Medtronic

CARDIAC RHYTHM DISEASE MANAGEMENT

Product Performance Report

Important Patient Management Information for Physicians

2007

Second Edition
Issue 57

A Message from the Vice President

Quality is much more than an internal business activity. The support and collaboration we receive from physicians, nurses, and others outside our company plays a significant role in many of our quality initiatives. While serving those in your care, you contribute to our ongoing quality efforts. Through sharing your observations, returning explanted products, conducting independent research, you provide us with invaluable information, direction, and advice. Your involvement enhances and expands our ability to effectively track, evaluate, and communicate the performance of our products.

We also rely on your engagement when awareness or action is needed. In the past few weeks, identified physicians with patients who have a Sprint Fidelis® lead received a letter from me and Medtronic outlining important product performance information. If you have not received this Sprint Fidelis letter and would like this information, please contact your Medtronic Representative or Medtronic Technical Services at 1 (800) 723-4636 (US).

Specific to Sprint Fidelis, we are extremely grateful for the invaluable guidance and consultation we received from our Independent Physician Quality Panel members:

R. Hardwin Mead, MD, Palo Alto, CA
Steven J. Compton, MD, Anchorage, AK
Kevin Hackett, MD, Columbus, OH
Hugh Calkins, MD, Baltimore, MD
John P. DiMarco, MD, PhD, Charlottesville, VA
Mariell Jessup, MD, Philadelphia, PA

We welcome your interest in our Independent Physician Quality Panel. Please direct questions or inquiries regarding this panel to me or David Steinhaus, MD, Vice President and Medical Director, Medtronic Cardiac Rhythm Disease Management.

Our commitment to you is best expressed in Medtronic's mission: "To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service." To this end, we continue to explore new ways to learn from and expand our system longevity studies. We seek to engage and develop new solutions that leverage our patient management systems, like Medtronic CareLink®, to monitor and measure the performance of products remotely.

As we constantly strive to exceed your needs and expectations, we thank you for your valued contributions.

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)
Fax: 1 (800) 824-2362
www.medtronic.com/corporate/contact.jsp

International Technical Centers

Europe (Heerlen NL)	+31-45-566-8844
Japan (Tokyo)	+81-3-5753-4116

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.
8200 Coral Sea Street NE MS MVN61
Mounds View, MN 55112 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 Medtronic 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
Minneapolis, MN 55432-3576 USA

Phone: 1 (800) 328-2518, ext. 44800
email: crdm.returnedproduct@medtronic.com

Editorial Staff

Editor

Reggie Groves, *Vice President, CRDM Quality and Regulatory*

Authors

Timothy Smith, *Senior Principal Product Performance Engineer, CRDM, Trending and Data Analysis*
Sheri Halverson, *Senior Clinical Trial Leader, CRDM*
Hongyan Qiao, *Statistician, CRDM*
Tim Hamann, *Graphic Designer, CRDM*

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CRDM Product Performance Report

2007 Second Edition

Date cutoff for this edition is July 31, 2007

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

WHAT'S NEW

Malfunction detail for newer CRT, ICD, and IPG models has been expanded to provide additional insight into the performance of these products, see page 10

Sprint Fidelis Advisory, see page 159

New Products

Adapta DR Models
ADDRL1
ADDRS1

Virtuoso VR Model
D154VWC/D164VWC

Introduction

All product performance reports are not created equal. For over 20 years, Medtronic 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 representative of worldwide performance.

Survival Estimates

Medtronic Cardiac Rhythm Disease Management (CRDM) uses both returned product analysis and multicenter clinical studies to monitor performance.

Medtronic, like other companies, monitors CRT, ICD, and IPG device performance using returned product analysis. We also monitor CRT, ICD, and IPG device performance using an active multicenter clinical study. Medtronic CRDM is unique in the industry in that we track CRT, ICD, and IPG 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 CRT, ICD, and IPG 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 CRT, ICD, and IPG 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 provides 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 CRT, ICD, and IPG 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.

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 summaries of all advisories applicable to the performance of the products included in the report. An advisory is added to the report when any product affected by the advisory remains in service and at risk of experiencing the behavior described in the advisory. The advisory will remain in the report until Medtronic estimates no product affected by the advisory remains active, or the risk of experiencing the behavior described in the advisory has passed.

For most advisories, the products subject to the advisory retain essentially the same survival probability as the products of the same model(s) not affected by the advisory. For those advisories where the survival probabilities of the affected and non-affected populations do differ significantly Medtronic will provide separate survival data for each population. The separate survival data will remain in the report until Medtronic estimates no affected product remains in active service.

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 explanted product 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 devices 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 or lead ceases to operate within performance limits. The length of time from implant to the event is recorded for each individual device and lead in the *population sample.* The population sample for CRT, ICD, and IPG devices 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 devices 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 CRT, ICD, and IPG Device Performance (page 9)* and *Method for Estimating Lead Performance (page 82).*

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.

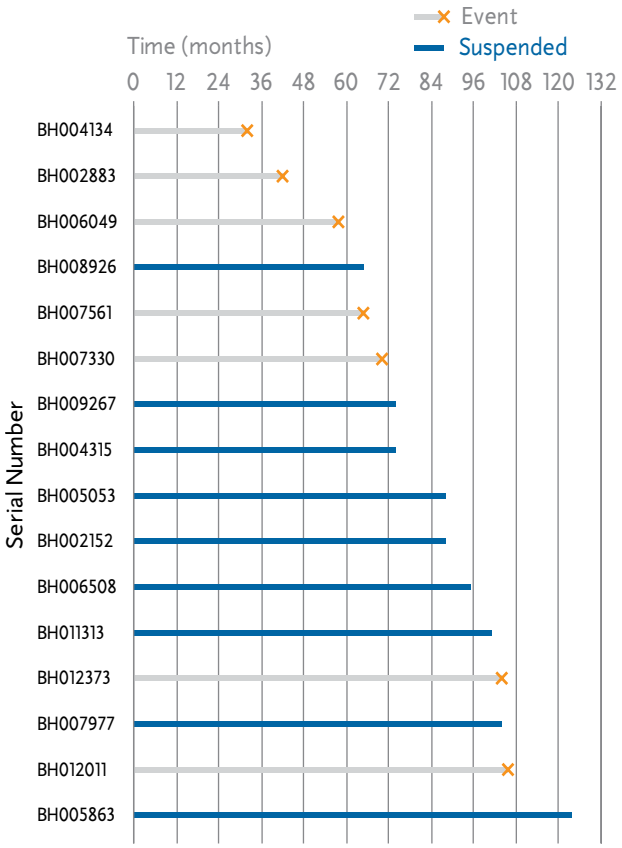


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because 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:

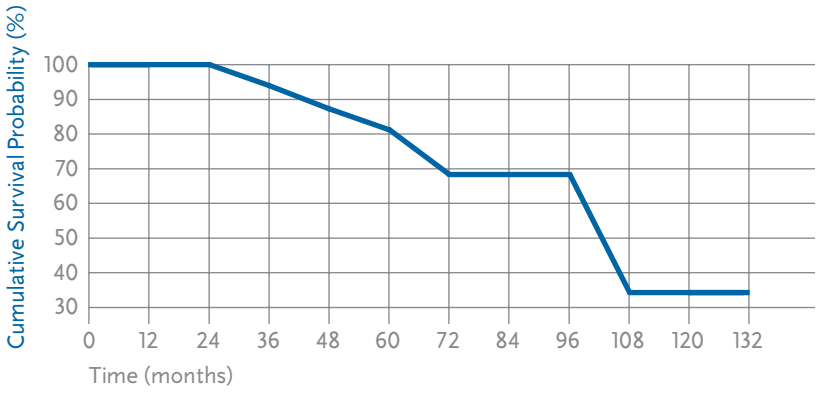
A	B	C	D	E	F	G
Number Entered	**Number Suspended**	**Number of Events**	**Effective Sample Size**	**Proportion with Event**	**Interval Survival Probability**	**Cumulative Survival Probability**
Number of devices active at the start of the interval	Number of devices removed from service for reasons other than an event	Number of units removed from service due to an event	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	Proportion of devices that had an event in the interval. Computed by dividing the Number of Events by the Effective Sample Size	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	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. 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 CRTs, ICDs, and IPGs, 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 CRTs, ICDs, and IPGs 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 CRT, ICD, and IPG devices) 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 CRT, ICD, and IPG Device 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 returned product 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 returned product 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.

New Expanded Malfunction Detail

This edition of the Product Performance Report introduces further detail about the nature of the confirmed malfunctions. As with the categorization of Malfunction with Compromised Therapy Function or Malfunction without Compromised Therapy Function, this new detail is presented for the most recently market-released models.

The malfunctions are further divided into categories that identify the subject area of the malfunction. The malfunctions are divided into the following subject areas:

Electrical Component – findings linked to electrical components such as integrated circuits, resistors, capacitors, diodes, etc.

Electrical Interconnect – findings linked to the connections between electrical components such as wires, solder joints, wire bonds, etc.

Battery – findings linked to the battery and its components

Software/Firmware – findings linked to software or firmware function

Possible Early Battery Depletion – findings where the actual reported implant time is less than 80% of the expected longevity calculated using the available device setting information with no device malfunction observed. There may not be sufficient device setting information to determine conclusively if battery depletion was normal or premature in the absence of a specific root cause finding. However, returned devices meeting the above criteria are conservatively classified as Possible Early Battery Depletion malfunctions.

Other – findings related to other components such as insulators, grommets, setscrews, and packaging, and findings where analysis is inconclusive.

Returned Product 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.

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.

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 a survival curve where events include malfunctions and normal battery depletions. This survival curve 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, a second curve is included to show survival excluding normal battery depletion. This curve 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, ICD, and IPG 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.

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.

continued

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.

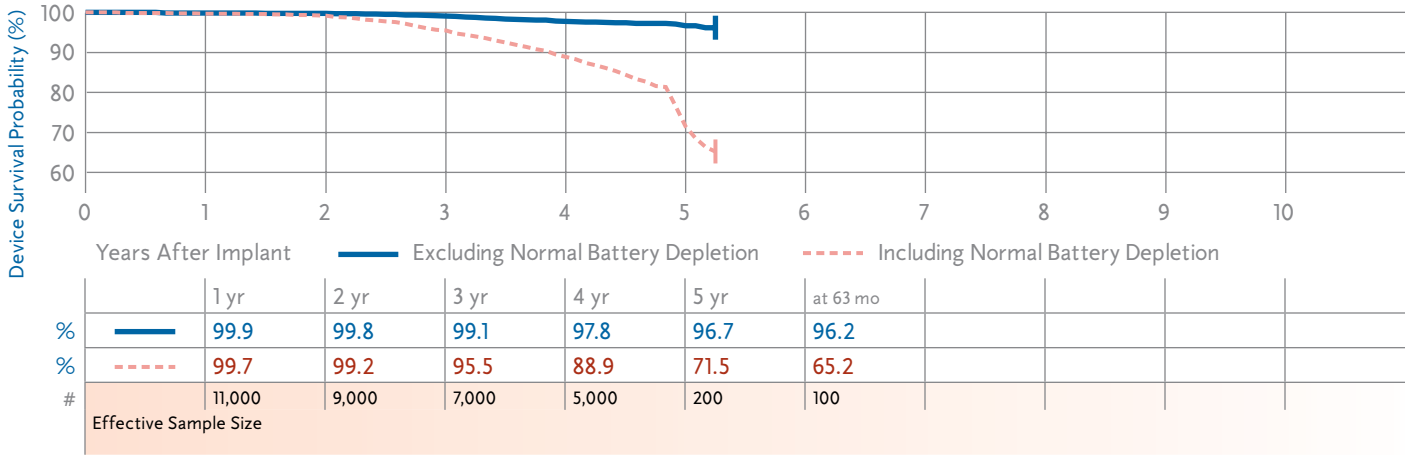
7272 InSync ICD

Product Characteristics

US Market Release	Jul-02
Registered US Implants	13,000
Estimated Active US Implants	4,000
Normal Battery Depletions	365
Advisories	None

Malfunctions	182
Therapy Function Not Compromised	168
Battery	1
Electrical Component	21
Software/Firmware	3
Possible Early Battery Depletion	143
Therapy Function Compromised	14
Battery	1
Electrical Component	13

NBD Code	VVED
Serial Number Prefix	PJP
Max Delivered Energy	34 J
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.9	99.8	99.1	97.8	96.7	96.2
%	99.7	99.2	95.5	88.9	71.5	65.2
#	11,000	9,000	7,000	5,000	200	100

Effective Sample Size

7277 InSync Marquis

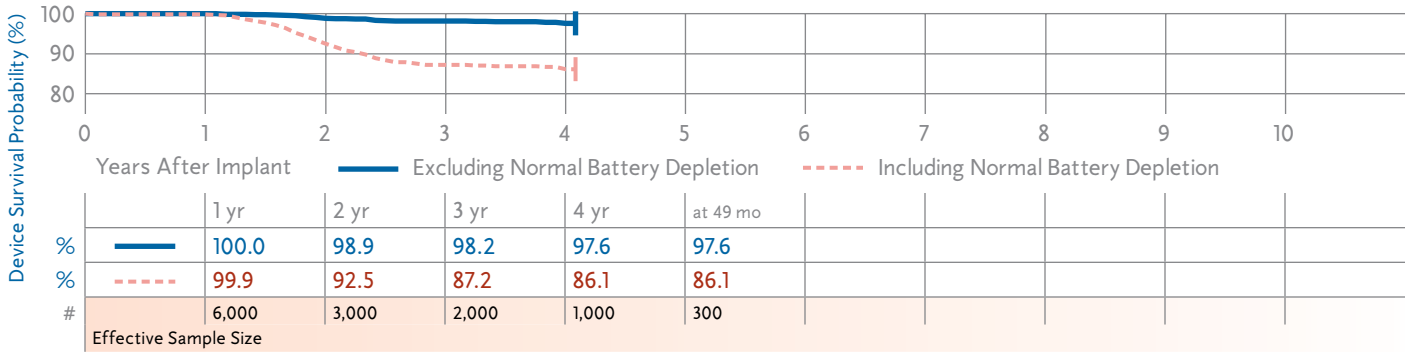
Product Characteristics

US Market Release	Mar-03
Registered US Implants	7,000
Estimated Active US Implants	1,000
Normal Battery Depletions	175

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	72
Therapy Function Not Compromised	62
Battery	1
Electrical Component	8
Software/Firmware	1
Possible Early Battery Depletion	52
Therapy Function Compromised	10
Battery *(9 malfunctions related to advisory)*	9
Electrical Component	1

NBD Code	VVED
Serial Number Prefix	PLT
Max Delivered Energy	30 J
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	4 yr	at 49 mo
%	100.0	98.9	98.2	97.6	97.6
%	99.9	92.5	87.2	86.1	86.1
#	6,000	3,000	2,000	1,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7289 InSync II Marquis

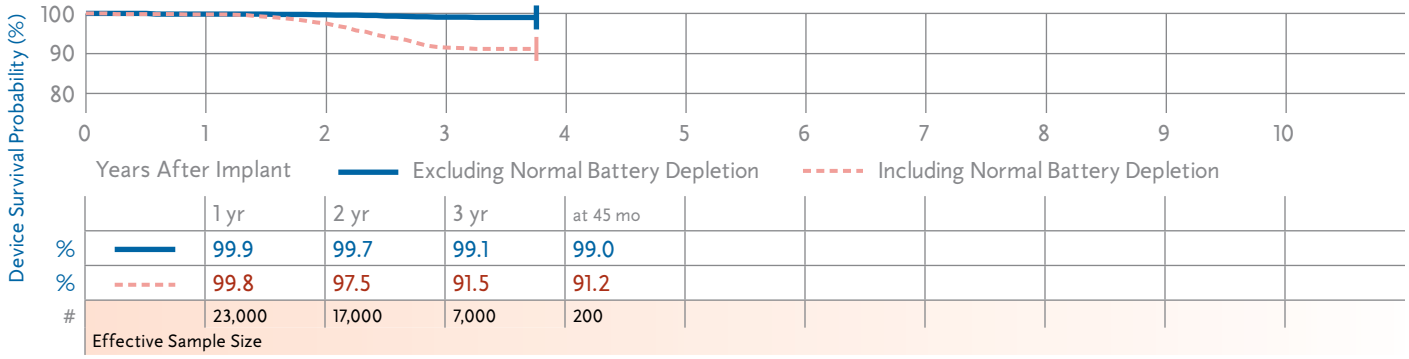
Product Characteristics

US Market Release	Jul-03
Registered US Implants	28,000
Estimated Active US Implants	12,000
Normal Battery Depletions	496

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	137
Therapy Function Not Compromised	109
Electrical Component	13
Software/Firmware	1
Possible Early Battery Depletion	95
Therapy Function Compromised	28
Battery *(8 malfunctions related to advisory)*	9
Electrical Component	19

NBD Code	VVED
Serial Number Prefix	PRJ
Max Delivered Energy	30 J
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	at 45 mo
%	99.9	99.7	99.1	99.0
%	99.8	97.5	91.5	91.2
#	23,000	17,000	7,000	200

Effective Sample Size

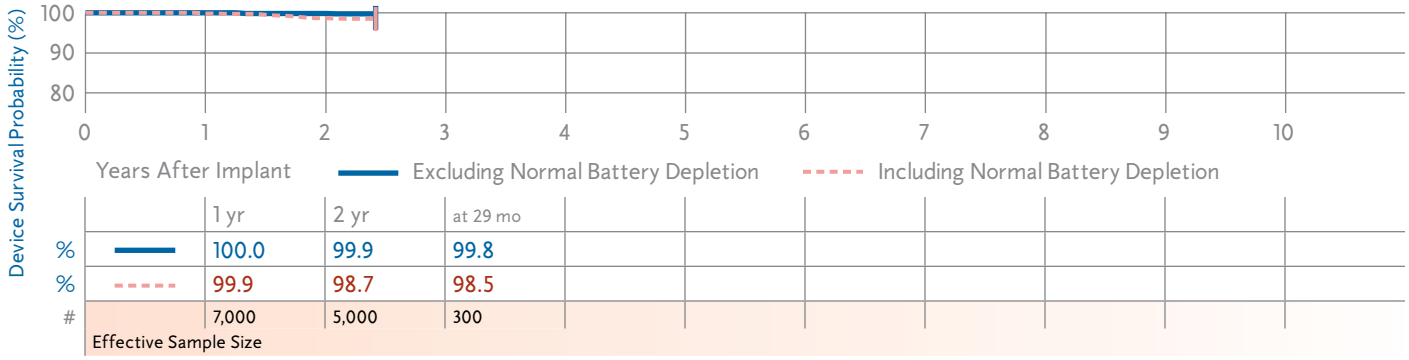
7297 InSync Sentry

Product Characteristics

US Market Release	Nov-04
Registered US Implants	9,000
Estimated Active US Implants	6,000
Normal Battery Depletions	34
Advisories	None

Malfunctions	11
Therapy Function Not Compromised	10
Battery	1
Electrical Component	3
Possible Early Battery Depletion	6
Therapy Function Compromised	1
Electrical Component	1

NBD Code	VVED
Serial Number Prefix	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	1 yr	2 yr	at 29 mo
%	100.0	99.9	99.8
%	99.9	98.7	98.5
#	7,000	5,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

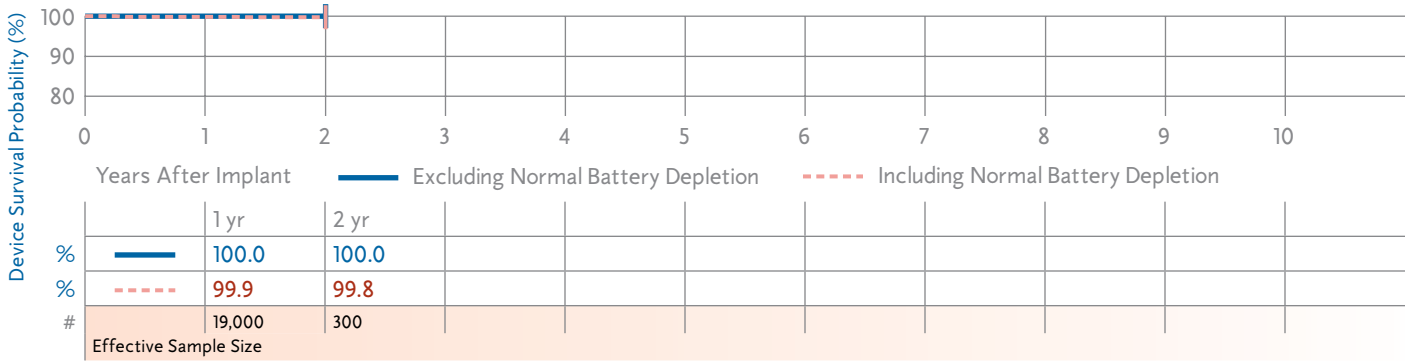
7299 InSync Sentry

Product Characteristics

US Market Release	Apr-05
Registered US Implants	29,000
Estimated Active US Implants	24,000
Normal Battery Depletions	12
Advisories	None

Malfunctions	8
Therapy Function Not Compromised	5
Electrical Component	3
Software/Firmware	2
Therapy Function Compromised	3
Electrical Component	3

NBD Code	VVED
Serial Number Prefix	PRK
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	1 yr	2 yr
%	100.0	100.0
%	99.9	99.8
#	19,000	300

Effective Sample Size

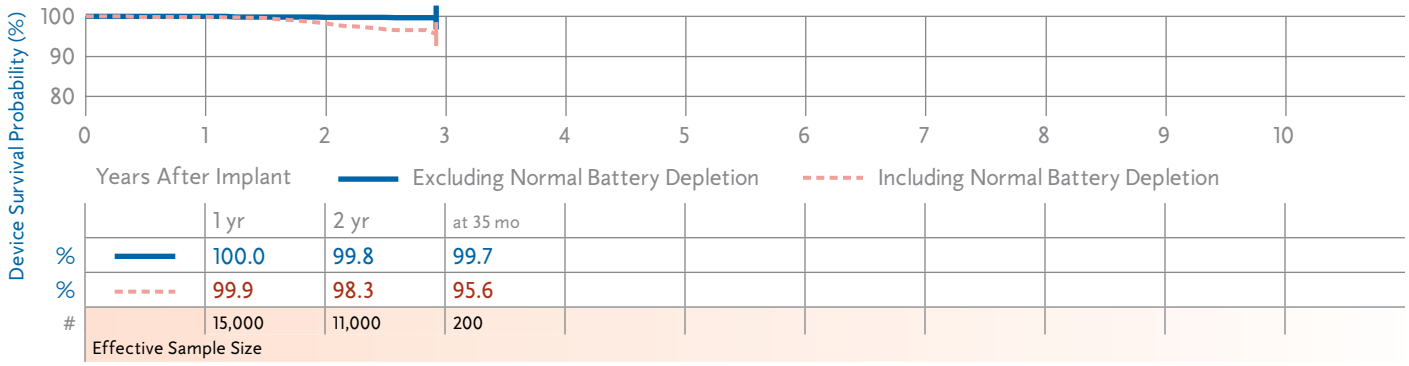
7303 InSync Maximo

Product Characteristics

US Market Release	Jun-04
Registered US Implants	17,000
Estimated Active US Implants	11,000
Normal Battery Depletions	143
Advisories	None

Malfunctions	27
Therapy Function Not Compromised	23
Electrical Component	4
Software/Firmware	1
Possible Early Battery Depletion	18
Therapy Function Compromised	4
Electrical Component	4

NBD Code	VVED
Serial Number Prefix	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	1 yr	2 yr	at 35 mo
%	100.0	99.8	99.7
%	99.9	98.3	95.6
#	15,000	11,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

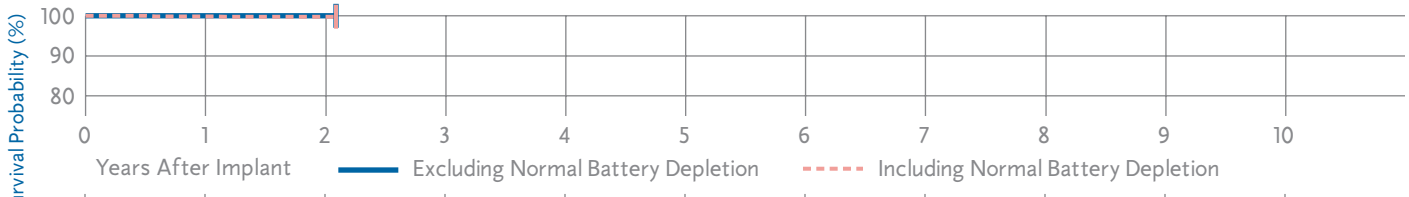
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	16,000
Estimated Active US Implants	13,000
Normal Battery Depletions	7
Advisories	None

Malfunctions	4
Therapy Function Not Compromised	3
Battery	1
Electrical Component	2
Therapy Function Compromised	1
Electrical Component	1

NBD Code	VVED
Serial Number Prefix	PRL
Max Delivered Energy	35 J
Estimated Longevity	See page 20



		1 yr	2 yr	at 25 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0
%	Including Normal Battery Depletion	99.9	99.8	99.8
#	Effective Sample Size	10,000	1,000	100

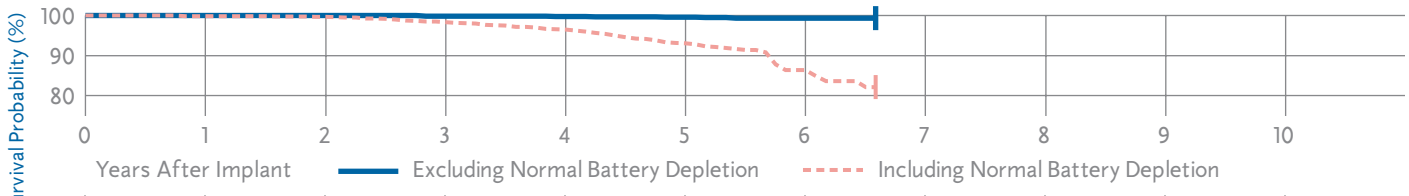
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,000
Estimated Active US Implants	5,000
Normal Battery Depletions	220
Advisories	None

Malfunctions	28
Therapy Function Not Compromised	8
Electrical Component	4
Electrical Interconnect	1
Possible Early Battery Depletion	3
Therapy Function Compromised	20
Electrical Interconnect	20

NBD Code	DDDR
Serial Number Prefix	PIN
Estimated Longevity	See page 20



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 79 mo
%	Excluding Normal Battery Depletion	100.0	100.0	99.9	99.8	99.6	99.4	99.4
%	Including Normal Battery Depletion	99.9	99.7	98.4	96.5	93.1	86.4	82.1
#	Effective Sample Size	12,000	10,000	8,000	6,000	2,000	100	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

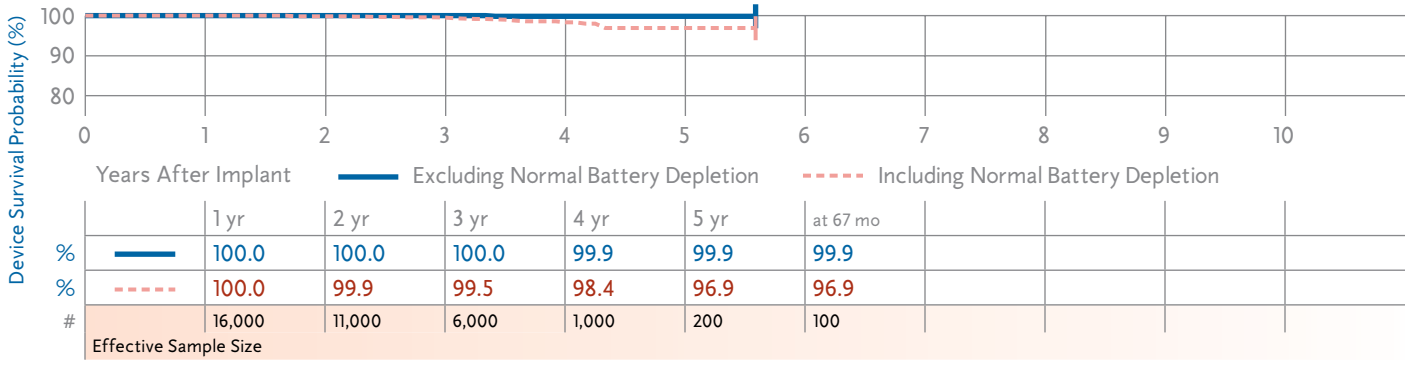
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	23,000
Estimated Active US Implants	14,000
Normal Battery Depletions	43
Advisories	None

Malfunctions	5
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	2
Electrical Interconnect	2

NBD Code	DDDR
Serial Number Prefix	PKF
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	4 yr	5 yr	at 67 mo
%	100.0	100.0	100.0	99.9	99.9	99.9
%	100.0	99.9	99.5	98.4	96.9	96.9
#	16,000	11,000	6,000	1,000	200	100

Effective Sample Size

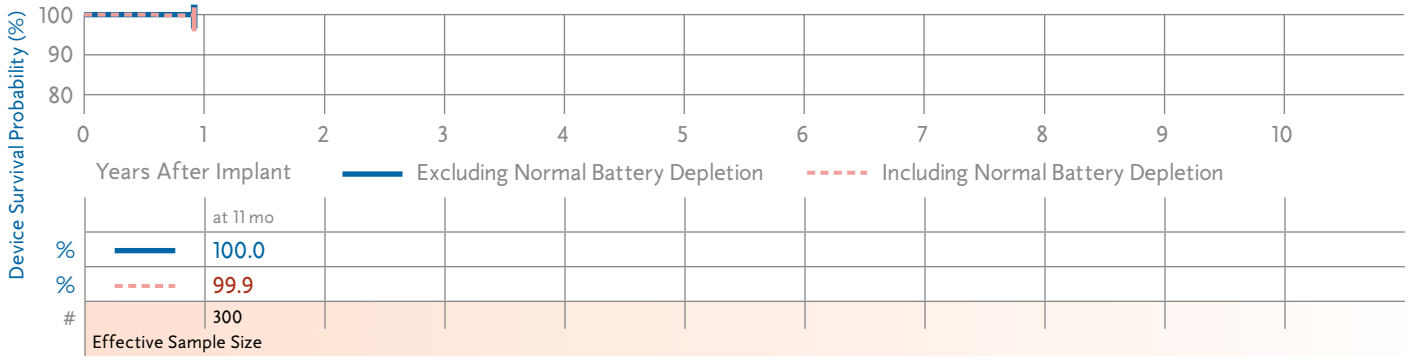
C154DWK, C164AWK, C174AWK Concerto

Product Characteristics

US Market Release	May-06
Registered US Implants	20,000
Estimated Active US Implants	19,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	4
Therapy Function Not Compromised	2
Electrical Component	2
Therapy Function Compromised	2
Electrical Component	2

NBD Code	VVED
Serial Number Prefix	PVU, PVT, PVR
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	at 11 mo
%	100.0
%	99.9
#	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Device Survival Summary (95% Confidence Interval)

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

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
7272	InSync ICD	Jul-02	13,000	4,000	365	14	168	182	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.1 +0.2/-0.2	97.8 +0.3/-0.4	96.7 +0.9/-1.2	96.2 +1.2/-1.6 at 63 mo			
									Including Normal Battery Depletion	99.7 +0.1/-0.1	99.2 +0.2/-0.2	95.5 +0.4/-0.5	88.9 +0.7/-0.8	71.5 +3.4/-3.7	65.2 +4.5/-4.9 at 63 mo			
7277	InSync Marquis	Mar-03	7,000	1,000	175	10	62	72	Excluding Normal Battery Depletion	100.0 +0.0/-0.1	98.9 +0.3/-0.4	98.2 +0.4/-0.5	97.6 +0.6/-0.8	97.6 +0.6/-0.8 at 49 mo				
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9) (advisory-related subset)	(0)	(9)	Including Normal Battery Depletion	99.9 +0.1/-0.1	92.5 +0.7/-0.8	87.2 +1.1/-1.2	86.1 +1.3/-1.4	86.1 +1.3/-1.4 at 49 mo				
7289	InSync II Marquis	Jul-03	28,000	12,000	496	28	109	137	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.1 +0.1/-0.2	99.0 +0.2/-0.2 at 45 mo					
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(8) (advisory-related subset)	(0)	(8)	Including Normal Battery Depletion	99.8 +0.0/-0.1	97.5 +0.2/-0.2	91.5 +0.5/-0.5	91.2 +0.5/-0.5 at 45 mo					
7297	InSync Sentry	Nov-04	9,000	6,000	34	1	10	11	Excluding Normal Battery Depletion	100.0 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.2 at 29 mo						
									Including Normal Battery Depletion	99.9 +0.1/-0.1	98.7 +0.2/-0.3	98.5 +0.3/-0.3 at 29 mo						
7299	InSync Sentry	Apr-05	29,000	24,000	12	3	5	8	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0							
									Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.1							
7303	InSync Maximo	Jun-04	17,000	11,000	143	4	23	27	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.7 +0.1/-0.1 at 35 mo						
									Including Normal Battery Depletion	99.9 +0.0/-0.1	98.3 +0.2/-0.2	95.6 +1.3/-1.8 at 35 mo						
7304	InSync Maximo	Apr-05	16,000	13,000	7	1	3	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 25 mo						
									Including Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 25 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	10 yr
8040	InSync	Aug-01	15,000	5,000	220	20	+	8	=	28	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.4 +0.2/-0.4	99.4 +0.2/-0.4 at 79 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	98.4 +0.2/-0.3	96.5 +0.4/-0.4	93.1 +0.6/-0.7	86.4 +2.9/-3.6	82.1 +4.1/-5.1 at 79 mo		
8042	InSync III	Feb-03	23,000	14,000	43	2	+	3	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 67 mo			
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.5 +0.1/-0.2	98.4 +0.4/-0.5	96.9 +1.3/-2.2	96.9 +1.3/-2.2 at 67 mo			
C154DWK, C164AWK, C174AWK	Concerto	May-06	20,000	19,000	0	2	+	2	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.1 at 11 mo								
											Including Normal Battery Depletion	99.9 +0.1/-0.2 at 11 mo								

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.

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	
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
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	> 16 second charge time	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	> 16 second charge time	3 months after ERI
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	> 16 second charge time	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	> 16 second charge time	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	> 16 second charge time	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	> 16 second charge time	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	> 16 second charge time	3 months after ERI

Family	Model Number	Estimated Longevity			Elective Replacement Time Indicators
		Amplitude Setting	500 Lead Ω	1000 Lead Ω	
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	**

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Recommended Replacement (RRT)***		End of Service (EOS)
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
C154DWK, C164AWK, C174AWK	Concerto	DR+LV true	38 cm 68 g	35 J	Monthly Quarterly Semiannual	3.8 5.5 6.3	4.3 6.8 8.0	4.8 8.0 9.8	5.0 8.8 11.0	≤ 2.62 V	—	3 month after RRT or › 16-second charge time

* 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 (or RRT and EOS) is 3 months (100% pacing, two charges per month).

‡ Pacing mode is DDD for CRT models. Parameter settings: lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510 ohm pace load per applicable channel. CRT models with shared biventricular pacing: InSync Marquis 7277 (LV impedance set to 510 ohms), InSync ICD 7272 (RV amplitude set to 4.0 V).

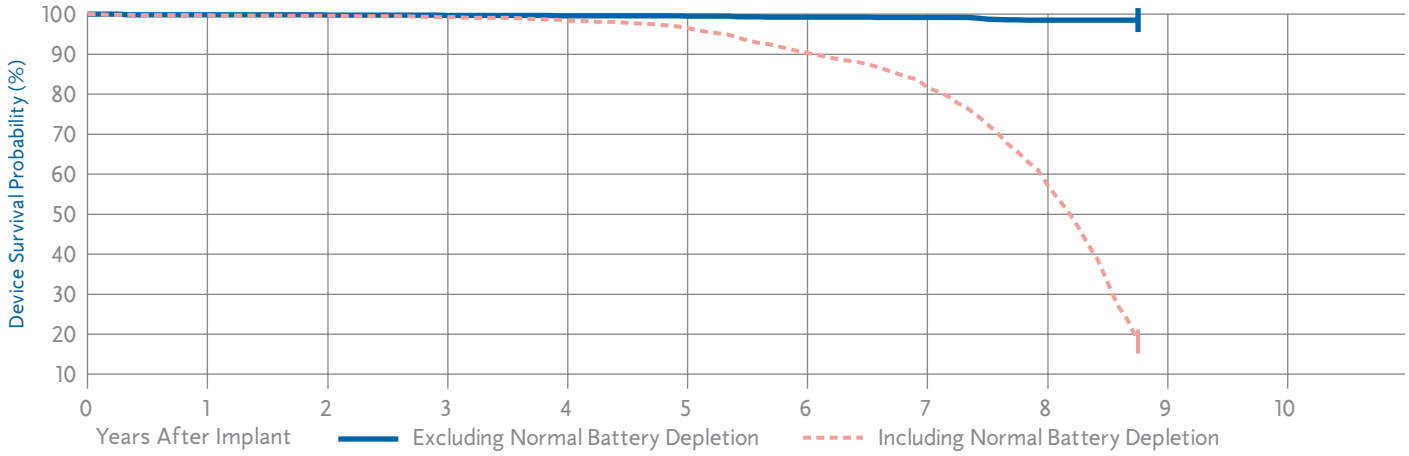
Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7223 Micro Jewel II

US Market Release	Nov-96
Registered US Implants	10,000
Estimated Active US Implants	300
Normal Battery Depletions	941
Advisories	None
Malfunctions	68

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PFR
Max Delivered Energy	30 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.9	99.8	99.7	99.6	99.5	99.3	99.2	98.5	98.5
%	99.8	99.6	99.3	98.4	96.5	90.3	81.7	57.2	18.2
#	9,000	8,000	7,000	6,000	5,000	4,000	3,000	1,000	100

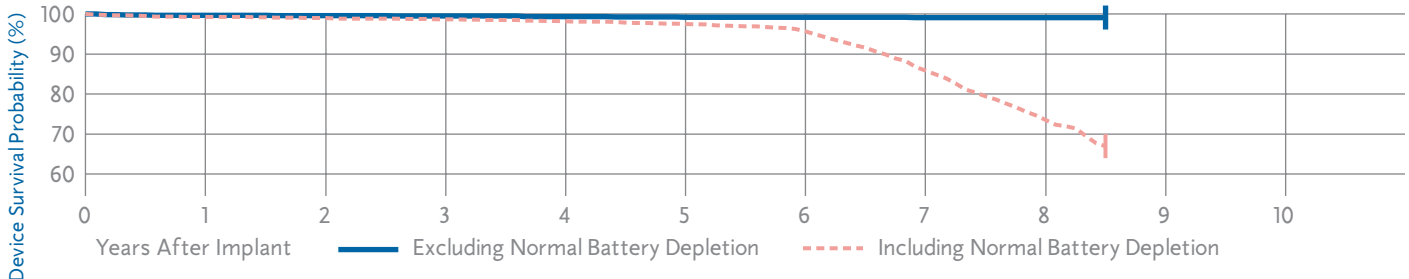
Effective Sample Size

7227 GEM

US Market Release	Oct-98
Registered US Implants	22,000
Estimated Active US Implants	7,000
Normal Battery Depletions	626
Advisories: See page 163 – 1999 Potential Circuit Overload	
Malfunctions	139

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PIP, PLN, PLP, PLR
Max Delivered Energy	35 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.7	99.6	99.5	99.4	99.2	99.2	99.1	99.1	99.1
%	99.3	99.0	98.7	98.2	97.5	95.7	85.9	73.5	67.0
#	20,000	17,000	15,000	13,000	10,000	7,000	4,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7229 GEM II VR

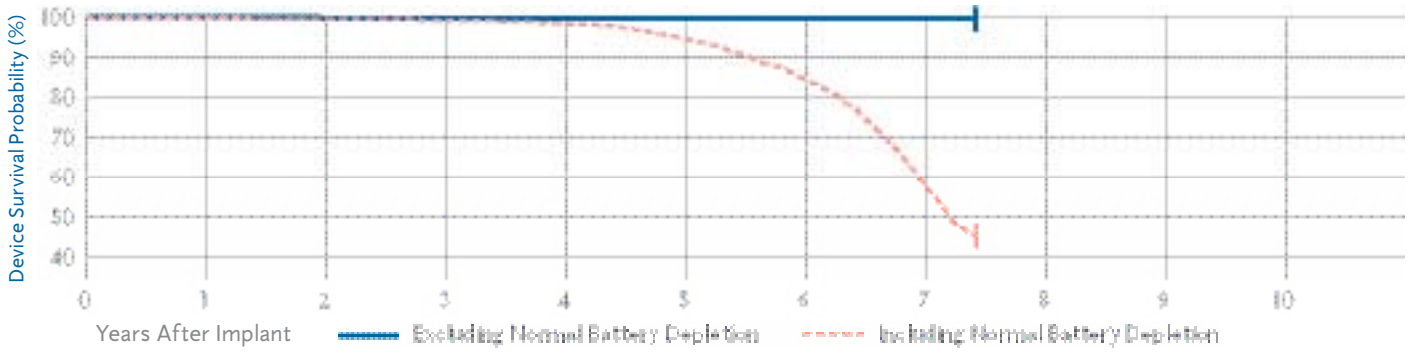
Product Characteristics

US Market Release	Jul-99
Registered US Implants	11,000
Estimated Active US Implants	2,000
Normal Battery Depletions	774

Advisories: See page 163 – 1999 Potential Circuit Overload
also see page 172 – Performance note on ICD Battery Discharge Behavior

Malfunctions	26

NBD Code	VVEV
Serial Number Prefix	PJJ
Max Delivered Energy	30 J
Estimated Longevity	See page 35



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 89 mo
%	Excluding Normal Battery Depletion	99.9	99.8	99.8	99.7	99.7	99.7	99.6	99.6
%	Including Normal Battery Depletion	99.8	99.5	99.3	98.4	94.5	84.3	57.7	45.0
#	Effective Sample Size	9,000	8,000	7,000	6,000	5,000	4,000	1,000	200

7230 Marquis VR

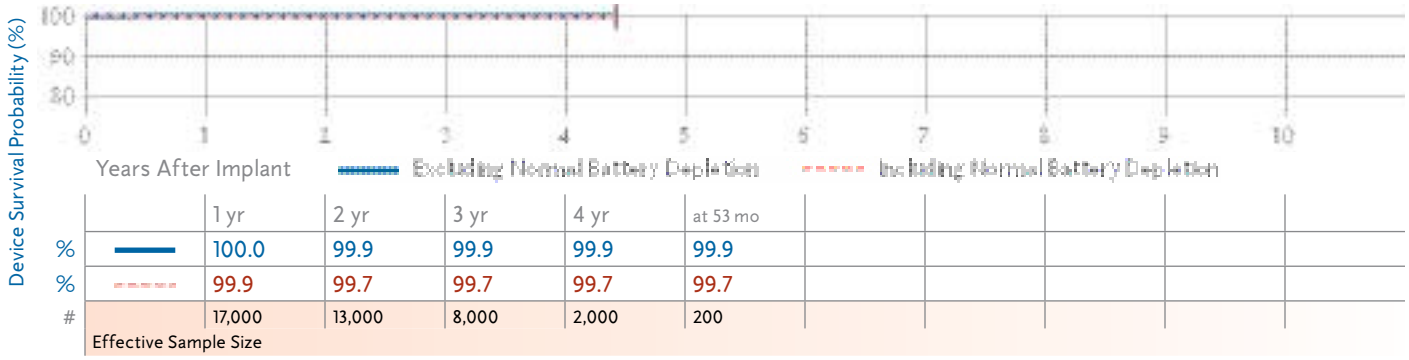
Product Characteristics

US Market Release	Dec-02
Registered US Implants	19,000
Estimated Active US Implants	11,000
Normal Battery Depletions	5

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	20
Therapy Function Not Compromised	14
Electrical Component	10
Possible Early Battery Depletion	3
Other	1
Therapy Function Compromised	6
Battery	1
Electrical Component	5

NBD Code	VVEV
Serial Number Prefix	PKD, PLW, PLY
Max Delivered Energy	30 J
Estimated Longevity	See page 35



		1 yr	2 yr	3 yr	4 yr	at 53 mo
%	Excluding Normal Battery Depletion	100.0	99.9	99.9	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.7	99.7	99.7
#	Effective Sample Size	17,000	13,000	8,000	2,000	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7231 GEM III VR

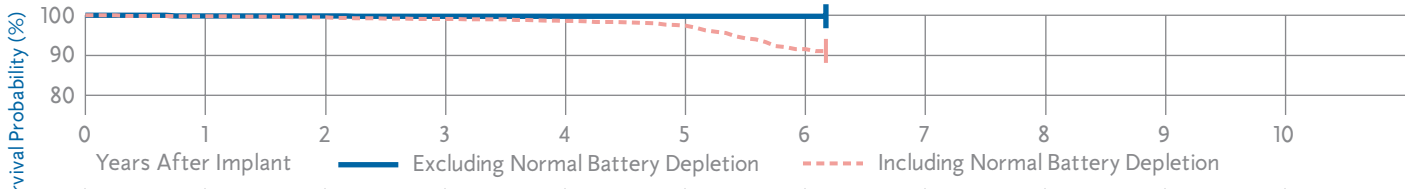
Product Characteristics

US Market Release	Dec-00
Registered US Implants	17,000
Estimated Active US Implants	9,000
Normal Battery Depletions	158

Performance Note: see page 172 – Performance note on ICD Battery Discharge Behavior

Malfunctions	30
Therapy Function Not Compromised	22
Battery	1
Electrical Component	18
Possible Early Battery Depletion	3
Therapy Function Compromised	8
Battery	1
Electrical Component	7

NBD Code	VVEV
Serial Number Prefix	PJL
Max Delivered Energy	30 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	99.9	99.9	99.8	99.8	99.8	99.8	99.8
%	99.8	99.5	99.1	98.6	97.4	91.6	91.1
#	15,000	13,000	11,000	9,000	4,000	1,000	200

Effective Sample Size

7232 Maximo VR

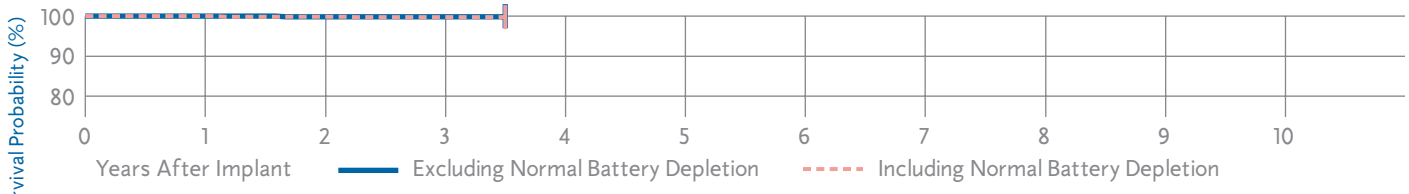
Product Characteristics

US Market Release	Oct-03
Registered US Implants	39,000
Estimated Active US Implants	33,000
Normal Battery Depletions	5

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	15
Therapy Function Not Compromised	9
Electrical Component	5
Possible Early Battery Depletion	4
Therapy Function Compromised	6
Electrical Component	5
Possible Early Battery Depletion	1

NBD Code	VVED
Serial Number Prefix	PRN
Max Delivered Energy	35 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	at 42 mo
%	100.0	99.9	99.9	99.9
%	100.0	99.9	99.8	99.8
#	29,000	13,000	2,000	200

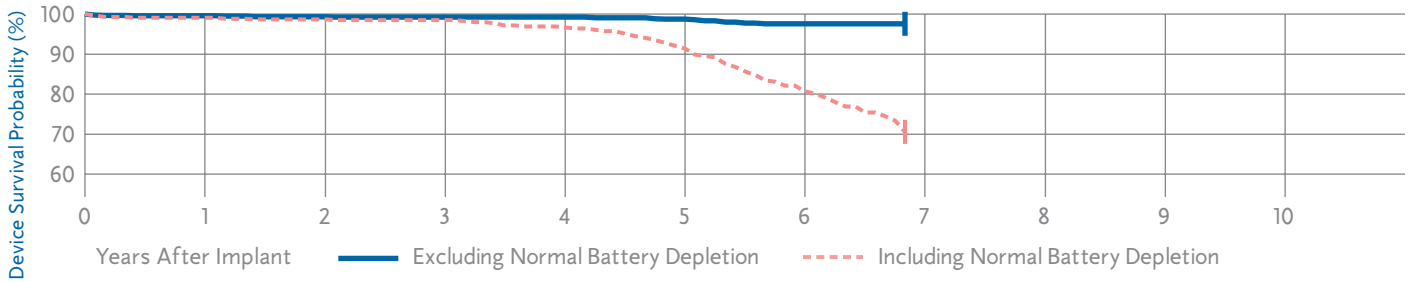
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7250 Jewel AF

Product Characteristics

US Market Release	Jun-00	Malfunctions	18	NBD Code	VVED
Registered US Implants	1,000			Serial Number Prefix	PID
Estimated Active US Implants	200			Max Delivered Energy	27 J
Normal Battery Depletions	78			Estimated Longevity	See page 35
Advisories	None				



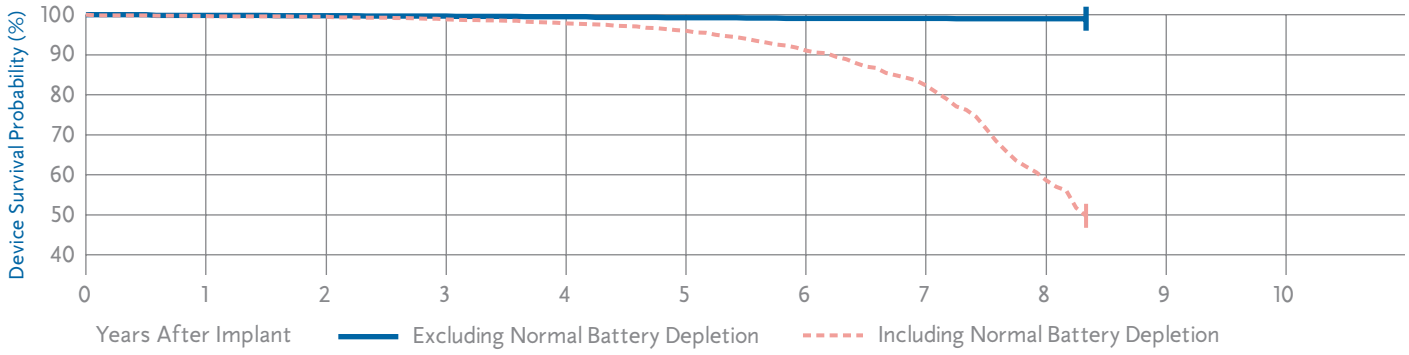
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 82 mo
%	99.6	99.4	99.3	99.3	98.8	97.6	97.6
%	99.1	98.7	98.5	96.7	91.4	80.7	70.6
#	1,000	1,000	1,000	1,000	1,000	300	100

Effective Sample Size

7271 GEM DR

Product Characteristics

US Market Release	Oct-98	Malfunctions	84	NBD Code	VVED
Registered US Implants	15,000			Serial Number Prefix	PIM
Estimated Active US Implants	4,000			Max Delivered Energy	27 J
Normal Battery Depletions	562			Estimated Longevity	See page 35
Advisories	None				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 100 mo
%	99.9	99.8	99.7	99.5	99.3	99.1	99.1	99.0	99.0
%	99.7	99.5	98.9	97.9	96.0	91.1	82.4	58.6	49.7
#	13,000	12,000	10,000	8,000	6,000	4,000	2,000	500	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7273 GEM II DR

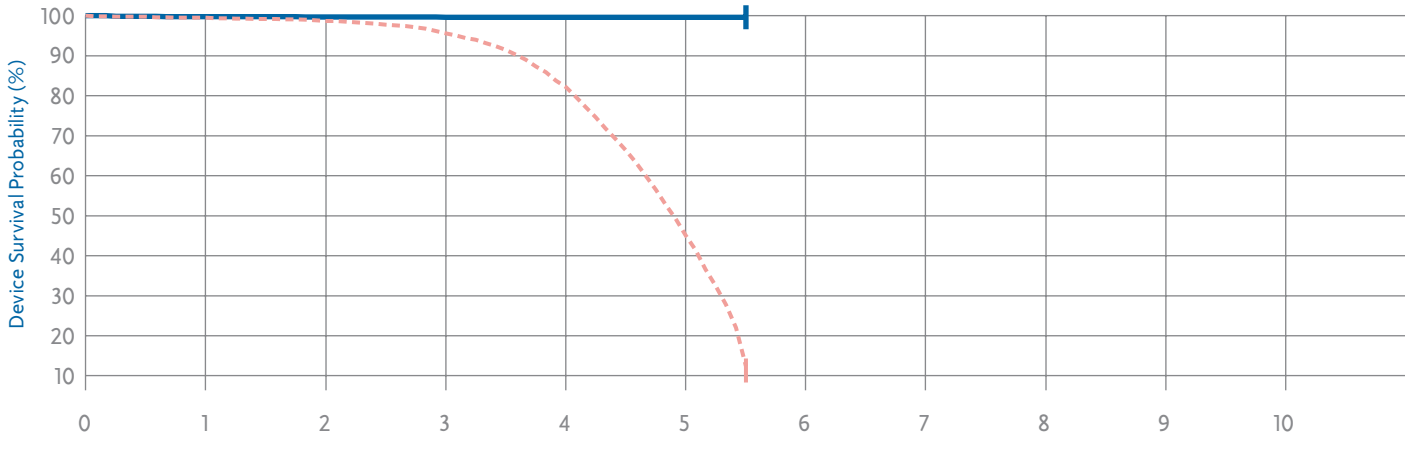
Product Characteristics

US Market Release	Feb-99
Registered US Implants	15,000
Estimated Active US Implants	10
Normal Battery Depletions	2,271

Performance Note: see page 172 – Performance note on ICD Battery Discharge Behavior

Malfunctions	52

NBD Code	VVED
Serial Number Prefix	PJK
Max Delivered Energy	30 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	99.8	99.7	99.6	99.6	99.6	99.6
%	99.5	98.7	95.6	82.2	45.1	12.4
#	13,000	12,000	9,000	6,000	2,000	200

Effective Sample Size

7274 Marquis DR

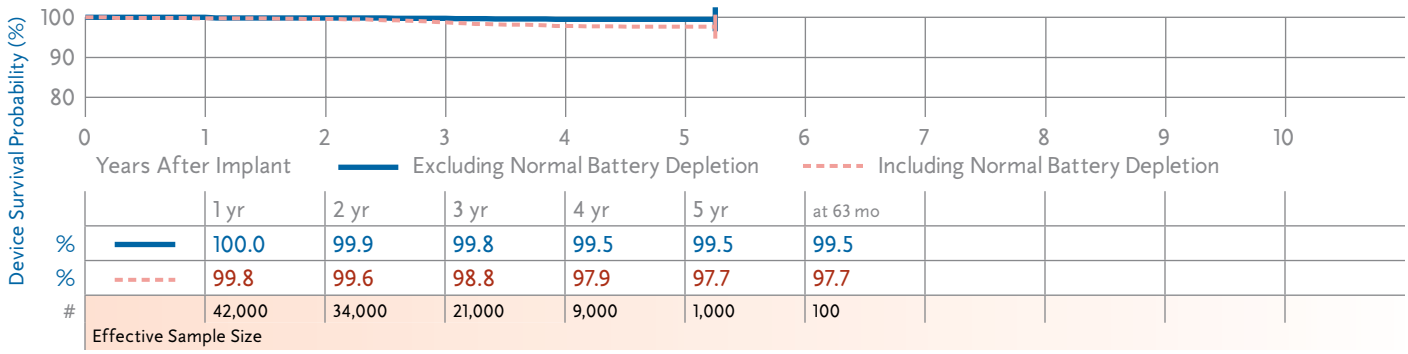
Product Characteristics

US Market Release	Mar-02
Registered US Implants	48,000
Estimated Active US Implants	22,000
Normal Battery Depletions	147

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	113
Therapy Function Not Compromised	50
Battery	4
Electrical Component	22
Possible Early Battery Depletion	24
Therapy Function Compromised	63
Battery *(36 malfunctions related to advisory)*	42
Electrical Component	21

NBD Code	VVED
Serial Number Prefix	PKC
Max Delivered Energy	30 J
Estimated Longevity	See page 35



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	99.9	99.8	99.5	99.5	99.5
%	99.8	99.6	98.8	97.9	97.7	97.7
#	42,000	34,000	21,000	9,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7275 GEM III DR

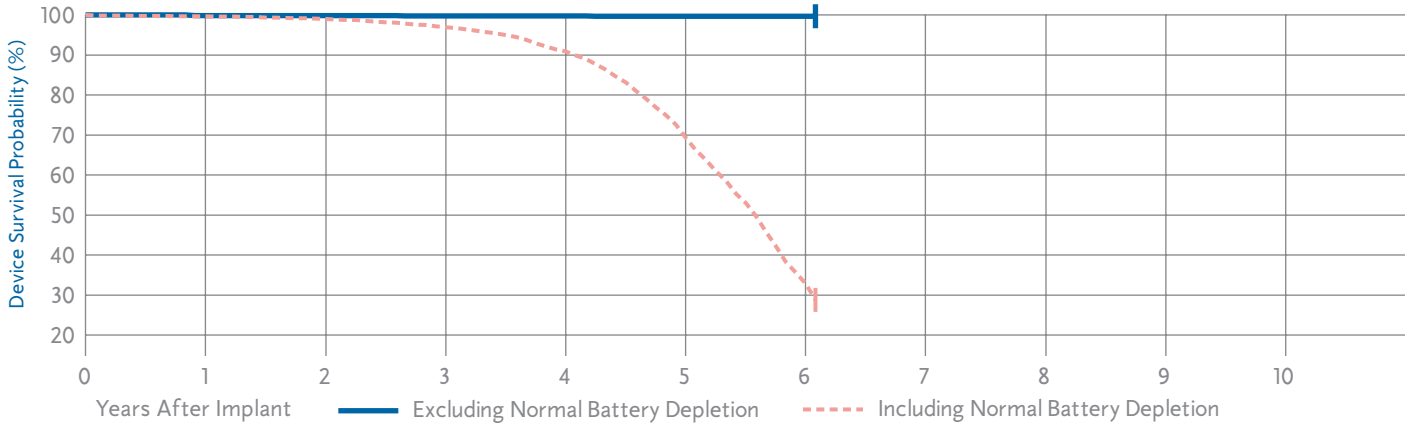
Product Characteristics

US Market Release	Nov-00
Registered US Implants	20,000
Estimated Active US Implants	5,000
Normal Battery Depletions	1,684

Performance Note: see page 172 – Performance note on ICD Battery Discharge Behavior

Malfunctions	38
Therapy Function Not Compromised	27
Battery	1
Electrical Component	11
Software/Firmware	1
Possible Early Battery Depletion	14
Therapy Function Compromised	11
Battery	2
Electrical Component	8
Electrical Interconnect	1

NBD Code	VVED
Serial Number Prefix	PJM
Max Delivered Energy	30 J
Estimated Longevity	See page 35



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 mo
%	———	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	- - - -	99.7	99.0	96.9	90.9	69.4	32.9	28.8
#	Effective Sample Size	17,000	15,000	12,000	8,000	4,000	200	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

7276 GEM III AT

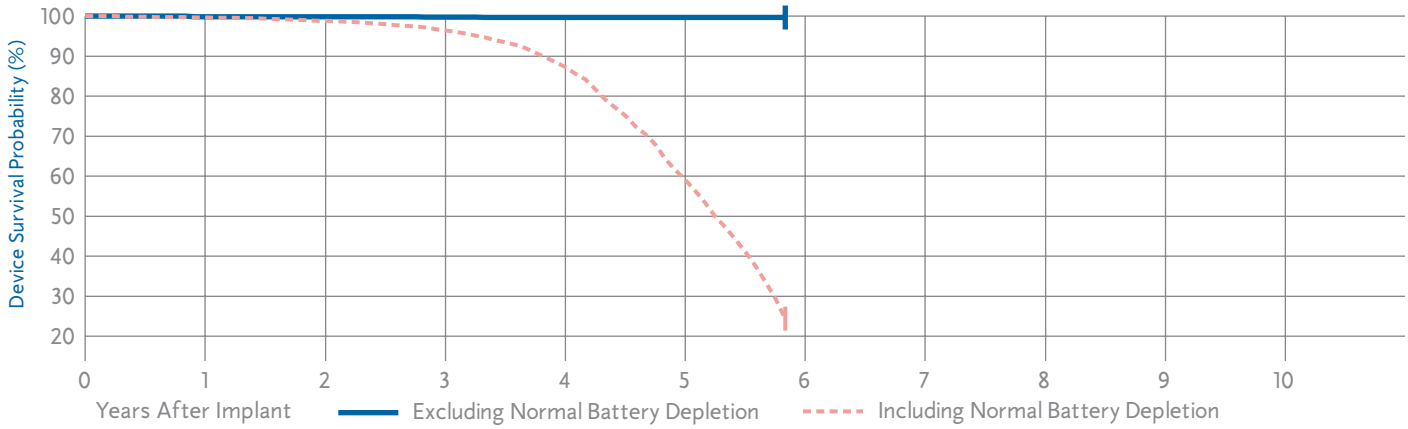
Product Characteristics

US Market Release	Feb-01
Registered US Implants	14,000
Estimated Active US Implants	3,000
Normal Battery Depletions	1,314

Performance Note: see page 172 – Performance note on ICD Battery Discharge Behavior

Malfunctions	31
Therapy Function Not Compromised	24
Electrical Component	6
Software/Firmware	1
Possible Early Battery Depletion	17
Therapy Function Compromised	7
Electrical Component	7

NBD Code	DDED
Serial Number Prefix	PKE
Max Delivered Energy	30 J
Estimated Longevity	See page 35



		1 yr	2 yr	3 yr	4 yr	5 yr	at 70 mo
%	———	99.9	99.9	99.8	99.7	99.7	99.7
%	- - - -	99.7	98.9	96.4	87.3	59.1	24.3
#	Effective Sample Size	12,000	10,000	8,000	5,000	2,000	100

7278 Maximo DR

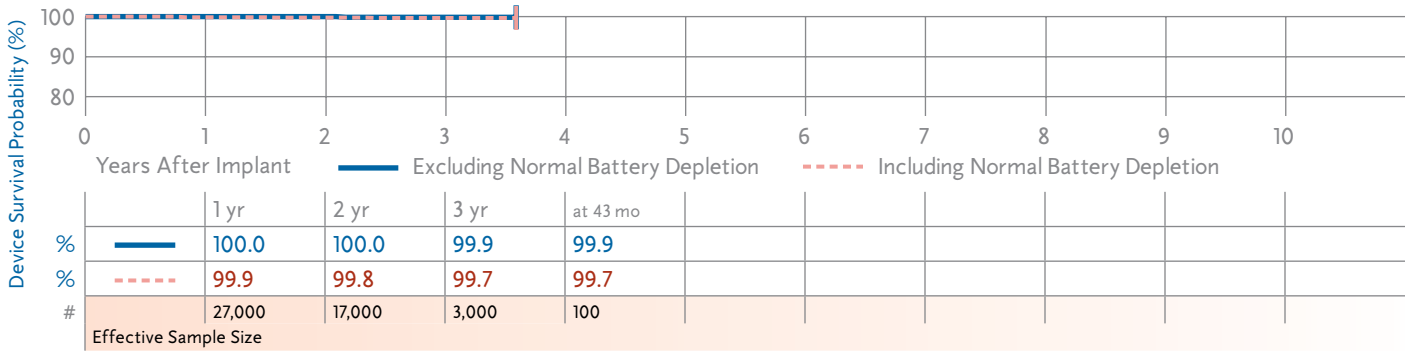
Product Characteristics

US Market Release	Oct-03
Registered US Implants	34,000
Estimated Active US Implants	27,000
Normal Battery Depletions	15

Advisories: See page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions	15
Therapy Function Not Compromised	9
Electrical Component	7
Possible Early Battery Depletion	2
Therapy Function Compromised	6
Electrical Component	5
Possible Early Battery Depletion	1

NBD Code	VVED
Serial Number Prefix	PRM
Max Delivered Energy	35 J
Estimated Longevity	See page 35



		1 yr	2 yr	3 yr	at 43 mo
%	———	100.0	100.0	99.9	99.9
%	- - - -	99.9	99.8	99.7	99.7
#	Effective Sample Size	27,000	17,000	3,000	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

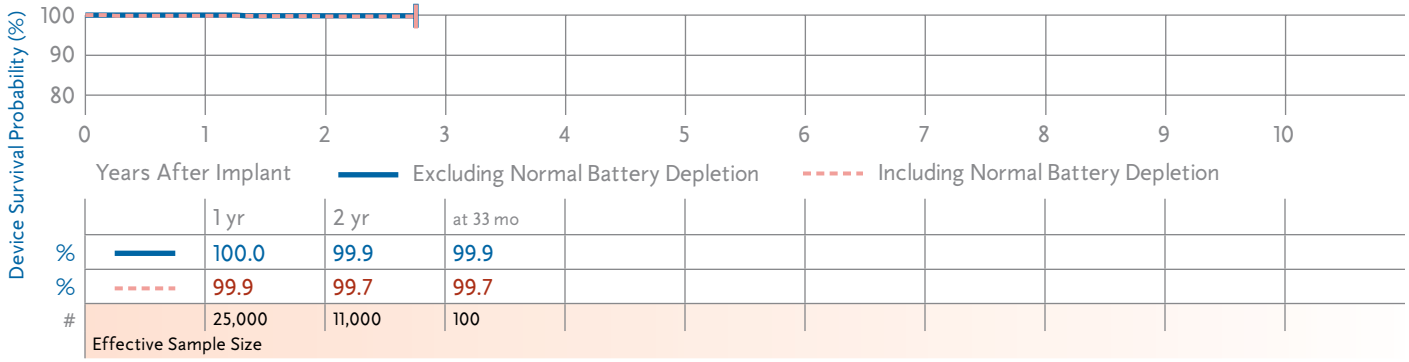
7288 Intrinsic

Product Characteristics

US Market Release	Aug-04
Registered US Implants	30,000
Estimated Active US Implants	25,000
Normal Battery Depletions	8
Advisories	None

Malfunctions	21
Therapy Function Not Compromised	15
Battery	2
Electrical Component	7
Software/Firmware	1
Possible Early Battery Depletion	5
Therapy Function Compromised	6
Electrical Component	6

NBD Code	VVED
Serial Number Prefix	PUB
Max Delivered Energy	35 J
Estimated Longevity	See page 35



		1 yr	2 yr	at 33 mo
%	Excluding Normal Battery Depletion	100.0	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.7	99.7
#	Effective Sample Size	25,000	11,000	100

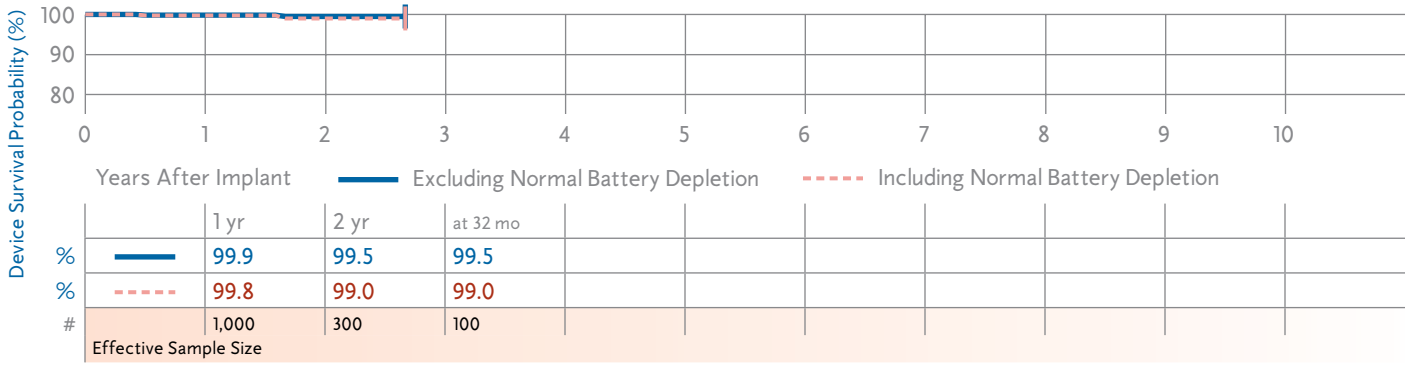
7290 Onyx

Product Characteristics

US Market Release	Mar-04
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	3
Therapy Function Not Compromised	2
Electrical Component	2
Therapy Function Compromised	1
Electrical Component	1

NBD Code	VVEV
Serial Number Prefix	PRP
Max Delivered Energy	30 J
Estimated Longevity	See page 35



		1 yr	2 yr	at 32 mo
%	Excluding Normal Battery Depletion	99.9	99.5	99.5
%	Including Normal Battery Depletion	99.8	99.0	99.0
#	Effective Sample Size	1,000	300	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

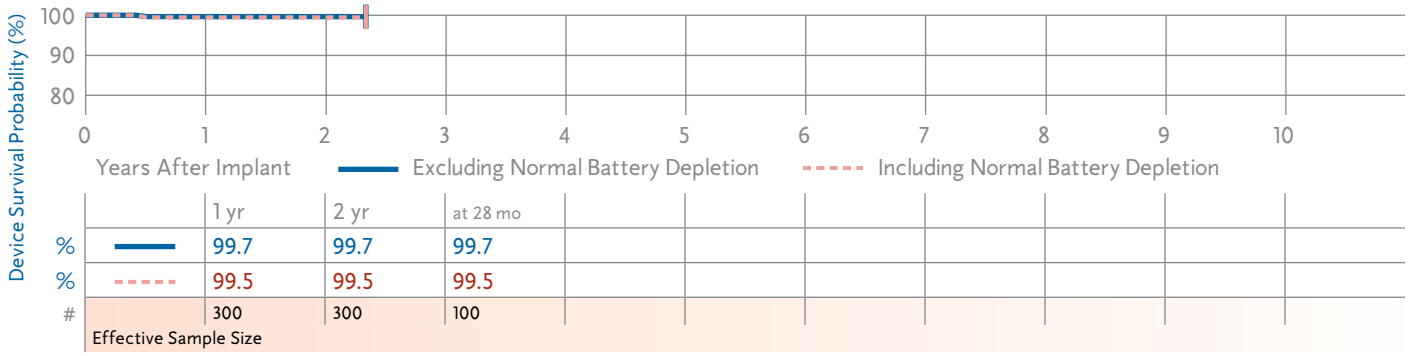
D153ATG, D153DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	400
Estimated Active US Implants	300
Normal Battery Depletions	0
Advisories	None

Malfunctions	2
Therapy Function Not Compromised	1
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Electrical Component	1

NBD Code	DDED, VVED
Serial Number Prefix	PNR
Max Delivered Energy	30 J
Estimated Longevity	See page 36



	1 yr	2 yr	at 28 mo
%	99.7	99.7	99.7
%	99.5	99.5	99.5
#	300	300	100

Effective Sample Size

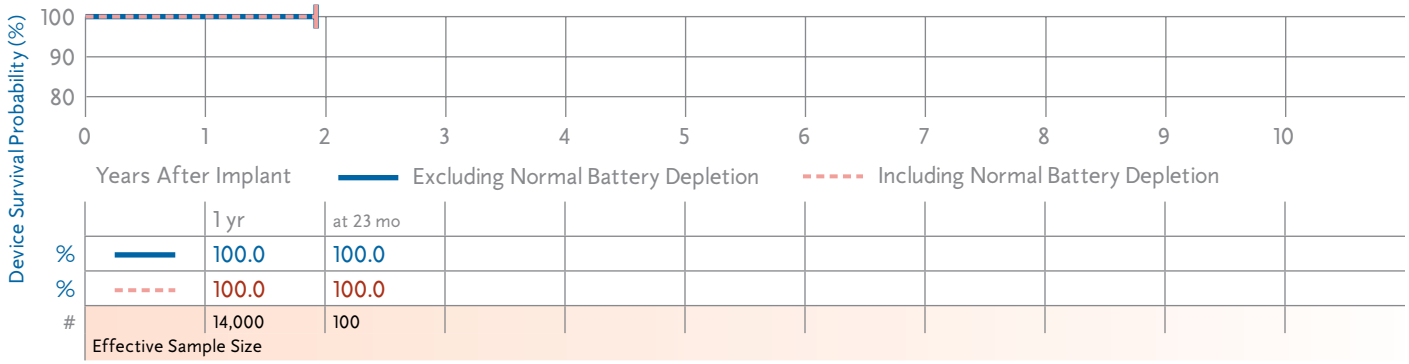
D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	25,000
Estimated Active US Implants	23,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	4
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	3
Electrical Component	3

NBD Code	DDED, VVED
Serial Number Prefix	PNR
Max Delivered Energy	35 J
Estimated Longevity	See page 36



	1 yr	at 23 mo
%	100.0	100.0
%	100.0	100.0
#	14,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

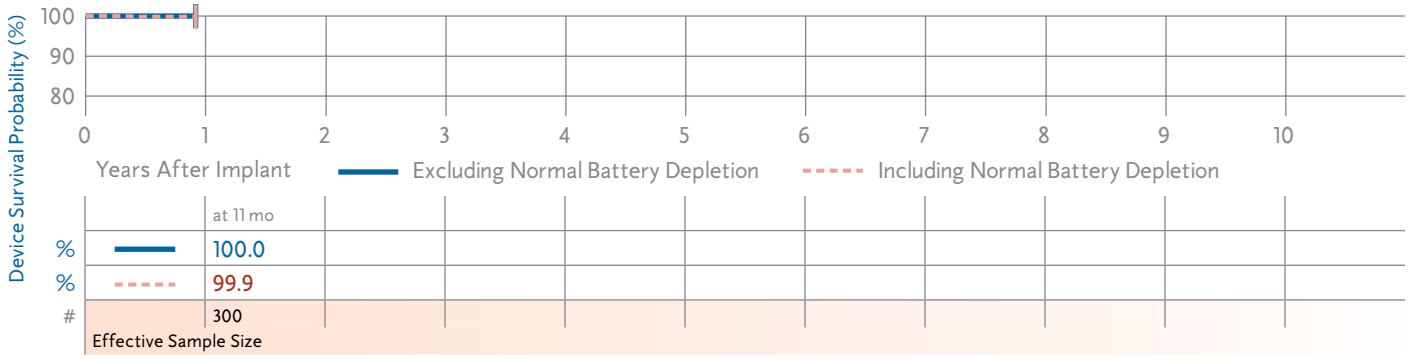
D154AWG, D164AWG Virtuoso

Product Characteristics

US Market Release	May-06
Registered US Implants	19,000
Estimated Active US Implants	18,000
Normal Battery Depletions	1
Advisories	None

Malfunctions	3
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	2
Electrical Component	2

NBD Code	VVED
Serial Number Prefix	PVV, PUL
Max Delivered Energy	35 J
Estimated Longevity	See page 36



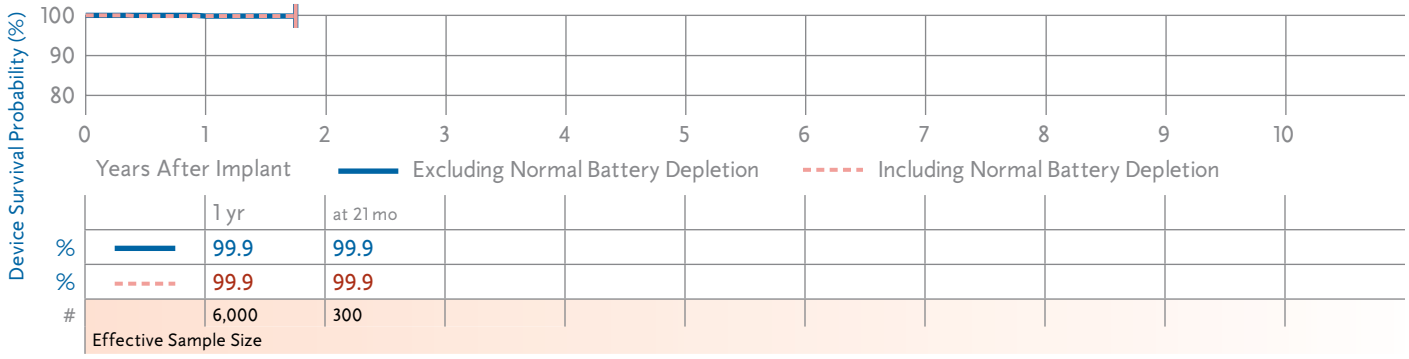
D154VRC EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	13,000
Estimated Active US Implants	12,000
Normal Battery Depletions	1
Advisories	None

Malfunctions	5
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	3
Electrical Component	3

NBD Code	VVEV
Serial Number Prefix	PNT
Max Delivered Energy	35 J
Estimated Longevity	See page 36



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

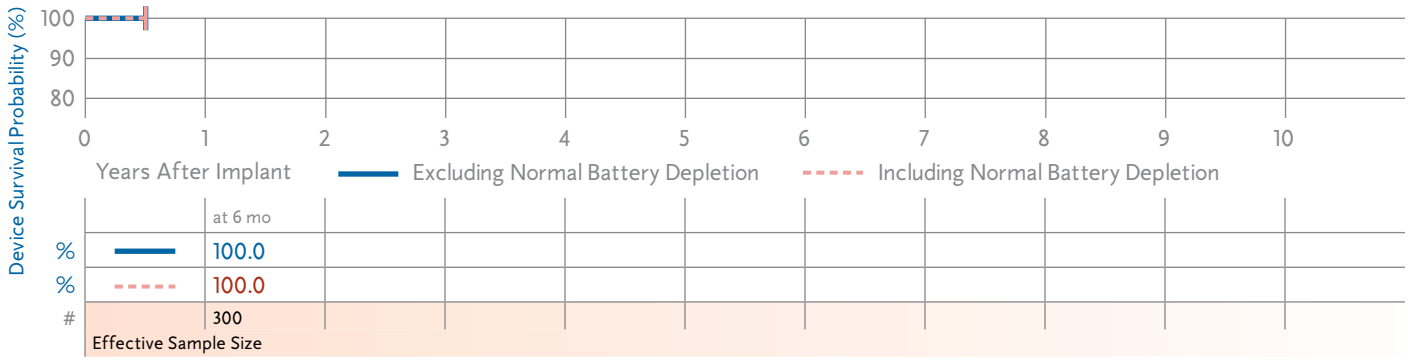
D154VWC, D164VWC Virtuoso

Product Characteristics

US Market Release	May-06
Registered US Implants	6,000
Estimated Active US Implants	6,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	1
Therapy Function Not Compromised	1
Electrical Interconnect	1
Therapy Function Compromised	0

NBD Code	VVEV
Serial Number Prefix	PUN
Max Delivered Energy	35 J
Estimated Longevity	See page 36



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Device Survival Summary (95% Confidence Interval)

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

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	Micro Jewel II	Nov-96	10,000	300	941	—	—	68	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.1/-0.2	99.3 +0.2/-0.3	99.2 +0.2/-0.3	98.5 +0.4/-0.5	98.5 +0.4/-0.5 at 105 mo
									Including Normal Battery Depletion	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.3 +0.2/-0.2	98.4 +0.3/-0.3	96.5 +0.4/-0.5	90.3 +0.8/-0.8	81.7 +1.1/-1.2	57.2 +1.8/-1.9	18.2 +2.5/-2.4 at 105 mo
7227	GEM	Oct-98	22,000	7,000	626	—	—	139	Excluding Normal Battery Depletion	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	99.1 +0.1/-0.2	99.1 +0.2/-0.2	99.1 +0.2/-0.2 at 102 mo
	Advisories: see page 163 – 1999 Potential Circuit Overload					—	—	—	Including Normal Battery Depletion	99.3 +0.1/-0.1	99.0 +0.1/-0.1	98.7 +0.1/-0.2	98.2 +0.2/-0.2	97.5 +0.2/-0.3	95.7 +0.4/-0.4	85.9 +0.8/-0.9	73.5 +1.4/-1.4	67.0 +2.3/-2.4 at 102 mo
7229	GEM II VR	Jul-99	11,000	2,000	774	—	—	26	Excluding Normal Battery Depletion	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	99.6 +0.1/-0.2	99.6 +0.1/-0.2 at 89 mo	
	Advisories: see page 163 – 1999 Potential Circuit Overload; also see page 172 – Performance note on ICD Battery Discharge Behavior					—	—	—	Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.2	99.3 +0.2/-0.2	98.4 +0.3/-0.3	94.5 +0.5/-0.6	84.3 +1.0/-1.0	57.7 +1.9/-2.0	45.0 +2.9/-2.9 at 89 mo	
7230	Marquis VR	Dec-02	19,000	11,000	5	6	14	20	Excluding Normal Battery Depletion	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 53 mo				
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-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 53 mo				
7231	GEM III VR	Dec-00	17,000	9,000	158	8	22	30	Excluding Normal Battery Depletion	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 at 74 mo		
	see page 172 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.1 +0.1/-0.2	98.6 +0.2/-0.2	97.4 +0.3/-0.4	91.6 +1.0/-1.2	91.1 +1.2/-1.4 at 74 mo		
7232	Maximo VR	Oct-03	39,000	33,000	5	6	9	15	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 42 mo					
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1					
7250	Jewel AF	Jun-00	1,000	200	78	—	—	18	Excluding Normal Battery Depletion	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/-1.0	97.6 +1.0/-1.6	97.6 +1.0/-1.6 at 82 mo		
									Including Normal Battery Depletion	99.1 +0.4/-0.7	98.7 +0.5/-0.9	98.5 +0.6/-0.9	96.7 +1.0/-1.4	91.4 +1.9/-2.4	80.7 +3.1/-3.6	70.6 +4.6/-5.2 at 82 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	10 yr
7271	GEM DR	Oct-98	15,000	4,000	562	—	—	84	Excluding Normal Battery Depletion	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 +0.1/-0.2	99.1 +0.2/-0.2	99.1 +0.2/-0.2	99.0 +0.2/-0.3	99.0 +0.2/-0.3 at 100 mo
									Including Normal Battery Depletion	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/-0.4	91.1 +0.7/-0.7	82.4 +1.1/-1.2	58.6 +2.3/-2.4	49.7 +3.7/-3.8 at 100 mo
7273	GEM II DR	Feb-99	15,000	10	2,271	—	—	52	Excluding Normal Battery Depletion	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			
	see page 172 – Performance note on ICD Battery Discharge Behavior					—	—	—	Including Normal Battery Depletion	99.5 +0.1/-0.1	98.7 +0.2/-0.2	95.6 +0.4/-0.4	82.2 +0.8/-0.8	45.1 +1.4/-1.4	12.4 +1.9/-1.8 at 66 mo			
7274	Marquis DR	Mar-02	48,000	22,000	147	63	50	113	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 63 mo			
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(34)	(2)	(36) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.0/-0.0	99.6 +0.1/-0.1	98.8 +0.1/-0.1	97.9 +0.2/-0.2	97.7 +0.2/-0.2	97.7 +0.2/-0.2			
7275	GEM III DR	Nov-00	20,000	5,000	1,684	11	27	38	Excluding Normal Battery Depletion	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	99.7 +0.1/-0.1 at 73 mo		
	see page 172 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.7 +0.1/-0.1	99.0 +0.1/-0.2	96.9 +0.3/-0.3	90.9 +0.5/-0.5	69.4 +1.1/-1.1	32.9 +2.3/-2.2	28.8 +2.7/-2.7 at 73 mo		
7276	GEM III AT	Feb-01	14,000	3,000	1,314	7	24	31	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.2	99.7 +0.1/-0.2	99.7 +0.1/-0.2 at 70 mo			
	see page 172 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.7 +0.1/-0.1	98.9 +0.2/-0.2	96.4 +0.4/-0.4	87.3 +0.7/-0.8	59.1 +1.5/-1.5	24.3 +3.0/-2.9 at 70 mo			
7278	Maximo DR	Oct-03	34,000	27,000	15	6	9	15	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 43 mo					
	Advisories: see page 161 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1					
7288	Intrinsic	Aug-04	30,000	25,000	8	6	15	21	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 33 mo						
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 33 mo						
7290	Onyx	Mar-04	1,000	1,000	0	1	2	3	Excluding Normal Battery Depletion	99.9 +0.1/-0.7	99.5 +0.4/-1.1	99.5 +0.4/-1.1 at 32 mo						
									Including Normal Battery Depletion	99.8 +0.2/-0.7	99.0 +0.6/-1.3	99.0 +0.6/-1.3 at 32 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
D153ATG, D153DRG	EnTrust DR	Jun-05	400	300	0	1	+	1	=	2	Excluding Normal Battery Depletion	99.7 +0.2/-1.6	99.7 +0.2/-1.6	99.7 +0.2/-1.6 at 28 mo					
											Including Normal Battery Depletion	99.5 +0.4/-1.6	99.5 +0.4/-1.6	99.5 +0.4/-1.6 at 28 mo					
D154ATG, D154DRG	EnTrust DR	Jun-05	25,000	23,000	0	3	+	1	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 23 mo						
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.1 at 23 mo						
D154AWG D164AWG	Virtuoso DR	May-06	19,000	18,000	1	2	+	1	=	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.1 at 11 mo							
											Including Normal Battery Depletion	99.9 +0.0/-0.1 at 11 mo							
D154VRC	EnTrust VR	Jun-05	13,000	12,000	1	3	+	2	=	5	Excluding Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 21 mo						
											Including Normal Battery Depletion	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 21 mo						
D154VWC, D164VWC	Virtuoso VR	May-06	6,000	6,000	0	0	+	1	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.1 at 6 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.1 at 6 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.

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	
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	> 16-second charge time	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	> 16-second charge time	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§
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	> 16-second charge time	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
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	> 16-second charge time	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	> 16-second charge time	3 months after ERI
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	> 16-second charge time	3 months after ERI
7290	Onyx	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	> 16-second charge time	≤ 2.40 V

* 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 VVI for single chamber models and DDD for dual chamber and CRT models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510 ohm pace load per applicable channel. CRT models with shared biventricular pacing; InSync Marquis 7277 (LV impedance set to 510 ohms), InSync ICD 7272 (RV amplitude set to 4.0 V).

‡‡ For Model 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.

continued

Reference Chart continued

Model Number	Family	Connector Style	Volume/ Mass*	Delivered Energy	Estimated Longevity					Recommended Replacement (RRT)***		End of Service (EOS)
					Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	
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 RRT or > 16-second charge time
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 RRT or > 16-second charge time
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 RRT or > 16-second charge time
D154AWG, D164AWG	Virtuoso	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.1 6.3 7.3	4.5 7.3 8.7	4.8 8.3 10.1	5.0 8.8 11.0	≤ 2.62 V	—	3 months after RRT or > 19-second charge time
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 RRT or > 16-second charge time
D154VWC, D164VWC	Virtuoso	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.8 8.1 10.0	5.1 9.0 11.2	5.3 9.6 12.3	5.4 10.0 12.9	≤ 2.62 V	—	3 months after RRT or > 19-second charge time

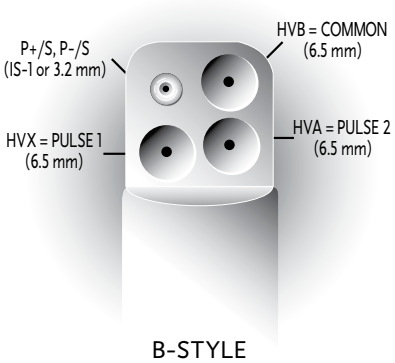
* Volume and mass differ by connector style.

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

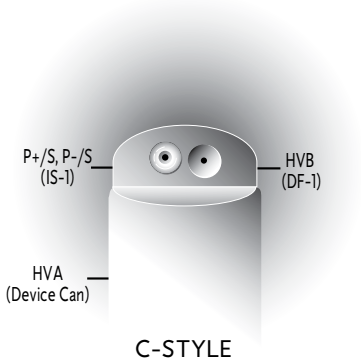
*** The minimum time between RRT and EOS is 3 months (100% pacing, two charges per month).

‡ Pacing mode is VVI for single chamber models and DDD for dual chamber models. Parameter settings; lower rate at 60 ppm, sensing rate at 70 bpm, (A, RV, LV) 3.0 V amplitude, 0.4 ms pulse width, and 510 ohm pace load per applicable channel.

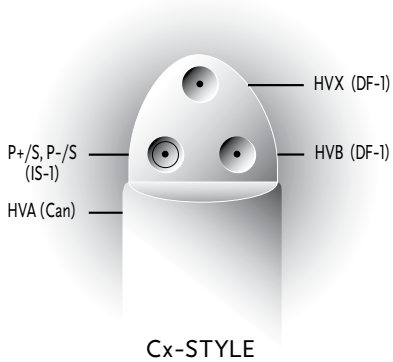
ICD Connector Styles



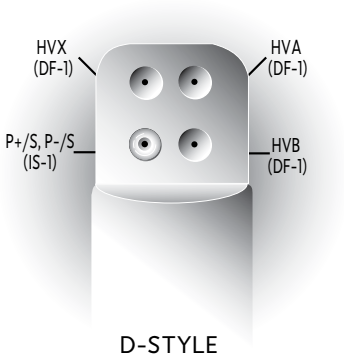
B-STYLE CONNECTOR



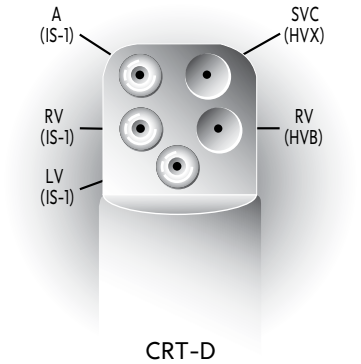
C-STYLE CONNECTOR



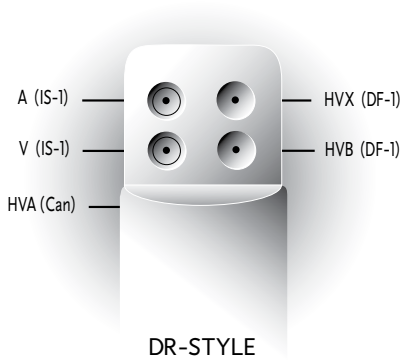
Cx-STYLE CONNECTOR



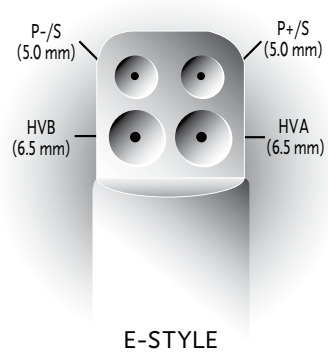
D-STYLE CONNECTOR



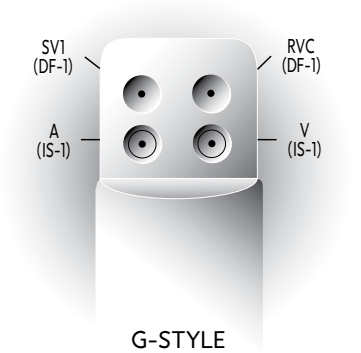
CRT-D CONNECTOR



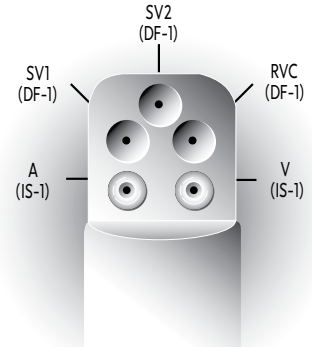
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR



H-STYLE CONNECTOR

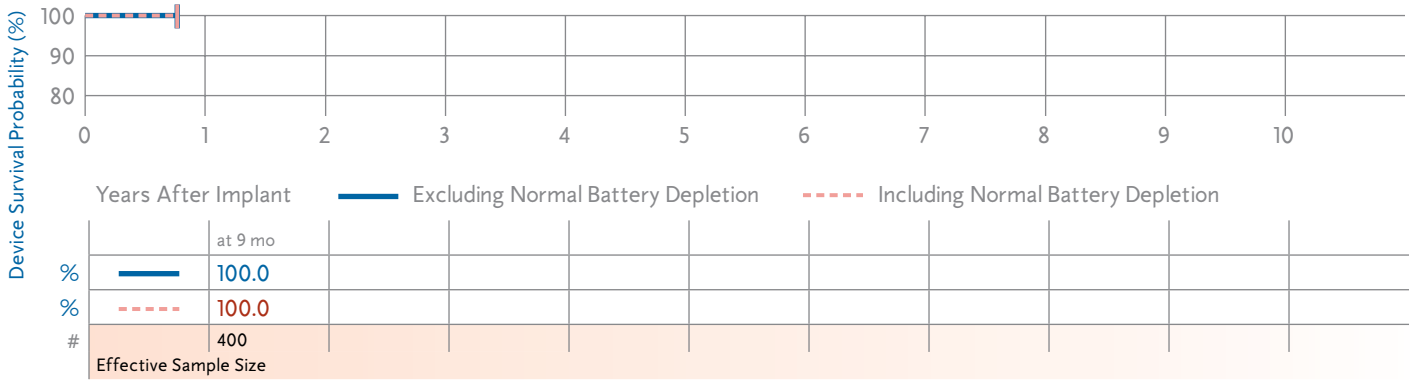
Adapta DR ADDR01, ADDR03, ADDR06, ADD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	30,000
Estimated Active US Implants	29,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBD Code	DDDR, DDD
Serial Number Prefix	PWB, PWD, PWC
Estimated Longevity	See page 78



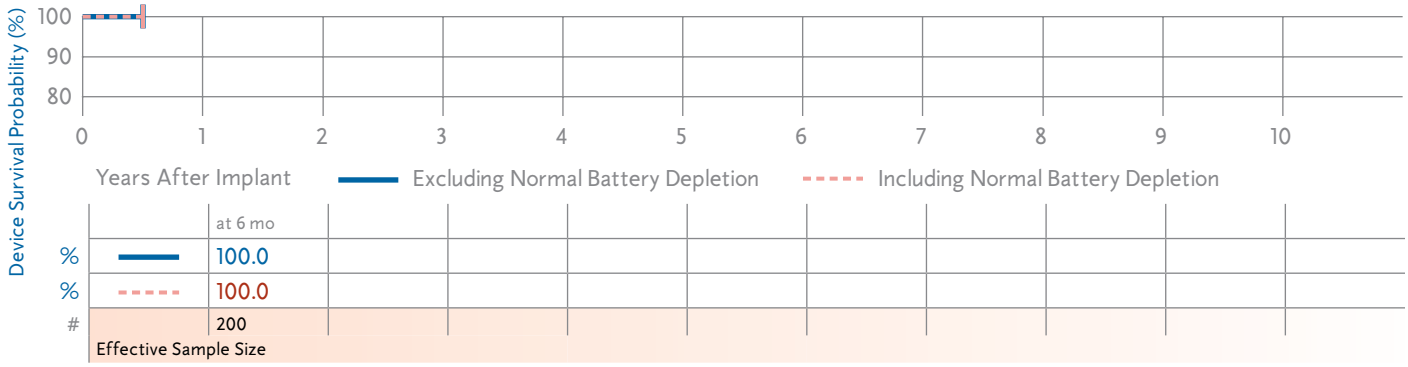
Adapta DR ADDRL1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSIR
Serial Number Prefix	PWM, PWP, PWN
Estimated Longevity	See page 78



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

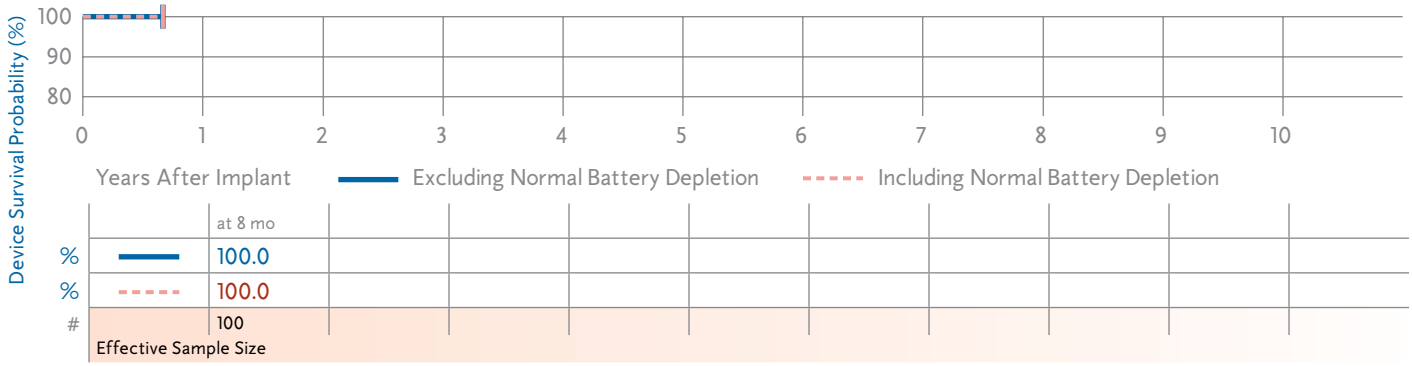
Adapta DR ADDRS1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	3,000
Estimated Active US Implants	2,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSIR
Serial Number Prefix	PWM, PWP, PWN
Estimated Longevity	See page 78



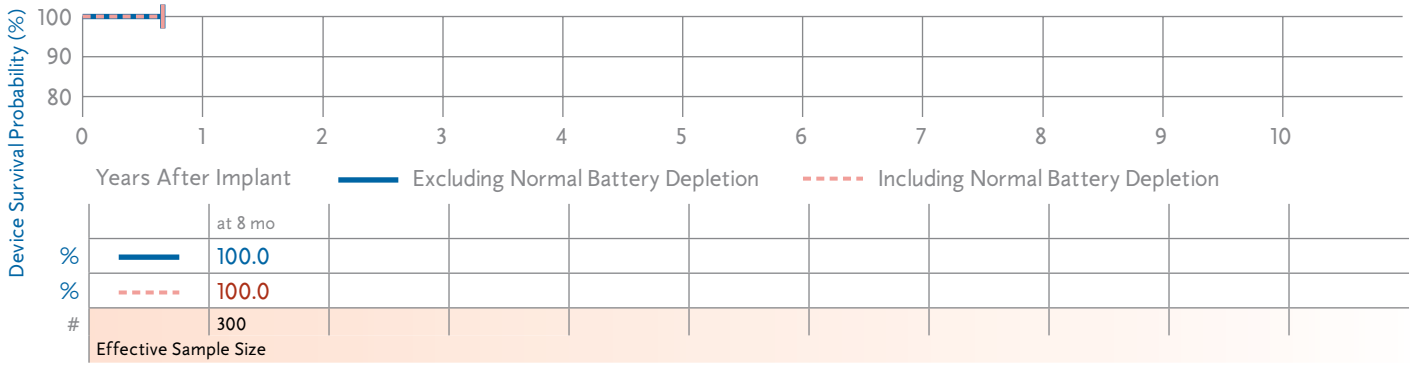
Adapta SR ADSR01, ADSR03, ADSR06

Product Characteristics

US Market Release	Jul-06
Registered US Implants	6,000
Estimated Active US Implants	6,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSIR
Serial Number Prefix	PWM, PWP, PWN
Estimated Longevity	See page 78



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

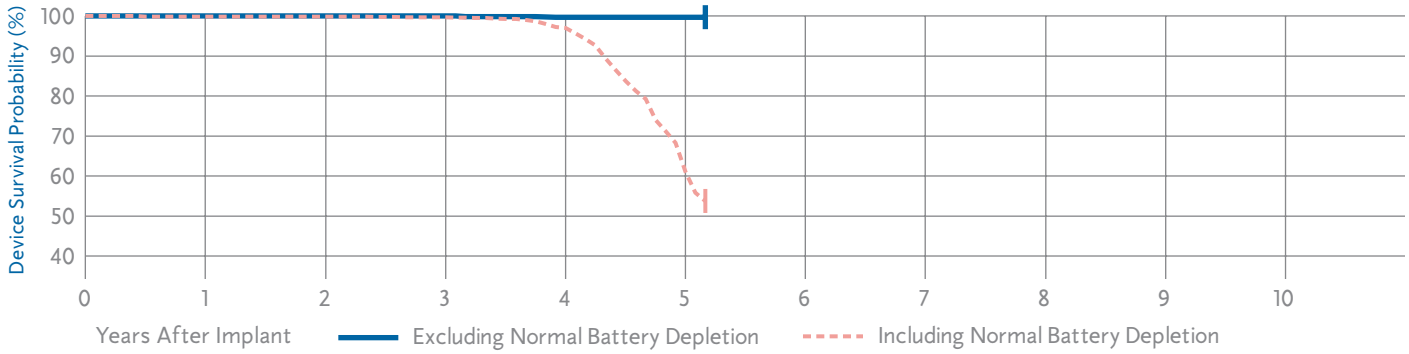
AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03
Registered US Implants	11,000
Estimated Active US Implants	7,000
Normal Battery Depletions	140
Advisories	None

Malfunctions	7
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	4
Electrical Component	3
Electrical Interconnect	1

NBG Code	DDDRP
Serial Number Prefix	IJF
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	100.0	100.0	100.0	99.7	99.7	99.7
%	99.9	99.9	99.7	97.0	61.1	53.7
#	10,000	9,000	5,000	1,000	200	100

Effective Sample Size

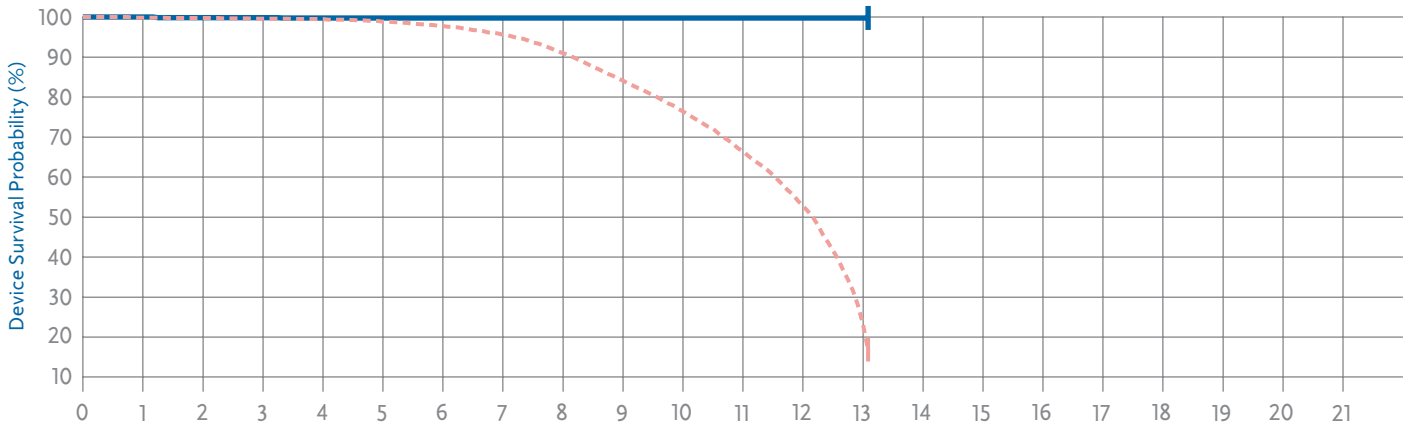
Elite 7074, 7075, 7076, 7077

Product Characteristics

US Market Release	Apr-91
Registered US Implants	48,000
Estimated Active US Implants	400
Normal Battery Depletions	3,572
Advisories	None

Malfunctions	85

NBG Code	DDD/RO
Serial Number Prefix	YE, YF, 2E, 1X
Estimated Longevity	See page 78



	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 157 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	99.8	99.8
%	99.9	99.8	99.6	99.5	98.9	97.8	95.6	91.0	84.1	76.4	66.5	52.8	23.0	16.7
#	43,000	39,000	35,000	31,000	27,000	24,000	20,000	16,000	12,000	9,000	6,000	3,000	300	100

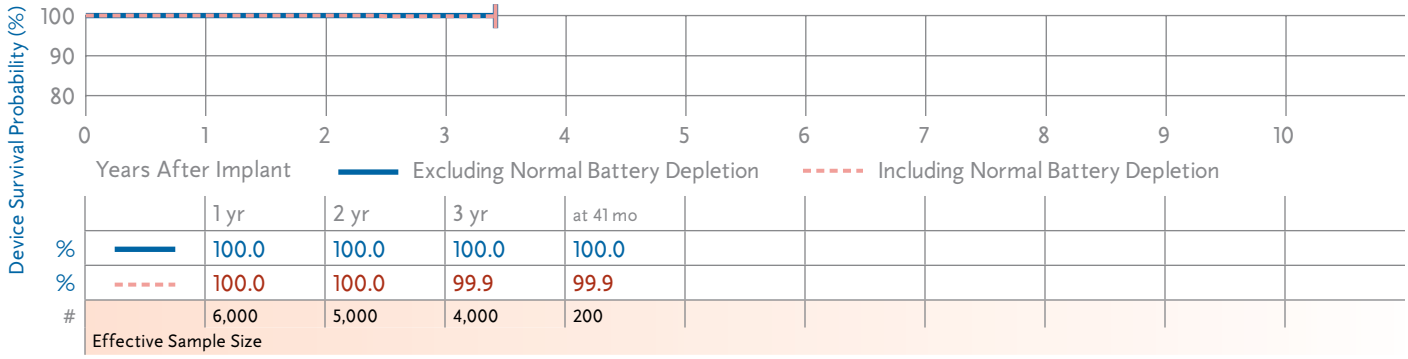
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

EnPulse DR E1DR01, E1DR03, E1DR06

Product Characteristics

US Market Release	Dec-03	Malfunctions	1	NBG Code	DDDR
Registered US Implants	7,000	**Therapy Function Not Compromised**	1	Serial Number Prefix	PRA
Estimated Active US Implants	5,000	Electrical Component	1	Estimated Longevity	See page 78
Normal Battery Depletions	2	**Therapy Function Compromised**	0		
Advisories	None				



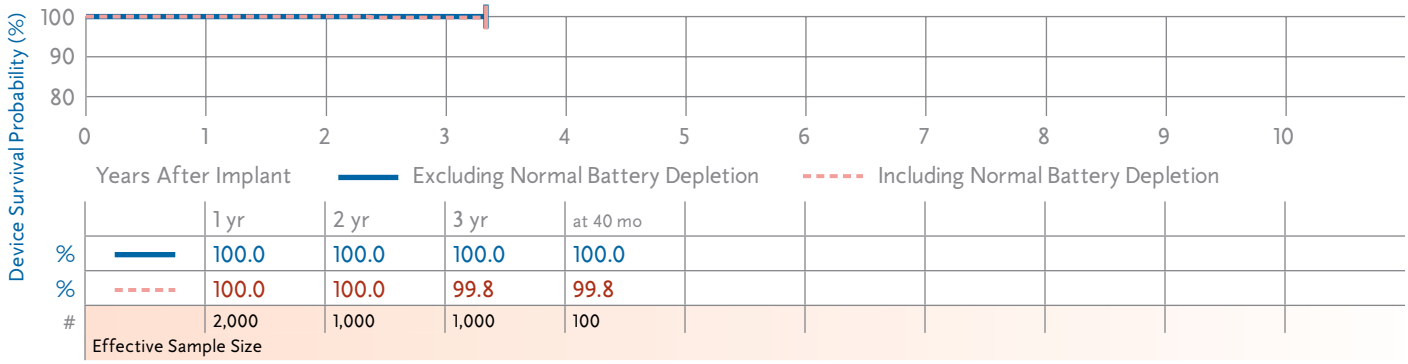
	1 yr	2 yr	3 yr	at 41 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.9
#	6,000	5,000	4,000	200

Effective Sample Size

EnPulse DR E1DR21

Product Characteristics

US Market Release	Dec-03	Malfunctions	0	NBG Code	DDDR
Registered US Implants	2,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PPT
Estimated Active US Implants	1,000	**Therapy Function Compromised**	0	Estimated Longevity	See page 78
Normal Battery Depletions	1				
Advisories	None				



	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.8
#	2,000	1,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

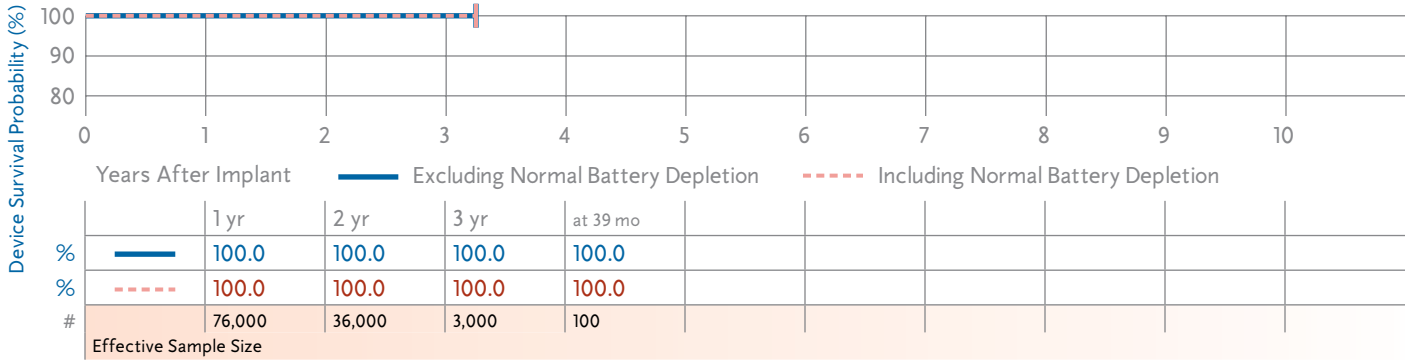
EnPulse 2 DR E2DR01, E2DR03, E2DR06

Product Characteristics

US Market Release	Feb-04
Registered US Implants	100,000
Estimated Active US Implants	82,000
Normal Battery Depletions	2
Advisories	None

Malfunctions	6
Therapy Function Not Compromised	3
Electrical Component	3
Therapy Function Compromised	3
Battery	1
Electrical Component	2

NBG Code	DDDR
Serial Number Prefix	PNB, PNC, PNH
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	at 39 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0
#	76,000	36,000	3,000	100

Effective Sample Size

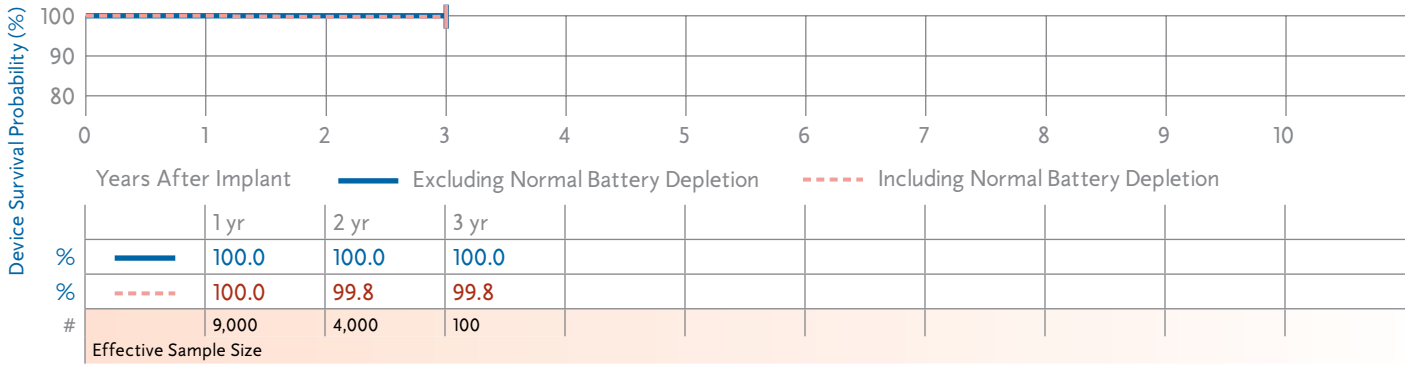
EnPulse 2 DR E2DR21

Product Characteristics

US Market Release	Feb-04
Registered US Implants	12,000
Estimated Active US Implants	10,000
Normal Battery Depletions	7
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDDR
Serial Number Prefix	PMU
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr
%	100.0	100.0	100.0
%	100.0	99.8	99.8
#	9,000	4,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

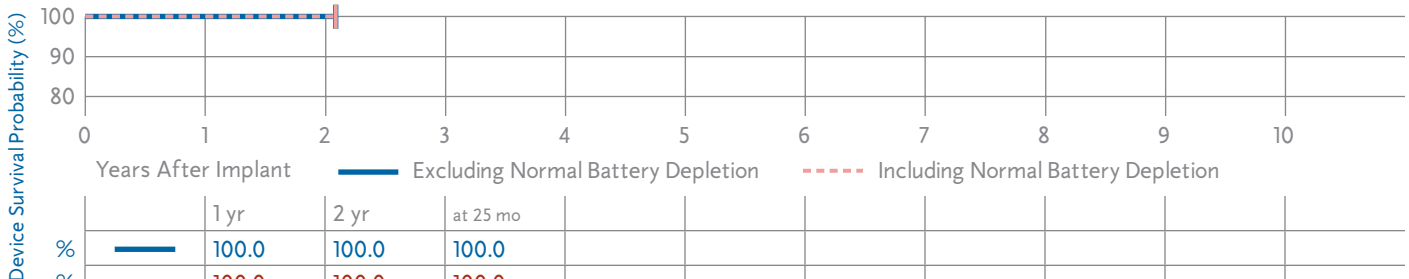
EnPulse 2 DR E2DR31, E2DR33

Product Characteristics

US Market Release	Feb-04
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDDR
Serial Number Prefix	PNL
Estimated Longevity	See page 78



	1 yr	2 yr	at 25 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	400	100	100

Effective Sample Size

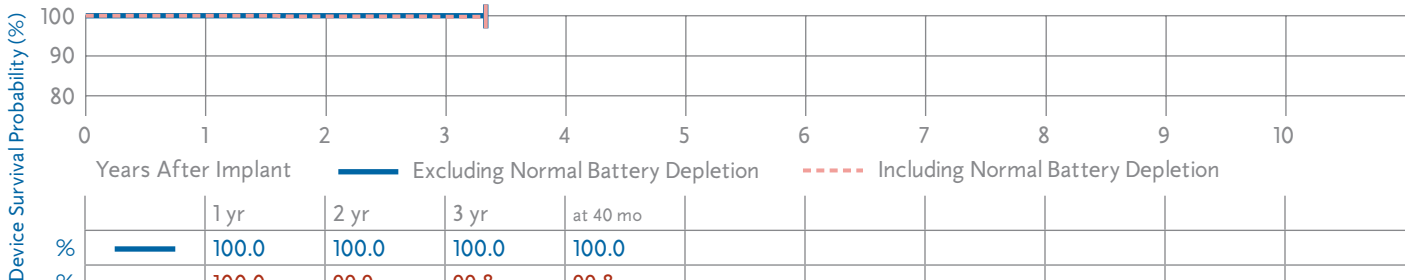
EnPulse 2 SR E2SR01, E2SR03, E2SR06

Product Characteristics

US Market Release	Dec-03
Registered US Implants	25,000
Estimated Active US Implants	19,000
Normal Battery Depletions	3
Advisories	None

Malfunctions	3
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Other	1

NBG Code	SSIR
Serial Number Prefix	PMW, PMY, PNA
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.8
#	17,000	7,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

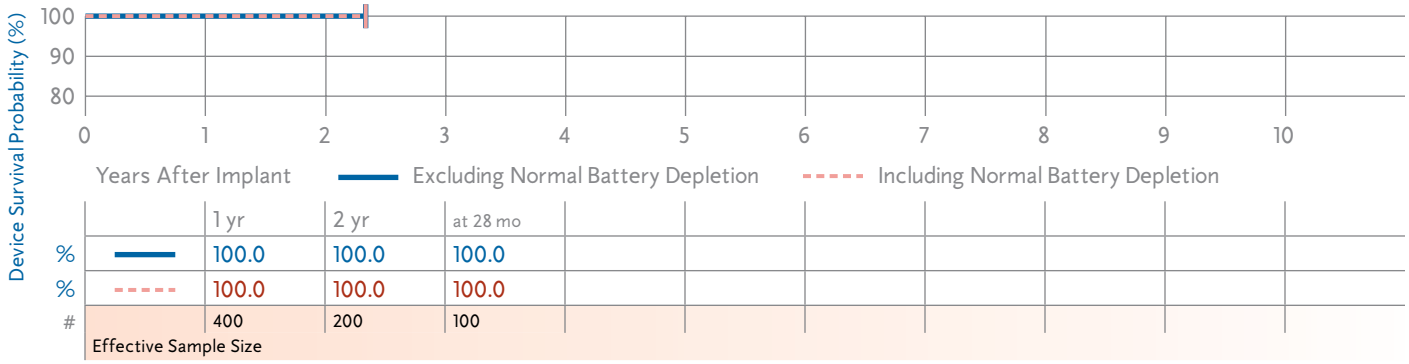
EnPulse 2 VDD E2VDD01

Product Characteristics

US Market Release	Dec-03
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PMV
Estimated Longevity	See page 78



	1 yr	2 yr	at 28 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	400	200	100

Effective Sample Size

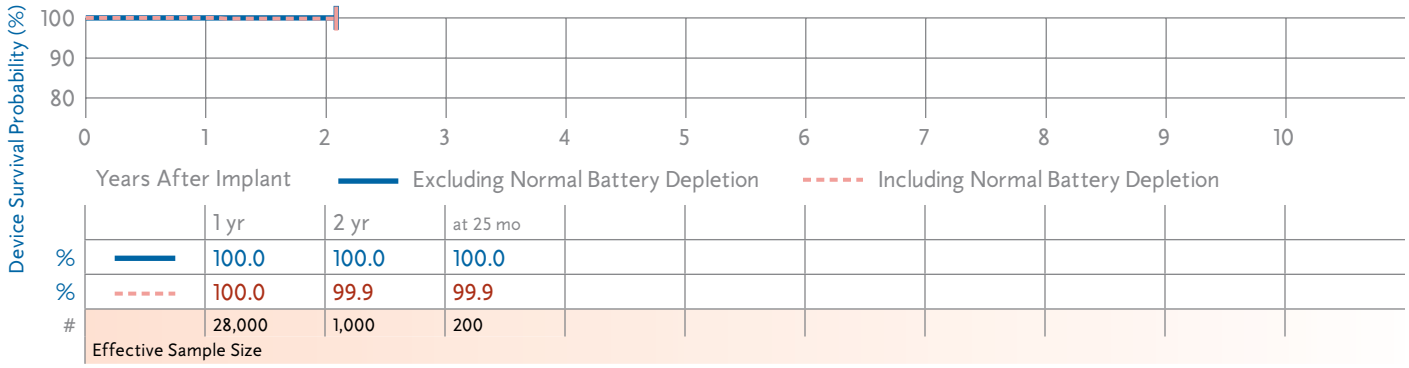
EnRhythm DR P1501DR

Product Characteristics

US Market Release	May-05
Registered US Implants	56,000
Estimated Active US Implants	50,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	13
Therapy Function Not Compromised	2
Electrical Component	2
Therapy Function Compromised	11
Electrical Component	11

NBG Code	DDDRP
Serial Number Prefix	PNP
Estimated Longevity	See page 78



	1 yr	2 yr	at 25 mo
%	100.0	100.0	100.0
%	100.0	99.9	99.9
#	28,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

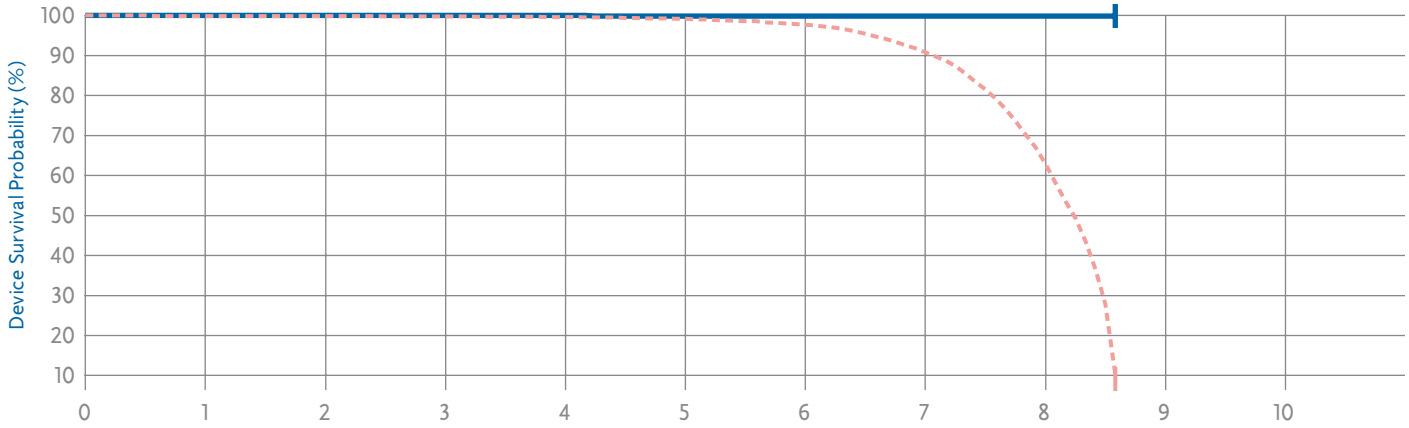
Kappa 400 DR KDR401, KDR403

Product Characteristics

US Market Release	Jan-98
Registered US Implants	47,000
Estimated Active US Implants	10,000
Normal Battery Depletions	2,767
Advisories	None

Malfunctions	21
Therapy Function Not Compromised	12
Electrical Component	9
Electrical Interconnect	1
Possible Early Battery Depletion	2
Therapy Function Compromised	9
Electrical Component	7
Electrical Interconnect	2

NBG Code	DDD/RO
Serial Number Prefix	PER, PET
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 103 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	97.7	90.8	62.8	10.3
#	42,000	37,000	33,000	28,000	24,000	18,000	12,000	4,000	300

Effective Sample Size

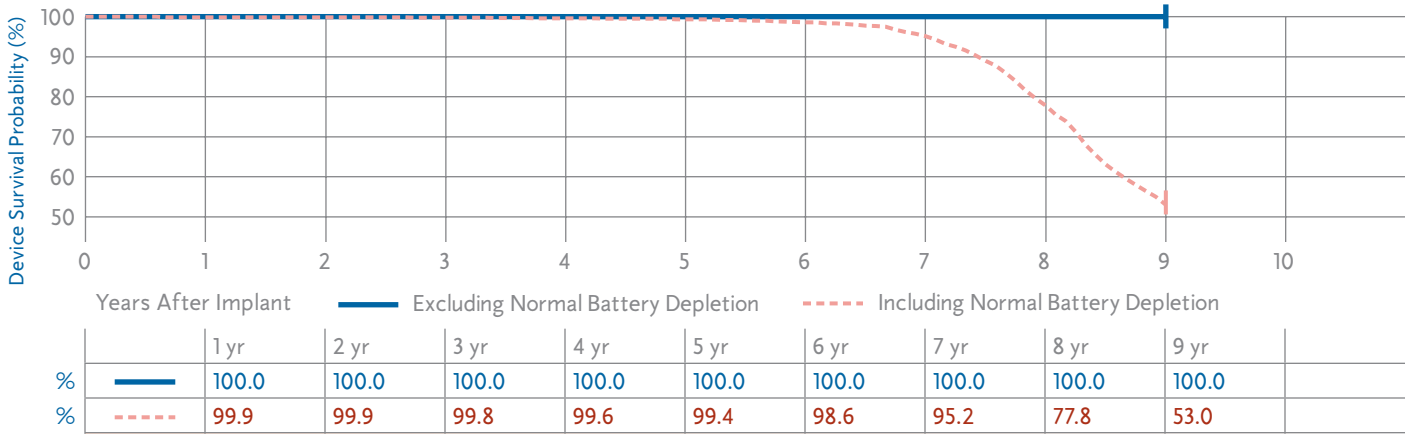
Kappa 400 SR KSR401, KSR403

Product Characteristics

US Market Release	Feb-98
Registered US Implants	15,000
Estimated Active US Implants	4,000
Normal Battery Depletions	383
Advisories	None

Malfunctions	4
Therapy Function Not Compromised	3
Electrical Component	3
Therapy Function Compromised	1
Electrical Interconnect	1

NBG Code	SSI/R
Serial Number Prefix	PEU, PGD
Estimated Longevity	See page 78



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	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	99.4	98.6	95.2	77.8	53.0
#	13,000	11,000	9,000	8,000	6,000	4,000	3,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Kappa 600 DR KDR601, KDR603, KDR606

Product Characteristics

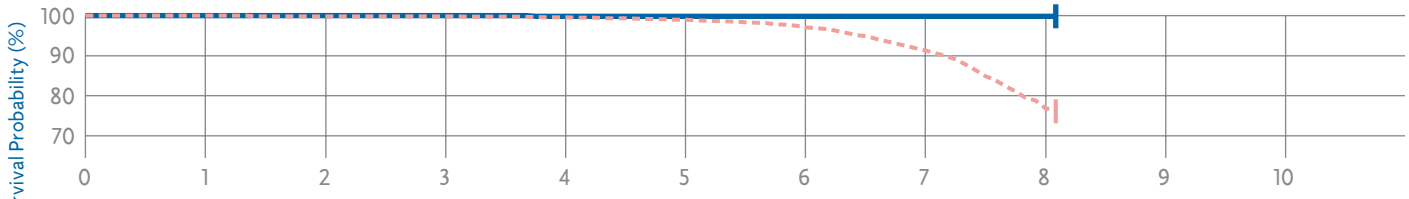
US Market Release	Jan-99
Registered US Implants	24,000
Estimated Active US Implants	8,000
Normal Battery Depletions	536

Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires

Malfunctions	20
Therapy Function Not Compromised	3
Electrical Component	3
Therapy Function Compromised	17
Electrical Component	2
Electrical Interconnect	15

(11 malfunctions related to advisory)

NBG Code	DDD/RO
Serial Number Prefix	PHF, PHH, PHG
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 97 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	99.9	99.9	99.6	99.0	97.1	91.3	76.8	76.8
#	21,000	19,000	17,000	15,000	13,000	11,000	5,000	200	100

Effective Sample Size

Kappa 600 DR KDR651, KDR653

Product Characteristics

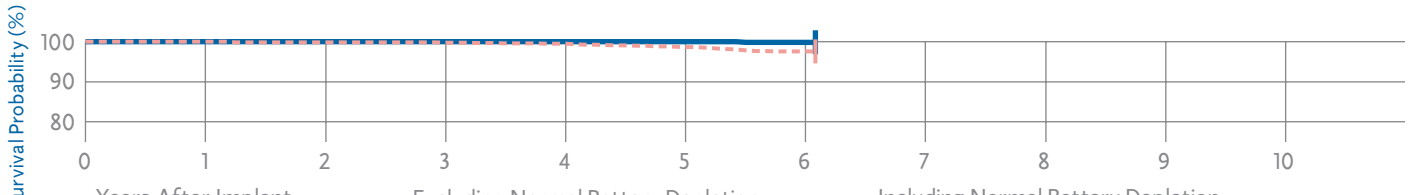
US Market Release	Mar-01
Registered US Implants	14,000
Estimated Active US Implants	7,000
Normal Battery Depletions	75

Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires

Malfunctions	4
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	2
Electrical Component	1
Electrical Interconnect	1

(1 malfunction related to advisory)

NBG Code	DDD/RO
Serial Number Prefix	PLJ, PLK
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	100.0	99.9	99.8	99.5	98.7	97.6	97.6
#	13,000	11,000	10,000	9,000	7,000	400	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Kappa 700 D KD701, KD703, KD706

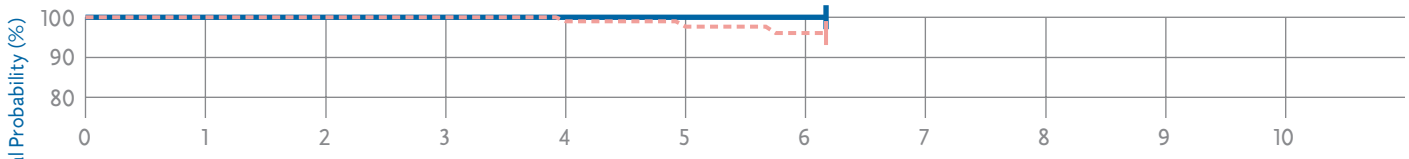
Product Characteristics

US Market Release	Jan-99
Registered US Implants	300
Estimated Active US Implants	100
Normal Battery Depletions	4

Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDD
Serial Number Prefix	PHK
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.0	97.7	96.1	96.1
#	300	200	200	200	200	100	100

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

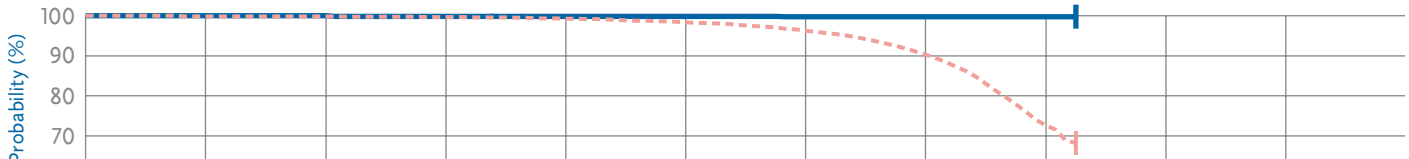
Product Characteristics

US Market Release	Feb-99
Registered US Implants	192,000
Estimated Active US Implants	94,000
Normal Battery Depletions	2,818

Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires

Malfunctions	199
Therapy Function Not Compromised	27
Battery	1
Electrical Component	20
Electrical Interconnect	3
Possible Early Battery Depletion	3
Therapy Function Compromised	172
Electrical Component	14
Electrical Interconnect	158
(117 malfunctions related to advisory)	

NBG Code	DDD/RO
Serial Number Prefix	PGU, PGY, PGW
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.9	99.7	99.3	98.4	96.3	90.3	72.6	68.2
#	170,000	146,000	122,000	97,000	74,000	44,000	18,000	2,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Kappa 700 DR KDR721

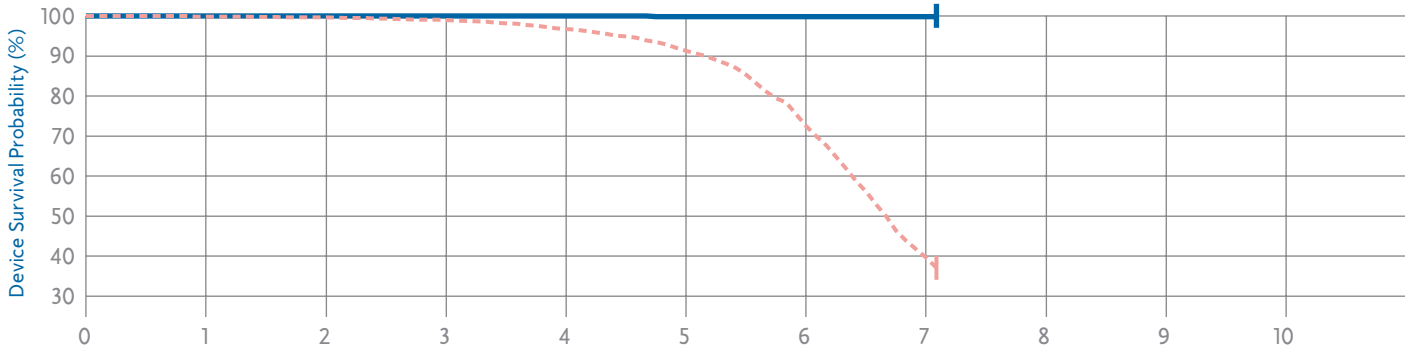
Product Characteristics

US Market Release	Feb-99
Registered US Implants	10,000
Estimated Active US Implants	2,000
Normal Battery Depletions	698

Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires

Malfunctions	5
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	4
Electrical Interconnect	4
(4 malfunctions related to advisory)	

NBG Code	DDD/RO
Serial Number Prefix	PGR
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 85 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.7	99.0	96.8	91.3	72.6	39.7	37.1
#	8,000	7,000	6,000	5,000	4,000	1,000	200	100

Effective Sample Size

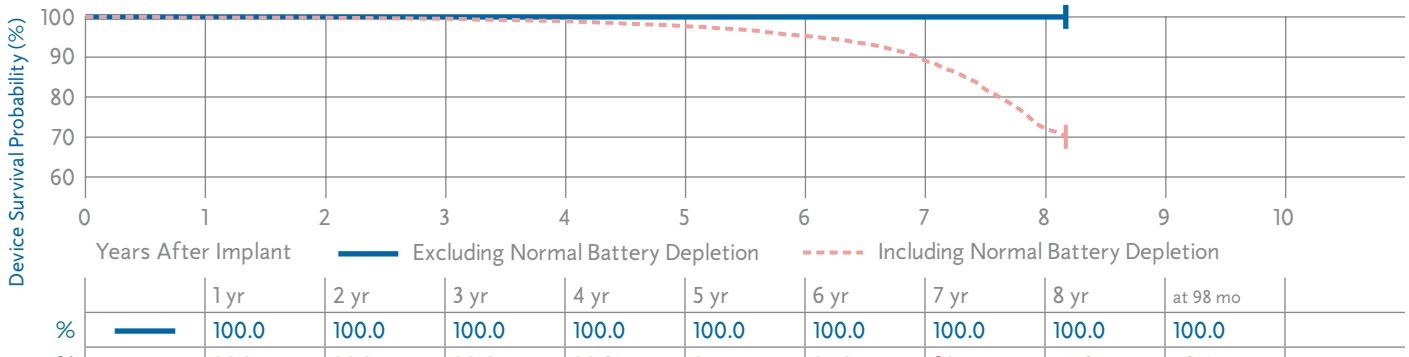
Kappa 700 SR KSR701, KSR703, KSR706

Product Characteristics

US Market Release	Feb-99
Registered US Implants	55,000
Estimated Active US Implants	22,000
Normal Battery Depletions	724
Advisories	None

Malfunctions	9
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	6
Electrical Component	4
Electrical Interconnect	2

NBG Code	SSI/R
Serial Number Prefix	PHT, PHW, PHU
Estimated Longevity	See page 79



	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	99.6	99.0	97.7	95.3	89.1	72.0	70.2
#	44,000	35,000	28,000	22,000	16,000	9,000	4,000	300	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

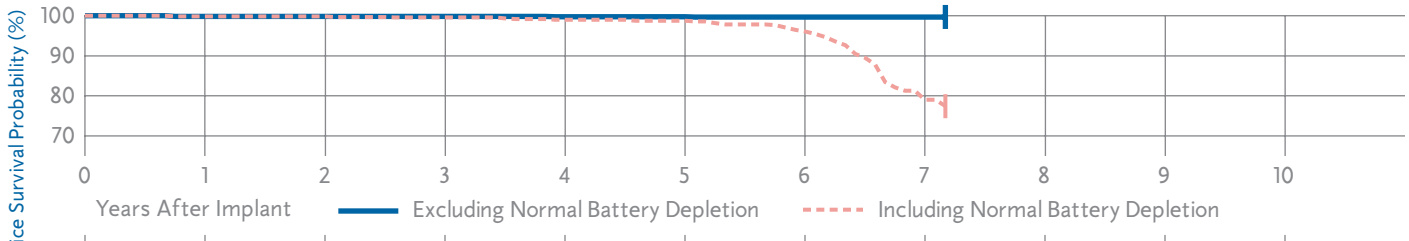
Kappa 700 VDD KVDD701

Product Characteristics

US Market Release	Jan-99
Registered US Implants	2,000
Estimated Active US Implants	1,000
Normal Battery Depletions	51
Advisories: See page 162 – 2002 Potential Fractured Power Supply Wires	

Malfunctions	3
Therapy Function Not Compromised	0
Therapy Function Compromised	3
Electrical Interconnect	3
(3 malfunctions related to advisory)	

NBG Code	VDD/RO
Serial Number Prefix	PHP
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	99.9	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	99.9	99.9	99.6	99.0	98.8	96.1	79.0	77.4
#	1,000	1,000	1,000	1,000	1,000	1,000	100	100

Effective Sample Size

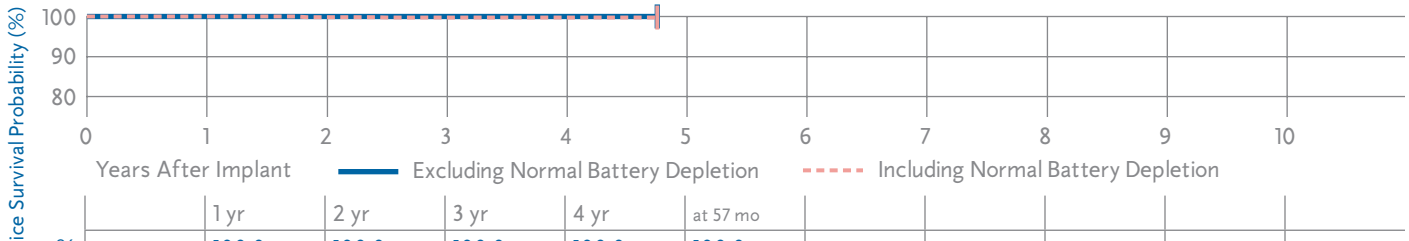
Kappa 800 DR KDR801, KDR803

Product Characteristics

US Market Release	Jan-02
Registered US Implants	4,000
Estimated Active US Implants	3,000
Normal Battery Depletions	3
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDD/RO
Serial Number Prefix	PKW, PKY
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.8	99.8
#	4,000	3,000	3,000	2,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

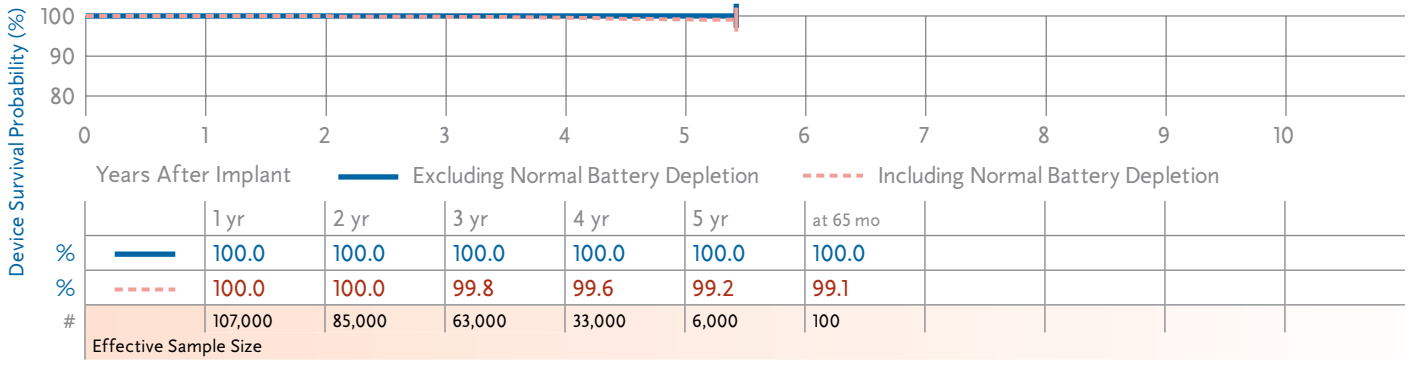
Kappa 900 DR KDR901, KDR903, KDR906

Product Characteristics

US Market Release	Jan-02
Registered US Implants	125,000
Estimated Active US Implants	86,000
Normal Battery Depletions	141
Advisories	None

Malfunctions	20
Therapy Function Not Compromised	10
Electrical Component	10
Therapy Function Compromised	10
Electrical Component	7
Electrical Interconnect	3

NBG Code	DDD/RO
Serial Number Prefix	PKM, PKN, PKP
Estimated Longevity	See page 79



	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	99.8	99.6	99.2	99.1
#	107,000	85,000	63,000	33,000	6,000	100

Effective Sample Size

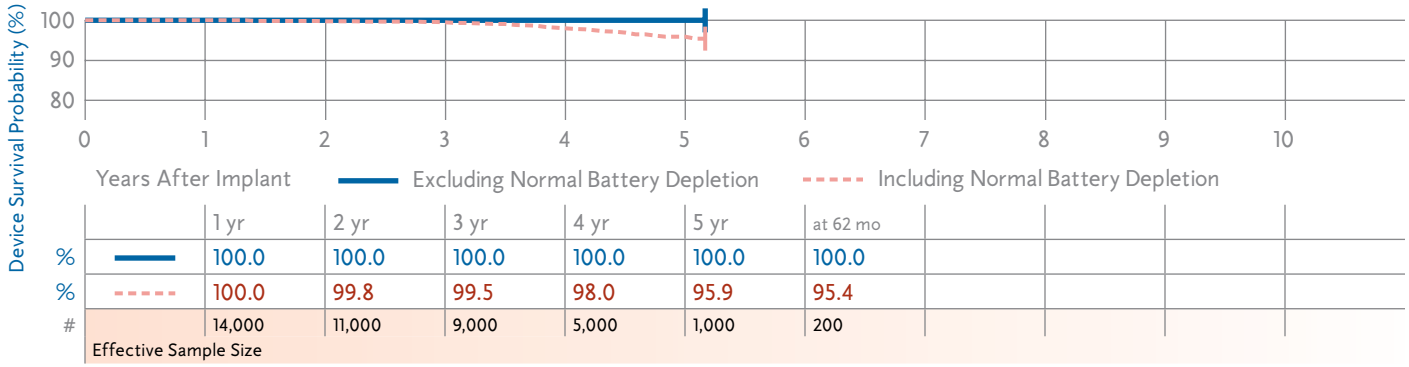
Kappa 920 DR KDR921

Product Characteristics

US Market Release	Jan-02
Registered US Implants	16,000
Estimated Active US Implants	10,000
Normal Battery Depletions	99
Advisories	None

Malfunctions	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Interconnect	1

NBG Code	DDD/RO
Serial Number Prefix	PKR
Estimated Longevity	See page 79



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.8	99.5	98.0	95.9	95.4
#	14,000	11,000	9,000	5,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

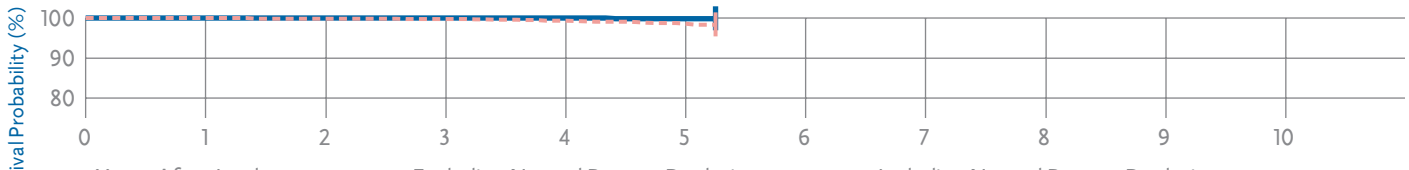
Kappa 900 SR KSR901, KSR903, KSR906

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	22,000
Normal Battery Depletions	45
Advisories	None

Malfunctions	9
Therapy Function Not Compromised	7
Electrical Component	7
Therapy Function Compromised	2
Electrical Interconnect	2

NBG Code	VVEV
Serial Number Prefix	PLF, PLG, PLH
Estimated Longevity	See page 79

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	100.0	100.0	100.0	99.9	99.9
%	100.0	99.9	99.8	99.4	98.6	98.4
#	28,000	19,000	13,000	6,000	1,000	200

Effective Sample Size

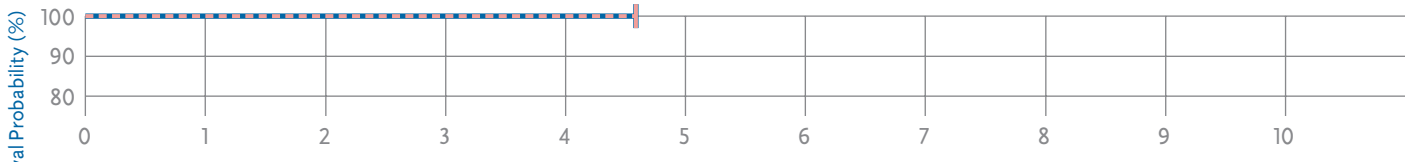
Kappa 900 VDD KVDD901

US Market Release	Jan-02
Registered US Implants	1,000
Estimated Active US Implants	400
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PLE
Estimated Longevity	See page 79

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	at 55 mo
%	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

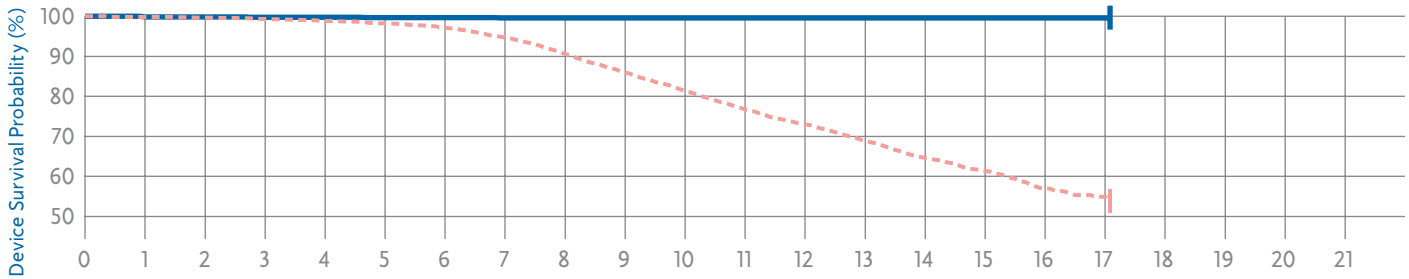
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Legend 8416, 8417, 8417M, 8418, 8419

US Market Release	Aug-89	Malfunctions	143	NBG Code	SSIRO
Registered US Implants	57,000			Serial Number Prefix	XT, WJ, WN, ZT
Estimated Active US Implants	3,000				
Normal Battery Depletions	2,645			Estimated Longevity	See page 79
Advisories	None				

Product Characteristics



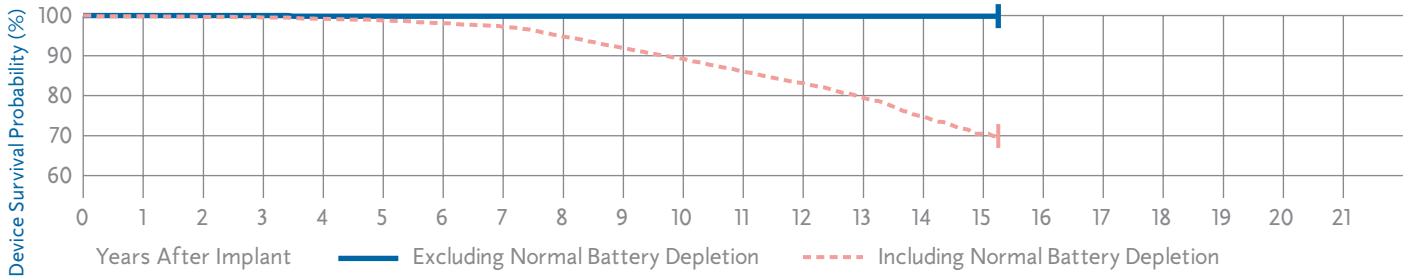
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	at 205 mo
%	99.9	99.9	99.8	99.8	99.7	99.7	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6	99.6
%	99.9	99.7	99.4	98.9	98.3	97.2	94.7	90.6	86.0	81.4	76.8	73.0	69.0	64.6	61.4	57.0	54.9	53.8
#	51,000	46,000	41,000	36,000	31,000	26,000	21,000	17,000	14,000	11,000	8,000	6,000	4,000	3,000	2,000	1,000	200	100

Effective Sample Size

Legend II 8424, 8426, 8427

US Market Release	Nov-91	Malfunctions	36	NBG Code	SSIRO
Registered US Implants	59,000			Serial Number Prefix	2P, 2T, 2U
Estimated Active US Implants	6,000			Estimated Longevity	See page 79
Normal Battery Depletions	1,774				
Advisories	None				

Product Characteristics



	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
%	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
%	99.9	99.7	99.5	99.2	98.8	98.1	97.2	94.8	91.9	89.2	86.0	83.1	79.4	74.8	70.5	69.9
#	52,000	46,000	41,000	35,000	31,000	27,000	23,000	20,000	16,000	12,000	10,000	8,000	5,000	2,000	400	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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

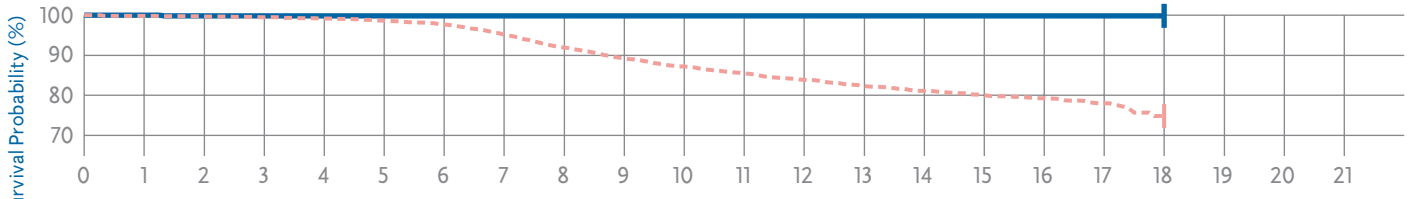
US Market Release	Dec-89
Registered US Implants	58,000
Estimated Active US Implants	5,000
Normal Battery Depletions	1,473

Advisories: See page 167 – 1991 Potential Delayed Restoration of Permanent Settings

Malfunctions	49

Product Characteristics

NBG Code	SSIRO
Serial Number Prefix	2P, 2T, 2U
Estimated Longevity	See page 79



	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
%	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	95.2	91.9	89.3	87.2	85.5	83.9	82.3	81.1	80.0	79.3	78.0	74.8
#	50,000	43,000	37,000	31,000	26,000	22,000	18,000	14,000	12,000	10,000	9,000	7,000	6,000	4,000	3,000	2,000	1,000	100

Effective Sample Size

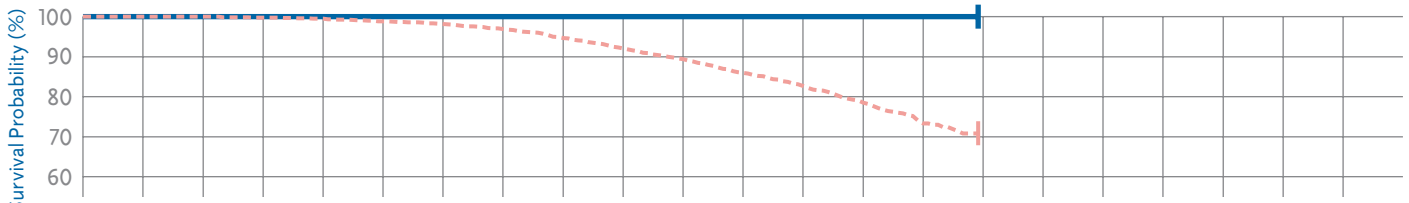
Minuet 7107, 7108

US Market Release	Mar-92
Registered US Implants	17,000
Estimated Active US Implants	2,000
Normal Battery Depletions	582
Advisories	None

Malfunctions	4

Product Characteristics

NBG Code	DDDCO
Serial Number Prefix	1Z1, 2G1
Estimated Longevity	See page 79



	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 179 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	100.0	99.8	99.5	98.9	98.2	96.9	94.7	92.1	89.4	86.0	82.7	78.5	73.3	70.8
#	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	1,000	100

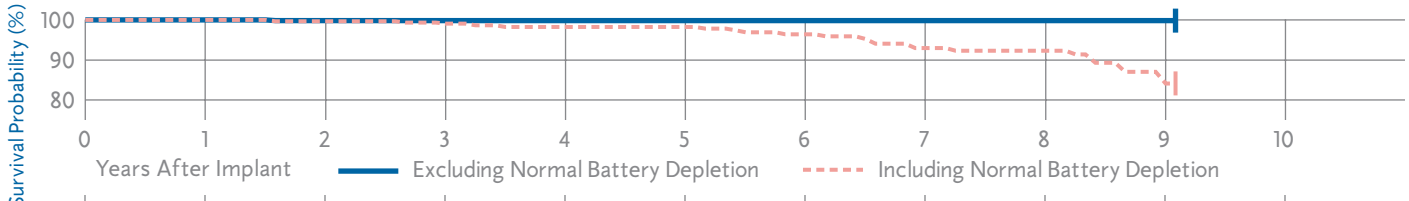
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Preva D 7068

US Market Release	Nov-96	Malfunctions	1	NBG Code	DDDCO
Registered US Implants	1,000			Serial Number Prefix	PIE
Estimated Active US Implants	200			Estimated Longevity	See page 79
Normal Battery Depletions	24				
Advisories	None				

Product Characteristics



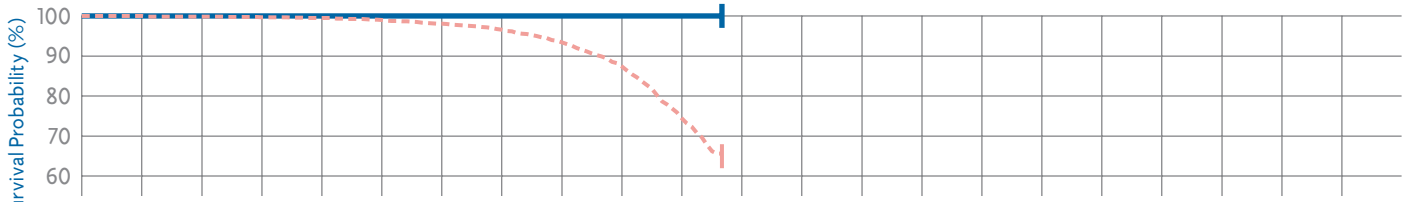
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 109 mo
%	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	100.0	99.7	99.1	98.3	98.3	96.4	93.0	92.3	84.1	84.1
#	1,000	1,000	1,000	1,000	400	400	300	200	100	100

Effective Sample Size

Preva DR 7088, 7089

US Market Release	Jul-96	Malfunctions	3	NBG Code	DDD/RO
Registered US Implants	26,000			Serial Number Prefix	PGJ, PGK
Estimated Active US Implants	6,000			Estimated Longevity	See page 80
Normal Battery Depletions	797				
Advisories	None				

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 128 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	99.5	99.0	98.1	96.6	93.4	87.4	74.4	65.6
#	22,000	20,000	18,000	16,000	14,000	12,000	11,000	8,000	4,000	1,000	200

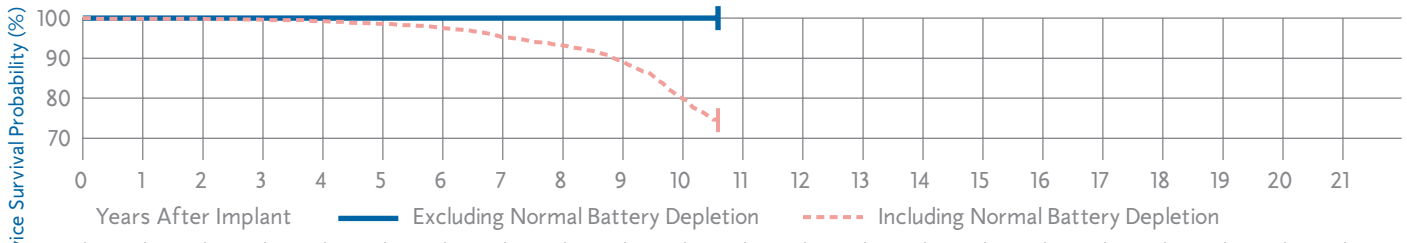
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Preva SR 8088, 8089

Product Characteristics

US Market Release	Jul-96	Malfunctions	1	NBG Code	SSI/R
Registered US Implants	18,000			Serial Number Prefix	PGL, PGM
Estimated Active US Implants	3,000			Estimated Longevity	See page 80
Normal Battery Depletions	347				
Advisories	None				



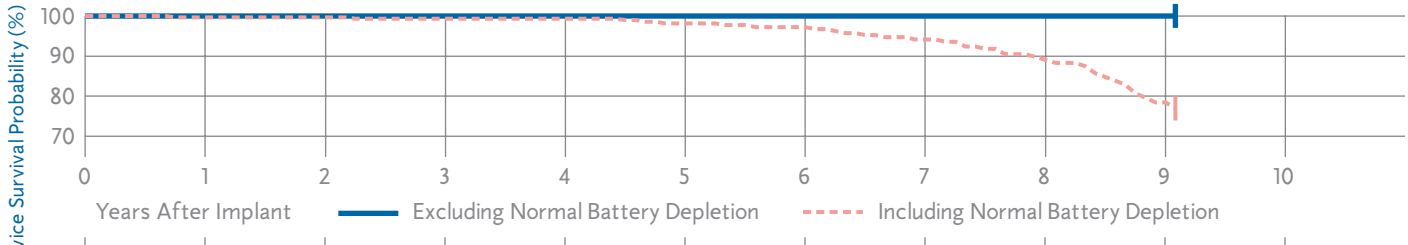
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 127 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.9	99.6	99.3	98.6	97.5	95.3	93.2	89.2	79.9	74.7
#	15,000	12,000	11,000	9,000	8,000	6,000	5,000	4,000	2,000	1,000	100

Effective Sample Size

Preva ST DR 7078

Product Characteristics

US Market Release	Nov-96	Malfunctions	0	NBG Code	DDD/RO
Registered US Implants	1,000			Serial Number Prefix	PIF
Estimated Active US Implants	100			Estimated Longevity	See page 80
Normal Battery Depletions	39				
Advisories	None				



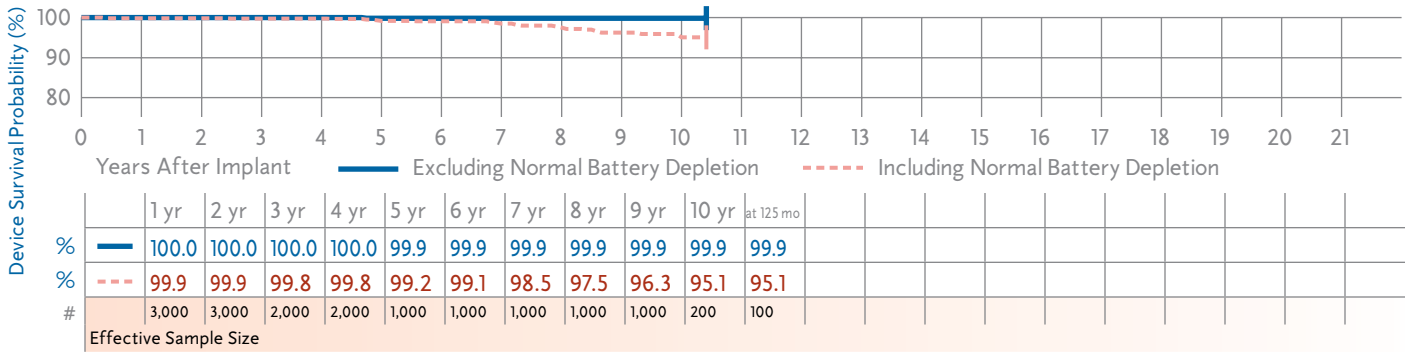
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 109 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.7	99.7	99.4	99.4	98.2	97.3	94.2	89.1	78.4	76.9
#	1,000	1,000	1,000	1,000	500	400	300	300	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Prevail S 8085, 8086

US Market Release	Oct-95	Malfunctions	1	Product Characteristics	
Registered US Implants	4,000			NBG Code	SSI
Estimated Active US Implants	1,000			Serial Number Prefix	PGL, PGM
Normal Battery Depletions	20			Estimated Longevity	See page 80
Advisories	None				

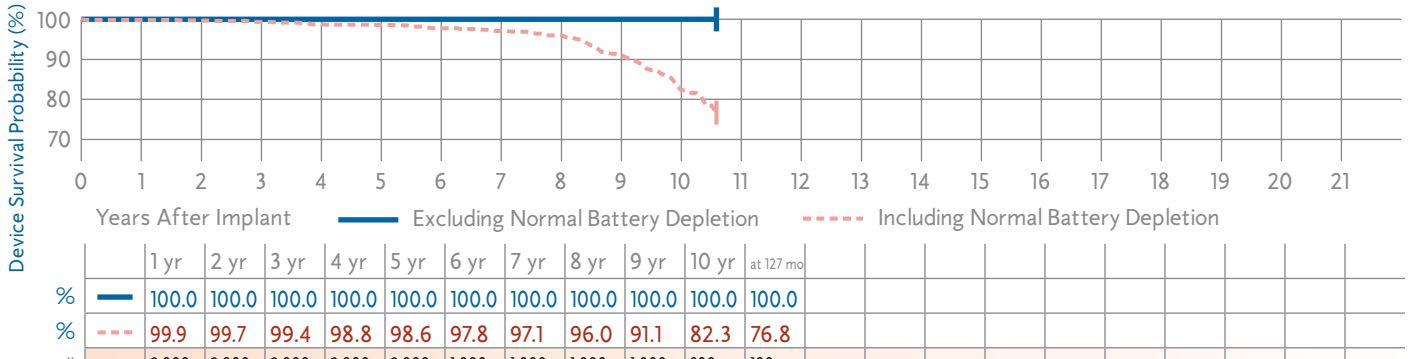


	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 125 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.9	99.8	99.8	99.2	99.1	98.5	97.5	96.3	95.1	95.1
#	3,000	3,000	2,000	2,000	1,000	1,000	1,000	1,000	1,000	200	100

Effective Sample Size

Prodigy D 7864, 7865, 7866

US Market Release	Oct-95	Malfunctions	0	Product Characteristics	
Registered US Implants	3,000			NBG Code	DDDCO
Estimated Active US Implants	1,000			Serial Number Prefix	PDL, PDM, PDN
Normal Battery Depletions	76			Estimated Longevity	See page 80
Advisories	None				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 127 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	99.4	98.8	98.6	97.8	97.1	96.0	91.1	82.3	76.8
#	2,000	2,000	2,000	2,000	2,000	1,000	1,000	1,000	1,000	300	100

Effective Sample Size

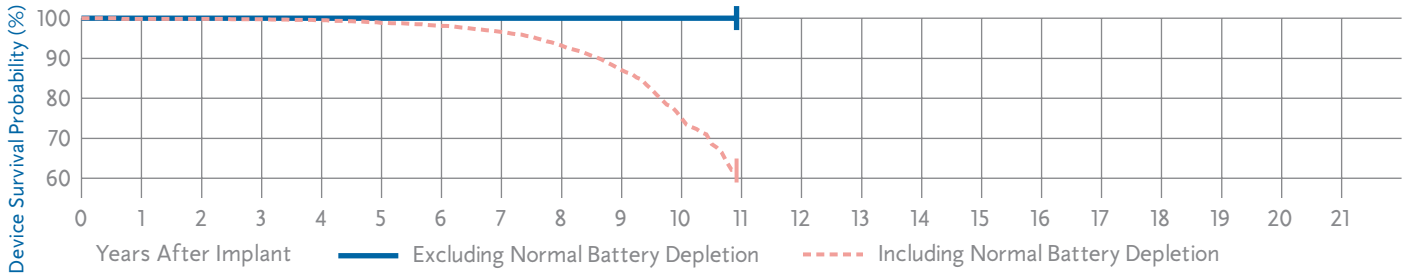
Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Prodigy DR 7860, 7861, 7862

US Market Release	Oct-95
Registered US Implants	38,000
Estimated Active US Implants	9,000
Normal Battery Depletions	1,127
Advisories	None
Malfunctions	11

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix	PDH, PDJ, PDK
Estimated Longevity	See page 80



	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	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	98.9	98.1	96.6	93.2	87.1	75.0	62.1
#	33,000	30,000	27,000	24,000	21,000	19,000	16,000	12,000	6,000	1,000	100

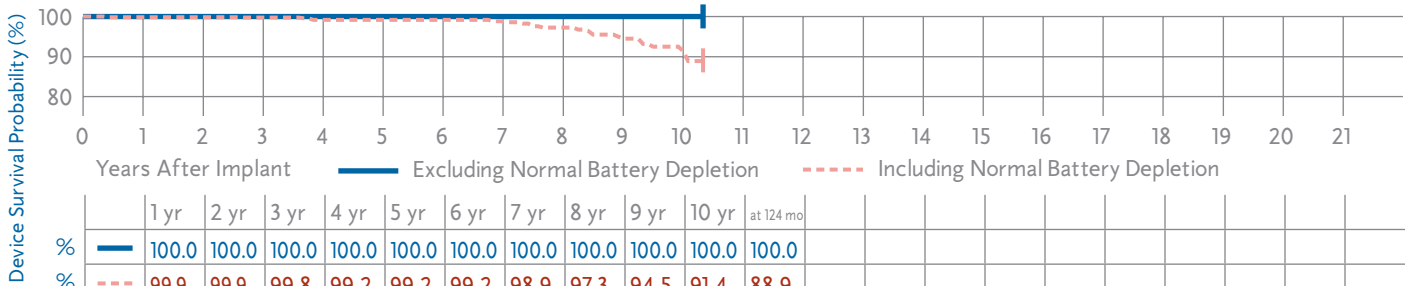
Effective Sample Size

Prodigy S 8164, 8165, 8166

US Market Release	Oct-95
Registered US Implants	2,000
Estimated Active US Implants	400
Normal Battery Depletions	23
Advisories	None
Malfunctions	0

Product Characteristics

NBG Code	SSIC
Serial Number Prefix	PEG, PEH, PEJ
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 124 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	99.2	99.2	99.2	98.9	97.3	94.5	91.4	88.9
#	2,000	1,000	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 July 31, 2007

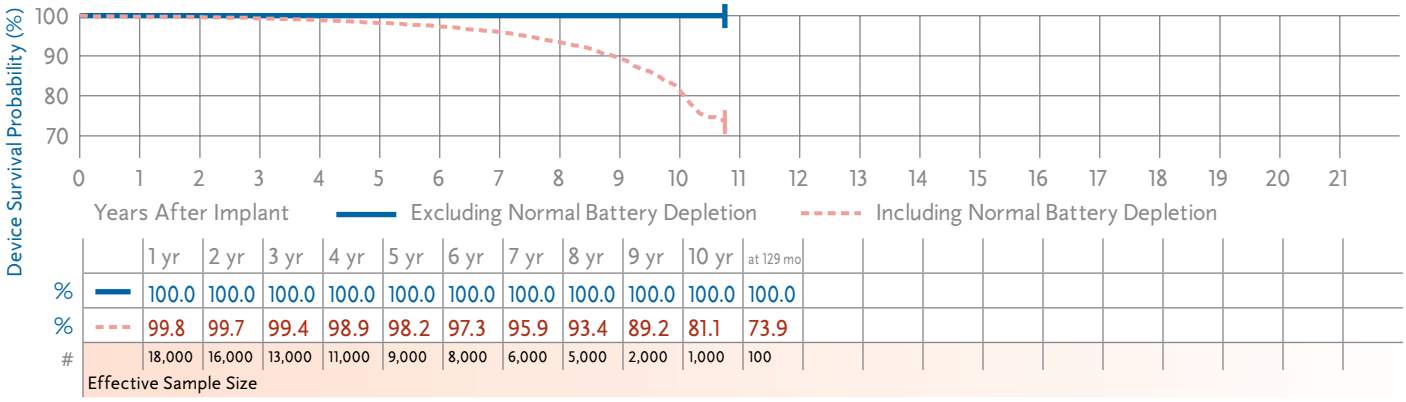
Prodigy SR 8158, 8160, 8161, 8162

US Market Release	Oct-95
Registered US Implants	22,000
Estimated Active US Implants	4,000
Normal Battery Depletions	433
Advisories	None

Malfunctions	5

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix	PEM, PED, PEE, PEF
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 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	99.7	99.4	98.9	98.2	97.3	95.9	93.4	89.2	81.1	73.9
#	18,000	16,000	13,000	11,000	9,000	8,000	6,000	5,000	2,000	1,000	100

Effective Sample Size

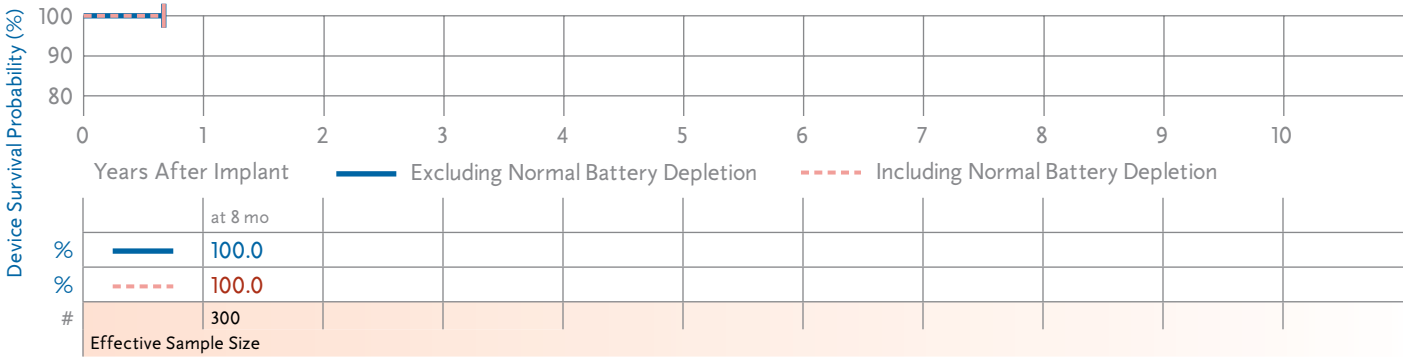
Sensia DR SEDR01, SED01

US Market Release	Jul-06
Registered US Implants	10,000
Estimated Active US Implants	9,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix	DDD, DDDR
Estimated Longevity	See page 80



	at 8 mo
%	100.0
%	100.0
#	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

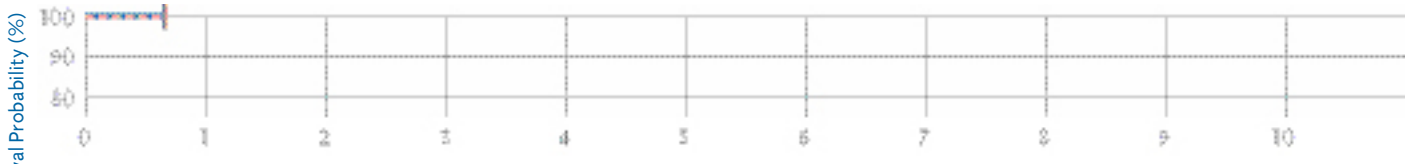
Sensia SR SESR01, SES01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	6,000
Estimated Active US Implants	6,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSIR, SSI
Serial Number Prefix	PWR, PWS
Estimated Longevity	See page 80



		at 8 mo
%	Excluding Normal Battery Depletion	100.0
%	Including Normal Battery Depletion	100.0
#	Effective Sample Size	200

Sigma 100 S SS103, SS106

Product Characteristics

US Market Release	Aug-99
Registered US Implants	1,000
Estimated Active US Implants	200
Normal Battery Depletions	3

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSI
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 80

		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	100.0	99.5	99.5	98.5	98.5	96.7
#	Effective Sample Size	1,000	500	400	300	200	100	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Sigma 200 DR SDR203

Product Characteristics

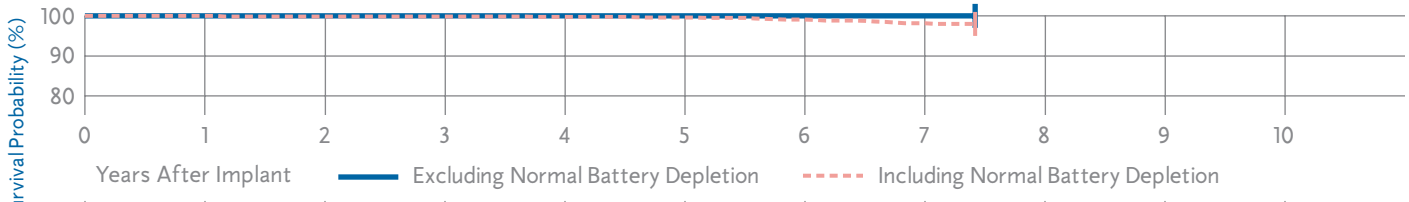
US Market Release	Aug-99
Registered US Implants	16,000
Estimated Active US Implants	8,000
Normal Battery Depletions	34

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	4
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	2
Electrical Component	1
Electrical Interconnect	2

(1 malfunction related to advisory)

NBG Code	DDD/RO
Serial Number Prefix	PJD
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 89 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	99.1	98.2	98.0
#	13,000	12,000	10,000	8,000	6,000	3,000	1,000	200

Effective Sample Size

Sigma 200 SR SSR203

Product Characteristics

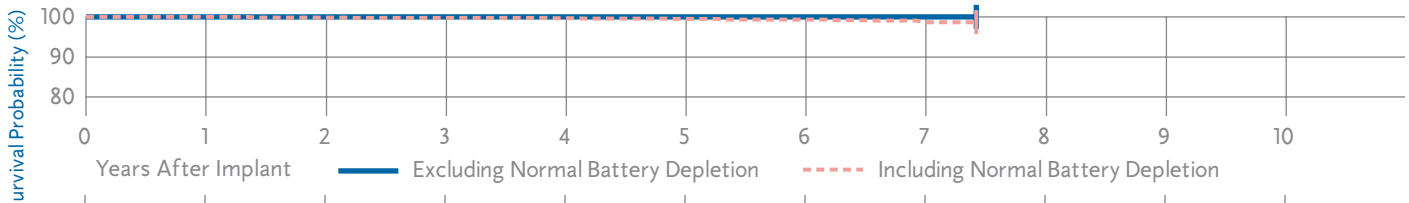
US Market Release	Sep-99
Registered US Implants	12,000
Estimated Active US Implants	5,000
Normal Battery Depletions	17

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	2
Therapy Function Not Compromised	0
Therapy Function Compromised	2
Electrical Interconnect	2

(2 malfunctions related to advisory)

NBG Code	SSI/R
Serial Number Prefix	PJG
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 89 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.7	99.5	99.4	98.7	98.7
#	10,000	8,000	6,000	5,000	3,000	2,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Sigma 300 DR SDR303, SDR306

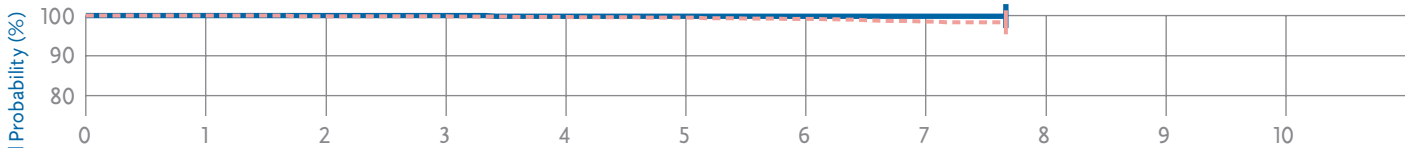
Product Characteristics

US Market Release	Aug-99
Registered US Implants	104,000
Estimated Active US Implants	62,000
Normal Battery Depletions	111

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	62
Therapy Function Not Compromised	8
Electrical Component	4
Electrical Interconnect	3
Possible Early Battery Depletion	1
Therapy Function Compromised	54
Electrical Component	6
Electrical Interconnect	48
(27 malfunctions related to advisory)	

NBG Code	DDD/RO
Serial Number Prefix	PJD, PJE
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 92 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	100.0	99.9	99.9	99.7	99.5	99.2	98.5	98.4
#	86,000	69,000	53,000	38,000	24,000	13,000	3,000	100

Effective Sample Size

Sigma 300 SR SSR303, SSR306

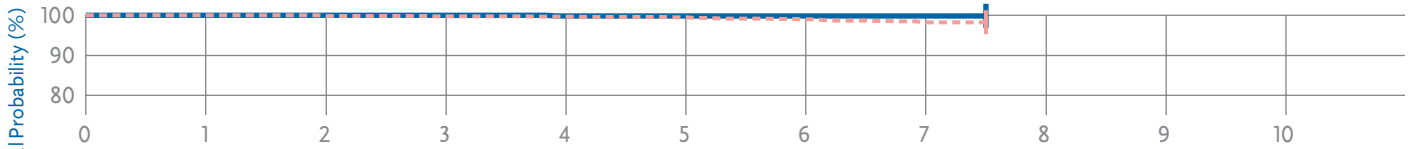
Product Characteristics

US Market Release	Sep-99
Registered US Implants	52,000
Estimated Active US Implants	25,000
Normal Battery Depletions	60

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	12
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	11
Electrical Component	3
Electrical Interconnect	8
(5 malfunctions related to advisory)	

NBG Code	SSI/R
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	100.0	99.9	99.8	99.7	99.5	99.0	98.3	98.3
#	39,000	29,000	21,000	14,000	9,000	4,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Sigma 300 VDD SVDD303

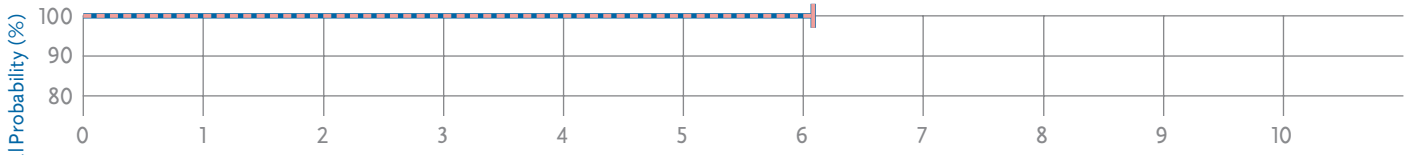
Product Characteristics

US Market Release	Sep-99
Registered US Implants	1,000
Estimated Active US Implants	300
Normal Battery Depletions	0

Advisories: See page 160 – 2005 Potential Separation of Interconnect Wires

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDDD
Serial Number Prefix	PJD
Estimated Longevity	See page 80



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 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
#	1,000	500	400	300	200	100	100

Effective Sample Size

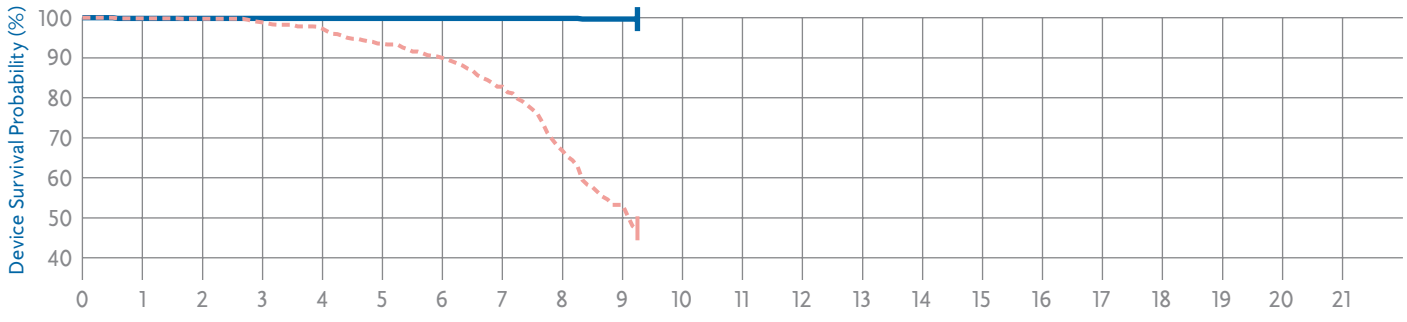
Thera D 7944, 7945, 7946

Product Characteristics

US Market Release	Jan-95
Registered US Implants	2,000
Estimated Active US Implants	0
Normal Battery Depletions	175
Advisories	None

Malfunctions	2

NBG Code	DDDCO
Serial Number Prefix	PBD, PBE, PBF
Estimated Longevity	See page 80



	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	47.0
#	2,000	1,000	1,000	1,000	1,000	1,000	1,000	300	100	100

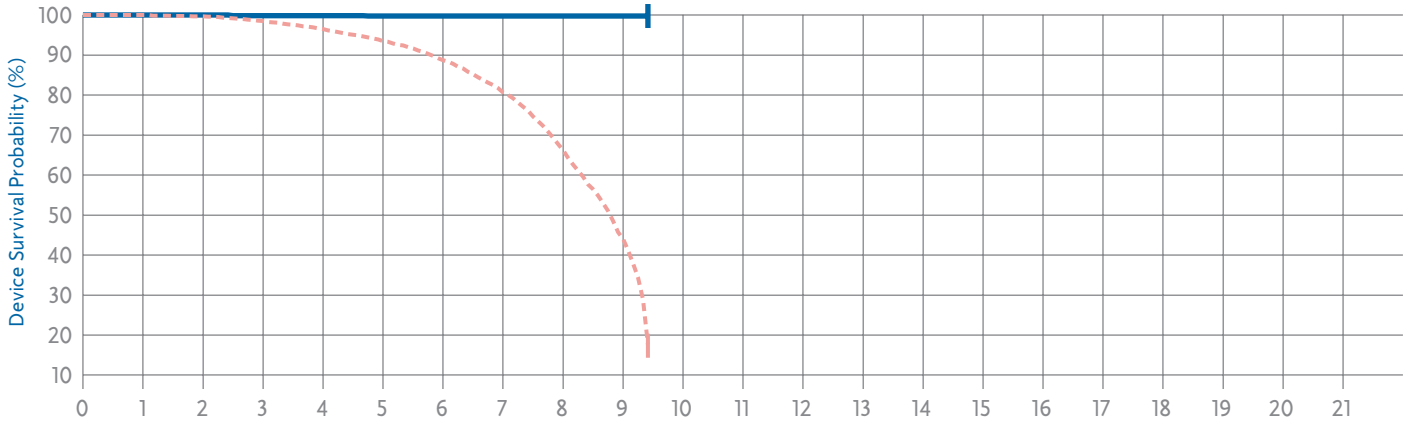
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Thera DR-40 7940, 7941, 7942

US Market Release	Jan-95	Malfunctions	37	NBG Code	DDD/RO
Registered US Implants	30,000			Serial Number Prefix	PAF, PAP, PAT
Estimated Active US Implants	1				
Normal Battery Depletions	3,027			Estimated Longevity	See page 80
Advisories	None				

Product Characteristics



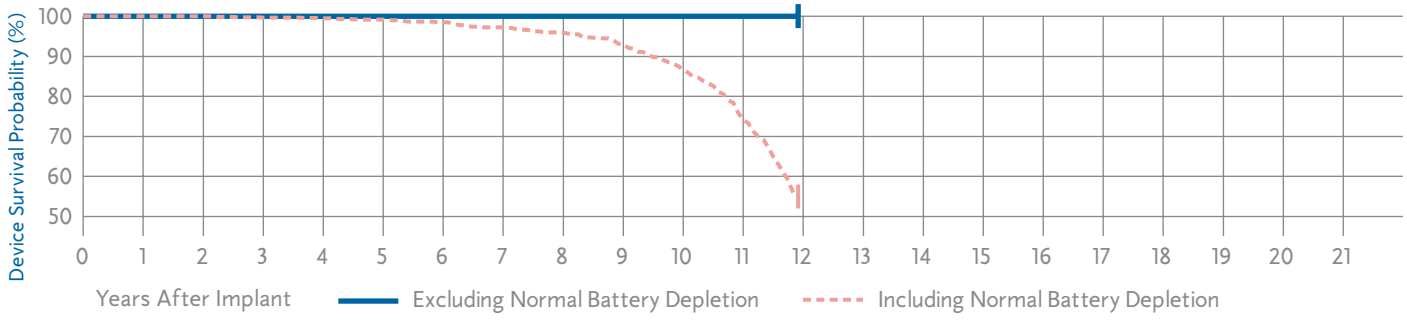
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 mo
%	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8
%	100.0	99.7	98.5	96.5	93.5	88.7	80.7	66.2	44.0	17.7
#	27,000	24,000	21,000	19,000	16,000	13,000	9,000	5,000	1,000	100

Effective Sample Size

Thera DR-50 7950, 7951, 7952

US Market Release	Jan-95	Malfunctions	1	NBG Code	DDD/RO
Registered US Implants	5,000			Serial Number Prefix	PBR, PBV, PBW
Estimated Active US Implants	400				
Normal Battery Depletions	236			Estimated Longevity	See page 80
Advisories	None				

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 143 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	95.9	93.0	86.6	74.2	54.9
#	4,000	4,000	3,000	3,000	3,000	2,000	2,000	2,000	1,000	1,000	1,000	100

Effective Sample Size

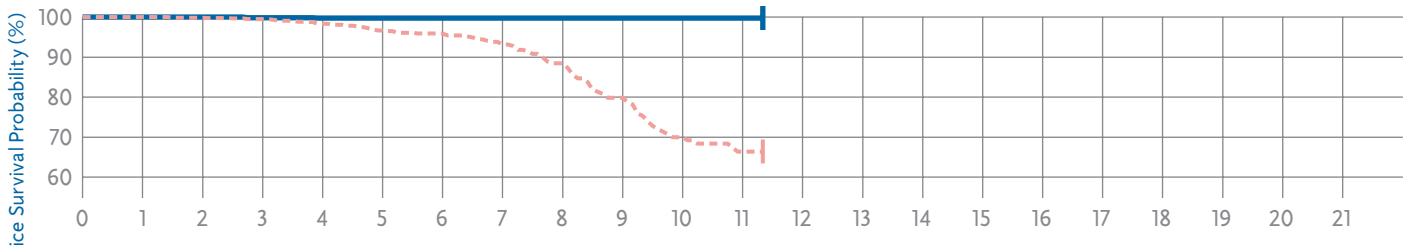
Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Thera S 8944, 8945, 8946

US Market Release	Jan-95
Registered US Implants	3,000
Estimated Active US Implants	100
Normal Battery Depletions	84
Advisories	None
Malfunctions	3

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix	PBG, PBH, PBJ
Estimated Longevity	See page 81



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 136 mo
%	100.0	100.0	99.9	99.8	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	70.0	66.4	66.4
#	2,000	2,000	1,000	1,000	1,000	1,000	1,000	400	300	200	100	100

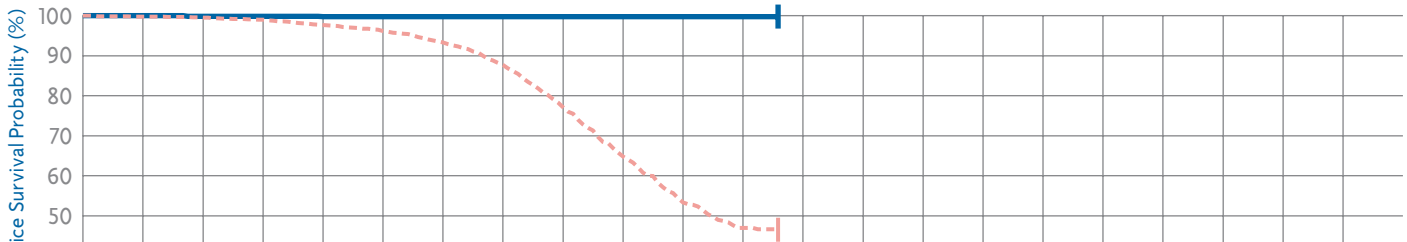
Effective Sample Size

Thera SR 8940, 8941, 8942

US Market Release	Jan-95
Registered US Implants	14,000
Estimated Active US Implants	200
Normal Battery Depletions	818
Advisories	None
Malfunctions	16

Product Characteristics

NBG Code	SSI/R
Serial Number Prefix	PAU, PAV, PAW
Estimated Longevity	See page 81



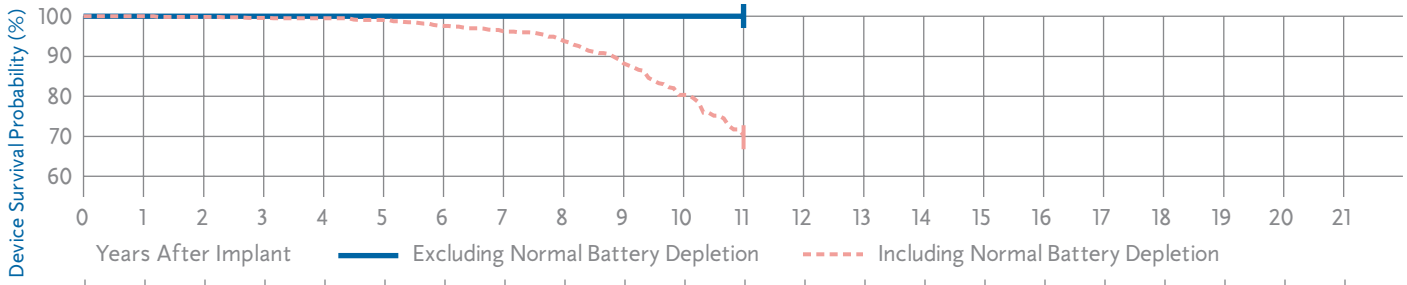
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 139 mo
%	100.0	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
%	99.8	99.5	99.0	97.7	96.2	93.3	87.7	77.1	64.8	53.3	47.0	46.6
#	12,000	10,000	9,000	8,000	7,000	5,000	4,000	2,000	1,000	1,000	300	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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

US Market Release	Oct-95	Malfunctions	1	Product Characteristics	
Registered US Implants	3,000			NBG Code	DDDCO
Estimated Active US Implants	1,000			Serial Number Prefix	PDE, PDF, PDG
Normal Battery Depletions	114			Estimated Longevity	See page 81
Advisories	None				

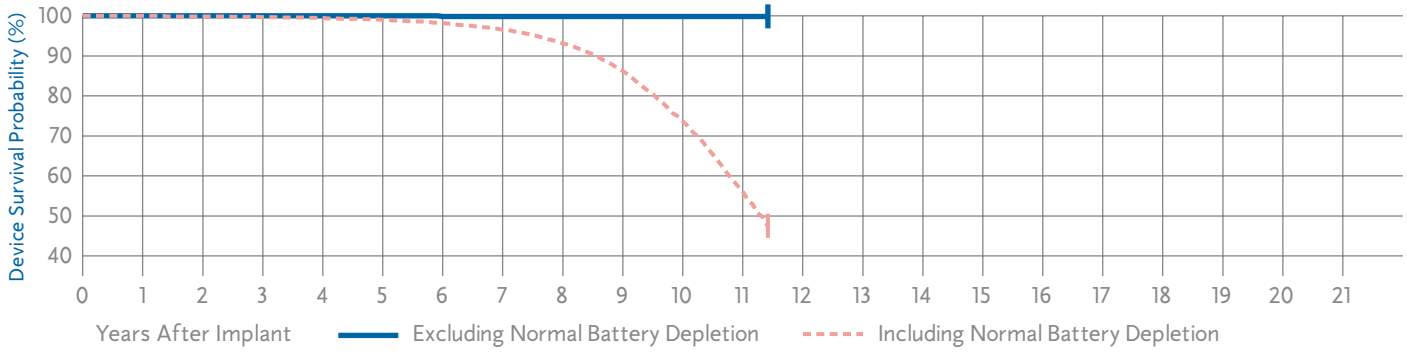


	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.6	99.5	99.1	97.6	96.3	93.8	88.2	80.4	70.3
#	3,000	3,000	2,000	2,000	2,000	2,000	1,000	1,000	1,000	400	100

Effective Sample Size

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

US Market Release	Oct-95	Malfunctions	50	Product Characteristics	
Registered US Implants	122,000			NBG Code	DDD/RO
Estimated Active US Implants	22,000			Serial Number Prefix	PDB, PDC, PDD
Normal Battery Depletions	5,227			Estimated Longevity	See page 81
Advisories	None				



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 137 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	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	93.1	86.2	73.7	56.2	47.4
#	109,000	99,000	89,000	80,000	71,000	62,000	53,000	42,000	26,000	10,000	2,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

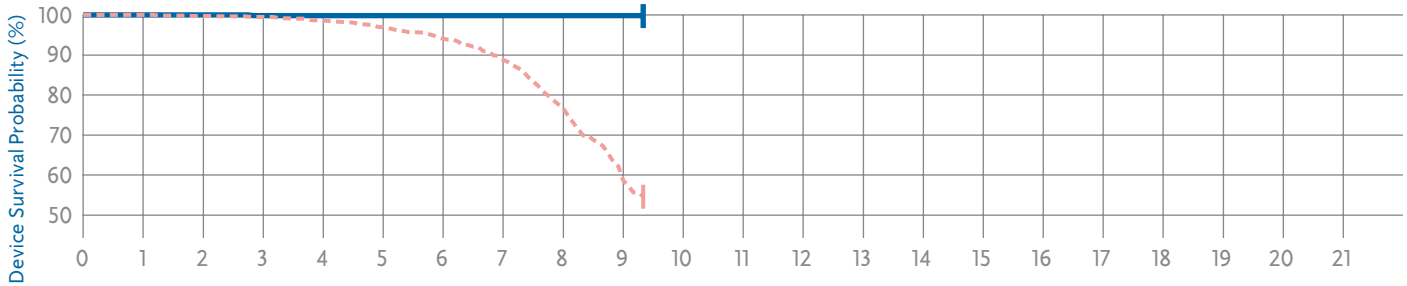
Thera-i DR 7968i

US Market Release	Jul-96
Registered US Implants	4,000
Estimated Active US Implants	400
Normal Battery Depletions	216
Advisories	None

Malfunctions	3

Product Characteristics

NBG Code	DDD/RO
Serial Number Prefix	PGH
Estimated Longevity	See page 81



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 112 mo
%	100.0	100.0	99.9	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	88.8	76.7	58.6	54.7
#	3,000	3,000	3,000	2,000	2,000	2,000	1,000	1,000	200	100

Effective Sample Size

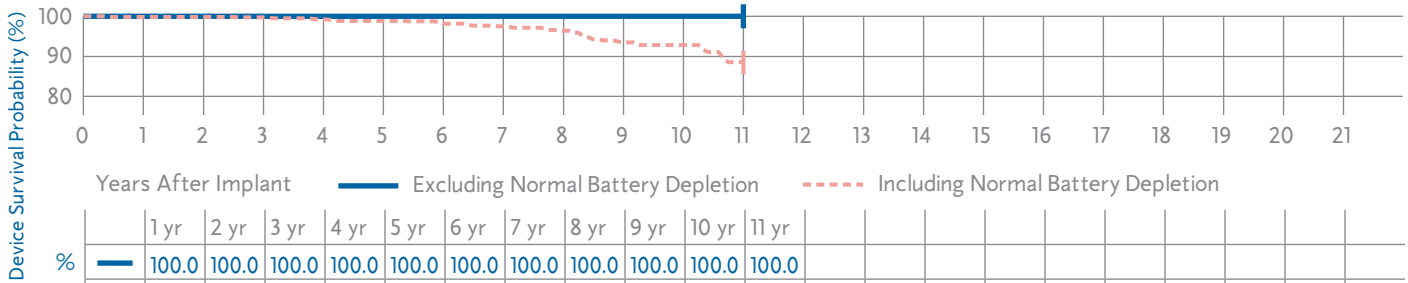
Thera-i S 8964i, 8965i, 8966i

US Market Release	Oct-95
Registered US Implants	4,000
Estimated Active US Implants	1,000
Normal Battery Depletions	45
Advisories	None

Malfunctions	1

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PDY, PEA, PEB
Estimated Longevity	See page 81



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	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	96.4	93.5	92.8	88.6
#	3,000	3,000	2,000	2,000	2,000	1,000	1,000	1,000	1,000	400	100

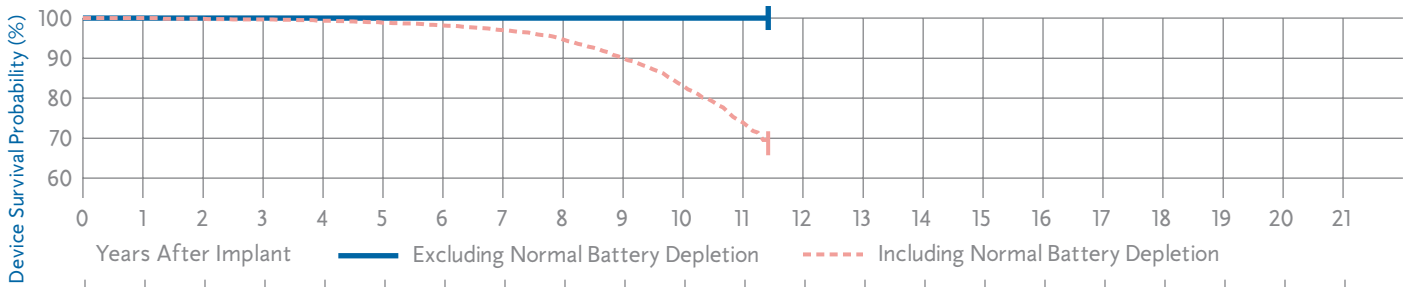
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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

US Market Release	Oct-95	Malfunctions	7	NBG Code	SSIR
Registered US Implants	50,000			Serial Number Prefix	PDU, PDV, PDW
Estimated Active US Implants	8,000			Estimated Longevity	See page 81
Normal Battery Depletions	1,133				
Advisories	None				

Product Characteristics

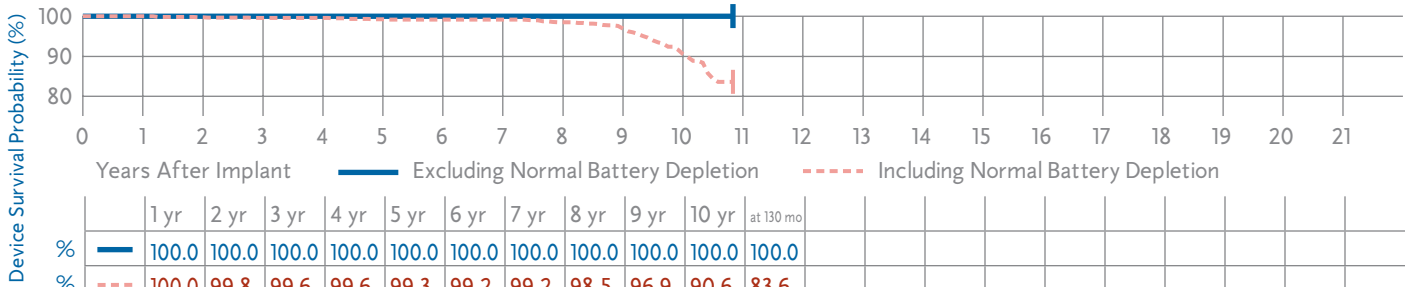


	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 137 mo
% —	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
% - - -	100.0	99.9	99.7	99.4	98.9	98.2	97.0	94.7	90.0	83.1	73.9	69.6
# Effective Sample Size	42,000	37,000	32,000	27,000	23,000	20,000	17,000	13,000	8,000	4,000	1,000	100

Thera-i VDD 8968i

US Market Release	Mar-96	Malfunctions	0	NBG Code	VDD
Registered US Implants	5,000			Serial Number Prefix	PEC
Estimated Active US Implants	1,000			Estimated Longevity	See page 81
Normal Battery Depletions	67				
Advisories	None				

Product Characteristics



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 130 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	99.8	99.6	99.6	99.3	99.2	99.2	98.5	96.9	90.6	83.6
# Effective Sample Size	4,000	4,000	3,000	3,000	3,000	2,000	2,000	2,000	1,000	1,000	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

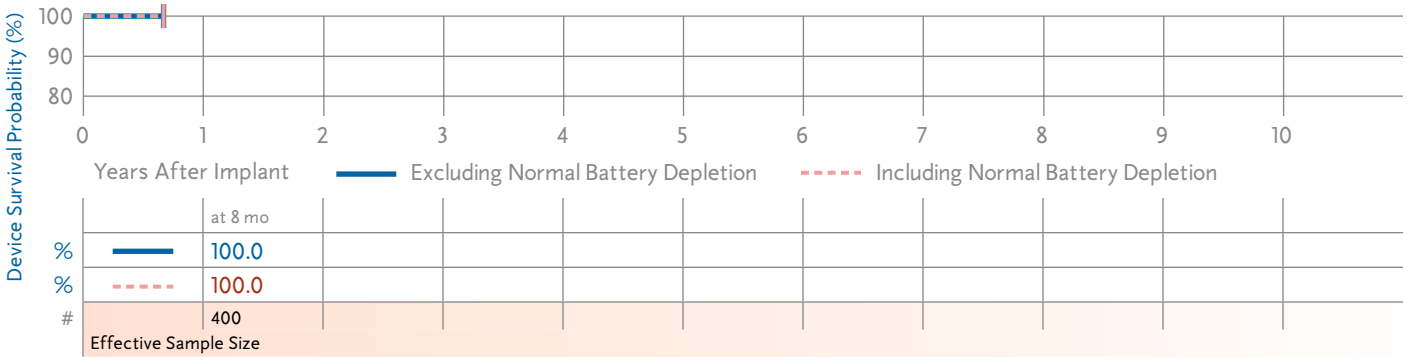
Versa DR VEDR01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	11,000
Estimated Active US Implants	10,000
Normal Battery Depletions	0
Advisories	None

Malfunctions	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDDR
Serial Number Prefix	PWH
Estimated Longevity	See page 81



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Jul-06	30,000	29,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 9 mo											
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 9 mo											
Adapta DR	ADDRL1	Jul-06	1,000	1,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 6 mo											
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 6 mo											
Adapta DR	ADDRS1	Jul-06	3,000	2,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	6,000	6,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
AT500	AT501, 7253	Mar-03	11,000	7,000	140	4	+	3	=	7	Excluding Normal Battery Depletion	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1	99.7 +0.2/-0.4	99.7 +0.2/-0.4	99.7 +0.2/-0.4 at 62 mo						
	see page 170 – Performance note on AT500 Pacing System Follow-Up Protocol										Including Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.7 +0.1/-0.2	97.0 +0.7/-1.0	61.1 +5.2/-5.7	53.7 +5.6/-6.0 at 62 mo						
Elite	7074, 7075, 7076, 7077	Apr-91	48,000	400	3,572	—		—		85	Excluding Normal Battery Depletion	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	
											Including Normal Battery Depletion	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	95.6 +0.2/-0.3	91.0 +0.4/-0.4	76.4 +0.7/-0.7	52.8 +1.1/-1.1	16.7 +2.5/-2.3 at 157 mo	
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	7,000	5,000	2	0	+	1	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 41 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 41 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
EnPulse DR	E1DR21	Dec-03	2,000	1,000	1	0	+	0	=	0	Excluding Normal Battery Depletion	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 40 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.1/-0.5	99.8 +0.1/-0.5 at 40 mo								
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	100,000	82,000	2	3	+	3	=	6	Excluding Normal Battery Depletion	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 39 mo								
											Including Normal Battery Depletion	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 39 mo								
EnPulse 2 DR	E2DR21	Feb-04	12,000	10,000	7	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0									
											Including Normal Battery Depletion	100.0 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.2									
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	1,000	1,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 25 mo									
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 25 mo									
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,000	19,000	3	1	+	2	=	3	Excluding Normal Battery Depletion	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 40 mo								
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.4	99.8 +0.1/-0.4 at 40 mo								
EnPulse 2 VDD	E2VDD01	Dec-03	1,000	1,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo									
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo									
EnRhythm DR	P1501DR	May-05	56,000	50,000	0	11	+	2	=	13	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 25 mo									
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 25 mo									
Kappa 400 DR	KDR401, KDR403	Jan-98	47,000	10,000	2,767	9	+	12	=	21	Excluding Normal Battery Depletion	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 103 mo			
											Including Normal Battery Depletion	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	97.7 +0.2/-0.2	90.8 +0.4/-0.5	62.8 +1.0/-1.0	10.3 +1.8/-1.6 at 103 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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 400 SR	KSR401, KSR403	Feb-98	15,000	4,000	383	1 + 3 = 4	Excluding Normal Battery Depletion	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 108 mo			
							Including Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.4 +0.1/-0.2	98.6 +0.3/-0.3	95.2 +0.6/-0.7	77.8 +1.7/-1.8	53.0 +3.7/-3.8 at 108 mo			
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	24,000	8,000	536	17 + 3 = 20	Excluding Normal Battery Depletion	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	99.9 +0.0/-0.1 at 97 mo			
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(11) + (0) = (11) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.0 +0.1/-0.2	97.1 +0.3/-0.3	91.3 +0.6/-0.6	76.8 +2.2/-2.4	76.8 +2.2/-2.4 at 97 mo			
Kappa 600 DR	KDR651, KDR653	Mar-01	14,000	7,000	75	2 + 2 = 4	Excluding Normal Battery Depletion	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	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 73 mo					
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(1) + (0) = (1) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.5 +0.1/-0.2	98.7 +0.2/-0.3	97.6 +0.4/-0.5	97.6 +0.4/-0.5 at 73 mo					
Kappa 700 D	KD701, KD703, KD706	Jan-99	300	100	4	0 + 0 = 0	Excluding Normal Battery Depletion	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 74 mo					
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(1) + (0) = (1) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.0 +0.8/-3.1	97.7 +1.4/-3.8	96.1 +2.2/-4.7	96.1 +2.2/-4.7 at 74 mo					
Kappa 700 DR	KDR701, KDR703, KDR706	Feb-99	192,000	94,000	2,818	172 + 27 = 199	Excluding Normal Battery Depletion	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	99.8 +0.0/-0.0	99.8 +0.0/-0.0	99.8 +0.0/-0.0	99.8 +0.0/-0.0 at 99 mo			
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(117) + (0) = (117) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.3 +0.0/-0.0	98.4 +0.1/-0.1	96.3 +0.1/-0.1	90.3 +0.3/-0.3	72.6 +1.0/-1.0	68.2 +1.6/-1.7 at 99 mo			
Kappa 700 DR	KDR721	Feb-99	10,000	2,000	698	4 + 1 = 5	Excluding Normal Battery Depletion	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 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 85 mo					
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(4) + (4) = (4) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.2	99.0 +0.2/-0.3	96.8 +0.4/-0.5	91.3 +0.7/-0.8	72.6 +1.5/-1.6	39.7 +3.2/-3.3	37.1 +3.5/-3.5 at 85 mo					
Kappa 700 SR	KSR701, KSR703, KSR706	Feb-99	55,000	22,000	724	6 + 3 = 9	Excluding Normal Battery Depletion	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/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 98 mo			
							Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.0 +0.1/-0.1	97.7 +0.2/-0.2	95.3 +0.3/-0.3	89.1 +0.7/-0.7	72.0 +2.3/-2.5	70.2 +2.8/-3.1 at 98 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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 VDD	KVDD701	Jan-99	2,000	1,000	51	3	0	3	Excluding Normal Battery Depletion	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	99.7 +0.2/-0.6	99.7 +0.2/-0.6	99.7 +0.2/-0.6 at 86 mo				
	Advisories: see page 162 – 2002 Potential Fractured Power Supply Wires					(3) (advisory-related subset)	(0)	(3)	Including Normal Battery Depletion	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	96.1 +1.1/-1.6	79.0 +3.9/-4.7	77.4 +4.3/-5.2 at 86 mo				
Kappa 800 DR	KDR801, KDR803	Jan-02	4,000	3,000	3	0	0	0	Excluding Normal Battery Depletion	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							
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.8 +0.1/-0.2	99.8 +0.1/-0.2 at 57 mo							
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,000	86,000	141	10	10	20	Excluding Normal Battery Depletion	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						
									Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.2 +0.1/-0.1	99.1 +0.2/-0.2 at 65 mo						
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	22,000	45	2	7	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.1	99.9 +0.1/-0.2	99.9 +0.1/-0.2 at 63 mo						
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.4 +0.1/-0.2	98.6 +0.3/-0.5	98.4 +0.5/-0.7 at 63 mo						
Kappa 900 VDD	KVDD901	Jan-02	1,000	400	0	0	0	0	Excluding Normal Battery Depletion	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 55 mo							
									Including Normal Battery Depletion	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 55 mo							
Kappa 920 DR	KDR921	Jan-02	16,000	10,000	99	1	0	1	Excluding Normal Battery Depletion	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 62 mo						
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.5 +0.1/-0.2	98.0 +0.3/-0.4	95.9 +0.6/-0.8	95.4 +0.9/-1.1 at 62 mo						
Legend	8416, 8417, 8417M, 8418, 8419	Aug-89	57,000	3,000	2,645	—	—	143	Excluding Normal Battery Depletion	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 205 mo
									Including Normal Battery Depletion	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	90.6 +0.4/-0.4	81.4 +0.6/-0.6	73.0 +0.7/-0.7	64.6 +0.9/-0.9	53.8 +2.1/-2.1 at 205 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
Legend II	8424, 8426, 8427	Nov-91	59,000	6,000	1,774	—	—	36	Excluding Normal Battery Depletion	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 183 mo
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.8 +0.1/-0.1	98.1 +0.1/-0.1	97.2 +0.2/-0.2	94.8 +0.3/-0.3	89.2 +0.4/-0.4	83.1 +0.6/-0.6	74.8 +0.9/-1.0	69.9 +1.6/-1.6 at 183 mo
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Dec-89	58,000	5,000	1,473	—	—	49	Excluding Normal Battery Depletion	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 216 mo
	Advisories: see page 167 - 1991 Potential Delayed Restoration of Permanent Settings					—	—	—	Including Normal Battery Depletion	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	95.2 +0.3/-0.3	91.9 +0.4/-0.4	87.2 +0.5/-0.5	83.9 +0.6/-0.6	81.1 +0.7/-0.7	74.8 +1.9/-2.0
Minuet	7107, 7108	Mar-92	17,000	2,000	582	—	—	4	Excluding Normal Battery Depletion	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	100.0 +0.0/-0.1	100.0 +0.0/-0.1	100.0 +0.0/-0.1 at 179 mo
									Including Normal Battery Depletion	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	82.7 +1.0/-1.1	73.3 +1.7/-1.8	70.8 +2.1/-2.3 at 179 mo
Preva D	7068	Nov-96	1,000	200	24	—	—	1	Excluding Normal Battery Depletion	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 109 mo			
									Including Normal Battery Depletion	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	93.0 +2.1/-3.0	92.3 +2.2/-3.1	84.1 +4.2/-5.5 at 109 mo			
Preva DR	7088, 7089	Jul-96	26,000	6,000	797	—	—	3	Excluding Normal Battery Depletion	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 128 mo		
									Including Normal Battery Depletion	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	96.6 +0.3/-0.3	93.4 +0.4/-0.5	74.4 +1.4/-1.5	65.6 +2.5/-2.6 at 128 mo		
Preva SR	8088, 8089	Jul-96	18,000	3,000	347	—	—	1	Excluding Normal Battery Depletion	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	100.0 +0.0/-0.1 at 127 mo		
									Including Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.3 +0.1/-0.2	98.6 +0.2/-0.3	97.5 +0.3/-0.4	95.3 +0.5/-0.5	93.2 +0.6/-0.7	79.9 +1.8/-1.9	74.7 +2.9/-3.2 at 127 mo		
Preva ST DR	7078	Nov-96	1,000	100	39	—	—	0	Excluding Normal Battery Depletion	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 109 mo			
									Including Normal Battery Depletion	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 +1.8/-2.7	89.1 +2.8/-3.7	76.9 +4.9/-6.0 at 109 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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
Prevail S	8085, 8086	Oct-95	4,000	1,000	20	—	—	1	Excluding Normal Battery Depletion	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	99.9 +0.1/-0.4 at 125 mo		
									Including Normal Battery Depletion	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.8 +0.1/-0.2	99.2 +0.3/-0.6	99.1 +0.4/-0.6	98.5 +0.6/-0.9	97.5 +0.8/-1.1	95.1 +1.5/-2.1	95.1 +1.5/-2.1 at 125 mo		
Prodigy D	7864, 7865, 7866	Oct-95	3,000	1,000	76	—	—	0	Excluding Normal Battery Depletion	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 127 mo		
									Including Normal Battery Depletion	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	97.8 +0.6/-0.8	97.1 +0.7/-1.0	96.0 +0.9/-1.2	82.3 +2.9/-3.4	76.8 +4.1/-4.9 at 127 mo		
Prodigy DR	7860, 7861, 7862	Oct-95	38,000	9,000	1,127	—	—	11	Excluding Normal Battery Depletion	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 131 mo		
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	98.9 +0.1/-0.1	98.1 +0.2/-0.2	96.6 +0.2/-0.3	93.2 +0.4/-0.4	75.0 +1.2/-1.3	62.1 +2.9/-3.0 at 131 mo		
Prodigy S	8164, 8165, 8166	Oct-95	2,000	400	23	—	—	0	Excluding Normal Battery Depletion	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 124 mo		
									Including Normal Battery Depletion	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	97.3 +1.0/-1.5	91.4 +2.5/-3.4	88.9 +3.2/-4.3 at 124 mo		
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,000	4,000	433	—	—	5	Excluding Normal Battery Depletion	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 129 mo		
									Including Normal Battery Depletion	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.9 +0.2/-0.2	98.2 +0.2/-0.2	97.3 +0.3/-0.3	95.9 +0.4/-0.4	93.4 +0.5/-0.6	81.3 +1.6/-1.7	73.9 +2.5/-2.7 at 129 mo		
Sensia DR	SEDR01, SED01	Jul-06	10,000	9,000	0	0	+ 0	= 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
									Including Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
Sensia SR	SESR01, SES01	Jul-06	6,000	6,000	0	0	+ 0	= 0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
									Including Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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
Sigma 100 S	SS103, SS106	Aug-99	1,000	200	3	0	0	0	Excluding Normal Battery Depletion	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 75 mo					
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.5 +0.3/-1.4	99.5 +0.3/-1.4	98.5 +1.0/-2.8	98.5 +1.0/-2.8	96.7 +1.9/-4.5 at 75 mo					
Sigma 200 DR	SDR203	Aug-99	16,000	8,000	34	3	1	4	Excluding Normal Battery Depletion	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 89 mo				
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(1)	(0)	(1) (advisory-related subset)	Including Normal Battery Depletion	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	99.1 +0.2/-0.3	98.2 +0.4/-0.6	98.0 +0.5/-0.7 at 89 mo				
Sigma 200 SR	SSR203	Sep-99	12,000	5,000	17	2	0	2	Excluding Normal Battery Depletion	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 at 89 mo				
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(2)	(0)	(2) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.2	99.5 +0.2/-0.2	99.4 +0.2/-0.3	98.7 +0.5/-0.8	98.7 +0.5/-0.8 at 89 mo				
Sigma 300 DR	SDR303, SDR306	Aug-99	104,000	62,000	111	54	8	62	Excluding Normal Battery Depletion	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 92 mo				
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(26)	(1)	(27) (advisory-related subset)	Including Normal Battery Depletion	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	99.2 +0.1/-0.1	98.5 +0.2/-0.2	98.4 +0.2/-0.3 at 92 mo				
Sigma 300 SR	SSR303, SSR306	Sep-99	52,000	25,000	60	11	1	12	Excluding Normal Battery Depletion	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 90 mo				
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(5)	(0)	(5) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.0 +0.2/-0.2	98.3 +0.4/-0.5	98.3 +0.4/-0.5 at 90 mo				
Sigma 300 VDD	SVDD303	Sep-99	1,000	300	0	0	0	0	Excluding Normal Battery Depletion	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 73 mo					
	Advisories: see page 160 – 2005 Potential Separation of Interconnect Wires					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	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 73 mo					
Thera D	7944, 7945, 7946	Jan-95	2,000	0	175	—	—	2	Excluding Normal Battery Depletion	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			
									Including Normal Battery Depletion	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	47.0 +4.9/-5.1 at 111 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
Thera DR-40	7940, 7941, 7942	Jan-95	30,000	1	3,027	—	—	37	Excluding Normal Battery Depletion	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			
									Including Normal Battery Depletion	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	88.7 +0.5/-0.5	80.7 +0.6/-0.6	66.2 +0.9/-0.9	17.7 +2.7/-2.5 at 113 mo			
Thera DR-50	7950, 7951, 7952	Jan-95	5,000	400	236	—	—	1	Excluding Normal Battery Depletion	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 143 mo		
						—	—	—	Including Normal Battery Depletion	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	95.9 +0.7/-0.9	86.6 +1.6/-1.8	54.9 +4.0/-4.2 at 143 mo		
Thera S	8944, 8945, 8946	Jan-95	3,000	100	84	—	—	3	Excluding Normal Battery Depletion	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 136 mo		
									Including Normal Battery Depletion	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	70.0 +4.1/-4.6	66.4 +4.5/-5.0 at 136 mo		
Thera SR	8940, 8941, 8942	Jan-95	14,000	200	818	—	—	16	Excluding Normal Battery Depletion	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 139 mo		
						—	—	—	Including Normal Battery Depletion	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	87.7 +0.8/-0.9	77.1 +1.2/-1.3	53.3 +2.2/-2.2	46.6 +2.5/-2.6 at 139 mo		
Thera-i D	7964i, 7965i, 7966i	Oct-95	3,000	1,000	114	—	—	1	Excluding Normal Battery Depletion	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 132 mo		
									Including Normal Battery Depletion	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	97.6 +0.6/-0.8	96.3 +0.8/-1.0	93.8 +1.1/-1.4	80.4 +2.5/-2.9	70.3 +4.1/-4.6 at 132 mo		
Thera-i DR	7960i, 7961i, 7962i	Oct-95	122,000	22,000	5,227	—	—	50	Excluding Normal Battery Depletion	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 137 mo		
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.5 +0.0/-0.0	99.0 +0.1/-0.1	98.2 +0.1/-0.1	96.6 +0.1/-0.1	93.1 +0.2/-0.2	73.7 +05/-0.5	47.4 +2.4/-2.4 at 137 mo		
Thera-i DR	7968i	Jul-96	4,000	400	216	—	—	3	Excluding Normal Battery Depletion	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 112 mo			
									Including Normal Battery Depletion	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	88.8 +1.4/-1.6	76.7 +2.3/-2.5	54.7 +4.2/-4.4 at 112 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

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 S	8964i, 8965i, 8966i	Oct-95	4,000	1,000	45	—		—		1	Excluding Normal Battery Depletion	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 132 mo		
											Including Normal Battery Depletion	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	96.4 +0.9/-1.2	92.8 +1.5/-1.8	88.6 +2.5/-3.2 at 132 mo		
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	8,000	1,133	—		—		7	Excluding Normal Battery Depletion	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 137 mo		
											Including Normal Battery Depletion	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	97.0 +0.2/-0.2	94.7 +0.3/-0.3	83.1 +0.8/-0.8	69.6 +2.1/-2.3 at 137 mo		
Thera-i VDD	8968i	Mar-96	5,000	1,000	67	—		—		0	Excluding Normal Battery Depletion	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 130 mo		
											Including Normal Battery Depletion	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	98.5 +0.4/-0.6	90.6 +1.7/-2.1	83.6 +3.0/-3.6 at 130 mo		
Versa DR	VEDR01	Jul-06	11,000	10,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											
											Including Normal Battery Depletion	100.0 +0.0/-0.0 at 8 mo											

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2007

Reference Chart

The longevity estimates provided are mean values calculated for the parameters given. 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.**

Family	Model Number	Estimated Longevity			Elective Replacement Indicators
		Amplitude Setting	500 Lead Ω	1000 Lead Ω	
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.3 6.0	**
Adapta DR	ADDRS1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	5.5 4.3 3.2	6.1 5.4 4.4	**
Adapta DR	ADDRL1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.1 7.4 5.4	10.1 9.0 7.3	**
Adapta SR	ADSR01, ADSR03, ADSR06	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.3 6.4 5.0	7.8 7.4 6.2	**
Adapta VDD	ADVDD01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	6.2 5.5 4.4	6.5 6.2 5.4	**
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	**
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	**

**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 Indicators
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	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	**
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	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	**

continued

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

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
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	**
Prevail S	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	**
Sensia DR	SEDR01, SED01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.1 4.5	8.3 7.4 6.0	**
Sensia DR	SEDRL1	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.1 7.4 5.4	10.1 9.0 7.3	**
Sensia SR	SESR01, SES01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.3 6.4 5.0	7.8 7.4 6.2	**
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	**

**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 Indicators
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	**
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	**
Versa DR	VEDR01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.5 6.1 4.5	8.3 7.4 6.0	**

**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

Implanted leads operate in the challenging biochemical environment of the human body and the body's response to foreign objects. Implanted leads are also subject to mechanical stresses associated with heart motion, body motion, and patient anatomy.

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 a 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 returned product 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 70,000 leads studied. More than 19,000 of these leads are currently active.

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 CRT, ICD, or IPG 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

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 United States, based on estimated US implants.

Chronic Lead Data Resolution

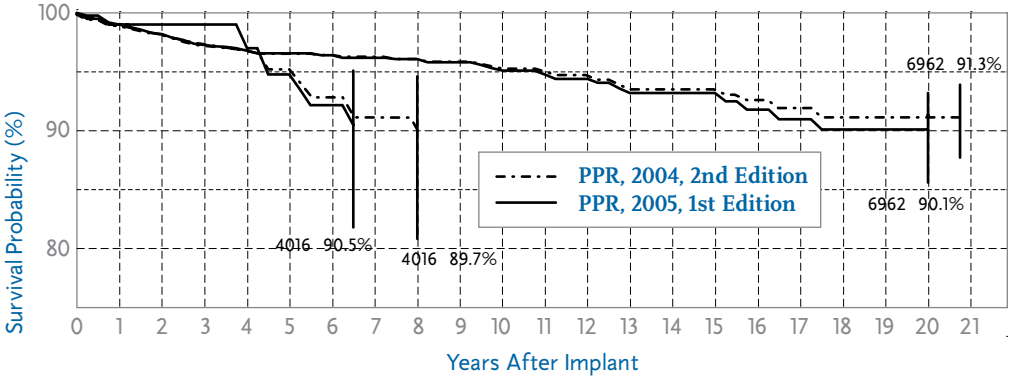
Because an accurate estimate of lead survival depends on an accurate estimate of the number of leads in service, it is important not to overstate the number of devices in service. Since the inception of the CLS and TCSS studies, the mechanism of patient follow-up has changed due to evolution in hospital 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.

Returned Product Analysis Results

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

For reporting returned product 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 returned product analysis 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 Returned Product Analysis 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 Returned Product Analysis tables are the actual numbers confirmed in the returned product analysis. 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. Returned Product Analysis 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	17,200	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Estimated US Active	10,700	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

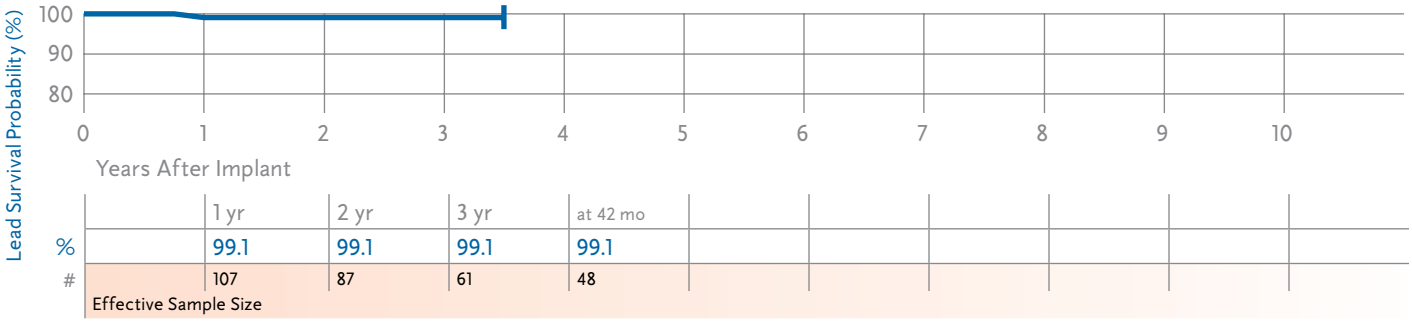
Implant Damage	7
Electrical Malfunction	0
Other	16

System Longevity Study Results

Number of Leads Enrolled in Study	133
Cumulative Months of Follow-Up	5,162

Qualifying Complications 1 Total

Failure to Capture	1



	1 yr	2 yr	3 yr	at 42 mo
%	99.1	99.1	99.1	99.1
#	107	87	61	48

Effective Sample Size

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	1,500	Polarity	Bipolar
Advisories	None	Steroid	No

Returned Product Analysis

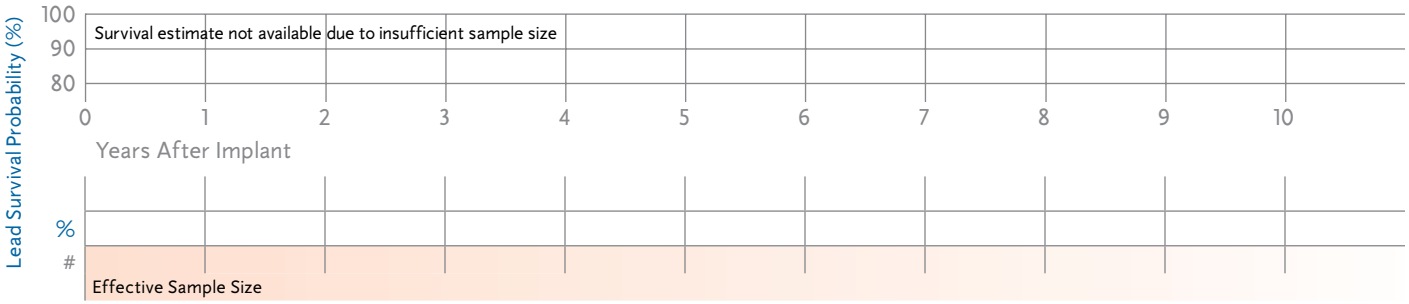
Implant Damage	1
Electrical Malfunction	1
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	14
Cumulative Months of Follow-Up	356

Qualifying Complications 1 Total

Extra Cardiac Stimulation	1



%	
#	

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Left-Heart Leads continued

4193 Attain

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Estimated US Implants	104,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated US Active	78,600	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	59
Electrical Malfunction	17
Other	63

System Longevity Study Results

Number of Leads Enrolled in Study	671
Cumulative Months of Follow-Up	17,788

Qualifying Complications 28 Total

Conductor Fracture	1
Extra Cardiac Stimulation	4
Failure to Capture	9
Lead Dislodgement	11
Unspecified Clinical Failure	3

	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	95.9	95.5	95.2	95.2	95.2
#	463	339	216	86	42

Effective Sample Size

4194 Attain

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Estimated US Implants	57,600	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated US Active	50,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	62
Electrical Malfunction	1
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	318
Cumulative Months of Follow-Up	4,693

Qualifying Complications 3 Total

Failure to Capture	1
Lead Dislodgement	2

	1 yr	2 yr
%	100.0	97.1
#	157	49

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Left-Heart Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Qualifying Complications	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	133	1	5,162	99.1 +0.8/-5.3	99.1 +0.8/-5.3	99.1 +0.8/-5.3	99.1 +0.8/-5.3 at 42 mo						
2188	Attain	Aug-01	14	1	356	Survival estimate not available due to insufficient sample size									
4193	Attain	May-02	671	28	17,788	95.9 +1.4/-1.9	95.5 +1.4/-2.1	95.2 +1.5/-2.2	95.2 +1.5/-2.2	95.2 +1.5/-2.2 at 54 mo					
4194	Attain	Aug-04	318	3	4,693	100.0	97.1 +2.0/-6.4								

Source: System Longevity Study
Data as of January 31, 2007

Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
2187	Attain	Aug-01	17,200	10,700	7	0	16
2188	Attain	Aug-01	2,800	1,500	1	1	0
4193	Attain	May-02	104,700	78,600	59	17	63
4194	Attain	Aug-04	57,600	50,500	62	1	6

Source: Returned Product Analysis
Data as of January 31, 2007

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	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	9,000	Type and/or Fixation	Epicardial Defib Patch, Suture
Estimated US Active	2,100	Polarity	Defib Electrode only
Advisories	None	Steroid	No

Returned Product Analysis

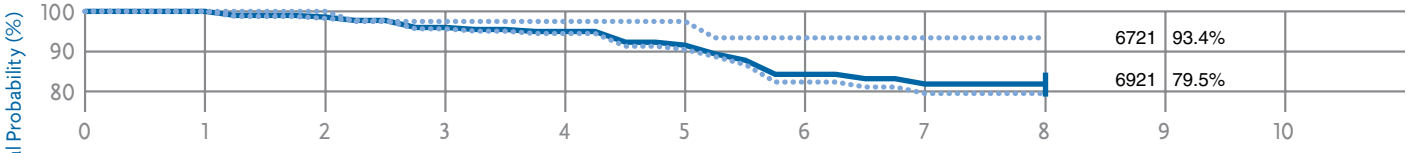
Implant Damage	5
Electrical Malfunction	79
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	407
Cumulative Months of Follow-Up	18,070

Qualifying Complications 28 Total

Conductor Fracture	20
Failure to Capture	2
Impedance Out of Range	3
Insulation (not further defined)	3



Years After Implant — Lead Group Overall — Individual Lead Models

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	100.0	98.6	96.0	95.0	91.6	84.3	81.9	81.9
#	297	248	192	151	124	81	60	49

Effective Sample Size of Lead Group Overall

6930 Sprint Fidelis

Product Characteristics

US Market Release	Jun-04	Serial Number Prefix	LFK
Estimated US Implants	300	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated US Active	300	Polarity	True Bipolar/One Coil
Advisories	1	Steroid	Yes

see page 159 – 2007 Potential Conductor Wire Fracture

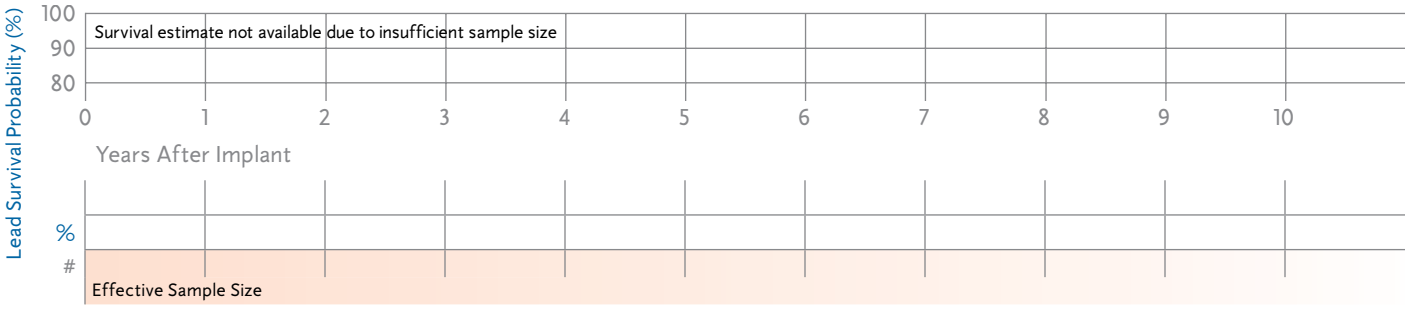
Returned Product Analysis

Implant Damage	0
Electrical Malfunction	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1
Cumulative Months of Follow-Up	4

Qualifying Complications 0 Total



Years After Implant

%								
#								

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Defibrillation Leads continued

6931 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFL
Estimated US Implants	7,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Estimated US Active	6,300	Polarity	True Bipolar/One Coil
Advisories	1	Steroid	Yes

see page 159 – 2007 Potential Conductor Wire Fracture

Returned Product Analysis

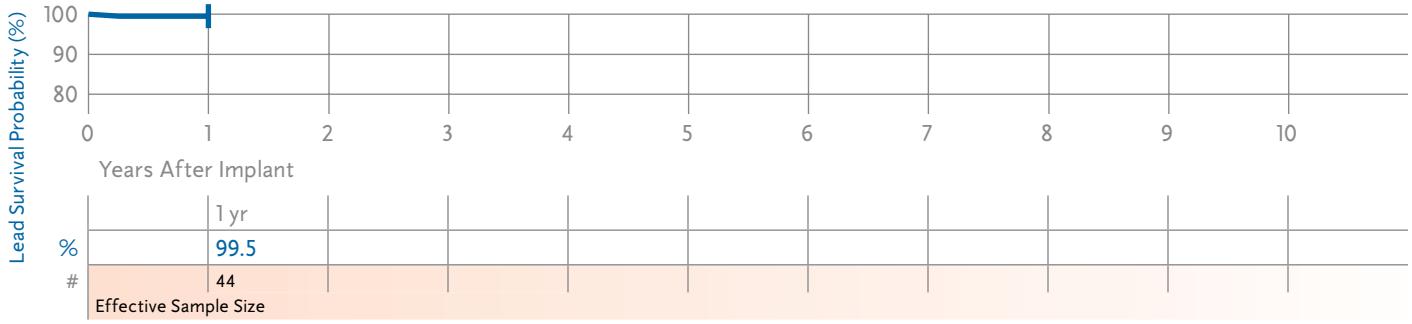
Implant Damage	19
Electrical Malfunction	39
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	212
Cumulative Months of Follow-Up	2,195

Qualifying Complications 1 Total

Lead Dislodgement	1



	1 yr
%	99.5
#	44

Effective Sample Size

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	6,500	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Returned Product Analysis

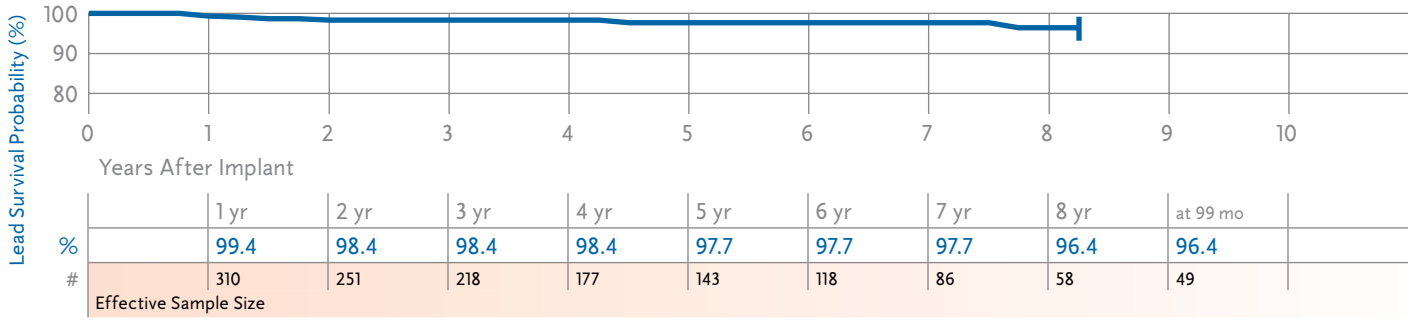
Implant Damage	16
Electrical Malfunction	37
Other	7

System Longevity Study Results

Number of Leads Enrolled in Study	410
Cumulative Months of Follow-Up	19,557

Qualifying Complications 8 Total

Extra Cardiac Stimulation	1
Failure to Capture	2
Failure to Sense	2
Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.4	98.4	98.4	98.4	97.7	97.7	97.7	96.4	96.4
#	310	251	218	177	143	118	86	58	49

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	17,400	Type and/or Fixation	Transvenous CS or SVC Defib
Estimated US Active	5,600	Polarity	One Defib Coil
Advisories	None	Steroid	No

Returned Product Analysis

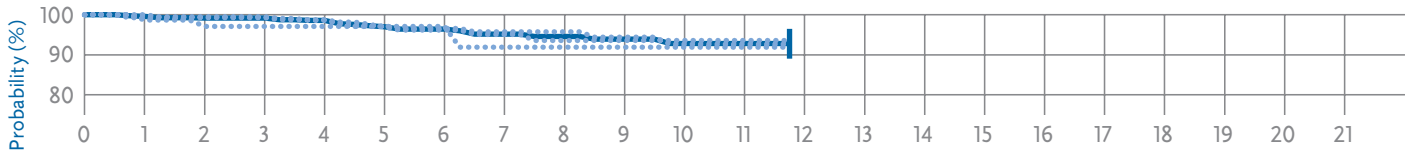
Implant Damage	31
Electrical Malfunction	192
Other	13

System Longevity Study Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	47,123

Qualifying Complications 23 Total

Conductor Fracture	14
Failure to Capture	1
Impedance Out of Range	2
Insulation (not further defined)	2
Lead Dislodgement	1
Unspecified Clinical Failure	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 141 mo
%	99.6	99.2	99.2	98.6	97.0	96.4	95.2	94.6	93.9	92.8	92.8	92.8
#	720	596	497	408	326	246	183	139	97	70	58	49

Effective Sample Size

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	5,900	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	No

Returned Product Analysis

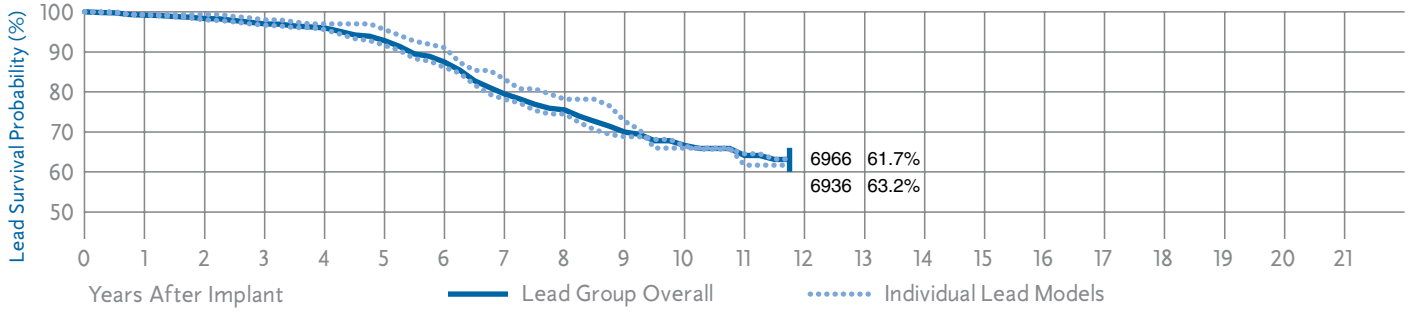
Implant Damage	90
Electrical Malfunction	457
Other	19

System Longevity Study Results

Number of Leads Enrolled in Study	1,349
Cumulative Months of Follow-Up	66,656

Qualifying Complications 143 Total

Conductor Fracture	17
Extra Cardiac Stimulation	2
Failure to Capture	8
Failure to Sense	4
Impedance Out of Range	4
Insulation (not further defined)	13
Oversensing	90
Unspecified Clinical Failure	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 141 mo
%	99.2	98.4	97.0	96.0	92.8	87.5	79.5	75.5	70.0	66.6	64.1	63.1
#	1,042	861	710	580	471	352	249	195	138	94	67	48

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	900	Polarity	Defib Electrode Only
Advisories	None	Steroid	No

Returned Product Analysis

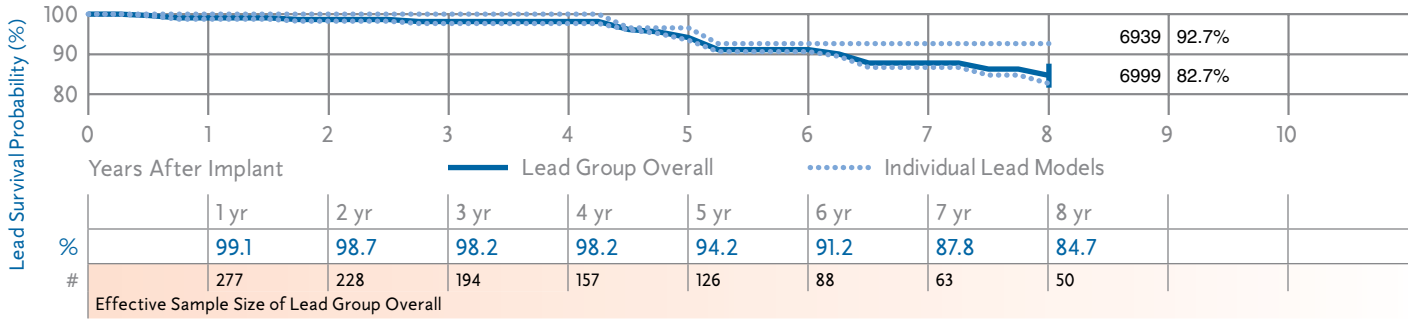
Implant Damage	4
Electrical Malfunction	32
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	384
Cumulative Months of Follow-Up	17,668

Qualifying Complications 20 Total

Conductor Fracture	10
Failure to Capture	2
Insulation (not further defined)	6
Unspecified Clinical Failure	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.1	98.7	98.2	98.2	94.2	91.2	87.8	84.7
#	277	228	194	157	126	88	63	50

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	8,300	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

Returned Product Analysis

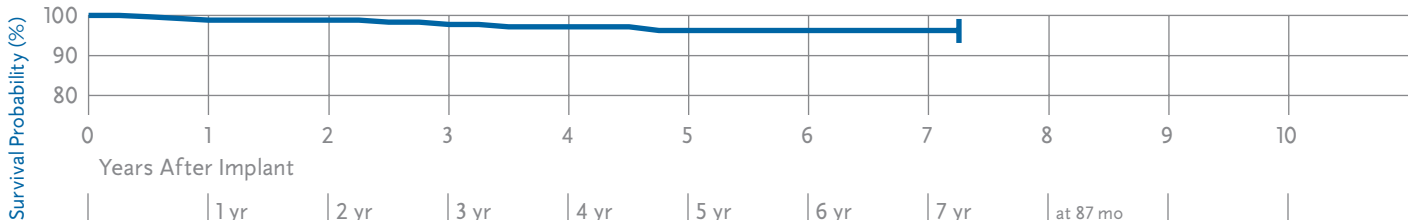
Implant Damage	31
Electrical Malfunction	37
Other	5

System Longevity Study Results

Number of Leads Enrolled in Study	352
Cumulative Months of Follow-Up	14,621

Qualifying Complications 7 Total

Conductor Fracture	1
Failure to Sense	1
Lead Dislodgement	1
Oversensing	3
Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 87 mo
%	98.9	98.9	97.8	97.2	96.3	96.3	96.3	96.3
#	247	200	155	128	108	84	61	53

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	9,900	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

Returned Product Analysis

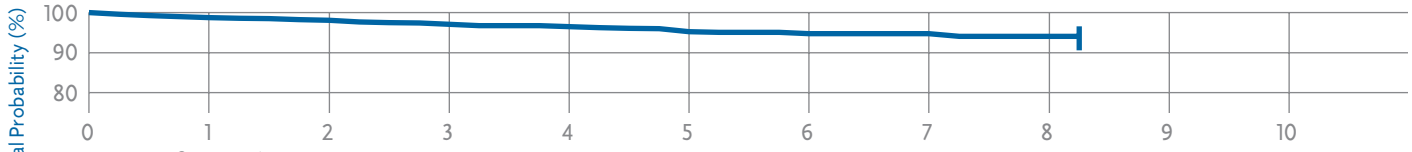
Implant Damage	50
Electrical Malfunction	63
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	1,309
Cumulative Months of Follow-Up	60,060

Qualifying Complications 45 Total

Conductor Fracture	8
Failure to Capture	4
Failure to Sense	3
Impedance Out of Range	3
Insulation (not further defined)	1
Lead Dislodgement	1
Oversensing	22
Unspecified Clinical Failure	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	98.8	98.1	97.1	96.5	95.3	94.8	94.8	94.1	94.1
#	1,073	942	770	577	414	258	140	66	47

Effective Sample Size

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Estimated US Implants	28,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated US Active	18,700	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Returned Product Analysis

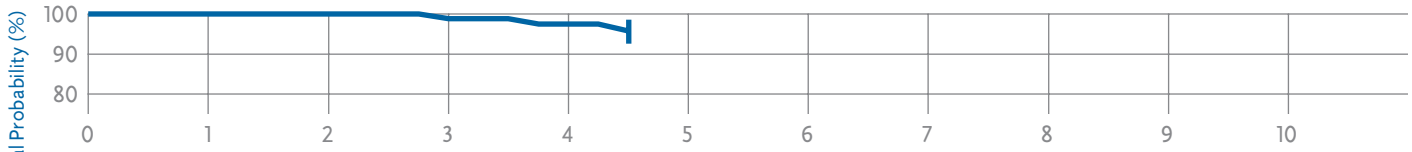
Implant Damage	23
Electrical Malfunction	31
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	170
Cumulative Months of Follow-Up	6,374

Qualifying Complications 3 Total

Oversensing	2
Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	100.0	100.0	98.9	97.5	95.8
#	124	104	83	62	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	21,800	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

Returned Product Analysis

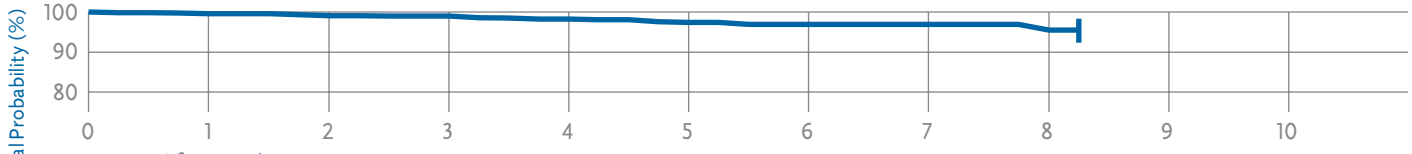
Implant Damage	197
Electrical Malfunction	90
Other	11

System Longevity Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	51,615

Qualifying Complications 20 Total

Conductor Fracture	2	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Oversensing	9
Failure to Capture	1	Unspecified Clinical Failure	1
Failure to Sense	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.6	99.1	99.0	98.3	97.4	96.9	96.9	95.5	95.5
#	912	746	623	489	383	274	153	58	47

Effective Sample Size

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Estimated US Implants	130,500	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated US Active	92,300	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

Returned Product Analysis

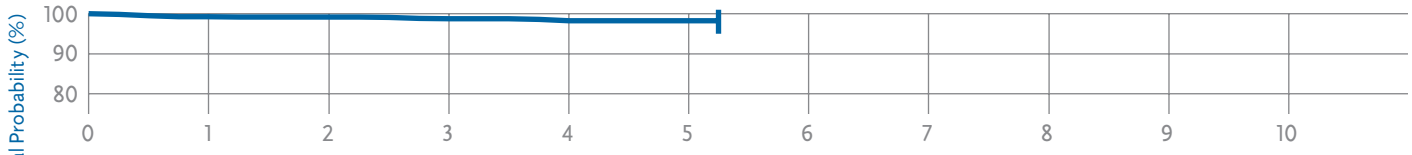
Implant Damage	228
Electrical Malfunction	90
Other	12

System Longevity Study Results

Number of Leads Enrolled in Study	1,354
Cumulative Months of Follow-Up	45,712

Qualifying Complications 15 Total

Conductor Fracture	2	Lead Dislodgement	3
Failure to Sense	1	Oversensing	5
Impedance Out of Range	1	Unspecified Clinical Failure	2
Insulation (not further defined)	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.3	99.2	98.8	98.3	98.3	98.3
#	1,059	906	652	320	82	40

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Defibrillation Leads continued

6948 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFH
Estimated US Implants	9,500	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Tines
Estimated US Active	8,500	Polarity	True Bipolar/Two Coils
Advisories	1	Steroid	Yes

see page 159 – 2007 Potential Conductor Wire Fracture

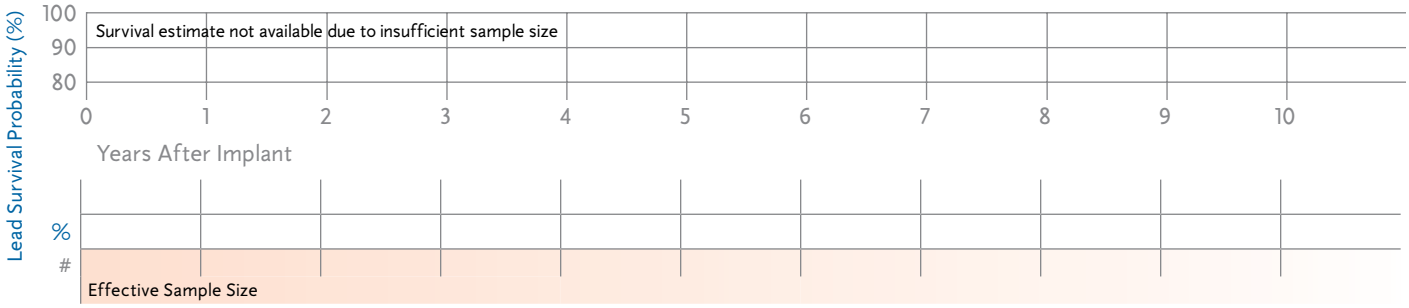
Returned Product Analysis

Implant Damage	8
Electrical Malfunction	5
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	24
Cumulative Months of Follow-Up	328

Qualifying Complications 0 Total



6949 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFJ
Estimated US Implants	174,600	Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Estimated US Active	152,100	Polarity	True Bipolar/Two Coils
Advisories	1	Steroid	Yes

see page 159 – 2007 Potential Conductor Wire Fracture

Returned Product Analysis

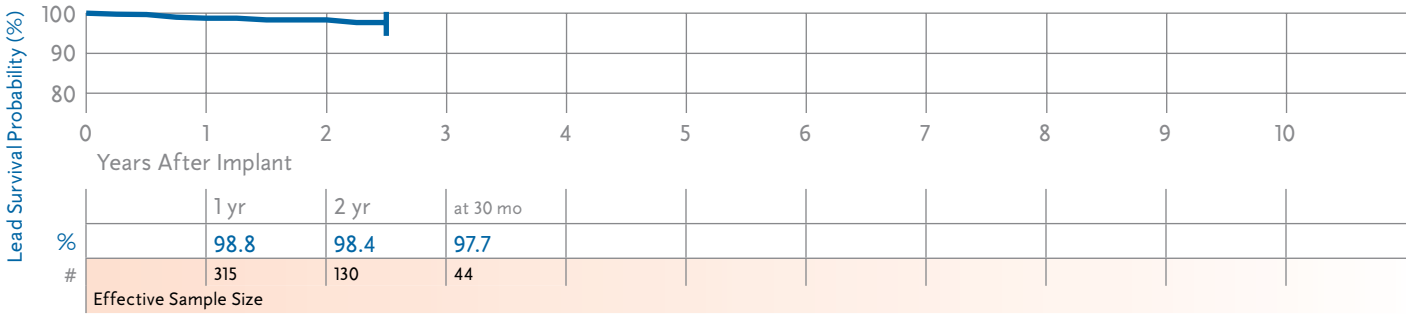
Implant Damage	420
Electrical Malfunction	468
Other	38

System Longevity Study Results

Number of Leads Enrolled in Study	654
Cumulative Months of Follow-Up	9,894

Qualifying Complications 9 Total

Conductor Fracture	1	Oversensing	4
Failure to Capture	2		
Failure to Sense	1		
Lead Dislodgement	1		



Source: System Longevity Study
Data as of July 31, 2007

Defibrillation Leads continued

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Estimated US Implants	2,200	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated US Active	1,800	Polarity	One Defib Coil
Advisories	None	Steroid	No

Returned Product Analysis

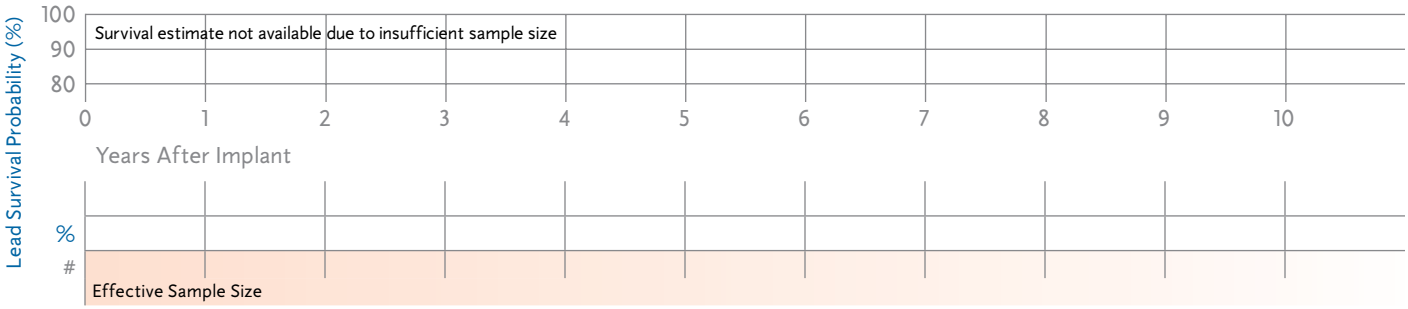
Implant Damage	0
Electrical Malfunction	2
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	12
Cumulative Months of Follow-Up	182

Qualifying Complications

0 Total



Source: System Longevity Study
Data as of July 31, 2007

Defibrillation Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Qualifying Complications	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
6721, 6921	Epicardial Patch	Feb-93	407	28	18,070	100.0	98.6 +0.9/-2.3	96.0 +1.9/-3.3	95.0 +2.1/-3.8	91.6 +3.2/-4.9	84.3 +5.0/-7.0	81.9 +5.6/-7.7	81.9 +5.6/-7.7		
6930	Sprint Fidelis	Jun-04	1	—	4	Survival estimate not available due to insufficient sample size									
	Advisories: see page 159 - 2007 Potential Conductor Wire Fracture														
6931	Sprint Fidelis	Sep-04	212	1	2,195	99.5 +0.4/-3.0									
	Advisories: see page 159 - 2007 Potential Conductor Wire Fracture														
6932	Sprint	Aug-96	410	8	19,557	99.4 +0.4/-1.8	98.4 +0.9/-2.3	98.4 +0.9/-2.3	98.4 +0.9/-2.3	97.7 +1.3/-2.8	97.7 +1.3/-2.8	97.7 +1.3/-2.8	96.4 +2.1/-5.1	96.4 +2.1/-5.1 at 99 mo	
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	966	23	47,123	99.6 +0.3/-0.8	99.2 +0.4/-1.0	99.2 +0.4/-1.0	98.6 +0.7/-1.4	97.0 +1.2/-2.0	96.4 +1.4/-2.2	95.2 +1.8/-2.8	94.6 +2.0/-3.1	92.8 +2.8/-4.6	92.8 +2.8/-4.6 at 141 mo
6936, 6966	Transvene	Dec-93	1,349	143	66,656	99.2 +0.4/-0.7	98.4 +0.6/-1.0	97.0 +0.9/-1.3	96.0 +1.1/-1.6	92.8 +1.7/-2.2	87.5 +2.4/-3.1	79.5 +3.5/-4.0	75.5 +3.9/-4.5	66.6 +5.0/-5.6	63.1 +5.7/-6.5 at 141 mo
6939, 6999	Sub-Q Patch	Dec-93	384	20	17,668	99.1 +0.6/-2.0	98.7 +0.8/-2.3	98.2 +1.1/-2.6	98.2 +1.1/-2.6	94.2 +2.6/-4.8	91.2 +3.5/-5.7	87.8 +4.6/-7.0	84.7 +5.6/-8.6		
6942	Sprint	Jul-97	352	7	14,621	98.9 +0.8/-2.2	98.9 +0.8/-2.2	97.8 +1.3/-3.1	97.2 +1.5/-3.6	96.3 +2.0/-4.2	96.3 +2.0/-4.2	96.3 +2.0/-4.2	96.3 +2.0/-4.2 at 87 mo		
6943	Sprint	Oct-97	1,309	45	60,060	98.8 +0.5/-0.8	98.1 +0.6/-1.0	97.1 +0.8/-1.3	96.5 +1.0/-1.4	95.3 +1.3/-1.7	94.8 +1.4/-2.0	94.8 +1.4/-2.0	94.1 +1.8/-2.5	94.1 +1.8/-2.5 at 99 mo	
6944	Sprint Quattro	Dec-00	170	3	6,374	100.0	100.0	98.9 +0.9/-6.6	97.5 +1.9/-7.2	95.8 +2.8/-8.6 at 54 mo					
6945	Sprint	Sep-97	1,158	20	51,615	99.6 +0.2/-0.7	99.1 +0.5/-0.9	99.0 +0.5/-1.0	98.3 +0.7/-1.2	97.4 +1.0/-1.6	96.9 +1.1/-1.9	96.9 +1.1/-1.9	95.5 +2.2/-4.1	95.5 +2.2/-4.1 at 99 mo	
6947	Sprint Quattro Secure	Nov-01	1,354	15	45,712	99.3 +0.3/-0.7	99.2 +0.4/-0.7	98.8 +0.5/-0.9	98.3 +0.7/-1.2	98.3 +0.7/-1.2	98.3 +0.7/-1.2 at 63 mo				
6948	Sprint Fidelis	Sep-04	24	0	328	Survival estimate not available due to insufficient sample size									
	Advisories: see page 159 - 2007 Potential Conductor Wire Fracture														
6949	Sprint Fidelis	Sep-04	654	9	9,894	98.8 +0.7/-1.5	98.4 +0.9/-1.8	97.7 +1.3/-3.0 at 30 mo							
	Advisories: see page 159 - 2007 Potential Conductor Wire Fracture														
6996	Sub-Q Lead	Jun-01	12	0	182	Survival estimate not available due to insufficient sample size									

Source: System Longevity Study
Data as of July 31, 2007

Defibrillation Leads continued

Returned Product 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	9,000	2,100	5	79	0
6930	Sprint Fidelis	Jun-04	300	300	0	0	0
6931	Sprint Fidelis	Sep-04	7,100	6,300	19	39	0
6932	Sprint	Aug-96	15,300	6,500	16	37	7
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	17,400	5,600	31	192	13
6936, 6966	Transvene	Dec-93	24,600	5,900	90	457	19
6939, 6999	Sub-Q Patch	Dec-93	4,300	900	4	32	1
6942	Sprint	Jul-97	18,100	8,300	31	37	5
6943	Sprint	Oct-97	21,300	9,900	50	63	8
6944	Sprint Quattro	Dec-00	28,600	18,700	23	31	8
6945	Sprint	Sep-97	44,000	21,800	197	90	11
6947	Sprint Quattro Secure	Nov-01	130,500	92,300	228	90	12
6948	Sprint Fidelis	Sep-04	9,500	8,500	8	5	3
6949	Sprint Fidelis	Sep-04	174,600	152,100	420	468	38
6996	Sub-Q Lead	Jun-01	2,200	1,800	0	2	0

Source: Returned Product Analysis
Data as of July 31, 2007

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	7,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	6,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	13
Electrical Malfunction	1
Other	1

Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	142
Cumulative Months of Follow-Up	4,285

Qualifying Complications 1 Total

Failure to Sense	1

	1 yr	2 yr	3 yr	at 42 mo
%	99.3	99.3	99.3	99.3
#	101	81	50	49

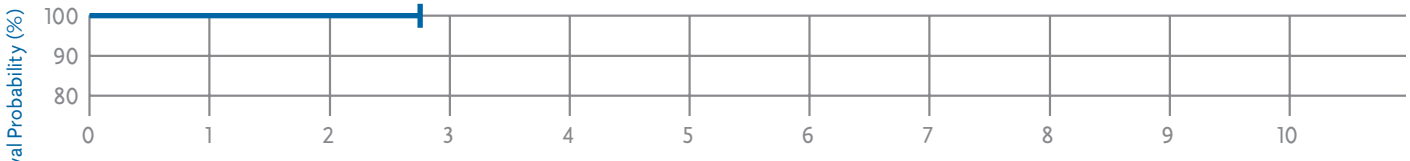
Effective Sample Size

Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	135
Cumulative Months of Follow-Up	4,241

Qualifying Complications 0 Total



	1 yr	2 yr	at 33 mo
%	100.0	100.0	100.0
#	100	79	54

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	7,100	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	24
Electrical Malfunction	57
Other	2

Ventricular Placement

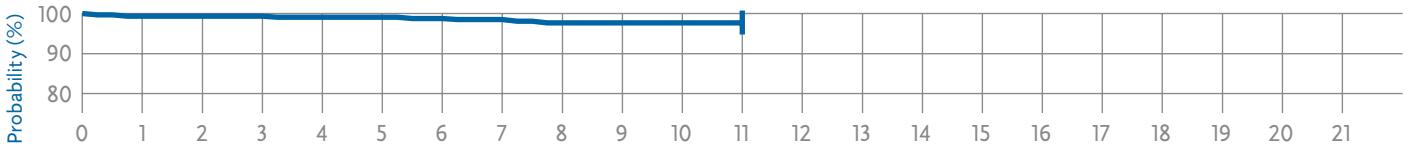
System Longevity Study Results

Number of Leads Enrolled in Study	711
Cumulative Months of Follow-Up	44,869

Qualifying Complications

10 Total

Extra Cardiac Stimulation	2
Failure to Capture	6
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.4	99.4	99.4	99.1	99.1	98.8	98.5	97.7	97.7	97.7	97.7
#	556	481	438	376	328	297	248	219	183	120	56

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	2,800	Polarity	Bipolar
Advisories	1	Steroid	Yes

see page 165 – 1993 Lead Survival Below Expectations

Returned Product Analysis

Implant Damage	55
Electrical Malfunction	683
Other	19

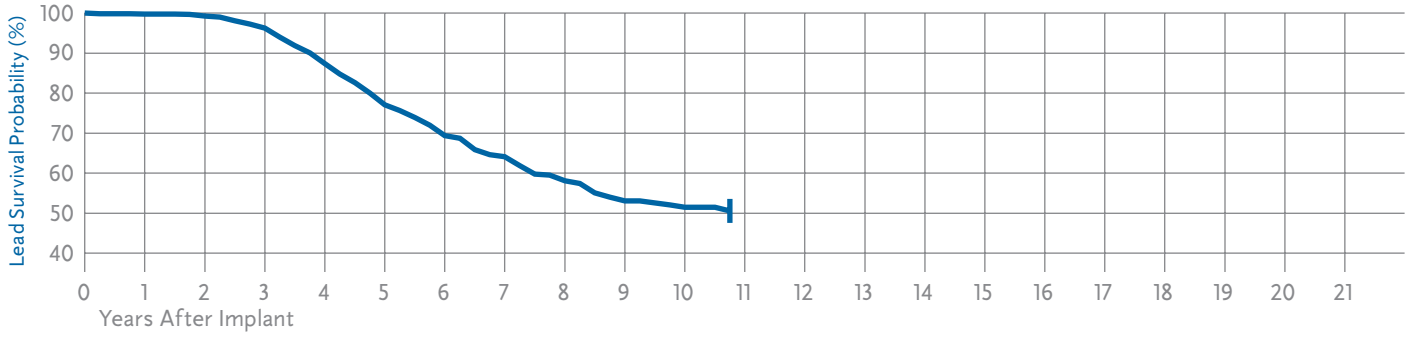
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,640
Cumulative Months of Follow-Up	71,581

Qualifying Complications 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	87.4	77.1	69.4	64.1	58.1	53.1	51.5	50.6
#	1,192	1,020	824	630	453	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	7,200	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	29
Electrical Malfunction	141
Other	5

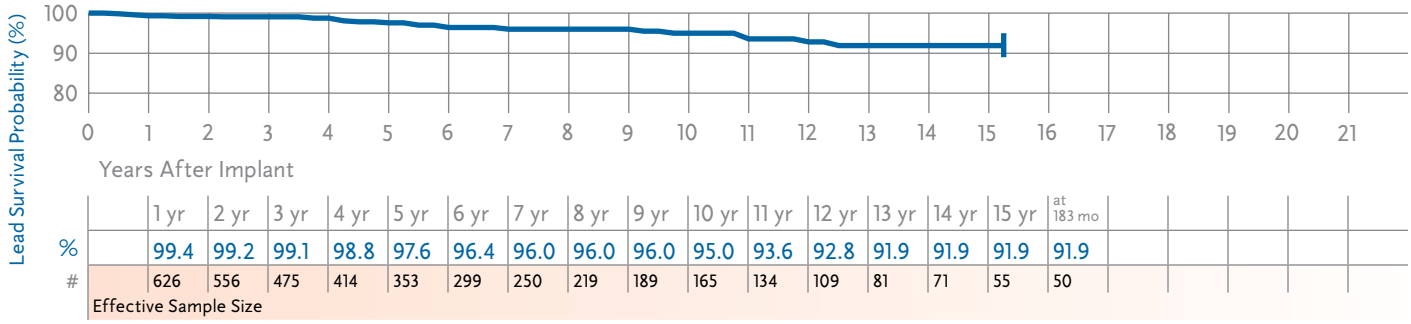
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	851
Cumulative Months of Follow-Up	54,376

Qualifying Complications 25 Total

Conductor Fracture	1	Oversensing	1
Extra Cardiac Stimulation	4		
Failure to Capture	9		
Insulation (not further defined)	10		



	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	96.0	96.0	96.0	95.0	93.6	92.8	91.9	91.9	91.9	91.9
#	626	556	475	414	353	299	250	219	189	165	134	109	81	71	55	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	5,700	Polarity	Bipolar
Advisories	1	Steroid	No

see page 166 – 1991 Lead Survival Below Expectations

Returned Product Analysis

Implant Damage	50
Electrical Malfunction	820
Other	34

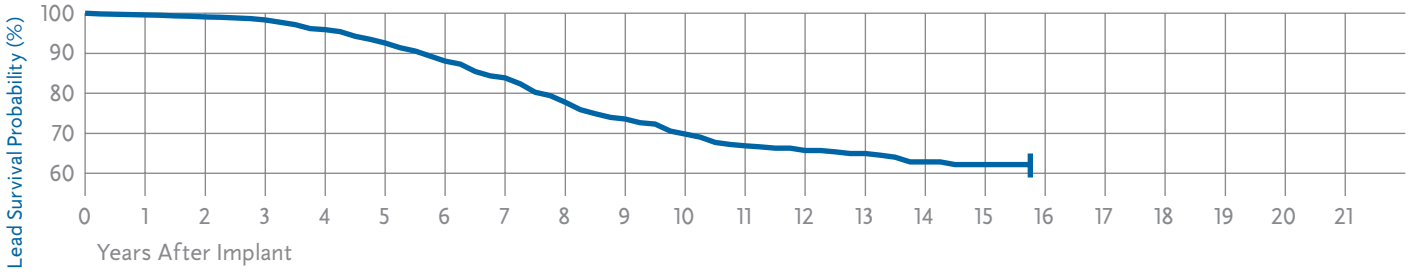
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,543
Cumulative Months of Follow-Up	150,950

Qualifying Complications 316 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	77	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	99.1	98.4	95.9	92.6	88.1	83.9	77.8	73.6	69.8	66.9	65.7	65.0	62.9	62.2	62.2
#	1,935	1,714	1,528	1,310	1,084	888	698	522	400	307	243	200	144	98	69	51

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	14,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	48
Electrical Malfunction	19
Other	6

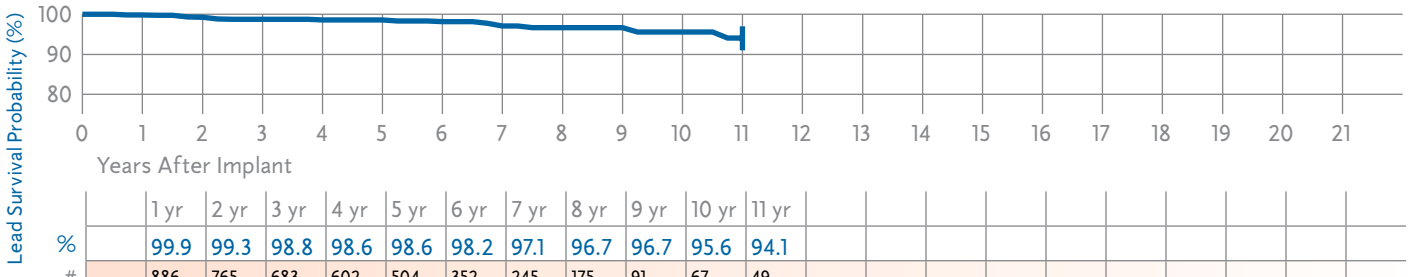
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	60,527

Qualifying Complications 19 Total

Extra Cardiac Stimulation	1	Lead Dislodgement	2
Failure to Capture	14		
Impedance Out of Range	1		
Insulation (not further defined)	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.9	99.3	98.8	98.6	98.6	98.2	97.1	96.7	96.7	95.6	94.1
#	886	765	683	602	504	352	245	175	91	67	49

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	84,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	264
Electrical Malfunction	103
Other	34

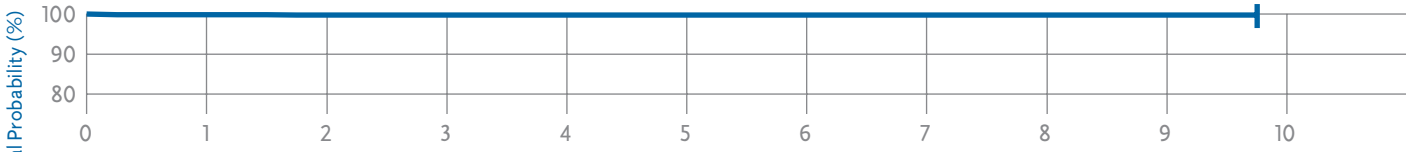
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	51,157

Qualifying Complications 3 Total

Failure to Capture	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8
#	871	685	556	417	324	244	190	128	61	49

Effective Sample Size

4033 CapSure Z

Product Characteristics

US Market Release	not US released	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

Returned Product Analysis

Implant Damage	2
Electrical Malfunction	0
Other	0

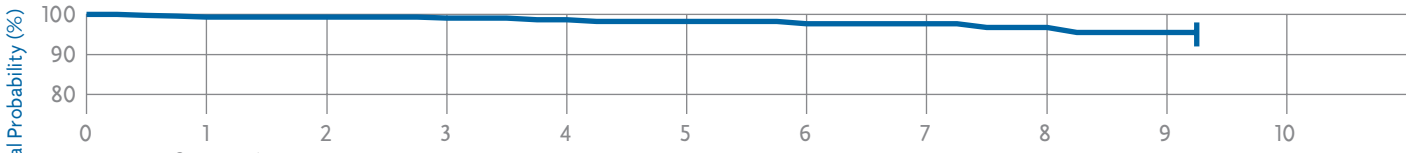
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	541
Cumulative Months of Follow-Up	28,053

Qualifying Complications 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	9 yr	at 111 mo
%	99.4	99.4	99.1	98.7	98.3	97.7	97.7	96.8	95.5	95.5
#	432	384	322	251	200	159	111	78	52	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	2,800	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	39
Electrical Malfunction	6
Other	4

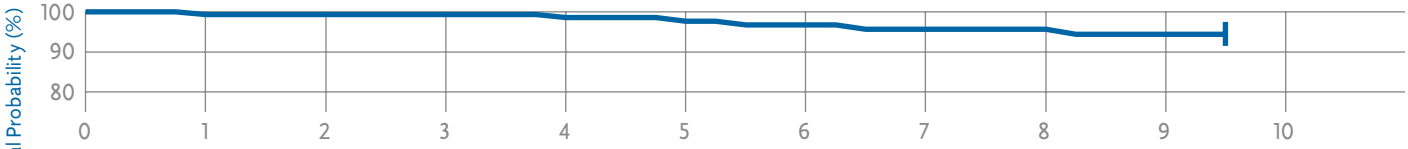
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	259
Cumulative Months of Follow-Up	15,216

Qualifying Complications 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	94.4	94.4
#	162	151	133	121	106	94	82	72	55	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	25,900	Polarity	Bipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	388
Electrical Malfunction	228
Other	23

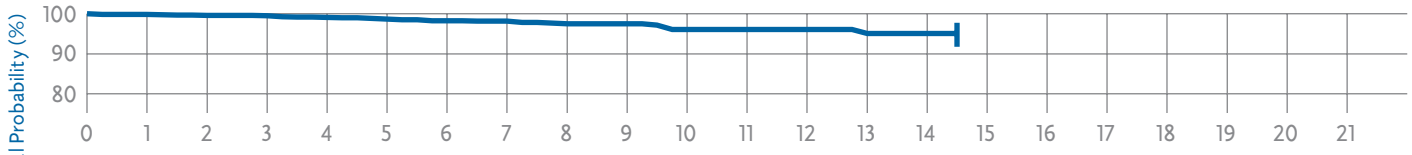
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,363
Cumulative Months of Follow-Up	131,020

Qualifying Complications 32 Total

Extra Cardiac Stimulation	1	Insulation (not further defined)	1
Failure to Capture	15	Lead Dislodgement	3
Failure to Sense	7	Oversensing	1
Impedance Out of Range	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	at 174 mo
%	99.9	99.6	99.5	99.1	98.7	98.3	98.2	97.5	97.5	96.1	96.1	96.1	95.1	95.1	95.1
#	1,756	1,547	1,336	1,156	993	791	611	457	338	223	158	118	88	57	48

Effective Sample Size

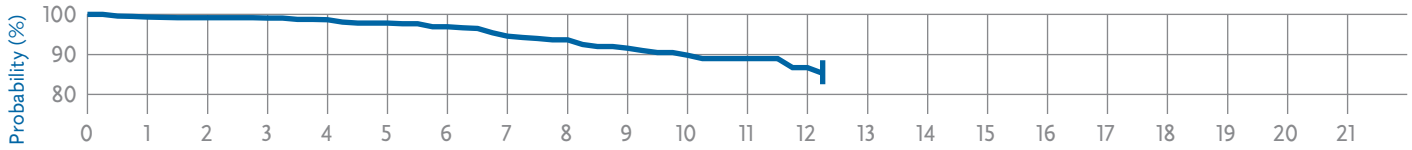
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,690
Cumulative Months of Follow-Up	76,590

Qualifying Complications 50 Total

Conductor Fracture	3	Impedance Out of Range	6
Extra Cardiac Stimulation	3	Insulation (not further defined)	4
Failure to Capture	22	Lead Dislodgement	1
Failure to Sense	10	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	at 147 mo
%	99.4	99.2	99.1	98.7	97.9	96.9	94.6	93.6	91.5	89.8	89.0	86.6	85.2
#	1,123	943	789	663	533	423	318	233	175	119	86	62	54

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	500	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	3
Electrical Malfunction	1
Other	1

Atrial Placement

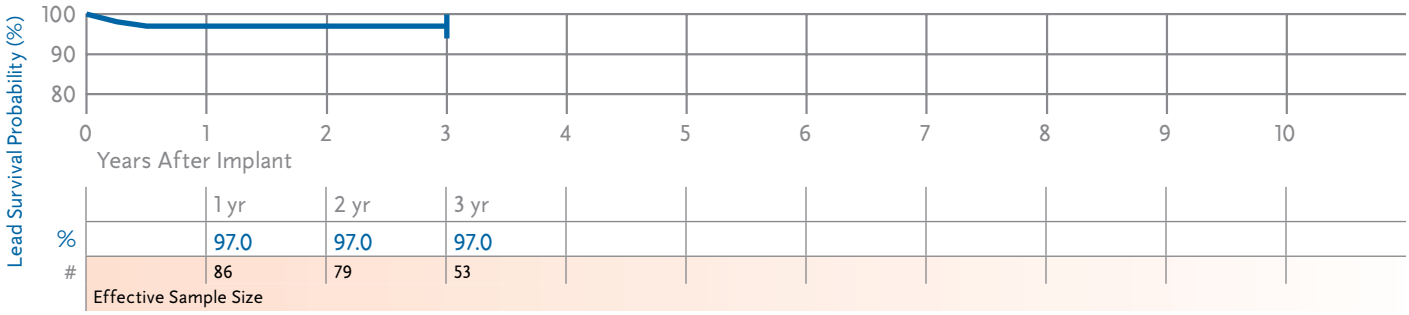
System Longevity Study Results

Number of Leads Enrolled in Study	108
Cumulative Months of Follow-Up	5,877

Qualifying Complications

6 Total

Failure to Capture	5
Oversensing	1



	1 yr	2 yr	3 yr
%	97.0	97.0	97.0
#	86	79	53

Effective Sample Size

Leads

Source: System Longevity Study
Data as of July 31, 2007

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	57,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	406
Electrical Malfunction	81
Other	11

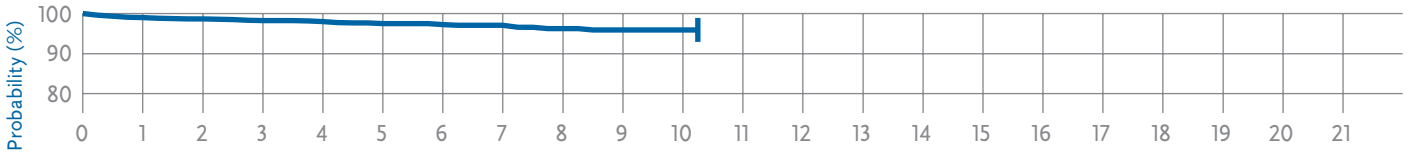
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,401
Cumulative Months of Follow-Up	114,150

Qualifying Complications 48 Total

Conductor Fracture	1	Insulation (ESC)	2
Extra Cardiac Stimulation	1	Lead Dislodgement	8
Failure to Capture	19	Oversensing	3
Failure to Sense	11	Unspecified Clinical Failure	1
Impedance Out of Range	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.0	98.8	98.3	98.0	97.5	97.4	97.2	96.4	96.0	96.0	96.0
#	1,897	1,620	1,352	1,067	782	537	385	269	172	68	51

Effective Sample Size

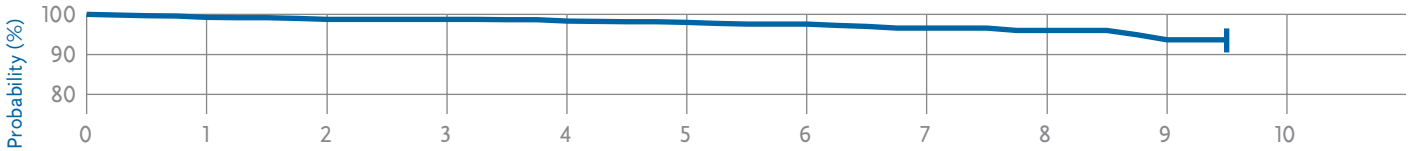
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	81,140

Qualifying Complications 32 Total

Conductor Fracture	2
Extra Cardiac Stimulation	2
Failure to Capture	19
Failure to Sense	3
Impedance Out of Range	4
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.3	98.8	98.8	98.4	98.0	97.6	96.6	96.0	93.7	93.7
#	1,426	1,215	1,034	764	548	339	209	111	72	53

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

4073 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBF
Estimated US Implants	500	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	400	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

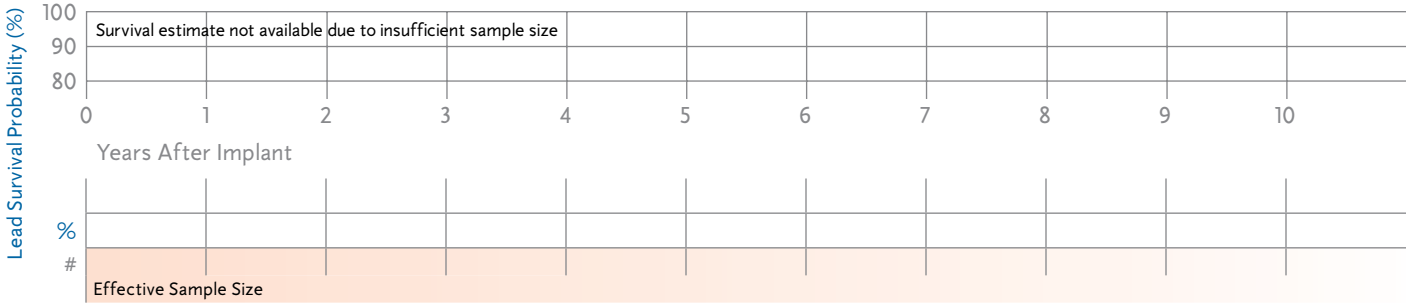
Implant Damage	1
Electrical Malfunction	0
Other	0

Atrial Placement

System Longevity Study Results

Qualifying Complications 0 Total

Number of Leads Enrolled in Study	1
Cumulative Months of Follow-Up	34

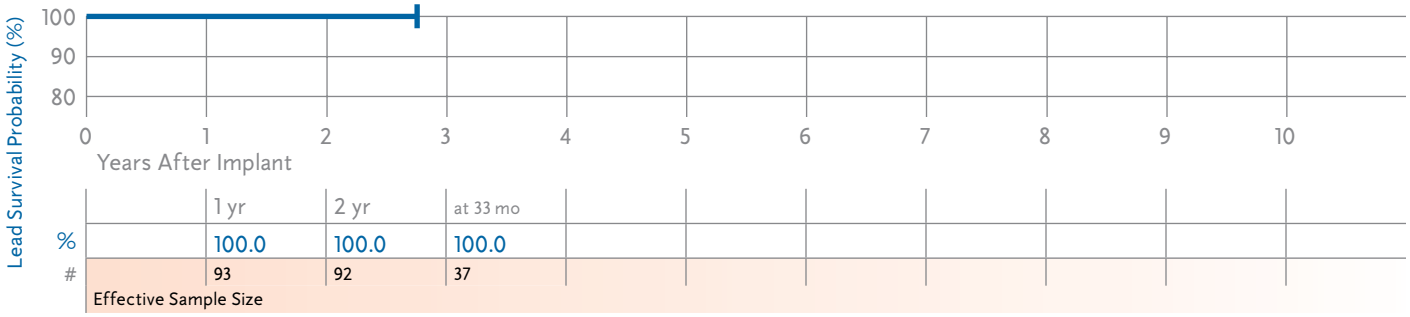


Ventricular Placement

System Longevity Study Results

Qualifying Complications 0 Total

Number of Leads Enrolled in Study	99
Cumulative Months of Follow-Up	3,300



Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Estimated US Implants	48,500	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	38,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	12
Electrical Malfunction	3
Other	1

Ventricular Placement

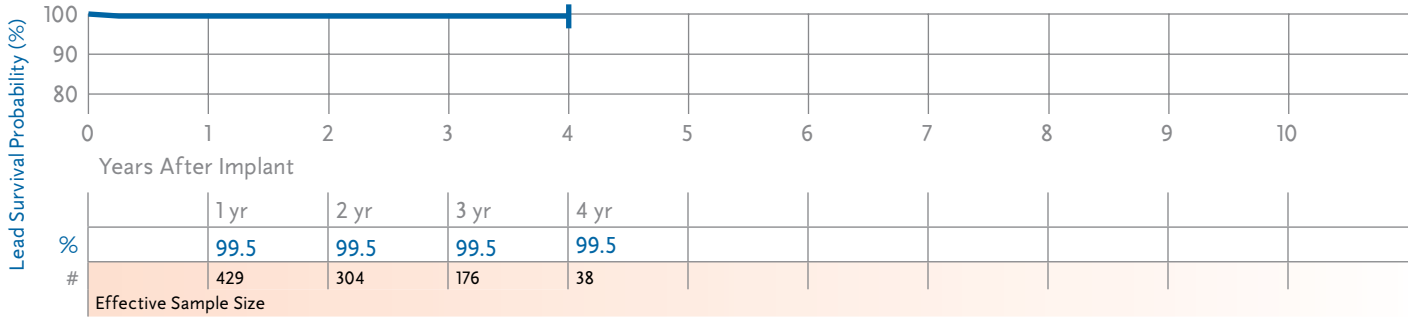
System Longevity Study Results

Number of Leads Enrolled in Study	611
Cumulative Months of Follow-Up	15,441

Qualifying Complications

3 Total

Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr
%	99.5	99.5	99.5	99.5
#	429	304	176	38

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Estimated US Implants	120,600	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	104,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	51
Electrical Malfunction	3
Other	5

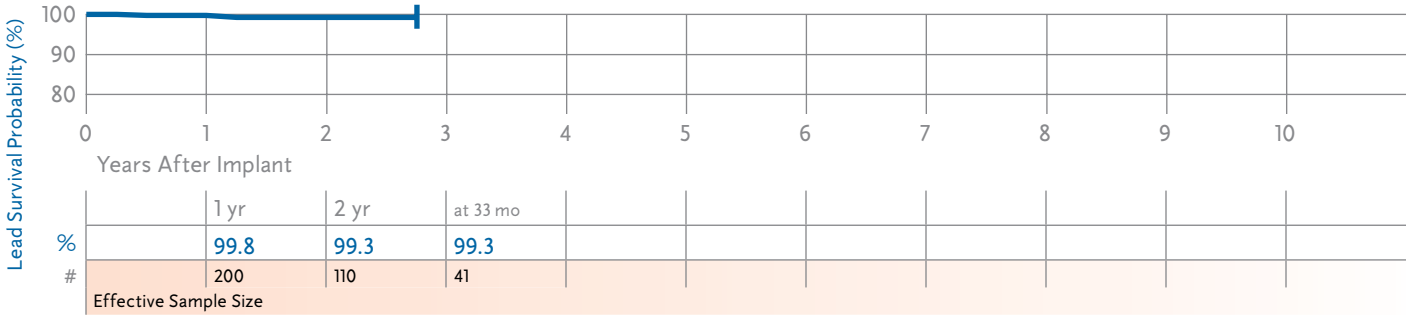
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	512
Cumulative Months of Follow-Up	7,482

Qualifying Complications 2 Total

Failure to Capture	1
Lead Dislodgement	1



	1 yr	2 yr	at 33 mo
%	99.8	99.3	99.3
#	200	110	41

Effective Sample Size

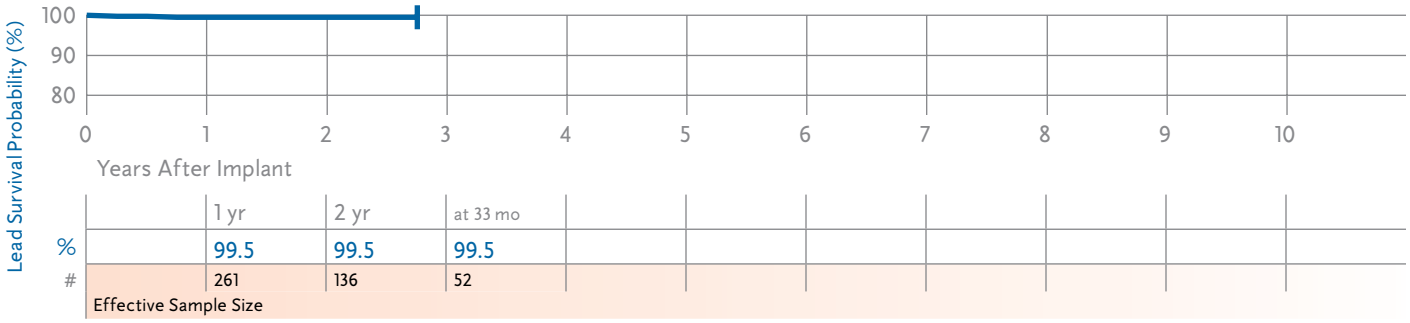
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	507
Cumulative Months of Follow-Up	8,765

Qualifying Complications 2 Total

Failure to Capture	2



	1 yr	2 yr	at 33 mo
%	99.5	99.5	99.5
#	261	136	52

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	900	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	4
Electrical Malfunction	5
Other	0

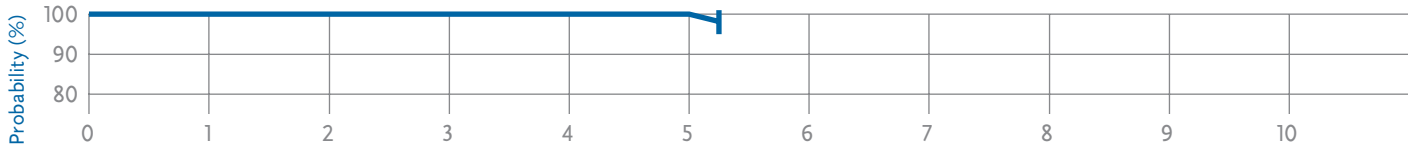
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	260
Cumulative Months of Follow-Up	9,783

Qualifying Complications 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	47

Effective Sample Size

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Estimated US Implants	139,700	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	90,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	32
Electrical Malfunction	11
Other	5

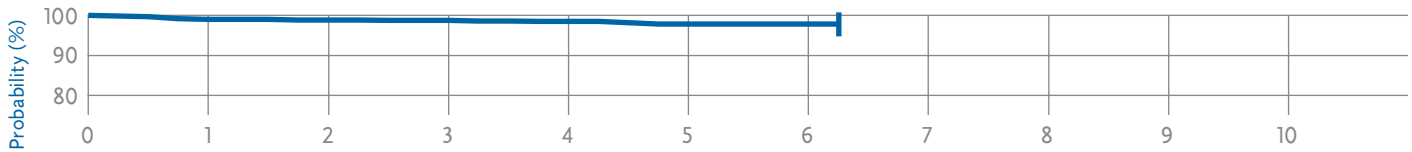
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,144
Cumulative Months of Follow-Up	46,393

Qualifying Complications 16 Total

Conductor Fracture	2
Extra Cardiac Stimulation	1
Failure to Capture	8
Impedance Out of Range	1
Lead Dislodgement	4



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	99.0	98.9	98.8	98.4	97.9	97.9	97.9
#	926	826	653	442	255	77	41

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	1,400	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	2
Electrical Malfunction	11
Other	0

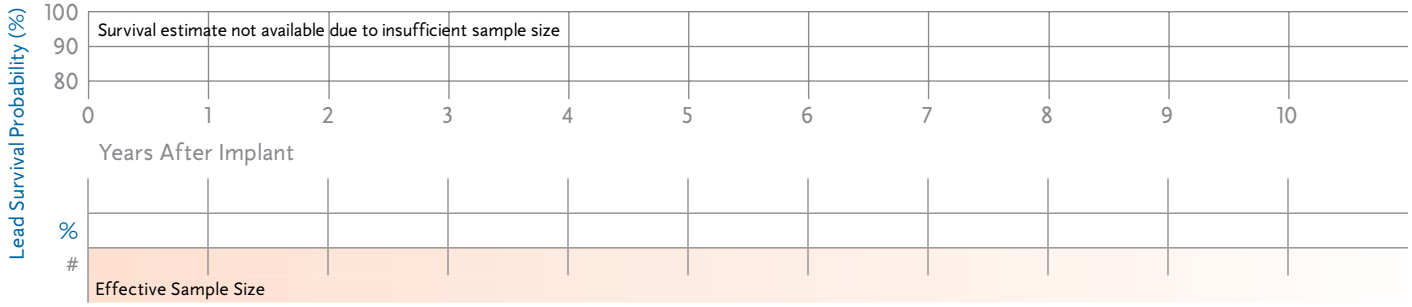
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	59
Cumulative Months of Follow-Up	3,179

Qualifying Complications 1

Failure to Sense	1



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	1,600	Polarity	Bipolar
Advisories	1	Steroid	Yes

see page 164 – 1996 Lead Survival Below Expectations

Returned Product Analysis

Implant Damage	5
Electrical Malfunction	171
Other	4

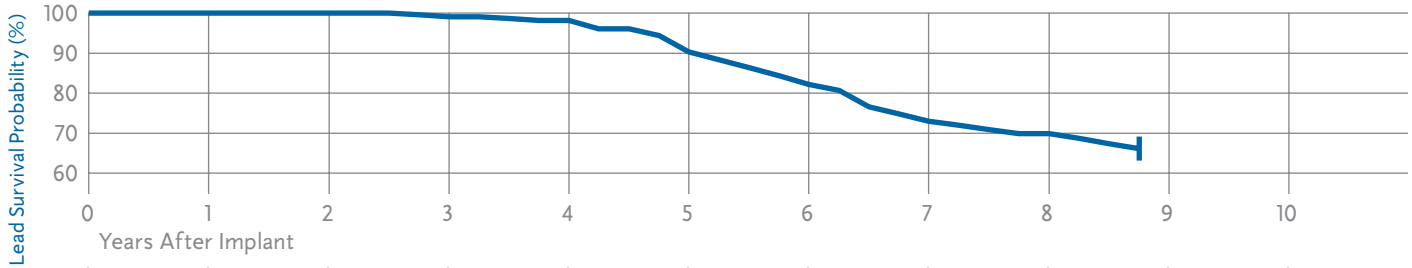
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	368
Cumulative Months of Follow-Up	19,861

Qualifying Complications 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 July 31, 2007

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	1,100	Polarity	Bipolar
Advisories	None	Steroid	No

Returned Product Analysis

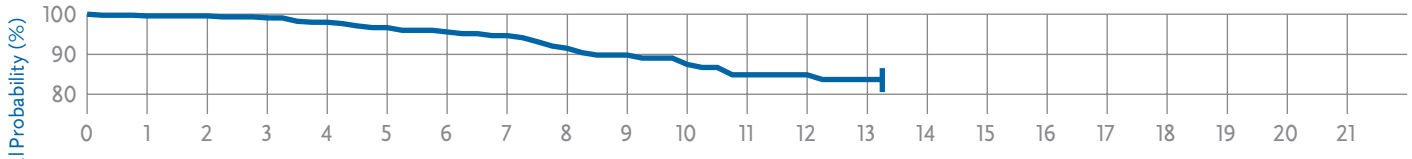
Implant Damage	4
Electrical Malfunction	83
Other	8

Atrial Placement
System Longevity Study Results

Number of Leads Enrolled in Study	600
Cumulative Months of Follow-Up	39,749

Qualifying Complications 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	96.7	95.6	94.7	91.5	89.7	87.5	84.8	84.8	83.6	83.6
#	454	410	370	326	272	224	190	157	129	105	88	71	53	49

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	3,500	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

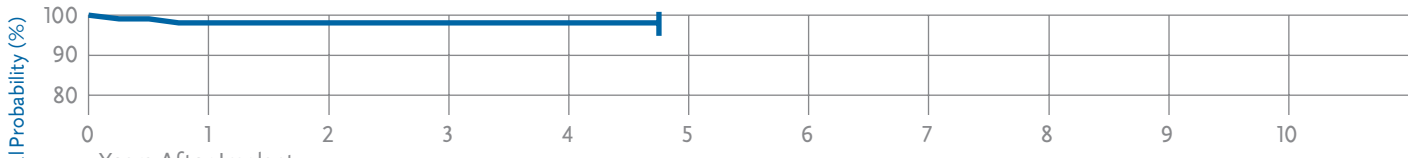
Implant Damage	5
Electrical Malfunction	2
Other	1

Atrial Placement
System Longevity Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	6,967

Qualifying Complications 4 Total

Impedance Out of Range	1
Lead Dislodgement	2
Oversensing	1



	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 July 31, 2007

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	38,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	47
Electrical Malfunction	21
Other	8

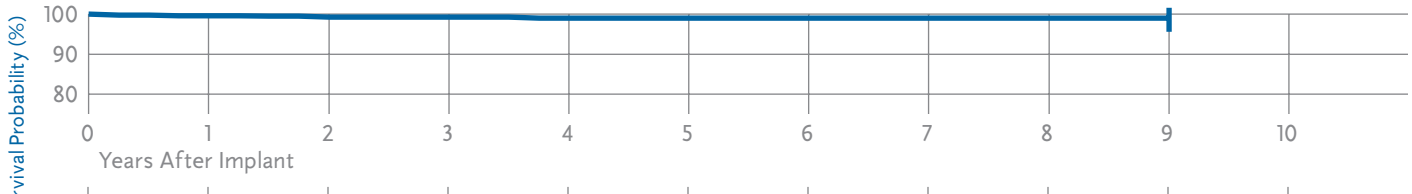
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	910
Cumulative Months of Follow-Up	38,794

Qualifying Complications 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	9 yr
%	99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0	99.0
#	681	536	426	328	253	182	135	86	52

Effective Sample Size

Leads

4533 CapSure Z

Product Characteristics

US Market Release	not US released	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

Returned Product Analysis

Implant Damage	0
Electrical Malfunction	0
Other	0

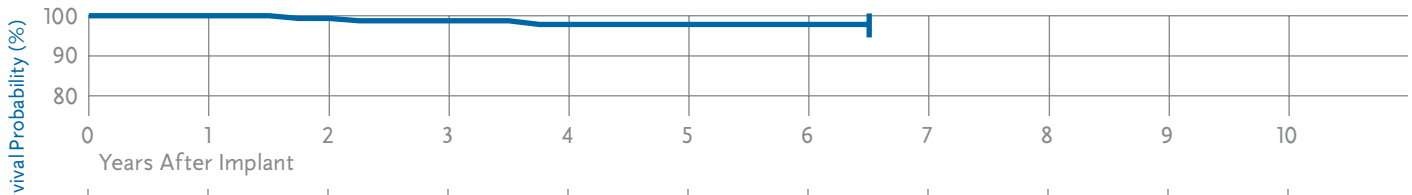
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	206
Cumulative Months of Follow-Up	11,038

Qualifying Complications 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 78 mo
%	100.0	99.4	98.8	97.9	97.9	97.9	97.9
#	176	158	132	101	77	60	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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-J, Screw-in
Estimated US Active	5,200	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	53
Electrical Malfunction	14
Other	4

Atrial Placement

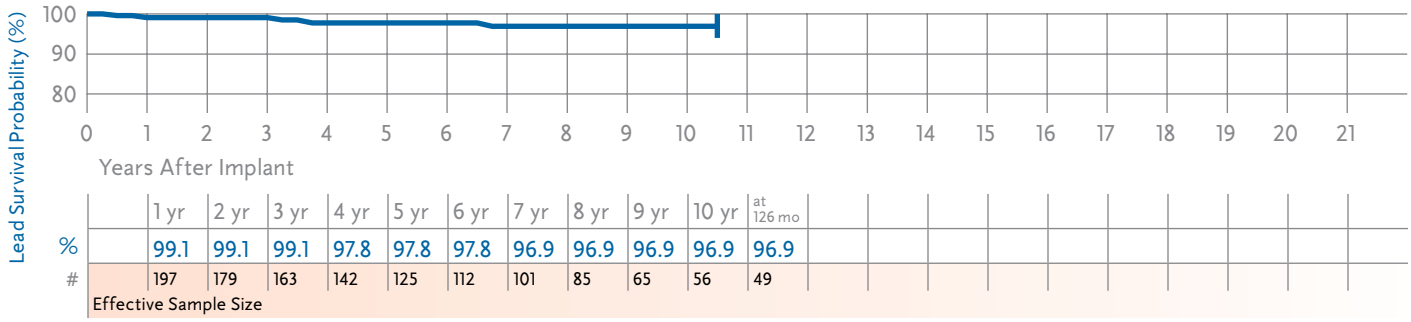
System Longevity Study Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	18,286

Qualifying Complications

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 126 mo
%	99.1	99.1	99.1	97.8	97.8	97.8	96.9	96.9	96.9	96.9	96.9
#	197	179	163	142	125	112	101	85	65	56	49

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	6,100	Polarity	Bipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	111
Electrical Malfunction	11
Other	1

Atrial Placement

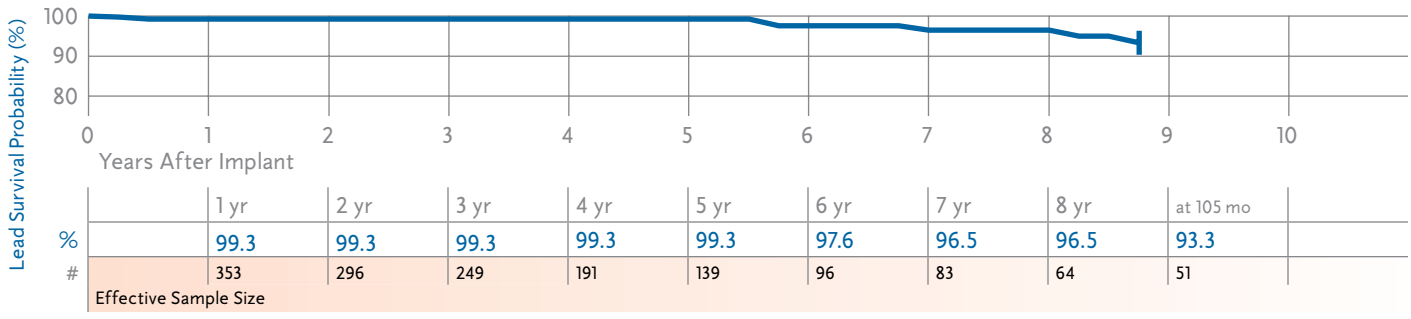
System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	21,989

Qualifying Complications

11 Total

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



	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	97.6	96.5	96.5	93.3
#	353	296	249	191	139	96	83	64	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Estimated US Implants	72,800	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated US Active	37,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	197
Electrical Malfunction	6
Other	4

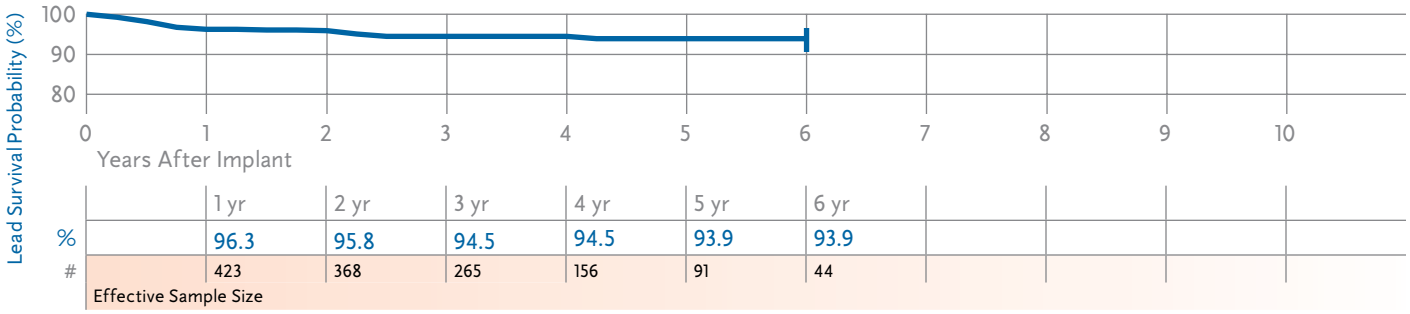
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	576
Cumulative Months of Follow-Up	20,494

Qualifying Complications 28 Total

Failure to Capture	19
Lead Dislodgement	8
Medical Judgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	96.3	95.8	94.5	94.5	93.9	93.9
#	423	368	265	156	91	44

Effective Sample Size

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Estimated US Implants	31,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	24,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

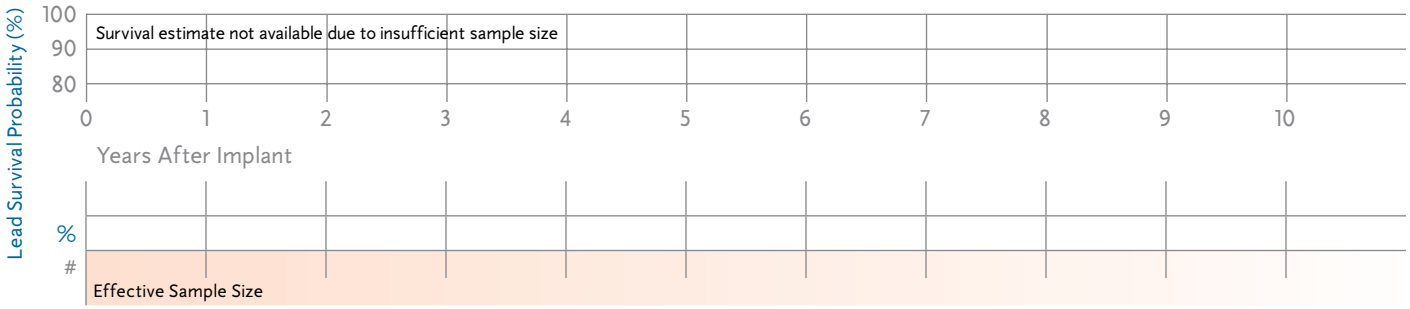
Implant Damage	6
Electrical Malfunction	1
Other	0

Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	5
Cumulative Months of Follow-Up	116

Qualifying Complications 0 Total



Leads

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Estimated US Implants	70,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	44,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	12
Electrical Malfunction	3
Other	0

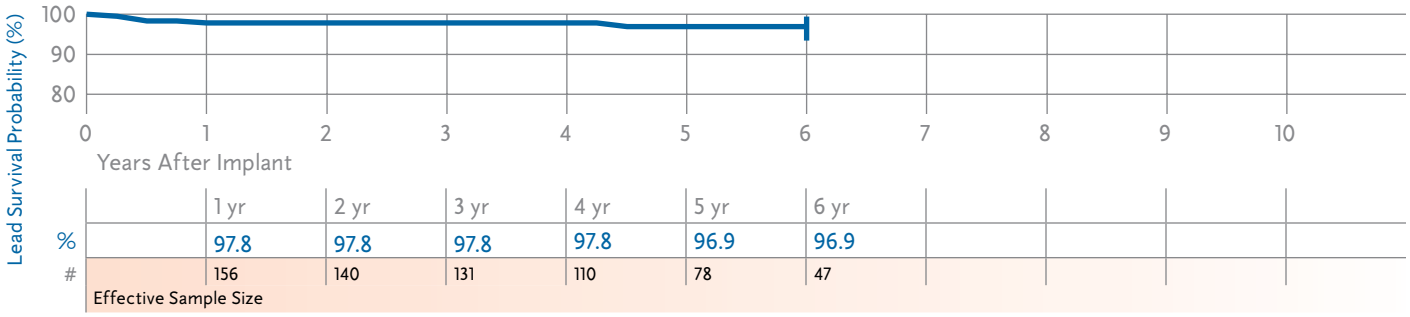
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	243
Cumulative Months of Follow-Up	9,505

Qualifying Complications 5 Total

Failure to Capture	2
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	97.8	97.8	97.8	97.8	96.9	96.9
#	156	140	131	110	78	47

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	2,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	15
Electrical Malfunction	7
Other	0

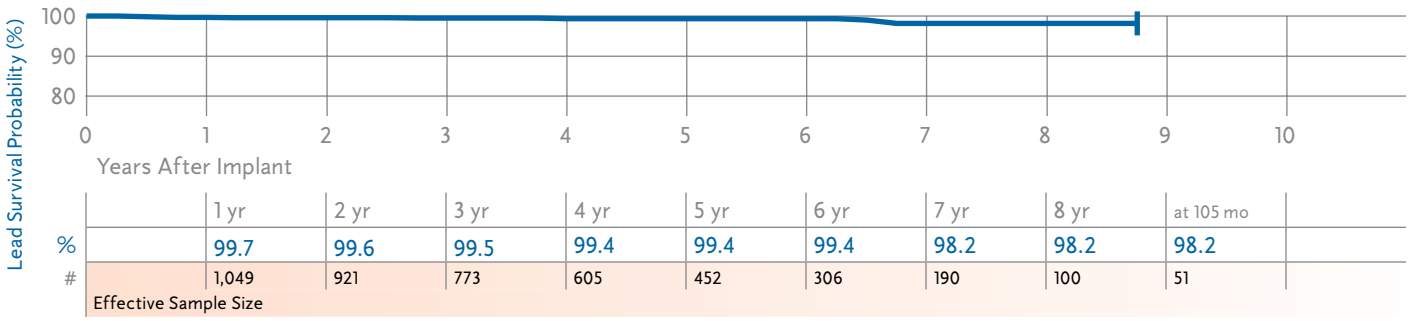
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,351
Cumulative Months of Follow-Up	62,593

Qualifying Complications 10 Total

Conductor Fracture	1
Extra Cardiac Stimulation	2
Failure to Capture	6
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.7	99.6	99.5	99.4	99.4	99.4	98.2	98.2	98.2
#	1,049	921	773	605	452	306	190	100	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	72,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	723
Electrical Malfunction	106
Other	29

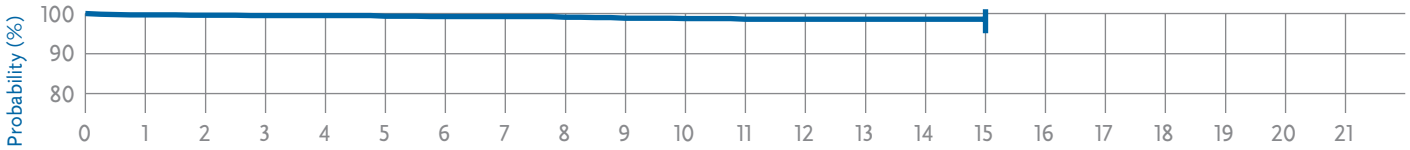
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	8,142
Cumulative Months of Follow-Up	421,081

Qualifying Complications 45 Total

Conductor Fracture	3	Insulation (ESC)	1
Extra Cardiac Stimulation	2	Insulation (not further defined)	5
Failure to Capture	24	Lead Dislodgement	5
Failure to Sense	2	Oversensing	1
Impedance Out of Range	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	14 yr	15 yr
%	99.7	99.6	99.5	99.5	99.4	99.3	99.3	99.1	98.9	98.8	98.6	98.6	98.6	98.6	98.6
#	6,123	5,272	4,473	3,742	3,098	2,400	1,822	1,301	909	601	403	245	154	93	44

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	1,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	60
Electrical Malfunction	7
Other	1

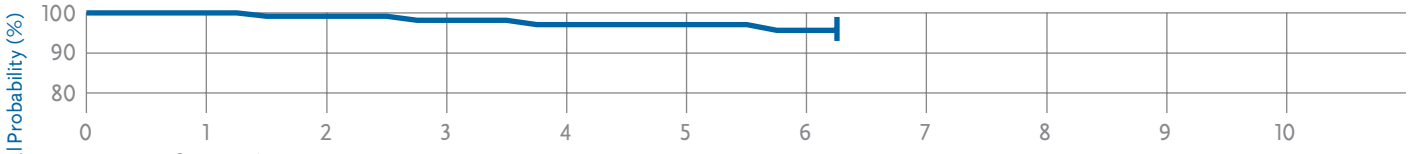
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	168
Cumulative Months of Follow-Up	9,522

Qualifying Complications 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 July 31, 2007

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	1,000	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	6
Electrical Malfunction	1
Other	3

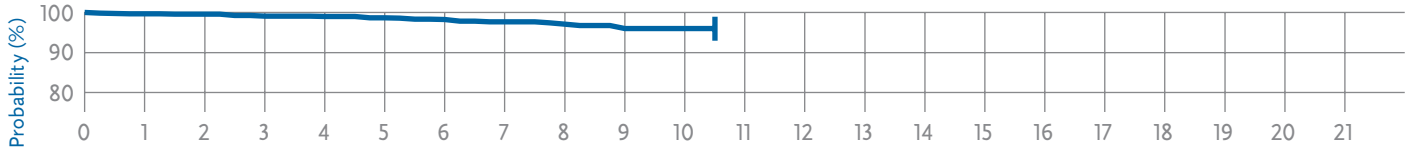
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,901
Cumulative Months of Follow-Up	90,664

Qualifying Complications 25 Total

Cardiac Perforation	1
Conductor Fracture	5
Failure to Capture	11
Impedance Out of Range	5
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	at 126 mo
%	99.7	99.6	99.1	99.0	98.7	98.3	97.7	97.1	96.0	96.0	96.0
#	1,414	1,140	939	783	655	527	414	312	213	90	46

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	23,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	85
Electrical Malfunction	29
Other	11

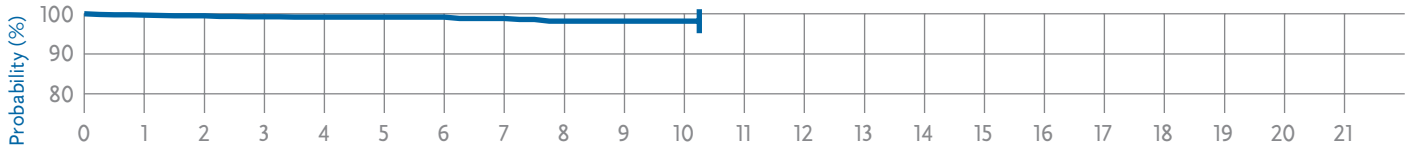
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,596
Cumulative Months of Follow-Up	78,752

Qualifying Complications 13 Total

Conductor Fracture	1
Failure to Capture	9
Failure to Sense	1
Impedance Out of Range	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.7	99.5	99.3	99.2	99.2	99.2	98.9	98.2	98.2	98.2	98.2
#	1,271	1,054	883	706	550	447	310	206	135	67	41

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Estimated US Implants	82,500	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	50,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	40
Electrical Malfunction	13
Other	6

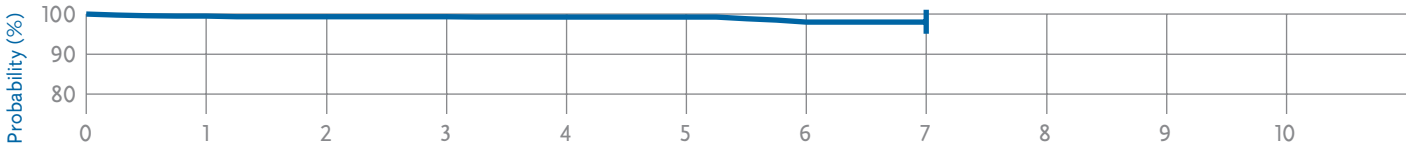
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,392
Cumulative Months of Follow-Up	53,726

Qualifying Complications 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	6 yr	7 yr
%	99.5	99.4	99.4	99.3	99.3	98.0	98.0
#	1,049	884	689	536	363	150	46

Effective Sample Size

Leads

Source: System Longevity Study
Data as of July 31, 2007

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	52,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	455
Electrical Malfunction	61
Other	15

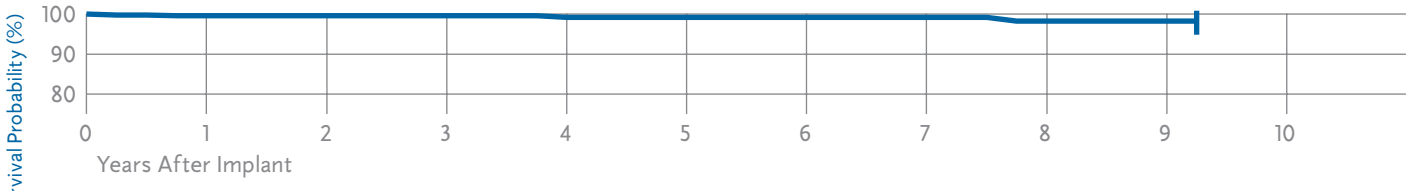
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	969
Cumulative Months of Follow-Up	32,259

Qualifying Complications — 5 Total

Failure to Capture	2
Impedance Out of Range	1
Lead Dislodgement	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.6	99.6	99.6	99.2	99.2	99.2	99.2	98.3	98.3	98.3
#	555	428	328	261	216	172	129	89	63	53

Effective Sample Size

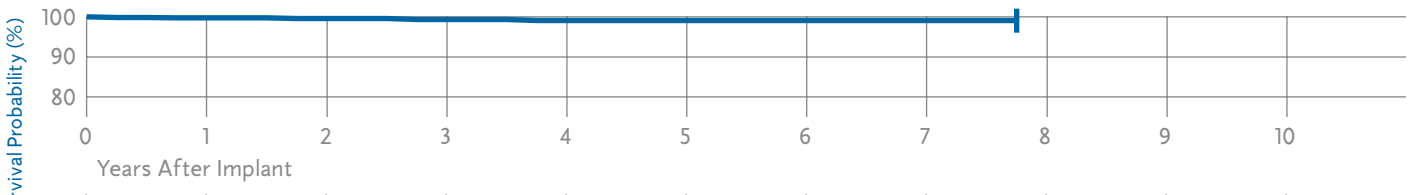
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,360
Cumulative Months of Follow-Up	34,937

Qualifying Complications — 5 Total

Conductor Fracture	1
Failure to Capture	3
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo		
%	99.8	99.6	99.4	99.1	99.1	99.1	99.1	99.1		
#	698	497	357	266	220	136	76	44		

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Estimated US Implants	8,900	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	5,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	26
Electrical Malfunction	4
Other	1

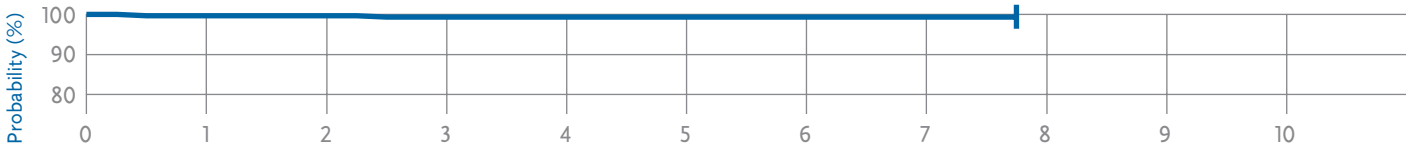
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	450
Cumulative Months of Follow-Up	20,567

Qualifying Complications 2 Total

Cardiac Perforation	1
Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	99.7	99.7	99.4	99.4	99.4	99.4	99.4	99.4
#	340	285	239	192	163	127	64	50

Effective Sample Size

Leads

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Estimated US Implants	838,700	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated US Active	625,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	691
Electrical Malfunction	156
Other	51

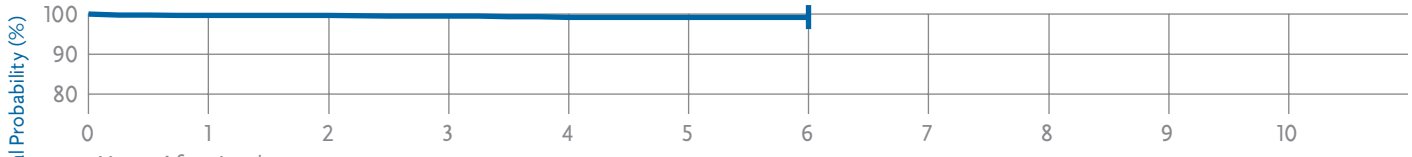
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,466
Cumulative Months of Follow-Up	73,716

Qualifying Complications — 13 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	99.7	99.7	99.5	99.2	99.2	99.2
#	1,754	1,278	870	551	295	61

Effective Sample Size

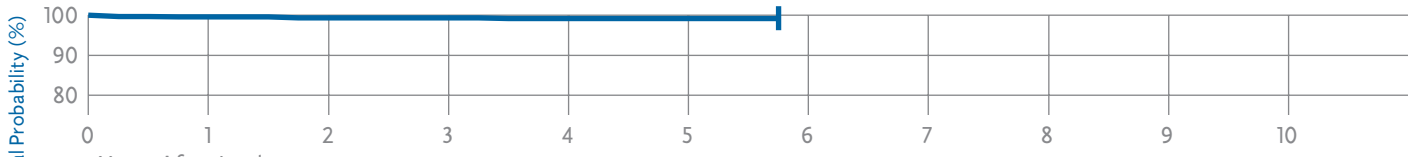
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,507
Cumulative Months of Follow-Up	44,927

Qualifying Complications — 8 Total

Cardiac Perforation	1
Failure to Capture	3
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
%	99.6	99.4	99.4	99.2	99.2	99.2
#	1,024	801	560	354	181	57

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Estimated US Implants	105,900	Type and/or Fixation	Transvenous, Vent., Tines
Estimated US Active	68,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	46
Electrical Malfunction	20
Other	11

Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,171
Cumulative Months of Follow-Up	37,536

Qualifying Complications

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 81 mo
%	99.6	99.5	99.3	99.0	99.0	99.0	99.0
#	783	620	465	321	201	98	49

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	23,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	66
Electrical Malfunction	21
Other	7

Atrial Placement

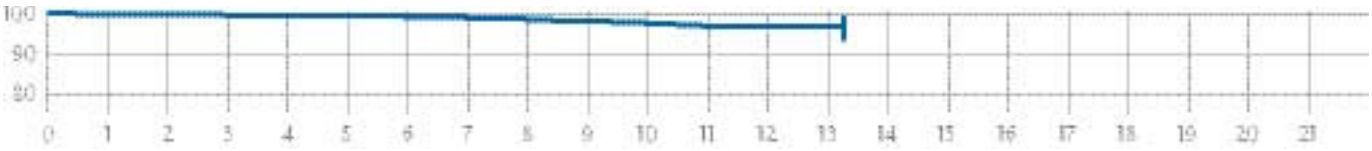
System Longevity Study Results

Number of Leads Enrolled in Study	4,433
Cumulative Months of Follow-Up	232,128

Qualifying Complications

37 Total

Conductor Fracture	1	Insulation (not further defined)	2
Failure to Capture	22	Lead Dislodgement	4
Failure to Sense	4	Oversensing	3
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 159 mo
%	99.8	99.8	99.5	99.4	99.3	99.2	98.9	98.5	98.0	97.5	96.7	96.7	96.7	96.7
#	3,384	2,923	2,506	2,107	1,751	1,340	993	693	492	327	198	121	55	47

Effective Sample Size

Leads

Source: System Longevity Study
Data as of July 31, 2007

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	9,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	29
Electrical Malfunction	6
Other	5

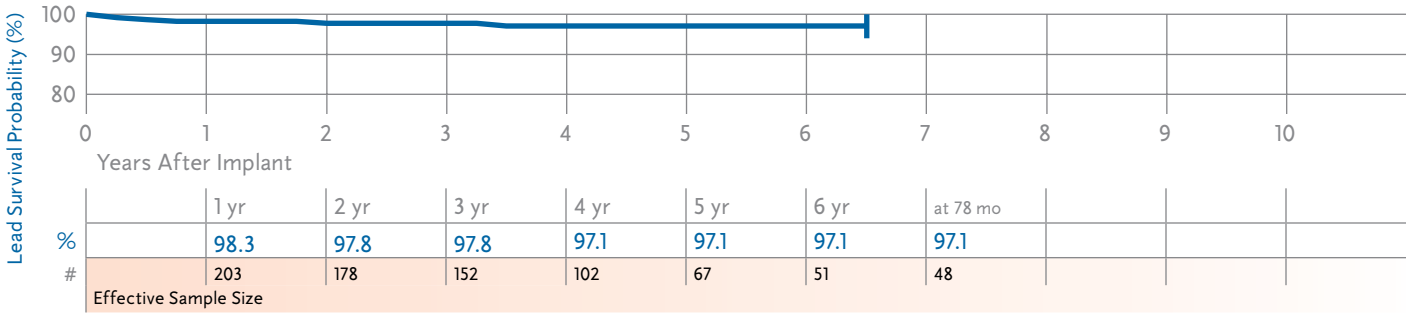
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	260
Cumulative Months of Follow-Up	12,319

Qualifying Complications 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	102	67	51	48

Effective Sample Size

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Estimated US Implants	53,000	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	32,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	7
Electrical Malfunction	6
Other	4

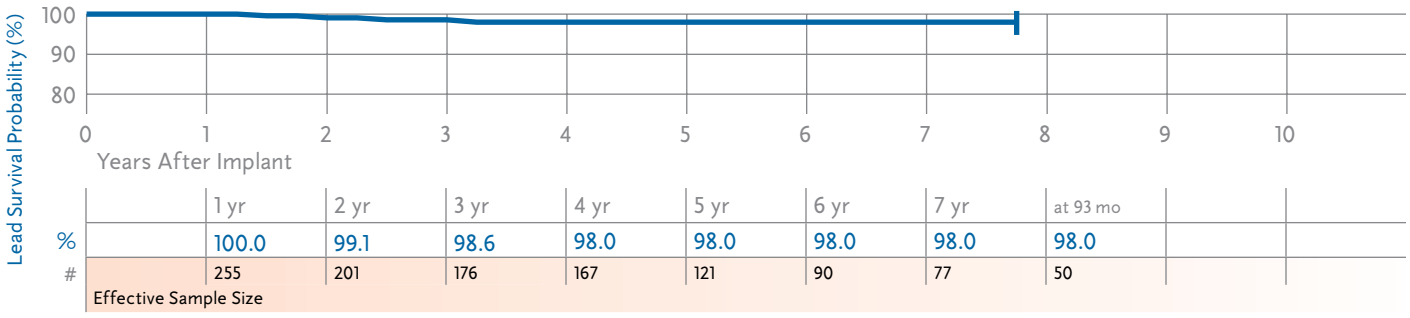
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	352
Cumulative Months of Follow-Up	15,861

Qualifying Complications 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	7 yr	at 93 mo
%	100.0	99.1	98.6	98.0	98.0	98.0	98.0	98.0
#	255	201	176	167	121	90	77	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Estimated US Implants	62,100	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated US Active	42,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	224
Electrical Malfunction	8
Other	9

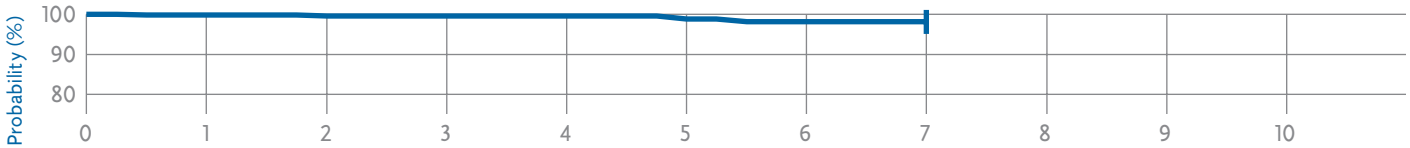
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	891
Cumulative Months of Follow-Up	25,288

Qualifying Complications 4 Total

Failure to Capture	2
Failure to Sense	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	99.9	99.6	99.6	99.6	98.9	98.2	98.2
#	543	374	250	168	139	85	47

Effective Sample Size

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Estimated US Implants	25,500	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	17,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	6
Electrical Malfunction	3
Other	0

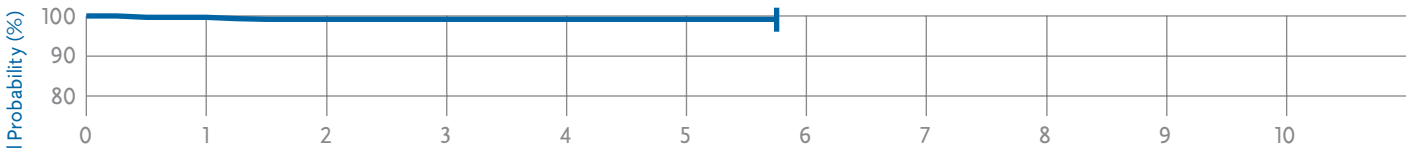
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	666
Cumulative Months of Follow-Up	22,653

Qualifying Complications 4 Total

Failure to Capture	2
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.7	99.2	99.2	99.2	99.2	99.2
#	488	398	294	193	109	51

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Pacing Leads continued

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Estimated US Implants	9,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated US Active	7,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

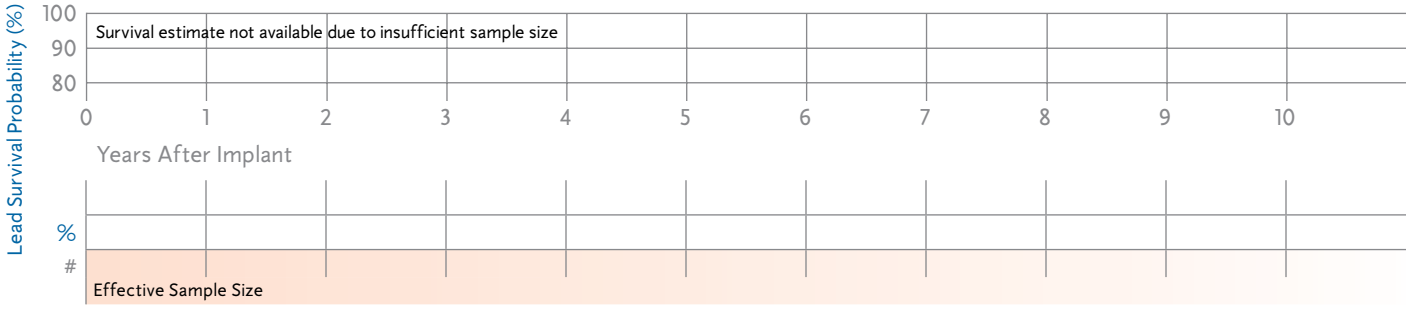
Implant Damage	0
Electrical Malfunction	1
Other	0

Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	17
Cumulative Months of Follow-Up	802

Qualifying Complications 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	700	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	3
Electrical Malfunction	25
Other	1

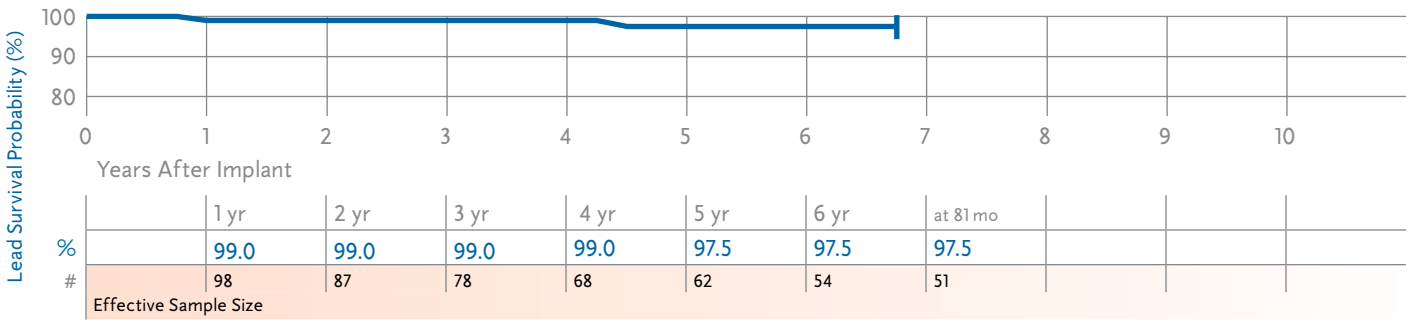
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	9,429

Qualifying Complications 6 Total

Failure to Capture	4
Oversensing	2



Source: System Longevity Study
Data as of July 31, 2007

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	12,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	114
Electrical Malfunction	19
Other	3

Atrial Placement

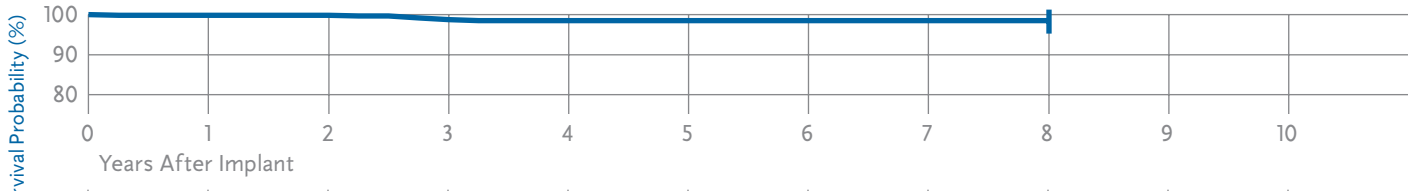
System Longevity Study Results

Number of Leads Enrolled in Study	819
Cumulative Months of Follow-Up	35,930

Qualifying Complications

7 Total

Conductor Fracture	1
Failure to Sense	2
Lead Dislodgement	1
Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.9	99.9	98.8	98.5	98.5	98.5	98.5	98.5
#	599	501	401	333	283	236	141	48

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	2,800	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	85
Electrical Malfunction	39
Other	25

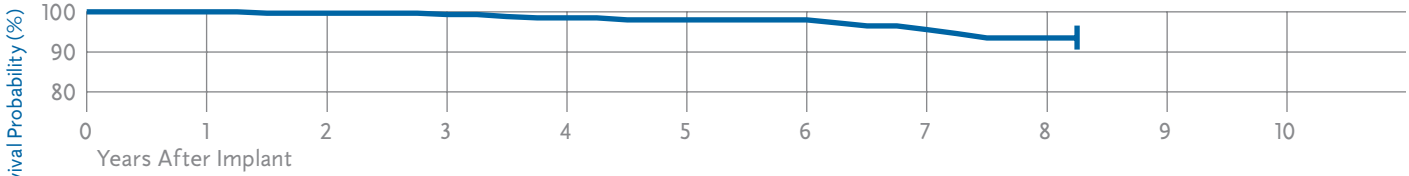
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	673
Cumulative Months of Follow-Up	24,255

Qualifying Complications — 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	95.6	93.5	93.5
#	399	312	249	204	170	138	97	61	52

Effective Sample Size

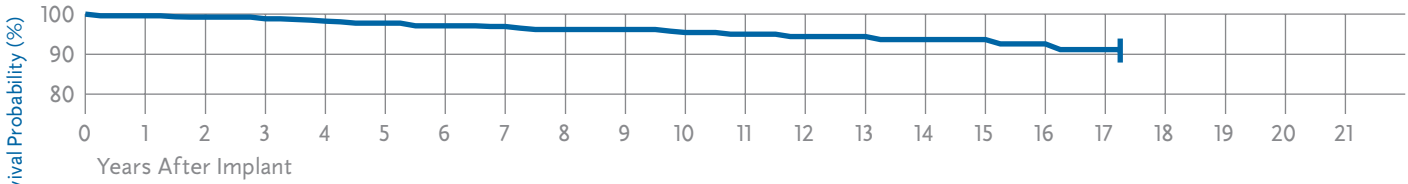
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,853
Cumulative Months of Follow-Up	96,047

Qualifying Complications — 41 Total

Conductor Fracture	13
Extra Cardiac Stimulation	2
Failure to Capture	18
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	at 207 mo
%	99.6	99.3	98.9	98.3	97.8	97.1	96.9	96.2	96.2	95.4	95.0	94.4	94.4	93.7	93.7	92.6	91.2	91.2
#	1,224	998	834	709	623	515	430	341	279	227	192	159	132	108	86	67	53	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	2,300	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	74
Electrical Malfunction	28
Other	30

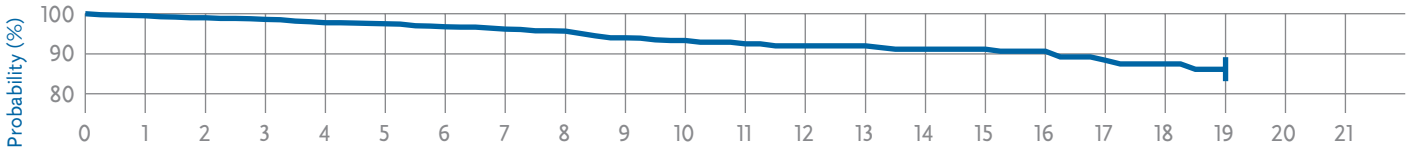
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,348
Cumulative Months of Follow-Up	160,163

Qualifying Complications 87 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	3
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	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr
%	99.5	99.0	98.6	97.8	97.5	96.8	96.2	95.7	94.0	93.3	92.5	92.0	92.0	91.2	91.2	90.7	88.4	87.5	86.1
#	1,775	1,556	1,359	1,205	1,076	915	766	652	554	465	393	320	257	207	160	125	99	69	49

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	1,300	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	103
Electrical Malfunction	27
Other	0

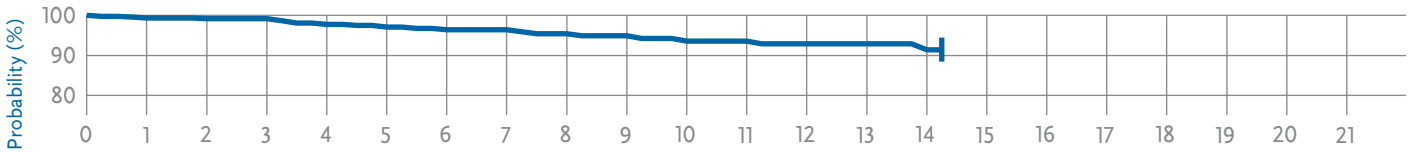
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	627
Cumulative Months of Follow-Up	42,864

Qualifying Complications 22 Total

Extra Cardiac Stimulation	4
Failure to Capture	8
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	93.6	93.6	92.9	92.9	91.4	91.4
#	466	406	365	322	270	235	209	186	159	140	120	93	75	57	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	2,400	Polarity	Bipolar
Advisories	None	Steroid	No

Returned Product Analysis

Implant Damage	170
Electrical Malfunction	84
Other	0

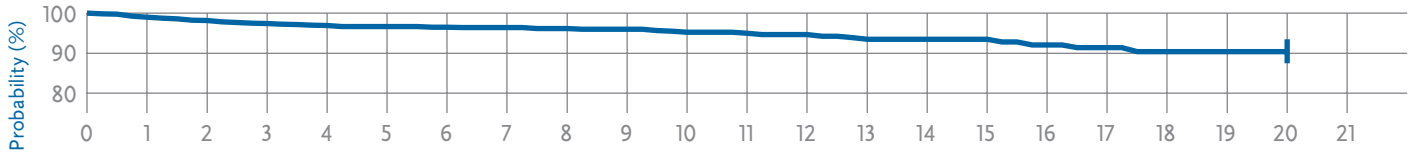
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,483
Cumulative Months of Follow-Up	110,113

Qualifying Complications 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
%	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	92.1	91.4	90.4	90.4	90.4
#	1,082	968	857	757	676	611	560	490	421	365	307	261	214	178	148	123	104	84	66	52

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Qualifying Complications	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	142	1	4,285	99.3 +0.6/-4.4	99.3 +0.6/-4.4	99.3 +0.6/-4.4	99.3 +0.6/-4.4 at 42 mo										
3830	SelectSecure	Vent	Aug-05	135	0	4,241	100.0	100.0	100.0 at 33 mo											
4003, 4003M	CapSure	Vent	Jul-86	711	10	44,869	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/-1.8	97.7 +1.1/-2.4	97.7 +1.1/-2.4	97.7 +1.1/-2.4 at 132 mo				
4004, 4004M	CapSure	Vent	Feb-89	1,640	276	71,581	99.8 +0.1/-0.5	99.3 +0.4/-0.7	96.3 +1.0/-1.4	87.4 +2.1/-2.4	77.1 +2.9/-3.2	69.4 +3.4/-3.7	64.1 +3.7/-4.1	58.1 +4.2/-4.5	51.5 +4.8/-5.0	50.6 +5.0/-5.2 at 129 mo				
	Advisories: see page 165 - 1993 Lead Survival Below Expectations																			
4011	Target Tip	Vent	Nov-82	851	25	54,376	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	96.0 +1.6/-2.4	96.0 +1.6/-2.4	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	316	150,950	99.6 +0.2/-0.3	99.1 +0.4/-0.5	98.4 +0.5/-0.7	95.9 +0.8/-1.1	92.6 +1.2/-1.5	88.1 +1.7/-1.9	83.9 +2.0/-2.2	77.8 +2.5/-2.7	69.8 +3.1/-3.4	65.7 +3.5/-3.7	62.9 +4.0/-4.2	62.2 +4.1/-4.4 at 189 mo		
	Advisories: see page 166 - 1991 Lead Survival Below Expectations																			
4023	CapSure SP	Vent	Aug-91	1,158	19	60,527	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	98.2 +0.8/-1.4	97.1 +1.2/-2.0	96.7 +1.4/-2.4	95.6 +2.0/-3.7	94.1 +2.9/-5.6 at 132 mo				
4024	CapSure SP	Vent	Oct-91	1,215	3	51,157	99.9 +0.1/-0.5	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7 at 117 mo					
4033	CapSure Z	Vent	not US released	541	9	28,053	99.4 +0.4/-1.4	99.4 +0.4/-1.4	99.1 +0.6/-1.6	98.7 +0.8/-1.8	98.3 +1.0/-2.1	97.7 +1.3/-2.6	97.7 +1.3/-2.6	96.8 +1.8/-3.9	95.5 +2.5/-5.2 at 111 mo					
4057, 4057M	Screw-In	Vent	Aug-88	259	7	15,216	99.4 +0.5/-3.5	99.4 +0.5/-3.5	99.4 +0.5/-3.5	98.6 +1.1/-4.1	97.7 +1.6/-4.7	96.8 +2.0/-5.3	95.7 +2.5/-5.9	95.7 +2.5/-5.9	94.4 +3.1/-6.8 at 114 mo					
4058, 4058M	Screw-In	Atrial	Jan-89	2,363	32	131,200	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	96.1 +1.4/-2.1	96.1 +1.4/-2.1	95.1 +2.0/-3.4	95.1 +2.0/-3.4 at 174 mo		
4058, 4058M	Screw-In	Vent	Jan-89	1,690	50	76,590	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	96.9 +1.1/-1.6	94.6 +1.7/-2.3	93.6 +1.9/-2.6	89.8 +2.9/-4.1	86.6 +4.1/-5.8	85.2 +4.7/-6.5 at 147 mo			
4067	CapSureFix	Atrial	Jan-97	108	6	5,877	97.0 +2.0/-5.9	97.0 +2.0/-5.9	97.0 +2.0/-5.9											
4068	CapSureFix	Atrial	Mar-96	2,401	48	114,150	99.0 +0.4/-0.5	98.8 +0.4/-0.6	98.3 +0.5/-0.7	98.0 +0.6/-0.7	97.5 +0.7/-0.9	97.4 +0.7-1.0	97.2 +0.8/-1.1	96.4 +1.1/-1.5	96.0 +1.2/-1.8	96.0 +1.2/-1.8 at 123 mo				
4068	CapSureFix	Vent	Mar-96	1,799	32	81,140	99.3 +0.3/-0.6	98.8 +0.4/-0.7	98.8 +0.4/-0.7	98.4 +0.6/-0.8	98.0 +0.7/-1.0	97.6 +0.8/-1.2	96.6 +1.2/-1.8	96.0 +1.5/-2.4	93.7 +2.8/-4.9 at 114 mo					

continued

Source: System Longevity Study
Data as of July 31, 2007

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Qualifying Complications	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	34	Survival estimate not available due to insufficient sample size													
4073	CapSure Sense	Vent	Jun-02	99	0	3,300	100.0	100.0	100.0 at 33 mo											
4074	CapSure Sense	Vent	Jun-02	611	3	15,441	99.5 +0.3/-1.0	99.5 +0.3/-1.0	99.5 +0.3/-1.0	99.5 +0.3/-1.0										
4076	CapSureFix Novus	Atrial	Feb-04	512	2	7,482	99.8 +0.2/-1.5	99.3 +0.5/-2.5	99.3 +0.5/-2.5 at 33 mo											
4076	CapSureFix Novus	Vent	Feb-04	507	2	8,765	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4 at 33 mo											
4081	Target Tip	Vent	Jul-89	260	3	9,783	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	1,144	16	46,393	99.0 +0.5/-0.8	98.9 +0.5/-0.9	98.8 +0.5/-0.9	98.4 +0.7/-1.0	97.9 +0.9/-1.4	97.9 +0.9/-1.4	97.9 +0.9/-1.4 at 75 mo							
4503, 4503M	CapSure	Atrial	Jul-86	59	1	3,179	Survival estimate not available due to insufficient sample size													
4504, 4504M	CapSure	Atrial	Mar-90	368	48	19,861	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					
	Advisories: see page 164 - 1996 Lead Survival Below Expectations																			
4512	Target Tip	Atrial	Jul-83	600	35	39,749	99.6 +0.3/-1.2	99.6 +0.3/-1.2	99.1 +0.6/-1.5	98.0 +1.0/-2.0	96.7 +1.4/-2.4	95.6 +1.8/-2.8	94.7 +2.0/-3.2	91.5 +2.9/-4.3	87.5 +3.9/-5.5	84.8 +4.6/-6.3	83.6 +5.0/-6.8 at 159 mo			
4523	CapSure SP	Atrial	Aug-91	121	4	6,967	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	910	6	38,794	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 108 mo					
4533	CapSure Z	Atrial	not US released	206	4	11,038	100.0	99.4 +0.5/-3.5	98.8 +0.9/-3.6	97.9 +1.4/-4.2	97.9 +1.4/-4.2	97.9 +1.4/-4.2	97.9 +1.4/-4.2 at 78 mo							
4557, 4557M	Screw-In	Atrial	Aug-88	294	6	18,286	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	97.8 +1.4/-3.6	97.8 +1.4/-3.6	97.8 +1.4/-3.6	96.9 +1.8/-4.4	96.9 +1.8/-4.4	96.9 +1.8/-4.4	96.9 +1.8/-4.4 at 126 mo				
4558M	Screw-In	Atrial	Nov-94	539	11	21,989	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	97.6 +1.6/-4.2	96.5 +2.1/-5.2	96.5 +2.1/-5.2	93.3 +3.7/-8.0 at 105 mo					

continued

Source: System Longevity Study
Data as of July 31, 2007

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Qualifying Complications	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	576	28	20,494	96.3 +1.4/-2.1	95.8 +1.5/-2.2	94.5 +1.8/-2.6	94.5 +1.8/-2.6	93.9 +2.0/-2.9	93.9 +2.0/-2.9								
4574	CapSure Sense	Atrial	Jun-02	5	0	116	Survival estimate not available due to insufficient sample size													
4592	CapSure SP Novus	Atrial	Oct-98	243	5	9,505	97.8 +1.4/-3.5	97.8 +1.4/-3.5	97.8 +1.4/-3.5	97.8 +1.4/-3.5	96.9 +1.8/-4.5	96.9 +1.8/-4.5								
5023, 5023M	CapSure SP	Vent	Nov-88	1,351	10	62,593	99.7 +0.2/-0.5	99.6 +0.3/-0.6	99.5 +0.3/-0.6	99.4 +0.3/-0.8	99.4 +0.3/-0.8	99.4 +0.3/-0.8	98.2 +1.0/-2.1	98.2 +1.0/-2.1	98.2 +1.0/-2.1 at 105 mo					
5024, 5024M	CapSure SP	Vent	Mar-90	8,142	45	421,081	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.5 +0.2/-0.2	99.5 +0.1/-0.2	99.4 +0.2/-0.2	99.3 +0.2/-0.2	99.3 +0.2/-0.3	99.1 +0.3/-0.4	98.8 +0.4/-0.6	98.6 +0.5/-0.9	98.6 +0.5/-0.9	98.6 +0.5/-0.9 at 180 mo		
5026	CapSure	Vent	Feb-88	168	4	9,522	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	1,901	25	90,664	99.7 +0.2/-0.4	99.6 +0.2/-0.4	99.1 +0.4/-0.7	99.0 +0.5/-0.7	98.7 +0.6/-0.9	98.3 +0.7/-1.2	97.7 +0.9/-1.4	97.1 +1.1/-1.6	96.0 +1.5/-2.3	96.0 +1.5/-2.3 at 126 mo				
5034	CapSure Z	Vent	Feb-96	1,596	13	78,752	99.7 +0.2/-0.4	99.5 +0.3/-0.6	99.3 +0.3/-0.7	99.2 +0.4/-0.8	99.2 +0.4/-0.8	99.2 +0.4/-0.8	98.9 +0.5/-0.9	98.2 +0.9/-1.6	98.2 +0.9/-1.6	98.2 +0.9/-1.6 at 123 mo				
5054	CapSure Z Novus	Vent	Jun-98	1,392	11	53,726	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	98.0 +1.1/-2.2	98.0 +1.1/-2.2							
5068	CapSureFix	Atrial	Jan-97	969	5	32,259	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.2 +0.5/-1.5	99.2 +0.5/-1.5	99.2 +0.5/-1.5	99.2 +0.5/-1.5	98.3 +1.2/-3.6	98.3 +1.2/-3.6 at 111 mo					
5068	CapSureFix	Vent	Jan-97	1,360	5	34,937	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.4 +0.4/-1.1	99.1 +0.5/-1.5	99.1 +0.5/-1.5	99.1 +0.5/-1.5	99.1 +0.5/-1.5	99.1 +0.5/-1.5 at 93 mo						
5072	SureFix	Atrial	Jun-98	450	2	20,567	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	99.4 +0.4/-1.9 at 93 mo						
5076	CapSureFix Novus	Atrial	Aug-00	2,466	13	73,716	99.7 +0.1/-0.4	99.7 +0.1/-0.4	99.5 +0.3/-0.5	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7								
5076	CapSureFix Novus	Vent	Aug-00	1,507	8	44,927	99.6 +0.2/-0.5	99.4 +0.3/-0.7	99.4 +0.3/-0.7	99.2 +0.4/-0.9	99.2 +0.4/-0.9	99.2 +0.4/-0.9 at 69 mo								
5092	CapSure SP Novus	Vent	Jun-98	1,171	8	37,536	99.6 +0.2/-0.7	99.5 +0.3/-0.8	99.3 +0.4/-1.0	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3 at 81 mo							
5524, 5524M	CapSure SP	Atrial	Mar-90	4,433	37	232,128	99.8 +0.1/-0.2	99.8 +0.1/-0.3	99.5 +0.2/-0.3	99.4 +0.2/-0.4	99.3 +0.2/-0.5	99.2 +0.3/-0.5	98.9 +0.4/-0.5	98.5 +0.5/-0.8	97.5 +0.9/-1.3	96.7 +1.2/-1.9	96.7 +1.2/-1.9 at 159 mo			

continued

Source: System Longevity Study
Data as of July 31, 2007

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Qualifying Complications	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	12,319	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	352	4	15,861	100.0	99.1 +0.7/-2.6	98.6 +0.9/-3.0	98.0 +1.3/-3.2	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 93 mo						
5568	CapSureFix	Atrial	Jan-97	891	4	25,288	99.9 +0.1/-0.9	99.6 +0.3/-1.2	99.6 +0.3/-1.2	99.6 +0.3/-1.2	98.9 +0.8/-3.0	98.2 +1.2/-3.9	98.2 +1.2/-3.9							
5592	CapSure SP Novus	Atrial	Jun-98	666	4	22,653	99.7 +0.2/-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	99.2 +0.5/-1.3 at 69 mo								
5594	CapSure SP Novus	Atrial	Jun-01	17	0	802	Survival estimate not available due to insufficient sample size													
6907R	(no brand name)	Vent	May-79	121	6	9,429	99.0 +0.9/-5.8	99.0 +0.9/-5.8	99.0 +0.9/-5.8	99.0 +0.9/-5.8	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	819	7	35,930	99.9 +0.1/-0.8	99.9 +0.1/-0.8	98.8 +0.6/-1.6	98.5 +0.8/-1.6	98.5 +0.8/-1.6	98.5 +0.8/-1.6	98.5 +0.8/-1.6	98.5 +0.8/-1.6						
6957	Spectraflex	Atrial	Jul-79	673	10	24,255	100.0	99.7 +0.3/-1.6	99.4 +0.4/-2.0	98.5 +0.9/-2.5	98.0 +1.2/-2.9	98.0 +1.2/-2.9	95.6 +2.3/-4.6	93.5 +3.1/-5.9	93.5 +3.1/-5.9 at 99 mo					
6957	Spectraflex	Vent	Jul-79	1,853	41	96,047	99.6 +0.2/-0.5	99.3 +0.3/-0.6	98.9 +0.4/-0.9	98.3 +0.7/-1.0	97.8 +0.8/-1.2	97.1 +1.0/-1.4	96.9 +1.0/-1.5	96.2 +1.2/-1.7	95.4 +1.5/-2.2	94.4 +1.9/-2.7	93.7 +2.2/-3.2	92.6 +2.7/-4.2	91.2 +3.4/-5.4 at 207 mo	
6957J	Spectraflex	Atrial	Sep-80	2,348	87	160,163	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/-1.0	96.8 +0.8/-1.1	96.2 +1.0/-1.2	95.7 +1.0/-1.3	93.3 +1.5/-1.8	92.0 +1.7/-2.2	91.2 +2.0/-2.4	90.7 +2.1/-2.8	87.5 +3.4/-4.5	86.1 +4.0/-5.4 at 228 mo
6961	Tenax	Vent	Jan-78	627	22	42,864	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/-3.1	93.6 +2.5/-3.8	92.9 +2.7/-4.3	91.4 +3.5/-5.7	91.4 +3.5/-5.7 at 171 mo		
6962	Tenax	Vent	Jan-78	1,483	51	110,113	99.0 +0.4/-0.8	98.2 +0.7/-0.9	97.4 +0.8/-1.2	96.9 +0.9/-1.2	96.7 +0.9/-1.4	96.5 +1.0/-1.3	96.4 +1.0/-1.4	96.2 +1.0/-1.5	95.3 +1.3/-1.8	94.7 +1.4/-2.1	93.5 +1.8/-2.6	92.1 +2.4/-3.3	90.4 +3.1/-4.3	90.4 +3.1/-4.3

Source: System Longevity Study
Data as of July 31, 2007

Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
3830	SelectSecure	Aug-05	7,300	6,500	13	1	1
4003, 4003M	CapSure	Jul-86	40,000	7,100	24	57	2
4004, 4004M	CapSure	Feb-89	74,500	2,800	55	683	19
4011	Target Tip	Nov-82	64,000	7,200	29	141	5
4012	Target Tip	Jul-83	96,800	5,700	50	820	34
4023	CapSure SP	Aug-91	43,700	14,900	48	19	6
4024	CapSure SP	Oct-91	229,200	84,600	264	103	34
4033	CapSure Z	not US released	N/A	N/A	2	0	0
4057, 4057M	Screw-in	Aug-88	12,100	2,800	39	6	4
4058, 4058M	Screw-in	Jan-89	111,100	25,900	388	228	23
4067	CapSureFix	Jan-97	1,300	500	3	1	1
4068	CapSureFix	Mar-96	131,700	57,500	406	81	11
4073	CapSure Sense	Jun-02	500	400	1	0	0
4074	CapSure Sense	Jun-02	48,500	38,700	12	3	1
4076	CapSureFix Novus	Feb-04	120,600	104,700	51	3	5
4081	Target Tip	Jul-89	4,100	900	4	5	0
4092	CapSure SP Novus	Sep-98	139,700	90,100	32	11	5
4503, 4503M	CapSure	Jul-86	9,000	1,400	2	11	0
4504, 4504M	CapSure	Mar-90	16,600	1,600	5	171	4
4512	Target Tip	Jul-83	11,600	1,100	4	83	8
4523	CapSure SP	Aug-91	12,000	3,500	5	2	1
4524	CapSure SP	Oct-91	106,900	38,200	47	21	8
4533	CapSure Z	not US released	N/A	N/A	0	0	0
4557, 4557M	Screw-in	Aug-88	22,500	5,200	53	14	4
4558M	Screw-in	Nov-94	21,000	6,100	111	11	1
4568	CapSureFix	Jan-97	72,800	37,900	197	6	4
4574	CapSure Sense	Jun-02	31,200	24,600	6	1	0
4592	CapSure SP Novus	Oct-98	70,800	44,500	12	3	0
5023, 5023M	CapSure SP	Nov-88	10,600	2,900	15	7	0
5024, 5024M	CapSure SP	Mar-90	211,400	72,800	723	106	29
5026	CapSure	Feb-88	7,800	1,300	60	7	1
5033	CapSure Z	Feb-96	2,500	1,000	6	1	3
5034	CapSure Z	Feb-96	58,700	23,000	85	29	11
5054	CapSure Z Novus	Jun-98	82,500	50,000	40	13	6
5068	CapSureFix	Jan-97	108,000	52,300	455	61	15
5072	SureFix	Jun-98	8,900	5,100	26	4	1
5076	CapSureFix Novus	Aug-00	838,700	625,300	691	156	51
5092	CapSure SP Novus	Jun-98	105,900	68,400	46	20	11
5524, 5524M	CapSure SP	Mar-90	63,800	23,400	66	21	7
5534	CapSure Z	Feb-96	27,700	9,200	29	6	5
5554	CapSure Z Novus	Jun-98	53,000	32,300	7	6	4
5568	CapSureFix	Jan-97	62,100	42,500	224	8	9
5592	CapSure SP Novus	Jun-98	25,500	17,900	6	3	0

continued

Source: Returned Product Analysis
Data as of July 31, 2007

Pacing Leads continued

Returned Product 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	9,300	7,100	0	1	0
6907R	(no brand name)	May-79	18,500	700	3	25	1
6940	CapSureFix	Oct-98	26,600	12,900	114	19	3
6957	Spectraflex	Jul-79	29,100	2,800	85	39	25
6957J	Spectraflex	Sep-80	30,000	2,300	74	28	30
6961	Tenax	Jan-78	44,700	1,300	103	27	0
6962	Tenax	Jan-78	70,600	2,400	170	84	0

Source: Returned Product Analysis
Data as of July 31, 2007

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-J Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	CapSure Z Novus	Transvenous Atrial-J Tines	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	25,300	Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Estimated US Active	3,700	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

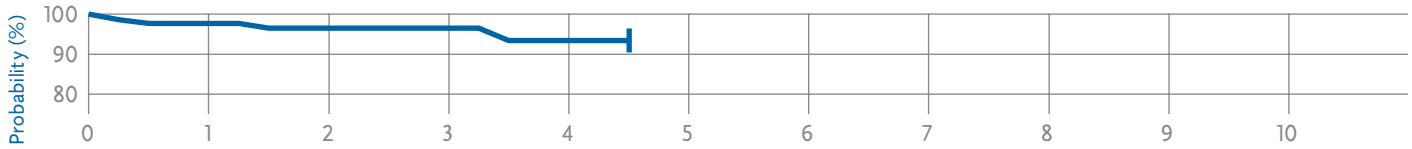
Implant Damage	15
Electrical Malfunction	95
Other	28

System Longevity Study Results

Number of Leads Enrolled in Study	179
Cumulative Months of Follow-Up	6,205

Qualifying Complications 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	at 54 mo
%	97.7	96.5	96.5	93.4	93.4
#	87	73	65	55	51

Effective Sample Size

4965 CapSure Epi

Product Characteristics

US Market Release	Sep-96	Serial Number Prefix	LBT
Estimated US Implants	18,600	Type and/or Fixation	Epicardial Suture-On V or A
Estimated US Active	10,600	Polarity	Unipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

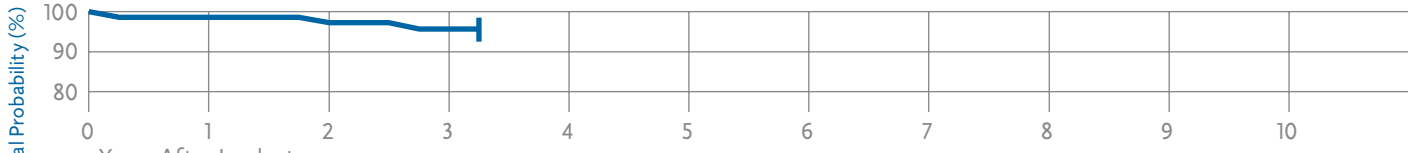
Implant Damage	8
Electrical Malfunction	78
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	170
Cumulative Months of Follow-Up	4,148

Qualifying Complications 8 Total

Conductor Fracture	3
Failure to Capture	2
Failure to Sense	1
Oversensing	2



	1 yr	2 yr	3 yr	at 39 mo
%	98.6	97.3	95.7	95.7
#	89	72	52	49

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

Product Characteristics

US Market Release	Sep-99	Serial Number Prefix	LEN
Estimated US Implants	13,800	Type and/or Fixation	Epicardial Suture-On V or A
Estimated US Active	10,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

Returned Product Analysis

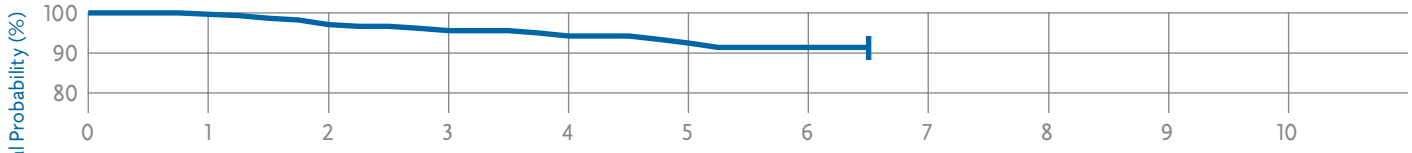
Implant Damage	2
Electrical Malfunction	3
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	442
Cumulative Months of Follow-Up	16,294

Qualifying Complications 24 Total

Conductor Fracture	5	Insulation (not further defined)	2
Failure to Capture	9	Oversensing	4
Failure to Sense	2		
Impedance Out of Range	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	99.7	97.1	95.6	94.2	92.4	91.4	91.4
#	310	224	163	125	88	56	49

Effective Sample Size

5071

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Estimated US Implants	34,100	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated US Active	21,100	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

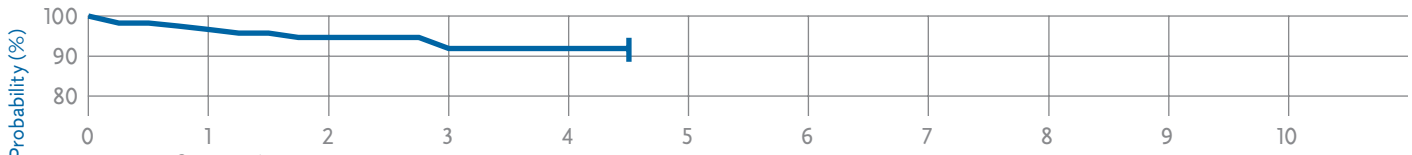
Implant Damage	24
Electrical Malfunction	4
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	210
Cumulative Months of Follow-Up	6,171

Qualifying Complications 10 Total

Failure to Capture	8
Oversensing	2



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	96.7	94.7	91.9	91.9	91.9
#	107	77	64	56	49

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

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	5,500	Polarity	Unipolar
Advisories	None	Steroid	No

Returned Product Analysis

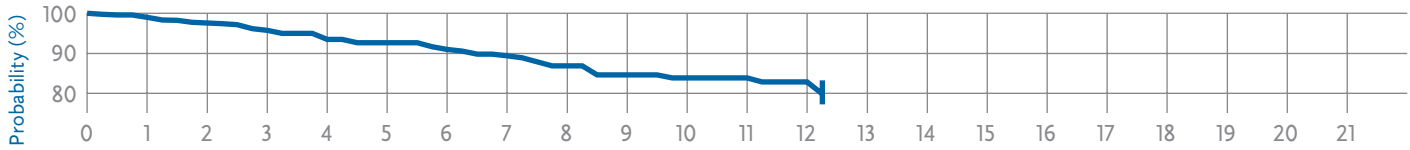
Implant Damage	115
Electrical Malfunction	42
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	985
Cumulative Months of Follow-Up	47,434

Qualifying Complications 69 Total

Conductor Fracture	6	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Insulation (MIO)	1
Failure to Capture	30	Oversensing	18
Failure to Sense	11		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 150 mo
%	99.0	97.6	95.9	93.6	92.8	91.1	89.5	87.2	85.0	84.2	84.2	83.2	80.4
#	638	546	463	371	319	248	197	167	137	93	84	58	50

Effective Sample Size

Source: System Longevity Study
Data as of July 31, 2007

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Qualifying Complications	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
4951, 4951M	Spectraflex	Oct-81	179	10	6,205	97.7 +1.6/-4.8	96.5 +2.2/-5.9	96.5 +2.2/-5.9	93.4 +3.7/-8.1	93.4 +3.7/-8.1 at 54 mo							
4965	CapSure Epi	Sep-96	170	8	4,148	98.6 +1.0/-4.1	97.3 +1.9/-6.0	95.7 +2.8/-7.4	95.7 +2.8/-7.4 at 39 mo								
4968	CapSure Epi	Sep-99	442	24	16,294	99.7 +0.3/-1.8	97.1 +1.4/-2.8	95.6 +2.0/-3.5	94.2 +2.5/-4.1	92.4 +3.1/-5.1	91.4 +3.5/-5.7	91.4 +3.5/-5.7 at 78 mo					
5071	(no brand name)	Dec-92	210	10	6,171	96.7 +1.9/-4.6	94.7 +2.8/-5.7	91.9 +4.0/-7.5	91.9 +4.0/-7.5	91.9 +4.0/-7.5 at 54 mo							
6917, 6917A	Tenax	Jun-73	985	69	47,434	99.0 +0.5/-1.0	97.6 +0.9/-1.5	95.9 +1.3/-2.0	93.6 +1.8/-2.5	92.8 +2.0/-2.6	91.1 +2.3/-3.1	89.5 +2.7/-3.4	87.2 +3.1/-4.1	84.2 +3.9/-4.8	83.2 +4.2/-5.3	80.4 +5.2/-6.8 at 150 mo	

Source: System Longevity Study
Data as of July 31, 2007

Epi/Myocardial Pacing Leads continued

Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Implant Damage	Electrical Malfunction	Other
4951, 4951M	Spectraflex	Oct-81	25,300	3,700	15	95	28
4965	CapSure Epi	Sep-96	18,600	10,600	8	78	2
4968	CapSure Epi	Sep-99	13,800	10,000	2	3	0
5071	(no brand name)	Dec-92	34,100	21,100	24	4	1
6917, 6917A	Tenax	Jun-73	180,100	5,500	115	42	1

Source: Returned Product Analysis
Data as of July 31, 2007

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	2,100	Polarity	Quadripolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	24
Electrical Malfunction	12
Other	0

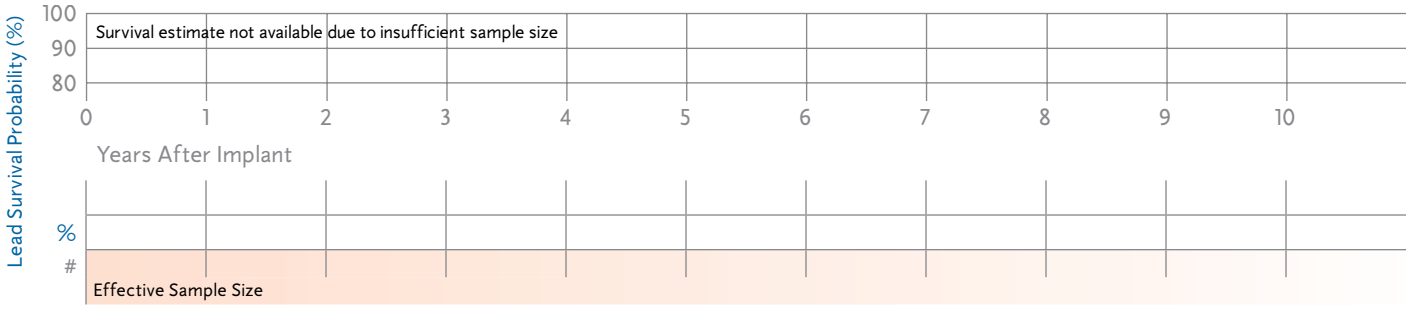
System Longevity Study Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,866

Qualifying Complications

1 Total

Failure to Sense	1



5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Estimated US Implants	7,600	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated US Active	4,400	Polarity	Quadripolar
Advisories	None	Steroid	Yes

Returned Product Analysis

Implant Damage	6
Electrical Malfunction	2
Other	1

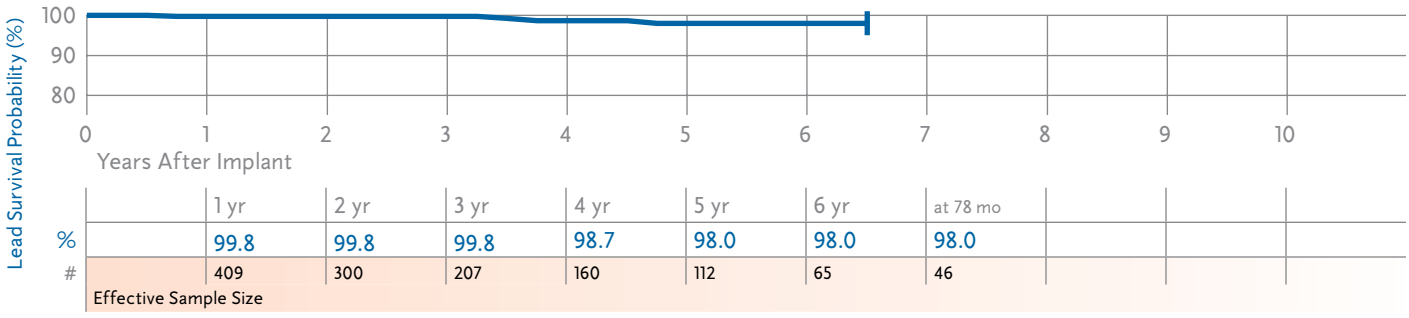
System Longevity Study Results

Number of Leads Enrolled in Study	545
Cumulative Months of Follow-Up	19,297

Qualifying Complications

4 Total

Conductor Fracture	1
Failure to Capture	1
Failure to Sense	2



Source: System Longevity Study
Data as of July 31, 2007

VDD Single Pass Pacing Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Qualifying Complications	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	1	1,866	Survival estimate not available due to insufficient sample size									
5038	CapSure VDD-2	Sep-98	545	4	19,297	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.8 +0.2/-1.4	98.7 +0.9/-2.9	98.0 +1.3/-3.5	98.0 +1.3/-3.5	98.0 +1.3/-3.5 at 78 mo			

Source: System Longevity Study
Data as of July 31, 2007

Returned Product 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	2,100	24	12	0
5038	CapSure VDD-2	Sep-98	7,600	4,400	6	2	1

Source: Returned Product Analysis
Data as of July 31, 2007

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 and CRT-D Charge Time Performance

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

Introduction

Information on charge time performance of Medtronic is presented in this section of the CRDM Product Performance Report. Medtronic implemented the collection of charge time data on July 1, 1999. The data are collected via our ongoing active clinical study of long-term system performance called the System Longevity Study. The study protocol requests device data be routinely taken and sent to Medtronic at no more than six-month intervals.

In our analysis performed for this report, 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. When more than one charge time is available in a six-month interval, a conservative approach has been adopted whereby only the maximum charge in each 6-month interval is reported. As charge time is directly proportional to the time elapsed since the last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.

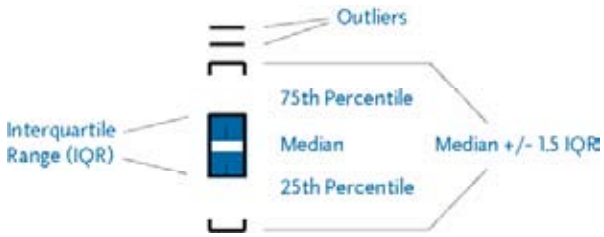
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide charge times that are short and consistent over the life of the product.

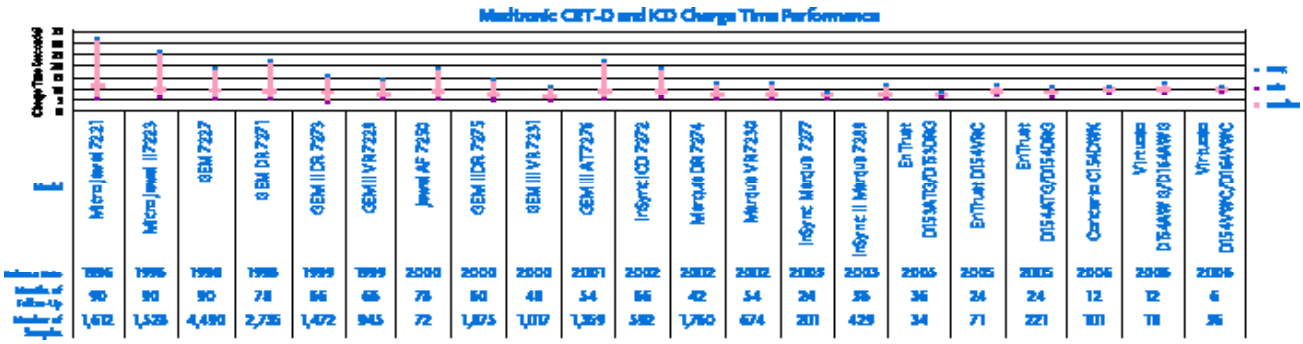
Data Presentation

Charge time data for ICD and CRT-D models are presented using 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.

Results

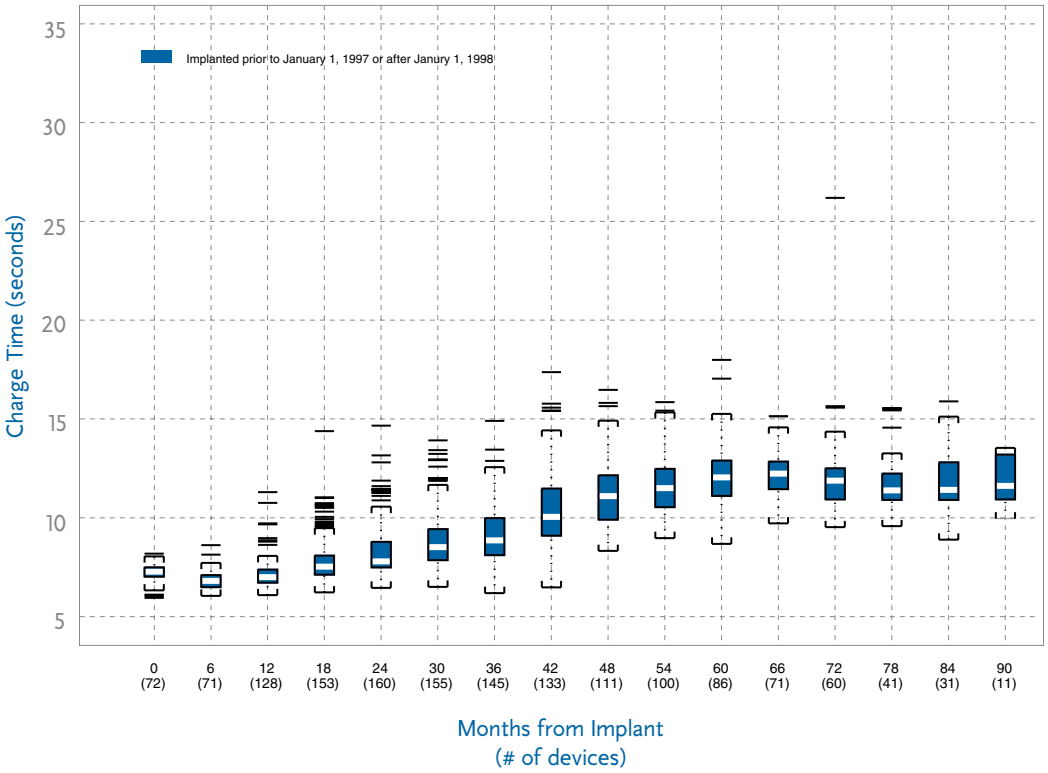
As shown in the graph below, the performance of Medtronic ICD and CRT-D devices has improved. This graph shows the overall maximums, minimums, and medians for Medtronic ICD and CRT-D products, beginning with the 7221 Micro Jewel. A progression toward shorter mean charge times and less variation has occurred between 1996 and 2002. Models released after 2002 have limited experience, but appear to be continuing this performance.



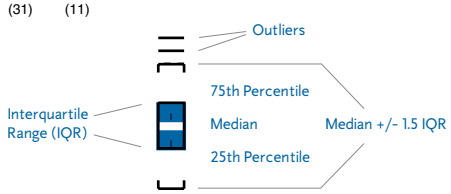


ICD and CRT-D Charge Time Performance continued

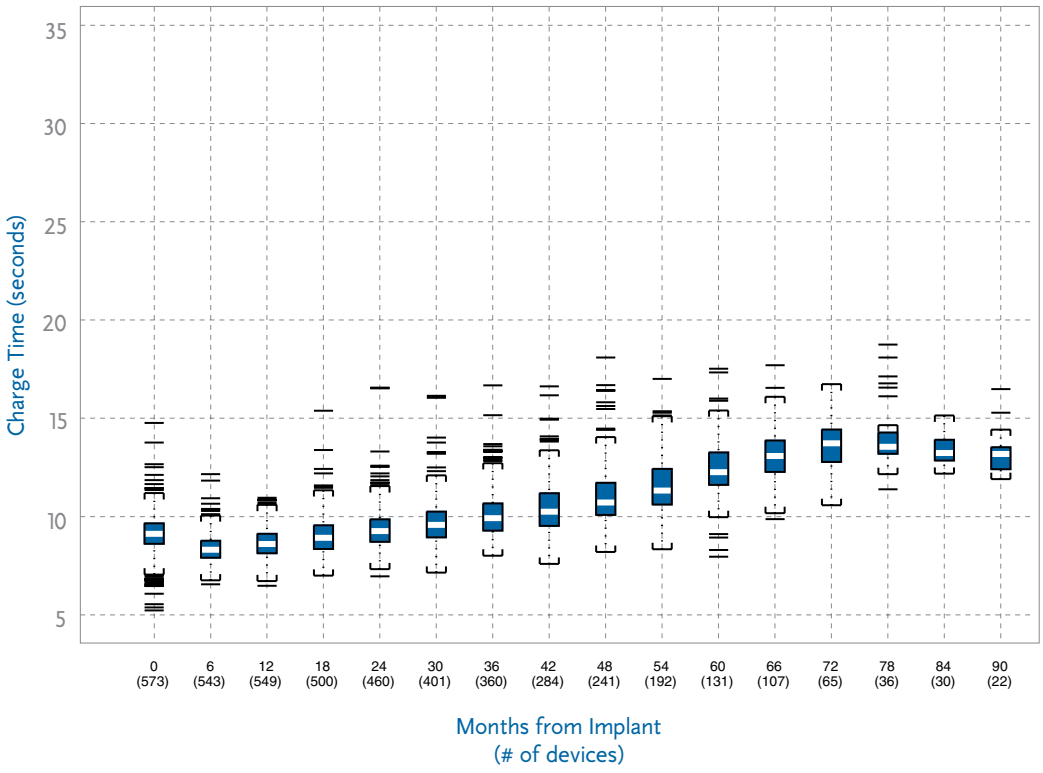
7223 Micro Jewel II Charge Time



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



7227 GEM Charge Time

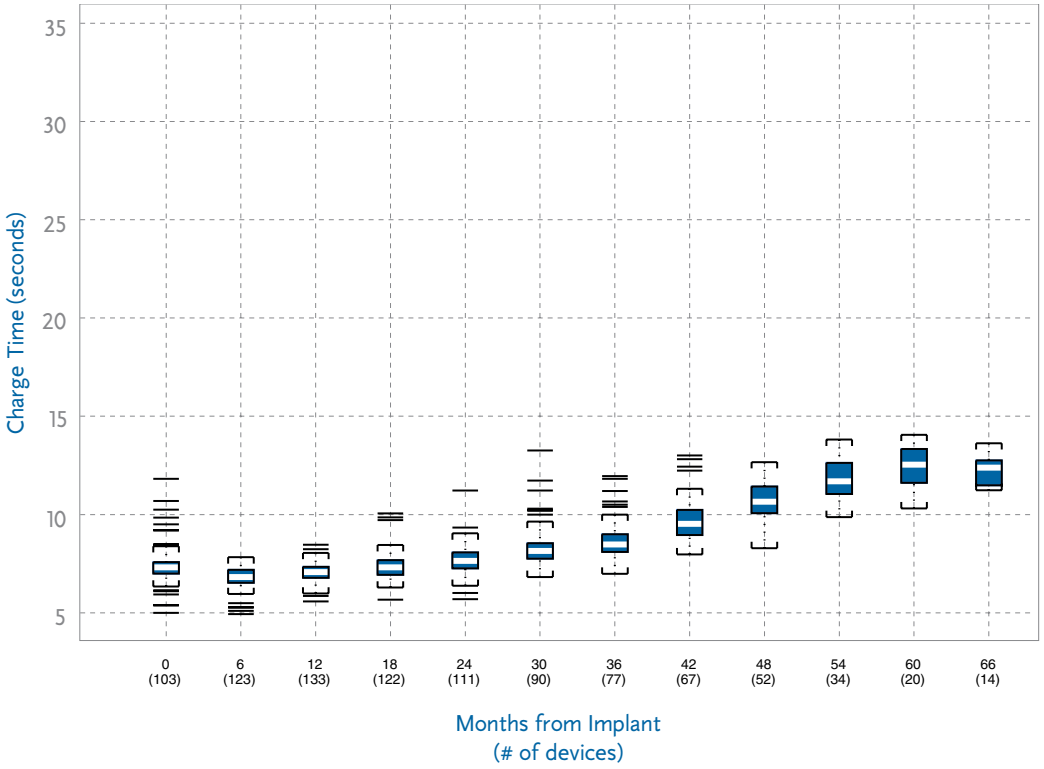


Save-to-Disk files have been collected 90 months post-implant. All observed charge times are below 20 seconds, with a maximum charge time of 18.75 seconds at 78 months post-implant.

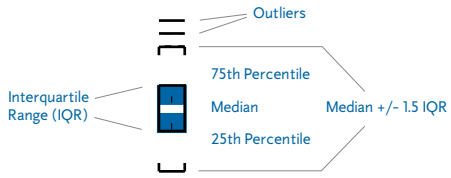
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

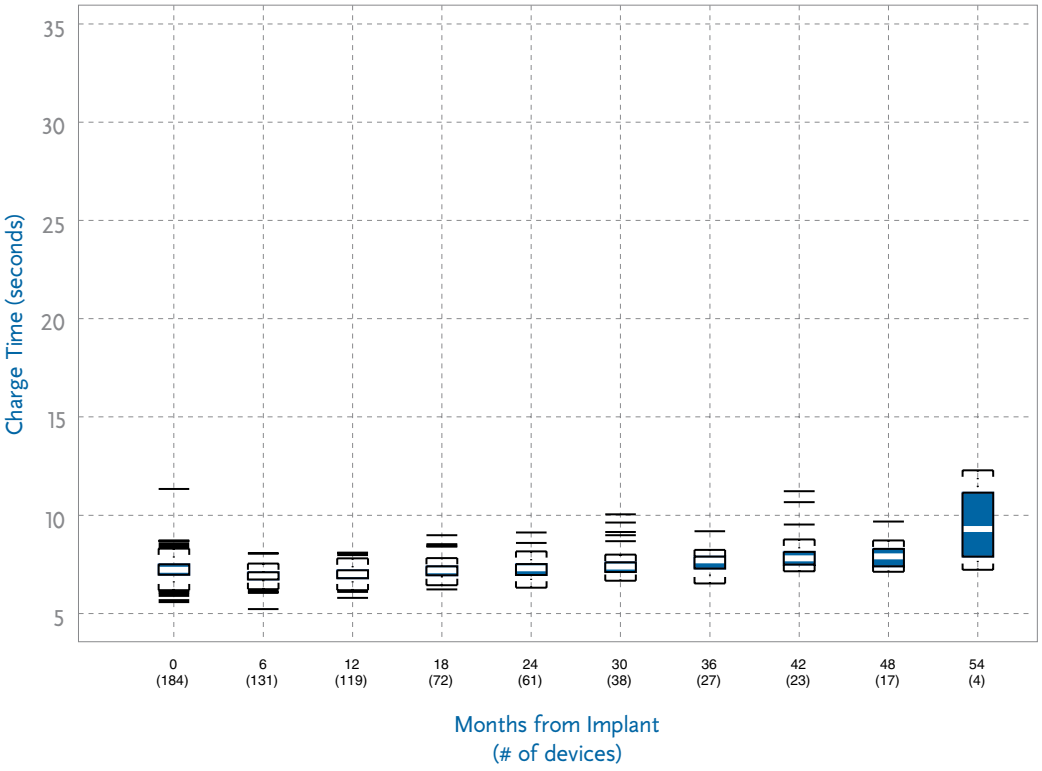
7229 GEM II VR Charge Time



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 14.06 seconds at 60 months post-implant.



7230 Marquis VR Charge Time

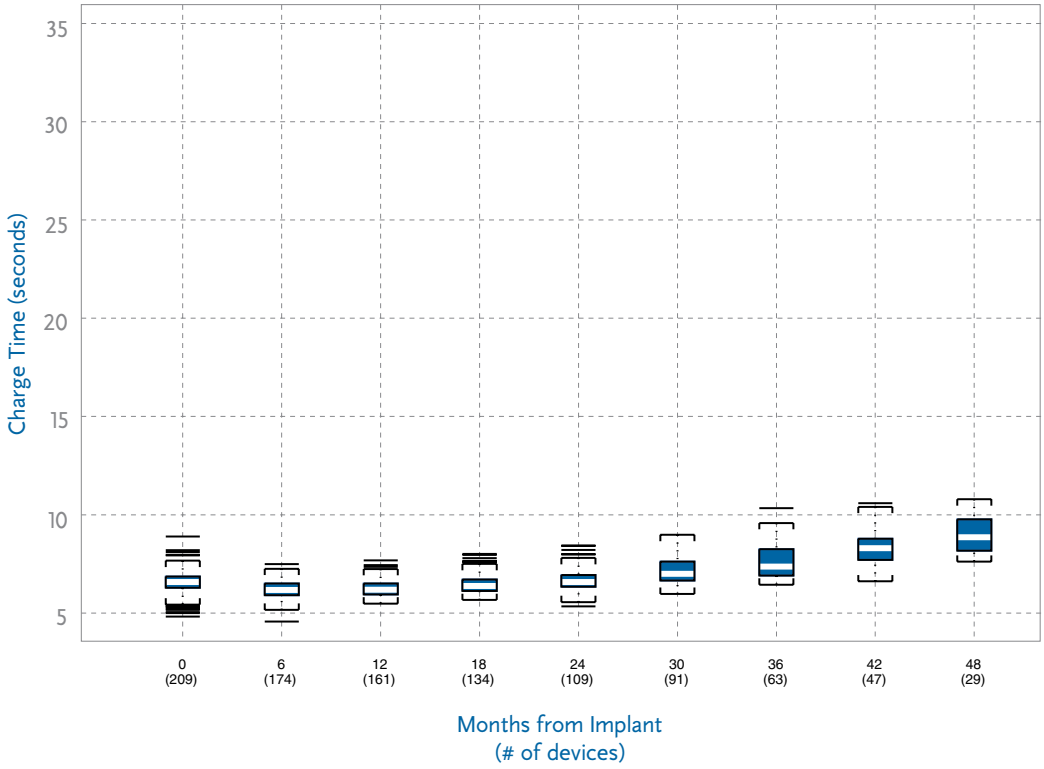


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 13 seconds with a maximum of 12.28 seconds observed at 54 months post-implant.

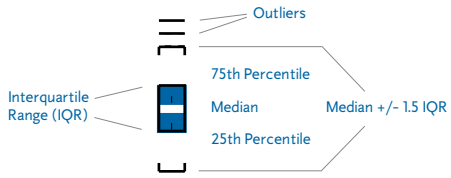
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

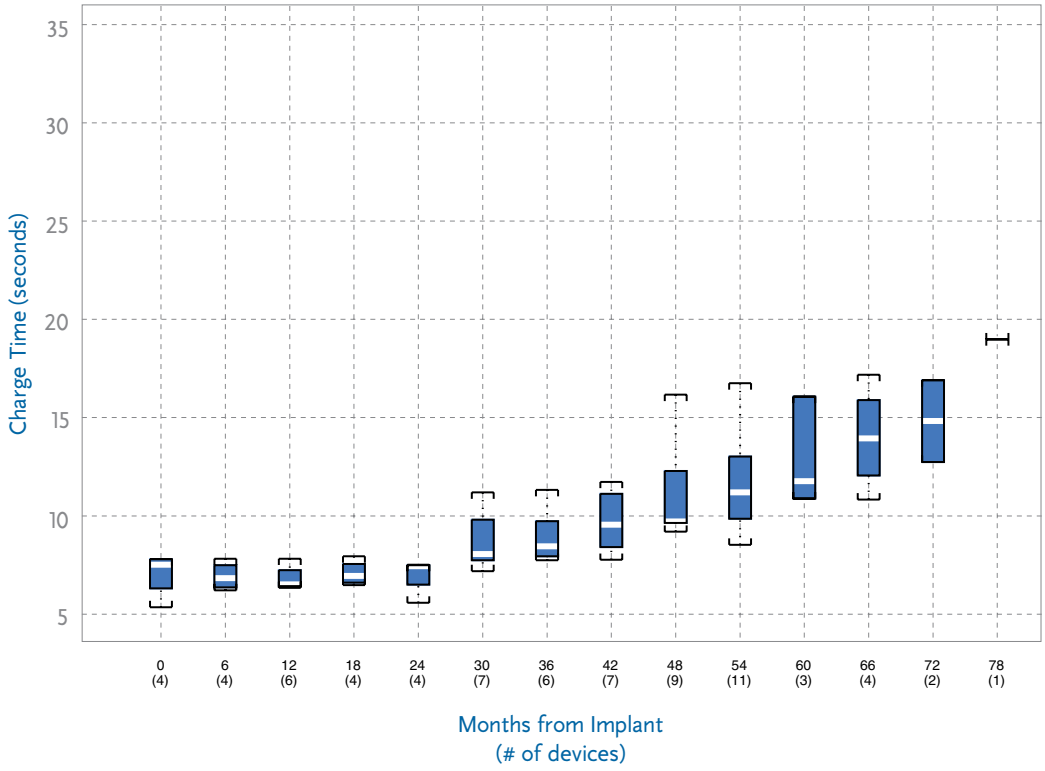
7231 GEM III VR Charge Time



Save-to-Disk files have been collected 48 months post-implant. All observed charge times are less than 12 seconds with a maximum of 10.79 seconds at 48 months post-implant.



7250 Jewel AF Charge Time

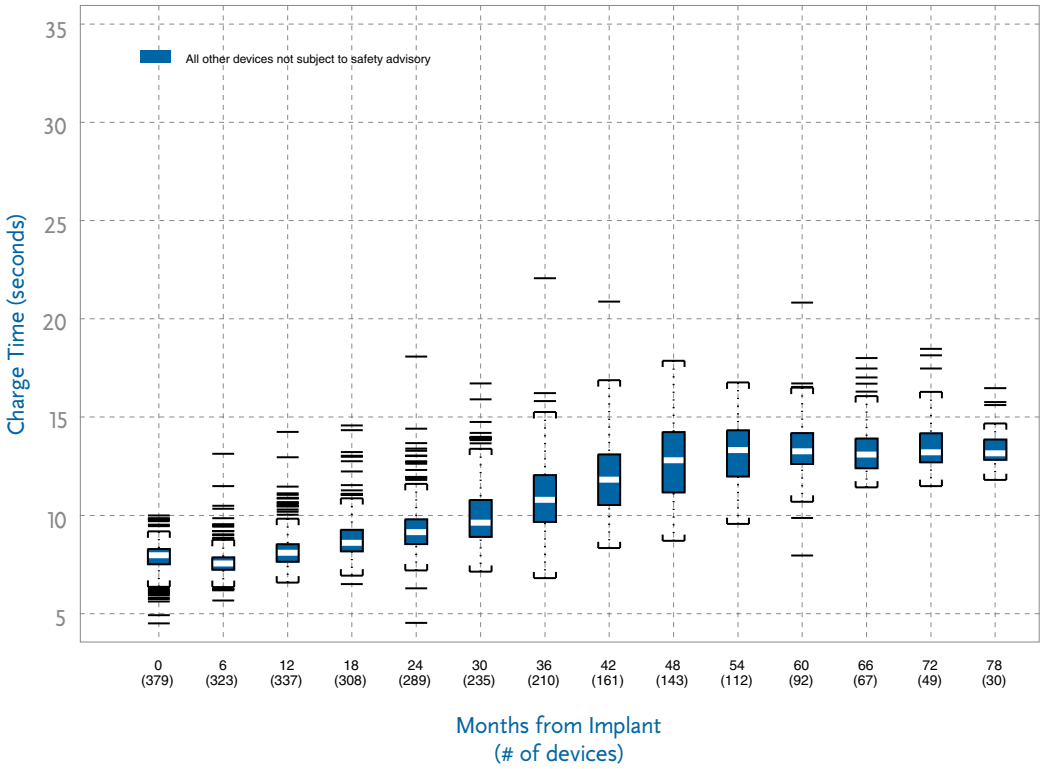


Save-to-Disk files have been collected 78 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.99 seconds observed at 78 months post-implant.

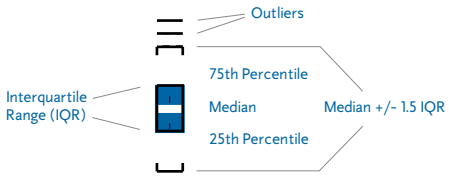
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

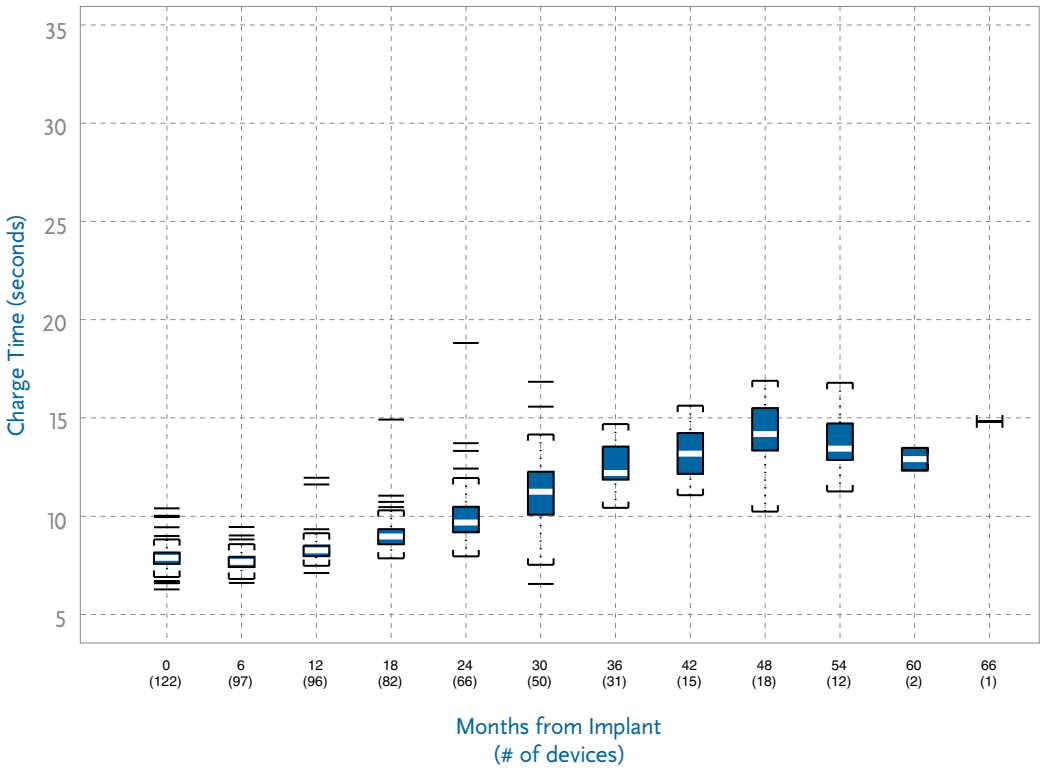
7271 GEM DR Charge Time



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

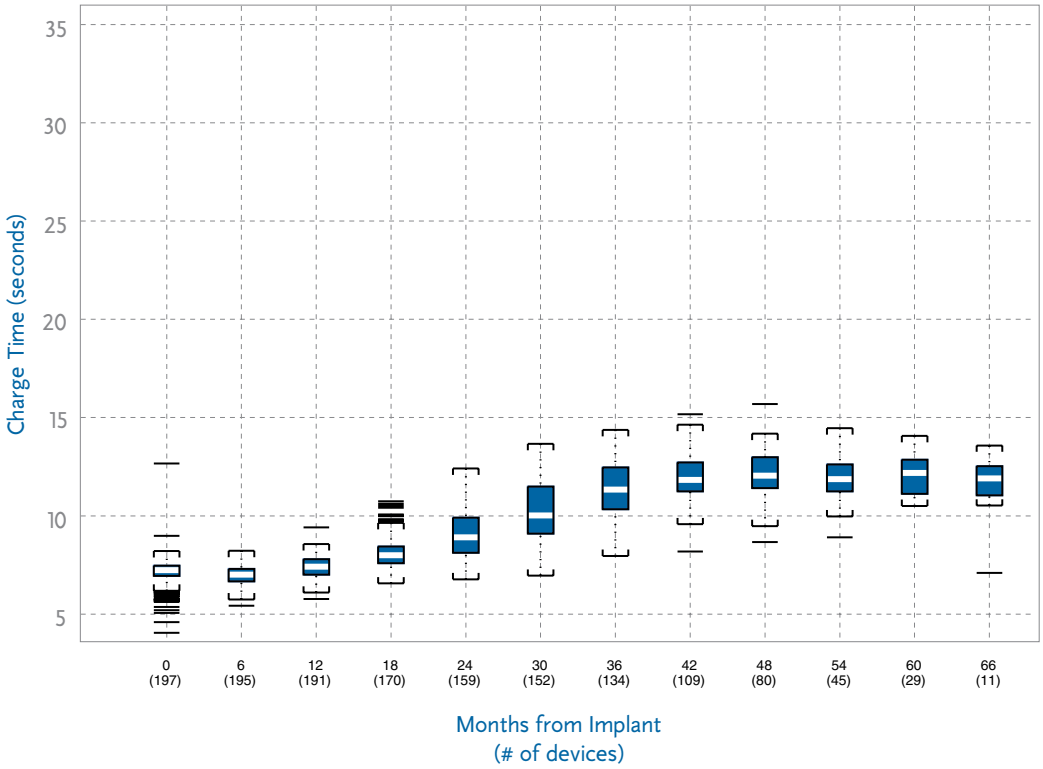


Save-to-Disk files have been collected 66 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.81 seconds observed at 24 months post-implant.

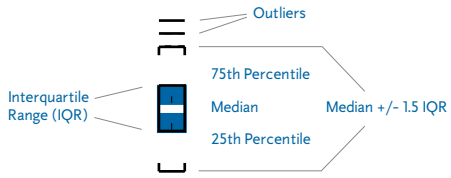
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

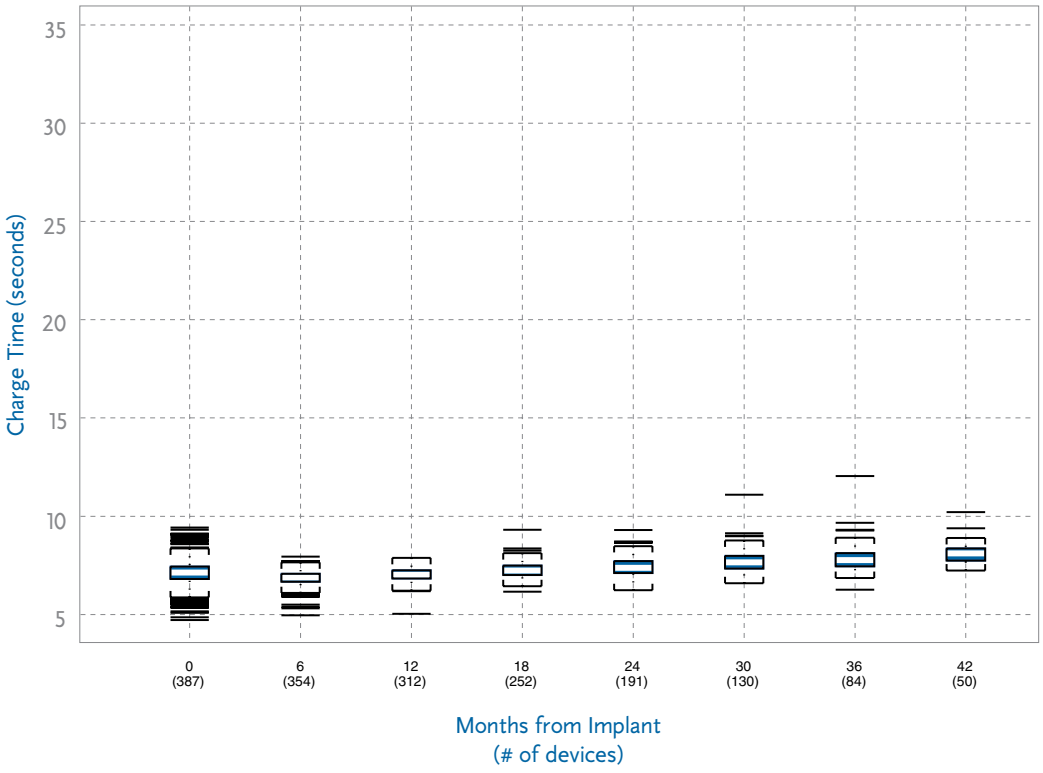
7273 GEM II DR Charge Time



Save-to-Disk files have been collected 66 months post-implant. All observed charge times are below 20 seconds, with a maximum charge time of 15.69 seconds observed at 48 months post-implant.



7274 Marquis DR Charge Time

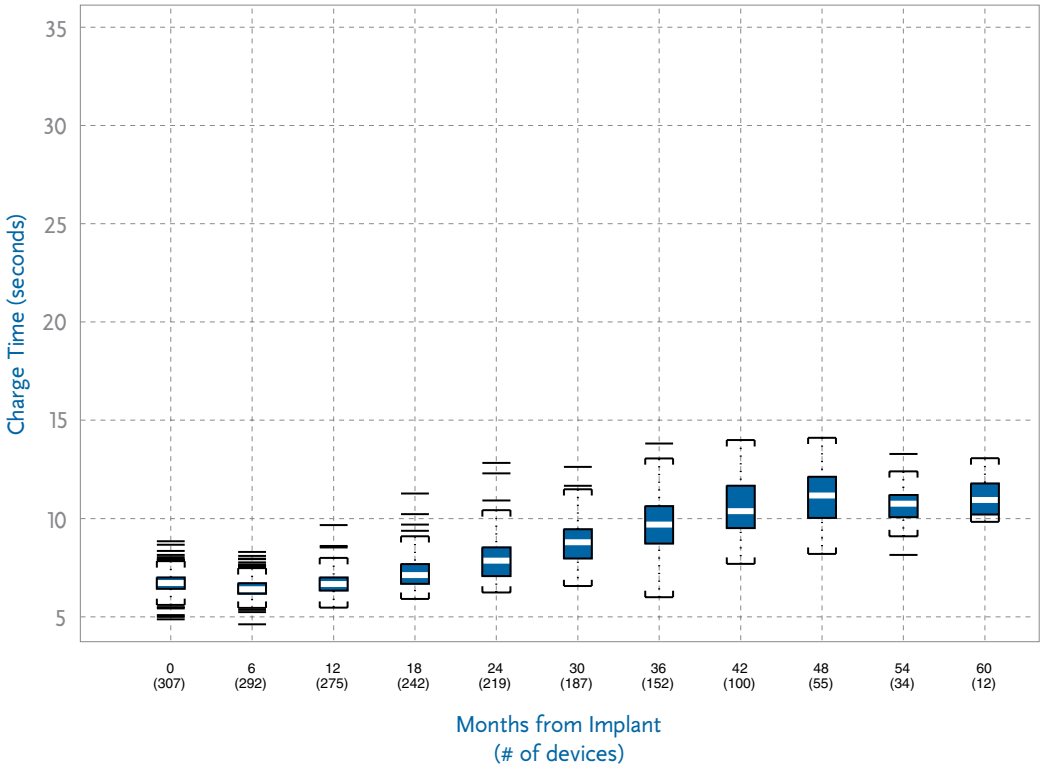


Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 13 seconds with a maximum of 12.05 seconds observed at 36 months post-implant.

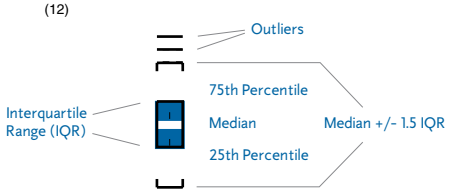
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

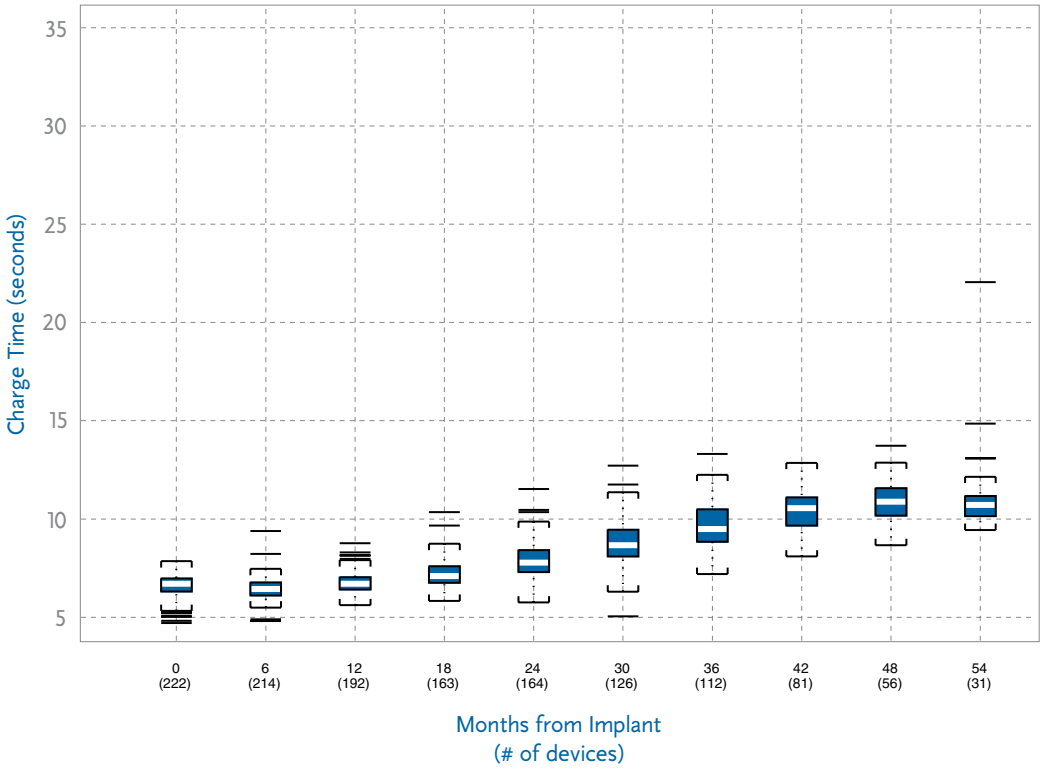
7275 GEM III DR Charge Time



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

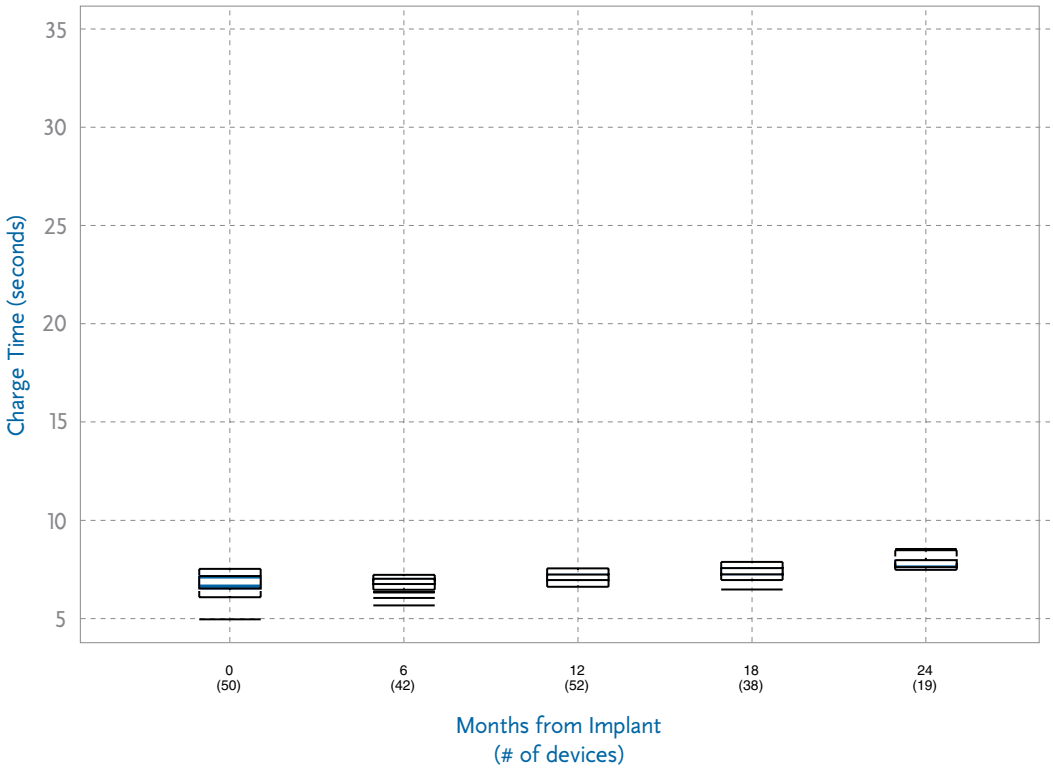


Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 15 seconds except one of 22.06 seconds observed at 54 months post-implant.

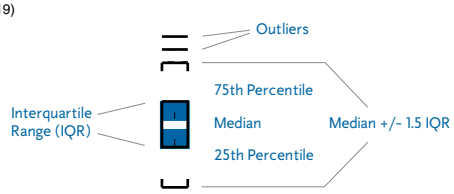
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

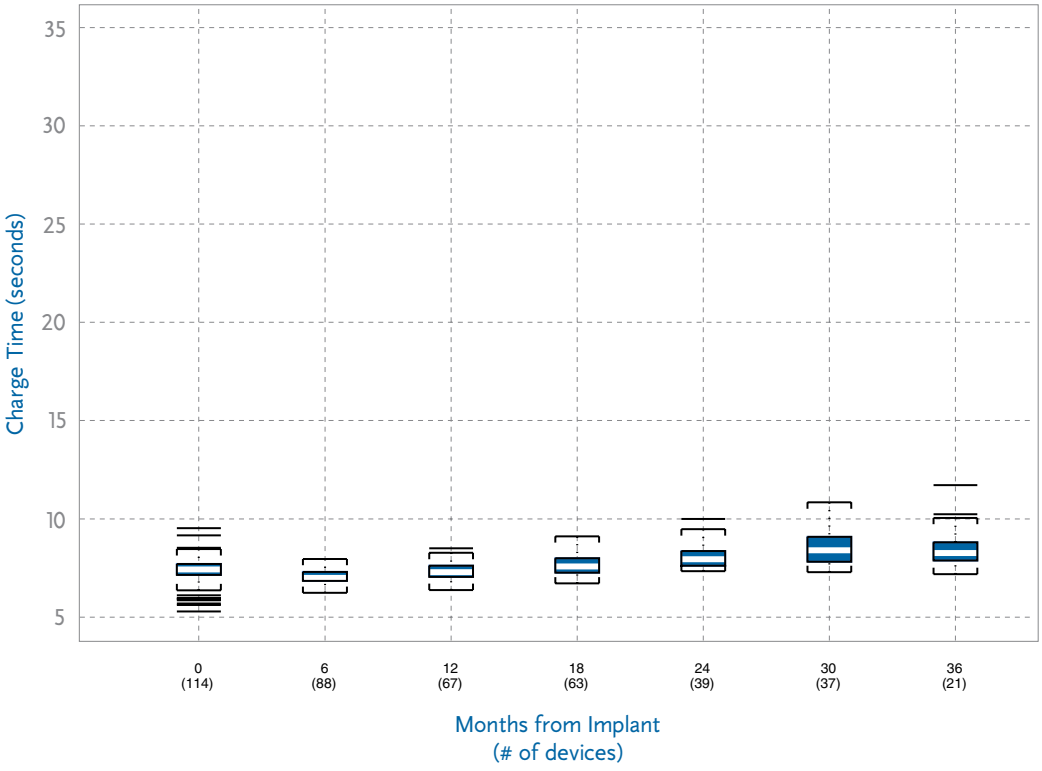
7277 InSync Marquis Charge Time



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

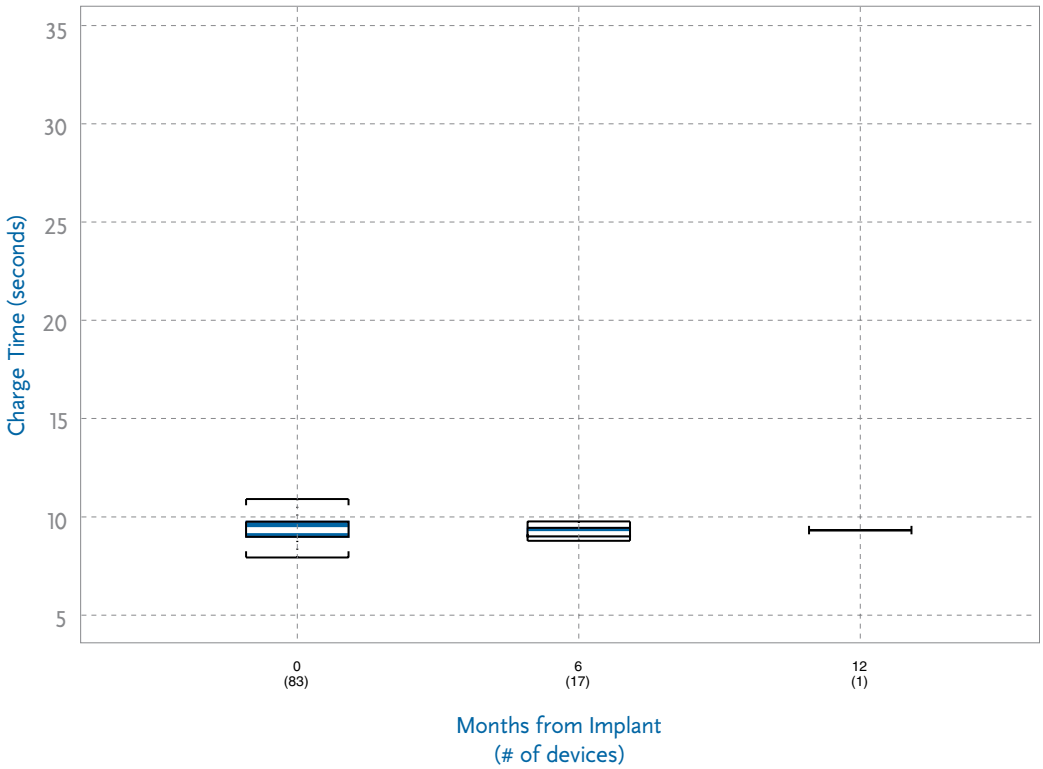


Save-to-Disk files have been collected 36 months post-implant. All observed charge times are less than 12 seconds with a maximum of 11.72 seconds observed at 36 months post-implant.

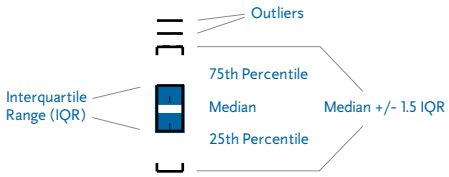
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

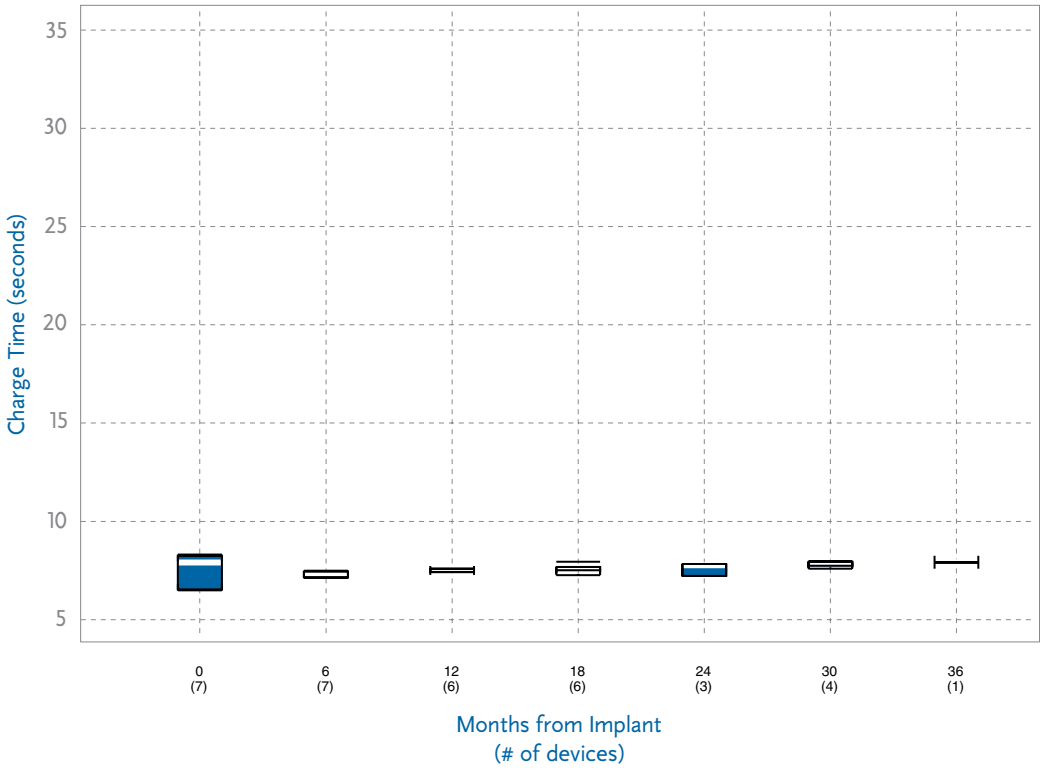
C154DWK Concerto Charge Time



Save-to-Disk files have been collected 12 months post-implant. All observed charge times are less than 12 seconds with a maximum of 10.91 seconds observed at implant.



D153ATG, D153DRG EnTrust Charge Time

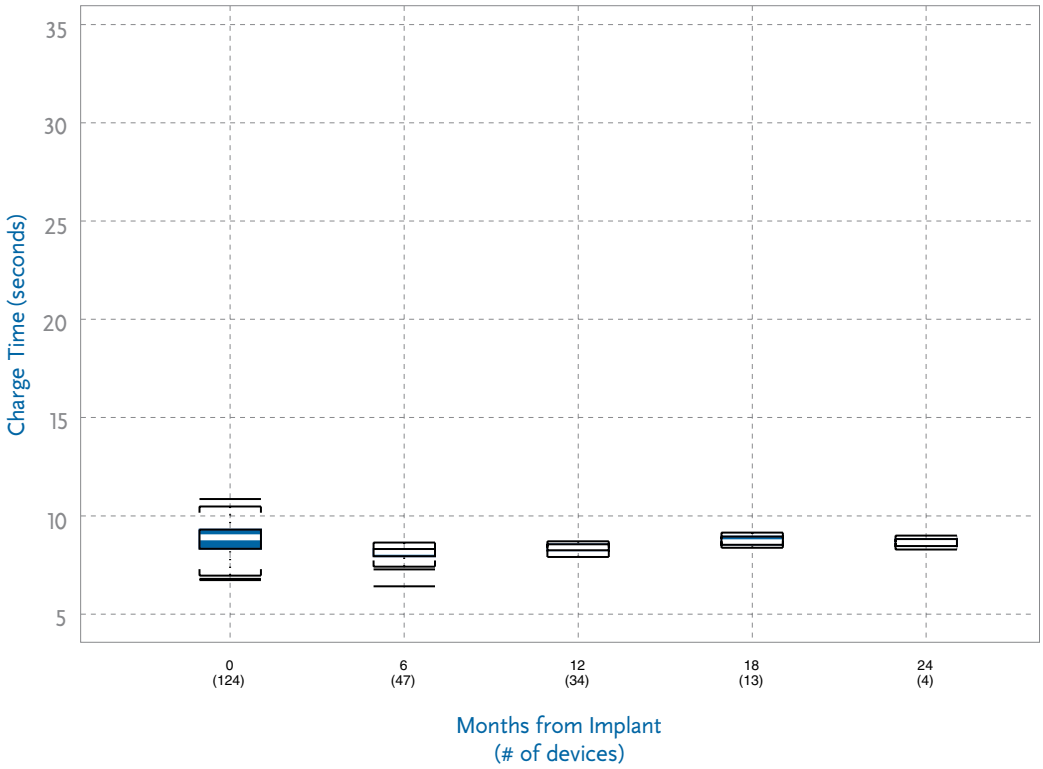


Save-to-Disk files have been collected 24 months post-implant. All observed charge times are less than 9 seconds with a maximum of 8.31 seconds observed at implant.

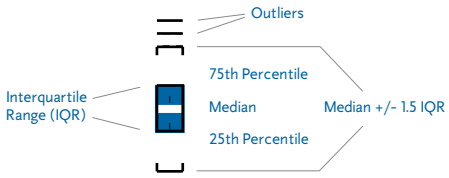
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

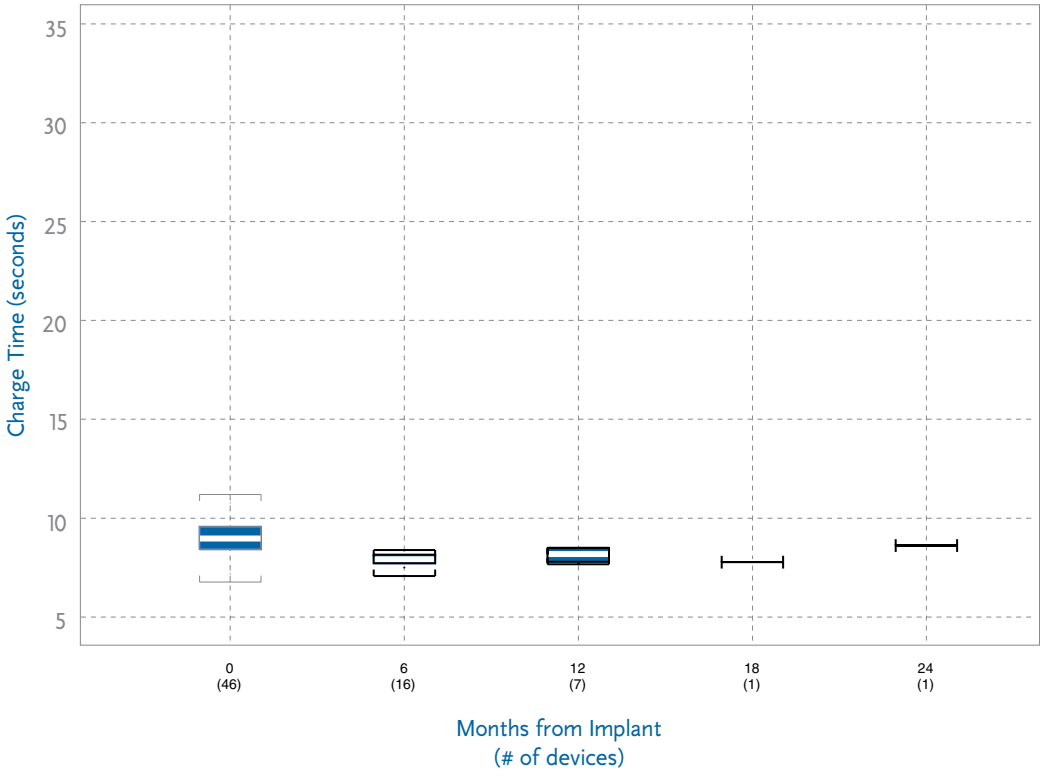
D154ATG, D154DRG EnTrust Charge Time



Save-to-Disk files have been collected 18 months post-implant. All observed charge times are less than 11 seconds with a maximum of 10.85 seconds observed at implant.



D154VRC EnTrust Charge Time

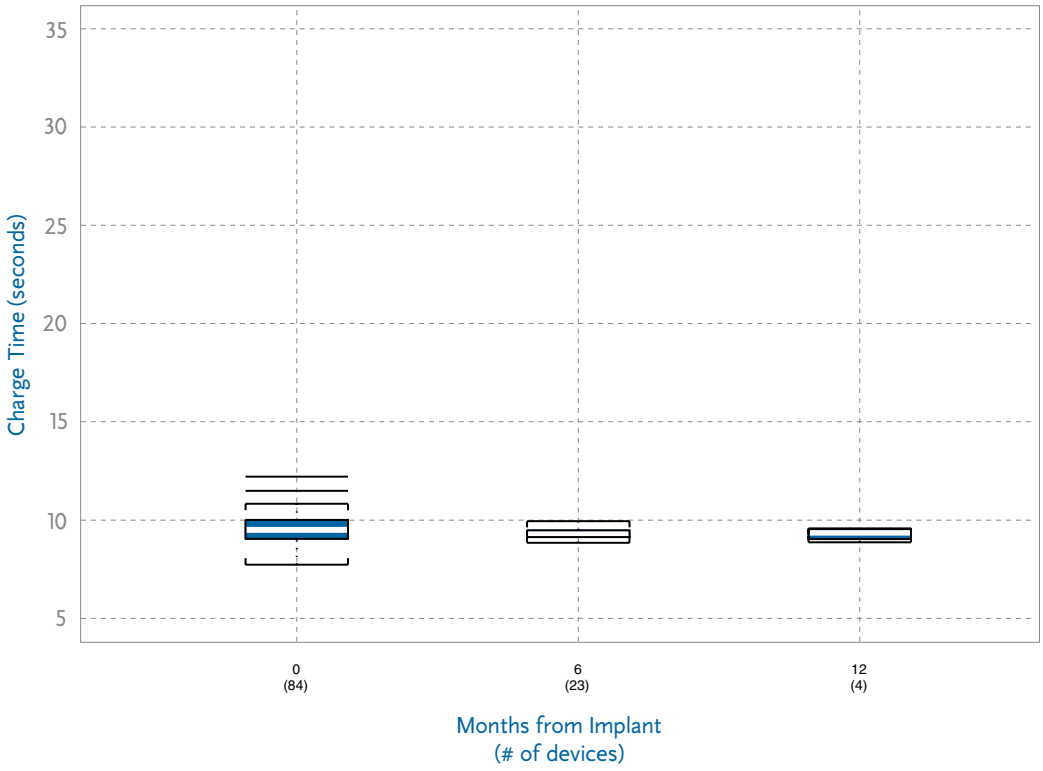


Save-to-Disk files have been collected 12 months post-implant. All observed charge times are less than 12 seconds with a maximum of 11.19 seconds observed at implant.

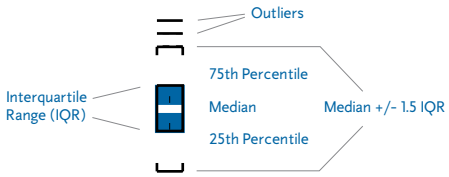
Source: System Longevity Study
Data as of July 31, 2007

ICD and CRT-D Charge Time Performance continued

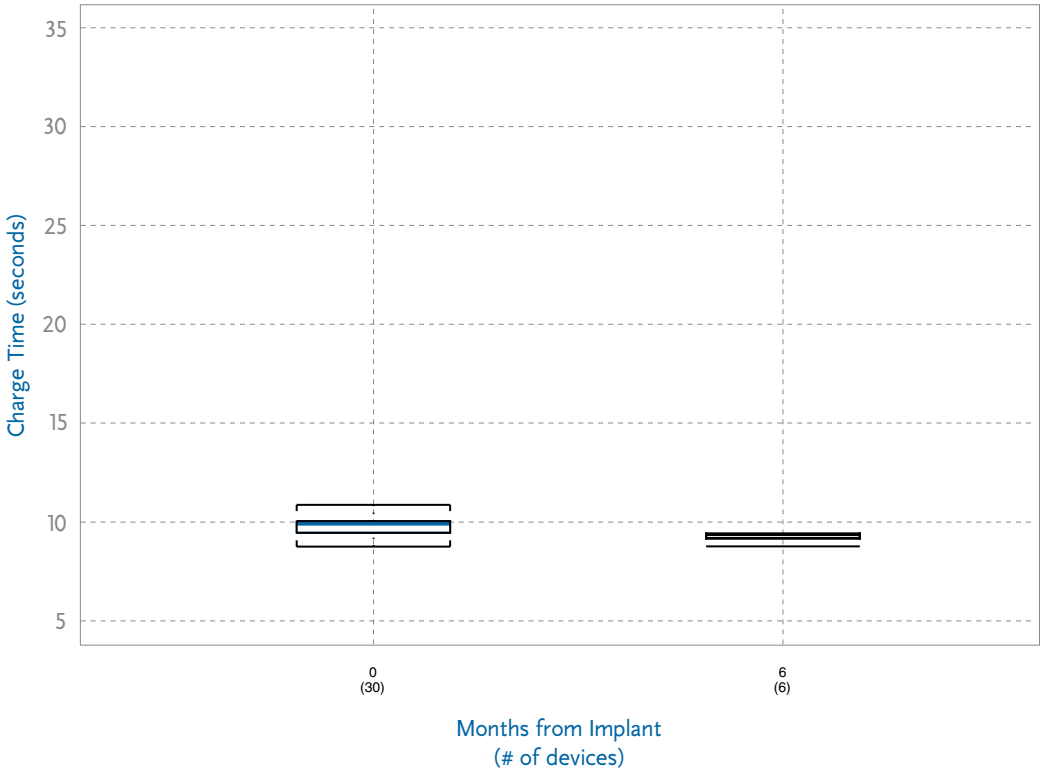
D154AWG Virtuoso Charge Time



Save-to-Disk files have been collected 12 months post-implant. All observed charge times are less than 13 seconds with a maximum of 12.2 seconds observed at implant.



D154VWC Virtuoso Charge Time



Save-to-Disk files have been collected 6 months post-implant. All observed charge times are less than 12 seconds with a maximum of 10.87 seconds observed at implant.

Source: System Longevity Study
Data as of July 31, 2007

Advisories

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Potential Conductor Wire Fracture

Product

All Models 6930, 6931, 6948, and 6949 Implantable Defibrillation Leads.

Advisory

There are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. These two locations account for 90% of the chronic fractures identified in Returned Product Analysis (RPA). The remaining 10% of chronic fractures occurred in the DF-1 connector leg and the proximal portion of the RV coil. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide and based on information available, we identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. We had confirmed 665 chronic fractures in returned leads. Approximately 90% of these fractures occurred in the anode or cathode conductors, while 10% occurred in the high voltage conductors.

As of October 4th, 2007, Returned Product Analysis of Sprint Fidelis leads showed a survival of 99.2% at 30 months. However, Returned Product Analysis overstates actual performance since it does not account for leads that are not returned. The Medtronic SLS data for the Model 6949 Sprint Fidelis lead indicated 97.7% [+1.3/-3.0] all-cause lead survival at 30 months. This was consistent with our analysis of Medtronic CareLink Network data from approximately 25,000 Sprint Fidelis leads, which indicated 97.7% [+0.6/-0.8] survival at 30 months.

As of October 4th, 2007, these survival rates were not statistically different from the all-cause lead survival of 99.1% [+0.4/-0.8] for the Model 6947 Sprint Quattro lead at 30 months from the SLS. However, we expect this difference will become statistically significant over time if the current failure rates remain constant.

Patient Management Recommendations

Medtronic recommends you consider the following as part of routine follow-up for each patient.

To reduce the risk of inappropriate detection and therapy due to oversensing, program VF detection for initial Number of Intervals to Detect (NID) to nominal settings (18/24) or longer at physician discretion and Redetect NID to nominal settings (12/16).

- Turn ON Patient Alert for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance. For Concerto and Virtuoso devices enrolled on the Medtronic CareLink Network, turn ON the Medtronic CareAlert notifications for these same parameters.
- To optimize effectiveness of the lead impedance alert:
  - Review V Pacing Lead Performance Trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms).
  - Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms, or
  - Program lead impedance alert threshold for RV Pacing to 1,500 ohms, if the typical chronic impedance for the patient is > 700 ohms.
  - Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.

The patient management recommendations set forth above should increase the likelihood that a fracture will be detected by Patient Alert and/or Medtronic CareAlert notifications and decrease the likelihood of inappropriate therapies. Based on our review of the available data, there does not appear to be a benefit to more frequent follow-up.

Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis leads except in unusual individual patient circumstances. Medtronic supports this position.

Lead extraction carries risks that should be considered in patient management. Published literature suggests major complications (death or surgical intervention) from lead extraction range from 1.4-7.3%. As always, with confirmed lead failure the risk of extraction should be weighed against the risk of adding an additional lead (see Appendix D of the physician letter).

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. 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.

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 (July 2007)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections. As of July 31, 2007, 102 devices out of approximately 40,000 devices worldwide (0.24% incidence) have been confirmed as having experienced interconnect wire separation while implanted. Thirty-five (35) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Fifty-seven (57) of the 102 devices were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 45 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 102 devices confirmed as having experienced interconnect wire separation has ranged between 17 and 61 months, with an average of 46 months.

Out of the initial advisory population of 40,000 worldwide, approximately 20,700 remain implanted. Approximately 4,800 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 (July 2007)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections. As of July 31, 2007, 91 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. Fifty-two (52) of these devices were returned from the United States. **There have been no confirmed serious injuries or deaths due to this issue.**

Of the 91 returns, 33 have been identified by patients reporting warmth in the ICD pocket, 36 by a regularly scheduled follow-up or during a nondevice related hospital visit, 11 by hand-held magnet test or CareLink attempt, 7 by return of bradycardia symptoms, and 4 by the Patient Alert sounding.

Implant duration for the 91 devices ranged between 11 to 53 months, with an average of 34 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, 46% occurred in the last quarter of device life and 29% in the last 10% of device life.

Out of the initial advisory population of 87,000 worldwide, approximately 33,600 remain implanted. Approximately 29,500 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.

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) 505-4636.

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. Patient management recommendations remain unchanged. As of July 31, 2007, 276 out of approximately 180,000 (0.15% incidence) Kappa family devices worldwide have been confirmed as having fractured power supply wires. One hundred thirty-nine (139) of these devices were returned from the United States. Out of the initial implant population of 121,000 in the United States, approximately 50,000 remain implanted.

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 Patient Alert 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. Patient management recommendations remain unchanged. Out of the initial implant population of 10,000 in the United States, approximately 2,500 remain implanted. 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.
Out of the initial implant population of 16,600 in the United States, approximately 1,600 remain implanted. According to System Longevity Study results, lead survival is estimated to be 66.1% at 8 years, 11 months.

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.
Out of the initial implant population of 77,000 in the United States, approximately 3,200 remain implanted. According to System Longevity Study results, lead survival is 50.6% 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. Out of the initial implant population of 96,800 in the United States, approximately 5,700 remain implanted. The System Longevity Study results show 62.2% 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. Patient management recommendations remain unchanged. Out of the initial implant population of 65,000 in the United States, approximately 5,000 remain implanted. The devices affected by this advisory are nearing the end of their expected longevity.

Performance Notes

Ensuring the Accuracy of Battery Longevity Estimates

Purpose of this Information

This article is intended to help the clinician understand how Medtronic estimates CRT-D, ICD, and IPG device longevity and Medtronic's performance against these estimates.

Device Longevity and Battery Depletion

The device service life ends when the usable battery capacity is depleted. The time to battery depletion depends on three factors:

- the amount of electrical energy expended in providing therapy to the patient
- the amount of energy consumed by the electronic circuitry to perform the functions of the device (e.g., operating the microprocessor, telemetry, memory, and charging component)
- the energy capacity of the battery

Medtronic has developed a statistical model for device longevity that accounts for each of these factors, and has validated the model with real time clinical performance. During the development of its products, Medtronic engineers characterize device longevity using this model. Testing begins during development and continues after market release to ensure the accuracy of device longevity estimates.

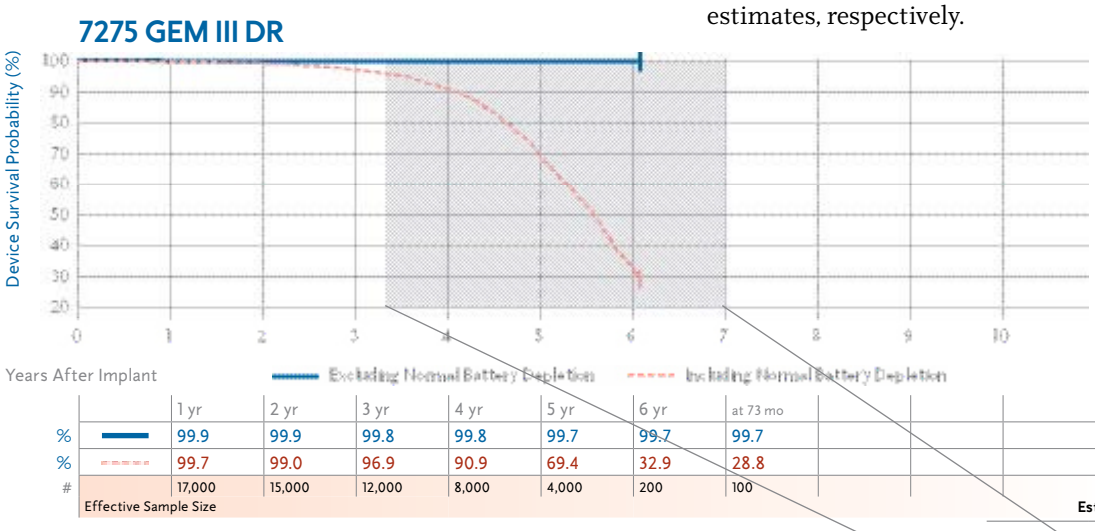
Using Survival Curves to Assess Longevity

The survival curves in the Product Performance Report represent the composite experience of thousands of devices over a wide range of programming options and patient use conditions. While the curves are useful for understanding the overall performance of a population of devices, they cannot be used to accurately predict the longevity of a specific device in a specific patient. To get a longevity prediction for a specific device, the longevity model must be used. The model is available by contacting Medtronic's Technical Services Department.

Because the survival curves are an aggregate result, the Reference pages in the Product Performance Report include several longevity estimates for a range of use conditions. These longevity estimates, originally published in the device Technical Manual, are mean values calculated for the parameters given. This range of longevity estimates can be compared to the survival curve including normal battery depletion to assess the overall clinical performance of a device model against the original longevity estimates.

If most of a device model's population is being used at nominal parameters and conditions, the time at which the survival curve including normal battery depletion equals 50% should approximate the midpoint in the range of longevity estimates.

If devices tend to be used at conditions that consume more or less energy than nominal, then the time at which the survival curve equals 50% should tend toward the lower or higher end of the range of longevity estimates, respectively.



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 73 mo
%	Excluding Normal Battery Depletion	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	Including Normal Battery Depletion	99.7	99.0	96.9	90.9	69.4	32.9	28.8
#	Effective Sample Size	17,000	15,000	12,000	8,000	4,000	200	100

Charging Frequency***	Estimated Longevity 100% Pacing†	50% Pacing†	15% Pacing†	100% Sensing
Monthly	3.3	3.8	4.3	4.4
Quarterly	4.2	5.0	5.8	6.3
Semiannual	4.5	5.5	6.5	7.0

This figure shows the range of the estimated longevity values given in the reference chart in relation to the survival curve for the Model 7275 ICD. The range of longevity is representative of a typical range of use values, not the absolute minimum or maximum longevities possible. In this example, the survival curve including normal battery depletion is approaching 50% at approximately the mid-point of the range of longevity values.

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 pacing modes[10], 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.).

References

[1] Steinberg JS, Fischer A, Wang P, et al. The clinical implications of cumulative right ventricular pacing in the Multicenter Automatic Defibrillator Trial II. *J Cardiovasc Electrophysiol*. April 2005;16(4):359-365.

[2] Pinski SL, Eguia LE, Trohman RG. What is the minimal pacing rate that prevents Torsades de Pointes? Insights from patients with permanent pacemakers. *PACE*. November 2002; 25(11):1612–1615.

[3] Goldman DS, Levine PA. Pacemaker-mediated polymorphic ventricular tachycardia. *PACE*. October 1998; 21(10):1993–1995.

[4] Gray CJ, Basta M, Sapp JL, Parkash R, Gardner MJ. Inappropriate application of managed ventricular pacing in a patient with Brugada syndrome leading to polymorphic ventricular tachycardia, ventricular fibrillation and implantable cardioverter debrillator shocks. *Heart Rhythm*. 2006, Abstract P1-89.

[5] Friedman PA, Jalal S, Kaufman S, et al. Effects of a rate smoothing algorithm for prevention of ventricular arrhythmias: results of the Ventricular Arrhythmia Suppression Trial (VAST). *Heart Rhythm*. May 2006;3(5):573-580.

[6] Himmrich E, Przibille O, Zellerhoff C, et al. Proarrhythmic effect of pacemaker stimulation in patients with implanted cardioverter-defibrillators. *Circulation*. July 15, 2003;108(2):192-197.

[7] Sweeney MO, Ellenbogen KA, Casavant D, et al. Multicenter, prospective, randomized trial of a new atrial-based Managed Ventricular Pacing Mode (MVP) in dual chamber ICDs. *J Cardiovasc Electrophysiol*. 2005:16:1-7.

[8] Sweeney MO, Shea JB, Fox V, et al. Randomized pilot study of a new atrial-based minimal ventricular pacing mode in dual-chamber implantable cardioverter-defibrillators. *Heart Rhythm*. July 2004;1(2):160-167.

[9] Gillis AM, Purerfellner H, Israel CW, et al. Reducing unnecessary right ventricular pacing with the managed ventricular pacing mode in patients with sinus node disease and AV block. *PACE*. July 2006; 29(7):697–705.

[10] The DAVID Trial Investigators. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. *JAMA*. December 25, 2002;288(24):3115-3123.

[11] Sweeney MO, Ellenbogen KA, Whellan D, et al. The Managed Ventricular Pacing vs. VVI 40 Pacing (MVP) Trial: Clinical Background, Rationale, Design and Implementation. *J Cardiovasc Electrophysiol*. 2006 (In Press).

[12] Sweeney MO, Hellkamp AS, Ellenbogen KA, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. *Circulation*. June 17, 2003;107(23):2932-2937.

[13] Nielsen JC, Kristensen L, Andersen HR, et al. A randomized comparison of atrial and dual-chamber pacing in 177 consecutive patients with sick sinus syndrome: echocardiographic and clinical outcome. *J Am Coll Cardiol*. August 20, 2003;42(4):614-623.

[14] Nielsen JC, Pedersen AK, Mortensen PT, Andersen HR. Programming a fixed long atrioventricular delay is not effective in preventing ventricular pacing in patients with sick sinus syndrome. *Europace*. April 1999; 1(2):113–120.

[15] Dennis MJ, Sparks PB. Pacemaker mediated tachycardia as a complication of the autointrinsic conduction search function. *PACE*. June 2004;27(6 Pt 1):824-826.

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.

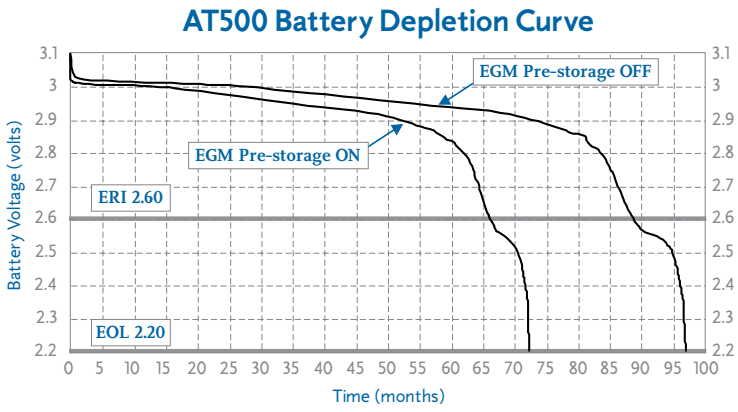


Figure 1

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.

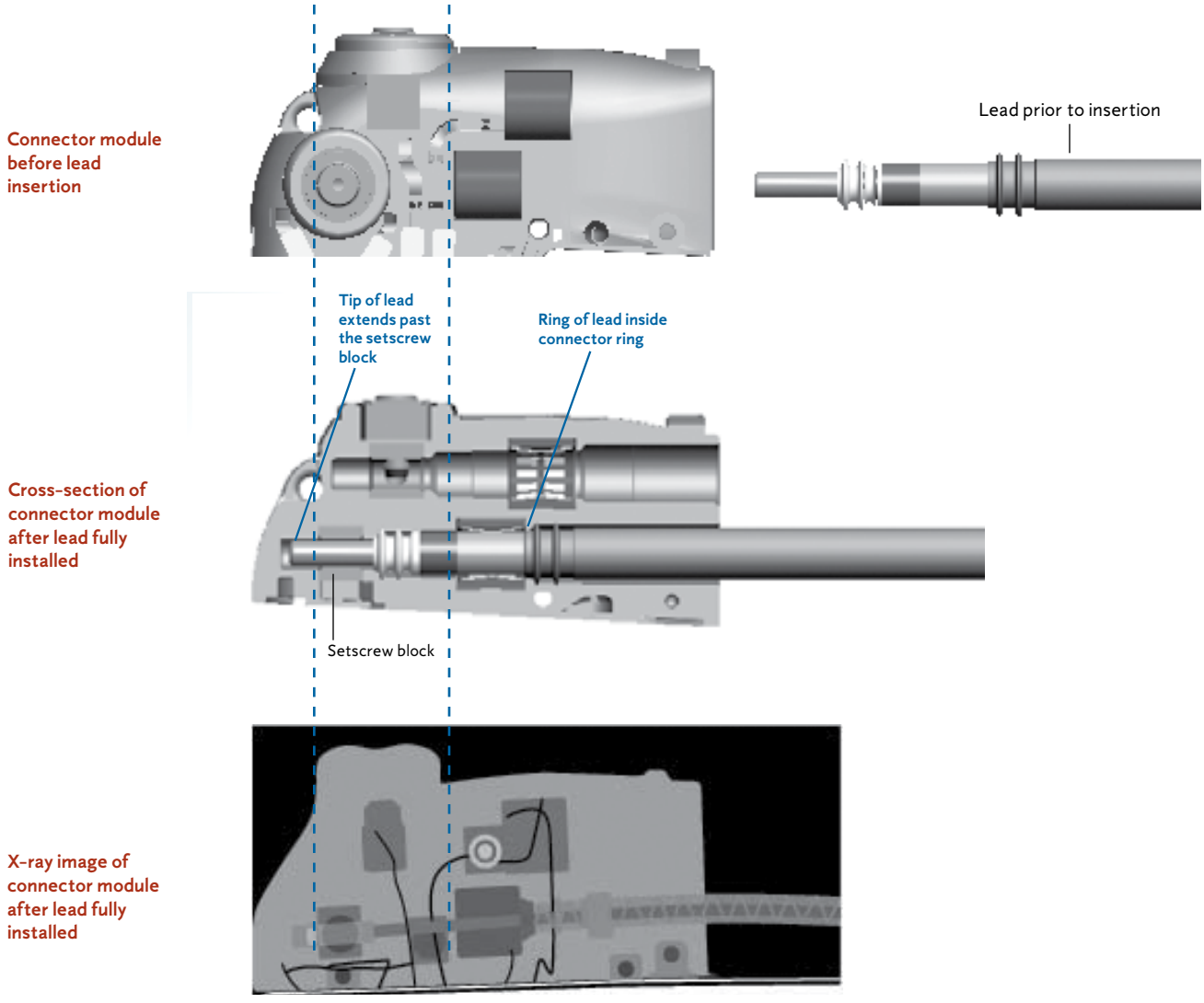
3 Push the lead into the connector port until the lead pin is clearly visible beyond the setscrew block.

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.

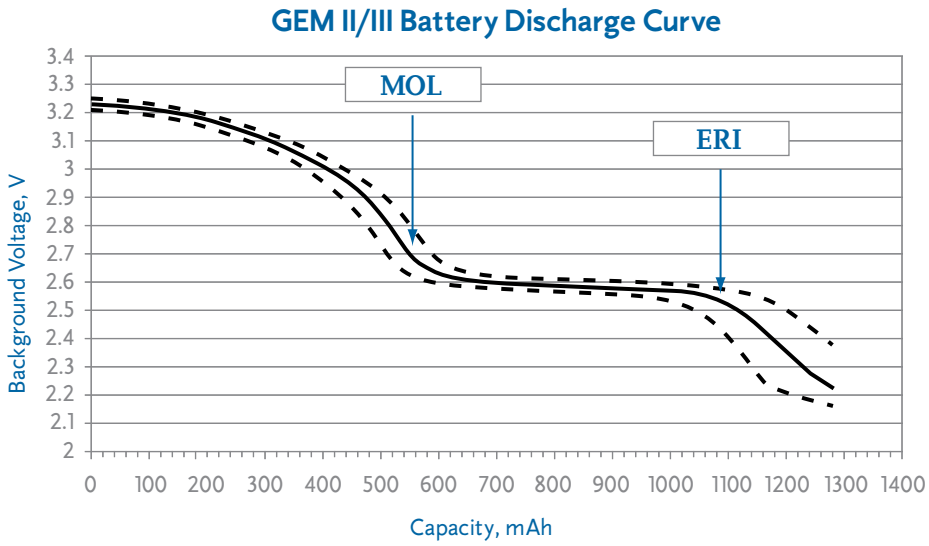
The battery discharge curve (see curve below) is characterized by a significant decrease in the battery voltage approaching Middle-of-Life (MOL), followed by a plateau (MOL to ERI) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily misinterpreted as the 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.



General Follow-Up and Replacement of ICD Leads

Implanted leads operate in the challenging biochemical environment of the human body and the body's response to foreign objects. Implanted leads are also subject to mechanical stresses associated with heart motion, body motion, and patient anatomy.

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 Patient Alert™ and performance information from the System Longevity Study (SLS).

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 System Longevity Study 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.[1-3] Ultimately, the decision to replace an implanted lead involves medical judgment.

[1] Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE.* June 2002;25(6):879-882.

[2] Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol.* January 1, 2003;41(1):73-80.

[3] Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early Failure of a Small Diameter High Voltage Implantable Cardioverter Defibrillator Lead, Heart Rhythm (2007), doi:10.1016/j.hrthm.2007.03.041

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	Effect 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	

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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.

CRDM Returned Product Analysis Laboratory
Medtronic, Inc.
7000 Central Avenue NE MS T172
Minneapolis, MN 55432-3576 USA

Phone: 1 (800) 328-2518, ext. 44800
email: crdm.returnedproduct@medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
www.medtronic.com

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

Europe
Medtronic International Trading Sàrl
Route du Molliau 31
CH-1131 Tolochenaz
Switzerland
Tel: (41 21) 802 7000
Fax: (41 21) 802 7900
www.medtronic.com

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel: (905) 826-6020
Fax: (905) 826-6620
Toll-free: 1 (800) 268-5346

Asia Pacific
Medtronic International, Ltd.
16/F Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel: (852) 2891 4456
Fax: (852) 2891 6830
enquiryap@medtronic.com
www.medtronic.com

Latin America
Medtronic USA, Inc.
Doral Corporate Center II
3750 NW 87th Avenue Suite 700
Miami, FL 33178
USA
Tel: (305) 500-9328
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