Medtronic

Cardiac Rhythm Disease Management
Product Performance Report

Important Patient Management Information for Physicians

2010

First Edition – Issue 62



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

A Message from the Vice President

Dear Customer,

At Medtronic, product quality and reliability have been and will continue to be a priority. For over 27 years, Medtronic has compiled and produced product performance reports with one primary goal, to provide you with the product information you need to best care for your patients.

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 continually explore new ways to expand, improve, and learn from our product performance systems and measures.

Our quality goals cannot be reached alone. We welcome your collaboration, insight, and recommendations. Please contact our Technical Services Department at 1 (800) 723-4636 with your feedback comments and any questions.

Your participation and assistance in returning explanted products are also critical. Returned products are tested and evaluated so that we can fully measure the performance of our devices. Please refer to the instructions on the next page for assistance in returning products to the Medtronic CRDM Returned Product Analysis Laboratory.

As we constantly strive to exceed your expectations, we thank you for your dedication to improving and saving the lives of those suffering from cardiac rhythm disorders.

With appreciation and warm regards,

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

Timothy Smith
Medtronic, Inc.
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

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

Editorial Staff

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CRDM Product Performance Report

2010 First Edition
Issue 62

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Introduction

All product performance reports are not created equal. For 27 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

Since May 2000, 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

Introduction continued

Medtronic urges all physicians to return explanted products 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 products 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 products 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 US 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 products from non-clinical sources, such as funeral homes, and will assume responsibility for storage and disposal of the product once received.

Mailer kits can be obtained by contacting the Returned Product Lab. For information on how to contact the Lab, refer to Contact Information 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 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 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 our multicenter, international prospective 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 in the study protocol.

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
- 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 6)* and *Method for Estimating Lead Performance (page 75)*.

continued

Introduction 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.

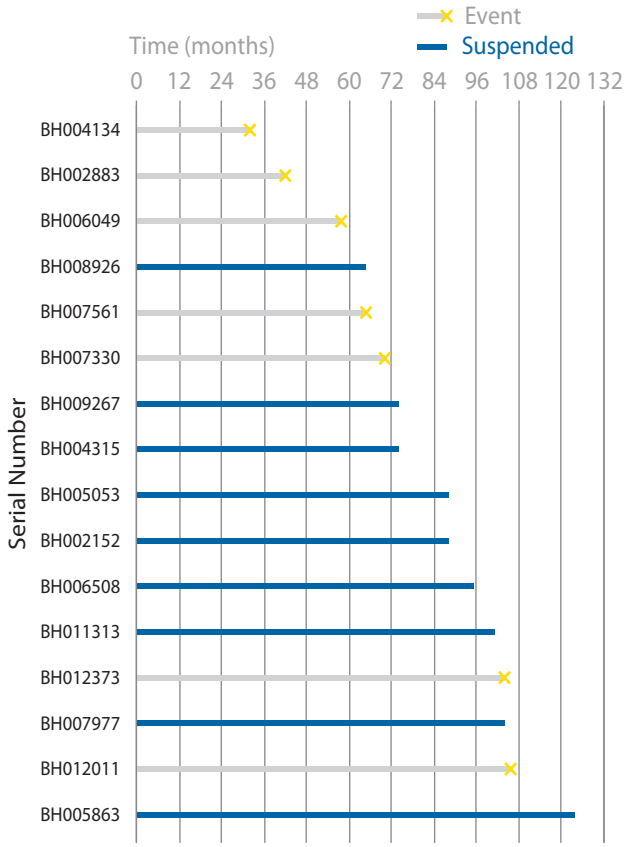


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because 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 seven of the 16 devices suffered events, and nine 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 the 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 overestimates the sample size because the suspended devices do not complete the interval. Ignoring the suspended devices underestimates 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

Introduction continued

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

Table 1 Life Table for Figure 1

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

Definitions:

A
Number Entered

Number of devices active at the start of the interval

B
Number Suspended

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

C
Number of Events

Number of units removed from service due to an event

D
Effective Sample Size

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

E
Proportion with Event

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

F
Interval Survival Probability

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

G
Cumulative Survival Probability

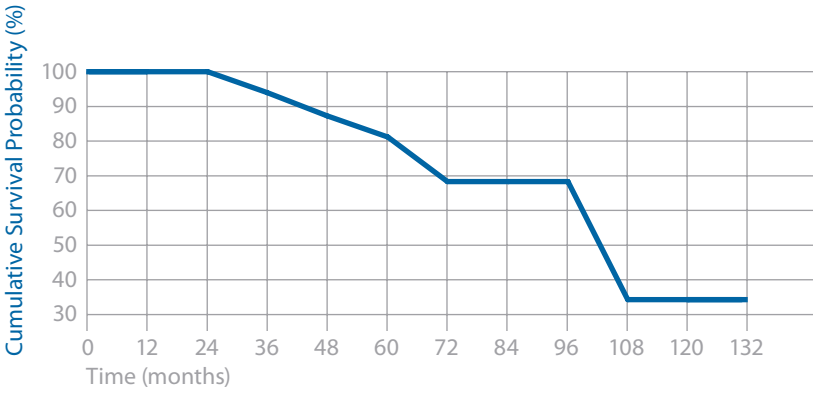
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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

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

continued

Figure 2 Survival Curve for Data Given in Table 1



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

Effective Sample Size

Confidence Intervals

Since survival curves are based on a sample of the device and lead population, they are only estimates of survival. 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 1-month intervals (for CRT, ICD, and IPG devices) or 3-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 products 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 United States device registration data and US 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.

Definition of Malfunction

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 estimated longevities 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 these estimates.

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.

Expanded Malfunction Detail

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 evenly within 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 5 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 are rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have one 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.

A CRT, ICD, or IPG 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 Medtronic's Device And Registrant Tracking (DART) system.

The DART system is an important element of Medtronic's Quality System. The DART system is designed to meet or exceed the US FDA's device tracking requirements set forth by the Safe Medical Devices Act. In the United States, over 98% of Medtronic's CRT, ICD, and IPG implants become registered in the DART system.

continued

Because pacemakers do not cure the patient's underlying health problem, when a pacemaker stops functioning (due to either normal battery replacement or malfunction) it is replaced with a new pacemaker. Therefore, the replacement recorded in the DART system is a good indication that the previous pacemaker experienced either battery depletion or malfunction. The fraction of replaced devices that are subsequently returned can be used to estimate the correction factor for the under reporting of the combination of battery depletion and malfunction.

Note that devices of patients who have expired do not factor into the calculation of the correction. It is possible some proportion of these device experienced battery depletion or malfunction. Since these are not counted into the correction factor based on the return rate of replaced devices, a correction factor based only on the return rate of replaced devices may still underestimate the true rate of battery depletion and malfunction. However, devices that are replaced because the patient is receiving a system upgrade or are removed because the patient no longer needs it (e.g., due to heart transplant) do contribute to the calculation of the correction factor and therefore impart an opposite bias.

Also note that this method of calculating the correction factor cannot distinguish between devices that are removed due to malfunction and those due to normal battery depletion. It might seem intuitive that devices that unexpectedly malfunction should be much more likely to be returned to the manufacturer than a device with ordinary normal battery depletion. But this has not been conclusively demonstrated. Therefore, this method only provides a correction factor reflecting the combination of battery depletion and malfunction.

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, Medtronic addresses this underreporting in two ways. Regular updates obtained from the Social Security Administration about deceased persons is used to update Medtronic's DART data about patients who have died but whose deaths had not been reported to Medtronic. In addition, the patient mortality rate derived from our DART 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 DART is significantly different from published rates, an adjustment is applied to correct the difference.

7289 InSync II Marquis

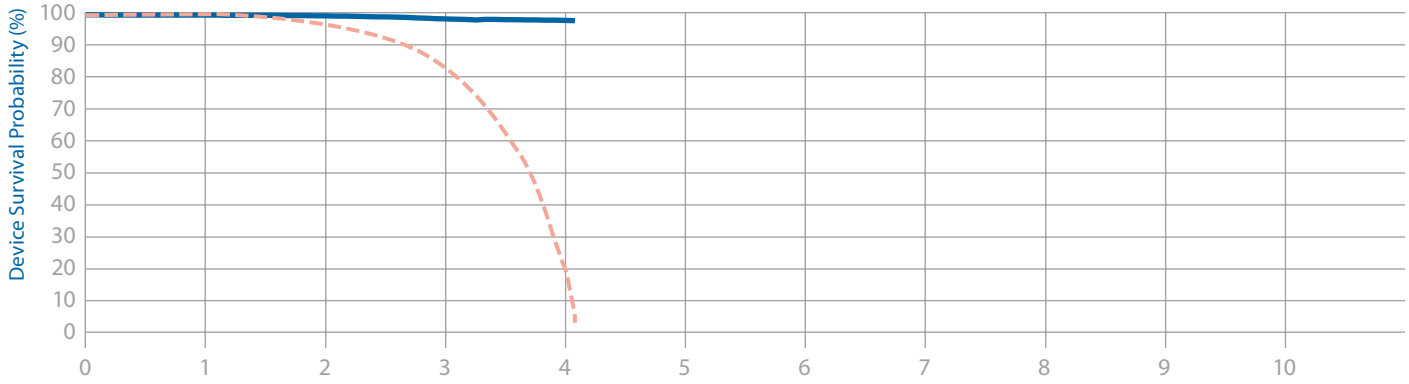
Product Characteristics

US Market Release	Jul-03
Registered US Implants	28,000
Estimated Active US Implants	300
Normal Battery Depletions (US)	6,237

Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	286
Therapy Function Not Compromised	255
Electrical Component	22
Software/Firmware	1
Possible Early Battery Depletion	232
Therapy Function Compromised	31
Battery *(9 malfunctions related to advisory)*	10
Electrical Component	21

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



		1 yr	2 yr	3 yr	4 yr	at 49 mo
%	———	99.9	99.7	98.7	98.0	97.9
%	- - - -	99.7	96.7	82.5	18.9	4.8
#	Effective Sample Size	24,000	17,000	12,000	2,000	1,000

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

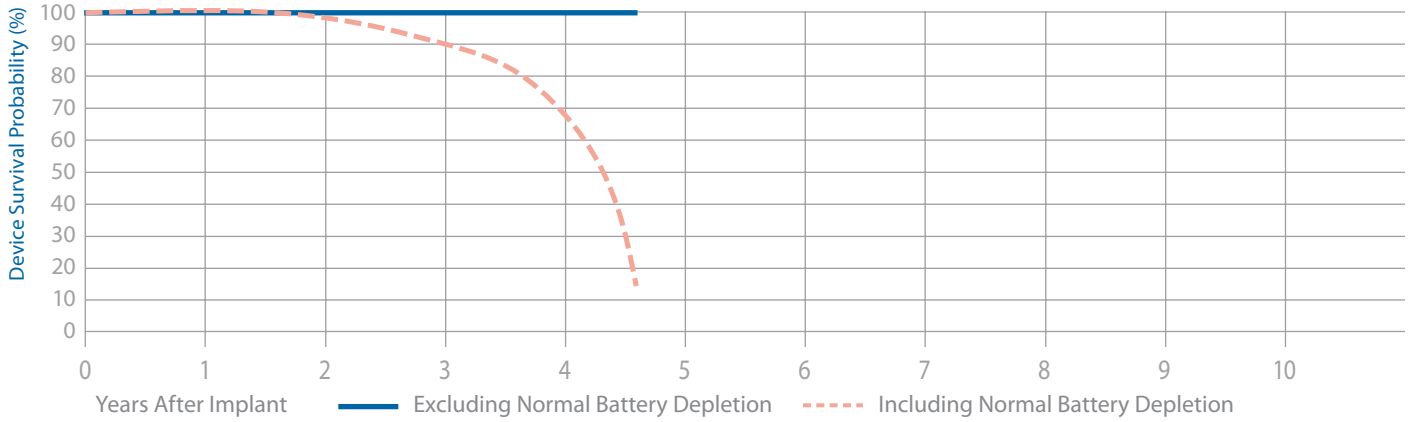
7297 InSync Sentry

Product Characteristics

US Market Release	Nov-04
Registered US Implants	9,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	1,459
Advisories	None

Malfunctions (US)	32
Therapy Function Not Compromised	31
Battery	1
Electrical Component	6
Software/Firmware	1
Possible Early Battery Depletion	23
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	3 yr	4 yr	at 55 mo
%	100.0	99.9	99.6	99.5	99.5
%	99.7	97.7	89.2	67.2	16.6
#	8,000	6,000	5,000	3,000	300

Effective Sample Size

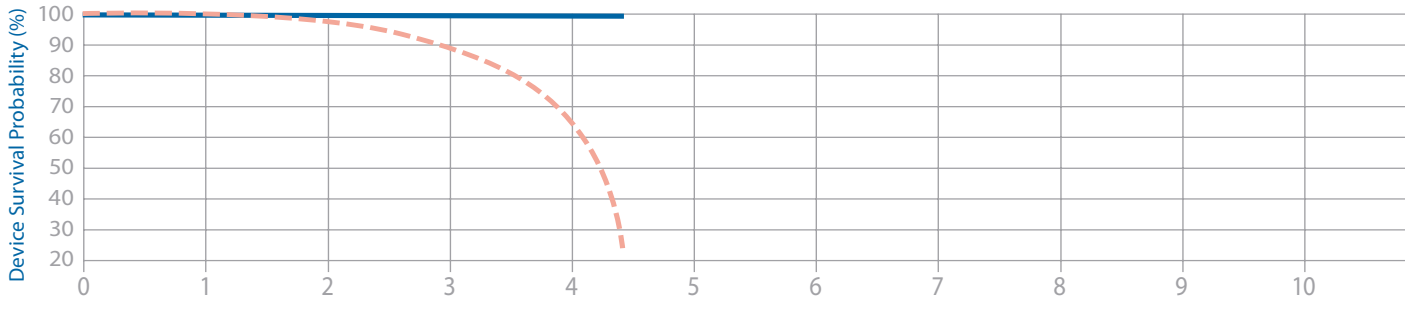
7299 InSync Sentry

Product Characteristics

US Market Release	Apr-05
Registered US Implants	31,000
Estimated Active US Implants	11,000
Normal Battery Depletions (US)	2,410
Advisories	None

Malfunctions (US)	67
Therapy Function Not Compromised	60
Electrical Component	11
Software/Firmware	2
Possible Early Battery Depletion	47
Therapy Function Compromised	7
Electrical Component	7

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



	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	99.9	99.7	99.6	99.6
%	99.8	97.9	89.7	64.7	27.5
#	27,000	22,000	15,000	3,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

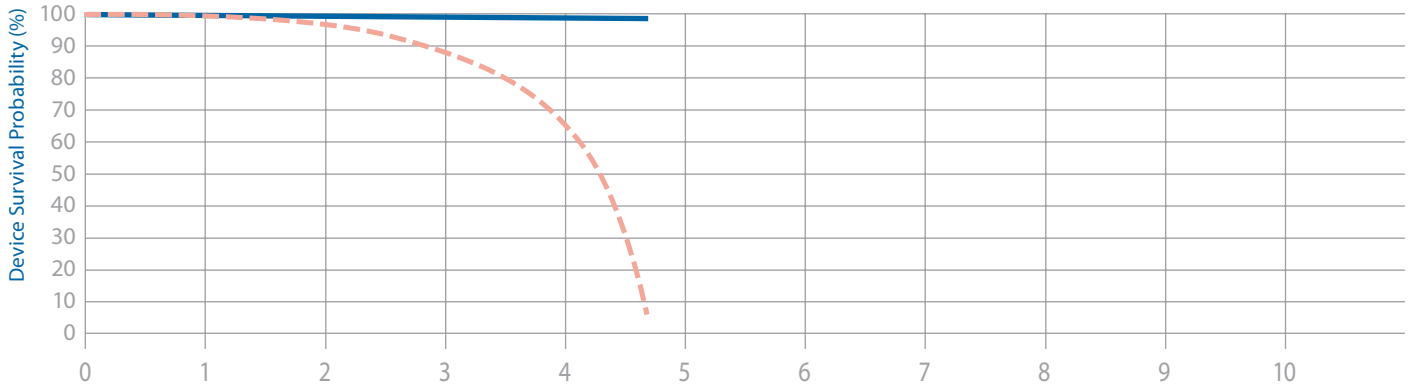
7303 InSync Maximo

Product Characteristics

US Market Release	Jun-04
Registered US Implants	17,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	3,501
Advisories	None

Malfunctions (US)	66
Therapy Function Not Compromised	60
Electrical Component	12
Software/Firmware	2
Possible Early Battery Depletion	46
Therapy Function Compromised	6
Electrical Component	6

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



	1 yr	2 yr	3 yr	4 yr	at 56 mo
%	100.0	99.8	99.6	99.4	99.4
%	99.8	97.6	88.8	64.3	6.6
#	15,000	12,000	9,000	5,000	400

Effective Sample Size

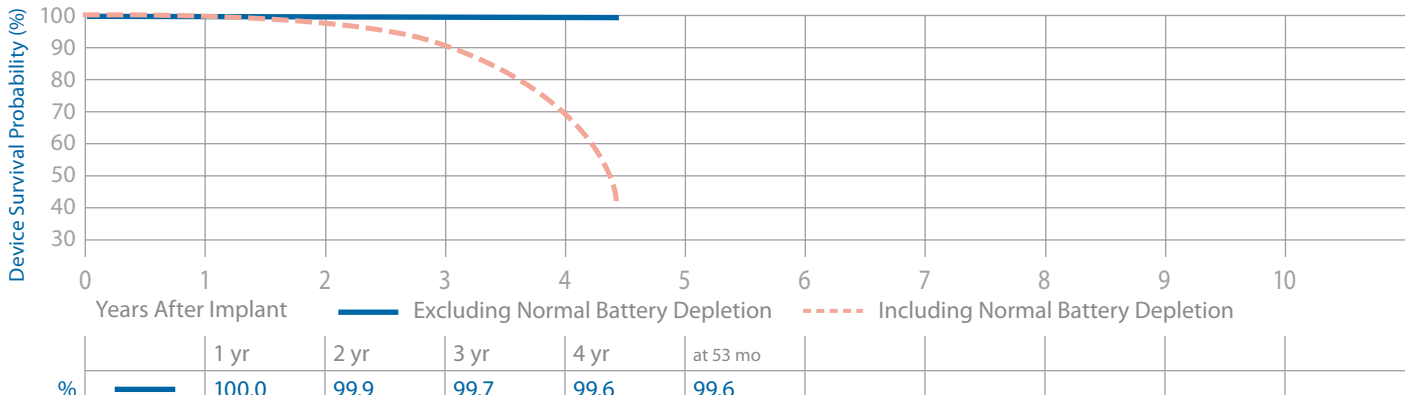
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	19,000
Estimated Active US Implants	8,000
Normal Battery Depletions (US)	1,202
Advisories	None

Malfunctions (US)	36
Therapy Function Not Compromised	34
Battery	1
Electrical Component	7
Possible Early Battery Depletion	26
Therapy Function Compromised	2
Electrical Component	2

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



	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	99.9	99.7	99.6	99.6
%	99.8	97.9	90.6	69.2	45.2
#	16,000	12,000	8,000	2,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

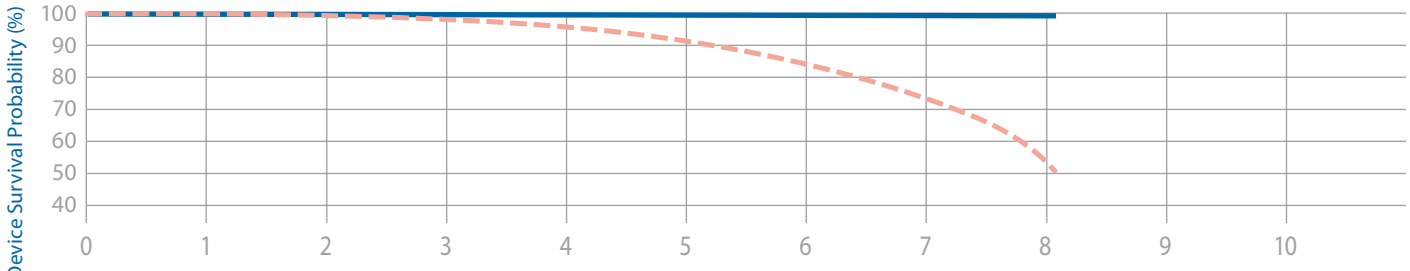
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	770
Advisories	None

Malfunctions (US)	28
Therapy Function Not Compromised	7
Electrical Component	4
Possible Early Battery Depletion	3
Therapy Function Compromised	21
Electrical Interconnect	21

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 97 mo
%	100.0	100.0	99.9	99.8	99.7	99.6	99.6	99.6	99.6
%	99.9	99.7	98.2	96.0	91.2	84.1	73.6	54.7	52.3
#	12,000	10,000	8,000	6,000	5,000	4,000	2,000	200	100

Effective Sample Size

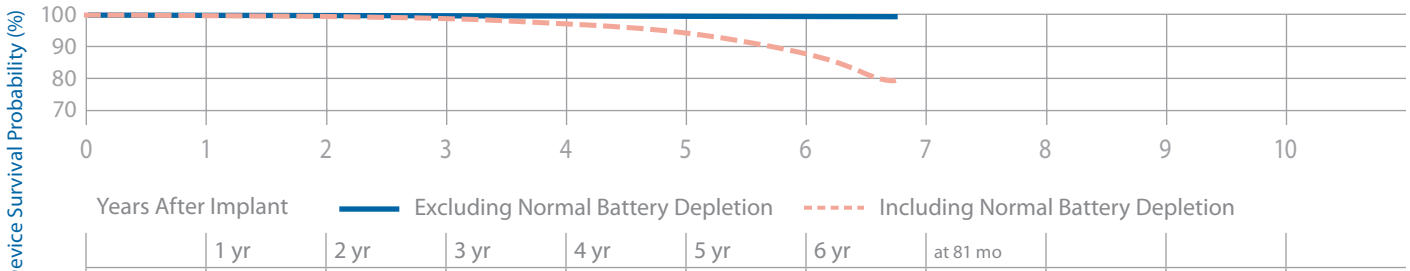
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	34,000
Estimated Active US Implants	17,000
Normal Battery Depletions (US)	414
Advisories	None

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

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9
%	100.0	99.9	99.2	97.4	94.2	88.0	79.9
#	24,000	18,000	12,000	8,000	5,000	2,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

C154DWK, C164AWK, C174AWK Concerto

US Market Release	May-06
Registered US Implants	84,000
Estimated Active US Implants	60,000
Normal Battery Depletions (US)	860

Advisories: See page 138 – 2009 Potential Reduced Device Longevity

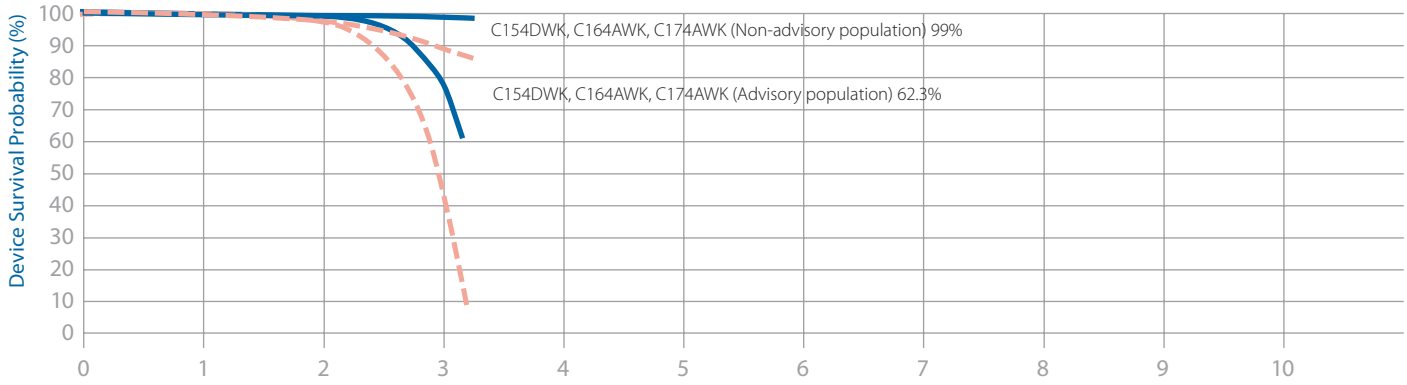
Performance Note: See page 146 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	130	724
Therapy Function Not Compromised	110	721
Electrical Component	10	718
Possible Early Battery Depletion	100	3
Therapy Function Compromised	20	3
Electrical Component	19	3
Electrical Interconnect	1	

(N) = Non-advisory population
(A) = Advisory population

Product Characteristics

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



Non-Adv	1 yr	2 yr	3 yr	at 39 mo
%	100.0	99.8	99.3	99.0
%	99.8	97.6	88.8	86.1
#	56,000	24,000	2,000	300
Effective Sample Size				

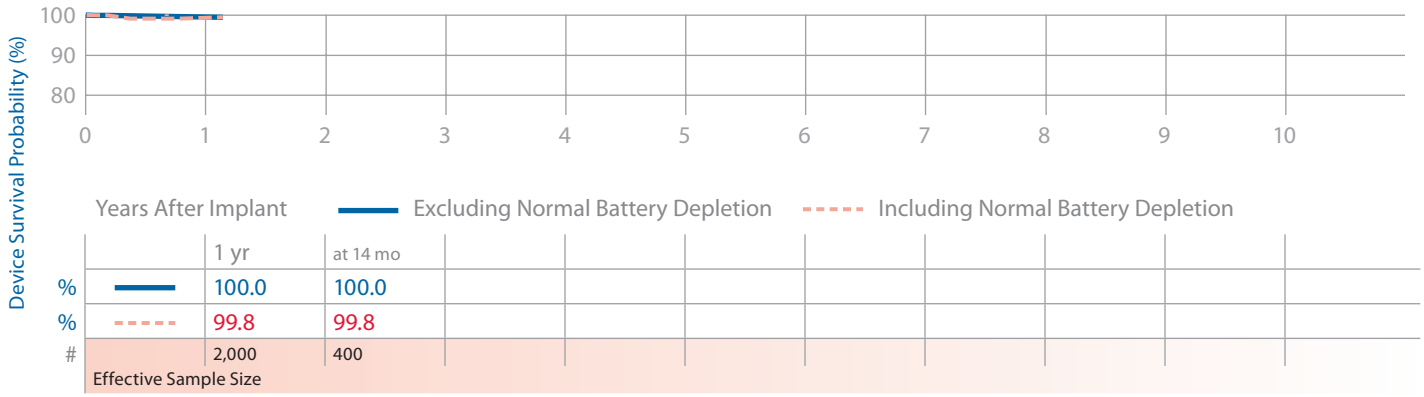
Adv Pop	1 yr	2 yr	3 yr	at 38 mo
%	99.9	99.5	76.4	62.3
%	99.7	97.1	44.2	10.5
#	3,000	3,000	1,000	300
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

D224TRK Consulta CRT-D

Product Characteristics

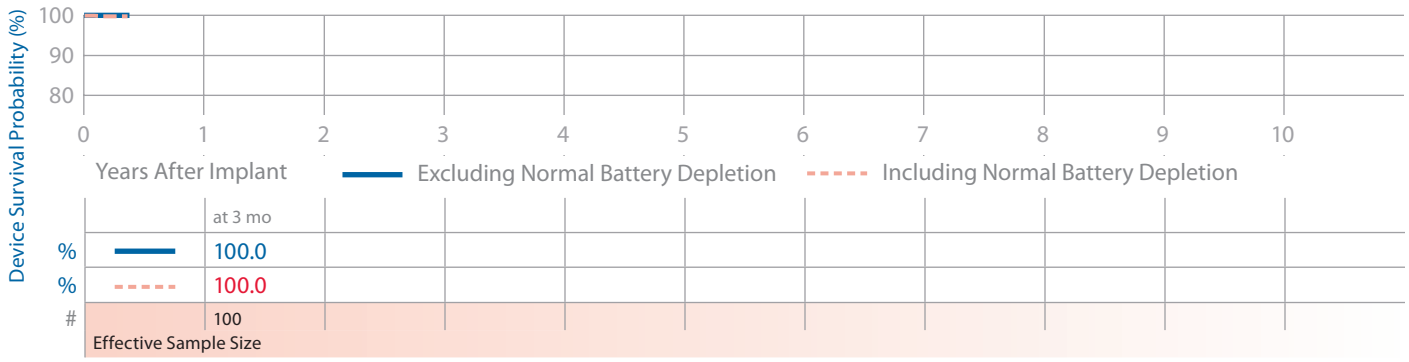
US Market Release	Aug-08	Malfunctions (US)	4	NBD Code	DDED
Registered US Implants	18,000	**Therapy Function Not Compromised**	3	Serial Number Prefix	PUD
Estimated Active US Implants	17,000	Electrical Component	2	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2	Software/Firmware	1	Estimated Longevity	See page 20
Advisories	None	**Therapy Function Compromised**	1		
		Electrical Component	1		



D274TRK Concerto II CRT-D

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	DDED
Registered US Implants	2,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PUE, PZB
Estimated Active US Implants	2,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0			Estimated Longevity	See page 20
Advisories	None				



Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

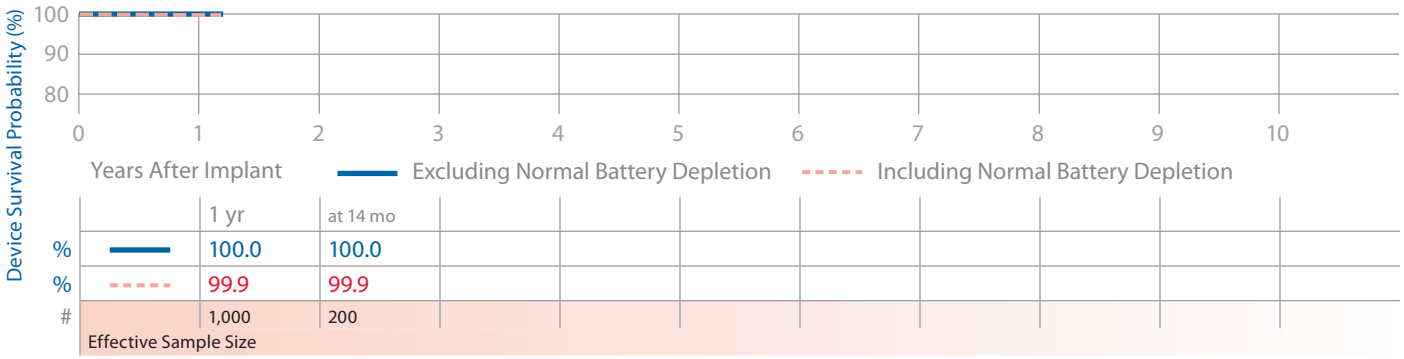
D284TRK Maximo II CRT-D

Product Characteristics

US Market Release	Mar-08
Registered US Implants	5,000
Estimated Active US Implants	5,000
Normal Battery Depletions (US)	3
Advisories	None

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

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



		1 yr	at 14 mo
%	Excluding Normal Battery Depletion	100.0	100.0
%	Including Normal Battery Depletion	99.9	99.9
#	Effective Sample Size	1,000	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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 (US)	Malfunctions (US)						Device Survival Probability (%)								
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant								
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
7289	InSync II Marquis	Jul-03	28,000	300	6,237	31	+	255	=	286	Excluding Normal Battery Depletion	99.9 +.0/-.0	99.7 +.1/-.1	98.7 +.2/-.2	98.0 +.2/-.3	97.9 +.2/-.3 at 49 mo				
	Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9) (advisory-related subset)	+	0	=	9	Including Normal Battery Depletion	99.7 +.1/-.1	96.7 +.2/-.3	82.5 +.6/-.6	18.9 +.9/-.9	4.8 +.6/-.6 at 49 mo				
7297	InSync Sentry	Nov-04	9,000	1,000	1,459	1	+	31	=	32	Excluding Normal Battery Depletion	100.0 +.0/-.1	99.9 +.1/-.1	99.6 +.1/-.2	99.5 +.2/-.2	99.5 +.2/-.2 at 55 mo				
											Including Normal Battery Depletion	99.7 +.1/-.1	97.7 +.3/-.4	89.2 +.8/-.8	67.2 +1.3/-1.4	16.6 +2.0/-1.9 at 55 mo				
7299	InSync Sentry	Apr-05	31,000	11,000	2,410	7	+	60	=	67	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.7 +.1/-.1	99.6 +.1/-.1	99.6 +.1/-.1 at 53 mo				
											Including Normal Battery Depletion	99.8 +.0/-.1	97.9 +.2/-.2	89.7 +.4/-.4	64.7 +1.0/-1.0	27.5 +3.5/-3.4 at 53 mo				
7303	InSync Maximo	Jun-04	17,000	1,000	3,501	6	+	60	=	66	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.8 +.1/-.1	99.6 +.1/-.1	99.4 +.1/-.2	99.4 +.1/-.2 at 56 mo				
											Including Normal Battery Depletion	99.8 +.1/-.1	97.6 +.2/-.3	88.8 +.6/-.6	64.3 +1.0/-1.0	6.6 +1.0/-.9 at 56 mo				
7304	InSync Maximo	Apr-05	19,000	8,000	1,202	2	+	34	=	36	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.7 +.1/-.1	99.6 +.1/-.2	99.6 +.1/-.2 at 53 mo				
											Including Normal Battery Depletion	99.8 +.1/-.1	97.9 +.2/-.3	90.6 +.5/-.6	69.2 +1.2/-1.3	45.2 +2.7/-2.7 at 53 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US): 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
8040	InSync	Aug-01	15,000	2,000	770	21	+	7	=	28	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.2	99.6 +.1/-.2	99.6 +.1/-.2	99.6 +.1/-.2	99.6 +.1/-.2 at 97 mo
											Including Normal Battery Depletion	99.9 +.0/-.1	99.7 +.1/-.1	98.2 +.2/-.3	96.0 +.4/-.5	91.2 +.7/-.7	84.1 +.9/-1.0	73.6 +1.3/-1.3	54.7 +2.6/-2.7	52.3 +3.1/-3.2 at 97 mo
8042	InSync III	Feb-03	34,000	17,000	414	6	+	3	=	9	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.1/-.3 at 81 mo		
											Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.2 +.1/-.2	97.4 +.3/-.3	94.2 +.5/-.5	88.0 +.9/-1.0	79.9 +2.0/-2.2 at 81 mo		
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	80,000	60,000	727	20	+	110	=	130	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.8 +.0/-.1	99.3 +.2/-.2	99.0 +.3/-.5 at 39 mo					
	See page 146 – Performance note on Anomalies in MOSFET Integrated Circuit Technology										Including Normal Battery Depletion	99.8 +.0/-.0	97.6 +.2/-.2	88.8 +.7/-.8	86.1 +1.4/-1.6 at 39 mo					
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	4,000	400	133	3	+	721	=	724	Excluding Normal Battery Depletion	99.9 +.1/-.2	99.5 +.2/-.3	76.4 +1.9/-2.0	62.3 +2.4/-2.5 at 38 mo					
	Advisories: See page 138 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.7 +.1/-.3	97.1 +.6/-.7	44.2 +2.2/-2.3	10.5 +1.9/-1.7 at 38 mo					
	See page 146 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																			

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)						Device Survival Probability (%)								
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant								
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
D224TRK	Consulta CRT-D	Aug-08	18,000	17,000	2	1	+	3	=	4	Excluding Normal Battery Depletion	100.0 +.0/-.1	100.0 +.0/-.1 at 14 mo							
											Including Normal Battery Depletion	99.8 +.1/-.2	99.8 +.1/-.2 at 14 mo							
D274TRK	Concerto II CRT-D	Aug-09	2,000	2,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0 at 3 mo								
											Including Normal Battery Depletion	100.0 +.0/-.0 at 3 mo								
D284TRK	Maximo II CRT-D	Mar-08	5,000	5,000	3	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0 at 14 mo							
											Including Normal Battery Depletion	99.9 +.1/-.2	99.9 +.1/-.2 at 14 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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	
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
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

Model Number	Family	Estimated Longevity			Elective Replacement Time Indicators
		Amplitude Setting	500 Lead Ω	1000 Lead Ω	
8040	InSync	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	**
8042	InSync III	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 cc 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
D224TRK	Consulta CRT-D	DR+LV true	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT or › 16-second charge time
D274TRK	Concerto II	DR+LV true	38 cc/ 68 g	text	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 V	—	3 month after RRT or › 16-second charge time
D284TRK	Maximo II CRT-D	DR+LV true	38 cc/ 68 g	35 J	Monthly Quarterly Semiannual	3.2 4.4 4.8	3.8 5.5 6.2	4.4 6.8 7.9	4.7 7.5 9.0	≤ 2.63 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 January 31, 2010

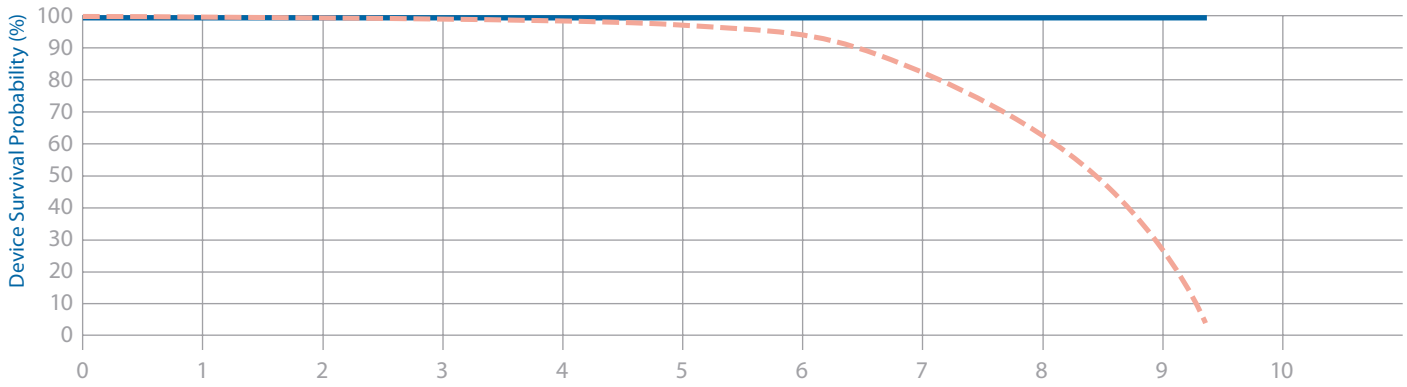
7227 GEM

US Market Release	Oct-98
Registered US Implants	22,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	2,562
Advisories	None

Malfunctions (US)	152

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PIP, PLN, PLP, PLR
Max Delivered Energy	35 J
Estimated Longevity	See page 36



Years After Implant — Excluding Normal Battery Depletion — Including Normal Battery Depletion

		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 112 mo
%	———	99.7	99.6	99.5	99.4	99.2	99.2	99.1	99.0	99.0	99.0
%	- - - -	99.3	98.9	98.6	98.1	97.1	94.4	81.7	62.4	27.5	4.4
#		20,000	17,000	15,000	13,000	11,000	9,000	6,000	3,000	1,000	200

Effective Sample Size

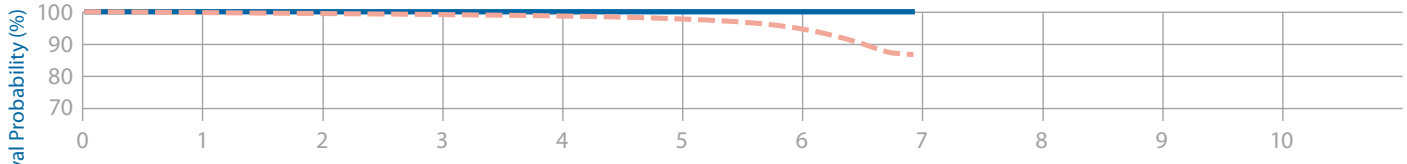
7230 Marquis VR

US Market Release	Dec-02
Registered US Implants	19,000
Estimated Active US Implants	8,000
Normal Battery Depletions (US)	216
Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short	

Malfunctions (US)	42
Therapy Function Not Compromised	27
Electrical Component	12
Software/Firmware	1
Possible Early Battery Depletion	13
Other	1
Therapy Function Compromised	15
Battery *(9 malfunctions related to advisory)*	10
Electrical Component	5

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PKD, PLW, PLY
Max Delivered Energy	30 J
Estimated Longevity	See page 36



Years After Implant — Excluding Normal Battery Depletion — Including Normal Battery Depletion

		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 83 mo
%	———	100.0	99.9	99.9	99.8	99.7	99.6	99.6
%	- - - -	99.8	99.6	99.4	99.1	98.3	94.9	86.8
#		17,000	13,000	11,000	10,000	8,000	3,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

7231 GEM III VR

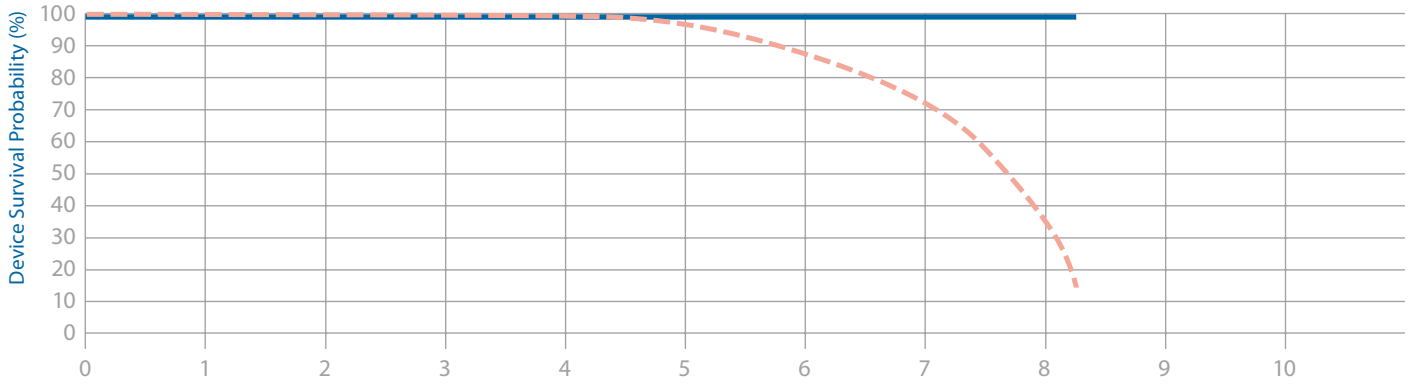
Product Characteristics

US Market Release	Dec-00
Registered US Implants	17,000
Estimated Active US Implants	4,000
Normal Battery Depletions (US)	1,582

Performance Note: See page 152 – Performance note on ICD Battery Discharge Behavior

Malfunctions (US)	36
Therapy Function Not Compromised	27
Battery	1
Electrical Component	22
Possible Early Battery Depletion	4
Therapy Function Compromised	9
Battery	1
Electrical Component	8

NBD Code	VVEV
Serial Number Prefix	PJL
Max Delivered Energy	30 J
Estimated Longevity	See page 36



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.9	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7
%	99.8	99.4	99.0	98.5	96.9	87.4	71.7	35.6	16.1
#	15,000	14,000	12,000	10,000	8,000	6,000	4,000	500	100

Effective Sample Size

7232 Maximo VR

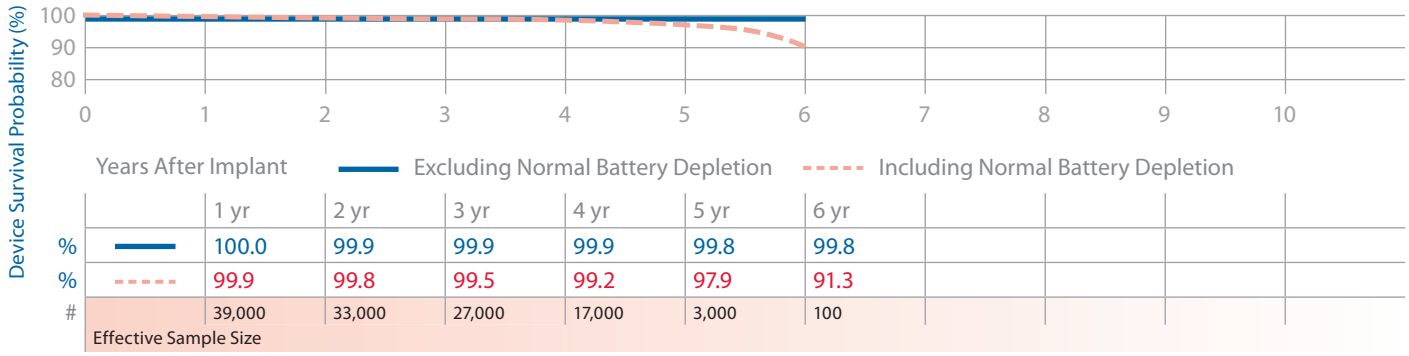
Product Characteristics

US Market Release	Oct-03
Registered US Implants	43,000
Estimated Active US Implants	27,000
Normal Battery Depletions (US)	141

Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	45
Therapy Function Not Compromised	33
Electrical Component	16
Possible Early Battery Depletion	16
Other	1
Therapy Function Compromised	12
Electrical Component	10
Electrical Interconnect	1
Possible Early Battery Depletion	1

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	100.0	99.9	99.9	99.9	99.8	99.8
%	99.9	99.8	99.5	99.2	97.9	91.3
#	39,000	33,000	27,000	17,000	3,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

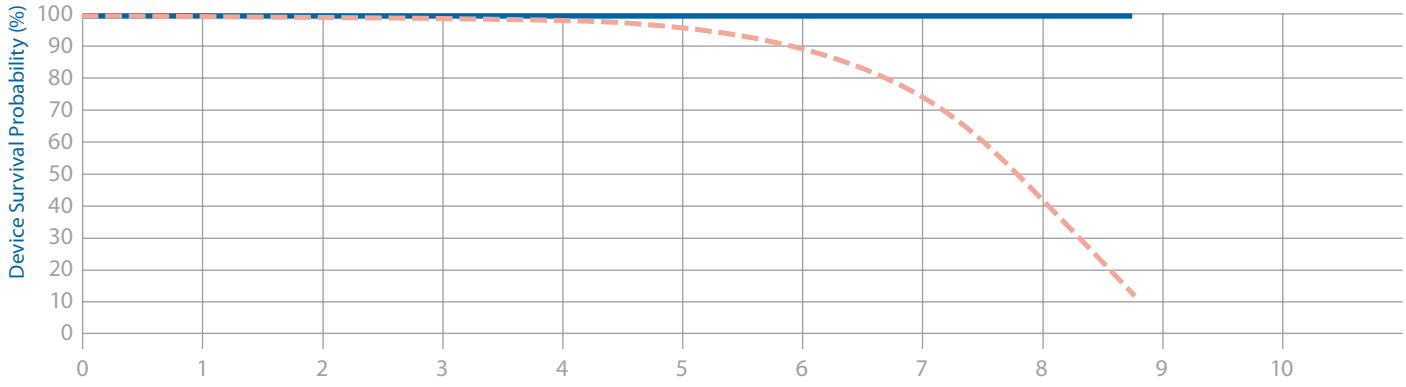
7271 GEM DR

Product Characteristics

US Market Release	Oct-98
Registered US Implants	15,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	1,786
Advisories	None

Malfunctions (US)	100

NBD Code	VVED
Serial Number Prefix	PIM
Max Delivered Energy	27 J
Estimated Longevity	See page 36



	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	99.5	99.3	99.1	99.0	98.8	98.8
%	99.6	99.4	98.7	97.7	95.4	89.2	75.1	41.7	11.4
#	13,000	12,000	10,000	9,000	7,000	5,000	3,000	1,000	200

Effective Sample Size

7274 Marquis DR

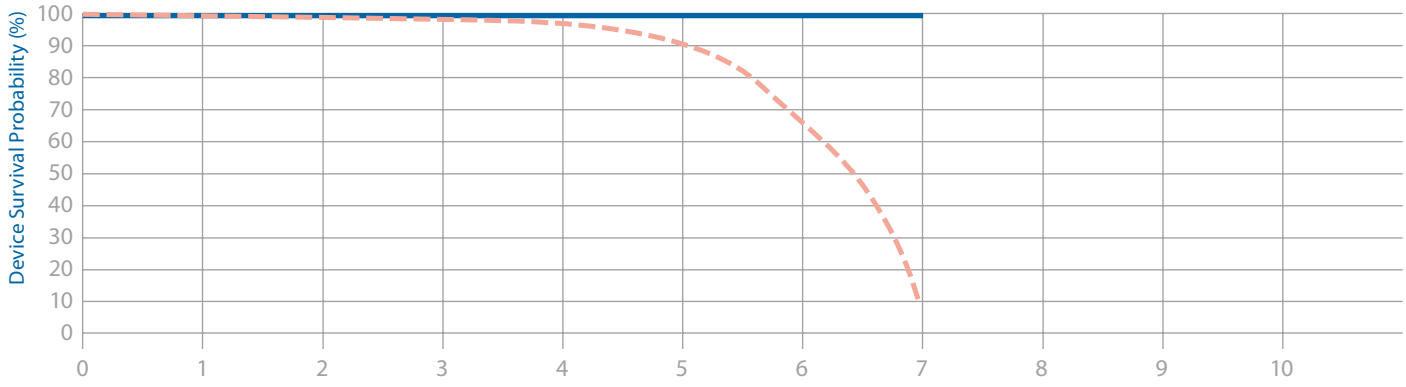
Product Characteristics

US Market Release	Mar-02
Registered US Implants	48,000
Estimated Active US Implants	8,000
Normal Battery Depletions (US)	3,830

Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	179
Therapy Function Not Compromised	79
Battery *(3 malfunctions related to advisory)*	5
Electrical Component	26
Possible Early Battery Depletion	48
Therapy Function Compromised	100
Battery *(69 malfunctions related to advisory)*	75
Electrical Component	25

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
%	100.0	99.9	99.8	99.6	99.4	99.2	99.2
%	99.8	99.5	98.5	97.0	90.6	65.9	4.0
#	42,000	34,000	26,000	22,000	16,000	6,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

7275 GEM III DR

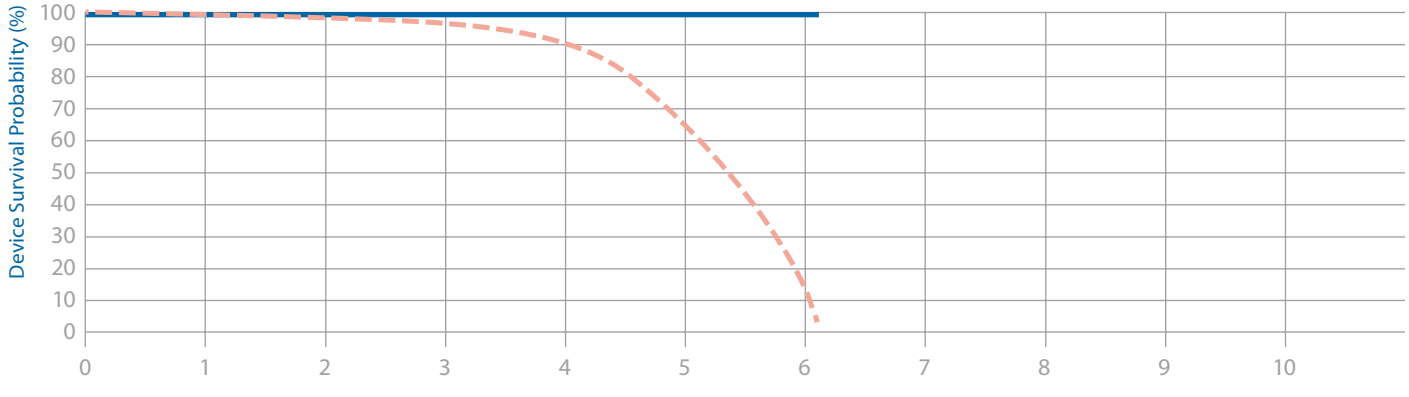
Product Characteristics

US Market Release	Nov-00
Registered US Implants	20,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	3,981

Performance Note: See page 152 – Performance note on ICD Battery Discharge Behavior

Malfunctions (US)	38
Therapy Function Not Compromised	27
Battery	1
Electrical Component	9
Software/Firmware	1
Possible Early Battery Depletion	16
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 36



		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
%	- - -	99.6	99.0	96.9	90.2	64.7	12.2	2.6
#		18,000	15,000	13,000	10,000	5,000	1,000	300

Effective Sample Size

7278 Maximo DR

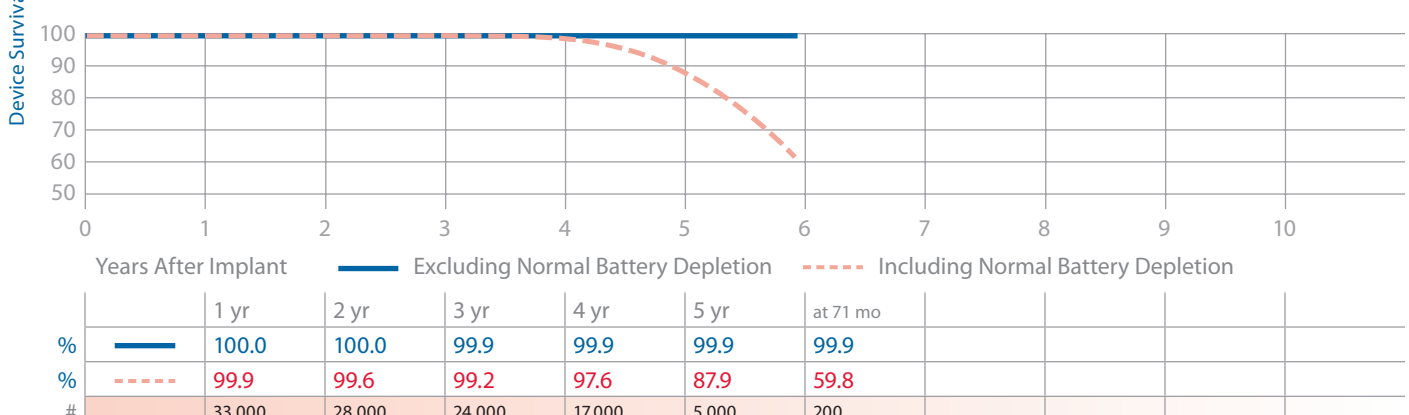
Product Characteristics

US Market Release	Oct-03
Registered US Implants	37,000
Estimated Active US Implants	21,000
Normal Battery Depletions (US)	973

Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	34
Therapy Function Not Compromised	26
Electrical Component	14
Possible Early Battery Depletion	12
Therapy Function Compromised	8
Electrical Component	7
Possible Early Battery Depletion	1

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



		1 yr	2 yr	3 yr	4 yr	5 yr	at 71 mo
%	———	100.0	100.0	99.9	99.9	99.9	99.9
%	- - -	99.9	99.6	99.2	97.6	87.9	59.8
#		33,000	28,000	24,000	17,000	5,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

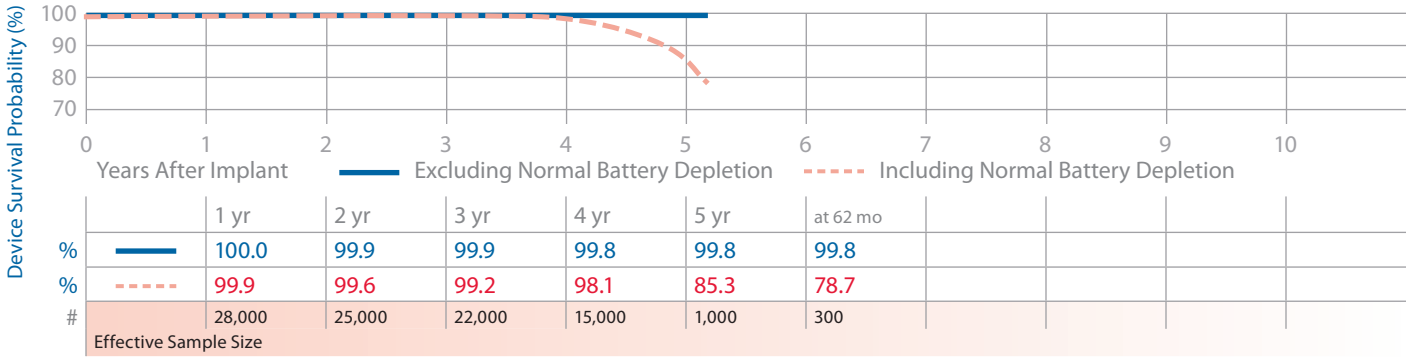
7288 Intrinsic

US Market Release	Aug-04
Registered US Implants	31,000
Estimated Active US Implants	19,000
Normal Battery Depletions (US)	489
Advisories	None

Malfunctions (US)	43
Therapy Function Not Compromised	36
Battery	2
Electrical Component	12
Software/Firmware	1
Possible Early Battery Depletion	21
Therapy Function Compromised	7
Electrical Component	7

Product Characteristics

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



	1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	100.0	99.9	99.9	99.8	99.8	99.8
%	99.9	99.6	99.2	98.1	85.3	78.7
#	28,000	25,000	22,000	15,000	1,000	300

Effective Sample Size

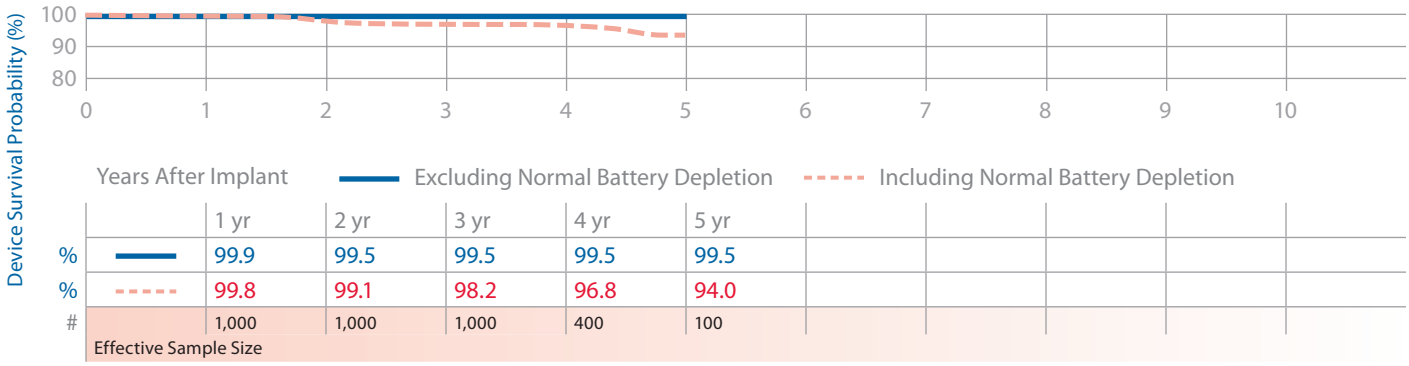
7290 Onyx

US Market Release	Mar-04
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	13
Advisories	None

Malfunctions (US)	4
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Electrical Component	1

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PRP
Max Delivered Energy	30 J
Estimated Longevity	See page 36



	1 yr	2 yr	3 yr	4 yr	5 yr
%	99.9	99.5	99.5	99.5	99.5
%	99.8	99.1	98.2	96.8	94.0
#	1,000	1,000	1,000	400	100

Effective Sample Size

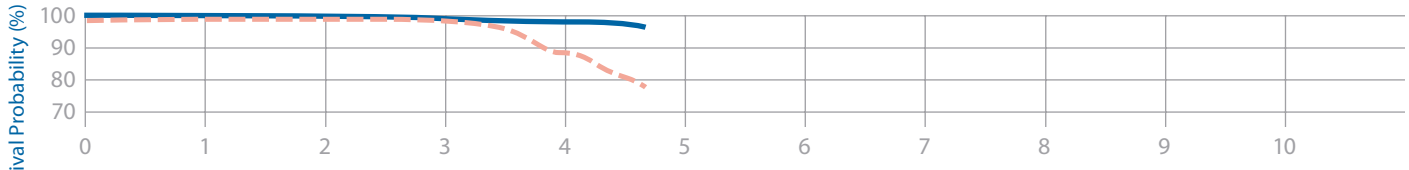
D153ATG, D153DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	500
Estimated Active US Implants	200
Normal Battery Depletions (US)	31
Advisories	None

Malfunctions (US)	7
Therapy Function Not Compromised	6
Possible Early Battery Depletion	6
Therapy Function Compromised	1
Electrical Component	1

NBD Code	DDED, VVED
Serial Number Prefix	PNR
Max Delivered Energy	30 J
Estimated Longevity	See page 37



	1 yr	2 yr	3 yr	4 yr	at 56 mo
%	99.8	99.8	99.2	98.4	97.2
%	99.5	99.5	97.7	89.0	77.4
#	400	400	300	200	100

Effective Sample Size

D154ATG, D154DRG EnTrust

Product Characteristics

US Market Release	Jun-05
Registered US Implants	28,000
Estimated Active US Implants	20,000
Normal Battery Depletions (US)	107
Advisories	None

Malfunctions (US)	43
Therapy Function Not Compromised	37
Electrical Component	10
Possible Early Battery Depletion	27
Therapy Function Compromised	6
Electrical Component	6

NBD Code	DDED, VVED
Serial Number Prefix	PNR
Max Delivered Energy	35 J
Estimated Longevity	See page 37

	1 yr	2 yr	3 yr	4 yr	at 52 mo
%	100.0	99.9	99.8	99.8	99.7
%	99.9	99.7	99.2	97.4	96.4
#	26,000	22,000	17,000	3,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

D154AWG, D164AWG Virtuoso DR

US Market Release	May-06
Registered US Implants	75,000
Estimated Active US Implants	62,000
Normal Battery Depletions (US)	62

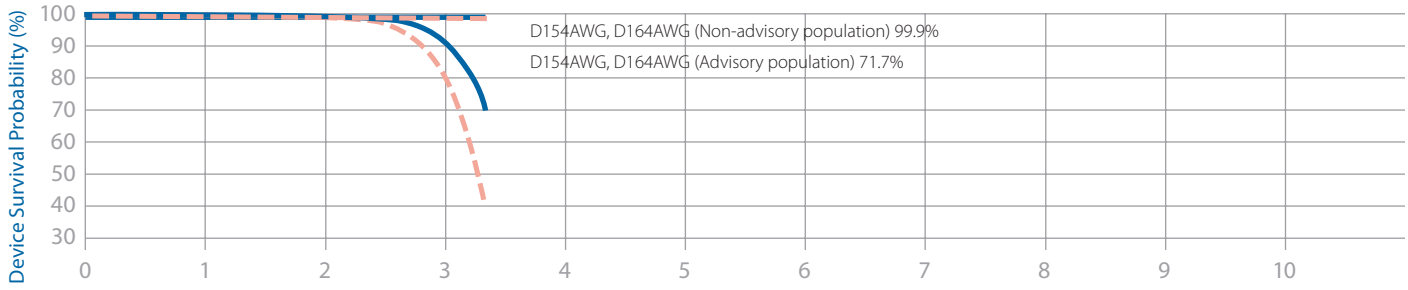
Advisories: See page 138 – 2009 Potential Reduced Device Longevity

Performance Note: See page 146 – Anomalies in MOSFET Integrated Circuit Technology

	(N)	(A)
Malfunctions (US)	34	492
Therapy Function Not Compromised	15	490
Electrical Component	6	490
Electrical Interconnect	1	
Possible Early Battery Depletion	8	
Therapy Function Compromised	19	2
Electrical Component	19	2

Product Characteristics

NBD Code	VVED
Serial Number Prefix	PVV, PUL
Max Delivered Energy	35 J
Estimated Longevity	See page 37



Non-Adv	1 yr	2 yr	3 yr	at 40 mo
%	100.0	99.9	99.9	99.9
%	99.9	99.7	99.3	99.1
#	54,000	26,000	2,000	200

Effective Sample Size

Advisory	1 yr	2 yr	3 yr	at 40 mo
%	100.0	99.9	90.6	71.7
%	100.0	99.7	80.9	40.0
#	4,000	3,000	2,000	200

Effective Sample Size

D154VRC EnTrust

US Market Release	Jun-05
Registered US Implants	14,000
Estimated Active US Implants	10,000
Normal Battery Depletions (US)	30
Advisories	None

Malfunctions (US)	26
Therapy Function Not Compromised	21
Battery	2
Electrical Component	9
Possible Early Battery Depletion	10
Therapy Function Compromised	5
Electrical Component	5

Product Characteristics

NBD Code	VVEV
Serial Number Prefix	PNT
Max Delivered Energy	35 J
Estimated Longevity	See page 37

	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	99.9	99.9	99.8	99.7	99.7
%	99.9	99.6	99.3	98.3	98.3
#	13,000	11,000	9,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

D154VWC, D164VWC Virtuoso VR

Product Characteristics

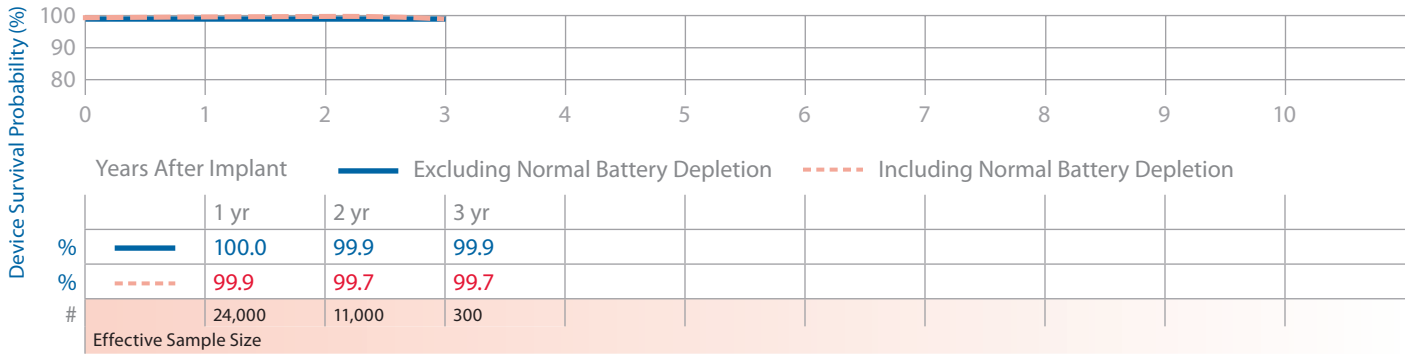
US Market Release	May-06
Registered US Implants	32,000
Estimated Active US Implants	27,000
Normal Battery Depletions (US)	16

Advisories: See page 138 – 2009 Potential Reduced Device Longevity

Performance Note: See page 146 – Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	13
Therapy Function Not Compromised	4
Electrical Component	3
Electrical Interconnect	1
Therapy Function Compromised	9
Electrical Component	9

NBD Code	VVEV
Serial Number Prefix	PUN, PUP
Max Delivered Energy	35 J
Estimated Longevity	See page 37



	1 yr	2 yr	3 yr
%	100.0	99.9	99.9
%	99.9	99.7	99.7
#	24,000	11,000	300

Effective Sample Size

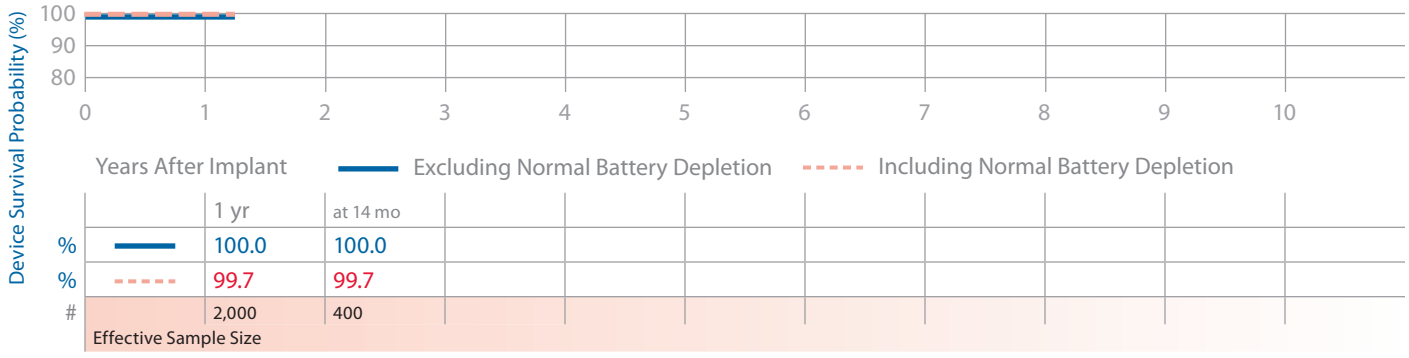
D224DRG Secura DR

Product Characteristics

US Market Release	Aug-08
Registered US Implants	14,000
Estimated Active US Implants	13,000
Normal Battery Depletions (US)	7
Advisories	None

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBD Code	DDED
Serial Number Prefix	DUH, PZE
Max Delivered Energy	35 J
Estimated Longevity	See page 37



	1 yr	at 14 mo
%	100.0	100.0
%	99.7	99.7
#	2,000	400

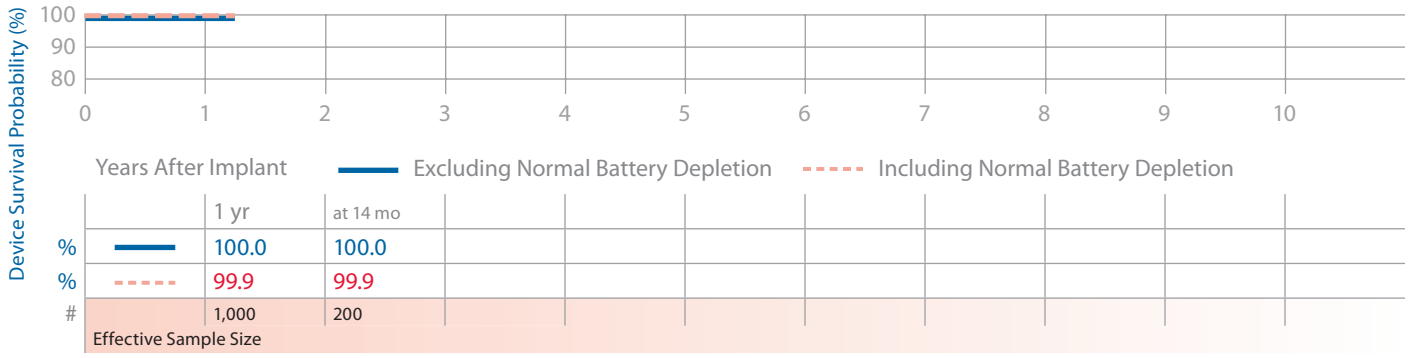
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

D224VRC Secura VR

Product Characteristics

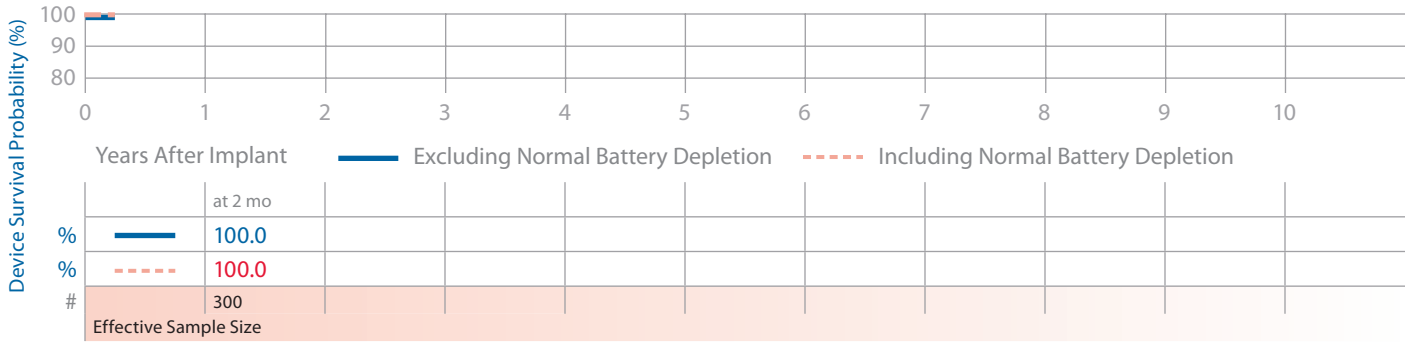
US Market Release	Aug-08	Malfunctions (US)	0	NBD Code	VVEV
Registered US Implants	6,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PUX
Estimated Active US Implants	6,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	2			Estimated Longevity	See page 37
Advisories	None				



D274DRG Virtuoso II DR

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVED
Registered US Implants	1,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	DUH, PZE
Estimated Active US Implants	1,000	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0			Estimated Longevity	See page 37
Advisories	None				

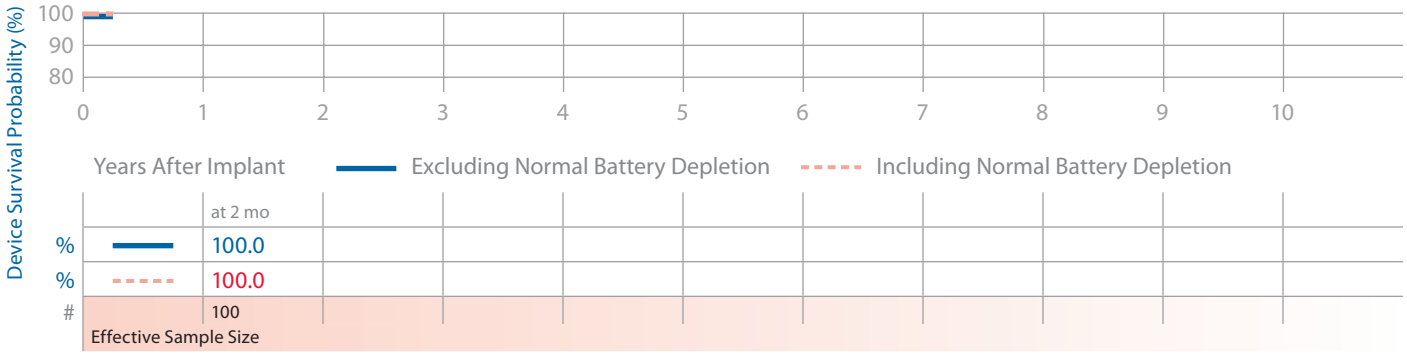


Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

D274VRC Virtuoso II VR

Product Characteristics

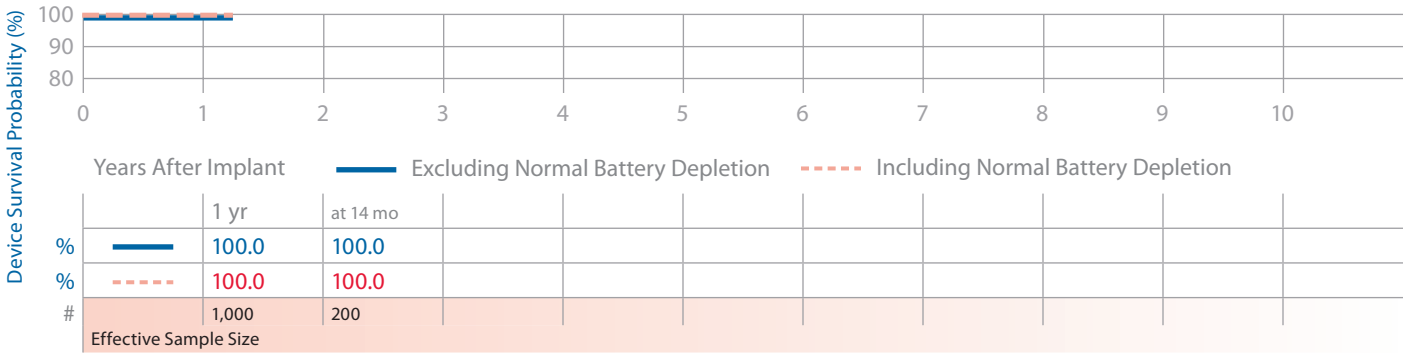
US Market Release	Aug-09	Malfunctions (US)	0	NBD Code	VVEV
Registered US Implants	400	**Therapy Function Not Compromised**	0	Serial Number Prefix	PUY, PZH
Estimated Active US Implants	400	**Therapy Function Compromised**	0	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0			Estimated Longevity	See page 37
Advisories	None				



D284DRG Maximo II DR

Product Characteristics

US Market Release	Mar-08	Malfunctions (US)	1	NBD Code	VVED
Registered US Implants	7,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZM
Estimated Active US Implants	7,000	**Therapy Function Compromised**	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	0	Electrical Component	1	Estimated Longevity	See page 37
Advisories	None				



Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

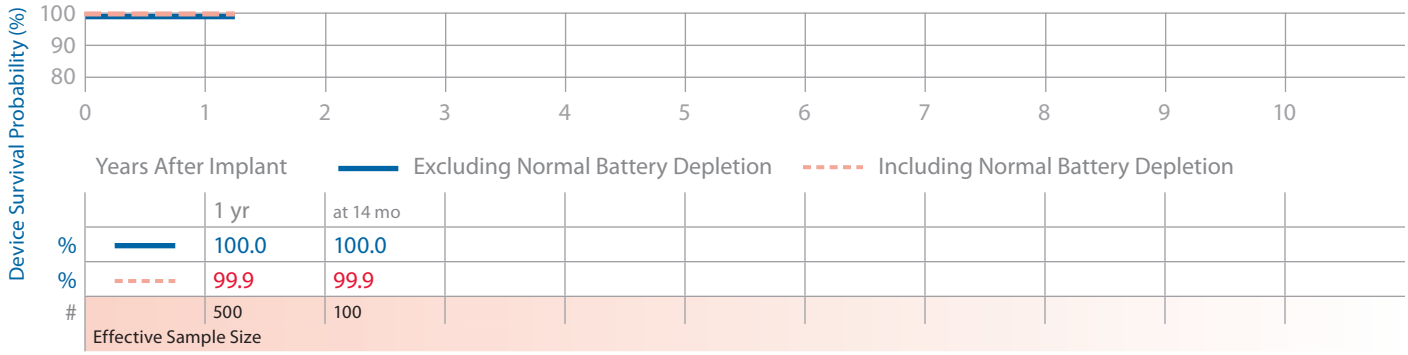
D284VRC Maximo II VR

Product Characteristics

US Market Release	Mar-08
Registered US Implants	4,000
Estimated Active US Implants	4,000
Normal Battery Depletions (US)	0
Advisories	None

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Component	1

NBD Code	VVEV
Serial Number Prefix	PZN
Max Delivered Energy	35 J
Estimated Longevity	See page 37



		1 yr	at 14 mo
%	———	100.0	100.0
%	- - - - -	99.9	99.9
#		500	100
Effective Sample Size			

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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 (US)	Malfunctions (US): Therapy Function Compromised	Malfunctions (US): Therapy Function Not Compromised	Malfunctions (US): 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
7227	GEM	Oct-98	22,000	2,000	2,562	—	—	152	Excluding Normal Battery Depletion	99.7 +.1/-.1	99.6 +.1/-.1	99.5 +.1/-.1	99.4 +.1/-.1	99.2 +.1/-.1	99.2 +.1/-.1	99.1 +.1/-.2	99.0 +.2/-.2	99.0 +.2/-.2 at 112 mo
									Including Normal Battery Depletion	99.3 +.1/-.1	98.9 +.1/-.2	98.6 +.2/-.2	98.1 +.2/-.2	97.1 +.3/-.3	94.4 +.4/-.4	81.7 +.8/-.8	62.4 +1.1/-1.2	4.4 +1.1/-.9 at 112 mo
7230	Marquis VR	Dec-02	19,000	8,000	216	15	27	42	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.6 +.1/-.2	99.6 +.1/-.2 at 83 mo		
	Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short					(9)	(0)	(9) (advisory-related subset)	Including Normal Battery Depletion	99.8 +.1/-.1	99.6 +.1/-.1	99.4 +.1/-.1	99.1 +.2/-.2	98.3 +.2/-.3	94.9 +.5/-.6	86.8 +1.5/-1.7 at 83 mo		
7231	GEM III VR	Dec-00	17,000	4,000	1,582	9	27	36	Excluding Normal Battery Depletion	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1 at 99 mo
	See page 152 – Performance note on ICD Battery Discharge Behavior								Including Normal Battery Depletion	99.8 +.1/-.1	99.4 +.1/-.1	99.0 +.1/-.2	98.5 +.2/-.2	96.9 +.3/-.4	87.4 +.7/-.7	71.7 +1.1/-1.1	35.6 +2.0/-2.0	16.1 +2.5/-2.3 at 99 mo
7232	Maximo VR	Oct-03	43,000	27,000	141	12	33	45	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.8 +.0/-.1			
	Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +.0/-.0	99.8 +.0/-.1	99.5 +.1/-.1	99.2 +.1/-.1	97.9 +.3/-.4	91.3 +2.0/-2.5			
7271	GEM DR	Oct-98	15,000	1,000	1,786	—	—	100	Excluding Normal Battery Depletion	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.5 +.1/-.2	99.3 +.1/-.2	99.1 +.2/-.2	99.0 +.2/-.2	98.8 +.2/-.3	98.8 +.2/-.3 at 105 mo
									Including Normal Battery Depletion	99.6 +.1/-.1	99.4 +.1/-.1	98.7 +.2/-.2	97.7 +.3/-.3	95.4 +.4/-.5	89.2 +.7/-.7	75.1 +1.1/-1.1	41.7 +1.6/-1.6	11.4 +1.5/-1.4 at 105 mo
7274	Marquis DR	Mar-02	48,000	8,000	3,830	100	79	179	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	99.4 +.1/-.1	99.2 +.1/-.1	99.2 +.1/-.2		
	Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short					(69)	(3)	(72) (advisory-related subset)	Including Normal Battery Depletion	99.8 +.0/-.0	99.5 +.1/-.1	98.5 +.1/-.1	97.0 +.2/-.2	90.6 +.4/-.4	65.9 +.8/-.8	4.0 +1.2/-1.0		

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	10 yr
7275	GEM III DR	Nov-00	20,000	1,000	2,564	11	+	27	=	38	Excluding Normal Battery Depletion	99.9 +.0/-.0	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1	99.7 +.1/-.1 at 73 mo		
	See page 152 – Performance note on ICD Battery Discharge Behavior										Including Normal Battery Depletion	99.6 +.1/-.1	99.0 +.1/-.2	96.9 +.3/-.3	90.2 +.5/-.5	64.7 +1.0/-1.0	12.2 +1.0/-1.0	2.6 +.7/-.6 at 73 mo		
7278	Maximo DR	Oct-03	37,000	21,000	973	8	+	26	=	34	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1 at 71 mo			
	Advisories: See page 143 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	+	(0)	=	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +.0/-.0	99.6 +.1/-.1	99.2 +.1/-.1	97.6 +.2/-.2	87.9 +.7/-.7	59.8 +3.1/-3.3 at 71 mo			
7288	Intrinsic	Aug-04	31,000	19,000	489	7	+	36	=	43	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1 at 62 mo			
											Including Normal Battery Depletion	99.9 +.0/-.0	99.6 +.1/-.1	99.2 +.1/-.1	98.1 +.2/-.2	85.3 +1.2/-1.2	78.7 +2.3/-2.6 at 62 mo			
7290	Onyx	Mar-04	1,000	1,000	13	1	+	3	=	4	Excluding Normal Battery Depletion	99.9 +.1/-.7	99.5 +.3/-.8	99.5 +.3/-.8	99.5 +.3/-.8	99.5 +.3/-.8				
											Including Normal Battery Depletion	99.8 +.2/-.7	99.1 +.5/-.9	98.2 +.7/-1.2	96.8 +1.1/-1.7	94.0 +2.0/-2.9				
D153ATG, D153DRG	EnTrust DR	Jun-05	500	200	31	1	+	6	=	7	Excluding Normal Battery Depletion	99.8 +.2/-1.4	99.8 +.2/-1.4	99.2 +.6/-1.8	98.4 +.9/-2.2	97.2 +1.5/-3.3 at 56 mo				
											Including Normal Battery Depletion	99.5 +.3/-1.4	99.5 +.3/-1.4	97.7 +1.2/-2.3	89.0 +3.3/-4.6	77.4 +5.1/-6.3 at 56 mo				
D154ATG, D154DRG	EnTrust DR	Jun-05	28,000	20,000	107	6	+	37	=	43	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.2 at 52 mo				
											Including Normal Battery Depletion	99.9 +.0/-.1	99.7 +.1/-.1	99.2 +.1/-.1	97.4 +.4/-.4	96.4 +.6/-.8 at 52 mo				
D154AWG D164AWG (Non-advisory population)	Virtuoso DR	May-06	71,000	60,000	58	19	+	15	=	34	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.1/-.1	99.9 +.1/-.1 at 40 mo					
											Including Normal Battery Depletion	99.9 +.0/-.0	99.7 +.0/-.1	99.3 +.2/-.2	99.1 +.3/-.4 at 40 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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
D154AWG D164AWG (Advisory population)	Virtuoso DR	May-06	4,000	2,000	4	2	+	490	=	492	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.1/-.2	90.6 +1.0/-1.2	71.7 +2.7/-3.0 at 40 mo				
	Advisories: See page 138 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	100.0 +.0/-.0	99.7 +.1/-.2	80.9 +1.4/-1.5	40.0 +3.7/-3.7 at 40 mo				
	See page 146 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																		
D154VRC	EnTrust VR	Jun-05	14,000	10,000	30	5	+	21	=	26	Excluding Normal Battery Depletion	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.2	99.7 +.1/-.2 at 51 mo			
											Including Normal Battery Depletion	99.9 +.0/-.1	99.6 +.1/-.1	99.3 +.1/-.2	98.3 +.4/-.5	98.3 +.4/-.5 at 51 mo			
D154VWC, D164VWC	Virtuoso VR	May-06	32,000	27,000	16	9	+	4	=	13	Excluding Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0					
	Advisories: See page 138 – 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.9 +.0/-.0	99.7 +.1/-.1	99.7 +.1/-.1					
	See page 146 – Performance note on Anomalies in MOSFET Integrated Circuit Technology																		
D224DRG	Secura DR	Aug-08	14,000	13,000	7	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0 at 14 mo						
											Including Normal Battery Depletion	99.7 +.1/-.3	99.7 +.1/-.3 at 14 mo						
D224VRC	Secura VR	Aug-08	6,000	6,000	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0 at 14 mo						
											Including Normal Battery Depletion	99.9 +.0/-.1	99.9 +.0/-.1 at 14 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
D274DRG	Virtuoso II DR	Aug-09	1,000	1,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0 at 2 mo							
											Including Normal Battery Depletion	100.0 +.0/-.0 at 2 mo							
D274VRC	Virtuoso II VR	Aug-09	400	400	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0 at 2 mo							
											Including Normal Battery Depletion	100.0 +.0/-.0 at 2 mo							
D284DRG	Maximo II DR	Mar-08	7,000	7,000	0	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +.0/-.1	100.0 +.0/-.1 at 14 mo						
											Including Normal Battery Depletion	100.0 +.0/-.1	100.0 +.0/-.1 at 14 mo						
D284VRC	Maximo II VR	Mar-08	4,000	4,000	0	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +.1/-.2	100.0 +.0/-.2 at 14 mo						
											Including Normal Battery Depletion	99.9 +.0/-.2	99.9 +.0/-.2 at 14 mo						

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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
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 > 16-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 > 16-second charge time
D224DRG	Secura DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.60 5.07 5.70	4.08 6.05 7.00	4.50 7.00 8.27	4.67 7.50 9.00	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D224VRC	Secura VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.33 6.67 7.76	4.67 7.45 8.85	4.92 8.05 9.79	5.00 8.41 10.25	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D274DRG	Virtuoso II DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.0 5.7	4.0 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D274VRC	Virtuoso II VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.0 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D284DRG	Maximo II DR	DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.60 5.07 5.70	4.08 6.05 7.00	4.50 7.00 8.27	4.67 7.50 9.00	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D284VRC	Maximo II VR	Cx	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.33 6.67 7.76	4.67 7.45 8.85	4.92 8.05 9.79	5.00 8.41 10.25	≤ 2.63 V	—	3 months after RRT or > 19-second charge time

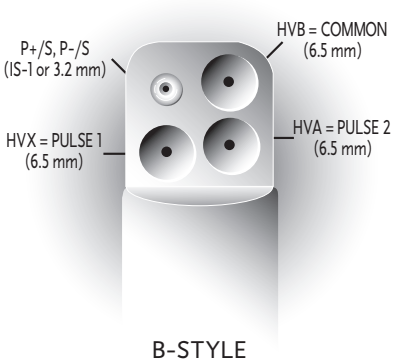
* Volume and mass differ by connector style.

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

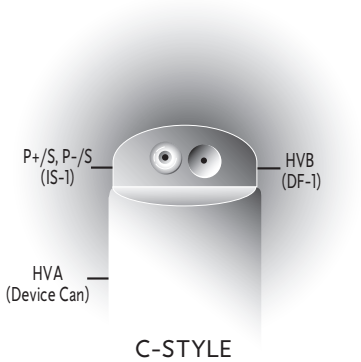
*** The minimum time between RRT and EOS is 3 months (100% pacing, two charges per month).

‡ 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.

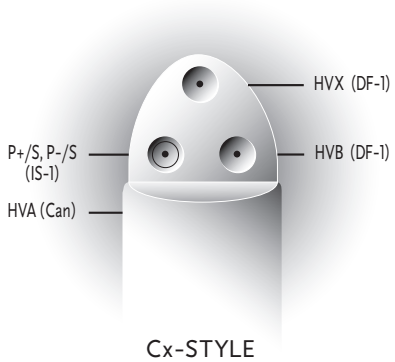
ICD Connector Styles



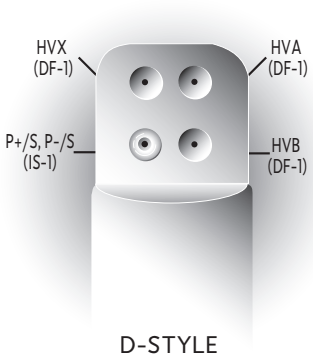
B-STYLE CONNECTOR



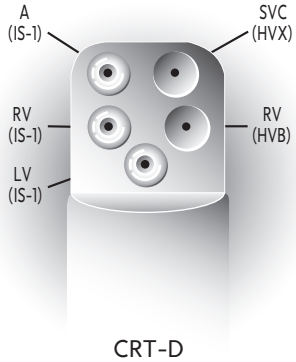
C-STYLE CONNECTOR



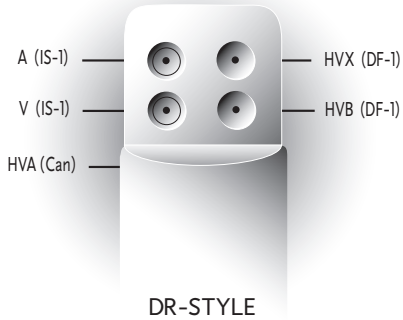
Cx-STYLE CONNECTOR



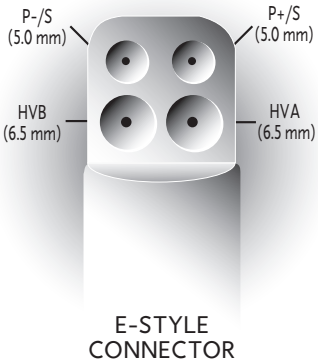
D-STYLE CONNECTOR



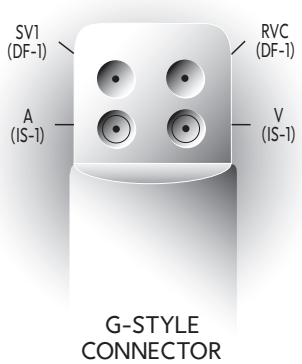
CRT-D CONNECTOR



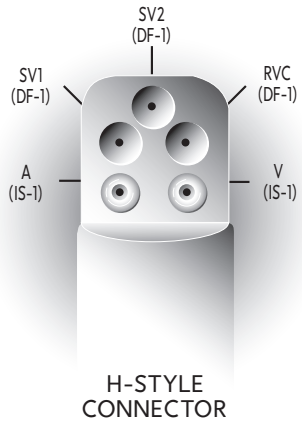
DR-STYLE CONNECTOR



E-STYLE CONNECTOR



G-STYLE CONNECTOR



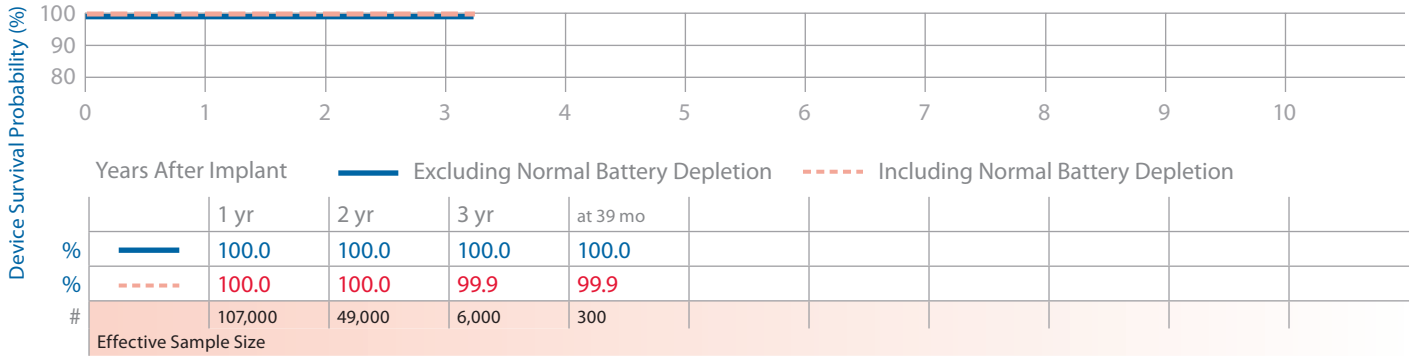
H-STYLE CONNECTOR

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Adapta DR ADDR01, ADDR03, ADDR06, ADD01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	19	NBG Code	DDDR, DDD
Registered US Implants	174,000	**Therapy Function Not Compromised**	13	Serial Number Prefix	PWB, PWD, PWC, PWF, NWB, NWC, NWD
Estimated Active US Implants	149,000	Electrical Component	13		
Normal Battery Depletions (US)	10	**Therapy Function Compromised**	6		
Advisories	None	Electrical Component	6	Estimated Longevity	See page 72



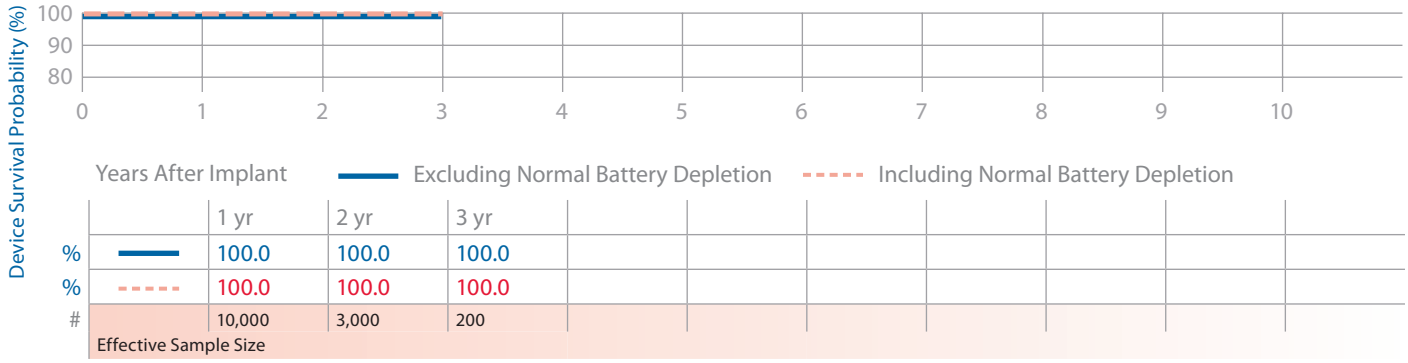
	1 yr	2 yr	3 yr	at 39 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.9
#	107,000	49,000	6,000	300

Effective Sample Size

Adapta DR ADDRL1

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	21,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PWE, NWE
Estimated Active US Implants	18,000	**Therapy Function Compromised**	0		
Normal Battery Depletions (US)	0			Estimated Longevity	See page 72
Advisories	None				



	1 yr	2 yr	3 yr
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	10,000	3,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Adapta DR ADDRS1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	16,000
Estimated Active US Implants	14,000
Normal Battery Depletions (US)	6
Advisories	None

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Component	1

NBG Code	SSIR
Serial Number Prefix	PWA
Estimated Longevity	See page 72

	1 yr	2 yr	3 yr	at 37 mo
%	100.0	100.0	100.0	100.0
%	100.0	99.8	99.8	99.8
#	9,000	4,000	400	200

Effective Sample Size

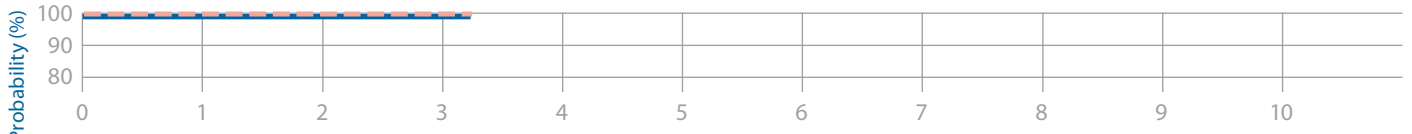
Adapta SR ADSR01, ADSR03, ADSR06

Product Characteristics

US Market Release	Jul-06
Registered US Implants	33,000
Estimated Active US Implants	26,000
Normal Battery Depletions (US)	8
Advisories	None

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	SSIR
Serial Number Prefix	NWN, NWM, NWP
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	at 38 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.8
#	19,000	9,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

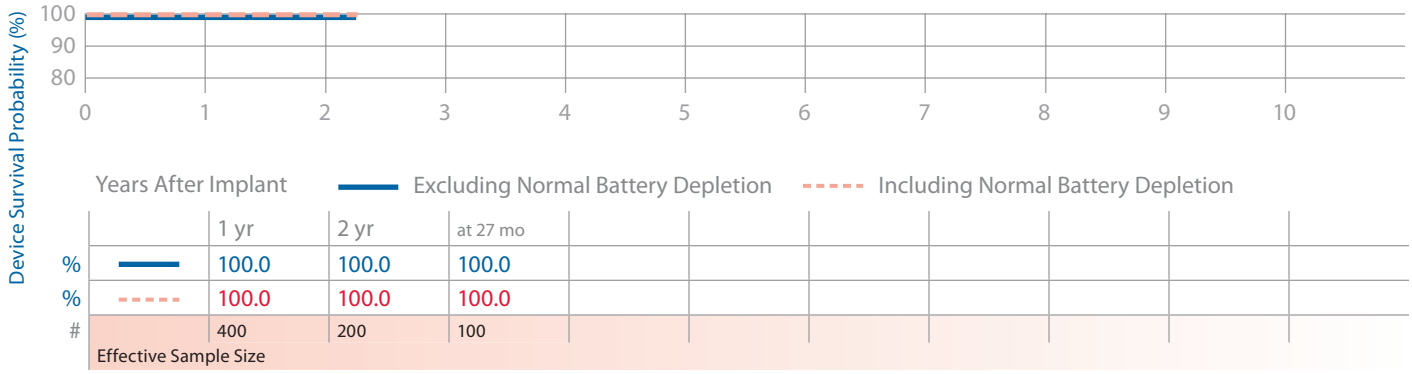
Adapta VDD ADVDD01

Product Characteristics

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

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDO
Serial Number Prefix	PWG, NWG
Estimated Longevity	See page 72



		1 yr	2 yr	at 27 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	100.0	100.0
#	Effective Sample Size	400	200	100

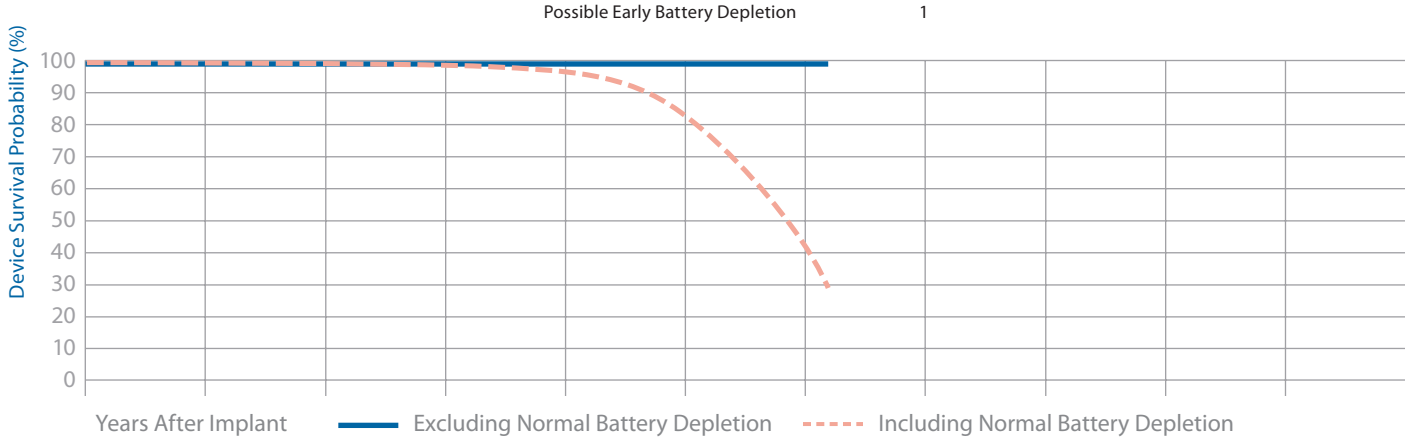
AT500 AT501, 7253

Product Characteristics

US Market Release	Mar-03
Registered US Implants	11,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	1,209
Performance Note: See page 150 – Performance note on AT500 Pacing System Follow-Up Protocol	

Malfunctions (US)	10
Therapy Function Not Compromised	5
Electrical Component	2
Possible Early Battery Depletion	3
Therapy Function Compromised	5
Electrical Component	3
Electrical Interconnect	1
Possible Early Battery Depletion	1

NBG Code	DDDRP
Serial Number Prefix	IJF
Estimated Longevity	See page 72

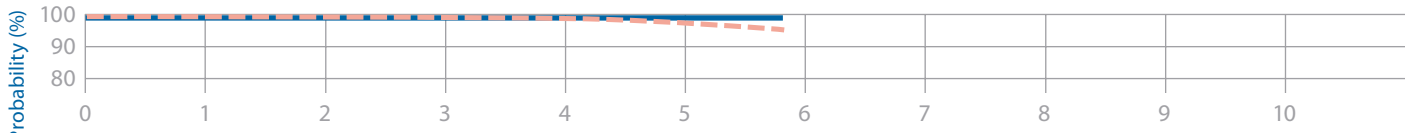


		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 74 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	Including Normal Battery Depletion	99.9	99.9	99.5	97.5	82.8	41.6	28.7
#	Effective Sample Size	10,000	9,000	8,000	7,000	4,000	1,000	200

EnPulse DR E1DR01, E1DR03, E1DR06

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	1	NBG Code	DDDR
Registered US Implants	7,000	**Therapy Function Not Compromised**	1	Serial Number Prefix	PRA
Estimated Active US Implants	4,000	Electrical Component	1	Estimated Longevity	See page 72
Normal Battery Depletions (US)	54	**Therapy Function Compromised**	0		
Advisories	None				

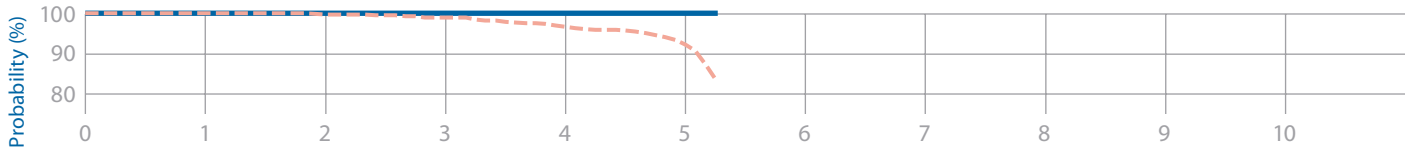


		1 yr	2 yr	3 yr	4 yr	5 yr	at 70 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	100.0	99.9	99.1	98.5	97.0
#	Effective Sample Size	6,000	6,000	5,000	4,000	4,000	1,000

EnPulse DR E1DR21

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	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 72
Normal Battery Depletions (US)	105				
Advisories	None				



		1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	99.7	99.0	96.9	93.3	64.1
#	Effective Sample Size	2,000	1,000	1,000	1,000	1,000	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

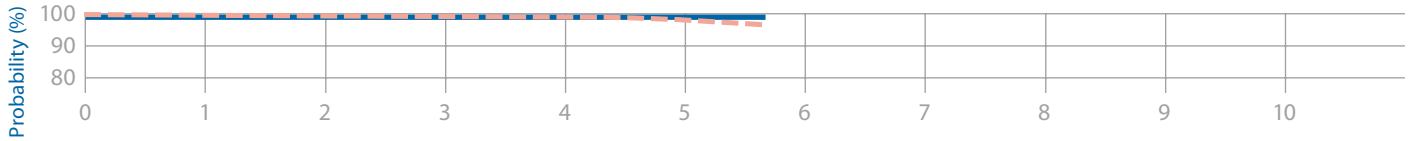
EnPulse 2 DR E2DR01, E2DR03, E2DR06

Product Characteristics

US Market Release	Feb-04
Registered US Implants	101,000
Estimated Active US Implants	62,000
Normal Battery Depletions (US)	216
Advisories	None

Malfunctions (US)	17
Therapy Function Not Compromised	14
Electrical Component	13
Possible Early Battery Depletion	1
Therapy Function Compromised	3
Battery	1
Electrical Component	2

NBG Code	DDDR
Serial Number Prefix	PNB, PNC, PNH
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	4 yr	5 yr	at 68 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	99.6	98.9	98.3
#	91,000	81,000	71,000	42,000	13,000	300

Effective Sample Size

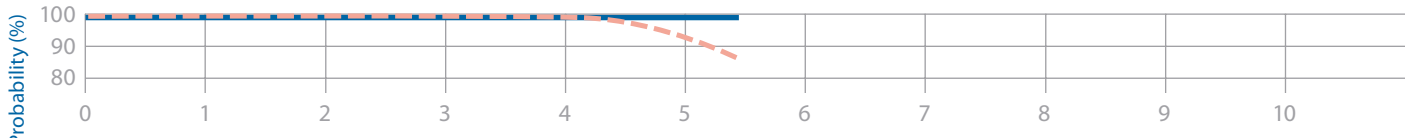
EnPulse 2 DR E2DR21

Product Characteristics

US Market Release	Feb-04
Registered US Implants	12,000
Estimated Active US Implants	7,000
Normal Battery Depletions (US)	155
Advisories	None

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Component	1

NBG Code	DDDR
Serial Number Prefix	PMU
Estimated Longevity	See page 72



	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
%	99.9	99.7	99.3	97.9	93.0	84.6
#	11,000	10,000	8,000	4,000	1,000	200

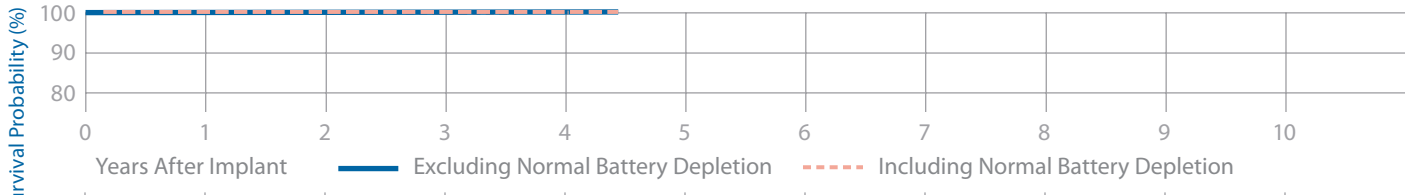
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

EnPulse 2 DR E2DR31, E2DR33

Product Characteristics

US Market Release	Feb-04	Malfunctions (US)	0	NBG Code	DDDR
Registered US Implants	1,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PNL
Estimated Active US Implants	400	**Therapy Function Compromised**	0	Estimated Longevity	See page 72
Normal Battery Depletions (US)	0				
Advisories	None				



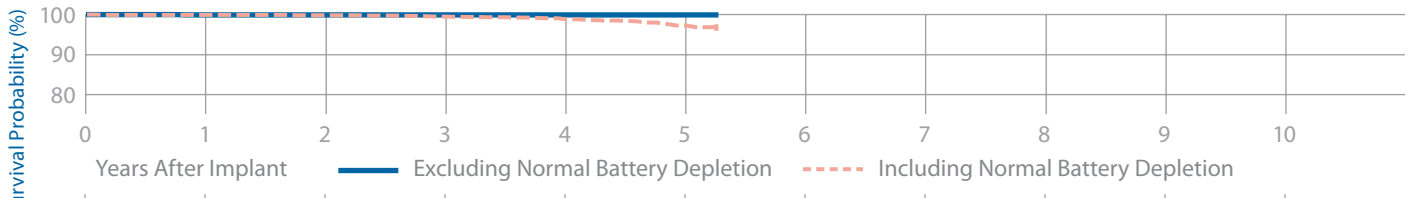
	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0
#	1,000	500	400	200	100

Effective Sample Size

EnPulse 2 SR E2SR01, E2SR03, E2SR06

Product Characteristics

US Market Release	Dec-03	Malfunctions (US)	4	NBG Code	SSIR
Registered US Implants	25,000	**Therapy Function Not Compromised**	3	Serial Number Prefix	PMW, PMY, PNA
Estimated Active US Implants	13,000	Electrical Component	2		
Normal Battery Depletions (US)	104	Possible Early Battery Depletion	1	Estimated Longevity	See page 72
Advisories	None	**Therapy Function Compromised**	1		
		Other	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.5	98.9	97.9	95.8
#	21,000	18,000	15,000	8,000	2,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

EnPulse 2 VDD E2VDD01

Product Characteristics

US Market Release	Dec-03
Registered US Implants	1,000
Estimated Active US Implants	400
Normal Battery Depletions (US)	3
Advisories	None

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PMV
Estimated Longevity	See page 72

	1 yr	2 yr	3 yr	4 yr	at 56 mo
%	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.3	99.3
#	1,000	1,000	400	200	100

Effective Sample Size

EnRhythm DR P1501DR

Product Characteristics

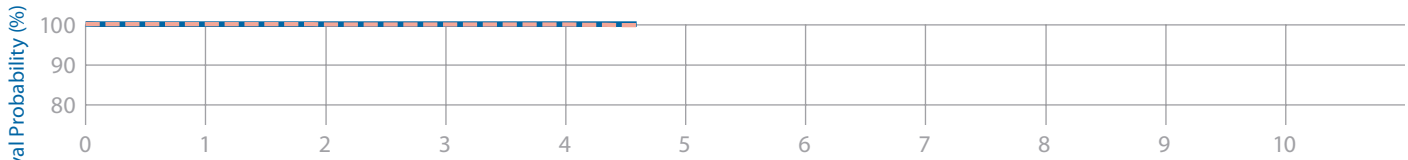
US Market Release	May-05
Registered US Implants	90,000
Estimated Active US Implants	68,000
Normal Battery Depletions (US)	20

Advisories: See page 137 – 2010 Low Battery Voltage Displayed at Device Interrogation

Performance Note: See page 146 – Anomalies in MOSFET Integrated Circuit Technology

Malfunctions (US)	45
Therapy Function Not Compromised	18
Battery	5
Electrical Component	6
Possible Early Battery Depletion	7
Therapy Function Compromised	27
Electrical Component	25
Electrical Interconnect	1
Possible Early Battery Depletion	1

NBG Code	DDDRP
Serial Number Prefix	PNP
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	4 yr	at 55 mo
%	100.0	100.0	99.9	99.9	99.9
%	100.0	99.9	99.9	99.7	99.6
#	70,000	52,000	35,000	9,000	200

Effective Sample Size

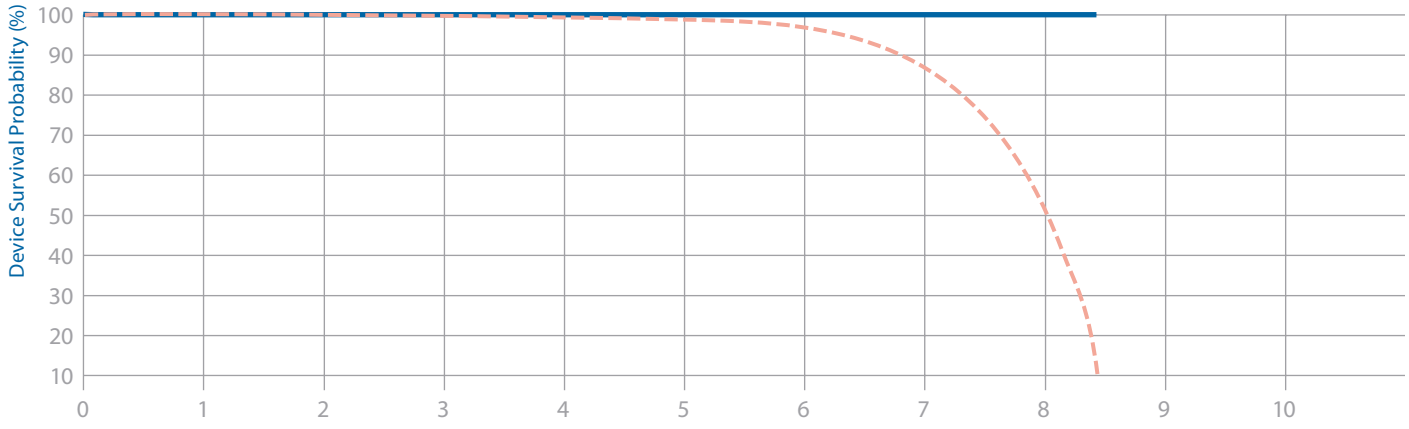
Kappa 400 DR KDR401, KDR403

Product Characteristics

US Market Release	Jan-98
Registered US Implants	47,000
Estimated Active US Implants	3,000
Normal Battery Depletions (US)	6,262
Advisories	None

Malfunctions (US)	22
Therapy Function Not Compromised	13
Electrical Component	9
Electrical Interconnect	1
Possible Early Battery Depletion	2
Other	1
Therapy Function Compromised	9
Electrical Component	7
Electrical Interconnect	2

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



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 101 mo
%	———	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9
%	- - - -	99.9	99.9	99.7	99.6	99.0	97.1	86.7	49.6	10.4
#	Effective Sample Size	42,000	38,000	34,000	30,000	26,000	22,000	15,000	5,000	1,000

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

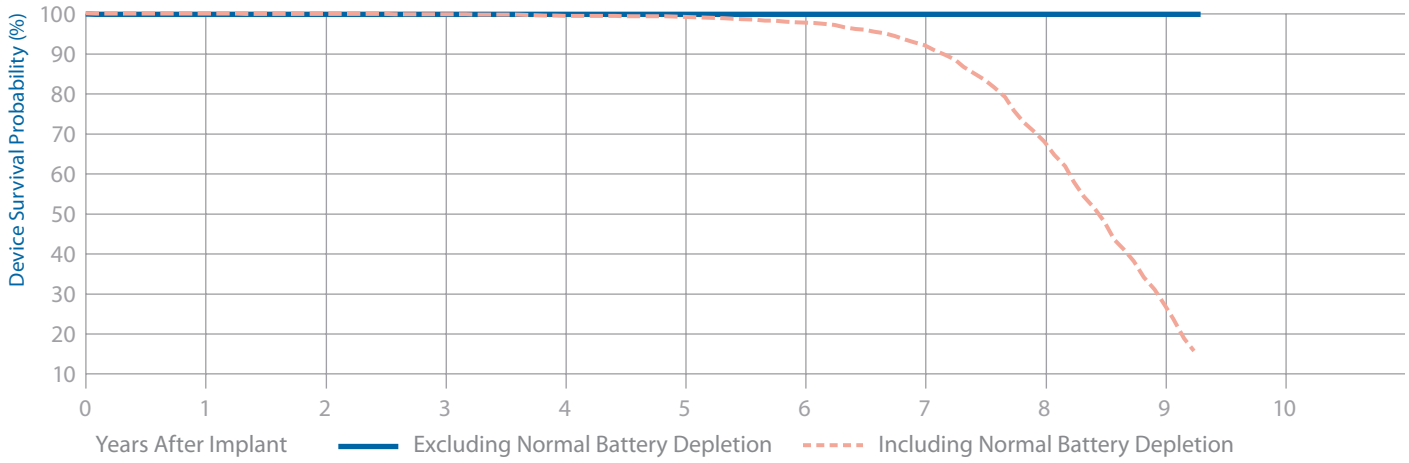
Kappa 400 SR KSR401, KSR403

Product Characteristics

US Market Release	Feb-98
Registered US Implants	15,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	1,100
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	4
Electrical Component	3
Possible Early Battery Depletion	1
Therapy Function Compromised	1
Electrical Interconnect	1

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



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	———	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	- - - -	99.9	99.8	99.7	99.3	98.9	97.4	91.5	67.3	26.8	15.1
#	Effective Sample Size	13,000	11,000	10,000	8,000	7,000	6,000	4,000	2,000	300	100

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Kappa 600 DR KDR601, KDR603, KDR606

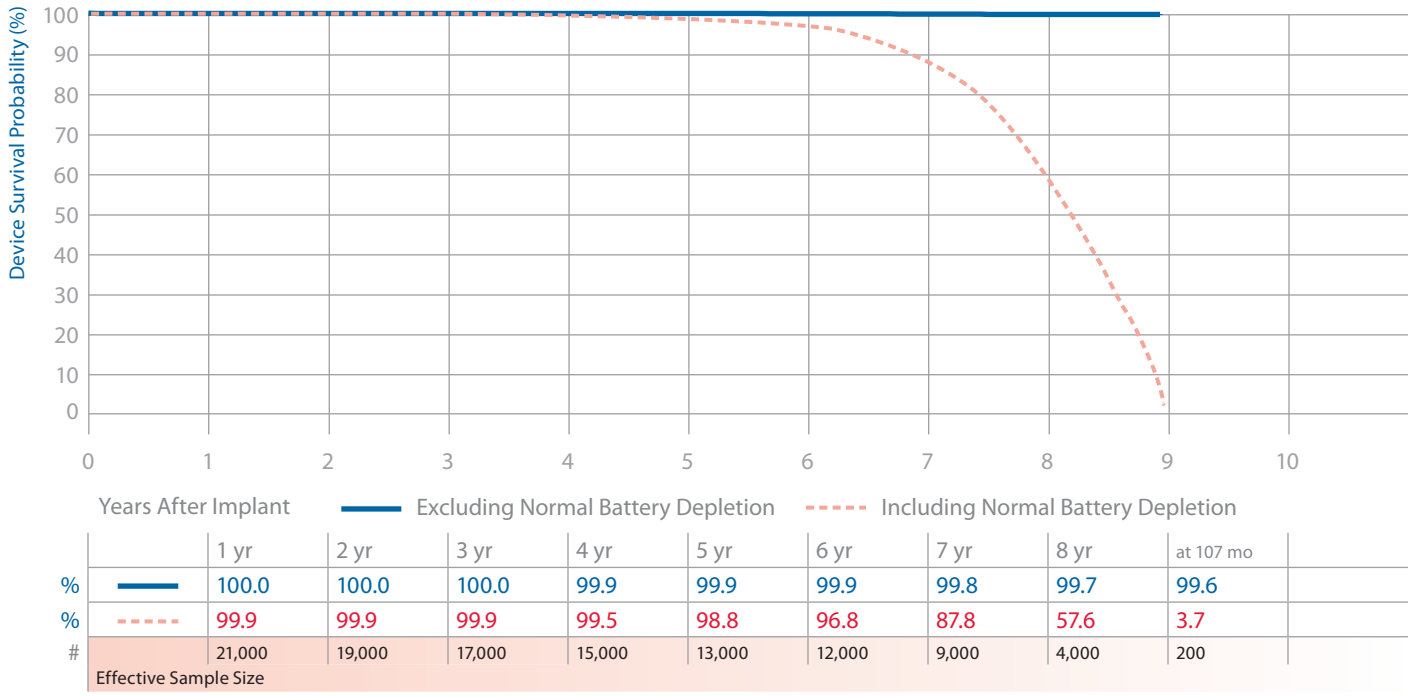
Product Characteristics

US Market Release	Jan-99
Registered US Implants	24,000
Estimated Active US Implants	100
Normal Battery Depletions (US)	3,260

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	37
Therapy Function Not Compromised	3
Electrical Component	3
Therapy Function Compromised	34
Electrical Component	2
Electrical Interconnect *(31 malfunctions related to advisory)*	32

NBG Code	DDD/RO
Serial Number Prefix	PHF, PHH, PHG
Estimated Longevity	See page 72



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 107 mo
%	———	100.0	100.0	100.0	99.9	99.9	99.9	99.8	99.7	99.6
%	- - - -	99.9	99.9	99.9	99.5	98.8	96.8	87.8	57.6	3.7
#		21,000	19,000	17,000	15,000	13,000	12,000	9,000	4,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Kappa 600 DR KDR651, KDR653

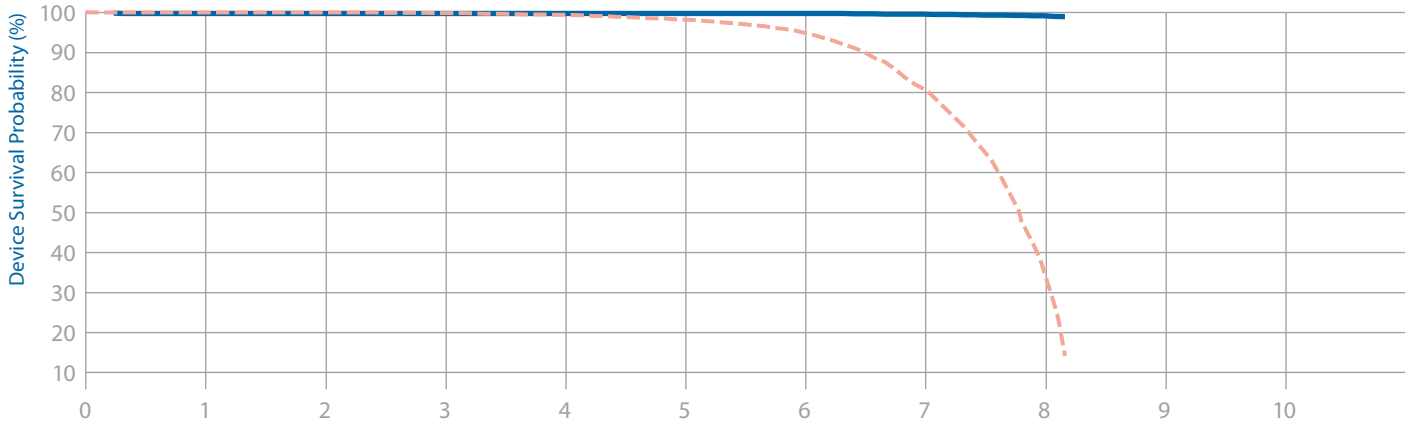
Product Characteristics

US Market Release	Mar-01
Registered US Implants	14,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	1,439

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	31
Therapy Function Not Compromised	2
Electrical Component	1
Possible Early Battery Depletion	1
Therapy Function Compromised	29
Electrical Component	1
Electrical Interconnect *(21 malfunctions related to advisory)*	28

NBG Code	DDD/RO
Serial Number Prefix	PLJ, PLK
Estimated Longevity	See page 72



	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	99.9	99.7	99.3	99.2
%	100.0	99.9	99.8	99.4	98.2	94.8	80.7	34.3	14.9
#	13,000	11,000	10,000	9,000	8,000	7,000	5,000	1,000	100

Effective Sample Size

Kappa 700 D KD701, KD703, KD706

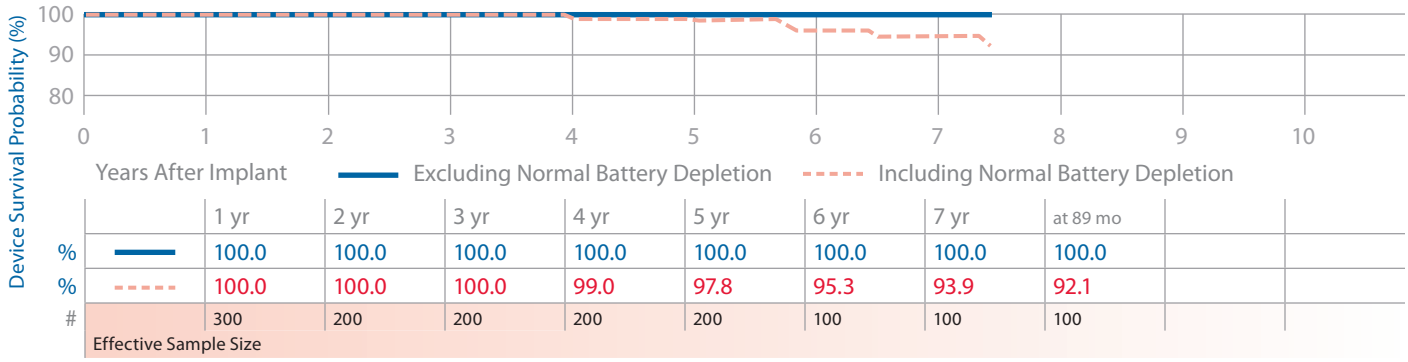
Product Characteristics

US Market Release	Jan-99
Registered US Implants	300
Estimated Active US Implants	50
Normal Battery Depletions (US)	17

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	DDD
Serial Number Prefix	PHK
Estimated Longevity	See page 73



	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	100.0	100.0	99.0	97.8	95.3	93.9	92.1
#	300	200	200	200	200	100	100	100

Effective Sample Size

Kappa 700 DR KDR701, KDR703, KDR706

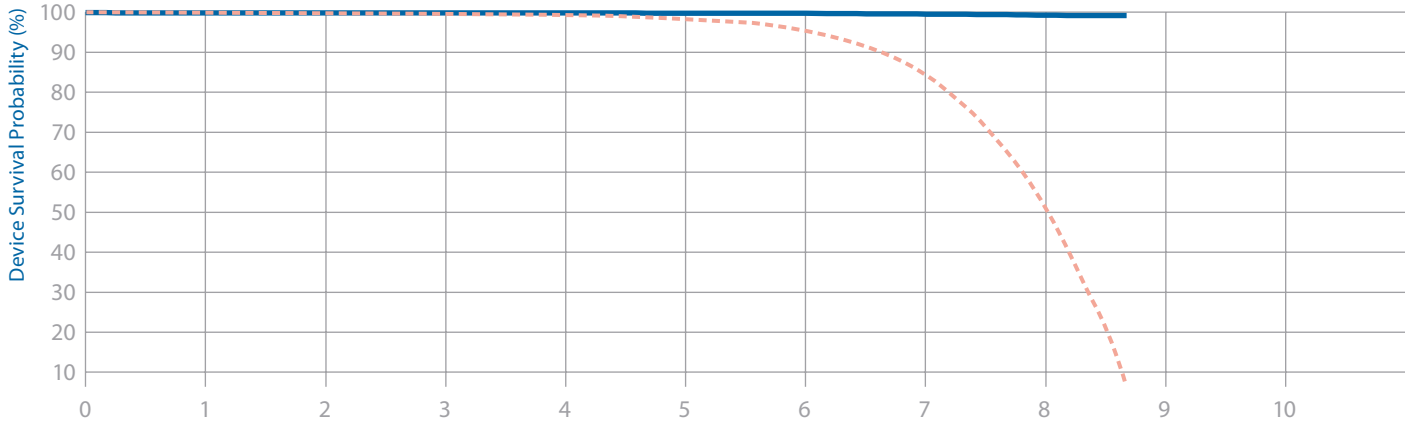
Product Characteristics

US Market Release	Feb-99
Registered US Implants	192,000
Estimated Active US Implants	33,000
Normal Battery Depletions (US)	20,148

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	441
Therapy Function Not Compromised	28
Battery	1
Electrical Component	21
Electrical Interconnect	1
Possible Early Battery Depletion	3
Other	2
Therapy Function Compromised	413
Electrical Component	15
Electrical Interconnect *(320 malfunctions related to advisory)*	398

NBG Code	DDD/RO
Serial Number Prefix	PGU, PGY, PGW
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 104 mo
%	100.0	100.0	99.9	99.9	99.9	99.8	99.7	99.5	99.3
%	99.9	99.8	99.6	99.2	98.1	95.2	84.1	50.7	5.5
#	173,000	156,000	139,000	119,000	99,000	78,000	51,000	19,000	1,000

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Kappa 700 DR KDR721

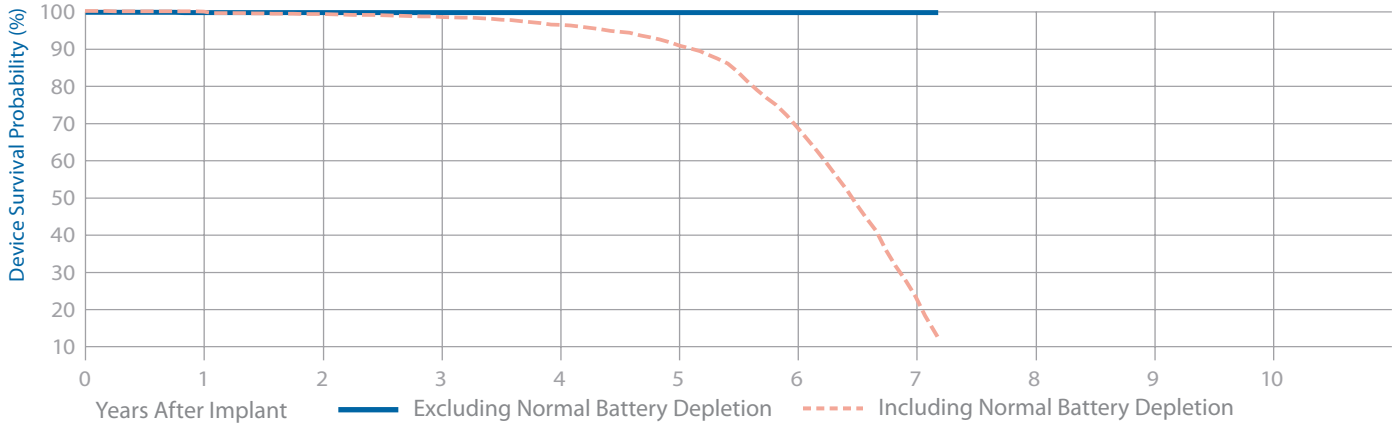
Product Characteristics

US Market Release	Feb-99
Registered US Implants	10,000
Estimated Active US Implants	1
Normal Battery Depletions (US)	1,294

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

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

NBG Code	DDD/RO
Serial Number Prefix	PGR
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.6	98.8	96.7	91.0	68.7	22.5	12.2
#	8,000	7,000	7,000	6,000	4,000	2,000	300	100

Effective Sample Size

Kappa 700 SR KSR701, KSR703, KSR706

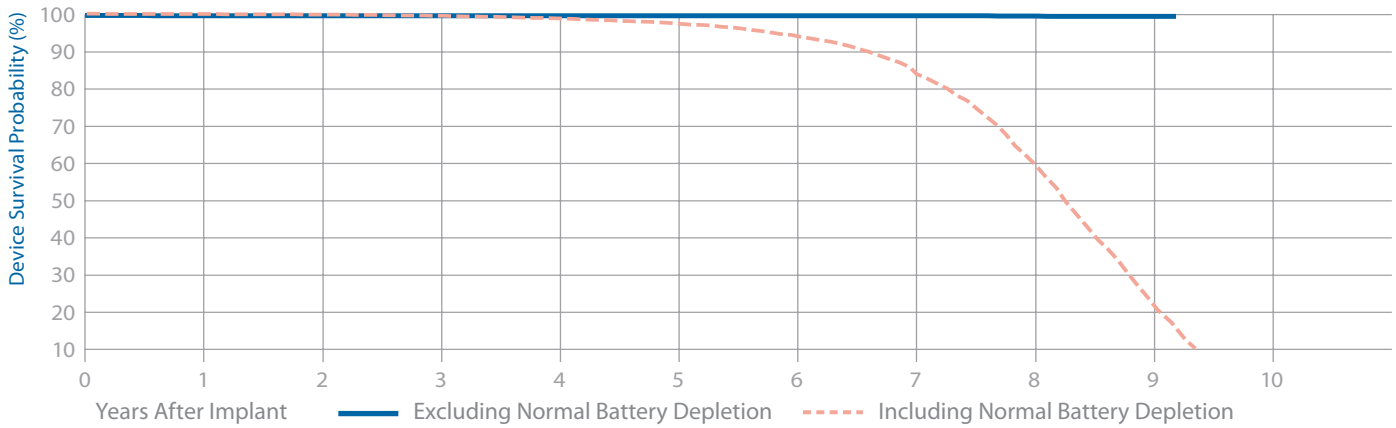
Product Characteristics

US Market Release	Feb-99
Registered US Implants	55,000
Estimated Active US Implants	8,000
Normal Battery Depletions (US)	3,362

Advisories: See page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	25
Therapy Function Not Compromised	3
Electrical Component	2
Possible Early Battery Depletion	1
Therapy Function Compromised	22
Electrical Component	4
Electrical Interconnect	18

NBG Code	SSI/R
Serial Number Prefix	PHT, PHW, PHU
Estimated Longevity	See page 73



	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	100.0	100.0	100.0	100.0	99.9	99.8	99.8	99.8
%	99.9	99.8	99.4	98.7	97.2	93.8	84.3	59.3	23.0	10.6
#	46,000	39,000	33,000	26,000	21,000	16,000	10,000	4,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Kappa 700 VDD KVDD701

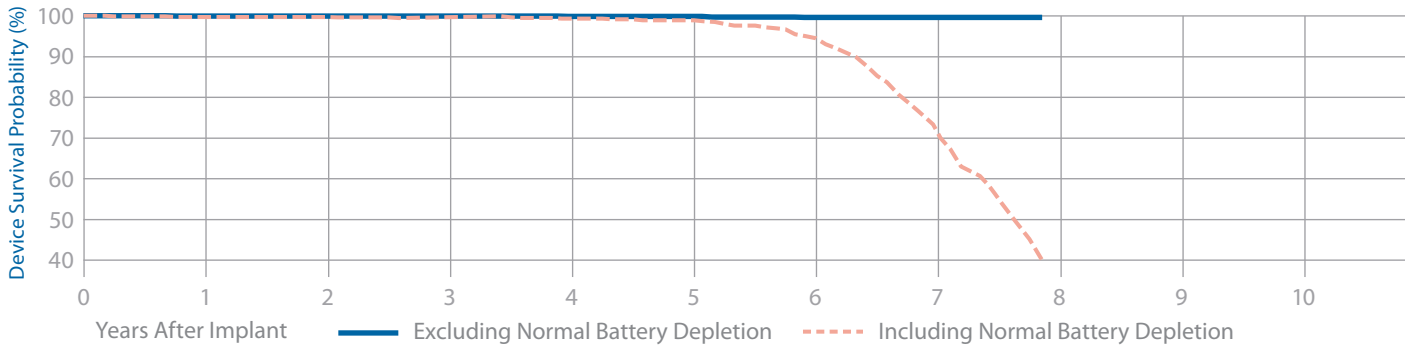
Product Characteristics

US Market Release	Jan-99
Registered US Implants	2,000
Estimated Active US Implants	100
Normal Battery Depletions (US)	164

Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	4
Therapy Function Not Compromised	0
Therapy Function Compromised	4
Electrical Interconnect *(4 malfunctions related to advisory)*	4

NBG Code	VDD/RO
Serial Number Prefix	PHP
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 94 mo
%	99.9	99.9	99.9	99.8	99.8	99.6	99.6	99.6
%	99.7	99.7	99.4	98.9	98.5	94.1	70.1	40.7
#	1,000	1,000	1,000	1,000	1,000	1,000	400	100

Effective Sample Size

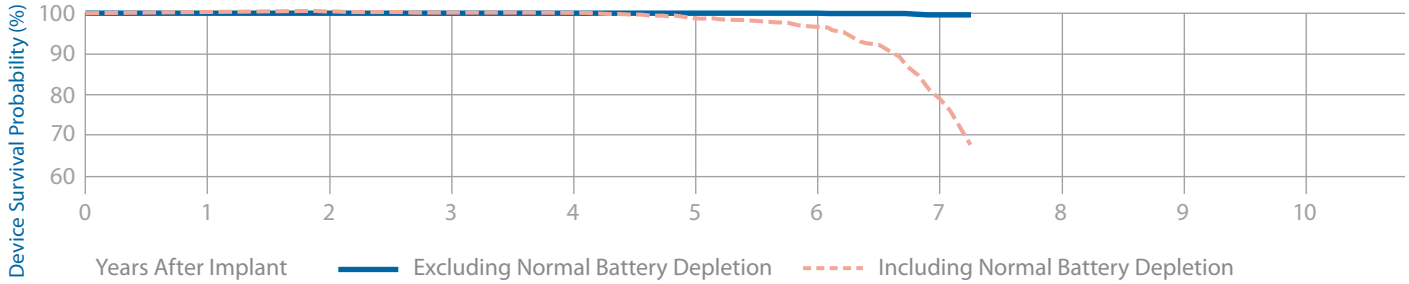
Kappa 800 DR KDR801, KDR803

Product Characteristics

US Market Release	Jan-02
Registered US Implants	4,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	131
Advisories	None

Malfunctions (US)	3
Therapy Function Not Compromised	0
Therapy Function Compromised	3
Electrical Interconnect	3

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 87 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.8
%	100.0	99.9	99.8	99.6	98.6	96.4	79.1	67.6
#	4,000	3,000	3,000	3,000	2,000	2,000	400	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

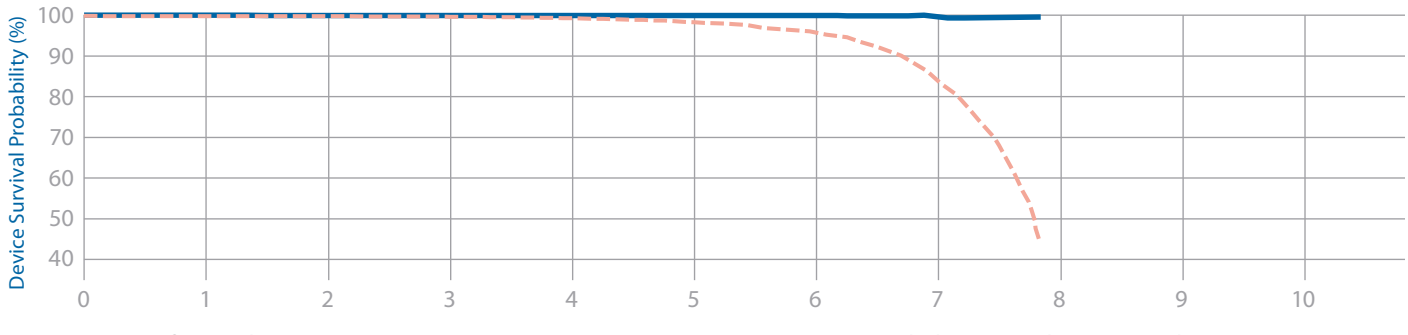
Kappa 900 DR KDR901, KDR903, KDR906

Product Characteristics

US Market Release	Jan-02
Registered US Implants	125,000
Estimated Active US Implants	58,000
Normal Battery Depletions (US)	2,973
Advisories	None

Malfunctions (US)	54
Therapy Function Not Compromised	13
Electrical Component	13
Therapy Function Compromised	41
Electrical Component	8
Electrical Interconnect	33

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 94 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.8
%	100.0	99.9	99.8	99.4	98.5	96.0	84.0	43.9
#	113,000	101,000	90,000	73,000	56,000	36,000	12,000	100

Effective Sample Size

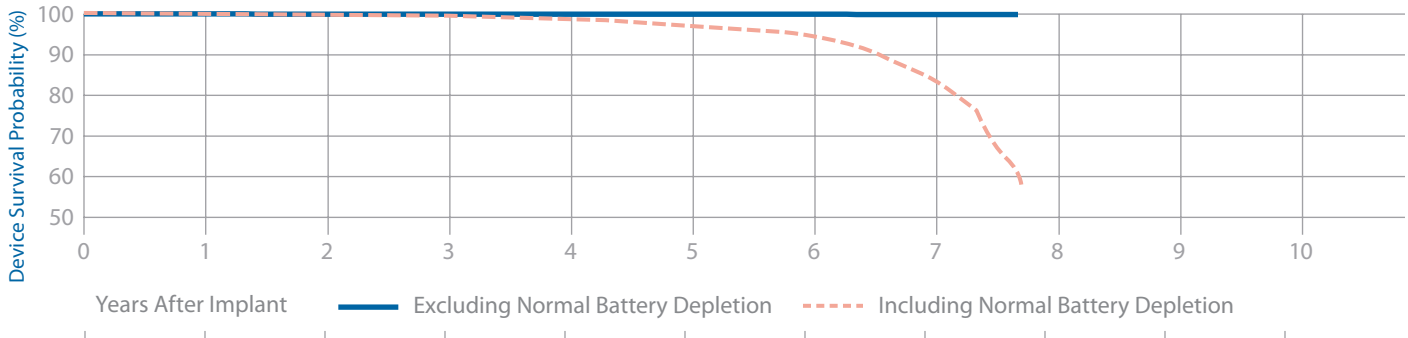
Kappa 900 SR KSR901, KSR903, KSR906

Product Characteristics

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	14,000
Normal Battery Depletions (US)	613
See page 139 – 2009 Potential Separation of Interconnect Wires	

Malfunctions (US)	13
Therapy Function Not Compromised	8
Electrical Component	7
Possible Early Battery Depletion	1
Therapy Function Compromised	5
Electrical Interconnect	5

NBG Code	VVEV
Serial Number Prefix	PLF, PLG, PLH
Estimated Longevity	See page 73



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 92 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.8	99.6	98.9	97.4	94.8	84.3	60.8
#	30,000	26,000	22,000	16,000	11,000	7,000	2,000	200

Effective Sample Size

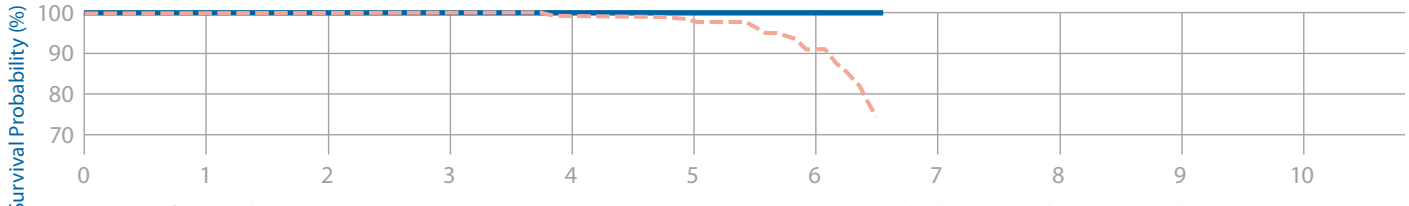
Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Kappa 900 VDD KVDD901

Product Characteristics

US Market Release	Jan-02	Malfunctions (US)	0	NBG Code	VDD
Registered US Implants	1,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PLE
Estimated Active US Implants	100	**Therapy Function Compromised**	0	Estimated Longevity	See page 73
Normal Battery Depletions (US)	47				

See page 139 – 2009 Potential Separation of Interconnect Wires



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.0	97.8	90.9	74.0
#	1,000	500	400	400	300	200	100

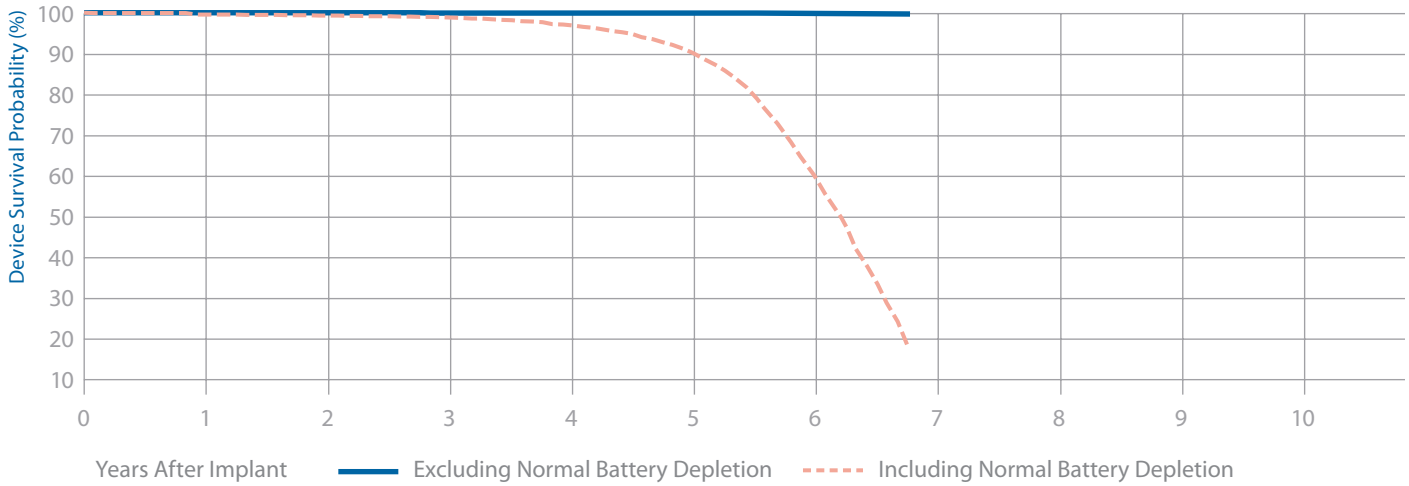
Effective Sample Size

Kappa 920 DR KSR921

Product Characteristics

US Market Release	Jan-02	Malfunctions (US)	3	NBG Code	VVEV
Registered US Implants	16,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PLF, PLG, PLH
Estimated Active US Implants	3,000	**Therapy Function Compromised**	3		
Normal Battery Depletions (US)	1,697	Electrical Interconnect	3	Estimated Longevity	See page 73

See page 139 – 2009 Potential Separation of Interconnect Wires



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.2	97.2	90.3	59.6	17.0
#	14,000	13,000	11,000	9,000	7,000	2,000	200

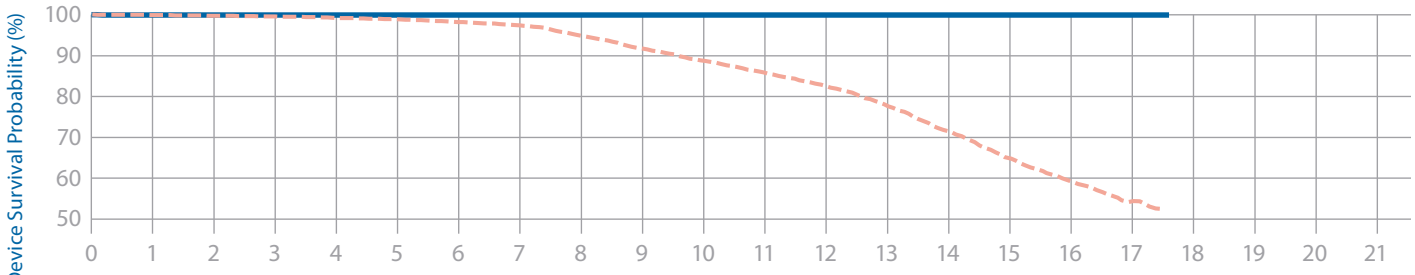
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Legend II 8424, 8426, 8427

US Market Release	Nov-91	Malfunctions (US)	34	NBG Code	SSIRO
Registered US Implants	58,000			Serial Number Prefix	2P, 2T, 2U
Estimated Active US Implants	3,000			Estimated Longevity	See page 73
Normal Battery Depletions (US)	2,369				
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 211 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	99.9
%	99.9	99.7	99.5	99.1	98.7	98.0	97.1	94.7	91.6	88.9	85.6	82.5	77.6	71.5	64.9	58.9	54.5	52.2
#	52,000	46,000	41,000	36,000	31,000	27,000	24,000	20,000	16,000	12,000	10,000	8,000	6,000	5,000	3,000	2,000	1,000	100

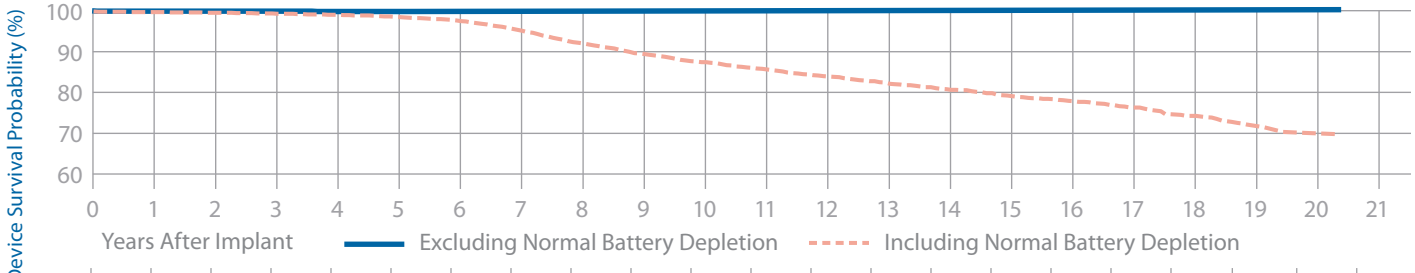
Effective Sample Size

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

US Market Release	Dec-89	Malfunctions (US)	49	NBG Code	SSIRO
Registered US Implants	58,000			Serial Number Prefix	2P, 2T, 2U
Estimated Active US Implants	3,000			Estimated Longevity	See page 73
Normal Battery Depletions (US)	1,643				

Advisories: See page 145 – 1991 Potential Delayed Restoration of Permanent Settings

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	18 yr	19 yr	20 yr	at 244 mo
%	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.7	99.5	99.2	98.7	97.6	95.3	92.1	89.5	87.5	85.8	84.1	82.3	80.8	79.3	78.0	76.4	74.3	72.1	70.1	70.1
#	50,000	43,000	37,000	32,000	27,000	23,000	19,000	15,000	13,000	11,000	9,000	8,000	7,000	6,000	4,000	3,000	2,000	1,000	1,000	200	100

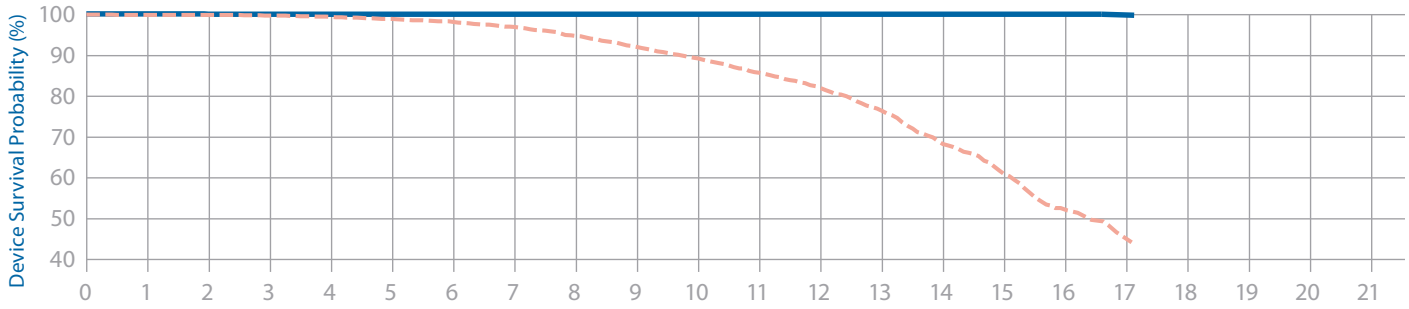
Effective Sample Size

Minuet 7107, 7108

US Market Release	Mar-92
Registered US Implants	17,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	852
Advisories	None
Malfunctions (US)	4

Product Characteristics

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	at 205 mo
%	100.0	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
%	100.0	100.0	99.8	99.5	98.9	98.2	97.0	94.8	92.1	89.3	85.8	82.1	76.5	68.1	60.7	52.2	45.0	44.1
#	15,000	13,000	12,000	11,000	9,000	8,000	7,000	6,000	5,000	4,000	4,000	3,000	2,000	2,000	1,000	500	100	100

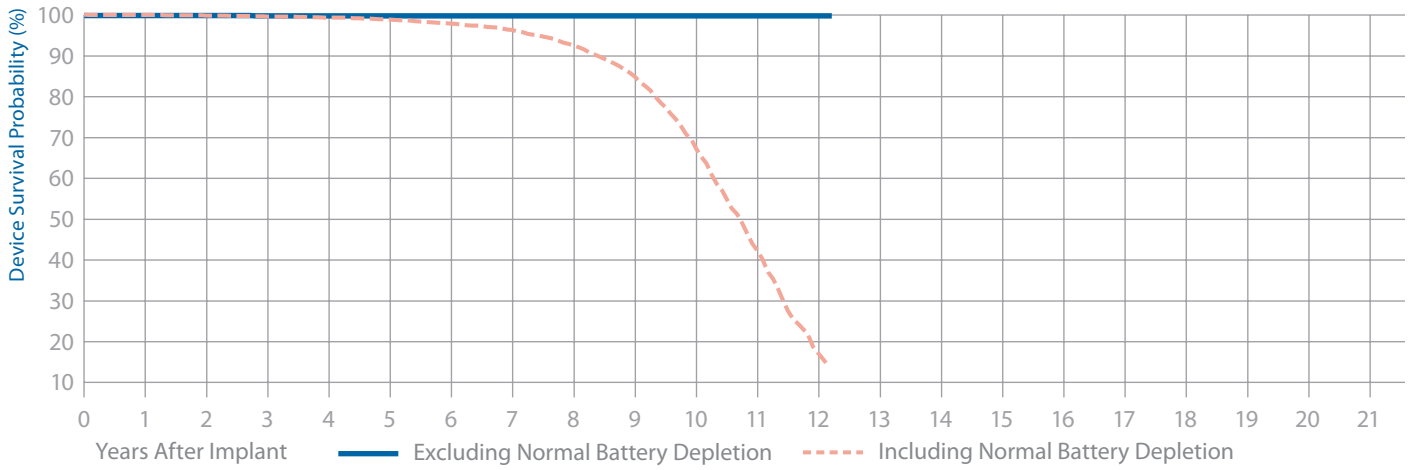
Effective Sample Size

Preva DR 7088, 7089

US Market Release	Jul-96
Registered US Implants	26,000
Estimated Active US Implants	1,000
Normal Battery Depletions (US)	2,358
Advisories	None
Malfunctions (US)	4

Product Characteristics

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 146 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	99.8	99.6	99.3	98.8	97.8	96.2	92.4	84.7	67.1	41.5	16.8	13.5
#	22,000	20,000	18,000	16,000	14,000	12,000	11,000	9,000	7,000	4,000	2,000	200	100

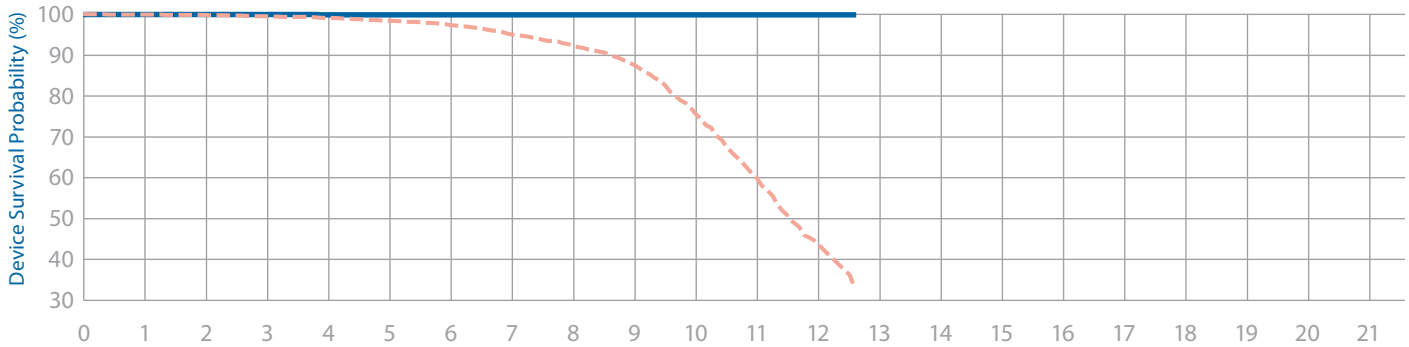
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Preva SR 8088, 8089

US Market Release	Jul-96	Malfunctions (US)	1	NBG Code	SSI/R
Registered US Implants	18,000			Serial Number Prefix	PGL, PGM
Estimated Active US Implants	1,000			Estimated Longevity	See page 73
Normal Battery Depletions (US)	878				
Advisories	None				

Product Characteristics



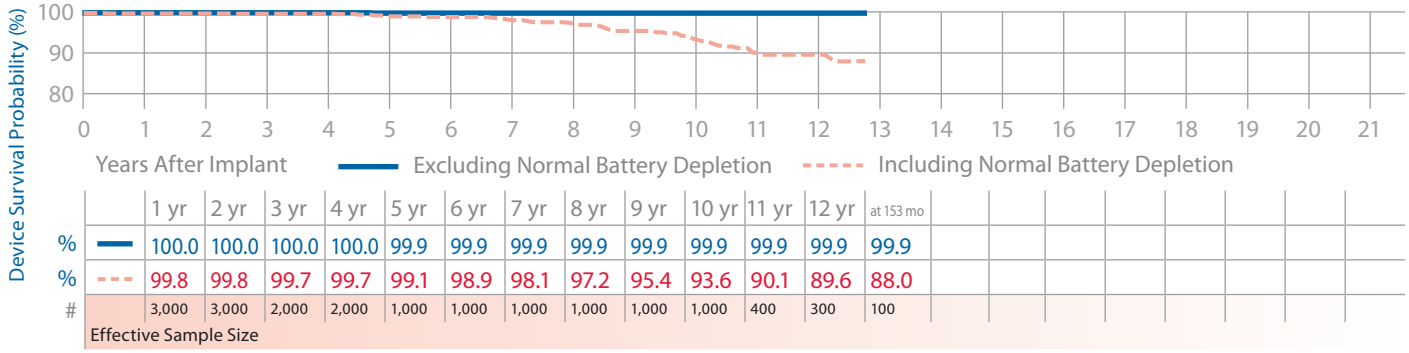
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 151 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.8	99.4	99.1	98.3	97.3	95.0	92.3	87.4	75.7	59.7	43.5	33.6
#	15,000	12,000	11,000	9,000	8,000	6,000	5,000	4,000	3,000	2,000	1,000	400	100

Effective Sample Size

Prevail S 8085, 8086

US Market Release	Oct-95	Malfunctions (US)	1	NBG Code	SSI
Registered US Implants	4,000			Serial Number Prefix	PGL, PGM
Estimated Active US Implants	400			Estimated Longevity	See page 73
Normal Battery Depletions (US)	44				
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	at 153 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	99.7	99.7	99.1	98.9	98.1	97.2	95.4	93.6	90.1	89.6	88.0
#	3,000	3,000	2,000	2,000	1,000	1,000	1,000	1,000	1,000	1,000	400	300	100

Effective Sample Size

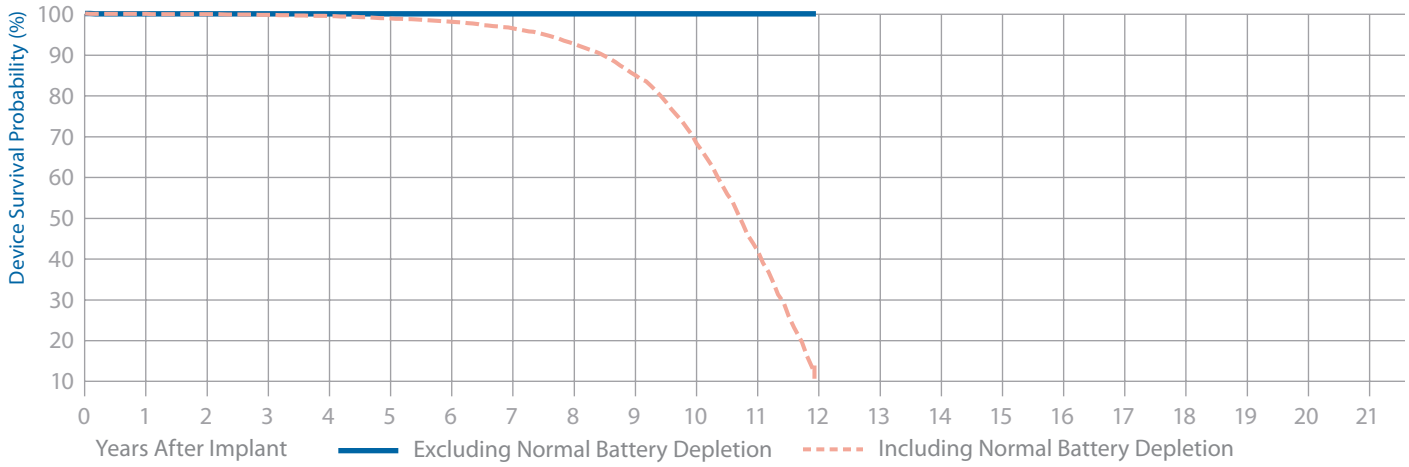
Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Prodigy DR 7860, 7861, 7862

Product Characteristics

US Market Release	Oct-95
Registered US Implants	38,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	3,261
Advisories	None
Malfunctions (US)	11

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	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
%	99.9	99.8	99.7	99.4	98.8	97.9	96.3	92.4	84.6	68.3	41.3	12.3
#	33,000	30,000	27,000	24,000	21,000	19,000	16,000	13,000	10,000	6,000	2,000	100

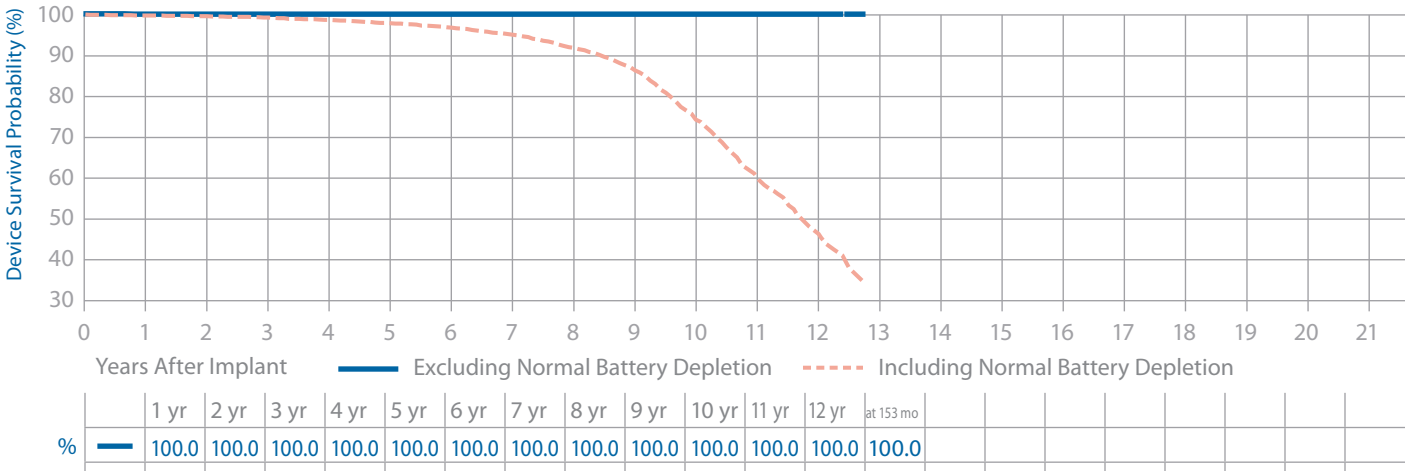
Effective Sample Size

Prodigy SR 8158, 8160, 8161, 8162

Product Characteristics

US Market Release	Oct-95
Registered US Implants	22,000
Estimated Active US Implants	2,000
Normal Battery Depletions (US)	1,067
Advisories	None
Malfunctions (US)	4

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 153 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
%	99.8	99.6	99.2	98.6	97.8	96.7	95.0	91.8	86.4	74.3	60.4	46.4	34.6
#	19,000	16,000	14,000	11,000	10,000	8,000	7,000	5,000	4,000	3,000	1,000	400	100

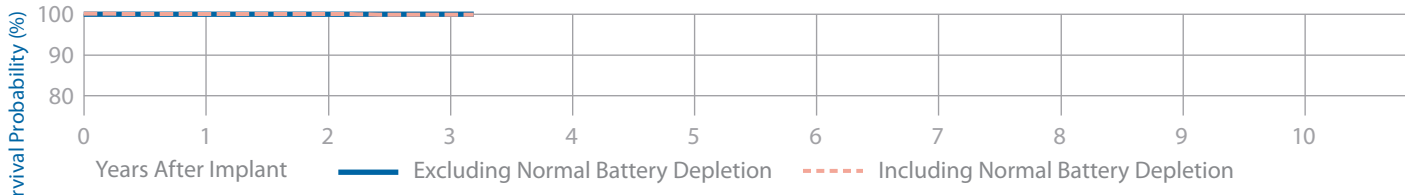
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Sensia DR SEDR01, SED01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	5	NBG Code	DDD, DDDR
Registered US Implants	65,000	**Therapy Function Not Compromised**	3	Serial Number Prefix	PWL, PWK, NWL
Estimated Active US Implants	55,000	Electrical Component	3		
Normal Battery Depletions (US)	7	**Therapy Function Compromised**	2	Estimated Longevity	See page 74
Advisories	None	Electrical Component	2		

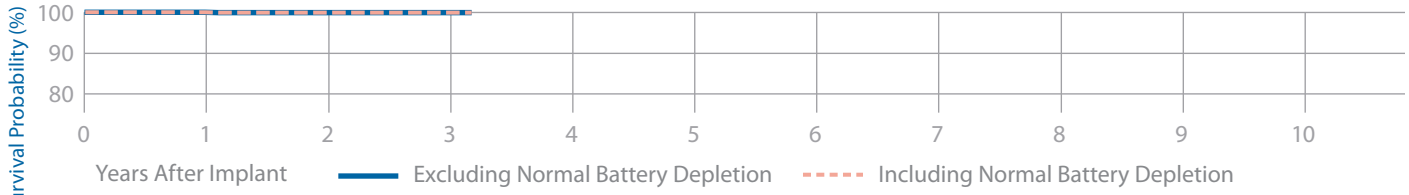


		1 yr	2 yr	3 yr	at 38 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	100.0	99.7	99.7
#	Effective Sample Size	38,000	16,000	2,000	200

Sensia SR SESR01, SESO1

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	1	NBG Code	SSIR, SSI
Registered US Implants	41,000	**Therapy Function Not Compromised**	1	Serial Number Prefix	PWR, PWS, NWR
Estimated Active US Implants	32,000	Electrical Component	1		
Normal Battery Depletions (US)	5	**Therapy Function Compromised**	0	Estimated Longevity	See page 74
Advisories	None				



		1 yr	2 yr	3 yr	at 38 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	99.9	99.9	99.9
#	Effective Sample Size	22,000	9,000	1,000	100

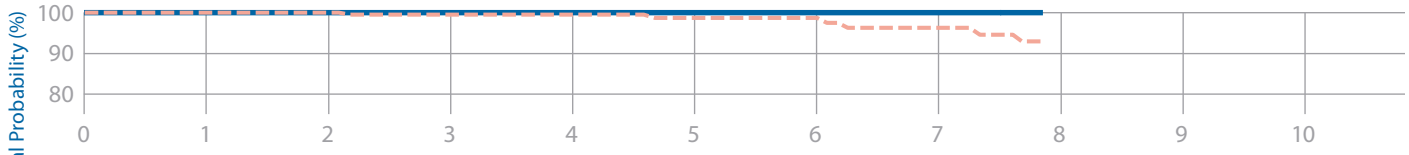
Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Sigma 100 S SS103, SS106

Product Characteristics

US Market Release	Aug-99	Malfunctions (US)	0	NBG Code	SSI
Registered US Implants	1,000	**Therapy Function Not Compromised**	0	Serial Number Prefix	PJG, PJH
Estimated Active US Implants	100	**Therapy Function Compromised**	0	Estimated Longevity	See page 74
Normal Battery Depletions (US)	13				

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 94 mo
%	———	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	- - - -	100.0	100.0	99.6	99.6	98.7	98.7	96.5	93.1
#		1,000	500	400	300	200	200	100	100

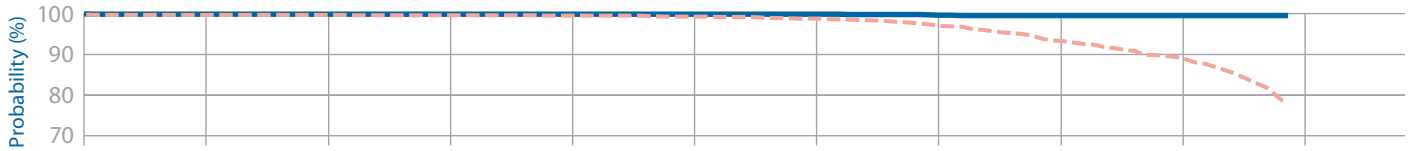
Effective Sample Size

Sigma 200 DR SDR203

Product Characteristics

US Market Release	Aug-99	Malfunctions (US)	24	NBG Code	DDD/RO
Registered US Implants	16,000	**Therapy Function Not Compromised**	2	Serial Number Prefix	PJD
Estimated Active US Implants	5,000	Electrical Component	1	Estimated Longevity	See page 74
Normal Battery Depletions (US)	223	Electrical Interconnect	1		
		Therapy Function Compromised	22		
		Electrical Component	1		
		Electrical Interconnect *(2 malfunctions related to advisory)*	21		

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 118 mo
%	———	100.0	100.0	100.0	100.0	100.0	99.9	99.8	99.6	99.6	99.6
%	- - - -	100.0	99.9	99.9	99.8	99.5	99.0	97.4	93.9	89.0	77.4
#		13,000	12,000	11,000	9,000	8,000	7,000	5,000	3,000	1,000	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Sigma 200 SR SSR203

Product Characteristics

US Market Release	Sep-99
Registered US Implants	12,000
Estimated Active US Implants	3,000
Normal Battery Depletions (US)	111

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	10
Therapy Function Not Compromised	0
Therapy Function Compromised	10
Electrical Interconnect *(3 malfunctions related to advisory)*	10

NBG Code	SSI/R
Serial Number Prefix	PJG
Estimated Longevity	See page 74

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 118 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8	99.8
%	99.9	99.9	99.8	99.7	99.2	98.6	97.0	94.8	90.8	85.2
#	10,000	8,000	7,000	6,000	5,000	4,000	3,000	2,000	1,000	100

Effective Sample Size

Sigma 300 DR SDR303, SDR306

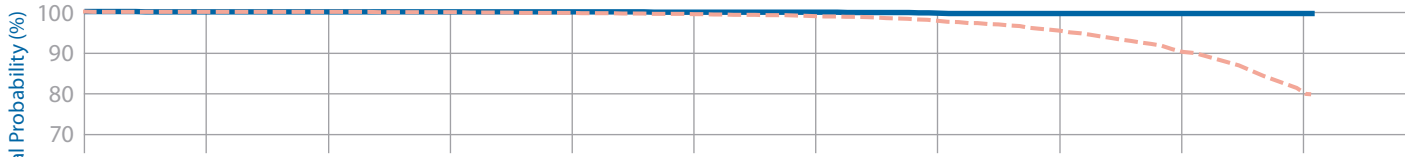
Product Characteristics

US Market Release	Aug-99
Registered US Implants	107,000
Estimated Active US Implants	46,000
Normal Battery Depletions (US)	804

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	165
Therapy Function Not Compromised	7
Electrical Component	5
Electrical Interconnect	1
Possible Early Battery Depletion	1
Therapy Function Compromised	158
Electrical Component	8
Electrical Interconnect *(30 malfunctions related to advisory)*	150

NBG Code	DDD/RO
Serial Number Prefix	PJD, PJE
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 121 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.7	99.5	99.5	99.5	99.5
%	100.0	99.9	99.8	99.7	99.4	98.9	97.9	95.0	90.6	80.0	80.0
#	92,000	82,000	70,000	57,000	45,000	33,000	22,000	13,000	5,000	200	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Sigma 300 SR SSR303, SSR306

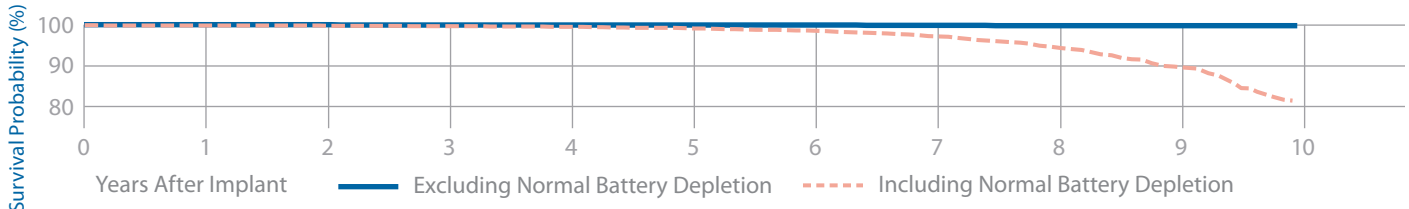
Product Characteristics

US Market Release	Sep-99
Registered US Implants	54,000
Estimated Active US Implants	17,000
Normal Battery Depletions (US)	352

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	26
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	25
Electrical Component	3
Electrical Interconnect *(6 malfunctions related to advisory)*	22

NBG Code	SSI/R
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 119 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8	99.8
%	100.0	99.9	99.8	99.6	99.2	98.6	97.4	94.6	89.9	81.3
#	43,000	36,000	28,000	22,000	16,000	12,000	7,000	4,000	2,000	100

Effective Sample Size

Sigma 300 VDD SVDD303

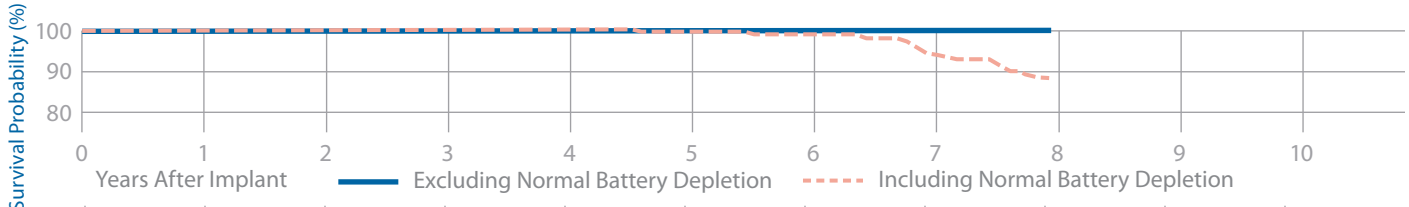
Product Characteristics

US Market Release	Sep-99
Registered US Implants	1,000
Estimated Active US Implants	200
Normal Battery Depletions (US)	21

Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires

Malfunctions (US)	0
Therapy Function Not Compromised	0
Therapy Function Compromised	0

NBG Code	VDDD
Serial Number Prefix	PJD
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 95 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	99.4	98.8	94.1	88.7
#	1,000	500	400	400	300	300	200	100

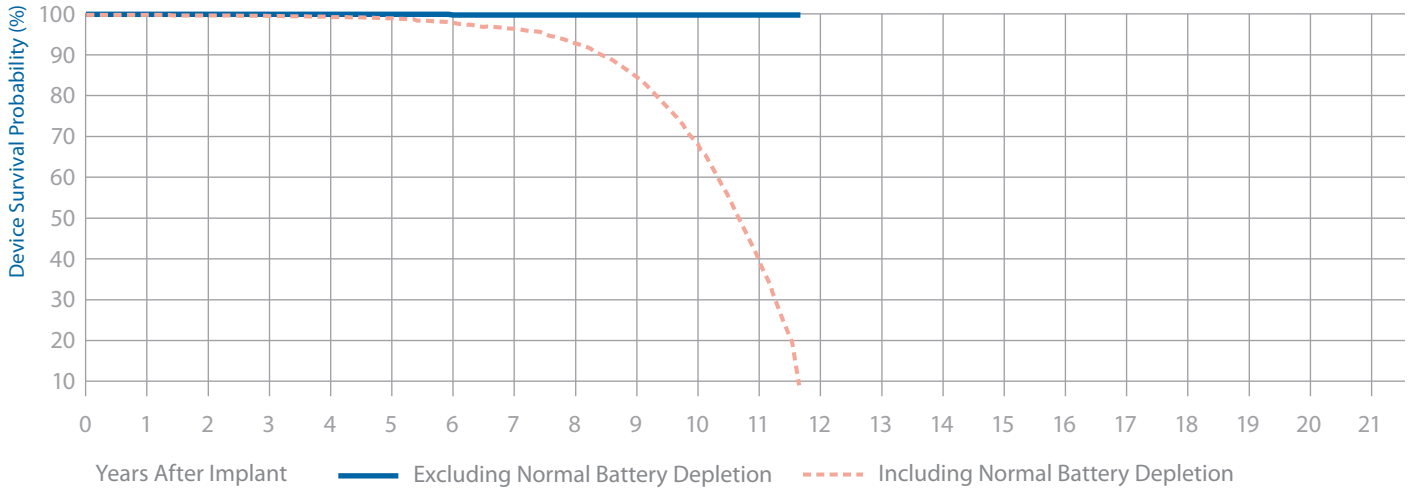
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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

US Market Release	Oct-95	Malfunctions (US)	50	NBG Code	DDD/RO
Registered US Implants	122,000			Serial Number Prefix	PDB, PDC, PDD
Estimated Active US Implants	2,000				
Normal Battery Depletions (US)	12,146			Estimated Longevity	See page 74
Advisories	None				

Product Characteristics



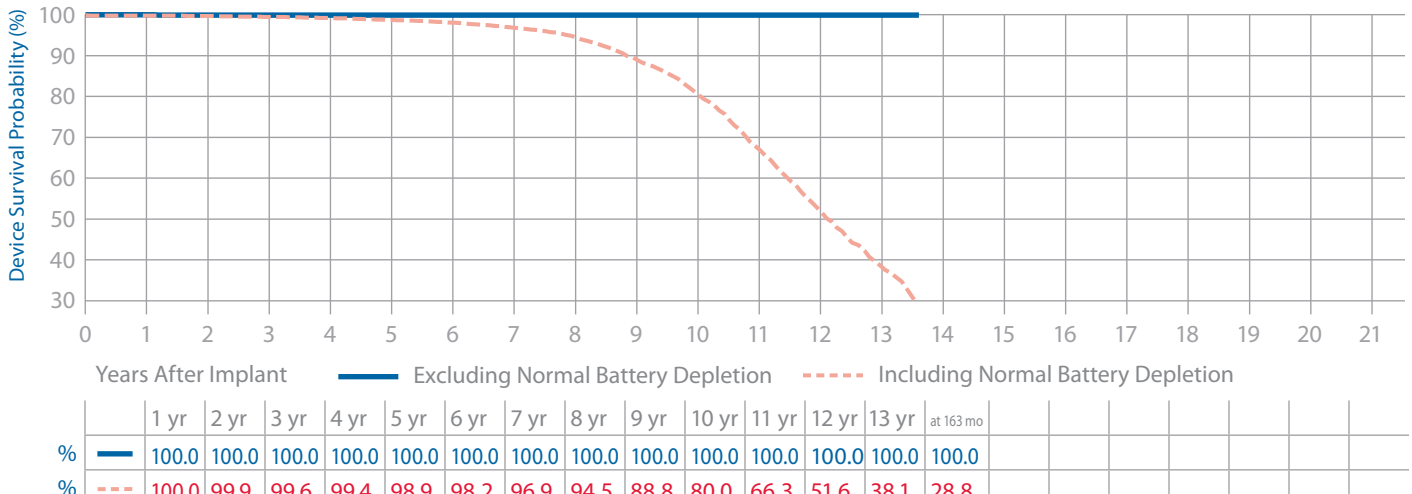
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 140 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.9	99.7	99.4	99.0	98.1	96.6	92.8	84.7	68.4	40.1	9.3
#	109,000	99,000	89,000	80,000	71,000	63,000	54,000	44,000	33,000	20,000	7,000	1,000

Effective Sample Size

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

US Market Release	Oct-95	Malfunctions (US)	7	NBG Code	SSIR
Registered US Implants	50,000			Serial Number Prefix	PDU, PDV, PDW
Estimated Active US Implants	3,000				
Normal Battery Depletions (US)	2,461			Estimated Longevity	See page 74
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	at 163 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	99.9	99.6	99.4	98.9	98.2	96.9	94.5	88.8	80.0	66.3	51.6	38.1	28.8
#	42,000	37,000	32,000	27,000	23,000	20,000	17,000	14,000	11,000	8,000	4,000	2,000	1,000	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

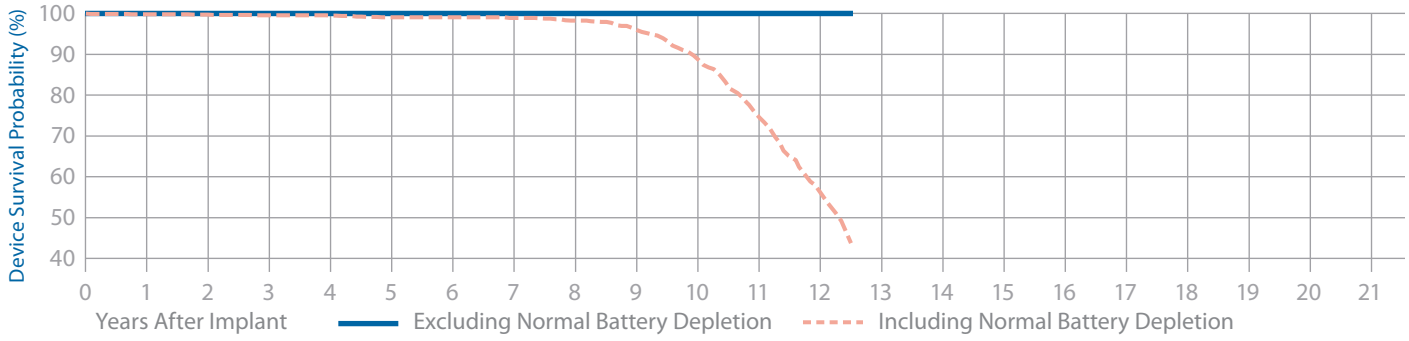
Thera-i VDD 8968i

US Market Release	Mar-96
Registered US Implants	5,000
Estimated Active US Implants	500
Normal Battery Depletions (US)	254
Advisories	None

Malfunctions (US)	0

Product Characteristics

NBG Code	VDD
Serial Number Prefix	PEC
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	at 150 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	99.8	99.6	99.5	99.1	99.0	98.9	98.1	95.8	88.9	74.6	55.9	44.8
#	4,000	4,000	3,000	3,000	3,000	2,000	2,000	2,000	2,000	1,000	1,000	200	100

Effective Sample Size

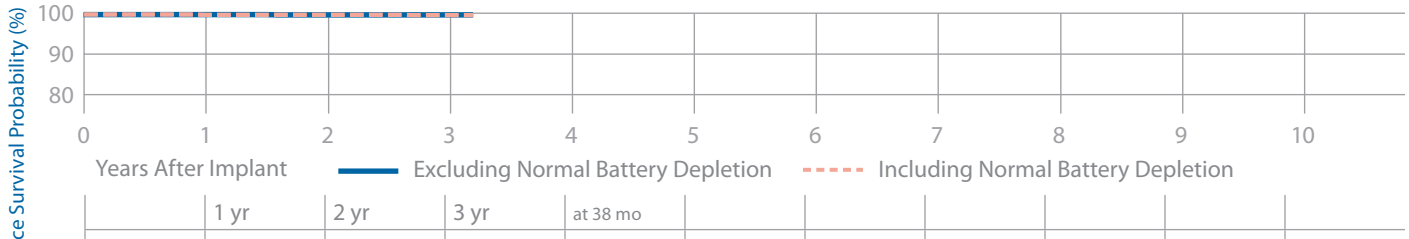
Versa DR VEDR01

US Market Release	Jul-06
Registered US Implants	55,000
Estimated Active US Implants	46,000
Normal Battery Depletions (US)	7
Advisories	None

Malfunctions (US)	4
Therapy Function Not Compromised	3
Electrical Component	3
Therapy Function Compromised	1
Electrical Component	1

Product Characteristics

NBG Code	DDDR
Serial Number Prefix	PWH, NWH
Estimated Longevity	See page 74



	1 yr	2 yr	3 yr	at 38 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	99.8	99.8
#	35,000	17,000	2,000	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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 (US)	Malfunctions (US): 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
Adapta DR	ADDR01, ADDR03, ADDR06,	Jul-06	174,000	149,000	10	6	+	13	=	19	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 39 mo								
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1 at 39 mo								
Adapta DR	ADDRL1	Jul-06	21,000	18,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0									
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0									
Adapta DR	ADDRS1	Jul-06	16,000	14,000	6	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 37 mo								
											Including Normal Battery Depletion	100.0 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 at 37 mo								
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	33,000	26,000	8	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 38 mo								
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.8 +.1/-.2	99.8 +.1/-.2 at 38 mo								
Adapta VDD	ADVDD01	Jul-06	1,000	1,000	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 27 mo									
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 27 mo									
AT500	AT501, 7253	Mar-03	11,000	2,000	1,209	5	+	5	=	10	Excluding Normal Battery Depletion	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	99.9 +.1/-.1	99.9 +.1/-.1	99.9 +.1/-.1	99.9 +.1/-.1 at 74 mo					
	See page 150 – Performance note on AT500 Pacing System Follow-Up Protocol										Including Normal Battery Depletion	99.9 +.0/-.1	99.9 +.1/-.1	99.5 +.1/-.2	97.5 +.3/-.4	82.8 +.9/-1.0	41.6 +2.0/-2.0	28.7 +2.5/-2.5 at 74 mo					
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	7,000	4,000	54	0	+	1	=	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 70 mo						
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.1/-.1	99.1 +.2/-.3	98.5 +.3/-.4	97.0 +.5/-.7 at 70 mo						
EnPulse DR	E1DR21	Dec-03	2,000	1,000	105	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 69 mo						
											Including Normal Battery Depletion	100.0 +.0/-.0	99.7 +.2/-.5	99.0 +.4/-.7	96.9 +.8/-1.1	93.3 +1.3/-1.6	64.1 +5.1/-5.6 at 69 mo						

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)						Device Survival Probability (%)											
						Therapy Function Compromised		Therapy Function Not Compromised		Total		Years After Implant											
												1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	101,000	62,000	216	3	+	14	=	17	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 68 mo						
											Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.6 +.1/-.1	98.9 +.1/-.1	98.3 +.2/-.3 at 68 mo						
EnPulse 2 DR	E2DR21	Feb-04	12,000	7,000	155	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 65 mo						
											Including Normal Battery Depletion	99.9 +.0/-.1	99.7 +.1/-.1	99.3 +.2/-.2	97.9 +.3/-.4	93.0 +.9/-1.0	84.6 +2.7/-3.2 at 65 mo						
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	1,000	400	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 53 mo							
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 53 mo							
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,000	13,000	104	1	+	3	=	4	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 69 mo						
											Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.5 +.1/-.1	98.9 +.2/-.2	97.9 +.3/-.4	95.8 +.8/-1.0 at 69 mo						
EnPulse 2 VDD	E2VDD01	Dec-03	1,000	400	3	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 56 mo							
											Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.3 +.5/-2.0	99.3 +.5/-2.0 at 56 mo							
EnRhythm DR	P1501DR	May-05	90,000	68,000	20	27	+	18	=	45	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1 at 55 mo							
	Advisories: See page 137 – 2010 Low Battery Voltage Displayed at Device Interrogation										Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.7 +.1/-.1	99.6 +.1/-.1 at 55 mo							
	See page 146 – Performance note on anomalies in MOSFET Integrated Circuit Technology																						
Kappa 400 DR	KDR401, KDR403	Jan-98	47,000	3,000	6,262	9	+	13	=	22	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 at 101 mo			
											Including Normal Battery Depletion	99.9 +.0/-.0	99.9 +.0/-.0	99.7 +.0/-.1	99.6 +.1/-.1	99.0 +.1/-.1	97.1 +.2/-.2	86.7 +.5/-.5	49.6 +.9/-.9	10.4 +1.0/-1.0 at 101 mo			
Kappa 400 SR	KSR401, KSR403	Feb-98	15,000	2,000	1,100	1	+	4	=	5	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 111 mo			
											Including Normal Battery Depletion	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.3 +.1/-.2	98.9 +.2/-.2	97.4 +.3/-.4	91.5 +.7/-.8	67.3 +1.5/-1.6	15.1 +2.3/-2.1 at 111 mo			

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions (US)	Malfunctions (US)					Device Survival Probability (%)											
						Therapy Function Compromised		Therapy Function Not Compromised		Total	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 600 DR	KDR601, KDR603, KDR606	Jan-99	24,000	100	3,260	34	+	3	=	37	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.7 +.1/-.1	99.6 +.1/-.2 at 107 mo			
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(31) (advisory-related subset)	+	(0)	=	(31)	Including Normal Battery Depletion	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.5 +.1/-.1	98.8 +.2/-.2	96.8 +.3/-.3	87.8 +.6/-.6	57.6 +1.1/-1.1	3.7 +.9/-.8 at 107 mo			
Kappa 600 DR	KDR651, KDR653	Mar-01	14,000	2,000	1,439	29	+	2	=	31	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	99.9 +.0/-.1	99.7 +.1/-.2	99.3 +.2/-.4	99.2 +.3/-.4 at 98 mo			
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(21) (advisory-related subset)	+	(0)	=	(21)	Including Normal Battery Depletion	100.0 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.4 +.1/-.2	98.2 +.3/-.3	94.8 +.5/-.5	80.7 +.9/-1.0	34.3 +1.9/-1.9	14.9 +2.6/-2.4 at 98 mo			
Kappa 700 D	KD701, KD703, KD706	Jan-99	300	50	17	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 89 mo				
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(0) (advisory-related subset)	+	(0)	=	(0)	Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.0 +.8/-3.1	97.8 +1.4/-3.5	95.3 +2.3/-4.5	93.9 +2.8/-4.9	92.1 +3.4/-5.7 at 89 mo				
Kappa 700 DR	KDR701, KDR703, KDR706	Feb-99	192,000	33,000	20,148	413	+	28	=	441	Excluding Normal Battery Depletion	100.0 +.0/-0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-0	99.8 +.0/-.0	99.7 +.0/-.0	99.5 +.1/-.1	99.3 +.1/-.1 at 104 mo			
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(320) (advisory-related subset)	+	(0)	=	(320)	Including Normal Battery Depletion	99.9 +./-.0	99.8 +./-.0	99.6 +./-.0	99.2 +./-.0	98.1 +.1/-.1	95.2 +.1/-.1	84.1 +.3/-.3	50.7 +.5/-.5	5.5 +.5/-.4 at 104 mo			
Kappa 700 DR	KDR721	Feb-99	10,000	1	1,294	4	+	1	=	5	Excluding Normal Battery Depletion	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1 at 86 mo				
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(4) (advisory-related subset)	+	(0)	=	(4)	Including Normal Battery Depletion	99.9 +.0/-.1	99.6 +.1/-.2	98.8 +.2/-.3	96.7 +.4/-.5	91.0 +.7/-.8	68.7 +1.4/-1.5	22.5 +2.0/-2.0	12.2 +2.0/-1.9 at 86 mo				
Kappa 700 SR	KSR701, KSR703, KSR706	Feb-99	55,000	8,000	3,362	22	+	3	=	25	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/0.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.1	99.8 +.1/-.1	99.8 +.1/-.1 at 112 mo			
	Advisories: See also page 139 – 2009 Potential Separation of Interconnect Wires					(0)	+	(0)	=	(0)	Including Normal Battery Depletion	99.9 +.0/-0.0	99.8 +.0/-0.0	99.4 +.1/-0.1	98.7 +.1/-0.1	97.2 +.2/-0.2	93.8 +.3/-0.3	84.3 +.6/-0.6	59.3 +1.0/-1.0	10.6 +1.6/-1.5 at 112 mo			
Kappa 700 VDD	KVDD701	Jan-99	2,000	100	164	4	+	0	=	4	Excluding Normal Battery Depletion	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.8 +.1/-.5	99.8 +.1/-.5	99.6 +.2/-.7	99.6 +.2/-.7	99.6 +.2/-.7 at 94 mo				
	Advisories: See page 144 – 2002 Potential Fractured Power Supply Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(4)	+	(0)	=	(4)	Including Normal Battery Depletion	99.7 +.2/-.4	99.7 +.2/-.4	99.4 +.3/-.6	98.9 +.5/-.8	98.5 +.6/-.9	94.1 +1.3/-1.7	70.1 +3.3/-3.7	40.7 +4.8/-4.9 at 94 mo				

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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 800 DR	KDR801, KDR803	Jan-02	4,000	2,000	131	3 +	0 =	3	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.3	99.8 +.1/-.5	99.8 +.1/-.5 at 87 mo				
									Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.1/-.2	99.8 +.1/-.2	99.6 +.2/-.3	98.6 +.4/-.5	96.4 +.7/-.8	79.1 +2.7/-3.0	67.6 +4.7/-5.3 at 87 mo				
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,000	58,000	2,973	41 +	13 =	54	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1 at 94 mo				
									Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.4 +.0/-.1	98.5 +.1/-.1	96.0 +.2/-.2	84.0 +.5/-.5	43.9 +4.1/-4.2 at 94 mo				
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	14,000	613	5 +	8 =	13	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.1	99.9 +.1/-.1	99.9 +.1/-.1 at 92 mo				
	See page 139 – 2009 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	98.9 +.1/-.2	97.4 +.2/-.3	94.8 +.4/-.4	84.3 +1.1/-1.1	60.8 +3.6/-3.8 at 92 mo				
Kappa 900 VDD	KVDD901	Jan-02	1,000	100	47	0 +	0 =	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 78 mo					
	See page 139 – 2009 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.0 +.6/-1.7	97.8 +1.1/-2.1	90.9 +2.9/-4.1	74.0 +5.9/-7.2 at 78 mo					
Kappa 920 DR	KDR921	Jan-02	16,000	3,000	1,697	3 +	0 =	3	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 81 mo					
	See page 139 – 2009 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	99.9 +.0/-.1	99.7 +.1/-.1	99.2 +.1/-.2	97.2 +.3/-.3	90.3 +.6/-.7	59.6 +1.3/-1.4	17.0 +2.1/-2.0 at 81 mo					
Legend II	8424, 8426, 8427	Nov-91	58,000	3,000	2,369	—	—	34	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 at 211 mo
									Including Normal Battery Depletion	99.9 +.0/-.0	99.7 +.0/-.0	99.5 +.1/-.1	99.1 +.1/-.1	98.7 +.1/-.1	98.0 +.1/-.2	97.1 +.2/-.2	94.7 +.3/-.3	88.9 +.4/-.4	82.5 +.6/-.6	71.5 +.8/-.9	52.2 +1.8/-1.8 at 211 mo
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Dec-89	58,000	3,000	1,643	—	—	49	Excluding Normal Battery Depletio	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 at 244 mo
	Advisories: See page 145 – 1991 Potential Delayed Restoration of Permanent Settings					—	—	—	Including Normal Battery Depletion	99.9 +.0/-.0	99.7 +.0/-.1	99.5 +.1/-.1	99.2 +.1/-.1	98.7 +.1/-.1	97.6 +.2/-.2	95.3 +.3/-.3	92.1 +.4/-.4	87.5 +.5/-.5	84.1 +.6/-.6	80.8 +.7/-.7	70.1 +1.6/-1.7 at 244 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
Minuet	7107, 7108	Mar-92	17,000	1,000	852	—	—	4	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 205 mo
									Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.8 +.1/-.1	99.5 +.1/-.1	98.9 +.2/-.2	98.2 +.2/-.3	97.0 +.3/-.4	94.8 +.5/-.5	89.3 +.7/-.8	82.1 +1.0/-1.1	68.1 +1.5/-1.6	44.1 +3.1/-3.1 at 205 mo
Preva DR	7088, 7089	Jul-96	26,000	2,000	2,358	—	—	4	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 146 mo	
									Including Normal Battery Depletion	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	99.3 +.1/-.1	98.8 +.2/-.2	97.8 +.2/-.2	96.2 +.3/-.3	92.4 +.5/-.5	67.1 +1.0/-1.1	16.8 +1.6/-1.5	13.5 +1.7/-1.6 at 146 mo	
Preva SR	8088, 8089	Jul-96	18,000	1,000	878	—	—	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1	100.0 +.0/-.1 at 151 mo	
									Including Normal Battery Depletion	99.9 +.0/-.1	99.8 +.1/-.1	99.4 +.1/-.1	99.1 +.2/-.2	98.3 +.2/-.3	97.3 +.3/-.4	95.0 +.5/-.5	92.3 +.6/-.7	75.7 +1.3/-1.4	43.5 +2.4/-2.4	33.6 +3.3/-3.3 at 151 mo	
Prevail S	8085, 8086	Oct-95	4,000	400	44	—	—	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4	99.9 +.1/-.4 at 153 mo	
									Including Normal Battery Depletion	99.8 +.1/-.2	99.8 +.1/-.2	99.7 +.1/-.3	99.7 +.1/-.3	99.1 +.4/-.6	98.9 +.4/-.7	98.1 +.6/-.9	97.2 +.8/-1.2	93.6 +1.5/-1.9	89.6 +2.0/-2.5	88.0 +2.5/-3.0 at 153 mo	
Prodigy DR	7860, 7861, 7862	Oct-95	38,000	2,000	3,261	—	—	11	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 143 mo		
									Including Normal Battery Depletion	99.9 +.0/-.0	99.8 +.0/-.0	99.7 +.1/-.1	99.4 +.1/-.1	98.8 +.1/-.1	97.9 +.2/-.2	96.3 +.3/-.3	92.4 +.4/-.4	68.3 +.9/-.9	12.3 +1.6/-1.5 at 143 mo		

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,000	2,000	1,067	—	—	4	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 153 mo	
									Including Normal Battery Depletion	99.8 +.1/-.1	99.6 +.1/-.1	99.2 +.1/-.1	98.6 +.2/-.2	97.8 +.2/-.3	96.7 +.3/-.4	95.0 +.4/-.5	91.8 +.6/-.6	74.3 +1.2/-1.3	46.4 +2.2/-2.2	34.6 +3.1/-3.1 at 153 mo	
Sensia DR	SEDR01, SED01	Jul-06	65,000	55,000	7	2	3	5	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 38 mo								
									Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.7 +.1/-.2	99.7 +.1/-.2 at 38 mo								
Sensia SR	SESR01, SES01	Jul-06	41,000	32,000	5	0	1	1	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 38 mo								
									Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.9 +.0/-.1 at 38 mo								
Sigma 100 S	SS103, SS106	Aug-99	1,000	100	13	0	0	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 94 mo				
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires					(0) (advisory-related subset)	(0)	(0)	Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.6 +.3/-1.3	99.6 +.3/-1.3	98.7 +.8/-2.2	98.7 +.8/-2.2	96.5 +1.8/-3.7	93.1 +3.1/-5.5 at 94 mo				
Sigma 200 DR	SDR203	Aug-99	16,000	5,000	223	22	2	24	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.2	99.6 +.1/-.2	99.6 +.1/-.2 at 118 mo			
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(2) (advisory-related subset)	(0)	(2)	Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.1	99.9 +.0/-.1	99.8 +.1/-.1	99.5 +.1/-.2	99.0 +.2/-.2	97.4 +.4/-.4	93.9 +.7/-.7	77.4 +3.1/-3.4 at 118 mo			
Sigma 200 SR	SSR203	Sep-99	12,000	3,000	111	10	0	10	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.1	99.9 +.0/-.1	99.9 +.1/-.2	99.8 +.1/-.2	99.8 +.1/-.2	99.8 +.1/-.2 at 118 mo			
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(3) (advisory-related subset)	(0)	(3)	Including Normal Battery Depletion	99.9 +.0/-.1	99.9 +.1/-.1	99.8 +.1/-.1	99.7 +.1/-.2	99.2 +.2/-.3	98.6 +.3/-.4	97.0 +.5/-.6	94.8 +.8/-.9	85.2 +2.6/-3.1 at 118 mo			
Sigma 300 DR	SDR303, SDR306	Aug-99	107,000	46,000	804	158	7	165	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.7 +.0/-.1	99.5 +.1/-.1	99.5 +.1/-.1	99.5 +.1/-.1 at 121 mo		
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(30) (advisory-related subset)	(0)	(30)	Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.0	99.7 +.0/-.0	99.4 +.1/-.1	98.9 +.1/-.1	97.9 +.1/-.2	95.0 +.3/-.3	80.0 +2.1/-2.3	80.0 +2.1/-2.3 at 121 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
Sigma 300 SR	SSR303, SSR306	Sep-99	54,000	17,000	352	25	+ 1	= 26	Excluding Normal Battery Depletio	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.1/-.1	99.8 +.1/-.1	99.8 +.1/-.1 at 119 mo			
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires; See also page 139 – 2009 Potential Separation of Interconnect Wires					(6)	+ (0)	= 6 (advisory-related subset)	Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.8 +.0/-.1	99.6 +.1/-.1	99.2 +.1/-.1	98.6 +.2/-.2	97.4 +.3/-.3	94.6 +.5/-.5	81.3 +2.2/-2.5 at 119 mo			
Sigma 300 VDD	SVDD303	Sep-99	1,000	200	21	0	+ 0	= 0	Excluding Normal Battery Depletio	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 95 mo				
	Advisories: See page 142 – 2005 Potential Separation of Interconnect Wires								Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.4 +.4/-1.7	98.8 +.7/-2.0	94.1 +2.4/-4.0	88.7 +3.9/-5.7 at 95 mo				
Thera-i DR	7960i, 7961i, 7962i	Oct-95	122,000	2,000	12,146	—	—	50	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0	99.9 +.0/-.0 at 140 mo		
									Including Normal Battery Depletion	99.9 +.0/-.0	99.9 +.0/-.0	99.7 +.0/-.0	99.4 +.0/-.1	99.0 +.1/-.1	98.1 +.1/-.1	96.6 +.1/-.1	92.8 +.2/-.2	68.4 +.5/-.5	9.3 +.8/-.7 at 140 mo		
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	3,000	2,461	—	—	7	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 163 mo	
									Including Normal Battery Depletion	100.0 +.0/-.0	99.9 +.0/-.0	99.6 +.1/-.1	99.4 +.1/-.1	98.9 +.1/-.1	98.2 +.2/-.2	96.9 +.2/-.2	94.5 +.3/-.3	80.0 +.7/-.7	51.6 +1.2/-1.2	28.8 +2.5/-2.5 at 163 mo	
Thera-i VDD	8968i	Mar-96	5,000	500	254	—	—	0	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 150 mo	
									Including Normal Battery Depletion	99.9 +.1/-.1	99.8 +.1/-.2	99.6 +.2/-.3	99.5 +.2/-.3	99.1 +.3/-.4	99.0 +.3/-.4	98.9 +.3/-.4	98.1 +.5/-.6	88.9 +1.4/-1.6	55.9 +3.5/-3.7	44.8 at+4.5/-4.6 at 150 mo	
Versa DR	VEDR01	Jul-06	55,000	46,000	7	1	+ 3	= 4	Excluding Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0	100.0 +.0/-.0 at 38 mo								
									Including Normal Battery Depletion	100.0 +.0/-.0	100.0 +.0/-.0	99.8 +.1/-.2	99.8 +.1/-.2 at 38 mo								

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.**

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

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

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Reference Chart continued

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

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

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω	Elective Replacement Indicators
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 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 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-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 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).

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Method for Estimating Lead Performance

Medtronic CRDM has tracked lead survival for over 27 years with its multicenter, global 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 that 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, non-randomized multicenter, global study designed to monitor the performance of market-released cardiac therapy products. Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study for 27 years and has evaluated the performance of more than 75,000 leads, with data reported from 14 countries on four continents.

The primary purpose of the SLS is to evaluate and publish the long-term reliability and performance of Medtronic market-released cardiac therapy products by analyzing product survival probabilities. Product-related adverse events, indicating the status of the product, are collected to measure survival probabilities. The data gathered in this study may also be used to support the design and development of investigational plans for new cardiac therapy products. The SLS is designed to continue indefinitely, encompassing new products as they become commercially available.

Eligible products for study enrollment include all Medtronic market-released cardiac therapy products. Medtronic may limit overall enrollment of any product when the number of enrollments provides an adequate number to effectively assess product survivability. Medtronic reserves the right to close enrollment of a product at a site level in order to ensure all participating sites have an equal opportunity to enroll.

To ensure a sufficiently large and representative source of data, participating clinical centers must meet specific selection criteria. In addition, centers are selected to be representative of the range of clinical environments in which Medtronic conducts business.

Investigators enroll qualified subjects with specific Medtronic market-released cardiac therapy products and follow these subjects from their implant date until they can no longer be followed (e.g., death and lost to follow-up). Using a Clinical Investigation Plan, each center monitors and reports on the performance of specific Medtronic market-released cardiac therapy products (e.g., product-related adverse events, replacements and abandonments) and subject status (e.g., subject death and subject withdrawal from the study). Subjects will be followed by their respective center in accordance with the center's established practices for routine follow-up.

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.

continued

Method for Estimating Lead Performance continued

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

The SLS protocol requires regular follow-up reporting on all leads actively followed in the study. The follow-up schedule for this study is based on utilizing routine, scheduled office/clinic visits and unscheduled office/clinic visits prompted by symptoms or complaints. Data collected at each follow-up includes routine clinical electrical data, any system modifications, and any lead or generator adverse events.

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 abandoned or explanted, the patient is no longer available for follow-up, or more than 24 months have passed since last follow-up. The data analyses assume that the patient is still part of the study and no lead complications had occurred as of the report cutoff date unless specifically reported by the center.

Medtronic evaluates center compliance with study protocol through clinical monitoring at each study site. Additionally, study center personnel must be trained in the study procedures prior to participating, and they must adhere to the policies and procedures of their local ethics boards.

Lead Complications

All adverse events are critically evaluated by a Medtronic technical review committee and the investigator is asked to assess the relationship of the adverse event to the presence or performance of the implanted system, generator and/or lead(s).

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 200-3,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20-200 ohms)
- Insulation breach, observed visually, that has degraded system performance
- Conductor fracture, observed visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

Clinical Actions

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

Note: Successful lead repositioning is not a qualifying action.

continued

Method for Estimating Lead Performance continued

Data Analysis 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.

Survival times are calculated from the implant date to the earlier of the complication date, out-of-service date (for example, subject leaves the study, the lead is no longer being used, or no data has been reported within a specified time interval), 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 in the tables in this report.

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 1-year intervals, the curves are actually computed and plotted using 3-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 one or more complications. This occurs because even with the complications, the data rounds to 100%.

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

continued

Method for Estimating Lead Performance continued

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

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, including data from 14 countries on four continents, 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 for at least 20 years as long as Medtronic estimates at least 500 leads remain active in the United States, based on estimated US implants.

Medtronic, at its discretion, may stop providing updated performance information on lead models that received original US market-release approval 20 or more years ago. These models may be removed from this report at that time.

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.

The results of the analysis is presented in four categories. The lead reporting categories are:

- Conductor Fracture: Conductor malfunction with complete or intermittent loss of continuity that could interrupt current flow (e.g., fractured conductors), including those associated with clavicle flex fatigue or crush damage.
- Insulation Breach: A malfunction of the insulation allowing inappropriate entry of body fluids or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, abrasions, and material degradation.
- Crimps/Welds/Bonds: Any malfunction in a conductor or lead body associated with a point of connection.
- Other: Malfunctions of specific lead mechanical attributes, such as sensors, connectors, seal rings, or malfunction modes not included in the three categories above.

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.

The numbers of malfunctions listed in the Returned Product Analysis tables are the actual numbers confirmed in the returned product analysis from the United States. The numbers of complications listed in the complications tables are the actual numbers observed in the SLS centers around the world.

US Reports of Acute Lead Observations (Occurring within First Month of Service)

In the first weeks following lead implantation, physiologic responses and lead performance can vary until long-term lead stability is attained. Acute (defined as the first month after implant) lead performance may be subject to a number of factors, including patient-specific anatomy,

continued

clinical conditions and/or varying implant conditions/techniques. After a period of time, the implant and the lead performance stabilizes. It is for this reason that the System Longevity Study results, which are intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

With this issue of the CRDM Product Performance Report, Medtronic is including information about the clinical experience in the first month of service. The source for this information is Medtronic's complaint handling system database. The information is summarized in tables titled "US Reports of Acute Lead Observations." To be included in this summary of observations, a lead must first be successfully implanted and registered in Medtronic's Device and Registrant Tracking system.

Each Event Report received by Medtronic's complaint handling system is assigned one or more Reason for Report codes based on the information received. The Reason for Report codes have been grouped into Acute Lead Observation categories. The categories used for this product performance report are drawn from the "FDA Guidance for Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adapter 510(k) Submissions." The categories are:

1. Cardiac Perforation
2. Conductor Fracture
3. Lead Dislodgement
4. Failure to Capture
5. Oversensing
6. Failure to Sense
7. Insulation Breach
8. Impedance Abnormal
9. Extracardiac Stimulation
10. Unspecified

Although multiple observations are possible for any given lead, only one observation is reported per lead. The observation reported is the observation highest on the list. For example, if an Event Report includes observations for both Lead Dislodgement and Failure to Sense, Lead Dislodgement is reported.

The lead event reported to Medtronic may or may not have involved clinical action or product returned to Medtronic. The lead may have remained implanted and in service.

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 the number of leads registered as implanted and the number remaining active in the United States based on the status recorded in the Medtronic Device and Registrant Tracking system.

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 LV

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEY
Registered US Implants	12,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Continuous Curve
Estimated Active US Implants	3,800	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	16

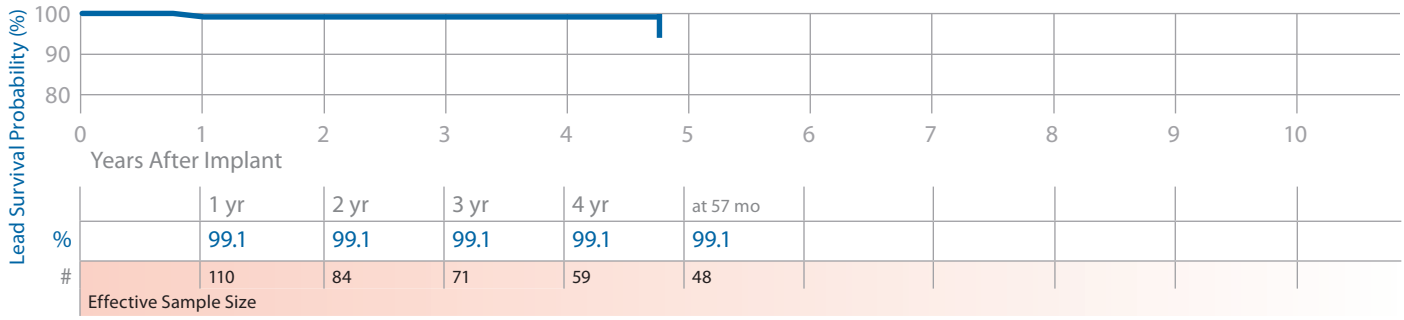
System Longevity Study Results

Number of Leads Enrolled in Study	134
Cumulative Months of Follow-Up	6,225
Number of Leads Active in Study	32

Qualifying Complications

1 Total

Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	99.1	99.1	99.1	99.1	99.1
#	110	84	71	59	48

Effective Sample Size

2188 Attain CS

Product Characteristics

US Market Release	Aug-01	Serial Number Prefix	LEB
Registered US Implants	1,800	Type and/or Fixation	Transvenous, Coronary Sinus/ Cardiac Vein, Canted
Estimated Active US Implants	400	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

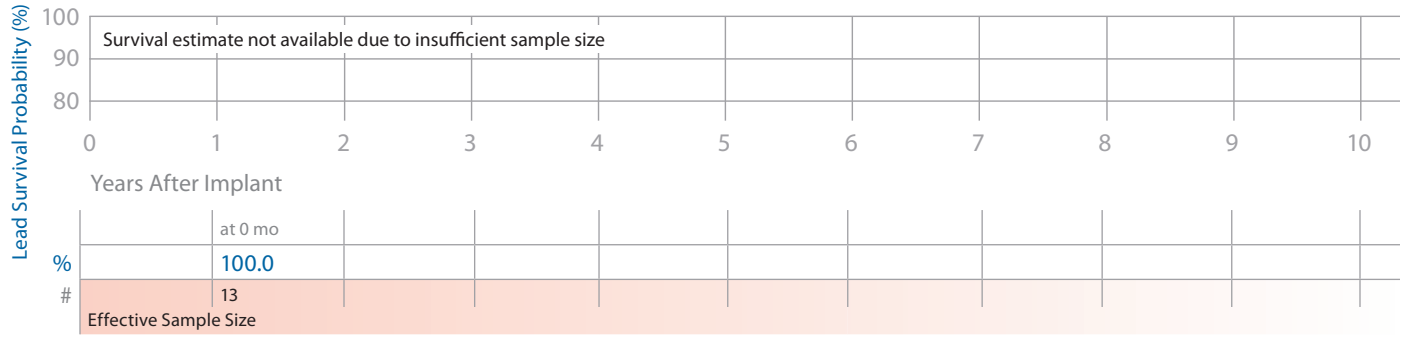
System Longevity Study Results

Number of Leads Enrolled in Study	15
Cumulative Months of Follow-Up	460
Number of Leads Active in Study	0

Qualifying Complications

1 Total

Extra Cardiac Stimulation	1



	at 0 mo
%	100.0
#	13

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Left-Heart Leads continued

4193 Attain OTW

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Registered US Implants	100,300	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	49,500	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

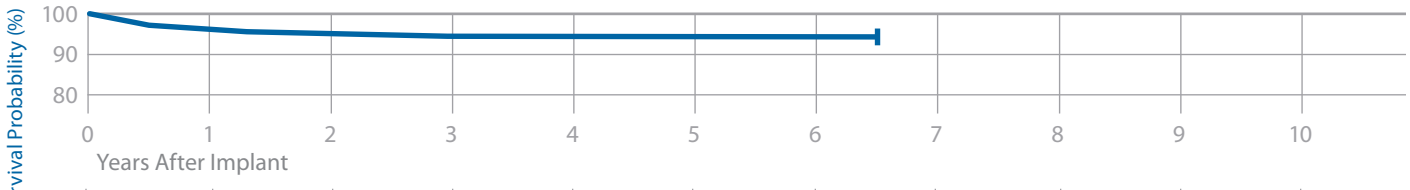
Conductor Fracture	21
Crimp/Weld/Bond	0
Insulation Breach	2
Other	71

System Longevity Study Results

Number of Leads Enrolled in Study	677
Cumulative Months of Follow-Up	26,842
Number of Leads Active in Study	218

Qualifying Complications 36 Total

Conductor Fracture	1	Lead Dislodgement	13
Extra Cardiac Stimulation	7	Unspecified Clinical Failure	3
Failure to Capture	12		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	95.9	95.0	94.2	94.2	94.2	94.2	94.2
#	549	429	345	245	159	80	47

Effective Sample Size

4194 Attain OTW

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Registered US Implants	86,500	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	62,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

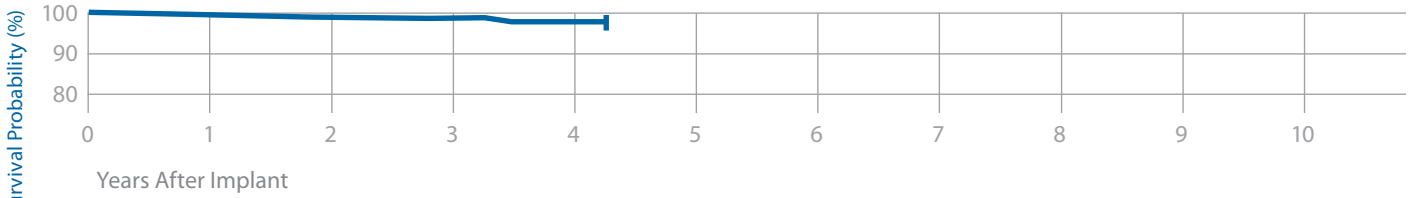
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	18
Other	12

System Longevity Study Results

Number of Leads Enrolled in Study	677
Cumulative Months of Follow-Up	26,842
Number of Leads Active in Study	218

Qualifying Complications 8 Total

Failure to Capture	1
Lead Dislodgement	6
Insulation (ESC)	1



	1 yr	2 yr	3 yr	4 yr	at 51 mo
%	99.4	98.6	98.6	97.9	97.9
#	479	300	179	66	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Left-Heart Leads continued

4195 Attain StarFix

Product Characteristics

US Market Release	Aug-08	Serial Number Prefix	AAD
Registered US Implants	6,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Deployable Lobe Fixation
Estimated Active US Implants	6,000	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	1
Other	16

System Longevity Study Results

Number of Leads Enrolled in Study	254
Cumulative Months of Follow-Up	3,088
Number of Leads Active in Study	233

Qualifying Complications 3 Total

Conductor Fracture	1
Extra Cardiac Stimulation	2

	1 yr	at 15 mo
%	99.6	99.6
#	58	47

Effective Sample Size

4196 Attain Ability

Product Characteristics

US Market Release	May-09	Serial Number Prefix	PVI
Registered US Implants	9,800	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Preformed Body, Double Curve
Estimated Active US Implants	9,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

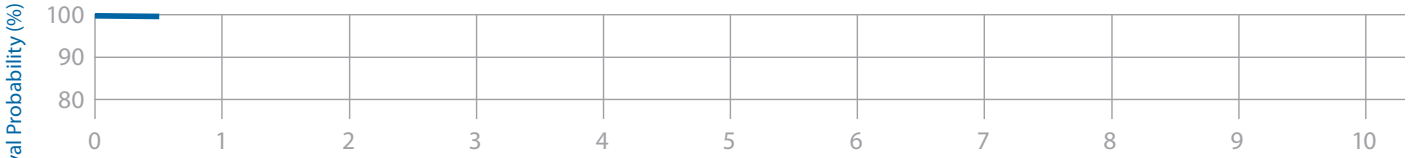
US Returned Product Analysis

Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	219
Cumulative Months of Follow-Up	1,331
Number of Leads Active in Study	211

Qualifying Complications 0 Total



	at 6 mo
%	100.0
#	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Left-Heart Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	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 LV	Aug-01	134	32	1	6,225	99.1 +.8/-5.1	99.1 +.8/-5.1	99.1 +.8/-5.1	99.1 +.8/-5.1	99.1 +.8/-5.1 at 57 mo					
2188	Attain CS	Aug-01	15	0	1	460	100.0 at 0 mo									
4193	Attain OTW	May-02	677	218	36	26,842	95.9 +1.3/-1.8	95.0 +1.4/-2.1	94.2 +1.7/-2.2	94.2 +1.7/-2.2	94.2 +1.7/-2.2	94.2 +1.7/-2.2	94.2 +1.7/-2.2 at 78 mo			
4194	Attain OTW	Aug-04	677	218	8	26,842	99.4 +.4/-1.1	98.6 +.8/-1.5	98.6 +.8/-1.5	97.9 +1.2/-2.6	97.9 +1.2/-2.6 at 51 mo					
4195	Attain StarFix	Aug-08	254	233	3	3,088	99.6 +.3/-2.6	99.6 +.3/-2.6 at 15 mo								
4196	Attain Ability	May-09	219	211	0	1,331	100.0 at 6 mo									

Source: System Longevity Study
Data as of January 31, 2010

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
2187	Attain LV	Aug-01	12,000	3,800	0	0	0	16
2188	Attain CS	Aug-01	1,800	400	1	0	0	0
4193	Attain OTW	May-02	100,300	49,500	21	0	2	71
4194	Attain OTW	Aug-04	86,500	62,300	3	0	18	12
4195	Attain StarFix	Aug-08	6,700	6,000	1	0	1	16
4196	Attain Ability	May-09	9,800	9,300	0	0	0	6

Source: Returned Product Analysis
Data as of January 31, 2010

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
2187	Attain LV	12,000	1	0	8	3	1	0	0	1	0
2188	Attain CS	1,800	0	0	2	0	0	0	0	0	0
4193	Attain OTW	100,300	0	1	49	13	0	0	1	17	0
4194	Attain OTW	86,500	0	1	38	13	0	0	1	9	3
4195	Attain StarFix	6,700	0	0	8	6	0	0	0	4	0
4196	Attain Ability	9,800	0	0	10	1	0	1	0	6	1

Report Cutoff Date: January 31, 2010

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Left-Heart Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
2187	Attain LV	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
2188	Attain CS	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 BI
4193	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
4194	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)/ Silicone (4719)	MP35N	Platinum Alloy	IS-1 BI
4195	Attain StarFix	Transvenous Cardiac Vein Deployable Lobes	Polyurethane (55D)	MP35N	Platinum Alloy	IS-1 Uni
4196	Attain Ability	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D), SI polyimide	Ag core – MP35N	Tapered, Annualar, Titanium nitride	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads

6721, 6921 Epicardial Patch

Product Characteristics

US Market Release	Feb-93	Serial Number Prefix	TBH, TBG, TBB, TAD, TAC, or TAB
Registered US Implants	8,400	Type and/or Fixation	Epicardial Defib Patch, Suture
Estimated Active US Implants	1,300	Polarity	Defib Electrode only
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	70
Crimp/Weld/Bond	1
Insulation Breach	10
Other	1

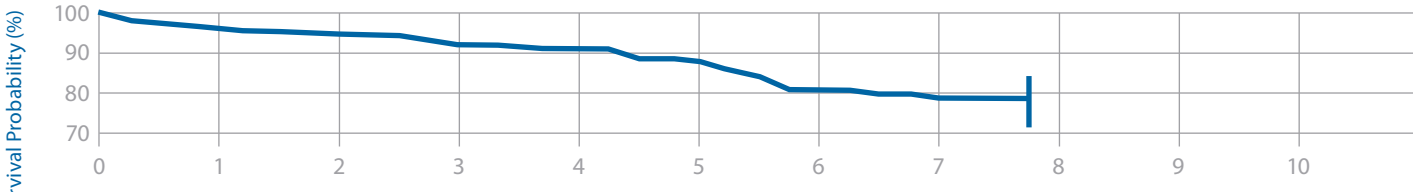
System Longevity Study Results

Number of Leads Enrolled in Study	407
Cumulative Months of Follow-Up	19,649
Number of Leads Active in Study	10

Qualifying Complications

52 Total

Conductor Fracture	21	Insulation (not further defined)	3
Failure to Capture	8	Oversensing	16
Impedance Out of Range	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	96.5	95.0	92.3	91.3	88.1	81.0	78.9	78.9
#	330	282	209	158	121	84	66	54

Effective Sample Size of Lead Group Overall

6930 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFK
Registered US Implants	400	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	200	Polarity	True Bipolar/One Coil
Advisories	1	Steroid	Yes

See page 141 – 2007 Potential Conductor Wire Fracture

US Returned Product Analysis

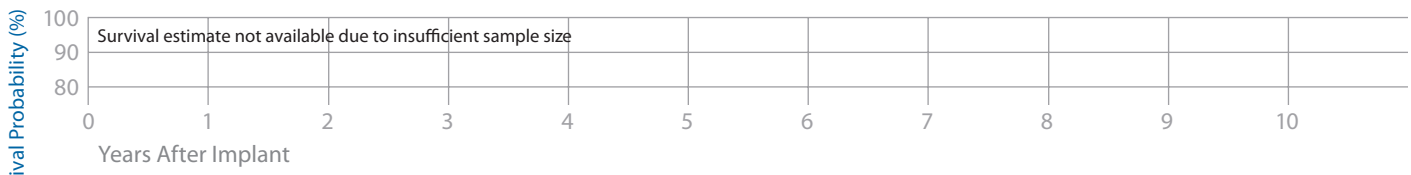
Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	131
Number of Leads Active in Study	4

Qualifying Complications

0 Total



	at 0 mo
%	100.0
#	4

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

6931 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFL
Registered US Implants	8,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	5,400	Polarity	True Bipolar/One Coil
Advisories	1	Steroid	Yes

See page 141 – 2007 Potential Conductor Wire Fracture

US Returned Product Analysis

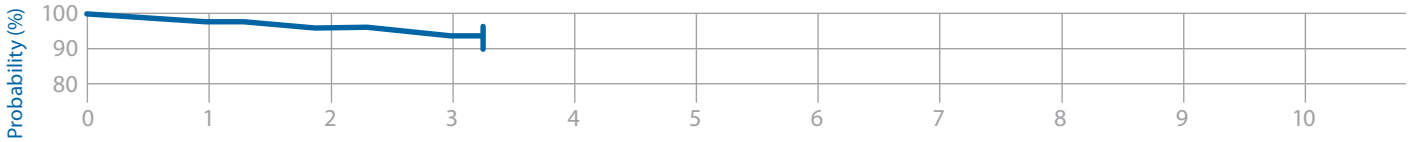
Conductor Fracture	267
Crimp/Weld/Bond	0
Insulation Breach	0
Other	2

System Longevity Study Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	9,168
Number of Leads Active in Study	208

Qualifying Complications 14 Total

Failure to Capture	3	Lead Dislodgement	2
Failure to Sense	1	Oversensing	3
Impedance Out of Range	2	Other	1
Conductor Fracture	2		



	1 yr	2 yr	3 yr	at 39 mo
%	98.2	96.2	93.9	93.9
#	260	223	96	52

Effective Sample Size

6932 Sprint

Product Characteristics

US Market Release	Aug-96	Serial Number Prefix	TCA
Registered US Implants	15,000	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	5,300	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

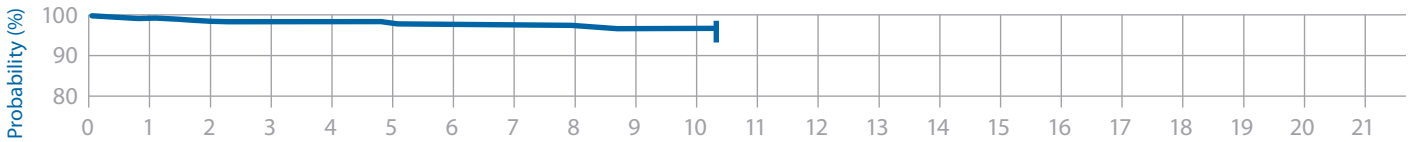
Conductor Fracture	19
Crimp/Weld/Bond	0
Insulation Breach	22
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	411
Cumulative Months of Follow-Up	23,445
Number of Leads Active in Study	67

Qualifying Complications 9 Total

Extra Cardiac Stimulation	1
Failure to Capture	2
Failure to Sense	2
Oversensing	4



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.2	98.3	98.3	98.3	97.7	97.7	97.7	96.8	96.8	96.8	96.8
#	355	277	230	191	152	125	105	90	77	51	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

6933, 6937, 6937A, 6963 SVC/CS

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAT, TBU, or TAF
Registered US Implants	15,900	Type and/or Fixation	Transvenous CS or SVC Defib
Estimated Active US Implants	2,600	Polarity	One Defib Coil
Advisories	None	Steroid	No

US Returned Product Analysis

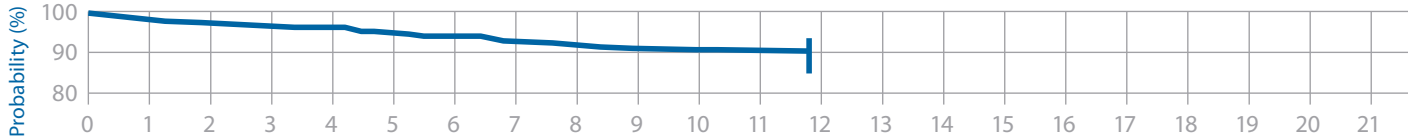
Conductor Fracture	166
Crimp/Weld/Bond	0
Insulation Breach	32
Other	16

System Longevity Study Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	49,623
Number of Leads Active in Study	31

Qualifying Complications 55 Total

Conductor Fracture	18	Lead Dislodgement	1
Extra Cardiac Stimulation	5	Insulation (not further defined)	2
Failure to Capture	8	Oversensing	12
Failure to Sense	1	Unspecified Clinical Failure	4
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	at 135 mo
%	98.4	97.5	97.2	96.6	95.0	94.4	93.2	92.7	91.3	90.2	90.2	90.2
#	809	629	501	403	315	249	179	139	95	71	54	49

Effective Sample Size

6935 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-08	Serial Number Prefix	TAU
Registered US Implants	7,100	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	6,900	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	9

System Longevity Study Results

Number of Leads Enrolled in Study	236
Cumulative Months of Follow-Up	1,608
Number of Leads Active in Study	229

Qualifying Complications 0 Total

	at 9 mo
%	100.0
#	40

Effective Sample Size

Leads

Defibrillation Leads continued

6936, 6966 Transvene

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TAV or TAL
Registered US Implants	23,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	2,900	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

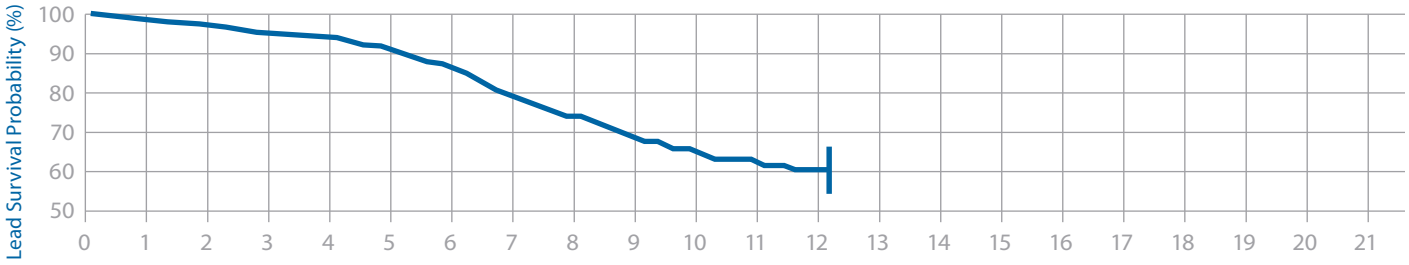
Conductor Fracture	177
Crimp/Weld/Bond	0
Insulation Breach	326
Other	20

System Longevity Study Results

Number of Leads Enrolled in Study	1,349
Cumulative Months of Follow-Up	69,969
Number of Leads Active in Study	36

Qualifying Complications 195 Total

Conductor Fracture	24	Impedance Out of Range	8
Extra Cardiac Stimulation	7	Insulation (not further defined)	13
Failure to Capture	18	Oversensing	115
Failure to Sense	5	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	12 yr	at 147 mo
%	98.2	97.0	95.1	94.1	90.4	85.8	78.1	73.8	67.8	63.8	61.6	60.7	59.5
#	1,140	906	734	580	458	359	248	188	132	99	73	54	50

Effective Sample Size

6939, 6999 Sub-Q Patch

Product Characteristics

US Market Release	Dec-93	Serial Number Prefix	TBA or TAP
Registered US Implants	3,600	Type and/or Fixation	Subcutaneous Defib Patch, Suture
Estimated Active US Implants	300	Polarity	Defib Electrode Only
Advisories	None	Steroid	No

US Returned Product Analysis

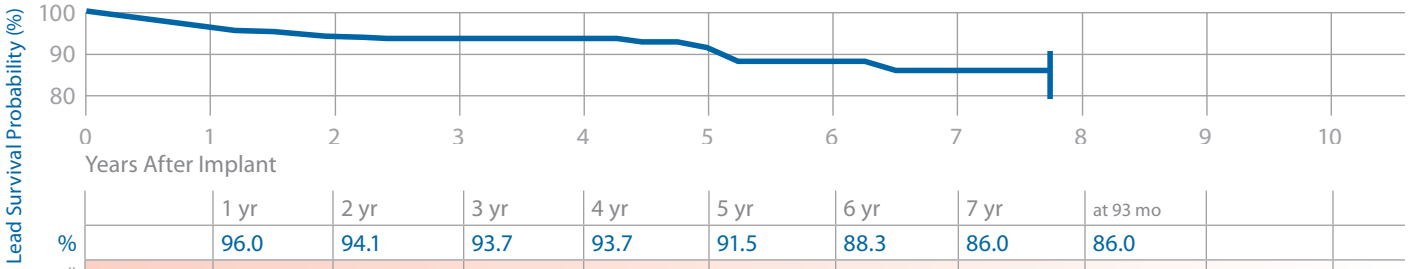
Conductor Fracture	28
Crimp/Weld/Bond	0
Insulation Breach	5
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	384
Cumulative Months of Follow-Up	18,121
Number of Leads Active in Study	4

Qualifying Complications 47 Total

Conductor Fracture	12	Impedance Out of Range	2
Extra Cardiac Stimulation	5	Insulation (not further defined)	4
Failure to Capture	11	Oversensing	10
Failure to Sense	1	Unspecified Clinical Failure	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	96.0	94.1	93.7	93.7	91.5	88.3	86.0	86.0
#	311	249	193	146	116	82	60	50

Effective Sample Size of Lead Group Overall

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

6942 Sprint

Product Characteristics

US Market Release	Jul-97	Serial Number Prefix	TCB
Registered US Implants	17,700	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	6,800	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp/Weld/Bond	1
Insulation Breach	21
Other	8

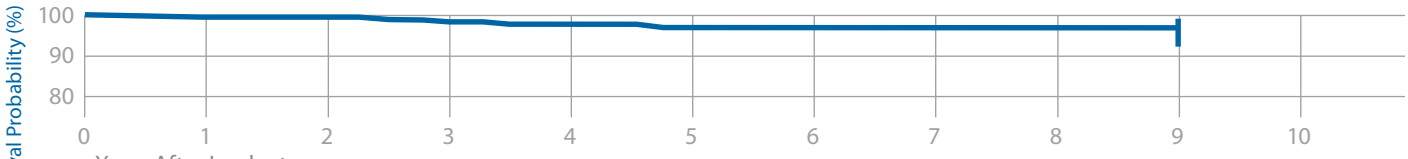
System Longevity Study Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	17,876
Number of Leads Active in Study	50

Qualifying Complications

7 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.1	99.1	98.1	97.5	96.7	96.7	96.7	96.7	96.7
#	294	227	176	134	112	97	75	66	52

Effective Sample Size

6943 Sprint

Product Characteristics

US Market Release	Oct-97	Serial Number Prefix	TCE
Registered US Implants	20,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	8,100	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	52
Crimp/Weld/Bond	1
Insulation Breach	22
Other	9

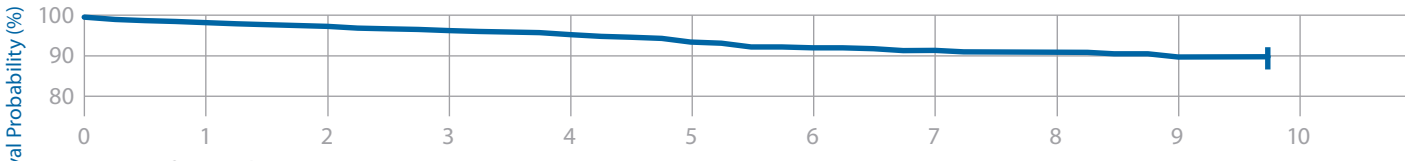
System Longevity Study Results

Number of Leads Enrolled in Study	1,311
Cumulative Months of Follow-Up	74,001
Number of Leads Active in Study	318

Qualifying Complications

83 Total

Conductor Fracture	18	Insulation (not further defined)	1
Failure to Capture	11	Lead Dislodgement	1
Failure to Sense	6	Oversensing	36
Impedance Out of Range	6	Unspecified Clinical Failure	3
		Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 117 mo
%	98.7	97.7	96.5	95.5	93.5	92.1	91.4	91.1	89.8	89.8
#	1,147	966	858	721	583	435	307	188	95	54

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Registered US Implants	34,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	20,400	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

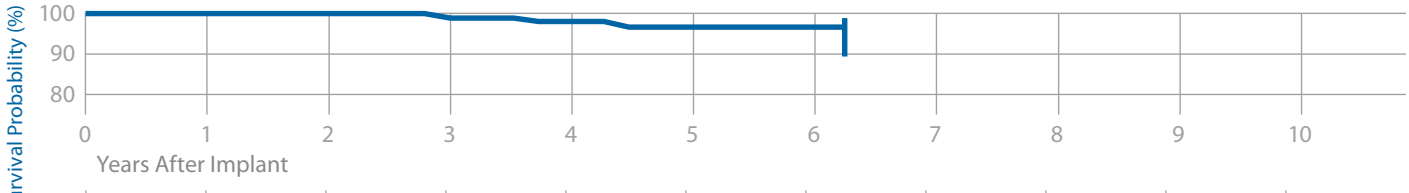
Conductor Fracture	44
Crimp/Weld/Bond	2
Insulation Breach	2
Other	9

System Longevity Study Results

Number of Leads Enrolled in Study	239
Cumulative Months of Follow-Up	9,387
Number of Leads Active in Study	117

Qualifying Complications 3 Total

Oversensing	2
Unspecified Clinical Failure	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	100.0	100.0	99.1	97.9	96.5	96.5	96.5
#	167	122	98	74	61	54	50

Effective Sample Size

6945 Sprint

Product Characteristics

US Market Release	Sep-97	Serial Number Prefix	TDA
Registered US Implants	42,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	16,600	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

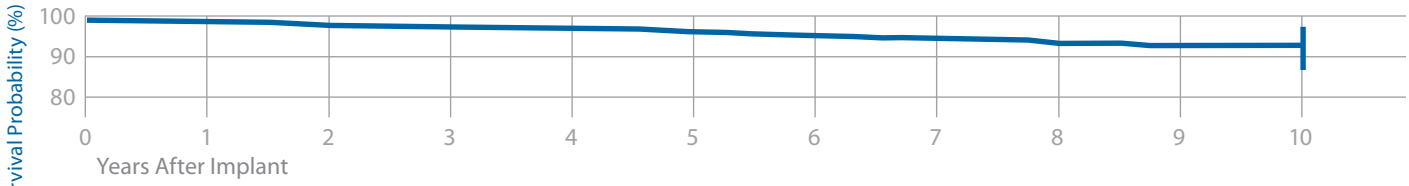
Conductor Fracture	100
Crimp/Weld/Bond	2
Insulation Breach	25
Other	14

System Longevity Study Results

Number of Leads Enrolled in Study	1,153
Cumulative Months of Follow-Up	61,419
Number of Leads Active in Study	181

Qualifying Complications 36 Total

Conductor Fracture	5	Impedance Out of Range	5
Extra Cardiac Stimulation	1	Oversensing	18
Failure to Capture	2	Unspecified Clinical Failure	1
Failure to Sense	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.4	98.7	98.3	97.7	96.8	95.8	95.2	94.0	93.4	93.4
#	995	801	657	533	429	347	286	202	113	45

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Registered US Implants	256,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	187,400	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

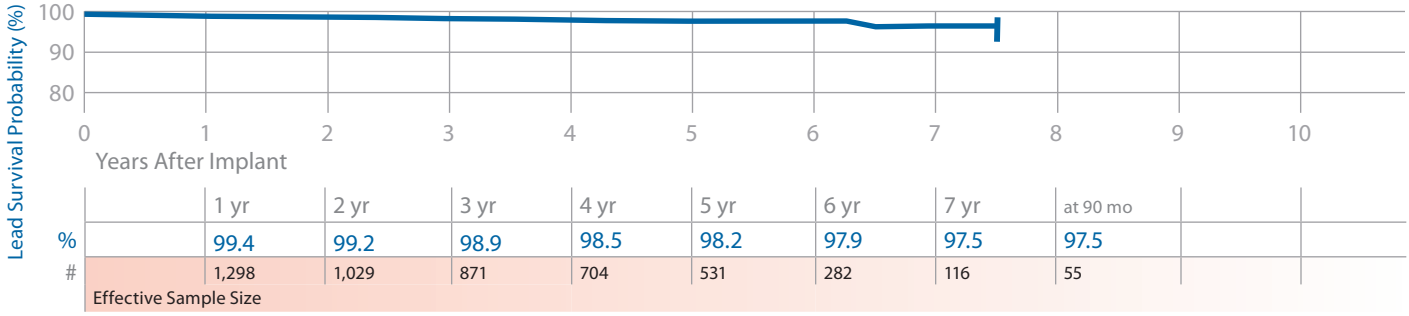
Conductor Fracture	139
Crimp/Weld/Bond	1
Insulation Breach	10
Other	91

System Longevity Study Results

Number of Leads Enrolled in Study	2,364
Cumulative Months of Follow-Up	74,555
Number of Leads Active in Study	1447

Qualifying Complications 27 Total

Conductor Fracture	3	Lead Dislodgement	3
Failure to Sense	2	Oversensing	8
Impedance Out of Range	7	Unspecified Clinical Failure	2
Insulation (not further defined)	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	99.4	99.2	98.9	98.5	98.2	97.9	97.5	97.5
#	1,298	1,029	871	704	531	282	116	55

Effective Sample Size

6948 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFH
Registered US Implants	10,400	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Tines
Estimated Active US Implants	7,100	Polarity	True Bipolar/Two Coils
Advisories	1	Steroid	Yes

See page 141 – 2007 Potential Conductor Wire Fracture

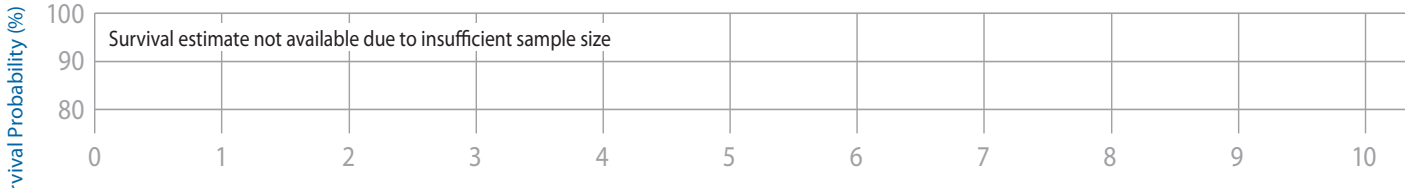
US Returned Product Analysis

Conductor Fracture	52
Crimp/Weld/Bond	0
Insulation Breach	0
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	30
Cumulative Months of Follow-Up	1,046
Number of Leads Active in Study	20

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	30

Effective Sample Size

Defibrillation Leads continued

6949 Sprint Fidelis

Product Characteristics

US Market Release	Sep-04	Serial Number Prefix	LFJ
Registered US Implants	186,800	Type and/or Fixation	Transvenous, Vent, Defib and Pace/Sense, Screw-in
Estimated Active US Implants	120,300	Polarity	True Bipolar/Two Coils
Advisories	1	Steroid	Yes

See page 141 – 2007 Potential Conductor Wire Fracture

US Returned Product Analysis

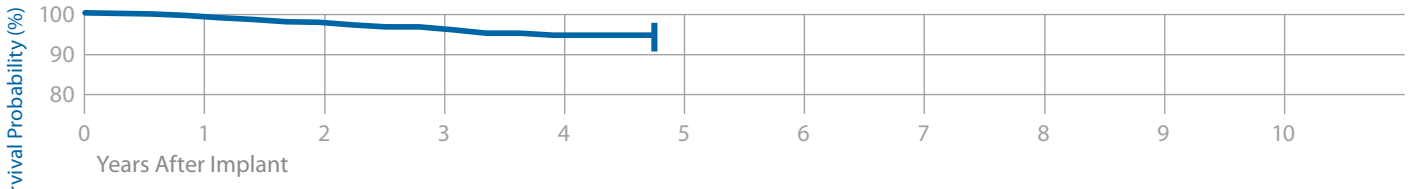
Conductor Fracture	3,109
Crimp/Weld/Bond	2
Insulation Breach	9
Other	54

System Longevity Study Results

Number of Leads Enrolled in Study	797
Cumulative Months of Follow-Up	28,466
Number of Leads Active in Study	508

Qualifying Complications 37 Total

Conductor Fracture	16	Insulation (not further defined)	1
Failure to Capture	2	Lead Dislodgement	1
Failure to Sense	2	Oversensing	10
Impedance Out of Range	5		



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	98.8	97.1	95.2	94.2	94.2
#	711	615	376	154	54

Effective Sample Size

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Registered US Implants	2,700	Type and/or Fixation	Subcutaneous Defib Coil, Suture
Estimated Active US Implants	1,700	Polarity	One Defib Coil
Advisories	None	Steroid	No

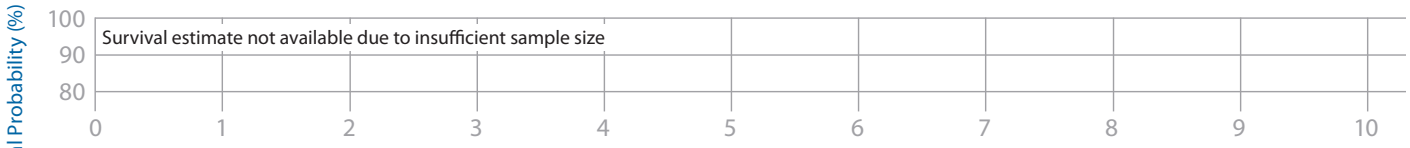
US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	21
Cumulative Months of Follow-Up	641
Number of Leads Active in Study	17

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	21

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	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
6721, 6921	Epicardial Patch	Feb-93	407	10	52	19,649	96.5 +1.5/-2.4	95.0 +1.8/-2.8	92.3 +2.5/-3.5	91.3 +2.7/-3.8	88.1 +3.6/-4.9	81.0 +5.1/-6.7	78.9 +5.6/-7.3	78.9 +5.6/-7.3 at 93 mo						
6930	Sprint Fidelis	Sep-04	4	4	0	107	100.0 at 0 mo													
	Advisories: See page 141 – 2007 Potential Conductor Wire Fracture																			
6931	Sprint Fidelis	Sep-04	294	208	14	9,168	98.2 +1.1/-2.5	96.2 +1.8/-3.1	93.9 +2.5/-4.1	93.9 +2.5/-4.1 at 39 mo											
	Advisories: See page 141 – 2007 Potential Conductor Wire Fracture																			
6932	Sprint	Aug-96	411	67	9	23,445	99.2 +.5/-1.7	98.3 +.9/-2.1	98.3 +.9/-2.1	98.3 +.9/-2.1	97.7 +1.3/-2.5	97.7 +1.3/-2.5	97.7 +1.3/-2.5	96.8 +1.7/-3.9	96.8 +1.7/-3.9	96.8 +1.7/-3.9 at 123 mo				
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	966	31	55	49,623	98.4 +.7/-1	97.5 +.9/-1.3	97.2 +.9/-1.4	96.6 +1.1/-1.6	95.0 +1.6/-2.1	94.4 +1.7/-2.3	93.2 +2/-2.8	92.7 +2.2/-3.1	90.2 +3.2/-4.7	90.2 +3.2/-4.7 at 135 mo				
6935	Sprint Quattro Secure	Nov-08	236	229	0	1,608	100.0 at 9 mo													
6936, 6966	Transvene	Dec-93	1,349	36	195	69,969	98.2 +.6/-1	97.0 +.8/-1.2	95.1 +1.2/-1.5	94.1 +1.3/-1.7	90.4 +1.9/-2.3	85.8 +2.5/-3	78.1 +3.5/-3.9	73.8 +3.9/-4.4	63.8 +5.1/-5.7	60.7 +5.6/-6.3	59.5 +6/-6.5 at 147 mo			
6939, 6999	Sub-Q Patch	Dec-93	384	4	47	18,121	96.0 +1.6/-2.7	94.1 +2/-3.2	93.7 +2.1/-3.3	93.7 +2.1/-3.3	91.5 +2.9/-4.4	88.3 +3.8/-5.5	86.0 +4.6/-6.5	86.0 +4.6/-6.5 at 93 mo						
6942	Sprint	Jul-97	351	50	7	17,876	99.1 +.6/-1.9	99.1 +.6/-1.9	98.1 +1.1/-2.8	97.5 +1.4/-3.2	96.7 +1.8/-3.9	96.7 +1.8/-3.9	96.7 +1.8/-3.9	96.7 +1.8/-3.9	96.7 +1.8/-3.9 at 108 mo					
6943	Sprint	Oct-97	1,311	318	83	74,001	98.7 +.5/-0.9	97.7 +.7/-1.1	96.5 +.9/-1.3	95.5 +1.1/-1.4	93.5 +1.5/-1.8	92.1 +1.7/-2	91.4 +1.8/-2.2	91.1 +1.9/-2.3	89.8 +2.4/-3.1 at 117 mo					
6944	Sprint Quattro	Dec-00	239	117	3	9,387	100.0	100.0	99.1 +.8/-5.6	97.9 +1.6/-6.1	96.5 +2.4/-7.2	96.5 +2.4/-7.2	96.5 +2.4/-7.2 at 75 mo							
6945	Sprint	Sep-97	1,153	181	36	61,419	99.4 +.4/-0.6	98.7 +.5/-1	98.3 +.6/-1.1	97.7 +.8/-1.3	96.8 +1.1/-1.6	95.8 +1.4/-1.9	95.2 +1.6/-2.1	94.0 +1.9/-2.7	93.4 +2.1/-3					
6947	Sprint Quattro Secure	Nov-01	2,364	1447	27	74,555	99.4 +.3/-0.4	99.2 +.3/-.6	98.9 +.4/-.7	98.5 +.6/-.9	98.2 +.7/-1.1	97.9 +.8/-1.2	97.5 +1/-1.6	97.5 +1/-1.6 at 90 mo						
6948	Sprint Fidelis	Sep-04	30	20	0	1,046	100 .0 at 0 mo													
	Advisories: See page 141 – 2007 Potential Conductor Wire Fracture																			
6949	Sprint Fidelis	Sep-04	797	508	37	28,466	98.8 +.6/-1.1	97.1 +1/-1.6	95.2 +1.4/-2	94.2 +1.7/-2.3	94.2 +1.7/-2.3 at 57 mo									
	Advisories: See page 141 – 2007 Potential Conductor Wire Fracture																			
6996	Sub-Q Lead	Jun-01	17	14	0	445	100.0 at 0 mo													

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Defibrillation Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
6721, 6921	Epicardial Patch	Feb-93	8,400	1,300	70	1	10	1
6930	Sprint Fidelis	Sep-04	400	200	2	0	0	0
6931	Sprint Fidelis	Sep-04	8,100	5,400	267	0	0	2
6932	Sprint	Aug-96	15,000	5,300	19	0	22	8
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	15,900	2,600	166	0	32	16
6935	Sprint Quattro Secure	Nov-08	7,100	6.900	0	0	0	9
6936, 6966	Transvene	Dec-93	23,700	2,900	177	0	326	20
6939, 6999	Sub-Q Patch	Dec-93	3,600	300	28	0	5	1
6942	Sprint	Jul-97	17,700	6,800	14	1	21	8
6943	Sprint	Oct-97	20,800	8,100	52	1	22	9
6944	Sprint Quattro	Dec-00	34,800	20,400	44	2	2	9
6945	Sprint	Sep-97	42,800	16,600	100	2	25	14
6947	Sprint Quattro Secure	Nov-01	256,800	187,400	139	1	10	91
6948	Sprint Fidelis	Sep-04	10,400	7,100	52	0	0	6
6949	Sprint Fidelis	Sep-04	186,800	120,300	3,109	2	9	54
6996	Sub-Q Lead	Jun-01	2,700	1,700	5	0	0	0

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
6721, 6921	Epicardial Patch	8,400	0	1	0	0	0	0	2	3	0	4
6931	Sprint Fidelis	8,100	1	2	1	1	3	1	0	0	0	1
6932	Sprint	15,000	0	0	3	2	0	2	0	1	0	0
6933, 6937, 6937A, 6963	SVC/CS	15,900	0	0	2	0	1	0	2	1	0	1
6935	Sprint Quattro Secure	7,100	1	1	1	1	0	0	0	2	0	0
6936, 6966	Transvene	23,700	7	2	1	6	4	5	1	1	0	4
6939, 6999	Sub-Q Patch	3,600	0	0	0	0	0	0	0	1	0	1
6942	Sprint	17,700	1	0	2	4	1	0	0	2	0	1
6943	Sprint	20,800	1	0	0	2	1	1	1	3	0	0
6944	Sprint Quattro	34,800	1	1	5	8	5	2	0	5	0	6
6945	Sprint	42,800	0	1	4	6	8	2	2	1	1	3
6947	Sprint Quattro Secure	256,800	8	11	32	27	48	11	3	17	0	9
6948	Sprint Fidelis	10,400	0	1	7	6	1	0	0	1	0	0
6949	Sprint Fidelis	186,800	9	26	26	31	29	24	6	23	0	12
6996	SubQ	2,700	0	0	0	0	0	0	0	1	0	0

Report Cutoff Date: January 31, 2010

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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
6935	Sprint Quattro Secure	Endo RV True Bipolar Sensing	IS-1	DF-1	8.2 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, 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

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Registered US Implants	15,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	13,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	3
Other	2

Atrial Placement

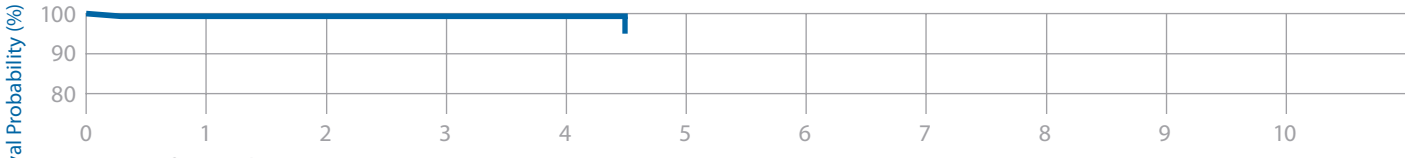
System Longevity Study Results

Number of Leads Enrolled in Study	278
Cumulative Months of Follow-Up	7,880
Number of Leads Active in Study	200

Qualifying Complications

1 Total

Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	99.6	99.6	99.6	99.6	99.6
#	163	127	85	59	49

Effective Sample Size

Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	210
Cumulative Months of Follow-Up	7,105
Number of Leads Active in Study	133

Qualifying Complications

0 Total

	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	100.0	100.0	100.0	100.0	100.0
#	143	118	84	58	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4023 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	LAK
Registered US Implants	41,200	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	8,700	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

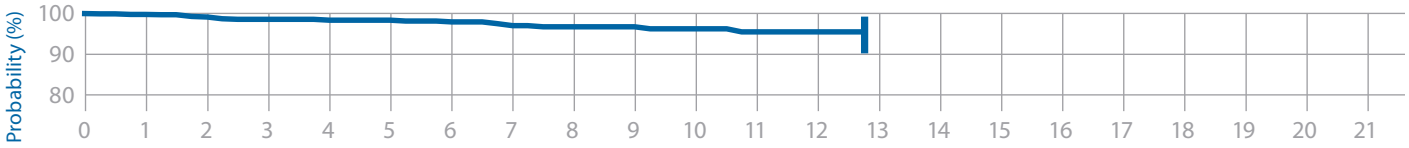
Conductor Fracture	17
Crimp/Weld/Bond	0
Insulation Breach	3
Other	8

System Longevity Study Results

Number of Leads Enrolled in Study	1,158
Cumulative Months of Follow-Up	66,921
Number of Leads Active in Study	323

Qualifying Complications 21 Total

Extra Cardiac Stimulation	1
Failure to Capture	16
Impedance Out of Range	1
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	11 yr	12 yr	at 153 mo
%	99.8	99.2	98.6	98.4	98.4	98.0	97.0	96.8	96.8	96.3	95.6	95.6	95.6
#	886	638	591	547	500	453	386	307	218	153	101	63	51

Effective Sample Size

4024 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAJ
Registered US Implants	222,300	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	51,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

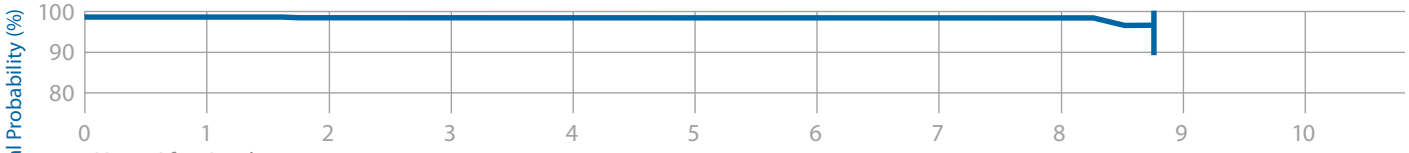
Conductor Fracture	26
Crimp/Weld/Bond	0
Insulation Breach	125
Other	41

System Longevity Study Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	30,002
Number of Leads Active in Study	20

Qualifying Complications 4 Total

Failure to Capture	3
Insulation (not further defined)	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	98.8
#	870	105	97	87	80	74	69	59	49

Effective Sample Size

Pacing Leads continued

4033 CapSure Z

Product Characteristics

US Market Release	Not US released	Serial Number Prefix	LCA
Registered US Implants	NA	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	NA	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

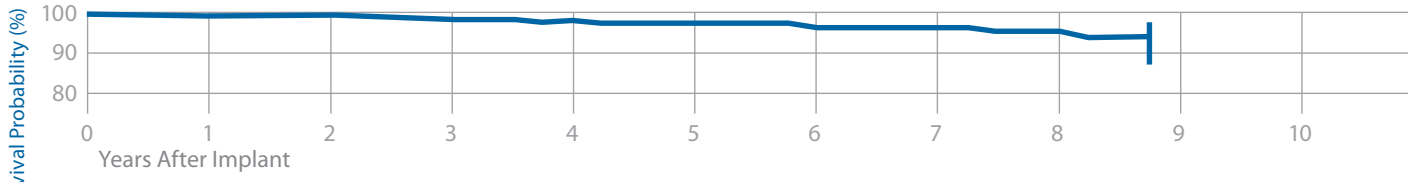
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	22,292
Number of Leads Active in Study	39

Qualifying Complications 10 Total

Conductor Fracture	1
Failure to Capture	8
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	99.4	99.4	98.1	97.5	96.8	96.0	96.0	94.8	93.3
#	430	166	154	145	131	111	85	64	50

Effective Sample Size

4067 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LCV
Registered US Implants	1,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	300	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

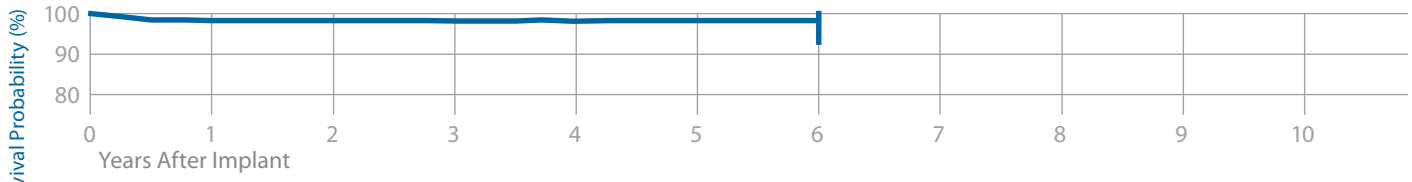
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	171
Cumulative Months of Follow-Up	9,899
Number of Leads Active in Study	59

Qualifying Complications 8 Total

Failure to Capture	6
Impedance Out of Range	1
Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	98.1	98.1	98.1	98.1	98.1	98.1
#	130	98	90	84	72	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4068 CapSureFix

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCE
Registered US Implants	124,900	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	39,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	39
Crimp/Weld/Bond	0
Insulation Breach	91
Other	15

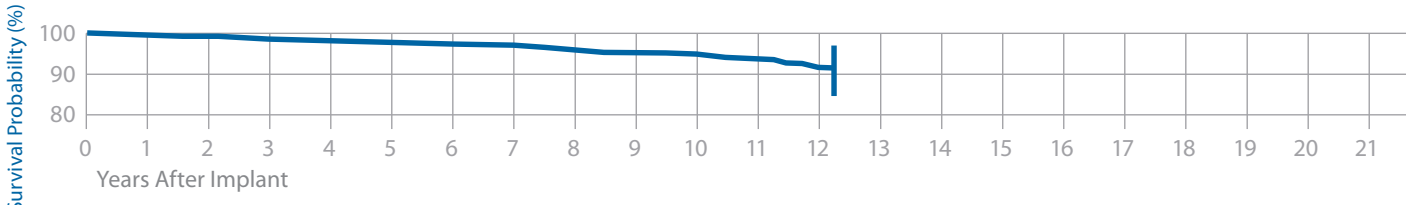
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,413
Cumulative Months of Follow-Up	120,127
Number of Leads Active in Study	517

Qualifying Complications 66 Total

Conductor Fracture	2	Insulation (ESC)	2
Extra Cardiac Stimulation	2	Insulation (not further defined)	2
Failure to Capture	21	Lead Dislodgement	8
Failure to Sense	11	Oversensing	7
Impedance Out of Range	6	Unspecified Clinical Failure	3
		Insulation (MIO)	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	at 147 mo
%	98.9	98.7	98.1	97.8	97.2	96.9	96.8	95.7	94.9	94.6	93.1	91.3	91.3
#	1,907	1,180	1,074	969	859	730	585	423	293	219	146	70	54

Effective Sample Size

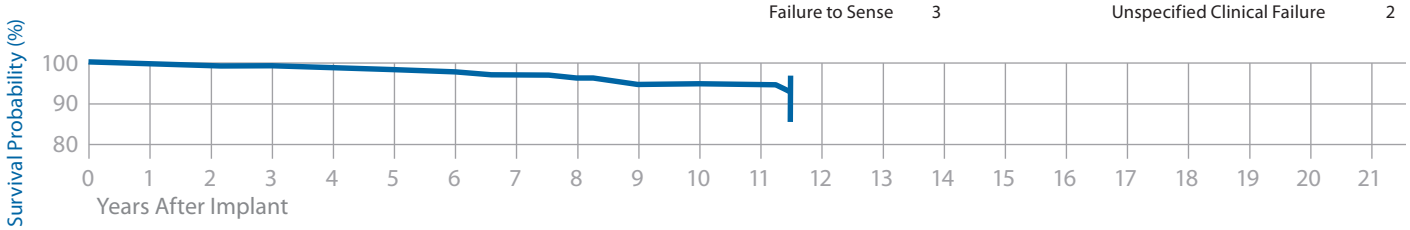
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	87,850
Number of Leads Active in Study	425

Qualifying Complications 39 Total

Conductor Fracture	2	Impedance Out of Range	5
Extra Cardiac Stimulation	2	Insulation (not further defined)	1
Failure to Capture	21	Oversensing	3
Failure to Sense	3	Unspecified Clinical Failure	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 138 mo
%	99.3	98.7	98.7	98.2	97.8	97.3	96.6	95.9	94.3	94.3	94.3	92.6
#	1,428	950	863	768	678	547	388	244	140	88	60	49

Effective Sample Size

Pacing Leads continued

4073 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBF
Registered US Implants	600	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	400	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

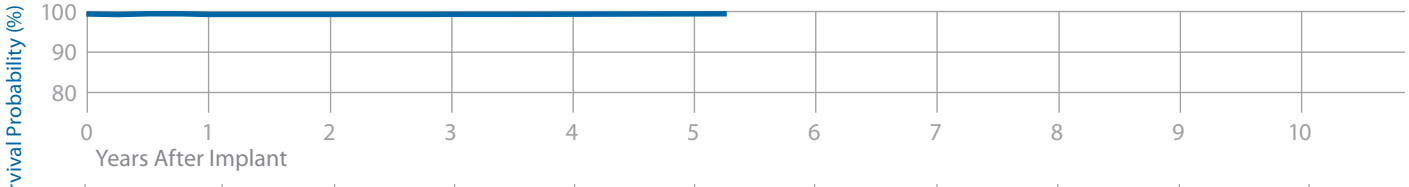
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	102
Cumulative Months of Follow-Up	5,930
Number of Leads Active in Study	83

Qualifying Complications

0 Total



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
#	99	92	86	85	64	34

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Registered US Implants	71,600	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	49,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	1
Insulation Breach	9
Other	3

Atrial Placement

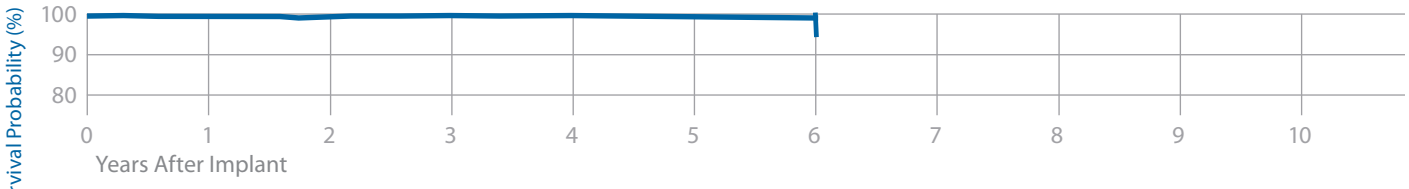
System Longevity Study Results

Number of Leads Enrolled in Study	212
Cumulative Months of Follow-Up	11,223
Number of Leads Active in Study	167

Qualifying Complications

2 Total

Failure to Capture	1
Failure to Sense	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	99.0	99.0	99.0	99.0	99.0	99.0
#	198	189	172	117	75	44

Effective Sample Size

Ventricular Placement

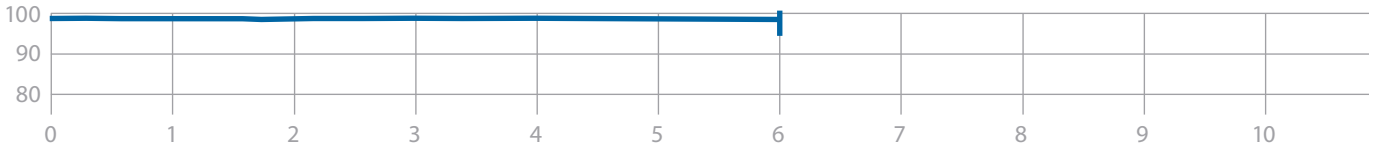
System Longevity Study Results

Number of Leads Enrolled in Study	415
Cumulative Months of Follow-Up	19,367
Number of Leads Active in Study	322

Qualifying Complications

4 Total

Impedance Out of Range	3
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	99.7	99.5	99.5	99.5	99.5	99.5
#	378	350	293	178	82	49

Effective Sample Size

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Registered US Implants	257,000	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	208,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	0
Insulation Breach	7
Other	15

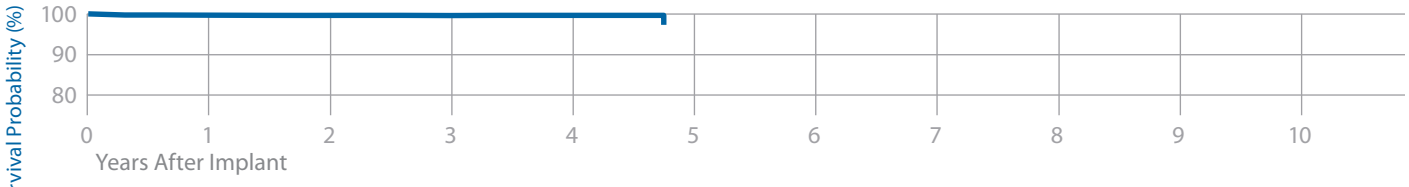
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,387
Cumulative Months of Follow-Up	29,085
Number of Leads Active in Study	1,214

Qualifying Complications 3 Total

Failure to Capture	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	99.8	99.7	99.7	99.7	99.7
#	708	492	280	128	51

Effective Sample Size

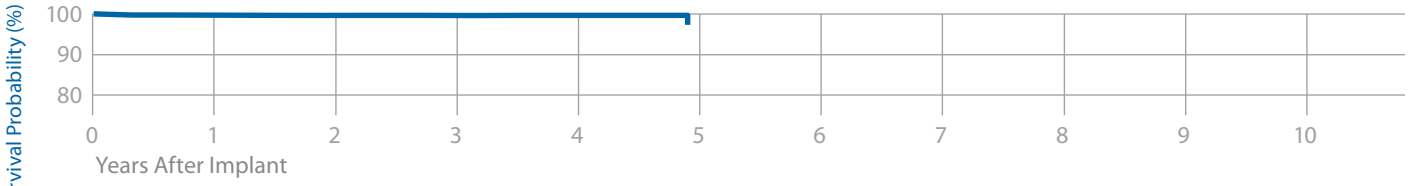
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,073
Cumulative Months of Follow-Up	26,878
Number of Leads Active in Study	926

Qualifying Complications 2 Total

Failure to Capture	2



	1 yr	2 yr	3 yr	4 yr	at 57 mo
%	99.8	99.8	99.8	99.8	99.8
#	632	473	329	156	39

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Registered US Implants	159,100	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	83,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

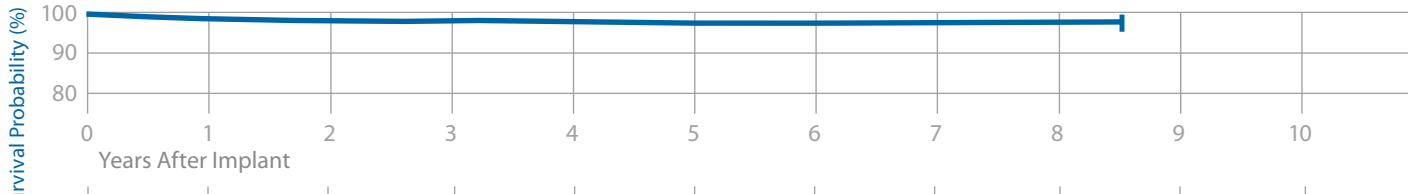
Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	18
Other	7

System Longevity Study Results

Number of Leads Enrolled in Study	1,147
Cumulative Months of Follow-Up	60,535
Number of Leads Active in Study	447

Qualifying Complications 17 Total

Conductor Fracture	3	Impedance Out of Range	1
Extra Cardiac Stimulation	1	Lead Dislodgement	4
Failure to Capture	8		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	98.9	98.8	98.7	98.4	98.1	98.1	98.1	98.1	98.1
#	930	806	717	628	538	383	241	112	49

Effective Sample Size

4523 CapSure SP

Product Characteristics

US Market Release	Aug-91	Serial Number Prefix	ZE
Registered US Implants	11,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	2,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

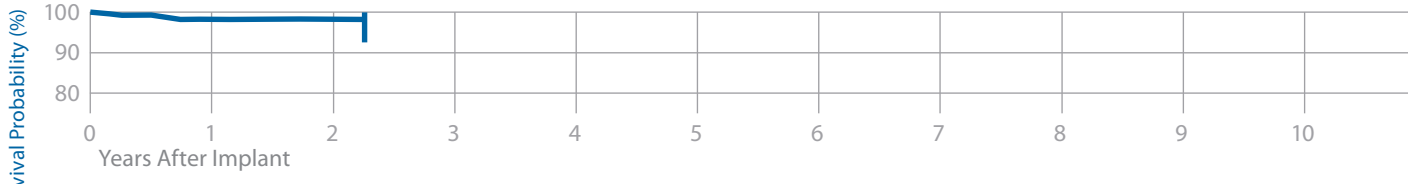
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	2
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	121
Cumulative Months of Follow-Up	6,686
Number of Leads Active in Study	13

Qualifying Complications 4 Total

Impedance Out of Range	1		
Lead Dislodgement	2		
Oversensing	1		



	1 yr	2 yr	at 27 mo
%	98.1	98.1	98.1
#	95	51	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4524 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAR
Registered US Implants	101,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	29,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	33
Other	13

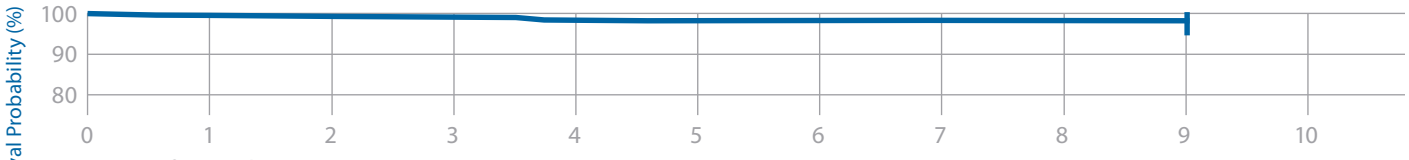
System Longevity Study Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	26,763
Number of Leads Active in Study	53

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	99.2	99.2	98.4	98.4	98.4	98.4	98.4	98.4
#	682	138	124	112	99	89	81	69	50

Effective Sample Size

4533 CapSure Z

Product Characteristics

US Market Release	Not US released	Serial Number Prefix	LCB
Registered US Implants	NA	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	NA	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

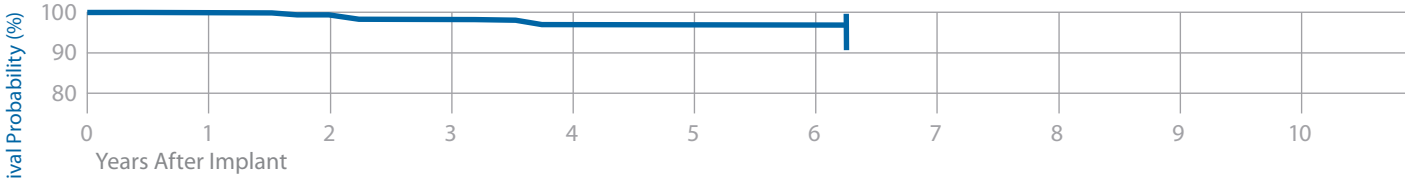
System Longevity Study Results

Number of Leads Enrolled in Study	206
Cumulative Months of Follow-Up	9,973
Number of Leads Active in Study	16

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 75 mo
%	100.0	99.4	98.4	97.2	97.2	97.2	97.2
#	176	96	88	78	66	52	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

4558M Screw-In

Product Characteristics

US Market Release	Nov-94	Serial Number Prefix	LDC
Registered US Implants	20,000	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	4,900	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

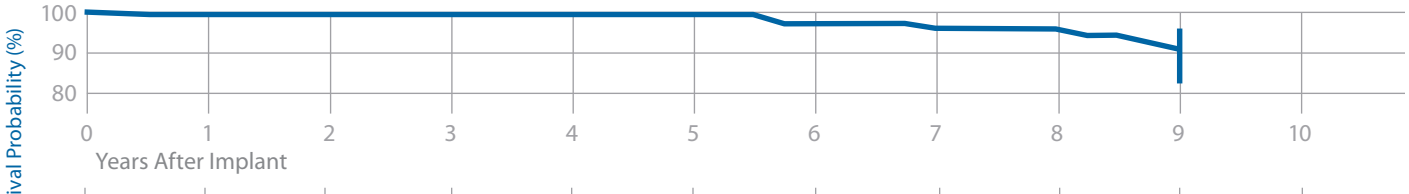
Conductor Fracture	1
Crimp/Weld/Bond	1
Insulation Breach	16
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	18,075
Number of Leads Active in Study	23

Qualifying Complications 13 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	99.3	99.3	99.3	99.3	99.3	97.2	95.9	95.9	91.1
#	353	125	111	106	99	82	75	62	50

Effective Sample Size

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Registered US Implants	69,800	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	28,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

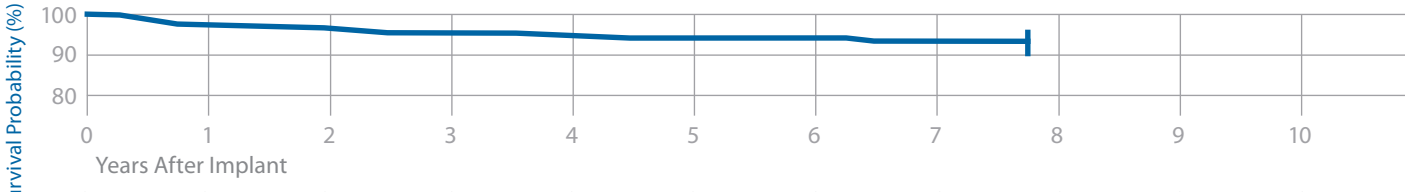
Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	22
Other	6

System Longevity Study Results

Number of Leads Enrolled in Study	656
Cumulative Months of Follow-Up	29,584
Number of Leads Active in Study	190

Qualifying Complications 33 Total

Failure to Capture	18	Lead Dislodgement	9
Failure to Sense	3	Medical Judgment	1
Impedance Out of Range	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	96.8	96.4	95.2	94.6	93.9	93.9	93.2	93.2
#	496	399	338	284	239	158	85	54

Effective Sample Size

Pacing Leads continued

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Registered US Implants	45,900	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	33,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

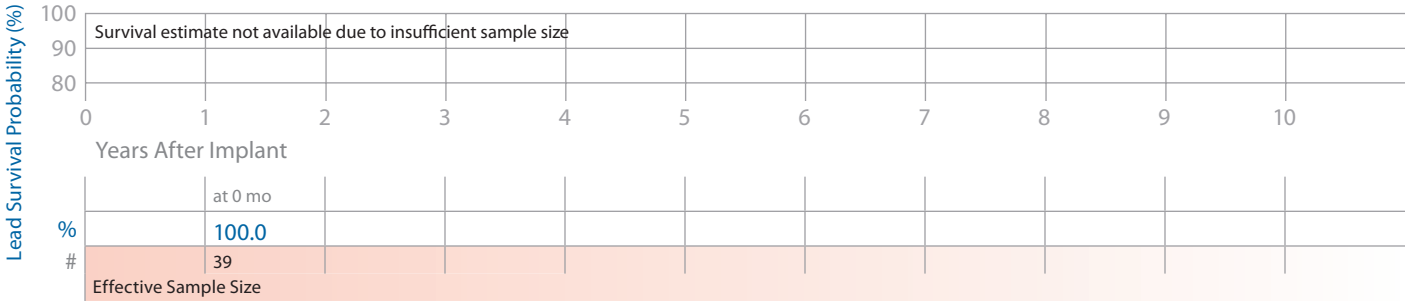
US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	1
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	39
Cumulative Months of Follow-Up	869
Number of Leads Active in Study	35

Qualifying Complications 0 Total



	at 0 mo
%	100.0
#	39

Effective Sample Size

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Registered US Implants	78,100	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	43,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

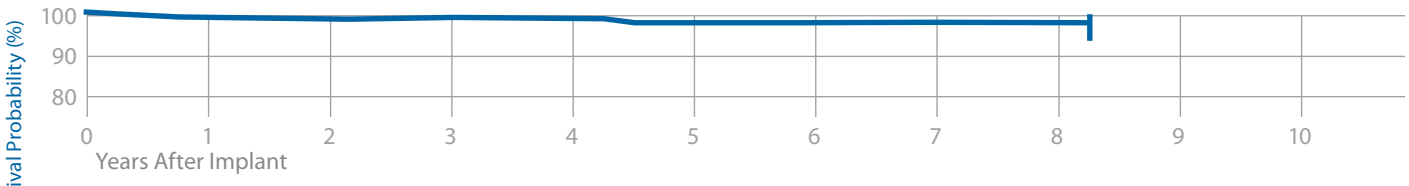
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	5
Other	1

System Longevity Study Results

Number of Leads Enrolled in Study	283
Cumulative Months of Follow-Up	13,360
Number of Leads Active in Study	86

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	7 yr	8 yr	at 99 mo
%	98.2	98.2	98.2	98.2	97.4	97.4	97.4	97.4	97.4
#	193	154	142	125	105	94	73	53	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5023, 5023M CapSure SP

Product Characteristics

US Market Release	Nov-88	Serial Number Prefix	SX or LAS
Registered US Implants	9,900	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	2,200	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

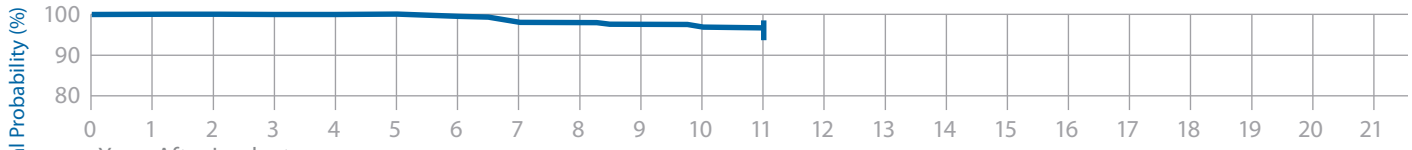
Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	1
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	1,354
Cumulative Months of Follow-Up	72,823
Number of Leads Active in Study	445

Qualifying Complications 19 Total

Conductor Fracture	2
Extra Cardiac Stimulation	4
Failure to Capture	10
Impedance Out of Range	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.7	99.7	99.5	99.4	99.4	98.8	97.5	97.5	97.1	96.2	96.2
#	1,077	818	761	698	622	500	374	260	173	102	48

Effective Sample Size

5024, 5024M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	SY or LAT
Registered US Implants	201,600	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	52,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

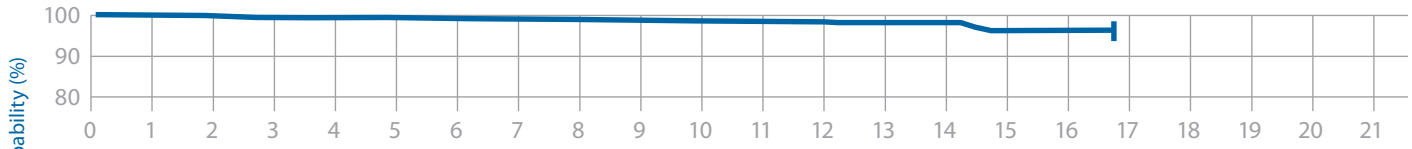
Conductor Fracture	50
Crimp/Weld/Bond	10
Insulation Breach	46
Other	39

System Longevity Study Results

Number of Leads Enrolled in Study	8,154
Cumulative Months of Follow-Up	326,440
Number of Leads Active in Study	529

Qualifying Complications 57 Total

Conductor Fracture	3
Extra Cardiac Stimulation	2
Failure to Capture	28
Failure to Sense	2
Impedance Out of Range	3
Insulation (ESC)	1
Insulation (not further defined)	5
Lead Dislodgement	5
Oversensing	5
Unspecified Clinical Failure	1
Other	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	16 yr	at 201 mo
%	99.6	99.5	99.3	99.2	99.1	99.0	98.8	98.6	98.4	98.3	98.2	98.2	97.9	97.9	96.2	96.2	96.2
#	6,128	2,101	1,996	1,893	1,788	1,618	1,410	1,179	960	736	561	406	285	200	120	80	51

Effective Sample Size

Pacing Leads continued

5033 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDK
Registered US Implants	2,400	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	600	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

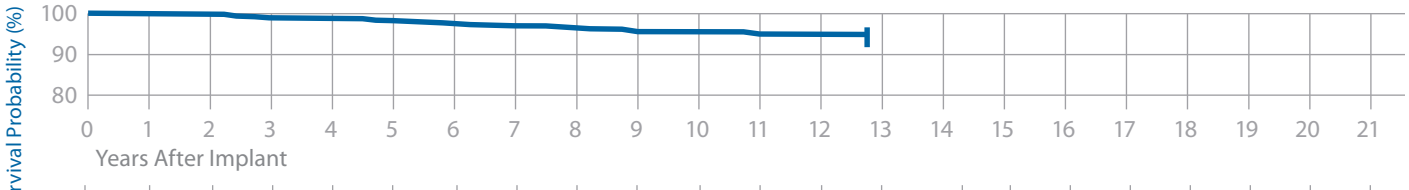
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	3

System Longevity Study Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	79,848
Number of Leads Active in Study	236

Qualifying Complications 26 Total

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	7	Insulation (not further defined)	1
Failure to Capture	11	Lead Dislodgement	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	at 153 mo
%	99.7	99.6	98.7	98.5	98.1	97.4	96.8	96.2	95.3	95.3	94.7	94.7	94.7
#	1,416	548	513	495	471	433	392	337	264	206	152	100	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5034 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDF
Registered US Implants	56,300	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	15,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	14
Crimp/Weld/Bond	1
Insulation Breach	14
Other	13

Atrial Placement

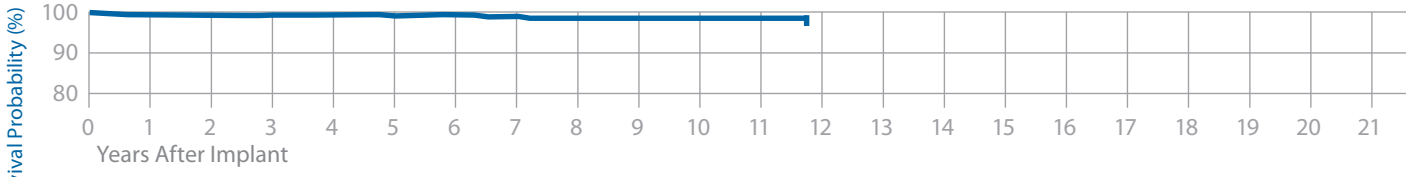
System Longevity Study Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	41,352
Number of Leads Active in Study	169

Qualifying Complications

5 Total

Conductor Fracture	2
Failure to Capture	2
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	at 141 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	99.2	98.8	98.8	98.8	98.8	98.8
#	383	382	379	373	354	329	293	248	198	135	86	49

Effective Sample Size

Ventricular Placement

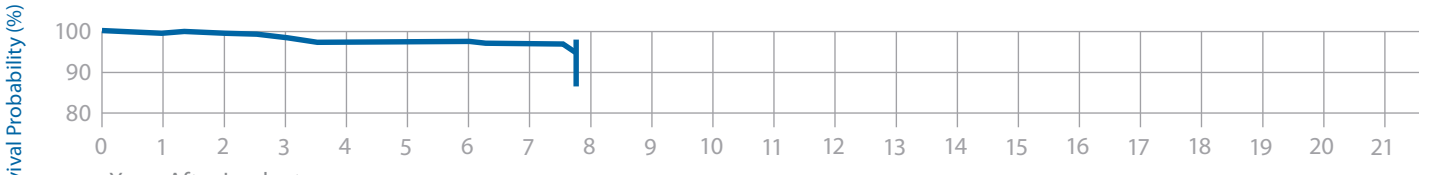
System Longevity Study Results

Number of Leads Enrolled in Study	1,210
Cumulative Months of Follow-Up	31,836
Number of Leads Active in Study	30

Qualifying Complications

11 Total

Conductor Fracture	1
Failure to Capture	7
Failure to Sense	2
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	99.7	99.4	98.2	97.5	97.5	97.5	96.3	94.5
#	887	170	145	131	106	82	56	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Registered US Implants	88,900	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	44,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	1
Insulation Breach	13
Other	6

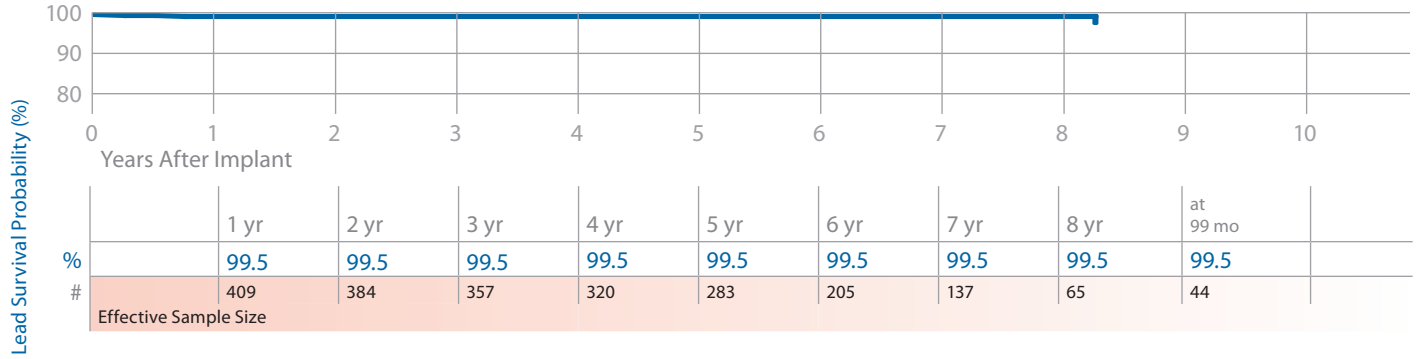
Atrial Placement

Longevity Study Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	29,216
Number of Leads Active in Study	225

Qualifying Complications 2 Total

Failure to Capture	1	Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
#	409	384	357	320	283	205	137	65	44

Effective Sample Size

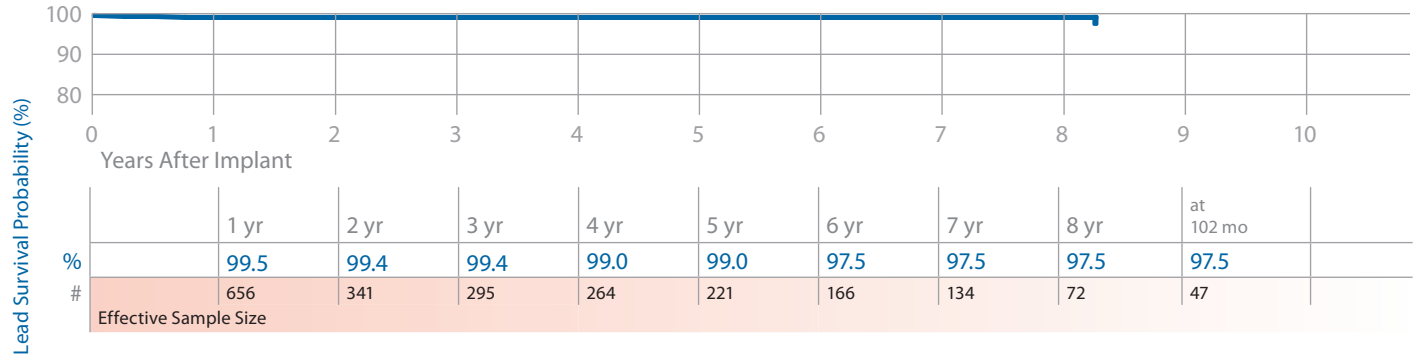
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	32,969
Number of Leads Active in Study	163

Qualifying Complications 9 Total

Failure to Capture	6	Lead Dislodgement	1
Failure to Sense	1		
Impedance Out of Range	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.5	99.4	99.4	99.0	99.0	97.5	97.5	97.5	97.5
#	656	341	295	264	221	166	134	72	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5068 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDJ
Registered US Implants	103,200	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	37,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	33
Crimp/Weld/Bond	3
Insulation Breach	46
Other	16

Atrial Placement

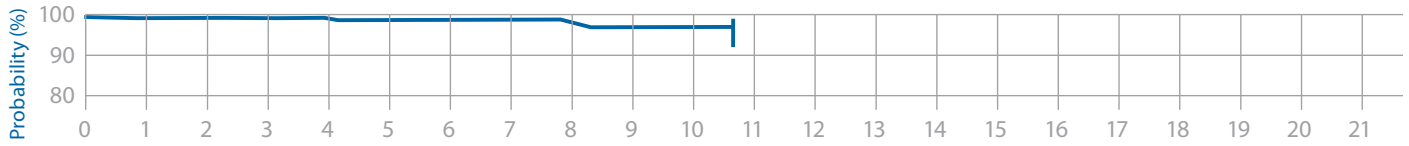
System Longevity Study Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	29,905
Number of Leads Active in Study	56

Qualifying Complications

8 Total

Failure to Capture	2	Insulation (not further defined)	2
Impedance Out of Range	2	Oversensing	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
%	99.6	99.6	99.6	99.1	99.1	99.1	99.1	97.4	97.4	97.4	97.4
#	552	259	232	207	184	150	128	103	76	55	49

Effective Sample Size

Ventricular Placement

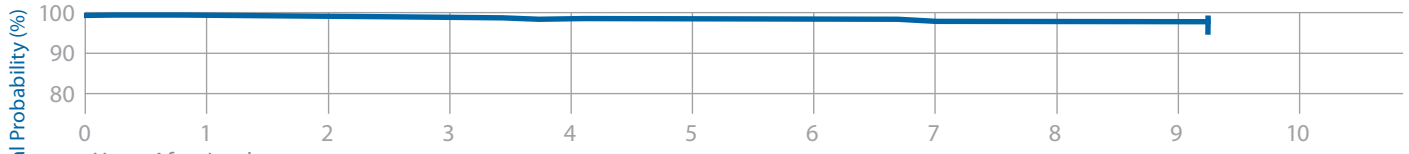
System Longevity Study Results

Number of Leads Enrolled in Study	1,362
Cumulative Months of Follow-Up	36,207
Number of Leads Active in Study	108

Qualifying Complications

6 Total

Conductor Fracture	1	Lead Dislodgement	1
Failure to Capture	3		
Insulation (not further defined)	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	99.8	99.6	99.3	98.9	98.9	98.9	98.3	98.3	98.3	98.3
#	700	324	287	241	218	187	155	113	64	54

Effective Sample Size

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Registered US Implants	9,100	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	4,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	2
Crimp/Weld/Bond	0
Insulation Breach	4
Other	1

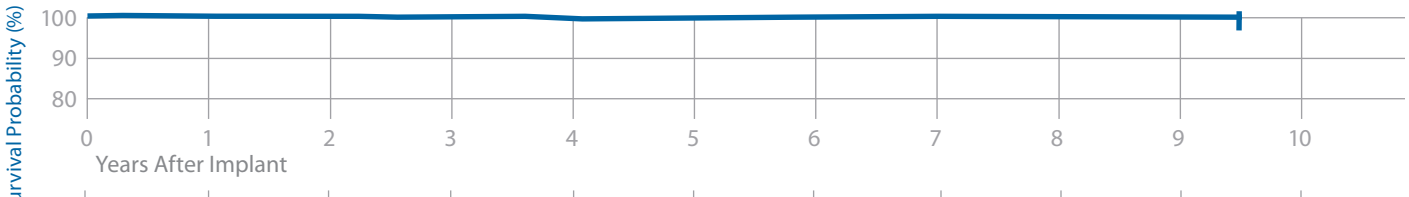
System Longevity Study Results

Number of Leads Enrolled in Study	508
Cumulative Months of Follow-Up	24,560
Number of Leads Active in Study	118

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	8 yr	9 yr	at 114 mo
%	99.8	99.8	99.3	99.3	99.3	99.3	99.3	99.3	99.3	99.3
#	376	219	210	203	187	164	142	112	69	46

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Registered US Implants	1,163,300	Type and/or Fixation	Transvenous, V or A, Screw-in
Estimated Active US Implants	797,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	188
Crimp/Weld/Bond	0
Insulation Breach	181
Other	144

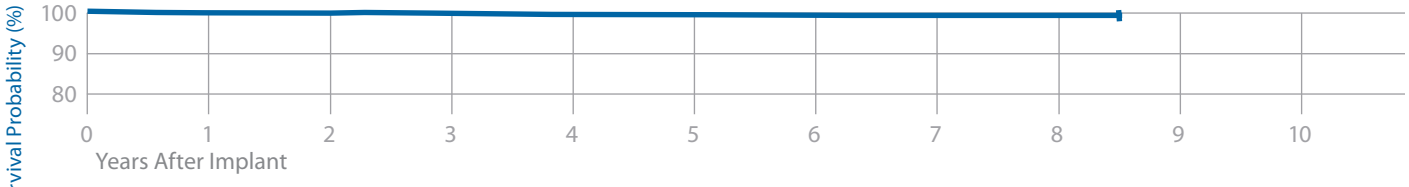
Atrial Placement

System Longevity Study Results

Number of Leads Enrolled in Study	2,706
Cumulative Months of Follow-Up	117,468
Number of Leads Active in Study	1,095

Qualifying Complications 18 Total

Cardiac Perforation	1	Impedance Out of Range	2
Conductor Fracture	1	Insulation (not further defined)	1
Extra Cardiac Stimulation	2	Lead Dislodgement	4
Failure to Capture	6	Oversensing	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.7	99.6	99.4	99.1	99.1	99.0	99.0	99.0	99.0
#	2,047	1,686	1,493	1,199	839	536	323	110	43

Effective Sample Size

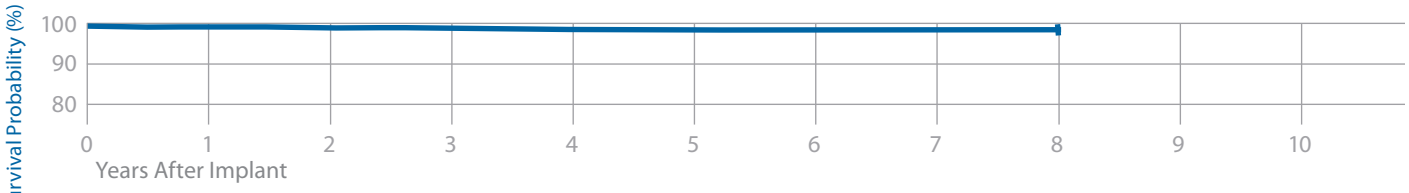
Ventricular Placement

System Longevity Study Results

Number of Leads Enrolled in Study	1,527
Cumulative Months of Follow-Up	60,524
Number of Leads Active in Study	495

Qualifying Complications 10 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.6	99.4	99.3	99.0	99.0	99.0	99.0	99.0
#	1,082	861	742	591	437	284	159	44

Effective Sample Size

Pacing Leads continued

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Registered US Implants	118,400	Type and/or Fixation	Transvenous, Vent., Tines
Estimated Active US Implants	62,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	30
Other	12

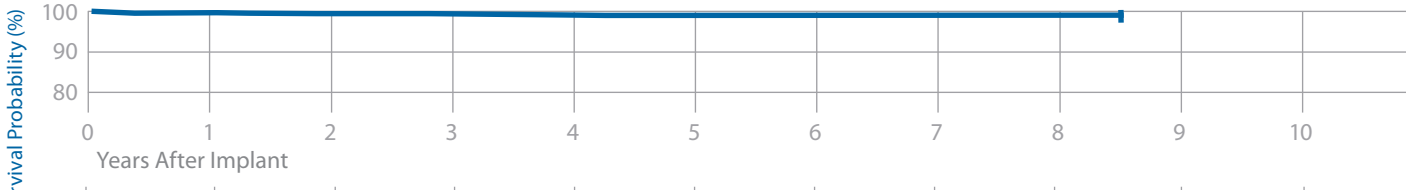
System Longevity Study Results

Number of Leads Enrolled in Study	1,170
Cumulative Months of Follow-Up	44,165
Number of Leads Active in Study	201

Qualifying Complications

7 Total

Extra Cardiac Stimulation	1
Failure to Capture	1
Lead Dislodgement	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.6	99.5	99.3	99.0	99.0	99.0	99.0	99.0	99.0
#	810	618	504	389	297	209	134	72	46

Effective Sample Size

5524, 5524M CapSure SP

Product Characteristics

US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Registered US Implants	60,600	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	19,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	2
Insulation Breach	12
Other	8

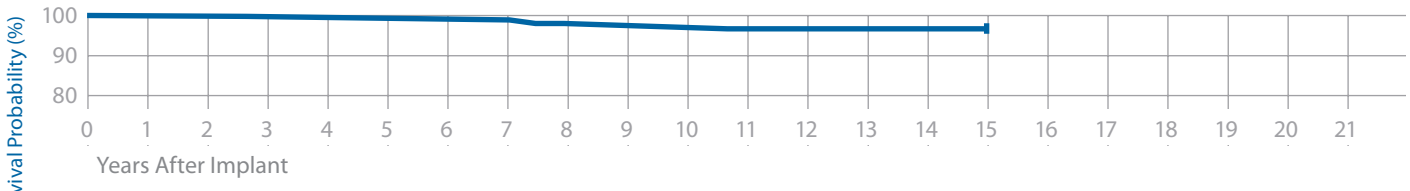
System Longevity Study Results

Number of Leads Enrolled in Study	4,497
Cumulative Months of Follow-Up	198,894
Number of Leads Active in Study	459

Qualifying Complications

39 Total

Conductor Fracture	1	Insulation (not further defined)	2
Failure to Capture	22	Lead Dislodgement	4
Failure to Sense	4	Oversensing	4
Impedance Out of Range	1	Other	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
%	99.8	99.7	99.3	99.0	98.9	98.8	98.5	97.8	97.4	97.0	96.8	96.8	96.8	96.8	96.8
#	3,439	1,470	1,375	1,285	1,182	1,057	907	753	611	472	355	258	166	105	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5534 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDG
Registered US Implants	26,300	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	8,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

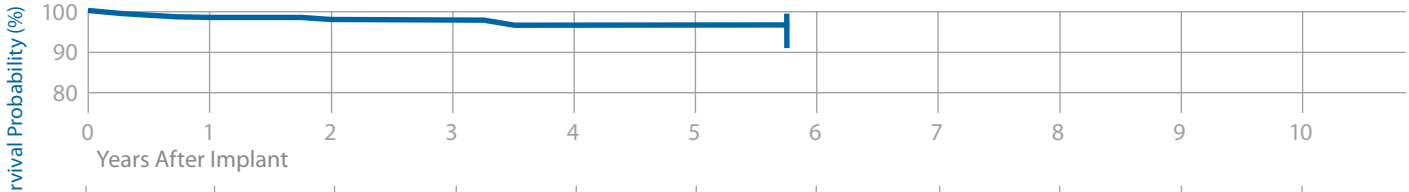
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	5
Other	5

System Longevity Study Results

Number of Leads Enrolled in Study	264
Cumulative Months of Follow-Up	10,730
Number of Leads Active in Study	17

Qualifying Complications 6 Total

Failure to Capture	5
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	98.3	97.6	97.6	96.5	96.5	96.5
#	207	93	84	75	57	48

Effective Sample Size

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Registered US Implants	57,200	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	31,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	10
Other	4

System Longevity Study Results

Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	10,087
Number of Leads Active in Study	47

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
%	100.0	99.0	98.0	96.7
#	273	102	78	51

Effective Sample Size

Leads

Pacing Leads continued

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Registered US Implants	77,100	Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Estimated Active US Implants	47,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	13
Other	15

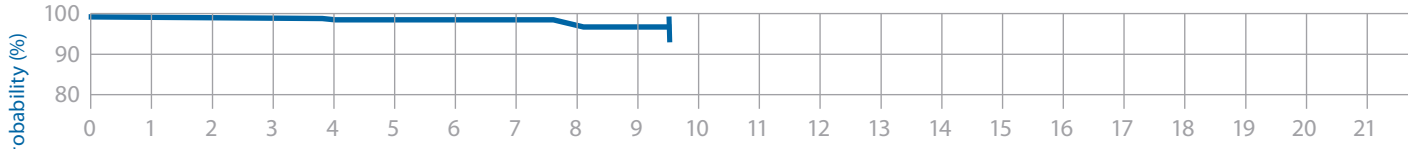
System Longevity Study Results

Number of Leads Enrolled in Study	1,052
Cumulative Months of Follow-Up	36,086
Number of Leads Active in Study	183

Qualifying Complications

12 Total

Conductor Fracture	3
Failure to Capture	5
Failure to Sense	2
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
%	99.8	99.3	99.3	98.9	98.1	97.0	97.0	97.0	97.0	97.0
#	711	384	346	247	200	160	130	98	57	51

Effective Sample Size

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Registered US Implants	29,800	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	18,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

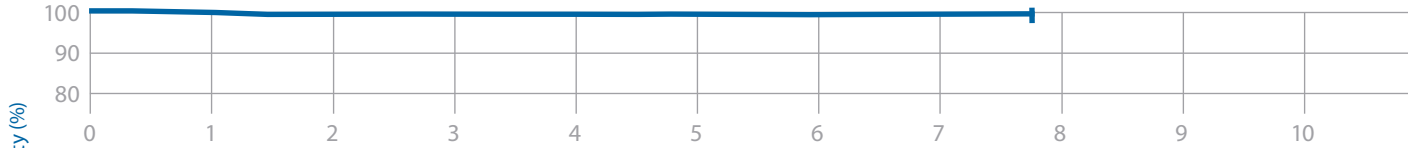
System Longevity Study Results

Number of Leads Enrolled in Study	670
Cumulative Months of Follow-Up	28,246
Number of Leads Active in Study	162

Qualifying Complications

4 Total

Failure to Capture	2
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 93 mo
%	99.7	99.3	99.3	99.3	99.3	99.3	99.3	99.3
#	516	421	339	261	201	128	71	45

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Registered US Implants	12,400	Type and/or Fixation	Transvenous, Atrial-J, Tines
Estimated Active US Implants	8,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	20
Cumulative Months of Follow-Up	1,330
Number of Leads Active in Study	13

Qualifying Complications 0 Total

	at 0 mo
%	100.0
#	20

Effective Sample Size

6940 CapSureFix

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	TCP
Registered US Implants	25,500	Type and/or Fixation	Transvenous, A or V, Screw-in
Estimated Active US Implants	9,300	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

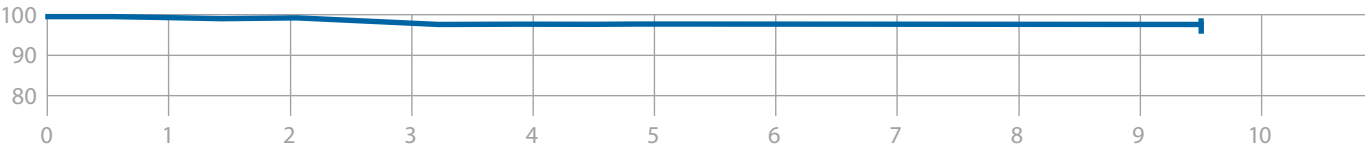
Conductor Fracture	10
Crimp/Weld/Bond	0
Insulation Breach	13
Other	4

System Longevity Study Results

Number of Leads Enrolled in Study	816
Cumulative Months of Follow-Up	40,238
Number of Leads Active in Study	119

Qualifying Complications 11 Total

Conductor Fracture	1
Failure to Sense	3
Lead Dislodgement	1
Oversensing	6



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 114 mo
%	99.7	99.6	98.3	98.0	98.0	98.0	98.0	98.0	98.0	98.0
#	641	506	413	331	277	237	196	146	102	60

Effective Sample Size

Leads

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	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	278	200	1	7,880	99.6 +.3/-2.2	99.6 +.3/-2.2	99.6 +.3/-2.2	99.6 +.3/-2.2	99.6 +.3/-2.2 at 54 mo									
3830	SelectSecure	Vent	Aug-05	210	133	0	7,105	100.0	100.0	100.0	100.0	100.0 at 54 mo									
4023	CapSure SP	Vent	Aug-91	1,158	323	21	66,921	99.8 +.2/-.6	99.2 +.4/-.9	98.6 +.6/-1.2	98.4 +.7/-1.3	98.4 +.7/-1.3	98.0 +.8/-1.4	97.0 +1.2/-1.8	96.8 +1.2/-1.9	96.3 +1.4/-2.2	95.6 +1.8/-2.8	95.6 +1.8/-2.8 at 153 mo			
4024	CapSure SP	Vent	Oct-91	1,215	20	4	30,002	99.9 +.1/-.5	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	98.0 +1.6/-9.1 at 105 mo					
4033	CapSure Z	Vent	Not US released	539	39	10	22,063	99.4 +.4/-1.4	99.4 +.4/-1.4	98.1 +1.2/-3	97.5 +1.5/-3.5	96.8 +1.8/-3.9	96.0 +2.1/-4.4	96.0 +2.1/-4.4	94.8 +2.7/-5.5	93.3 +3.4/-6.7 at 105 mo					
4067	CapSureFix	Atrial	Jan-97	171	59	8	9,899	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9	98.1 +1.3/-3.9								
4068	CapSureFix	Atrial	Mar-96	2,413	517	66	120,127	98.9 +.4/-.5	98.7 +.4/-.6	98.1 +.5/-.8	97.8 +.6/-.9	97.2 +.8/-1	96.9 +.8/-1.1	96.8 +.8/-1.2	95.7 +1.1/-1.6	94.6 +1.4/-2	91.3 +2.9/-4.1	91.3 +2.9/-4.1 at 147 mo			
4068	CapSureFix	Vent	Mar-96	1,799	425	39	87,850	99.3 +.3/-.6	98.7 +.5/-.8	98.7 +.5/-.8	98.2 +.6/-1	97.8 +.7/-1.1	97.3 +.9/-1.2	96.6 +1/-1.5	95.9 +1.3/-1.8	94.3 +2/-2.9	92.6 +3.1/-5.4 at 138 mo				
4073	CapSure Sense	Vent	Jun-02	102	83	0	5,930	100.0	100.0	100.0	100.0	100.0	100.0 at 57 mo								
4074	CapSure Sense	Atrial	Jun-02	212	167	2	11,223	99.0 +.8/-2.7	99.0 +.8/-2.7	99.0 +.8/-2.7	99.0 +.8/-2.7	99.0 +.8/-2.7	99.0 +.8/-2.7								
4074	CapSure Sense	Vent	Jun-02	415	322	4	19,367	99.7 +.3/-1.5	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6								
4076	CapSureFix Novus	Atrial	Feb-04	1,387	1,214	3	29,085	99.8 +.2/-.4	99.7 +.2/-.7	99.7 +.2/-.7	99.7 +.2/-.7	99.7 +.2/-.7 at 57 mo									
4076	CapSureFix Novus	Vent	Feb-04	1,073	926	2	26,878	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-.7	99.8 +.1/-07	99.8 +.1/-.7									
4092	CapSure SP Novus	Vent	Sep-98	1,147	447	17	60,535	98.9 +.5/-.8	98.8 +.5/-.9	98.7 +.5/-1	98.4 +.6/-1.1	98.1 +.7/-1.2	98.1 +.7/-1.2	98.1 +.7/-1.2	98.1 +.7/-1.2	98.1 +.7/-1.2 at 102 mo					

continued

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	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
4523	CapSure SP	Atrial	Aug-91	121	13	4	6,686	98.1 +1.4/-5.3	98.1 +1.4/-5.3	98.1 +1.4/-5.3 at 27 mo											
4524	CapSure SP	Atrial	Oct-91	911	53	6	26,763	99.6 +.3/-0.7	99.2 +.5/-1.2	99.2 +.5/-1.2	98.4 +1.1/-3.3	98.4 +1.1/-3.3	98.4 +1.1/-3.3	98.4 +1.1/-3.3	98.4 +1.1/-3.3	98.4 +1.1/-3.3 at 108 mo					
4533	CapSure Z	Atrial	Not US released	206	16	4	9,973	100.0	99.4 +.5/-3.5	98.4 +1.2/-5.1	97.2 +1.9/-6	97.2 +1.9/-6	97.2 +1.9/-6	97.2 +1.9/-6 at 75 mo							
4558M	Screw-In	Atrial	Nov-94	539	23	13	18,075	99.3 +.5/-1.4	99.3 +.5/-1.4	99.3 +.5/-1.4	99.3 +.5/-1.4	99.3 +.5/-1.4	97.2 +1.8/-5.4	95.9 +2.5/-6.3	95.9 +2.5/-6.3	91.1 +4.6/-9.3 at 108 mo					
4568	CapSureFix	Atrial	Jan-97	656	190	33	29,584	96.8 +1.2/-1.8	96.4 +1.3/-1.9	95.2 +1.5/-2.3	94.6 +1.7/-2.5	93.9 +1.9/-2.7	93.9 +1.9/-2.7	93.2 +2.2/-3.2	93.2 +2.2/-3.2 at 93 mo						
4574	CapSure Sense	Atrial	Jun-02	39	35	0	869	100.0 at 0 mo													
4592	CapSure SP Novus	Atrial	Oct-98	283	86	5	13,360	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3	98.2 +1.1/-3	97.4 +1.5/-3.9	97.4 +1.5/-3.9	97.4 +1.5/-3.9	97.4 +1.5/-3.9	97.4 +1.5/-3.9 at 99 mo					
5023, 5023M	CapSure SP	Vent	Nov-88	1,354	445	19	72,823	99.7 +.2/-.5	99.7 +.2/-.6	99.5 +.3/-.7	99.4 +.3/-.8	98.8 +.6/-1.1	98.8 +.6/-1.1	97.5 +1/-1.8	97.5 +1/-1.8	96.2 +1.7/-3	96.2 +1.7/-3 at 132 mo				
5024, 5024M	CapSure SP	Vent	Mar-90	8,154	529	57	326,440	99.5 +.1/-.2	99.5 +.2/-.1	99.2 +.2/-.3	99.2 +.3/-.4	99.1 +.3/-.4	99.0 +.3/-.5	98.8 +.4/-.5	98.6 +.4/-.5	98.3 +.5/-7	98.0 +.7/-.1	97.9 +1/-1.4	96.8 +1.6/-2.8	96.2 +1.6/-2.8 at 201 mo	
5033	CapSure Z	Vent	Feb-96	1,899	236	26	79,848	99.7 +.2/-.4	99.6 +.2/-.4	98.7 +.6/-1.2	98.5 +.7/-1.3	98.1 +.8/-1.5	97.4 +1.1/-1.7	96.8 +1.2/-2	96.2 +1.4/-2.1	95.3 +1.6/-2.5	94.7 +1.8/-2.8	94.7 +1.8/-2.8 at 153 mo			
5034	CapSure Z	Atrial	Feb-96	386	169	5	41,352	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.5 +.4/-1.6	99.2 +.5/-1.8	98.8 +.8/-1.9	98.8 +.8/-1.9	98.8 +.8/-1.9 at 141 mo				
5034	CapSure Z	Vent	Feb-96	1,210	30	11	31,836	99.7 +.2/-.6	99.4 +.3/-.8	98.2 +1.1/-2.9	97.5 +1.4/-3.5	97.5 +1.4/-3.5	97.5 +1.4/-3.5	96.3 +2.1/-5	94.5 +3.1/-7.3 at 93 mo						
5054	CapSure Z Novus	Atrial	Jun-98	424	225	2	29,216	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	99.5 +.4/-1.4	97.5 +.4/-1.4 at 99 mo					
5054	CapSure Z Novus	Vent	Jun-98	967	163	9	32,969	99.5 +.3/-.8	99.4 +.3/-.9	99.4 +.3/-.9	99.0 +.6/-1.4	99.0 +.6/-1.4	97.5 +1.3/-2.9	97.5 +1.3/-2.9	97.5 +1.3/-2.9	97.5 +1.3/-2.9 at 102 mo					

continued

Lead Survival Summary continued

Model Number	Family	Chamber	US Market Release	Leads Enrolled	Leads Active in Study	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
5068	CapSureFix	Atrial	Jan-97	967	56	8	29,905	99.5 +.3/-.8	99.4 +.3/-0.9	99.4 +.3/-.9	99.0 +.6/-1.4	99.0 +.6/-1.4	97.5 +1.3/-2.9	97.5 +1.3/-2.9	97.5 +1.3/-2.9	97.5 +1.3/-2.9 at 102 mo					
5068	CapSureFix	Vent	Jan-97	1,362	108	6	36,207	99.8 +.1/-.6	99.6 +.3/-.8	99.3 +.5/-1.4	98.9 +.7/-1.8	98.9 +.7/-1.8	98.9 +.7/-1.8	98.3 +1/-2.6	98.3 +1/-2.6	8.3 +1/-2.6 at 111 mo					
5072	SureFix	Atrial	Jun-98	508	118	6	24,560	99.8 +.2/-1.4	99.8 +.2/-1.4	99.3 +.5/-2.2	99.3 +.5/-2.2	99.3 +.5/-2.2	99.3 +.5/-2.2	99.3 +.5/-2.2	99.3 +.5/-2.2	99.3 +.5/-2.2 at 114 mo.					
5076	CapSureFix Novus	Atrial	Aug-00	2,706	1,095	18	117,468	99.7 +.1/-.4	99.6 +.2/-.3	99.4 +.3/-.4	99.1 +.4/-.5	99.1 +.4/-.5	99.0 +.4/-.7	99.0 +.4/-.7	99.0 +.4/-.7	99.0 +.4/-.7 at 102 mo					
5076	CapSureFix Novus	Vent	Aug-00	1,527	495	10	60,524	99.6 +.2/-.5	99.4 +.3/-.6	99.3 +.4/-.7	99.0 +.5/-.9	99.0 +.5/-.9	99 .0 +.5/-.9	99.0 +.5/-.9	99.0 +.5/-.9						
5092	CapSure SP Novus	Vent	Jun-98	1,170	201	7	44,165	99.6 +.2/-.7	99.5 +.3/-.8	99.3 +.4/-.9	99.0 +.6/-1.1	99.0 +.6/-1.1	99.0 +.6/-1.1	99.0 +.6/-1.1	99.0 +.6/-1.1	99.0 +.6/-1.1 at 102 mo					
5524, 5524M	CapSure SP	Atrial	Mar-90	4,497	459	39	198,894	99.8 +.1/-.3	99.7 +.2/-.2	99.3 +.3/-.5	99.0 +.4/-.6	98.9 +.4/-.7	98.8 +.4/-.7	98.5 +.5/-.8	97.8 +.7/-1.1	97.0 +.9/-1.3	96.8 +1/-1.4	96.8 +1/-1.4	96.8 +1/-1.4 at 180 mo		
5534	CapSure Z	Atrial	Feb-96	264	17	6	10,730	98.3 +1.1/-2.7	97.6 +1.4/-3.3	97.6 +1.4/-3.3	96.5 +2/-4.9	96.5 +2/-4.9	96.5 +2/-4.9 at 69 mo								
5554	CapSure Z Novus	Atrial	Jun-98	344	47	4	10,087	100.0	99.0 +.8/-2.8	98.0 +1.4/-4.8	96.7 +2.2/-6										
5568	CapSureFix	Atrial	Jan-97	1,052	183	12	36,086	99.8 +.1/-.7	99.3 +.4/-1.1	99.3 +.4/-1.1	98.9 +.7/-1.5	98.1 +1/-2.4	97.0 +1.5/-3.1	97.0 +1.5/-3.1	97.0 +1.5/-3.1	97.0 +1.5/-3.1 at 111 mo					
5592	CapSure SP Novus	Atrial	Jun-98	670	162	4	28,246	99.7 +.2/-1.1	99.3 +.4/-1.3	99.3 +.4/-1.3	99.3 +.4/-1.3	99.3 +.4/-1.3	99.3 +.4/-1.3	99.3 +.4/-1.3	99.3 +.4/-1.3 at 93 mo						
5594	CapSure SP Novus	Atrial	Jun-01	20	13	0	1,330	100.0 at 0 mo													
6940	CapSureFix	Atrial	Oct-98	816	119	11	40,238	99.7 +.2/-.8	99.6 +.3/-1	98.3 +.8/-1.6	98.0 +1/-1.6	98.0 +1/-1.6	98.0 +1/-1.6	98.0 +1/-1.6	98.0 +1/-1.6	98.0 +1/-1.6 at 114 mo.					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
3830	SelectSecure	Aug-05	15,300	13,000	2	0	3	2
4023	CapSure SP	Aug-91	41,200	8,700	17	0	3	8
4024	CapSure SP	Oct-91	222,300	51,200	26	0	125	41
4033	CapSure Z	Not US released	NA	NA	0	0	0	0
4067	CapSureFix	Jan-97	1,000	300	1	0	0	1
4068	CapSureFix	Mar-96	124,900	39,800	39	0	91	15
4073	CapSure Sense	Jun-02	600	400	0	0	0	0
4074	CapSure Sense	Jun-02	71,600	49,300	1	1	9	3
4076	CapSureFix Novus	Feb-04	257,000	208,200	10	0	7	15
4092	CapSure SP Novus	Sep-98	159,100	83,200	6	0	18	7
4523	CapSure SP	Aug-91	11,200	2,900	1	0	2	1
4524	CapSure SP	Oct-91	101,800	29,600	1	0	33	13
4533	CapSure Z	Not US released	NA	NA	1	0	0	0
4558M	Screw-in	Nov-94	20,000	4,900	1	1	16	1
4568	CapSureFix	Jan-97	69,800	28,800	2	0	22	6
4574	CapSure Sense	Jun-02	45,900	33,700	3	0	1	0
4592	CapSure SP Novus	Oct-98	78,100	43,300	3	0	5	1
5023, 5023M	CapSure SP	Nov-88	9,900	2,200	6	0	1	0
5024, 5024M	CapSure SP	Mar-90	201,600	52,000	50	10	46	39
5033	CapSure Z	Feb-96	2,400	600	1	0	0	3
5034	CapSure Z	Feb-96	56,300	15,600	14	1	14	13
5054	CapSure Z Novus	Jun-98	88,900	44,300	5	1	13	6
5068	CapSureFix	Jan-97	103,200	37,300	33	3	46	16
5072	SureFix	Jun-98	9,100	4,400	2	0	4	1
5076	CapSureFix Novus	Aug-00	1,163,300	797,600	188	0	181	144
5092	CapSure SP Novus	Jun-98	118,400	62,000	5	0	30	12
5524, 5524M	CapSure SP	Mar-90	60,600	19,500	10	2	12	8
5534	CapSure Z	Feb-96	26,300	8,500	3	0	5	5
5554	CapSure Z Novus	Jun-98	57,200	31,200	6	0	10	4
5568	CapSureFix	Jan-97	77,100	47,700	6	0	13	15
5592	CapSure SP Novus	Jun-98	29,800	18,500	1	0	3	0
5594	CapSure SP Novus	Jun-01	12,400	8,900	3	0	3	0
6940	CapSureFix	Oct-98	25,500	9,300	10	0	13	4

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
3830	SelectSecure	15,300	5	0	10	7	1	1	1	0	0	0
4023	CapSure SP	41,200	0	1	3	3	1	0	3	0	1	0
4024	CapSure SP	222,300	15	11	51	107	0	15	1	8	2	16
4067	CapSure Fix	1,000	1	0	0	0	0	0	0	0	0	0
4068	CapSure Fix	124,900	5	3	30	28	0	5	1	2	1	1
4074	CapSure Sense	71,600	4	0	7	18	0	0	0	1	0	0
4076	CapSure Fix Novus	257,000	16	2	33	21	0	6	1	6	2	1
4092	CapSure SP Novus	159,100	1	5	12	19	0	0	0	2	0	1
4523	CapSure SP	11,200	0	0	2	2	0	1	0	0	0	0
4524	CapSure SP	101,800	0	2	23	16	0	5	2	1	0	8
4558M	Screw-in	20,000	2	0	4	3	0	1	0	2	0	0
4568	CapSure Fix	69,800	3	1	4	6	0	1	0	2	0	1
4574	CapSure Sense	45,900	0	0	10	2	1	3	0	0	0	2
4592	CapSure SP Novus	78,100	0	0	10	5	0	2	0	1	0	2
5023, 5023M	CapSure SP	9,900	0	1	2	0	1	0	0	0	0	1
5024, 5024M	CapSure SP	201,600	11	7	26	48	1	10	5	3	3	9
5033	CapSure Z	2,400	0	0	1	0	0	0	0	0	0	0
5034	CapSure Z	56,300	4	6	15	31	0	3	2	0	0	10
5054	CapSure Z Novus	88,900	1	1	5	17	0	2	2	0	0	9
5068	CapSure Fix	103,200	15	3	21	32	0	5	1	2	0	2
5072	SureFix	9,100	0	0	2	0	0	0	0	1	0	0
5076	CapSure Fix Novus	1,163,300	65	9	194	127	12	24	6	16	7	16
5092	CapSure SP Novus	118,400	2	1	21	24	0	5	2	2	1	7
5524, 5524M	CapSure SP	60,600	1	4	15	11	0	9	2	0	0	8
5534	CapSure Z	26,300	0	0	4	3	0	1	0	0	2	4
5554	CapSure Z Novus	57,200	0	1	17	15	0	0	0	0	0	3
5568	CapSure Fix	77,100	3	0	13	11	0	3	1	1	1	1
5592	CapSure SP Novus	29,800	0	0	15	2	0	0	0	0	0	1
5594	CapSure SP Novus	12,400	0	0	0	0	0	0	0	0	0	2
6940	CapSure Fix	25,500	0	0	5	1	0	0	0	0	0	1

Report Cutoff Date: January 31, 2010

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
3830	SelectSecure	Transvenous V or A Screw-In	Polyurethane/Silicone (55D,4719)	MP35N 5 Filars/ Cable	1.8 mm Helix/Steroid	IS-1 BI
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
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
4092	CapSure SP Novus	Transvenous Ventricular Tines	Polyurethane/Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/ Steroid	IS-1 BI
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
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)
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)
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

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Pacing Leads continued

Reference Chart continued

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
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
6940	CapSureFix	Transvenous A or V Screw-In	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Epi/Myocardial Pacing Leads

4951, 4951M Spectraflex

Product Characteristics

US Market Release	Oct-81	Serial Number Prefix	TF or LBJ
Registered US Implants	23,100	Type and/or Fixation	Myocardial Stab-in, V or A, Peds
Estimated Active US Implants	2,300	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	56
Crimp/Weld/Bond	0
Insulation Breach	39
Other	29

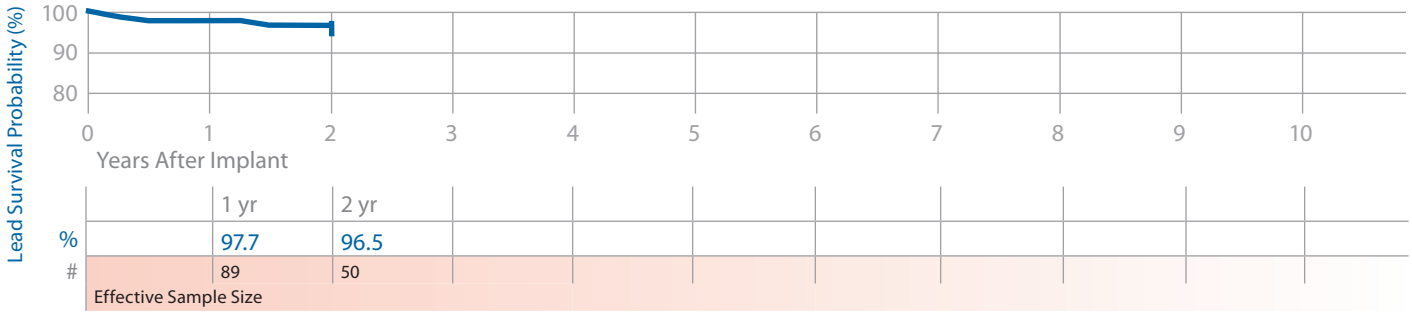
System Longevity Study Results

Number of Leads Enrolled in Study	179
Cumulative Months of Follow-Up	4,518
Number of Leads Active in Study	4

Qualifying Complications

14 Total

Conductor Fracture	1	Impedance Out of Range	1
Failure to Capture	7	Insulation (ESC)	1
Failure to Sense	3	Insulation (not further defined)	1



	1 yr	2 yr
%	97.7	96.5
#	89	50

Effective Sample Size

4965 CapSure Epi

Product Characteristics

US Market Release	Sep-96	Serial Number Prefix	LBT
Registered US Implants	18,700	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	9,200	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	105
Crimp/Weld/Bond	1
Insulation Breach	26
Other	2

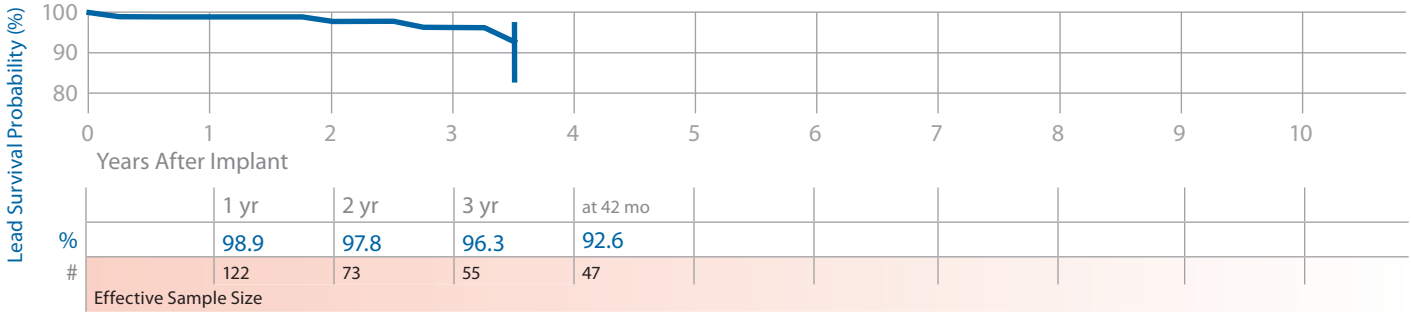
System Longevity Study Results

Number of Leads Enrolled in Study	207
Cumulative Months of Follow-Up	5,354
Number of Leads Active in Study	41

Qualifying Complications

8 Total

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



	1 yr	2 yr	3 yr	at 42 mo
%	98.9	97.8	96.3	92.6
#	122	73	55	47

Effective Sample Size

Epi/Myocardial Pacing Leads continued

4968 CapSure Epi

Product Characteristics

US Market Release	Sep-99	Serial Number Prefix	LEN
Registered US Implants	18,800	Type and/or Fixation	Epicardial Suture-On V or A
Estimated Active US Implants	11,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

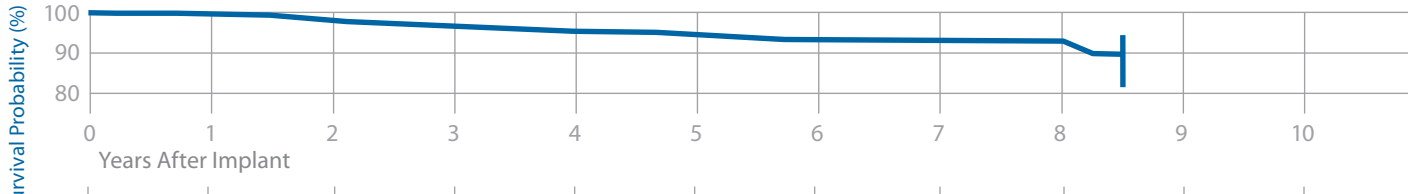
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	5
Other	0

System Longevity Study Results

Number of Leads Enrolled in Study	608
Cumulative Months of Follow-Up	27,547
Number of Leads Active in Study	360

Qualifying Complications 22 Total

Conductor Fracture	5	Impedance Out of Range	3
Failure to Capture	6	Insulation (not further defined)	1
Failure to Sense	4	Oversensing	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	99.6	97.6	96.5	95.3	94.3	93.0	93.0	93.0	89.9
#	487	381	289	219	163	123	85	59	49

Effective Sample Size

5071 Screw-in

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Registered US Implants	36,900	Type and/or Fixation	Myocardial Screw-in Vent.
Estimated Active US Implants	14,200	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	1
Other	5

System Longevity Study Results

Number of Leads Enrolled in Study	243
Cumulative Months of Follow-Up	5,536
Number of Leads Active in Study	43

Qualifying Complications 13 Total

Failure to Capture	10		
Oversensing	2		
Impedance Out of Range	1		

	1 yr	2 yr
%	96.7	93.7
#	124	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	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	4	14	4,518	97.7 +1.6/-4.8	96.5 +2.2/-5.8										
4965	CapSure Epi	Sep-96	207	41	8	5,354	98.9 +.8/-3.2	97.8 +1.5/-5	96.3 +2.4/-6.9	92.6 +4.3/-9.5 at 42 mo								
4968	CapSure Epi	Sep-99	608	360	22	27,547	99.6 +.3/-1	97.6 +1.1/-1.9	96.5 +1.4/-2.3	95.3 +1.8/-2.7	94.3 +2.1/-3.3	93.0 +2.5/-3.8	93.0 +2.5/-3.8	93.0 +2.5/-3.8	89.9 +4.1/-6.8 at 102 mo			
5071	(No brand name)	Dec-92	243	43	13	5,536	96.7 +1.8/-4	93.7 +3.1/-5.9										

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

Epi/Myocardial Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
4951, 4951M	Spectraflex	Oct-81	23,100	2,300	56	0	39	29
4965	CapSure Epi	Sep-96	18,700	9,200	105	1	26	2
4968	CapSure Epi	Sep-99	18,800	11,900	12	0	5	0
5071	Screw-in	Dec-92	36,900	14,200	6	0	1	5

Source: Returned Product Analysis
Data as of January 31, 2010

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Impedance Abnormal	Extracardiac Stimulation	Unspecified
4951, 4951M	Spectraflex	23,100	1	1	0	13	0	0	2
4965	CapSure Epi	18,700	0	0	1	2	2	0	0
4968	CapSure Epi	18,800	1	0	3	2	0	0	0
5071	Screw-in	36,900	1	0	0	17	3	1	1

Report Cutoff Date: January 31, 2010

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 B1
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

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

VDD Single Pass Pacing Leads

5032 CapSure VDD

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCL, LCN, LCM
Registered US Implants	5,400	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated Active US Implants	1,500	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	6
Crimp/Weld/Bond	0
Insulation Breach	7
Other	0

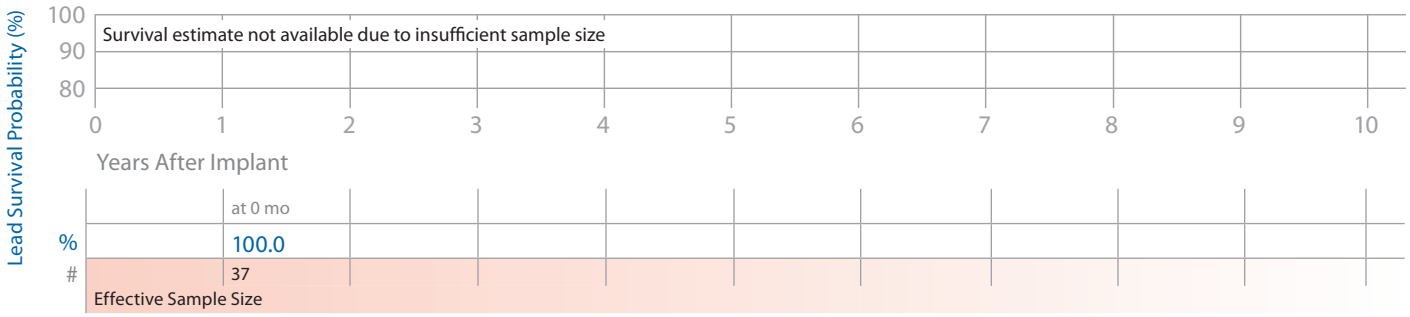
System Longevity Study Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	751
Number of Leads Active in Study	0

Qualifying Complications

1 Total

Failure to Sense	1



	at 0 mo
%	100.0
#	37

Effective Sample Size

5038 CapSure VDD-2

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEE, LEG, or LEF
Registered US Implants	8,500	Type and/or Fixation	Transvenous, Atr-Vent.,Tines
Estimated Active US Implants	3,700	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	1
Insulation Breach	1
Other	1

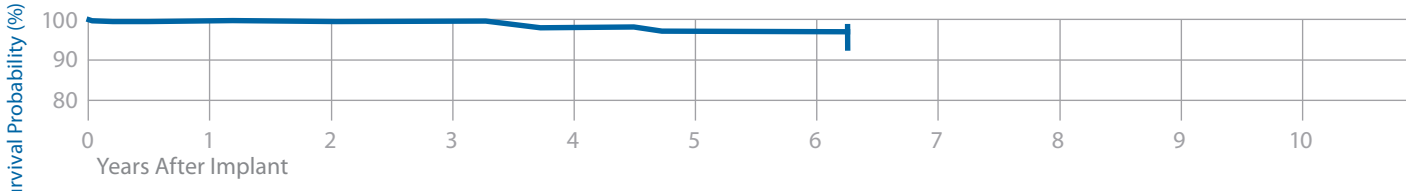
System Longevity Study Results

Number of Leads Enrolled in Study	552
Cumulative Months of Follow-Up	16,995
Number of Leads Active in Study	58

Qualifying Complications

5 Total

Conductor Fracture	2
Failure to Capture	1
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 75 mo
%	99.8	99.8	99.8	98.3	97.4	97.4	97.4
#	419	171	147	120	97	57	50

Effective Sample Size

Leads

VDD Single Pass Pacing Leads continued

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Leads Active in Study	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	0	1	751	100.0 at 0 mo									
5038	CapSure VDD-2	Sep-98	552	58	5	16,995	99.8 +.2/-1.4	99.8 +.2/-1.4	99.8 +.2/-1.4	98.3 +1.2/-3.9	97.4 +1.7/-4.6	97.4 +1.7/-4.6	97.4 +1.7/-4.6 at 75 mo			

Source: System Longevity Study
Data as of January 31, 2010

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/ Bond	Insulation Breach	Other
5032	CapSure VDD	Mar-96	5,400	1,500	6	0	7	0
5038	CapSure VDD-2	Sep-98	8,500	3,700	3	1	1	1

Source: Returned Product Analysis
Data as of January 31, 2010

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Lead Dislodgement	Failure to Capture	Failure to Sense	Extracardiac Stimulation
5032	CapSure VDD	5,400	1	4	1	0
5038	CapSure VDD-2	8,500	0	1	0	1

Report Cutoff Date: January 31, 2010

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

Source: Medtronic Device Registration and Returned Product Analysis
Data as of January 31, 2010

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 products 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 6-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 6-month interval, a conservative approach has been adopted whereby only the maximum charge time 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.

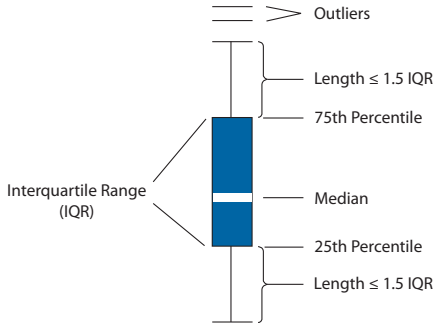
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

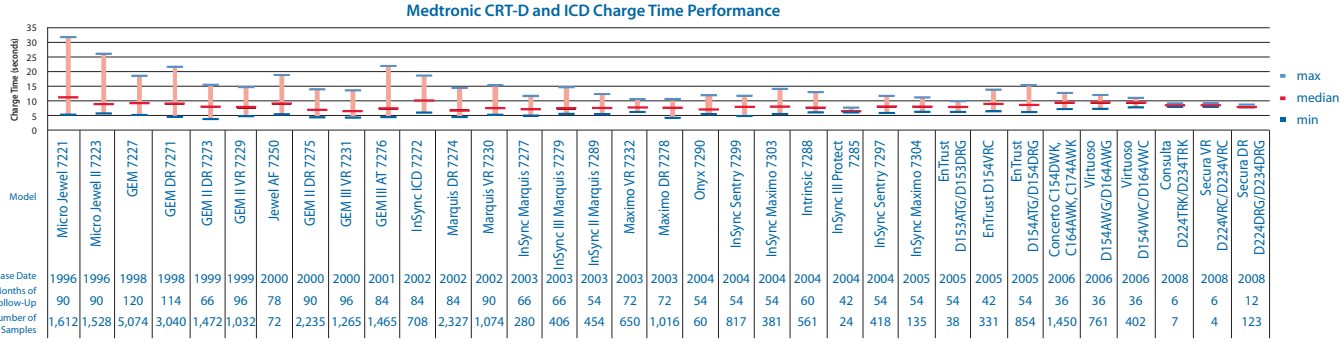
Data Presentation

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 third quartile or the 75th percentile (i.e., 75% of all charge times fall below this line), whereas the bottom of the box represents the first quartile or the 25th percentile. Vertical lines are drawn from the quartiles to the farthest value not more than 1.5 times the interquartile range. Any values more extreme than the vertical lines are considered outliers.

Results

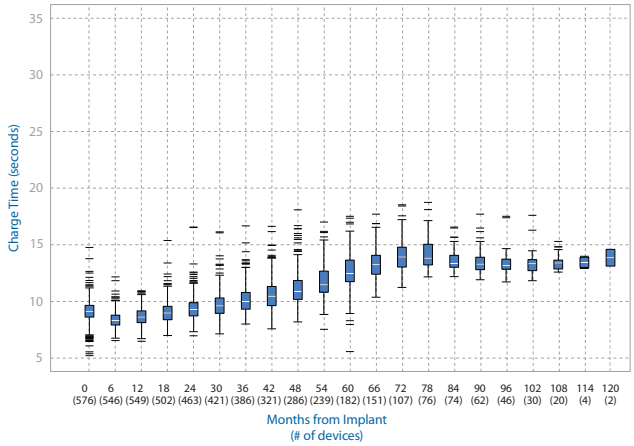
The graph below shows the overall maximums, minimums, and medians for Medtronic ICD and CRT-D products, beginning with the 7221 Micro Jewel.



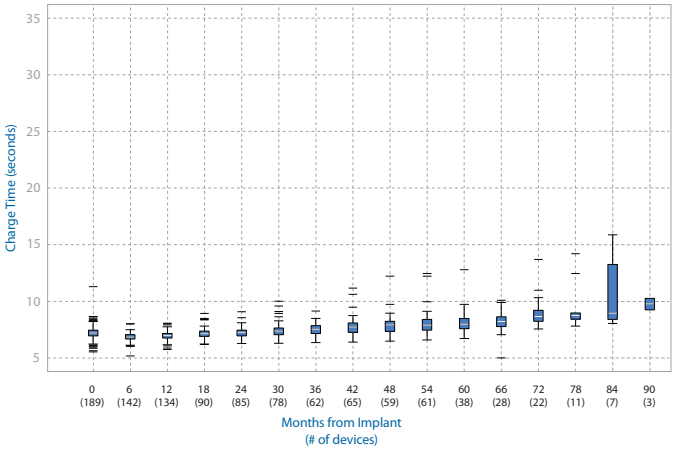


ICD and CRT-D Charge Time Performance continued

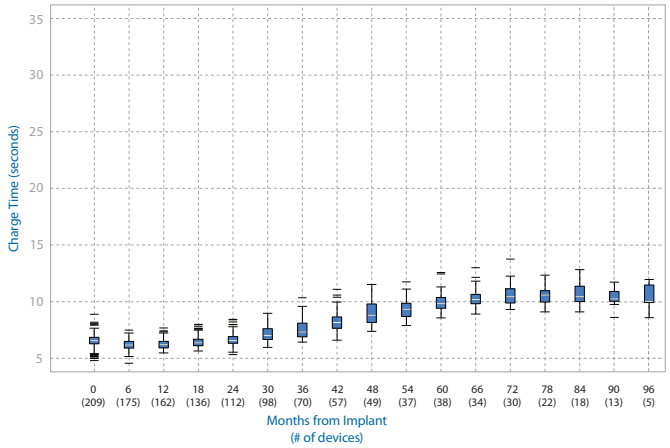
7227 GEM Charge Time



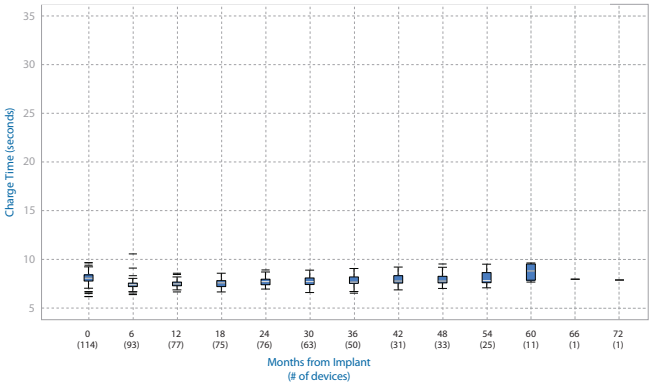
7230 Marquis VR Charge Time



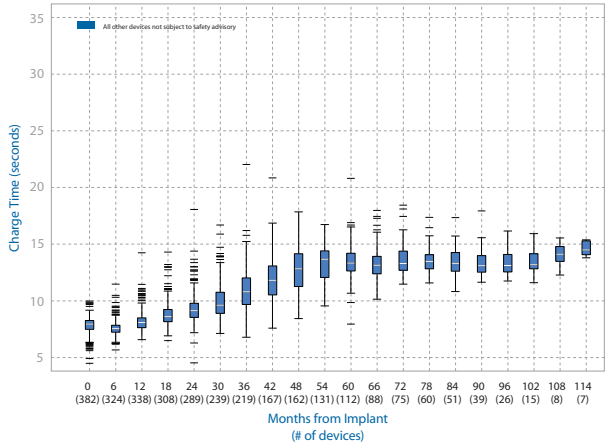
7231 GEM III VR Charge Time



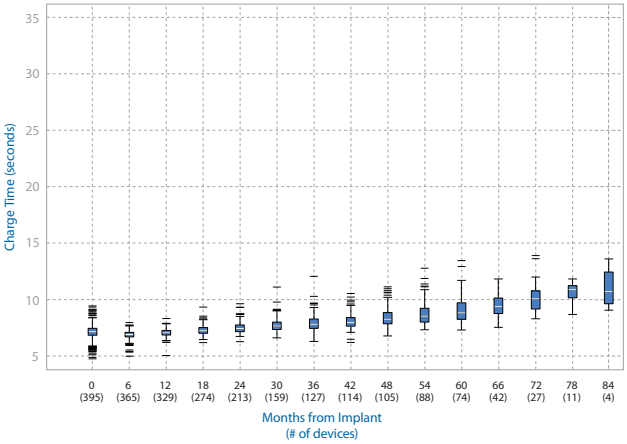
7232 Maximo VR Charge Time



7271 GEM DR Charge Time



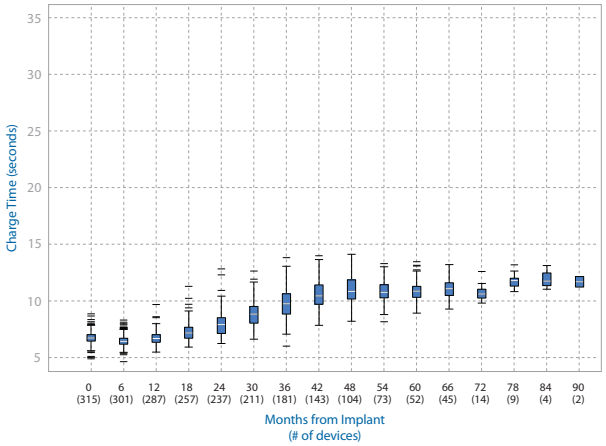
7274 Marquis DR Charge Time



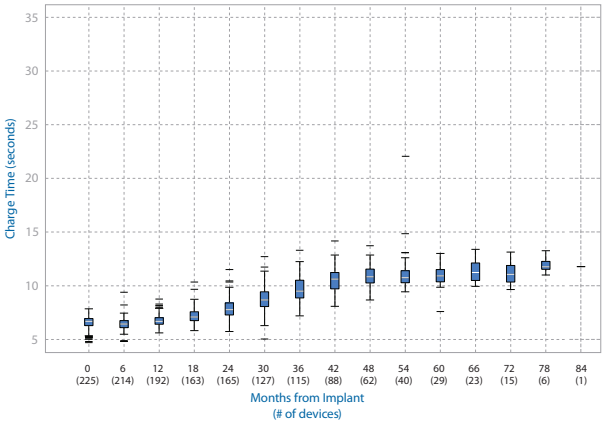
Source: System Longevity Study
Data as of January 31, 2010

ICD and CRT-D Charge Time Performance continued

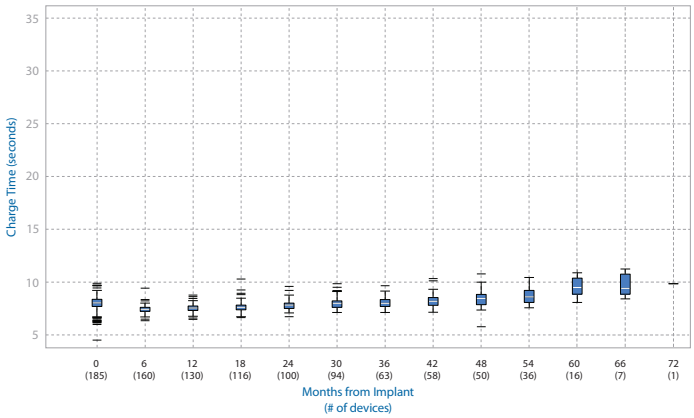
7275 GEM III DR Charge Time



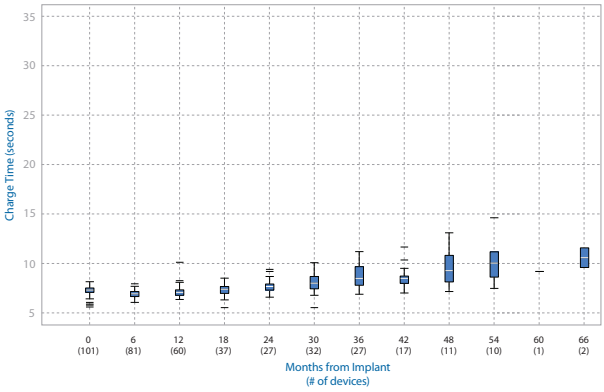
7276 GEM III AT Charge Time



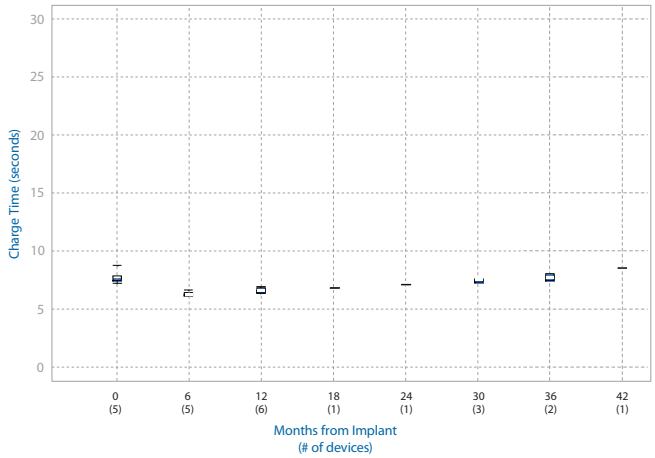
7278 Maximo DR Charge Time



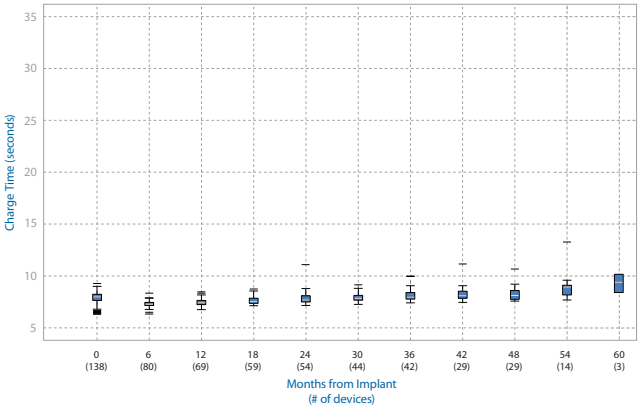
7279 InSync III Marquis Charge Time



7285 InSync III Protect Charge Time



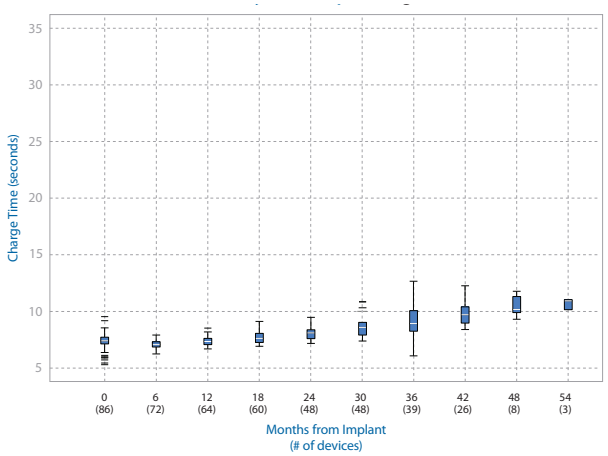
7288 Intrinsic Charge Time



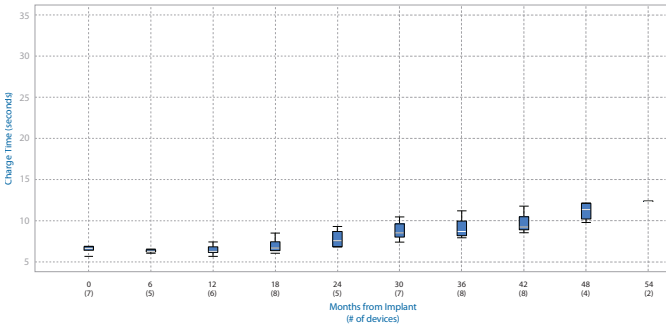
Source: System Longevity Study
Data as of January 31, 2010

ICD and CRT-D Charge Time Performance continued

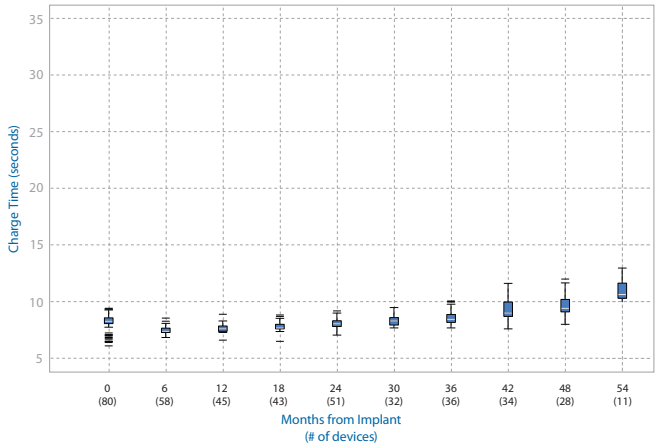
7289 InSync II Marquis Charge Time



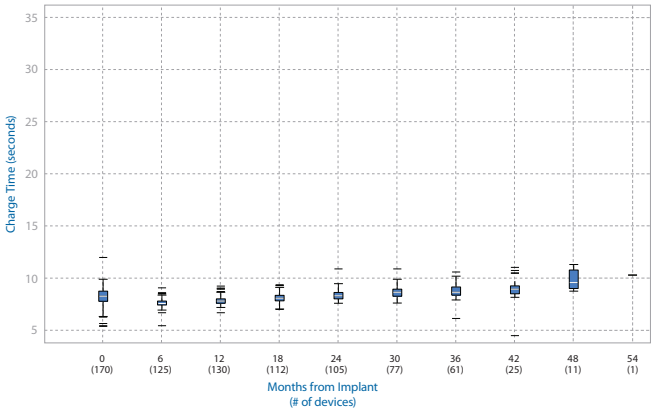
7290 Onyx Charge Time



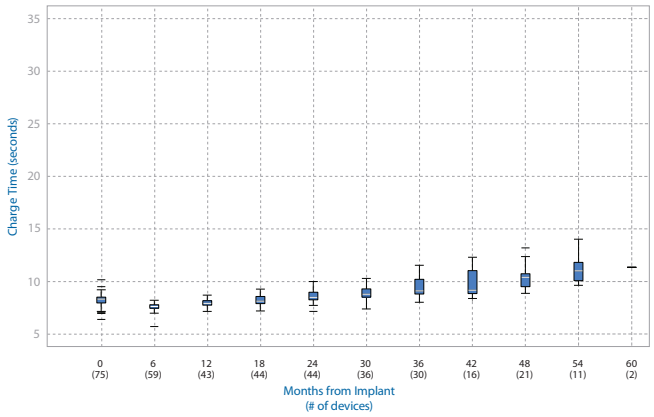
7297 InSync Sentry Charge Time



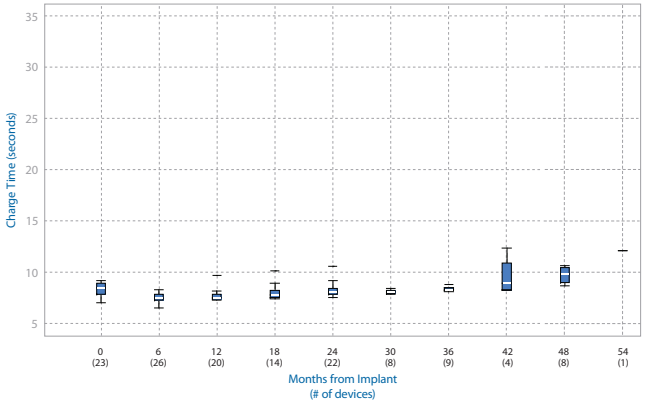
7299 InSync Sentry Charge Time



7303 InSync Maximo Charge Time



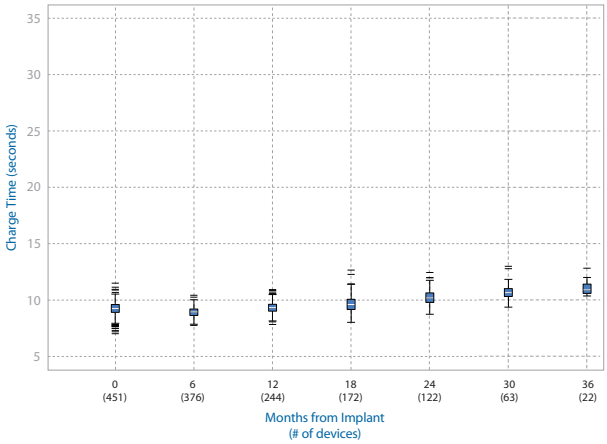
7304 InSync Maximo Charge Time



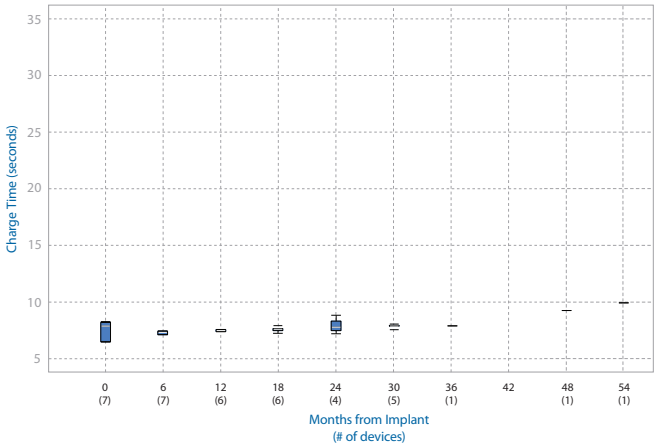
Source: System Longevity Study
Data as of January 31, 2010

ICD and CRT-D Charge Time Performance continued

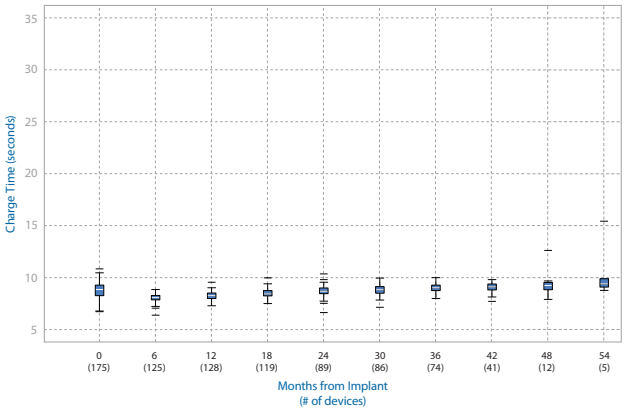
C154DWK Concerto Charge Time



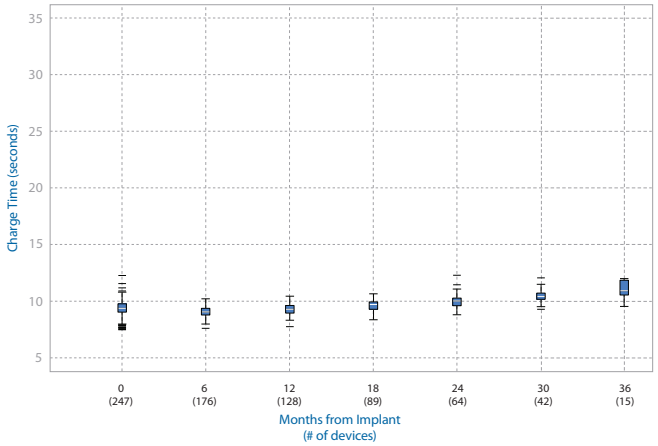
D153ATG, D153DRG EnTrust Charge Time



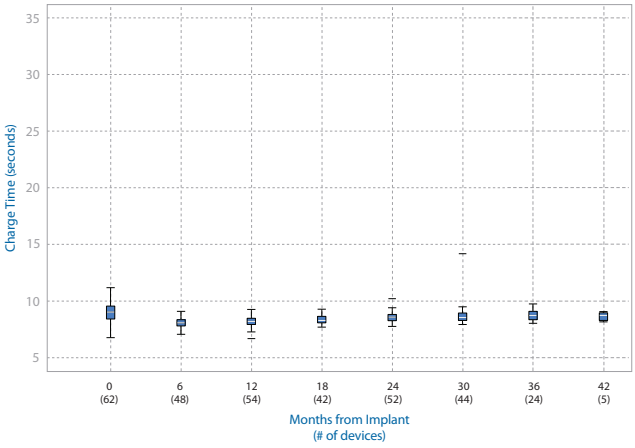
D154ATG, D154DRG EnTrust Charge Time



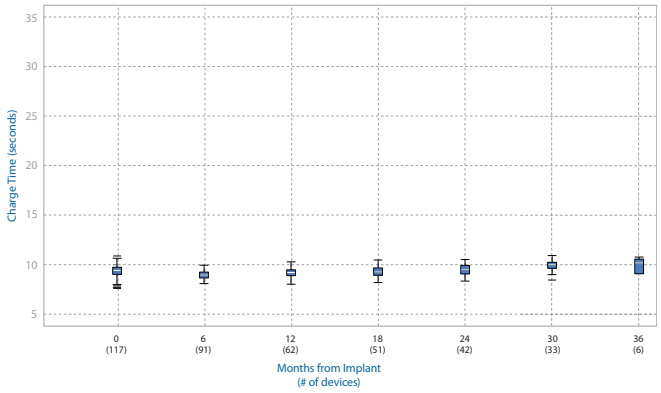
D154AWG Virtuoso Charge Time



D154VRC EnTrust Charge Time



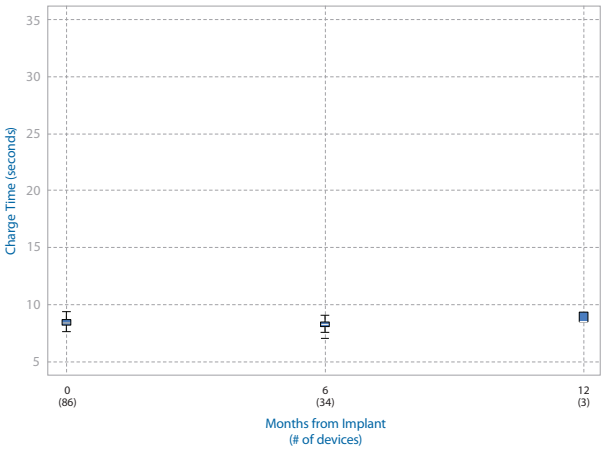
D154VWC Virtuoso Charge Time



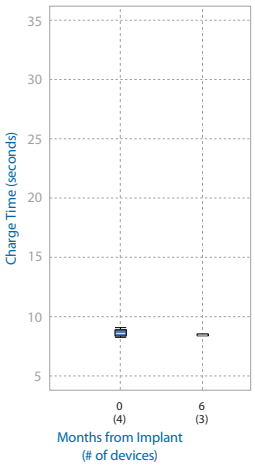
Source: System Longevity Study
Data as of January 31, 2010

ICD and CRT-D Charge Time Performance continued

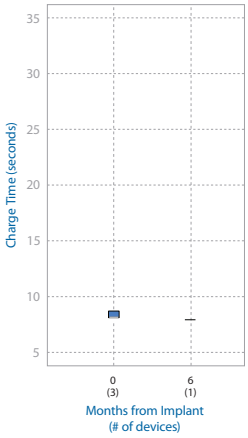
D224DRG, D234DRG Secura DR Charge Time



D234TRK Consulta Charge Time



D234VRC Secura VR Charge Time



Source: System Longevity Study
Data as of January 31, 2010

Advisories

EnRhythm Pacemakers

Original Date of Advisory: February 2010

Low Battery Voltage Displayed at Device Interrogation

Product

All EnRhythm pacemakers.

Advisory

Two specific battery issues with EnRhythm pacemakers have been identified and both will be addressed by a Medtronic software update available mid-2010. EnRhythm devices were commercially released in 2005, and these devices have been implanted for less than 5 years.

First Issue

As of February 2010, Medtronic had received 62 reports (out of approximately 110,000 devices worldwide) indicating that the battery voltage at device interrogation was lower than the battery voltage that is tracked by the device to provide data for the elective replacement indicator (ERI) notification. The lower voltage measurement has caused confusion and occasionally has resulted in unnecessary explants.

Medtronic's investigation has shown that none of these reports have resulted in loss of therapy. Importantly, the ERI notification, which uses the nightly battery measurement, is unaffected and accurate. Medtronic has identified the root cause as higher than expected battery resistance.

Medtronic's internal testing has shown that there is no current risk for compromised therapy delivery. If the software update referenced above is not implemented, there will be a potential risk of loss of device functionality in a small percent (less than 0.08% 6 years post-implant) of devices. The software update will eliminate this risk.

Patient Management Recommendations

Medtronic recommends physicians continue to use the ERI notification to determine time for device replacement. At this time, no other action, reprogramming, or change in the frequency of follow-up is recommended.

Second Issue

Through internal accelerated testing, Medtronic has identified a second issue that projects battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion. This issue has not been clinically observed and is not expected to occur for another 4 years (approximately 9 years post-implant). If the software update referenced above is not implemented, there may be a potential risk for loss of therapy at or near ERI in a small number of devices. The software will eliminate this issue by changing ERI criteria.

Summary

The software update will eliminate any potential future risk of the two battery issues described above by changing the ERI criteria. This update will reduce longevity of these devices by approximately 10-15%, but the expected average longevity will still be 8.5 to 10.5 years depending on device settings.[1] At this time, no other action, reprogramming, or change in the frequency of patient follow-up is recommended. Your Medtronic representative will notify you when the software update is available, following regulatory approval.

[1] The 8.5 year estimate represents a high use scenario (DDD, 100% pacing in atrium and ventricle with 3.0 V output in both chambers). The 10.5 year estimate represents a typical use scenario for a sinus node dysfunction patient with the MVP function ON (AAI(R) <=> DDD(R), 50% pacing in atrium and 5% pacing in ventricle with 3.0 V output in both chambers).

Concerto CRT-D and Virtuoso ICD

Original Date of Advisory: September 2009

Potential Reduced Device Longevity

Product

A subset of Concerto CRT-D and Virtuoso ICD devices may not meet expected device longevity. Specific model and serial numbers of affected devices are available online at: http://cvsnlist.medtronic.com/

Advisory

A subset of Concerto CRT-D and Virtuoso ICD devices may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation. This issue may present in the affected devices as reaching the Recommended Replacement Time (RRT) earlier than projected. This issue does not compromise device functionality or affect therapy delivery.

Based on information from returned devices, Medtronic expects that affected devices will continue to provide at least 3 months of normal device function between RRT and End of Service (EOS) as described in device labeling.

A total of 8,900 devices worldwide are affected by this advisory. An estimated 6,300 of these devices were active at the time of the original advisory communication.

Concerto and Virtuoso devices in the affected subset were manufactured primarily in 2006 and can be traced to a specific subset of low voltage capacitors.

Patient Management Recommendations

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients with devices in the affected subset:

Physicians should continue routine follow-up sessions at least every 3 months in accordance with product labeling.

Physicians should verify that the Low Battery Voltage RRT alert is programmed to "On-High." This provides an audible, alternating tone when the device reaches RRT. These devices are shipped with this alert programmed nominally to "On-High."

Physicians may consider monitoring patients through CareLink. The CareLink home monitor can be used to automatically notify the clinician when the device reaches RRT.

Status Update

As of January 31, 2010, 1,344 devices out of approximately 8,900 devices worldwide have been confirmed as having exhibited this capacitor degradation. To date, there have been no related confirmed failures in Concerto and Virtuoso devices outside of this subset, including devices that were manufactured during the same time.

Out of the initial advisory population of 8,900 worldwide, approximately 3,000 remain implanted. Approximately 2,400 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)
8,900 Implanted worldwide (**7,000** United States)	**1,344** Worldwide (**1,148** United States)	**3,000** Worldwide (**2,400** United States)	**15%** Worldwide (**16%** United States)

Kappa 600/700/900 Pacemakers
Sigma 100/200/300 Pacemakers

Original Date of Advisory: May 2009

Potential Separation of Interconnect Wires

Product

A specific subset of Kappa and 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://kappasigmasnlist.medtronic.com

Advisory Population

Specific subsets of Kappa and Sigma series pacemakers may fail at a higher than expected rate due to separation of wires that connect the electronic circuit to other pacemaker components (e.g., battery, connector). This may present clinically as loss of rate response, premature battery depletion, loss of telemetry, or no output.

Some patients, whose devices experience a wire separation resulting in a loss of pacing output, will experience a return of bradycardia symptoms (e.g., fainting or lightheadedness). In rare cases involving pacemaker dependent patients, loss of pacing output may result in death or serious injury.

Since 1997, there have been over 1.7 million Kappa and Sigma devices implanted worldwide. . At the time of the original advisory communication, an estimated 15,200 Kappa and 6,100 Sigma devices affected by the advisory remained implanted and active. These devices were manufactured primarily between November 2000 and November 2002. Most of these devices have been implanted in patients for five years or longer and may be nearing normal elective replacement time.

There is no provocative testing that can predict which specific devices may fail, and no device programming can mitigate this issue if it occurs.

Patient Management Recommendations

We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients:

- Physicians should advise their patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness).
- Physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets. Medtronic will offer a supplemental device warranty if the device is not already at elective replacement time.
- Physicians should continue routine follow-up in accordance with standard practice for those patients who are not pacemaker dependent.

Status Update

Advisory Population

Patient management recommendations remain unchanged. As of January 31, 2010, Medtronic has observed 415 Kappa devices and 205 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.71% (Kappa) and 1.37% (Sigma) of the original affected implant population.

Three hundred eighty six (386) of the Kappa devices (0.66%) and 157 of the Sigma devices (1.05%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 29 Kappa devices (0.05%) and 48 Sigma devices (0.32%) 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 remaining devices are conservatively categorized as having experienced interconnect wire separation while implanted.

Our modeling predicts failure rates of 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime of these pacemakers due to this issue.

Out of the initial advisory population of 58,300 Kappa devices and 14,900 Sigma devices worldwide, approximately 7,400 Kappa devices and 4,000 Sigma devices remain implanted. Of these, approximately 2,200 Kappa and 1,000 Sigma devices are in the United States.

Continued Vigilance

Included in the advisory communication was information about an additional subset of Kappa devices where we have observed a much lower rate of occurrence of this issue. Approximately 75,000 devices of this subset remain active. We have observed a failure rate of approximately 0.06% in this subset and our modeling predicts a failure rate of 0.12% over the remaining device life. After review with our Independent Physician Quality Panel, we do not recommend any specific actions for this group of devices. We will continue to monitor performance and inform you if any specific patient management recommendations are warranted.

continued

Kappa 600/700/900 Pacemakers
Sigma 100/200/300 Pacemakers

Original Date of Advisory: May 2009

Potential Separation of Interconnect Wires, continued

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted Population
Kappa Pacemakers				
58,300 Implanted Worldwide (est.) (**17,600** United States)	**386** Worldwide (**206** United States) with information indicating a clinical presentation. An additional **29** worldwide (**19** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**7,400** Worldwide (**2,200** United States)	**0.71%** Worldwide **1.28%** (United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**157** Worldwide (**34** United States) with information indicating a clinical presentation. An additional **48** worldwide (**11** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**4,000** Worldwide (**1,000** United States)	**1.37%** Worldwide **1.21%** (United States)	**4.8%**

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Potential Conductor Wire Fracture

Product

All Model 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 approximately 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.

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 (8/24) 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, Virtuoso, Consulta, Secura and Maximo II 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

Status Update

Sprint Fidelis lead performance continues to be in line with the information provided in the October 2007, May 2008 and March 2009 advisory communications. In consultation with the Independent Physician Quality Panel, our patient management recommendations are as follows:

- When a lead fracture is suspected or confirmed, we strongly recommend prompt patient attention. Patients should contact their physician without delay if they experience unexpected shocks.
- The Lead Integrity Alert (LIA†) is expected to provide 3 days advance notice prior to inappropriate therapy to 76% of the patients with lead fractures. As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly.
- The risk of prophylactic intervention appears to be greater than the risk of serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician
- Special circumstances may apply to device change-out or upgrade procedures when a lead fracture has not occurred. At least four options are available, each of which carries risks and benefits that should be taken into consideration:
  - Leave a properly performing lead intact; this is likely to be the best choice for the majority of patients
  - Place a new ICD lead without extraction of the existing lead
  - Place a pace sense lead without the extraction of the existing lead. This option reflects the observation that approximately 90% of Fidelis failures are related to fractures in the pace sense circuit. It is unknown what the failure rate of the high voltage conductor would be should a pace sense conductor failure occur in the existing Sprint Fidelis lead.
  - Unusual patient circumstances may warrant extracting and implanting a new ICD lead. Factors to consider when making this decision include patient life expectancy, age, and comorbidities, number of implanted leads and duration of implant, and patient preference. **Medtronic's Independent Physician Quality Panel recommends that if a lead requires removal, the procedure be performed by a physician with extensive lead extraction experience.**

As of January 31, 2010, of the initial implant population of 204,000 in the United States, approximately 133,000 remain implanted. According to System Longevity Study results, lead survival is estimated to be 94.2 (+1.7/-2.3) at 57 months. As the implanted population ages and the sample size increases for each time interval, the accuracy of the estimated survival probability will increase as shown by tighter confidence intervals.

As part of our commitment to keep you informed about Sprint Fidelis lead performance, Medtronic publishes the quarterly System Longevity Study's all-cause lead survival curve and the CareLink dataset lead survival curve for the Model 6949 lead at: www.medtronic.com/fidelis. Semi-annual updates will also continue to be provided in the Product Performance Report. Additional information about the Sprint Fidelis lead is available at: www.medtronic.com/fidelis.

Lead Integrity Alert†

Medtronic has released Lead Integrity Alert (LIA) software. LIA was designed to provide patients more advance notice via an audible sound of a potential lead fracture that could result in an unnecessary shock.

Data show that with LIA, approximately 76% of the patients with Sprint Fidelis leads are expected to receive 3 or more days advance warning of a potential lead fracture that could result in an unnecessary shock.

Upon hearing the alert, patients should contact their physician without delay.

LIA can be downloaded into nearly all Medtronic implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) implanted worldwide.

† LIA software released September 2008

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.

No provocative testing can predict which devices may fail.

Patient Management Recommendations

Recommendation for the management of patients who have pacemakers affected by this advisory were changed in May 2009. Current recommendations are:

We realize that each patient requires unique clinical consideration and we support your judgment in caring for your patients. After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following recommendations for patients in the 2005 Sigma advisory:

- Physicians should advise their patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness).
- Physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets. Medtronic will offer a supplemental device warranty if the device is not already at elective replacement time.
- Physicians should continue routine follow-up in accordance with standard practice for those patients who are not pacemaker dependent.

Status Update

Patient management recommendations remain unchanged. As of January 31, 2010, 522 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Two hundred thirty seven (237) of the Sigma devices (0.57%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 285 Sigma devices (0.70%) 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 remaining devices are conservatively categorized as having experienced interconnect wire separation while implanted.

Our original modeling predicted a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. However, updated modeling now predicts a failure rate of 3.9% over the remaining device life.

Out of the initial advisory population of 40,000 worldwide, approximately 11,000 remain implanted. Approximately 2,700 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted Population
40,000 Implanted Worldwide (est.) (**9,900** United States)	**237** Worldwide (**54** United States) with information indicating a clinical presentation.An additional **285** worldwide (**54** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**11,000** Worldwide (**2,700** United States)	**1.3%** Worldwide **1.1%** (United States)	**3.9%**

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 3 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

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections. As of January 31, 2010, 171 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. One hundred (100) of these devices were returned from the United States.

Out of the initial advisory population of 87,000 worldwide, approximately 16,000 remain implanted. Approximately 14,000 of these are in the United States.

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

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted Population
87,000 Implanted Worldwide (**76,000** United States)	**171** Worldwide (**100** United States)	**16,000** Worldwide (**14,000** United States)	**0.20%** Worldwide (**0.13%** United States)	Consistent with Medtronic projections, the observed rate of shorting may increase to between **0.2%** and **1.5%** over the second half of device life.

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 has 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

Patient management recommendations remain unchanged. As of January 31, 2010, 320 out of approximately 180,000 distributed (0.18% incidence) Kappa family devices worldwide have been confirmed as having fractured power supply wires. One hundred sixty-five (165) of these devices were returned from the United States. Out of the initial implant population of 121,000 in the United States, approximately 5,900 remain implanted.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted Population
180,00 Active Worldwide at time of advisory (**121,000** United States)	**320** Worldwide (**165** United States)	**9,000** Worldwide (**5,900** United States)	**0.18%** Worldwide (**0.14%** United States)	**0.03%**

Minix and Minix ST IPGs

Original Date of Advisory: May 6, 1991

Potential Delayed Restoration of Permanent Settings

Product

All Models of the Minix and Minix ST 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 3,500 remain implanted. The devices affected by this advisory are nearing the end of their expected longevity.

Performance Notes

Potential Malfunction of CRT, ICD, and IPG Products due to Anomalies in MOSFET Integrated Circuit Technology

Medtronic has detected a specific pattern of MOSFET IC malfunctions in its Concerto, Virtuoso and EnRhythm family of devices. As of July 2009, Medtronic has confirmed twenty-eight (28) malfunctions related to this pattern out of 115,000 EnRhythm and 233,000 Concerto/Virtuoso products distributed worldwide. Reliability analysis of this pattern shows the probability of occurrence decreases with time and, to date over 90% of the malfunctions related to the pattern have occurred within the first twelve months after implant. With process improvements in place, Medtronic expects few, if any, additional malfunctions related to this pattern.

The pattern involves metal-oxide-semiconductor field-effect transistors (MOSFET). A MOSFET is an electronic circuit used to amplify or switch electronic signals. MOSFETs have been used in the electronics industries for decades and MOSFET technology is the most widely used type of integrated circuit. Medtronic uses this technology in the circuitry of its CRT, ICD, and IPG products. Each product contains thousands of MOSFETs in its electronic circuitry.

Each MOSFET depends on a layer of insulating material to electrically isolate its components. The integrity of this insulating layer is important to the operation of the MOSFET. Variation in the thickness of the insulating layer can cause the MOSFET to operate in an undesirable manner. Process variations for electronic circuits can affect the integrity of the insulating material, and can lead to MOSFET malfunction. Medtronic's quality system strives to control process variation and detect undesired anomalies that are characteristic of all MOSFET manufacturing. In addition, Medtronic's post-market vigilance activities monitor malfunctions and may implement screening and testing improvements when a pattern of related malfunctions is identified.

The pattern with the Concerto, Virtuoso and EnRhythm models has presented clinically as high lead impedance, sensing difficulty, loss of pacing therapy and/or early battery depletion due to higher than normal battery drain. The degree of battery drain varies case by case, such that the time from the onset to battery depletion has ranged from several days to several months. If not detected by normal patient follow-up procedures, the use of patient alerts or CareLink remote monitoring, the battery will fully deplete, leaving the patient without therapy.

As of March 2009, Medtronic has implemented additional electrical screening and stress tests to address this specific pattern for products being sold.

Since these rates of malfunction are low and the probability of occurrence decreases with time, Medtronic recommends physicians continue following patients in accordance with standard practice.

Clinical Management of VCM near Elective Replacement

Background

Medtronic Technical Services has received reports of devices going to ERI or end of life (EOL) sooner than expected after a normal follow-up in which the device longevity was projected to be approximately 18 months. It has been noted that these cases typically involve Kappa 700 devices where Ventricular Capture Management set the ventricular lead to high output (5 V, 1 ms), which occurs by device design when a high threshold is measured. It is important for physicians and allied professionals to understand VCM behavior as it relates to longevity so that they can, in turn, understand how this affects management of the device and follow-up visits as VCM equipped IPGs near the end of their expected longevity.

Device Longevity and VCM Behavior

Ventricular Capture Management is a feature that uses evoked response sensing to determine the stimulation threshold needed to capture the ventricular chamber. Proper detection of the evoked response is crucial to the VCM algorithm determining an accurate capture threshold. There are rare conditions, however, during which the VCM algorithm will not be able to measure the evoked response accurately.[1] When this occurs, for safety reasons the VCM algorithm will reprogram the output to 5 V, 1 ms until the subsequent VCM measurement.

If the device has considerable remaining longevity, these occasional excursions to high output do not substantially affect remaining longevity. However, if the device has less than approximately 18 months remaining longevity, there is the possibility that the high output condition caused by the 5 V, 1 ms output will drain the battery and trigger ERI.

When ERI is declared by the device, VCM is disabled and the outputs are left at 5 V, 1 ms until the device is reprogrammed at an in-office follow-up. This increased current drain of a high output condition will speed depletion of the device, possibly resulting in the device getting to the EOL (battery voltage ≤ 2.15 V).

Please note that the following parameter changes occur when the device goes to ERI:

Table: IPG Therapy Parameter Changes at ERI

Parameter	Value
Pacing Mode	VVI
Lower Rate	65 bpm
Single Chamber Hysteresis	OFF
Sleep Function	OFF
Ventricular Capture Management	OFF
Atrial Sensing Assurance	OFF
Ventricular Sensing Assurance	OFF

Kappa 700 is Medtronic's first-generation VCM algorithm, which has a relatively higher incidence of evoked response undersensing compared to subsequent algorithms, resulting in more frequent high output conditions. Therefore, Kappa 700 products are the primary focus of this note. It should be noted that IPGs equipped with the second-generation VCM algorithm (Kappa 900, EnPulse, Adapta/Versa/Sensia, and Relia) have not been observed with evoked response undersensing in the general population, though the items listed in "Follow-Up Considerations" may also be used on these devices.

Follow-Up Considerations

- Estimated longevity in the event the device goes to high output can be determined by the following steps. This allows the clinician to determine follow-up frequency if he or she is concerned the device may go to ERI due to high output.
  - Program the ventricular channel to 5 V, 1 ms
  - Navigate to Data/Battery and Lead Measurements
  - When the message stating "Warning – Old Data" is displayed, select "Yes" to measure battery voltage and lead impedance at the new ventricular outputs
  - An updated remaining longevity estimate will be calculated on the elevated outputs. Note the "Minimum Remaining Longevity." Clinical decisions can be based on this value.
  - Program the Amplitude and Pulse Widths back to their original values before leaving the session
- If the capture trends and lead impedance trends are stable, VCM can be programmed to "Monitor Only" for the remaining device life. This should be considered only if remaining longevity is 18 months or less.
- Follow-up frequency can be increased for those patients who do not have stable capture or lead impedance trends. This can be done via a CareLink Home Monitor, or in-office.

[1] Medtronic, Inc. (2001). Medtronic Kappa 700/600 Series Pacemaker Reference Guide (Chapter 4, p. 27). Can be retrieved from http://manuals.medtronic.com.

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

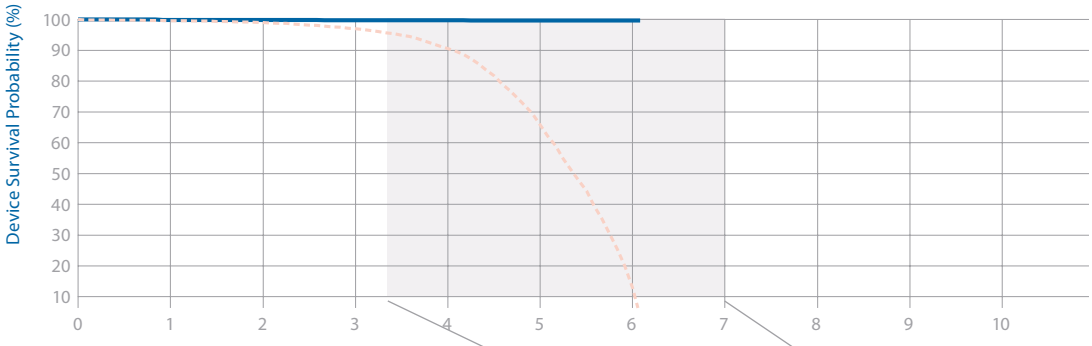
The survival curves in the Product Performance Report represent the composite experience of thousands of devices over a wide range of programming options and patient use conditions. While the curves are useful for understanding the overall performance of a population of devices, they cannot be used to 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 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.

EXAMPLE



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
%	———	99.9	99.9	99.8	99.7	99.7	99.7
%	- - - -	99.6	99.0	96.9	90.1	64.5	8.8
#		18,000	15,000	13,000	10,000	5,000	300

Effective Sample Size

Estimated Longevity

Charging Frequency**	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. 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 > 1,000 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, 1,000-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 that 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 versus ensuring ventricular rate support must be weighed when choosing optimal hardware (ICD vs. pacemaker) and pacemaker programming (pacing mode, lower rate, etc.).

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AT500 Pacing System Follow-Up Protocol

Purpose of This Information

This article is intended to provide clinical guidance regarding follow-up practice and patient management when the AT500 battery voltage approaches the Elective Replacement Indicator (ERI) level of 2.6 volts.

Background

Many AT500 pacing systems are now reaching their ERI voltage level (2.6 volts). This is expected since the battery used has an approximate longevity of 5-6 years under normal conditions (100% DDD pacing, 3 volts, 0.4 ms).

Technical Services has received reports of battery voltage levels below end of life (EOL of 2.2 volts) where EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary. It is important for physicians and allied professionals to understand battery depletion characteristics between ERI and EOL so that they, in turn, can understand how this affects management of follow-up visits for the AT500 as this device nears the end of its expected longevity.

AT500 Battery and Longevity Information

In contrast to other IPGs, the AT500 does not change its mode, stimulation rate, or any other parameter when the battery voltage drops below the ERI level of 2.6 volts (with or without magnet applied). The Threshold Margin Test (TMT) is also not available.

Therefore, it is not possible to perform transtelephonic 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 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.

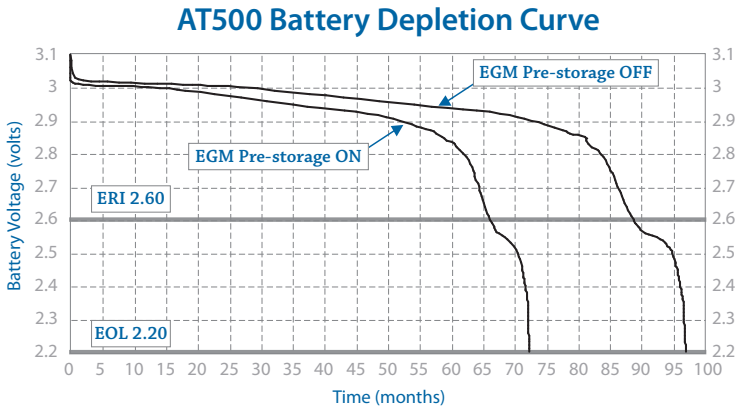

Figure 1

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 one 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 performance note, "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]

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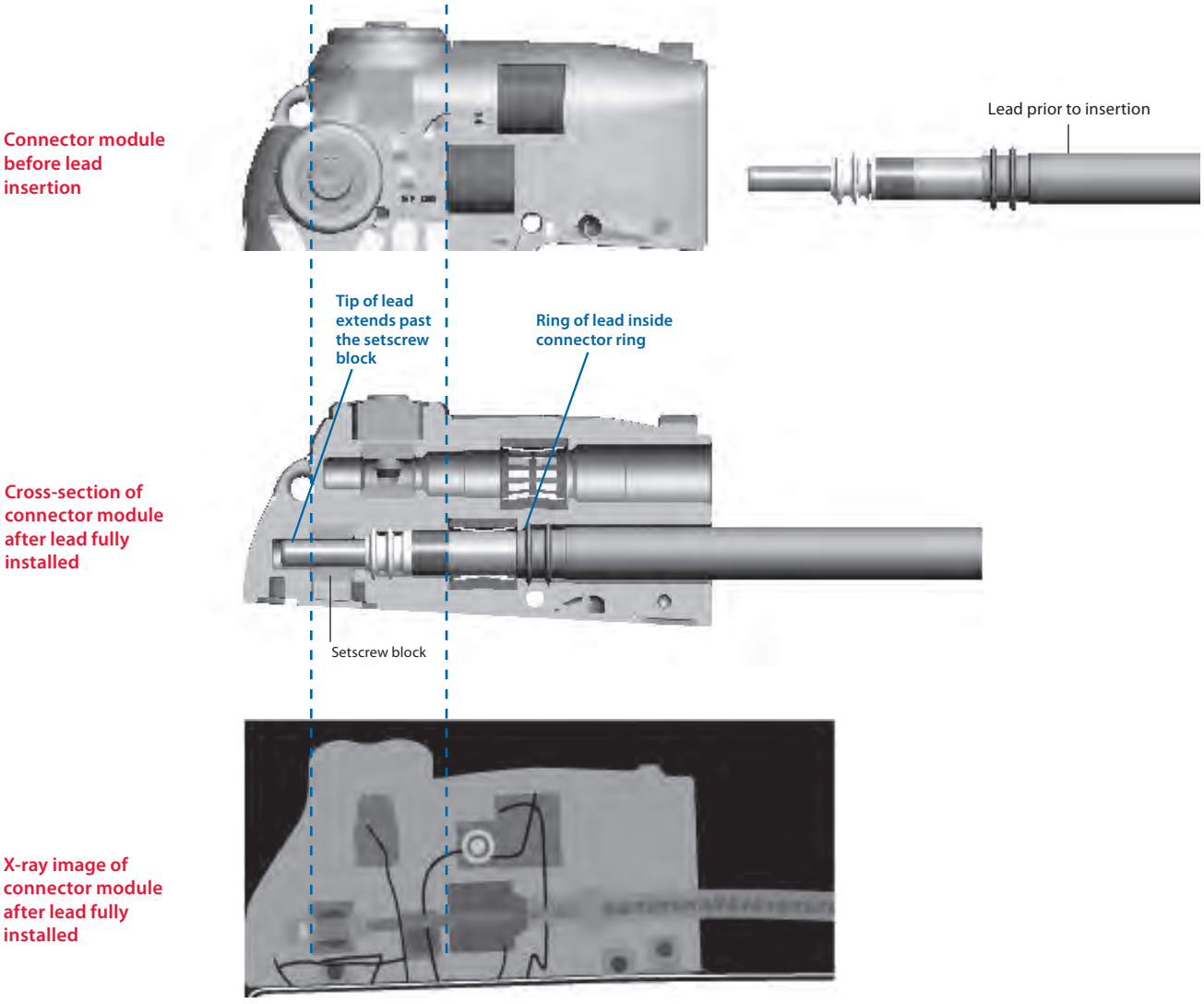


GEM II DR/VR and GEM III DR/VR/AT ICD Battery Discharge Behavior

Medtronic manufactured and utilized 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.

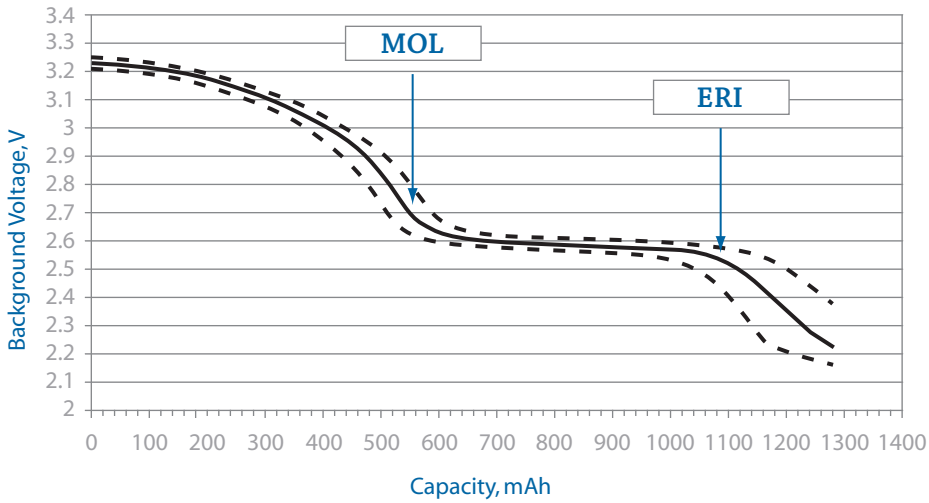
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

As a general rule of thumb, the longevity from implant to MOL = MOL to ERI.

The design of the battery in subsequently released models has been modified to present a more linear battery discharge curve.

If you are concerned about early ERI in your patient's device, you can utilize the battery trend measurements stored in the save-to-disk file, which can be accessed and interpreted through the Medtronic Technical Services at 1 (800) 723-4636.

GEM II/III Battery Discharge Curve



General Follow-Up and Replacement of ICD Leads

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 nonsustained 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 that 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 that 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.

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Clinical Management of High-Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus, ICD systems attempt to dynamically adjust sensing of electrical events and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T and far-field P waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high-voltage therapies. This is due, in part, to the desire to err on the side of delivering lifesaving high voltage therapy rather than withholding it. Thus, an ICD system that 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 or complete 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-to-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-to-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.
Oversensing during interrogation with programming head (not wireless telemetry) with complete lead fracture	Interrogation with a programming head in combination with complete lead fracture that creates an open circuit can induce noise on the sensing circuitry inside the ICD can	Nonphysiologic sensed event on EGM. If detection is enabled during interrogation, oversensing may result in inappropriate therapy.	Quickly remove the programming head. CANCEL the interrupted interrogation and manually load the software for the specific device model. Reposition the programmer head over the device and immediately select SUSPEND. Device will resume detection when programming head is removed, or when RESUME is selected. Replace lead.

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	

Mailer Kits Available for Returning Product

Medtronic urges all physicians to return explanted products 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 products vary by geographic location.

Mailer kits 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 US 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.

Mailer kits can be obtained by contacting the Returned Product Lab.

CRDM Returned Product Analysis Laboratory

Phone: 1 (800) 328-2518, ext. 44800
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