Medtronic

CRDM PRODUCT PERFORMANCE REPORT

Important Patient Management Information for Physicians

2006 Second Edition
Issue 55

A Message from the Vice President

Medtronic Quality

Worldwide, more than 2.4 million people are living with a Medtronic pacemaker or defibrillator. More than 99% of our ICDs have performed as designed at five years or more post-implant. ICD therapy is proven 98% effective in treating life-threatening arrhythmias due to VT and VF. It may be difficult to find another drug or medical intervention that can match this performance record, yet we continue to seek ways to improve all levels of product quality and reliability. For each patient, with each device, quality means everything.

How does Medtronic qualify and test its medical devices to ensure years of precise and sophisticated performance inside a human body? Over 3,100 tests are conducted on each device and its components before implant. We then aggressively track actual performance through clinical studies, system longevity studies, chronic lead studies, and returned product analysis. For the past 23 years, we've measured our product performance and shared this information with physicians. We have continually applied this data to advance and refine our quality and reliability processes. Product design, development, and quality assurance testing have all been advanced through this valuable measurement.

At Medtronic, product quality and reliability has been and will continue to be a priority. This is the 55th report Medtronic has published and distributed since originating the industry's first Product Performance Report in 1983. It has been our mission 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."

Our quality goals cannot be reached without your help. We welcome your collaboration, insight, and recommendations. Please contact me with your feedback, comments, and any questions.

Your participation and assistance in returning explanted products is also critical. Returned product is tested and evaluated so that we can fully measure the performance of our devices. Please contact CRDM Returned Product Quality at 1 (800) 328-2518, extension 48644 or ask your local Medtronic representative to help facilitate the return of explanted Medtronic devices.

Sudden Cardiac Arrest (SCA) is a worldwide killer. Every day, nearly 1,000 people die in the United States alone from SCA. As you know, questions related to quality and reliability of medical devices have increased patient concern, fear, and device refusal, leaving thousands unprotected and at risk of SCA. Please join us in our efforts to increase awareness of this epidemic and share your stories of the lives you have saved through proven and reliable ICD therapy.

With appreciation and warm regards,

Reggie Groves
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Disease Management
Medtronic, Inc.

Contact Information

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

US Technical Services Department

Phone: 1 (800) 723-4636 (Tachy)
1 (800) 505-4636 (Brady)
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International Technical Centers

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For questions related to this CRDM Product Performance Report, please call US Technical Services at the number above, or write to:

Timothy Smith
Medtronic, Inc.
7000 Central Avenue NE MS T135
Minneapolis, MN 55432-3576 USA

email: tim.smith@medtronic.com

For questions related to returning explanted product or returning product that shows signs of malfunction, please contact:

Outside the United States:
Your Metronic representative or international technical center at the number above.

Within the United States:
Your Medtronic representative or

CRDM Returned Product Analysis Laboratory
Medtronic, Inc.
7000 Central Avenue NE MS T172
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Phone: 1 (800) 328-2518, ext. 44800
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Preva®
Prevail®
Prodigy®
Quick Look™
SelectSecure™
Sigma®
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Synergyst™
Target Tip®
Tenax™
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CRDM Product Performance Report

2006 Second Edition

Date cutoff for this edition is
April 1, 2006 for leads and
August 7, 2006 for devices

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

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires

Status Update (August 2006)

In November 2005, Medtronic advised physicians that a specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit.

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections. As of August 22, 2006, 43 devices out of approximately 40,000 devices worldwide (0.10% incidence) have been confirmed as having experienced interconnect wire separation while implanted. Twenty-four (24) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Twenty-five (25) of the 43 devices were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 18 devices were returned with no information indicating a potential malfunction while implanted or with insufficient information to determine the state of the device at explant. Lacking definite information indicating proper operation until explant, these devices are conservatively categorized as having experienced interconnect wire separation while implanted.

Implant duration for the 43 devices confirmed as having experienced interconnect wire separation has ranged between 17 and 50 months, with an average of 38 months.

Out of the initial advisory population of 40,000 worldwide, approximately 25,000 remain implanted. Approximately 5,800 of these are in the United States.

The Patient Management Recommendations set forth in the advisory remain unchanged.

See page 152 for the full advisory text. In the next issue of the Product Performance Report, the advisory status update will be located in the Advisory section of the report.

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

Original Date of Advisory: February 2005

Potential Premature Battery Depletion Due to Battery Short

Status Update (August 2006)

In February 2005, Medtronic advised physicians that 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.

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections. As of August 22, 2006, 38 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. Twenty-six (26) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Of the 38 returns, 16 have been identified by a regularly scheduled follow-up or during a nondevice related hospital visit, 16 by patients reporting warmth in the ICD pocket, 1 by return of bradycardia symptoms, 2 by the PatientAlert sounding, and 3 by hand-held magnet test.

Implant duration for the 38 devices ranged between 11 to 46 months, with an average of 26 months.

Consistent with Medtronic projections, the observed rate of shorting is higher in the second half of device life than in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 59% occurred in the last quarter of device life, and 41% in the last 10% of device life.

Out of the initial advisory population of 87,000 worldwide, approximately 53,000 remain implanted. Approximately 36,000 of these are in the United States.

The Patient Management Recommendations set forth in the advisory remain unchanged.

Warranty

All Marquis devices are subject to a Limited Warranty. Devices returned to Medtronic and determined to be malfunctioning will be replaced or credited in accordance with the warranty terms. In addition, for devices subject to the Marquis advisory, should a physician decide to replace a device for a patient who is pacemaker dependent or who receives frequent VT/VF therapy, Medtronic will, upon receipt of a written statement from the physician setting forth the basis for early replacement of the device, provide a replacement device at no cost.

See page 153 for the full advisory text. In the next issue of the Product Performance Report, the advisory status update will be located in the Advisory section of the report.

Introduction

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

This Product Performance Report (PPR) presents device survival estimates, advisory summaries, performance notes, and other information pertinent to assessing the performance of Medtronic implantable pulse generators (IPGs), implantable cardioverter defibrillators (ICDs), Cardiac Resynchronization Therapy (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

Medtronic CRDM uses both returned product analysis and multicenter clinical studies to monitor performance.

Medtronic, like other companies, monitors IPG, ICD, and CRT device performance using returned product analysis. We also monitor device performance using an active multicenter clinical study. Medtronic CRDM 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 devices are based on returned product analysis. This approach is suitable because a significant number of explanted generators are returned for analysis.

Lead performance is monitored differently. In contrast to devices, 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 leads are based on clinical observations recorded via Medtronic CRDM's System Longevity Study. This multicenter clinical study is 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.

The actuarial life table method is applied to the data collected for both devices and leads to provide the survival estimates included in this report. A general introduction to understanding this method of survival analysis is given later in this introduction.

The survival estimates for the IPG, ICD, and CRT devices are based on data available as of August 7, 2006. The survival estimates for leads are based on data available as of April 1, 2006. The cutoff dates for leads is different than the cutoff date for devices because of different data gathering processes between the active clinical study (for leads) and returned product analysis (for devices).

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 System Longevity Study.

Advisory Summaries

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.

Performance Notes

This report concludes with a number of Performance Notes developed by Medtronic to provide additional product performance information relevant to follow-up practice and patient management.

continued

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 or removal from use.

How You Can Help

Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of the reason for explant or removal from use. The procedures for returning product vary by geographic location.

Mailer kits with prepaid US postage are available for use within the United States to send CRTs, ICDs, IPGs, and leads to Medtronic's CRDM Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet postal regulations for mailing biohazard materials.

If the product being returned is located outside the United States, please contact your local Medtronic representative for instructions.

Medtronic also requests the return of devices from non-clinical sources such as funeral homes, and will assume responsibility for storage and disposal of the product once received. For return of larger quantities of explanted products than the mailer can accommodate, Medtronic has handling and shipping guidelines available upon request.

Both mailers and guidelines can be requested by contacting the Returned Product Lab. For information on how to contact the Lab, refer to Contact Information on page 2 of this report.

We continually strive to improve this CRDM 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. For information on how to comment on this report, see Contact Information on page 2 of this report.

Overview of Survival Analysis

Medtronic uses the Cutler-Ederer actuarial life table method to estimate the length of time over which ICDs, IPGs, and leads will perform within performance limits established by Medtronic. This probability to perform within performance limits over time is called the *survival probability.*

Devices and leads are followed until an *event* occurs where the device ceases to operate within performance limits. The length of time from implant to the event is recorded for each individual device in the *population sample.* The population sample for IPGs and ICDs is made up of patients whose devices are registered as implanted in the United States. For leads, the population sample is the patients enrolled in the System Longevity Study.

For IPGs and ICDs, the events can be normal battery depletion or a device malfunction. For leads, the events are complications as defined for the study.

The actuarial life table method allows Medtronic to account for devices and leads removed from service for reasons unrelated to performance. Devices and leads removed for these reasons are said to be *suspended.* Examples include IPGs, ICDs, and leads:

- still in service at the time the analysis is performed
- removed to upgrade the device or lead
- no longer in service due to the death of the patient for reasons unrelated to the device or leads, or
- implanted in patients who are lost to follow-up.

For each suspension, the device or lead has performed within performance limits for a period of time, after which its performance is unknown.

An Example

The following example describes the survival analysis method used to establish the survival probability estimates for Medtronic CRDM devices and leads. The example is intended to provide an overview of the analysis process. The definitions of malfunctions and complications, and other details specific to calculating device and lead survival estimates, are provided in the articles *Method for Estimating ICD and Pulse Generator Performance (page 10)* and *Method for Estimating Lead Performance (page 76).*

continued

This simple example describes the survival analysis method used to establish the survival probability estimates for Medtronic CRDM devices and leads.

Figure 1

Implant times for devices of 16 patients. Gray bars with an orange X indicate devices removed from service due to an event. Blue bars indicate suspended devices.

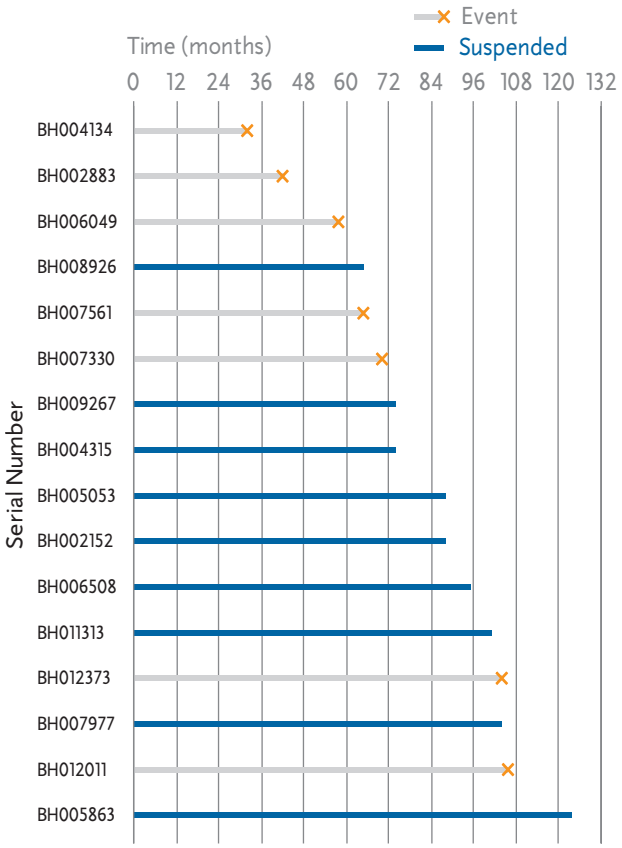


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because it was still in service at the time of the analysis. This patient had 66 months of implant experience. In this example, Figure 1 shows that 7 of the 16 devices suffered events, and 9 are suspended.

The first step in the life table method is to divide the implant time into intervals of a specific length. This example will use 12-month intervals.

The number of devices entered, suspended, and removed due to an event are counted and summarized as shown in Table 1. For the first two intervals, all 16 devices survived and none were removed. In the interval (24-36 months), device BH004134 was removed due to an event. Therefore the table entries show that 16 entered the interval, none were suspended, and one was removed due to an event.

For interval from 36-48 months, only 15 devices entered the interval and one was removed for an event. The remaining intervals are examined and the data entered in columns A, B, and C in like manner. The rest of the columns are filled in using calculations on the data in columns A, B, and C.

The *Effective Sample Size* (D) is the number of devices with full opportunity to experience a qualifying event in the interval. This is computed by subtracting one half the number suspended in the interval from the number that entered the interval. This calculation more accurately reflects the number of devices that could have experienced a qualifying event than simply using the number that entered the interval. Using the number of devices that enter an interval over-estimates the sample size because the suspended devices do not complete the interval. Ignoring the suspended devices under-estimates the sample size because suspended devices are not credited with their full service time. Using one half the number of suspended devices effectively splits the difference.

The next column in the table is the *Proportion with Event* (E). This is the proportion of devices that had an event in the interval. It is calculated by dividing the *Number of Events* (C) by the *Effective Sample Size* (D). The number can be interpreted as the estimated rate at which events occur in the time interval.

The *Interval Survival Probability* (F) is the estimate of probability of surviving to the end of the interval assuming the device was working at the beginning of the interval. It is calculated as 1 minus the *Proportion With Event* (E). This number can be interpreted as the estimated rate at which events **do not** occur in the time interval.

continued

The Cumulative Survival Probabilities from (G) the last column of the life table can be plotted versus time intervals in the first column to give a survival curve. Figure 2 shows the survival curve for the data shown in Table 1.

Table 1 Life Table for Figure 1

	A	B	C	D	E	F	G
Interval in Months	Number Entered	Number Suspended	Number of Events	Effective Sample Size	Proportion with Event	Interval Survival Probability	Cumulative Survival Probability
0	16	0	0	16	0.000	1.000	1.000
0–12	16	0	0	16	0.000	1.000	1.000
12–24	16	0	0	16	0.000	1.000	1.000
24–36	16	0	1	16	0.063	0.938	0.938
36–48	15	0	1	15	0.067	0.933	0.875
48–60	14	0	1	14	0.071	0.929	0.813
60–72	13	1	2	12.5	0.160	0.840	0.683
72–84	10	2	0	9	0.000	1.000	0.683
84–96	8	3	0	6.5	0.000	1.000	0.683
96–108	5	2	2	4	0.500	0.500	0.341
108–120	1	0	0	1	0.000	1.000	0.341
120–132	1	1	0	0.5	0.000	1.000	0.341

Definitions:

A
Number Entered

Number of devices active at the start of the interval

B
Number Suspended

Number of devices removed from service for reasons other than an event

C
Number of Events

Number of units removed from service due to an event

D
Effective Sample Size

Number of units with full opportunity to experience a qualifying event in the interval. Computed by subtracting one half the Number Suspended from the Number Entered

E
Proportion with Event

Proportion of devices that had an event in the interval. Computed by dividing the Number of Events by the Effective Sample Size

F
Interval Survival Probability

The probability of surviving to the end of the interval, assuming the device was working at the beginning of the interval. Computed as 1 minus the Proportion With Event

G
Cumulative Survival Probability

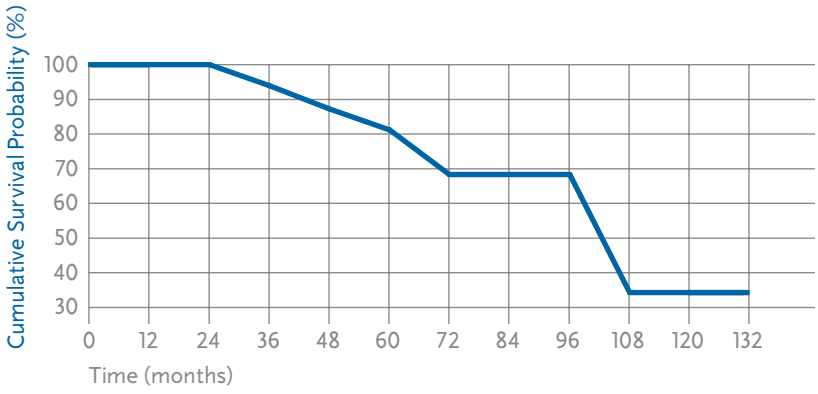
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability

Cumulative Survival Probability (G) is the estimate of the unconditional probability of surviving to the end of the interval. It is computed by multiplying the *Interval Survival Probability* (F) by the previous interval's Cumulative Survival Probability. The probability of surviving to 132 months in the example is estimated for the table to be 0.341, or 34.1%.

The *Cumulative Survival Probabilities* (G) of the life table can be plotted versus time intervals in the first column to give a survival curve. Figure 2 shows the survival curve for the data in Table 1.

continued

Figure 2 Survival Curve for Data Given in Table 1



	0	12	24	36	48	60	72	84	96	108	120	132
%	100	100	100	93.8	87.5	81.3	68.3	68.3	68.3	34.1	34.1	34.1
#	16	16	16	16	15	14	12.5	9	6.5	4	1	0.5

Effective Sample Size

Confidence Intervals

Since survival curves are based on a sample of the device and lead population, they are only estimates of survival. Generally, the larger the effective sample size, the more confident the estimate. A confidence interval can be calculated to assess the confidence in an estimate. In the Product Performance Report, Medtronic provides a 95% confidence interval. This can be interpreted as meaning that 95% of the time, the true survival of the device will fall somewhere in the interval.

Survival Curves in the Product Performance Report

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for IPGs and ICDs, and when the number entered is less than 50 for leads.
The survival charts in the Product Performance Report show the effective sample size for each year interval where Medtronic has experience. When the effective sample size reaches 100 for IPGs and ICDs or when the number entered reaches 50 for leads, the next data point is added to the survival curve.

Although the report provides tabular data in one year intervals, the curves are actually computed and plotted using one-month intervals (for IPGs and ICDs) or three-month intervals (for leads).

A number of references are available for additional information on survival analysis using the Cutler-Ederer life table method.[1]

[1] Lee, Elisa T.(2003) Statistical Methods for Survival Data Analysis – 3rd Edition (Wiley Series in Probability and Statistics)

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 or removal from use.

The performance of CRT, ICD and IPG devices is expressed in terms of device survival estimates, where "survival" refers to the 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 with neither malfunction nor battery depletion.

The survival estimates are determined from the analysis of Medtronic CRDM'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, the performance data does not reflect any device-related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition.

Categorization of Depleted and Malfunctioning Devices for Survival Analysis

For survival estimation, every device returned to Medtronic CRDM and analyzed in the CRDM 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 CRDM 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. To be considered a malfunction or battery depletion, the device must have been returned to Medtronic and analyzed.

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 CRDM and found, through analysis, to actually have performed 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.

To provide insight into the nature of malfunctions, each malfunction is categorized as Malfunction with Compromised Therapy Function or Malfunction without Compromised Therapy Function. 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 CRDM 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

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 experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate a 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 CRDM 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 assumed distributed across the intervals (Cutler-Ederer Method), is used to determine estimates of IPG and ICD survival. This method is commonly used by medical researchers and clinicians.

Implant times are calculated from the implant date to the earlier of the explant date or the cutoff date of the report. From this data an estimate of the probability of device survival is calculated at each monthly interval.

On the following pages, each graph includes an all-cause survival curve, where events include malfunctions and battery depletions. The all-cause survival is a good representation of the probability a device will survive a period of time without malfunction and without 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 battery depletion or malfunction in the first five years following implant.

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 includes only malfunctions as events and excludes normal battery depletion.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the effective sample size is less than 100 for CRT, IPG, and ICD devices. The survival charts in the Product Performance Report show the effective sample size for each year interval where we have experience. When the effective sample size reaches 100, the next data point is added to the survival curve.

continued

Medtronic CRDM 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.

Although the report provides tabular data in one-year intervals, the curves are actually computed and plotted using one-month intervals.

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 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 US 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.

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.

Methods Used to Adjust for Underreporting of Malfunction and Battery Depletion

The tables on the following pages show the actual number of malfunctions and battery depletions recorded by the analysis lab for US registered devices. Since not all devices are returned to Medtronic CRDM for analysis, these numbers underestimate the true number of malfunctions and battery depletions. To more accurately estimate the all-cause device survival probabilities, the number of malfunctions and battery depletions used to plot each interval of the all-cause survival curves is adjusted (multiplied) by a factor that is based on an estimate of the magnitude of underreporting. The magnitude of underreporting is estimated by analyzing experience in clinical studies (including the System Longevity Study) and the 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 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.

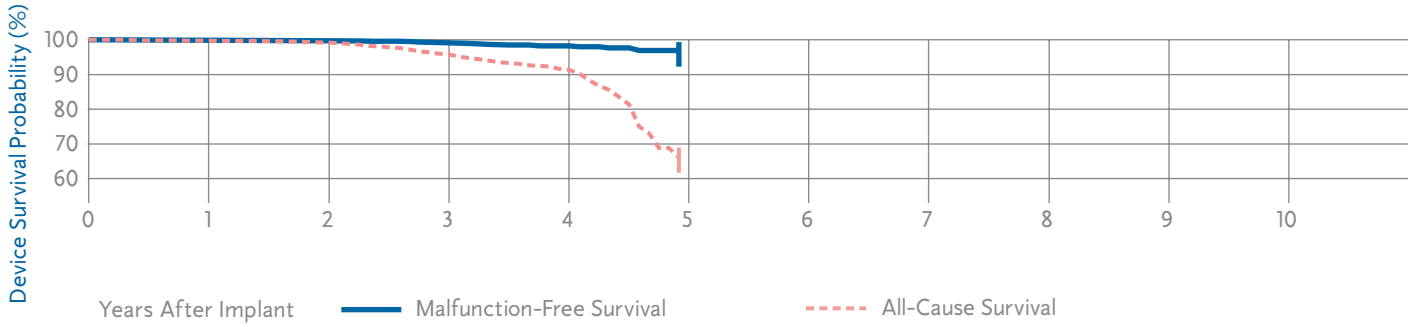
To ensure the number of devices in service is not overstated, the patient mortality rate derived from our device registration system is monitored and compared to published mortality rates for comparable patient populations. If, during calculation of the survival curves, the patient mortality indicated 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	6,000
Normal Battery Depletions	182
Malfunctions	116
Therapy Function Not Compromised	103
Therapy Function Compromised	13
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PJP
Max Delivered Energy	34 J
Estimated Longevity	See page 34



	1 yr	2 yr	3 yr	4 yr	at 59 mo
%	99.9	99.8	99.2	98.3	96.9
%	99.8	99.2	95.8	91.3	66.1
#	11,000	9,000	7,000	400	100

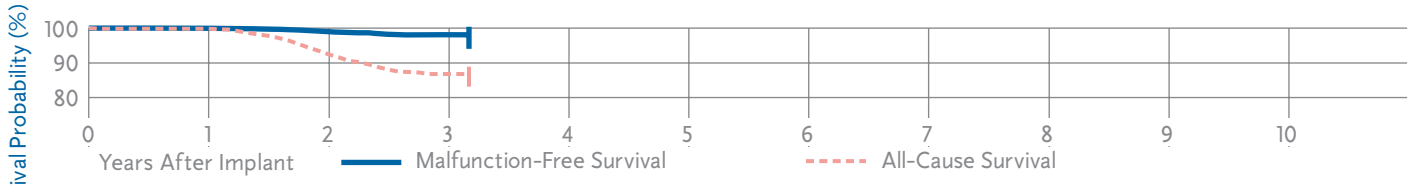
Effective Sample Size

7277 InSync Marquis

US Market Release	Mar-03
Registered US Implants	7,000
Estimated Active US Implants	2,000
Normal Battery Depletions	174
Malfunctions	65 (6 related to advisory)
Therapy Function Not Compromised	58 (0 related to advisory)
Therapy Function Compromised	7 (6 related to advisory)
Advisories	1 see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PLT
Max Delivered Energy	30 J
Estimated Longevity	See page 34



	1 yr	2 yr	3 yr	at 38 mo
%	100.0	99.0	98.1	98.1
%	99.9	92.4	86.8	86.8
#	6,000	3,000	1,000	100

Effective Sample Size

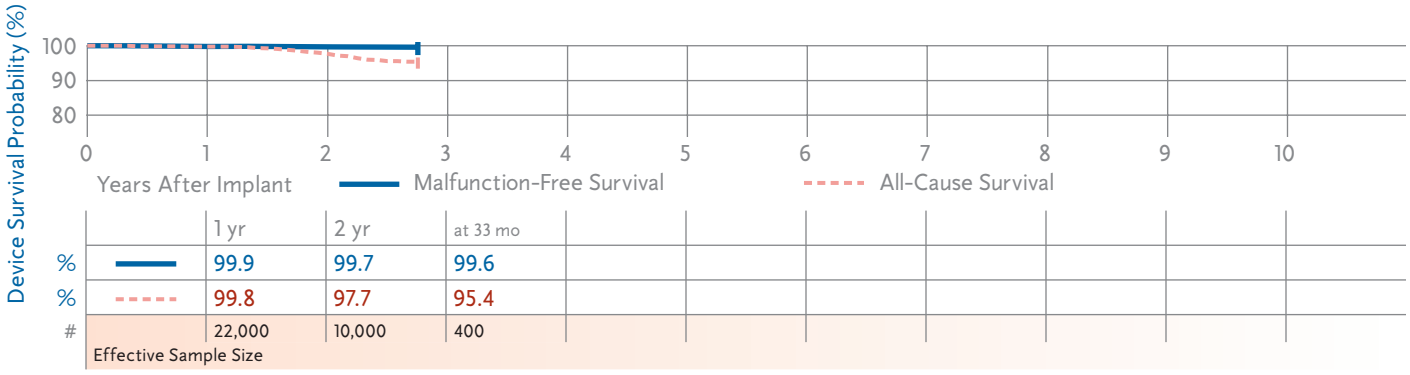
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7289 InSync II Marquis

US Market Release	Jul-03
Registered US Implants	27,000
Estimated Active US Implants	17,000
Normal Battery Depletions	174
Malfunctions	54 (3 related to advisory)
Therapy Function Not Compromised	36 (0 related to advisory)
Therapy Function Compromised	18 (3 related to advisory)
Advisories	1 see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PRJ
Max Delivered Energy	30 J
Estimated Longevity	See page 35



	1 yr	2 yr	at 33 mo
%	99.9	99.7	99.6
%	99.8	97.7	95.4
#	22,000	10,000	400

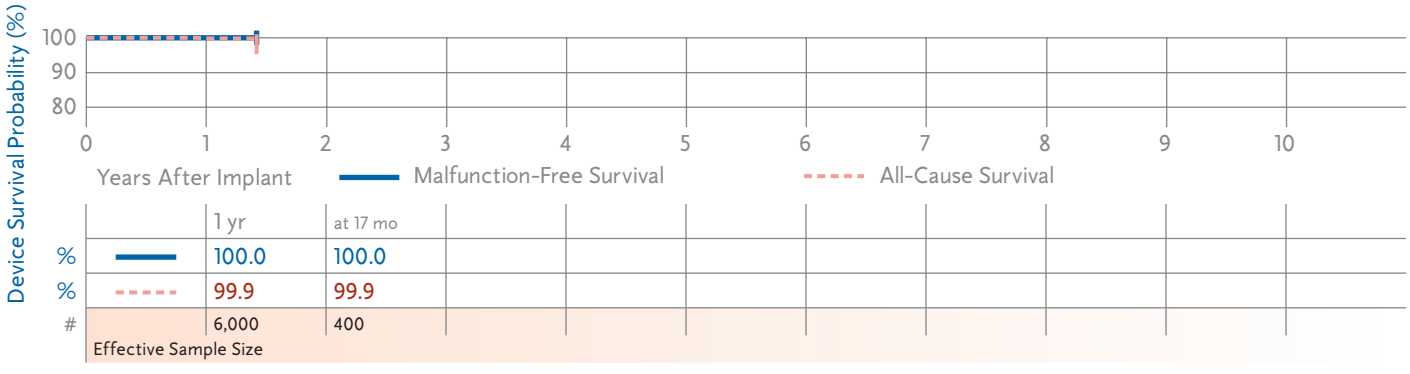
Effective Sample Size

7297 InSync Sentry

US Market Release	Nov-04
Registered US Implants	9,000
Estimated Active US Implants	7,000
Normal Battery Depletions	2
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 35



	1 yr	at 17 mo
%	100.0	100.0
%	99.9	99.9
#	6,000	400

Effective Sample Size

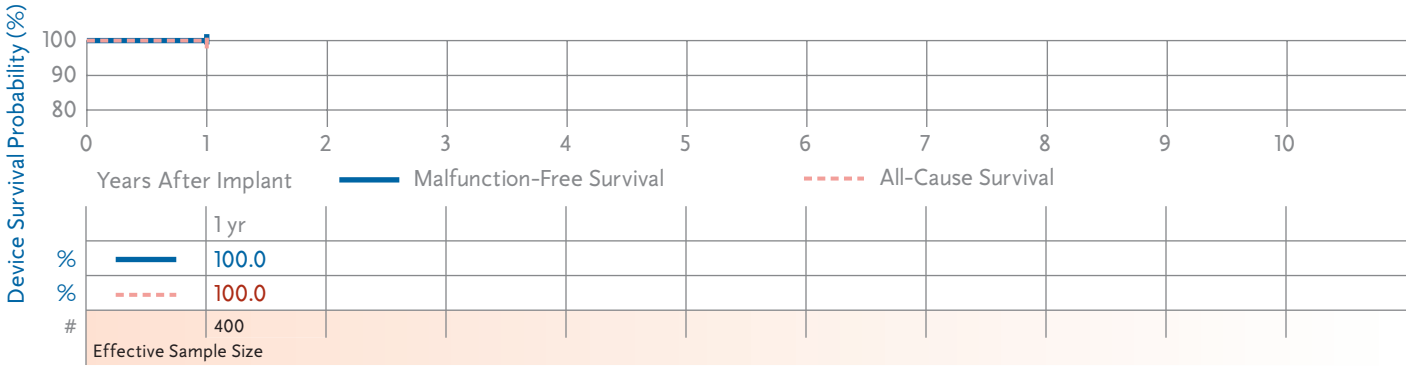
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7299 InSync Sentry

US Market Release	Apr-05
Registered US Implants	20,000
Estimated Active US Implants	19,000
Normal Battery Depletions	1
Malfunctions	2
Therapy Function Not Compromised	2
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 35



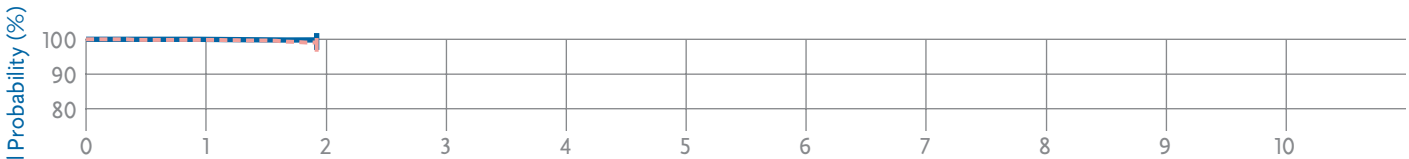
		1 yr
%	Malfunction-Free Survival	100.0
%	All-Cause Survival	100.0
#	Effective Sample Size	400

7303 InSync Maximo

US Market Release	Jun-04
Registered US Implants	17,000
Estimated Active US Implants	14,000
Normal Battery Depletions	13
Malfunctions	11
Therapy Function Not Compromised	8
Therapy Function Compromised	3
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 35



		1 yr	at 23 mo
%	Malfunction-Free Survival	100.0	99.9
%	All-Cause Survival	99.9	99.1
#	Effective Sample Size	13,000	300

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7304 InSync Maximo

US Market Release	Apr-05
Registered US Implants	11,000
Estimated Active US Implants	10,000
Normal Battery Depletions	1
Malfunctions	2
Therapy Function Not Compromised	1
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 35

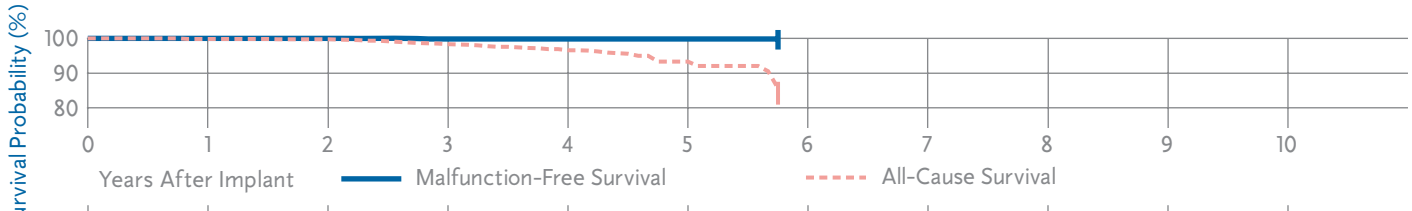
	1 yr	at 13 mo
%	100.0	100.0
%	99.9	99.9
#	1,000	100
Effective Sample Size		

8040 InSync

US Market Release	Aug-01
Registered US Implants	15,000
Estimated Active US Implants	6,000
Normal Battery Depletions	133
Malfunctions	11
Therapy Function Not Compromised	5
Therapy Function Compromised	6
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/X-ray ID	PIN
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.8	98.4	96.6	93.3	85.6
#	12,000	10,000	8,000	3,000	200	100
Effective Sample Size						

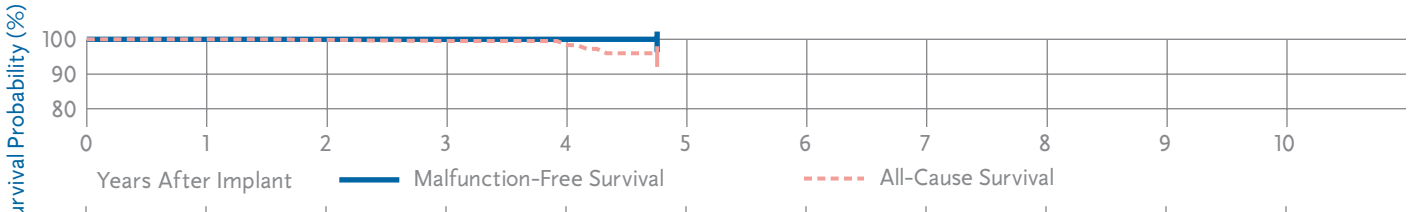
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	19,000
Estimated Active US Implants	13,000
Normal Battery Depletions	16
Malfunctions	2
Therapy Function Not Compromised	1
Therapy Function Compromised	1
Advisories	None

NBG Code	DDDR
Serial Number Prefix/X-ray ID	PKF
Estimated Longevity	See page 72



		1 yr	2 yr	3 yr	4 yr	at 57 mo
%	Malfunction-Free Survival	100.0	100.0	100.0	100.0	100.0
%	All-Cause Survival	100.0	99.9	99.5	98.4	96.0
#	Effective Sample Size	13,000	8,000	2,000	200	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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 Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
7272	InSync ICD	Jul-02	13,000	6,000	182	13	103	116	Malfunction-free	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.2 +0.2/-0.2	98.3 +0.3/-0.4	96.9 +1.2/-1.8 at 59 mo	
									All-cause	99.8 +0.1/-0.1	99.2 +0.2/-0.2	95.8 +0.4/-0.5	91.3 +1.0/-1.2	66.1 +5.3/-6.0 at 59 mo	
7277	InSync Marquis	Mar-03	7,000	2,000	174	7	58	65	Malfunction-free	100.0 +0.0/-0.1	99.0 +0.3/-0.4	98.1 +0.4/-0.5	98.1 +0.4/-0.5 at 38 mo		
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(6) (advisory-related subset)	(0)	(6)	All-cause	99.9 +0.1/-0.1	92.4 +0.8/-0.8	86.8 +1.1/-1.2	86.8 +1.1/-1.2 at 38 mo		
7289	InSync II Marquis	Jul-03	27,000	17,000	174	18	36	54	Malfunction-free	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.6 +0.1/-0.1 at 33 mo			
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(3) (advisory-related subset)	(0)	(3)	All-cause	99.8 +0.0/-0.1	97.7 +0.2/-0.3	95.4 +0.6/-0.6 at 33 mo			
7297	InSync Sentry	Nov-04	9,000	7,000	2	1	0	1	Malfunction-free	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 17 mo				
									All-cause	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 17 mo				
7299	InSync Sentry	Apr-05	20,000	19,000	1	0	2	2	Malfunction-free	100.0 +0.0/-0.0					
									All-cause	100.0 +0.0/-0.1					
7303	InSync Maximo	Jun-04	17,000	14,000	13	3	8	11	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.1/-0.1 at 23 mo				
									All-cause	99.9 +0.0/-0.1	99.1 +0.3/-0.5 at 23 mo				
7304	InSync Maximo	Apr-05	11,000	10,000	1	1	1	2	Malfunction-free	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 13 mo				
									All-cause	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 13 mo				
8040	InSync	Aug-01	15,000	6,000	133	6	5	11	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 69 mo
									All-cause	99.9 +0.0/-0.1	99.8 +0.1/-0.1	98.4 +0.2/-0.3	96.69 +0.4/-0.5	93.3 +1.6/-2.1	85.6 +4.2/-5.7 at 69 mo
8042	InSync III	Feb-03	19,000	13,000	16	1	1	2	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 57 mo	
									All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.5 +0.2/-0.3	98.4 +1.0/-2.4	96.0 +2.0/-3.9 at 57 mo	

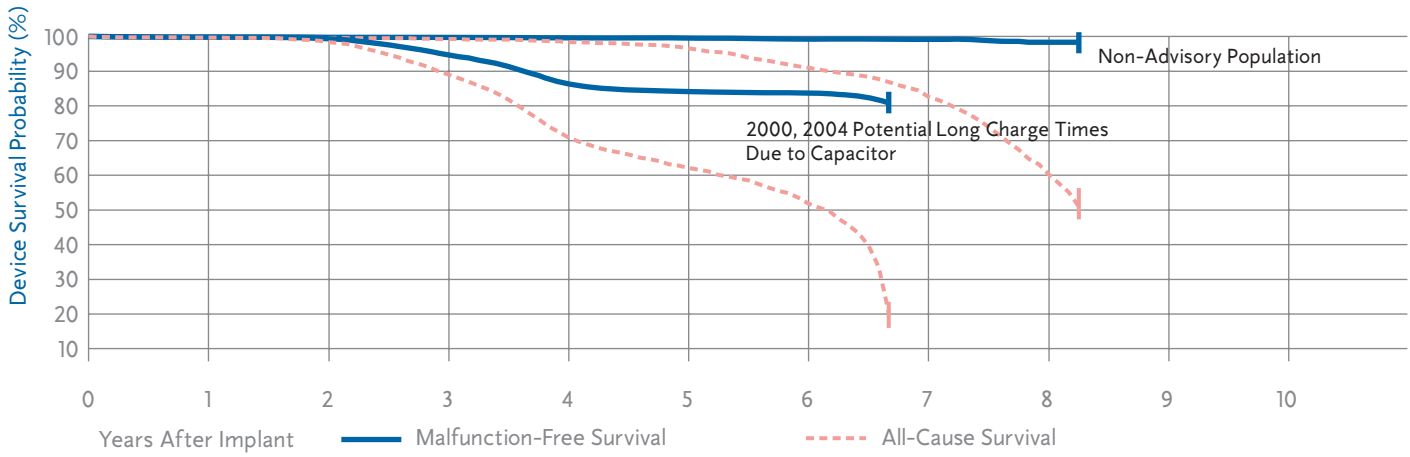
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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	589	497
Malfunctions	65	1,292
Advisories	2	see page 159 – 2000 Potential Long Charge Times Due to Capacitor see page 154 – 2004 Potential Long Charge Times Due to Capacitor – Supplement

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/X-ray ID	PFR
Max Delivered Energy	30 J
Estimated Longevity	See page 34



Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.9	99.8	99.7	99.6	99.6	99.3	99.2	98.4	98.4
%	99.8	99.6	99.3	98.4	96.6	91.0	82.6	60.2	51.0
#	9,000	8,000	7,000	6,000	5,000	4,000	3,000	1,000	100

Effective Sample Size

Adv Pop	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	99.9	99.3	94.7	86.3	84.1	83.7	80.9
%	99.7	98.4	89.0	70.8	62.1	51.8	20.4
#	10,000	9,000	7,000	4,000	2,000	1,000	100

Effective Sample Size

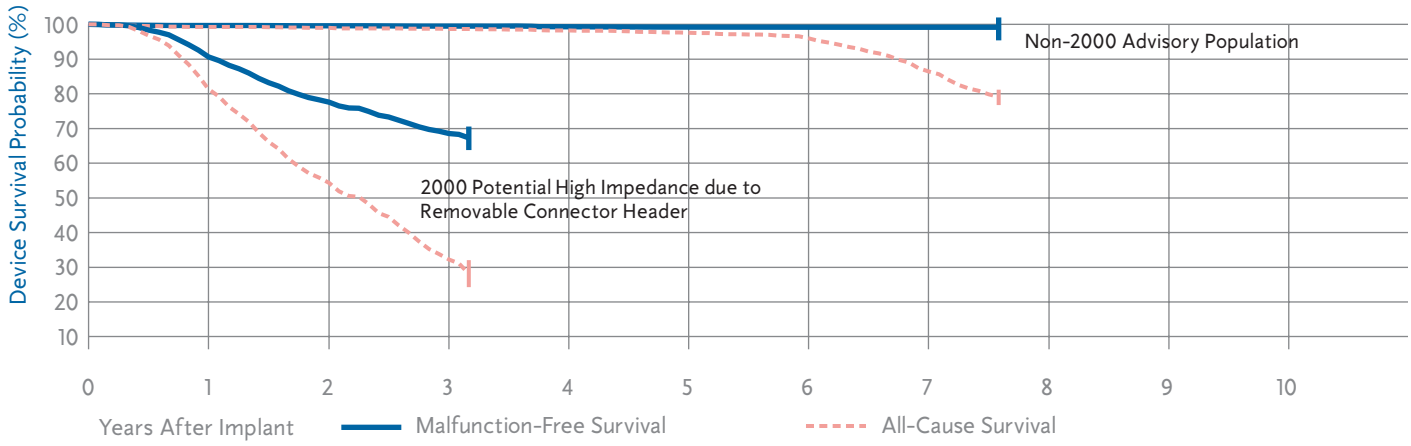
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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	9,000	0
Normal Battery Depletions	315	2
Malfunctions	131	304
Advisories	3	see page 162 – 1999 Potential Circuit Overload see page 164 – 1999 Potential High Current Drain see page 158 – 2000 Potential High Impedance Due to Removable Connector Header

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/X-ray ID	PIP, PLN, PLP, PLR
Max Delivered Energy	35 J
Estimated Longevity	See page 34



Non-2000	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 91 mo
%	99.7	99.6	99.5	99.4	99.2	99.2	99.2	99.2
%	99.3	99.0	98.7	98.3	97.6	96.0	86.5	79.1
#	20,000	17,000	15,000	11,000	8,000	5,000	2,000	200

Effective Sample Size

2000 Adv	1 yr	2 yr	3 yr	at 38 mo
%	90.7	77.6	68.6	67.3
%	81.4	54.3	32.2	28.1
#	1,000	400	100	100

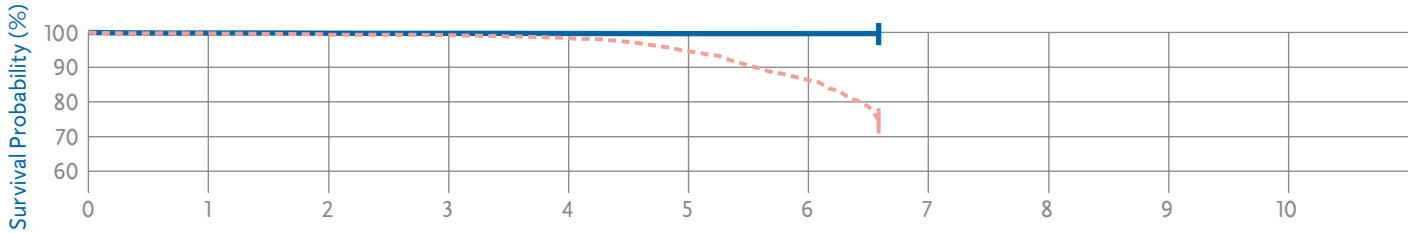
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7229 GEM II VR

Product Characteristics

US Market Release	Jul-99	NBD Code	VVEV
Registered US Implants	11,000	Serial Number Prefix/X-ray ID	PJJ
Estimated Active US Implants	4,000	Max Delivered Energy	30 J
Normal Battery Depletions	331	Estimated Longevity	See page 34
Malfunctions	24		
Advisories	2	see page 160 – 2000 Potential Weak Solder Connection see page 162 – 1999 Potential Circuit Overload also see page 174 – Performance note on ICD Battery Discharge Behavior	



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 79 mo
%	99.9	99.8	99.8	99.7	99.7	99.7	99.7
%	99.8	99.4	99.3	98.4	94.6	86.3	74.8
#	9,000	8,000	7,000	6,000	5,000	2,000	100

Effective Sample Size

7230 Marquis VR

Product Characteristics

US Market Release	Dec-02	NBD Code	VVEV
Registered US Implants	19,000	Serial Number Prefix/X-ray ID	PKD, PLW, PLY
Estimated Active US Implants	12,000	Max Delivered Energy	30 J
Normal Battery Depletions	6	Estimated Longevity	See page 34
Malfunctions	17 (0 related to advisory)		
Therapy Function Not Compromised	12 (0 related to advisory)		
Therapy Function Compromised	5 (0 related to advisory)		
Advisories	1	see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short	

	1 yr	2 yr	3 yr	at 42 mo
%	100.0	99.9	99.8	99.8
%	99.9	99.7	99.6	99.6
#	17,000	9,000	2,000	100

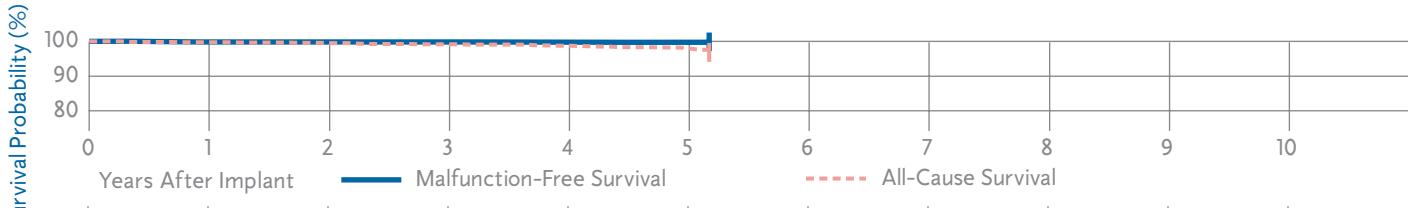
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7231 GEM III VR

Product Characteristics

US Market Release	Dec-00	NBD Code	VVEV
Registered US Implants	17,000	Serial Number Prefix/X-ray ID	PJL
Estimated Active US Implants	11,000	Max Delivered Energy	30 J
Normal Battery Depletions	56	Estimated Longevity	See page 34
Malfunctions	21		
Therapy Function Not Compromised	15		
Therapy Function Compromised	6		
Advisories	None see page 174 – Technical article on ICD Battery Discharge Behavior		



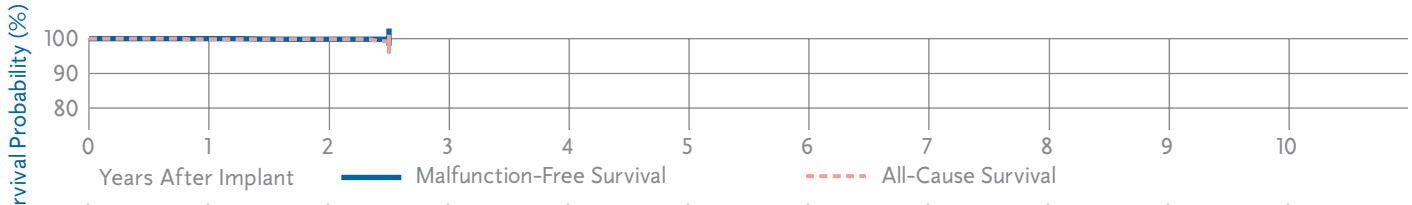
	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	99.9	99.9	99.9	99.8	99.8	99.8
%	99.8	99.5	99.2	98.8	98.0	97.6
#	14,000	12,000	10,000	5,000	1,000	300

Effective Sample Size

7232 Maximo VR

Product Characteristics

US Market Release	Oct-03	NBD Code	VVED
Registered US Implants	32,000	Serial Number Prefix/X-ray ID	PRN
Estimated Active US Implants	28,000	Max Delivered Energy	35 J
Normal Battery Depletions	3	Estimated Longevity	See page 34
Malfunctions	8 (0 related to advisory)		
Therapy Function Not Compromised	5 (0 related to advisory)		
Therapy Function Compromised	3 (0 related to advisory)		
Advisories	1 see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short		



	1 yr	2 yr	at 30 mo
%	100.0	99.9	99.9
%	99.9	99.9	99.3
#	15,000	2,000	200

Effective Sample Size

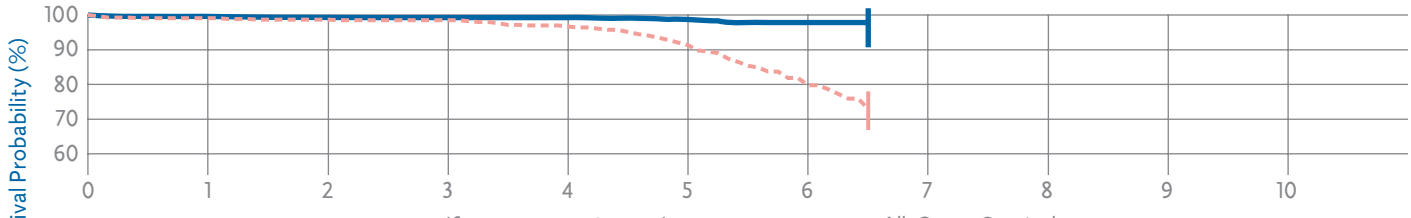
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7250 Jewel AF

US Market Release	Jun-00
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	56
Malfunctions	16
Advisories	None

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PID
Max Delivered Energy	27 J
Estimated Longevity	See page 34



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	Malfunction-Free Survival	99.6	99.4	99.3	99.3	98.8	97.9	97.9
%	All-Cause Survival	99.1	98.7	98.5	96.7	91.3	79.8	72.9
#	Effective Sample Size	1,000	1,000	1,000	1,000	1,000	200	100

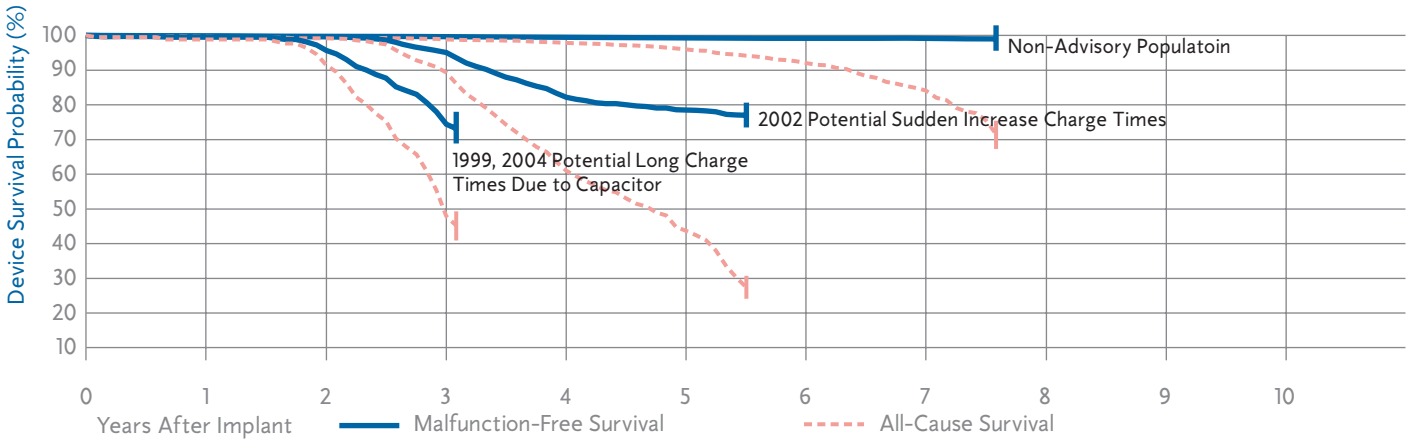
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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	6,000	2	0
Normal Battery Depletions	283	168	17
Malfunctions	73	501	112
Advisories		3	see page 156 – 2002 Potential Sudden Increase in Charge Times see page 161 – 1999 Potential Long Charge Times Due to Capacitor see page 154 – 2004 Potential Long Charge Times Due to Capacitor – Supplement

Product Characteristics

NBD Code	VVED
Serial Number Prefix/X-ray ID	PIM
Max Delivered Energy	35 J
Estimated Longevity	See page 34



Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 91 mo
%	99.9	99.8	99.7	99.5	99.3	99.2	99.2	99.0
%	99.7	99.5	98.9	97.9	96.0	92.1	84.1	71.6
#	13,000	12,000	10,000	7,000	5,000	3,000	1,000	100
Effective Sample Size								

2002 Adv	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	99.9	99.6	95.1	82.2	78.5	77.0
%	99.7	99.2	89.3	61.0	43.7	27.4
#	3,000	3,000	2,000	1,000	400	100
Effective Sample Size						

1999, 2004 Adv	1 yr	2 yr	3 yr	at 37 mo
%	99.5	95.7	74.4	73.2
%	98.9	91.4	47.9	45.2
#	300	300	100	100
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

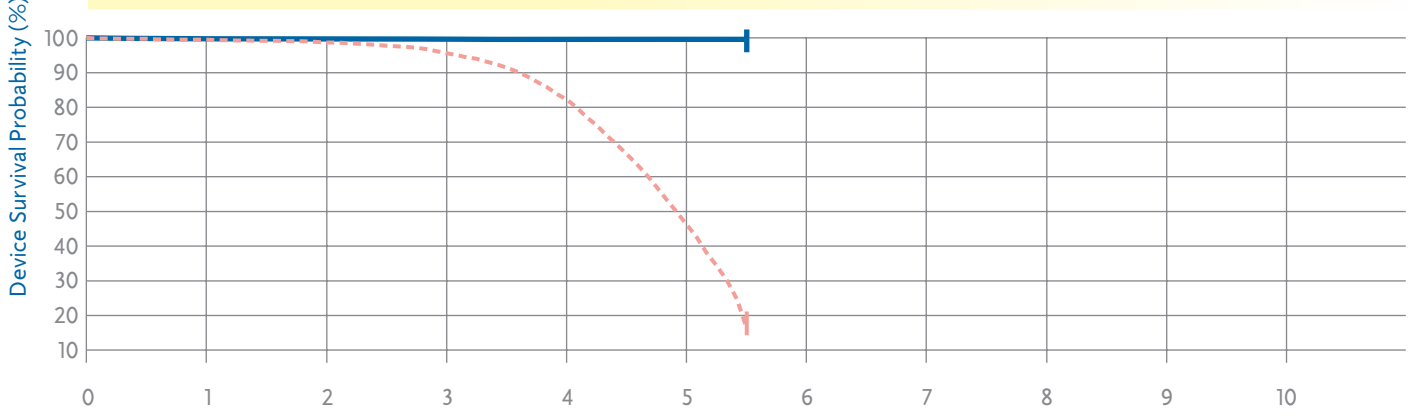
7273 GEM II DR

Product Characteristics

US Market Release	Feb-99
Registered US Implants	15,000
Estimated Active US Implants	200
Normal Battery Depletions	2,065
Malfunctions	52

NBD Code	VVED
Serial Number Prefix/X-ray ID	PJK
Max Delivered Energy	30 J
Estimated Longevity	See page 34

Advisories	1 see page 160 – 2000 Potential Weak Solder Connection also see page 174 – Performance note on ICD Battery Discharge Behavior



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
% Malfunction-Free Survival	99.8	99.7	99.6	99.6	99.6	99.6
% All-Cause Survival	99.5	98.7	95.6	82.3	46.3	16.2
# Effective Sample Size	13,000	12,000	9,000	6,000	2,000	200

7274 Marquis DR

Product Characteristics

US Market Release	Mar-02
Registered US Implants	48,000
Estimated Active US Implants	26,000
Normal Battery Depletions	142
Malfunctions	87 (17 related to advisory)
Therapy Function Not Compromised	46 (1 related to advisory)
Therapy Function Compromised	41 (16 related to advisory)

NBD Code	VVED
Serial Number Prefix/X-ray ID	PKC
Max Delivered Energy	30 J
Estimated Longevity	See page 34

Advisories	1 see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short

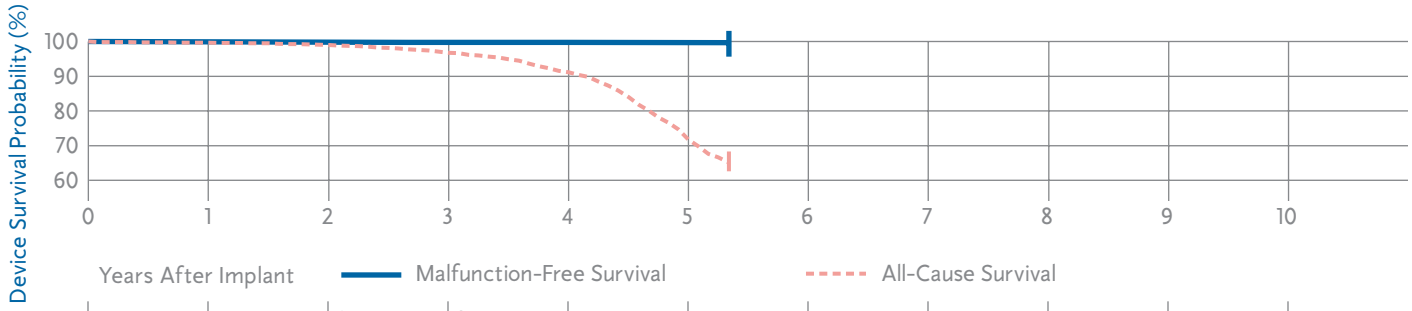
	1 yr	2 yr	3 yr	4 yr	at 51 mo
% Malfunction-Free Survival	100.0	99.9	99.7	99.5	99.5
% All-Cause Survival	99.8	99.6	98.3	96.6	96.6
# Effective Sample Size	42,000	28,000	11,000	1,000	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7275 GEM III DR

Product Characteristics

US Market Release	Nov-00	NBD Code	VVED
Registered US Implants	20,000	Serial Number Prefix/X-ray ID	PJM
Estimated Active US Implants	9,000	Max Delivered Energy	30 J
Normal Battery Depletions	810	Estimated Longevity	See page 34
Malfunctions	34		
Therapy Function Not Compromised	24		
Therapy Function Compromised	10		
Advisories	None see page 174 – Performance note on ICD Battery Discharge Behavior		



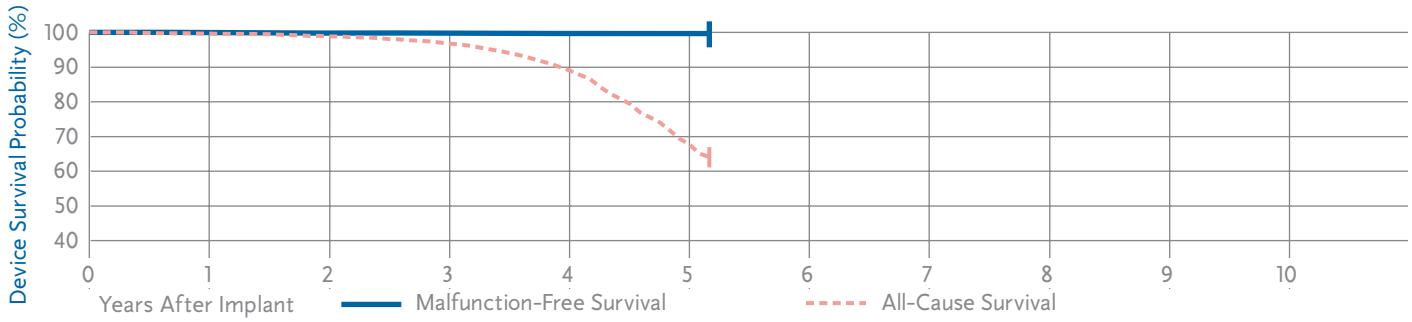
	1 yr	2 yr	3 yr	4 yr	5 yr	at 64 mo
%	99.9	99.9	99.8	99.8	99.7	99.7
%	99.7	99.0	96.8	91.2	71.7	65.1
#	17,000	14,000	11,000	7,000	1,000	200

Effective Sample Size

7276 GEM III AT

Product Characteristics

US Market Release	Feb-01	NBD Code	DDED
Registered US Implants	14,000	Serial Number Prefix/X-ray ID	PKE
Estimated Active US Implants	6,000	Max Delivered Energy	30 J
Normal Battery Depletions	582	Estimated Longevity	See page 34
Malfunctions	21		
Therapy Function Not Compromised	14		
Therapy Function Compromised	7		
Advisories	None see page 174 – Performance note on ICD Battery Discharge Behavior		



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	100.0	99.9	99.8	99.7	99.7	99.7
%	99.7	98.9	96.8	89.1	67.7	64.1
#	12,000	10,000	7,000	4,000	400	100

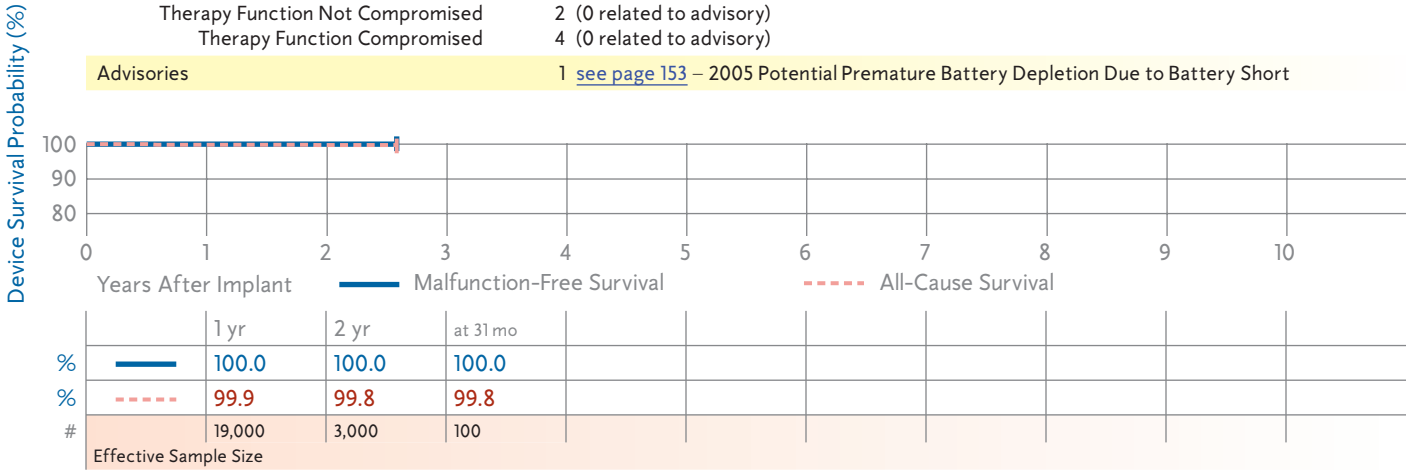
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7278 Maximo DR

Product Characteristics

US Market Release	Oct-03	NBD Code	VVED
Registered US Implants	30,000	Serial Number Prefix/X-ray ID	PRM
Estimated Active US Implants	26,000	Max Delivered Energy	35 J
Normal Battery Depletions	7	Estimated Longevity	See page 34
Malfunctions	6 (0 related to advisory)		
Therapy Function Not Compromised	2 (0 related to advisory)		
Therapy Function Compromised	4 (0 related to advisory)		
Advisories	1 see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short		



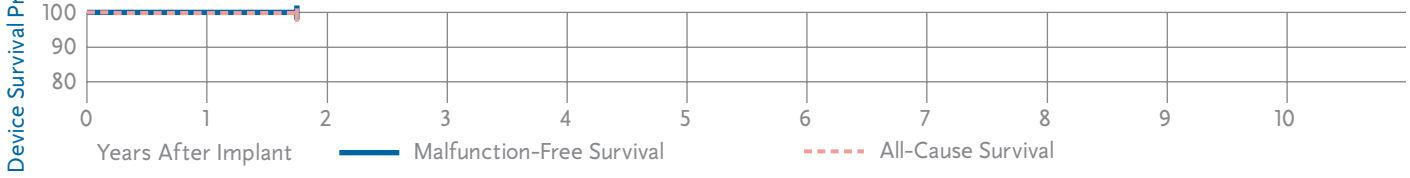
	1 yr	2 yr	at 31 mo
%	100.0	100.0	100.0
%	99.9	99.8	99.8
#	19,000	3,000	100

Effective Sample Size

7288 Intrinsic

Product Characteristics

US Market Release	Aug-04	NBD Code	VVED
Registered US Implants	26,000	Serial Number Prefix/X-ray ID	PUB
Estimated Active US Implants	24,000	Max Delivered Energy	35 J
Normal Battery Depletions	3	Estimated Longevity	See page 35
Malfunctions	7		
Therapy Function Not Compromised	4		
Therapy Function Compromised	3		
Advisories	None		



	1 yr	at 21 mo
%	100.0	100.0
%	99.9	99.9
#	12,000	100

Effective Sample Size

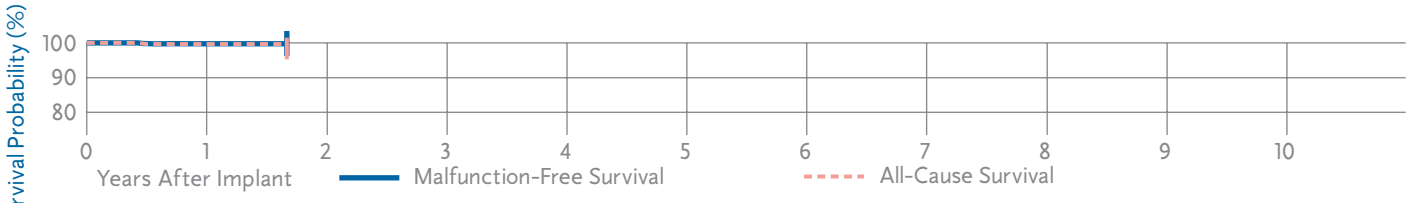
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

7290 Onyx VR

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

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/X-ray ID	PRP
Max Delivered Energy	30 J
Estimated Longevity	See page 35



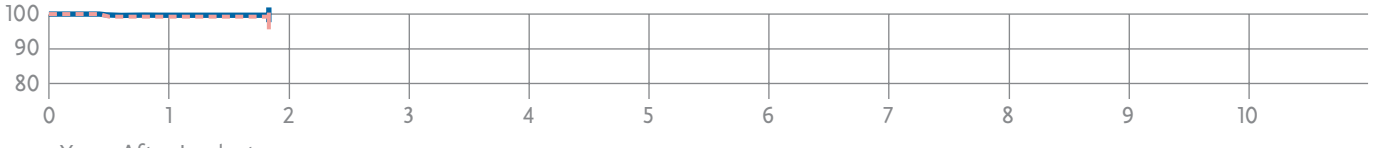
	1 yr	at 20 mo
%	99.8	99.8
%	99.7	99.7
#	400	100
Effective Sample Size		

D153ATG, D153DRG EnTrust

US Market Release	Jun-05
Registered US Implants	400
Estimated Active US Implants	300
Normal Battery Depletions	0
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBD Code	DDED,VVED
Serial Number Prefix/X-ray ID	PNR
Max Delivered Energy	30J
Estimated Longevity	See page 35



	1 yr	at 22 mo
%	99.7	99.7
%	99.3	99.3
#	300	100
Effective Sample Size		

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05	NBD Code	DDED,VVED
Registered US Implants	15,000	Serial Number Prefix/X-ray ID	PNR
Estimated Active US Implants	14,000	Max Delivered Energy	35J
Normal Battery Depletions	0	Estimated Longevity	See page 35
Malfunctions	1		
Therapy Function Not Compromised	0		
Therapy Function Compromised	1		
Advisories	None		

		at 11 mo
%	Malfunction-Free Survival	100.0
%	All-Cause Survival	100.0
#	Effective Sample Size	100

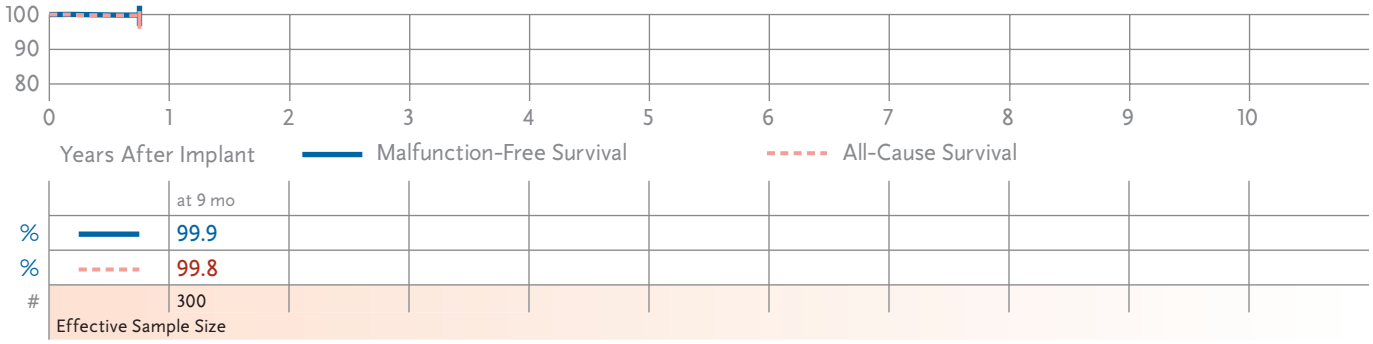
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

D154VRC EnTrust

US Market Release	Jun-05
Registered US Implants	6,000
Estimated Active US Implants	5,000
Normal Battery Depletions	0
Malfunctions	2
Therapy Function Not Compromised	0
Therapy Function Compromised	2
Advisories	None

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/X-ray ID	PNT
Max Delivered Energy	35J
Estimated Longevity	See page 35



Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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 Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
7223 Non-Advisory Population	Micro Jewel II	Nov-96	10,000	2,000	589	—	—	65	Malfunction-free	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2	99.6 +0.1/-0.2	99.3 +0.2/-0.2	99.2 +0.2/-0.3	98.4 +0.4/-0.5	98.4 +0.4/-0.5 at 99 mo
									All-cause	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.3 +0.2/-0.2	98.4 +0.3/-0.3	96.6 +0.4/-0.5	91.0 +0.7/-0.8	82.6 +1.1/-1.2	60.2 +2.0/-2.1	51.0 +3.6/-3.7 at 99 mo
7223 2000, 2004 Advisory Population	Micro Jewel II	Nov-96	11,000	0	497	—	—	1,292	Malfunction-free	99.9 +0.1/-0.1	99.3 +0.2/-0.2	94.7 +0.5/-0.5	86.3 +0.8/-0.8	84.1 +0.8/-0.9	83.7 +0.9/-0.9	80.9 +1.1/-1.1 at 80 mo		
	Advisories: see page 159 – 2000 Potential Long Charge Times Due to Capacitor; and page 154 – 2004 Potential Long Charge Times Due to Capacitor – Supplement					—	—	—	All-cause	99.7 +0.1/-0.1	98.4 +0.2/-0.3	89.0 +0.6/-0.7	70.8 +1.0/-1.1	62.1 +1.2/-1.2	51.8 +1.5/-1.5	20.4 +3.1/-3.0 at 80 mo		
7227 Non-2000 Advisory Population	GEM	Oct-98	22,000	9,000	315	—	—	131	Malfunction-free	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.1	99.4 +0.1/-0.1	99.2 +0.1/-0.1	99.2 +0.1/-0.2	99.2 +0.1/-0.2	99.2 +0.1/-0.2 at 91 mo	
	Advisories: see page 162 – 1999 Potential Circuit Overload; and page 164 – 1999 Potential High Current Drain					—	—	—	All-cause	99.3 +0.1/-0.1	99.0 +0.1/-0.1	98.7 +0.1/-0.2	98.3 +0.2/-0.2	97.6 +0.2/-0.3	96.0 +0.4/-0.4	86.5 +1.0/-1.1	79.1 +2.1/-2.3 at 91 mo	
7227 B, D, E 2000 Advisory Population	GEM	Oct-98	1,000	0	2	—	—	304	Malfunction-free	90.7 +1.7/-2.0	77.6 +2.6/-2.9	68.6 +3.2/-3.4	67.3 +3.2/-3.5 at 38 mo					
	Advisory: see page 158 – 2000 Potential High Impedance Due to Removable Connector Header					—	—	—	All-cause	81.4 +2.3/-2.6	54.3 +3.3/-3.4	32.2 +3.8/-3.8	28.1 +3.9/-3.8					
7229	GEM II VR	Jul-99	11,000	4,000	331	—	—	24	Malfunction-free	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 79 mo		
	Advisories: see page 160 – 2000 Potential Weak Solder Connection; and page 162 – 1999 Potential Circuit Overload; also see page 174 – Performance note on ICD Battery Discharge Behavior					—	—	—	All-cause	99.8 +0.1/-0.1	99.4 +0.1/-0.2	99.3 +0.2/-0.2	98.4 +0.3/-0.3	94.6 +0.5/-0.6	86.3 +1.0/-1.1	74.8 +3.4/-3.8 at 79 mo		
7230	Marquis VR	Dec-02	19,000	12,000	6	5	12	17	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 42 mo					
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	(0)	(0)	All-cause	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2	99.6 +0.1/-0.2					
7231	GEM III VR	Dec-00	17,000	11,000	56	6	15	21	Malfunction-free	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 62 mo			
	see page 174 – Performance note on ICD Battery Discharge Behavior								All-cause	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.2	98.8 +0.2/-0.2	98.0 +0.4/-0.6	97.6 +0.6/-0.9 at 62 mo			

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7232	Maximo VR	Oct-03	32,000	28,000	3	3 +	5 =	8	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 30 mo					
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) +	(0) =	(0) (advisory-related subset)	All-cause	99.9 +0.0/-0.0	99.9 +0.1/-0.1	99.3 +0.5/-1.4 at 30 mo					
7250	Jewel AF	Jun-00	1,000	300	56	—	—	16	Malfunction-free	99.6 +0.3/-0.6	99.4 +0.3/-0.7	99.3 +0.4/-0.7	99.3 +0.4/-0.7	98.8 +0.6/-1.1	97.9 +0.9/-1.4	97.9 +0.9/-1.4 at 78 mo	
									All-cause	99.1 +0.4/-0.7	98.7 +0.5/-0.9	98.5 +0.6/-0.9	96.7 +1.0/-1.4	91.3 +1.9/-2.4	79.8 +3.7/-4.4	72.9 +5.1/-6.0 at 78 mo	
7271 Non-Advisory Population	GEM DR	Oct-98	15,000	6,000	283	—	—	73	Malfunction-free	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.2	99.3 +0.2/-0.2	99.2 +0.2/-0.2	99.2 +0.2/-0.2	99.0 +0.3/-0.5 at 91 mo
									All-cause	99.7 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	97.9 +0.3/-0.3	96.0 +0.4/-0.5	92.1 +0.7/-0.8	84.1 +1.3/-1.4	71.6 +3.8/-4.3 at 91 mo
7271 2002 Advisory Population	GEM DR	Oct-98	4,000	2	168	—	—	501	Malfunction-free	99.9 +0.1/-0.2	99.6 +0.2/-0.3	95.1 +0.7/-0.9	82.2 +1.5/-1.6	78.5 +1.7/-1.8	77.0 +1.8/-2.0 at 66 mo		
	Advisory: see page 156 – 2002 Potential Sudden Increase in Charge Times					—	—	—	All-cause	99.7 +0.1/-0.2	99.2 +0.3/-0.4	89.3 +1.1/-1.2	61.0 +2.0/-2.1	43.7 +2.5/-2.5	27.4 +3.3/-3.2 at 66 mo		
7271 1999, 2004 Advisory Population	GEM DR	Oct-98	400	0	17	—	—	112	Malfunction-free	99.5 +0.4/-1.6	95.7 +1.7/-2.9	74.4 +4.7/-5.5	73.2 +4.8/-5.6 at 37 mo				
	Advisories: see page 161 – 1999 Potential Long Charge Times Due to Capacitor; and page 154 – 2004 Potential Long Charge Times Due to Capacitor – Supplement					—	—	—	All-cause	98.9 +0.7/-1.8	91.4 +2.6/-3.6	47.9 +5.9/-6.1	45.2 +5.9/-6.1 at 37 mo				
7273	GEM II DR	Feb-99	15,000	200	2,065	—	—	52	Malfunction-free	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1 at 66 mo		
	Advisory: see page 160 – 2000 Potential Weak Solder Connection; also see page 174 – Performance note on ICD Battery Discharge Behavior					—	—	—	All-cause	99.5 +0.1/-0.1	98.7 +0.2/-0.2	95.6 +0.4/-0.4	82.3 +0.8/-0.8	46.3 +1.4/-1.4	16.2 +2.1/-1.9 at 66 mo		
7274	Marquis DR	Mar-02	48,000	26,000	142	41 +	46 =	87	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.5 +0.1/-0.2	99.5 +0.1/-0.2 at 51 mo			
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(16) +	(1) =	(17) (advisory-related subset)	All-cause	99.8 +0.0/-0.0	99.6 +0.1/-0.1	98.3 +0.2/-0.2	96.6 +0.4/-0.5	96.6 +0.4/-0.5 at 51 mo			
7275	GEM III DR	Nov-00	20,000	9,000	810	10 +	24 =	34	Malfunction-free	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 64 mo		
	see page 174 – Technical article on ICD Battery Discharge Behavior								All-cause	99.7 +0.1/-0.1	99.0 +0.1/-0.2	96.8 +0.3/-0.3	91.2 +0.5/-0.6	71.7 +1.5/-1.6	65.1 +2.4/-2.5 at 64 mo		

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7276	GEM III AT	Feb-01	14,000	6,000	582	7	+	14	=	21	Malfunction-free	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 62 mo		
	see page 174 – Technical article on ICD Battery Discharge Behavior										All-cause	99.7 +0.1/-0.1	98.9 +0.2/-0.2	96.8 +0.3/-0.4	89.1 +0.8/-0.8	67.7 +2.1/-2.3	64.1 +2.8/-3.0 at 62 mo		
7278	Maximo DR	Oct-03	30,000	26,000	7	4	+	2	=	6	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 31 mo					
	Advisory: see page 153 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0) (advisory-related subset)	+	(0)	=	(0)	All-cause	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 31 mo					
7288	Intrinsic	Aug-04	26,000	24,000	3	3	+	4	=	7	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.1 at 21 mo						
											All-cause	99.9 +0.0/-0.0	99.9 +0.0/-0.1 at 21 mo						
7290	Onyx VR	Mar-04	1,000	1,000	0	0	+	1	=	1	Malfunction-free	99.8 +0.1/-1.0	99.8 +0.1/-1.0 at 20 mo						
											All-cause	99.7 +0.2/-0.9	99.7 +0.2/-0.9 at 20 mo						
D153ATG, D153DRG	EnTrust	Jun-05	400	300	0	1	+	0	=	1	Malfunction-free	99.7 +0.3/-2.0	99.7 +0.3/-2.0 at 22 mo						
											All-cause	99.3 +0.5/-1.9	99.3 +0.5/-1.9 at 22 mo						
D154ATG, D154DRG	EnTrust	Jun-05	15,000	14,000	0	1	+	0	=	1	Malfunction-free	100.0 +0.0/-0.0 at 11 mo							
											All-cause	100.0 +0.0/-0.0 at 11 mo							
D154VRC	EnTrust	Jun-05	6,000	5,000	0	2	+	0	=	2	Malfunction-free	99.9 +0.1/-0.3 at 9 mo							
											All-cause	99.8 +0.1/-0.3 at 9 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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

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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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 Semiannual	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;

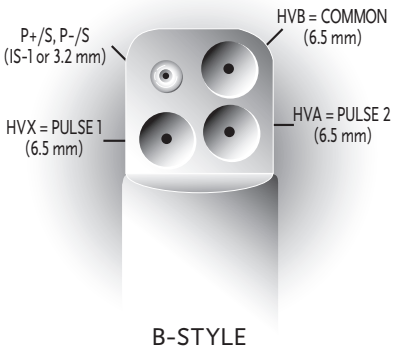
65 ppm, 5.6 V, 0.5 ms, and 500 ohms for Jewel 7219, Jewel Plus 7220, and Jewel CD 7202.

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

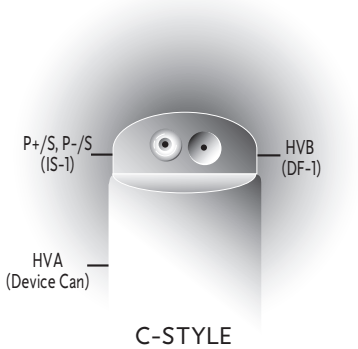
‡‡ For Model 7221 and 7223 devices, if charge time exceeds 60 seconds, the devices are at EOL. If 2 consecutive charge cycles exceed 60 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency output VVI pacing are disabled.

§ 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.

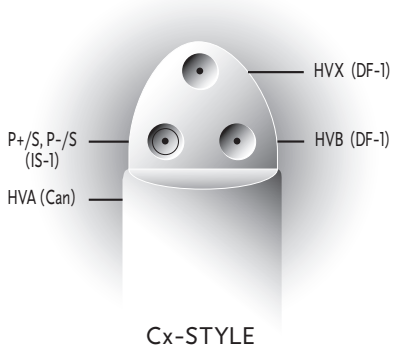
ICD Connector Styles



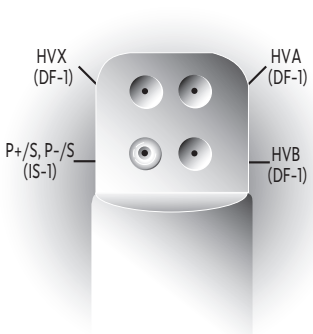
B-STYLE CONNECTOR



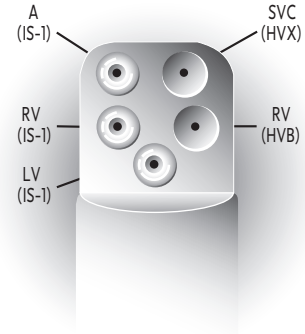
C-STYLE CONNECTOR



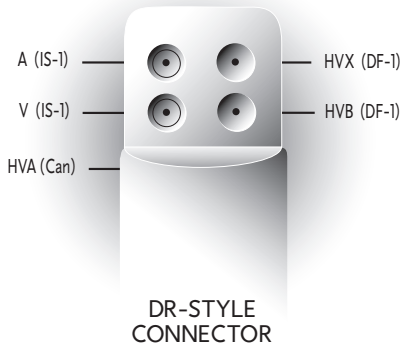
Cx-STYLE CONNECTOR



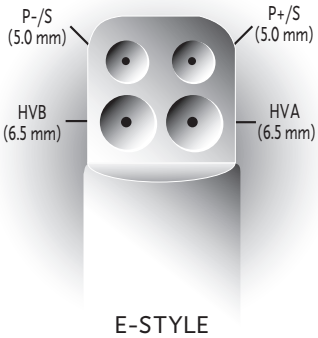
D-STYLE CONNECTOR



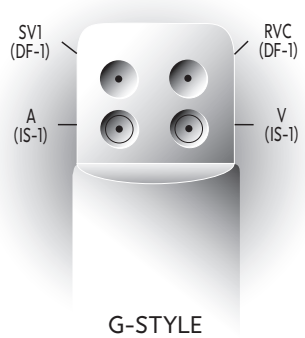
CRT-D CONNECTOR



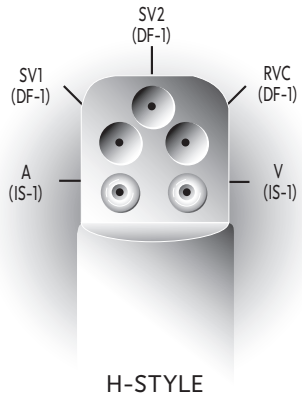
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR

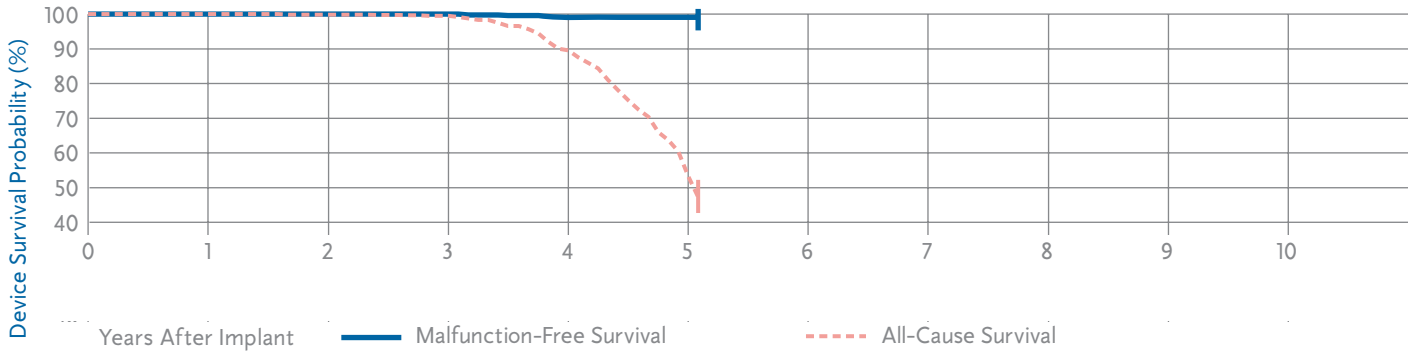


H-STYLE CONNECTOR

AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03	NBG Code	DDDRP
Registered US Implants	11,000	Serial Number Prefix/X-ray ID	IJF
Estimated Active US Implants	8,000	Estimated Longevity	See page 72
Normal Battery Depletions	113		
Malfunctions	6 (2 related to advisory)		
Therapy Function Not Compromised	3 (1 related to advisory)		
Therapy Function Compromised	3 (1 related to advisory)		
Advisories	1 see page 155 – 2003 Potential Incorrect Memory Circuit Setting also see page 172 – Performance note on AT500 Pacing System Follow-Up Protocol		

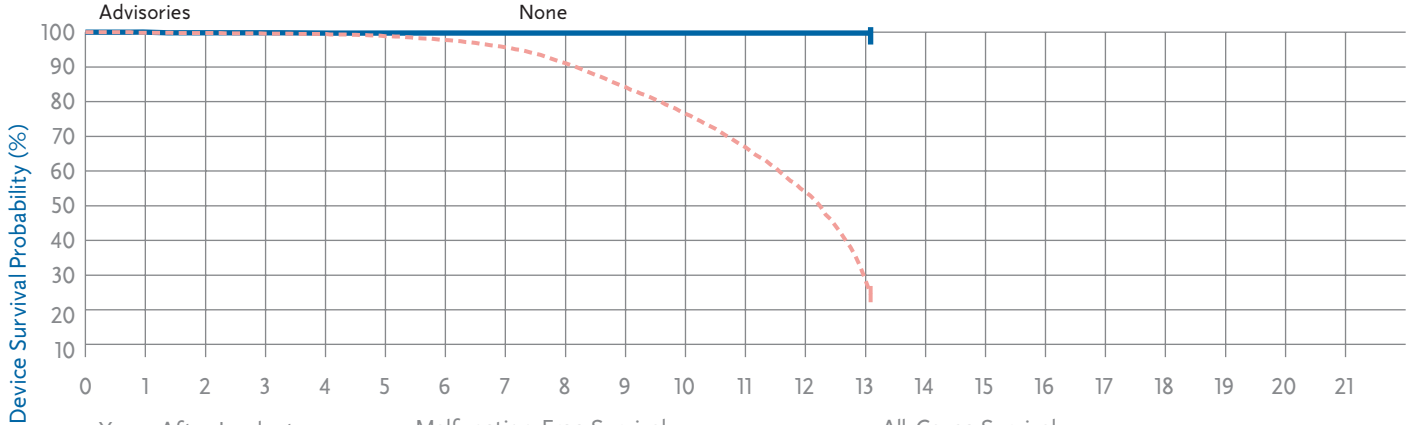


	1 yr	2 yr	3 yr	4 yr	5 yr	at 61 mo
% Malfunction-Free Survival	100.0	100.0	100.0	99.1	99.1	99.1
% All-Cause Survival	100.0	99.9	99.5	89.6	53.3	47.3
# Effective Sample Size	10,000	6,000	1,000	400	100	100

Elite 7074, 7075, 7076, 7077

Product Characteristics

US Market Release	Apr-91	NBG Code	DDD/RO
Registered US Implants	48,000	Serial Number Prefix/X-ray ID	YE, YF, 2E, 1X
Estimated Active US Implants	1,000	Estimated Longevity	See page 72
Normal Battery Depletions	3,240		
Malfunctions	85		
Advisories	None		



	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	at 157mo
% Malfunction-Free Survival	100.0	99.9	99.9	99.8	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	84.2	76.5	66.9	54.0	28.4	24.5
# Effective Sample Size	43,000	39,000	35,000	31,000	27,000	24,000	20,000	16,000	12,000	9,000	5,000	2,000	300	100

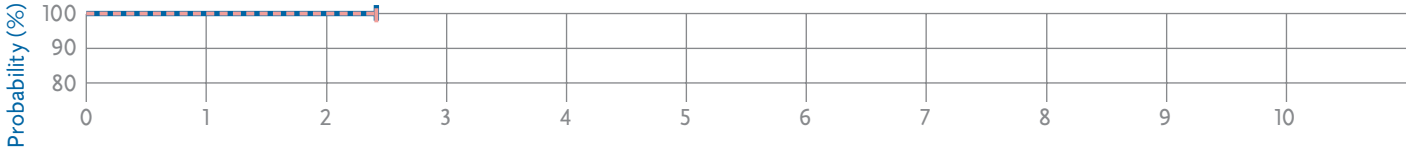
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

EnPulse DR E1DR01, E1DR03, E1DR06

US Market Release	Dec-03
Registered US Implants	7,000
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/X-ray ID	PRA
Estimated Longevity	See page 72



	1 yr	2 yr	at 29 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	6,000	5,000	300

Effective Sample Size

EnPulse DR E1DR21

US Market Release	Dec-03
Registered US Implants	2,000
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

NBG Code	DDDR
Serial Number Prefix/X-ray ID	PPT
Estimated Longevity	See page 72

	1 yr	2 yr	at 28 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	2,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

EnPulse 2 DR E2DR01, E2DR03, E2DR06

US Market Release	Feb-04
Registered US Implants	82,000
Estimated Active US Implants	73,000
Normal Battery Depletions	0
Malfunctions	2
Therapy Function Not Compromised	1
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	DDDR
Serial Number Prefix/X-ray ID	PNB, PNC, PNH
Estimated Longevity	See page 72

	1 yr	2 yr	at 27 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	40,000	3,000	100

Effective Sample Size

EnPulse 2 DR E2DR21

US Market Release	Feb-04
Registered US Implants	9,000
Estimated Active US Implants	8,000
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/X-ray ID	PMU
Estimated Longevity	See page 72

	1 yr	2 yr
%	100.0	100.0
%	100.0	100.0
#	4,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

EnPulse 2 DR E2DR31, E2DR33

US Market Release	Feb-04
Registered US Implants	400
Estimated Active US Implants	400
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/X-ray ID	PNL
Estimated Longevity	See page 72

	1 yr	at 14 mo
%	100.0	100.0
%	100.0	100.0
#	100	100

Effective Sample Size

EnPulse 2 SR E2SR01, E2SR03, E2SR06

US Market Release	Dec-03
Registered US Implants	19,000
Estimated Active US Implants	16.000
Normal Battery Depletions	1
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/X-ray ID	PMW, PMY, PNA
Estimated Longevity	See page 72

	1 yr	2 yr	at 28 mo
%	100.0	100.0	100.0
%	100.0	99.9	99.9
#	8,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

EnPulse 2 VDD E2VDD01

US Market Release	Dec-03
Registered US Implants	500
Estimated Active US Implants	400
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/X-ray ID	PMV
Estimated Longevity	See page 72

EnRhythm DR P1501DR

US Market Release	May-05
Registered US Implants	29,000
Estimated Active US Implants	28,000
Normal Battery Depletions	0
Malfunctions	6
Therapy Function Not Compromised	2
Therapy Function Compromised	4
Advisories	None

Product Characteristics

NBG Code	DDDRP
Serial Number Prefix/X-ray ID	PNP
Estimated Longevity	See page 72

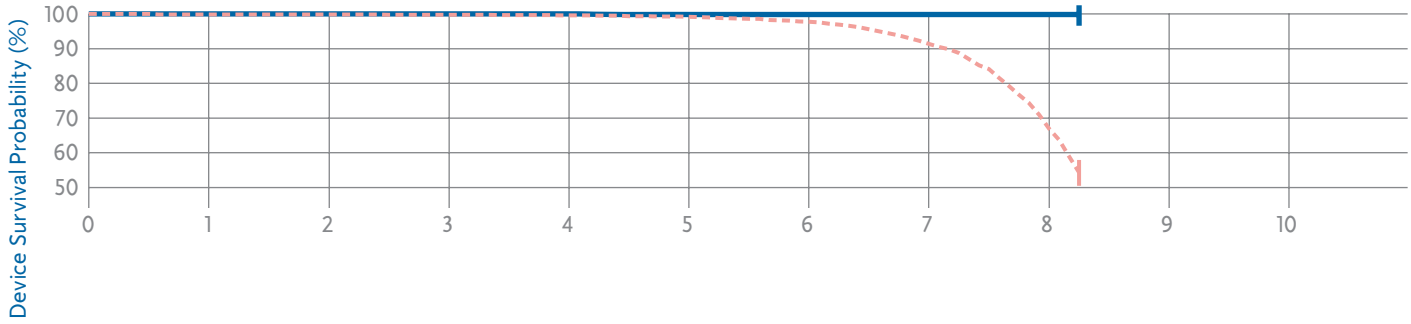
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 400 DR KDR401, KDR403

US Market Release	Jan-98
Registered US Implants	46,000
Estimated Active US Implants	16,000
Normal Battery Depletions	1,284
Malfunctions	21
Therapy Function Not Compromised	12
Therapy Function Compromised	9
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PER, PET
Estimated Longevity	See page 72



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	at 99 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	99.9	99.9	99.8	99.6	99.2	97.8	91.4	66.9	54.3
#	41,000	37,000	32,000	27,000	21,000	16,000	10,000	1,000	100

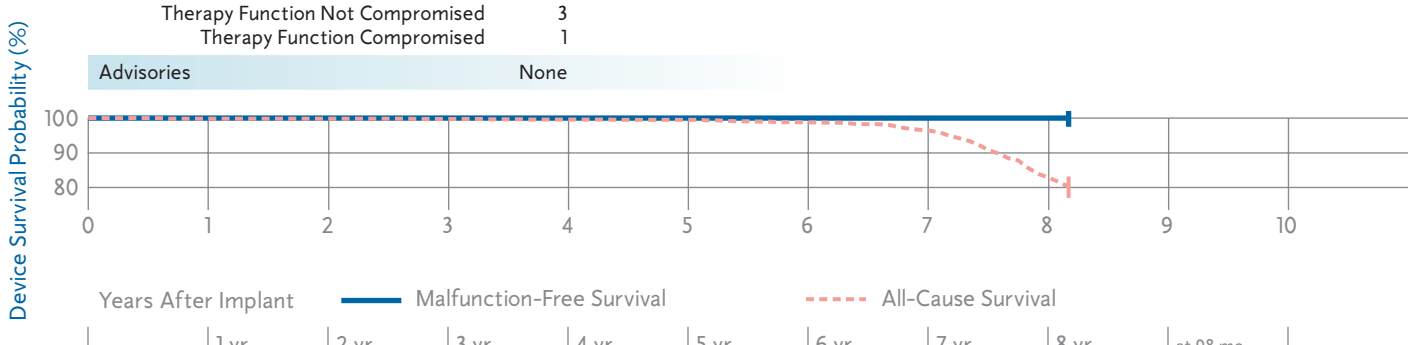
Effective Sample Size

Kappa 400 SR KSR401, KSR403

US Market Release	Feb-98
Registered US Implants	15,000
Estimated Active US Implants	6,000
Normal Battery Depletions	147
Malfunctions	4
Therapy Function Not Compromised	3
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PEU, PGD
Estimated Longevity	See page 72



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	at 98 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.8	99.6	99.5	98.8	96.4	82.9	80.3
#	12,000	10,000	9,000	7,000	5,000	4,000	2,000	400	100

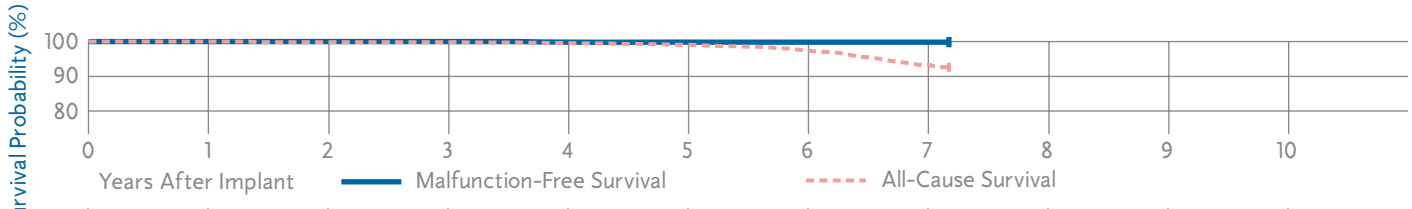
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 600 DR KDR601, KDR603, KDR606

Product Characteristics

US Market Release	Jan-99	NBG Code	DDD/RO
Registered US Implants	24,000	Serial Number Prefix/X-ray ID	PHF, PHH, PHG
Estimated Active US Implants	11,000	Estimated Longevity	See page 72
Normal Battery Depletions	185		
Malfunctions	15 (10 related to advisory)		
Therapy Function Not Compromised	4 (0 related to advisory)		
Therapy Function Compromised	11 (10 related to advisory)		
Advisories	1 see page 157 – 2002 Potential Fractured Power Supply Wires		



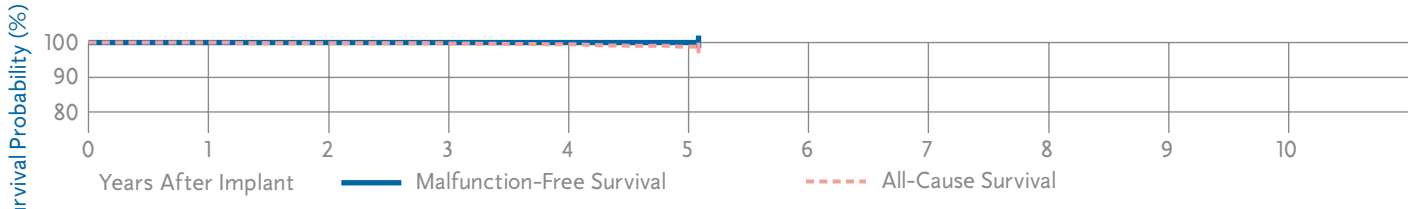
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	100.0	99.9	99.9	99.6	99.1	97.4	93.3	92.7
#	21,000	19,000	17,000	15,000	13,000	6,000	500	100

Effective Sample Size

Kappa 600 DR KDR651, KDR653, KDR656

Product Characteristics

US Market Release	Mar-01	NBG Code	DDD/RO
Registered US Implants	14,000	Serial Number Prefix/X-ray ID	PLJ, PLK
Estimated Active US Implants	8,000	Estimated Longevity	See page 72
Normal Battery Depletions	34		
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 157 – 2002 Potential Fractured Power Supply Wires		



	1 yr	2 yr	3 yr	4 yr	5 yr	at 61 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.5	98.9	98.9
#	12,000	11,000	10,000	7,000	500	200

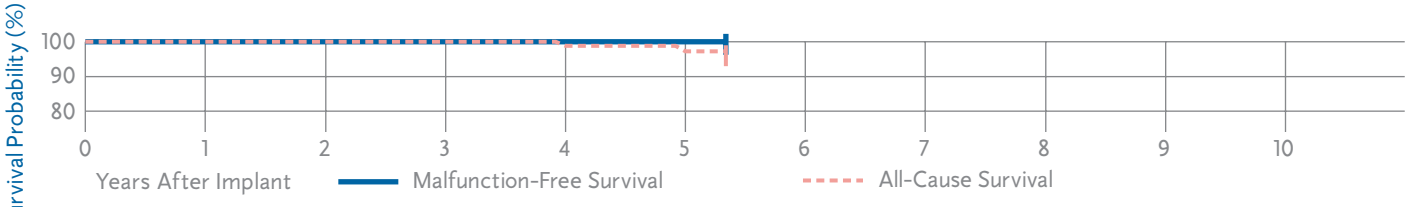
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 700 D KD701, KD703, KD706

Product Characteristics

US Market Release	Jan-99	NBG Code	DDD
Registered US Implants	300	Serial Number Prefix/X-ray ID	PHK
Estimated Active US Implants	200	Estimated Longevity	See page 72
Normal Battery Depletions	3		
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 157 – 2002 Potential Fractured Power Supply Wires		



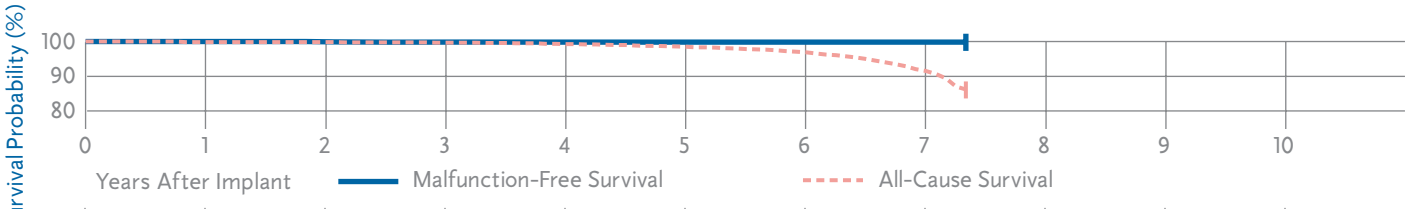
	1 yr	2 yr	3 yr	4 yr	5 yr	at 64 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	98.9	97.3	97.3
#	300	200	200	200	100	100

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

Product Characteristics

US Market Release	Feb-99	NBG Code	DDD/RO
Registered US Implants	189,000	Serial Number Prefix/X-ray ID	PGU, PGY, PGW
Estimated Active US Implants	110,000	Estimated Longevity	See page 73
Normal Battery Depletions	1,094		
Malfunctions	138 (100 related to advisory)		
Therapy Function Not Compromised	19 (0 related to advisory)		
Therapy Function Compromised	119 (100 related to advisory)		
Advisories	1 see page 157 – 2002 Potential Fractured Power Supply Wires		



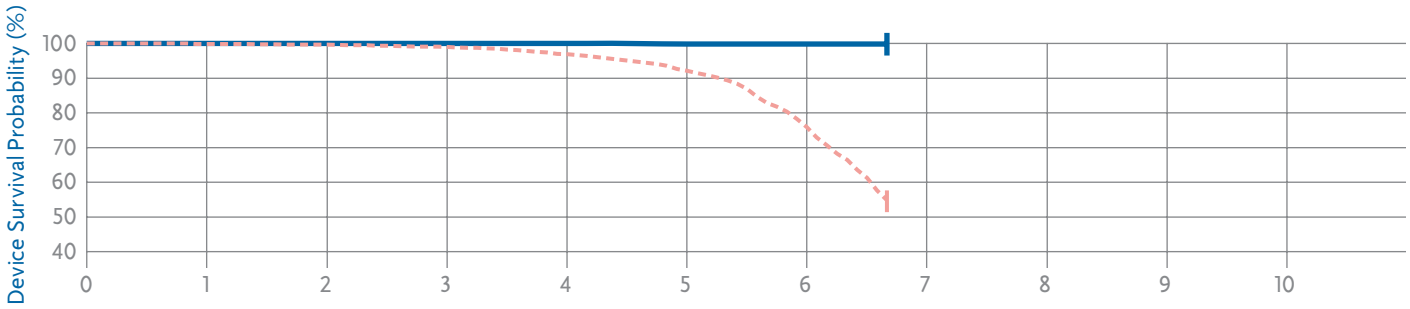
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 88 mo
%	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.9	99.7	99.3	98.5	96.9	91.6	86.2
#	162,000	136,000	109,000	84,000	52,000	23,000	4,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 700 DR KDR721

		Product Characteristics	
US Market Release	Feb-99	NBG Code	DDD/RO
Registered US Implants	10,000	Serial Number Prefix/X-ray ID	PGR
Estimated Active US Implants	3,000	Estimated Longevity	See page 73
Normal Battery Depletions	375		
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 157 – 2002 Potential Fractured Power Supply Wires		



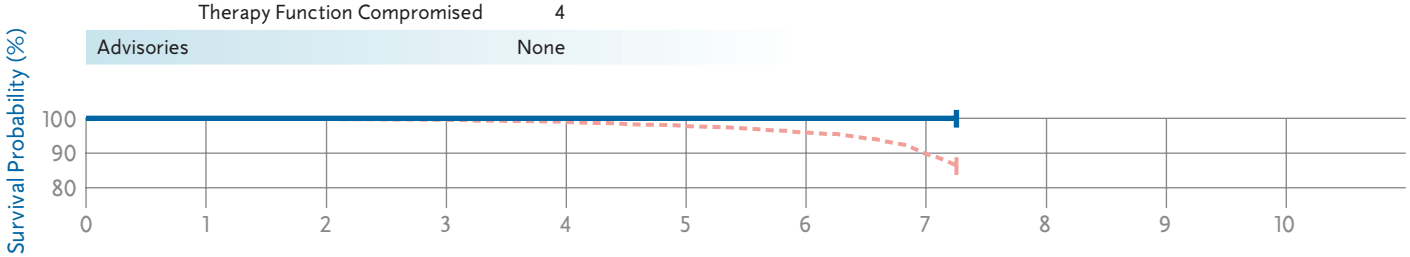
Years After Implant — Malfunction-Free Survival — All-Cause Survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9
%	99.9	99.7	99.0	96.9	92.2	75.9	54.8
#	8,000	7,000	6,000	5,000	3,000	1,000	100

Effective Sample Size

Kappa 700 SR KSR701, KSR703, KSR706

		Product Characteristics	
US Market Release	Feb-99	NBG Code	SSI/R
Registered US Implants	53,000	Serial Number Prefix/X-ray ID	PHT, PHW, PHU
Estimated Active US Implants	25,000	Estimated Longevity	See page 73
Normal Battery Depletions	342		
Malfunctions	5		
Therapy Function Not Compromised	1		
Therapy Function Compromised	4		
Advisories	None		



Years After Implant — Malfunction-Free Survival — All-Cause Survival

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 87 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.6	99.0	97.8	95.9	89.7	86.5
#	41,000	33,000	25,000	19,000	11,000	5,000	1,000	100

Effective Sample Size

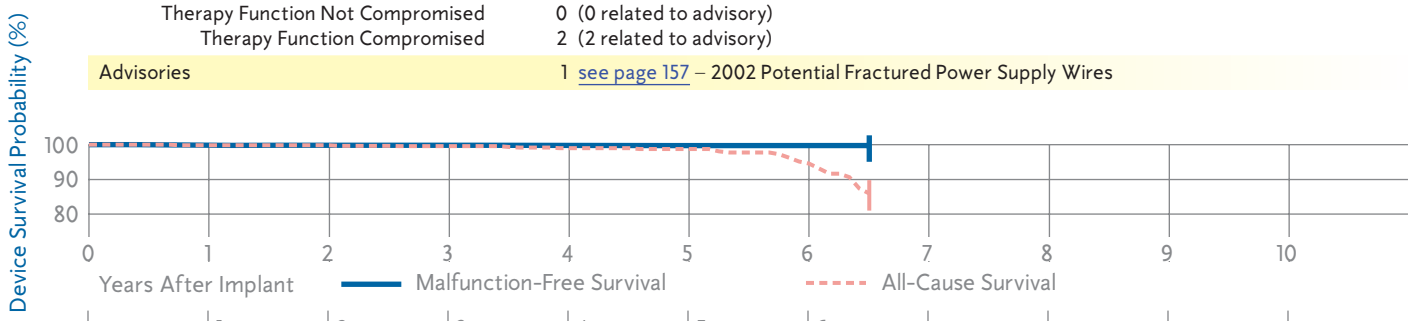
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 700 VDD KVDD701

Product Characteristics

US Market Release	Jan-99
Registered US Implants	2,000
Estimated Active US Implants	1,000
Normal Battery Depletions	29
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 157 – 2002 Potential Fractured Power Supply Wires

NBG Code	VDD/RO
Serial Number Prefix/X-ray ID	PHP
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	99.9	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.9	99.6	99.0	98.8	94.6	86.0
#	1,000	1,000	1,000	1,000	1,000	300	100

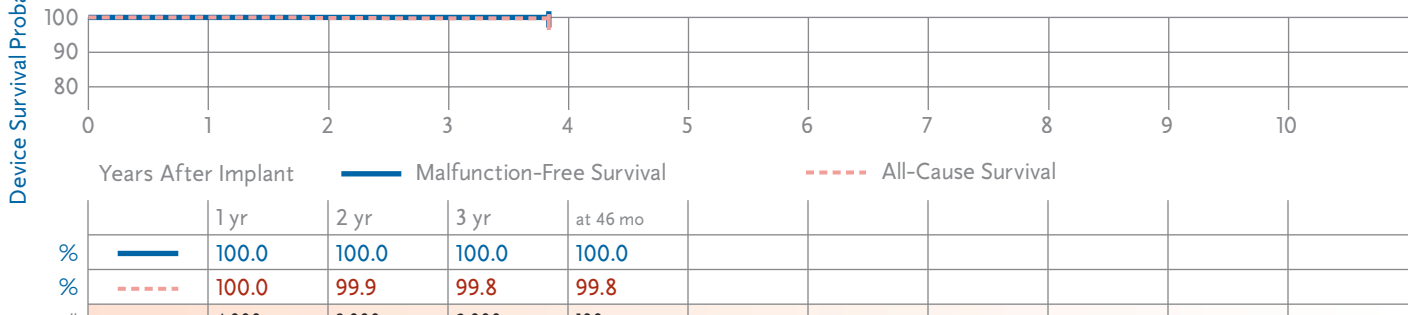
Effective Sample Size

Kappa 800 DR KDR801, KDR803, KDR806

Product Characteristics

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

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PKW, PKY
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	at 46 mo
%	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.8
#	4,000	3,000	2,000	100

Effective Sample Size

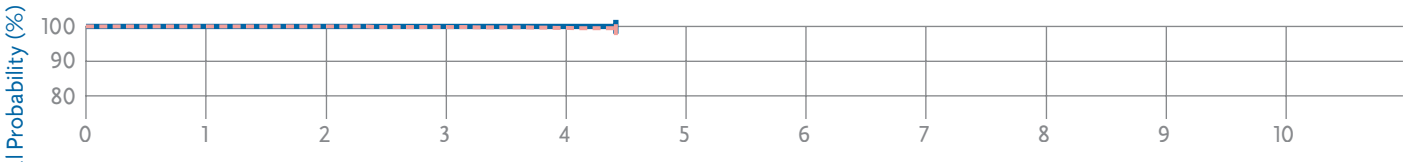
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 900 DR KDR901, KDR903, KDR906

US Market Release	Jan-02
Registered US Implants	119,000
Estimated Active US Implants	89,000
Normal Battery Depletions	50
Malfunctions	12
Therapy Function Not Compromised	8
Therapy Function Compromised	4
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PKM, PKN, PKP
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.6	99.5
#	95,000	71,000	37,000	7,000	100

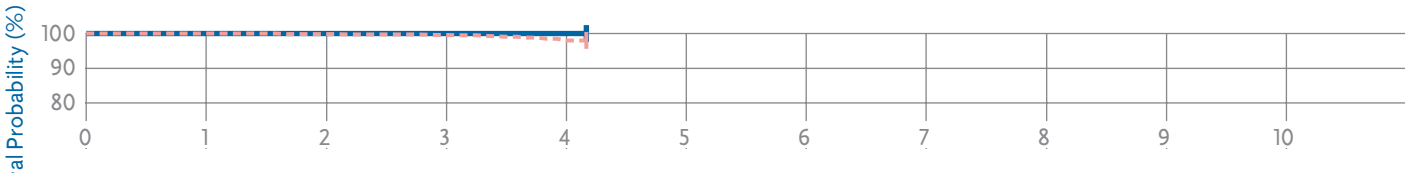
Effective Sample Size

Kappa 920 DR KDR921

US Market Release	Jan-02
Registered US Implants	16,000
Estimated Active US Implants	11,000
Normal Battery Depletions	31
Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PKR
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	at 50 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.6	98.0	98.0
#	13,000	10,000	5,000	1,000	200

Effective Sample Size

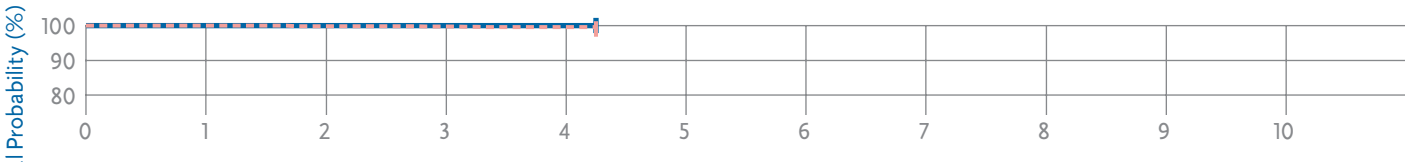
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Kappa 900 SR KSR901, KSR903, KSR906

US Market Release	Jan-02
Registered US Implants	34,000
Estimated Active US Implants	23,000
Normal Battery Depletions	14
Malfunctions	4
Therapy Function Not Compromised	4
Therapy Function Compromised	0
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PLF, PLG, PLH
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.6	99.6
#	23,000	15,000	7,000	1,000	200

Effective Sample Size

Kappa 900 VDD KVDD901

US Market Release	Jan-02
Registered US Implants	1,000
Estimated Active US Implants	400
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/X-ray ID	PLE
Estimated Longevity	See page 73

	1 yr	2 yr	3 yr	at 44 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0
#	1,000	500	300	100

Effective Sample Size

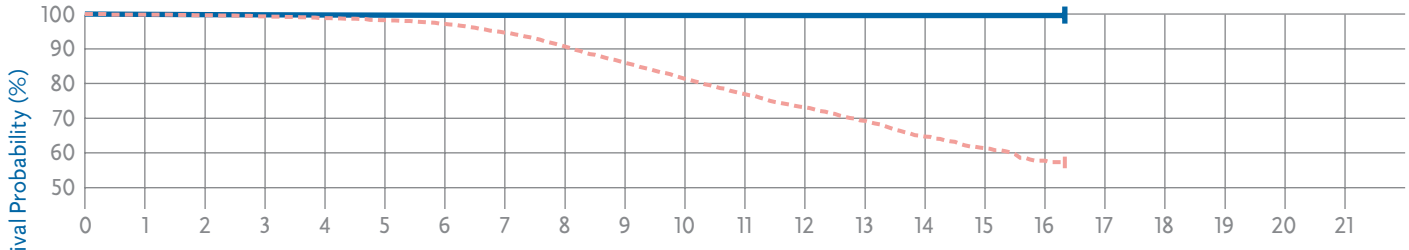
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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	2,535
Malfunctions	145
Advisories	None

Product Characteristics

NBG Code	SSIRO
Serial Number Prefix/X-ray ID	XT, WJ, WN, ZT
Estimated Longevity	See page 73



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	at 196 mo
%	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	99.6
%	99.9	99.7	99.4	98.9	98.3	97.2	94.7	90.7	86.0	81.4	76.9	73.2	69.2	64.7	61.4	57.8	57.3
#	51,000	46,000	41,000	36,000	31,000	26,000	21,000	17,000	14,000	11,000	8,000	6,000	4,000	3,000	1,000	300	100

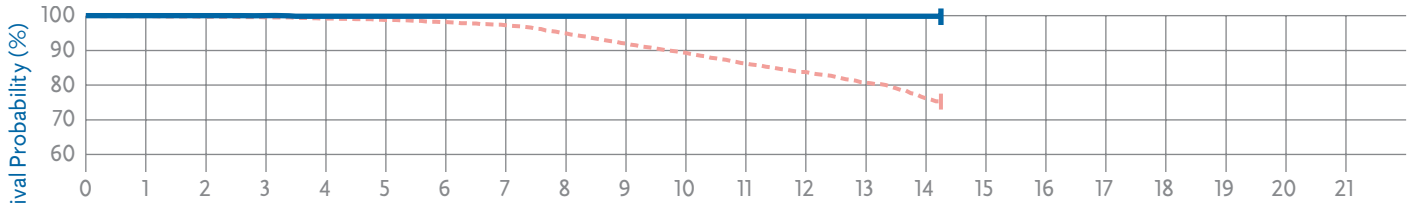
Effective Sample Size

Legend II 8424, 8426, 8427

US Market Release	Nov-91
Registered US Implants	59,000
Estimated Active US Implants	7,000
Normal Battery Depletions	1,555
Malfunctions	37
Advisories	None

Product Characteristics

NBG Code	SSIR0
Serial Number Prefix/X-ray ID	2P, 2T, 2U
Estimated Longevity	See page 73



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	at 171 mo
%	100.0	100.0	100.0	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	99.7	99.5	99.2	98.8	98.2	97.3	94.9	92.0	89.3	86.2	83.8	80.7	76.2	75.3
#	52,000	46,000	41,000	35,000	31,000	27,000	23,000	20,000	16,000	12,000	9,000	6,000	3,000	1,000	200

Effective Sample Size

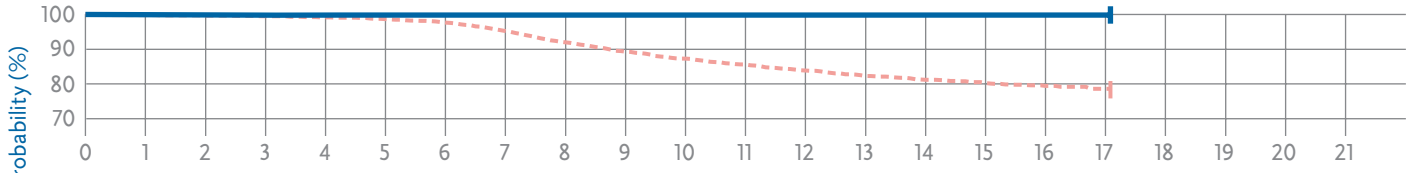
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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

Product Characteristics

US Market Release	Dec-89
Registered US Implants	58,000
Estimated Active US Implants	6,000
Normal Battery Depletions	1,409
Malfunctions	49
Advisories	1 see page 170 – 1991 Potential Delayed Restoration of Permanent Settings

NBG Code	SSIR0
Serial Number Prefix/X-ray ID	2P, 2T, 2U
Estimated Longevity	See page 73



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	at 205 mo
%	100.0	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	99.9
%	99.9	99.7	99.5	99.2	98.7	97.7	95.3	92.0	89.3	87.3	85.6	83.9	82.3	81.2	80.3	79.4	78.6	78.6
#	50,000	43,000	37,000	31,000	26,000	22,000	18,000	14,000	12,000	10,000	8,000	6,000	5,000	3,000	2,000	1,000	200	100

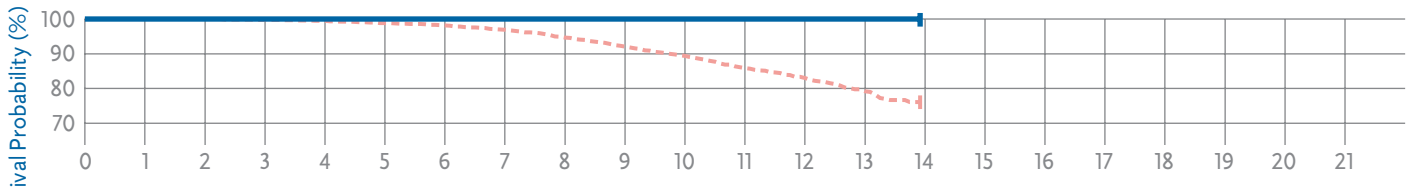
Effective Sample Size

Minuet 7107, 7108

Product Characteristics

US Market Release	Mar-92
Registered US Implants	17,000
Estimated Active US Implants	3,000
Normal Battery Depletions	513
Malfunctions	4
Advisories	None

NBG Code	DDDCO
Serial Number Prefix/Xray ID	1Z1, 2G1
Estimated Longevity	See page 73



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	at 167 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.5	98.9	98.2	96.9	94.7	92.1	89.4	85.9	83.0	79.2	76.1
#	15,000	13,000	12,000	11,000	9,000	8,000	7,000	6,000	5,000	4,000	3,000	2,000	1,000	100

Effective Sample Size

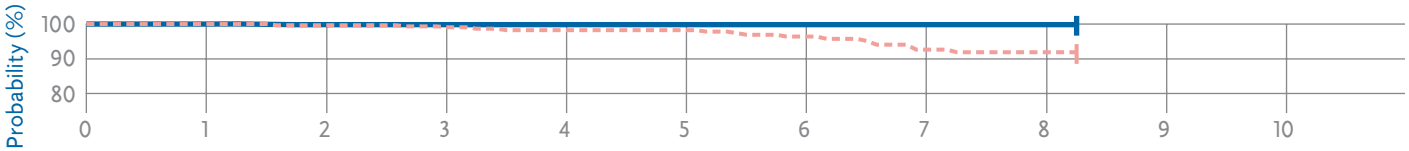
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Preva D 7068

US Market Release	Nov-96
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	16
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/X-ray ID	PIE
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	99.7	99.1	98.3	98.3	96.4	92.7	91.9	91.9
#	1,000	1,000	1,000	1,000	400	400	300	200	100

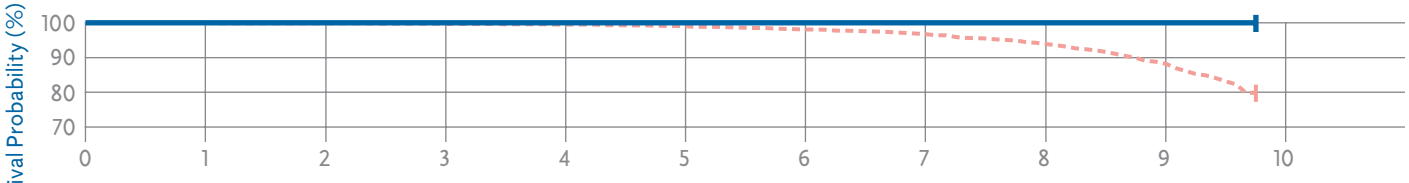
Effective Sample Size

Preva DR 7088, 7089

US Market Release	Jul-96
Registered US Implants	25,000
Estimated Active US Implants	8,000
Normal Battery Depletions	457
Malfunctions	3
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PGJ, PGK
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.7	99.5	99.0	98.1	96.8	93.9	88.2	79.9
#	22,000	20,000	18,000	16,000	14,000	12,000	10,000	5,000	2,000	200

Effective Sample Size

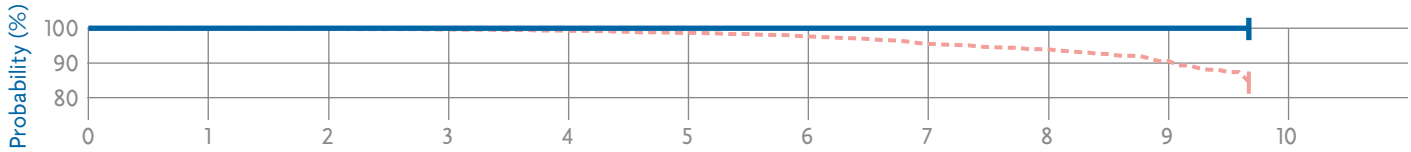
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Preva SR 8088, 8089

US Market Release	Jul-96
Registered US Implants	18,000
Estimated Active US Implants	4,000
Normal Battery Depletions	225
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PGL, PGM
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 116 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.7	99.3	98.7	97.7	95.5	93.9	90.6	84.6
#	15,000	12,000	11,000	9,000	8,000	6,000	5,000	3,000	1,000	100

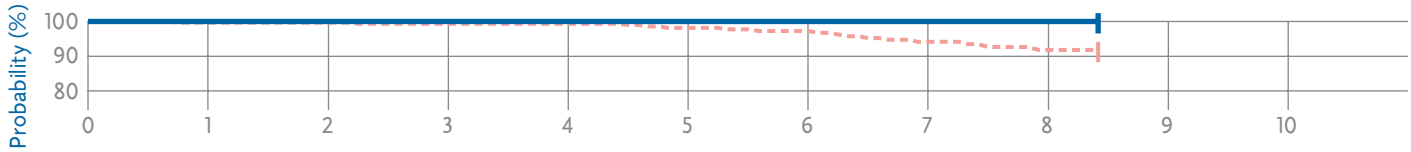
Effective Sample Size

Preva ST DR 7078

US Market Release	Nov-96
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	18
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PIF
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 101 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.7	99.7	99.4	99.4	98.2	97.3	94.2	91.8	91.8
#	1,000	1,000	1,000	1,000	500	400	300	200	100

Effective Sample Size

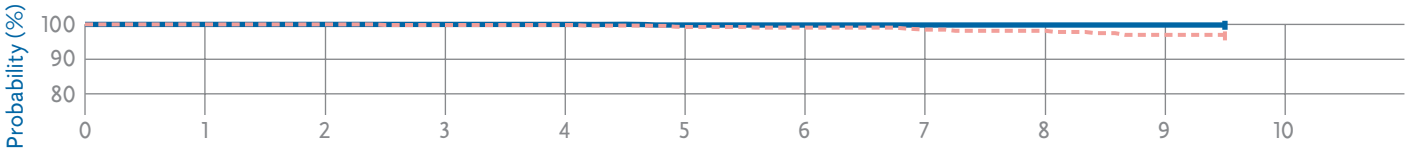
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Prevail S 8084, 8085, 8086

US Market Release	Oct-95
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	13
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSI
Serial Number Prefix/X-ray ID	PGL, PGM
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	100.0	99.9	99.9	99.3	99.1	98.5	98.2	97.0	97.0
#	3,000	3,000	2,000	2,000	1,000	1,000	1,000	1,000	300	100

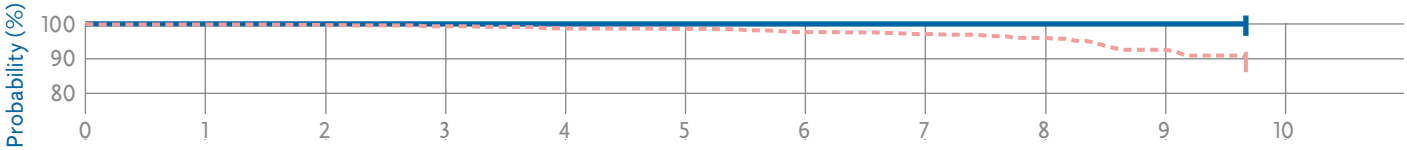
Effective Sample Size

Prodigy D 7864, 7865, 7866

US Market Release	Oct-95
Registered US Implants	3,000
Estimated Active US Implants	1,000
Normal Battery Depletions	45
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/X-ray ID	PDL, PDM, PDN
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 116 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.4	98.8	98.6	97.7	97.1	96.0	92.6	89.4
#	2,000	2,000	2,000	2,000	2,000	1,000	1,000	1,000	400	100

Effective Sample Size

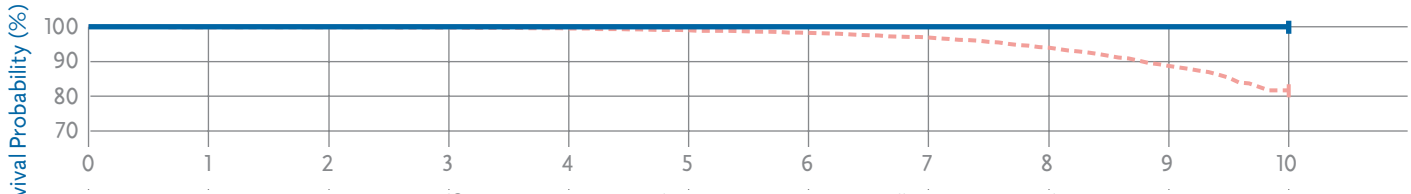
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Prodigy DR 7860, 7861, 7862

US Market Release	Oct-95
Registered US Implants	37,000
Estimated Active US Implants	12,000
Normal Battery Depletions	627
Malfunctions	10
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PDH, PDJ, PDK
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.8	99.5	99.0	98.3	96.9	94.0	88.7	81.7
#	33,000	30,000	27,000	24,000	21,000	19,000	14,000	8,000	2,000	100

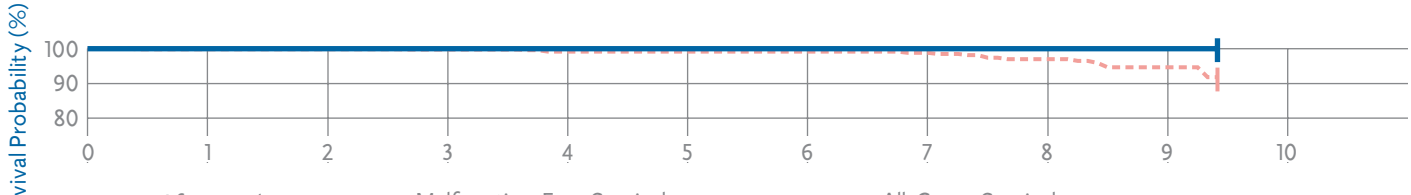
Effective Sample Size

Prodigy S 8164, 8165, 8166

US Market Release	Oct-95
Registered US Implants	2,000
Estimated Active US Implants	500
Normal Battery Depletions	17
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	SSIC
Serial Number Prefix/X-ray ID	PEG, PEH, PEJ
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.8	99.2	99.2	99.2	98.9	97.0	94.7	91.8
#	2,000	1,000	1,000	1,000	1,000	1,000	1,000	400	200	100

Effective Sample Size

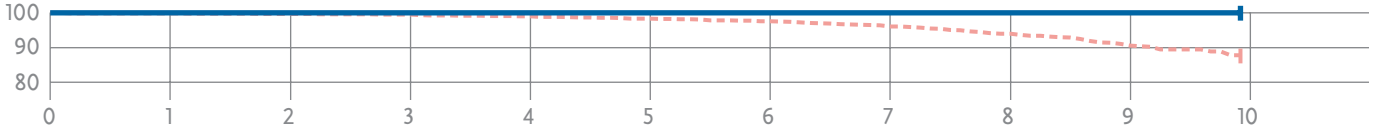
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Prodigy SR 8158, 8160, 8161, 8162

US Market Release	Oct-95
Registered US Implants	22,000
Estimated Active US Implants	6,000
Normal Battery Depletions	271
Malfunctions	5
Advisories	None

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PEM, PED, PEE, PEF
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 119 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.5	99.0	98.4	97.6	96.1	94.0	90.6	87.8
#	18,000	16,000	13,000	11,000	9,000	8,000	6,000	3,000	1,000	100

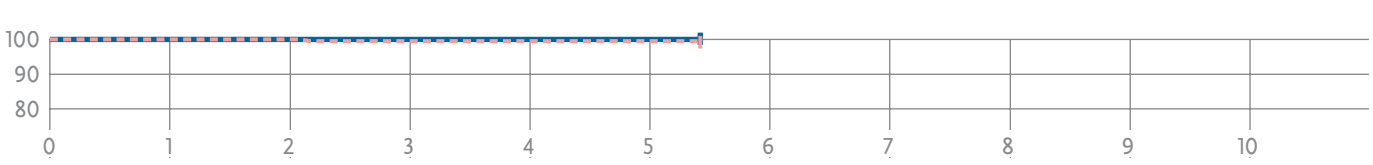
Effective Sample Size

Sigma 100 S SS103, SS106

US Market Release	Aug-99
Registered US Implants	1,000
Estimated Active US Implants	200
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 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue

Product Characteristics

NBG Code	SSI
Serial Number Prefix/X-ray ID	PJG, PJH
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	at 65 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.5	99.5	99.5	99.5
#	1,000	400	300	200	100	100

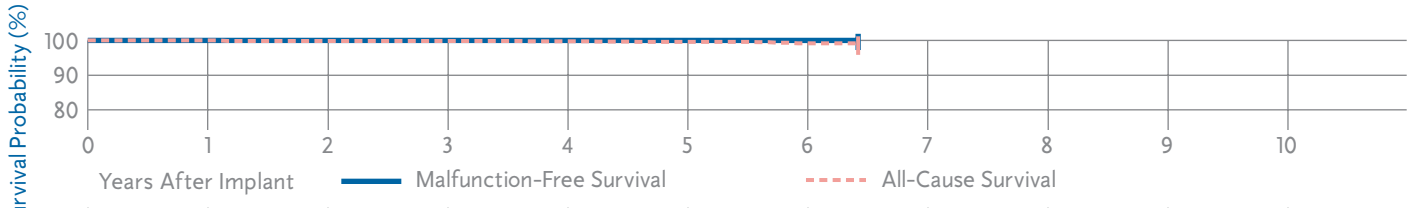
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Sigma 200 DR SDR203

Product Characteristics

US Market Release	Aug-99	NBG Code	DDD/RO
Registered US Implants	16,000	Serial Number Prefix/X-ray ID	PJD
Estimated Active US Implants	9,000	Estimated Longevity	See page 74
Normal Battery Depletions	16		
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 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue		



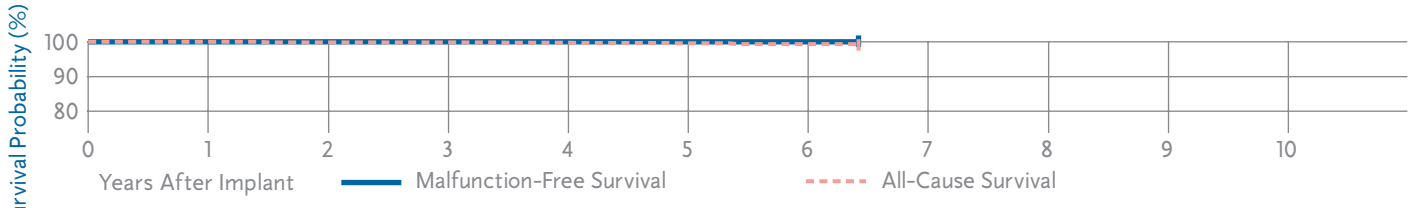
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.9	99.8	99.6	99.2	99.2
#	13,000	11,000	9,000	6,000	4,000	1,000	200

Effective Sample Size

Sigma 200 SR SSR203

Product Characteristics

US Market Release	Sep-99	NBG Code	SSI/R
Registered US Implants	12,000	Serial Number Prefix/X-ray ID	PJG
Estimated Active US Implants	5,000	Estimated Longevity	See page 74
Normal Battery Depletions	10		
Malfunctions	2 (2 related to advisory)		
Therapy Function Not Compromised	0 (0 related to advisory)		
Therapy Function Compromised	2 (2 related to advisory)		
Advisories	2 see page 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.9	99.8	99.6	99.4	99.4
#	9,000	7,000	5,000	4,000	2,000	1,000	100

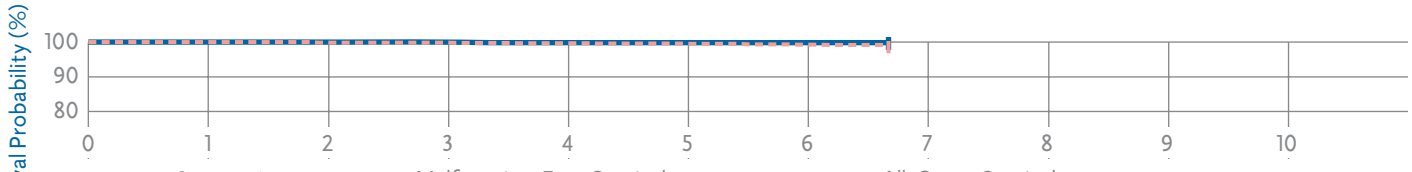
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Sigma 300 DR SDR303, SDR306

Product Characteristics

US Market Release	Aug-99	NBG Code	DDD/RO
Registered US Implants	98,000	Serial Number Prefix/X-ray ID	PJD, PJE
Estimated Active US Implants	64,000	Estimated Longevity	See page 74
Normal Battery Depletions	61		
Malfunctions	38 (17 related to advisory)		
Therapy Function Not Compromised	3 (0 related to advisory)		
Therapy Function Compromised	35 (17 related to advisory)		
Advisories	2 see page 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue		



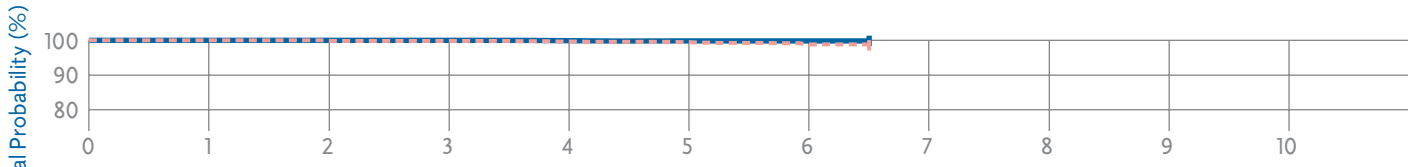
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	100.0	99.9	99.9	99.7	99.5	99.3	99.2
#	77,000	60,000	42,000	27,000	14,000	4,000	100

Effective Sample Size

Sigma 300 SR SSR303, SSR306

Product Characteristics

US Market Release	Sep-99	NBG Code	SSI/R
Registered US Implants	48,000	Serial Number Prefix/X-ray ID	PJG, PJH
Estimated Active US Implants	25,000	Estimated Longevity	See page 74
Normal Battery Depletions	34		
Malfunctions	8 (5 related to advisory)		
Therapy Function Not Compromised	1 (0 related to advisory)		
Therapy Function Compromised	7 (5 related to advisory)		
Advisories	2 see page 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	100.0	99.9	99.9	99.7	99.5	98.9	98.9
#	35,000	25,000	17,000	10,000	5,000	1,000	100

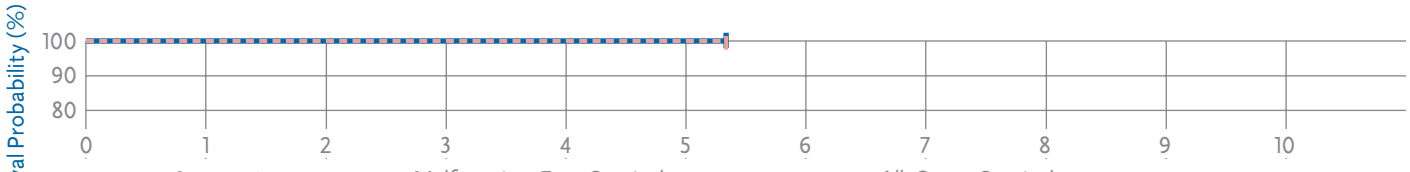
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Sigma 300 VDD SVDD303

Product Characteristics

US Market Release	Sep-99	NBG Code	VDDD
Registered US Implants	1,000	Serial Number Prefix/X-ray ID	PJD
Estimated Active US Implants	300	Estimated Longevity	See page 74
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 152 – 2005 Potential Separation of Interconnect Wires and page 163 – 1999 Manufacturing Issue		



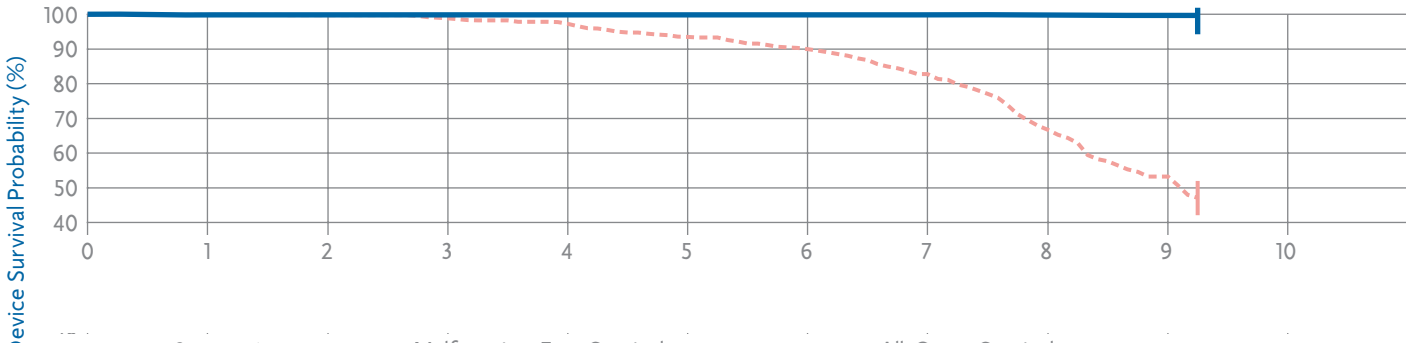
	1 yr	2 yr	3 yr	4 yr	5 yr	at 64 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0	100.0
#	1,000	500	400	200	100	100

Effective Sample Size

Thera D 7944, 7945, 7946

Product Characteristics

US Market Release	Jan-95	NBG Code	DDDCO
Registered US Implants	2,000	Serial Number Prefix/X-ray ID	PBD, PBE, PBF
Estimated Active US Implants	5	Estimated Longevity	See page 74
Normal Battery Depletions	174		
Malfunctions	2		
Advisories	None		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.7	99.7
%	99.9	99.8	98.9	97.3	93.5	90.0	82.8	66.7	53.2	47.1
#	2,000	1,000	1,000	1,000	1,000	1,000	1,000	300	100	100

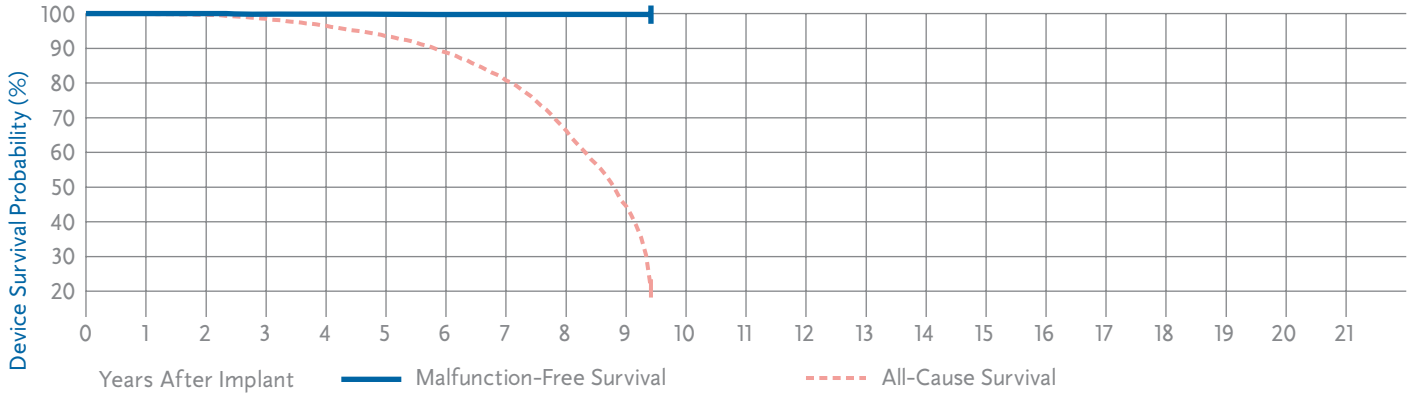
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Thera DR-40 7940, 7941, 7942

Product Characteristics

US Market Release	Jan-95	NBG Code	DDD/RO
Registered US Implants	30,000	Serial Number Prefix/X-ray ID	PAF, PAP, PAT
Estimated Active US Implants	10	Estimated Longevity	See page 74
Normal Battery Depletions	2,945		
Malfunctions	37		
Advisories	1	see page 165 – 1997 Potential Integrated Circuit Failure	



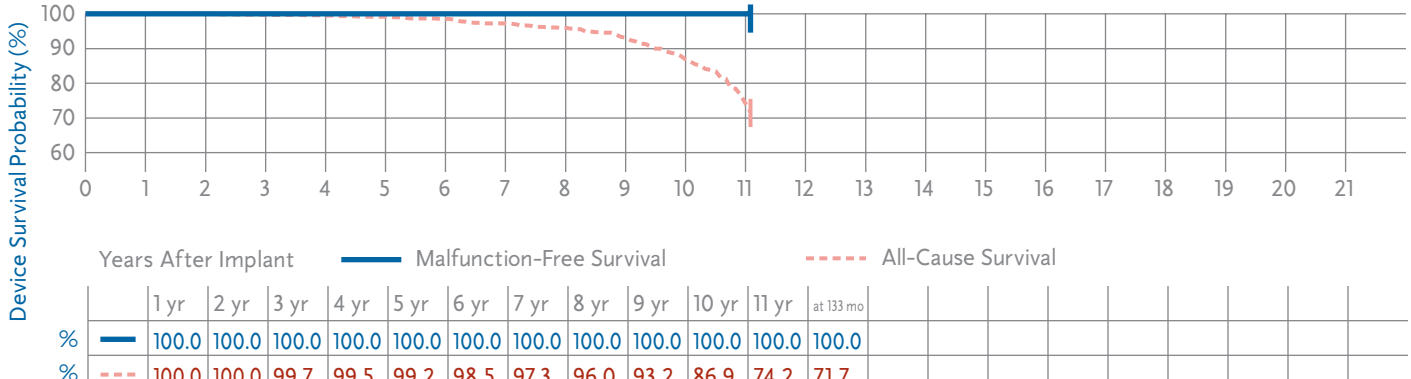
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 mo
%	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8
%	100.0	99.7	98.5	96.5	93.5	88.8	80.8	66.3	44.5	20.7
#	27,000	24,000	21,000	19,000	16,000	13,000	9,000	5,000	1,000	200

Effective Sample Size

Thera DR-50 7950, 7951, 7952

Product Characteristics

US Market Release	Jan-95	NBG Code	DDD/RO
Registered US Implants	5,000	Serial Number Prefix/X-ray ID	PBR, PBV, PBW
Estimated Active US Implants	1,000	Estimated Longevity	See page 74
Normal Battery Depletions	156		
Malfunctions	1		
Advisories	1	see page 165 – 1997 Potential Integrated Circuit Failure	



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 133 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.7	99.5	99.2	98.5	97.3	96.0	93.2	86.9	74.2	71.7
#	4,000	4,000	3,000	3,000	3,000	2,000	2,000	2,000	1,000	1,000	200	100

Effective Sample Size

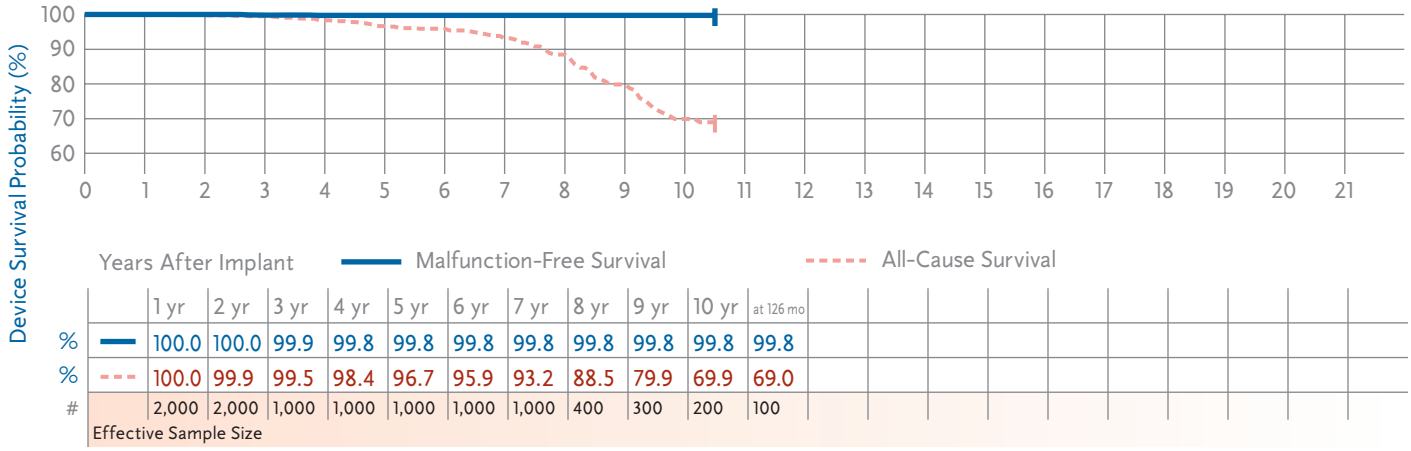
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Thera S 8944, 8945, 8946

Product Characteristics

US Market Release	Jan-95
Registered US Implants	3,000
Estimated Active US Implants	200
Normal Battery Depletions	80
Malfunctions	3
Advisories	None

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PBG, PBH, PBJ
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	100.0	100.0	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
%	100.0	99.9	99.5	98.4	96.7	95.9	93.2	88.5	79.9	69.9	69.0
#	2,000	2,000	1,000	1,000	1,000	1,000	1,000	400	300	200	100

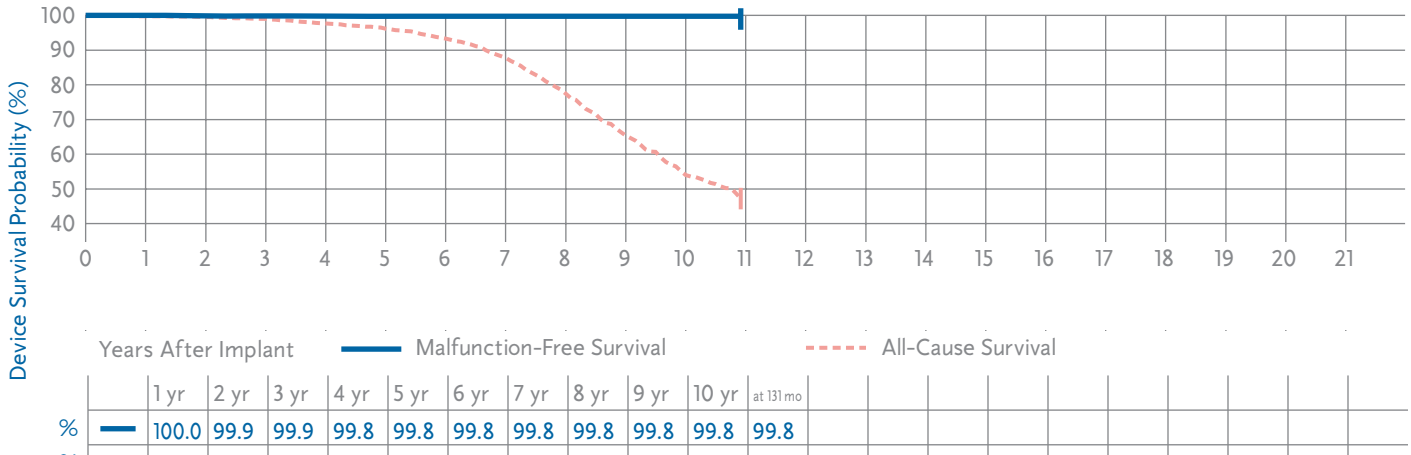
Effective Sample Size

Thera SR 8940, 8941, 8942

Product Characteristics

US Market Release	Jan-95
Registered US Implants	14,000
Estimated Active US Implants	400
Normal Battery Depletions	800
Malfunctions	16
Advisories	1 see page 165 – 1997 Potential Integrated Circuit Failure

NBG Code	SSI/R
Serial Number Prefix/X-ray ID	PAU, PAV, PAW
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 131 mo
%	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
%	99.8	99.5	99.0	97.7	96.2	93.3	87.8	77.4	65.4	54.0	47.2
#	12,000	10,000	9,000	8,000	7,000	5,000	4,000	2,000	1,000	1,000	100

Effective Sample Size

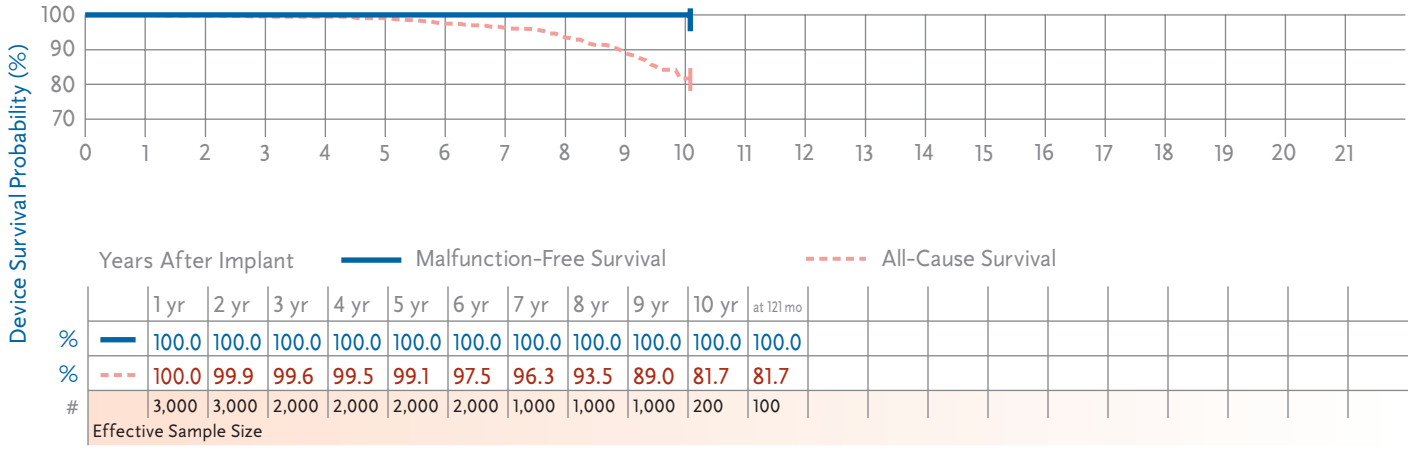
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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	79
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix/X-ray ID	PDE, PDF, PDG
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 121 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.6	99.5	99.1	97.5	96.3	93.5	89.0	81.7	81.7
#	3,000	3,000	2,000	2,000	2,000	2,000	1,000	1,000	1,000	200	100

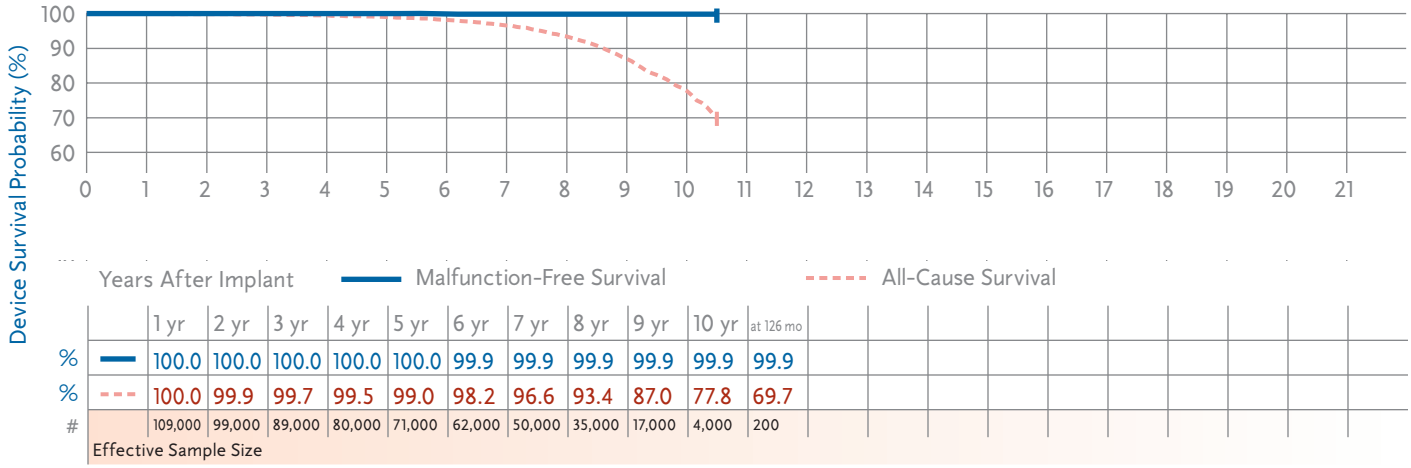
Effective Sample Size

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

US Market Release	Oct-95
Registered US Implants	122,000
Estimated Active US Implants	34,000
Normal Battery Depletions	3,210
Malfunctions	50
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PDB,PDC, PDD
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	99.9	99.7	99.5	99.0	98.2	96.6	93.4	87.0	77.8	69.7
#	109,000	99,000	89,000	80,000	71,000	62,000	50,000	35,000	17,000	4,000	200

Effective Sample Size

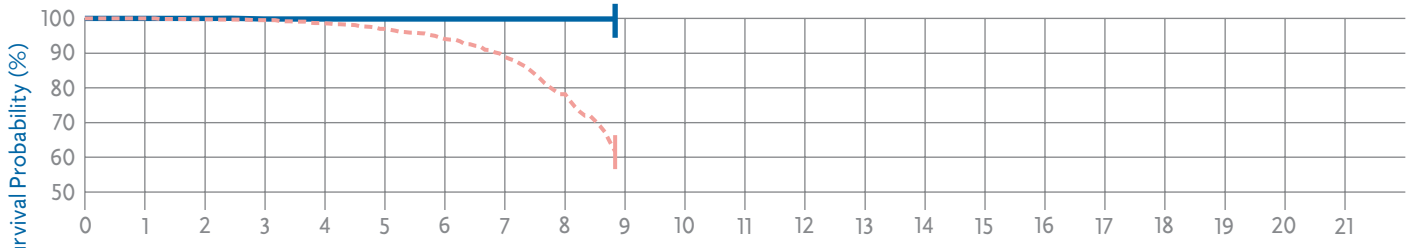
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Thera-i DR 7968i

US Market Release	Jul-96
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	164
Malfunctions	3
Advisories	None

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix/X-ray ID	PGH
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 106 mo
%	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	99.8	99.5	98.6	97.0	94.1	88.9	78.2	61.7
#	3,000	3,000	3,000	2,000	2,000	2,000	1,000	400	100

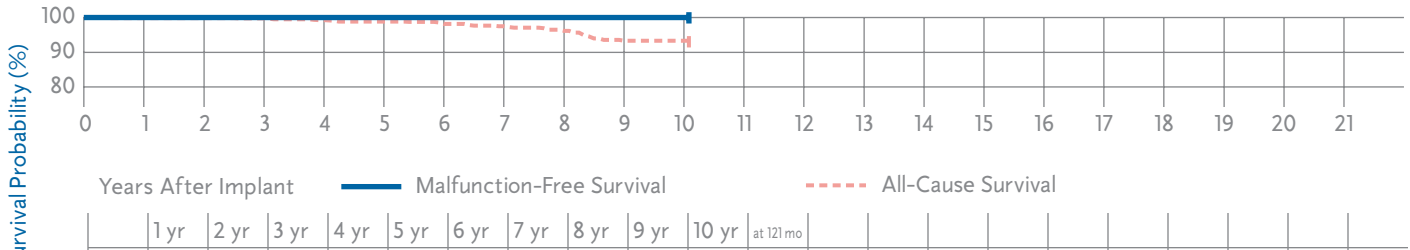
Effective Sample Size

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	35
Malfunctions	1
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/X-ray ID	PDY, PEA, PEB
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 121 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.8	99.3	98.9	98.2	97.5	96.2	93.3	93.3	93.3
#	3,000	3,000	2,000	2,000	2,000	1,000	1,000	1,000	500	200	100

Effective Sample Size

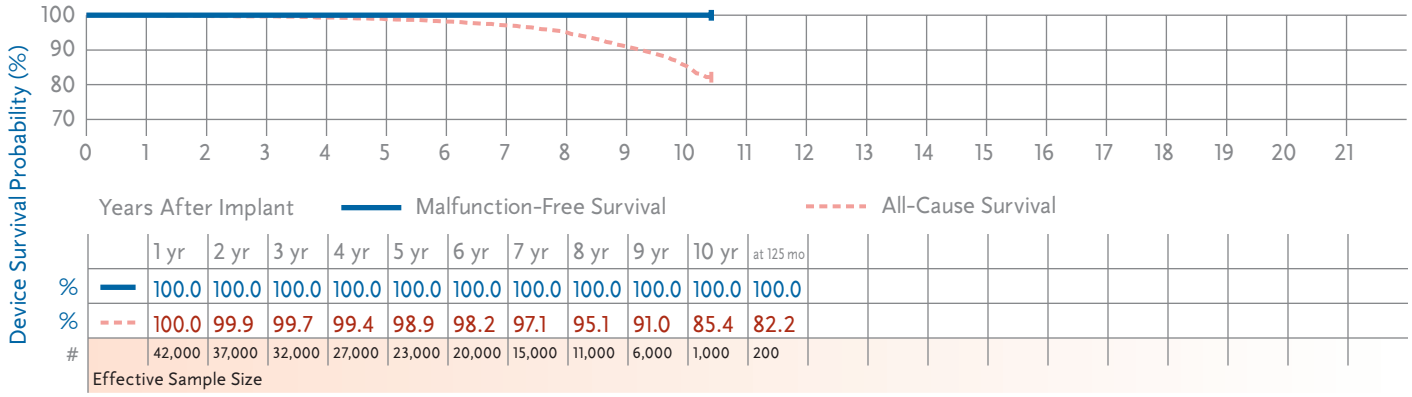
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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

US Market Release	Oct-95
Registered US Implants	50,000
Estimated Active US Implants	11,000
Normal Battery Depletions	736
Malfunctions	7
Advisories	None

Product Characteristics

NBG Code	SSIR
Serial Number Prefix/X-ray ID	PDU, PDV, PDW
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 125 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.7	99.4	98.9	98.2	97.1	95.1	91.0	85.4	82.2
#	42,000	37,000	32,000	27,000	23,000	20,000	15,000	11,000	6,000	1,000	200

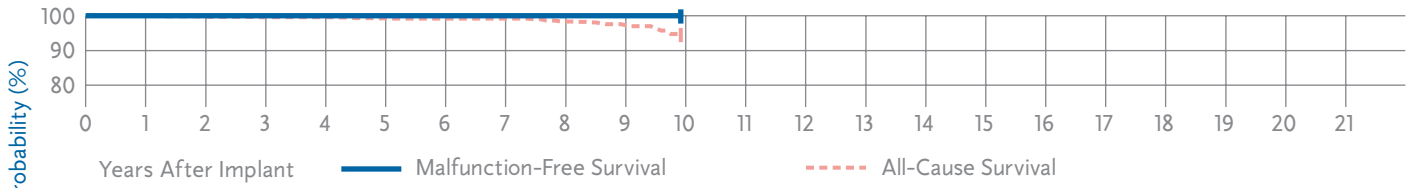
Effective Sample Size

Thera-i VDD 8968i

US Market Release	Mar-96
Registered US Implants	5,000
Estimated Active US Implants	2,000
Normal Battery Depletions	28
Malfunctions	0
Advisories	None

Product Characteristics

NBG Code	VDD
Serial Number Prefix/X-ray ID	PEC
Estimated Longevity	See page 75



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 119 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.8	99.6	99.6	99.3	99.2	99.2	98.4	97.3	94.8
#	4,000	4,000	3,000	3,000	3,000	2,000	2,000	1,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

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 Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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	8,000	113	3	3	6	Malfunction-free	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	99.1 +0.6/-1.5	99.1 +0.6/-1.5	99.1 +0.6/-1.5 at 61 mo						
						(1)	(1)	(2)	All-cause	100.0 +0.0/-0.1	99.9 +0.1/-0.1	99.5 +0.2/-0.4	89.6 +2.5/-3.2	53.3 +5.6/-5.9	47.3 +5.9/-6.1 at 61 mo						
	Advisory: see page 155 – 2003 Potential Incorrect Memory Circuit Setting; also see page 172 – Performance note on AT500 Pacing System Follow-Up Protocol					(advisory-related subset)															
Elite	7074, 7075, 7076, 7077	Apr-91	48,000	1,000	3,240	—	—	85	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1 at 157 mo	
									All-cause	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.1/-0.1	97.8 +0.2/-0.2	95.7 +0.2/-0.3	91.1 +0.4/-0.4	76.5 +0.7/-0.7	54.0 +1.1/-1.1	24.5 +2.4/-2.3 at 157 mo	
EnPulse DR	E1DR01	Dec-03	7,000	5,000	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 29 mo									
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 29 mo									
EnPulse DR	E1DR21	Dec-03	2,000	1,000	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo									
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo									
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	82,000	73,000	0	1	1	2	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 27 mo									
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 27 mo									
EnPulse 2 DR	E2DR21	Feb-04	9,000	8,000	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0										
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0										
EnPulse 2 DR	E2DR31	Feb-04	400	400	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 14 mo										
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 14 mo										

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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	19,000	16,000	1	1	0	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo									
									All-cause	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 28 mo									
EnPulse 2 VDD	E2VDD01	Dec-03	500	400	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 17 mo										
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 17 mo										
EnRhythm DR	P1501DR	May-05	29,000	28,000	0	4	2	6	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 13 mo										
									All-cause	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 13 mo										
Kappa 400 DR	KDR401, KDR403	Jan-98	46,000	16,000	1,284	9	12	21	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 99 mo			
									All-cause	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	97.8 +0.2/-0.2	91.4 +0.5/-0.5	66.9 +1.4/-1.5	54.3 +3.6/-3.8 at 99 mo			
Kappa 400 SR	KSR401, KSR403	Feb-98	15,000	6,000	147	1	3	4	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 98 mo			
									All-cause	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.1/-0.2	98.8 +0.3/-0.3	96.4 +0.6/-0.7	82.9 +2.2/-2.4	80.3 +2.9/-3.3 at 98 mo			
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	24,000	11,000	185	11	4	15	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 86 mo				
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(10)	(0)	(10) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.1 +0.1/-0.2	97.4 +0.3/-0.3	93.3 +0.9/-1.0	92.7 +1.2/-1.4 at 86 mo				
Kappa 600 DR	KDR651, KDR653	Mar-01	14,000	8,000	34	1	2	3	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 61 mo						
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.2	98.9 +0.3/-0.4	98.9 +0.3/-0.4 at 61 mo						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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 D	KD701	Jan-99	300	200	3	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 64 mo						
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	98.9 +0.9/-3.3	97.3 +1.7/-4.3	97.3 +1.7/-4.3 at 64 mo						
Kappa 700 DR	KDR701, KDR703, KDR706	Feb-99	189,000	110,000	1,094	119	19	138	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 88 mo				
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(100)	(0)	(100) (advisory-related subset)	All-cause	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.3 +0.0/-0.1	98.5 +0.1/-0.1	96.9 +0.2/-0.2	91.6 +0.5/-0.5	86.2 +1.7/-1.9 at 88 mo				
Kappa 700 DR	KDR721	Feb-99	10,000	3,000	375	4	1	5	Malfunction-free	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 80 mo					
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(4)	(0)	(4) (advisory-related subset)	All-cause	99.9 +0.0/-0.1	99.7 +0.1/-0.2	99.0 +0.2/-0.3	96.9 +0.4/-0.5	92.2 +0.7/-0.8	75.9 +2.0/-2.1	54.8 +4.2/-4.4 at 80 mo					
Kappa 700 SR	KSR701, KSR703, KSR706	Feb-99	53,000	25,000	342	4	1	5	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 87 mo				
									All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.0 +0.1/-0.1	97.8 +0.2/-0.2	95.9 +0.4/-0.4	89.7 +1.3/-1.5	86.5 +2.3/-2.8 at 87 mo				
Kappa 700 VDD	KVDD701	Jan-99	2,000	1,000	29	2	0	2	Malfunction-free	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.8 +0.1/-0.5	99.8 +0.1/-0.5	99.8 +0.1/-0.5	99.8 +0.1/-0.5 at 78 mo					
	Advisory: see page 157 – 2002 Potential Fractured Power Supply Wires					(2)	(0)	(2) (advisory-related subset)	All-cause	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.6 +0.2/-0.5	99.0 +0.4/-0.8	98.8 +0.5/-0.8	94.6 +1.7/-2.5	86.0 +3.8/-5.0 at 78 mo					
Kappa 800 DR	KDR801, KDR803	Jan-02	4,000	3,000	3	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 46 mo								
									All-cause	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.8 +0.1/-0.2 at 46 mo								
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	119,000	89,000	50	4	8	12	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 53 mo							
									All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.5 +0.1/-0.1 at 53 mo							

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 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 900 SR	KSR901, KSR903, KSR906	Jan-02	34,000	23,000	14	0	+	4	=	4	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 51 mo							
											All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.6 +0.1/-0.2 at 51 mo							
Kappa 900 VDD	KVDD901	Jan-02	1,000	400	0	0	+	0	=	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 44 mo								
											All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 44 mo								
Kappa 920 DR	KDR921	Jan-02	16,000	11,000	31	1	+	0	=	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 50 mo							
											All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.2	98.0 +0.6/-0.8	98.0 +0.6/-0.8 at 50 mo							
Legend	8416, 8417, 8417M, 8418, 8419	Aug-89	57,000	4,000	2,535	—		—		145	Malfunction-free	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.8 +0.0/-0.0	99.7 +0.0/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1	99.6 +0.1/-0.1 at 196 mo
											All-cause	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.4 +0.1/-0.1	98.9 +0.1/-0.1	98.3 +0.1/-0.1	97.2 +0.2/-0.2	94.7 +0.3/-0.3	90.7 +0.4/-0.4	81.4 +0.6/-0.6	73.2 +0.7/-0.7	64.7 +1.0/-1.0	57.3 +1.6/-1.7 at 196 mo
Legend II	8424, 8426, 8427	Nov-91	59,000	7,000	1,555	—		—		37	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 171 mo
											All-cause	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.8 +0.1/-0.1	98.2 +0.1/-0.1	97.3 +0.2/-0.2	94.9 +0.3/-0.3	89.3 +0.4/-0.4	83.8 +0.6/-0.6	76.2 +1.3/-1.4	75.3 +1.5/-1.6 at 171 mo
Minuet	7107, 7108	Mar-92	17,000	3,000	513	—		—		4	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 167 mo	
											All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	98.2 +0.2/-0.3	96.9 +0.3/-0.4	94.7 +0.5/-0.5	89.4 +0.7/-0.8	83.0 +1.1/-1.1	76.1 +1.9/-2.0 at 167 mo	
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Dec-89	58,000	6,000	1,409	—		—		49	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 205 mo
	Advisory: see page 170 - 1991 Potential Delayed Restoration of Permanent Settings					—		—		—	All-cause	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.7 +0.1/-0.1	97.7 +0.2/-0.2	95.3 +0.3/-0.3	92.0 +0.4/-0.4	87.3 +0.5/-0.5	83.9 +0.6/-0.6	81.2 +0.7/-0.7	78.6 +1.2/-1.3 at 205 mo

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Preva D	7068	Nov-96	1,000	300	16	—	—	1	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9	99.9 +0.1/-0.9 at 99 mo			
									All-cause	100.0 +0.0/-0.0	99.7 +0.2/-0.8	99.1 +0.5/-1.2	98.3 +0.8/-1.4	98.3 +0.8/-1.4	96.4 +1.3/-2.1	92.7 +2.2/-3.1	91.9 +2.4/-3.3	91.9 +2.4/-3.3 at 99 mo			
Preva DR	7088, 7089	Jul-96	25,000	8,000	457	—	—	3	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 117 mo			
									All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.1/-0.2	98.1 +0.2/-0.2	96.8 +0.3/-0.3	93.9 +0.5/-0.5	79.9 +2.3/-2.5 at 117 mo			
Preva SR	8088, 8089	Jul-96	18,000	4,000	225	—	—	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 116 mo			
									All-cause	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.3 +0.1/-0.2	98.7 +0.2/-0.3	97.7 +0.3/-0.4	95.5 +0.5/-0.5	93.9 +0.6/-0.7	84.6 +2.9/-3.6 at 116 mo			
Preva ST DR	7078	Nov-96	1,000	300	18	—	—	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 101 mo			
									All-cause	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.4 +0.4/-0.9	99.4 +0.4/-0.9	98.2 +0.8/-1.5	97.3 +1.1/-1.8	94.2 +1.9/-2.7	91.8 +2.5/-3.4	91.8 +2.5/-3.4 at 101 mo			
Prevail S	8084, 8085, 8086	Oct-95	4,000	1,000	13	—	—	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.9 +0.1/-0.4	99.9 +0.1/-0.4 at 114 mo			
									All-cause	100.0 +0.0/-0.1	100.0 +0.0/-0.1	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.3 +0.3/-0.6	99.1 +0.4/-0.6	98.5 +0.6/-0.9	98.2 +0.6/-1.0	97.0 +1.0/-1.6 at 114 mo			
Prodigy D	7864, 7865, 7866	Oct-95	3,000	1,000	45	—	—	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 116 mo			
									All-cause	99.9 +0.1/-0.2	99.7 +0.2/-0.3	99.4 +0.3/-0.4	98.8 +0.4/-0.6	98.6 +0.4/-0.6	97.7 +0.6/-0.8	97.1 +0.7/-1.0	96.0 +0.9/-1.2	89.4 +2.6/-3.4 at 116 mo			
Prodigy DR	7860, 7861, 7862	Oct-95	37,000	12,000	627	—	—	10	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0			
									All-cause	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	99.0 +0.1/-0.1	98.3 +0.2/-0.2	96.9 +0.2/-0.3	94.0 +0.4/-0.4	81.7 +1.8/-2.0			
Prodigy S	8164, 8165, 8166	Oct-95	2,000	500	17	—	—	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 113 mo			
									All-cause	99.9 +0.1/-0.3	99.9 +0.1/-0.3	99.8 +0.2/-0.4	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7	98.9 +0.5/-0.9	97.0 +1.1/-1.6	91.8 +2.8/-4.2 at 113 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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 SR	8158, 8160, 8161, 8162	Oct-95	22,000	6,000	271	—	—	5	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 119 mo			
									All-cause	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.1/-0.2	98.4 +0.2/-0.2	97.6 +0.3/-0.3	96.1 +0.4/-0.4	94.0 +0.6/-0.6	87.8 +1.9/-2.3 at 119 mo			
Sigma 100 S	SS103, SS106	Aug-99	1,000	200	1	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 65 mo						
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4 at 65 mo						
Sigma 200 DR	SDR203	Aug-99	16,000	9,000	16	2	1	3	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 77 mo					
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.2 +0.3/-0.4	99.2 +0.3/-0.4 at 77 mo					
Sigma 200 SR	SSR203	Sep-99	12,000	5,000	10	2	0	2	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 77 mo					
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(2)	(0)	(2) (advisory-related subset)	All-cause	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.2	99.6 +0.2/-0.3	99.4 +0.2/-0.4	99.4 +0.2/-0.4 at 77 mo					
Sigma 300 DR	SDR303, SDR306	Aug-99	98,000	64,000	61	35	3	38	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 80 mo					
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(17)	(0)	(17) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.3 +0.1/-0.2	99.2 +0.2/-0.2 at 80 mo					
Sigma 300 SR	SSR303, SSR306	Sep-99	48,000	25,000	34	7	1	8	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 78 mo					
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(5)	(0)	(5) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.2	98.9 +0.3/-0.4	98.9 +0.3/-0.4 at 78 mo					
Sigma 300 VDD	SVDD303	Sep-99	1,000	300	0	0	0	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 64 mo						
	Advisories: see page 152 – 2005 Potential Separation of Interconnect Wires; and page 163 – 1999 Manufacturing Issue					(0)	(0)	(0) (advisory-related subset)	All-cause	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 64 mo						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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 D	7944, 7945, 7946	Jan-95	2,000	5	174	—	—	2	Malfunction-free	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.9 +0.0/-0.3	99.7 +0.3/-1.3 at 111 mo			
									All-cause	99.9 +0.1/-0.3	99.8 +0.2/-0.4	98.9 +0.4/-0.7	97.3 +0.8/-1.0	93.5 +1.3/-1.6	90.0 +1.6/-2.0	82.8 +2.3/-2.6	66.7 +3.5/-3.8	47.1 +4.9/-5.0 at 111 mo			
Thera DR-40	7940, 7941, 7942	Jan-95	30,000	10	2,945	—	—	37	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.0/-0.1 at 113 mo			
	Advisory: see page 165 – 1997 Potential Integrated Circuit Failure					—	—	—	All-cause	100.0 +0.0/-0.0	99.7 +0.1/-0.1	98.5 +0.2/-0.2	96.5 +0.2/-0.3	93.5 +0.3/-0.4	88.8 +0.5/-0.5	80.8 +0.6/-0.6	66.3 +0.9/-0.9	20.7 +2.6/-2.5 at 113 mo			
Thera DR-50	7950, 7951, 7952	Jan-95	5,000	1,000	156	—	—	1	Malfunction-free	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 133 mo		
	Advisory: see page 165 – 1997 Potential Integrated Circuit Failure					—	—	—	All-cause	100.0 +0.0/-0.1	100.0 +0.0/-0.1	99.7 +0.1/-0.2	99.5 +0.2/-0.3	99.2 +0.3/-0.4	98.5 +0.4/-0.5	97.3 +0.6/-0.7	96.0 +0.7/-0.9	86.9 +1.6/-1.8	71.7 +3.8/-4.3 at 133 mo		
Thera S	8944, 8945, 8946	Jan-95	3,000	200	80	—	—	3	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.4	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5 at 126 mo		
									All-cause	100.0 +0.0/-0.0	99.9 +0.1/-0.3	99.5 +0.2/-0.5	98.4 +0.5/-0.8	96.7 +0.9/-1.2	95.9 +1.0/-1.3	93.2 +1.5/-1.8	88.5 +2.1/-2.6	69.9 +4.1/-4.6	69.0 +4.3/-4.8 at 126 mo		
Thera SR	8940, 8941, 8942	Jan-95	14,000	400	800	—	—	16	Malfunction-free	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 131 mo		
	Advisory: see page 165 – 1997 Potential Integrated Circuit Failure					—	—	—	All-cause	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.2/-0.2	97.7 +0.3/-0.3	96.2 +0.4/-0.4	93.3 +0.6/-0.6	87.8 +0.8/-0.9	77.4 +1.2/-1.3	54.0 +2.2/-2.2	47.2 +3.0/-3.1 at 131 mo		
Thera-i D	7964i, 7965i, 7966i	Oct-95	3,000	1,000	79	—	—	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2	100.0 +0.0/-0.2 at 121 mo		
									All-cause	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.6 +0.2/-0.3	99.5 +0.2/-0.4	99.1 +0.3/-0.5	97.5 +0.6/-0.8	96.3 +0.8/-1.0	93.5 +1.2/-1.5	81.7 +3.1/-3.6	81.7 +3.1/-3.6 at 121 mo		
Thera-i DR	7960i, 7961i, 7962i	Oct-95	122,000	34,000	3,210	—	—	50	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 126 mo		
									All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.0/-0.1	99.0 +0.1/-0.1	98.2 +0.1/-0.1	96.6 +0.1/-0.1	93.4 +0.2/-0.2	77.8 +07/-0.7	69.7 +2.0/-2.1 at 126 mo		

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 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-i DR	7968i	Jul-96	4,000	1,000	164	—	—	3	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 106 mo			
									All-cause	100.0 +0.0/-0.0	99.8 +0.1/-0.2	99.5 +0.2/-0.3	98.6 +0.4/-0.6	97.0 +0.6/-0.8	94.1 +1.0/-1.1	88.9 +1.4/-1.6	78.2 +2.4/-2.7	61.7 +4.7/-5.1 at 106 mo			
Thera-i S	8964i, 8965i, 8966i	Oct-95	4,000	1,000	35	—	—	1	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.3	100.0 +0.0/-0.3	100.0 +0.0/-0.3	100.0 +0.0/-0.3	100.0 +0.0/-0.3	100.0 +0.0/-0.3	100.0 +0.0/-0.3 at 121 mo		
									All-cause	99.9 +0.0/-0.2	99.9 +0.1/-0.2	99.8 +0.1/-0.3	99.3 +0.3/-0.5	98.9 +0.4/-0.6	98.2 +0.5/-0.8	97.5 +0.7/-0.9	96.2 +0.9/-1.2	93.3 +1.5/-1.9	93.3 +1.5/-1.9 at 121 mo		
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	11,000	736	—	—	7	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 125 mo		
									All-cause	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.9 +0.1/-0.1	98.2 +0.2/-0.2	97.1 +0.2/-0.2	95.1 +0.3/-0.3	85.4 +1.0/-1.0	82.2 +1.5/-1.6 at 125 mo		
Thera-i VDD	8968i	Mar-96	5,000	2,000	28	—	—	0	Malfunction-free	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 119 mo			
									All-cause	100.0 +0.0/-0.1	99.8 +0.1/-0.2	99.6 +0.1/-0.3	99.6 +0.2/-0.3	99.3 +0.2/-0.4	99.2 +0.3/-0.4	99.2 +0.3/-0.4	98.4 +0.5/-0.6	94.8 +1.7/-2.4 at 119 mo			

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 7, 2006

Reference Chart

The longevity estimates shown here assume a lower rate of 60 ppm, 100% pacing, and pulse width of 0.4 ms unless noted otherwise. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from these estimates. The elective replacement time is indicated via telemetry indication, and rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet), unless noted otherwise.

		Estimated Longevity			
Family	Model Number	Amplitude Setting	500 Lead Ω	1000 Lead Ω	Elective Replacement Time Indicators
AT500	AT501, 7253	Low 2.0 V (A, RV) Nominal 3.0 V (A, RV) High 5.0 V (A, RV)	7.7 5.8 3.7	8.3 7.0 5.2	Telemetry indication. Pacing mode and rate (magnet and non-magnet) as programmed.
Elite	7074, 7075, 7076, 7077	Low 2.5 V, 0.36 ms (A, RV) Nominal 3.3 V, 0.36 ms (A, RV) High 5.0 V, 0.36 ms (A, RV)	11.8 8.6 6.7	13.2 11.0 9.4	**
EnPulse DR	E1DR01, E1DR03, E1DR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.2 4.4	8.5 7.6 5.9	**
EnPulse DR	E1DR21	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.4 4.3 3.0	6.0 5.4 4.2	**
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.2 4.4	8.5 7.6 5.9	**
EnPulse 2 DR	E2DR21	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.4 4.3 3.0	6.0 5.4 4.2	**
EnPulse 2 DR	E2DR31, E2DR33	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.0 7.4 5.2	10.1 9.1 7.1	**
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.2 6.3 4.8	7.7 7.3 6.1	**
EnPulse 2 VDD	E2VDD01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.1 5.5 4.3	6.5 6.2 5.4	**
EnRhythm DR	P1501DR	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.6 8.0 5.4	12.3 10.3 7.8	**
InSync	8040	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	11.9 8.9 6.6	13.7 11.4 9.1	**
InSync III	8042	Low 2.5 V (A, RV, LV) Nominal 3.5 V (A, RV, LV) High 5.0 V (A, RV, LV)	8.3 5.9 4.1	9.9 7.8 6.0	**
Kappa 400 DR	KDR401, KDR403	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.8 6.4 5.1	8.5 7.5 6.5	**
Kappa 400 SR	KSR401, KSR403	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.9 6.9 5.8	8.4 7.7 7.0	**
Kappa 600 DR	KDR601, KDR603, KDR606	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 600 DR	KDR651, KDR653, KDR656	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 700 D	KD701, KD703, KD706	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

continued

Reference Chart continued

Family	Model Number	Estimated Longevity: Amplitude Setting	500 Lead Ω	1000 Lead Ω	Elective Replacement Time Indicators
Kappa 700 DR	KDR701, KDR703, KDR706	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 700 DR	KDR721	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.4 3.0	6.1 5.5 4.2	**
Kappa 700 SR	KSR701, KSR703, KSR706	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 4.9	7.9 7.5 6.2	**
Kappa 700 VDD	KVDD701	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.6 4.4	6.6 6.3 5.3	**
Kappa 800 DR	KDR801, KDR803, KDR806	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 900 DR	KDR901, KDR903, KDR906	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.7 6.3 4.4	8.6 7.7 6.0	**
Kappa 920 DR	KDR921	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.4 3.0	6.1 5.5 4.3	**
Kappa 900 SR	KSR901, KSR903, KSR906	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.3 6.4 4.9	7.9 7.4 6.1	**
Kappa 900 VDD	KVDD901	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.6 4.4	6.6 6.3 5.4	**
Legend	8416, 8417, 8417M, 8418, 8419	Low 2.5 V (RV) Nominal 3.3 V (RV) High 5.0 V (RV)	15.6 11.3 9.0	17.7 14.5 12.5	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 II	8424, 8426, 8427	Low 2.5 V, 0.36 ms (RV) Nominal 3.3 V, 0.36 ms (RV) High 5.0 V, 0.36 ms (RV)	12.9 9.4 7.8	14.5 11.8 10.5	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.
Minix	8340, 8341, 8341M, 8342	Low 2.5 V (RV) Nominal 3.3 V (RV) High 5.0 V (RV)	14.9 10.2 7.9	17.3 13.6 11.3	Telemetry indication. Rate decrease of 10% from programmed rate.
Minix ST	8330, 8331, 8331M	Low 2.5 V (RV) Nominal 5.0 V (RV) High 8.0 V (RV)	14.9 7.9 4.0	17.3 11.4 7.0	Telemetry indication. Rate decrease of 10% from programmed rate.
Minuet	7107, 7108	Low 2.5 V, 0.36 ms (A, RV) Nominal 4.0 V, 0.36 ms (A, RV) High 5.0 V, 0.36 ms (A, RV)	12.5 7.7 4.7	15.6 10.9 7.6	**
Preva D	7068	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.0 7.4 5.4	11.4 9.5 7.6	**
Preva DR	7088, 7089	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Preva SR	8088, 8089	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Preva ST DR	7078	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

continued

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Time Indicators
Prevail S	8084, 8085, 8086	Low 2.5 V, 0.42 ms (RV) Nominal 3.3 V, 0.42 ms (RV) High 5.0 V, 0.42 ms (RV)	16.4 10.8 8.6	19.4 14.4 12.4	Telemetry indication. Rate decrease of 10% from programmed rate.
Prodigy D	7864, 7865, 7866	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.0 7.4 5.4	11.4 9.5 7.6	**
Prodigy DR	7860, 7861, 7862	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Prodigy S	8164, 8165, 8166	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.0 8.1 6.4	10.9 9.6 8.2	**
Prodigy SR	8158, 8160, 8161, 8162	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Sigma 100 S	SS103, SS106	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 200 DR	SDR203	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.1 7.5 5.5	11.7 9.6 7.8	**
Sigma 200 SR	SSR203	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 300 DR	SDR303, SDR306	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.1 7.5 5.5	11.7 9.6 7.8	**
Sigma 300 SR	SSR303, SSR306	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.1 8.2 6.4	11.1 9.8 8.4	**
Sigma 300 VDD	SVDD303	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	8.9 7.3 5.8	9.7 8.6 7.4	**
Thera D	7944, 7945, 7946	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.6 5.5 3.7	8.8 7.1 5.6	**
Thera DR-40	7940, 7941, 7942	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.6 5.5 3.7	8.7 7.0 5.6	**
Thera DR-50	7950, 7951, 7952	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	12.2 9.1 6.7	14.0 11.6 9.3	**
Thera S	8944, 8945, 8946	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.5 6.1 4.8	8.2 7.2 6.2	**
Thera SR	8940, 8941, 8942	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.0 4.8	8.0 7.1 6.1	**
Thera-i D	7964i, 7965i, 7966i	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	10.0 7.4 5.4	11.4 9.5 7.6	**
Thera-i DR	7960i, 7961i, 7962i	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.9 7.4 5.4	11.3 9.4 7.5	**
Thera-i DR	7968i	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.2 5.4 3.9	8.3 6.9 5.5	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

continued

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Time Indicators
Thera-i S	8964i, 8965i, 8966i	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	10.0 8.1 6.4	10.9 9.6 8.2	**
Thera-i SR	8960i, 8961i, 8962i	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	9.8 8.0 6.4	10.7 9.5 8.1	**
Thera-i VDD	8968i	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	11.5 9.6 7.7	12.4 11.1 9.7	**

**Telemetry indication. Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

Method for Estimating Lead Performance

Medtronic CRDM 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 IPGs and 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, regular monitoring while implanted, and evaluation of lead integrity upon IPG or ICD replacement, is necessary to determine if lead may be approaching the end of its service life.

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. Although laboratory analysis results are presented in this report, Medtronic tracks lead survival through 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 in 2007. 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 market-released Medtronic cardiac therapy product; complete implant and follow-up data are available; and the data is appropriately and legally released for use in the study.

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

continued

Method for Estimating Lead Performance continued

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

- 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.

Methods

The performance of leads is expressed in terms of lead survival estimates, where "survival" refers to the function of the lead, not the survival of the patient. These survival estimates are intended to illustrate the probability that a lead will survive for a given number of years without a lead-related complication.

The survival estimates are determined from the analysis of the data collected through the SLS. These data are presented graphically and numerically.

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. Under the study protocol, each lead is assumed to be normally active unless a lead-related complication is confirmed, the lead is electively abandoned or explanted, or the patient is no longer available for follow-up. The data analyses assume that the patient is still part of the study and there are no lead complications at the time of the report cutoff date unless specifically reported by the center or by correlation with returned product analysis. Implant 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.

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions assumed distributed across the intervals (Cutler-Ederer Method), is used to determine estimates of lead survival. This method is commonly used by medical researchers and clinicians.

On the following pages, each graph includes a survival curve where events include qualifying lead-related complications. This survival estimate is a good representation of the probability a lead will survive a period of time without a lead-related complication. For example, if a survival probability is 95% after 5 years of service, then the lead has a 5% chance of experiencing a lead-related complication in the first 5 years following implant.

Since the survival estimate can become very imprecise with small effective sample sizes, Medtronic truncates the survival curve when the number of leads entering an interval is less than 50 leads. When the number of leads entering an interval reaches 50, the next data point is added to the survival curve.

Although the report provides tabular data in one year intervals, the curves are actually computed and plotted using three-month intervals.

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 complications. This occurs because even with the complications, the data rounds to 100%.

The survival curves are statistical estimates. As 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.

continued

Method for Estimating Lead Performance continued

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 patients successfully enrolled in the SLS as of the report cutoff date. The number of enrolled implants is listed for each model.

This sample based on SLS enrollments 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.

In general, a model or model family will be included in this report when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Models will remain in the report as long as Medtronic estimates at least 500 leads remain active in the US, based on estimated US implants.

Chronic Lead Data Resolution

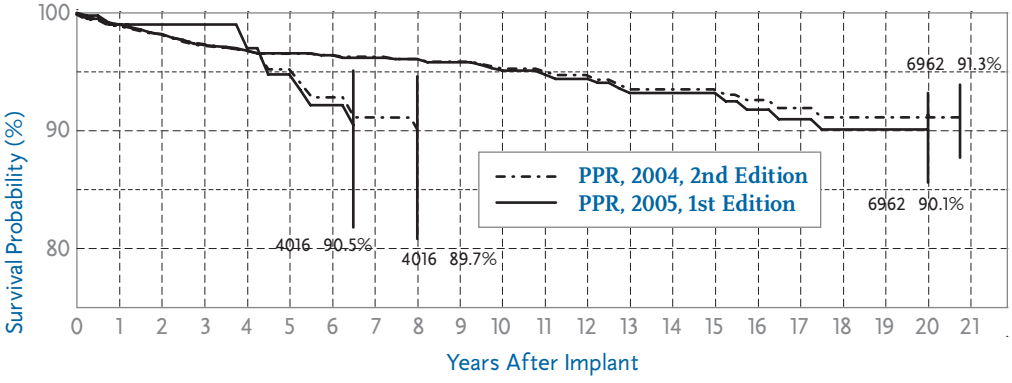
Because an accurate estimate of lead survival depends on an accurate estimate of the number of leads in service, it is important not to overstate the number of devices in service. Since the inception of the CLS and TCSS studies, the mechanism of patient follow-up has changed due to evolution in hospital 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 actually no longer available for study follow-up. Therefore, Medtronic has initiated an additional data resolution process to verify lead status for all active study patients. This process is ongoing and is expected to conclude in 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 reflect this additional process.

This data resolution process can change survival estimates 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 Second Edition PPR, but extends to 6.5 years with an estimated survival probability of 90.5% in the 2005 First 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 Second Edition, but extends to 20 years with an estimated survival probability of 90.1% in the 2005 First 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.

continued

4016, 6962 Ventricular Pacing Leads



Method for Estimating Lead Performance continued

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 or removal from use.

Laboratory Analysis Results

Every lead or lead portion returned to Medtronic receives an analysis. Although the laboratory analysis data is not used to generate the survival estimates, the data provides valuable insight into the causes of lead malfunction.

For reporting laboratory analysis results, Medtronic CRDM considers a lead as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service. To be considered a malfunction for laboratory results reporting, the lead must have been returned to Medtronic and analyzed.

Lead malfunctions 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 malfunction is defined as a hardware malfunction 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.

Leads damaged after explant or damaged due to failure to heed warnings or contraindications in the labeling are not considered device malfunctions.

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

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

Estimated Number of Implanted and Active Leads in the United States

In addition to providing the number of leads enrolled in the SLS, this report also provides estimates for the number of leads implanted in the United States and the number remaining active in the United States. 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. The number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure.

The numbers of malfunctions listed in the Laboratory Results tables are the actual numbers confirmed in the laboratory. The numbers of complications listed in the complications tables are the actual numbers observed in the SLS.

Some lead models do not have a survival curve presented 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.

Left-Heart Leads

2187 Attain

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEY
Estimated US Implants	17,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Estimated US Active	11,900	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

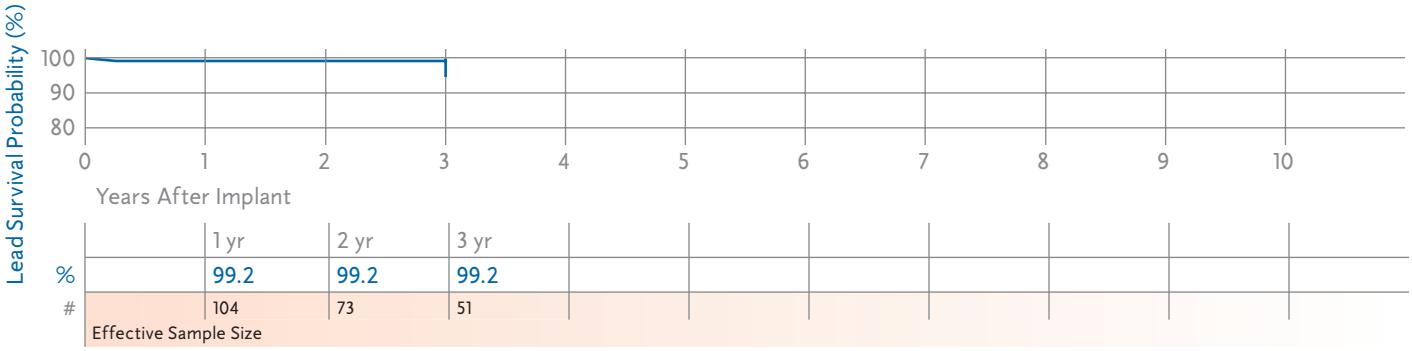
Implant Damage	7
Electrical Malfunction	0
Other	16

Prospective Clinical Study Results

Number of Leads Enrolled in Study	132
Cumulative Months of Follow-Up	4,313

Complications in Study 1 Total

Failure to Capture	1



2188 Attain

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEB
Estimated US Implants	2,800	Type and/or Fixation	Transvenous, Coronary Sinus/ Cardiac Vein, Canted
Estimated US Active	1,700	Polarity	Bipolar
Advisories	None	Steroid	No

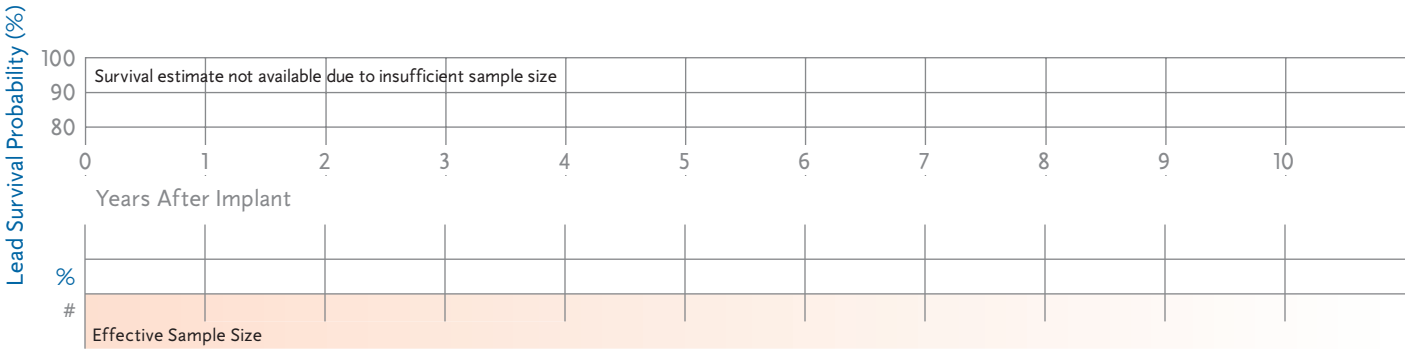
Laboratory Analysis

Implant Damage	1
Electrical Malfunction	1
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	57

Complications in Study 0 Total



Source: System Longevity Study
Data as of April 1, 2006

Left-Heart Leads continued

4193 Attain OTW

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Estimated US Implants	89,100	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated US Active	72,500	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

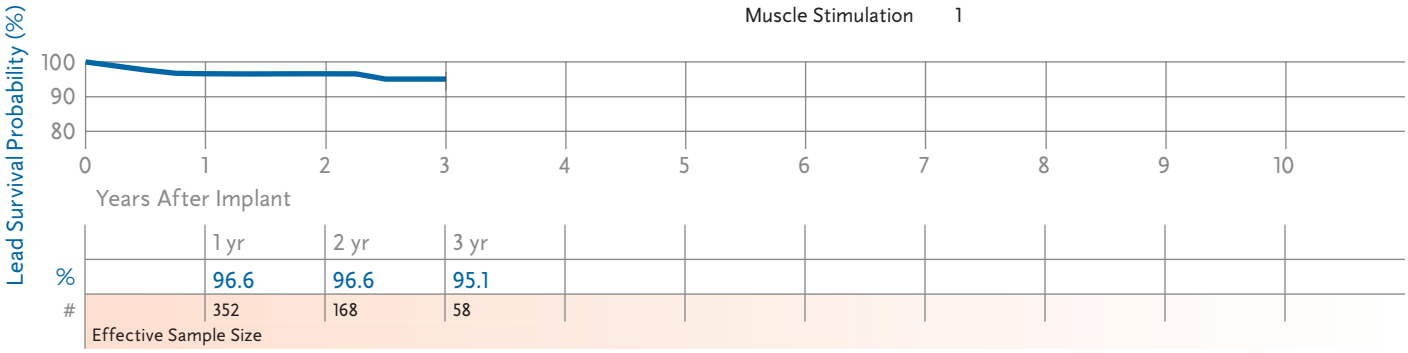
Implant Damage	55
Electrical Malfunction	11
Other	59

Prospective Clinical Study Results

Number of Leads Enrolled in Study	618
Cumulative Months of Follow-Up	10,844

Complications in Study 19 Total

Dislodgement	7
Failure to Capture	8
Misc: Other	3
Muscle Stimulation	1



4194 Attain

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Estimated US Implants	29,400	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated US Active	27,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

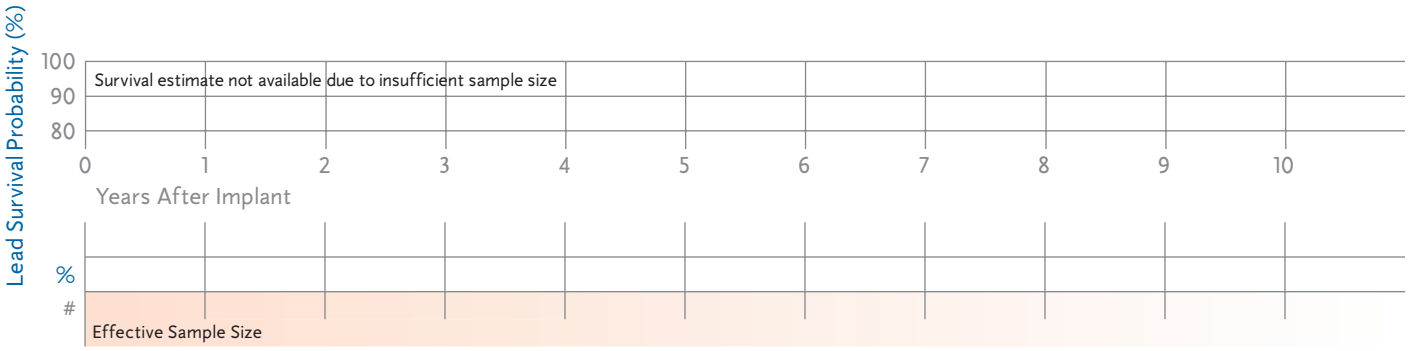
Implant Damage	31
Electrical Malfunction	1
Other	6

Prospective Clinical Study Results

Number of Leads Enrolled in Study	117
Cumulative Months of Follow-Up	611

Complications in Study 1 Total

Dislodgement	1



Leads

Source: System Longevity Study
Data as of April 1, 2006

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 (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
2187	Attain	Aug-01	132	1	4,313	99.2 +0.7/-4.6	99.2 +0.7/-4.6	99.2 +0.7/-4.6							
2188	Attain	Aug-01	4	0	57	Survival estimate not available due to insufficient sample size									
4193	Attain OTW	May-02	618	19	10,844	96.6 +1.3/-2.0	96.6 +1.3/-2.0	95.1 +2.0/-3.3							
4194	Attain	Aug-04	117	1	611	Survival estimate not available due to insufficient sample size									

Source: System Longevity Study
Data as of April 1, 2006

Laboratory Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
2187	Attain	Aug-01	17,000	11,900	7	0	16
2188	Attain	Aug-01	2,800	1,700	1	1	0
4193	Attain OTW	May-02	89,100	72,500	55	11	59
4194	Attain	Aug-04	29,400	27,300	31	1	6

Source: Returned Product Analysis
Data as of April 30, 2006

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 (55D)/ Silicone (4719)	MP35N	Platinum Alloy	IS-1 BI

Defibrillation Leads

6721, 6921 Epicardial Patch

Product Characteristics

US Market Release	Feb-93	Serial Number Prefix	TBH, TBG, TBB, TAD, TAC, or TAB
Estimated US Implants	8,800	Type and/or Fixation	Epicardial Defib Patch, Suture
Estimated US Active	2,200	Polarity	Defib Electrode only
Advisories	None	Steroid	No

Laboratory Analysis

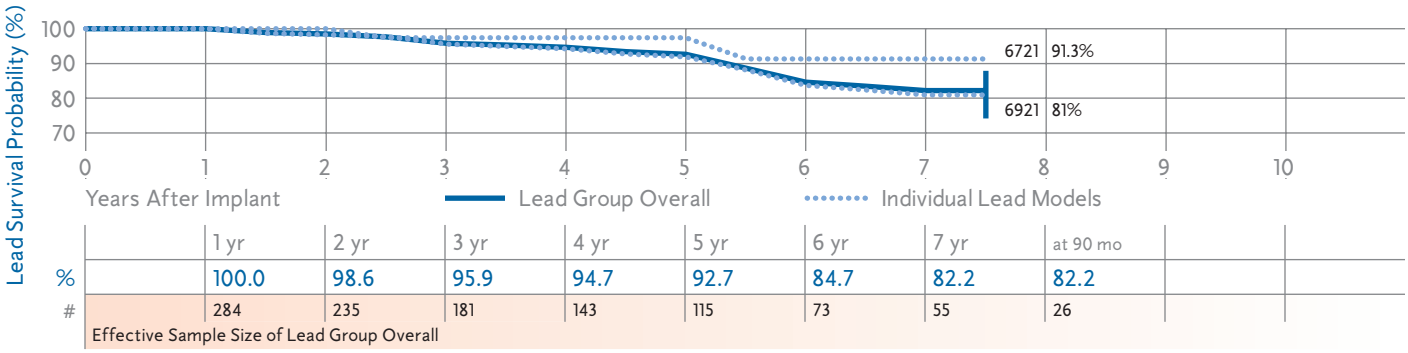
Implant Damage	5
Electrical Malfunction	78
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	398
Cumulative Months of Follow-Up	17,338

Complications in Study 26 Total

Conductor Fracture	20
Insulation Breach	1
Failure to Cardiovert/Defibrillate	2
Defib Impedance Out of Range	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	100.0	98.6	95.9	94.7	92.7	84.7	82.2	82.2
#	284	235	181	143	115	73	55	26

Effective Sample Size of Lead Group Overall

6930 Sprint Fidelis

Product Characteristics

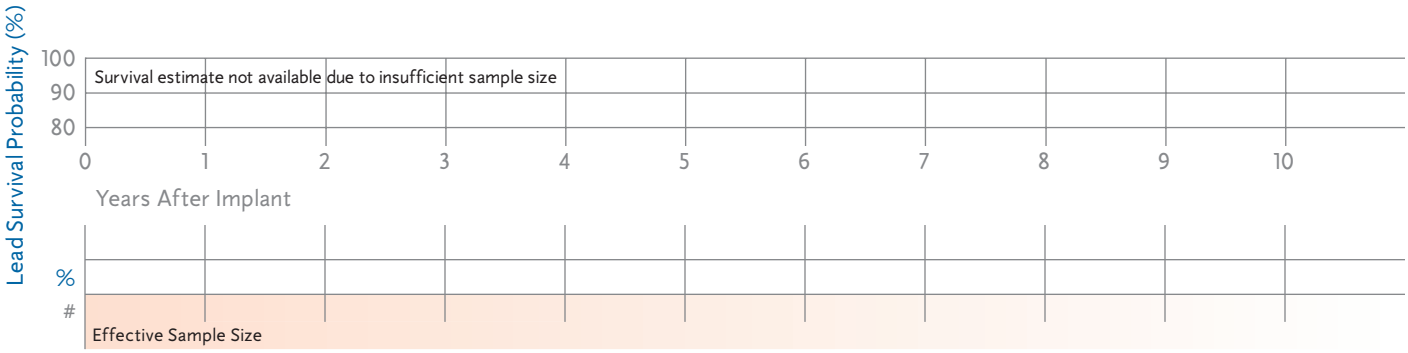
US Market Release	Jun-04	Serial Number Prefix	LFK
Estimated US Implants	100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Tines
Estimated US Active	100	Polarity	True Bipolar/ One Coil
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	0
Electrical Malfunction	0
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0



%	
#	

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6931 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFL
Estimated US Implants	2,900	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Estimated US Active	2,800	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

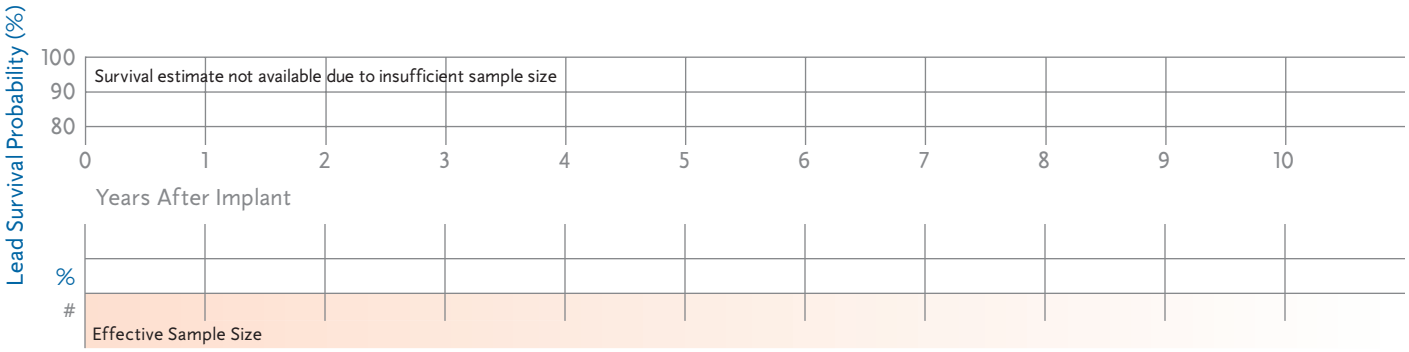
Laboratory Analysis

Implant Damage	6
Electrical Malfunction	7
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	36
Cumulative Months of Follow-Up	35

Complications in Study 0 Total



6932 Sprint

Product Characteristics

US Market Release	Aug-96	Serial Number Prefix	TCA
Estimated US Implants	15,300	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Tines
Estimated US Active	7,300	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Laboratory Analysis

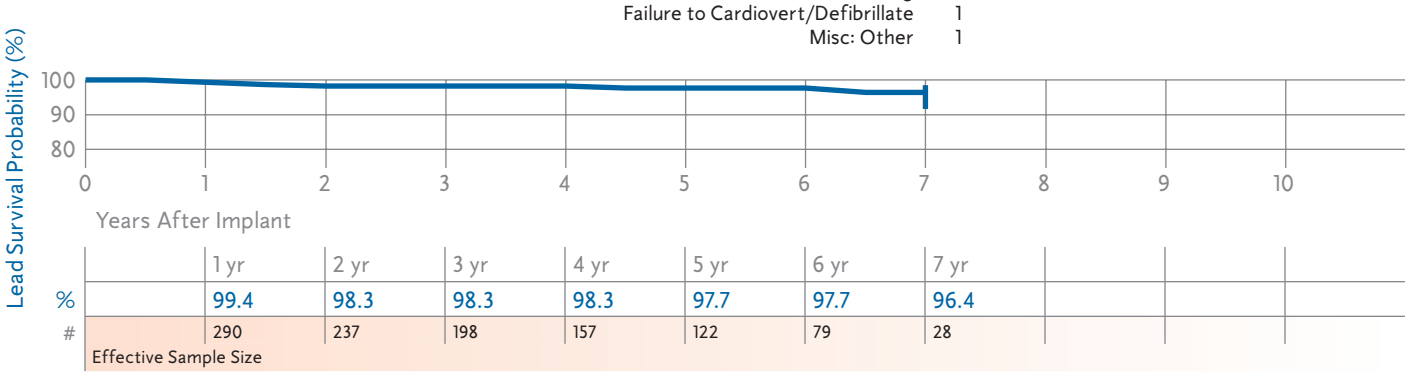
Implant Damage	16
Electrical Malfunction	36
Other	7

Prospective Clinical Study Results

Number of Leads Enrolled in Study	411
Cumulative Months of Follow-Up	16,924

Complications in Study 8 Total

Muscle Stimulation	1
Failure to Capture	1
Failure to Sense	2
Oversensing	2
Failure to Cardiovert/Defibrillate	1
Misc: Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	99.4	98.3	98.3	98.3	97.7	97.7	96.4
#	290	237	198	157	122	79	28

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6933, 6937, 6937A, 6963 SVC/CS

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAT, TBU, or TAF
Estimated US Implants	17,100	Type and/or Fixation	Transvenous CS or SVC Defib
Estimated US Active	6,100	Polarity	One Defib Coil
Advisories	None	Steroid	No

Laboratory Analysis

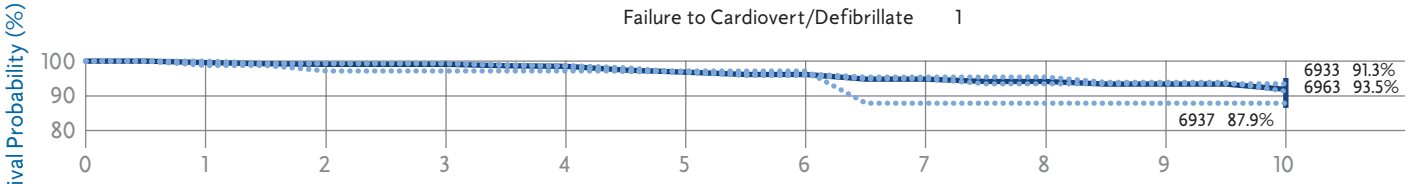
Implant Damage	31
Electrical Malfunction	190
Other	13

Prospective Clinical Study Results

Number of Leads Enrolled in Study	965
Cumulative Months of Follow-Up	43,517

Complications in Study 24 Total

Oversensing	1	Defib Impedance Out of Range	2
Conductor Fracture	14	Dislodgement	1
Insulation Breach	2	Misc: Other	3
Failure to Cardiovert/Defibrillate	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.6	99.2	99.2	98.5	96.8	96.2	94.8	94.2	93.4	91.9
#	683	561	467	371	288	213	156	119	80	27

Effective Sample Size of Lead Group Overall

6936, 6966 Transvene

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAV or TAL
Estimated US Implants	24,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated US Active	6,600	Polarity	True Bipolar/ One Coil
Advisories	None	Steroid	No

Laboratory Analysis

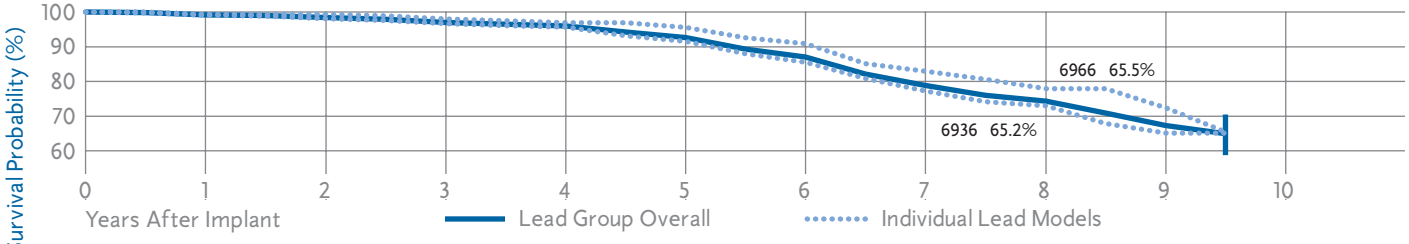
Implant Damage	90
Electrical Malfunction	448
Other	19

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,353
Cumulative Months of Follow-Up	61,968

Complications in Study 136 Total

Muscle Stimulation	1	Failure to Cardiovert/Defibrillate	5
Failure to Capture	1	Pacing Impedance Out of Range	3
Failure to Sense	3	Defib Impedance Out of Range	2
Oversensing	74	Inappropriate VT	1
Conductor Fracture	16	Inappropriate VF	13
Insulation Breach	12	Misc: Other	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.2	98.5	97.1	96.0	92.7	87.1	78.9	74.4	67.3	65.0
#	995	821	675	546	433	314	220	152	87	39

Effective Sample Size of Lead Group Overall

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6939, 6999 Sub-Q Patch

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TBA or TAP
Estimated US Implants	4,300	Type and/or Fixation	Subcutaneous Defib Patch, Suture
Estimated US Active	1,100	Polarity	Defib Electrode Only
Advisories	None	Steroid	No

Laboratory Analysis

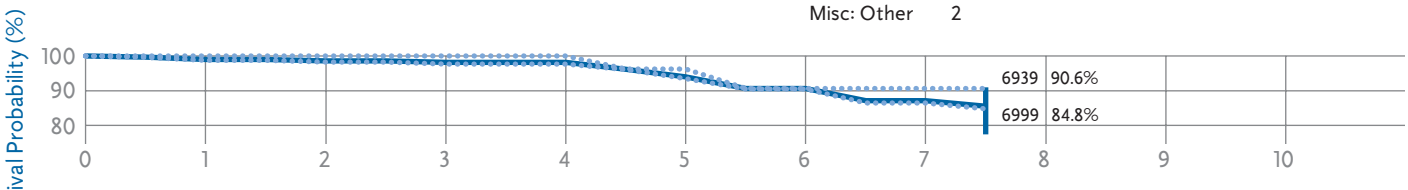
Implant Damage	4
Electrical Malfunction	32
Other	1

Prospective Clinical Study Results

Number of Leads Enrolled in Study	389
Cumulative Months of Follow-Up	17,003

Complications in Study 20 Total

Conductor Fracture	10
Insulation Breach	6
Failure to Cardiovert/Defibrillate	2
Misc: Other	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	99.1	98.7	98.2	98.2	94.0	90.6	87.1	85.6
#	269	224	188	150	111	78	57	26

Effective Sample Size of Lead Group Overall

6942 Sprint

Product Characteristics

US Market Release	Jul-97	Serial Number Prefix	TCB
Estimated US Implants	18,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated US Active	9,400	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

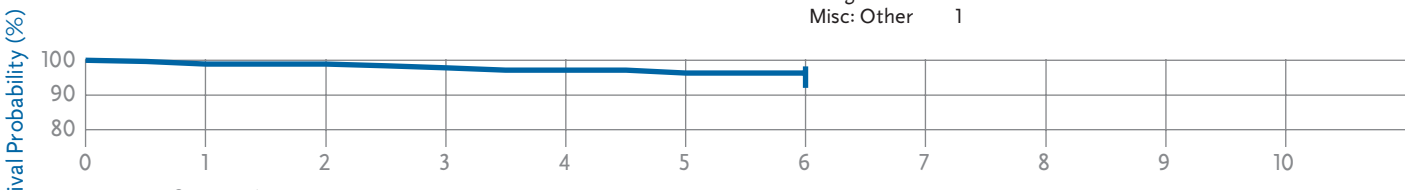
Implant Damage	31
Electrical Malfunction	35
Other	5

Prospective Clinical Study Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	13,032

Complications in Study 7 Total

Failure to Sense	1
Oversensing	3
Conductor Fracture	1
Dislodgement	1
Misc: Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	99.0	99.0	97.9	97.2	96.3	96.3
#	239	193	150	124	89	27

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6943 Sprint

Product Characteristics

US Market Release	Oct-97	Serial Number Prefix	TCE
Estimated US Implants	21,300	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated US Active	11,200	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Laboratory Analysis

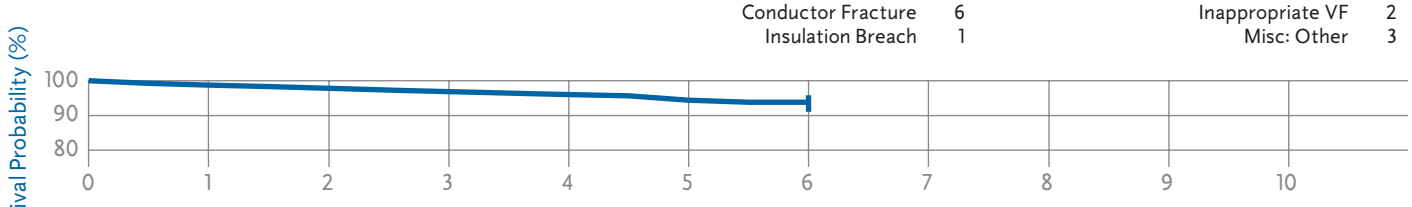
Implant Damage	50
Electrical Malfunction	58
Other	8

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,302
Cumulative Months of Follow-Up	43,051

Complications in Study 38 Total

Failure to Capture	3	Failure to Cardiovert/Defibrillate	1
Failure to Sense	3	Pacing Impedance Out of Range	2
Oversensing	16	Dislodgement	1
Conductor Fracture	6	Inappropriate VF	2
Insulation Breach	1	Misc: Other	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	98.8	97.9	96.9	96.0	94.4	93.9
#	940	726	502	302	169	42

Effective Sample Size

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Estimated US Implants	27,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated US Active	20,300	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

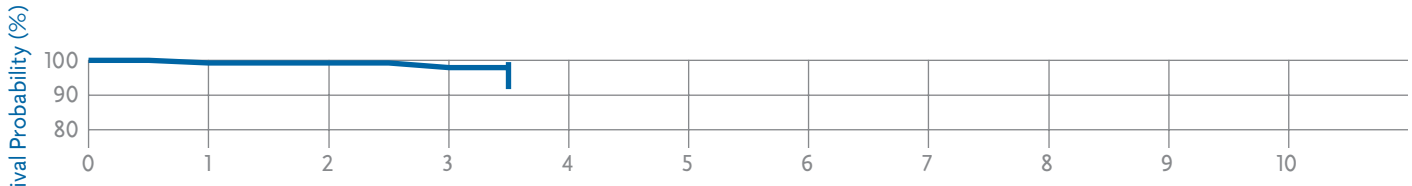
Implant Damage	22
Electrical Malfunction	24
Other	8

Prospective Clinical Study Results

Number of Leads Enrolled in Study	164
Cumulative Months of Follow-Up	4,883

Complications in Study 3 Total

Inappropriate VF	1
Misc: Other	2



	1 yr	2 yr	3 yr	at 42 mo
%	99.2	99.2	98.0	98.0
#	116	91	65	30

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6945 Sprint

Product Characteristics

US Market Release	Sep-97	Serial Number Prefix	TDA
Estimated US Implants	44,000	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated US Active	24,700	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

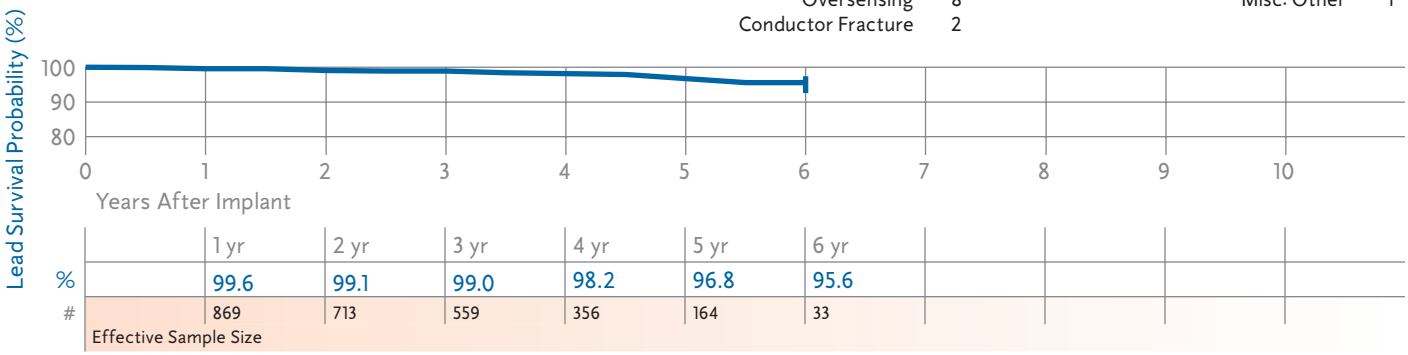
Implant Damage	195
Electrical Malfunction	78
Other	11

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,152
Cumulative Months of Follow-Up	41,795

Complications in Study 19 Total

Muscle Stimulation	1	Pacing Impedance Out of Range	2
Failure to Sense	3	Inappropriate VF	2
Oversensing	8	Misc: Other	1
Conductor Fracture	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	99.6	99.1	99.0	98.2	96.8	95.6
#	869	713	559	356	164	33

Effective Sample Size

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Estimated US Implants	121,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated US Active	94,800	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

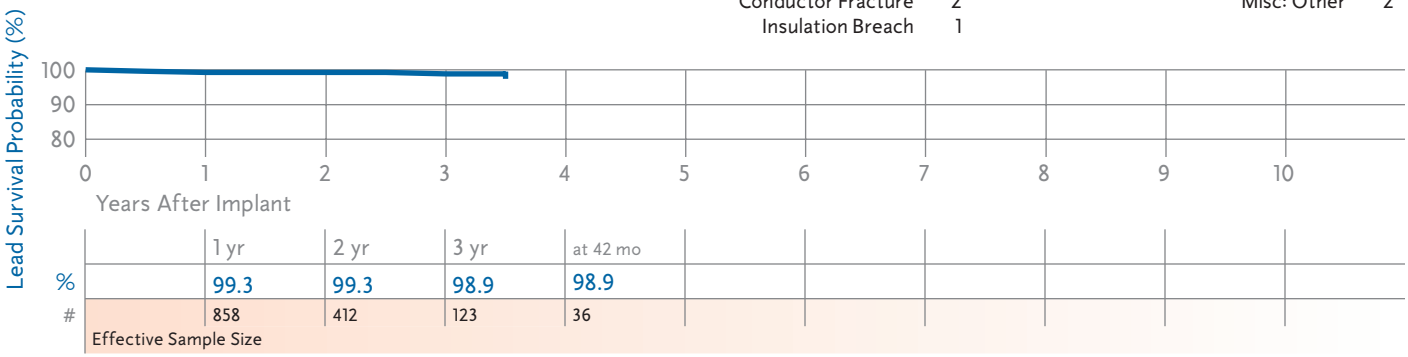
Implant Damage	209
Electrical Malfunction	71
Other	12

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,339
Cumulative Months of Follow-Up	27,598

Complications in Study 10 Total

Failure to Sense	1	Defib Impedance Out of Range	1
Oversensing	1	Dislodgement	2
Conductor Fracture	2	Misc: Other	2
Insulation Breach	1		



	1 yr	2 yr	3 yr	at 42 mo
%	99.3	99.3	98.9	98.9
#	858	412	123	36

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6948 Sprint Fidelis

Product Characteristics

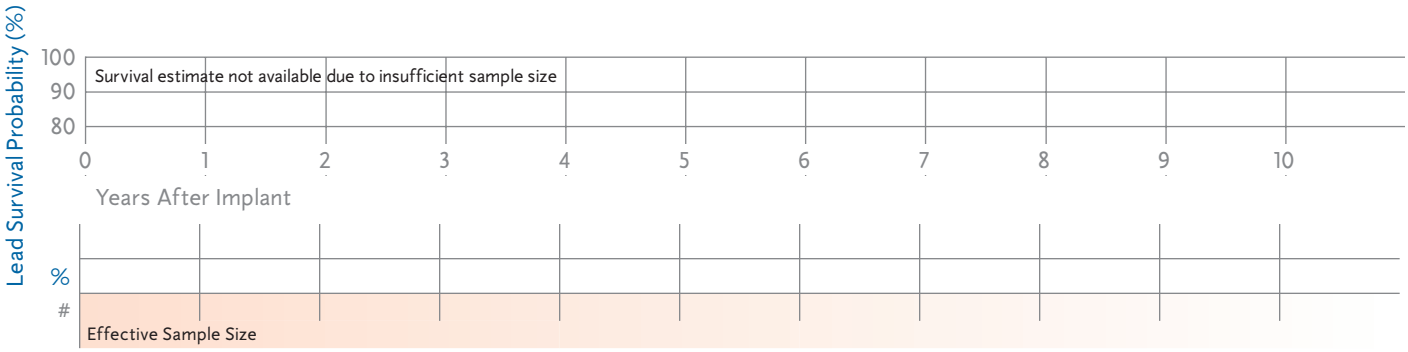
US Market Release	Sep-04	Serial Number Prefix	LFH
Estimated US Implants	4,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Tines
Estimated US Active	3,900	Polarity	True Bipolar/ Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	1
Electrical Malfunction	0
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0



6949 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFJ
Estimated US Implants	93,200	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Estimated US Active	86,500	Polarity	True Bipolar/ Two Coils
Advisories	None	Steroid	Yes

Laboratory Analysis

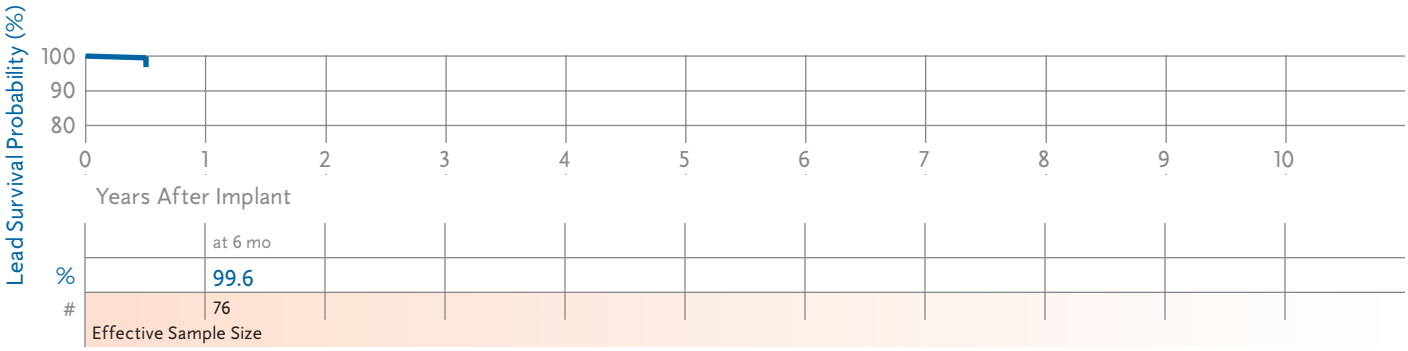
Implant Damage	241
Electrical Malfunction	55
Other	28

Prospective Clinical Study Results

Number of Leads Enrolled in Study	293
Cumulative Months of Follow-Up	1,796

Complications in Study 3 Total

Failure to Capture	1
Oversensing	2



Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Estimated US Implants	1,500	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated US Active	1,200	Polarity	One Defib Coil
Advisories	None	Steroid	No

Laboratory Analysis

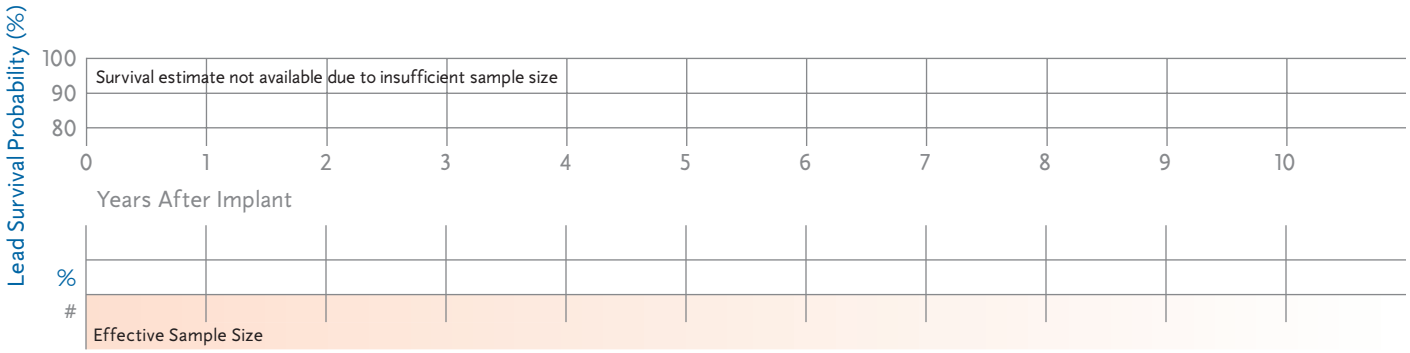
Implant Damage	0
Electrical Malfunction	0
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	3
Cumulative Months of Follow-Up	36

Complications in Study

0 Total



Source: System Longevity Study
Data as of April 1, 2006

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 (%) Years After Implant 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	17,338	100.0	98.6 +0.9/-2.4	95.9 +1.9/-3.5	94.7 +2.3/-3.9	92.7 +2.9/-4.7	84.7 +5.0/-7.3	82.2 +5.7/-8.0	82.2 +5.7/-8.0 at 90 mo		
6930	Sprint Fidelis	Jun-04	0	—	0	Survival estimate not available due to insufficient sample size									
6931	Sprint Fidelis	Sep-04	36	0	35	Survival estimate not available due to insufficient sample size									
6932	Sprint	Aug-96	411	8	16,924	99.4 +0.5/-1.9	98.3 +1.0/-2.3	98.3 +1.0/-2.3	98.3 +1.0/-2.3	97.7 +1.3/-2.9	97.7 +1.3/-2.9	96.4 +2.1/-4.8			
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	965	24	43,517	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/-2.1	96.2 +1.5/-2.4	94.8 +1.9/-3.0	94.2 +2.2/-3.3	93.4 +2.5/-3.8	91.9 +3.3/-5.3
6936, 6966	Transvene	Dec-93	1,353	136	61,968	99.2 +0.4/-0.7	98.5 +0.6/-1.0	97.1 +0.9/-1.4	96.0 +1.2/-1.6	92.7 +1.8/-2.2	87.1 +2.6/-3.2	78.9 +3.6/-4.2	74.4 +4.1/-4.8	67.3 +5.1/-5.8	65.0 +5.5/-6.2 at 114 mo
6939, 6999	Sub-Q Patch	Dec-93	389	20	17,003	99.1 +0.6/-2.0	98.7 +0.8/-2.3	98.2 +1.1/-2.6	98.2 +1.1/-2.6	94.0 +2.7/-4.8	90.6 +3.8/-6.1	87.1 +4.9/-7.5	85.6 +5.4/-8.2 at 90 mo		
6942	Sprint	Jul-97	351	7	13,032	99.0 +0.7/-2.2	99.0 +0.7/-2.2	97.9 +1.2/-3.1	97.2 +1.6/-3.5	96.3 +2.0/-4.2	96.3 +2.0/-4.2				
6943	Sprint	Oct-97	1,302	38	43,051	98.8 +0.5/-0.8	97.9 +0.7/-1.1	96.9 +1.0/-1.4	96.0 +1.2/-1.7	94.4 +1.8/-2.5	93.9 +1.9/-2.8				
6944	Sprint Quattro	Dec-00	164	3	4,883	99.2 +0.7/-4.4	99.2 +0.7/-4.4	98.0 +1.5/-6.3	98.0 +1.5/-6.3 at 42 mo						
6945	Sprint	Sep-97	1,152	19	41,795	99.6 +0.3/-0.7	99.1 +0.5/-0.9	99.0 +0.5/-1.0	98.2 +0.8/-1.3	96.8 +1.3/-2.2	95.6 +1.8/-3.0				
6947	Sprint Quattro Secure	Nov-01	1,339	10	27,598	99.3 +0.4/-0.7	99.3 +0.4/-0.7	98.9 +0.6/-1.4	98.9 +0.6/-1.4 at 42 mo						
6948	Sprint Fidelis	Sep-04	0	—	0	Survival estimate not available due to insufficient sample size									
6949	Sprint Fidelis	Sep-04	293	3	1,796	99.6 +0.3/-2.7 at 6 mo									
6996	Sub-Q Lead	Jun-01	3	0	36	Survival estimate not available due to insufficient sample size									

Source: System Longevity Study
Data as of April 1, 2006

Defibrillation Leads continued

Laboratory Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
6721, 6921	Epicardial Patch	Feb-93	8,800	2,200	5	78	0
6930	Sprint Fidelis	Jun-04	100	100	0	0	0
6931	Sprint Fidelis	Sep-04	2,900	2,800	6	7	0
6932	Sprint	Aug-96	15,300	7,300	16	36	7
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	17,100	6,100	31	190	13
6936, 6966	Transvene	Dec-93	24,600	6,600	90	448	19
6939, 6999	Sub-Q Patch	Dec-93	4,300	1,100	4	32	1
6942	Sprint	Jul-97	18,100	9,400	31	35	5
6943	Sprint	Oct-97	21,300	11,200	50	58	8
6944	Sprint Quattro	Dec-00	27,800	20,300	22	24	8
6945	Sprint	Sep-97	44,000	24,700	195	78	11
6947	Sprint Quattro Secure	Nov-01	121,700	94,800	209	71	12
6948	Sprint Fidelis	Sep-04	4,100	3,900	1	0	0
6949	Sprint Fidelis	Sep-04	93,200	86,500	241	55	28
6996	Sub-Q Lead	Jun-01	1,500	1,200	0	0	0

Source: Returned Product Analysis
Data as of April 30, 2006

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

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Estimated US Implants	1,700	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	1,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	5
Electrical Malfunction	0
Other	1

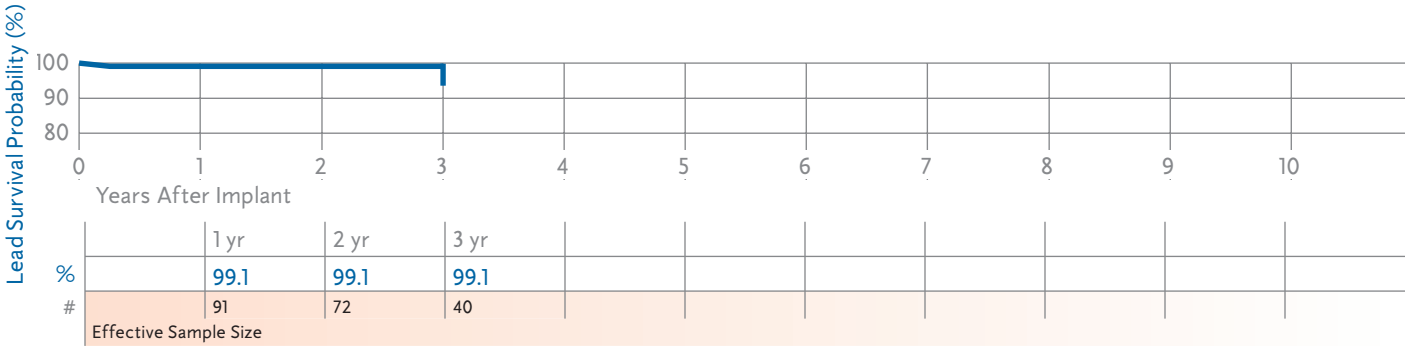
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	111
Cumulative Months of Follow-Up	3,223

Complications in Study — 1 Total

Failure to Sense	1



	1 yr	2 yr	3 yr
%	99.1	99.1	99.1
#	91	72	40

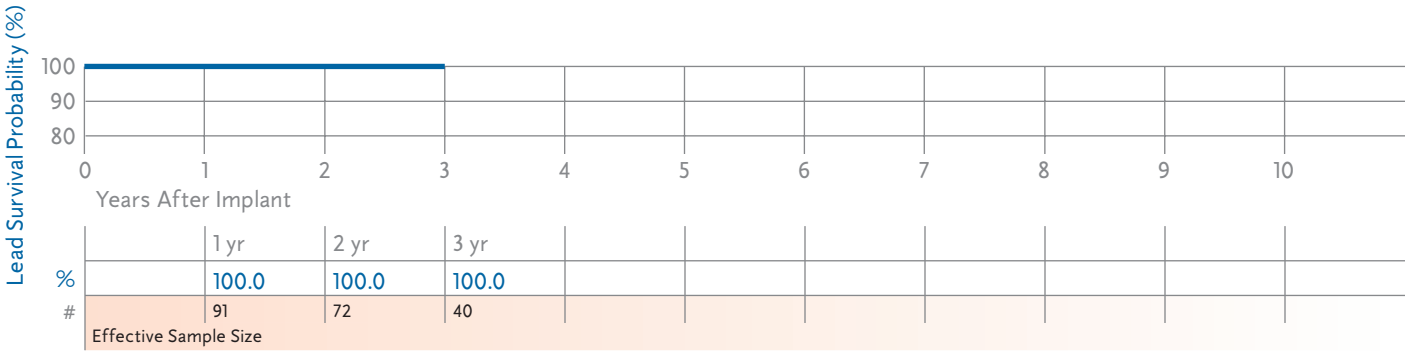
Effective Sample Size

Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	108
Cumulative Months of Follow-Up	3,204

Complications in Study — 0 Total



	1 yr	2 yr	3 yr
%	100.0	100.0	100.0
#	91	72	40

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4003, 4003M CapSure

Product Characteristics

US Market Release	Jul-86	Serial Number Prefix	IH or LAX
Estimated US Implants	40,000	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	8,100	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	24
Electrical Malfunction	54
Other	2

Ventricular Placement

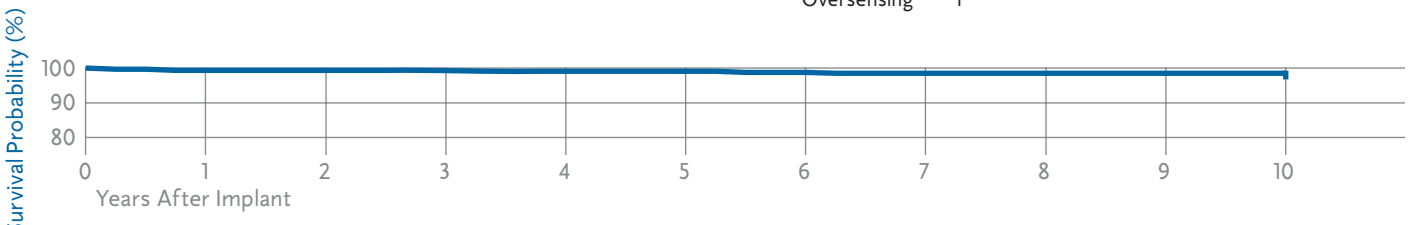
Prospective Clinical Study Results

Number of Leads Enrolled in Study	711
Cumulative Months of Follow-Up	42,829

Complications in Study

7 Total

Extra Cardiac Stimulation	2
Failure to Capture	4
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.4	99.4	99.4	99.1	99.1	98.8	98.5	98.5	98.5	98.5
#	559	484	440	378	329	299	246	205	125	42

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4004, 4004M CapSure

Product Characteristics

US Market Release	Feb-89	Serial Number Prefix	PS or LAV
Estimated US Implants	74,500	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	3,700	Polarity	Bipolar
Advisories	1	Steroid	Yes

see page 168 – 1993 Lead Survival Below Expectations

Laboratory Analysis

Implant Damage	55
Electrical Malfunction	680
Other	19

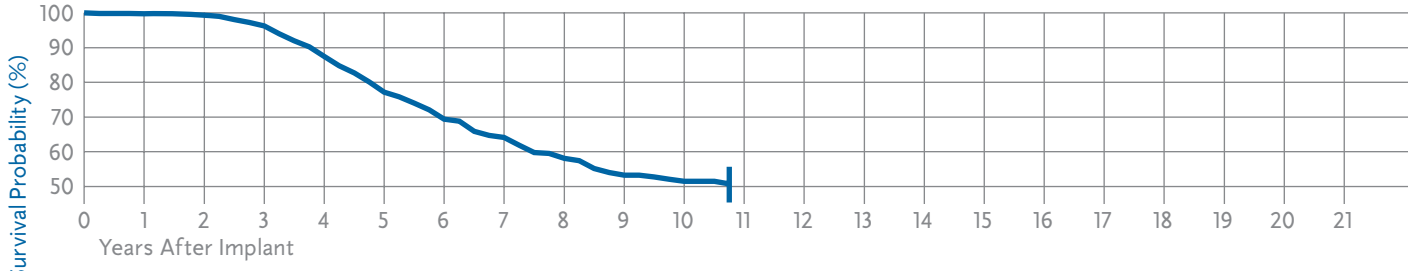
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,640
Cumulative Months of Follow-Up	71,612

Complications in Study 276 Total

Conductor Fracture	7	Insulation (ESC)	4
Electrical Abandonment	1	Insulation (MIO)	4
Extra Cardiac Stimulation	2	Insulation (not further defined)	6
Failure to Capture	131	Medical Judgement	1
Failure to Sense	62	Oversensing	25
Impedance Out of Range	32	Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 mo
%	99.8	99.3	96.3	87.5	77.2	69.4	64.1	58.1	53.2	51.5	50.7
#	1,195	1,023	826	631	454	314	231	161	118	78	51

Effective Sample Size

4011 Target Tip

Product Characteristics

US Market Release	Nov-82	Serial Number Prefix	IB
Estimated US Implants	64,000	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	8,200	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	29
Electrical Malfunction	141
Other	5

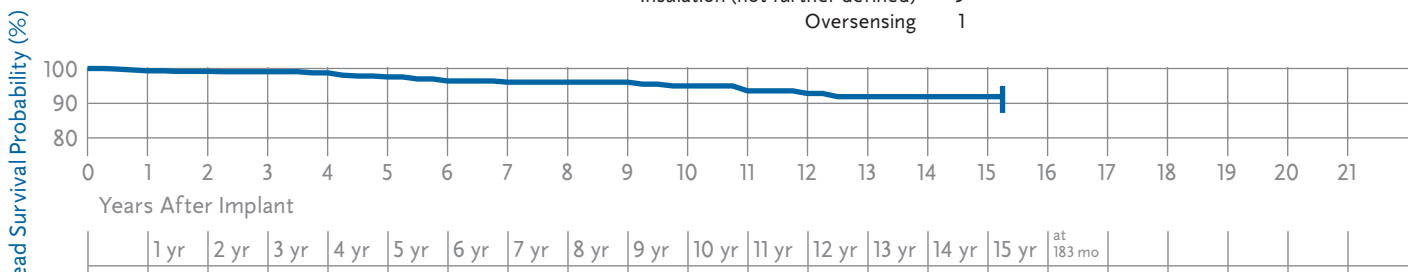
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	851
Cumulative Months of Follow-Up	54,346

Complications in Study 23 Total

Extra Cardiac Stimulation	4
Failure to Capture	9
Insulation (not further defined)	9
Oversensing	1



	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	at 183 mo
%	99.4	99.2	99.1	98.8	97.6	96.4	96.1	96.1	96.1	95.0	93.6	92.8	91.9	91.9	91.9	91.9
#	627	557	476	415	354	300	250	219	189	165	134	109	81	71	55	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4012 Target Tip

Product Characteristics

US Market Release	Jul-83	Serial Number Prefix	HQ
Estimated US Implants	96,800	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	6,700	Polarity	Bipolar
Advisories	1	Steroid	No

see page 169 – 1991 Lead Survival Below Expectations

Laboratory Analysis

Implant Damage	50
Electrical Malfunction	817
Other	34

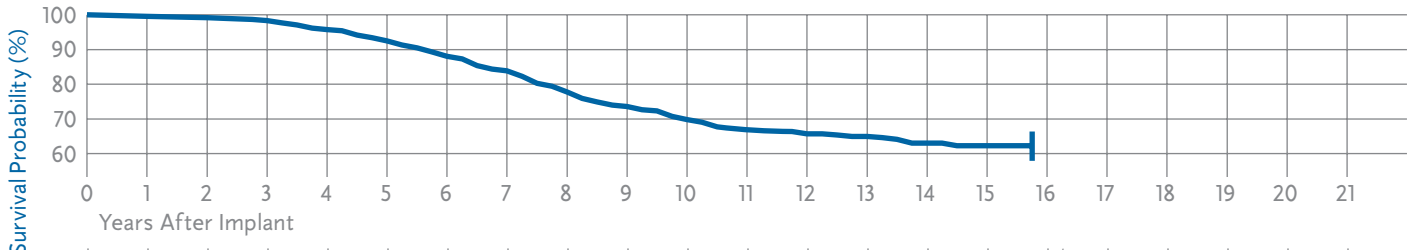
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	2,543
Cumulative Months of Follow-Up	151,264

Complications in Study 315 Total

Conductor Fracture	6	Insulation (ESC)	9
Extra Cardiac Stimulation	3	Insulation (MIO)	4
Failure to Capture	126	Insulation (not further defined)	16
Failure to Sense	76	Medical Judgement	1
Impedance Out of Range	26	Oversensing	48



	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	at 189 mo
%	99.6	99.2	98.4	95.8	92.5	88.1	83.9	77.8	73.6	69.8	66.9	65.7	65.0	63.0	62.3	62.3
#	1,941	1,720	1,534	1,313	1,087	889	699	524	402	308	244	201	145	99	70	52

Effective Sample Size

4023 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	LAK
Estimated US Implants	43,700	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	16,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	48
Electrical Malfunction	18
Other	6

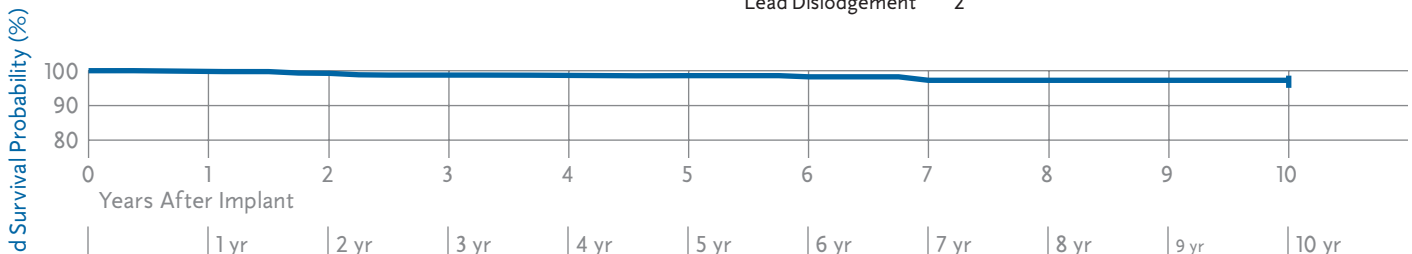
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	54,878

Complications in Study 15 Total

Failure to Capture	12
Insulation (not further defined)	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.9	99.3	98.8	98.6	98.6	98.3	97.3	97.3	97.3	97.3
#	889	769	682	550	392	264	182	101	81	43

Effective Sample Size

Leads

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4024 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAJ
Estimated US Implants	229,200	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	95,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	264
Electrical Malfunction	89
Other	34

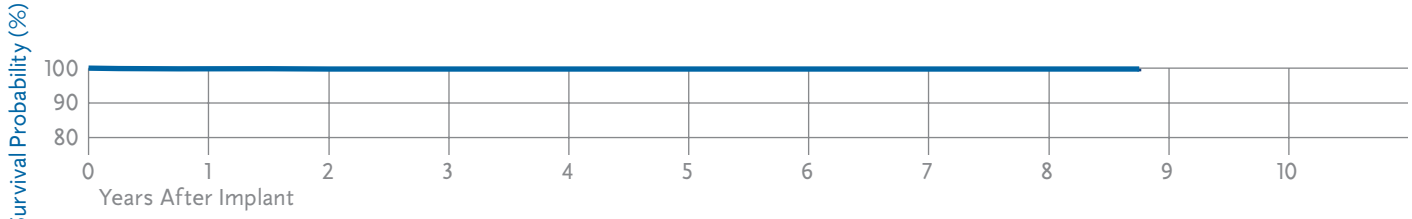
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	50,045

Complications in Study — 3 Total

Failure to Capture	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
#	872	687	558	420	319	230	164	102	55

Effective Sample Size

4033 CapSure Z

Product Characteristics

US Market Release	n/a	Serial Number Prefix	LCA
Estimated US Implants	n/a	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	n/a	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	2
Electrical Malfunction	0
Other	0

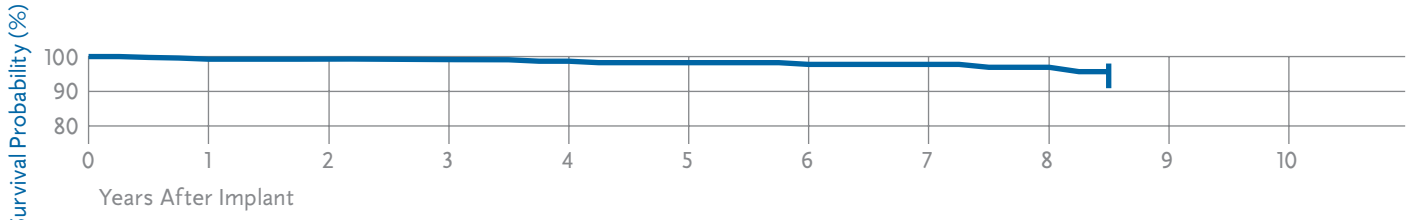
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	541
Cumulative Months of Follow-Up	27,571

Complications in Study — 9 Total

Conductor Fracture	1
Failure to Capture	8



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.3	99.3	99.1	98.7	98.3	97.8	97.8	96.9	95.7
#	428	382	322	249	200	165	119	86	55

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4057, 4057M Screw-In

Product Characteristics

US Market Release	Aug-88	Serial Number Prefix	XQ or LAN
Estimated US Implants	12,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	3,100	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	39
Electrical Malfunction	6
Other	4

Ventricular Placement

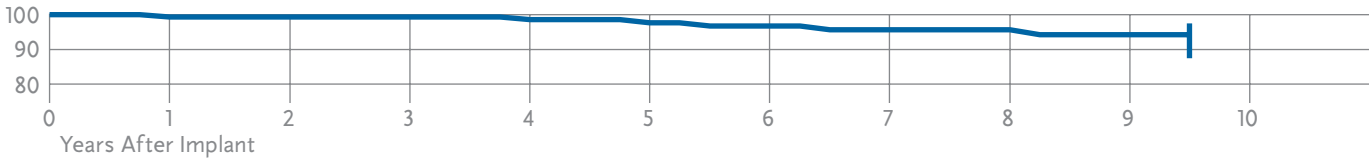
Prospective Clinical Study Results

Number of Leads Enrolled in Study	259
Cumulative Months of Follow-Up	14,990

Complications in Study

7 Total

Conductor Fracture	2
Extra Cardiac Stimulation	2
Failure to Capture	2
Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.4	99.4	99.4	98.6	97.7	96.8	95.7	95.7	94.3	94.3
#	163	152	134	122	106	94	81	71	55	51

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4058, 4058M Screw-In

Product Characteristics

US Market Release	Jan-89	Serial Number Prefix	ZY or LAW
Estimated US Implants	111,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	29,600	Polarity	Bipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	388
Electrical Malfunction	223
Other	23

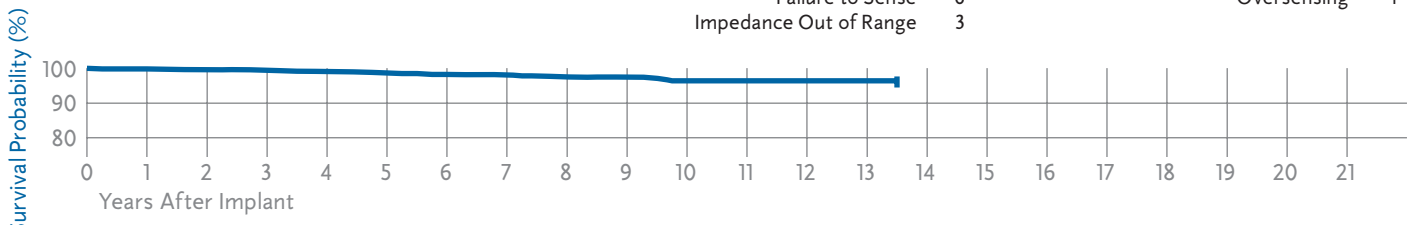
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	2,364
Cumulative Months of Follow-Up	129,835

Complications in Study — 30 Total

Extra Cardiac Stimulation	1	Insulation (not further defined)	1
Failure to Capture	15	Lead Dislodgement	3
Failure to Sense	6	Oversensing	1
Impedance Out of Range	3		



	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	at 162 mo
%	99.9	99.6	99.5	99.1	98.7	98.3	98.2	97.5	97.5	96.4	96.4	96.4	96.4	96.4
#	1,759	1,550	1,337	1,156	993	791	610	456	336	217	148	104	72	54

Effective Sample Size

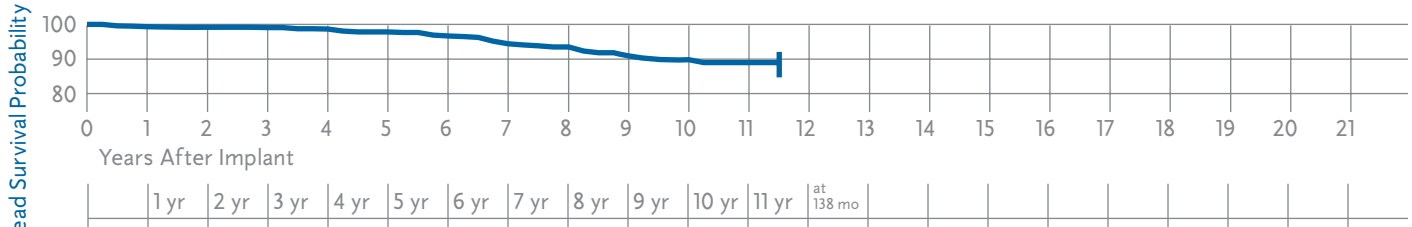
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,691
Cumulative Months of Follow-Up	75,820

Complications in Study — 47 Total

Conductor Fracture	2	Impedance Out of Range	4
Extra Cardiac Stimulation	3	Insulation (not further defined)	3
Failure to Capture	22	Lead Dislodgement	1
Failure to Sense	11	Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 138 mo
%	99.4	99.2	99.1	98.7	97.9	96.7	94.4	93.5	90.9	89.8	89.0	89.0
#	1,127	947	793	668	538	426	318	232	174	112	67	47

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4067 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LCV
Estimated US Implants	1,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	600	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	3
Electrical Malfunction	1
Other	1

Atrial Placement

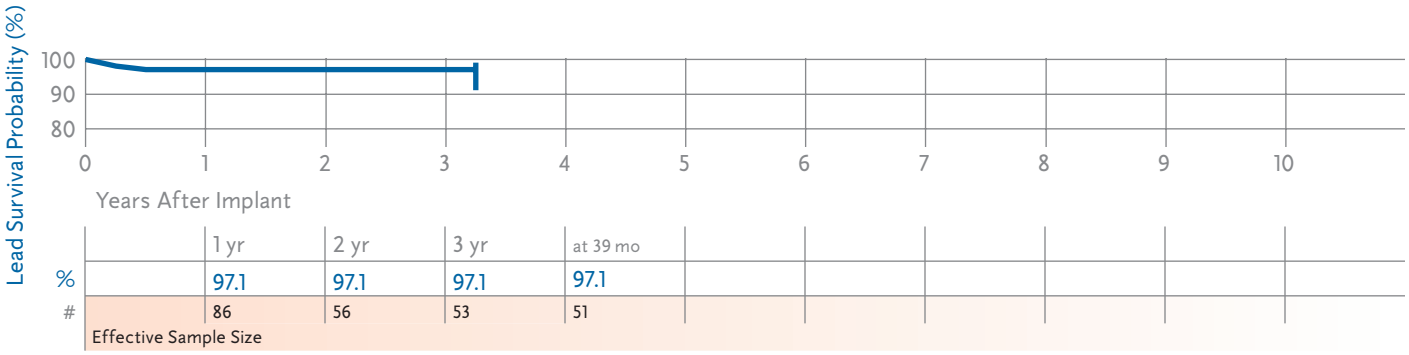
Prospective Clinical Study Results

Number of Leads Enrolled in Study	108
Cumulative Months of Follow-Up	5,503

Complications in Study

3 Total

Failure to Capture	3



	1 yr	2 yr	3 yr	at 39 mo
%	97.1	97.1	97.1	97.1
#	86	56	53	51

Effective Sample Size

Leads

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4068 CapSureFix

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCE
Estimated US Implants	131,700	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	65,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	406
Electrical Malfunction	68
Other	11

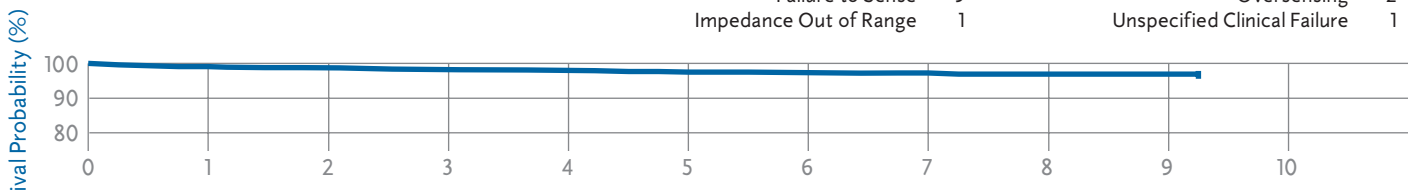
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	2,388
Cumulative Months of Follow-Up	105,192

Complications in Study — 43 Total

Extra Cardiac Stimulation	1	Insulation (ESC)	2
Failure to Capture	19	Lead Dislodgement	8
Failure to Sense	9	Oversensing	2
Impedance Out of Range	1	Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.1	98.8	98.2	98.0	97.5	97.3	97.3	96.9	96.9	96.9
#	1,900	1,625	1,298	953	637	454	299	182	68	49

Effective Sample Size

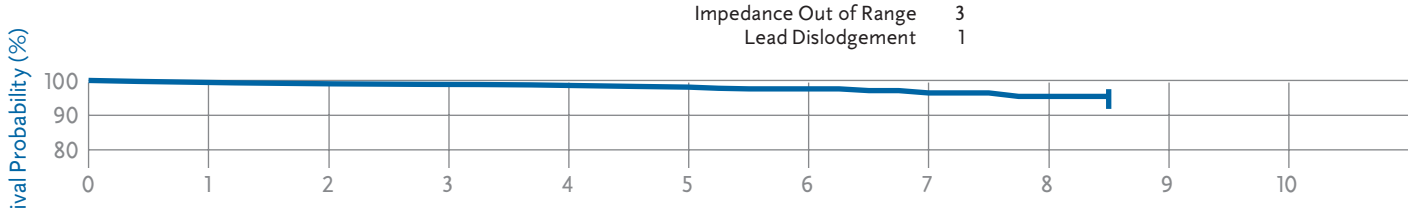
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,787
Cumulative Months of Follow-Up	72,497

Complications in Study — 27 Total

Conductor Fracture	1
Extra Cardiac Stimulation	1
Failure to Capture	19
Failure to Sense	2
Impedance Out of Range	3
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.4	99.0	98.9	98.5	98.1	97.6	96.4	95.4	95.4
#	1,424	1,212	913	637	393	225	122	79	46

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4073 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBF
Estimated US Implants	400	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	300	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

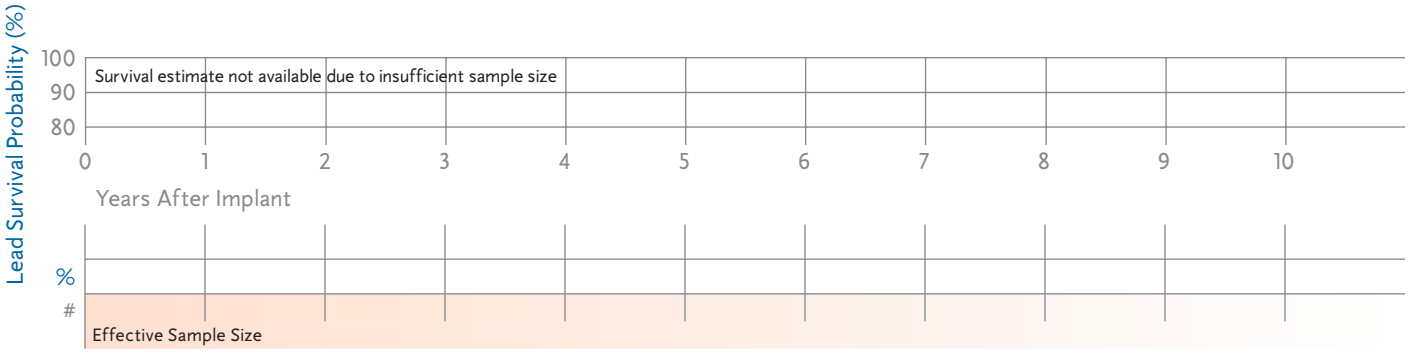
Implant Damage	0
Electrical Malfunction	0
Other	0

Atrial Placement

Prospective Clinical Study Results

Complications in Study 0 Total

Number of Leads Enrolled in Study	1
Cumulative Months of Follow-Up	18

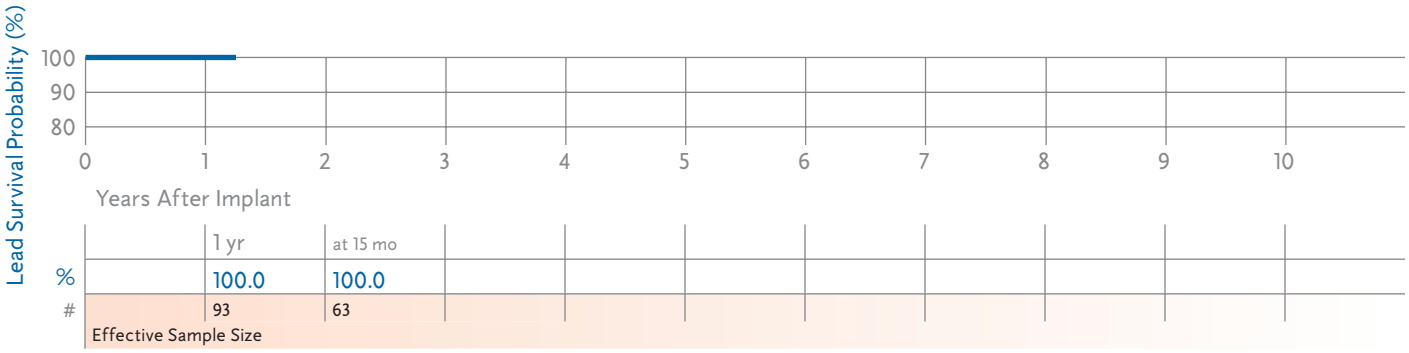


Ventricular Placement

Prospective Clinical Study Results

Complications in Study 0 Total

Number of Leads Enrolled in Study	101
Cumulative Months of Follow-Up	1,926



Leads

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Estimated US Implants	35,000	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	29,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	10
Electrical Malfunction	1
Other	1

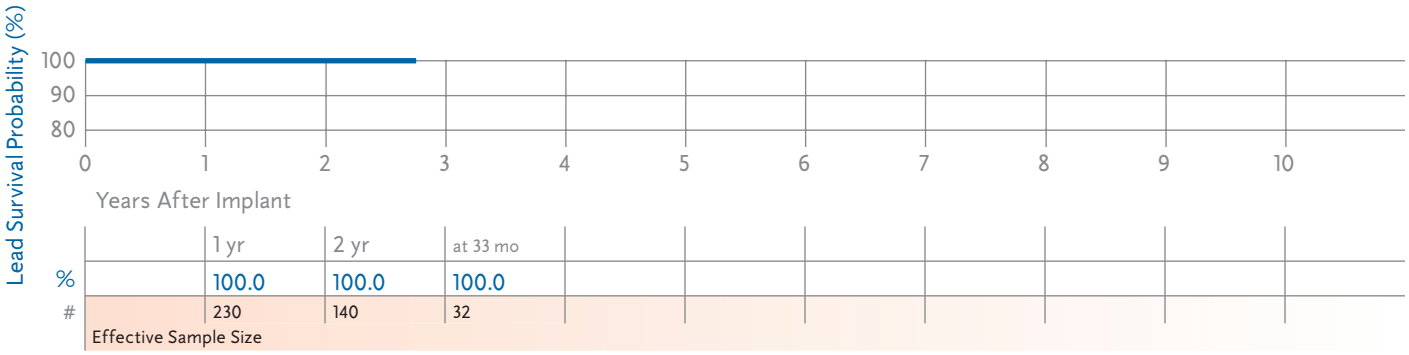
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	382
Cumulative Months of Follow-Up	7,648

Complications in Study

0 Total



	1 yr	2 yr	at 33 mo
%	100.0	100.0	100.0
#	230	140	32

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Estimated US Implants	60,600	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	55,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	27
Electrical Malfunction	2
Other	4

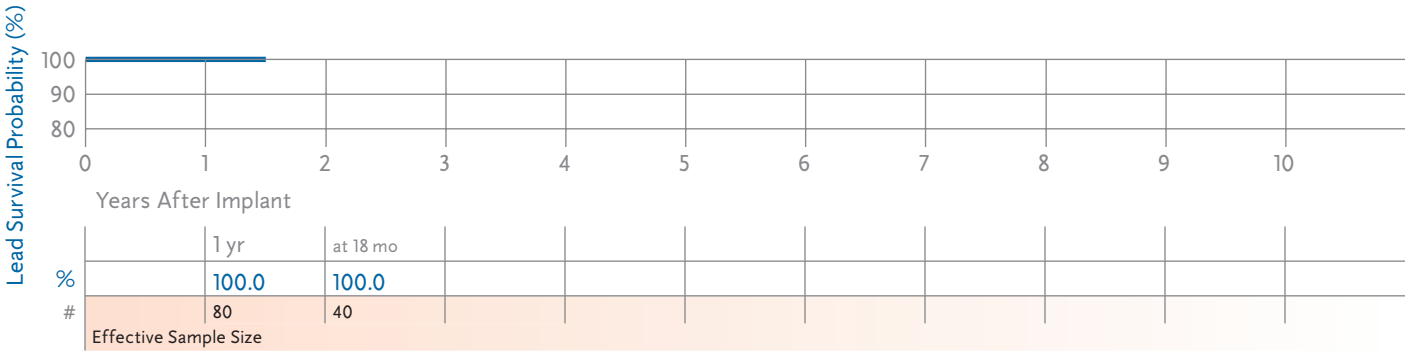
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	140
Cumulative Months of Follow-Up	2,011

Complications in Study

0 Total



Ventricular Placement

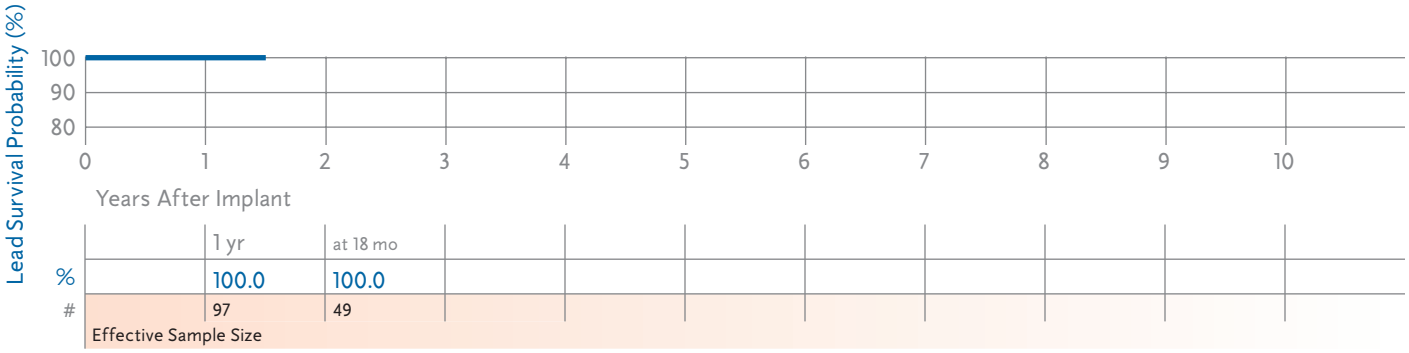
Prospective Clinical Study Results

Number of Leads Enrolled in Study	169
Cumulative Months of Follow-Up	2,414

Complications in Study

1 Total

Failure to Capture	1



Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4081 Target Tip

Product Characteristics

US Market Release	Jul-89	Serial Number Prefix	LAC
Estimated US Implants	4,100	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	1,000	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	4
Electrical Malfunction	5
Other	0

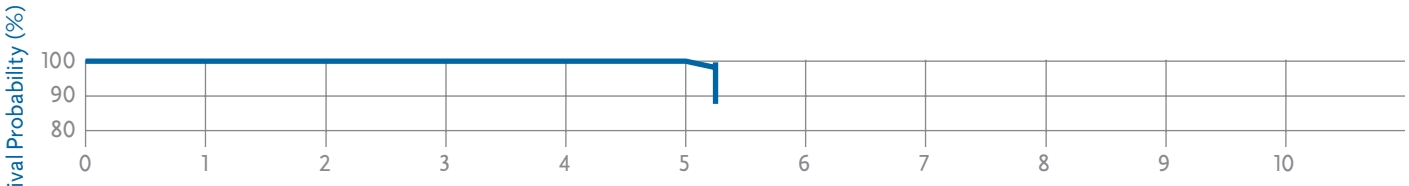
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	260
Cumulative Months of Follow-Up	9,587

Complications in Study 3 Total

Conductor Fracture	1
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	100.0	100.0	100.0	100.0	98.2
#	191	156	116	81	55	45

Effective Sample Size

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Estimated US Implants	126,200	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	88,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	30
Electrical Malfunction	7
Other	5

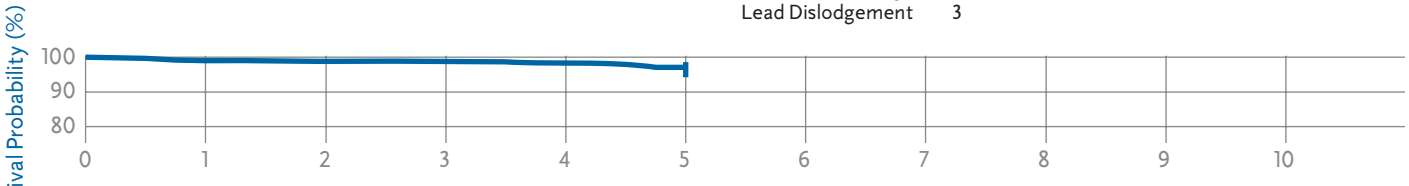
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,139
Cumulative Months of Follow-Up	37,061

Complications in Study 15 Total

Conductor Fracture	2
Extra Cardiac Stimulation	1
Failure to Capture	8
Impedance Out of Range	1
Lead Dislodgement	3



	1 yr	2 yr	3 yr	4 yr	5 yr
%	99.0	98.9	98.9	98.4	97.1
#	935	716	475	240	42

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4503, 4503M CapSure

Product Characteristics

US Market Release	Jul-86	Serial Number Prefix	MQ,LAY
Estimated US Implants	9,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	1,600	Polarity	Unipolar
Advisories	None	Steroid	Yes

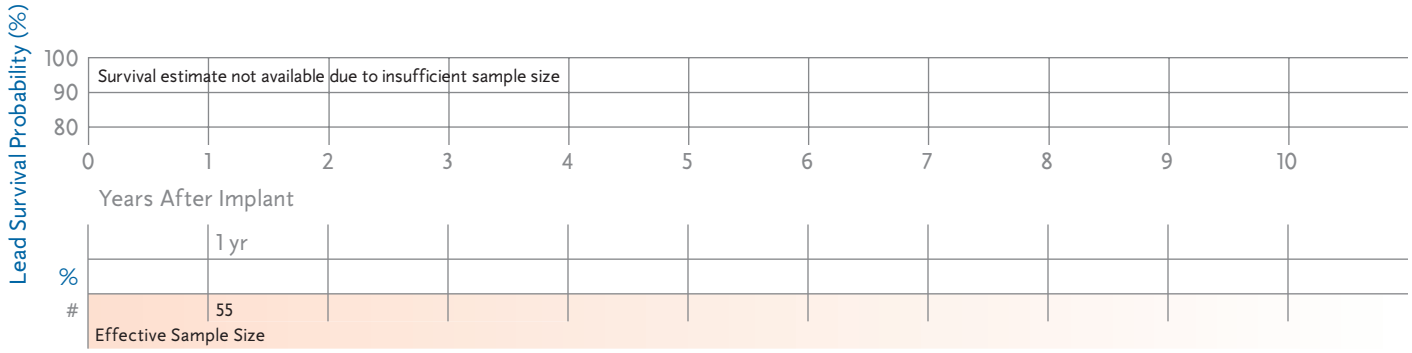
Laboratory Analysis

Implant Damage	2
Electrical Malfunction	9
Other	0

Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	59
Cumulative Months of Follow-Up	3,059



	1 yr
%	
#	55

Effective Sample Size

Leads

4504, 4504M CapSure

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	QM or LBA
Estimated US Implants	16,600	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	1,900	Polarity	Bipolar
Advisories	1	Steroid	Yes

see page 166 – 1996 Lead Survival Below Expectations

Laboratory Analysis

Implant Damage	5
Electrical Malfunction	170
Other	4

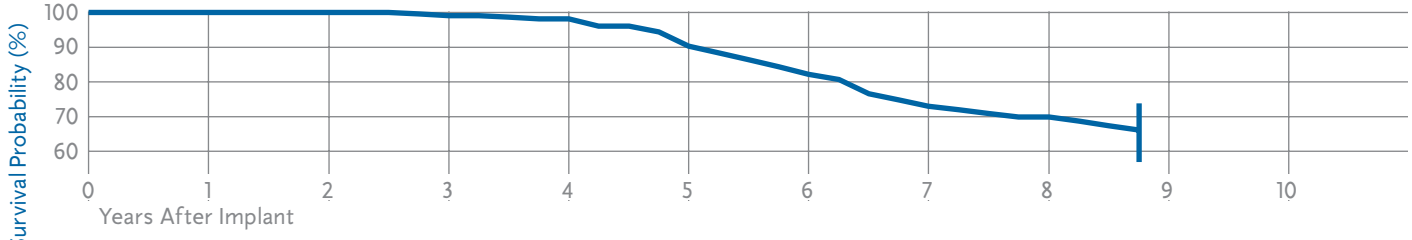
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	368
Cumulative Months of Follow-Up	19,857

Complications in Study 48 Total

Electrical Abandonment	3	Impedance Out of Range	9
Extra Cardiac Stimulation	1	Insulation (MIO)	1
Failure to Capture	14	Lead Dislodgement	1
Failure to Sense	16	Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	100.0	100.0	99.1	98.2	90.3	82.2	73.0	69.9	66.1
#	294	260	220	186	145	109	74	59	47

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4512 Target Tip

Product Characteristics

US Market Release	Jul-83	Serial Number Prefix	PF
Estimated US Implants	11,600	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	1,200	Polarity	Bipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	4
Electrical Malfunction	82
Other	8

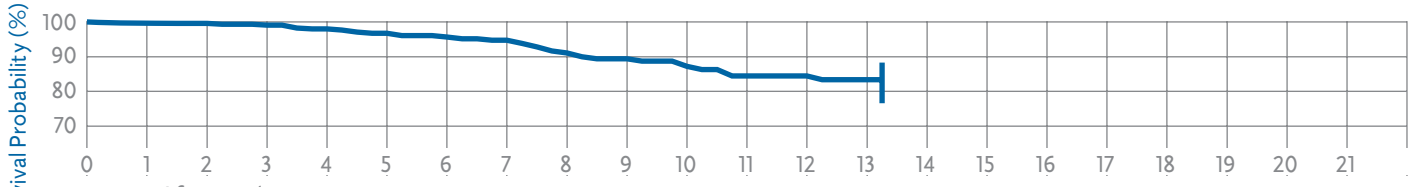
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	600
Cumulative Months of Follow-Up	40,029

Complications in Study — 35 Total

Electrical Abandonment	1	Insulation (MIO)	4
Failure to Capture	6	Insulation (not further defined)	2
Failure to Sense	14	Lead Dislodgement	1
Impedance Out of Range	3	Oversensing	2
Insulation (ESC)	2		



	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	at 159 mo
%	99.6	99.6	99.1	98.0	96.8	95.7	94.8	91.1	89.4	87.2	84.5	84.5	83.4	83.4
#	459	414	374	330	275	227	194	159	130	106	89	72	54	50

Effective Sample Size

4523 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	ZE
Estimated US Implants	12,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	4,000	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	5
Electrical Malfunction	2
Other	1

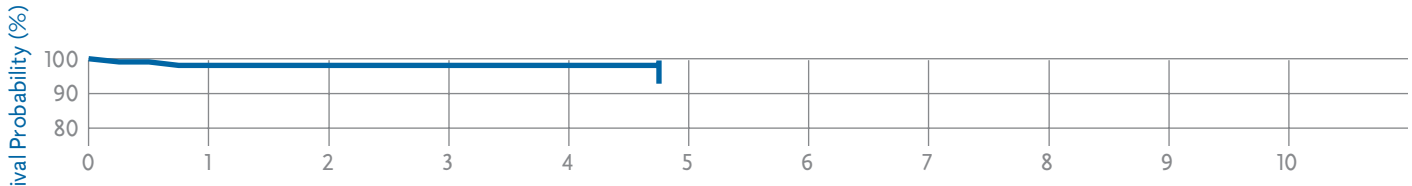
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	6,713

Complications in Study — 3 Total

Failure to Capture	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	98.1	98.1	98.1	98.1	98.1
#	95	81	71	58	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4524 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAR
Estimated US Implants	106,900	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	43,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	47
Electrical Malfunction	17
Other	8

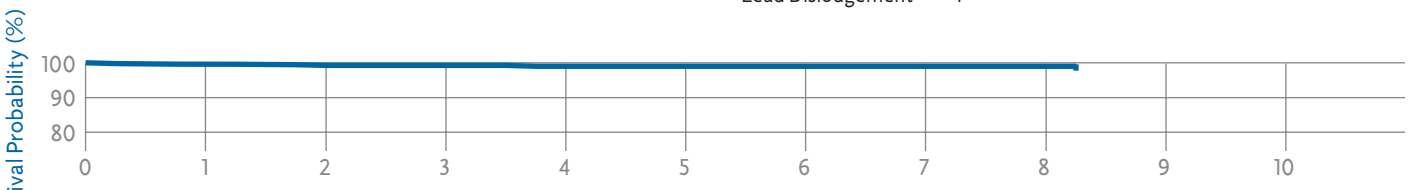
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	37,375

Complications in Study — 6 Total

Failure to Capture	3
Failure to Sense	2
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0	99.0
#	681	536	427	326	240	170	116	65	50

Effective Sample Size

4533 CapSure Z

Product Characteristics

US Market Release	n/a	Serial Number Prefix	LCB
Estimated US Implants	n/a	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	n/a	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	0
Electrical Malfunction	0
Other	0

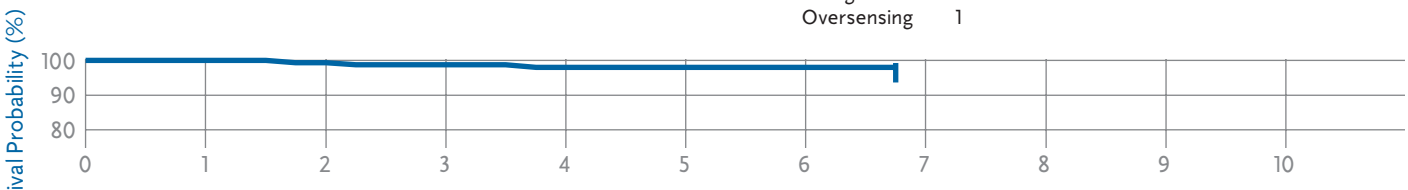
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	206
Cumulative Months of Follow-Up	10,903

Complications in Study — 4 Total

Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	99.4	98.8	98.0	98.0	98.0	98.0
#	177	159	133	102	78	62	48

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4557, 4557M Screw-In

Product Characteristics

US Market Release	Aug-88	Serial Number Prefix	VQ or LAM
Estimated US Implants	22,500	Type and/or Fixation	Transvenous, Atrial, Screw-in
Estimated US Active	6,000	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	53
Electrical Malfunction	14
Other	4

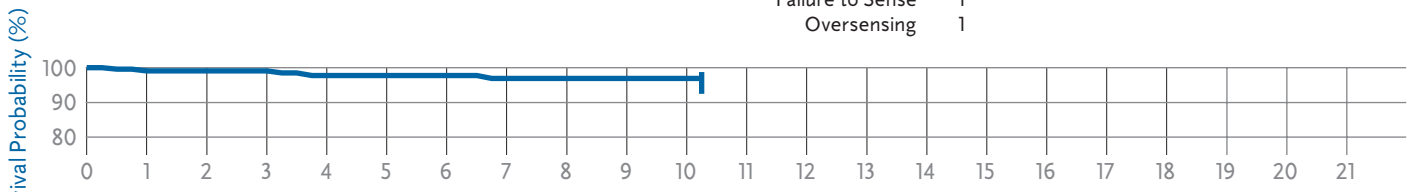
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	18,182

Complications in Study — 6 Total

Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.1	99.1	99.1	97.8	97.8	97.8	96.9	96.9	96.9	96.9	96.9
#	199	181	165	144	127	113	100	85	64	56	52

Effective Sample Size

4558M Screw-In

Product Characteristics

US Market Release	Nov-94	Serial Number Prefix	LDC
Estimated US Implants	21,000	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated US Active	7,100	Polarity	Bipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	111
Electrical Malfunction	10
Other	1

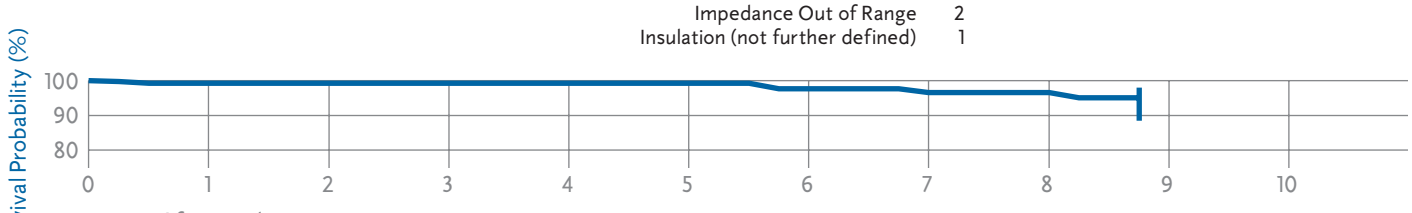
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	21,930

Complications in Study — 10 Total

Electrical Abandonment	1
Failure to Capture	3
Failure to Sense	3
Impedance Out of Range	2
Insulation (not further defined)	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.3	99.3	99.3	99.3	99.3	97.7	96.6	96.6	95.1
#	357	300	251	193	142	99	87	64	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Estimated US Implants	72,700	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated US Active	43,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	196
Electrical Malfunction	5
Other	4

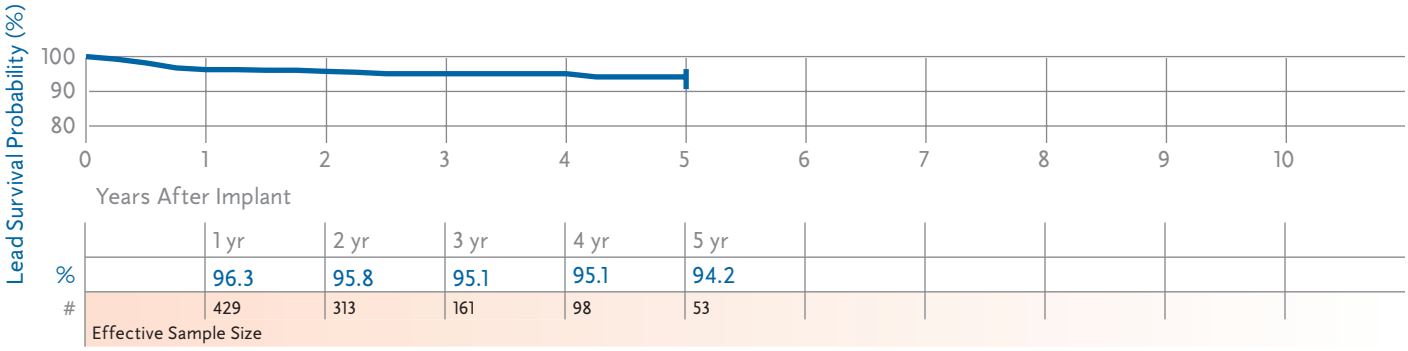
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	573
Cumulative Months of Follow-Up	16,801

Complications in Study 25 Total

Failure to Capture	17
Lead Dislodgement	7
Medical Judgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr
%	96.3	95.8	95.1	95.1	94.2
#	429	313	161	98	53

Effective Sample Size

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Estimated US Implants	22,500	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	18,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

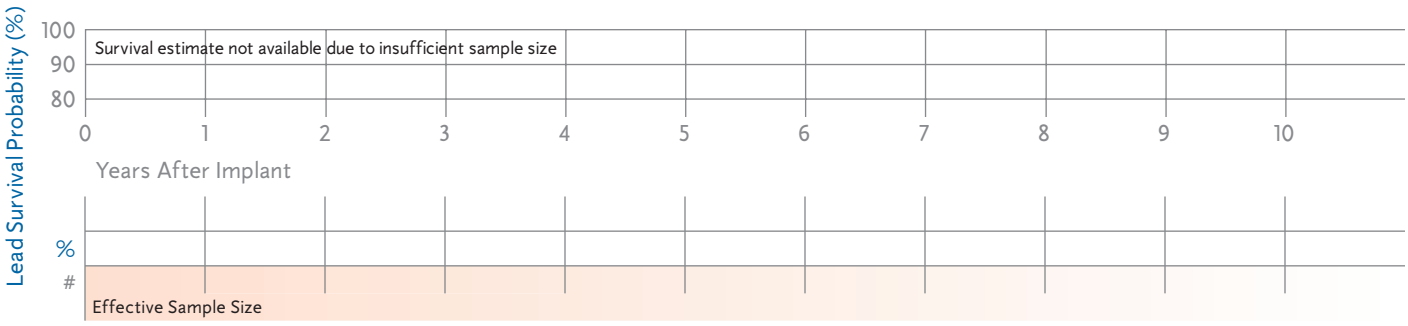
Implant Damage	5
Electrical Malfunction	0
Other	0

Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	3
Cumulative Months of Follow-Up	73

Complications in Study 0 Total



Leads

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Estimated US Implants	64,900	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	44,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	11
Electrical Malfunction	2
Other	0

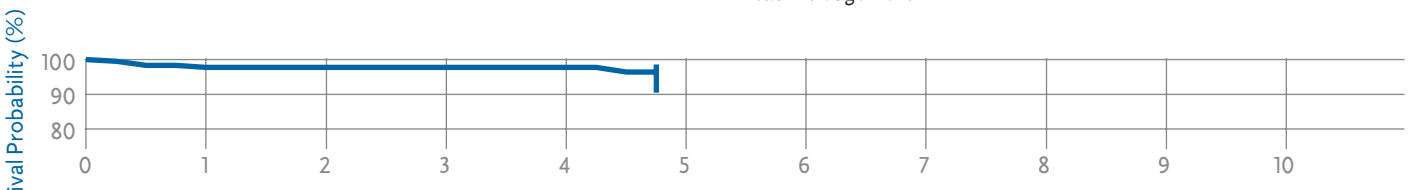
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	239
Cumulative Months of Follow-Up	8,037

Complications in Study — 5 Total

Failure to Capture	2
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	97.8	97.8	97.8	97.8	96.4
#	159	141	119	78	48

Effective Sample Size

5023, 5023M CapSure SP

Product Characteristics

US Market Release	Nov-88	Serial Number Prefix	SX or LAS
Estimated US Implants	10,600	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	3,300	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	15
Electrical Malfunction	7
Other	0

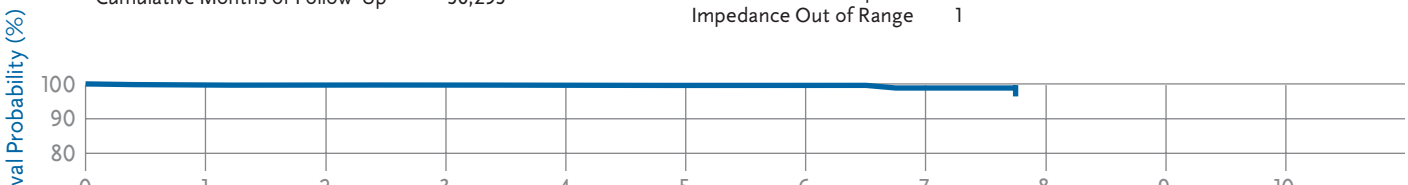
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,348
Cumulative Months of Follow-Up	56,295

Complications in Study — 5 Total

Extra Cardiac Stimulation	1
Failure to Capture	3
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	99.7	99.7	99.7	99.6	99.6	99.6	98.9	98.9
#	1,081	888	708	511	360	218	105	45

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5024, 5024M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	SY or LAT
Estimated US Implants	211,400	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	82,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	723
Electrical Malfunction	103
Other	29

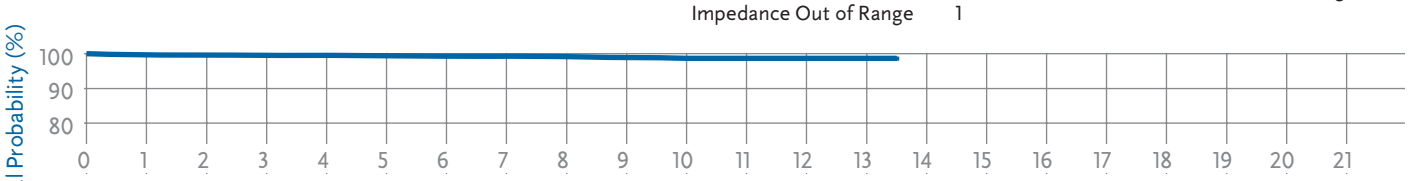
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	8,142
Cumulative Months of Follow-Up	411,193

Complications in Study 43 Total

Conductor Fracture	3	Insulation (ESC)	1
Extra Cardiac Stimulation	1	Insulation (not further defined)	4
Failure to Capture	25	Lead Dislodgement	5
Failure to Sense	2	Oversensing	1
Impedance Out of Range	1		



	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	at 162 mo
%	99.7	99.6	99.5	99.5	99.4	99.4	99.3	99.1	98.9	98.7	98.7	98.7	98.7	98.7
#	6,148	5,301	4,499	3,746	3,055	2,323	1,736	1,189	775	482	280	172	93	61

Effective Sample Size

5026 CapSure

Product Characteristics

US Market Release	Feb-88	Serial Number Prefix	RZ
Estimated US Implants	7,800	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	1,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	60
Electrical Malfunction	7
Other	1

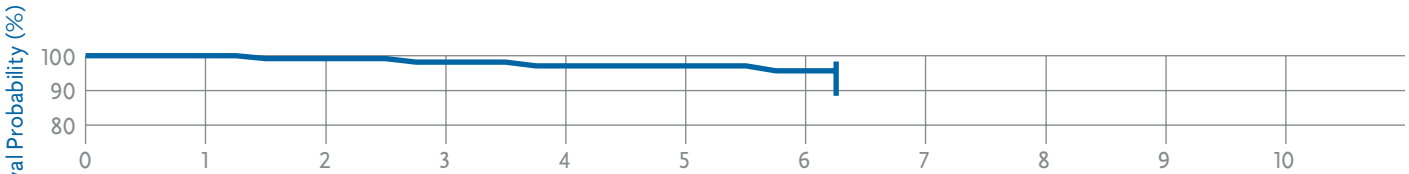
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	168
Cumulative Months of Follow-Up	9,439

Complications in Study 4 Total

Electrical Abandonment	1
Failure to Capture	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	100.0	99.2	98.2	97.1	97.1	95.7	95.7
#	128	111	96	83	70	56	52

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5033 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDK
Estimated US Implants	2,500	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	1,200	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	6
Electrical Malfunction	1
Other	3

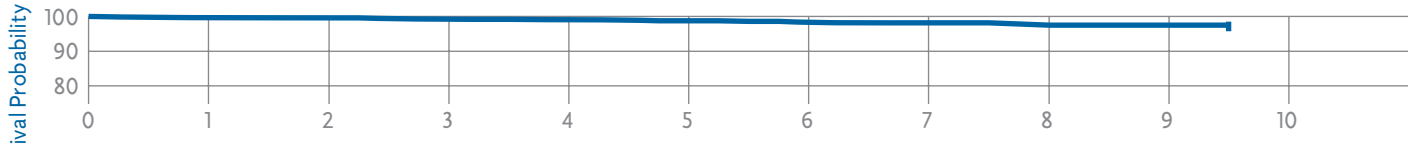
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	85,907

Complications in Study 19 Total

Cardiac Perforation	1
Conductor Fracture	4
Failure to Capture	9
Impedance Out of Range	2
Insulation (not further defined)	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.7	99.6	99.2	99.0	98.8	98.4	98.2	97.5	97.5	97.5
#	1,417	1,148	950	801	638	484	354	226	75	41

Effective Sample Size

5034 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDF
Estimated US Implants	58,700	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	26,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	85
Electrical Malfunction	29
Other	11

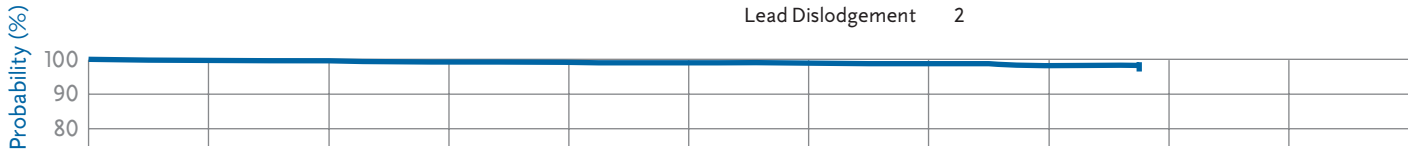
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,596
Cumulative Months of Follow-Up	75,632

Complications in Study 13 Total

Conductor Fracture	1
Failure to Capture	9
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.8	99.6	99.3	99.2	99.0	99.0	98.8	98.3	98.3
#	1,279	1,064	896	728	576	392	251	151	65

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Estimated US Implants	76,700	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	50,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	40
Electrical Malfunction	11
Other	6

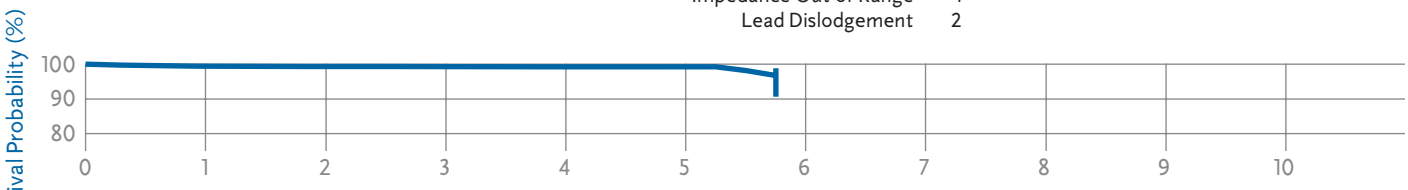
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,381
Cumulative Months of Follow-Up	45,382

Complications in Study — 11 Total

Failure to Capture	7
Failure to Sense	1
Impedance Out of Range	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.5	99.4	99.4	99.3	99.3	96.8
#	1,063	817	613	358	138	48

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5068 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDJ
Estimated US Implants	108,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	59,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	455
Electrical Malfunction	52
Other	15

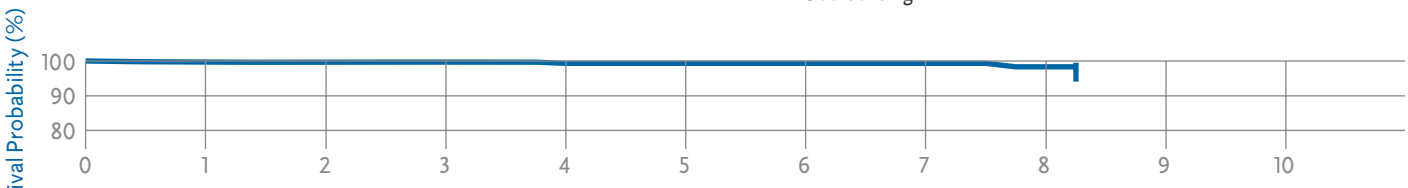
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	963
Cumulative Months of Follow-Up	31,081

Complications in Study — 4 Total

Failure to Capture	2
Impedance Out of Range	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.7	99.7	99.7	99.4	99.4	99.4	99.4	98.4	98.4
#	560	434	334	265	216	158	114	69	46

Effective Sample Size

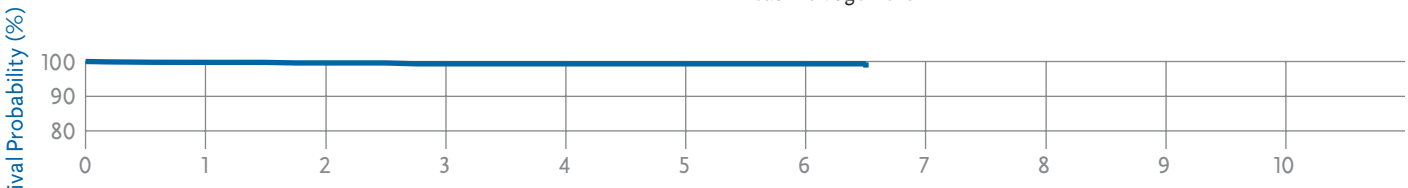
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,359
Cumulative Months of Follow-Up	32,031

Complications in Study — 5 Total

Conductor Fracture	1
Failure to Capture	3
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	99.8	99.6	99.4	99.4	99.4	99.4	99.4
#	696	493	357	244	152	74	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Estimated US Implants	8,500	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	5,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	21
Electrical Malfunction	2
Other	1

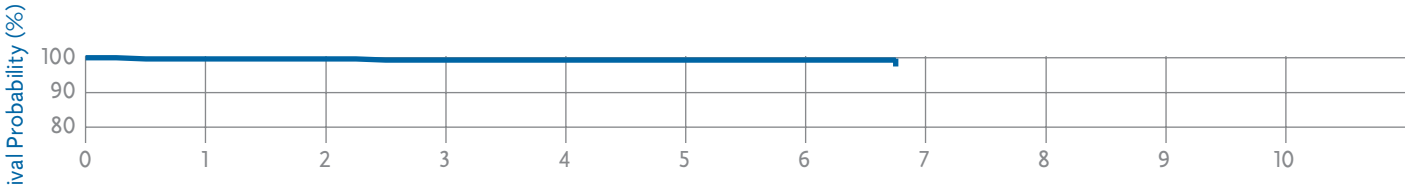
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	451
Cumulative Months of Follow-Up	19,235

Complications in Study 2 Total

Cardiac Perforation	1
Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	99.7	99.7	99.4	99.4	99.4	99.4	99.4
#	342	291	250	212	137	77	49

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Estimated US Implants	653,200	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	513,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	599
Electrical Malfunction	105
Other	45

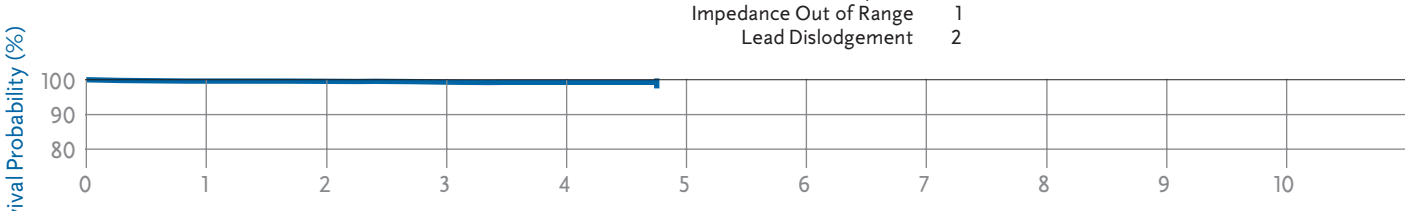
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,920
Cumulative Months of Follow-Up	45,796

Complications in Study — 8 Total

Cardiac Perforation	1
Conductor Fracture	1
Extra Cardiac Stimulation	2
Failure to Capture	1
Impedance Out of Range	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	99.6	99.6	99.3	99.3	99.3
#	1,251	774	533	225	50

Effective Sample Size

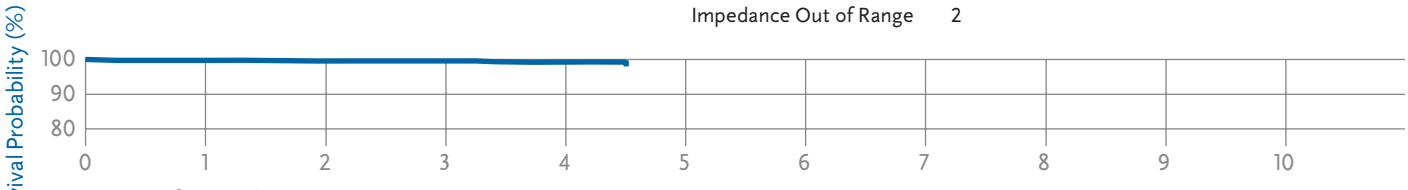
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,425
Cumulative Months of Follow-Up	33,991

Complications in Study — 6 Total

Cardiac Perforation	1
Failure to Capture	2
Failure to Sense	1
Impedance Out of Range	2



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	99.8	99.6	99.6	99.3	99.3
#	960	592	371	145	55

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Estimated US Implants	95,200	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	66,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	42
Electrical Malfunction	15
Other	10

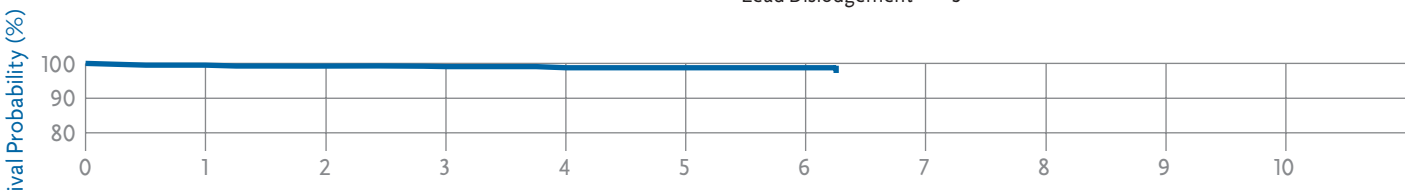
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,144
Cumulative Months of Follow-Up	33,503

Complications in Study — 8 Total

Extra Cardiac Stimulation	1
Failure to Capture	2
Lead Dislodgement	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	99.5	99.3	99.1	98.8	98.8	98.8	98.8
#	780	585	411	248	121	56	46

Effective Sample Size

5524, 5524M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Estimated US Implants	63,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	26,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	66
Electrical Malfunction	18
Other	7

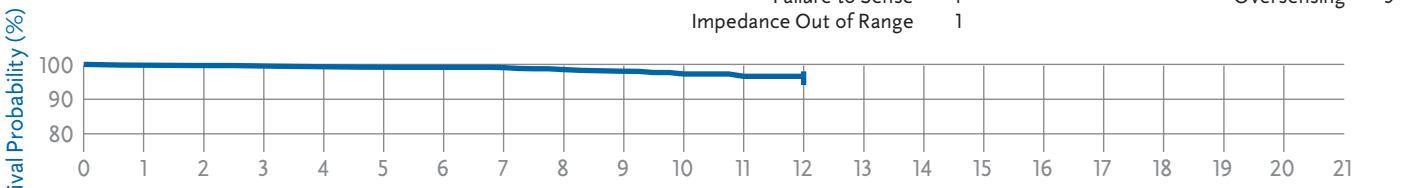
Arial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	4,432
Cumulative Months of Follow-Up	223,597

Complications in Study — 34 Total

Conductor Fracture	1
Failure to Capture	20
Failure to Sense	4
Impedance Out of Range	1
Insulation (not further defined)	1
Lead Dislodgement	4
Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr
%	99.8	99.7	99.5	99.3	99.2	99.2	99.1	98.5	98.0	97.3	96.6	96.6
#	3,396	2,941	2,517	2,106	1,694	1,262	912	611	369	217	109	53

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5534 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDG
Estimated US Implants	27,700	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	10,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	29
Electrical Malfunction	6
Other	5

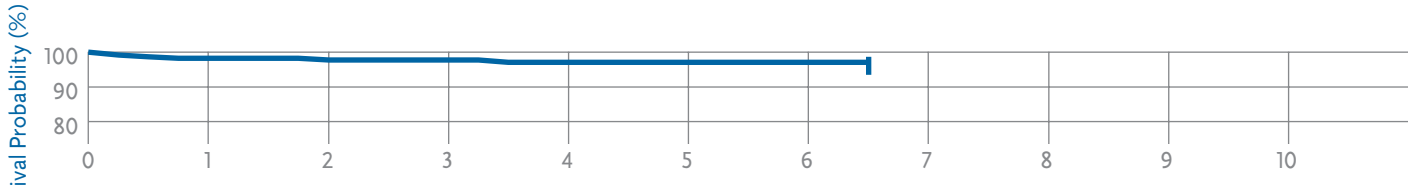
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	260
Cumulative Months of Follow-Up	12,005

Complications in Study — 6 Total

Failure to Capture	5
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	98.3	97.8	97.8	97.1	97.1	97.1	97.1
#	203	178	152	105	69	52	48

Effective Sample Size

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Estimated US Implants	48,900	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	32,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	7
Electrical Malfunction	6
Other	4

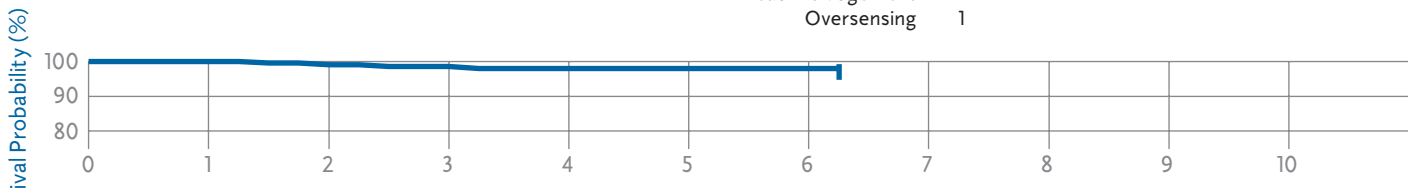
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	316
Cumulative Months of Follow-Up	13,204

Complications in Study — 4 Total

Failure to Capture	1
Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	100.0	99.1	98.6	98.0	98.0	98.0	98.0
#	249	205	174	120	92	68	57

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Estimated US Implants	50,000	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated US Active	35,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	209
Electrical Malfunction	7
Other	7

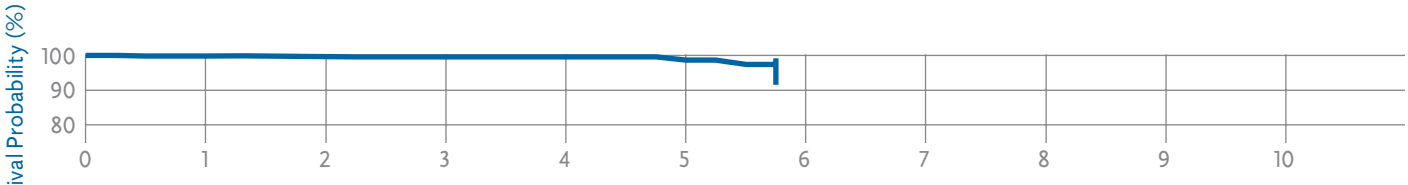
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	825
Cumulative Months of Follow-Up	21,957

Complications in Study — 4 Total

Failure to Capture	2
Failure to Sense	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.9	99.6	99.6	99.6	98.7	97.4
#	503	346	237	147	91	51

Effective Sample Size

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Estimated US Implants	22,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	16,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	5
Electrical Malfunction	2
Other	0

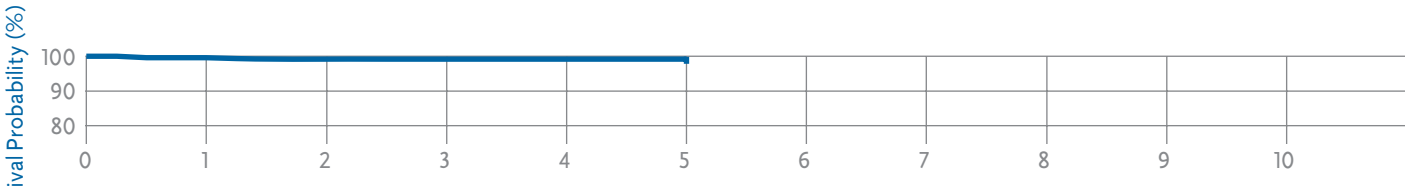
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	632
Cumulative Months of Follow-Up	19,036

Complications in Study — 4 Total

Failure to Capture	2
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr
%	99.6	99.2	99.2	99.2	99.2
#	473	357	229	124	49

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Estimated US Implants	7,400	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	6,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	0
Electrical Malfunction	1
Other	0

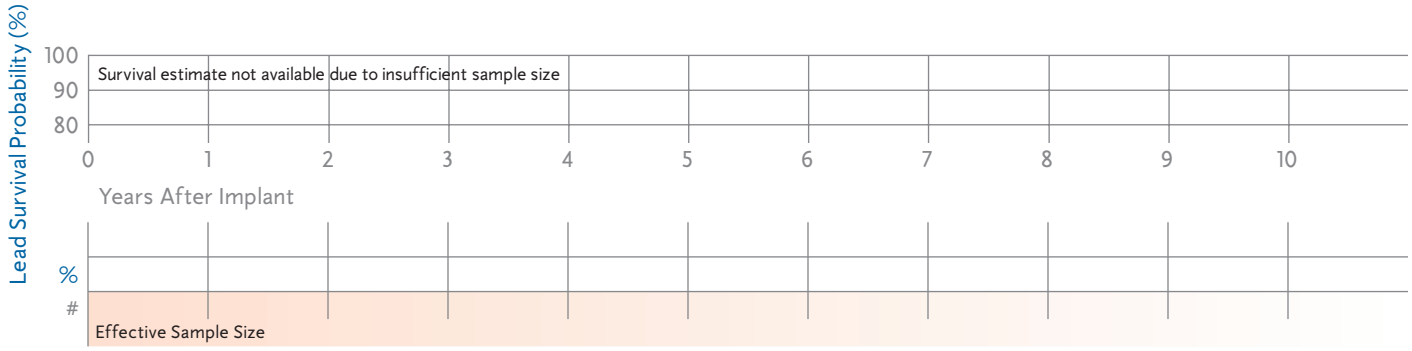
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	10
Cumulative Months of Follow-Up	382

Complications in Study

0 Total



6907R

Product Characteristics

US Market Release	May-79	Serial Number Prefix	FY
Estimated US Implants	18,500	Type and/or Fixation	Transvenous, Vent., Flange
Estimated US Active	1,300	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	3
Electrical Malfunction	25
Other	1

Ventricular Placement

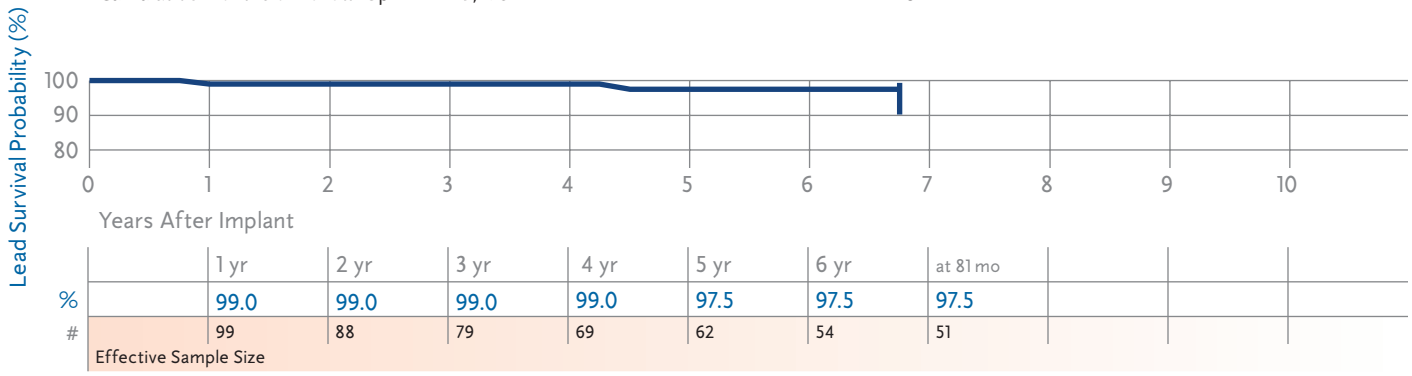
Prospective Clinical Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	9,478

Complications in Study

6 Total

Failure to Capture	4
Oversensing	2



Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

6940 CapSureFix

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	TCP
Estimated US Implants	26,600	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated US Active	14,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

Implant Damage	114
Electrical Malfunction	18
Other	3

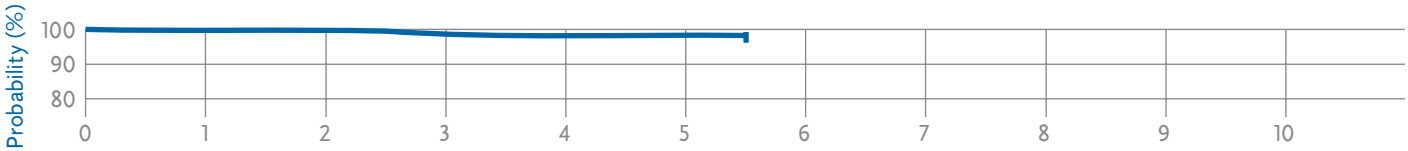
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	616
Cumulative Months of Follow-Up	22,623

Complications in Study 6 Total

Failure to Sense	2
Oversensing	2
Conductor Fracture	1
Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	99.8	99.8	98.6	98.3	98.3	98.3
#	450	366	292	224	123	45

Effective Sample Size

Leads

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

6957 Spectraflex

Product Characteristics

US Market Release	Jul-79	Serial Number Prefix	VC
Estimated US Implants	29,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	3,300	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	85
Electrical Malfunction	39
Other	25

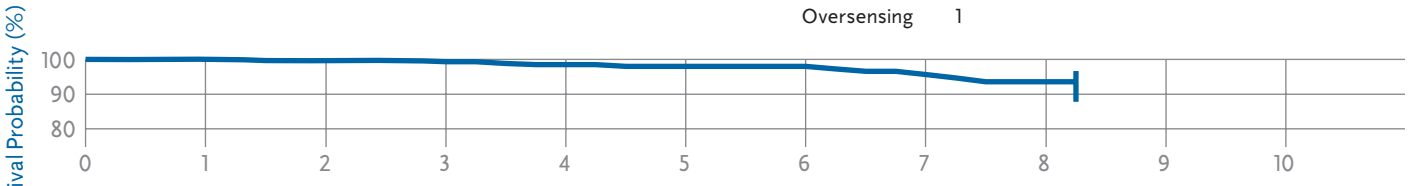
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	677
Cumulative Months of Follow-Up	24,622

Complications in Study — 10 Total

Extra Cardiac Stimulation	1
Failure to Capture	3
Failure to Sense	5
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	99.7	99.4	98.5	98.0	98.0	95.7	93.6	93.6
#	403	316	253	208	173	140	98	62	53

Effective Sample Size

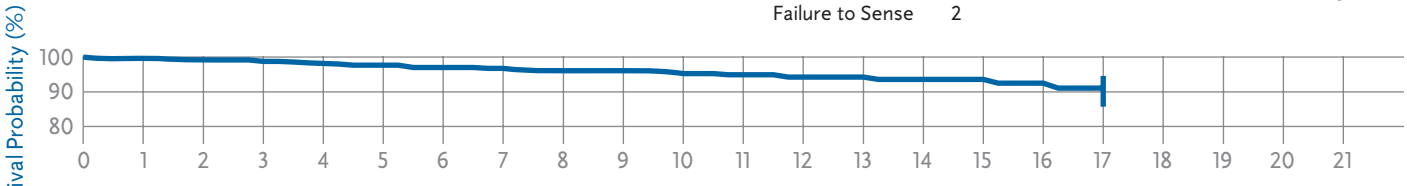
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,854
Cumulative Months of Follow-Up	95,874

Complications in Study — 42 Total

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



	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
%	99.6	99.2	98.8	98.2	97.7	97.0	96.8	96.1	96.1	95.3	94.9	94.3	94.3	93.6	93.6	92.5	91.1
#	1,227	1,000	836	711	624	516	431	342	280	228	192	159	132	108	86	66	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

6957J Spectraflex

Product Characteristics

US Market Release	Sep-80	Serial Number Prefix	GG
Estimated US Implants	30,000	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated US Active	2,700	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	74
Electrical Malfunction	28
Other	30

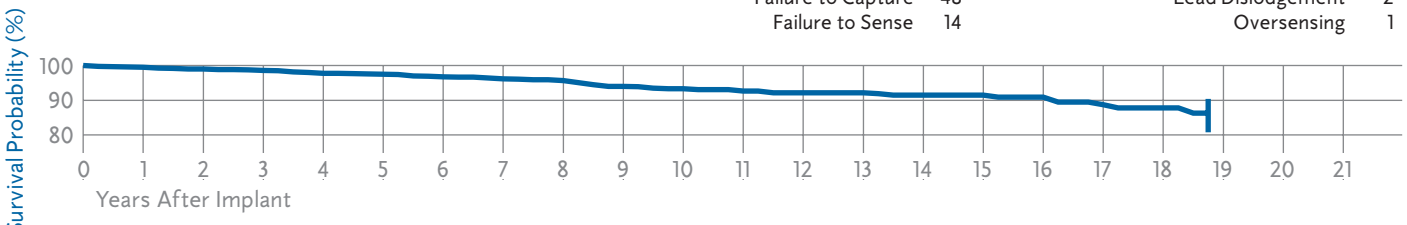
Atrial Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	2,348
Cumulative Months of Follow-Up	160,448

Complications in Study — 84 Total

Conductor Fracture	12	Insulation (ESC)	1
Extra Cardiac Stimulation	3	Insulation (not further defined)	3
Failure to Capture	48	Lead Dislodgement	2
Failure to Sense	14	Oversensing	1



	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	at 225 mo
%	99.5	99.0	98.6	97.8	97.5	96.8	96.2	95.7	94.0	93.3	92.7	92.2	92.2	91.5	91.5	90.9	88.7	87.8	86.3
#	1,780	1,560	1,363	1,209	1,080	918	769	655	557	468	396	323	260	210	163	128	100	66	50

Effective Sample Size

6961 Tenax

Product Characteristics

US Market Release	Jan-78	Serial Number Prefix	TB
Estimated US Implants	44,700	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	2,000	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	103
Electrical Malfunction	27
Other	0

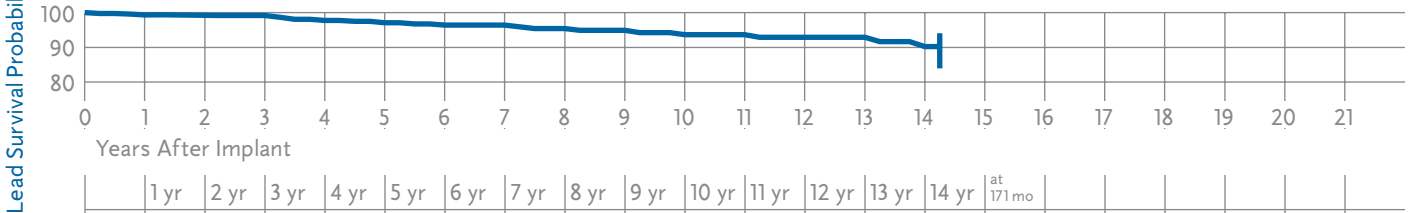
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	627
Cumulative Months of Follow-Up	43,069

Complications in Study — 21 Total

Extra Cardiac Stimulation	4
Failure to Capture	7
Failure to Sense	6
Insulation (not further defined)	2
Lead Dislodgement	1
Oversensing	1



	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	at 171 mo
%	99.4	99.2	99.2	97.8	97.1	96.4	96.4	95.4	94.9	93.7	93.7	92.9	92.9	90.2	90.2
#	468	408	366	323	271	236	210	187	160	141	121	95	77	58	50

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

6962 Tenax

Product Characteristics

US Market Release	Jan-78	Serial Number Prefix	UB
Estimated US Implants	70,600	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	3,700	Polarity	Bipolar
Advisories	None	Steroid	No

Laboratory Analysis

Implant Damage	170
Electrical Malfunction	84
Other	0

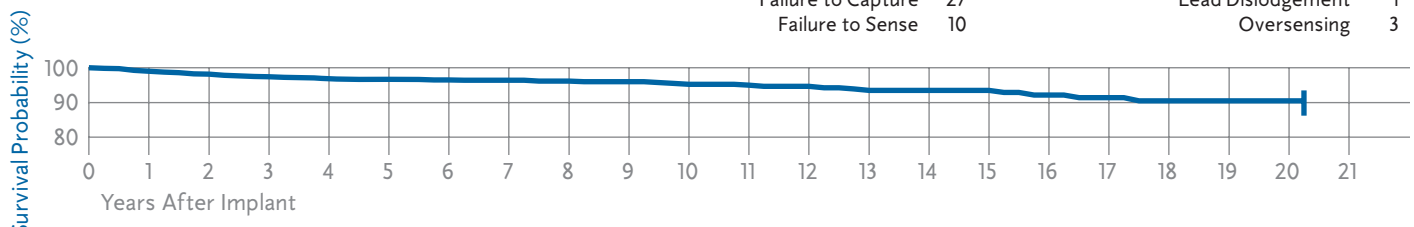
Ventricular Placement

Prospective Clinical Study Results

Number of Leads Enrolled in Study	1,483
Cumulative Months of Follow-Up	110,904

Complications in Study 51 Total

Conductor Fracture	5	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Insulation (not further defined)	2
Failure to Capture	27	Lead Dislodgement	1
Failure to Sense	10	Oversensing	3



	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	at 243 mo
%	99.0	98.2	97.4	96.9	96.7	96.5	96.4	96.2	96.0	95.3	95.0	94.7	93.5	93.5	93.5	92.2	91.4	90.5	90.5	90.5	90.5
#	1,085	971	860	761	680	615	563	493	424	368	310	264	217	181	150	125	106	86	68	54	48

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 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
3830	SelectSecure	Atrial	Aug-05	111	1	3,223	99.1 +0.8/-5.5	99.1 +0.8/-5.5	99.1 +0.8/-5.5											
3830	SelectSecure	Vent	Aug-05	108	0	3,204	100.0	100.0	100.0											
4003, 4003M	CapSure	Vent	Jul-86	711	7	42,829	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.1 +0.5/-1.2	99.1 +0.5/-1.2	98.8 +0.7/-1.5	98.5 +0.8/-1.7	98.5 +0.8/-1.7	98.5 +0.8/-1.7					
4004, 4004M	CapSure	Vent	Feb-89	1,640	276	71,612	99.8 +0.1/-0.5	99.3 +0.4/-0.7	96.3 +1.0/-1.4	87.5 +2.0/-2.5	77.2 +2.8/-3.2	69.4 +3.4/-3.7	64.1 +3.8/-4.0	58.1 +4.2/-4.4	51.5 +4.8/-5.0	50.7 +5.0/-5.3 at 129 mo				
	Advisory: see page 168 - 1993 Lead Survival Below Expectations																			
4011	Target Tip	Vent	Nov-82	851	23	54,346	99.4 +0.4/-1.0	99.2 +0.5/-1.0	99.1 +0.5/-1.2	98.8 +0.7/-1.2	97.6 +1.1/-1.8	96.4 +1.4/-2.3	96.1 +1.5/-2.5	96.1 +1.5/-2.5	95.0 +1.9/-3.0	92.8 +2.7/-4.2	91.9 +3.1/-4.7	91.9 +3.1/-4.7 at 183 mo		
4012	Target Tip	Vent	Jul-83	2,543	315	151,264	99.6 +0.2/-0.3	99.2 +0.3/-0.6	98.4 +0.5/-0.7	95.8 +0.9/-1.1	92.5 +1.3/-1.5	88.1 +1.7/-1.9	83.9 +2.0/-2.3	77.8 +2.5/-2.7	69.8 +3.1/-3.3	65.7 +3.5/-3.7	63.0 +3.9/-4.3	62.3 +4.1/-4.4 at 189 mo		
	Advisory: see page 169 - 1991 Lead Survival Below Expectations																			
4023	CapSure SP	Vent	Aug-91	1,158	15	54,878	99.9 +0.1/-0.6	99.3 +0.4/-0.9	98.8 +0.5/-1.1	98.6 +0.6/-1.1	98.6 +0.6/-1.1	98.3 +0.8/-1.5	97.3 +1.3/-2.2	97.3 +1.3/-2.2	97.3 +1.3/-2.2					
4024	CapSure SP	Vent	Oct-91	1,215	3	50,045	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 at 105 mo						
4033	CapSure Z	Vent	Mar-94	541	9	27,571	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 +1.0/-2.1	97.8 +1.2/-2.7	97.8 +1.2/-2.7	96.9 +1.7/-3.7	95.7 +2.3/-4.8 at 102 mo					
4057, 4057M	Screw-In	Vent	Aug-88	259	7	14,990	99.4 +0.5/-3.5	99.4 +0.5/-3.5	99.4 +0.5/-3.5	98.6 +1.1/-4.0	97.7 +1.6/-4.7	96.8 +2.0/-5.3	95.7 +2.5/-5.9	95.7 +2.5/-5.9	94.3 +3.2/-6.8 at 114 mo					
4058, 4058M	Screw-In	Atrial	Jan-89	2,364	30	129,835	99.9 +0.1/-0.4	99.6 +0.2/-0.4	99.5 +0.2/-0.5	99.1 +0.4/-0.6	98.7 +0.5/-0.7	98.3 +0.6/-0.9	98.2 +0.6/-1.0	97.5 +0.8/-1.3	96.4 +1.3/-1.9	96.4 +1.3/-1.9	96.4 +1.3/-1.9 at 162 mo			
4058, 4058M	Screw-In	Vent	Jan-89	1,691	47	75,820	99.4 +0.3/-0.7	99.2 +0.4/-0.7	99.1 +0.4/-0.8	98.7 +0.5/-1.0	97.9 +0.8/-1.2	96.7 +1.1/-1.6	94.4 +1.7/-2.3	93.5 +1.9/-2.7	89.8 +2.8/-3.9	89.0 +3.1/-4.3 at 138 mo				
4067	CapSureFix	Atrial	Jan-97	108	3	5,503	97.1 +2.0/-5.9	97.1 +2.0/-5.9	97.1 +2.0/-5.9	97.1 +2.0/-5.9 at 39 mo										
4068	CapSureFix	Atrial	Mar-96	2,388	43	105,192	99.1 +0.3/-0.5	98.8 +0.4/-0.6	98.2 +0.5/-0.7	98.0 +0.5/-0.8	97.5 +0.7/-1.0	97.3 +0.7-1.1	97.3 +0.7/-1.1	96.9 +1.0/-1.3	96.9 +1.0/-1.3 at 111 mo					
4068	CapSureFix	Vent	Mar-96	1,787	27	72,497	99.4 +0.3/-0.5	99.0 +0.4/-0.7	98.9 +0.4/-0.7	98.5 +0.6/-0.9	98.1 +0.7/-1.1	97.6 +0.9/-1.5	96.4 +1.5/-2.7	95.4 +2.1/-3.6	95.4 +2.1/-3.6 at 102 mo					

continued

Source: System Longevity Study
Data as of April 1, 2006

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 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
4073	CapSure Sense	Atrial	Jun-02	1	0	18	Survival estimate not available due to insufficient sample size													
4073	CapSure Sense	Vent	Jun-02	101	0	1,926	100.0	100.0 at 15 mo												
4074	CapSure Sense	Vent	Jun-02	382	0	7,648	100.0	100.0	100.0 at 33 mo											
4076	CapSureFix Novus	Atrial	Feb-04	140	0	2,011	100.0	100.0 at 18 mo												
4076	CapSureFix Novus	Vent	Feb-04	169	1	2,414	100.0	100.0 at 18 mo												
4081	Target Tip	Vent	Jul-89	260	3	9,587	100.0	100.0	100.0	100.0	100.0	98.2 +1.5/-10.5 at 63 mo								
4092	CapSure SP Novus	Vent	Sep-98	1,139	15	37,061	99.0 +0.5/-0.8	98.9 +0.5/-0.9	98.9 +0.5/-0.9	98.4 +0.7/-1.3	97.1 +1.5/-2.8									
4503, 4503M	CapSure	Atrial	Jul-86	59	—	3,059	Survival estimate not available due to insufficient sample size													
4504, 4504M	CapSure	Atrial	Mar-90	368	48	19,857	100.0	100.0	99.1 +0.7/-2.5	98.2 +1.1/-3.0	90.3 +3.5/-5.3	82.2 +5.1/-6.8	73.0 +6.5/-8.2	69.9 +7.0/-8.7	66.1 +7.7/-9.2 at 105 mo					
	Advisory: see page 166 - 1996 Lead Survival Below Expectations																			
4512	Target Tip	Atrial	Jul-83	600	35	40,029	99.6 +0.3/-1.2	99.6 +0.3/-1.2	99.1 +0.6/-1.5	98.0 +1.0/-2.0	96.8 +1.4/-2.5	95.7 +1.7/-2.9	94.8 +2.0/-3.2	91.1 +3.0/-4.3	87.2 +3.9/-5.5	84.5 +4.6/-6.2	83.4 +4.9/-6.8 at 159 mo			
4523	CapSure SP	Atrial	Aug-91	121	3	6,713	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3 at 57 mo									
4524	CapSure SP	Atrial	Oct-91	911	6	37,375	99.6 +0.3/-0.7	99.3 +0.4/-1.0	99.3 +0.4/-1.0	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2	99.0 +0.6/-1.2 at 99 mo					
4533	CapSure Z	Atrial	Mar-94	206	4	10,903	100.0	99.4 +0.5/-3.5	98.8 +0.9/-3.6	98.0 +1.3/-4.3	98.0 +1.3/-4.3	98.0 +1.3/-4.3	98.0 +1.3/-4.3 at 81 mo							
4557, 4557M	Screw-In	Atrial	Aug-88	294	6	18,182	99.1 +0.7/-2.7	99.1 +0.7/-2.7	99.1 +0.7/-2.7	97.8 +1.4/-3.5	97.8 +1.4/-3.5	97.8 +1.4/-3.5	96.9 +1.9/-4.4	96.9 +1.9/-4.4	96.9 +1.9/-4.4	96.9 +1.9/-4.4 at 123 mo				
4558M	Screw-In	Atrial	Nov-94	539	10	21,930	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	97.7 +1.5/-4.1	96.6 +2.1/-5.0	96.6 +2.1/-5.0	95.1 +2.9/-6.6 at 105 mo					

continued

Source: System Longevity Study
Data as of April 1, 2006

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant 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
4568	CapSureFix	Atrial	Jan-97	573	25	16,801	96.3 +1.4/-2.1	95.8 +1.5/-2.2	95.1 +1.7/-2.4	95.1 +1.7/-2.4	94.2 +2.2/-3.5									
4574	CapSure Sense	Atrial	Jun-02	3	0	73	Survival estimate not available due to insufficient sample size													
4592	CapSure SP Novus	Atrial	Oct-98	239	5	8,037	97.8 +1.4/-3.5	97.8 +1.4/-3.5	97.8 +1.4/-3.5	97.8 +1.4/-3.5	96.4 +2.2/-5.9 at 57 mo									
5023, 5023M	CapSure SP	Vent	Nov-88	1,348	5	56,295	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.6 +0.2/-0.8	99.6 +0.2/-0.8	99.6 +0.2/-0.8	98.9 +0.8/-2.5	98.9 +0.8/-2.5 at 93 mo						
5024, 5024M	CapSure SP	Vent	Mar-90	8,142	43	411,193	99.7 +0.1/-0.2	99.6 +0.1/-0.1	99.5 +0.2/-0.1	99.5 +0.1/-0.2	99.4 +0.2/-0.2	99.4 +0.2/-0.3	99.3 +0.2/-0.3	99.1 +0.3/-0.4	98.7 +0.5/-0.7	98.7 +0.5/-0.7	98.7 +0.5/-0.7 at 162 mo			
5026	CapSure	Vent	Feb-88	168	4	9,439	100.0	99.2 +0.7/-4.8	98.2 +1.4/-5.2	97.1 +2.0/-5.9	97.1 +2.0/-5.9	95.7 +2.7/-7.2	95.7 +2.7/-7.2 at 75 mo							
5033	CapSure Z	Vent	Feb-96	1,899	19	85,907	99.7 +0.2/-0.4	99.6 +0.2/-0.4	99.2 +0.3/-0.7	99.0 +0.5/-0.7	98.8 +0.5/-0.9	98.4 +0.7/-1.1	98.2 +0.7/-1.2	97.5 +1.0/-1.7	97.5 +1.0/-1.7 at 114 mo					
5034	CapSure Z	Vent	Feb-96	1,596	13	75,632	99.8 +0.1/-0.4	99.6 +0.2/-0.6	99.3 +0.3/-0.7	99.2 +0.3/-0.8	99.0 +0.5/-0.8	99.0 +0.5/-0.8	98.8 +0.5/-1.1	98.3 +0.9/-1.8	98.3 +0.9/-1.8 at 105 mo					
5054	CapSure Z Novus	Vent	Jun-98	1,381	11	45,382	99.5 +0.3/-0.6	99.4 +0.3/-0.6	99.4 +0.3/-0.6	99.3 +0.3/-0.8	99.3 +0.3/-0.8	96.8 +2.1/-6.1 at 69 mo								
5068	CapSureFix	Atrial	Jan-97	963	4	31,081	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6	98.4 +1.1/-4.3	98.4 +1.1/-4.3 at 99 mo					
5068	CapSureFix	Vent	Jan-97	1,359	5	32,031	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1 at 78 mo							
5072	SureFix	Atrial	Jun-98	451	2	19,235	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	99.4 +0.4/-1.9 at 81 mo							
5076	CapSureFix Novus	Atrial	Aug-00	1,920	8	45,796	99.6 +0.2/-0.4	99.6 +0.2/-0.4	99.3 +0.4/-0.7	99.3 +0.4/-0.7	99.3 +0.4/-0.7 at 57 mo									
5076	CapSureFix Novus	Vent	Aug-00	1,425	6	33,991	99.8 +0.1/-0.5	99.6 +0.3/-0.6	99.6 +0.3/-0.6	99.3 +0.5/-1.3	99.3 +0.5/-1.3 at 54 mo									
5092	CapSure SP Novus	Vent	Jun-98	1,144	8	33,503	99.5 +0.3/-0.8	99.3 +0.4/-0.8	99.1 +0.5/-1.0	98.8 +0.6/-1.5	98.8 +0.6/-1.5	98.8 +0.6/-1.5	98.8 +0.6/-1.5 at 75 mo							
5524, 5524M	CapSure SP	Atrial	Mar-90	4,432	34	223,597	99.8 +0.1/-0.3	99.7 +0.2/-0.2	99.5 +0.2/-0.3	99.3 +0.3/-0.3	99.2 +0.3/-0.4	99.2 +0.3/-0.4	99.1 +0.3/-0.6	98.5 +0.6/-0.8	97.3 +1.0/-1.7	96.6 +1.4/-2.5				

continued

Source: System Longevity Study
Data as of April 1, 2006

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device Survival Probability (%) Years After Implant												
							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
5534	CapSure Z	Atrial	Feb-96	260	6	12,005	98.3 +1.1/-2.8	97.8 +1.3/-3.1	97.8 +1.3/-3.1	97.1 +1.6/-3.6	97.1 +1.6/-3.6	97.1 +1.6/-3.6	97.1 +1.6/-3.6 at 78 mo							
5554	CapSure Z Novus	Atrial	Jun-98	316	4	13,204	100.0	99.1 +0.7/-2.6	98.6 +0.9/-2.9	98.0 +1.3/-3.2	98.0 +1.3/-3.2	98.0 +1.3/-3.2	98.0 +1.3/-3.2 at 75 mo							
5568	CapSureFix	Atrial	Jan-97	825	4	21,957	99.9 +0.1/-1.0	99.6 +0.3/-1.3	99.6 +0.3/-1.3	99.6 +0.3/-1.3	98.7 +1.0/-4.2	97.4 +1.8/-5.8 at 69 mo								
5592	CapSure SP Novus	Atrial	Jun-98	632	4	19,036	99.6 +0.3/-1.1	99.2 +0.5/-1.3	99.2 +0.5/-1.3	99.2 +0.5/-1.3	99.2 +0.5/-1.3									
5594	CapSure SP Novus	Atrial	Jun-01	10	0	382	Survival estimate not available due to insufficient sample size													
6907R	(no brand name)	Vent	May-79	121	6	9,478	100.0	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	97.5 +1.9/-7.3	97.5 +1.9/-7.3	97.5 +1.9/-7.3 at 81 mo						
6940	CapSureFix	Atrial	Oct-98	616	6	22,623	99.8 +0.2/-1.0	99.8 +0.2/-1.0	98.6 +0.8/-1.9	98.3 +0.9/-2.1	98.3 +0.9/-2.1	98.3 +0.9/-2.1 at 66 mo								
6957	Spectraflex	Atrial	Jul-79	677	10	24,622	100.0	99.7 +0.3/-1.6	99.4 +0.4/-2.0	98.5 +0.9/-2.5	98.0 +1.2/-2.8	98.0 +1.2/-2.8	95.7 +2.2/-4.6	93.6 +3.1/-5.8 at 99 mo						
6957	Spectraflex	Vent	Jul-79	1,854	42	95,874	99.6 +0.2/-0.5	99.2 +0.4/-0.6	98.8 +0.5/-0.9	98.2 +0.7/-1.0	97.7 +0.8/-1.2	97.0 +1.0/-1.4	96.8 +1.0/-1.5	96.1 +1.2/-1.7	95.3 +1.5/-2.1	94.3 +1.9/-2.7	93.6 +2.2/-3.2	92.5 +2.8/-4.2	91.1 +3.5/-5.4 at 17 yr	
6957J	Spectraflex	Atrial	Sep-80	2,348	84	160,448	99.5 +0.2/-0.5	99.0 +0.4/-0.6	98.6 +0.4/-0.7	97.8 +0.6/-0.8	97.5 +0.7/-0.9	96.8 +0.8/-1.1	96.2 +1.0/-1.2	95.7 +1.0/-1.3	93.3 +1.5/-1.8	92.2 +1.7/-2.1	91.5 +1.9/-2.4	90.9 +2.1/-2.7	87.8 +3.3/-4.4	87.8 +4.1/-5.5 at 225 mo
6961	Tenax	Vent	Jan-78	627	21	43,069	99.4 +0.4/-1.1	99.2 +0.5/-1.3	99.2 +0.5/-1.3	97.8 +1.1/-2.0	97.1 +1.3/-2.3	96.4 +1.5/-2.7	96.4 +1.5/-2.7	95.4 +1.9/-3.0	93.7 +2.4/-3.9	92.9 +2.7/-4.3	90.2 +3.9/-6.2	90.2 +3.9/-6.2 at 171 mo		
6962	Tenax	Vent	Jan-78	1,483	51	110,904	99.0 +0.4/-0.8	98.2 +0.7/-0.9	97.4 +0.8/-1.1	96.9 +0.9/-1.2	96.7 +0.9/-1.3	96.5 +1.0/-1.3	96.4 +1.0/-1.4	96.2 +1.1/-1.5	95.3 +1.3/-1.8	94.7 +1.5/-2.0	93.5 +1.8/-2.5	92.2 +2.4/-3.3	90.5 +3.0/-4.3	90.5 +3.0/-4.3 at 243 mo

Source: System Longevity Study
Data as of April 1, 2006

Pacing Leads continued

Laboratory Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
3830	SelectSecure	Aug-05	1,700	1,500	5	0	1
4003, 4003M	CapSure	Jul-86	40,000	8,100	24	54	2
4004, 4004M	CapSure	Feb-89	74,500	3,700	55	680	19
4011	Target Tip	Nov-82	64,000	8,200	29	141	5
4012	Target Tip	Jul-83	96,800	6,700	50	817	34
4023	CapSure SP	Aug-91	43,700	16,900	48	18	6
4024	CapSure SP	Oct-91	229,200	95,300	264	89	34
4033	CapSure Z	not US released	—	—	2	0	0
4057, 4057M	Screw-in	Aug-88	12,100	3,100	39	6	4
4058, 4058M	Screw-in	Jan-89	111,100	29,600	388	223	23
4067	CapSureFix	Jan-97	1,300	600	3	1	1
4068	CapSureFix	Mar-96	131,700	65,200	406	68	11
4073	CapSure Sense	Jun-02	400	300	0	0	0
4074	CapSure Sense	Jun-02	35,000	29,700	10	1	1
4076	CapSureFix Novus	Feb-04	60,600	55,400	27	2	4
4081	Target Tip	Jul-89	4,100	1,000	4	5	0
4092	CapSure SP Novus	Sep-98	126,200	88,200	30	7	5
4503, 4503M	CapSure	Jul-86	9,000	1,600	2	9	0
4504, 4504M	CapSure	Mar-90	16,600	1,900	5	170	4
4512	Target Tip	Jul-83	11,600	1,200	4	82	8
4523	CapSure SP	Aug-91	12,000	4,000	5	2	1
4524	CapSure SP	Oct-91	106,900	43,200	47	17	8
4533	CapSure Z	not US released	—	—	0	0	0
4557, 4557M	Screw-in	Aug-88	22,500	6,000	53	14	4
4558M	Screw-in	Nov-94	21,000	7,100	111	10	1
4568	CapSureFix	Jan-97	72,700	43,600	196	5	4
4574	CapSure Sense	Jun-02	22,500	18,900	5	0	0
4592	CapSure SP Novus	Oct-98	64,900	44,300	11	2	0
5023, 5023M	CapSure SP	Nov-88	10,600	3,300	15	7	0
5024, 5024M	CapSure SP	Mar-90	211,400	82,500	723	103	29
5026	CapSure	Feb-88	7,800	1,500	60	7	1
5033	CapSure Z	Feb-96	2,500	1,200	6	1	3
5034	CapSure Z	Feb-96	58,700	26,000	85	29	11
5054	CapSure Z Novus	Jun-98	76,700	50,300	40	11	6
5068	CapSureFix	Jan-97	108,000	59,100	455	52	15
5072	SureFix	Jun-98	8,500	5,300	21	2	1
5076	CapSureFix Novus	Aug-00	653,200	513,400	599	105	45
5092	CapSure SP Novus	Jun-98	95,200	66,000	42	15	10
5524, 5524M	CapSure SP	Mar-90	63,800	26,400	66	18	7
5534	CapSure Z	Feb-96	27,700	10,700	29	6	5
5554	CapSure Z Novus	Jun-98	48,900	32,200	7	6	4
5568	CapSureFix	Jan-97	50,000	35,300	209	7	7
5592	CapSure SP Novus	Jun-98	22,000	16,500	5	2	0

continued

Source: Returned Product Analysis
Data as of April 30, 2006

Pacing Leads continued

Laboratory Analysis Summary continued

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
5594	CapSure SP Novus	Jun-01	7,400	6,000	0	1	0
6907R	(no brand name)	May-79	18,500	1,300	3	25	1
6940	CapSureFix	Oct-98	26,600	14,600	114	18	3
6957	Spectraflex	Jul-79	29,100	3,300	85	39	25
6957J	Spectraflex	Sep-80	30,000	2,700	74	28	30
6961	Tenax	Jan-78	44,700	2,000	103	27	0
6962	Tenax	Jan-78	70,600	3,700	170	84	0

Source: Returned Product Analysis
Data as of April 30, 2006

Pacing Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
3830	SelectSecure	Transvenous V or A Screw-In	Polyurethane/ Silicone (55D,4719)	MP35N 5 Filars/ Cable	1.8 mm Helix/Steroid	IS-1 BI
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
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
4073	CapSure Sense	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 5 Filars	TiN Coated Platinum Iridium/Steroid	IS-1 UNI
4074	CapSure Sense	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D, 4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium/ Steroid	IS-1 BI
4076	CapSureFix Novus	Transvenous V or A Screw-In	Polyurethane/ Silicone (55D, 4719)	MP35N 4/6 Filars	TiN Coated Platinum Alloy/Steroid	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
4092	CapSure SP Novus	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/ Steroid	IS-1 BI
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)
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
5023, 5023M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm (5023) IS-1 UNI (5023M)

continued

Pacing Leads continued

Reference Chart continued

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
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)
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
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 4/6 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
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/ Steroid	IS-1 BI
6907R	(no brand name)	Transvenous Ventricular Flange	Silicone	MP35N 2 Filars	Ring Tip	5 mm
6940	CapSureFix	Transvenous A or V Screw-in	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI
6957	Spectraflex	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm
6957J	Spectraflex	Transvenous Atrial-J Screw-In	Polyurethane (80A)	MP35N 1 Filar	1.5 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

Epi/Myocardial Pacing Leads

4951, 4951M Spectraflex

Product Characteristics

US Market Release	Oct-81	Serial Number Prefix	TF or LBJ
Estimated US Implants	25,100	Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Estimated US Active	4,200	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

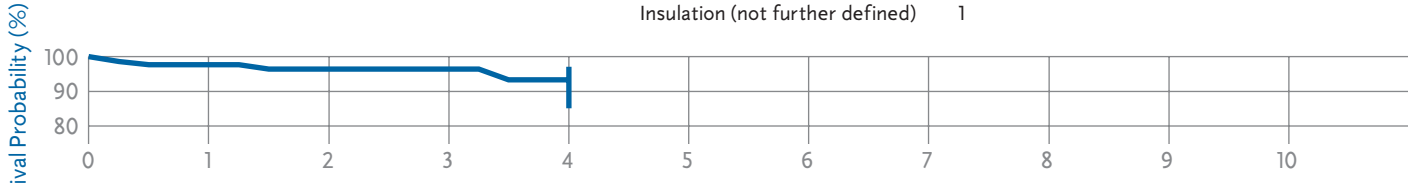
Implant Damage	15
Electrical Malfunction	95
Other	28

Prospective Clinical Study Results

Number of Leads Enrolled in Study	177
Cumulative Months of Follow-Up	5,941

Complications in Study 10 Total

Failure to Capture	4
Failure to Sense	3
Impedance Out of Range	1
Insulation (ESC)	1
Insulation (not further defined)	1



	1 yr	2 yr	3 yr	4 yr
%	97.7	96.4	96.4	93.3
#	87	73	65	49

Effective Sample Size

4965 CapSure Epi

Product Characteristics

US Market Release	Sep-96	Serial Number Prefix	LBT
Estimated US Implants	16,400	Type and/or Fixation	Epicardial Suture-On V or A
Estimated US Active	9,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

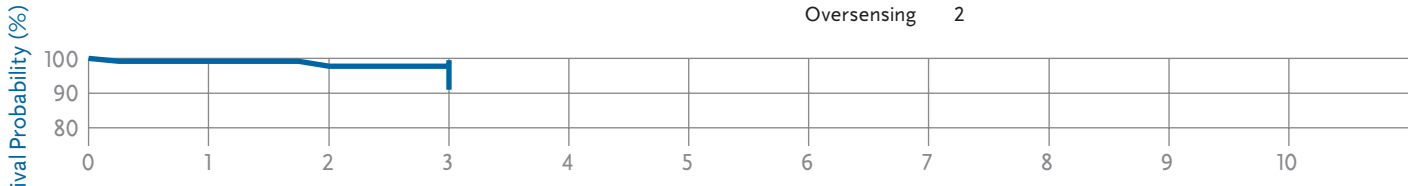
Implant Damage	7
Electrical Malfunction	74
Other	2

Prospective Clinical Study Results

Number of Leads Enrolled in Study	158
Cumulative Months of Follow-Up	3,837

Complications in Study 6 Total

Conductor Fracture	2
Failure to Capture	1
Failure to Sense	1
Oversensing	2



	1 yr	2 yr	3 yr
%	99.2	97.8	97.8
#	81	68	51

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

Product Characteristics

US Market Release	Sep-99	Serial Number Prefix	LEN
Estimated US Implants	10,200	Type and/or Fixation	Epicardial Suture-On V or A
Estimated US Active	7,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

Laboratory Analysis

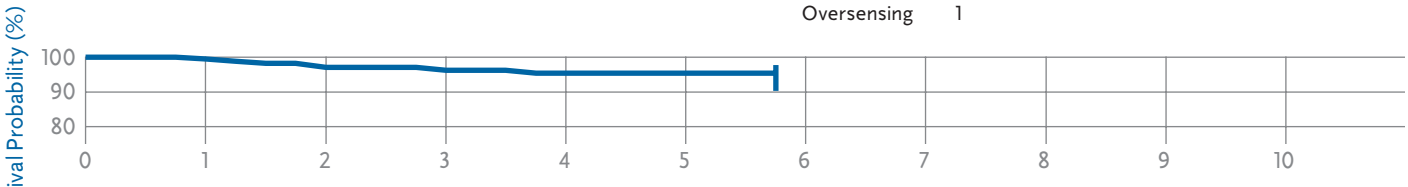
Implant Damage	2
Electrical Malfunction	3
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	220
Cumulative Months of Follow-Up	10,332

Complications in Study 9 Total

Conductor Fracture	4
Failure to Capture	3
Failure to Sense	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.5	97.1	96.3	95.4	95.4	95.4
#	179	148	115	78	58	49

Effective Sample Size

5071

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Estimated US Implants	27,900	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated US Active	18,300	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

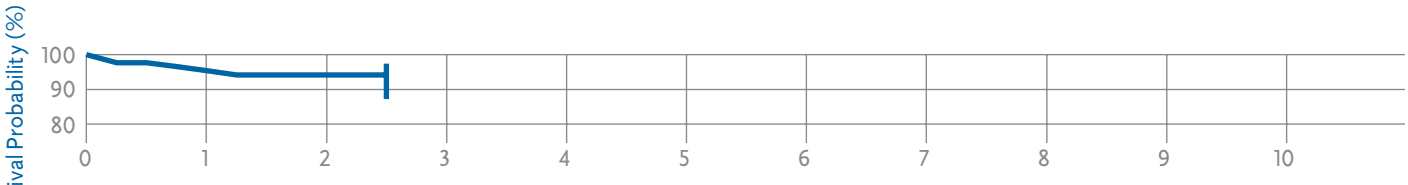
Implant Damage	23
Electrical Malfunction	4
Other	1

Prospective Clinical Study Results

Number of Leads Enrolled in Study	158
Cumulative Months of Follow-Up	4,253

Complications in Study 7 Total

Failure to Capture	7



	1 yr	2 yr	at 30 mo
%	95.4	94.2	94.2
#	75	55	48

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

Epi/Myocardial Pacing Leads continued

6917, 6917A Tenax

Product Characteristics

US Market Release	Jun-73	Serial Number Prefix	WV or WC
Estimated US Implants	180,100	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated US Active	7,000	Polarity	Unipolar
Advisories	None	Steroid	No

Laboratory Analysis

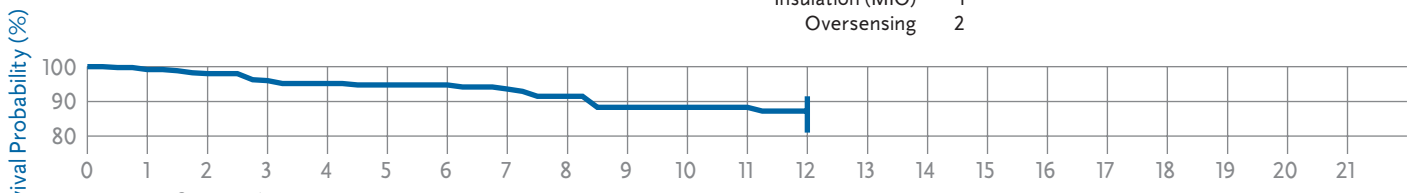
Implant Damage	115
Electrical Malfunction	42
Other	1

Prospective Clinical Study Results

Number of Leads Enrolled in Study	598
Cumulative Months of Follow-Up	30,424

Complications in Study 35 Total

Failure to Capture	26
Failure to Sense	6
Insulation (MIO)	1
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr
%	99.2	98.0	96.0	95.2	94.8	94.8	93.6	91.5	88.3	88.3	88.3	87.2
#	345	304	270	232	203	166	137	119	104	85	79	53

Effective Sample Size

Source: System Longevity Study
Data as of April 1, 2006

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 (%) 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
4951, 4951M	Spectraflex	Oct-81	177	10	5,941	97.7 +1.5/-4.9	96.4 +2.3/-5.9	96.4 +2.3/-5.9	93.3 +3.8/-8.2								
4965	CapSure Epi	Sep-96	158	6	3,837	99.2 +0.7/-4.5	97.8 +1.7/-6.8	97.8 +1.7/-6.8									
4968	CapSure Epi	Sep-99	220	9	10,332	99.5 +0.4/-3.2	97.1 +1.7/-3.9	96.3 +2.0/-4.4	95.4 +2.4/-5.1	95.4 +2.4/-5.1	95.4 +2.4/-5.1 at 69 mo						
5071	(no brand name)	Dec-92	158	7	4,253	95.4 +2.7/-6.2	94.2 +3.2/-7.0	94.2 +3.2/-7.0 at 30 mo									
6917, 6917A	Tenax	Jun-73	598	35	30,424	99.2 +0.5/-1.7	98.0 +1.0/-2.2	96.0 +1.6/-2.9	95.2 +1.9/-3.0	94.8 +2.0/-3.2	94.8 +2.0/-3.2	93.6 +2.4/-3.8	91.5 +3.0/-4.6	88.3 +3.9/-5.7	88.3 +3.9/-5.7	88.3 +3.9/-5.7	87.2 +4.3/-6.2

Source: System Longevity Study
Data as of April 1, 2006

Epi/Myocardial Pacing Leads continued

Laboratory Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
4951, 4951M	Spectraflex	Oct-81	25,100	4,200	15	95	28
4965	CapSure Epi	Sep-96	16,400	9,900	7	74	2
4968	CapSure Epi	Sep-99	10,200	7,700	2	3	0
5071	(no brand name)	Dec-92	27,900	18,300	23	4	1
6917, 6917A	Tenax	Jun-73	180,100	7,000	115	42	1

Source: Returned Product Analysis
Data as of April 30, 2006

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

5032 CapSure VDD

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCL, LCN, LCM
Estimated US Implants	5,400	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated US Active	2,400	Polarity	Quadripolar
Advisories	None	Steroid	Yes

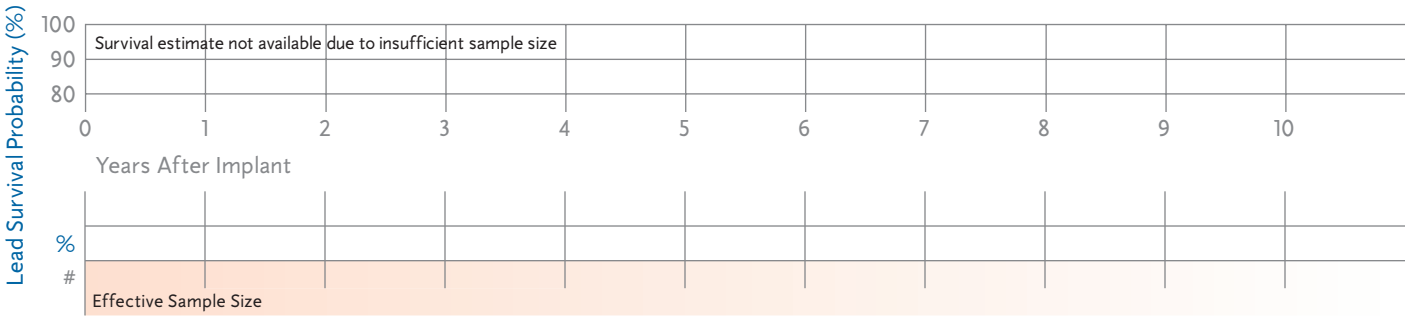
Laboratory Analysis

Implant Damage	24
Electrical Malfunction	12
Other	0

Prospective Clinical Study Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,739

Complications in Study 0 Total



5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Estimated US Implants	7,200	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated US Active	4,500	Polarity	Quadripolar
Advisories	None	Steroid	Yes

Laboratory Analysis

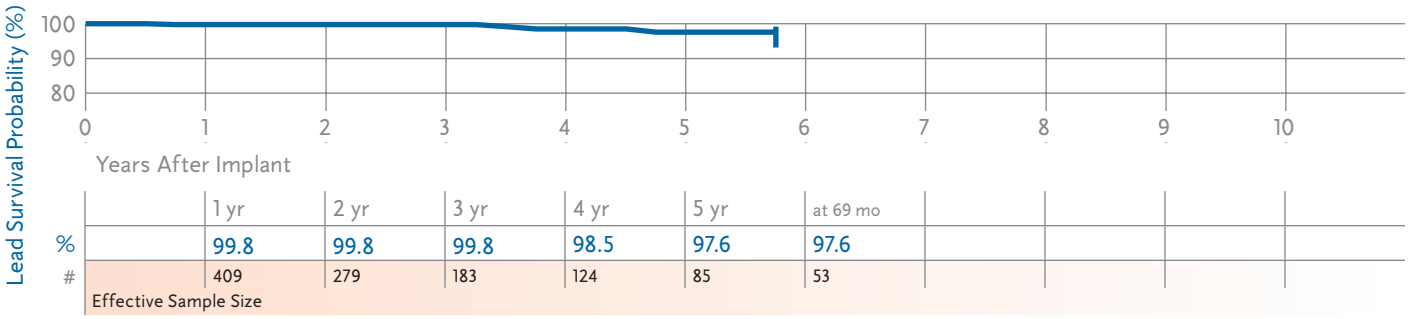
Implant Damage	6
Electrical Malfunction	2
Other	1

Prospective Clinical Study Results

Number of Leads Enrolled in Study	542
Cumulative Months of Follow-Up	17,209

Complications in Study 4 Total

Conductor Fracture	1
Failure to Capture	1
Failure to Sense	2



Source: System Longevity Study
Data as of April 1, 2006

VDD Single Pass Pacing 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 (%) Years After Implant 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
5032	CapSure VDD	Mar-96	38	0	1,739	Survival estimate not available due to insufficient sample size									
5038	CapSure VDD-2	Sep-98	542	4	17,209	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4	98.5 +1.1/-3.5	97.6 +1.6/-4.4	97.6 +1.6/-4.4 at 69 mo				

Source: System Longevity Study
Data as of April 1, 2006

Laboratory Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
5032	CapSure VDD	Mar-96	5,400	2,400	24	12	0
5038	CapSure VDD-2	Sep-98	7,200	4,500	6	2	1

Source: Returned Product Analysis
Data as of April 30, 2006

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 CRDM 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

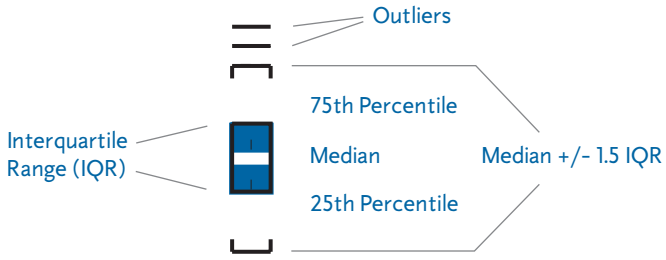
(c) The different rates of capacitor deformation due to component variability.

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

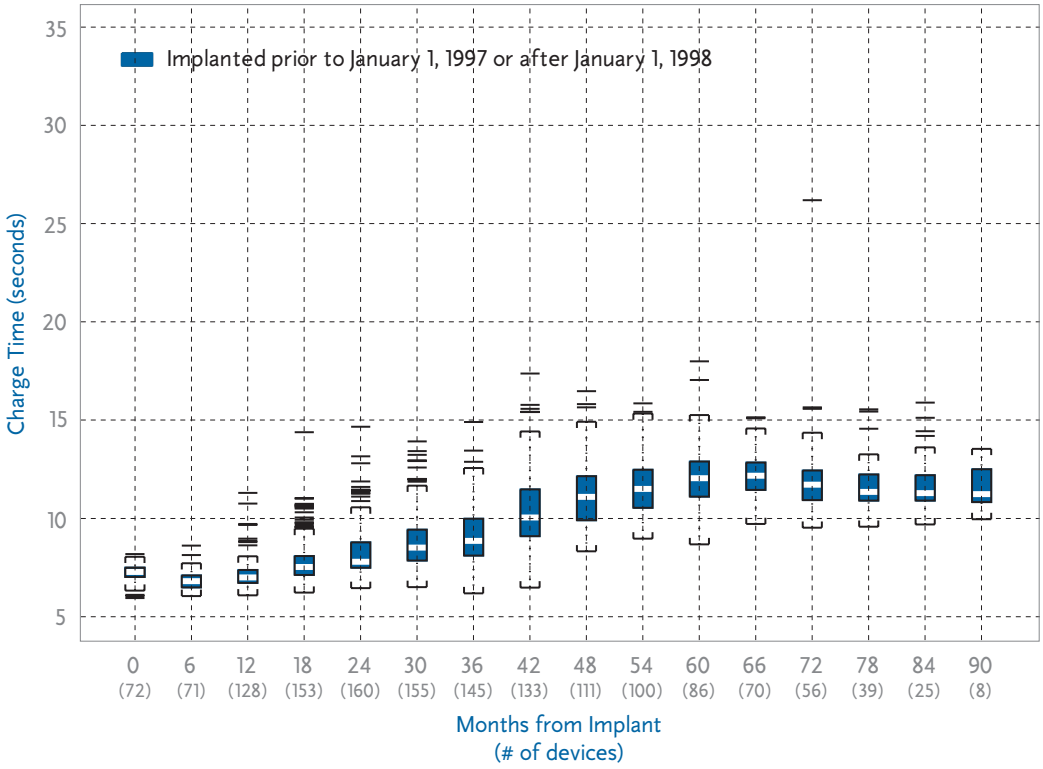
Charge time data for ICD models are presented via boxplots at 6-month intervals. The shaded box on the plots represents the middle half of the data – the Interquartile Range (IQR). The white line in the middle of each box is the median charge time. The top of the box representing the IQR is the 75th 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.

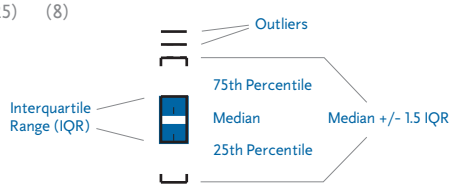


ICD Charge Times continued

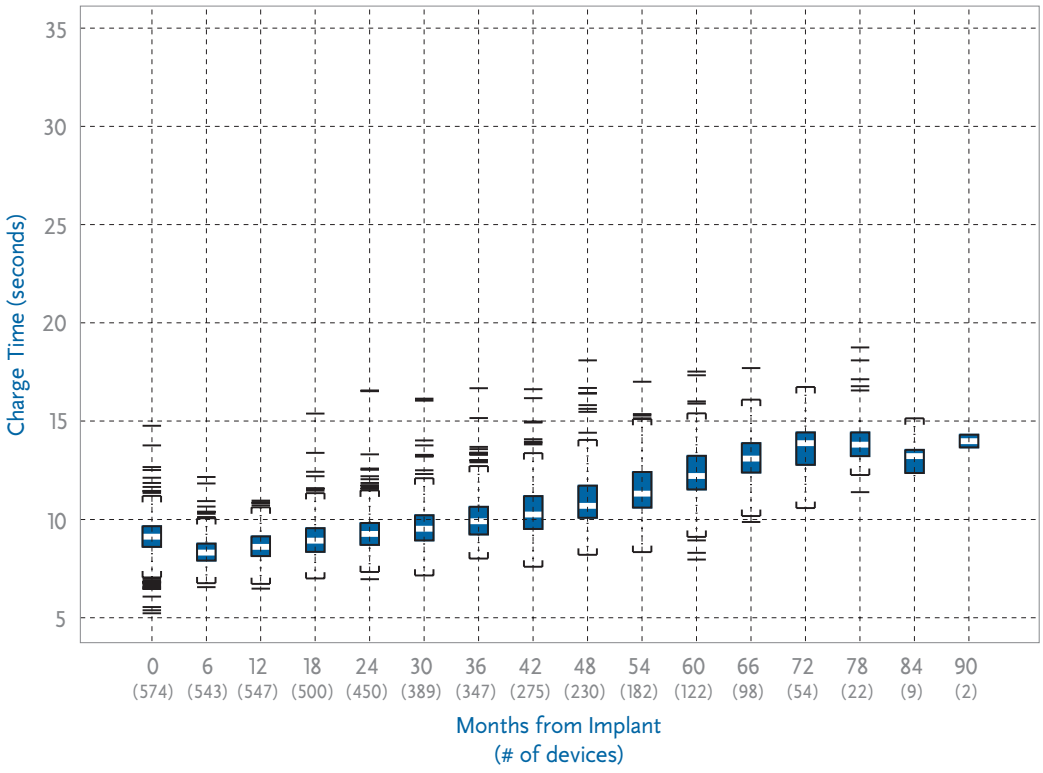
7223 Micro Jewel II Charge Time



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

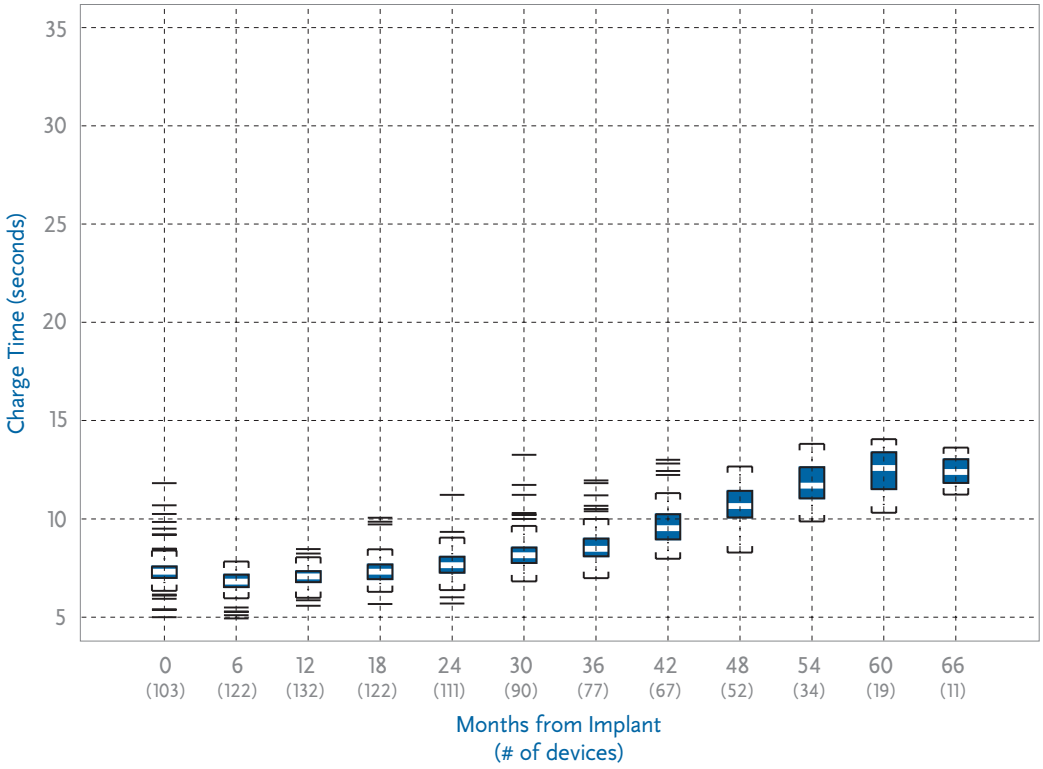


Save-to-Disk files have been collected 90 months post-implant. All observed charge times are below 20 seconds, with a maximum charge time of 18.75 seconds at 78 months post-implant.

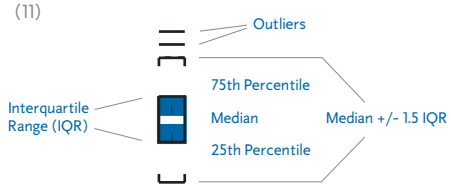
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

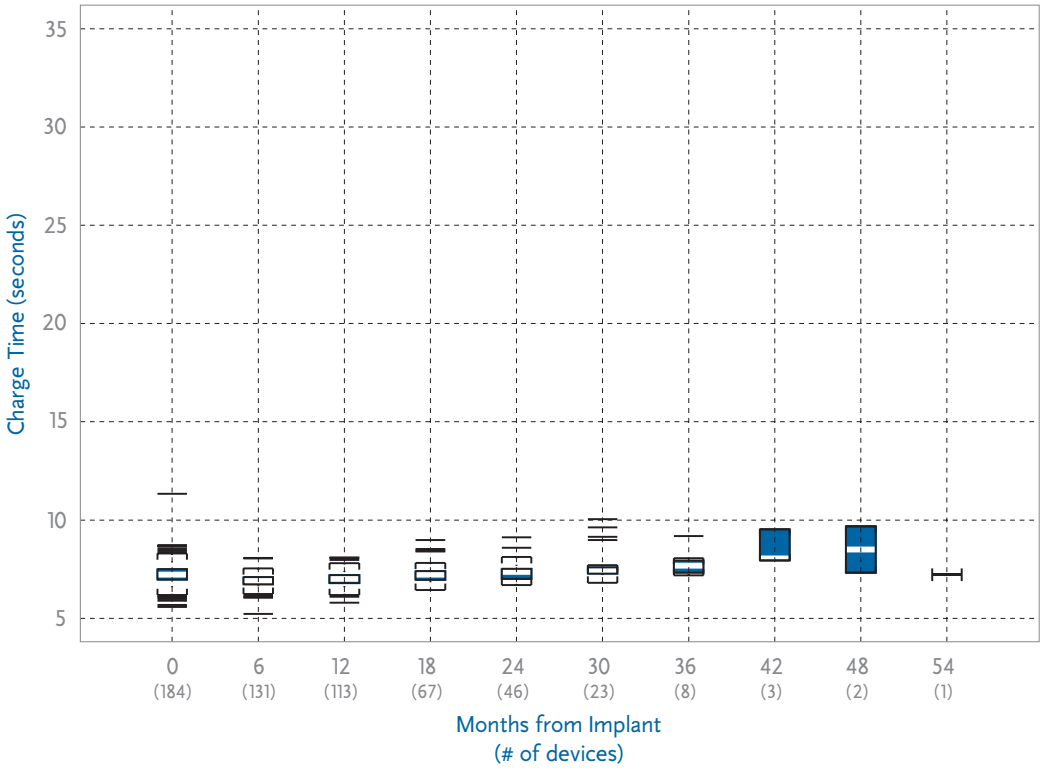
7229 GEM II VR Charge Time



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

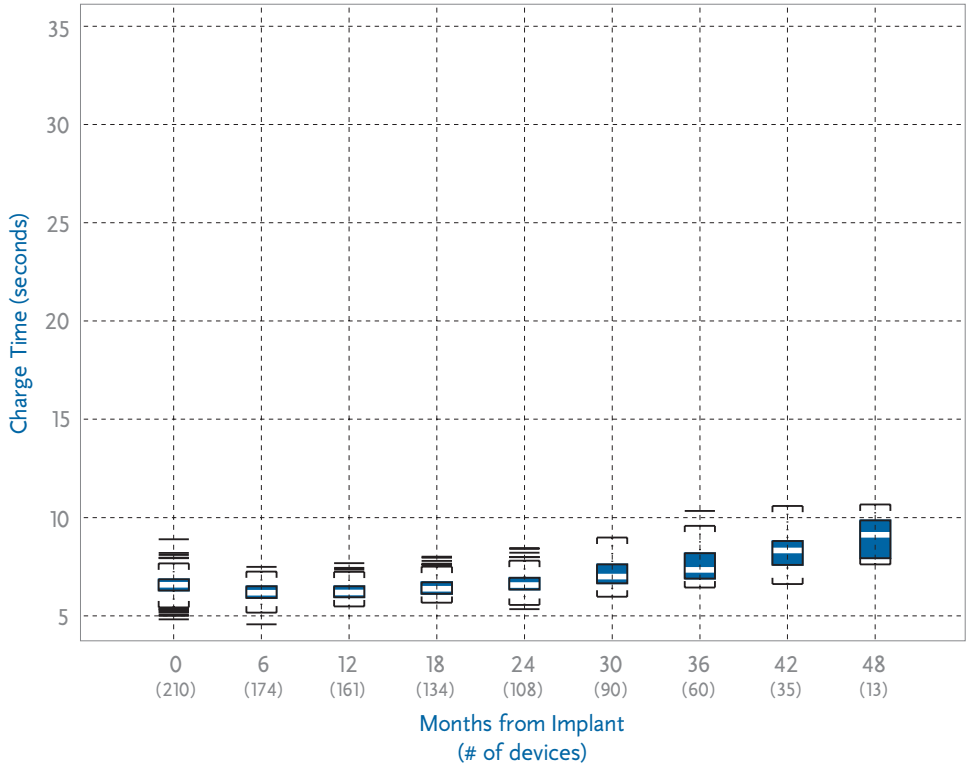


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 12 seconds with a maximum of 11.34 seconds observed at implant.

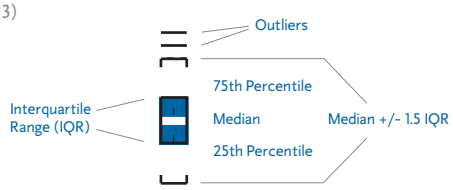
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

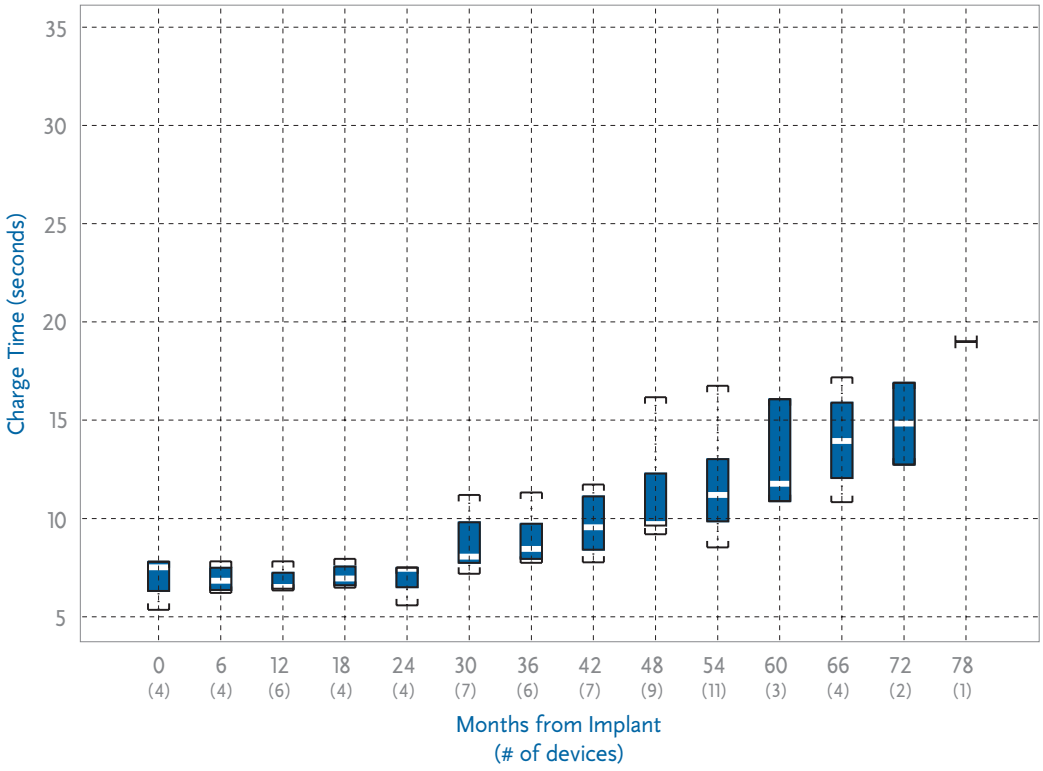
7231 GEM III VR Charge Time



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

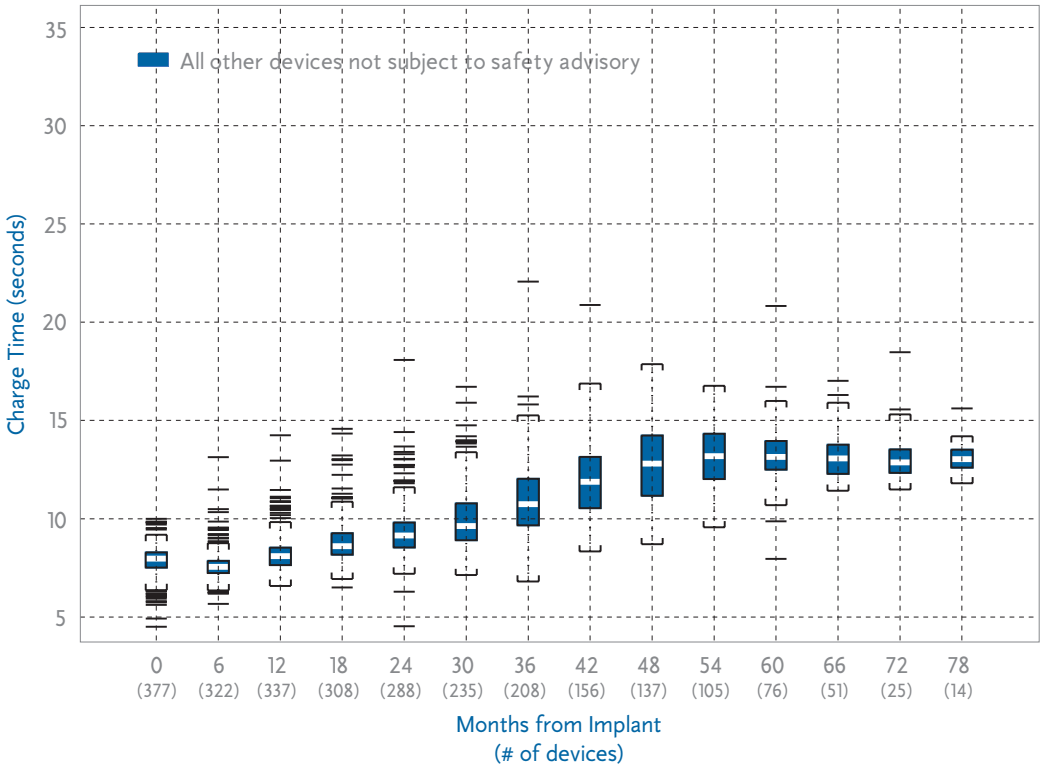


Save-to-Disk files have been collected 78 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.99 seconds observed at 78 months post-implant.

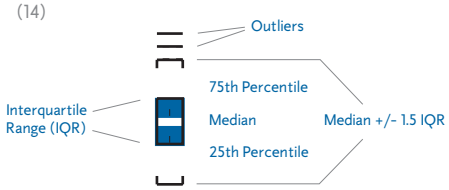
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

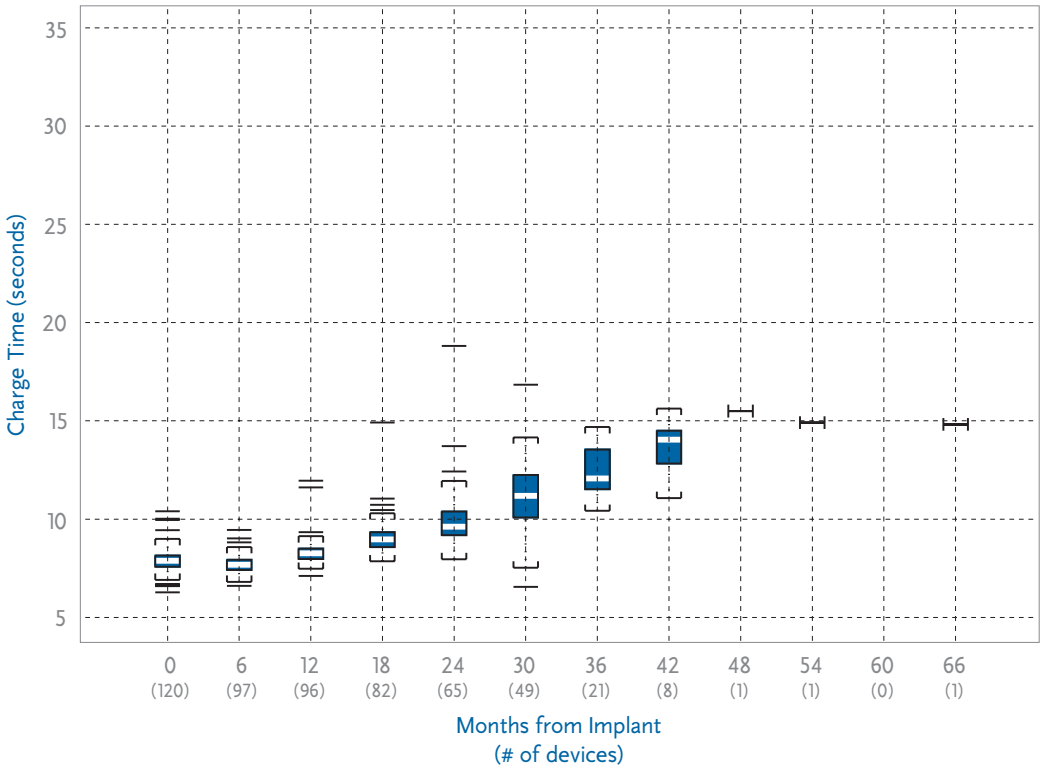
7271 GEM DR Charge Time



Save-to-Disk files have been collected 78 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.



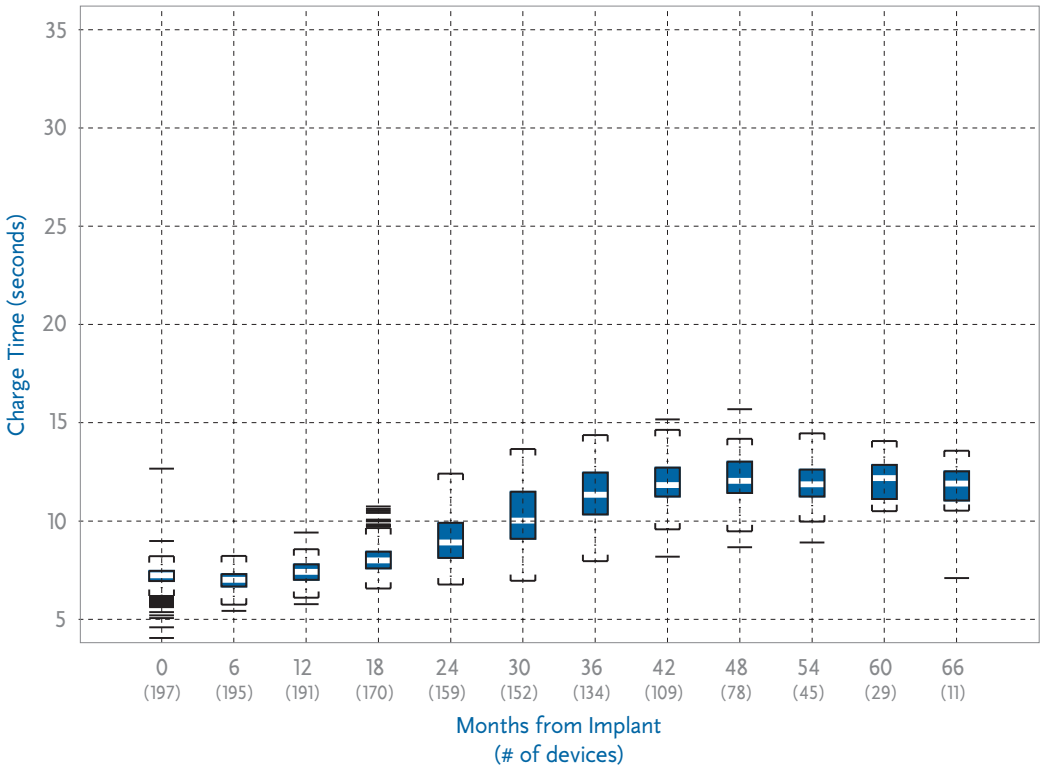
7272 InSync ICD Charge Time



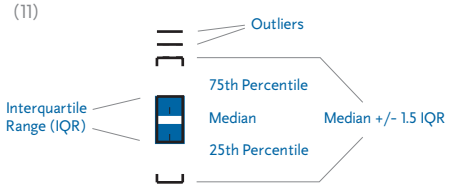
Save-to-Disk files have been collected 66 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.81 seconds observed at 24 months post-implant.

Source: System Longevity Study
Data as of April 1, 2006

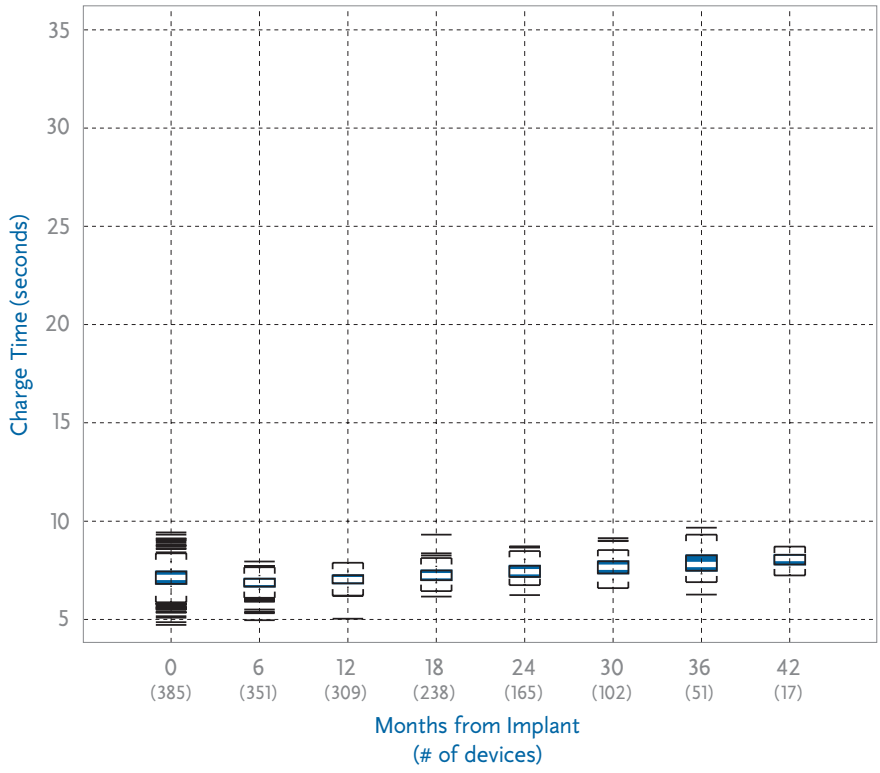
7273 GEM II DR Charge Time



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

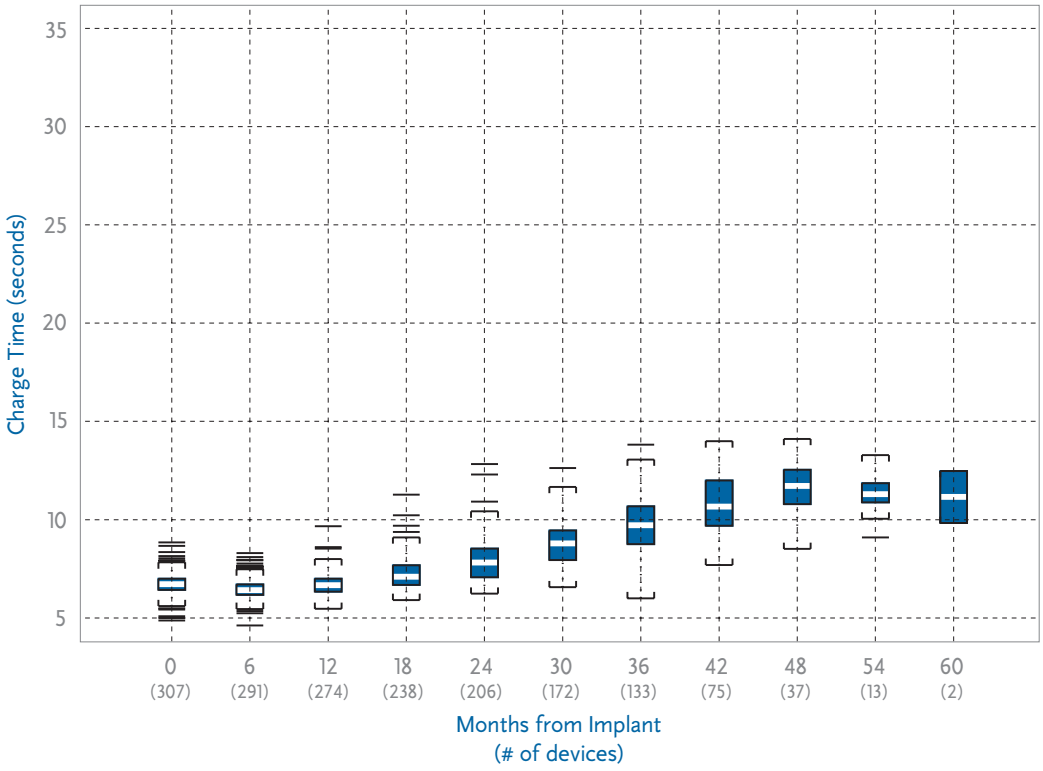


Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.67 seconds observed at 36 months post-implant.

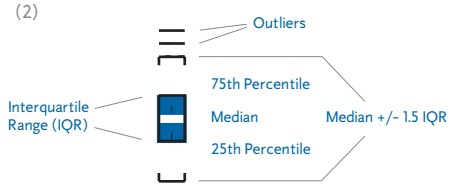
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

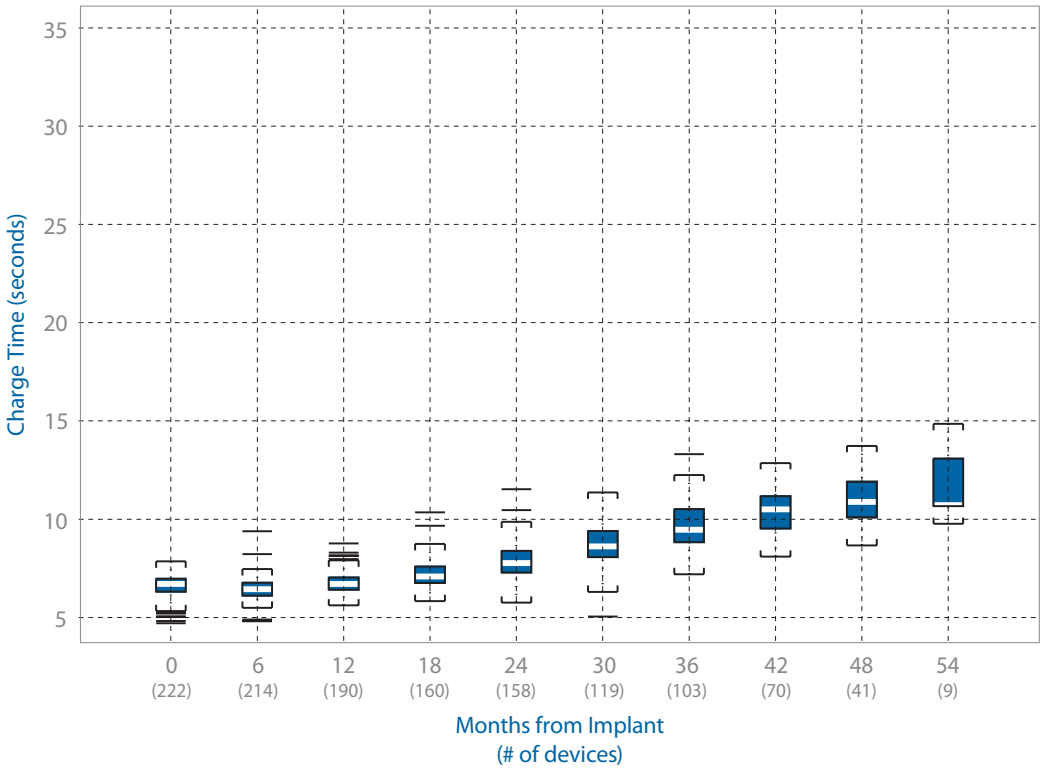
7275 GEM III DR Charge Time



Save-to-Disk files have been collected 60 months post-implant. All observed charge times are less than 15 seconds with a maximum of 14.11 seconds seen at 48 months post-implant.



7276 GEM III AT Charge Time

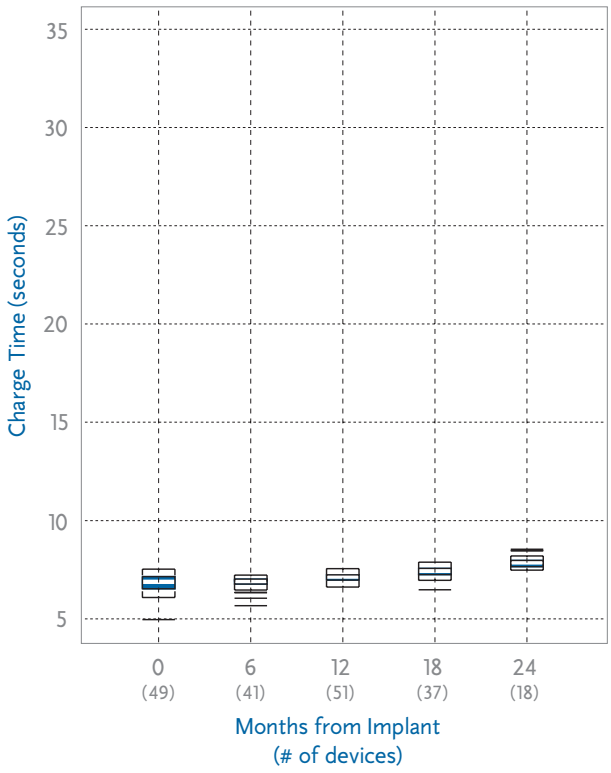


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 15 seconds with a maximum of 14.85 seconds observed at 54 months post-implant.

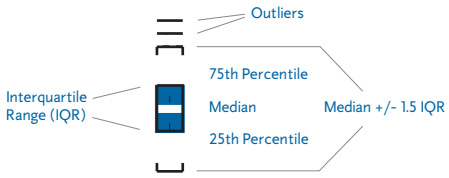
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

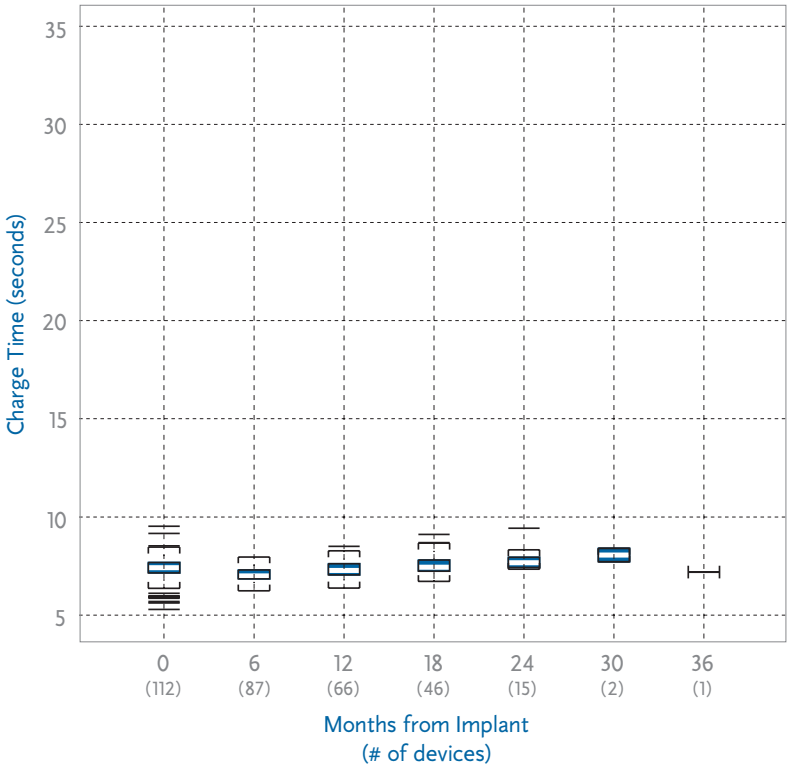
7277 InSync Marquis Charge Time



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.



7289 InSync II Marquis Charge Time

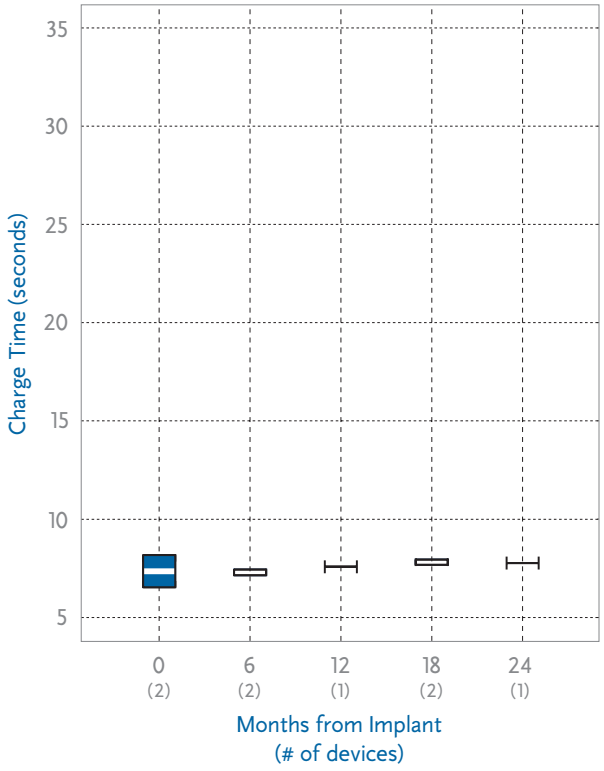


Save-to-Disk files have been collected 36 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.52 seconds observed at implant.

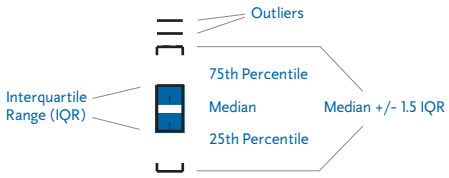
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

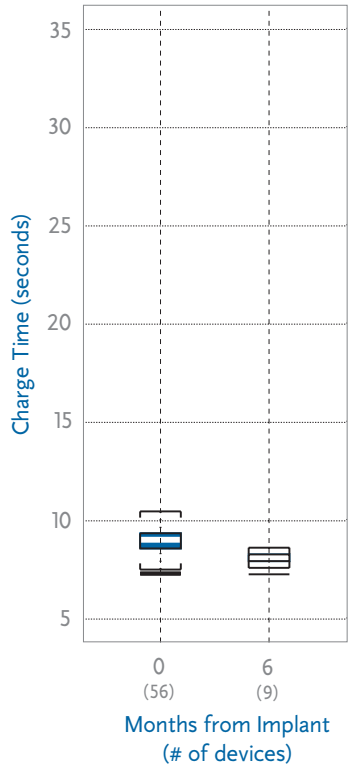
D153ATG, D153DRG EnTrust Charge Time



Save-to-Disk files have been collected 24 months post-implant. All observed charge times are less than 9 seconds with a maximum of 8.2 seconds observed at implant.



D154ATG, D154DRG EnTrust Charge Time

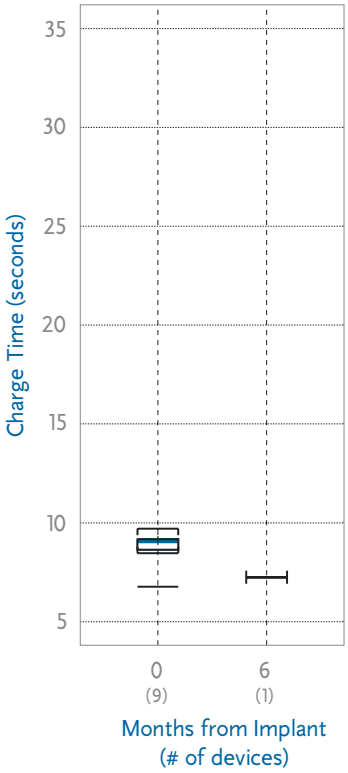


Save-to-Disk files have been collected 6 months post-implant. All observed charge times are less than 11 seconds with a maximum of 10.5 seconds observed at implant.

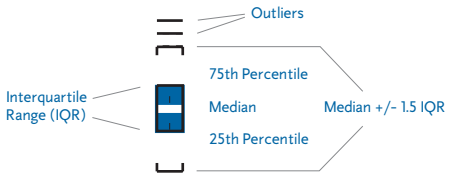
Source: System Longevity Study
Data as of April 1, 2006

ICD Charge Times continued

D154VRC EnTrust Charge Time



Save-to-Disk files have been collected 6 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.7 seconds observed at implant.



Source: System Longevity Study
Data as of April 1, 2006

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 (August 2006)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections. As of August 22, 2006, 43 devices out of approximately 40,000 devices worldwide (0.10% incidence) have been confirmed as having experienced interconnect wire separation while implanted. Twenty-four (24) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Twenty-five (25) of the 43 devices were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 18 devices were returned with no information indicating a potential malfunction while implanted or with insufficient information to determine the state of the device at explant. Lacking definite information indicating proper operation until explant, these devices are conservatively categorized as having experienced interconnect wire separation while implanted.

Implant duration for the 43 devices confirmed as having experienced interconnect wire separation has ranged between 17 and 50 months, with an average of 38 months.

Out of the initial advisory population of 40,000 worldwide, approximately 25,000 remain implanted. Approximately 5,800 of these are in the United States.

The Patient Management Recommendations set forth in the advisory remain unchanged.

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

We recommend you consider the following patient management options:

- Conduct quarterly (i.e., every three months) follow-up procedures.
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care promptly.
- Program Low Battery Voltage ERI Patient Alert to "On-High." This will result in an audible, alternating tone in the limited circumstances where a battery depletes slowly over a number of days. Data indicates most shorts will occur rapidly and will not be detected by this feature.
- Provide a hand-held magnet to patients to check device status and program the Low Battery Voltage ERI Patient Alert to "On-High." Device operation may be monitored periodically (e.g., daily) by patients placing the magnet over the device for 1-2 seconds. If the device is functional, a steady tone will sound for approximately 20 seconds. If no tone is heard, follow-up care should be sought promptly.

Status Update (August 2006)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections. As of August 22, 2006, 38 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. Twenty-six (26) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Of the 38 returns, 16 have been identified by a regularly scheduled follow-up or during a nondevice related hospital visit, 16 by patients reporting warmth in the ICD pocket, 1 by return of bradycardia symptoms, 2 by the PatientAlert sounding, and 3 by hand-held magnet test.

Implant duration for the 38 devices ranged between 11 to 46 months, with an average of 26 months.

Consistent with Medtronic projections, the observed rate of shorting is higher in the second half of device life than in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 59% occurred in the last quarter of device life and 41% in the last 10% of device life.

Out of the initial advisory population of 87,000 worldwide, approximately 53,000 remain implanted. Approximately 36,000 of these are in the United States.

The Patient Management Recommendations set forth in the advisory remain unchanged.

Warranty

All Marquis devices are subject to a Limited Warranty. Devices returned to Medtronic and determined to be malfunctioning will be replaced or credited in accordance with the warranty terms. In addition, for devices subject to the Marquis advisory, should a physician decide to replace a device for a patient who is pacemaker dependent or who receives frequent VT/VF therapy, Medtronic will, upon receipt of a written statement from the physician setting forth the basis for early replacement of the device, provide a replacement device at no cost.

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
  - 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 recommendations remain unchanged. Medtronic estimates that very few, if any, of the devices affected by this advisory remain active and in service.

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 midpoint 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. Very few, if any, of the devices affected by this advisory remain active and in service.

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.

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 recommendations remain unchanged. Medtronic estimates that very few, if any, of the devices affected by this advisory remain active and in service.

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 recommendations remain unchanged. Medtronic estimates that very few, if any, of the devices affected by this advisory remain active and in service.

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 remain 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 recommendations remain unchanged. Medtronic estimates that very few, if any, of the devices affected by this advisory remain active and in service.

7227Cx GEM
7229Cx GEM II VR

Original Date of Advisory: October 15, 1999

Potential Circuit Overload

Product

Model 7227Cx and Model 7229Cx 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 remain 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 remain unchanged. The devices affected by this advisory are beyond the midpoint of their expected battery longevity.

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 recommendations remain unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

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 remain unchanged. Laboratory analysis trends and engineering conclusions remain unchanged. According to System Longevity Study results, lead survival is estimated to be 66.1% at 8 years, 9 months.

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 recommendations remain 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 remain unchanged. Laboratory analysis trends and engineering conclusions remain unchanged. According to System Longevity Study results, lead survival is 50.7% at 10 years, 9 months.

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 remain unchanged. Laboratory analysis trends and engineering conclusions remain unchanged. The System Longevity Study results show 62.3% lead survival at 15 years, 9 months.

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 recommendations remain unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

Performance Notes

Interactions between Cardiac Pacing and Ventricular Arrhythmia Initiation.

Purpose of this Information

This article is intended to provide information for consideration when programming pacemaker operation in ICDs and pacemakers.

Background

Right ventricular pacing has been associated with increased risk of appropriate therapy for ventricular tachycardia (VT) and ventricular fibrillation (VF) in ICD patients.[1] Abrupt changes in ventricular cycle lengths (short-long-short, S-L-S) may precede initiation of VT/VF in some instances. S-L-S sequences may be permitted in all forms of cardiac pacing. The pause lengths depend upon pacing mode and lower rate programming.[2-4] Because pauses may be associated with VT/VF initiation, pause suppression algorithms have been developed in ICDs. Although pause suppression may have utility in specific patients with repolarization abnormalities and pause dependent VT, it has not been shown to reduce arrhythmia incidence in the general ICD population.[5] Conversely, S-L-S sequences may occur with ventricular pacing in a variety of ways, including atrial tracking of premature atrial contractions (PACs) or by terminating pauses with ventricular paced beats.[6] In some patients, the ectopic depolarization pattern of a ventricular paced beat may be pro-arrhythmic, independent of pause timing. These observations have further enforced the desire to reduce unnecessary ventricular pacing.

Clinical Trial Observations

Medtronic-sponsored clinical trials were retrospectively analyzed to further understand pause-mediated (i.e., S-L-S) scenarios prior to VT/VF. S-L-S onset scenarios were observed in a minority of patients in all pacing modes. Pacemaker interactions prior to VT/VF are dependent on patient conditions, as well as the technical aspects of pacing operation (i.e., pacing mode, lower rate and AV interval). Because a very low frequency of ventricular pacing is observed during Managed Ventricular Pacing (MVP)[7-9] or VVI 40[10] pacing modes, the long interval tended to terminate with a ventricular sense. In DDD mode, the long interval tended to be terminated by a ventricular pace. Long intervals of > 1000 ms prior to VT/VF were rare in MVP mode. In these analyses, only an association between cardiac pacing and VT/VF initiation can be observed, causality cannot be established. The ongoing MVP (Managed Ventricular Pacing vs. VVI 40 Pacing) Trial, a 2-year, 1000-patient prospective, randomized trial in ICD patients may offer more insight into the frequency of VT/VF across pacing modes.[11]

Pacemaker Patients

In pacemaker patients, ventricular pacing has been associated with higher incidence of AT/AF and heart failure hospitalization.[12,13] MVP provides atrial rate support while dramatically reducing ventricular pacing in patients with sinus node dysfunction and transient AV block.[9] However, as stated in Medtronic reference manuals, depending upon the patient's intrinsic rhythm and conduction, MVP may allow ventricular cycle variation and occasional pauses of up to twice the lower rate.

DDD pacing with long AV intervals may reduce ventricular pacing and may decrease the potential length of pauses compared to MVP. However, DDD with long AV interval programming does not appear to be as effective as AAI-based pacing modes at reducing ventricular pacing,[13,14] may lead to endless loop tachycardia,[14,15] and does not completely eliminate pauses. Also, in DDD mode, a higher programmed lower rate or activation of rate response can lead to an increase in AV conduction times and a higher percentage of ventricular pacing. The potential benefits of reducing ventricular pacing must be weighed against the potential for longer ventricular pauses. Therefore, careful consideration should be given to pacemaker mode and lower rate programming, particularly in the setting of frequent AV block and repolarization abnormalities due to congenital Long QT, electrolyte imbalances, and some medications which prolong QT.

Conclusion

Pacemaker operation may interact with VT/VF initiation in a variety of ways. The patient's heart failure status, arrhythmia substrate, medications, and the relative importance of maintaining ventricular synchrony vs. ensuring ventricular rate support must be weighed when choosing optimal hardware (ICD vs. pacemaker) and pacemaker programming (pacing mode, lower rate, etc.).

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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 ERI 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 2.2 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 2.6 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.

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.

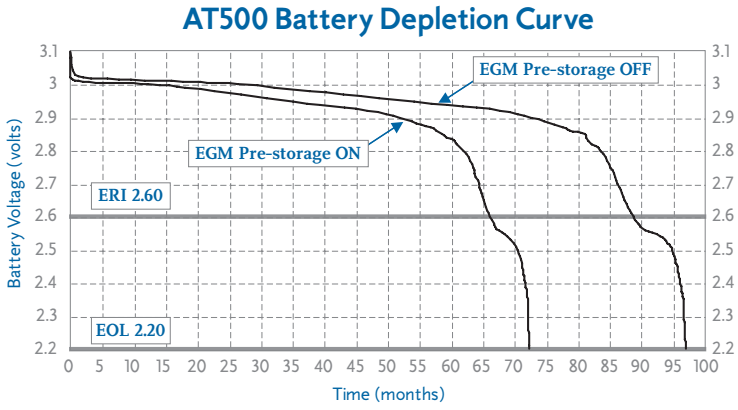


Figure 1

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.

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.

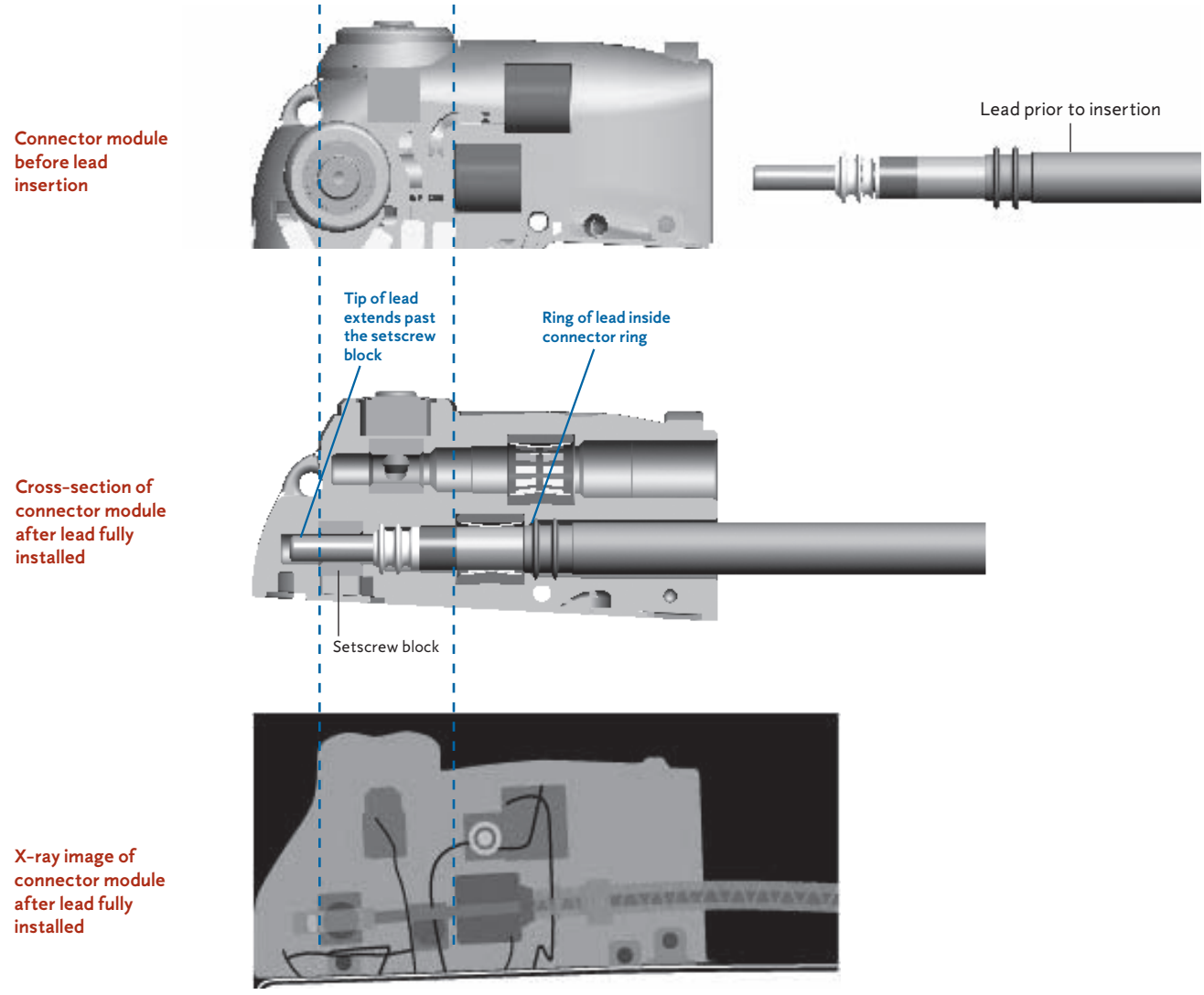
3 Push the lead into the connector port until the lead pin is clearly visible beyond the setscrew block.

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.

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 ERI) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily misinterpreted as the battery rapidly approaches ERI, which occurs at 2.55 volts, when the battery may in fact have several years remaining until ERI.

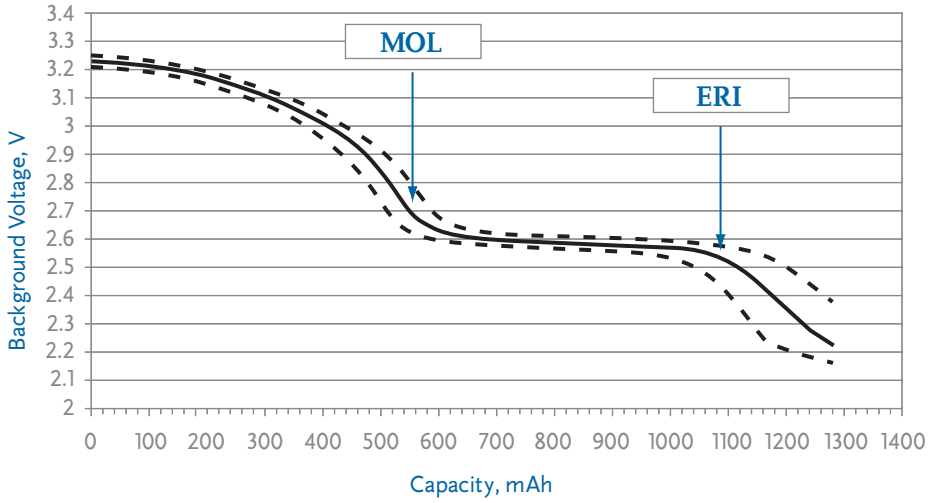
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

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).

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.

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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 setscrew, cross-threaded setscrew, 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

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).

Mailer Kits Available for Returning Product

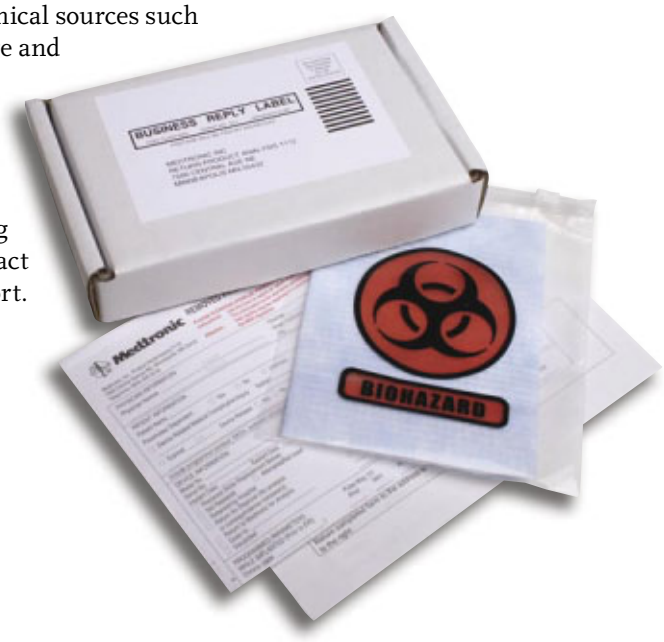
Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of reason for explant or removal from use. The procedures for returning product vary by geographic location.

Mailer kits (pictured right) with prepaid US postage are available for use within the United States to send CRT, ICD, IPG and leads to Medtronic's CRDM Returned Product Analysis Lab. These mailers are sized to accommodate the devices and leads from a single patient or clinical event and are designed to meet postal regulations for mailing biohazard materials.

If the product being returned is located outside the United States, please contact your local Medtronic representative for instructions.

Medtronic also requests the return of devices from non-clinical sources such as funeral homes, and will assume responsibility for storage and disposal of the product once received. For return of larger quantities of explanted products than the mailer can accommodate, Medtronic has handling and shipping guidelines available upon request.

Both mailers and guidelines can be requested by contacting the Returned Product Lab. For information on how to contact the Lab, refer to Contact Information on page 2 of this report.



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