Medtronic

CRM PRODUCT PERFORMANCE REPORT

Important Patient Management Information for Physicians

2006 **First Edition**

This report is available online at
www.CRMPPR.medtronic.com

Medtronic Commitment to Quality

For each patient, with each device, quality means everything. Quality is at the core of our Medtronic Mission which has driven our actions since 1960...

"To strive without reserve for the greatest possible reliability and quality in our products, to be the unsurpassed standard of comparison, and to be recognized as a company of dedication, honesty, integrity, and service."

Medtronic instituted the industry's first product performance reports in 1983 by publishing data on our chronic lead studies. Pacemakers and other devices followed as our performance reporting has constantly evolved based on customer need and feedback. One thing has been a constant. It is our sincere commitment to communicate clearly, offering timely and appropriate product performance data and reliability information. This has always been and will continue to be our goal.

In keeping with our commitment, this edition of our product performance report includes a number of updates and additions:

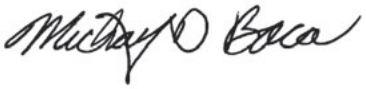
- New, easy-to-use format organized by product family and model number. Data on each model is presented in one place with links provided when additional details are available.
- Extended malfunction listings to include the number of malfunctions that have affected the generator's ability to deliver therapy. This provides a perspective on how often a malfunction may have the potential for more serious clinical impact.
- Addition of a malfunction-free survival curve for all generator models. This allows comparison of overall device survival with and without normal battery depletion data.
- Expanded discussion of the methods and assumptions used to determine survival estimates. This enables comparison of our performance results with those published by others in the industry.

Through the AdvaMed Pacemaker/ICD Working Group, Medtronic is helping lead an effort to standardize the reporting of product performance data across the industry. We feel strongly that uniform standards will further help physicians and patients gain greater understanding that will allow them to weigh the risks and benefits related to individual products or overall device-based therapies. Physician and patient confidence is critical to fully realizing the life saving and quality of life benefits medical device technologies can offer.

Your feedback is of the utmost importance. As in all quality efforts, we must continue to listen and learn while effectively and efficiently providing the information you need.

Please contact CRM Returned Product Quality at 1 (800) 328-2518, extension 48644 or our Technical Services Department at 1 (800) 723-4636 with any comments or questions. Your input will help us continue to advance and improve our communication of vital product performance information.

Thank you for your support and dedication.



Michael D. Baca
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Contact Information

We invite our customers to use these telephone numbers to call with suggestions, inquiries, or specific problems related to our products.

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CRM Product Performance Report

2006 First Edition

Date cutoff for this edition is July 11, 2005 for leads and October 31, 2005 for devices

This report is available online at www.CRMPPR.medtronic.com

New with This Edition

Survival data for:
7297 InSync Sentry
7299 InSync Sentry
7304 InSync Maximo
7288 Intrinsic
7290 Onyx VR
2187 Attain
4076 CapSureFix Novus
E2DR31 EnPulse 2 DR
E2VDD01 EnPulse 2 VDD
P1501DR EnRhythm DR

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Approximately 28,000 devices, with approximately 6,650 in the United States, out of an initial implant population of 40,000 worldwide, remain implanted and in service. Specific model and serial numbers of affected devices are available online at http://SigmaSNList.medtronic.com.

Advisory

This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Separation of redundant interconnect wires has been observed on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. In October 2005, testing and analysis identified the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. No provocative testing can predict which devices may fail.

Patient Management Recommendations

To assist physicians in their patient care and after discussion with physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow-up in accordance with standard practice.
- Advise patients to seek attention immediately if they experience return of symptoms (e.g., syncope or light headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient's medical history and consideration of the relative risks of an invasive procedure.

Status Update (December 2005)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 25 devices out of approximately 40,000 devices worldwide (0.063% incidence) have been confirmed as having interconnect wire separation. Sixteen (16) of these devices were returned from the United States. **There have been no reported serious injuries or deaths due to this issue.**

Seventeen (17) of the 25 returns were identified via either a regularly scheduled follow-up or during a non-device related hospital visit. Two (2) devices were identified due to the patient experiencing syncope. The other 6 devices were replaced with no clinical symptoms associated with the interconnect wire separation. Among the 6 devices, 4 were returned due to a device/system upgrade, and 2 were returned due to infection.

Consistent with previous Medtronic projections, the probability of occurrence remains low and is within failure rate predictions. Implant duration for the 25 failures has ranged from 17-44 months.

7274 Marquis® DR
7230 Marquis® VR
7278 Maximo® DR
7232 Maximo® VR
7277 InSync Marquis™
7289 InSync II Marquis™
7279 InSync III Marquis™
7285 InSync III Protect™

Original Date of Advisory: February 2005

Potential Premature Battery Depletion Due to Battery Short

Product

The specific subset of Marquis family ICD and CRT-D devices having batteries manufactured prior to December 2003 is affected. Devices manufactured with batteries produced after December 2003 are not affected. Specific model and serial numbers of affected devices are available online at http://MarquisSNList.medtronic.com.

Advisory

Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. Battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism.

Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. As of February 2005, the rate of shorting was approximately 1 in 10,000 (0.01%); bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.

No provocative testing can predict which of these devices will experience this issue. Once a short occurs, battery depletion can take place within a few hours to a few days. After depletion the device ceases to function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

Patient Management Recommendations

The following recommendations apply to the affected population:

- Continue to conduct routine (e.g., quarterly) follow-up procedures.
- Turn on low battery voltage PatientAlert indicator.
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care.
- Consider providing patients with a hand-held magnet to check device status. Device operation may be monitored periodically (e.g., daily) by patients using the magnet, which will result in a device tone indicating device function (provided PatientAlert is turned on). If no tone is heard, follow-up care should be sought.

Status Update (December 2005)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 30 Marquis Family devices have been confirmed as having the internal battery shorting mechanism. Eighteen (18) of these devices were returned from the United States. **There have been no reported serious injuries or deaths due to this issue.**

Fourteen (14) of the 30 returns have been identified via either a regularly scheduled follow-up or during a non-device related hospital visit, 13 by patients reporting warmth in the ICD pocket, 1 for return of bradycardia symptoms, and 2 due to the PatientAlert sounding.

Consistent with previous Medtronic projections, the observed rate of shorting in the second half of device life is higher than that observed in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 67% occurred in the last quarter of device life, and 53% in the last 10% of device life.

Discussion of Changes to Report Layout and Format

Medtronic first published a product performance report in 1983. Since that time, the report has evolved to include more information on an ever increasing number of products.

With this issue of the report, we have incorporated a new layout and format for the report with the goal of making the report more valuable and useful.

For the past several months, Medtronic CRM has been helping lead an effort by an industry working group to develop requirements for uniform product performance reporting. The goal of this effort is to have product performance reports provide the most objective, feasible representation of device performance and to make comparison across different manufacturers practical. This report conforms to the latest working draft of those requirements.

In addition, this version of the product performance report has been prepared in accordance to International Standard ISO 5841-2:2000(E).

Highlights of Changes

- Since its inception, Medtronic has used the standard actuarial method to determine survival probabilities and Greenwood's formula for calculating confidence intervals. Medtronic has also routinely adjusted its results to address underreporting of events. While these techniques have not changed, new in this issue is an expanded discussion of how these techniques are applied.
- As long ago as 1987, Medtronic included in its product performance report a table that separately identifies the number of malfunctions as well as the number of normal battery depletions for its implantable pulse generators, and more recently, implantable cardioverter defibrillators. With this issue, malfunctions for many models are further separated into malfunctions with compromised therapy function and malfunctions without compromised therapy function.
- Since 1998 for ICD leads and since 2002 for pacing leads, Medtronic has included tables showing the nature and frequency of lead complications observed via our multicenter prospective clinical studies. With this issue, the complication tables are positioned adjacent to the survival curves for easier reference.
- For over 10 years, safety advisory information has been summarized in the product performance report. With this issue, the advisory summaries have been reformatted and more clearly linked to the affected products.

The intent of these changes, and other changes not highlighted above, is to make this report more useful for anyone seeking to understand the performance of these products. If you have comments or additional suggestions on the content and format of this report, please contact us. Contact information can be found on page 2.

Introduction

All product performance reports are not created equal. For over 20 years, Medtronic CRM has monitored performance with both returned product analysis and multicenter clinical studies.

This Product Performance Report (PPR) presents device survival estimates, advisory summaries, technical articles, and other information pertinent to assessing the performance of Medtronic IPG, ICD, and CRT devices, and implantable pacing and defibrillation leads.

This product performance report has been prepared in accordance with International Standard ISO 5841-2:2000(E).

The survival estimates provided in this report are considered to be generally representative of worldwide performance.

Survival Estimates

All product performance reports are not created equal. Medtronic CRM uses both returned product analysis and multicenter clinical studies to monitor performance.

Medtronic, like other companies, monitors device performance using returned product analysis. We also monitor device performance using an active multicenter clinical study. Medtronic CRM is unique in the industry in that we track device survival using both methods.

Returned product analysis is a passive approach to assessing product performance. This approach provides a suitable measure of product performance only when a significant number of explanted products are returned to the manufacturer. Returned product analysis provides a measure of hardware performance, but not necessarily the total clinical performance (e.g., the incidence of complications such as infection, erosion, muscle stimulation, etc. are not estimated).

The survival estimates provided in this report for IPG, ICD, and CRT generators are based on returned product analysis. This approach is suitable because a significant number of explanted generators are returned for analysis.

In contrast, a very small percentage of leads are returned to the manufacturer due to the difficulty of explanting them. For leads, an active clinical study will provide much more accurate survival estimates compared to estimates based solely on returned product analysis.

Survival estimates for implantable pacing and defibrillation leads are based on clinical observations recorded via Medtronic CRM's chronic leads studies. These multicenter clinical studies are designed to record clinical observations representative of the total clinical experience. Therefore, the lead survival estimates include both lead hardware failure *and* lead related medical complications, and do not differentiate a lead hardware failure from other clinical events such as exit block, perforation, dislodgement, or concurrent pulse generator failure.

ICD Charge Times

For several years, Medtronic has provided important information on charge time performance of ICDs. The information provided in this report shows how ICD charge time can vary during the time a device is implanted. The information is presented in graphical format showing charge time as a function of implant time. The data for charge times are collected from devices enrolled in the multicenter clinical studies.

Advisory Summaries and Technical Articles

This product performance report includes advisory summaries applicable to the performance of the devices included in the report. Each summary includes a description of the devices affected by the advisory, a description of the reason for the advisory, and patient management recommendations.

In addition to advisories, this report includes a number of Technical Articles selected to provide additional performance information relevant to follow-up practice and patient management.

How You Can Help

We continually strive to improve this CRM Product Performance Report. In keeping with this philosophy, we ask for your suggestions on the content and format of this report, as well as any information you have regarding the performance of Medtronic products.

Chronic Lead Data Resolution

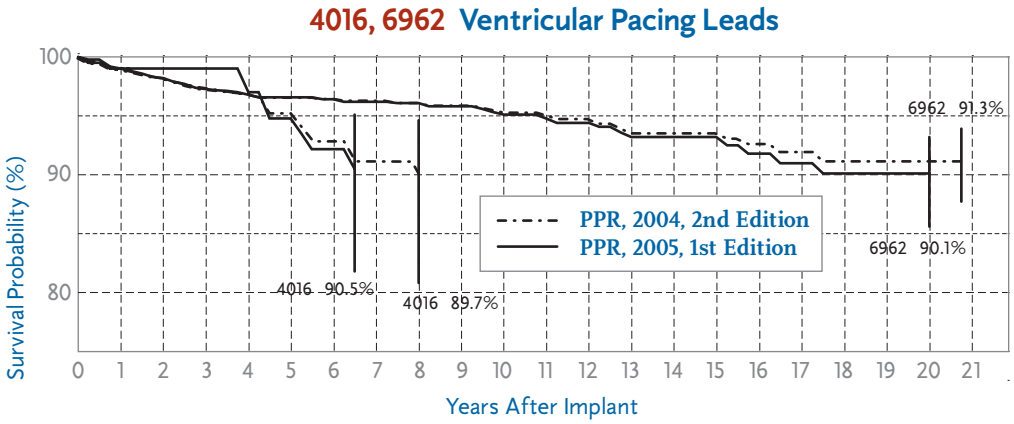
Medtronic is the only company that uses active post-market studies to monitor lead performance, conducting chronic lead studies for over 20 years.

For more than 20 years, Medtronic has remained committed to reporting the performance of chronically implanted devices via multicenter prospective clinical studies. The Chronic Lead Study for pacing leads and the Tachyarrhythmia Chronic Systems Study for ICD leads have been ongoing in several geographies since 1983 and 1991, respectively. Currently these two studies are undergoing unification into one study named the System Longevity Study.

Since the inception of these studies, the mechanism of patient follow-up has changed due to evolution in hospital follow-up practices and extrinsic issues such as the impact of the Health Insurance Portability and Accountability Act for US centers. As a result, some patients who were thought to be active participants in the study are no longer available for study follow-up. Therefore, Medtronic has initiated an additional process to verify lead status for all active study patients. This process is ongoing and is expected to conclude in the year 2007. Combined with our prospective study monitoring practices, this process aligns with our continuous efforts to improve product performance reporting. The survival curves in this edition of the Product Performance Report (PPR) reflect this additional process.

Under the study protocol, each lead is assumed to be event-free unless a failure event is confirmed, it is electively abandoned or explanted, or the patient is no longer available for follow-up. Changes in the survival curves can occur when patients in whom leads were thought to be active at the time of the previous analysis have since been determined to no longer be available for follow-up. This has the effect of shortening the curve if leads that were previously presumed to be among those with the longest survival are no longer active at that time. Such a determination also decreases the number of leads remaining in the analysis cohort, which generally lowers the estimated probability of survival.

As the data resolution process proceeds, survival curves can change from one issue of the PPR to the next. For example, as noted in the figure below, the curve for the ventricular lead model 4016 extends to 8 years with an estimated survival probability of 89.7% in the 2004 2nd Edition PPR, but extends to 6.5 years with an estimated survival probability of 90.5% in the 2005 1st Edition. In contrast, the curve for the ventricular lead model 6962 extends to 20.75 years with an estimated survival probability of 91.3% in the 2004 2nd Edition, but extends to 20 years with an estimated survival probability of 90.1% in the 2005 1st Edition. The confidence intervals at the ends of the curves are included here for consistency with those in the rest of the report. In general, these confidence intervals are not statistically comparable for assessing whether survival probability has changed between different editions of the PPR.



Method for Estimating ICD and Pulse Generator Performance

Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of reason for explant.

The next sections of the Product Performance Report present the performance of Medtronic IPG, ICD, and CRT devices. The performance of these devices is expressed in terms of device survival estimates, where "survival" refers to the proper function of the device, not the survival of the patient. These survival estimates are intended to illustrate the probability that a device will survive for a given number of years without malfunction or normal battery depletion.

The survival estimates are determined from the analysis of Medtronic CRM's device registration data and returned product analysis data. These data are presented graphically and numerically.

Because this analysis is based on returned product analysis, IPG and ICD performance data does not reflect any IPG or ICD related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition.

Categorization of Depleted and Malfunction Devices for Survival Analysis

For survival estimation, every device returned to Medtronic CRM and analyzed in the CRM Returned Product Analysis laboratory is assigned to one of three categories. The device 1) has functioned normally, 2) has reached normal battery depletion, or 3) has malfunctioned. This categorization is combined with data from our device registry for the total number of implants and the implant durations to create the survival curves presented on the following pages.

Medtronic CRM considers a device as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service.

Devices damaged after explant, damaged due to failure to heed warnings or contraindications in the labeling, or damaged due to interaction with other implanted devices (including leads) are not considered device malfunctions.

A device subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRM and found, through analysis, to actually be outside the performance limits established by Medtronic.

Not all malfunctions expose the patient to a loss of pacing or defibrillation therapy. Some malfunctions included in the following survival estimates may not have been detected at all by the physician or the patient. These malfunctions, however, are included in the survival estimates and provide important feedback to our product development organization. For this reason, **Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of reason for explant.**

To provide insight into the nature of malfunctions, each malfunction is categorized as Therapy Function Compromised or Therapy Function Not Compromised. A summary of these malfunctions is presented for the most recently market released models.

For this report, Normal Battery Depletion, Malfunction with Compromised Therapy Function and Malfunction without Compromised Therapy Function are defined as follows:

Normal Battery Depletion – The condition when

(a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or

(b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information.

Medtronic CRM establishes expected longevity by statistically characterizing the power consumed by the device and the power available from the device battery. This characterization is applied to a number of parameter configurations to derive a statistical mean longevity value and standard deviation for each parameter configuration. The statistical mean value minus three standard deviations is used as the expected longevity for determining if a battery depleted normally.

continued

Method for Estimating ICD and Pulse Generator Performance, continued

The Standard Actuarial Method is used to estimate IPG and ICD survival. This product performance report has been prepared in accordance with International Standard ISO 5841-2:2000(E).

For reference purposes, the following pages include an estimated longevity for each model. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from this estimate.

Malfunction with Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation), while implanted and in service, as confirmed by laboratory analysis.

Examples: Sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted delivery of therapy, intermittent malfunction where therapy is compromised while in the malfunction state.

Malfunction without Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that *did not* compromise pacing or defibrillation therapy, while implanted and in service, as confirmed by laboratory analysis.

Examples: Error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Laboratory Analysis Process

Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual field experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate performance concern from a customer, or to collect specific reliability data.

When a device is returned with a performance concern from a customer, the general analysis process includes a preliminary analysis of the device in its as-received condition, followed by an automated functional test using test equipment equivalent to the equipment used in manufacturing.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRM maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Statistical Methods for Survival Analysis

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions distributed across the intervals, is used to determine estimates of IPG and ICD survival. This method is chosen because the calculations are relatively straight forward and many medical researchers and clinicians are accustomed to this approach.

For the IPGs and ICDs that remain implanted and in service, we determine the number of months each has been in service. For devices no longer in service and returned for analysis, we determine the number of months they were in service and the reason for removal from service. From this data an estimate of the probability of device survival is calculated at each month interval.

continued

Method for Estimating ICD and Pulse Generator Performance, continued

Medtronic CRM adjusts all-cause survival estimates to account for underreporting. While this lowers our all-cause survival estimates, we feel it gives a more accurate perspective on real performance.

On the following pages, each graph includes an all-cause survival curve, where all-cause includes malfunctions and normal battery depletions. The all-cause survival is a good representation of the probability for a device to survive a period of time without malfunction and without normal battery depletion. For example, if a device survival probability is 95% after 5 years of service, then the device has a 5% chance of being removed due to normal battery depletion or malfunction.

In addition to the all-cause survival curve, a second curve is included to show malfunction-free survival. Malfunction-free survival is a good representation of the probability for a device to survive without malfunction. This curve excludes normal battery depletion.

Because these survival curves are based on returned product analysis, IPG and ICD survival curves do not reflect any IPG or ICD related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition.

For some models, the length of the survival curve is less than the period of time since the model was market released. This is because a minimum sample size is required before a survival estimate is calculated. For IPG and ICD curves, data is presented for each month where at least 100 devices have been exposed.

The plotted data is also presented, in yearly intervals, in table form above each graph. The data in the tables is rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have 1 or more malfunctions or battery depletions. This occurs because even with the malfunctions or battery depletions, the data rounds to 100%.

The survival curves are statistical estimates. As field performance experience accumulates, the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate corresponding 95% confidence intervals for the standard errors and the complementary log-log method is used to produce the confidence bounds.

Sample Size and How the Population and Population Samples Are Defined

The population sample from which the survival estimates are derived is comprised of the devices registered as implanted in the United States as of the report cutoff date. The number of registered implants, as well as an estimate of the number that remain in active service, is listed for each model. To be included in the population, the device must have been registered with Medtronic's registration system and implanted for at least one day.

This sample based on United States implants is considered to be representative of the worldwide population, and therefore the survival estimates shown in this report should be representative of the performance worldwide of these models.

To be considered a malfunction or normal battery depletion the device must have been returned to Medtronic and analyzed. The analysis findings are used to classify a device as malfunction, normal battery depletion, or OK (within performance limits established by Medtronic). The tables on the following pages list the number of normal battery depletions and malfunctions recorded for each model.

In general, a model or model family will be included in this report when it has accumulated at least 10,000 implant months, and will remain in the report as long as at least 500 devices remain active.

continued

Methods Used to Adjust for Underreporting of Malfunction and Normal Battery Depletion

The tables on the following pages show the actual number of malfunctions and normal battery depletions recorded by our analysis lab. Since not all devices are returned to Medtronic CRM for analysis, these numbers underestimate the true number of malfunction and normal battery depletions. To more accurately estimate the all-cause device survival probabilities, the number of malfunction and normal battery depletions used to plot the all-cause survival curves is adjusted (increased) by an amount that is based on our estimates of the magnitude of underreporting. The magnitude of underreporting is estimated by analyzing our experience in clinical studies (including our System Longevity Study) and our device registration system.

However, at this time, no adjustment for underreporting is applied to the malfunction-free survival curve because a method for estimating malfunction-only underreporting has not been developed.

Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

Devices are at times removed from service for reasons other than device malfunction or normal battery depletion. Examples are devices removed from service due to non-device related patient mortality and devices removed due to changes in the patient's medical condition. Because an accurate estimate of device survival depends on an accurate estimate of the number of devices in service, it is important not to overstate the number of devices in service.

To ensure the number of devices in service is not overstated, the patient mortality rate derived from our device registration system is monitored and compared to published mortality rates for comparable patient populations. If, during calculation of the survival curves, the patient mortality indicated by the data in our device registration is significantly different from published rates, an adjustment is applied to correct the difference.

7272 InSync ICD

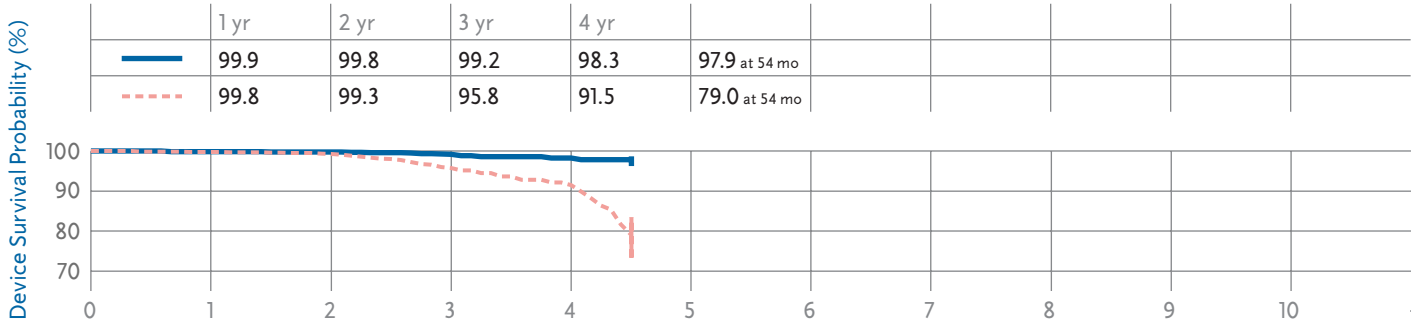
US Market Release	Jul-02
Registered US Implants	13,000
Estimated Active US Implants	7,000
Normal Battery Depletions	107
Malfunctions	63
Therapy Function Not Compromised	50
Therapy Function Compromised	13
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PJP
Max Delivered Energy	34 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	
Malfunction-free survival	99.9	99.8	99.2	98.3	97.9 at 54 mo
All-cause survival	99.8	99.3	95.8	91.5	79.0 at 54 mo



7277 InSync Marquis

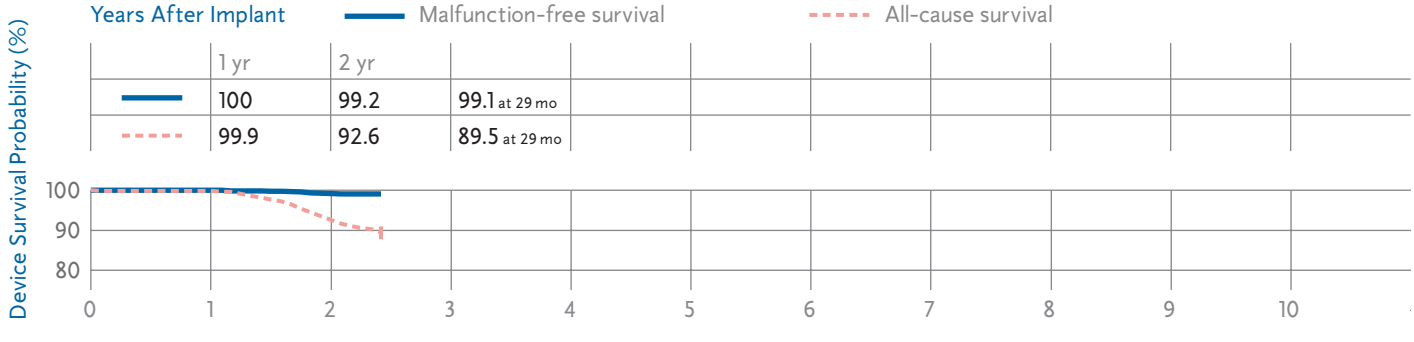
US Market Release	Mar-03
Registered US Implants	7,000
Estimated Active US Implants	3,000
Normal Battery Depletions	142
Malfunctions	35 (5 related to advisory)
Therapy Function Not Compromised	29 (0 related to advisory)
Therapy Function Compromised	6 (5 related to advisory)
Advisories	1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PLT
Max Delivered Energy	30 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

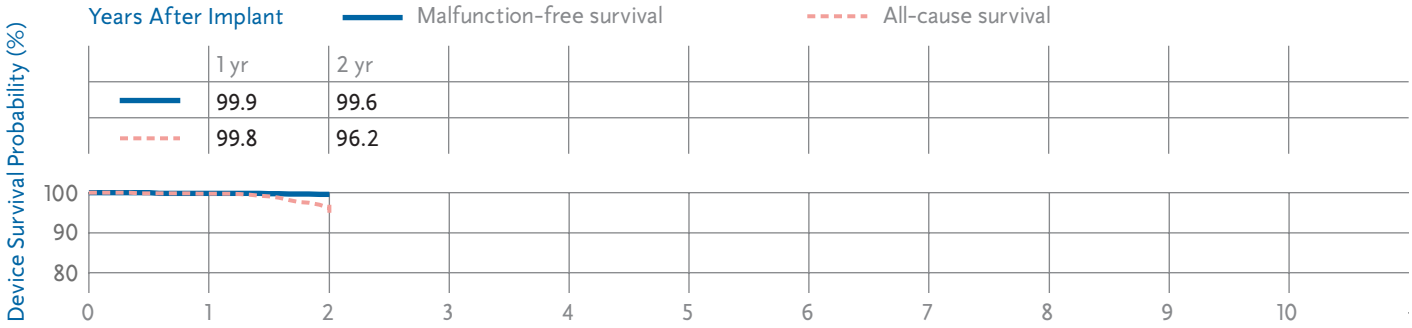
	1 yr	2 yr	
Malfunction-free survival	100	99.2	99.1 at 29 mo
All-cause survival	99.9	92.6	89.5 at 29 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

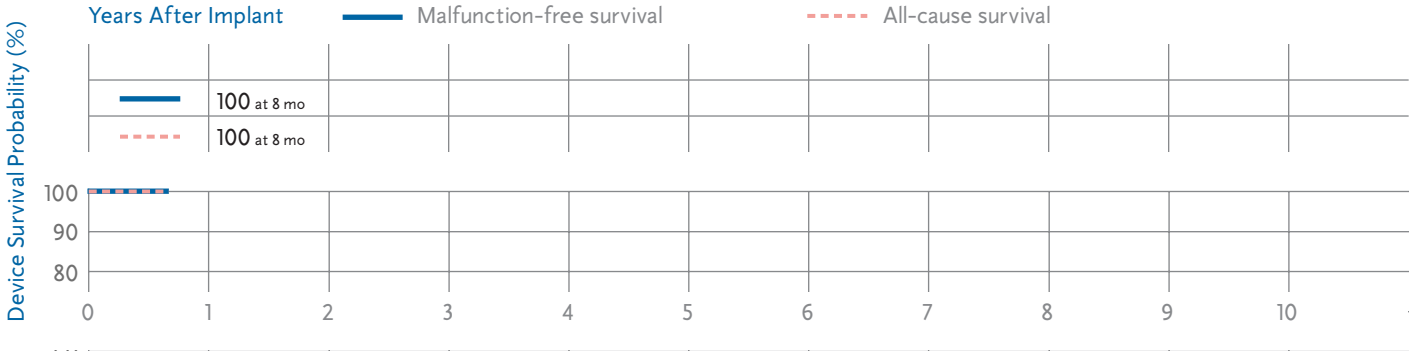
7289 InSync II Marquis

		Product Characteristics	
US Market Release	Jul-03	NBD Code	VVED
Registered US Implants	27,000	Serial Number Prefix/Xray ID	PRJ
Estimated Active US Implants	19,000	Max Delivered Energy	30 J
Normal Battery Depletions	56	Longevity	See page 33
Malfunctions	32 (2 related to advisory)		
Therapy Function Not Compromised	15 (0 related to advisory)		
Therapy Function Compromised	17 (2 related to advisory)		
Advisories	1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short		



7297 InSync Sentry

		Product Characteristics	
US Market Release	Nov-04	NBD Code	VVED
Registered US Implants	8,000	Serial Number Prefix/Xray ID	PRK
Estimated Active US Implants	8,000	Max Delivered Energy	35 J
Normal Battery Depletions	1	Longevity	See page 33
Malfunctions	0		
Therapy Function Not Compromised	0		
Therapy Function Compromised	0		
Advisories	None		



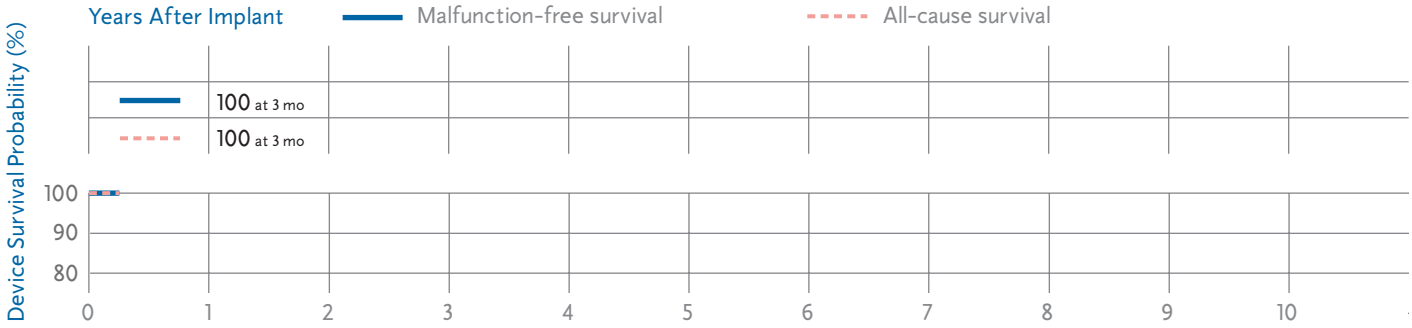
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7299 InSync Sentry

US Market Release	Apr-05
Registered US Implants	4,000
Estimated Active US Implants	4,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PRK
Max Delivered Energy	35 J
Longevity	See page 33

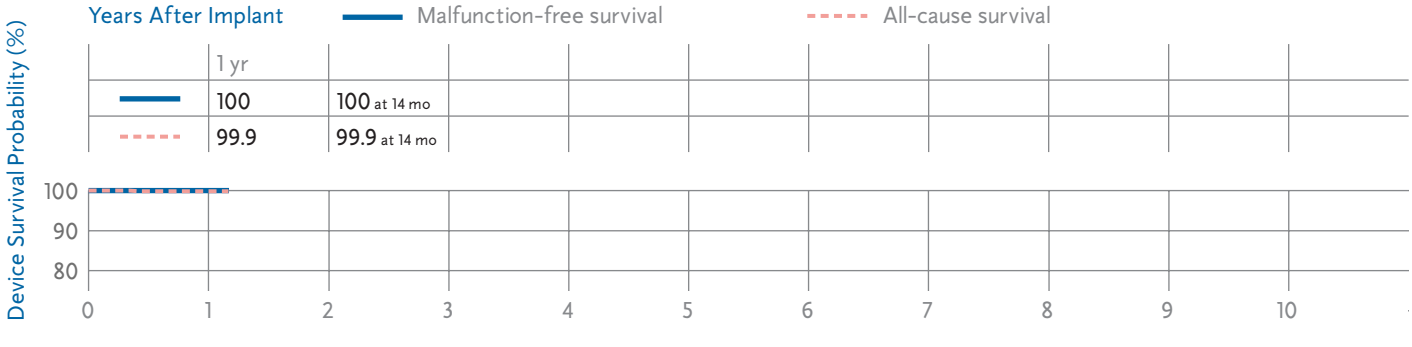


7303 InSync Maximo

US Market Release	Jun-04
Registered US Implants	16,000
Estimated Active US Implants	15,000
Normal Battery Depletions	2
Malfunctions	5
Therapy Function Not Compromised	3
Therapy Function Compromised	2
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PRL
Max Delivered Energy	35 J
Longevity	See page 33



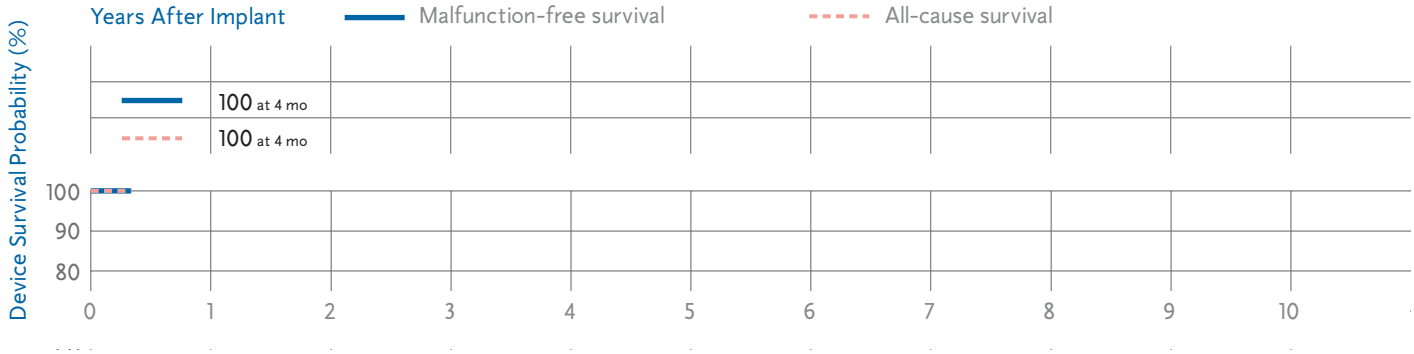
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7304 InSync Maximo

US Market Release	Apr-05
Registered US Implants	3,000
Estimated Active US Implants	3,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PRL
Max Delivered Energy	35 J
Longevity	See page 33

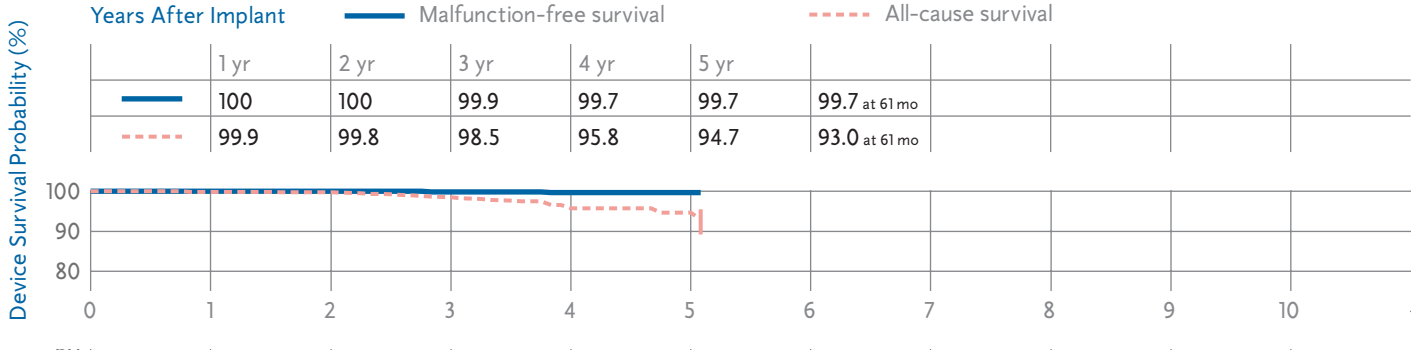


8040 InSync

US Market Release	Aug-01
Registered US Implants	15,000
Estimated Active US Implants	7,000
Normal Battery Depletions	79
Malfunctions	10
Therapy Function Not Compromised	4
Therapy Function Compromised	6
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PIN
Longevity	6.8 yrs @ 2.5 V(A), 5.0 V(V)



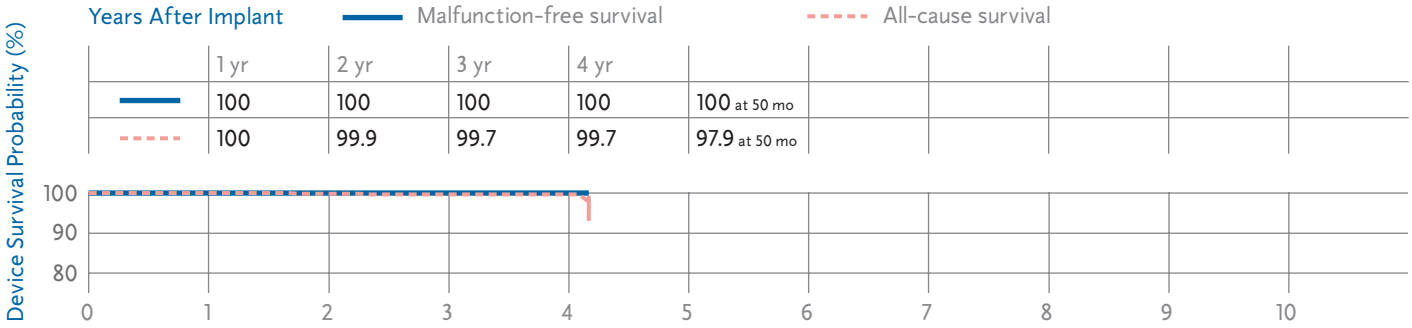
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

8042 InSync III

US Market Release	Feb-03
Registered US Implants	17,000
Estimated Active US Implants	12,000
Normal Battery Depletions	6
Malfunctions	2
Therapy Function Not Compromised	1
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PKF
Longevity	6.8 yrs @ 2.5 V



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary (95% Confidence Interval)

The following table shows CRT device survival estimates with 95% confidence intervals. Estimates are shown for both malfunction-free survival (which excludes normal battery depletion) and all-cause survival (which includes both malfunctions and normal battery depletion).

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
7272	InSync ICD	Jul-02	13,000	7,000	107	63	50	13	Malfunction-free	99.9 +.0/-.1	99.8 +.1/-.1	99.2 +.2/-.3	98.3 +.7/-1.1	97.9 +.9/-1.5 (54 mo)	
									All-cause	99.8 +.1/-.1	99.3 +.1/-.2	95.8 +.5/-.6	91.5 +1.8/-2.2	79.0 +4.6/-5.6 (54 mo)	
7277	InSync Marquis	Mar-03	7,000	3,000	142	35	29	6	Malfunction-free	100.0 +.0/-.1	99.2 +.2/-.3	99.1 +.3/-.4 (29 mo)			
	Advisory: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(5)	(0)	(5) (advisory-related subset)	All-cause	99.9 +.1/-.1	92.6 +.8/-.9	89.5 +1.5/-1.7 (29 mo)			
7289	InSync II Marquis	Jul-03	27,000	19,000	56	32	15	17	Malfunction-free	99.9 +.0/-.0	99.6 +.2/-.3				
	Advisory: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(2)	(0)	(2) (advisory-related subset)	All-cause	99.8 +.0/-.1	96.2 +.9/-1.2				
7297	InSync Sentry	Nov-04	8,000	8,000	1	0	0	0	Malfunction-free	100.0 +.0/-.0 (8 mo)					
									All-cause	100.0 +.0/-.1 (8 mo)					
7299	InSync Sentry	Apr-05	4,000	4,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0 (3 mo)					
									All-cause	100.0 +.0/-.0 (3 mo)					
7303	InSync Maximo	Jun-04	16,000	15,000	2	5	3	2	Malfunction-free	100.0 +.0/-.1	100.0 +.0/-.1 (14 mo)				
									All-cause	99.9 +.0/-.1	99.9 +.0/-.1 (14 mo)				
7304	InSync Maximo	Apr-05	3,000	3,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0 (4 mo)					
									All-cause	100.0 +.0/-.0 (4 mo)					
8040	InSync	Aug-01	15,000	7,000	79	10	4	6	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.7 +.2/-.4	99.7 +.2/-.4	99.7 +.2/-.4 (61 mo)
									All-cause	99.9 +.0/-.1	99.8 +.1/-.1	98.5 +.2/-.3	95.8 +1.1/-1.5	94.7 +1.7/-2.4	93.0 +2.5/-3.8 (61 mo)
8042	InSync III	Feb-03	17,000	12,000	6	2	1	1	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (50 mo)	
									All-cause	100.0 +.0/-.1	99.9 +.0/-.1	99.7 +.2/-.3	99.7 +.2/-.3	97.9 +1.5/-4.8 (50 mo)	

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7223 Micro Jewel II

	Non-Advisory Population	Advisory Population
US Market Release	Nov-96	Nov-96
Registered US Implants	10,000	11,000
Estimated Active US Implants	2,000	0
Normal Battery Depletions	386	453
Malfunctions	62	1,291
Advisories	2	see page 148 – 2000 Potential Long Charge Times Due to Capacitor see page 143 – 2004 Potential Long Charge Times Due to Capacitor – Supplement

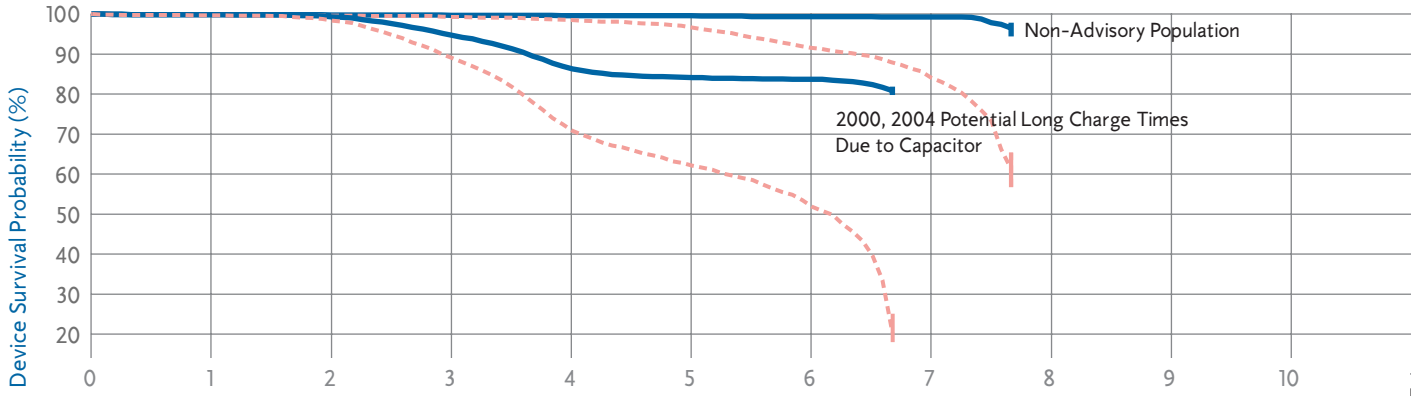
Product Characteristics

NBD Code	VVEV
Serial Number Prefix/Xray ID	PFR
Max Delivered Energy	30 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	
Malfunction-free survival	99.9	99.8	99.7	99.6	99.6	99.4	99.3	96.5 at 92 mo
All-cause survival	99.8	99.6	99.3	98.5	96.7	91.6	84.1	61.3 at 92 mo

Adv Pop	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	99.9	99.3	94.7	86.3	84.1	83.7	80.9 at 80 mo
All-cause survival	99.7	98.4	89.0	70.8	62.1	51.8	20.3 at 80 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7227 GEM

	Non-2000 Advisory Population	2000 Advisory Population
US Market Release	Oct-98	Oct-98
Registered US Implants	22,000	1,000
Estimated Active US Implants	11,000	0
Normal Battery Depletions	137	0
Malfunctions	129	297
Advisories	3	see page 151 – 1999 Potential Circuit Overload see page 153 – 1999 Potential High Current Drain see page 147 – 2000 Potential High Impedance Due to Removable Connector Header

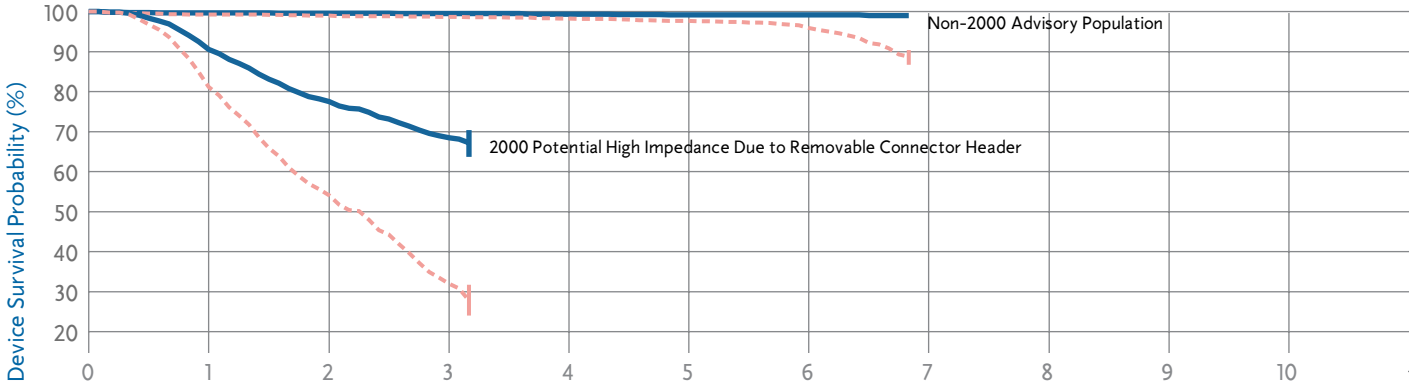
Product Characteristics

NBD Code	VVEV
Serial Number Prefix/Xray ID	PIP, PLN, PLP, PLR
Max Delivered Energy	35 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

Non-2000	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	99.7	99.6	99.5	99.4	99.2	99.2	99.0 at 82 mo
All-cause survival	99.3	99.0	98.7	98.3	97.7	95.9	88.7 at 82 mo

2000 Adv	1 yr	2 yr	3 yr	
Malfunction-free survival	90.6	77.5	68.5	67.2 at 38 mo
All-cause survival	81.2	54.1	32.0	27.8 at 38 mo

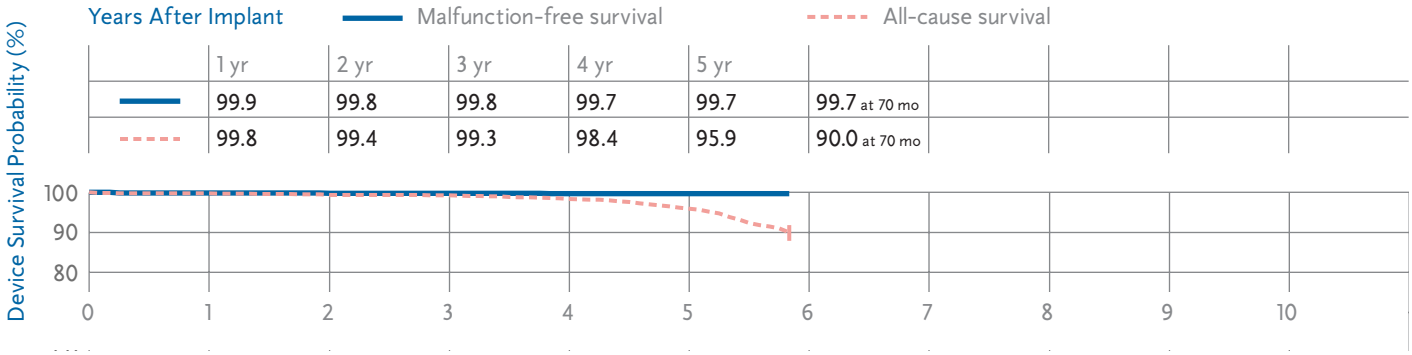


Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7229 GEM II VR

Product Characteristics

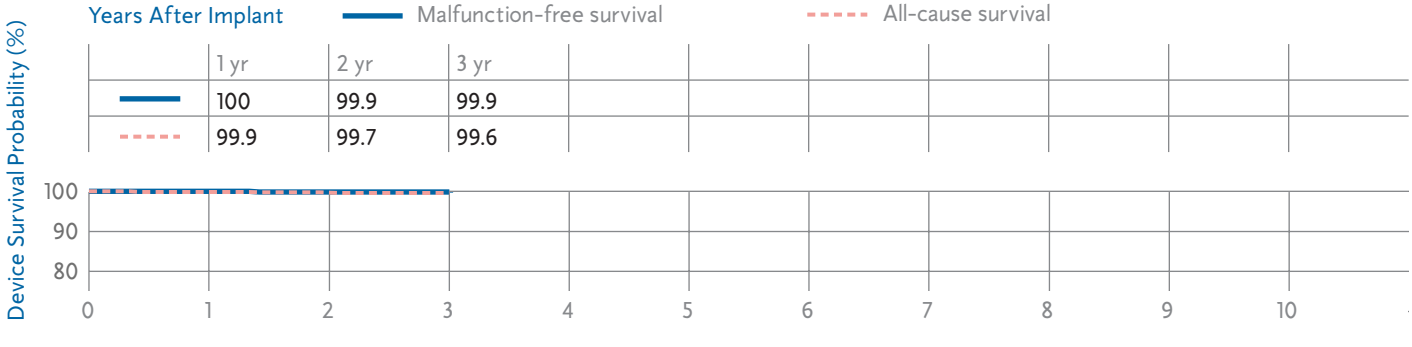
US Market Release	Jul-99	NBD Code	VVEV
Registered US Implants	11,000	Serial Number Prefix/Xray ID	PJJ
Estimated Active US Implants	5,000	Max Delivered Energy	30 J
Normal Battery Depletions	136	Longevity	See page 32
Malfunctions	24		
Advisories	2	see page 149 – 2000 Potential Weak Solder Connection see page 151 – 1999 Potential Circuit Overload also see page 164 – Technical article on ICD battery discharge behavior	



7230 Marquis VR

Product Characteristics

US Market Release	Dec-02	NBD Code	VVEV
Registered US Implants	19,000	Serial Number Prefix/Xray ID	PKD, PLW, PLY
Estimated Active US Implants	13,000	Max Delivered Energy	30 J
Normal Battery Depletions	6	Longevity	See page 32
Malfunctions	13 (0 related to advisory)		
Therapy Function Not Compromised	8 (0 related to advisory)		
Therapy Function Compromised	5 (0 related to advisory)		
Advisories	1	see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short	

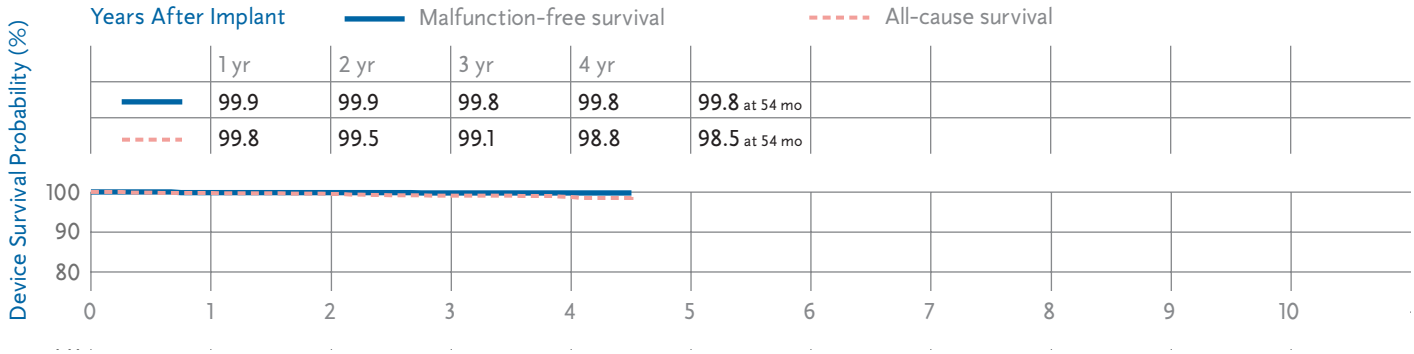


Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7231 GEM III VR

Product Characteristics

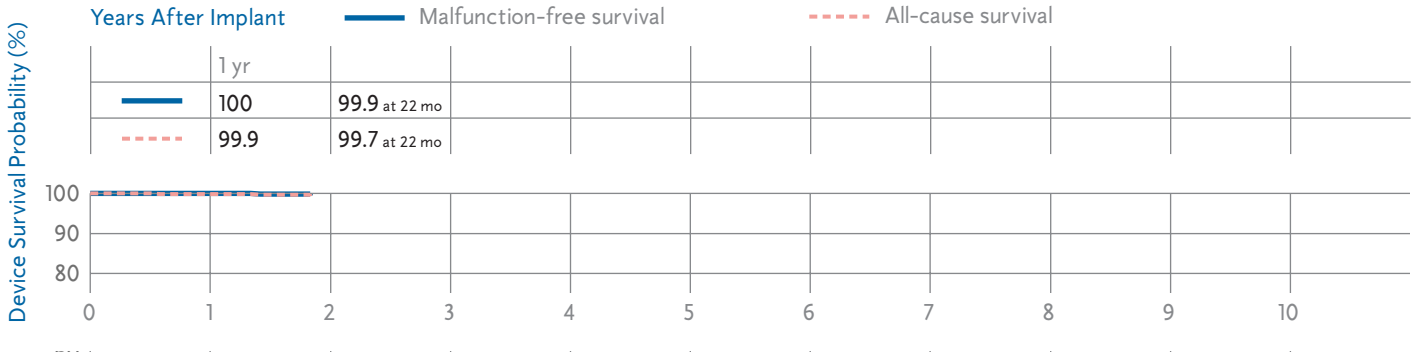
US Market Release	Dec-00	NBD Code	VVEV
Registered US Implants	17,000	Serial Number Prefix/Xray ID	PJL
Estimated Active US Implants	11,000	Max Delivered Energy	30 J
Normal Battery Depletions	40	Longevity	See page 32
Malfunctions	20		
Therapy Function Not Compromised	15		
Therapy Function Compromised	5		
Advisories	None see page 164 – Technical article on ICD battery discharge behavior		



7232 Maximo VR

Product Characteristics

US Market Release	Oct-03	NBD Code	VVED
Registered US Implants	21,000	Serial Number Prefix/Xray ID	PRN
Estimated Active US Implants	19,000	Max Delivered Energy	35 J
Normal Battery Depletions	1	Longevity	See page 32
Malfunctions	4 (0 related to advisory)		
Therapy Function Not Compromised	2 (0 related to advisory)		
Therapy Function Compromised	2 (0 related to advisory)		
Advisories	1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short		



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7250 Jewel AF

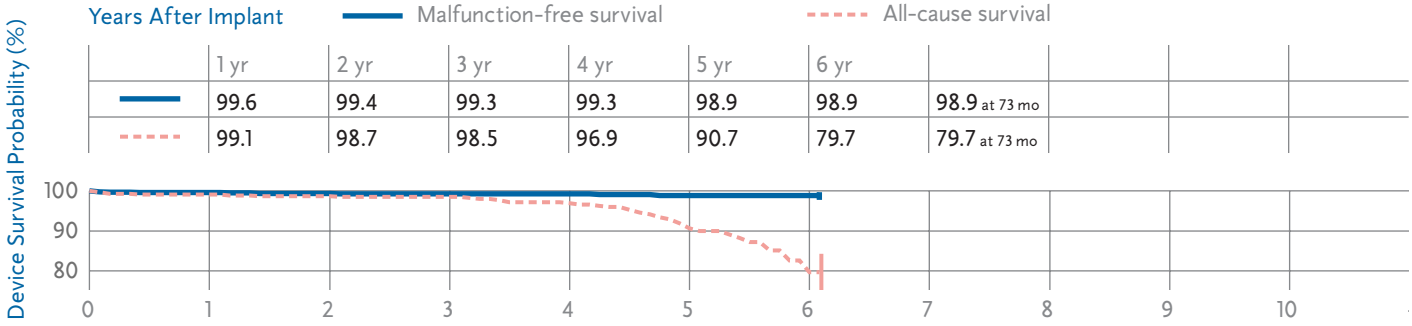
US Market Release	Jun-00
Registered US Implants	1,000
Estimated Active US Implants	400
Normal Battery Depletions	40
Malfunctions	11
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PID
Max Delivered Energy	27 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	99.6	99.4	99.3	99.3	98.9	98.9	98.9 at 73 mo
All-cause survival	99.1	98.7	98.5	96.9	90.7	79.7	79.7 at 73 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7271 GEM DR

	Non-Advisory Population	2002 Advisory Population	1999, 2004 Advisory Population
US Market Release	Oct-98	Oct-98	Oct-98
Registered US Implants	15,000	4,000	400
Estimated Active US Implants	7,000	40	0
Normal Battery Depletions	163	145	17
Malfunctions	67	499	112
Advisories	3	see page 145 – 2002 Potential Sudden Increase in Charge Times see page 150 – 1999 Potential Long Charge Times Due to Capacitor see page 143 – 2004 Potential Long Charge Times Due to Capacitor – Supplement	

Product Characteristics

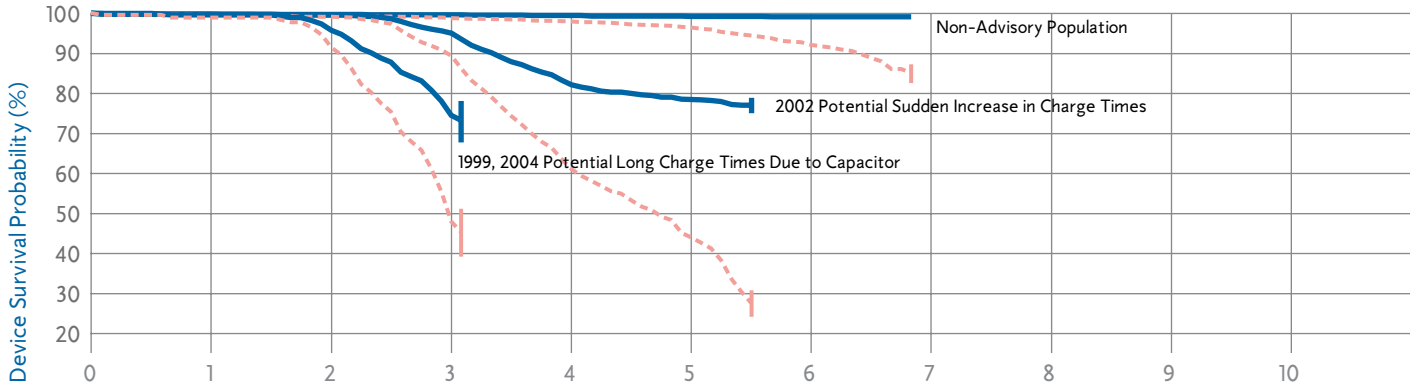
NBD Code	VVED
Serial Number Prefix/Xray ID	PIM
Max Delivered Energy	35 J
Longevity	See page 32

Years After Implant — Malfunction-free survival — All-cause survival

Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 82 mo
Malfunction-free survival	99.9	99.8	99.7	99.5	99.3	99.2	99.2
All-cause survival	99.7	99.5	98.9	98.0	96.5	92.2	85.1

2002 Adv	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
Malfunction-free survival	99.9	99.6	95.1	82.2	78.5	77.1
All-cause survival	99.7	99.2	89.4	61.1	44.0	27.5

1999, 2004 Adv	1 yr	2 yr	3 yr	at 37 mo
Malfunction-free survival	99.5	95.7	74.4	73.2
All-cause survival	98.9	91.4	47.9	45.2



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

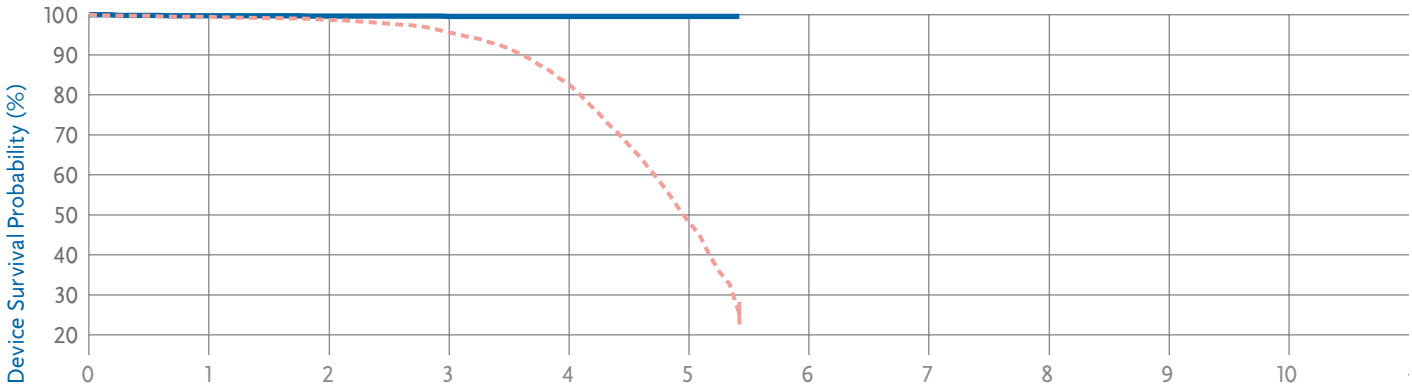
7273 GEM II DR

Product Characteristics

US Market Release	Feb-99	NBD Code	VVED
Registered US Implants	15,000	Serial Number Prefix/Xray ID	PJK
Estimated Active US Implants	1,000	Max Delivered Energy	30 J
Normal Battery Depletions	1,628	Longevity	See page 32
Malfunctions	52		
Advisories	1	see page 149 – 2000 Potential Weak Solder Connection also see page 164 – Technical article on ICD battery discharge behavior	

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	99.8	99.7	99.6	99.6	99.6	99.6 at 65 mo
All-cause survival	99.5	98.7	95.6	82.6	48.1	25.3 at 65 mo



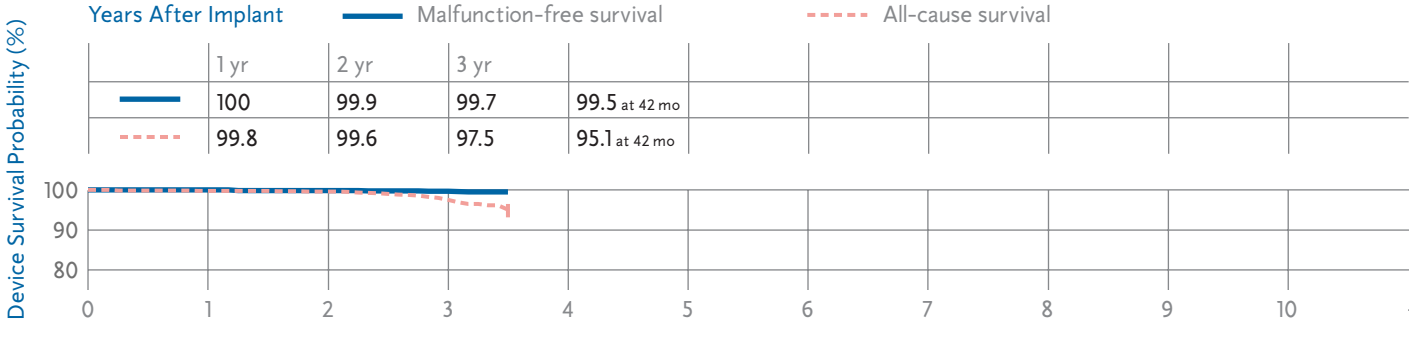
7274 Marquis DR

Product Characteristics

US Market Release	Mar-02	NBD Code	VVED
Registered US Implants	48,000	Serial Number Prefix/Xray ID	PKC
Estimated Active US Implants	29,000	Max Delivered Energy	30 J
Normal Battery Depletions	111	Longevity	See page 32
Malfunctions	64 (9 related to advisory)		
Therapy Function Not Compromised	32 (1 related to advisory)		
Therapy Function Compromised	32 (8 related to advisory)		
Advisories	1	see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short	

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	
Malfunction-free survival	100	99.9	99.7	99.5 at 42 mo
All-cause survival	99.8	99.6	97.5	95.1 at 42 mo

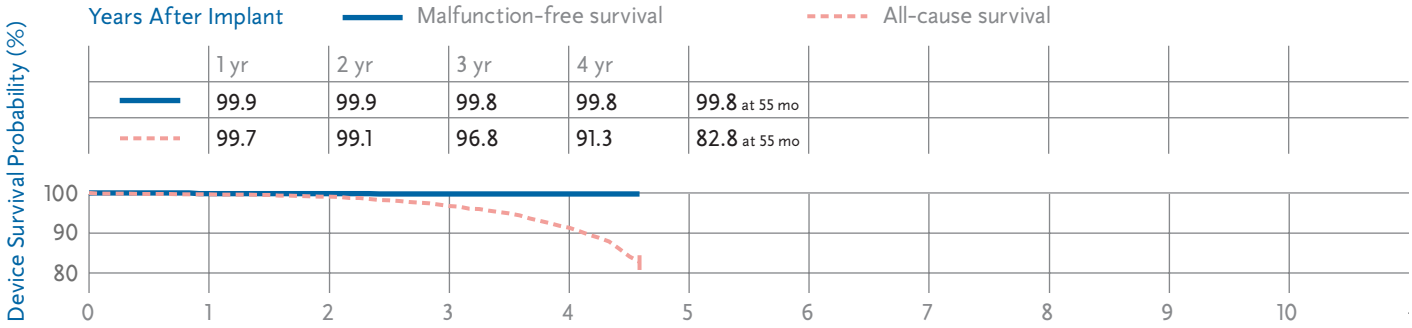


Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7275 GEM III DR

Product Characteristics

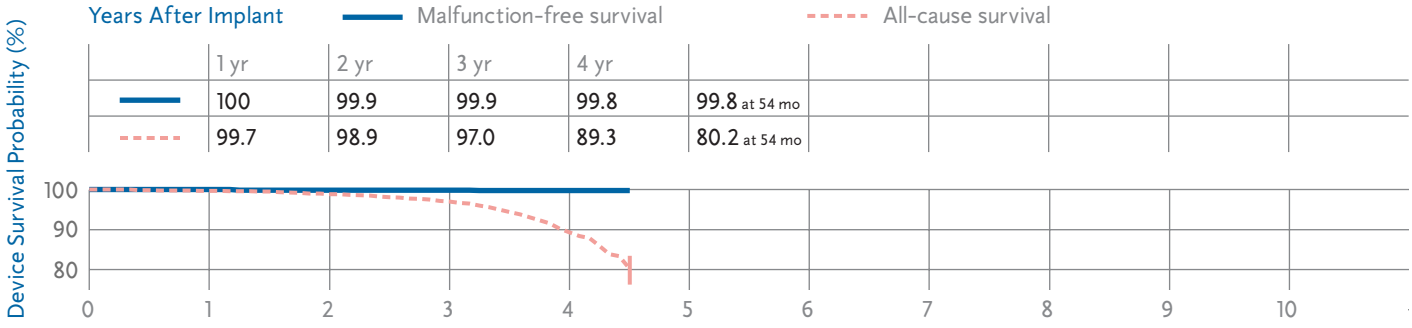
US Market Release	Nov-00	NBD Code	VVED
Registered US Implants	20,000	Serial Number Prefix/Xray ID	PJM
Estimated Active US Implants	11,000	Max Delivered Energy	30 J
Normal Battery Depletions	404	Longevity	See page 32
Malfunctions	28		
Therapy Function Not Compromised	18		
Therapy Function Compromised	10		
Advisories	None see page 164 – Technical article on ICD battery discharge behavior		



7276 GEM III AT

Product Characteristics

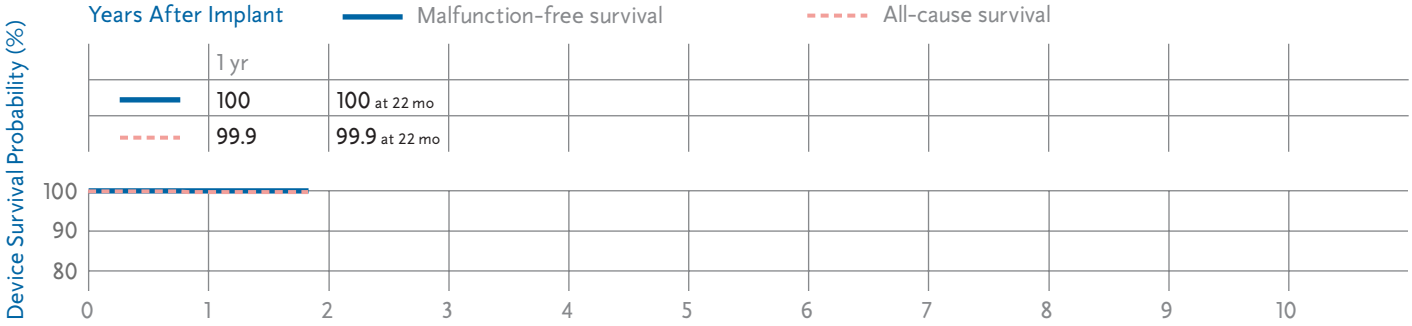
US Market Release	Feb-01	NBD Code	DDED
Registered US Implants	14,000	Serial Number Prefix/Xray ID	PKE
Estimated Active US Implants	8,000	Max Delivered Energy	30 J
Normal Battery Depletions	274	Longevity	See page 32
Malfunctions	14		
Therapy Function Not Compromised	8		
Therapy Function Compromised	6		
Advisories	None see page 164 – Technical article on ICD battery discharge behavior		



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

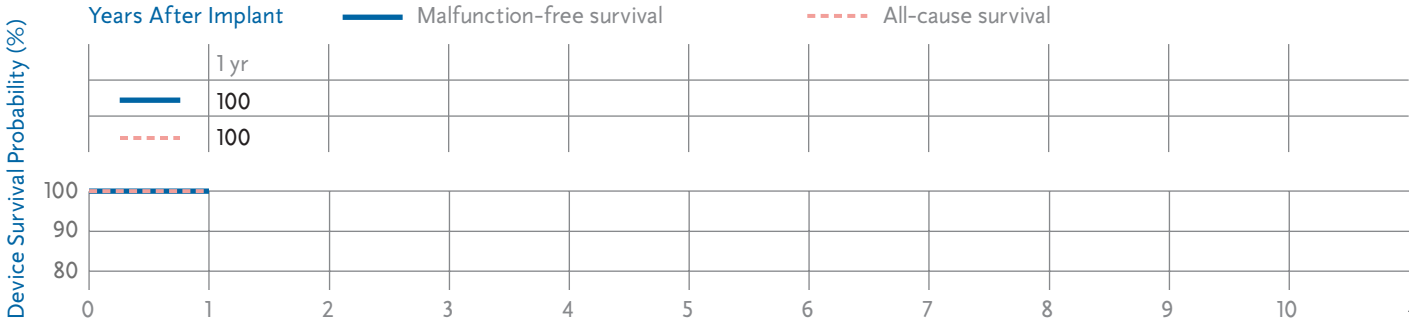
7278 Maximo DR

		Product Characteristics	
US Market Release	Oct-03	NBD Code	VVED
Registered US Implants	24,000	Serial Number Prefix/Xray ID	PRM
Estimated Active US Implants	21,000	Max Delivered Energy	35 J
Normal Battery Depletions	2	Longevity	See page 32
Malfunctions	4 (0 related to advisory)		
Therapy Function Not Compromised	0 (0 related to advisory)		
Therapy Function Compromised	4 (0 related to advisory)		
Advisories	1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short		



7288 Intrinsic

		Product Characteristics	
US Market Release	Aug-04	NBD Code	VVED
Registered US Implants	18,000	Serial Number Prefix/Xray ID	PUB
Estimated Active US Implants	17,000	Max Delivered Energy	35 J
Normal Battery Depletions	1	Longevity	See page 33
Malfunctions	2		
Therapy Function Not Compromised	2		
Therapy Function Compromised	0		
Advisories	None		



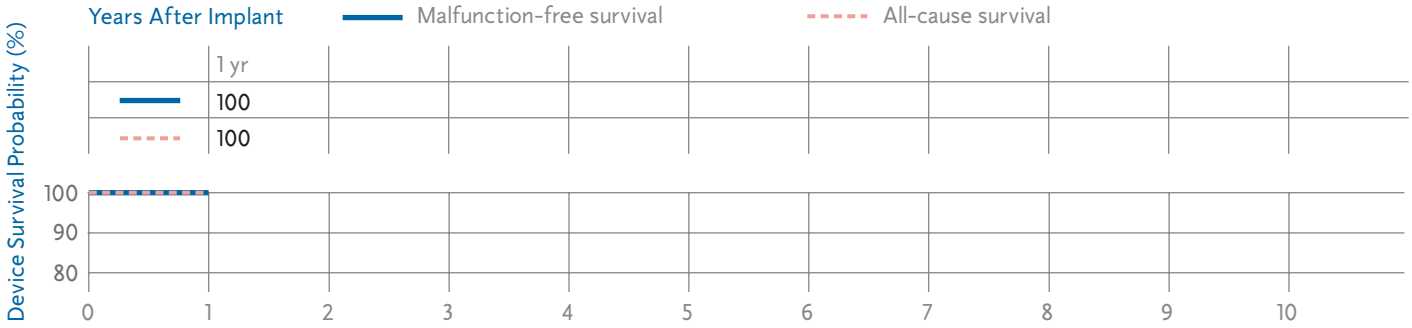
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

7290 Onyx VR

US Market Release	Mar-04
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/Xray ID	PRP
Max Delivered Energy	30 J
Longevity	See page 33



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary (95% Confidence Interval)

The following table shows ICD device survival estimates with 95% confidence intervals. Estimates are shown for both malfunction-free survival (which excludes normal battery depletion) and all-cause survival (which includes both malfunctions and normal battery depletion).

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7223 Non-Advisory Population	Micro Jewel II	Nov-96	10,000	2,000	386	62	—	—	Malfunction-free	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.6 +.1/-.2	99.6 +.1/-.2	99.4 +.2/-.2	99.3 +.2/-.3	96.5 +1.3/-2.1 (92 mo)
									All-cause	99.8 +.1/-.1	99.6 +.1/-.1	99.3 +.2/-.2	98.5 +.3/-.3	96.7 +.4/-.5	91.6 +.7/-.8	84.1 +1.1/-1.2	61.3 +4.1/-4.5 (92 mo)
7223 2000, 2004 Advisory Population	Micro Jewel II	Nov-96	11,000	0	453	1,291	—	—	Malfunction-free	99.9 +.1/-.1	99.3 +.2/-.2	94.7 +.5/-.5	86.3 +.8/-.8	84.1 +.8/-.9	83.7 +.9/-.9	80.9 +1.1/-1.1 (80 mo)	
	Advisories: see page 148 – 2000 Potential Long Charge Times Due to Capacitor; and page 143 – 2004 Potential Long Charge Times Due to Capacitor – Supplement						—	—	All-cause	99.7 +.1/-.1	98.4 +.2/-.3	89.0 +.6/-.7	70.8 +1.0/-1.1	62.1 +1.2/-1.2	51.8 +1.5/-1.5	20.3 +3.1/-3.0 (80 mo)	
7227 Non-2000 Advisory Population	GEM	Oct-98	22,000	11,000	137	129	—	—	Malfunction-free	99.7 +.1/-.1	99.6 +.1/-.1	99.5 +.1/-.1	99.4 +.1/-.1	99.2 +.1/-.2	99.2 +.1/-.2	99.0 +.2/-.3 (82 mo)	
	Advisories: see page 151 – 1999 Potential Circuit Overload; and page 153 – 1999 Potential High Current Drain						—	—	All-cause	99.3 +.1/-.1	99.0 +.1/-.1	98.7 +.2/-.2	98.3 +.2/-.2	97.7 +.2/-.3	95.9 +.4/-.5	88.7 +1.7/-1.9 (82 mo)	
7227 B, D, E 2000 Advisory Population	GEM	Oct-98	1,000	0	0	297	—	—	Malfunction-free	90.6 +1.7/-2.0	77.5 +2.6/-2.9	68.5 +3.2/-3.4	67.2 +3.2/-3.5 (38 mo)				
	Advisory: see page 147 – 2000 Potential High Impedance Due to Removable Connector Header						—	—	All-cause	81.2 +2.3/-2.6	54.1 +3.3/-3.4	32.0 +3.8/-3.8	27.8 +3.9/-3.8 (38 mo)				
7229	GEM II VR	Jul-99	11,000	5,000	136	24	—	—	Malfunction-free	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1 (70 mo)		
	Advisories: see page 149 – 2000 Potential Weak Solder Connection; and page 151 – 1999 Potential Circuit Overload; also see page 164 – Technical article on ICD battery discharge behavior						—	—	All-cause	99.8 +.1/-.1	99.4 +.1/-.2	99.3 +.2/-.2	98.4 +.3/-.3	95.9 +.5/-.6	90.0 +1.8/-2.1 (70 mo)		
7230	Marquis VR	Dec-02	19,000	13,000	6	13	8 total	5	Malfunction-free	100.0 +.0/-.0	99.9 +.1/-.1	99.9 +.1/-.1					
	Advisories: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	(0)	(0)	All-cause	99.9 +.0/-.1	99.7 +.1/-.1	99.6 +.1/-.2					
7231	GEM III VR	Dec-00	17,000	11,000	40	20	15	5	Malfunction-free	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 (54 mo)			
	see page 164 – Technical article on ICD battery discharge behavior								All-cause	99.8 +.1/-.1	99.5 +.1/-.1	99.1 +.2/-.2	98.8 +.3/-.3	98.5 +.3/-.5 (54 mo)			
7232	Maximo VR	Oct-03	21,000	19,000	1	4	2 total	2	Malfunction-free	100.0 +.0/-.1	99.9 +.1/-.3 (22 mo)						
	Advisory: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	(0)	(0)	All-cause	99.9 +.0/-.1	99.7 +.1/-.4 (22 mo)						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7250	Jewel AF	Jun-00	1,000	400	40	11	—	—	Malfunction-free	99.6 +.3/-.6	99.4 +.3/-.7	99.3 +.4/-.7	99.3 +.4/-.7	98.9 +.5/-1.0	98.9 +.5/-1.0	98.9 +.5/-1.0 (73 mo)	
									All-cause	99.1 +.4/-.7	98.7 +.5/-.9	98.5 +.6/-.9	96.9 +1.0/-1.4	90.7 +2.2/-2.8	79.7 +4.6/-5.7	79.7 +4.6/-5.7 (73 mo)	
7271 Non-Advisory Population	GEM DR	Oct-98	15,000	7,000	163	67	—	—	Malfunction-free	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.5 +.1/-.2	99.3 +.2/-.2	99.2 +.2/-.2	99.2 +.2/-.2 (82 mo)	
									All-cause	99.7 +.1/-.1	99.5 +.1/-.1	98.9 +.2/-.2	98.0 +.3/-.3	96.5 +.4/-.5	92.2 +.8/-.9	85.1 +2.2/-2.5 (82 mo)	
7271 2002 Advisory Population	GEM DR	Oct-98	4,000	40	145	499	—	—	Malfunction-free	99.9 +.1/-.2	99.6 +.2/-.3	95.1 +.7/-.9	82.2 +1.5/-1.6	78.5 +1.7/-1.8	77.1 +1.8/-2.0 (66 mo)		
	Advisory: see page 145 – 2002 Potential Sudden Increase in Charge Times						—	—	All-cause	99.7 +.1/-.2	99.2 +.3/-.4	89.4 +1.1/-1.2	61.1 +2.0/-2.1	44.0 +2.5/-2.5	27.5 +3.4/-3.3 (66 mo)		
7271 1999, 2004 Advisory Population	GEM DR	Oct-98	400	0	17	112	—	—	Malfunction-free	99.5 +.4/-1.6	95.7 +1.7/-2.9	74.4 +4.7/-5.5	73.2 +4.8/-5.6 (37 mo)				
	Advisories: see page 150 – 1999 Potential Long Charge Times Due to Capacitor; and page 143 – 2004 Potential Long Charge Times Due to Capacitor – Supplement						—	—	All-cause	98.9 +.7/-1.8	91.4 +2.6/-3.6	47.9 +5.9/-6.1	45.2 +5.9/-6.1 (37 mo)				
7273	GEM II DR	Feb-99	15,000	1,000	1,628	52	—	—	Malfunction-free	99.8 +.1/-.1	99.7 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.2	99.6 +.1/-.2 (65 mo)		
	Advisory: see page 149 – 2000 Potential Weak Solder Connection; also see page 164 – Technical article on ICD battery discharge behavior						—	—	All-cause	99.5 +.1/-.1	98.7 +.2/-.2	95.6 +.4/-.4	82.6 +.8/-.8	48.1 +1.5/-1.6	25.3 +2.9/-2.8 (65 mo)		
7274	Marquis DR	Mar-02	48,000	29,000	111	64 (——— total ———)	32	32	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.0	99.7 +.1/-.1	99.5 +.1/-.2 (42 mo)				
	Advisory: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9) (advisory-related subset)	(1)	(8)	All-cause	99.8 +.0/-.0	99.6 +.1/-.1	97.5 +.3/-.4	95.1 +1.4/-2.0 (42 mo)				
7275	GEM III DR	Nov-00	20,000	11,000	404	28	18	10	Malfunction-free	99.9 +.0/-.0	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 (55 mo)			
	see page 164 – Technical article on ICD battery discharge behavior								All-cause	99.7 +.1/-.1	99.1 +.1/-.2	96.8 +.3/-.3	91.3 +.6/-.7	82.8 +1.8/-2.0 (55 mo)			
7276	GEM III AT	Feb-01	14,000	8,000	274	14	8	6	Malfunction-free	100.0 +.0/-.1	99.9 +.0/-.1	99.9 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 (54 mo)			
	see page 164 – Technical article on ICD battery discharge behavior								All-cause	99.7 +.1/-.1	98.9 +.2/-.2	97.0 +.3/-.4	89.3 +1.0/-1.1	80.2 +3.3/-3.9 (54 mo)			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7278	Maximo DR	Oct-03	24,000	21,000	2	4	0	4	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.1 (22 mo)						
						(total)											
	Advisory: see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0)	All-cause	99.9 +.0/-.1	99.9 +.1/-.1 (22 mo)						
						(advisory-related subset)											
7288	Intrinsic	Aug-04	18,000	17,000	1	2	2	0	Malfunction-free	100.0 +.0/-.0							
									All-cause	100.0 +.0/-.1							
7290	Onyx VR	Mar-04	1,000	1,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0							
									All-cause	100.0 +.0/-.0							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

ICD Reference Chart

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Elective Replacement (ERI)***		End of Life (EOL) Battery Voltage
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
7202	Jewel CD	C, D, E	80–83 cc* 129–139 g	34 J	Monthly Quarterly Biannual	3.6 4.5 4.8	4.1 5.3 5.7	4.5 6.0 6.6	4.7 6.4 7.1	≤ 4.91 V	Two ≥ 14.5 sec	≤ 4.57 V
7219	Jewel	B, C, D, E	80–83 cc* 129–139 g	34 J	Monthly Quarterly Biannual	3.6 4.5 4.8	4.1 5.3 5.7	4.5 6.0 6.6	4.7 6.4 7.1	≤ 4.91 V	Two ≥ 14.5 sec	≤ 4.57 V
7220	Jewel Plus	B, C, D, E	80–83 cc* 135–143 g	34 J	Monthly Quarterly Biannual	3.7 4.4 4.7	4.2 5.2 5.5	4.6 5.9 6.4	4.8 6.3 6.8	≤ 4.91 V	Two ≥ 14.5 sec	≤ 4.57 V
7221	Micro Jewel	B, Cx, D, E	69–72 cc* 118–125 g	34 J	Monthly Quarterly Biannual	4.4 5.7 6.2	4.8 6.4 7.0	5.2 7.0 7.7	5.3 7.2 8.0	≤ 4.91 V	—	≤ 4.57 V‡‡
7223	Micro Jewel II	Cx	54 cc 97 g	30 J	Monthly Quarterly Biannual	4.9 6.3 6.8	5.4 7.1 7.7	5.8 7.8 8.5	6.0 8.1 9.0	≤ 4.91 V	—	≤ 4.57 V‡‡
7227	GEM	B, Cx, D, E	49 cc* 90 g	35 J	Monthly Quarterly Biannual	5.3 7.7 8.8	5.7 8.5 10.0	6.0 9.3 11.0	6.1 9.6 11.5	≤ 2.55 V	—	≤ 2.40 V§
7229	GEM II VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.6 5.0 5.6	3.9 5.5 6.3	4.1 6.0 6.9	4.2 6.2 7.1	≤ 2.55 V	—	≤ 2.40 V
7230	Marquis VR	B, Cx, E	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.9 7.3 8.5	5.2 8.0 9.3	5.4 8.5 10.0	5.5 8.7 10.4	≤ 2.62 V	—	3 months after ERI
7231	GEM III VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Biannual	4.3 6.0 6.6	4.7 6.8 7.5	5.0 7.4 8.5	5.2 7.8 8.9	≤ 2.55 V	—	≤ 2.40 V
7232	Maximo VR	B, Cx, E	39 cc 76 g	35 J	Monthly Quarterly Biannual	4.4 7.0 8.2	4.7 7.5 9.0	4.8 8.0 9.7	4.9 8.3 10.0	≤ 2.62 V	—	3 months after ERI
7250	Jewel AF	G, H	56 cc* 96 g	27 J	Monthly Quarterly Biannual	5.3 6.5 7.0	6.1 7.6 8.2	6.7 8.7 9.4	7.0 9.2 10.0	≤ 4.94 V	—	≤ 4.50 V
7271	GEM DR	DR	62 cc 115 g	35 J	Monthly Quarterly Biannual	6.0 7.4 7.9	6.9 8.4 9.0	7.5 9.3 10.0	7.8 9.8 10.6	≤ 4.91 V	—	≤ 4.57 V§
7272	InSync ICD	DR+LV	66 cc 117 g	34 J	Monthly Quarterly Biannual	5.4 6.5 6.9	6.3 8.0 8.5	7.3 9.4 10.3	7.8 10.3 11.2	≤ 4.91 V	—	≤ 4.57 V
7273	GEM II DR	DR	39.5 cc 77 g	30 J	Monthly Quarterly Biannual	2.8 3.7 4.0	3.2 4.3 4.7	3.5 4.8 5.4	3.7 5.1 5.8	≤ 2.55 V	—	≤ 2.40 V
7274	Marquis DR	DR+LV	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.0 5.6 6.2	4.4 6.4 7.2	4.8 7.1 8.1	4.9 7.5 8.6	≤ 2.62 V	—	3 months after ERI
7275	GEM III DR	DR	39.5 cc 78 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.8 5.0 5.5	4.3 5.8 6.5	4.4 6.3 7.0	≤ 2.55 V	—	≤ 2.40 V
7276	GEM III AT	DR	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.3 4.3 4.5	3.8 5.1 5.5	4.3 5.9 6.5	4.5 6.3 7.0	≤ 2.55 V	—	≤ 2.40 V
7277	InSync Marquis	DR+LV split	38 cc 77 g	30 J	Monthly Quarterly Biannual	3.7 5.0 5.5	4.3 6.0 6.7	4.7 7.0 8.0	4.9 7.5 8.6	≤ 2.62 V	—	3 months after ERI
7278	Maximo DR	DR	39 cc 77 g	35 J	Monthly Quarterly Biannual	3.7 5.3 6.0	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	—	3 months after ERI
7287	Intrinsic 30	DR	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.0 5.5 6.2	4.3 6.3 7.2	4.7 7.0 8.2	4.8 7.4 8.6	≤ 2.62 V	—	3 months after ERI

continued

ICD Reference Chart continued

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Elective Replacement (ERI)***		End of Life (EOL) Battery Voltage
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
7288	Intrinsic	DR	38 cc 76 g	35 J	Monthly Quarterly Biannual	3.7 5.4 6.1	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	—	3 months after ERI
7289	InSync II Marquis	DR+LV true	38 cc 76 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.6 4.9 5.4	4.0 5.5 6.1	4.2 5.8 6.6	≤ 2.62 V	—	3 months after ERI
7290	Onyx VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.8 5.0 5.4	4.1 5.6 6.1	4.3 6.2 6.7	4.5 6.4 7.0	≤ 2.55 V	—	≤ 2.40 V
7295	InSync II Protect	DR+LV true	38 cc 77 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.7 4.9 5.4	4.0 5.5 6.2	4.2 5.9 6.6	≤ 2.62 V	—	3 months after ERI
7297	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	—	3 months after ERI
7299	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	—	3 months after ERI
7303	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	—	3 months after ERI
7304	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	—	3 months after ERI
D153ATG, D153DRG	EnTrust	DR	33 cc 63 g	30 J	Monthly Quarterly Biannual	3.5 4.8 5.3	3.8 5.4 6.1	4.1 6.0 6.9	4.2 6.3 7.2	≤ 2.61 V	—	3 months after ERI
D153VRC	EnTrust	Cx	32 cc 63 g	30 J	Monthly Quarterly Biannual	4.4 6.8 7.9	4.7 7.4 8.7	4.9 7.9 9.5	5.0 8.1 9.8	≤ 2.61 V	—	3 months after ERI
D154ATG, D154DRG	EnTrust	DR	35 cc 68 g	35 J	Monthly Quarterly Biannual	3.8 5.5 6.1	4.2 6.1 7.0	4.4 6.8 7.9	4.6 7.0 8.3	≤ 2.61 V	—	3 months after ERI
D154VRC	EnTrust	Cx	35 cc 68 g	35 J	Monthly Quarterly Biannual	4.8 7.5 9.0	5.0 8.3 10.0	5.2 8.8 10.7	5.3 9.0 11.0	≤ 2.61 V	—	3 months after ERI

* Volume and mass differ by connector style.

** A full charge is a full energy therapeutic shock or capacitor reformation.

*** The minimum time between ERI and EOL is 3 months (100% pacing, two charges per month).

‡ Pacing mode is DDD for dual chamber devices and VVI for others:

60 ppm, 3.0 V, 0.4 ms, 510 ohms for Intrinsic 30 7287, Intrinsic 7288, EnTrust D153ATG / D153DRG / D153VRC, EnTrust D154ATG / D154DRG / D154VRC, Onyx VR 7290, InSync Sentry 7299 (LV:3.0 V, 0.4 ms, 510 ohms), InSync II Protect 7295 (LV:3.0 V, 0.4 ms, 510 ohms), Maximo DR 7278, Maximo VR 7230, InSync II Marquis 7289 (LV:3.0 V, 0.4 ms, 510 ohms), InSync Marquis 7277 (LV:510 ohms), Marquis DR 7274, Marquis VR 7230, GEM III AT 7276, GEM III DR 7275, GEM III VR 7231, GEM II DR 7273, GEM II VR 7229, GEM DR 7271, GEM 7227, and Jewel AF 7250.

60 ppm biventricular pacing, 4.0 V, 0.4 ms, and 510 ohms for InSync ICD 7272;

65 ppm, 4.0 V, 0.4 ms, and 500 ohms for Micro Jewel II 7223 and Micro Jewel 7221;

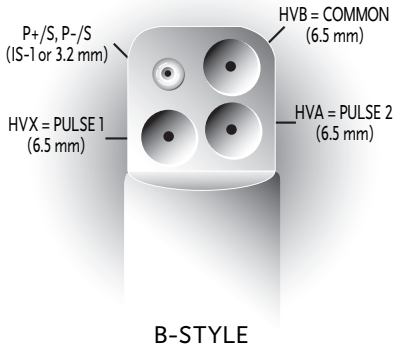
65 ppm, 5.6 V, 0.5 ms, and 500 ohms for Jewel 7219, Jewel Plus 7220, and Jewel CD 7202.

For all cases, sensing rate was assumed at 70 bpm.

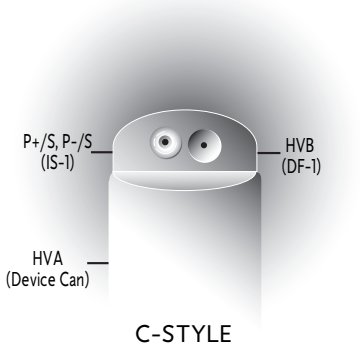
‡‡ For Model 7221 and 7223 devices, if charge time exceeds 60 seconds, the devices are at EOL. If 2 consecutive charge cycles exceed 60 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency output VVI pacing are disabled.

§ For Model 7271 and 7227 devices, if charge time exceeds 30 seconds, the device is at EOL. Immediate replacement is recommended. If 3 consecutive charge cycles exceed 30 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency VVI pacing are disabled.

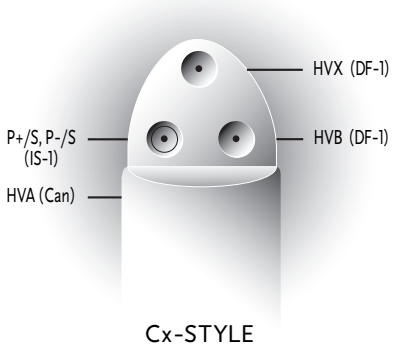
ICD Connector Styles



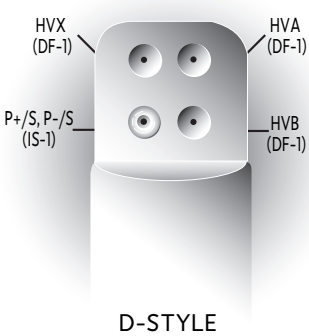
B-STYLE CONNECTOR



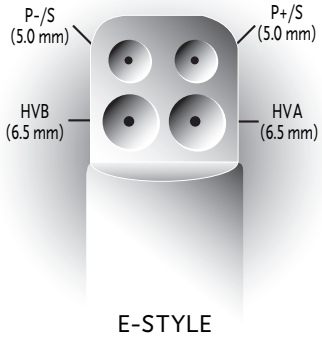
C-STYLE CONNECTOR



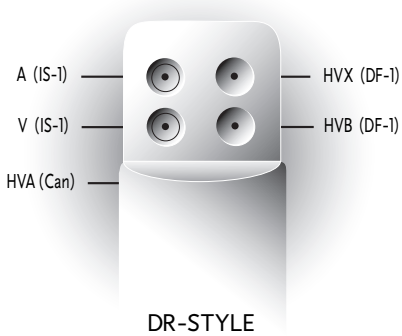
Cx-STYLE CONNECTOR



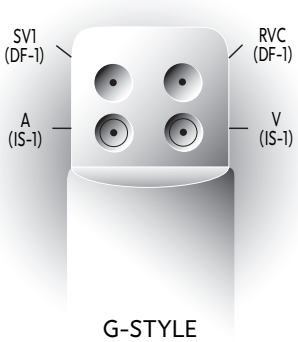
D-STYLE CONNECTOR



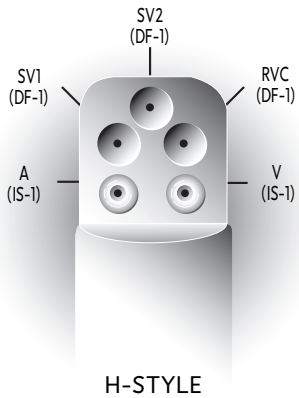
E-STYLE CONNECTOR



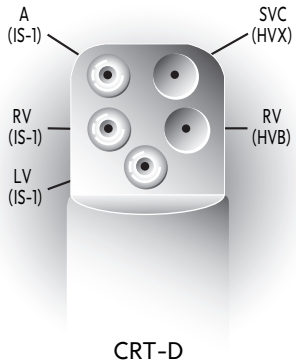
DR-STYLE CONNECTOR



G-STYLE CONNECTOR



H-STYLE CONNECTOR



CRT-D CONNECTOR

AT500 AT501, 7253

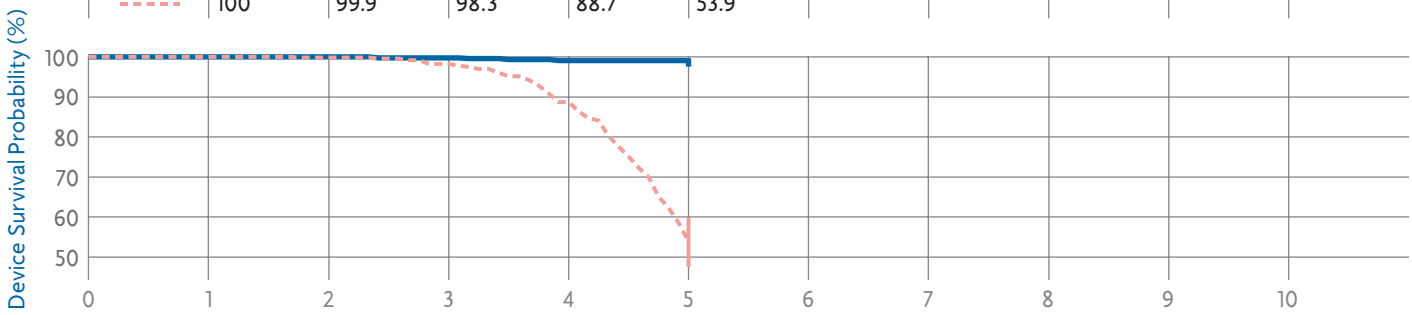
US Market Release	Mar-03
Registered US Implants	11,000
Estimated Active US Implants	9,000
Normal Battery Depletions	75
Malfunctions	5 (2 related to advisory)
Therapy Function Not Compromised	2 (1 related to advisory)
Therapy Function Compromised	3 (1 related to advisory)
Advisories	1 see page 144 – 2003 Potential Incorrect Memory Circuit Setting also see page 160 – Technical article on AT500 Pacing System Follow-Up Protocol

Product Characteristics

NBG Code	DDDRP
Serial Number Prefix/Xray ID	IJF
Estimated Longevity	5.8 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr
Malfunction-free survival	100	100	99.8	99.1	99.1
All-cause survival	100	99.9	98.3	88.7	53.9



Elite 7074, 7075, 7076, 7077

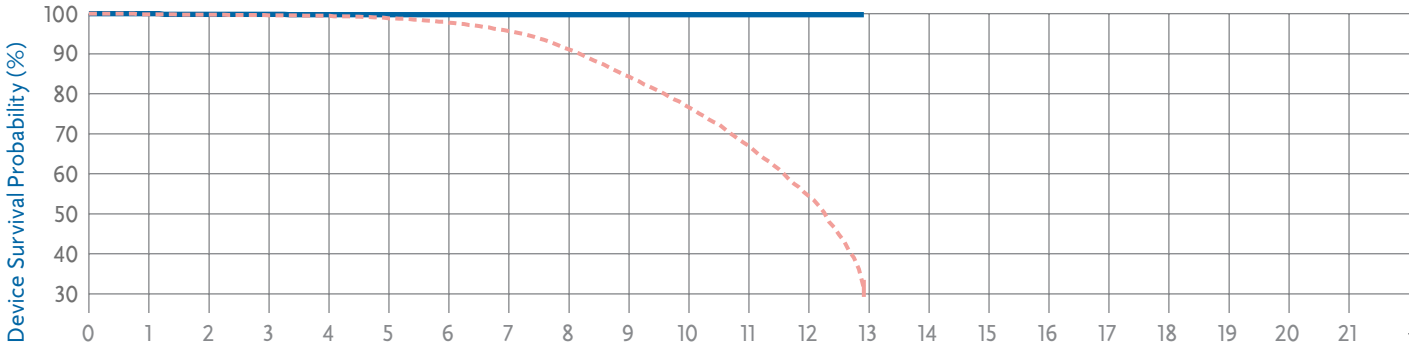
US Market Release	Apr-91
Registered US Implants	48,000
Estimated Active US Implants	2,000
Normal Battery Depletions	2,993
Malfunctions	85
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	YE, YF, 2E, 1X
Estimated Longevity	11.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	
Malfunction-free survival	100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
All-cause survival	99.9	99.8	99.6	99.5	98.9	97.8	95.7	91.1	84.3	76.6	67.0	54.4	31.4 at 155 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Elite II 7084, 7085, 7086

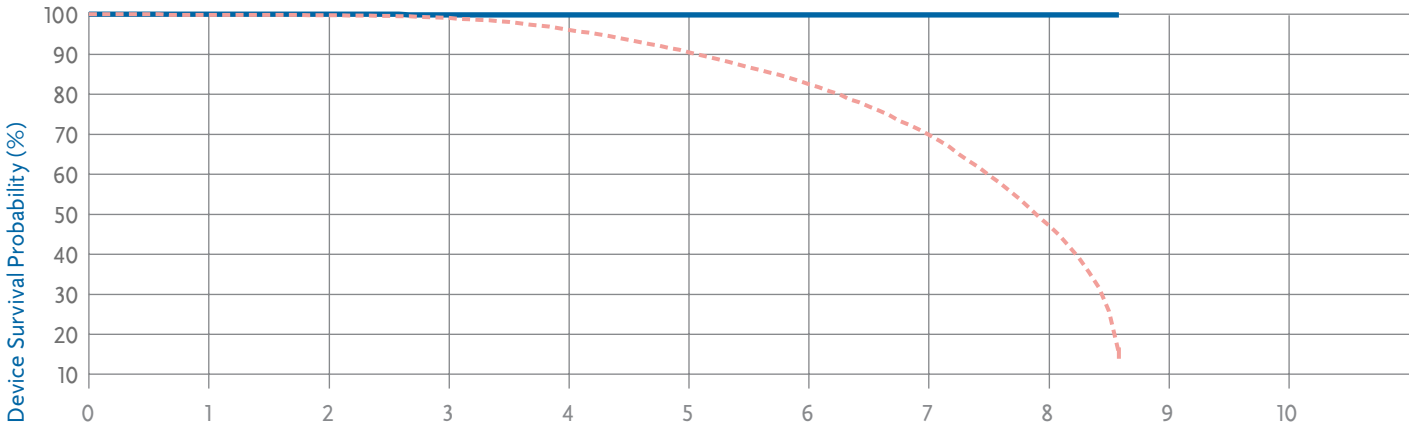
US Market Release	Dec-92
Registered US Implants	57,000
Estimated Active US Implants	4
Normal Battery Depletions	7,108
Malfunctions	45
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	3U, 3V, 3Y
Estimated Longevity	7.0 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
Malfunction-free survival	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9 at 103 mo
All-cause survival	99.9	99.8	99.1	96.1	90.5	82.5	69.9	47.1	15.3 at 103 mo



EnPulse DR E1DR01

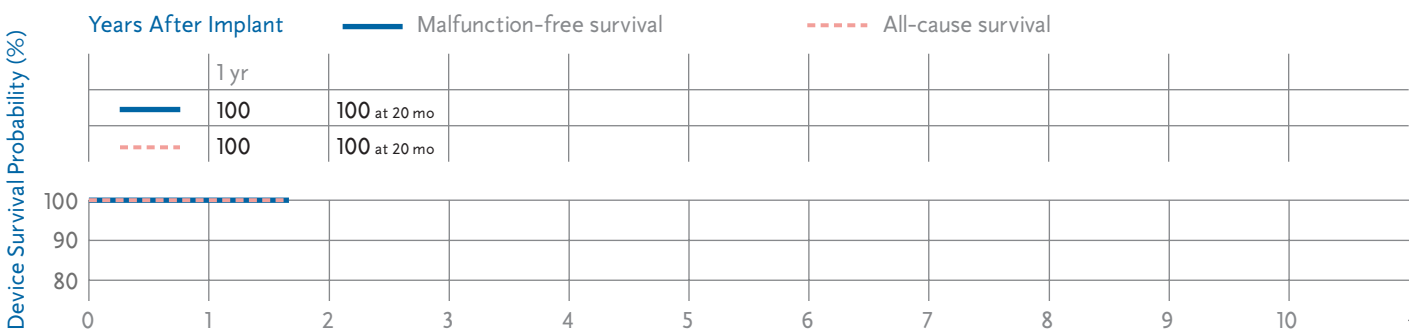
US Market Release	Dec-03
Registered US Implants	7,000
Estimated Active US Implants	6,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PRA
Estimated Longevity	7.5 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	
Malfunction-free survival	100	100 at 20 mo
All-cause survival	100	100 at 20 mo



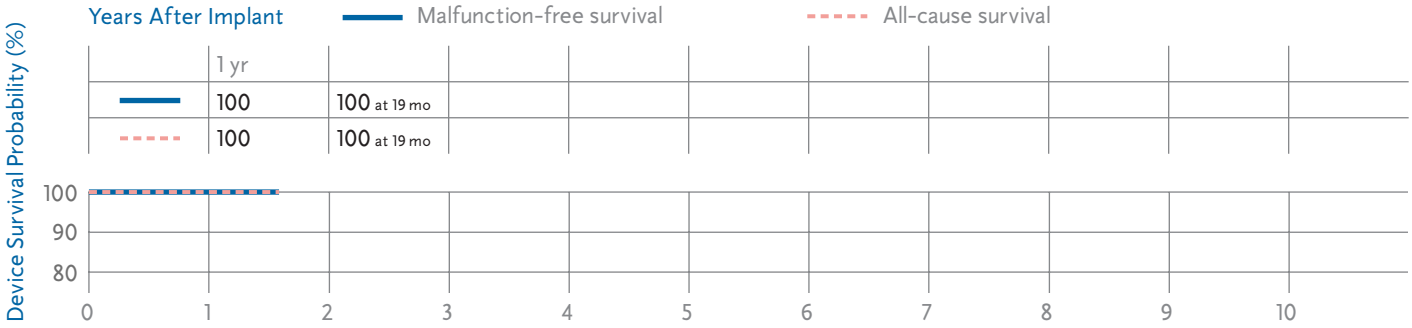
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

EnPulse DR E1DR21

US Market Release	Dec-03
Registered US Implants	2,000
Estimated Active US Implants	2,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PPT
Estimated Longevity	5.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

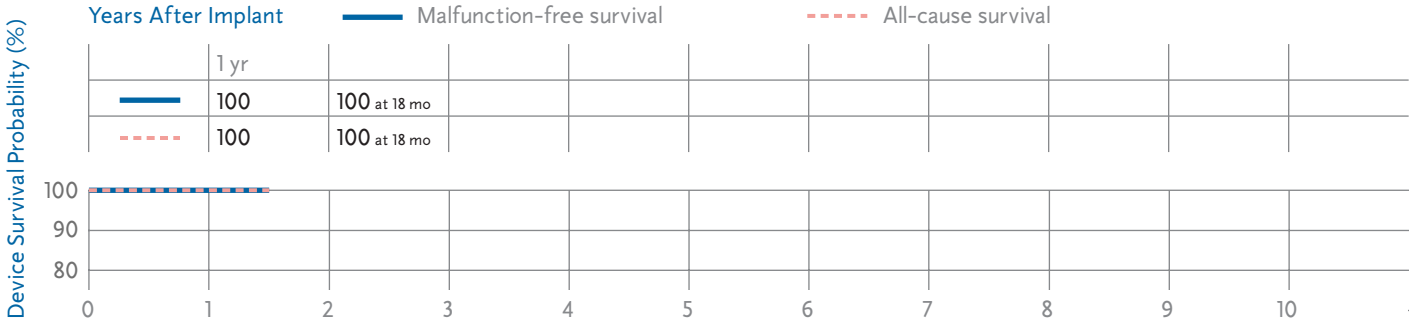


EnPulse 2 DR E2DR01, E2DR03, E2DR06

US Market Release	Feb-04
Registered US Implants	53,000
Estimated Active US Implants	50,000
Normal Battery Depletions	0
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PNB, PNC, PNH
Estimated Longevity	7.5 yrs @ 2.5 V 500 Ω impedance 100% pacing



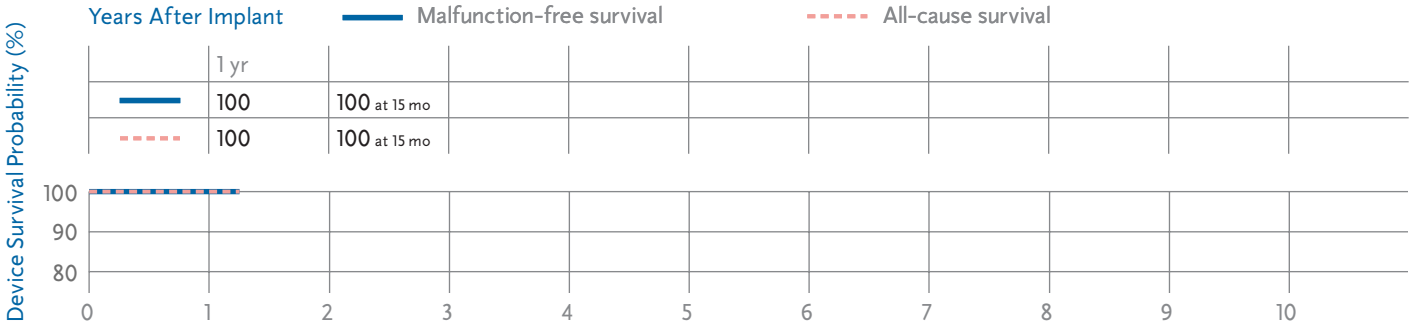
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

EnPulse 2 DR E2DR21

US Market Release	Feb-04
Registered US Implants	6,000
Estimated Active US Implants	5,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PMU
Estimated Longevity	5.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

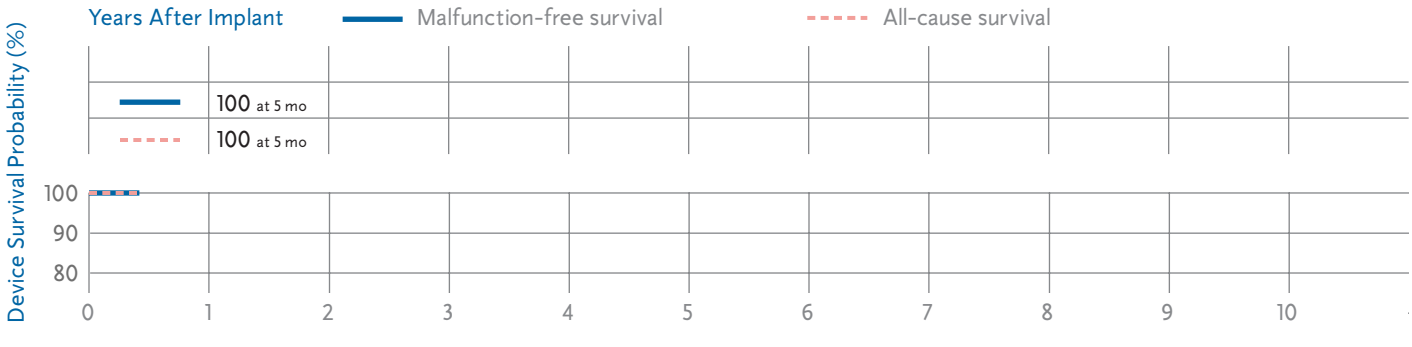


EnPulse 2 DR E2DR31

US Market Release	Feb-04
Registered US Implants	200
Estimated Active US Implants	200
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/Xray ID	PNL
Estimated Longevity	9.0 yrs @ 2.5 V 500 Ω impedance 100% pacing



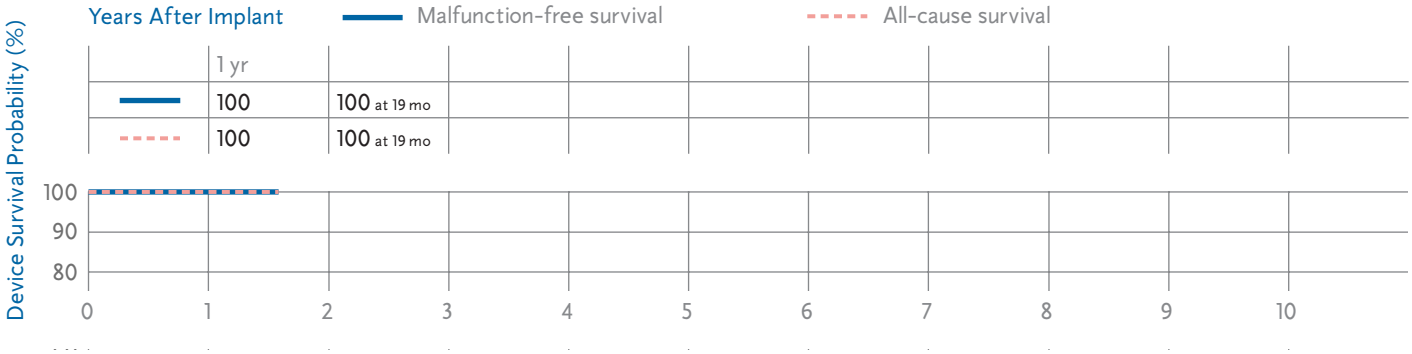
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

EnPulse 2 SR E2SR01, E2SR03, E2SR06

US Market Release	Dec-03
Registered US Implants	11,000
Estimated Active US Implants	10,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/Xray ID	PMW, PMY, PNA
Estimated Longevity	7.2 yrs @ 2.5 V 500 Ω impedance 100% pacing

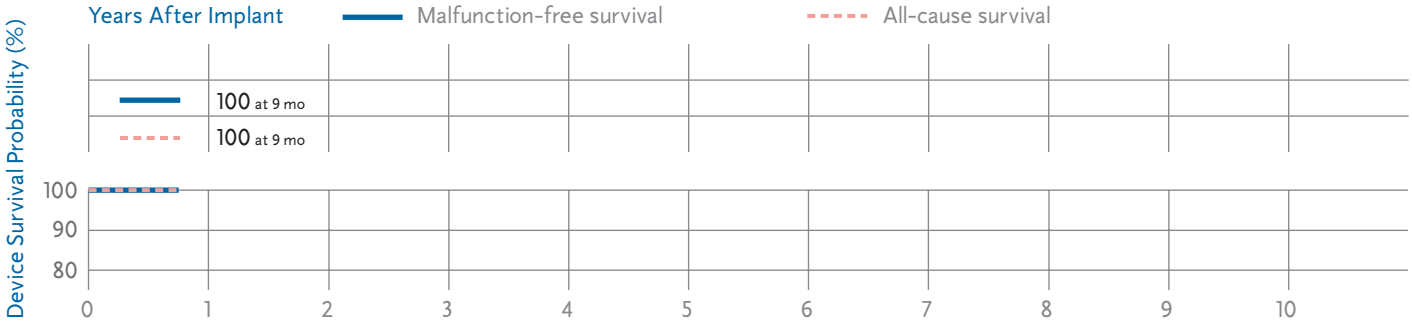


EnPulse 2 VDD E2VDD01

US Market Release	Dec-03
Registered US Implants	300
Estimated Active US Implants	200
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	VDD
Serial Number Prefix/Xray ID	PMV
Estimated Longevity	6.1 yrs @ 2.5 V 500 Ω impedance 100% pacing



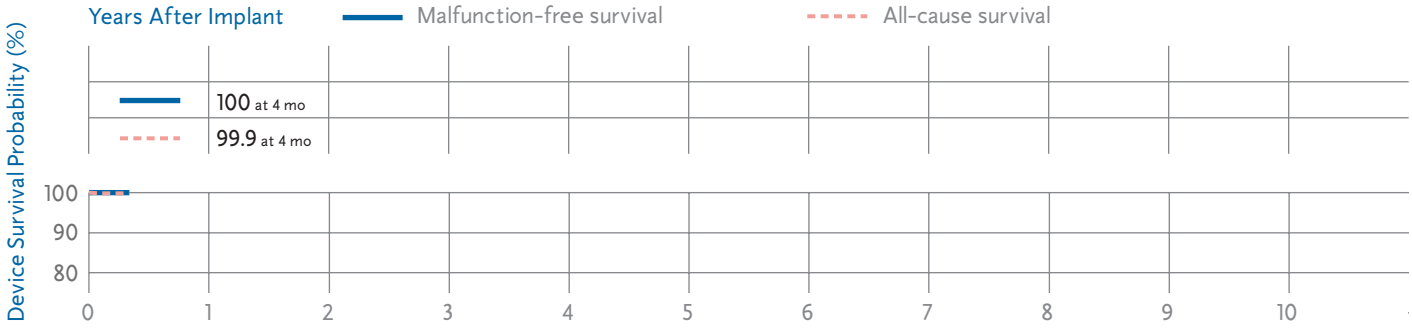
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

EnRhythm DR P1501DR

US Market Release	May-05
Registered US Implants	5,000
Estimated Active US Implants	5,000
Normal Battery Depletions	0
Malfunctions	1
Therapy Function Not Compromised	1
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDDRP
Serial Number Prefix/Xray ID	PNP
Estimated Longevity	10.5 yrs @ 2.5 V 500 Ω impedance 100% pacing

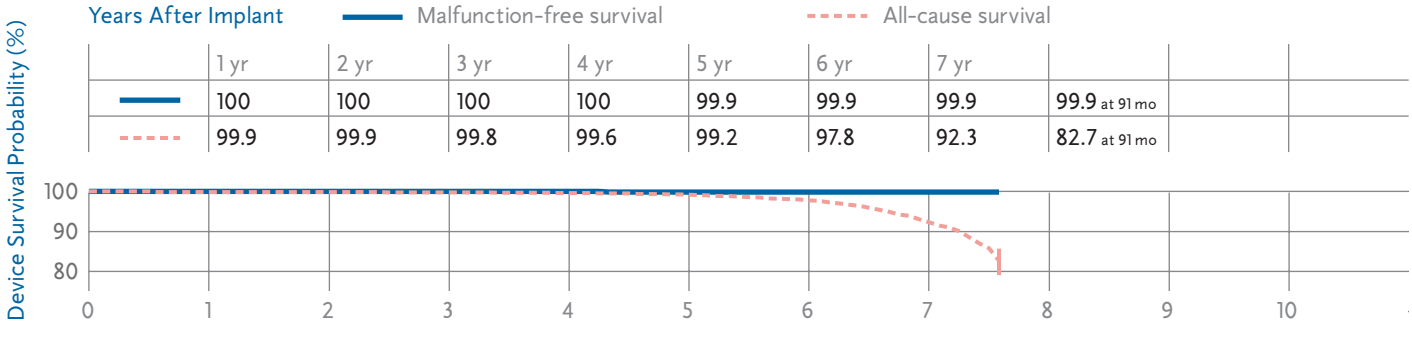


Kappa 400 DR KDR401, KDR403

US Market Release	Jan-98
Registered US Implants	46,000
Estimated Active US Implants	21,000
Normal Battery Depletions	547
Malfunctions	19
Therapy Function Not Compromised	10
Therapy Function Compromised	9
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PER, PET
Estimated Longevity	7.8 yrs @ 2.5 V 500 Ω impedance 100% pacing



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 400 SR KSR401, KSR403

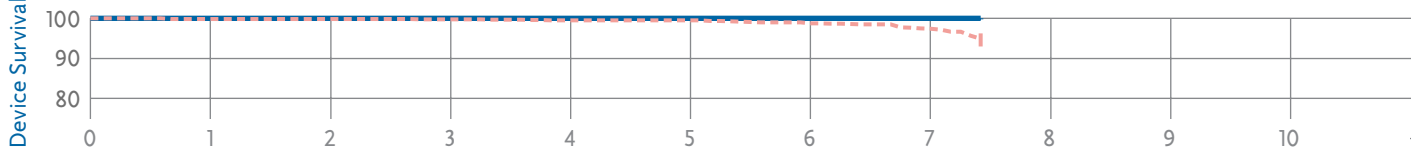
US Market Release	Feb-98
Registered US Implants	15,000
Estimated Active US Implants	7,000
Normal Battery Depletions	48
Malfunctions	4
Therapy Function Not Compromised	3
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PEU, PGD
Estimated Longevity	7.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100 at 89 mo
All-cause survival	99.9	99.9	99.8	99.5	99.5	98.8	97.4	94.9 at 89 mo



Kappa 600 DR KDR601, KDR603, KDR606

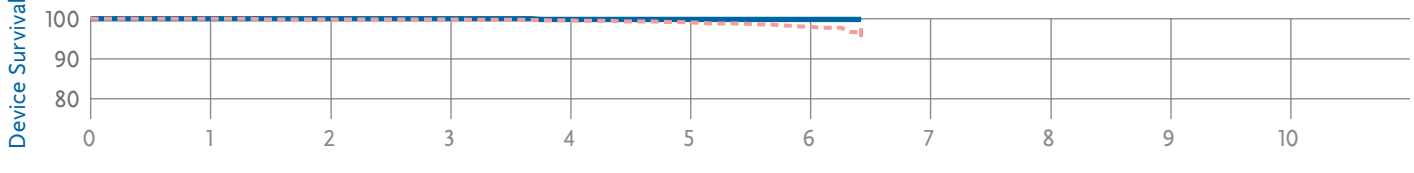
US Market Release	Jan-99
Registered US Implants	23,000
Estimated Active US Implants	13,000
Normal Battery Depletions	76
Malfunctions	13 (8 related to advisory)
Therapy Function Not Compromised	4 (1 related to advisory)
Therapy Function Compromised	9 (7 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PHF, PHH, PHG
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	100	100	100	99.9	99.9	99.9	99.9 at 77 mo
All-cause survival	100	99.9	99.9	99.6	99.1	98.0	96.7 at 77 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 600 DR KDR651, KDR653

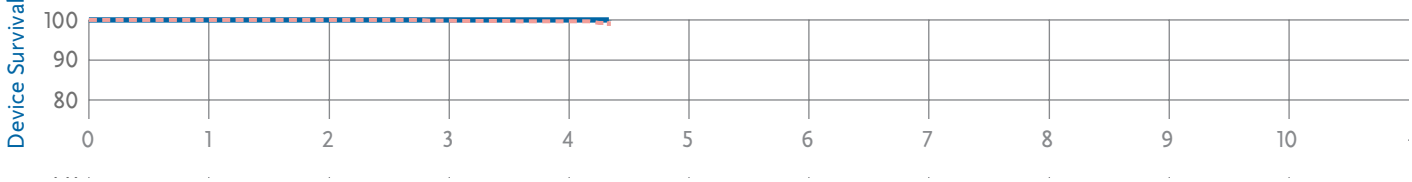
US Market Release	Mar-01
Registered US Implants	14,000
Estimated Active US Implants	9,000
Normal Battery Depletions	11
Malfunctions	3 (0 related to advisory)
Therapy Function Not Compromised	2 (0 related to advisory)
Therapy Function Compromised	1 (0 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PLJ, PLK
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	
Malfunction-free survival	100	100	100	100	100 at 52 mo
All-cause survival	100	100	99.9	99.7	99.3 at 52 mo



Kappa 700 D KD701

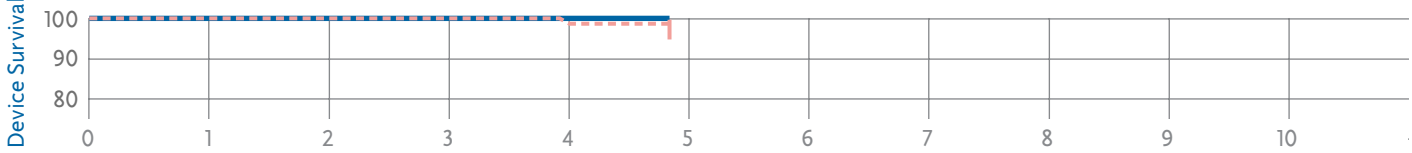
US Market Release	Jan-99
Registered US Implants	300
Estimated Active US Implants	200
Normal Battery Depletions	2
Malfunctions	0 (0 related to advisory)
Therapy Function Not Compromised	0 (0 related to advisory)
Therapy Function Compromised	0 (0 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	DDD
Serial Number Prefix/Xray ID	PHK
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	
Malfunction-free survival	100	100	100	100	100 at 58 mo
All-cause survival	100	100	100	98.7	98.7 at 58 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 700 DR KDR701, KDR703, KDR706

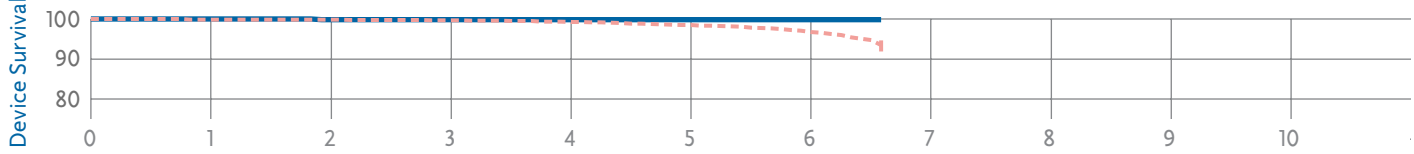
US Market Release	Feb-99
Registered US Implants	182,000
Estimated Active US Implants	116,000
Normal Battery Depletions	599
Malfunctions	123 (91 related to advisory)
Therapy Function Not Compromised	17 (0 related to advisory)
Therapy Function Compromised	106 (91 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PGU, PGY, PGW
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	100	99.9	99.9	99.9	99.9	99.9	99.9 at 79 mo
All-cause survival	99.9	99.9	99.7	99.3	98.5	96.8	93.5 at 79 mo



Kappa 700 DR KDR721

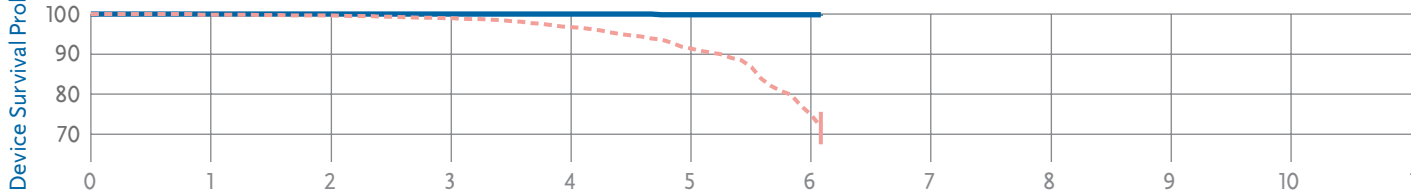
US Market Release	Feb-99
Registered US Implants	10,000
Estimated Active US Implants	4,000
Normal Battery Depletions	224
Malfunctions	5 (4 related to advisory)
Therapy Function Not Compromised	1 (0 related to advisory)
Therapy Function Compromised	4 (4 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PGR
Estimated Longevity	5.5 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	100	100	100	100	99.9	99.9	99.9 at 73 mo
All-cause survival	99.9	99.7	99.0	96.8	91.4	74.9	71.8 at 73 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 700 SR KSR701, KSR703, KSR706

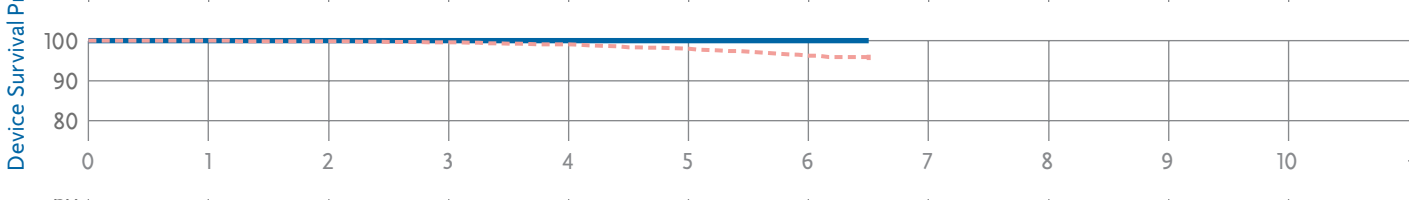
US Market Release	Feb-99
Registered US Implants	50,000
Estimated Active US Implants	26,000
Normal Battery Depletions	201
Malfunctions	5
Therapy Function Not Compromised	1
Therapy Function Compromised	4
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PHT, PHW, PHU
Estimated Longevity	7.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
Malfunction-free survival	100	100	100	100	100	100	100 at 78 mo
All-cause survival	100	99.9	99.6	99.1	98.0	96.3	95.9 at 78 mo



Kappa 700 VDD KVDD701

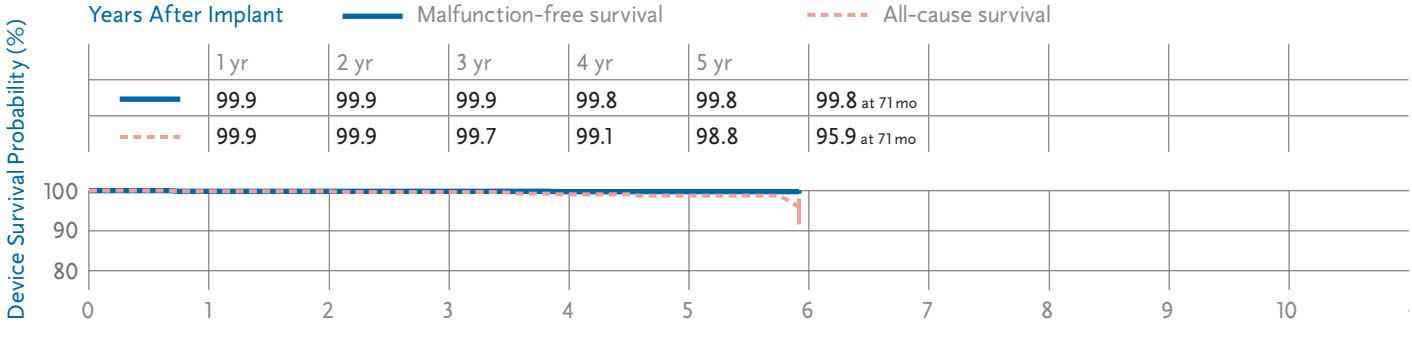
US Market Release	Jan-99
Registered US Implants	2,000
Estimated Active US Implants	1,000
Normal Battery Depletions	7
Malfunctions	2 (2 related to advisory)
Therapy Function Not Compromised	0 (0 related to advisory)
Therapy Function Compromised	2 (2 related to advisory)
Advisories	1 see page 146 – 2002 Potential Fractured Power Supply Wires

Product Characteristics

NBG Code	VDD/RO
Serial Number Prefix/Xray ID	PHP
Estimated Longevity	6.3 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	99.9	99.9	99.9	99.8	99.8	99.8 at 71 mo
All-cause survival	99.9	99.9	99.7	99.1	98.8	95.9 at 71 mo



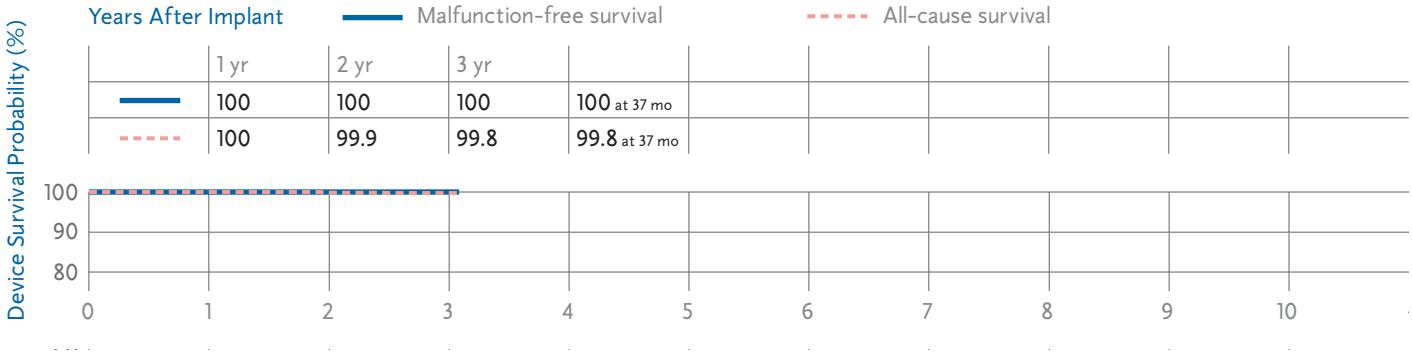
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 800 DR KDR801, KDR803

US Market Release	Jan-02
Registered US Implants	4,000
Estimated Active US Implants	3,000
Normal Battery Depletions	2
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PKW, PKY
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

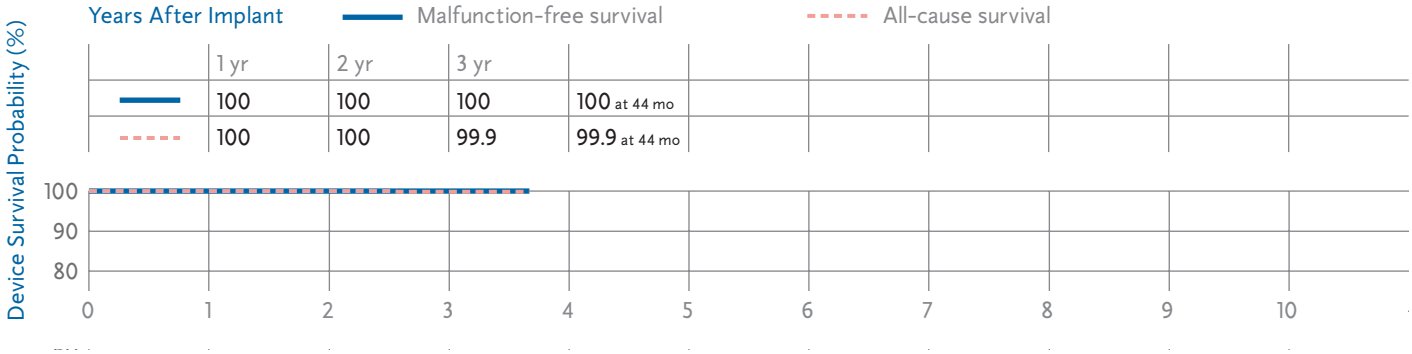


Kappa 900 DR KDR901, KDR903, KDR906

US Market Release	Jan-02
Registered US Implants	108,000
Estimated Active US Implants	87,000
Normal Battery Depletions	17
Malfunctions	6
Therapy Function Not Compromised	4
Therapy Function Compromised	2
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PKM, PKN, PKP
Estimated Longevity	7.7 yrs @ 2.5 V 500 Ω impedance 100% pacing



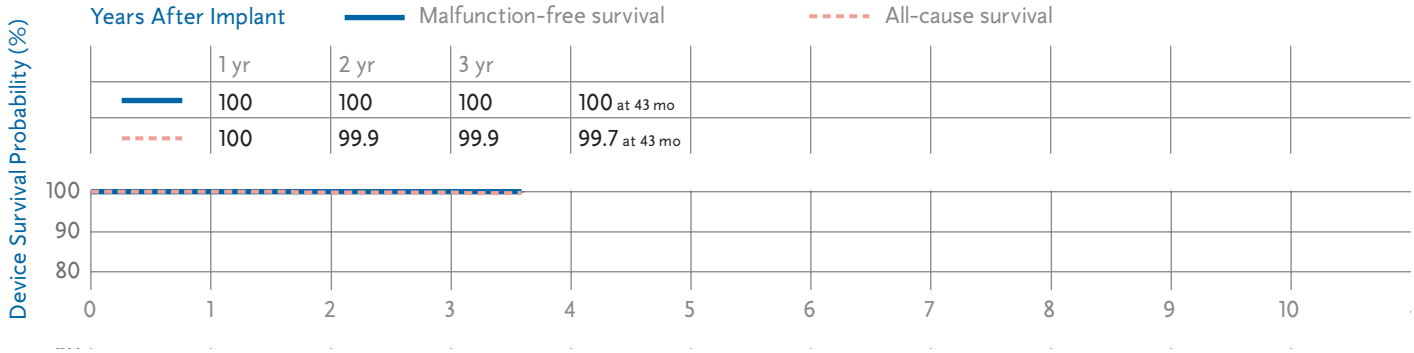
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 900 SR KSR901, KSR903, KSR906

US Market Release	Jan-02
Registered US Implants	29,000
Estimated Active US Implants	20,000
Normal Battery Depletions	6
Malfunctions	3
Therapy Function Not Compromised	3
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PLF, PLG, PLH
Estimated Longevity	7.3 yrs @ 2.5 V 500 Ω impedance 100% pacing

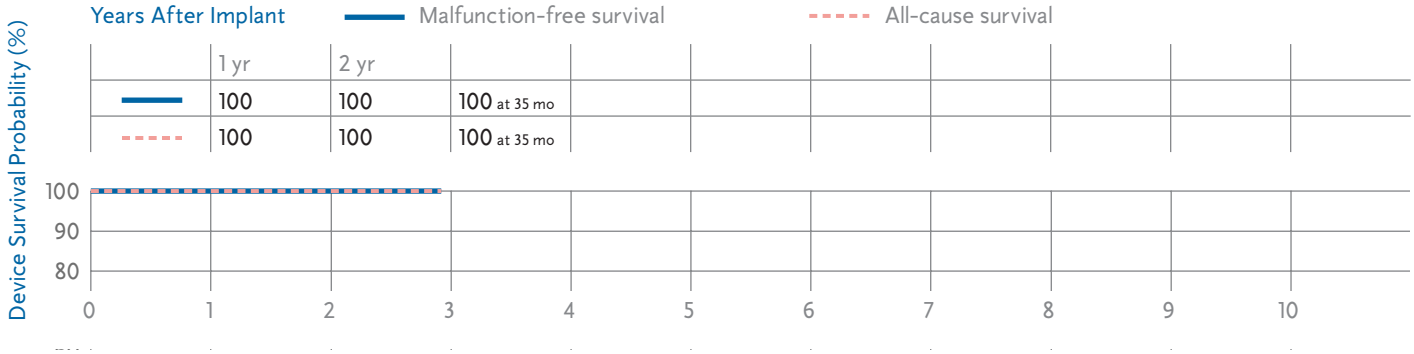


Kappa 900 VDD KVDD901

US Market Release	Jan-02
Registered US Implants	1,000
Estimated Active US Implants	500
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	VDD
Serial Number Prefix/Xray ID	PLE
Estimated Longevity	6.3 yrs @ 2.5 V 500 Ω impedance 100% pacing



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Kappa 920 DR KDR921

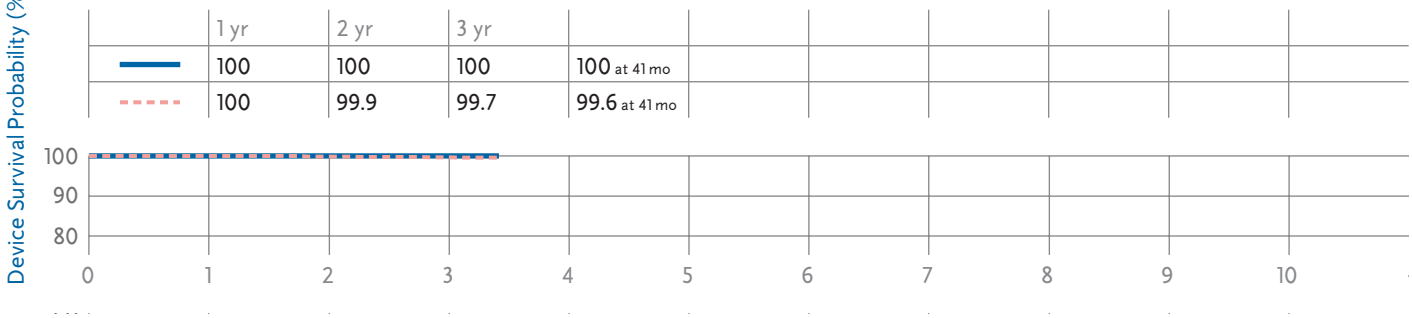
US Market Release	Jan-02
Registered US Implants	15,000
Estimated Active US Implants	11,000
Normal Battery Depletions	8
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PKR
Estimated Longevity	5.5 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	
Malfunction-free survival	100	100	100	100 at 41 mo
All-cause survival	100	99.9	99.7	99.6 at 41 mo



Legend 8416, 8417, 8417M, 8418, 8419

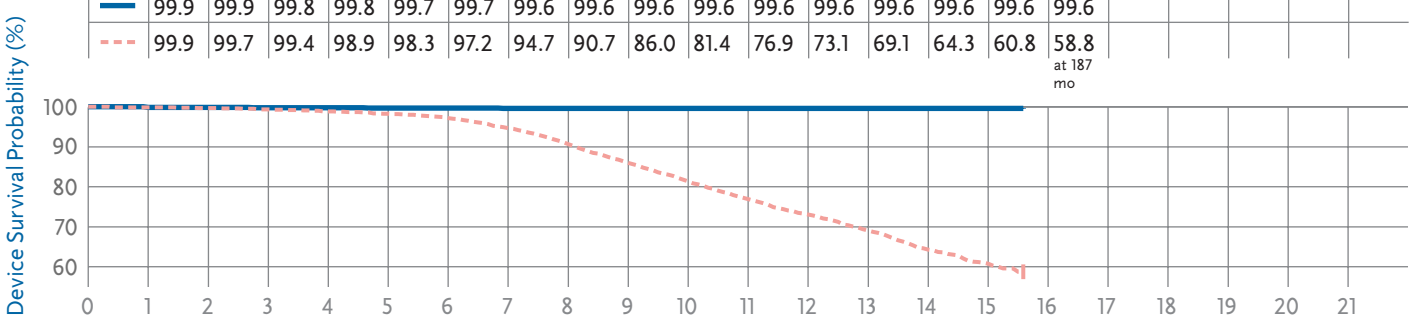
US Market Release	Aug-89
Registered US Implants	57,000
Estimated Active US Implants	4,000
Normal Battery Depletions	2,441
Malfunctions	145
Advisories	None

Product Characteristics

NBG Code	SSIRO
Serial Number Prefix/Xray ID	XT, WJ, WN, ZT
Estimated Longevity	13.1 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	
Malfunction-free survival	99.9	99.9	99.8	99.8	99.7	99.7	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6
All-cause survival	99.9	99.7	99.4	98.9	98.3	97.2	94.7	90.7	86.0	81.4	76.9	73.1	69.1	64.3	60.8	58.8 at 187 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Legend II 8424, 8426, 8427

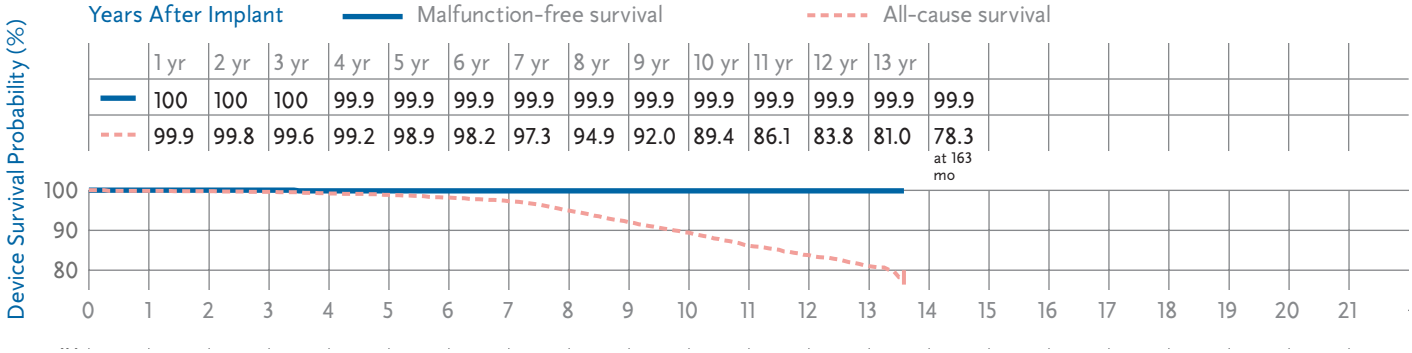
US Market Release	Nov-91
Registered US Implants	58,000
Estimated Active US Implants	8,000
Normal Battery Depletions	1,424
Malfunctions	37
Advisories	None

Product Characteristics

NBG Code	SSIR0
Serial Number Prefix/Xray ID	2P, 2T, 2U
Estimated Longevity	11.2 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	
Malfunction-free survival	100	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
All-cause survival	99.9	99.8	99.6	99.2	98.9	98.2	97.3	94.9	92.0	89.4	86.1	83.8	81.0	78.3 at 163 mo



Micro Minix 8360

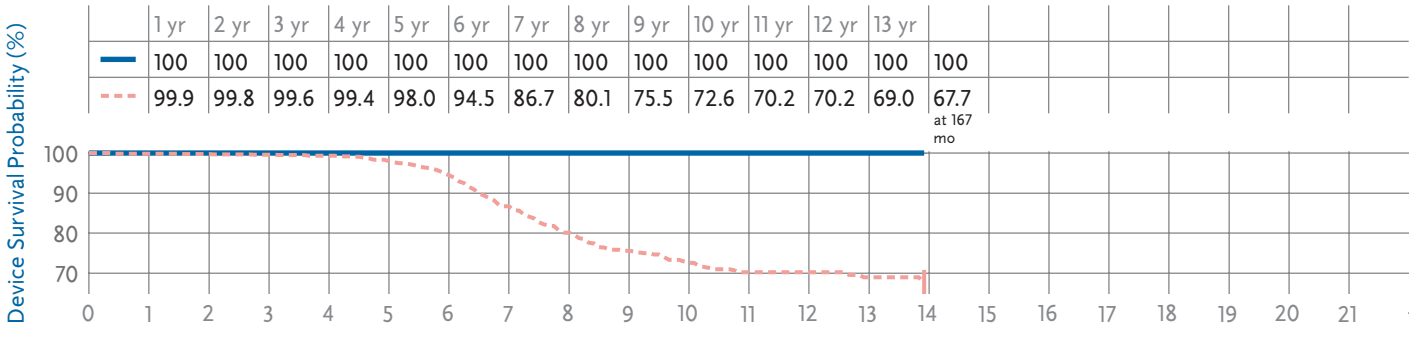
US Market Release	Oct-90
Registered US Implants	7,000
Estimated Active US Implants	400
Normal Battery Depletions	255
Malfunctions	2
Advisories	1 see page 159 – 1991 Potential Delayed Restoration of Permanent Settings

Product Characteristics

NBG Code	SSICO
Serial Number Prefix/Xray ID	ZU
Estimated Longevity	6.3 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100	100	100	100	100
All-cause survival	99.9	99.8	99.6	99.4	98.0	94.5	86.7	80.1	75.5	72.6	70.2	70.2	69.0	67.7 at 167 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Minix/Minix ST 8330, 8331, 8331M, 8340, 8341, 8341M, 8342

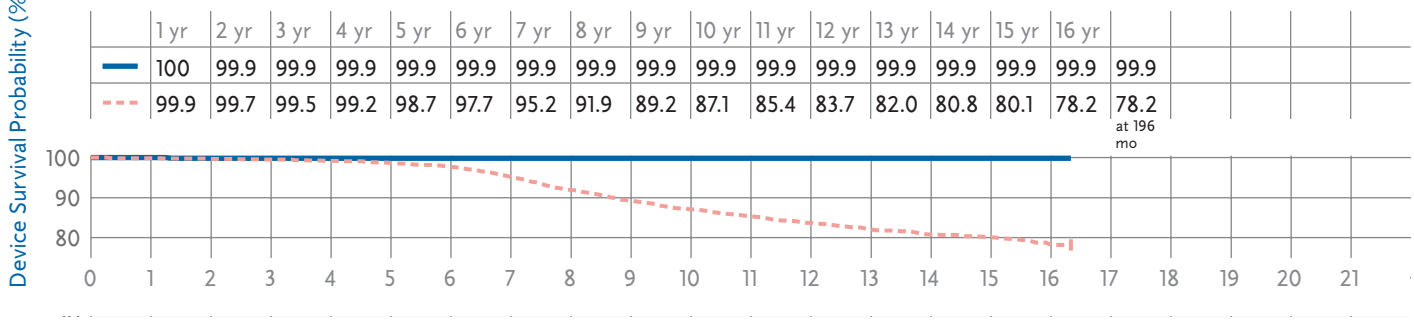
US Market Release	Dec-89
Registered US Implants	58,000
Estimated Active US Implants	6,000
Normal Battery Depletions	1,371
Malfunctions	49
Advisories	1 see page 159 – 1991 Potential Delayed Restoration of Permanent Settings

Product Characteristics

NBG Code	SSIR0
Serial Number Prefix/Xray ID	2P, 2T, 2U
Estimated Longevity	11.2 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	
Malfunction-free survival	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
All-cause survival	99.9	99.7	99.5	99.2	98.7	97.7	95.2	91.9	89.2	87.1	85.4	83.7	82.0	80.8	80.1	78.2	78.2 at 196 mo



Minuet 7107, 7108

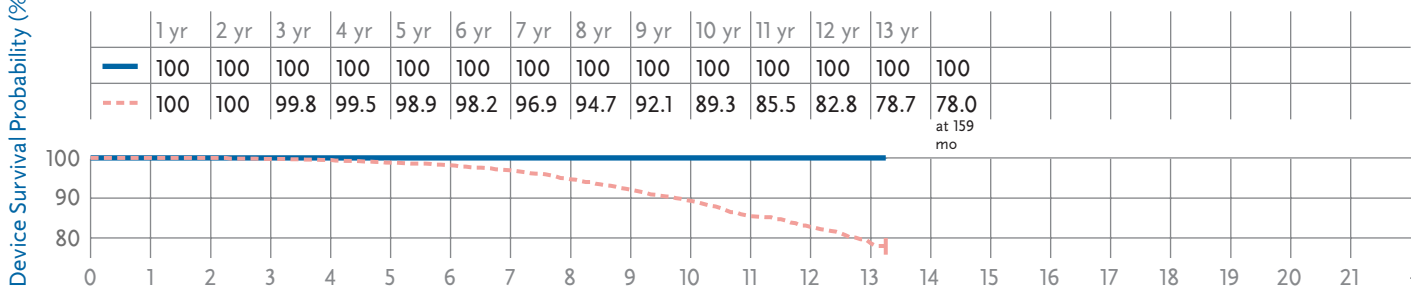
US Market Release	Mar-92
Registered US Implants	17,000
Estimated Active US Implants	3,000
Normal Battery Depletions	470
Malfunctions	4
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/Xray ID	1Z1, 2G1
Estimated Longevity	11.8 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100	100	100	100	100
All-cause survival	100	100	99.8	99.5	98.9	98.2	96.9	94.7	92.1	89.3	85.5	82.8	78.7	78.0 at 159 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Pasys/Pasys ST 8316, 8317, 8318, 8320, 8322, 8329

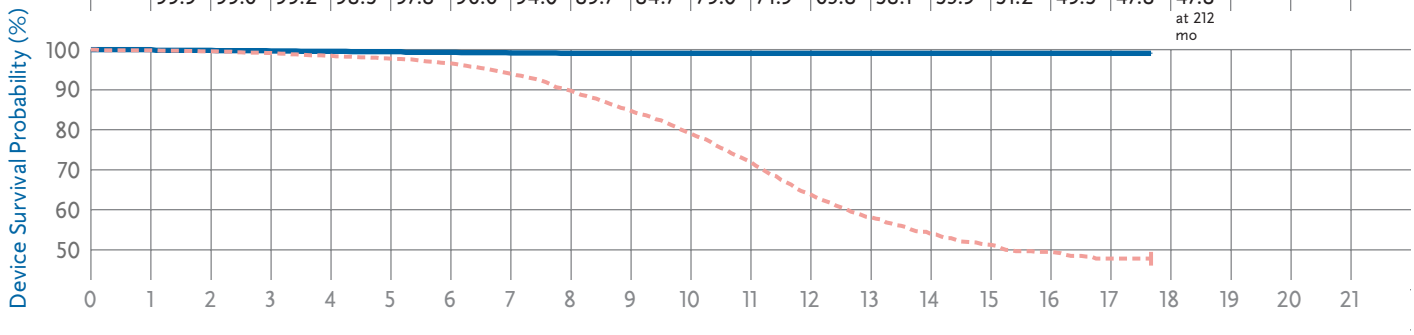
US Market Release	Mar-86
Registered US Implants	28,000
Estimated Active US Implants	1,000
Normal Battery Depletions	1,430
Malfunctions	145
Advisories	None

Product Characteristics

NBG Code	SSICO, VVICO
Serial Number Prefix/Xray ID	JU, LL, VB, NX, NZ, PJ
Estimated Longevity	10.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	
Malfunction-free survival	100	99.9	99.7	99.6	99.5	99.4	99.2	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1
All-cause survival	99.9	99.6	99.2	98.5	97.8	96.6	94.0	89.7	84.7	79.0	71.9	63.8	58.1	53.9	51.2	49.5	47.8	47.8 at 212 mo



Preva D 7068

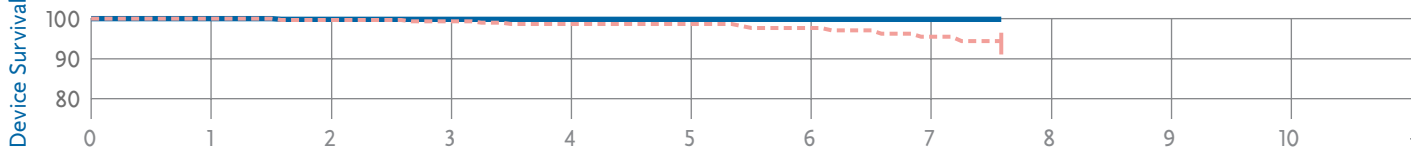
US Market Release	Nov-96
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	9
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/Xray ID	PIE
Estimated Longevity	9.8 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	
Malfunction-free survival	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9 at 91 mo
All-cause survival	100	99.7	99.4	98.7	98.7	97.7	95.5	94.4 at 91 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Preva DR 7088, 7089

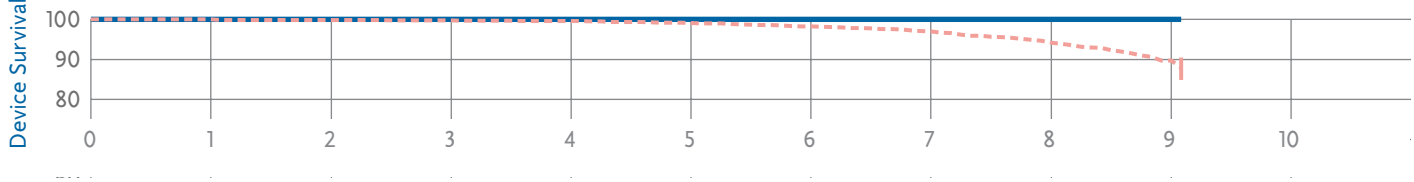
US Market Release	Jul-96
Registered US Implants	25,000
Estimated Active US Implants	10,000
Normal Battery Depletions	286
Malfunctions	3
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PGJ, PGK
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 109 mo
All-cause survival	100	99.9	99.8	99.6	99.1	98.3	97.0	94.2	89.7	88.0 at 109 mo



Preva SR 8088, 8089

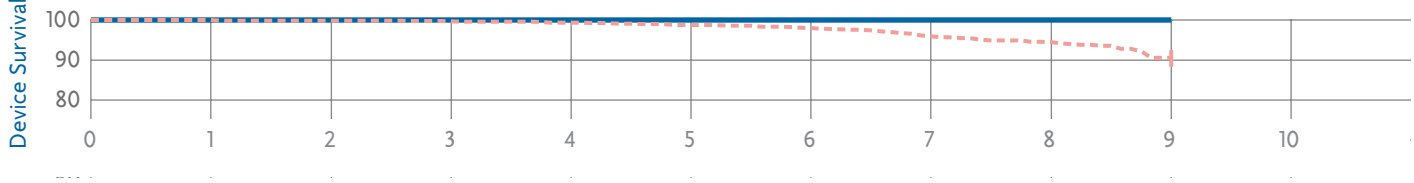
US Market Release	Jul-96
Registered US Implants	18,000
Estimated Active US Implants	5,000
Normal Battery Depletions	157
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PGL, PGM
Estimated Longevity	9.6 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
Malfunction-free survival	100	100	100	100	100	100	100	100	100
All-cause survival	100	99.9	99.7	99.4	98.8	98.0	95.9	94.5	90.6



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Preva ST DR 7078

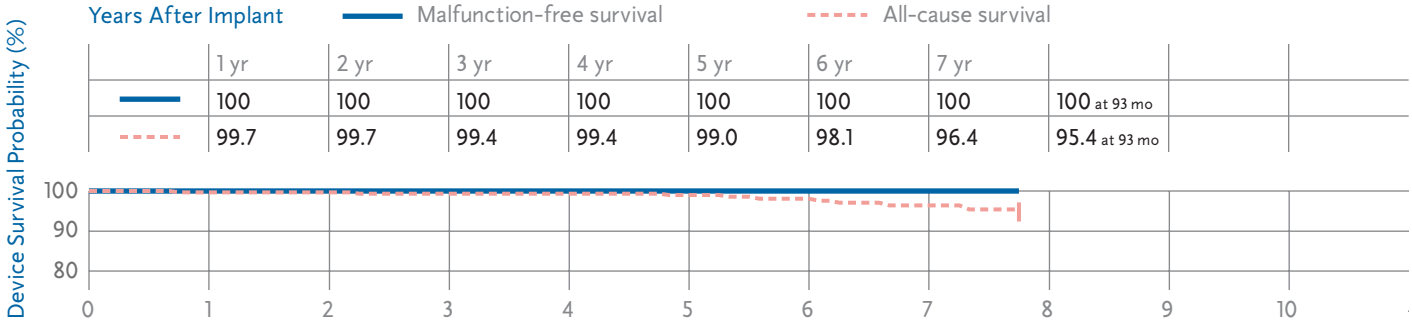
US Market Release	Nov-96
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	9
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PIF
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr		
Malfunction-free survival	100	100	100	100	100	100	100	100 at 93 mo	
All-cause survival	99.7	99.7	99.4	99.4	99.0	98.1	96.4	95.4 at 93 mo	



Prevail S 8085, 8086

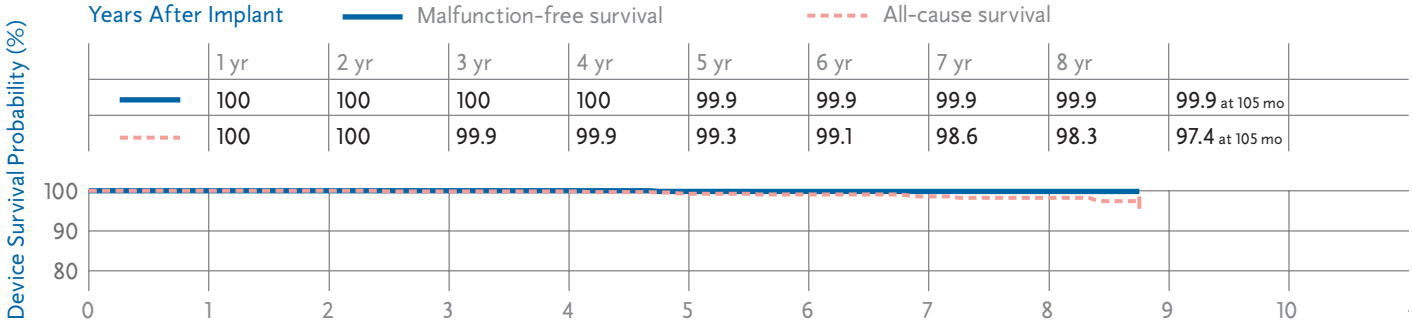
US Market Release	Oct-95
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	10
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSI
Serial Number Prefix/Xray ID	PGL, PGM
Estimated Longevity	9.6 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
Malfunction-free survival	100	100	100	100	99.9	99.9	99.9	99.9	99.9 at 105 mo
All-cause survival	100	100	99.9	99.9	99.3	99.1	98.6	98.3	97.4 at 105 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Prodigy D 7864, 7865, 7866

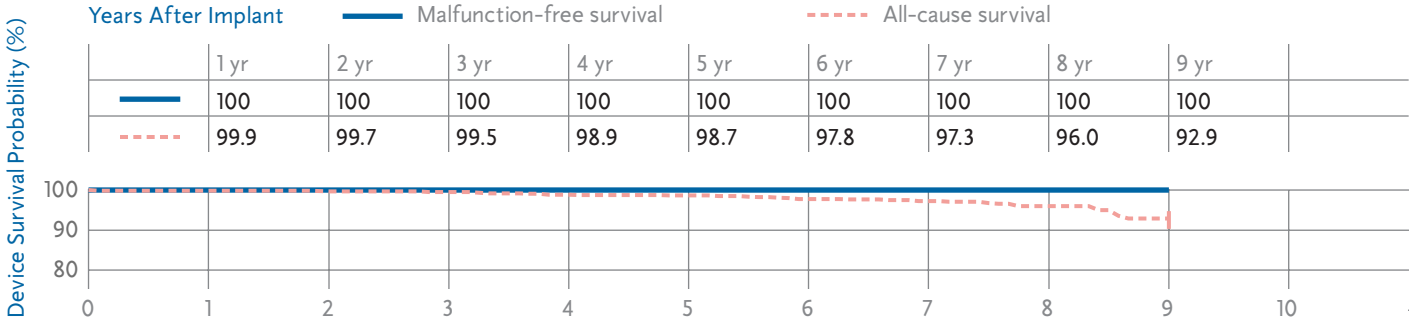
US Market Release	Oct-95
Registered US Implants	3,000
Estimated Active US Implants	1,000
Normal Battery Depletions	33
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/Xray ID	PDL, PDM, PDN
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
Malfunction-free survival	100	100	100	100	100	100	100	100	100
All-cause survival	99.9	99.7	99.5	98.9	98.7	97.8	97.3	96.0	92.9



Prodigy DR 7860, 7861, 7862

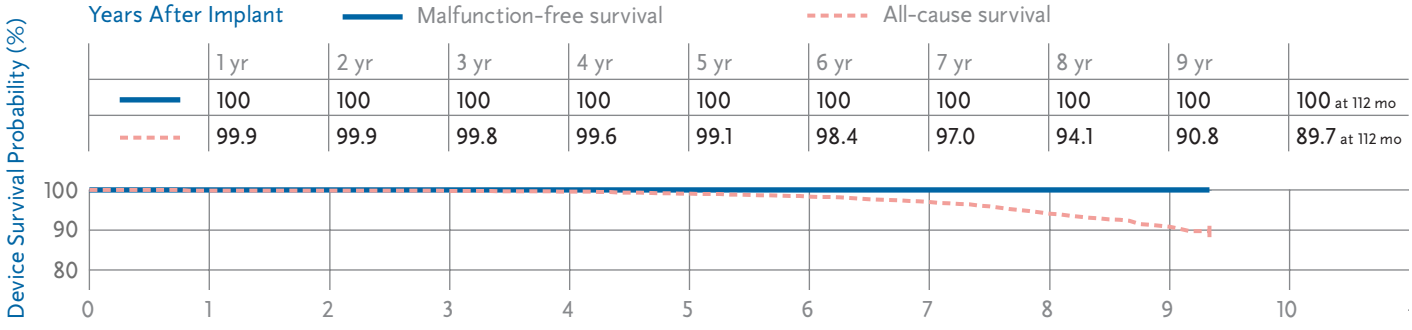
US Market Release	Oct-95
Registered US Implants	37,000
Estimated Active US Implants	14,000
Normal Battery Depletions	403
Malfunctions	10
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PDH, PDJ, PDK
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 112 mo
All-cause survival	99.9	99.9	99.8	99.6	99.1	98.4	97.0	94.1	90.8	89.7 at 112 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Prodigy S 8164, 8165, 8166

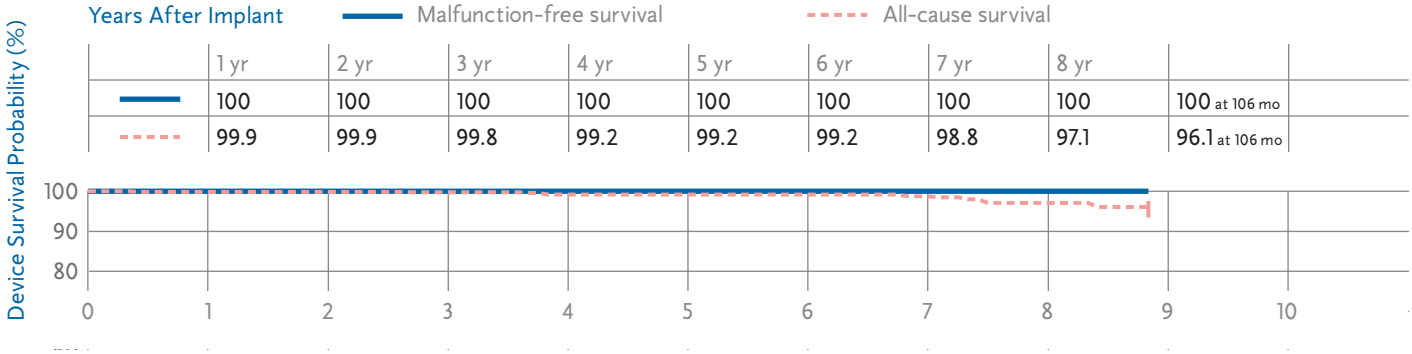
US Market Release	Oct-95
Registered US Implants	2,000
Estimated Active US Implants	1,000
Normal Battery Depletions	11
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	SSIC
Serial Number Prefix/Xray ID	PEG, PEH, PEJ
Estimated Longevity	9.8 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100 at 106 mo
All-cause survival	99.9	99.9	99.8	99.2	99.2	99.2	98.8	97.1	96.1 at 106 mo



Prodigy SR 8158, 8160, 8161, 8162

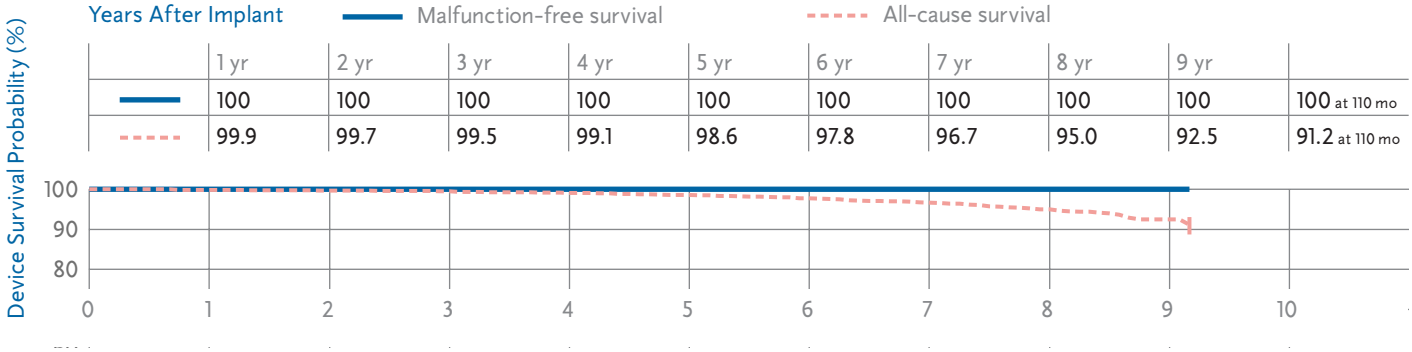
US Market Release	Oct-95
Registered US Implants	22,000
Estimated Active US Implants	7,000
Normal Battery Depletions	189
Malfunctions	5
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PEM, PED, PEE, PEF
Estimated Longevity	9.6 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 110 mo
All-cause survival	99.9	99.7	99.5	99.1	98.6	97.8	96.7	95.0	92.5	91.2 at 110 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Sigma 100 S SS103, SS106

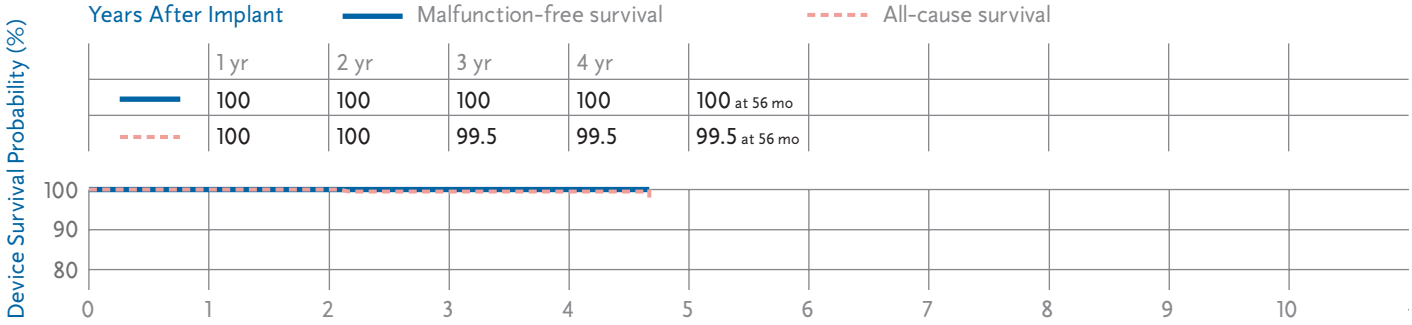
Product Characteristics

US Market Release	Aug-99
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	1
Malfunctions	0 (0 related to advisory)
Therapy Function Not Compromised	0 (0 related to advisory)
Therapy Function Compromised	0 (0 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

NBG Code	SSI
Serial Number Prefix/Xray ID	PJG, PJH
Estimated Longevity	9.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	
Malfunction-free survival	100	100	100	100	100 at 56 mo
All-cause survival	100	100	99.5	99.5	99.5 at 56 mo



Sigma 200 DR SDR203

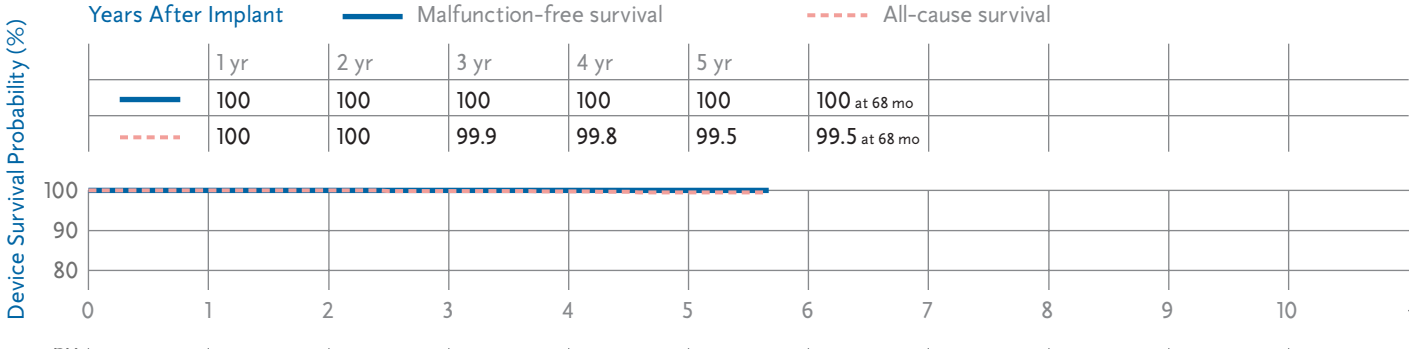
Product Characteristics

US Market Release	Aug-99
Registered US Implants	15,000
Estimated Active US Implants	10,000
Normal Battery Depletions	10
Malfunctions	3 (0 related to advisory)
Therapy Function Not Compromised	1 (0 related to advisory)
Therapy Function Compromised	2 (0 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PJD
Estimated Longevity	9.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	100	100	100	100	100	100 at 68 mo
All-cause survival	100	100	99.9	99.8	99.5	99.5 at 68 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Sigma 200 SR SSR203

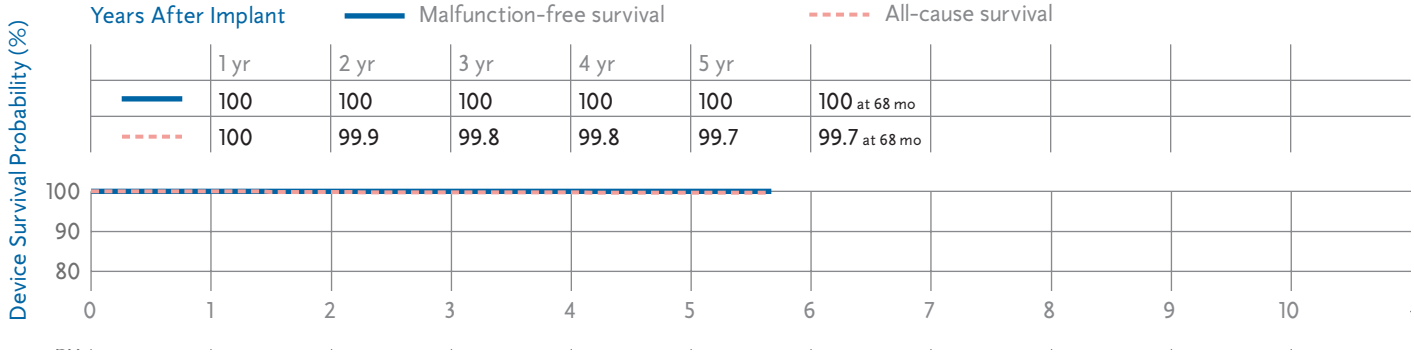
US Market Release	Sep-99
Registered US Implants	12,000
Estimated Active US Implants	6,000
Normal Battery Depletions	8
Malfunctions	0 (0 related to advisory)
Therapy Function Not Compromised	0 (0 related to advisory)
Therapy Function Compromised	0 (0 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PJG
Estimated Longevity	9.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	100	100	100	100	100	100 at 68 mo
All-cause survival	100	99.9	99.8	99.8	99.7	99.7 at 68 mo



Sigma 300 DR SDR303, SDR306

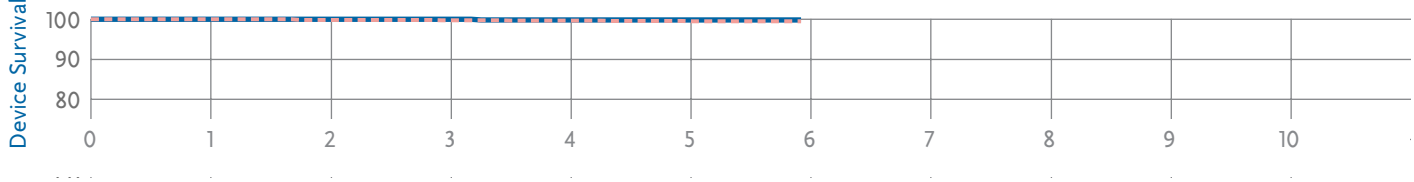
US Market Release	Aug-99
Registered US Implants	91,000
Estimated Active US Implants	62,000
Normal Battery Depletions	42
Malfunctions	28 (10 related to advisory)
Therapy Function Not Compromised	2 (0 related to advisory)
Therapy Function Compromised	26 (10 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PJD, PJE
Estimated Longevity	9.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	100	100	100	99.9	99.9	99.9 at 71 mo
All-cause survival	100	99.9	99.8	99.7	99.5	99.5 at 71 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Sigma 300 SR SSR303, SSR306

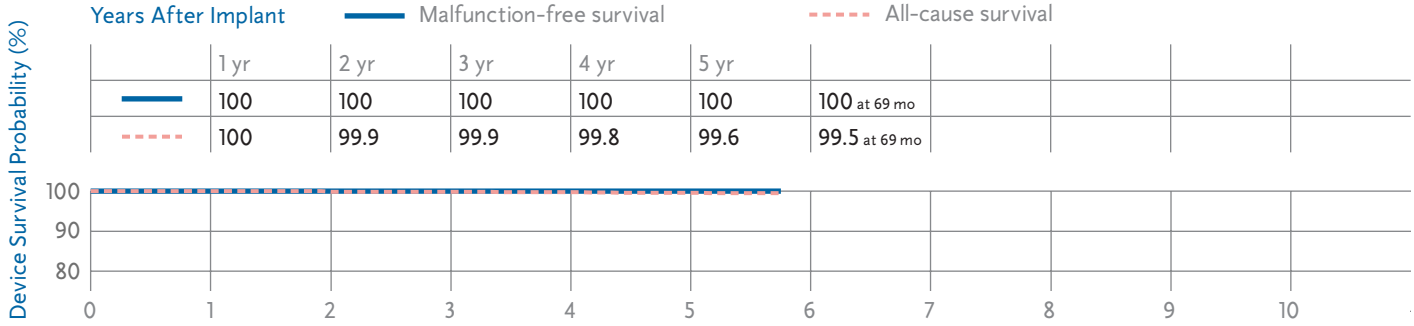
US Market Release	Sep-99
Registered US Implants	45,000
Estimated Active US Implants	26,000
Normal Battery Depletions	22
Malfunctions	4 (1 related to advisory)
Therapy Function Not Compromised	1 (0 related to advisory)
Therapy Function Compromised	3 (1 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PJG, PJH
Estimated Longevity	9.9 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	
Malfunction-free survival	100	100	100	100	100	100 at 69 mo
All-cause survival	100	99.9	99.9	99.8	99.6	99.5 at 69 mo



Sigma 300 VDD SVDD303

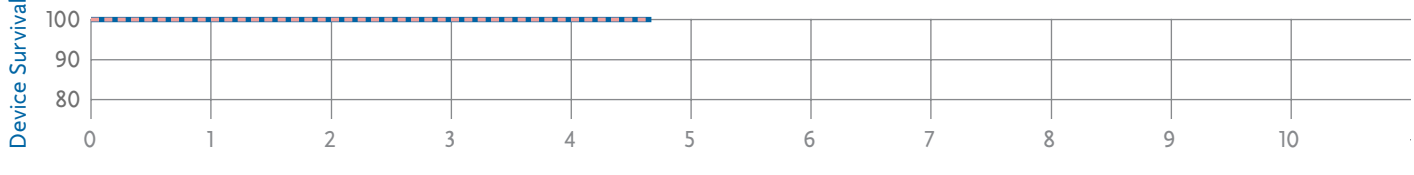
US Market Release	Sep-99
Registered US Implants	1,000
Estimated Active US Implants	400
Normal Battery Depletions	0
Malfunctions	0 (0 related to advisory)
Therapy Function Not Compromised	0 (0 related to advisory)
Therapy Function Compromised	0 (0 related to advisory)
Advisories	2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue

Product Characteristics

NBG Code	VDDD
Serial Number Prefix/Xray ID	PJD
Estimated Longevity	9.2 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	
Malfunction-free survival	100	100	100	100	100 at 56 mo
All-cause survival	100	100	100	100	100 at 56 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Spectrax S 5940, 5940LP, 5941

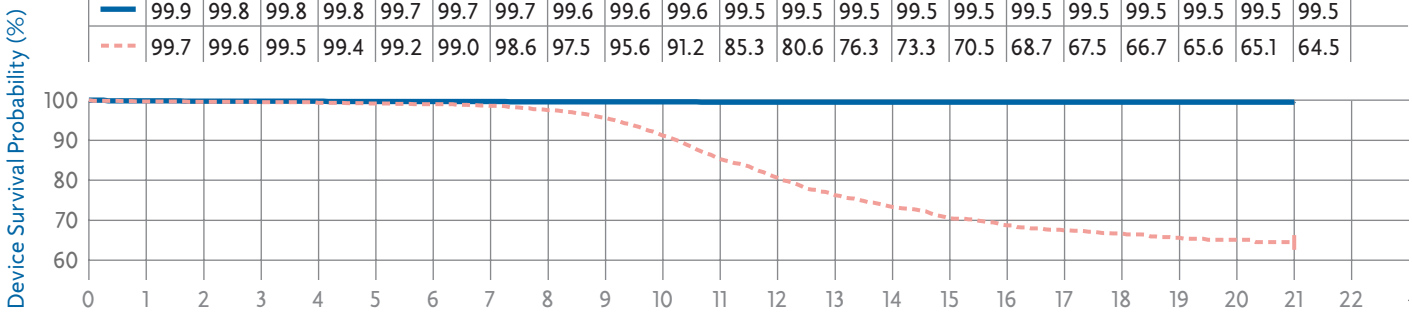
US Market Release	Jul-83
Registered US Implants	25,000
Estimated Active US Implants	1,000
Normal Battery Depletions	802
Malfunctions	76
Advisories	None

Product Characteristics

NBG Code	VVIPO
Serial Number Prefix/Xray ID	NF, PD, LP
Estimated Longevity	9.0 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr	20 yr	21 yr
Malfunction-free survival	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.6	99.6	99.6	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
All-cause survival	99.7	99.6	99.5	99.4	99.2	99.0	98.6	97.5	95.6	91.2	85.3	80.6	76.3	73.3	70.5	68.7	67.5	66.7	65.6	65.1	64.5



Spectrax SXT 8420, 8422, 8423, 8423M

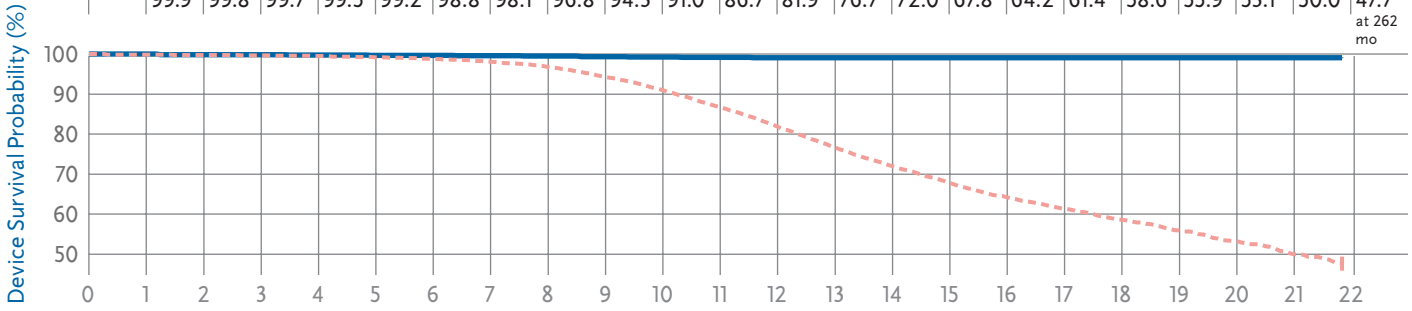
US Market Release	Oct-81
Registered US Implants	111,000
Estimated Active US Implants	3,000
Normal Battery Depletions	4,391
Malfunctions	466
Advisories	None

Product Characteristics

NBG Code	SSIMO
Serial Number Prefix/Xray ID	GL, HJ, HN, 3E
Estimated Longevity	13.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr	20 yr	21 yr	
Malfunction-free survival	100	99.9	99.9	99.8	99.7	99.7	99.6	99.5	99.4	99.3	99.2	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1
All-cause survival	99.9	99.8	99.7	99.5	99.2	98.8	98.1	96.8	94.3	91.0	86.7	81.9	76.7	72.0	67.8	64.2	61.4	58.6	55.9	53.1	50.0	47.7 at 262 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera D 7944, 7945, 7946

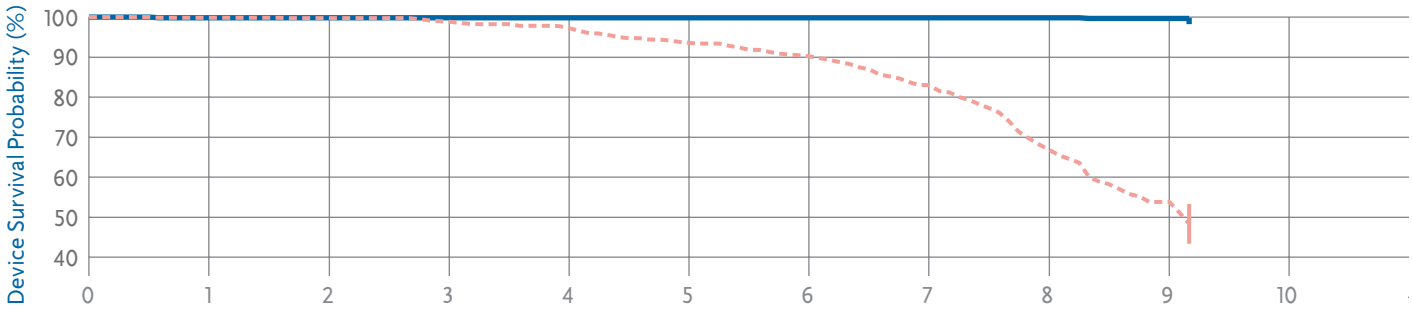
US Market Release	Jan-95
Registered US Implants	2,000
Estimated Active US Implants	30
Normal Battery Depletions	168
Malfunctions	2
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/Xray ID	PBD, PBE, PBF
Estimated Longevity	7.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.7	99.7 at 110 mo
All-cause survival	99.9	99.8	98.9	97.3	93.6	90.2	83.0	66.8	53.8	48.4 at 110 mo



Thera DR-40 7940, 7941, 7942

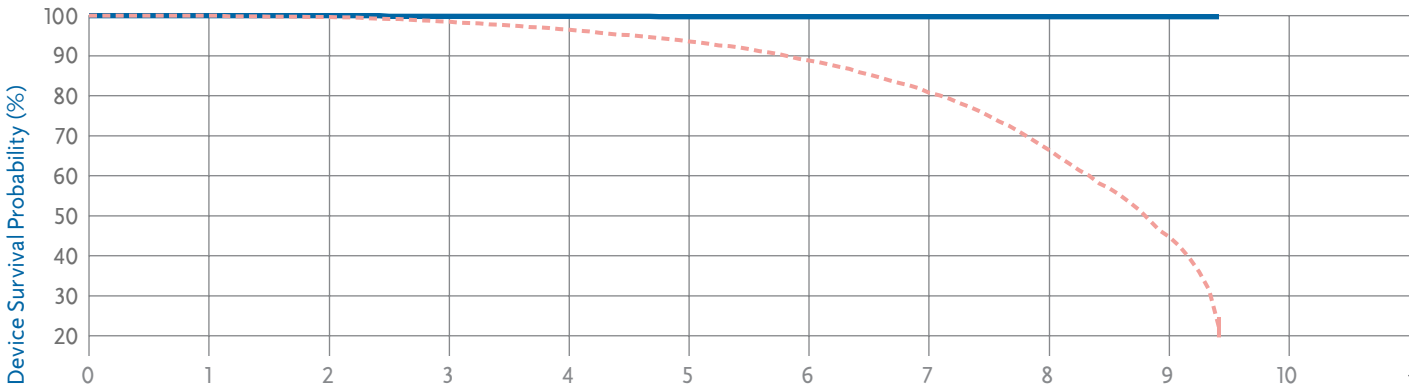
US Market Release	Jan-95
Registered US Implants	30,000
Estimated Active US Implants	20
Normal Battery Depletions	2,828
Malfunctions	37
Advisories	1 see page 154 – 1997 Potential Integrated Circuit Failure

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PAF, PAP, PAT
Estimated Longevity	7.4 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8 at 113 mo
All-cause survival	100	99.7	98.5	96.5	93.6	88.8	80.8	66.4	48.9	22.1 at 113 mo



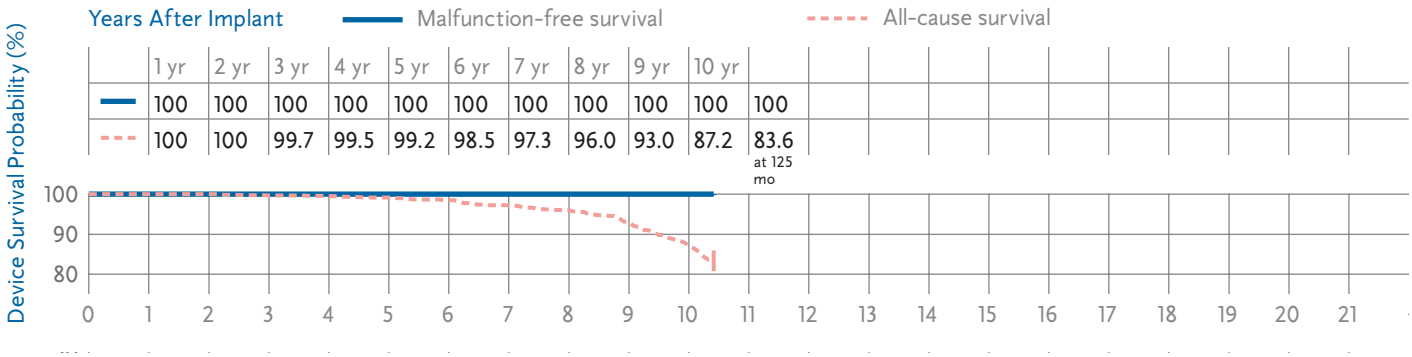
Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera DR-50 7950, 7951, 7952

US Market Release	Jan-95
Registered US Implants	5,000
Estimated Active US Implants	1,000
Normal Battery Depletions	111
Malfunctions	1
Advisories	1 see page 154 – 1997 Potential Integrated Circuit Failure

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PBR, PBV, PBW
Estimated Longevity	12.0 yrs @ 2.5 V 500 Ω impedance 100% pacing

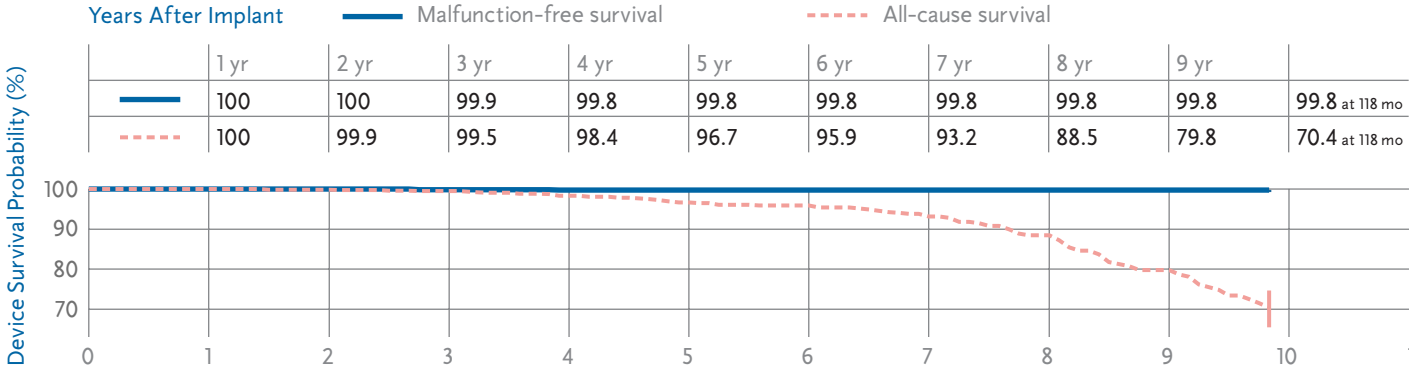


Thera S 8944, 8945, 8946

US Market Release	Jan-95
Registered US Implants	3,000
Estimated Active US Implants	200
Normal Battery Depletions	76
Malfunctions	3
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PBG, PBH, PBJ
Estimated Longevity	7.4 yrs @ 2.5 V 500 Ω impedance 100% pacing



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera SR 8940, 8941, 8942

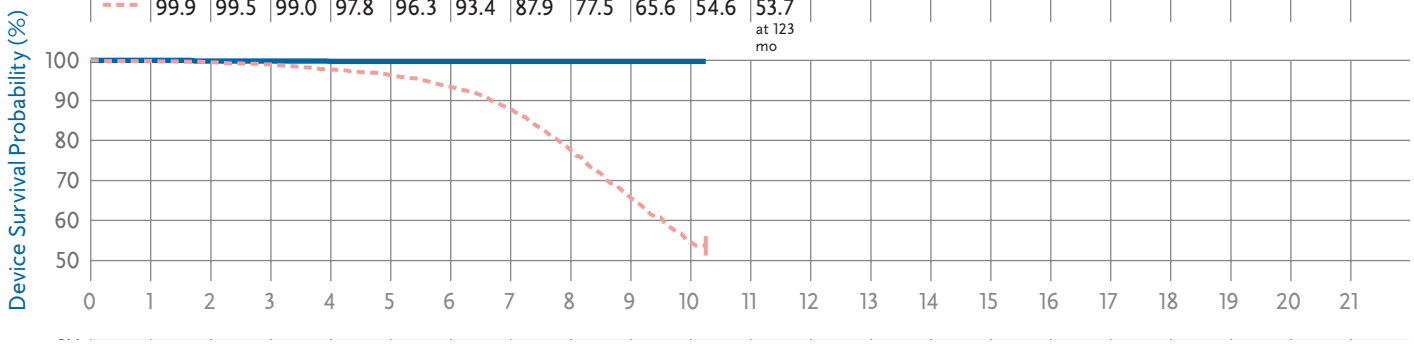
US Market Release	Jan-95
Registered US Implants	14,000
Estimated Active US Implants	1,000
Normal Battery Depletions	770
Malfunctions	16
Advisories	1 see page 154 – 1997 Potential Integrated Circuit Failure

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/Xray ID	PAU, PAV, PAW
Estimated Longevity	7.3 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	
Malfunction-free survival	100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
All-cause survival	99.9	99.5	99.0	97.8	96.3	93.4	87.9	77.5	65.6	54.6	53.7 at 123 mo



Thera-i D 7964i, 7965i, 7966i

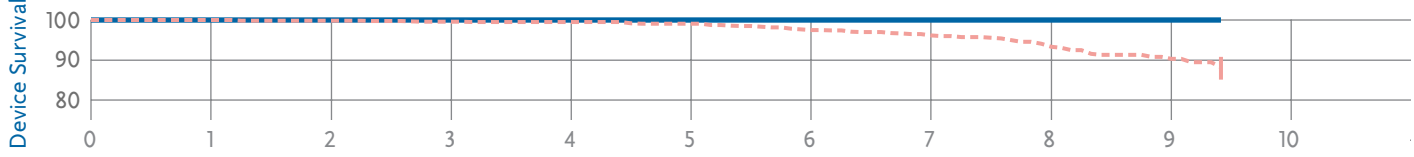
US Market Release	Oct-95
Registered US Implants	3,000
Estimated Active US Implants	1,000
Normal Battery Depletions	57
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/Xray ID	PDE, PDF, PDG
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 113 mo
All-cause survival	100	99.9	99.6	99.5	99.1	97.5	96.2	93.3	90.3	88.2 at 113 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera-i DR 7960i, 7961i, 7962i

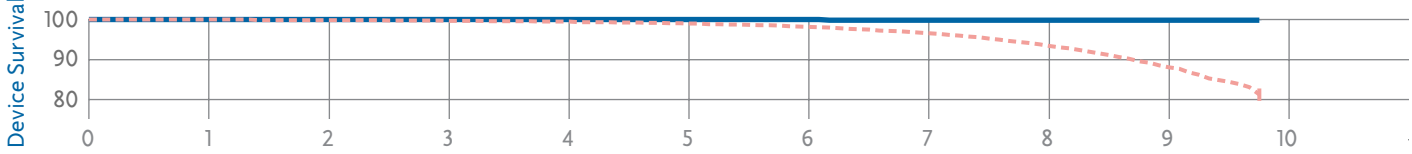
US Market Release	Oct-95
Registered US Implants	122,000
Estimated Active US Implants	42,000
Normal Battery Depletions	2,176
Malfunctions	49
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PDB,PDC, PDD
Estimated Longevity	9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	99.9	99.9	99.9	99.9 at 117 mo
All-cause survival	100	99.9	99.7	99.5	99.0	98.2	96.6	93.4	88.1	81.3 at 117 mo



Thera-i DR 7968i

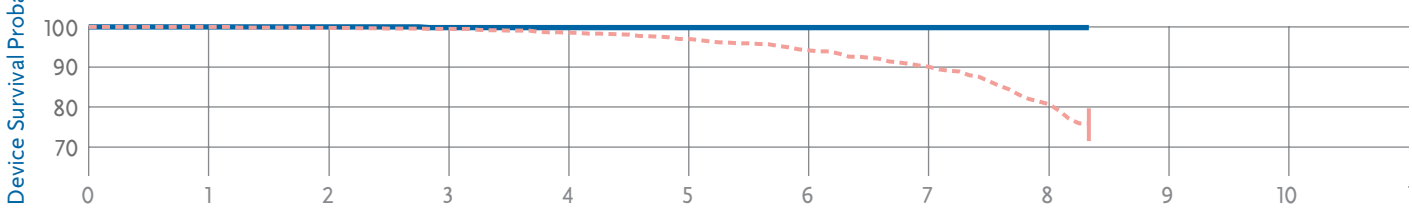
US Market Release	Jul-96
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	112
Malfunctions	3
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/Xray ID	PGH
Estimated Longevity	7.0 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
Malfunction-free survival	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9 at 100 mo
All-cause survival	100	99.8	99.5	98.6	97.0	94.2	90.1	80.7	75.9 at 100 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera-i S 8964i, 8965i, 8966i

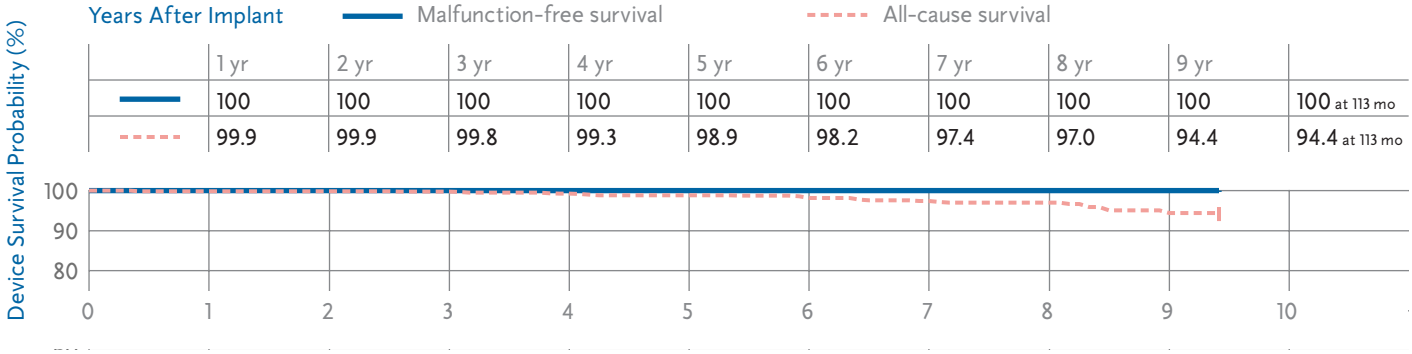
US Market Release	Oct-95
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	27
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/Xray ID	PDY, PEA, PEB
Estimated Longevity	9.8 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 113 mo
All-cause survival	99.9	99.9	99.8	99.3	98.9	98.2	97.4	97.0	94.4	94.4 at 113 mo



Thera-i SR 8960i, 8961i, 8962i

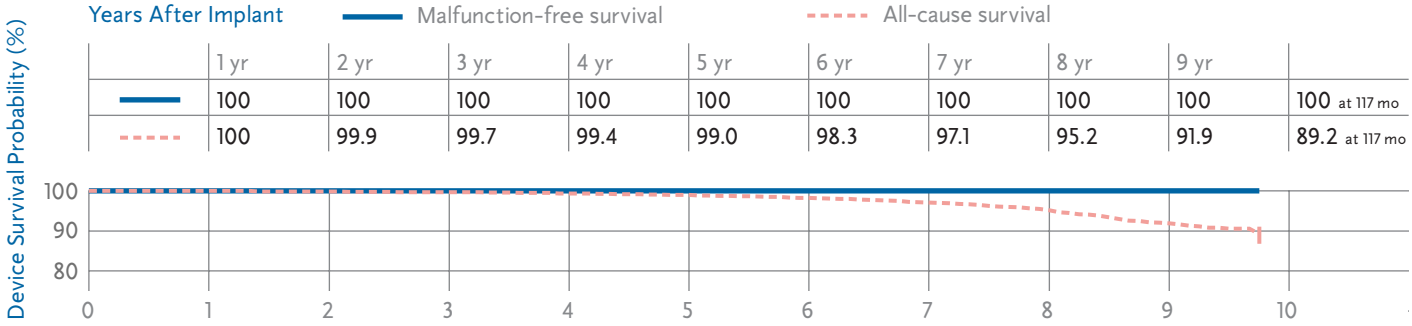
US Market Release	Oct-95
Registered US Implants	50,000
Estimated Active US Implants	13,000
Normal Battery Depletions	522
Malfunctions	7
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/Xray ID	PDU, PDV, PDW
Estimated Longevity	9.6 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 117 mo
All-cause survival	100	99.9	99.7	99.4	99.0	98.3	97.1	95.2	91.9	89.2 at 117 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Thera-i VDD 8968i

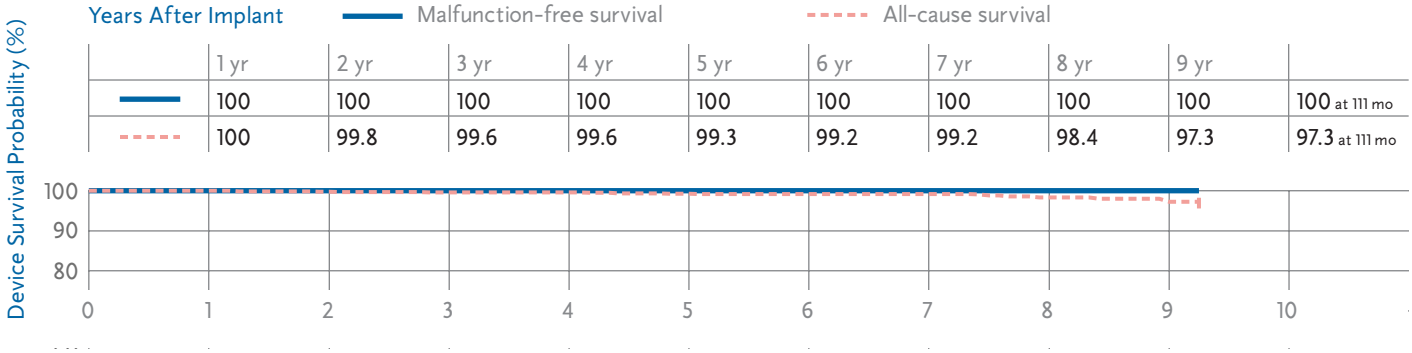
US Market Release	Mar-96
Registered US Implants	5,000
Estimated Active US Implants	2,000
Normal Battery Depletions	20
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	VDD
Serial Number Prefix/Xray ID	PEC
Estimated Longevity	11.5 yrs @ 2.5 V 500 Ω impedance 100% pacing

Years After Implant — Malfunction-free survival — All-cause survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
Malfunction-free survival	100	100	100	100	100	100	100	100	100	100 at 111 mo
All-cause survival	100	99.8	99.6	99.6	99.3	99.2	99.2	98.4	97.3	97.3 at 111 mo



Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary (95% Confidence Interval)

The following table shows IPG device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
AT500	AT501, 7253	Mar-03	11,000	9,000	75	5 (——— total ———)	2	3	Malfunction-free	100.0 +.0/-.1	100.0 +.0/-.1	99.8 +.2/-1.0	99.1 +.6/-1.5	99.1 +.6/-1.5							
	Advisory: see page 144 – 2003 Potential Incorrect Memory Circuit Setting; also see page 160 – Technical article on AT500 Pacing System Follow-Up Protocol					(2)	(1)	(1) (advisory-related subset)	All-cause	100.0 +.0/-.1	99.9 +.1/-.1	98.3 +.8/-1.5	88.7 +2.7/-3.4	53.9 +5.9/-6.4							
Elite	7074, 7075, 7076, 7077	Apr-91	48,000	2,000	2,993	85	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1 (155 mo)	
									All-cause	99.9 +.0/-.0	99.8 +.0/-.0	99.6 +.1/-.1	99.5 +.1/-.1	98.9 +.1/-.1	97.8 +.2/-.2	95.7 +.2/-.3	91.1 +.4/-.4	76.6 +.7/-.7	54.4 +1.1/-1.1	31.4 +2.2/-2.2 (155 mo)	
Elite II	7084, 7085, 7086	Dec-92	57,000	4	7,108	45	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (103 mo)			
									All-cause	99.9 +.0/-.0	99.8 +.0/-.0	99.1 +.1/-.1	96.1 +.2/-.2	90.5 +.3/-.3	82.5 +.4/-.4	69.9 +.6/-.6	47.1 +.8/-.8	15.3 +1.4/-1.4 (103 mo)			
EnPulse DR	E1DR01	Dec-03	7,000	6,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0 (20 mo)										
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0 (20 mo)										
EnPulse DR	E1DR21	Dec-03	2,000	2,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0 (19 mo)										
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0 (19 mo)										
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	53,000	50,000	0	1	0	1	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0 (18 mo)										
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0 (18 mo)										
EnPulse 2 DR	E2DR21	Feb-04	6,000	5,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0 (15 mo)										
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0 (15 mo)										
EnPulse 2 DR	E2DR31	Feb-04	200	200	0	0	0	0	Malfunction-free	100.0 +.0/-.0 (5 mo)											
									All-cause	100.0 +.0/-.0 (5 mo)											

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	11,000	10,000	0	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0 (19 mo)										
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0 (19 mo)										
EnPulse 2 VDD	E2VDD01	Dec-03	300	200	0	0	0	0	Malfunction-free	100.0 +.0/-.0 (9 mo)											
									All-cause	100.0 +.0/-.0 (9 mo)											
EnRhythm DR	P1501DR	May-05	5,000	5,000	0	1	1	0	Malfunction-free	100.0 +.0/-.2 (4 mo)											
									All-cause	99.9 +.0/-.2 (4 mo)											
Kappa 400 DR	KDR401, KDR403	Jan-98	46,000	21,000	547	19	10	9	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (91 mo)				
									All-cause	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	99.2 +.1/-.1	97.8 +.2/-.2	92.3 +.5/-.5	82.7 +3.0/-3.6 (91 mo)				
Kappa 400 SR	KSR401, KSR403	Feb-98	15,000	7,000	48	4	3	1	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 (89 mo)				
									All-cause	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.5 +.1/-.2	99.5 +.1/-.2	98.8 +.3/-.3	97.4 +.6/-.7	94.9 +1.4/-1.9 (89 mo)				
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	23,000	13,000	76	13 (——— total ———)	4	9	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1 (77 mo)					
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(8) (advisory-related subset)	(1)	(7)	All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.6 +.1/-.1	99.1 +.1/-.2	98.0 +.4/-.4	96.7 +1.0/-1.4 (77 mo)					
Kappa 600 DR	KDR651, KDR653	Mar-01	14,000	9,000	11	3 (——— total ———)	2	1	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1 (52 mo)							
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(0) (advisory-related subset)	(0)	(0)	All-cause	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.7 +.1/-.2	99.3 +.4/-.8 (52 mo)							
Kappa 700 D	KD701	Jan-99	300	200	2	0 (——— total ———)	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (58 mo)							
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(0) (advisory-related subset)	(0)	(0)	All-cause	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	98.7 +1.0/-3.8	98.7 +1.0/-3.8 (58 mo)							

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 700 DR	KDR701, KDR703, KDR706	Feb-99	182,000	116,000	599	123	17 total	106	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (79 mo)					
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(91)	(0)	(91) (advisory-related subset)	All-cause	99.9 +.0/-.0	99.9 +.0/-.0	99.7 +.0/-.0	99.3 +.1/-.1	98.5 +.1/-.1	96.8 +.2/-.2	93.5 +1.3/-1.6 (79 mo)					
Kappa 700 DR	KDR721	Feb-99	10,000	4,000	224	5	1 total	4	Malfunction-free	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	99.9 +.1/-.3	99.9 +.1/-.3	99.9 +.1/-.3 (73 mo)					
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(4)	(0)	(4) (advisory-related subset)	All-cause	99.9 +.0/-.1	99.7 +.1/-.2	99.0 +.2/-.3	96.8 +.4/-.5	91.4 +1.0/-1.1	74.9 +3.2/-3.5	71.8 +3.8/-4.3 (73 mo)					
Kappa 700 SR	KSR701, KSR703, KSR706	Feb-99	50,000	26,000	201	5	1	4	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (78 mo)					
									All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.6 +.1/-.1	99.1 +.1/-.1	98.0 +.2/-.3	96.3 +.5/-.5	95.9 +.6/-.7 (78 mo)					
Kappa 700 VDD	KVDD701	Jan-99	2,000	1,000	7	2	0 total	2	Malfunction-free	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.8 +.1/-.5	99.8 +.1/-.5	99.8 +.1/-.5 (71 mo)						
	Advisory: see page 146 – 2002 Potential Fractured Power Supply Wires					(2)	(0)	(2) (advisory-related subset)	All-cause	99.9 +.1/-.4	99.9 +.1/-.4	99.7 +.2/-.5	99.1 +.4/-.7	98.8 +.5/-.9	95.9 +2.1/-4.2 (71 mo)						
Kappa 800 DR	KDR801, KDR803	Jan-02	4,000	3,000	2	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (37 mo)								
									All-cause	100.0 +.0/-.0	99.9 +.1/-.2	99.8 +.2/-.4	99.8 +.2/-.4 (37 mo)								
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	108,000	87,000	17	6	4	2	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (44 mo)								
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (44 mo)								
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	29,000	20,000	6	3	3	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1 (43 mo)								
									All-cause	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.1/-.1	99.7 +.2/-.3 (43 mo)								
Kappa 900 VDD	KVDD901	Jan-02	1,000	500	0	0	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (35 mo)									
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (35 mo)									

continued

Source: Medtronic Device Registration and Returned Product Analysis Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 920 DR	KDR921	Jan-02	15,000	11,000	8	1	0	1	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.2	100.0 +.0/-.2 (41 mo)								
									All-cause	100.0 +.0/-.0	99.9 +.1/-.1	99.7 +.1/-.2	99.6 +.2/-.3 (41 mo)								
Legend	8416, 8417, 8417M, 8418, 8419	Aug-89	57,000	4,000	2,441	145	—	—	Malfunction-free	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.8 +.0/-.0	99.7 +.0/-.1	99.7 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1 (187 mo)
									All-cause	99.9 +.0/-.0	99.7 +.0/-.1	99.4 +.1/-.1	98.9 +.1/-.1	98.3 +.1/-.1	97.2 +.2/-.2	94.7 +.3/-.3	90.7 +.4/-.4	81.4 +.6/-.6	73.1 +.7/-.8	64.3 +1.0/-1.0	58.8 +1.8/-1.9 (187 mo)
Legend II	8424, 8426, 8427	Nov-91	58,000	8,000	1,424	37	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (163 mo)	
									All-cause	99.9 +.0/-.0	99.8 +.0/-.0	99.6 +.1/-.1	99.2 +.1/-.1	98.9 +.1/-.1	98.2 +.1/-.1	97.3 +.2/-.2	94.9 +.3/-.3	89.4 +.4/-.4	83.8 +.6/-.6	78.3 +1.8/-1.9 (163 mo)	
Micro Minix	8360	Oct-90	7,000	400	255	2	—	—	Malfunction-free	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 (167 mo)	
	Advisory: see page 159 - 1991 Potential Delayed Restoration of Permanent Settings					—	—	—	All-cause	99.9 +.1/-.1	99.8 +.1/-.1	99.6 +.1/-.2	99.4 +.2/-.3	98.0 +.4/-.5	94.5 +.8/-.9	86.7 +1.4/-1.5	80.1 +1.7/-1.9	72.6 +2.2/-2.4	70.2 +2.4/-2.6	67.7 +3.1/-3.3 (167 mo)	
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Dec-89	58,000	6,000	1,371	49	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (196 mo)
	Advisory: see page 159 - 1991 Potential Delayed Restoration of Permanent Settings					—	—	—	All-cause	99.9 +.0/-.0	99.7 +.0/-.0	99.5 +.1/-.1	99.2 +.1/-.1	98.7 +.1/-.1	97.7 +.2/-.2	95.2 +.3/-.3	91.9 +.4/-.4	87.1 +.5/-.5	83.7 +.6/-.6	80.8 +.8/-.8	78.2 +1.4/-1.4 (196 mo)
Minuet	7107, 7108	Mar-92	17,000	3,000	470	4	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 (159 mo)	
									All-cause	100.0 +.0/-.0	100.0 +.0/-.0	99.8 +.1/-.1	99.5 +.1/-.1	98.9 +.2/-.2	98.2 +.2/-.3	96.9 +.3/-.4	94.7 +.5/-.5	89.3 +.7/-.8	82.8 +1.2/-1.2	78.0 +2.0/-2.2 (159 mo)	

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Pasys/ Pasys ST	8316, 8317, 8318, 8320, 8322, 8329	Mar-86	28,000	1,000	1,430	145	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.1	99.7 +.1/-.1	99.6 +.1/-.1	99.5 +.1/-.1	99.4 +.1/-.1	99.2 +.1/-.1	99.1 +.1/-.2	99.1 +.1/-.2	99.1 +.1/-.2	99.1 +.1/-.2	99.1 +.1/-.2 (212 mo)
									All-cause	99.9 +.0/-.0	99.6 +.1/-.1	99.2 +.1/-.1	98.5 +.2/-.2	97.8 +.2/-.2	96.6 +.3/-.3	94.0 +.4/-.4	89.7 +.5/-.6	79.0 +.9/-.9	63.8 +1.2/-1.3	53.9 +1.5/-1.5	47.8 +1.8/-1.8 (212 mo)
Preva D	7068	Nov-96	1,000	300	9	1	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.1/-.9	99.9 +.1/-.9	99.9 +.1/-.9	99.9 +.1/-.9	99.9 +.1/-.9	99.9 +.1/-.9	99.9 +.1/-.9 (91 mo)				
									All-cause	100.0 +.0/-.0	99.7 +.2/-.8	99.4 +.4/-1.0	98.7 +.7/-1.3	98.7 +.7/-1.3	97.7 +1.0/-1.8	95.5 +1.7/-2.8	94.4 +2.1/-3.3 (91 mo)				
Preva DR	7088, 7089	Jul-96	25,000	10,000	286	3	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (109 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.0/-.1	99.8 +.1/-.1	99.6 +.1/-.1	99.1 +.1/-.2	98.3 +.2/-.2	97.0 +.3/-.3	94.2 +.5/-.6	88.0 +2.5/-3.1 (109 mo)			
Preva SR	8088, 8089	Jul-96	18,000	5,000	157	1	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 (108 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.0/-.1	99.7 +.1/-.1	99.4 +.1/-.2	98.8 +.2/-.2	98.0 +.3/-.3	95.9 +.5/-.6	94.5 +.7/-.7	90.6 +1.9/-2.3 (108 mo)			
Preva ST DR	7078	Nov-96	1,000	300	9	0	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (93 mo)				
									All-cause	99.7 +.2/-.8	99.7 +.2/-.8	99.4 +.4/-.9	99.4 +.4/-.9	99.0 +.5/-1.2	98.1 +.9/-1.6	96.4 +1.4/-2.3	95.4 +1.8/-2.9 (93 mo)				
Prevail S	8085, 8086	Oct-95	4,000	1,000	10	1	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4 (105 mo)			
									All-cause	100.0 +.0/-.1	100.0 +.0/-.1	99.9 +.1/-.2	99.9 +.1/-.2	99.3 +.3/-.6	99.1 +.4/-.6	98.6 +.5/-.9	98.3 +.6/-1.0	97.4 +1.1/-1.9 (105 mo)			
Prodigy D	7864, 7865, 7866	Oct-95	3,000	1,000	33	0	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (108 mo)			
									All-cause	99.9 +.1/-.2	99.7 +.1/-.3	99.5 +.2/-.4	98.9 +.4/-.6	98.7 +.4/-.6	97.8 +.6/-.8	97.3 +.7/-.9	96.0 +1.0/-1.3	92.9 +1.9/-2.6 (108 mo)			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Prodigy DR	7860, 7861, 7862	Oct-95	37,000	14,000	403	10	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (112 mo)			
									All-cause	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	99.1 +.1/-.1	98.4 +.2/-.2	97.0 +.2/-.3	94.1 +.5/-.5	89.7 +1.4/-1.6 (112 mo)			
Prodigy S	8164, 8165, 8166	Oct-95	2,000	1,000	11	0	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (106 mo)			
									All-cause	99.9 +.1/-.3	99.9 +.1/-.3	99.8 +.2/-.4	99.2 +.4/-.7	99.2 +.4/-.7	99.2 +.4/-.7	98.8 +.5/-1.0	97.1 +1.1/-1.8	96.1 +1.6/-2.6 (106 mo)			
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,000	7,000	189	5	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (110 mo)			
									All-cause	99.9 +.0/-.1	99.7 +.1/-.1	99.5 +.1/-.1	99.1 +.1/-.2	98.6 +.2/-.2	97.8 +.3/-.3	96.7 +.4/-.4	95.0 +.6/-.6	91.2 +2.0/-2.5 (110 mo)			
Sigma 100 S	SS103, SS106	Aug-99	1,000	300	1	0 (—— total ——)	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (56 mo)							
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(0) (advisory-related subset)	(0)	(0)	All-cause	100.0 +.0/-.0	100.0 +.0/-.0	99.5 +.4/-1.5	99.5 +.4/-1.5	99.5 +.4/-1.5 (56 mo)							
Sigma 200 DR	SDR203	Aug-99	15,000	10,000	10	3 (—— total ——)	1	2	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (68 mo)						
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(0) (advisory-related subset)	(0)	(0)	All-cause	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.5 +.2/-.3	99.5 +.2/-.3 (68 mo)						
Sigma 200 SR	SSR203	Sep-99	12,000	6,000	8	0 (—— total ——)	0	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (68 mo)						
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(0) (advisory-related subset)	(0)	(0)	All-cause	100.0 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.2	99.7 +.1/-.2 (68 mo)						
Sigma 300 DR	SDR303, SDR306	Aug-99	91,000	62,000	42	28 (—— total ——)	2	26	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (71 mo)						
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(10) (advisory-related subset)	(0)	(10)	All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.7 +.1/-.1	99.5 +.1/-.1	99.5 +.1/-.1 (71 mo)						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Sigma 300 SR	SSR303, SSR306	Sep-99	45,000	26,000	22	4	1 total	3	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (69 mo)						
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(1)	(0)	(1) (advisory-related subset)	All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.8 +.1/-.1	99.6 +.1/-.2	99.5 +.2/-.3 (69 mo)						
Sigma 300 VDD	SVDD303	Sep-99	1,000	400	0	0	0 total	0	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (56 mo)							
	Advisories: see page 141 – 2005 Potential Separation of Interconnect Wires; and page 152 – 1999 Manufacturing Issue					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (56 mo)							
Spectrax S	5940, 5940LP, 5941	Jul-83	25,000	1,000	802	76	—	—	Malfunction-free	99.9 +.0/-.1	99.8 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1	99.5 +.1/-.1	99.5 +.1/-.1	99.5 +.1/-.2 (252 mo)
									All-cause	99.7 +.1/-.1	99.6 +.1/-.1	99.5 +.1/-.1	99.4 +.1/-.1	99.2 +.1/-.1	99.0 +.1/-.2	98.6 +.2/-.2	97.5 +.3/-.3	91.2 +.6/-.6	80.6 +1.0/-1.0	73.3 +1.2/-1.3	64.5 +1.8/-1.9 (252 mo)
Spectrax SXT	8420, 8422, 8423, 8423M	Oct-81	111,000	3,000	4,391	466	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.7 +.0/-.0	99.7 +.0/-.0	99.6 +.0/-.1	99.5 +.1/-.1	99.3 +.1/-.1	99.1 +.1/-.1	99.1 +.1/-.1	99.1 +.1/-.1 (262 mo)
									All-cause	99.9 +.0/-.0	99.8 +.0/-.0	99.7 +.0/-.0	99.5 +.0/-.0	99.2 +.1/-.1	98.8 +.1/-.1	98.1 +.1/-.1	96.8 +.1/-.2	91.0 +.3/-.3	81.9 +.4/-.4	72.0 +.6/-.6	47.7 +1.7/-1.8 (262 mo)
Thera D	7944, 7945, 7946	Jan-95	2,000	30	168	2	—	—	Malfunction-free	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.9 +.0/-.3	99.7 +.3/-1.3 (110 mo)			
									All-cause	99.9 +.1/-.3	99.8 +.2/-.4	98.9 +.4/-.7	97.3 +.8/-1.0	93.6 +1.3/-1.6	90.2 +1.6/-1.9	83.0 +2.3/-2.6	66.8 +3.5/-3.8	48.4 +4.8/-5.0 (110 mo)			
Thera DR-40	7940, 7941, 7942	Jan-95	30,000	20	2,828	37	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1	99.8 +.0/-.1 (113 mo)			
	Advisory: see page 154 – 1997 Potential Integrated Circuit Failure					—	—	—	All-cause	100.0 +.0/-.0	99.7 +.1/-.1	98.5 +.1/-.2	96.5 +.2/-.3	93.6 +.3/-.4	88.8 +.5/-.5	80.8 +.6/-.6	66.4 +.9/-.9	22.1 +2.6/-2.5 (113 mo)			
Thera DR-50	7950, 7951, 7952	Jan-95	5,000	1,000	111	1	—	—	Malfunction-free	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 (125 mo)		
	Advisory: see page 154 – 1997 Potential Integrated Circuit Failure					—	—	—	All-cause	100.0 +.0/-.1	100.0 +.0/-.1	99.7 +.1/-.2	99.5 +.2/-.3	99.2 +.3/-.4	98.5 +.4/-.5	97.3 +.6/-.7	96.0 +.7/-.9	87.2 +1.7/-1.9	83.6 +2.4/-2.8 (125 mo)		

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Thera S	8944, 8945, 8946	Jan-95	3,000	200	76	3	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.1/-.4	99.8 +.2/-.5	99.8 +.2/-.5	99.8 +.2/-.5	99.8 +.2/-.5	99.8 +.2/-.5	99.8 +.2/-.5 (118 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.1/-.3	99.5 +.2/-.5	98.4 +.5/-.8	96.7 +.9/-1.2	95.9 +1.0/-1.3	93.2 +1.5/-1.8	88.5 +2.1/-2.6	70.4 +4.3/-4.9 (118 mo)			
Thera SR	8940, 8941, 8942	Jan-95	14,000	1,000	770	16	—	—	Malfunction-free	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 (123 mo)		
	Advisory: see page 154 – 1997 Potential Integrated Circuit Failure						—	—	All-cause	99.9 +.1/-.1	99.5 +.1/-.1	99.0 +.2/-.2	97.8 +.3/-.3	96.3 +.4/-.4	93.4 +.5/-.6	87.9 +.8/-.9	77.5 +1.2/-1.3	54.6 +2.3/-2.4	53.7 +2.4/-2.5 (123 mo)		
Thera-i D	7964i, 7965i, 7966i	Oct-95	3,000	1,000	57	1	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2	100.0 +.0/-.2 (113 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.1/-.2	99.6 +.2/-.3	99.5 +.2/-.4	99.1 +.3/-.5	97.5 +.6/-.8	96.2 +.8/-1.1	93.3 +1.3/-1.6	88.2 +2.5/-3.2 (113 mo)			
Thera-i DR	7960i, 7961i, 7962i	Oct-95	122,000	42,000	2,176	49	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 (117 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.7 +.0/-.0	99.5 +.0/-.0	99.0 +.1/-.1	98.2 +.1/-.1	96.6 +.1/-.1	93.4 +.2/-.2	81.3 +1.5/-1.6 (117 mo)			
Thera-i DR	7968i	Jul-96	4,000	1,000	112	3	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.1/-.2	99.9 +.1/-.2	99.9 +.1/-.2	99.9 +.1/-.2	99.9 +.1/-.2	99.9 +.1/-.2	99.9 +.1/-.2 (100 mo)			
									All-cause	100.0 +.0/-.0	99.8 +.1/-.2	99.5 +.2/-.3	98.6 +.4/-.6	97.0 +.6/-.8	94.2 +1.0/-1.1	90.1 +1.4/-1.6	80.7 +2.8/-3.2	75.9 +3.8/-4.3 (100 mo)			
Thera-i S	8964i, 8965i, 8966i	Oct-95	4,000	1,000	27	1	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.3	100.0 +.0/-.3	100.0 +.0/-.3	100.0 +.0/-.3	100.0 +.0/-.3	100.0 +.0/-.3 (113 mo)			
									All-cause	99.9 +.0/-.2	99.9 +.1/-.2	99.8 +.1/-.3	99.3 +.3/-.5	98.9 +.4/-.6	98.2 +.5/-.8	97.4 +.7/-1.0	97.0 +.8/-1.1	94.4 +1.5/-2.0 (113 mo)			
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	13,000	522	7	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (117 mo)			
									All-cause	100.0 +.0/-.0	99.9 +.0/-.0	99.7 +.1/-.1	99.4 +.1/-.1	99.0 +.1/-.1	98.3 +.2/-.2	97.1 +.2/-.2	95.2 +.3/-.4	89.2 +2.0/-2.4 (117 mo)			
Thera-i VDD	8968i	Mar-96	5,000	2,000	20	0	—	—	Malfunction-free	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 (111 mo)			
									All-cause	100.0 +.0/-.1	99.8 +.1/-.2	99.6 +.1/-.3	99.6 +.2/-.3	99.3 +.2/-.4	99.2 +.3/-.4	99.2 +.3/-.4	98.4 +.5/-.7	97.3 +1.0/-1.7 (111 mo)			

Source: Medtronic Device Registration and Returned Product Analysis
Data as of October 31, 2005

IPG Elective Replacement Time Indicators

Family	Model Number	Indicators*
Activitrax	8400, 8402, 8403, 8403M	Rate and mode change to 65 ppm and VVI (non-rate responsive). Telemetry indication.
Activitrax II	8412, 8413, 8413M, 8414	**If programmed to non-rate responsive mode (e.g. VVI), rate decrease of 10% from programmed rate.** Telemetry indication. If programmed to rate responsive mode (e.g. VVIR), rate change to 65 ppm and mode change to VVI. Telemetry indication.
Legend	8416, 8417, 8417M, 8418, 8419	
Legend II	8424, 8426, 8427	
AT500	AT501, 7253, 7253B	– Telemetry indication. – Pacing mode and rate (magnet and non-magnet) as programmed
Classix	8436, 8437, 8438	30% increase in pulse width (measured with the Model 9431 transmitter). Rate decrease of 10% from programmed rate. Telemetry indication.
Micro Minix	8360	Rate decrease of 10% from programmed rate. Telemetry indication. In a 1993 Product Education Brief, Medtronic provided an update to the longevity of the Micro Minix Model 8360 pacemaker. Analysis indicates that the Micro Minix battery delivers approximately 0.1 amp-hour less capacity than originally projected during the period from ERI. This represents an average longevity from BOL to ERI of 6.7 years (≥ 90 days from ERI to EOL) under nominal parameters, 500 ohms and 100% pacing. The original projection was 7.8 and 1.5 years respectively under the same conditions.
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Rate decrease of 10% from programmed rate. Telemetry indication.
Pasys/ Pasys ST	8316, 8317, 8318, 8320, 8322, 8329	Rate decrease of 10% from programmed rate. Telemetry indication.
Prevail S	8084, 8085, 8086	
Spectrax S	5940, 5940LP, 5941, 5984, 5984LP, 5985	Rate decrease of 10% from preset or programmed rate. Telemetry indication in SXT family devices.
Spectrax SXT	5976, 5977 (SX-HT), 8420, 8422, 8423, 8423M,	
Synergyst II	7070, 7071, 7071A, 7071M	– Telemetry indication. – Magnet rate of 75 ppm, or Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

Family	Model Number	Indicators*
Elite	7074, 7075, 7076, 7077	– Telemetry indication. – Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).
Elite II	7084, 7085, 7086	
EnPulse DR	E1DR01, E1DR06, E1DR21	
EnPulse 2 DR	E2DR01, E2DR03, E2DR06, E2DR21, E2DR31	
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	
EnPulse 2 VDD	E2VDD01	
EnRhythm DR	P1501DR	
InSync	8040	
InSync III	8042	
Kappa 400 DR	KDR401, KDR403	
Kappa 400 SR	KSR401, KSR403	
Kappa 600 DR	KDR601, KDR603, KDR606, KDR651, KDR653	
Kappa 700 D	KD701	
Kappa 700 DR	KDR701, KDR703, KDR706, KDR721	
Kappa 700 SR	KSR701, KSR703, KSR706	
Kappa 700 VDD	KVDD701	
Kappa 800 DR	KDR801, KDR803	
Kappa 900 DR	KDR901, KDR903, KDR906	
Kappa 900 SR	KSR901, KSR903, KSR906	
Kappa 900 VDD	KVDD901	
Kappa 920 DR	KDR921	
Minuet	7107, 7108	
Preva D	7068	
Preva DR	7088, 7089	
Preva SR	8088, 8089	
Preva ST DR	7078	
Prodigy D	7864, 7865, 7866	
Prodigy DR	7860, 7861, 7862	
Prodigy S	8164, 8165, 8166	
Prodigy SR	8158, 8160, 8161, 8162	
Sigma 100 S	SS103, SS106	
Sigma 200 D	SD203	
Sigma 200 DR	SDR203	
Sigma 200 SR	SSR203	
Sigma 300 DR	SDR303, SDR306	
Sigma 300 S	SS303	
Sigma 300 SR	SSR303, SSR306	
Sigma 300 VDD	SVDD303	
Symbios	7005, 7005L, 7006, 7008	
Thera D	7944, 7945, 7946	
Thera DR-40	7940, 7941, 7942	
Thera DR-50	7950, 7951, 7952	
Thera S	8944, 8945, 8946	
Thera SR	8940, 8941, 8942	
Thera-i D	7964i, 7965i, 7966i	
Thera-i DR	7960i, 7961i, 7962i, 7968i	
Thera-i S	8964i, 8965i, 8966i	
Thera-i SR	8960i, 8961i, 8962i	
Thera-i VDD	8968i	

* Unless otherwise specified, "rate" refers to pacing rate without magnet applied

Note: Testing of explanted units at room temperature may introduce an error due to the change in temperature in certain models. For details, call Medtronic Technical Services at 1 (800) 505-4636.

Method for Estimating Lead Performance

Medtronic CRM has tracked lead survival for over 20 years with its multicenter chronic lead studies.

Leads Performance Analysis

The human body is a hostile environment for an implantable device. Typically, the human body will attack and attempt to isolate or destroy any foreign object, including leads. Additionally, implanted leads are subjected to bending and twisting associated with heart motion, body motion, and patient anatomy, which can cause a lead to wear out.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. While implantable pulse generators (IPGs) and implantable cardioverter defibrillators (ICDs) have a battery that will deplete after a predictable length of time, a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. Therefore, to determine that a lead may be approaching the end of its service life requires regular monitoring while implanted and evaluation of lead integrity upon IPG or ICD replacement.

Returned Product Analysis Shortfalls

All leads and lead segments returned to Medtronic are analyzed to determine whether or not they meet performance limits established by Medtronic. Although returned product analyses are valuable for gaining insight into lead failure mechanisms, this data cannot be used by itself for determining the survival probability of leads because only a small fraction of leads are explanted and returned for analysis. Additionally, those leads which are returned cannot be assumed to be statistically representative of the performance of the total population for a given lead model. Partial or total lead extraction can result in significant damage to a lead, making a definitive analysis of a suspected failure and its cause impossible. Thus, lead survival probabilities are more appropriately determined through a clinical surveillance study. Medtronic's study for tracking lead survival is its System Longevity Study.

System Longevity Study (SLS)

The SLS is a prospective, multicenter study designed to monitor the performance of market released cardiac therapy products. The SLS is the unification of the Chronic Lead Study (CLS) for pacing leads and the Tachyarrhythmia Chronic Systems Study (TCSS) for ICD leads, which have been ongoing in several geographies since 1983 and 1991, respectively. More than 35 centers participating as CLS study sites or TCSS study sites, or both, are expected to complete the unification to become SLS study sites throughout the next year. Through these studies, Medtronic has over 20 years of lead data from over 65,000 leads studied.

Patients are eligible for enrollment in the study if

1) They are within 6 months post-implant of a Medtronic market-released lead connected to a market-released IPG, ICD, or CRT device and the lead is used for a pacing, sensing, or defibrillation application, or
2) They participated in a qualifying study of a Medtronic cardiac therapy product and for whom the product is market-released, complete implant and follow-up data are available, and the data is appropriately and legally released for use in the study.

Methods

The SLS protocol requires regular follow-up reporting on all leads actively followed in the study. Each study center must inform Medtronic whenever a lead complication has occurred or when a patient is no longer participating in the study. The data analyses assume that the patient is still part of the study and there are no lead complications at the time of data update unless specifically reported by the center or by correlation with returned product analysis. Follow-up times are calculated from the implant date to the earlier of the complication date, out-of-service date (for example, patient leaves the study or the lead is no longer being used), or the cutoff date of the report. If a lead experiences more than one complication, the first is used to calculate survival time; although all complications associated with a lead are reported in PPR tables.

continued

Method for Estimating Lead Performance continued

The Standard Actuarial Method is used to determine estimates of lead survival.

The actuarial method is used to determine estimates of lead-related adverse event-free survival. Greenwood's formula is used to calculate corresponding 95% confidence intervals for the standard errors and the complementary log-log method is used to produce the confidence bounds. Survival curves are presented for leads, grouped according to similarity in design and function. New leads are added when there are more than 100 implanted and no fewer than 50 leads followed for at least 6 months. Data for individual models are plotted against grouped results for comparative purposes; however, the minimum 50 lead criterion is not applied to these curves.

Lead Complications

The SLS complication criteria are defined below. These criteria do not, however, enable a lead integrity or "hardware" failure to be conclusively differentiated from other clinical events such as an undetected lead dislodgement, exit block, or concurrent pulse generator failure manifested as a sensing or capture problem.

A lead-related complication is considered to have occurred if at least one of the following clinical observations is reported and at least one of the following clinical actions is made 30 days or more after the implant.

Clinical Observations

- Failure to capture
- Failure to sense/Undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200-3000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20-200 ohms)
- Insulation breach, observed visually, that has degraded system performance
- Conductor fracture, observed visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

Clinical Actions

- Lead surgically abandoned/capped
- Lead electrically abandoned/capped
- Lead explanted
- Lead replaced
- Polarity reprogrammed (i.e., bipolar to unipolar; unipolar to bipolar)
- Lead use continued based on medical judgment despite a known clinical performance issue
- Other lead-related surgery performed (e.g., lead mechanical alteration or unsuccessful repositioning)

Note: Successful lead repositioning is not a qualifying action.

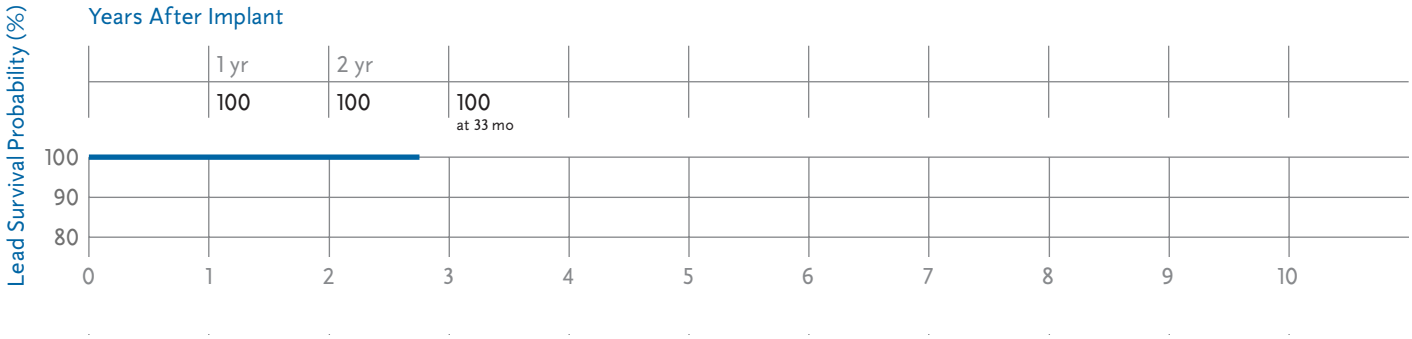
Left-Heart Leads

2187 Attain

US Market Release	Aug-01
Number of Leads Enrolled in Study	125
Complications in Study	0
Cumulative Months of Follow-Up in Study	3,779
Advisories	None

Product Characteristics

Serial Number Prefix	LEY
Type and/or Fixation	Tranvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Polarity	Unipolar
Steroid	No

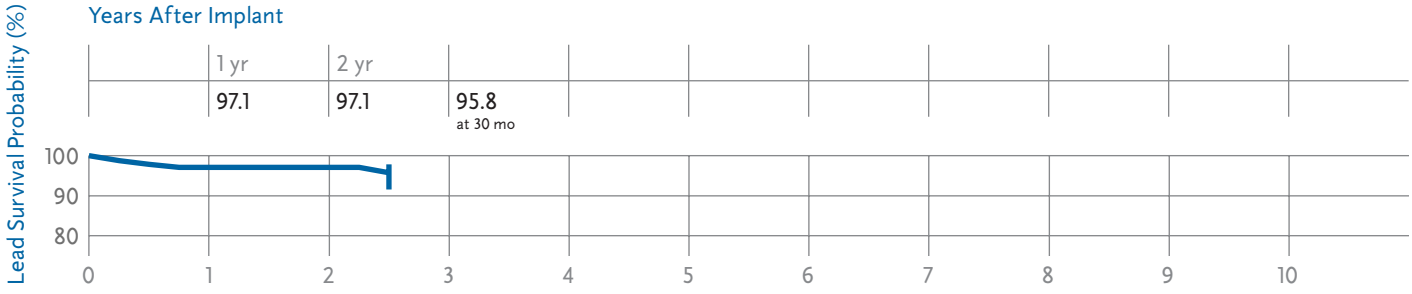


4193 Attain OTW

US Market Release	May-02
Number of Leads Enrolled in Study	563
Complications in Study	14
Extra Cardiac Stimulation	1
Failure to Capture	6
Dislodgement	4
Misc: Other	3
Cumulative Months of Follow-Up in Study	8,096
Advisories	None

Product Characteristics

Serial Number Prefix	BAA
Type and/or Fixation	Tranvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Polarity	Unipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Left-Heart Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
2187	Attain	Aug-01	125	0	3,779	100.0	100.0	100.0 at 33 mo							
4193	Attain OTW	May-02	563	14	8,096	97.1 +1.2/-2	97.1 +1.2/-2	95.8 +2.1/-4.2 at 30 mo							

Source: System Longevity Study
Data as of July 11, 2005

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
2187	Attain	Aug-01	16,800	12,400	7	0	16
2188	Attain	Aug-05	2,800	1,800	1	1	0
4193	Attain OTW	May-02	81,500	68,400	51	8	56
4194	Attain	Aug-04	18,200	17,300	16	1	3

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Source: US Returned Product Analysis
Data as of October 31, 2005

Left-Heart Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
2187	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
2188	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 BI
4193	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
4194	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane/ Silicone (55D)	MP35N	Platinum Alloy	IS-1 BI

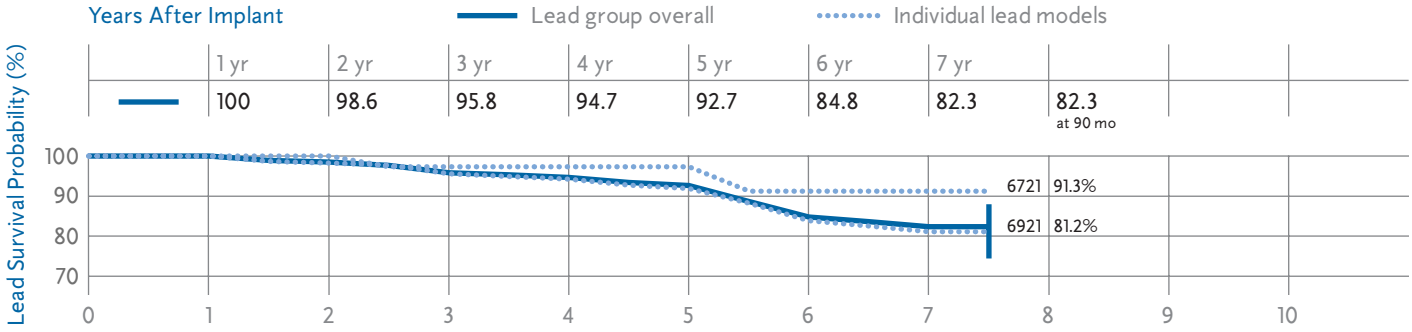
Defibrillation Leads

6721, 6921 Epicardial Patch

US Market Release	Feb-93
Number of Leads Enrolled in Study	398
Complications in Study	26
Conductor Fracture	20
Defib Impedance Out of Range	3
Fail to Cardiovert/Defibrillate	2
Insulation Breach	1
Cumulative Months of Follow-Up in Study	17,432
Advisories	None

Product Characteristics

Serial Number Prefix	TBH, TBG, TBB, TAD, TAC, or TAB
Type and/or Fixation	Epicardial Defib Patch, Suture
Polarity	Defib Electrode only
Steroid	No

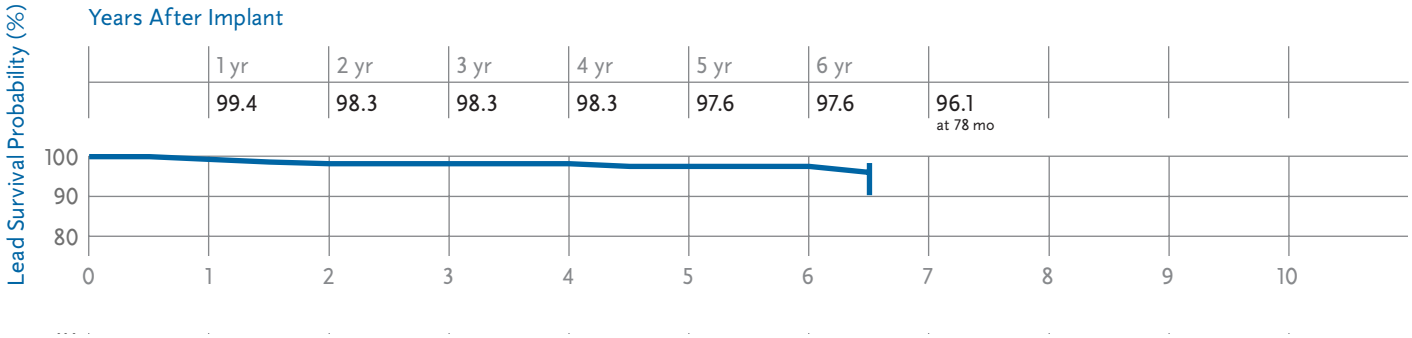


6932 Sprint

US Market Release	Aug-96
Number of Leads Enrolled in Study	409
Complications in Study	7
Fail to Cardiovert/Defibrillate	1
Failure to Capture	1
Failure to Sense	2
Misc: Other	1
Oversensing	2
Cumulative Months of Follow-Up in Study	15,744
Advisories	None

Product Characteristics

Serial Number Prefix	TCA
Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Polarity	True bipolar with one coil
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

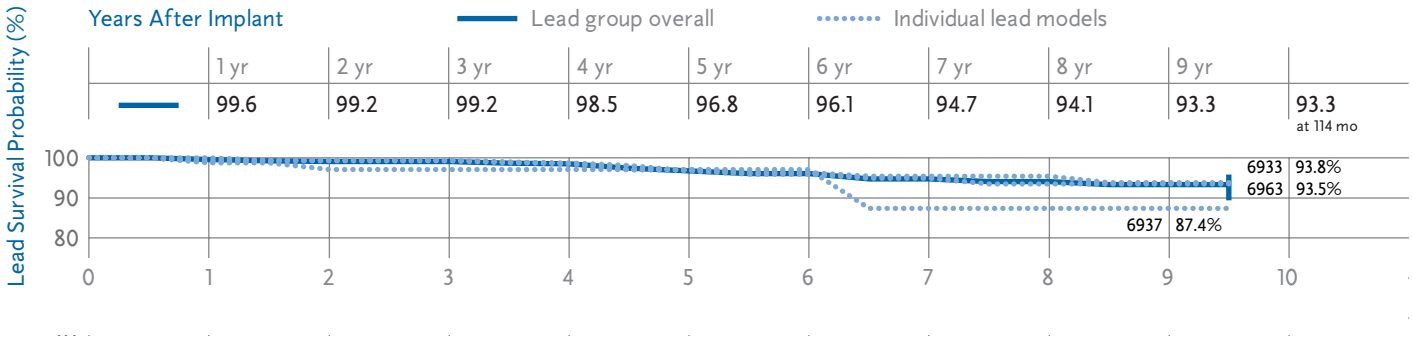
Defibrillation Leads continued

6933, 6937, 6963 SVC/CS

US Market Release	Dec-93
Number of Leads Enrolled in Study	964
Complications in Study	23
Conductor Fracture	14
Defib Impedance Out of Range	2
Dislodgement	1
Fail to Cardiovert/Defibrillate	1
Insulation Breach	2
Misc: Other	3
Cumulative Months of Follow-Up in Study	42,935
Advisories	None

Product Characteristics

Serial Number Prefix	TAT, TBU, or TAF
Type and/or Fixation	Tranveneous CS or SVC Defib
Polarity	One Defib Coil
Steroid	No

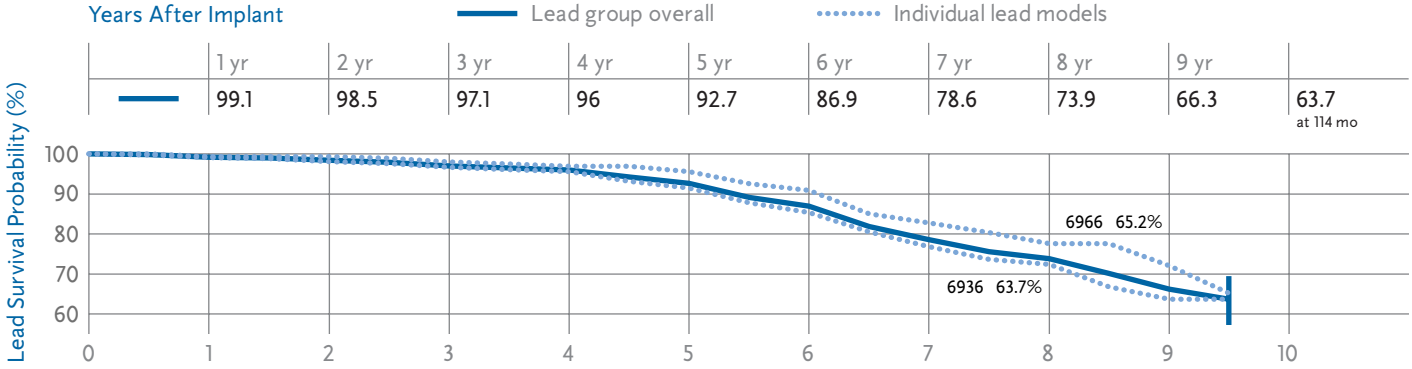


6936, 6966 Transvene

US Market Release	Dec-93
Number of Leads Enrolled in Study	1,351
Complications in Study	135
Conductor Fracture	16
Defib Impedance Out of Range	2
Fail to Cardiovert/Defibrillate	5
Failure to Capture	1
Failure to Sense	3
Inappropriate VF	13
Inappropriate VT	1
Insulation Breach	12
Misc: Other	5
Muscle Stimulation	1
Oversensing	73
Pacing Impedance Out of Range	3
Cumulative Months of Follow-Up in Study	61,100
Advisories	None

Product Characteristics

Serial Number Prefix	TAV or TAL
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	True Bipolar/ One Coil
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

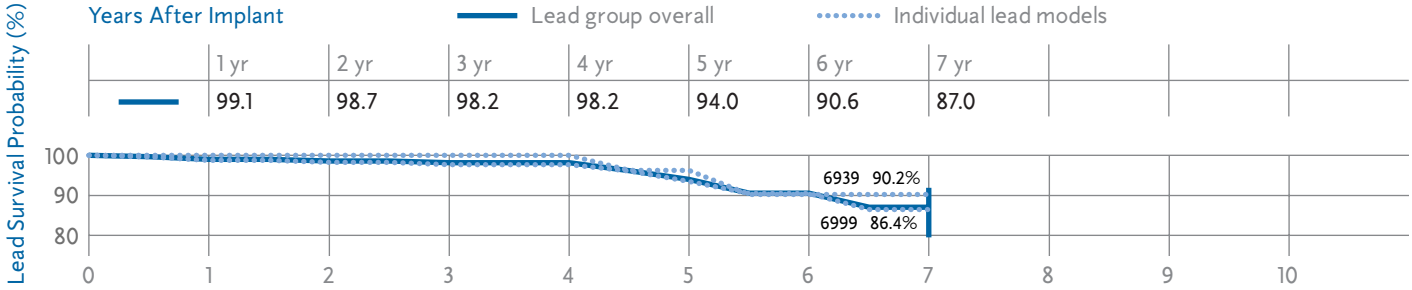
Defibrillation Leads continued

6939, 6999 Sub-Q Patch

US Market Release	Dec-93
Number of Leads Enrolled in Study	389
Complications in Study	20
Conductor Fracture	10
Fail to Cardiovert/Defibrillate	2
Insulation Breach	6
Misc: Other	2
Cumulative Months of Follow-Up in Study	16,873
Advisories	None

Product Characteristics

Serial Number Prefix	TBA or TAP
Type and/or Fixation	Subcutaneous Defib Patch, Suture
Polarity	Defib Electrode only
Steroid	No

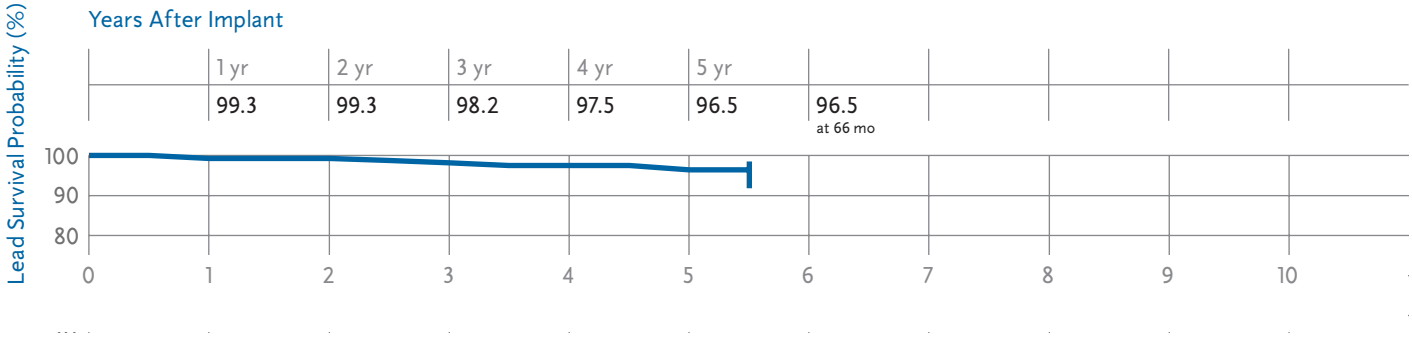


6942 Sprint

US Market Release	Jul-97
Number of Leads Enrolled in Study	350
Complications in Study	6
Conductor Fracture	1
Failure to Sense	1
Misc: Other	1
Oversensing	3
Cumulative Months of Follow-Up in Study	12,444
Advisories	None

Product Characteristics

Serial Number Prefix	TCB
Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Polarity	Integrated Bipolar/Two Coils
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

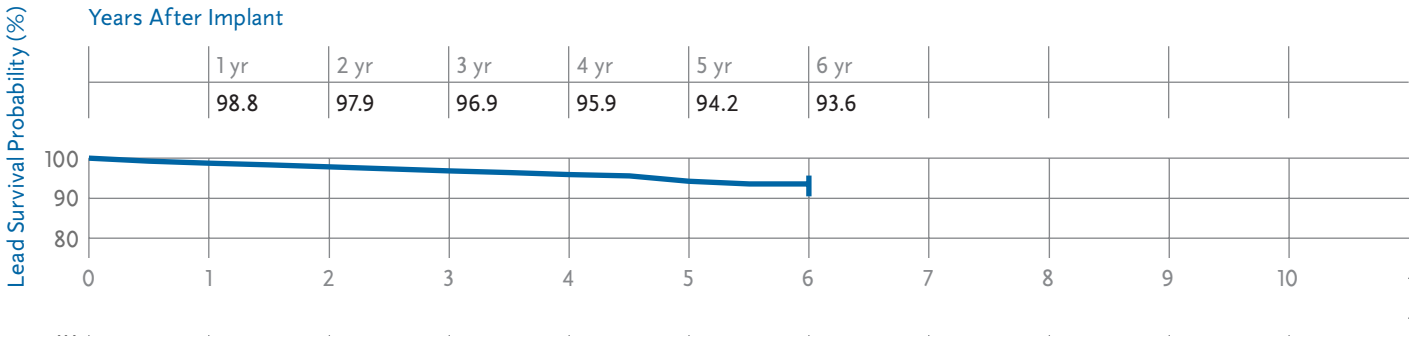
Defibrillation Leads continued

6943 Sprint

US Market Release	Oct-97
Number of Leads Enrolled in Study	1,302
Complications in Study	38
Conductor Fracture	6
Dislodgement	1
Fail to Cardiovert/Defibrillate	1
Failure to Capture	3
Failure to Sense	3
Inappropriate VF	2
Insulation Breach	1
Misc: Other	3
Oversensing	16
Pacing Impedance Out of Range	2
Cumulative Months of Follow-Up in Study	41,763
Advisories	None

Product Characteristics

Serial Number Prefix	TCE
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	True Bipolar/One Coil
Steroid	Yes

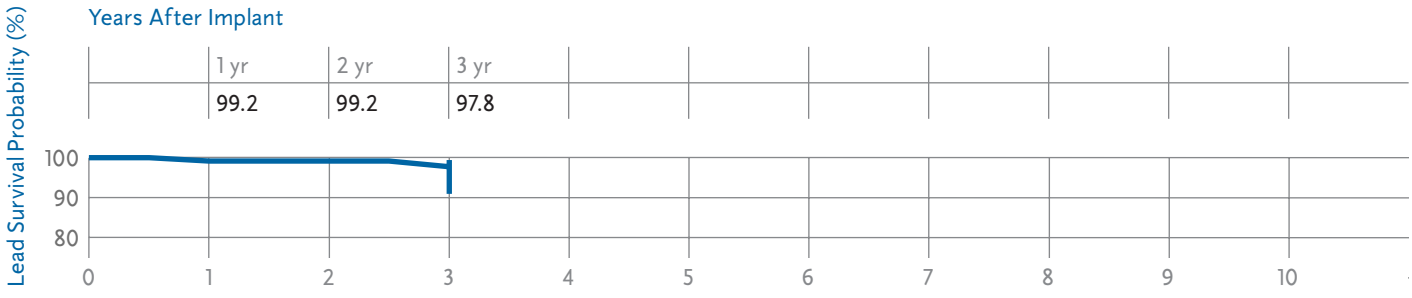


6944 Sprint Quattro

US Market Release	Dec-00
Number of Leads Enrolled in Study	162
Complications in Study	3
Inappropriate VF	1
Misc: Other	2
Cumulative Months of Follow-Up in Study	4,284
Advisories	None

Product Characteristics

Serial Number Prefix	TDC
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Tines
Polarity	True Bipolar/Two Coils
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Defibrillation Leads continued

6945 Sprint

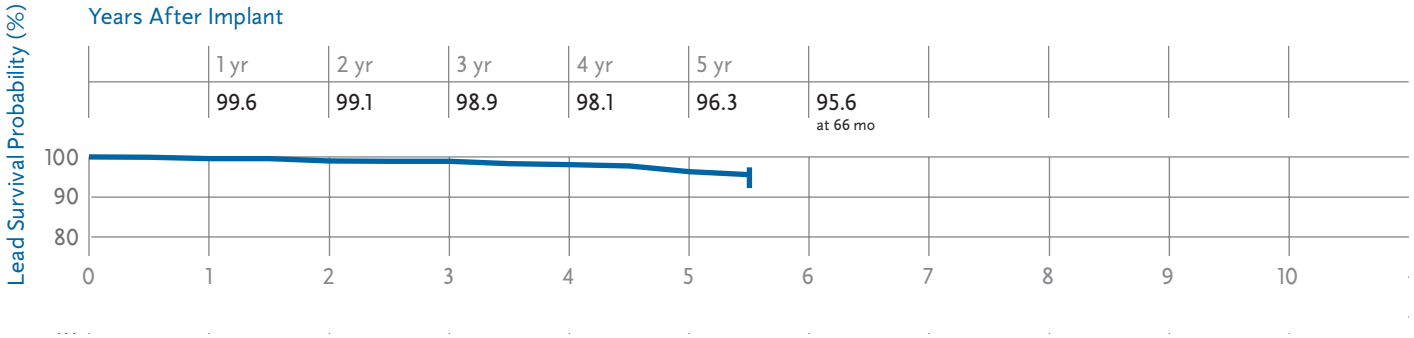
US Market Release	Sep-97
Number of Leads Enrolled in Study	1,150
Complications in Study	18
Conductor Fracture	2
Failure to Sense	3
Inappropriate VF	2
Misc: Other	1
Muscle Stimulation	1
Oversensing	7
Pacing Impedance Out of Range	2
Cumulative Months of Follow-Up in Study	39,033
Advisories	None

Product Characteristics

Serial Number Prefix	TDA
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	Integrated Bipolar/Two Coils
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
99.6	99.1	98.9	98.1	96.3	95.6 at 66 mo



6947 Sprint Quattro Secure

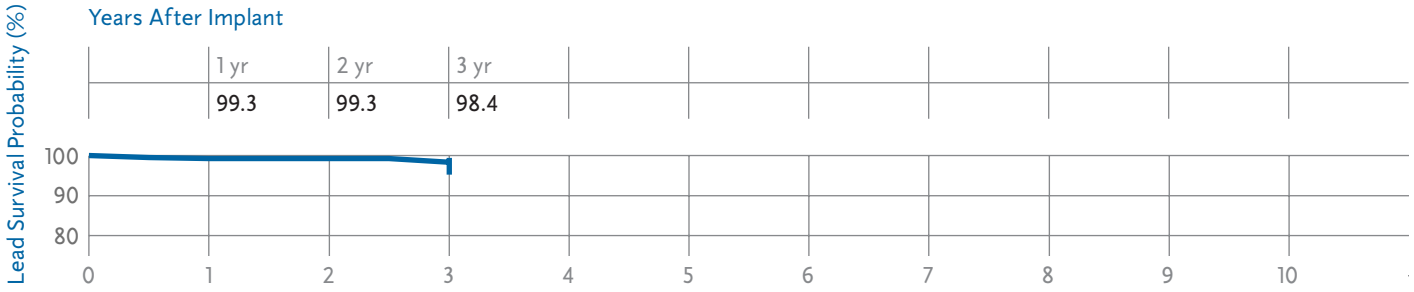
US Market Release	Nov-01
Number of Leads Enrolled in Study	1,317
Complications in Study	9
Conductor Fracture	1
Defib Impedance Out of Range	1
Dislodgement	2
Failure to Sense	1
Insulation Breach	1
Misc: Other	2
Oversensing	1
Cumulative Months of Follow-Up in Study	21,747
Advisories	None

Product Characteristics

Serial Number Prefix	TDG
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	True Bipolar/Two Coils
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr
99.3	99.3	98.4



Source: System Longevity Study
Data as of July 11, 2005

Defibrillation Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
6721, 6921	Epicardial Patch	Feb-93	398	26	17,432	100.0	98.6 +0.9/-2.4	95.8 +2/-3.4	94.7 +2.3/-3.9	92.7 +2.9/-4.7	84.8 +5/-7.2	82.3 +5.7/-7.9	82.3 +5.7/-7.9 at 90 mo		
6932	Sprint	Aug-96	409	7	15,744	99.4 +0.4/-1.9	98.3 +1/-2.4	98.3 +1/-2.4	98.3 +1/-2.4	97.6 +1.4/-3	97.6 +1.4/-3	96.1 +2.3/-5.7 at 78 mo			
6933, 6937, 6963	SVC/CS	Dec-93	964	23	42,935	99.6 +0.3/-0.8	99.2 +0.4/-1.1	99.2 +0.4/-1.1	98.5 +0.7/-1.4	96.8 +1.3/-2.2	96.1 +1.5/-2.4	94.7 +2/-3	94.1 +2.2/-3.4	93.3 +2.5/-3.9	93.3 +2.5/-3.9 at 114 mo
6936, 6966	Transvene	Dec-93	1,351	135	61,100	99.2 +0.4/-0.7	98.5 +0.6/-1	97.1 +0.9/-1.4	96.0 +1.2/-1.6	92.7 +1.7/-2.3	86.9 +2.6/-3.1	78.6 +3.6/-4.3	73.9 +4.2/-4.9	66.3 +5.3/-6.1	63.7 +5.8/-6.5 at 114 mo
6939, 6999	Sub-Q Patch	Dec-93	389	20	16,873	99.1 +0.6/-2	98.7 +0.8/-2.3	98.2 +1/-2.6	98.2 +1/-2.6	94.0 +2.7/-4.9	90.6 +3.8/-6.2	87.0 +4.9/-7.5			
6942	Sprint	Jul-97	350	6	12,444	99.3 +0.5/-2.2	99.3 +0.5/-2.2	98.2 +1.1/-3.1	97.5 +1.5/-3.5	96.5 +2/-4.7	96.5 +2/-4.7 at 66 mo				
6943	Sprint	Oct-97	1,302	38	41,763	98.8 +0.5/-0.8	97.9 +0.7/-1.1	96.9 +0.9/-1.4	95.9 +1.3/-1.7	94.2 +1.9/-2.7	93.6 +2.1/-3.1				
6944	Sprint Quattro	Dec-00	162	3	4,284	99.2 +0.7/-4.7	99.2 +0.7/-4.7	97.8 +1.7/-6.8							
6945	Sprint	Sep-97	1,150	18	39,033	99.6 +0.3/-0.7	99.1 +0.4/-1	98.9 +0.6/-1	98.1 +0.8/-1.5	96.3 +1.6/-2.6	95.6 +1.9/-3.4 at 66 mo				
6947	Sprint Quattro Secure	Nov-01	1,317	9	21,747	99.3 +0.3/-0.8	99.3 +0.3/-0.8	98.4 +1.1/-3.1							

Source: System Longevity Study
Data as of July 11, 2005

Defibrillation Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
6721	Epicardial Patch	Mar-94	1,700	800	0	12	0
6921	Epicardial Patch	Feb-93	7,000	1,400	5	65	0
6930	Sprint Fidelis	Jun-04	100	100	0	0	0
6931	Sprint Fidelis	Sep-04	1,400	1,300	2	1	0
6932	Sprint	Aug-96	15,200	7,700	16	36	7
6933	SVC/CS	Apr-94	8,500	3,000	17	118	5
6934S	Transvene	Mar-96	400	200	0	4	0
6936	Transvene	Apr-94	19,400	5,900	57	364	16
6937	SVC/CS	Mar-96	2,500	1,300	0	12	0
6937A	SVC/CS	Apr-01	600	500	0	0	0
6939	Sub-Q Patch	Apr-94	1,200	300	2	6	0
6942	Sprint	Jul-97	18,100	9,800	31	32	5
6943	Sprint	Oct-97	21,300	11,800	50	56	8
6944	Sprint Quattro	Dec-00	27,400	20,900	22	21	8
6945	Sprint	Sep-97	44,000	25,900	195	74	11
6947	Sprint Quattro Secure	Nov-01	118,500	96,300	204	60	12
6948	Sprint Fidelis	Sep-04	1,600	1,600	1	0	0
6949	Sprint Fidelis	Sep-04	57,700	54,900	176	17	19
6963	SVC/CS	Dec-93	5,400	1,600	14	59	8
6966	Transvene	Dec-93	5,200	1,100	33	81	3
6996	Sub-Q Lead	Jun-01	1,000	800	0	0	0
6999	Sub-Q Patch	Dec-93	3,100	800	2	26	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Source: US Returned Product Analysis
Data as of October 31, 2005

Defibrillation Leads continued

Reference Chart

Model Number	Family	Type	Pin Configuration		Lead Body Diameter	Insulation, Lead Body	Fixation, Steroid
			Pace/ Sense	High Voltage			
6721	Epicardial Patch	Epi Patch	—	DF-1	S, M, L	Silicone, Single Lumen	Suture
6921	Epicardial Patch	Epi Patch	—	6.5 mm	S, M, L	Silicone, Single Lumen	Suture
6930	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6931	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6932	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6933	SVC/CS	Endo SVC/CS Coil	—	DF-1	7 Fr	Silicone, Single Lumen	Passive
6934S	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	12 Fr	Silicone, Coaxial	Passive, Steroid
6936	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	10 Fr	Polyurethane, Coaxial	Active
6937	SVC/CS	Endo SVC Coil	—	DF-1	5.5 Fr	Silicone, Single Lumen	Passive
6937A	SVC/CS	Endo SVC Coil	—	DF-1	7.5 Fr	Silicone with polyurethane overlay, Single Lumen	Passive
6939	Sub-Q Patch	SQ Patch	—	DF-1	One Size	Silicone, Single Lumen	Suture
6942	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6943	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6944	Sprint Quattro	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6945	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6947	Sprint Quattro Secure	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6948	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6949	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6963	SVC/CS	Endo SVC/CS Coil	—	6.5 mm	7 Fr	Silicone, Single Lumen	Passive
6966	Transvene	Endo RV True Bipolar Sensing	3.2 mm L.P.	6.5 mm	10 Fr	Polyurethane, Coaxial	Active
6996	Sub-Q Lead	SQ Coil	—	DF-1	7.5 Fr	Silicone, Single Lumen	Passive
6999	Sub-Q Patch	SQ Patch	—	6.5 mm	One Size	Silicone, Single Lumen	Suture

Ventricular Pacing Leads

4003, 4003M CapSure

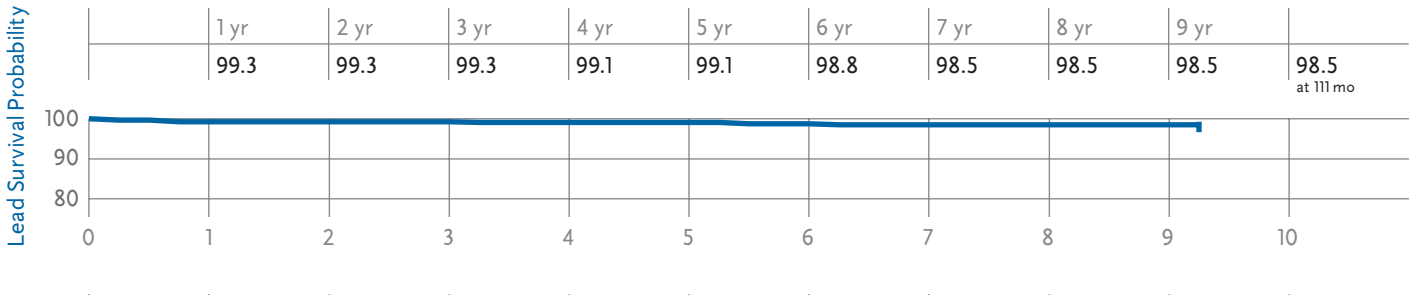
Product Characteristics

US Market Release	Jul-86
Number of Leads Enrolled in Study	684
Complications in Study	7
Extra Cardiac Stimulation	2
Failure to Capture	4
Oversensing	1
Cumulative Months of Follow-Up in Study	41,175
Advisories	None

Serial Number Prefix	IH or LAX
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
99.3	99.3	99.3	99.1	99.1	98.8	98.5	98.5	98.5	98.5 at 111 mo



4004, 4004M CapSure

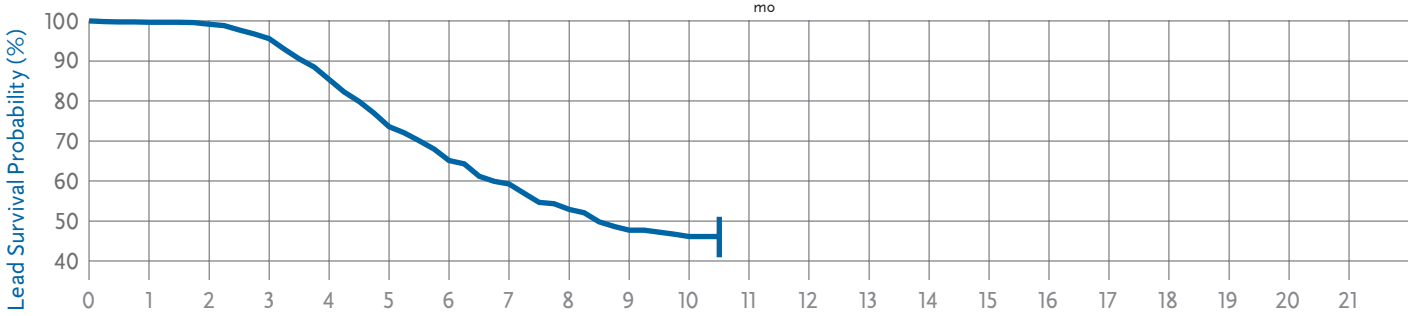
Product Characteristics

US Market Release	Feb-89
Number of Leads Enrolled in Study	1,462
Complications in Study	276
Conductor Fracture	7
Electrical Abandonment	1
Extra Cardiac Stimulation	2
Failure to Capture	131
Failure to Sense	62
Impedance Out of Range	32
Insulation (ESC)	4
Insulation (MIO)	4
Insulation (not further defined)	6
Medical Judgment	1
Oversensing	25
Unspecified Clinical Failure	1
Cumulative Months of Follow-Up in Study	71,546
Advisories	1 see page 157 – 1993 Lead Survival Below Expectations

Serial Number Prefix	PS or LAV
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	
99.7	99.2	95.6	85.4	73.6	65.1	59.3	52.9	47.7	46.1	46.1 at 126 mo



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

4011 Target Tip

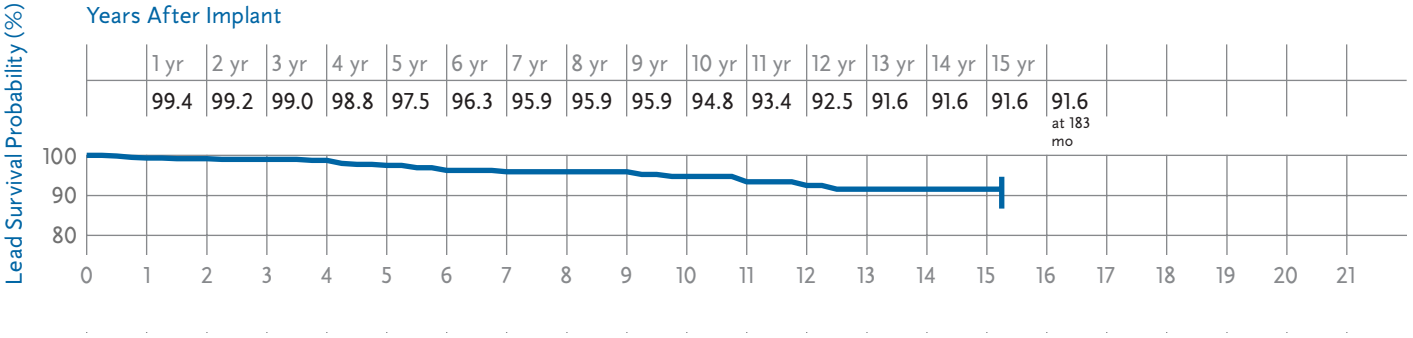
US Market Release	Nov-82
Number of Leads Enrolled in Study	821
Complications in Study	23
Extra Cardiac Stimulation	4
Failure to Capture	9
Insulation (not further defined)	9
Oversensing	1
Cumulative Months of Follow-Up in Study	54,262
Advisories	None

Product Characteristics

Serial Number Prefix	IB
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	
99.4	99.2	99.0	98.8	97.5	96.3	95.9	95.9	95.9	94.8	93.4	92.5	91.6	91.6	91.6	91.6 at 183 mo



4012 Target Tip

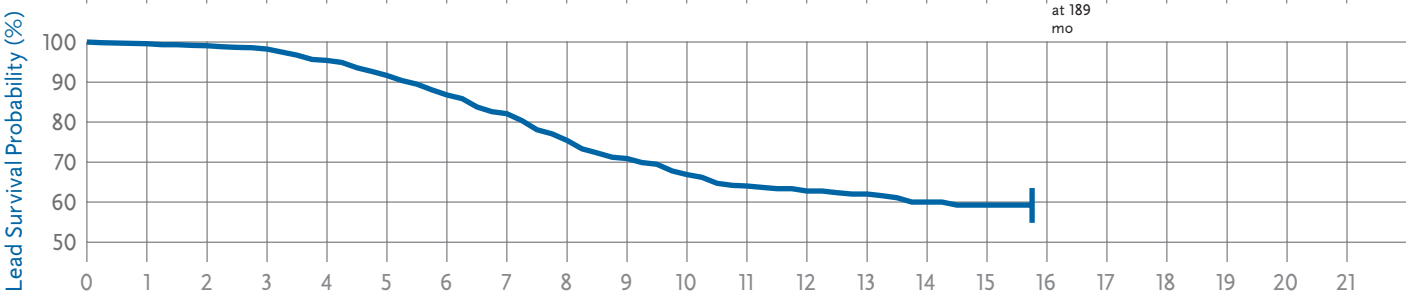
US Market Release	Jul-83
Number of Leads Enrolled in Study	2,349
Complications in Study	315
Conductor Fracture	6
Extra Cardiac Stimulation	3
Failure to Capture	126
Failure to Sense	76
Impedance Out of Range	26
Insulation (ESC)	9
Insulation (MIO)	4
Insulation (not further defined)	16
Medical Judgment	1
Oversensing	48
Cumulative Months of Follow-Up in Study	151,033
Advisories	1 see page 158 – 1991 Lead Survival Below Expectations

Product Characteristics

Serial Number Prefix	HQ
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	
99.6	99.1	98.3	95.4	91.7	86.8	82.1	75.4	70.9	66.9	64.0	62.8	62.0	60.0	59.3	59.3 at 189 mo



Source: System Longevity Study
Data as of July 11, 2005

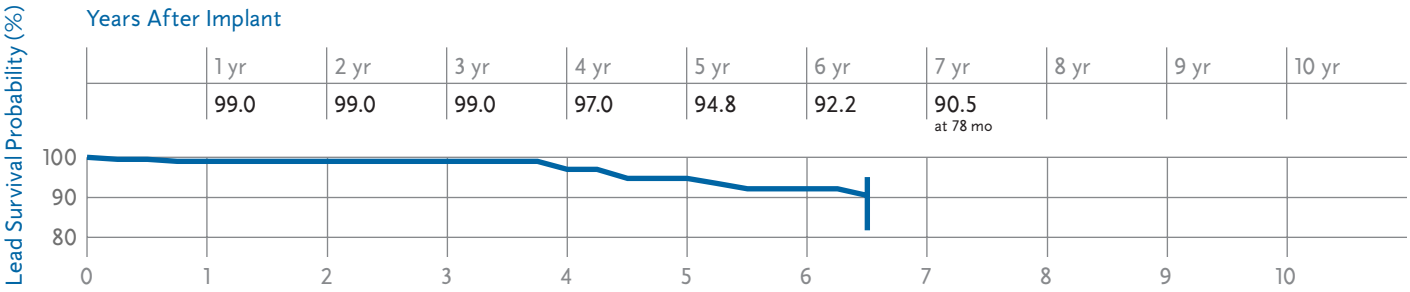
Ventricular Pacing Leads continued

4016 Screw-In

US Market Release	Aug-85
Number of Leads Enrolled in Study	215
Complications in Study	14
Conductor Fracture	2
Failure to Capture	4
Failure to Sense	2
Impedance Out of Range	1
Insulation (not further defined)	2
Oversensing	3
Cumulative Months of Follow-Up in Study	12,880
Advisories	None

Product Characteristics

Serial Number Prefix	KY
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

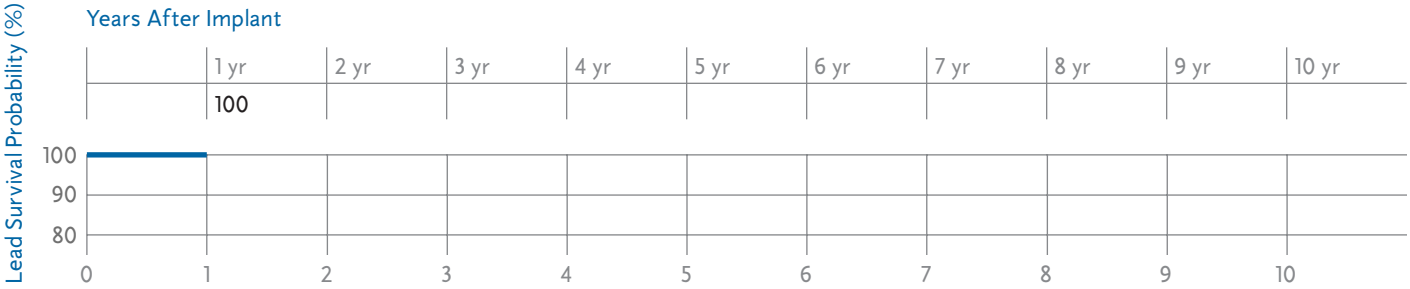


4016A Screw-In

US Market Release	Feb-88
Number of Leads Enrolled in Study	68
Complications in Study	1
Failure to Capture	1
Cumulative Months of Follow-Up in Study	3,354
Advisories	None

Product Characteristics

Serial Number Prefix	XB
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

4023 CapSure SP

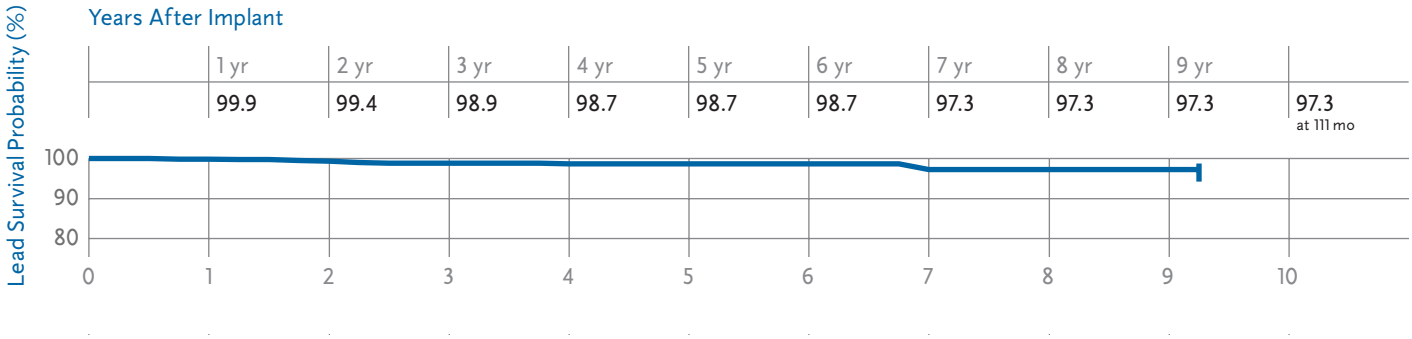
US Market Release	Aug-91
Number of Leads Enrolled in Study	1,140
Complications in Study	12
Failure to Capture	9
Insulation (not further defined)	1
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	50,766
Advisories	None

Product Characteristics

Serial Number Prefix	LAK
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
99.9	99.4	98.9	98.7	98.7	98.7	97.3	97.3	97.3	97.3 at 111 mo



4024 CapSure SP

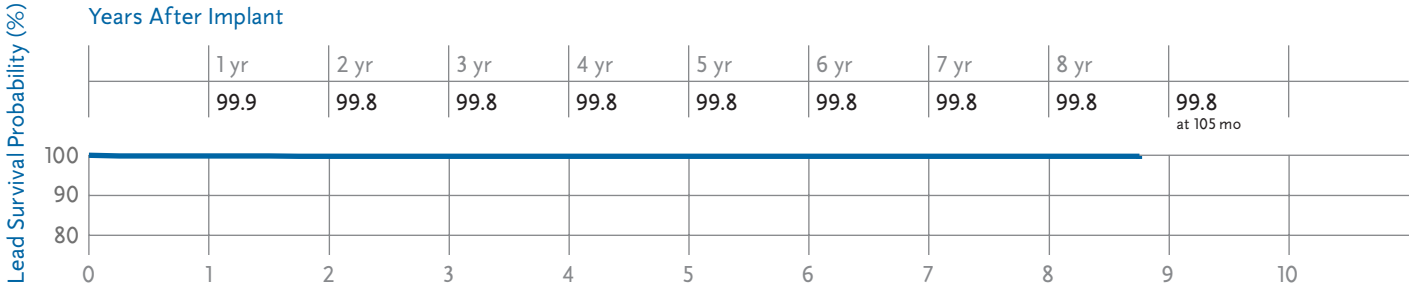
US Market Release	Oct-91
Number of Leads Enrolled in Study	1,202
Complications in Study	3
Failure to Capture	3
Cumulative Months of Follow-Up in Study	49,361
Advisories	None

Product Characteristics

Serial Number Prefix	LAJ
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8 at 105 mo



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

4033 CapSure Z

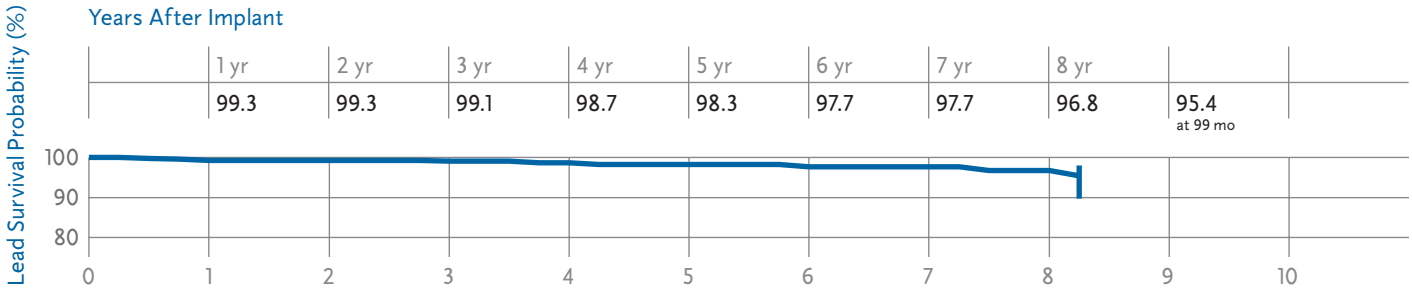
US Market Release	Mar-94
Number of Leads Enrolled in Study	536
Complications in Study	9
Conductor Fracture	1
Failure to Capture	8
Cumulative Months of Follow-Up in Study	26,989
Advisories	None

Product Characteristics

Serial Number Prefix	LCA
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
99.3	99.3	99.1	98.7	98.3	97.7	97.7	96.8	95.4 at 99 mo



4057, 4057M Screw-In

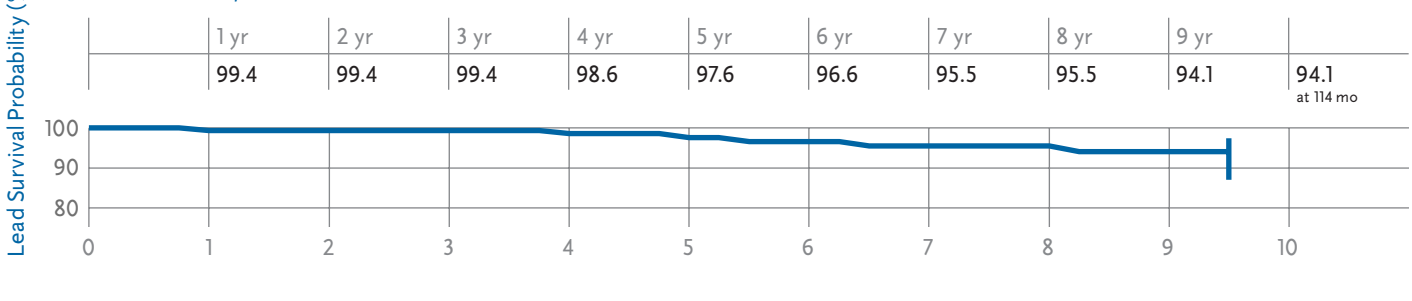
US Market Release	Aug-88
Number of Leads Enrolled in Study	250
Complications in Study	7
Conductor Fracture	2
Extra Cardiac Stimulation	2
Failure to Capture	2
Failure to Sense	1
Cumulative Months of Follow-Up in Study	14,957
Advisories	None

Product Characteristics

Serial Number Prefix	XQ or LAN
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
99.4	99.4	99.4	98.6	97.6	96.6	95.5	95.5	94.1	94.1 at 114 mo



Source: System Longevity Study
Data as of July 11, 2005

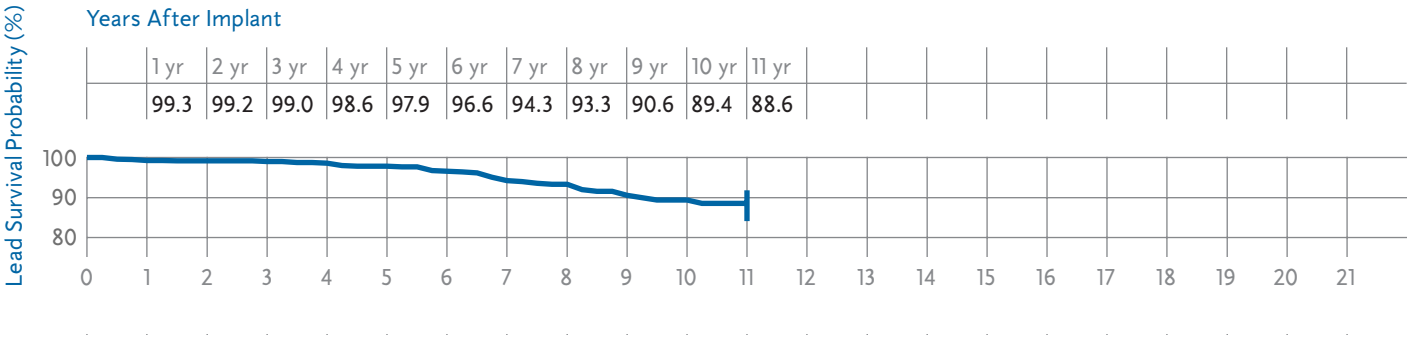
Ventricular Pacing Leads continued

4058, 4058M Screw-In

US Market Release	Jan-89
Number of Leads Enrolled in Study	1,634
Complications in Study	46
Conductor Fracture	2
Extra Cardiac Stimulation	3
Failure to Capture	21
Failure to Sense	11
Impedance Out of Range	4
Insulation (not further defined)	3
Lead Dislodgement	1
Oversensing	1
Cumulative Months of Follow-Up in Study	75,270
Advisories	None

Product Characteristics

Serial Number Prefix	ZY or LAW
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

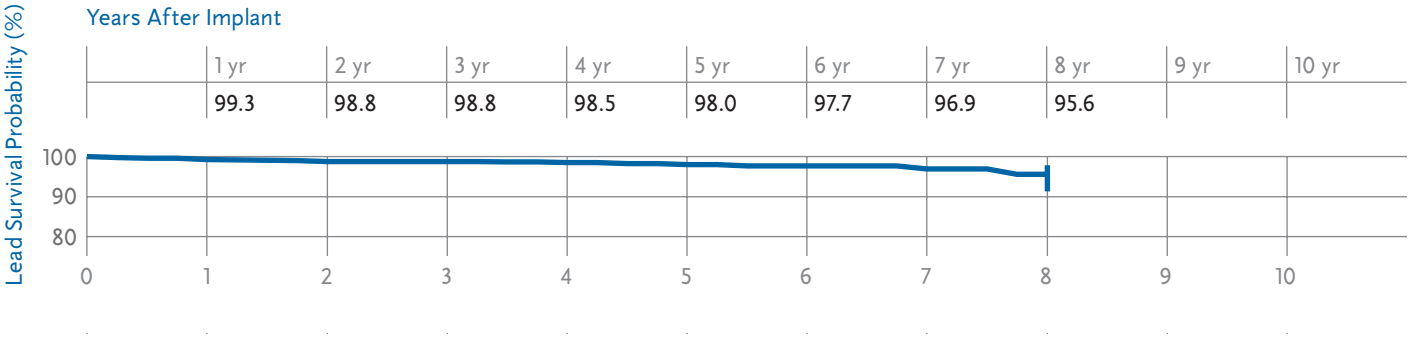


4068 CapSureFix

US Market Release	Mar-96
Number of Leads Enrolled in Study	1,726
Complications in Study	24
Conductor Fracture	1
Extra Cardiac Stimulation	1
Failure to Capture	18
Failure to Sense	3
Impedance Out of Range	1
Cumulative Months of Follow-Up in Study	67,434
Advisories	None

Product Characteristics

Serial Number Prefix	LCE
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

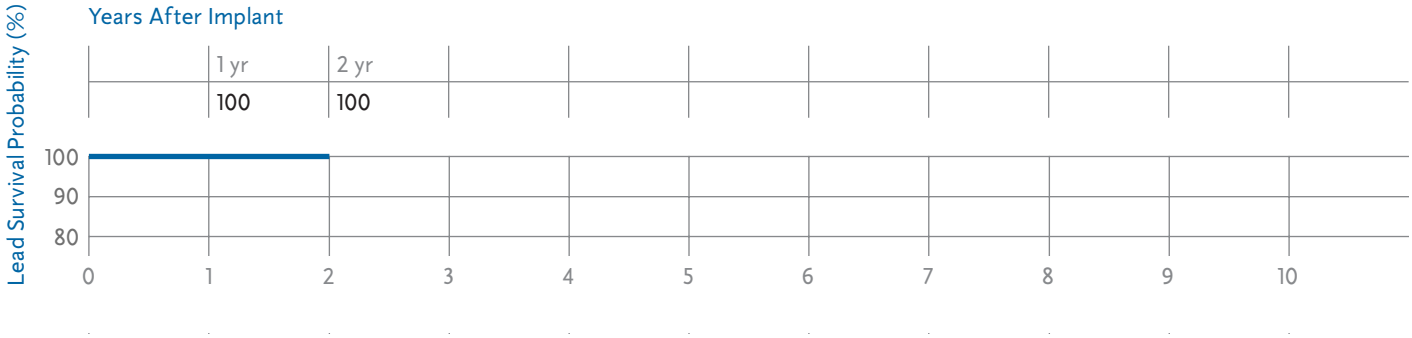
Ventricular Pacing Leads continued

4074 CapSure Sense

US Market Release	Jun-02
Number of Leads Enrolled in Study	362
Complications in Study	0
Cumulative Months of Follow-Up in Study	4,557
Advisories	None

Product Characteristics

Serial Number Prefix	BBD
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

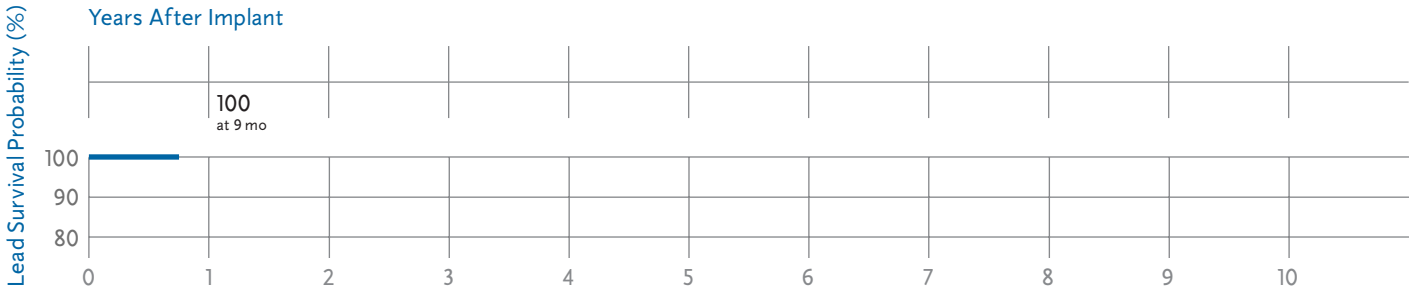


4076 CapSureFix Novus

US Market Release	Feb-04
Number of Leads Enrolled in Study	143
Complications in Study	0
Cumulative Months of Follow-Up in Study	1,217
Advisories	None

Product Characteristics

Serial Number Prefix	BBL
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

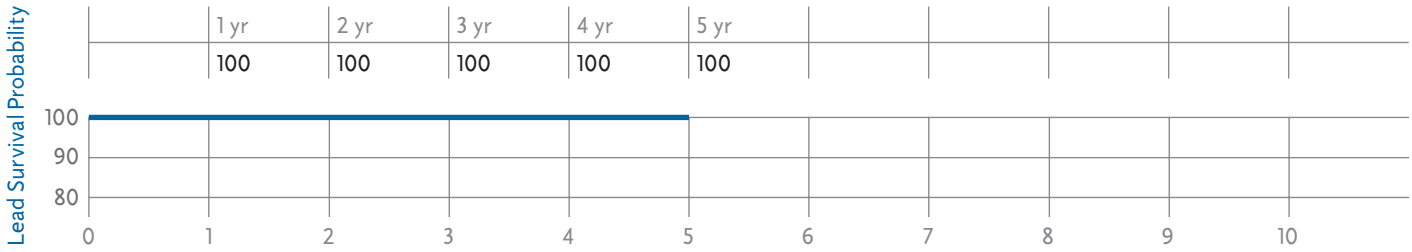
4081 Target Tip

US Market Release	Jul-89
Number of Leads Enrolled in Study	255
Complications in Study	3
Conductor Fracture	1
Failure to Sense	2
Cumulative Months of Follow-Up in Study	9,447
Advisories	None

Product Characteristics

Serial Number Prefix	LAC
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

Years After Implant



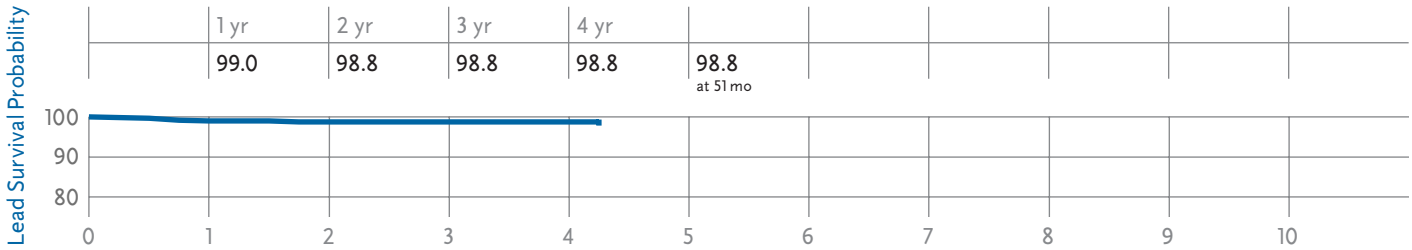
4092 CapSure SP Novus

US Market Release	Sep-98
Number of Leads Enrolled in Study	1,124
Complications in Study	11
Conductor Fracture	2
Extra Cardiac Stimulation	1
Failure to Capture	5
Lead Dislodgement	3
Cumulative Months of Follow-Up in Study	30,268
Advisories	None

Product Characteristics

Serial Number Prefix	LEP
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5023, 5023M CapSure SP

US Market Release	Nov-88
Number of Leads Enrolled in Study	1,343
Complications in Study	4
Extra Cardiac Stimulation	1
Failure to Capture	2
Impedance Out of Range	1
Cumulative Months of Follow-Up in Study	49,609
Advisories	None

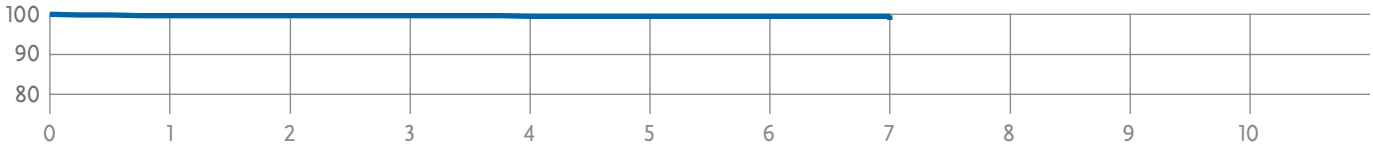
Product Characteristics

Serial Number Prefix	SX or LAS
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

Lead Survival Probability (%)

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
99.7	99.7	99.7	99.5	99.5	99.5	99.5



5024, 5024M CapSure SP

US Market Release	Mar-90
Number of Leads Enrolled in Study	7,964
Complications in Study	39
Conductor Fracture	3
Extra Cardiac Stimulation	1
Failure to Capture	23
Failure to Sense	2
Insulation (ESC)	1
Insulation (not further defined)	4
Lead Dislodgement	4
Oversensing	1
Cumulative Months of Follow-Up in Study	401,731
Advisories	None

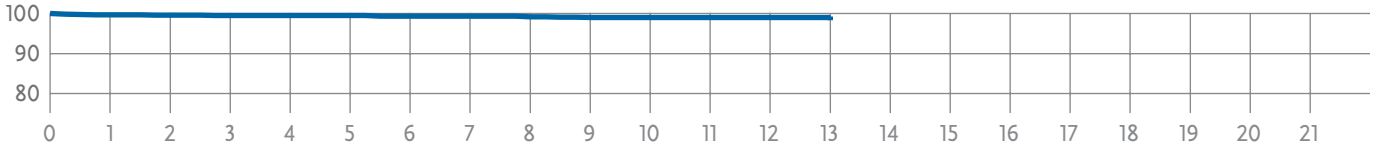
Product Characteristics

Serial Number Prefix	SY or LAT
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Lead Survival Probability (%)

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr
99.7	99.6	99.5	99.5	99.5	99.4	99.4	99.2	99.0	99.0	99.0	99.0	99.0



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5026 CapSure

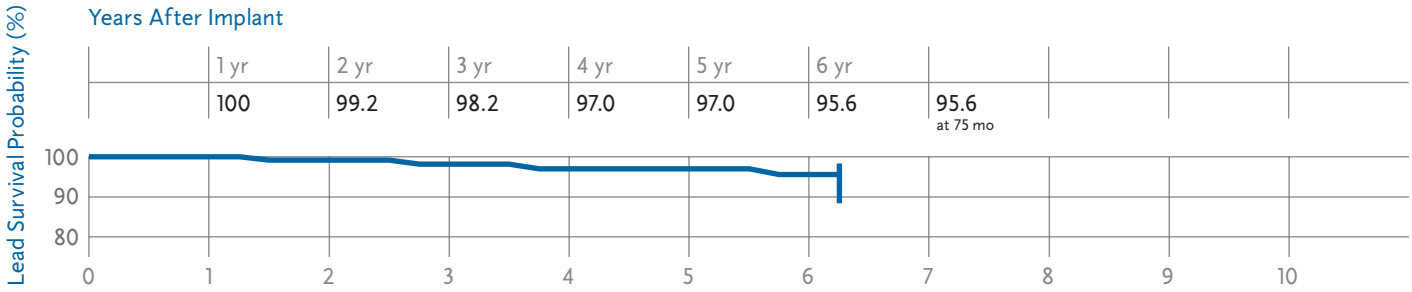
US Market Release	Feb-88
Number of Leads Enrolled in Study	165
Complications in Study	4
Electrical Abandonment	1
Failure to Capture	3
Cumulative Months of Follow-Up in Study	9,398
Advisories	None

Product Characteristics

Serial Number Prefix	RZ
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
100	99.2	98.2	97.0	97.0	95.6	95.6 at 75 mo



5033 CapSure Z

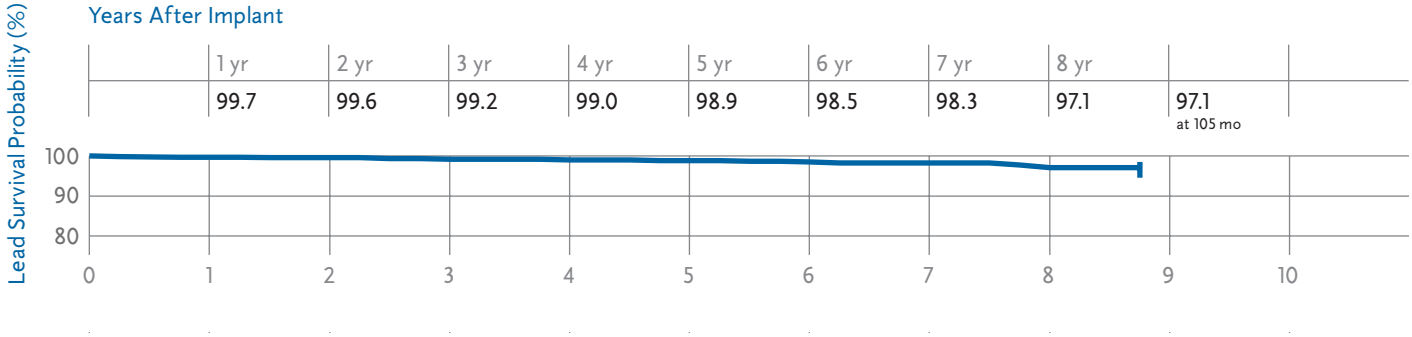
US Market Release	Feb-96
Number of Leads Enrolled in Study	1,885
Complications in Study	18
Cardiac Perforation	1
Conductor Fracture	4
Failure to Capture	8
Impedance Out of Range	2
Insulation (not further defined)	1
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	81,324
Advisories	None

Product Characteristics

Serial Number Prefix	LDK
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
99.7	99.6	99.2	99.0	98.9	98.5	98.3	97.1	97.1 at 105 mo



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5034 CapSure Z

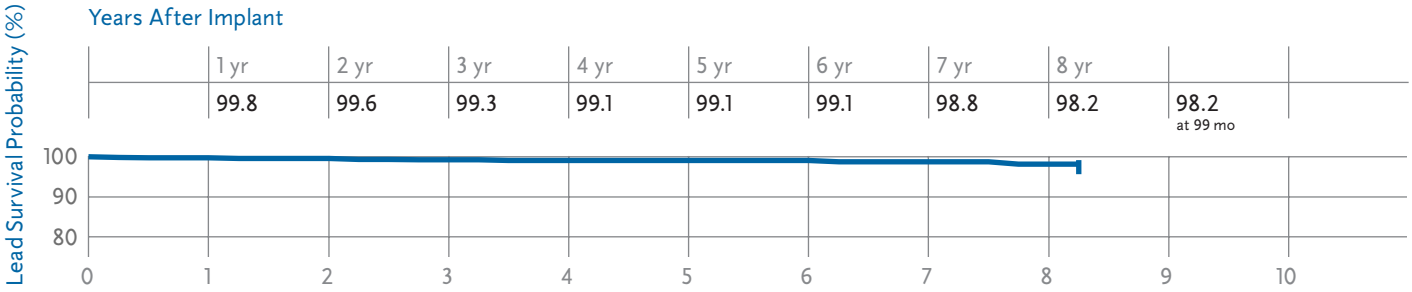
US Market Release	Feb-96
Number of Leads Enrolled in Study	1,577
Complications in Study	12
Conductor Fracture	1
Failure to Capture	8
Failure to Sense	1
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	72,028
Advisories	None

Product Characteristics

Serial Number Prefix	LDF
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
99.8	99.6	99.3	99.1	99.1	99.1	98.8	98.2	98.2 at 99 mo



5054 CapSure Z Novus

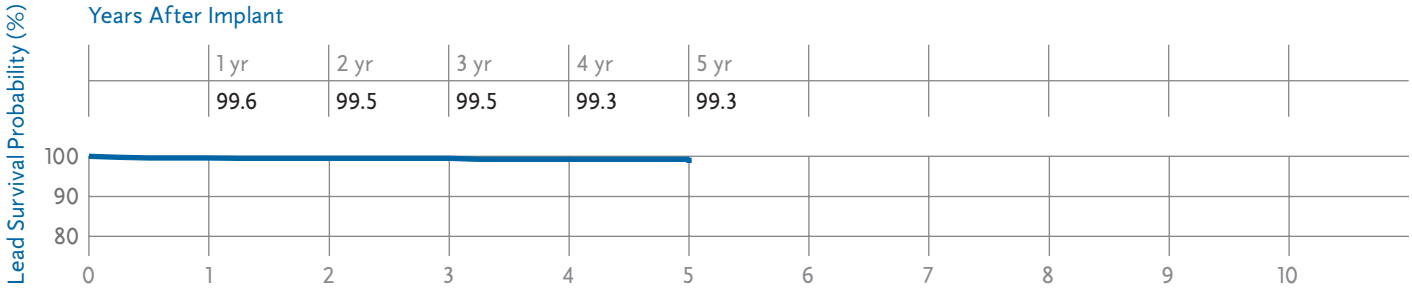
US Market Release	Jun-98
Number of Leads Enrolled in Study	1,378
Complications in Study	9
Failure to Capture	5
Failure to Sense	1
Impedance Out of Range	1
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	39,024
Advisories	None

Product Characteristics

Serial Number Prefix	LEH
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr
99.6	99.5	99.5	99.3	99.3



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5061 Target Tip

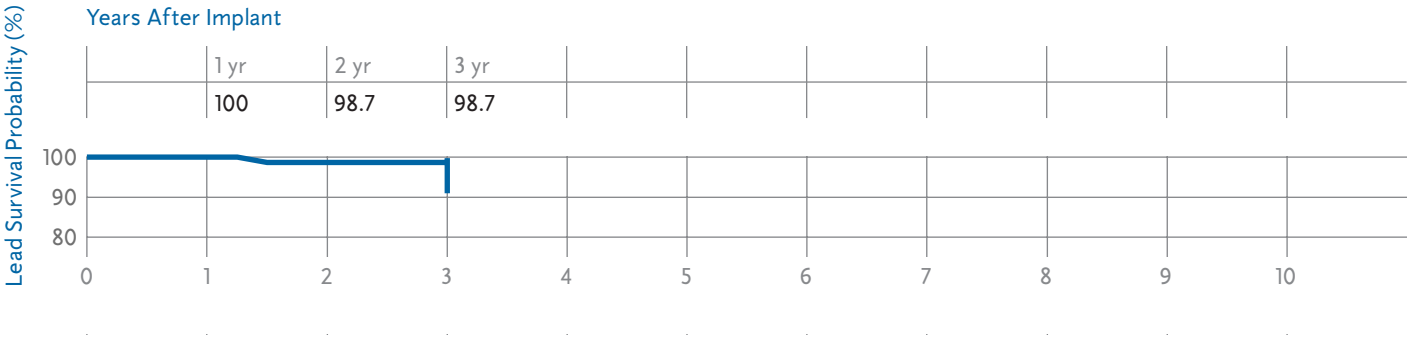
US Market Release	Mar-85
Number of Leads Enrolled in Study	118
Complications in Study	1
Failure to Capture	1
Cumulative Months of Follow-Up in Study	4,868
Advisories	None

Product Characteristics

Serial Number Prefix	GX
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr
100	98.7	98.7



5064 Target Tip

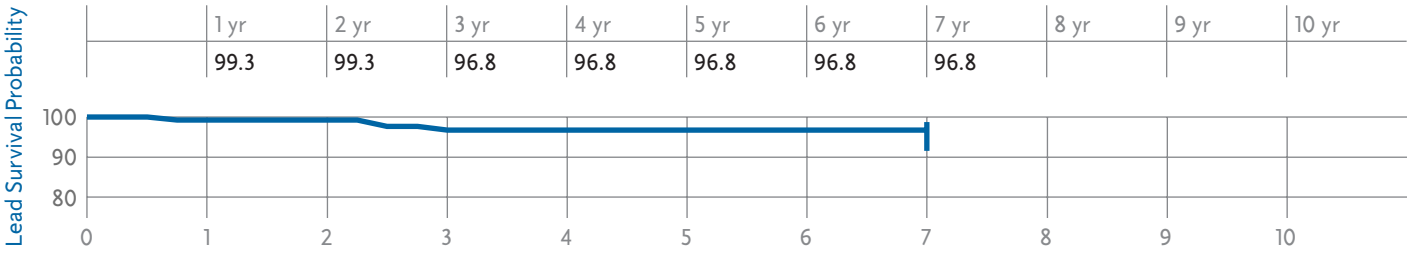
US Market Release	Jun-85
Number of Leads Enrolled in Study	176
Complications in Study	4
Failure to Capture	2
Failure to Sense	1
Oversensing	1
Cumulative Months of Follow-Up in Study	11,547
Advisories	None

Product Characteristics

Serial Number Prefix	IZ
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
99.3	99.3	96.8	96.8	96.8	96.8	96.8			



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5068 CapSureFix

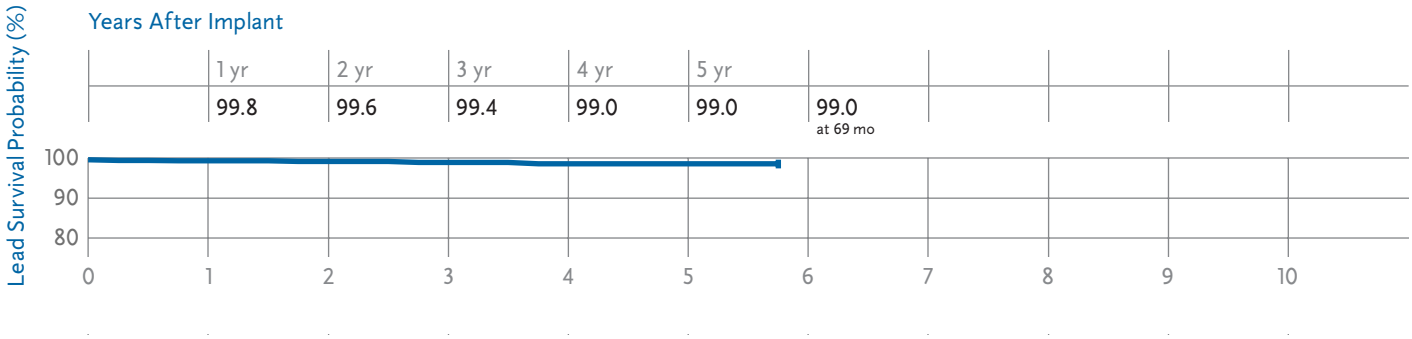
US Market Release	Jan-97
Number of Leads Enrolled in Study	1,336
Complications in Study	5
Conductor Fracture	1
Failure to Capture	3
Lead Dislodgement	1
Cumulative Months of Follow-Up in Study	30,450
Advisories	None

Product Characteristics

Serial Number Prefix	LDJ
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
99.8	99.6	99.4	99.0	99.0	99.0 at 69 mo



5076 CapSureFix Novus

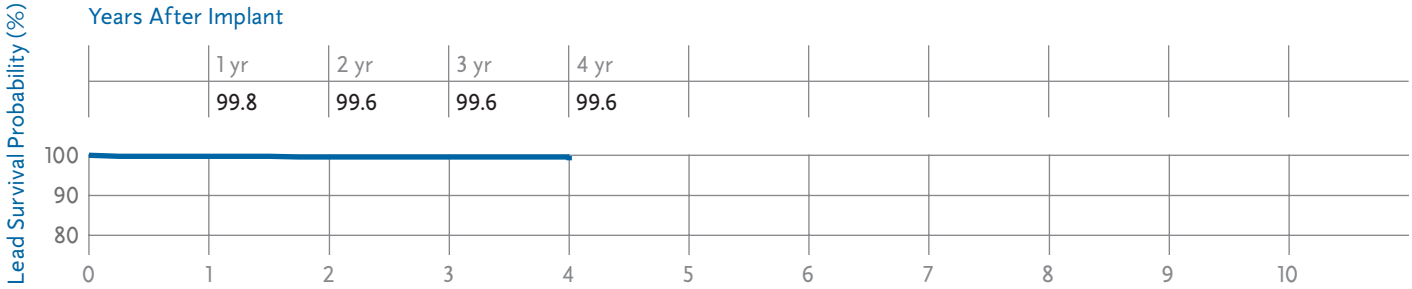
US Market Release	Aug-00
Number of Leads Enrolled in Study	1,294
Complications in Study	4
Cardiac Perforation	1
Failure to Capture	2
Failure to Sense	1
Cumulative Months of Follow-Up in Study	26,518
Advisories	None

Product Characteristics

Serial Number Prefix	PJN
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr
99.8	99.6	99.6	99.6



Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

5092 CapSure SP Novus

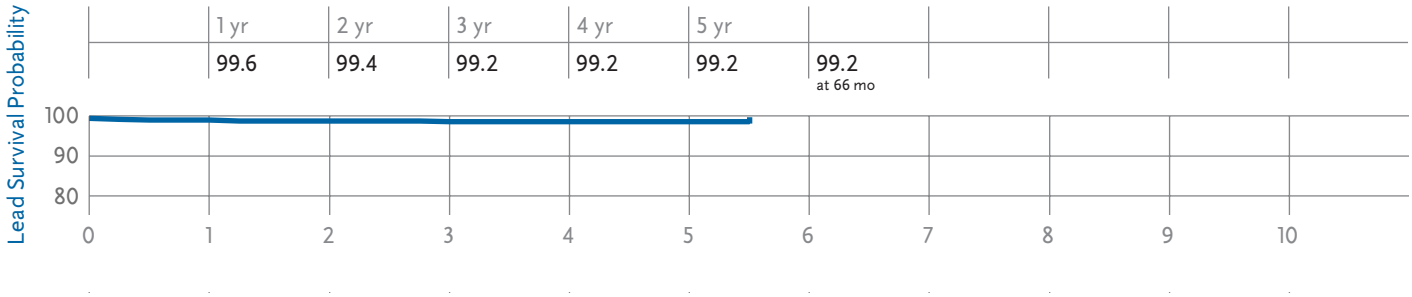
US Market Release	Jun-98
Number of Leads Enrolled in Study	1,131
Complications in Study	6
Failure to Capture	1
Lead Dislodgement	5
Cumulative Months of Follow-Up in Study	29,399
Advisories	None

Product Characteristics

Serial Number Prefix	LET
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
99.6	99.4	99.2	99.2	99.2	99.2 at 66 mo



6957 Spectraflex

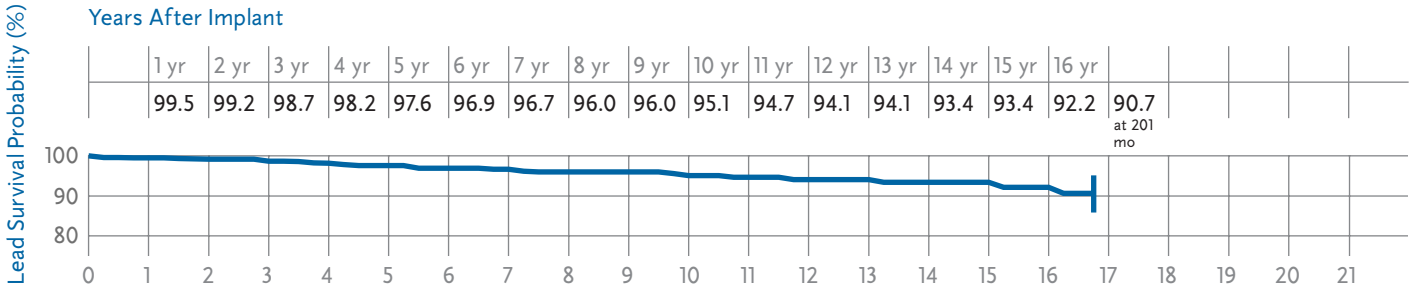
US Market Release	Jul-79
Number of Leads Enrolled in Study	1,780
Complications in Study	42
Conductor Fracture	13
Extra Cardiac Stimulation	2
Failure to Capture	19
Failure to Sense	2
Impedance Out of Range	1
Insulation (not further defined)	1
Oversensing	4
Cumulative Months of Follow-Up in Study	95,710
Advisories	None

Product Characteristics

Serial Number Prefix	VC
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	
99.5	99.2	98.7	98.2	97.6	96.9	96.7	96.0	96.0	95.1	94.7	94.1	94.1	93.4	93.4	92.2	90.7 at 201 mo



Source: System Longevity Study
Data as of July 11, 2005

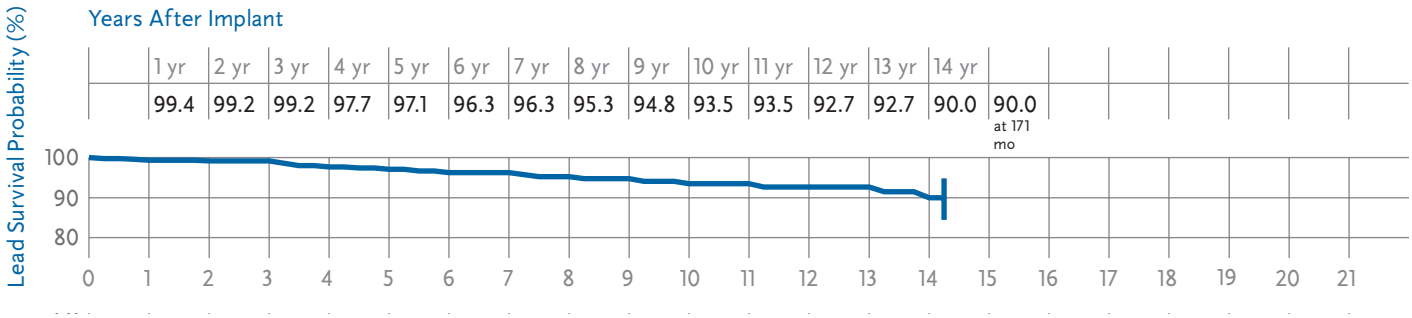
Ventricular Pacing Leads continued

6961 Tenax

US Market Release	Jan-78
Number of Leads Enrolled in Study	608
Complications in Study	21
Extra Cardiac Stimulation	4
Failure to Capture	7
Failure to Sense	6
Insulation (not further defined)	2
Lead Dislodgement	1
Oversensing	1
Cumulative Months of Follow-Up in Study	43,052
Advisories	None

Product Characteristics

Serial Number Prefix	TB
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

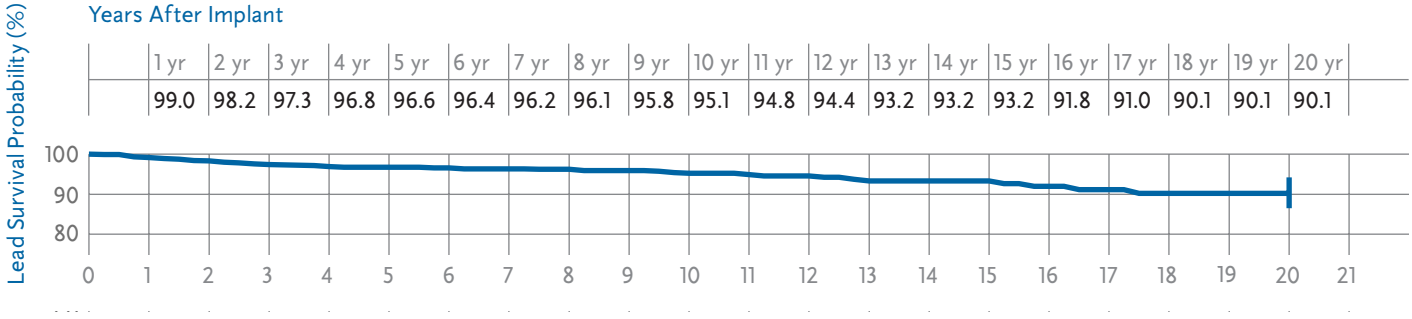


6962 Tenax

US Market Release	Jan-78
Number of Leads Enrolled in Study	1,435
Complications in Study	51
Conductor Fracture	5
Extra Cardiac Stimulation	1
Failure to Capture	27
Failure to Sense	10
Impedance Out of Range	2
Insulation (not further defined)	2
Lead Dislodgement	1
Oversensing	3
Cumulative Months of Follow-Up in Study	110,834
Advisories	None

Product Characteristics

Serial Number Prefix	UB
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4003, 4003M	CapSure	Jul-86	684	7	41,175	99.3 +0.5/-1	99.3 +0.5/-1	99.3 +0.5/-1	99.1 +0.5/-1.2	99.1 +0.5/-1.2	98.8 +0.7/-1.5	98.5 +0.8/-1.8	98.5 +0.8/-1.8	98.5 +0.8/-1.8 at 111 mo					
4004, 4004M	CapSure	Feb-89	1,462	276	71,546	99.7 +0.2/-0.5	99.2 +0.4/-0.8	95.6 +1.2/-1.6	85.4 +2.4/-2.8	73.6 +3.2/-3.6	65.1 +3.7/-4.1	59.3 +4.1/-4.4	52.9 +4.5/-4.7	46.1 +5/-5.2	46.1 +5/-5.2 at 126 mo				
	Advisory: see page 157 - 1993 Lead Survival Below Expectations																		
4011	Target Tip	Nov-82	821	23	54,262	99.4 +0.4/-1	99.2 +0.5/-1.1	99.0 +0.6/-1.2	98.8 +0.6/-1.3	97.5 +1.1/-1.9	96.3 +1.4/-2.4	95.9 +1.6/-2.6	95.9 +1.6/-2.6	94.8 +2/-3.2	92.5 +2.8/-4.4	91.6 +3.1/-4.9	91.6 +3.1/-4.9 at 183 mo		
4012	Target Tip	Jul-83	2,349	315	151,033	99.6 +0.2/-0.4	99.1 +0.3/-0.6	98.3 +0.5/-0.8	95.4 +0.9/-1.3	91.7 +1.4/-1.6	86.8 +1.8/-2.1	82.1 +2.2/-2.5	75.4 +2.7/-3	66.9 +3.3/-3.6	62.8 +3.6/-3.9	60.0 +4.1/-4.3	59.3 +4.2/-4.5 at 189 mo		
	Advisory: see page 158 - 1991 Lead Survival Below Expectations																		
4016	Screw-In	Aug-85	215	14	12,880	99.0 +0.7/-3.1	99.0 +0.7/-3.1	99.0 +0.7/-3.1	97.0 +1.9/-5.2	94.8 +2.9/-6.4	92.2 +4/-7.6	90.5 +4.6/-8.7 at 78 mo							
4016A	Screw-In	Feb-88	68	1	3,354	100.0													
4023	CapSure SP	Aug-91	1,140	12	50,766	99.9 +0.1/-0.7	99.4 +0.4/-0.8	98.9 +0.5/-1	98.7 +0.6/-1.2	98.7 +0.6/-1.2	98.7 +0.6/-1.2	97.3 +1.5/-3	97.3 +1.5/-3	97.3 +1.5/-3 at 111 mo					
4024	CapSure SP	Oct-91	1,202	3	49,361	99.9 +0.1/-0.5	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7 at 105 mo					
4033	CapSure Z	Mar-94	536	9	26,989	99.3 +0.5/-1.3	99.3 +0.5/-1.3	99.1 +0.5/-1.6	98.7 +0.8/-1.8	98.3 +1/-2.1	97.7 +1.3/-2.6	97.7 +1.3/-2.6	96.8 +1.8/-3.7	95.4 +2.6/-5.7 at 99 mo					
4057, 4057M	Screw-In	Aug-88	250	7	14,957	99.4 +0.5/-3.7	99.4 +0.5/-3.7	99.4 +0.5/-3.7	98.6 +1/-4.3	97.6 +1.6/-4.9	96.6 +2.1/-5.4	95.5 +2.6/-6.1	95.5 +2.6/-6.1	94.1 +3.3/-7 at 114 mo					
4058, 4058M	Screw-In	Jan-89	1,634	46	75,270	99.3 +0.4/-0.6	99.2 +0.3/-0.8	99.0 +0.5/-0.7	98.6 +0.6/-1	97.9 +0.7/-1.3	96.6 +1.2/-1.7	94.3 +1.7/-2.5	93.3 +1.9/-2.8	89.4 +3/-4	88.6 +3.2/-4.5 at 132 mo				
4068	CapSureFix	Mar-96	1,726	24	67,434	99.3 +0.3/-0.6	98.8 +0.5/-0.7	98.8 +0.5/-0.7	98.5 +0.6/-0.9	98.0 +0.8/-1.2	97.7 +0.9/-1.6	96.9 +1.4/-2.8	95.6 +2.3/-4.3						
4074	CapSure Sense	Jun-02	362	0	4,557	100.0	100.0												
4076	CapSureFix Novus	Feb-04	143	0	1,217	100.0 at 9 mo													
4081	Target Tip	Jul-89	255	3	9,447	100.0	100.0	100.0	100.0	100.0									
4092	CapSure SP Novus	Sep-98	1,124	11	30,268	99.0 +0.5/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9 at 51 mo									
5023, 5023M	CapSure SP	Nov-88	1,343	4	49,609	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.5 +0.3/-0.9	99.5 +0.3/-0.9	99.5 +0.3/-0.9	99.5 +0.3/-0.9							

continued

Source: System Longevity Study
Data as of July 11, 2005

Lead Survival Summary continued

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%)													
						1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
5024, 5024M	CapSure SP	Mar-90	7,964	39	401,731	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.5 +0.2/-0.2	99.5 +0.1/-0.2	99.5 +0.1/-0.3	99.4 +0.2/-0.2	99.4 +0.2/-0.3	99.2 +0.3/-0.4	99.0 +0.3/-0.6	99.0 +0.3/-0.6	99.0 +0.3/-0.6 at 156 mo			
5026	CapSure	Feb-88	165	4	9,398	100.0	99.2 +0.7/-4.9	98.2 +1.3/-5.4	97.0 +2/-6	97.0 +2/-6	95.6 +2.8/-7.2	95.6 +2.8/-7.2 at 75 mo							
5033	CapSure Z	Feb-96	1,885	18	81,324	99.7 +0.2/-0.4	99.6 +0.2/-0.4	99.2 +0.3/-0.8	99.0 +0.5/-0.7	98.9 +0.5/-0.9	98.5 +0.6/-1.1	98.3 +0.7/-1.3	97.1 +1.4/-2.5	97.1 +1.4/-2.5 at 105 mo					
5034	CapSure Z	Feb-96	1,577	12	72,028	99.8 +0.1/-0.4	99.6 +0.2/-0.6	99.3 +0.3/-0.7	99.1 +0.4/-0.7	99.1 +0.4/-0.7	99.1 +0.4/-0.7	98.8 +0.6/-1.1	98.2 +1/-2.5	98.2 +1/-2.5 at 99 mo					
5054	CapSure Z Novus	Jun-98	1,378	9	39,024	99.6 +0.2/-0.6	99.5 +0.3/-0.6	99.5 +0.3/-0.6	99.3 +0.4/-0.9	99.3 +0.4/-0.9									
5061	Target Tip	Mar-85	118	1	4,868	100.0	98.7 +1.1/-7.7	98.7 +1.1/-7.7											
5064	Target Tip	Jun-85	176	4	11,547	99.3 +0.6/-3.9	99.3 +0.6/-3.9	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2							
5068	CapSureFix	Jan-97	1,336	5	30,450	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.4 +0.4/-1.1	99.0 +0.6/-1.6	99.0 +0.6/-1.6	99.0 +0.6/-1.6 at 69 mo								
5076	CapSureFix Novus	Aug-00	1,294	4	26,518	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.6 +0.3/-0.8	99.6 +0.3/-0.8										
5092	CapSure SP Novus	Jun-98	1,131	6	29,399	99.6 +0.2/-0.7	99.4 +0.4/-0.7	99.2 +0.5/-1.1	99.2 +0.5/-1.1	99.2 +0.5/-1.1	99.2 +0.5/-1.1 at 66 mo								
6957	Spectraflex	Jul-79	1,780	42	95,710	99.5 +0.3/-0.4	99.2 +0.3/-0.7	98.7 +0.5/-0.9	98.2 +0.7/-1.1	97.6 +0.8/-1.3	96.9 +1/-1.5	96.7 +1.1/-1.6	96.0 +1.2/-1.9	95.1 +1.6/-2.2	94.1 +2/-2.8	93.4 +2.2/-3.4	92.2 +2.9/-4.3	90.7 +3.6/-5.7 at 201 mo	
6961	Tenax	Jan-78	608	21	43,052	99.4 +0.4/-1.2	99.2 +0.5/-1.4	99.2 +0.5/-1.4	97.7 +1.1/-2.1	97.1 +1.3/-2.4	96.3 +1.5/-2.8	96.3 +1.5/-2.8	95.3 +1.9/-3.2	93.5 +2.5/-4	92.7 +2.8/-4.4	90.0 +4/-6.4	90.0 +4/-6.4 at 171 mo		
6962	Tenax	Jan-78	1,435	51	110,834	99.0 +0.4/-0.8	98.2 +0.6/-1	97.3 +0.8/-1.2	96.8 +0.9/-1.3	96.6 +0.9/-1.4	96.4 +1/-1.4	96.2 +1.1/-1.4	96.1 +1/-1.6	95.1 +1.3/-1.9	94.4 +1.6/-2.1	93.2 +1.9/-2.7	91.8 +2.5/-3.5	90.1 +3.1/-4.6	90.1 +3.1/-4.6

Source: System Longevity Study
Data as of July 11, 2005

Ventricular Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4003, 4003M	CapSure	Jul-86	40,000	8,500	24	54	2
4004, 4004M	CapSure	Feb-89	74,500	4,100	55	679	19
4011	Target Tip	Nov-82	64,000	8,600	29	138	5
4012	Target Tip	Jul-83	96,800	7,100	50	814	34
4016	Screw-In	Aug-85	8,100	1,100	57	59	3
4016A	Screw-In	Feb-88	3,800	700	19	20	0
4023	CapSure SP	Aug-91	43,700	17,800	48	18	6
4024	CapSure SP	Oct-91	229,200	99,900	264	82	34
4057, 4057M	Screw-In	Aug-88	12,100	3,300	39	6	4
4058, 4058M	Screw-In	Jan-89	111,100	31,200	388	220	23
4067	CapSureFix	Jan-97	1,300	600	3	1	1
4068	CapSureFix	Mar-96	131,700	68,600	406	66	11
4074	CapSure Sense	Jun-02	29,400	25,500	7	1	1
4076	CapSureFix Novus	Feb-04	38,900	36,300	16	2	1
4081	Target Tip	Jul-89	4,100	1,100	4	5	0
4092	CapSure SP Novus	Sep-98	120,400	86,900	30	5	5
5023, 5023M	CapSure SP	Nov-88	10,600	3,500	15	7	0
5024, 5024M	CapSure SP	Mar-90	211,400	86,700	723	99	29
5025	CapSure	Jul-86	1,600	300	1	3	0
5026	CapSure	Feb-88	7,800	1,600	60	7	1
5033	CapSure Z	Feb-96	2,500	1,200	6	1	3
5034	CapSure Z	Feb-96	58,700	27,300	85	29	11
5054	CapSure Z Novus	Jun-98	74,100	50,200	39	11	6
5061	Target Tip	Mar-85	5,500	1,000	5	1	0
5062	Target Tip	Dec-85	2,800	500	10	1	1
5064	Target Tip	Jun-85	8,500	1,500	11	15	0
5067	CapSureFix	Jan-97	200	120	0	0	0
5068	CapSureFix	Jan-97	108,000	62,000	455	46	15
5072	SureFix	Jun-98	8,200	5,300	21	2	1
5076	CapSureFix Novus	Aug-00	580,200	465,800	531	80	42
5092	CapSure SP Novus	Jun-98	90,600	64,600	37	12	10
6957	Spectraflex	Jul-79	29,100	3,400	85	39	25
6961	Tenax	Jan-78	44,700	2,500	103	27	0
6962	Tenax	Jan-78	70,600	4,400	170	84	0

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and

continued

Source: US Returned Product Analysis
Data as of October 31, 2005

Ventricular Pacing Leads continued

Laboratory Analysis continued

metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4003, 4003M	CapSure	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4003) IS-1 UNI (4003M)
4004, 4004M	CapSure	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Porous/Steroid	3.2 mm Low Profile (4004) IS-1 BI (4004M)
4011	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
4012	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4016	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/2 Filars	1.5 mm Helix	3.2 mm Low Profile
4016A	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/2 Filars	2.0 mm Helix	3.2 mm Low Profile
4023	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4 Filars	Porous Platinized/ Steroid	IS-1 UNI
4024	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4033	CapSure Z	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4057, 4057M	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm (4057) IS-1 UNI (4057M)
4058, 4058M	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/1 Filars	2.0 mm Helix	3.2 mm Low Profile (4058) IS-1 BI (4058M)
4067	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
4068	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4074	CapSure Sense	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D, 4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium	IS-1 BI
4076	CapSureFix Novus	Transvenous V or A Screw-In	Polyurethane/ Silicone (55D, 4719)	MP35N 4/6 Filars	TiN Coated Platinum Alloy	IS-1 BI
4081	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	IS-1 UNI w/Removable 5 mm Sleeve
4082	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Target Tip Concentric Grooves	IS-1 BI

Ventricular Pacing Leads continued

Reference Chart continued

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4092	CapSure SP Novus	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/ Steroid	IS-1 BI
5023, 5023M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm (5023) IS-1 UNI (5023M)
5024, 5024M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile (5024) IS-1 BI (5024M)
5025	CapSure	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm Unipolar
5026	CapSure	Transvenous Ventricular Tines	Silicone	MP35N 6/4 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile
5033	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
5034	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5054	CapSure Z Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	CapSure Z Porous/Platinized/ Steroid	IS-1 BI
5061	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
5062	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
5064	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm Bifurcated
5067	CapSureFix	Transvenous V or A Screw-In	Silicone	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
5068	CapSureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5072	SureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/5 Filars	1.8 mm Helix/Steroid	IS-1 BI
5076	CapSureFix Novus	Transvenous V or A Screw-In	Silicone (4719)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5092	CapSure SP Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	Porous Platinized/ Steroid	IS-1 BI
6907	(no brand name)	Transvenous Ventricular Flange	Silicone	MP35N 2 Filars	Cylinder Tip	5 mm
6907R	(no brand name)	Transvenous Ventricular Flange	Silicone	MP35N 2 Filars	Ring Tip	5 mm
6957	Spectraflex	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm
6961	Tenax	Transvenous Ventricular Tines	Silicone	MP35N 3 Filars	Ring Tip	5 mm
6962	Tenax	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Ring Tip	5 mm Bifurcated

Atrial Pacing Leads

4016 Screw-In

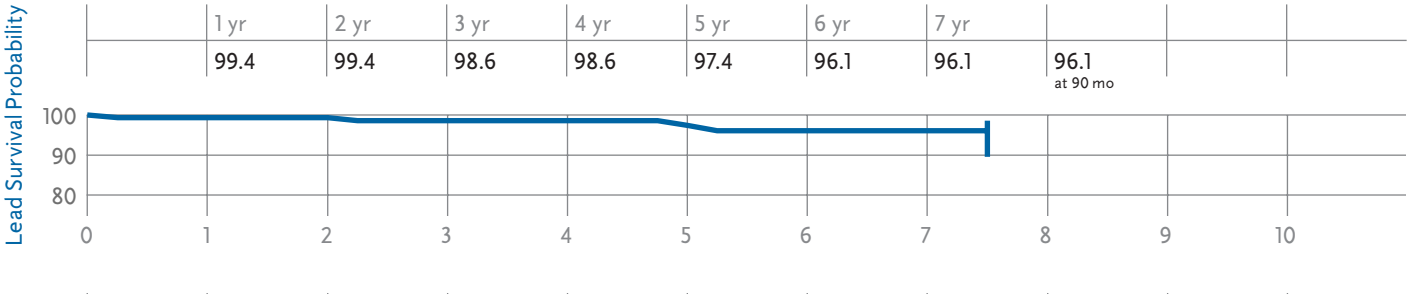
US Market Release	Aug-85
Number of Leads Enrolled in Study	172
Complications in Study	5
Failure to Capture	2
Failure to Sense	1
Insulation (ESC)	1
Insulation (not further defined)	1
Cumulative Months of Follow-Up in Study	11,442
Advisories	None

Product Characteristics

Serial Number Prefix	KY
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	
99.4	99.4	98.6	98.6	97.4	96.1	96.1	96.1 at 90 mo



4016A Screw-In

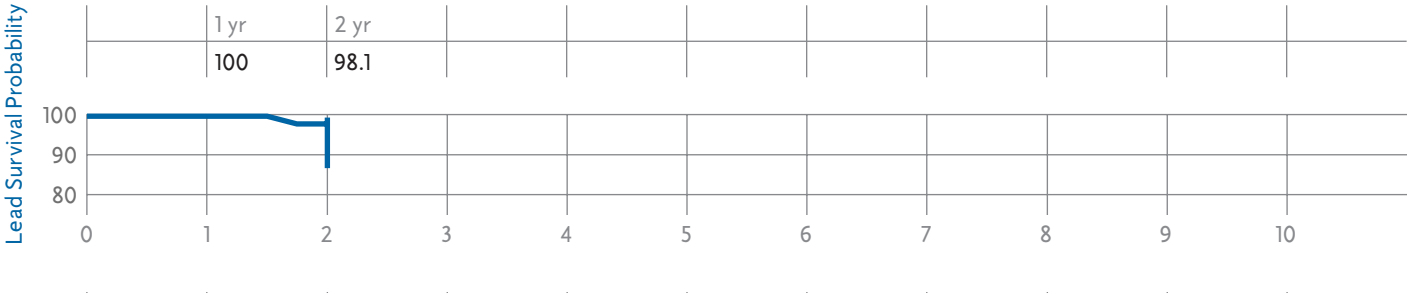
US Market Release	Feb-88
Number of Leads Enrolled in Study	67
Complications in Study	3
Failure to Capture	1
Failure to Sense	1
Oversensing	1
Cumulative Months of Follow-Up in Study	5,285
Advisories	None

Product Characteristics

Serial Number Prefix	XB
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

Years After Implant

1 yr	2 yr
100	98.1



Source: System Longevity Study
Data as of July 11, 2005

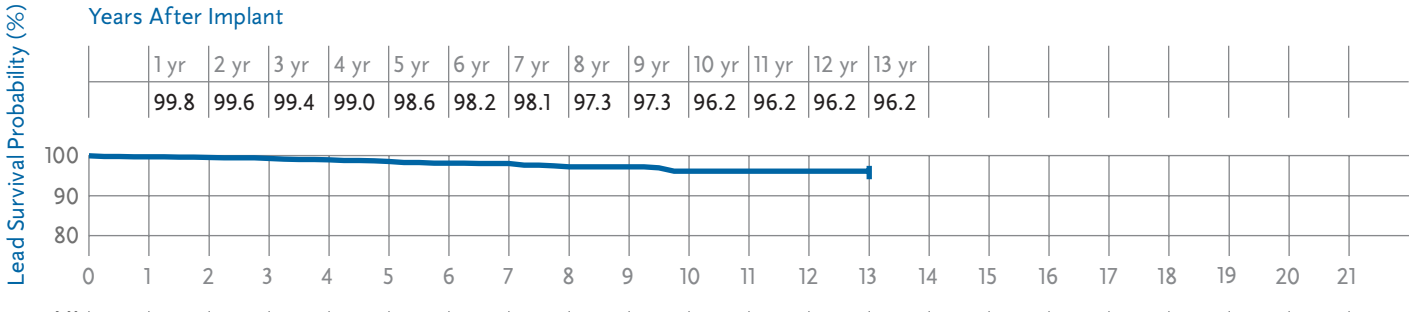
Atrial Pacing Leads continued

4058, 4058M Screw-In

US Market Release	Jan-89
Number of Leads Enrolled in Study	2,204
Complications in Study	30
Extra Cardiac Stimulation	1
Failure to Capture	15
Failure to Sense	6
Impedance Out of Range	3
Insulation (not further defined)	1
Lead Dislodgement	3
Oversensing	1
Cumulative Months of Follow-Up in Study	129,085
Advisories	None

Product Characteristics

Serial Number Prefix	ZY or LAW
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

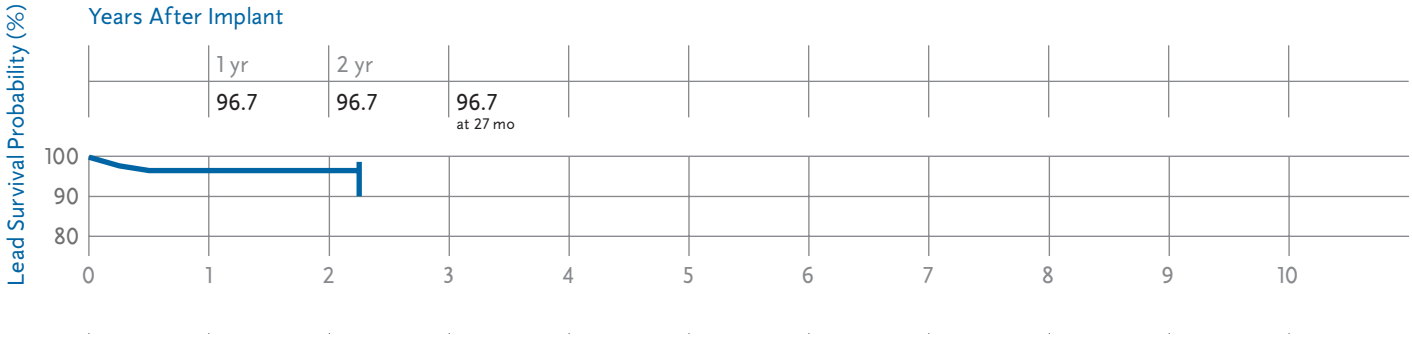


4067 CapSureFix

US Market Release	Jan-97
Number of Leads Enrolled in Study	97
Complications in Study	3
Failure to Capture	3
Cumulative Months of Follow-Up in Study	4,985
Advisories	None

Product Characteristics

Serial Number Prefix	LCV
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Unipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

4068 CapSureFix

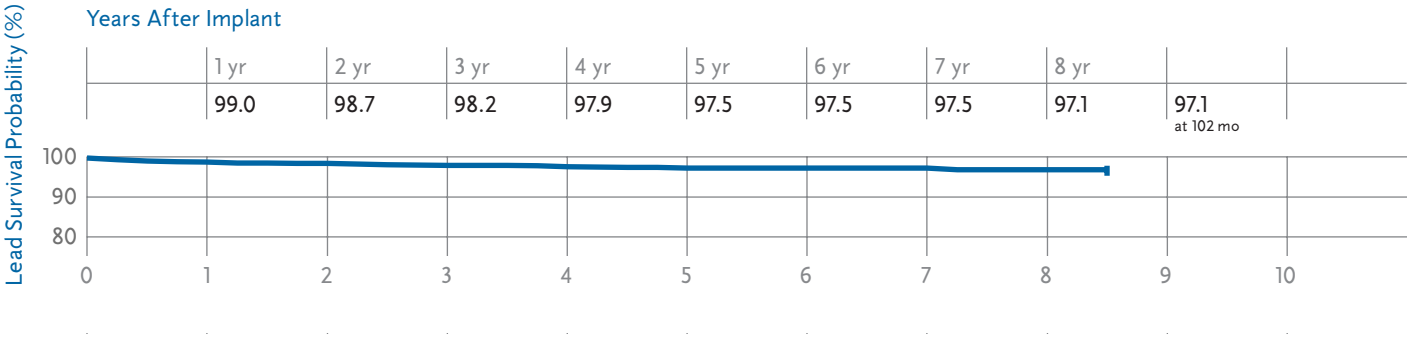
US Market Release	Mar-96
Number of Leads Enrolled in Study	2,223
Complications in Study	39
Extra Cardiac Stimulation	1
Failure to Capture	16
Failure to Sense	8
Impedance Out of Range	1
Insulation (ESC)	2
Lead Dislodgement	8
Oversensing	2
Unspecified Clinical Failure	1
Cumulative Months of Follow-Up in Study	98,939
Advisories	None

Product Characteristics

Serial Number Prefix	LCE
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
99.0	98.7	98.2	97.9	97.5	97.5	97.5	97.1	97.1 at 102 mo



4076 CapSureFix Novus

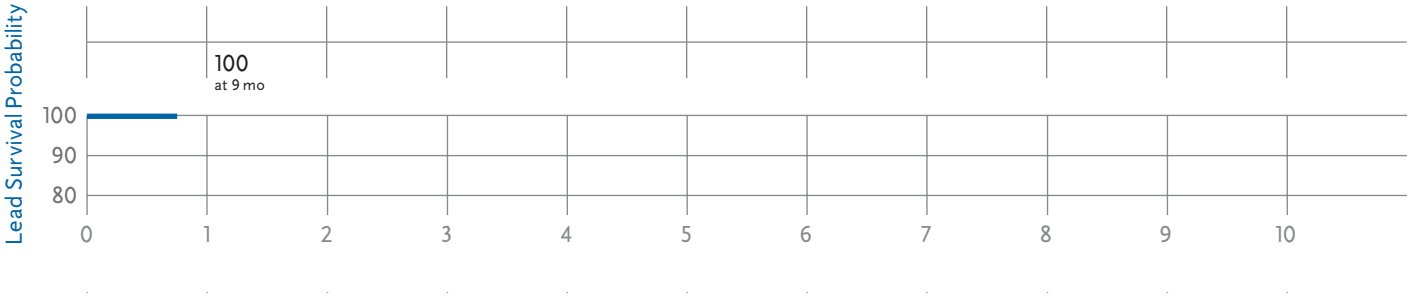
US Market Release	Feb-04
Number of Leads Enrolled in Study	121
Complications in Study	0
Cumulative Months of Follow-Up in Study	1,031
Advisories	None

Product Characteristics

Serial Number Prefix	BBL
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
100 at 9 mo								



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

4504, 4504M CapSure

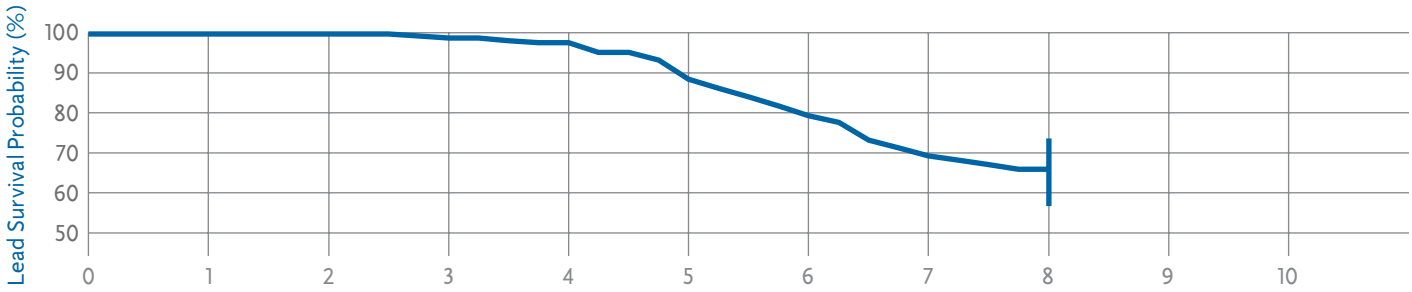
US Market Release	Mar-90
Number of Leads Enrolled in Study	323
Complications in Study	48
Electrical Abandonment	3
Extra Cardiac Stimulation	1
Failure to Capture	14
Failure to Sense	16
Impedance Out of Range	9
Insulation (MIO)	1
Lead Dislodgement	1
Oversensing	3
Cumulative Months of Follow-Up in Study	19,824
Advisories	1 see page 155 – 1996 Lead Survival Below Expectations

Product Characteristics

Serial Number Prefix	QM or LBA
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
100	100	99.0	97.9	88.7	79.6	69.6	66.2



4511 Target Tip

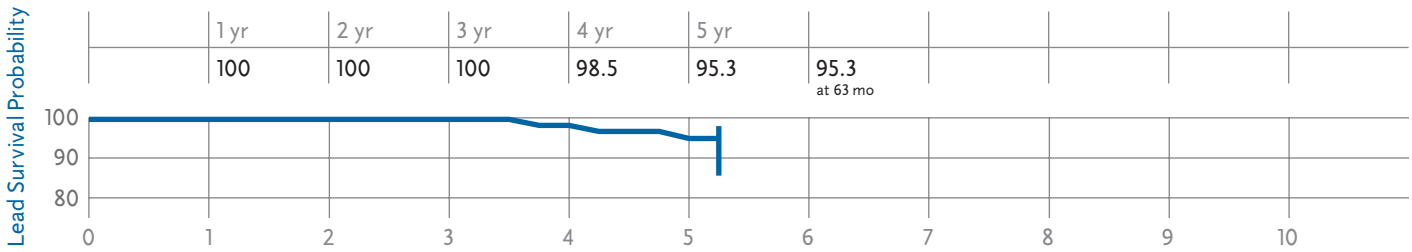
US Market Release	Nov-82
Number of Leads Enrolled in Study	144
Complications in Study	3
Failure to Capture	2
Oversensing	1
Cumulative Months of Follow-Up in Study	9,096
Advisories	None

Product Characteristics

Serial Number Prefix	MB
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
100	100	100	98.5	95.3	95.3 at 63 mo



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

4512 Target Tip

US Market Release	Jul-83
Number of Leads Enrolled in Study	556
Complications in Study	35
Electrical Abandonment	1
Failure to Capture	6
Failure to Sense	14
Impedance Out of Range	3
Insulation (ESC)	2
Insulation (MIO)	4
Insulation (not further defined)	2
Lead Dislodgement	1
Oversensing	2
Cumulative Months of Follow-Up in Study	40,010
Advisories	None

Product Characteristics

Serial Number Prefix	PF
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	No

Years After Implant

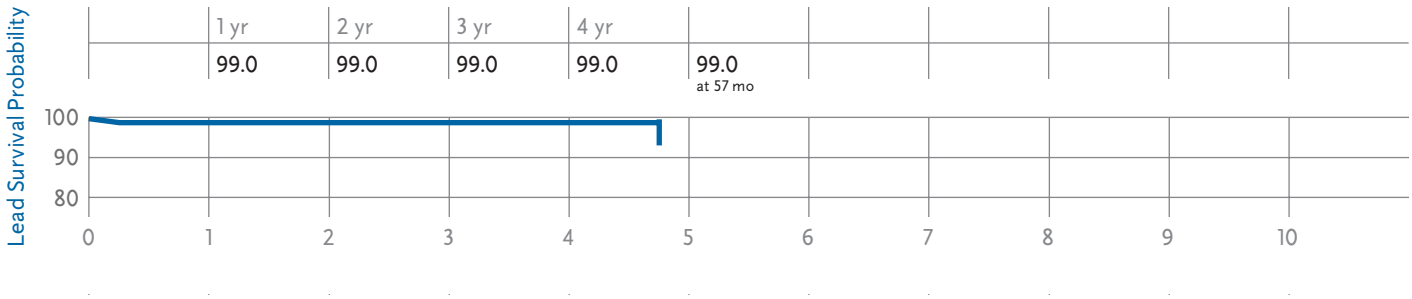
4523 CapSure SP

US Market Release	Aug-91
Number of Leads Enrolled in Study	110
Complications in Study	1
Lead Dislodgement	1
Cumulative Months of Follow-Up in Study	6,567
Advisories	None

Product Characteristics

Serial Number Prefix	ZE
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

4524 CapSure SP

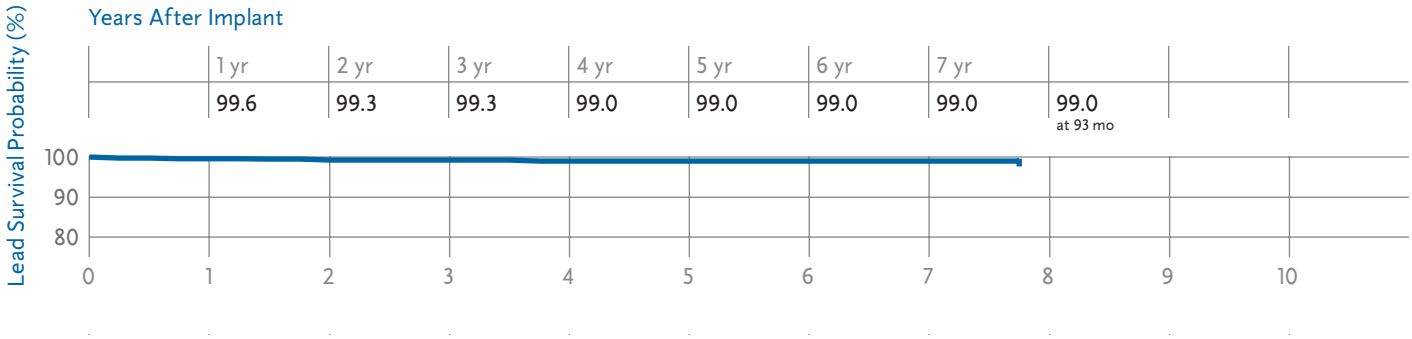
US Market Release	Oct-91
Number of Leads Enrolled in Study	879
Complications in Study	6
Failure to Capture	3
Failure to Sense	2
Lead Dislodgement	1
Cumulative Months of Follow-Up in Study	36,369
Advisories	None

Product Characteristics

Serial Number Prefix	LAR
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	
99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0 at 93 mo



4533 CapSure Z

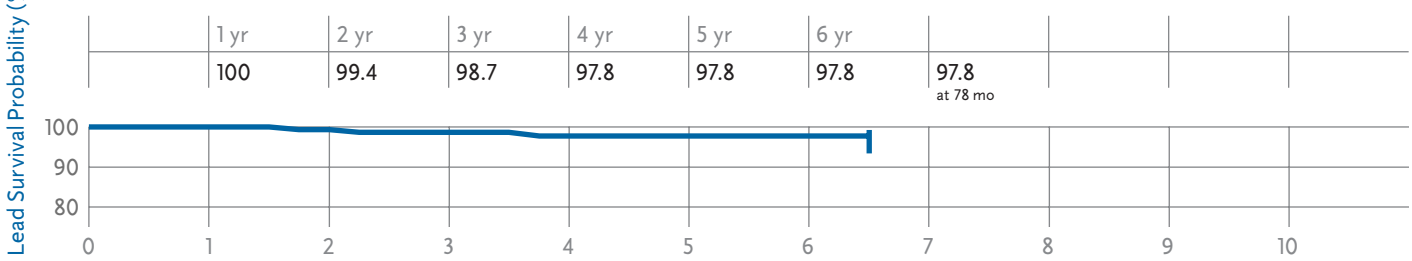
US Market Release	Mar-94
Number of Leads Enrolled in Study	198
Complications in Study	4
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	1
Oversensing	1
Cumulative Months of Follow-Up in Study	10,718
Advisories	None

Product Characteristics

Serial Number Prefix	LCB
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Unipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	
100	99.4	98.7	97.8	97.8	97.8	97.8 at 78 mo



Source: System Longevity Study
Data as of July 11, 2005

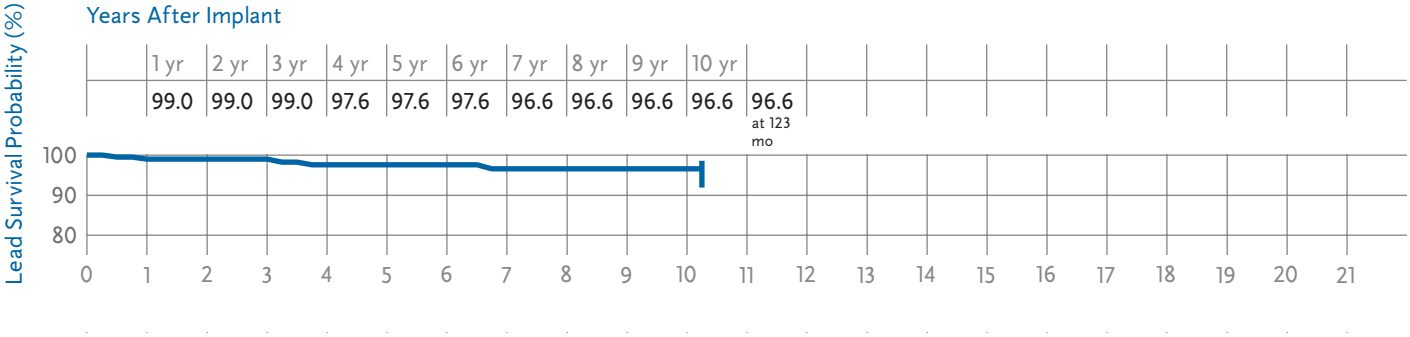
Atrial Pacing Leads continued

4557, 4557M Screw-In

US Market Release	Aug-88
Number of Leads Enrolled in Study	272
Complications in Study	6
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	1
Oversensing	1
Cumulative Months of Follow-Up in Study	18,076
Advisories	None

Product Characteristics

Serial Number Prefix	VQ or LAM
Type and/or Fixation	Transvenous, Atrial, Screw-in
Polarity	Unipolar
Steroid	No

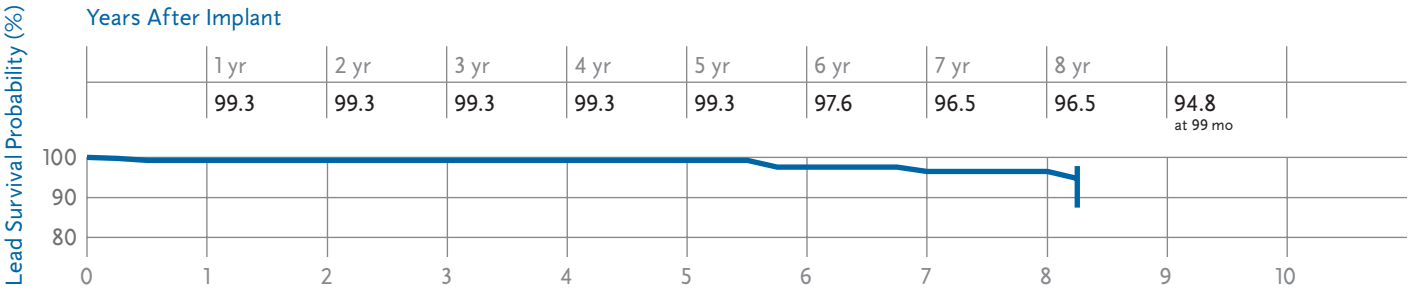


4558M Screw-In

US Market Release	Nov-94
Number of Leads Enrolled in Study	506
Complications in Study	9
Electrical Abandonment	1
Failure to Capture	3
Failure to Sense	2
Impedance Out of Range	2
Insulation (not further defined)	1
Cumulative Months of Follow-Up in Study	21,556
Advisories	None

Product Characteristics

Serial Number Prefix	LDC
Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Polarity	Bipolar
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

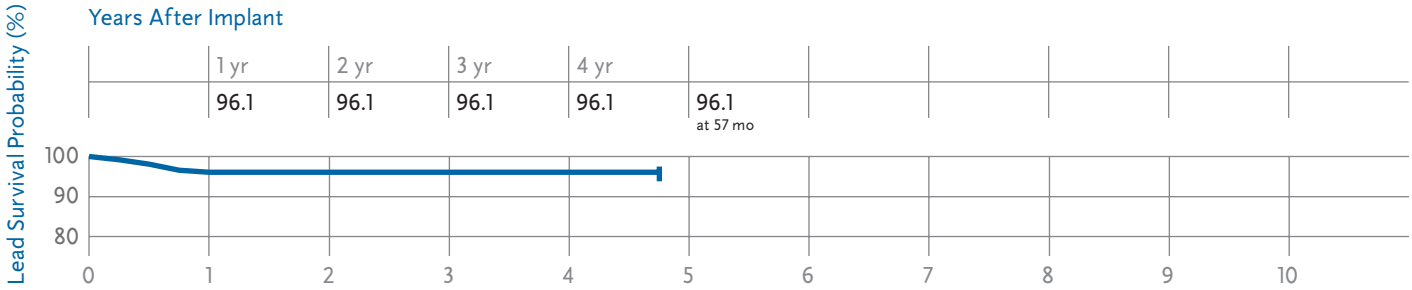
Atrial Pacing Leads continued

4568 CapSureFix

US Market Release	Jan-97
Number of Leads Enrolled in Study	534
Complications in Study	19
Failure to Capture	11
Lead Dislodgement	7
Medical Judgment	1
Cumulative Months of Follow-Up in Study	14,295
Advisories	None

Product Characteristics

Serial Number Prefix	LDD
Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Polarity	Bipolar
Steroid	Yes

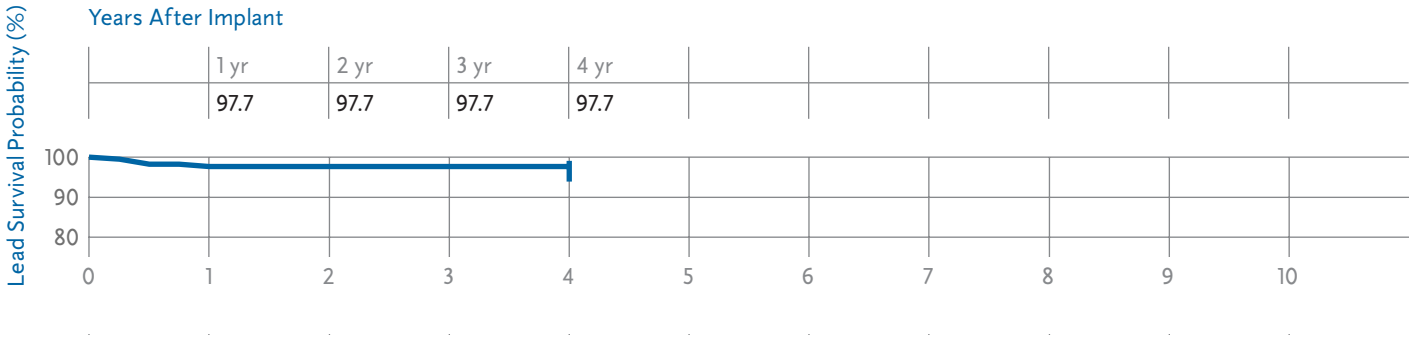


4592 CapSure SP Novus

US Market Release	Oct-98
Number of Leads Enrolled in Study	224
Complications in Study	4
Failure to Capture	2
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	6,979
Advisories	None

Product Characteristics

Serial Number Prefix	LER
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

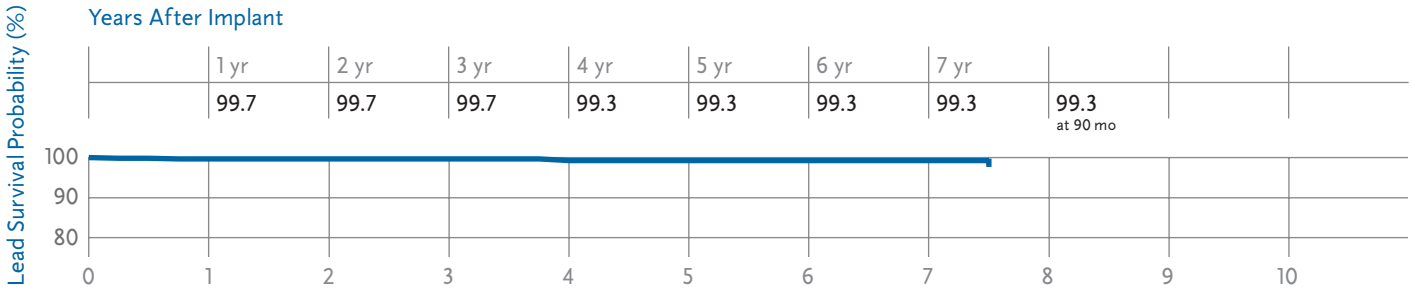
Atrial Pacing Leads continued

5068 CapSureFix

US Market Release	Jan-97
Number of Leads Enrolled in Study	935
Complications in Study	3
Failure to Capture	2
Impedance Out of Range	1
Cumulative Months of Follow-Up in Study	29,605
Advisories	None

Product Characteristics

Serial Number Prefix	LDJ
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

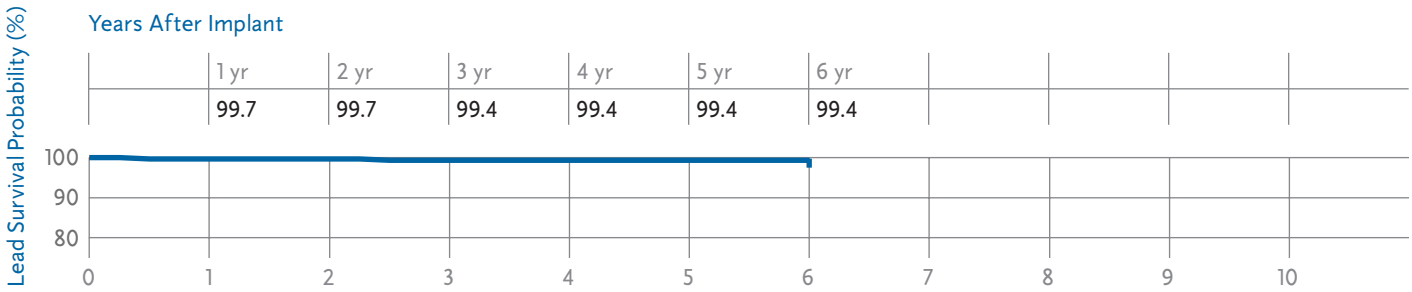


5072 SureFix

US Market Release	Jun-98
Number of Leads Enrolled in Study	449
Complications in Study	2
Cardiac Perforation	1
Failure to Capture	1
Cumulative Months of Follow-Up in Study	17,684
Advisories	None

Product Characteristics

Serial Number Prefix	LEM
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

5076 CapSureFix Novus

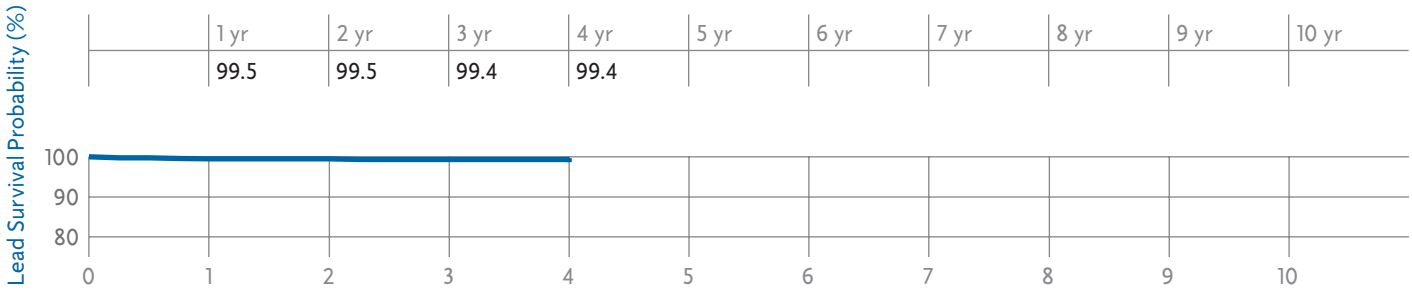
US Market Release	Aug-00
Number of Leads Enrolled in Study	1,668
Complications in Study	7
Cardiac Perforation	1
Conductor Fracture	1
Extra Cardiac Stimulation	2
Failure to Capture	1
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	35,679
Advisories	None

Product Characteristics

Serial Number Prefix	PJN
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
99.5	99.5	99.4	99.4						



5524, 5524M CapSure SP

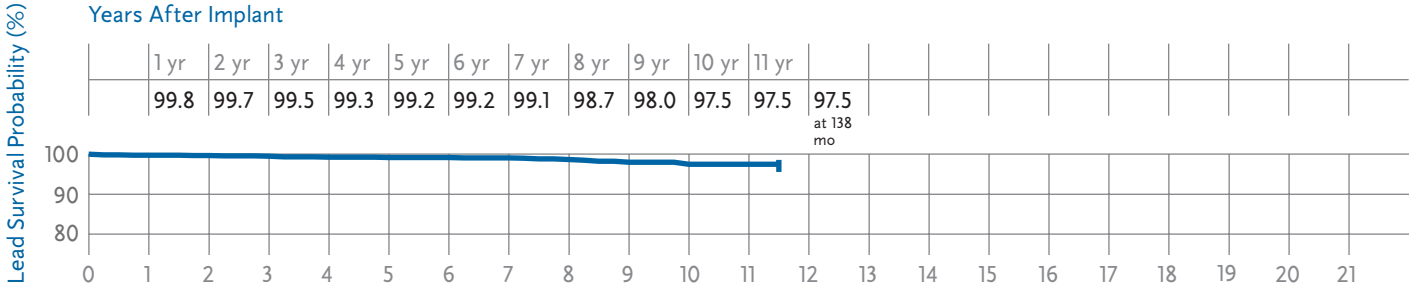
US Market Release	Mar-90
Number of Leads Enrolled in Study	4,231
Complications in Study	30
Conductor Fracture	1
Failure to Capture	18
Failure to Sense	3
Insulation (not further defined)	1
Lead Dislodgement	4
Oversensing	3
Cumulative Months of Follow-Up in Study	217,340
Advisories	None

Product Characteristics

Serial Number Prefix	XV or LAV
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	
99.8	99.7	99.5	99.3	99.2	99.2	99.1	98.7	98.0	97.5	97.5	97.5 at 138 mo



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

5534 CapSure Z

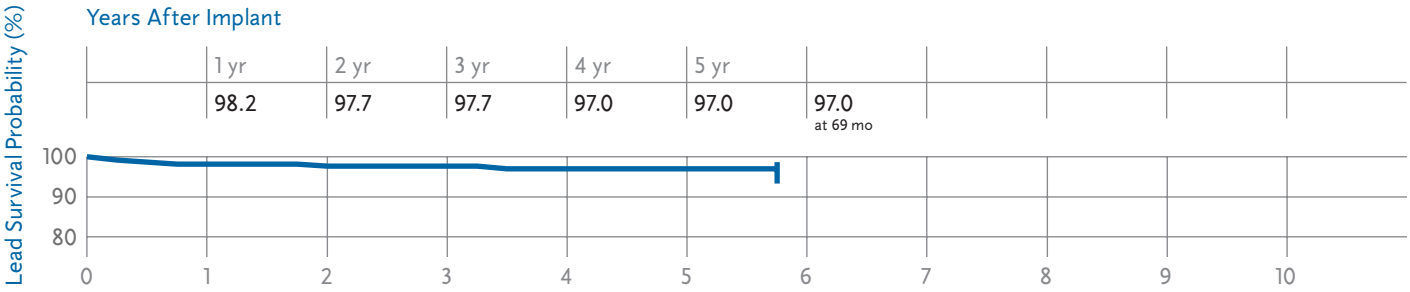
US Market Release	Feb-96
Number of Leads Enrolled in Study	252
Complications in Study	6
Failure to Capture	5
Impedance Out of Range	1
Cumulative Months of Follow-Up in Study	11,756
Advisories	None

Product Characteristics

Serial Number Prefix	LDG
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
98.2	97.7	97.7	97.0	97.0	97.0 at 69 mo



5554 CapSure Z Novus

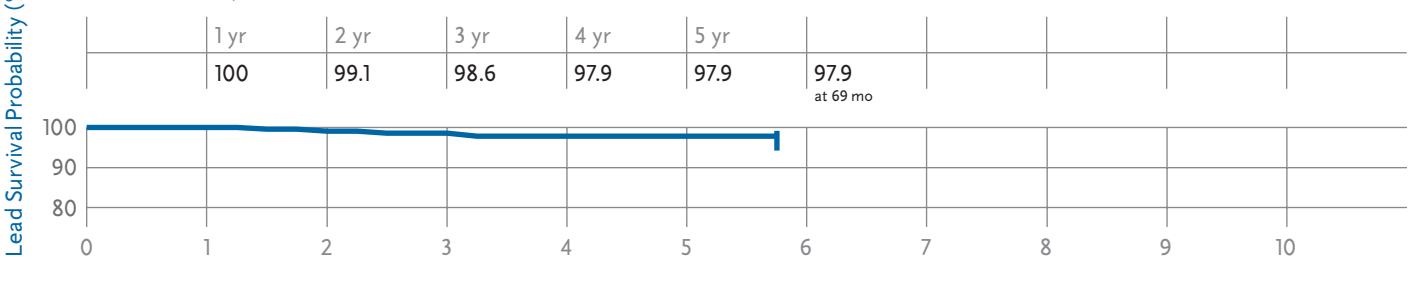
US Market Release	Jun-98
Number of Leads Enrolled in Study	308
Complications in Study	4
Failure to Capture	1
Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	1
Cumulative Months of Follow-Up in Study	11,861
Advisories	None

Product Characteristics

Serial Number Prefix	LEJ
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
100	99.1	98.6	97.9	97.9	97.9 at 69 mo



Source: System Longevity Study
Data as of July 11, 2005

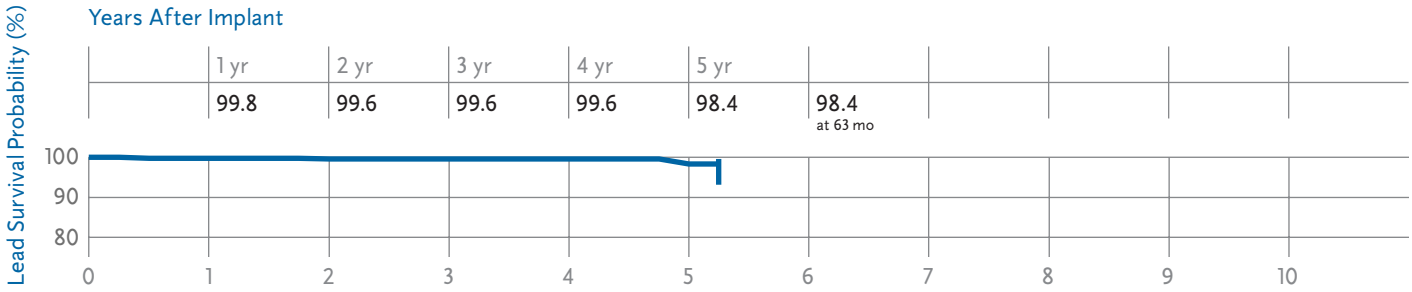
Atrial Pacing Leads continued

5568 CapSureFix

US Market Release	Jan-97
Number of Leads Enrolled in Study	811
Complications in Study	3
Failure to Capture	2
Lead Dislodgement	1
Cumulative Months of Follow-Up in Study	20,708
Advisories	None

Product Characteristics

Serial Number Prefix	LDN
Type and/or Fixation	Transvenous, A or V, Screw-in
Polarity	Bipolar
Steroid	Yes

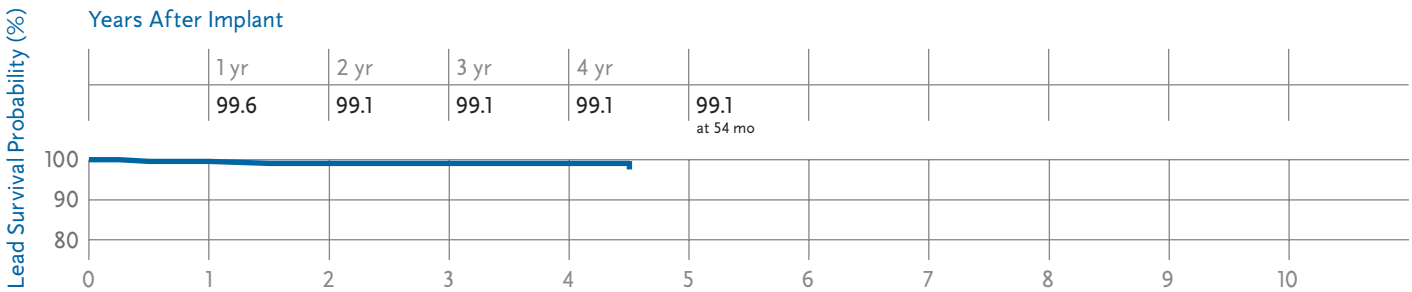


5592 CapSure SP Novus

US Market Release	Jul-98
Number of Leads Enrolled in Study	600
Complications in Study	4
Failure to Capture	2
Lead Dislodgement	2
Cumulative Months of Follow-Up in Study	16,147
Advisories	None

Product Characteristics

Serial Number Prefix	LEU
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

6940 CapSureFix

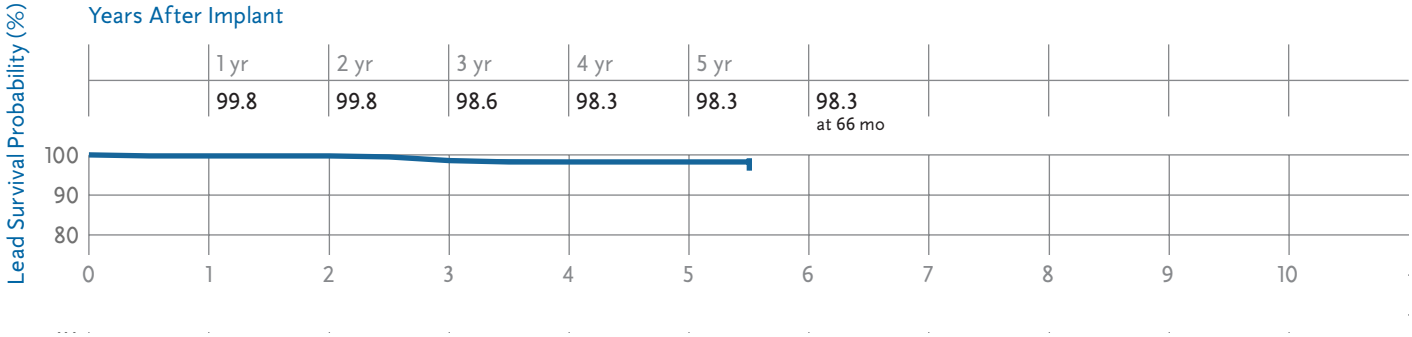
US Market Release	Oct-98
Number of Leads Enrolled in Study	615
Complications in Study	6
Conductor Fracture	1
Dislodgement	1
Failure to Sense	2
Oversensing	2
Cumulative Months of Follow-Up in Study	21,567
Advisories	None

Product Characteristics

Serial Number Prefix	TCP
Type and/or Fixation	Transvenous, A or V, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	
99.8	99.8	98.6	98.3	98.3	98.3 at 66 mo



6957 Spectraflex

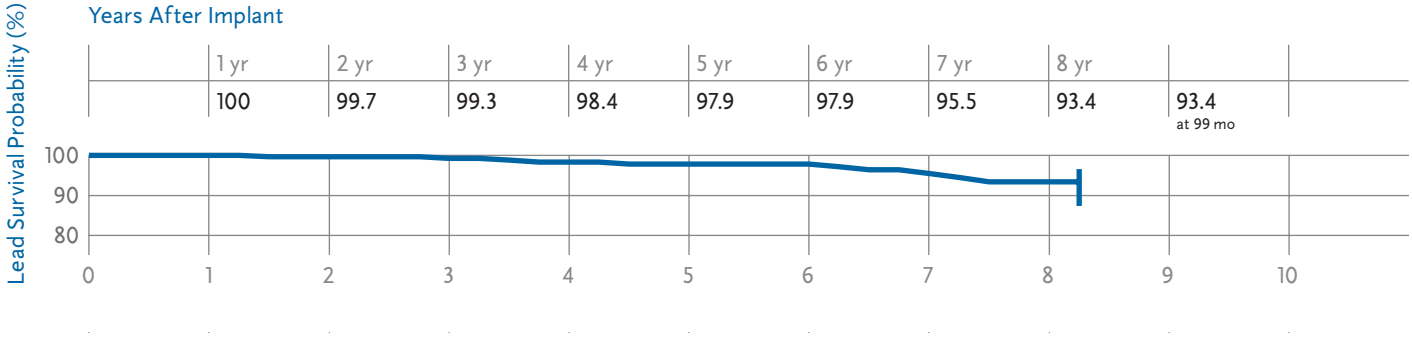
US Market Release	Jul-79
Number of Leads Enrolled in Study	651
Complications in Study	10
Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	5
Oversensing	1
Cumulative Months of Follow-Up in Study	24,607
Advisories	None

Product Characteristics

Serial Number Prefix	VC
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
100	99.7	99.3	98.4	97.9	97.9	95.5	93.4	93.4 at 99 mo



Source: System Longevity Study
Data as of July 11, 2005

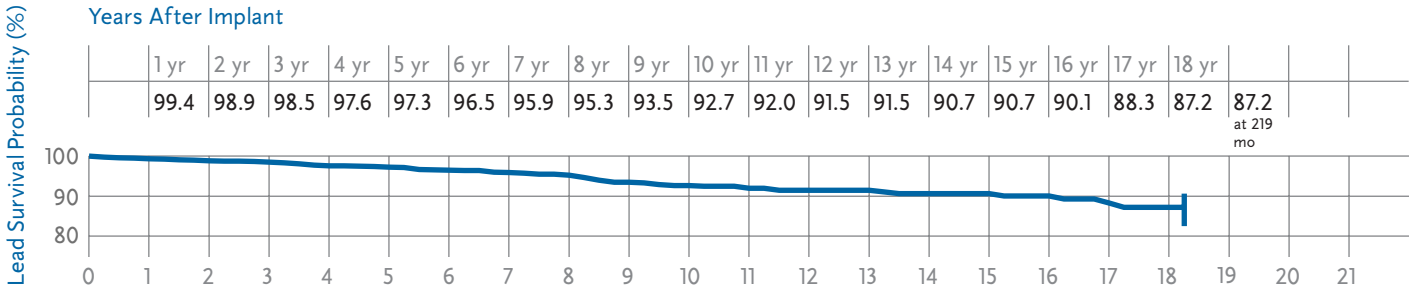
Atrial Pacing Leads continued

6957J Spectraflex

US Market Release	Sep-80
Number of Leads Enrolled in Study	2,180
Complications in Study	82
Conductor Fracture	11
Extra Cardiac Stimulation	3
Failure to Capture	48
Failure to Sense	13
Insulation (ESC)	1
Insulation (not further defined)	3
Lead Dislodgement	2
Oversensing	1
Cumulative Months of Follow-Up in Study	160,202
Advisories	None

Product Characteristics

Serial Number Prefix	GG
Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Polarity	Unipolar
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4016	Screw-In	Aug-85	172	5	11,442	99.4 +0.5/-3.6	99.4 +0.5/-3.6	98.6 +1.1/-4.2	98.6 +1.1/-4.2	97.4 +1.8/-5.7	96.1 +2.5/-6.5	96.1 +2.5/-6.5	96.1 +2.5/-6.5 at 90 mo						
4016A	Screw-In	Feb-88	67	3	5,285	100.0	98.1 +1.6/-11												
4058, 4058M	Screw-In	Jan-89	2,204	30	129,085	99.8 +0.1/-0.3	99.6 +0.2/-0.5	99.4 +0.3/-0.5	99.0 +0.4/-0.6	98.6 +0.5/-0.8	98.2 +0.6/-1	98.1 +0.6/-1.1	97.3 +0.9/-1.3	96.2 +1.3/-2	96.2 +1.3/-2	96.2 +1.3/-2 at 156 mo			
4067	CapSureFix	Jan-97	97	3	4,985	96.7 +2.2/-6.5	96.7 +2.2/-6.5	96.7 +2.2/-6.5 at 27 mo											
4068	CapSureFix	Mar-96	2,223	39	98,939	99.0 +0.4/-0.5	98.7 +0.4/-0.6	98.2 +0.6/-0.7	97.9 +0.6/-0.8	97.5 +0.7/-1	97.5 +0.7/-1	97.5 +0.7/-1	97.1 +1/-1.5	97.1 +1/-1.5 at 102 mo					
4076	CapSureFix Novus	Feb-04	121	0	1,031	100.0 at 9 mo													
4504, 4504M	CapSure	Mar-90	323	48	19,824	100.0	100.0	99.0 +0.7/-2.9	97.9 +1.3/-3.5	88.7 +4/-6.1	79.6 +5.7/-7.6	69.6 +7.2/-8.8	66.2 +7.7/-9.2						
	Advisory: see page 155 - 1996 Lead Survival Below Expectations																		
4511	Target Tip	Nov-82	144	3	9,096	100.0	100.0	100.0	98.5 +1.3/-8.6	95.3 +3.1/-9.3	95.3 +3.1/-9.3 at 63 mo								
4512	Target Tip	Jul-83	556	35	40,010	99.6 +0.3/-1.3	99.6 +0.3/-1.3	99.0 +0.6/-1.6	97.8 +1.1/-2.2	96.4 +1.6/-2.6	95.2 +1.9/-3.1	94.3 +2.1/-3.5	90.3 +3.2/-4.7	86.1 +4.2/-5.9	83.4 +4.9/-6.6	82.2 +5.2/-7 at 159 mo			
4523	CapSure SP	Aug-91	110	1	6,567	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7 at 57 mo									
4524	CapSure SP	Oct-91	879	6	36,369	99.6 +0.3/-0.8	99.3 +0.4/-1	99.3 +0.4/-1	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3 at 93 mo						
4533	CapSure Z	Mar-94	198	4	10,718	100.0	99.4 +0.5/-3.7	98.7 +1/-3.7	97.8 +1.5/-4.4	97.8 +1.5/-4.4	97.8 +1.5/-4.4	97.8 +1.5/-4.4 at 78 mo							
4557, 4557M	Screw-In	Aug-88	272	6	18,076	99.0 +0.7/-3	99.0 +0.7/-3	99.0 +0.7/-3	97.6 +1.5/-3.9	97.6 +1.5/-3.9	97.6 +1.5/-3.9	96.6 +2/-4.7	96.6 +2/-4.7	96.6 +2/-4.7	96.6 +2/-4.7 at 123 mo				
4558M	Screw-In	Nov-94	506	9	21,556	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	97.6 +1.5/-4.2	96.5 +2.1/-5.3	96.5 +2.1/-5.3	94.8 +3.1/-7.3 at 99 mo					
4568	CapSureFix	Jan-97	534	19	14,295	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3 at 57 mo									

continued

Source: System Longevity Study
Data as of July 11, 2005

Lead Survival Summary continued

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%)													
						1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4592	CapSure SP Novus	Oct-98	224	4	6,979	97.7 +1.4/-3.8	97.7 +1.4/-3.8	97.7 +1.4/-3.8	97.7 +1.4/-3.8										
5068	CapSureFix	Jan-97	935	3	29,605	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6 at 90 mo						
5072	SureFix	Jun-98	449	2	17,684	99.7 +0.3/-1.5	99.7 +0.3/-1.5	99.4 +0.4/-1.9	99.4 +0.4/-1.9	99.4 +0.4/-1.9	99.4 +0.4/-1.9								
5076	CapSureFix Novus	Aug-00	1,668	7	35,679	99.5 +0.3/-0.5	99.5 +0.3/-0.5	99.4 +0.3/-0.7	99.4 +0.3/-0.7										
5524, 5524M	CapSure SP	Mar-90	4,231	30	217,340	99.8 +0.1/-0.3	99.7 +0.1/-0.2	99.5 +0.2/-0.3	99.3 +0.3/-0.4	99.2 +0.3/-0.4	99.2 +0.3/-0.4	99.1 +0.3/-0.5	98.7 +0.5/-0.8	97.5 +1.1/-1.9	97.5 +1.1/-1.9 at 138 mo				
5534	CapSure Z	Feb-96	252	6	11,756	98.2 +1.1/-2.8	97.7 +1.3/-3.2	97.7 +1.3/-3.2	97.0 +1.7/-3.7	97.0 +1.7/-3.7	97.0 +1.7/-3.7 at 69 mo								
5554	CapSure Z Novus	Jun-98	308	4	11,861	100.0	99.1 +0.7/-2.6	98.6 +0.9/-2.9	97.9 +1.3/-3.6	97.9 +1.3/-3.6	97.9 +1.3/-3.6 at 69 mo								
5568	CapSureFix	Jan-97	811	3	20,708	99.8 +0.2/-0.9	99.6 +0.3/-1.3	99.6 +0.3/-1.3	99.6 +0.3/-1.3	98.4 +1.2/-5.2	98.4 +1.2/-5.2 at 63 mo								
5592	CapSure SP Novus	Jun-98	600	4	16,147	99.6 +0.3/-1.2	99.1 +0.6/-1.5	99.1 +0.6/-1.5	99.1 +0.6/-1.5	99.1 +0.6/-1.5 at 54 mo									
6940	CapSureFix	Oct-98	615	6	21,567	99.8 +0.2/-1	99.8 +0.2/-1	98.6 +0.8/-2	98.3 +0.9/-2.2	98.3 +0.9/-2.2	98.3 +0.9/-2.2 at 66 mo								
6957	Spectraflex	Jul-79	651	10	24,607	100.0	99.7 +0.3/-1.7	99.3 +0.5/-2	98.4 +1/-2.6	97.9 +1.2/-3	97.9 +1.2/-3	95.5 +2.3/-4.7	93.4 +3.2/-6	93.4 +3.2/-6 at 99 mo					
6957J	Spectraflex	Sep-80	2,180	82	160,202	99.4 +0.3/-0.5	98.9 +0.4/-0.6	98.5 +0.5/-0.8	97.6 +0.7/-0.9	97.3 +0.7/-1.1	96.5 +0.9/-1.1	95.9 +1/-1.3	95.3 +1.1/-1.4	92.7 +1.6/-2	91.5 +1.8/-2.4	90.7 +2.1/-2.6	90.1 +2.3/-3	87.2 +3.5/-4.7	87.2 +3.5/-4.7 at 219 mo

Source: System Longevity Study
Data as of July 11, 2005

Atrial Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4016	Screw-In	Aug-85	8,100	1,100	57	59	3
4016A	Screw-In	Feb-88	3,800	700	19	20	0
4058, 4058M	Screw-In	Jan-89	111,100	31,200	388	220	23
4067	CapSureFix	Jan-97	1,300	600	3	1	1
4068	CapSureFix	Mar-96	131,700	68,600	406	66	11
4076	CapSureFix Novus	Feb-04	38,900	36,300	16	2	1
4503, 4503M	CapSure	Jul-86	8,900	1,800	2	9	0
4504, 4504M	CapSure	Mar-90	16,600	2,000	5	169	4
4511	Target Tip	Nov-82	10,300	1,000	5	22	3
4512	Target Tip	Jul-83	11,600	1,300	4	82	8
4523	CapSure SP	Aug-91	12,000	4,300	5	2	1
4524	CapSure SP	Oct-91	106,900	45,400	47	15	8
4557, 4557M	Screw-In	Aug-88	22,500	6,400	53	14	4
4558M	Screw-In	Nov-94	21,000	7,500	111	10	1
4568	CapSureFix	Jan-97	72,500	45,900	195	3	4
4592	CapSure SP Novus	Oct-98	62,100	43,800	10	1	0
5068	CapSureFix	Jan-97	108,000	62,000	455	46	15
5072	SureFix	Jun-98	8,200	5,300	21	2	1
5076	CapSureFix Novus	Aug-00	580,200	465,800	531	80	42
5524, 5524M	CapSure SP	Mar-90	63,700	27,700	65	17	7
5534	CapSure Z	Feb-96	27,700	11,300	29	6	5
5554	CapSure Z Novus	Jun-98	47,200	32,000	7	6	4
5568	CapSureFix	Jan-97	45,000	32,000	189	7	7
5592	CapSure SP Novus	Jun-98	20,400	15,700	4	2	0
6940	CapSureFix	Oct-98	26,600	15,300	114	16	3
6957	Spectraflex	Jul-79	29,100	3,400	85	39	25
6957J	Spectraflex	Sep-80	30,000	2,800	74	28	30

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

continued

Source: US Returned Product Analysis
Data as of October 31, 2005

Atrial Pacing Leads continued

Laboratory Analysis continued

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4503, 4503M	CapSure	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4503) IS-1 UNI (4503M)
4504, 4504M	CapSure	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 3/4 Filars	Porous/Steroid	3.2 mm Low Profile (4504) IS-1 BI (4504M)
4511	Target Tip	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 4/3 Filars	Target Tip Concentric Grooves	5 mm
4512	Target Tip	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 2/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4523	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	Porous Platinized/ Steroid	IS-1 UNI
4524	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4533	CapSure Z	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4557, 4557M	Screw-In	Transvenous Atrial-J Screw-In	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm (4557) IS-1 UNI (4557M)
4558M	Screw-In	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4568	CapSureFix	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4574	CapSure Sense	Transvenous Atrial -J Tines	Polyurethane/ Silicone (55D,4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium	IS-1 BI
4592	CapSure SP Novus	Transvenous Atrial-J Tines	Polyurethane/ Silicone (55D/4719)	MP35N 6/3 Filars	Porous Platinized/ Steroid	IS-1 BI
5032	CapSure VDD	Transvenous V or A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	IS-1 BI
5524, 5524M	CapSure SP	Transvenous Atrial-J Tines	Silicone	MP35N 6/5 Filars	Porous Platinized/Steroid	3.2 mm Low Profile (5524) IS-1 BI (5524M)
5534	CapSure Z	Transvenous Atrial Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	CapSure Z Novus	Transvenous Atrial-J Screw-In	Silicone (4719)	MP35N 6/5 Filars	CapSure Z Porous Platinized/ Steroid	IS-1 BI
5568	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5592	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5594	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Platinized Platinum	IS-1 BI
6940	CapSureFix	Transvenous A or V Screw-in	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI
6957J	Spectraflex	Transvenous Atrial-J Screw-In	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm

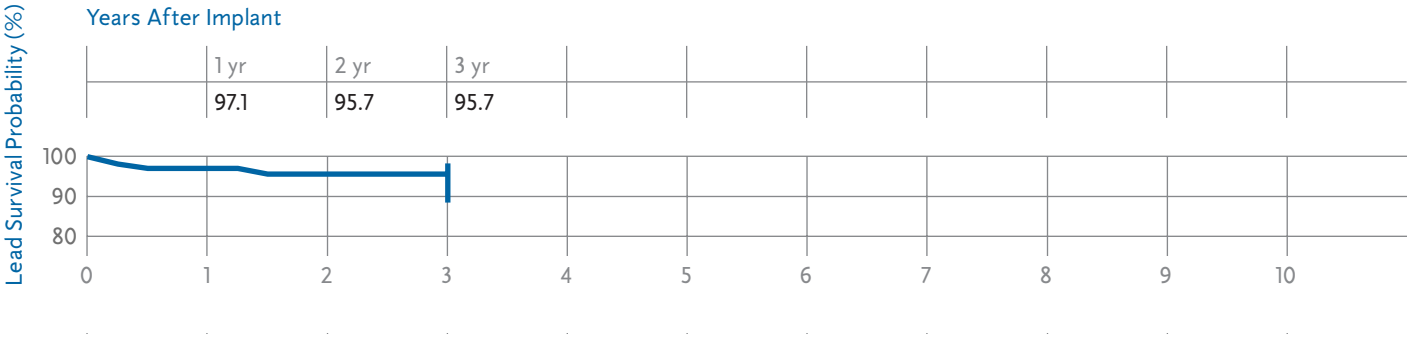
Epi/Myocardial Pacing Leads

4951, 4951M Spectraflex

US Market Release	Oct-81
Number of Leads Enrolled in Study	133
Complications in Study	10
Failure to Capture	4
Failure to Sense	3
Impedance Out of Range	1
Insulation (ESC)	1
Insulation (not further defined)	1
Cumulative Months of Follow-Up in Study	5,811
Advisories	None

Product Characteristics

Serial Number Prefix	TF or LBJ
Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Polarity	Unipolar
Steroid	No

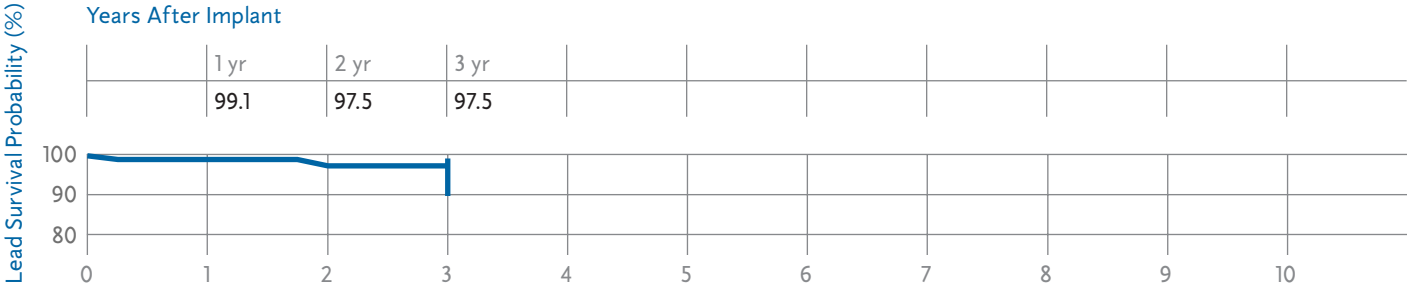


4965 CapSure Epi

US Market Release	Sep-96
Number of Leads Enrolled in Study	141
Complications in Study	6
Conductor Fracture	2
Failure to Capture	1
Failure to Sense	1
Oversensing	2
Cumulative Months of Follow-Up in Study	4,032
Advisories	None

Product Characteristics

Serial Number Prefix	LBT
Type and/or Fixation	Epicardial Suture-On V or A
Polarity	Unipolar
Steroid	Yes



Source: System Longevity Study
Data as of July 11, 2005

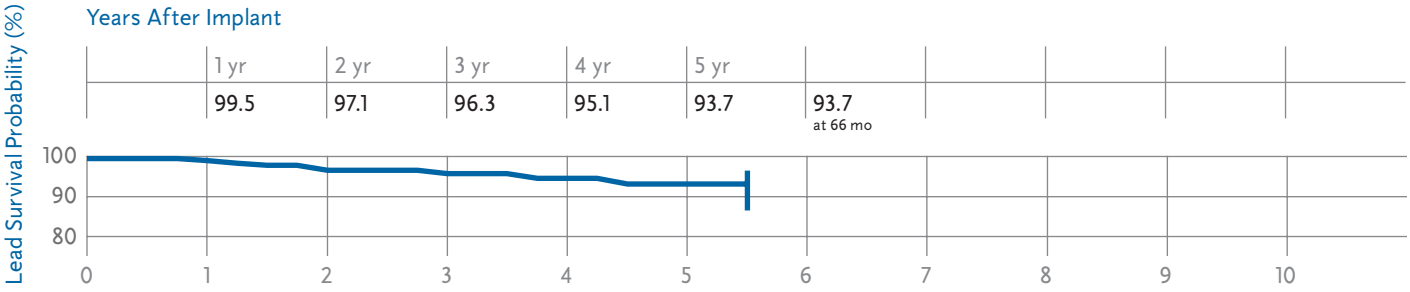
Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

US Market Release	Sep-99
Number of Leads Enrolled in Study	211
Complications in Study	9
Conductor Fracture	4
Failure to Capture	3
Failure to Sense	1
Oversensing	1
Cumulative Months of Follow-Up in Study	10,206
Advisories	None

Product Characteristics

Serial Number Prefix	LEN
Type and/or Fixation	Epicardial Suture-On V or A
Polarity	Bipolar
Steroid	Yes

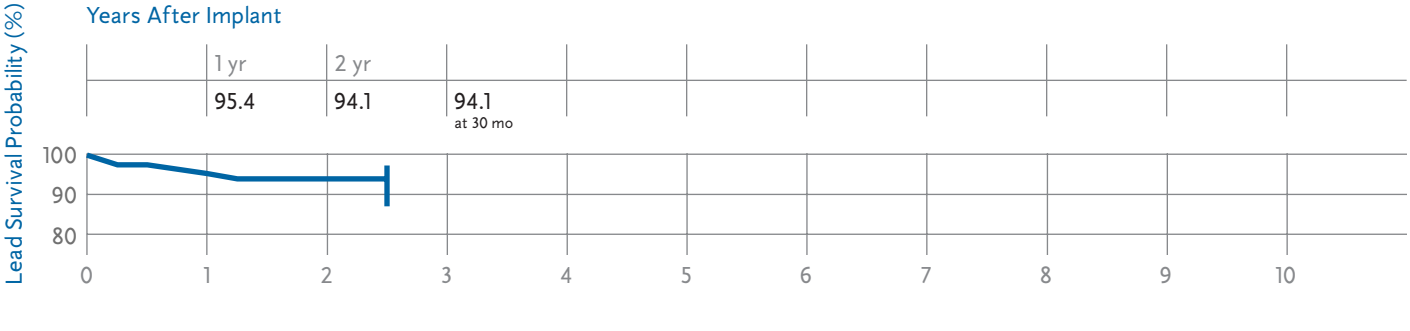


5071

US Market Release	Dec-92
Number of Leads Enrolled in Study	151
Complications in Study	7
Failure to Capture	7
Cumulative Months of Follow-Up in Study	4,110
Advisories	None

Product Characteristics

Serial Number Prefix	LAQ
Type and/or Fixation	Myocardial Screw-in Vent.
Polarity	Unipolar
Steroid	No



Source: System Longevity Study
Data as of July 11, 2005

Epi/Myocardial Pacing Leads continued

6917, 6917A Tenax

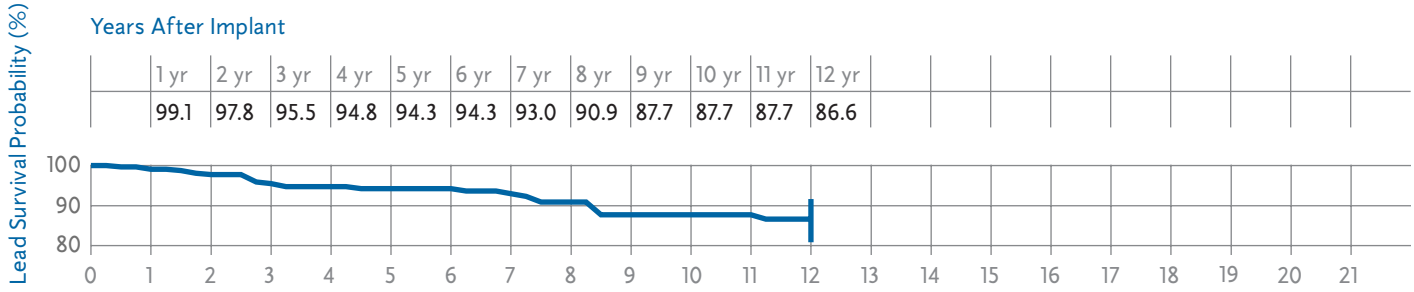
US Market Release	Jun-73
Number of Leads Enrolled in Study	495
Complications in Study	35
Failure to Capture	26
Failure to Sense	6
Insulation (MIO)	1
Oversensing	2
Cumulative Months of Follow-Up in Study	30,407
Advisories	None

Product Characteristics

Serial Number Prefix	WV or WC
Type and/or Fixation	Myocardial Screw-in Vent.
Polarity	Unipolar
Steroid	No

Years After Implant

1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr
99.1	97.8	95.5	94.8	94.3	94.3	93.0	90.9	87.7	87.7	87.7	86.6



Source: System Longevity Study
Data as of July 11, 2005

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr
4951, 4951M	Spectraflex	Oct-81	133	10	5,811	97.1 +2/-5.8	95.7 +2.7/-7.1	95.7 +2.7/-7.1									
4965	CapSure Epi	Sep-96	141	6	4,032	99.1 +0.8/-5	97.5 +1.9/-7.5	97.5 +1.9/-7.5									
4968	CapSure Epi	Sep-99	211	9	10,206	99.5 +0.4/-3.1	97.1 +1.7/-4	96.3 +2/-4.5	95.1 +2.6/-5.5	93.7 +3.3/-6.6	93.7 +3.3/-6.6 at 66 mo						
5071	(no brand name)	Dec-92	151	7	4,110	95.4 +2.7/-6.3	94.1 +3.3/-6.9	94.1 +3.3/-6.9 at 30 mo									
6917, 6917A	Tenax	Jun-73	495	35	30,407	99.1 +0.6/-1.8	97.8 +1.1/-2.5	95.5 +1.9/-3.1	94.8 +2/-3.4	94.3 +2.2/-3.5	94.3 +2.2/-3.5	93.0 +2.6/-4	90.9 +3.2/-4.8	87.7 +4.1/-5.9	87.7 +4.1/-5.9	87.7 +4.1/-5.9	86.6 +4.4/-6.4

Source: System Longevity Study
Data as of July 11, 2005

Epi/Myocardial Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4951, 4951M	Spectraflex	Oct-81	25,000	4,400	15	93	28
4965	CapSure Epi	Sep-96	15,400	9,600	7	70	2
4968	CapSure Epi	Sep-99	8,900	6,900	1	3	0
5071	(no brand name)	Dec-92	25,100	16,700	20	3	1
6917, 6917A	Tenax	Jun-73	180,200	7,700	115	42	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Source: US Returned Product Analysis
Data as of October 31, 2005

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4951, 4951M	Spectraflex	Myocardial Stab-In V or A/Peds	Polyurethane (80A)	MP35N 4 Filars	Barb	5 mm (4951) IS-1 UNI (4951M)
4965	CapSure Epi	Epicardial Suture-On V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 UNI
4968	CapSure Epi	Epicardial Suture V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 BI
5069	(no brand name)	Myocardial Screw-In	Silicone	MP35N Multifilars	3-Turn Helix	IS-1 UNI
5071	(no brand name)	Myocardial Screw-In Ventricular	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI
6917	Tenax	Myocardial Screw-In Ventricular	Silicone	Pt Ir Tinsel Wire	3-Turn Helix	5 mm
6917A	Tenax	Myocardial Screw-In Ventricular	Silicone	Pt Ir Tinsel Wire	2-Turn Helix	5 mm

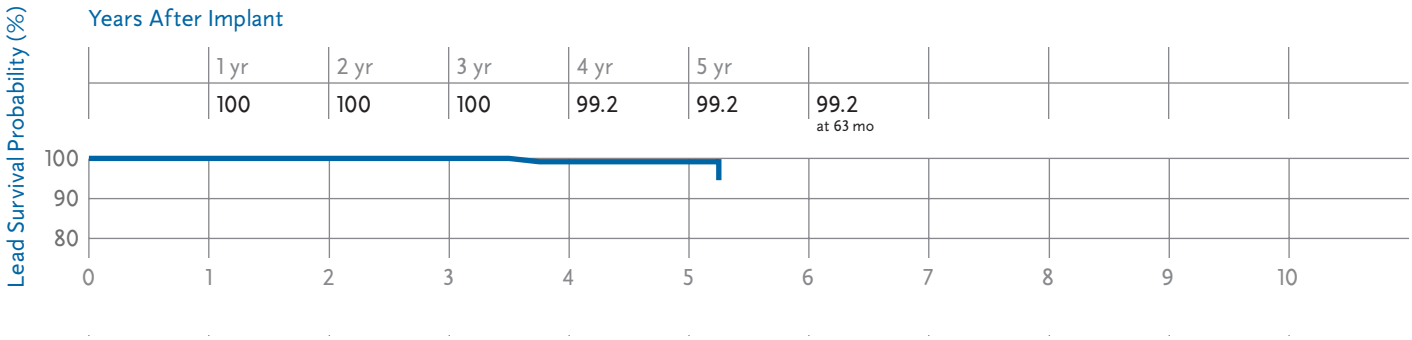
VDD Single Pass Pacing Leads

5038 CapSure VDD-2

US Market Release	Sep-98
Number of Leads Enrolled in Study	535
Complications in Study	1
Failure to Sense	1
Cumulative Months of Follow-Up in Study	15,691
Advisories	None

Product Characteristics

Serial Number Prefix	LEE, LEG, or LEF
Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Polarity	Quadripolar
Steroid	Yes



Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
5038	CapSure VDD-2	Sep-98	535	1	15,691	100.0	100.0	100.0	99.2 +0.7/-4.6	99.2 +0.7/-4.6	99.2 +0.7/-4.6 at 63 mo				

Source: System Longevity Study
Data as of July 11, 2005

VDD Single Pass Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
5032	CapSure VDD	Mar-96	5,500	2,500	21	10	0
5038	CapSure VDD-2	Sep-98	5,900	3,800	6	2	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Source: US Returned Product Analysis
Data as of October 31, 2005

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
5032	CapSure VDD	Transvenous V and A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI
5038	CapSure VDD-2	Transvenous Ventricular Tines	Silicone	MP35N	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI

ICD Charge Time Data

Medtronic continues its commitment to providing updated information on charge time performance of Medtronic ICDs.

Introduction

Information on charge time performance of Medtronic ICDs is presented in this section of the CRM Product Performance Report. The collection of Save-to-Disk files for all Medtronic ICD models, from 7221 Micro Jewel onwards, was implemented on July 1, 1999. The files are collected via our ongoing active clinical study of long-term system performance called the System Longevity Study.

Charge times are normally affected by several factors:

(a) the gradual decline in battery voltage and increase in battery resistance that occurs over the life of the device,

(b) the deformation of capacitors that occurs normally between capacitor formations, and

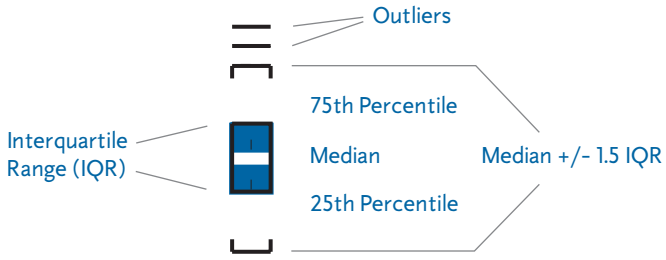
(c) the different rates of capacitor deformation due to component variability.

Certain early Model 7223Cx and Model 7271 devices demonstrated longer than typical charge times due to greater component variability in the capacitors used in these devices. This information has been communicated directly to physicians via Safety Advisories. At this time, we estimate very few, if any, of the affected advisory populations of 7223Cx and 7271 ICDs remain implanted and in-service. Charge time data for these advisory populations are no longer included in this issue of the Performance Report.

Data Presentation

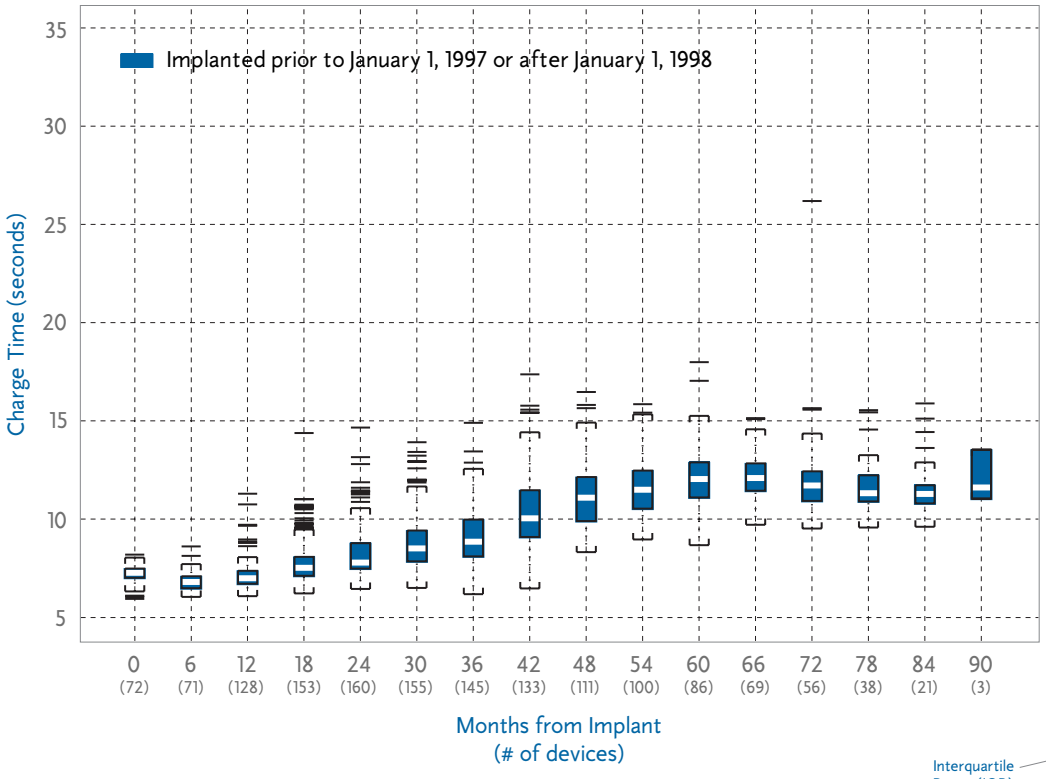
Charge time data for ICD models are presented via boxplots at 6-month intervals. The shaded box on the plots represents the middle half of the data – the Interquartile Range (IQR). The white line in the middle of each box is the median charge time. The top of the box representing the IQR is the 75th percentile (i.e., 75% of all charge times fall below this line), whereas the bottom of the box represents the 25th percentile. The brackets around the box represent the variance in charge times (analogous to a confidence interval), and are calculated as a function of the median and IQR. Individual values falling outside the brackets are labeled as outliers.

Only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. A conservative approach has been adopted whereby only the maximum charge in each 6-month interval is reported. As charge time is a direct product of time since last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.

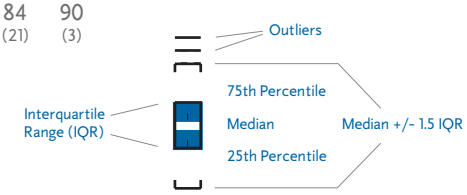


ICD Charge Times continued

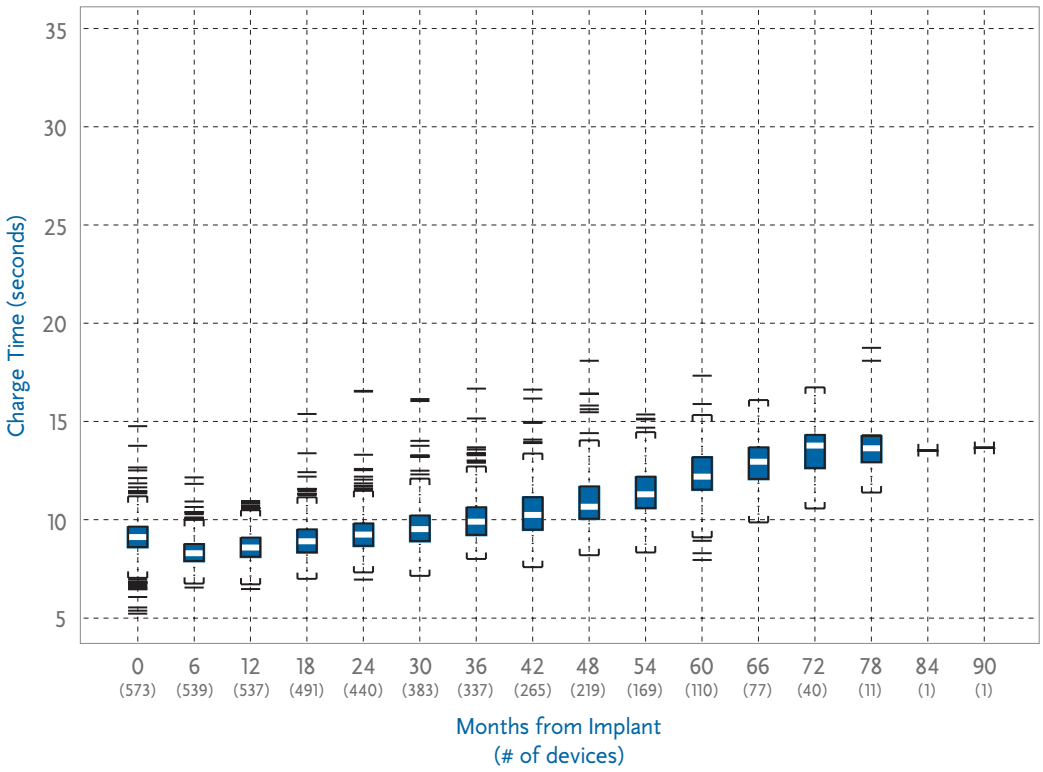
7223 Micro Jewel II Charge Time



Save-to-Disk files have been collected 90 months post-implant. All observed charge times are below 20 seconds, except one of 26.2 seconds at 72 months post-implant.



7227 GEM Charge Time

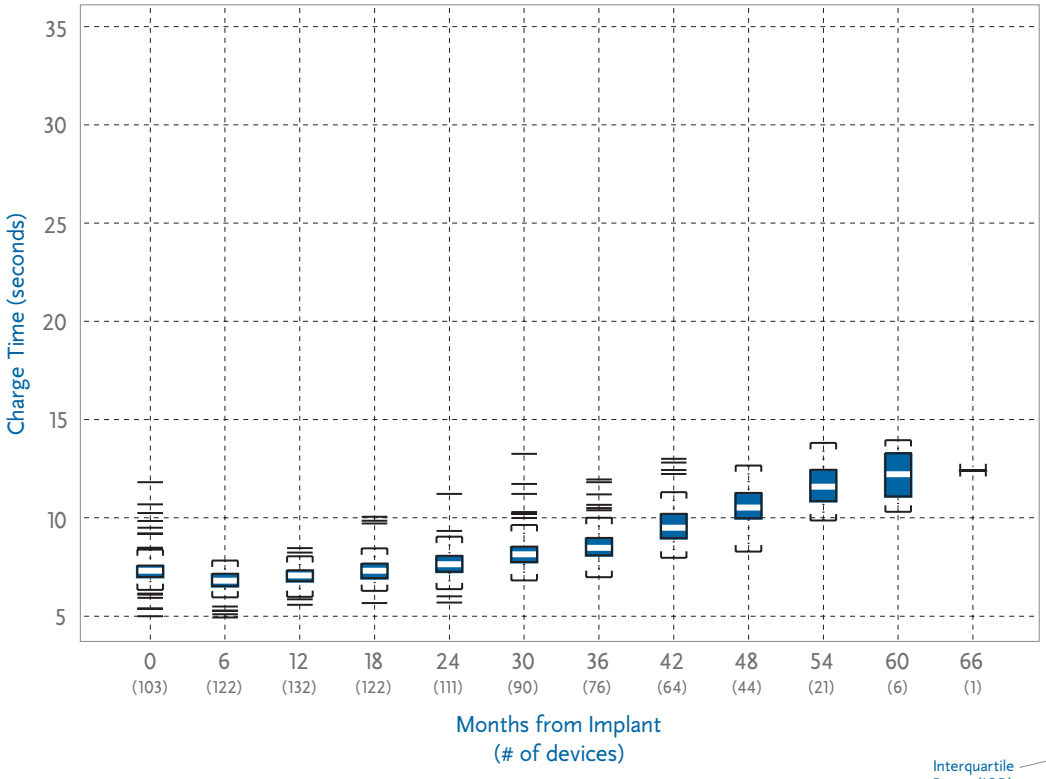


Save-to-Disk files have been collected 90 months post-implant. All observed charge times are below 20 seconds, with a maximum charge time of 18.75 seconds at 78 months post-implant.

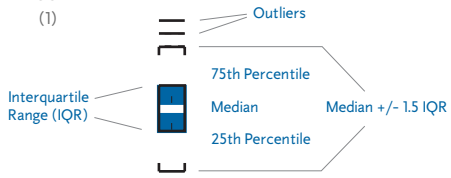
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

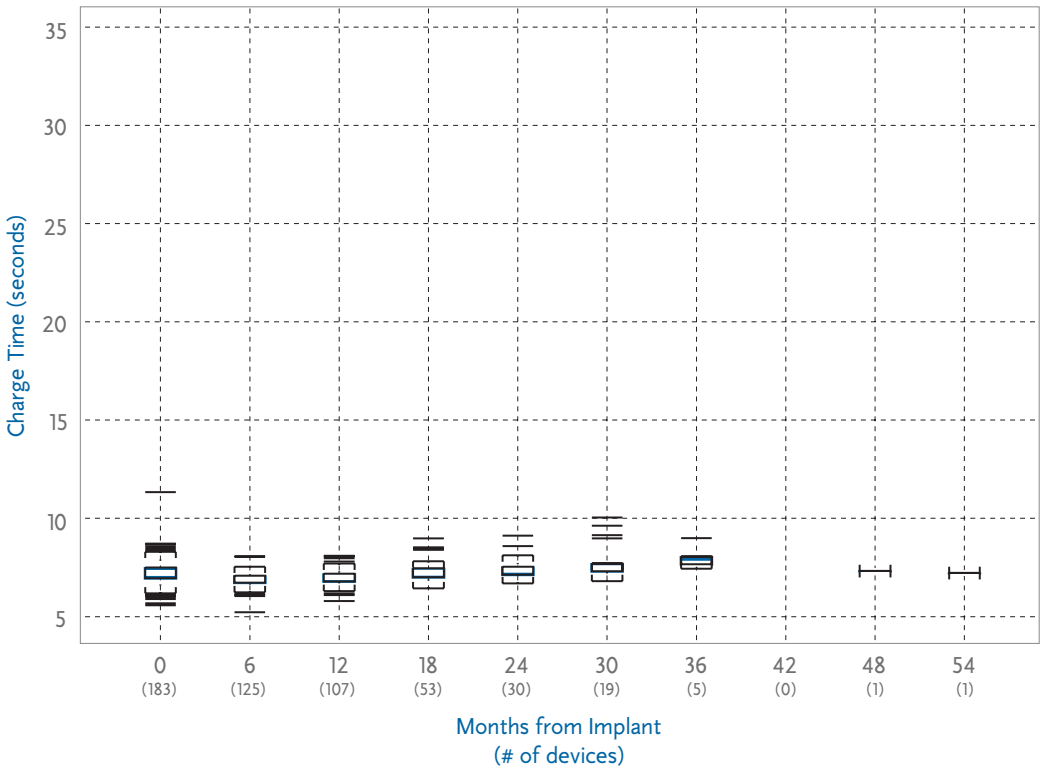
7229 GEM II VR Charge Time



Save-to-Disk files have been collected 66 months post-implant. All observed charge times are below 15 seconds, with a maximum charge time of 13.96 seconds at 60 months post-implant.



7230 Marquis VR Charge Time

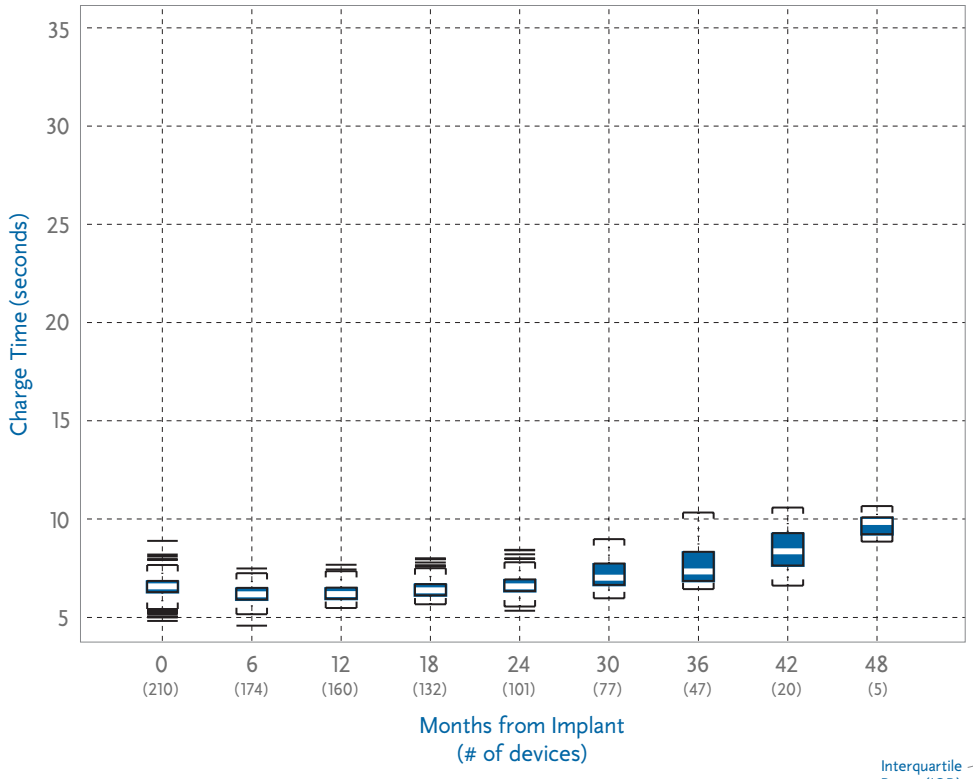


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 12 seconds with a maximum of 11.34 seconds observed at implant.

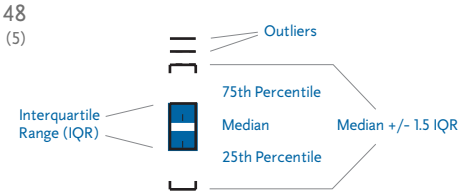
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

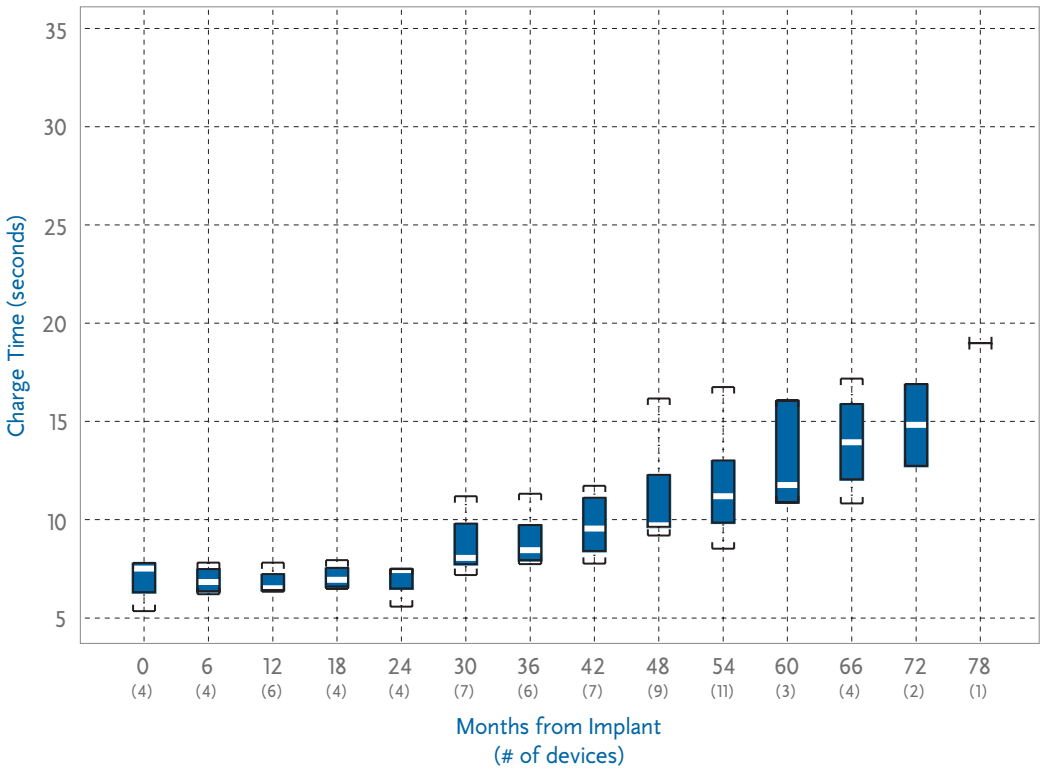
7231 GEM III VR Charge Time



Save-to-Disk files have been collected 48 months post-implant. All observed charge times are less than 12 seconds with a maximum of 10.66 seconds at 48 months post-implant.



7250 Jewel AF Charge Time

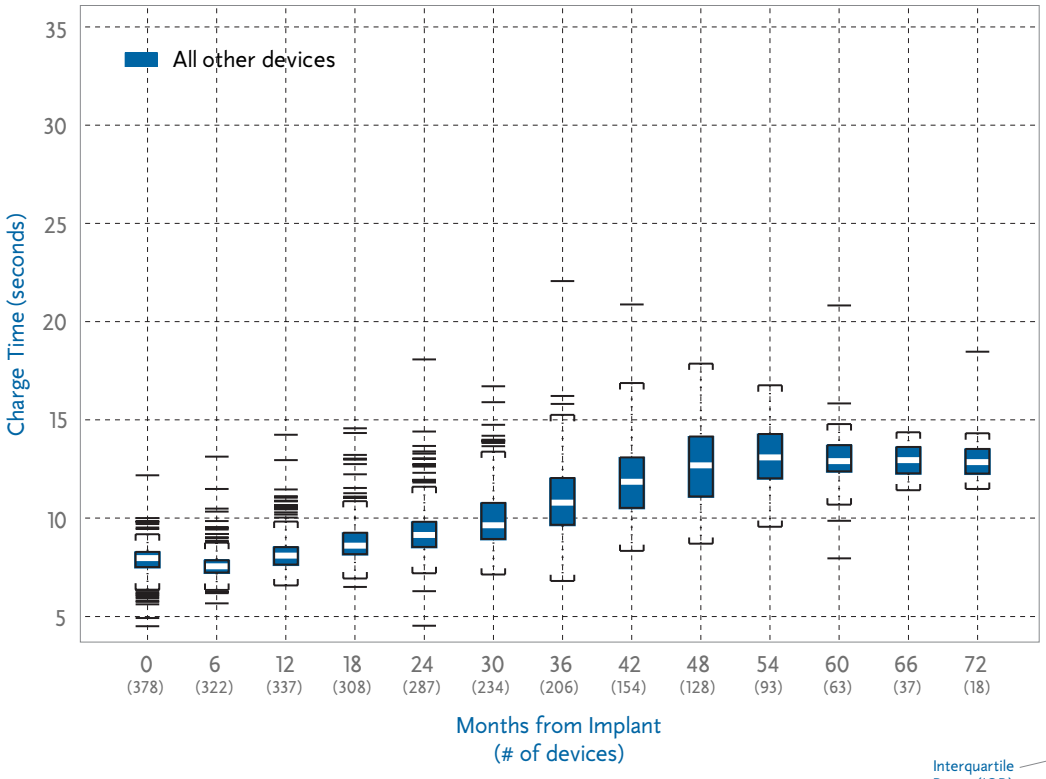


Save-to-Disk files have been collected 78 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.99 seconds observed at 78 months post-implant.

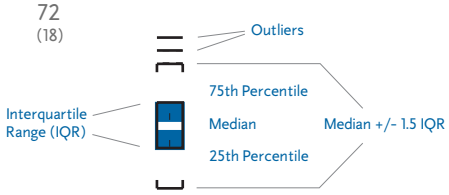
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

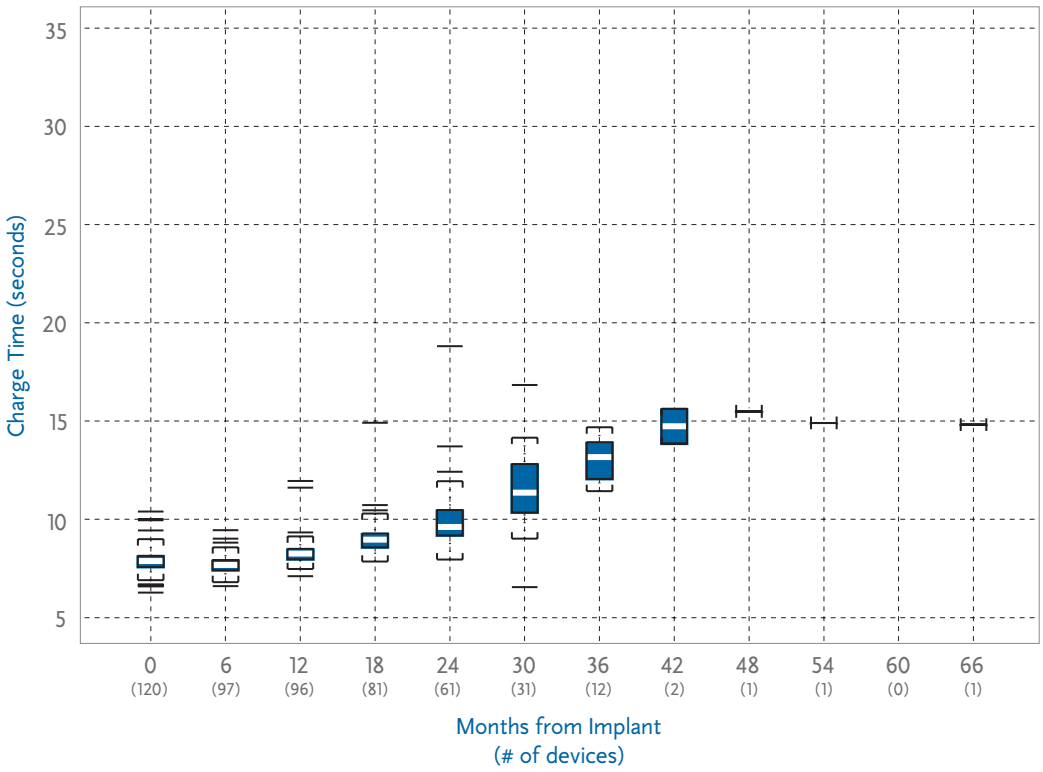
7271 GEM DR Charge Time



Save-to-Disk files have been collected 72 months post-implant. All observed charge times are less than 25 seconds with a maximum of 22.07 seconds observed at 36 months post-implant.



7272 InSync ICD Charge Time

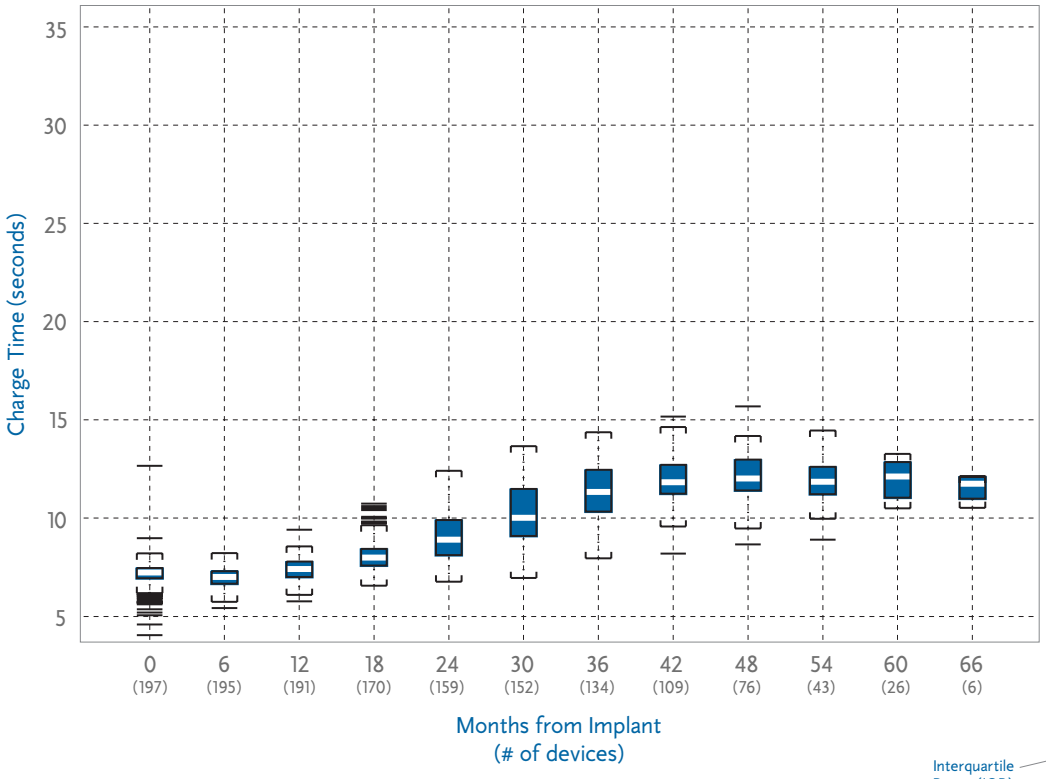


Save-to-Disk files have been collected 66 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.81 seconds observed at 24 months post-implant.

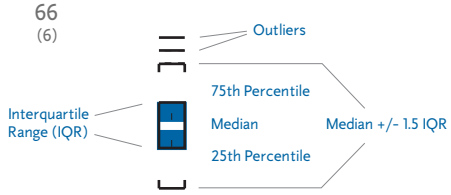
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

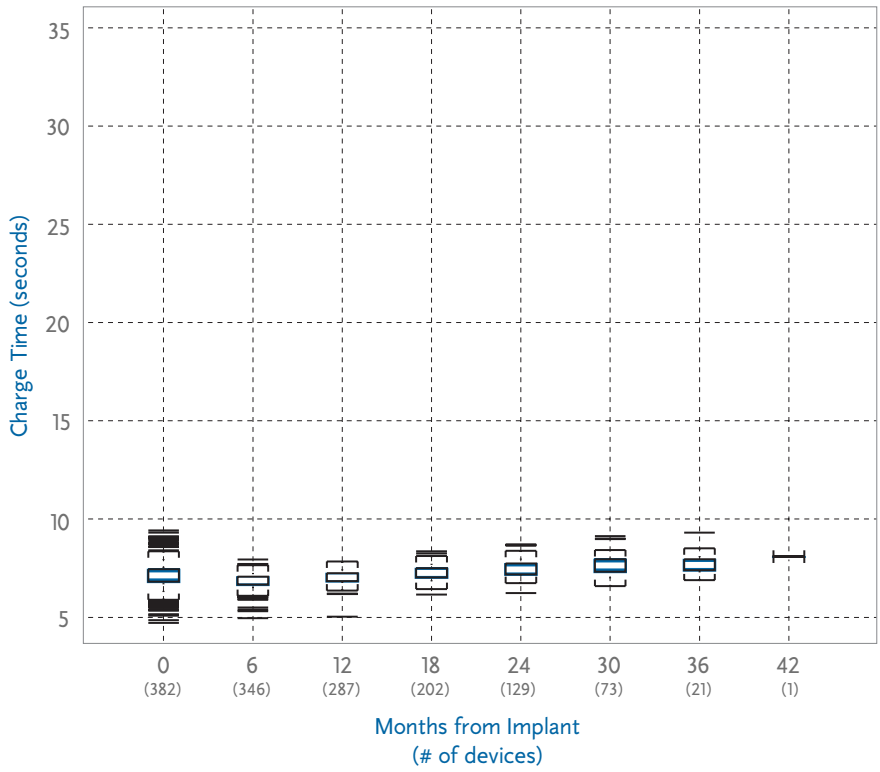
7273 GEM II DR Charge Time



Save-to-Disk files have been collected 66 months post-implant. All observed charge times are generally below 15 seconds, with a maximum charge time of 15.69 seconds observed at 48 months post-implant.



7274 Marquis DR Charge Time

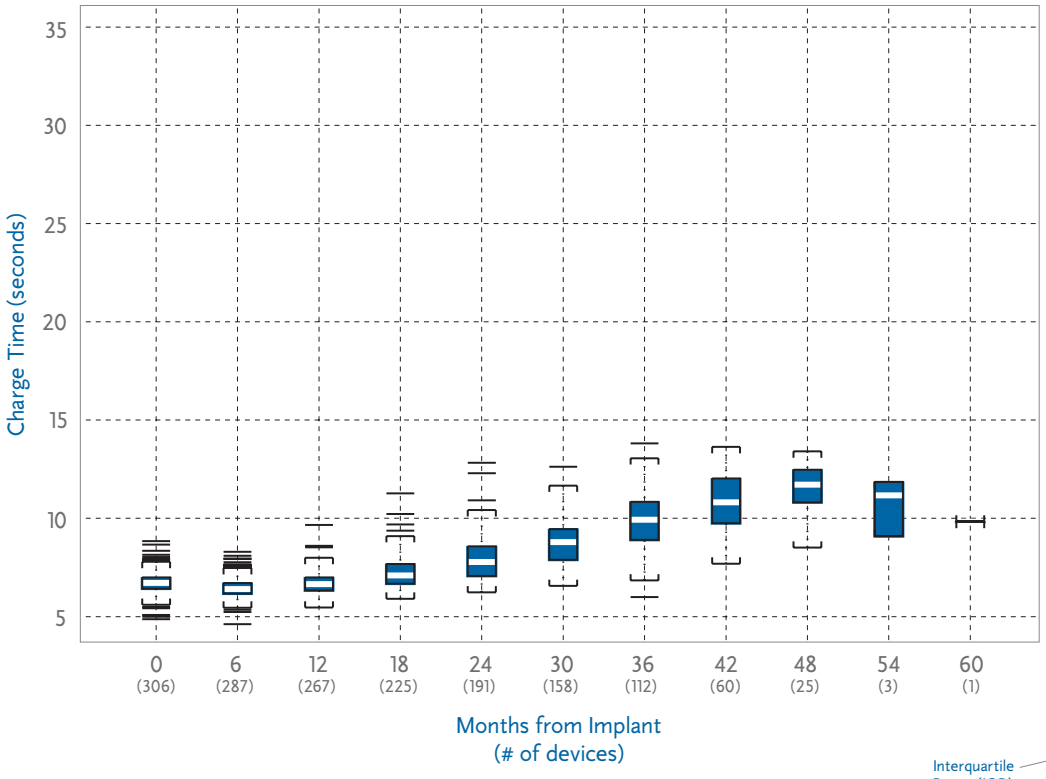


Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.42 seconds observed at implant.

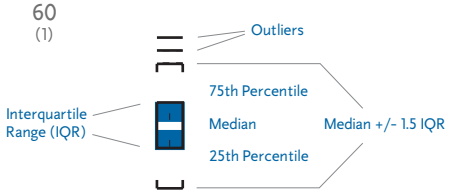
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

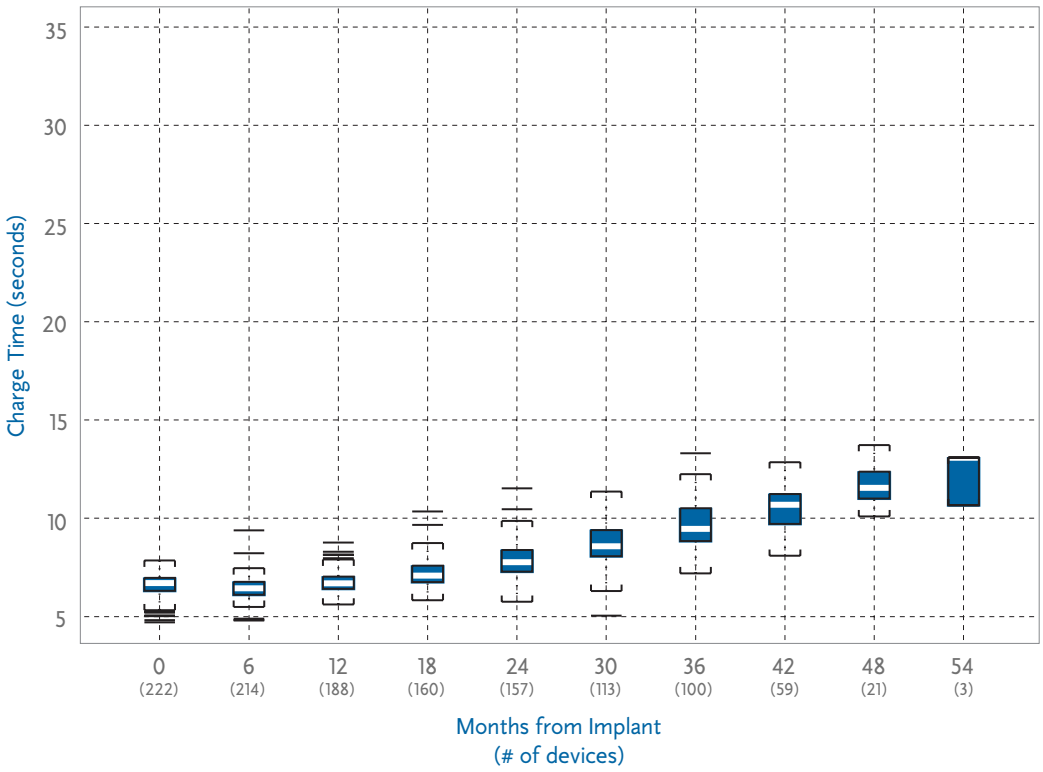
7275 GEM III DR Charge Time



Save-to-Disk files have been collected 60 months post-implant. All observed charge times are less than 15 seconds with a maximum of 13.82 seconds seen at 36 months post-implant.



7276 GEM III AT Charge Time

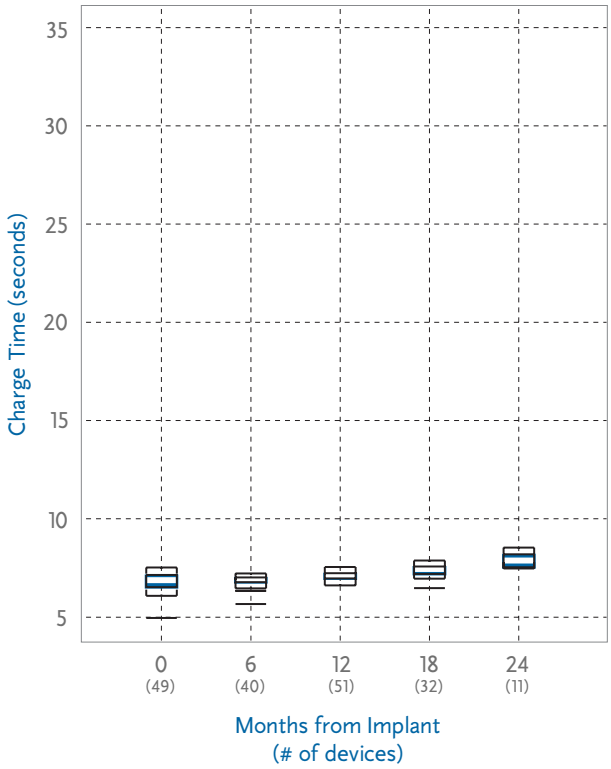


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 15 seconds with a maximum of 13.73 seconds observed at 48 months post-implant.

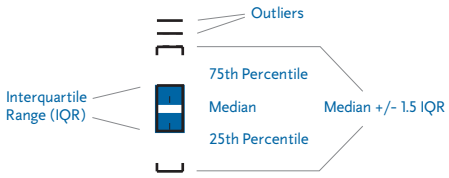
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

7277 InSync Marquis Charge Time



Save-to-Disk files have been collected 24 months post-implant. All observed charge times are less than 9 seconds with a maximum of 8.54 seconds observed at 24 months post-implant.

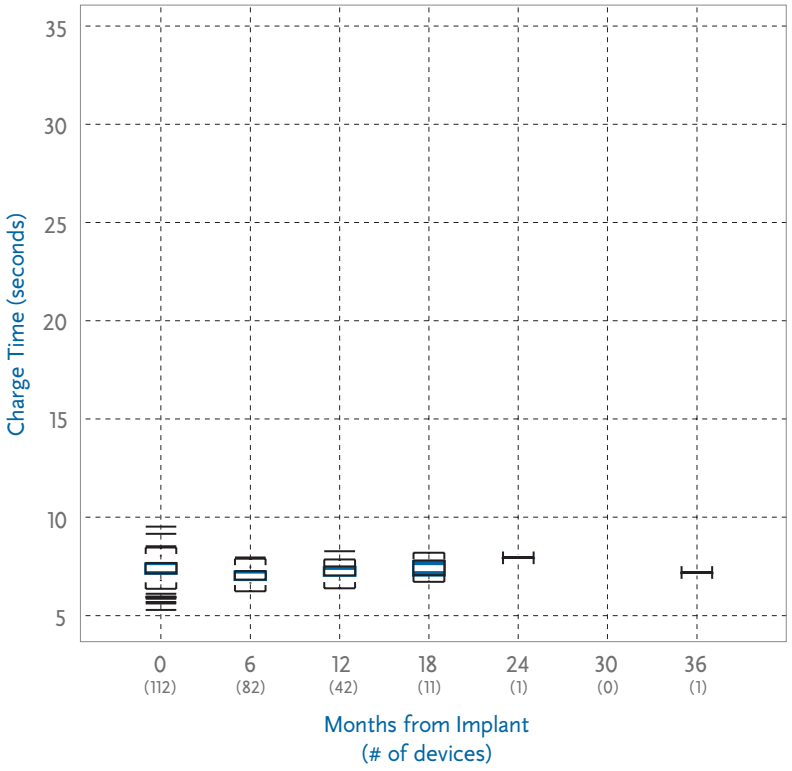


continued

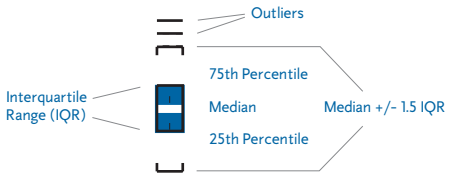
Source: System Longevity Study
Data as of July 11, 2005

ICD Charge Times continued

7289 InSync II Marquis Charge Time



Save-to-Disk files have been collected 36 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.52 seconds observed at implant.



Source: System Longevity Study
Data as of July 11, 2005

Advisories

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Approximately 28,000 devices, with approximately 6,650 in the United States, out of an initial implant population of 40,000 worldwide, remain implanted and in service. Specific model and serial numbers of affected devices are available online at http://SigmaSNList.medtronic.com.

Advisory

This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Separation of redundant interconnect wires has been observed on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. In October 2005, testing and analysis identified the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. No provocative testing can predict which devices may fail.

Patient Management Recommendations

To assist physicians in their patient care and after discussion with physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow-up in accordance with standard practice.
- Advise patients to seek attention immediately if they experience return of symptoms (e.g., syncope or light-headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient's medical history, and consideration of the relative risks of an invasive procedure.

Status Update (December 2005)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 25 devices out of approximately 40,000 devices worldwide (0.063% incidence), have been confirmed as having interconnect wire separation. Sixteen (16) of these devices were returned from the United States. **There have been no reported serious injuries or deaths due to this issue.**

Seventeen (17) of the 25 returns were identified via either a regularly scheduled follow-up or during a non-device related hospital visit. Two (2) devices were identified due to the patient experiencing syncope. The other 6 devices were replaced with no clinical symptoms associated with the interconnect wire separation. Among the 6 devices, 4 were returned due to a device/system upgrade, and 2 were returned due to infection.

Consistent with previous Medtronic projections, the probability of occurrence remains low and is within failure rate predictions. Implant duration for the 25 failures has ranged from 17-44 months.

7274 Marquis DR
7230 Marquis VR
7278 Maximo DR
7232 Maximo VR
7277 InSync Marquis
7289 InSync II Marquis
7279 InSync III Marquis
7285 InSync III Protect

Original Date of Advisory: February 2005

Potential Premature Battery Depletion Due to Battery Short

Product

The specific subset of Marquis family ICD and CRT-D devices having batteries manufactured prior to December 2003 is affected. Devices manufactured with batteries produced after December 2003 are not affected. Specific model and serial numbers of affected devices are available online at http://MarquisSNList.medtronic.com.

Advisory

Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. Battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism.

Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. As of February 2005, the rate of shorting was approximately 1 in 10,000 (0.01%); bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.

No provocative testing can predict which of these devices will experience this issue. Once a short occurs, battery depletion can take place within a few hours to a few days. After depletion the device ceases to function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

Patient Management Recommendations

The following recommendations apply to the affected population:

- Continue to conduct routine (e.g., quarterly) follow-up procedures.
- Turn on low battery voltage PatientAlert indicator.
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care.
- Consider providing patients with a hand-held magnet to check device status. Device operation may be monitored periodically (e.g., daily) by patients using the magnet, which will result in a device tone indicating device function (provided PatientAlert is turned on). If no tone is heard, follow-up care should be sought.

Status Update (December 2005)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 30 Marquis Family devices have been confirmed as having the internal battery shorting mechanism. Eighteen (18) of these devices were returned from the United States. **There have been no reported serious injuries or deaths due to this issue.**

Fourteen (14) of the 30 returns have been identified via either a regularly scheduled follow-up or during a non-device related hospital visit, 13 by patients reporting warmth in the ICD pocket, 1 for return of bradycardia symptoms, and 2 due to the PatientAlert sounding.

Consistent with previous Medtronic projections, the observed rate of shorting in the second half of device life is higher than that observed in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 67% occurred in the last quarter of device life, and 53% in the last 10% of device life.

7223 Micro Jewel II
7271 GEM DR

Original Date of Advisory: April 5, 2004

Potential Long Charge Times Due to Capacitor – Supplement

Product

Micro Jewel II Model 7223Cx ICDs with capacitor lots received from a supplier that were implanted in 1997 and GEM DR Model 7271 ICDs with capacitor lots received from a supplier that were implanted between November 1997 and December 1998. It is estimated that less than 0.5% of currently implanted Micro Jewel II and GEM DR devices built with these specific capacitors may exhibit performance concerns with typical battery depletion.

Affected devices that were subjects of previous physician letters in 1999 and 2000, defined as an isolated group of suspect capacitors, may not be consistently capable of providing high voltage energy delivery near or at ERI (4.91 volts) and continuing through EOL (4.57 volts).

Advisory

Several Micro Jewel II devices have been reported or returned which exhibited the inability to provide a full energy shock when the battery voltage was below 5.13 volts.

Because the same capacitor component lots were also used in a small subset of GEM DR Model 7271 ICDs (implanted from late 1997 through 1998) the company is providing these recommendations for both devices.

Patient Management Recommendations

April 5, 2004 letter supplements earlier Micro Jewel II letters (August 1999 and November 2000) and a GEM DR letter (December 1999) regarding this same previously identified population of devices with capacitors from specific component lots.

The following recommendations apply to Micro Jewel II 7223 and GEM DR Model 7271 devices for advisory population.

- As soon as possible, verify the charge time and battery voltage of each affected device by scheduling a follow-up with the patient, or, if the patient's last follow-up was within the previous 3 months, through review of the patient's medical records.
- Schedule replacement for any device with:
  - Battery voltage of 5.16 volts or less (NEW RECOMMENDATION)
  - OR charge time of 18 seconds or greater.
- If the verified charge time is less than 18 seconds but greater than 14 seconds, program the Automatic Capacitor Formation Interval to 1 month. If verified charge time is less than 14 seconds, no additional reprogramming is required.
- Follow these patients every 3 months, at a minimum.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

AT500 Pacing System

Original Date of Advisory: September 15, 2003

Potential Incorrect Memory Circuit Setting

Product

The affected devices are limited to AT500 implantable pulse generators manufactured prior to November 2001 and it is predicted that less than 1% of these devices will experience this high current drain. A list of affected serial numbers is attached to the September 15, 2003 physician communication letter, or is available from your Medtronic representative, or by calling US Technical Services at 1 (800) 723-4636.

AT500 devices manufactured after October 2001 are not affected.

Advisory

At the time of the advisory, Medtronic had received 14 AT500 Pacing System devices Model AT501 returned for premature battery depletion due to high current drain from a subpopulation of approximately 4,500 devices. Our investigation isolated the root cause to a unique condition that involves the use of the AT/AF EGM "All Episodes" (Episode Full Disclosure mode) feature. The affected device's memory circuit contains 4 bytes of information that can cause the high current drain when specific memory locations store patient intrinsic activity. This results in sooner than anticipated battery depletion; generally within a 2-month period from the time the error occurs. While implanted, each of the returned devices initially appeared to be operating normally and in many cases had been through multiple follow-ups in which the battery level was monitored and at predicted levels.

Patient Management Recommendations

A simple non-invasive procedure will permanently correct the memory circuit and prevent this cause of premature depletion from occurring in the affected AT500 devices. It involves programming the diagnostic setup for Summary Data and EGM strips to "Treated Episodes" followed by a reprogramming to "All Episodes." Note that diagnostic data will be cleared with this programming; therefore, we recommend that a full summary printout or a save-to-disk be done. This will correctly reset the device's software and prevent the identified premature depletion. Programming will only need to be done once over the life of the device. Step-by-step reprogramming instructions are available from your Medtronic representative.

For patients who are pacemaker dependent with no underlying rhythm, it is recommended the reprogramming be done as soon as possible. For non-pacemaker dependent patients the reprogramming could be done at the next regularly scheduled follow-up.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged. The devices affected by this advisory are generally at or beyond the mid point of their expected battery longevity.

7271 GEM DR ICDs

Original Date of Advisory: November 14, 2002

Potential Sudden Increase in Charge Times

Product

A specific subset of devices consisting of less than 20% of the GEM DR ICD manufactured between 1998 to 1999 have suspect batteries that could exhibit sudden increased charge times. Suspect devices are GEM DR Model 7271 ICDs with the engineering series number "4" in the fourth position of the serial number. For example, PIM4xxxxxx.

Advisory

Suspect GEM DR devices can exhibit sudden increase in charge times (charge time greater than 18 seconds) at approximately 32 months post-implant.

Patient Management Recommendations

Verify the charge time of each affected suspect device either by scheduling a follow-up with the patient, or through review of the patient's medical records, if the patient's last follow-up was within the previous 3 months.

- Automatic capacitor formation should be programmed to monthly on all suspect devices. This will provide additional warning should an extended charge time unexpectedly occur.
- PatientAlert for Excessive Charge Time should be programmed ON. 18 seconds is the default setting for PatientAlert – Excessive Charge Time.
- Replacement of the device should be considered for any GEM DR device with an unformed charge time of 18 seconds or greater.

At the time of the advisory, a written communication was provided to physicians who have patients implanted with the affected devices, along with serial numbers of those devices.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

Kappa 600, 700 Dual Chamber (D, DR, and VDD) IPGs

Original Date of Advisory: March 15, 2002

Potential Fractured Power Supply Wires

Product

A specific subset of Kappa 700/600 Dual Chamber (D, DR, and VDD) Implantable Pulse Generators have been identified by serial numbers. Hospitals and Physicians were notified. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

Advisory

As of March 15, 2002, Medtronic observed 53 related failures (0.02%) in over 255,000 Kappa 700/600 Dual Chamber (D, DR, and VDD) Series devices sold worldwide. Medtronic voluntarily communicated this information to physicians because these failures had been observed in patients having submuscular implants. There have been no reports of serious injury or death related to this issue.

These devices have presented with an electrical reset, intermittent output, or no output. Our investigation identified the root cause as fractured wires supplying power to the pacemaker. This has been directly correlated to submuscular placement of these devices. Submuscular implant locations (e.g., subpectoral, abdominal, etc.) can result in additional stress and repetitive flexing on the implanted device causing excessive fatigue on these wires. Of the estimated 4,000 devices implanted submuscular, approximately 200 (5%) may experience this failure. These stresses on the implanted device are unique to submuscular implant sites and do not exist with subcutaneous implants.

Patient Management Recommendations

While there is no provocative testing or time dependency that will predict which submuscular placed device will fail, certain electrical resets may be an indicator that a wire fracture has occurred. Normal electrical resets can occur as a result of electrosurgical procedures such as cautery and ablation or from defibrillation therapy. If none of the normal causes of electrical reset can be confirmed, or if a device serial number presents as "000000" following an electrical reset, this may be an indicator of a wire fracture.

For patients who have submuscular implants of devices within the designated serial number range and who are pacemaker dependent with no underlying rhythm, replacement of the device should be considered. Medtronic will provide the replacement device free-of-charge under the terms of its warranty program if a device is replaced in these patients.

For patients having subcutaneous implants, no change to your current patient care and follow-up is advised.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged.

7227 with Interchangeable Connector System

Original Date of Advisory: December 20, 2000

Potential High Impedance Due to Removable Connector Header

Product

All Model 7227 devices with the interchangeable connector system may be affected.

Advisory

Affected devices may exhibit high impedance warnings due to the connection between the removable header piece and its receptacle on the device. These high impedance measurements may trigger the PatientAlert feature.

Testing and analysis indicate that despite the high connector impedance, after further evaluation and confirmation of lead integrity, these devices should continue to provide therapy over their service life.

As of December 20, 2000, 45 instances of this out of 1,200 implants worldwide have been identified where connector-related high impedance warnings have occurred. While the warning messages displayed at device interrogation appear to indicate a potential lead problem, it is possible for the source of the high impedance measurement to be located in the connection between the removable header piece and its receptacle on the device.

If device interrogation displays a high impedance warning message, further investigation is recommended prior to taking corrective action. In cases where a high impedance warning is displayed and follow-up has determined that the lead is functioning normally, analysis indicates that:

- High voltage therapy delivery is not affected.
- Sensing of VT and VF will not be affected.
- Oversensing may occur which could potentially result in unwarranted delivery of therapy.
- Pacing threshold increases may be observed.

Patient Management Recommendations

- The PatientAlert option for "Lead Impedance Out-of-Range" should be enabled at the next scheduled follow-up for both the pacing and defibrillation lead. This will support identification of patients with out-of-range lead impedances.
- When a patient presents with a high impedance warning, a "Save To Disk" file should be created and forwarded to Medtronic Technical Services. Your Medtronic representative can coordinate and support evaluation of the implanted system. Analysis of this data can identify if the impedance increase is a result of connector issues, lead failure, or a combination of both. The save-to-disk file can be sent as an email attachment to crmtechnicalservices@medtronic.com. Medtronic Technical Services can also be contacted at 1(800) 723-4636.
- After a high impedance trigger of the PatientAlert has occurred as a result of this issue, we would recommend disabling the feature for that lead to avoid recurrent triggering of the alert tone. In cases where the interchangeable connector is the source of the impedance increase, routine follow-up of the patient to assess pacing, sensing, and defibrillation performance is warranted.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7223Cx Micro Jewel II ICDs

Original Date of Advisory: November 20, 2000

Potential Long Charge Times Due to Capacitor

Product

Affected devices within an isolated group of suspect capacitors could exhibit a sudden increase in charge times > 18 seconds.

Several Micro Jewel II devices have been returned which exhibited charge times in excess of 60 seconds.

November 20, 2000 letter updating previous recommendations communicated August 5, 1999. A separate written communication has been provided to physicians who have patients implanted with the affected devices, along with serial numbers of those devices.

Advisory

May 2000 Product Performance Report combines the Micro Jewel II Model 7223Cx and GEM DR Model 7271 advisory. Based on performance differences these model advisories have been separated.

Micro Jewel II devices implanted throughout 1997 can exhibit formed and/or unformed charge times greater than 18 seconds at approximately 18 months post-implant. Devices displaying this behavior contain capacitors from specific component lots.

Patient Management Recommendations

The following recommendations apply to Micro Jewel II 7223 devices.

- As soon as possible, verify the charge time of each affected device either by scheduling a follow-up with the patient, or through review of the patient's medical records, if the patient's last follow-up was within the previous 3 months.
- If you identify any affected devices that have a charge time of 18 seconds or greater, replacement of the device is recommended. If the verified charge time is less than 18 seconds, at a minimum, quarterly follow-ups are recommended for those patients.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7273 GEM II DR
7229Cx GEM II VR

Original Date of Advisory: February 11, 2000

Potential Weak Solder Connection

Product

Sixteen hundred (1,600) devices with potential for a weakened solder connection have been implanted worldwide. Medtronic estimates that this failure mode will affect less than 50 devices worldwide. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

IMPORTANT REMINDER:

Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the PatientAlert feature "ON" without delay.

Advisory

Solder connections on a specific component may exhibit loss of integrity.

Affected devices have solder connection that may weaken over time and can result in loss of telemetry and device therapy output.

Patient Management Recommendations

- Program "Lead Impedance Out-of-Range" to ON within the PatientAlert feature. *Both pacing and defibrillation lead alerts must be enabled.*
- In the event of a device malfunction, the pacing or defibrillation lead impedance will be reported as out-of-range – this will cause an activated PatientAlert tone to sound. The PatientAlert feature will check the lead impedances once each day.
- If the PatientAlert tone sounds, evaluate the device to determine the cause of the alert. **If the device cannot be interrogated (no telemetry), then device replacement is recommended.** If the device can be interrogated, it is unlikely the alert tone is due to this issue, and other potential causes for the PatientAlert tone should be investigated.

The PatientAlert parameter must be programmed ON for the remainder of the device life in order to detect any future occurrences of this failure mode.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

7271 GEM DR ICDs

Original Date of Advisory: December 16, 1999

Potential Long Charge Times Due to Capacitor

Product

GEM DR devices implanted November 1997 - December 1998 (during the PMA clinical trial and early commercial release) can exhibit unformed charge times greater than 18 seconds, and formed charge times greater than 10 seconds, at approximately 18 months post-implant.

Advisory

Affected devices can exhibit unformed charge times > 18 seconds 12-24 months post-implant.

Devices displaying this behavior contain capacitors from specific component lots.

Patient Management Recommendations

The following recommendations apply to the GEM DR 7271 device.

- At normal scheduled follow-up, check the stored automatic capacitor formation time to ensure the charge time is in a range acceptable for each individual patient.
- If the charge time is greater than 14 seconds prior to battery elective replacement indicator (ERI), program the Automatic Capacitor Formation Interval to 1 month.

Note: Stabilization and/or reduction in charge times may take 3-6 months to become apparent after programming the formation to 1 month.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7227Cx GEM
7229Cx GEM II VR

Original Date of Advisory: October 15, 1999

Potential Circuit Overload

Product

Model 7227Cx Implantable Cardioverter Defibrillators supplied before October 15, 1999, with serial numbers ending in an "H." For example, PIPxxxxxxH or PJJxxxxxxH, where x is a variable numeric, may be affected. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

IMPORTANT REMINDER:

Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the PatientAlert feature "ON" without delay.

Advisory

Manufacturing error in a small percentage of devices may cause circuit overload when AX ≥ B High Voltage energy is delivered via an integrated bipolar lead. GEM Model 7227Cx and GEM II VR Model 7229Cx devices with dedicated bipolar sensing leads are not affected by this issue. Devices affected may not be able to subsequently charge to full energy and experience "charge circuit timeout."

Patient Management Recommendations

- Assessment of all patients with the potentially affected devices implanted **AND** an integrated bipolar ICD lead such as the 6942 and 6945 should take place without delay.
- Reprogram polarity pathway to B ≥ AX for all cardioversion and defibrillation therapies.
- Confirm correct device function:
  - Perform a full energy charging sequence.
  - If "charge circuit timeout" is observed, contact your Medtronic representative.
  - If device charges normally, it has not been damaged and will function appropriately with polarity programmed B ≥ AX.

Recent studies have demonstrated that DFTs are similar or lower in a B ≥ AX polarity pathway when compared to AX ≥ B.

Devices implanted with functional dedicated bipolar leads such as the 6932, 6934S, 6936, 6943, and 6966 are not affected.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

Sigma Implantable Pulse Generators

Original Date of Advisory: September 27, 1999

Manufacturing Issue

Product

The affected devices are limited to subset of Sigma pulse generators manufactured between July 5, 1999 and August 31, 1999. All affected devices were distributed outside the United States. Medtronic representatives provided a list of affected device serial numbers of this Implantable Pulse Generator.

Advisory

A manufacturing issue was identified which could result in a sudden loss of sensing or pacing output, under worst case conditions. The cause was isolated to a defined manufacturing time period, a specific manufacturing process, and a limited number of units distributed in various countries outside the United States.

Patient Management Recommendations

There is no patient monitoring or provocative testing that will predict the occurrence of this potential failure. If any of these devices have been implanted, you may wish to consider whether prophylactic replacement would be appropriate, especially in patients at high risk such as pacemaker dependent patients. However, individual patient circumstances and medical judgment should, as always, dictate patient care. If you choose to replace the device, Medtronic will provide a new device under the applicable warranty program.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged.

7227Cx GEM ICDs

Original Date of Advisory: April 2, 1999

Potential High Current Drain

Product

Affected devices can be identified by reviewing battery voltage: If the battery voltage is > 3.03 volts and it is at least 3 months post-implant, then the ICD is not affected. Model 7227Cx devices delivered after April 2, 1999 are not affected.

Advisory

High current drain in the electronic hybrid circuit causes premature battery depletion in affected devices. The high current drain occurred during manufacturing and has been traced to a specific component.

Patient Management Recommendations

Review battery voltage records for each 7227Cx patient.

1) If the battery voltage at implant was

- ≤ 3.07 volts or unknown, then bring the patient in for evaluation as soon as possible.
- > 3.07 volts, then review the battery voltage at 3 months post-implant.

2) If the battery voltage at the 3 month follow-up is

- ≤ 3.03 volts, then contact your Medtronic representative for further evaluation.
- > 3.03 volts, then no further action is required.

Status

All potentially affected implanted devices have been implanted for at least 3 months. No further action is required.

Thera Implantable Pulse Generators

Original Date of Advisory: February 18, 1997

Potential Integrated Circuit Failure

Product

One hundred seventy-seven (177) Thera Implantable Pulse Generators are affected. These have been identified by serial number and each respective physician has been notified. The models of the affected generators include 7940, 7941, 7942, 7950, 8940, 8941, 8942, and 8948. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

Advisory

These devices are susceptible to a sudden loss of telemetry, sensing, or pacing output functions.

The cause of the anomaly is a potential failure in one integrated circuit.

Patient Management Recommendations

There is no patient monitoring or provocative testing that will predict the occurrence of this anomaly. You may wish to consider prophylactic replacement of the device if your patient is at high risk, e.g., pacemaker dependent.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged.

4504, 4504M CapSure Atrial Lead
4582 Target Tip Atrial Lead

Original Date of Advisory: October 4, 1996

Lead Survival Below Expectations

Product

All Models 4504, 4504M, and 4582 Implantable Pacing Leads

Advisory

Lead survival probability is below expectations and is primarily associated with insulation degradation due to Metal Ion Oxidation (MIO).

Patient Management Recommendations

- Follow patients in accordance with Medicare Guidelines.
- Avoid the use of the AAI or AOO mode.
- During patient evaluation, give careful attention to lead performance such as:
  - Review patient ECG for indications of transient sensing and/or capture abnormalities.
  - Monitor in clinic for impedance less than 250 ohms or a decrease of more than 30% from implant values (or an established baseline using telemetry) which would suggest lead failure.
- Consider the use of unipolar if the pulse generator has this capability.
- At the time of pacemaker system revision (e.g., normal pulse generator or ventricular lead revision), carefully evaluate lead integrity and patient status before choosing to reuse.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. According to System Longevity Study results, lead survival is estimated to be 66.2% at 8 years.

8446, 8448 Legend Plus IPGs

Original Date of Advisory: June 14, 1996

Potential for Improper Programming

Product

All Models 8446 and 8448 Implantable Pulse Generators

Advisory

Potential for improper acceptance of the programming of a rate responsive mode resulting in irregular rate intervals.

Patient Management Recommendations

The anomaly can be initiated only during the programming (or reprogramming) of the pacing system to a rate responsive mode. In the unlikely event that the anomaly occurs, reprogramming the pacing system to the desired mode should restore normal operation.

- New software has been developed that provides clinicians the ability to verify the proper programming of the rate responsive modes.
- As always, individual circumstances and medical judgment dictate patient care.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

4004, 4004M CapSure Ventricular Lead
4082 Target Tip Ventricular Lead

Original Date of Advisory: October 8, 1993

Lead Survival Below Expectations

Product

All Models 4004/4004M and 4082 Implantable Pacing Leads

Advisory

Lead survival probability is below expectations due primarily to polyurethane insulation failure (MIO) and conductor fracture (associated with "subclavian crush").

Patient Management Recommendations

- Increase, as appropriate, the frequency of patient evaluation through in-clinic visits supplemented with transtelephonic and/or ambulatory monitoring; for example, consistent with Guideline I under Medicare Pacemaker Monitoring Guidelines (50-1 Cardiac Pacemaker Evaluation Services).
- During patient evaluations, give careful attention to lead performance such as:
  - Reviewing patient ECGs carefully for indications of transient sensing and/or capture abnormalities.
  - Monitoring in-clinic for impedances less than 300 ohms or a decrease of more than 30% from implant values (or an established baseline using telemetry) which would suggest lead failure.
  - Eliciting and thoroughly investigating any patient complaints suggestive of lead failure.
- Consider whether prophylactic replacement would be appropriate, especially in patients at high risk, such as pacemaker dependent patients.
- Carefully evaluate lead integrity when performing routine pulse generator replacements. Replace lead if:
  - Insulation breaches are observed.
  - Lead impedance is less than 300 ohms or has decreased by more than 30% from implant values.
  - Impedance or voltage threshold measurements vary significantly when multiple readings are taken.
  - If the risk of continued use outweighs the risk associated with implanting a new lead.
- As always, individual circumstances and medical judgment dictate patient care and frequency of follow-up.
- Consider lead replacement during normal pulse generator change-out. Carefully evaluate lead integrity and patient status before choosing to reuse.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. According to System Longevity Study results, lead survival is 46.1% at 10 years.

4012 Target Tip Ventricular Lead

Original Date of Advisory: September 26, 1991

Lead Survival Below Expectations

Product

All Model 4012 Implantable Pacing Leads

Advisory

Lead survival probability beyond 5 years is below expectations due primarily to polyurethane insulation failure (due to ESC and/or MIO) and conductor fracture (associated with "subclavian crush").

Patient Management Recommendations

Consider increasing frequency of monitoring (e.g., from quarterly to bimonthly or monthly). Consider the following activities as part of normal follow-up procedures:

- Monitor for significant changes in impedance which could be an indication of impending failure (pulse generator must have impedance telemetry capabilities).
- Review patient ECGs carefully for indications of transient sensing and/or capture abnormalities. This can be done using transtelephonic or in-clinic monitoring and/or using ambulatory monitoring.
- Elicit any patient complaints suggestive of lead failure and investigate thoroughly lead integrity/performance characteristics following reports of patient complaints or symptoms using the above techniques.
- Consider whether prophylactic replacement would be appropriate in patients at high risk, such as pacemaker dependent patients.
- Evaluate carefully the integrity of the lead during routine pulse generator replacement before choosing to reuse. Specifically, Medtronic recommends placement of a new lead if:
  - Insulation breaches are observed.
  - Lead impedance is less than 300 ohms or has decreased by more than 30% from implant values.
  - Electrical properties such as impedance and threshold vary significantly when multiple readings are taken.

As always, medical judgment must be used to establish the appropriate schedule and course of care for every individual, particularly pacemaker dependent or other patients at higher risk.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. The System Longevity Study results show 59.3% lead survival at 15 years.

Minix, Minix ST, Micro Minix IPGs

Original Date of Advisory: May 6, 1991

Potential Delayed Restoration of Permanent Settings

Product

All Models of the Minix, Minix ST, and Micro Minix families of Implantable Pulse Generators

Advisory

Possibility of delayed restoration of permanent pacing mode and parameters, after the magnet or programming head is removed under certain conditions.

Patient Management Recommendations

To eliminate any potential risk associated with temporary programming, depress the INTERROGATE KEY and verify successful interrogation before moving the programming head away from the pulse generator. The delay condition can also be terminated by repositioning the programming head and depressing the EMERGENCY VVI key.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

Technical Articles

AT500 Pacing System Follow-Up Protocol

Purpose of This Information

This article is intended to provide clinical guidance regarding follow-up practice and patient management when the AT500 battery voltage approaches the Elective Replacement Indicator (ERI) level of 2.6 volts.

Background

Many AT500 pacing systems are now reaching their Elective Replacement Indicator voltage level (2.6 volts). This is expected since the battery used has an approximate longevity of 5-6 years under normal conditions (100% DDD pacing, 3 volts, 0.4 ms).

Technical Services has received reports of battery voltage levels below End-of-Life (EOL of 2.20 volts) where EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary. It is important for Physicians and Allied Professionals to understand battery depletion characteristics between ERI and EOL so that they, in turn, can understand how this affects management of follow-up visits for the AT500 as this device nears the end of its expected longevity.

AT500 Battery and Longevity Information

In contrast to other IPGs, the AT500 does not change its mode, stimulation rate, or any other parameter when the battery voltage drops below the ERI level of 2.60 volts (with or without magnet applied). The Threshold Margin Test (TMT) is also not available.

Therefore, it is not possible to perform trans-telephonic assessment of AT500 battery status. This must be done during an in-clinic follow-up session. A warning will be displayed on the Quick Look screen at the beginning of a programmer (follow-up) session when the ERI battery level occurs. The measured battery voltage will also appear on the programmer display and on printouts.

Battery depletion curves at **common parameter settings** are shown in Figure 1, with special focus on device longevity when programming EGM pre-storage ON or OFF.

continued

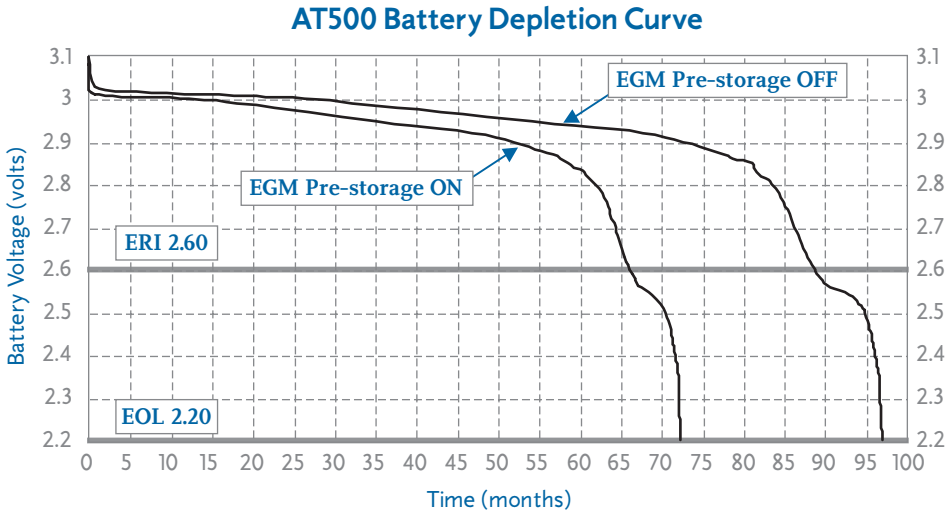


Figure 1

AT500 battery depletion curve for common parameter settings of DDDR, LR 70 ppm, UR 120 ppm, 100% pacing, Atrial – 2 V, 0.4 ms, 600 ohms, Ventricle – 2 V, 0.6 ms, 900 ohms, and EGM Pre-storage ON versus OFF.

AT500 Pacing System Follow-Up Protocol continued

Medtronic's review of ongoing AT500 battery life test data matches our original longevity modeling and so meets our expectations. However, when using longer durations between follow-up periods (> 3 months), clinicians should consider the following in setting their remaining longevity expectations:

– Enabling the "EGM Pre-storage On" capability will increase current and reduce device longevity by approximately 9 days for each month pre-storage is ON.

– Longevity decreases with an increase in pacing rate, an increase in pacing amplitude or pulse width, a decrease in pacing impedance, a higher ratio of paced to sensed events, or extended use of the Atrial Preference Pacing, EGM pre-storage, or Holter Telemetry features.

Recommendations

Follow-up frequency should always be accelerated as devices reach ERI voltage levels to ensure device explant/replacement occurs prior to End of Life voltage levels. With the wide variety of follow-up schedules being used, Medtronic recommends a 3-month follow-up frequency for the AT500 pacing systems. This is particularly important for patients in whom EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary.

Insertion of the Lead into the Device

The implantable system consists of a pulse generator and at least 1 lead. The system operation depends on proper electrical and mechanical operation. With the advent of internationally recognized connector standards the challenge of ensuring proper mechanical fit between the lead and device connectors has been simplified, although the international connector standard does not address all aspects of the procedure for connecting a lead to the device.

If the lead connector is not fully installed, oversensing may result as described in the connector problems section of the technical article, "Clinical Management of High Voltage Lead System Oversensing."

Performing the following steps can be used for each lead connection during the implant procedure:

1 Insert the torque wrench into the appropriate setscrew. For easier lead insertion, insert the lead closest to the device first.

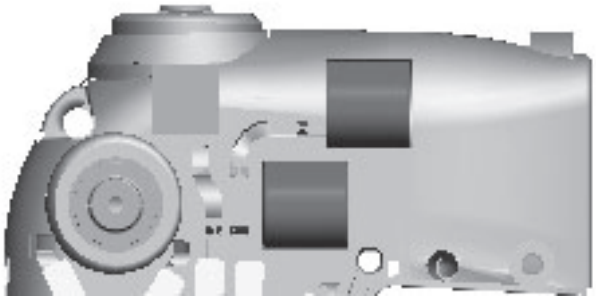
2 Look down the connector port to verify that the port is not obstructed. If the port is obstructed retract the setscrew to clear the bore. Take care not to disengage the setscrew from the connector block.

3 Push the lead into the connector port until the lead pin is clearly visible beyond the setscrew block.

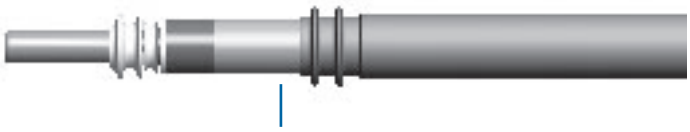
4 Hold the lead in position while tightening the setscrew until the torque wrench clicks.

5 Tug gently on the lead to confirm a secure fit.

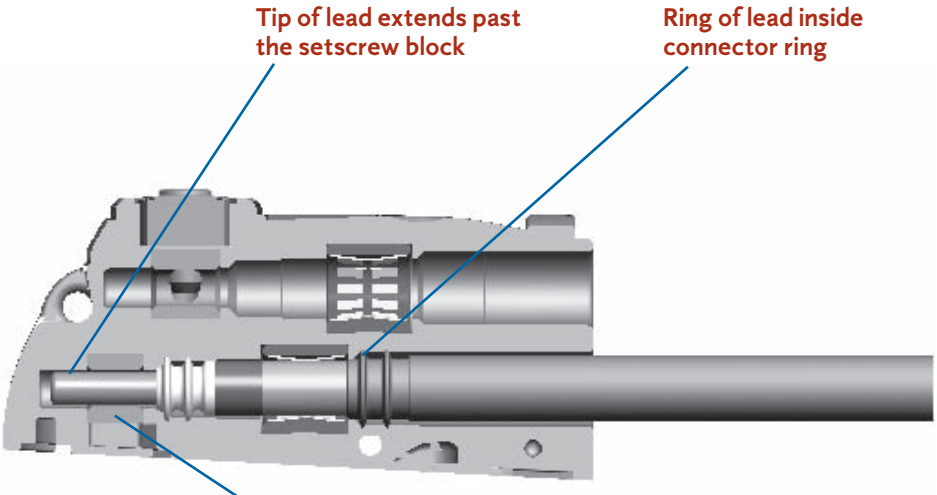
continued



Connector Module



Lead prior to insertion



Insertion of the Lead into the Device continued

X-ray image of the lead fully installed

Current publications may provide additional information on implant procedures used by others, e.g., radiographic evaluation of the terminal pin beyond the terminal post.[1]

[1] Pickett RA III, Saavedra P, Ali MF, Darbar D, Rottman JN. Implantable cardioverter-defibrillator malfunction due to mechanical failure of the header connection. *J Cardiovasc Electrophysiol*. September 2004;15(9):1095-1099.

GEM II DR/VR and GEM III DR/VR/AT ICD Battery Discharge Behavior

Medtronic manufactures and utilizes a unique Lithium/Silver Vanadium Oxide battery in the GEM II/III family of ICDs. This battery has a distinctive voltage discharge with two regions of constant voltage at 3.2 volts and 2.6 volts.

The battery discharge curve (see curve below) is characterized by a significant decrease in the battery voltage approaching middle-of-life (MOL), followed by a plateau (MOL to Elective Replacement Indicator) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily misinterpreted as the battery rapidly approaches ERI, when the battery in fact may have several years remaining until ERI; which occurs at 2.55 volts.

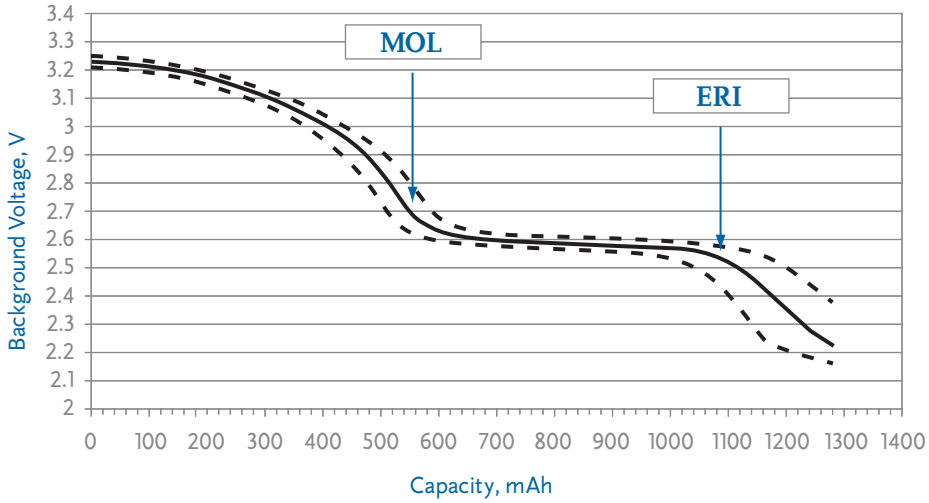
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

As a general rule of thumb, the longevity from implant to MOL = MOL to ERI.

The design of the recently released Marquis battery has been modified to present a more linear battery discharge curve.

If you are concerned about early ERI in your patient's device, you can utilize the battery trend measurements stored in the save-to-disk file, which can be accessed and interpreted through the Medtronic Technical Services at 1 (800) 723-4636.

GEM II/III Battery Discharge Curve



General Follow-Up and Replacement of ICD Leads

The human body is a hostile environment for an implantable device. Typically, the human body will attack and attempt to isolate or destroy any foreign object. Additionally, implanted leads are subjected to continuous flexural and torsional stresses associated with cardiac activity, body motion, and patient anatomy, which can adversely impact lead integrity.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. Unlike implantable cardioverter defibrillators (ICDs), a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. The determination that a lead may be approaching end of service life requires follow-up of the chronically implanted lead and thorough evaluation of lead integrity at ICD replacement.

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/clinic follow-up practice, and Medicare guidelines. In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity:

- Measure pacing and sensing threshold and compare to the chronic baseline. Significant increases or decreases may be indicative of lead failure, dislodgement, perforation, exit block, etc.
- Measure pacing impedance where possible and compare to the chronic baseline. Decreases of 30% or more or pacing impedances below 200-250 ohms may be indicative of insulation failure. Sudden and significant increases in pacing impedance may be indicative of conductor fracture.
- High voltage lead circuit impedance should be between 10-75 ohms at system implant. Chronic measurements below 10 and above 200 ohms may be indicative of high voltage lead circuit failure.
- Carefully review ECGs or the non-sustained detection log on Medtronic ICDs for indications of pacing and/or sensing abnormalities such as oversensing, undersensing, and loss of capture.
- Elicit and investigate any patient complaints/symptoms which may be suggestive of potential lead failure.

Where routine follow-up indicates, additional tools should be used to further evaluate performance. Tools include radiographic data, ICD electrograms, ICD PatientAlert and performance information from the Tachyarrhythmia Chronic Systems Study (TCSS).

continued

General Follow-Up and Replacement of ICD Leads continued

The final decision on the functional integrity and continued use of an implanted lead must be a matter of medical judgment based on these factors as well as specific patient conditions.

General Criteria for Lead Replacement

The evaluation of a chronically implanted lead is an important part of the decision to continue to use the lead with a new ICD. However, these results alone do not necessarily predict the future integrity of that lead. With the expected longevity of today's ICDs varying between approximately 5 and 10 years, a physician replacing a device should consider a number of factors, including those listed below.

Factors which should be considered in a decision to replace or continue to use include:

- Pacing and sensing thresholds should be evaluated for the potential to maintain acceptable levels.
- Pacing impedance should be measured. Bear in mind that pacing impedance below 250 ohms results in excessive battery current drain, which may seriously compromise ICD longevity, regardless of lead integrity.
- The physical appearance of the lead should be examined for insulation cracks, breaches, or other indications of lead wear or degradation.
- Medtronic Chronic Systems data should be referenced. Actuarial survival of the lead and the observed lead failure mechanisms are specific factors to consider. Use of a new lead should be considered if failure mechanisms suggest an increased time dependency as suggested in the shape of performance curve for the specific lead model.
- Current publications may provide additional information on the clinical management of leads.[1,2] Ultimately, the decision to replace an implanted lead involves medical judgment.

[1] Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE*. June 2002;25(6):879-882.

[2] Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol*. January 1, 2003;41(1):73-80.

Clinical Management of High Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T-waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus ICD systems attempt to dynamically adjust sensing of electrical events, and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T- and far field P-waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high voltage therapies. This is due, in part, to the desire to err on the side of delivering life-saving high voltage therapy rather than withholding it. Thus, an ICD system which is experiencing oversensing issues will continue to deliver therapeutic shocks as required, but may also subject the patient to unnecessary shocks.

Oversensing can be difficult to manage, in that the precipitating cause of the oversensing can be problematic to isolate. Oversensing can be caused by many factors, including myopotentials/far field sensing, electromagnetic interference, T-wave sensing, connector issues, incomplete conductor fractures, and insulation breaches. While the individual physician must exercise medical judgment in determination of appropriate clinical management of ICD systems, the chart below may assist in the process of causal factor differentiation and possible intervention.

Phenomenon	Causal Factors	Characteristics	Management/Comments
Myopotentials/ Far Field Sensing	Diaphragmatic muscle potentials in breathing, wide tip-ring (coil on integrated bipolar leads) spacing.	Nonphysiological sensed event on EGM, which may confuse detection potentially resulting in false positive shocks.	Check R-waves for deterioration. Reprogram sensitivity. Try repositioning lead. Consider change-out to true bipolar lead, or if true bipolar lead in use – one with closer tip-ring spacing than current lead.
EMI (Electro-Magnetic Interference)	Arc welders, electrical generators, store walk-through security scanners, poorly insulated electrical equipment.	Multiple and consecutive short intervals (< 140 ms) independent of underlying sinus beats. Associated with proximity to the EMI source.	Avoid EMI areas. True bipolar leads less susceptible.
T-wave Sensing	Drugs, ischemic tissue, exercise, long QT syndrome, electrolyte imbalance.	Sense markers seen on EGM related to T-wave. False positive detection.	Check for R-wave deterioration and characteristics. If R-wave > 3.0 mV reprogram sensitivity. If R-wave < 3.0 mV – reposition/replace lead. Address causal factor (e.g., drugs [if appropriate/medically viable]).
Connector Problems	Loose set screw, cross-threaded set screw, incomplete lead insertion into header.	This is an acute phenomenon seen within 6 months of implant (usually sooner).	Requires invasive check of connections. May be reproducible with pocket manipulation.
Incomplete Conductor Fracture	One or more filars of a multifilar conductor fracturing while leaving enough filars intact to provide a conduction circuit.	Characterized by chaotic oversensing related to motion of the fracture site.	Check EGMs and x-rays. Manipulate lead at suspected fracture site if possible as a provocative test. If confirmed – replace lead.
Lead Insulation Breach	Cuts, tears, metal ion oxidization, abrasion, cold flow, environmental stress cracking.	Characterized by cyclical and/or erratic, intermittent, spontaneous oversensing, often post-pace or post-shock can cause false positives.	Replace lead. If acute, usually secondary to implant damage/ replacement damage. If late – material characteristic.

Technical Services is available at all times to advise clinicians in the troubleshooting and management of Medtronic products. For assistance in the United States, please call 1 (800) 723-4636. In other countries, please contact your local Medtronic representative.

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

Test/Observation	Possible Insulation Failure	Possible Conductor Failure	Possible Other System Failure	Affect on Test/ Observation
Pacing Impedance (Telemetered or Measured Invasively)	Sudden and Significant Decrease	Sudden and Significant Increase	Dislodgement Perforation Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Increase or Decrease Increase or Decrease Increase or Decrease
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase Especially in Bipolar System	Sudden and Significant Increase	Dislodgement Exit Block Infarct at Electrode Site Perforation Improper IPG/Lead Connection	Increase Increase Increase Increase Increase
Electrograms (Telemetered or Measured Invasively)	Sudden and Significant Decrease in Amplitudes and/or Slew Rates for P- and/or R-Waves	Sudden and Significant Decrease or Disappearance of Amplitudes and/or Slew Rates for P- and/or R-Waves	Dislodgement Perforation Infarct at Electrode Site Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Decrease Decrease Decrease Decrease
Waveform Analysis (Oscillographs of Pacer Artifact from ECG Electrodes)	Sudden Increase in Ratios of Leading-Edge Voltages to Trailing-Edge Voltages (i.e., over 25% increase)	Intermittent or No Pacer Artifacts (even in asynchronous mode)	Improper IPG/Lead Connection	Intermittent or No Pacer Artifacts (even in asynchronous mode)
Radiographs (Post-Implant, Recent, Current)	Not Discernible	Visual Observation of Conductor/Connector/ Electrode Fracture (sometimes discernible)	Dislodgement or Perforation Improper IPG/Lead Connection	Sometimes Discernible
Visual Inspection (Invasive)	Insulation Breach and/or Degradation, or Ligature Cut-Through	Not Easily Discernible	Connector Defect or Connector Pulled Apart Improper IPG/Lead Connection	Sometimes Discernible
Pectoral Muscle Stimulation	Sudden Onset Especially in Bipolar System		Connector Defect in Bipolar or Unipolar. Hypersensitivity to Unipolar Pulse Generator Can. Anti-Stim Coating or Protection Deficient	
Phrenic Nerve/ Diaphragmatic Stimulation	Sudden Onset in Bipolar or Unipolar Systems		Perforation or Displacement of Atrial Lead (phrenic nerve)	
Pacemaker ECG Stimulus Artifact Size and Morphology Change (May Not Be Possible with Digital ECG)	Sudden Onset and Significant Change, Especially in Bipolar System (Increase in Size)	Sudden Changes, Usually a Decrease in Size	Perforation or Dislodgement Connector Defect Improper IPG/Lead Connection	Sometimes Discernible
Oversensing (Intermittent or Continuous)	Sudden Onset, Especially in Bipolar Systems		Physical Contact between the Electrode(s) on the Lead and That of Another Lead. Inappropriate IPG parameter setting. Improper IPG/Lead Connection	Sometimes Discernible
Undersensing (Intermittent or Continuous)	Sudden Onset in Either Unipolar or Bipolar Systems	Sudden Onset in Either Unipolar or Bipolar Systems	Dislodgement or Perforation Infarct at Electrode Site Electrolyte Imbalance. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection	Sometimes Discernible
Loss of Capture	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	

Index

By Model Number

By Family

continued

By Family continued

If you are looking for a model number or family that is not included in this report, you may call US Technical Services (see page 2).

The Medtronic Mission

In 1960, Earl Bakken, with the help of the company's board of directors, produced a formal statement of Medtronic's objectives. Nearly a half-century later, the Mission Statement continues to serve as both the ethical and practical framework for Medtronic's operations. It reads as follows:

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.
- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.
- To maintain good citizenship as a company.

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UC200602744 EN

Printed in USA
January 2006