Product Performance Report

Cardiac Rhythm Management

April 2007

ST. JUDE MEDICAL

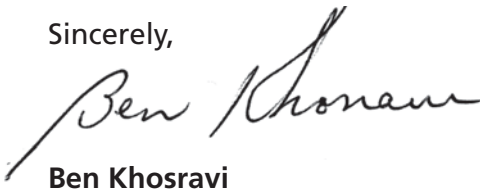
APRIL 2007

As world leaders in the development of state-of-the-art technology for cardiac rhythm management (CRM) devices, St. Jude Medical appreciates that our products are implanted in people whose health and well-being depend on their performance. From product design through patient follow-up, St. Jude Medical employees are dedicated to product quality and patient safety. In keeping with this commitment, we publish a product performance report semi-annually to keep the healthcare community and the patients it serves 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 have worked together through AdvaMed to establish a proposal for "Requirements for Uniform Reporting of Clinical Performance of Pulse Generators." This proposal, which St. Jude Medical has adopted, 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 a result of this cooperation with AdvaMed and other cardiac device companies, St. Jude Medical has further modified its product performance report as described on the following pages.

As we continually strive to provide transparent and consistent 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,



Ben Khosravi
Executive Vice President
Technology Program Management,
Quality & Leads Business Unit

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Serving our mission

St. Jude Medical's mission is to make life better through excellence in medical device technology and services. Toward that effort, 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; 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, 2006, 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 starting in 2003.

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 22 for Cardiac Resynchronization Therapy (CRT) ICDs, for CRT-Pulse Generators page 28, for ICDs pages 48 and 62 and for Pulse Generators pages 96 and 116.

For ICDs prior to Photon Micro and pacemakers prior to Affinity, you will find analysis of the data collected through December 31, 2006, consistent with previous product performance reports. These device models include:

ICDs

Photon DR V-230HV
Profile V-186F, V-186HV3
Contour MD V-175, V-175AC, V-175B, V-175C, V-175D
Contour II V-185, V-185AC, V-185B, V-185C, V-185D

Pulse Generators (Pacemakers)

Meta DDDR 1256D
Tempo D 2902
Tempo DR 2102
Meta DDDR 1256
Trilogy DC+ 2318
Trilogy DR+ 2360, 2364
Trilogy DR 2350
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, 2006. 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 failure -** a disruption in the insulation or conductors resulting in compromised electrical performance.
- **Other -** includes other sources of malfunction not attributed to damage incurred at the attempted implant and not resulting in compromised electrical failures. This category also includes any partial leads returned with an alleged malfunction even if it was not possible to perform analysis to 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

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.

What's new in this report

Starting with this version of the St. Jude Medical Product Performance Report, a summary description section has been added to each survival chart, 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)

For the CRT ICD, ICD, and Pulse Generator (Pacemaker) tabulated data, the following data has been added:

- Number of Returns with Malfunction due to Premature Battery Depletion

Leads

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

Additionally, the method to calculate leads survival has been revised to only include lead complications (returns and complaints not returned) with implant duration greater than 30 days. Lead complications under 30 days are not considered to be related to a lead malfunction and are therefore excluded from the survival calculations, consistent with industry practice.

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 the risk to patients of explanting these devices.

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. 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.

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. At the time of this report, St. Jude Medical is not using data from leads registry studies.

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.

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.

Medical Advisory Board Review

St. Jude Medical has established separate 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. For example, approximately 85% of St. Jude Medical pacemakers are expected to survive up to their estimated longevity based on 3.5 V pacing output, 100% DDD pacing, 500 ohms lead impedance, stored EGMs Off, and AutoCapture Off. Also, we have revised our definition of normal battery depletion to 75% of estimated longevity, consistent with the AdvaMed proposal and other product performance reports in our industry.

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, Identity pacemaker model 5386 has an estimated longevity of 6.9 years based on 3.5 V pacing output, 100% DDD pacing, 500 ohms lead impedance, stored EGMs Off, and AutoCapture Off.

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

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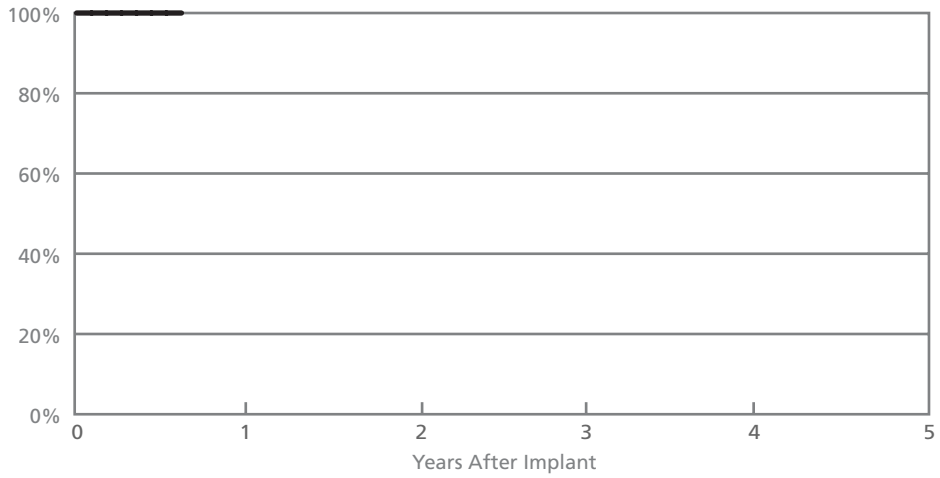
Epic™ II HF (Model V-355)

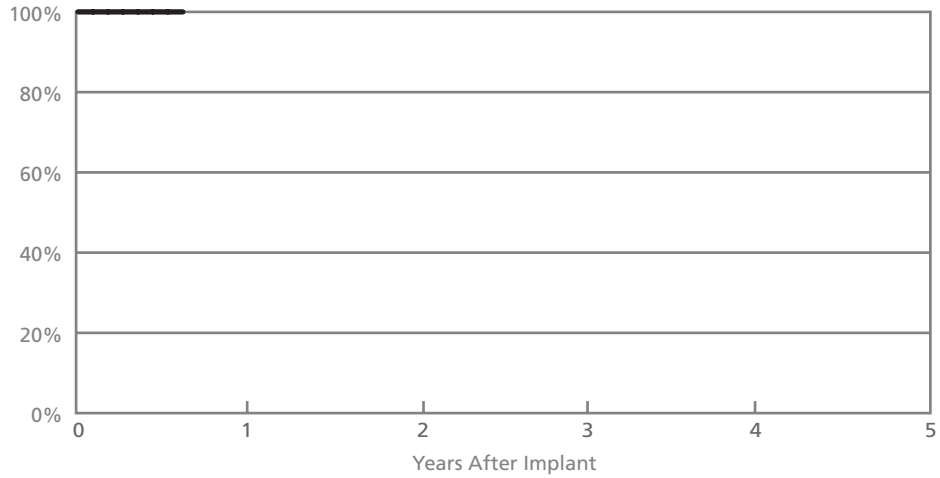
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	233	Malfunctions	0
Estimated Active US Implants	232	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 8 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	100				

Excluding Normal Battery Depletion

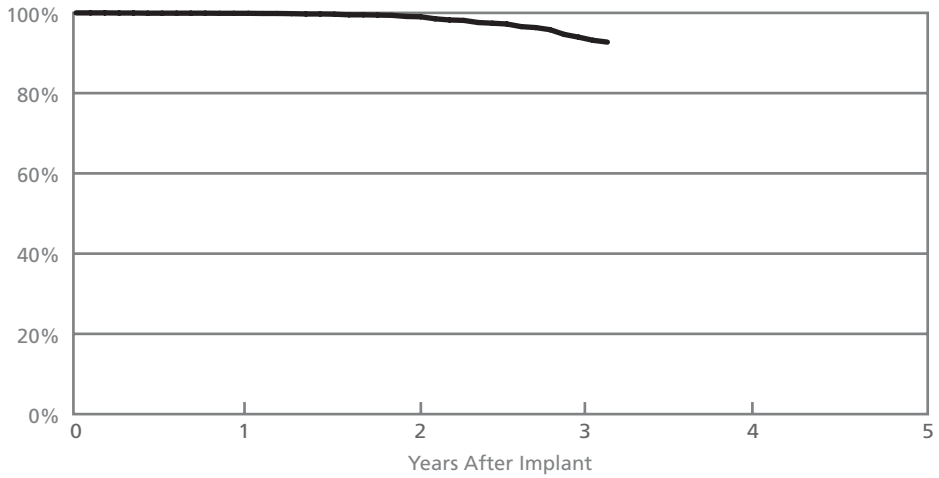


Year	at 8 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Epic™ HF (Model V-338)

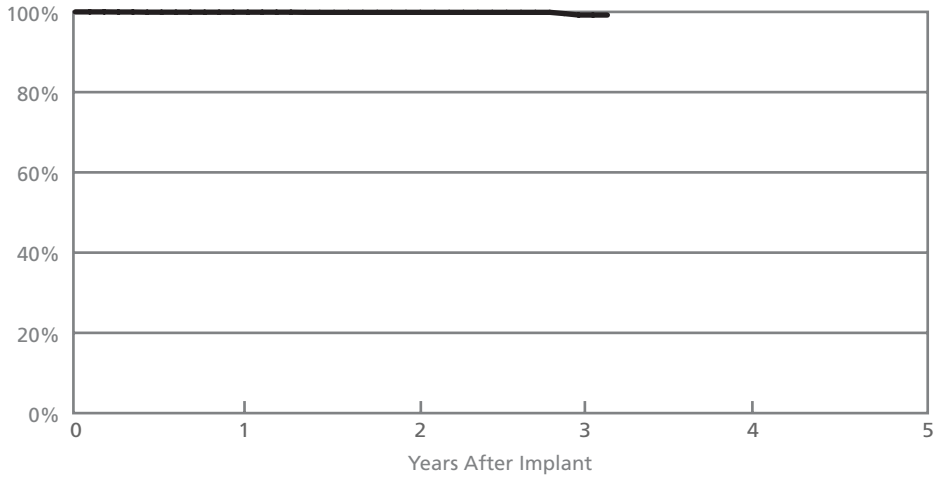
US Market Release	June 2004	Normal Battery Depletion	55
Registered US Implants	3,080	Malfunctions	6
Estimated Active US Implants	2,378	Malfunctions w/ Compromised Therapy (0 related to Advisory)	2
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	4
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	3	at 38 months	
Survival Probability	99.90%	99.11%	93.95%	92.72%	
± 1 standard error	0.06%	0.22%	0.96%	1.19%	
Sample Size	3080	2100	900	200	

Excluding Normal Battery Depletion

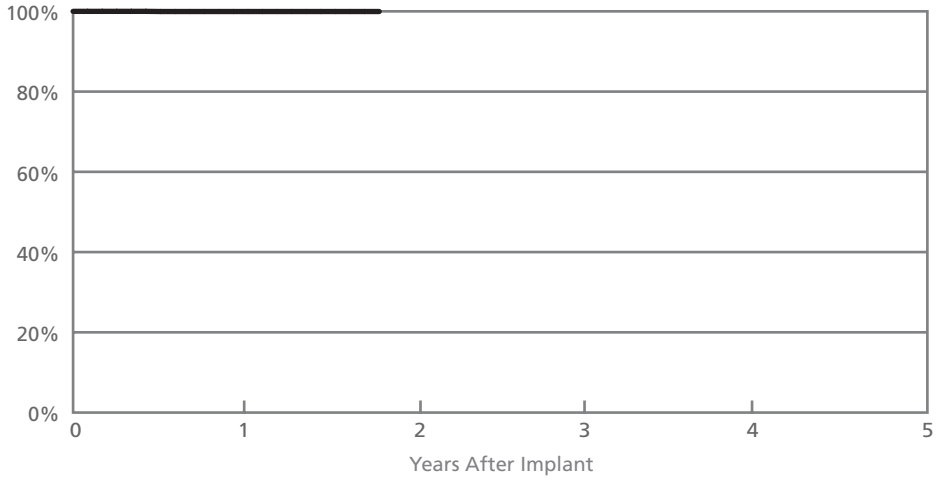


Year	1	2	3	at 38 months	
Survival Probability	99.93%	99.89%	99.22%	99.22%	
± 1 standard error	0.05%	0.07%	0.32%	0.48%	

Epic™ HF (Model V-337)

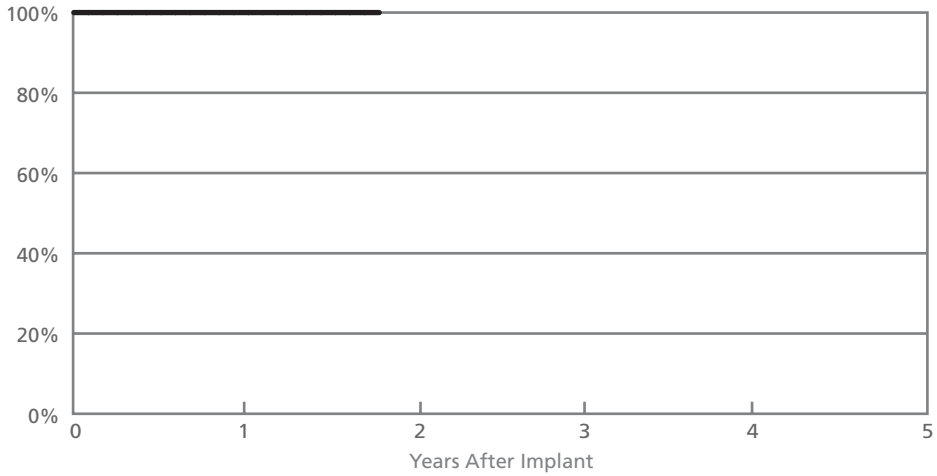
US Market Release	November 2004	Normal Battery Depletion	1
Registered US Implants	3,412	Malfunctions	0
Estimated Active US Implants	3,168	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	at 22 months			
Survival Probability	99.96%	99.96%			
± 1 standard error	0.04%	0.04%			
Sample Size	2500	800			

Excluding Normal Battery Depletion

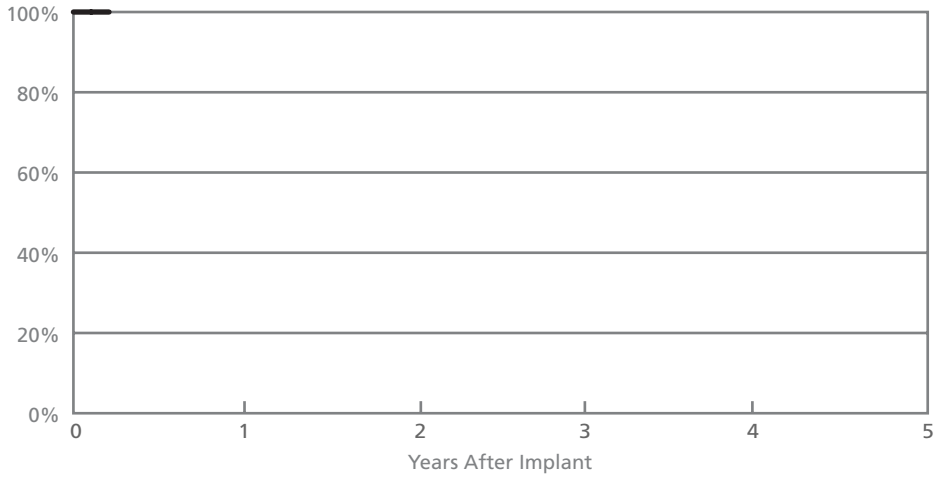


Year	1	at 22 months			
Survival Probability	100.00%	100.00%			
± 1 standard error	0.00%	0.00%			

Atlas® II HF (Model V-365)

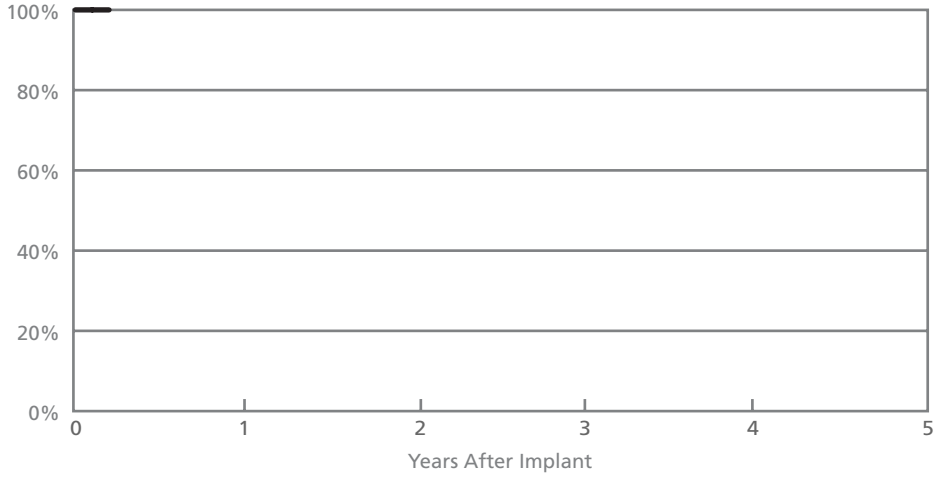
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	978	Malfunctions	0
Estimated Active US Implants	973	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 3 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	500				

Excluding Normal Battery Depletion

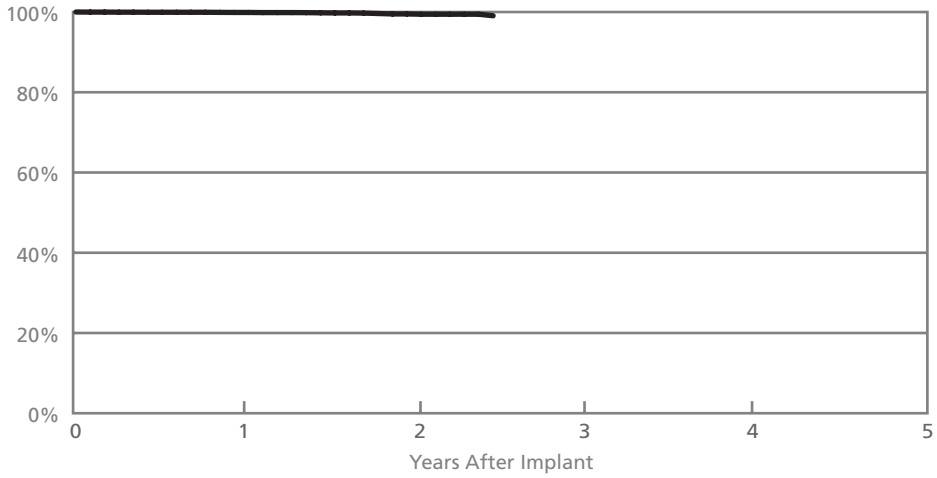


Year	at 3 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® + HF (Model V-340)

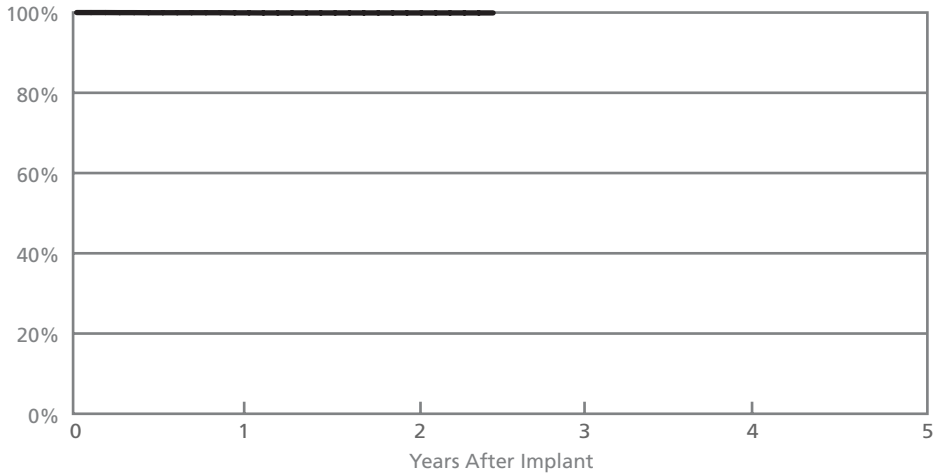
US Market Release	June 2004	Normal Battery Depletion	12
Registered US Implants	4,898	Malfunctions	4
Estimated Active US Implants	4,050	Malfunctions w/ Compromised Therapy (0 related to Advisory)	3
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	at 30 months		
Survival Probability	99.89%	99.52%	99.07%		
± 1 standard error	0.04%	0.14%	0.15%		
Sample Size	4890	3000	900		

Excluding Normal Battery Depletion

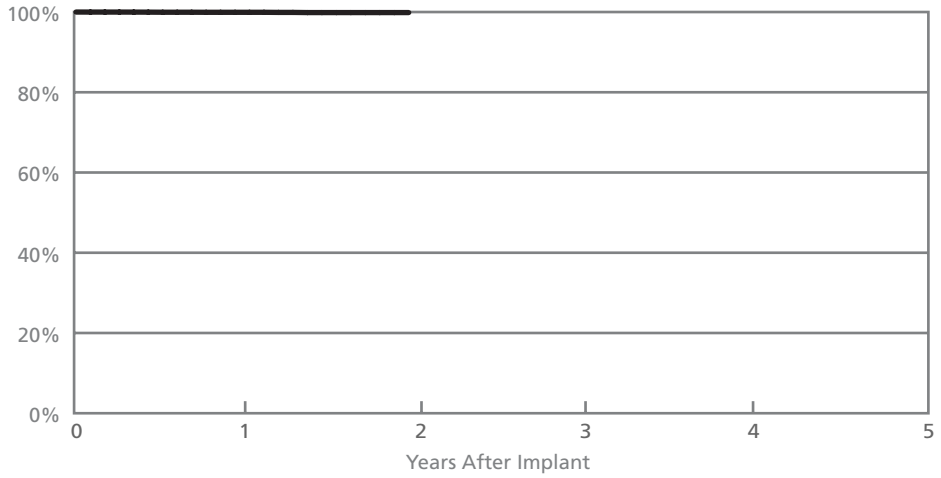


Year	1	2	at 30 months		
Survival Probability	99.93%	99.91%	99.91%		
± 1 standard error	0.03%	0.05%	0.05%		

Atlas® + HF (Model V-343)

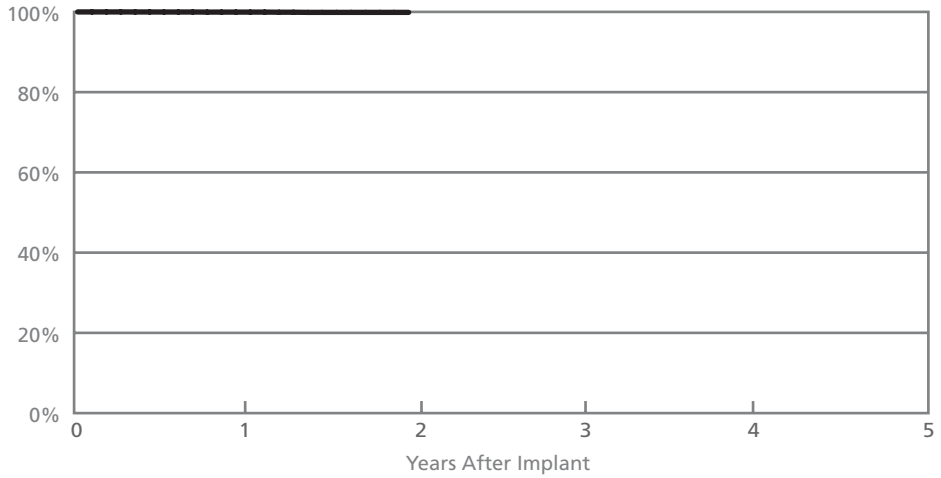
US Market Release	November 2004	Normal Battery Depletion	2
Registered US Implants	14,389	Malfunctions	7
Estimated Active US Implants	13,527	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 22)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	3
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2			
Survival Probability	99.93%	99.86%			
± 1 standard error	0.03%	0.06%			
Sample Size	10100	2600			

Excluding Normal Battery Depletion



Year	1	2			
Survival Probability	99.95%	99.88%			
± 1 standard error	0.02%	0.05%			

Summary Information

Cardiac Resynchronization Therapy
CRT 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 (premature battery depletion)	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion	Survival Probability**		
											1 year	2 year	3 year
V-355	Epic II HF	May 06	233	232	0	0	0	0	0	0			
V-338	Epic HF	June 04	3080	2378	2	0	1	3	6	55	99.90%	99.11%	93.95%
V-337	Epic HF	November 04	3412	3168	0	0	0	0	0	1	99.96%		
V-365	Atlas II HF	August 06	978	973	0	0	0	0	0	0			
V-340	Atlas + HF	June 04	4898	4050	2	1	1	0	4	12	99.89%	99.52%	
V-343	Atlas + HF	November 04	14389	13527	2	2	3	0	7	2	99.93%	99.86%	

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 (premature battery depletion)	Malfunctions w/o Compromised Therapy	Malfunctions w/o Compromised Therapy (premature battery depletion)	Total Malfunctions	Survival Probability**		
										1 year	2 year	3 year
V-355	Epic II HF	May 06	233	232	0	0	0	0	0			
V-338	Epic HF	June 04	3080	2378	2	0	1	3	6	99.93%	99.89%	99.22%
V-337	Epic HF	November 04	3412	3168	0	0	0	0	0	100.00%		
V-365	Atlas II HF	August 06	978	973	0	0	0	0	0			
V-340	Atlas + HF	June 04	4898	4050	2	1	1	0	4	99.93%	99.91%	
V-343	Atlas + HF	November 04	14389	13527	2	2	3	0	7	99.95%	99.88%	

Battery Longevity

Models	Family	Approximate Duration (years)†			
		No Pacing	25% Pacing	50% Pacing	100% Pacing
V-355	Epic II HF	6.5	5.9	5.4	4.6
V-338, V-337	Epic HF, serial numbers <13000	6.0	5.6	5.3	4.9
	Epic HF, serial numbers >13000	6.5	6.0	5.6	4.9
V-365	Atlas II HF	8.2	7.5	7.0	6.1
V-340	Atlas + HF	7.9	7.3	6.9	6.1
V-343	Atlas + HF	7.9	7.3	6.9	6.1

** Based on returned product analysis as of December 31, 2006.*

*** 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 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. (See the reference manuals for more information.)

Cardiac Resynchronization Therapy

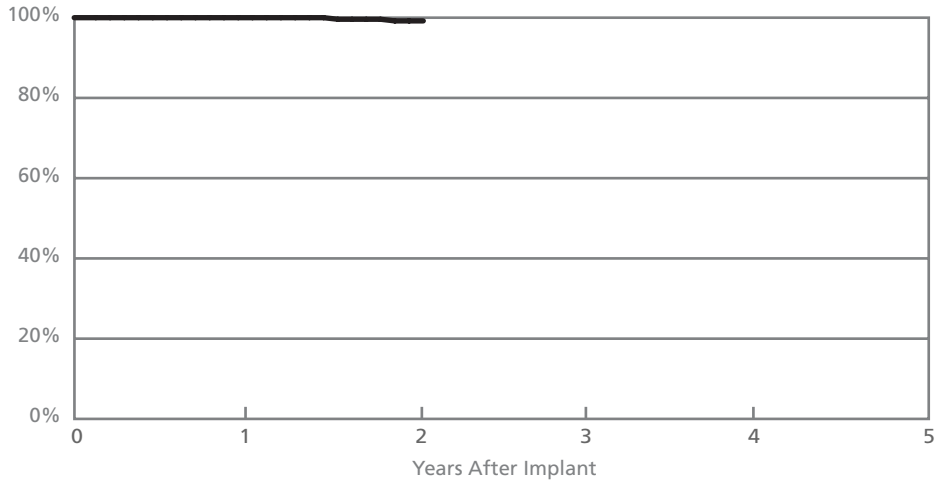
Pulse Generators

ST. JUDE MEDICAL

Frontier® (Model 5508)

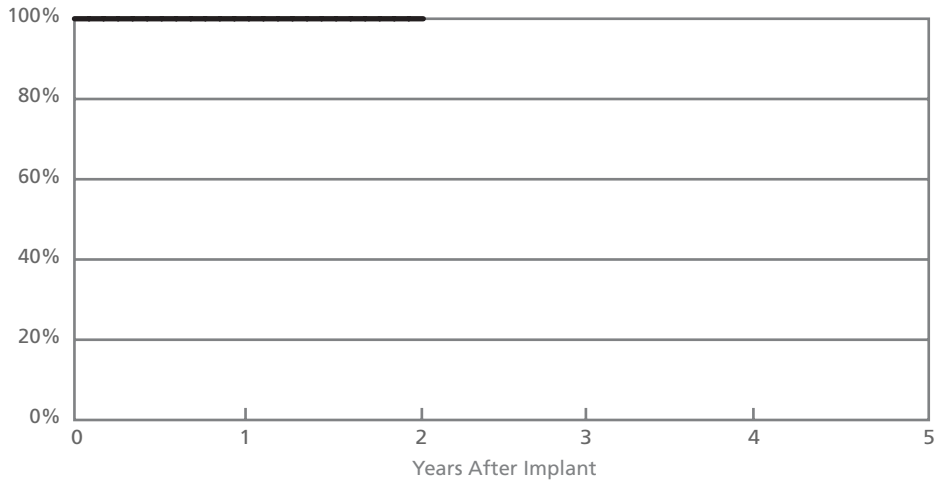
US Market Release	May 2004	Normal Battery Depletion	1
Registered US Implants	374	Malfunctions	0
Estimated Active US Implants	241	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.9 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	at 25 months		
Survival Probability	100.00%	99.20%	99.20%		
± 1 standard error	0.00%	0.57%	0.57%		
Sample Size	370	300	200		

Excluding Normal Battery Depletion

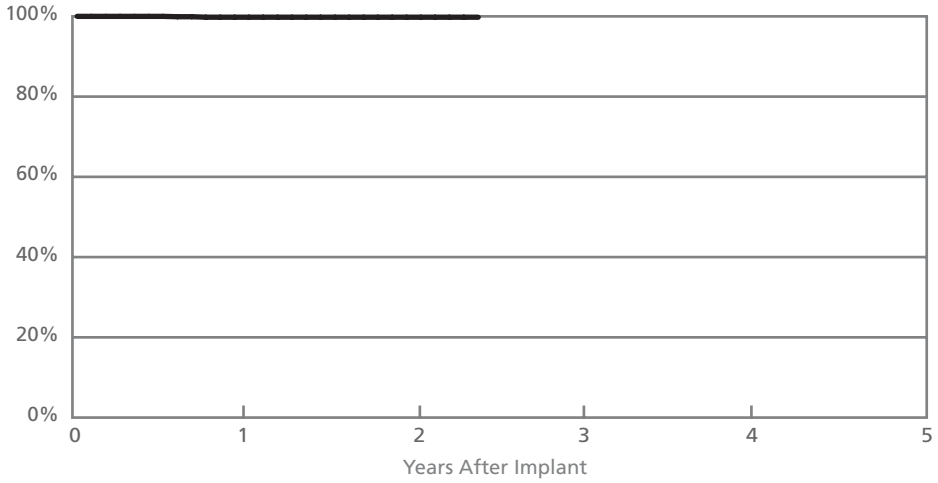


Year	1	2	at 25 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		

Frontier® II (Model 5586)

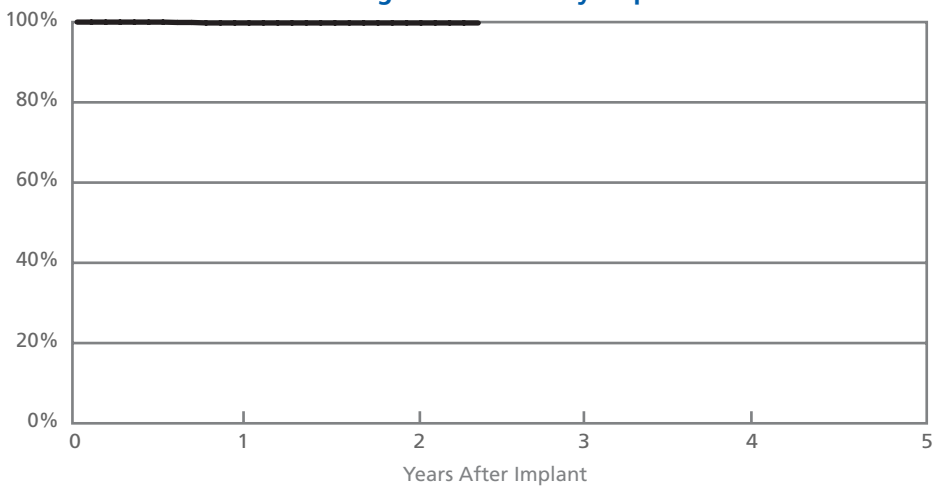
US Market Release	August 2004	Normal Battery Depletion	0
Registered US Implants	1,864	Malfunctions	2
Estimated Active US Implants	1,649	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	6.5 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	at 29 months		
Survival Probability	99.79%	99.79%	99.79%		
± 1 standard error	0.15%	0.15%	0.15%		
Sample Size	1400	700	300		

Excluding Normal Battery Depletion



Year	1	2	at 29 months		
Survival Probability	99.79%	99.79%	99.79%		
± 1 standard error	0.15%	0.15%	0.15%		

Summary Information

Cardiac Resynchronization Therapy Pulse Generators

ST. JUDE MEDICAL

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 (premature battery depletion)	Total Malfunctions	Total Normal Battery Depletion	Survival Probability		
										1 year	2 year	3 year
5508	Frontier	May 2004	374	241	0	0	0	0	1	100.00%	99.20%	
5586	Frontier II	August 2004	1864	1649	1	1	0	2	0	99.79%	99.79%	

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 (premature battery depletion)	Total Malfunctions	Survival Probability		
									1 year	2 year	3 year
5508	Frontier	May 2004	374	241	0	0	0	0	100.00%	100.00%	
5586	Frontier II	August 2004	1864	1649	1	1	0	2	99.79%	99.79%	

**Based on returned product analysis as of December 31, 2006.*

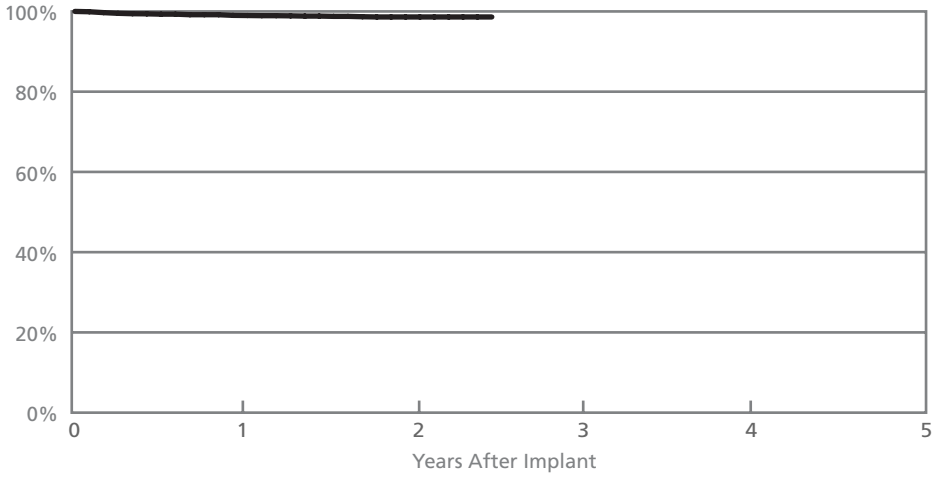
Cardiac Resynchronization Therapy

Left Heart Leads

ST. JUDE MEDICAL

QuickSite® (Model 1056K)	Laboratory Analysis:	Implant Damage: 80	Electrical Malfunction: 2	Other: 68

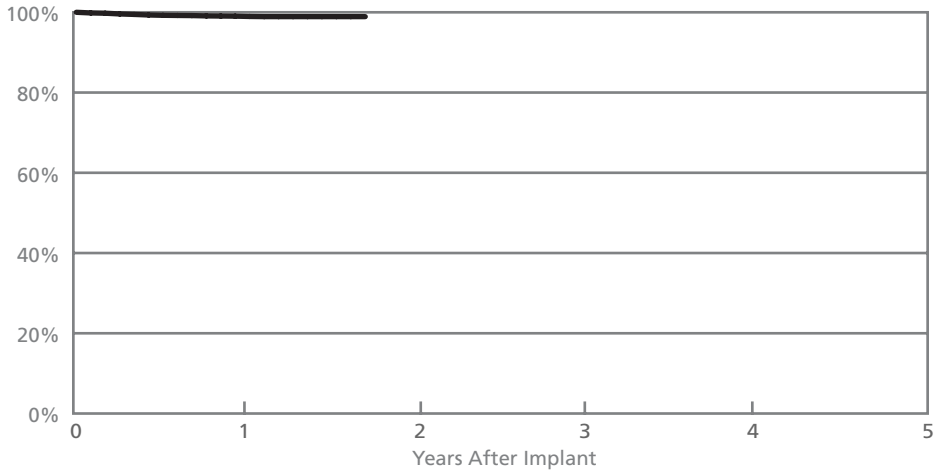
US Market Release	June 2004	Type and/or Fixation	S-Curve
Registered US Implants	6,523	Polarity	Unipolar
Estimated Active US Implants	5,142	Steroid	Yes
		Number of Advisories	None



Year	1	2	at 30 months		
Survival Probability	99.02%	98.62%	98.62%		
± 1 standard error	0.12%	0.16%	0.16%		
Sample Size	6200	3900	1300		

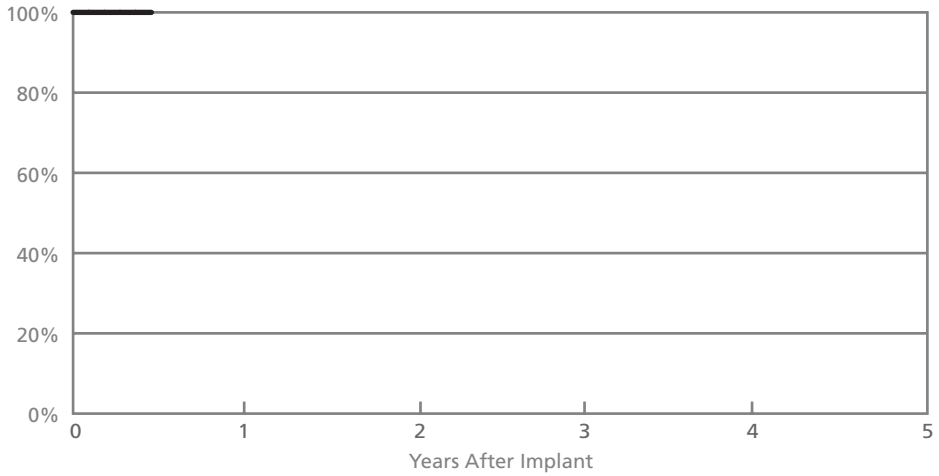
QuickSite® (Model 1056T)	Laboratory Analysis:	Implant Damage: 59	Electrical Malfunction: 1	Other: 125

US Market Release	April 2005	Type and/or Fixation	S-Curve
Registered US Implants	17,543	Polarity	Bipolar
Estimated Active US Implants	15,924	Steroid	Yes
		Number of Advisories	None



Year	1	at 21 months			
Survival Probability	99.04%	98.92%			
± 1 standard error	0.09%	0.10%			
Sample Size	12500	3100			

QuickSite® (Model 1058T)	Laboratory Analysis:	Implant Damage: 6	Electrical Malfunction: 0	Other: 3
US Market Release	February 2006	Type and/or Fixation		S-Curve
Registered US Implants	1,469	Polarity		Bipolar
Estimated Active US Implants	1,423	Steroid		Yes
		Number of Advisories		None



Year	at 6 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	700				

Laboratory Analysis*

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Implant Damage	Electrical Malfunctions	Other
1056K	June 04	6523	5142	80	2	68
1056T	April 05	17543	15924	59	1	125
1058T	February 06	1469	1423	6	0	3

Laboratory analysis of all returned leads from the U.S. is summarized by model for the most recently market released cardiac resynchronization therapy (CRT) lead models included in this Product Performance Report. The Laboratory analysis results are categorized into one of the following three categories:

- Implant Damage - Obvious damage incurred at the time of 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.
- Other - Includes other sources of malfunction not attributed to damage incurred at implant and not resulting in compromised electrical failures. This category also includes any partial leads returned with an alleged malfunction even if it was not possible to perform analysis to confirm the malfunction.

**Based on returned product analysis as of December 31, 2006.*

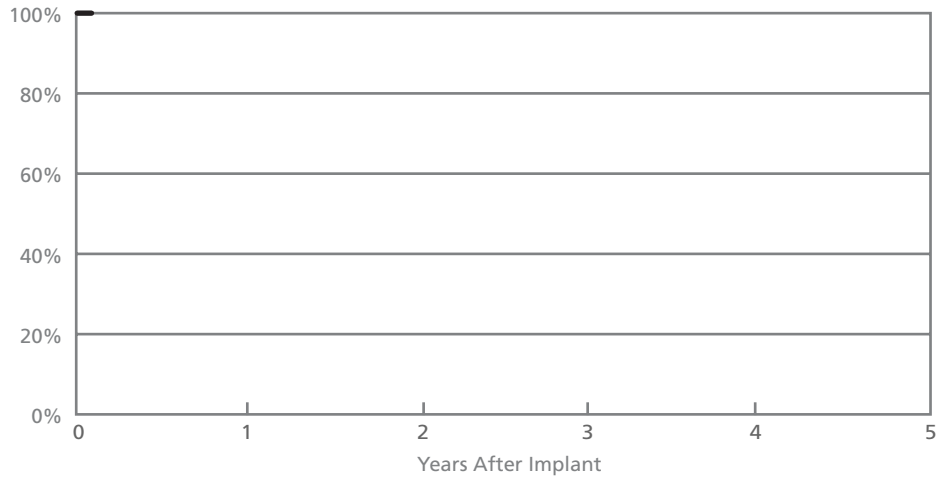
ICDs
Dual-Chamber

ST. JUDE MEDICAL

Atlas® II DR (Model V-265)

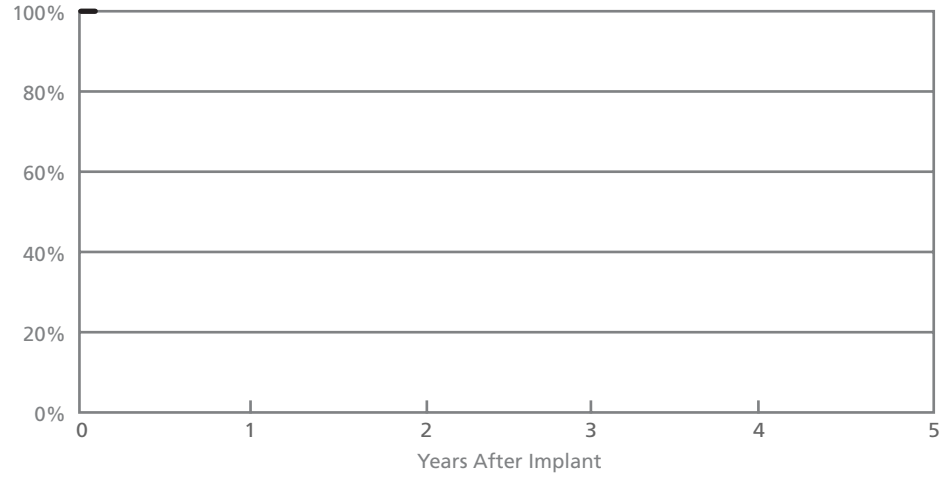
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	208	Malfunctions	0
Estimated Active US Implants	205	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	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

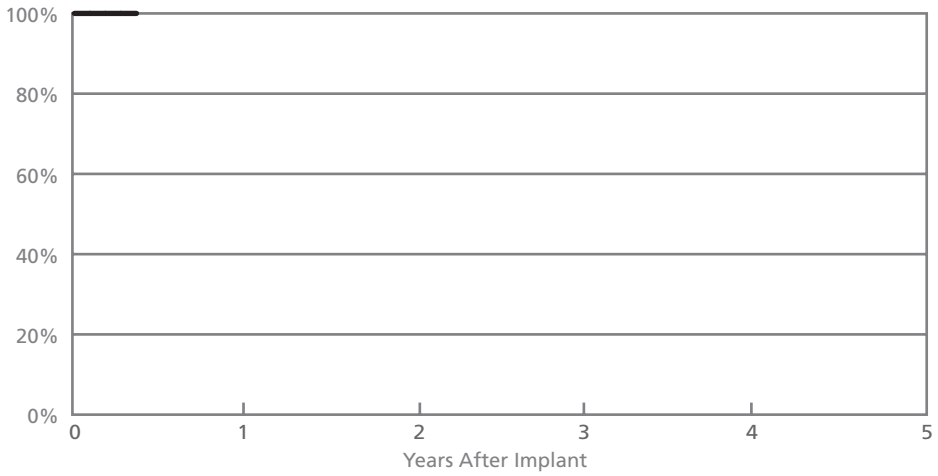


Year	at 1 month				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® II DR (Model V-268)

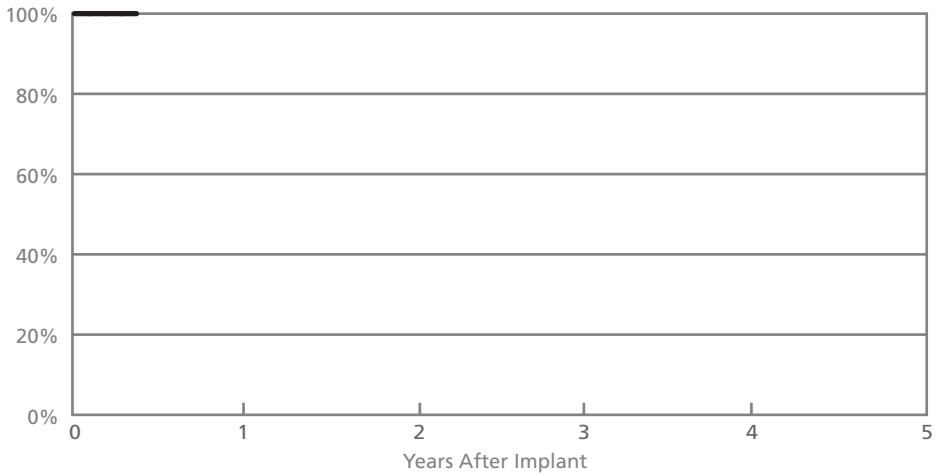
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	1,078	Malfunctions	0
Estimated Active US Implants	1,074	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



Year	at 3 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	500				

Excluding Normal Battery Depletion

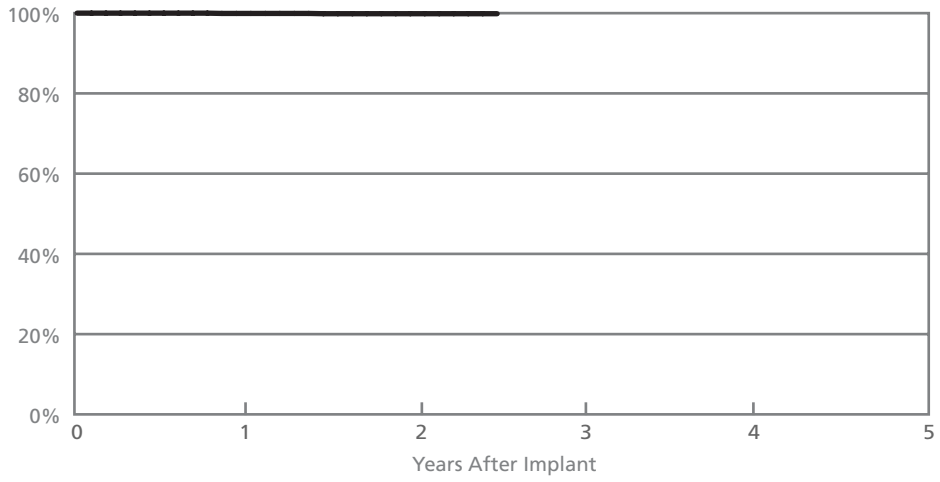


Year	at 3 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® DR (Model V-242)

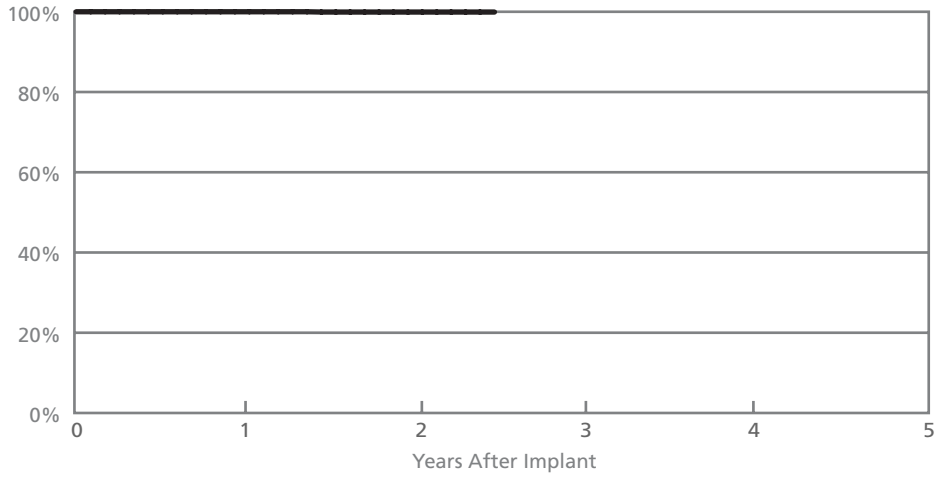
US Market Release	October 2003	Normal Battery Depletion	2
Registered US Implants	4,161	Malfunctions	1
Estimated Active US Implants	3,770	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	at 30 months		
Survival Probability	99.93%	99.86%	99.86%		
± 1 standard error	0.05%	0.08%	0.08%		
Sample Size	3500	1600	400		

Excluding Normal Battery Depletion

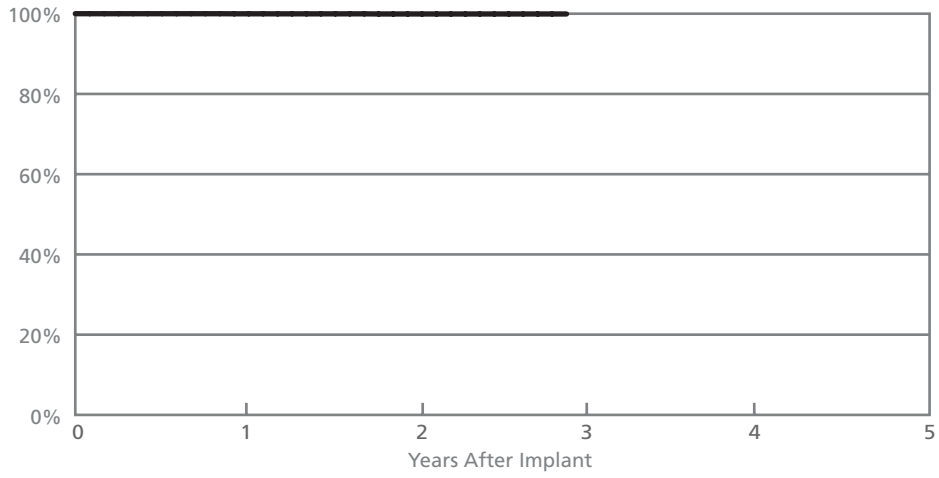


Year	1	2	at 30 months		
Survival Probability	100.00%	99.93%	99.93%		
± 1 standard error	0.00%	0.07%	0.07%		

Atlas® + DR (Model V-243)

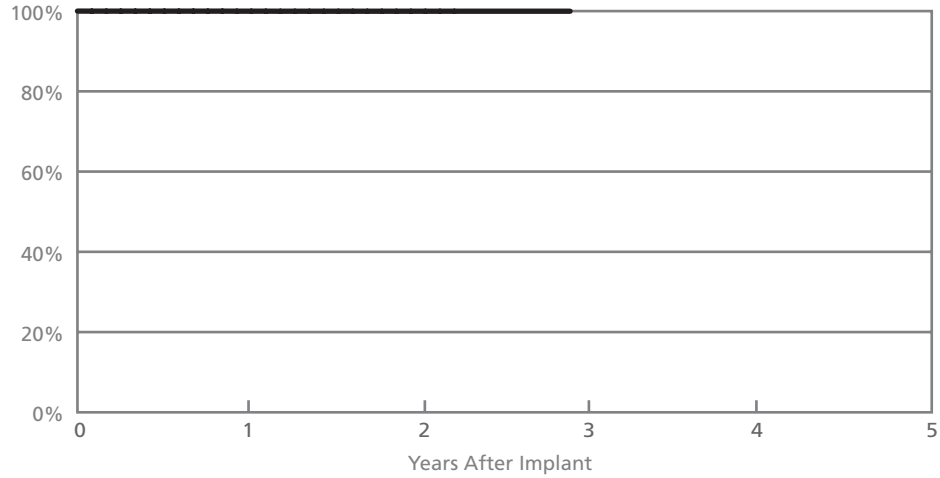
US Market Release	October 2003	Normal Battery Depletion	2
Registered US Implants	17,049	Malfunctions	3
Estimated Active US Implants	15,728	Malfunctions w/ Compromised Therapy (0 related to Advisory)	2
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	at 35 months		
Survival Probability	99.97%	99.93%	99.93%		
± 1 standard error	0.01%	0.04%	0.04%		
Sample Size	13200	5700	1200		

Excluding Normal Battery Depletion

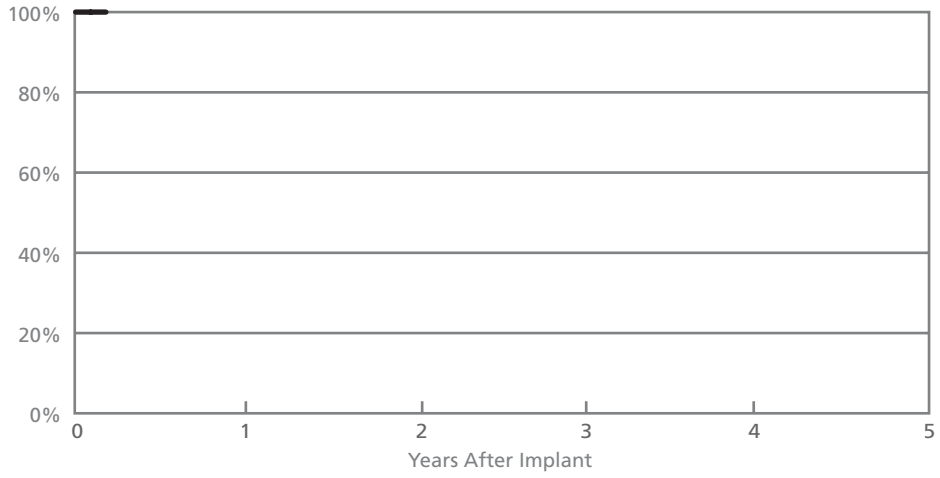


Year	1	2	at 35 months		
Survival Probability	99.98%	99.97%	99.97%		
± 1 standard error	0.01%	0.02%	0.02%		

Epic™ II DR (Model V-258)

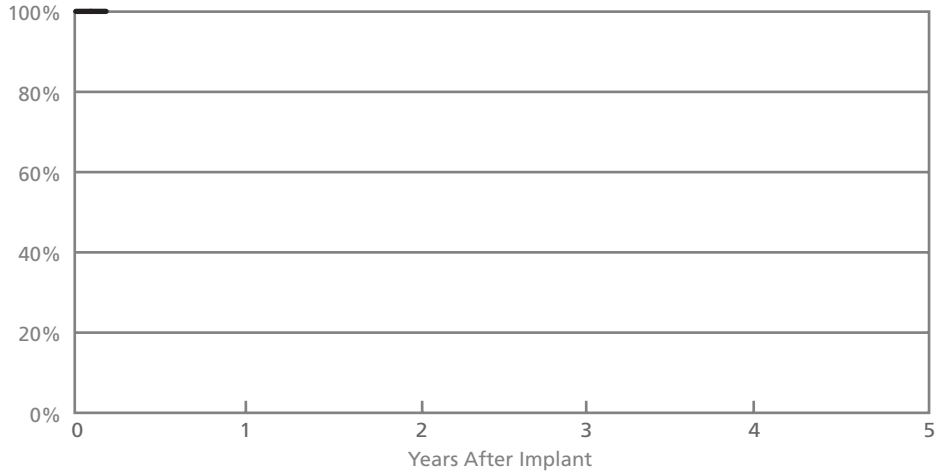
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	270	Malfunctions	0
Estimated Active US Implants	265	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

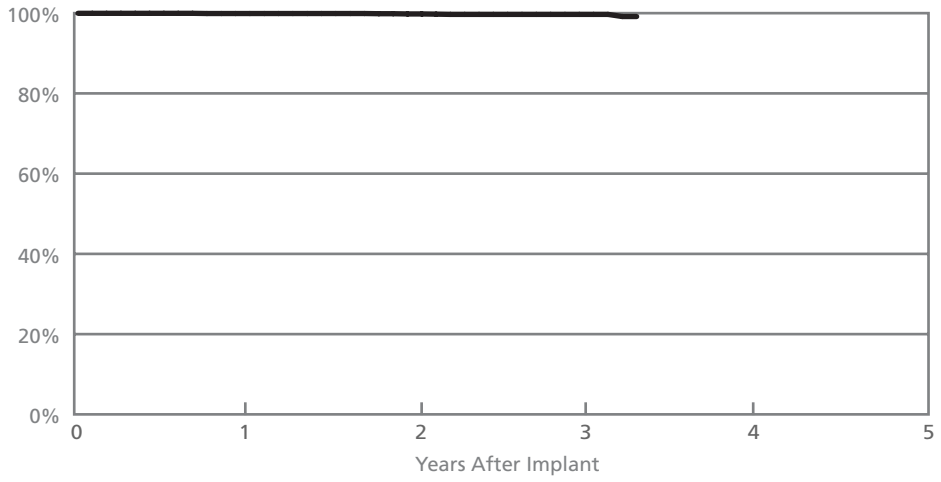


Year	at 2 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Epic™ + DR (Model V-236)

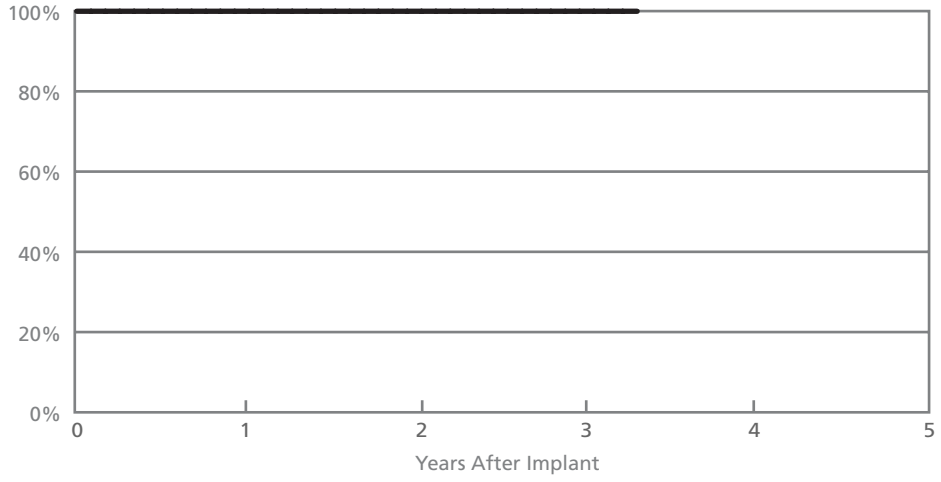
US Market Release	April 2003	Normal Battery Depletion	7
Registered US Implants	2,334	Malfunctions	1
Estimated Active US Implants	1,751	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	1
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	3	at 40 months	
Survival Probability	99.91%	99.80%	99.69%	99.16%	
± 1 standard error	0.08%	0.08%	0.13%	0.40%	
Sample Size	2300	2100	1400	500	

Excluding Normal Battery Depletion

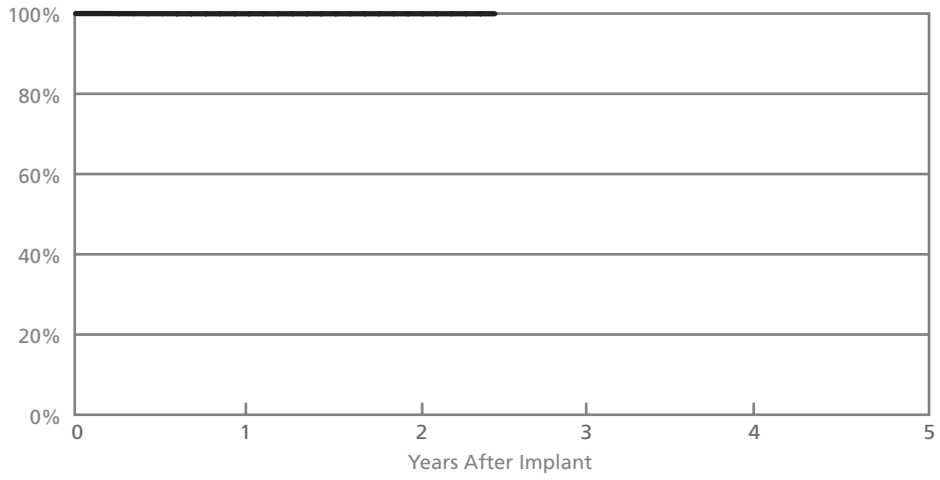


Year	1	2	3	at 40 months	
Survival Probability	99.96%	99.96%	99.96%	99.96%	
± 1 standard error	0.04%	0.04%	0.04%	0.04%	

Epic™ + DR (Model V-239)

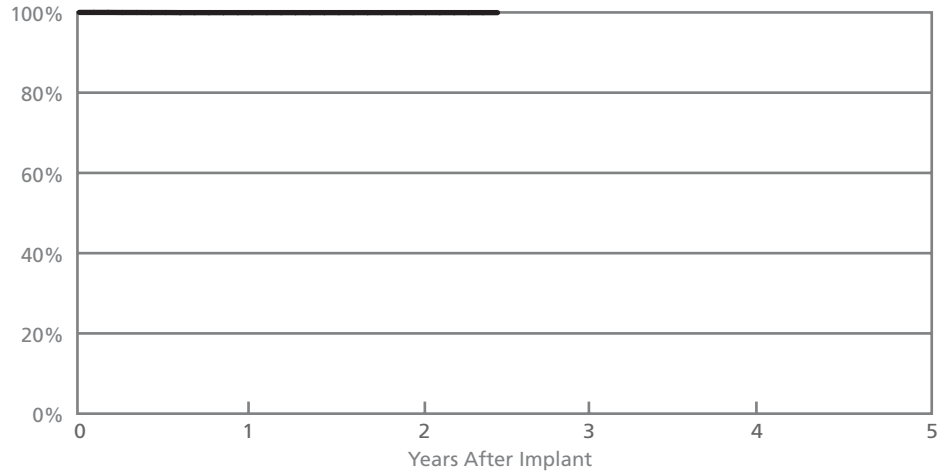
US Market Release	October 2003	Normal Battery Depletion	0
Registered US Implants	6,944	Malfunctions	3
Estimated Active US Implants	6,336	Malfunctions w/ Compromised Therapy (0 related to Advisory)	3
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	at 30 months		
Survival Probability	99.95%	99.95%	99.95%		
± 1 standard error	0.03%	0.03%	0.03%		
Sample Size	5800	2700	700		

Excluding Normal Battery Depletion

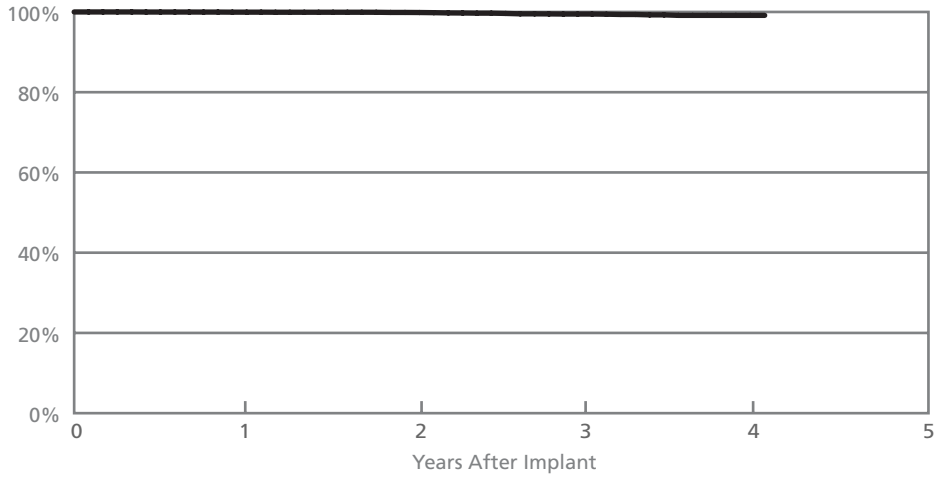


Year	1	2	at 30 months		
Survival Probability	99.95%	99.95%	99.95%		
± 1 standard error	0.03%	0.03%	0.03%		

Epic™ DR (Model V-235)

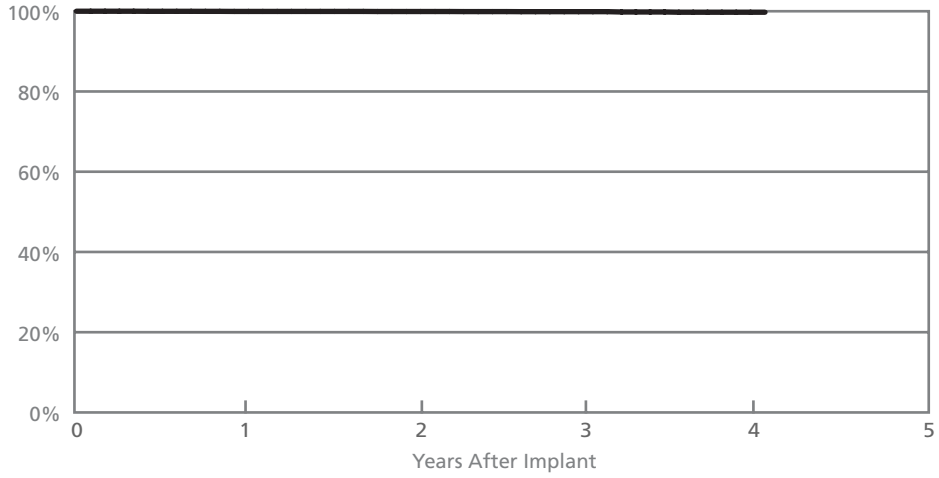
US Market Release	July 2002	Normal Battery Depletion	23
Registered US Implants	6,567	Malfunctions	9
Estimated Active US Implants	4,747	Malfunctions w/ Compromised Therapy (0 related to Advisory)	3
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	6
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 49 months
Survival Probability	99.95%	99.88%	99.48%	99.15%	99.15%
± 1 standard error	0.02%	0.05%	0.11%	0.16%	0.16%
Sample Size	6560	5800	4500	2000	200

Excluding Normal Battery Depletion

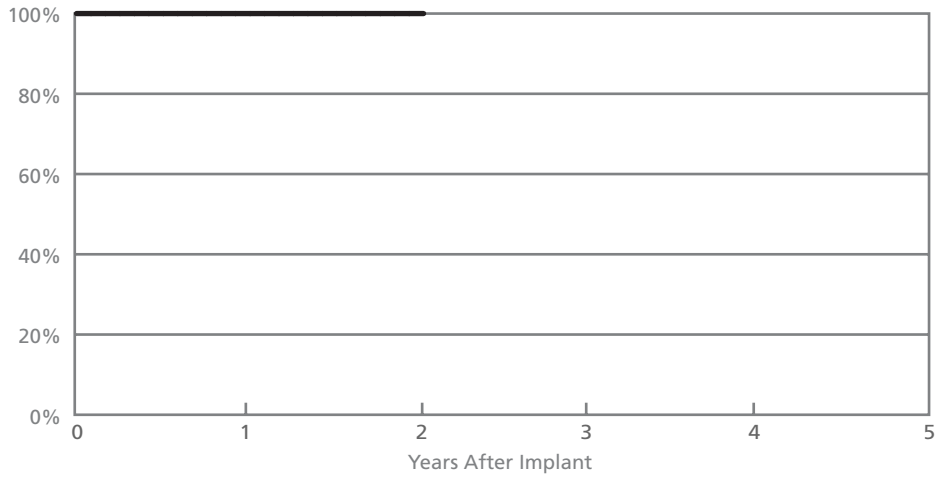


Year	1	2	3	4	at 49 months
Survival Probability	99.95%	99.93%	99.89%	99.75%	99.75%
± 1 standard error	0.02%	0.03%	0.05%	0.09%	0.09%

Epic™ DR (Model V-233)

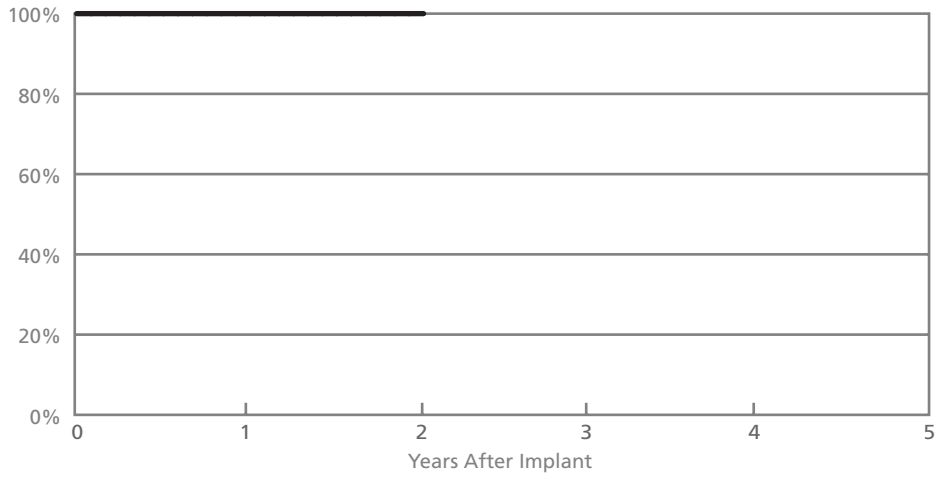
US Market Release	October 2003	Normal Battery Depletion	0
Registered US Implants	1,754	Malfunctions	0
Estimated Active US Implants	1,604	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	at 25 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		
Sample Size	1500	700	200		

Excluding Normal Battery Depletion

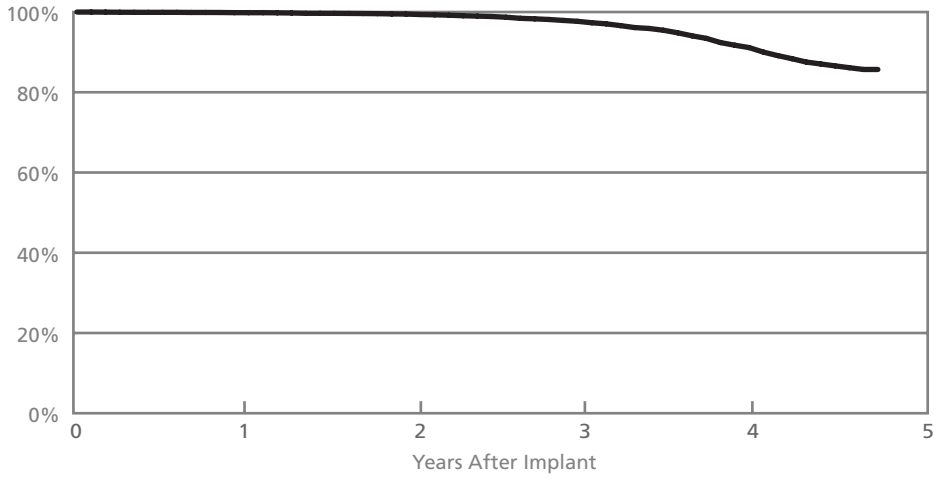


Year	1	2	at 25 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		

Atlas® DR (Model V-240)

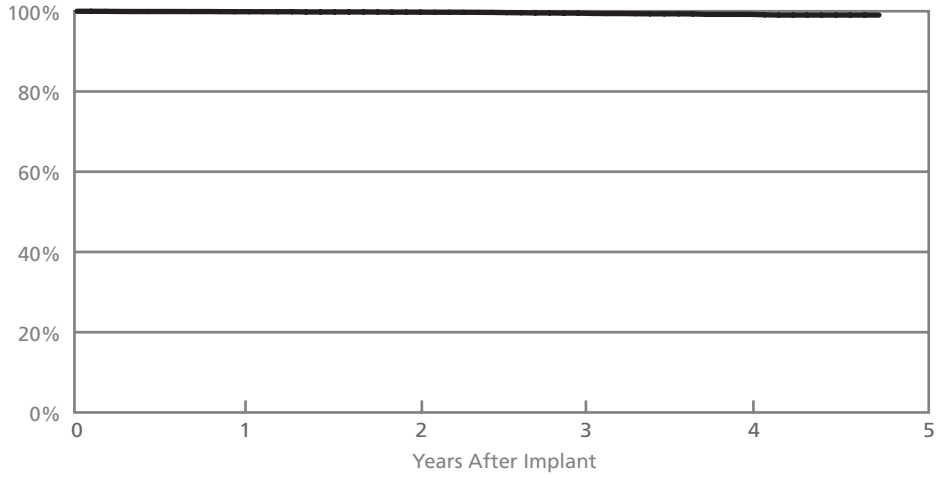
US Market Release	December 2001	Normal Battery Depletion	404
Registered US Implants	8,823	Malfunctions	47
Estimated Active US Implants	4,059	Malfunctions w/ Compromised Therapy (20 related to Advisory)	28
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	19
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 57 months
Survival Probability	99.84%	99.49%	97.68%	91.13%	85.68%
± 1 standard error	0.04%	0.08%	0.18%	0.44%	0.81%
Sample Size	8800	7700	6400	4100	1300

Excluding Normal Battery Depletion

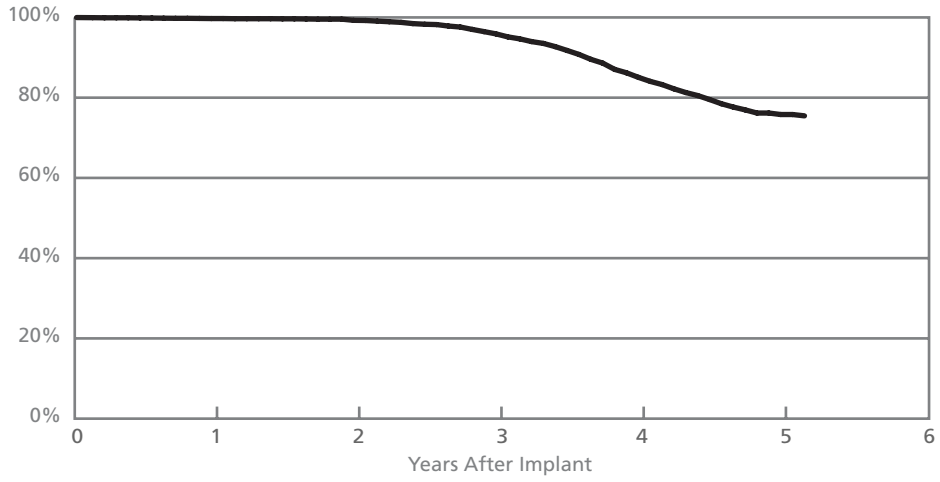


Year	1	2	3	4	at 57 months
Survival Probability	99.88%	99.78%	99.53%	99.22%	99.05%
± 1 standard error	0.03%	0.05%	0.08%	0.12%	0.16%

Photon® µ DR (Model V-232)

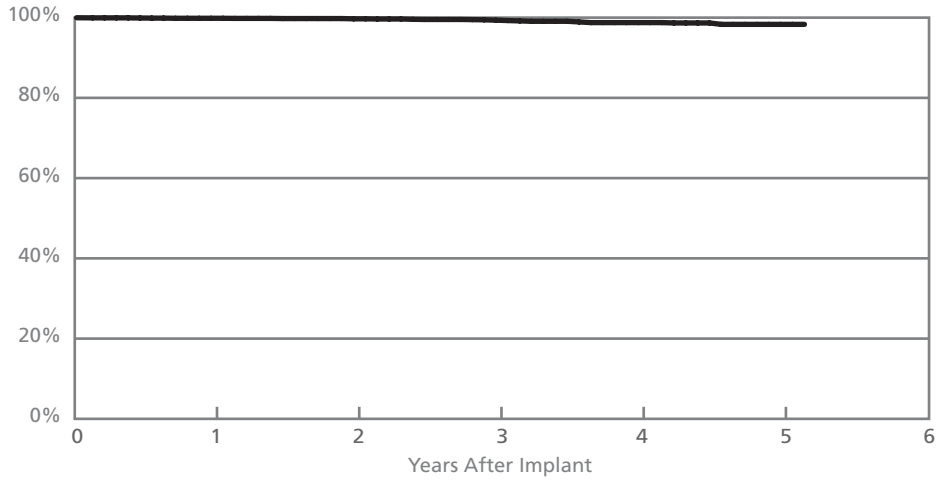
US Market Release	June 2001	Normal Battery Depletion	396
Registered US Implants	3,403	Malfunctions	33
Estimated Active US Implants	932	Malfunctions w/ Compromised Therapy (10 related to Advisory)	16
Estimated Longevity	(see table on page 50)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	17
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 62 months
Survival Probability	99.72%	99.28%	95.90%	85.07%	75.80%	75.47%
± 1 standard error	0.09%	0.16%	0.37%	0.75%	0.93%	1.12%
Sample Size	3400	3000	2700	2200	1100	300

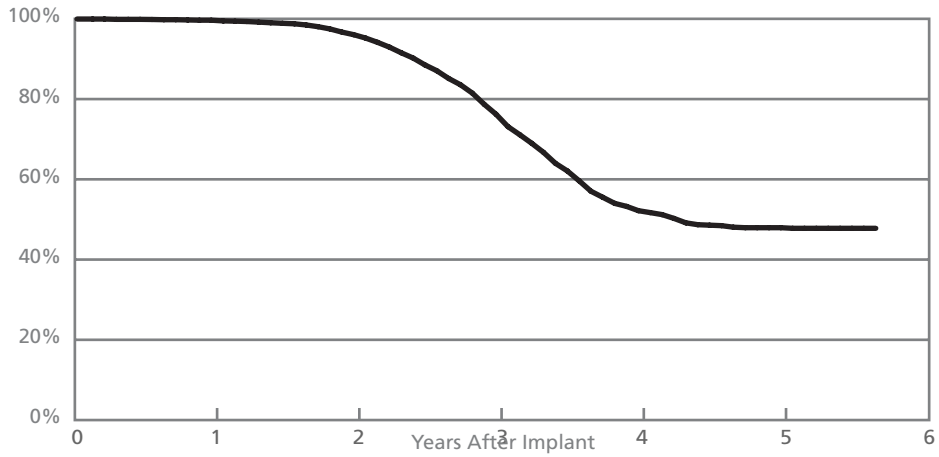
Excluding Normal Battery Depletion



Year	1	2	3	4	5	at 62 months
Survival Probability	99.84%	99.70%	99.37%	98.76%	98.32%	98.32%
± 1 standard error	0.07%	0.09%	0.14%	0.23%	0.32%	0.32%

Photon® DR (Model V-230HV)

US Market Release	October 2000
Registered US Implants	3,883
Estimated Active US Implants	321
Estimated Longevity	(see table on page 50)
Number of Advisories (see pages 130-136)	One



Year	1	2	3	4	5	at 68 months
Survival Probability	99.66%	96.05%	78.21%	52.18%	48.45%	47.79%
± 1 standard error	0.10%	0.32%	0.81%	1.17%	1.26%	1.28%
Sample Size	3880	3300	2800	1600	600	300

Summary & Longevity Information

ICDs Dual-Chamber

ST. JUDE MEDICAL

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
V-265	Atlas II DR	August 06	208	205	0	0	0	0	0	0	0
V-268	Atlas II DR	August 06	1078	1074	0	0	0	0	0	0	0
V-242	Atlas DR	October 03	4161	3770	0	0	0	1	0	1	2
V-243	Atlas + DR	October 03	17049	15728	2	0	0	1	0	3	2
V-258	Epic II DR	May 06	270	265	0	0	0	0	0	0	0
V-236	Epic + DR	April 03	2334	1751	0	0	0	1	0	1	7
V-239	Epic + DR	October 03	6944	6336	3	0	0	0	0	3	0
V-235	Epic DR	July 02	6567	4747	2	0	1	5	1	9	23
V-233	Epic DR	October 03	1754	1604	0	0	0	0	0	0	0
V-240	Atlas DR	December 01	8823	4059	8	20	0	10	9	47	404
V-232	Photon µ DR	June 01	3403	932	6	10	0	6	11	33	396

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
V-265	Atlas II DR	August 06	208	205	0	0	0	0	0	0
V-268	Atlas II DR	August 06	1078	1074	0	0	0	0	0	0
V-242	Atlas DR	October 03	4161	3770	0	0	0	1	0	1
V-243	Atlas + DR	October 03	17049	15728	2	0	0	1	0	3
V-258	Epic II DR	May 06	270	265	0	0	0	0	0	0
V-236	Epic + DR	April 03	2334	1751	0	0	0	1	0	1
V-239	Epic + DR	October 03	6944	6336	3	0	0	0	0	3
V-235	Epic DR	July 02	6567	4747	2	0	1	5	1	9
V-233	Epic DR	October 03	1754	1604	0	0	0	0	0	0
V-240	Atlas DR	December 01	8823	4059	8	20	0	10	9	47
V-232	Photon µ DR	June 01	3403	932	6	10	0	6	11	33

**Based on returned product analysis as of December 31, 2006.*

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
V-265	Atlas II DR										
V-268	Atlas II DR										
V-242	Atlas DR	99.93%	99.86%								
V-243	Atlas + DR	99.97%	99.93%								
V-258	Epic II DR										
V-236	Epic + DR	99.91%	99.80%	99.69%							
V-239	Epic + DR	99.95%	99.95%								
V-235	Epic DR	99.95%	99.88%	99.48%	99.15%						
V-233	Epic DR	100.00%	100.00%								
V-240	Atlas DR	99.84%	99.49%	97.68%	91.13%						
V-232	Photon µ DR	99.72%	99.28%	95.90%	85.07%	75.80%					

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
V-265	Atlas II DR										
V-268	Atlas II DR										
V-242	Atlas DR	100.00%	99.93%								
V-243	Atlas + DR	99.98%	99.97%								
V-258	Epic II DR										
V-236	Epic + DR	99.96%	99.96%	99.96%							
V-239	Epic + DR	99.95%	99.95%								
V-235	Epic DR	99.95%	99.93%	99.89%	99.75%						
V-233	Epic DR	100.00%	100.00%								
V-240	Atlas DR	99.90%	99.78%	99.53%	99.22%						
V-232	Photon µ DR	99.84%	99.70%	99.37%	98.76%	98.32%					

**Based on returned product analysis as of December 31, 2006.*

***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
V-265	Atlas II DR	8.2	7.5	7.0	6.1
V-268	Atlas II +	8.2	7.5	7.0	6.1
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-258	Epic II +	6.5	5.9	5.4	4.6
V-236	Epic + DR	5.8	5.4	5.1	4.5
V-239	Epic + DR	6.4	6.0	5.6	4.5
V-235	Epic DR	5.6	5.3	4.9	4.4
V-233	Epic DR	6.4	6.0	5.6	4.9
V-240	Atlas DR	6.0	5.6	5.2	4.6
V-232	Photon µ DR	6.6	6.1	5.6	4.9
V-230HV	Photon DR	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. (See the reference manuals for more information.)

ICDs
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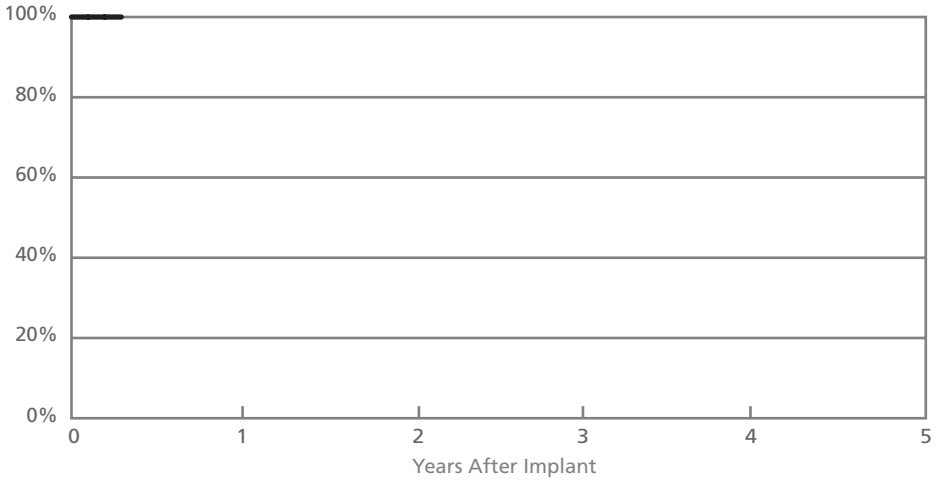
Atlas® II VR (Model V-168)

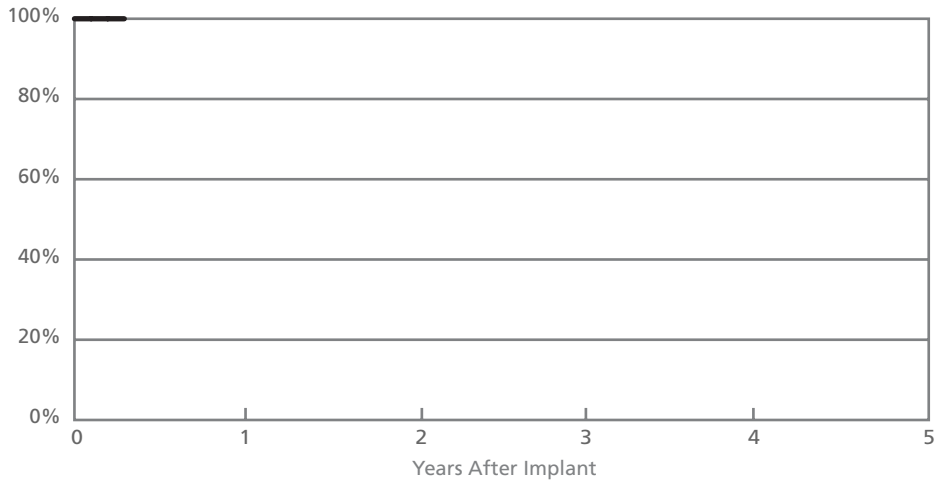
US Market Release	August 2006	Normal Battery Depletion	0
Registered US Implants	654	Malfunctions	0
Estimated Active US Implants	650	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	36 joules	Number of Advisories	None

Including Normal Battery Depletion



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

Excluding Normal Battery Depletion

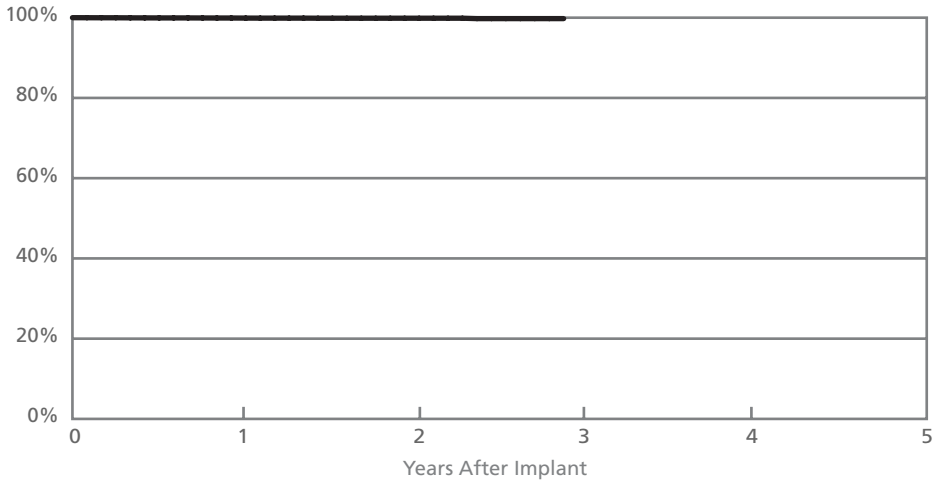


Year	at 3 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Atlas® + VR (Model V-193)

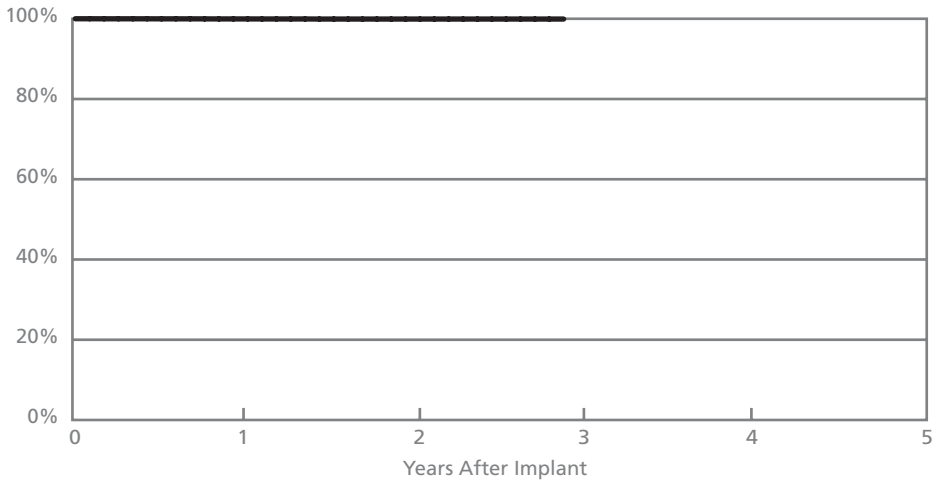
US Market Release	October 2003	Normal Battery Depletion	8
Registered US Implants	16,581	Malfunctions	7
Estimated Active US Implants	15,288	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	3
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	at 35 months		
Survival Probability	99.92%	99.87%	99.77%		
± 1 standard error	0.03%	0.04%	0.11%		
Sample Size	13100	5400	1000		

Excluding Normal Battery Depletion

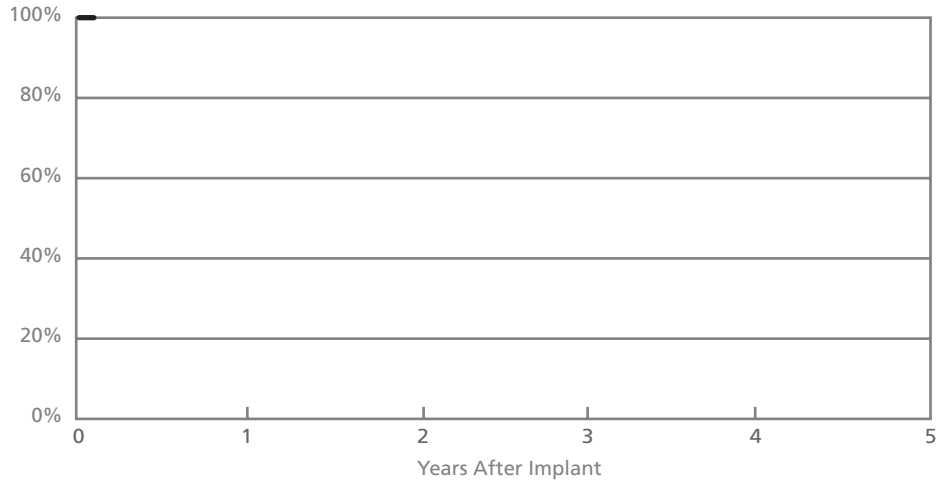


Year	1	2	at 35 months		
Survival Probability	99.96%	99.93%	99.93%		
± 1 standard error	0.02%	0.03%	0.03%		

Epic™ II VR (Model V-158)

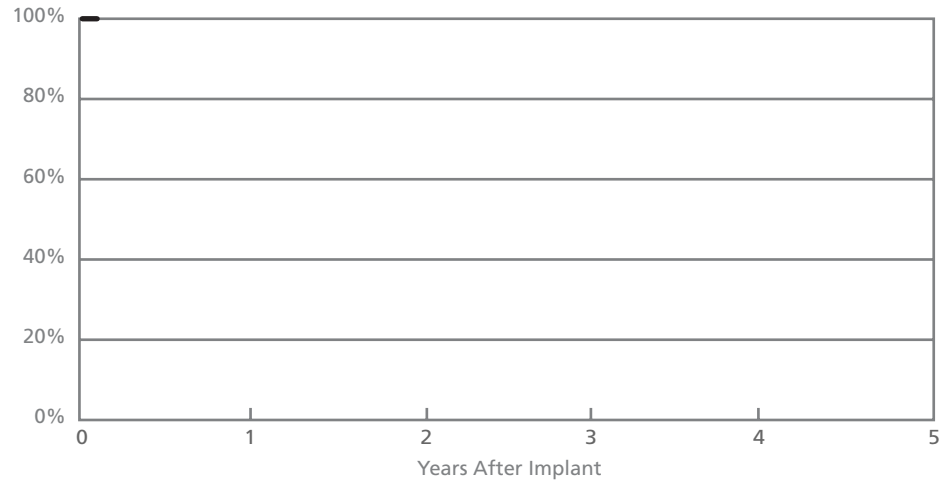
US Market Release	May 2006	Normal Battery Depletion	0
Registered US Implants	226	Malfunctions	0
Estimated Active US Implants	225	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories	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

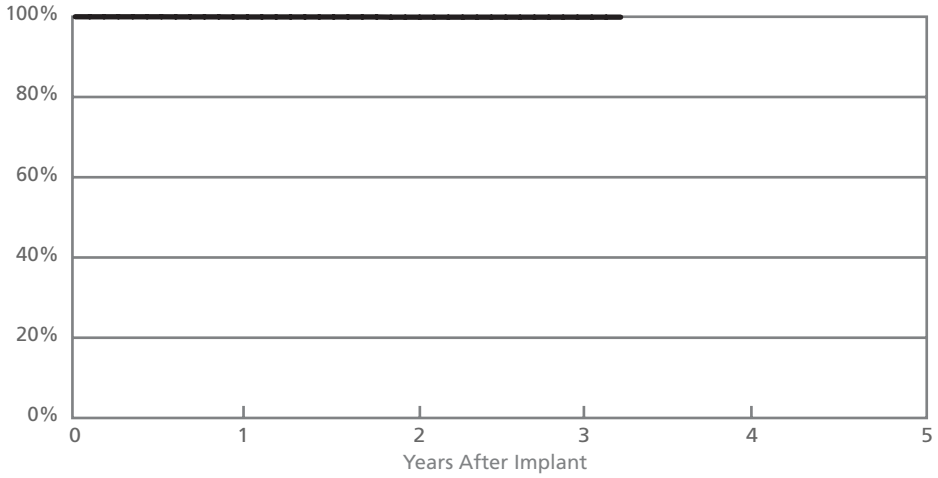


Year	at 1 month				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Epic™ + VR (Model V-196)

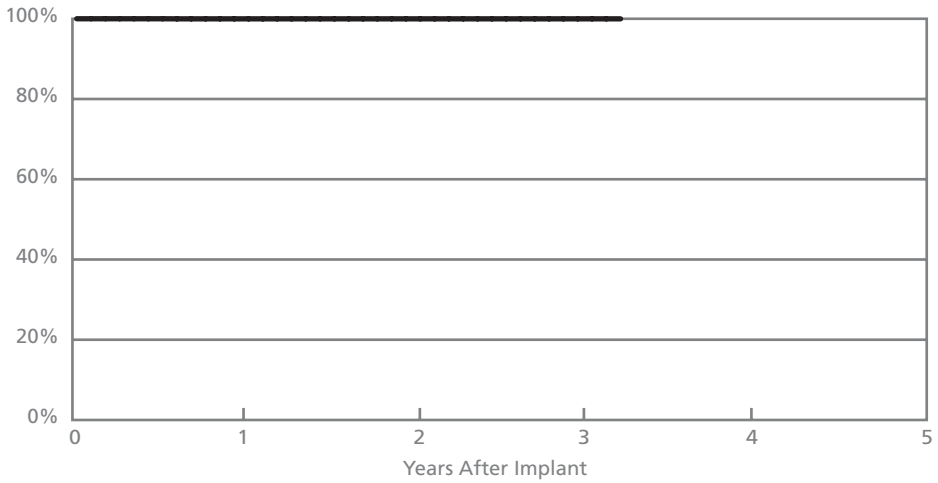
US Market Release	April 2003	Normal Battery Depletion	3
Registered US Implants	7,218	Malfunctions	1
Estimated Active US Implants	6,356	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy	0
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	Two

Including Normal Battery Depletion



Year	1	2	3	at 39 months	
Survival Probability	99.95%	99.90%	99.90%	99.90%	
± 1 standard error	0.02%	0.06%	0.06%	0.06%	
Sample Size	6200	3400	800	300	

Excluding Normal Battery Depletion

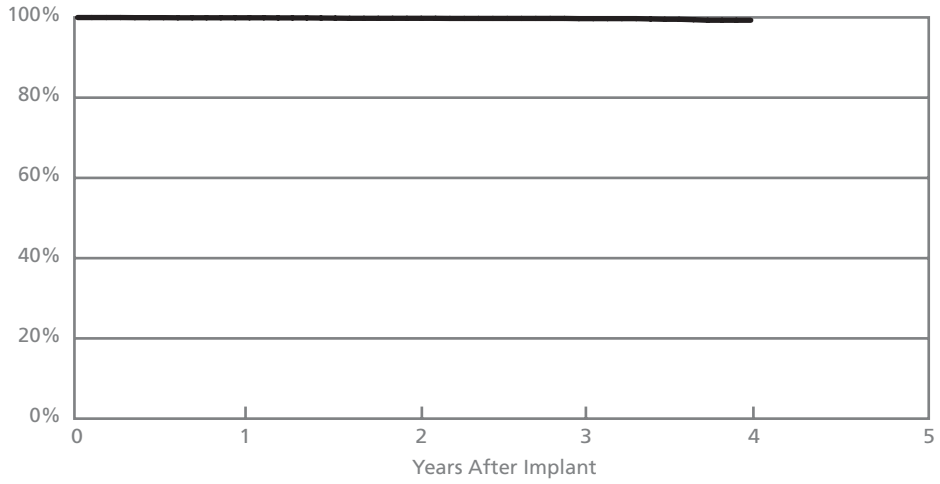


Year	1	2	3	at 39 months	
Survival Probability	99.98%	99.98%	99.98%	99.98%	
± 1 standard error	0.02%	0.02%	0.02%	0.02%	

Epic™ VR (Model V-197)

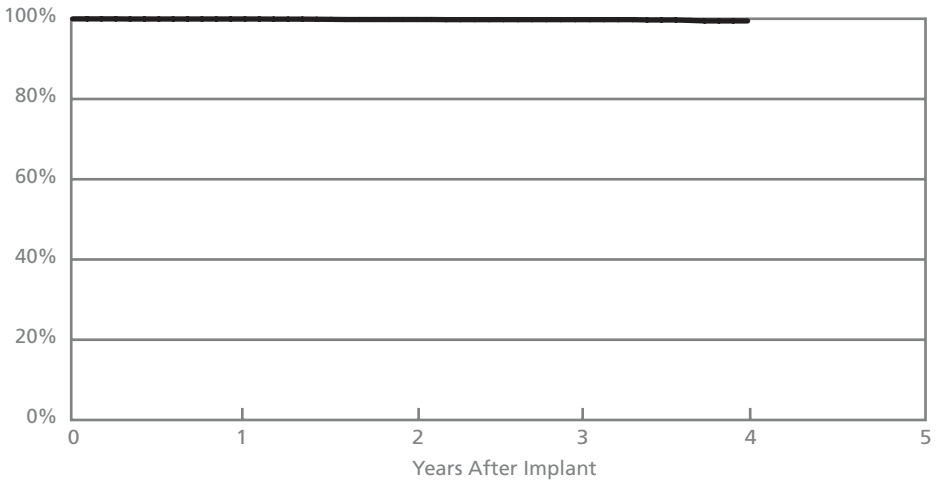
US Market Release	July 2002	Normal Battery Depletion	3
Registered US Implants	3,644	Malfunctions	10
Estimated Active US Implants	2,643	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	5
Max. Delivered Energy	30 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	
Survival Probability	99.91%	99.78%	99.70%	99.30%	
± 1 standard error	0.06%	0.08%	0.09%	0.23%	
Sample Size	3600	3100	2400	1000	

Excluding Normal Battery Depletion

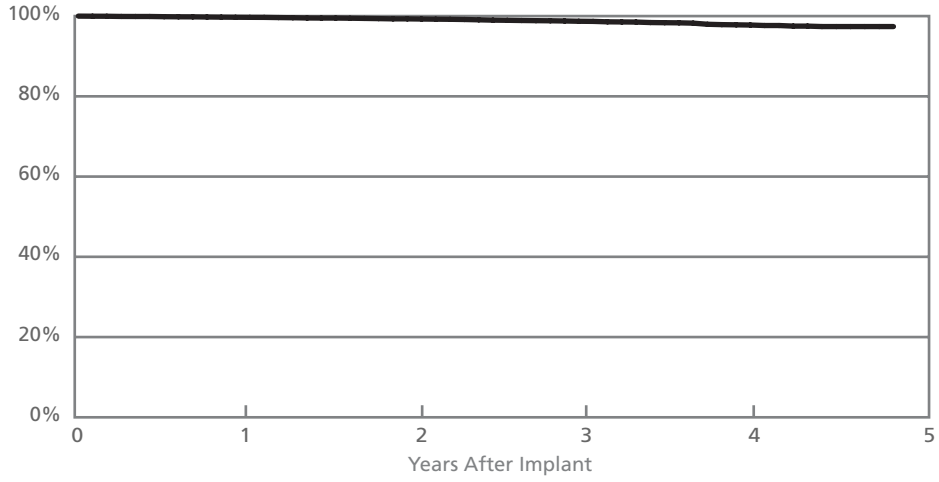


Year	1	2	3	4	
Survival Probability	99.94%	99.81%	99.78%	99.46%	
± 1 standard error	0.04%	0.08%	0.09%	0.21%	

Atlas® VR (Model V-199)

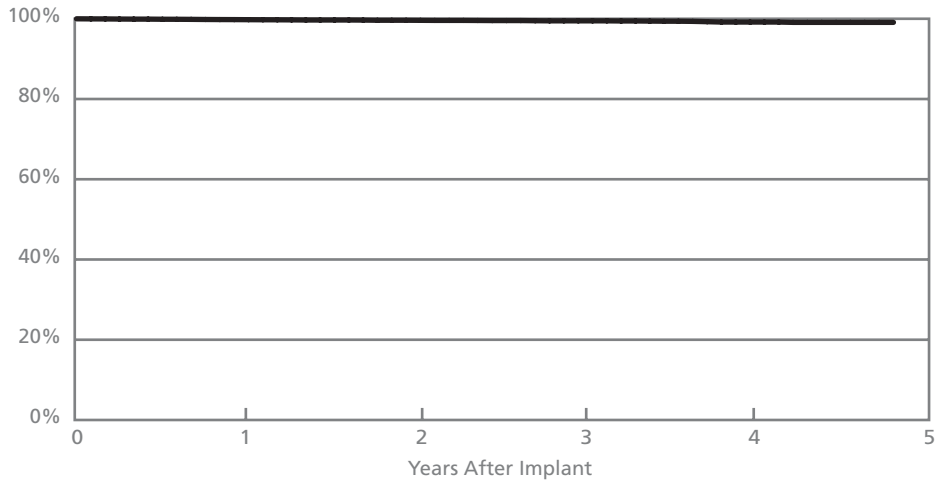
US Market Release	December 2001	Normal Battery Depletion	63
Registered US Implants	7,078	Malfunctions	39
Estimated Active US Implants	4,214	Malfunctions w/ Compromised Therapy (19 related to Advisory)	26
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	13
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 58 months
Survival Probability	99.71%	99.31%	98.71%	97.77%	97.39%
± 1 standard error	0.06%	0.11%	0.15%	0.24%	0.30%
Sample Size	7000	6100	4900	3300	1000

Excluding Normal Battery Depletion

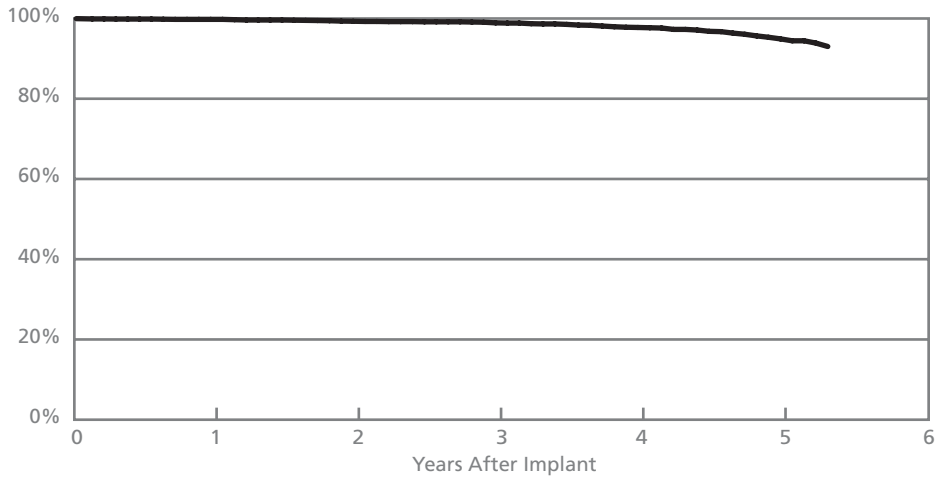


Year	1	2	3	4	at 58 months
Survival Probability	99.79%	99.63%	99.48%	99.18%	99.10%
± 1 standard error	0.05%	0.08%	0.10%	0.14%	0.16%

Photon® µ VR (Model V-194)

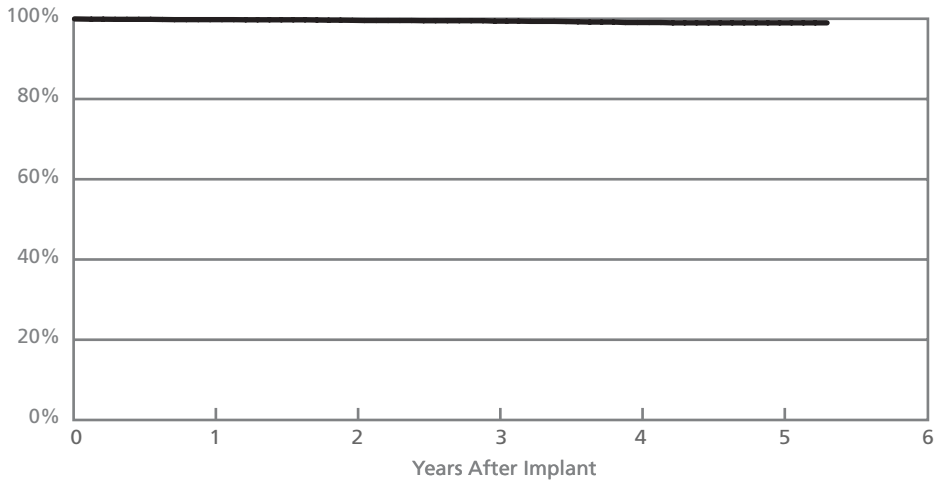
US Market Release	June 2001	Normal Battery Depletion	64
Registered US Implants	2,833	Malfunctions	21
Estimated Active US Implants	1,286	Malfunctions w/ Compromised Therapy (5 related to Advisory)	12
Estimated Longevity	(see table on page 64)	Malfunctions w/o Compromised Therapy (0 related to Advisory)	9
Max. Delivered Energy	36 joules	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	5	at 64 months
Survival Probability	99.78%	99.31%	98.91%	97.76%	94.92%	93.02%
± 1 standard error	0.09%	0.16%	0.20%	0.33%	0.57%	0.78%
Sample Size	2800	2500	2200	1800	1200	400

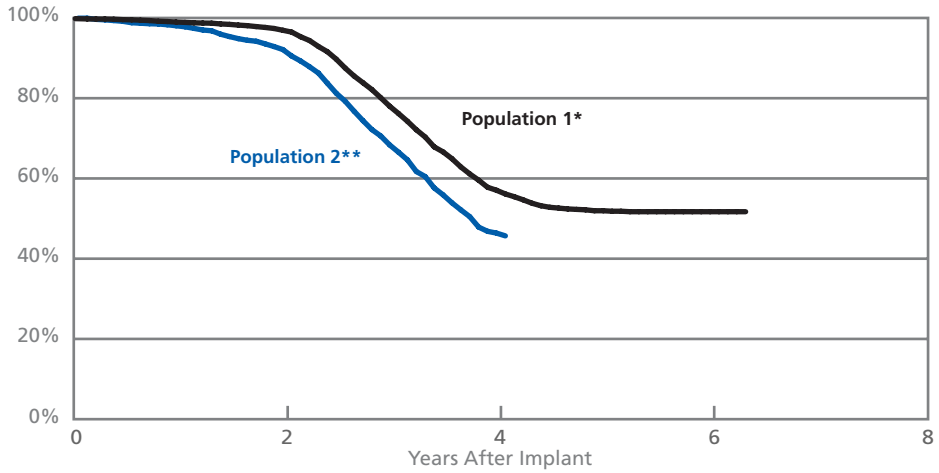
Excluding Normal Battery Depletion



Year	1	2	3	4	5	at 64 months
Survival Probability	99.78%	99.61%	99.41%	99.06%	98.98%	98.98%
± 1 standard error	0.09%	0.12%	0.16%	0.21%	0.23%	0.25%

Profile™ (Models V-186F & V-186HV3)

*Population 1		** Population 2	
*(These models are no longer being manufactured)		**(These models are no longer being manufactured)	
*US Market Release	November 1998	**US Market Release	November 1998
*Registered US Implants	4,226	**Registered US Implants	1,771
*Estimated Active US Implants	363	**Estimated Active US Implants	108
*Estimated Longevity	(see table on page 64)	**Estimated Longevity	(see table on page 64)
*Number of Advisories	None	**Number of Advisories (see pages 130-136)	One



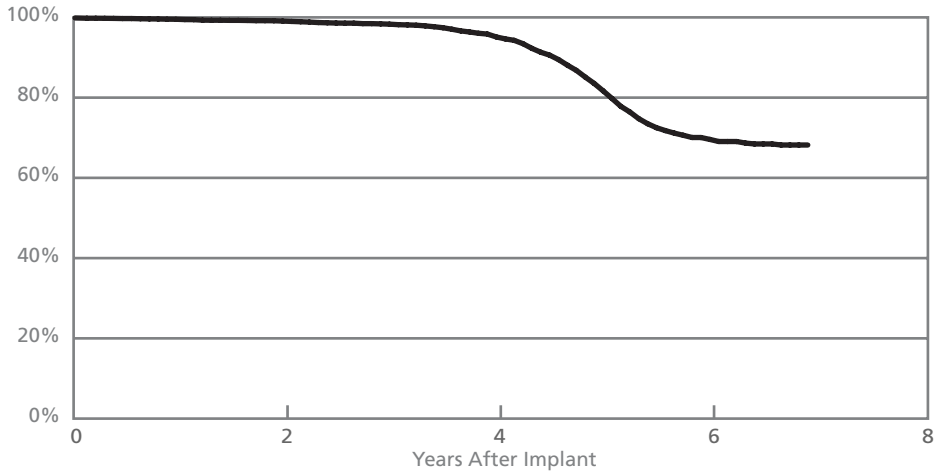
Population 1*

Year	2	4	6	at 76 months
Survival Probability	96.93%	57.06%	51.71%	51.71%
± 1 standard error	0.27%	1.03%	1.15%	1.15%
Sample Size	3700	2000	400	200

Population 2**

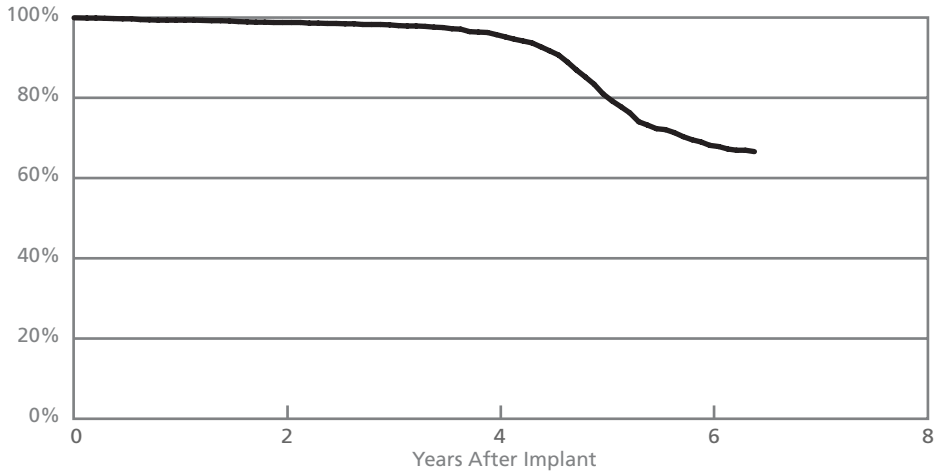
Year	2	4	at 49 months	
Survival Probability	92.88%	46.82%	45.69%	
± 1 standard error	0.69%	1.85%	1.86%	
Sample Size	1500	600	200	

Contour® MD (Models V-175, V-175AC, V-175B, V-175C & V-175D)	
US Market Release	October 1998
Registered US Implants	4,915
Estimated Active US Implants	858
Estimated Longevity	(see table on page 64)
Number of Advisories	None



Year	2	4	6	at 83 months
Survival Probability	99.08%	95.12%	69.58%	68.19%
± 1 standard error	0.14%	0.36%	1.27%	1.37%
Sample Size	4200	2900	1000	300

Contour® II (Models V-185, V-185AC, V-185B, V-185C & V-185D)	
US Market Release	February 1998
Registered US Implants	1,670
Estimated Active US Implants	146
Estimated Longevity	(see table on page 64)
Number of Advisories	None



Year	2	4	6	at 77 months
Survival Probability	98.77%	95.74%	68.14%	66.59%
± 1 standard error	0.29%	0.56%	1.91%	2.00%
Sample Size	1400	1100	500	200

Summary & Longevity Information

ICDs Single-Chamber

ST. JUDE MEDICAL

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
V-168	Atlas II VR	August 06	654	650	0	0	0	0	0	0	0
V-193	Atlas + VR	October 03	16581	15288	3	0	1	3	0	7	8
V-158	Epic II VR	May 06	226	225	0	0	0	0	0	0	0
V-196	Epic + VR	April 03	7218	6356	0	0	1	0	0	1	3
V-197	Epic VR	July 02	3644	2643	3	0	2	5	0	10	3
V-199	Atlas VR	December 01	7078	4214	7	19	0	11	2	39	63
V-194	Photon µ VR	June 01	2833	1286	5	5	2	9	0	21	64

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
V-168	Atlas II VR	August 06	654	650	0	0	0	0	0	0
V-193	Atlas + VR	October 03	16581	15288	3	0	1	3	0	7
V-158	Epic II VR	May 06	226	225	0	0	0	0	0	0
V-196	Epic + VR	April 03	7218	6356	0	0	1	0	0	1
V-197	Epic VR	July 02	3644	2643	3	0	2	5	0	10
V-199	Atlas VR	December 01	7078	4214	7	19	0	11	2	39
V-194	Photon µ VR	June 01	2833	1286	5	5	2	9	0	21

**Based on returned product analysis as of December 31, 2006.*

*** St. Jude Medical. ICD Memory Chip Component Anomaly (advisory). October 7, 2005.*

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
V-168	Atlas II VR										
V-193	Atlas + VR	99.92%	99.87%								
V-158	Epic II VR										
V-196	Epic + VR	99.95%	99.90%	99.90%							
V-197	Epic VR	99.91%	99.78%	99.70%	99.30%						
V-199	Atlas VR	99.71%	99.31%	98.71%	97.77%						
V-194	Photon µ VR	99.78%	99.31%	98.91%	97.76%	94.92%					

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
V-168	Atlas II VR										
V-193	Atlas + VR	99.96%	99.93%								
V-158	Epic II VR										
V-196	Epic + VR	99.98%	99.98%	99.98%							
V-197	Epic VR	99.94%	99.81%	99.78%	99.46%						
V-199	Atlas VR	99.79%	99.63%	99.48%	99.18%						
V-194	Photon µ VR	99.78%	99.61%	99.41%	99.06%	98.98%					

**Based on returned product analysis as of December 31, 2006.*

†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
V-168	Atals II VR	8.4	8.0	7.6	7.0
V-193	Atlas + VR	8.6	8.2	7.9	7.3
V-158	Epic II VR	6.7	6.4	6.1	5.6
V-196**	Epic + VR	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	8.1	7.7	7.4	6.8

**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. (See the reference manuals for more information.)
***Serial numbers 115000 (for serial numbers <11500, refer to previous User's Manual or contact Customer Service)*

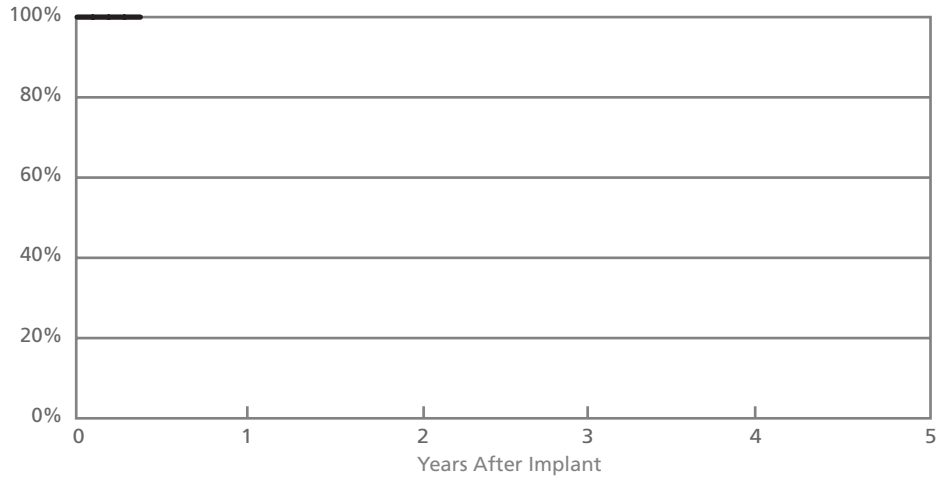
Models	Family	4 Max charges/Yr. No Pacing	1 Maximum High Voltage Charge/Month†		
			No Pacing	15% Pacing	100% Pacing
V-186F, V-186HV3	Profile	5.8 yr.	4.3 yr.	4.0 yr.	3.7 yr.
V-175, V-175AC, V-175B, V-175C, V-175D	Contour MD	6.5 yr.	4.8 yr.	4.4 yr.	3.5 yr.
V-185, V-185AC, V-185B, V-185C, V-185D	Contour II	6.5 yr.	4.8 yr.	4.4 yr.	3.5 yr.

†Pacing parameters: DDD, 2.5V, 0.5 ms, 60 ppm, 500 ohms
Battery Voltage Range: 3.20 – 2.55

Defibrillation Leads

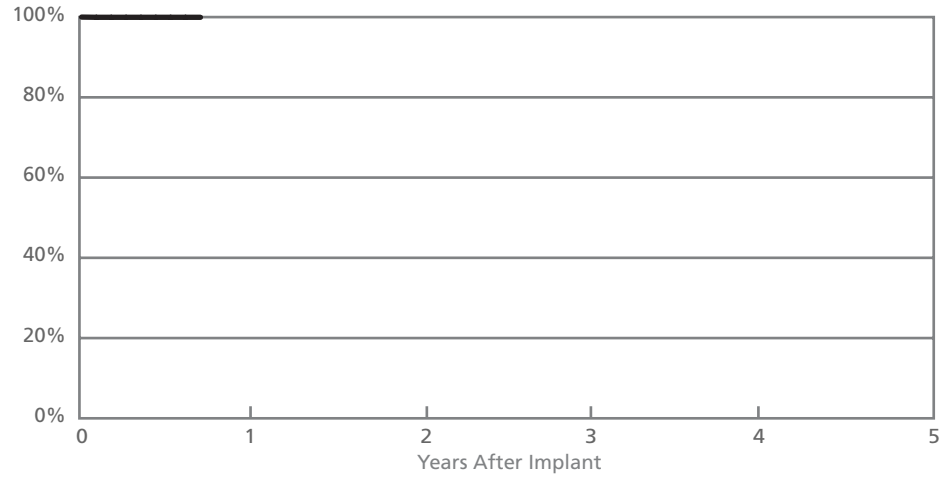
ST. JUDE MEDICAL

Riata® ST (Model 7002)	Laboratory Analysis: Implant Damage 0	Electrical Malfunction 0	Other 0
US Market Release	March 2006	Type and/or Fixation	Single Coil, Active
Registered US Implants	436	Polarity	Bipolar
Estimated Active US Implants	433	Steroid	Yes
		Number of Advisories	None



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

Riata® ST (Models 7000 & 7001)	Laboratory Analysis: Implant Damage 47	Electrical Malfunction 4	Other 19
US Market Release	March 2006	Type and/or Fixation	Dual Coil, Active
Registered US Implants	10,907	Polarity	Bipolar
Estimated Active US Implants	10,807	Steroid	Yes
		Number of Advisories	None

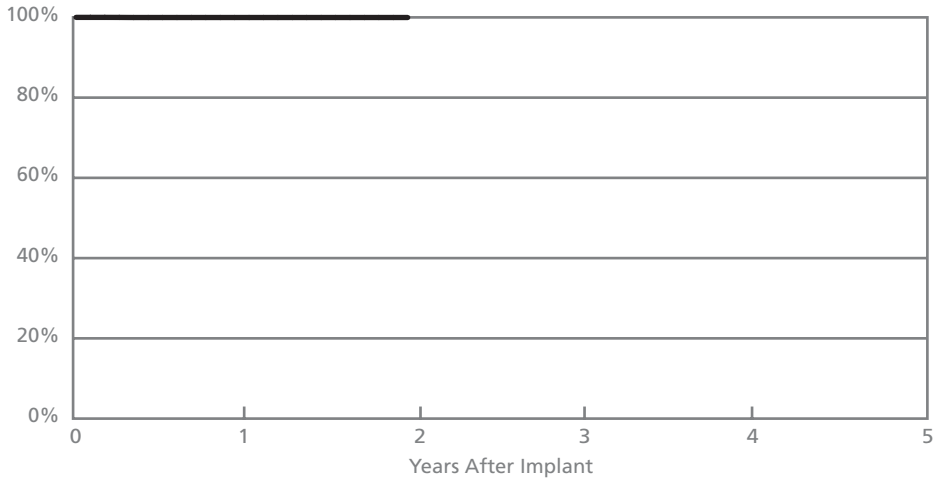


Year	at 9 months				
Survival Probability	99.95%				
± 1 standard error	0.02%				
Sample Size	5500				

Riata® *i* (Models 1590 & 1591)

Laboratory Analysis: Implant Damage 21 Electrical Malfunction 2 Other 2

US Market Release	April 2004	Type and/or Fixation	Dual Coil, Active
Registered US Implants	8,451	Polarity	Bipolar
Estimated Active US Implants	7,973	Steroid	Yes
		Number of Advisories	None

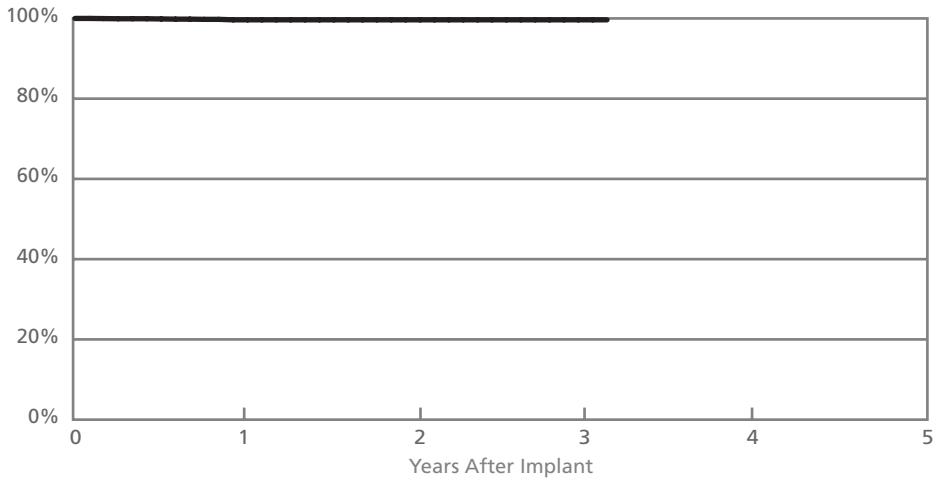


Year	1	2			
Survival Probability	99.97%	99.97%			
± 1 standard error	0.02%	0.02%			
Sample Size	6800	2500			

Riata® (Model 1582)

Laboratory Analysis: Implant Damage 9 Electrical Malfunction 6 Other 5

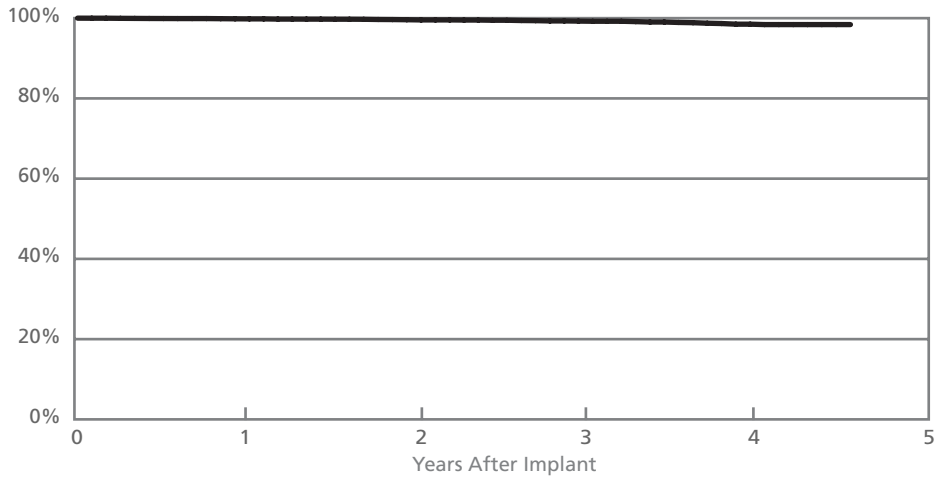
US Market Release	March 2003	Type and/or Fixation	Single Coil, Active
Registered US Implants	2,505	Polarity	Bipolar
Estimated Active US Implants	2,186	Steroid	Yes
		Number of Advisories	None



Year	1	2	3	at 38 months	
Survival Probability	99.65%	99.65%	99.65%	99.65%	
± 1 standard error	0.10%	0.13%	0.13%	0.13%	
Sample Size	2500	1300	500	100	

Riata® (Models 1570 & 1571) Laboratory Analysis: Implant Damage 31 Electrical Malfunction 11 Other 21

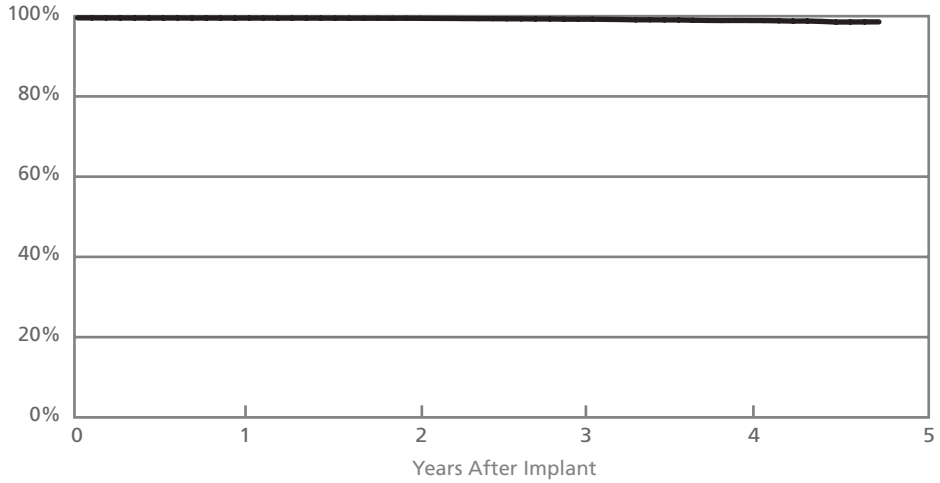
US Market Release	March 2002	Type and/or Fixation	Dual Coil, Passive
Registered US Implants	8,512	Polarity	Bipolar (Quadripolar)
Estimated Active US Implants	7,167	Steroid	Yes
		Number of Advisories	None



Year	1	2	3	4	at 55 months
Survival Probability	99.84%	99.61%	99.27%	98.50%	98.40%
± 1 standard error	0.04%	0.08%	0.13%	0.25%	0.27%
Sample Size	7800	5600	3500	1800	500

Riata® (Models 1580 & 1581) Laboratory Analysis: Implant Damage 218 Electrical Malfunction 68 Other 170

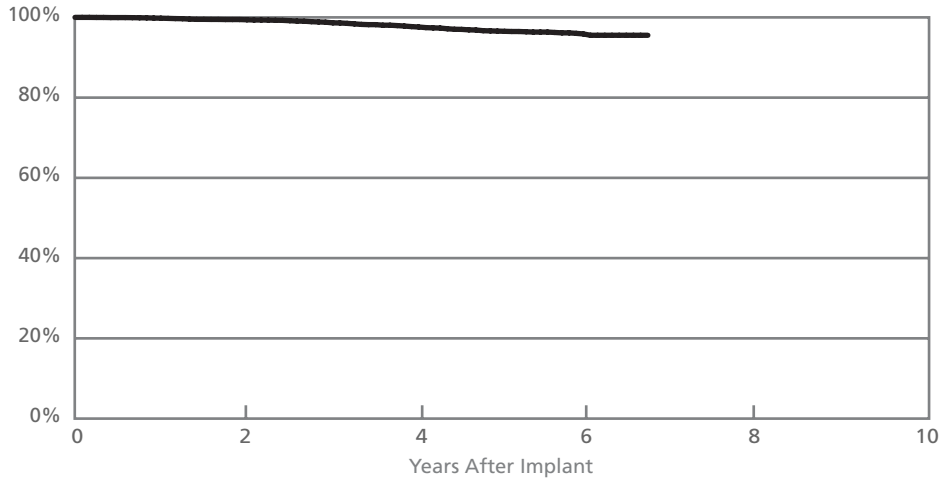
US Market Release	March 2002	Type and/or Fixation	Dual Coil, Active
Registered US Implants	59,981	Polarity	Bipolar (Quadripolar)
Estimated Active US Implants	51,978	Steroid	Yes
		Number of Advisories	None



Year	1	2	3	4	at 57 months
Survival Probability	99.77%	99.56%	99.14%	98.63%	98.16%
± 1 standard error	0.02%	0.03%	0.06%	0.10%	0.20%
Sample Size	53800	34100	17400	7400	1800

TVL®-ADX (Model 1559)

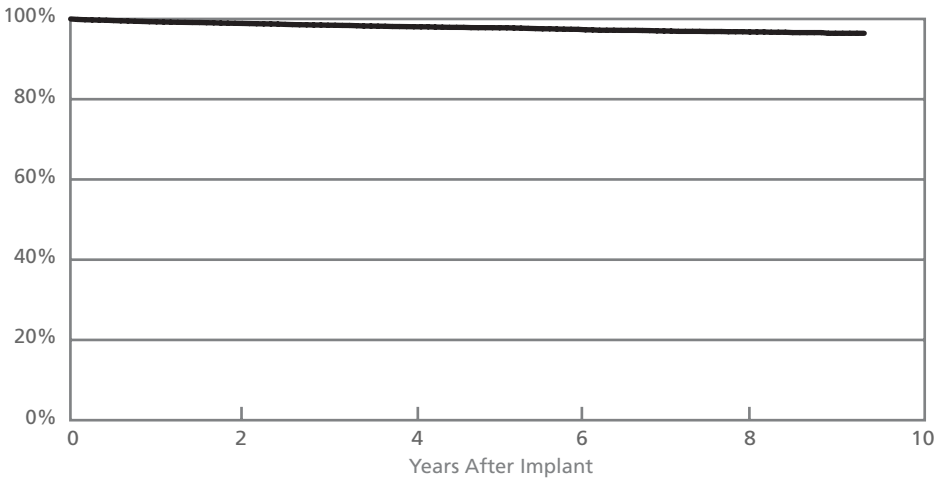
US Market Release	November 1999	Type and/or Fixation	Single Coil, Active
Registered US Implants	4,569	Polarity	Bipolar
Estimated Active US Implants	2,577	Steroid	Yes
		Number of Advisories	None



Year	2	4	6	at 81 months	
Survival Probability	99.46%	97.70%	95.87%	95.54%	
± 1 standard error	0.12%	0.25%	0.40%	0.48%	
Sample Size	3900	3100	1300	400	

SPL® (Models SP01, SP02, SP03 & SP04)

US Market Release	September 1997	Type and/or Fixation	Dual Coil, Passive
Registered US Implants	12,414	Polarity	Bipolar
Estimated Active US Implants	6,684	Steroid	No
		Number of Advisories	None



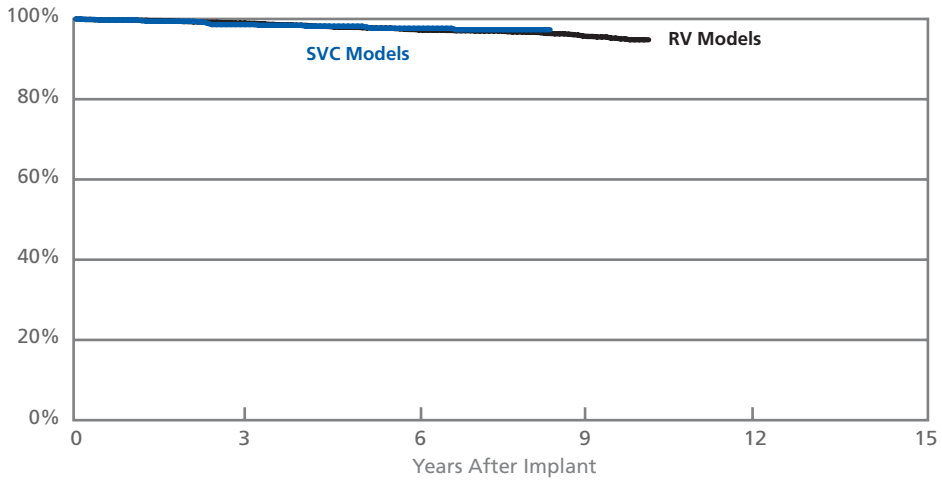
Year	2	4	6	8	at 112 months
Survival Probability	98.92%	98.09%	97.41%	96.76%	96.43%
± 1 standard error	0.10%	0.14%	0.17%	0.21%	0.30%
Sample Size	11000	8900	5900	2400	200

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	3,499	RV	1,413
SVC	804	SVC	317

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



RV Models

Year	3	6	9	at 123 months	
Survival Probability	98.98%	97.38%	95.98%	94.82%	
± 1 standard error	0.19%	0.33%	0.46%	0.63%	
Sample Size	2800	1900	1100	300	

SVC Models

Year	3	6	at 102 months		
Survival Probability	98.59%	97.68%	97.32%		
± 1 standard error	0.47%	0.65%	0.74%		
Sample Size	600	400	200		

Laboratory Analysis*

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Implant Damage	Electrical Malfunctions	Other
7002	March 06	436	433	0	0	0
7000/7001	March 06	10907	10807	47	4	19
1590/1591	April 04	8451	7973	21	2	2
1582	March 03	2505	2186	9	6	5
1570/1571	March 02	8512	7167	31	11	21
1580/1581	March 02	59981	51978	218	68	170

Laboratory analysis of all returned leads from the U.S. is summarized by model for the most recently market released defibrillation lead models included in this Product Performance Report. The Laboratory analysis results are categorized into one of the following three categories:

- Implant Damage - Obvious damage incurred at the time of 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.
- Other - Includes other sources of malfunction not attributed to damage incurred at implant and not resulting in compromised electrical failures. This category also includes any partial leads returned with an alleged malfunction even if it was not possible to perform analysis to confirm the malfunction.

**Based on returned product analysis as of December 31, 2006.*

Pulse Generators

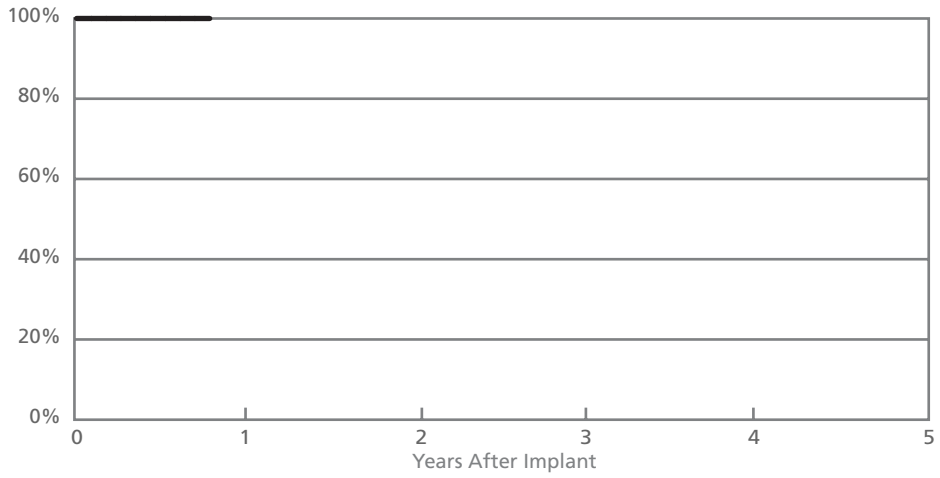
Dual-Chamber

ST. JUDE MEDICAL

Victory® DR (Model 5810) Victory® XL (Model 5816)

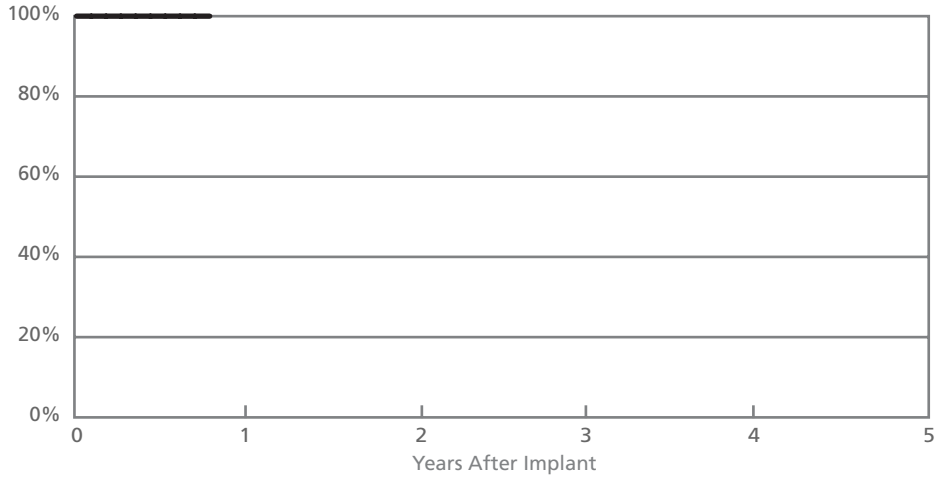
US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	21,428	Malfunctions	0
Estimated Active US Implants	21,199	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	(5810) 4.0 Years	Malfunctions w/o Compromised Therapy	0
	(5816) 7.2 years	Number of Advisories	None

Including Normal Battery Depletion



Year	at 11 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	21400				

Excluding Normal Battery Depletion

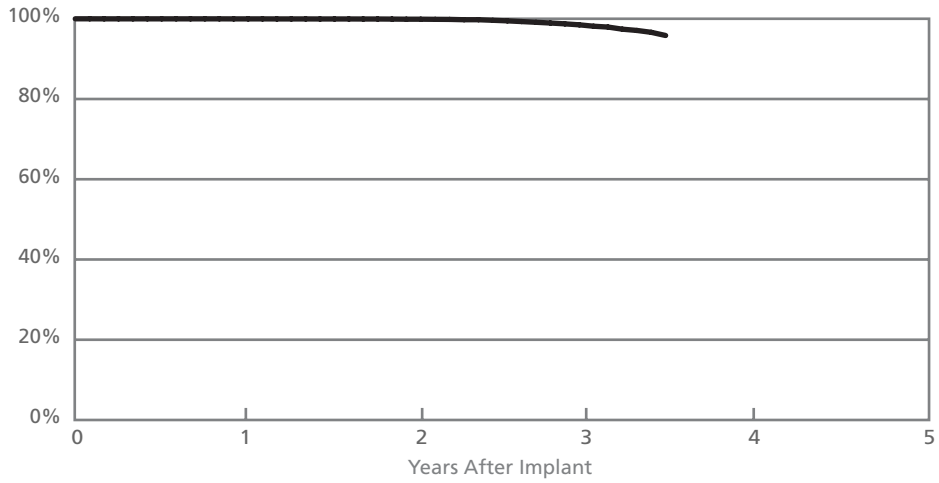


Year	at 11 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Identity® ADx DR (Model 5380)

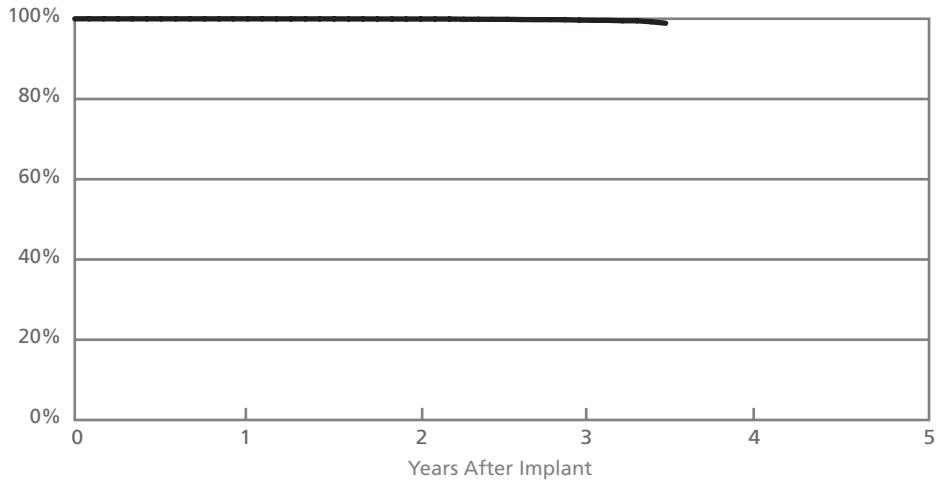
US Market Release	March 2003	Normal Battery Depletion	236
Registered US Implants	46,062	Malfunctions	18
Estimated Active US Implants	39,954	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	18
		Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	at 42 months	
Survival Probability	99.97%	99.89%	98.49%	95.83%	
± 1 standard error	0.01%	0.02%	0.09%	0.32%	
Sample Size	40300	22600	7900	1200	

Excluding Normal Battery Depletion

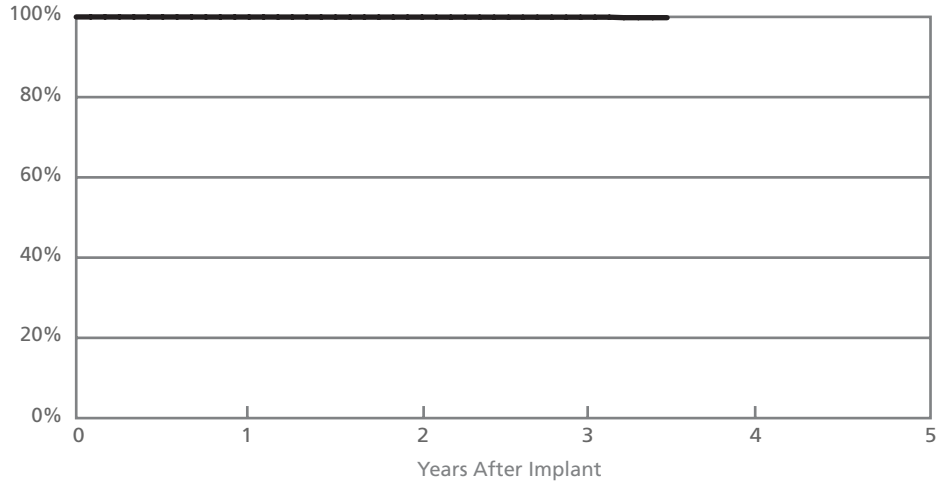


Year	1	2	3	at 42 months	
Survival Probability	99.98%	99.94%	99.67%	98.88%	
± 1 standard error	0.01%	0.02%	0.06%	0.29%	

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

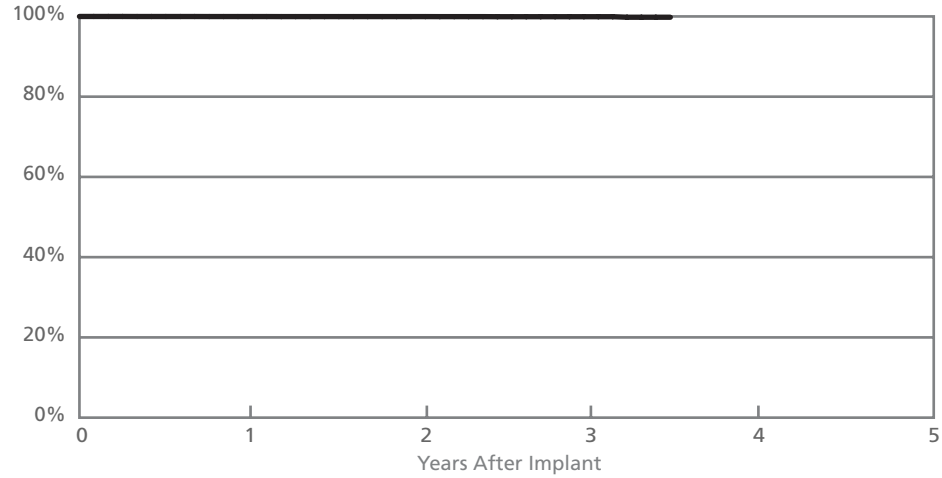
US Market Release	March 2003	Normal Battery Depletion	1
Registered US Implants	48,321	Malfunctions	16
Estimated Active US Implants	44,137	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	15
		Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	at 42 months	
Survival Probability	99.97%	99.95%	99.93%	99.80%	
± 1 standard error	0.01%	0.01%	0.02%	0.13%	
Sample Size	40600	21300	6900	900	

Excluding Normal Battery Depletion

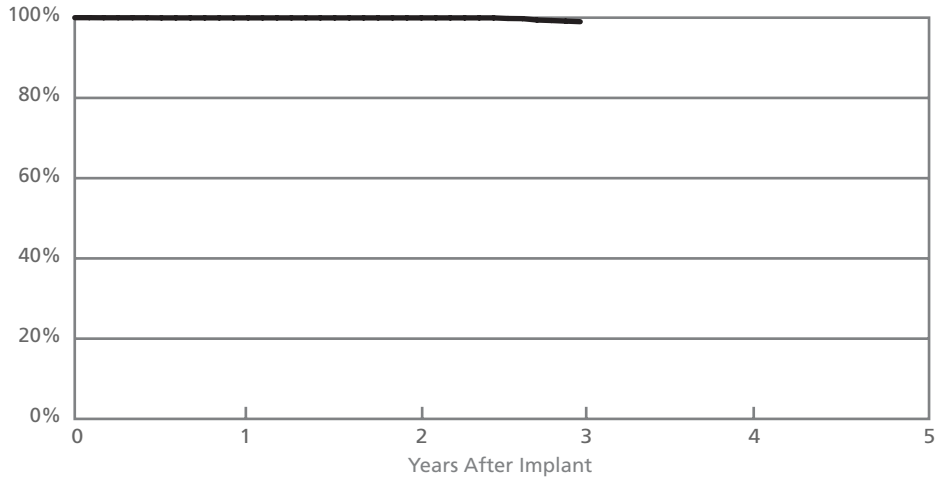


Year	1	2	3	at 42 months	
Survival Probability	99.97%	99.96%	99.93%	99.80%	
± 1 standard error	0.01%	0.01%	0.02%	0.13%	

Integrity® ADx DR (Model 5360)

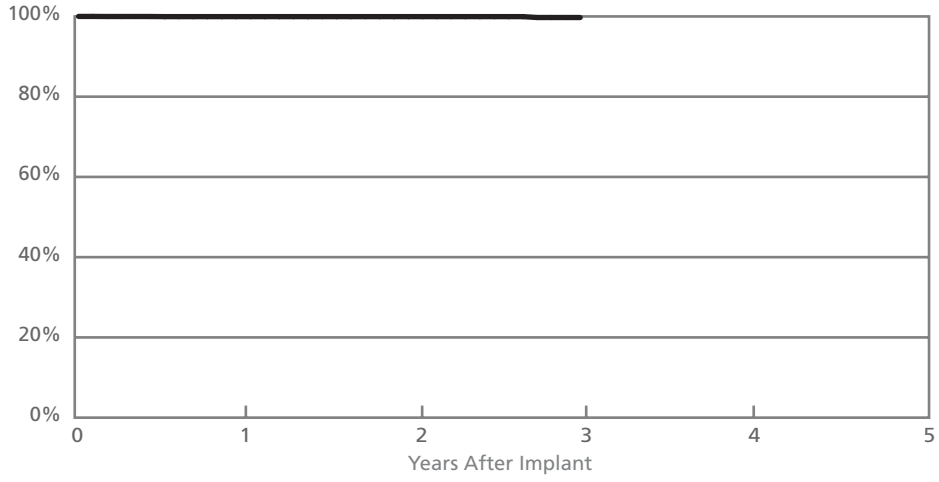
US Market Release	May 2003	Normal Battery Depletion	16
Registered US Implants	4,951	Malfunctions	2
Estimated Active US Implants	4,276	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3		
Survival Probability	99.95%	99.95%	99.00%		
± 1 standard error	0.03%	0.03%	0.23%		
Sample Size	4400	2500	900		

Excluding Normal Battery Depletion

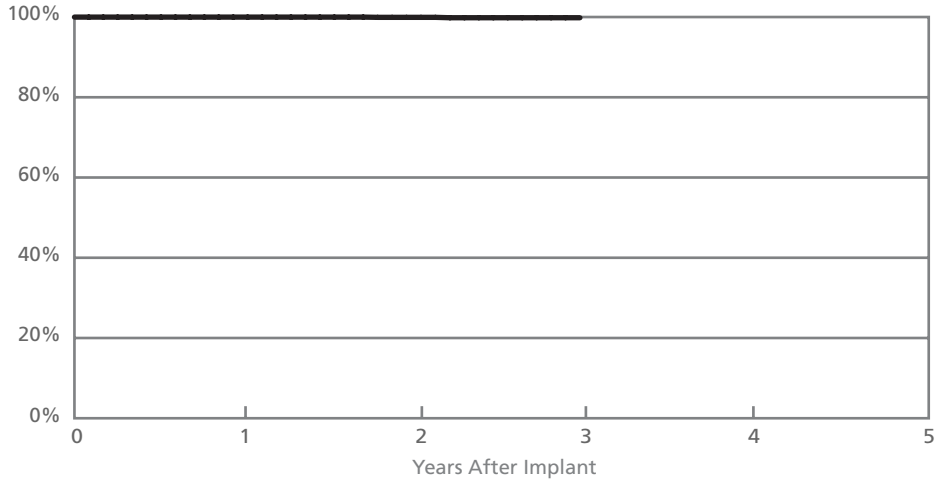


Year	1	2	3		
Survival Probability	99.95%	99.95%	99.73%		
± 1 standard error	0.03%	0.03%	0.23%		

Integrity® ADx XL DR (Model 5366)

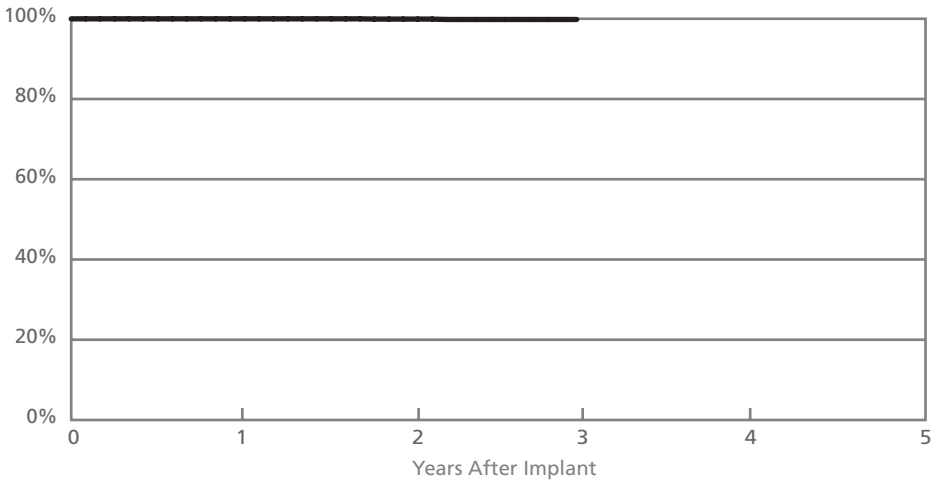
US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	5,829	Malfunctions	1
Estimated Active US Implants	5,292	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	1
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3		
Survival Probability	99.98%	99.92%	99.82%		
± 1 standard error	0.02%	0.06%	0.12%		
Sample Size	4700	2400	800		

Excluding Normal Battery Depletion

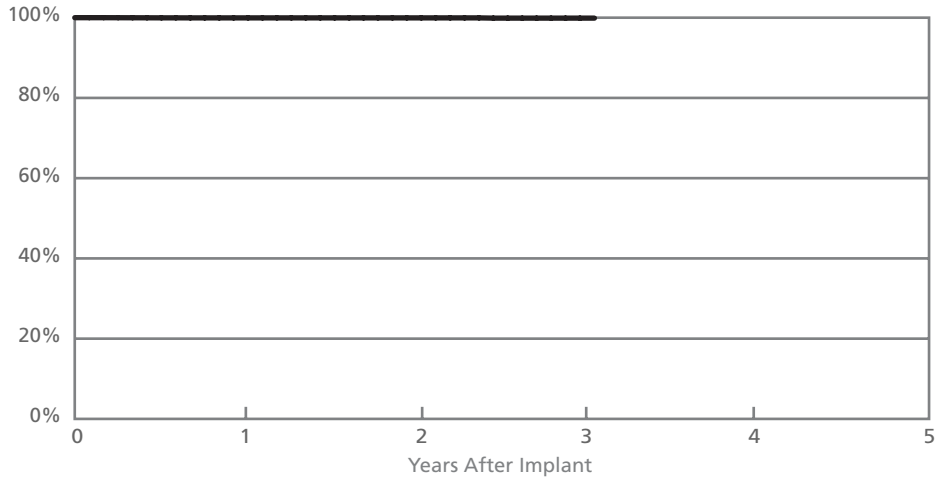


Year	1	2	3		
Survival Probability	99.98%	99.92%	99.82%		
± 1 standard error	0.02%	0.06%	0.12%		

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

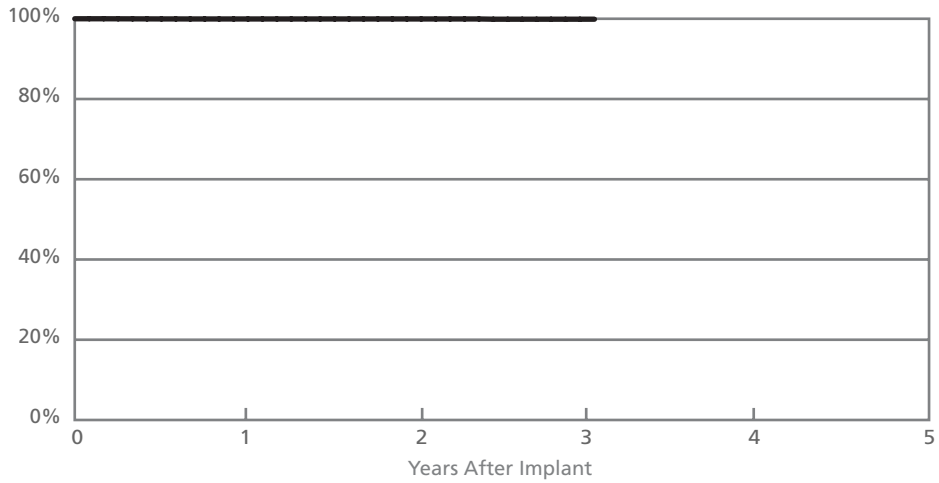
US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	12,206	Malfunctions	5
Estimated Active US Implants	10,716	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy	5
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 37 months	
Survival Probability	99.95%	99.95%	99.89%	99.89%	
± 1 standard error	0.02%	0.02%	0.07%	0.07%	
Sample Size	10400	5600	1600	100	

Excluding Normal Battery Depletion

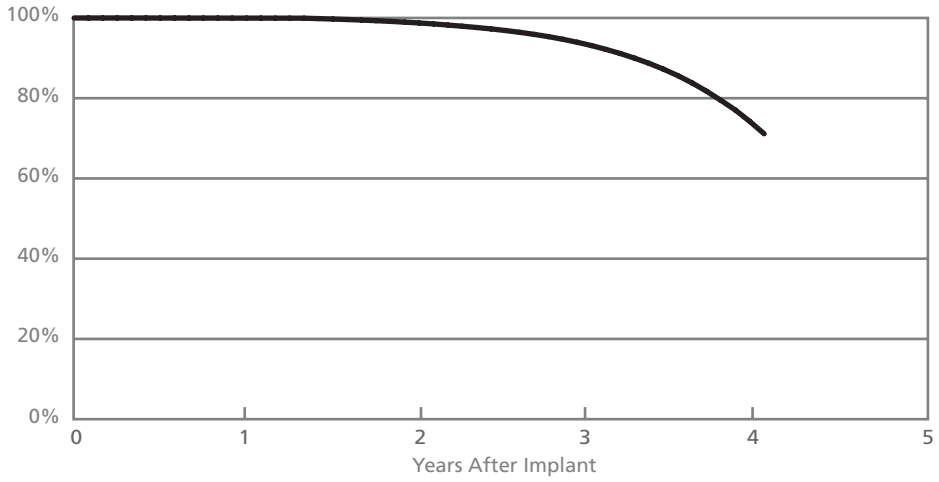


Year	1	2	3	at 37 months	
Survival Probability	99.95%	99.95%	99.89%	99.89%	
± 1 standard error	0.02%	0.02%	0.07%	0.07%	

Identity® (Model 5370)

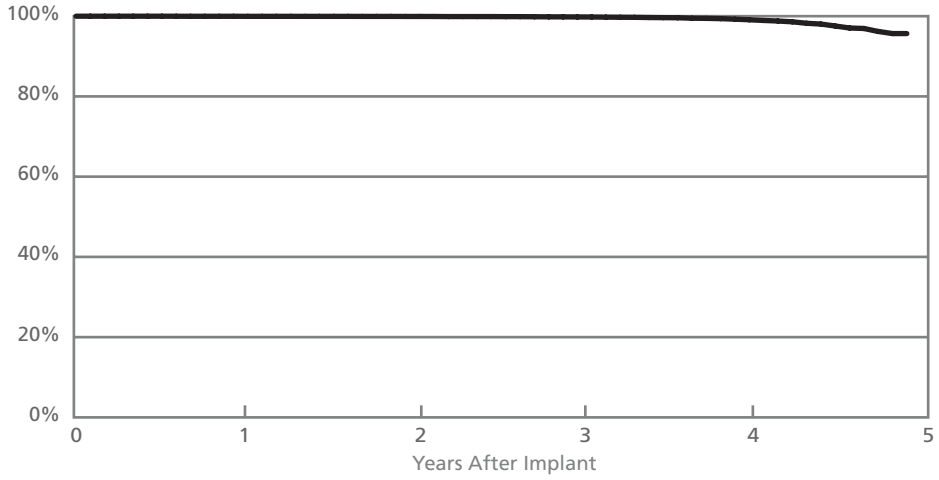
US Market Release	November 2001	Normal Battery Depletion	22,829
Registered US Implants	56,860	Malfunctions	94
Estimated Active US Implants	15,841	Malfunctions w/ Compromised Therapy (0 related to Advisory)	5
Estimated Longevity	3.8 Years	Malfunctions w/o Compromised Therapy (12 related to Advisory)	89
		Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 50 months
Survival Probability	99.96%	98.96%	93.94%	74.20%	67.87%
± 1 standard error	0.01%	0.02%	0.04%	0.14%	0.18%
Sample Size	55100	43800	32900	25000	1600

Excluding Normal Battery Depletion

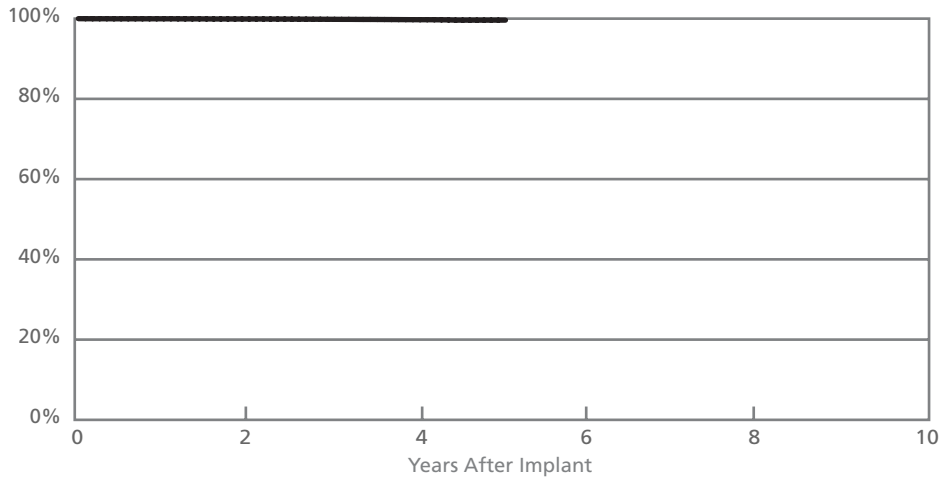


Year	1	2	3	4	at 59 months
Survival Probability	99.97%	99.93%	99.80%	99.10%	95.66%
± 1 standard error	0.01%	0.01%	0.02%	0.07%	0.48%

Identity® XL (Model 5376)

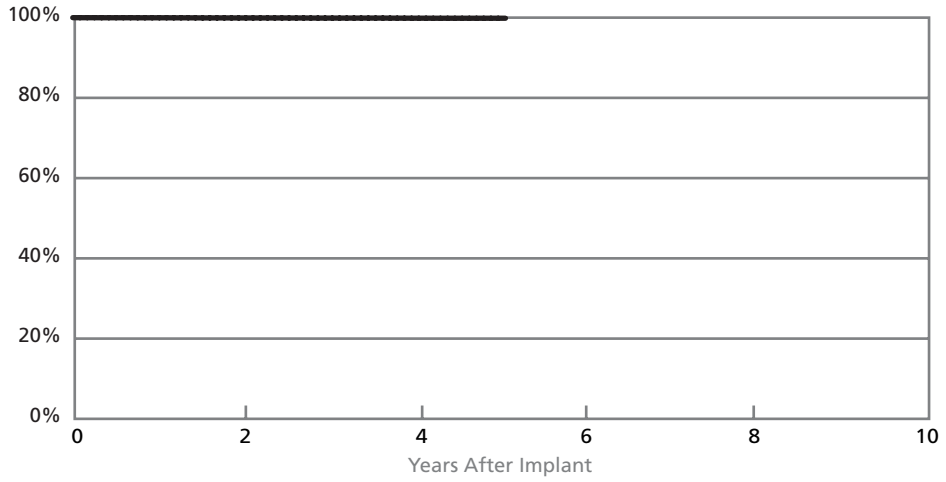
US Market Release	November 2001	Normal Battery Depletion	33
Registered US Implants	49,465	Malfunctions	41
Estimated Active US Implants	39,466	Malfunctions w/ Compromised Therapy (0 related to Advisory)	6
Estimated Longevity	6.9 Years	Malfunctions w/o Compromised Therapy (5 related to Advisory)	35
		Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	2	4	at 61 months		
Survival Probability	99.91%	99.74%	99.63%		
± 1 standard error	0.01%	0.03%	0.06%		
Sample Size	38600	17100	4900		

Excluding Normal Battery Depletion

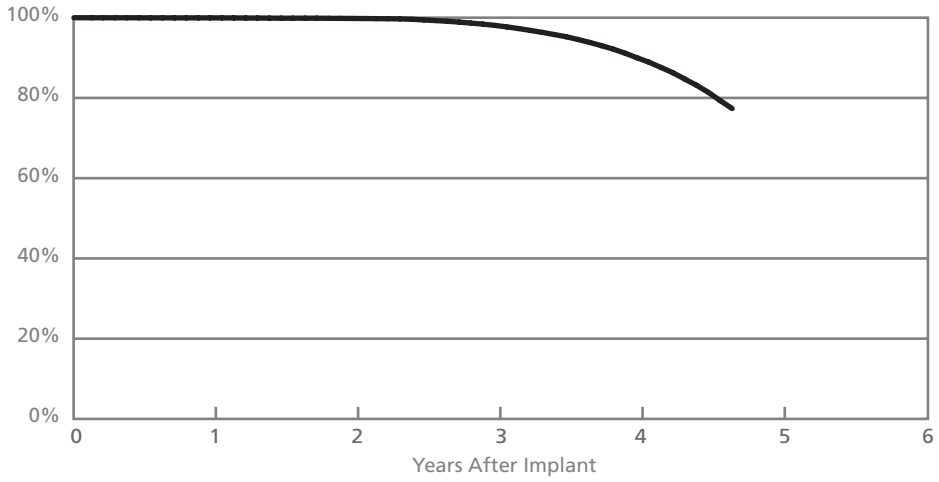


Year	2	4	at 61 months		
Survival Probability	99.92%	99.86%	99.85%		
± 1 standard error	0.01%	0.02%	0.03%		

Integrity® µ DR (Model 5336)

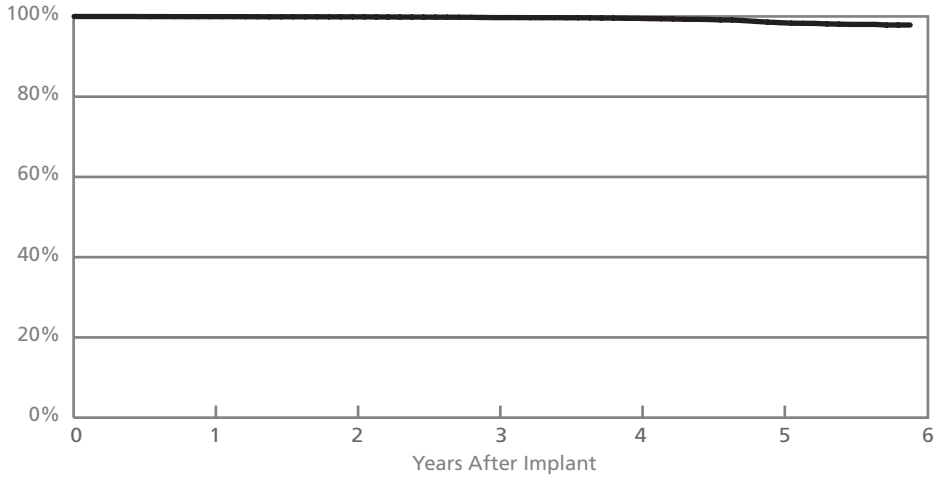
US Market Release	December 2000	Normal Battery Depletion	8017
Registered US Implants	29,281	Malfunctions	60
Estimated Active US Implants	5,288	Malfunctions w/ Compromised Therapy	7
Estimated Longevity	4.0 Years	Malfunctions w/o Compromised Therapy	53
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	4	at 56 months	
Survival Probability	99.95%	99.81%	98.08%	89.99%	77.35%	
± 1 standard error	0.01%	0.03%	0.06%	0.15%	0.24%	
Sample Size	29200	24900	21200	16300	11300	

Excluding Normal Battery Depletion

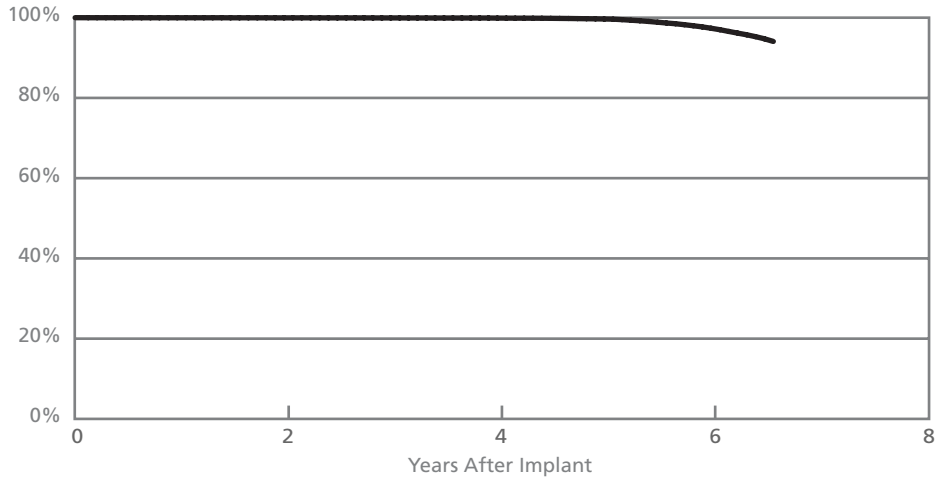


Year	1	2	3	4	5	at 71 months
Survival Probability	99.95%	99.90%	99.71%	99.52%	98.45%	97.86%
± 1 standard error	0.01%	0.02%	0.04%	0.05%	0.13%	0.19%

Integrity® AFx DR (Models 5342 & 5346)

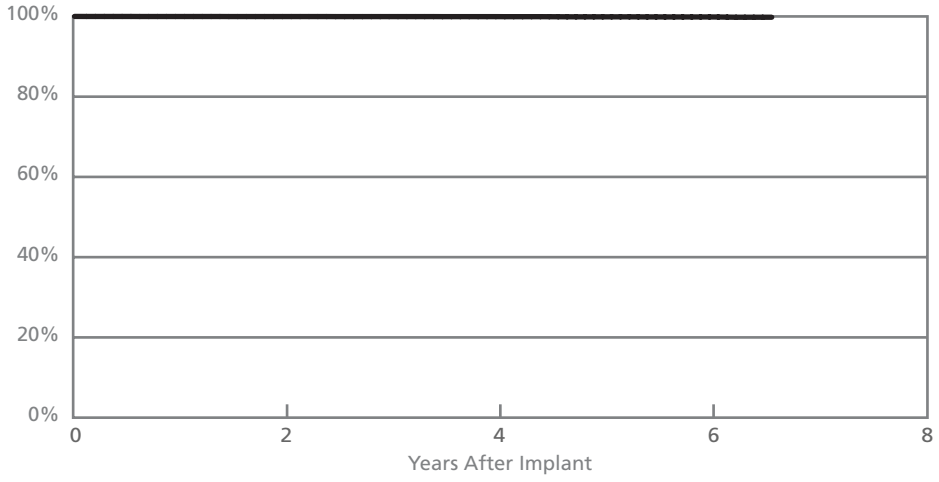
US Market Release	April 2000	Normal Battery Depletion	1526
Registered US Implants	47,315	Malfunctions	54
Estimated Active US Implants	28,000	Malfunctions w/ Compromised Therapy	5
Estimated Longevity	6.3 Years	Malfunctions w/o Compromised Therapy	49
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 79 months
Survival Probability	99.96%	99.90%	97.37%	94.08%
± 1 standard error	0.01%	0.02%	0.07%	0.10%
Sample Size	41900	32600	13300	3700

Excluding Normal Battery Depletion

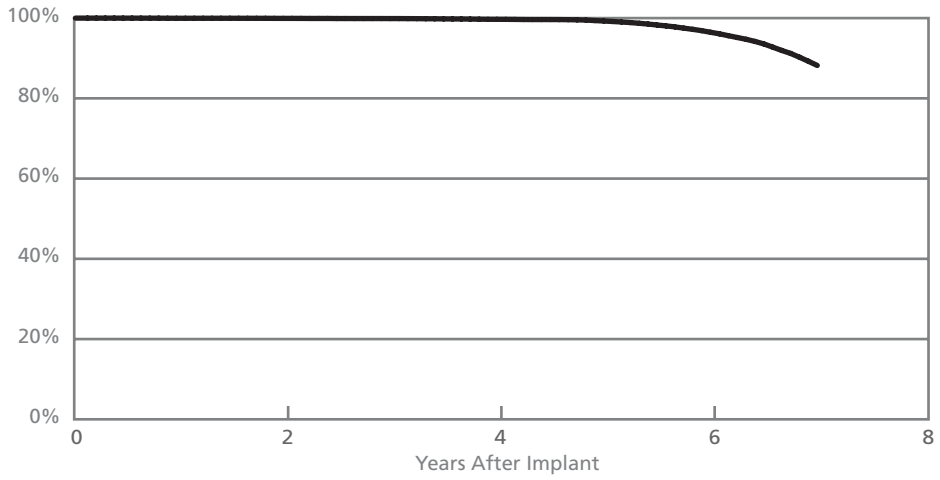


Year	2	4	6	at 79 months
Survival Probability	99.97%	99.95%	99.87%	99.80%
± 1 standard error	0.01%	0.01%	0.02%	0.05%

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

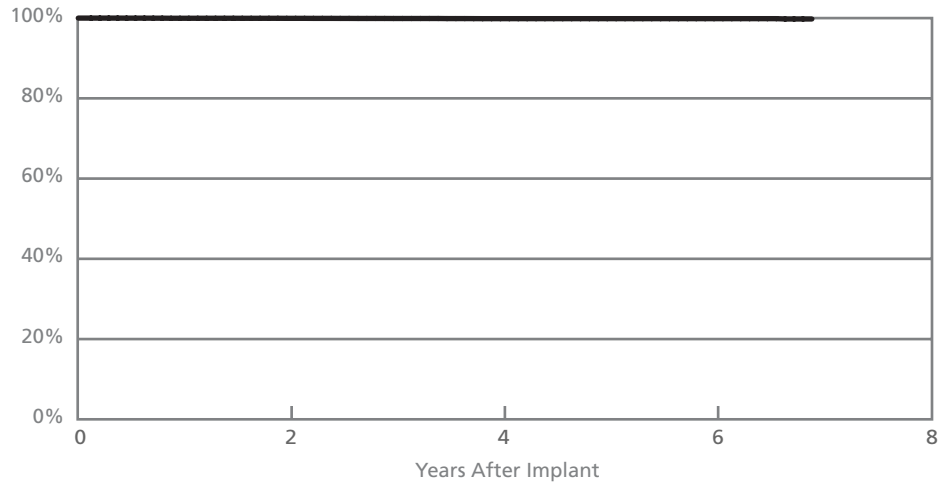
US Market Release	June 1999	Normal Battery Depletion	719
Registered US Implants	21,774	Malfunctions	23
Estimated Active US Implants	10,771	Malfunctions w/ Compromised Therapy	3
Estimated Longevity	6.3 Years	Malfunctions w/o Compromised Therapy	20
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 83 months
Survival Probability	99.93%	99.70%	96.47%	89.24%
± 1 standard error	0.02%	0.05%	0.13%	0.20%
Sample Size	18800	14100	10700	2100

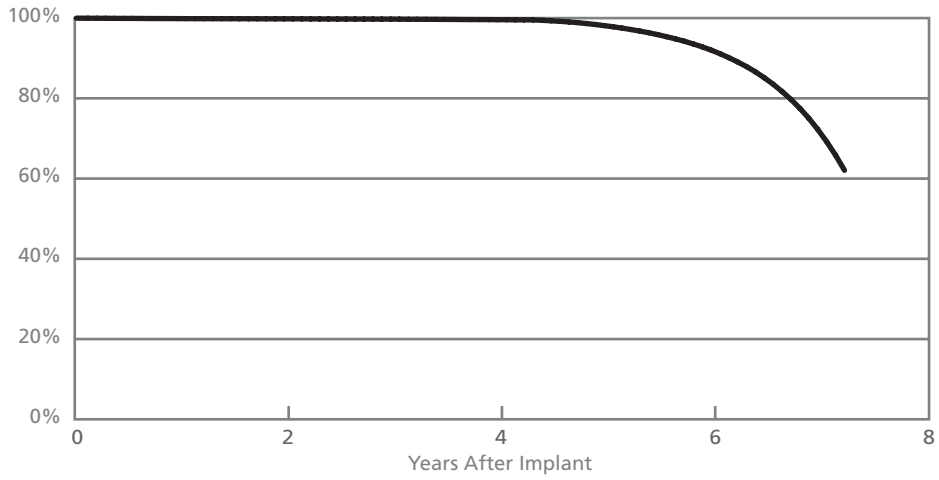
Excluding Normal Battery Depletion



Year	2	4	6	at 83 months
Survival Probability	99.94%	99.86%	99.86%	99.78%
± 1 standard error	0.02%	0.03%	0.03%	0.09 %

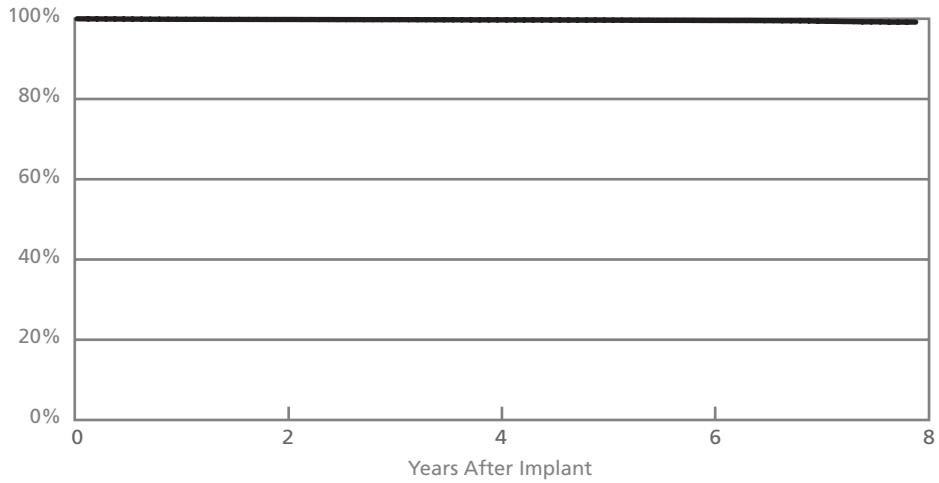
Affinity® DR (Models 5330 & 5331)		Affinity® DC (Model 5230)	
US Market Release	(5330) Jan. 1999 (5230 & 5331) June 1999	Normal Battery Depletion	13,033
		Malfunctions	187
Registered US Implants	65,463	Malfunctions w/ Compromised Therapy (0 related to Advisory)	15
Estimated Active US Implants	19,251	Malfunctions w/o Compromised Therapy (64 related to Advisory)	172
Estimated Longevity	6.3 Years	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	2	4	6	at 87 months
Survival Probability	99.82%	99.60%	92.04%	62.07%
± 1 standard error	0.02%	0.03%	0.07%	0.14%
Sample Size	57900	45800	31500	4000

Excluding Normal Battery Depletion

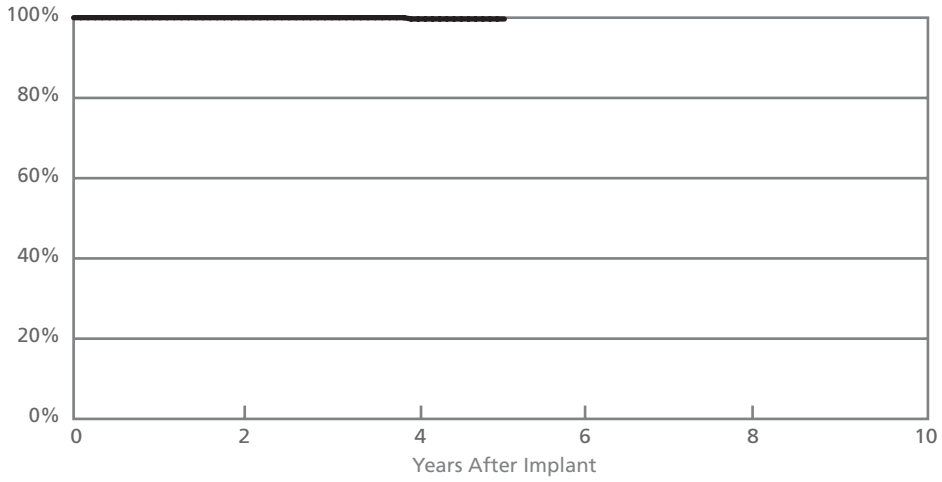


Year	2	4	6	at 95 months
Survival Probability	99.82%	99.72%	99.66%	99.17%
± 1 standard error	0.02%	0.02%	0.03%	0.10%

Affinity® VDR (Model 5430)

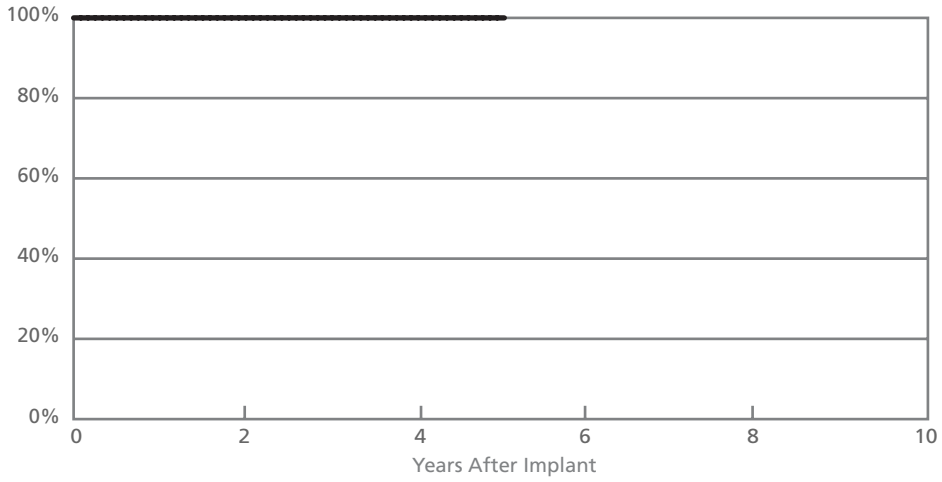
US Market Release	April 2000	Normal Battery Depletion	1
Registered US Implants	664	Malfunctions	0
Estimated Active US Implants	350	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	at 61 months		
Survival Probability	100.00%	99.68%	99.68%		
± 1 standard error	0.00%	0.00%	0.32%		
Sample Size	600	400	100		

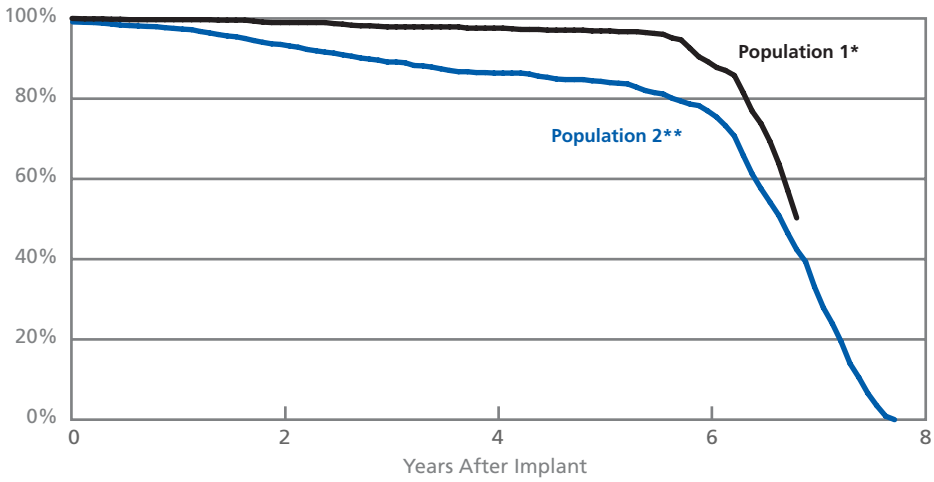
Excluding Normal Battery Depletion



Year	2	4	at 61 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		

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	1,035	**Registered US Implants	2,577
*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 130-136)	(1256D/2102) Three; (2902) Two



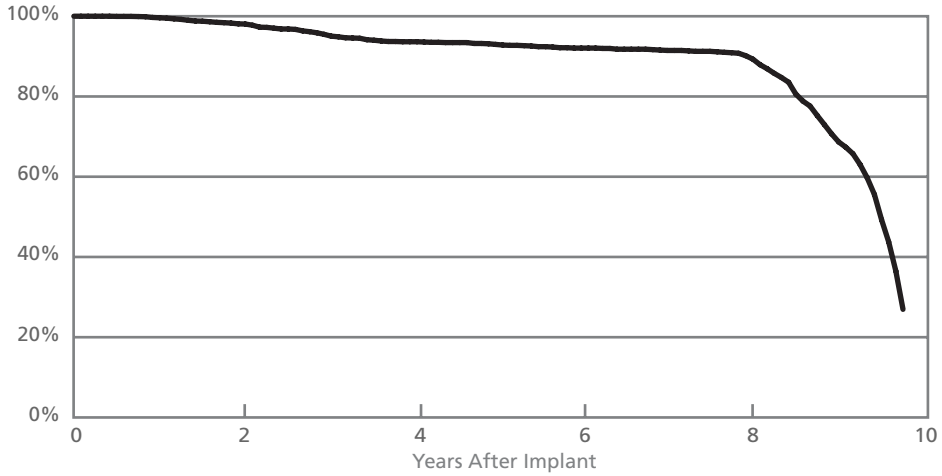
Population 1*

Year	2	4	6	at 82 months
Survival Probability	98.97%	97.58%	89.24%	50.28%
± 1 standard error	0.34%	0.55%	1.32%	2.49%
Sample Size	900	700	500	100

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

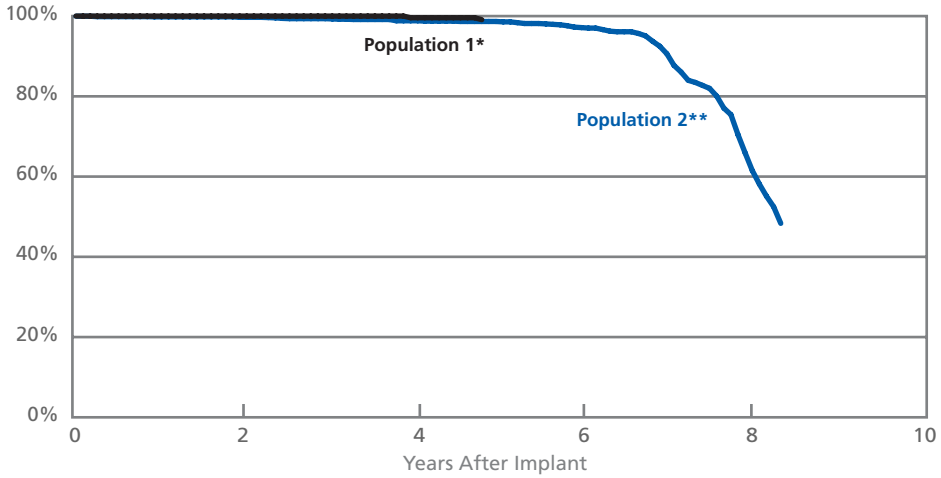
Meta™ DDDR (Model 1256)	
US Market Release	April 1997
Registered US Implants	2,625
Estimated Longevity	6.6 Years
Number of Advisories (see pages 130-136)	One



Year	2	4	6	8	at 117 months
Survival Probability	98.10%	93.64%	92.06%	89.30%	26.95%
± 1 standard error	0.28%	0.56%	0.65%	0.79%	1.84%
Sample Size	2600	1700	1200	900	500

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	2,577
*Estimated Longevity	5.0 Years	**Estimated Longevity	5.0 Years
*Number of Advisories	None	**Number of Advisories (see pages 130-136)	Two



Population 1*

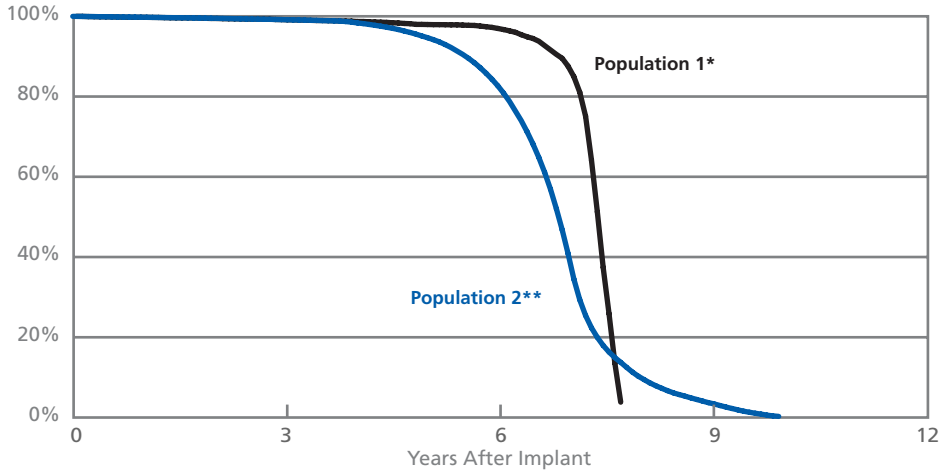
Year	2	4	at 58 months		
Survival Probability	100.00%	99.59%	99.11%		
± 1 standard error	0.00%	0.00%	0.41%		
Sample Size	400	300	200		

Population 2**

Year	2	4	6	8	at 100 months
Survival Probability	99.86%	99.43%	98.74%	61.49	48.34%
± 1 standard error	0.10%	0.28%	0.49%	2.04%	2.25%
Sample Size	1900	1400	1000	600	300

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	7,015	**Registered US Implants	58,715
*Estimated Longevity	5.0 Years	**Estimated Longevity	5.0 Years
*Number of Advisories	None	**Number of Advisories (see pages 130-136)	Two



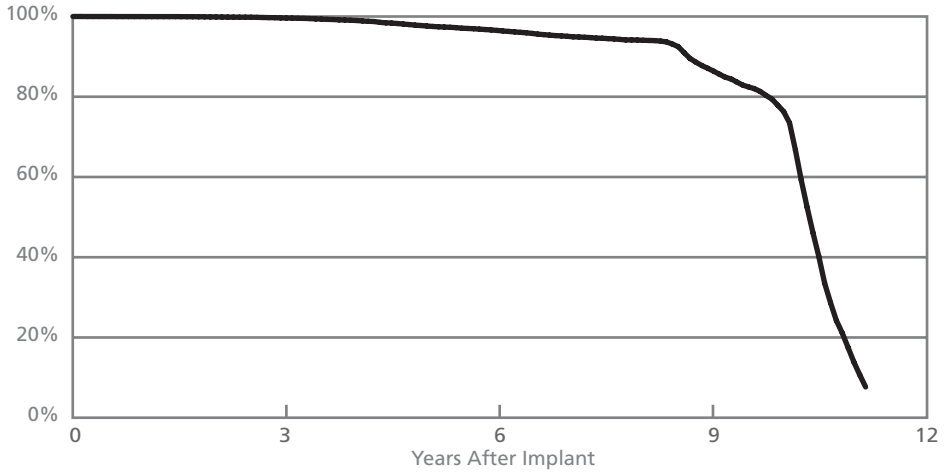
Population 1*

Year	3	6	at 94 months	
Survival Probability	99.18%	97.23%	3.83%	
± 1 standard error	0.12%	0.24%	0.77%	
Sample Size	5500	3700	2100	

Population 2**

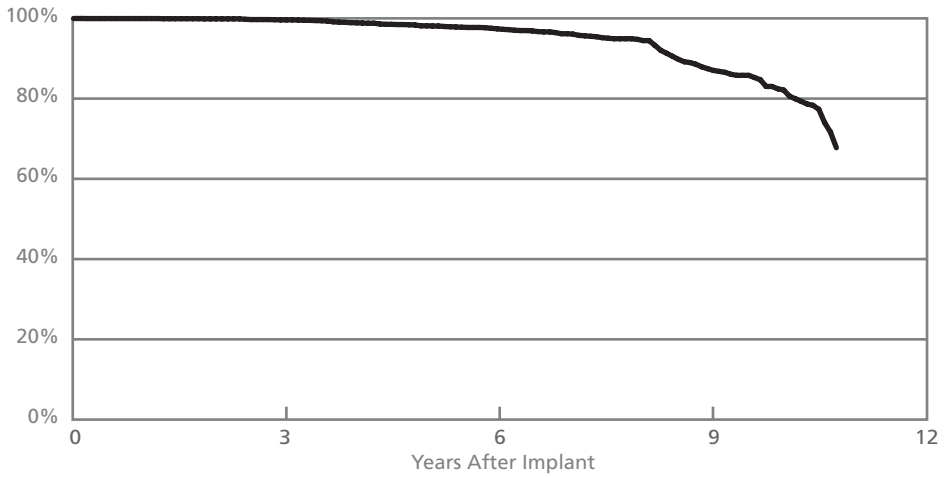
Year	3	6	9	at 121 months
Survival Probability	99.18%	84.31%	4.09%	0.28%
± 1 standard error	0.04%	0.09%	0.45%	0.15%
Sample Size	47300	32100	10200	200

Trilogy® DR (Model 2350)	
US Market Release	June 1995
Registered US Implants	18,726
Estimated Longevity	5.1 Years
Number of Advisories (see pages 130-136)	Two



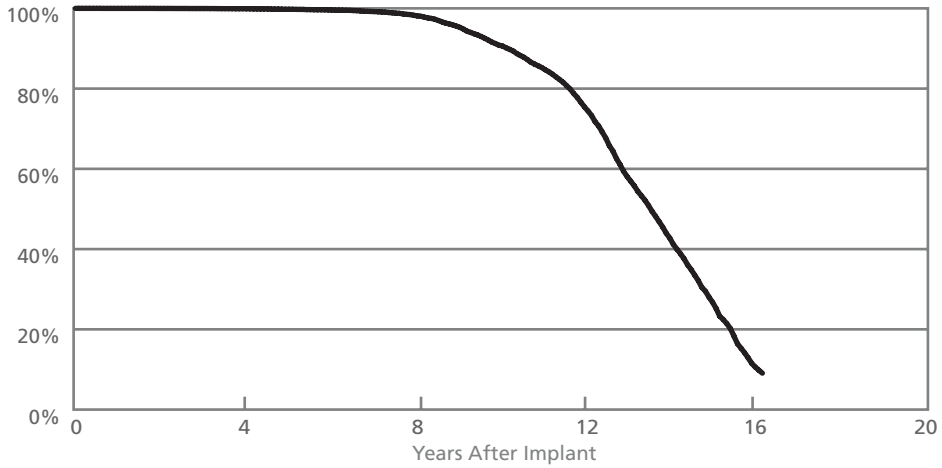
Year	3	6	9	at 135 months
Survival Probability	99.65%	96.65%	87.78%	10.68%
± 1 standard error	0.04%	0.17%	0.51%	0.86%
Sample Size	15300	10300	3500	300

Paragon™ III (Models 2304, 2314, 2315)	
US Market Release	October 1994
Registered US Implants	3,828
Estimated Longevity	6.3 Years
Number of Advisories	None



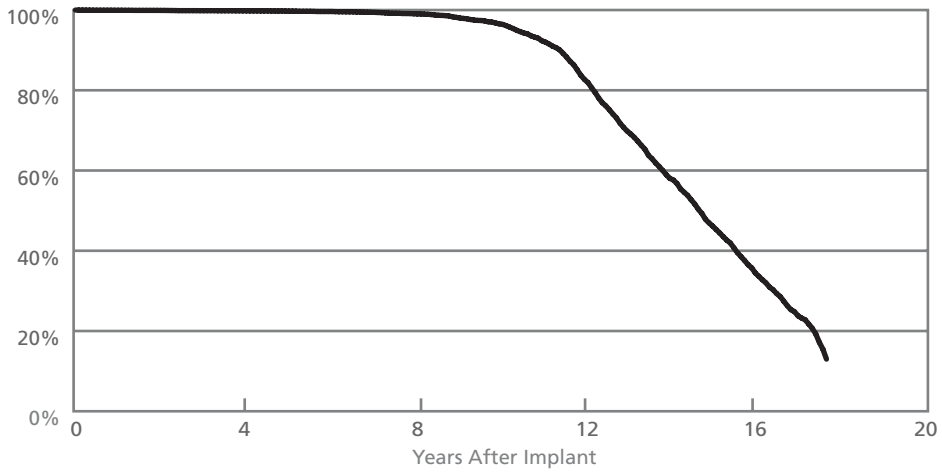
Year	3	6	9	at 131 months
Survival Probability	99.62%	97.53%	87.92%	67.77%
± 1 standard error	0.11%	0.34%	1.18%	2.27%
Sample Size	3800	1800	600	300

Paragon™ II (Model 2016)	
US Market Release	April 1989
Registered US Implants	29,064
Estimated Longevity	7.7 Years
Number of Advisories	None



Year	4	8	12	16	at 194 months
Survival Probability	99.91%	98.28%	75.45%	10.60%	9.08%
± 1 standard error	0.02%	0.11%	0.60%	0.66%	0.62%
Sample Size	20100	11200	3800	600	200

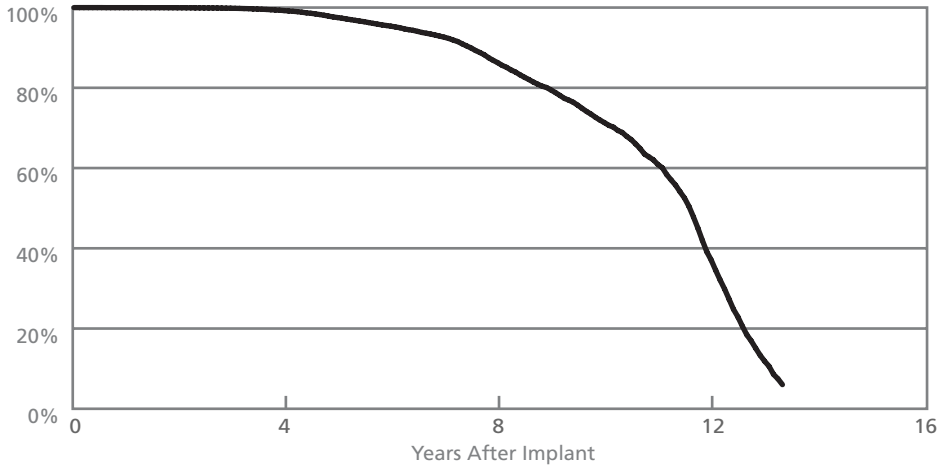
Paragon™ (Models 2010, 2011 & 2012)	
US Market Release	September 1988
Registered US Implants	16,671
Estimated Longevity	7.2 Years
Number of Advisories	None



Year	4	8	12	16	at 212 months
Survival Probability	99.80%	99.07%	82.71%	34.46%	13.00%
± 1 standard error	0.04%	0.10%	0.63%	1.08%	0.91%
Sample Size	11900	6900	3100	800	300

Synchrony® III (Models 2028 & 2029)

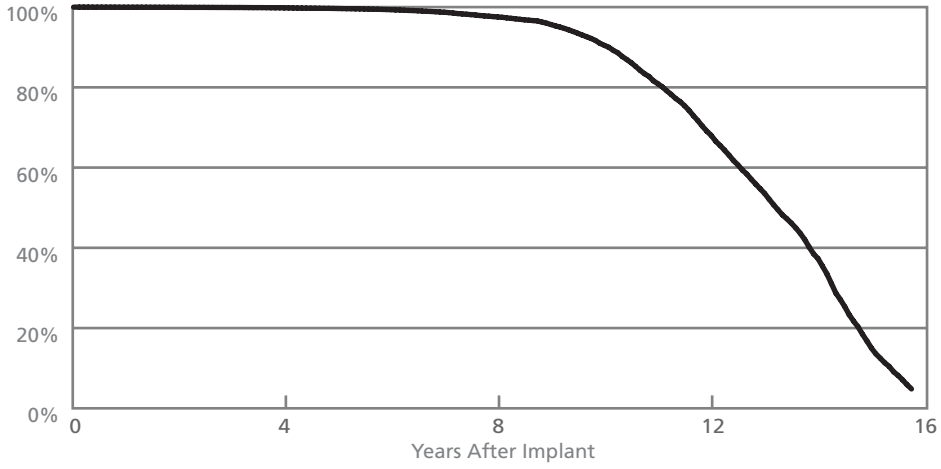
US Market Release	February 1993
Registered US Implants	43,409
Estimated Longevity	5.5 Years
Number of Advisories	None



Year	4	8	12	at 160 months
Survival Probability	99.25%	86.27%	37.05%	6.02%
± 1 standard error	0.05%	0.31%	0.83%	0.49%
Sample Size	15300	10300	1600	300

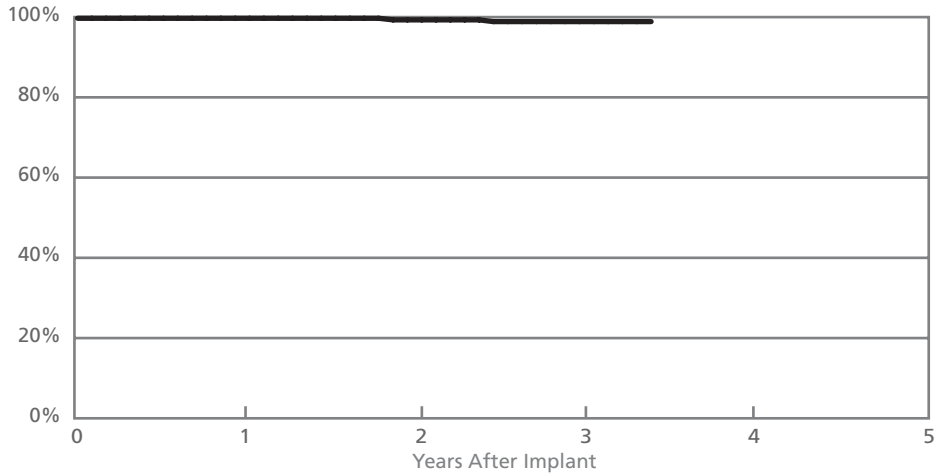
Synchrony® II (Models 2022 & 2023)

US Market Release	June 1990
Registered US Implants	47,244
Estimated Longevity	8.0 Years
Number of Advisories	None



Year	4	8	12	at 189 months
Survival Probability	99.81%	97.54%	68.01%	4.83%
± 1 standard error	0.02%	0.10%	0.49%	0.37%
Sample Size	36000	21800	6700	200

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 41 months	
Survival Probability	99.71%	99.31%	98.88%	98.88%	
± 1 standard error	0.29%	0.49%	0.65%	0.65%	
Sample Size	300	300	200	100	

Summary Information

Pulse Generators Dual-Chamber

ST. JUDE MEDICAL

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
5810/5816	Victory DR/XL	Dec-05	21428	21199	0	0	0	0	0	0
5380	Identity ADx DR	Mar-03	46062	39954	0	16	0	2	18	236
5386/5286	Identity ADx XL DR/DC	Mar-03	48321	44137	1	15	0	0	16	1
5360	Integrity ADx DR	May-03	4951	4276	0	2	0	0	2	16
5366	Integrity ADx XL DR	May-03	5829	5292	0	1	0	0	1	0
5356/5357/5256	Verity ADX XL DR/ DR(M/S)/DC	May-03	12206	10716	0	5	0	0	5	0
5370	Identity	Nov-01	56860	15841	5	73	12	4	94	22829
5376	Identity XL	Nov-01	49465	39466	6	30	5	0	41	33
5336	Integrity µ DR	Dec-00	29281	5288	7	53	0	0	60	8017
5342/5346	Integrity AFx DR	Apr-00	47315	28000	5	49	0	0	54	1526
5326/5226	Entity DR/DC	Jun-99	21774	10771	3	19	0	1	23	719
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65463	19251	15	108	64	0	187	13033
5430	Affinity VDR	Apr-00	664	350	0	0	0	0	0	1

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
5810/5816	Victory DR/XL	Dec-05	21428	21199	0	0	0	0	0
5380	Identity ADx DR	Mar-03	46062	39954	0	16	0	2	18
5386/5286	Identity ADx XL DR/DC	Mar-03	48321	44137	1	15	0	0	16
5360	Integrity ADx DR	May-03	4951	4276	0	2	0	0	2
5366	Integrity ADx XL DR	May-03	5829	5292	0	1	0	0	1
5356/5357/5256	Verity ADX XL DR/ DR(M/S)/DC	May-03	12206	10716	0	5	0	0	5
5370	Identity	Nov-01	56860	15841	5	73	12	4	94
5376	Identity XL	Nov-01	49465	39466	6	30	5	0	41
5336	Integrity µ DR	Dec-00	29281	5288	7	53	0	0	60
5342/5346	Integrity AFx DR	Apr-00	47315	28000	5	49	0	0	54
5326/5226	Entity DR/DC	Jun-99	21774	10771	3	19	0	1	23
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65463	19251	15	108	64	0	187
5430	Affinity VDR	Apr-00	664	350	0	0	0	0	0

**Based on returned product analysis as of December 31, 2006.*

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
5810/5816	Victory DR/XL	100% (11mo)							
5380	Identity ADx DR	99.97%	99.89%	98.49%					
5386/5286	Identity ADx XL DR/DC	99.97%	99.95%	99.93%					
5360	Integrity ADx DR	99.95%	99.95%	99.00%					
5366	Integrity ADx XL DR	99.98%	99.92%	99.82%					
5356/5357/5256	Verity ADX XL DR/ DR(M/S)/DC	99.95%	99.95%	99.89%					
5370	Identity	99.96%	98.96%	93.94%	74.20%				
5376	Identity XL	99.96%	99.91%	99.84%	99.74%	99.63%			
5336	Integrity µ DR	99.95%	99.81%	98.08%	89.99%				
5342/5346	Integrity AFx DR	99.98%	99.96%	99.94%	99.90%	99.67%	97.37%		
5326/5226	Entity DR/DC	99.96%	99.93%	99.88%	99.70%	99.28%	96.47%		
5330/5331/5230	Affinity DR/DC	99.87%	99.82%	99.74%	99.60%	98.12%	92.04%	92.04%	
5430	Affinity VDR	100.00%	100.00%	100.00%	99.68%	99.68%			

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
5810/5816	Victory DR/XL	100% (11mo)							
5380	Identity ADx DR	99.98%	99.94%	99.67%					
5386/5286	Identity ADx XL DR/DC	99.97%	99.96%	99.93%					
5360	Integrity ADx DR	99.95%	99.95%	99.73%					
5366	Integrity ADx XL DR	99.98%	99.92%	99.82%					
5356/5357/5256	Verity ADX XL DR/ DR(M/S)/DC	99.95%	99.95%	99.89%					
5370	Identity	99.97%	99.93%	99.80%	99.10%				
5376	Identity XL	99.96%	99.92%	99.89%	99.86%	99.85%			
5336	Integrity µ DR	99.95%	99.90%	99.71%	99.52%	98.45%			
5342/5346	Integrity AFx DR	99.98%	99.97%	99.96%	99.95%	99.90%	99.87%		
5326/5226	Entity DR/DC	99.96%	99.94%	99.90%	99.86%	99.86%	96.36%		
5330/5331/5230	Affinity DR/DC	99.87%	99.82%	99.78%	99.72%	99.66%	99.66%	99.41%	
5430	Affinity VDR	100.00%	100.00%	100.00%	100.00%	100.00%			

**Based on returned product analysis as of December 31, 2006.*

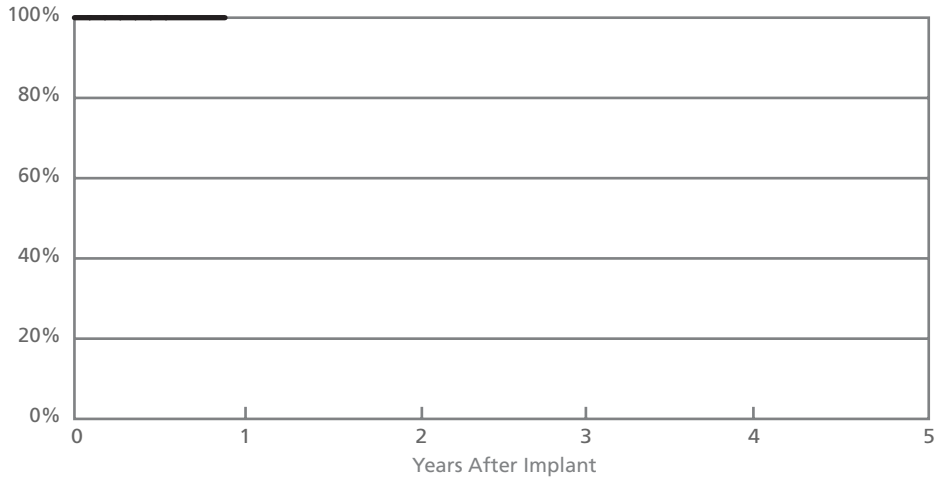
Pulse Generators
Single-Chamber

ST. JUDE MEDICAL

Victory® SR (Model 5610)

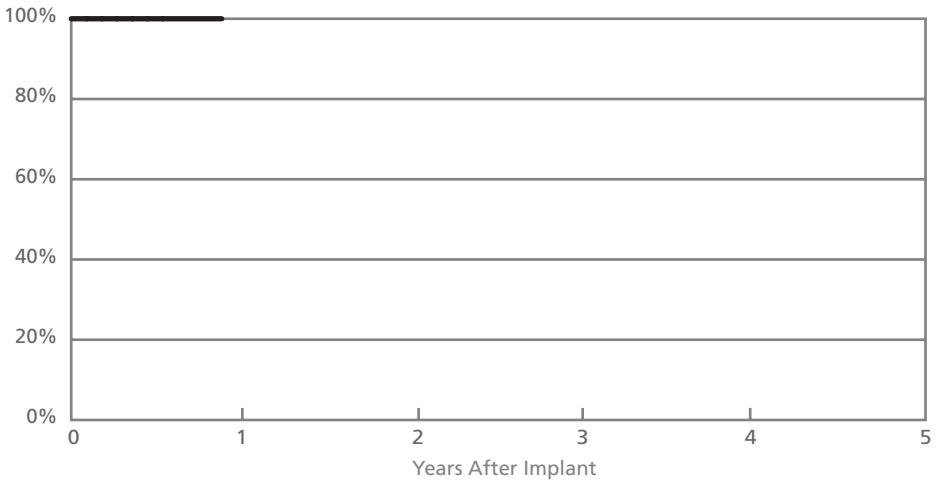
US Market Release	December 2005	Normal Battery Depletion	0
Registered US Implants	2,975	Malfunctions	0
Estimated Active US Implants	2,921	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	6.2 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	at 11 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				
Sample Size	1500				

Excluding Normal Battery Depletion

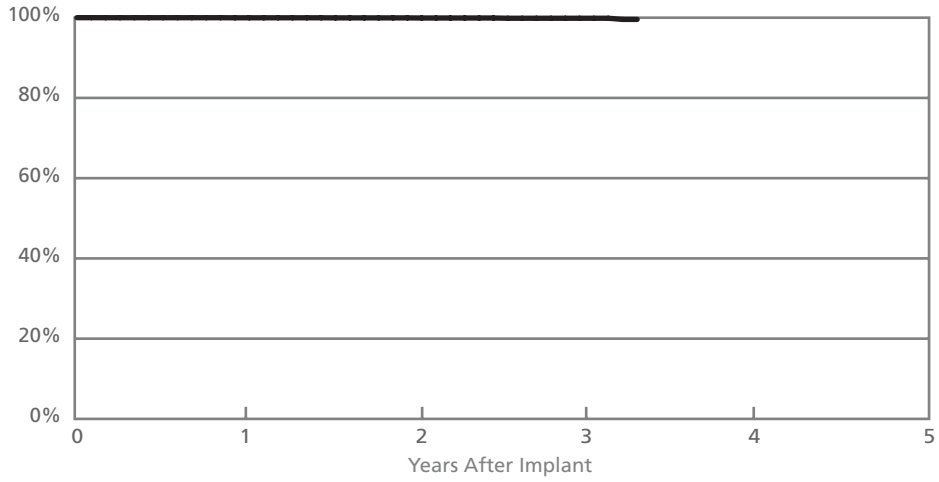


Year	at 11 months				
Survival Probability	100.00%				
± 1 standard error	0.00%				

Identity® ADx SR (Model 5180)

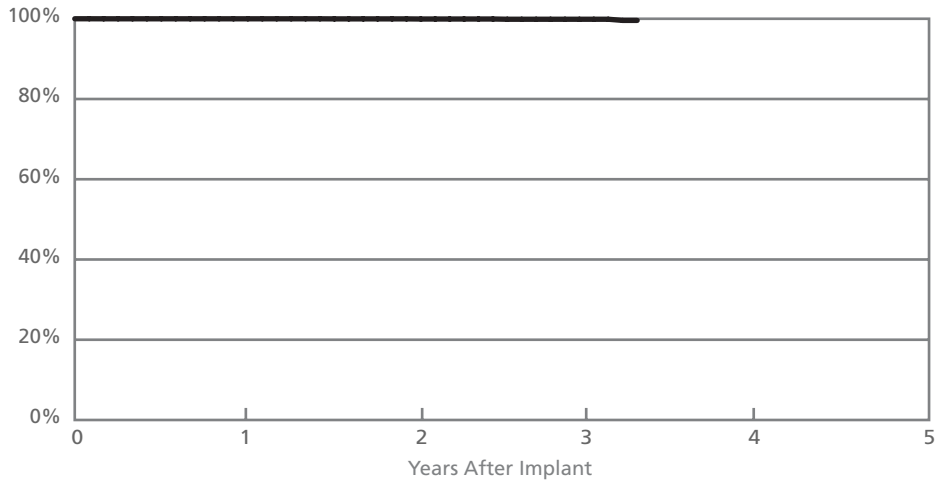
US Market Release	May 2003	Normal Battery Depletion	2
Registered US Implants	15,171	Malfunctions	3
Estimated Active US Implants	12,483	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 40 months	
Survival Probability	99.97%	99.95%	99.86%	99.57%	
± 1 standard error	0.01%	0.03%	0.07%	0.30%	
Sample Size	12700	6100	2100	300	

Excluding Normal Battery Depletion

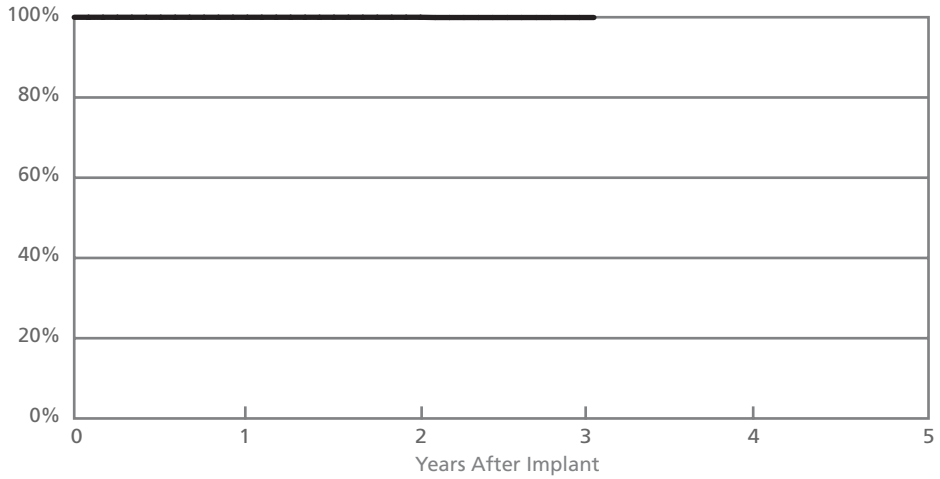


Year	1	2	3	at 40 months	
Survival Probability	99.99%	99.97%	99.88%	99.59%	
± 1 standard error	0.01%	0.02%	0.07%	0.30%	

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

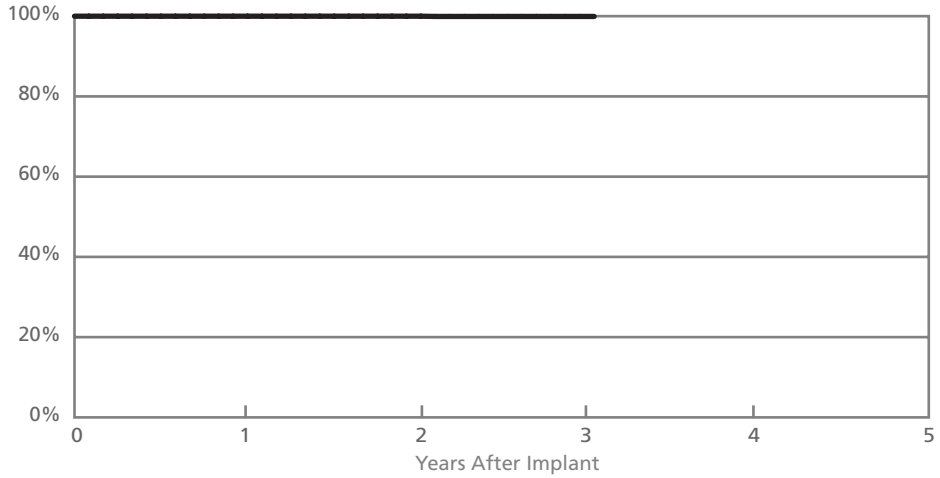
US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	8,360	Malfunctions	2
Estimated Active US Implants	7,005	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	10.2 Years	Malfunctions w/o Compromised Therapy	2
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	3	at 37 months	
Survival Probability	99.99%	99.99%	99.93%	99.93%	
± 1 standard error	0.01%	0.01%	0.06%	0.06%	
Sample Size	6900	3300	1100	100	

Excluding Normal Battery Depletion

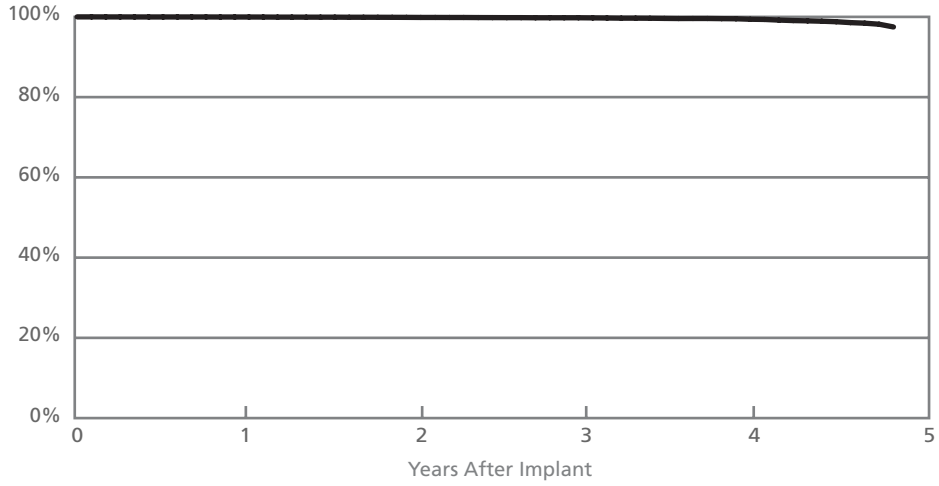


Year	1	2	3	at 37 months	
Survival Probability	99.99%	99.99%	99.93%	99.93%	
± 1 standard error	0.01%	0.01%	0.06%	0.06%	

Identity® SR (Model 5172)

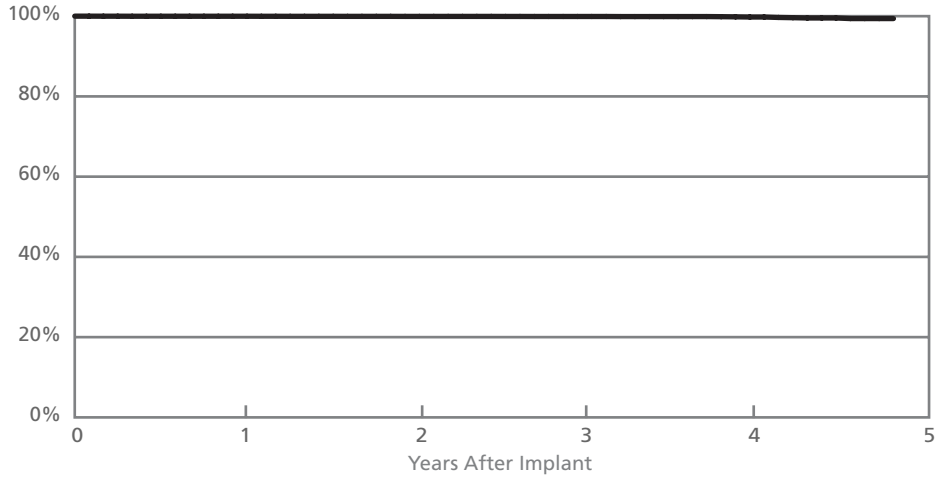
US Market Release	November 2001	Normal Battery Depletion	40
Registered US Implants	20,684	Malfunctions	12
Estimated Active US Implants	13,764	Malfunctions w/ Compromised Therapy (0 related to Advisory)	1
Estimated Longevity	7.8 Years	Malfunctions w/o Compromised Therapy (0 related to Advisory)	11
		Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	1	2	3	4	at 58 months
Survival Probability	99.97%	99.88%	99.78%	99.41%	97.70%
± 1 standard error	0.01%	0.02%	0.04%	0.06%	0.09%
Sample Size	19800	13900	9200	4600	1200

Excluding Normal Battery Depletion

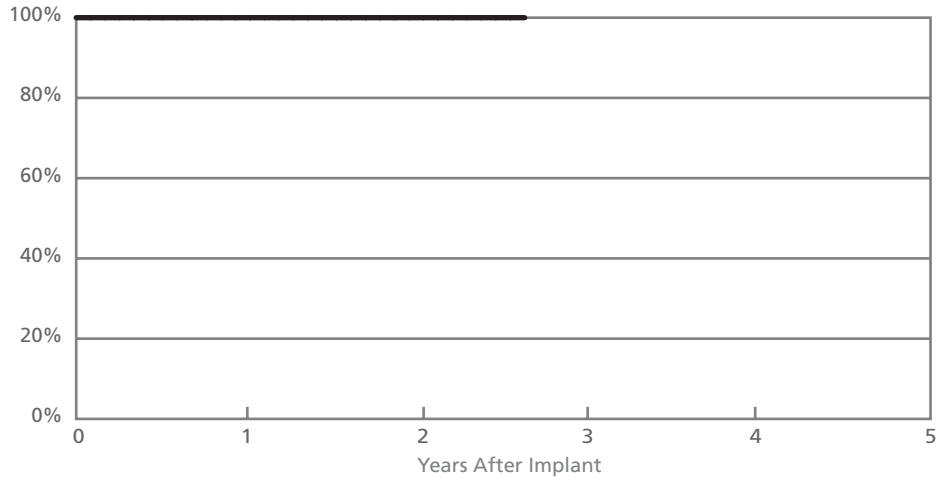


Year	1	2	3	4	at 58 months
Survival Probability	99.98%	99.94%	99.92%	99.79%	99.40%
± 1 standard error	0.01%	0.02%	0.03%	0.06%	0.21%

Integrity® ADx SR (Model 5160)

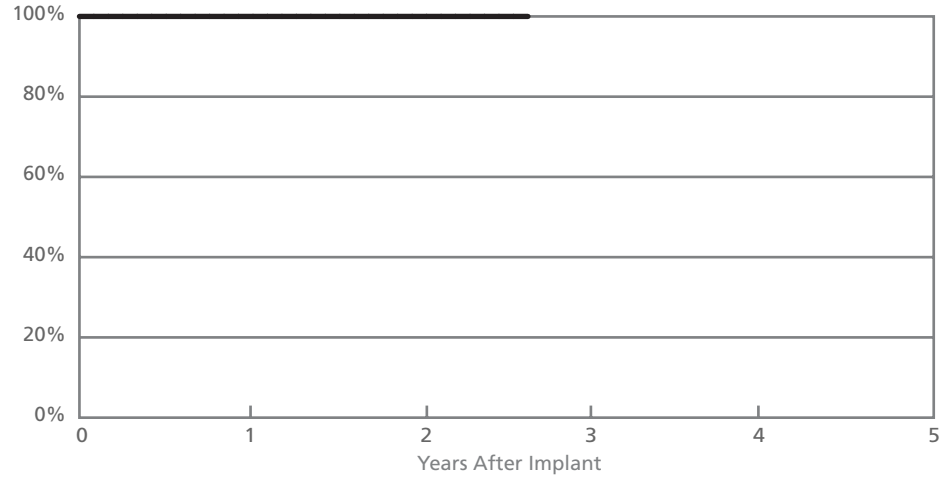
US Market Release	May 2003	Normal Battery Depletion	0
Registered US Implants	2,745	Malfunctions	0
Estimated Active US Implants	2,214	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.7 Years	Malfunctions w/o Compromised Therapy	0
		Number of Advisories	None

Including Normal Battery Depletion



Year	1	2	at 32 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		
Sample Size	2400	1200	300		

Excluding Normal Battery Depletion

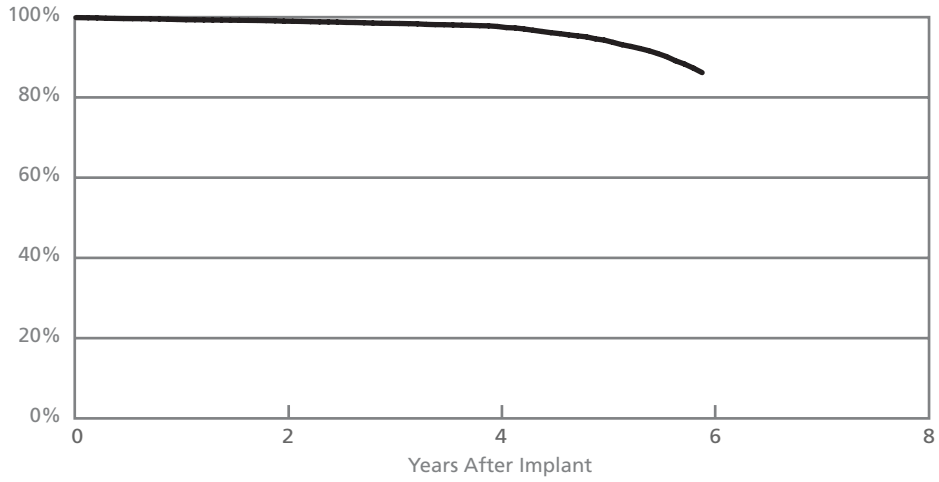


Year	1	2	at 32 months		
Survival Probability	100.00%	100.00%	100.00%		
± 1 standard error	0.00%	0.00%	0.00%		

Integrity® µ SR (Model 5136)

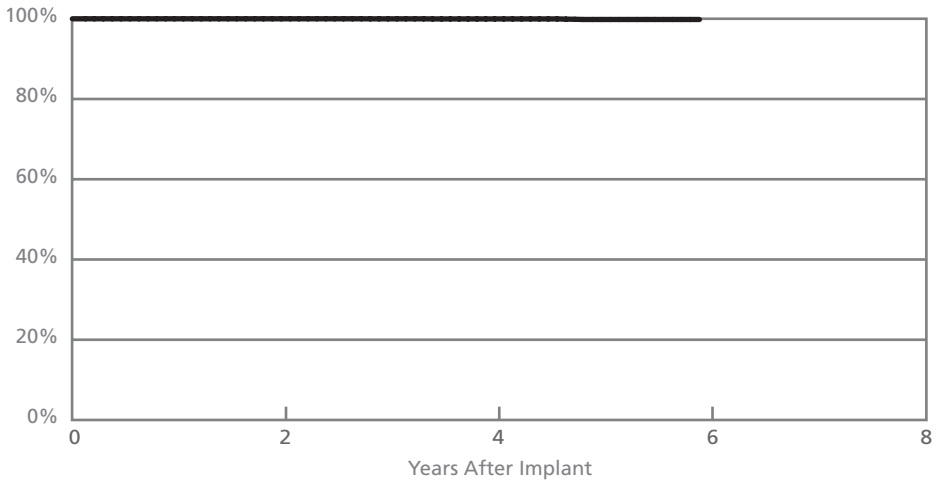
US Market Release	December 2000	Normal Battery Depletion	309
Registered US Implants	11,929	Malfunctions	4
Estimated Active US Implants	5,663	Malfunctions w/ Compromised Therapy	0
Estimated Longevity	5.3 Years	Malfunctions w/o Compromised Therapy	4
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	at 71 months	
Survival Probability	99.01%	97.68%	86.18%	
± 1 standard error	0.10%	0.18%	0.35%	
Sample Size	9100	4900	1100	

Excluding Normal Battery Depletion

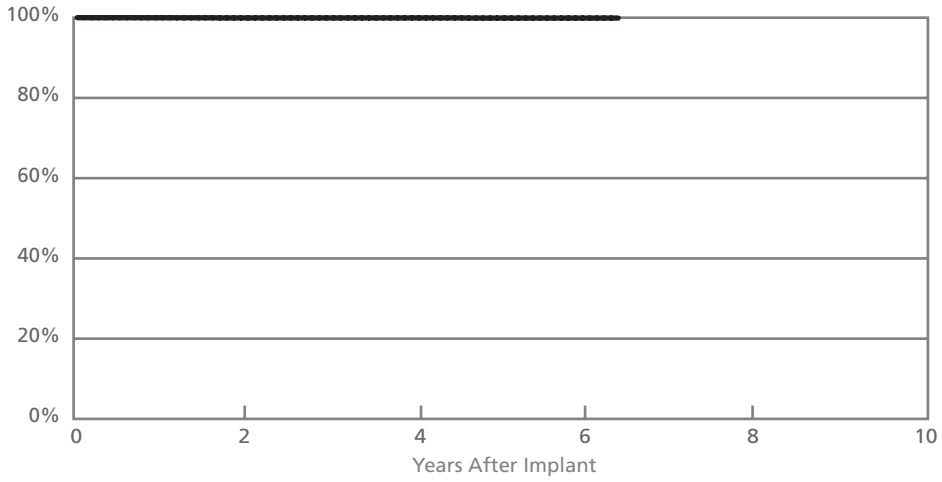


Year	2	4	at 71 months	
Survival Probability	99.99%	99.96%	99.82%	
± 1 standard error	0.01%	0.03%	0.08%	

Integrity® SR (Model 5142)

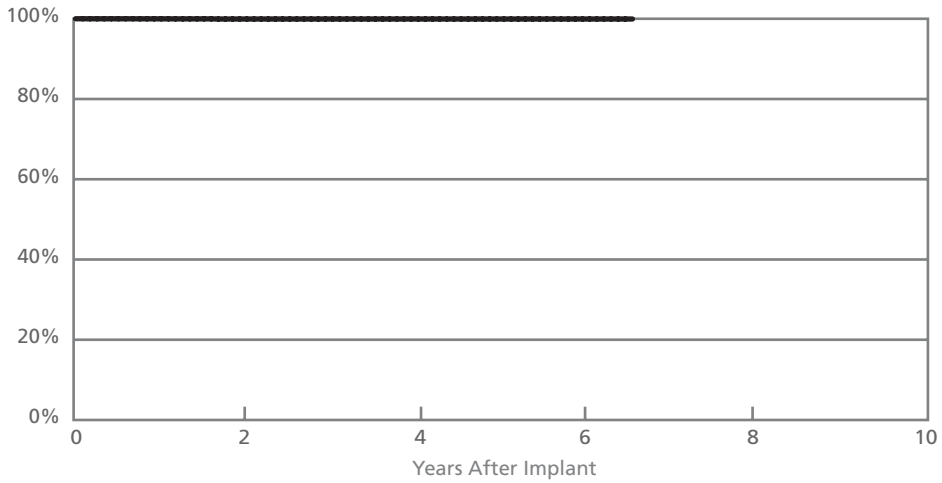
US Market Release	April 2000	Normal Battery Depletion	1
Registered US Implants	10,468	Malfunctions	4
Estimated Active US Implants	5,269	Malfunctions w/ Compromised Therapy	1
Estimated Longevity	8.6 Years	Malfunctions w/o Compromised Therapy	3
		Number of Advisories	None

Including Normal Battery Depletion



Year	2	4	6	at 77 months	
Survival Probability	99.94%	99.94%	99.91%	99.91%	
± 1 standard error	0.03%	0.03%	0.04%	0.04%	
Sample Size	8500	5500	2000	500	

Excluding Normal Battery Depletion

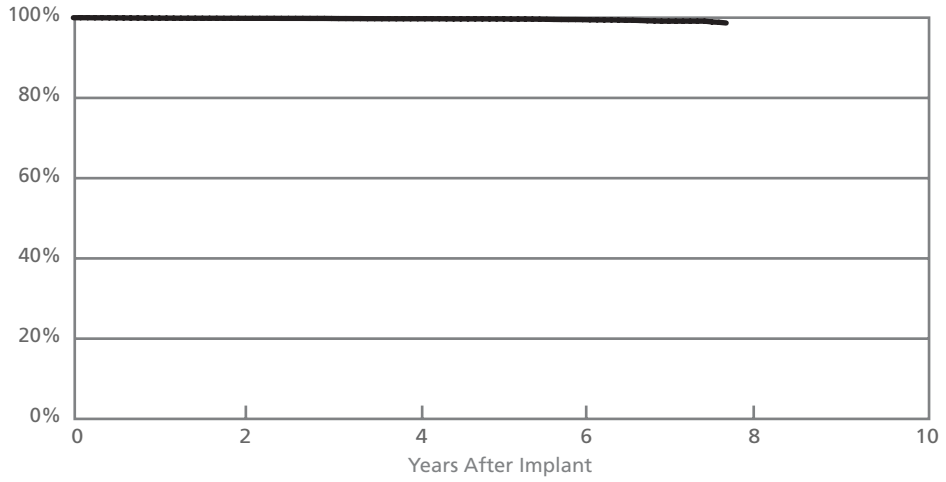


Year	2	4	6	at 77 months	
Survival Probability	99.94%	99.94%	99.94%	99.94%	
± 1 standard error	0.03%	0.03%	0.03%	0.03%	

Affinity® SR (Models 5130 & 5131)

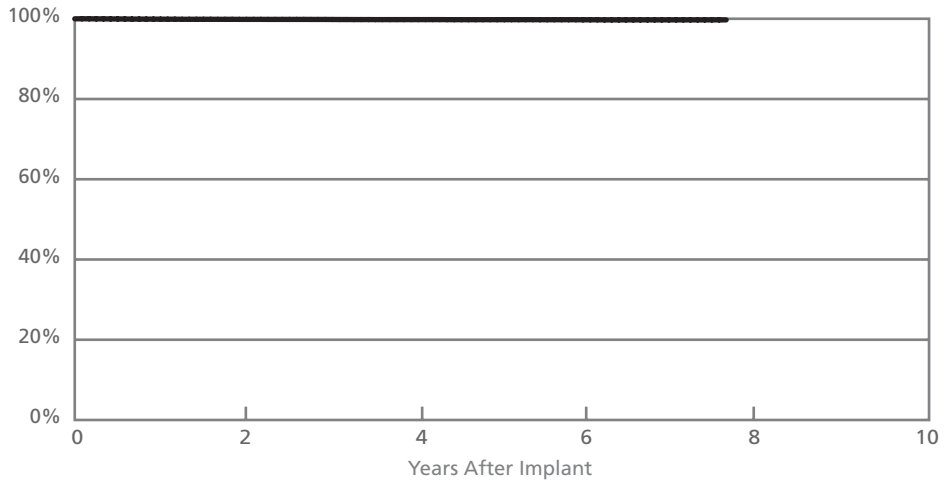
US Market Release	(5130) January 99 (5131) June 99	Normal Battery Depletion	45
		Malfunctions	52
Registered US Implants	28,634	Malfunctions w/ Compromised Therapy (0 related to Advisory)	4
Estimated Active US Implants	11,754	Malfunctions w/o Compromised Therapy (17 related to Advisory)	48
Estimated Longevity	8.6 Years	Number of Advisories (see pages 130-136)	One

Including Normal Battery Depletion



Year	2	4	6	at 92 months	
Survival Probability	99.85%	99.73%	99.51%	98.68%	
± 1 standard error	0.03%	0.04%	0.06%	0.13%	
Sample Size	23200	15800	7900	800	

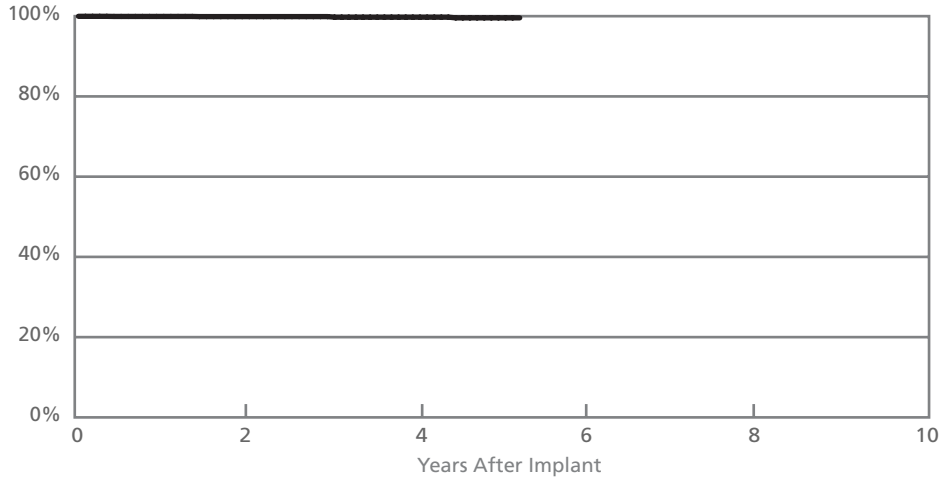
Excluding Normal Battery Depletion



Year	2	4	6	at 92 months	
Survival Probability	99.85%	99.79%	99.74%	99.72%	
± 1 standard error	0.02%	0.03%	0.04%	0.05%	

Microny® (Models 2425T, 2525T & 2535K)

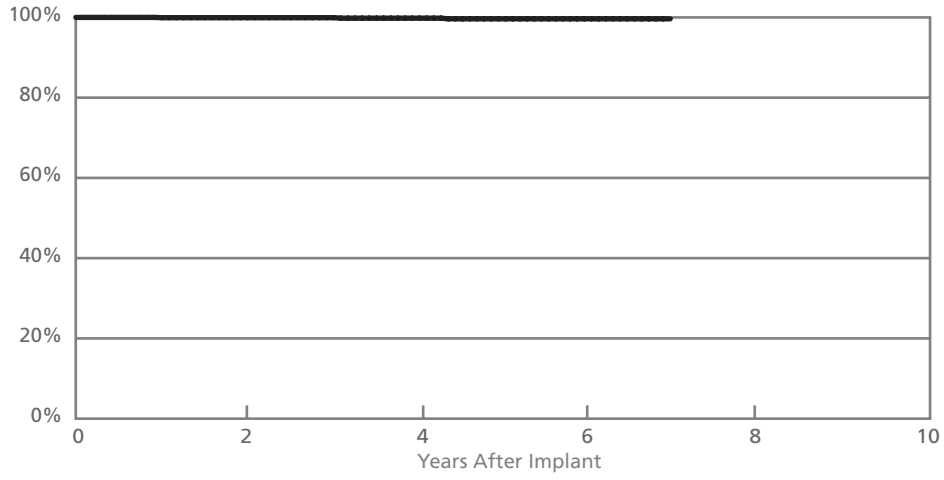
US Market Release	April 2001
Registered US Implants	4,898
Estimated Longevity	7.5 Years
Number of Advisories	None



Year	2	4	at 63 months		
Survival Probability	99.89%	99.75%	99.58%		
± 1 standard error	0.05%	0.11%	0.20%		
Sample Size	2900	1200	100		

Regency® SC+ (Models 2400L & 2402L)

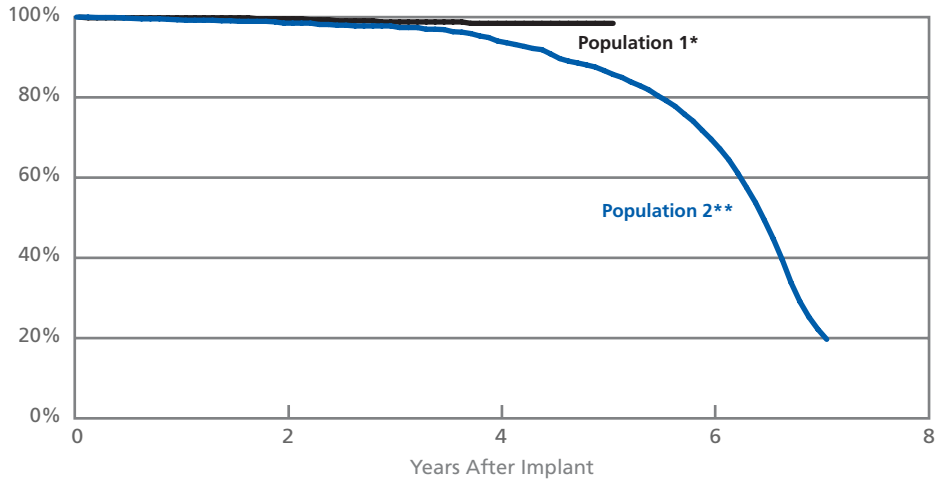
US Market Release	May 1998
Registered US Implants	2,059
Estimated Longevity	9.1 Years
Number of Advisories	None



Year	2	4	6	at 84 months	
Survival Probability	99.93%	99.82%	99.65%	99.65%	
± 1 standard error	0.07%	0.13%	0.21%	0.21%	
Sample Size	1400	900	500	200	

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

*Population 1		** Population 2	
*(These models are no longer being manufactured)		**(These models are no longer being manufactured)	
*US Market Release	August 1997	**US Market Release	August 1997
*Registered US Implants	604	**Registered US Implants	1,061
*Estimated Longevity	5.3 Years	**Estimated Longevity	5.3 Years
*Number of Advisories	None	**Number of Advisories (see pages 130-136)	Two



Population 1*

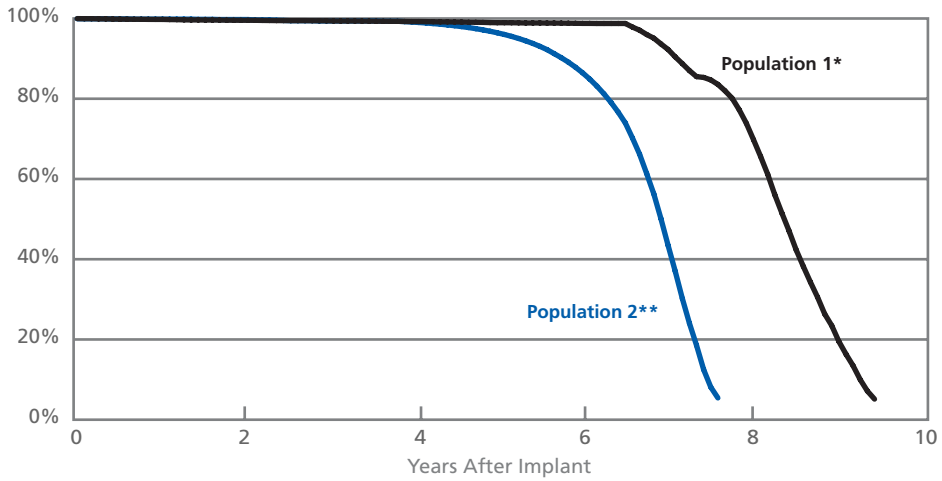
Year	2	4	at 61 months	
Survival Probability	99.83%	99.09%	98.45%	
± 1 standard error	0.29%	0.64%	0.64%	
Sample Size	500	300	200	

Population 2**

Year	2	4	6	at 85 months
Survival Probability	98.50%	94.05%	69.60%	19.69%
± 1 standard error	0.38%	0.87%	1.46%	1.64%
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	15,320	**Registered US Implants	2,774
*Estimated Longevity	7.7 Years	**Estimated Longevity	7.7 Years
*Number of Advisories	None	**Number of Advisories (see pages 130-136)	Two



Population 1*

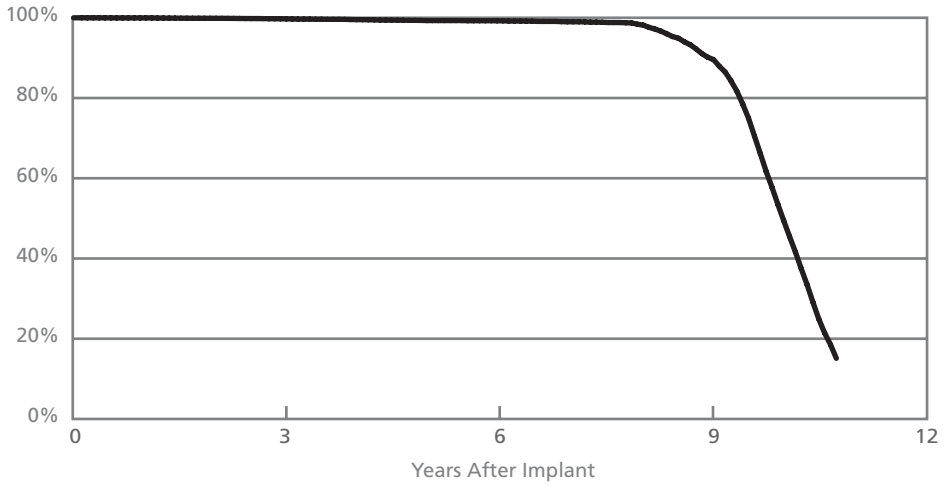
Year	2	4	6	8	at 113 months
Survival Probability	99.86%	99.48%	99.13%	69.80%	5.14%
± 1 standard error	0.06%	0.08%	0.12%	0.70%	0.47%
Sample Size	12400	8900	6200	3900	600

Population 2**

Year	2	4	6	at 91 months	
Survival Probability	99.74%	99.12%	86.45%	5.43%	
± 1 standard error	0.11%	0.19%	0.22%	1.80%	
Sample Size	2200	1500	1000	600	

Trilogy® SR (Model 2250)

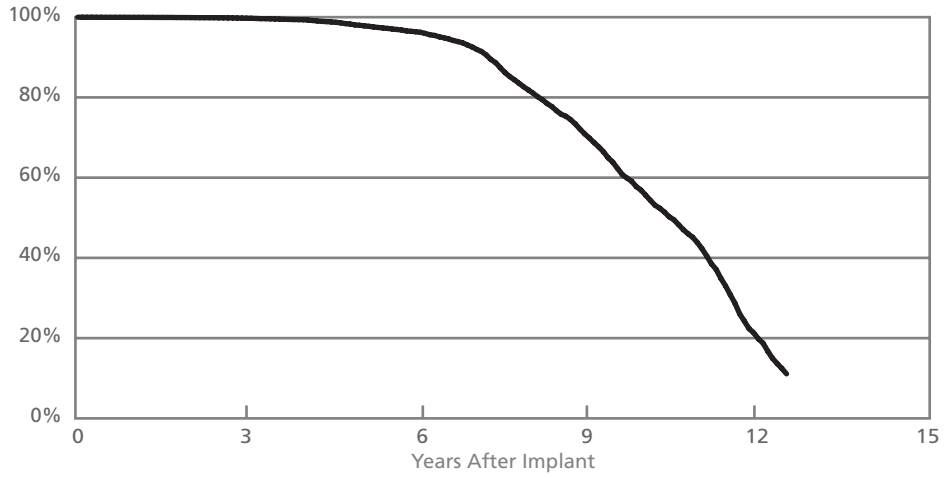
US Market Release	June 1995
Registered US Implants	12,450
Estimated Longevity	7.7 Years
Number of Advisories (see pages 130-136)	Two



Year	3	6	9	at 131 months
Survival Probability	99.74%	99.26%	91.08%	15.12%
± 1 standard error	0.05%	0.10%	0.52%	1.05%
Sample Size	8900	5200	2800	900

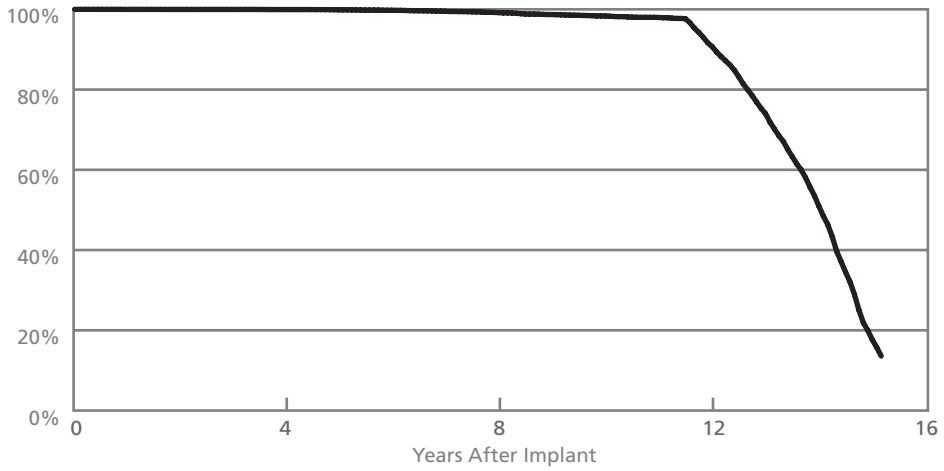
Solus® II (Models 2006 & 2007)

US Market Release	February 1993
Registered US Implants	32,286
Estimated Longevity	6.0 Years
Number of Advisories	None



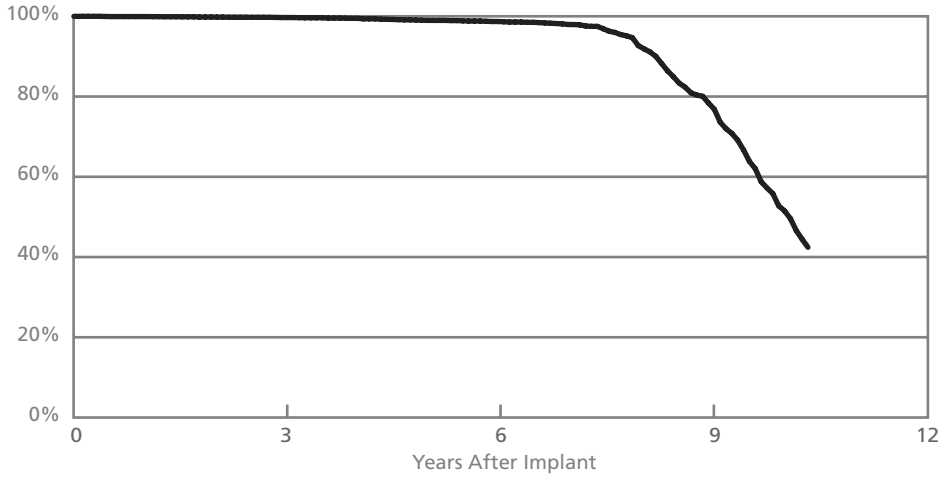
Year	3	6	9	12	at 152 months
Survival Probability	99.76%	96.47%	72.09%	22.38%	11.10%
± 1 standard error	0.03%	0.16%	0.67%	0.95%	0.76%
Sample Size	22900	13200	3200	900	400

Solus® (Models 2002 $ 2003)	
US Market Release	June 1990
Registered US Implants	23,852
Estimated Longevity	11.3 Years
Number of Advisories	None



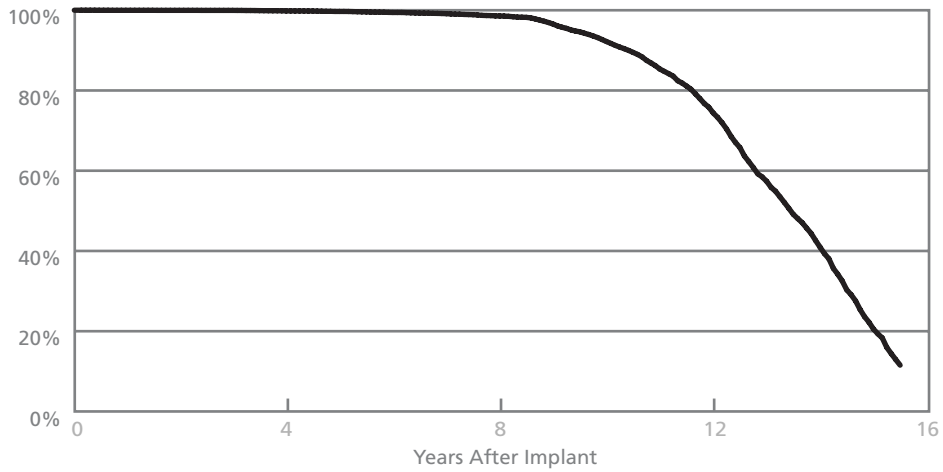
Year	4	8	12	at 182 months
Survival Probability	99.94%	99.18%	90.72%	13.59%
± 1 standard error	0.02%	0.09%	0.51%	0.95%
Sample Size	15500	8300	3000	200

Phoenix® III (Models 2204 & 2205)	
US Market Release	October 1994
Registered US Implants	6,744
Estimated Longevity	6.3 Years
Number of Advisories	None



Year	3	6	9	at 126 months
Survival Probability	99.69%	98.70%	80.06%	42.43%
± 1 standard error	0.08%	0.23%	1.38%	2.10%
Sample Size	4100	1600	500	300

Phoenix® II (Models 2005, 2008 & 2009)	
US Market Release	July 1990
Registered US Implants	26,746
Estimated Longevity	8.3 Years
Number of Advisories	None



Year	4	8	12	at 186 months
Survival Probability	99.83%	98.57%	74.38%	11.54%
± 1 standard error	0.03%	0.14%	0.79%	0.81%
Sample Size	14600	6600	2300	300

Summary Information

Pulse Generators Single-Chamber

ST. JUDE MEDICAL

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
5610	Victory SR	Dec-05	2975	2921	0	0	0	0	0	0
5180	Identity ADx SR	May-03	15171	12483	0	3	0	0	3	2
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	May-03	8360	7005	0	2	0	0	2	0
5172	Identity SR	Nov-01	20684	13764	1	11	0	0	12	40
5160	Integrity ADx SR	May-03	2745	2214	0	0	0	0	0	0
5136	Integrity µ SR	Dec-00	11929	5663	0	4	0	0	4	309
5142	Integrity SR	Apr-00	10468	5269	1	3	0	0	4	1
5130/5131	Affinity SR	Jan-99/Jun-99	28634	11754	4	31	17	0	52	45

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
5610	Victory SR	Dec-05	2975	2921	0	0	0	0	0
5180	Identity ADx SR	May-03	15171	12483	0	3	0	0	3
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	May-03	8360	7005	0	2	0	0	2
5172	Identity SR	Nov-01	20684	13764	1	11	0	0	12
5160	Integrity ADx SR	May-03	2745	2214	0	0	0	0	0
5136	Integrity µ SR	Dec-00	11929	5663	0	4	0	0	4
5142	Integrity SR	Apr-00	10468	5269	1	3	0	0	4
5130/5131	Affinity SR	Jan-99/Jun-99	28634	11754	4	31	17	0	52

**Based on returned product analysis as of December 31, 2006.*

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
5610	Victory SR	100% (11mo)							
5180	Identity ADx SR	99.97%	99.95%	99.86%					
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	99.99%	99.99%	99.93%					
5172	Identity SR	99.97%	99.88%	99.78%	99.41%				
5160	Integrity ADx SR	100.00%	100.00%						
5136	Integrity µ SR	99.42%	99.01%	98.45%	97.68%	94.28%			
5142	Integrity SR	99.98%	99.94%	99.94%	99.94%	99.91%	99.91%		
5130/5131	Affinity SR	99.90%	99.85%	99.82%	99.73%	99.69%	99.51%	99.14%	

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
5610	Victory SR	100% (11mo)							
5180	Identity ADx SR	99.99%	99.97%	99.88%					
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	99.99%	99.99%	99.93%					
5172	Identity SR	99.98%	99.94%	99.92%	99.79%				
5160	Integrity ADx SR	100.00%	100.00%						
5136	Integrity µ SR	99.99%	99.99%	99.98%	99.96%	99.82%			
5142	Integrity SR	99.98%	99.94%	99.94%	99.94%	99.94%	99.94%		
5130/5131	Affinity SR	99.91%	99.85%	99.83%	99.79%	99.77%	99.74%	99.72%	

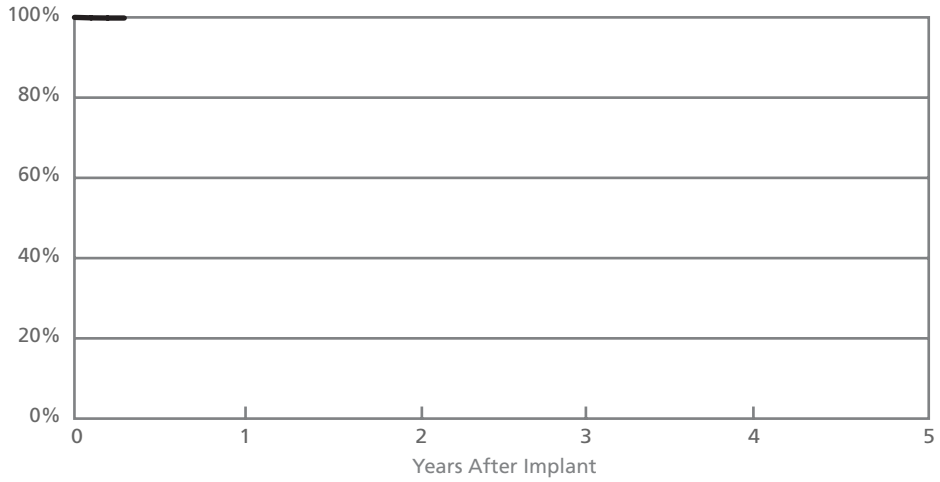
**Based on returned product analysis as of December 31, 2006.*

Pacing Leads

Bipolar & Unipolar
Active & Passive Fixation

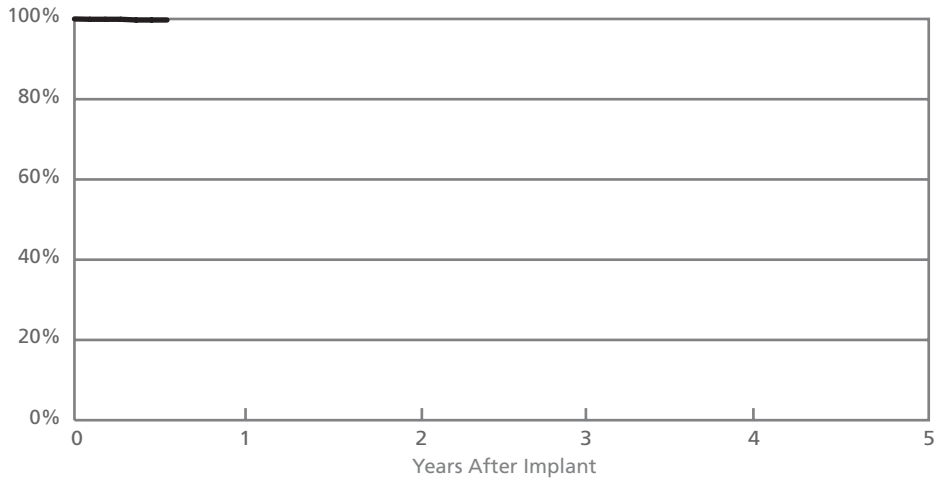
ST. JUDE MEDICAL

Tendril® (Model 1788T)	Laboratory Analysis: Implant Damage 38	Electrical Malfunction 0	Other 4
US Market Release	February 2006	Type and/or Fixation	Active
Registered US Implants	7,693	Polarity	Bipolar
Estimated Active US Implants	7,595	Steroid	Yes
		Number of Advisories	None



Year	at 4 months				
Survival Probability	99.84%				
± 1 standard error	0.07%				
Sample Size	3900				

Tendril® (Model 1782T)	Laboratory Analysis: Implant Damage 27	Electrical Malfunction 0	Other 0
US Market Release	February 2006	Type and/or Fixation	Active
Registered US Implants	1,735	Polarity	Bipolar
Estimated Active US Implants	1,705	Steroid	Yes
		Number of Advisories	None

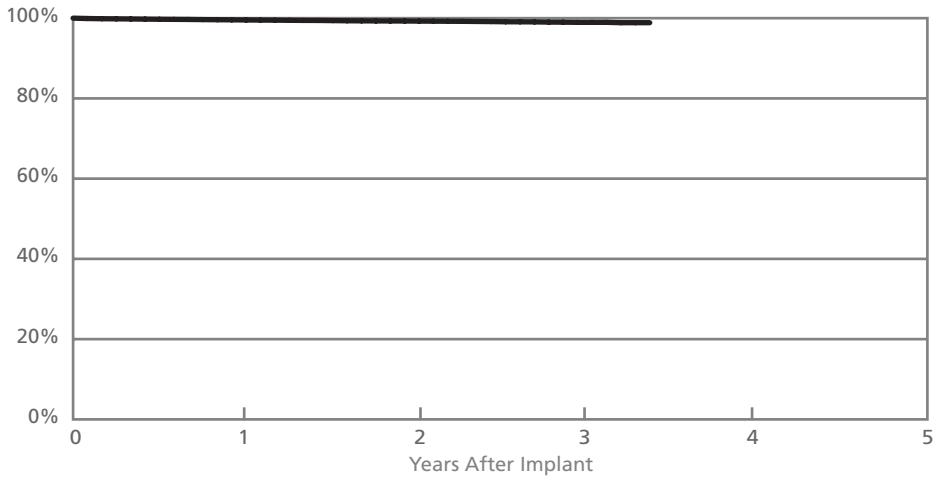


Year	at 7 months				
Survival Probability	99.74%				
± 1 standard error	0.20%				
Sample Size	900				

Tendril® SDX (Model 1688T)

Laboratory Analysis: Implant Damage 365 Electrical Malfunction 51 Other 76

US Market Release	June 2003	Type and/or Fixation	Active
Registered US Implants	196,536	Polarity	Bipolar
Estimated Active US Implants	176,195	Steroid	Yes
		Number of Advisories	None

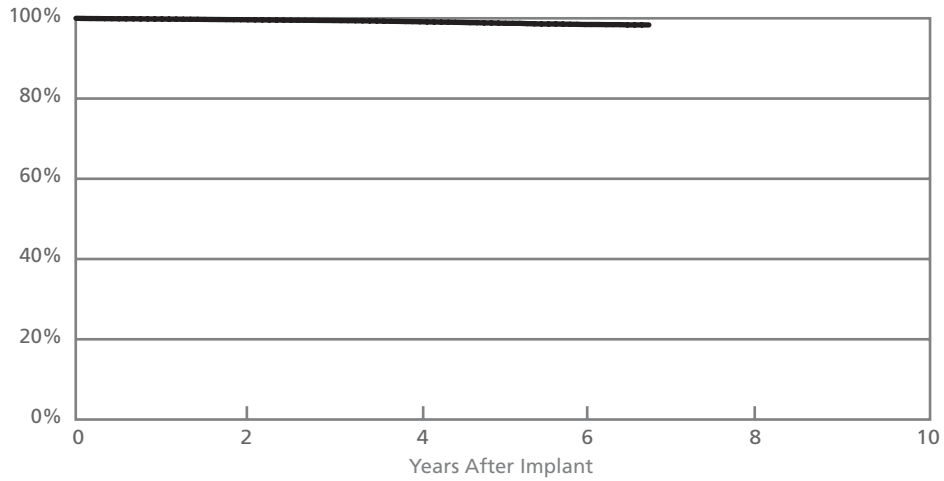


Year	1	2	3	at 41 months	
Survival Probability	99.58%	99.29%	98.96%	98.87%	
± 1 standard error	0.02%	0.03%	0.05%	0.09%	
Sample Size	157600	76000	23900	2600	

Tendril® SDX (Model 1488T & 1488TC)

Laboratory Analysis: Implant Damage 777 Electrical Malfunction 158 Other 147

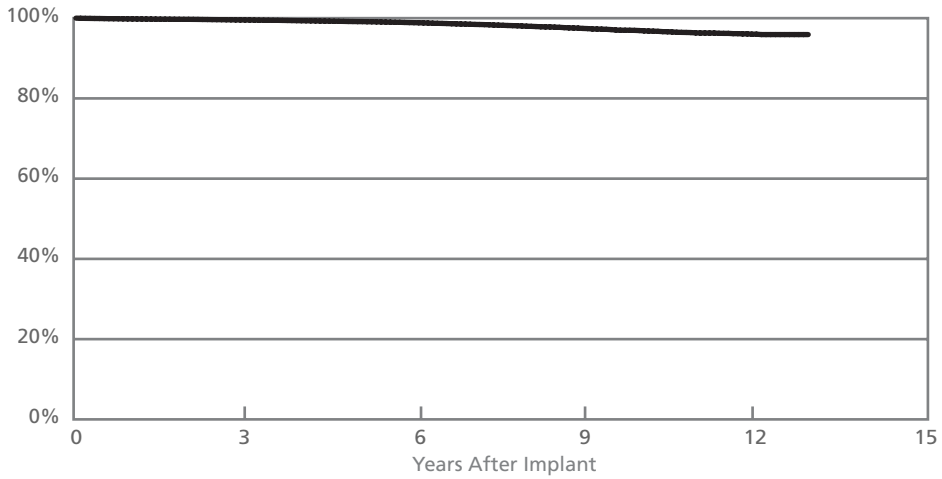
US Market Release	March 2000	Type and/or Fixation	Active
Registered US Implants	261,639	Polarity	Bipolar
Estimated Active US Implants	184,844	Steroid	Yes
		Number of Advisories	None



Year	2	4	6	at 81 months	
Survival Probability	99.65%	99.17%	98.45%	98.35%	
± 1 standard error	0.01%	0.02%	0.05%	0.08%	
Sample Size	205900	16330	23900	5000	

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

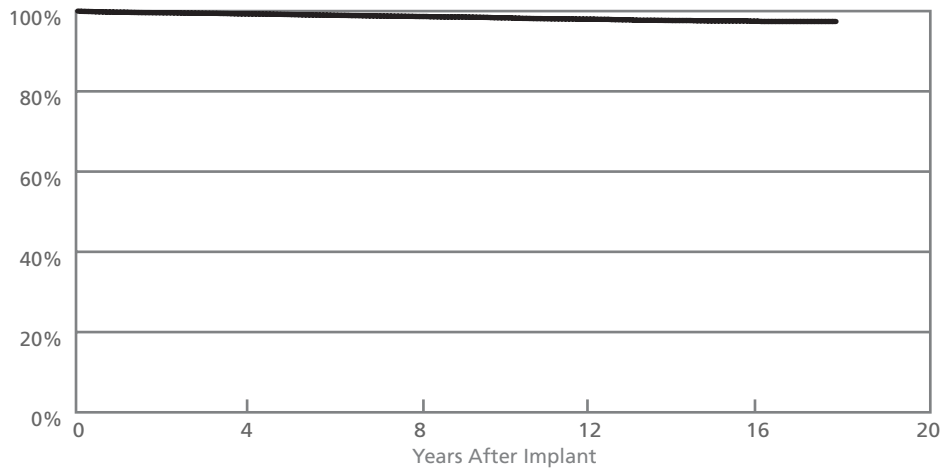
US Market Release	(1148) June 1993; (1188T) June 1994; (1388T) June 1997	Type and/or Fixation	Active
		Polarity	Bipolar
Registered US Implants	308,356	Steroid	(1148/1188) No; (1388) Yes
Estimated Active US Implants	156,445	Number of Advisories	None



Year	3	6	9	12	at 157 months
Survival Probability	99.56%	98.90%	97.52%	96.08%	95.91%
± 1 standard error	0.01%	0.02%	0.06%	0.13%	0.16%
Sample Size	220900	123300	35200	5300	100

Fast-Pass® (Models 1018 & 1028T)

US Market Release (1018T) February 1988; (1028T) July 1990		Type and/or Fixation	Active
Registered US Implants	28,024	Polarity	Bipolar
Estimated Active US Implants	5,694	Steroid	No
		Number of Advisories	None

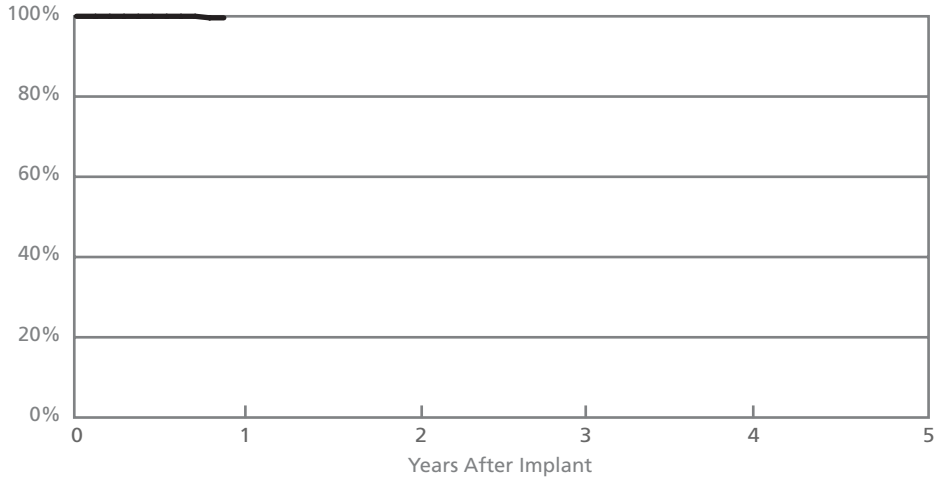


Year	4	8	12	16	at 214 months
Survival Probability	99.31%	98.66%	97.99%	97.49%	97.41%
± 1 standard error	0.05%	0.08%	0.12%	0.16%	0.18%
Sample Size	20500	13700	8400	1900	100

IsoFlex® P (Models 1644T & 1648T)

Laboratory Analysis: Implant Damage 1 Electrical Malfunction 0 Other 0

US Market Release	April 2005	Type and/or Fixation	Passive
Registered US Implants	1,020	Polarity	Bipolar
Estimated Active US Implants	243	Steroid	Yes
		Number of Advisories	None

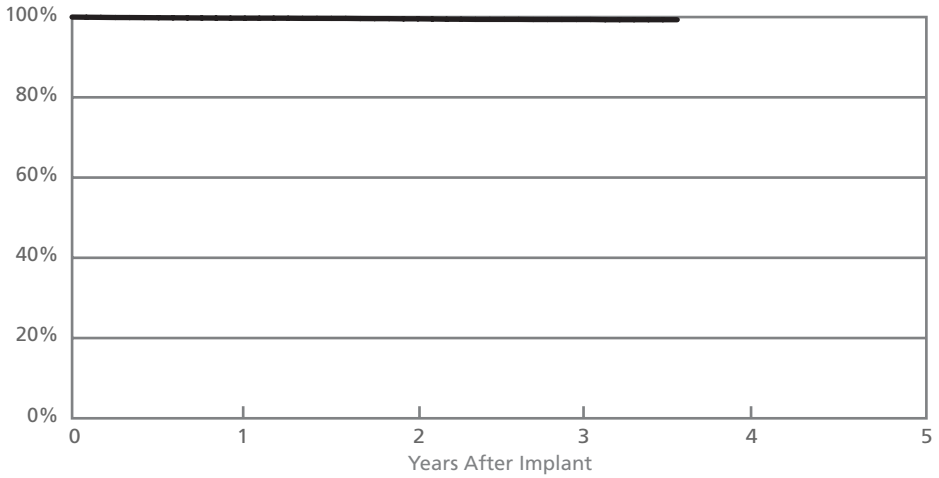


Year	at 11 months				
Survival Probability	99.62%				
± 1 standard error	0.38%				
Sample Size	500				

IsoFlex® S (Models 1642T & 1646T)

Laboratory Analysis: Implant Damage 90 Electrical Malfunction 9 Other 20

US Market Release	April 2003	Type and/or Fixation	Passive
Registered US Implants	54,029	Polarity	Bipolar
Estimated Active US Implants	46,425	Steroid	Yes
		Number of Advisories	None

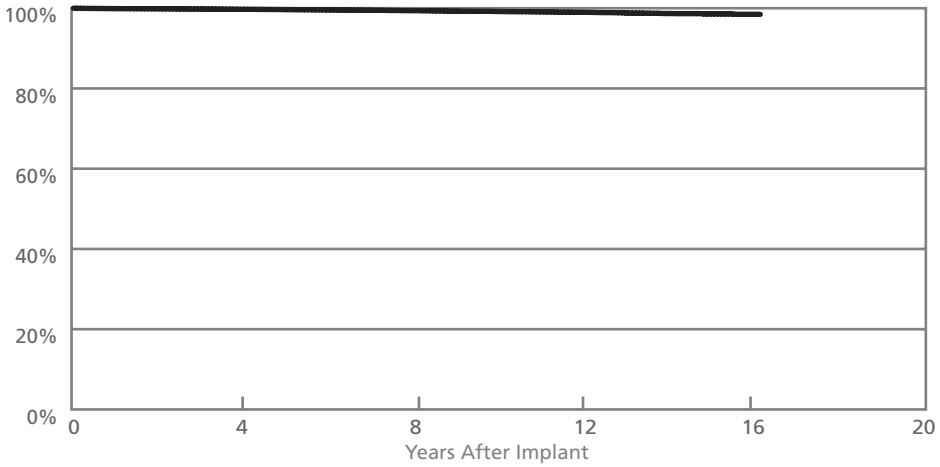


Year	1	2	3	at 43 months	
Survival Probability	99.73%	99.56%	99.39%	99.34%	
± 1 standard error	0.02%	0.03%	0.05%	0.07%	
Sample Size	45100	24900	10400	2200	

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

US Market Release	(1336T) August 1999; (1342T, 1346T) January 1998; (1136T, 1142T, 1146T) June 1994; (1222T, 1226T, 1236T, 1242T, 1246T) April 1990	Type and/or Fixation	Passive
		Polarity	Bipolar
Registered US Implants	368,122	Steroid	(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T, 1246T) No; (1336T, 1342T, 1346T) Yes
Estimated Active US Implants	155,225	Number of Advisories	None

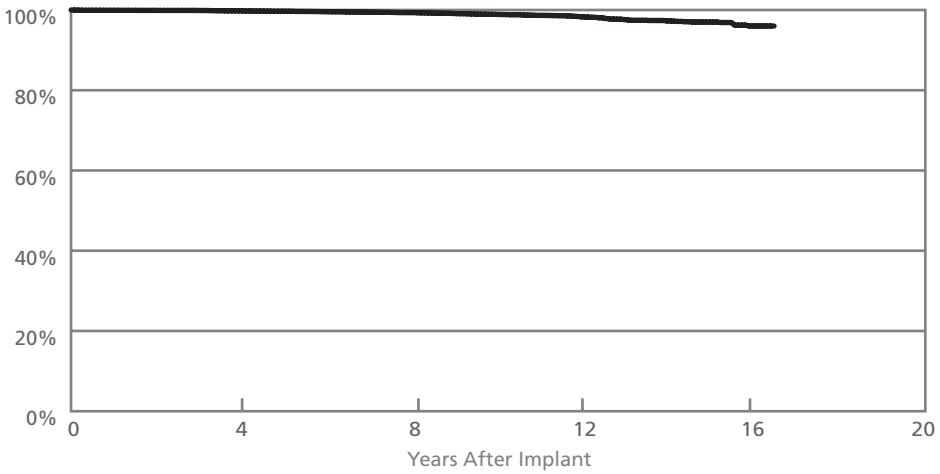
(1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T & 1246T) are no longer being manufactured.



Year	4	8	12	16	at 194 months
Survival Probability	99.73%	99.40%	98.99%	98.47%	98.47%
± 1 standard error	0.01%	0.02%	0.04%	0.14%	0.14%
Sample Size	23800	94500	22100	1100	300

Permathane® Ace (Models 1036T & 1038T)

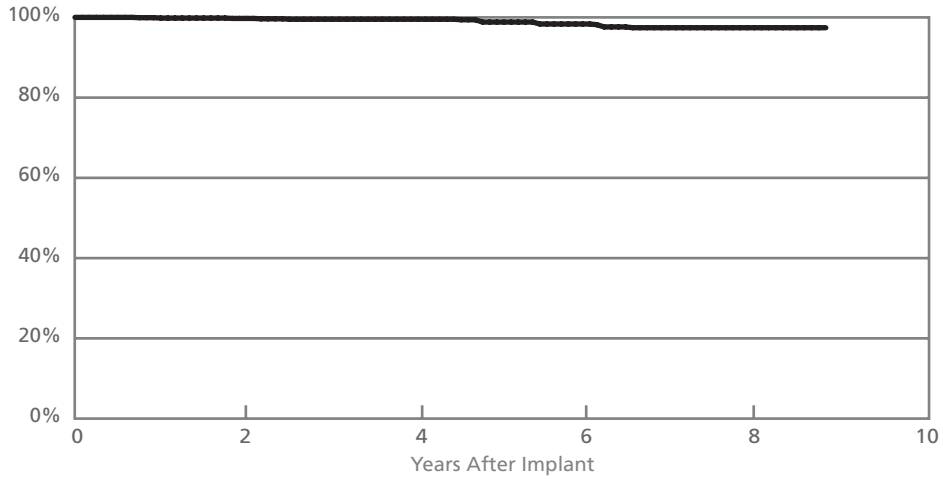
US Market Release	June 1989	Type and/or Fixation	Passive
Registered US Implants	19,707	Polarity	Bipolar
Estimated Active US Implants	3,834	Steroid	No
		Number of Advisories	None



Year	4	8	12	16	at 198 months
Survival Probability	99.78%	99.35%	98.29%	96.01%	96.01%
± 1 standard error	0.04%	0.08%	0.15%	0.49%	0.49%
Sample Size	13900	8700	4800	700	600

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

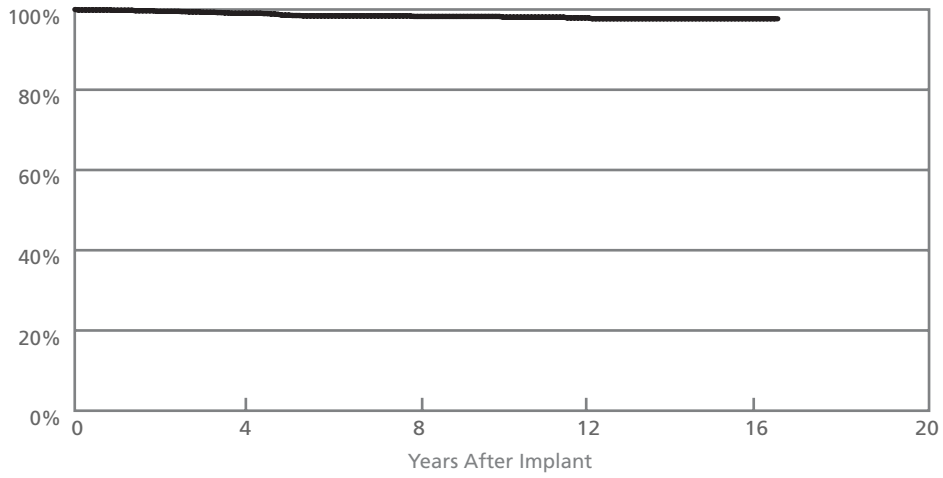
US Market Release (1188K) June 1995; (1388K) June 1997		Type and/or Fixation	Active
Registered US Implants	1,338	Polarity	Unipolar
Estimated Active US Implants	518	Steroid	(1188K) No; (1388K) Yes
		Number of Advisories	None



Year	2	4	6	8	at 106 months
Survival Probability	99.74%	99.54%	98.35%	97.42%	97.42%
± 1 standard error	0.15%	0.21%	0.47%	0.62%	0.62%
Sample Size	1200	900	600	400	200

Fast-Pass® (Model 1007)

US Market Release	June 1987	Type and/or Fixation	Active
Registered US Implants	1,736	Polarity	Unipolar
Estimated Active US Implants	281	Steroid	No
		Number of Advisories	None

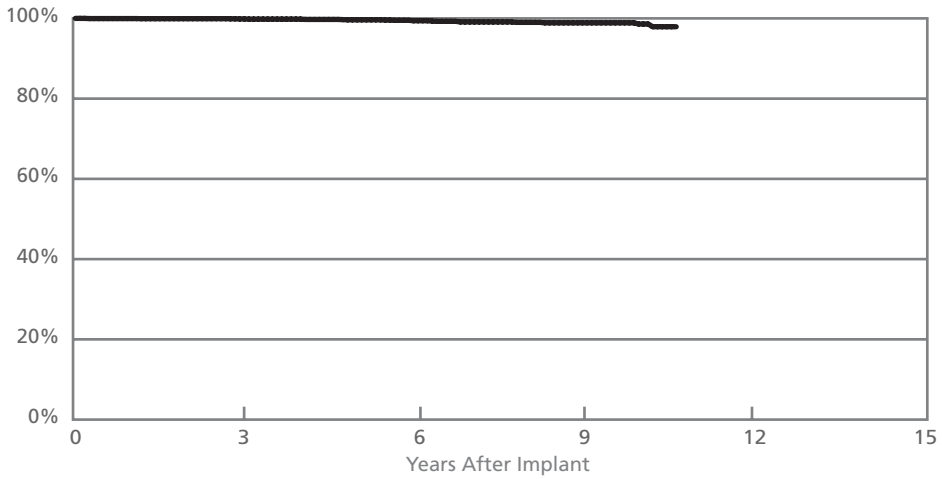


Year	4	8	12	16	at 198 months
Survival Probability	99.07%	98.27%	97.90%	97.69%	97.69%
± 1 standard error	0.26%	0.36%	0.46%	0.51%	0.51%
Sample Size	1300	800	500	300	200

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	4,472		
Estimated Active US Implants	1,568	Number of Advisories	None

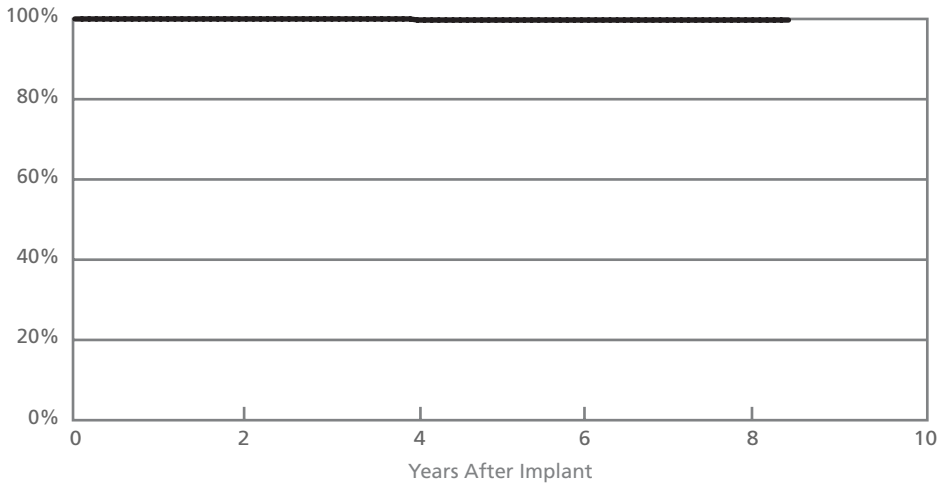
(1135K, 1143K, 1145K, 1235K, 1243K & 1245K) are no longer being manufactured.



Year	3	6	9	at 129 months	
Survival Probability	99.86%	99.53%	98.89%	97.92%	
± 1 standard error	0.06%	0.14%	0.27%	0.62%	
Sample Size	3300	1900	800	300	

Permathane® Ace (Model 1035)

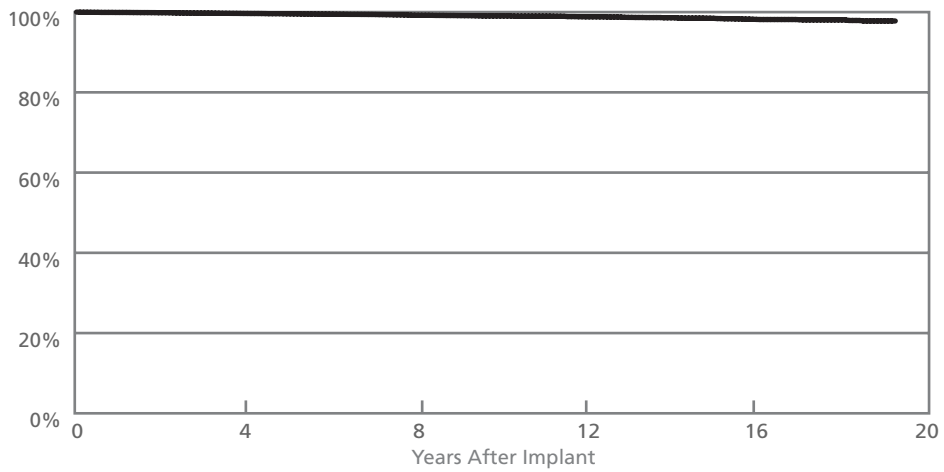
US Market Release	March 1987	Type and/or Fixation	Passive
Registered US Implants	655	Polarity	Unipolar
Estimated Active US Implants	85	Steroid	No
		Number of Advisories	None



Year	2	4	6	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

Ace® (Models 1015M & 1025M)

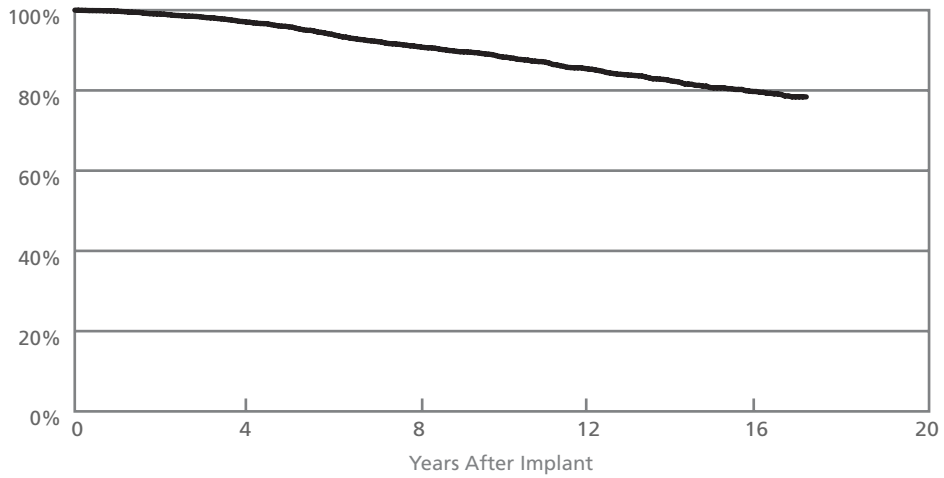
US Market Release (1025M) Aug. 1982; (1015M) Aug. 1991		Type and/or Fixation	Passive
Registered US Implants	23,483	Polarity	Unipolar
Estimated Active US Implants	3,749	Steroid	No
		Number of Advisories	None



Year	4	8	12	16	at 231 months
Survival Probability	99.66%	99.22%	98.83%	98.18%	97.79%
± 1 standard error	0.04%	0.07%	0.11%	0.16%	0.24%
Sample Size	16400	10300	6500	3500	200

ACE® (Model 1026T)

US Market Release	October 1987	Type and/or Fixation	Passive
Registered US Implants	6,516	Polarity	Unipolar
Estimated Active US Implants	744	Steroid	No
		Number of Advisories	None



Year	4	8	12	16	at 206 months
Survival Probability	97.17%	91.07%	85.45%	79.73%	78.39%
± 1 standard error	0.23%	0.46%	0.67%	0.91%	1.00%
Sample Size	4800	2800	1600	900	100

Laboratory Analysis*

Models	US Market Release Date	Registered US Implants	Estimated Active US Implants	Implant Damage	Electrical Malfunctions	Other
1788T	February 06	7693	7595	38	0	4
1782T	February 06	1735	1705	27	0	0
1688T	June 03	196536	176195	365	51	76
1488T/TC	March 00	261639	184844	777	158	147
1644T/1648T	April 05	1020	243	1	0	0
1642T/1646T	April 03	54029	46425	90	9	20

Laboratory analysis of all returned leads from the U.S. is summarized by model for the most recently market released pacing lead models included in this Product Performance Report. The Laboratory analysis results are categorized into one of the following three categories:

- Implant Damage - Obvious damage incurred at the time of implant, including but not limited to insulation cuts and damage, helix overtorque, and stylet perforation.
- Electrical Failure - A disruption in the insulation or conductors resulting in compromised electrical performance.
- Other - Includes other sources of malfunction not attributed to damage incurred at implant and not resulting in compromised electrical failures. This category also includes any partial leads returned with an alleged malfunction even if it was not possible to perform analysis to confirm the malfunction.

**Based on returned product analysis as of December 31, 2006.*

Advisories & Safety Alerts

ST. JUDE MEDICAL

Advisories & Safety Alerts

The following table summarizes recalls, Advisories and safety alerts regarding St. Jude Medical devices. These Advisories have been previously communicated to physicians. 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
CPS Direct™ SL (Models 410110, 410111, 410112, 410113, 410114, 410115, 410116, 410120, 410121, 410122, 410123, 410124, 410125, 410126). Of these models numbers only Sterile Lot Numbers beginning with S, CR or any C4 lot number starting with C4-05274 or higher are subject to this advisory.	03/20/07 Class II A number of the Cardiac Positioning System (CPS) Direct SL, slittable CRT lead delivery tools have been found to have a durability issue that results in separation of one of the marker bands during implant.	Of the estimated 12,000 Cardiac Positioning System CPS Direct SL, slittable CRT catheters used, St. Jude Medical has received 12 field reports that the CPS Direct SL catheters have experienced a separation at one of the proximal (light blue) marker bands when being manipulated during an implant procedure. There have been no reports of patient injuries or deaths attributed to the catheter separations and in every case the entire catheter was easily removed from the patient. This advisory is associated with product supplied by one particular component manufacturer. All of the referenced products were requested returned immediately to St. Jude Medical and SJM representatives will assist in the replacement of returned inventory with product that has been determined to be free of this potential issue.
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 (Dec. 31, 2006):** At the time of the advisory, there were 53 worldwide (50 U.S.) devices confirmed to have been affected by this issue. As of Dec. 31, 2006 there were an additional 36 worldwide (33 U.S.) devices confirmed with this issue, all prior to the distribution of the software fix.
CPS Direct™ SL (Models 410110 through 410126) CPS Aim™ (Models 410140 through 410148) CPS™ Implant Kit (Model 410190) CPS™ Slitter (Model 410191) CPS™ Valve Bypass Tool SL (Model 410192)	06/01/06 Class II A small percentage of the sterile packages containing the listed products did not meet St. Jude Medical's seal strength specifications.	It was discovered that some of the sterile pouches in which the above listed products are packaged may not have been properly sealed during their packaging process. This was the result of use by one of our outside vendors' equipment performing outside of its packaging specifications. This issue was not related to the CPS products themselves, but was only related to the sealing process used in packaging the products. All products of the above model numbers were requested returned immediately to St. Jude Medical for re-inspection. Returned inventory was replaced with products that has been inspected and determined to be free of this potential issue. A small green dot on the outer package label indicated that the package passed inspection. **Current Status (Dec. 31, 2006):** Product has been retrieved from the field for re-inspection and redistribution.

Model Identification	Advisory	Follow-up Recommendations at Time of Advisory
Photon DR (V-230HV) (certain serial numbers), Photon Micro VR/DR (Models V-194/V-232), Atlas VR/DR (Models V-199/V-240)	10/7/05 Class II A particular vendor-supplied memory chip can be affected at a low frequency rate by background levels of atmospheric ionizing cosmic radiation ("background cosmic radiation"). The anomaly can trigger a temporary loss of pacing function and permanent loss of defibrillation support.	In the unlikely event that a device chip is affected by background cosmic radiation, the high current drain condition will deplete the battery voltage rapidly. This can result in loss of output for a period up to approximately 48 hours. During this period, the patient would be without pacing or defibrillation therapy. After this initial period, the battery will reach a voltage level at which the device will enter its "Hardware Reset Mode." This safety mode is designed to preserve the device's ability to provide VVI pacing support. A device that has been reset to the Hardware Reset Mode will operate in the VVI mode at 60 ppm, but will not be capable of providing tachycardia detection or therapy. This will be noted by a warning message on the programmer screen upon device interrogation. To assist in your patient care and following discussions with our independent Medical Advisory Board, St. Jude Medical recommends: • If it is not already your current practice, physicians should perform routine device monitoring every three months for patients with the affected models listed above. • In determining whether additional patient management or follow up may be needed, consider the low failure rate for the anomaly and the unique medical needs and situation of each individual patient, including whether the patient is pacemaker dependent or at high risk for life-threatening arrhythmias. • If a patient's device is found in the Hardware Reset Mode, you should arrange for device replacement as soon as possible. • You should continue to provide patients with the usual admonitions to keep scheduled appointments and to report all changes in symptoms. **Current Status (Dec. 31, 2006):** 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, 2006 there were an additional 32 worldwide (24 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 (Dec. 31, 2006):** 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
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 (Dec. 31, 2006):** 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 (Dec. 31, 2006):** 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.

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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Ordering No. **F0067** Printed in USA 04071.5