Medtronic

Cardiac Rhythm Disease Management

Product Performance Report

Important Patient Management Information for Physicians

2013

Second Edition – Issue 69

This report is available online at
www.medtronic.com/CRDMProductPerformance

Our Commitment to Quality

Medtronic was founded in 1949 and has grown to become a global leader in medical technology. Seeing what a difference medical technology could make in the lives of patients inspired our founder to develop the Medtronic Mission, which remains unchanged today.

The third tenet of the mission is all about quality:

"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."

Regardless of function, all CRDM employees play a role in product quality. Whether designing new therapies, sourcing components, manufacturing products, hiring talented people, assigning financial resources to project teams, or serving in one of the hundreds of other roles, every employee has an influence on product quality.

Product performance information is received from many sources through various channels. Medtronic monitors information from many sources from Research and Development through Manufacturing and Field Performance Vigilance.

When a device is returned to Medtronic, laboratory technicians and engineers assess overall device function. 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 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.

Analysis results are compared to original manufacturing records and design intent. Clinical observations are added to laboratory findings to help determine root cause. Each event is then compared to other events. If a pattern is detected, actions are taken to identify a common root cause, assess patient risk and an appropriate course of action.

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

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
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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:

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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

2013 Second Edition
Issue 69

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This report is available online at www.medtronic.com/CRDMProductPerformance

Introduction

All product performance reports are not created equal. For 30 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, 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.

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 Product Surveillance Registry.

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 the Contact Information page 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 the Contact Information page 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 devices and leads 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 Product Surveillance Registry.

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 and for device and leads still in service. Devices and leads removed for reasons unrelated to performance or are still in service are said to be suspended. Examples of devices and leads removed from service for reasons unrelated to performance include:

- 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 74)*.

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 a yellow X indicate devices removed from service due to an event. Blue bars indicate suspended devices.

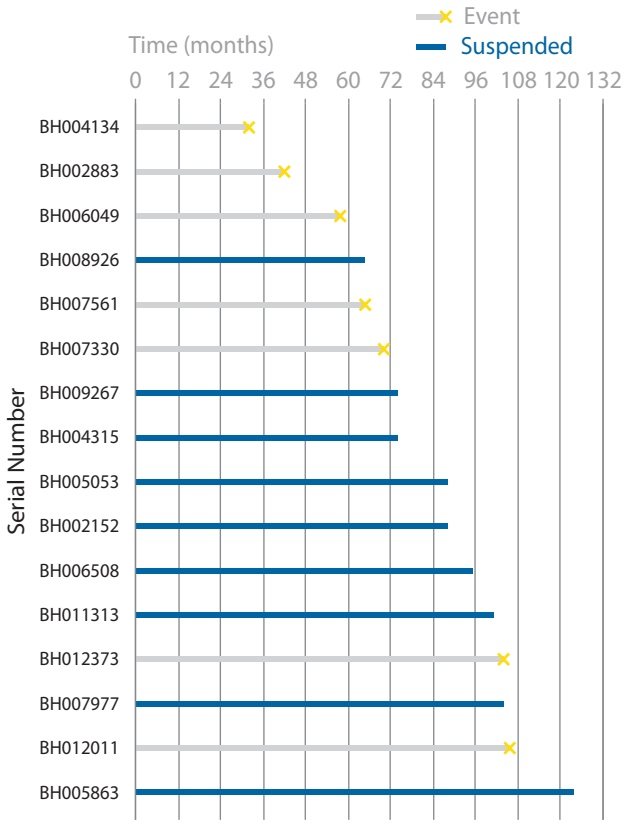


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

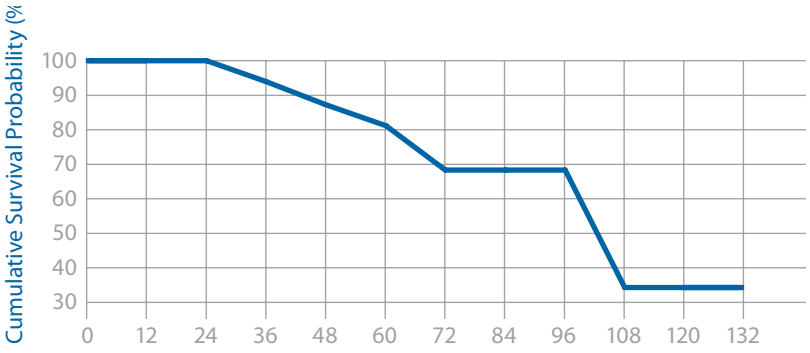
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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) is functioning 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.

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

Method for Estimating CRT, ICD, and IPG Device Performance

continued

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

For reference purposes, the following pages include 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

Method for Estimating CRT, ICD, and IPG Device Performance

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

Method for Estimating CRT, ICD, and IPG Device Performance

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.

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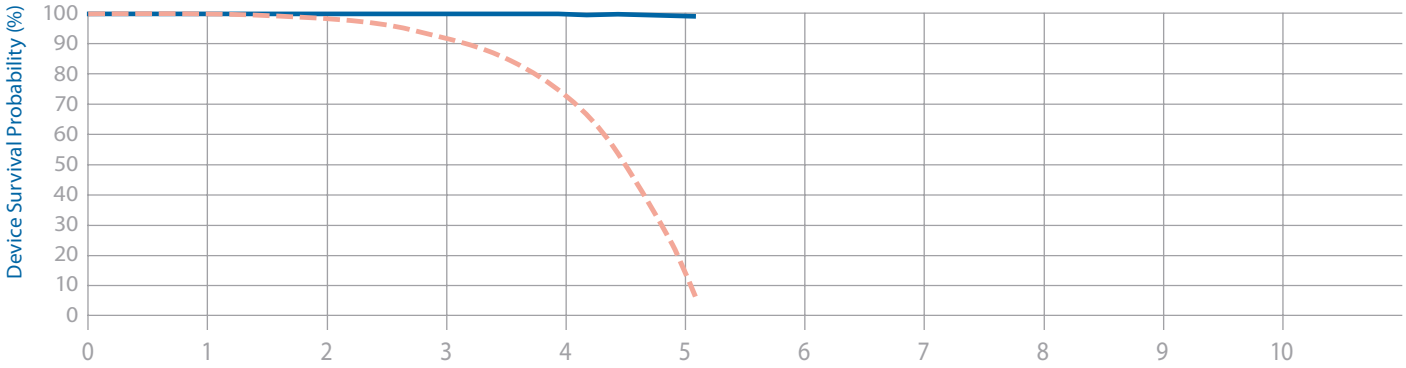
Product Characteristics

US Market Release	Apr-05
Registered US Implants	31,200
Estimated Active US Implants	2,100
Normal Battery Depletions (US)	9,674
Advisories	None

Malfunctions (US)	178
Therapy Function Not Compromised	168
Electrical Component	18
Possible Early Battery Depletion	147
Software Malfunction	2
Other	1
Therapy Function Compromised	10
Electrical Component	10

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



		1 yr	2 yr	3 yr	4 yr	5 yr	at 61 mo
%	———	100.0	99.9	99.7	99.2	99.0	98.9
%	- - - -	99.7	98.1	91.7	71.9	13.2	5.0
#	Effective Sample Size	27,200	23,800	19,000	11,900	1,700	870

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

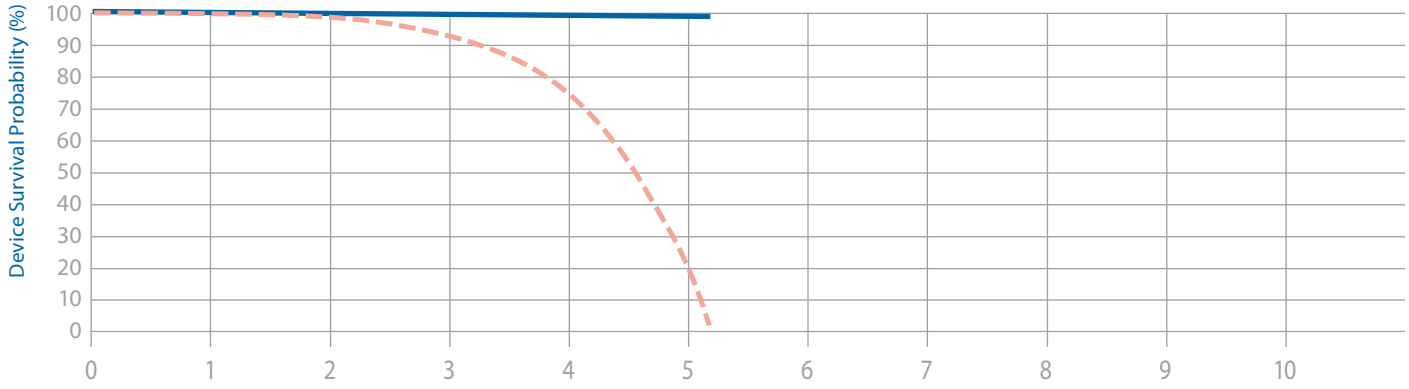
7304 InSync Maximo

Product Characteristics

US Market Release	Apr-05
Registered US Implants	19,000
Estimated Active US Implants	1,800
Normal Battery Depletions (US)	5,309
Advisories	None

Malfunctions (US)	111
Therapy Function Not Compromised	106
Electrical Component	14
Battery Malfunction	1
Possible Early Battery Depletion	90
Other	1
Therapy Function Compromised	5
Electrical Component	4
Other	1

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



		1 yr	2 yr	3 yr	4 yr	5 yr	at 62 mo
%	———	100.0	99.9	99.6	99.2	99.1	99.1
%	- - - -	99.7	98.1	92.4	74.5	20.6	4.5
#	Effective Sample Size	16,900	14,800	11,900	7,600	1,200	350

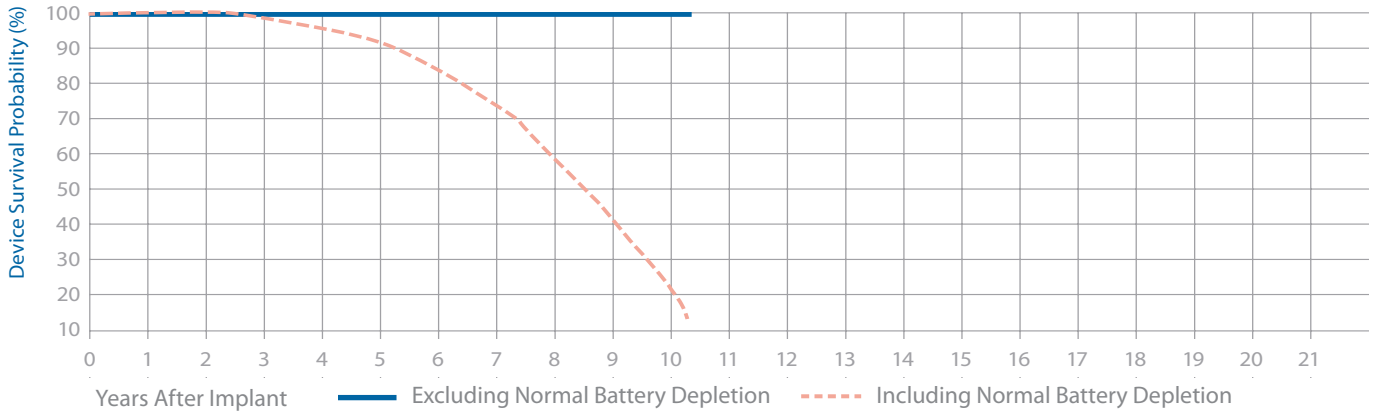
8040 InSync

Product Characteristics

US Market Release	Aug-01
Registered US Implants	15,400
Estimated Active US Implants	1,300
Normal Battery Depletions (US)	1,386
Advisories	None

Malfunctions (US)	34
Therapy Function Not Compromised	24
Electrical Component	4
Electrical Interconnect	16
Possible Early Battery Depletion	3
Other	1
Therapy Function Compromised	10
Electrical Interconnect	10

NBG Code	DDDR
Serial Number Prefix	PIN
Estimated Longevity	See page 21



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 124 mo
%	100.0	100.0	99.9	99.8	99.7	99.6	99.6	99.6	99.5	99.4	99.4
%	99.8	99.5	98.0	95.7	90.8	83.5	73.1	58.5	40.7	20.6	10.3
#	12,300	10,100	8,100	6,400	5,000	3,700	2,600	1,600	900	300	110

Effective Sample Size

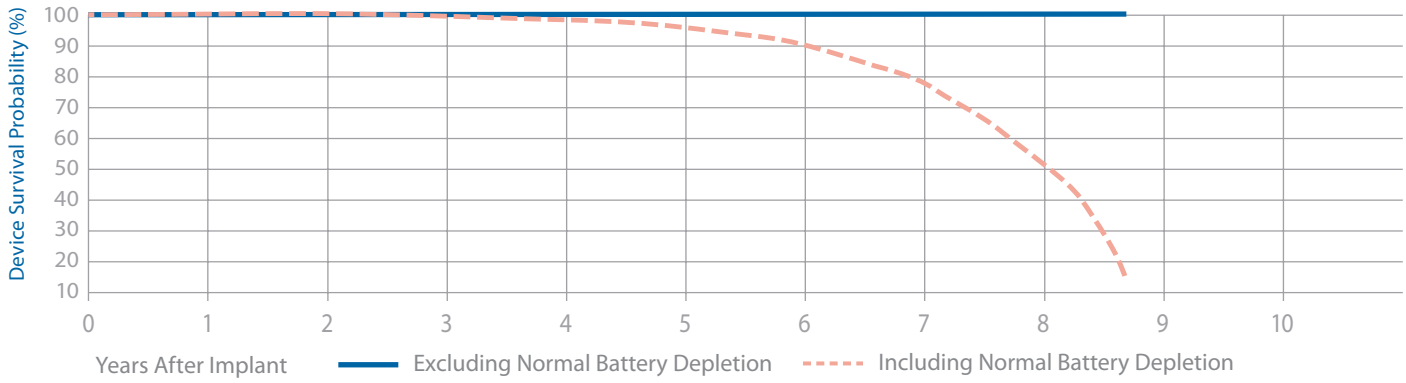
8042 InSync III

Product Characteristics

US Market Release	Feb-03
Registered US Implants	39,500
Estimated Active US Implants	14,100
Normal Battery Depletions (US)	2,138
Advisories	None

Malfunctions (US)	23
Therapy Function Not Compromised	13
Electrical Component	2
Electrical Interconnect	3
Possible Early Battery Depletion	1
Other	7
Therapy Function Compromised	10
Electrical Interconnect	10

NBG Code	DDDR
Serial Number Prefix	PKF
Estimated Longevity	See page 21



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 104 mo
%	100.0	100.0	100.0	99.9	99.9	99.9	99.9	99.9	99.9
%	99.9	99.8	99.2	97.7	95.1	89.7	77.2	50.8	15.4
#	34,500	30,100	25,100	18,000	12,500	8,100	4,400	1,500	180

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

C154DWK, C164AWK, C174AWK Concerto

Product Characteristics

	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	81,500	3,500
Estimated Active US Implants	22,600	200
Normal Battery Depletions (US)	16,614	267

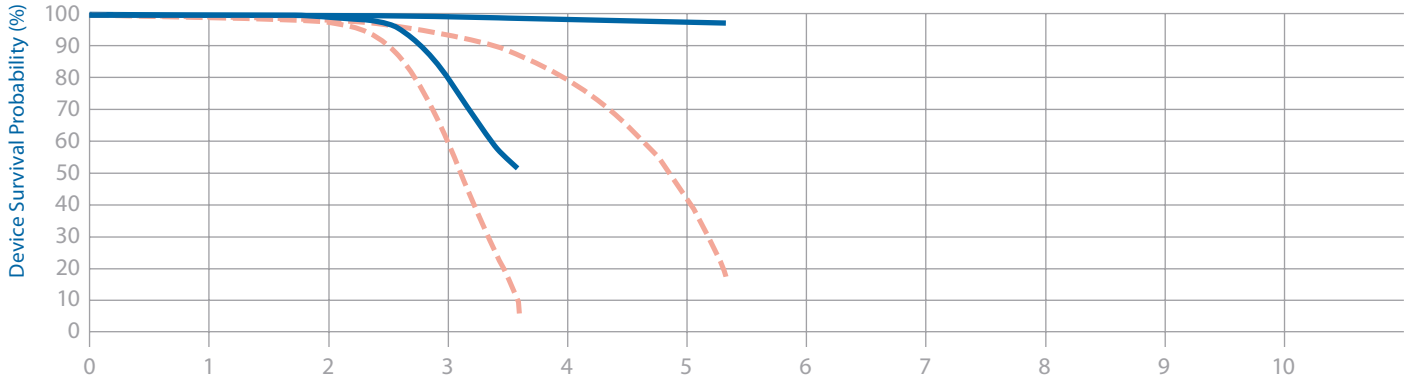
Advisories: See page 139 – 2009 Potential Reduced Device Longevity

	(N)	(A)
Malfunctions (US)	1,377	1,298
Therapy Function Not Compromised	1,337	1,284
Electrical Component	678	1,280
Electrical Interconnect	2	0
Software/Firmware	3	0
Possible Early Battery Depletion	651	4
Other	3	0
Therapy Function Compromised	40	14
Electrical Component	38	12
Electrical Interconnect	2	1
Other	0	1

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

(N) = Non-advisory population

(A) = Advisory population



Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	at 64 mo
%	100.0	99.8	99.5	98.4	96.8	96.8
%	99.8	98.3	93.4	79.3	41.5	18.1
#	72,800	64,100	53,900	38,000	9,000	1,900
Effective Sample Size						

Advisory	1 yr	2 yr	3 yr	at 43 mo
%	99.8	99.4	79.1	51.2
%	99.7	97.5	59.9	8.0
#	3,100	2,700	1,500	200
Effective Sample Size				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

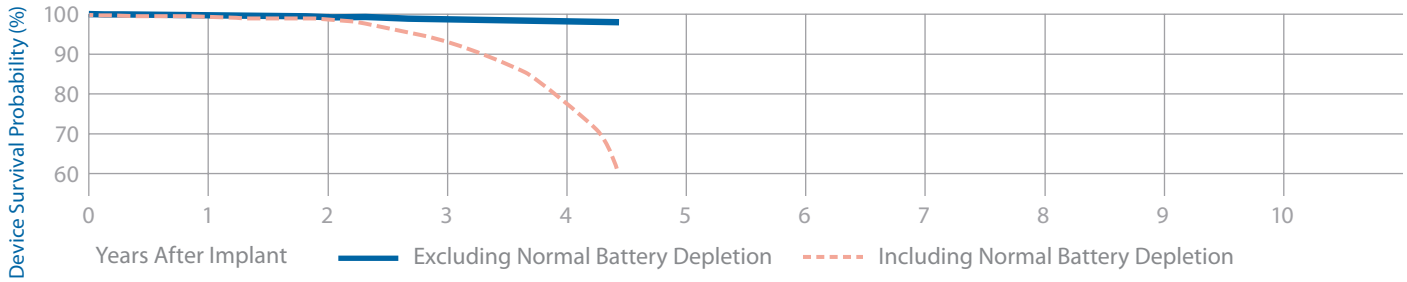
D224TRK, D234TRK, D204TRM, D214TRM Consulta CRT-D

Product Characteristics

US Market Release	Sep-08
Registered US Implants	66,700
Estimated Active US Implants	48,000
Normal Battery Depletions (US)	2,844
Advisories	None

Malfunctions (US)	440
Therapy Function Not Compromised	424
Electrical Component	24
Electrical Interconnect	1
Possible Early Battery Depletion	393
Software Malfunction	5
Other	1
Therapy Function Compromised	16
Electrical Component	16

NBD Code	DDE-DDDR
Serial Number Prefix	PUC , PUD, PYZ, PZA
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	4 yr	at 53 mo
%	100.0	99.7	99.2	98.5	98.3
%	99.8	98.5	92.9	77.5	61.2
#	56,900	45,500	24,400	5,500	650

Effective Sample Size

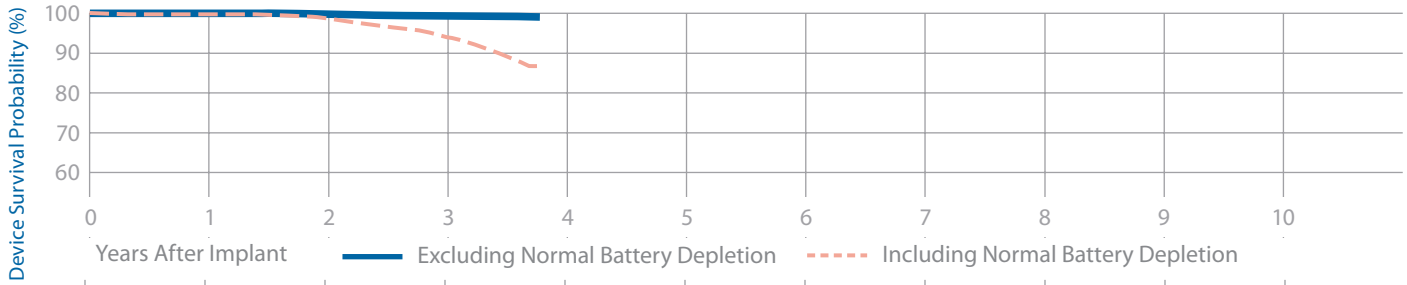
D274TRK, D294TRK Concerto II CRT-D

Product Characteristics

US Market Release	Aug-09
Registered US Implants	30,200
Estimated Active US Implants	22,900
Normal Battery Depletions (US)	784
Advisories	None

Malfunctions (US)	110
Therapy Function Not Compromised	108
Electrical Component	11
Possible Early Battery Depletion	96
Software/Firmware	1
Therapy Function Compromised	2
Electrical Component	2

NBD Code	DDE-DDDR
Serial Number Prefix	PZV, PZU
Max Delivered Energy	35 J
Estimated Longevity	See page 20



	1 yr	2 yr	3 yr	at 45 mo
%	100.0	99.8	99.5	99.3
%	99.9	98.7	93.9	87.1
#	27,400	22,800	10,200	570

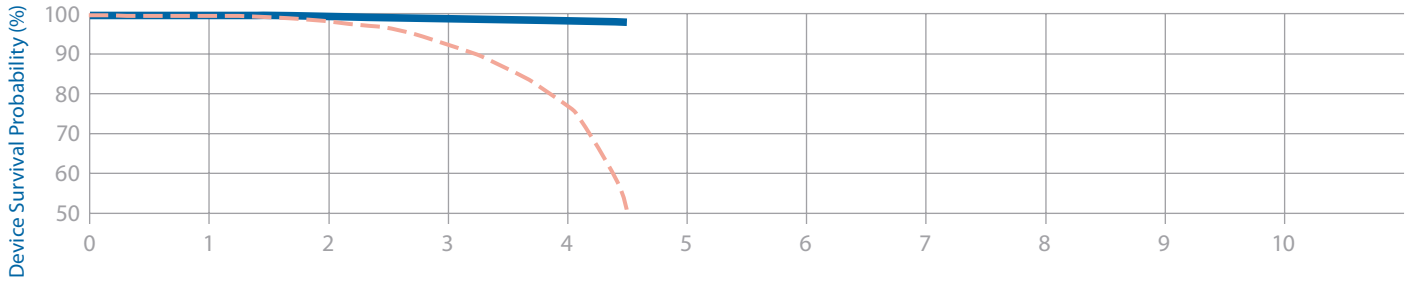
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

D264TRM, D284TRK Maximo II CRT-D

Product Characteristics

US Market Release	Sep-08	Malfunctions (US)	112	NBD Code	VVE-DDDR
Registered US Implants	14,900	**Therapy Function Not Compromised**	109	Serial Number Prefix	PZP, PZO
Estimated Active US Implants	10,300	Electrical Component	3	Max Delivered Energy	35 J
Normal Battery Depletions (US)	799	Possible Early Battery Depletion	106	Estimated Longevity	See page 20
Advisories	None	**Therapy Function Compromised**	3		
		Electrical Component	3		

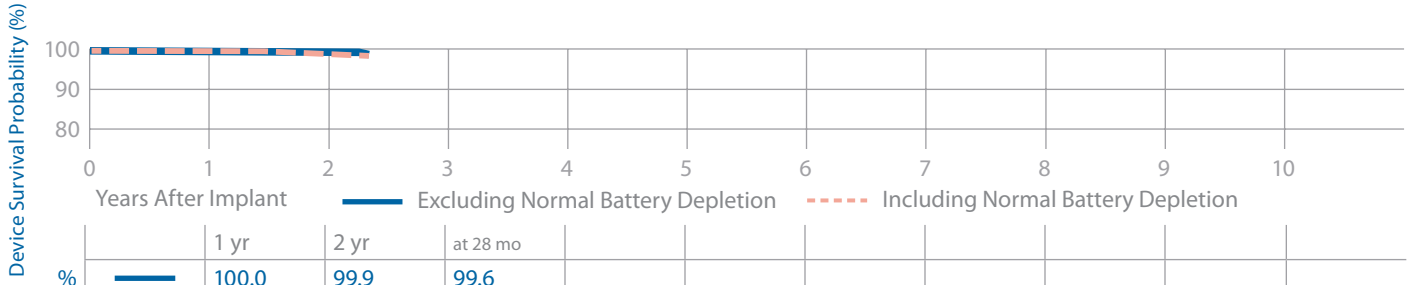


		1 yr	2 yr	3 yr	4 yr	at 54 mo
%	———	100.0	99.7	99.2	98.3	97.9
%	- - - -	99.9	98.4	92.8	77.4	50.4
#	Effective Sample Size	12,900	9,900	6,000	1,800	100

D314TRG, D314TRM, D334TRG, D334TRM, D354TRG, D354TRM, D364TRG, D364TRM Protecta/Protecta XT DR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	16	NBD Code	DDE-DDDR, VVE-DDDR
Registered US Implants	57,000	**Therapy Function Not Compromised**	13	Serial Number Prefix	PFS, PSE, PSF, PSI, PSL, PSO, PTB, PTE, PXI, PXJ
Estimated Active US Implants	53,700	Electrical Component	8	Max Delivered Energy	35J
Normal Battery Depletions (US)	67	Possible Early Battery Depletion	5	Estimated Longevity	See page 20
Advisories	None	**Therapy Function Compromised**	3		
		Electrical Component	3		



		1 yr	2 yr	at 28 mo
%	———	100.0	99.9	99.6
%	- - - -	99.9	99.1	97.9
#	Effective Sample Size	28,400	3,600	230

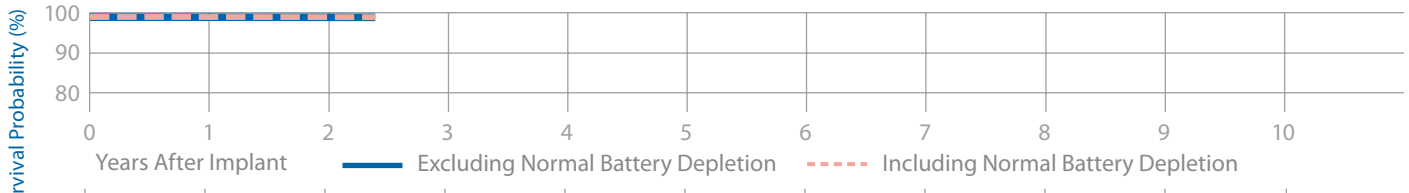
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

C2TR01 Syncra CRT-P, C3TR01, C4TR01 Consulta CRT-P

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	0	NBG Code	OAE-DDDR, OOE-DDDR
Registered US Implants	15,300	**Therapy Function Not Compromised**	0	Serial Number Prefix	PVX, PZI, PZX
Estimated Active US Implants	14,000	**Therapy Function Compromised**	0	Max Delivered Energy	NA
Normal Battery Depletions (US)	2			Estimated Longevity	See page 21

Advisories: See page 135 2013 Potential Loss of Device Hermeticity



		1 yr	2 yr	at 29 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0
%	Including Normal Battery Depletion	100.0	100.0	100.0
#	Effective Sample Size	8,800	2,400	200

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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	12 yr
7299	InSync Sentry	Apr-05	31,200	2,100	9,674	10	+	168	=	178	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.2 +0.1/-0.1	99.0 +0.1/-0.2	98.9 +0.2/-0.2 at 61 mo				
											Including Normal Battery Depletion	99.7 +0.1/-0.1	98.1 +0.2/-0.2	91.7 +0.4/-0.4	71.9 +0.6/-0.7	13.2 +0.7/-0.7	5.0 +0.5/-0.5 at 61 mo				
7304	InSync Maximo	Apr-05	19,000	1,800	5,309	5	+	106	=	111	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.2/-0.2	99.1 +0.2/-0.2	99.1 +0.2/-0.2 at 62 mo				
											Including Normal Battery Depletion	99.7 +0.1/-0.1	98.1 +0.2/-0.2	92.4 +0.4/-0.5	74.5 +0.8/-0.8	20.6 +1.0/-1.0	4.5 +0.8/-0.7 at 62 mo				
8040	InSync	Aug-01	15,400	1,300	1,386	10	+	24	=	34	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.6 +0.1/-0.2	99.6 +0.1/-0.2	99.4 +0.2/-0.3	99.4 +0.2/-0.3 at 124 mo
								-			Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.1	98.0 +0.3/-0.3	95.7 +0.4/-0.5	90.8 +0.7/-0.7	83.5 +0.9/-1.0	73.1 +1.2/-1.3	58.5 +1.6/-1.6	20.6 +1.9/-1.9	10.3 +1.9/-1.7 at 124 mo
8042	InSync III	Feb-03	39,500	14,100	2,138	10	+	13	=	23	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 104 mo	
								-			Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.2 +0.1/-0.1	97.7 +0.2/-0.2	95.1 +0.3/-0.3	89.7 +0.5/-0.5	77.2 +0.9/-0.9	50.8 +1.5/-1.5	15.4 +2.3/-2.2 at 104 mo	
C154DWK, C164AWK, C174AWK (Non-advisory population)	Concerto	May-06	81,500	22,600	16,614	40	+	1,337	=	1,377	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.0	99.5 +0.1/-0.1	98.4 +0.1/-0.1	96.8 +0.2/-0.2	96.8 +0.2/-0.2 at 64 mo				
											Including Normal Battery Depletion	99.8 +0.0/-0.0	98.3 +0.1/-0.1	93.4 +0.2/-0.2	79.2 +0.3/-0.3	41.5 +0.6/-0.6	18.1 +0.7/-0.7 at 64 mo				

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
C154DWK, C164AWK, C174AWK (Advisory population)	Concerto	May-06	3,500	200	267	14	+	1,284	=	1,298	Excluding Normal Battery Depletion	99.8 +0.1/-0.2	99.4 +0.2/-0.3	79.1 +1.6/-1.7	51.2 +2.2/-2.2 at 43 mo					
	Advisories: See page 139– 2009 Potential Reduced Device Longevity										Including Normal Battery Depletion	99.7 +0.1/-0.3	97.5 +0.5/-0.6	59.9 +1.9/-2.0	8.0 +1.5/-1.3 at 43 mo					
D224TRK, D234TRK, D204TRM, D214TRM	Consulta CRT-D/ CRT-D	Sep-08	66,700	48,000	2,845	16	+	424	=	440	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.7 +0.0/-0.0	99.2 +0.1/-0.1	98.5 +0.2/-0.2	98.3 +0.2/-0.2 at 53 mo				
											Including Normal Battery Depletion	99.8 +0.0/-0.0	98.5 +0.1/-0.1	92.9 +0.3/-0.3	77.58 +0.7/-0.7	61.2 +1.8/-1.9 at 53 mo				
D274TRK, D294TRK	Concerto II CRT-D	Aug-09	30,200	22,900	784	2	+	108	=	110	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.0/-0.1	99.5 +0.1/-0.1	99.3 +0.2/-0.2 at 45 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	98.7 +0.1/-0.1	93.9 +0.4/-0.4	87.1 +0.9/-1.0 at 45 mo					
D264TRM, D284TRK	Maximo II CRT-D/ CRT-D	Sep-08	14,900	10,300	799	3	+	109	=	112	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.7 +0.1/-0.1	99.2 +0.2/-0.2	98.3 +0.3/-0.4	97.9 +0.4/-0.5 at 54 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.1	98.4 +0.2/-0.2	92.8 +0.5/-0.6	77.4 +1.3/-1.3	50.4 +4.5/-4.7 at 54 mo				
D314TRG, D314TRM, D334TRG, D334TRM, D354TRG, D354TRM, D364TRG, D364TRM	Protecta/ Protecta XT CRT-D	Mar-11	57,000	53,700	68	3	+	13	=	16	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.3/-1.9 at 28 mo						
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.1 +0.2/-0.2	97.9 +0.9/-1.5 at 28 mo						

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
C2TR01, C3TR01, C4TR01	Syncra CRT-P, Consulta CRT-P	Mar-11	15,200	14,000	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 29 mo						
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 29 mo						
	Advisories: See page 139 – 2013 Potential Loss of Device Hermeticity																			

continued

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	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	
7299	InSync Sentry	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 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	40 cc 78 g	35 J	Monthly Quarterly Semiannual	3.3 4.5 5.0	3.8 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	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	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 10.9	≤ 2.62 V	—	3 month after RRT or › 16-second charge time
D224TRK, D234TRK, D204TRM, D214TRM	Consulta CRT-D CRT-D M4	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 D294TRK	Concerto II	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
D284TRK, D264TRM	Maximo II CRT-D CRT-D M4	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
D314TRG, D354TRG, D314TRM, D354TRM	Protecta XT CRT-D CRT-D M4	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
D334TRG, D364TRG, D334TRM, D364TRM	Protecta CRT-D CRT-D M4	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

* 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.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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	Estimated Longevity		
		Amplitude Setting	500 Lead Ω	1,000 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
C2TR01	Syncra CRT-P	Low 2.5 V (A, RV) Normal 3.5 V (A, RV) High 5.0 V (A, RV)	8.7 6.0 3.3	10.7 8.2 5.1
C3TR01 C4TR01	Consulta CRT-P	Low 2.5 V (A, RV) Normal 3.5 V (A, RV) High 5.0 V (A, RV)	8.7 6.0 3.3	10.7 8.2 5.1

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

7230Cx, B, E Marquis VR

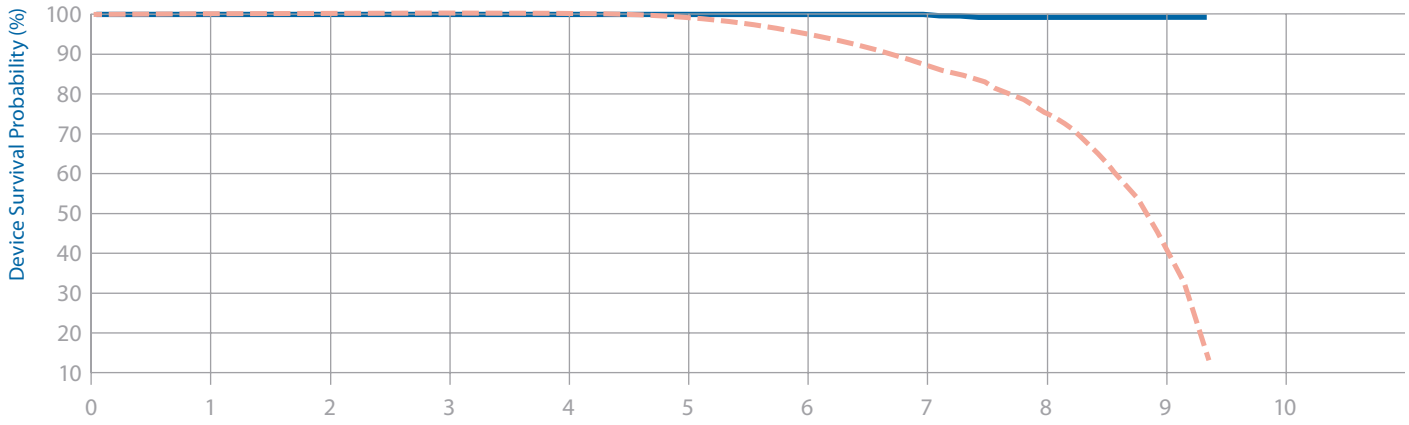
US Market Release	Dec-02
Registered US Implants	19,400
Estimated Active US Implants	2,770
Normal Battery Depletions (US)	2,753

Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	61
Therapy Function Not Compromised	32
Electrical Component	15
Software/Firmware	1
Battery Malfunction (*1 malfunction due to advisory*)	1
Possible Early Battery Depletion	14
Other	1
Therapy Function Compromised	29
Battery Malfunction (*19 malfunctions due to advisory*)	20
Electrical Component	9

Product Characteristics

NBD Code	VVE-VVIR
Serial Number Prefix	PKD, PLW, PLY
Max Delivered Energy	30 J
Estimated Longevity	See page 39



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 112 mo
%	———	99.9	99.9	99.9	99.8	99.7	99.6	99.5	99.4	99.4	99.4
%	- - - -	99.7	99.4	99.1	98.7	98.1	94.6	86.8	75.0	40.2	12.4
#	Effective Sample Size	17,300	13,600	11,300	10,200	9,100	7,900	6,600	5,000	1,500	250

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

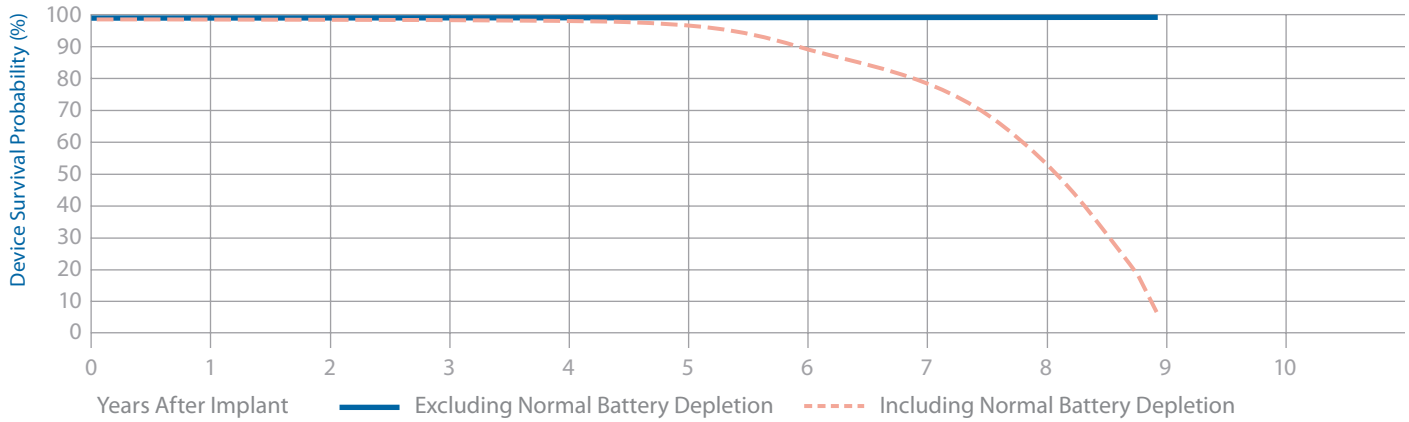
7231Cx GEM III VR

US Market Release	Dec-00
Registered US Implants	17,500
Estimated Active US Implants	1,800
Normal Battery Depletions (US)	3,684

Malfunctions (US)	37
Therapy Function Not Compromised	27
Electrical Component	22
Battery Malfunction	1
Possible Early Battery Depletion	4
Therapy Function Compromised	10
Electrical Component	8
Electrical Interconnect	1
Battery Malfunction	1

Product Characteristics

NBD Code	VVE-VVIR
Serial Number Prefix	PJL
Max Delivered Energy	30 J
Estimated Longevity	See page 39



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 107 mo
%	99.9	99.9	99.8	99.8	99.8	99.7	99.7	99.7	99.7
%	99.8	99.5	99.1	98.7	97.3	89.7	78.4	53.3	4.9
#	15,800	14,100	12,500	11,000	9,600	7,900	6,000	3,200	240

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

7232B, Cx, E Maximo VR

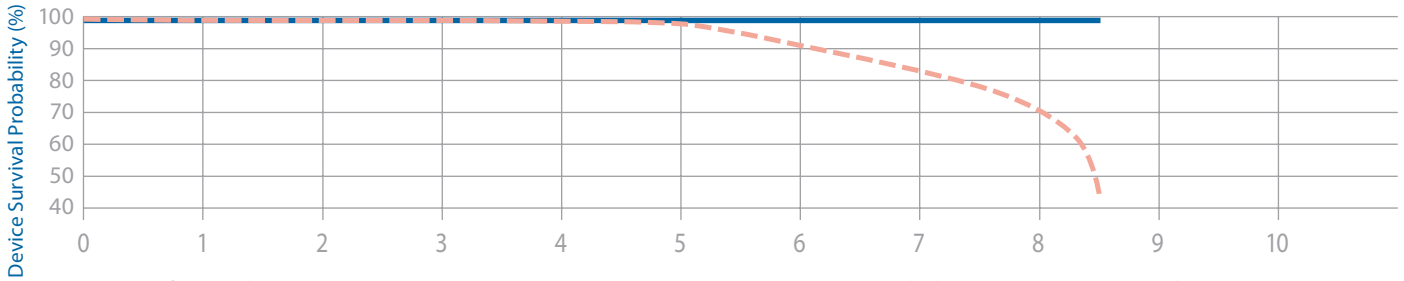
Product Characteristics

US Market Release	Oct-03
Registered US Implants	44,300
Estimated Active US Implants	17,100
Normal Battery Depletions (US)	3,737

Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	73
Therapy Function Not Compromised	57
Electrical Component	28
Possible Early Battery Depletion	23
Other	6
Therapy Function Compromised	16
Electrical Component	13
Electrical Interconnect	1
Possible Early Battery Depletion	1
Other	1

NBD Code	VVE-VVIR
Serial Number Prefix	PRN, PVF, PVG
Max Delivered Energy	35 J
Estimated Longevity	See page 39



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 102 mo
%	———	100.0	99.9	99.9	99.9	99.8	99.8	99.8	99.8	99.8
%	- - - -	99.9	99.7	99.4	99.1	97.7	91.5	83.1	71.5	44.8
#	Effective Sample Size	40,800	36,700	32,800	28,900	25,000	19,900	13,700	5,600	420

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

7274 Marquis DR

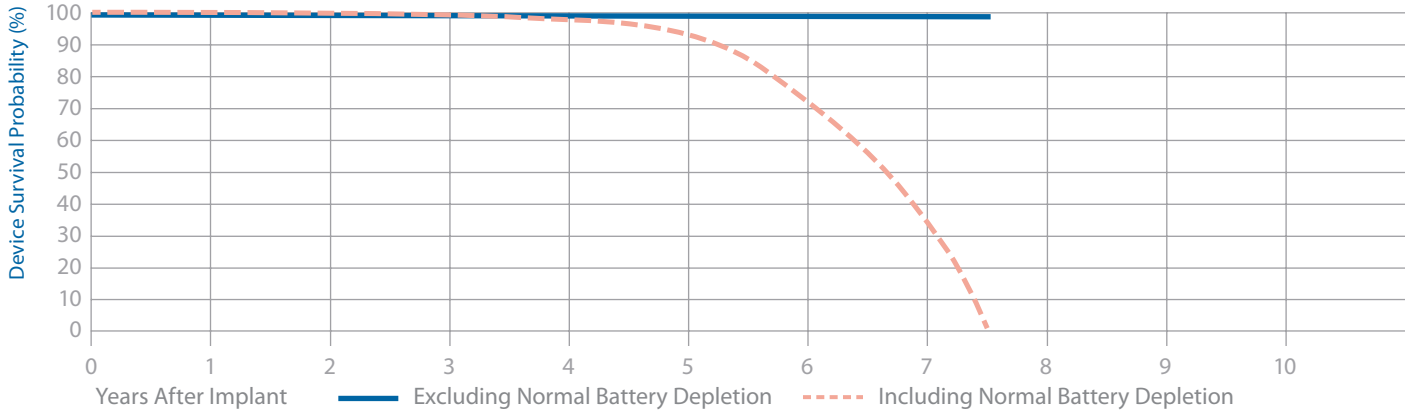
Product Characteristics

US Market Release	Mar-02
Registered US Implants	48,400
Estimated Active US Implants	2,300
Normal Battery Depletions (US)	8,904

Advisories: See page 145– 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	196
Therapy Function Not Compromised	89
Battery Malfunction (*73 malfunctions due to advisory*)	6
Electrical Component	31
Possible Early Battery Depletion	51
Other	1
Therapy Function Compromised	107
Battery Malfunction (*3 malfunctions due to advisory*)	80
Electrical Component	27

NBD Code	VVE-DDDR
Serial Number Prefix	PKC
Max Delivered Energy	30 J
Estimated Longevity	See page 39



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 90 mo
%	———	100.0	99.9	99.8	99.6	99.4	99.3	99.2	99.2
%	- - - -	99.8	99.5	98.6	97.3	92.1	72.5	34.2	1.1
#	Effective Sample Size	43,000	34,600	26,600	22,500	18,500	12,100	4,100	400

7278 Maximo DR

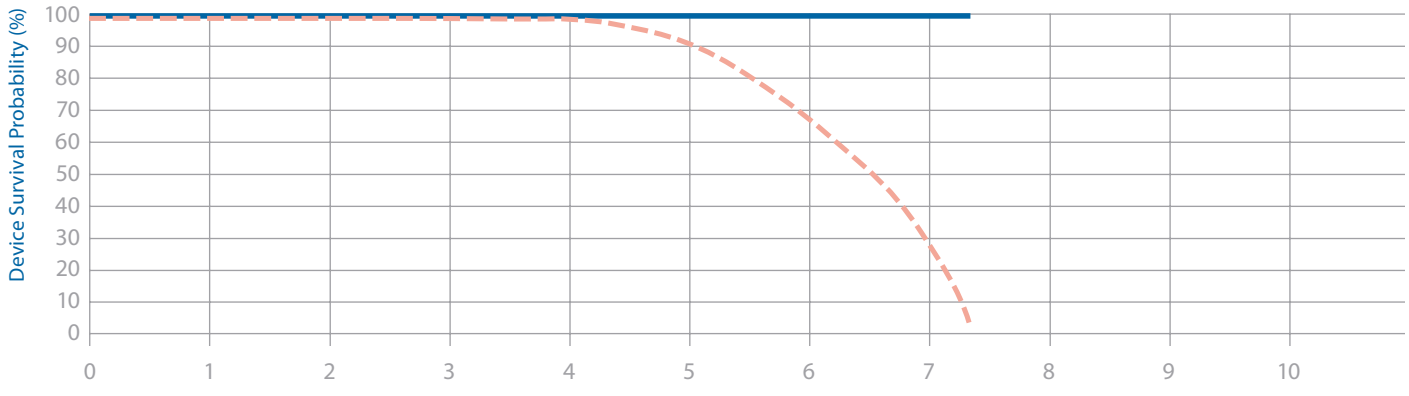
US Market Release	Oct-03
Registered US Implants	37,700
Estimated Active US Implants	5,800
Normal Battery Depletions (US)	9,134

Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short

Malfunctions (US)	70
Therapy Function Not Compromised	60
Electrical Component	22
Possible Early Battery Depletion	34
Other	4
Therapy Function Compromised	10
Electrical Component	9
Possible Early Battery Depletion	1

Product Characteristics

NBD Code	VVE-DDDR
Serial Number Prefix	PRM
Max Delivered Energy	35 J
Estimated Longevity	See page 39



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 88 mo
%	———	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	- - -	99.9	99.6	99.1	97.7	90.2	67.0	28.5	3.2
#		34,000	30,400	27,200	23,800	19,000	11,200	3,100	470

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

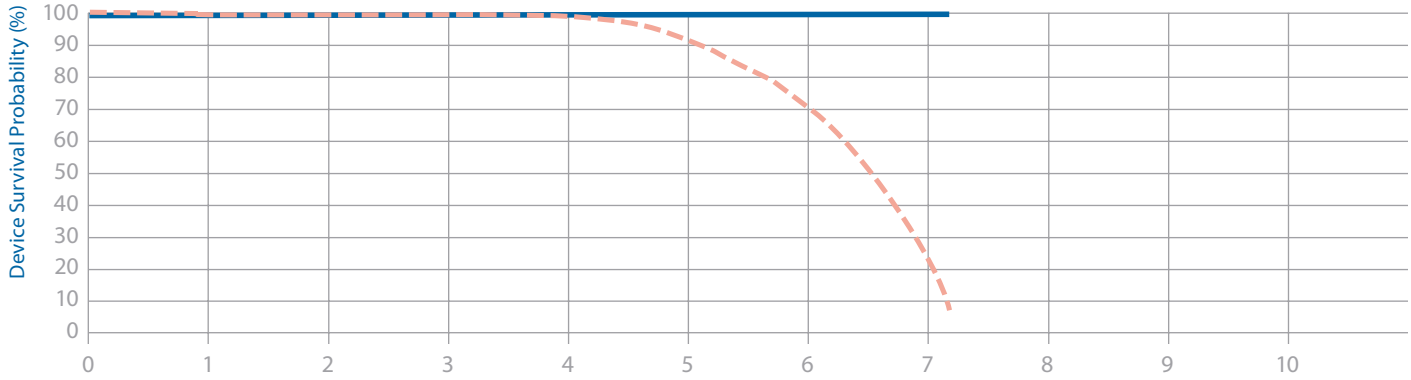
7288 Intrinsic

Product Characteristics

US Market Release	Jun-04
Registered US Implants	30,700
Estimated Active US Implants	3,900
Normal Battery Depletions (US)	9,100
Advisories	None

Malfunctions (US)	71
Therapy Function Not Compromised	64
Electrical Component	27
Battery Malfunction	2
Possible Early Battery Depletion	33
Software Malfunction	1
Other	1
Therapy Function Compromised	7
Electrical Component	5
Other	2

NBD Code	VVE-DDDR
Serial Number Prefix	PUB
Max Delivered Energy	35 J
Estimated Longevity	See page 39



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	99.9	99.9	99.8	99.8	99.7	99.7	99.7
%	99.9	99.6	99.2	98.2	90.7	70.4	22.1	7.8
#	28,700	26,400	23,800	21,000	17,500	11,500	2,600	970

Effective Sample Size

D154ATG, D154DRG EnTrust

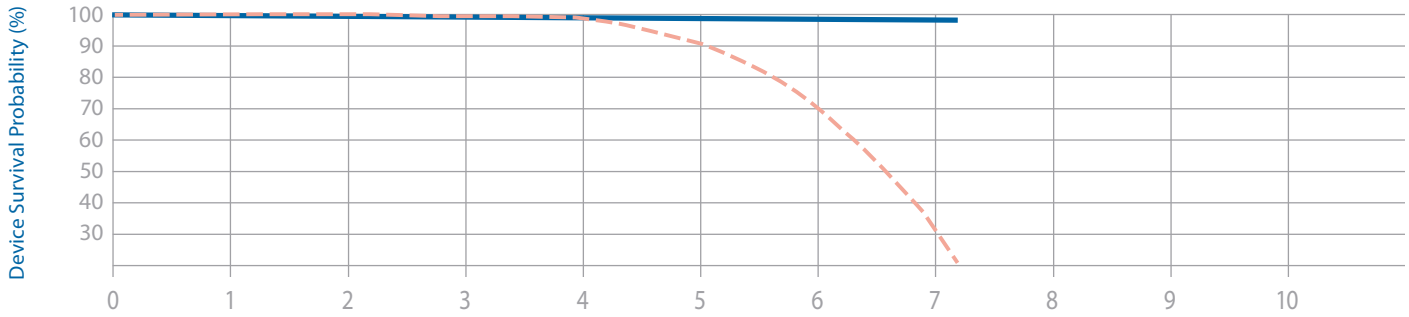
Product Characteristics

US Market Release	Jun-05
Registered US Implants	28,200
Estimated Active US Implants	7,200
Normal Battery Depletions (US)	5,787

Advisories: See page 136 – 2012 Potential Rapid Battery Depletion

Malfunctions (US)	122
Therapy Function Not Compromised	108
Electrical Component (*9 malfunctions due to advisory*)	29
Electrical Interconnect	1
Software Malfunction	3
Possible Early Battery Depletion	74
Other	1
Therapy Function Compromised	14
Electrical Component (*2 malfunctions due to advisory*)	14

NBD Code	DDE-DDDR, VVE-DDDR
Serial Number Prefix	PNR
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 86 mo
%	100.0	99.9	99.8	99.7	99.4	99.4	99.4	99.6
%	99.8	99.6	99.1	97.9	90.5	69.6	32.8	21.4
#	26,300	24,100	21,700	19,100	15,400	9,500	2,100	668

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

D154AWG, D164AWG Virtuoso DR

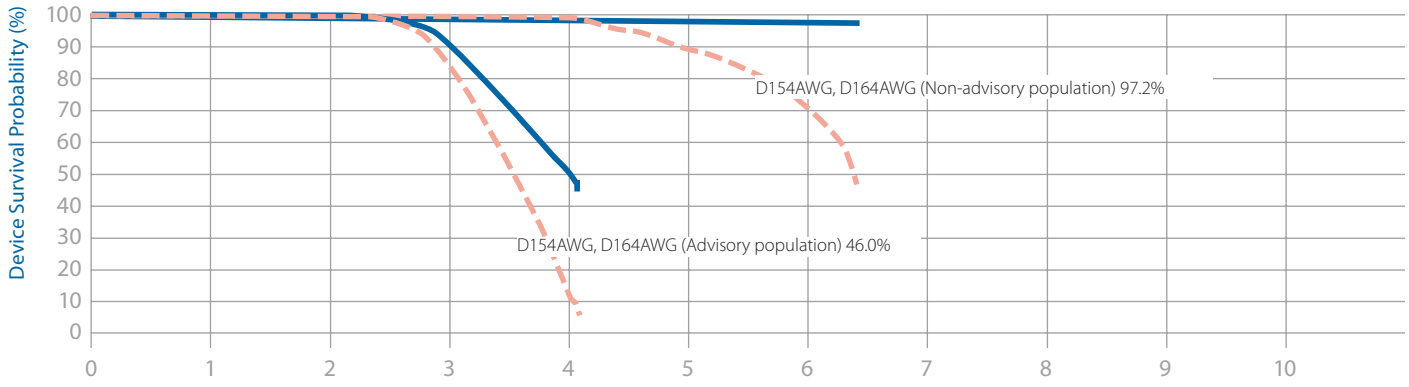
Product Characteristics

	(N)	(A)
US Market Release	May-06	May-06
Registered US Implants	72,700	4,100
Estimated Active US Implants	40,200	300
Normal Battery Depletions (US)	4,514	117

Advisories: See page 139 – 2009 Potential Reduced Device Longevity

	(N)	(A)
Malfunctions (US)	1,219	1,874
Therapy Function Not Compromised	1,190	1,861
Electrical Component	1,056	1,860
Electrical Interconnect	2	0
Possible Early Battery Depletion	127	0
Software Malfunction	1	0
Other	4	1
Therapy Function Compromised	29	13
Electrical Component	26	13
Possible Early Battery Depletion	1	0
Other	2	0

NBD Code	DDE-DDDR
Serial Number Prefix	PVV, PUL
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	———	100.0	99.9	99.9	99.4	97.3	97.2	97.2
%	- - - - -	99.9	99.7	99.4	98.0	89.5	70.6	46.9
#		67,700	62,400	56,900	49,400	30,500	7,700	690
Effective Sample Size								

	Advisory	1 yr	2 yr	3 yr	4 yr	at 49 mo
%	———	100.0	99.9	90.5	49.5	46.0
%	- - - - -	99.9	99.6	84.1	13.9	6.5
#		3,800	3,500	2,800	400	250
Effective Sample Size						

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

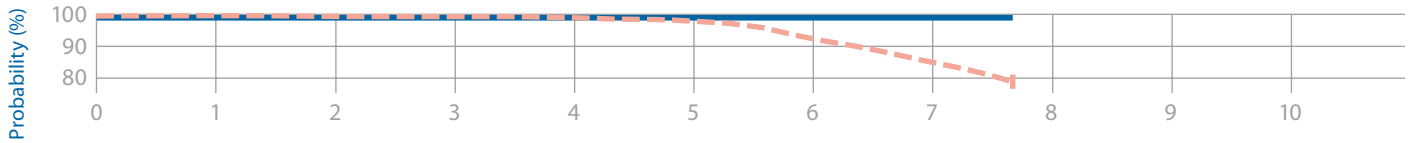
D154VRC EnTrust VR

Product Characteristics

US Market Release	Jun-05
Registered US Implants	14,500
Estimated Active US Implants	6,900
Normal Battery Depletions (US)	678
Advisories	None

Malfunctions (US)	99
Therapy Function Not Compromised	80
Battery Malfunction	2
Electrical Component	44
Possible Early Battery Depletion	24
Other	10
Therapy Function Compromised	19
Electrical Component	18
Other	1

NBD Code	VVE-VVIR
Serial Number Prefix	PNT
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 92 mo
%	100.0	99.9	99.8	99.7	99.5	99.2	98.9	98.9
%	99.9	99.6	99.4	98.9	97.9	92.3	84.5	78.0
#	13,700	12,400	11,200	9,900	8,700	6,800	3,400	290

Effective Sample Size

D154VWC, D164VWC Virtuoso VR

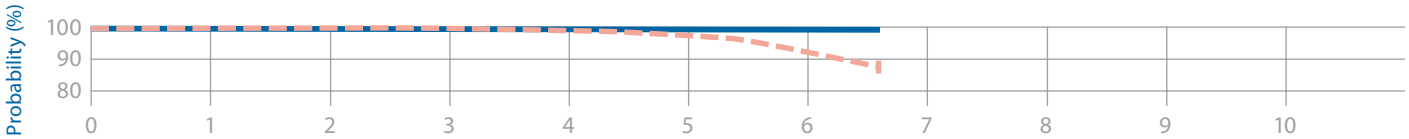
Product Characteristics

US Market Release	May-06
Registered US Implants	33,100
Estimated Active US Implants	20,800
Normal Battery Depletions (US)	432

Advisories: See page 139– 2009 Potential Reduced Device Longevity

Malfunctions (US)	306
Therapy Function Not Compromised	292
Electrical Component (*4 malfunctions due to advisory*)	273
Electrical Interconnect	1
Possible Early Battery Depletion	14
Other	4
Therapy Function Compromised	14
Electrical Component	14

NBD Code	VVE-VVIR
Serial Number Prefix	PUN, PUP
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 79 mo
%	100.0	99.9	99.9	99.7	98.6	98.5	98.5
%	99.9	99.8	99.6	99.1	96.7	92.1	87.4
#	30,900	28,300	25,800	22,700	15,000	4,900	300

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

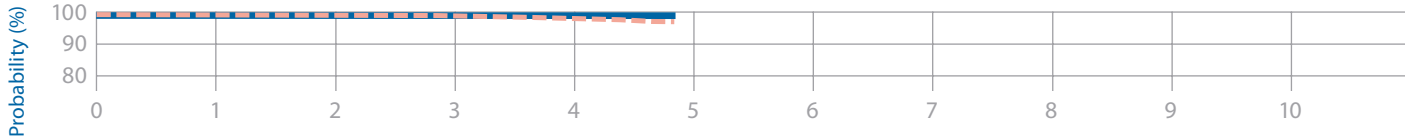
D224DRG, D234DRG, D204DRM, D214DRM Secura DR/DR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	50,800
Estimated Active US Implants	42,400
Normal Battery Depletions (US)	207
Advisories	None

Malfunctions (US)	63
Therapy Function Not Compromised	49
Electrical Component	15
Possible Early Battery Depletion	23
Software Malfunction	9
Other	2
Therapy Function Compromised	14
Electrical Component	12
Possible Early Battery Depletion	1
Software Malfunction	1

NBD Code	DDE-DDDR
Serial Number Prefix	PUF, PUG, PZC, PZD
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	99.9	99.9	99.8	99.7
%	99.8	99.6	99.3	98.4	97.1
#	45,300	38,000	22,500	7,900	250

Effective Sample Size

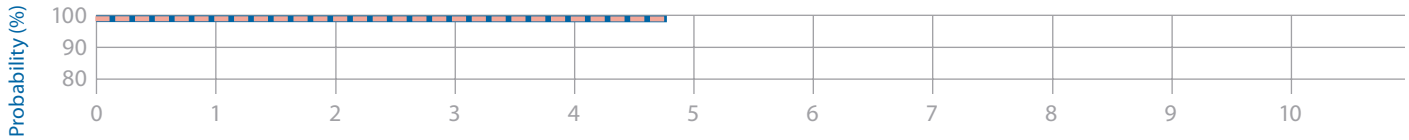
D224VRC, D234VRC, D204VRM, D214VRM Secura VR/VR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	20,600
Estimated Active US Implants	17,300
Normal Battery Depletions (US)	38
Advisories	None

Malfunctions (US)	15
Therapy Function Not Compromised	10
Electrical Component	2
Possible Early Battery Depletion	5
Software Malfunction	2
Other	1
Therapy Function Compromised	5
Electrical Component	4
Software/Firmware	1

NBD Code	VVE-VVIR
Serial Number Prefix	PUK, PUX, PZF, PZG
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	99.9	99.9	99.9	99.9
%	99.9	99.7	99.5	99.4	99.4
#	18,100	14,700	9,100	3,500	160

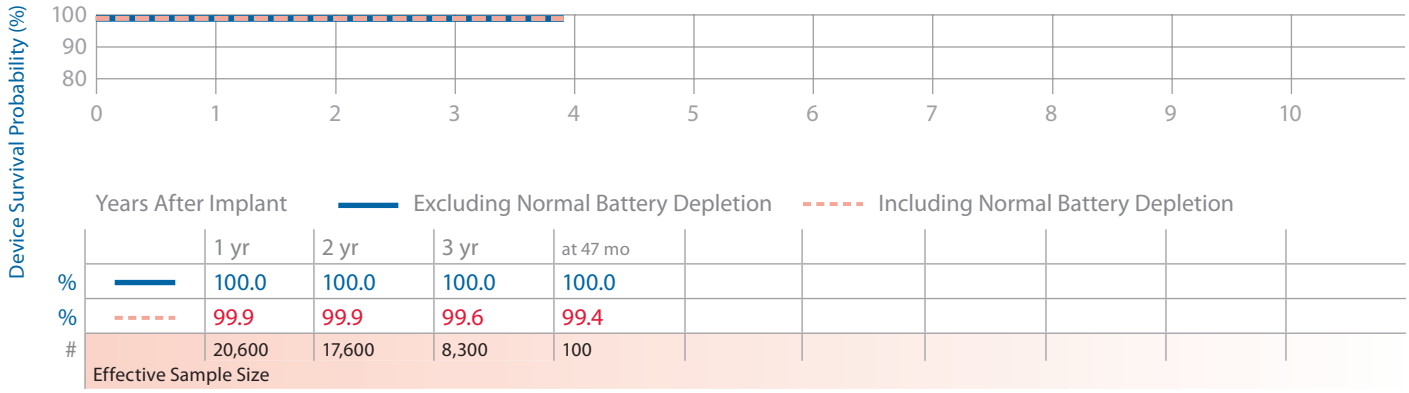
Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

D274DRG, D294DRG Virtuoso II DR

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	3	NBD Code	DDE-DDDR
Registered US Implants	22,200	**Therapy Function Not Compromised**	2	Serial Number Prefix	PZS, PZT
Estimated Active US Implants	18,800	Battery Malfunction	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	38	Possible Early Battery Depletion	1	Estimated Longevity	See page 40
Advisories	None	**Therapy Function Compromised**	1		
		Electrical Component	1		

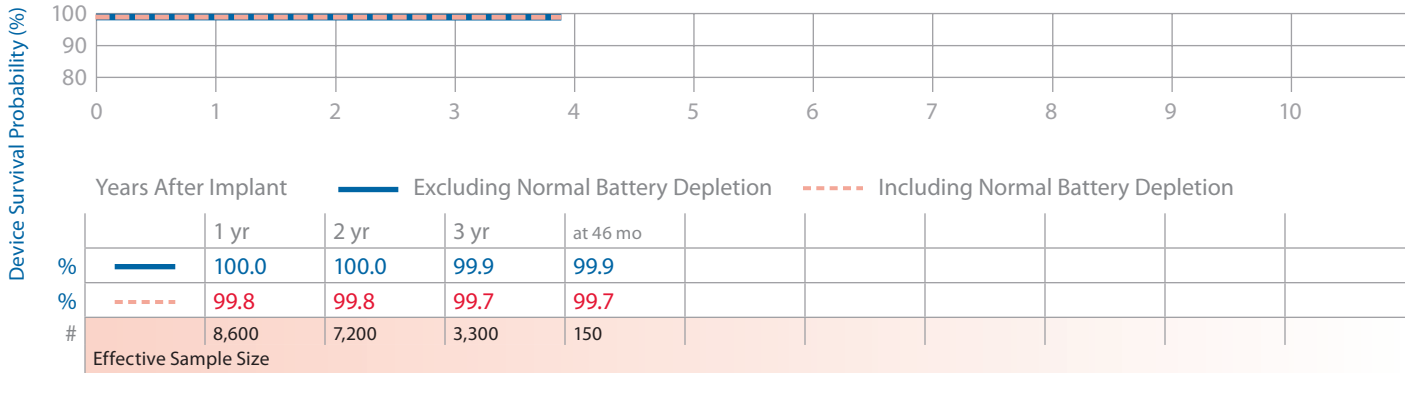


		1 yr	2 yr	3 yr	at 47 mo
%	Excluding Normal Battery Depletion	100.0	100.0	100.0	100.0
%	Including Normal Battery Depletion	99.9	99.9	99.6	99.4
#	Effective Sample Size	20,600	17,600	8,300	100

D274VRC, D294VRC Virtuoso II VR

Product Characteristics

US Market Release	Aug-09	Malfunctions (US)	3	NBD Code	VVE-VVIR
Registered US Implants	9,100	**Therapy Function Not Compromised**	3	Serial Number Prefix	PZQ, PZR
Estimated Active US Implants	7,800	Electrical Component	1	Max Delivered Energy	35 J
Normal Battery Depletions (US)	11	Possible Early Battery Depletion	1	Estimated Longevity	See page 40
Advisories	None	Software Malfunction	1		
		Therapy Function Compromised	0		



		1 yr	2 yr	3 yr	at 46 mo
%	Excluding Normal Battery Depletion	100.0	100.0	99.9	99.9
%	Including Normal Battery Depletion	99.8	99.8	99.7	99.7
#	Effective Sample Size	8,600	7,200	3,300	150

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

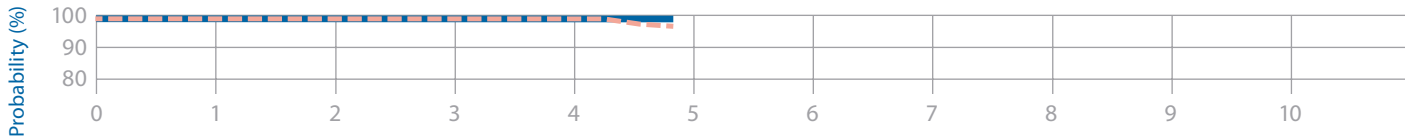
D264DRM, D284DRG Maximo II DR/DR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	19,700
Estimated Active US Implants	16,300
Normal Battery Depletions (US)	84
Advisories	None

Malfunctions (US)	20
Therapy Function Not Compromised	15
Electrical Component	4
Possible Early Battery Depletion	11
Therapy Function Compromised	5
Electrical Component	5

NBD Code	VVE-DDDR
Serial Number Prefix	PUJ, PZM
Max Delivered Energy	35 J
Estimated Longevity	See page 40



	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	100.0	99.9	99.8	99.8
%	100.0	99.8	99.4	98.5	96.7
#	17,700	14,300	9,500	4,100	190

Effective Sample Size

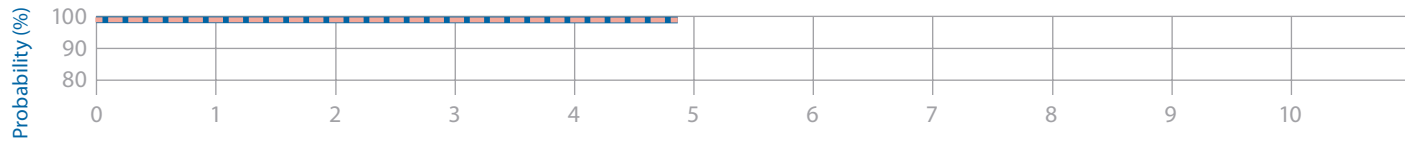
D264VRM, D284VRC Maximo II VR/VR

Product Characteristics

US Market Release	Sep-08
Registered US Implants	12,700
Estimated Active US Implants	10,700
Normal Battery Depletions (US)	27
Advisories	None

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

NBD Code	VVE-VVIR
Serial Number Prefix	PUZ, PZN
Max Delivered Energy	35 J
Estimated Longevity	See page 40



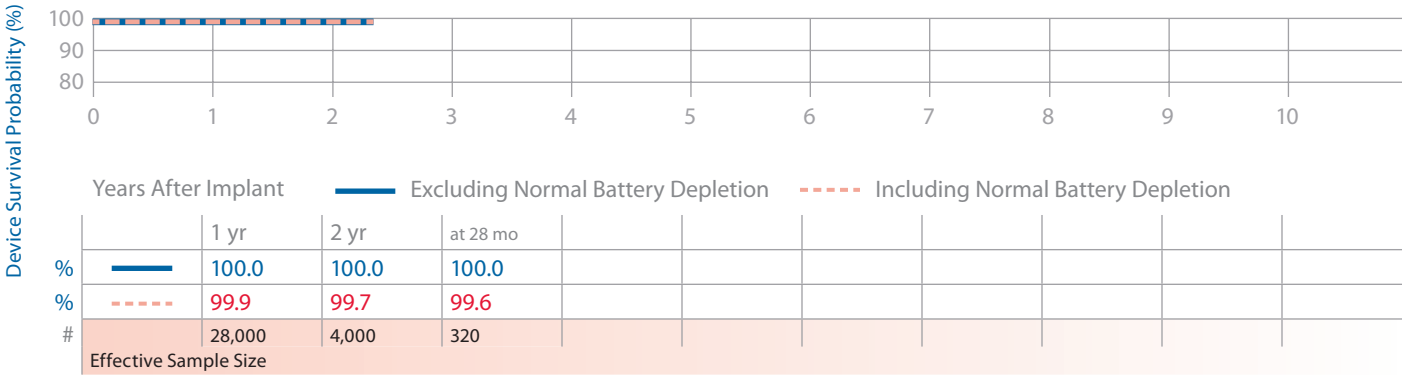
	1 yr	2 yr	3 yr	4 yr	at 58 mo
%	100.0	100.0	99.9	99.9	99.9
%	99.9	99.7	99.5	99.4	99.3
#	11,900	9,500	6,100	2,500	110

Effective Sample Size

D314DRG, D314DRM, D334DRG, D334DRM, D354DRG, D354DRM, D364DRG, D364DRM Protecta/Protecta XT DR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	18	NBD Code	DDE-DDDR, VVE-DDDR
Registered US Implants	52,300	**Therapy Function Not Compromised**	13	Serial Number Prefix	PSC, PSD, PSJ, PSK, PSM, PSP, PTC, PTF, PXF, PXP
Estimated Active US Implants	50,000	Electrical Component	13	Max Delivered Energy	35 J
Normal Battery Depletions (US)	26	**Therapy Function Compromised**	5	Estimated Longevity	See page 40
Advisories	None	Electrical Component	5		



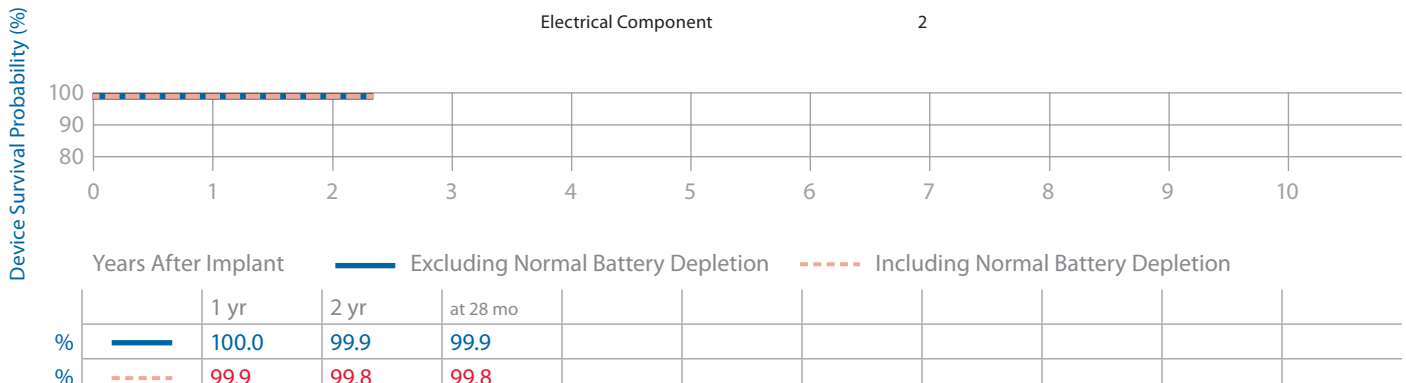
	1 yr	2 yr	at 28 mo
%	100.0	100.0	100.0
%	99.9	99.7	99.6
#	28,000	4,000	320

Effective Sample Size

D314VRG, D314VRM, D334VRG, D334VRM, D354VRG, D354VRM, D364VRG, D364VRM Protecta/Protecta XT VR

Product Characteristics

US Market Release	Mar-11	Malfunctions (US)	5	NBD Code	VVE-VVIR
Registered US Implants	17,600	**Therapy Function Not Compromised**	3	Serial Number Prefix	PSA, PSG, PSH, PSN, PSX, PTD, PTG, PXK, PXO
Estimated Active US Implants	16,800	Electrical Component	2	Max Delivered Energy	35 J
Normal Battery Depletions (US)	8	Other	1	Estimated Longevity	See page 40
Advisories	None	**Therapy Function Compromised**	2		
		Electrical Component	2		



	1 yr	2 yr	at 28 mo
%	100.0	99.9	99.9
%	99.9	99.8	99.8
#	11,900	1,600	150

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
7230Cx B, E	Marquis VR	Dec-02	19,400	2,700	2,770	29	+ 32	= 61	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.6 +0.1/-0.1	99.5 +0.1/-0.2	99.4 +0.1/-0.2	99.4 +0.2/-0.2 at 112 mo
	Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short					(19)	+ (1)	(20) (advisory-related subset)	Including Normal Battery Depletion	99.7 +0.1/-0.1	99.4 +0.1/-0.1	99.1 +0.1/-0.2	98.7 +0.2/-0.2	98.1 +0.2/-0.3	94.6 +0.4/-0.5	86.8 +0.7/-0.7	75.0 +1.0/-1.0	12.4 +1.7/-1.6 at 112 mo
7231Cx	GEM III VR	Dec-00	17,500	1,800	3,684	10	+ 27	= 37	Excluding Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 107 mo
									Including Normal Battery Depletion	99.8 +0.1/-0.1	99.5 +0.1/-0.1	99.1 +0.1/-0.2	98.7 +0.2/-0.2	97.3 +0.3/-0.3	89.7 +0.6/-0.6	78.4 +0.9/-0.9	53.5 +1.2/-1.2	4.9 +0.9/-0.8 at 107 mo
7232Cx B, E	Maximo VR	Oct-03	44,300	17,200	3,737	16	+ 57	= 73	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 102 mo
	Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.4 +0.1/-0.1	99.1 +0.1/-0.1	97.7 +0.2/-0.2	91.5 +0.3/-0.4	83.1 +0.5/-0.5	71.5 +0.7/-0.7	44.8 +2.5/-2.5 at 102 mo
7274	Marquis DR	Mar-02	48,400	2,800	8,904	107	+ 89	= 196	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.1	99.3 +0.1/-0.1	99.2 +0.1/-0.1	99.2 +0.1/-0.1 at 90 mo	
	Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short					(73)	+ (3)	= (76) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.0/-0.1	99.5 +0.1/-0.1	98.6 +0.1/-0.1	97.3 +0.2/-0.2	92.1 +0.3/-0.4	72.5 +0.6/-0.7	34.2 +0.8/-0.8	1.1 +0.3/-0.3 at 90 mo	
7278	Maximo DR	Oct-03	37,600	5,800	9,134	10	+ 60	= 70	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 88 mo	
	Advisories: See page 145 – 2005 Potential Premature Battery Depletion Due to Battery Short					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.6 +0.1/-0.1	99.1 +0.1/-0.1	97.7 +0.2/-0.2	90.2 +0.4/-0.4	67.0 +0.7/-0.7	28.5 +0.8/-0.8	3.2 +0.6/-0.5 at 88 mo	
7288	Intrinsic	Jun-04	30,700	3,900	9,100	7	+ 64	= 71	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1 at 86 mo	
									Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.2 +0.1/-0.1	98.2 +0.2/-0.2	90.7 +0.4/-0.4	70.4 +0.7/-0.7	22.1 +0.8/-0.8	7.8 +0.6/-0.6 at 86 mo	

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	Malfunctions: Therapy Function Not Compromised	Malfunctions: Total	Device Survival Probability (%)	Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr
D154ATG, D154DRG	EnTrust	Jun-05	28,200	7,200	5,787	14	+ 108	= 122	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1 at 86 mo	
	Advisories: See page 136 – 2012 Potential Rapid Battery Depletion					(2)	+ (9)	= (11) (advisory-related subset)	Including Normal Battery Depletion	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.1 +0.1/-0.1	97.9 +0.2/-0.2	90.5 +0.4/-0.4	69.6 +0.7/-0.7	32.8 +1.0/-1.0	21.4 +1.2/-1.2 at 86 mo	
D154AWG D164AWG (Non-advisory population)	Virtuoso DR	May-06	72,700	40,200	4,514	29	+ 1,190	= 1,219	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.4 +0.1/-0.1	97.3 +0.1/-0.2	97.2 +0.2/-0.2	97.2 +0.2/-0.2 at 77 mo		
									Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.4 +0.1/-0.1	98.0 +0.1/-0.1	89.5 +0.3/-0.3	70.6 +0.6/-0.6	46.9 +1.8/-1.9 at 77 mo		
D154AWG D164AWG (Advisory population)	Virtuoso DR	May-06	4,100	200	117	13	+ 1,861	= 1,874	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.1/-0.2	90.5 +1.0/-1.1	49.5 +1.9/-1.9	46.0 +1.9/-1.9 at 49 mo				
	Advisories: See page 139 – 2009 Potential Reduced Device Longevity								Including Normal Battery Depletion	99.9 +0.1/-0.1	99.6 +0.2/-0.3	84.1 +1.2/-1.3	13.9 +1.5/-1.4	6.5 +1.2/-1.0 at 49 mo				
D154VRC	EnTrust VR	Jun-05	14,500	6,900	678	19	+ 80	= 99	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.2	99.2 +0.2/-0.2	98.9 +0.2/-0.3	98.8 +0.2/-0.3 at 92 mo	
	Advisories: See page 136 – 2012 Potential Rapid Battery Depletion					(9)	+ (39)	= (48) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.1/-0.2	98.9 +0.2/-0.2	97.9 +0.3/-0.3	92.3 +0.6/-0.6	85.4 +0.8/-0.9	78.0 +1.8/-1.9 at 92 mo	
D154VWC D164VWC	Virtuoso VR	May-06	33,100	20,800	432	14	+ 292	= 306	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.1/-0.1	98.6 +0.2/-0.2	98.5 +0.2/-0.2	98.5 +0.2/-0.2 at 79 mo		
	Advisories: See page 139 – 2009 Potential Reduced Device Longevity					(0)	+ (4)	= (4) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.1 +0.1/-0.1	96.7 +0.2/-0.3	92.1 +0.5/-0.5	87.4 +1.3/-1.5 at 79 mo		

continued

Device Survival Summary continued

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised	+	Therapy Function Not Compromised	=	Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
D224DRG, D234DRG, D204DRM, D214DRM	Secura DR	Sep-08	50,800	42,400	207	14	+	49	=	63	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.3 at 58 mo			
											Including Normal Battery Depletion	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.3 +0.1/-0.1	98.4 +0.2/-0.2	97.1 +0.4/-0.5 at 58 mo			
D224VRC, D234VRC, D204VRM , D214VRM	Secura VR	Sep-08	20,600	17,300	38	5	+	10	=	15	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.1/-0.1 at 58 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.4 +0.1/-0.2	99.4 +0.1/-0.2 at 58 mo			
D274DRG, D294DRG	Virtuoso II DR	Aug-09	22,200	18,800	38	1	+	2	=	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 47 mo				
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.4 +0.2/-0.2 at 47 mo				
D274VRC, D294VRC	Virtuoso II VR	Aug-09	9,100	7,800	11	0	+	3	=	3	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.1 at 46 mo				
											Including Normal Battery Depletion	99.8 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.1/-0.2	99.7 +0.1/-0.2 at 46 mo				
D284DRG, D264DRM	Maximo II DR	Sep-08	19,700	16,300	84	5	+	15	=	20	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.8 +0.1/-0.2 at 58 mo			
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.8 +0.1/-0.1	99.4 +0.1/-0.1	98.5 +0.3/-0.3	96.7 +0.7/-1.0 at 58 mo			
D284VRC, D264VRM	Maximo II VR	Sep-08	12,700	10,700	27	3	+	6	=	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 58 mo			
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.2	99.4 +0.2/-0.2	99.3 +0.2/-0.3 at 58 mo			

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
D314DRG, D354DRG, D314DRM, D354DRM, D334DRG, D364DRG, D334DRM, D364DRM, Protecta/ Protecta XT DR	Protecta XT DR/ DR	Mar-11	54,700	52,300	29	5	+	13	=	18	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 28 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.6 +0.1/-0.2 at 28 mo					
D314VRG, D354VRG, D314VRM, D354VRM, D334VRG, D364VRG, D334VRM, D364VRM, Protecta/ Protecta XT VR	Protecta XT VR/ VR	Mar-11	25,300	24,200	8	2	+	3	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 28 mo					
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 28 mo					

continued

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	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	
7230	Marquis VR	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
7231Cx	GEM III VR	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 Cx, E	Maximo VR	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
7274	Marquis DR	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
7278	Maximo 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	38 cc 76 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

* 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 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.

Reference Chart continued

Model Number	Family	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	
D154ATG, D154DRG	EnTrust	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 VR	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	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, D234DRG, D204DRM, D214DRM	Secura DR/ DR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.1 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
D224VRC, D234VRC, D204VRM, D214VRM	Secura VR/ VR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.7 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D274DRG, D294DRG	Virtuoso II DR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 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, D294VRC	Virtuoso II VR	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8,	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D284DRG, D264DRM	Maximo II DR/DR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.1 7.0	4.5 7.0 8.2	4.6 7.5 9.0	≤ 2.63 V	—	3 months after RRT or > 16-second charge time
D284VRC, D264VRM	Maximo II VR/ VR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.6 7.7	4.6 7.4 8.8	4.9 8.1 9.7	5.0 8.4 10.2	≤ 2.63 V	—	3 months after RRT or > 19-second charge time
D314DRG, D354DRG, D314DRM, D354DRM	Protecta XT DR/DR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT
D314VRG, D354VRG, D314VRM, D354VRM	Protecta XT VR/VR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT
D334DRG, D364DRG, D334DRM, D364DRM	Protecta DR/ DR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	3.6 5.1 5.7	4.1 6.0 7.0	4.5 7.0 8.3	4.7 7.5 9.0	≤ 2.63 V	—	3 months after RRT
D334VRG, D364VRG, D334VRM, D364VRM	Protecta VR/ VR M4	37 cc 68 g	35 J	Monthly Quarterly Semiannual	4.3 6.7 7.8	4.7 7.5 8.9	4.9 8.1 9.8	5.0 8.4 10.3	≤ 2.63 V	—	3 months after RRT

* 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.

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

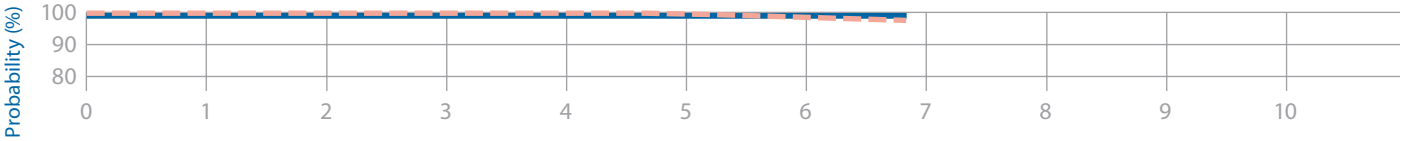
Adapta DR ADDR01, ADDR03, ADDR06, ADD01

Product Characteristics

US Market Release	Jul-06
Registered US Implants	361,100
Estimated Active US Implants	295,800
Normal Battery Depletions (US)	570
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	60
Therapy Function Not Compromised	38
Electrical Component	36
Electrical Interconnect	1
Other	1
Therapy Function Compromised	22
Electrical Component	18
Electrical Interconnect	2
Other	2

NBG Code	DDD, DDDR
Serial Number Prefix	NWB, NWC, NWD, NWF, PWB, PWC, PWD, PWF
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 82 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.9	99.8	99.4	98.7	97.7
#	307,500	245,700	185,200	126,900	74,200	29,400	1,380

Effective Sample Size

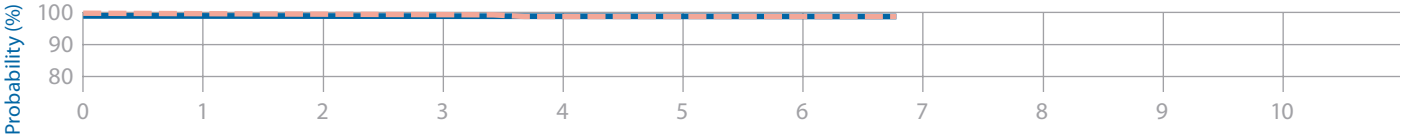
Adapta DR ADDRL1

Product Characteristics

US Market Release	Jul-06
Registered US Implants	81,800
Estimated Active US Implants	73,700
Normal Battery Depletions (US)	36
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	9
Therapy Function Not Compromised	6
Electrical Component	5
Electrical Interconnect	1
Therapy Function Compromised	3
Electrical Interconnect	1
Other	2

NBG Code	DDDR
Serial Number Prefix	PWE, NWE
Estimated Longevity	See page 70



	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
%	100.0	100.0	99.9	99.8	99.6	99.3	99.2
#	64,600	45,300	29,600	16,600	7,600	2,200	170

Effective Sample Size

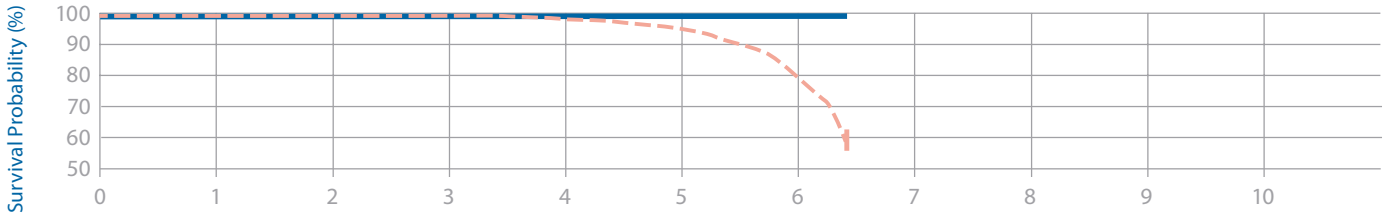
Adapta DR ADDRS1

US Market Release	Jul-06
Registered US Implants	35,200
Estimated Active US Implants	26,100
Normal Battery Depletions (US)	514
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

Malfunctions (US)	10
Therapy Function Not Compromised	6
Electrical Component	5
Possible Early Battery Depletion	1
Therapy Function Compromised	4
Electrical Component	2
Other	2

Product Characteristics

NBG Code	DDDR
Serial Number Prefix	PWA, NWA
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 77 mo
%	100.0	100.0	100.0	100.0	100.0	99.9	99.9
%	99.9	99.8	99.6	98.8	95.3	79.4	59.0
#	28,600	21,700	15,600	9,900	5,300	1,400	190

Effective Sample Size

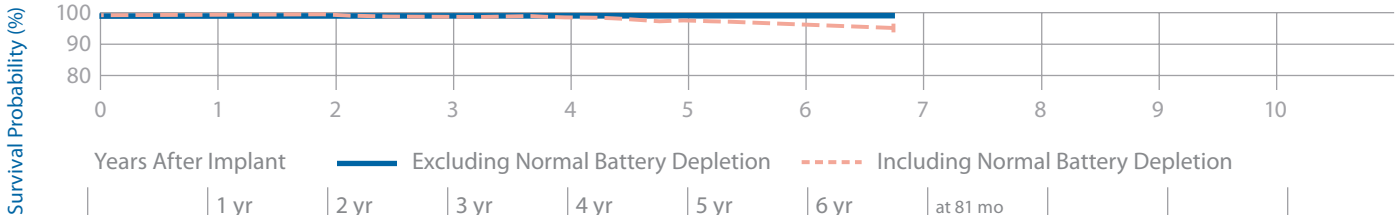
Adapta SR ADSR01, ADSR03, ADSR06

US Market Release	Jul-06
Registered US Implants	69,000
Estimated Active US Implants	48,700
Normal Battery Depletions (US)	236
Advisories	None

Malfunctions (US)	9
Therapy Function Not Compromised	5
Electrical Component	3
Electrical Interconnect	1
Possible Early Battery Depletion	1
Therapy Function Compromised	4
Electrical Component	3
Electrical Interconnect	1

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	NWN, NWM, NWP, PWP, PWM, PWN
Estimated Longevity	See page 70



	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
%	100.0	99.9	99.7	99.4	98.5	96.7	95.1
#	57,000	42,600	30,600	20,400	11,600	4,400	310

Effective Sample Size

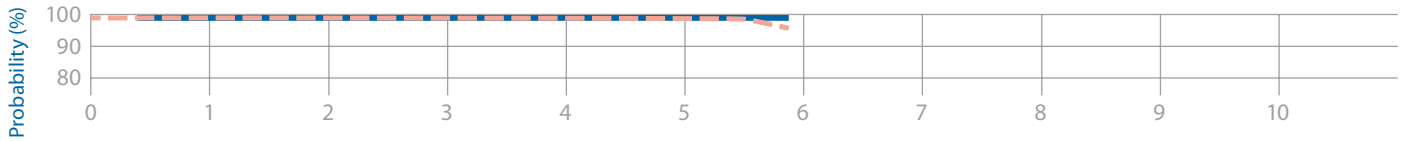
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Adapta VDD ADVDD01

Product Characteristics

US Market Release	Jul-06	Malfunctions (US)	0	NBG Code	VDD
Registered US Implants	1,100	**Therapy Function Not Compromised**	0	Serial Number Prefix	PWG, NWG
Estimated Active US Implants	800	**Therapy Function Compromised**	0	Estimated Longevity	See page 70
Normal Battery Depletions (US)	2				

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI



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

	1 yr	2 yr	3 yr	4 yr	5 yr	at 71 mo
%	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0	97.2
#	1,100	900	700	500	300	110

Effective Sample Size

Advisa DR / DR MRI A2DR01, A3DR01, A4DR01, A5DR01 Ensura MRI EN1DR01

Product Characteristics

US Market Release	Apr-11	Malfunctions (US)	0	NBG Code	OAE - DDDR OOE - DDDR
Registered US Implants	8,500	**Therapy Function Not Compromised**	0	Serial Number Prefix	PZK, PZJ, PZL, PZW, PVY
Estimated Active US Implants	8,400	**Therapy Function Compromised**	0	Estimated Longevity	See page 70
Normal Battery Depletions (US)	0				

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

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

	1 yr	2 yr	3 yr	at 40 mo
%	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0
#	9,300	4,700	1,100	150

Effective Sample Size

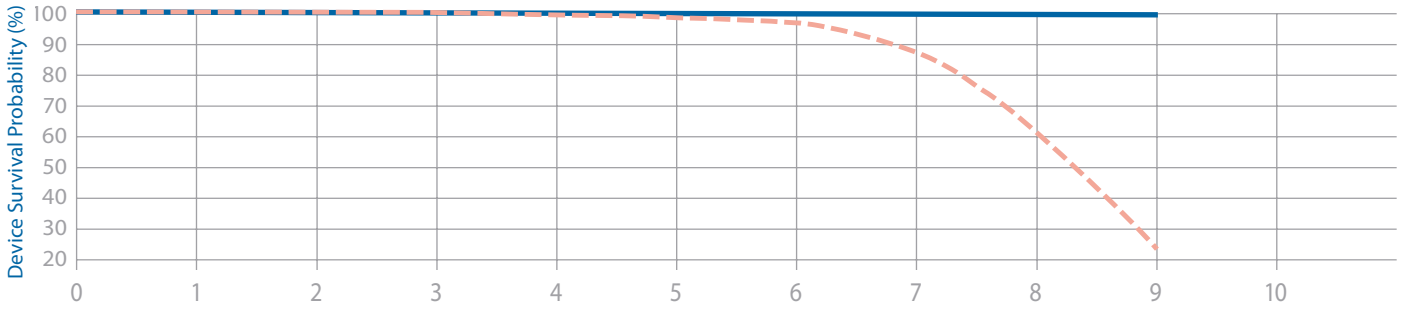
EnPulse DR E1DR01, E1DR03, E1DR06

Product Characteristics

US Market Release	Dec-03
Registered US Implants	6,800
Estimated Active US Implants	1,200
Normal Battery Depletions (US)	1,298
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	1

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

NBG Code	DDDR
Serial Number Prefix	PRA, PRB, PRE
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.8	98.9	98.0	96.5	86.8	59.8	13.1
#	6,200	5,800	5,300	4,900	4,400	4,000	3,200	1,800	200

Effective Sample Size

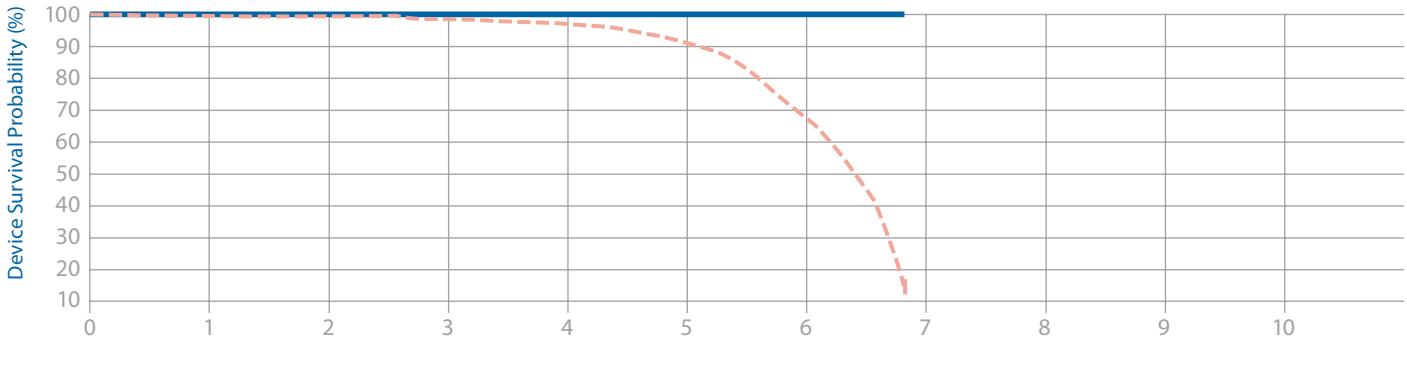
EnPulse DR E1DR21

Product Characteristics

US Market Release	Dec-03
Registered US Implants	1,900
Estimated Active US Implants	150
Normal Battery Depletions (US)	374
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

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

NBG Code	DDDR
Serial Number Prefix	PPT
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 80 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.6	98.6	96.2	91.9	61.3	23.6
#	1,600	1,500	1,300	1,200	1,000	500	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

EnPulse 2 DR E2DR01, E2DR03, E2DR06, E2D01, E2D03

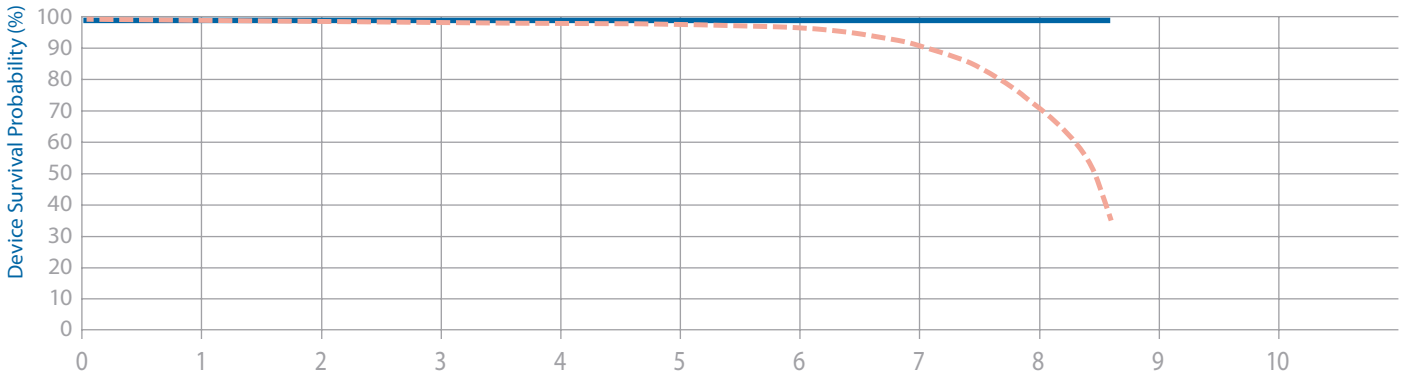
Product Characteristics

US Market Release	Feb-04
Registered US Implants	101,000
Estimated Active US Implants	40,300
Normal Battery Depletions (US)	8,189

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	26
Therapy Function Not Compromised	20
Electrical Component	17
Possible Early Battery Depletion	2
Other	1
Therapy Function Compromised	6
Electrical Component	3
Electrical Interconnect	2
Battery Malfunction	1

NBG Code	DDD, DDDR
Serial Number Prefix	PNB, PNC, PNF. PNG, PNH
Estimated Longevity	See page 70



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 103 mo
%	———	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	- - - -	99.9	99.9	99.8	99.4	98.7	97.1	91.4	70.9	34.3
#	Effective Sample Size	94,800	87,700	80,600	73,800	67,200	60,700	48,300	16,800	1,190

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

EnPulse 2 DR E2DR21

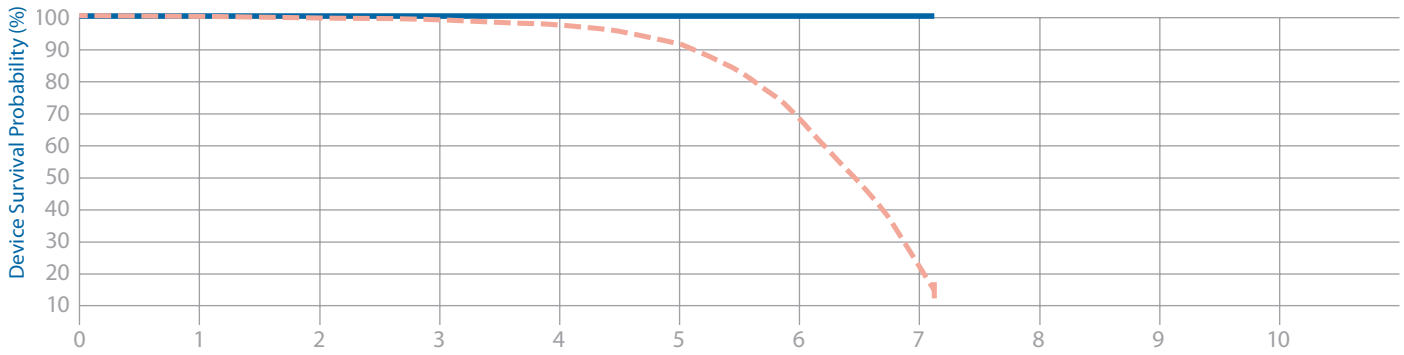
Product Characteristics

US Market Release	Feb-04
Registered US Implants	12,200
Estimated Active US Implants	1,900
Normal Battery Depletions (US)	2,074

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

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 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 85 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.5	98.9	97.1	91.0	67.7	22.5	14.5
#	10,900	9,800	8,800	7,700	6,300	3,700	500	210

Effective Sample Size

EnPulse 2 DR E2DR31, E2DR33

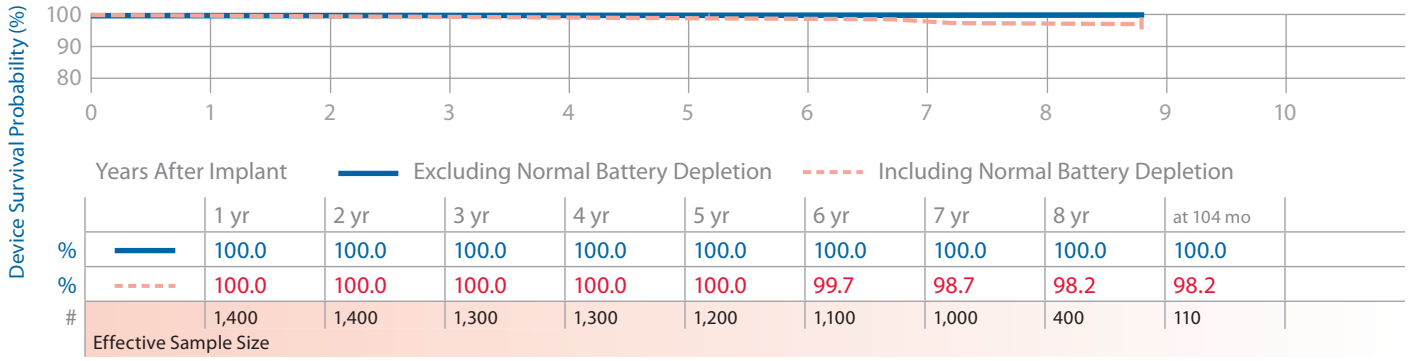
Product Characteristics

US Market Release	Feb-04
Registered US Implants	600
Estimated Active US Implants	400
Normal Battery Depletions (US)	10

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

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

NBG Code	DDDR
Serial Number Prefix	PNL, PNM
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 104 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	100.0	100.0	99.7	98.7	98.2	98.2
#	1,400	1,400	1,300	1,300	1,200	1,100	1,000	400	110

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

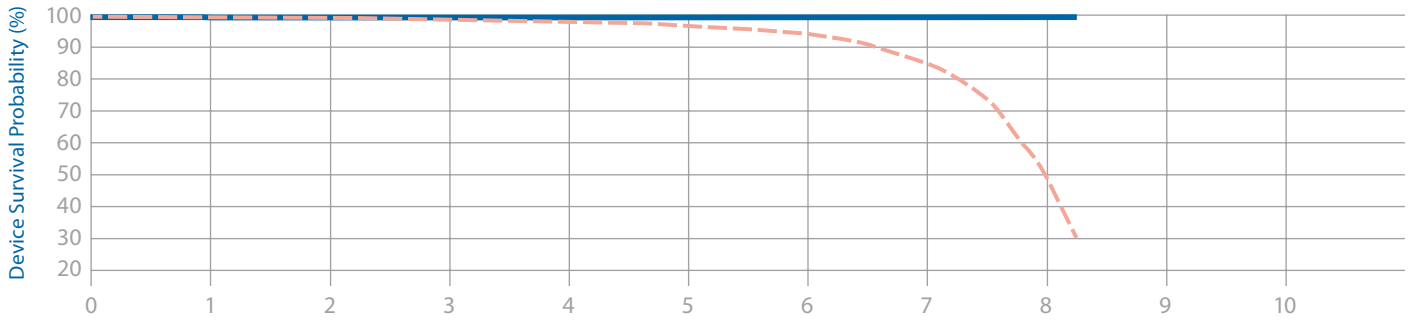
EnPulse 2 SR E2SR01, E2SR03, E2SR06

Product Characteristics

US Market Release	Dec-03
Registered US Implants	25,500
Estimated Active US Implants	6,400
Normal Battery Depletions (US)	1,754
Advisories	None

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

NBG Code	SSIR
Serial Number Prefix	PMW, PMY, PNA
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 99 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.9
%	99.9	99.7	99.4	98.7	97.3	94.1	84.6	53.1	31.1
#	22,600	19,600	17,100	15,000	12,800	10,900	7,500	1,200	200

Effective Sample Size

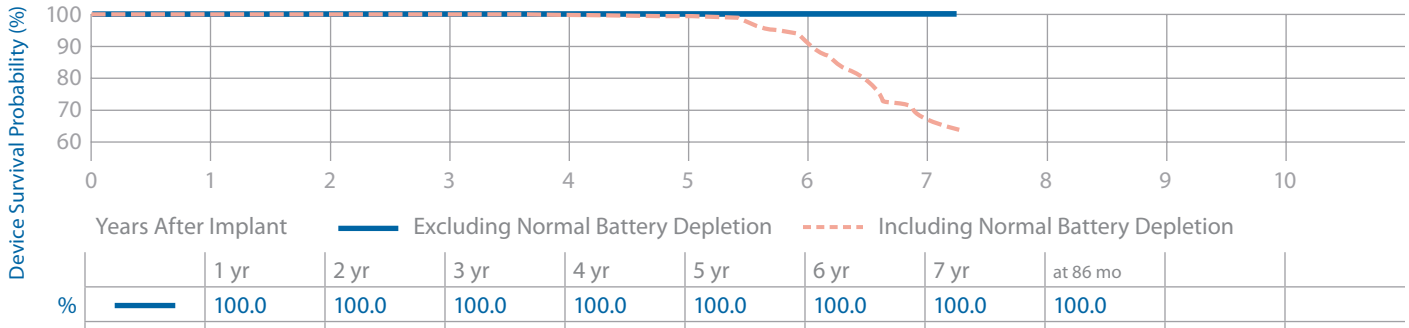
EnPulse 2 VDD E2VDD01

Product Characteristics

US Market Release	Dec-03
Registered US Implants	600
Estimated Active US Implants	200
Normal Battery Depletions (US)	73
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI	

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

NBG Code	VDD
Serial Number Prefix	PMV
Estimated Longevity	See page 70



	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	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.6	98.5	90.5	65.5	62.4
#	700	700	600	600	500	400	150	110

Effective Sample Size

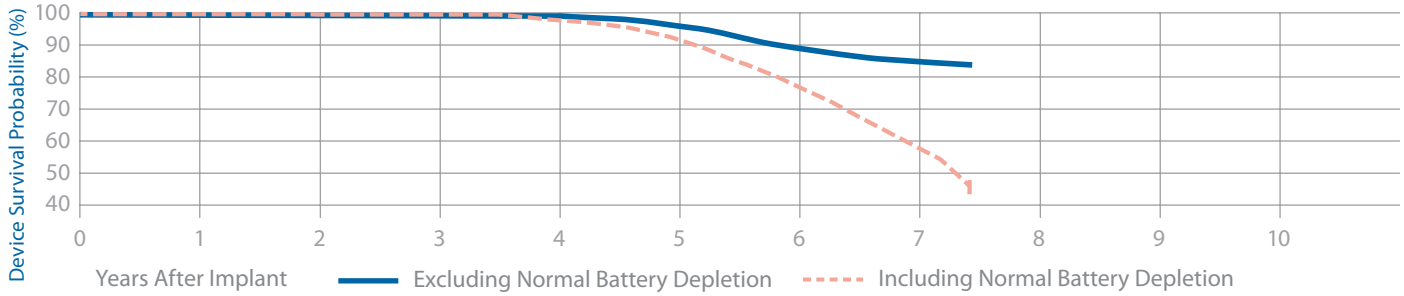
EnRhythm DR P1501DR

Product Characteristics

US Market Release	May-05
Registered US Implants	110,200
Estimated Active US Implants	63,600
Normal Battery Depletions (US)	1,651
Advisories: See page 137 – 2010 Low Battery Voltage Displayed at Device Interrogation	

Malfunctions (US)	7,445
Therapy Function Not Compromised	7,392
Battery Malfuntion (*229 malfunctions due to advisory*)	7,307
Electrical Component (*2 malfunctions due to advisory*)	38
Possible Early Battery Depletion	45
Electrical Interconnect	2
Therapy Function Compromised	53
Electrical Component	37
Electrical Interconnect	4
Battery Malfunction	5
Possible Early Battery Depletion	2
Other	5

NBG Code	DDDRP
Serial Number Prefix	PNP
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 89 mo
%	100.0	100.0	99.8	98.9	95.7	89.0	83.8	82.6
%	99.9	99.9	99.6	97.5	90.7	75.9	58.4	45.5
#	104,200	96,700	82,900	66,000	48,000	28,400	10,200	1,500

Effective Sample Size

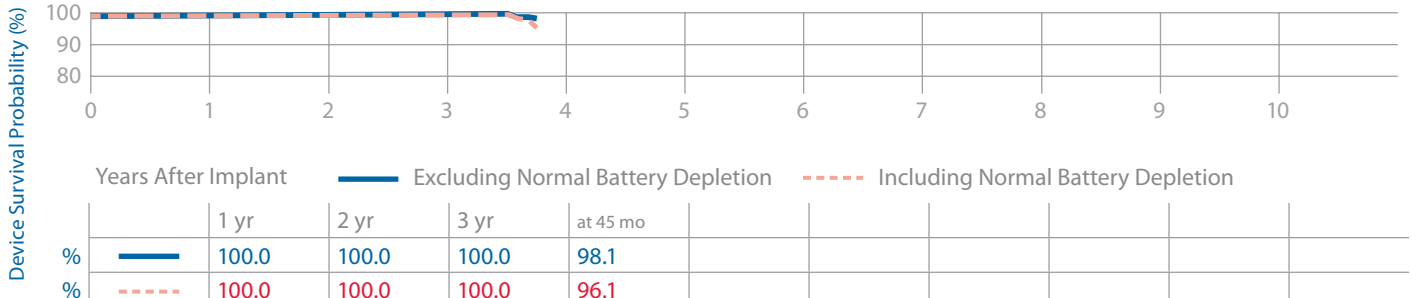
EnRhythm MRI EMDR01

Product Characteristics

US Market Release	N/A
Registered US Implants	100
Estimated Active US Implants	80
Normal Battery Depletions (US)	0
Advisories	None

Malfunctions (US)	10
Therapy Function Not Compromised	10
Battery Malfunction	10
Therapy Function Compromised	0

NBG Code	DDDRP
Serial Number Prefix	PTA
Estimated Longevity	See page 70



	1 yr	2 yr	3 yr	at 45 mo
%	100.0	100.0	100.0	98.1
%	100.0	100.0	100.0	96.1
#	200	200	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

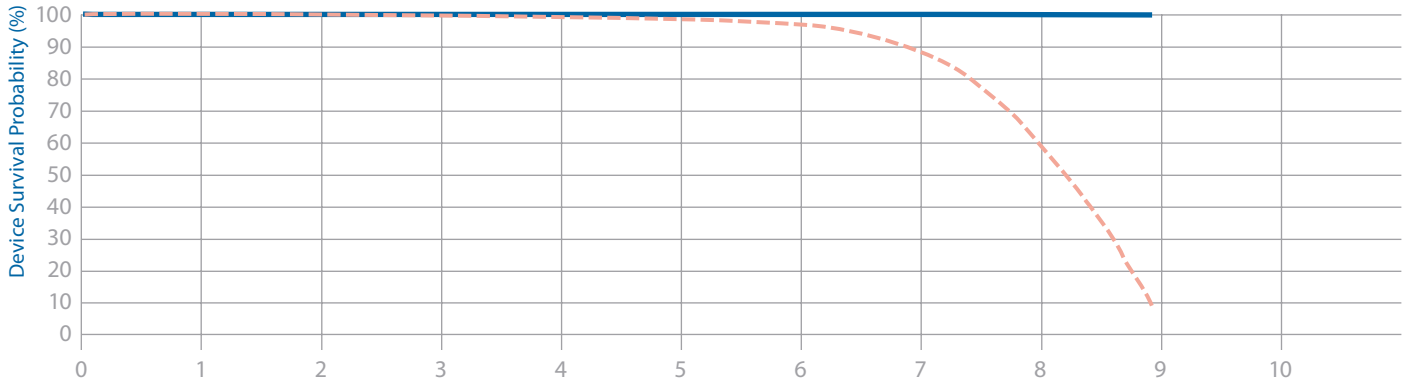
Kappa 400 DR KDR401, KDR403

Product Characteristics

US Market Release	Jan-98
Registered US Implants	46,700
Estimated Active US Implants	4,000
Normal Battery Depletions (US)	7,981
Advisories	None

Malfunctions (US)	27
Therapy Function Not Compromised	15
Electrical Component	10
Electrical Interconnect	1
Possible Early Battery Depletion	2
Other	2
Therapy Function Compromised	12
Electrical Component	6
Electrical Interconnect	6

NBG Code	DDDR
Serial Number Prefix	PER, PET
Estimated Longevity	See page 71



		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	100.0	99.9	99.9	99.9	99.9	99.9
%	- - -	99.9	99.8	99.7	99.4	98.8	97.1	88.1	58.8	7.8
#	Effective Sample Size	44,200	41,100	37,900	34,800	31,500	27,700	21,300	9,800	670

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

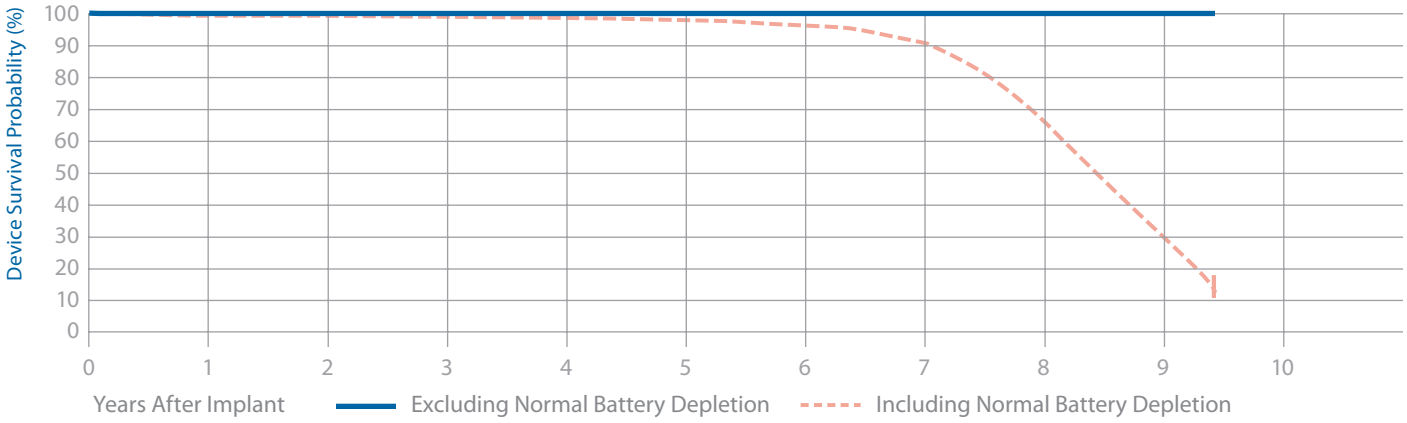
Kappa 400 SR KSR401, KSR403

US Market Release	Feb-98
Registered US Implants	15,400
Estimated Active US Implants	1,500
Normal Battery Depletions (US)	1,547
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

Product Characteristics

NBG Code	SSIR
Serial Number Prefix	PEU, PGD
Estimated Longevity	See page 71



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 113 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.7	99.5	98.9	98.4	96.6	90.2	66.0	29.7	14.4
#	13,600	12,000	10,500	9,200	7,900	6,700	5,200	2,600	600	150

Effective Sample Size

Kappa 700 DR KD701, KD703, KD706

US Market Release	Jan-99
Registered US Implants	300
Estimated Active US Implants	70
Normal Battery Depletions (US)	21

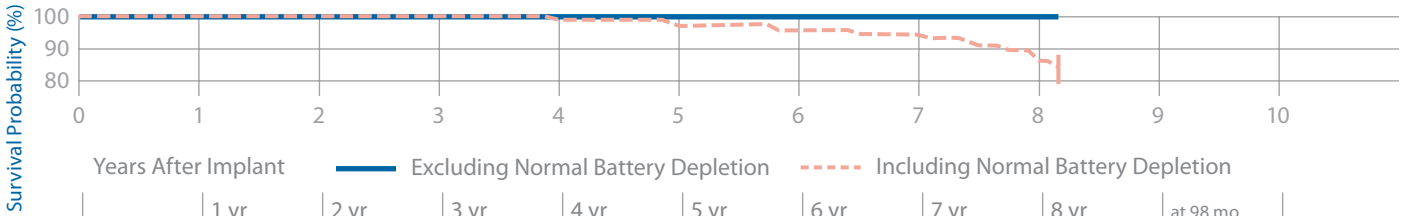
Advisories: See page 140– 2009 Potential Separation of Interconnect Wires

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

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

Product Characteristics

NBG Code	DDD
Serial Number Prefix	PHK, PHM, PHL
Estimated Longevity	See page 71



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 98 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	100.0	99.0	98.0	95.8	94.7	86.5	84.8
#	300	300	200	200	200	200	200	100	100

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Kappa 700 DR KDR701, KDR703, KDR706

Product Characteristics

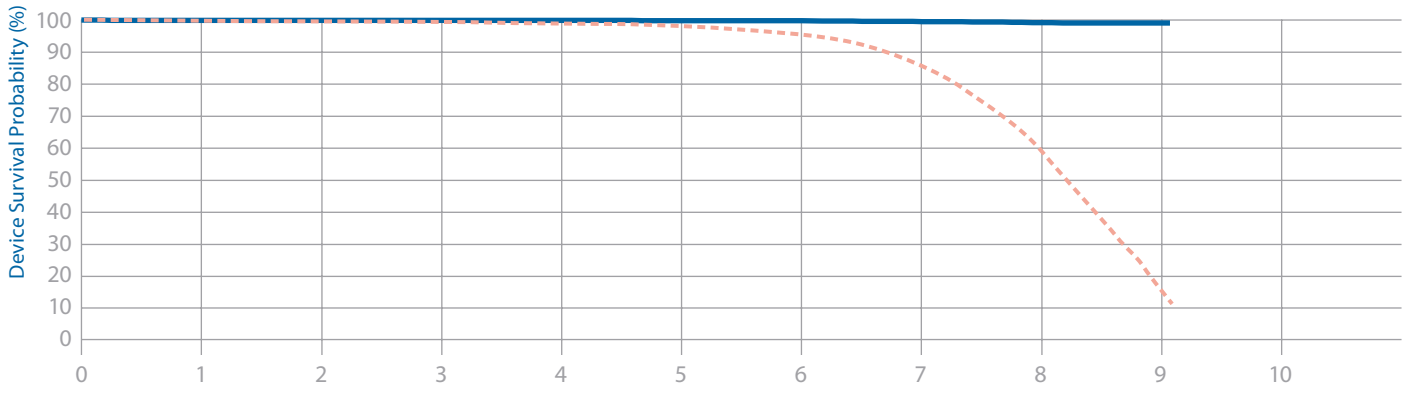
US Market Release	Jan-99
Registered US Implants	206,200
Estimated Active US Implants	22,200
Normal Battery Depletions (US)	35,745

Advisories: See page 140– 2009 Potential Separation of Interconnect Wires

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	744
Therapy Function Not Compromised	53
Electrical Component	26
Electrical Interconnect	19
Battery Malfunction	1
Possible Early Battery Depletion	4
Other	3
Therapy Function Compromised	691
Electrical Component	17
Electrical Interconnect (*206 malfunctions due to advisory*)	673
Possible Early Battery Depletion	1

NBG Code	DDD , DDD/RO
Serial Number Prefix	PGT, PGU, PGW, PGY, PHJ
Estimated Longevity	See page 71



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 109 mo
%	———	100.0	100.0	99.9	99.9	99.9	99.9	99.7	99.6	99.4	99.4
%	- - -	99.9	99.8	99.6	99.1	98.0	95.4	85.9	59.3	12.4	3.2
#		180,500	165,500	151,000	136,600	122,400	107,000	83,000	41,900	3,700	1,600

Effective Sample Size

Kappa 700 DR KDR721

Product Characteristics

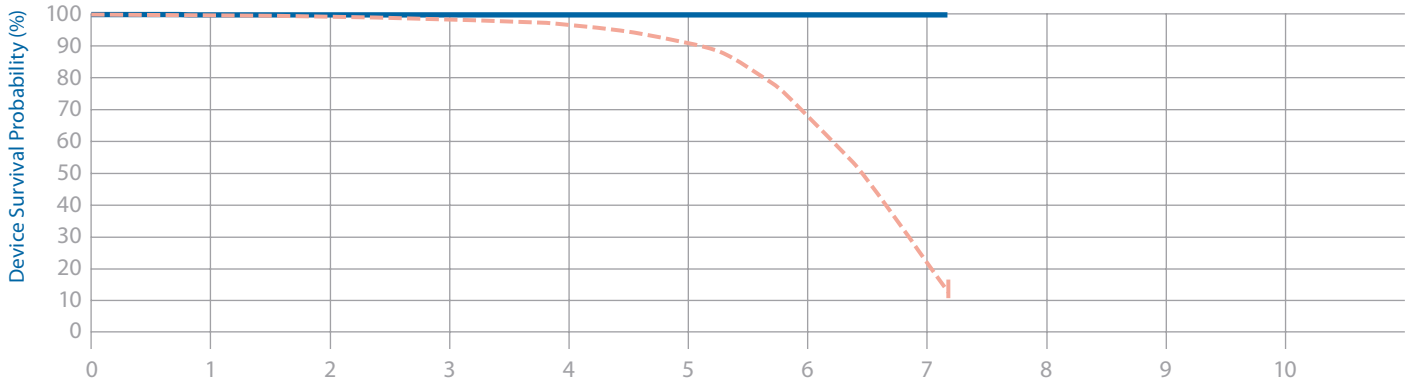
US Market Release	Feb-99
Registered US Implants	9,800
Estimated Active US Implants	700
Normal Battery Depletions (US)	1,349

Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	5
Therapy Function Not Compromised	1
Electrical Component	1
Therapy Function Compromised	4
Electrical Interconnect	4

NBG Code	DDD/RO
Serial Number Prefix	PGR
Estimated Longevity	See page 71



		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	99.5	98.7	96.6	90.7	68.8	22.2	12.4
#	Effective Sample Size	8,600	7,600	6,600	5,600	4,500	2,300	300	130

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Kappa 700 SR KSR701, KSR703, KSR706

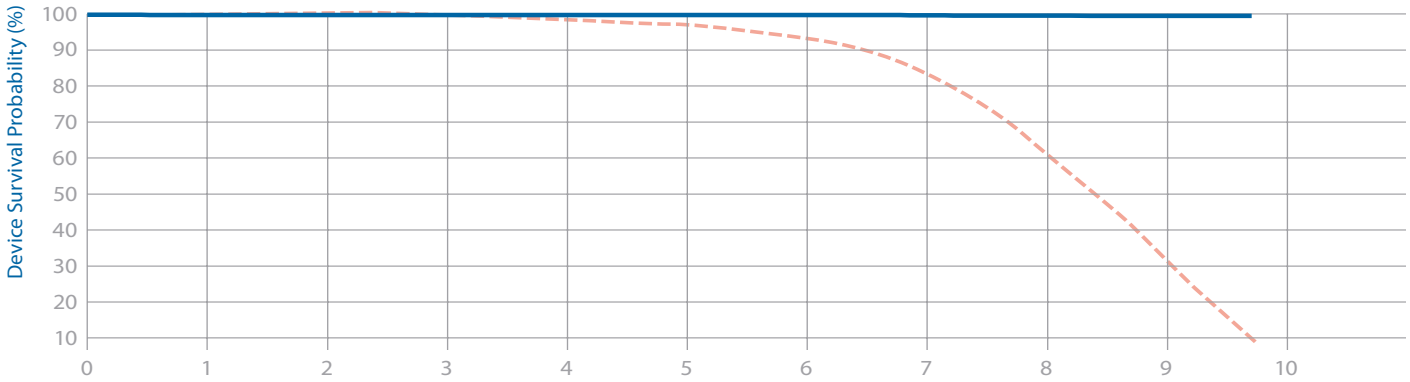
Product Characteristics

US Market Release	Jan-99
Registered US Implants	55,200
Estimated Active US Implants	5,700
Normal Battery Depletions (US)	5,272

Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	28
Therapy Function Not Compromised	4
Electrical Component	2
Electrical Interconnect	1
Possible Early Battery Depletion	1
Therapy Function Compromised	24
Electrical Component	4
Electrical Interconnect	20

NBG Code	SSIR
Serial Number Prefix	PHR, PHT, PHU, PHW
Estimated Longevity	See page 71



		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 116 mo
%	———	100.0	100.0	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.8
%	- - -	99.9	99.7	99.3	98.5	97.0	93.5	84.2	61.5	29.5	8.5
#		48,300	41,700	35,700	30,600	25,900	21,400	15,800	7,900	1,800	130

Effective Sample Size

IPG

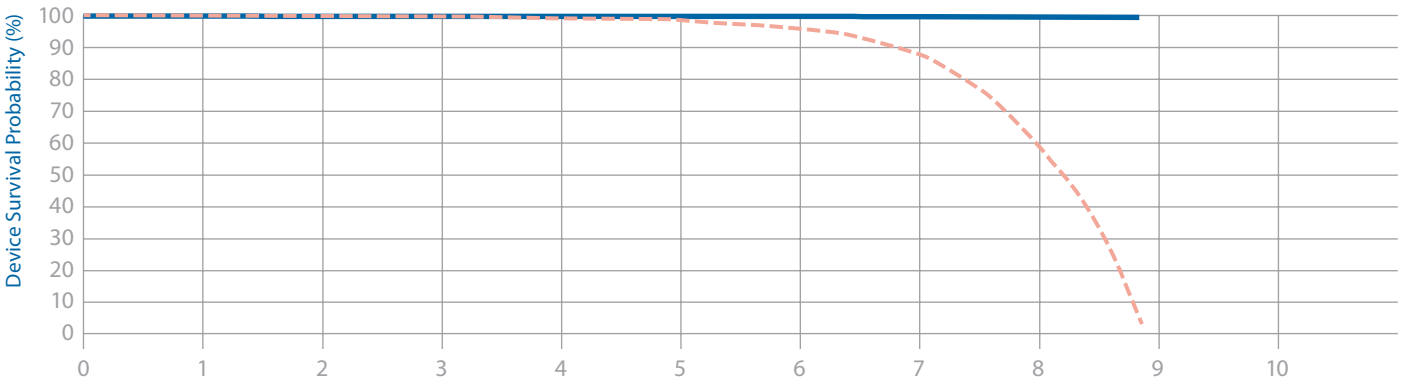
Kappa 900 DR KDR901, KDR903, KDR906

Product Characteristics

US Market Release	Jan-02
Registered US Implants	125,600
Estimated Active US Implants	22,900
Normal Battery Depletions (US)	21,661
Advisories	None
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ER	

Malfunctions (US)	74
Therapy Function Not Compromised	21
Electrical Component	16
Electrical Interconnect	4
Other	1
Therapy Function Compromised	53
Electrical Component	9
Electrical Interconnect	44

NBG Code	DDD, DDDR
Serial Number Prefix	PKM, PKN, PKP, PLB, PLC, PLD
Estimated Longevity	See page 71



		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	100.0	100.0	100.0	99.9	99.9	99.9
%	- - - -	99.9	99.9	99.7	99.3	98.4	96.2	87.9	60.4	11.8
#	Effective Sample Size	117,400	108,100	99,000	90,200	81,500	72,500	57,900	28,000	2,400

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Kappa 900 SR KSR901, KSR903, KSR906

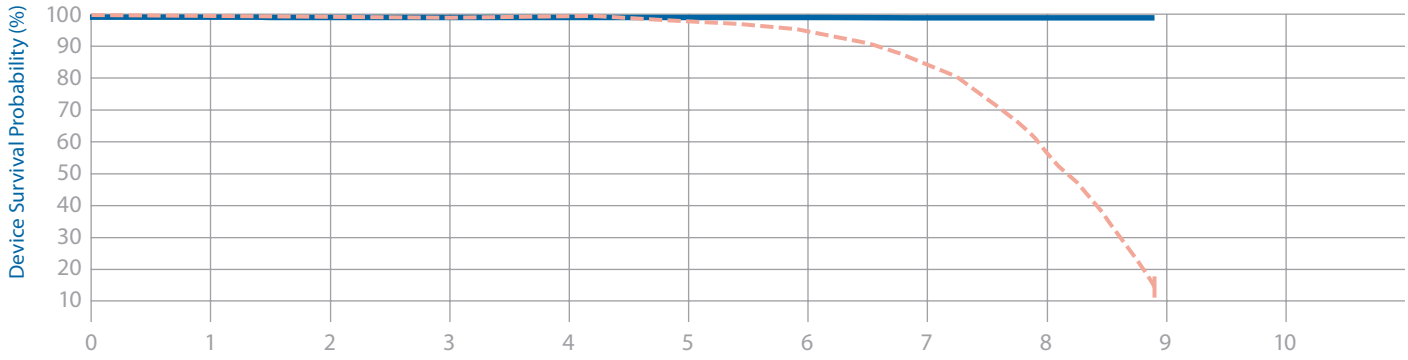
Product Characteristics

US Market Release	Jan-02
Registered US Implants	37,000
Estimated Active US Implants	5,700
Normal Battery Depletions (US)	3,480

Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	17
Therapy Function Not Compromised	8
Electrical Component	7
Possible Early Battery Depletion	1
Therapy Function Compromised	9
Electrical Interconnect	9

NBG Code	SSIR
Serial Number Prefix	PLF, PLG, PLH
Estimated Longevity	See page 71



	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	100.0	100.0	99.9	99.9	99.9	99.9
%	99.9	99.7	99.4	98.6	97.3	94.4	84.9	56.8	13.0
#	32,000	27,600	24,000	20,700	17,700	14,900	10,880	4,100	260

Effective Sample Size

Kappa 900 VDD KVDD901

Product Characteristics

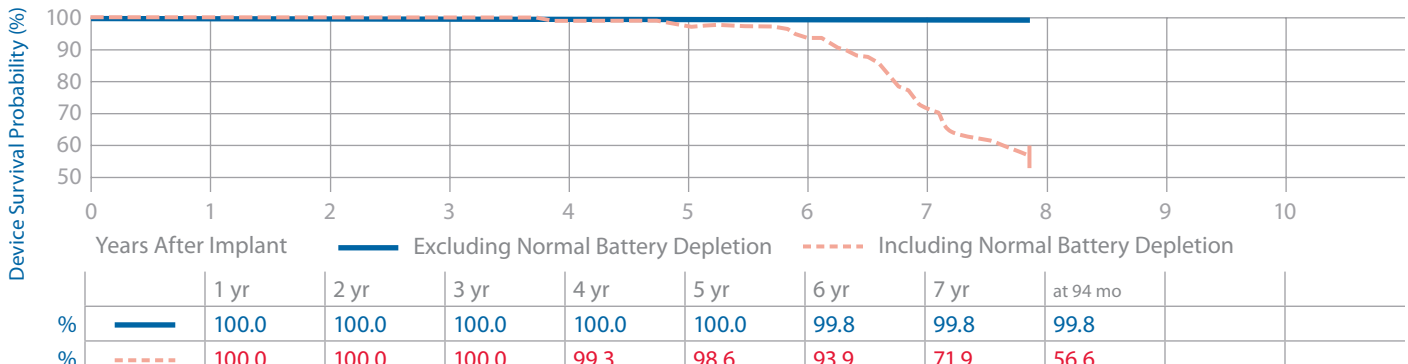
US Market Release	Jan-02
Registered US Implants	700
Estimated Active US Implants	100
Normal Battery Depletions (US)	82

Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	1
Therapy Function Not Compromised	1
Other	1
Therapy Function Compromised	0

NBG Code	VDD
Serial Number Prefix	PLE
Estimated Longevity	See page 71



	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	99.8	99.8	99.8
%	100.0	100.0	100.0	99.3	98.6	93.9	71.9	56.6
#	800	700	700	600	600	500	200	100

Effective Sample Size

Kappa 920 DR KDR921

Product Characteristics

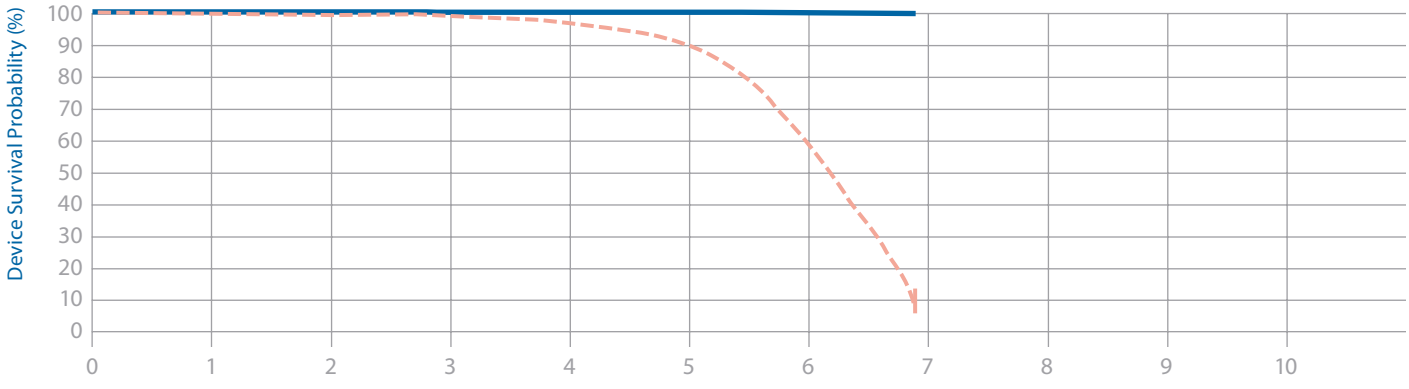
US Market Release	Jan-02
Registered US Implants	16,300
Estimated Active US Implants	1,400
Normal Battery Depletions (US)	2,823

Advisories: See page 140 – 2009
Potential Separation of Interconnect Wires

Performance Note: See page 146 –
Performance note on Dual Chamber Pacemakers with Measurement Lock-up ER

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

NBG Code	DDDR
Serial Number Prefix	PKR
Estimated Longevity	See page 71



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 83 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	99.9	99.6	99.0	96.8	89.7	59.5	0.5
#	14,200	12,700	11,200	9,700	7,700	3,500	120

Effective Sample Size

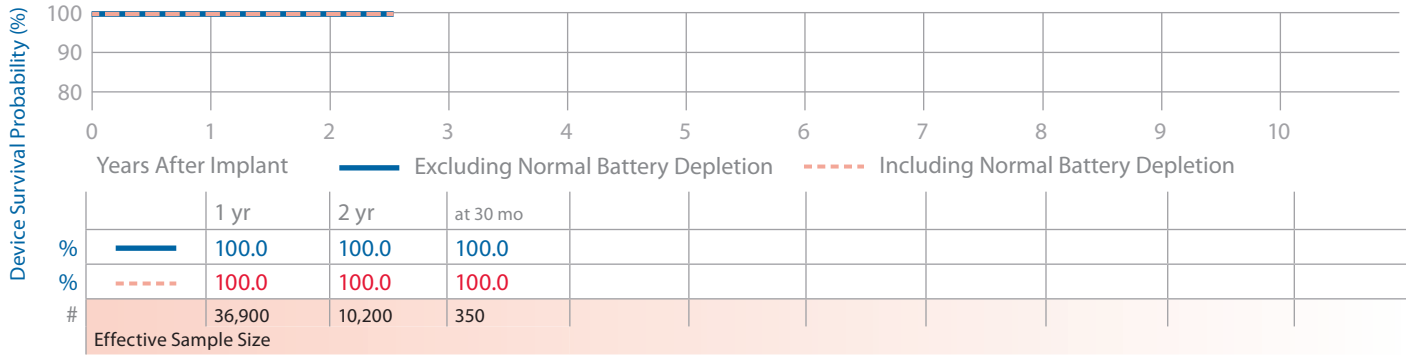
Revo MRI SureScan RVDR01

Product Characteristics

US Market Release	Feb-11
Registered US Implants	58,700
Estimated Active US Implants	56,600
Normal Battery Depletions (US)	2
Advisories	None

Malfunctions (US)	5
Therapy Function Not Compromised	4
Electrical Component	4
Therapy Function Compromised	1
Electrical Component	1

NBG Code	DDDRP
Serial Number Prefix	PTN
Estimated Longevity	See page 71



	1 yr	2 yr	at 30 mo
%	100.0	100.0	100.0
%	100.0	100.0	100.0
#	36,900	10,200	350

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

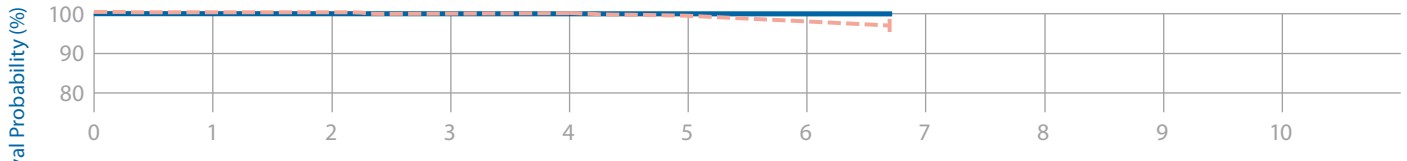
Sensia DR SEDR01, SED01

US Market Release	Jul-06
Registered US Implants	124,600
Estimated Active US Implants	93,600
Normal Battery Depletions (US)	250
Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ER	

Malfunctions (US)	24
Therapy Function Not Compromised	14
Electrical Component	12
Electrical Interconnect	1
Other	1
Therapy Function Compromised	10
Electrical Component	4
Electrical Interconnect	1
Other	5

Product Characteristics

NBG Code	DDD, DDDR
Serial Number Prefix	PWL, PWK, NWL, NWK
Estimated Longevity	See page 71



	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
%	100.0	100.0	99.9	99.6	99.1	98.1	97.1
#	104,000	82,000	60,900	40,900	22,300	7,800	500

Effective Sample Size

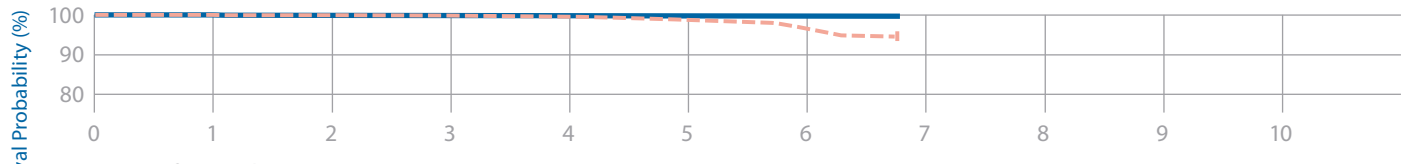
Sensia SR SESR01, SES01

US Market Release	Jul-06
Registered US Implants	87,800
Estimated Active US Implants	61,200
Normal Battery Depletions (US)	198
Advisories	None

Malfunctions (US)	8
Therapy Function Not Compromised	6
Electrical Component	5
Other	1
Therapy Function Compromised	2
Electrical Component	1
Electrical Interconnect	1

Product Characteristics

NBG Code	SSIR, SSI
Serial Number Prefix	PWR, PWS, NWR, NWS
Estimated Longevit	See page 71



	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
%	100.0	99.9	99.8	99.6	99.0	97.6	94.7
#	70,300	51,900	36,400	22,900	11,700	4,000	110

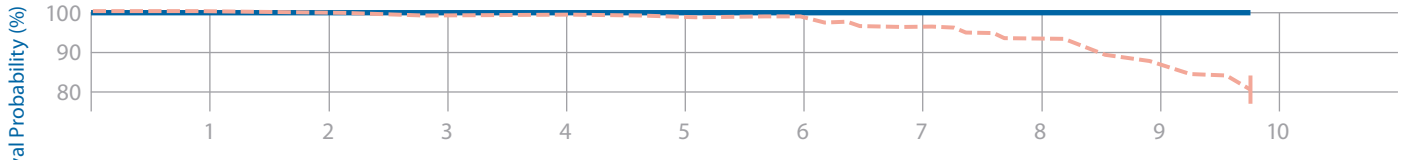
Effective Sample Size

Sigma 100 S SS103, SS106

Product Characteristics

US Market Release	Aug-99	Malfunctions (US)	0	NBG Code	SSI
Registered US Implants	800	**Therapy Function Not Compromised**	0	Serial Number Prefix	PJG, PJH
Estimated Active US Implants	100	**Therapy Function Compromised**	0	Estimated Longevity	See page 71
Normal Battery Depletions (US)	26				

Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 116 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	100.0	99.6	99.6	98.8	98.8	97.0	93.8	85.7	79.6
#	600	500	400	300	300	200	200	200	100	100

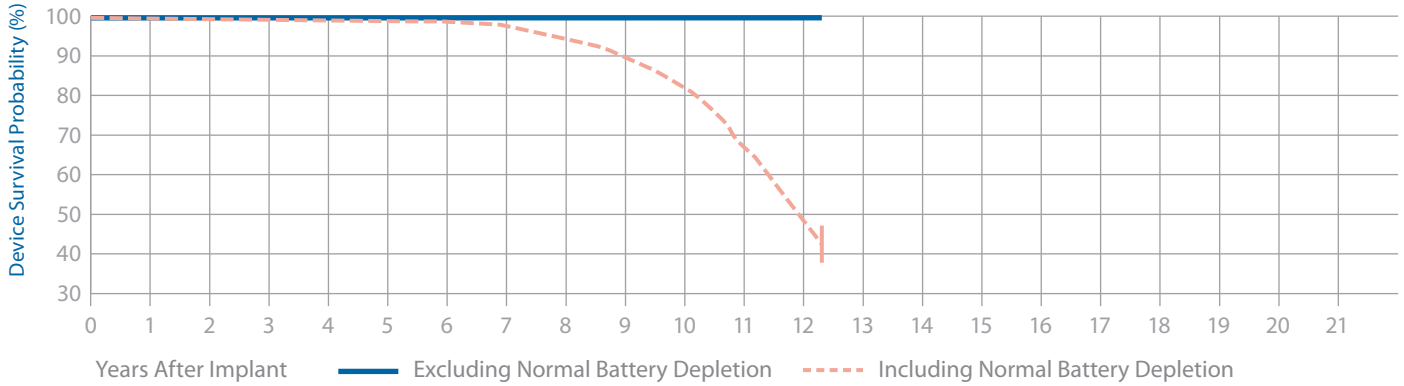
Effective Sample Size

Sigma 200 DR SDR203

Product Characteristics

US Market Release	Aug-99	Malfunctions (US)	36	NBG Code	DDD/RO
Registered US Implants	15,900	**Therapy Function Not Compromised**	10	Serial Number Prefix	PJD
Estimated Active US Implants	3,100	Electrical Component	1	Estimated Longevity	See page 72
Normal Battery Depletions (US)	915	Electrical Interconnect *(1 malfunction due to advisory)*	9		
		Therapy Function Compromised	26		
		Electrical Component	2		
		Electrical Interconnect *(20 malfunctions due to advisory)*	23		
		Other	1		

Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires



	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 148 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.6	99.5	99.5	99.5	99.4	99.4
%	100.0	99.9	99.9	99.7	99.4	98.8	97.3	94.3	90.3	83.5	69.9	51.9	41.4
#	14,200	12,700	11,300	10,100	9,000	8,000	6,900	5,900	4,800	3,500	1,900	500	160

Effective Sample Size

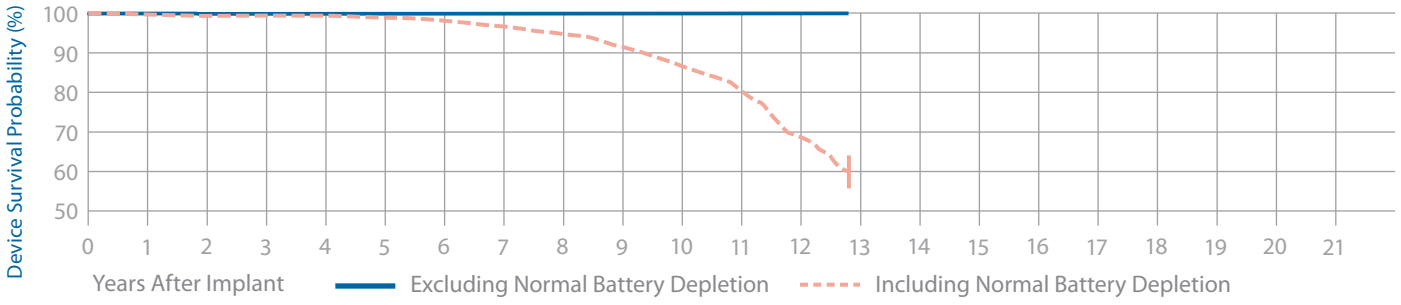
Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Sigma 200 SR SSR203, SS203

Product Characteristics

US Market Release	Sep-99	Malfunctions (US)	14	NBG Code	SSIR, SSI
Registered US Implants	12,100	**Therapy Function Not Compromised**	0	Serial Number Prefix	PJG
Estimated Active US Implants	1,700	**Therapy Function Compromised**	14	Estimated Longevity	See page 72
Normal Battery Depletions (US)	434	Electrical Interconnect *(13 malfunctions due to advisory)*	14		

Advisories: See page 144– 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires



	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 154 mo
%	100.0	100.0	100.0	100.0	99.9	99.9	99.8	99.7	99.6	99.6	99.6	99.6	99.6
%	99.9	99.9	99.8	99.7	99.2	98.6	97.2	95.2	92.1	86.6	76.0	66.5	57.7
#	10,300	8,700	7,400	6,400	5,500	4,800	4,100	3,600	2,900	2,200	1,400	700	130

Effective Sample Size

Sigma 300 DR SDR303, SDR306

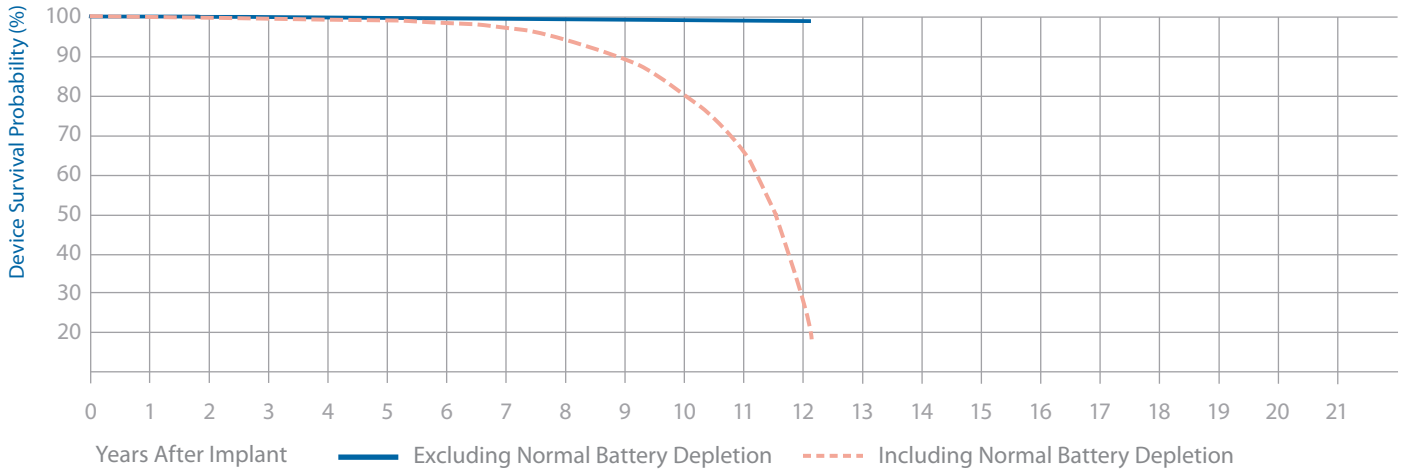
Product Characteristics

US Market Release	Aug-99
Registered US Implants	106,900
Estimated Active US Implants	28,400
Normal Battery Depletions (US)	4,553

Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	249
Therapy Function Not Compromised	53
Electrical Component	7
Electrical Interconnect *(4 malfunctions due to advisory)*	44
Possible Early Battery Depletion	1
Other	1
Therapy Function Compromised	196
Electrical Component	7
Electrical Interconnect *(123 malfunctions due to advisory)*	188
Other	1

NBG Code	DDD/RO, DDD
Serial Number Prefix	PJD, PJE
Estimated Longevity	See page 72



	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	99.9	99.9	99.9	99.8	99.6	99.5	99.4	99.4	99.4	99.4
%	99.9	99.9	99.8	99.6	99.3	98.7	97.7	95.1	90.9	83.6	69.7	43.5	18.2
#	96,600	86,500	77,500	69,100	61,400	54,000	45,200	35,500	26,300	16,600	7,900	1,100	200

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Sigma 300 SR SSR303, SSR306

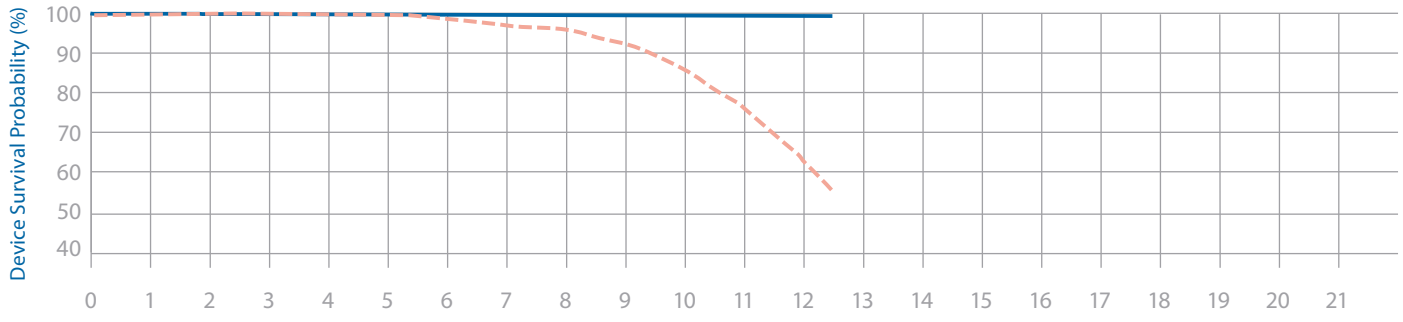
Product Characteristics

US Market Release	Aug-99
Registered US Implants	54,200
Estimated Active US Implants	10,300
Normal Battery Depletions (US)	1,420

Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires

Malfunctions (US)	57
Therapy Function Not Compromised	15
Electrical Component	1
Electrical Interconnect *(3 malfunctions due to advisory)*	12
Other	2
Therapy Function Compromised	42
Electrical Component	3
Electrical Interconnect *(20 malfunctions due to advisory)*	39

NBG Code	SSIR, SSI
Serial Number Prefix	PJG, PJH
Estimated Longevity	See page 72



	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	99.9	99.8	99.7	99.7	99.7	99.6	99.5	99.5
%	99.9	99.9	99.7	99.5	99.2	98.6	97.5	95.5	91.9	85.8	76.0	63.3	54.2
#	47,100	40,000	34,100	29,400	25,400	21,500	17,500	13,900	10,300	6,600	3,400	1,100	170

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Sigma 300 VDD SVDD303

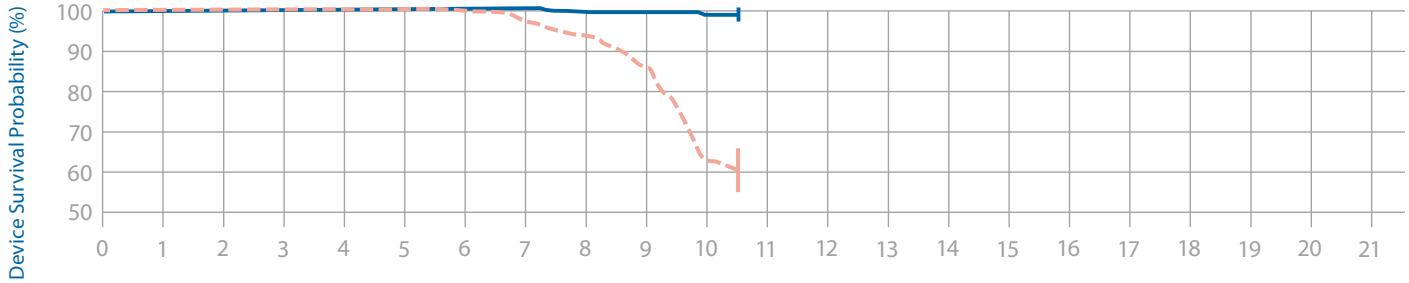
Product Characteristics

US Market Release	Sep-99
Registered US Implants	650
Estimated Active US Implants	80
Normal Battery Depletions (US)	71

Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires

Malfunctions (US)	1
Therapy Function Not Compromised	0
Therapy Function Compromised	1
Electrical Interconnect *(1 malfunction due to advisory)*	1

NBG Code	VDDD
Serial Number Prefix	PJD
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 127 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	99.8	99.2	99.2	98.8	98.8
%	100.0	100.0	100.0	100.0	99.7	99.1	96.6	93.2	85.3	64.6	59.7
#	900	800	800	700	700	600	500	500	300	200	100

Effective Sample Size

Versa DR VEDR01

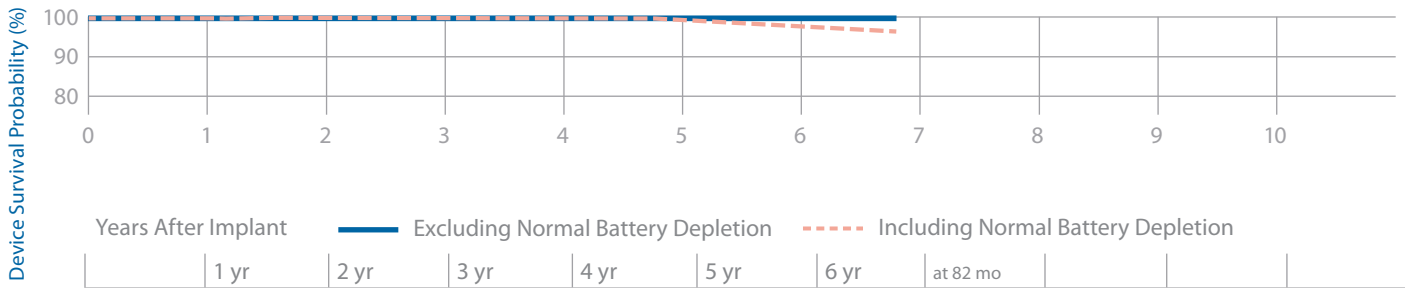
Product Characteristics

US Market Release	Jul-06
Registered US Implants	97,400
Estimated Active US Implants	73,700
Normal Battery Depletions (US)	245

Performance Note: See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI

Malfunctions (US)	13
Therapy Function Not Compromised	7
Electrical Component	5
Electrical Interconnect	2
Other	0
Therapy Function Compromised	6
Electrical Component	2
Other	4

NBG Code	DDDR
Serial Number Prefix	PWH, NWH
Estimated Longevity	See page 72



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 82 mo
%	100.0	100.0	100.0	100.0	100.0	100.0	100.0
%	100.0	99.9	99.9	99.7	99.2	98.2	97.0
#	85,500	69,200	53,100	37,400	22,300	9,200	130

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Jul-06	361,100	295,800	570	22	+	38	=	60	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 82 mo				
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.0/-0.0	98.7 +0.1/-0.1	97.7 +0.2/-0.2 at 82 mo				
Adapta DR	ADDRL1	Jul-06	81,800	73,700	36	3	+	6	=	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 81 mo				
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	99.3 +0.2/-0.2	99.2 +0.2/-0.3 at 81 mo				
Adapta DR	ADDRS1	Jul-06	35,200	26,100	514	4	+	6	=	10	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 77 mo				
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.6 +0.1/-0.1	98.8 +0.2/-0.2	95.3 +0.4/-0.5	79.4 +1.4/-1.5	59.0 +3.7/-3.9 at 77 mo				
Adapta SR	ADSR01, ADSR03, ADSR06	Jul-06	69,000	48,700	236	4	+	5	=	9	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 81 mo				
											Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.4 +0.1/-0.1	98.5 +0.2/-0.2	96.7 +0.3/-0.4	95.1 +0.7/-0.9 at 81 mo				
Adapta VDD	ADVDD01	Jul-06	1,100	800	2	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 71 mo					
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	97.2 +1.7/-4.5 at 71 mo					
Advisa DR MRI Ensura	A2DR01, A3DR01, A4DR01, A5DR01, ENDR01	Apr-11	8,500	8,400	0	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 40 mo							
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 40 mo							

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
EnPulse DR	E1DR01, E1DR03, E1DR06	Dec-03	6,800	1,200	1,298	0	+	1	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 108 mo		
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.2	98.9 +0.2/-0.3	98.0 +0.4/-0.4	96.5 +0.5/-0.6	86.8 +1.0/-1.1	59.8 +1.7/-1.7	13.1 +1.7/-1.6 at 108 mo		
EnPulse DR	E1DR21	Dec-03	1,900	150	374	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 80 mo				
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	99.6 +0.2/-0.5	98.6 +0.5/-0.8	96.2 +0.9/-1.2	91.9 +1.4/-1.7	61.3 +3.2/-3.3	23.6 +3.8/-3.6 at 80 mo				
EnPulse 2 DR	E2DR01, E2DR03, E2DR06, E2D01, E2D03	Feb-04	101,000	40,300	8,198	6	+	20	=	26	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 103 mo		
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.4 +0.1/-0.1	98.7 +0.1/-0.1	97.1 +0.1/-0.1	91.4 +0.2/-0.2	70.9 +0.5/-0.5	34.3 +1.3/-1.3 at 103 mo		
EnPulse 2 DR	E2DR21	Feb-04	12,200	1,900	2,074	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 85 mo			
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	99.9 +0.0/-0.1	99.5 +0.1/-0.2	98.9 +0.2/-0.2	97.1 +0.3/-0.4	91.0 +0.6/-0.7	67.7 +1.2/-1.2	22.5 +1.6/-1.5	14.5 +1.8/-1.7 at 85 mo			
EnPulse 2 DR	E2DR31, E2DR33	Feb-04	600	400	10	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 104 mo		
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.7 +0.2/-0.6	98.7 +0.5/-0.9	98.2 +0.7/-1.0	98.2 +0.7/-1.0 at 104 mo		
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	25,500	6,400	1,754	1	+	3	=	4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0. at 99 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.7 +0.2/-0.2	97.3 +0.2/-0.3	94.1 +0.4/-0.4	84.6 +0.7/-0.7	53.1 +1.6/-1.6	31.1 +3.0/-3.0 at 99 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
EnPulse 2 VDD	E2VDD01	Dec-03	600	190	73	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 86 mo			
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI										Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.6 +0.3/-0.9	98.5 +0.7/-1.5	90.5 +2.4/-3.1	65.5 +4.9/-5.5	62.4 +5.2/-5.8 at 86 mo			
EnRhythm DR	P1501DR	May-05	110,200	63,600	1,651	53	+	7,392	=	7,445	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.0/-0.0	98.9 +0.1/-0.1	95.7 +0.2/-0.2	89.0 +0.3/-0.3	83.8 +0.4/-0.4	82.6 +0.4/-0.4 at 89 mo			
	See page 137 – 2010 Low Battery Voltage Displayed at Device Interrogation					(0) (advisory-related subset)	+	(231)	=	231	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.0/-0.0	97.5 +0.1/-0.1	90.7 +0.2/-0.2	75.9 +0.4/-0.4	58.4 +0.5/-0.5	45.5 +1.0/-1.0 at 89 mo			
EnRhythm MRI	EMDR01	N/A	110	80	0	0	+	10	=	10	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	98.1 +1.4/-5.7 at 45 mo							
											Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	96.1 +2.4/-6.1 at 45 mo							
Kappa 400 DR	KDR401, KDR403	Jan-98	46,700	4,000	7,981	12	+	15	=	27	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 107 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.8 +0.1/-0.1	97.1 +0.2/-0.2	88.1 +0.4/-0.4	58.8 +0.7/-0.7	7.8 +0.7/-0.7 at 107 mo		
Kappa 400 SR	KSR401, KSR403	Feb-98	15,400	1,500	1,547	1	+	4	=	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 113 mo		
											Including Normal Battery Depletion	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	98.4 +0.2/-0.3	96.6 +0.4/-0.4	90.2 +0.7/-0.7	66.0 +1.3/-1.4	14.4 +1.9/-1.8 at 113 mo		
Kappa 700 DR	KD701, KD703, KD706	Jan-99	300	100	21	0	+	0	=	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 98 mo		
	See page 140 – 2009 Potential Separation of Interconnect Wires					(0) (advisory-related subset)	+	(0)	=	(0)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.0 +0.7/-2.7	98.0 +1.2/-3.2	95.8 +2.1/-4.0	94.7 +2.4/-4.3	86.5 +4.5/-6.4	84.8 +4.8/-6.8 at 98 mo		
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																					

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
Kappa 700 DR	KDR701, KDR703, KDR706	Jan-99	206,200	22,200	33,745	691	53	744	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.6 +0.0/-0.0	99.4 +0.1/-0.1 at 109 mo		
	See page 140 – 2009 Potential Separation of Interconnect Wires					(206)	(0)	(206) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	99.1 +0.0/-0.0	98.0 +0.1/-0.1	95.4 +0.1/-0.1	85.9 +0.2/-0.2	59.3 +0.3/-0.3	3.2 +0.3/-0.3 at 109 mo		
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																			
Kappa 700 DR	KDR721	Feb-99	9,800	700	1,349	4	1	5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1	99.9 +0.1/-0.1 at 86 mo			
	See page 140 – 2009 Potential Separation of Interconnect Wires					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.1/-0.1	99.5 +0.1/-0.2	98.7 +0.2/-0.3	96.6 +0.4/-0.5	90.7 +0.7/-0.8	68.8 +1.4/-1.5	22.2 +2.0/-1.9	12.4 +2.0/-1.8 at 86 mo			
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																			
Kappa 700 SR	KSR701, KSR703, KSR706	Jan-99	55,300	5,700	5,273	24	4	28	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.8 +0.1/-0.1 at 116 mo		
	See page 140 – 2009 Potential Separation of Interconnect Wires					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.3 +0.1/-0.1	98.5 +0.1/-0.1	97.0 +0.2/-0.2	93.5 +0.3/-0.3	84.2 +0.5/-0.5	61.5 +0.7/-0.8	8.5 +1.3/-1.2 at 116 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
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	125,600	22,900	21,661	53	+ 21	= 74	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0 at 107 mo			
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI								Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.0	99.3 +0.0/-0.1	98.4 +0.1/-0.1	96.2 +0.1/-0.1	87.9 +0.2/-0.2	60.4 +0.4/-0.4	11.8 +0.5/-0.5 at 107 mo			
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	37,000	5,700	3,480	9	+ 8	= 17	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1 at 107 mo			
	Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires					(0)	+ (0)	= (0) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.7 +0.1/-0.1	99.4 +0.1/-0.1	98.6 +0.1/-0.2	97.3 +0.2/-0.2	94.4 +0.3/-0.3	84.9 +0.6/-0.6	56.8 +1.0/-1.0	13.0 +1.5/-1.4 at 107 mo			
Kappa 900 VDD	KVDD901	Jan-02	650	75	82	0	+ 1	= 1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.2/-1.3	99.8 +0.2/-1.3	99.8 +0.2/-1.3 at 94 mo				
	Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires					(0)	+ (0)	= 0 (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.3 +0.4/-1.0	98.6 +0.7/-1.3	93.9 +1.8/-2.4	71.9 +4.1/-4.7	56.6 +5.3/-5.7 at 94 mo				
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Kappa 920 DR	KDR921	Jan-02	16,300	1,400	2,823	3	+ 1	= 4	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 83 mo					
	Advisories: See page 140 – 2009 Potential Separation of Interconnect Wires					(0)	+ (0)	= 0 (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.6 +0.1/-0.1	99.0 +0.2/-0.2	96.8 +0.3/-0.3	89.7 +0.6/-0.6	59.5 +1.1/-1.2	.5 +0.6/-0.3 at 83 mo					
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI																				
Revo MRI SureScan	RVDR01	Feb-11	58,700	56,600	2	1	+ 4	= 5	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 30 mo									
									Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 30 mo									
Sensia DR	SEDR01, SED01	Jul-06	124,600	93,600	250	10	+ 14	= 24	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 81 mo					
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI								Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.6 +0.0/-0.1	99.1 +0.1/-0.1	98.1 +0.2/-0.2	97.1 +0.6/-0.7 at 81 mo					
Sensia SR	SESR01, SES01	Jul-06	87,800	61,200	198	2	+ 6	= 8	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 81 mo					
									Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.0 +0.1/-0.1	97.6 +0.3/-0.3	94.7 +0.8/-1.0 at 81 mo					

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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
Sigma 100 S	SS103, SS106	Aug-99	830	110	26	0	0	0	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 116 mo		
	Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires					(0)	(0)	(0) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.6 +0.3/-1.3	99.6 +0.3/-1.3	98.8 +0.7/-2.0	98.8 +0.7/-2.0	97.0 +1.5/-3.0	93.8 +2.6/-4.3	79.6 +5.6/-7.3 at 116 mo		
Sigma 200 DR	SDR203	Aug-99	15,900	3,100	915	26	10	36	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.8 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.1/-0.2	99.4 +0.2/-0.3	99.4 +0.2/-0.3 at 148 mo
	Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires					(20)	(0)	(20) (advisory-related subset)	Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.0/-0.1	99.7 +0.1/-0.1	99.4 +0.1/-0.2	98.8 +0.2/-0.2	97.3 +0.3/-0.4	94.3 +0.5/-0.6	83.5 +1.0/-1.0	51.9 +2.0/-2.1	41.4 +2.9/-2.9 at 148 mo
Sigma 200 SR	SSR203, SS203	Aug-99	12,100	1,700	434	14	0	14	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.1	99.9 +0.1/-0.2	99.8 +0.1/-0.2	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.6 +0.1/-0.2	99.6 +0.1/-0.2 at 154 mo
	Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires					(13)	(0)	(13) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.1	99.9 +0.1/-0.1	99.8 +0.1/-0.1	99.7 +0.2/-0.2	99.2 +0.2/-0.2	98.6 +0.3/-0.3	97.2 +0.4/-0.5	95.2 +0.6/-0.7	86.6 +1.1/-1.2	65.5 +2.1/-2.2	57.7 +3.2/-3.4 at 154 mo
Sigma 300 DR	SDR303, SDR306	Aug-99	106,800	28,500	4,553	196	53	249	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1	99.4 +0.1/-0.1 at 146 mo
	Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires					(123)	(4)	(127) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.0	99.6 +0.0/-0.0	99.3 +0.1/-0.1	98.7 +0.1/-0.1	97.7 +0.1/-0.1	95.1 +0.2/-0.2	83.6 +0.4/-0.4	43.5 +1.3/-1.3	18.2 +2.8/-2.6 at 146 mo
Sigma 300 SR	SSR303, SSR306	Aug-99	54,200	10,300	1,420	42	15	57	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.8 +0.0/-0.1	99.7 +0.1/-0.1	99.7 +0.1/-0.1	99.5 +0.1/-0.1	99.5 +0.1/-0.1 at 150 mo
	Advisories: See page 144– 2005 Potential Separation of Interconnect Wires; See also page 140 – 2009 Potential Separation of Interconnect Wires					(20)	(3)	(23) (advisory-related subset)	Including Normal Battery Depletion	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.5 +0.1/-0.1	99.2 +0.1/-0.1	98.6 +0.1/-0.1	97.5 +0.2/-0.2	95.5 +0.3/-0.3	85.8 +0.6/-0.7	63.3 +1.5/-1.5	54.2 +2.4/-2.5 at 150 mo

continued

Device Survival Summary continued

Family	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions: Therapy Function Compromised		Therapy Function Not Compromised		Total		Device Survival Probability (%) Years After Implant: 1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Sigma 300 VDD	SVDD303	Sep-99	650	80	71	1	+	0	=	1	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.8 +0.2/-0.9	99.2 +0.5/-1.2	98.8 +0.7/-1.8	98.8 +0.7/-1.8 at 127 mo		
	Advisories: See page 144 – 2005 Potential Separation of Interconnect Wires					(1)	+	0	=	(1)	Including Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	99.7 +0.2/-0.9	99.1 +0.5/-1.1	96.6 +1.2/-1.8	93.2 +1.8/-2.4	64.6 +4.8/-5.3	59.7 +5.3/-5.7 at 127 mo		
Versa DR	VEDR01	Jul-06	97,400	73,700	245	6	+	7	=	13	Excluding Normal Battery Depletion	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0	100.0 +0.0/-0.0 at 82 mo					
	See page 146 – Performance note on Dual Chamber Pacemakers with Measurement Lock-up ERI					(advisory-related subset)					Including Normal Battery Depletion	100.0 +0.0/-0.0	99.9 +0.0/-0.0	99.9 +0.0/-0.0	99.7 +0.0/-0.1	99.2 +0.1/-0.1	98.2 +0.2/-0.2	97.0 +0.4/-0.4 at 82 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

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.

Family	Model Number	Estimated Longevity		
		Amplitude Setting	500 Lead Ω	1000 Lead Ω
Adapta DR	ADDR01, ADDR03, ADDR06, ADD01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	7.4 6.0 4.5	8.2 7.4 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)	9.0 7.3 5.4	10.0 8.9 7.2
Adapta SR	ADSR01, ADSR03, ADSR06	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 5.1	7.9 7.5 6.3
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
Advisa DR	A4DR01, A5DR01	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
Advisa DR MRI+C82	A3DR01	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 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, E2D01, E2D03	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)	9.7 7.3 4.9	11.2 9.4 7.1
EnRhythm MRI	EMDR01	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

continued

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Reference Chart continued

Family	Model Number	Amplitude Setting	Estimated Longevity 500 Lead Ω	Estimated Longevity 1000 Lead Ω
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 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 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
Revo MRI SureScan	RVDR01	Low 2.5 V (A, RV) Nominal 3.5 V (A, RV) High 5.0 V (A, RV)	9.7 7.3 4.9	11.2 9.4 7.1
Sensia DR	SEDR01, SED01	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 7.4 6.0
Sensia SR	SESR01, SES01	Low 2.5 V (RV) Nominal 3.5 V (RV) High 5.0 V (RV)	7.4 6.5 5.1	7.9 7.5 6.3
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

continued

Reference Chart continued

Family	Model Number	Estimated Longevity		
		Amplitude Setting	500 Lead Ω	1000 Lead Ω
Sigma 200 DR	SDR203	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 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
Versa DR	VEDR01	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 7.4 6.0

Source: Medtronic Device Registration and Returned Product Analysis
Data as of August 9, 2013

Method for Estimating Lead Performance

Medtronic CRDM has tracked lead survival for over 30 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.

Shortfalls of Using Returned Product and Complaints to Estimate Lead Performance

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.

To account for the under reporting inherent with lead survival analysis based solely on returned product, some manufacturers add reported complaints where adverse product performance is evident but the product itself has not been returned. The improvement to the accuracy of survival estimates depends on the degree to which all complaints are actually communicated to the manufacturer. Since not all complaints are communicated to the manufacturer, adding complaints to the survival analysis does not completely solve the under reporting problem.

Thus, lead survival probabilities are more appropriately determined through a clinical surveillance study that includes active follow-up with the patients. Although Medtronic monitors returned product analysis and complaints, these are not used to determine lead survival estimates.

Medtronic tracks lead survival through its Product Surveillance Registry. The registry 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 lead need not be returned to Medtronic.

Product Surveillance Registry (PSR)

Medtronic has been monitoring the performance of its cardiac therapy products with a multicenter study since 1983 and has evaluated the performance of more than 95,000 leads, with data reported from countries around the world. Throughout this time period, Medtronic has continually worked to adapt systems and processes to more effectively monitor product performance following market release. The following summarizes current registry requirements.

Medtronic's global Product Surveillance Registry has a prospective, non-randomized, observational design. A key purpose of the registry is to provide continuing evaluation and periodic reporting of the long-term reliability and performance of Medtronic market-released cardiac therapy products. Product-related adverse events, indicating the status of the product, are collected to measure survival probabilities. The data gathered may also be used to support the design and development of investigational plans for new cardiac therapy products. The registry is designed to continue indefinitely, encompassing new products as they become commercially available.

To ensure a sufficiently large and representative source of data, participating clinical sites must meet pre-specified selection criteria. The number of participants is regularly reviewed to ensure the necessary capacity to meet Medtronic's ongoing prospective post-market surveillance needs is available. Every effort is made to ensure participants are representative of the range of clinical environments in which Medtronic cardiac rhythm products are used. Eligible products for enrollment include Medtronic market-released cardiac rhythm therapy products for which additional information to further characterize product performance following market release is desired. Enrollment may be capped at a product when the number enrolled ensures sufficient precision to effectively characterize product survivability.

continued

Method for Estimating Lead Performance continued

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

Enrolled patients are followed in accordance with the standard care practices of their care provider from their implant date until they can no longer be followed (e.g., death, lost to follow-up, etc.). However, to ensure regular patient status assessments are completed, follow-up windows consistent with typical care practices have been established with a minimum annual follow-up requirement. Product-related adverse events, system modifications and changes in patient status (e.g., death and withdrawal from the study) are required to be reported upon occurrence. This active surveillance model ensures a robust dataset for effectively monitoring product performance.

Patients are eligible for enrollment if:

- They are intended to be implanted or are within 30 days 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
- They participated in a qualifying investigational study of a Medtronic cardiac therapy product that is now market-released; complete implant and follow-up data are available; and the data can be appropriately and legally released.

Each site must inform Medtronic whenever a lead complication has occurred or when a patient is no longer participating. Chronic product performance is analyzed as a function of time using the survival analysis method.

Medtronic continually evaluates the quality and integrity of the data through a combination of on-site and centralized monitoring activities.

Lead Complications

The data presented characterizes chronic lead performance by estimating lead-related complication-free survival probabilities. For analysis purposes, the complication criteria, which align with the AdvaMed 'Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads', 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.

All reported lead-related adverse events are classified by the reporting investigator and are adjudicated by an independent event adjudication committee.[1] A lead-related complication is considered to have occurred if a clinical observation occurs more than 30 days after implant, is adjudicated with at least one of the following event classifications and at least one of the following clinical actions is made. Events with an onset date 30 days or less after the implant are considered procedure-related and therefore not included as chronic lead-related complications.

Event Classifications

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200 - 2,000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20 - 200 ohms)
- Insulation breach
- Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

Clinical Actions

- Lead surgically abandoned/capped
- Lead electrically abandoned
- Lead explanted
- Lead replaced
- Lead conductor taken out of service (polarity reprogrammed to remove defective conductor, e.g., bipolar to unipolar)

continued

[1] During the evolution of PSR, event adjudication was transitioned from a Medtronic technical review committee to an independent event adjudication committee in 2011. Data analyses include adjudication using both methods.

- 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.

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 chronic lead-related complication.

Survival times are calculated from the implant date to the earliest of the complication date, out-of-service date (for example, subject leaves the study or the lead is no longer being used) or the last follow-up date. If a lead experiences more than one complication, the first is used to calculate survival time; although all complications associated with a lead are included in the summary tables.

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

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.

Although tabular data is provided 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 the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.

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. For those lead models that do not have sufficient sample size, a survival curve will not be presented.

Definition of Analysis Dataset

The survival estimates are derived from all device components successfully enrolled as of the data cutoff date. The number of enrollments is listed for each lead model.

This sample is considered to be representative of the worldwide population, and therefore the survival estimates shown should be representative of the performance worldwide of these models.

Criteria for Model Inclusion

Performance information for a model or model family will be published when more than 100 leads have been enrolled and no fewer than 50 leads followed for at least 6 months. Models will continue to be published 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.

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.

Returned Product Analysis Results

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 PSR 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, 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 Product Surveillance Registry results, which are intended to measure long-term performance, do not include complications that occur within the first 30 days after implant.

Information about the clinical experience in the first month of service is included in this report. 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 PSR , 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 Product Surveillance Registry. Returned Product Analysis results for these models are included here for reference and comparison.

Left-Heart Leads continued

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	2,700	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

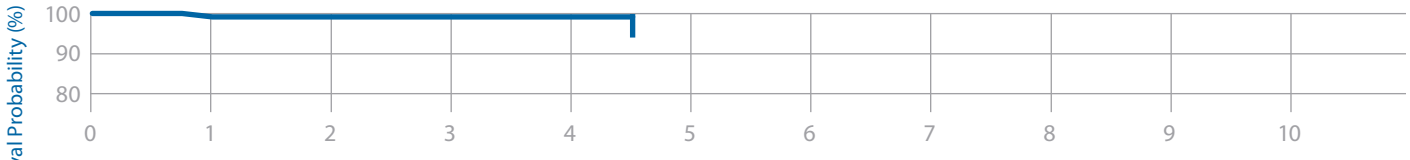
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	134
Cumulative Months of Follow-Up	6,763
Number of Leads Active in Study	11

Qualifying Complications 1 Total

Failure to Capture	1



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	99.1	99.1	99.1	99.1	99.1
#	109	91	70	56	50

Effective Sample Size

4193 Attain OTW

Product Characteristics

US Market Release	May-02	Serial Number Prefix	BAA
Registered US Implants	100,800	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	34,100	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

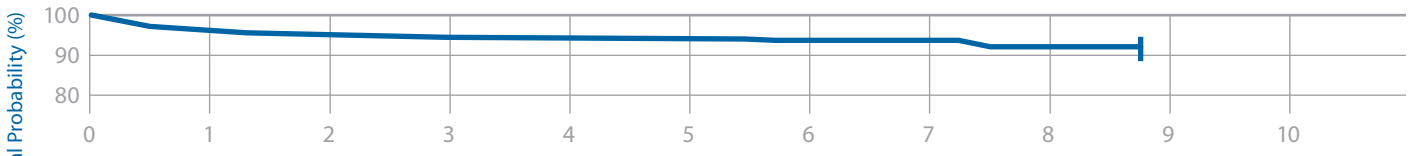
Conductor Fracture	52
Crimp/Weld/Bond	0
Insulation Breach	8
Other	48

Product Surveillance Registry Results

Number of Leads Enrolled in Study	675
Cumulative Months of Follow-Up	31,621
Number of Leads Active in Study	103

Qualifying Complications 39 Total

Conductor Fracture	1
Extra Cardiac Stimulation	8
Failure to Capture	13
Lead Dislodgement	14
Unspecified Clinical Failure	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 105 mo
%	95.9	95.0	94.3	94.0	93.6	93.1	93.1	92.2	92.2
#	546	437	357	274	208	162	118	82	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Left-Heart Leads

4194 Attain OTW

Product Characteristics

US Market Release	Aug-04	Serial Number Prefix	LFG
Registered US Implants	109,700	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	65,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	13
Crimp/Weld/Bond	0
Insulation Breach	58
Other	9

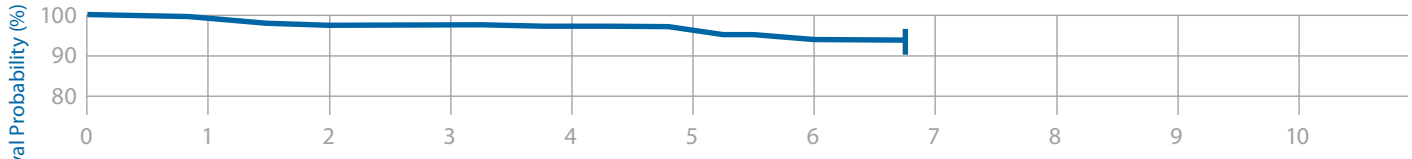
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,223
Cumulative Months of Follow-Up	42,016
Number of Leads Active in Study	648

Qualifying Complications

36 Total

Extra Cardiac Stimulation	8
Failure to Capture	11
Insulation (ESC)	1
Insulation (not further defined)	2
Lead Dislodgement	14



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	98.6	97.3	97.2	96.6	96.1	93.6	93.6
#	1,018	729	436	269	171	108	52

Effective Sample Size

4195 Attain StarFix

Product Characteristics

US Market Release	Aug-08	Serial Number Prefix	AAD
Registered US Implants	15,100	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Deployable Lobe Fixation
Estimated Active US Implants	11,900	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

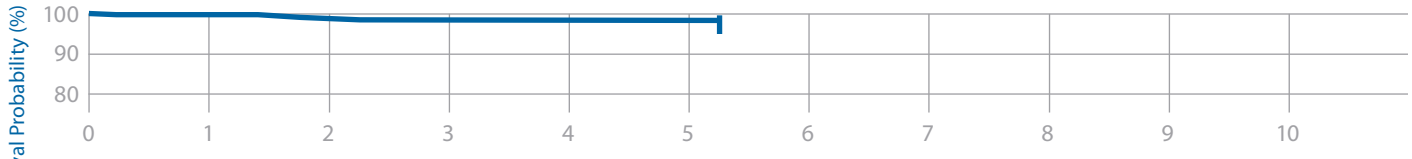
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,279
Cumulative Months of Follow-Up	30,282
Number of Leads Active in Study	886

Qualifying Complications

15 Total

Conductor Fracture	1
Extra Cardiac Stimulation	8
Failure to Capture	2
Insulation (not further defined)	1
Lead Dislodgement	3



	1 yr	2 yr	3 yr	4 yr	5 yr	at 63 mo
%	99.2	98.6	98.2	98.2	98.2	98.2
#	885	510	230	77	52	49

Effective Sample Size

Left-Heart Leads continued

4196 Attain Ability

Product Characteristics

US Market Release	May-09	Serial Number Prefix	PVI
Registered US Implants	52,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Double Curve
Estimated Active US Implants	43,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

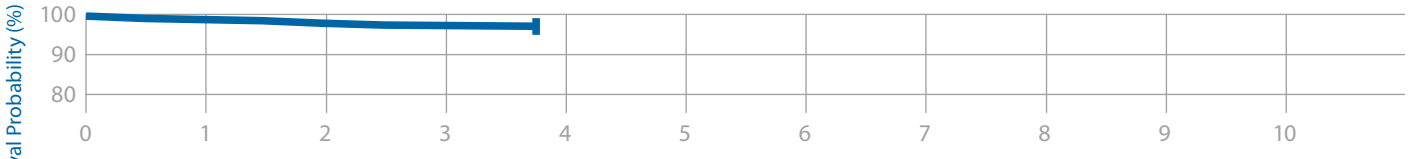
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,878
Cumulative Months of Follow-Up	43,029
Number of Leads Active in Study	1,104

Qualifying Complications

46 Total

Conductor Fracture	1	Lead Dislodgement	16
Extra Cardiac Stimulation	14		
Failure to Capture	15		



	1 yr	2 yr	3 yr	at 45 mo
%	98.0	97.4	96.8	96.8
#	1,432	798	206	38
	Effective Sample Size			

4296 Attain Ability Plus

Product Characteristics

US Market Release	Apr-11	Serial Number Prefix	RRA
Registered US Implants	16,000	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Distal Double Curve
Estimated Active US Implants	15,000	Polarity	Dual Electrodes
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

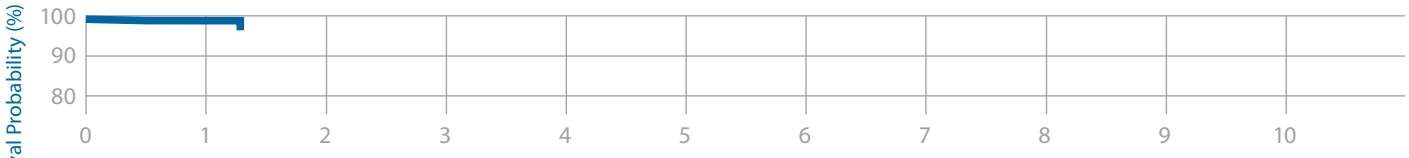
Product Surveillance Registry Results

Number of Leads Enrolled in Study	819
Cumulative Months of Follow-Up	6,360
Number of Leads Active in Study	679

Qualifying Complications

3 Total

Extracardiac Stimulation	1		
Lead Dislodgement	2		



	1 yr	at 15 mo
	99.4	99.4
#	179	96
	Effective Sample Size	

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Left-Heart Leads continued

4396 Attain Ability Straight

Product Characteristics

US Market Release	Mar-11	Serial Number Prefix	RAE
Registered US Implants	3,600	Type and/or Fixation	Transvenous, Left Ventricular Cardiac Vein, Tines
Estimated Active US Implants	3,300	Polarity	Dual Electrodes
Advisories	None	Steroid	Yes

US Returned Product Analysis

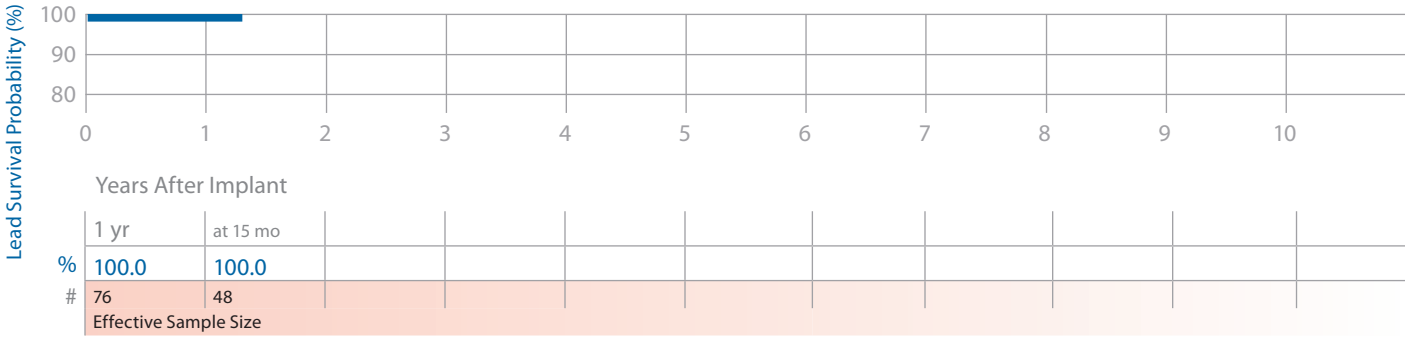
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	211
Cumulative Months of Follow-Up	2,520
Number of Leads Active in Study	165

Qualifying Complications

0 Total



	1 yr	at 15 mo
%	100.0	100.0
#	76	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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	11	1	6,763	99.1 +0.7/-5.1	99.1 +0.7/-5.1	99.1 +0.7/-5.1	99.1 +0.7/-5.1	99.1 +0.7/-5.1 at 54 mo					
4193	Attain OTW	May-02	675	103	39	31,621	95.9 +1.3/-1.9	95.0 +1.5/-2.1	94.3 +1.6/-2.2	94.0 +1.7/-2.3	93.6 +1.8/-2.5	93.1 +2.0/-2.7	93.1 +2.0/-2.7	92.2 +2.4/-3.4	92.2 +2.4/-3.4 at 105 mo	
4194	Attain OTW	Aug-04	1,223	648	36	42,016	98.6 +0.5/-0.9	97.3 +0.8/-1.2	97.2 +0.9/-1.2	96.6 +1.1/-1.5	96.1 +1.3/-2.0	93.6 +2.4/-3.6	93.6 +2.4/-3.6 at 81 mo			
4195	Attain StarFix	Aug-08	1,279	886	15	30,282	99.2 +0.4/-0.8	98.6 +0.6/-1.0	98.2 +0.8/-1.3	98.2 +0.8/-1.3	98.2 +0.8/-1.3	98.2 +0.8/-1.3 at 63 mo				
4196	Attain Ability	May-09	1,878	1,104	46	43,029	98.0 +0.6/-0.8	97.4 +0.7/-0.9	96.8 +0.8/-1.1	96.8 +0.8/-1.1 at 45 mo						
4296	Attain Ability Plus	Apr-11	819	679	3	6,360	99.4 +0.4/-1.3	99.4 +0.4/-1.3 at 15 mo								
4396	Attain Ability Straight	Mar-11	211	165	0	2,520	100 .0	100 .0								

Source: Product Surveillance Registry
Data as of July 31, 2013

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/Weld/ Bond	Other
2187	Attain LV	Aug-01	12,000	2,700	1	0	0	4
4193	Attain OTW	May-02	100,800	34,100	52	8	0	48
4194	Attain OTW	Aug-04	109,700	65,000	13	58	0	9
4195	Attain StarFix	Aug-08	15,100	11,900	1	1	0	3
4196	Attain Ability	May-09	52,000	43,100	6	0	0	6
4296	Attain Ability Plus	Apr-11	16,000	15,000	0	0	0	2
4396	Attain Ability Straight	Mar-11	3,600	3,300	0	0	0	0

Source: Returned Product Analysis
Data as of July 31, 2013

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
2187	Attain LV	12,000	0	0	9	3	0	1	0	0	1	0
4193	Attain OTW	100,800	0	0	45	11	1	0	0	0	16	2
4194	Attain OTW	109,700	2	2	121	36	2	0	0	6	29	5
4195	Attain StarFix	15,100	0	0	23	15	0	0	0	1	22	1
4196	Attain Ability	52,000	1	1	129	35	1	1	1	5	62	3
4296	Attain Ability Plus	16,000	1	0	51	8	0	0	1	0	17	0
4396	Attain Ability Straight	3,600	0	1	16	4	0	0	0	0	5	0

Report Cutoff Date: September 10, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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
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 (outer) SI-polyimide (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI
4296	Attain Ability Plus	Transvenous Cardiac Vein Distal Double Curve	Polyurethane (outer) Silicone (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI
4396	Attain Ability Straight	Transvenous Cardiac Vein Tines	Polyurethane (outer) Silicone (inner)	Ag-core-MP35N	Platinum iridium alloy with titanium nitride coating	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Defibrillation Leads

6721 Epicardial Patch

Product Characteristics

US Market Release	Mar-94	Serial Number Prefix	TBH, TBG, TBB
Registered US Implants	2,900	Type and/or Fixation	Epi Patch, Epicardial Suture
Estimated Active US Implants	1,100	Polarity	NA
Advisories	None	Steroid	No

US Returned Product Analysis

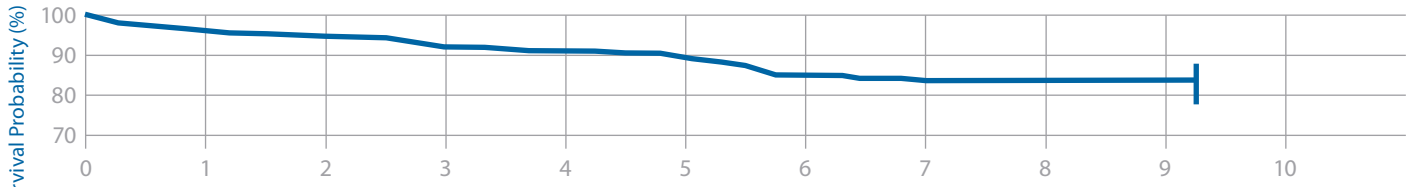
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	1
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	407
Cumulative Months of Follow-Up	23,401
Number of Leads Active in Study	4

Qualifying Complications 47 Total

Conductor Fracture	21	Insulation (not further defined)	2
Failure to Capture	8	Oversensing	12
Impedance Out of Range	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	96.5	95.0	92.7	91.9	90.0	85.1	83.7	83.7	83.7	83.7
#	330	300	256	208	176	132	95	65	55	50

Effective Sample Size

6930 Sprint Fidelis

Product Characteristics

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

See page 142– 2007 Potential Conductor Wire Fracture

US Returned Product Analysis

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

Product Surveillance Registry Results

Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	188
Number of Leads Active in Study	2

Qualifying Complications 0 Total

	at 0 mo
%	100.00
#	4

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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, Right Ventricle, Active Screw-in
Estimated Active US Implants	3,500	Polarity	True Bipolar/One Coil
Advisories		Steroid	Yes
See page 142 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

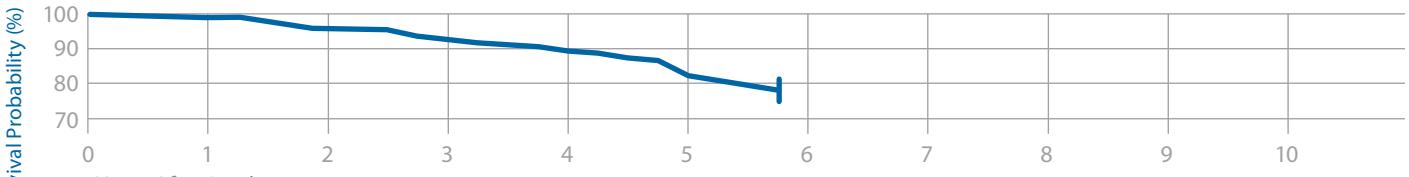
Conductor Fracture	532
Crimp/Weld/Bond	0
Insulation Breach	1
Other	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	294
Cumulative Months of Follow-Up	13,526
Number of Leads Active in Study	113

Qualifying Complications 43 Total

Conductor Fracture	24
Failure to Capture	3
Failure to Sense	1
Impedance Out of Range	8
Lead Dislodgement	2
Oversensing	5



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	98.2	96.2	93.0	88.4	81.9	78.1
#	257	226	193	144	100	46

Effective Sample Size

6932 Sprint

Product Characteristics

US Market Release	Aug-96	Serial Number Prefix	TCA
Registered US Implants	14,900	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	4,200	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

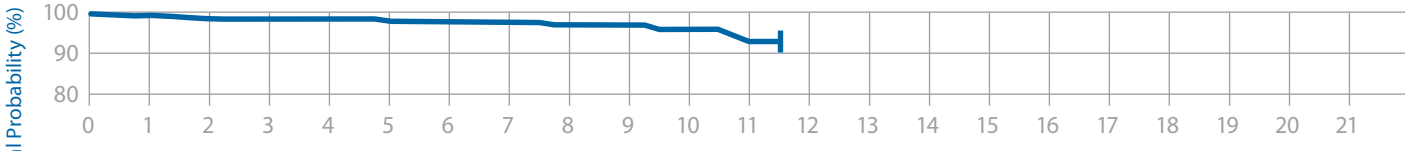
Conductor Fracture	22
Crimp/Weld/Bond	0
Insulation Breach	24
Other	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	412
Cumulative Months of Follow-Up	25,811
Number of Leads Active in Study	38

Qualifying Complications 11 Total

Extra Cardiac Stimulation	1
Failure to Capture	2
Failure to Sense	2
Impedance Out of Range	2
Oversensing	4



	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
%	99.2	98.3	98.3	98.3	97.8	97.8	97.8	96.8	96.8	95.6	92.6	92.6
#	355	296	240	199	161	129	110	94	82	71	56	50

Effective Sample Size

Leads

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Defibrillation Leads continued

6933, 6937, 6937A, SVC/CS

Product Characteristics

US Market Release	Apr-94	Serial Number Prefix	TAT, TBU, TDB
Registered US Implants	11,900	Type and/or Fixation	Transvenous, SVC/CS, Passive
Estimated Active US Implants	2,400	Polarity	One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

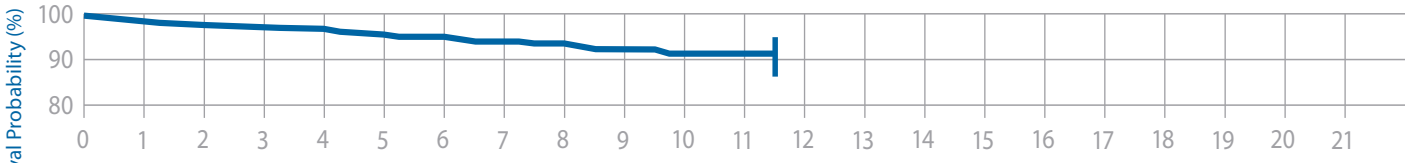
Conductor Fracture	127
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,489
Number of Leads Active in Study	11

Qualifying Complications 47 Total

Conductor Fracture	16	Insulation (not further defined)	2
Extra Cardiac Stimulation	4	Lead Dislodgement	1
Failure to Capture	6	Oversensing	10
Failure to Sense	1	Unspecified Clinical Failure	4
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	at 138 mo
%	98.4	97.5	97.2	96.7	95.4	94.9	93.9	93.4	92.2	91.2	91.2	91.2
#	809	676	565	470	380	297	212	162	107	77	57	49

Effective Sample Size

6935 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-08	Serial Number Prefix	TAU
Registered US Implants	42,900	Type and/or Fixation	Transvenous, Right Ventricle, Active Screw-in
Estimated Active US Implants	38,800	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

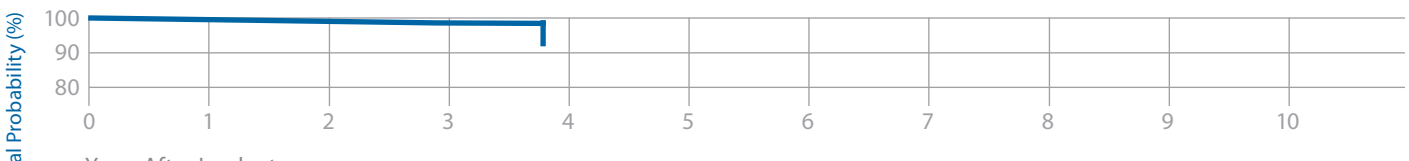
Conductor Fracture	61
Crimp/Weld/Bond	0
Insulation Breach	2
Other	35

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,026
Cumulative Months of Follow-Up	36,705
Number of Leads Active in Study	1,550

Qualifying Complications 14 Total

Conductor Fracture	4	Oversensing	3
Failure to Capture	2		
Failure to Sense	1		
Lead Dislodgement	4		



	1 yr	2 yr	3 yr	at 45 mo
%	99.5	99.2	98.6	98.6
#	1,187	566	197	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Defibrillation Leads continued

6935M Sprint Quattro Secure

Product Characteristics

US Market Release	Aug-12	Serial Number Prefix	TDL
Registered US Implants	12,700	Type and/or Fixation	Transvenous, Right Ventricle, Active Screw-in
Estimated Active US Implants	12,400	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

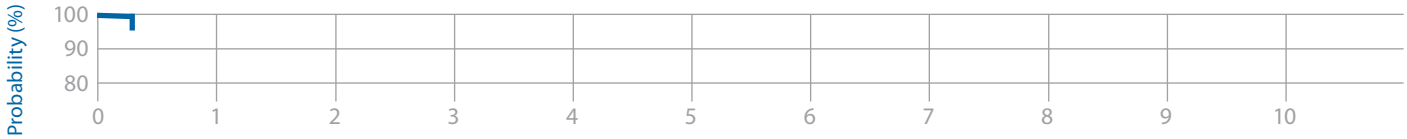
Conductor Fracture	0
Crimp/Weld/Bond	0
Insulation Breach	0
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	339
Cumulative Months of Follow-Up	943
Number of Leads Active in Study	307

Qualifying Complications 1 Total

Other	1



	at 3 mo
%	99.6
#	108

Effective Sample Size

6942 Sprint

Product Characteristics

US Market Release	Jul-97	Serial Number Prefix	TCB
Registered US Implants	17,700	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	5,300	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

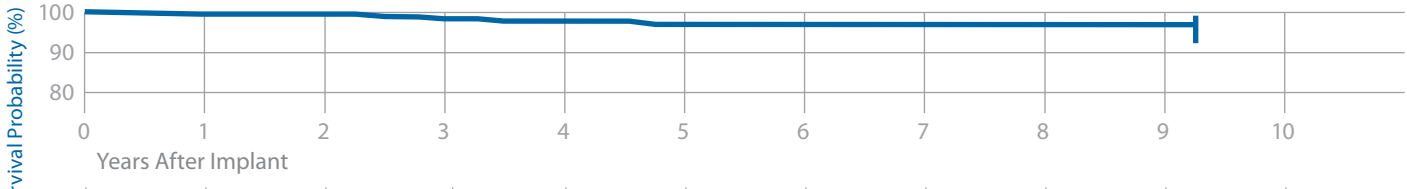
Conductor Fracture	15
Crimp/Weld/Bond	1
Insulation Breach	22
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	351
Cumulative Months of Follow-Up	19,347
Number of Leads Active in Study	25

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	at 111 mo
%	99.1	99.1	98.1	97.5	96.8	96.8	96.8	96.8	96.8	96.8
#	294	230	179	140	117	100	77	66	53	48

Effective Sample Size

Leads

Defibrillation Leads continued

6943 Sprint

Product Characteristics

US Market Release	Oct-97	Serial Number Prefix	TCE
Registered US Implants	20,600	Type and/or Fixation	Transvenous, Right Ventrile, Active Screw-in
Estimated Active US Implants	6,200	Polarity	True Bipolar/One Coil
Advisories	None	Steroid	Yes

US Returned Product Analysis

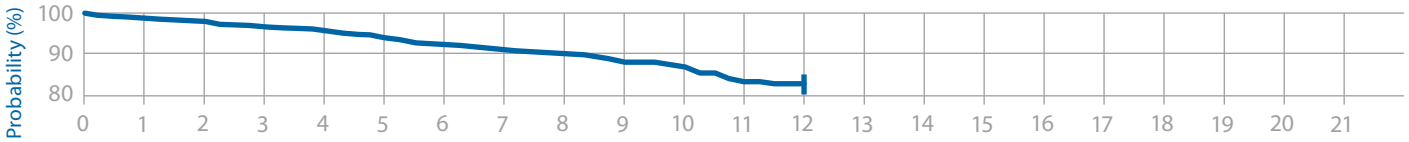
Conductor Fracture	73
Crimp/Weld/Bond	1
Insulation Breach	29
Other	5

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,311
Cumulative Months of Follow-Up	81,556
Number of Leads Active in Study	220

Qualifying Complications 94 Total

Conductor Fracture	24	Insulation (not further defined)	1
Failure to Capture	8	Lead Dislodgement	2
Failure to Sense	7	Other	1
Impedance Out of Range	8	Oversensing	40
		Unspecified Clinical Failure	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr
%	98.6	97.7	96.6	95.7	93.8	92.2	91.0	90.1	88.1	87.0	83.4	82.3
#	1,146	982	876	746	629	512	405	319	217	138	91	49

Effective Sample Size

6944 Sprint Quattro

Product Characteristics

US Market Release	Dec-00	Serial Number Prefix	TDC
Registered US Implants	41,900	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	21,900	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

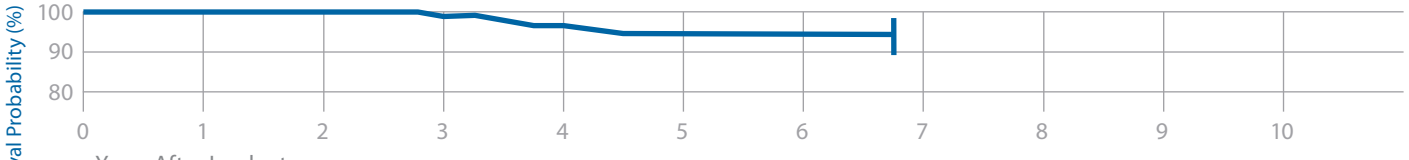
Conductor Fracture	106
Crimp/Weld/Bond	1
Insulation Breach	3
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	520
Cumulative Months of Follow-Up	18,398
Number of Leads Active in Study	270

Qualifying Complications 7 Total

Conductor Fracture	2	Unspecified Clinical Failure	1
Failure to Sense	1		
Impedance Out of Range	1		
Oversensing	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	100.0	100.0	99.5	97.9	97.9	95.6	95.6
#	417	274	158	91	66	60	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Defibrillation Leads continued

6945 Sprint

Product Characteristics

US Market Release	Sep-97	Serial Number Prefix	TDA
Registered US Implants	42,700	Type and/or Fixation	Transvenous, Right Ventricle, Active Screw-in
Estimated Active US Implants	12,600	Polarity	Integrated Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

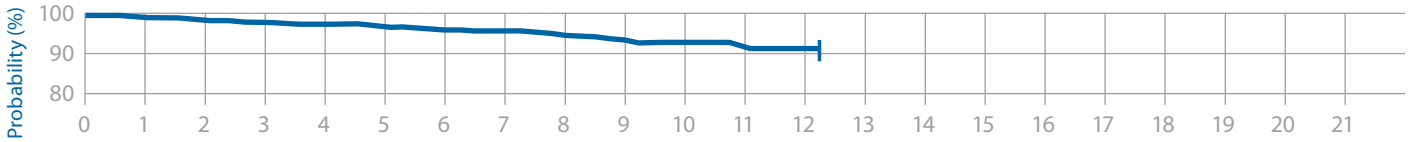
Conductor Fracture	127
Crimp/Weld/Bond	1
Insulation Breach	40
Other	6

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,155
Cumulative Months of Follow-Up	68,458
Number of Leads Active in Study	111

Qualifying Complications 40 Total

Conductor Fracture	9	Impedance Out of Range	6
Extra Cardiac Stimulation	1	Oversensing	17
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	11 yr	12 yr	at 147 mo
%	99.4	98.7	98.2	97.6	96.8	96.1	95.6	94.5	92.8	92.3	91.5	90.7	90.7
#	997	823	684	567	466	382	315	239	185	147	108	63	54

Effective Sample Size

6947M Sprint Quattro Secure

Product Characteristics

US Market Release	Feb-12	Serial Number Prefix	TDK
Registered US Implants	30,200	Type and/or Fixation	Transvenous, Right Ventricle, Active Screw-in
Estimated Active US Implants	29,300	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

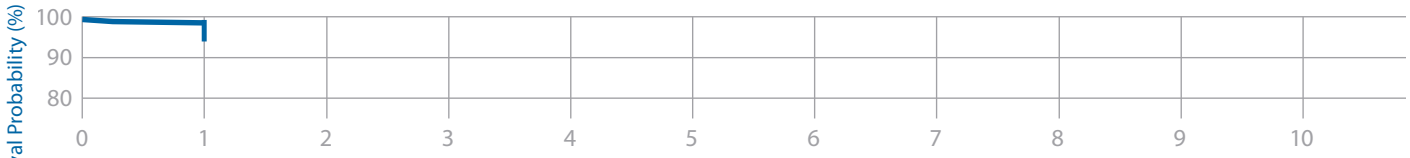
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	0
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,212
Cumulative Months of Follow-Up	7,132
Number of Leads Active in Study	1,125

Qualifying Complications 2 Total

Failure to Capture	2



	1 yr
%	99.8
#	82

Effective Sample Size

Leads

Defibrillation Leads continued

6947 Sprint Quattro Secure

Product Characteristics

US Market Release	Nov-01	Serial Number Prefix	TDG
Registered US Implants	362,600	Type and/or Fixation	Transvenous, Right Ventricle, Active Screw-in
Estimated Active US Implants	243,500	Polarity	True Bipolar/Two Coils
Advisories	None	Steroid	Yes

US Returned Product Analysis

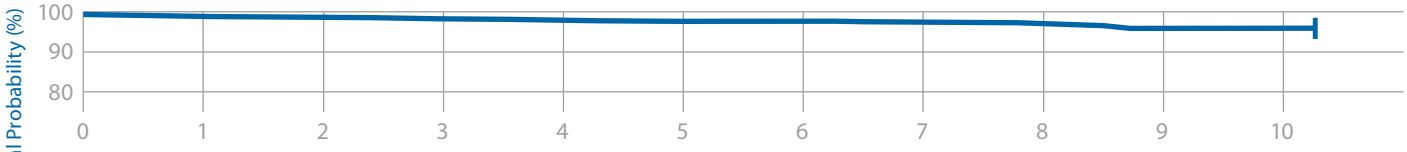
Conductor Fracture	504
Crimp/Weld/Bond	4
Insulation Breach	32
Other	211

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,718
Cumulative Months of Follow-Up	122,934
Number of Leads Active in Study	1,026

Qualifying Complications 41 Total

Conductor Fracture	8	Lead Dislodgement	4
Failure to Capture	1	Oversensing	13
Failure to Sense	2	Unspecified Clinical Failure	2
Impedance Out of Range	8		
Insulation (not further defined)	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.5	99.2	98.9	98.5	98.1	97.5	97.0	96.7	95.9	95.9	95.9
#	2,397	1,993	1,486	818	582	449	356	275	151	66	52

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, Right Ventricle, Tines
Estimated Active US Implants	4,700	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes

See page 142 – 2007 Potential Conductor Wire Fracture

US Returned Product Analysis

Conductor Fracture	154
Crimp/Weld/Bond	0
Insulation Breach	2
Other	2

Product Surveillance Registry Results

Number of Leads Enrolled in Study	30
Cumulative Months of Follow-Up	1,462
Number of Leads Active in Study	12

Qualifying Complications 2 Total

Conductor Fracture	2

	at 0 mo
%	
#	

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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, Right Ventricle, Active Screw-in
Estimated Active US Implants	76,100	Polarity	True Bipolar/Two Coils
Advisories		Steroid	Yes
See page 142 – 2007 Potential Conductor Wire Fracture			

US Returned Product Analysis

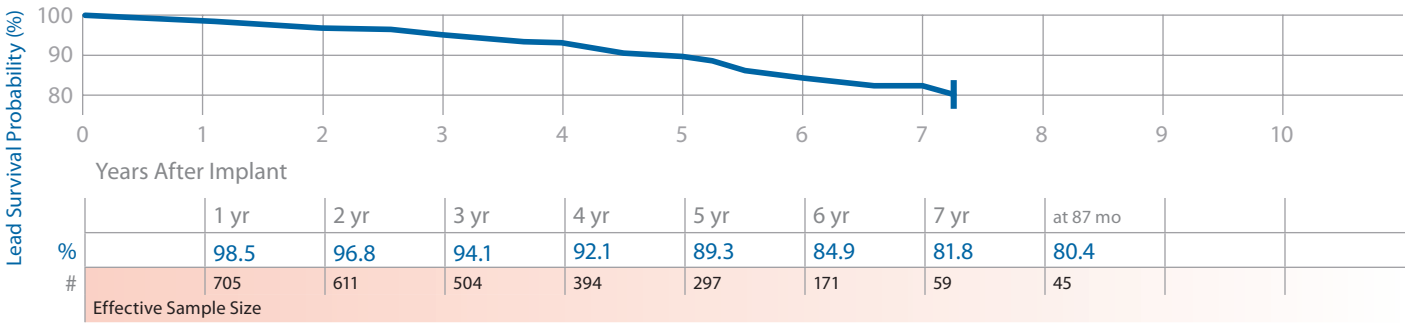
Conductor Fracture	6,376
Crimp/Weld/Bond	3
Insulation Breach	29
Other	69

Product Surveillance Registry Results

Number of Leads Enrolled in Study	796
Cumulative Months of Follow-Up	38,922
Number of Leads Active in Study	217

Qualifying Complications 80 Total

Conductor Fracture	38	Insulation (not further defined)	2
Failure to Capture	2	Lead Dislodgement	1
Failure to Sense	4	Oversensing	16
Impedance Out of Range	16	Unspecified Clinical Failure	
		Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	at 87 mo
%	98.5	96.8	94.1	92.1	89.3	84.9	81.8	80.4
#	705	611	504	394	297	171	59	45

Effective Sample Size

6996 Sub-Q Lead

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	TCR
Registered US Implants	3,900	Type and/or Fixation	Subcutaneous, Defibrillation, Suture on Anchor Sleeve
Estimated Active US Implants	2,300	Polarity	One Coil
Advisories	None	Steroid	No

US Returned Product Analysis

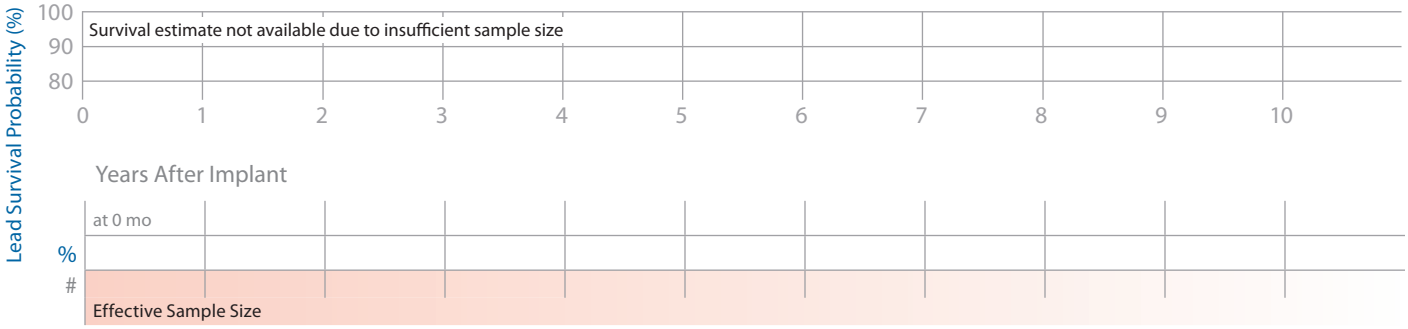
Conductor Fracture	20
Crimp/Weld/Bond	0
Insulation Breach	0
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	43
Cumulative Months of Follow-Up	1,190
Number of Leads Active in Study	20

Qualifying Complications 2 Total

Conductor Fracture	1
Impedance Out of Range	1



	at 0 mo
%	
#	

Effective Sample Size

Leads

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
6721	Epicardial Patch	Mar-94	407	4	47	23,401	96.5 +1.4/-2.4	95 .0 +1.8/-2.8	92.7 +2.3/-3.3	91.9 +2.5/-3.5	90 .0 +2.9/-4.0	85.1 +3.9/-5.2	83.7 +4.3/-5.5	83.7 +4.3/-5.5	83.7 +4.3/-5.5 at 111 mo				
6930	Sprint Fidelis	Sep-04	4	2	0	188	100.0 at 0 mo												
	Advisories: See page 142 – 2007 Potential Conductor Wire Fracture																		
6931	Sprint Fidelis	Sep-04	294	113	43	13,526	98.2 +1.0/-2.5	96.2 +1.7/-3.2	93.0 +2.6/-4.1	88.4 +3.6/-5.1	81.9 +5.0/-6.5	78.1 +5.8/-7.5 at 69 mo							
	Advisories: See page 142 – 2007 Potential Conductor Wire Fracture																		
6932	Sprint	Aug-96	412	38	11	25,811	99.2 +0.5/-1.7	98.3 +0.9/-2.0	98.3 +0.9/-2.0	98.3 +0.9/-2.0	97.8 +1.2/-2.5	97.8 +1.2/-2.5	97.8 +1.2/-2.5	96.8 +1.7/-3.7	95.6 +2.4/-5.0	92.6 +3.8/-7.5 at 138 mo			
6933, 6937, 6937A	SVC/CS	Apr-94	966	11	47	54,489	98.4 +0.6/-1.1	97.5 +0.9/-1.3	97.2 +0.9/-1.4	96.7 +1.1/-1.5	95.4 +1.4/-1.9	94.9 +1.5/-2.1	93.9 +1.8/-2.5	93.4 +1.9/-2.7	91.2 +2.8/-4.1	91.2 +2.8/-4.1 at 138 mo			
6935	Sprint Quattro Secure	Nov-08	2,026	1,550	14	36,705	99.5 +0.3/-0.5	99.2 +0.4/-0.7	98.6 +0.7/-1.3	98.6 +0.7/-1.3 at 45 mo									
6935M	Sprint Quattro Secure	Aug-12	339	307	1	75,241	99.6 +0.3/-2.4 at 3 mo												
6942	Sprint	Jul-97	351	25	7	19,347	99.1 +0.6/-1.9	99.1 +0.6/-1.9	98.1 +1.1/-2.7	97.5 +1.4/-3.1	96.8 +1.8/-3.7	96.8 +1.8/-3.7	96.8 +1.8/-3.7	96.8 +1.8/-3.7	96.8 +1.8/-3.7 at 111 mo				
6943	Sprint	Oct-97	1,311	199	94	83,217	98.6 +0.5/-0.8	97.7 +0.7/-1.0	96.6 +0.9/-1.2	95.7 +1.1/-1.4	93.8 +1.4/-1.8	92.2 +1.6/-2.0	91.0 +1.8/-2.3	90.1 +2.0/-2.5	87.0 +2.7/-3.4	82.3 +4.2/-5.3 at 144 mo			
6944	Sprint Quattro	Dec-00	520	270	7	18,398	100.0	100.0	99.5 +0.5/-3.2	97.9 +1.4/-4.4	95.6 +2.6/-6.1	95.6 +2.6/-6.1	95.6 +2.6/-6.1 at 81 mo						
6945	Sprint	Sep-97	1,155	111	40	68,458	99.4 +0.3/-0.7	98.7 +0.6/-1.0	98.2 +0.7/-1.1	97.6 +0.8/-1.3	96.8 +1.1/-1.6	96.1 +1.2/-1.8	95.6 +1.4/-2.0	94.5 +1.7/-2.4	92.3 +2.3/-3.3	90.7 +3.0/-4.2 at 147 mo			
6947	Sprint Quattro Secure	Nov-01	2,718	1,026	41	122,934	99.5 +0.2/-0.4	99.2 +0.3/-0.4	98.9 +0.4/-0.5	98.5 +0.5/-0.7	98.1 +0.6/-0.9	97.5 +0.8/-1.2	97.0 +1.0/-1.4	96.7 +1.1/-1.6	95.9 +1.4/-2.1 at 123 mo				
6947M	Sprint Quattro Secure	Feb-12	1,212	1,125	2	7,132	99.8 +0.2/-0.7 at 12 mo												
6948	Sprint Fidelis	Sep-04	30	12	2	1,462	100.0 at 0 mo												
	Advisories: See page 142 – 2007 Potential Conductor Wire Fracture																		
6949	Sprint Fidelis	Sep-04	796	217	80	38,922	98.5 +0.6/-1.2	96.8 +1.1/-1.6	94.1 +1.6/-2.1	92.1 +1.9/-2.5	89.3 +2.4/-3.0	84.9 +3.1/-3.8	81.8 +3.9/-4.8	80.4 +4.5/-5.6 at 87 mo					
	Advisories: See page 142 – 2007 Potential Conductor Wire Fracture																		
6996	Sub-Q Lead	Jun-01	43	20	2	1,190	100.0 at 0 mo												

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Defibrillation Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
6721	Epicardial Patch	Mar-94	2,900	1,100	12	1	0	0
6930	Sprint Fidelis	Sep-04	400	200	3	0	0	0
6931	Sprint Fidelis	Sep-04	8,100	3,500	532	1	0	5
6932	Sprint	Aug-96	14,900	4,200	22	24	0	2
6933, 6937, 6937A	SVC/CS	Apr-94	11,900	2,400	127	17	0	1
6935	Sprint Quattro Secure	Nov-08	42,900	38,800	61	2	0	35
6935M	Sprint Quattro Secure	Aug-12	12,700	12,400	0	0	0	1
6942	Sprint	Jul-97	17,700	5,300	15	22	1	4
6943	Sprint	Oct-97	20,600	6,200	73	29	1	5
6944	Sprint Quattro	Dec-00	41,900	21,900	106	3	1	4
6945	Sprint	Sep-97	42,700	12,600	127	40	1	6
6947	Sprint Quattro Secure	Nov-01	362,600	243,500	504	36	4	211
6947M	Sprint Quattro Secure	Feb-12	30,200	29,300	3	0	0	4
6948	Sprint Fidelis	Sep-04	10,400	4,700	154	2	0	2
6949	Sprint Fidelis	Sep-04	186,800	76,100	6,376	29	3	69
6996	Sub-Q Lead	Jun-01	3,900	2,300	20	0	0	0

Source: Returned Product Analysis
Data as of July 31, 2013

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	Epicardial Patch	2,900	1	2	0	0	1	1	0	3	0	0
6930	Sprint Fidelis	400	0	0	0	0	0	0	0	0	0	1
6931	Sprint Fidelis	8,100	1	2	1	1	3	1	0	0	0	1
6932	Sprint	14,900	0	0	4	2	0	2	0	1	0	2
6933, 6937, 6937A	SVC/CS	11,900	0	0	1	1	0	0	0	0	0	5
6935	Sprint Quattro Secure	42,900	12	0	27	16	27	5	1	10	0	5
6935M	Sprint Quattro Secure	12,700	1	0	16	13	16	1	0	1	3	0
6942	Sprint	17,700	0	1	1	4	1	0	0	2	0	1
6943	Sprint	20,600	1	0	0	1	1	1	1	2	0	0
6944	Sprint Quattro	41,900	0	2	17	11	11	3	0	8	0	6
6945	Sprint	42,700	1	1	4	6	7	2	2	0	1	2
6947	Sprint Quattro Secure	362,600	24	18	99	66	113	29	4	47	2	22
6947M	Sprint Quattro Secure	30,200	2	1	32	18	11	3	0	2	1	0
6948	Sprint Fidelis	10,400	0	2	7	6	1	0	0	0	0	3
6949	Sprint Fidelis	186,800	10	41	23	32	30	19	6	17	0	25
6996	SubQ	3,900	0	0	1	1	0	0	0	2	0	0

Report Cutoff Date: September 10, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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
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
6935	Sprint Quattro Secure	Endo RV True Bipolar Sensing	IS-1	DF-1	8.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6935M	Sprint Quattro Secure	Endo RV True Bipolar Sensing	DF-4	DF-4	8.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
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
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	8.6 Fr	Silicone with Polyurethane Overlay, Multilumen	Active, Steroid
6947M	Sprint Quattro Secure	Endo RV/SVC True Bipolar Sensing	DF4	DF4	8.6 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
6996	Sub-Q Lead	SQ Coil	—	DF-1	7.5 Fr	Silicone, Single Lumen	Passive

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads

3830 SelectSecure

Product Characteristics

US Market Release	Aug-05	Serial Number Prefix	LFF
Registered US Implants	21,600	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Fixed Screw
Estimated Active US Implants	16,400	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	14
Other	3

Atrial Placement

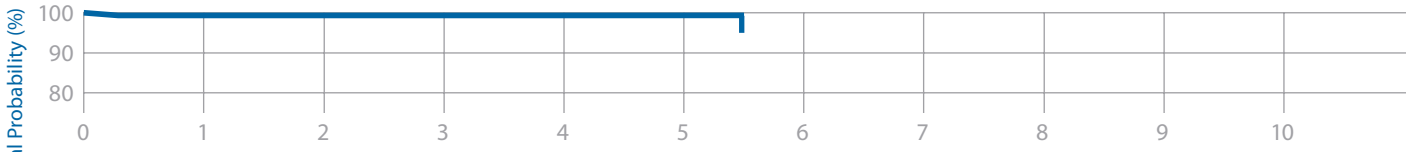
Product Surveillance Registry Results

Number of Leads Enrolled in Study	778
Cumulative Months of Follow-Up	25,544
Number of Leads Active in Study	493

Qualifying Complications

7 Total

Cardiac Perforation	1
Conductor Fracture	1
Extra Cardiac Stimulation	1
Failure to Capture	1
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo
%	99.2	99.2	99.2	99.2	99.2	99.2
#	672	456	229	111	67	51

Effective Sample Size

Ventricular Placement

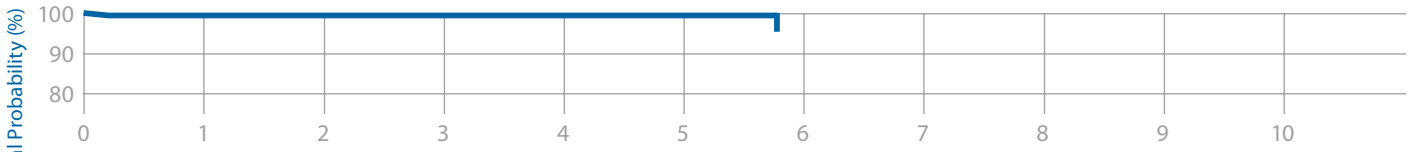
Product Surveillance Registry Results

Number of Leads Enrolled in Study	482
Cumulative Months of Follow-Up	17,389
Number of Leads Active in Study	283

Qualifying Complications

4 Total

Failure To Capture	1
Impedance Out of Range	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	at 69 mo
%	99.3	99.3	99.3	99.3	99.3	99.3
#	416	291	167	96	65	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4024 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAJ
Registered US Implants	219,400	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	40,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	28
Crimp/Weld/Bond	0
Insulation Breach	183
Other	12

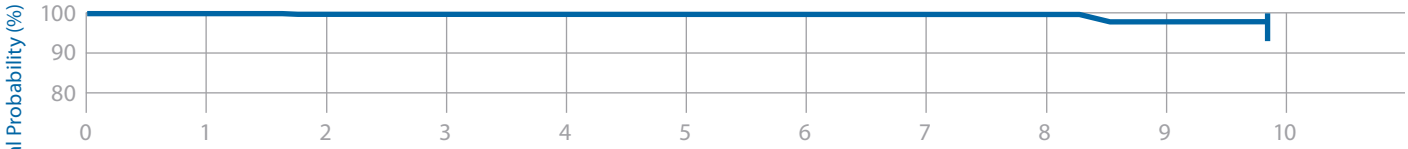
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,215
Cumulative Months of Follow-Up	50,987
Number of Leads Active in Study	10

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	9 yr	at 117 mo
%	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	98.8	98.8
#	869	684	556	416	323	229	166	110	63	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4068 CapSureFix

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCE
Registered US Implants	124,300	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Active Screw-in
Estimated Active US Implants	29,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	50
Crimp/Weld/Bond	0
Insulation Breach	167
Other	93

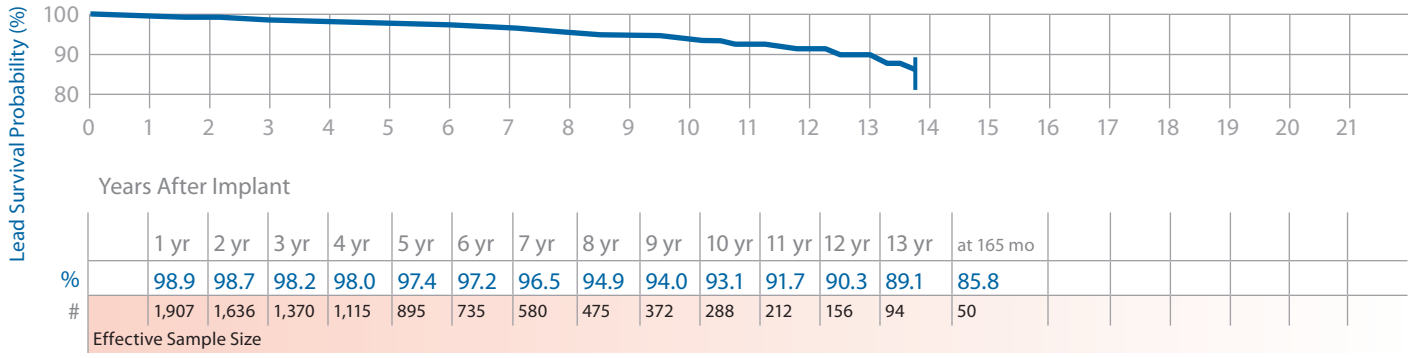
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,413
Cumulative Months of Follow-Up	135,071
Number of Leads Active in Study	224

Qualifying Complications — 86 Total

Conductor Fracture	3	Insulation (ESC)	2
Extra Cardiac Stimulation	3	Insulation (MIO)	2
Failure to Capture	23	Insulation (not further defined)	2
Failure to Sense	16	Lead Dislodgement	8
Impedance Out of Range	11	Oversensing	13
		Unspecified Clinical Failure	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	at 165 mo
%	98.9	98.7	98.2	98.0	97.4	97.2	96.5	94.9	94.0	93.1	91.7	90.3	89.1	85.8
#	1,907	1,636	1,370	1,115	895	735	580	475	372	288	212	156	94	50

Effective Sample Size

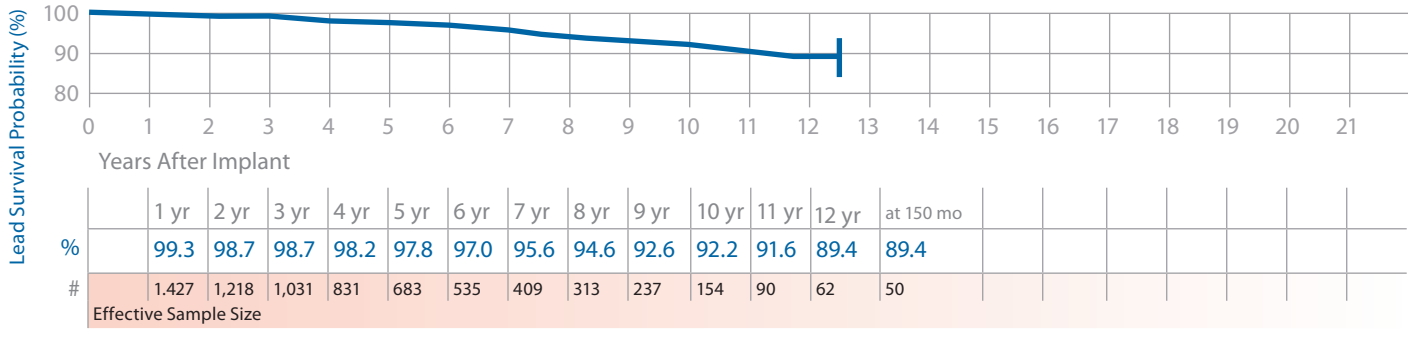
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,799
Cumulative Months of Follow-Up	96,956
Number of Leads Active in Study	128

Qualifying Complications — 56 Total

Conductor Fracture	3	Impedance Out of Range	16
Extra Cardiac Stimulation	2	Insulation (not further defined)	1
Failure to Capture	22	Oversensing	7
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	12 yr	at 150 mo
%	99.3	98.7	98.7	98.2	97.8	97.0	95.6	94.6	92.6	92.2	91.6	89.4	89.4
#	1.427	1,218	1,031	831	683	535	409	313	237	154	90	62	50

Effective Sample Size

Pacing Leads continued

4074 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBD
Registered US Implants	94,100	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	58,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	20
Other	0

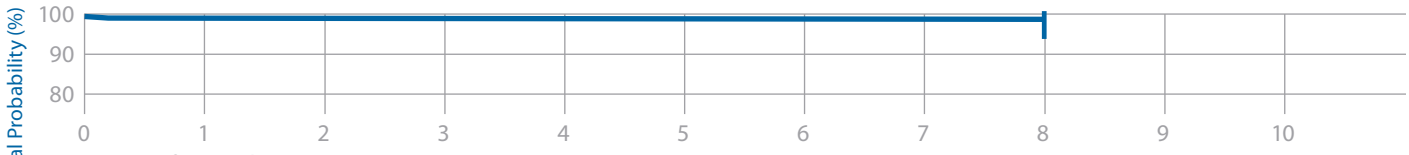
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	15,716
Number of Leads Active in Study	132

Qualifying Complications 2 Total

Failure to Sense	1
Lead Dislodgement	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.1	99.1	99.1	99.1	99.1	99.1	99.1	99.1
#	199	189	183	171	153	122	82	54

Effective Sample Size

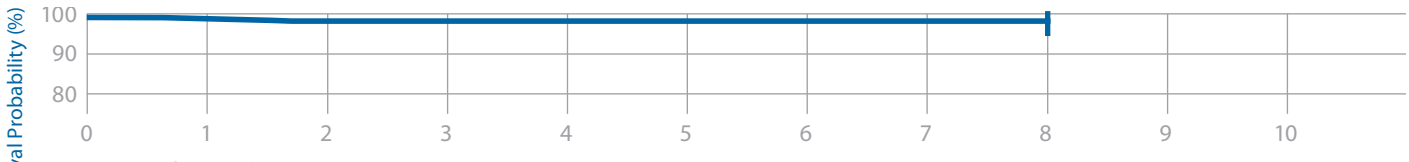
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	988
Cumulative Months of Follow-Up	35,488
Number of Leads Active in Study	618

Qualifying Complications 3 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
%	99.8	99.6	99.6	99.6	99.6	99.6	99.6	99.6
#	665	474	339	305	262	176	100	54

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4076 CapSureFix Novus

Product Characteristics

US Market Release	Feb-04	Serial Number Prefix	BBL
Registered US Implants	452,200	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Active Screw-in
Estimated Active US Implants	347,600	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	39
Crimp/Weld/Bond	1
Insulation Breach	35
Other	18

Atrial Placement

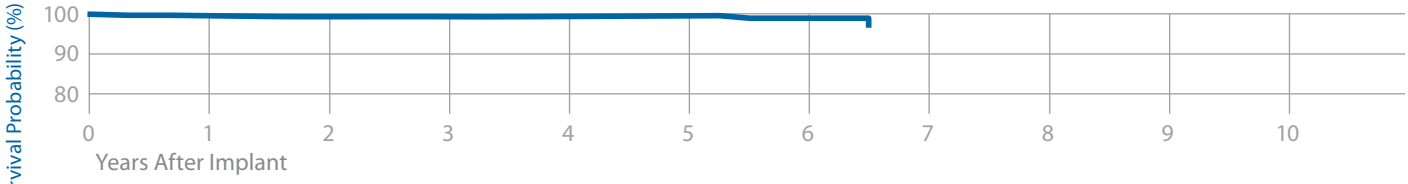
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,663
Cumulative Months of Follow-Up	65,593
Number of Leads Active in Study	894

Qualifying Complications

9 Total

Conductor Fracture	1
Failure to Capture	2
Failure to Sense	2
Insulation (not further defined)	1
Lead Dislodgement	3



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	99.8	99.6	99.4	99.4	99.4	99.0	99.0
#	1,483	1,239	873	443	248	107	54

Effective Sample Size

Ventricular Placement

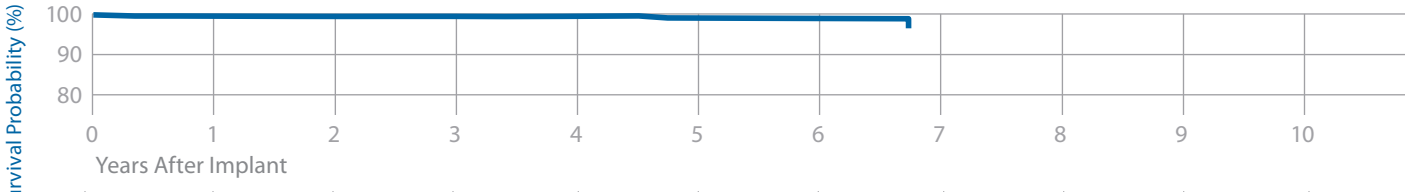
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,229
Cumulative Months of Follow-Up	51,284
Number of Leads Active in Study	653

Qualifying Complications

6 Total

Extra Cardiac Stimulation	1
Failure to Capture	3
Impedance Out of Range	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	99.8	99.8	99.7	99.6	99.0	99.0	99.0
#	1,091	930	683	404	234	103	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4092 CapSure SP Novus

Product Characteristics

US Market Release	Sep-98	Serial Number Prefix	LEP
Registered US Implants	179,200	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	80,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

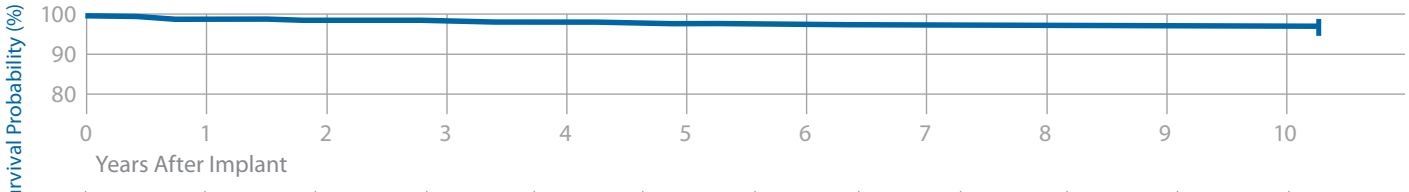
Conductor Fracture	11
Crimp/Weld/Bond	0
Insulation Breach	53
Other	23

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,147
Cumulative Months of Follow-Up	66,685
Number of Leads Active in Study	261

Qualifying Complications 19 Total

Conductor Fracture	3	Impedance Out of Range	2
Extra Cardiac Stimulation	1	Lead Dislodgement	4
Failure to Capture	9		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	98.9	98.8	98.7	98.4	98.1	97.7	97.7	97.7	97.7	97.7	97.7
#	928	831	734	636	553	451	326	220	145	54	40

Effective Sample Size

4524 CapSure SP

Product Characteristics

US Market Release	Oct-91	Serial Number Prefix	LAR
Registered US Implants	100,300	Type and/or Fixation	Transvenous, Atrium, J-Shape, Tines
Estimated Active US Implants	23,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

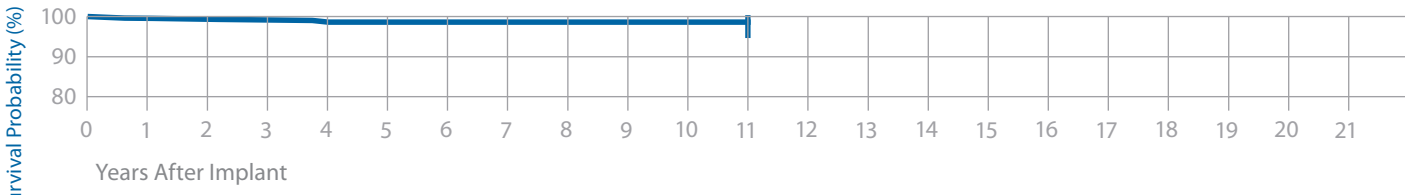
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	67
Other	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	911
Cumulative Months of Follow-Up	40,951
Number of Leads Active in Study	29

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	10 yr	11 yr
%	99.6	99.3	99.3	99.0	99.0	99.0	99.0	99.0	99.0	99.0	99.0
#	682	536	426	328	250	182	133	87	64	55	49

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4558M Screw-In

Product Characteristics

US Market Release	Nov-94	Serial Number Prefix	LDC
Registered US Implants	19,700	Type and/or Fixation	Transvenous, Atrium-J, Active Screw-in
Estimated Active US Implants	3,800	Polarity	Bipolar
Advisories	None	Steroid	No

US Returned Product Analysis

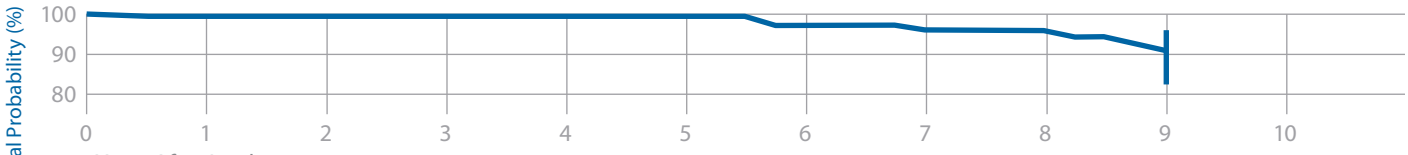
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	21
Other	20

Product Surveillance Registry Results

Number of Leads Enrolled in Study	539
Cumulative Months of Follow-Up	23,280
Number of Leads Active in Study	5

Qualifying Complications 12 Total

Electrical Abandonment	1	Impedance Out of Range	2
Failure to Capture	3	Insulation (not further defined)	2
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	97.6	96.5	96.5	91.8
#	353	295	248	191	139	96	83	65	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDD
Registered US Implants	69,500	Type and/or Fixation	Transvenous, Atrium, J-Shape, Screw-in
Estimated Active US Implants	21,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

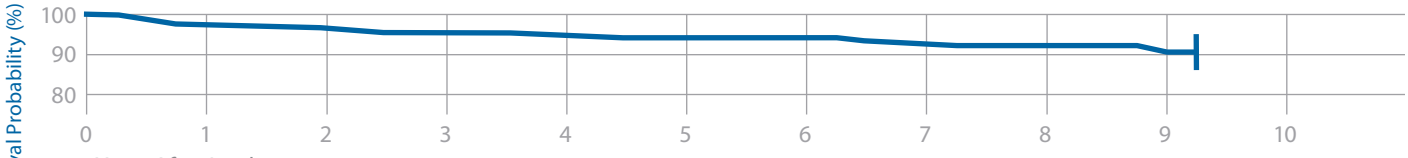
Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	86
Other	52

Product Surveillance Registry Results

Number of Leads Enrolled in Study	656
Cumulative Months of Follow-Up	32,664
Number of Leads Active in Study	115

Qualifying Complications 36 Total

Failure to Capture	18	Lead Dislodgement	9
Failure to Sense	4	Medical Judgment	1
Impedance Out of Range	4		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	at 111 mo
%	96.8	96.4	95.3	94.7	94.0	94.0	92.9	92.2	90.8	90.8
#	494	431	349	292	241	187	143	87	60	54

Effective Sample Size

4574 CapSure Sense

Product Characteristics

US Market Release	Jun-02	Serial Number Prefix	BBE
Registered US Implants	62,900	Type and/or Fixation	Transvenous, Atrium, J-Shape, Tines
Estimated Active US Implants	42,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

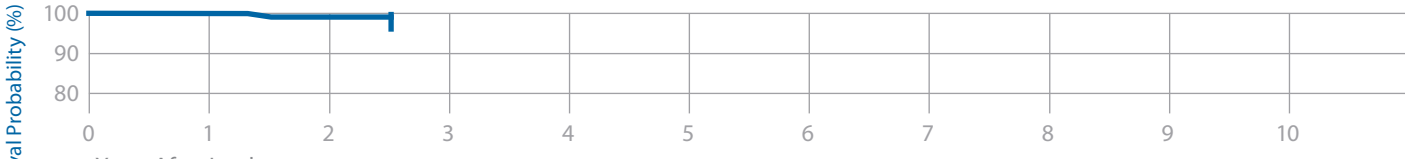
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	3
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	520
Cumulative Months of Follow-Up	7,525
Number of Leads Active in Study	387

Qualifying Complications 4 Total

Failure to Capture	1		
Lead Dislodgement	3		



	1 yr	2 yr	at 30 mo
%	99.0	99.0	99.0
#	231	79	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

4592 CapSure SP Novus

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	LER
Registered US Implants	86,300	Type and/or Fixation	Transvenous, Atrium, J-Shape, Tines
Estimated Active US Implants	40,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

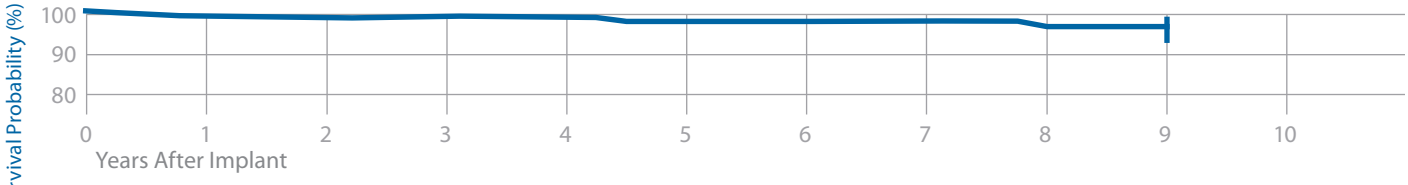
Conductor Fracture	7
Crimp/Weld/Bond	0
Insulation Breach	18
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	283
Cumulative Months of Follow-Up	14,887
Number of Leads Active in Study	56

Qualifying Complications 7 Total

Failure to Capture	4
Failure to Sense	1
Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr
%	98.2	98.2	98.2	98.2	97.4	97.4	97.4	96.0	96.0
#	193	170	152	130	112	103	82	68	48

Effective Sample Size

Pacing Leads continued

5033 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDK
Registered US Implants	2,300	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	500	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

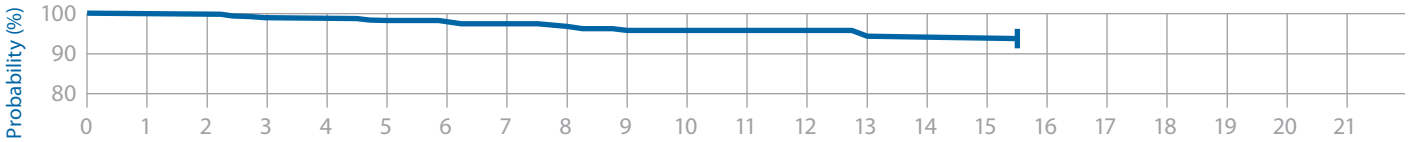
Conductor Fracture	1
Crimp/Weld/Bond	0
Insulation Breach	0
Other	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,899
Cumulative Months of Follow-Up	101,933
Number of Leads Active in Study	134

Qualifying Complications 31 Total

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	8	Insulation (not further defined)	1
Failure to Capture	15	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	13 yr	14 yr	15 yr	at 186 mo
%	99.7	99.6	99.1	99.0	98.8	98.3	97.7	96.9	96.0	96.0	95.6	95.6	94.9	93.9	93.9	93.9
#	1,414	1,142	943	794	658	527	416	347	292	246	194	157	131	96	65	43

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5034 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDF
Registered US Implants	55,400	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	12,200	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	15
Other	7

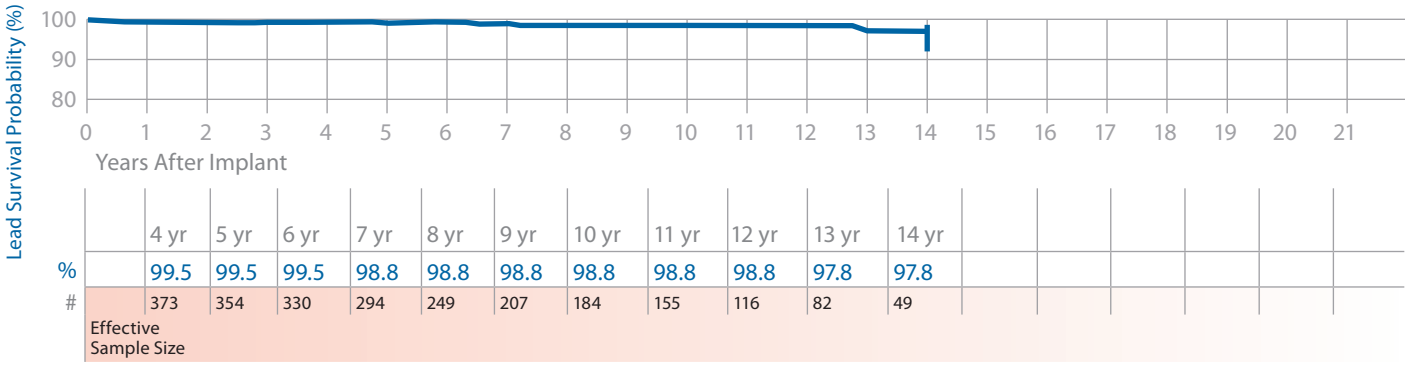
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	44,612
Number of Leads Active in Study	111

Qualifying Complications 5 Total

Conductor Fracture	1
Failure to Capture	2
Failure to Sense	1
Impedance Out of Range	1



	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr
%	99.5	99.5	99.5	98.8	98.8	98.8	98.8	98.8	98.8	97.8	97.8
#	373	354	330	294	249	207	184	155	116	82	49

Effective Sample Size

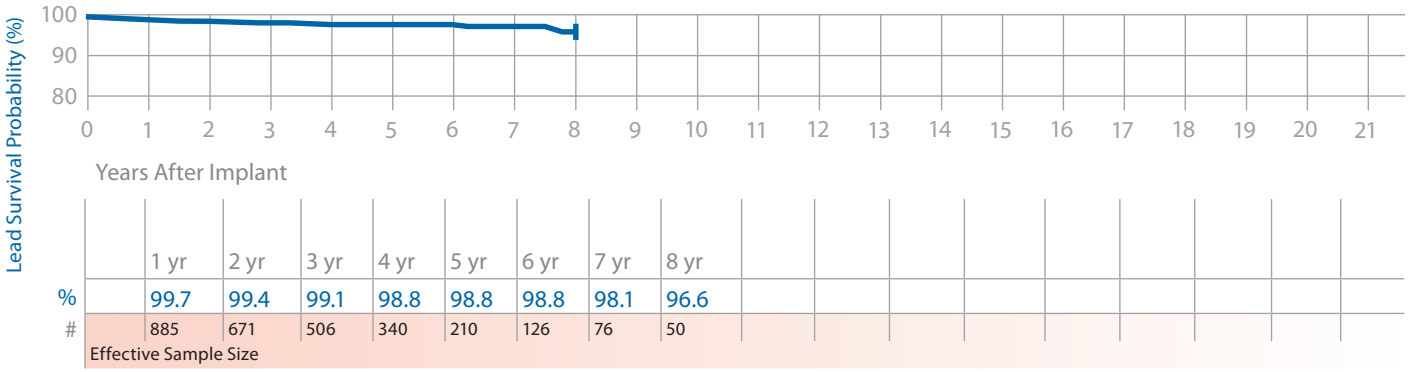
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,209
Cumulative Months of Follow-Up	44,680
Number of Leads Active in Study	11

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	8 yr
%	99.7	99.4	99.1	98.8	98.8	98.8	98.1	96.6
#	885	671	506	340	210	126	76	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5054 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEH
Registered US Implants	96,600	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	41,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	10
Crimp/Weld/Bond	1
Insulation Breach	25
Other	3

Atrial Placement

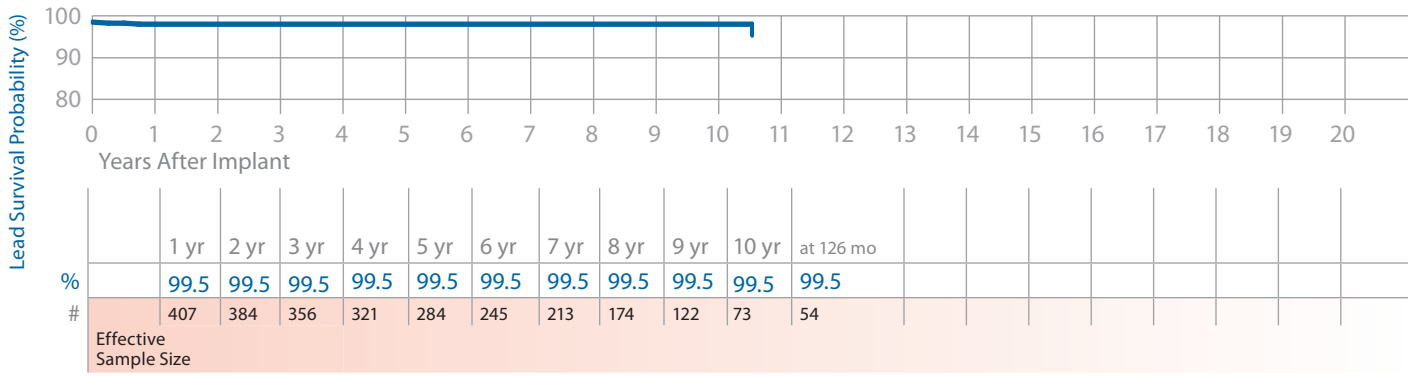
Product Surveillance Registry Results

Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	34,515
Number of Leads Active in Study	115

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	9 yr	10 yr	at 126 mo
%	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5	99.5
#	407	384	356	321	284	245	213	174	122	73	54

Effective Sample Size

Ventricular Placement

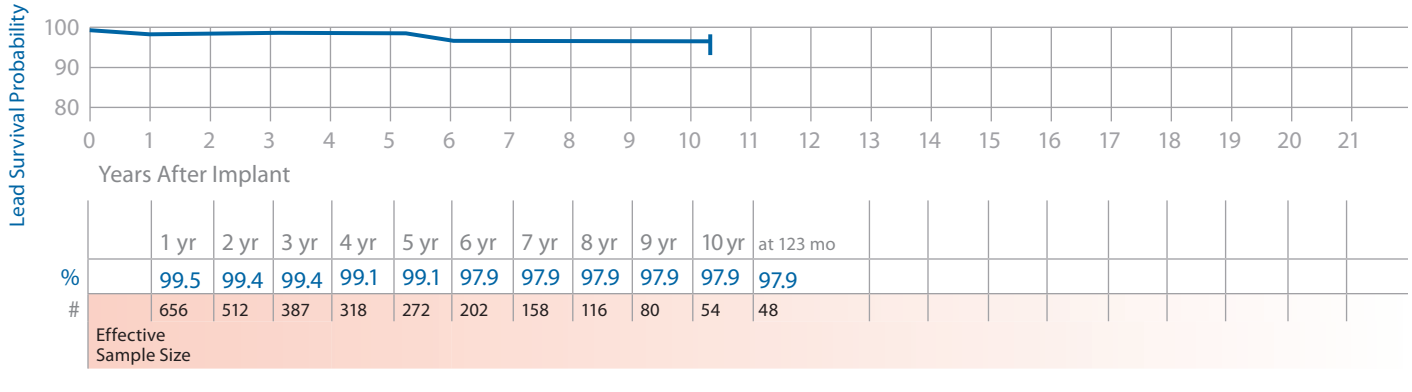
Product Surveillance Registry Results

Number of Leads Enrolled in Study	967
Cumulative Months of Follow-Up	39,578
Number of Leads Active in Study	84

Qualifying Complications

9 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.5	99.4	99.4	99.1	99.1	97.9	97.9	97.9	97.9	97.9	97.9
#	656	512	387	318	272	202	158	116	80	54	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5068 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDJ
Registered US Implants	102,400	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Active Screw-in
Estimated Active US Implants	28,800	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	41
Crimp/Weld/Bond	2
Insulation Breach	56
Other	83

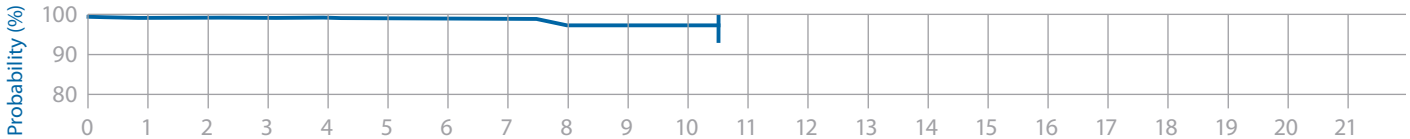
Atrial Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	968
Cumulative Months of Follow-Up	34,293
Number of Leads Active in Study	29

Qualifying Complications 6 Total

Failure to Capture	2	Lead Dislodgement	1
Impedance Out of Range	1	Oversensing	1
Insulation (not further defined)	1		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 126 mo
%	99.6	99.6	99.3	99.3	99.3	99.3	99.3	97.6	97.6	97.6	97.6
#	552	424	321	254	210	160	130	104	78	63	49

Effective Sample Size

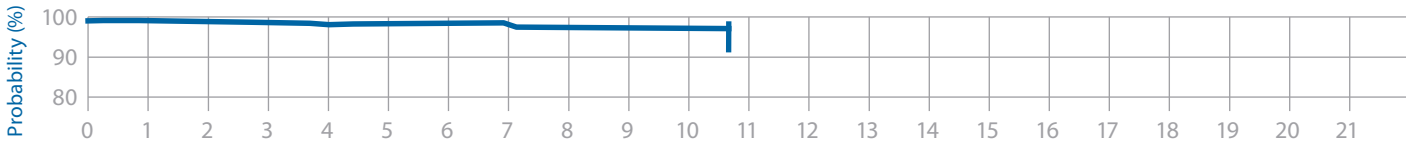
Ventricular Placement

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,362
Cumulative Months of Follow-Up	40,745
Number of Leads Active in Study	56

Qualifying Complications 8 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 mo
%	99.9	99.7	99.5	99.2	99.2	99.2	98.5	97.2	97.2	97.2	97.2
#	700	499	362	267	226	189	152	127	103	75	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5072 SureFix

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEM
Registered US Implants	10,000	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Fixed Screw
Estimated Active US Implants	4,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

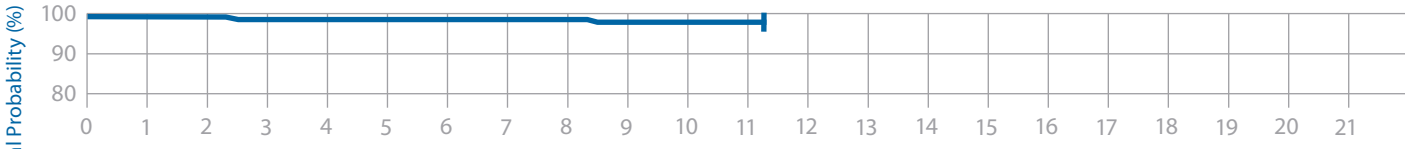
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	6
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	508
Cumulative Months of Follow-Up	28,227
Number of Leads Active in Study	50

Qualifying Complications 3 Total

Cardiac Perforation	1
Failure to Capture	1
Failure to Sense	1



	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
%	99.8	99.8	99.4	99.4	99.4	99.4	99.4	99.4	98.5	98.5	98.5	98.5
#	376	315	267	222	185	164	133	112	93	76	59	50

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5076 CapSureFix Novus

Product Characteristics

US Market Release	Aug-00	Serial Number Prefix	PJN
Registered US Implants	1,552,400	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Active Screw-in
Estimated Active US Implants	981,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	435
Crimp/Weld/Bond	0
Insulation Breach	452
Other	186

Atrial Placement

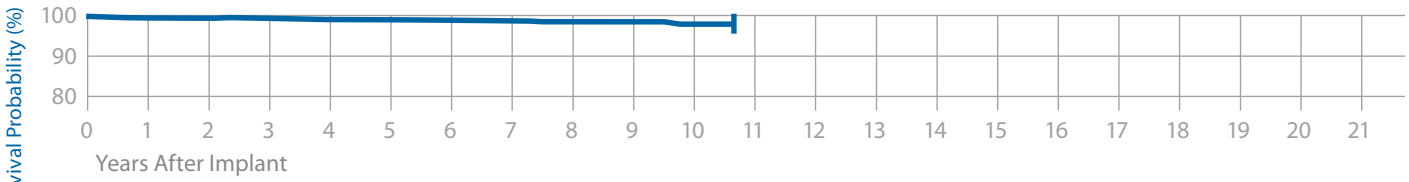
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,744
Cumulative Months of Follow-Up	142,851
Number of Leads Active in Study	593

Qualifying Complications

28 Total

Cardiac Perforation	1	Impedance Out of Range	4
Conductor Fracture	3	Insulation (not further defined)	1
Extra Cardiac Stimulation	2	Lead Dislodgement	5
Failure to Capture	6	Oversensing	2
Failure to Sense	2	Other	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 129 mo
%	99.6	99.6	99.4	98.9	98.7	98.5	98.5	98.3	98.3	97.8	97.8
#	2,088	1,798	1,538	1,316	1,124	931	684	452	268	120	51

Effective Sample Size

Ventricular Placement

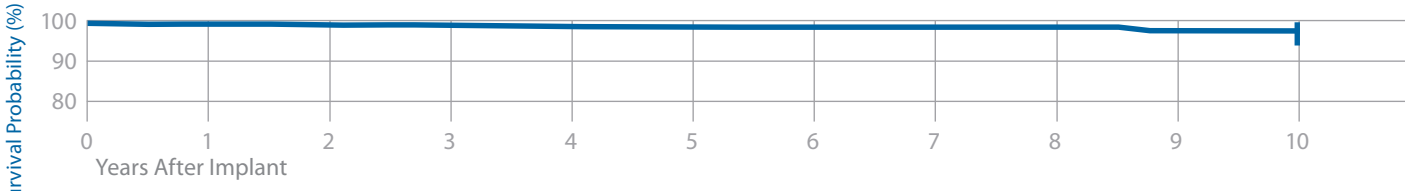
Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,539
Cumulative Months of Follow-Up	69,416
Number of Leads Active in Study	247

Qualifying Complications

14 Total

Cardiac Perforation	1	Failure to Sense	1
Conductor Fracture	2	Impedance Out of Range	3
Failure to Capture	5	Lead Dislodgement	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.6	99.4	99.3	99.0	99.0	98.6	98.3	98.3	97.7	97.7
#	1,084	903	746	611	499	404	306	203	115	56

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5086MRI CapSureFix Novus

Product Characteristics

US Market Release	Feb-11	Serial Number Prefix	LFP
Registered US Implants	128,800	Type and/or Fixation	Transvenous, Atrium or Right Ventricle, Active Screw-in
Estimated Active US Implants	124,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	5
Other	8

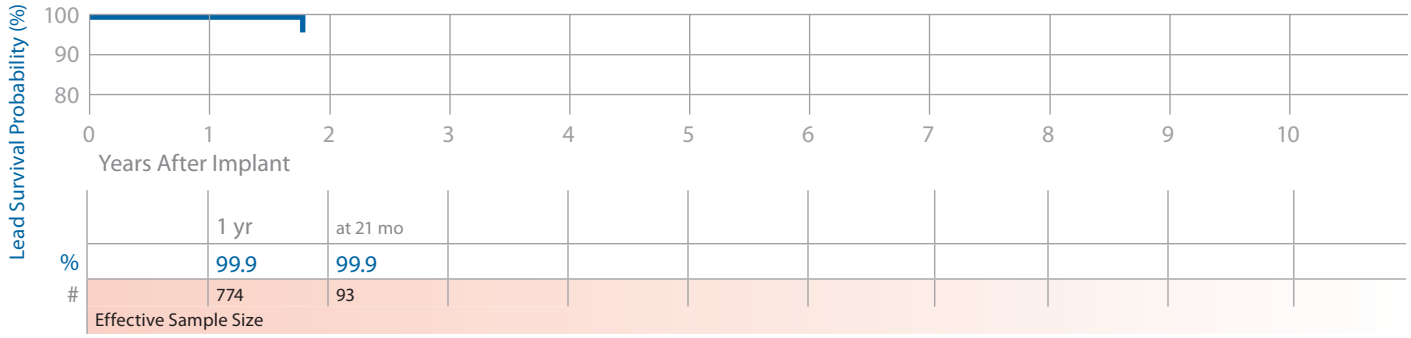
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,532
Cumulative Months of Follow-Up	25,622
Number of Leads Active in Study	2,216

Qualifying Complications

2 Total

Lead Dislodgement	2



Ventricular Placement

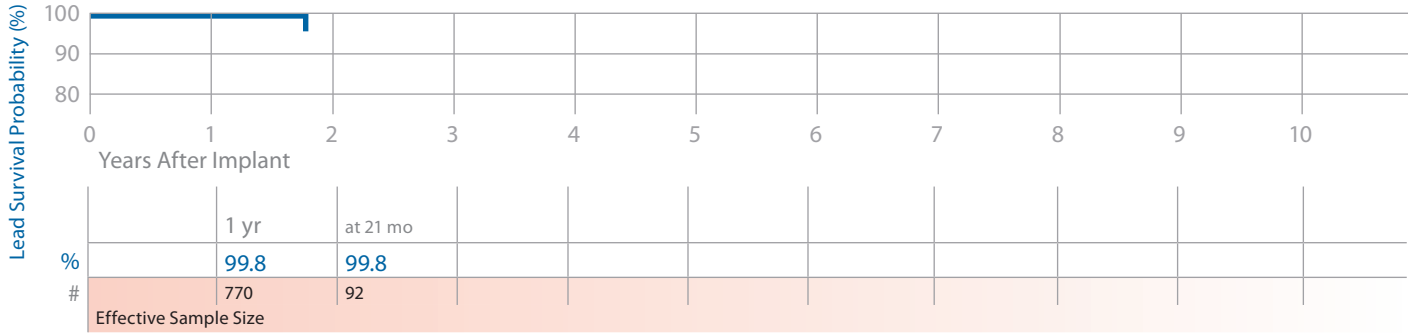
Product Surveillance Registry Results

Number of Leads Enrolled in Study	2,518
Cumulative Months of Follow-Up	25,436
Number of Leads Active in Study	2,206

Qualifying Complications

4 Total

Failure to Capture	2
Failure to Sense	1
Lead Dislodgement	1



Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5092 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LET
Registered US Implants	134,300	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	61,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

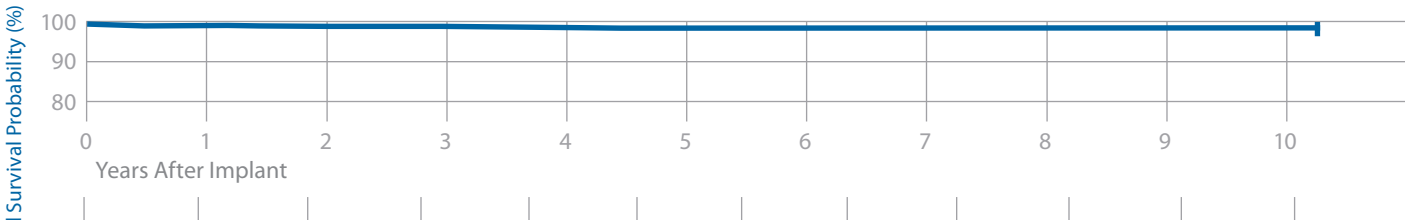
Conductor Fracture	11
Crimp/Weld/Bond	0
Insulation Breach	38
Other	3

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,172
Cumulative Months of Follow-Up	48,445
Number of Leads Active in Study	125

Qualifying Complications 9 Total

Extra Cardiac Stimulation	1
Failure to Capture	2
Impedance Out of Range	1
Lead Dislodgement	5



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	at 123 mo
%	99.5	99.4	99.2	99.0	99.0	98.6	98.6	98.6	98.6	98.6	98.6
#	812	650	517	407	315	239	180	131	91	59	51

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5534 CapSure Z

Product Characteristics

US Market Release	Feb-96	Serial Number Prefix	LDG
Registered US Implants	25,800	Type and/or Fixation	Transvenous, Atrium-J, Tines
Estimated Active US Implants	6,700	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

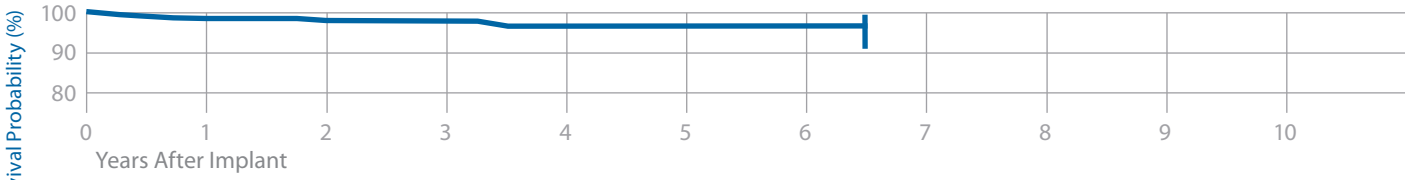
Conductor Fracture	3
Crimp/Weld/Bond	0
Insulation Breach	4
Other	4

Product Surveillance Registry Results

Number of Leads Enrolled in Study	264
Cumulative Months of Follow-Up	13,141
Number of Leads Active in Study	5

Qualifying Complications 6 Total

Failure to Capture	5
Impedance Out of Range	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	98.3	97.8	97.8	97.1	97.1	97.1	97.1
#	207	182	154	1087	71	55	50

Effective Sample Size

5554 CapSure Z Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEJ
Registered US Implants	62,500	Type and/or Fixation	Transvenous, Atrium-J, Tines
Estimated Active US Implants	29,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

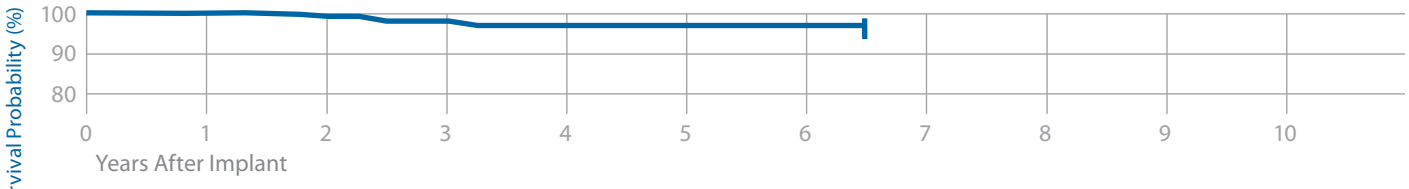
Conductor Fracture	9
Crimp/Weld/Bond	0
Insulation Breach	18
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	15,883
Number of Leads Active in Study	33

Qualifying Complications 5 Total

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



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 78 mo
%	100.0	99.2	98.7	98.2	98.2	98.2	98.2
#	272	227	182	158	137	80	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

5568 CapSureFix

Product Characteristics

US Market Release	Jan-97	Serial Number Prefix	LDN
Registered US Implants	92,200	Type and/or Fixation	Transvenous, Atrium-J, Active Screw-in
Estimated Active US Implants	50,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

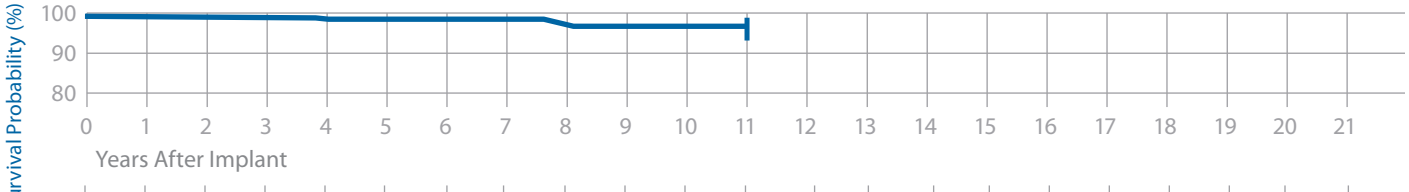
Conductor Fracture	13
Crimp/Weld/Bond	0
Insulation Breach	28
Other	37

Product Surveillance Registry Results

Number of Leads Enrolled in Study	1,053
Cumulative Months of Follow-Up	41,190
Number of Leads Active in Study	82

Qualifying Complications 13 Total

Conductor Fracture	1	Failure to Sense	2
Extra Cardiac Stimulation	1	Lead Dislodgement	1
Failure to Capture	6	Oversensing	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr
%	99.7	99.2	99.2	99.2	98.8	97.8	97.8	96.4	96.4	96.4	96.4
#	711	525	401	287	228	176	139	118	99	77	51

Effective Sample Size

5592 CapSure SP Novus

Product Characteristics

US Market Release	Jun-98	Serial Number Prefix	LEU
Registered US Implants	35,000	Type and/or Fixation	Transvenous, Atrium-J, Tines
Estimated Active US Implants	19,000	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

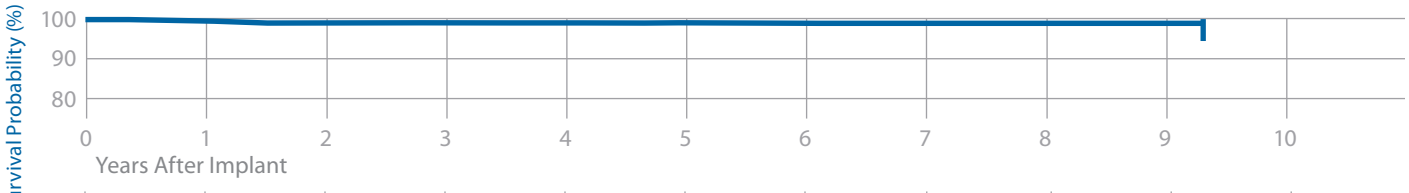
Conductor Fracture	4
Crimp/Weld/Bond	0
Insulation Breach	4
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	672
Cumulative Months of Follow-Up	31,531
Number of Leads Active in Study	106

Qualifying Complications 5 Total

Failure to Capture	3		
Lead Dislodgement	2		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	at 111 mo
%	99.7	99.3	99.3	98.9	98.9	98.9	98.9	98.9	98.9
#	517	433	347	283	220	154	115	86	47

Effective Sample Size

Pacing Leads continued

5594 CapSure SP Novus

Product Characteristics

US Market Release	Jun-01	Serial Number Prefix	LFD
Registered US Implants	16,100	Type and/or Fixation	Transvenous, Atrium-J, Tines
Estimated Active US Implants	10,500	Polarity	Bipolar
Advisories	None	Steroid	Yes

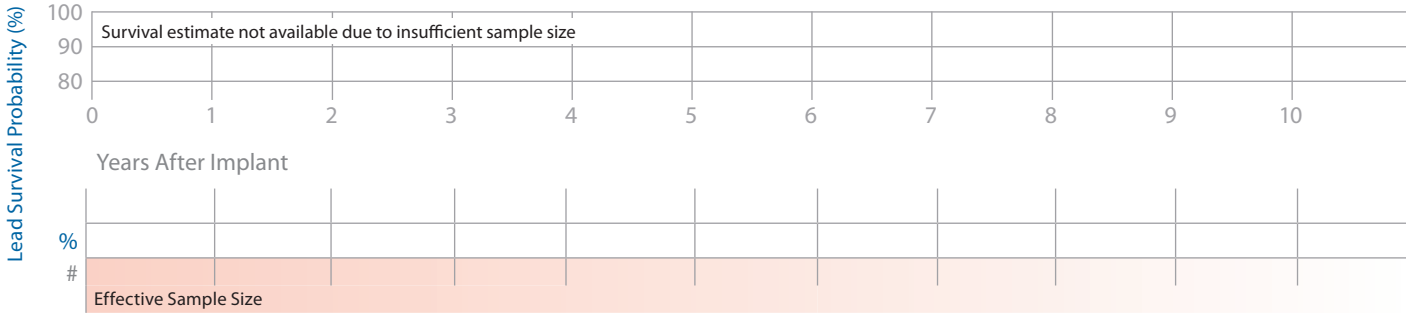
US Returned Product Analysis

Conductor Fracture	5
Crimp/Weld/Bond	0
Insulation Breach	7
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	20
Cumulative Months of Follow-Up	1,568
Number of Leads Active in Study	9

Qualifying Complications 0 Total



6940 CapSureFix

Product Characteristics

US Market Release	Oct-98	Serial Number Prefix	TCP
Registered US Implants	25,400	Type and/or Fixation	Transvenous, Atrium-J, Active Screw-in
Estimated Active US Implants	7,100	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

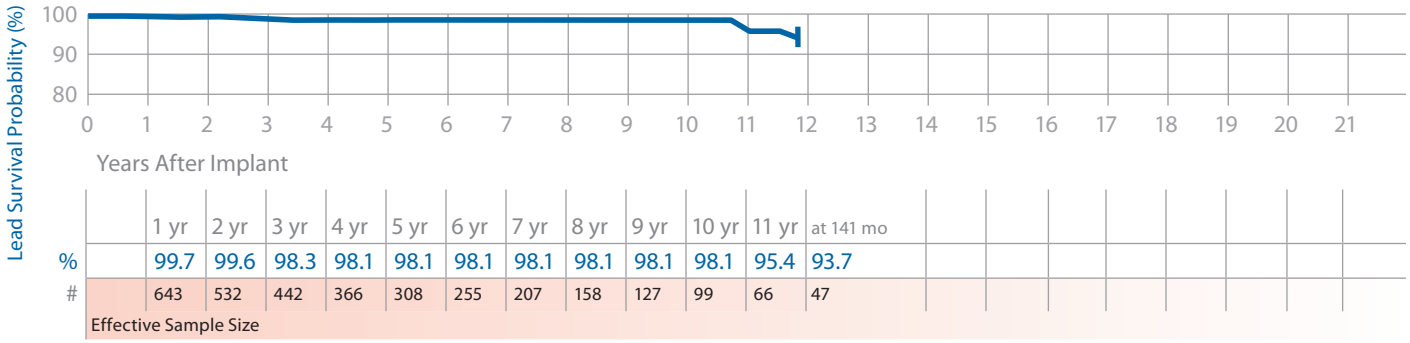
Conductor Fracture	12
Crimp/Weld/Bond	0
Insulation Breach	18
Other	12

Product Surveillance Registry Results

Number of Leads Enrolled in Study	818
Cumulative Months of Follow-Up	44,783
Number of Leads Active in Study	67

Qualifying Complications 13 Total

Conductor Fracture	1	Lead Dislodgement	3
Failure to Capture	1	Oversensing	5
Failure to Sense	3		



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	at 141 mo
%	99.7	99.6	98.3	98.1	98.1	98.1	98.1	98.1	98.1	98.1	95.4	93.7
#	643	532	442	366	308	255	207	158	127	99	66	47

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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	778	493	7	25,544	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0 at 66 mo								
3830	SelectSecure	Vent	Aug-05	482	283	4	17,389	99.3 +0.4/-1.4	99.3 +0.4/-1.4	99.3 +0.4/-1.4	99.3 +0.4/-1.4	99.3 +0.4/-1.4	99.3 +0.4/-1.4 at 69 mo								
4024	CapSure SP	Vent	Oct-91	1,215	10	4	50,987	99.9 +0.1/-0.5	99.8 +0.2/-0.7	99.8 +0.2/-0.7	99.8 +0.2/-0.7	99.8 +0.2/-0.7	99.8 +0.2/-0.7	99.8 +0.2/-0.7	99.8 +0.2/-0.7	98.8 +1/-5.0 at 117 mo					
4068	CapSureFix	Atrial	Mar-96	2,413	224	86	135,071	98.9 +0.4/-0.5	98.7 +0.4/-0.6	98.2 +0.5/-0.7	98.0 +0.6/-0.8	97.4 +0.7/-0.9	97.2 +0.7/-1.0	96.5 +0.9/-1.2	94.9 +1.3/-1.7	93.1 +1.7/-2.2	90.3 +2.4/-3.2	85.8 +4.1/-5.7 at 165 mo			
4068	CapSureFix	Vent	Mar-96	1,799	128	56	96,956	99.3 +0.3/-0.6	98.7 +0.5/-0.7	98.7 +0.5/-0.7	98.2 +0.6/-0.9	97.8 +0.7/-1.0	97.0 +0.9/-1.3	95.6 +1.3/-1.8	94.6 +1.5/-2.1	92.2 +2.1/-2.9	89.4 +3.4/-4.9 at 150 mo				
4074	CapSure Sense	Atrial	Jun-02	214	132	2	15,716	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8	99.1 +0.7/-2.8 at 96 mo						
4074	CapSure Sense	Vent	Jun-02	998	618	3	35,488	99.8 +0.2/-0.7	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9 at 96 mo						
4076	CapSureFix Novus	Atrial	Feb-04	1,663	894	9	65,593	99.8 +0.2/-0.4	99.6 +0.2/-0.5	99.4 +0.3/-0.6	99.4 +0.3/-0.6	99.4 +0.3/-0.6	99.0 +0.6/-1.7	99.0 +0.6/-1.7 at 78 mo							
4076	CapSureFix Novus	Vent	Feb-04	1,229	653	6	51,284	99.8 +0.1/-0.5	99.8 +0.1/-0.5	99.7 +0.2/-0.6	99.6 +0.3/-0.8	99.0 +0.6/-1.4	99.0 +0.6/-1.4	99.0 +0.6/-1.4 at 81 mo							
4092	CapSure SP Novus	Vent	Sep-98	1,147	261	19	66,685	98.9 +0.5/-0.9	98.8 +0.5/-0.9	98.7 +0.6/-0.9	98.4 +0.6/-1.1	98.1 +0.7/-1.2	97.7 +0.9/-1.3	97.7 +0.9/-1.3	97.7 +0.9/-1.3	97.7 +0.9/-1.3 at 123 mo					

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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
4524	CapSure SP	Atrial	Oct-91	911	29	6	40,951	99.6 +0.2/-0.8	99.3 +0.4/-1.0	99.3 +0.4/-1.0	99.0 +0.5/-1.3	99.0 +0.5/-1.3	99.0 +0.5/-1.3	99.0 +0.5/-1.3	99.0 +0.5/-1.3	99.0 +0.5/-1.3	99.0 +0.5/-1.3 at 132 mo				
4558M	Screw-In	Atrial	Nov-94	539	5	12	23,280	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	97.6 +1.5/-4.2	96.5 +2.1/-5.2	96.5 +2.1/-5.2	91.8 +4.3/-8.7 at 108 mo					
4568	CapSureFix	Atrial	Jan-97	656	115	36	32,664	96.8 +1.2/-1.8	96.4 +1.3/-1.9	95.3 +1.5/-2.2	94.7 +1.7/-2.4	94.0 +1.8/-2.6	94.0 +1.8/-2.6	92.9 +2.2/-3.2	92.2 +2.5/-3.5	90.8 +3.3/-5.0 at 111 mo					
4574	CapSure Sense	Atrial	Jun-02	520	387	4	7,525	99.0 +0.7/-1.8	99.0 +0.7/-1.8	99.0 +0.7/-1.8 at 30 mo											
4592	CapSure SP Novus	Atrial	Oct-98	283	56	7	14,887	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	97.4 +1.6/-3.8	97.4 +1.6/-3.8	97.4 +1.6/-3.8	96.0 +2.3/-5.5	96.0 +2.3/-5.5 at 108 m0					
5033	CapSure Z	Vent	Feb-96	1,899	134	31	101,933	99.7 +0.2/-0.4	99.6 +0.2/-0.5	99.1 +0.4/-0.7	99.0 +0.4/-0.8	98.8 +0.5/-0.9	98.3 +0.7/-1.1	97.7 +0.9/-1.4	96.9 +1.1/-1.7	96.0 +1.4/-2.1	95.6 +1.6/-2.4	93.3 +2.5/-4.0	93.3 +2.5/-4.0 at 186 mo		
5034	CapSure Z	Atrial	Feb-96	386	111	5	45,612	99.5 +0.4/-1.5	99.5 +0.4/-1.5	99.5 +0.4/-1.5	99.5 +0.4/-1.5	99.5 +0.4/-1.5	99.5 +0.4/-1.5	98.8 +0.7/-1.9	98.8 +0.7/-1.9	98.8 +0.7/-1.9	98.8 +0.7/-1.9	97.8 +1.4/-4.1 at 168 mo			
5034	CapSure Z	Vent	Feb-96	1,209	11	11	44,680	99.7 +0.2/-0.6	99.4 +0.3/-0.8	99.1 +0.5/-1.0	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.8 +0.6/-1.1	98.1 +1.1/-2.7	96.6 +2.2/-5.6 at 96 mo						
5054	CapSure Z Novus	Atrial	Jun-98	424	115	2	34,515	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4	99.5 +0.4/-1.4 at 126 mo					
5054	CapSure Z Novus	Vent	Jun-98	967	84	9	39,578	99.5 +0.3/-0.8	99.4 +0.4/-0.9	99.4 +0.4/-0.9	99.1 +0.5/-1.2	99.1 +0.5/-1.2	97.9 +1.1/-2.3	97.9 +1.1/-2.3	97.9 +1.1/-2.3	97.9 +1.1/-2.3 at 123 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	968	29	6	34,293	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.3 +0.4/-1.2	99.3 +0.4/-1.2	99.3 +0.4/-1.2	99.3 +0.4/-1.2	99.3 +0.4/-1.2	97.6 +1.5/-4.2	97.6 +1.5/-4.2	97.6 +1.5/-4.2 at 126 mo				
5068	CapSureFix	Vent	Jan-97	1,362	56	8	40,745	99.9 +0.1/-0.7	99.7 +0.2/-0.9	99.5 +0.4/-1.2	99.2 +0.5/-1.5	99.2 +0.5/-1.5	99.2 +0.5/-1.5	98.5 +0.9/-2.6	97.2 +1.6/-3.7	97.2 +1.6/-3.7	97.2 +1.6/-3.7 at 129 mo				
5072	SureFix	A or V	Jun-98	508	50	3	28,227	99.8 +0.2/-1.4	99.8 +0.2/-1.4	99.4 +0.4/-1.7	99.4 +0.4/-1.7	99.4 +0.4/-1.7	99.4 +0.4/-1.7	99.4 +0.4/-1.7	99.4 +0.4/-1.7	98.5 +1.1/-4.1	98.5 +1.1/-4.1	98.5 +1.1/-4.1 at 135 mo			
5076	CapSureFix Novus	Atrial	Aug-00	2,744	593	28	142,851	99.6 +0.2/-0.3	99.6 +0.2/-0.4	99.4 +0.3/-0.5	98.9 +0.4/-0.6	98.7 +0.5/-0.7	98.5 +0.5/-0.8	98.5 +0.5/-0.8	98.3 +0.6/-0.8	97.8 +0.9/-1.6	97.8 +0.9/-1.6 at 129 mo				
5076	CapSureFix Novus	Vent	Aug-00	1,539	247	14	69,416	99.6 +0.2/-0.5	99.4 +0.3/-0.6	99.3 +0.4/-0.7	99.0 +0.5/-0.9	99.0 +0.5/-0.9	98.6 +0.7/-1.2	98.3 +0.8/-1.4	98.3 +0.8/-1.4	97.7 +1.2/-2.3 at 120 mo					
5086MRI	CapSureFix Novus	Atrial	Feb-11	2,532	2,216	2	25,622	99.9 +0.1/-0.3	99.9 +0.1/-0.3 at 21 mo												
5086MRI	CapSureFix Novus	Vent	Feb-11	2,518	2,206	4	25,436	99.8 +0.1/-0.3	99.8 +0.1/-0.3 at 21 mo												
5092	CapSure SP Novus	Vent	Jun-98	1,172	125	9	48,445	99.5 +0.3/-0.7	99.4 +0.3/-0.8	99.2 +0.4/-0.9	99.0 +0.5/-1.1	99.0 +0.5/-1.1	98.6 +0.8/-1.6	98.6 +0.8/-1.6	98.6 +0.8/-1.6	98.6 +0.8/-1.6 at 123 mo					
5534	CapSure Z	Atrial	Feb-96	264	5	6	13,141	98.3 +1.0/-2.7	97.8 +1.3/-3.0	97.8 +1.3/-3.0	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5 at 78 mo							
5554	CapSure Z Novus	Atrial	Jun-98	344	33	5	15,883	100.0	99.2 +0.6/-2.4	98.7 +0.9/-2.6	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0	98.2 +1.1/-3.0 at 78 mo							
5568	CapSureFix	Atrial	Jan-97	1,053	82	13	41,190	99.7 +0.2/-0.7	99.2 +0.4/-1.0	99.2 +0.4/-1.0	99.2 +0.4/-1.0	98.8 +0.7/-1.6	97.8 +1.2/-2.5	97.8 +1.2/-2.5	96.4 +1.8/-3.7	96.4 +1.8/-3.7	96.4 +1.8/-3.7 at 132 mo				
5592	CapSure SP Novus	Atrial	Jun-98	672	106	5	31,531	99.7 +0.3/-1.0	99.3 +0.5/-1.2	99.3 +0.5/-1.2	98.9 +0.6/-1.6	98.9 +0.6/-1.6	98.9 +0.6/-1.6	98.9 +0.6/-1.6	98.9 +0.6/-1.6	98.9 +0.6/-1.6 at 111 mo					
5594	CapSure SP Novus	Atrial	Jun-01	20	9	0	1,568	100.0 at 0 mo													
6940	CapSureFix	Atrial	Oct-98	818	67	13	44,783	99.7 +0.2/-0.8	99.6 +0.3/-0.9	98.3 +0.8/-1.5	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	98.1 +0.9/-1.6	93.7 +3.5/-7.6 at 141 mo				

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
3830	SelectSecure	Aug-05	21,600	16,400	4	14	0	3
4024	CapSure SP	Oct-91	219,400	40,700	28	183	0	12
4068	CapSureFix	Mar-96	124,300	29,800	50	167	0	93
4074	CapSure Sense	Jun-02	94,100	58,800	3	20	0	0
4076	CapSureFix Novus	Feb-04	452,200	347,600	39	35	1	18
4092	CapSure SP Novus	Sep-98	179,200	80,700	11	53	0	2
4524	CapSure SP	Oct-91	100,300	23,200	1	67	0	3
4558M	Screw-in	Nov-94	19,700	3,800	1	21	0	20
4568	CapSureFix	Jan-97	69,500	21,100	5	86	0	52
4574	CapSure Sense	Jun-02	62,900	42,200	7	3	0	0
4592	CapSure SP Novus	Oct-98	86,300	40,700	7	18	0	1
5033	CapSure Z	Feb-96	2,300	500	1	0	0	3
5034	CapSure Z	Feb-96	55,400	12,200	12	15	0	7
5054	CapSure Z Novus	Jun-98	96,600	41,100	10	25	1	3
5068	CapSureFix	Jan-97	102,400	28,800	41	56	2	83
5072	SureFix	Jun-98	10,000	4,100	3	6	0	0
5076	CapSureFix Novus	Aug-00	1,552,400	981,100	435	452	0	186
5086MRI	CapSureFix Novus MRI	Feb-11	128,800	124,700	3	5	0	8
5092	CapSure SP Novus	Jun-98	134,300	61,100	11	38	0	3
5534	CapSure Z	Feb-96	25,800	6,700	3	4	0	4
5554	CapSure Z Novus	Jun-98	62,500	29,100	9	18	0	1
5568	CapSureFix	Jan-97	92,900	50,900	13	28	0	37
5592	CapSure SP Novus	Jun-98	35,000	19,000	4	4	0	0
5594	CapSure SP Novus	Jun-01	16,100	10,500	5	7	0	1
6940	CapSureFix	Oct-98	25,400	7,100	12	18	0	12

Source: Returned Product Analysis
Data as of July 31, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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	Extracardiac Stimulation	Impedance Abnormal	Unspecified
3830	SelectSecure	21,600	6	1	29	14	3	1	1	0	0	2
4024	CapSure SP	219,400	13	11	49	103	1	16	1	2	8	20
4068	CapSureFix	124,300	5	3	31	23	0	5	1	1	2	4
4074	CapSure Sense	94,100	10	1	32	30	0	1	0	0	3	0
4076	CapSureFix Novus	452,200	54	4	134	66	6	17	1	9	12	12
4092	CapSure SP Novus	179,200	1	4	22	29	0	0	1	2	0	2
4524	CapSure SP	100,300	2	2	23	15	0	4	2	1	0	12
4558M	Screw-in	19,700	2	0	2	2	0	1	0	1	1	1
4568	CapSureFix	69,500	3	1	4	6	1	1	0	0	2	1
4574	CapSure Sense	62,900	0	1	39	16	1	8	0	0	0	4
4592	CapSure SP Novus	86,300	0	0	25	8	1	1	1	0	0	2
5033	CapSure Z	2,300	0	0	0	0	0	0	0	0	0	1
5034	CapSure Z	55,400	2	2	14	28	0	3	3	0	0	12
5054	CapSure Z Novus	96,600	1	1	22	22	0	0	1	0	2	9
5068	CapSureFix	102,400	16	4	20	31	1	5	1	0	1	7
5072	SureFix	10,000	0	0	2	2	0	0	0	0	0	0
5076	CapSureFix Novus	1,552,400	167	11	529	241	28	36	8	13	14	31
5086MRI	CapsureFix Novus	128,800	119	2	151	74	20	13	1	10	4	0
5092	CapSure SP Novus	134,300	5	1	51	34	1	6	3	3	0	9
5534	CapSure Z	25,800	0	0	6	3	0	1	0	1	0	4
5554	CapSure Z Novus	62,500	0	1	31	28	0	2	0	0	0	3
5568	CapSureFix	92,200	8	0	33	19	2	2	1	2	2	4
5592	CapSure SP Novus	35,000	1	0	27	4	0	2	0	0	0	1
5594	CapSure SP Novus	16,100	0	0	8	0	0	0	0	0	0	2
6940	CapSureFix	25,400	0	1	6	1	0	0	0	0	1	0

Report Cutoff Date: September 10, 2013

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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
4024	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4068	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4074	CapSure Sense	Transvenous Ventricular Tines	Polyurethane/Silicone (55D, 4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium/ 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
4524	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
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
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
5086MRI	CapsureFix Novus	Transvenous A or V Screw-in	Silicone	MP35N	Titanium nitride coated platinum alloy	IS-1 BI
5092	CapSure SP Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5534	CapSure Z	Transvenous Atrial-J Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	CapSure Z Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	CapSure Z Porous Platinized/ Steroid	IS-1 BI
5568	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5592	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5594	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Platinized Platinum/ Steroid	IS-1 BI
6940	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Epi/Myocardial Pacing Leads

4965 CapSure Epi

Product Characteristics

US Market Release	Sep-96	Serial Number Prefix	LBT
Registered US Implants	20,900	Type and/or Fixation	Myocardial, Atrium or Right Ventricle, Suture
Estimated Active US Implants	9,400	Polarity	Unipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

Conductor Fracture	171
Crimp/Weld/Bond	1
Insulation Breach	37
Other	0

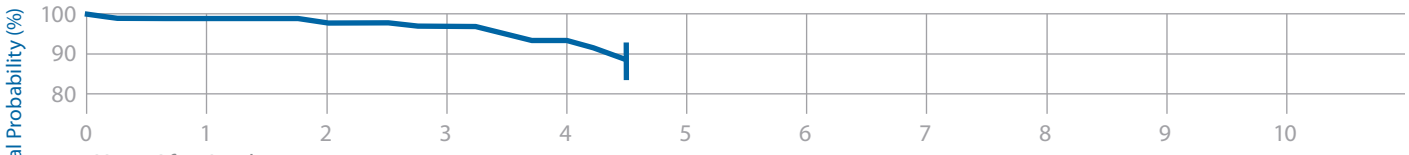
Product Surveillance Registry Results

Number of Leads Enrolled in Study	219
Cumulative Months of Follow-Up	7,786
Number of Leads Active in Study	24

Qualifying Complications

12 Total

Conductor Fracture	5	Insulation (not further defined)	1
Failure to Capture	3	Oversensing	2
Failure to Sense	1		



	1 yr	2 yr	3 yr	4 yr	at 54 mo
%	99.0	98.2	97.2	92.8	88.1
#	139	116	93	63	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	29,000	Type and/or Fixation	Myocardial, Atrium or Right Ventricle, Suture
Estimated Active US Implants	17,900	Polarity	Bipolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

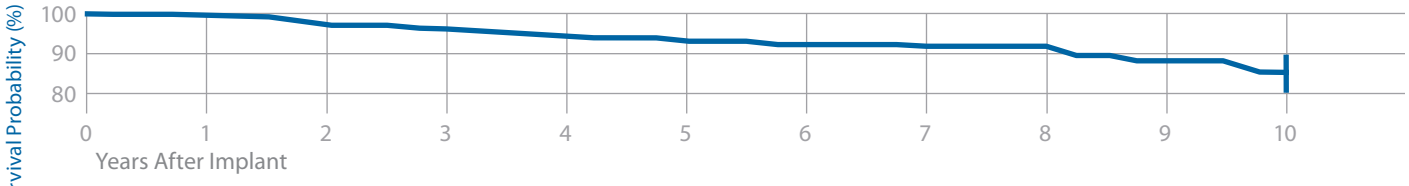
Conductor Fracture	35
Crimp/Weld/Bond	0
Insulation Breach	17
Other	1

Product Surveillance Registry Results

Number of Leads Enrolled in Study	819
Cumulative Months of Follow-Up	41,146
Number of Leads Active in Study	312

Qualifying Complications 59 Total

Conductor Fracture	12	Impedance Out of Range	5
Extra Cardiac Stimulation	2	Insulation (not further defined)	3
Failure to Capture	21	Oversensing	12
Failure to Sense	3	Other	1



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
%	99.5	97.6	95.9	93.6	92.5	90.9	89.0	89.0	86.4	84.9
#	646	547	447	350	285	210	155	109	66	50

Effective Sample Size

5071 Screw-in

Product Characteristics

US Market Release	Dec-92	Serial Number Prefix	LAQ
Registered US Implants	45,200	Type and/or Fixation	Myocardial, Right Ventricle, Fixed Screw-in.
Estimated Active US Implants	15,400	Polarity	Unipolar
Advisories	None	Steroid	No

US Returned Product Analysis

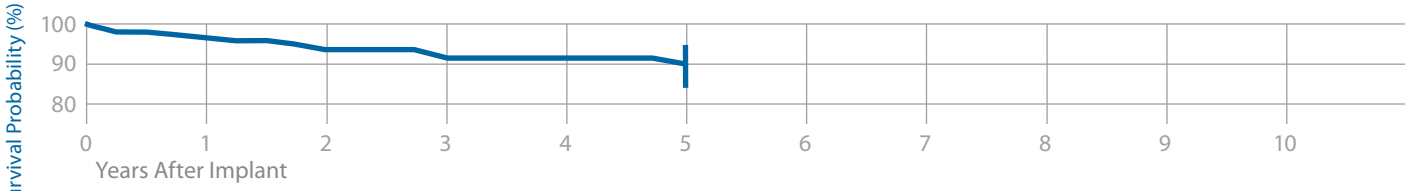
Conductor Fracture	13
Crimp/Weld/Bond	0
Insulation Breach	2
Other	0

Product Surveillance Registry Results

Number of Leads Enrolled in Study	302
Cumulative Months of Follow-Up	8,521
Number of Leads Active in Study	63

Qualifying Complications 15 Total

Failure to Capture	12		
Impedance Out of Range	1		
Oversensing	2		



	1 yr	2 yr	3 yr	4 yr	5 yr
%	96.9	94.0	91.8	91.8	90.1
#	153	105	78	63	48

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

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
4965	CapSure Epi	Sep-96	219	24	12	7,786	99 .0 +0.8/-3.0	98.2 +1.3/-3.9	97.2 +1.8/-4.7	92.8 +3.6/-7.0	88.1 +5.4/-9.3 at 54 mo							
4968	CapSure Epi	Sep-99	819	312	59	41,146	99.5 +0.3/-0.9	97.67 +0.9/-1.5	95.9 +1.3/-2.0	93.6 +1.8/-2.5	92.5 +2.0/-2.8	90.9 +2.4/-3.2	89.0 +2.9/-3.8	89.0 +2.9/-3.8	84.9 +4.4/-6.0 at 120 mo			
5071	Screw -in	Dec-92	302	63	15	8,521	96.9 +1.6/-3.3	94.0 +2.7/-4.9	91.8 +3.6/-6.1	91.8 +3.6/-6.1	90.1 +4.3/-7.3 at 60 mo							

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

Epi/Myocardial Pacing Leads continued

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/ Weld/Bond	Other
4965	CapSure Epi	Sep-96	21,200	9,400	171	37	1	0
4968	CapSure Epi	Sep-99	29,000	17,900	35	17	0	1
5071	Screw-in	Dec-92	45,200	15,400	13	2	0	0

Source: Returned Product Analysis
Data as of July 31, 2013

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	Impedance Abnormal	Extracardiac Stimulation
4965	CapSure Epi	21,200	0	1	0	4	1	4	4	0
4968	CapSure Epi	29,000	0	0	3	14	2	0	2	0
5071	Screw-in	45,200	1	0	0	33	0	2	2	3

Model Number	Family	Estimated US Implants	Insulation Breach	Unspecified
4965	CapSure Epi	20,900	0	3
4968	CapSure Epi	27,800	1	0
5071	Screw-in	44,300	0	1

Report Cutoff Date: Data as of September 10, 2013

Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4965	CapSure Epi	Epicardial Suture 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
5071	Screw-in	Myocardial Screw-In Ventricular	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

VDD Single Pass Pacing Leads

5032 CapSure VDD

Product Characteristics

US Market Release	Mar-96	Serial Number Prefix	LCL, LCN, LCM
Registered US Implants	5,300	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	1,200	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

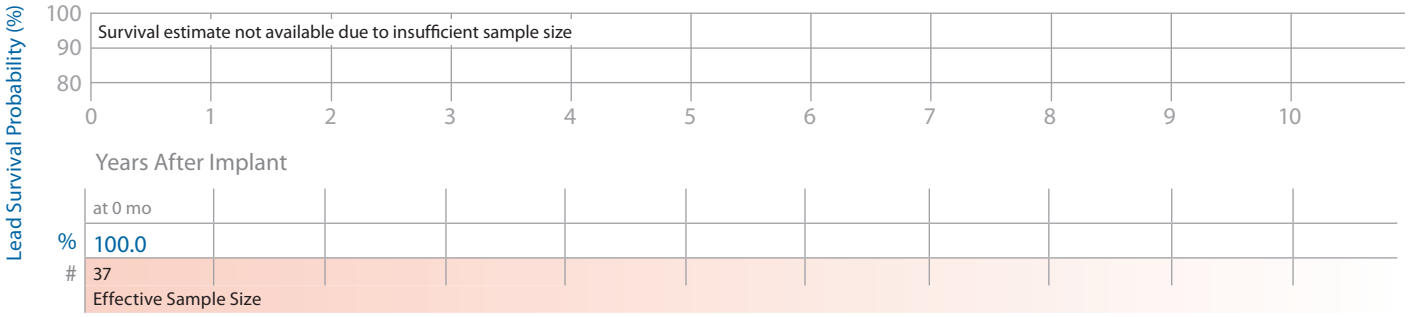
Product Surveillance Registry Results

Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	1,683
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	9,200	Type and/or Fixation	Transvenous, Right Ventricle, Tines
Estimated Active US Implants	3,600	Polarity	Quadripolar
Advisories	None	Steroid	Yes

US Returned Product Analysis

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

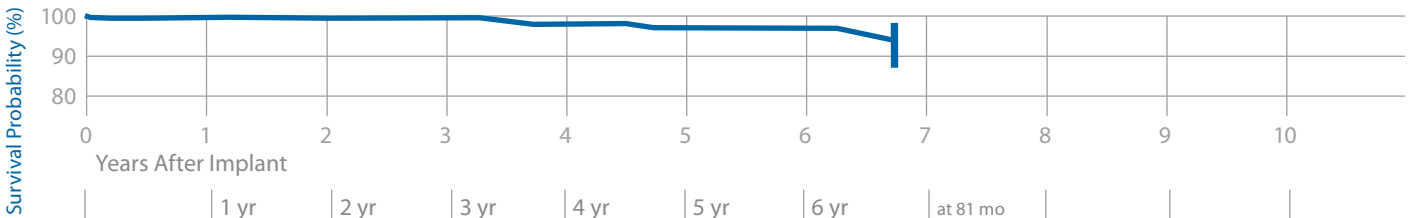
Product Surveillance Registry Results

Number of Leads Enrolled in Study	558
Cumulative Months of Follow-Up	20,842
Number of Leads Active in Study	41

Qualifying Complications

6 Total

Conductor Fracture	3
Failure to Capture	1
Failure to Sense	2



	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	at 81 mo
%	99.8	99.8	99.8	98.8	98.2	98.2	95.2
#	419	307	220	176	134	82	52

Effective Sample Size

Source: Medtronic Device Registration and Returned Product Analysis
Data as of July 31, 2013

VDD Single Pass Pacing Leads

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	1,683	100.0 at 0 mo									
5038	CapSure VDD-2	Sep-98	558	41	6	20,842	99.8 +0.2/-1.3	99.8 +0.2/-1.3	99.8 +0.2/-1.3	98.8 +0.8/-2.7	98.2 +1.2/-3.2	98.2 +1.2/-3.2	95.2 +2.9/-7.2 at 81 mo			

Source: Product Surveillance Registry
Data as of July 31, 2013

US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Insulation Breach	Crimp/Weld/ Bond	Other
5032	CapSure VDD	Mar-96	5,300	1,200	7	6	0	0
5038	CapSure VDD-2	Sep-98	9,200	3,600	4	1	0	0

Source: Returned Product Analysis
Data as of July 31, 2013

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Lead Dislodgement	Failure to Capture	Failure to Sense	Extracardiac Stimulation	Unspecified
5032	CapSure VDD	5,300	1	1	1	0	1
5038	CapSure VDD-2	9,200	2	1	1	1	0

Report Cutoff Date: September 10, 2013

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 V and A 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 July 31, 2013

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 Product Surveillance Registry. 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.

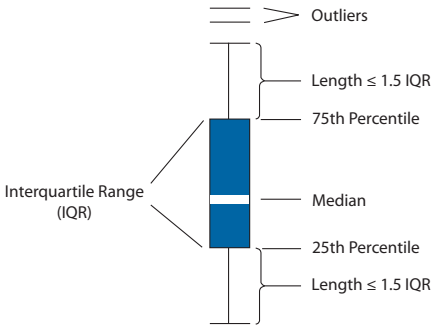
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

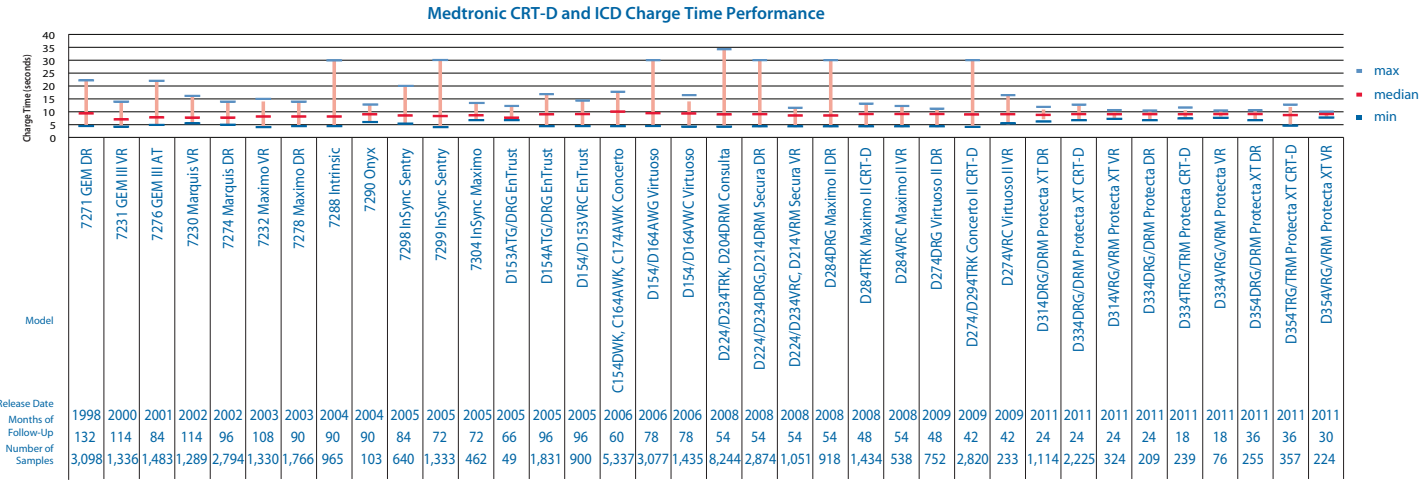
Data Presentation

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.

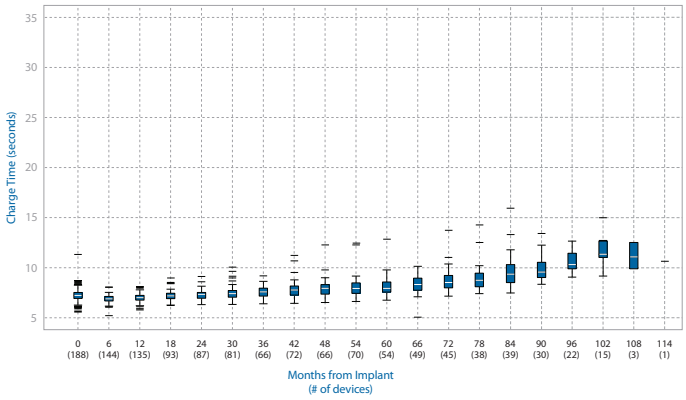




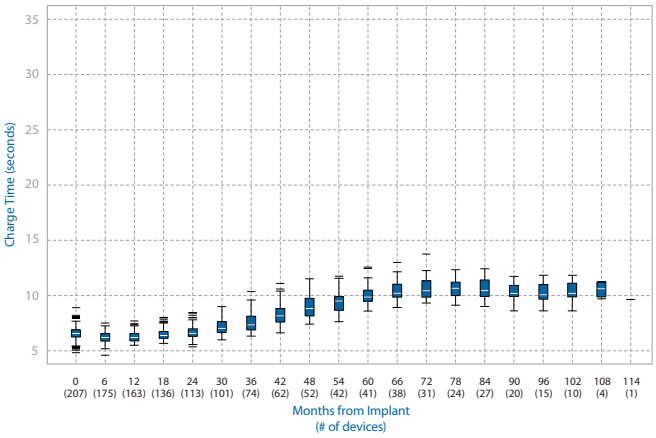
Source: Product Surveillance Registry
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

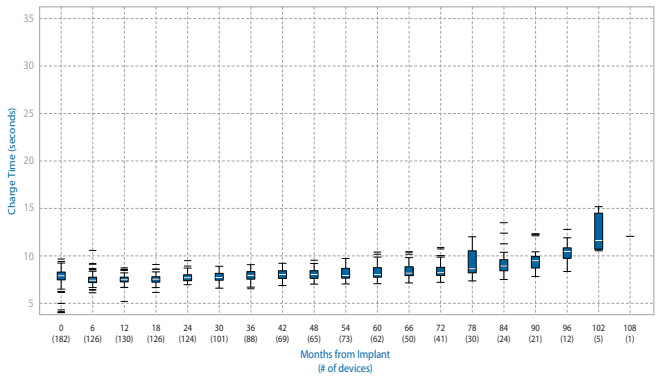
7230 Marquis VR Charge Time



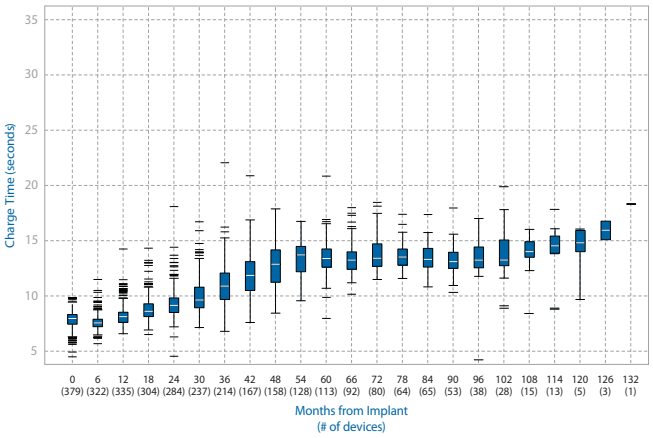
7231 GEM III VR Charge Time



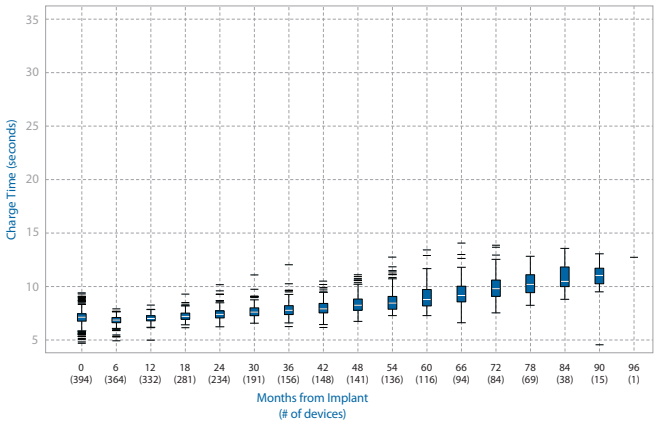
7232 Maximo VR Charge Time



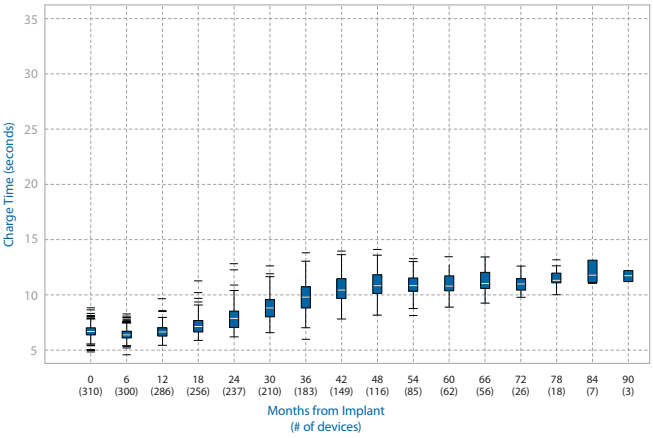
7271 GEM DR Charge Time



7274 Marquis DR Charge Time



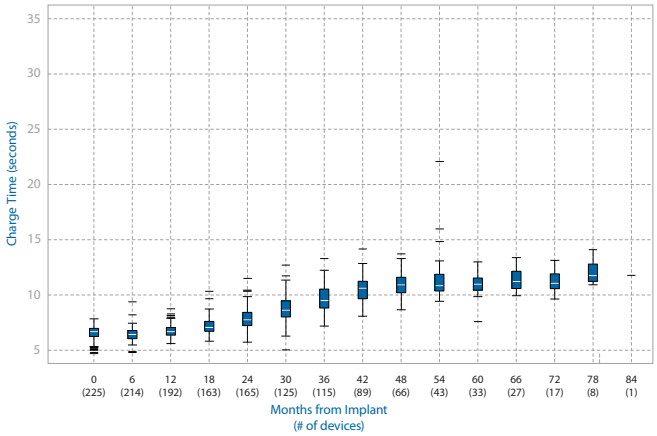
7275 GEM III DR Charge Time



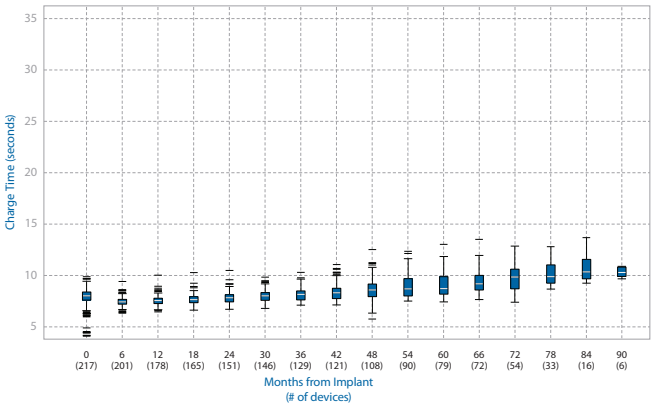
Source: System Longevity Study
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

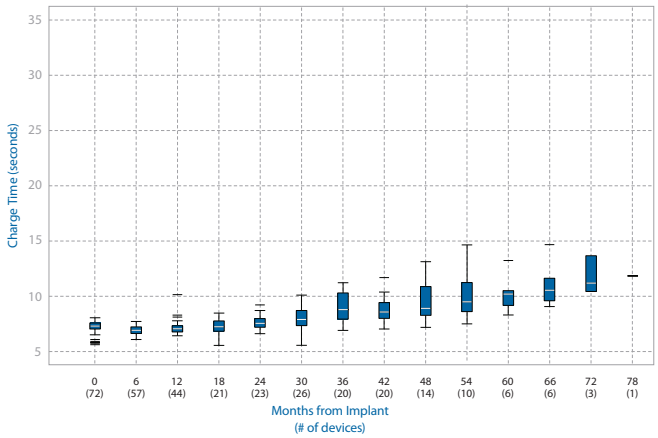
7276 GEM III AT Charge Time



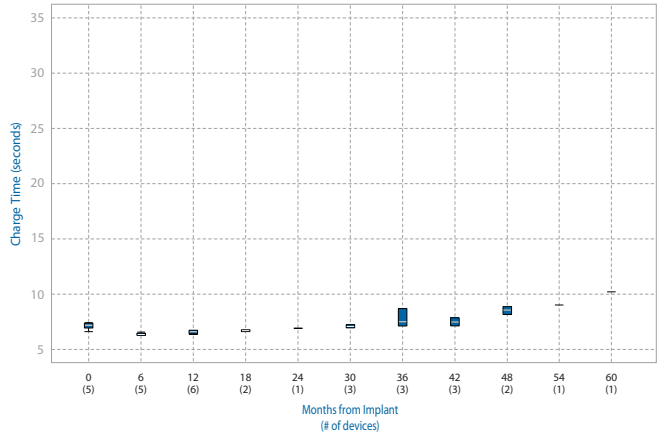
7278 Maximo DR Charge Time



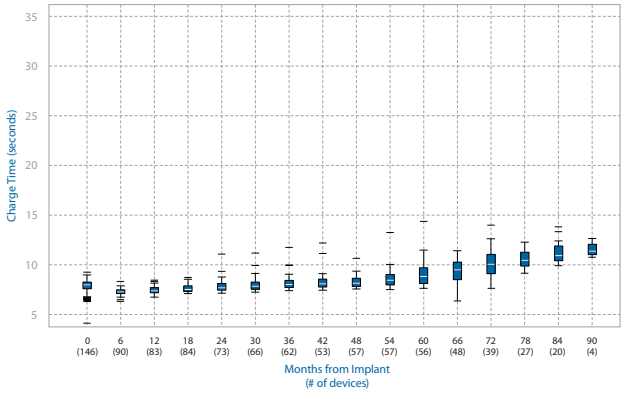
7279 InSync III Marquis Charge Time



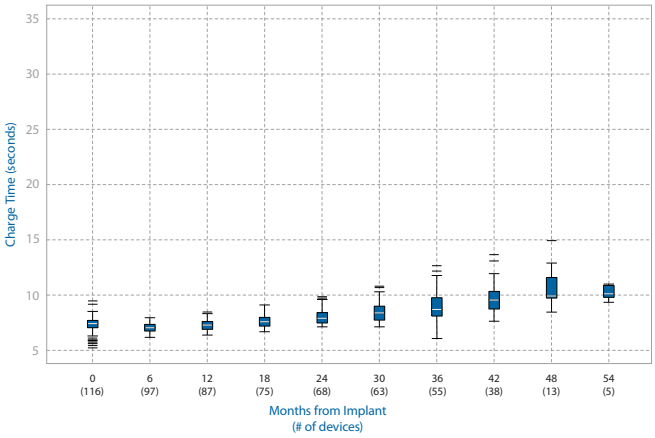
7285 InSync III Protect Charge Time



7288 Intrinsic Charge Time



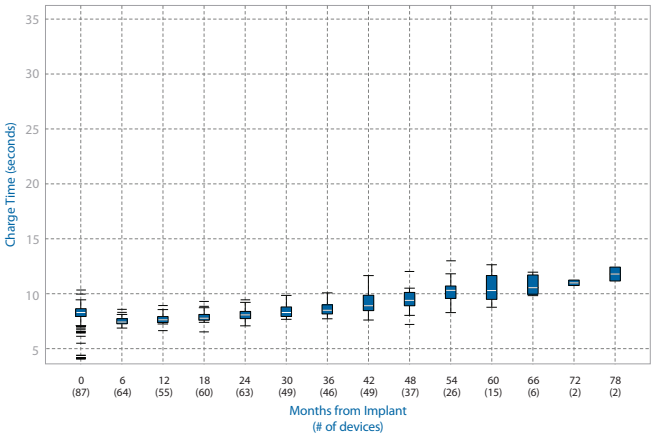
7289 InSync II Marquis Charge Time



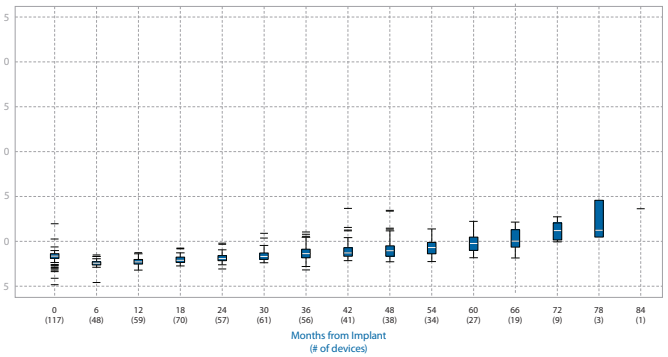
Source: Product Surveillance Registry
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

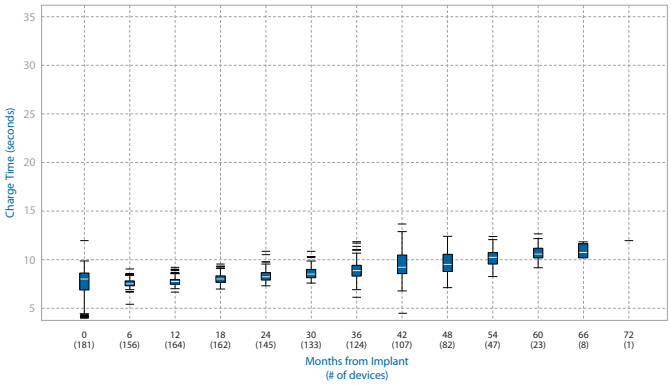
7297 InSync Sentry Charge Time



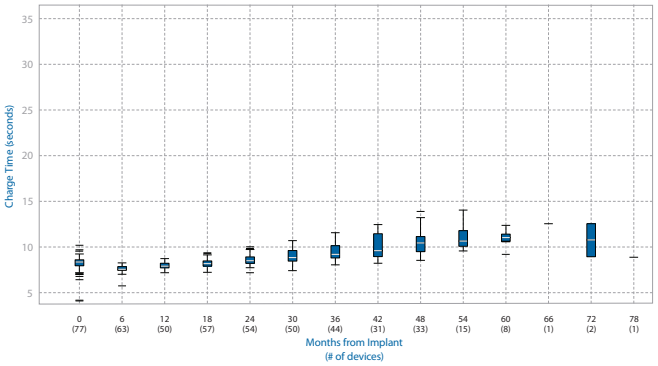
7298 InSync Sentry Charge Time



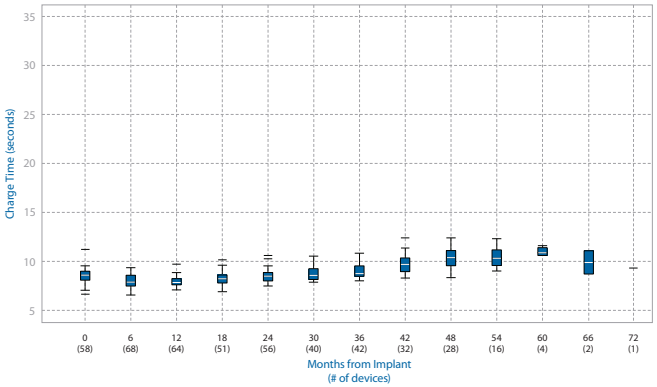
7299 InSync Sentry Charge Time



7303 InSync Maximo Charge Time



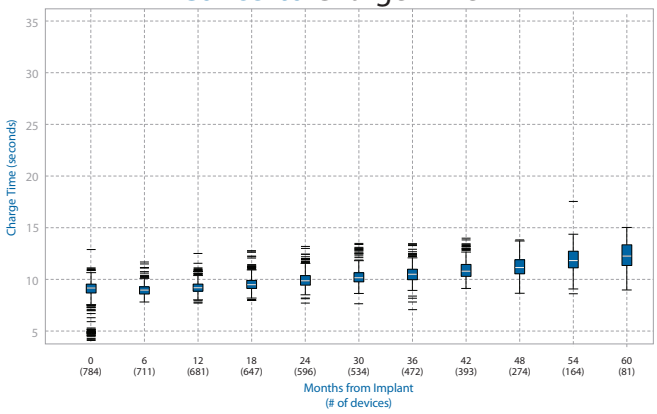
7304 InSync Maximo Charge Time



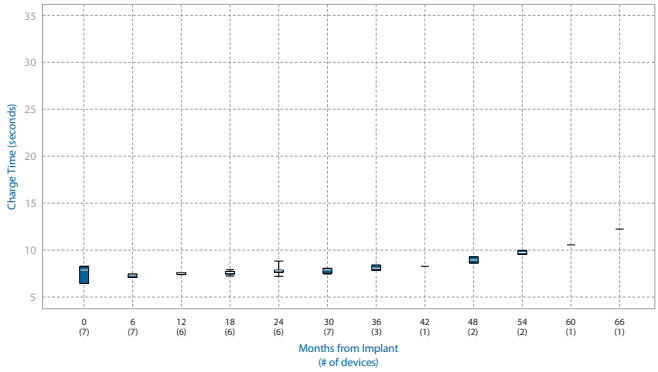
Source: System Longevity Study
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

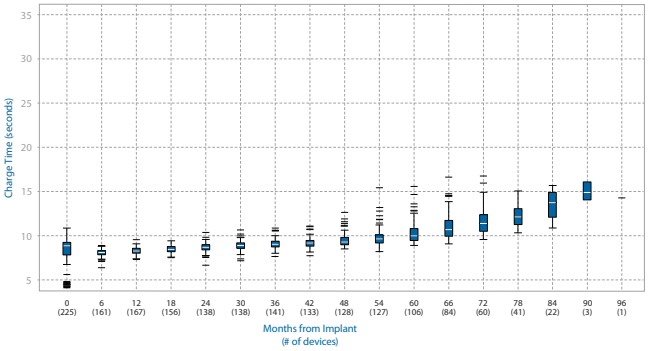
C154DWK, C164AWK, C174AWK Concerto Charge Time



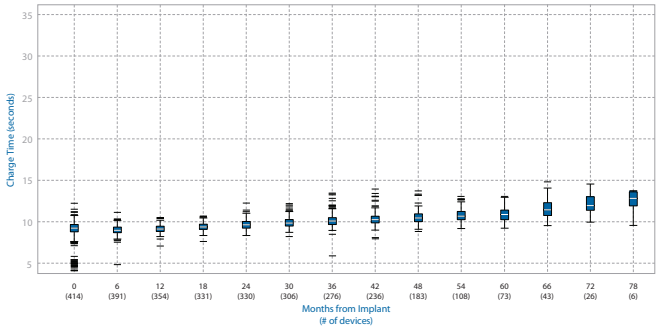
D153ATG/DRG EnTrust Charge Time



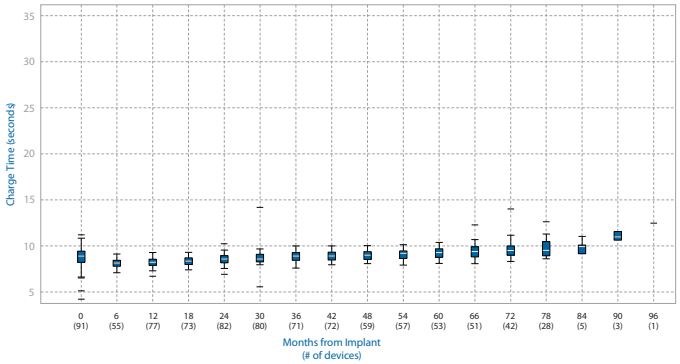
D154ATG/DRG EnTrust Charge Time



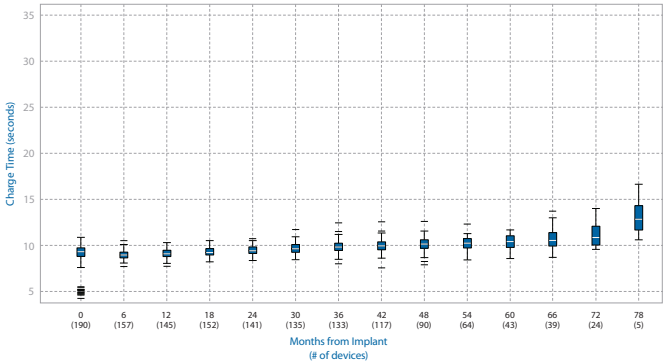
D154AWG/164 Virtuoso Charge Time



D154VRC/153 EnTrust Charge Time



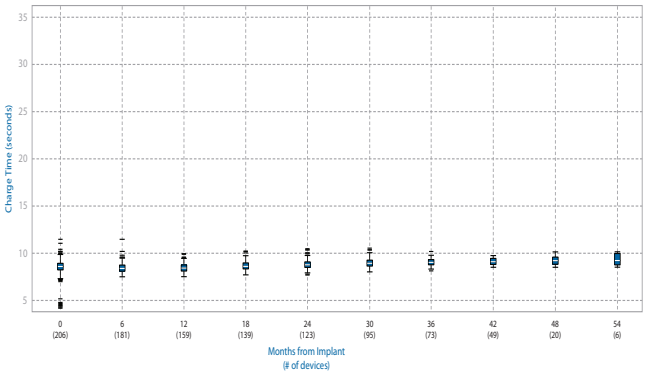
D154VWC/164 Virtuoso Charge Time



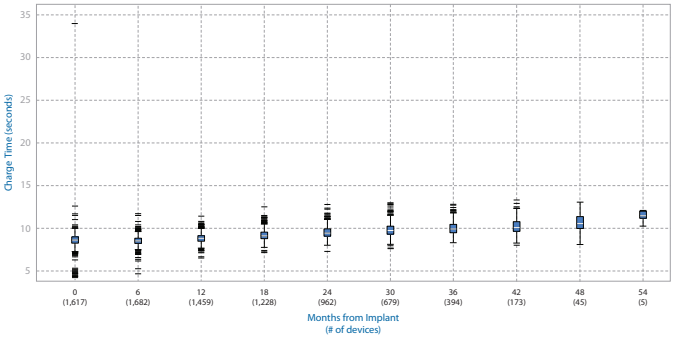
Source: Product Surveillance Registry
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

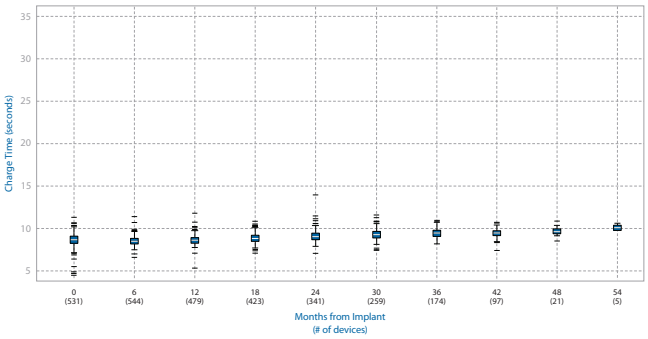
D224VRC/234 Secura VR Charge Time



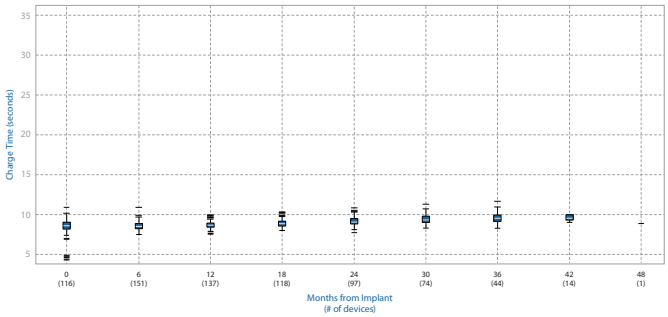
D224TRK/234/204TRM Consulta Charge Time



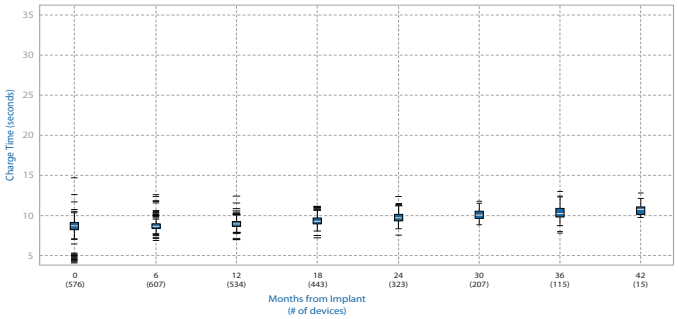
D224DRG/234/204DRM Secura DR Charge Time



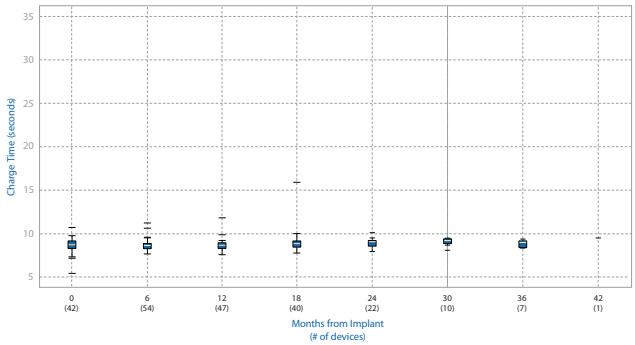
D274DRG Virtuoso II DR Charge Time



D274TRK/294 Concerto II CRT-D Charge Time



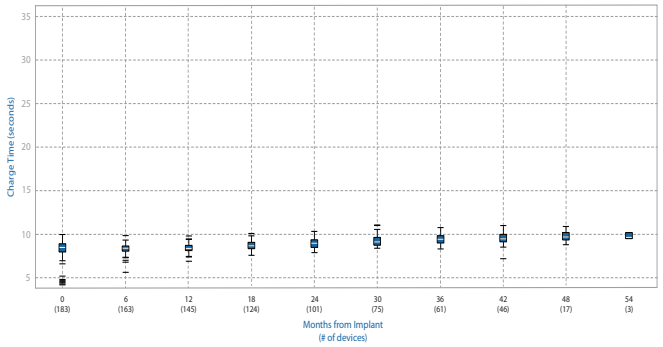
D274VRC Virtuoso II VR Charge Time



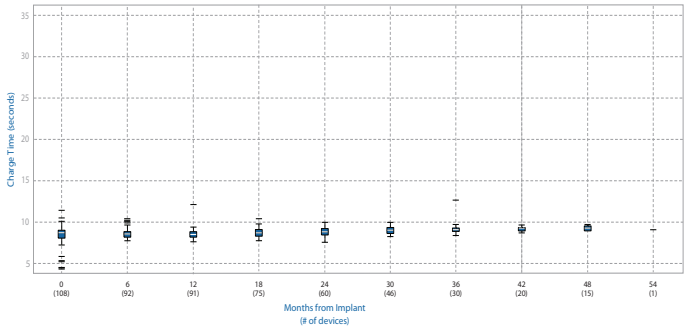
Source: System Longevity Study
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

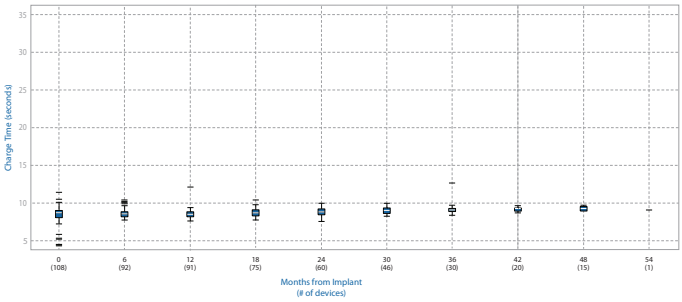
D284DRG Maximo II DR Charge Time



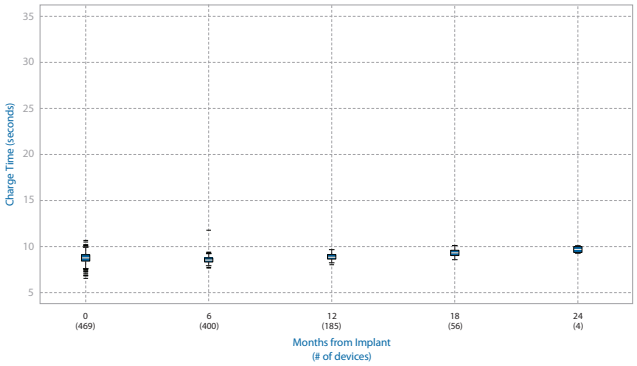
D284TRK Maximo II CRT-D Charge Time



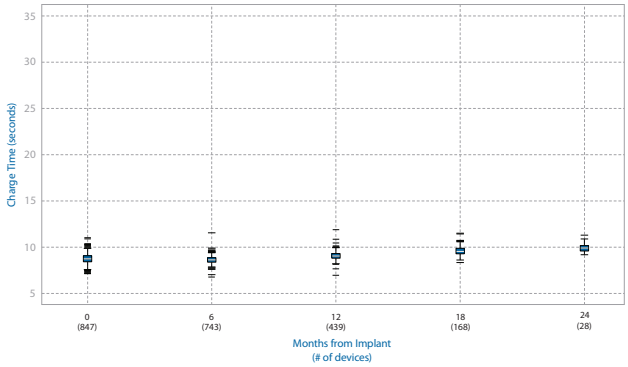
D284VRC Maximo II VR Charge Time



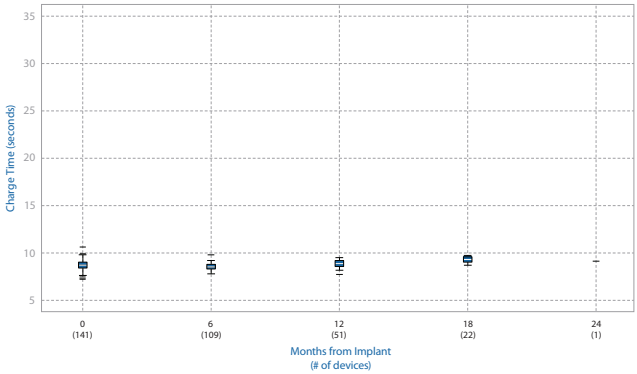
D314DRG/DRM Protecta XT DR Charge Time



D314TRG/TRM Protecta XT CRT-D Charge Time



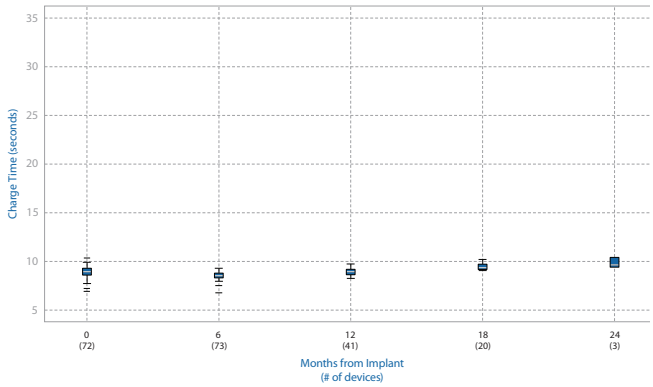
D314VRG/VRM Protecta XT VR Charge Time



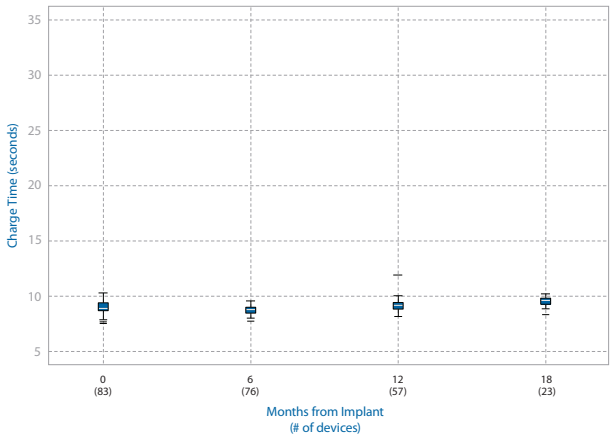
Source: Product Surveillance Registry
Data as of July 31, 2013

ICD and CRT-D Charge Time Performance continued

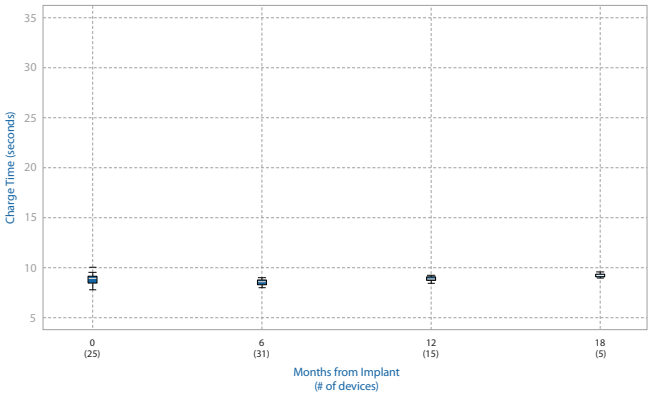
D334DRG/DRM Protecta DR Charge Time



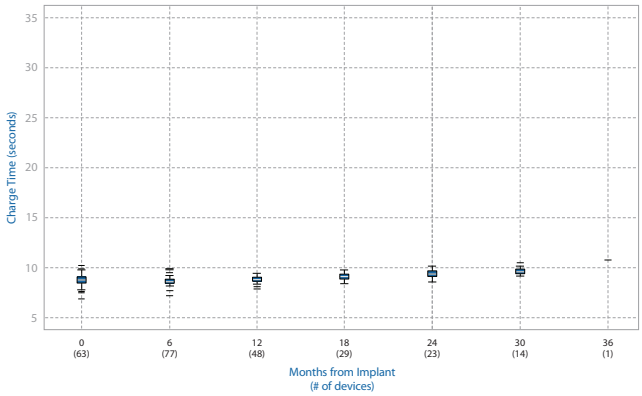
D334TRG/TRM Protecta CRT-D Charge Time



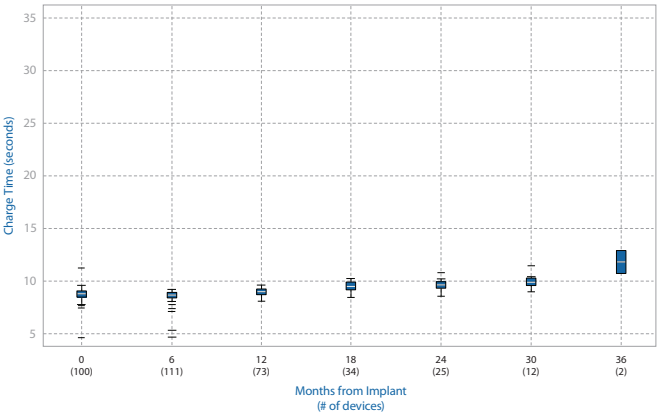
D334VRG/VRM Protecta VR Charge Time



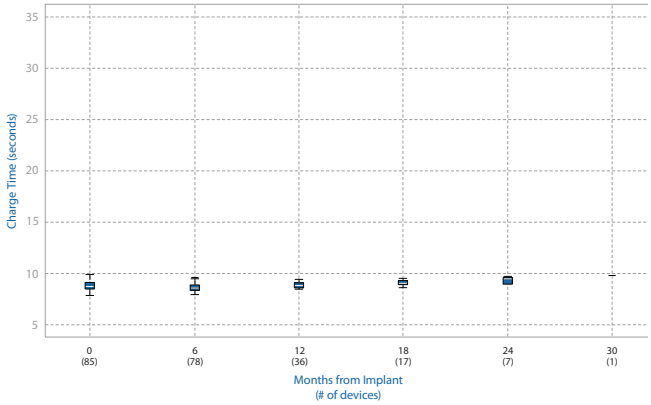
D354DRG/DRM Protecta XT DR Charge Time



D354TRG/TRM Protecta XT CRT-D Charge Time



D354VRG/VRM Protecta XT VR Charge Time



Source: System Longevity Study
Data as of July 31, 2013

Advisories

Consulta CRT-P and Syncra CRT-P

Original Date of Advisory: June 2013

Potential Loss Of Device Hermeticity

Product

Consulta® CRT-P and Syncra® CRT-P

Advisory

Medtronic has identified an issue with a connector bracket weld on a subset of Consulta CRT-P models and Syncra CRT-P devices manufactured between April 1 and May 13, 2013. This type of connector bracket weld is unique to Consulta and Syncra CRT-P devices and no other Medtronic device models are affected.

An out-of-specification weld could result in a loss of device hermeticity and compromised device functionality. **There have been no reported or confirmed device failures or patient injuries.** Medtronic estimates the rate of out-of-specification welds to be 1-2% in this subset of devices.

Non-implanted devices from this subset have been recalled to Medtronic for re-inspection with additional controls to ensure that the weld meets specification. In June 2013, Medtronic communicated to impacted physicians that up to 779 devices worldwide (43 in the U.S.) may have been implanted from this subset.

Patient Management Recommendations (As of June 2013)

As a result of on-going investigation and consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient management recommendations:

- Physicians should advise their patients to seek medical attention immediately if they experience a return of symptoms related to bradycardia or heart failure.
- If considering prophylactic device replacement for pacemaker-dependent patients with a device in the identified subset, physicians should carefully assess individual patient circumstances against the known risk of a device replacement.
- Physicians should continue routine follow-up in accordance with standard practice.

Status Update

As of September 10, 2013, 536 of the 779 devices have been returned from field inventory. Medtronic estimates the remaining 243 devices (44 in the U.S.) have been implanted. There have been no reported or confirmed device failures or patient injuries.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)
Up to 779 Worldwide (**44** United States)	**0** Worldwide (**0** United States)	**243** Worldwide (**43** United States)	**0%** Worldwide (**0%** United States)

EnTrust ICDs

Original Date of Advisory: March 2012

Potential Rapid Battery Depletion

Product

All EnTrust ICDs.

Advisory

A small percentage of EnTrust ICDs may not meet expected longevity or provide at least three months of device operation between the Elective Replacement Indicator (ERI) and End of Life (EOL) due to a more-rapid-than-expected drop in battery voltage. No patient deaths or serious injuries have been reported as a result of this issue.

The reported events have involved a drop in battery voltage from ~3.0 V to ERI (2.61 V) over a time period ranging from approximately one week to six months. All reported events have occurred at least 30 months after implant.

Medtronic has identified the cause of these occurrences to be an internal battery short that develops as the battery capacity is consumed.

Patient Management Recommendations (As of March 2012)

After consultation with Medtronic's Independent Physician Quality Panel, Medtronic offers the following patient management recommendations:

- Physicians should continue routine follow-up sessions at least every three months in accordance with product labeling.
- Physicians should program the audible patient alerts for "Low Battery Voltage ERI" and "Excessive Charge Time EOL" to ON.
- Physicians should replace devices promptly after they reach ERI if the decline in voltage is more rapid than expected.
- Prophylactic replacement of EnTrust ICDs is not recommended.

Status Update

As of September 10, 2013, there have been 83 confirmed events. No patient deaths have been reported due to this issue. No reports have been made of a failure to deliver high voltage therapy.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed Malfunctions over total population)
69,000 Worldwide (**43,200** United States)	**83** Worldwide (**63** United States)	**23,300** Worldwide (**14,600** United States)	**0.12%** Worldwide (**0.15%** United States)

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 are addressed by a Medtronic software update.

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 caused confusion and occasionally resulted in unnecessary explants.

Medtronic's investigation has shown that none of these reports 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 eliminates this risk.

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 until 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.

Software Update (As of October 2010)

The battery issues described above and subsequent software update are summarized in the table below. When a device receives the software update, if battery impedance is greater than the new ERI threshold, ERI will be triggered shortly thereafter. Therefore, clinicians may observe an ERI/EOL indicator at the next patient follow-up. When ERI is triggered by battery impedance, additional battery capacity remains and can support device function at ERI parameters for at least one year. Medtronic is not aware of any reports of loss of therapy due to this issue.

As a reminder, when ERI is triggered, EnRhythm devices revert to VVI pacing at 65 ppm at the programmed output settings. EOL is declared 90 days after ERI or at a battery voltage of 2.69 V, whichever comes sooner.

Battery Issue	Software Update
Battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion	Changed ERI battery voltage threshold from 2.59 V to 2.81 V to ensure 90 days of therapy from ERI to EOL
Higher than expected battery impedance	Added a secondary ERI trigger based on battery impedance. This new criteria will identify devices with increased battery impedance before device performance is impacted. If triggered, displayed battery voltage is reset to 2.81 V to ensure alignment with ERI battery voltage threshold.

Updated Performance Information (as of August 2011)

We now have access to battery impedance and ERI performance on more than 5,000 EnRhythm devices that have received the EnRhythm software update. Our modeling based on these data shows that approximately 6-10% of devices will reach ERI within 5 years post-implant. Consistent with our previous communications, we continue to expect average device longevity to be reduced by approximately 10-15%, with the expected average longevity remaining at 8.5 to 10.5 years, depending on device settings.[1]

Updated Patient Management Recommendations (as of August 2011)

After consultation with Medtronic's Independent Physician Quality Panel, we recommend:

Performing a device follow-up within 90 days after the software download to identify devices that triggered ERI shortly after the software update. Subsequent follow-up can be performed per standard practice. During programmer interrogation of a device at ERI, there is a slight possibility a transient drop in pacing amplitude could occur. If this is noted, either remove the programmer head or temporarily program to a higher output voltage.

continued

EnRhythm Pacemakers

Original Date of Advisory: February 2010

Low Battery Voltage Displayed at Device Interrogation, continued

If an unanticipated ERI/EOL is declared, it is likely due to battery impedance. In such cases, additional battery capacity remains and can support device function at ERI parameters for at least one year. However, when ERI or EOL (typically 90 days after ERI) declaration is seen, schedule device replacement.

[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). Projections are based on modeling and not actual field returns, due to limited availability of implant experience beyond 6 years. Field performance will continue to be monitored and modeling updated to reflect actual data.

Status Update

As of September 10, 2013, 381 devices out of approximately 146,500 devices worldwide have been confirmed as having exhibited an advisory event related to the original advisory, in which higher than expected battery impedance caused a drop in battery voltage at interrogation.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)	The software update eliminates any potential future risk of the two battery issues described above by changing the ERI criteria.
All EnRhythm pacemakers (**146,500** Worldwide)	**381** Worldwide	**84,700** Worldwide	**0.25%**	

Included in the August 2011 Performance Update was information about the projected percentage of devices that would encounter an early ERI due to unexpected high battery impedance. As of February 25, 2013, percentage of devices that have encountered ERI due to battery impedance has not exceeded the rate of 6-10% within 5 years post-implant as communicated with our August 2011 Performance Update.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Only devices using the updated software can trigger ERI due to impedance.
All EnRhythm pacemakers (**146,500** Worldwide)	**8,805** Worldwide	**84,700** Worldwide	

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. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

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 September 10, 2013, 3,684 devices out of approximately 8,900 devices in this subset worldwide have been confirmed as having exhibited this capacitor degradation. Out of the initial advisory population of 8,900 worldwide, less than 300 remain implanted worldwide.

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)	**3,684** Worldwide (**3,168** United States)	**< 300** Worldwide (**< 300** United States)	**42%** Worldwide (**45%** United States)

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

Original Date of Advisory: May 2009

Potential Separation of Interconnect Wires (2009)

Product

A specific subset of Kappa and Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

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 September 10, 2013, Medtronic has observed 458 Kappa devices and 299 Sigma devices with this failure mechanism from the Kappa and new Sigma device subsets. This represents 0.79% (Kappa) and 2% (Sigma) of the original affected implant population.

Four hundred twenty-one (421) of the Kappa devices (0.72%) and 232 of the Sigma devices (1.56%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 37 Kappa devices (0.06%) and 67 Sigma devices (0.44%) 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.

As of May 2009, our modeling predicts failure rates due to this issue of 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime of those pacemakers still in service at that time.

Out of the initial advisory population of 58,300 Kappa devices and 14,900 Sigma devices worldwide, less than 200 Kappa devices remain implanted worldwide and 2,000 Sigma devices remain implanted worldwide. Of these, 500 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. Less than 200 devices of this subset remain active. We have observed a failure rate of approximately 0.096% in this subset and our May 2009 modeling predicts a failure rate of 0.12% over the remaining device life of those pacemakers still in service at that time. 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 and Unconfirmed 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)	**421** Worldwide (**221** United States) with information indicating a clinical presentation. An additional **37** worldwide (**25** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**< 200** Worldwide (**< 100** United States)	**0.79%** Worldwide **1.40%** (United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**232** Worldwide (**49** United States) with information indicating a clinical presentation. An additional **67** worldwide (**17** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**2,000** Worldwide (**500** United States)	**2%** Worldwide **1.8%** (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 (Updated April 2011)

The Lead Integrity Alert (LIA) provides three days advance notice prior to inappropriate therapy to 76% of patients with lead fractures.[1] As a result, we strongly recommend that all Sprint Fidelis patients who have the ability to upgrade to Lead Integrity Alert do so promptly. Also ensure that high voltage lead impedance alerts (maximum of 100 ohms) are programmed. When a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended. Physicians should inform their patients to seek medical attention without delay if they experience unexpected shocks

- **If a Fidelis lead fracture of any type has occurred, we recommend implanting a new high voltage lead with or without extraction of the Fidelis lead.**
- In patients with normal device function and no manifestation of lead fracture, no action is recommended. The risk of prophylactic intervention appears to be greater than serious injury resulting from lead fracture even for pacemaker dependent patients, except in select individual patient circumstances as determined by the physician.
- In the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data above, as well as patient life expectancy, co-morbidities, ease of extraction related to implant time, patient preference, etc., for the following options:
  - Leave a properly performing lead intact.
  - Implant a new ICD lead without extraction of the existing lead.
  - Carefully consider all factors before prophylactic placement of a pace-sense lead. Data shows an increased risk of high voltage conductor fracture if a pace-sense conductor fracture has previously occurred. This data is available at www.medtronic.com/fidelis
  - Individual patient circumstances may warrant extracting and implanting a new ICD lead. If warranted, Medtronic's Independent Physician Quality Panel recommends the lead extraction procedure be performed by a physician with extensive lead extraction experience.[2]

Status Update

As of September 10, 2013, of the initial implant population of 205,600 in the United States, approximately 88,300 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 80.4% (+4.5/-5.6) at 87 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.

[1] Swerdlow C, Gunderson B, Ousdigian K, et al. Downloadable Algorithm to Reduce Inappropriate Shocks Caused by Fractures of Implantable Cardioverter-Defibrillator Leads, *Circulation*. November 2008;118:2122-2129.

[2] Wilkoff B, Love C, Byrd C, et al. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. *Heart Rhythm*. July 2009;6:1085-1104.

continued

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads

Original Date of Advisory: October 2007

Potential Conductor Wire Fracture, continued

Keeping Physicians Informed

The most recent Sprint Fidelis lead performance information, including survival curves, physician letters, and subpopulation data, can be found at www.medtronic.com/fidelis and will be updated semi-annually. Medtronic's website also has a selected list of peer-reviewed publications related to Fidelis lead performance and extraction. Medtronic is committed to answering your questions and keeping you informed. If you have any questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1 (800) 723-4636 (US).

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Additional information about the Sprint Fidelis lead is available at: www.medtronic.com/fidelis.
279,500 Worldwide (**205,600** United States)	**6,330** Worldwide (**4,471** United States)	**120,000** Worldwide (**83,300** United States)	

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires (2005)

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

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 September 10, 2013, 806 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred forty-two (442) of the Sigma devices (1%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 364 Sigma devices (0.90%) 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, as of May 2009, updated modeling now predicts a failure rate of 3.9% over the remaining device life of those devices still in service at that time.

Out of the initial advisory population of 40,000 worldwide, approximately 5,900 remain implanted. Approximately 1,400 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (Confirmed and Unconfirmed Malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still in Service as of May 2009
40,000 Implanted Worldwide (est.) (**9,900** United States)	**442** Worldwide (**86** United States) with information indicating a clinical presentation.An additional **364** Worldwide (**66** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**5,900** Worldwide (**1,400** United States)	**2.0%** Worldwide **1.5%** (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. Go to www.medtronic.com/CRDMProductPerformance to determine if a specific device is affected.

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 September 10, 2013, 193 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. One hundred fifteen (115) of these devices were returned from the United States.

Out of the initial advisory population of 87,000 worldwide, approximately 1,600 remain implanted. Approximately 1,400 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)	**193** Worldwide (**115** United States)	**1,600** Worldwide (**1,400** United States)	**0.22%** Worldwide (**0.15%** 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.

Performance Notes

Dual Chamber Pacemakers with Measurement Lock-up ERI
Kappa 600, 700, 800, 900, EnPulse, Adapta, Versa, Sensia, Relia, and Vitatron Models E50A1, E60A1, and G70A1

Purpose of this Information

This Performance Note describes a rare measurement lock-up issue that impacts the Medtronic dual chamber pacemakers listed above. If this measurement lock-up occurs, the device will trigger a false Elective Replacement Indicator (ERI). A reset is available to clear this condition and there is no need to explant the device. This issue does not impact battery longevity.

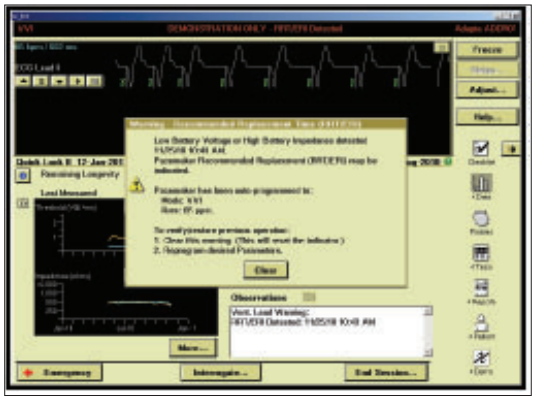
Background

If this rare measurement lock-up occurs in the pacemaker, it causes the device to read a value of zero for battery voltage. After four measurements of zero, the device will trigger ERI and revert to a VVI pacing mode at 65 bpm. There is no loss of ventricular pacing and the output voltage will remain the same.

Programmer Software Reset Method (Adapta, Versa, Sensia, Relia, Vitatron Series E and G)

Programmer software is available which can differentiate a regular ERI and an ERI caused by the measurement lock-up issue. Upon interrogation of a device with the measurement lock-up ERI, the programmer software recognizes the issue and guides the clinician to clear the ERI (Example 1). Following an ERI reset, the device parameters should be reviewed and reprogrammed to clinician specifications.

Example 1 – Programmer Software Detects Measurement Lock-up ERI

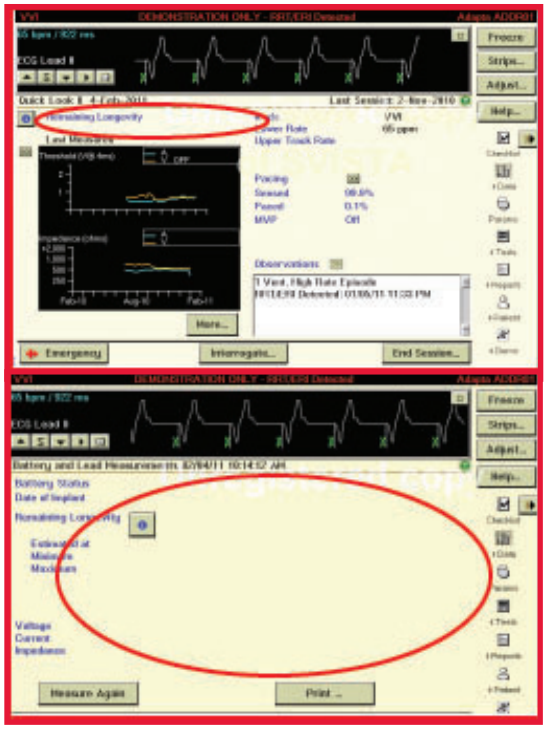


Reset Method for Kappa and EnPulse

A service tool continues to be available through Medtronic Technical Services to clear the measurement lock-up issue for Kappa and EnPulse devices.

The issue can be identified using the programmer or via CareLink transmission; the battery voltage measurements and remaining longevity will appear as blank values (Example 2). If this measurement lock-up occurs, contact Medtronic Brady Technical Services at 1-800-505-4636 for assistance.

Example 2 – Programmer Screens for Measurement Lock-up ERI (Kappa and EnPulse)



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.

Performance Notes

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 Product Surveillance Registry (PSR).

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.

[1] Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE*. June 2002;25(6):879-882.

[2] Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol*. January 1, 2003;41(1):73-80.

[3] Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. *Heart Rhythm*. July 2007;4(7):892-896.

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.

Performance Notes

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
Email: crdm.returnedproduct@medtronic.com

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