Product Performance Report

Cardiac Rhythm Management

April 2006

ST. JUDE MEDICAL

Letter from St. Jude Medical

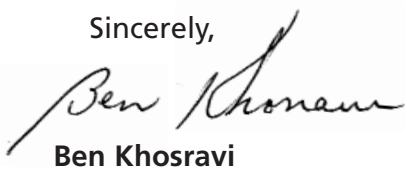
APRIL 2006

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 Uniform CRM Product Performance Reporting." 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 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
Quality, Leads Development and Operations

Table of Contents

Introduction and Overview

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 January 31, 2006, including:

- A graph of survival probability that reflects all device malfunctions known to us (including normal battery depletion, malfunction with compromised therapy, and malfunction without compromised therapy);
- A graph of survival probability that excludes normal battery depletion in the analysis; and
- A table that accompanies each graph and summarizes the data in it.

Additional tables that aggregate and summarize the data in the report can be found on pages 14 (CRT ICDs), 32 (ICDs) and 68 (Pulse Generators).

For ICDs prior to Photon Micro, pacemakers prior to Affinity and all pacing and defibrillation leads, you will find analysis of the data collected through January 31, 2006, consistent with previous product performance reports.

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.

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.

Here is 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 hardware 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.

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.

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.

Let us know

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.

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

We have used the following definitions in preparing this report. AdvaMed Proposal definitions were used where applicable, denoted by *.

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.

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.

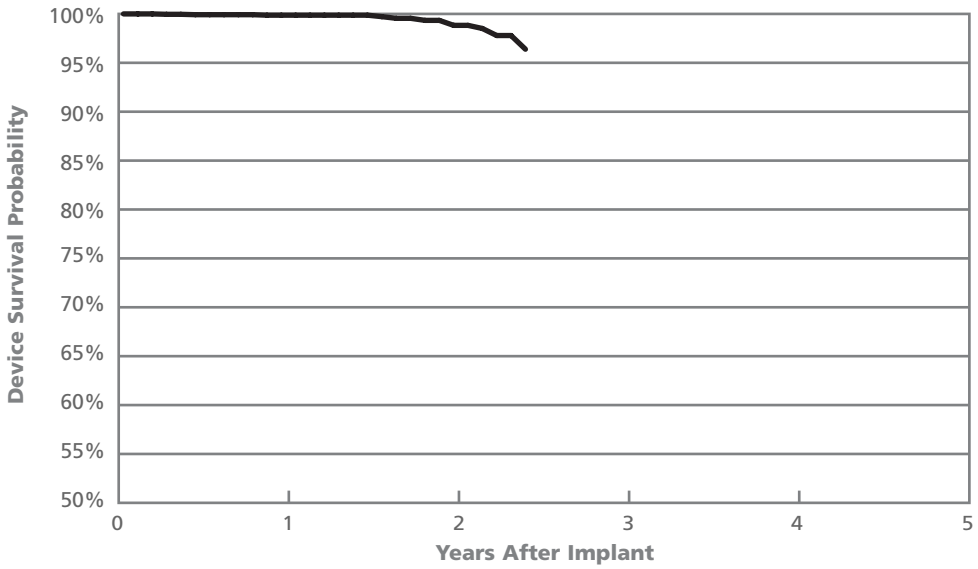
Changes in device setting that occur as intended by the design (for example, reversion to a designed Safe Mode or Power-On Reset [POR]) that do not result in loss of critical patient protective therapies but are the reported reasons for explant shall be categorized as a Malfunction without Compromised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

Normal Battery Depletion - The condition where a returned device:

- Reached its elective replacement indicator voltage;
- Tested within electrical specifications, and
- Had an implant duration exceeding 80% of its projected longevity.

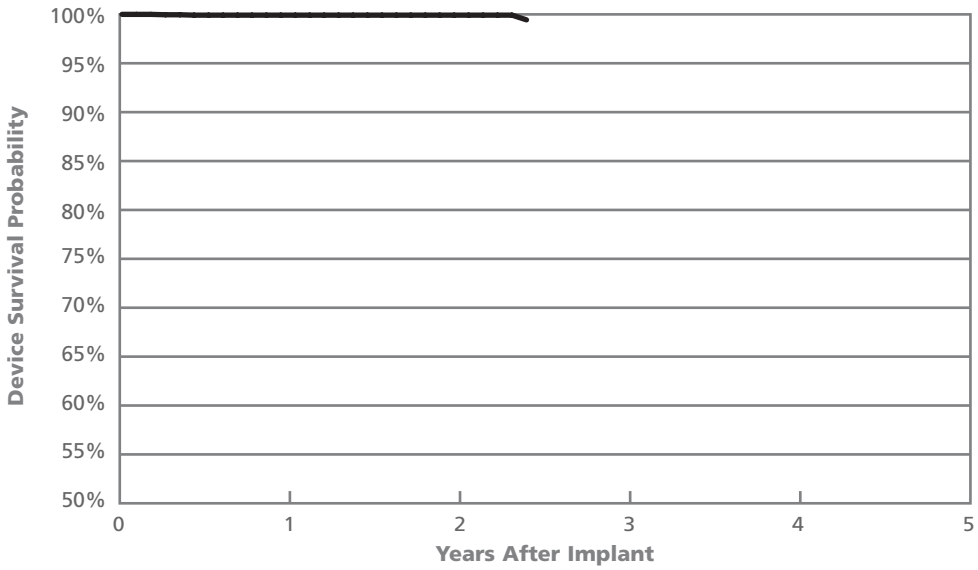
*AdvaMed Proposal - Requirements for Uniform Reporting of Clinical Performance of Pulse Generators.

Epic™ HF
(Model V-338)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.87%	98.83%			
± 1 standard error	0.05%	0.32%			

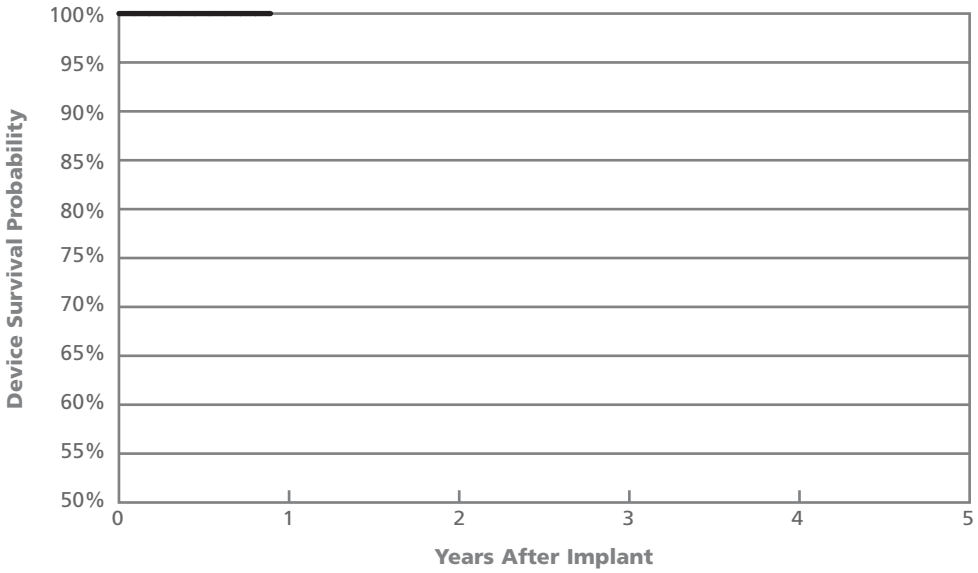
Epic™ HF
(Model V-338)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.92%	99.92%			
± 1 standard error	0.05%	0.05%			

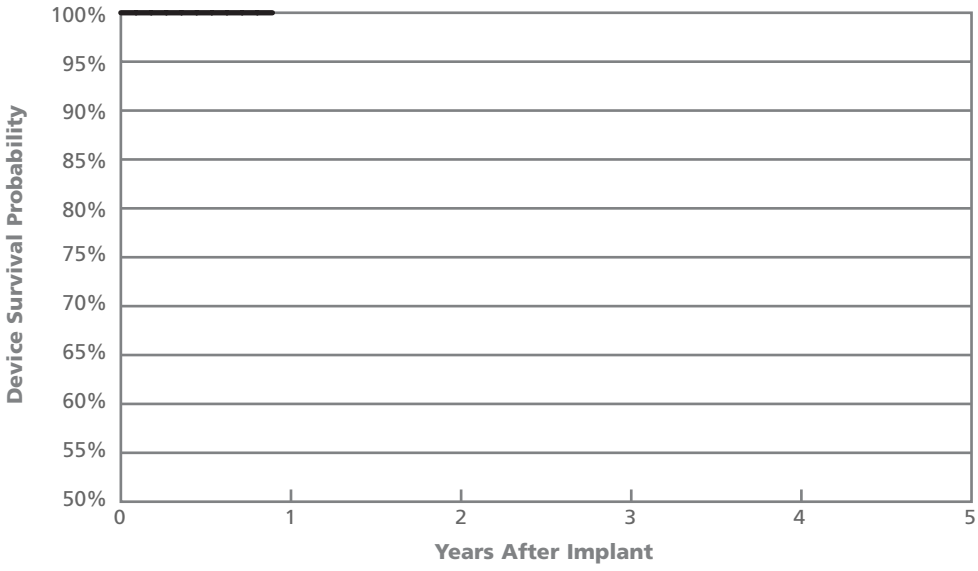
The Epic™ HF cardiac resynchronization therapy defibrillator was approved for use in June 2004.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,122 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™ HF
(Model V-337)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability*					
± 1 standard error					

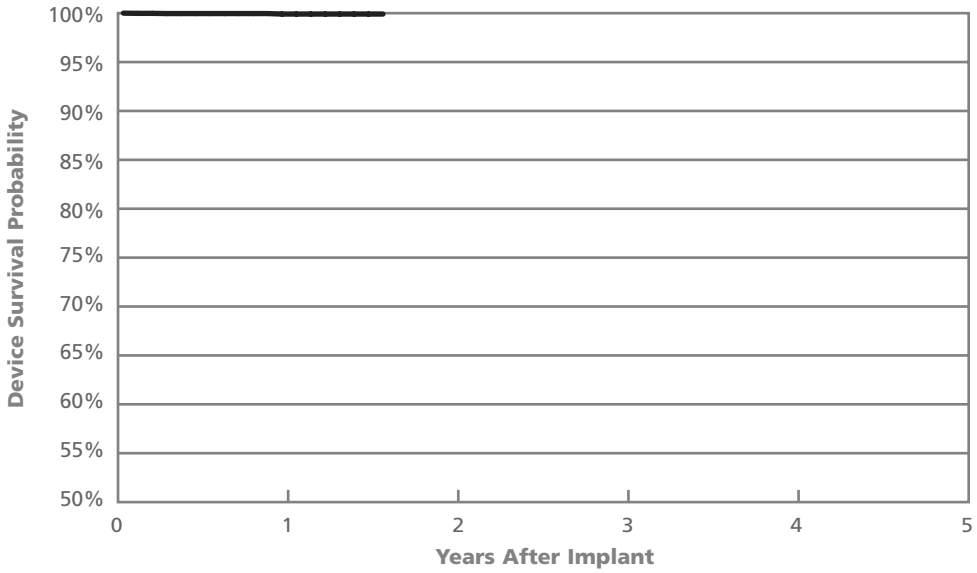
Epic™ HF
(Model V-337)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability*					
± 1 standard error					

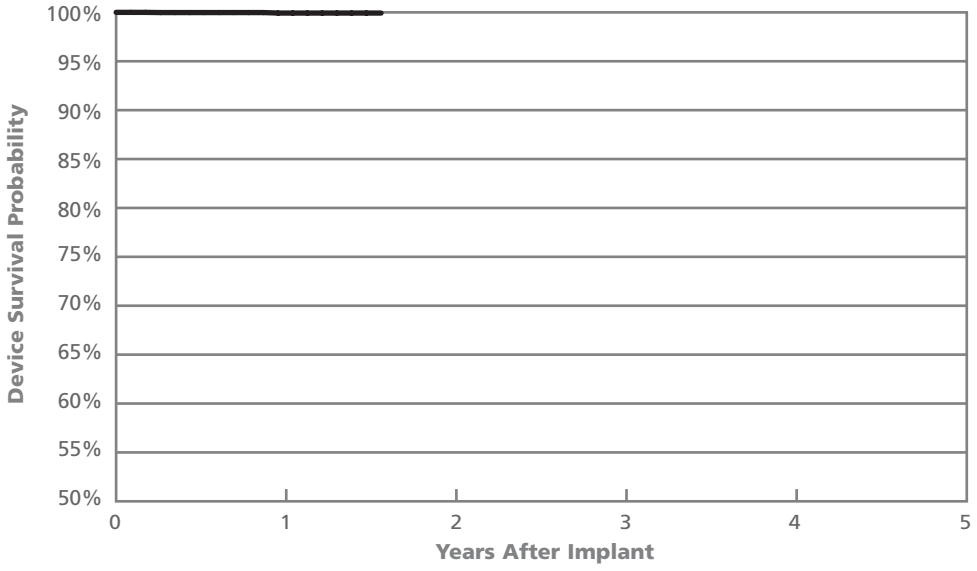
The Epic™ HF cardiac resynchronization therapy defibrillator was approved for use in November 2004.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
1,806 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)
**No survival probability is stated at 1 year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data.*

Atlas®+ HF
(Model V-340)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.91%				
± 1 standard error	0.03%				

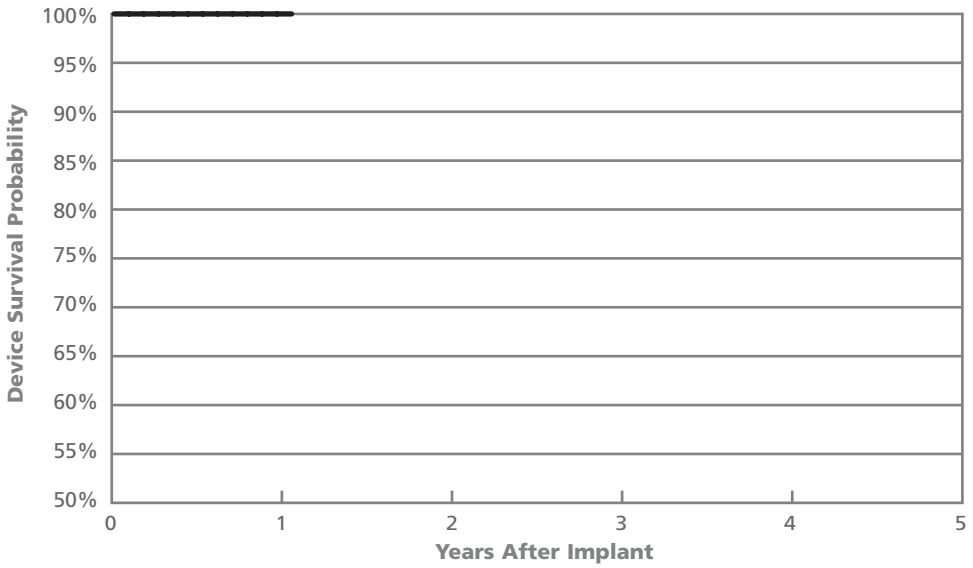
Atlas®+ HF
(Model V-340)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%				
± 1 standard error	0.02%				

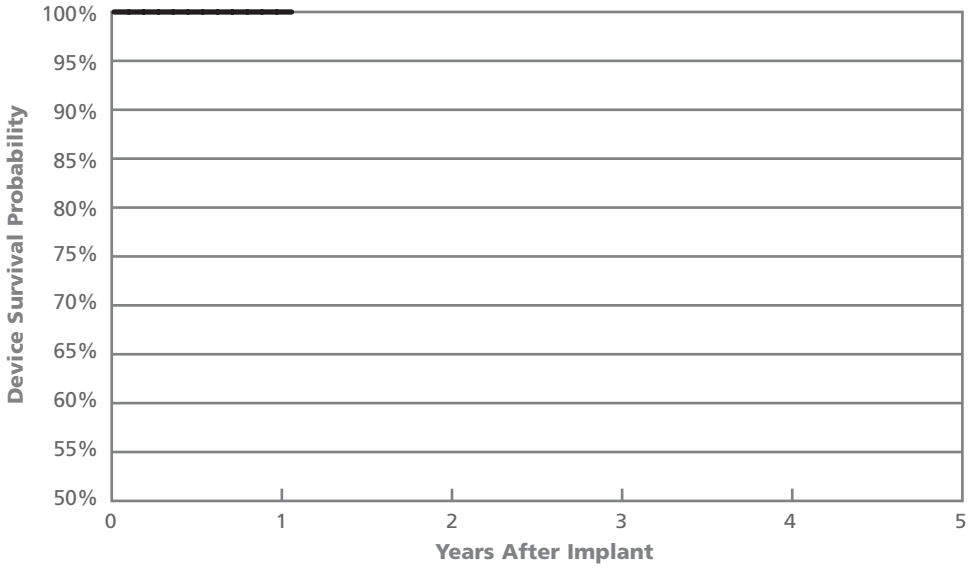
The Atlas®+ HF cardiac resynchronization therapy defibrillator was approved for use in June 2004.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
4,912 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Atlas®+ HF
(Model V-343)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

Atlas®+ HF
(Model V-343)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

The Atlas®+ HF cardiac resynchronization therapy defibrillator was approved for use in November 2004.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
6,107 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Cardiac Resynchronization Therapy *CRT ICDs* Summary Information*

Including Normal Battery Depletion

Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy	Malfunctions w/o Compromised Therapy	Total Malfunctions	Normal Battery Depletion	Survival Probability			
									1 year	2 years	3 years	4 years
V-338	Epic HF	Jun-04	3122	2701	1	2	3	14	99.87%	98.83%		
V-337**	Epic HF	Nov-04	1806	1712	0	0	0	0				
V-340	Atlas + HF	Jun-04	4912	4481	2	0	2	1	99.91%			
V-343	Atlas + HF	Nov-04	6107	5920	0	0	0	0	100%			

Excluding Normal Battery Depletion

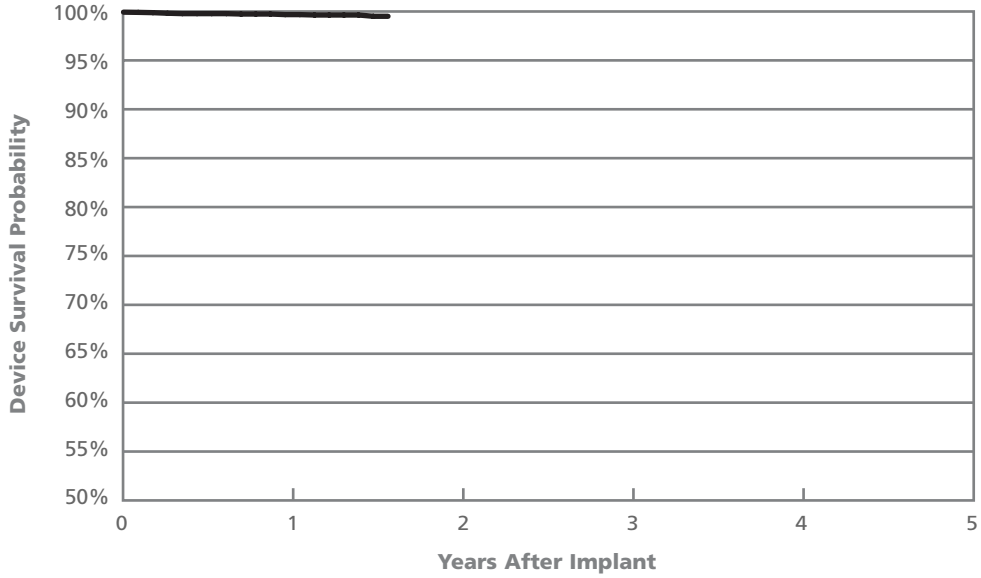
Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy	Malfunctions w/o Compromised Therapy	Total Malfunctions	Survival Probability			
								1 year	2 years	3 years	4 years
V-338	Epic HF	Jun-04	3122	2701	1	2	3	99.92%	99.92%		
V-337**	Epic HF	Nov-04	1806	1712	0	0	0				
V-340	Atlas + HF	Jun-04	4912	4481	2	0	2	99.93%			
V-343	Atlas + HF	Nov-04	6107	5920	0	0	0	100%			

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

***No survival probability is stated at 1 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.*

QuickSite® (Model 1056K)

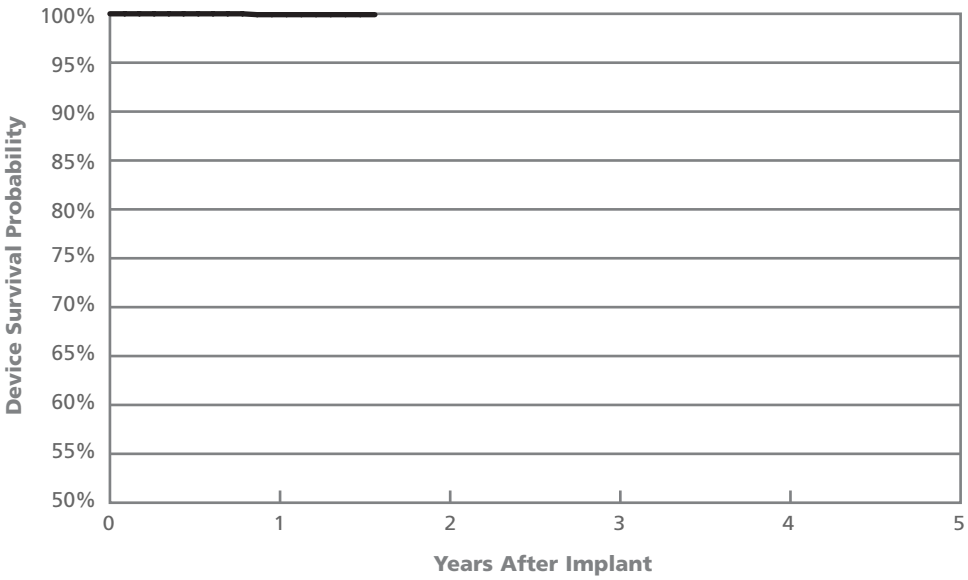
Unipolar Polyurethane/Silicone Left Heart Lead



Year	1	2	3	4	5
Survival Probability	99.68%				
± 1 standard error	0.07%				

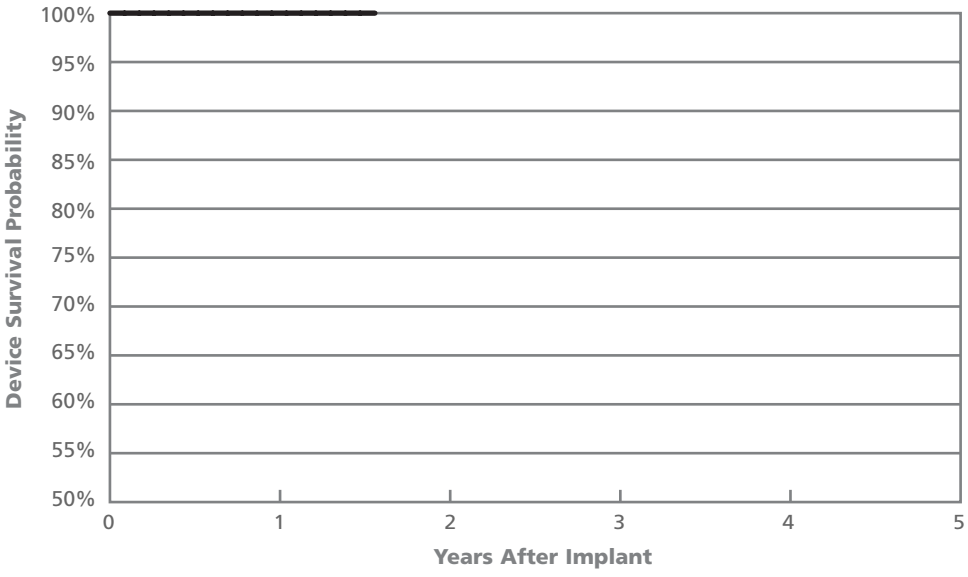
Data is current as of January 31, 2006
3,696 of these leads have been implanted.
(Approval date: June 2004)

Atlas® DR
(Model V-242)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.91%				
± 1 standard error	0.10%				

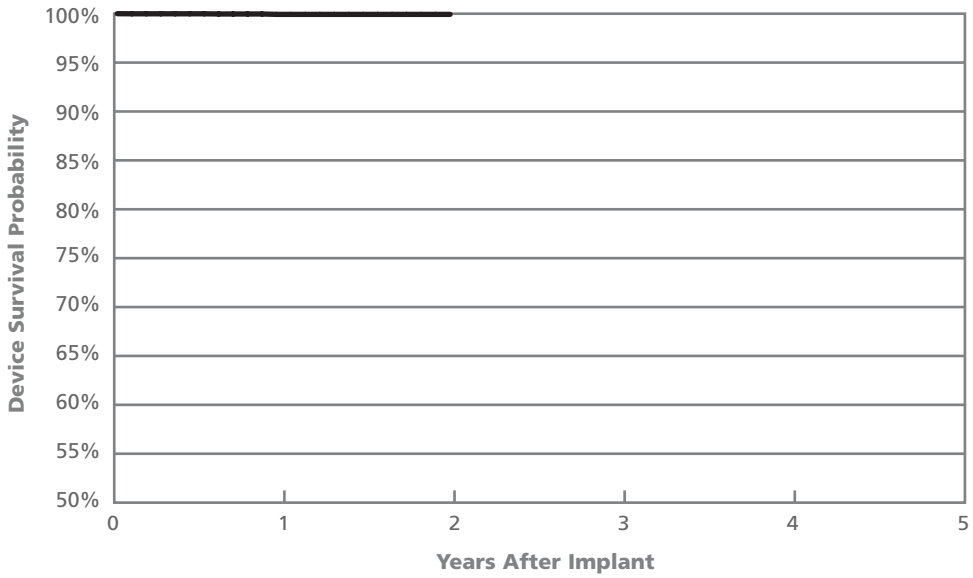
Atlas® DR
(Model V-242)
Excluding Normal Battery Depletion



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

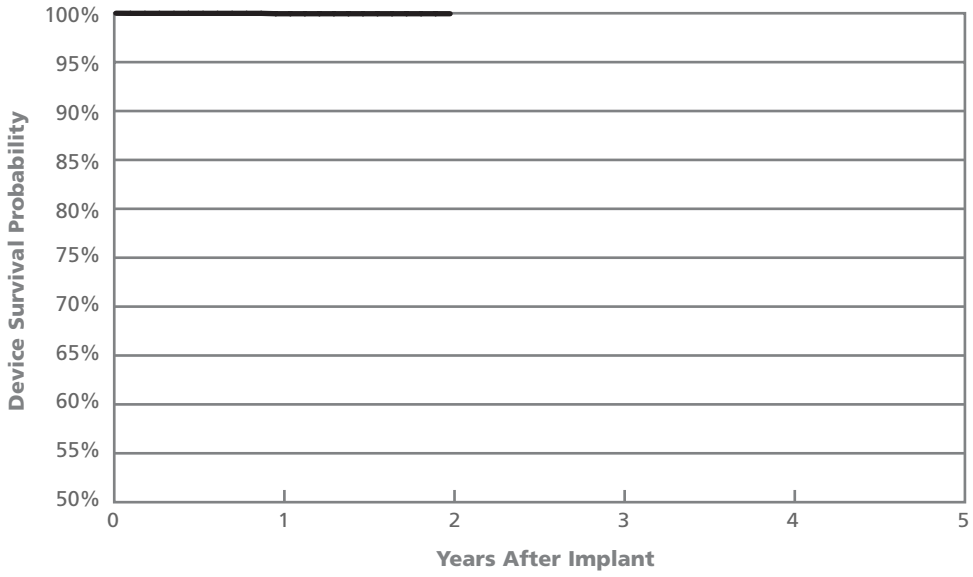
The Atlas®+ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,910 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Atlas®+ DR
(Model V-243)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.93%			
± 1 standard error	0.04%	0.04%			

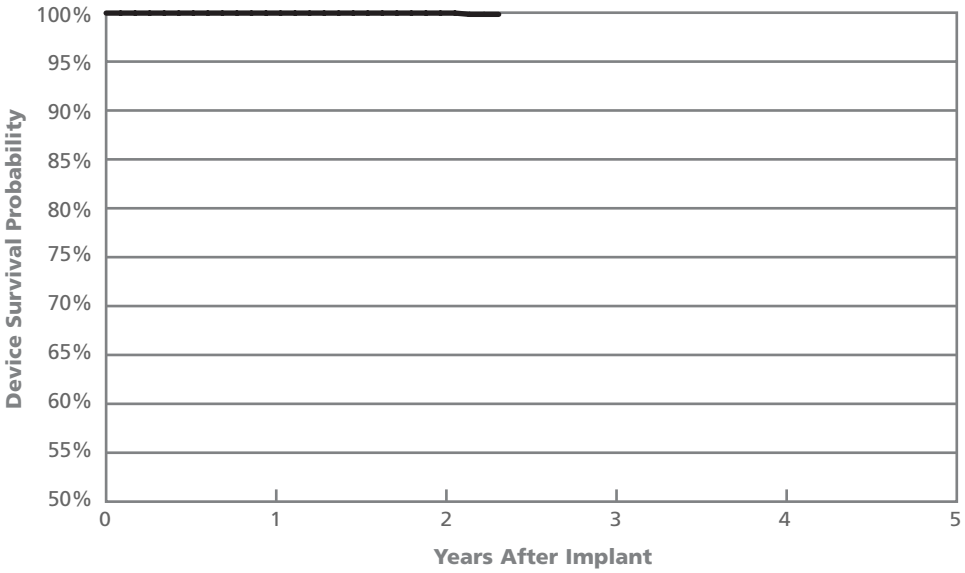
Atlas®+ DR
(Model V-243)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.95%			
± 1 standard error	0.01%	0.04%			

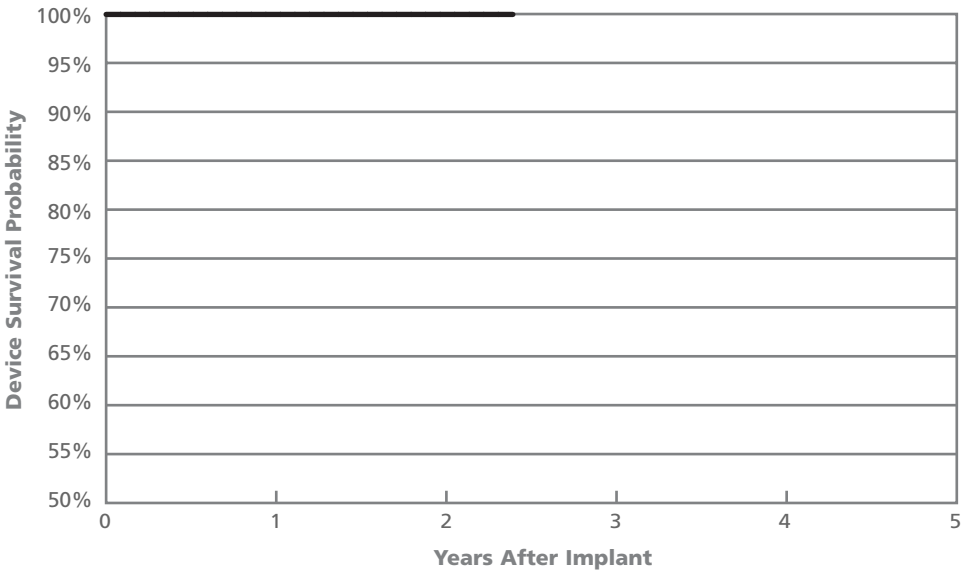
The Atlas®+ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
9,866 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™+ DR
(Model V-236)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.96%	99.83%			
± 1 standard error	0.04%	0.04%			

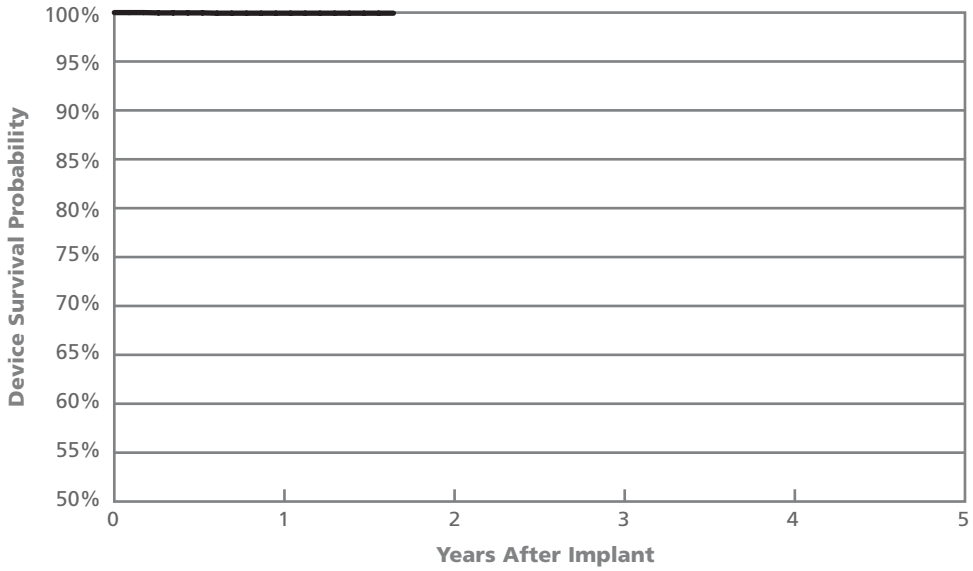
Epic™+ DR
(Model V-236)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.96%	99.96%			
± 1 standard error	0.04%	0.04%			

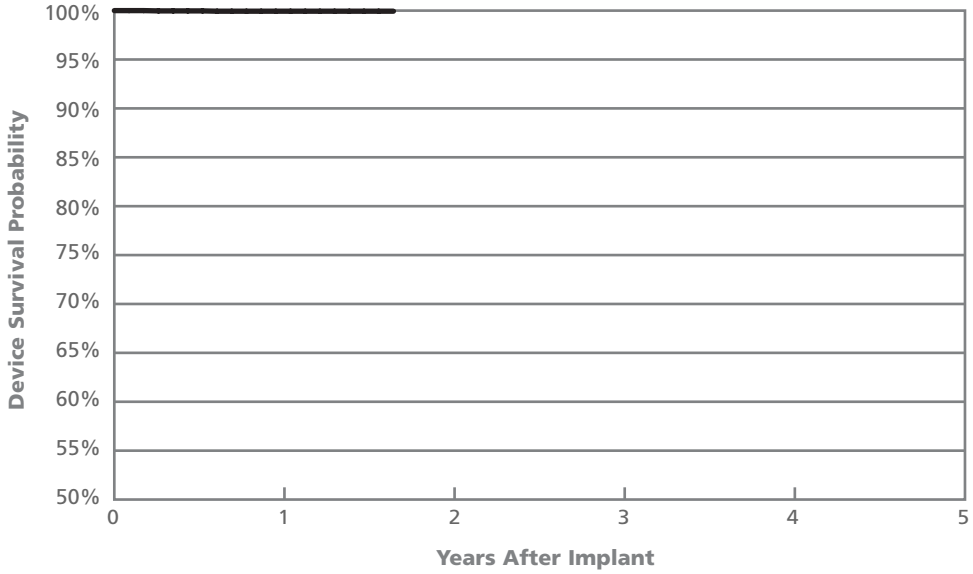
The Epic™+ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in April 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,393 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™+ DR
(Model V-239)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.94%				
± 1 standard error	0.05%				

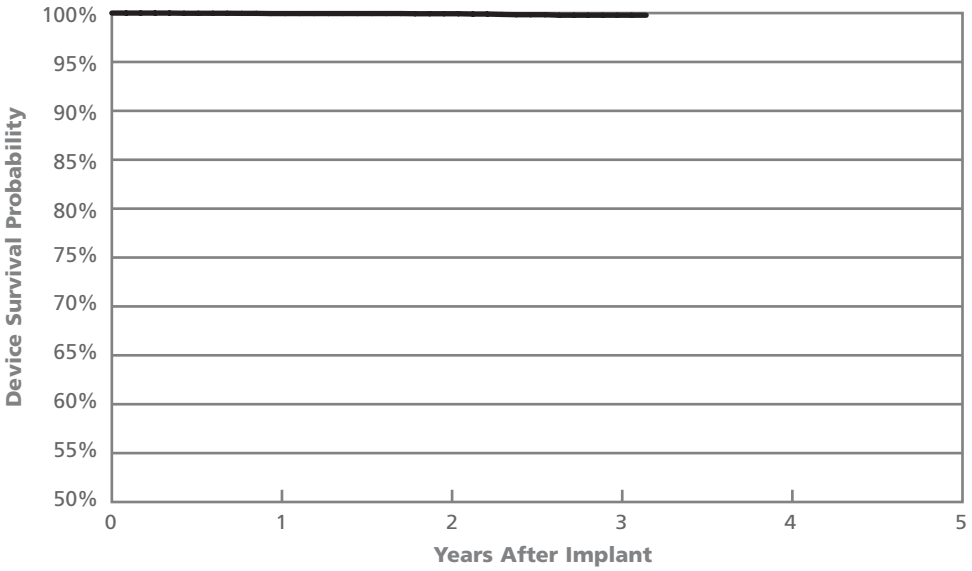
Epic™+ DR
(Model V-239)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.94%				
± 1 standard error	0.05%				

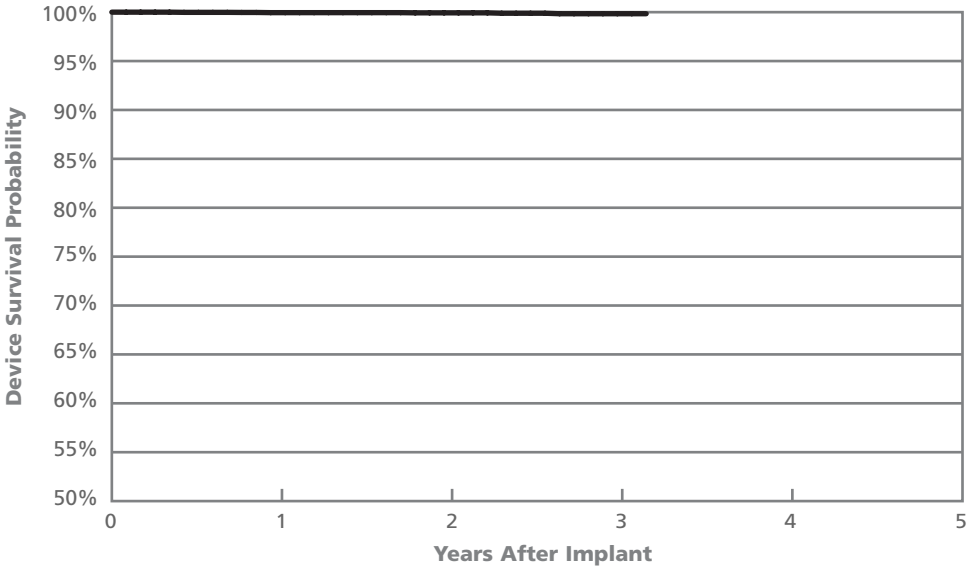
The Epic™+ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
4,922 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™ DR
(Model V-235)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.93%	99.78%		
± 1 standard error	0.02%	0.04%	0.09%		

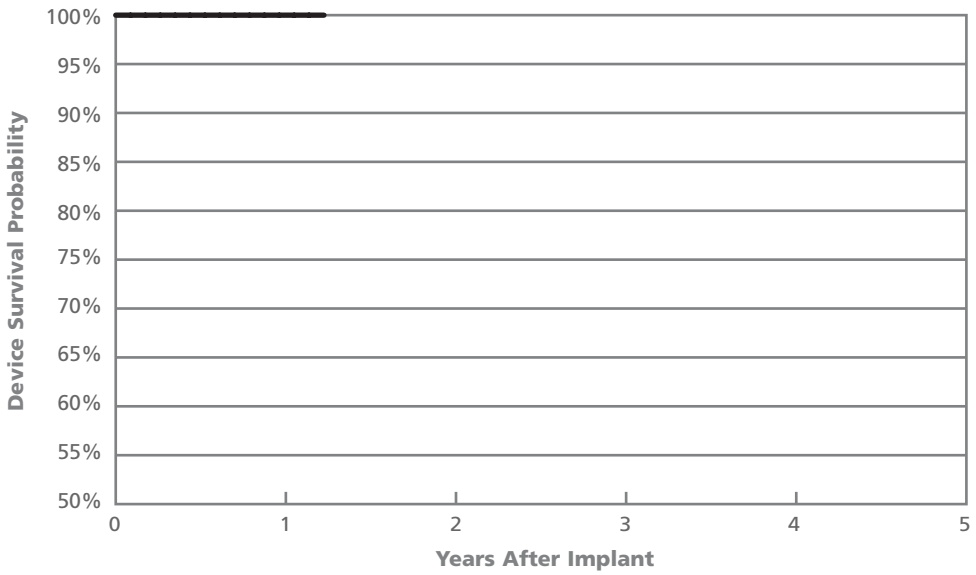
Epic™ DR
(Model V-235)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.97%	99.93%	99.84%		
± 1 standard error	0.02%	0.04%	0.07%		

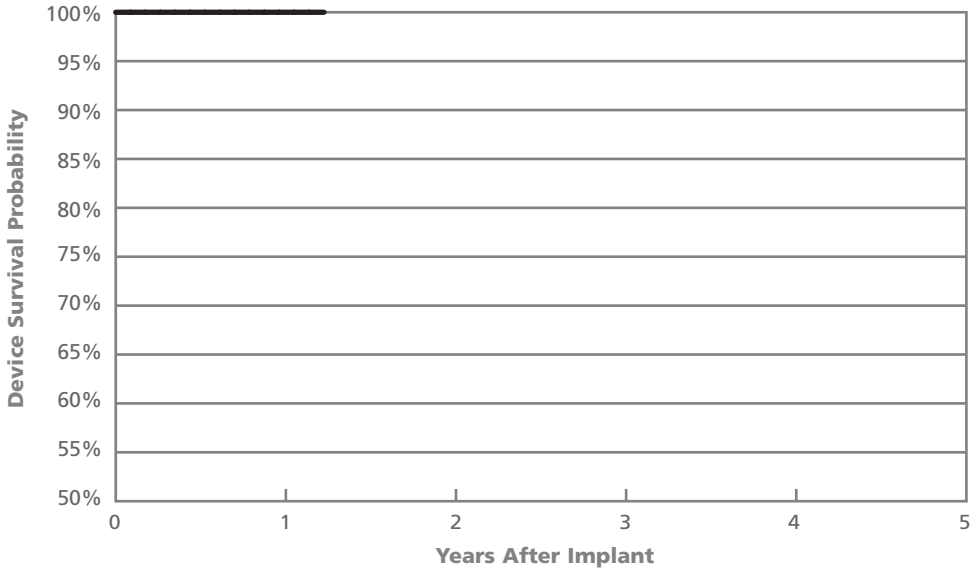
The Epic™ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in July 2002.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
6,723 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™ DR
(Model V-233)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

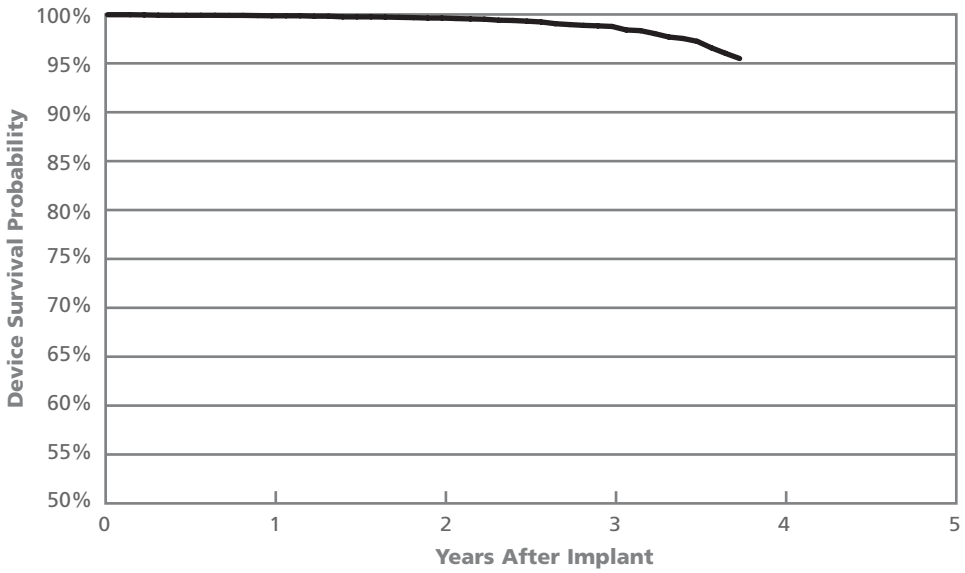
Epic™ DR
(Model V-233)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

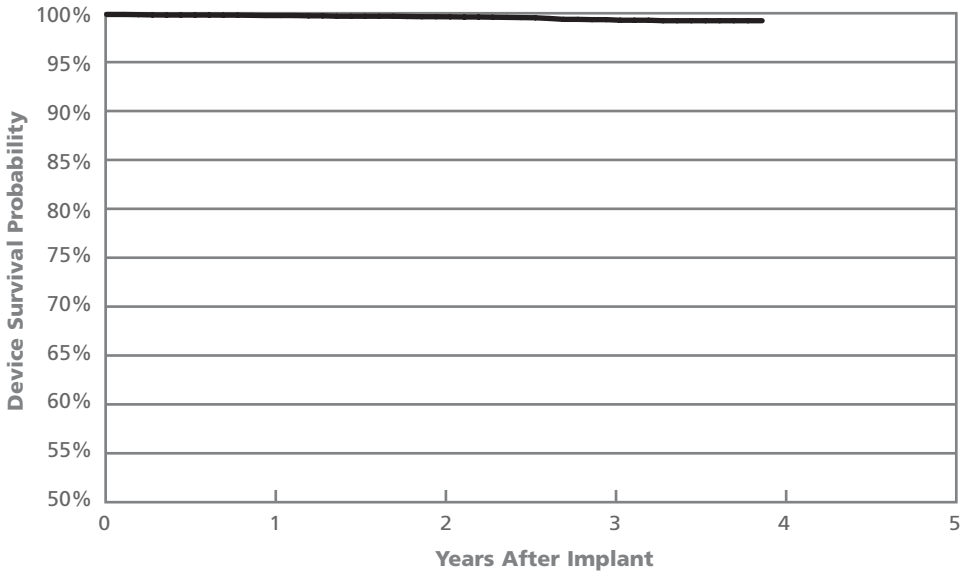
The Epic™ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
1,344 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Atlas® DR
(Model V-240)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.88%	99.65%	98.79%		
± 1 standard error	0.03%	0.07%	0.15%		

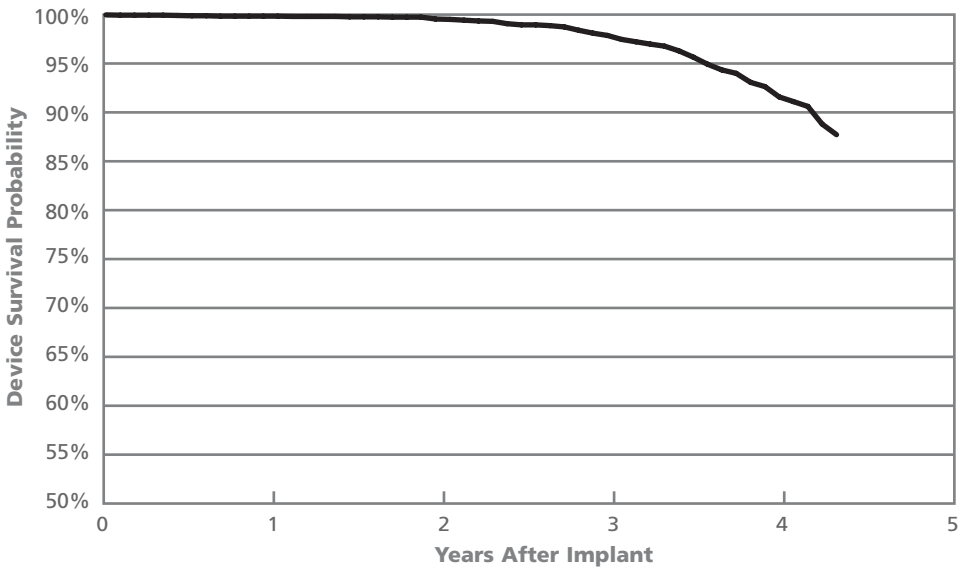
Atlas® DR
(Model V-240)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.88%	99.76%	99.46%		
± 1 standard error	0.03%	0.06%	0.10%		

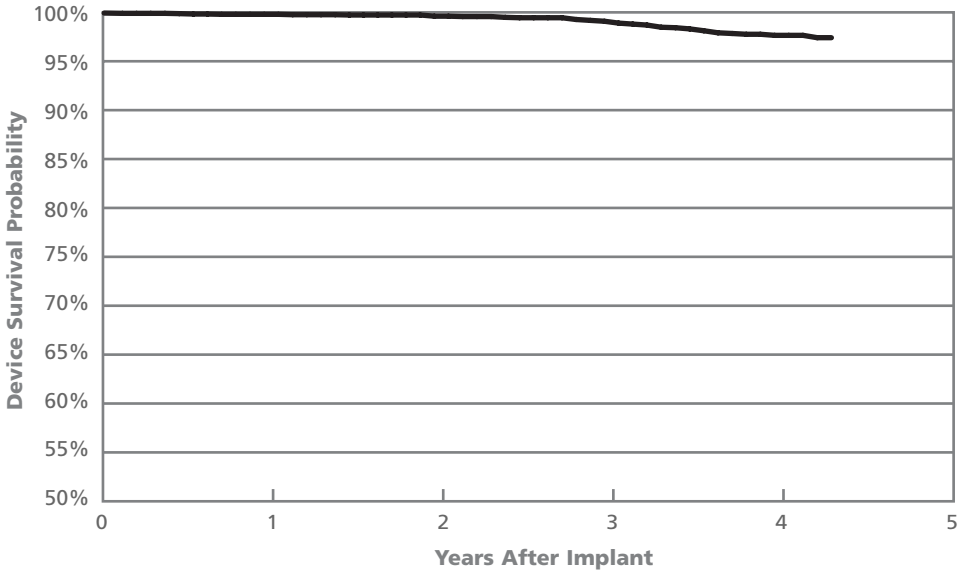
The Atlas® DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in December 2001.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
8,898 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Photon® µ DR
(Model V-232)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.84%	99.55%	97.87%	91.58%	
± 1 standard error	0.07%	0.09%	0.27%	0.62%	

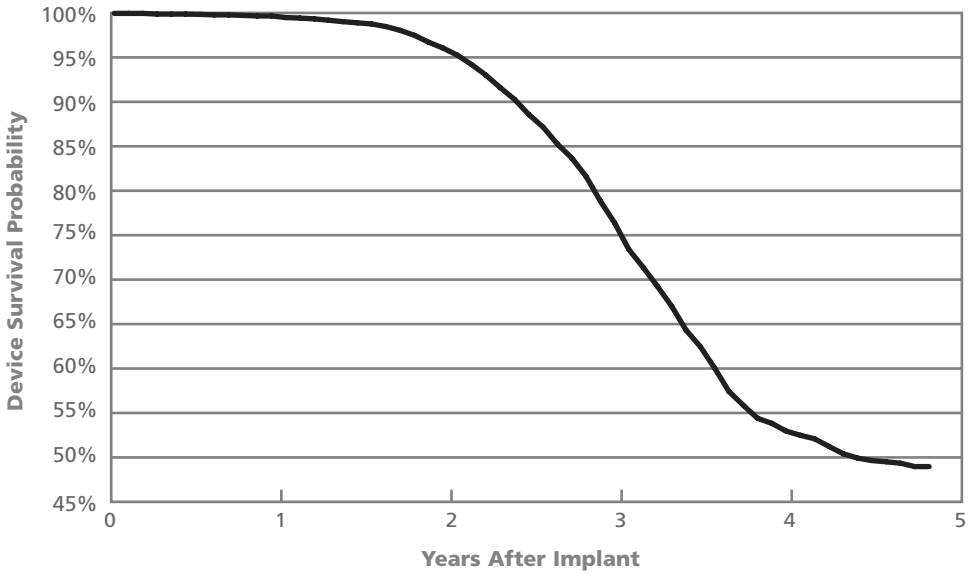
Photon® µ DR
(Model V-232)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.84%	99.65%	99.13%	97.69	
± 1 standard error	0.07%	0.09%	0.18%	0.33%	

The Photon® µ DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in June 2001.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,518 of these devices have been implanted.

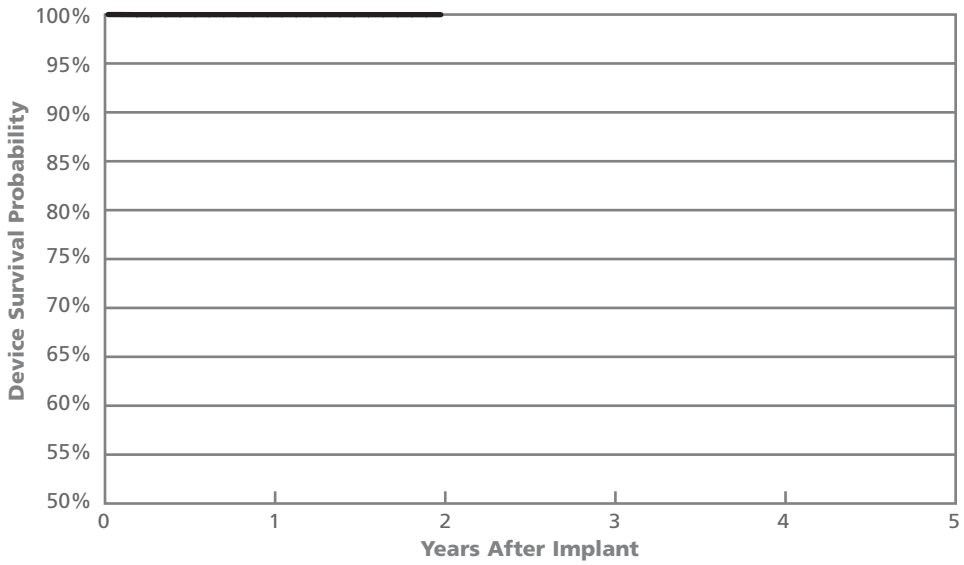
Photon® DR
(Model V-230HV)



Year	1	2	3	4	5
Survival Probability	99.66%	96.05%	76.39%	52.96%	
± 1 standard error	0.10%	0.32%	0.80%	1.16%	

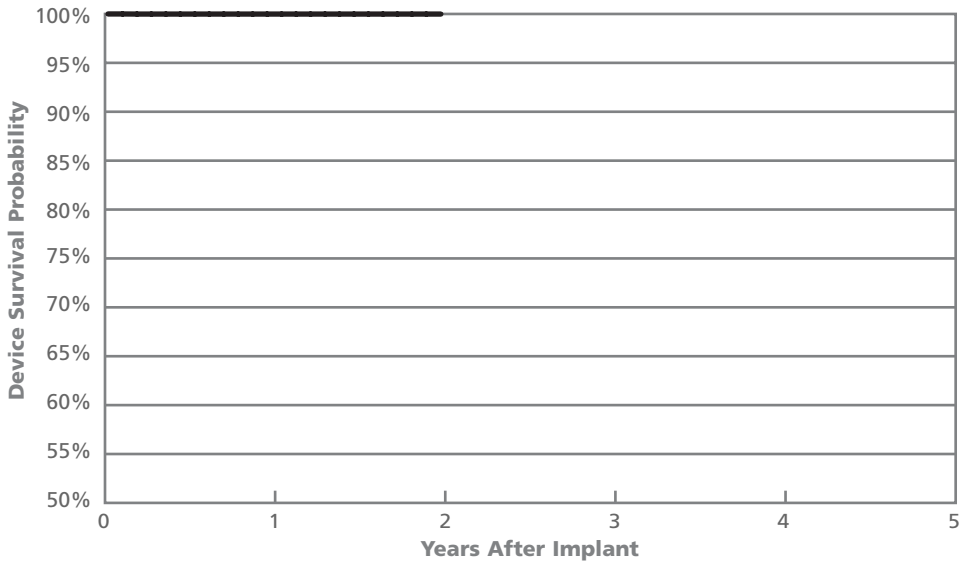
The Photon® DR dual-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2000. This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,882 of these devices have been implanted.

Atlas®+ VR
(Model V-193)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.99%	99.99%			
± 1 standard error	0.01%	0.01%			

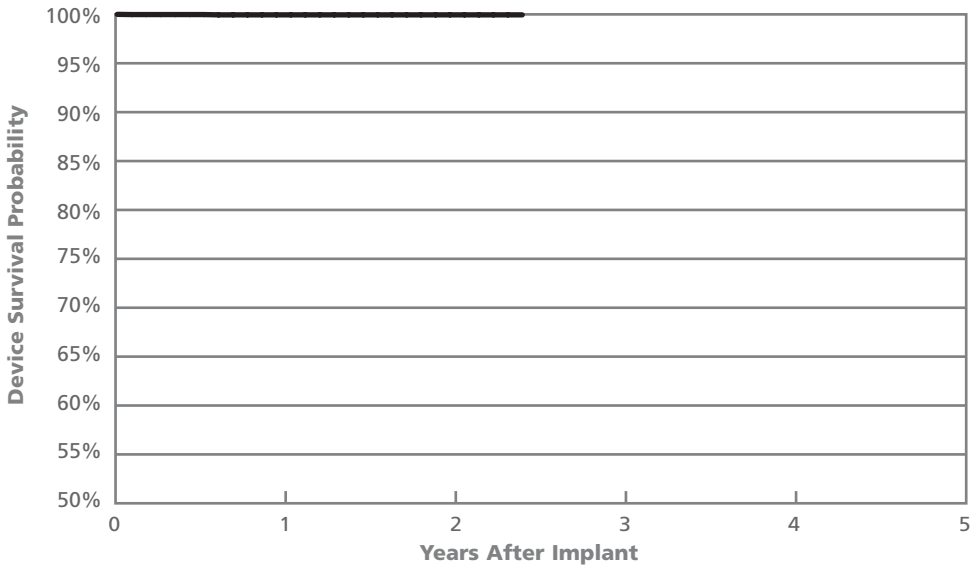
Atlas®+ VR
(Model V-193)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.99%	99.99%			
± 1 standard error	0.01%	0.01%			

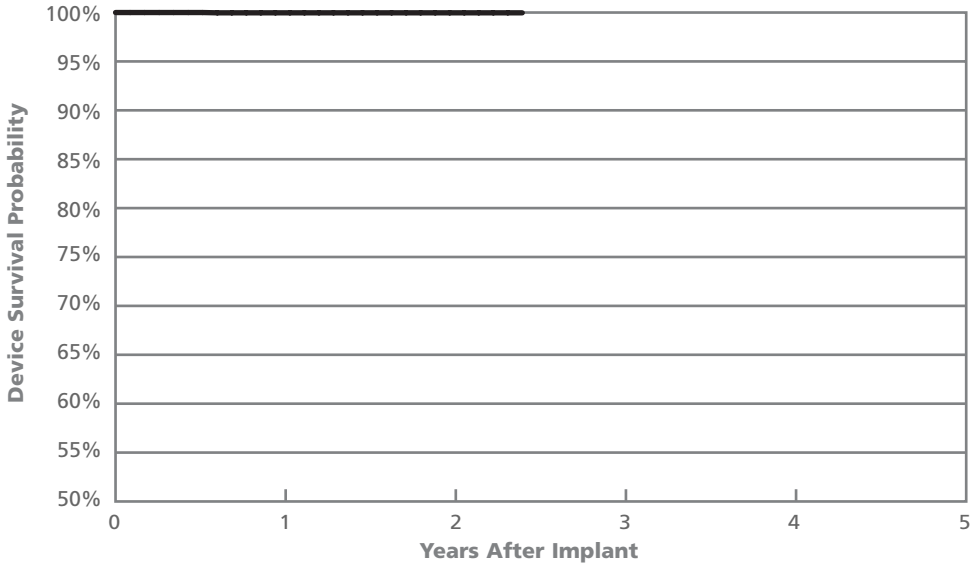
The Atlas®+ VR single-chamber-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in October 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
10,168 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™+ VR
(Model V-196)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.95%			
± 1 standard error	0.04%	0.04%			

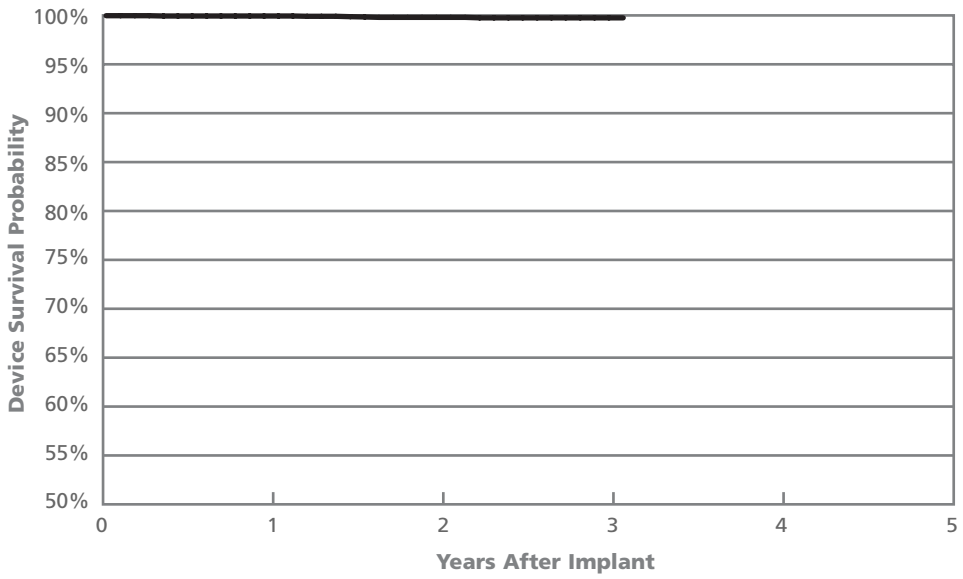
Epic™+ VR
(Model V-196)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.97%	99.97%			
± 1 standard error	0.03%	0.03%			

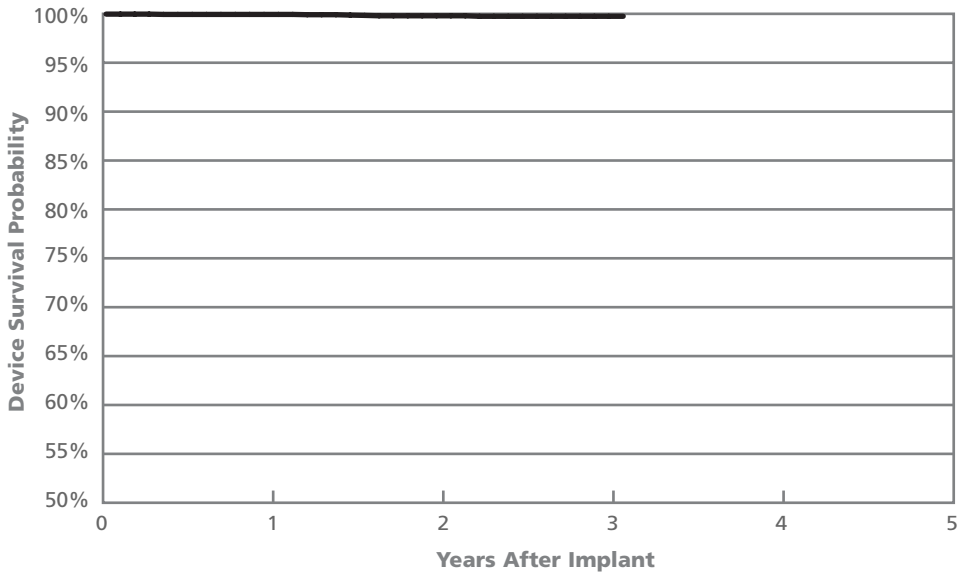
The Epic™+ VR single-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in April 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
5,538 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Epic™ VR
(Model V-197)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.94%	99.80%	99.75%		
± 1 standard error	0.04%	0.08%	0.10%		

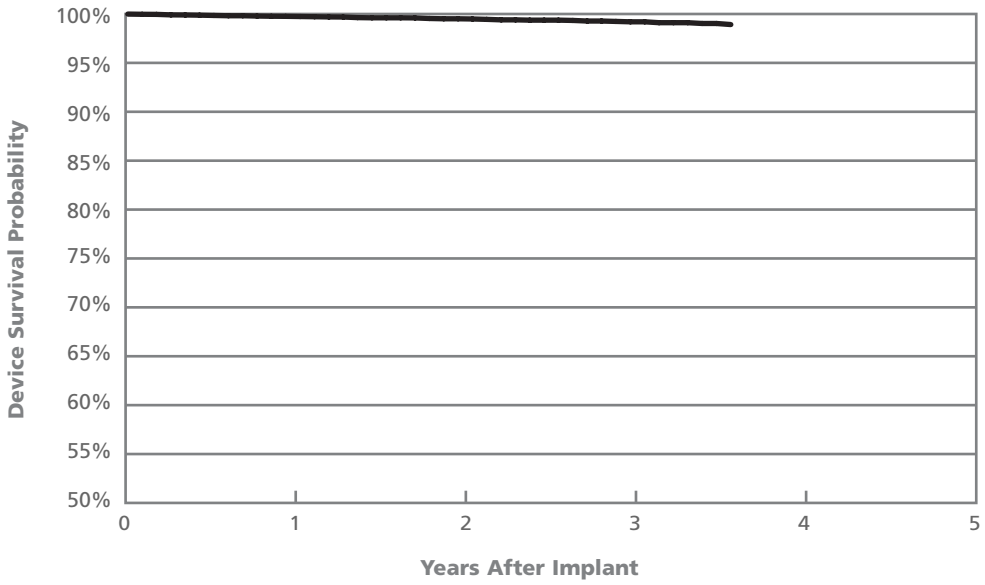
Epic™ VR
(Model V-197)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.94%	99.80%	99.75%		
± 1 standard error	0.04%	0.08%	0.10%		

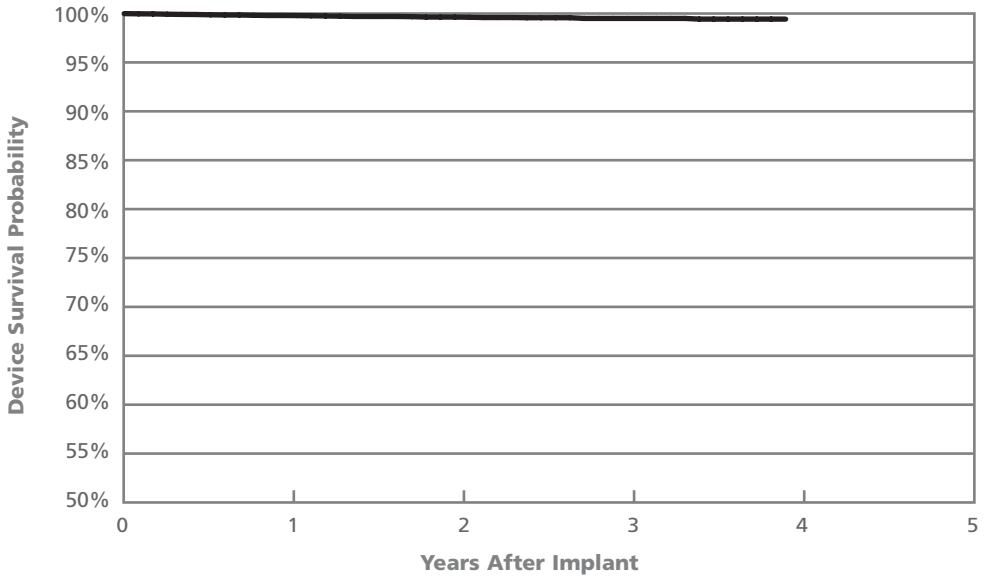
The Epic™ VR single-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in July 2002.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,752 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Atlas® VR
(Model V-199)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.76%	99.51%	99.20%		
± 1 standard error	0.06%	0.09%	0.13%		

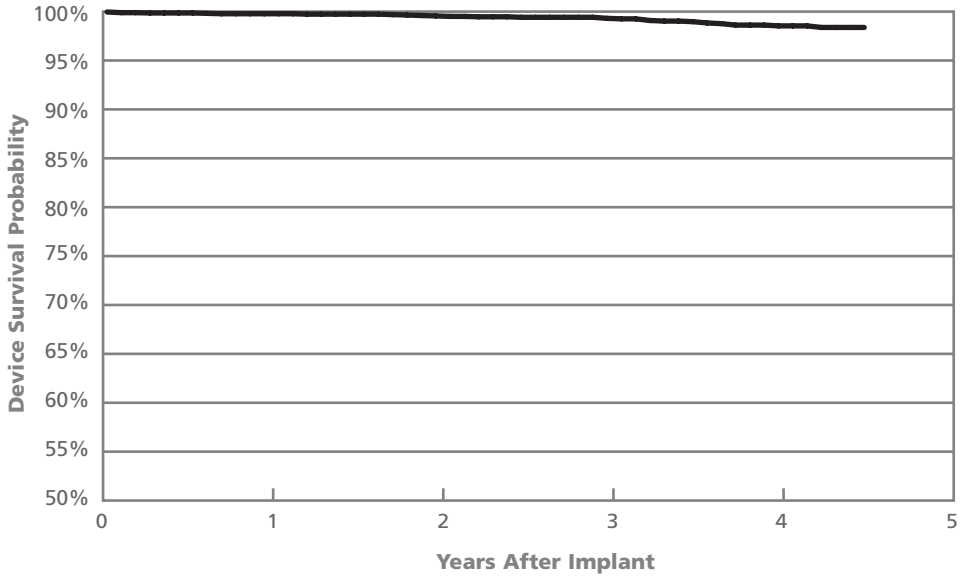
Atlas® VR
(Model V-199)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.80%	99.64%	99.50%		
± 1 standard error	0.05%	0.08%	0.10%		

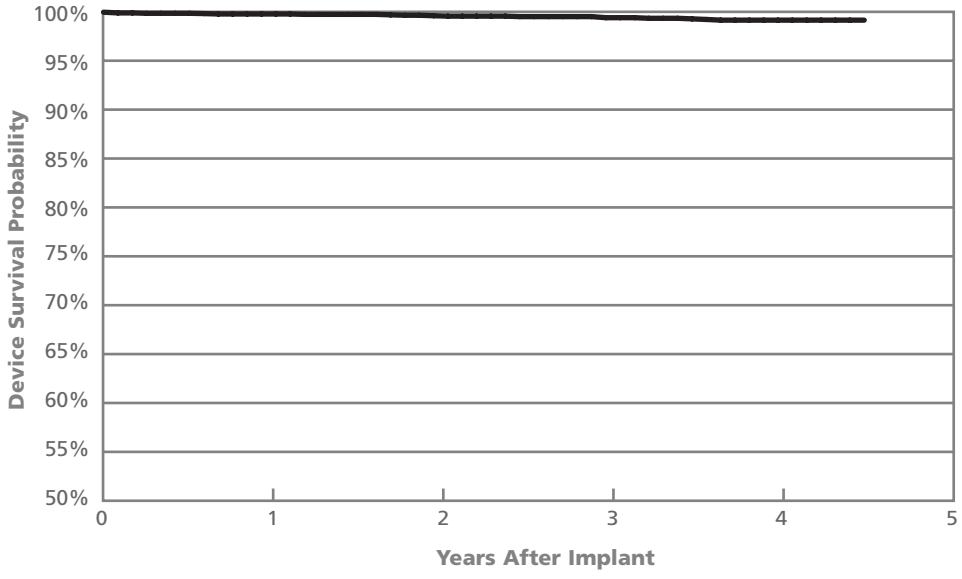
The Atlas® VR single-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in December 2001.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
7,150 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Photon® µ VR
(Model V-194)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.78%	99.56%	99.31%	98.54%	
± 1 standard error	0.09%	0.13%	0.16%	0.27%	

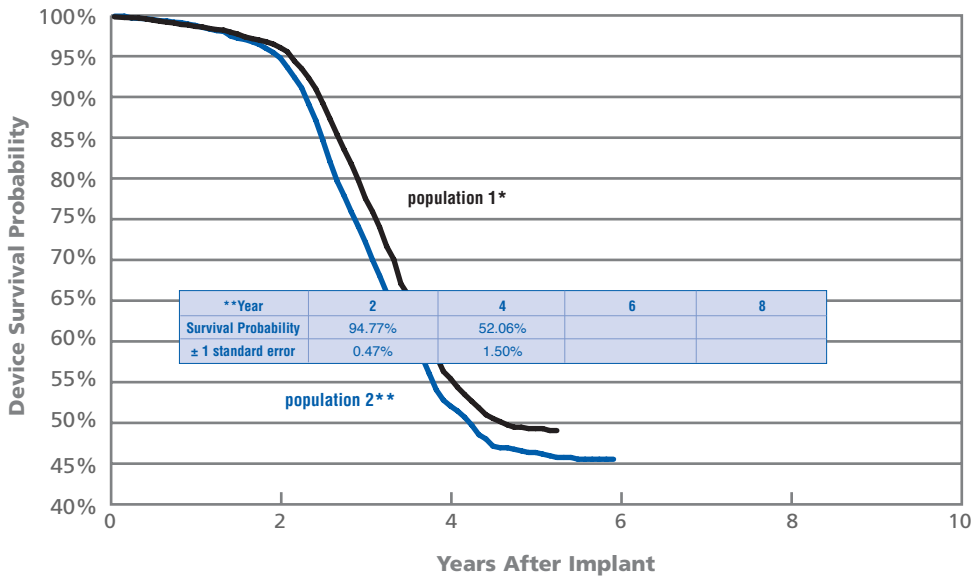
Photon® µ VR
(Model V-194)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.78%	99.60%	99.40%	99.15%	
± 1 standard error	0.09%	0.12%	0.14%	0.21%	

The Photon® µ VR single-chamber, rate-responsive implantable cardioverter defibrillator was approved for use in June 2001.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,928 of these devices have been implanted.

Profile™
(Models V-186F & V-186HV3)

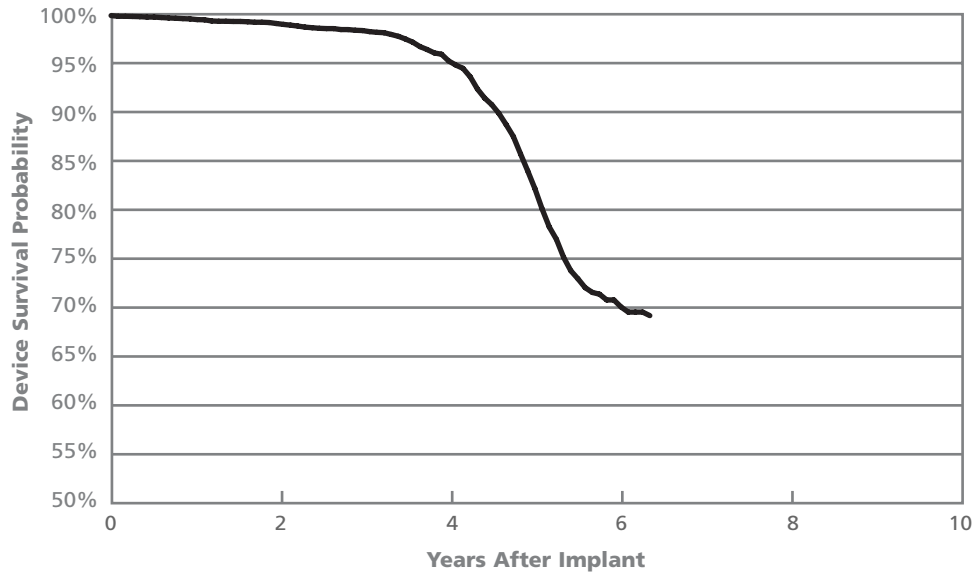


**Year	2	4	6	8
Survival Probability	94.77%	52.06%		
± 1 standard error	0.47%	1.50%		

*Year	2	4	6	8	10
Survival Probability	96.05%	55.44%			
± 1 standard error	0.33%	1.13%			

The Profile™ series of single-chamber implantable cardioverter defibrillators was approved for use in November 1998.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**These devices are not under advisory. 3,684 of these devices were implanted.*
***This group of devices is subject to an advisory. See pp. 76-79 for more information. 2,295 of these devices were implanted.*

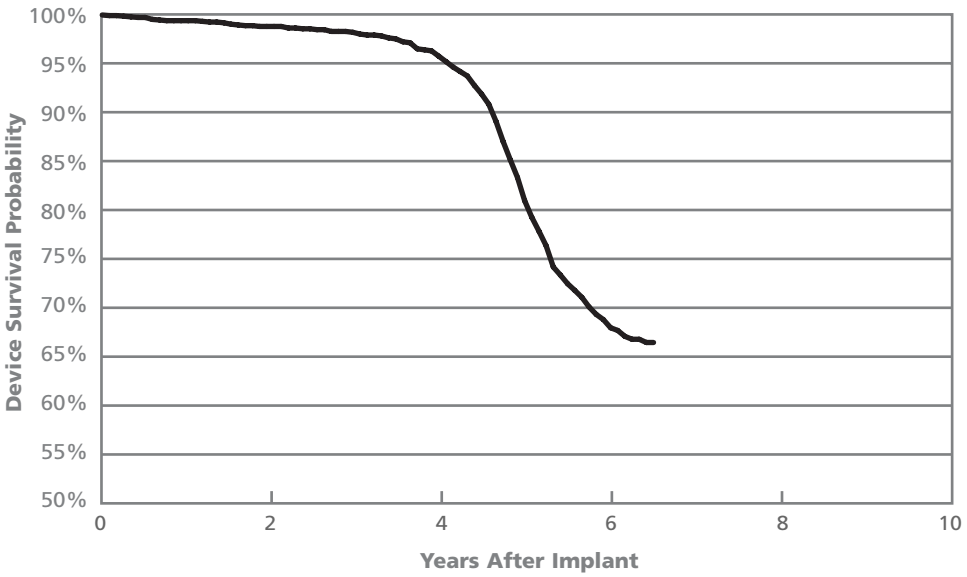
Contour® MD
(Models V-175, V-175AC, V-175B, V-175C & V-175D)



Year	2	4	6	8	10
Survival Probability	99.05%	95.22%	70.06%		
± 1 standard error	0.14%	0.37%	1.36%		

The Contour® MD series of single-chamber implantable cardioverter defibrillators was approved for use in October 1998.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
4,908 of these devices have been implanted.

Contour® II
(Models V-185, V-185AC, V-185B, V-185C & V-185D)



Year	2	4	6	8	10
Survival Probability	98.77%	95.73%	67.96%		
± 1 standard error	0.29%	0.56%	1.90%		

The Contour® II series was approved for use in February 1998.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
1,667 of these devices have been implanted.

ICDs Summary Information*

Including Normal Battery Depletion

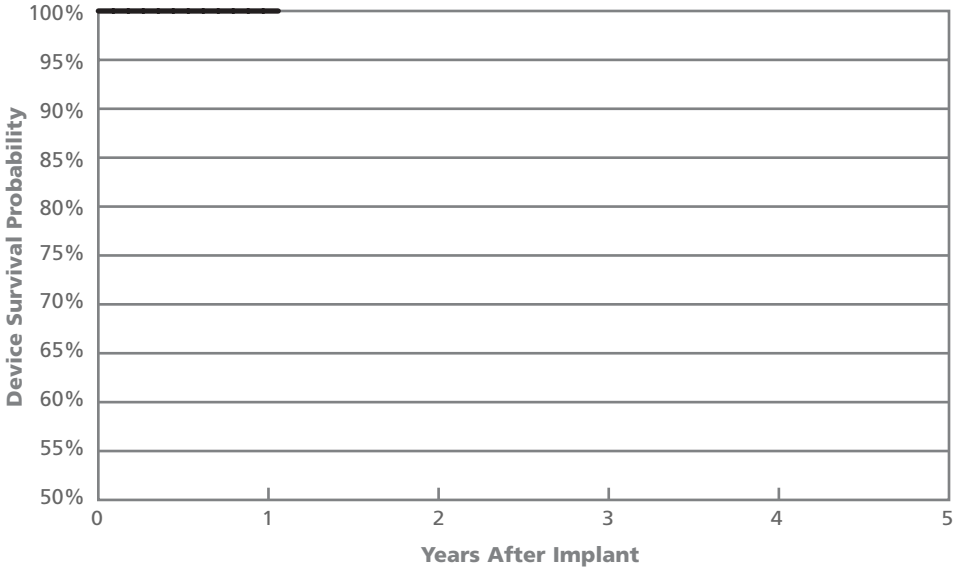
Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy (not under advisory)	Malfunctions w/ Compromised Therapy (under advisory**)	Malfunctions w/o Compromised Therapy	Total Malfunctions	Normal Battery Depletion	Survival Probability			
										1 year	2 years	3 years	4 years
V-242	Atlas DR	Oct-03	2910	2715	0	0	0	0	1	99.91%			
V-243	Atlas + DR	Oct-03	9866	9266	1	0	1	2	1	99.93%	99.93%		
V-236	Epic + DR	Apr-03	2393	1937	0	0	1	1	1	99.96%	99.83%		
V-239	Epic + DR	Oct-03	4922	4592	2	0	0	2	0	99.94%			
V-235	Epic DR	Jul-02	6723	5368	3	0	3	6	2	99.95%	99.93%	99.78%	
V-233	Epic DR	Oct-03	1344	1248	0	0	0	0	0	100%			
V-240	Atlas DR	Dec-01	8898	5584	8	13	14	35	89	99.88%	99.65%	98.79%	
V-232	Photon µ DR	Jun-01	3518	1513	7	7	33	47	122	99.84%	99.55%	97.87%	91.58%
V-193	Atlas + VR	Oct-03	10168	9583	0	0	1	1	0	99.99%	99.99%		
V-196	Epic + VR	Apr-03	5538	4946	1	0	0	1	1	99.95%	99.95%		
V-197	Epic VR	Jul-02	3752	2884	5	0	2	7	0	99.94%	99.80%	99.75%	
V-199	Atlas VR	Dec-01	7150	4881	6	16	6	28	18	99.76%	99.51%	99.20%	
V-194	Photon µ VR	Jun-01	2928	1585	7	4	7	18	11	99.78%	99.56%	99.31%	98.54%

Excluding Normal Battery Depletion

Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy (not under advisory)	Malfunctions w/ Compromised Therapy (under advisory**)	Malfunctions w/o Compromised Therapy	Total Malfunctions	Survival Probability			
									1 year	2 years	3 years	4 years
V-242	Atlas DR	Oct-03	2910	2715	0	0	0	0	100%			
V-243	Atlas + DR	Oct-03	9866	9266	1	0	1	2	99.95%	99.95%		
V-236	Epic + DR	Apr-03	2393	1937	0	0	1	1	99.96%	99.96%		
V-239	Epic + DR	Oct-03	4922	4592	2	0	0	2	99.94%			
V-235	Epic DR	Jul-02	6723	5368	3	0	3	6	99.97%	99.93%	99.84%	
V-233	Epic DR	Oct-03	1344	1248	0	0	0	0	100%			
V-240	Atlas DR	Dec-01	8898	5584	8	13	14	35	99.88%	99.76%	99.46%	
V-232	Photon µ DR	Jun-01	3518	1513	7	7	33	47	99.84%	99.65%	99.13%	97.69%
V-193	Atlas + VR	Oct-03	10168	9583	0	0	1	1	99.99%	99.99%		
V-196	Epic + VR	Apr-03	5538	4946	1	0	0	1	99.97%	99.97%		
V-197	Epic VR	Jul-02	3752	2884	5	0	2	7	99.94%	99.80%	99.75%	
V-199	Atlas VR	Dec-01	7150	4881	6	16	6	28	99.80%	99.64%	99.50%	
V-194	Photon µ VR	Jun-01	2928	1585	7	4	7	18	99.78%	99.60%	99.40%	99.15%

**Based on returned product analysis as of January 31, 2006.*
***St. Jude Medical. ICD Memory Chip Component Anomaly (advisory). October 7, 2005.*

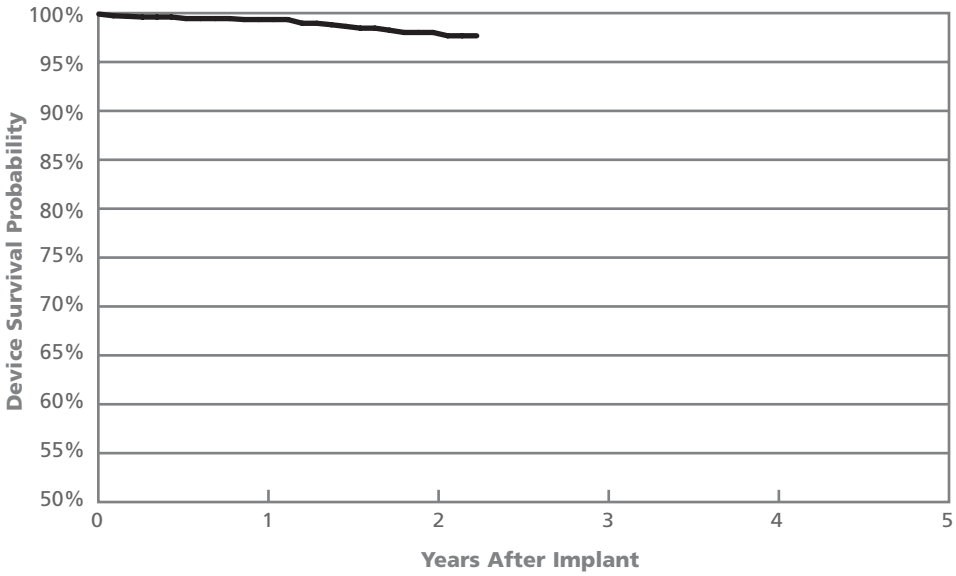
Riata®*i* (Model 1590 & 1591)
Active Fixation Dual-Coil ICD Lead



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

Data is current as of January 31, 2006
5,424 of these leads have been implanted.
(Approval date: April 2004)

Riata® (Model 1582)
Active Fixation Single-Coil ICD Lead

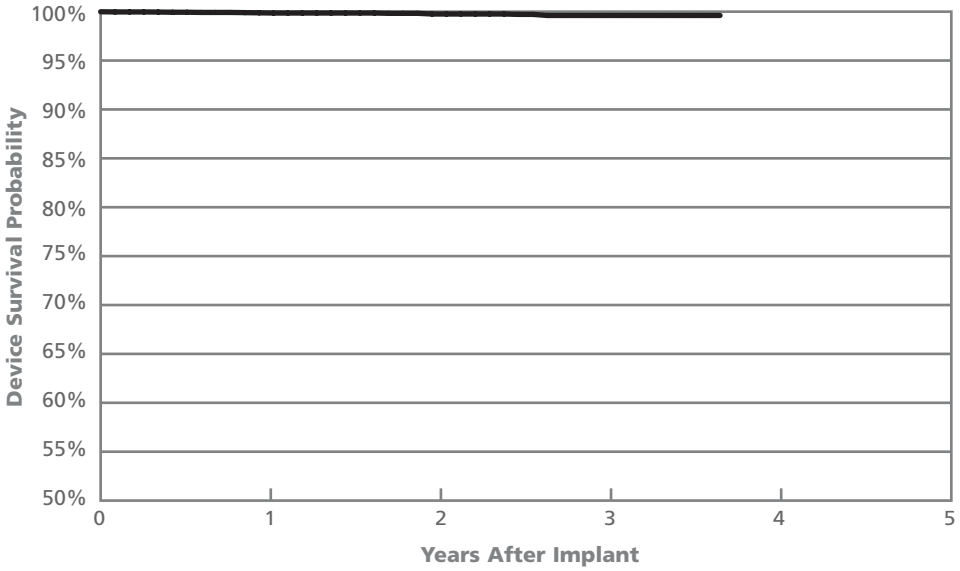


Year	1	2	3	4	5
Survival Probability	99.34%	98.02%			
± 1 standard error	0.21%	0.52%			

Data is current as of January 31, 2006.
1,972 of these leads have been implanted.
(Approval date: March 2003)

Defibrillation Leads

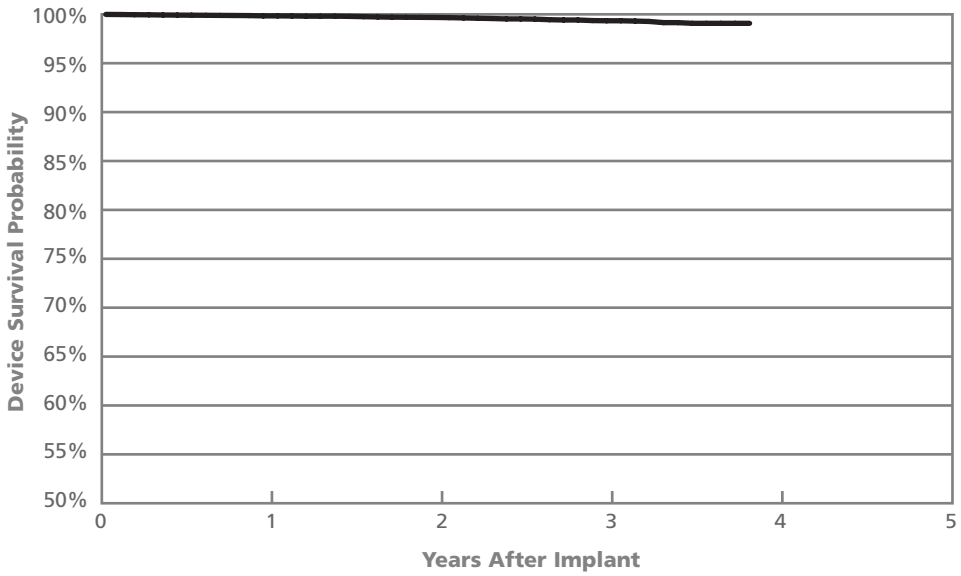
Riata® (Models 1570 & 1571)
Passive Fixation Dual-Coil ICD Leads



Year	1	2	3	4	5
Survival Probability	99.88%	99.76%	99.61%		
± 1 standard error	0.04%	0.06%	0.12%		

Data is current as of January 31, 2006.
7,387 of these leads have been implanted.
(Approval date: March 2002)

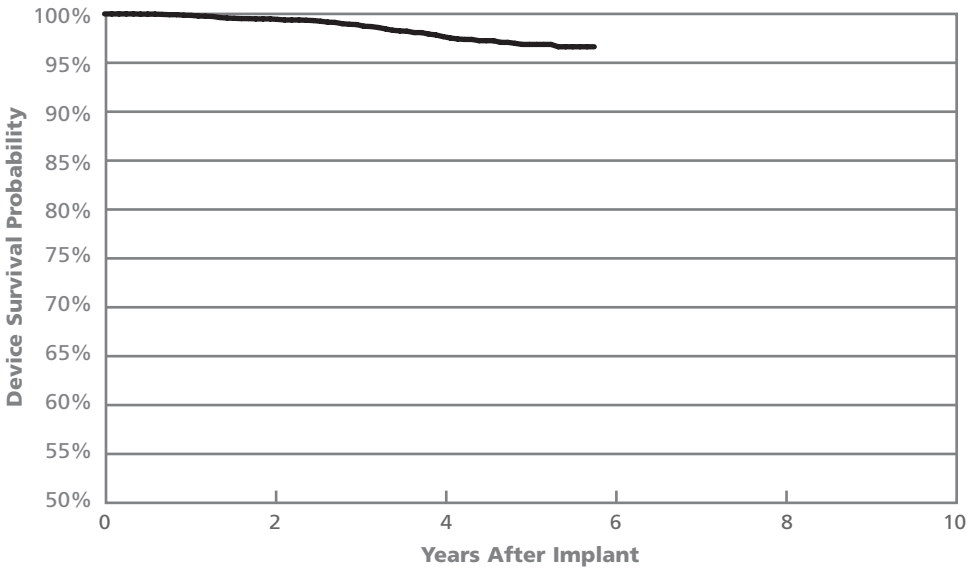
Riata® (Model 1580 & 1581)
Active Fixation Dual-Coil ICD Leads



Year	1	2	3	4	5
Survival Probability	99.84%	99.68%	99.34%		
± 1 standard error	0.02%	0.04%	0.07%		

Data is current as of January 31, 2006.
49,092 of these leads have been implanted.
(Approval date: March 2002)

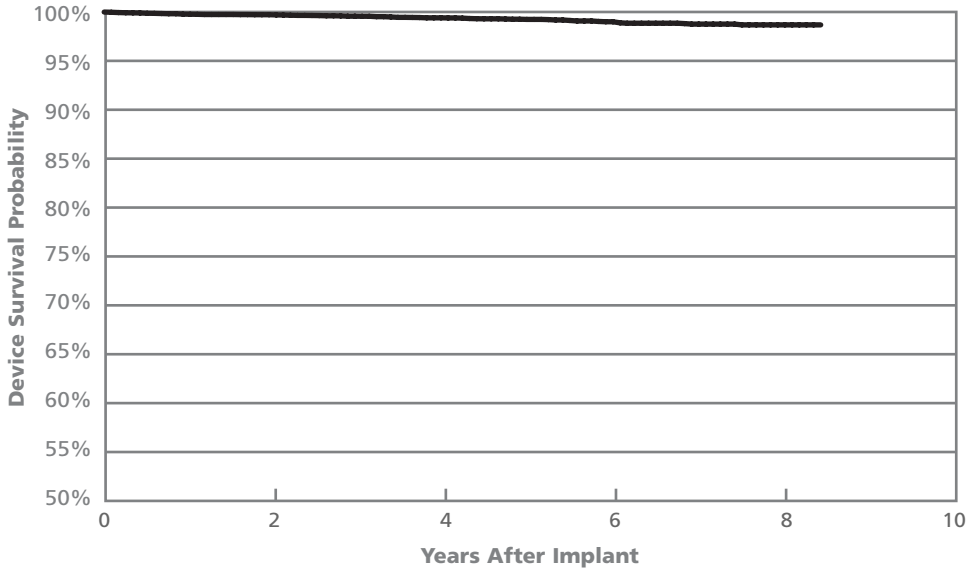
TVL®-ADX (Model 1559)
Active Fixation Single-Coil ICD Lead



Year	2	4	6	8	10
Survival Probability	99.47%	97.68%			
± 1 standard error	0.12%	0.26%			

Data is current as of January 31, 2006.
This lead model is no longer being manufactured.
4,448 of these leads have been implanted.
(Approval date: November 1999)

SPL® (Models SP01, SP02, SP03 & SP04)
Passive Fixation Dual-Coil ICD Leads

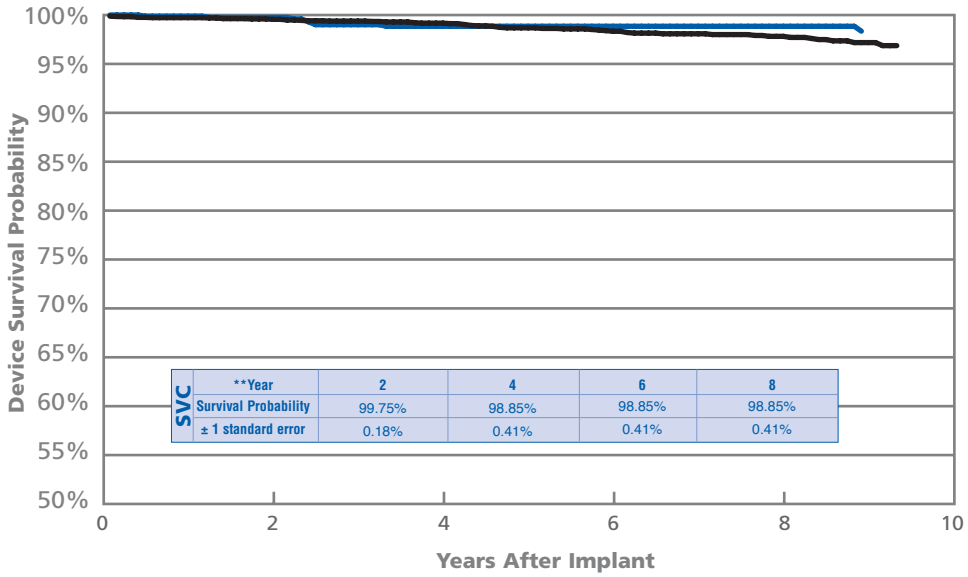


Year	2	4	6	8	10
Survival Probability	99.72%	99.40%	99.00%	98.68%	
± 1 standard error	0.05%	0.08%	0.12%	0.17%	

Data is current as of January 31, 2006.
These lead models are no longer being manufactured.
12,345 of these leads have been implanted.
(Approval date: September 1997)

Defibrillation Leads

TVL® RV (Models RV01, RV02, RV03, RV06 & RV07)
TVL® SVC (Models SV01, SV02 & SV03) Passive Fixation Single-Coil ICD Leads

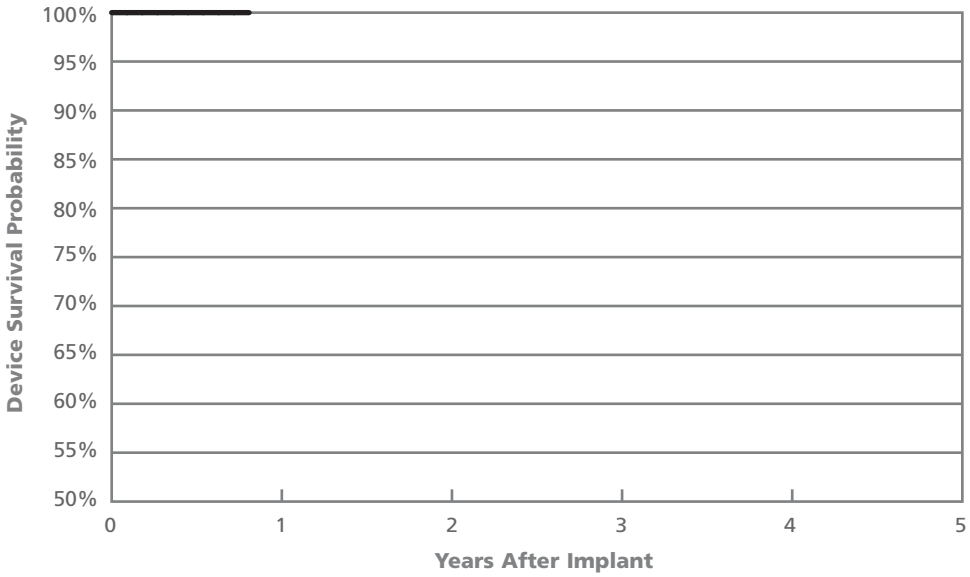


SVC	**Year	2	4	6	8
	Survival Probability	99.75%	98.85%	98.85%	98.85%
	± 1 standard error	0.18%	0.41%	0.41%	0.41%

RV	Year	2	4	6	8	10
	Survival Probability	99.56%	99.17%	98.34%	97.82%	
	± 1 standard error	0.11%	0.17%	0.26%	0.33%	

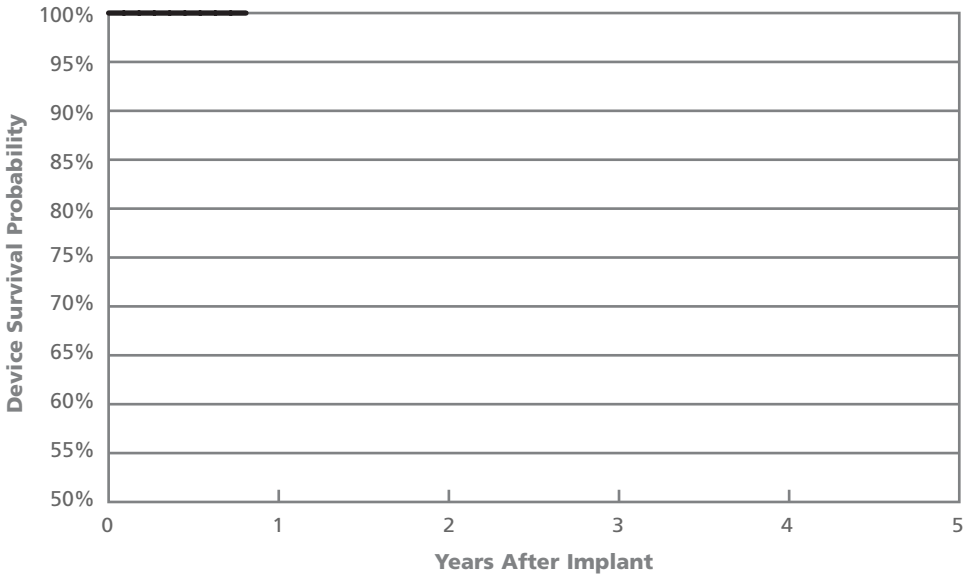
Data is current as of January 31, 2006.
These lead models are no longer being manufactured.
3,478 TVL® RV leads have been implanted, and 909 TVL® SVC leads have been implanted.
(Approval dates: RV01, RV02, SV01, SV02, SV03–May 1996; RV03–April 1997; RV06, RV07–July 2000)

Frontier™ II
(Model 5586)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability*					
± 1 standard error					

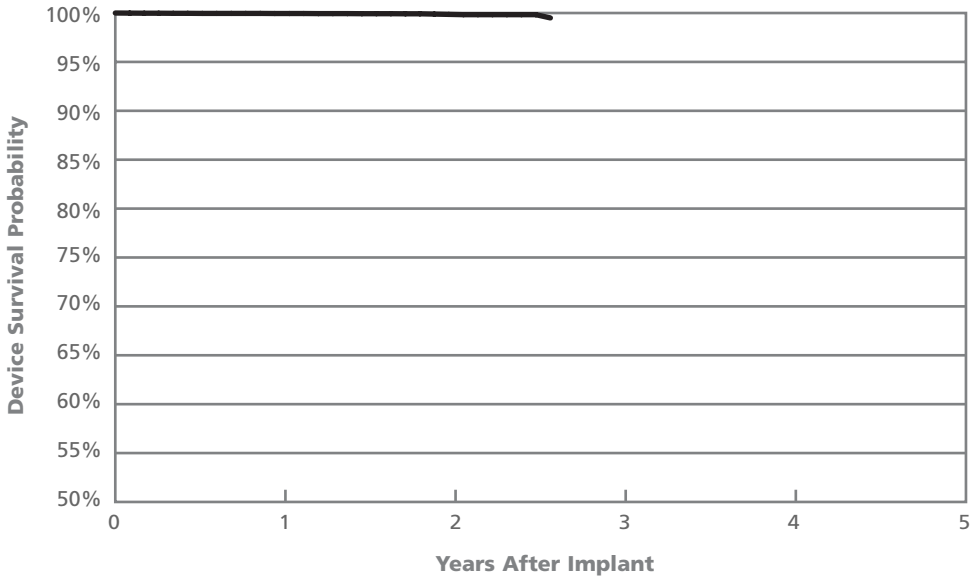
Frontier™ II
(Model 5586)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability*					
± 1 standard error					

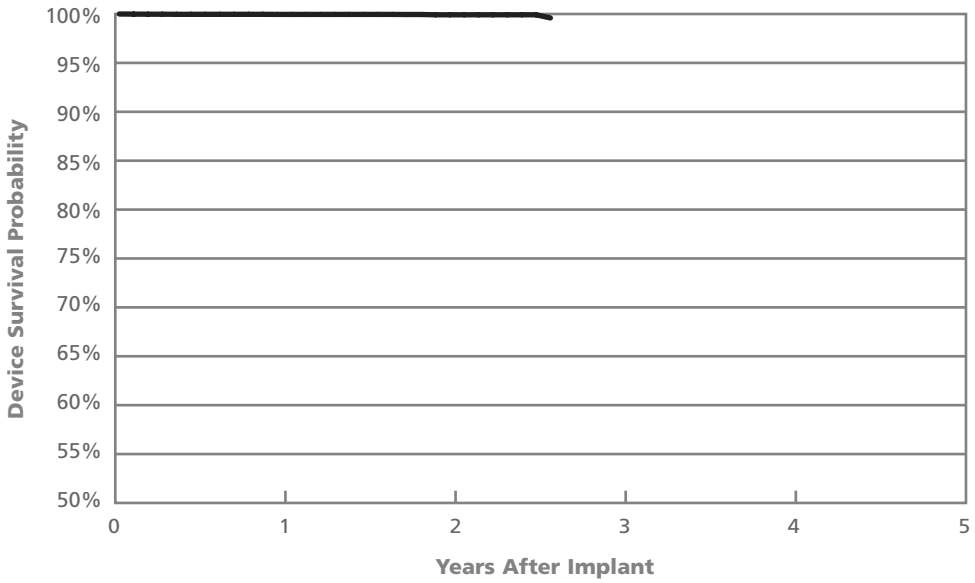
The Frontier™ dual-chamber, rate-responsive pulse generator was approved for use in August 2004.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
859 of these devices have been implanted.
**No survival probability is stated at 1 year due to the device not meeting the required minimum sample size of 200 U.S. implants with 12 consecutive months of data.*

Identity® ADx DR
(Model 5380)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.86%			
± 1 standard error	0.01%	0.03%			

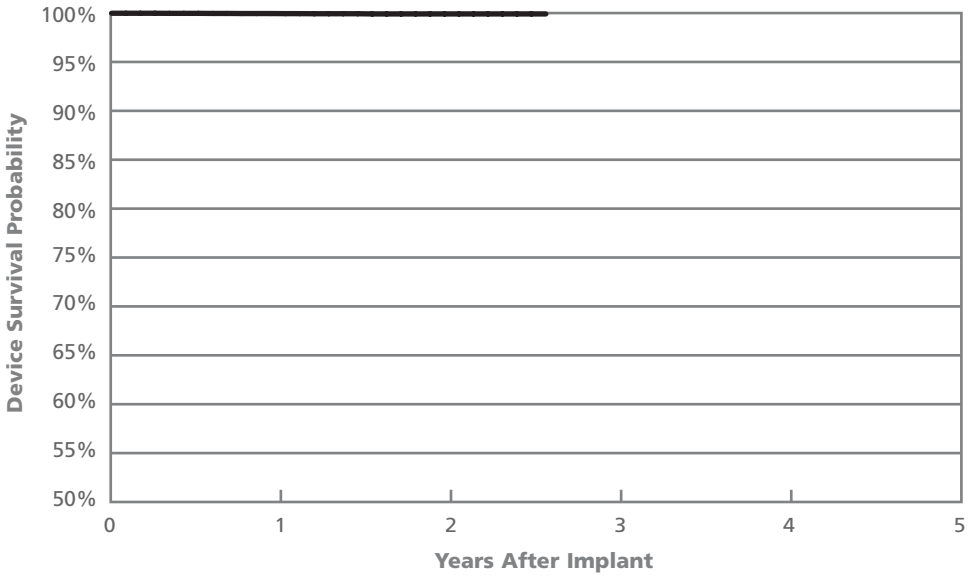
Identity® ADx DR
(Model 5380)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.96%	99.92%			
± 1 standard error	0.01%	0.03%			

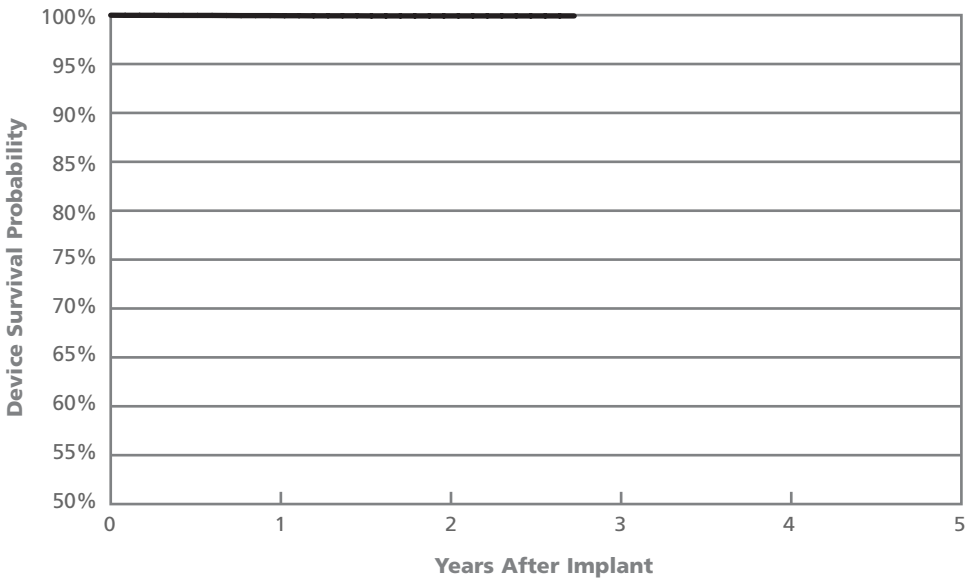
The Identity® ADx DR dual-chamber, rate-responsive pulse generator was approved for use in March 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
35,373 of these devices have been implanted.

Identity® ADx XL DR (Model 5386)
Identity® ADx XL DC (Model 5286)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.91%			
± 1 standard error	0.02%	0.02%			

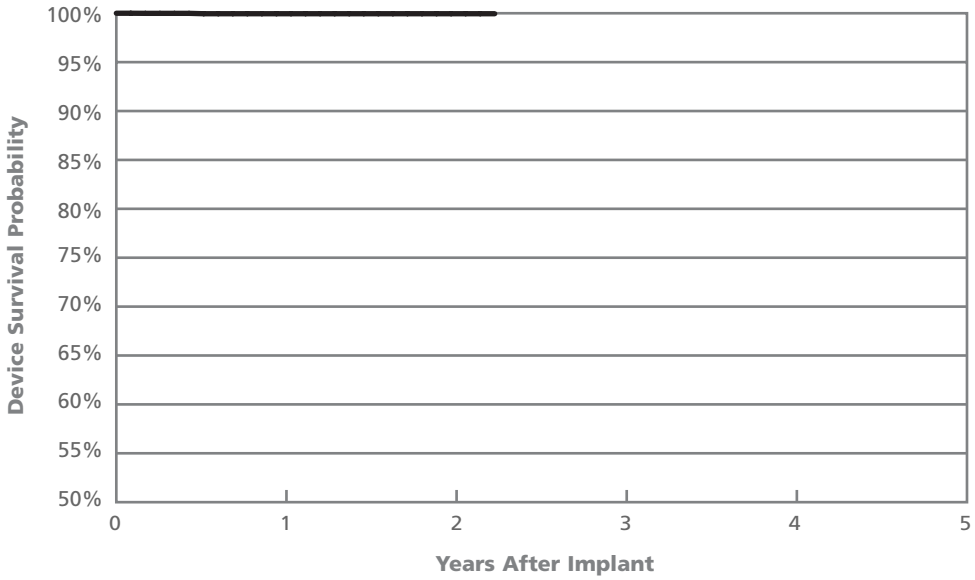
Identity® ADx XL DR (Model 5386)
Identity® ADx XL DC (Model 5286)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.92%			
± 1 standard error	0.02%	0.02%			

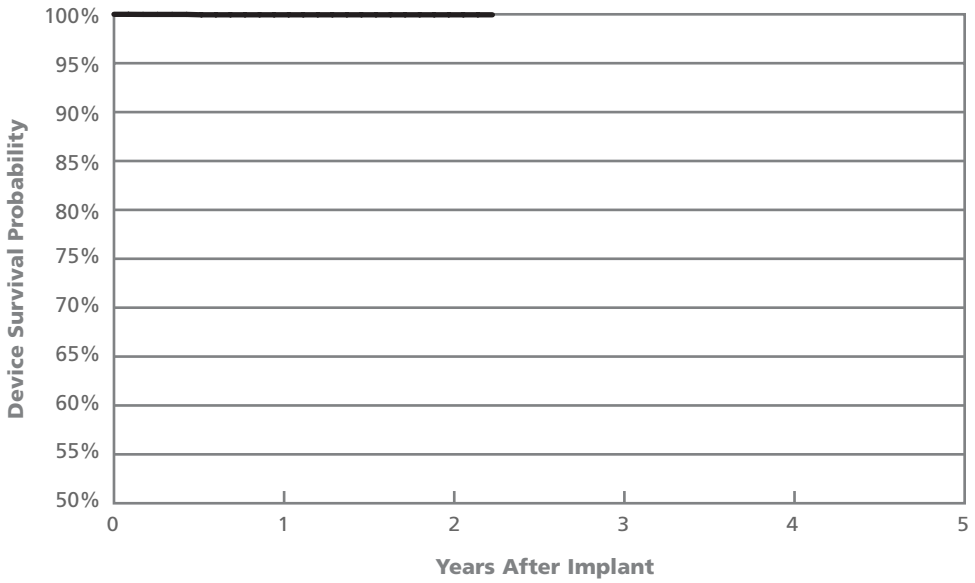
The Identity® ADx XL DR dual-chamber, rate-responsive pulse generator and the Identity® ADx XL DC dual-chamber pulse generator were approved for use in March 2003. Survival probability (%) is based on returned product analysis as of January 31, 2006. 33,958 of these devices have been implanted.

Integrity® ADx DR
(Models 5360 & 5366)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.95%			
± 1 standard error	0.03%	0.03%			

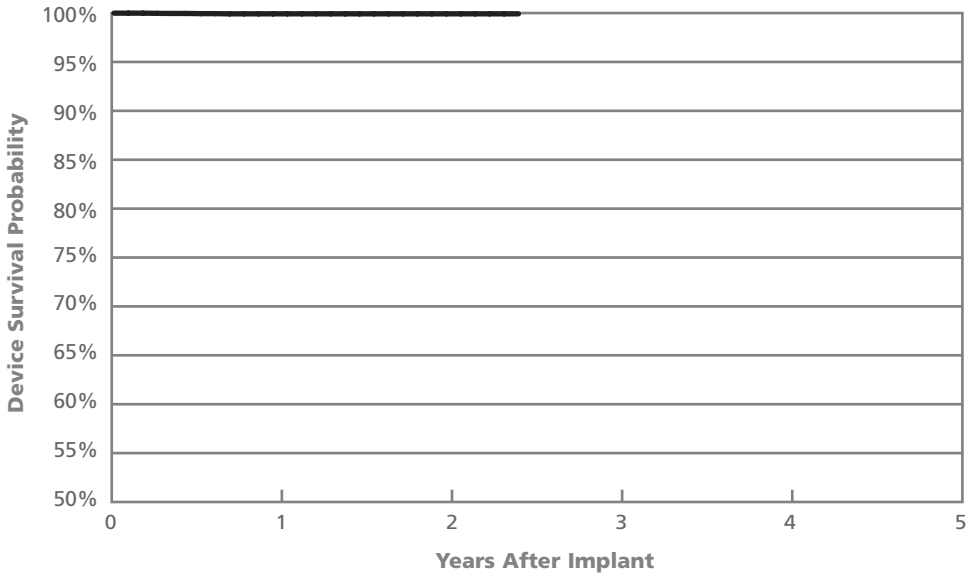
Integrity® ADx DR
(Models 5360 & 5366)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.95%			
± 1 standard error	0.03%	0.03%			

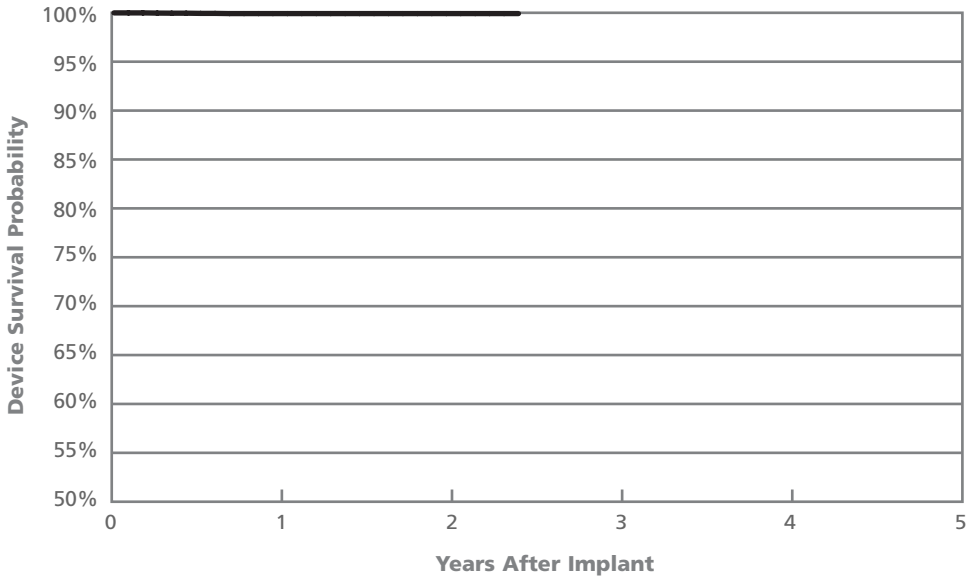
The Integrity® ADx DR dual-chamber, rate-responsive pulse generator was approved for use in May 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
7,474 of these devices have been implanted.

Verity® ADx XL DR (Model 5356)
Verity® ADx XL DR M/S (Model 5357M/S); Verity® ADx XL DC (Model 5256)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.93%			
± 1 standard error	0.03%	0.03%			

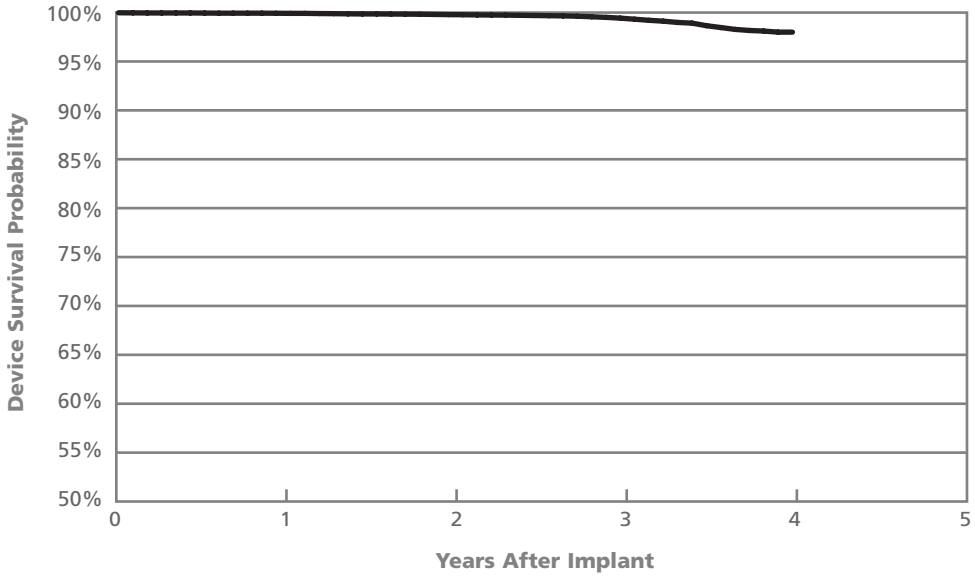
Verity® ADx XL DR (Model 5356)
Verity® ADx XL DR M/S (Model 5357M/S); Verity® ADx XL DC (Model 5256)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.93%			
± 1 standard error	0.03%	0.03%			

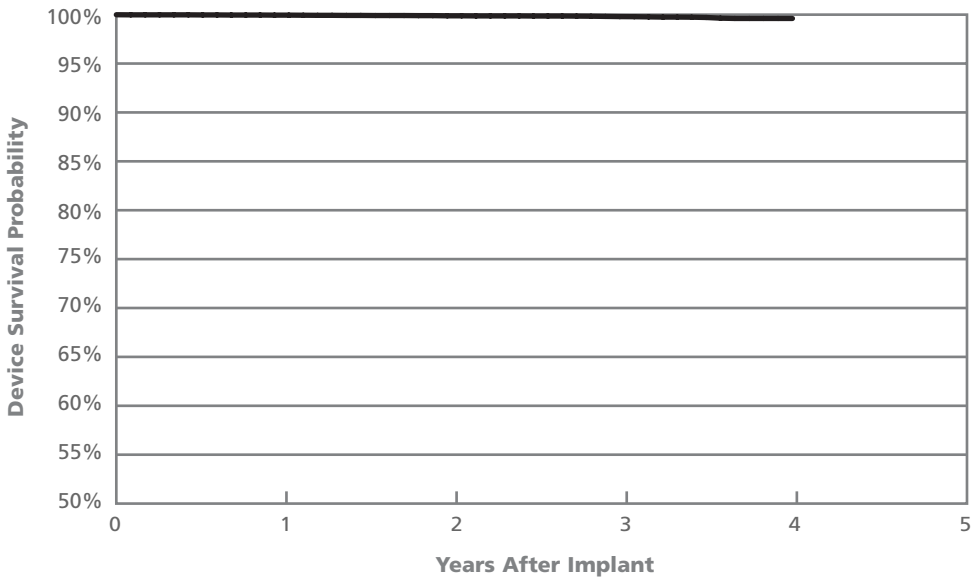
The Verity® ADx XL DR and the Verity® ADx XL DR M/S dual-chamber, rate-responsive pulse generators and the Verity® ADx XL DC dual-chamber pulse generator were approved for use in May 2003. Survival probability (%) is based on returned product analysis as of January 31, 2006. 8,568 of these devices have been implanted.

Identity®
(Model 5370)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.79%	99.43%	98.00%	
± 1 standard error	0.01%	0.02%	0.05%	0.20%	

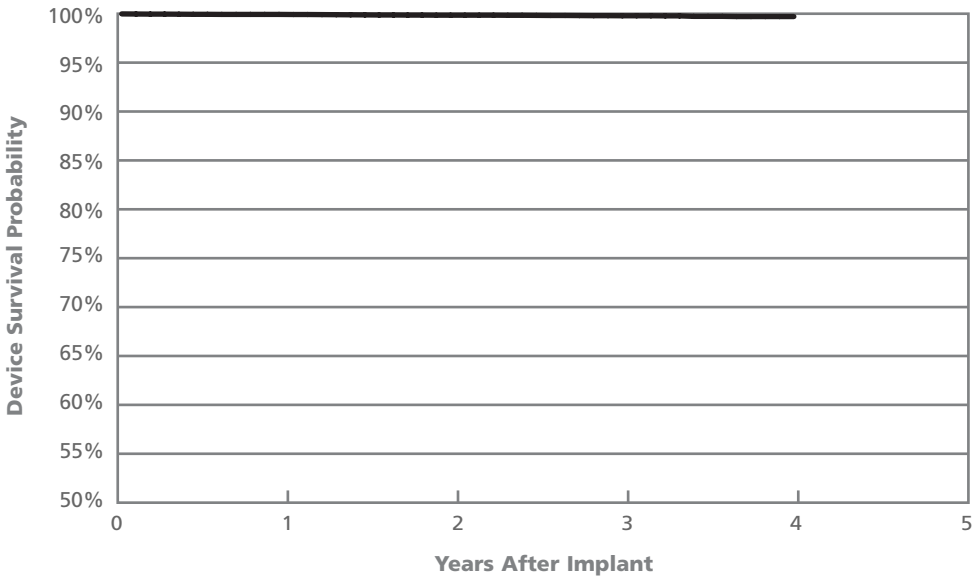
Identity®
(Model 5370)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.95%	99.88%	99.80%	99.61%	
± 1 standard error	0.01%	0.02%	0.03%	0.06%	

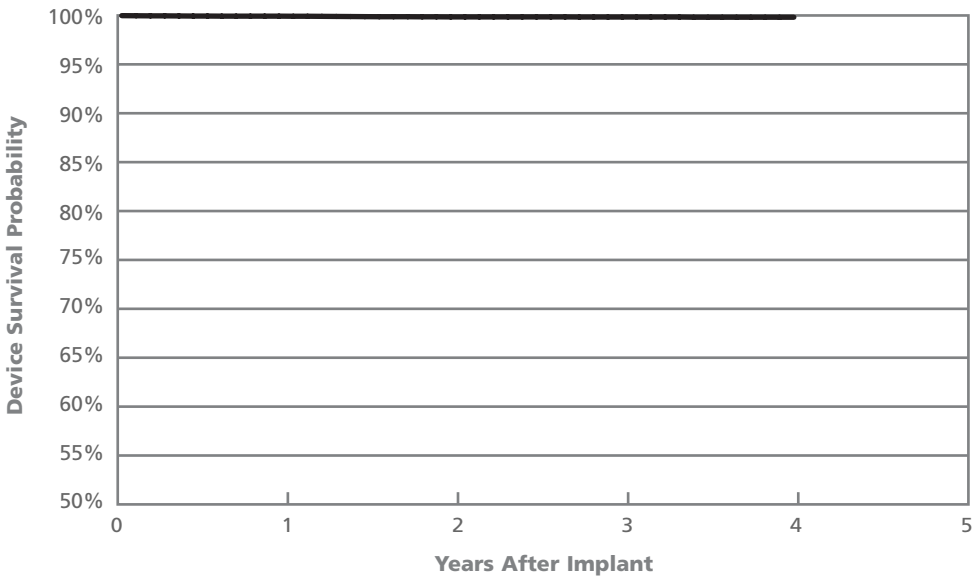
The Identity® dual-chamber, rate-responsive pulse generator was approved for use in November 2001.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
53,478 of these devices have been implanted.

Identity® XL
(Model 5376)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.85%	99.79%	99.71%	
± 1 standard error	0.01%	0.02%	0.03%	0.05%	

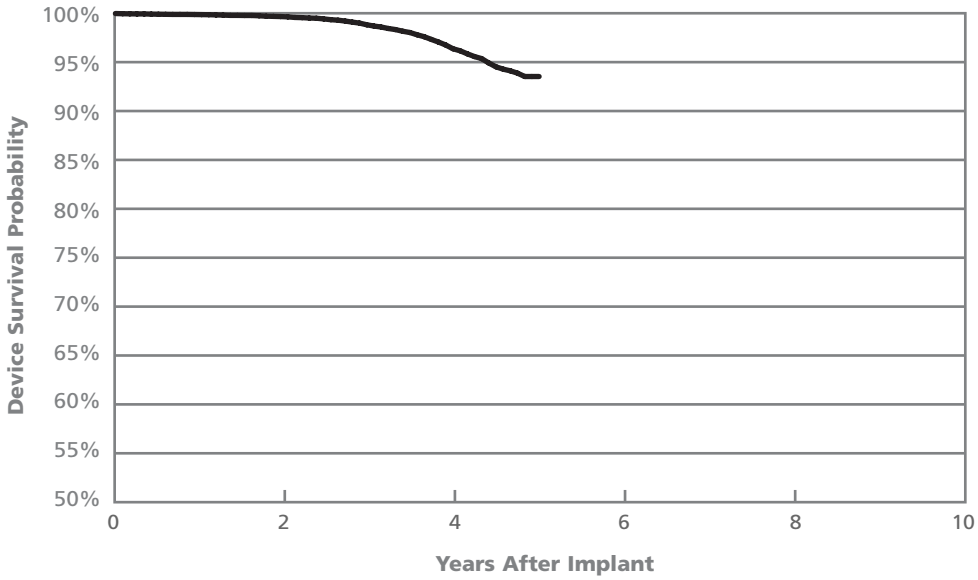
Identity® XL
(Model 5376)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.93%	99.85%	99.84%	99.82%	
± 1 standard error	0.01%	0.02%	0.02%	0.03%	

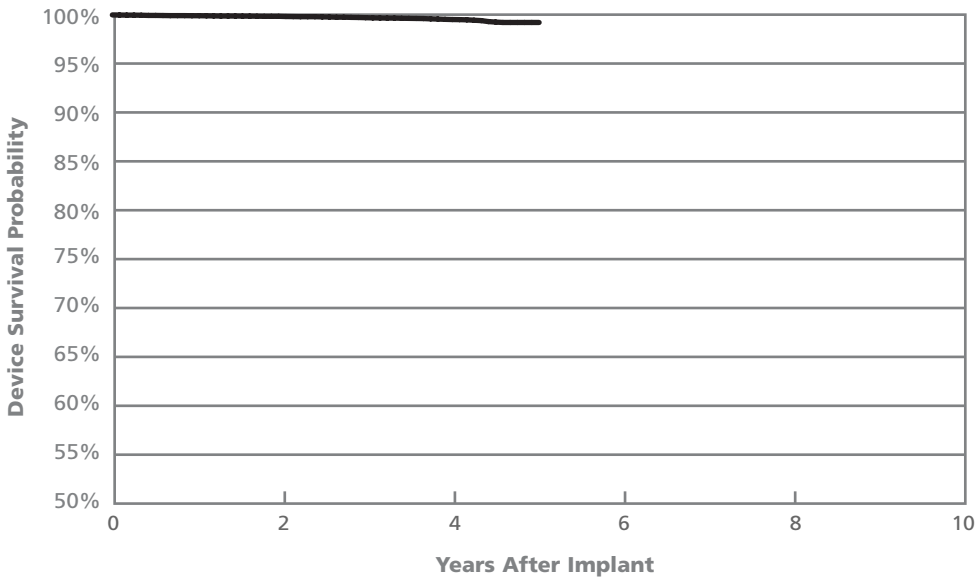
The Identity® XL dual-chamber, rate-responsive pulse generator was approved for use in November 2001.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
45,706 of these devices have been implanted.

Integrity® µ DR
(Model 5336)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.66%	96.37%			
± 1 standard error	0.04%	0.16%			

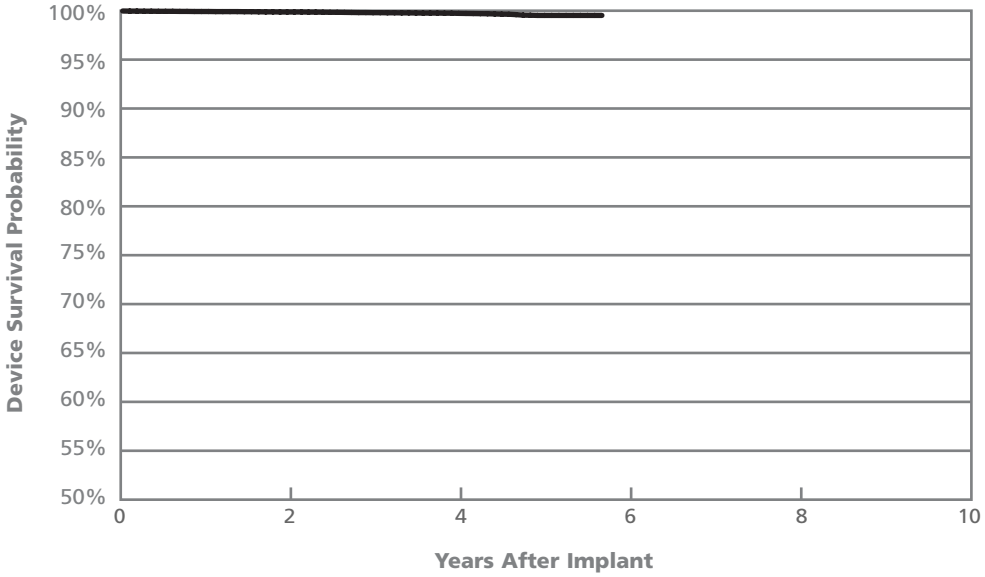
Integrity® µ DR
(Model 5336)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.83%	99.50%			
± 1 standard error	0.03%	0.05%			

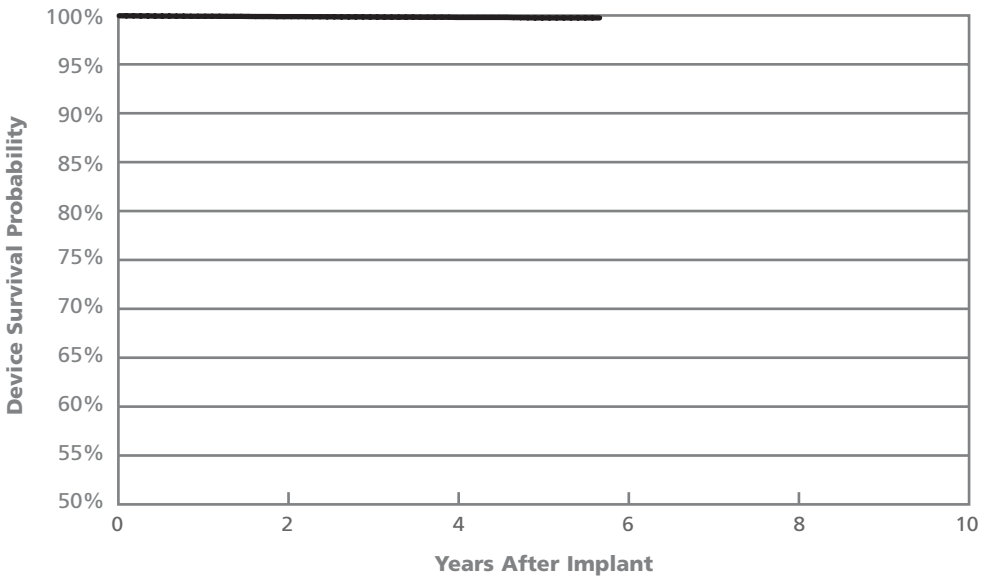
The Integrity® µ DR dual-chamber, rate-responsive pulse generator was approved for use in December 2000.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
29,000 of these devices have been implanted.

Integrity® AFx DR
(Models 5342 & 5346)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.87%	99.73%			
± 1 standard error	0.02%	0.03%			

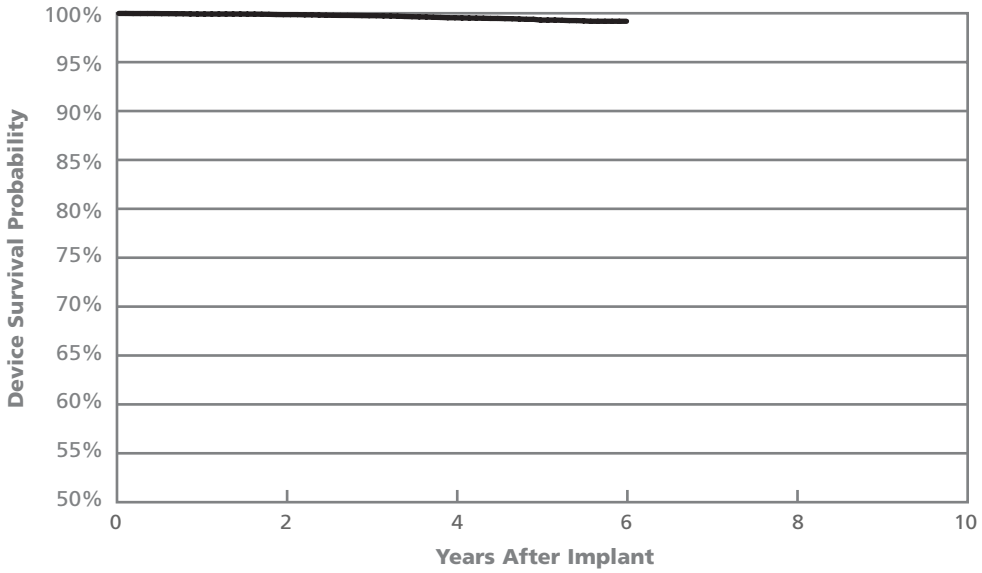
Integrity® AFx DR
(Models 5342 & 5346)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.88%	99.80%			
± 1 standard error	0.02%	0.02%			

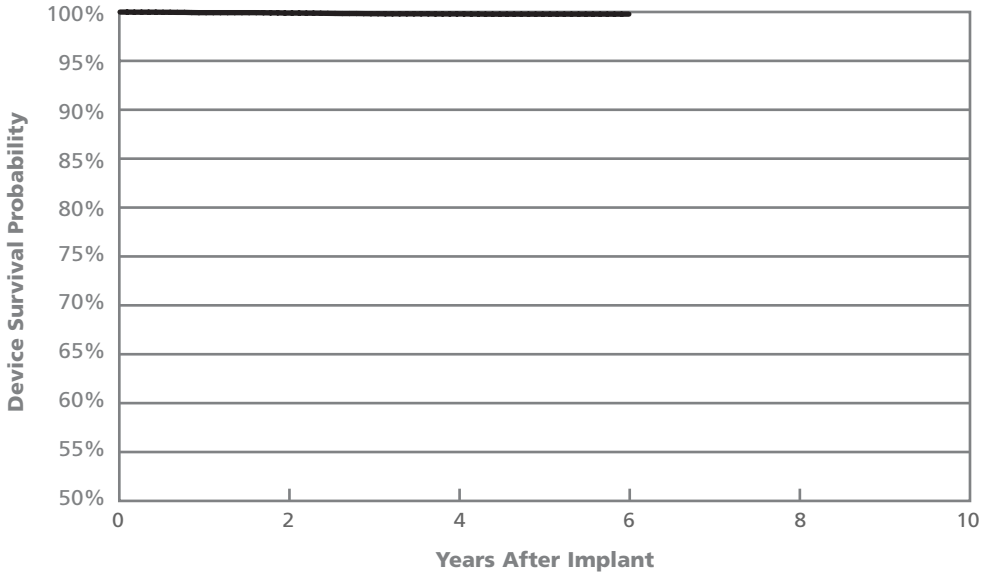
The Integrity® AFx DR model 5342 dual-chamber, rate-responsive pulse generator was approved for use in April 2000.
The Integrity® AFx DR model 5346 dual-chamber, rate-responsive pulse generator was approved for use in July 2001.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
46,991 of these devices have been implanted.

Entity® DR (Model 5326)
Entity® DC (Model 5226)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.86%	99.54%	99.18%		
± 1 standard error	0.03%	0.06%	0.11%		

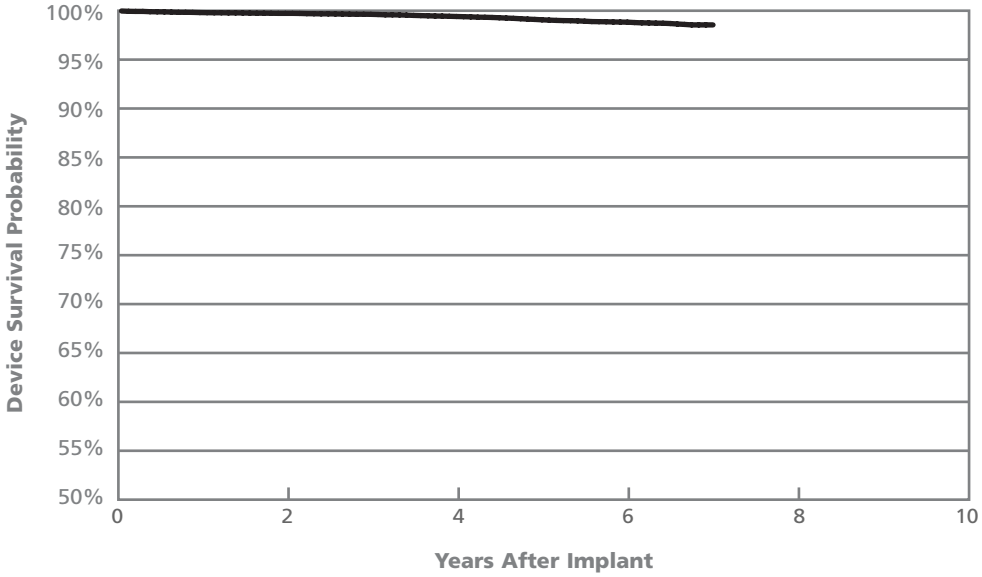
Entity® DR (Model 5326)
Entity® DC (Model 5226)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.89%	99.80%	99.78%		
± 1 standard error	0.02%	0.03%	0.04%		

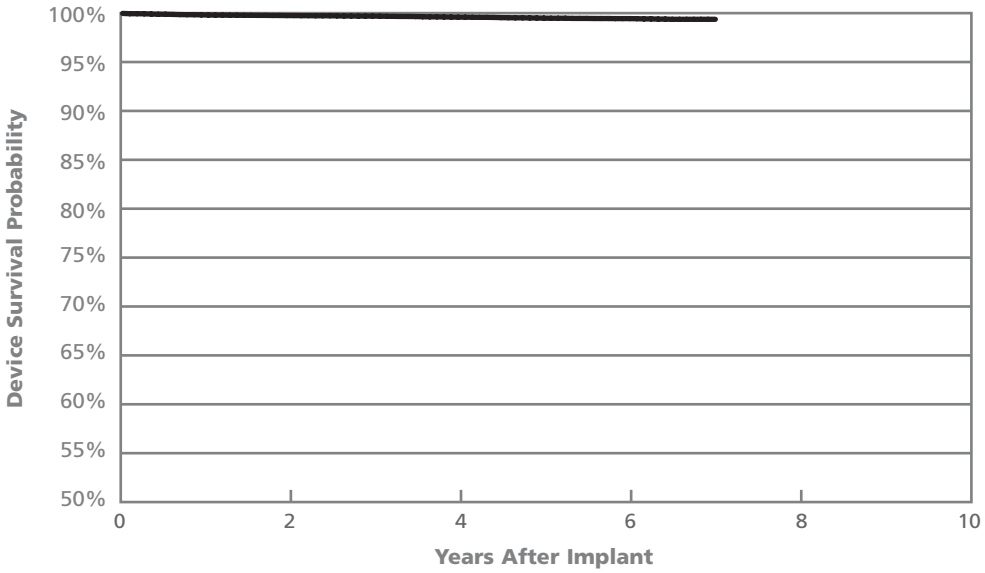
The Entity® DR dual-chamber, rate-responsive pulse generator and the Entity® DC dual-chamber, pulse generator were approved for use in June 1999. Survival probability (%) is based on returned product analysis as of January 31, 2006. 21,740 of these devices have been implanted.

Affinity® DR (Models 5330 & 5331)
Affinity® DC (Model 5230)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.73%	99.41%	98.83%		
± 1 standard error	0.02%	0.03%	0.06%		

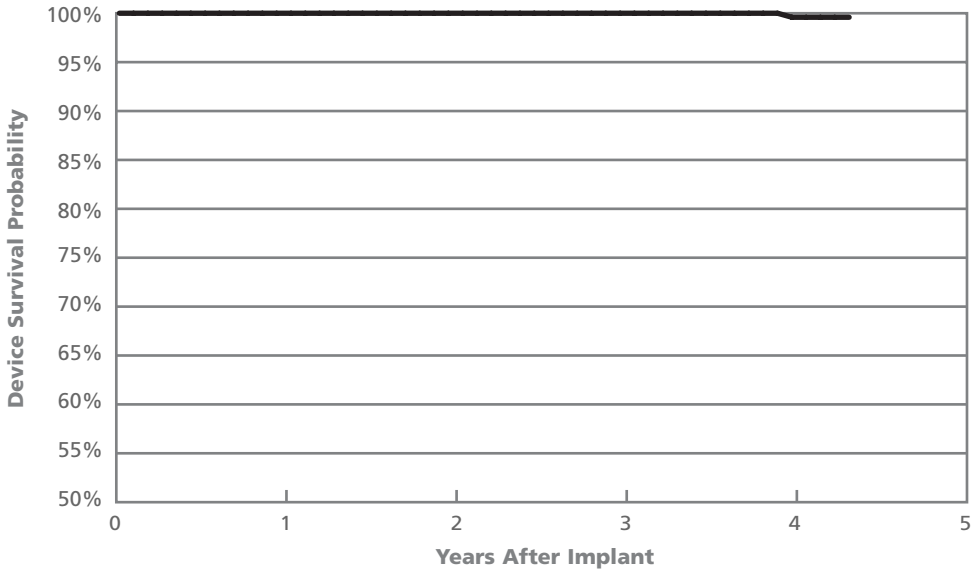
Affinity® DR (Models 5330 & 5331)
Affinity® DC (Model 5230)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.75%	99.59%	99.44%		
± 1 standard error	0.02%	0.03%	0.04%		

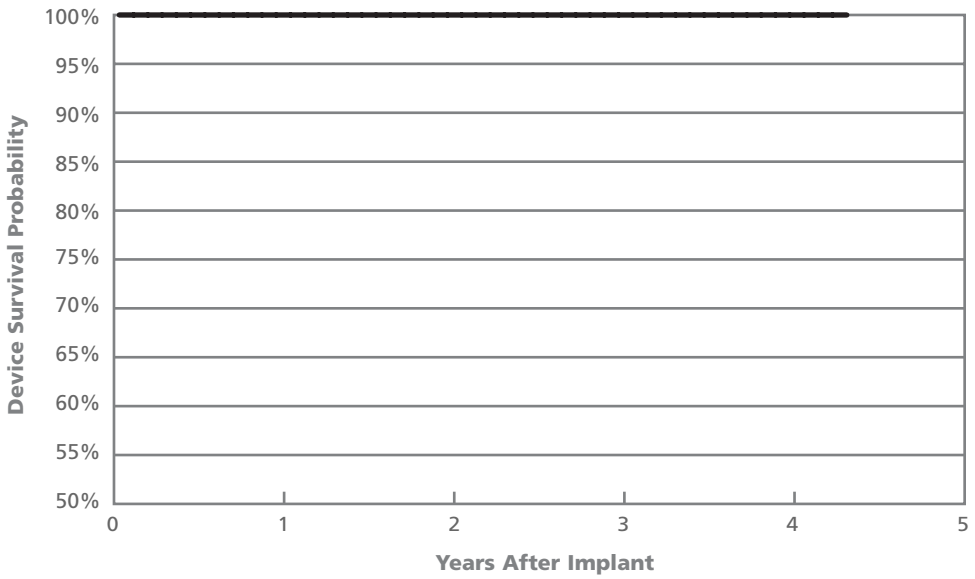
The Affinity® DR model 5330 dual-chamber, rate-responsive pulse generator was approved for use in January 1999. The Affinity® DC model 5230 dual-chamber pulse generator and the Affinity® DR model 5331 dual-chamber, rate-responsive pulse generator were approved for use in June 1999. Survival probability (%) is based on returned product analysis as of January 31, 2006. 65,333 of these devices have been implanted. (Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

Affinity® VDR
(Models 5430)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%	100%	100%	99.59%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	

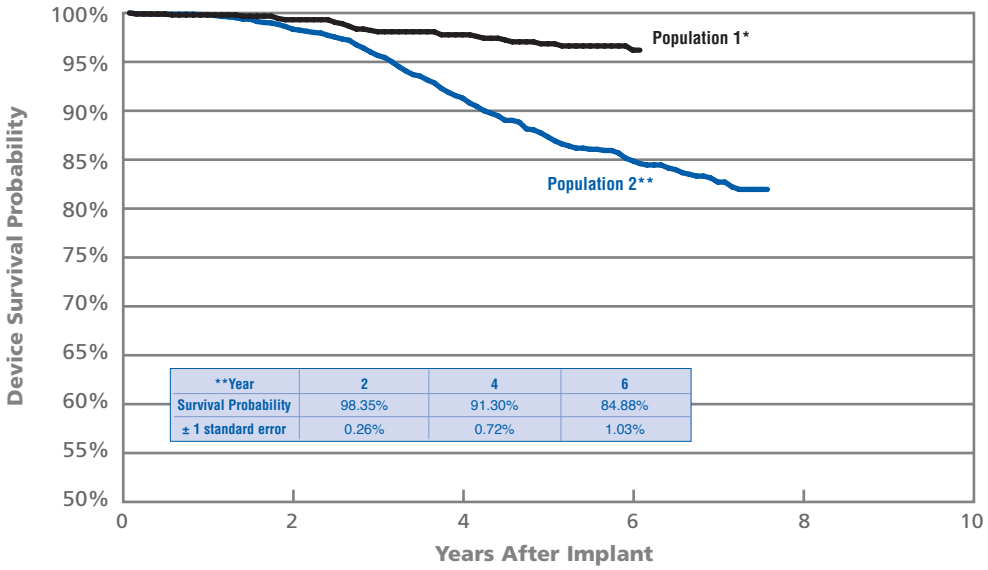
Affinity® VDR
(Models 5430)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%	100%	100%	100%	
± 1 standard error	0.00%	0.00%	0.00%	0.00%	

The Affinity® VDR single-lead, dual-chamber, rate-responsive pulse generator was approved for use in April 2000.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
663 of these devices have been implanted.

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

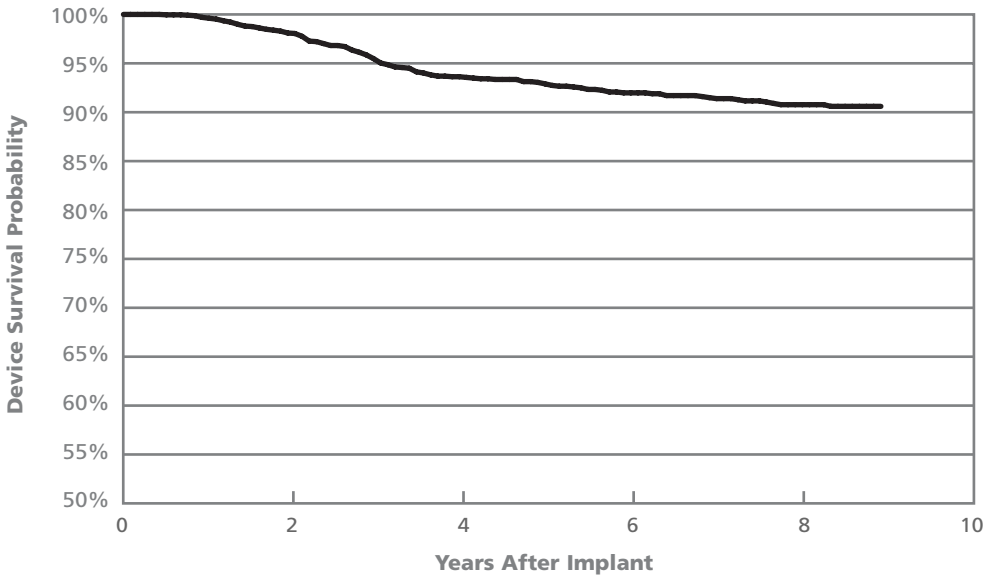


**Year	2	4	6
Survival Probability	98.35%	91.30%	84.88%
± 1 standard error	0.26%	0.72%	1.03%

*Year	2	4	6	8	10
Survival Probability	99.31%	97.77%	96.20%		
± 1 standard error	0.28%	0.54%	0.71%		

The Tempo® D series of dual-chamber pulse generators and the Tempo® DR series of dual-chamber, rate-responsive pulse generators were approved for use in August 1997. The Meta™ DDDR pulse generator was approved for use in April 1997. These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**This group of devices is not under advisory. 1,035 of these devices were implanted.*
***This group of devices is subject to an advisory. See pp. 76-79 for more information. 2,583 of these devices were implanted.*

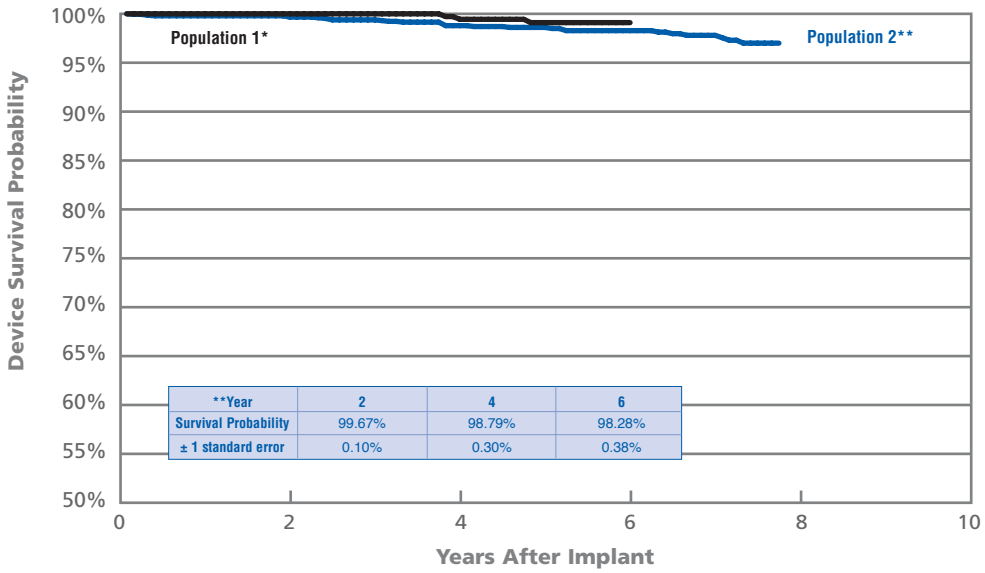
Meta™ DDDR (Model 1256)



Year	2	4	6	8	10
Survival Probability	98.10%	93.63%	91.98%	90.77%	
± 1 standard error	0.28%	0.56%	0.66%	0.74%	

The Meta™ DDDR dual-chamber, rate-responsive pulse generator was approved for use in April 1997. This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,624 of these devices have been implanted.
(Note: These devices are subject to an advisory. See pp. 76-79 for more information.)

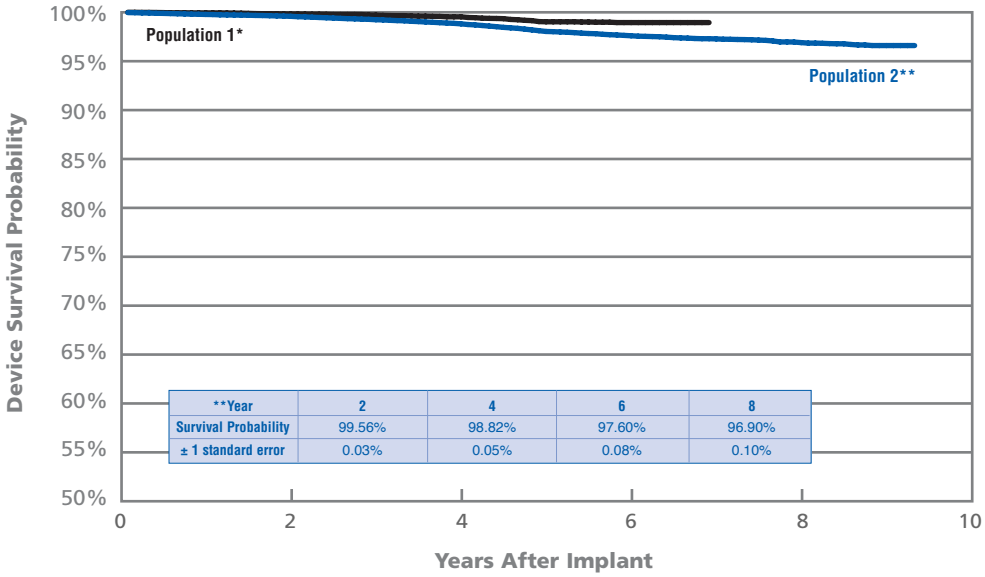
Trilogy® DC+
(Model 2318)



*Year	2	4	6	8	10
Survival Probability	100%	99.44%	99.10%		
± 1 standard error	0.00%	0.28%	0.52%		

The Trilogy® DC+ series of dual-chamber pulse generators was approved for use in January 1997.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**This group of devices is not under advisory. 611 of these devices were implanted.*
***This group of devices is subject to an advisory. See pp. 76-79 for more information. 2,111 of these devices were implanted.*

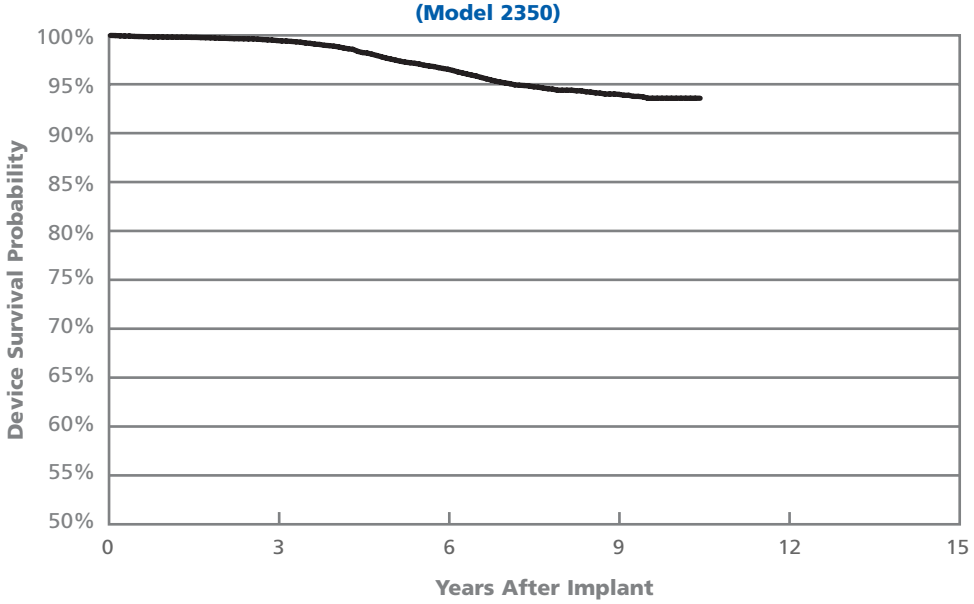
Trilogy® DR+
(Models 2360 & 2364)



*Year	2	4	6	8	10
Survival Probability	99.83%	99.54%	98.95%		
± 1 standard error	0.04%	0.07%	0.12%		

The Trilogy® DR+ series of dual-chamber, rate-responsive pulse generators was approved for use in September 1996.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**These devices are not under advisory. 11,679 of these devices were implanted.*
***These devices are subject to an advisory. See pp. 76-79 for more information. 57,945 of these devices were implanted.*

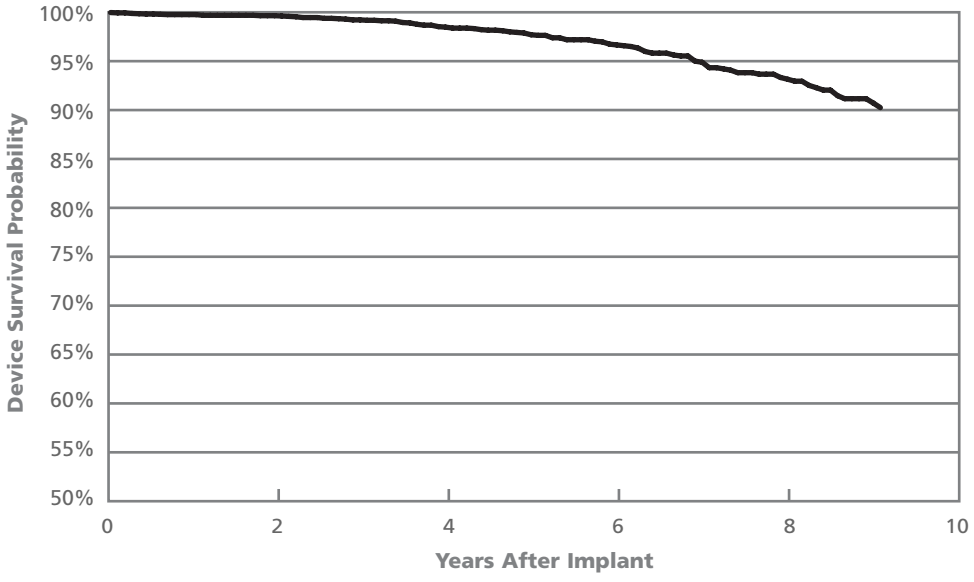
Trilogy® DR
(Model 2350)



Year	3	6	9	12	15
Survival Probability	99.47%	96.53%	93.96%		
± 1 standard error	0.05%	0.17%	0.28%		

The Trilogy® DR dual-chamber, rate-responsive pulse generator was approved for use in June 1995.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
18,739 of these devices have been implanted.
(Note: These devices are subject to an advisory. See pp. 76-79 for more information.)

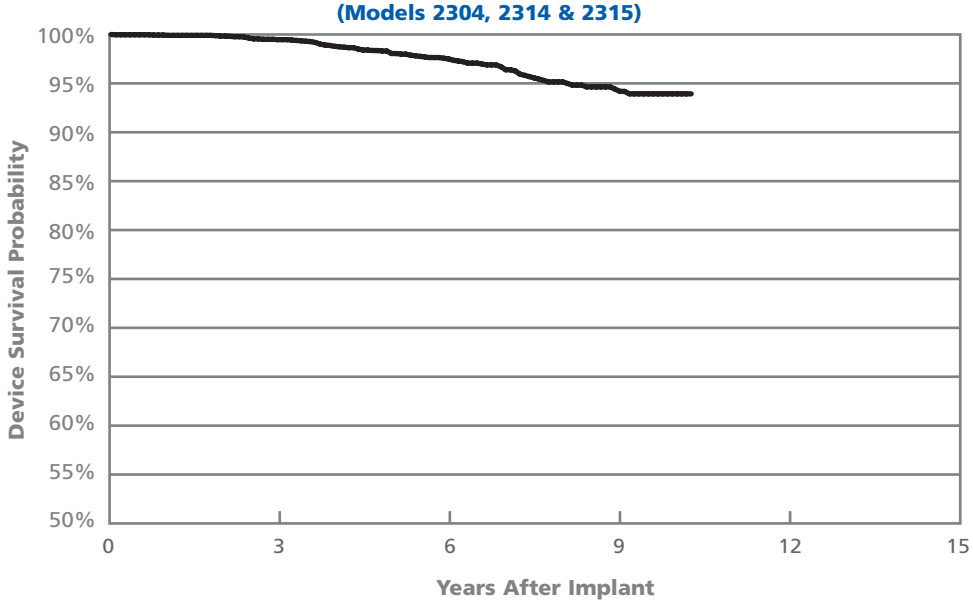
Trilogy® DC
(Model 2308)



Year	2	4	6	8	10
Survival Probability	99.65%	98.48%	96.66%	93.15%	
± 1 standard error	0.11%	0.24%	0.41%	0.73%	

The Trilogy® DC dual-chamber pulse generator was approved for use in June 1995.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,550 of these devices have been implanted.
(Note: These devices are subject to an advisory. See pp. 76-79 for more information.)

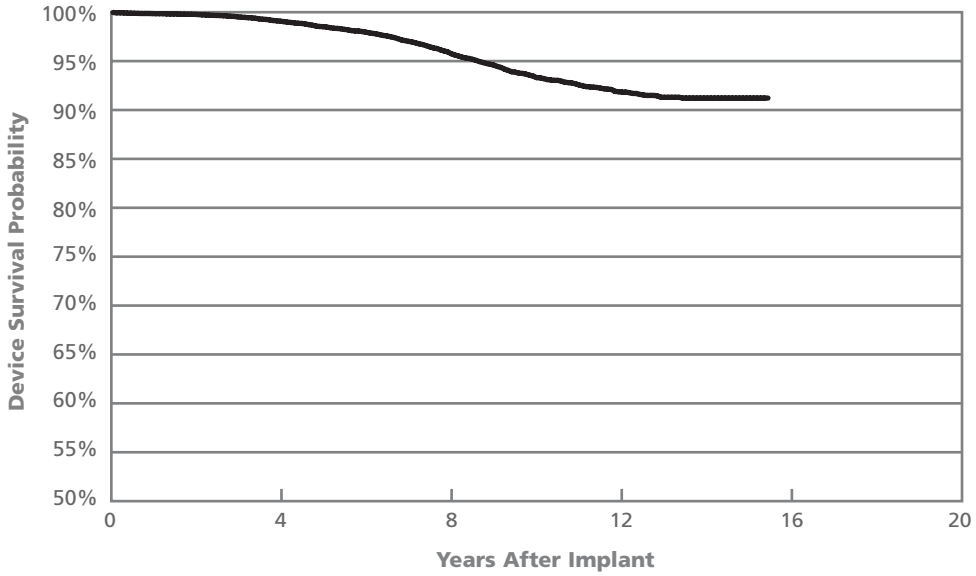
Paragon™ III
(Models 2304, 2314 & 2315)



Year	3	6	9	12	15
Survival Probability	99.47%	97.50%	94.18%		
± 1 standard error	0.13%	0.33%	0.70%		

The Paragon™ III series of dual-chamber pulse generators was introduced in October 1994.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
3,827 of these devices have been implanted.

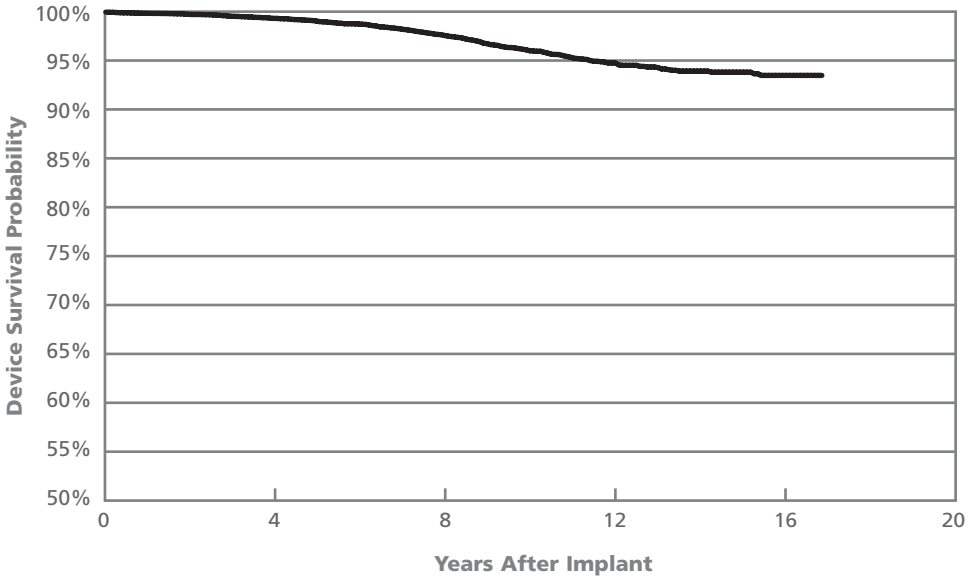
Paragon™ II
(Model 2016)



Year	4	8	12	16	20
Survival Probability	99.08%	95.76%	91.83%		
± 1 standard error	0.06%	0.17%	0.32%		

The Paragon™ II series of dual-chamber pulse generators was introduced in April 1989.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
29,058 of these devices have been implanted.

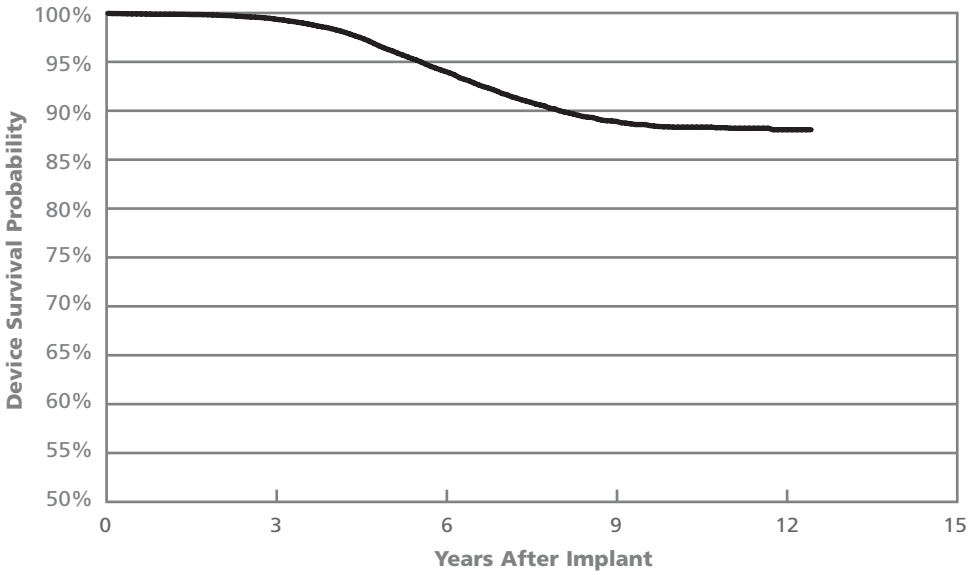
Paragon™
(Models 2010, 2011 & 2012)



Year	4	8	12	16	20
Survival Probability	99.31%	97.57%	94.75%	93.48%	
± 1 standard error	0.07%	0.16%	0.31%	0.46%	

The Paragon™ series of dual-chamber pulse generators was introduced in September 1988.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
16,663 of these devices have been implanted.

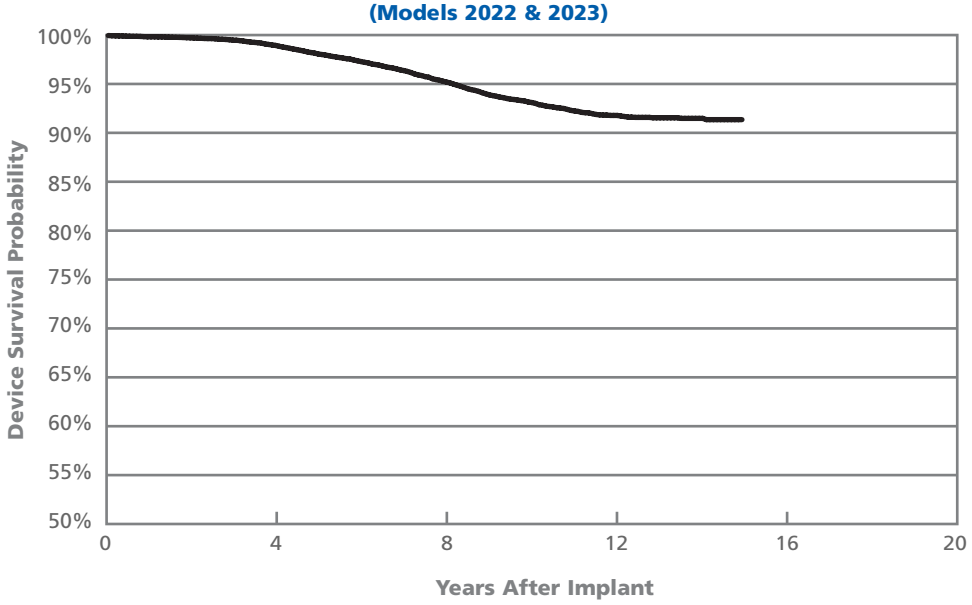
Synchrony® III
(Models 2028 & 2029)



Year	3	6	9	12	15
Survival Probability	99.39%	94.02%	88.91%	88.06%	
± 1 standard error	0.04%	0.15%	0.28%	0.35%	

The Synchrony® III series of dual-chamber, rate-responsive pulse generators was released in February 1993.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
43,430 of these devices have been implanted.

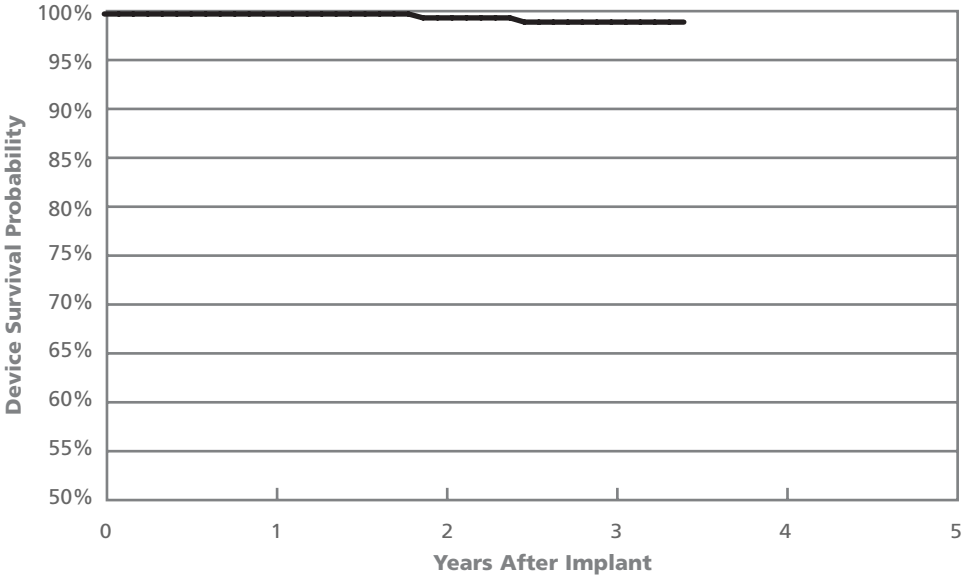
Synchrony® II
(Models 2022 & 2023)



Year	4	8	12	16	20
Survival Probability	98.94%	95.19%	91.78%		
± 1 standard error	0.05%	0.13%	0.22%		

The Synchrony® II series of dual-chamber, rate-responsive pulse generators was released in June 1990.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
47,238 of these devices have been implanted.

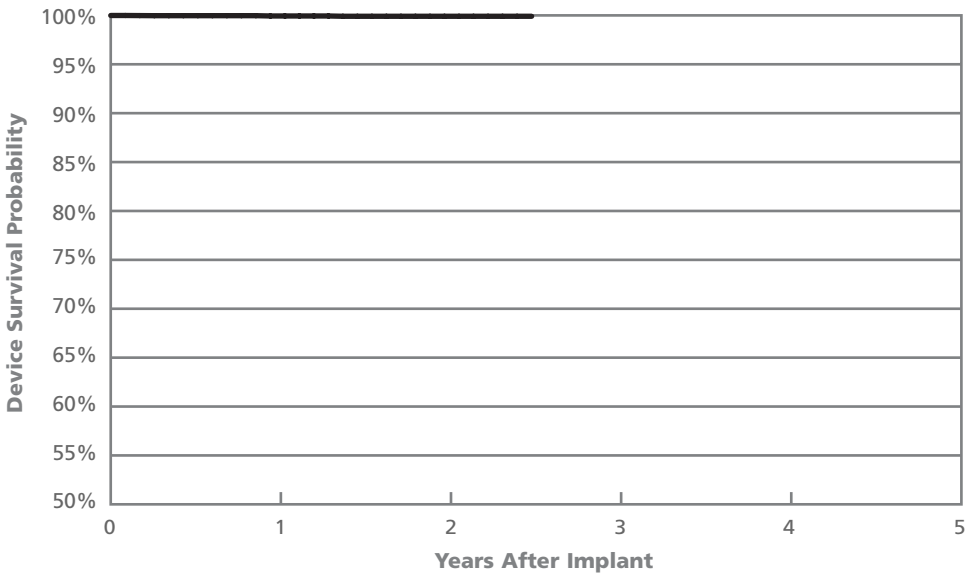
AddVent®
(Model 2060)



Year	1	2	3	4	5
Survival Probability	99.71%	99.31%	98.88%		
± 1 standard error	0.29%	0.49%	0.65%		

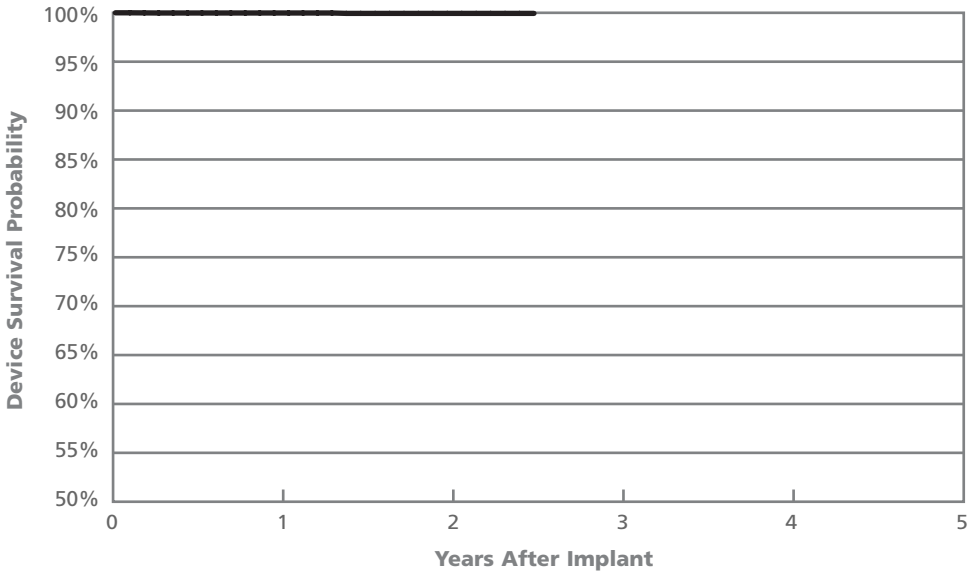
The AddVent® single-lead, dual-chamber pulse generator was approved for use in May 1999.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
353 of these devices have been implanted.

Identity® ADx SR
(Model 5180)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.94%	99.91%			
± 1 standard error	0.02%	0.05%			

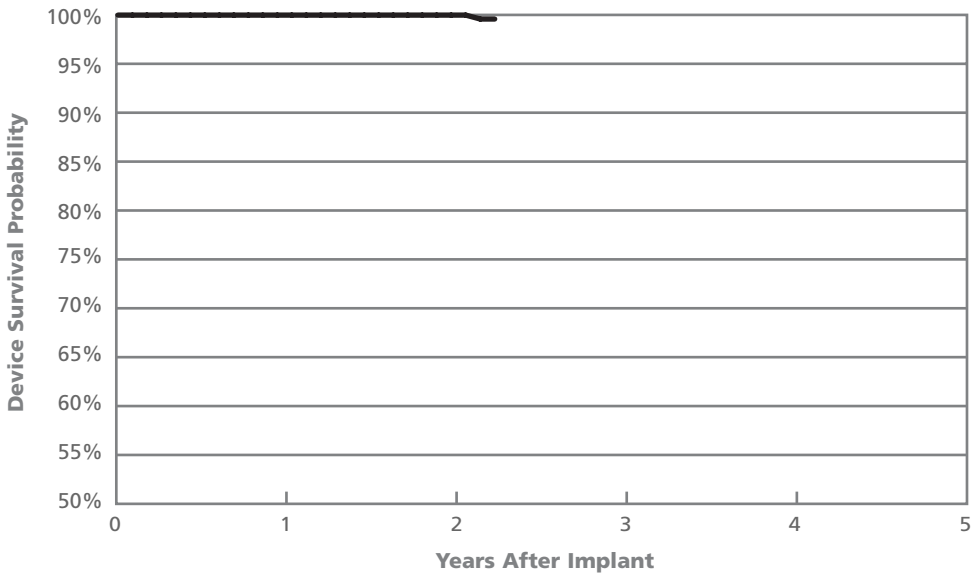
Identity® ADx SR
(Model 5180)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.98%	99.94%			
± 1 standard error	0.02%	0.04%			

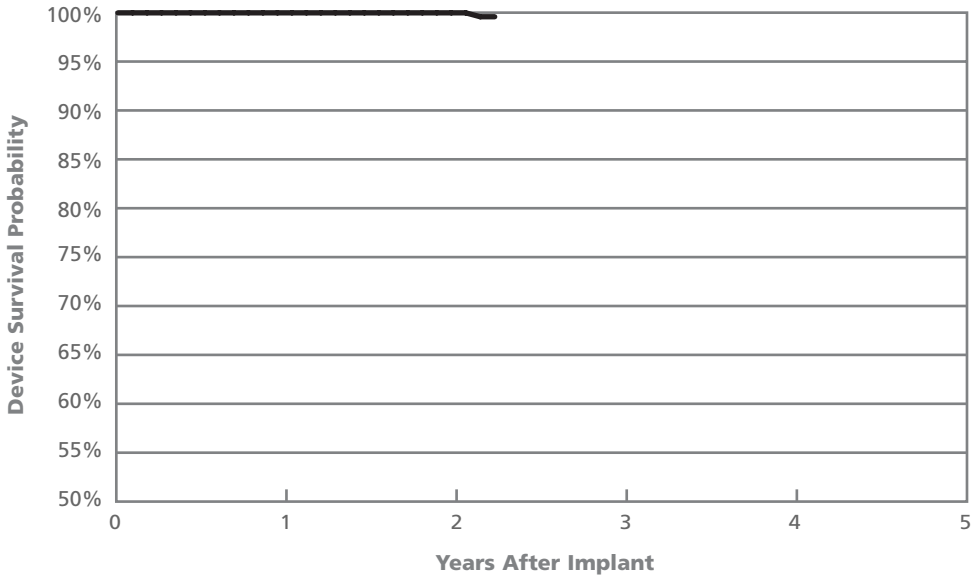
The Identity® ADx SR single-chamber, rate-responsive pulse generator was approved for use in May 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
10,449 of these devices have been implanted.

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



Year	1	2	3	4	5
Survival Probability	99.98%	99.98%			
± 1 standard error	0.02%	0.02%			

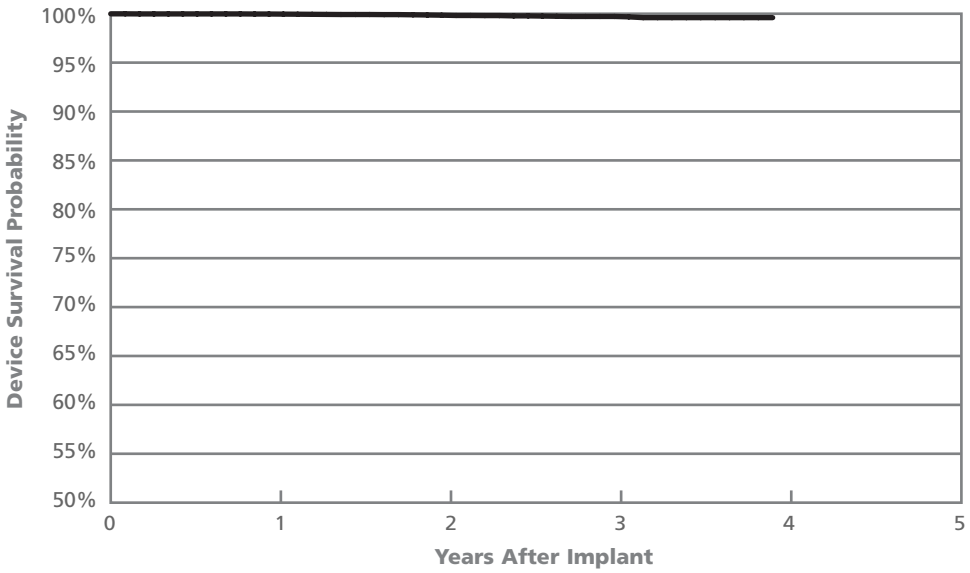
Verity® ADx XL SR (Model 5156)
Verity® ADx XL SR M/S (Model 5157M/S); Verity® ADx XL SC (Model 5056)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.98%	99.98%			
± 1 standard error	0.02%	0.02%			

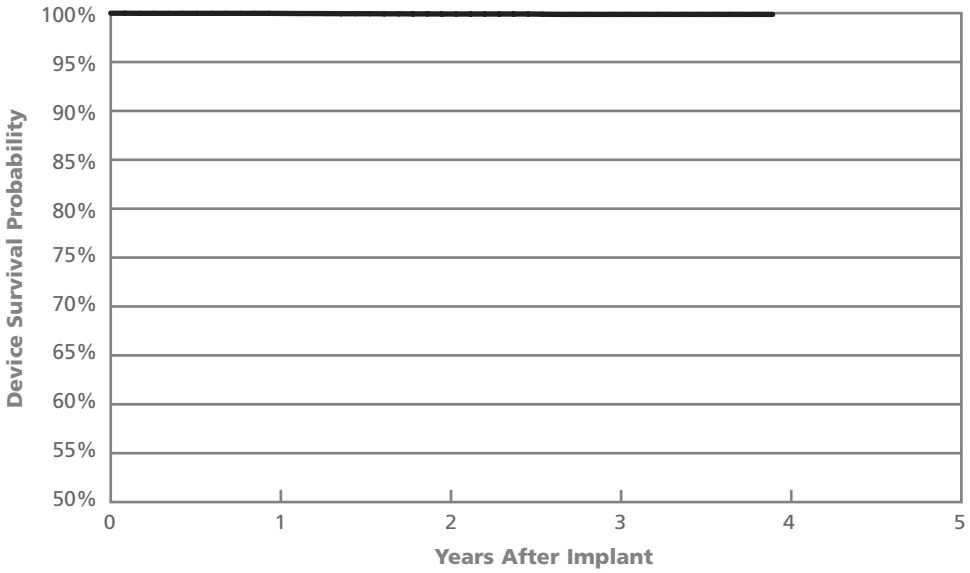
The Verity® ADx XL SR and Verity® ADx XL SR M/S single-chamber, rate-responsive pulse generators and the Verity® ADx XL SC single-chamber pulse generator were approved for use in May 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
5,576 of these devices have been implanted.

Identity® SR
(Model 5172)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.97%	99.85%	99.72%		
± 1 standard error	0.01%	0.03%	0.06%		

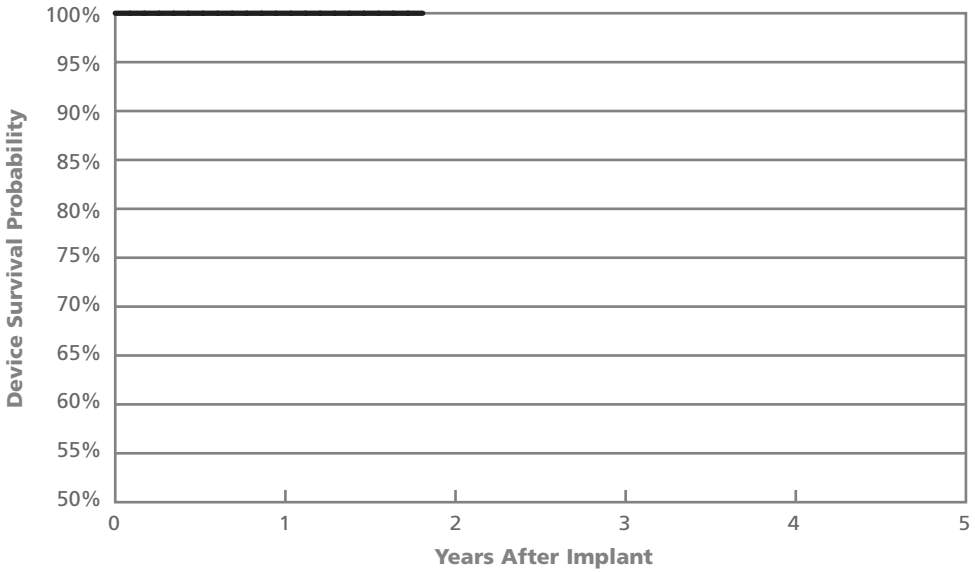
Identity® SR
(Model 5172)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	99.98%	99.91%	99.87%		
± 1 standard error	0.01%	0.03%	0.04%		

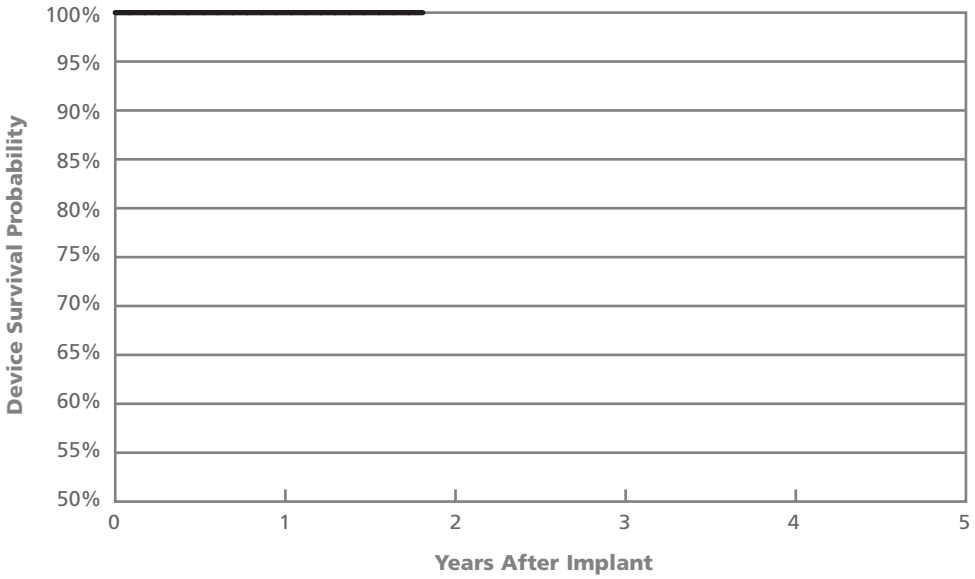
The Identity® SR single-chamber, rate-responsive pulse generator was approved for use in November 2001.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
18,850 of these devices have been implanted.

Integrity® ADx SR
(Model 5160)
Including Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

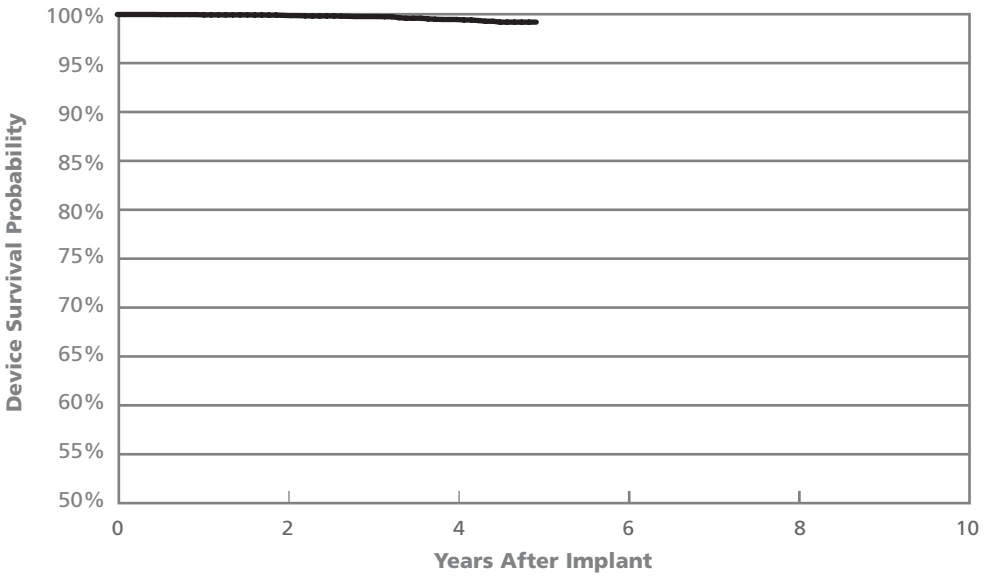
Integrity® ADx SR
(Model 5160)
Excluding Normal Battery Depletion



Year	1	2	3	4	5
Survival Probability	100%				
± 1 standard error	0.00%				

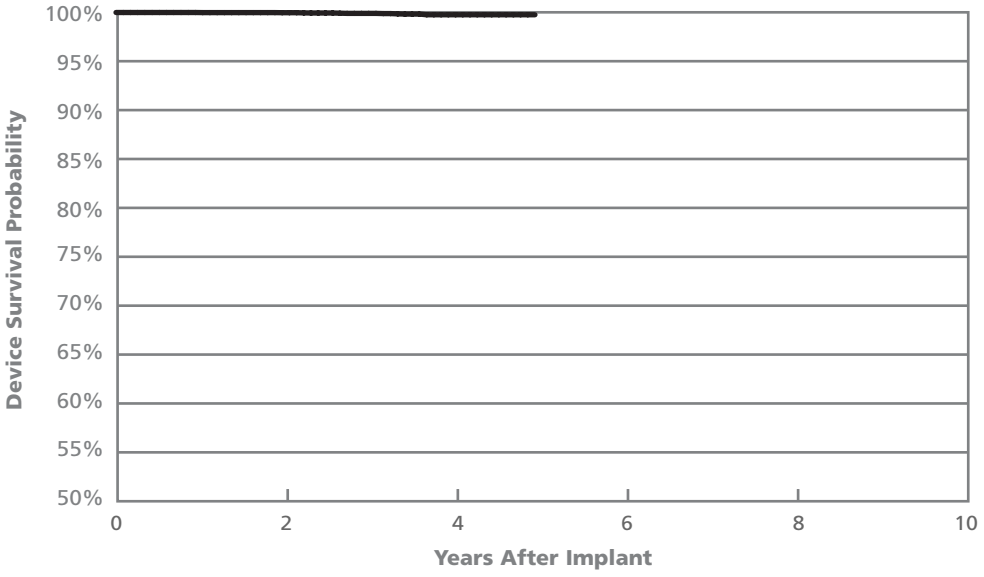
The Integrity® ADX SR single-chamber, rate-responsive pulse generator was approved for use in May 2003.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,025 of these devices have been implanted.

Integrity® µ SR
(Model 5136)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.88%	99.46%			
± 1 standard error	0.03%	0.11%			

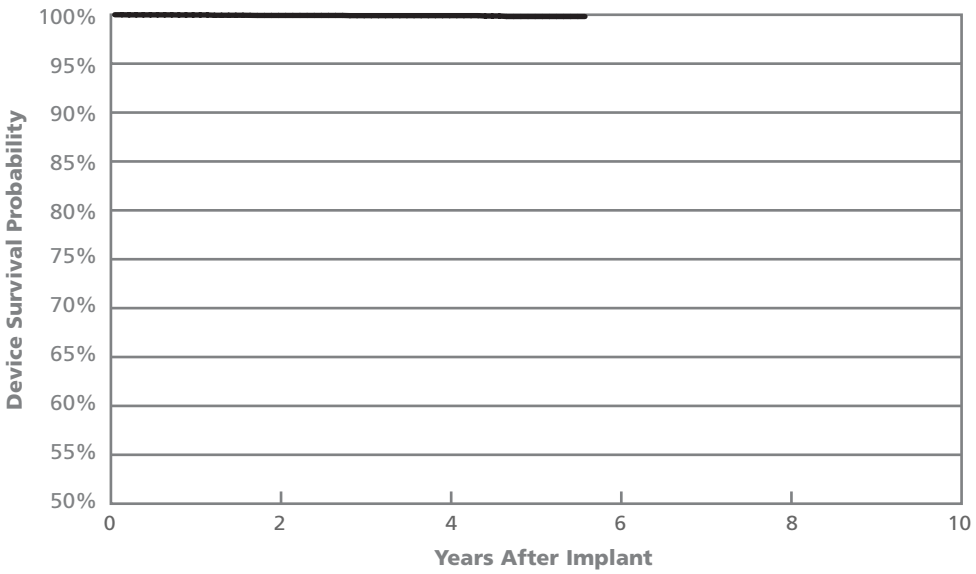
Integrity® µ SR
(Model 5136)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.96%	99.75%			
± 1 standard error	0.02%	0.07%			

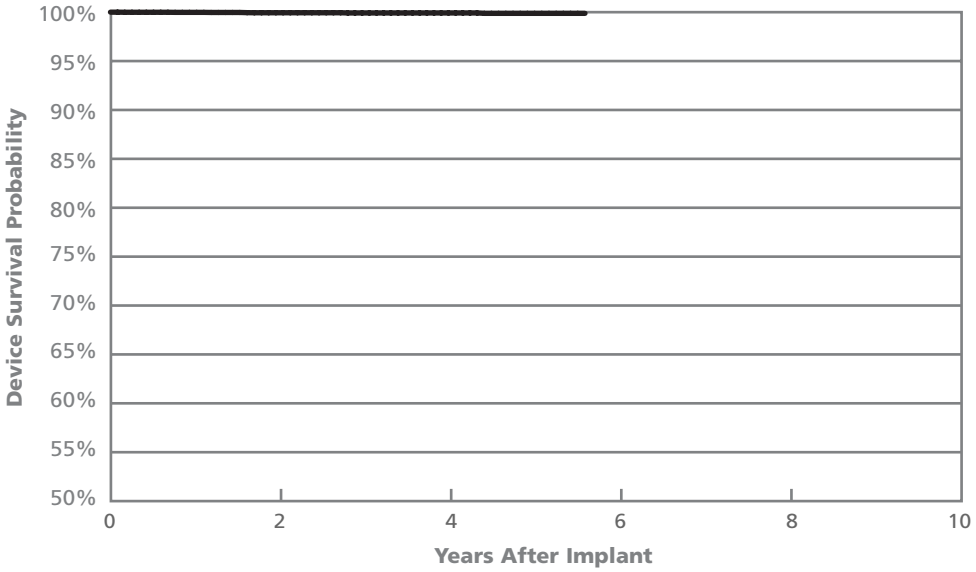
The Integrity® µ SR single-chamber, rate-responsive pulse generator was approved for use in December 2000.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
11,684 of these devices have been implanted.

Integrity® SR
(Model 5142)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.93%	99.91%			
± 1 standard error	0.03%	0.03%			

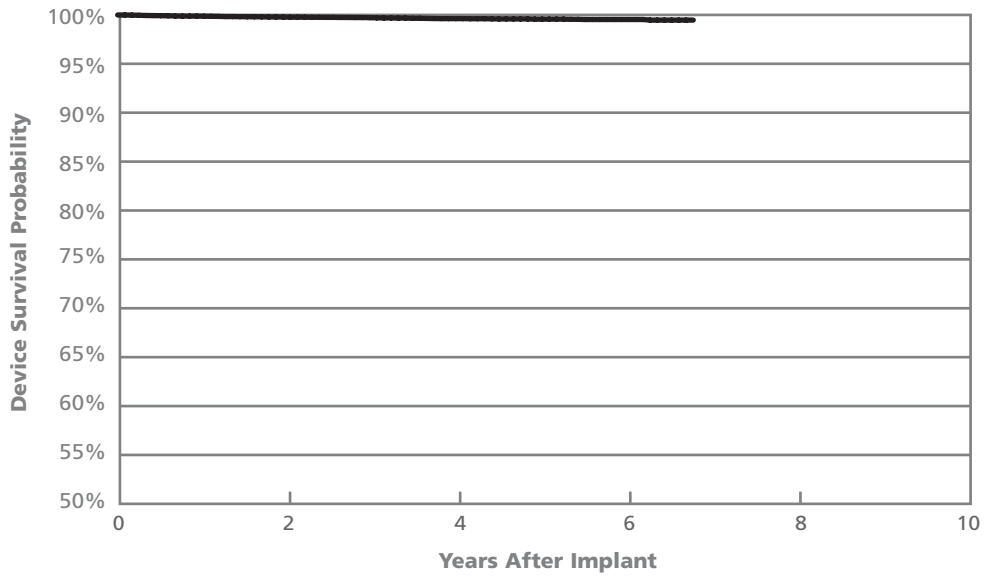
Integrity® SR
(Model 5142)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.94%	99.92%			
± 1 standard error	0.03%	0.03%			

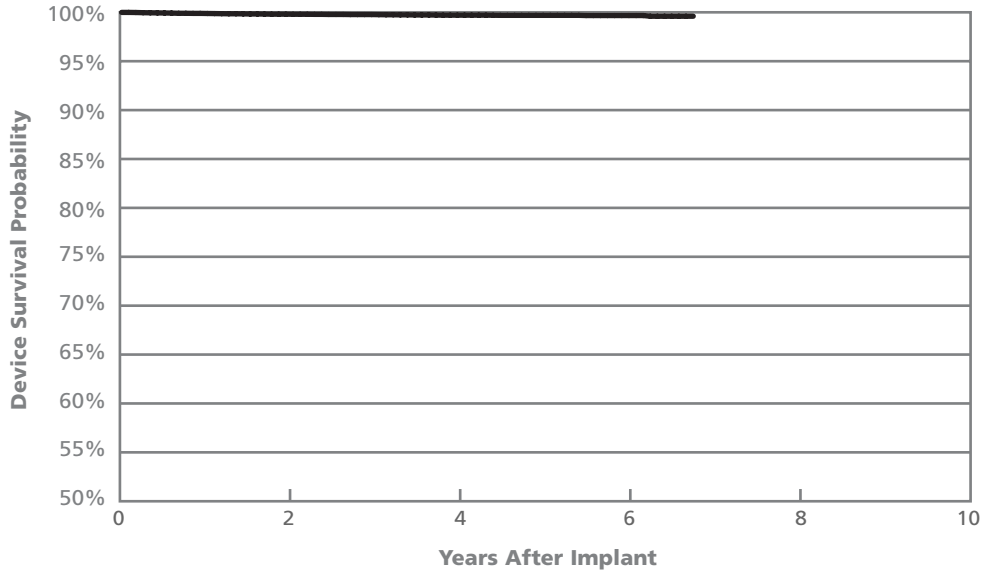
The Integrity® SR single-chamber, rate-responsive pulse generator was approved for use in April 2000.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
10,388 of these devices have been implanted.

Affinity® SR
(Models 5130 & 5131)
Including Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.78%	99.62%	99.53%		
± 1 standard error	0.03%	0.05%	0.06%		

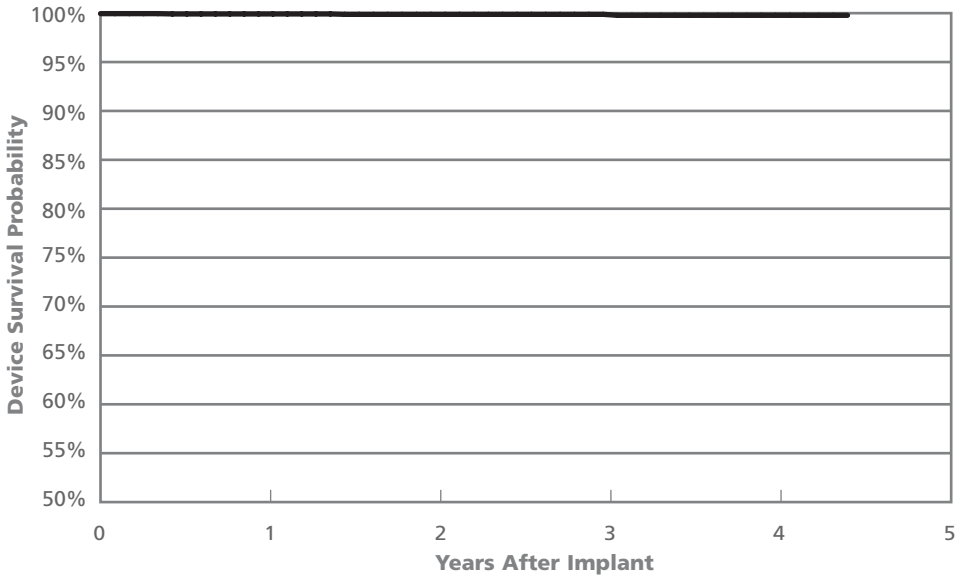
Affinity® SR
(Models 5130 & 5131)
Excluding Normal Battery Depletion



Year	2	4	6	8	10
Survival Probability	99.81%	99.71%	99.67%		
± 1 standard error	0.03%	0.04%	0.05%		

The Affinity® SR model 5130 single-chamber, rate-responsive pulse generator was approved for use in January 1999.
The Affinity® SR model 5131 single-chamber, rate-responsive pulse generator was approved for use in June 1999.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
28,582 of these devices have been implanted.
(Note: Some of these devices are subject to an advisory. See pp. 76-79 for more information.)

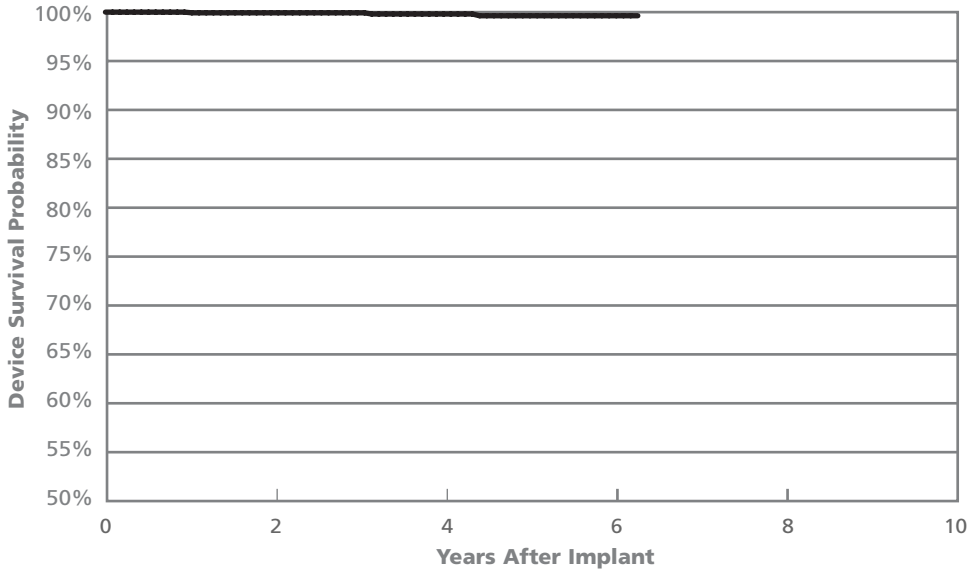
Microny®
(Models 2425T, 2525T & 2535K)



Year	1	2	3	4	5
Survival Probability	99.92%	99.88%	99.88%	99.78%	
± 1 standard error	0.04%	0.06%	0.06%	0.12%	

The Microny® model 2425T single-chamber, rate-responsive pulse generator was approved for use in December 2000.
The Microny® models 2525T and 2535K single-chamber, rate-responsive pulse generators were approved for use in April 2001.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
4,394 of these devices have been implanted.

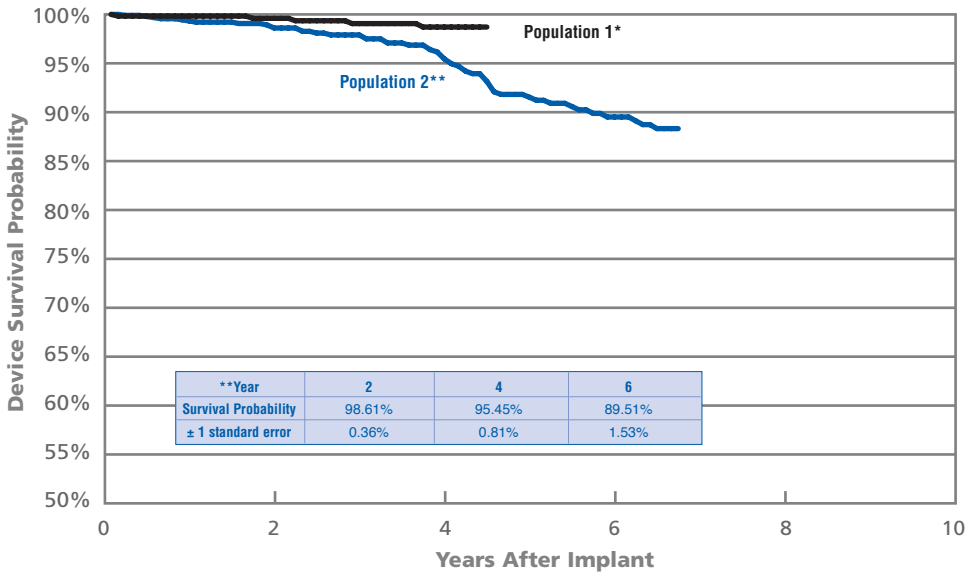
Regency® SC+
(Models 2400L & 2402L)



Year	2	4	6	8	10
Survival Probability	99.93%	99.81%	99.63%		
± 1 standard error	0.07%	0.14%	0.23%		

The Regency® SC+ series of single-chamber pulse generators was approved for use in May 1998.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
2,053 of these devices have been implanted.

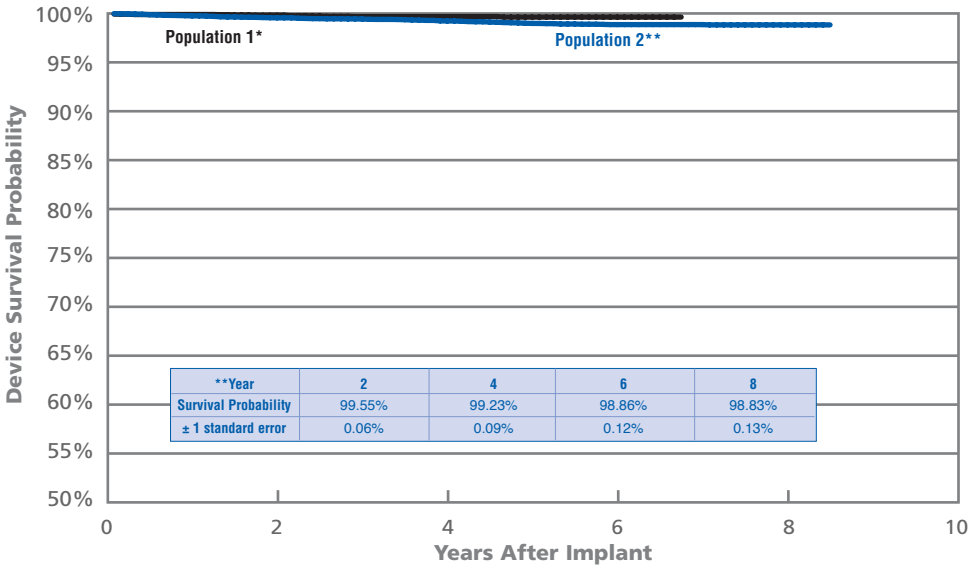
Tempo® V (Model 1102)
Tempo® VR (Model 1902)



*Year	2	4	6	8	10
Survival Probability	99.60%	98.71%			
± 1 standard error	0.29%	0.59%			

The Tempo® V single-chamber pulse generator and the Tempo® VR single-chamber, rate-responsive pulse generator were approved for use in August 1997. These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**This group of devices is not under advisory. 604 of these devices were implanted.*
***This group of devices is subject to an advisory. See pp. 76-79 for more information. 1,046 of these devices were implanted.*

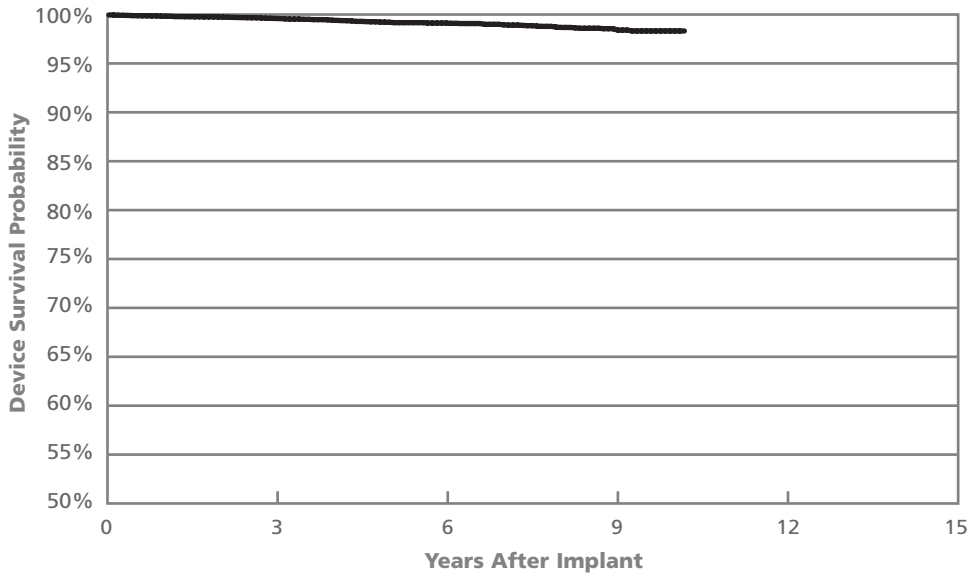
Trilogy® SR+
(Models 2260 & 2264)



*Year	2	4	6	8	10
Survival Probability	99.82%	99.68%	99.63%		
± 1 standard error	0.06%	0.09%	0.10%		

The Trilogy® SR+ series of single-chamber, rate-responsive pulse generators was approved for use in March 1997. These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
**This group of devices is not under advisory. 5,796 of these devices were implanted.*
***This group of devices is subject to an advisory. See pp. 76-79 for more information. 12,949 of these devices were implanted.*

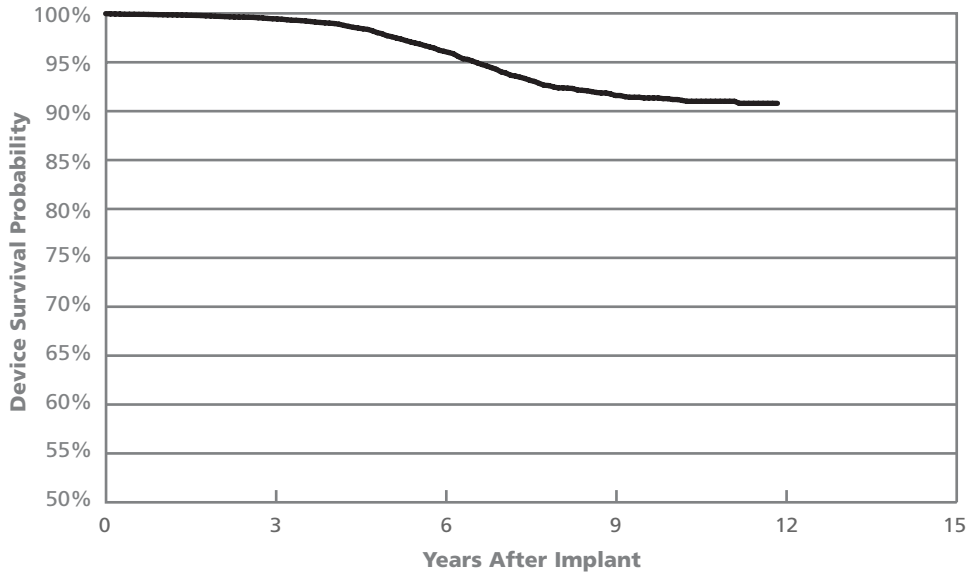
Trilogy® SR
(Models 2250)



Year	3	6	9	12	15
Survival Probability	99.60%	99.13%	98.41%		
± 1 standard error	0.06%	0.11%	0.18%		

The Trilogy® SR single-chamber, rate-responsive pulse generator was approved for use in June 1995.
This model is no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
12,441 of these devices have been implanted.
(Note: These devices are subject to an advisory. See pp. 76-79 for more information.)

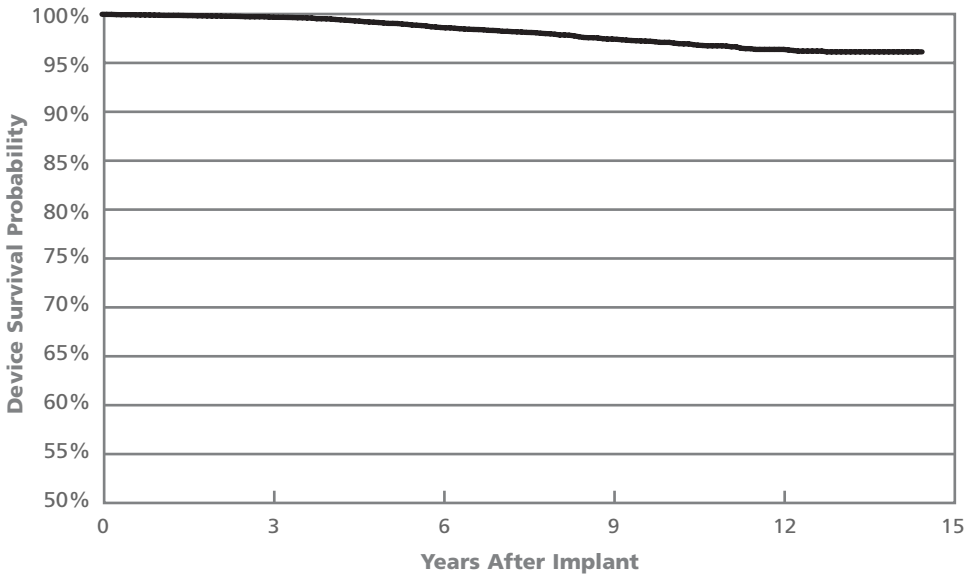
Solus® II
(Models 2006 & 2007)



Year	3	6	9	12	15
Survival Probability	99.45%	96.12%	91.60%		
± 1 standard error	0.05%	0.16%	0.34%		

The Solus® II series of single-chamber, rate-responsive pulse generators was introduced in February 1993.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
32,317 of these devices have been implanted.

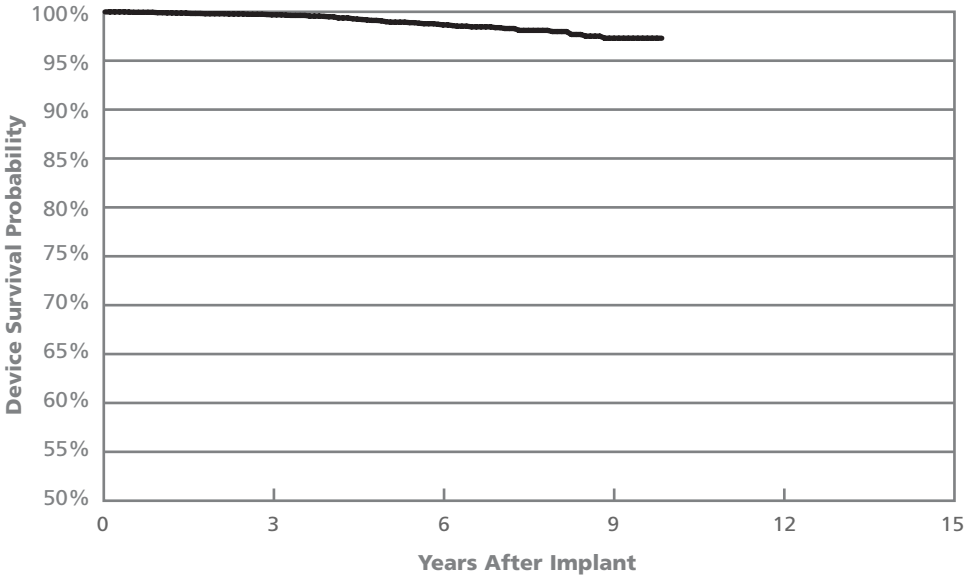
Solus®
(Models 2002 & 2003)



Year	3	6	9	12	15
Survival Probability	99.69%	98.62%	97.44%	96.38%	
± 1 standard error	0.04%	0.10%	0.16%	0.24%	

The Solus® series of single-chamber, rate-responsive pulse generators was introduced in June 1990.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
23,851 of these devices have been implanted.

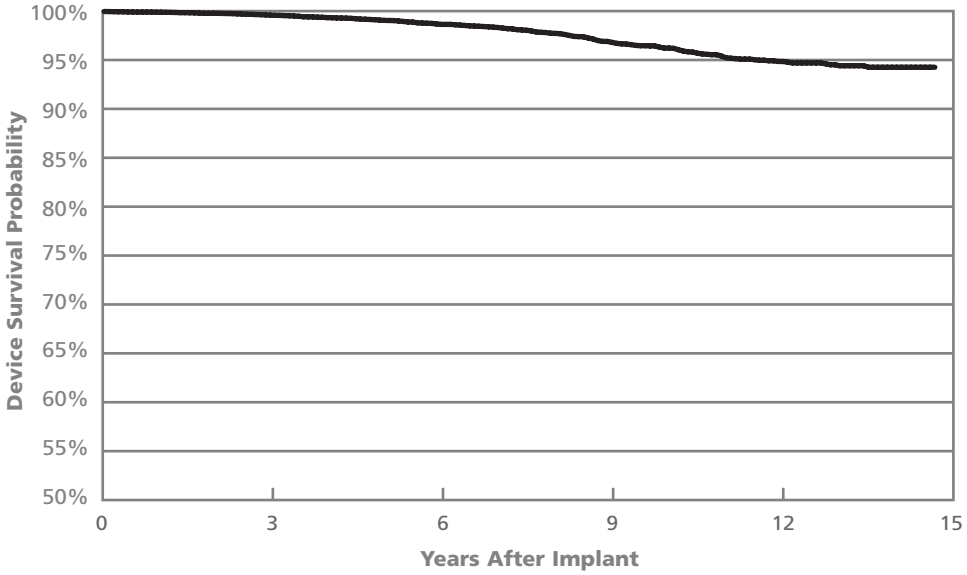
Phoenix® III
(Models 2204 & 2205)



Year	3	6	9	12	15
Survival Probability	99.69%	98.66%	97.30%		
± 1 standard error	0.08%	0.22%	0.48%		

The Phoenix® III series of single-chamber pulse generators was introduced in October 1994.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
6,744 of these devices have been implanted.

Phoenix® 2
(Models 2005, 2008 & 2009)



Year	3	6	9	12	15
Survival Probability	99.59%	98.64%	96.80%	94.85%	
± 1 standard error	0.05%	0.10%	0.21%	0.34%	

The Phoenix® 2 series of single-chamber pulse generators was introduced in July 1990.
These models are no longer being manufactured.
Survival probability (%) is based on returned product analysis as of January 31, 2006.
26,757 of these devices have been implanted.

Pulse Generators Summary Information*

Including Normal Battery Depletion

Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy (not under advisory)	Malfunctions w/o Compromised Therapy (under advisory**)	Malfunctions w/o Compromised Therapy	Total Malfunctions	Normal Battery Depletion
5586	Frontier II	Aug-04	859	815	0	0	0	0	0
5380	Identity ADx DR	Mar-03	35373	32564	0	0	2	2	3
5386/5286	Identity ADx XL DR/DC	Mar-03	33958	32116	1	0	8	9	0
5360/5366	Integrity ADx DR	May-03	7474	6938	0	0	3	3	0
5356/5357/5256	Verity ADX XL DR/ DR(M/S) / DC	May-03	8568	7863	0	0	4	4	0
5370	Identity	Nov-01	53478	41852	5	0	26	31	149
5376	Identity XL	Nov-01	45706	38793	6	0	23	29	15
5336	Integrity µ DR	Dec-00	29000	17014	6	0	27	33	484
5342/5346	Integrity AFx DR	Apr-00/Jul-01	46991	32509	4	0	34	38	66
5326/5226	Entity DR/DC	Jun-99	21740	13010	3	0	16	19	58
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65333	37250	14	64	81	159	342
5430	Affinity VDR	Apr-00	663	390	0	0	0	0	1
5180	Integrity ADx SR	May-03	10449	9201	0	0	1	1	2
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	May-03	5576	4928	0	0	2	2	0
5172	Identity SR	Nov-01	18850	13944	1	0	8	9	18
5160	Integrity ADx SR	May-03	2025	1764	0	0	0	0	0
5136	Integrity µ SR	Dec-00	11684	6766	0	0	2	2	17
5142	Integrity SR	Apr-00	10388	5921	1	0	2	3	2
5130/5131	Affinity SR	Jan-99/Jun-99	28582	13553	4	17	25	46	36

Excluding Normal Battery Depletion

Model	Family	Market Release Date	Registered US implants	Estimated Active US implants	Malfunctions w/ Compromised Therapy (not under advisory)	Malfunctions w/o Compromised Therapy (under advisory**)	Malfunctions w/o Compromised Therapy	Total Malfunctions
5586	Frontier II	Aug-04	859	815	0	0	0	0
5380	Identity ADx DR	Mar-03	35373	32564	0	0	2	2
5386/5286	Identity ADx XL DR/DC	Mar-03	33958	32116	1	0	8	9
5360/5366	Integrity ADx DR	May-03	7474	6938	0	0	3	3
5356/5357/5256	Verity ADX XL DR/ DR(M/S) / DC	May-03	8568	7863	0	0	4	4
5370	Identity	Nov-01	53478	41852	5	0	26	31
5376	Identity XL	Nov-01	45706	38793	6	0	23	29
5336	Integrity µ DR	Dec-00	29000	17014	6	0	27	33
5342/5346	Integrity AFx DR	Apr-00/Jul-01	46991	32509	4	0	34	38
5326/5226	Entity DR/DC	Jun-99	21740	13010	3	0	16	19
5330/5331/5230	Affinity DR/DC	Jan-99/Jun-99	65333	37250	14	64	81	159
5430	Affinity VDR	Apr-00	663	390	0	0	0	0
5180	Integrity ADx SR	May-03	10449	9201	0	0	1	1
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	May-03	5576	4928	0	0	2	2
5172	Identity SR	Nov-01	18850	13944	1	0	8	9
5160	Integrity ADx SR	May-03	2025	1764	0	0	0	0
5136	Integrity µ SR	Dec-00	11684	6766	0	0	2	2
5142	Integrity SR	Apr-00	10388	5921	1	0	2	3
5130/5131	Affinity SR	Jan-99/Jun-99	28582	13553	4	17	25	46

Pulse Generators Summary Information*

Including Normal Battery Depletion

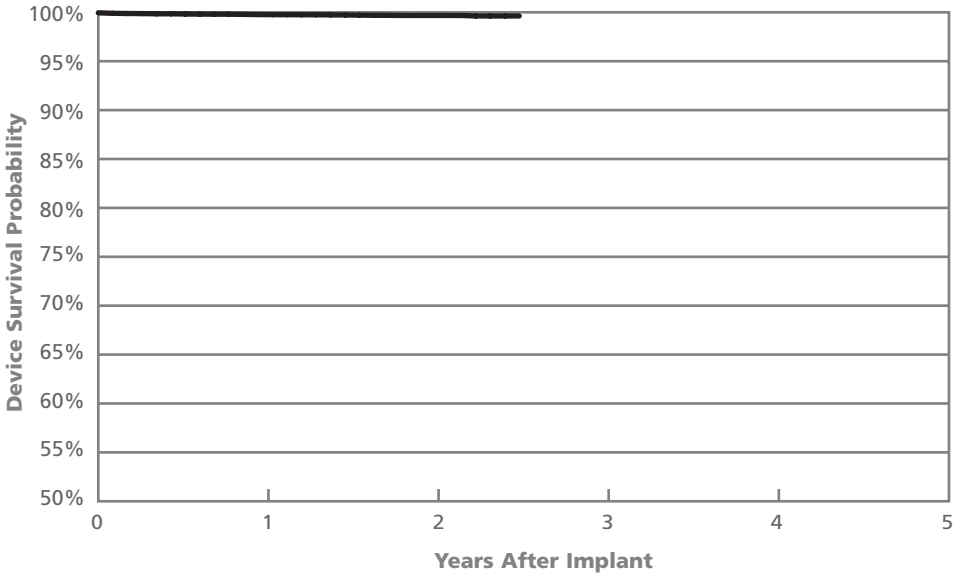
Model	Family	Survival Probability							
		1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
5586	Frontier II†								
5380	Identity ADx DR	99.95%	99.86%						
5386/5286	Identity ADx XL DR/DC	99.95%	99.91%						
5360/5366	Integrity ADx DR	99.95%	99.95%						
5356/5357/5256	Verity ADX XL DR/ DR(M/S) / DC	99.93%	99.93%						
5370	Identity	99.93%	99.79%	99.43%	98.00%				
5376	Identity XL	99.93%	99.85%	99.79%	99.71%				
5336	Integrity µ DR	99.87%	99.66%	98.82%	96.37%	93.53%			
5342/5346	Integrity AFx DR	99.92%	99.87%	99.80%	99.73%	99.52%			
5326/5226	Entity DR/DC	99.92%	99.86%	99.75%	99.54%	99.30%	99.18%		
5330/5331/5230	Affinity DR/DC	99.81%	99.73%	99.63%	99.41%	99.07%	98.83%	98.55%	
5430	Affinity VDR	100%	100%	100%	99.59%				
5180	Integrity ADx SR	99.94%	99.91%						
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	99.98%	99.98%						
5172	Identity SR	99.97%	99.85%	99.72%					
5160	Integrity ADx SR	100%							
5136	Integrity µ SR	99.96%	99.88%	99.76%	99.46%				
5142	Integrity SR	99.98%	99.93%	99.91%	99.91%	99.82%			
5130/5131	Affinity SR	99.88%	99.78%	99.72%	99.62%	99.57%	99.53%		

Excluding Normal Battery Depletion

Model	Family	Survival Probability							
		1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
5586	Frontier II†								
5380	Identity ADx DR	99.96%	99.92%						
5386/5286	Identity ADx XL DR/DC	99.95%	99.92%						
5360/5366	Integrity ADx DR	99.95%	99.95%						
5356/5357/5256	Verity ADX XL DR/ DR(M/S) / DC	99.93%	99.93%						
5370	Identity	99.95%	99.88%	99.80%	99.61%				
5376	Identity XL	99.93%	99.85%	99.84%	99.82%				
5336	Integrity µ DR	99.89%	99.83%	99.69%	99.50%	99.20%			
5342/5346	Integrity AFx DR	99.92%	99.88%	99.84%	99.80%	99.75%			
5326/5226	Entity DR/DC	99.93%	99.89%	99.82%	99.80%	99.78%	99.78%		
5330/5331/5230	Affinity DR/DC	99.82%	99.75%	99.70%	99.59%	99.49%	99.44%	99.37%	
5430	Affinity VDR	100%	100%	100%	100%				
5180	Integrity ADx SR	99.98%	99.94%						
5156/5157/5056	Verity ADX XL SR/ SR(M/S) / SC	99.98%	99.98%						
5172	Identity SR	99.98%	99.91%	99.87%					
5160	Integrity ADx SR	100%							
5136	Integrity µ SR	99.98%	99.96%	99.89%	99.75%				
5142	Integrity SR	99.98%	99.94%	99.92%	99.92%	99.88%			
5130/5131	Affinity SR	99.89%	99.81%	99.77%	99.71%	99.69%	99.67%		

*Based on returned product analysis as of January 31, 2006.
**St. Jude Medical. Affinity unsecured resistor connection (advisory). February 2000.
†No survival probability is stated at 1 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.

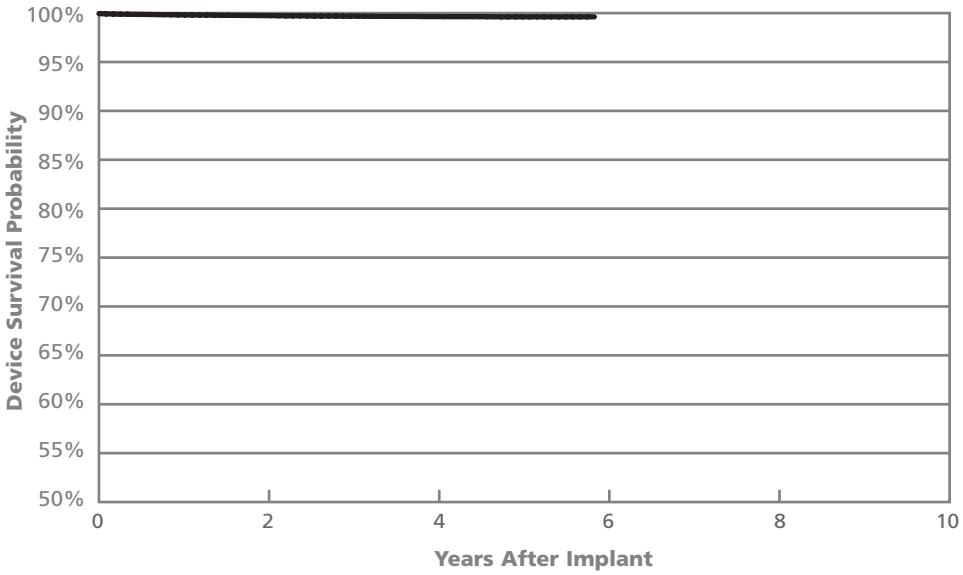
Tendril® SDX (Model 1688T)
Bipolar Active Fixation Silicone Lead



Year	1	2	3	4	5
Survival Probability	99.77%	99.68%			
± 1 standard error	0.02%	0.03%			

Data is current as of January 31, 2006.
123,768 of these leads have been implanted.
(Approval date: June 2003)

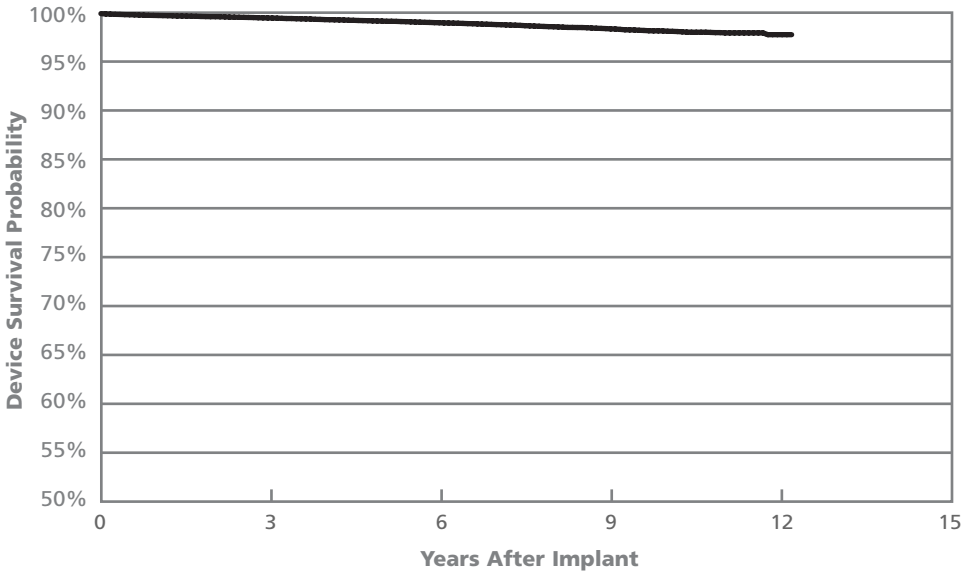
Tendril® SDX (Models 1488T & 1488TC)
Bipolar Active Fixation Silicone Leads



Year	2	4	6	8	10
Survival Probability	99.75%	99.64%			
± 1 standard error	0.01%	0.02%			

Data is current as of January 31, 2006.
239,762 of these leads have been implanted.
(Approval date: March 2000)

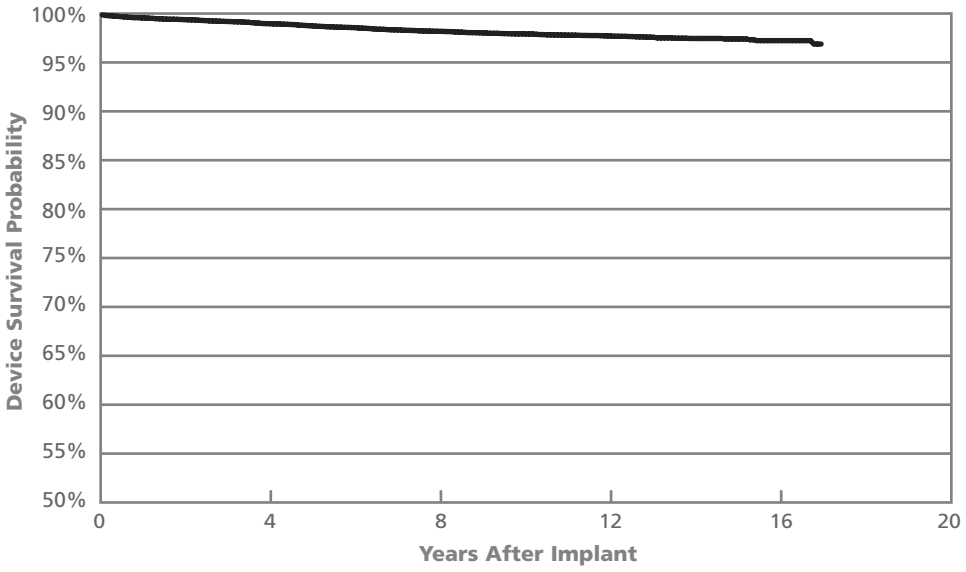
Tendril® (Models 1148 & 1188T); Tendril® DX (Models 1388T & 1388TC)
Bipolar Active Fixation Silicone Leads



Year	3	6	9	12	15
Survival Probability	99.46%	98.97%	98.34%	97.75%	
± 1 standard error	0.01%	0.02%	0.05%	0.16%	

Data is current as of January 31, 2006.
The Tendril® lead models 1148 and 1188T are no longer being manufactured.
296,697 of these leads have been implanted.
(Approval dates: 1148–June 1993; 1188T–June 1994; 1388T–June 1997; 1388TC–March 1998)

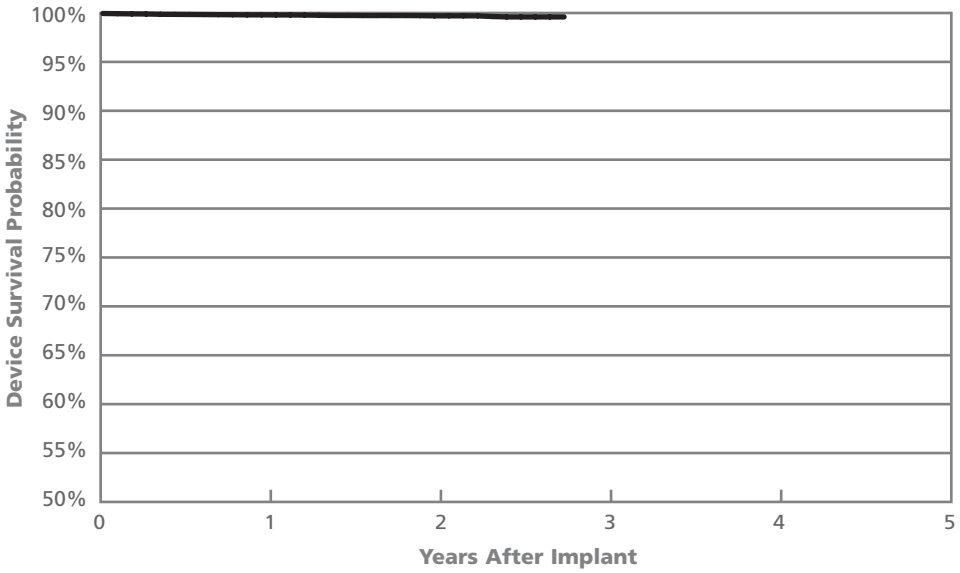
Fast-Pass® (Models 1018T & 1028T)
Bipolar Active Fixation Silicone Leads



Year	4	8	12	16	20
Survival Probability	98.96%	98.18%	97.70%	97.23%	
± 1 standard error	0.07%	0.10%	0.12%	0.19%	

Data is current as of January 31, 2006.
These lead models are no longer being manufactured.
28,031 of these leads have been implanted.
(Approval dates: 1018T–February 1988; 1028T–July 1990)

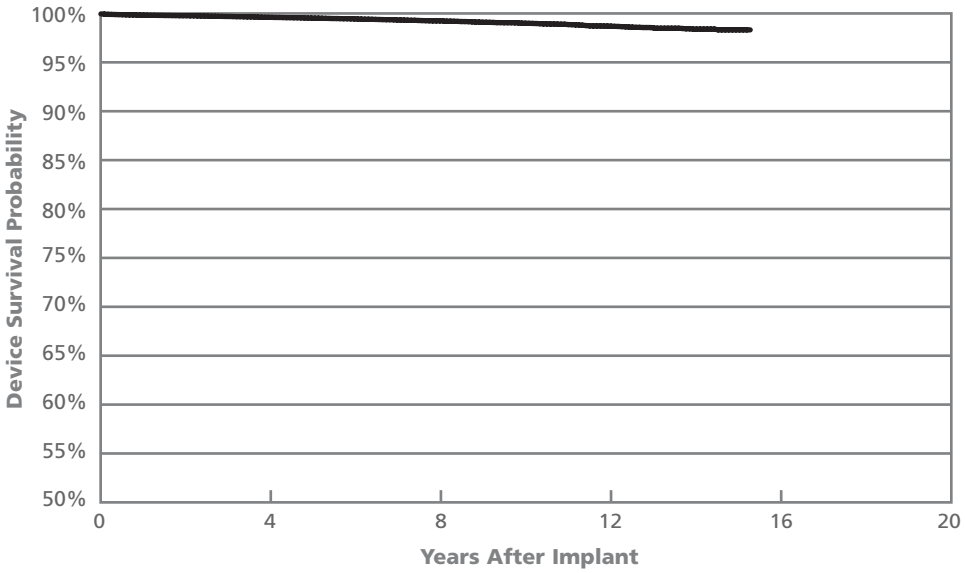
IsoFlex® S (Models 1642T & 1646T)
Bipolar Passive Fixation Silicone Leads



Year	1	2	3	4	5
Survival Probability	99.81%	99.71%			
± 1 standard error	0.03%	0.04%			

Data is current as of January 31, 2006.
37,773 of these leads have been implanted.
(Approval date: April 2003)

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

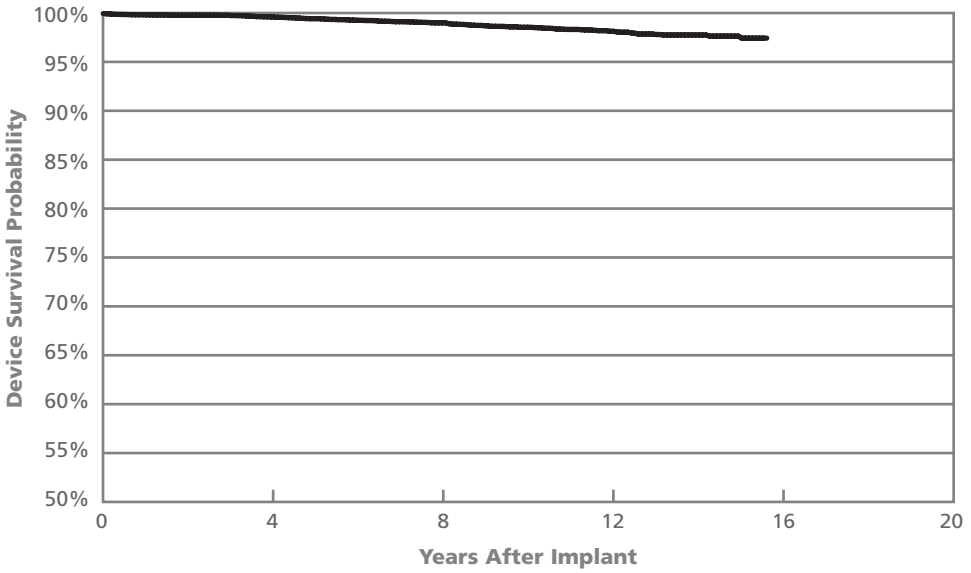


Year	4	8	12	16	20
Survival Probability	99.61%	99.24%	98.71%		
± 1 standard error	0.01%	0.02%	0.05%		

Data is current as of January 31, 2006.
The Passive Plus® lead models 1136T, 1142T, 1146T, 1222T, 1226T, 1236T, 1242T and 1246T are no longer being manufactured.
366,204 of these leads have been implanted.
(Approval dates: 1136T, 1142T, 1146T–June 1994; 1222T, 1226T, 1236T, 1242T, 1246T–April 1990; 1336T–August 1999; 1342T, 1346T–January 1998)

Permathane® ACE (Models 1036T & 1038T)

Bipolar Passive Fixation Polyurethane Leads

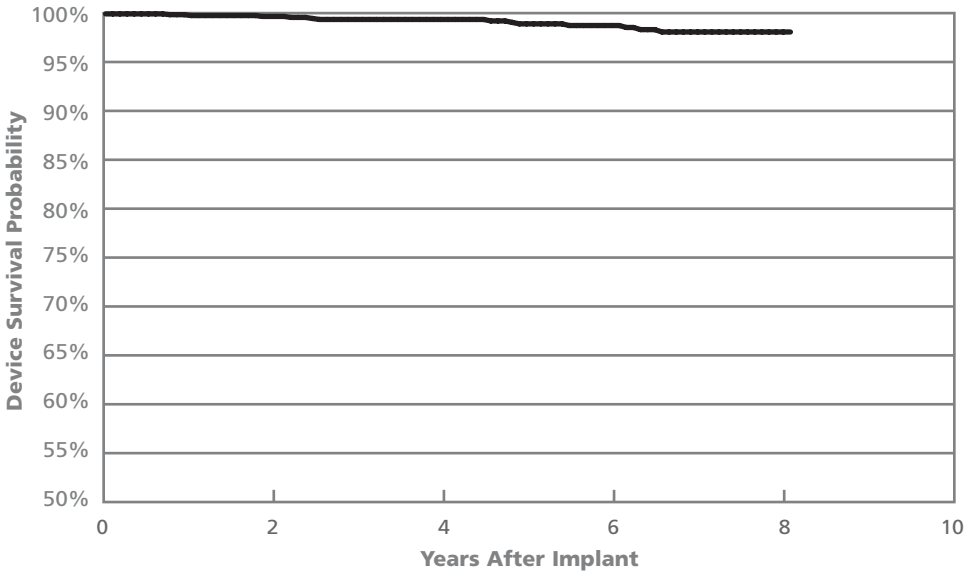


Year	4	8	12	16	20
Survival Probability	99.60%	98.99%	98.13%		
± 1 standard error	0.05%	0.09%	0.16%		

Data is current as of January 31, 2006.
These lead models are no longer being manufactured.
19,678 of these leads have been implanted.
(Approval date: June 1989)

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

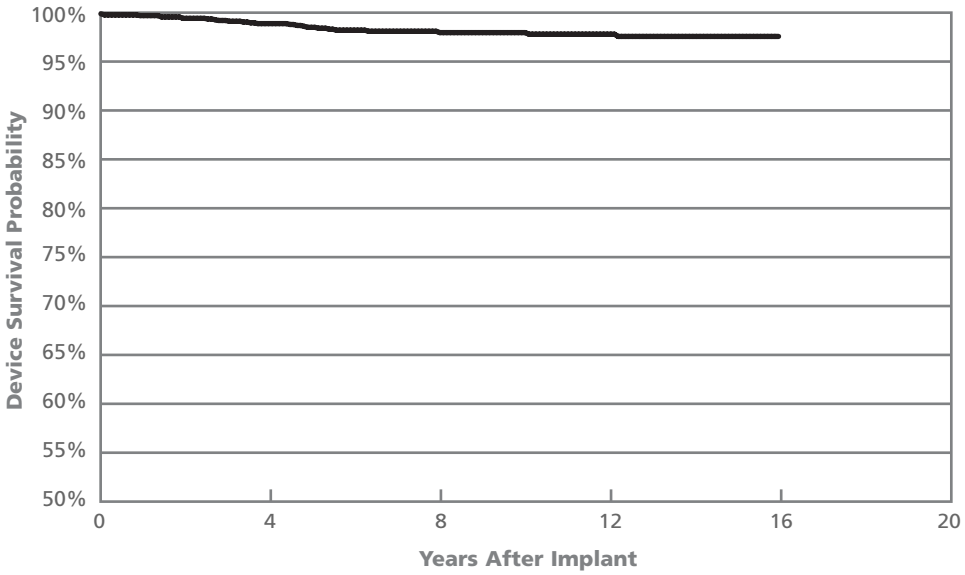
Unipolar Active Fixation Silicone Leads



Year	2	4	6	8	10
Survival Probability	99.66%	99.35%	98.73%	98.07%	
± 1 standard error	0.17%	0.25%	0.40%	0.55%	

Data is current as of January 31, 2006.
The Tendril® lead model 1188K is no longer being manufactured.
1,330 of these leads have been implanted.
(Approval dates: 1188K–June 1995; 1388K–June 1997)

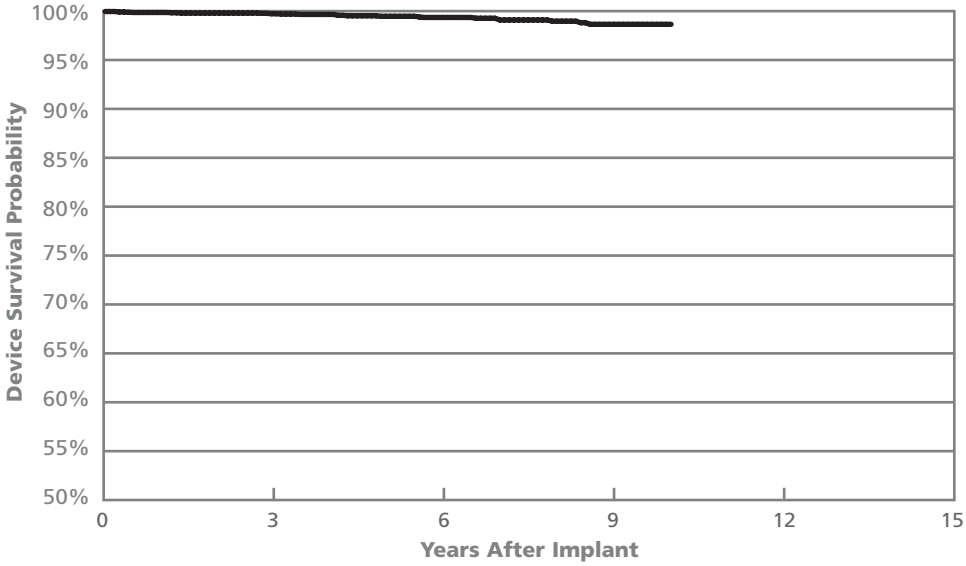
Fast-Pass® (Model 1007)
Unipolar Active Fixation Silicone Lead



Year	4	8	12	16	20
Survival Probability	98.88%	97.96%	97.80%	97.57%	
± 1 standard error	0.28%	0.39%	0.45%	0.50%	

Data is current as of January 31, 2006.
This lead model is no longer being manufactured.
1,737 of these leads have been implanted.
(Approval date: June 1987)

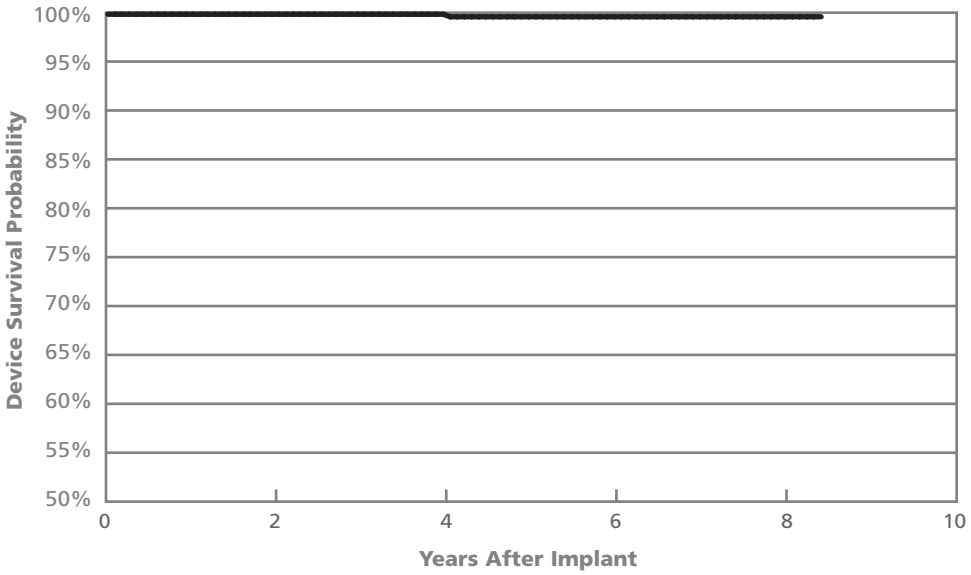
Passive Plus® (Models 1135K, 1143K, 1145K, 1235K, 1243K & 1245K)
Passive Plus® DX (Models 1343K & 1345K)
Unipolar Passive Fixation Silicone Leads



Year	3	6	9	12	15
Survival Probability	99.73%	99.35%	98.65%		
± 1 standard error	0.08%	0.16%	0.34%		

Data is current as of January 31, 2006.
The Passive Plus® lead models 1135K, 1143K, 1145K, 1235K, 1243K and 1245K are no longer being manufactured.
4,481 of these leads have been implanted.
(Approval dates: 1135K, 1143K, 1145K–July 1994; 1235K, 1243K, 1245K–August 1995;
1343K, 1345K–June 1998)

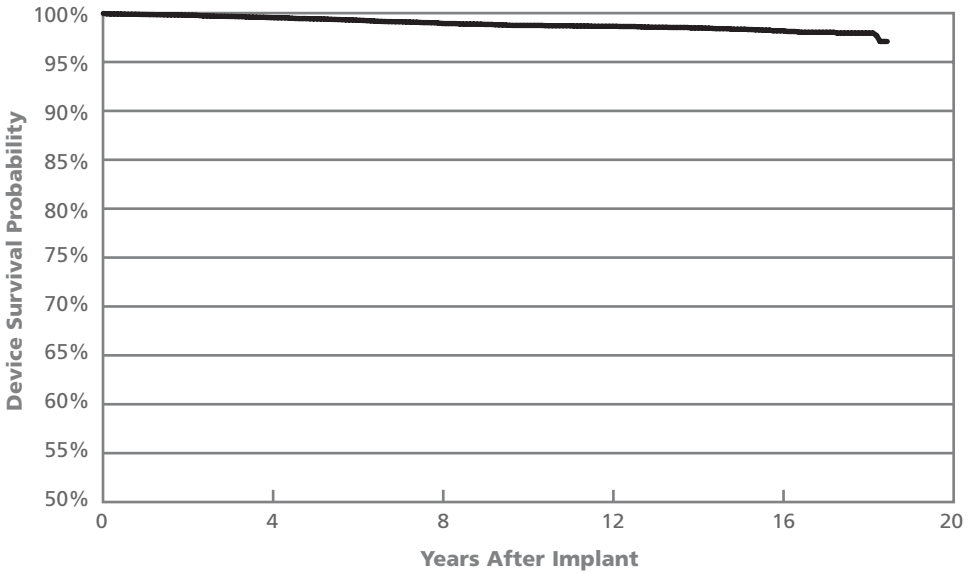
Permathane® ACE (Model 1035M)
Unipolar Passive Fixation Polyurethane Lead



Year	2	4	6	8	10
Survival Probability	99.84%	99.84%	99.58%	99.58%	
± 1 standard error	0.16%	0.16%	0.31%	0.31%	

Data is current as of January 31, 2006.
This lead is no longer being manufactured.
655 of these leads have been implanted.
(Approval date: March 1987)

ACE (Models 1015M & 1025M)
Unipolar Passive Fixation Silicone Leads



Year	4	8	12	16	20
Survival Probability	99.54%	98.94%	98.65%	98.19%	
± 1 standard error	0.05%	0.08%	0.11%	0.15%	

Data is current as of January 31, 2006.
These lead models are no longer being manufactured.
23,901 of these leads have been implanted.
(Approval dates: 1015M–August 1991; 1025M–August 1982)

Advisories and 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
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 3 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.
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 6 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 3 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.

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.
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.
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.

Advisories and Safety Alerts

Model Identification	Advisory	Follow-Up Recommendations at Time of Advisory
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.
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.

Model Identification	Advisory	Follow-Up Recommendations at Time of Advisory
Trilogy 2250L, 2260L, 2264L, 2308L, 2318L, 2350L, 2360L, 2364L	3/10/00 Class II Risk of malfunction due to an anomaly of the pacemaker's microprocessor. Typical manifestations of this anomaly are dashes observed on the programmer screen, unexpected rate variation, abnormally high battery current drain, and mode change.	Continued monitoring of Trilogy devices affected by an Advisory issued in July 1999 has revealed an additional low level of adverse events. A sub-population of the above models, principally those manufactured before January 1999, is potentially affected by a risk of malfunction due to an anomaly of the pacemaker's microprocessor. To date this has been reported in only 0.11% of the implanted population. Typical manifestations of this anomaly are: • Interrogation/programming difficulties, including the presence of dashes (—) on the programmer screen for some parameter values after interrogation • Unexpected rate variations • Abnormally high battery current drain • Mode change The presence of dashes on the programmer screen is typically caused by partial programming of one or more of the programmed parameters and may be corrected by reprogramming. In the event that observed dashes (—-) cannot be resolved by reprogramming, please contact your St. Jude Medical representative, as it may be possible to resolve the situation non-invasively via special programming and may not be indicative of a microprocessor anomaly. Considering the low level of incidence of this anomaly, the following steps are recommended: 1. Assess the patient population, relative to the potential for an inappropriate mode change to single-chamber atrial pacing, to determine which patients are pacemaker-dependent and have an inadequate ventricular escape rhythm. 2. Replacement of a device always remains a matter of clinical judgement, including balancing the clinical risk associated with pacemaker replacement against the risk of device malfunction. 3. Almost all microprocessor malfunctions described in this notification were found during routine follow-up. This reinforces the importance that pacemaker patients should be followed regularly in accordance with best prevailing medical practices.
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 2 months or has not had a device interrogation with measured data within the last 3 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 6 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 2 years, it is likely that the system is demonstrating accelerated battery depletion. Please contact your local Field Representative or Technical Services.

Index

ST. JUDE MEDICAL

Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
1 888 SJM-CRMD
818 362-6822
818 362-7182 Fax

St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
SWEDEN
+ 46 8 474 4000
+ 46 8 760 9542 Fax

www.sjm.com

60036812_REV_A

Ordering No. **F0063** Printed in USA 04061.5