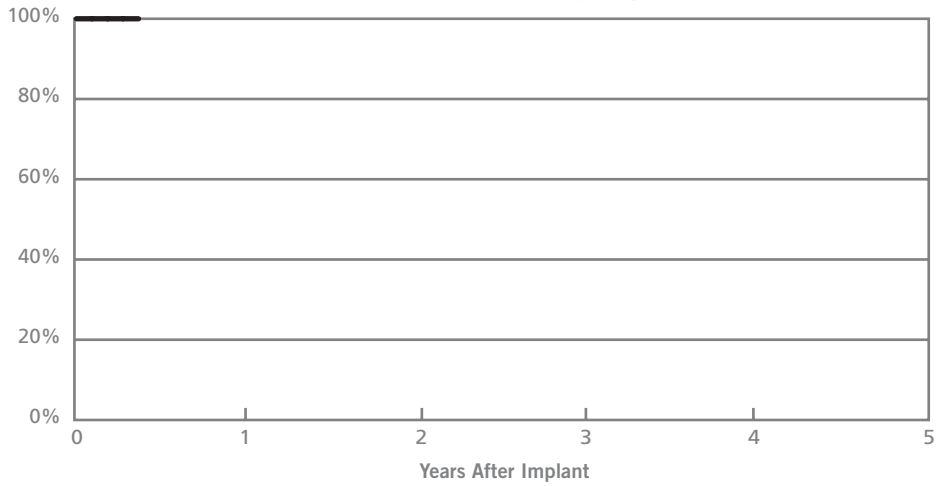
US Market Release	May 2007	Normal Battery Depletion	0
Registered US Implants	1,294	Malfunctions	0
Estimated Active US Implants	1,283	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	15.8 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	100				

Excluding Normal Battery Depletion

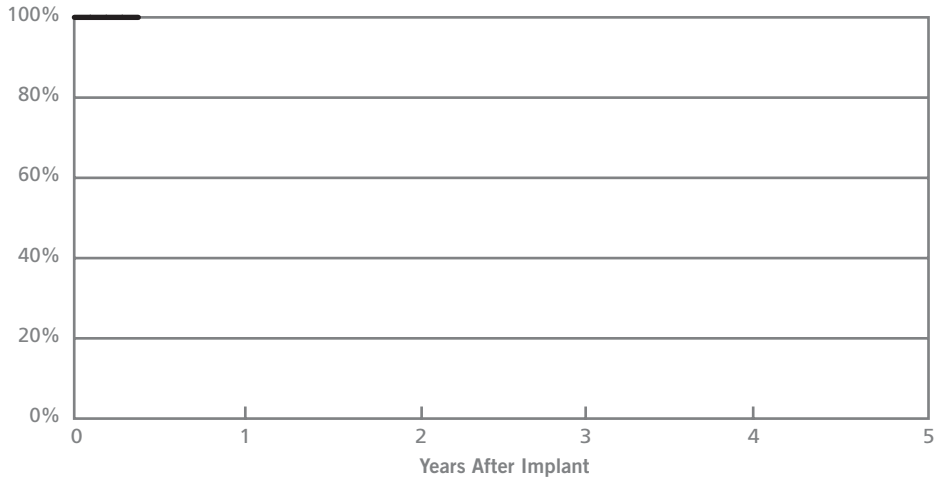


Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Zephyr™ SR (Model 5620)

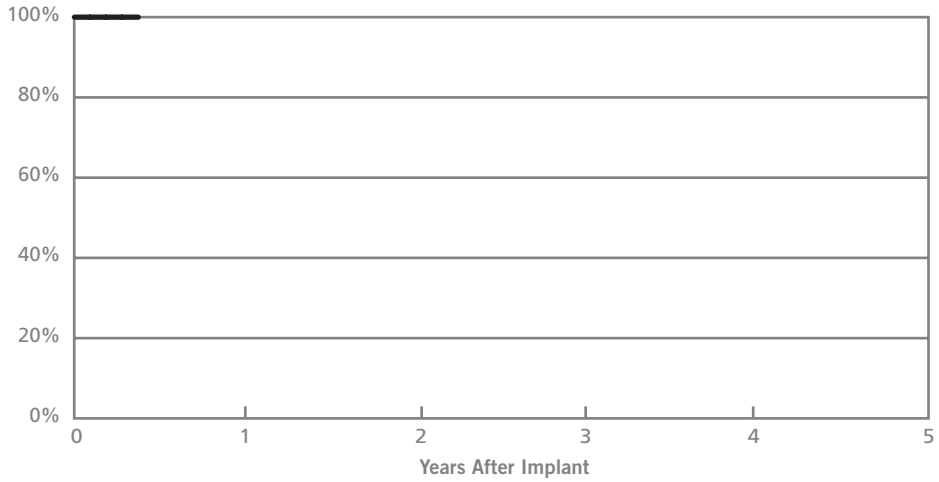
US Market Release	March 2007	Normal Battery Depletion	0
Registered US Implants	866	Malfunctions	0
Estimated Active US Implants	853	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.8 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	100				

Excluding Normal Battery Depletion

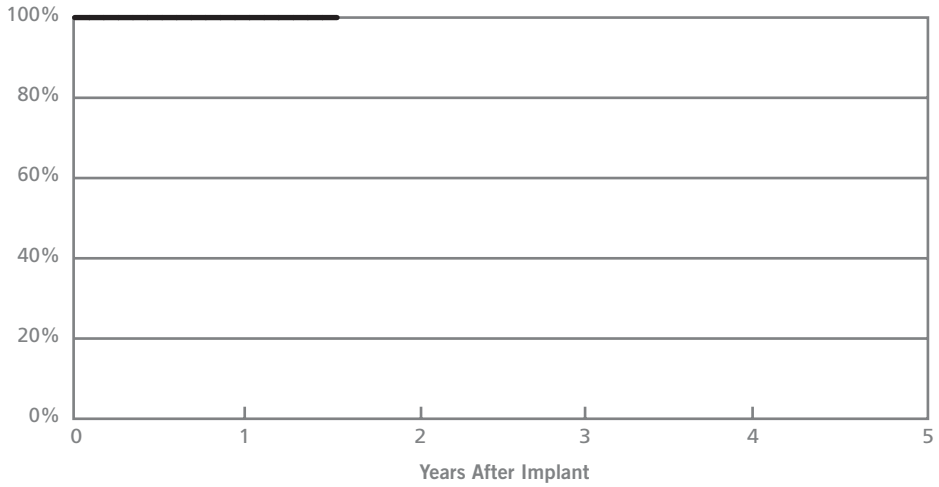


Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Victory® SR (Model 5610)

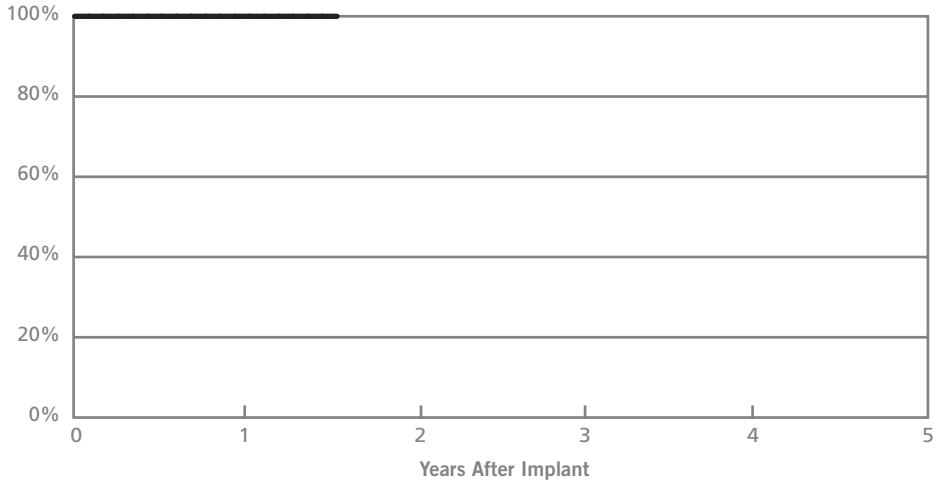
US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	8,574	Malfunctions	0
Estimated Active US Implants	8,022	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.2 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	at 20 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			
Sample Size	5900	200			

Excluding Normal Battery Depletion

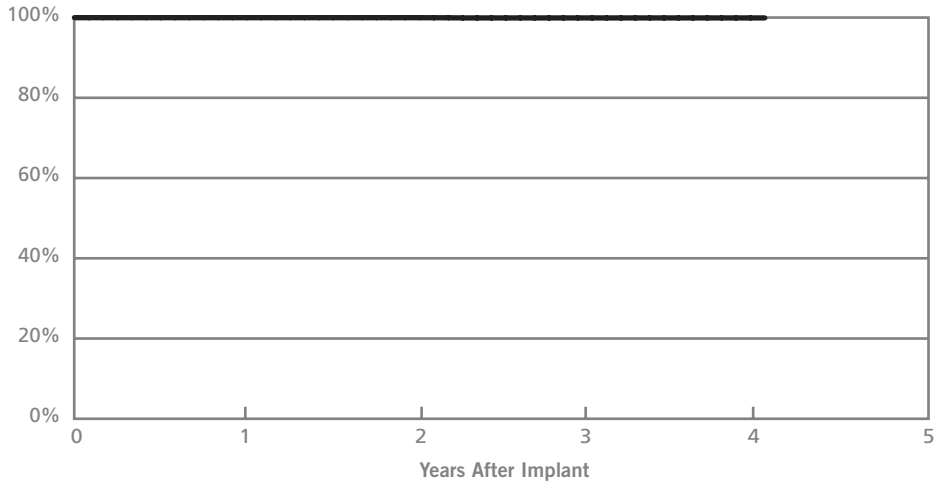


Year	1	at 20 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

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

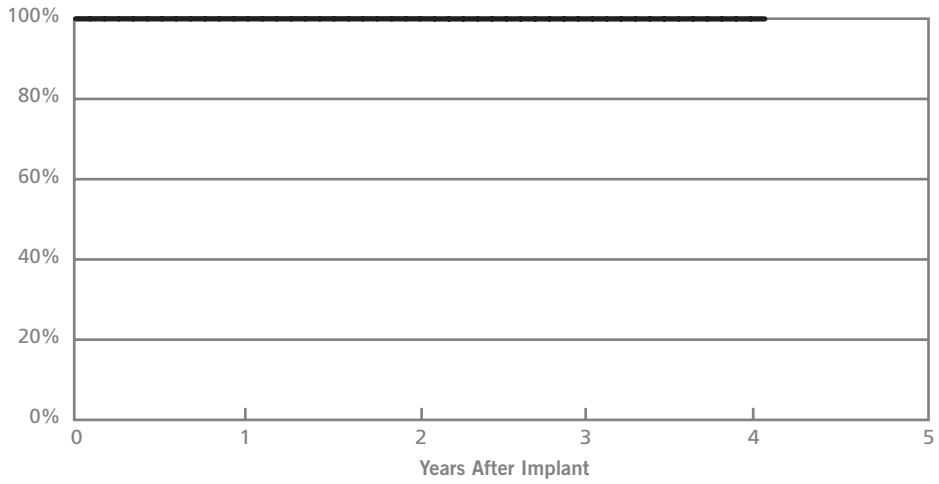
US Market Release	May 2003	Normal Battery Depletion	1
Registered US Implants	11,279	Malfunctions	4
Estimated Active US Implants	9,030	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	10.2 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	at 49 months
Survival Probability	99.97%	99.97%	99.91%	99.91%	99.91%
± 1 standard error	0.02%	0.02%	0.05%	0.05%	0.05%
Sample Size	9900	5700	2900	1000	100

Excluding Normal Battery Depletion

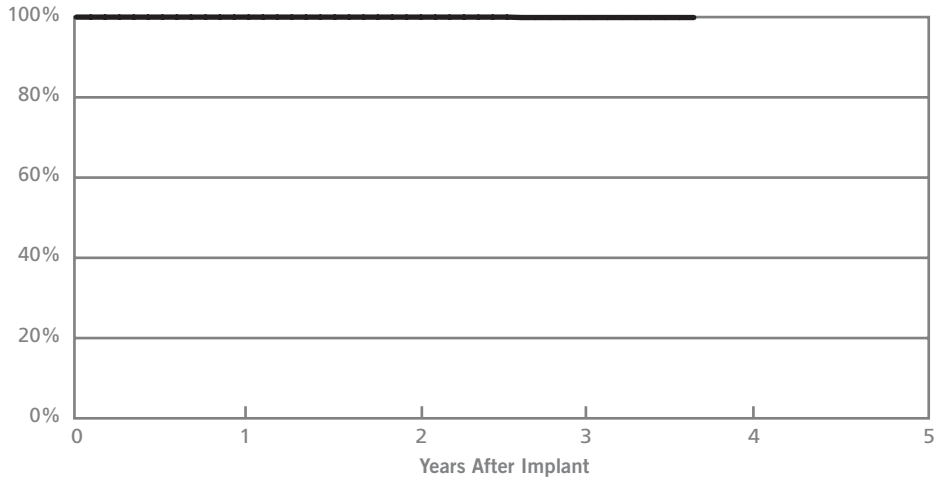


Year	1	2	3	4	at 49 months
Survival Probability	99.97%	99.97%	99.95%	99.95%	99.95%
± 1 standard error	0.02%	0.02%	0.03%	0.03%	0.03%

Integrity® ADx SR (Model 5160)

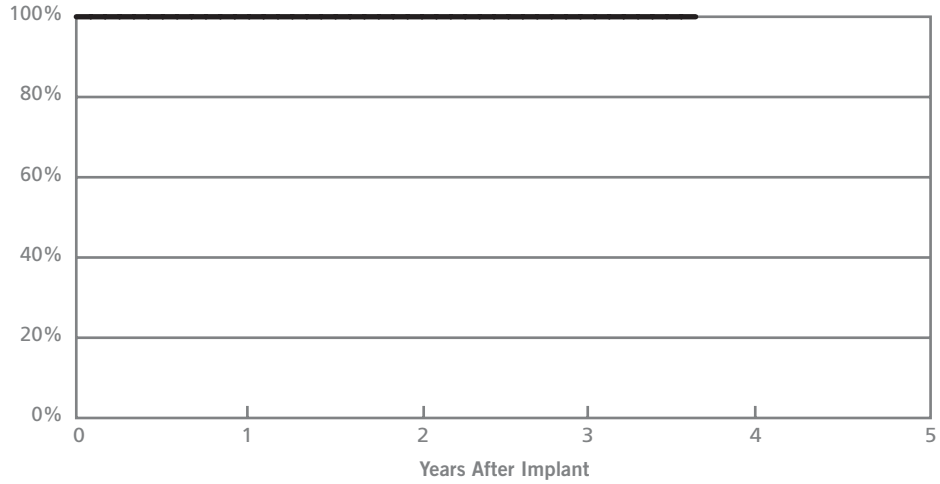
US Market Release	May 2003	Normal Battery Depletion	1
Registered US Implants	3,293	Malfunctions	0
Estimated Active US Implants	2,446	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 44 months	
Survival Probability	100.00%	100.00%	99.89%	99.89%	
± 1 standard error	0.00%	0.00%	0.11%	0.11%	
Sample Size	3000	1900	1000	100	

Excluding Normal Battery Depletion

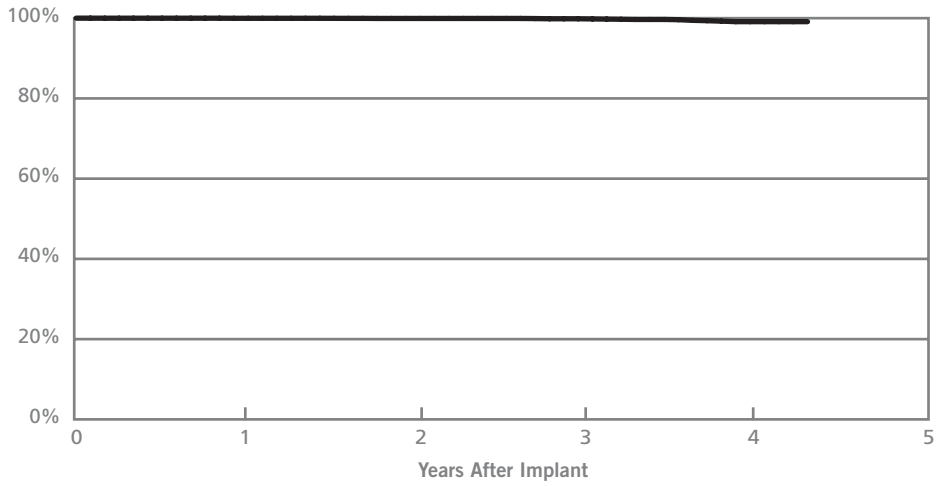


Year	1	2	3	at 44 months	
Survival Probability	100.00%	100.00%	100.00%	100.00%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	

Identity® ADx SR (Model 5180)

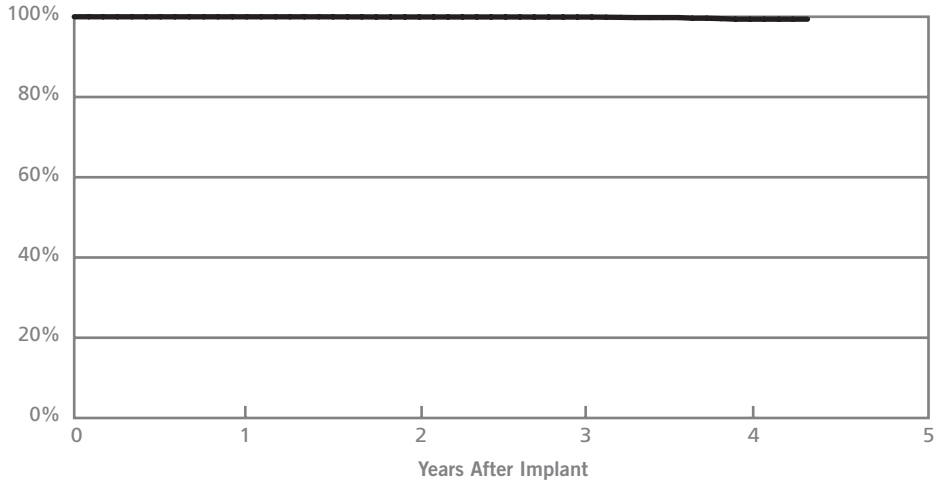
US Market Release	May 2003	Normal Battery Depletion	8
Registered US Implants	17,725	Malfunctions	6
Estimated Active US Implants	13,393	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	6
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	at 52 months
Survival Probability	99.97%	99.93%	99.85%	99.13%	99.13%
± 1 standard error	0.01%	0.03%	0.05%	0.25%	0.25%
Sample Size	16500	10400	5300	1800	100

Excluding Normal Battery Depletion

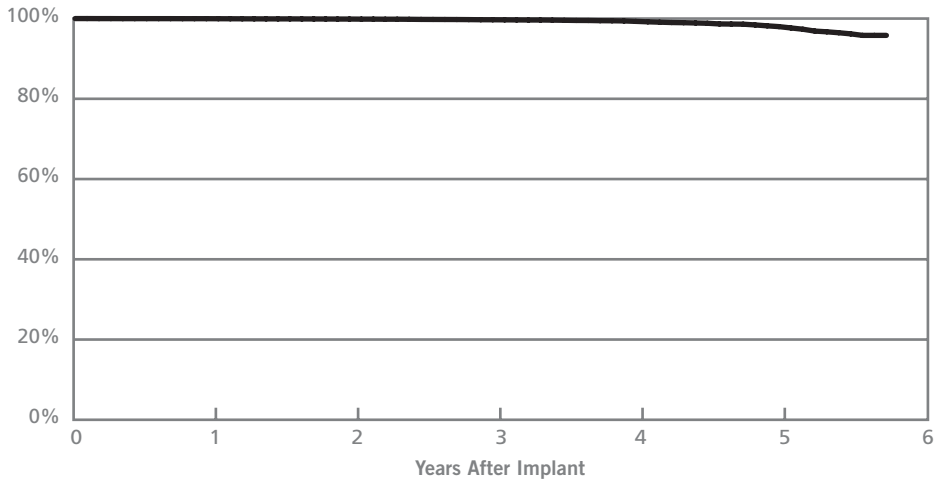


Year	1	2	3	4	at 52 months
Survival Probability	99.99%	99.95%	99.93%	99.40%	99.40%
± 1 standard error	0.01%	0.02%	0.03%	0.22%	0.22%

Identity® SR (Model 5172)

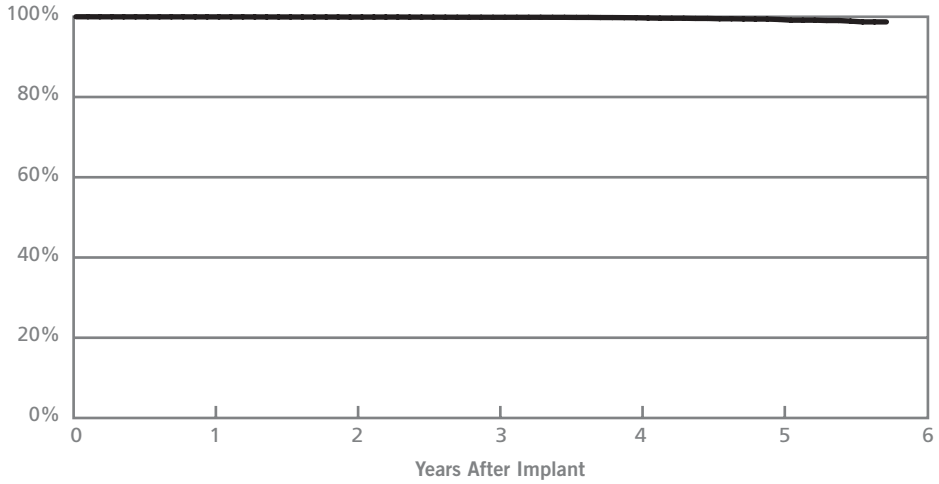
US Market Release	November 2001	Normal Battery Depletion	90
Registered US Implants	21,573	Malfunctions	25
Estimated Active US Implants	12,431	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	7.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	24
		Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



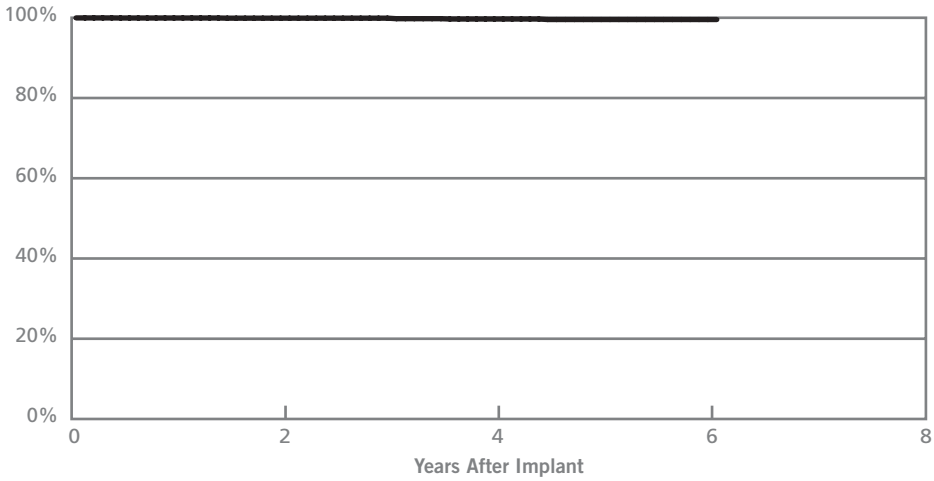
Year	1	2	3	4	5	at 69 months
Survival Probability	99.97%	99.88%	99.70%	99.30%	97.99%	95.81%
± 1 standard error	0.01%	0.03%	0.05%	0.08%	0.20%	0.53%
Sample Size	21200	16100	11900	7900	4000	100

Excluding Normal Battery Depletion



Year	1	2	3	4	5	at 69 months
Survival Probability	99.97%	99.93%	99.87%	99.75%	99.32%	98.72%
± 1 standard error	0.01%	0.02%	0.03%	0.05%	0.11%	0.31%

Microny® (Models 2425T, 2525T & 2535K)	
US Market Release	April 2001
Registered US Implants	5,354
Estimated Longevity	7.5 Years
Number of Advisories	None

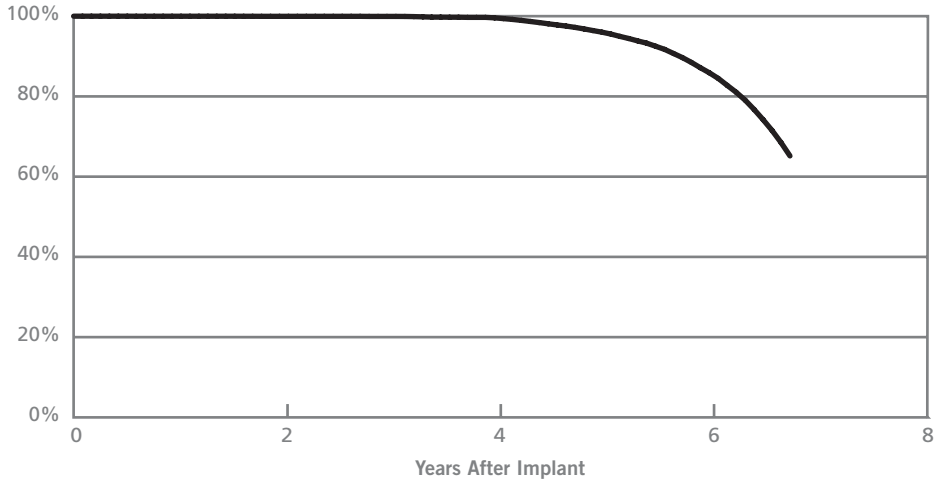


Year	2	4	6	at 73 months
Survival Probability	99.90%	99.69%	99.56%	99.56%
± 1 standard error	0.05%	0.13%	0.19%	0.19%
Sample Size	3500	1700	600	200

Integrity® µ SR (Model 5136)

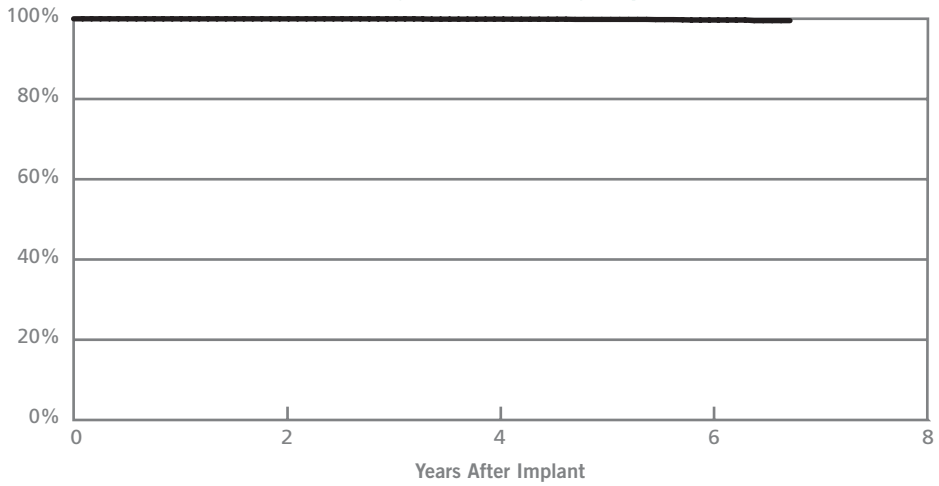
US Market Release	December 2000	Normal Battery Depletion	4,762
Registered US Implants	11,939	Malfunctions	5
Estimated Active US Implants	4,753	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.3 Years	Malfunctions w/o Compromised Therapy	5
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 81 months
Survival Probability	99.96%	99.58%	85.88%	65.17%
± 1 standard error	0.02%	0.07%	0.34%	0.57%
Sample Size	9400	6400	3000	300

Excluding Normal Battery Depletion

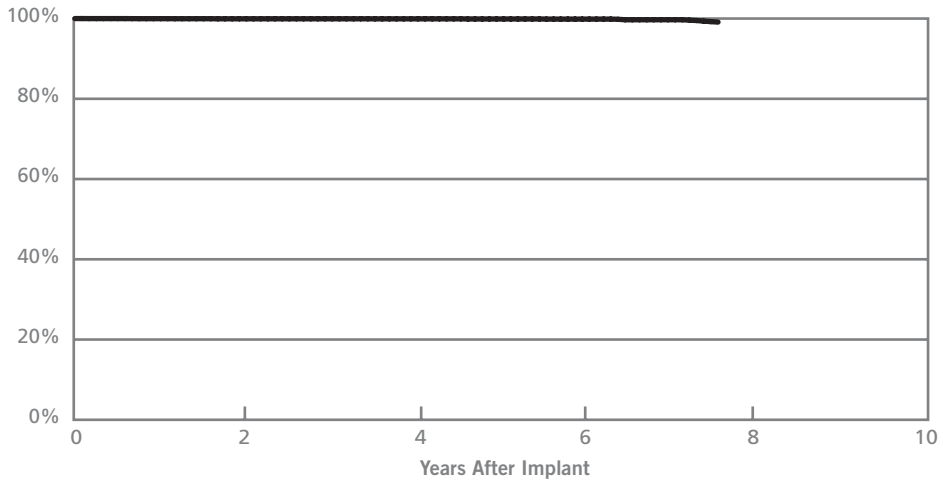


Year	2	4	6	at 81 months
Survival Probability	99.98%	99.91%	99.68%	99.53%
± 1 standard error	0.01%	0.04%	0.11%	0.18%

Integrity® SR (Model 5142)

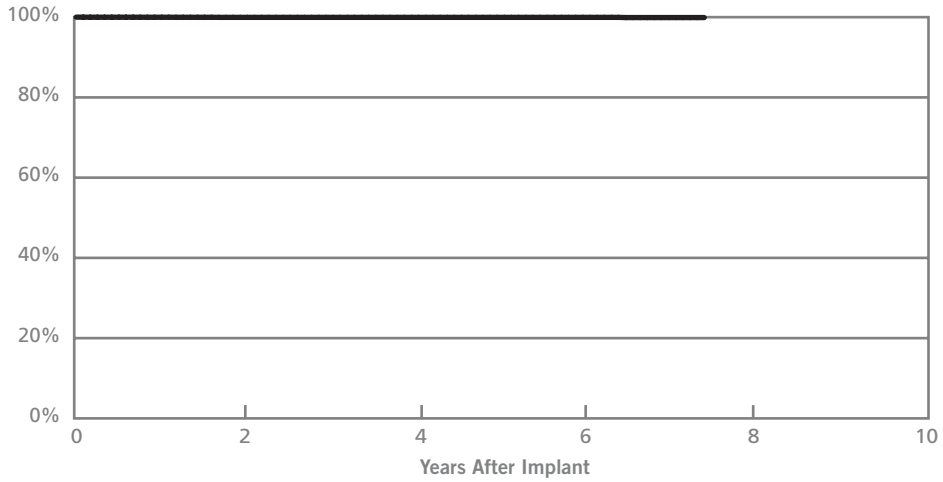
US Market Release	April 2000	Normal Battery Depletion	9
Registered US Implants	10,469	Malfunctions	4
Estimated Active US Implants	4,556	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 89 months	
Survival Probability	99.94%	99.93%	99.87%	99.12%	
± 1 standard error	0.03%	0.03%	0.05%	0.11%	
Sample Size	8700	6100	3500	200	

Excluding Normal Battery Depletion

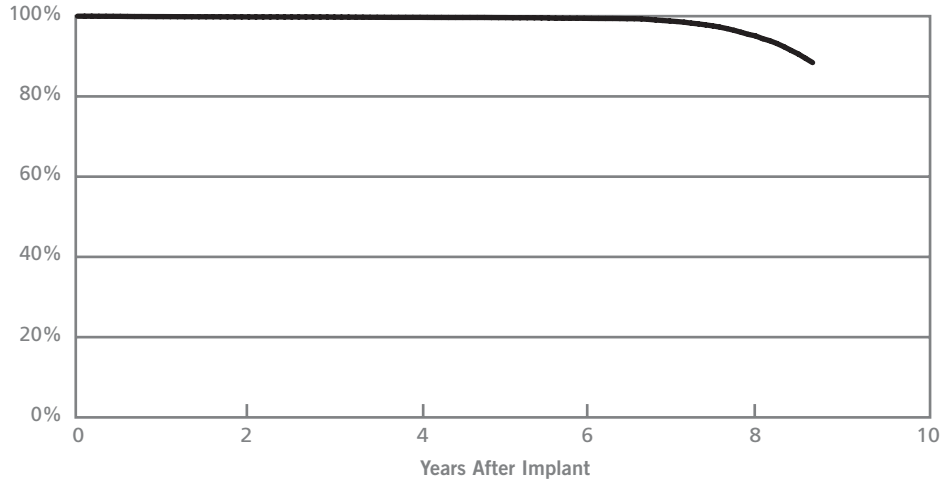


Year	2	4	6	at 89 months	
Survival Probability	99.95%	99.95%	99.95%	99.90%	
± 1 standard error	0.02%	0.02%	0.02%	0.06%	

Affinity® SR (Models 5130 & 5131)

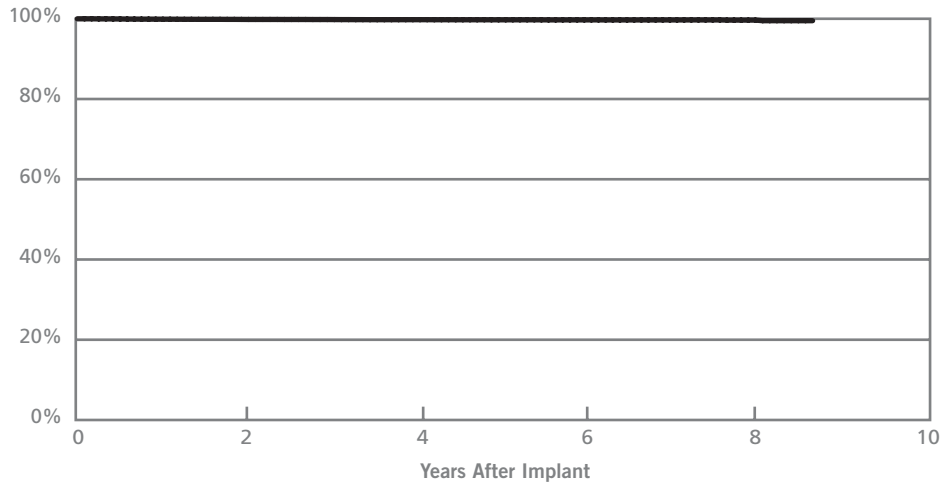
US Market Release	(5130) January 1999 (5131) June 1999	Normal Battery Depletion	1,114
		Malfunctions	56
Registered US Implants	28,642	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Active US Implants	10,159	Malfunctions w/o Compromised Therapy (17 related to Advisory)	52
Estimated Longevity	8.6 Years	Number of Advisories (see pages 168-173)	One

Including Normal Battery Depletion



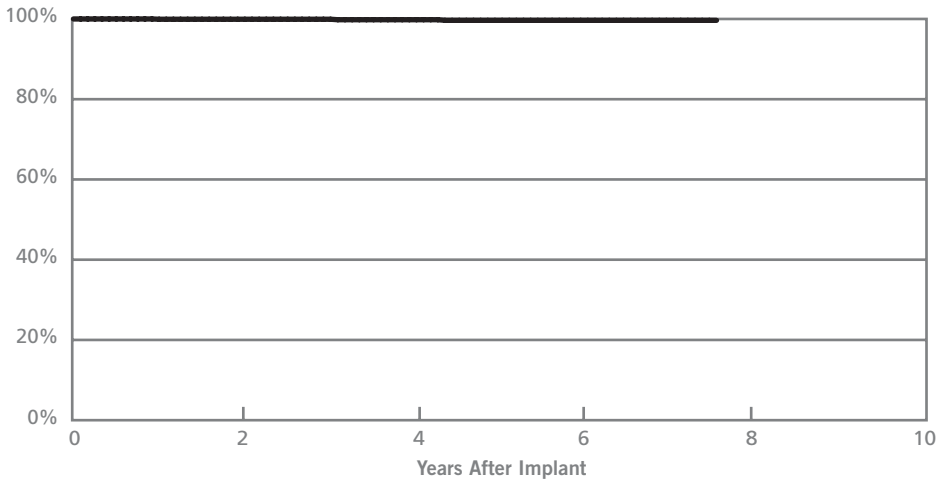
Year	2	4	6	8	at 104 months
Survival Probability	99.82%	99.70%	99.47%	95.08%	88.43%
± 1 standard error	0.03%	0.04%	0.06%	0.15%	0.23%
Sample Size	23200	16600	10000	3200	200

Excluding Normal Battery Depletion



Year	2	4	6	8	at 104 months
Survival Probability	99.84%	99.77%	99.72%	99.67%	99.52%
± 1 standard error	0.03%	0.03%	0.04%	0.06%	0.12%

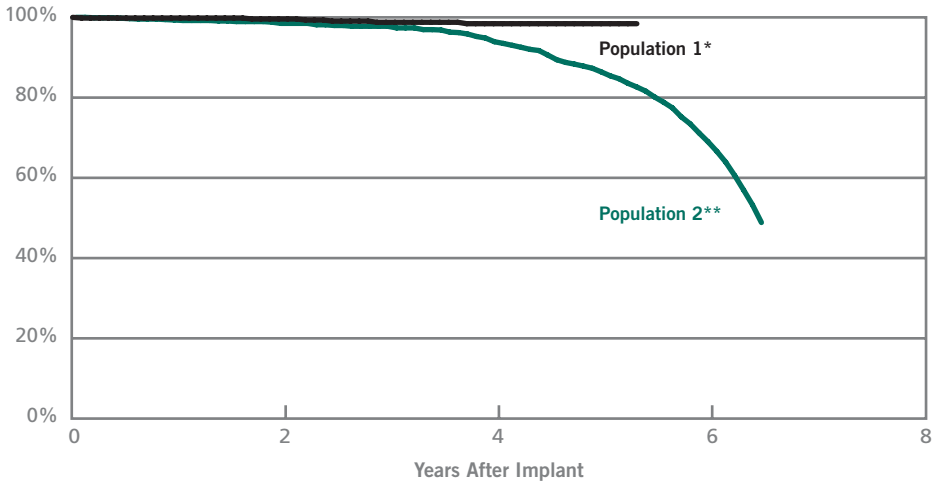
Regency® SC+ (Models 2400L & 2402L)	
US Market Release	May 1998
Registered US Implants	2,062
Estimated Longevity	9.1 Years
Number of Advisories	None



Year	2	4	6	at 91 months	
Survival Probability	99.93%	99.81%	99.66%	99.66%	
± 1 standard error	0.07%	0.14%	0.21%	0.21%	
Sample Size	1400	900	500	100	

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 168-173)	Two



Population 1*

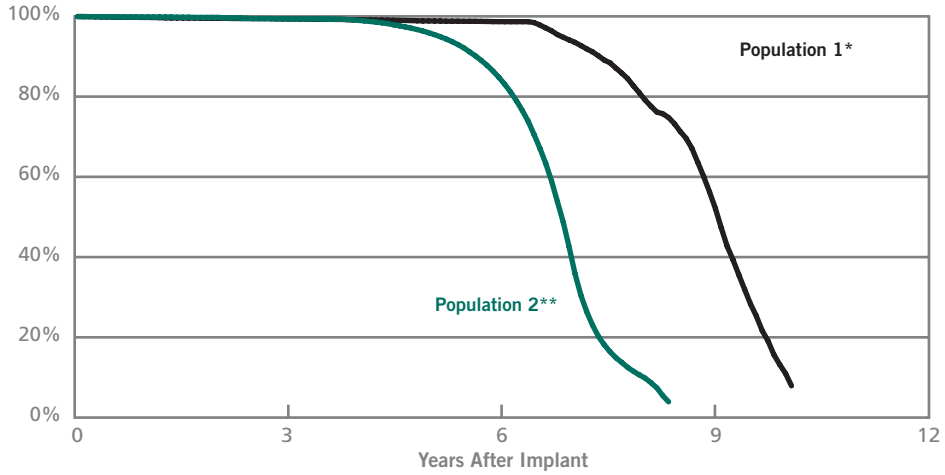
Year	2	4	at 64 months	
Survival Probability	99.83%	99.07%	98.42%	
± 1 standard error	0.29%	0.66%	0.66%	
Sample Size	500	300	200	

Population 2**

Year	2	4	6	at 78 months
Survival Probability	98.50%	93.93%	69.00%	48.87%
± 1 standard error	0.38%	0.89%	1.57%	1.67%
Sample Size	800	500	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 168-173)	Two



Population 1*

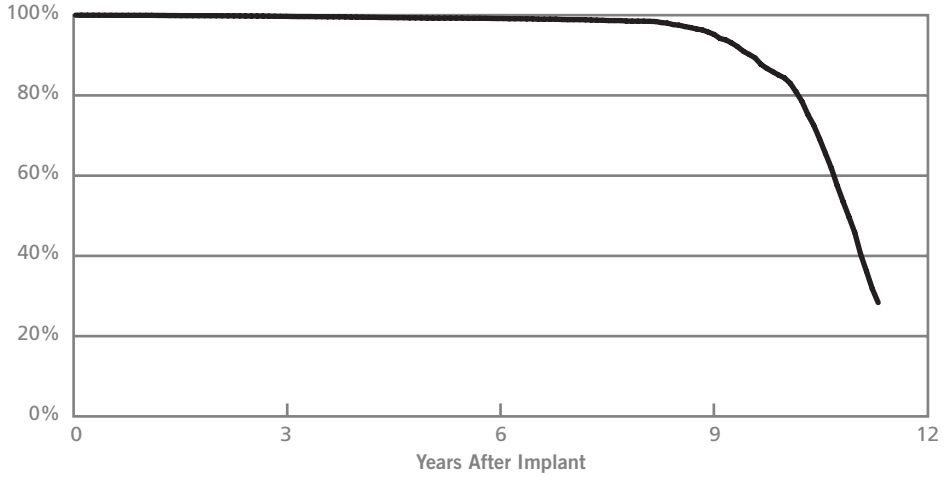
Year	3	6	9	at 123 months
Survival Probability	99.39%	98.69%	60.05%	7.92%
± 1 standard error	0.07%	0.12%	0.86%	0.67%
Sample Size	10500	6000	2700	200

Population 2**

Year	3	6	at 102 months	
Survival Probability	99.38%	86.36%	3.93%	
± 1 standard error	0.18%	0.24%	2.13%	
Sample Size	1800	1000	200	

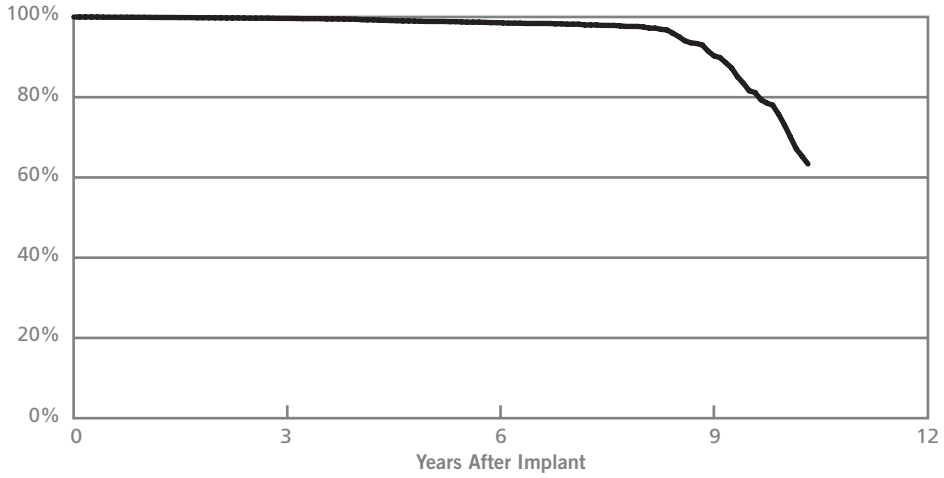
Pulse Generators

Trilogy® SR (Model 2250)	
US Market Release	June 1995
Registered US Implants	12,479
Estimated Longevity	7.7 Years
Number of Advisories (see pages 168-173)	Two



Year	3	6	9	at 138 months
Survival Probability	99.71%	99.18%	96.32%	28.37%
± 1 standard error	0.06%	0.11%	0.35%	1.63%
Sample Size	8800	5100	2500	200

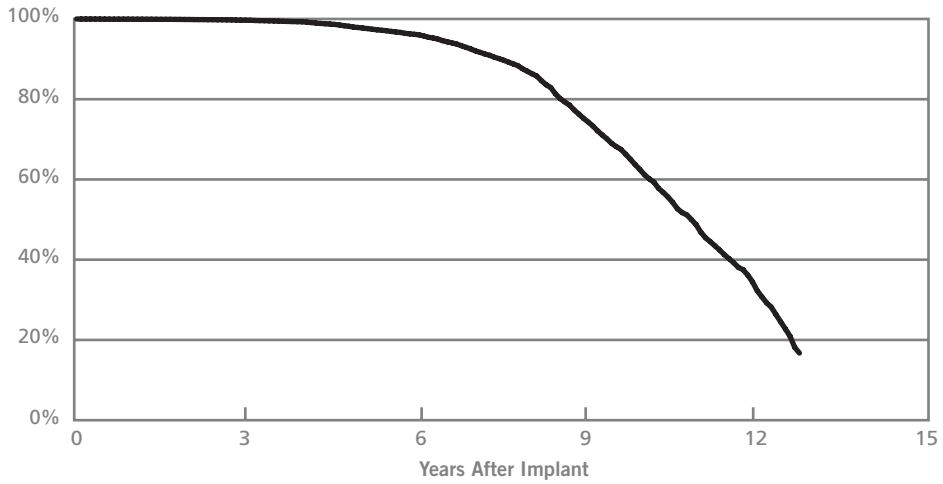
Phoenix® III (Models 2204 & 2205)	
US Market Release	October 1994
Registered US Implants	6,748
Estimated Longevity	6.3 Years
Number of Advisories	None



Year	3	6	9	at 126 months
Survival Probability	99.64%	98.59%	93.02%	63.36%
± 1 standard error	0.09%	0.24%	0.90%	2.37%
Sample Size	4100	2000	700	200

Solus® II (Models 2006 & 2007)

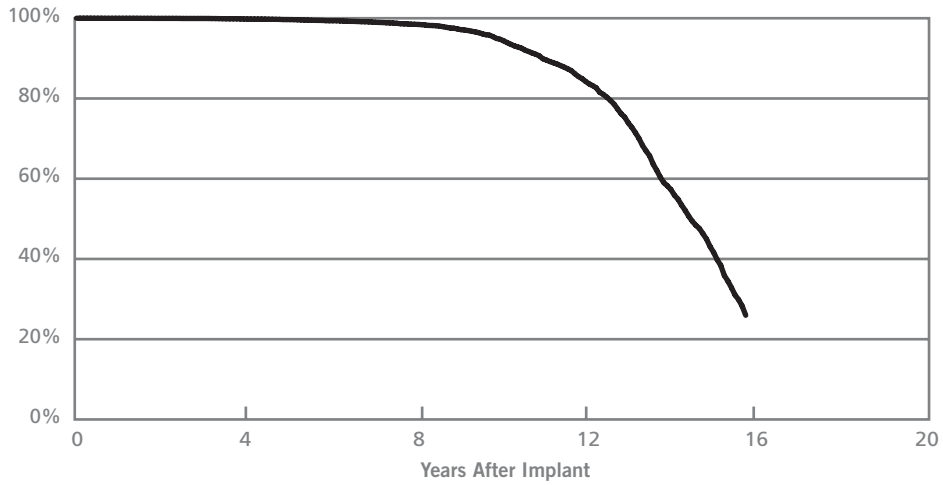
US Market Release	February 1993
Registered US Implants	32,331
Estimated Longevity	6.0 Years
Number of Advisories	None



Year	3	6	9	12	at 155 months
Survival Probability	99.71%	96.29%	76.31%	36.16%	16.73%
± 1 standard error	0.03%	0.16%	0.69%	1.19%	1.06%
Sample Size	22900	13000	3100	700	200

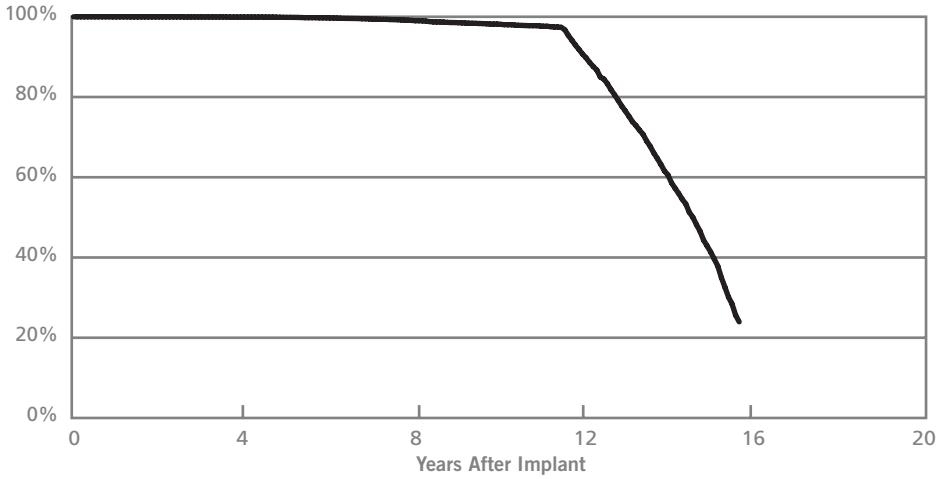
Phoenix® II (Models 2005, 2008 & 2009)

US Market Release	July 1990
Registered US Implants	26,771
Estimated Longevity	8.3 Years
Number of Advisories	None



Year	4	8	12	at 189 months	
Survival Probability	99.81%	98.49%	84.26%	25.97%	
± 1 standard error	0.03%	0.14%	0.64%	1.08%	
Sample Size	14500	6300	1900	200	

Solus® (Models 2002 & 2003)	
US Market Release	June 1990
Registered US Implants	23,866
Estimated Longevity	11.3 Years
Number of Advisories	None



Year	4	8	12	at 188 months	
Survival Probability	99.93%	99.09%	90.70%	23.97%	
± 1 standard error	0.02%	0.10%	0.53%	1.42%	
Sample Size	15400	8000	2800	200	

SUMMARY INFORMATION

Pulse Generators
Single-Chamber

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Pulse Generators

Including 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	1294	1283	0	0	0	0	0	0
5620	Zephyr SR	Mar-07	866	853	0	0	0	0	0	0
5610	Victory SR	Dec-05	8574	8022	0	0	0	0	0	0
5160	Integrity Adx SR	May-03	3293	2446	0	0	0	0	0	1
5156/5157/5056	Verity Adx XL SR/ SR(M/S)/SC	May-03	11279	9030	1	3	0	0	4	1
5180	Identity Adx SR	May-03	17725	13393	0	4	0	2	6	8
5172	Identity SR	Nov-01	21573	12431	1	20	0	4	25	90
5136	Integrity µ SR	Dec-00	11939	4753	0	5	0	0	5	4762
5142	Integrity SR	Apr-00	10469	4556	1	3	0	0	4	9
5130/5131	Affinity SR	Jan-99/Jun-99	28642	10159	4	35	17	0	56	1114

Excluding 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	1294	1283	0	0	0	0	0	0
5620	Zephyr SR	Mar-07	866	853	0	0	0	0	0	0
5610	Victory SR	Dec-05	8574	8022	0	0	0	0	0	0
5160	Integrity Adx SR	May-03	3293	2446	0	0	0	0	0	1
5156/5157/5056	Verity Adx XL SR/ SR(M/S)/SC	May-03	11279	9030	1	3	0	0	4	1
5180	Identity Adx SR	May-03	17725	13393	0	4	0	2	6	8
5172	Identity SR	Nov-01	21573	12431	1	20	0	4	25	90
5136	Integrity µ SR	Dec-00	11939	4753	0	5	0	0	5	4762
5142	Integrity SR	Apr-00	10469	4556	1	3	0	0	4	9
5130/5131	Affinity SR	Jan-99/Jun-99	28642	10159	4	35	17	0	56	1114

**Based on returned product analysis as of December 31, 2007.*

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
5626	Zephyr XL SR**								
5620	Zephyr SR**								
5610	Victory SR	100.00%							
5160	Integrity Adx SR	100.00%	100.00%	99.89%					
5156/5157/5056	Verity Adx XL SR/ SR(M/S)/SC	99.97%	99.97%	99.91%	99.91%				
5180	Identity Adx SR	99.97%	99.93%	99.85%	99.13%				
5172	Identity SR	99.97%	99.88%	99.70%	99.30%	97.99%			
5136	Integrity µ SR	99.98%	99.96%	99.94%	99.58%	96.01%	85.88%		
5142	Integrity SR	99.97%	99.94%	99.94%	99.93%	99.90%	99.87%	99.70%	
5130/5131	Affinity SR	99.89%	99.82%	99.79%	99.70%	99.64%	99.47%	98.79%	95.08%

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
5626	Zephyr XL SR**								
5620	Zephyr SR**								
5610	Victory SR	100.00%							
5160	Integrity Adx SR	100.00%	100.00%	100.00%					
5156/5157/5056	Verity Adx XL SR/ SR(M/S)/SC	99.97%	99.97%	99.95%	99.95%				
5180	Identity Adx SR	99.99%	99.95%	99.93%	99.40%				
5172	Identity SR	99.97%	99.93%	99.87%	99.75%	99.32%			
5136	Integrity µ SR	99.98%	99.98%	99.97%	99.91%	99.84%	99.68%		
5142	Integrity SR	99.98%	99.95%	99.95%	99.95%	99.95%	99.95%	99.90%	
5130/5131	Affinity SR	99.90%	99.84%	99.81%	99.77%	99.74%	99.72%	99.71%	99.67%

**Based on returned product analysis as of December 31, 2007.*

***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™
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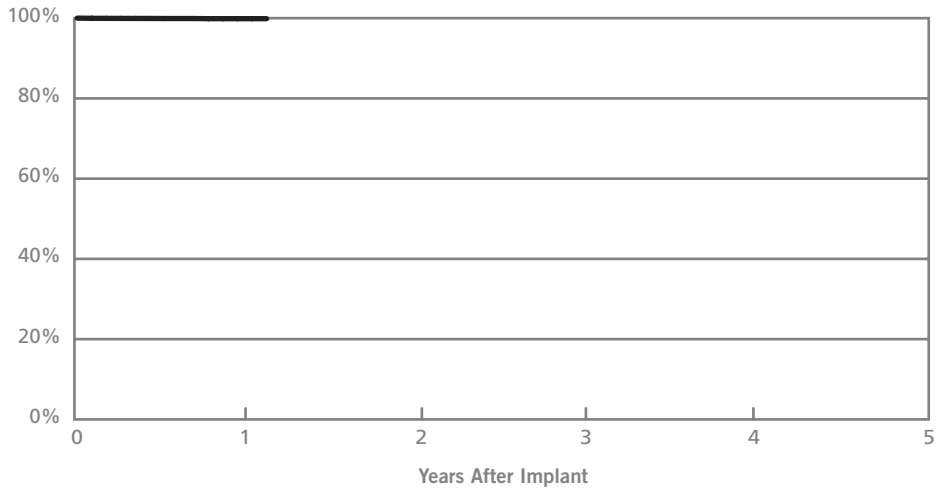
Tendril® ST Optim™ (Models 1888T & 1888TC)

US Market Release	June 2006	Type and/or Fixation	Active
Registered US Implants	27,261	Polarity	Bipolar
Estimated Active US Implants	26,563	Steroid	Yes
Insulation	Optim*	Number of Advisories	None

Laboratory Analysis

Implant Damage	**28**	**Electrical Malfunction**	**0**	**Other**	**9**
		Insulation Disruption	0	Explant Damage	8
		Conductor Disruption	0	Non-Electrical Workmanship	1
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	0
				Partial Lead	0



Year	1	at 14 months			
Survival Probability	99.87%	99.87%			
± 1 standard error	0.05%	0.05%			
Sample Size	14100	200			

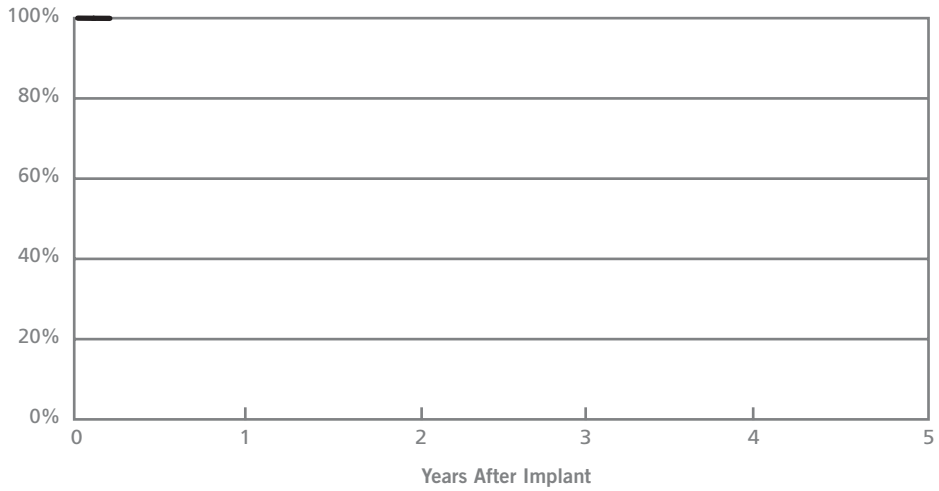
**Optim® insulation is a copolymer of silicone and polyurethane.*

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

US Market Release	June 2006	Type and/or Fixation	Active
Registered US Implants	612	Polarity	Bipolar
Estimated Active US Implants	603	Steroid	Yes
Insulation	Optim*	Number of Advisories	None

Laboratory Analysis

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



Year	at 3 months				
Survival Probability	99.95%				
± 1 standard error	0.01%				
Sample Size	100				

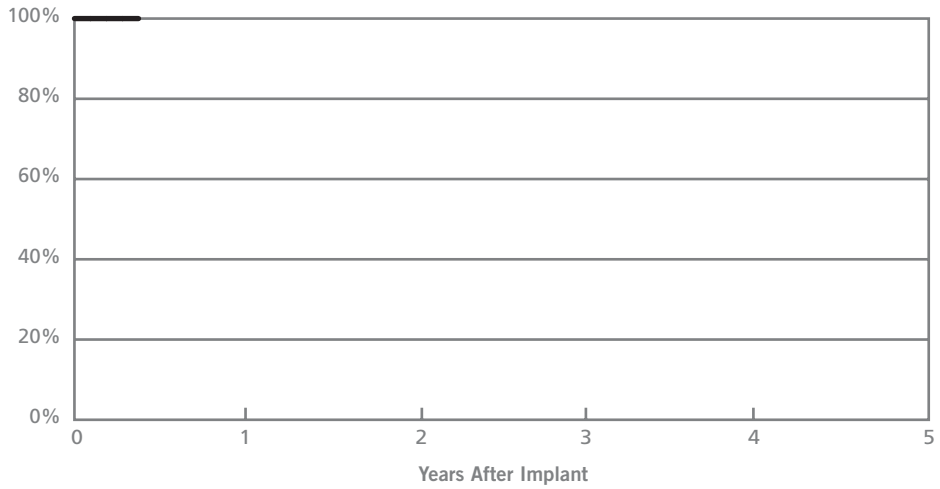
**Optim® insulation is a copolymer of silicone and polyurethane.*

OptiSense® (Models 1699T & 1699TC)

US Market Release	June 2006	Type and/or Fixation	Active
Registered US Implants	2,044	Polarity	Bipolar
Estimated Active US Implants	2,012	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

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



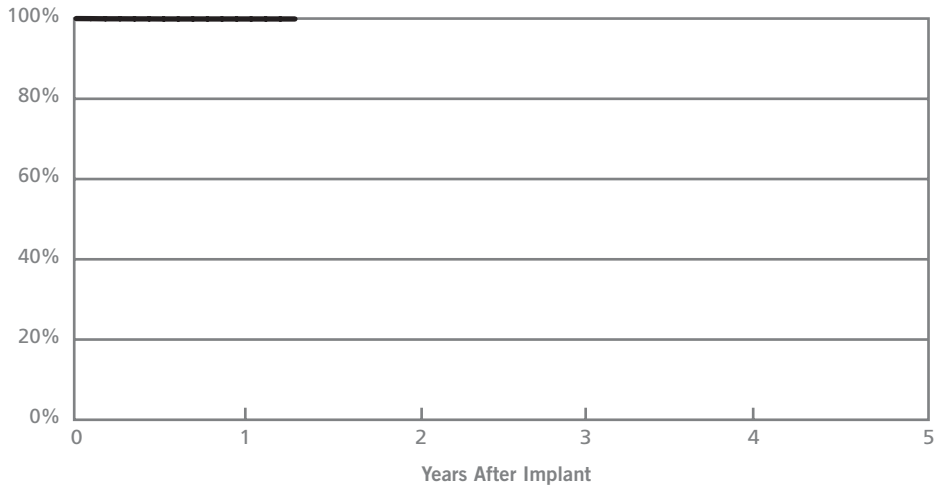
Year	at 5 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	200				

Tendril® (Models 1788T & 1788TC)

US Market Release	February 2006	Type and/or Fixation	Active
Registered US Implants	35,997	Polarity	Bipolar
Estimated Active US Implants	34,170	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**231**	**Electrical Malfunction**	**3**	**Other**	**29**
		Insulation Disruption	3	Explant Damage	18
		Conductor Disruption	0	Non-Electrical Workmanship	11
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	0
				Partial Lead	0



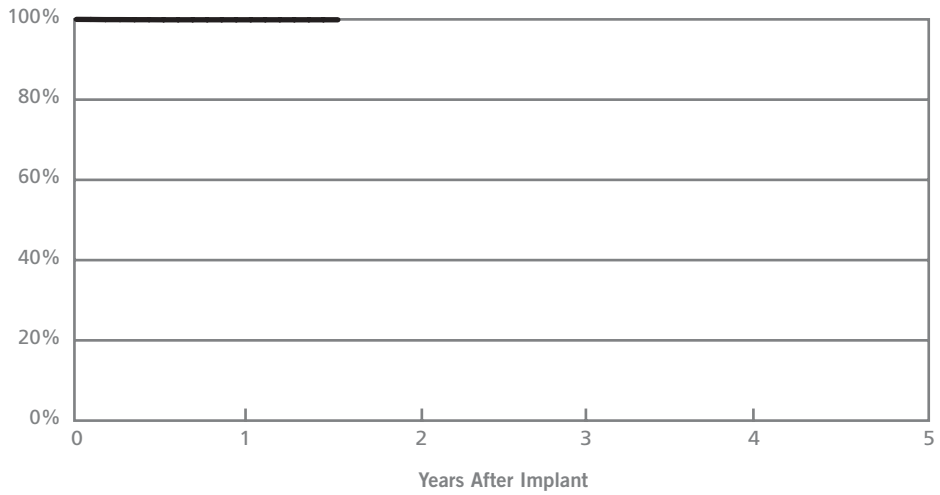
Year	1	at 16 months			
Survival Probability	99.90%	99.90%			
± 1 standard error	0.05%	0.05%			
Sample Size	22300	600			

Tendril® (Models 1782T & 1782TC)

US Market Release	February 2006	Type and/or Fixation	Active
Registered US Implants	6,267	Polarity	Bipolar
Estimated Active US Implants	5,960	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**68**	**Electrical Malfunction**	**1**	**Other**	**6**
		Insulation Disruption	0	Explant Damage	4
		Conductor Disruption	1	Non-Electrical Workmanship	1
		Crimps, Welds, Bonds	0	Non-Electrical Anomaly	1
				Partial Lead	0



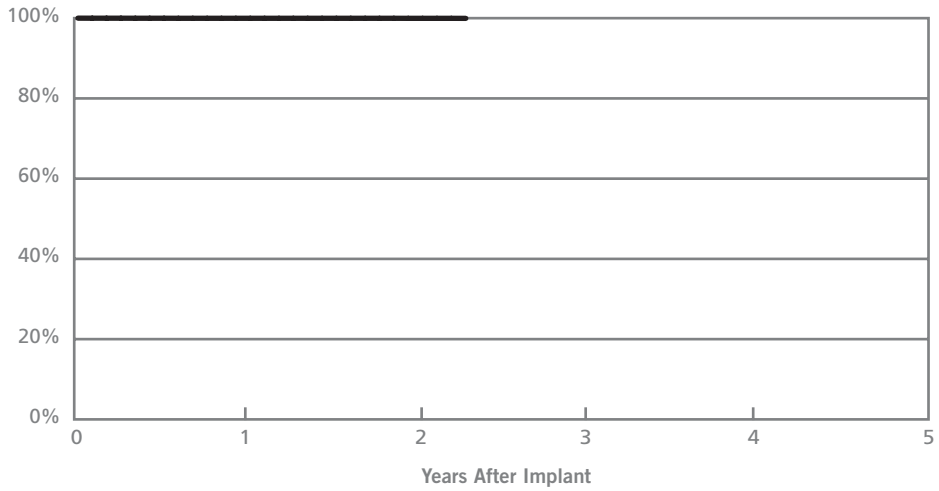
Year	1	at 19 months			
Survival Probability	99.90%	99.90%			
± 1 standard error	0.05%	0.05%			
Sample Size	4100	100			

IsoFlex® P (Models 1644T & 1648T)

US Market Release	April 2005	Type and/or Fixation	Passive
Registered US Implants	2,516	Polarity	Bipolar
Estimated Active US Implants	2,264	Steroid	Yes
Insulation	Polyurethane	Number of Advisories	None

Laboratory Analysis

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



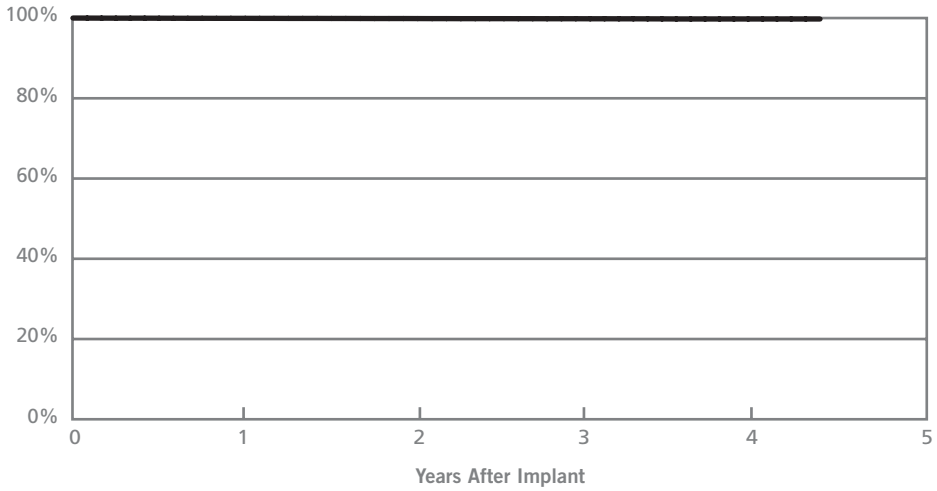
Year	1	2	at 28 months		
Survival Probability	99.97%	99.96%	99.95%		
± 1 standard error	0.07%	0.01%	0.01%		
Sample Size	1900	700	200		

Tendril® SDX (Models 1688T & 1688TC)

US Market Release	June 2003	Type and/or Fixation	Active
Registered US Implants	244,285	Polarity	Bipolar
Estimated Active US Implants	209,182	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**449**	**Electrical Malfunction**	**93**	**Other**	**98**
		Insulation Disruption	31	Explant Damage	63
		Conductor Disruption	47	Non-Electrical Workmanship	29
		Crimps, Welds, Bonds	15	Non-Electrical Anomaly	1
				Partial Lead	5



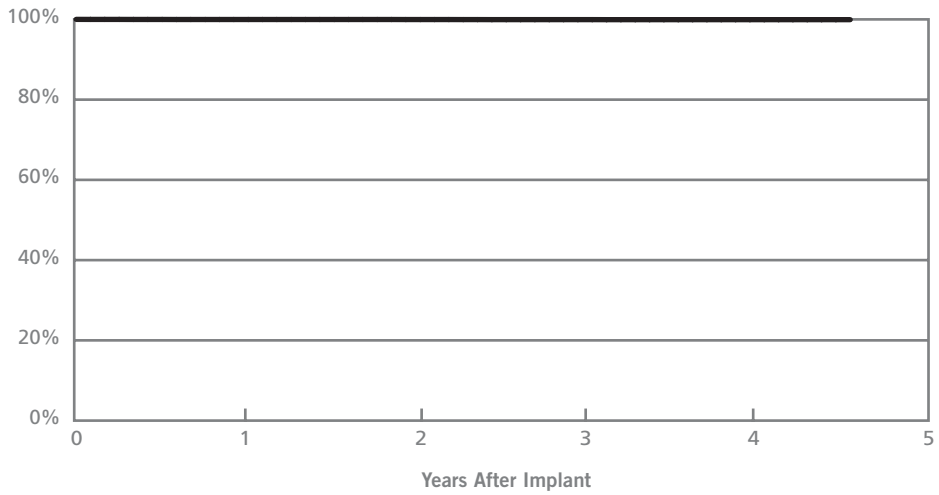
Year	1	2	3	4	at 53 months
Survival Probability	99.93%	99.88%	99.83%	99.77%	99.77%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%
Sample Size	219600	141200	70000	22100	200

IsoFlex® S (Models 1642T & 1646T)

US Market Release	April 2003	Type and/or Fixation	Passive
Registered US Implants	71,483	Polarity	Bipolar
Estimated Active US Implants	59,421	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

Implant Damage	**113**	**Electrical Malfunction**	**9**	**Other**	**24**
		Insulation Disruption	3	Explant Damage	14
		Conductor Disruption	3	Non-Electrical Workmanship	9
		Crimps, Welds, Bonds	3	Non-Electrical Anomaly	0
				Partial Lead	1



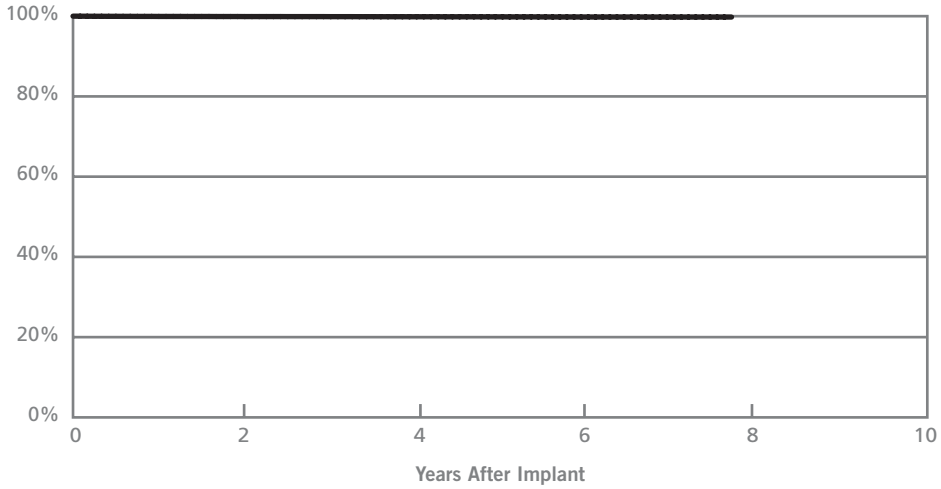
Year	1	2	3	4	at 56 months
Survival Probability	99.97%	99.96%	99.94%	99.93%	99.93%
± 1 standard error	0.01%	0.01%	0.01%	0.02%	0.02%
Sample Size	62500	39900	22800	9700	100

Tendril® SDX (Models 1488T & 1488TC)

US Market Release	March 2000	Type and/or Fixation	Active
Registered US Implants	265,333	Polarity	Bipolar
Estimated Active US Implants	173,155	Steroid	Yes
Insulation	Silicone	Number of Advisories	None

Laboratory Analysis

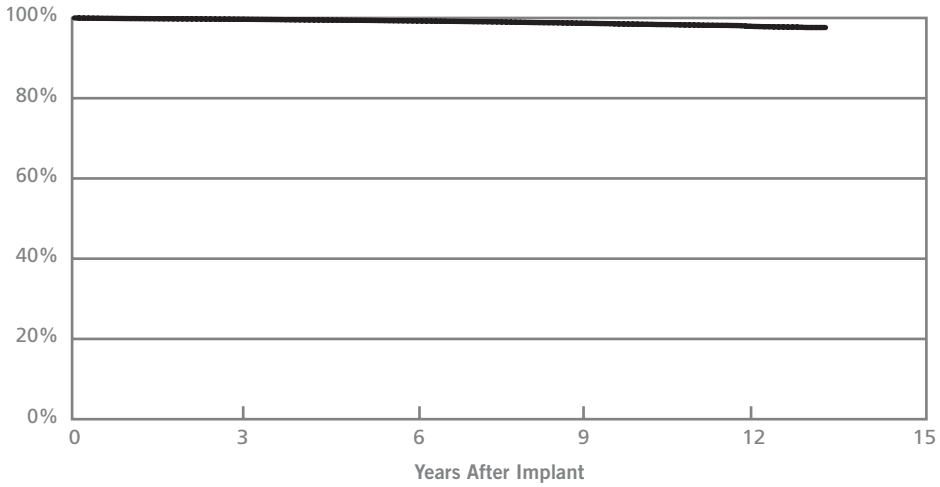
Implant Damage	**787**	**Electrical Malfunction**	**176**	**Other**	**154**
		Insulation Disruption	52	Explant Damage	103
		Conductor Disruption	115	Non-Electrical Workmanship	34
		Crimps, Welds, Bonds	9	Non-Electrical Anomaly	3
				Partial Lead	14



Year	2	4	6	at 93 months	
Survival Probability	99.91%	99.85%	99.79%	99.78%	
± 1 standard error	0.01%	0.01%	0.01%	0.02%	
Sample Size	222300	148300	73381	200	

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

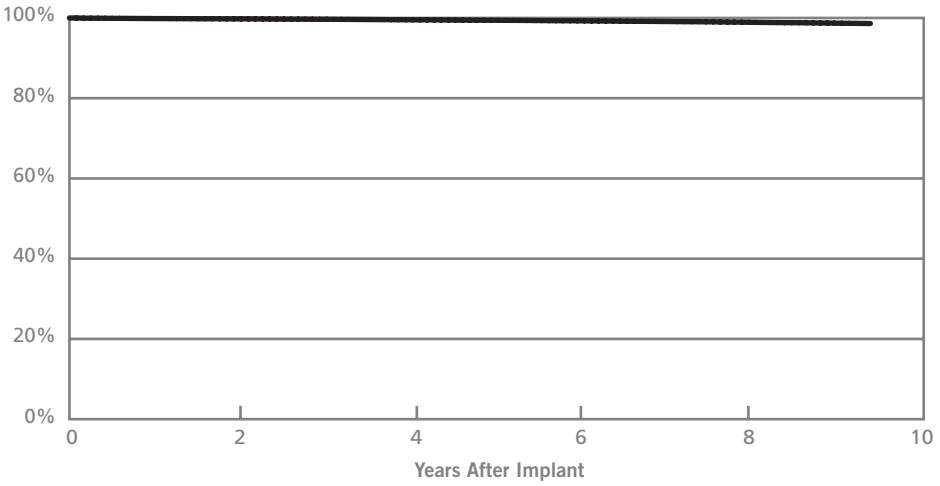
US Market Release	(1148) June 1993; (1188T) June 1994; (1388T) June 1997	Type and/or Fixation	Active
Registered US Implants	313,776	Polarity	Bipolar
Estimated Active US Implants	149,494	Steroid	(1148/1188) No; (1388) Yes
Insulation	Silicone	Number of Advisories	None



Year	3	6	9	12	at 169 months
Survival Probability	99.68%	99.29%	98.71%	97.98%	97.52%
± 1 standard error	0.01%	0.02%	0.03%	0.07%	0.16%
Sample Size	231200	140300	55000	10600	100

Tendril® (Model 1188K) Tendril® DX (Model 1388K)

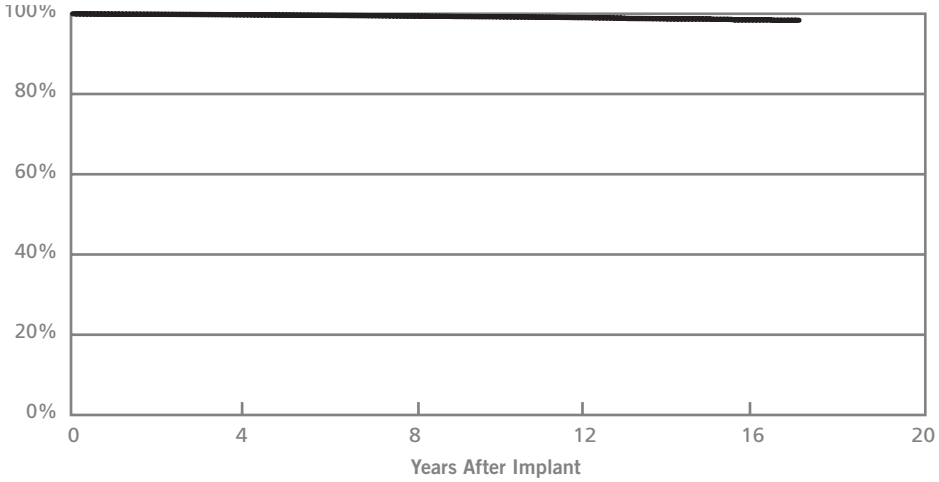
US Market Release (1188K) June 1995; (1388K) June 1997		Type and/or Fixation	Active
Registered US Implants	1,330	Polarity	Unipolar
Estimated Active US Implants	455	Steroid	(1188K) No; (1388K) Yes
Insulation	Silicone	Number of Advisories	None



Year	2	4	6	8	at 113 months
Survival Probability	99.78%	99.55%	99.29%	98.93%	98.61%
± 1 standard error	0.01%	0.01%	0.02%	0.03%	0.04%
Sample Size	1200	900	700	500	200

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

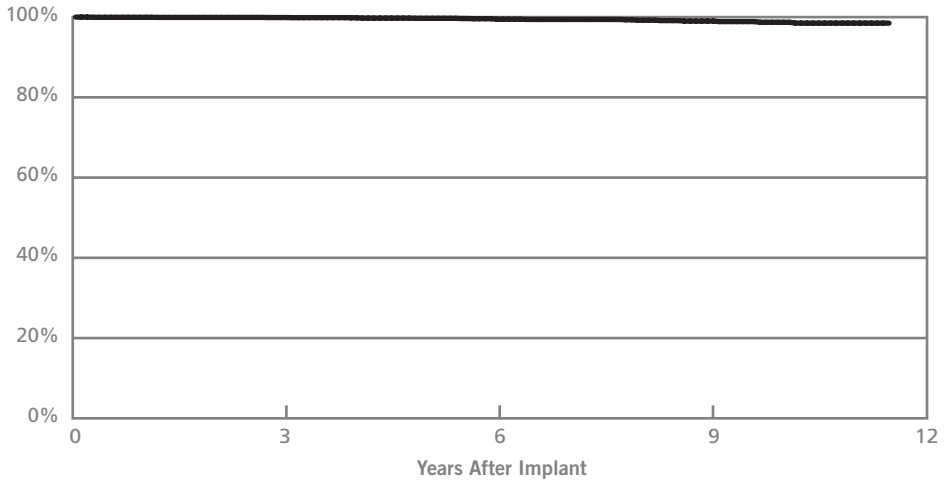
US Market Release	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990	Type and/or Fixation	Passive
		Polarity	Bipolar
		Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Registered US Implants	369,888	Number of Advisories	None
Estimated Active US Implants	142,285	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T) are no longer being manufactured.	
Insulation	Silicone		



Year	4	8	12	16	at 205 months
Survival Probability	99.75%	99.44%	99.05%	98.48%	98.38%
± 1 standard error	0.01%	0.02%	0.03%	0.10%	0.14%
Sample Size	249200	112700	31900	3500	100

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	4,545	Number of Advisories	None
Estimated Active US Implants	1,395	(1135K, 1143K, 1145K, 1235K, 1243K & 1245K) are no longer being manufactured.	
Insulation	Silicone		

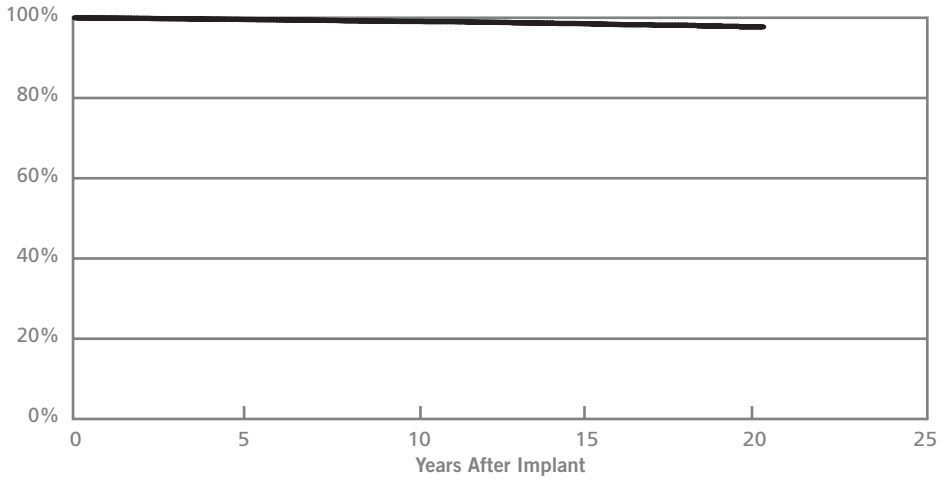


Year	3	6	9	at 140 months
Survival Probability	99.89%	99.59%	99.01%	98.50%
± 1 standard error	0.05%	0.13%	0.26%	0.39%
Sample Size	3300	2100	1000	100

Pacing Leads

ACE® (Models 1015M & 1025M)

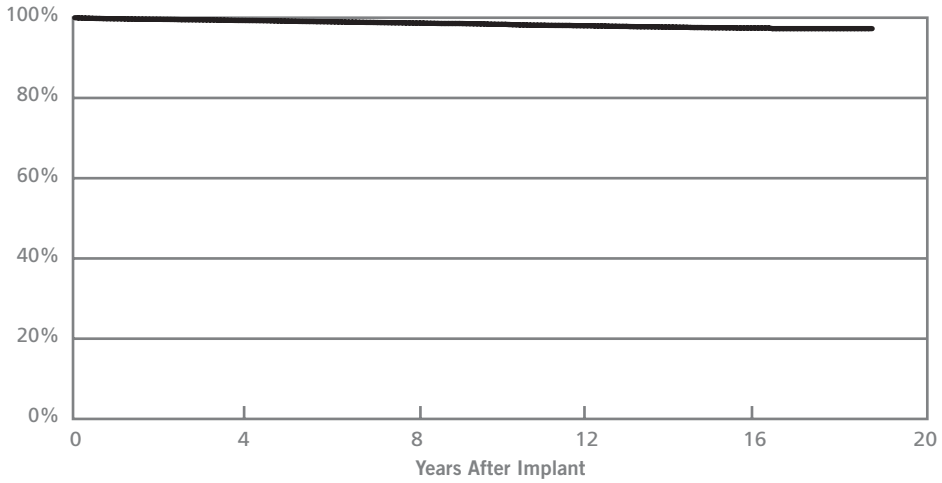
US Market Release (1025M) August 1982; (1015M) August 1991		Type and/or Fixation	Passive
Registered US Implants	23,854	Polarity	Unipolar
Estimated Active US Implants	3,571	Steroid	No
Insulation	Silicone	Number of Advisories	None



Year	5	10	15	20	at 243 months
Survival Probability	99.58%	99.09%	98.52%	97.73%	97.73%
± 1 standard error	0.05%	0.09%	0.13%	0.25%	0.25%
Sample Size	15000	8400	4500	900	100

Fast-Pass® (Models 1018T & 1028T)

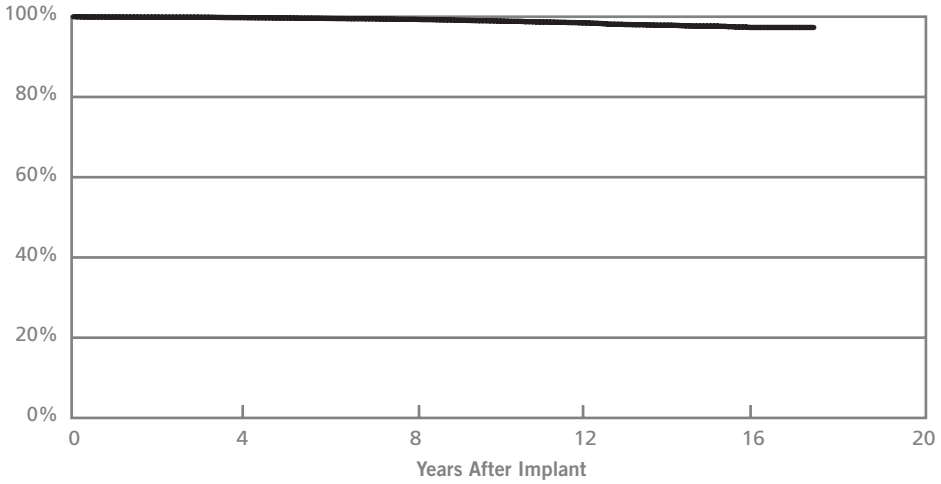
US Market Release (1018T) February 1988; (1028T) July 1990		Type and/or Fixation	Active
Registered US Implants	28,096	Polarity	Bipolar
Estimated Active US Implants	5,113	Steroid	No
Insulation	Silicone	Number of Advisories	None



Year	4	8	12	16	at 225 months
Survival Probability	99.32%	98.68%	98.00%	97.44%	97.28%
± 1 standard error	0.05%	0.08%	0.12%	0.15%	0.18%
Sample Size	20500	13900	8600	3300	100

Permathane® ACE (Models 1036T & 1038T)

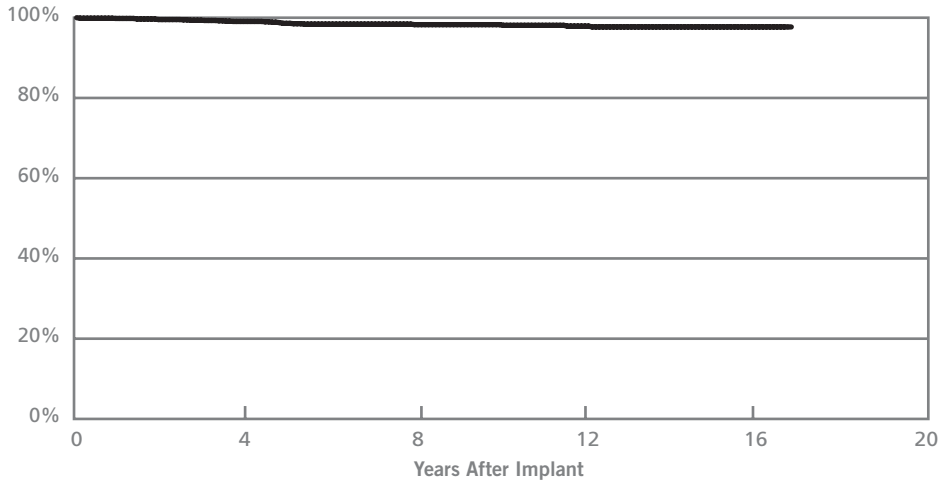
US Market Release	June 1989	Type and/or Fixation	Passive
Registered US Implants	19,712	Polarity	Bipolar
Estimated Active US Implants	3,391	Steroid	No
Insulation	Polyurethane	Number of Advisories	None



Year	4	8	12	16	at 209 months
Survival Probability	99.78%	99.35%	98.47%	97.32%	97.32%
± 1 standard error	0.04%	0.08%	0.14%	0.28%	0.28%
Sample Size	13800	8800	5100	1300	100

Fast-Pass® (Model 1007)

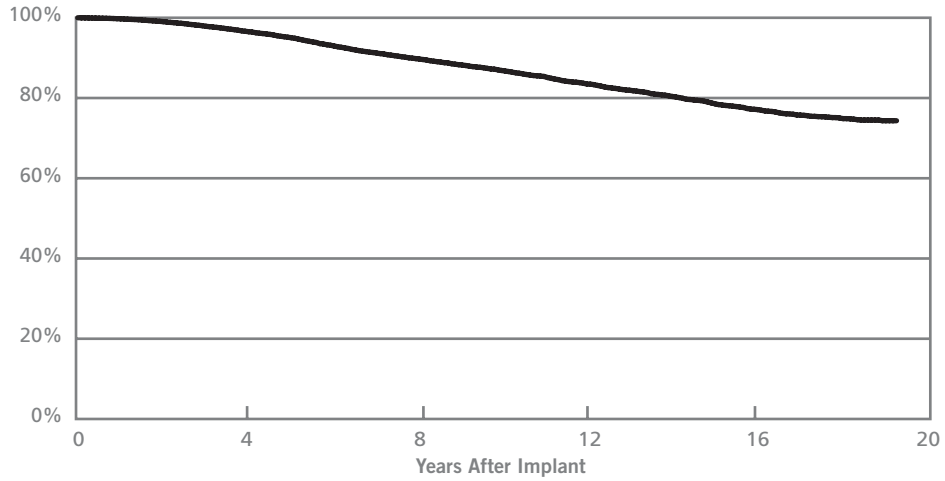
US Market Release	June 1987	Type and/or Fixation	Active
Registered US Implants	1,737	Polarity	Unipolar
Estimated Active US Implants	268	Steroid	No
Insulation	Silicone	Number of Advisories	None



Year	4	8	12	16	at 202 months
Survival Probability	99.07%	98.27%	97.91%	97.70%	97.70%
± 1 standard error	0.26%	0.36%	0.46%	0.50%	0.50%
Sample Size	1300	800	500	300	100

ACE® (Models 1016T & 1026T)

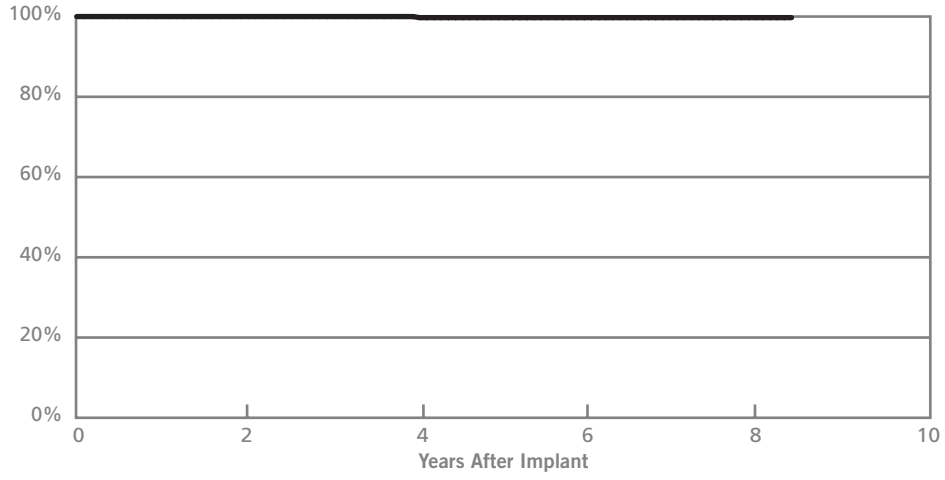
US Market Release	June 1987	Type and/or Fixation	Active
Registered US Implants	24,255	Polarity	Bipolar
Estimated Active US Implants	2,424	Steroid	No
Insulation	Silicone	Number of Advisories (see pages 168-173)	One



Year	4	8	12	16	at 231 months
Survival Probability	96.64%	89.81%	83.50%	77.11%	74.34%
± 1 standard error	0.13%	0.26%	0.37%	0.49%	0.59%
Sample Size	17200	10200	5800	3300	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	77	Steroid	No
Insulation	Polyurethane	Number of Advisories	None



Year	2	4	12	8	at 101 months
Survival Probability	100.00%	100.00%	99.73%	99.73%	99.73%
± 1 standard error	0.00%	0.00%	0.27%	0.27%	0.27%
Sample Size	500	400	300	200	200

LABORATORY ANALYSIS

Pacing Leads
Bipolar & Unipolar
Active & Passive Fixation

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
1888T/TC	Jun-06	27261	26563	28	0	0	0	0	8	1	0	0	9
1882T/TC	Jun-06	612	603	1	0	0	0	0	0	0	0	0	0
1699T/TC	Jun-06	2044	2012	1	0	0	0	0	0	0	0	1	1
1788T/TC	Feb-06	35997	34170	231	3	0	0	3	18	11	0	0	29
1782T/TC	Feb-06	6267	5960	68	0	1	0	1	4	1	1	0	6
1644T/1648T	Apr-05	2516	2264	2	0	0	0	0	0	0	0	0	0
1688T/TC	Jun-03	244285	209182	449	31	47	15	93	63	29	1	5	98
1642T/1646T	Apr-03	71483	59421	113	3	3	3	9	14	9	0	1	24
1488T/TC	Mar-00	265333	173155	787	52	115	9	176	103	34	3	14	154

**Based on returned product analysis as of December 31, 2007.*

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.

ADVISORIES & SAFETY ALERTS

Advisories & Safety Alerts

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

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic ICDs (Models V-197, V-235, V-337, V-338, V-339), Epic + ICDs (Models V-196, V-233, V-236, V-239, V-350) Epic II ICDs (Models V-158, V-255, V-258, V-355, V-356, V-357) Atlas + ICDs (Model V-240, V-341, V-343, V-193, V-242, V-243) Atlas II ICDs (Models V-168, V-265, V-268, V-365, V-366, V-367)	01/16/08 Class TBD 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 and 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. St. Jude Medical, along with our independent Medical Advisory Board members, has determined that no other action is recommended.
Identity SR (5172) Identity DR (5370) Identity XL DR (5376)	10/12/06 Class II A programmer software anomaly can lead to incorrect reporting of battery voltage, expected battery longevity and elective replacement indicator (ERI) status in St. Jude Medical Identity pacemakers. The anomaly does not affect the device's actual battery voltage, longevity or functionality, but could result in inaccurate reporting of the status of these measured data parameters. This software anomaly can appear in the St. Jude Medical Identity family of pacemakers when programmed by the St. Jude Medical APS III Model 3500/3510 or Merlin 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. **Current Status (December 31, 2007):** 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, 2007 there were an additional 67 worldwide (55 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.
Photon DR (V-230HV) (certain serial numbers), Photon Micro VR/DR (Models V-194/V-232), Atlas VR/DR (Models V-199/V-240)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: • If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. • In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. • If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible. • You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (December 31, 2007):** 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, 2007 there were an additional 38 worldwide (28 U.S.) devices confirmed with this issue. This is within the 95% confidence interval prediction made at the time of the advisory. There have been no reports of serious injury or death.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic DR/HF (V-233/V-337/V-338), Epic Plus DR/VR/HF (V-236/V-239/V-196/ V-239T/V-196T/V-350), Atlas DR (V-242), and Atlas Plus DR/VR/HF (V-243/V-193/V-193C/ V-340/V-341/V-343).	6/13/05 Class II Two anomalies have been identified: 1. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. 2. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On", this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed.	Two anomalies were discovered during routine product monitoring. **Neither of these anomalies presents a significant clinical risk** to your patients, and no clinical complications have been reported to St. Jude Medical. **Both are easily corrected** by performing a simple, automated software download to the device. This potentially affects approximately 30,000 implanted ICDs in the United States and includes the following model numbers: Epic DR/HF (V-233/V-337/V-338), Epic Plus DR/VR/HF (V-236/V-239/V-196/V-239T/V-196T/ V-350), Atlas DR (V-242), and Atlas Plus DR/VR/HF (V-243/V-193/V-193C/V-340/V-341/V-343). The first anomaly can occur when one of the affected devices attempts to deliver multiple shocks in rapid succession. Due to a device software anomaly, it is possible that when the device's battery is nearing its elective replacement indicator (ERI), a charging cycle may be skipped. If this were to occur, the first shock will always be delivered as programmed and, if needed, the next shock in the programmed sequence would be delivered after a delay of only two to four seconds. A skipped charge would result in less than the full number of programmed shocks being available for delivery during that episode, but all delivered shocks would be at their programmed energy. This behavior was discovered as an incidental finding during analysis of one returned device that had delivered a large number of high-voltage shocks over a short time period. A second anomaly is caused by electrical "noise" generated as a result of the charging of the device's high-voltage capacitors. After a capacitor charge, if a rate responsive pacing mode (e.g., DDDR, VVIR, etc.) is programmed "On", this "noise" may be interpreted by the device's accelerometer (activity sensor) as physical activity, causing a temporary increase in the pacing rate that may persist after charging is completed. The degree and duration of the rate increase will depend on a variety of factors, but the rate will never exceed the programmed Maximum Sensor Rate, and the device will gradually return to the appropriate rate. The anomalous behavior, which has been observed during the performance of manual capacitor maintenance, has been traced back to a component supplied to St. Jude Medical by one vendor; therefore, only the subset of the device models listed above that were manufactured with the affected component (device serial numbers below 141000 for any model) will exhibit this behavior. St. Jude Medical has developed **programmer software that will automatically detect the affected ICDs and download device software that will correct the "skipped charge" anomaly and mitigate the response to electrical noise.** Once the upgrade is performed, the potential for a skipped charge will be eliminated. Additionally, once the upgrade is performed if a rate responsive mode is programmed "On", devices with serial numbers below 141000 will have their rate response functions suspended for the time period during which the electrical noise could be present (i.e., while significant residual voltage remains on the high-voltage capacitors); non-rate responsive pacing at the programmed base rate will continue to be provided as appropriate. This period during which rate response is suspended may last anywhere from a few minutes up to approximately 90 minutes. If rate responsive pacing was ongoing prior to charging, the pacing rate will gradually decrease to the base pacing rate according to the normal rate response recovery algorithm and will remain there while rate responsive pacing is suspended. The rate response behavior for devices with serial numbers greater than 141000 will not be affected by the software download. The software download for potentially affected devices will automatically be initiated the next time the patient's device is interrogated with the v4.8.5 programmer software. Since a skipped charge is more likely to occur in devices that are closer to their elective replacement indicator (ERI), St. Jude Medical recommends that if the next patient follow-up is not scheduled to occur within the next six months that the patient be seen within this time period. In addition, if devices are programmed to pacing settings that result in high current consumption, such as high output bi-ventricular pacing, consideration should be given to scheduling the patient for a follow-up visit within three months if it is not scheduled to occur within that time period. As always, St. Jude Medical defers to your clinical judgment on any decisions regarding the management of your patients. **Current Status (December 31, 2007):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Advisories & Safety Alerts

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Epic (V-197, V-235), Epic+ (V-196, V-236), Epic HF (V-338), Epic+ HF (V-250), Atlas+ (V-193, V-243), Atlas+ HF (V-340), or Atlas (model V-242) ICDs	3/10/05 Class II A software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value which could prevent these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied.	During routine product evaluation, St. Jude Medical Quality Assurance identified that a software parameter that affects the sensitivity of the reed switch in the listed devices was being set to an incorrect value during manufacturing beginning in late November of last year. This has the effect of preventing these devices from entering the magnet mode to inhibit tachy therapy when an external magnet is applied. **This is a software controlled parameter that can be easily corrected via the programmer.** All other bradycardia pacing and tachyarrhythmia detection and therapy features are not affected in devices subject to this notification. Until the magnet sensitivity parameter is corrected via the programmer, tachy therapy may not be properly inhibited as is customary with placement of an external magnet, but can be inhibited by using the programmer to program the device to Defib Off, and then back On as needed. The affected devices were manufactured during a three month period beginning November 22, 2004. **To date, there have been no field reports of any magnet mode failures, nor have there been any clinical complications reported associated with this issue.** Magnet mode application is usually used to inhibit tachycardia therapy such as when a patient is subjected to electrocautery during a surgical procedure. In order to remedy this situation, in addition to this notification, St. Jude Medical Sales Representatives and Field Clinical Engineers have been provided with a simple software tool that can be used to set, via the programmer, the reed switch's magnet sensitivity to the proper value. You may contact them to schedule this reprogramming at the patient's next scheduled follow-up visit or at your discretion. **Current Status (December 31, 2007):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.
Identity ADx DR Models 5286, 5380, 5386 and 5480	07/31/03 Class II An anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances could deliver a short coupled pacing interval of 300 ms (200 ppm). Consecutive (up to a maximum of 12) shorter than anticipated pacing intervals could be experienced.	St. Jude Medical's software engineering department has identified an anomaly in the pacemaker code, which under a certain set of programmed settings and specific event timing circumstances has a potential to deliver a short coupled pacing interval of approximately 300 milliseconds (200 ppm). It is also possible, however unlikely, that a patient could experience consecutive (up to a maximum of 12) shorter than anticipated pacing intervals. **To date, the only clinical observation has been the delivery of a single short interval. There have been no reports of patient injury as a result of the shortened pacing interval.** In order for the above mentioned shortened pacing interval to potentially occur, the programmed settings of the dual chamber device would have to satisfy both of the following conditions: • Base rate, rate hysteresis or rest rate programmed to 55 ppm or lower • Autocapture programmed ON Additionally, it should be noted that even with the following settings, the shortened pacing interval will not occur unless specific internal timing and other conditions are met. If the device is programmed to any other combination of settings (e.g. base rate, hysteresis rate and rest rate all at 60 ppm or above, or Autocapture programmed OFF), the scenario described above cannot occur. St. Jude Medical recommends that physicians review their records to identify which, if any, of their patients implanted with a subject device have programmed settings as described above. For these patients, they should schedule a pacemaker programming session as soon as possible to temporarily program Autocapture OFF or adjust the base rate, rate hysteresis and rest rate to 60 ppm or above. The root cause of potentially delivering the short pacing interval has been identified and a downloadable firmware correction has been developed to prevent any future occurrence. The revised firmware will be made available to the physicians via a new programmer software version immediately following FDA approval. The revised code will be downloaded automatically during pacer interrogation and will take approximately six seconds. At the time of the FDA approval, all newly manufactured and distributed products will also have the new pacemaker code. There is no need to consider replacement of the devices as the temporary programming outlined above and the forthcoming device firmware update will eliminate the potential for the described phenomenon from occurring in the future. **Current Status (December 31, 2007):** There have been no implanted devices confirmed to have been affected by this issue since the time of the advisory.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Tempo 2102 and Meta 1256D	11/04/02 Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	Decreased reliability has been observed in a group of these devices. The devices in the advisory population were manufactured at the Telectronics' manufacturing facility between the second quarter of 1996 and the second quarter of 1997. Premature battery depletion resulting from bridging between adjacent connectors has resulted in no output or no telemetry in 1% of this population of devices to date. The following recommendations are made: Physicians are advised to review patients who have 1256D/2102 pacemakers at an early date to evaluate pacemaker function. **For patients who are pacemaker dependent,** the physician should give consideration to explantation and replacement as soon as practicable. **For patients who are not considered pacemaker dependent,** the physician should consider replacement only if any abnormal function is identified (such as no output, telemetry loss, telemetry abnormality or premature end of life indication). All remaining non-pacemaker dependent patients with 1256D/2102 pacemakers should subsequently be reviewed at least every six months.
Tempo 1102, 1902, 2102, 2902 and Meta 1256D	11/04/02 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	This Advisory applies to a well-defined group of Tempo and Meta 1256D pulse generators which have been observed to exhibit premature battery depletion. This is an extension of a previous Tempo/Meta advisory dated 6/6/00. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.
Profile V-186	7/13/01 Class II Failure of a ceramic capacitor could lead to sensing anomalies/early battery depletion	This Advisory applies to a well-defined group of Profile MD (Model V-186HV3) implantable cardioverter-defibrillators (ICDs) which have been observed to exhibit decreased reliability. These devices had specific modules (subcircuits) manufactured during a five-month period during the first half of 1999. **Those potentially affected devices that have not exhibited any anomalous behavior within 24 months of manufacture are not at increased risk of failure at a later date.** These failures were caused by a component anomaly that is limited to a specific, traceable lot (group) of capacitors. If these capacitors fail, two different clinical manifestations may be observed, depending on the location of the failed capacitors: **Low Voltage Module:** The devices may exhibit sudden loss of sensing or oversensing of internally generated interference (noise) resulting in aborted or delivered shocks. Due to the potential for sudden loss of sensing, which would prevent the ICD from detecting ventricular tachyarrhythmias, device replacement should be considered for patients with devices incorporating the suspect capacitors in this location. In making this decision, you should weigh the likelihood that your patient will have one of the few additional devices expected to fail against the risk associated with the replacement procedure. For patients who do not have their devices replaced, St. Jude Medical recommends monthly monitoring for the remaining months during which additional failures are expected to occur and every three months thereafter. **High-Voltage Module:** The devices may exhibit premature battery depletion with no other clinical manifestations. While the battery voltage may drop rapidly to a value near or below the device's ERI, it stabilizes for several months at a value at which the device continues to detect arrhythmias and deliver therapy appropriately. In addition, some of these devices may exhibit oversensing of internally generated electrical interference (noise), which may result in false detection of tachyarrhythmias. However, during charging, the interference abates, and the therapy is usually aborted without the delivery of inappropriate shocks to the patient. Because these devices generally continue to respond appropriately to spontaneous tachyarrhythmias, and because the battery voltage stabilizes for several months at a level that does not compromise device function, St. Jude Medical recommends that patients with devices incorporating suspect capacitors in this location be monitored monthly for the remaining months during which additional failures are expected to occur and every three months thereafter.

Advisories & Safety Alerts

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Meta DDDR 1256	6/6/00 Class II Integrated circuit failure due to electrostatic discharge during manufacturing resulting in no output or sensing anomalies.	This Advisory applies to a well-defined group of Meta 1256 pulse generators, which have been observed to exhibit decreased reliability. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.
Tempo 1102, 1902, 2102, 2902, and Meta 1256D	6/6/00 Class II Dendritic growth at the battery/hybrid connection could cause a short circuit, which in turn could result in premature battery depletion.	This Advisory applies to a well-defined group of Tempo and Meta 1256D pulse generators, which have been observed to exhibit premature battery depletion. The following recommendations are made: **For patients who are significantly pacemaker dependent.** The decision as to whether or not to replace a pulse generator prophylactically remains one of clinical judgment. We therefore recommend that you strongly consider replacing these pulse generators on a prophylactic basis for all patients who are significantly pacemaker dependent, unless pulse generator replacement is medically contraindicated. **For patients who are not considered pacemaker dependent.** Again, this is a matter of clinical judgment. In the event a device is not replaced, continued routine monitoring is advised.
Trilogy 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	3/10/00 Class II Risk of malfunction due to an anomaly of the pacemaker's microprocessor. Typical mani-festations of this anomaly are dashes observed on the programmer screen, unexpected rate variation, abnormally high battery current drain, and mode change.	Continued monitoring of Trilogy devices affected by an Advisory issued in July 1999 has revealed an additional low level of adverse events. A sub-population of the above models, principally those manufactured before January 1999, is potentially affected by a risk of malfunction due to an anomaly of the pacemaker's microprocessor. To date this has been reported in only 0.11% of the implanted population. Typical manifestations of this anomaly are: • Interrogation/programming difficulties, including the presence of dashes (—) on the programmer screen for some parameter values after interrogation • Unexpected rate variations • Abnormally high battery current drain • Mode change The presence of dashes on the programmer screen is typically caused by partial programming of one or more of the programmed parameters and may be corrected by reprogramming. In the event that observed dashes (—-) cannot be resolved by reprogramming, please contact your St. Jude Medical representative, as it may be possible to resolve the situation non-invasively via special programming and may not be indicative of a microprocessor anomaly. Considering the low level of incidence of this anomaly, the following steps are recommended: 1. Assess the patient population, relative to the potential for an inappropriate mode change to single-chamber atrial pacing, to determine which patients are pacemaker-dependent and have an inadequate ventricular escape rhythm. 2. Replacement of a device always remains a matter of clinical judgement, including balancing the clinical risk associated with pacemaker replacement against the risk of device malfunction. 3. Almost all microprocessor malfunctions described in this notification were found during routine follow-up. This reinforces the importance that pacemaker patients should be followed regularly in accordance with best prevailing medical practices.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Affinity 5130L, 5130R, 5330L, 5330R, 5230L, 5230R	2/14/00 Class II An unsecured resistor connection to the hybrid circuit might cause abnormal measured data, false RRT indication, backup VVI mode, or intermittent loss of output.	This advisory applies to a very specific, well-defined group of Affinity devices that have been implanted worldwide. The device may exhibit any or all of the following output anomalies: • Abnormal measured battery data, • A false recommended replacement (RRT) indication, • Reversion to back-up VVI mode, • Intermittent loss of output. One marker of an affected device that may be apparent during a routine follow-up interrogation is an abnormally high reading for battery current (taking into consideration the device's programmed output parameters). If this or an early indication of RRT or reversion to back-up VVI mode is observed, please contact your local St. Jude Medical representative or Technical Services. Although the time course is variable, these behavioral anomalies will occur before there is any affect on device output.
Trilogy 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	7/19/99 Class II Premature battery depletion caused by a current leakage path that could be created during the laser welding process to attach the battery to the device hybrid	Analysis of the clinical data associated with the failed devices has shown that an early increase in battery impedance could be observed at one or more previous routine follow-up visits prior to reaching RRT. The observed rise in battery impedance is an earlier and more reliable indicator than the reported battery voltage. The battery depletion, although accelerated, does not occur abruptly and patients can be monitored using the measured data telemetry in the pacemaker. The following follow-up schedule and device monitoring is advised. 1. For patients who have had a follow-up visit at least 12 months after their device was implanted, check the measured data printout from the last follow-up evaluation. If a battery impedance of "< 1 kOhm" was recorded, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every 6 months is not your routine schedule, then an additional visit at 18 months should be performed. 2. For patients who have not yet had a follow-up visit at least 12 months after their device was implanted, the following is recommended: • If the patient has had their device implanted for less than two months or has not had a device interrogation with measured data within the last three months, an evaluation of the battery impedance is recommended as soon as possible. This should be printed and a copy retained in the patient's pacemaker or office chart. • Otherwise, if the battery impedance from the most recent evaluation is "< 1 kOhm," begin an every 3-month follow-up schedule with respect to measured data telemetry until that value has been recorded at least 12 months post-implant. Thereafter, continue to monitor the battery impedance with your routine follow-up schedule for that patient (6-month intervals recommended). If follow-up visits every six months is not your routine schedule, then an additional visit at 18 months should be performed. If the battery impedance reading is 1 kOhm or higher and the pulse generator has been implanted for less than two years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services.

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