Medtronic

Cardiac Rhythm Disease Management

Product Performance Report

Important Patient Management Information for Physicians

2014

First Edition – Issue 70

CRDM Product Performance Report

2014 First Edition
Issue 70

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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)
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Mounds View, MN 55112 USA

Email: chris.m.haenisch@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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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

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

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.

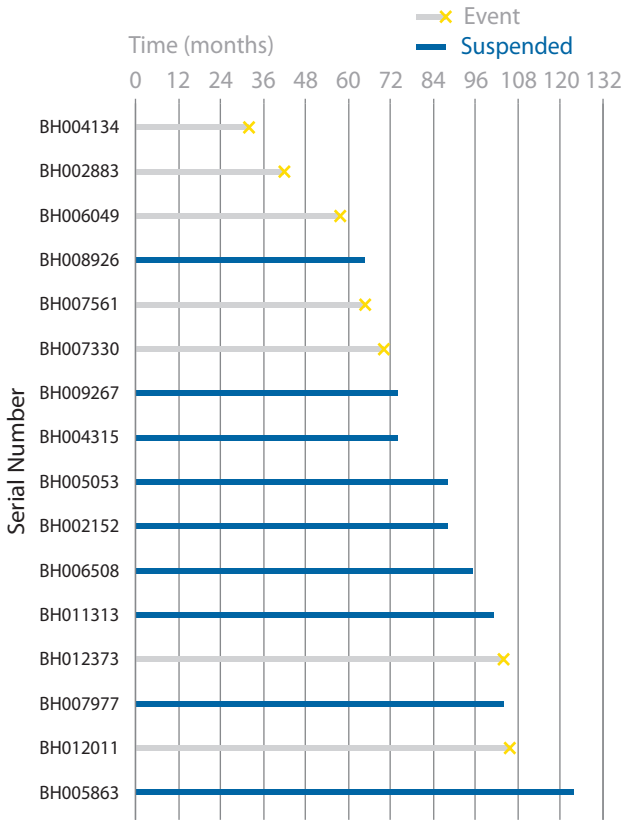


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

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

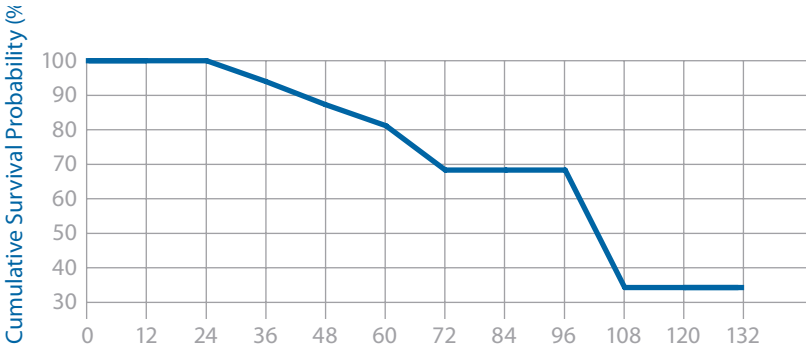
The overall probability of surviving to the end of the interval. Computed by multiplying the Interval Survival Probability by the previous interval's Cumulative Survival Probability.

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

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.

Cardiac Resynchronization Therapy

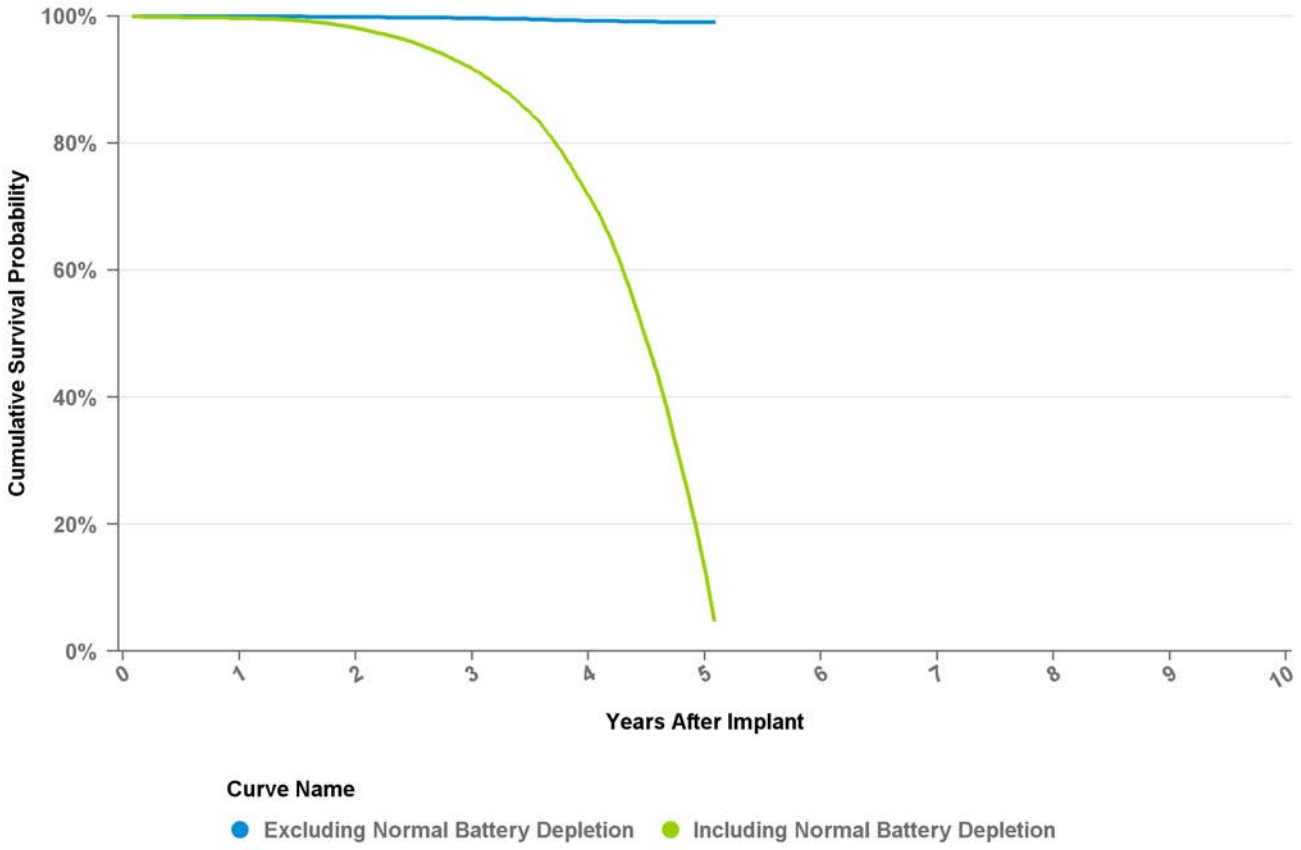
7299 InSync Sentry

US Market Release Date	4/8/2005
CE Market Approval Date	
Registered US Implants	31,187
Estimated Active US Implants	2,068
Normal Battery Depletions (US)	9,725

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	178
Therapy Not Compromised Malfunction	168
Battery Malfunction	0
Electrical Component	18
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	147
Software Malfunction	2
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7299, Survival Curve



Years	1	2	3	4	5	at 61 mo
Excluding NBD	100.0%	99.9%	99.7%	99.2%	99.0%	99.0%
Including NBD	99.7%	98.1%	91.7%	71.8%	13.1%	4.9%
Effective Sample Size	27219	23770	18979	11900	1675	871

Cardiac Resynchronization Therapy

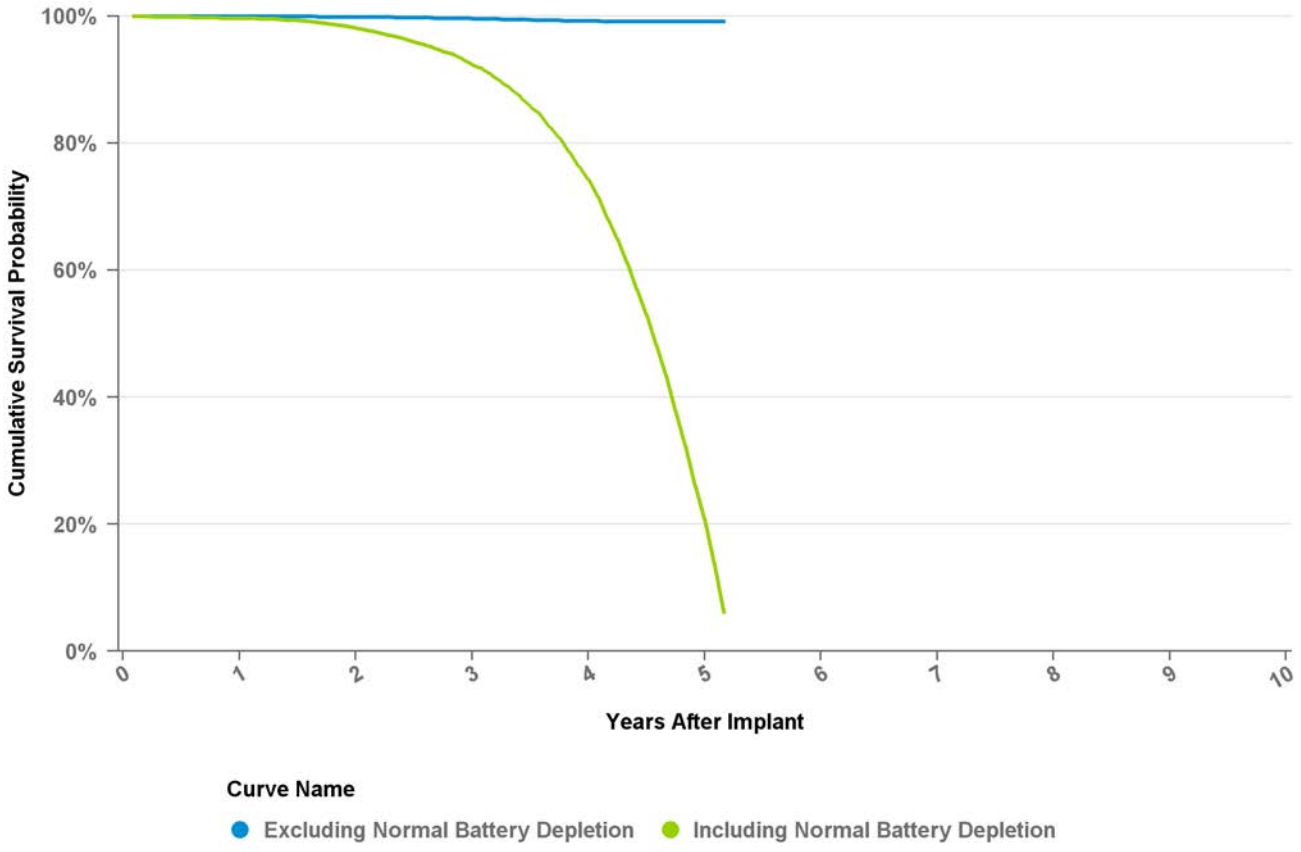
7304 InSync Maximo

US Market Release Date	4/8/2005
CE Market Approval Date	1/14/2005
Registered US Implants	18,984
Estimated Active US Implants	1,622
Normal Battery Depletions (US)	5,423

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	112
Therapy Not Compromised Malfunction	107
Battery Malfunction	1
Electrical Component	15
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	90
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0

7304, Survival Curve



Years	1	2	3	4	5	at 62 mo
Excluding NBD	100.0%	99.9%	99.6%	99.2%	99.1%	99.1%
Including NBD	99.7%	98.1%	92.3%	74.3%	20.8%	6.1%
Effective Sample Size	16895	14749	11875	7602	1255	428

Cardiac Resynchronization Therapy

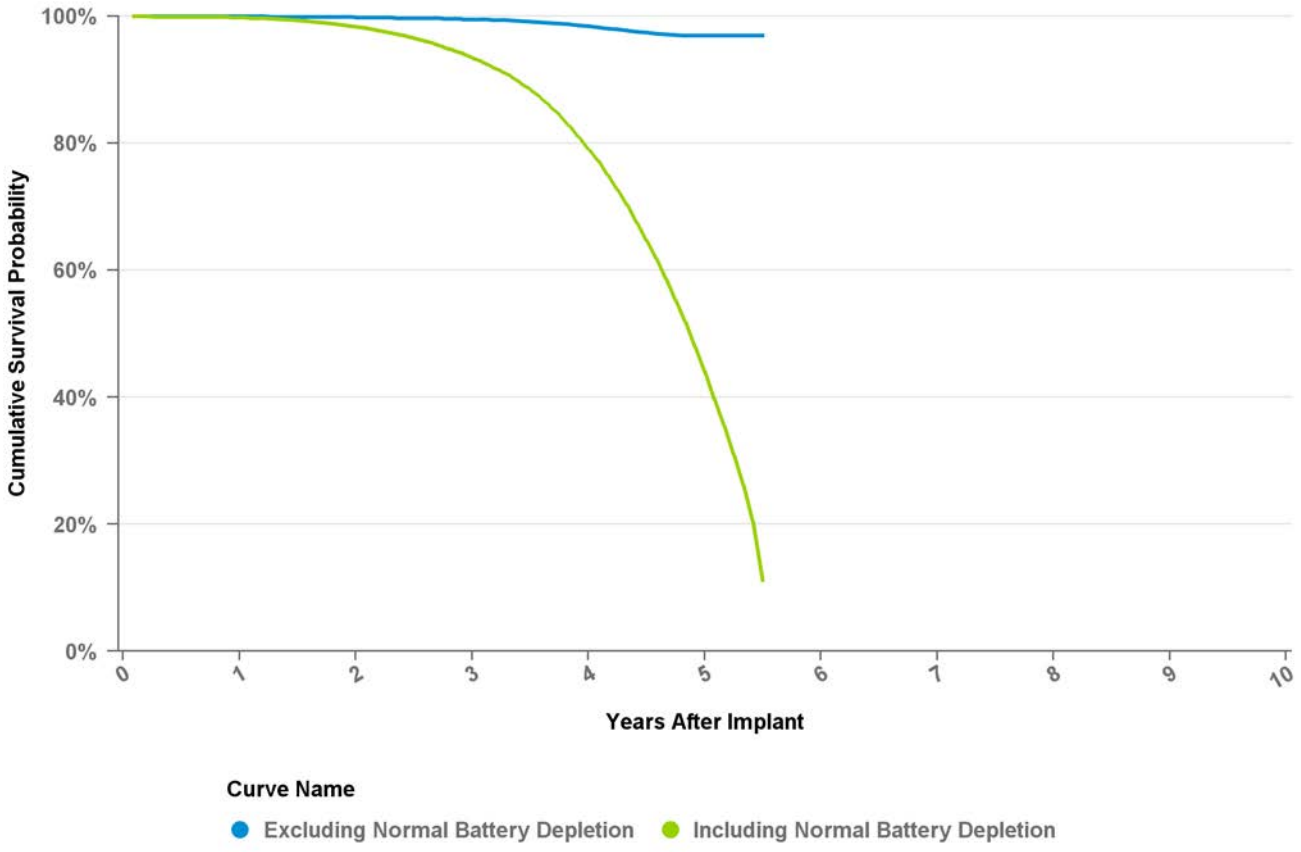
C154DWK Concerto CRT-D Non-Advisory

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	81,298
Estimated Active US Implants	18,503
Normal Battery Depletions (US)	19,048

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,404
Therapy Not Compromised Malfunction	1,363
Battery Malfunction	0
Electrical Component	707
Electrical Interconnect	2
Other Malfunction	3
Poss Early Battery Depltn	648
Software Malfunction	3
Therapy Compromised Malfunctions	41
Battery Malfunction	0
Electrical Component	39
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C154DWK, C164AWK, C174AWK, Survival Curve



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%
Including NBD	99.8%	98.3%	93.4%	79.1%	44.1%	11.1%
Effective Sample Size	72840	64155	53986	39678	12806	1364

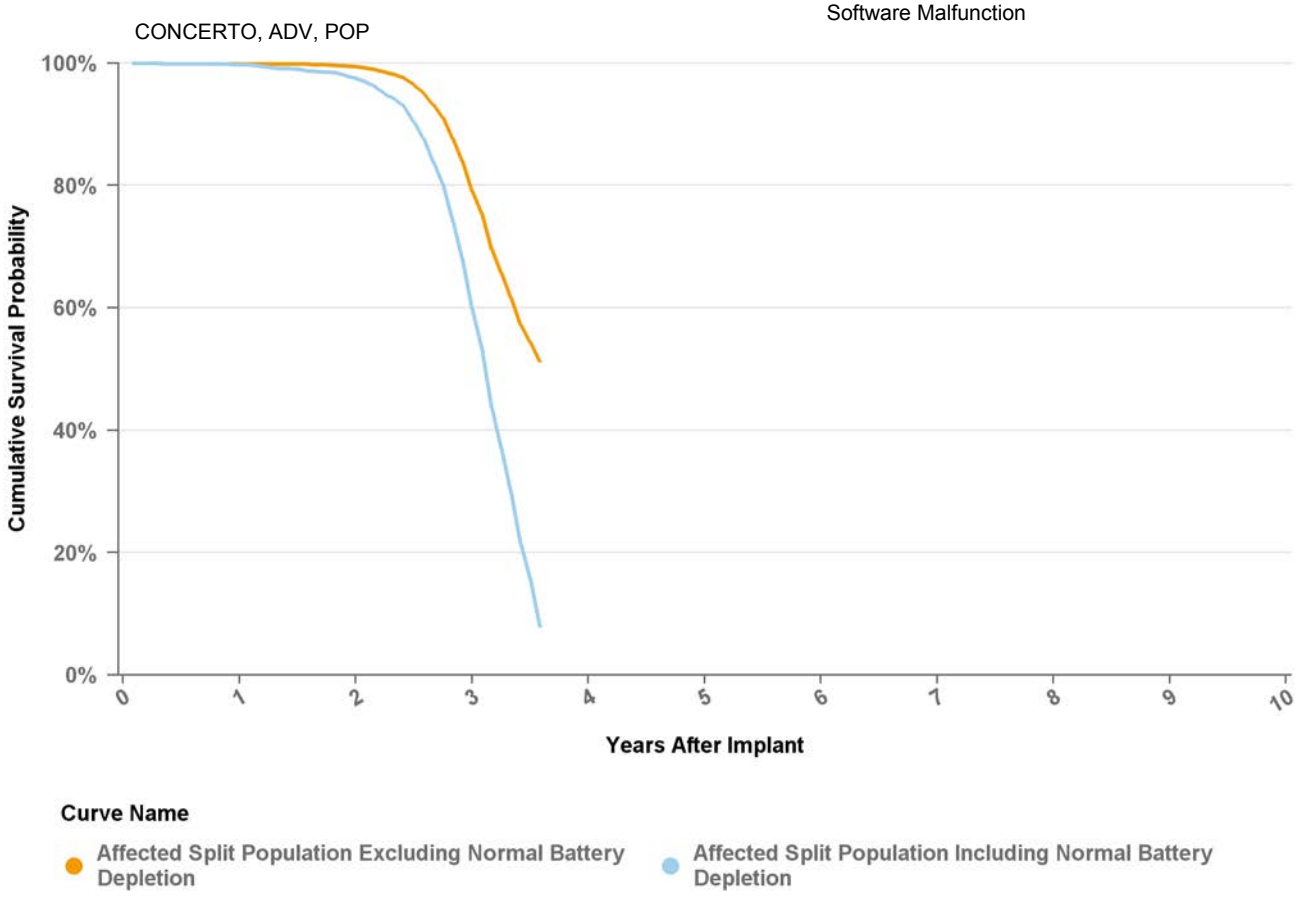
Cardiac Resynchronization Therapy

C154DWK Concerto CRT-D Advisory

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	3,540
Estimated Active US Implants	187
Normal Battery Depletions (US)	270

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,298
Therapy Not Compromised Malfunction	1,284
Battery Malfunction	0
Electrical Component	1,280
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 43 mo
Excluding NBD	99.8%	99.4%	79.1%	51.3%
Including NBD	99.7%	97.5%	59.9%	8.0%
Effective Sample Size	3121	2711	1524	197

Cardiac Resynchronization Therapy

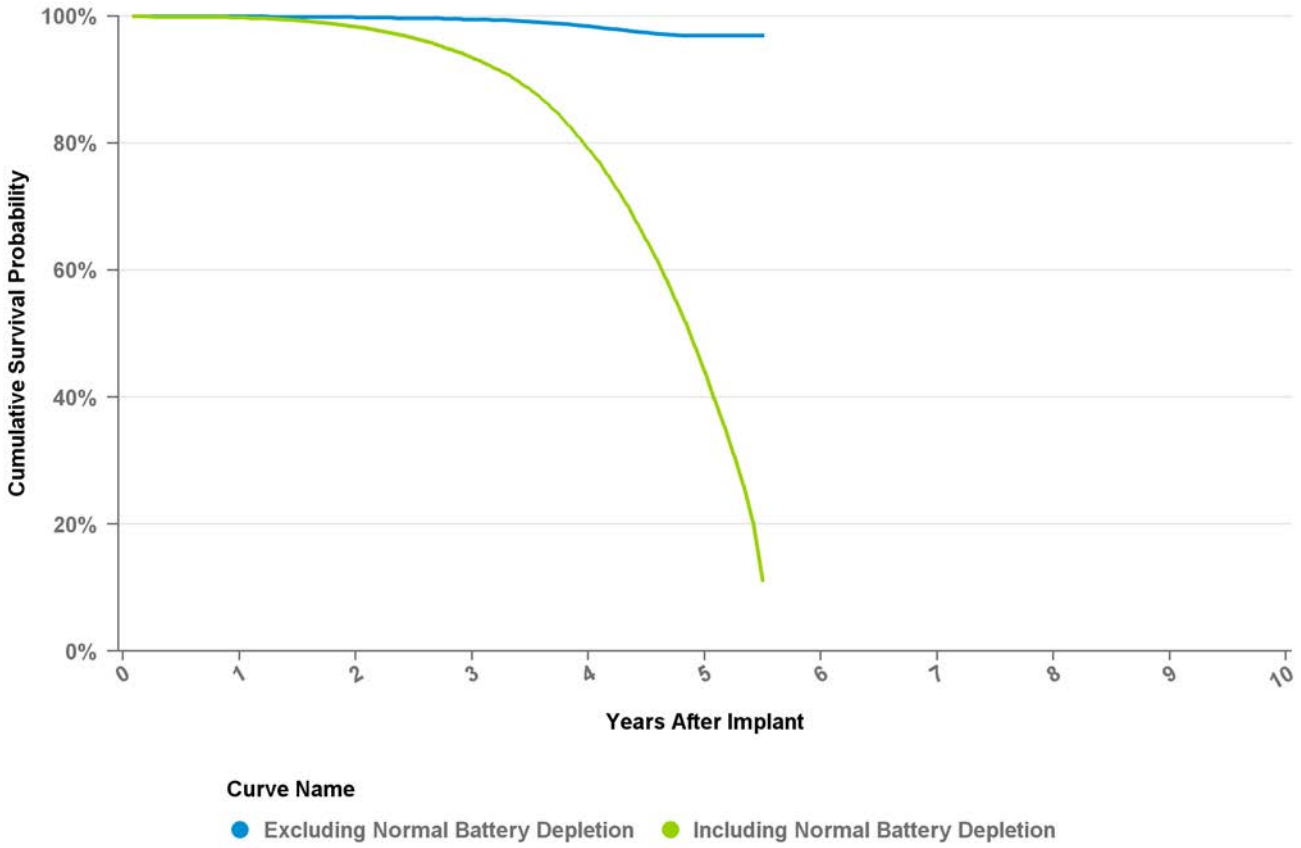
C164AWK Concerto CRT-D Non-Advisory

US Market Release Date	4/17/2007
CE Market Approval Date	
Registered US Implants	178
Estimated Active US Implants	5
Normal Battery Depletions (US)	72

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C154DWK, C164AWK, C174AWK, Survival Curve



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%
Including NBD	99.8%	98.3%	93.4%	79.1%	44.1%	11.1%
Effective Sample Size	72840	64155	53986	39678	12806	1364

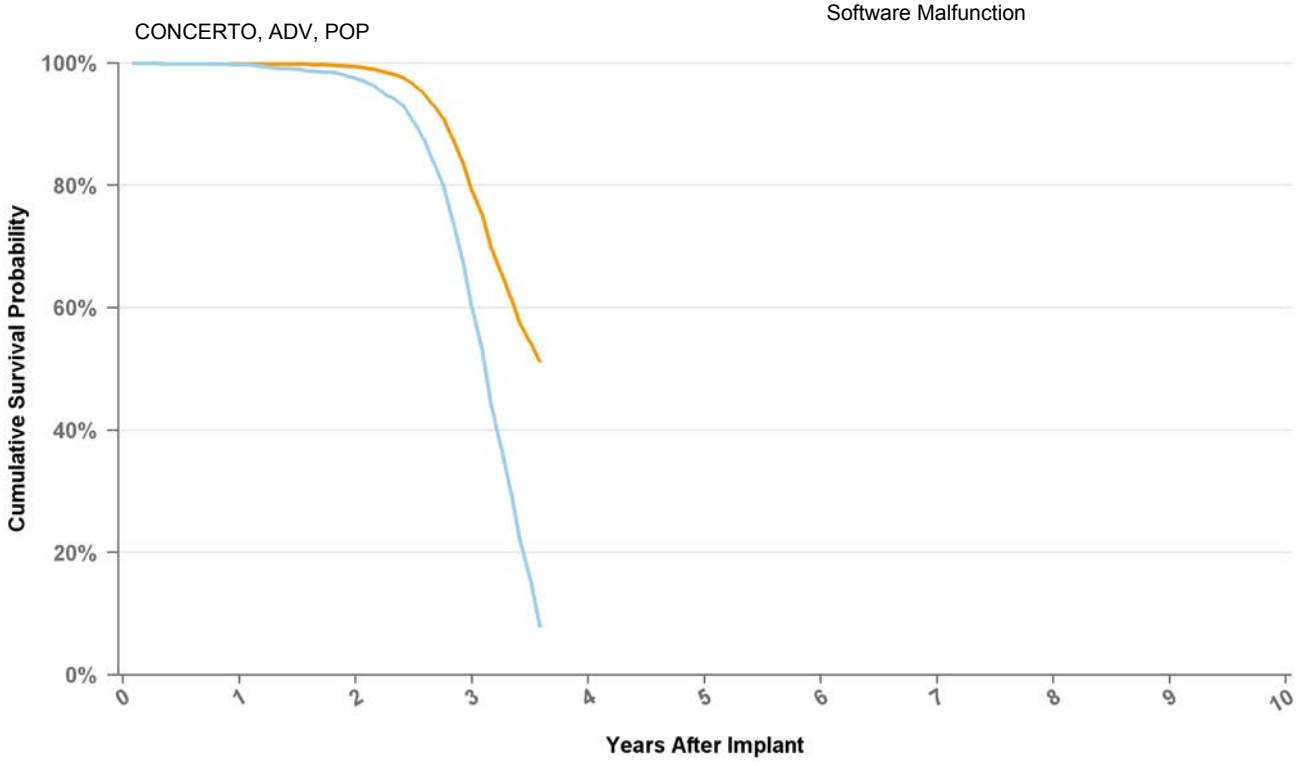
Cardiac Resynchronization Therapy

C164AWK Concerto CRT-D Advisory

US Market Release Date	4/17/2007
CE Market Approval Date	
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 43 mo
Excluding NBD	99.8%	99.4%	79.1%	51.3%
Including NBD	99.7%	97.5%	59.9%	8.0%
Effective Sample Size	3121	2711	1524	197

Cardiac Resynchronization Therapy

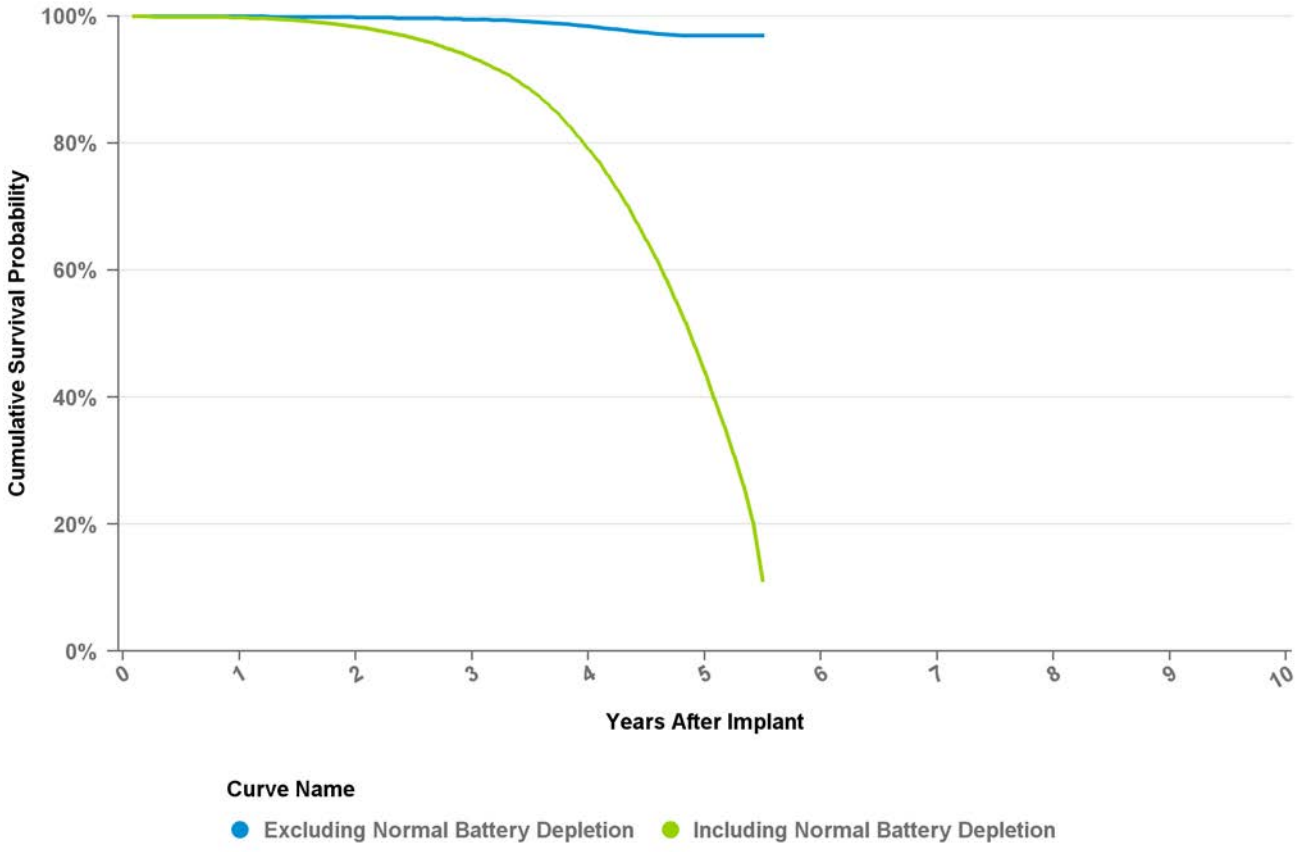
C174AWK Concerto CRT-D Non-Advisory

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	5
Estimated Active US Implants	3
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C154DWK, C164AWK, C174AWK, Survival Curve



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%
Including NBD	99.8%	98.3%	93.4%	79.1%	44.1%	11.1%
Effective Sample Size	72840	64155	53986	39678	12806	1364

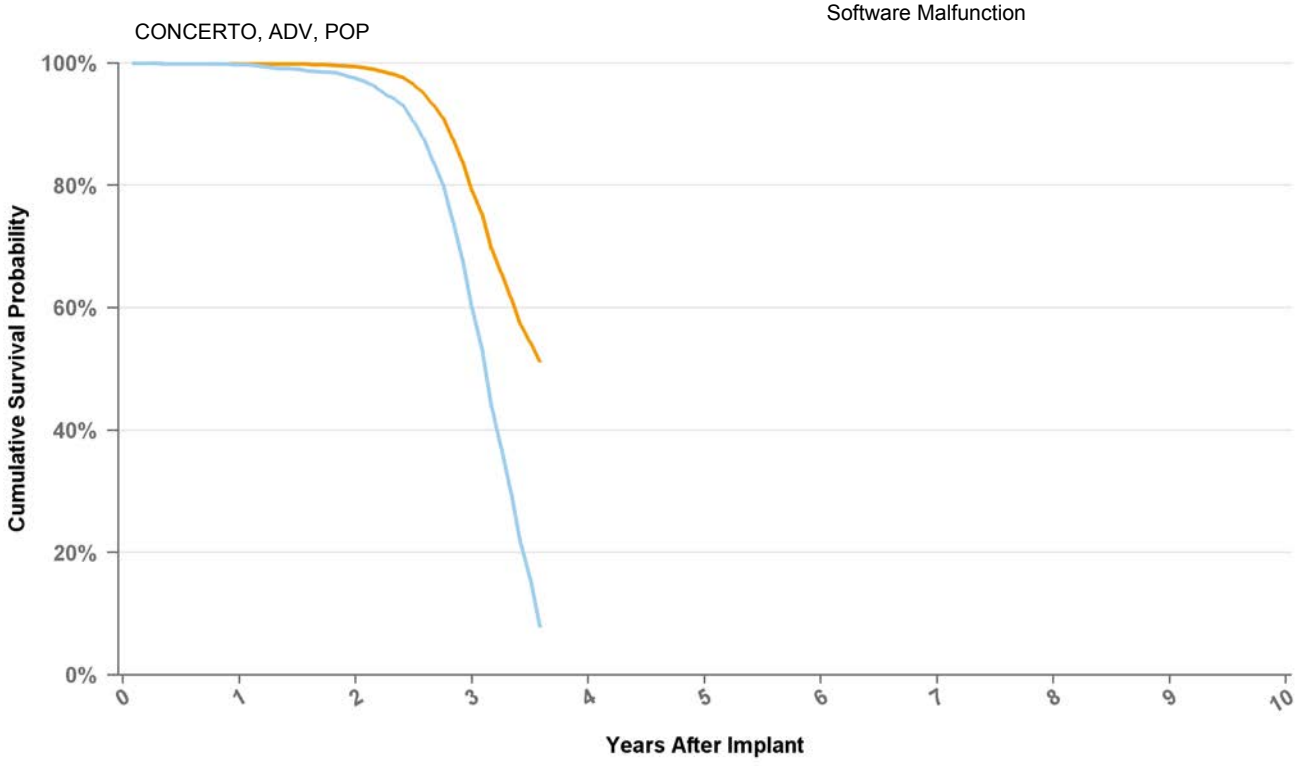
Cardiac Resynchronization Therapy

C174AWK Concerto CRT-D Advisory

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	at 43 mo
Excluding NBD	99.8%	99.4%	79.1%	51.3%
Including NBD	99.7%	97.5%	59.9%	8.0%
Effective Sample Size	3121	2711	1524	197

Cardiac Resynchronization Therapy

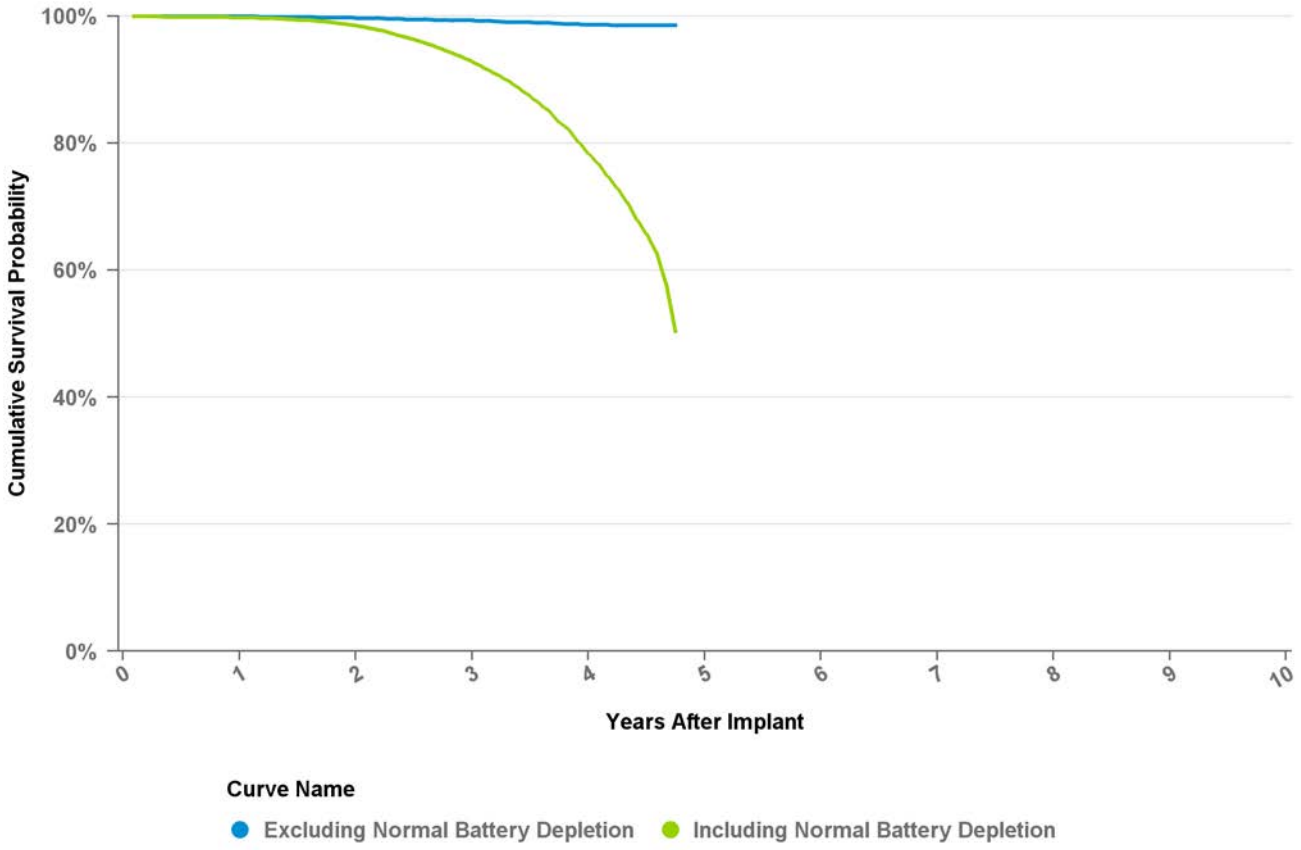
D204TRM Consulta CRT-D

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	2,010
Estimated Active US Implants	1,905
Normal Battery Depletions (US)	1

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONSULTA, CRT, Survival Curve



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.5%
Including NBD	99.8%	98.5%	92.8%	78.4%	50.3%
Effective Sample Size	59535	48909	33231	10902	488

Cardiac Resynchronization Therapy

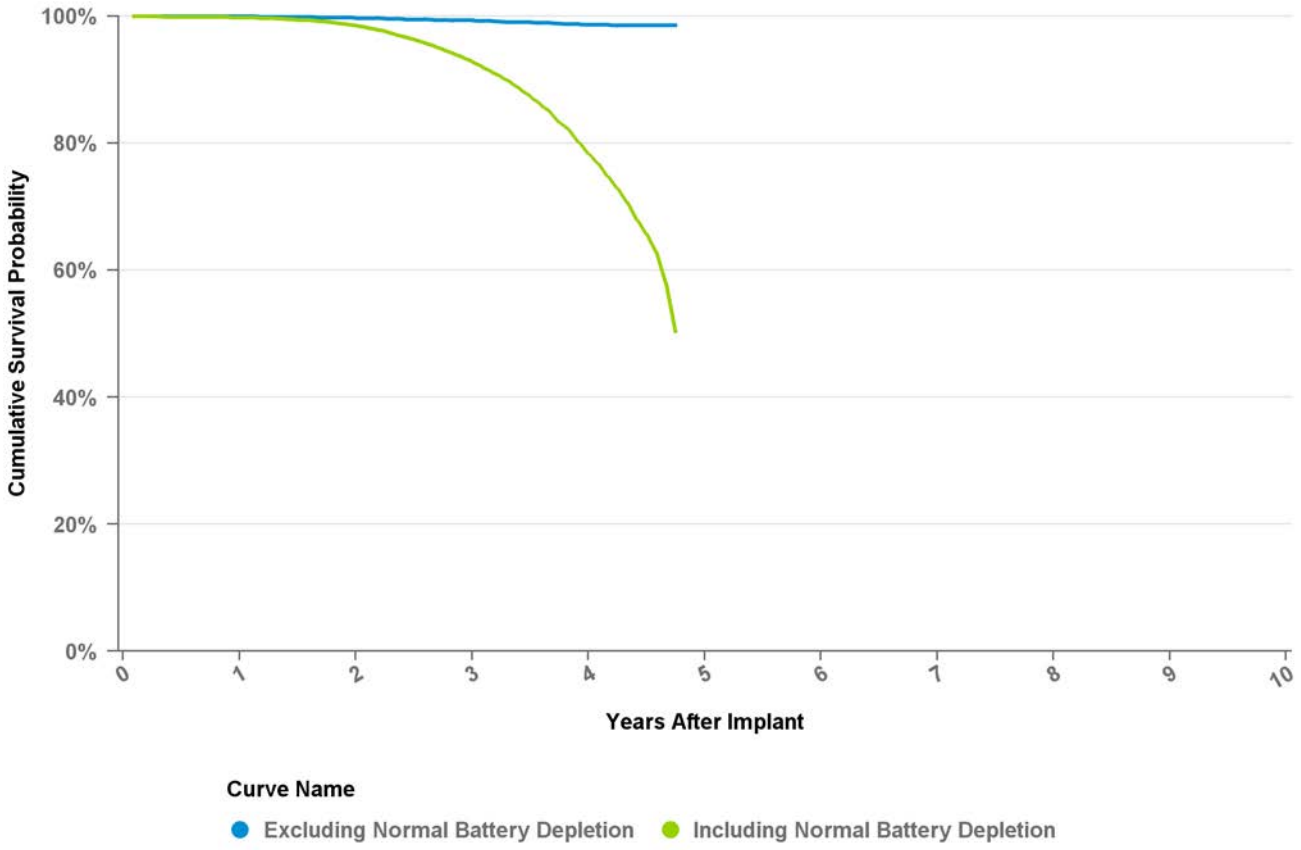
D214TRM Consulta CRT-D

US Market Release Date	
CE Market Approval Date	7/22/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONSULTA, CRT, Survival Curve



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.5%
Including NBD	99.8%	98.5%	92.8%	78.4%	50.3%
Effective Sample Size	59535	48909	33231	10902	488

Cardiac Resynchronization Therapy

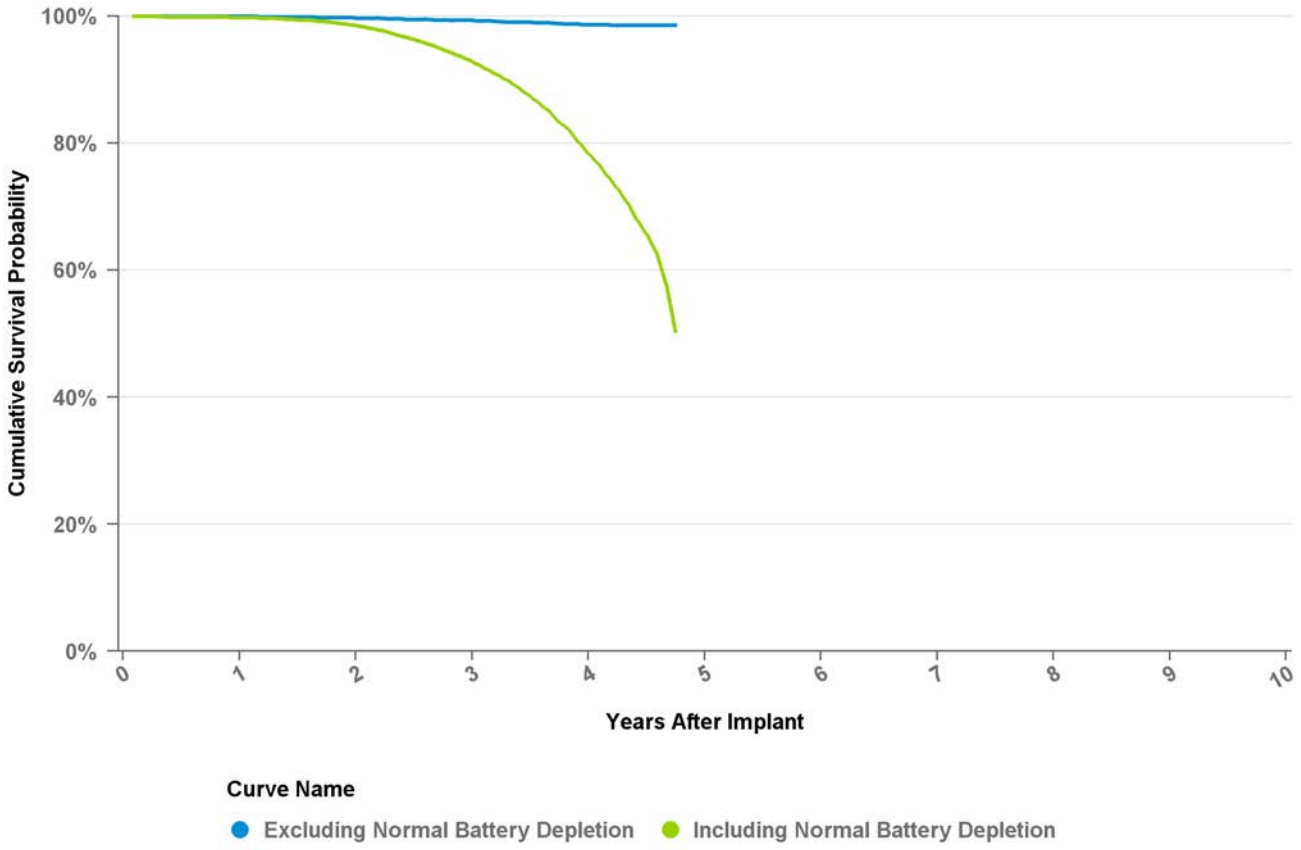
D224TRK Consulta CRT-D

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	65,593
Estimated Active US Implants	43,058
Normal Battery Depletions (US)	4,326

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	506
Therapy Not Compromised Malfunction	489
Battery Malfunction	0
Electrical Component	25
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	457
Software Malfunction	5
Therapy Compromised Malfunctions	17
Battery Malfunction	0
Electrical Component	17
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONSULTA, CRT, Survival Curve



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.5%
Including NBD	99.8%	98.5%	92.8%	78.4%	50.3%
Effective Sample Size	59535	48909	33231	10902	488

Cardiac Resynchronization Therapy

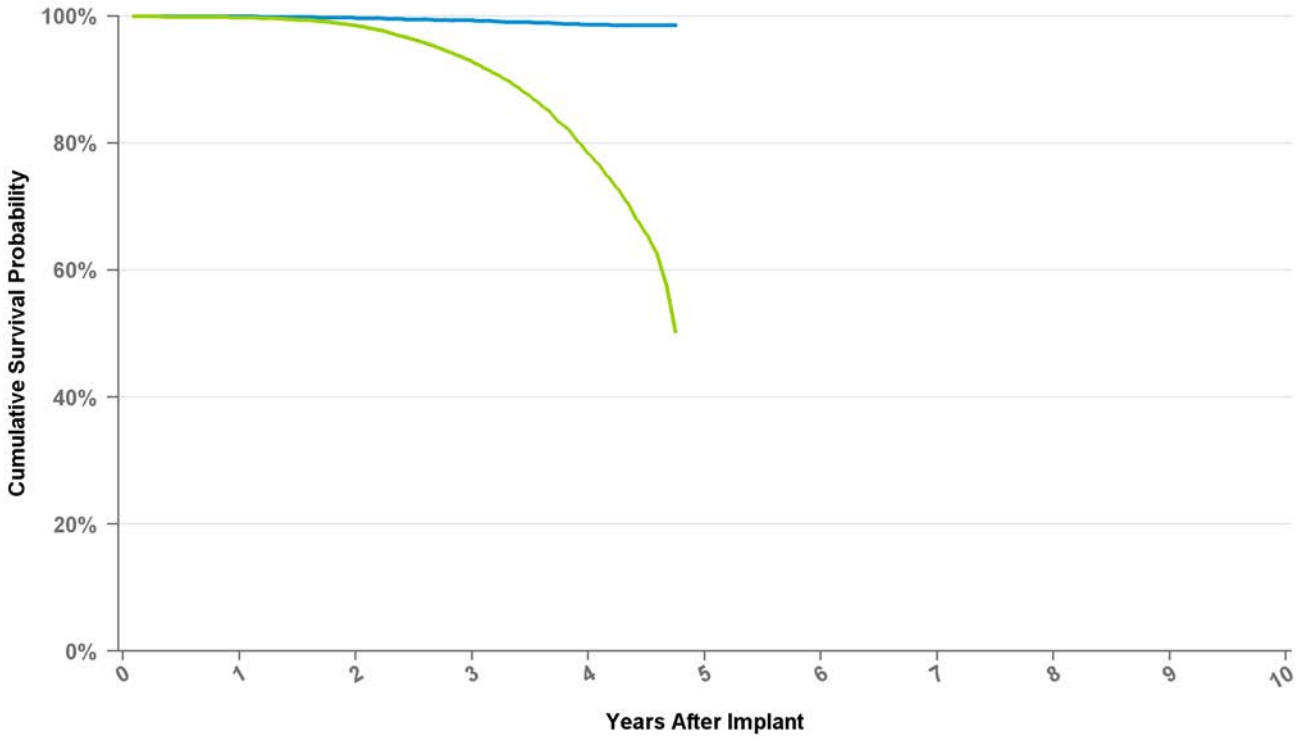
D234TRK Consulta CRT-D

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONSULTA, CRT, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.5%
Including NBD	99.8%	98.5%	92.8%	78.4%	50.3%
Effective Sample Size	59535	48909	33231	10902	488

Cardiac Resynchronization Therapy

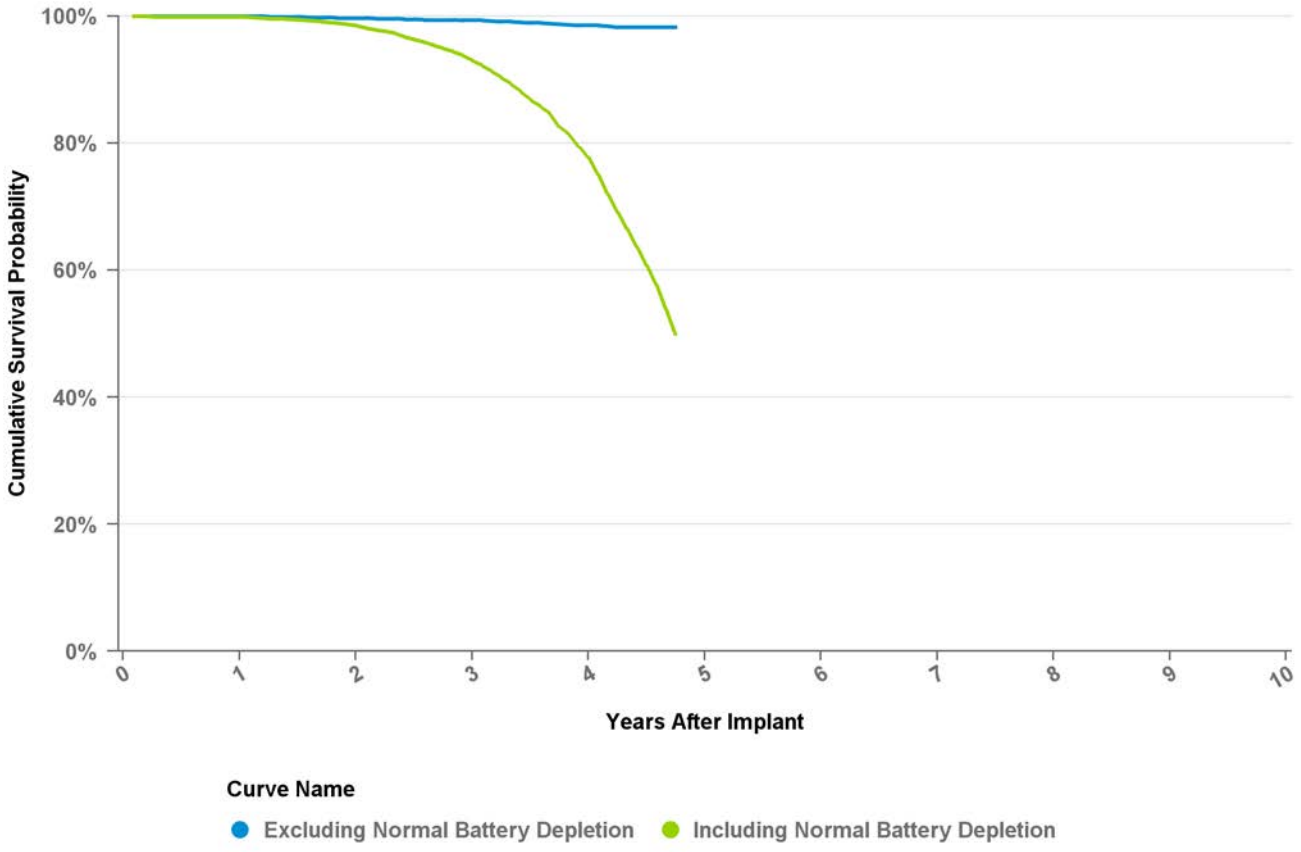
D264TRM Maximo II CRT-D

US Market Release Date	1/9/2012
CE Market Approval Date	7/22/2010
Registered US Implants	15
Estimated Active US Implants	14
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

MAXIMO, II, CRT, Survival Curve



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.5%	98.2%
Including NBD	99.9%	98.5%	93.0%	77.8%	49.9%
Effective Sample Size	13451	10921	7404	3034	241

Cardiac Resynchronization Therapy

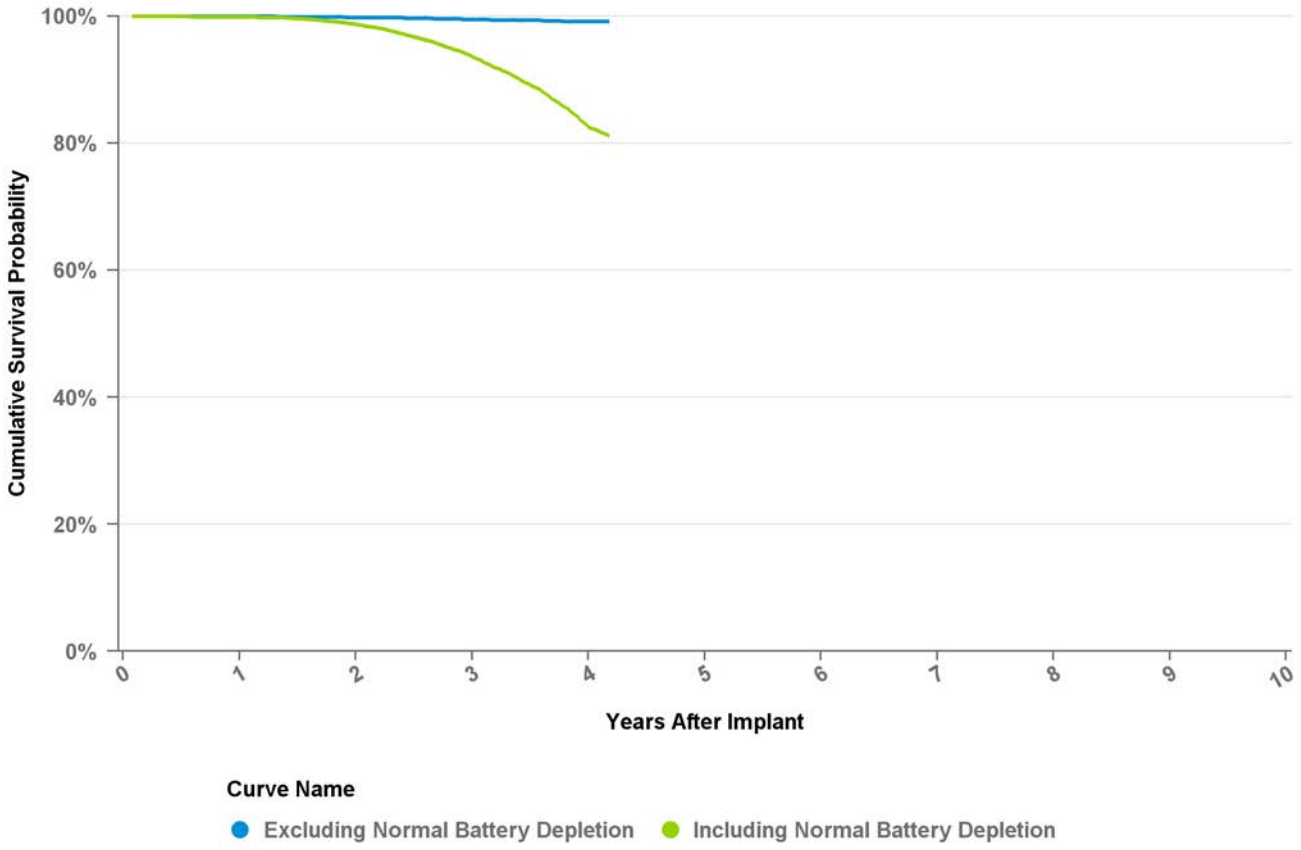
D274TRK Concerto II CRT-D

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	30,156
Estimated Active US Implants	21,363
Normal Battery Depletions (US)	1,319

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	153
Therapy Not Compromised Malfunction	150
Battery Malfunction	0
Electrical Component	11
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	138
Software Malfunction	1
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONCERTO, II, Survival Curve



Years	1	2	3	4	at 50 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%
Including NBD	99.9%	98.7%	93.6%	82.5%	81.2%
Effective Sample Size	27422	24684	15928	2301	640

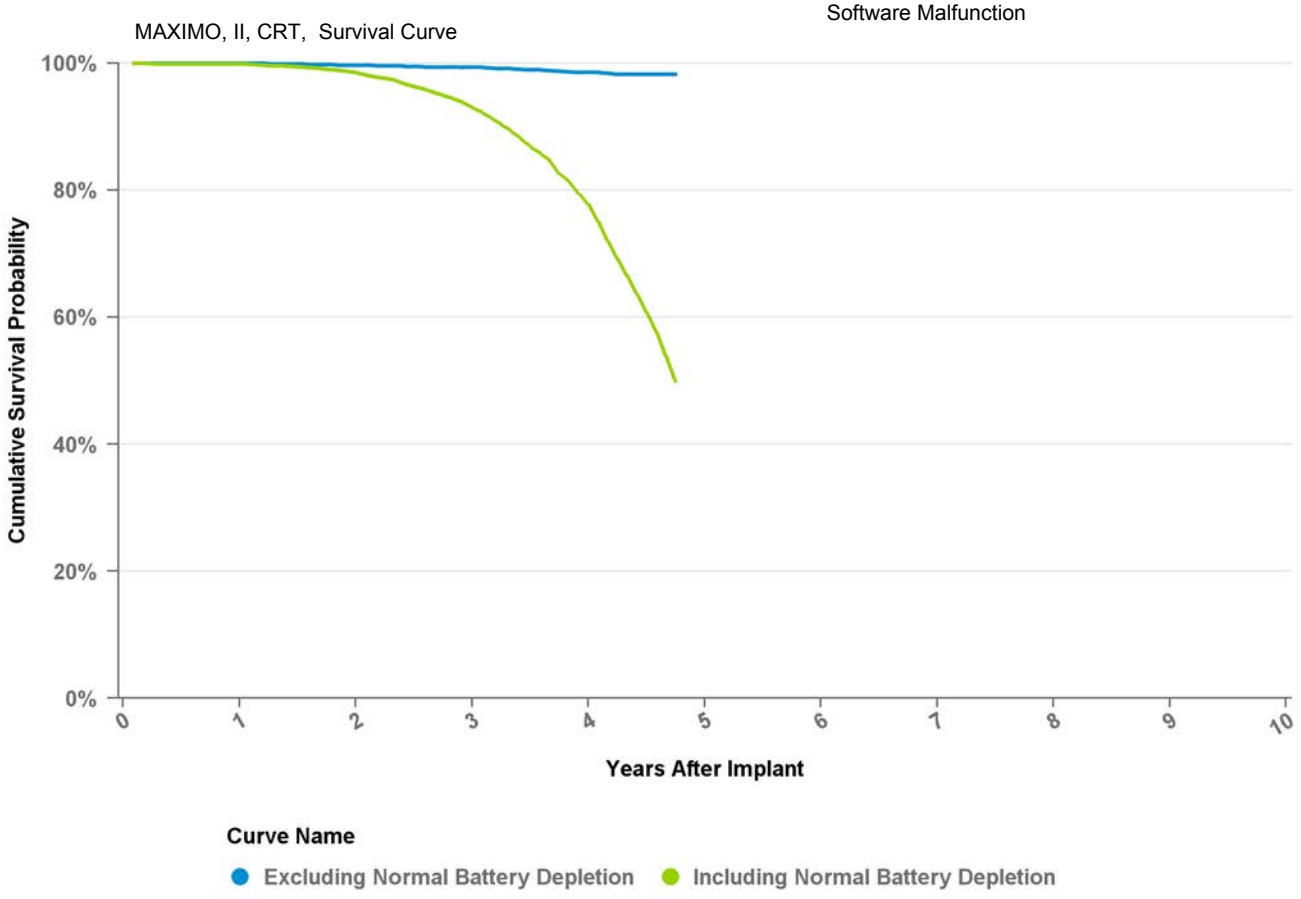
Cardiac Resynchronization Therapy

D284TRK Maximo II CRT-D

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	15,121
Estimated Active US Implants	9,608
Normal Battery Depletions (US)	1,173

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	126
Therapy Not Compromised Malfunction	123
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	120
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	99.7%	99.3%	98.5%	98.2%
Including NBD	99.9%	98.5%	93.0%	77.8%	49.9%
Effective Sample Size	13451	10921	7404	3034	241

Cardiac Resynchronization Therapy

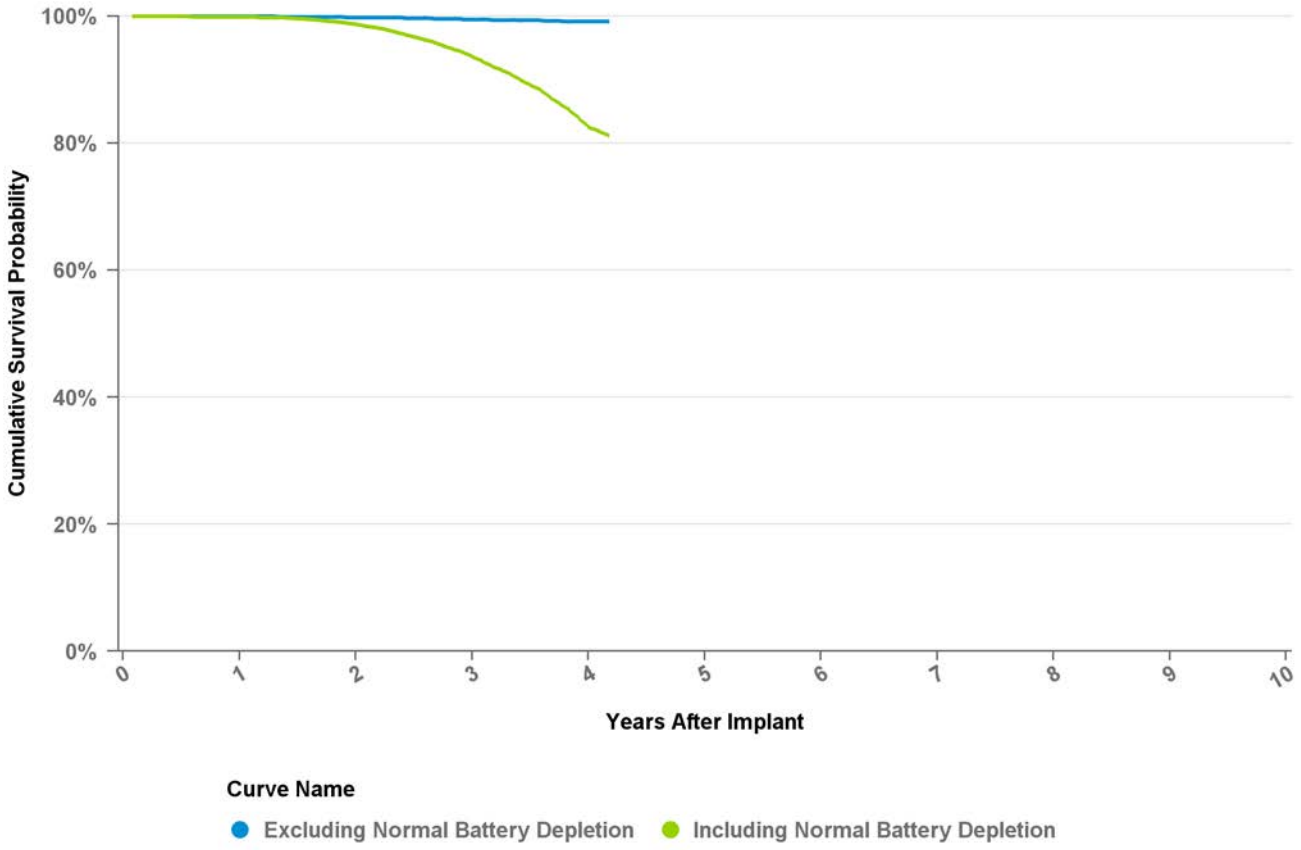
D294TRK Concerto II CRT-D

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

CONCERTO, II, Survival Curve



Years	1	2	3	4	at 50 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%
Including NBD	99.9%	98.7%	93.6%	82.5%	81.2%
Effective Sample Size	27422	24684	15928	2301	640

Cardiac Resynchronization Therapy

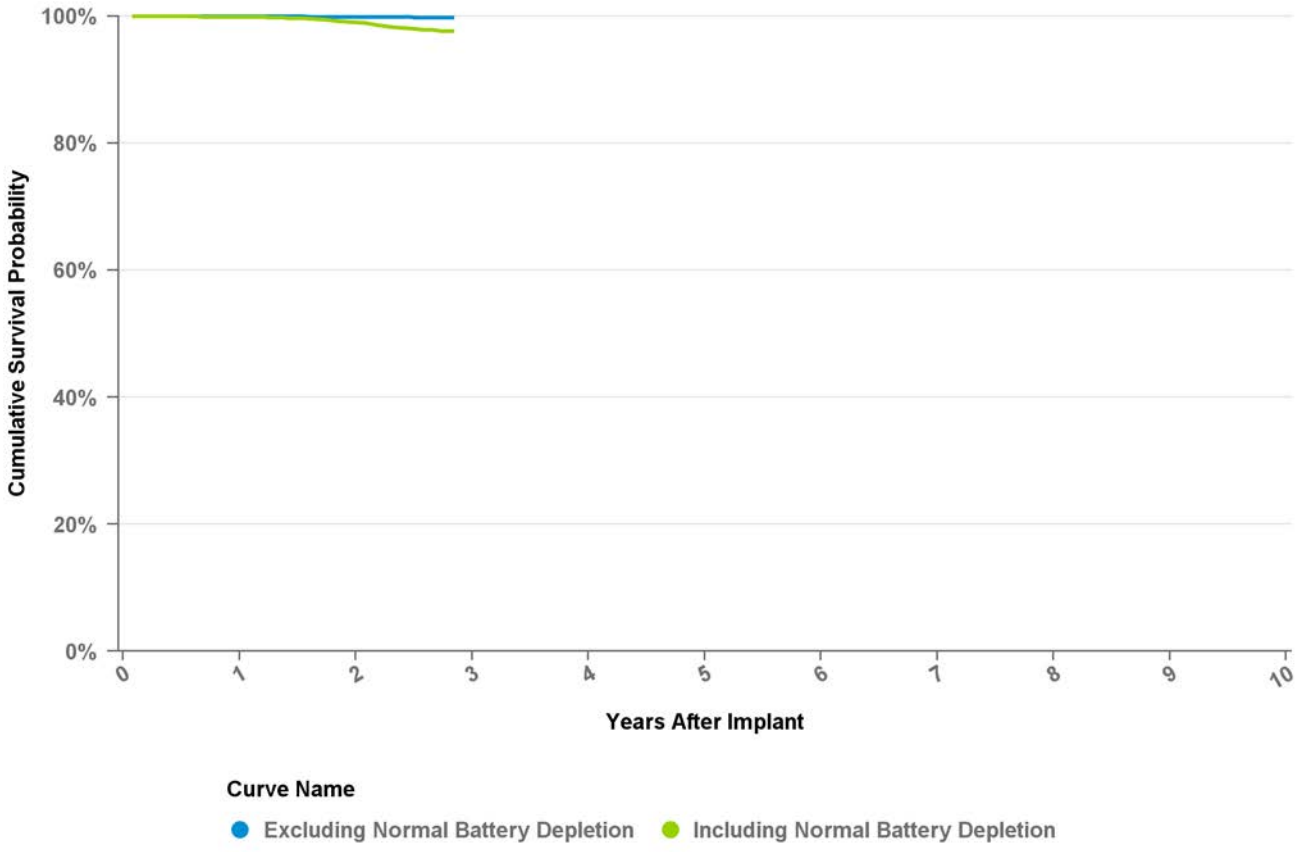
D314TRG Protecta XT CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	40,097
Estimated Active US Implants	36,426
Normal Battery Depletions (US)	146

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	27
Therapy Not Compromised Malfunction	26
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	18
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

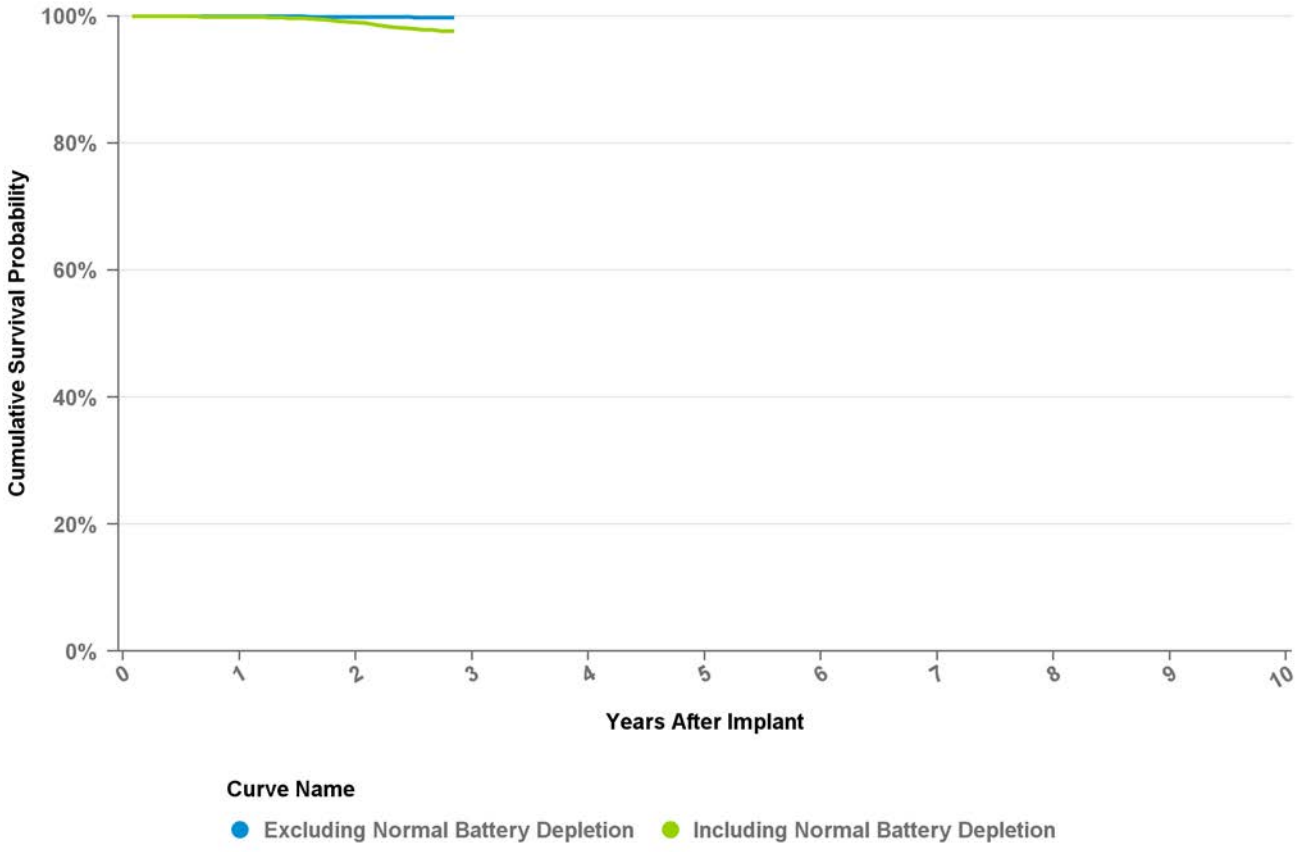
D314TRM Protecta XT CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	11,756
Estimated Active US Implants	11,215
Normal Battery Depletions (US)	7

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	6
Therapy Not Compromised Malfunction	5
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

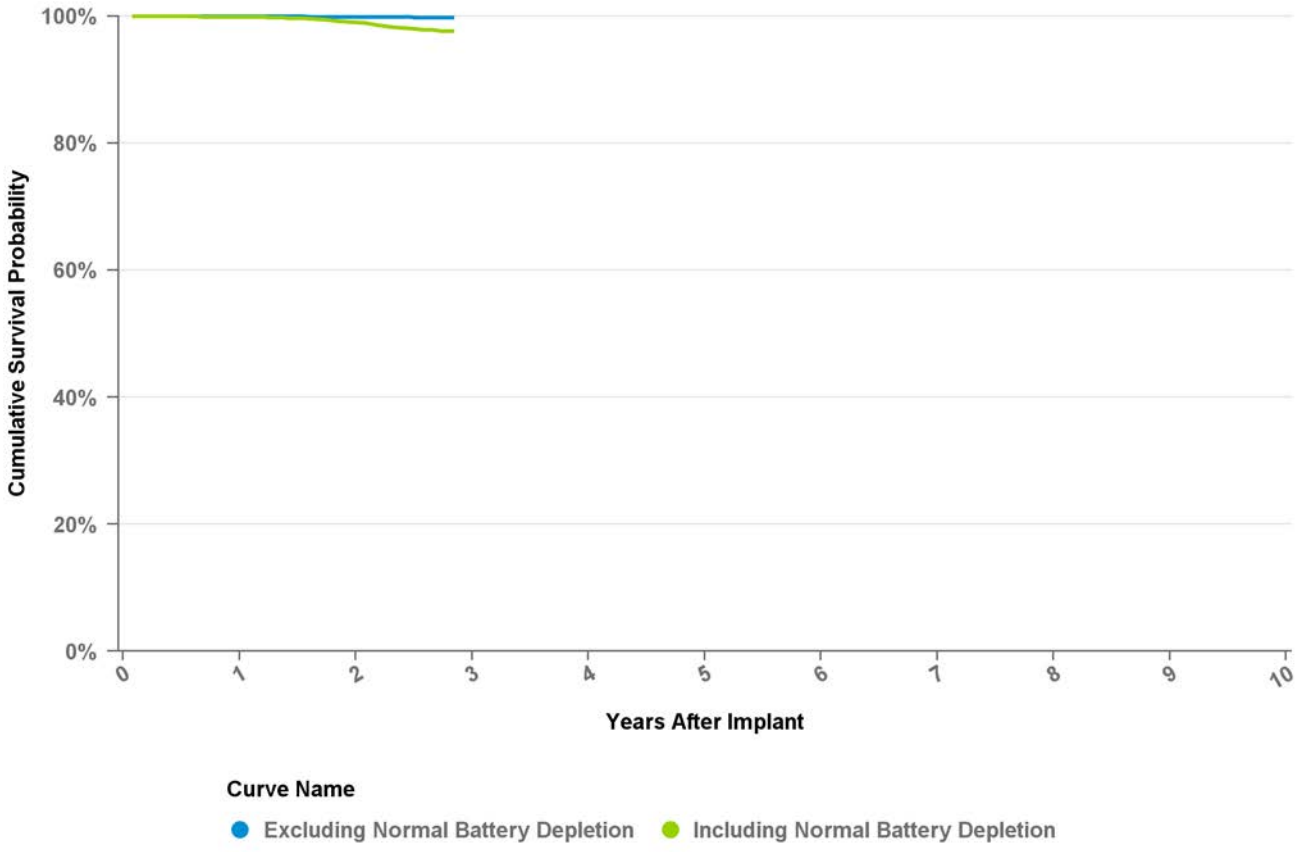
D334TRG Protecta CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	7,135
Estimated Active US Implants	6,515
Normal Battery Depletions (US)	17

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

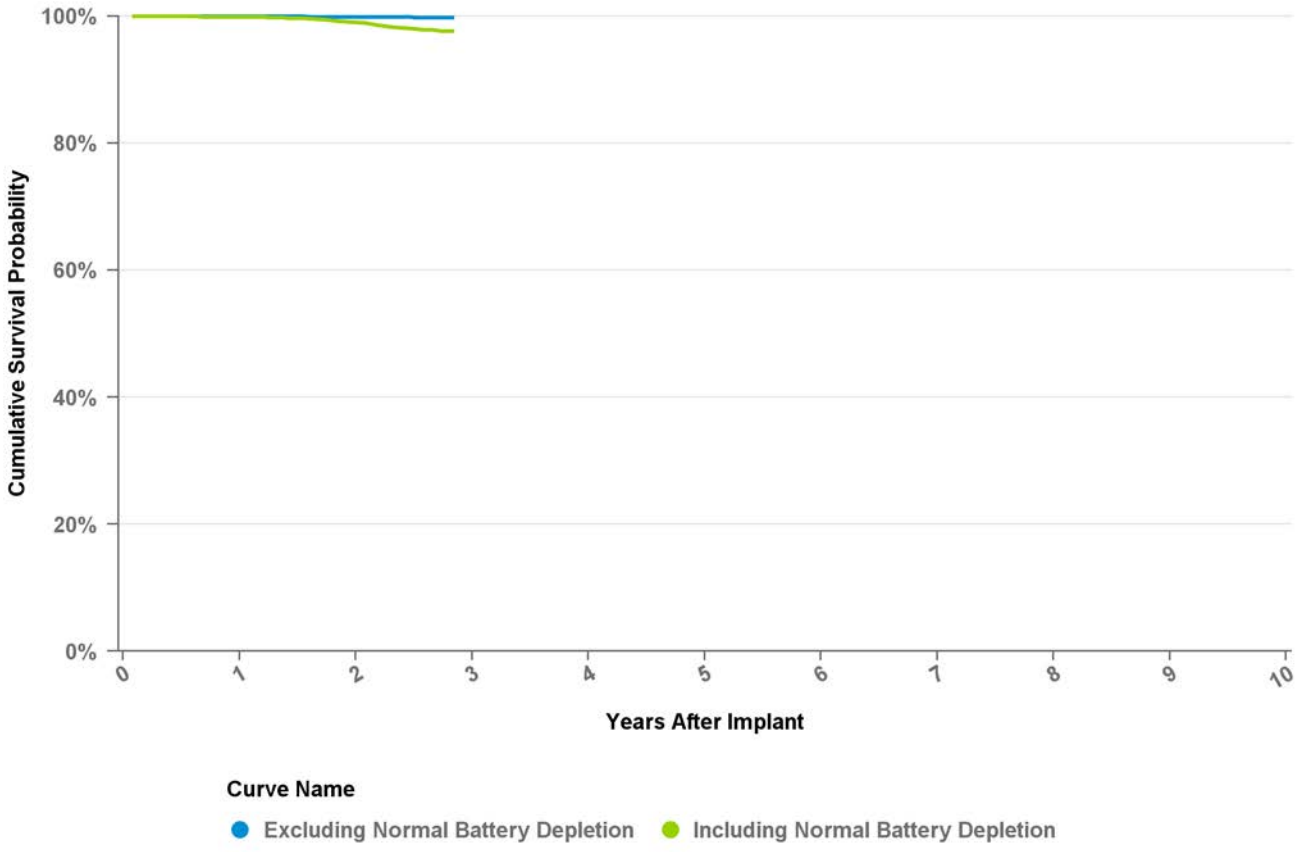
D334TRM Protecta CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	1,551
Estimated Active US Implants	1,473
Normal Battery Depletions (US)	3

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

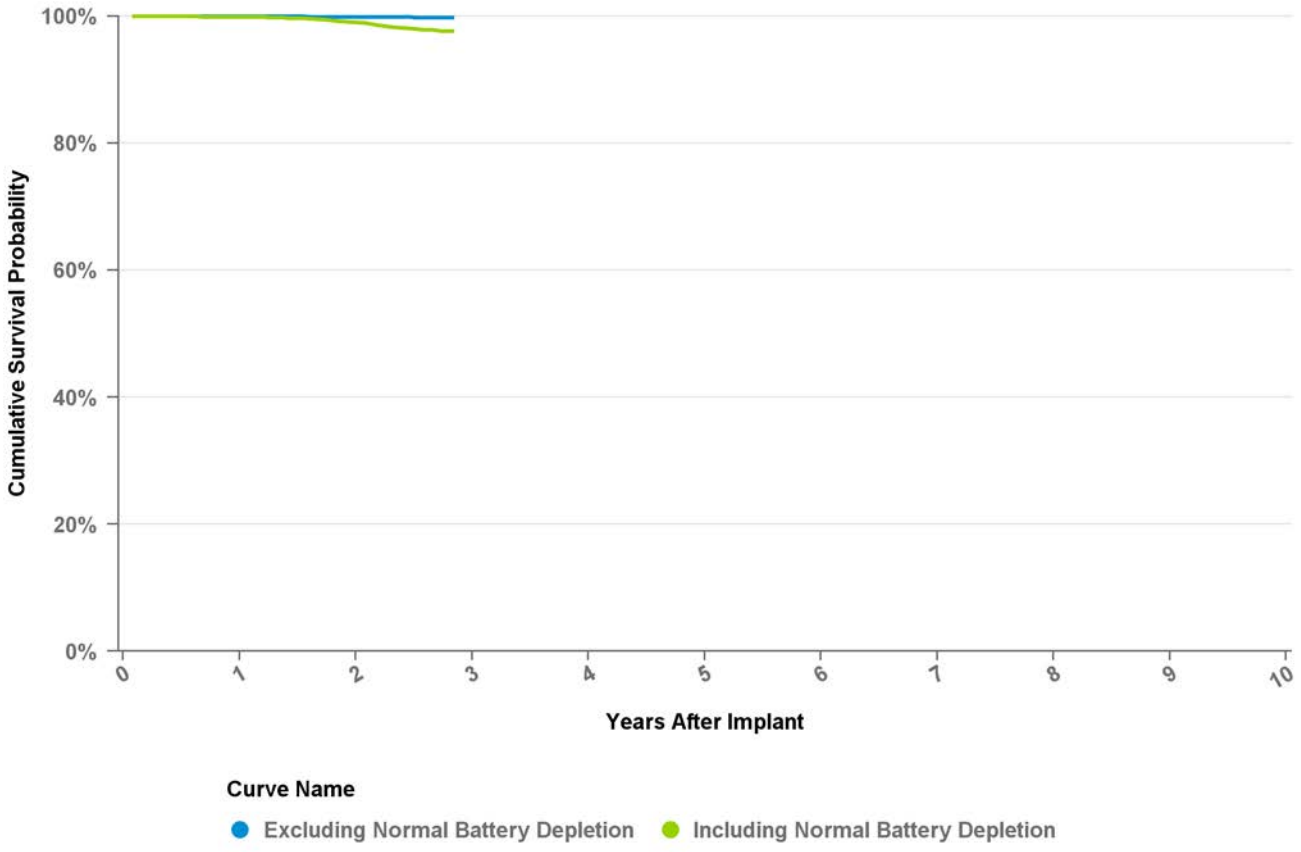
D354TRG Protecta XT CRT-D

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

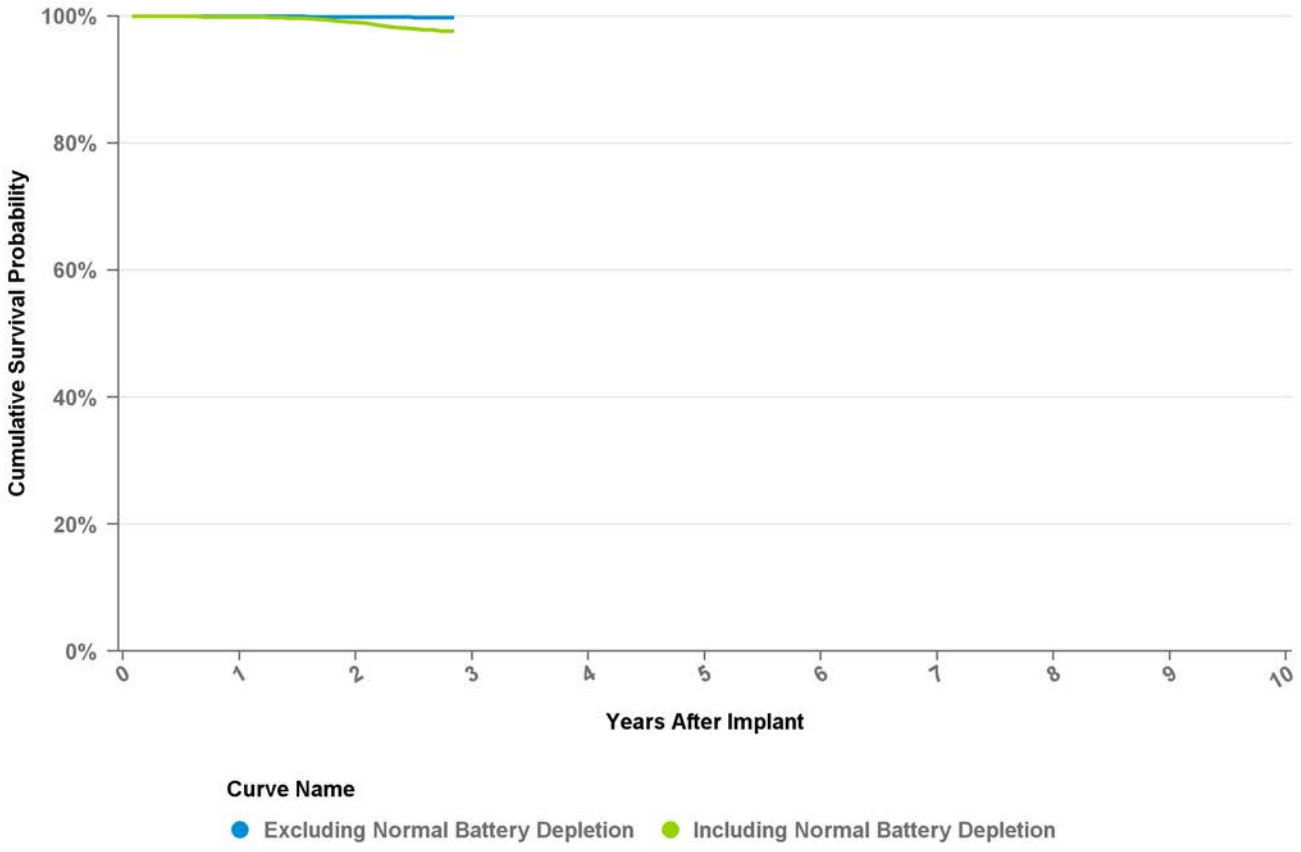
D354TRM Protecta XT CRT-D

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

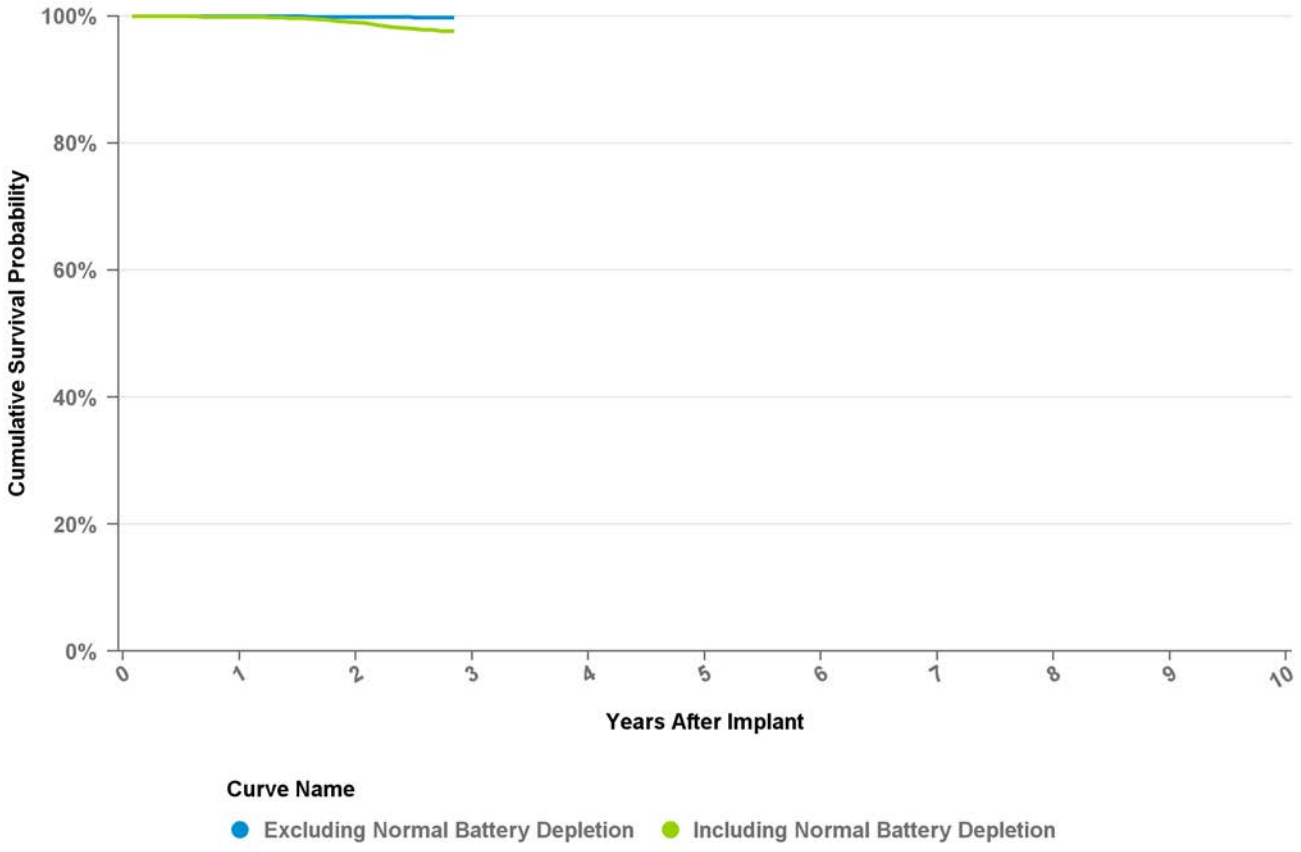
D364TRG Protecta CRT-D

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

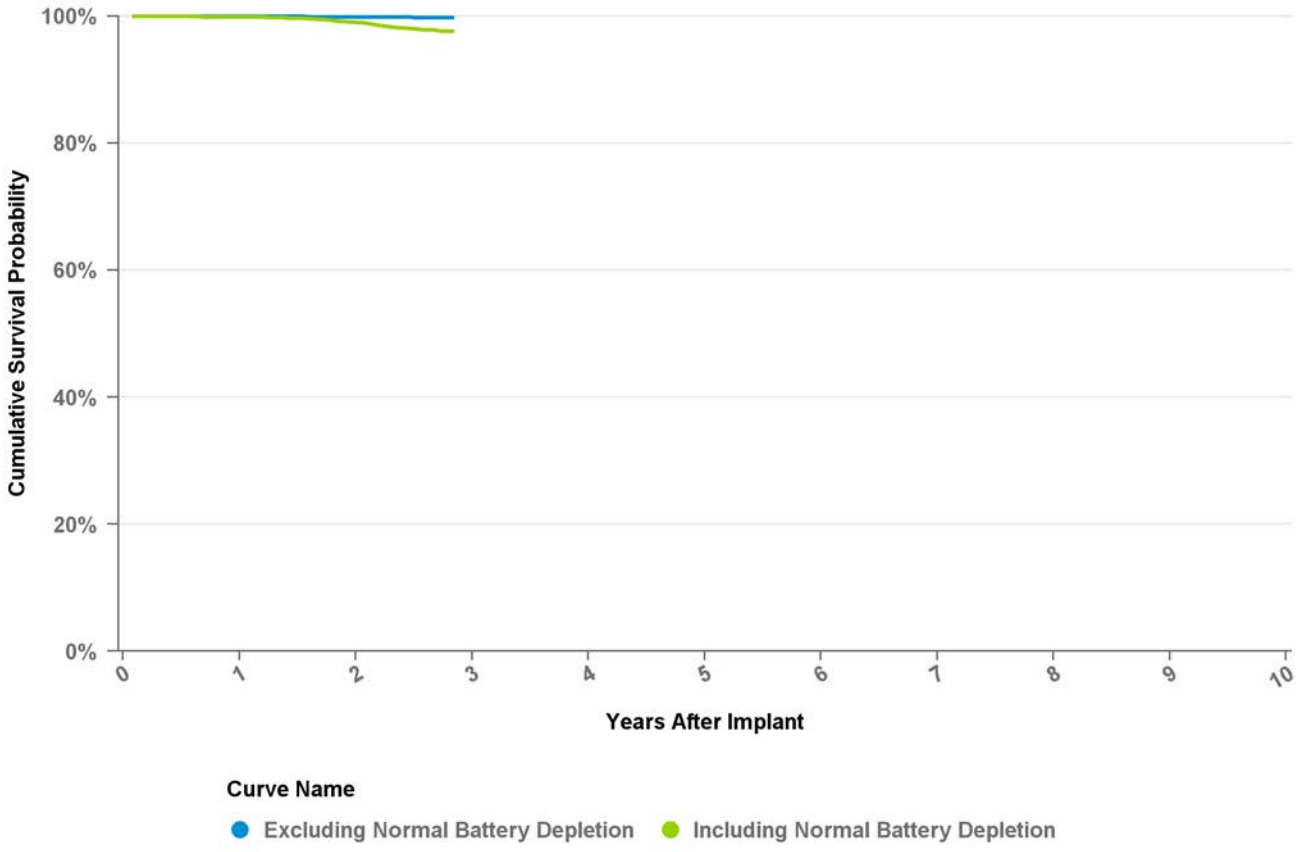
D364TRM Protecta CRT-D

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

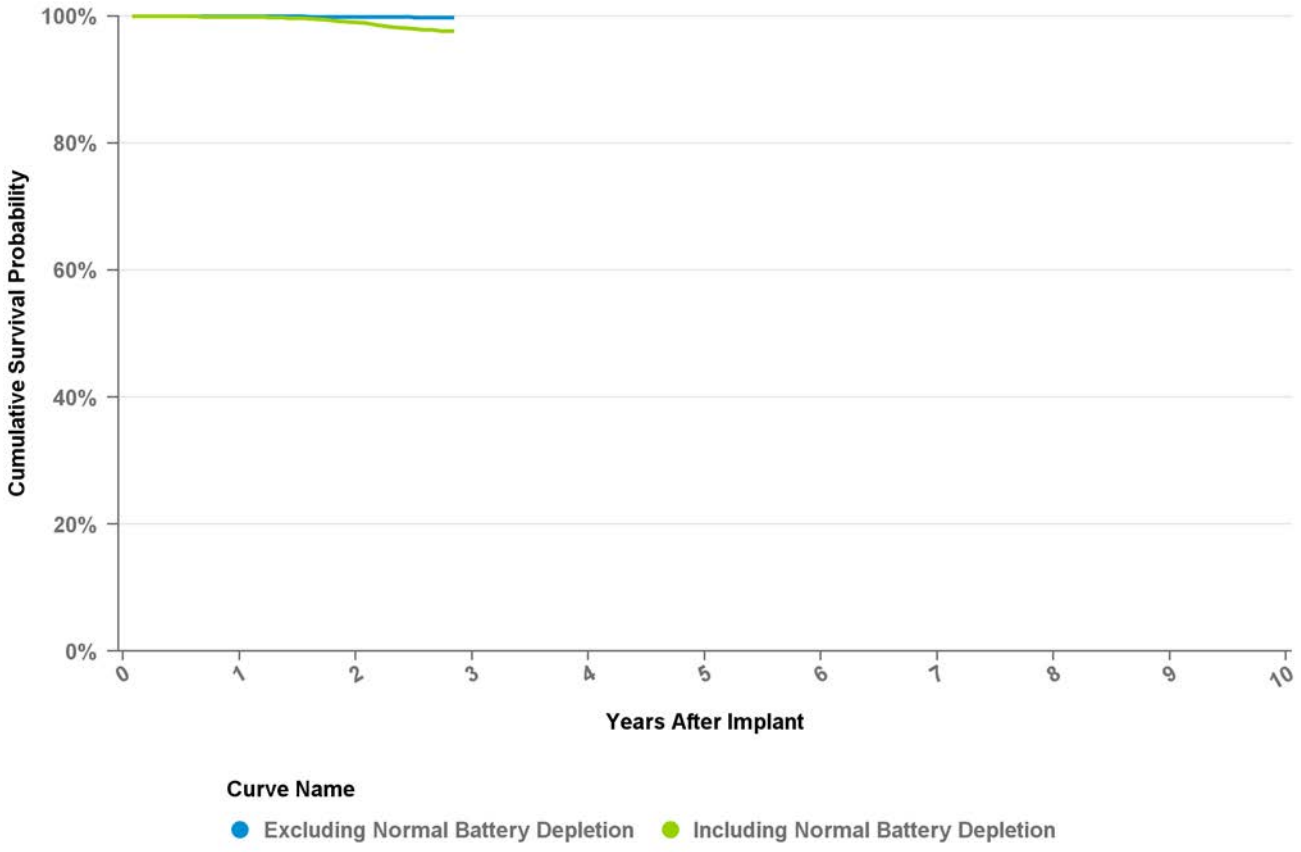
D384TRG Cardia CRT-D

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

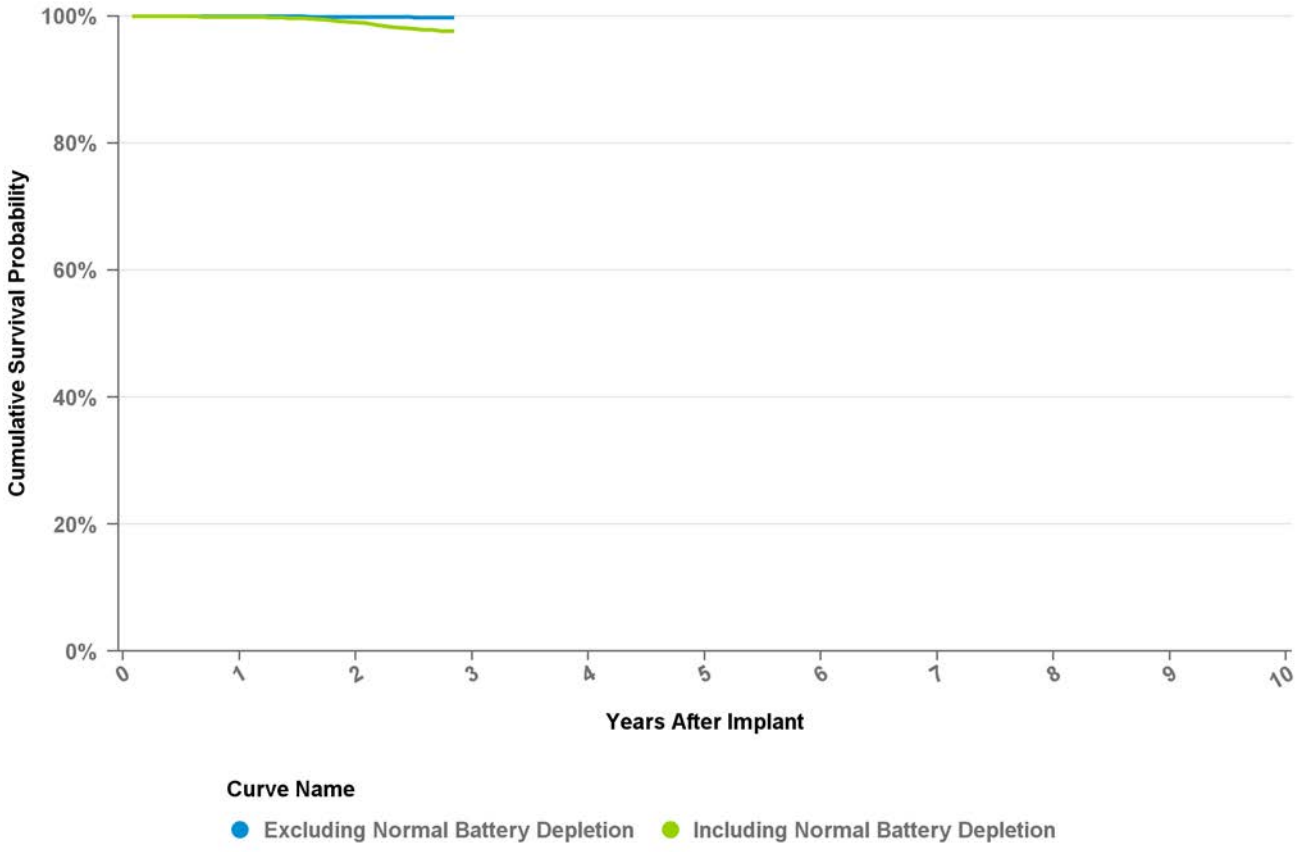
D394TRG Egida CRT-D

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxTRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.8%
Including NBD	99.9%	99.0%	97.6%
Effective Sample Size	42652	13478	99

Cardiac Resynchronization Therapy

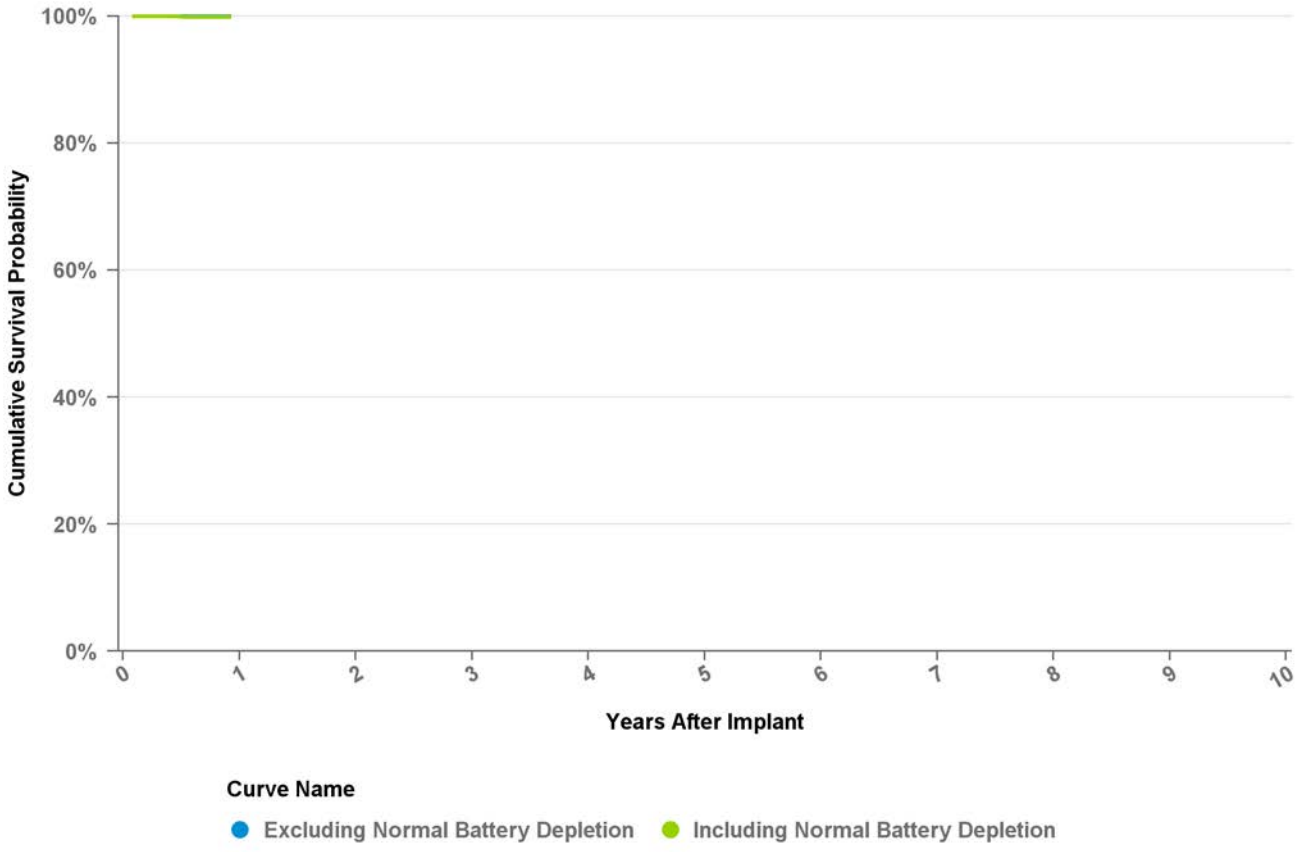
DTBA1D1 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	6,224
Estimated Active US Implants	6,125
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

Viva XT CRT-D, Survival Curve



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	99.9%
Effective Sample Size	111

Cardiac Resynchronization Therapy

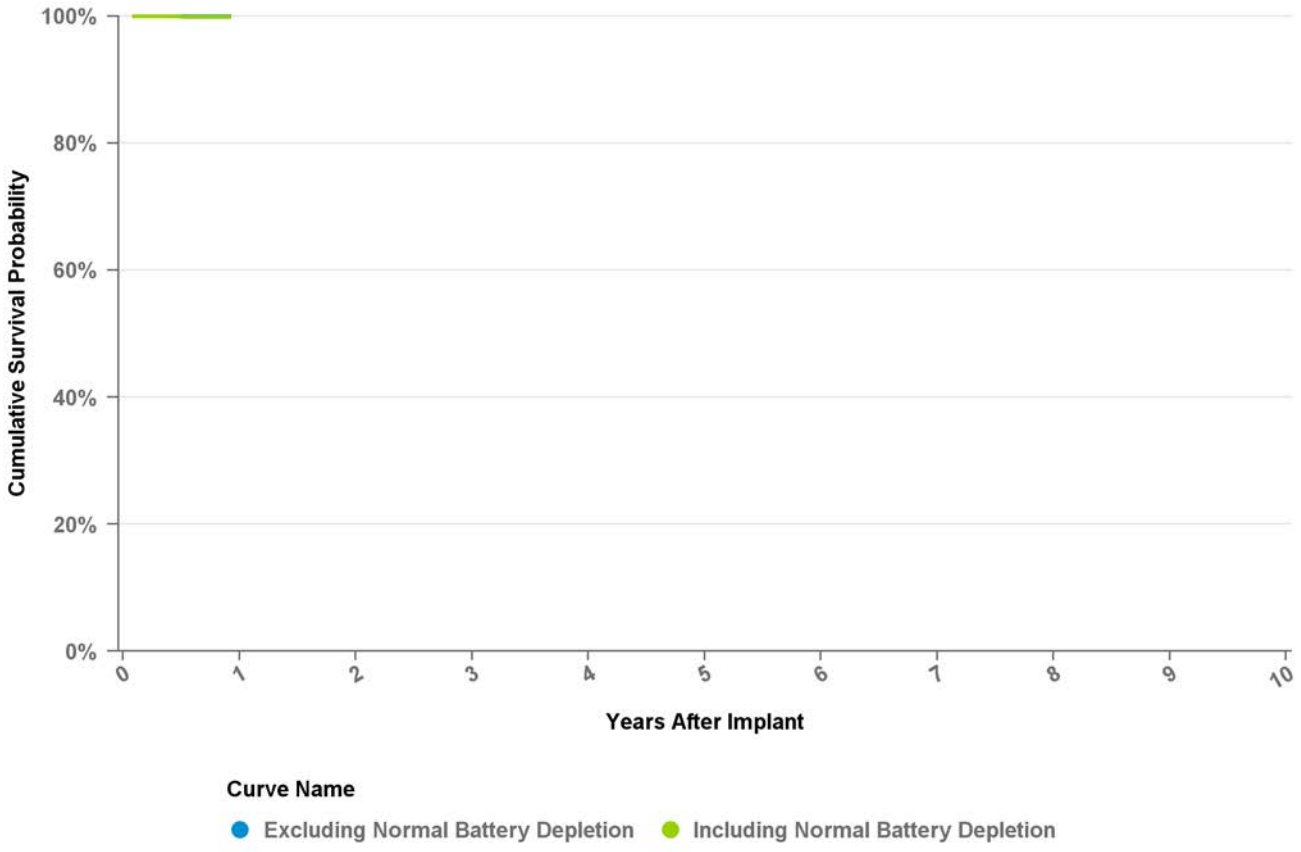
DTBA1D4 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	4,414
Estimated Active US Implants	4,358
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

Viva XT CRT-D, Survival Curve



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	99.9%
Effective Sample Size	111

Cardiac Resynchronization Therapy

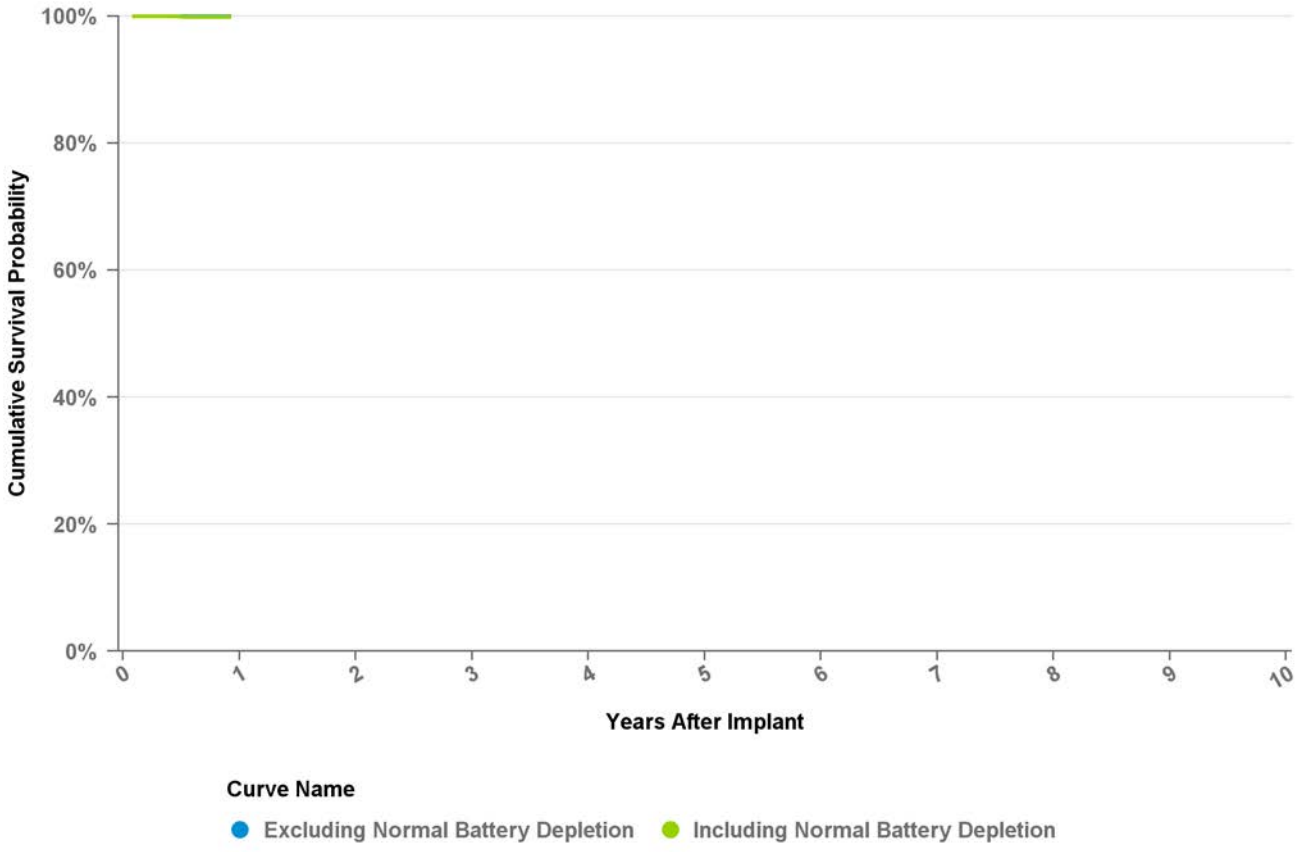
DTBA2D1 Viva XT

US Market Release Date	
CE Market Approval Date	8/10/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

Viva XT CRT-D, Survival Curve



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	99.9%
Effective Sample Size	111

Cardiac Resynchronization Therapy

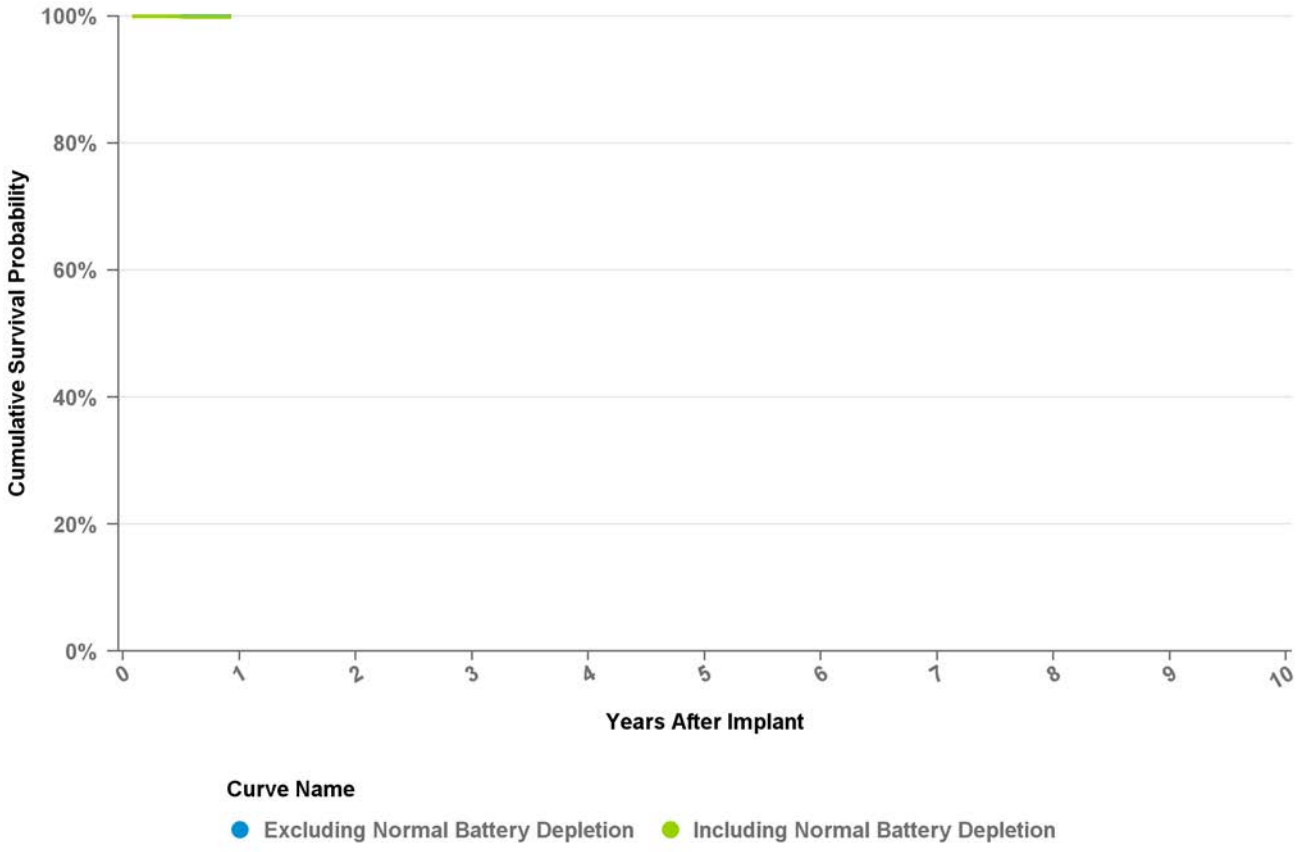
DTBA2D4 Viva XT

US Market Release Date	
CE Market Approval Date	8/10/2012
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

Viva XT CRT-D, Survival Curve



Years	at 11 mo
Excluding NBD	100.0%
Including NBD	99.9%
Effective Sample Size	111

Implantable Cardioverter Defibrillator

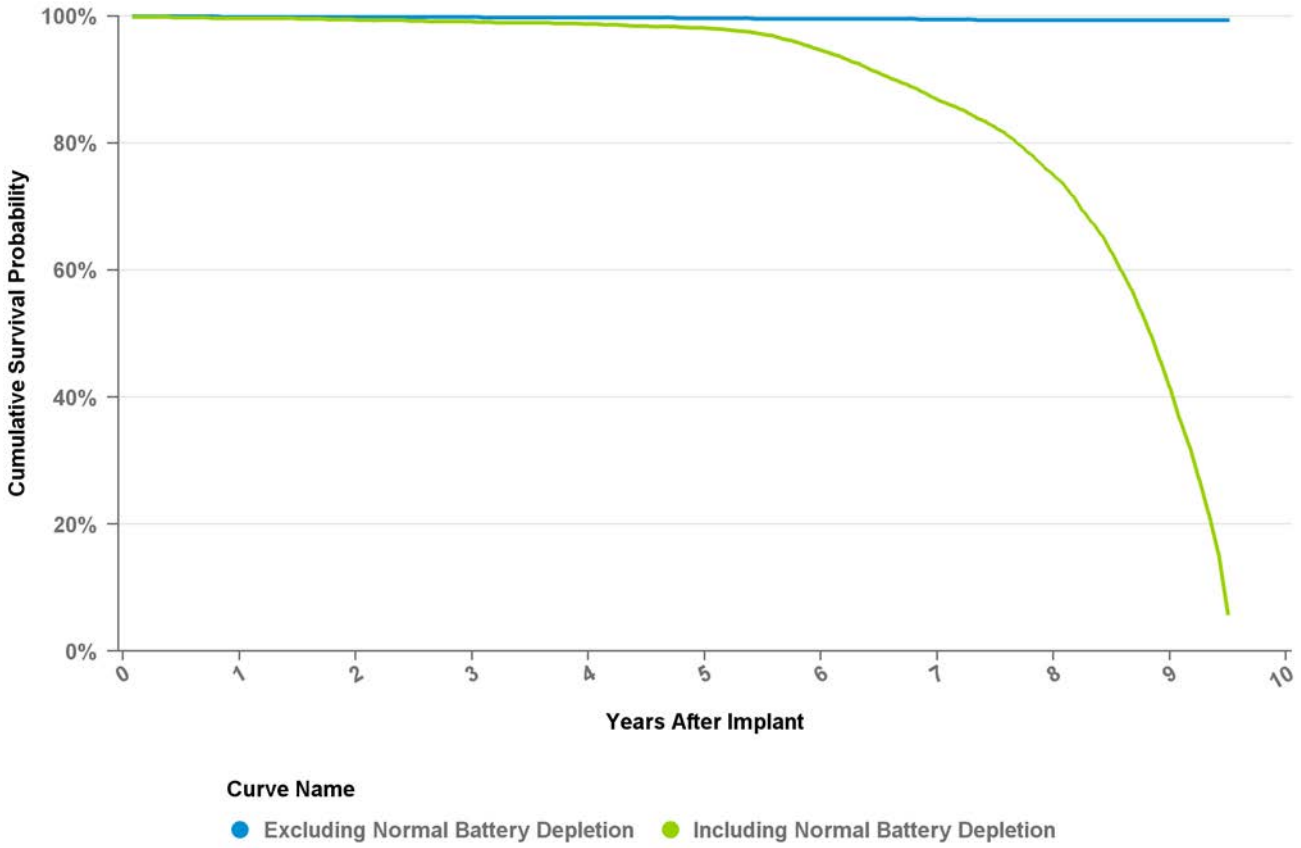
7230B Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	8/21/2002
Registered US Implants	237
Estimated Active US Implants	18
Normal Battery Depletions (US)	23

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	1
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7230, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.7%	98.1%	94.6%	86.8%	74.9%	41.5%	5.9%
Effective Sample Size	17350	13576	11353	10184	9107	7940	6573	5067	1996	173

Implantable Cardioverter Defibrillator

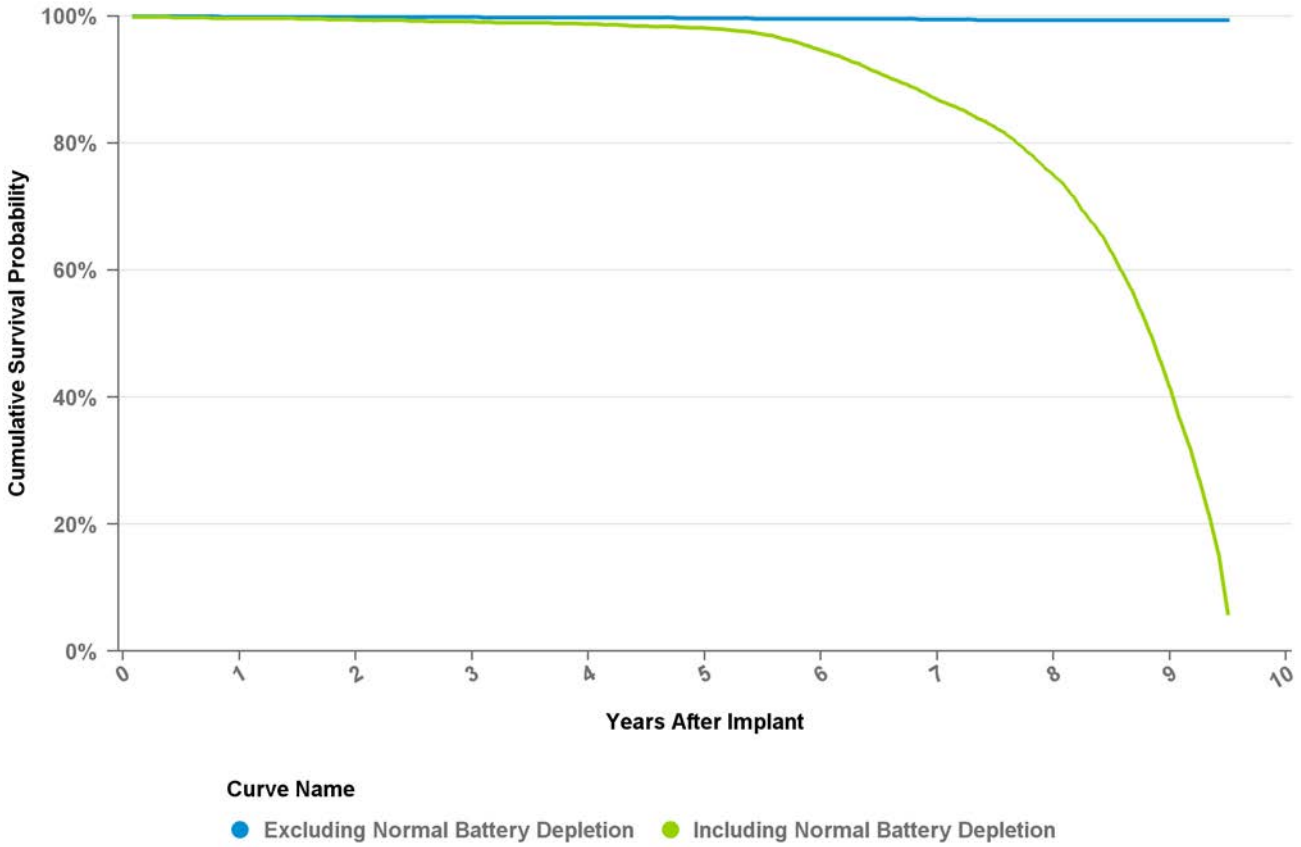
7230Cx Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	4/10/2002
Registered US Implants	18,568
Estimated Active US Implants	2,181
Normal Battery Depletions (US)	2,973

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	57
Therapy Not Compromised Malfunction	31
Battery Malfunction	1
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	14
Software Malfunction	1
Therapy Compromised Malfunctions	26
Battery Malfunction	17
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7230, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.7%	98.1%	94.6%	86.8%	74.9%	41.5%	5.9%
Effective Sample Size	17350	13576	11353	10184	9107	7940	6573	5067	1996	173

Implantable Cardioverter Defibrillator

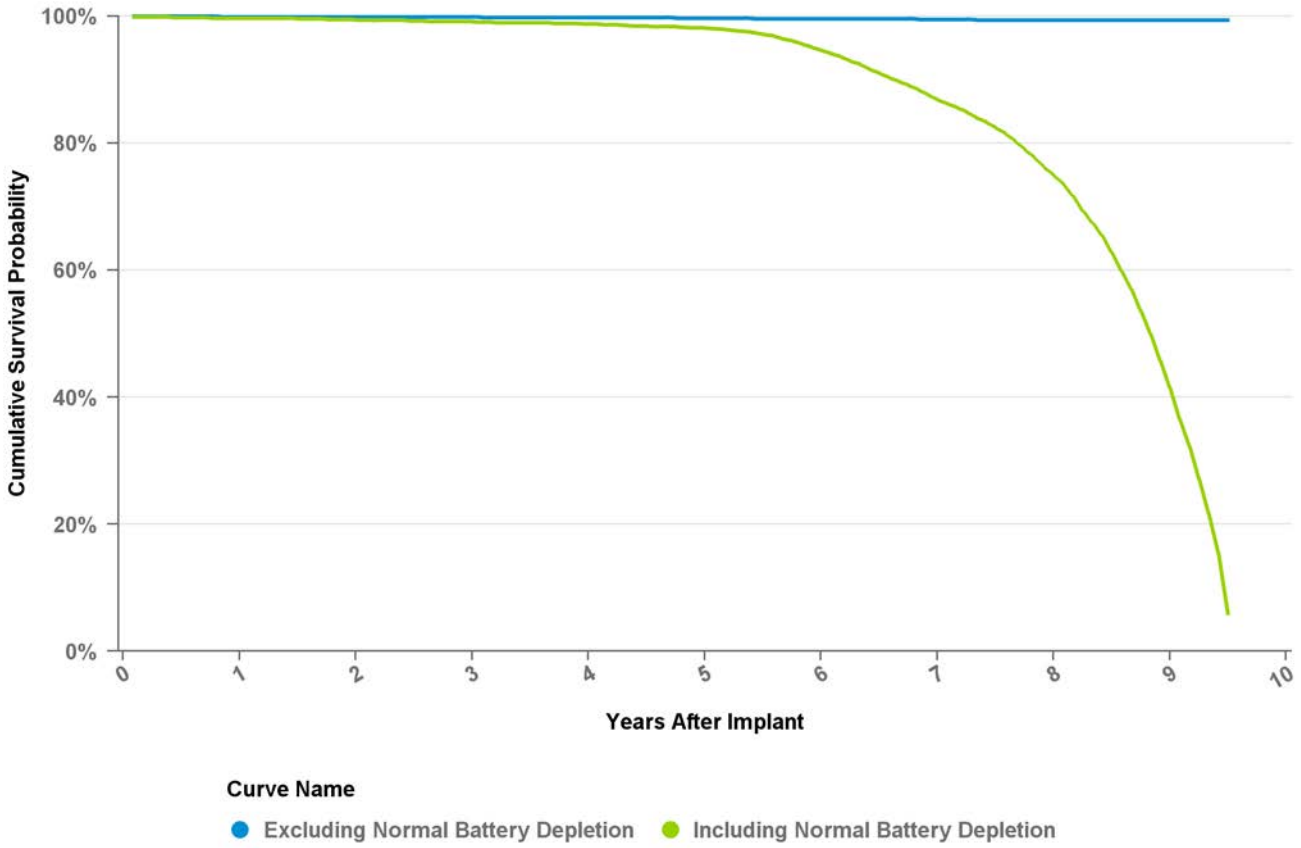
7230E Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	8/21/2002
Registered US Implants	633
Estimated Active US Implants	67
Normal Battery Depletions (US)	71

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	2
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7230, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%
Including NBD	99.7%	99.4%	99.1%	98.7%	98.1%	94.6%	86.8%	74.9%	41.5%	5.9%
Effective Sample Size	17350	13576	11353	10184	9107	7940	6573	5067	1996	173

Implantable Cardioverter Defibrillator

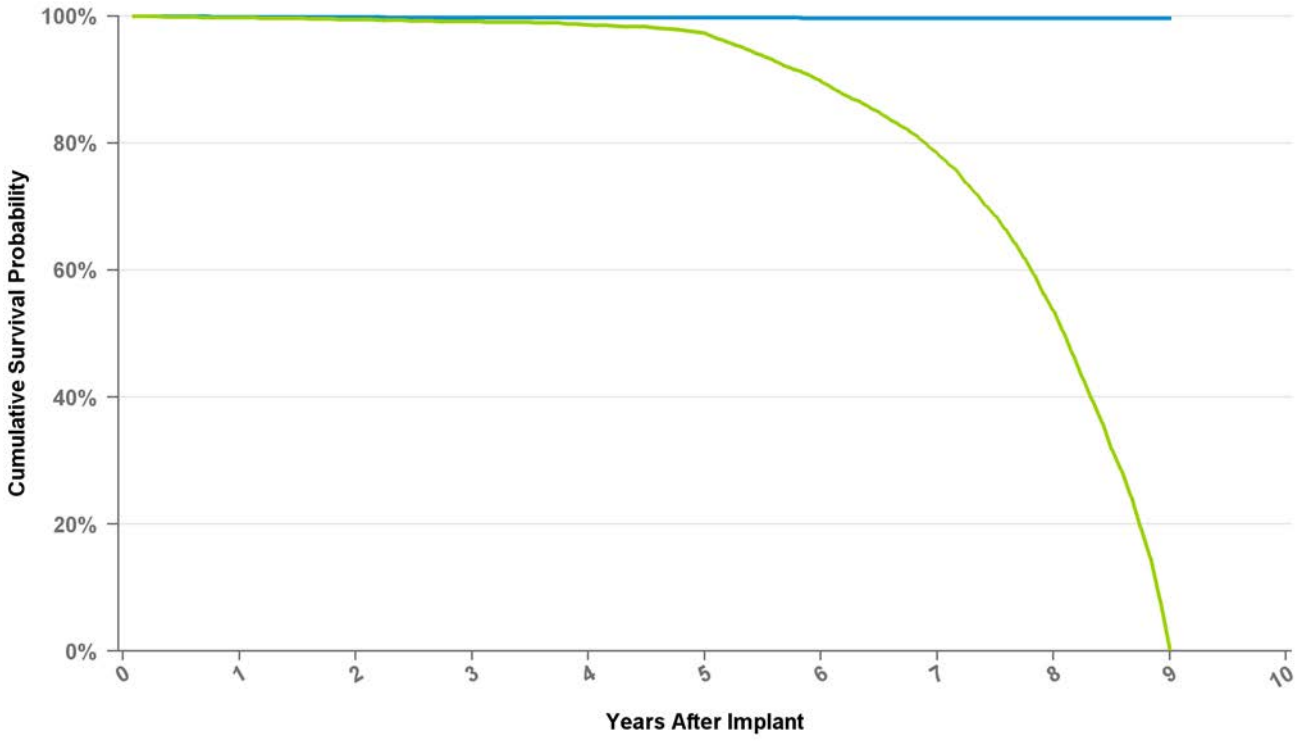
7231Cx GEM III VR

US Market Release Date	12/12/2000
CE Market Approval Date	12/8/2000
Registered US Implants	17,493
Estimated Active US Implants	1,679
Normal Battery Depletions (US)	3,753

NBG Code	VVE-VVIR
Max Delivered Energy	30J

Total Malfunctions (US)	37
Therapy Not Compromised Malfunction	27
Battery Malfunction	1
Electrical Component	22
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	4
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	1
Electrical Component	8
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7231, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.8%	99.5%	99.1%	98.6%	97.3%	89.7%	78.3%	53.6%	0.4%
Effective Sample Size	15791	14114	12517	11031	9633	7933	6061	3255	100

Implantable Cardioverter Defibrillator

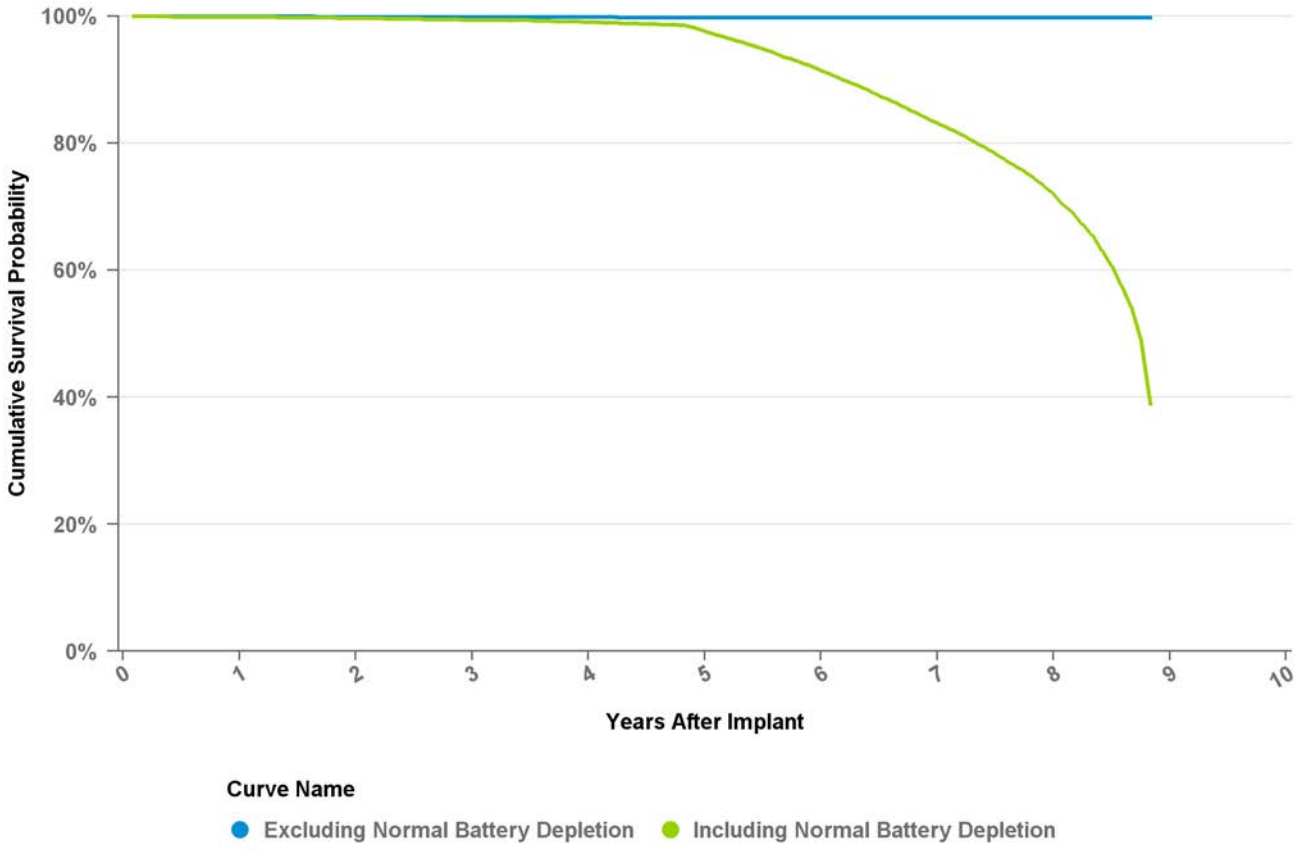
7232B Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	170
Estimated Active US Implants	74
Normal Battery Depletions (US)	7

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7232, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.4%	99.0%	97.6%	91.4%	83.1%	71.9%	38.9%
Effective Sample Size	40772	36679	32868	29053	25410	20758	15427	8662	632

Implantable Cardioverter Defibrillator

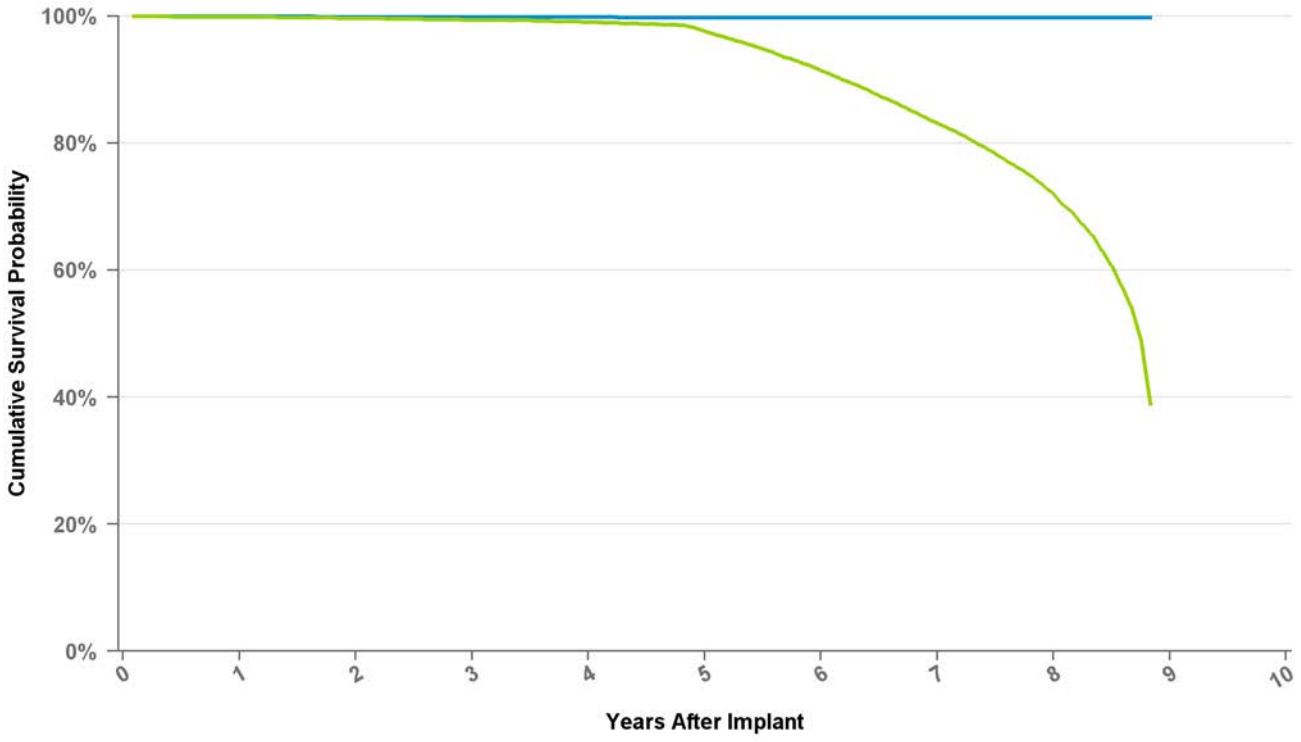
7232Cx Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	43,679
Estimated Active US Implants	15,169
Normal Battery Depletions (US)	4,689

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	74
Therapy Not Compromised Malfunction	59
Battery Malfunction	0
Electrical Component	28
Electrical Interconnect	0
Other Malfunction	6
Poss Early Battery Depltn	25
Software Malfunction	0
Therapy Compromised Malfunctions	15
Battery Malfunction	0
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0

7232, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.4%	99.0%	97.6%	91.4%	83.1%	71.9%	38.9%
Effective Sample Size	40772	36679	32868	29053	25410	20758	15427	8662	632

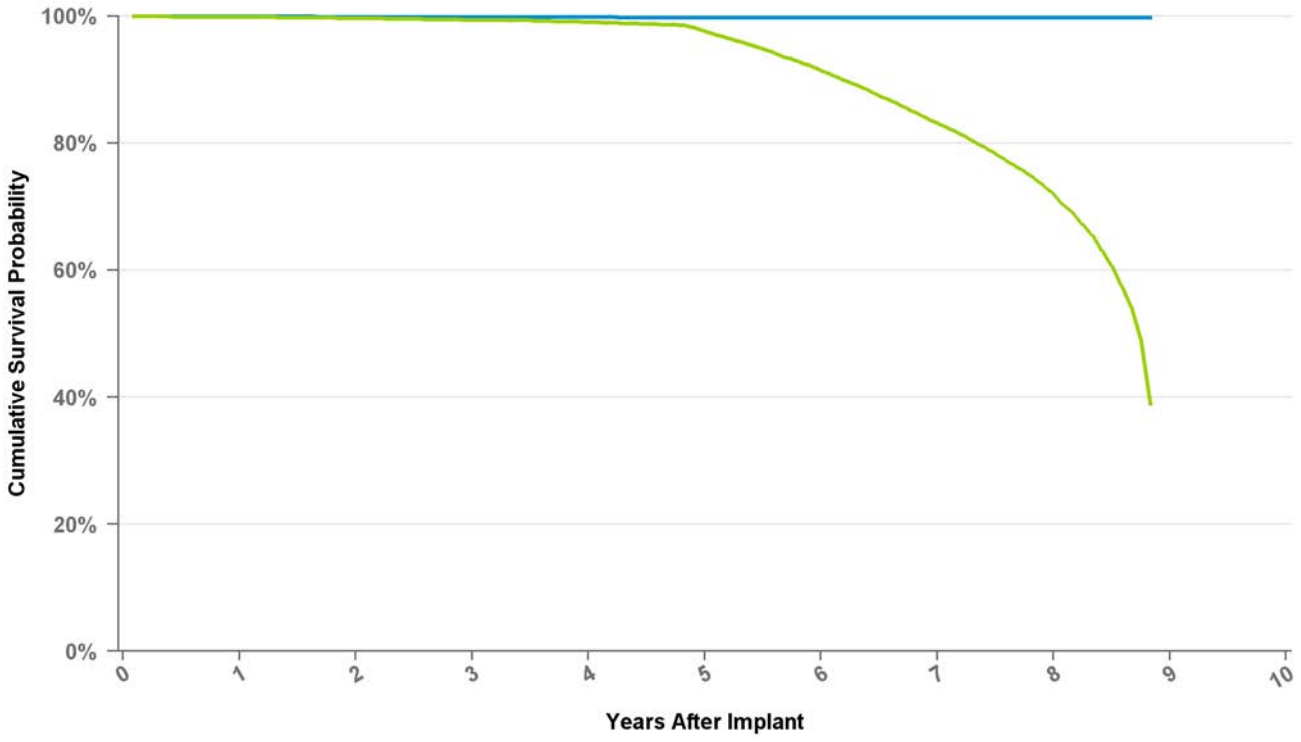
Implantable Cardioverter Defibrillator

7232E Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	491
Estimated Active US Implants	194
Normal Battery Depletions (US)	16
NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7232, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%
Including NBD	99.9%	99.7%	99.4%	99.0%	97.6%	91.4%	83.1%	71.9%	38.9%
Effective Sample Size	40772	36679	32868	29053	25410	20758	15427	8662	632

Implantable Cardioverter Defibrillator

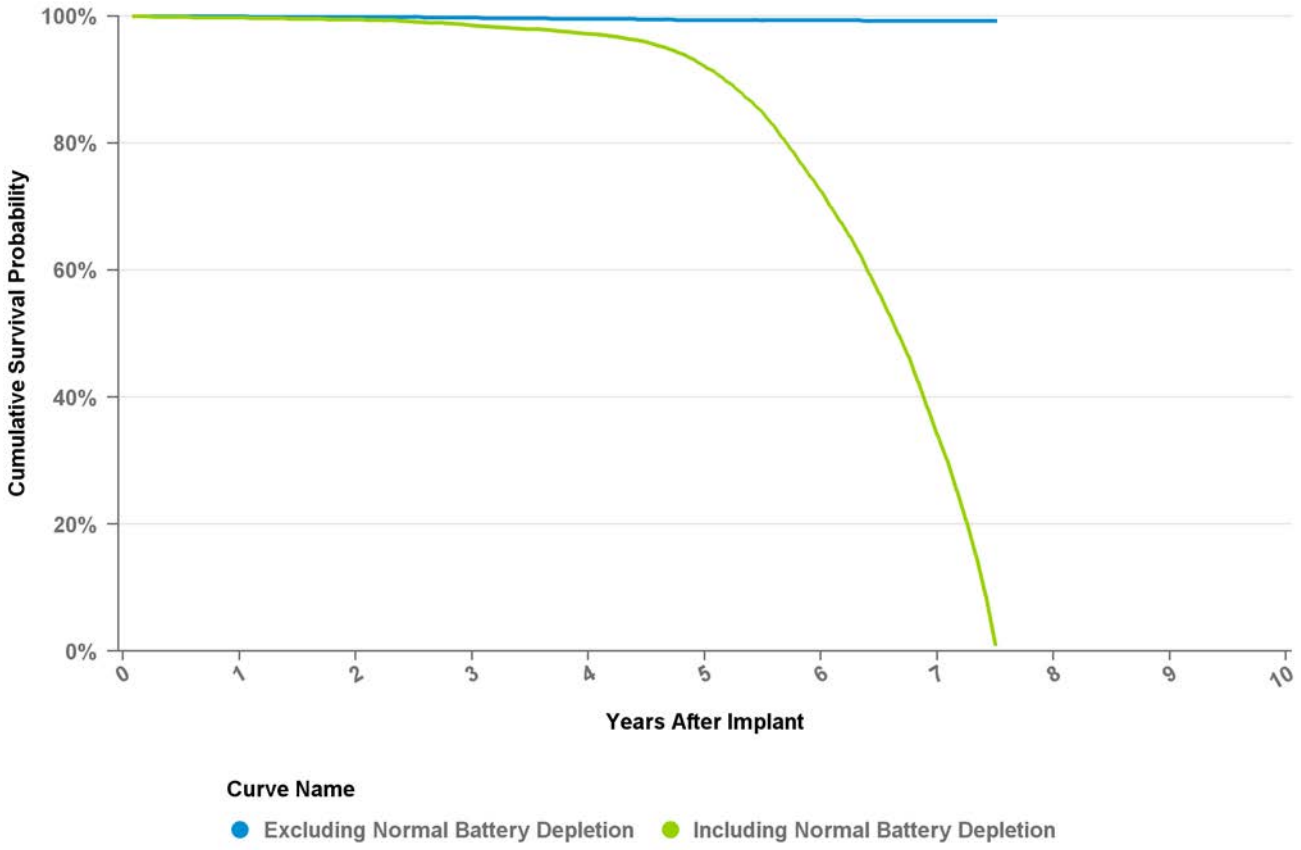
7274 Marquis DR

US Market Release Date	3/1/2002
CE Market Approval Date	2/25/2002
Registered US Implants	48,394
Estimated Active US Implants	2,731
Normal Battery Depletions (US)	8,945

NBG Code	VVE-DDDR
Max Delivered Energy	30J

Total Malfunctions (US)	196
Therapy Not Compromised Malfunction	89
Battery Malfunction	6
Electrical Component	31
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	51
Software Malfunction	0
Therapy Compromised Malfunctions	107
Battery Malfunction	80
Electrical Component	27
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

7274, Survival Curve



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	99.9%	99.8%	99.6%	99.4%	99.3%	99.2%	99.2%
Including NBD	99.8%	99.5%	98.5%	97.2%	92.0%	72.5%	34.1%	1.1%
Effective Sample Size	42973	34597	26575	22515	18501	12063	4135	404

Implantable Cardioverter Defibrillator

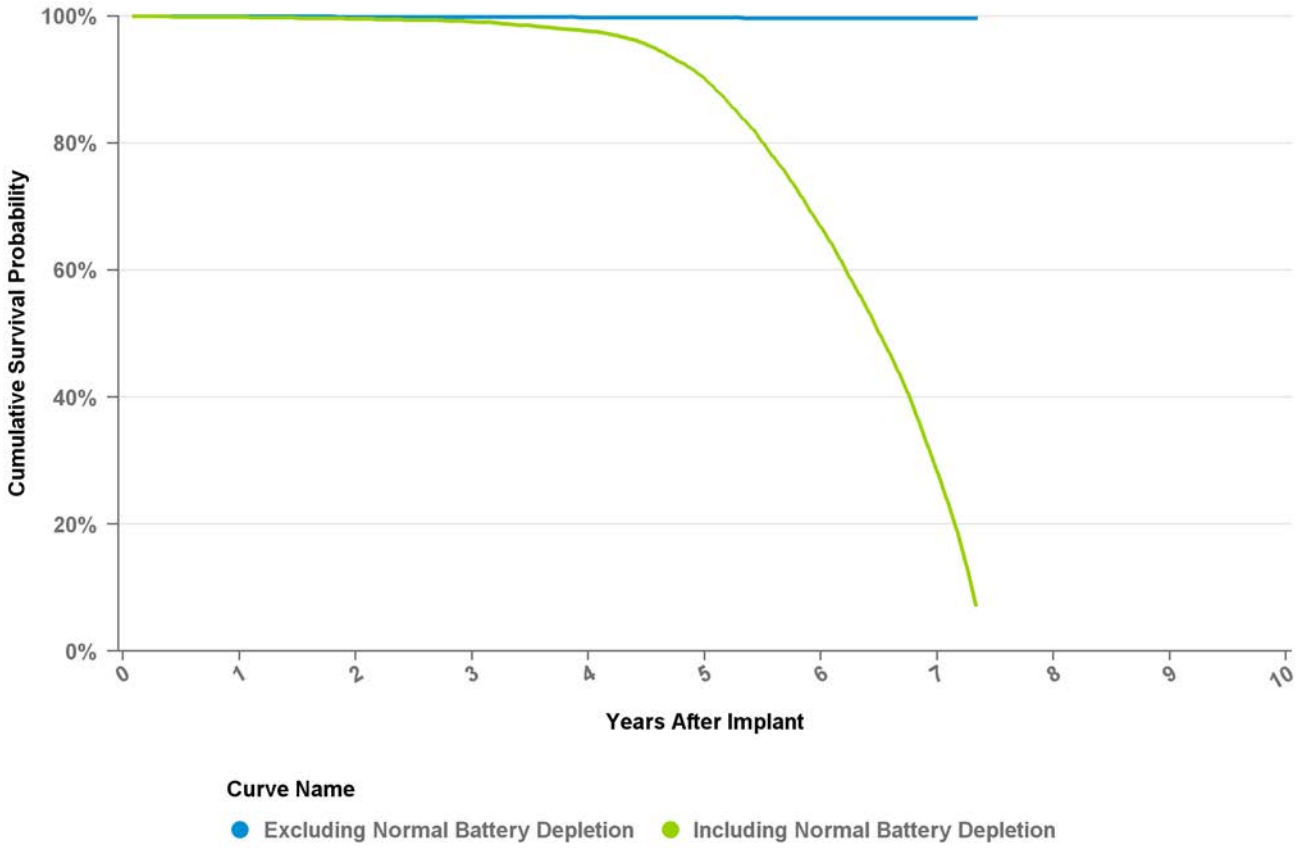
7278 Maximo DR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	37,666
Estimated Active US Implants	4,967
Normal Battery Depletions (US)	9,740

NBG Code	VVE-DDDR
Max Delivered Energy	35J

Total Malfunctions (US)	70
Therapy Not Compromised Malfunction	60
Battery Malfunction	0
Electrical Component	22
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	34
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0

7278, Survival Curve



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.6%	99.1%	97.6%	90.1%	66.8%	28.3%	7.2%
Effective Sample Size	33995	30419	27269	23892	19330	11540	3315	777

Implantable Cardioverter Defibrillator

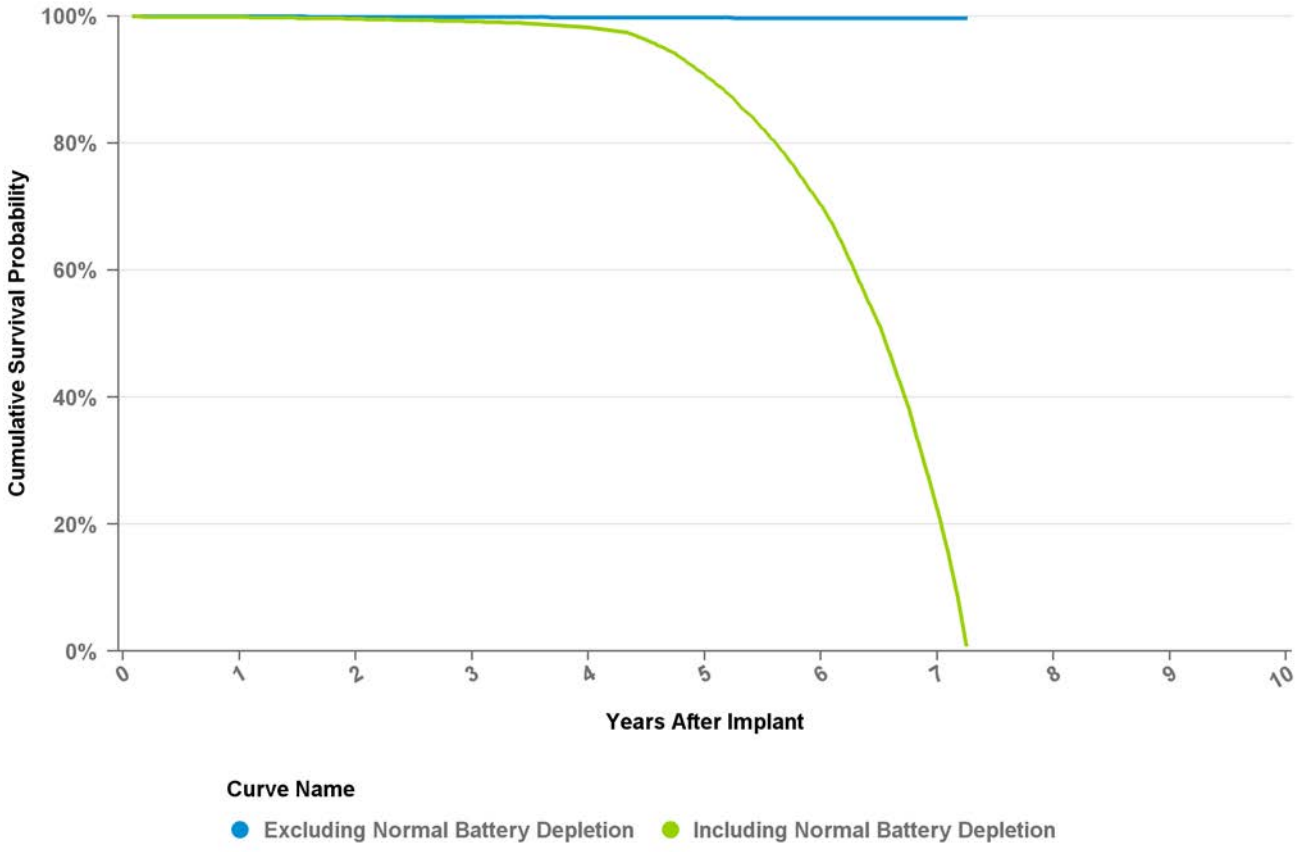
7288 Intrinsic

US Market Release Date	6/21/2004
CE Market Approval Date	5/4/2004
Registered US Implants	30,665
Estimated Active US Implants	3,227
Normal Battery Depletions (US)	9,607

NBG Code	VVE-DDDR
Max Delivered Energy	35J

Total Malfunctions (US)	71
Therapy Not Compromised Malfunction	64
Battery Malfunction	2
Electrical Component	27
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	33
Software Malfunction	1
Therapy Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0

7288, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%
Including NBD	99.9%	99.6%	99.1%	98.2%	90.7%	70.3%	22.4%	1.0%
Effective Sample Size	28722	26379	23781	21023	17499	11642	2797	505

Implantable Cardioverter Defibrillator

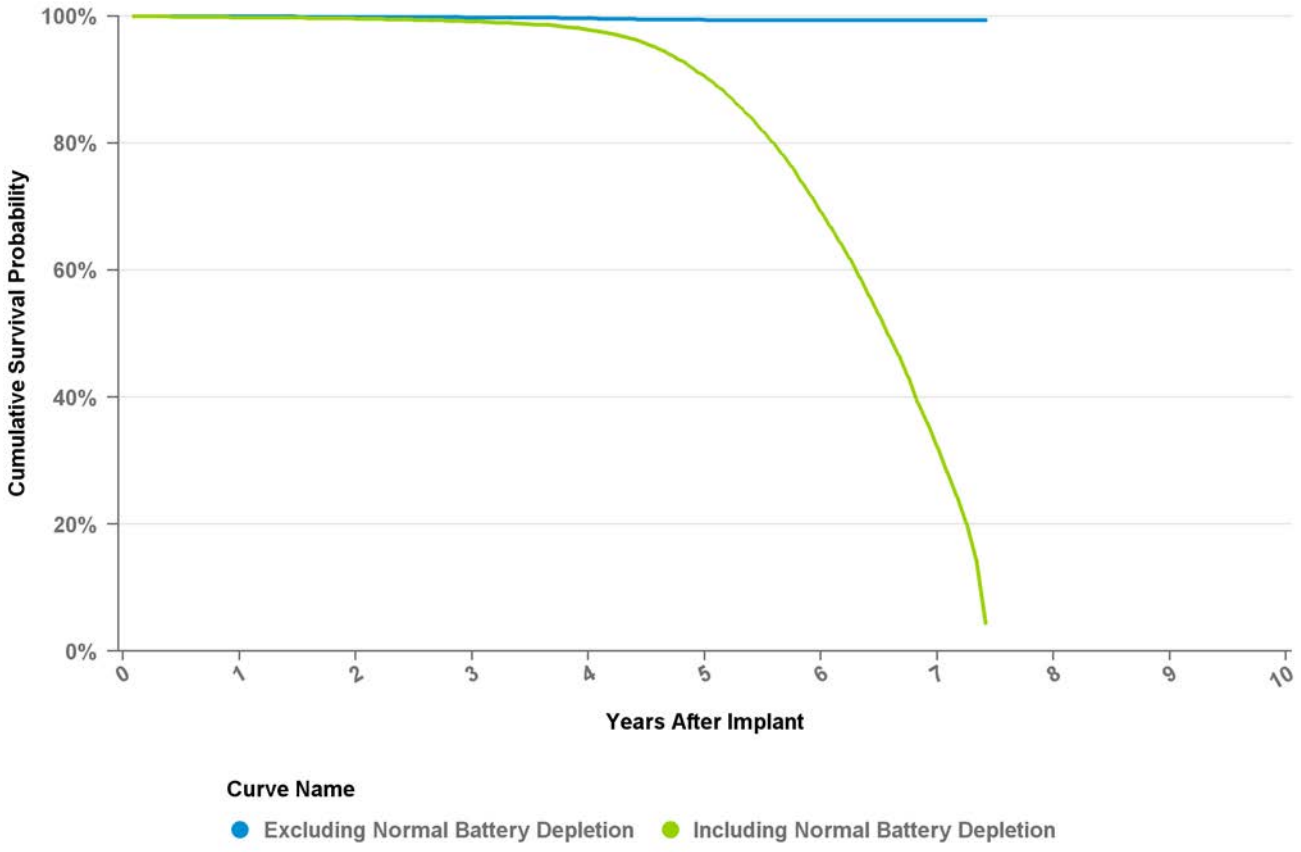
D144DRG Entrust Escudo

US Market Release Date	
CE Market Approval Date	6/5/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D144DRG, D154ATG, D154DRG, Survival Curve



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.8%	99.6%	99.1%	97.8%	90.5%	69.2%	32.2%	4.4%
Effective Sample Size	26335	24105	21695	19181	15658	10024	3112	370

Implantable Cardioverter Defibrillator

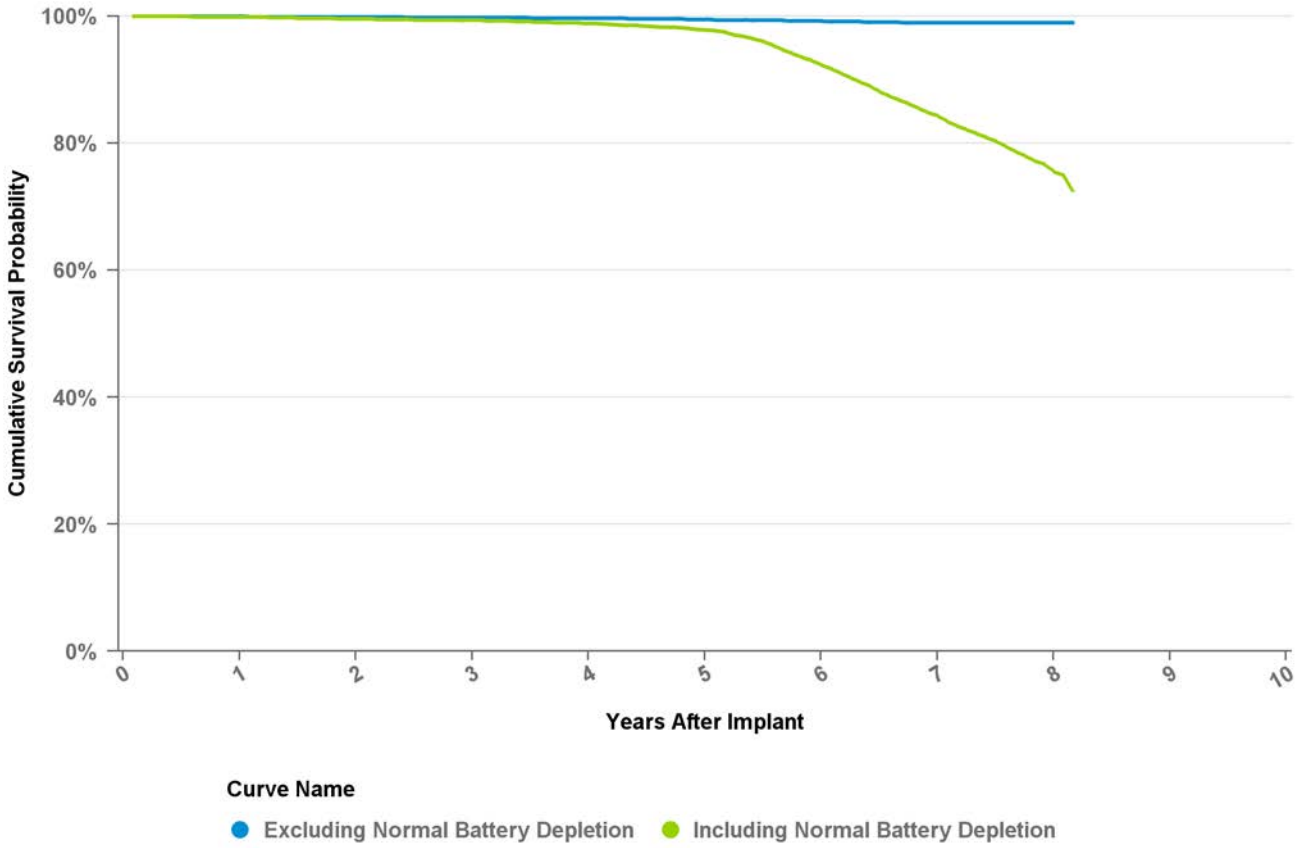
D144VRC Entrust Escudo

US Market Release Date	
CE Market Approval Date	6/5/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D144VRC, D154VRC, Survival Curve



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.9%	98.9%
Including NBD	99.9%	99.6%	99.3%	98.8%	97.8%	92.3%	84.3%	75.5%	72.5%
Effective Sample Size	13657	12422	11160	9907	8779	7279	5310	722	104

Implantable Cardioverter Defibrillator

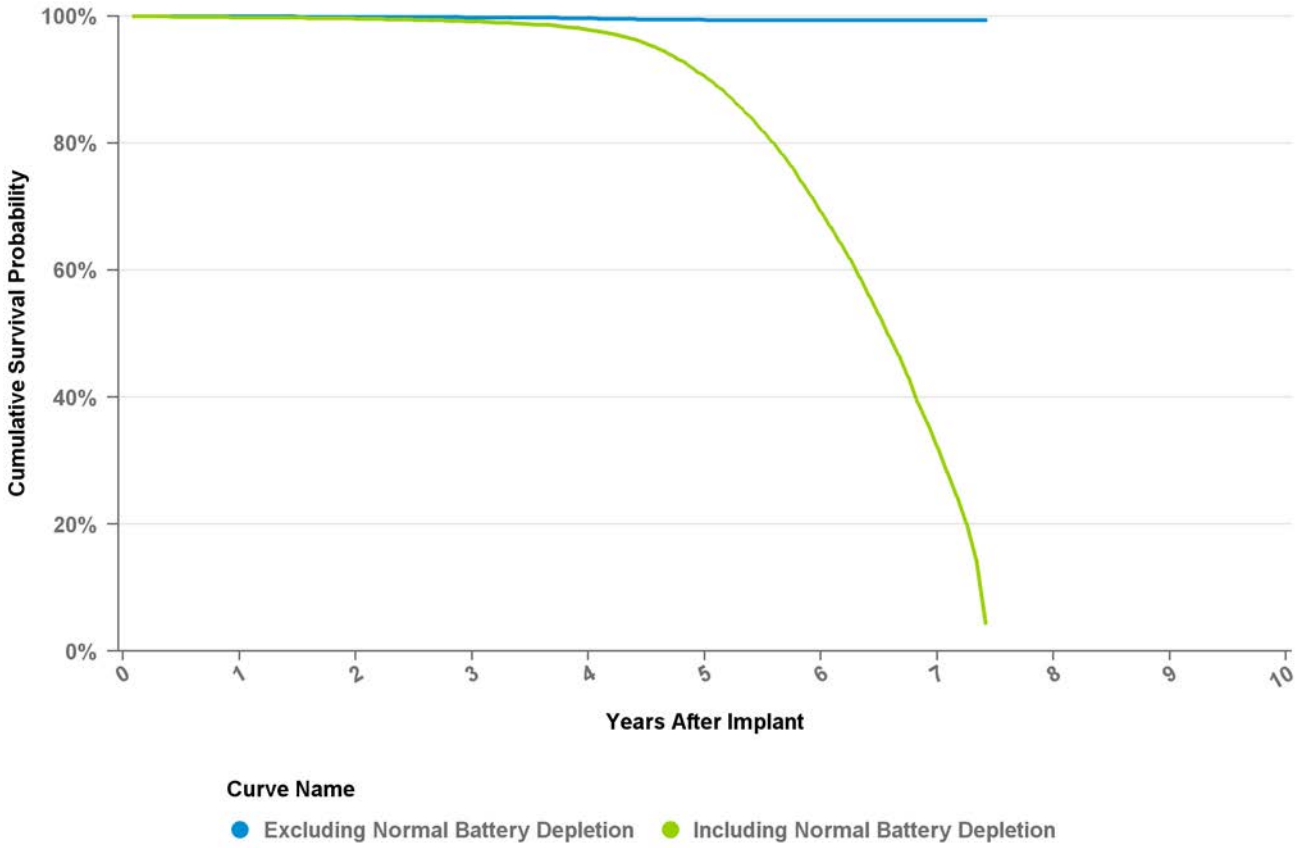
D154ATG Entrust AT

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	28,176
Estimated Active US Implants	5,458
Normal Battery Depletions (US)	7,036

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	123
Therapy Not Compromised Malfunction	109
Battery Malfunction	0
Electrical Component	29
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	75
Software Malfunction	3
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D144DRG, D154ATG, D154DRG, Survival Curve



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.8%	99.6%	99.1%	97.8%	90.5%	69.2%	32.2%	4.4%
Effective Sample Size	26335	24105	21695	19181	15658	10024	3112	370

Implantable Cardioverter Defibrillator

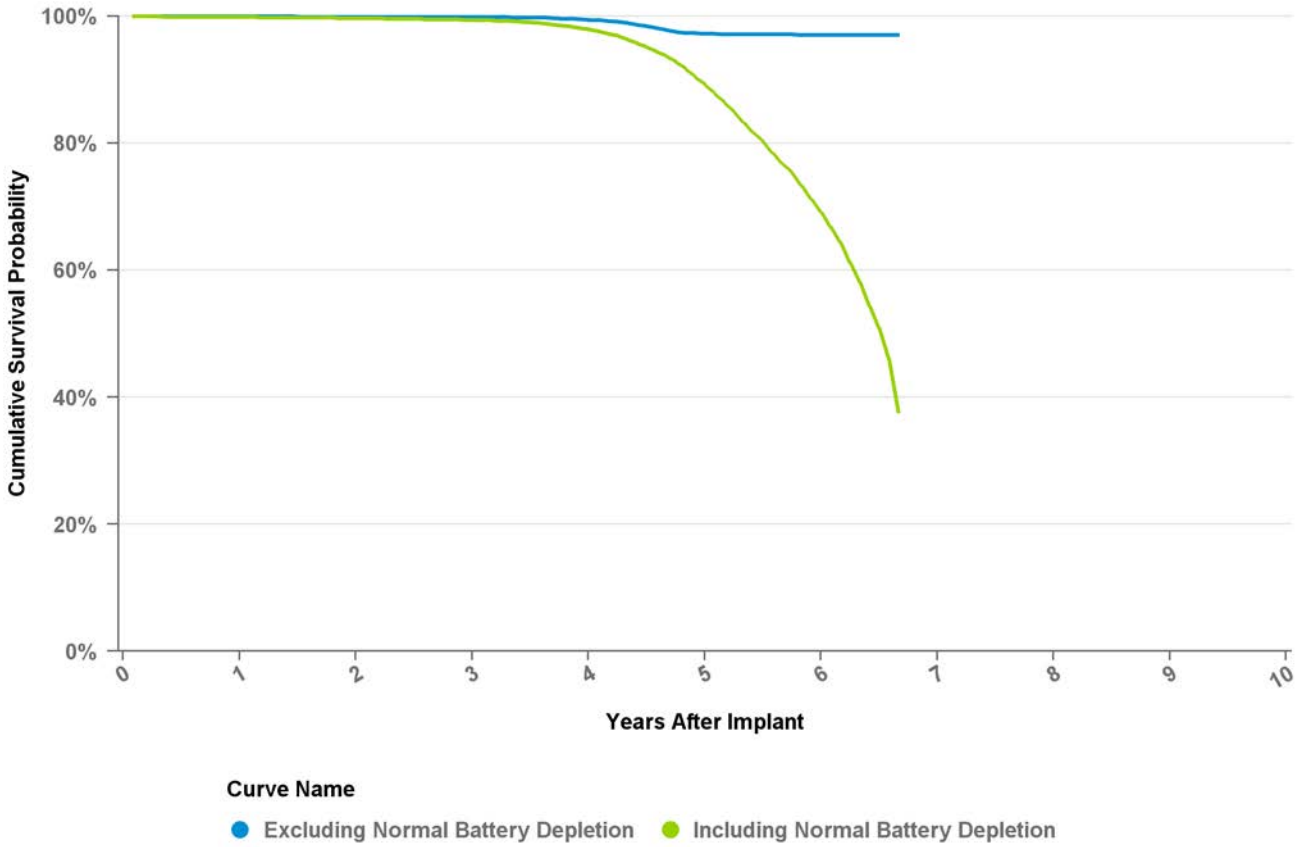
D154AWG Virtuoso DR Non-Advisory

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	72,694
Estimated Active US Implants	35,113
Normal Battery Depletions (US)	7,415

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,398
Therapy Not Compromised Malfunction	1,369
Battery Malfunction	2
Electrical Component	1,230
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	130
Software Malfunction	1
Therapy Compromised Malfunctions	29
Battery Malfunction	0
Electrical Component	26
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	1
Software Malfunction	0

D154AWG, D16AWG, Survival Curve



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.2%	97.0%	97.0%
Including NBD	99.9%	99.7%	99.4%	97.9%	89.2%	69.2%	37.7%
Effective Sample Size	67740	62405	57121	51427	36734	14492	1068

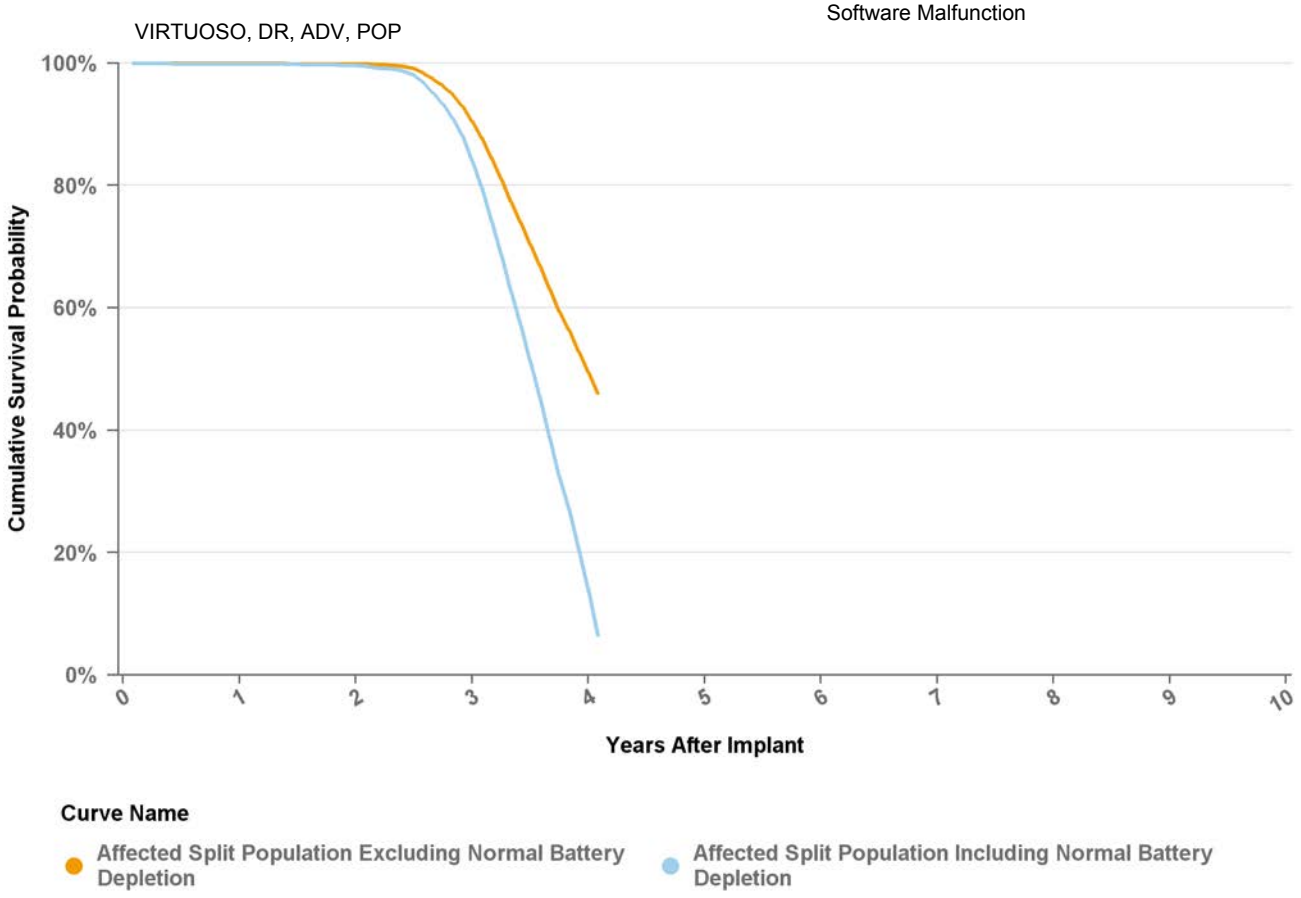
Implantable Cardioverter Defibrillator

D154AWG Virtuoso DR Advisory

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	4,146
Estimated Active US Implants	286
Normal Battery Depletions (US)	123

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,874
Therapy Not Compromised Malfunction	1,861
Battery Malfunction	0
Electrical Component	1,860
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	13
Battery Malfunction	0
Electrical Component	13
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	99.9%	90.5%	49.5%	46.0%
Including NBD	99.9%	99.6%	84.1%	13.9%	6.5%
Effective Sample Size	3806	3492	2755	404	246

Implantable Cardioverter Defibrillator

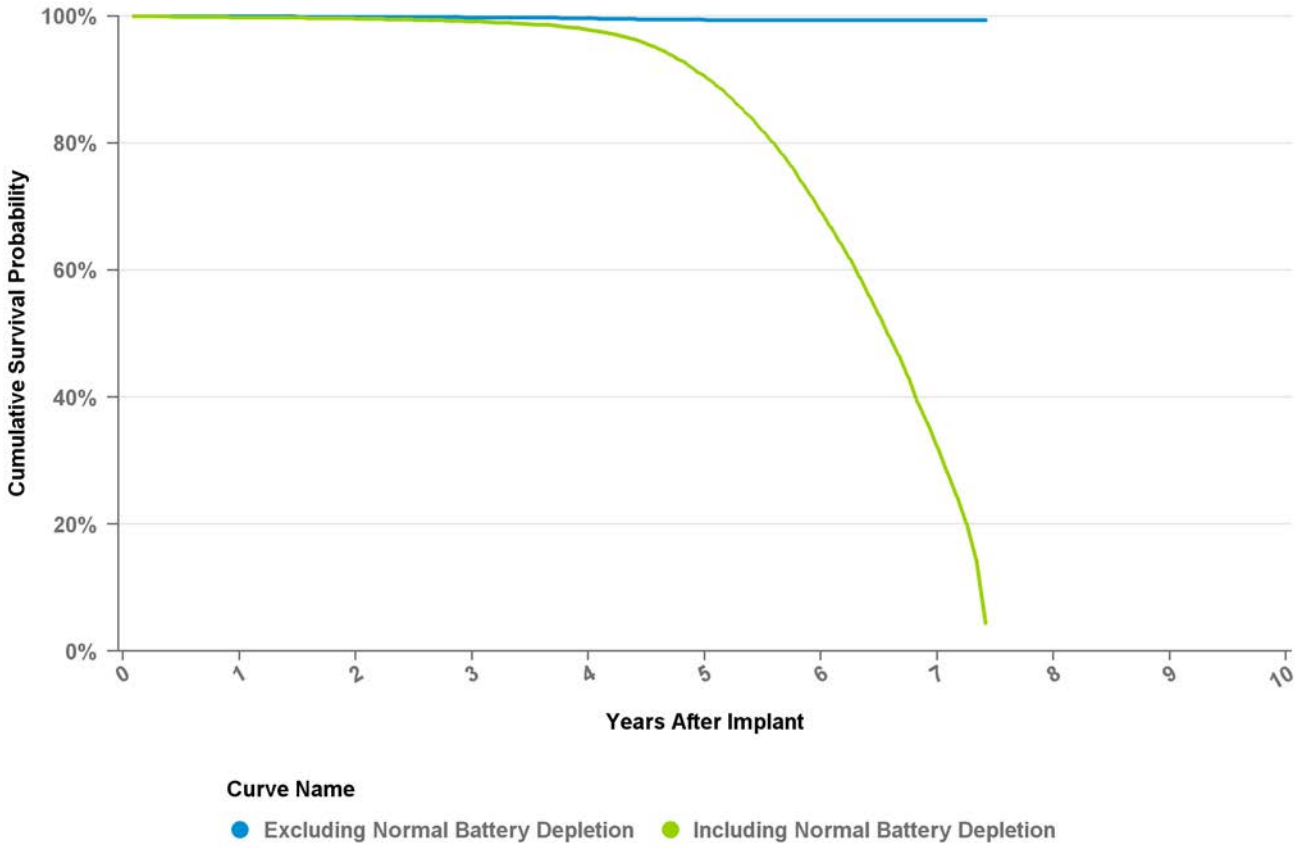
D154DRG Entrust DR

US Market Release Date	6/14/2005
CE Market Approval Date	2/4/2005
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D144DRG, D154ATG, D154DRG, Survival Curve



Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.8%	99.6%	99.1%	97.8%	90.5%	69.2%	32.2%	4.4%
Effective Sample Size	26335	24105	21695	19181	15658	10024	3112	370

Implantable Cardioverter Defibrillator

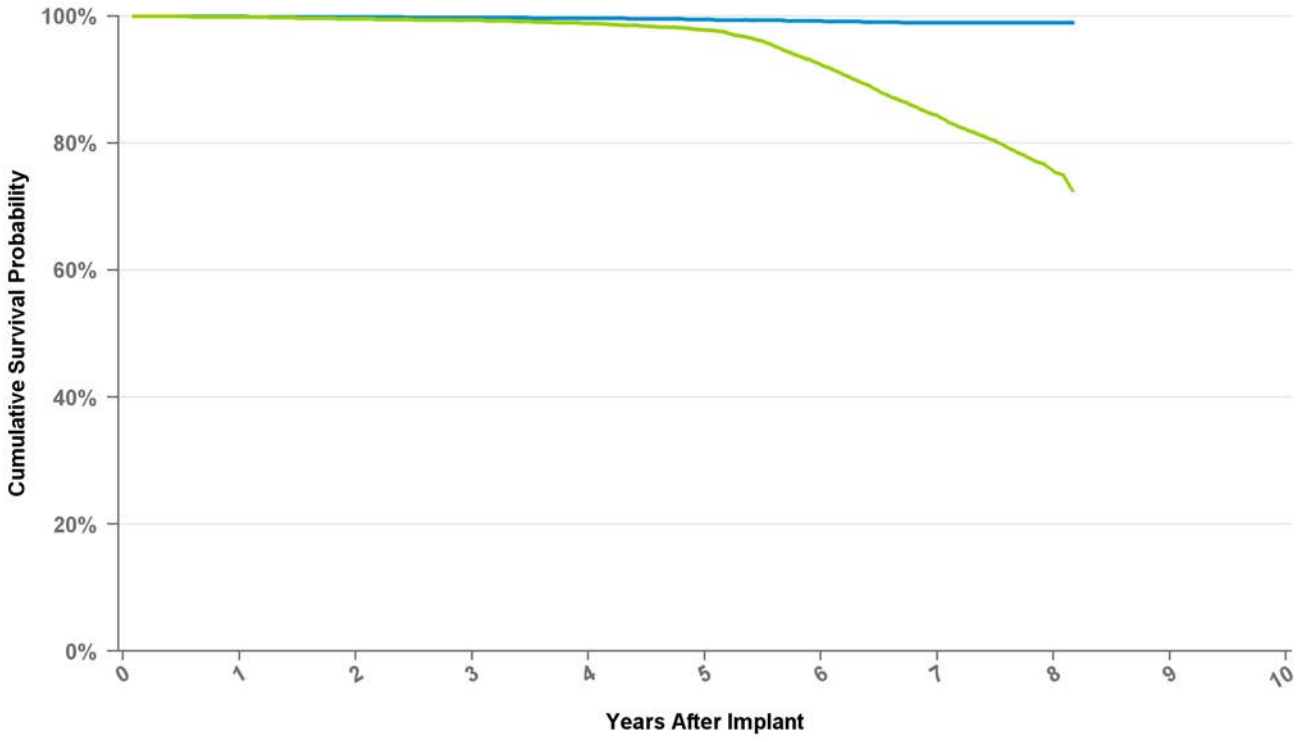
D154VRC Entrust VR

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	14,468
Estimated Active US Implants	6,577
Normal Battery Depletions (US)	874

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	100
Therapy Not Compromised Malfunction	81
Battery Malfunction	3
Electrical Component	44
Electrical Interconnect	0
Other Malfunction	10
Poss Early Battery Depltn	24
Software Malfunction	0
Therapy Compromised Malfunctions	19
Battery Malfunction	0
Electrical Component	18
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0

D144VRC, D154VRC, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.9%	98.9%
Including NBD	99.9%	99.6%	99.3%	98.8%	97.8%	92.3%	84.3%	75.5%	72.5%
Effective Sample Size	13657	12422	11160	9907	8779	7279	5310	722	104

Implantable Cardioverter Defibrillator

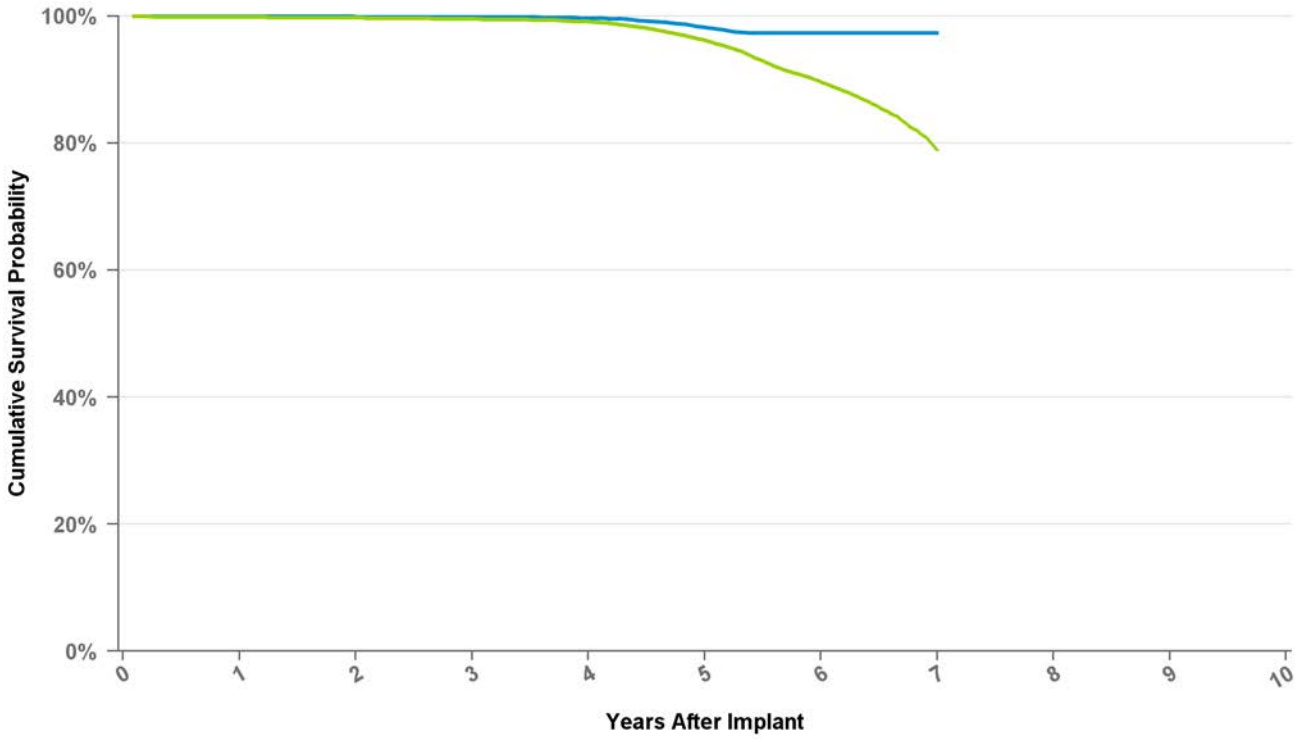
D154VWC Virtuoso VR

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	33,129
Estimated Active US Implants	19,464
Normal Battery Depletions (US)	826

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	541
Therapy Not Compromised Malfunction	527
Battery Malfunction	0
Electrical Component	507
Electrical Interconnect	1
Other Malfunction	4
Poss Early Battery Depltn	15
Software Malfunction	0
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D154VWC,D164VWC, Survival Curve



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.2%	97.3%	97.3%
Including NBD	99.9%	99.8%	99.6%	99.1%	96.2%	89.6%	79.0%
Effective Sample Size	30872	28306	25930	23547	18174	8822	333

Implantable Cardioverter Defibrillator

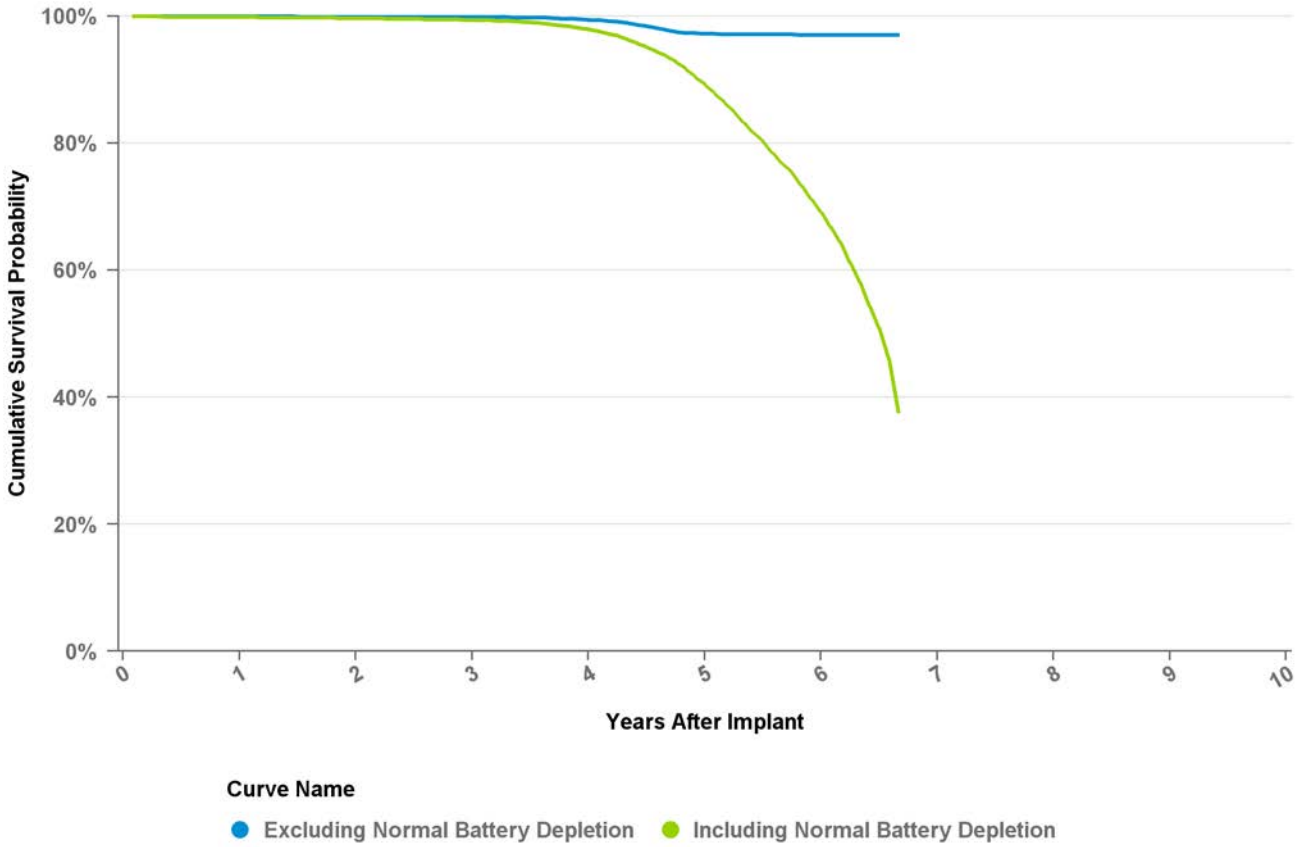
D164AWG Virtuoso DR Non-Advisory

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	8
Estimated Active US Implants	7
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D154AWG, D16AWG, Survival Curve



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.2%	97.0%	97.0%
Including NBD	99.9%	99.7%	99.4%	97.9%	89.2%	69.2%	37.7%
Effective Sample Size	67740	62405	57121	51427	36734	14492	1068

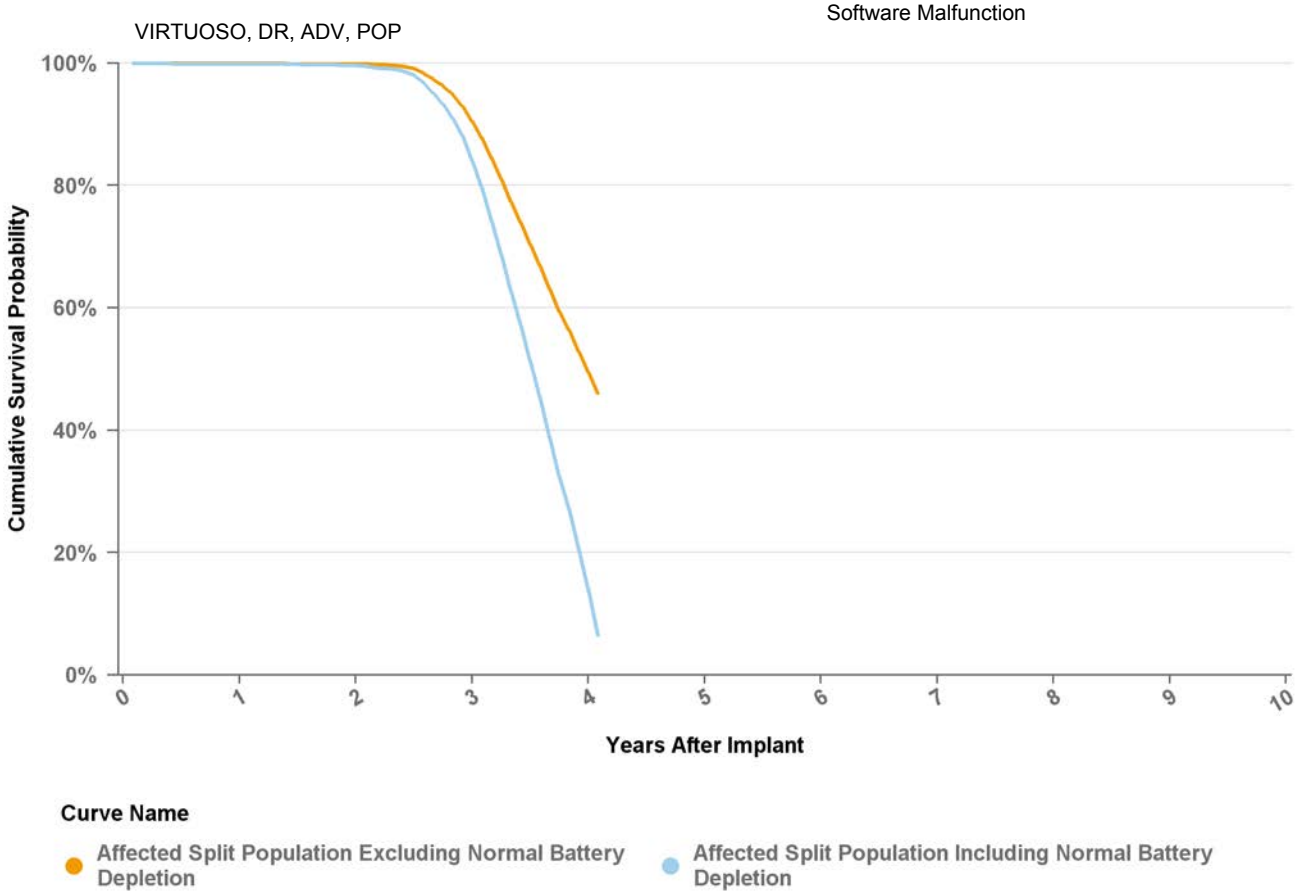
Implantable Cardioverter Defibrillator

D164AWG Virtuoso DR Advisory

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	99.9%	90.5%	49.5%	46.0%
Including NBD	99.9%	99.6%	84.1%	13.9%	6.5%
Effective Sample Size	3806	3492	2755	404	246

Implantable Cardioverter Defibrillator

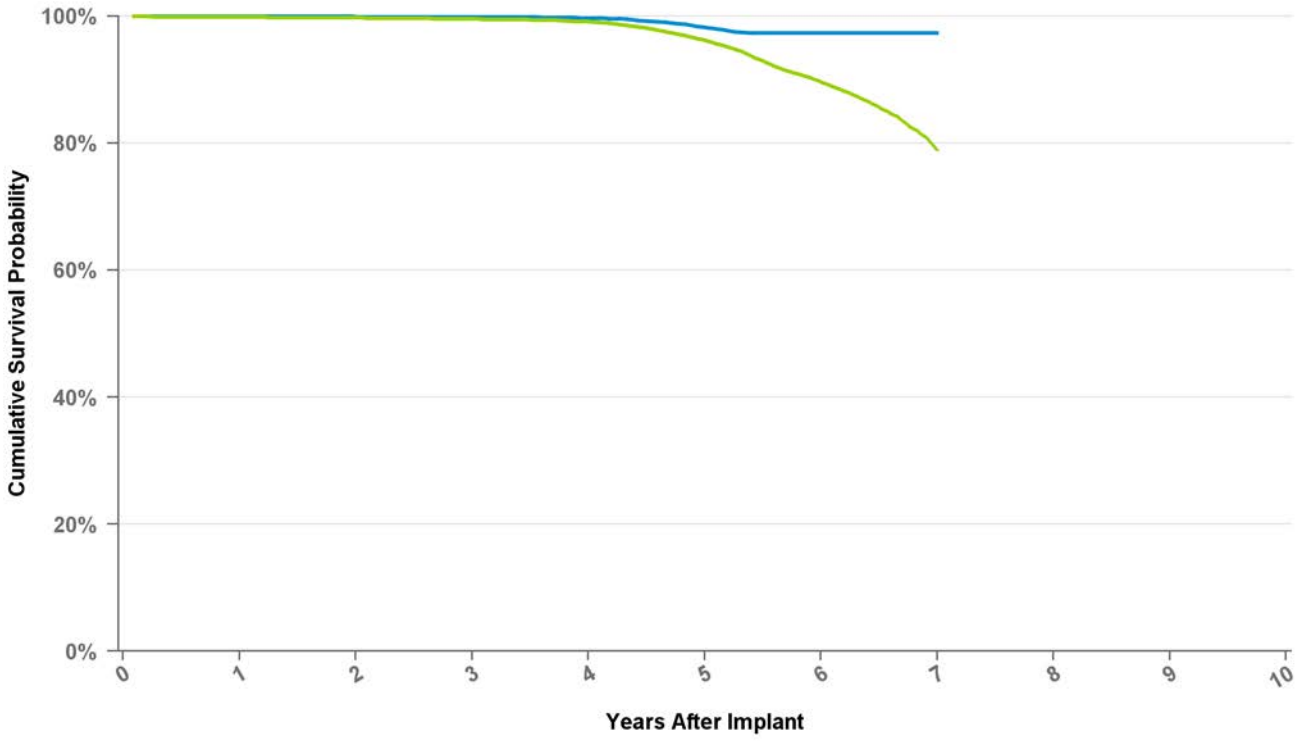
D164VWC Virtuoso VR

US Market Release Date	
CE Market Approval Date	3/7/2006
Registered US Implants	6
Estimated Active US Implants	5
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D154VWC,D164VWC, Survival Curve



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.2%	97.3%	97.3%
Including NBD	99.9%	99.8%	99.6%	99.1%	96.2%	89.6%	79.0%
Effective Sample Size	30872	28306	25930	23547	18174	8822	333

Implantable Cardioverter Defibrillator

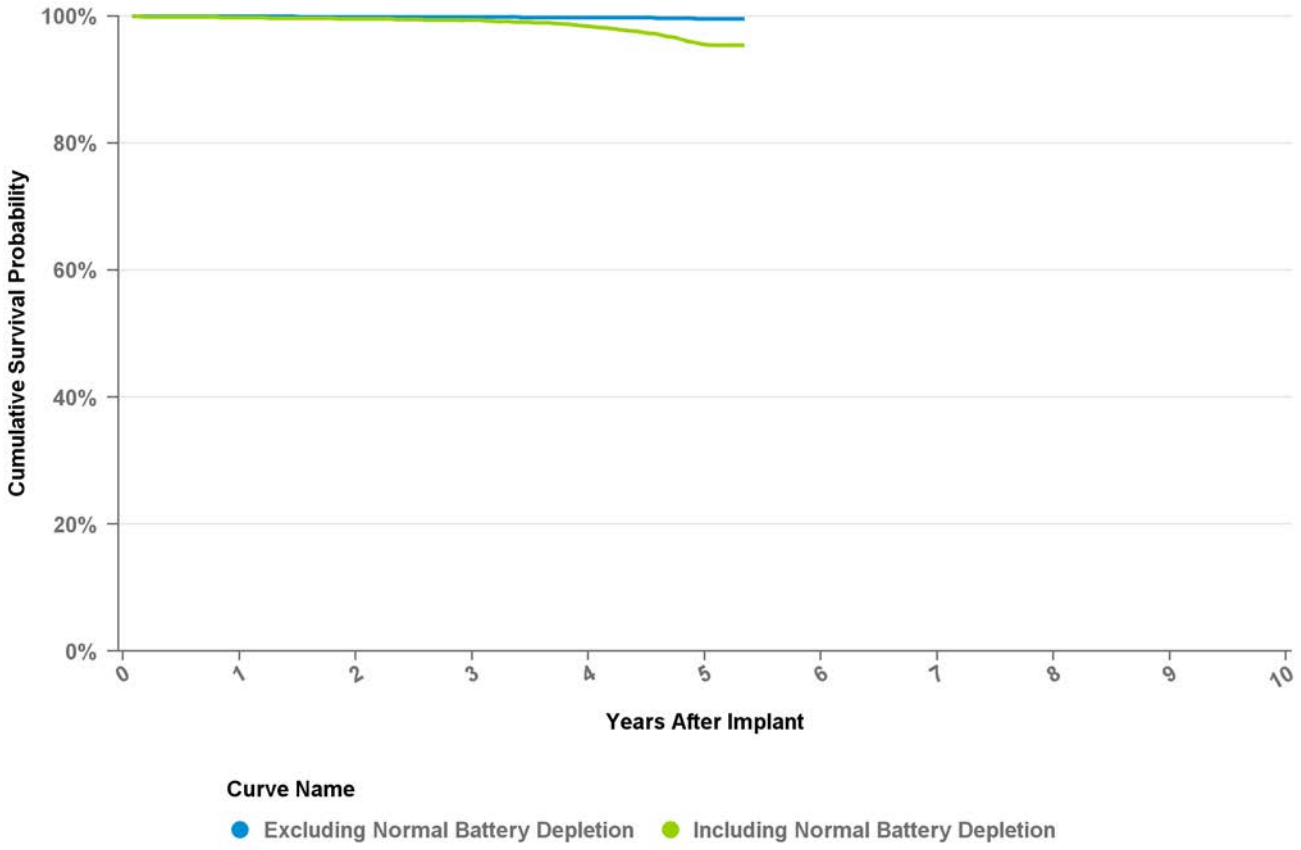
D204DRM Secura DR

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	1,753
Estimated Active US Implants	1,688
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, DR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.5%	95.4%
Effective Sample Size	47092	40630	30449	13889	2275	106

Implantable Cardioverter Defibrillator

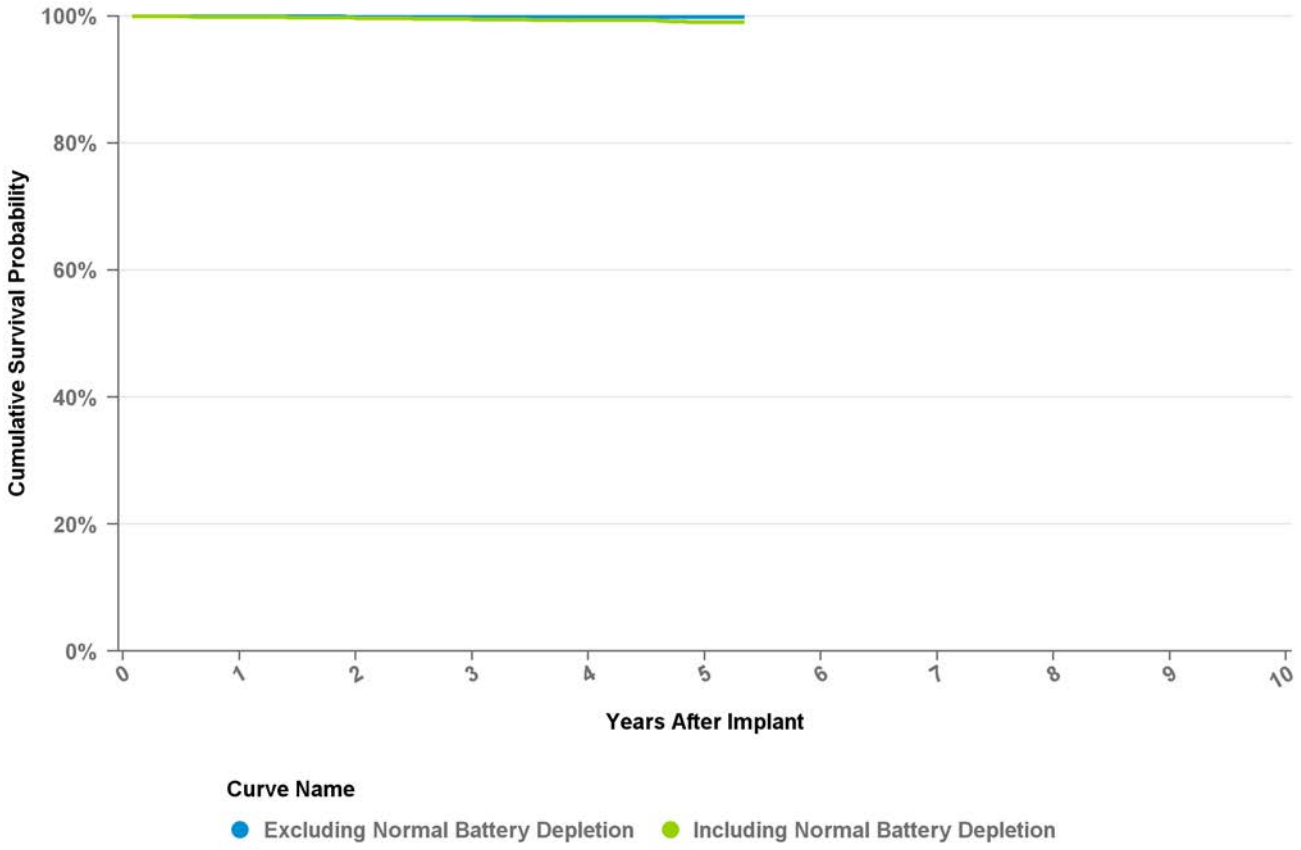
D204VRM Secura VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	1,098
Estimated Active US Implants	1,062
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, VR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	19088	16034	11831	5863	1124	134

Implantable Cardioverter Defibrillator

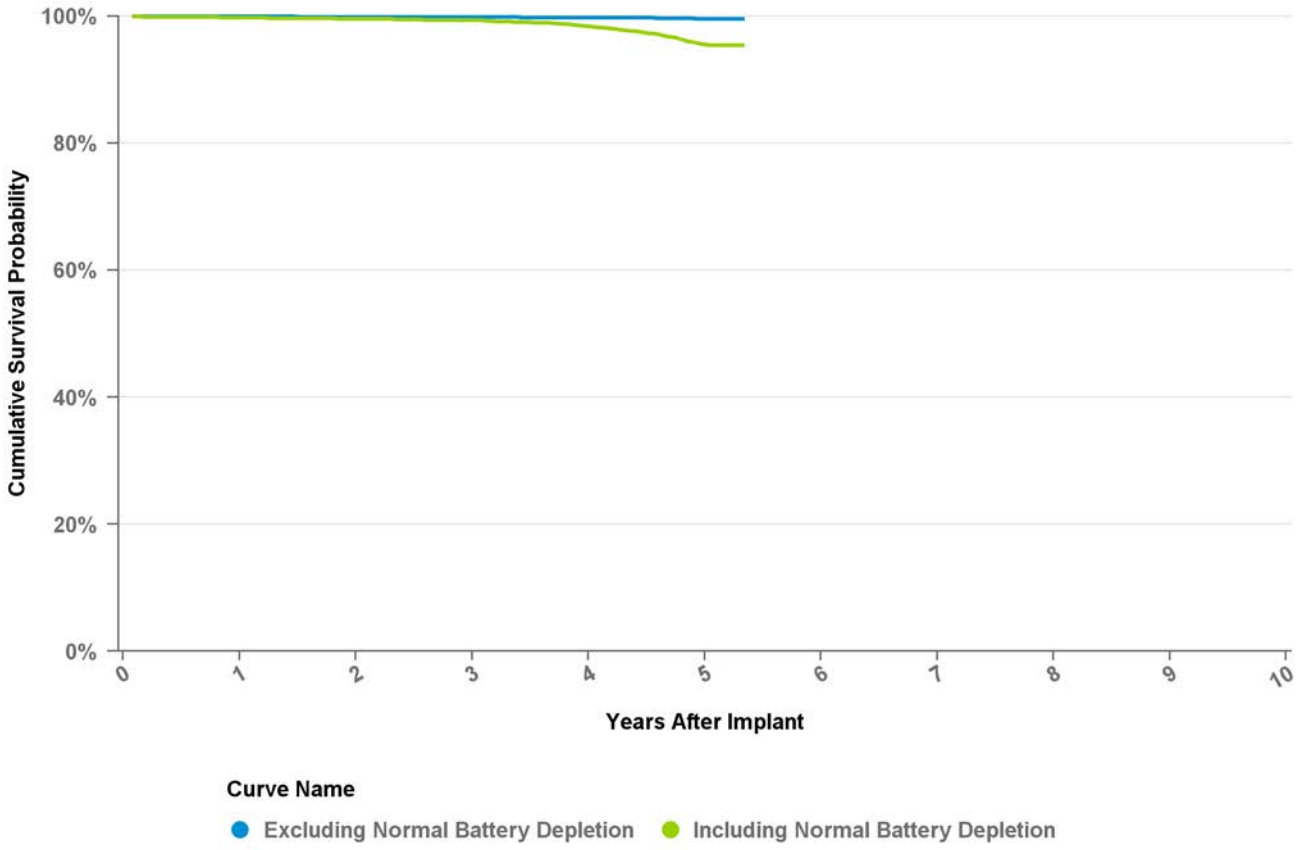
D214DRM Secura DR

US Market Release Date	
CE Market Approval Date	7/22/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, DR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.5%	95.4%
Effective Sample Size	47092	40630	30449	13889	2275	106

Implantable Cardioverter Defibrillator

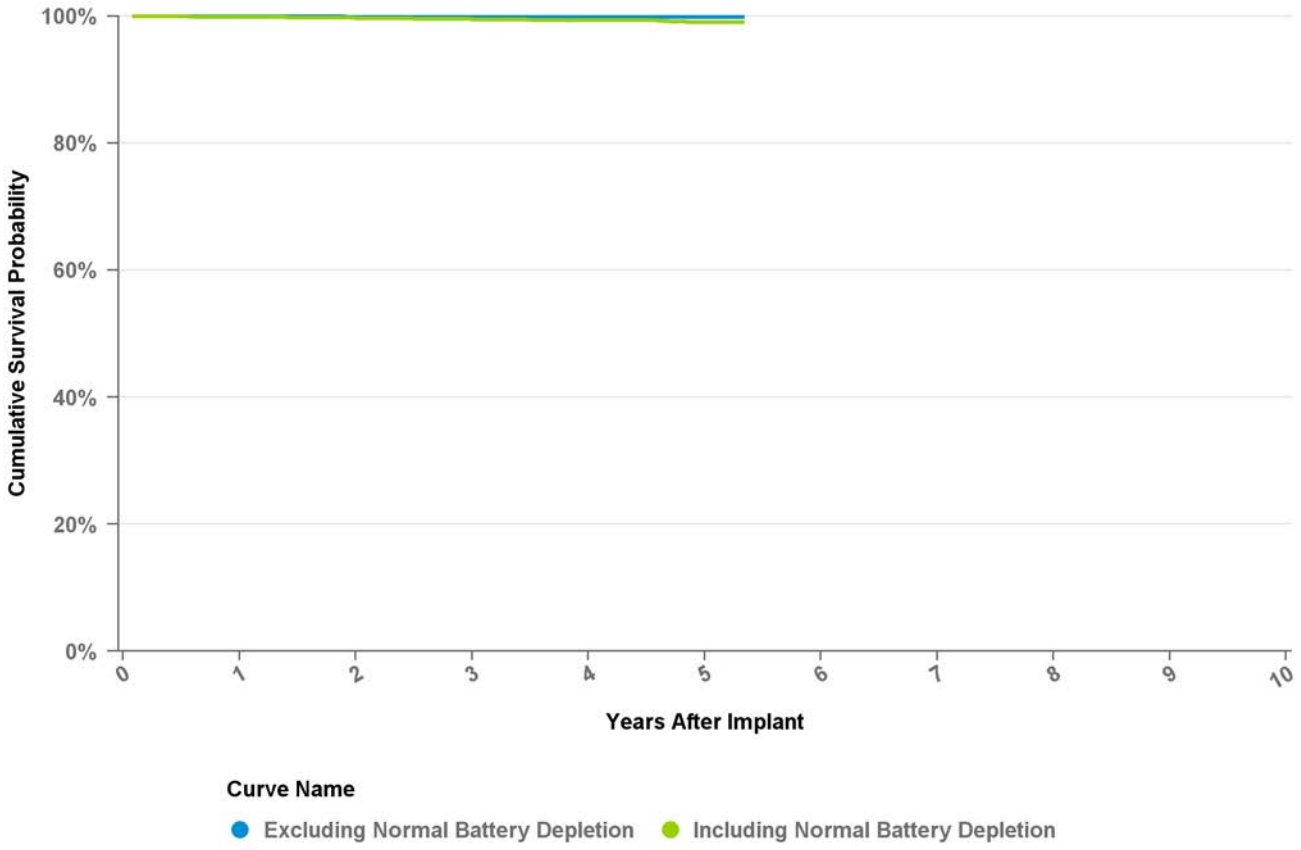
D214VRM Secura VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, VR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	19088	16034	11831	5863	1124	134

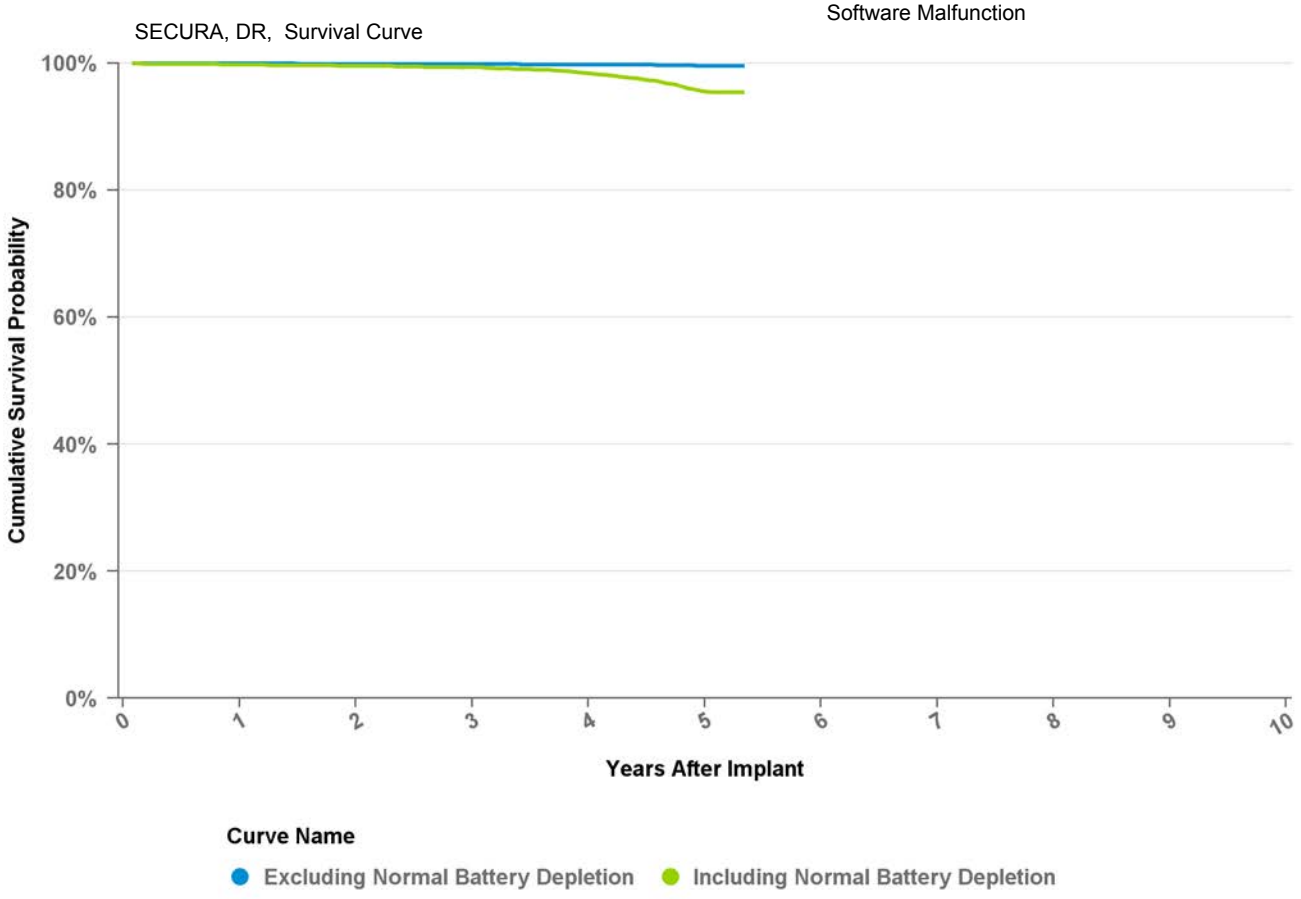
Implantable Cardioverter Defibrillator

D224DRG Secura DR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	49,693
Estimated Active US Implants	40,160
Normal Battery Depletions (US)	338

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	75
Therapy Not Compromised Malfunction	63
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	37
Software Malfunction	9
Therapy Compromised Malfunctions	12
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	1



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.5%	95.4%
Effective Sample Size	47092	40630	30449	13889	2275	106

Implantable Cardioverter Defibrillator

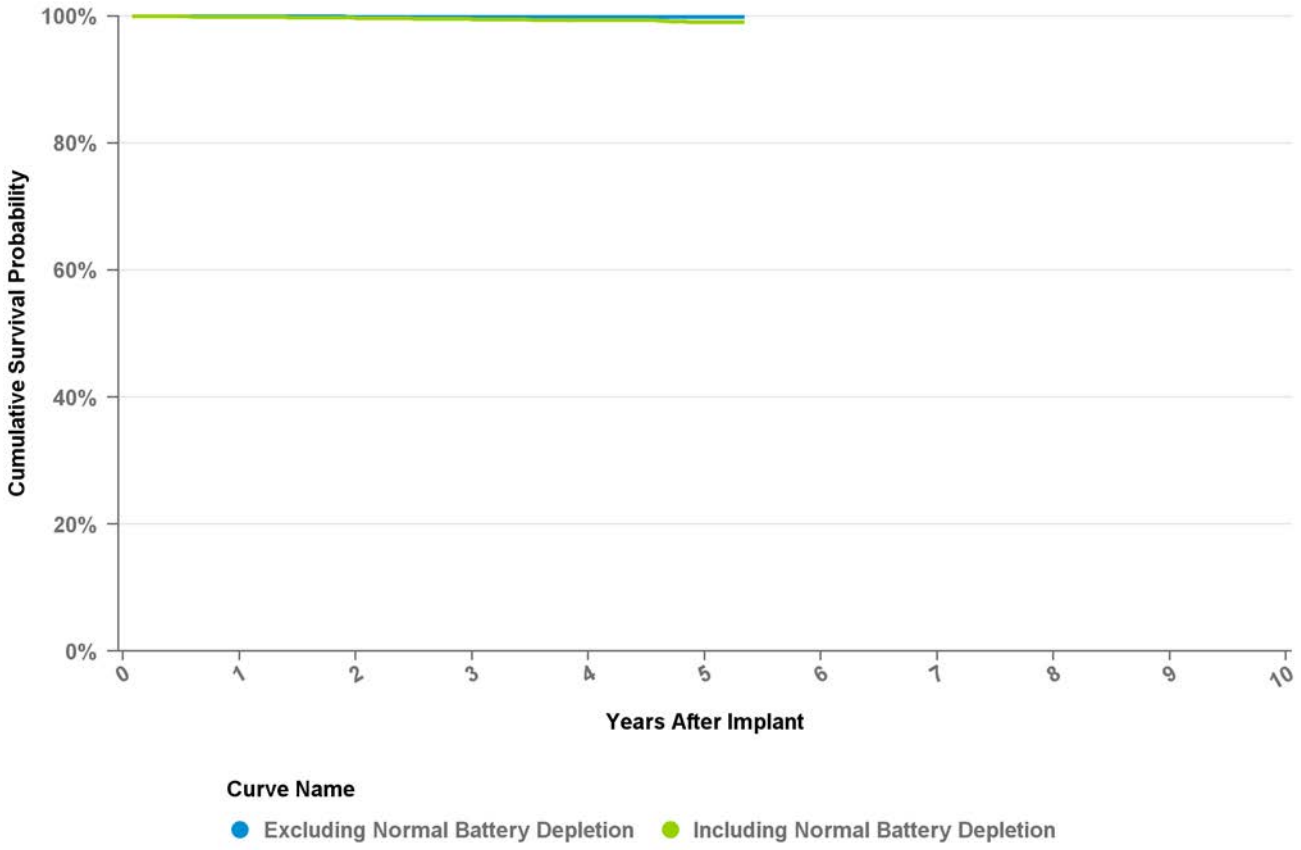
D224VRC Secura VR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	19,910
Estimated Active US Implants	16,240
Normal Battery Depletions (US)	49

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	18
Therapy Not Compromised Malfunction	12
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	7
Software Malfunction	2
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	1

SECURA, VR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	19088	16034	11831	5863	1124	134

Implantable Cardioverter Defibrillator

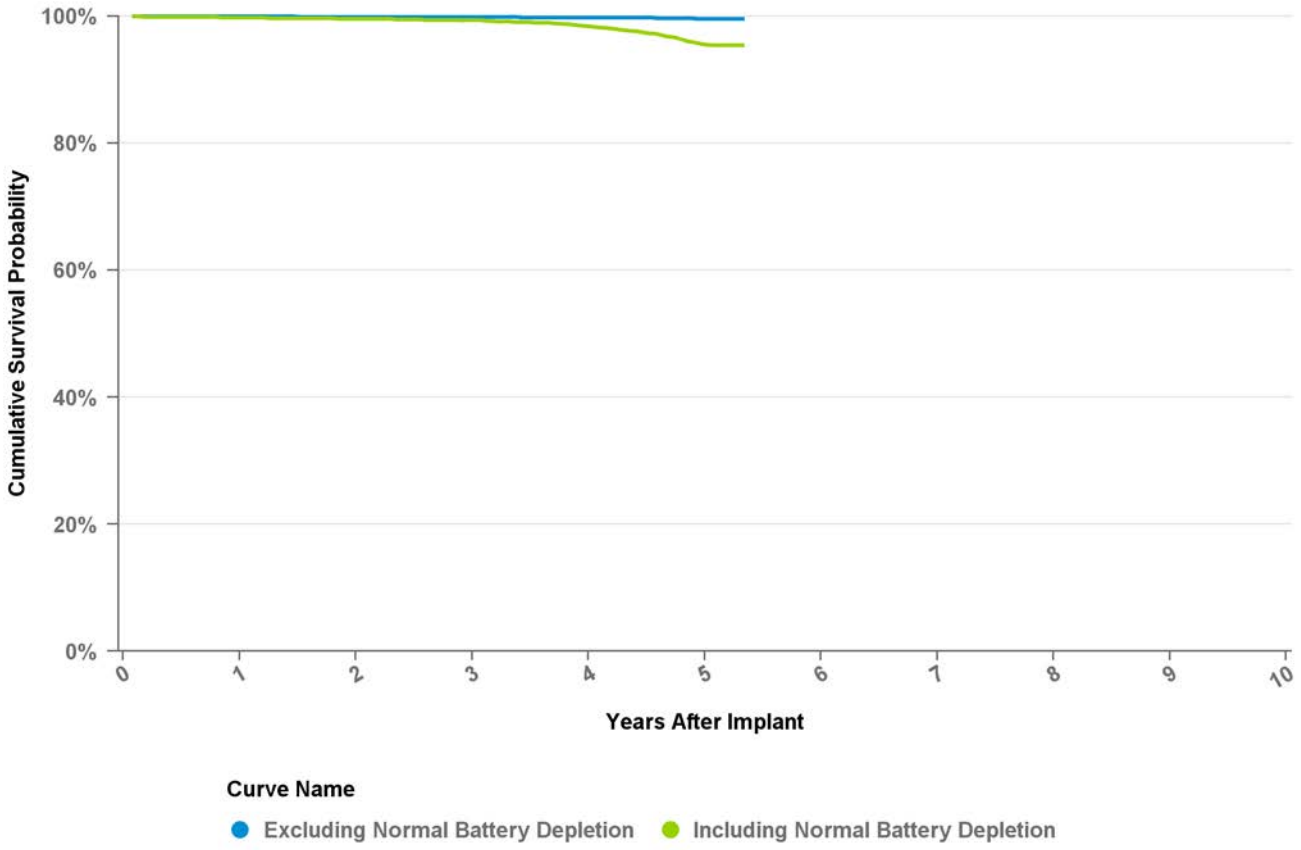
D234DRG Secura DR

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, DR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.5%	95.4%
Effective Sample Size	47092	40630	30449	13889	2275	106

Implantable Cardioverter Defibrillator

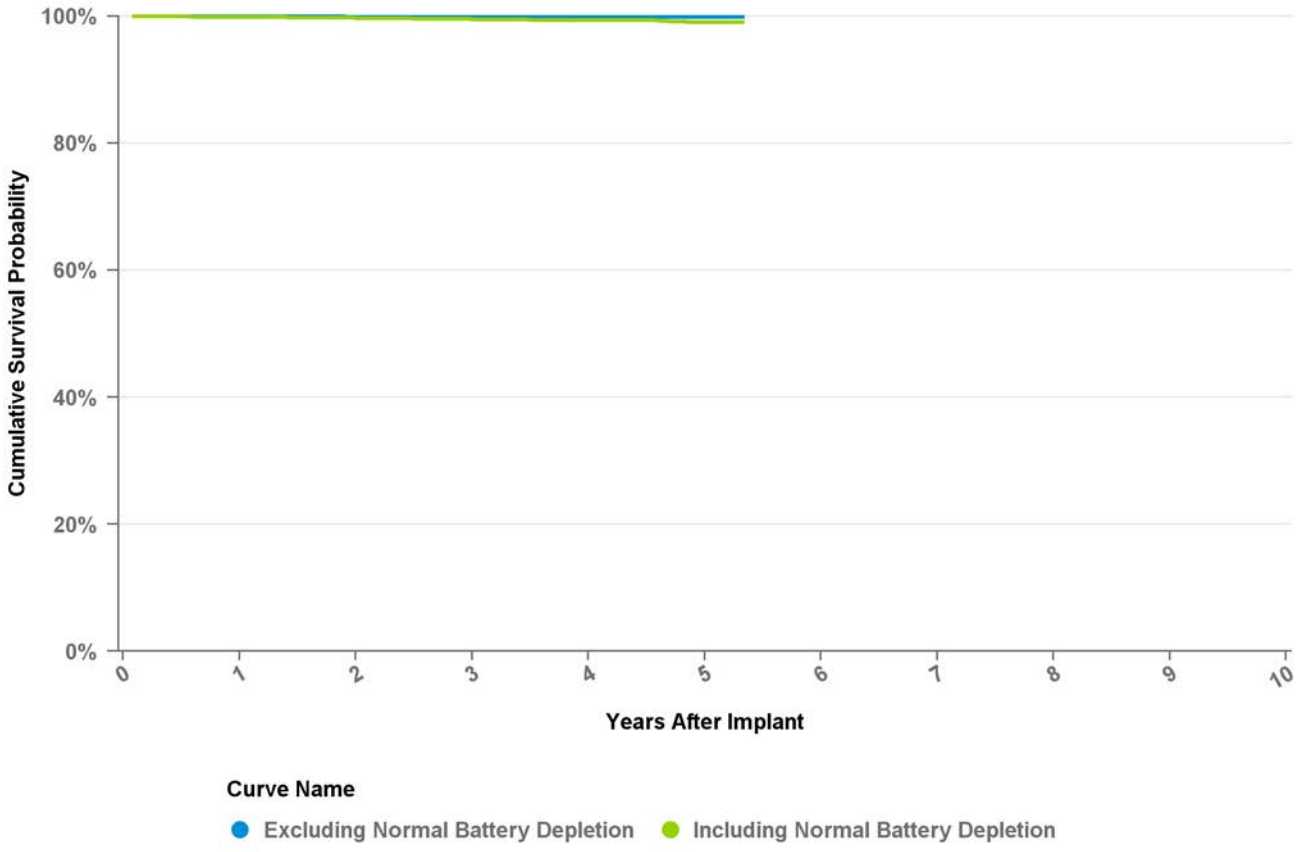
D234VRC Secura VR

US Market Release Date	
CE Market Approval Date	3/14/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SECURA, VR, Survival Curve



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	99.0%
Effective Sample Size	19088	16034	11831	5863	1124	134

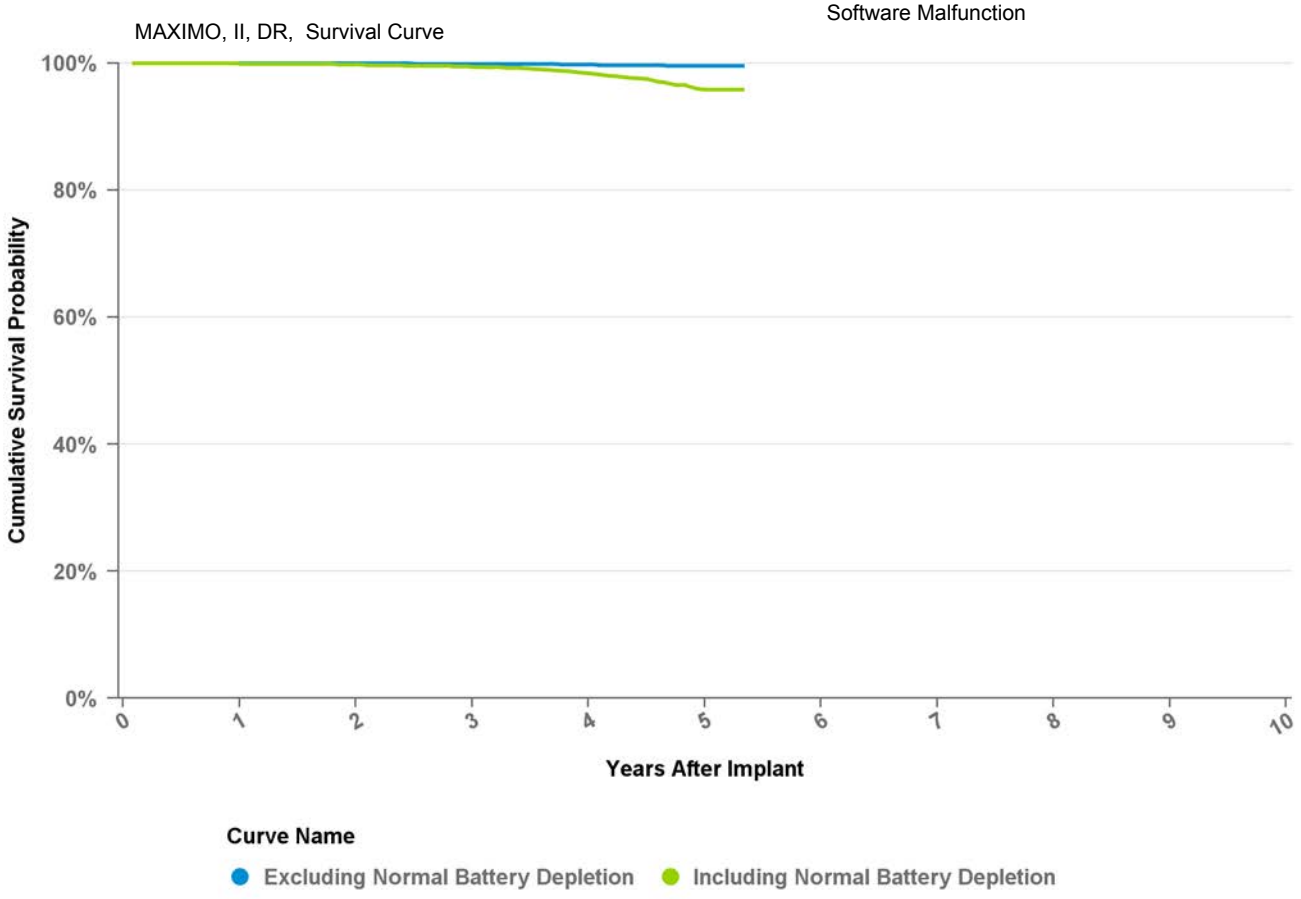
Implantable Cardioverter Defibrillator

D264DRM Maximo II DR

US Market Release Date	1/9/2012
CE Market Approval Date	7/22/2010
Registered US Implants	6
Estimated Active US Implants	6
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.8%	95.8%
Effective Sample Size	18445	15627	11658	6404	1351	124

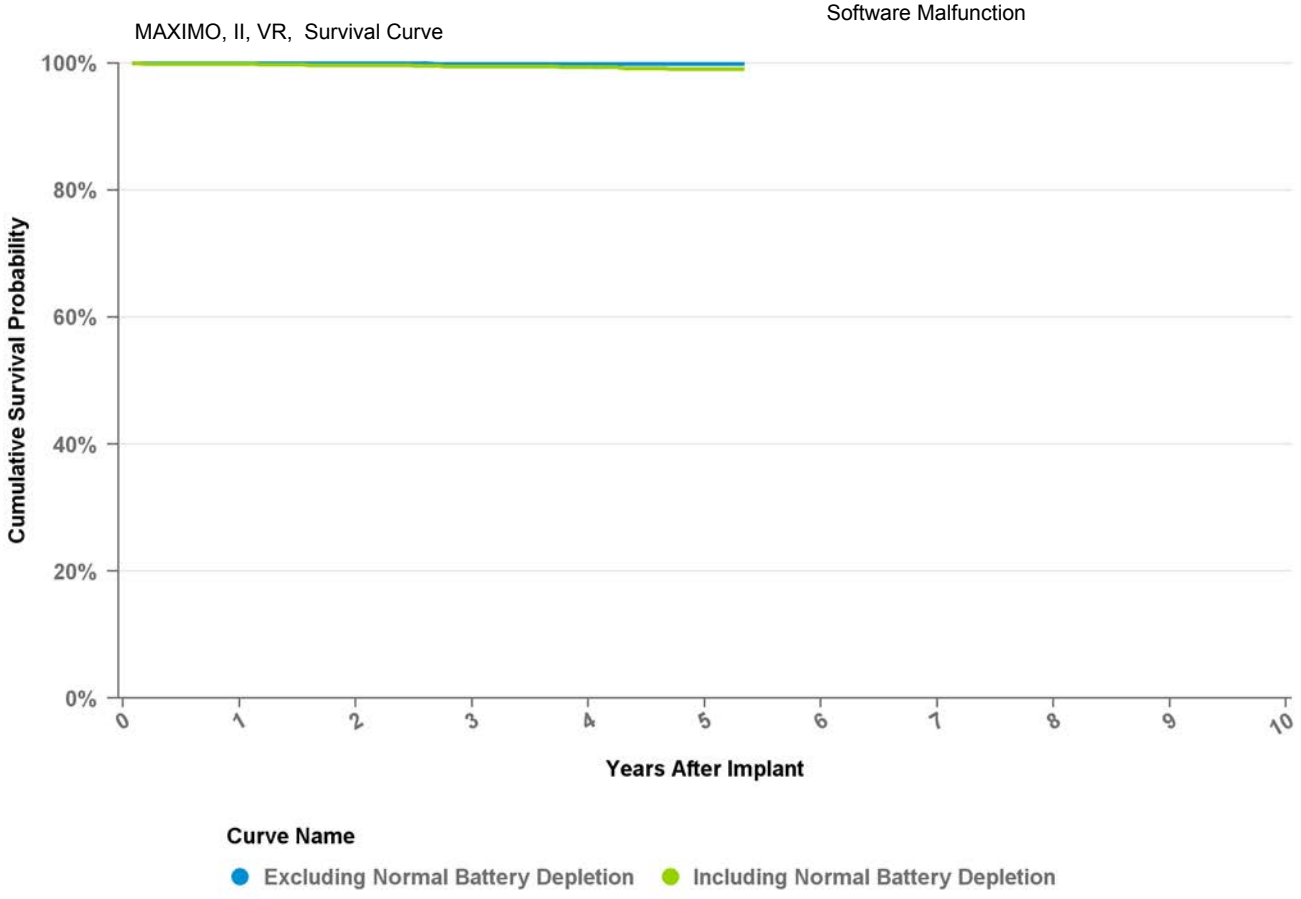
Implantable Cardioverter Defibrillator

D264VRM Maximo II VR

US Market Release Date	5/2/2012
CE Market Approval Date	12/17/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.4%	99.0%	99.0%
Effective Sample Size	12480	10479	7652	4141	819	100

Implantable Cardioverter Defibrillator

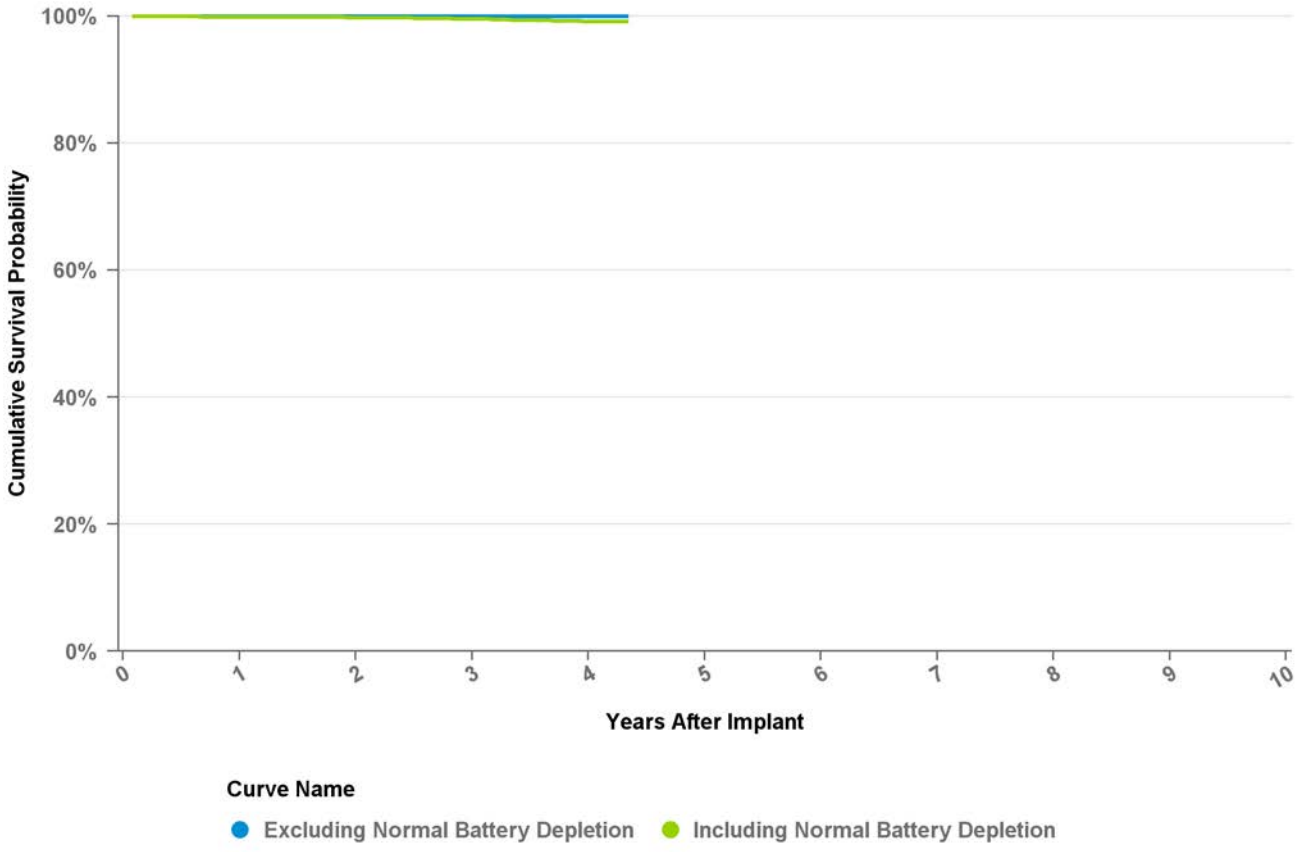
D274DRG Virtuoso II DR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	22,213
Estimated Active US Implants	18,305
Normal Battery Depletions (US)	62

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	6
Therapy Not Compromised Malfunction	5
Battery Malfunction	2
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	1
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

VIRTUOSO, II, DR, Survival Curve



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.6%	99.1%	99.1%
Effective Sample Size	20623	19032	13088	2742	303

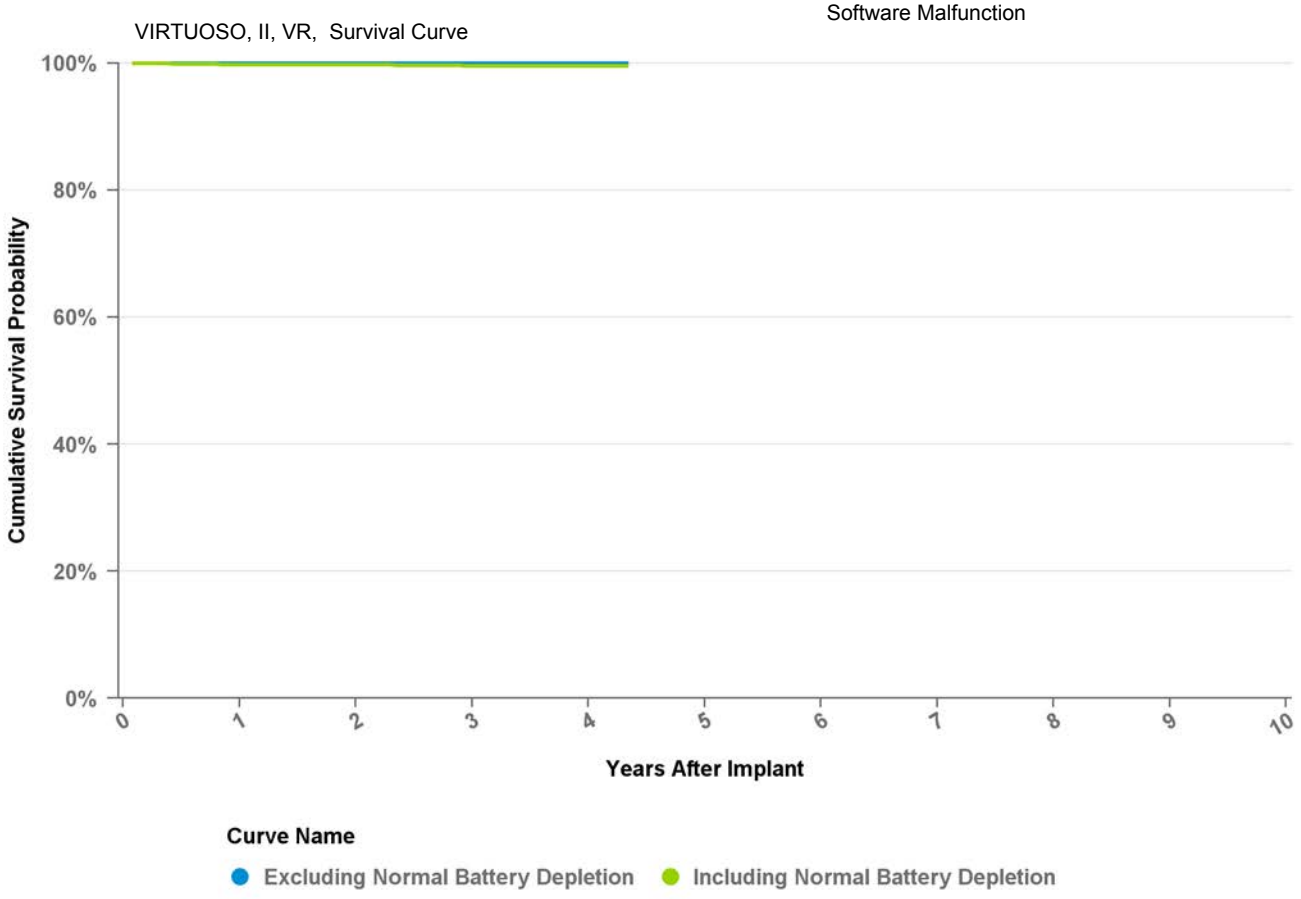
Implantable Cardioverter Defibrillator

D274VRC Virtuoso II VR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	9,111
Estimated Active US Implants	7,666
Normal Battery Depletions (US)	15

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	3
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	1
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.6%	99.6%	99.6%
Effective Sample Size	8631	7969	5305	1089	133

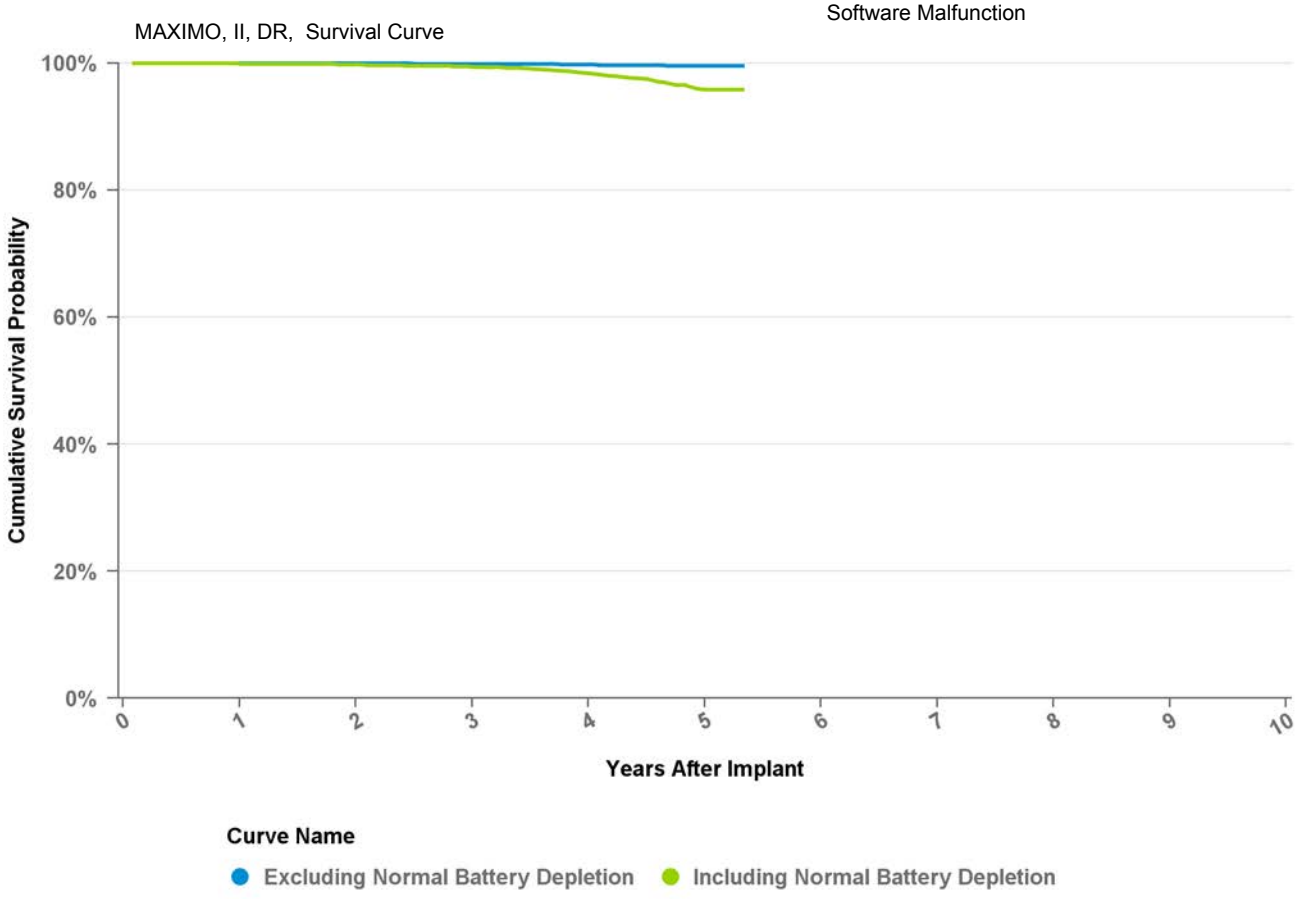
Implantable Cardioverter Defibrillator

D284DRG Maximo II DR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	19,956
Estimated Active US Implants	16,154
Normal Battery Depletions (US)	131

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	34
Therapy Not Compromised Malfunction	29
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	26
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.6%	99.6%
Including NBD	99.9%	99.8%	99.4%	98.4%	95.8%	95.8%
Effective Sample Size	18445	15627	11658	6404	1351	124

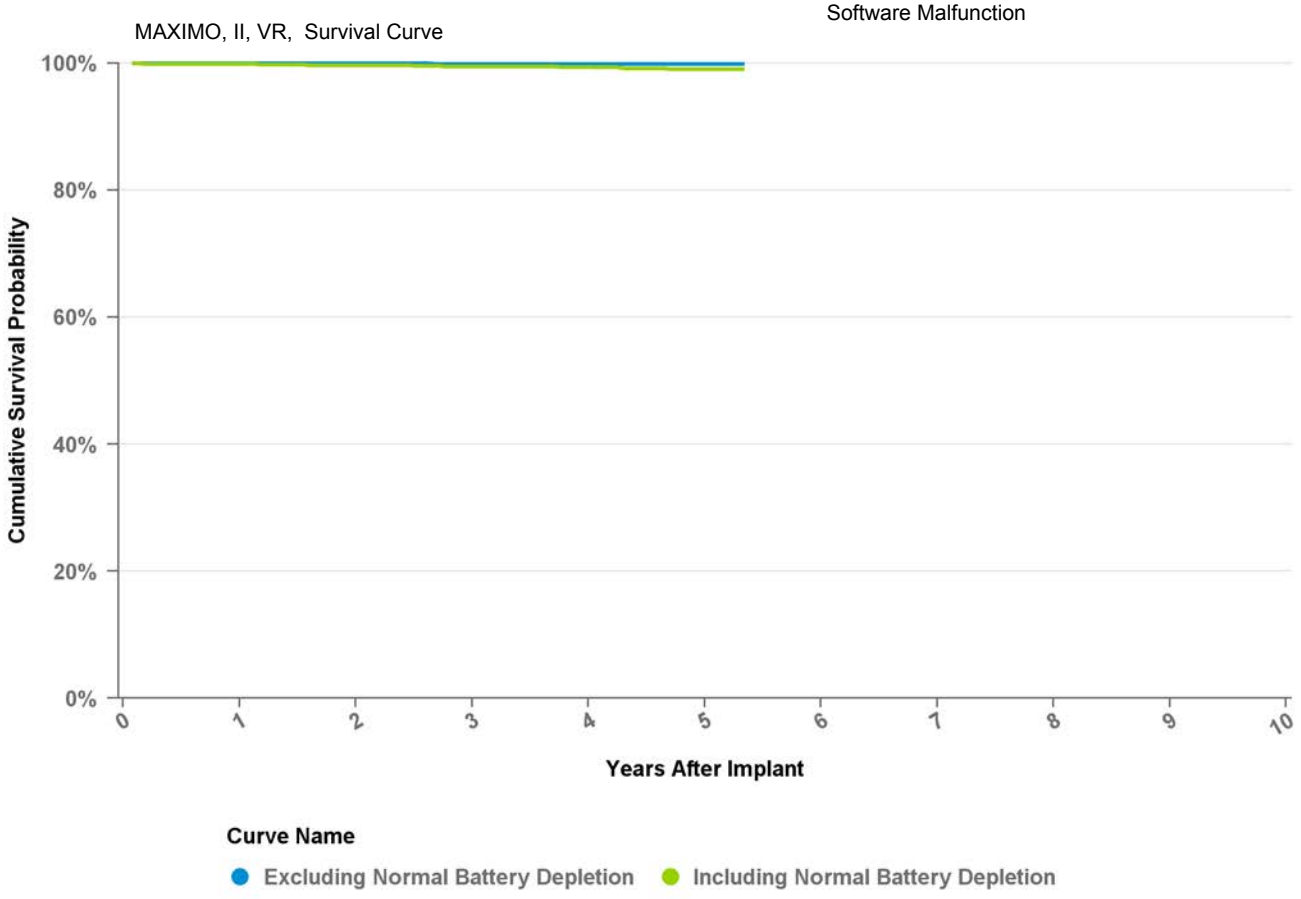
Implantable Cardioverter Defibrillator

D284VRC Maximo II VR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	12,898
Estimated Active US Implants	10,655
Normal Battery Depletions (US)	34

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	11
Therapy Not Compromised Malfunction	8
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	3
Software Malfunction	2
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	1



Years	1	2	3	4	5	at 64 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.4%	99.0%	99.0%
Effective Sample Size	12480	10479	7652	4141	819	100

Implantable Cardioverter Defibrillator

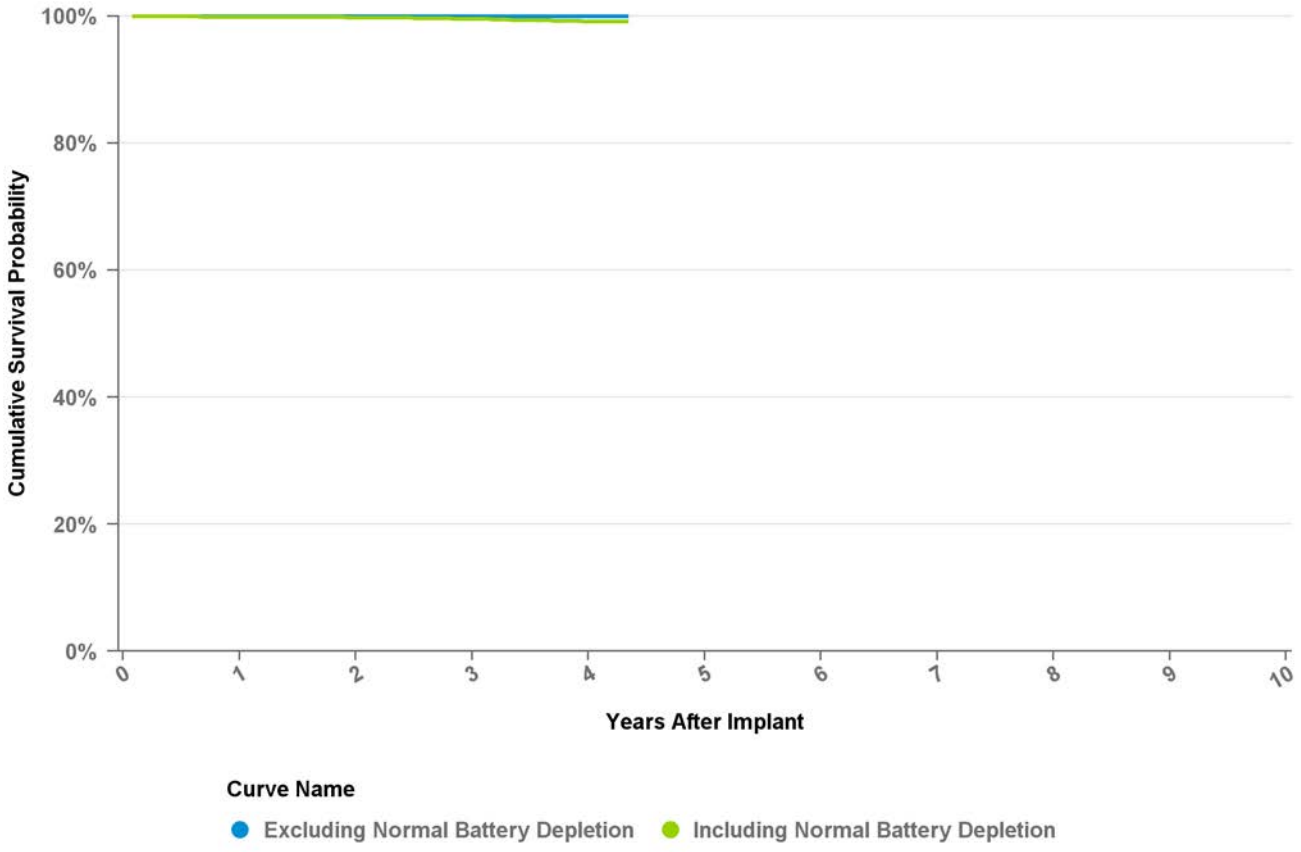
D294DRG Virtuoso II DR

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

VIRTUOSO, II, DR, Survival Curve



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.6%	99.1%	99.1%
Effective Sample Size	20623	19032	13088	2742	303

Implantable Cardioverter Defibrillator

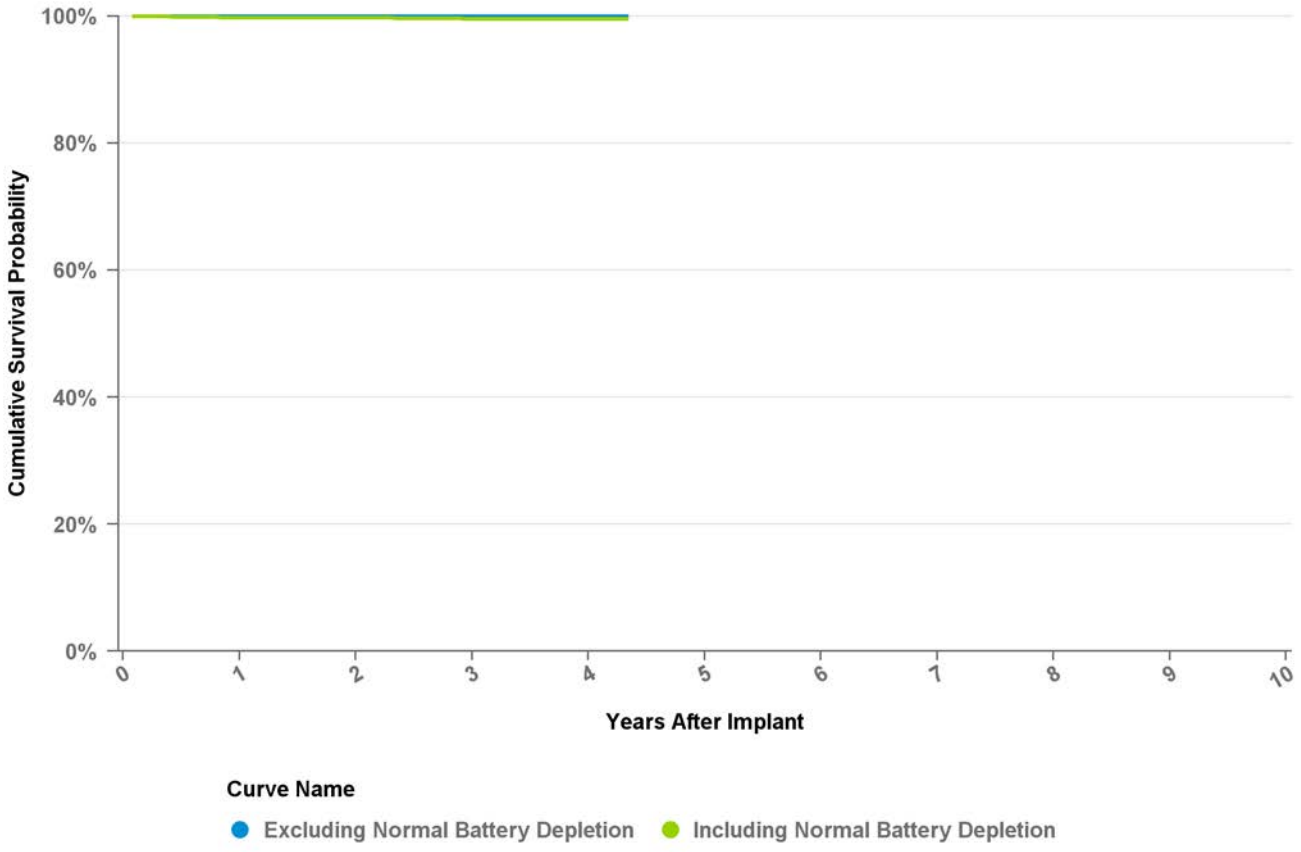
D294VRC Virtuoso II VR

US Market Release Date	
CE Market Approval Date	8/20/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

VIRTUOSO, II, VR, Survival Curve



Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.8%	99.6%	99.6%	99.6%
Effective Sample Size	8631	7969	5305	1089	133

Implantable Cardioverter Defibrillator

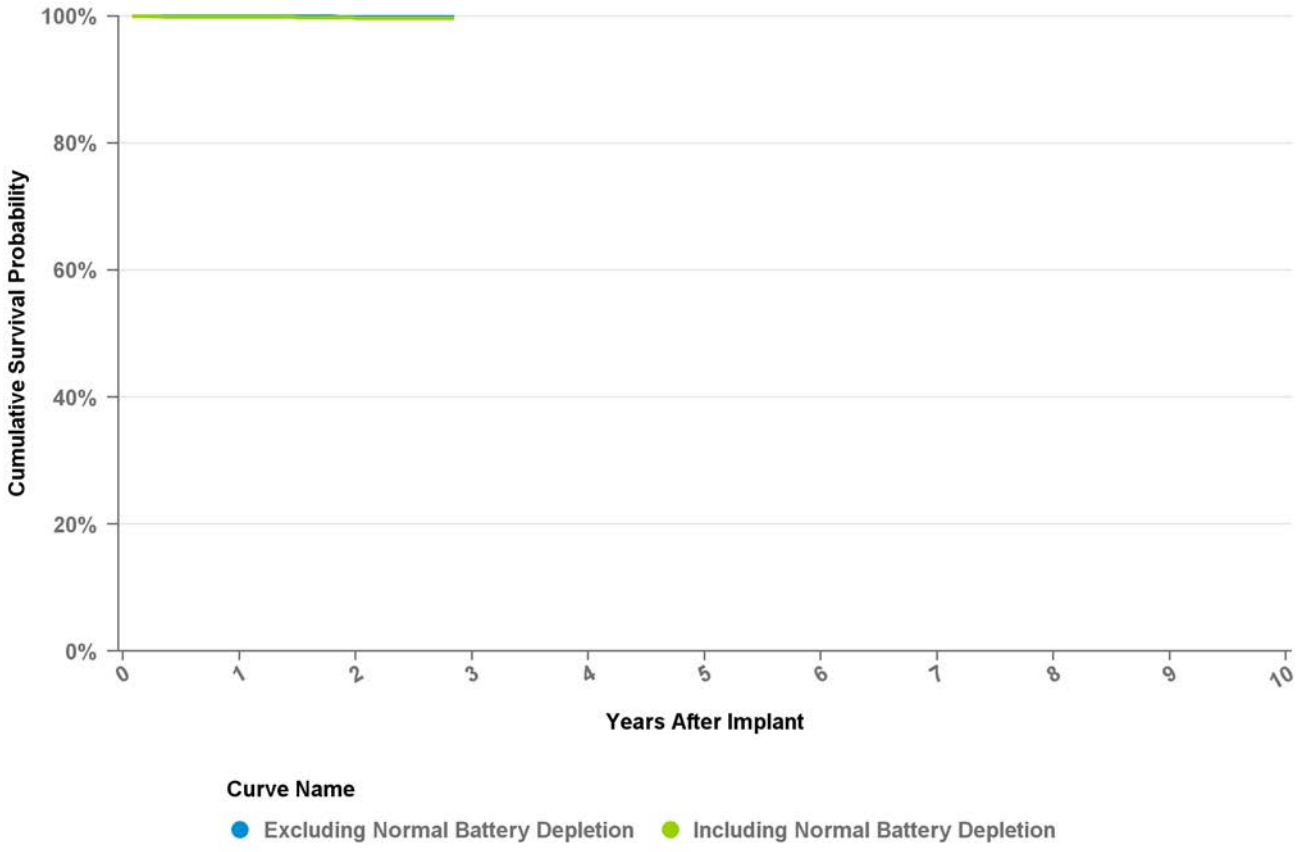
D314DRG Protecta XT DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	33,082
Estimated Active US Implants	30,818
Normal Battery Depletions (US)	23

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	13
Therapy Not Compromised Malfunction	9
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

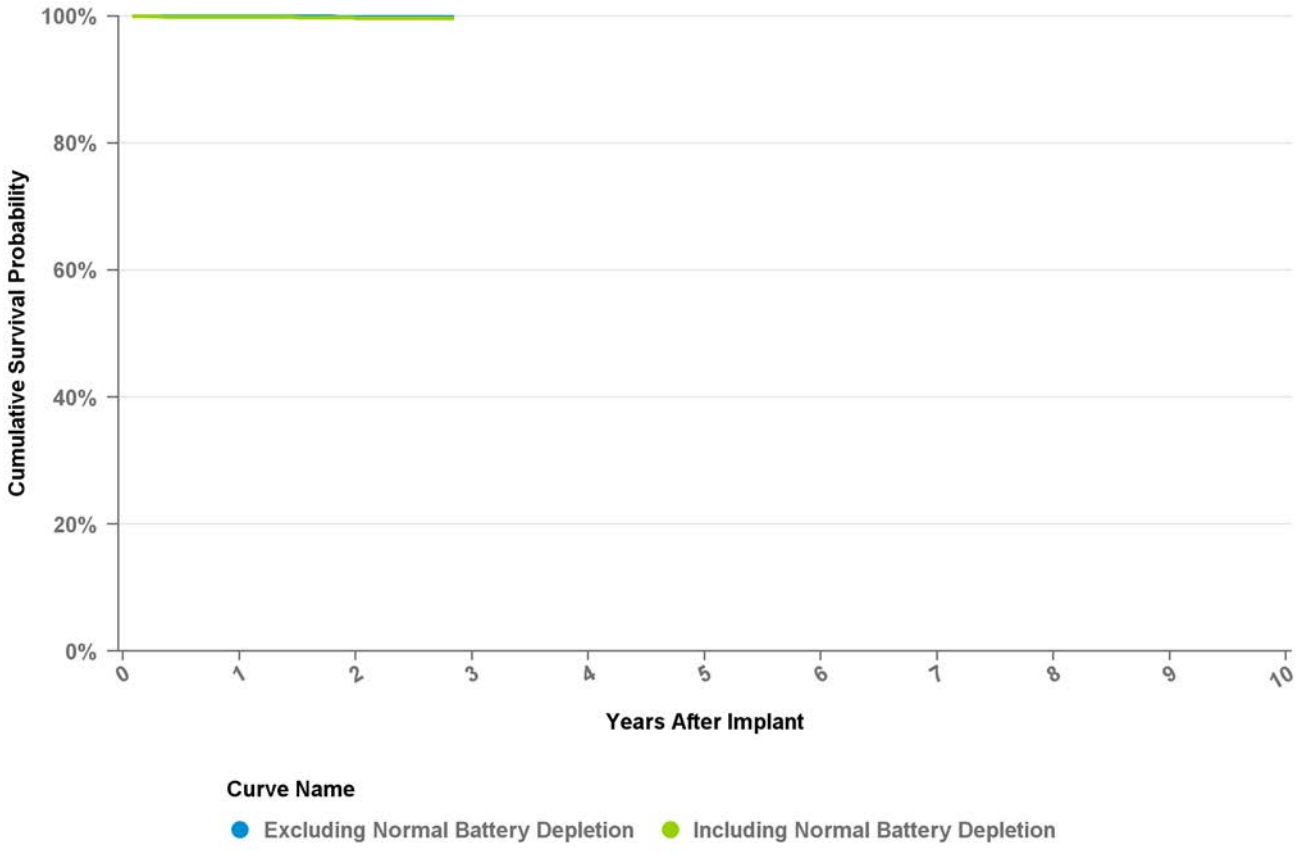
D314DRM Protecta XT DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	13,069
Estimated Active US Implants	12,516
Normal Battery Depletions (US)	5

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	3
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

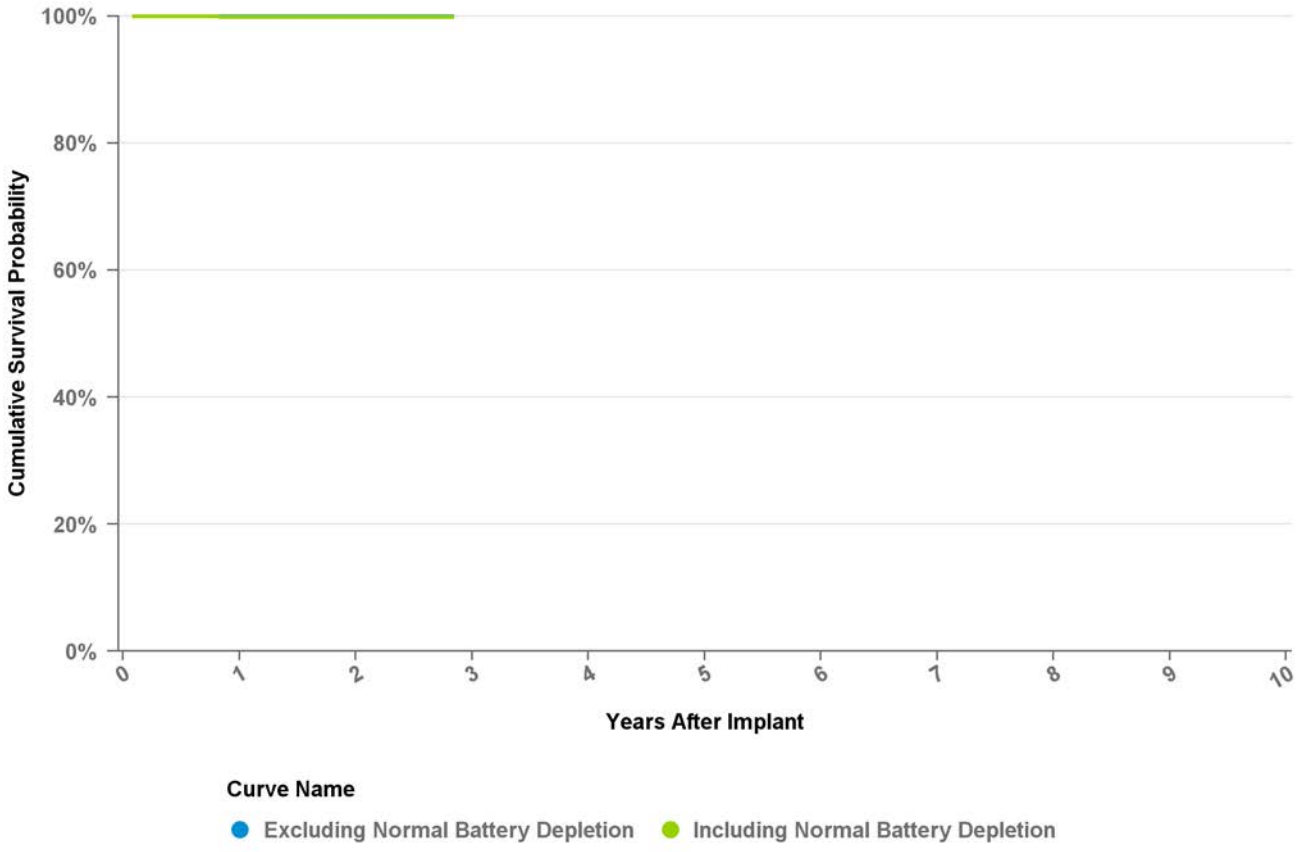
D314VRG Protecta XT VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	13,234
Estimated Active US Implants	12,365
Normal Battery Depletions (US)	7

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxVRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

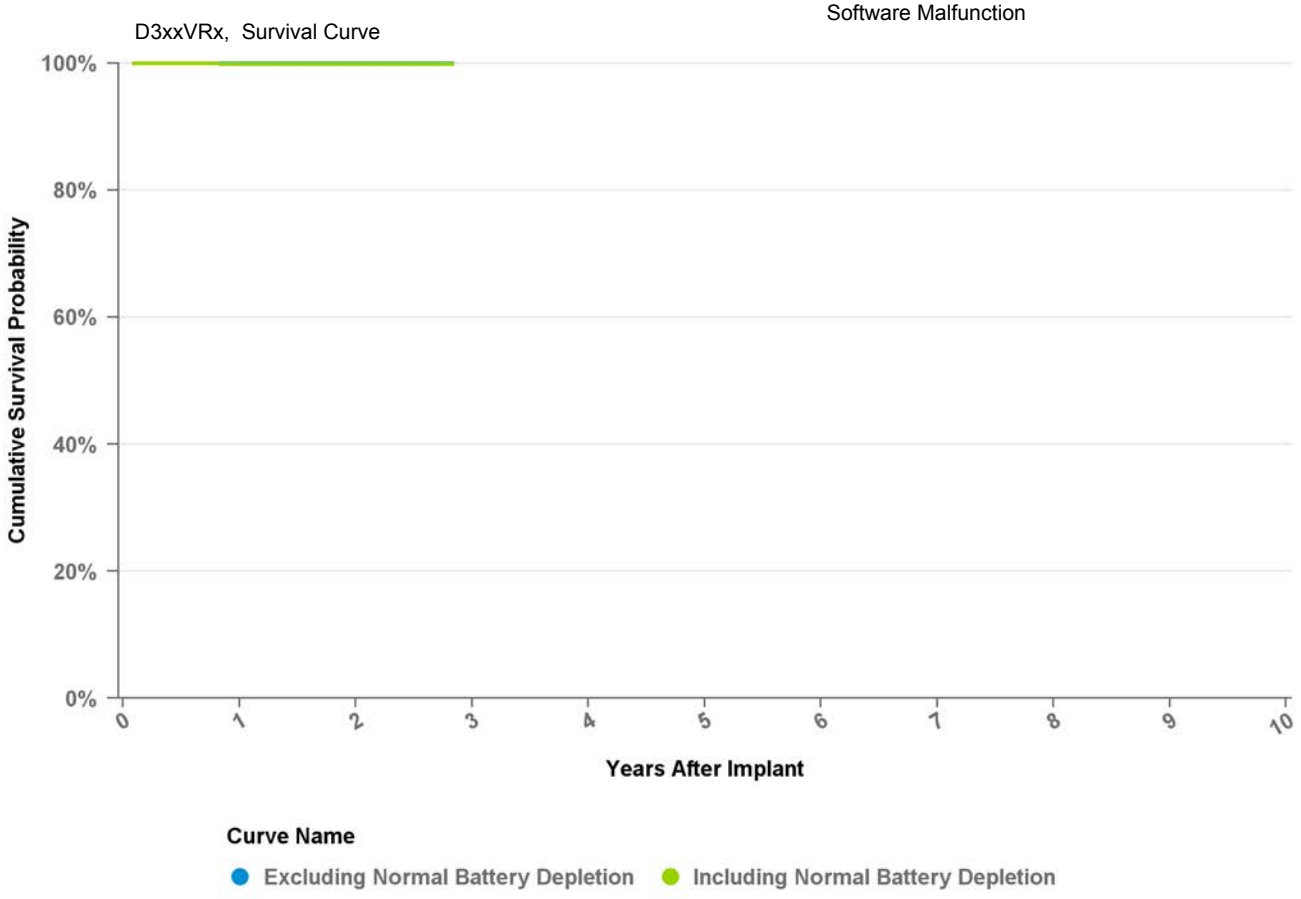
Implantable Cardioverter Defibrillator

D314VRM Protecta XT VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	6,797
Estimated Active US Implants	6,550
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

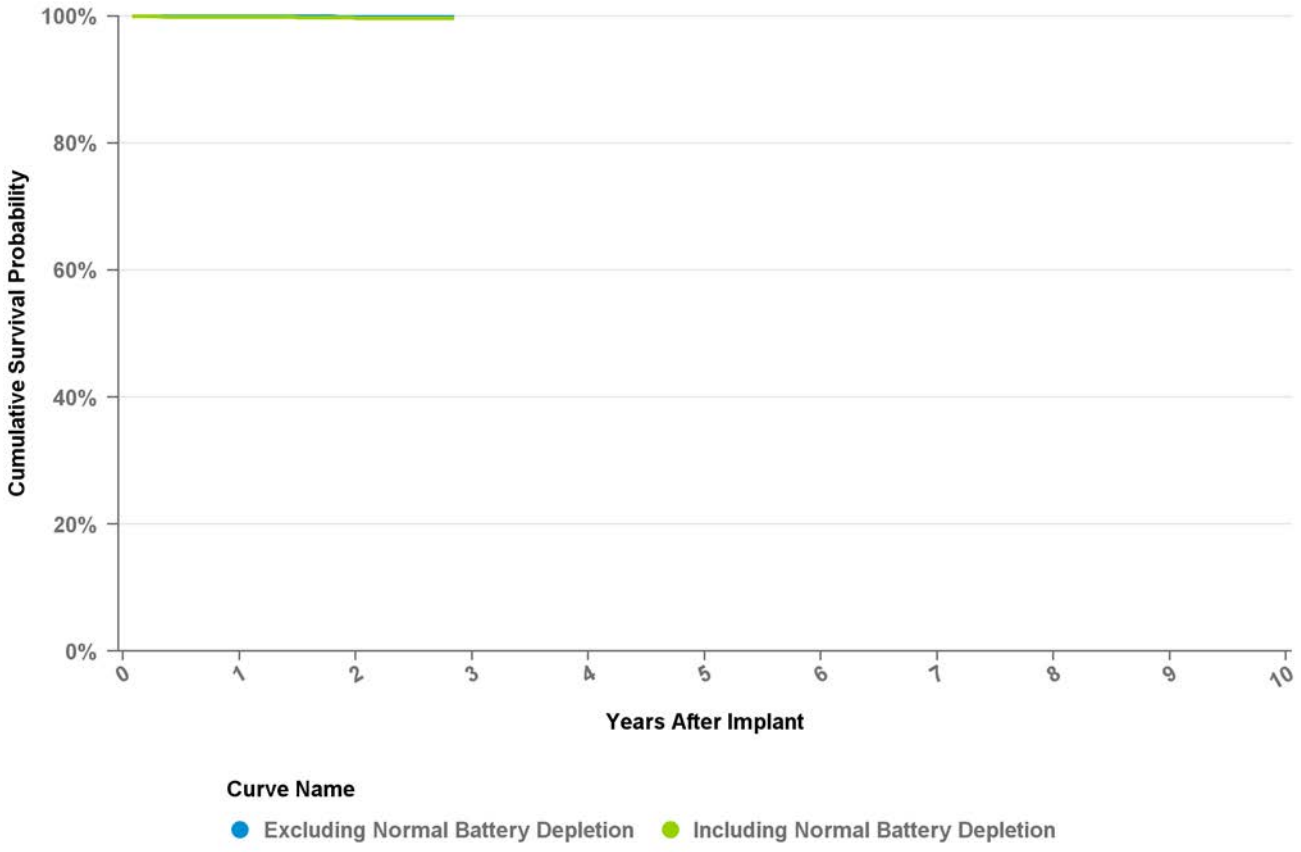
D334DRG Protecta DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	9,693
Estimated Active US Implants	9,076
Normal Battery Depletions (US)	10

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	8
Therapy Not Compromised Malfunction	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

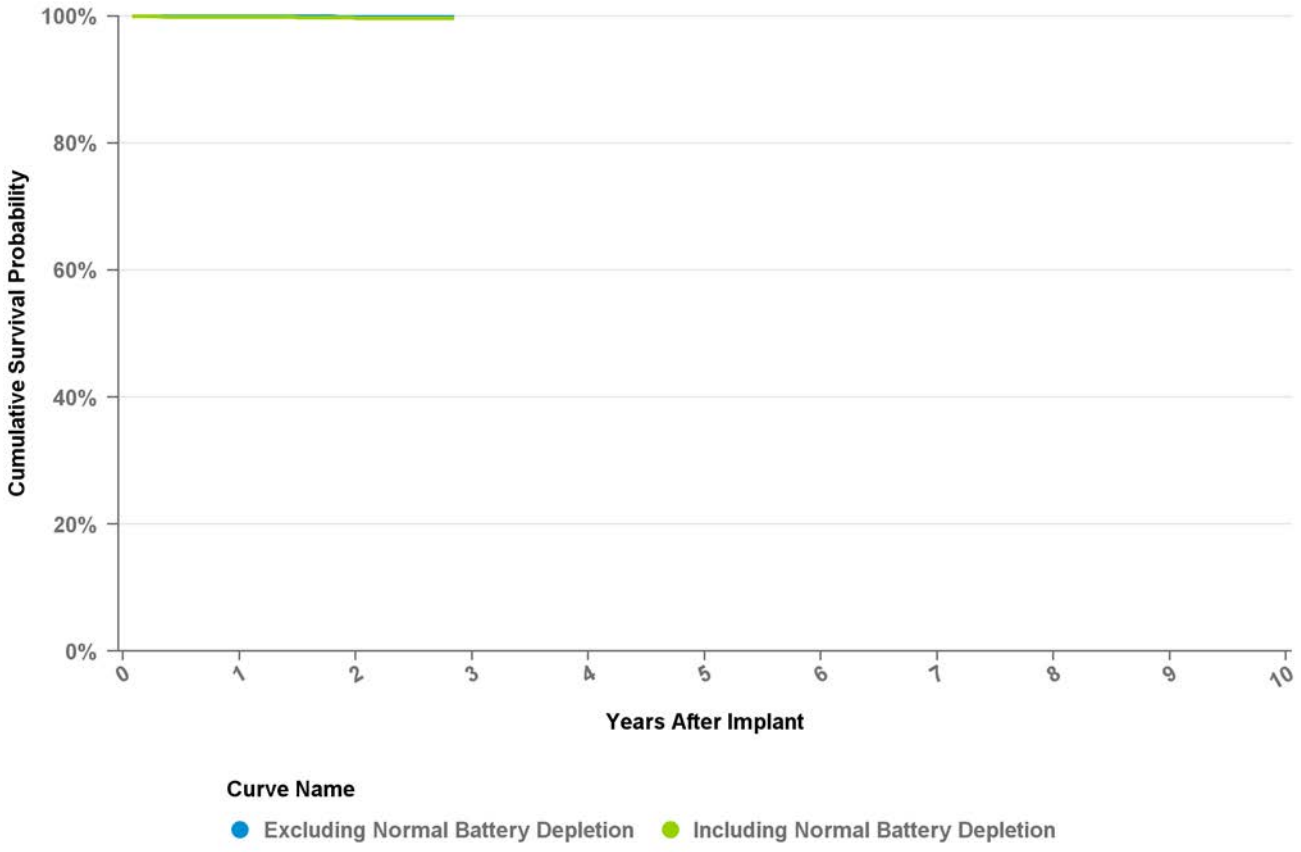
D334DRM Protecta DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	2,616
Estimated Active US Implants	2,518
Normal Battery Depletions (US)	3

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

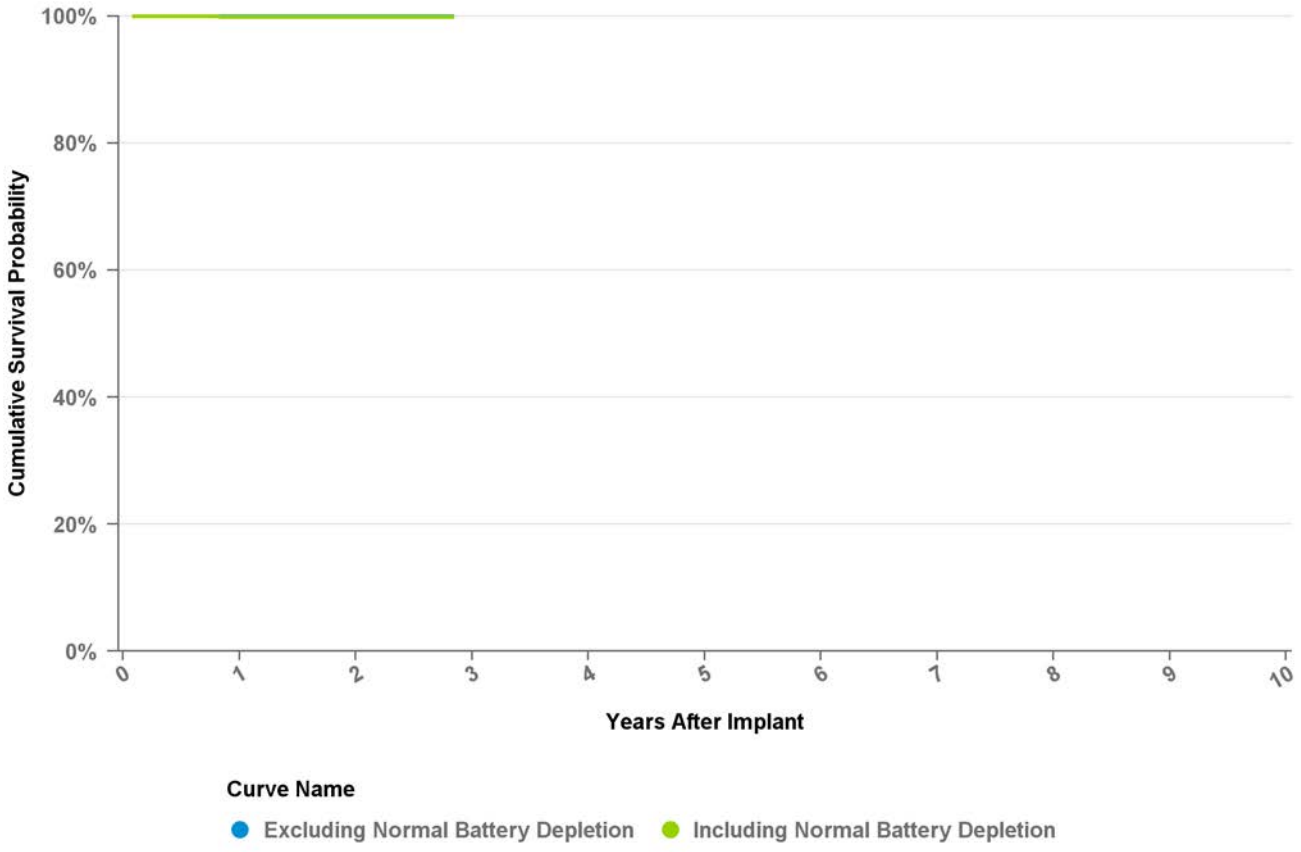
D334VRG Protecta VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	5,612
Estimated Active US Implants	5,270
Normal Battery Depletions (US)	2

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxVRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

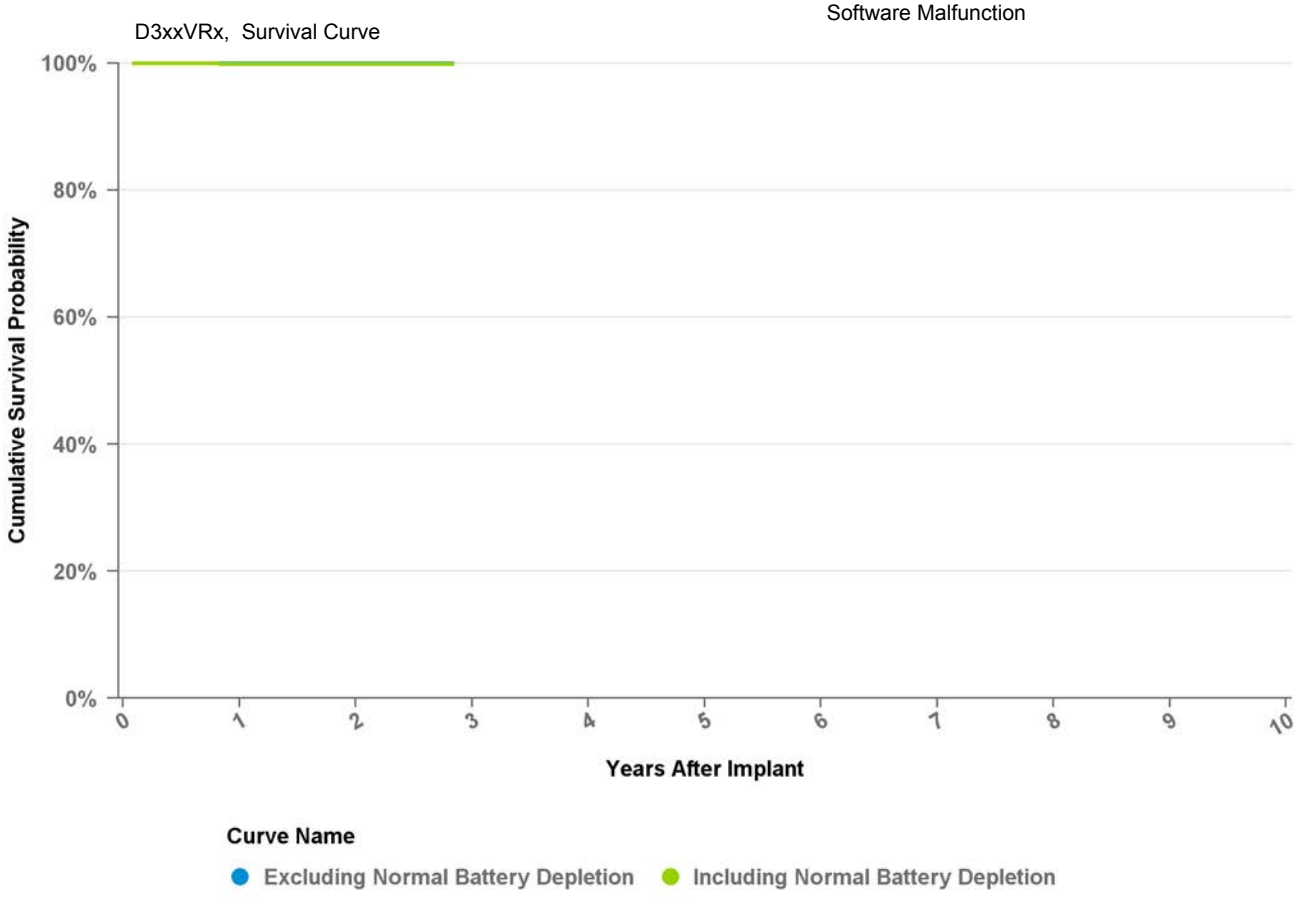
Implantable Cardioverter Defibrillator

D334VRM Protecta VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	1,876
Estimated Active US Implants	1,815
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

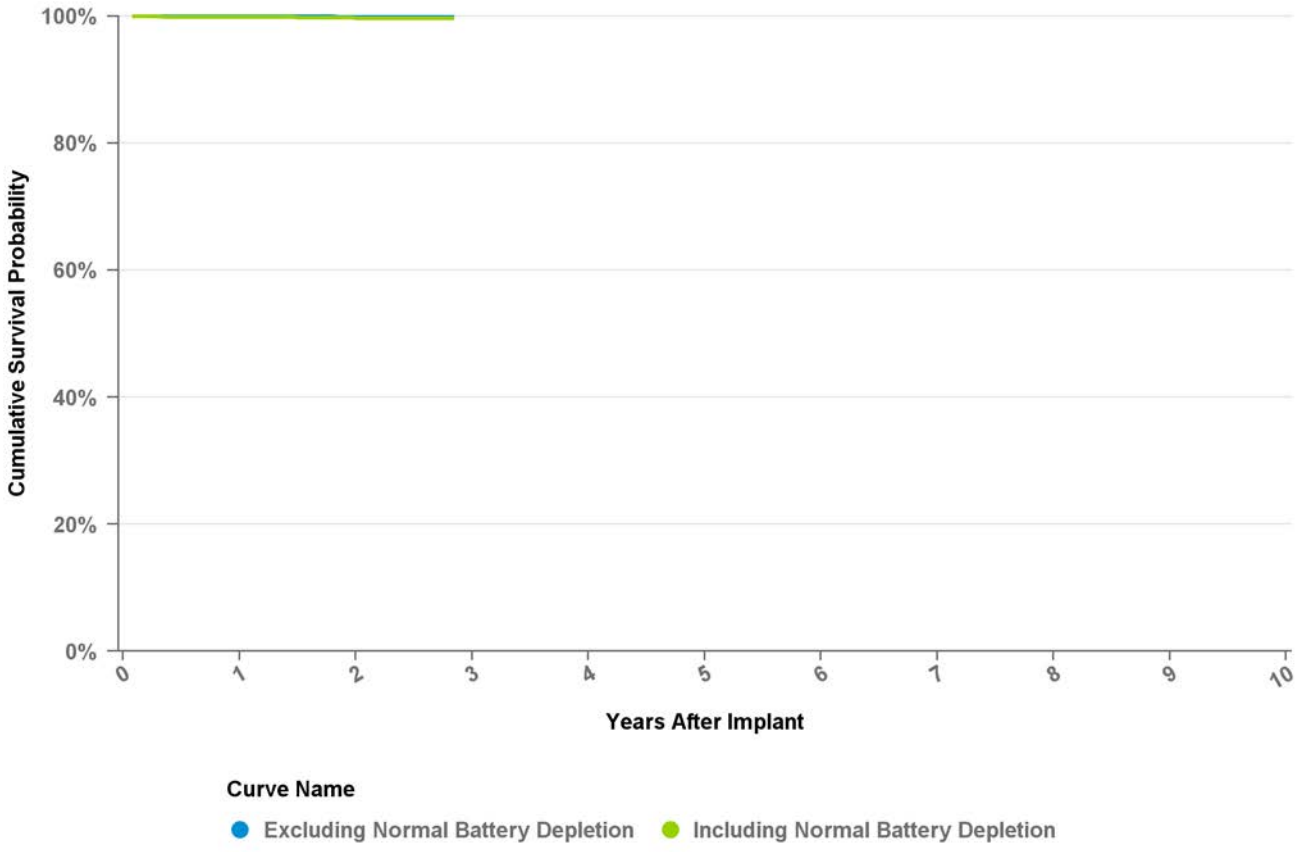
D354DRG Protecta XT DR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

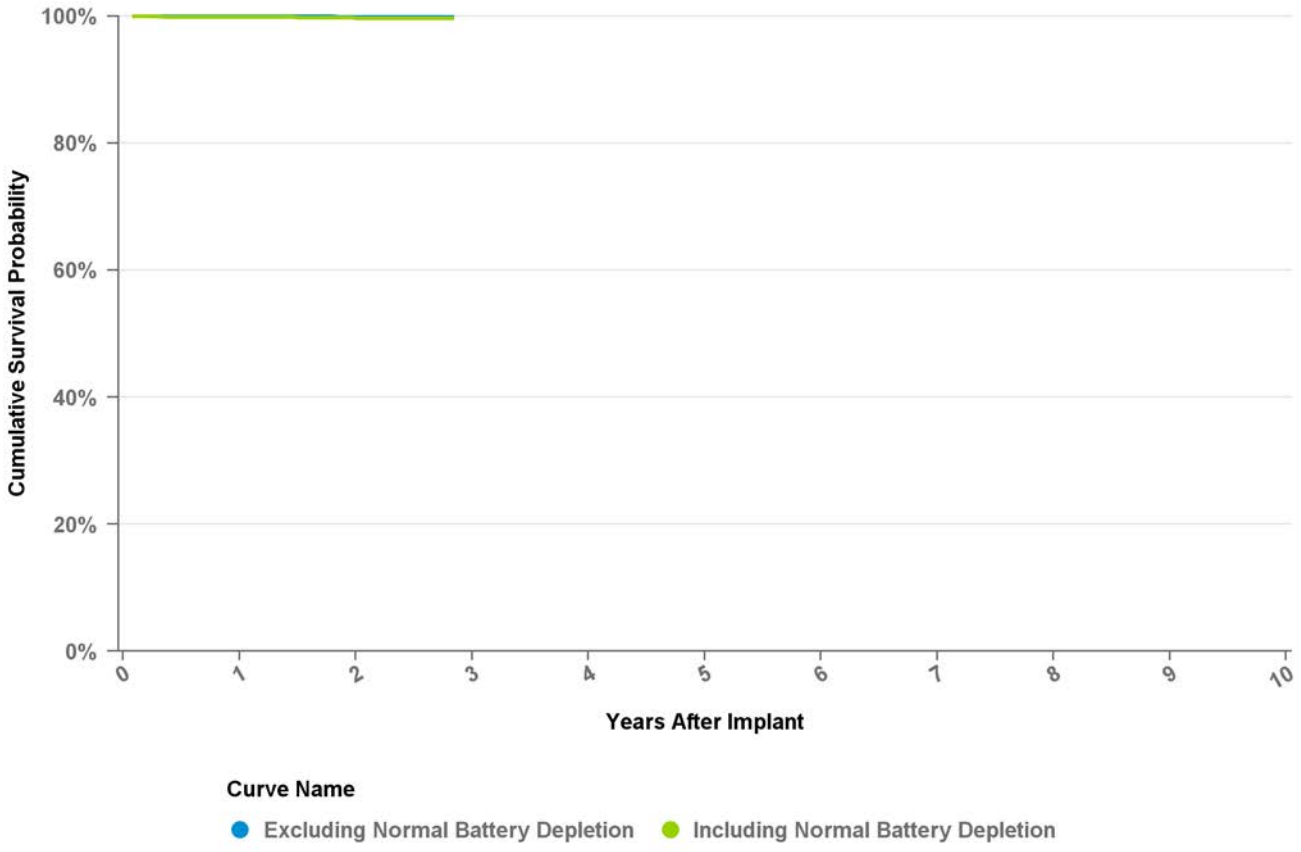
D354DRM Protecta XT DR

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

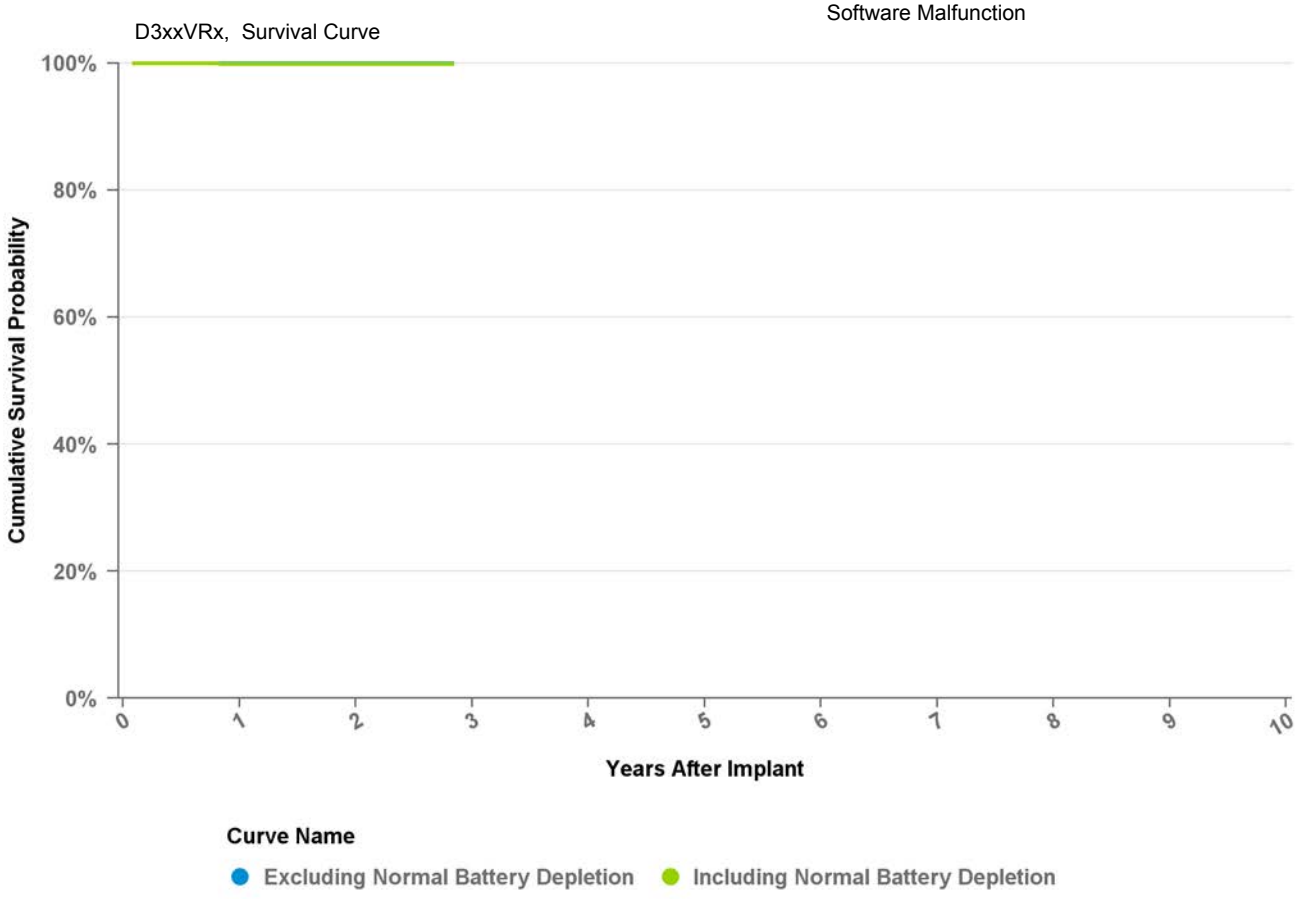
Implantable Cardioverter Defibrillator

D354VRG Protecta XT VR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

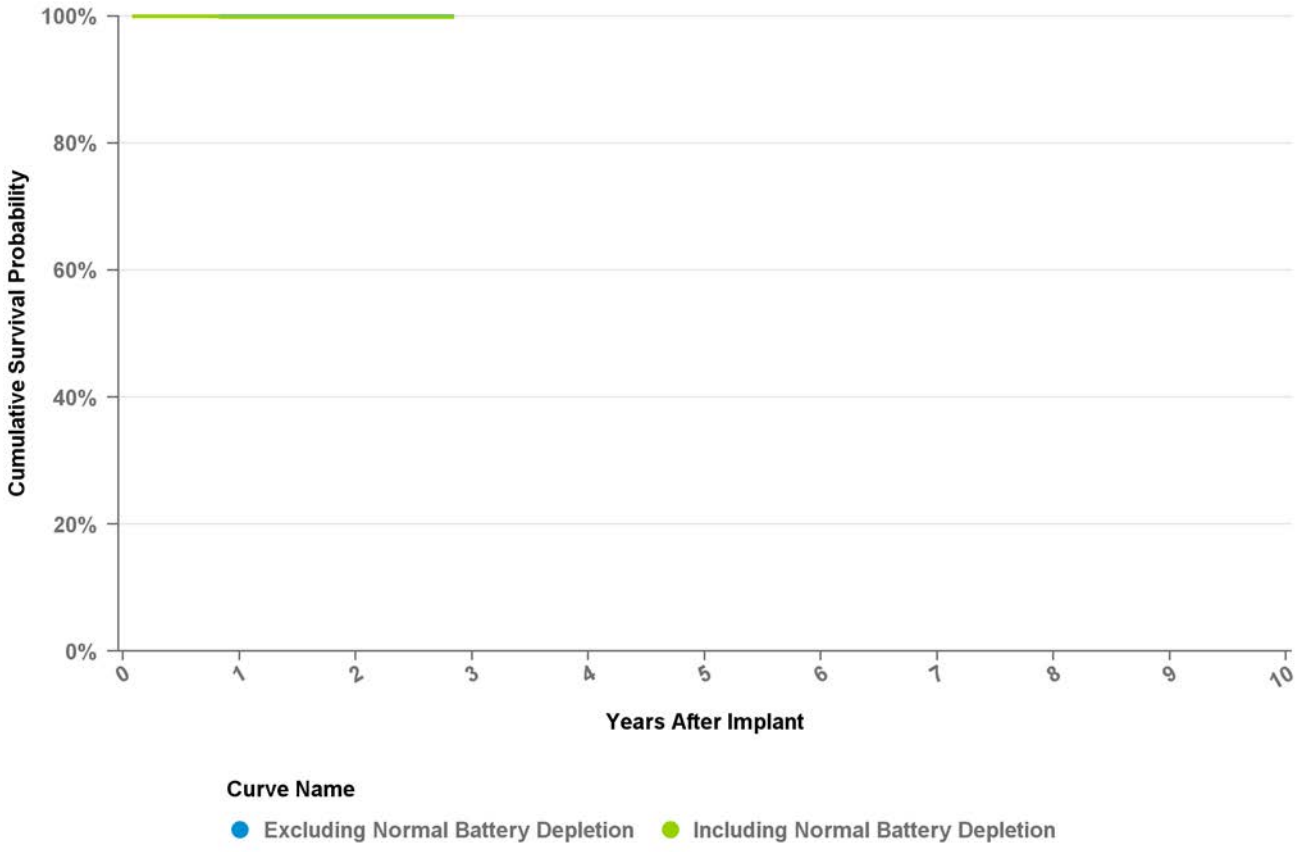
D354VRM Protecta XT VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxVRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

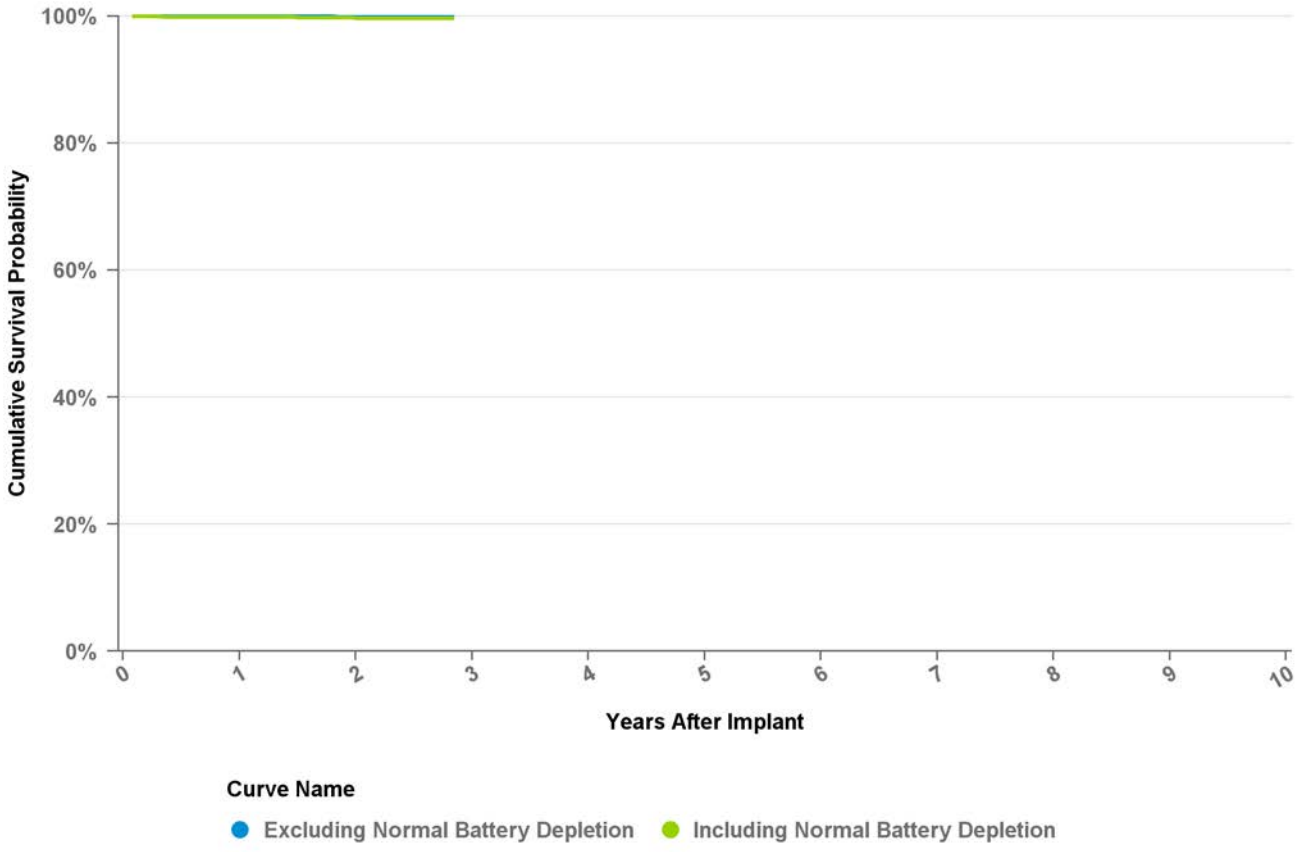
D364DRG Protecta DR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

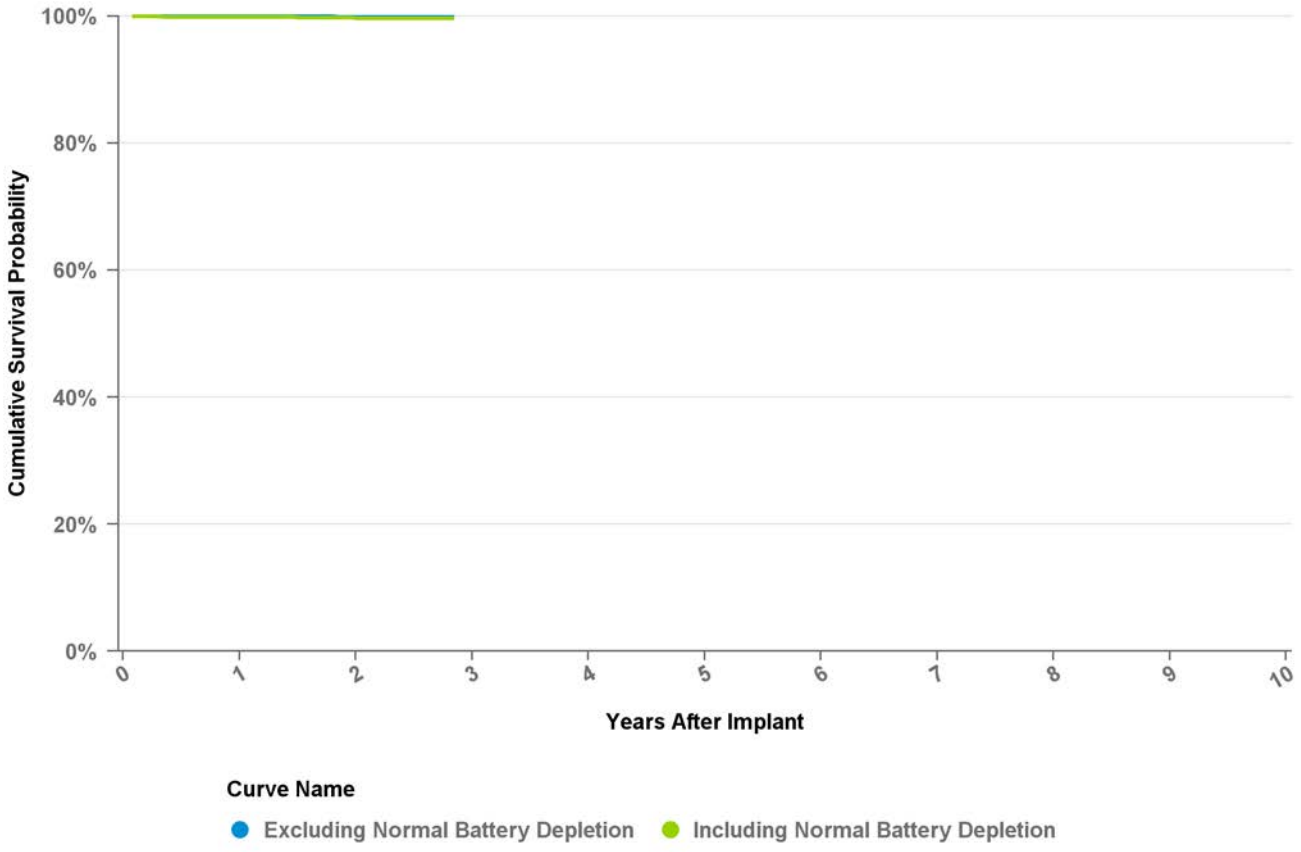
D364DRM Protecta DR

US Market Release Date	
CE Market Approval Date	7/15/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

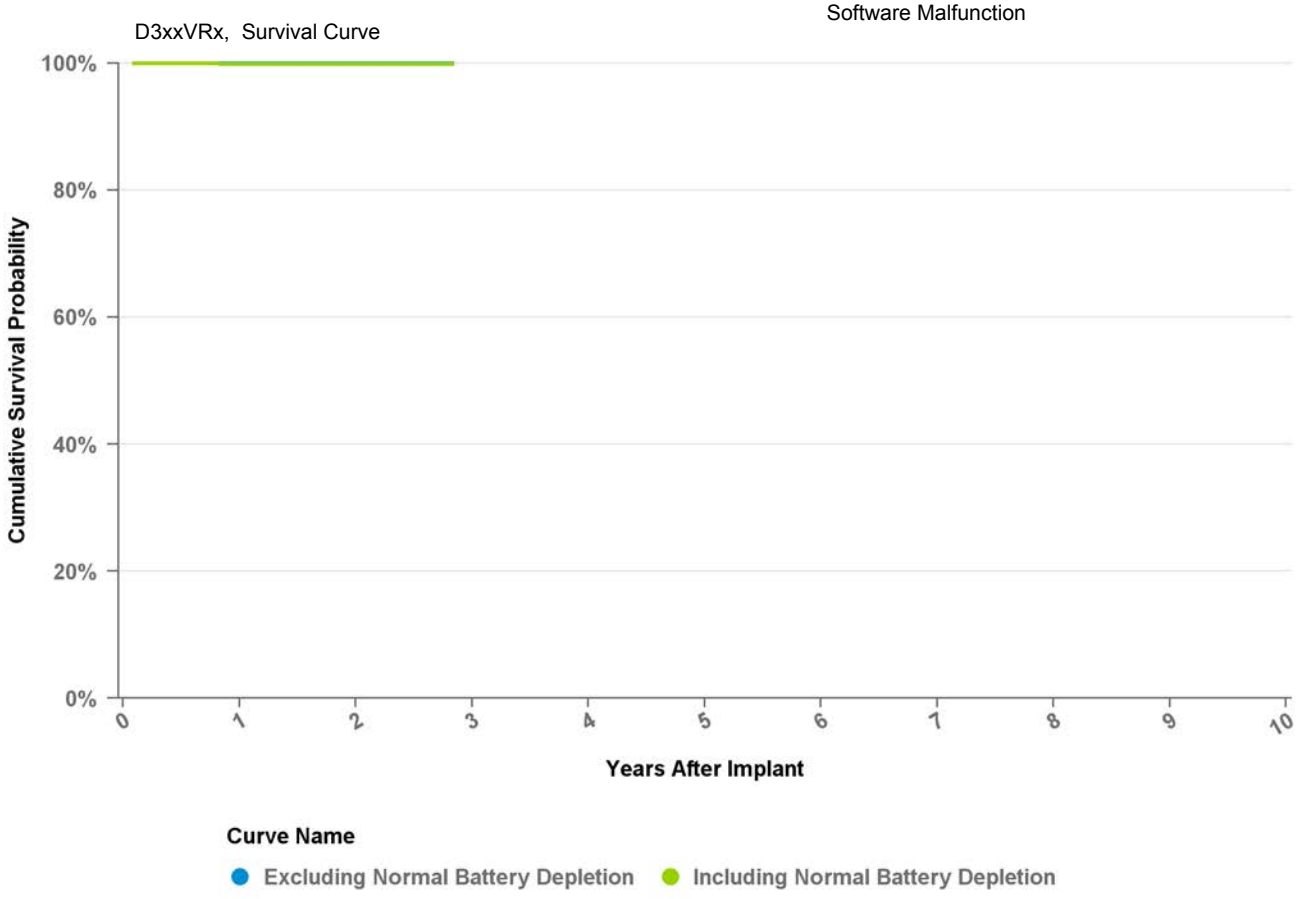
Implantable Cardioverter Defibrillator

D364VRG Protecta VR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

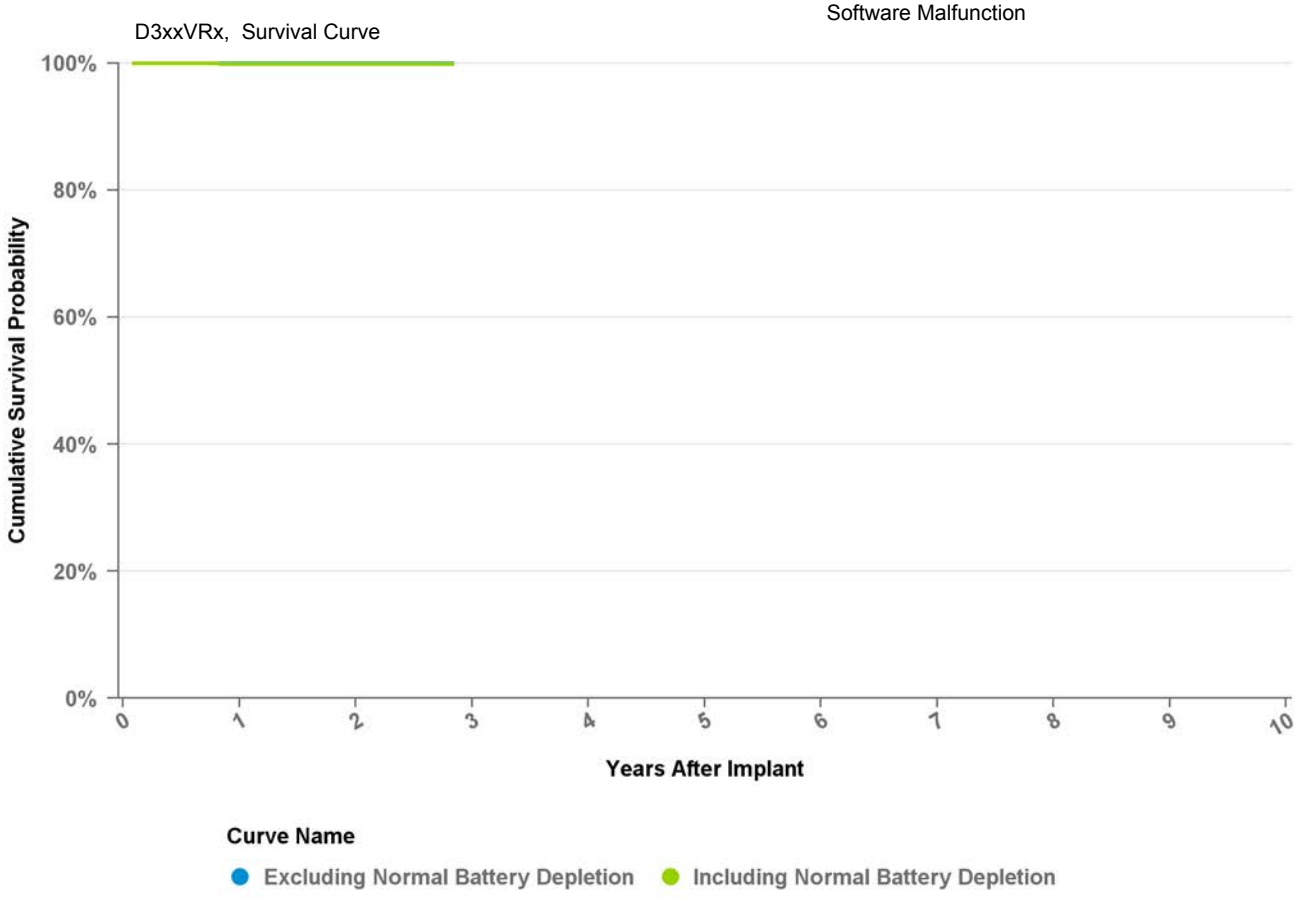
Implantable Cardioverter Defibrillator

D364VRM Protecta VR

US Market Release Date	
CE Market Approval Date	12/17/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

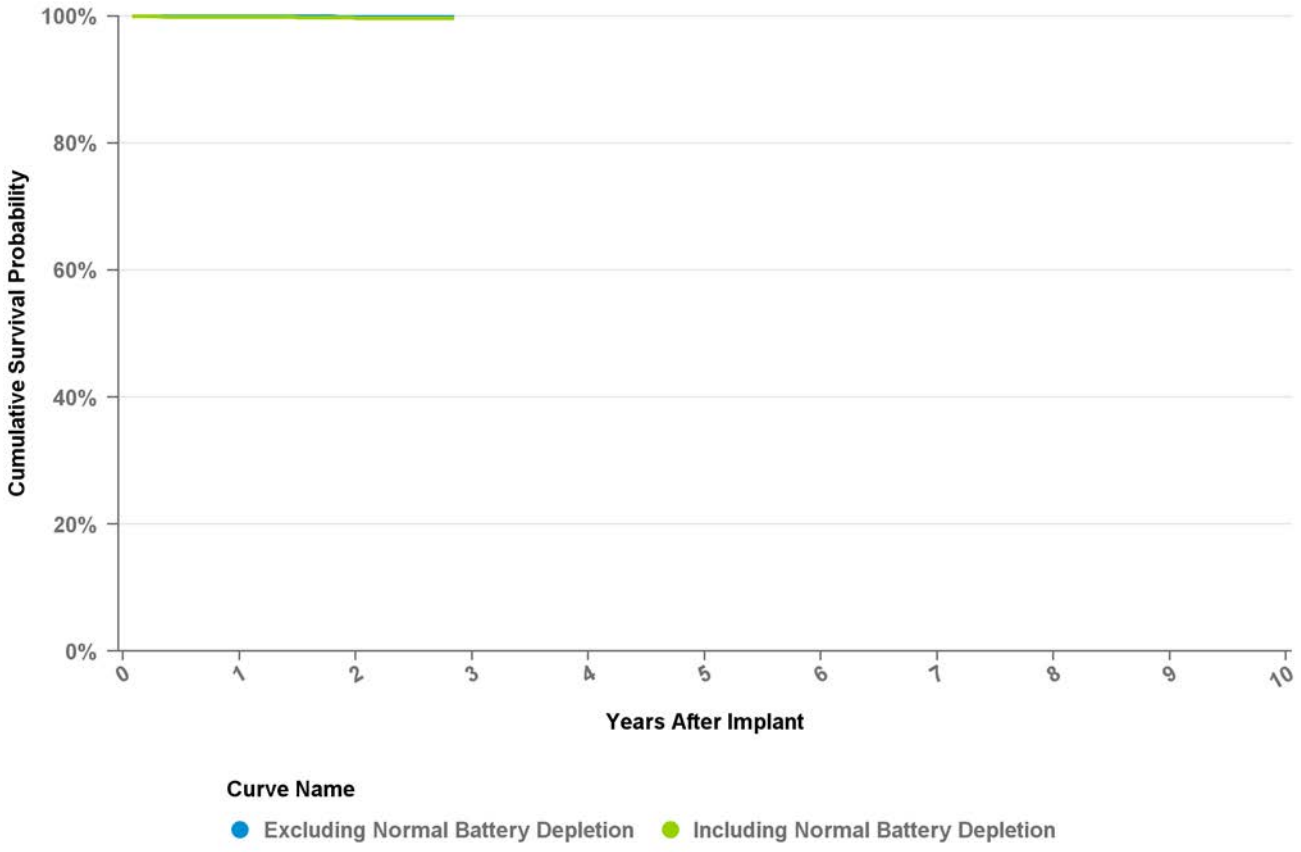
D384DRG Cardia DR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

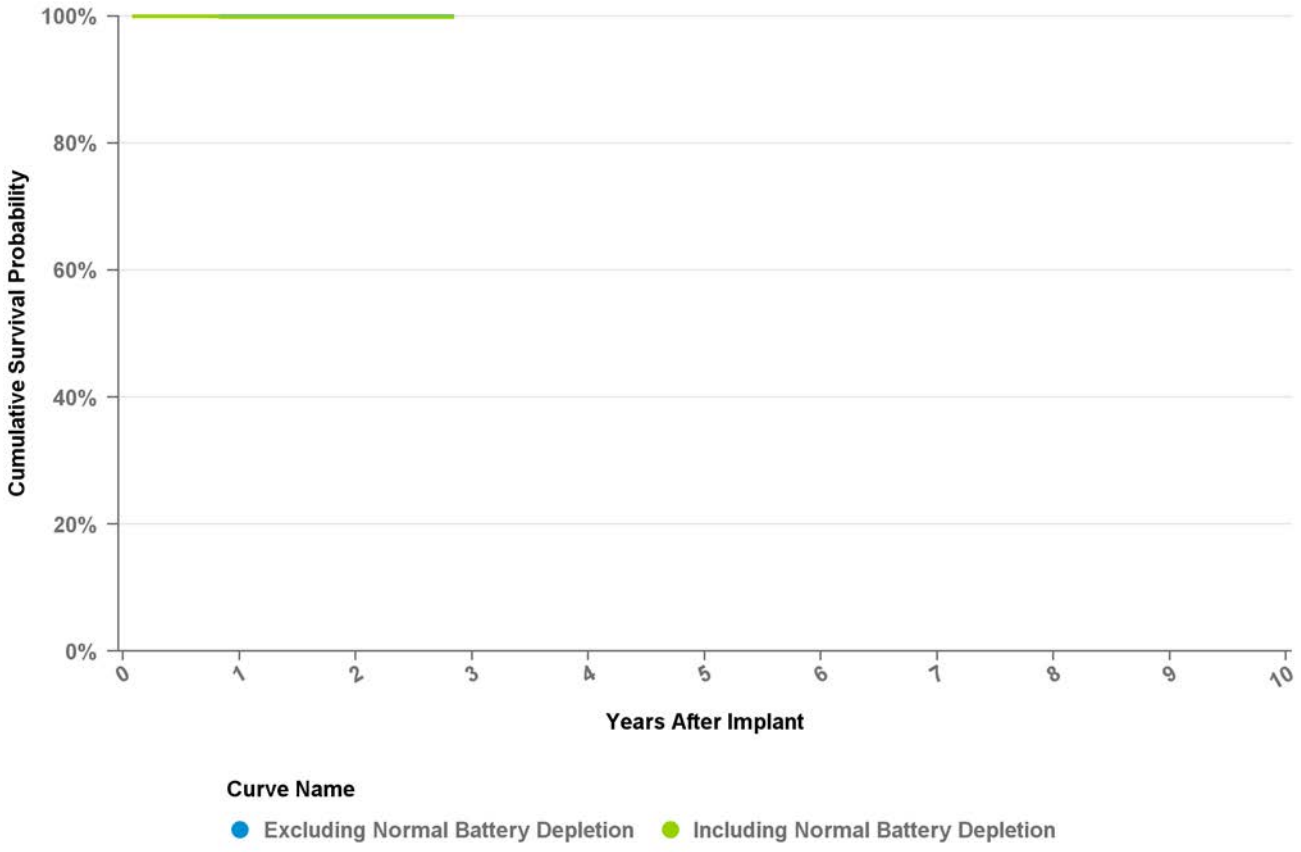
D384VRG Cardia VR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxVRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Implantable Cardioverter Defibrillator

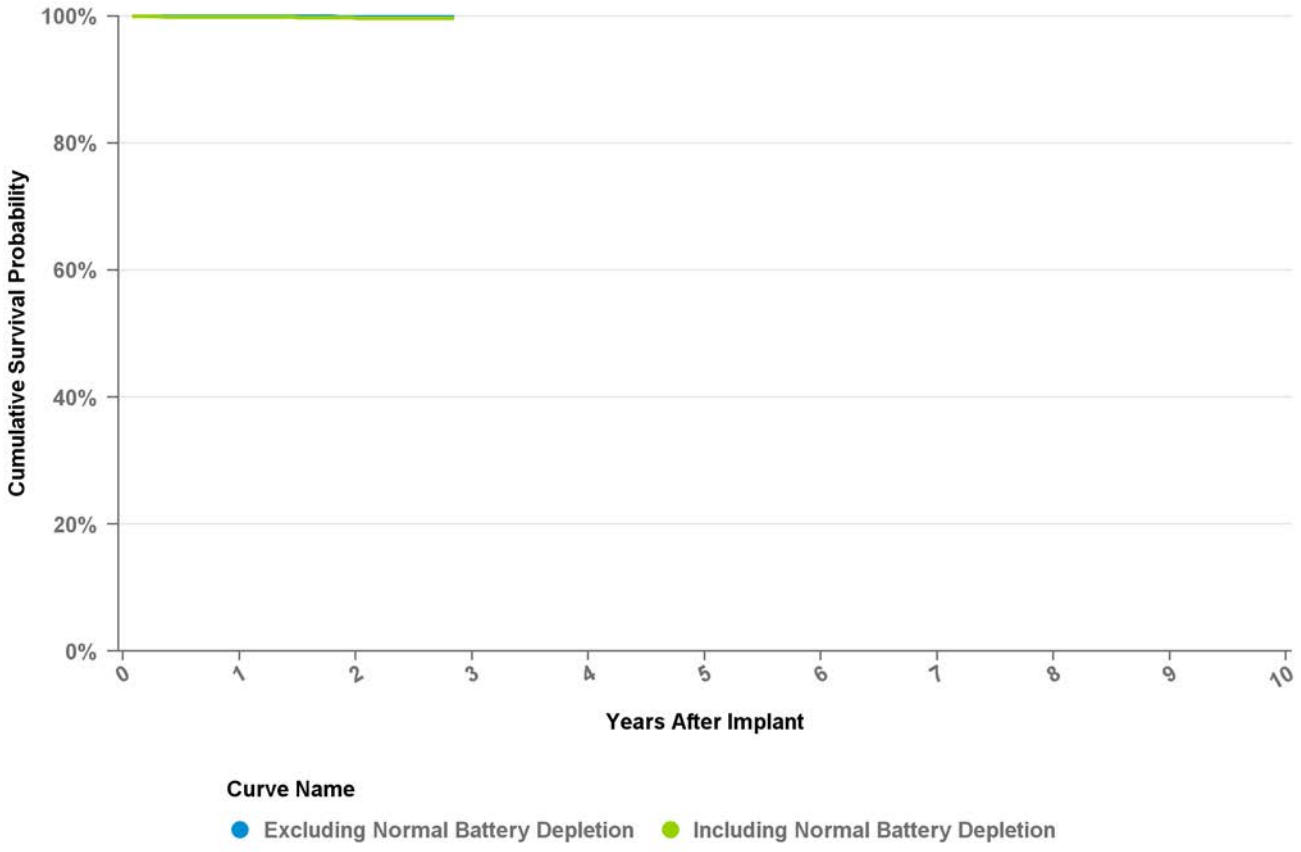
D394DRG Egida DR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxDRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.7%
Effective Sample Size	41967	13808	267

Implantable Cardioverter Defibrillator

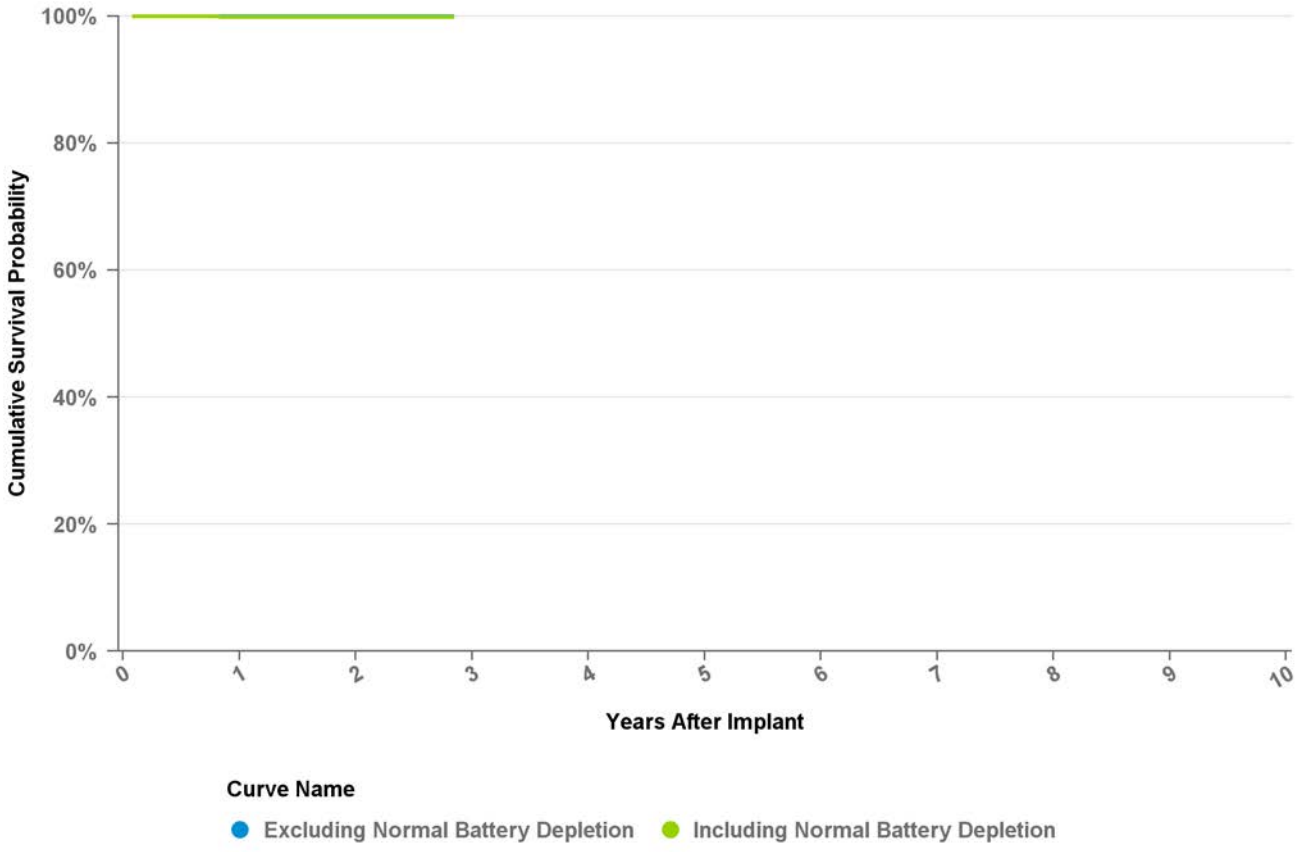
D394VRG Egida VR

US Market Release Date	
CE Market Approval Date	1/12/2011
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D3xxVRx, Survival Curve



Years	1	2	at 34 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.9%
Effective Sample Size	18941	5840	137

Cardiac Resynchronization Therapy

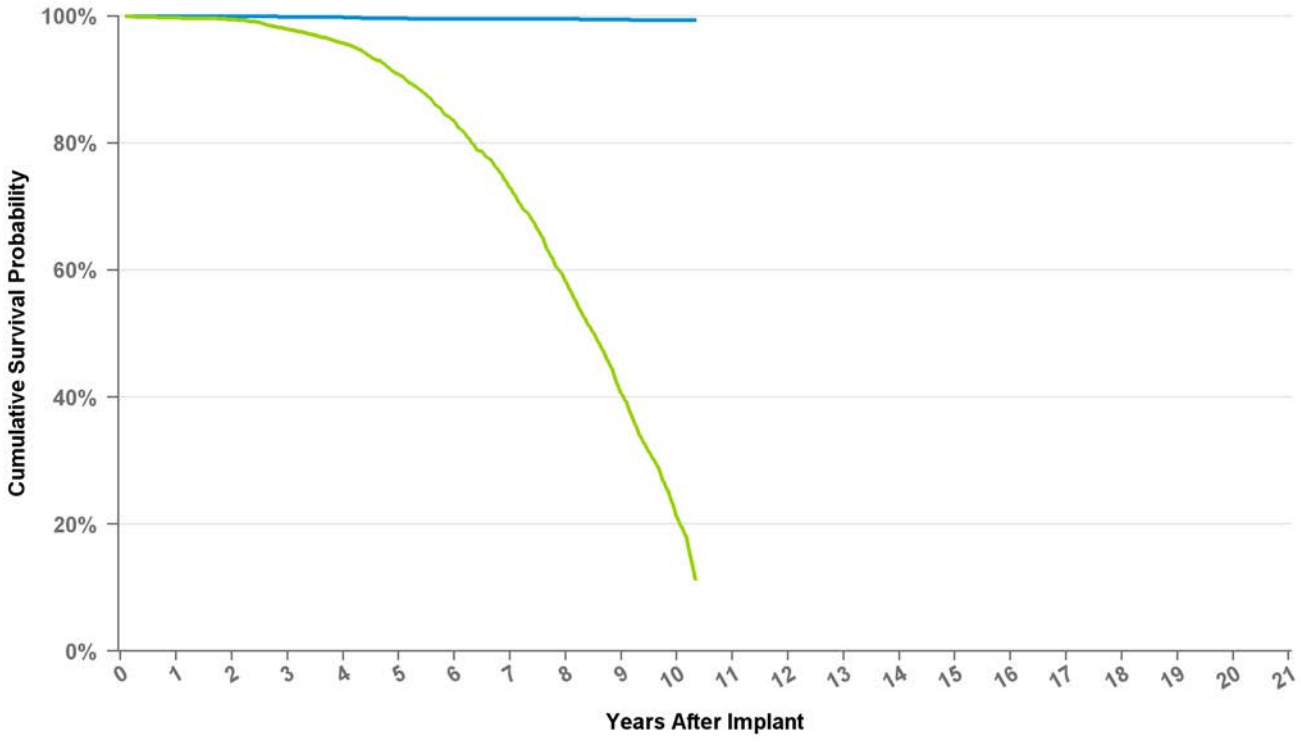
8040 InSync

US Market Release Date	8/28/2001
CE Market Approval Date	
Registered US Implants	15,332
Estimated Active US Implants	1,230
Normal Battery Depletions (US)	1,428

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	34
Therapy Not Compromised Malfunction	24
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	16
Other Malfunction	1
Poss Early Battery Depltn	3
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	10
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

8040, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 124 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.5%	99.4%	99.4%
Including NBD	99.8%	21.1%	99.5%	97.9%	95.7%	90.8%	83.4%	73.0%	58.3%	40.6%	11.4%
Effective Sample Size	12259	296	10095	8103	6369	4969	3720	2613	1622	860	127

Cardiac Resynchronization Therapy

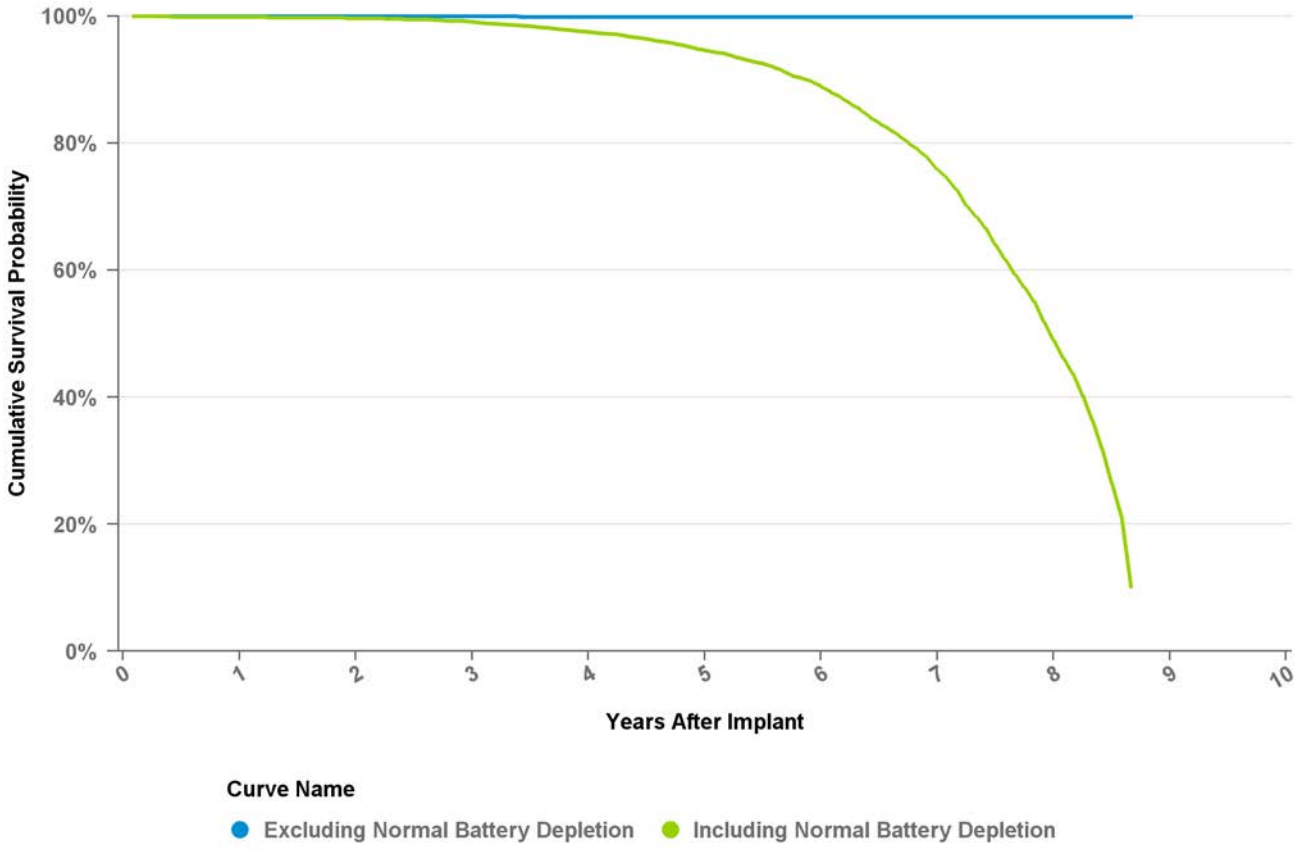
8042 InSync III

US Market Release Date	2/25/2003
CE Market Approval Date	2/7/2001
Registered US Implants	39,430
Estimated Active US Implants	13,260
Normal Battery Depletions (US)	2,555

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	24
Therapy Not Compromised Malfunction	14
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	3
Other Malfunction	7
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	10
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

8042, Survival Curve



Years	1	2	3	4	5	6	7	8	at 104 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.1%	97.5%	94.6%	88.9%	75.9%	49.0%	10.1%
Effective Sample Size	34526	30141	26399	19729	13654	8884	4874	1661	138

Cardiac Resynchronization Therapy

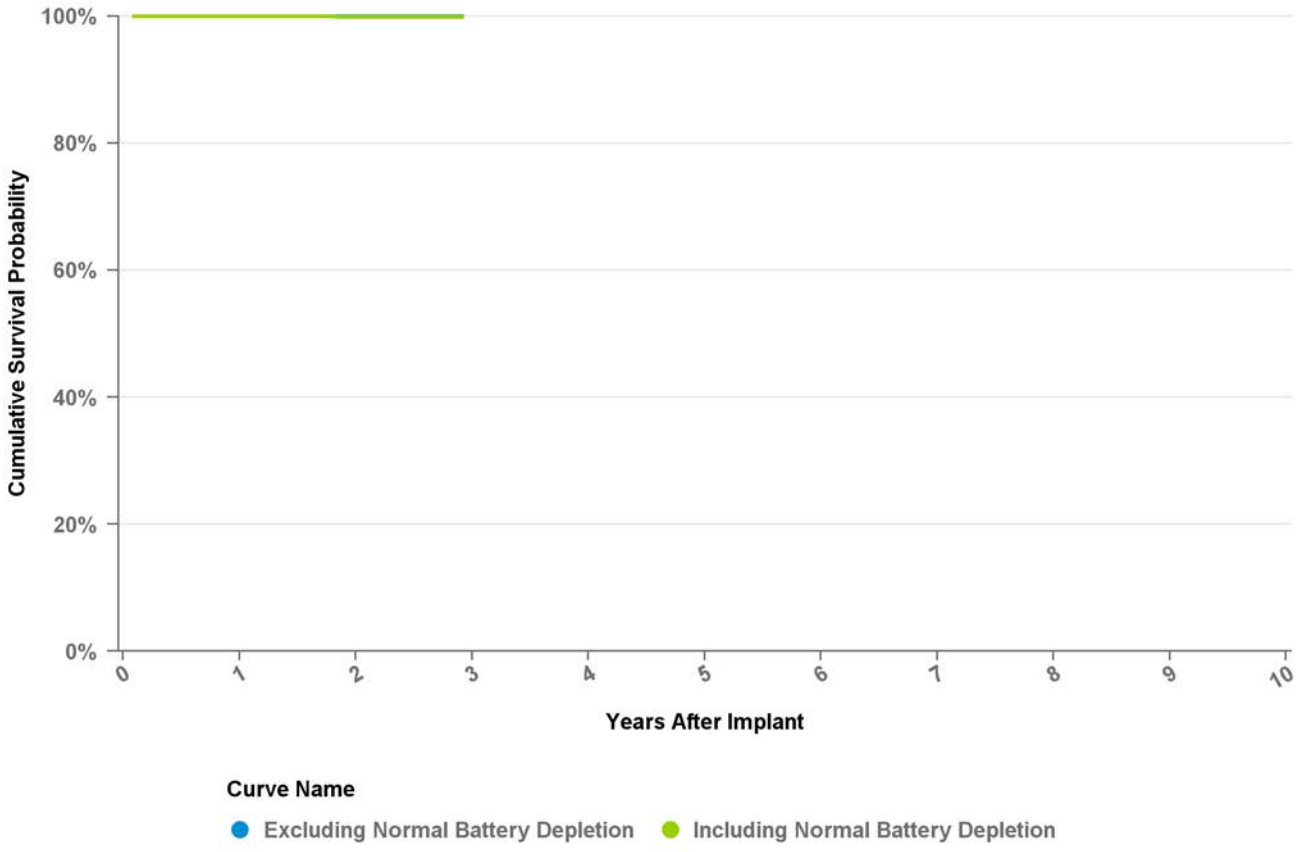
C2TR01 Syncra CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	5/11/2010
Registered US Implants	6,995
Estimated Active US Implants	6,211
Normal Battery Depletions (US)	1

NBG Code	OOE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C2TR01, C3TR01, C4TR01, Survival Curve



Years	1	2	at 35 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	11951	5278	184

Cardiac Resynchronization Therapy

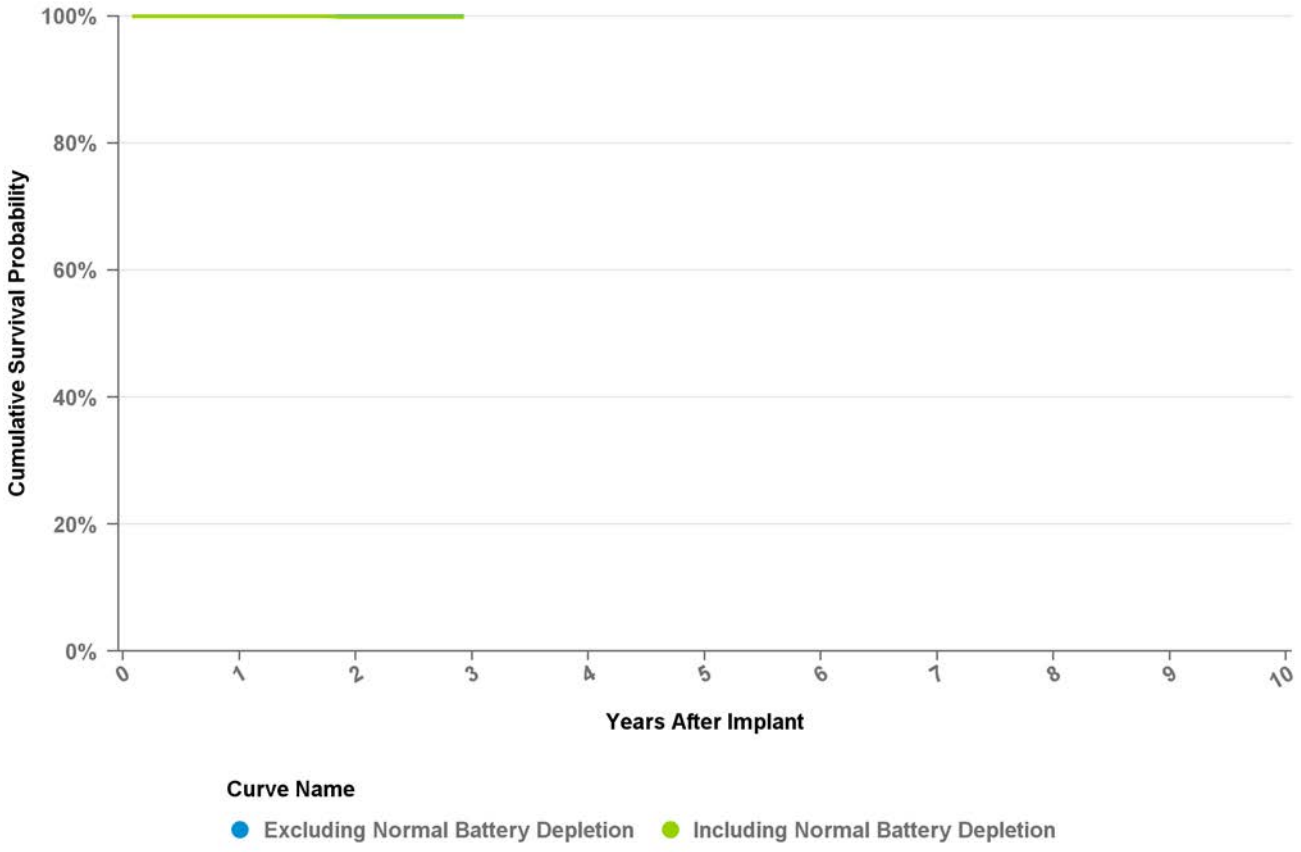
C3TR01 Consulta CRT-P

US Market Release Date	
CE Market Approval Date	5/11/2010
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C2TR01, C3TR01, C4TR01, Survival Curve



Years	1	2	at 35 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	11951	5278	184

Cardiac Resynchronization Therapy

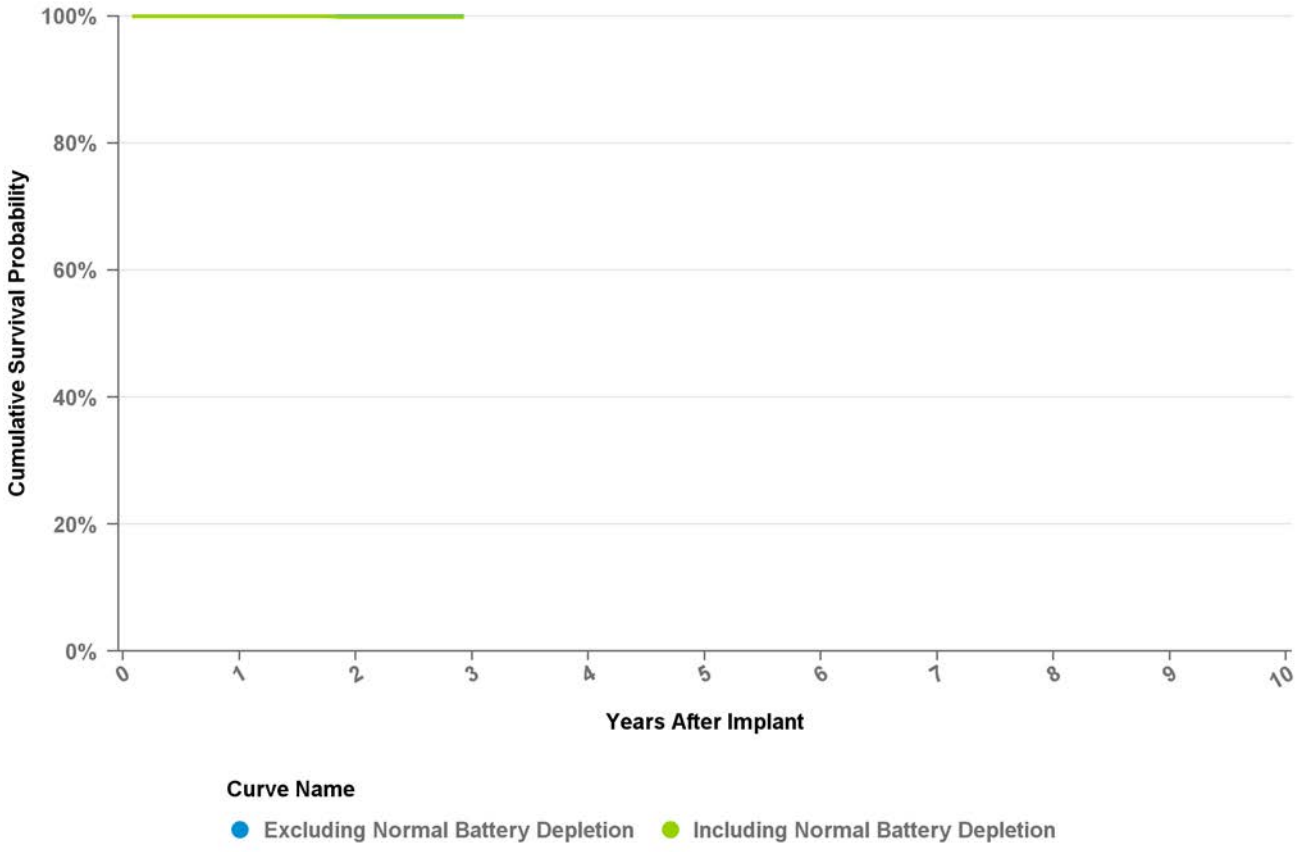
C4TR01 Consulta CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	
Registered US Implants	11,487
Estimated Active US Implants	10,554
Normal Battery Depletions (US)	4

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

C2TR01, C3TR01, C4TR01, Survival Curve



Years	1	2	at 35 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%
Effective Sample Size	11951	5278	184

Implantable Pulse Generator

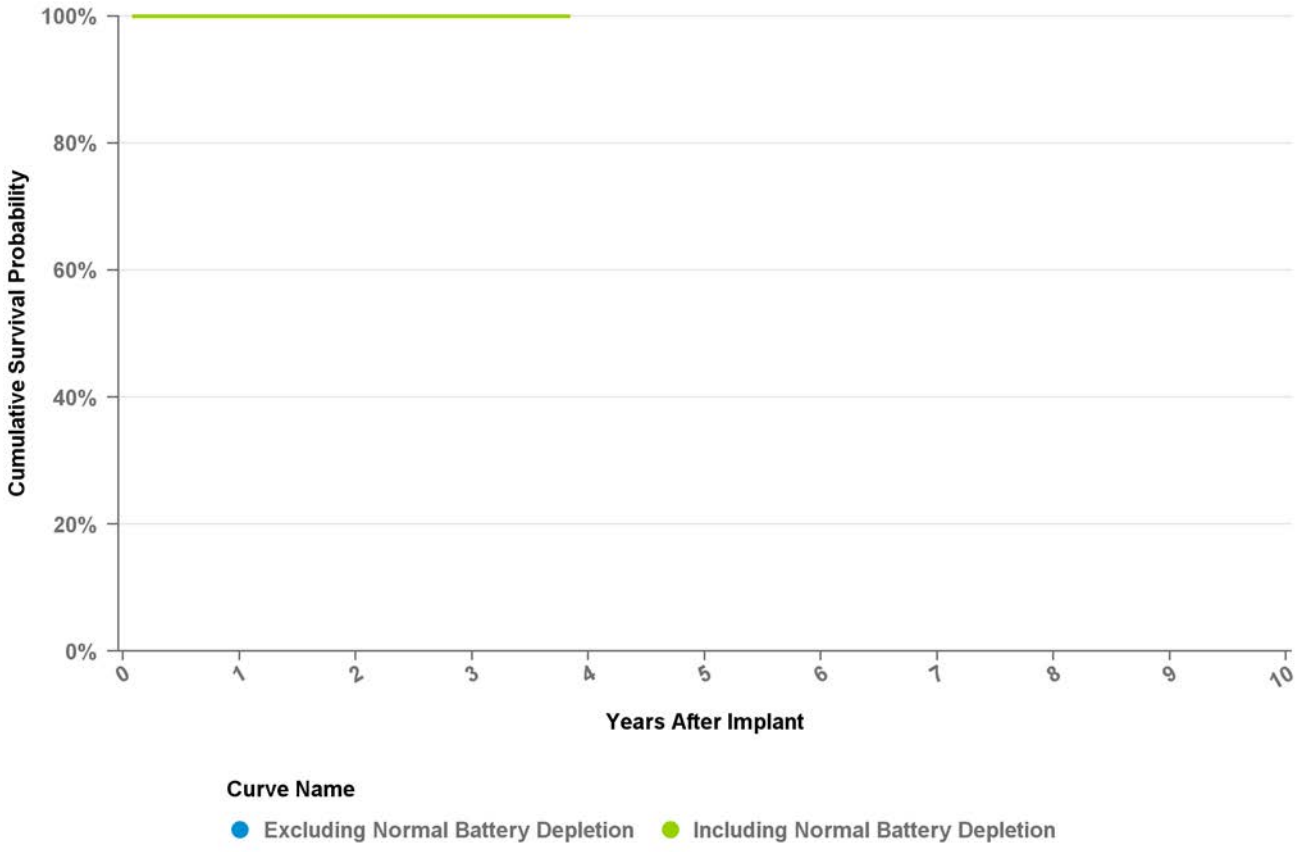
A2DR01 Advisa DR MRI

US Market Release Date	1/15/2013
CE Market Approval Date	
Registered US Implants	21,627
Estimated Active US Implants	21,346
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

A2DR01, A3DR01, A5DR01, EN1DR01, Survival Curve



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	11896	6792	2754	137

Implantable Pulse Generator

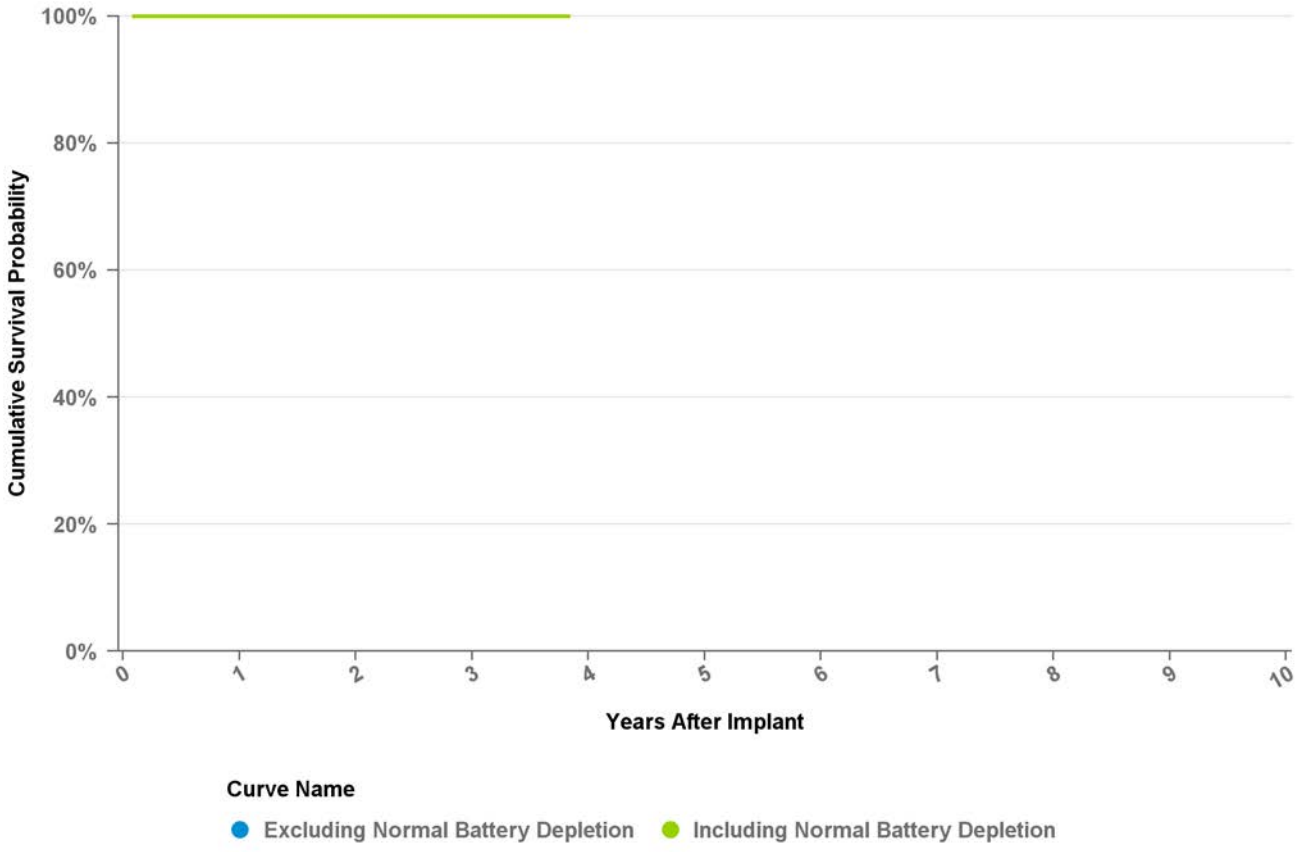
A3DR01 Advisa DR MRI

US Market Release Date	
CE Market Approval Date	6/2/2009
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

A2DR01, A3DR01, A5DR01, EN1DR01, Survival Curve



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	11896	6792	2754	137

Implantable Pulse Generator

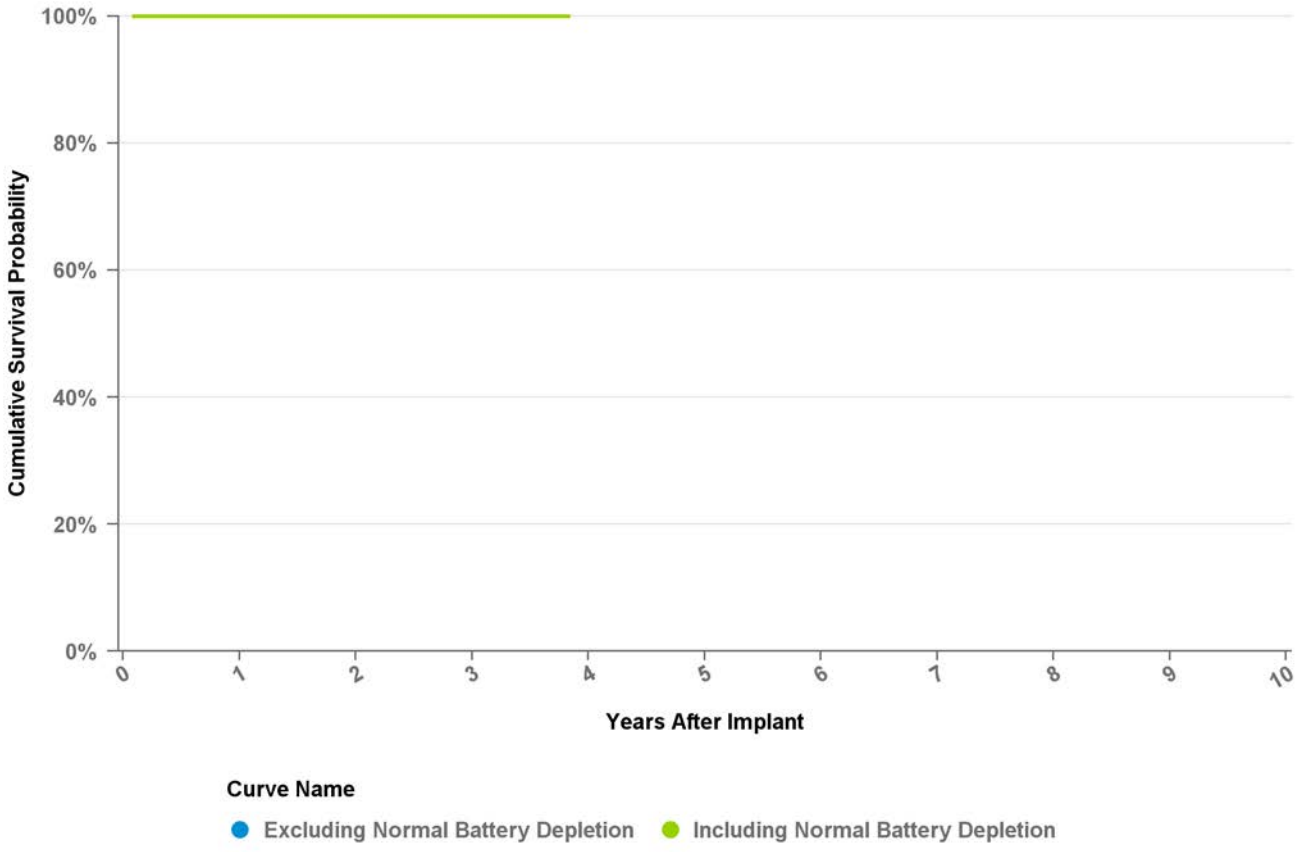
A4DR01 Advisa DR

US Market Release Date	4/4/2011
CE Market Approval Date	
Registered US Implants	1,465
Estimated Active US Implants	1,408
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

A2DR01, A3DR01, A5DR01, EN1DR01, Survival Curve



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	11896	6792	2754	137

Implantable Pulse Generator

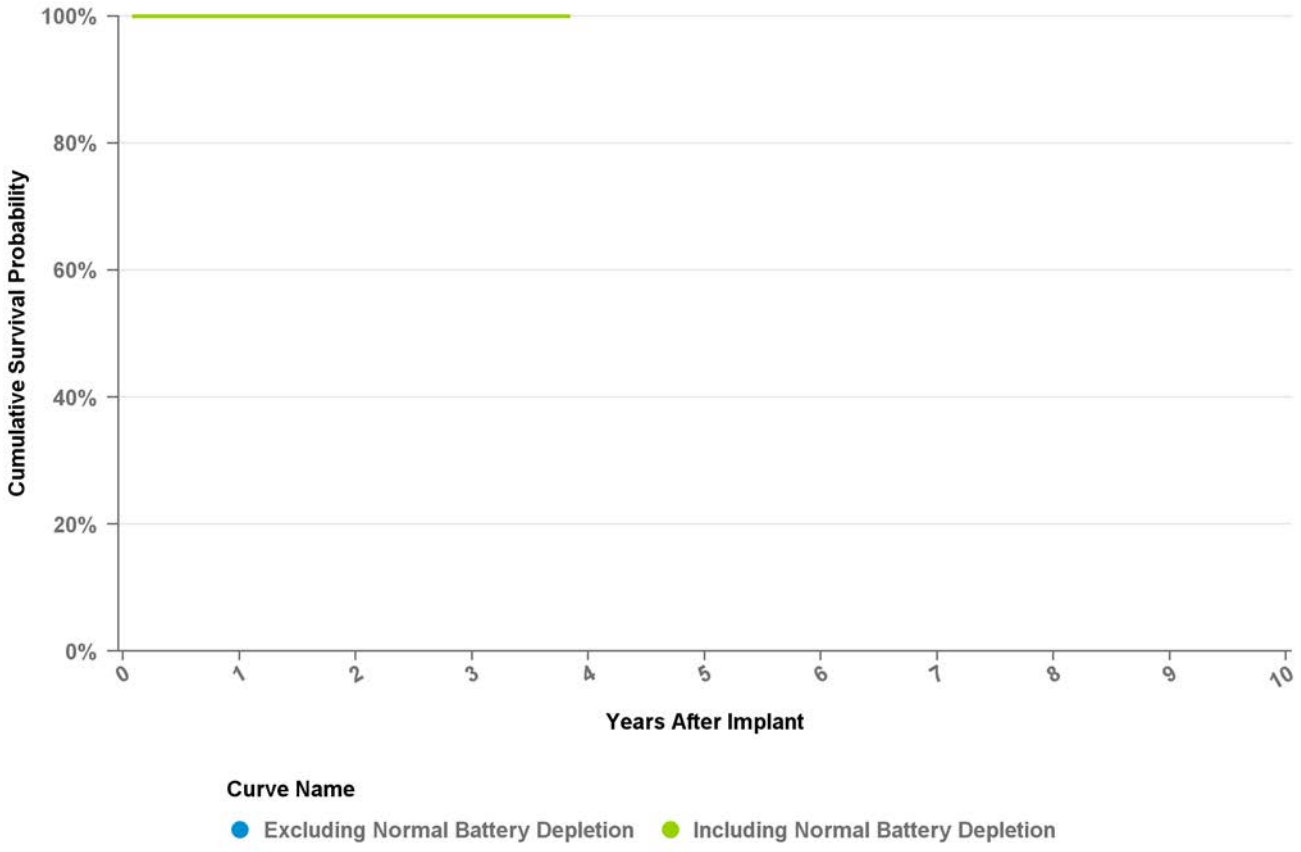
A5DR01 Advisa DR

US Market Release Date	
CE Market Approval Date	6/2/2009
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	OAE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

A2DR01, A3DR01, A5DR01, EN1DR01, Survival Curve



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	11896	6792	2754	137

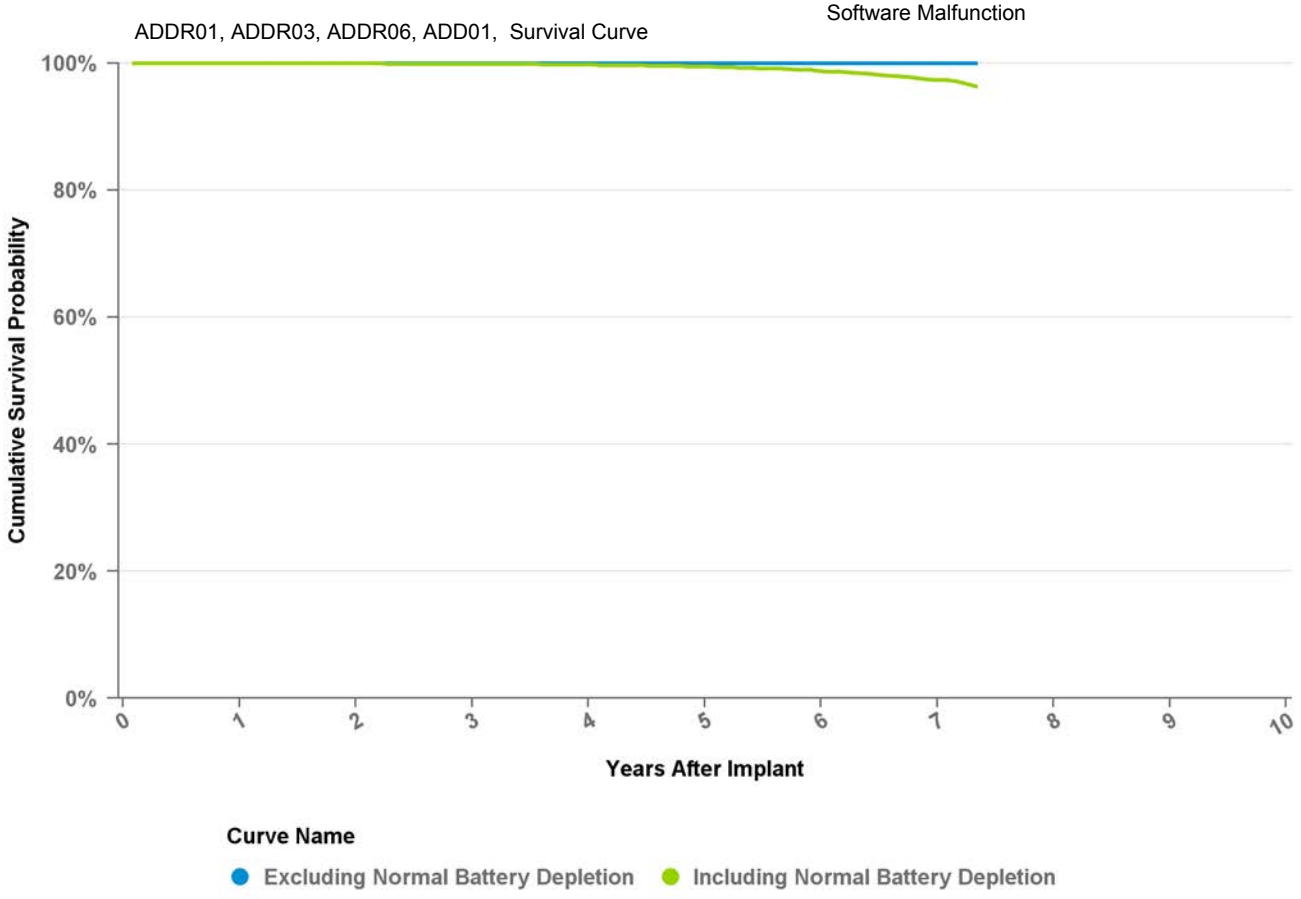
Implantable Pulse Generator

ADD01 Adapta D

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	98.7%	97.3%	96.3%
Effective Sample Size	329230	267912	209832	150084	95822	48683	9626	933

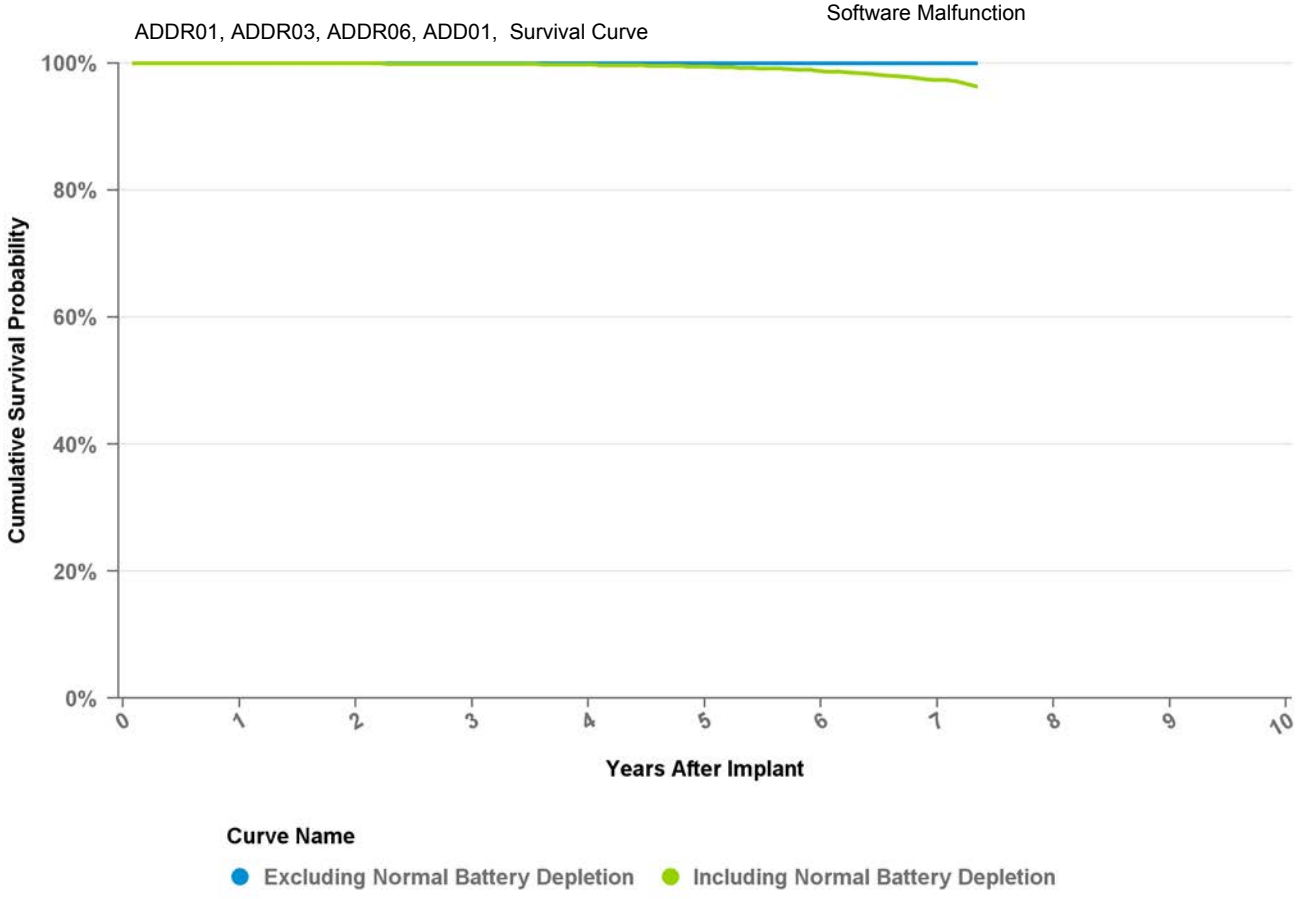
Implantable Pulse Generator

ADDR01 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	372,519
Estimated Active US Implants	303,168
Normal Battery Depletions (US)	753

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	63
Therapy Not Compromised Malfunction	42
Battery Malfunction	0
Electrical Component	40
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	21
Battery Malfunction	0
Electrical Component	17
Electrical Interconnect	2
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	98.7%	97.3%	96.3%
Effective Sample Size	329230	267912	209832	150084	95822	48683	9626	933

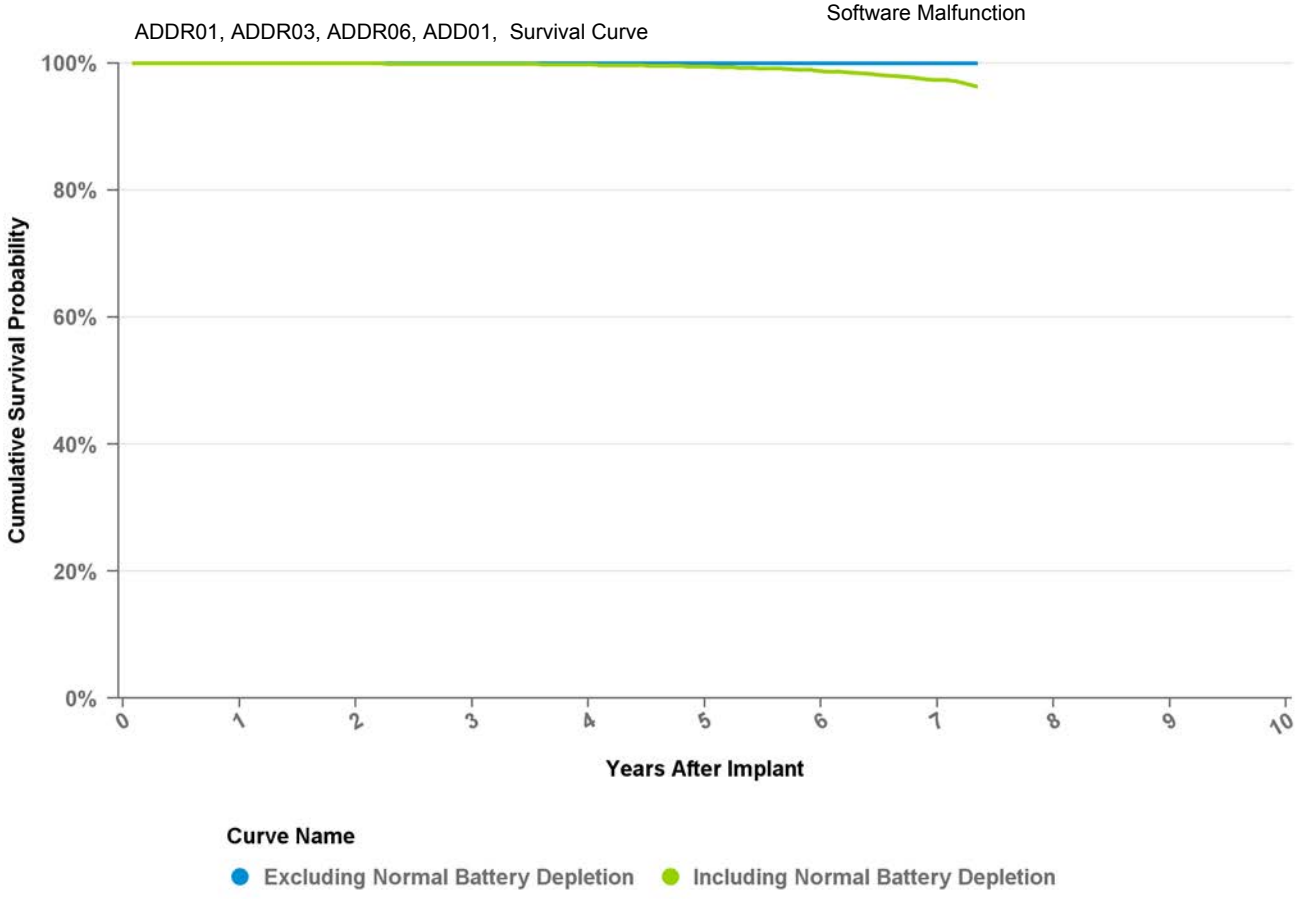
Implantable Pulse Generator

ADDR03 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	3,439
Estimated Active US Implants	2,639
Normal Battery Depletions (US)	21

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	98.7%	97.3%	96.3%
Effective Sample Size	329230	267912	209832	150084	95822	48683	9626	933

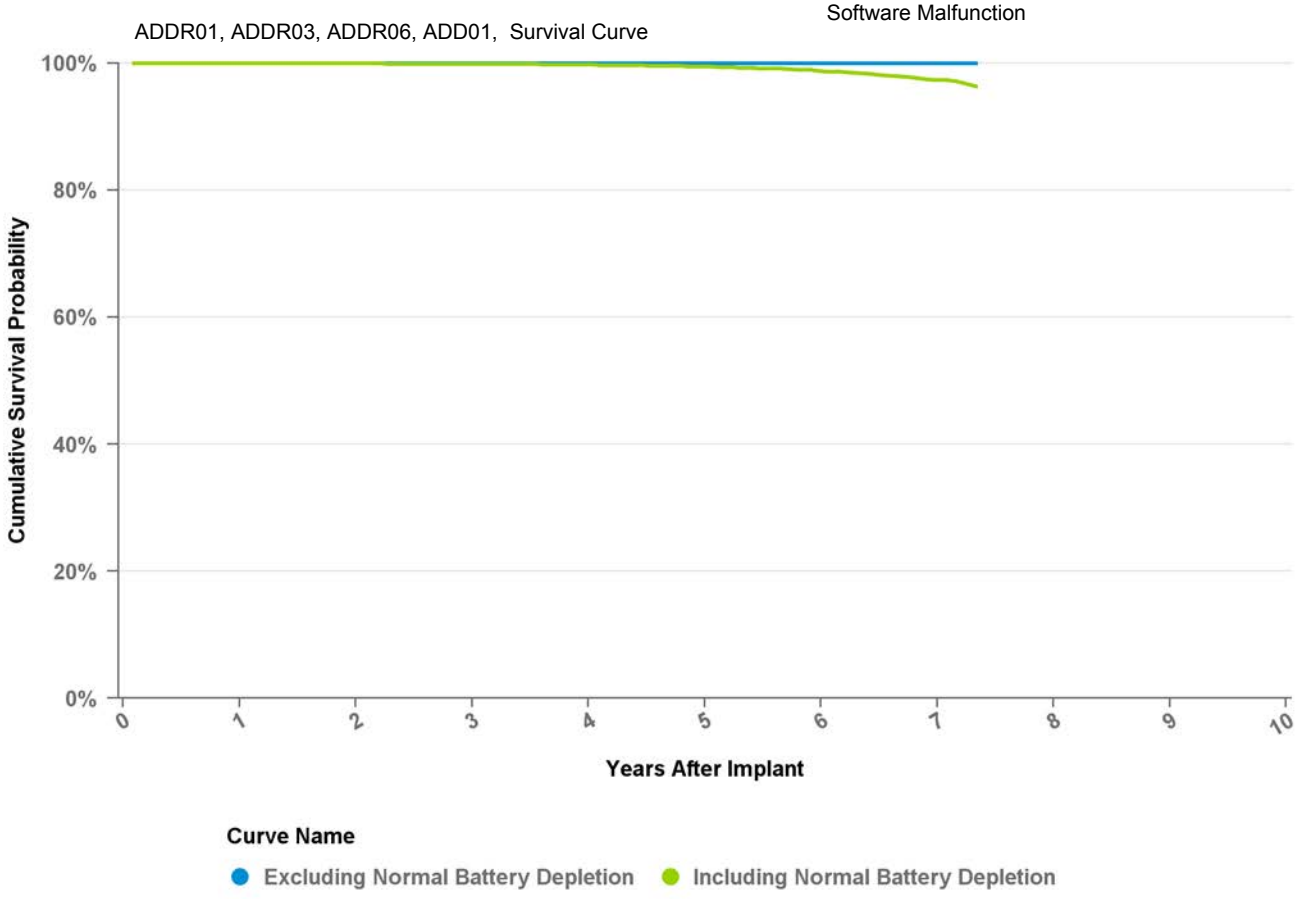
Implantable Pulse Generator

ADDR06 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2,738
Estimated Active US Implants	1,881
Normal Battery Depletions (US)	40

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 88 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.5%	98.7%	97.3%	96.3%
Effective Sample Size	329230	267912	209832	150084	95822	48683	9626	933

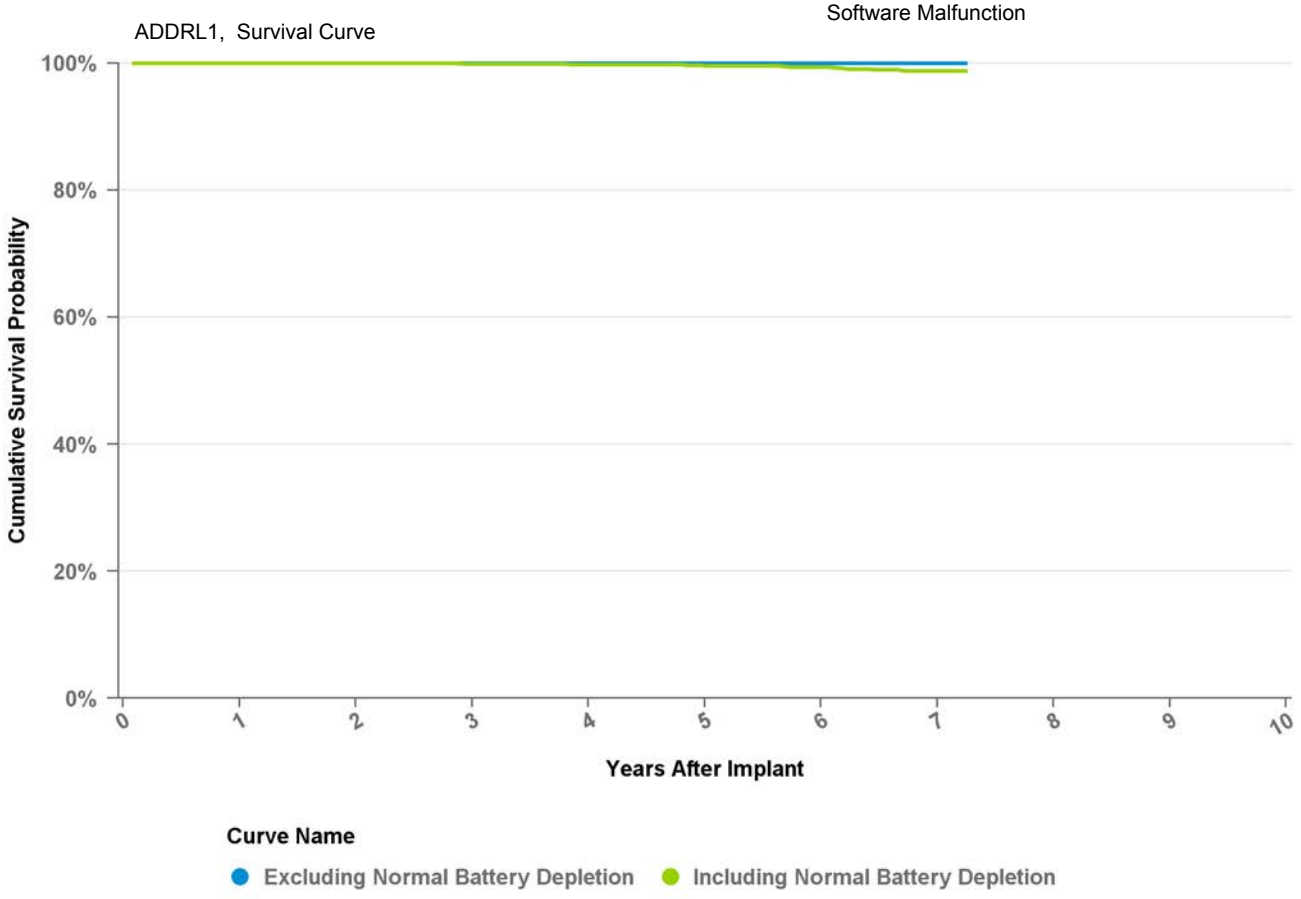
Implantable Pulse Generator

ADDRL1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	90,194
Estimated Active US Implants	80,834
Normal Battery Depletions (US)	56

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	10
Therapy Not Compromised Malfunction	7
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.8%	99.6%	99.3%	98.7%	98.7%
Effective Sample Size	73603	53286	36417	22030	11226	4406	570	138

Implantable Pulse Generator

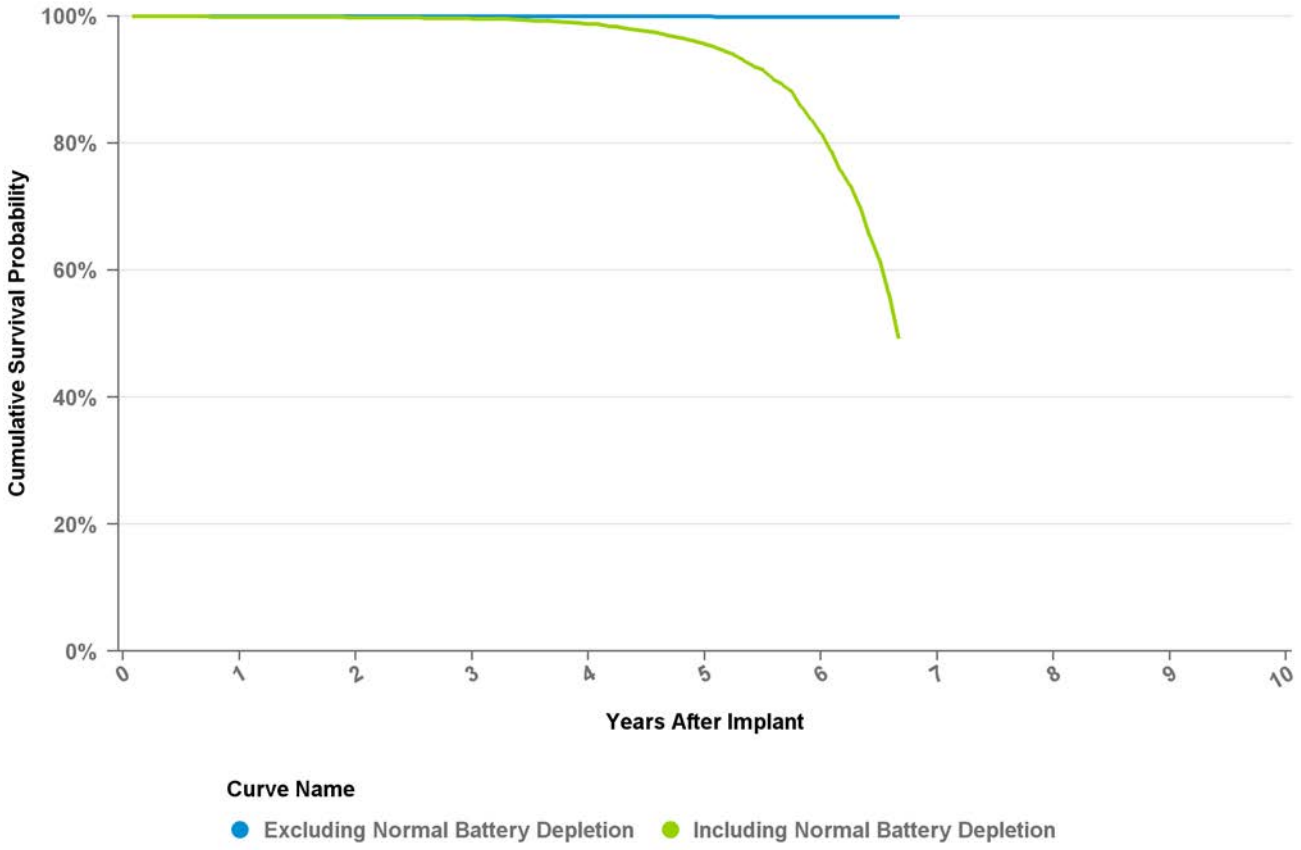
ADDRS1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	37,390
Estimated Active US Implants	27,249
Normal Battery Depletions (US)	807

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	10
Therapy Not Compromised Malfunction	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0

ADDRS1, Survival Curve



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	98.7%	95.6%	81.6%	49.4%
Effective Sample Size	30870	24046	17830	12030	6970	2462	263

Implantable Pulse Generator

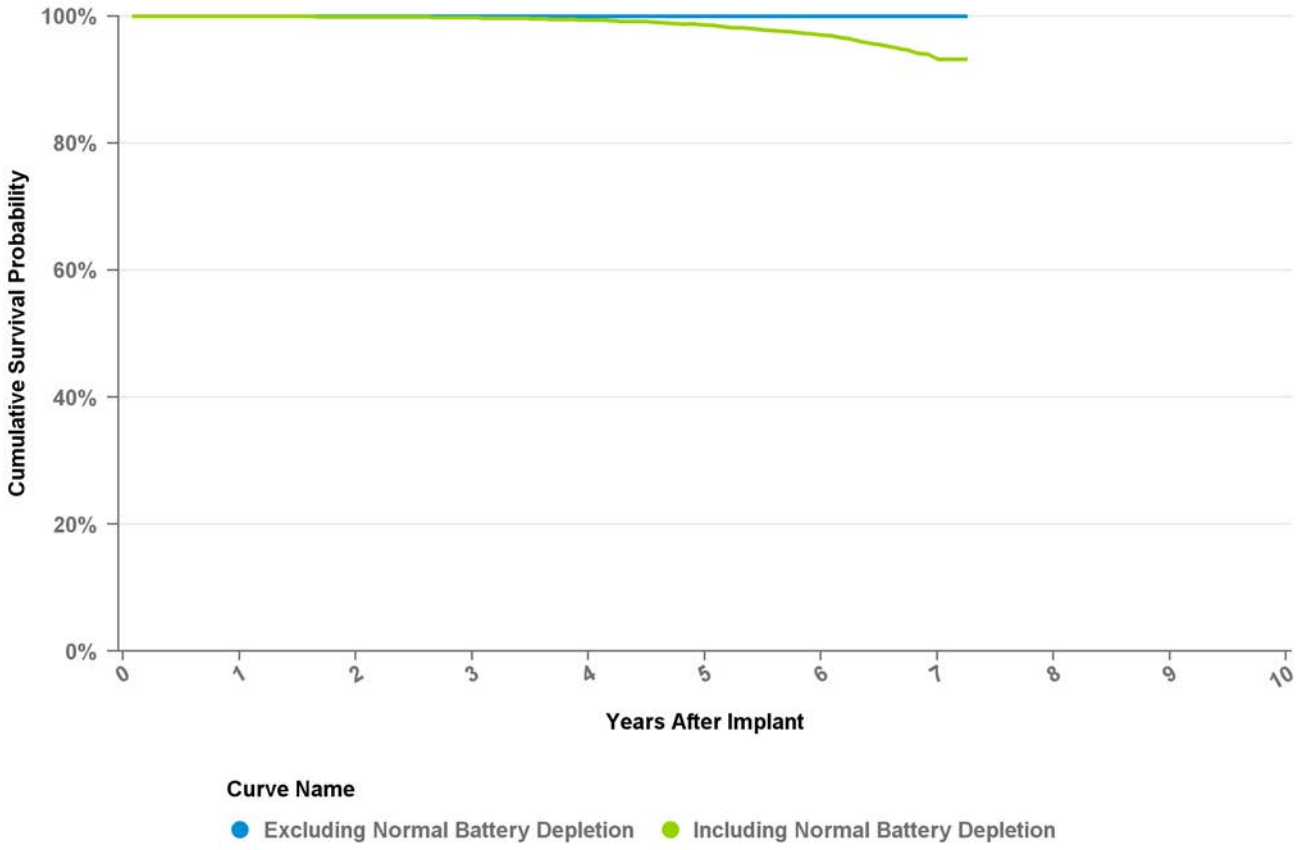
ADSR01 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	69,074
Estimated Active US Implants	48,735
Normal Battery Depletions (US)	271

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	8
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

ADSR01, ADSR03, ADSR06, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.6%	97.0%	93.2%	93.2%
Effective Sample Size	61920	47098	34597	24019	14955	7279	1207	161

Implantable Pulse Generator

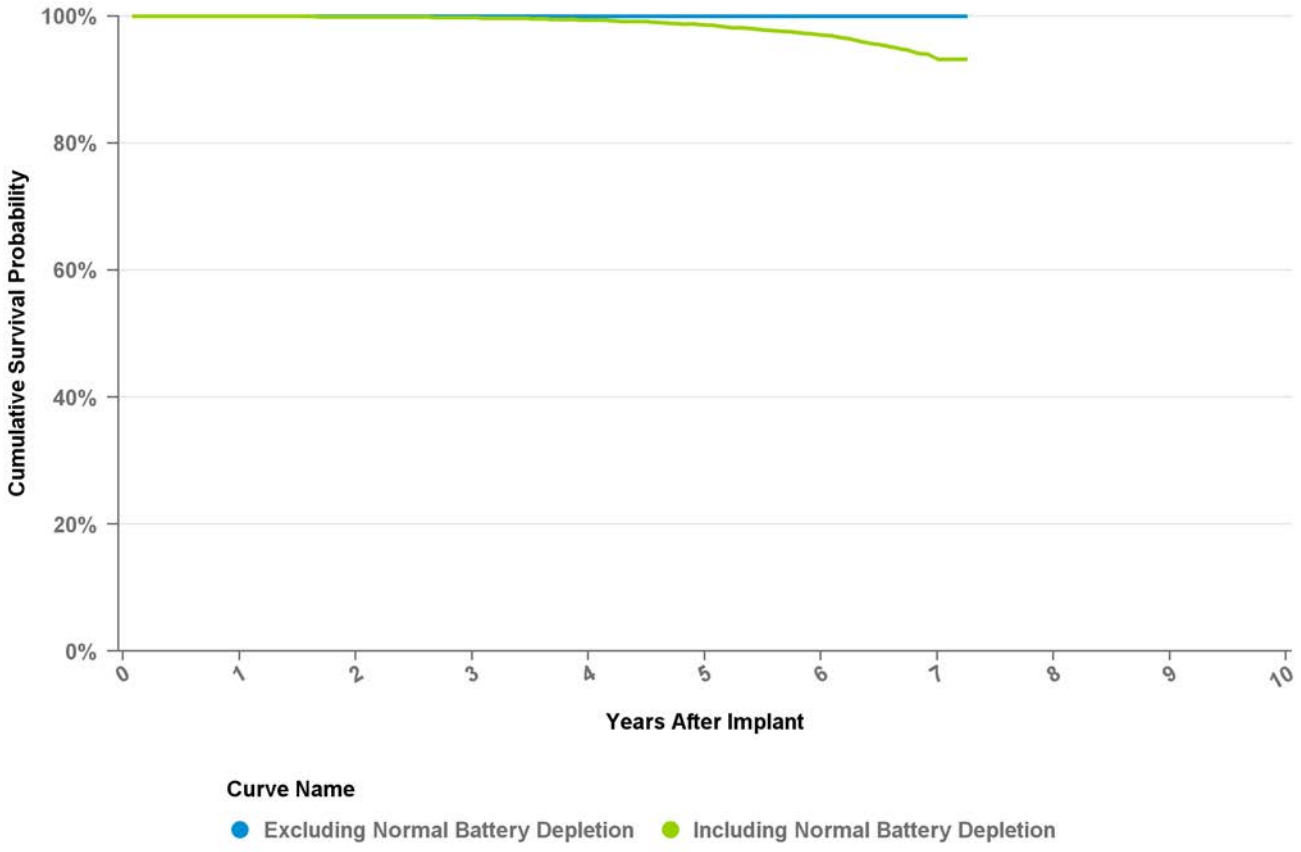
ADSR03 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1,693
Estimated Active US Implants	1,131
Normal Battery Depletions (US)	8

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

ADSR01, ADSR03, ADSR06, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.6%	97.0%	93.2%	93.2%
Effective Sample Size	61920	47098	34597	24019	14955	7279	1207	161

Implantable Pulse Generator

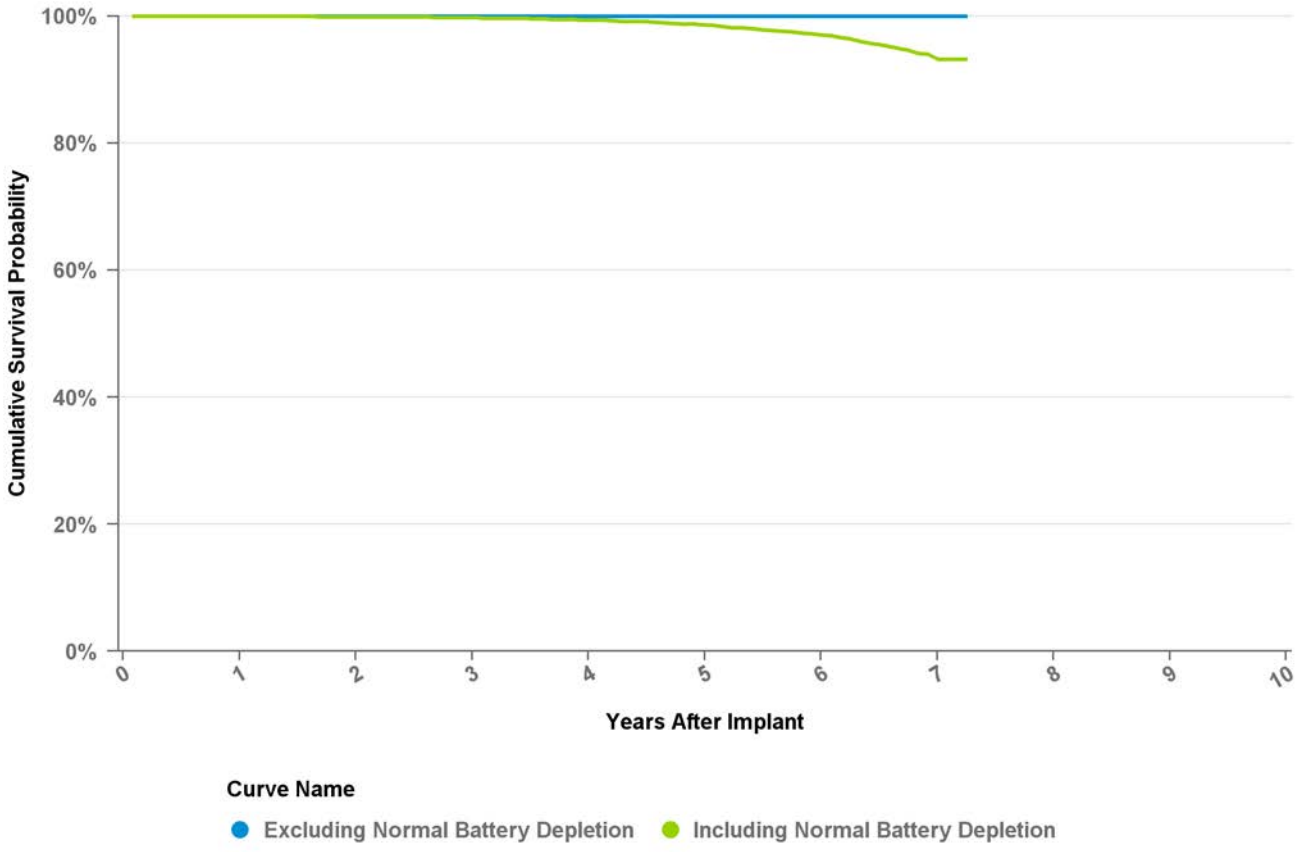
ADSR06 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2,317
Estimated Active US Implants	1,415
Normal Battery Depletions (US)	43

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

ADSR01, ADSR03, ADSR06, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.6%	97.0%	93.2%	93.2%
Effective Sample Size	61920	47098	34597	24019	14955	7279	1207	161

Implantable Pulse Generator

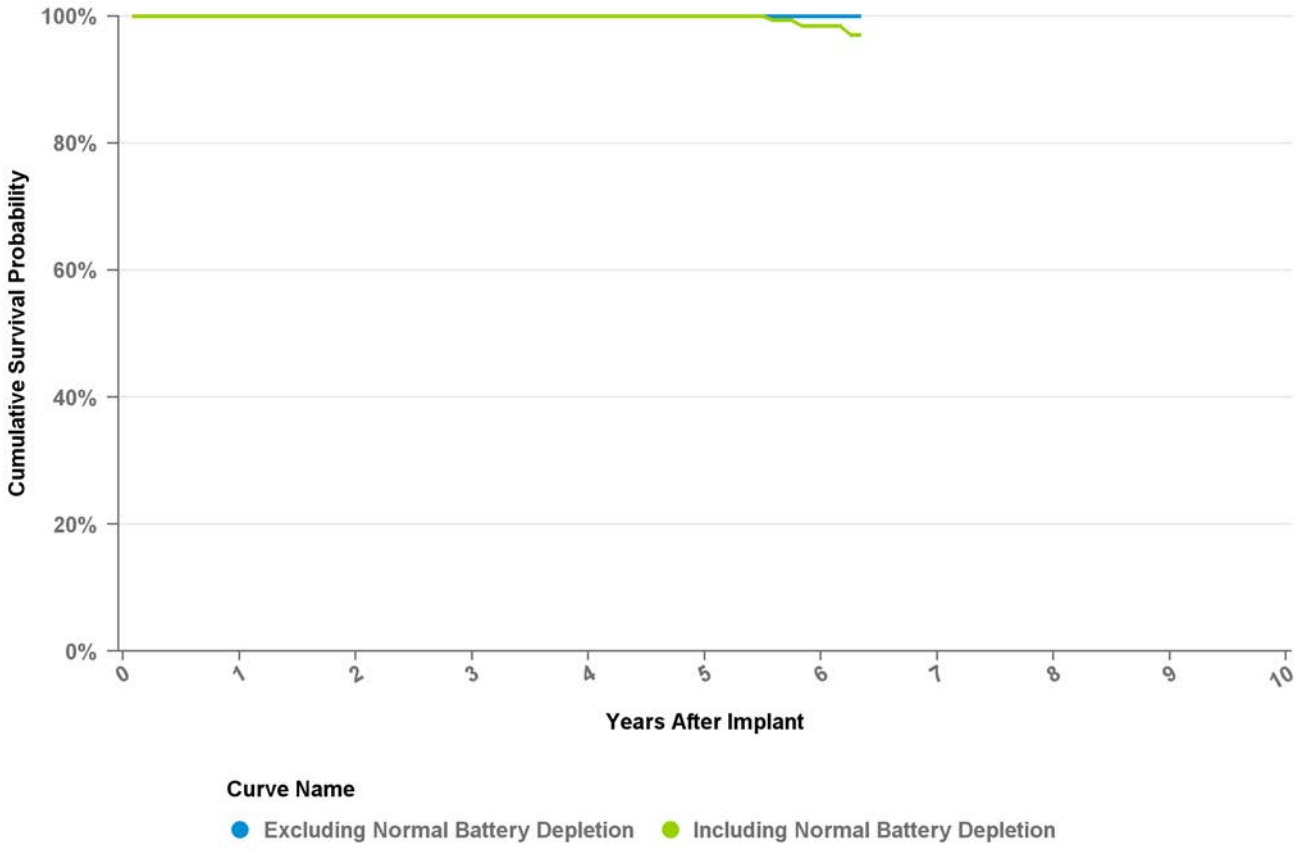
ADVDD01 Adapta VDD

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	981
Estimated Active US Implants	707
Normal Battery Depletions (US)	7

NBG Code	VDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

ADVDD01, Survival Curve



Years	1	2	3	4	5	6	at 76 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	98.4%	97.0%
Effective Sample Size	1228	1010	802	625	421	182	114

Implantable Pulse Generator

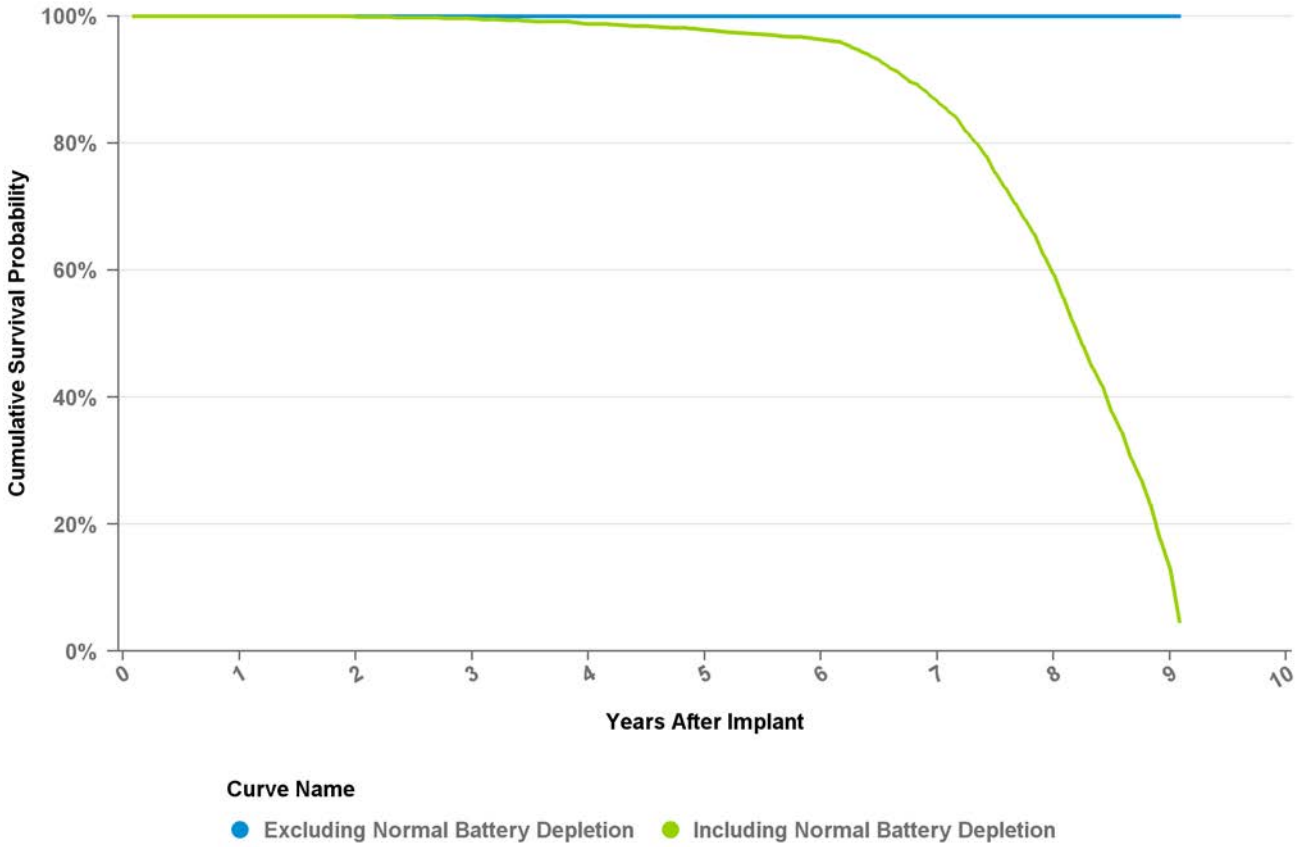
E1DR01 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	6,842
Estimated Active US Implants	955
Normal Battery Depletions (US)	1,495

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E1DR01, E1DR03, E1DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.6%	98.7%	97.8%	96.3%	86.5%	59.4%	13.2%	4.7%
Effective Sample Size	6223	5773	5325	4848	4406	3950	3175	1798	258	149

Implantable Pulse Generator

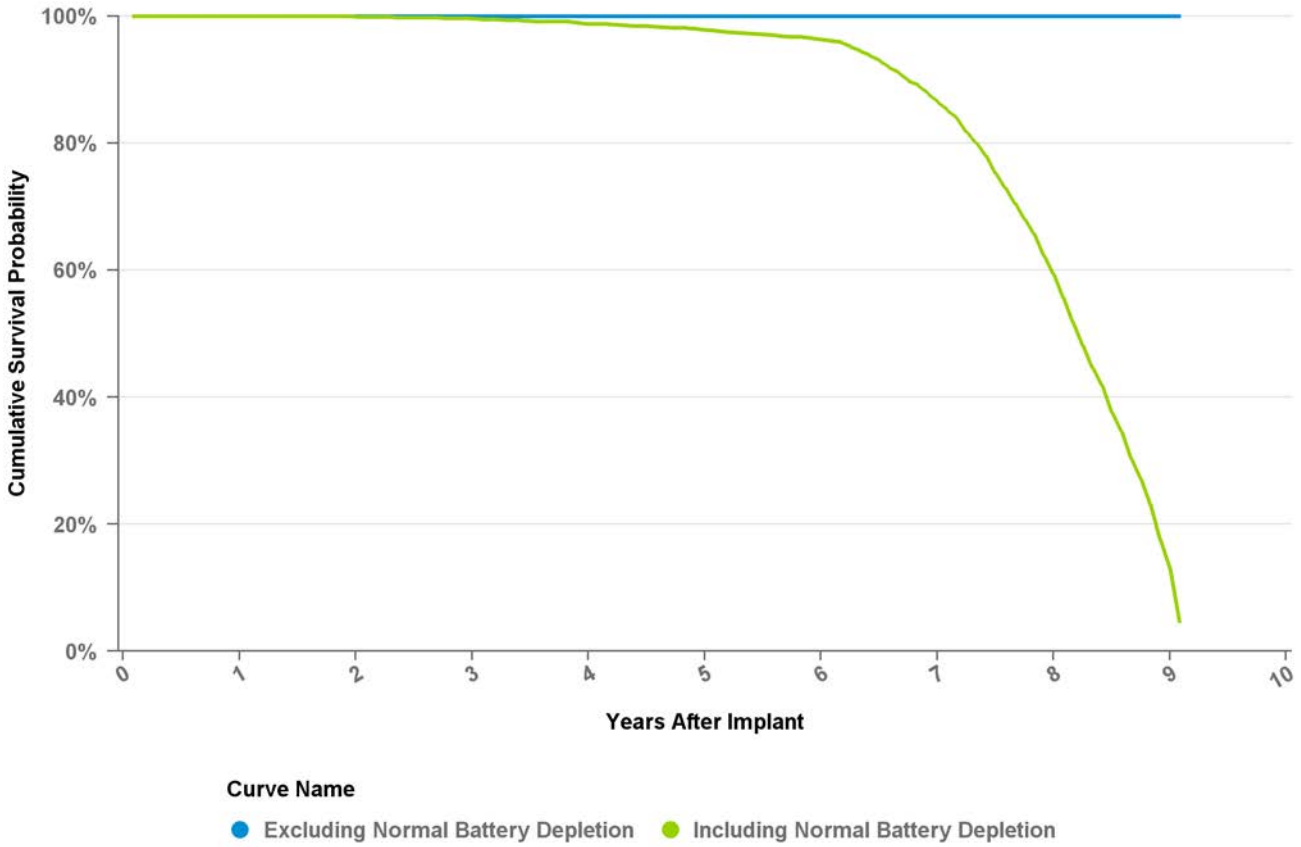
E1DR03 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E1DR01, E1DR03, E1DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.6%	98.7%	97.8%	96.3%	86.5%	59.4%	13.2%	4.7%
Effective Sample Size	6223	5773	5325	4848	4406	3950	3175	1798	258	149

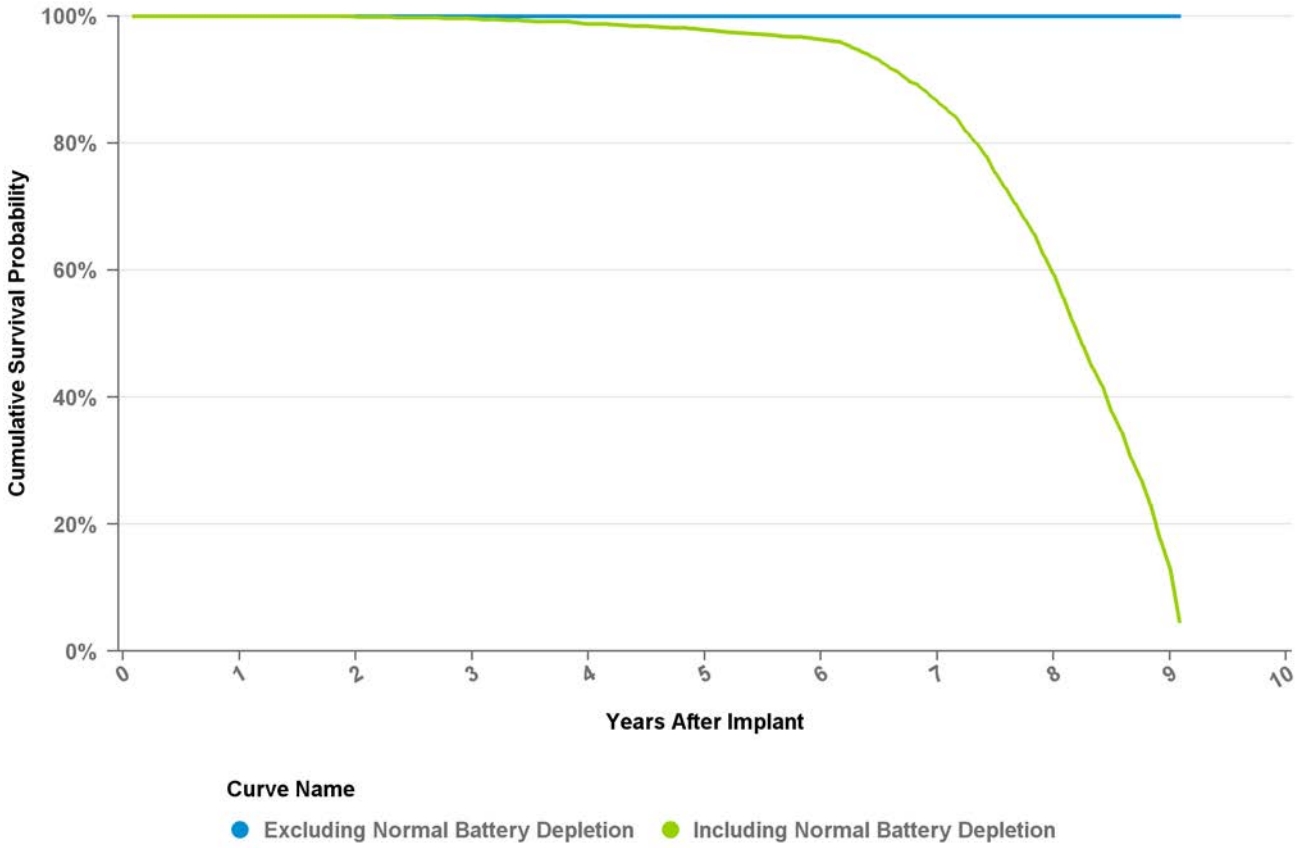
Implantable Pulse Generator

E1DR06 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0
NBG Code	DDDR
Max Delivered Energy	

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E1DR01, E1DR03, E1DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.6%	98.7%	97.8%	96.3%	86.5%	59.4%	13.2%	4.7%
Effective Sample Size	6223	5773	5325	4848	4406	3950	3175	1798	258	149

Implantable Pulse Generator

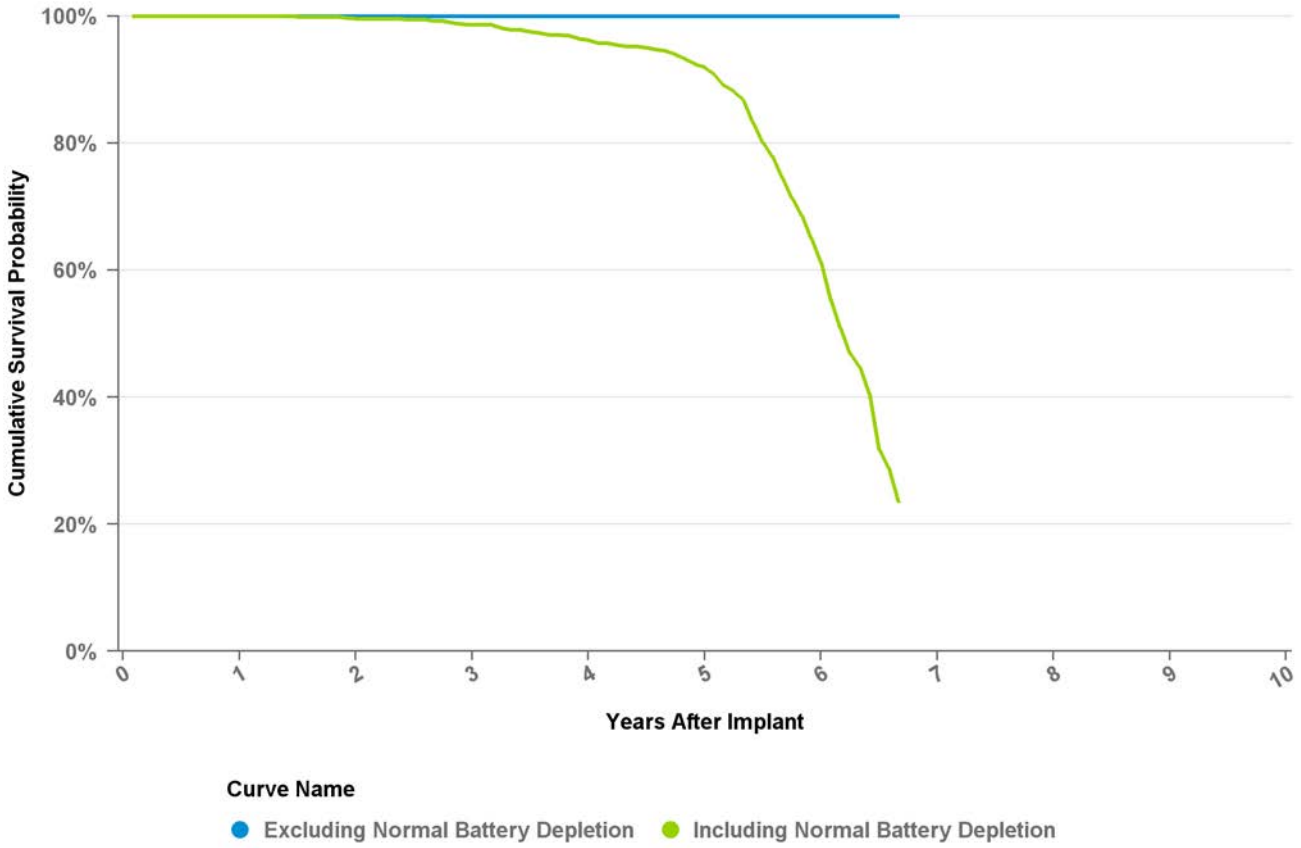
E1DR21 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	1,856
Estimated Active US Implants	149
Normal Battery Depletions (US)	374

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E1DR21, Survival Curve



Years	1	2	3	4	5	6	at 80 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.6%	98.6%	96.2%	91.9%	61.3%	23.6%
Effective Sample Size	1640	1486	1326	1161	967	464	108

Implantable Pulse Generator

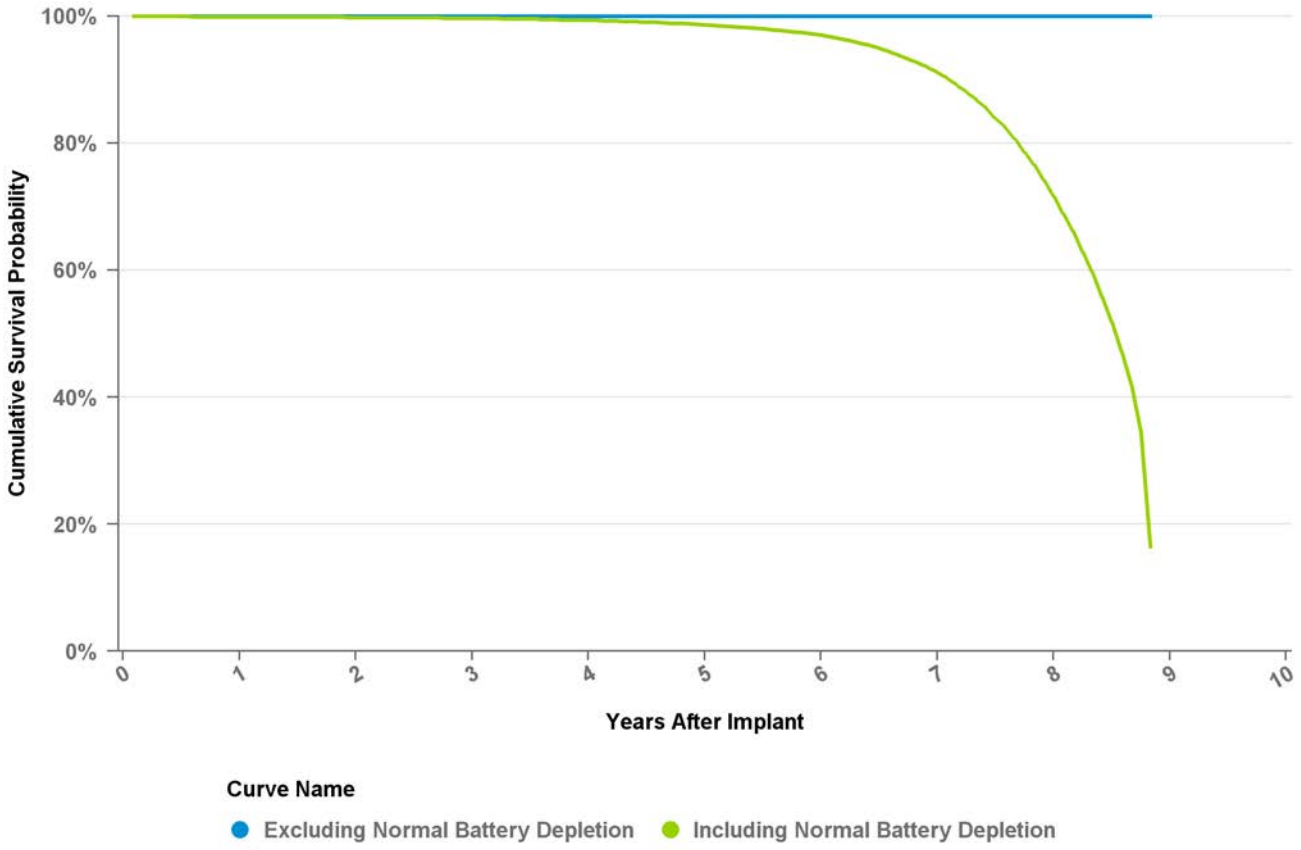
E2D01 EnPulse 2

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.3%	98.6%	97.0%	91.1%	71.7%	16.4%
Effective Sample Size	94881	87687	80618	73900	67280	60796	52249	24499	817

Implantable Pulse Generator

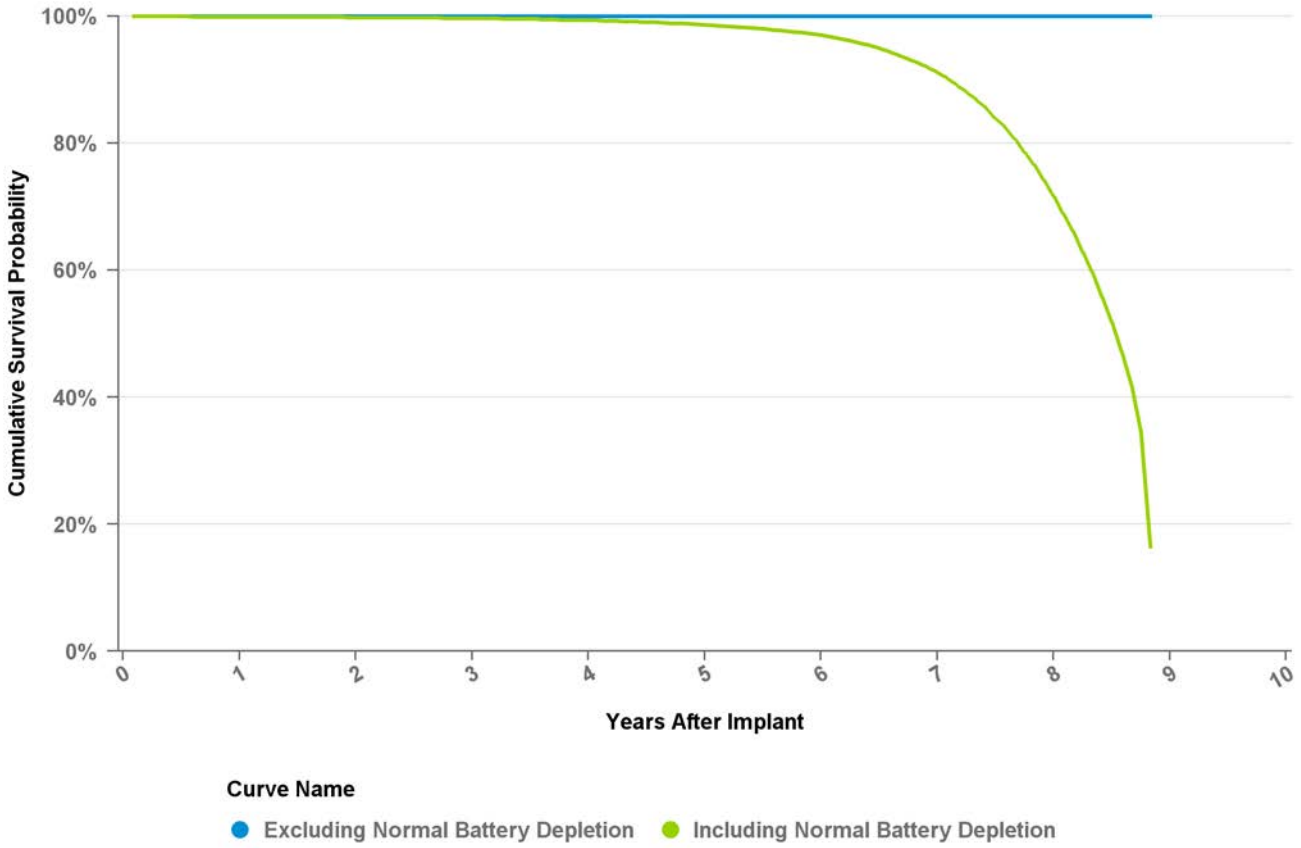
E2D03 EnPulse 2

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.3%	98.6%	97.0%	91.1%	71.7%	16.4%
Effective Sample Size	94881	87687	80618	73900	67280	60796	52249	24499	817

Implantable Pulse Generator

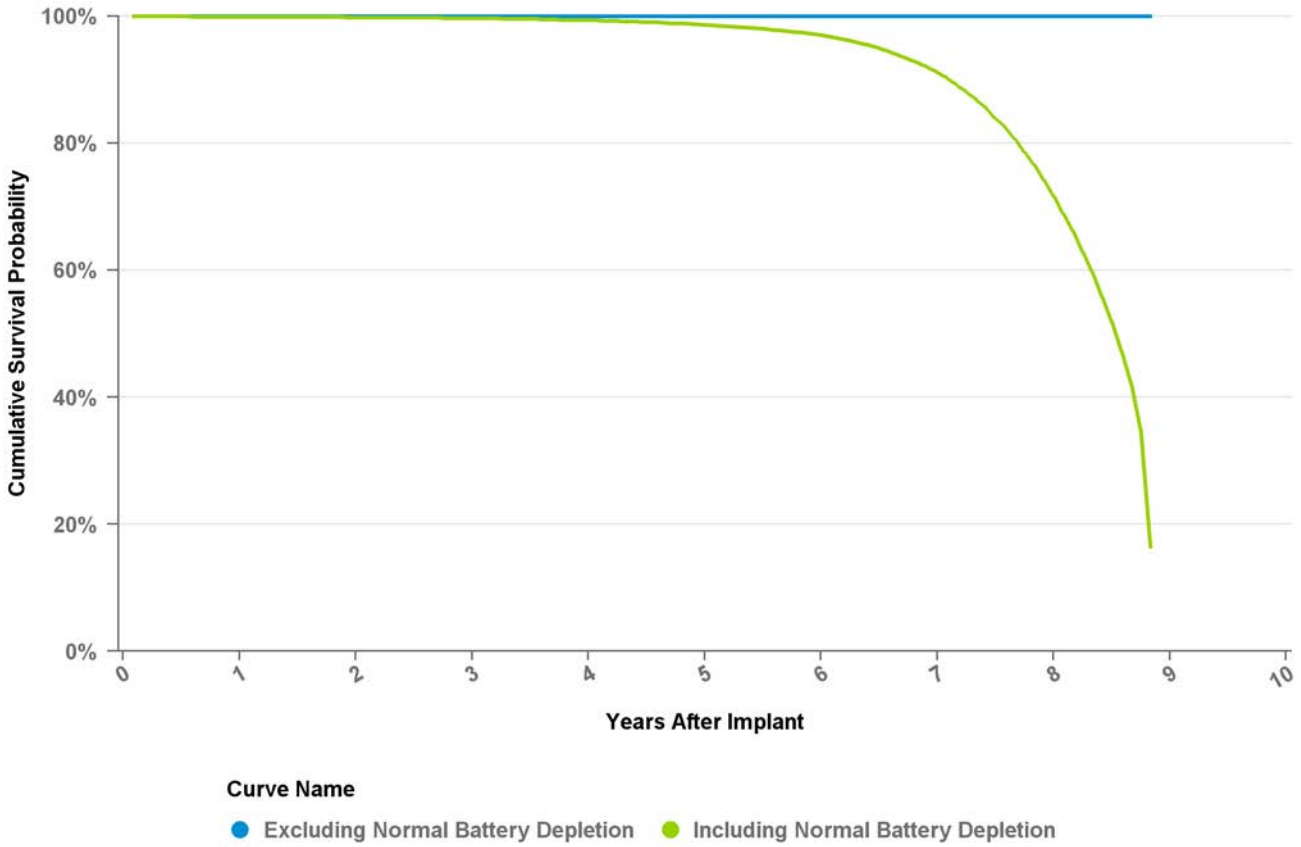
E2DR01 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	97,065
Estimated Active US Implants	33,200
Normal Battery Depletions (US)	10,791

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	25
Therapy Not Compromised Malfunction	20
Battery Malfunction	0
Electrical Component	18
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	1
Electrical Component	3
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.3%	98.6%	97.0%	91.1%	71.7%	16.4%
Effective Sample Size	94881	87687	80618	73900	67280	60796	52249	24499	817

Implantable Pulse Generator

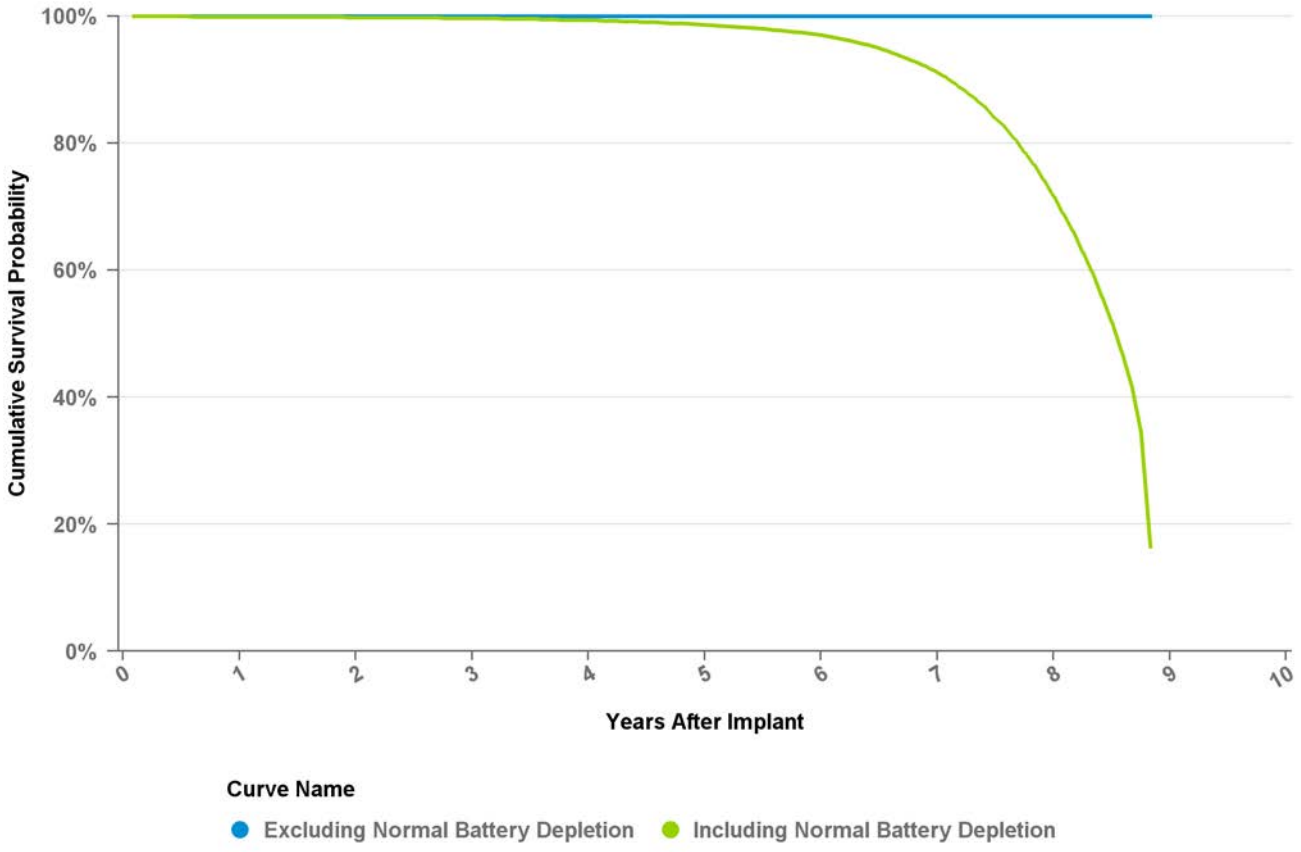
E2DR03 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	2,047
Estimated Active US Implants	736
Normal Battery Depletions (US)	232

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.3%	98.6%	97.0%	91.1%	71.7%	16.4%
Effective Sample Size	94881	87687	80618	73900	67280	60796	52249	24499	817

Implantable Pulse Generator

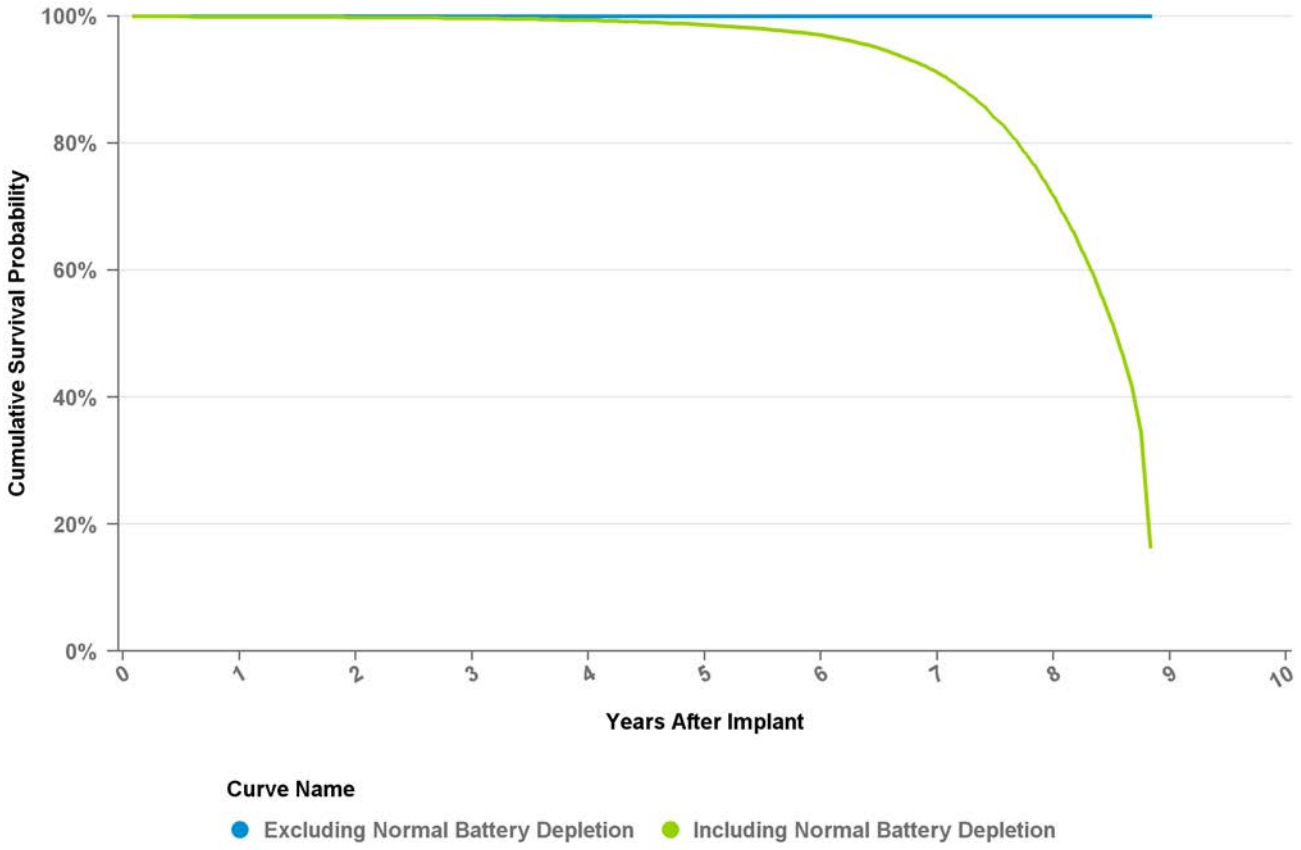
E2DR06 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	1,626
Estimated Active US Implants	419
Normal Battery Depletions (US)	195

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2D01, E2D03, E2DR01, E2DR03, E2DR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.8%	99.7%	99.3%	98.6%	97.0%	91.1%	71.7%	16.4%
Effective Sample Size	94881	87687	80618	73900	67280	60796	52249	24499	817

Implantable Pulse Generator

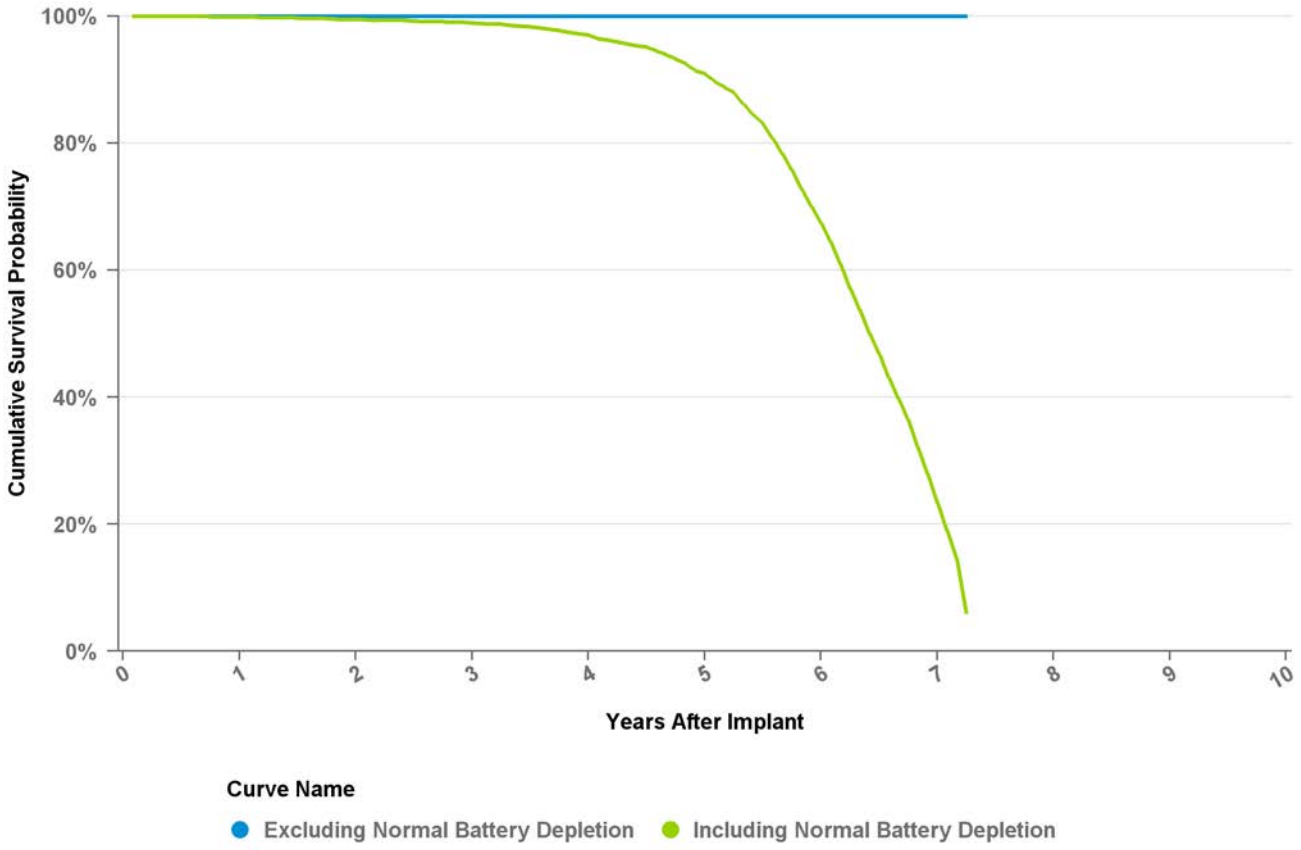
E2DR21 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	12,199
Estimated Active US Implants	1,681
Normal Battery Depletions (US)	2,173

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2DR21, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.5%	98.9%	97.0%	90.9%	67.5%	23.5%	6.1%
Effective Sample Size	10874	9752	8759	7661	6293	3689	697	158

Implantable Pulse Generator

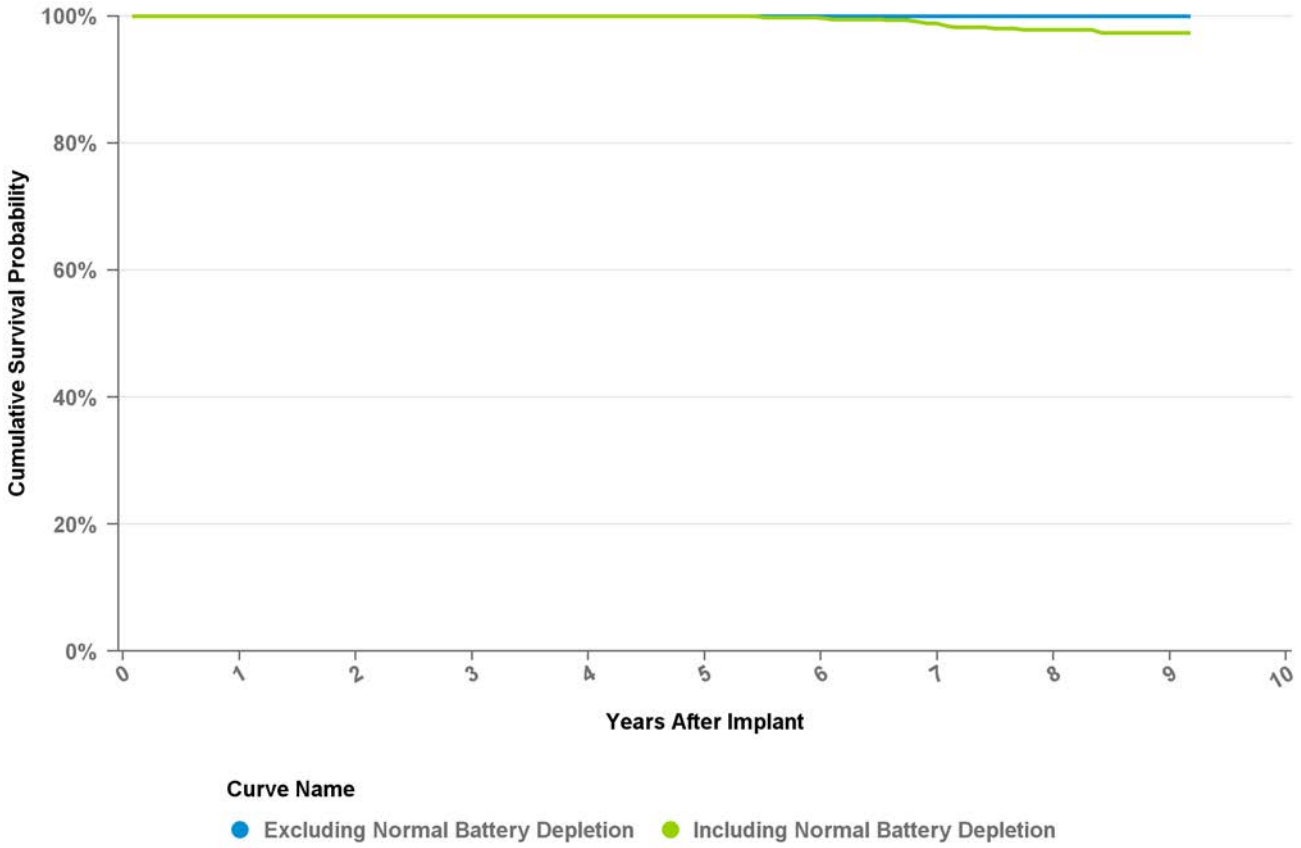
E2DR31 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	587
Estimated Active US Implants	377
Normal Battery Depletions (US)	14

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2DR31, E2DR33, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.7%	98.8%	97.8%	97.3%	97.3%
Effective Sample Size	1401	1367	1328	1287	1245	1150	1087	672	166	103

Implantable Pulse Generator

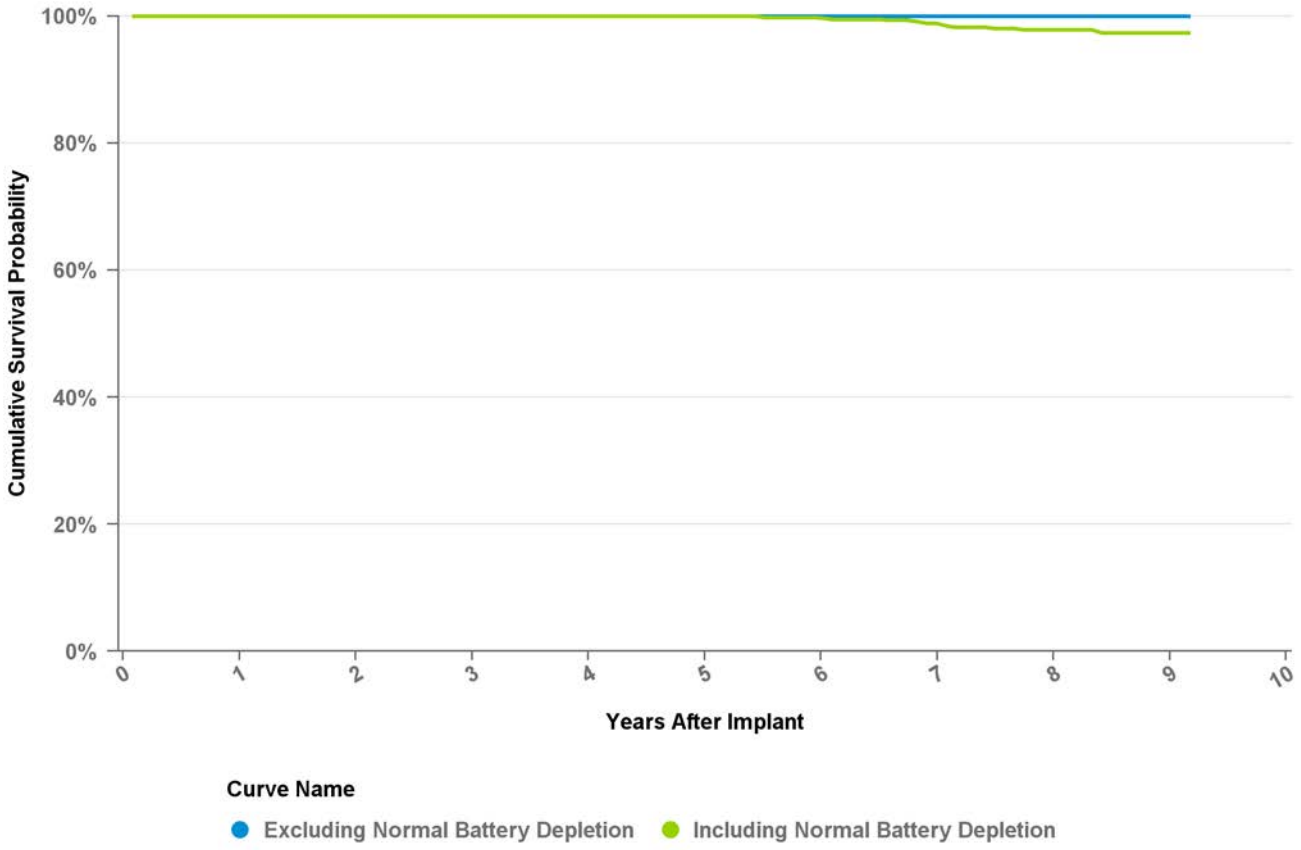
E2DR33 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	5
Estimated Active US Implants	5
Normal Battery Depletions (US)	0

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2DR31, E2DR33, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 110 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.7%	98.8%	97.8%	97.3%	97.3%
Effective Sample Size	1401	1367	1328	1287	1245	1150	1087	672	166	103

Implantable Pulse Generator

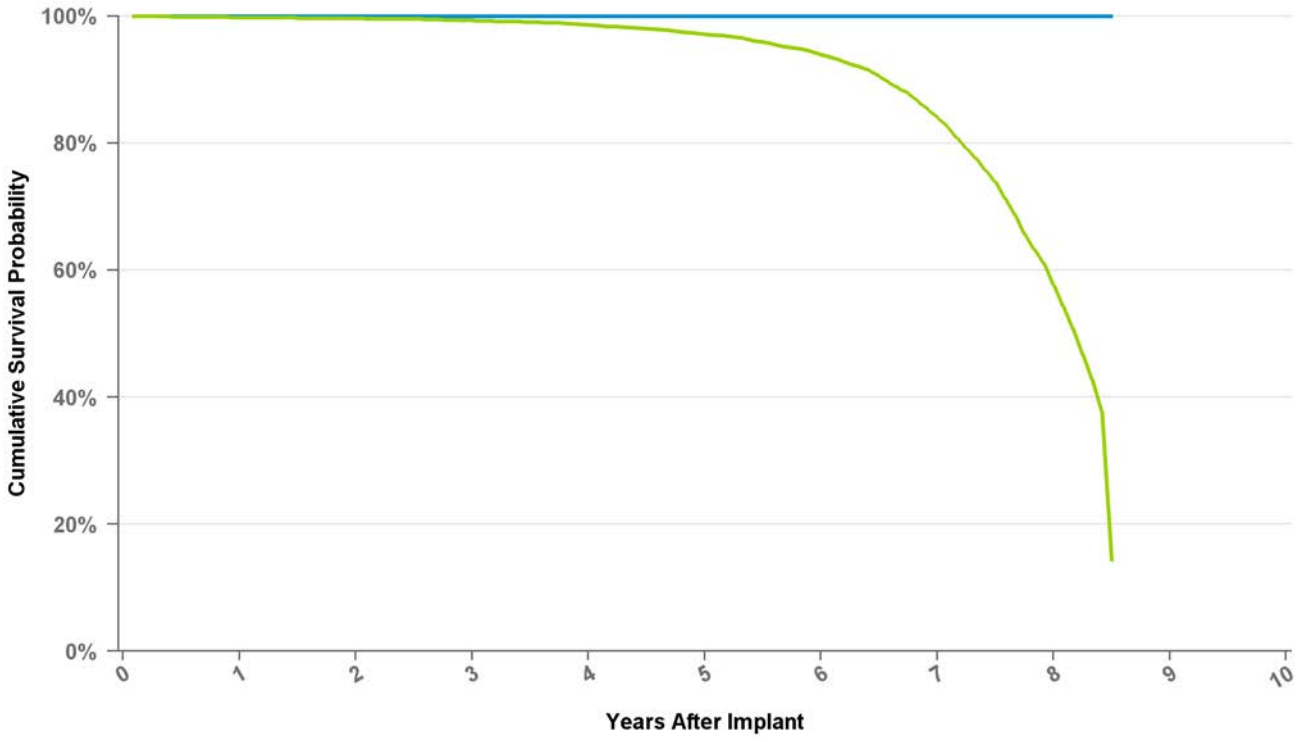
E2SR01 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	22,530
Estimated Active US Implants	4,818
Normal Battery Depletions (US)	1,940

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0

E2SR01, E2SR03, E2SR06, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.6%	97.1%	93.9%	84.0%	57.7%	14.4%
Effective Sample Size	22615	19631	17131	14982	12829	10942	8435	2388	117

Implantable Pulse Generator

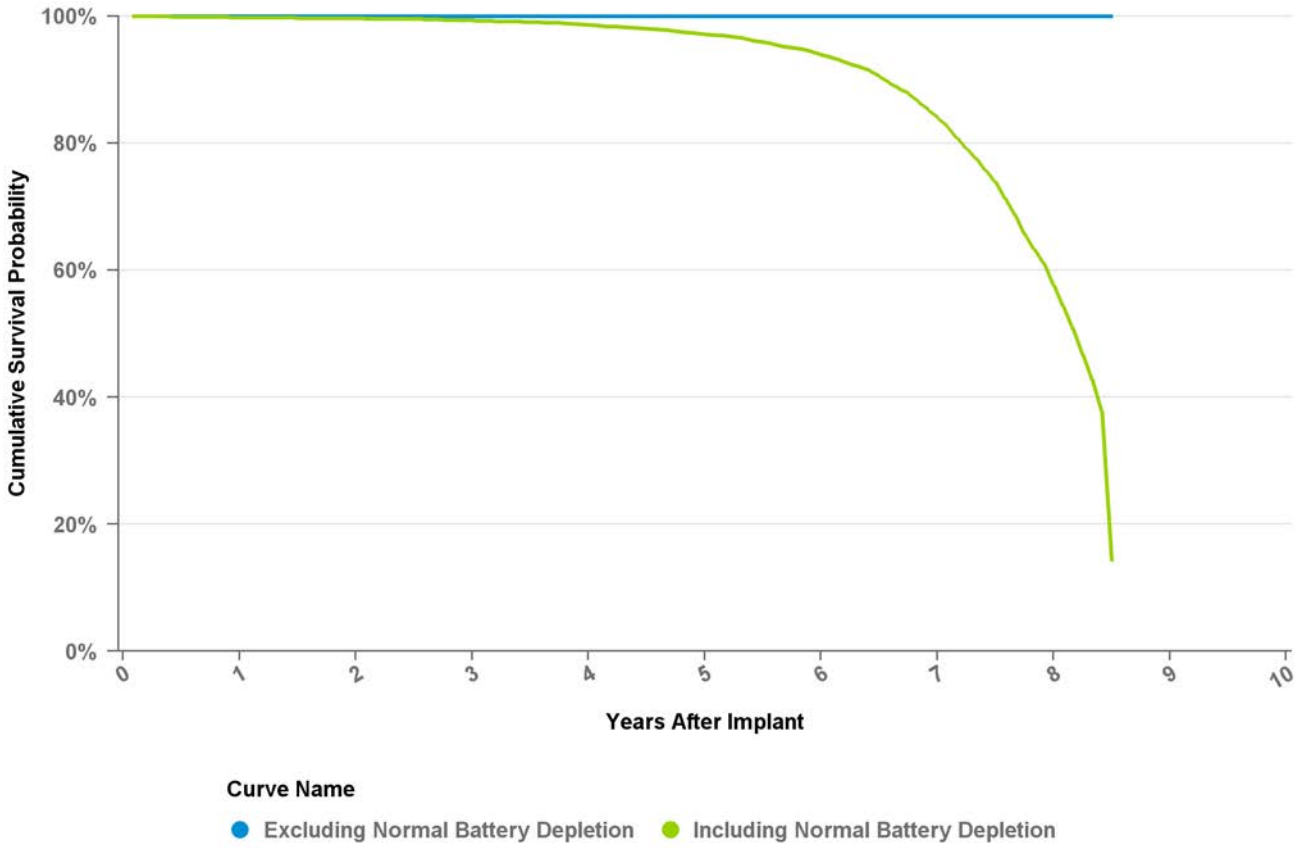
E2SR03 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,098
Estimated Active US Implants	242
Normal Battery Depletions (US)	93

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2SR01, E2SR03, E2SR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.6%	97.1%	93.9%	84.0%	57.7%	14.4%
Effective Sample Size	22615	19631	17131	14982	12829	10942	8435	2388	117

Implantable Pulse Generator

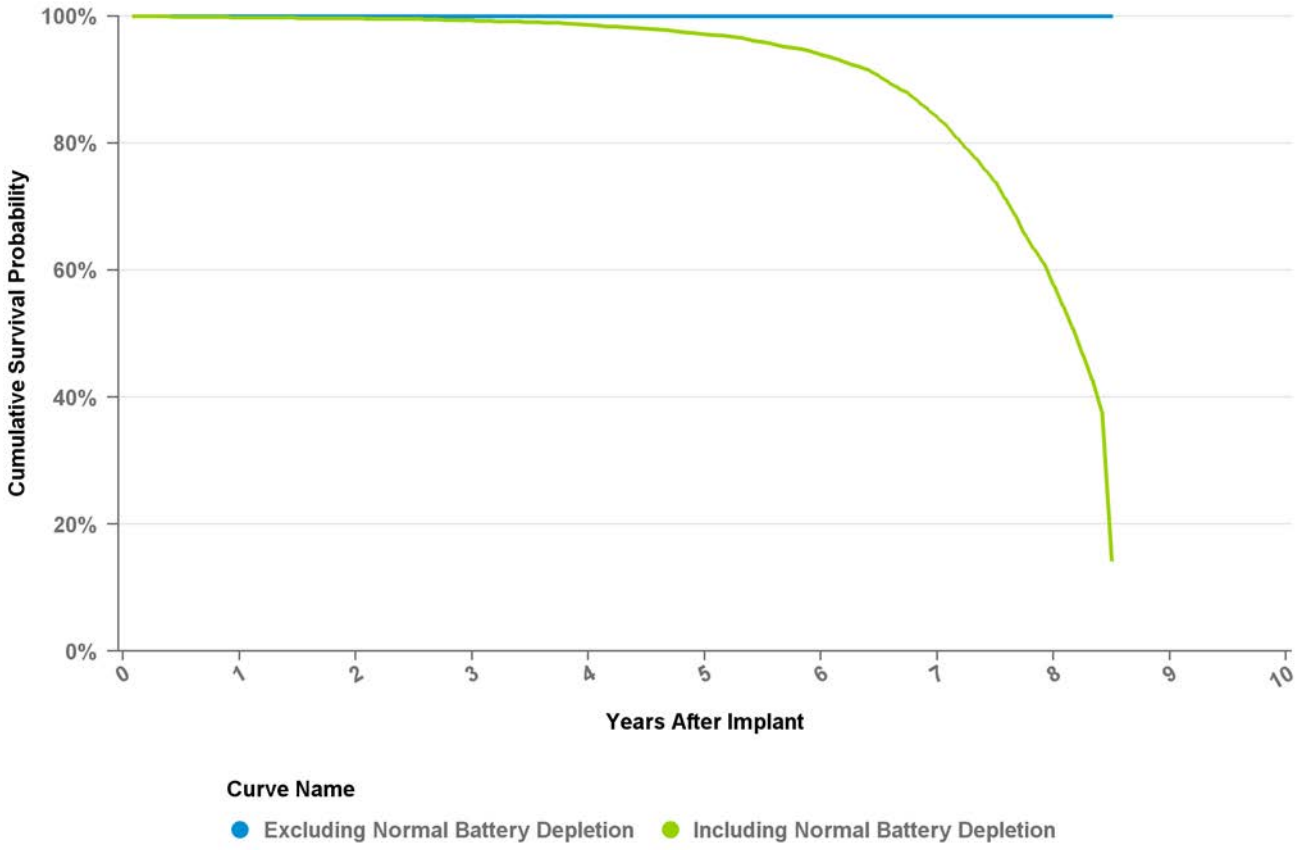
E2SR06 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,749
Estimated Active US Implants	348
Normal Battery Depletions (US)	137

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2SR01, E2SR03, E2SR06, Survival Curve



Years	1	2	3	4	5	6	7	8	at 102 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.8%	99.7%	99.3%	98.6%	97.1%	93.9%	84.0%	57.7%	14.4%
Effective Sample Size	22615	19631	17131	14982	12829	10942	8435	2388	117

Implantable Pulse Generator

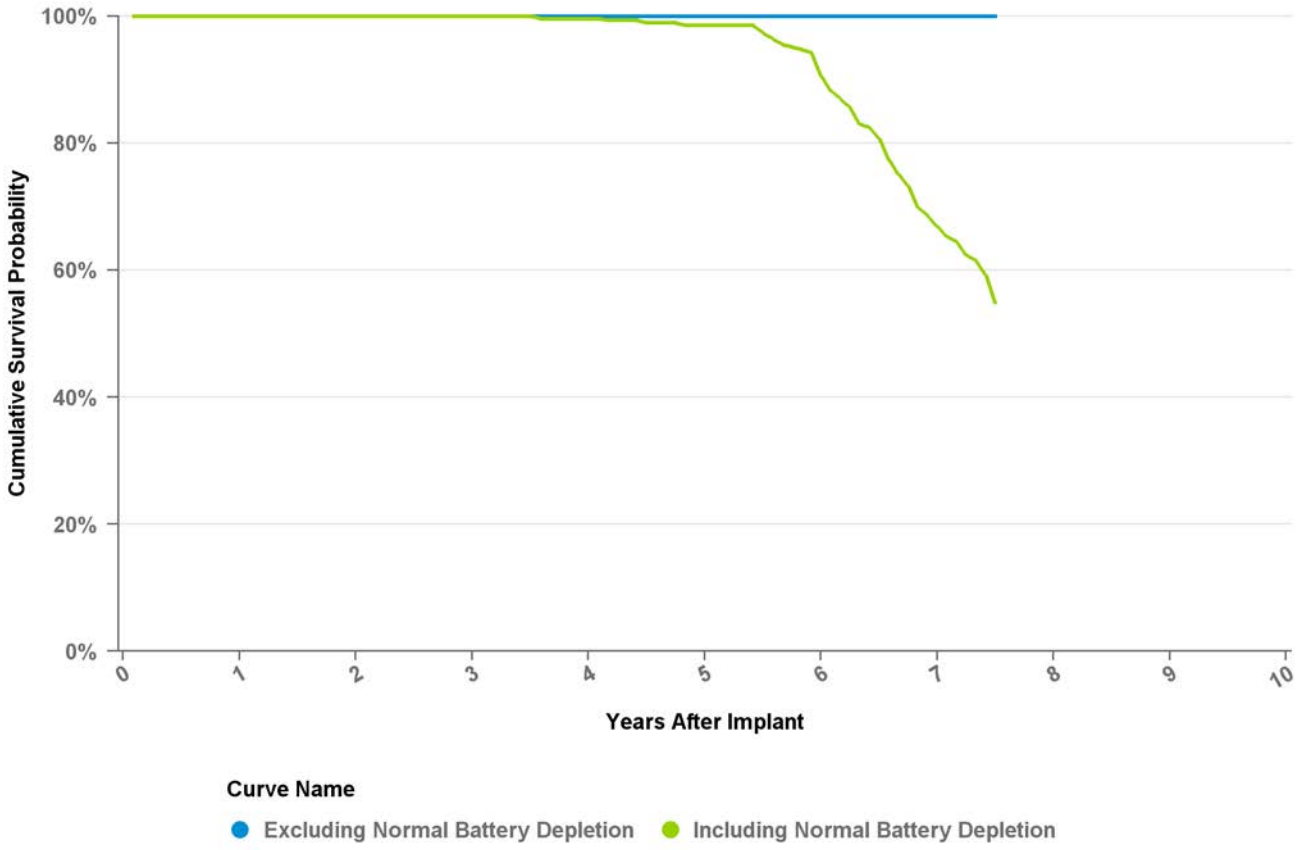
E2VDD01 EnPulse 2 VDD

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	556
Estimated Active US Implants	105
Normal Battery Depletions (US)	83

NBG Code	VDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

E2VDD01, Survival Curve



Years	1	2	3	4	5	6	7	at 90 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.6%	98.5%	90.6%	66.9%	54.8%
Effective Sample Size	709	655	603	551	498	419	178	104

Implantable Pulse Generator

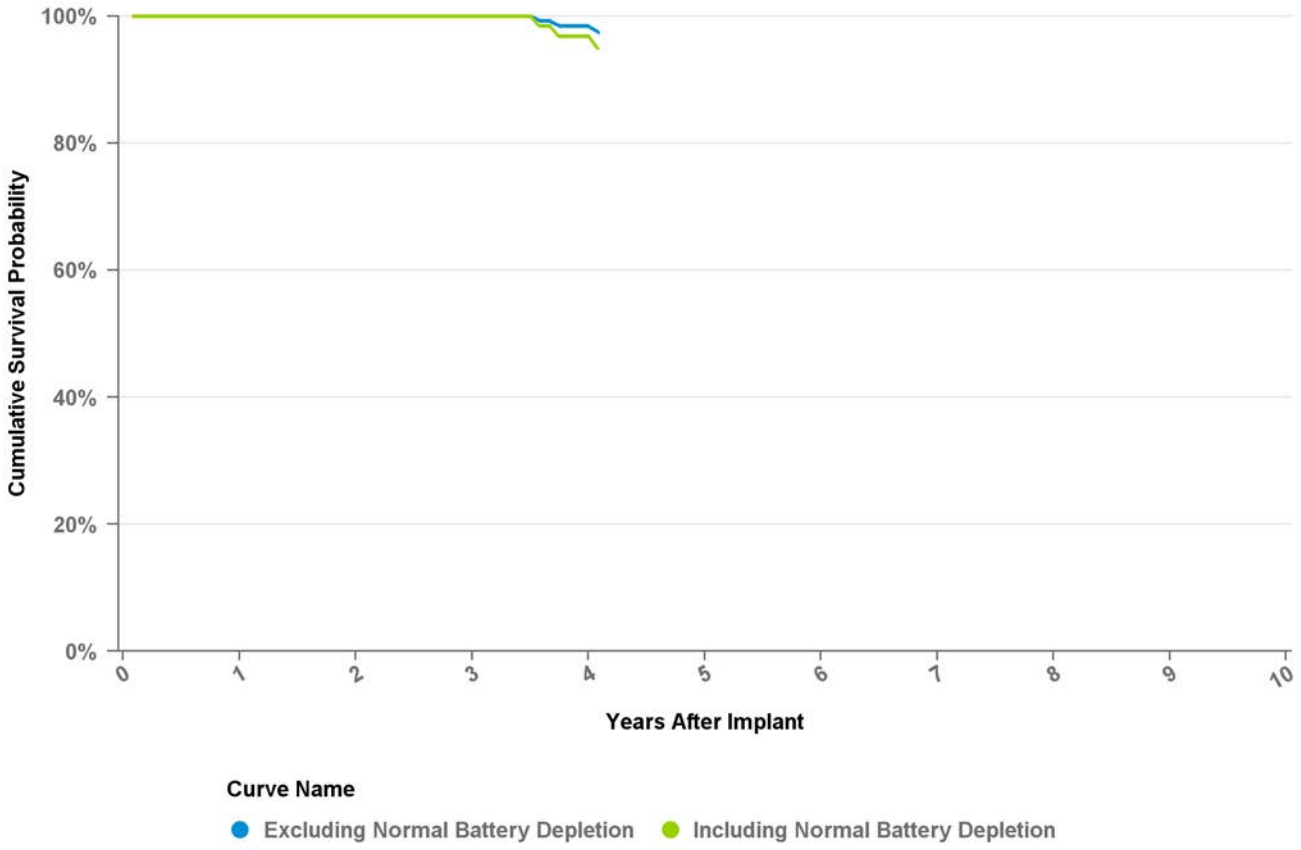
EMDR01 EnRhythm MRI

US Market Release Date	
CE Market Approval Date	9/30/2008
Registered US Implants	111
Estimated Active US Implants	72
Normal Battery Depletions (US)	0

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	11
Therapy Not Compromised Malfunction	11
Battery Malfunction	11
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

EMDR01, EMDR02, Survival Curve



Years	1	2	3	4	at 49 mo
Excluding NBD	100.0%	100.0%	100.0%	98.4%	97.4%
Including NBD	100.0%	100.0%	100.0%	96.8%	94.9%
Effective Sample Size	156	153	141	106	100

Implantable Pulse Generator

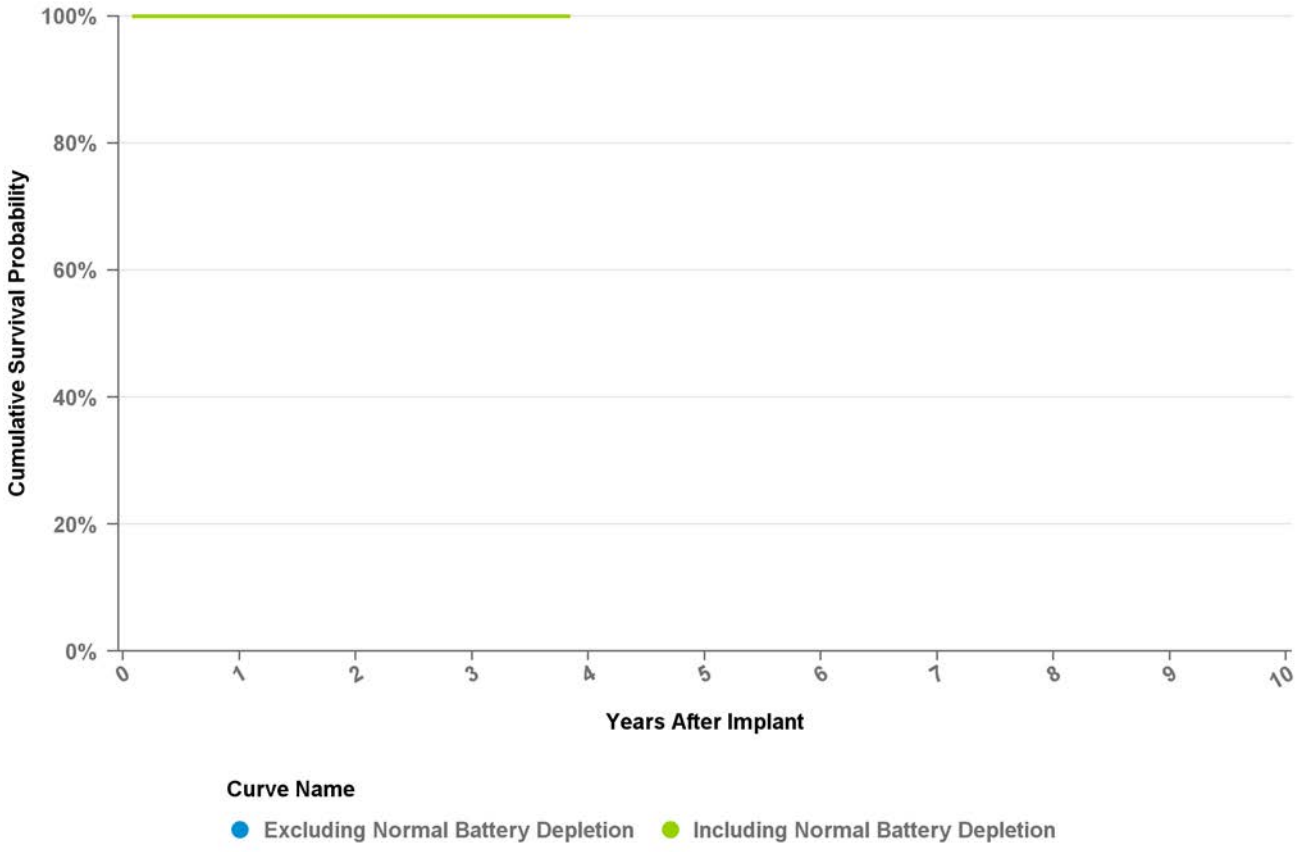
EN1DR01 Ensura MRI

US Market Release Date	
CE Market Approval Date	6/23/2010
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	OOE-DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

A2DR01, A3DR01, A5DR01, EN1DR01, Survival Curve



Years	1	2	3	at 46 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	11896	6792	2754	137

Implantable Pulse Generator

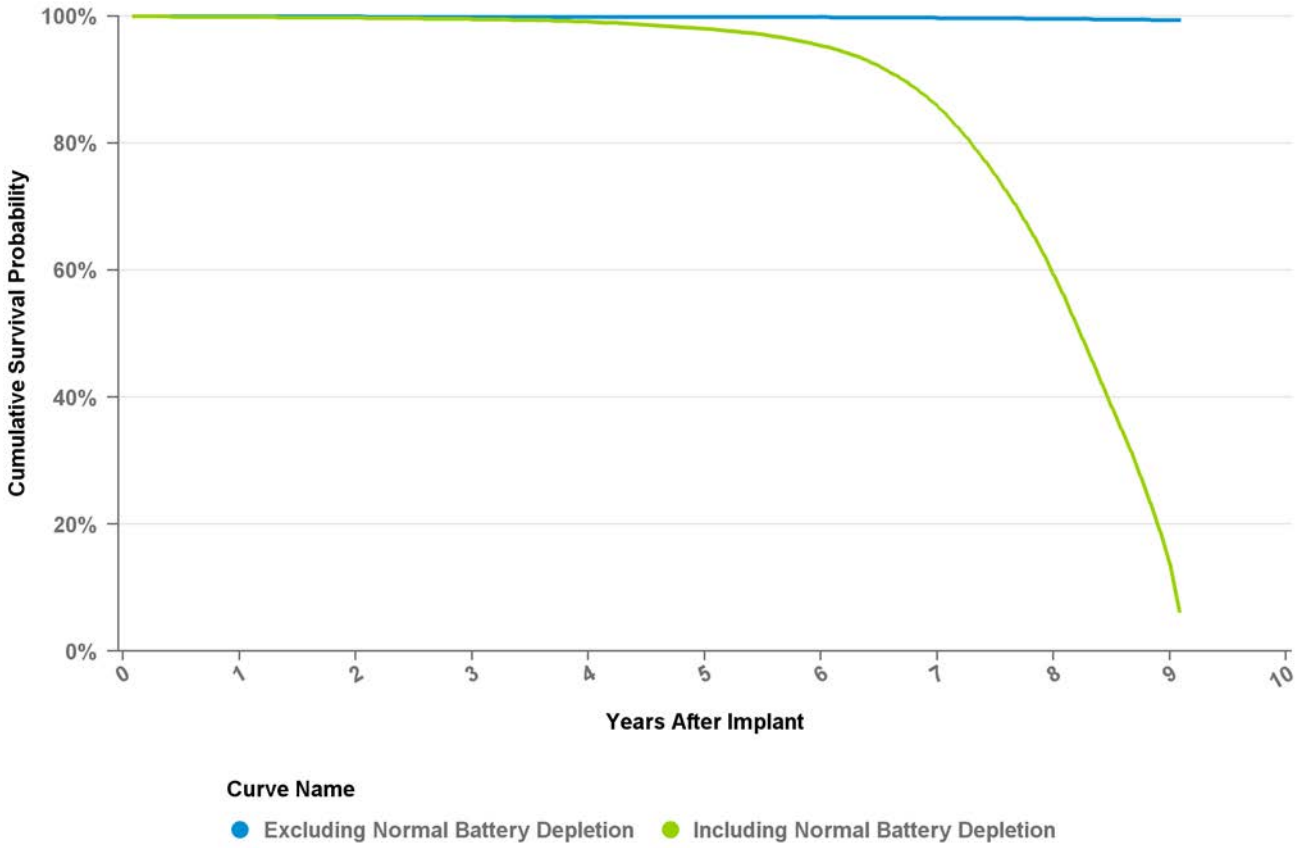
KD700 Kappa 700 DR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.9%	99.8%	99.5%	99.1%	98.0%	95.3%	85.8%	59.3%	13.8%	6.3%
Effective Sample Size	180525	165538	151029	136576	122438	106991	83675	43045	4419	2245

Implantable Pulse Generator

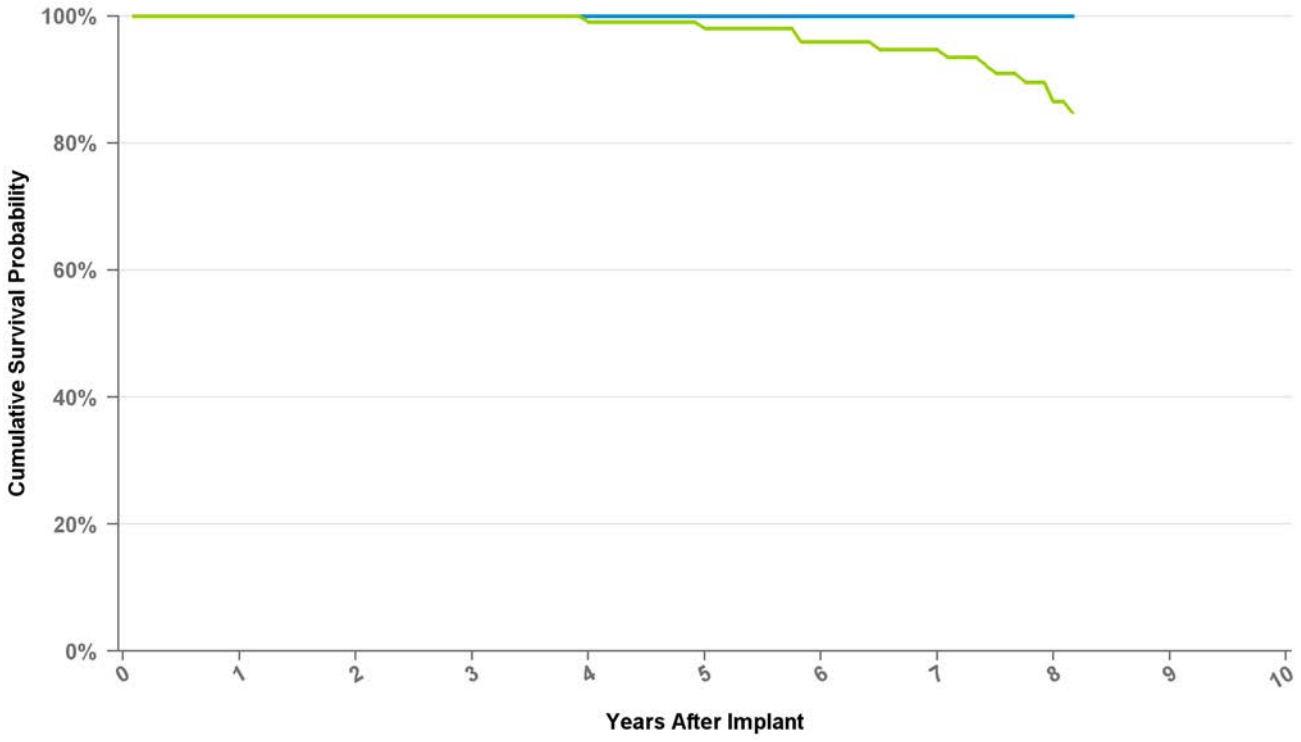
KD701 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	242
Estimated Active US Implants	47
Normal Battery Depletions (US)	21

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD701, KD703, KD706, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.0%	98.0%	95.9%	94.7%	86.5%	84.8%
Effective Sample Size	287	261	231	210	196	174	157	116	104

Implantable Pulse Generator

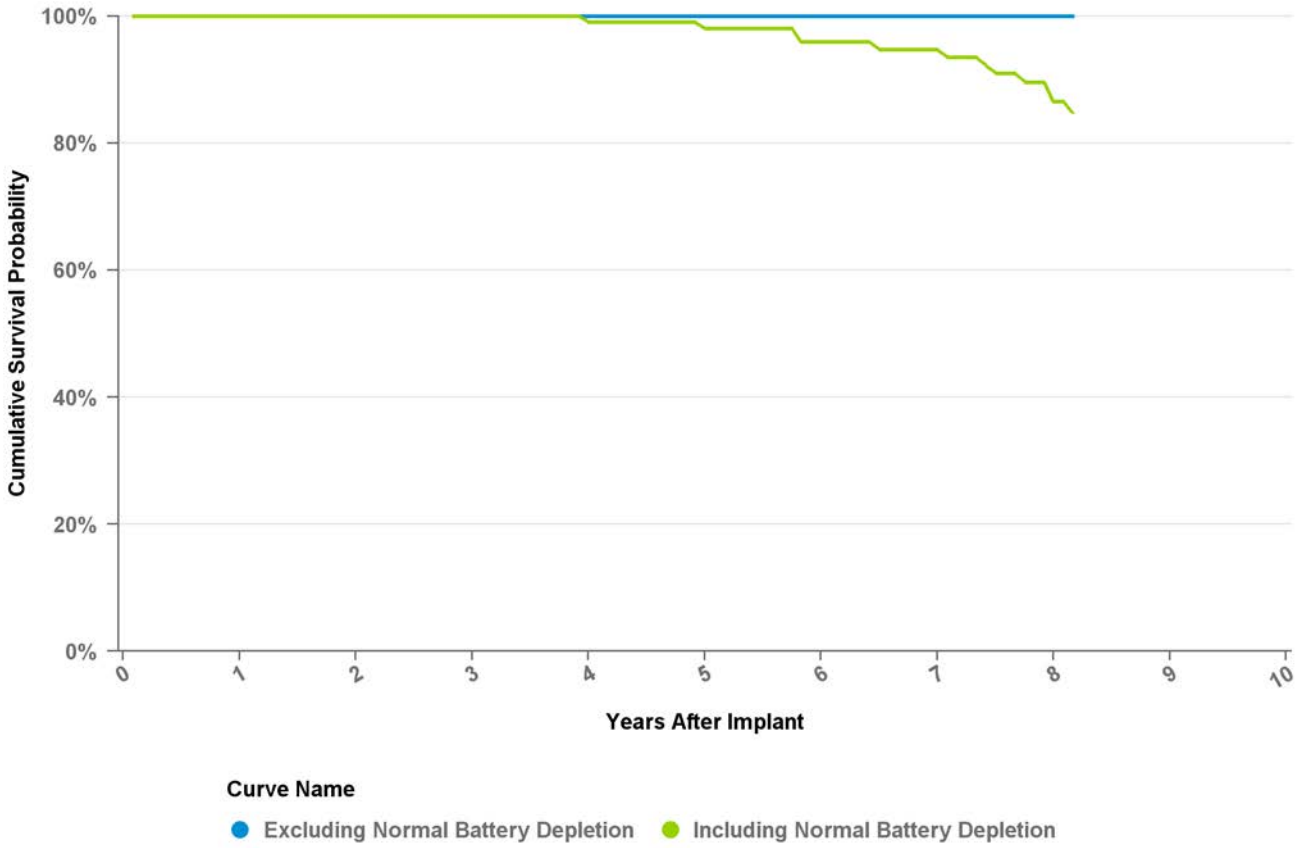
KD703 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD701, KD703, KD706, Survival Curve



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.0%	98.0%	95.9%	94.7%	86.5%	84.8%
Effective Sample Size	287	261	231	210	196	174	157	116	104

Implantable Pulse Generator

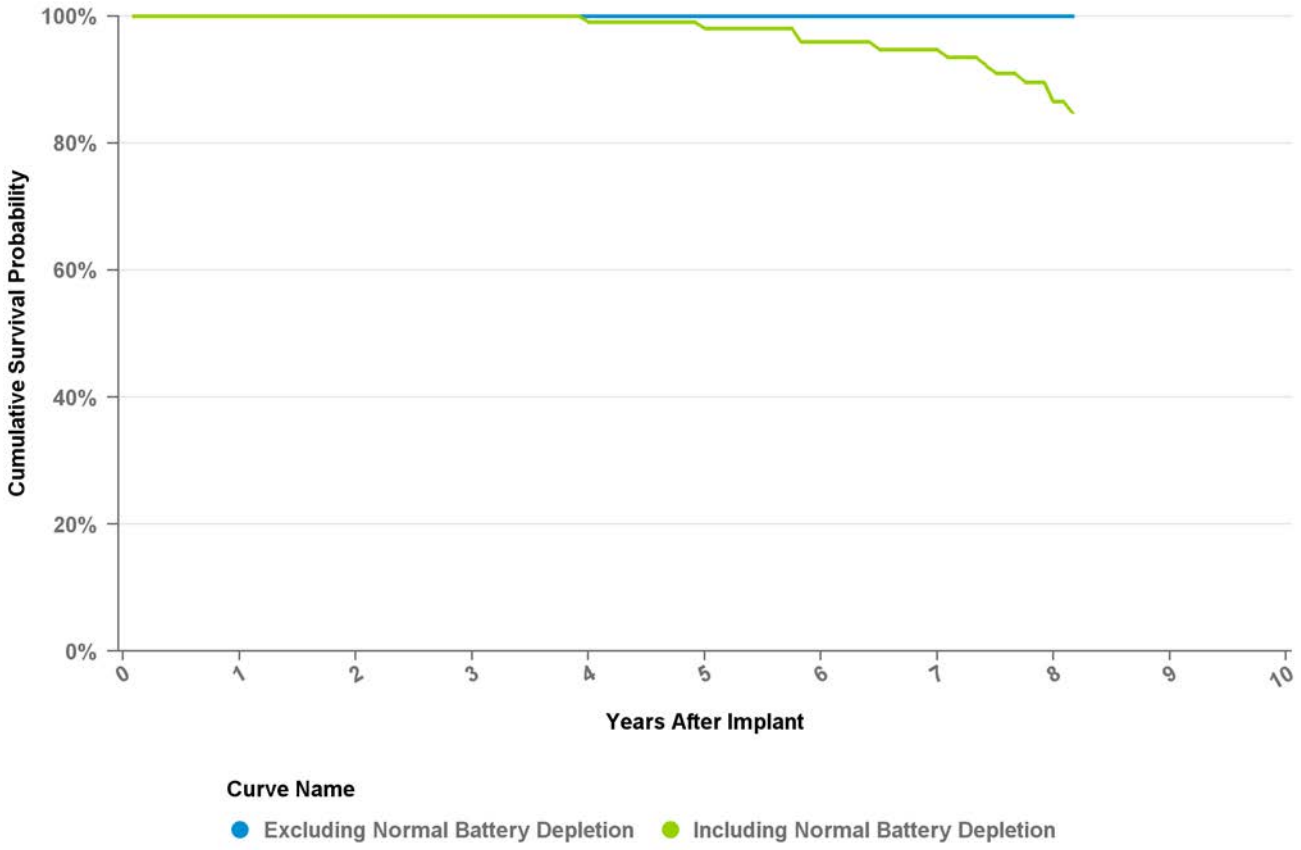
KD706 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD701, KD703, KD706, Survival Curve



Years	1	2	3	4	5	6	7	8	at 98 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.0%	98.0%	95.9%	94.7%	86.5%	84.8%
Effective Sample Size	287	261	231	210	196	174	157	116	104

Implantable Pulse Generator

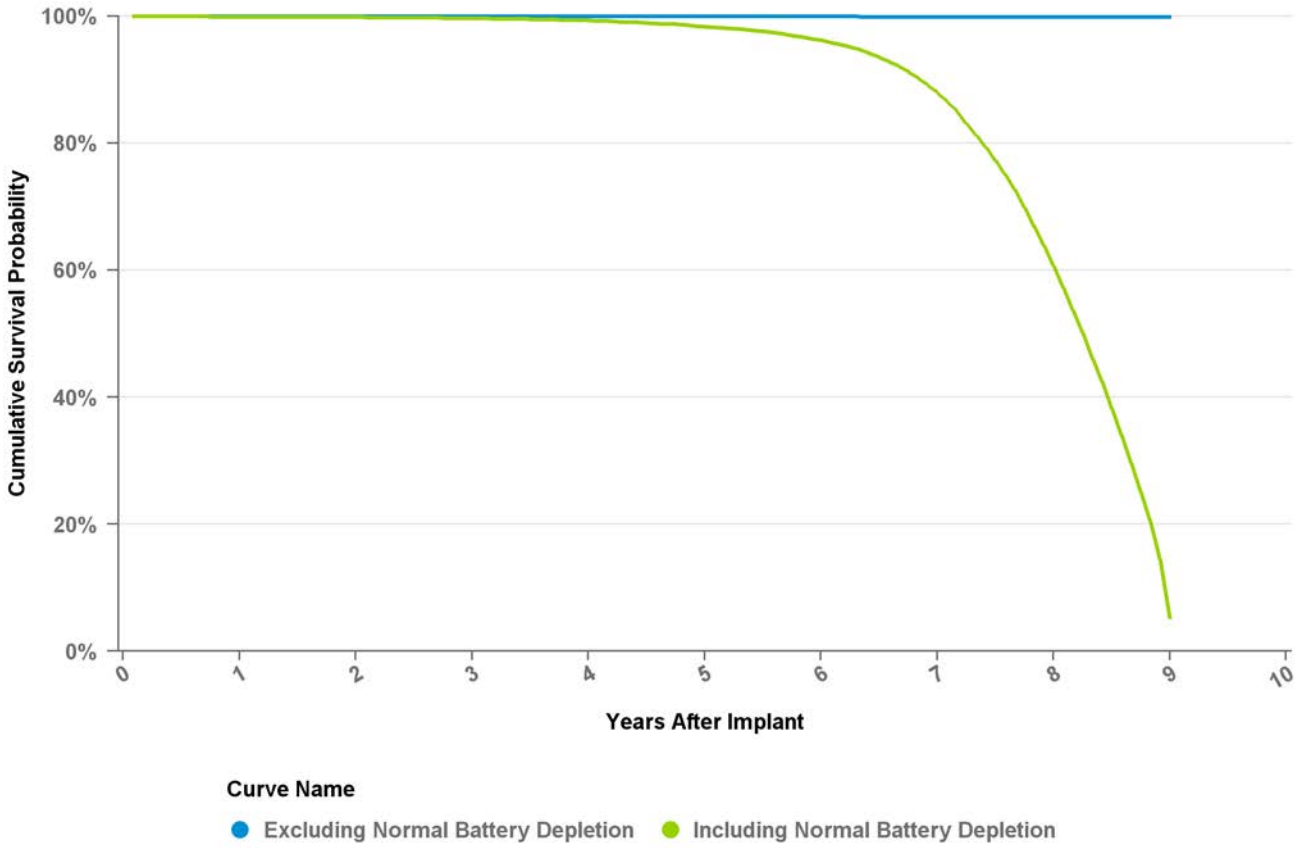
KD901 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

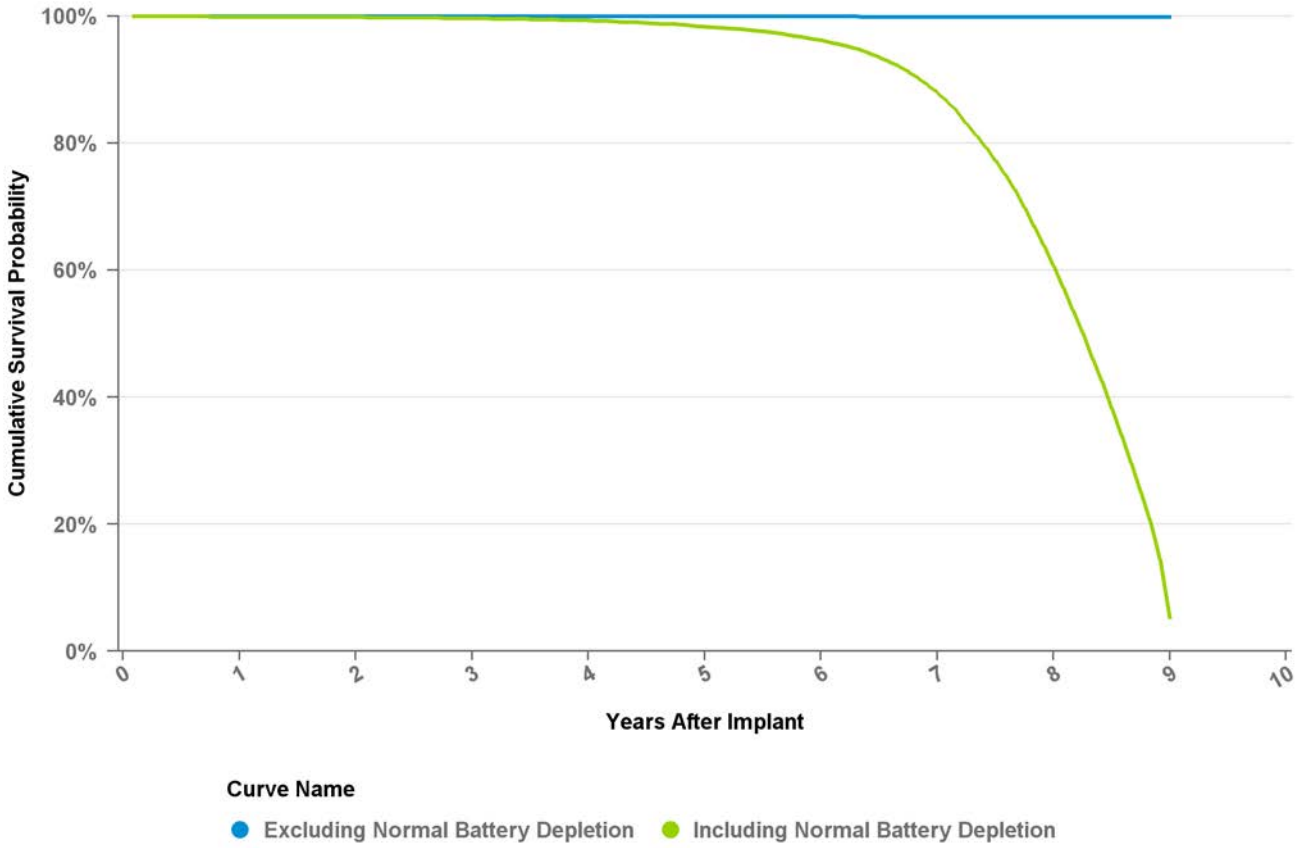
KD903 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

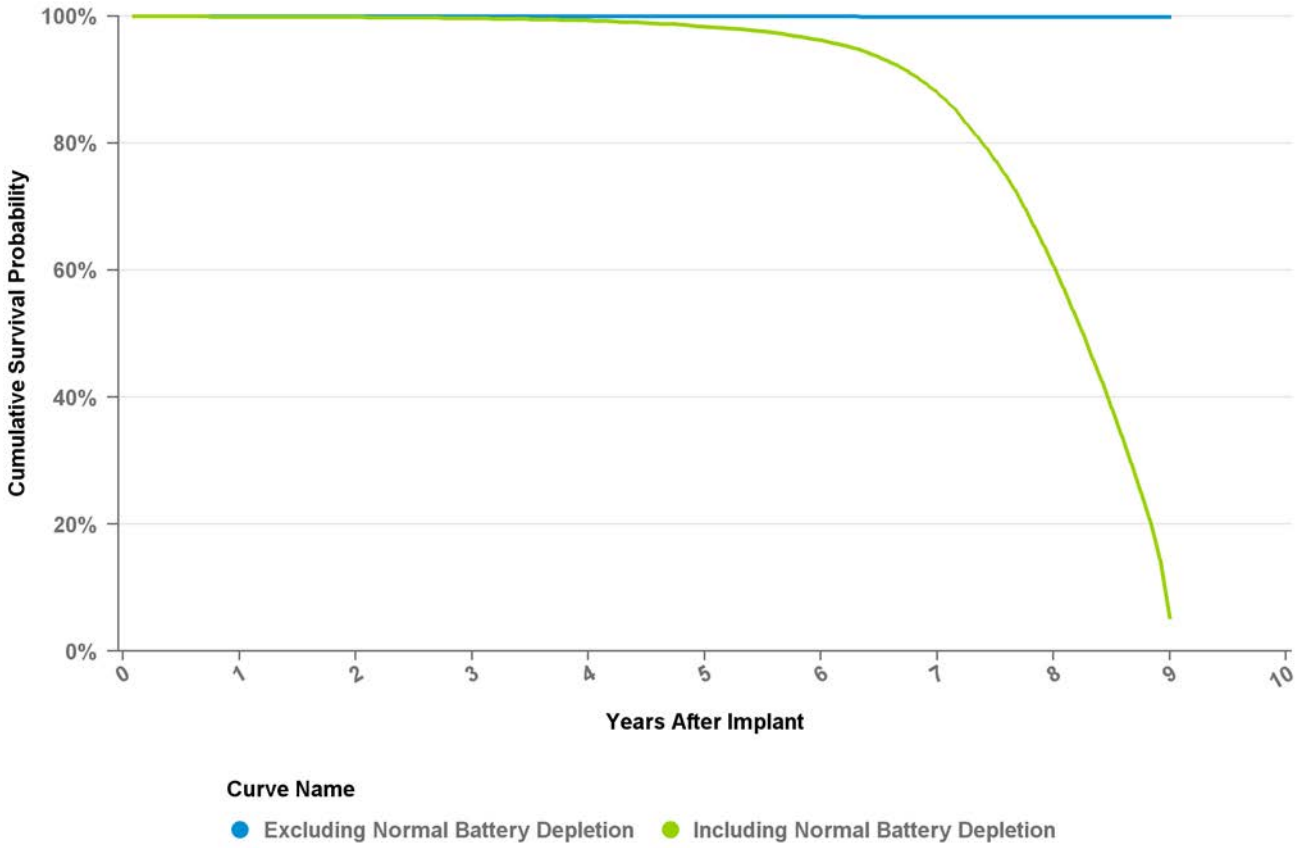
KD906 Kappa 900 D

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

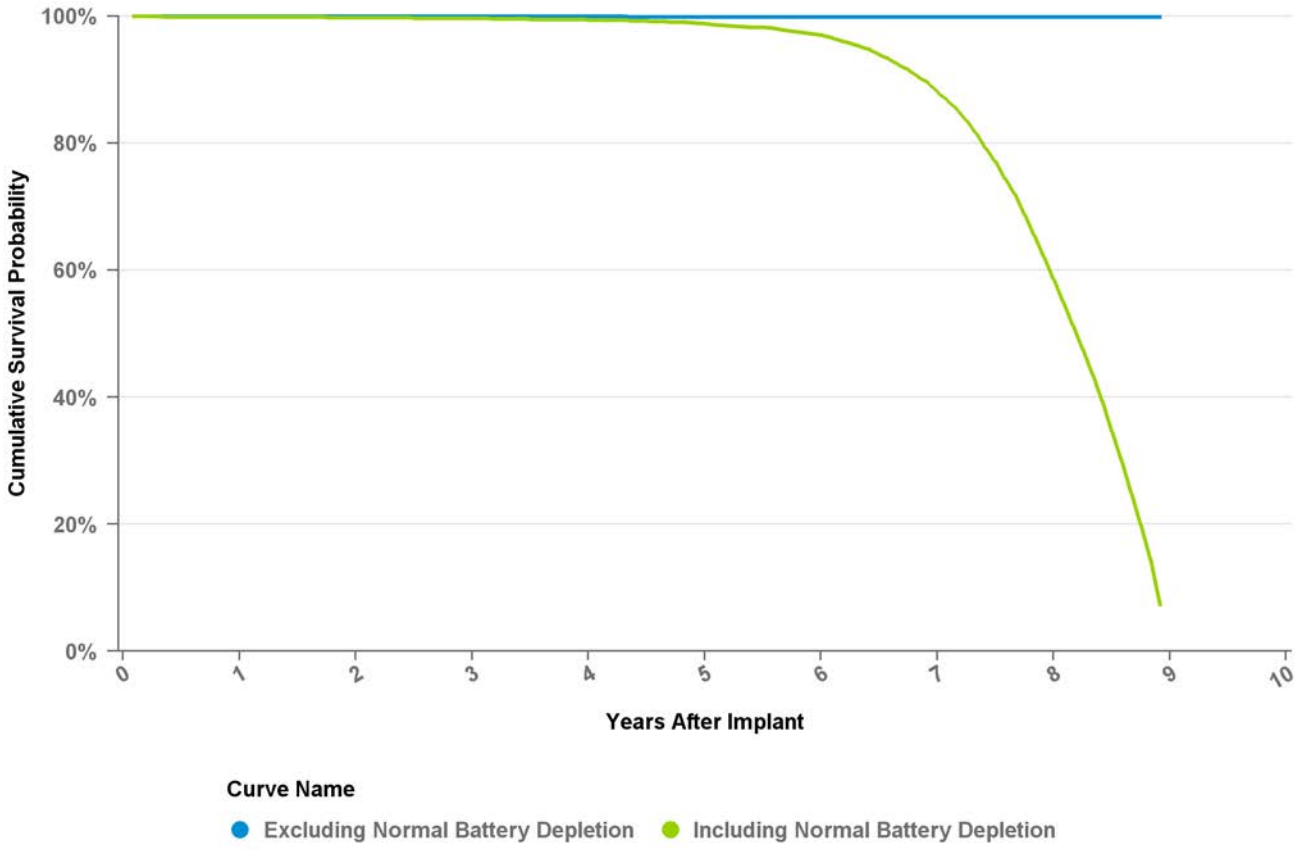
KDR401 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	39,405
Estimated Active US Implants	2,939
Normal Battery Depletions (US)	7,045

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	22
Therapy Not Compromised Malfunction	13
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	1
Other Malfunction	2
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KDR401, KDR403, Survival Curve



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.7%	99.4%	98.8%	97.0%	88.0%	58.6%	7.3%
Effective Sample Size	44246	41117	37950	34857	31529	27770	21360	9814	645

Implantable Pulse Generator

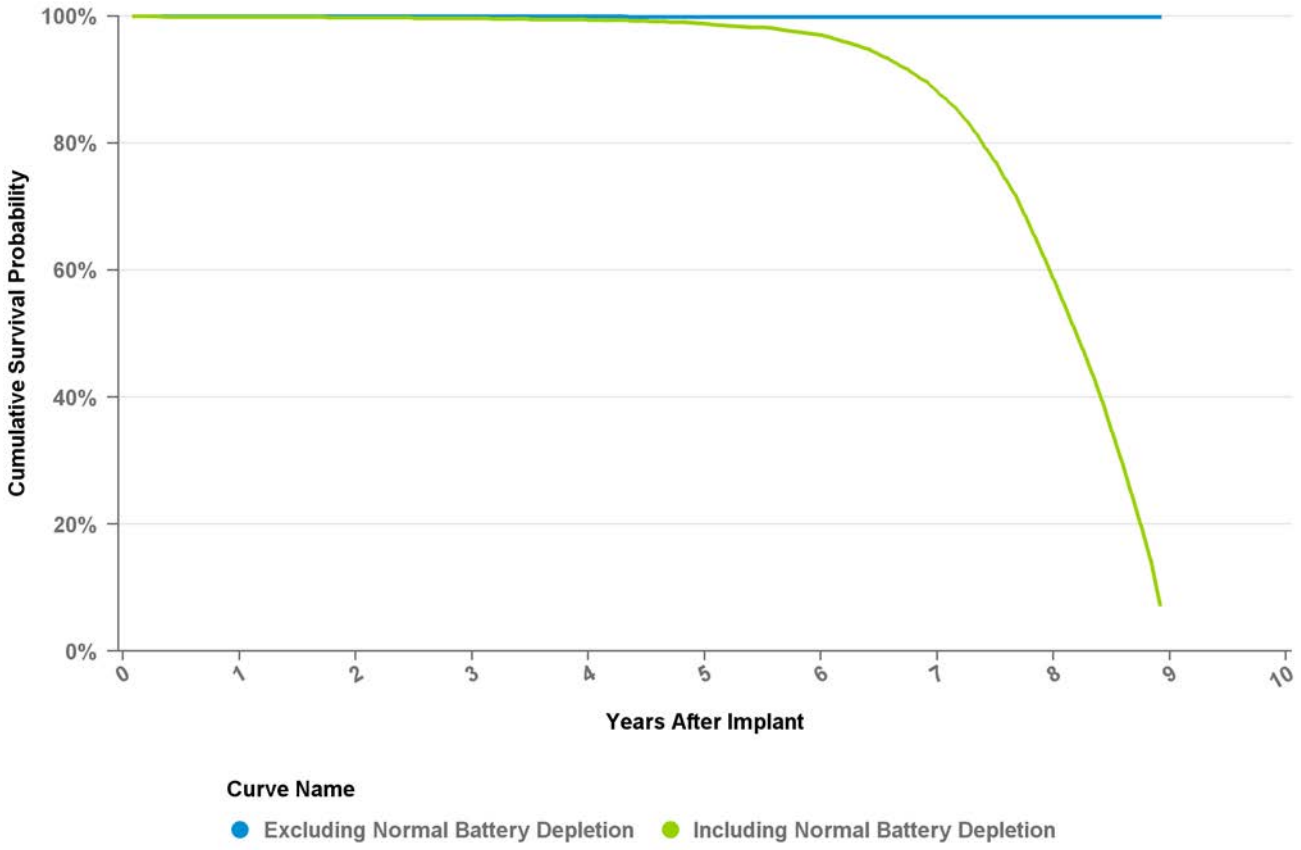
KDR403 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	7,309
Estimated Active US Implants	924
Normal Battery Depletions (US)	1,046

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	6
Therapy Not Compromised Malfunction	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KDR401, KDR403, Survival Curve



Years	1	2	3	4	5	6	7	8	at 107 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.7%	99.4%	98.8%	97.0%	88.0%	58.6%	7.3%
Effective Sample Size	44246	41117	37950	34857	31529	27770	21360	9814	645

Implantable Pulse Generator

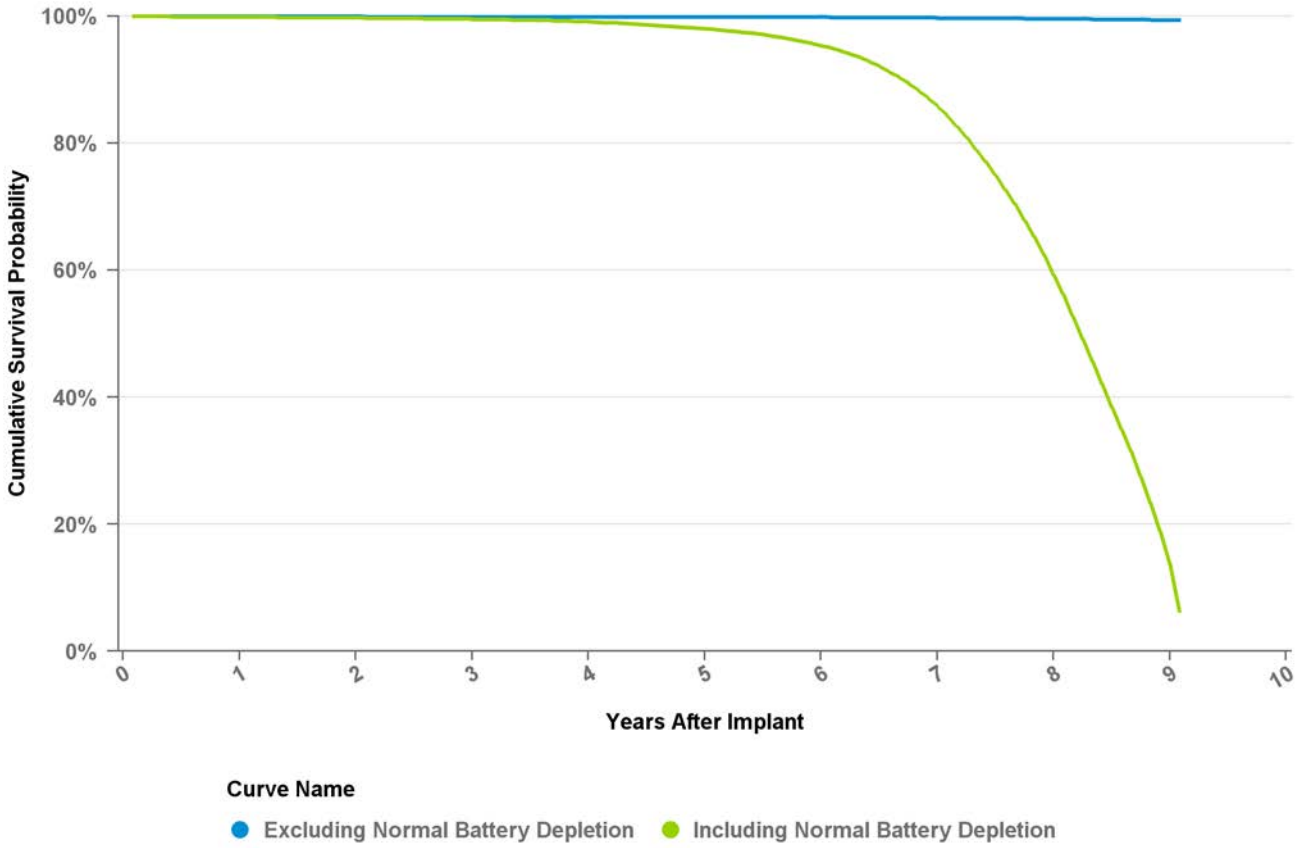
KDR700 Kappa 700 DR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	15
Estimated Active US Implants	1
Normal Battery Depletions (US)	4

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.9%	99.8%	99.5%	99.1%	98.0%	95.3%	85.8%	59.3%	13.8%	6.3%
Effective Sample Size	180525	165538	151029	136576	122438	106991	83675	43045	4419	2245

Implantable Pulse Generator

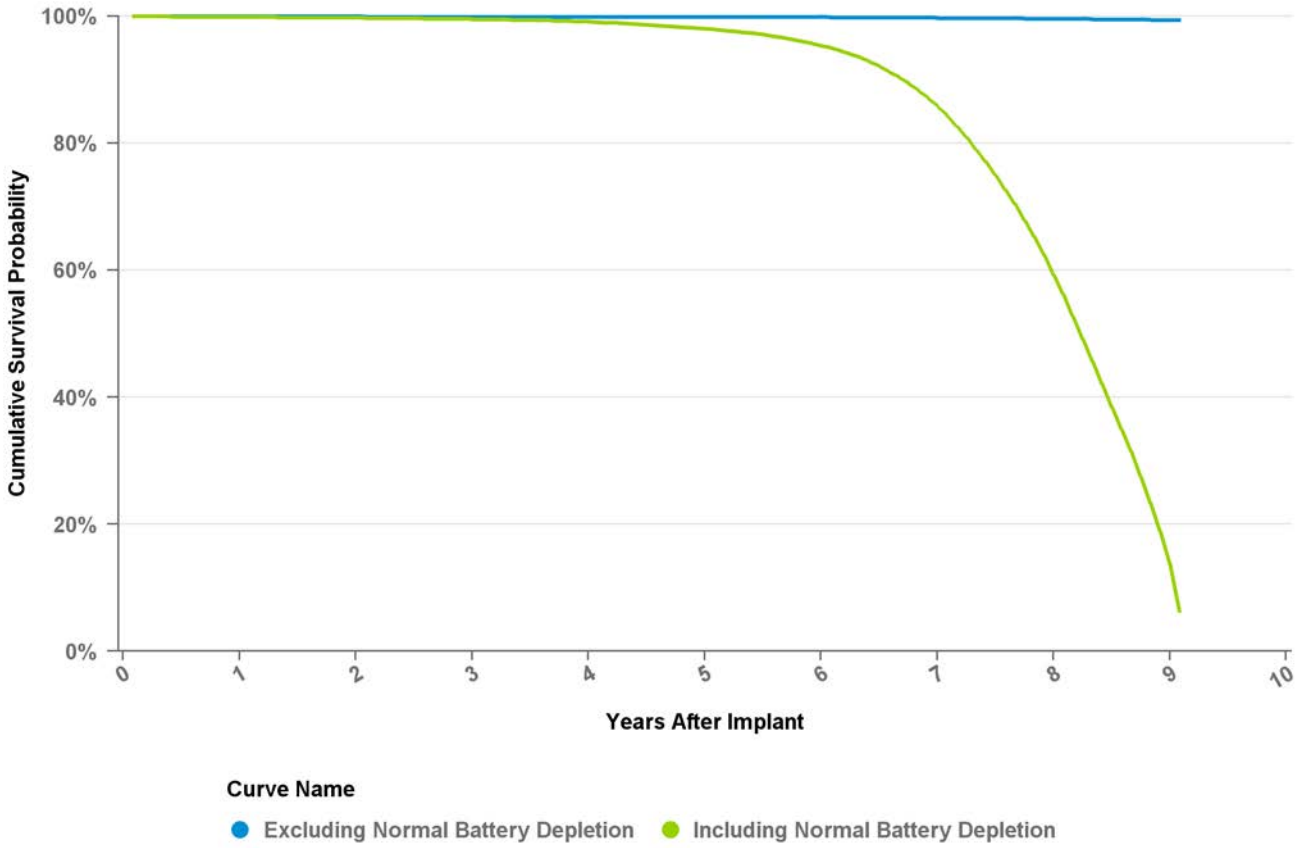
KDR701 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	194,135
Estimated Active US Implants	19,630
Normal Battery Depletions (US)	34,721

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	702
Therapy Not Compromised Malfunction	50
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	20
Other Malfunction	3
Poss Early Battery Depltn	3
Software Malfunction	0
Therapy Compromised Malfunctions	652
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	635
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.9%	99.8%	99.5%	99.1%	98.0%	95.3%	85.8%	59.3%	13.8%	6.3%
Effective Sample Size	180525	165538	151029	136576	122438	106991	83675	43045	4419	2245

Implantable Pulse Generator

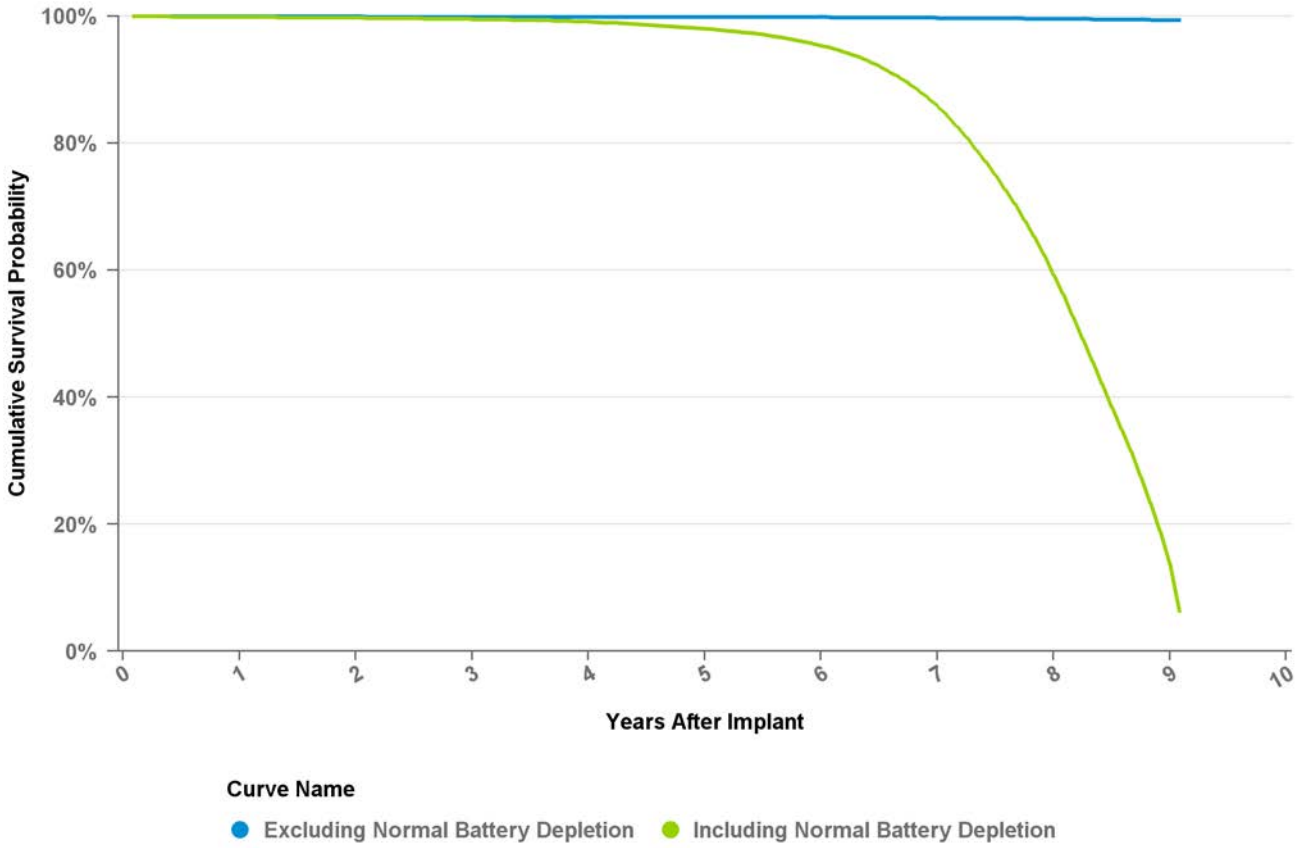
KDR703 Kappa 700 DR

US Market Release Date	2/5/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,226
Estimated Active US Implants	793
Normal Battery Depletions (US)	1,506

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	34
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	30
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	29
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.9%	99.8%	99.5%	99.1%	98.0%	95.3%	85.8%	59.3%	13.8%	6.3%
Effective Sample Size	180525	165538	151029	136576	122438	106991	83675	43045	4419	2245

Implantable Pulse Generator

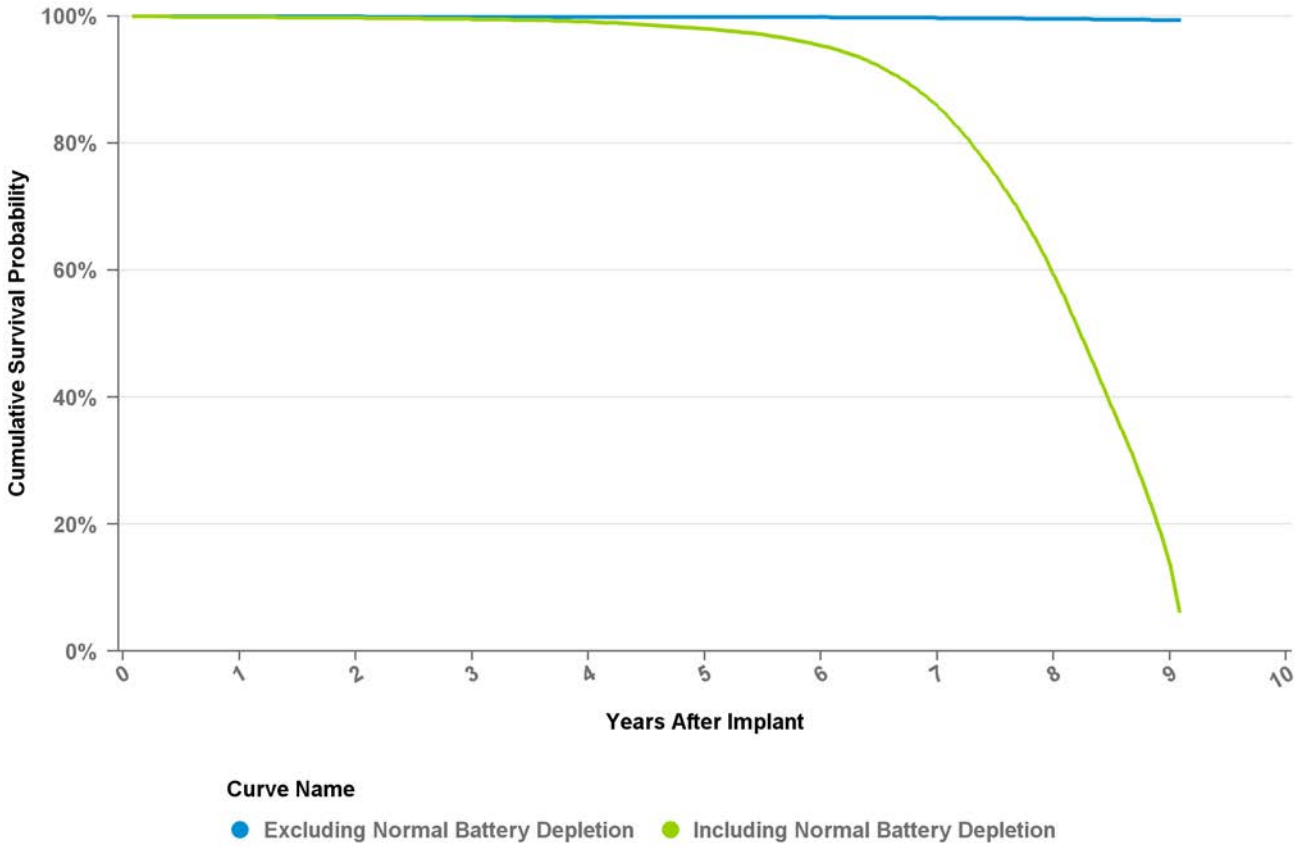
KDR706 Kappa 700 DR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,635
Estimated Active US Implants	182
Normal Battery Depletions (US)	400

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	10
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	9
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	9
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD700, KDR700, KDR701, KDR703, KDR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 109 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.7%	99.6%	99.4%	99.4%
Including NBD	99.9%	99.8%	99.5%	99.1%	98.0%	95.3%	85.8%	59.3%	13.8%	6.3%
Effective Sample Size	180525	165538	151029	136576	122438	106991	83675	43045	4419	2245

Implantable Pulse Generator

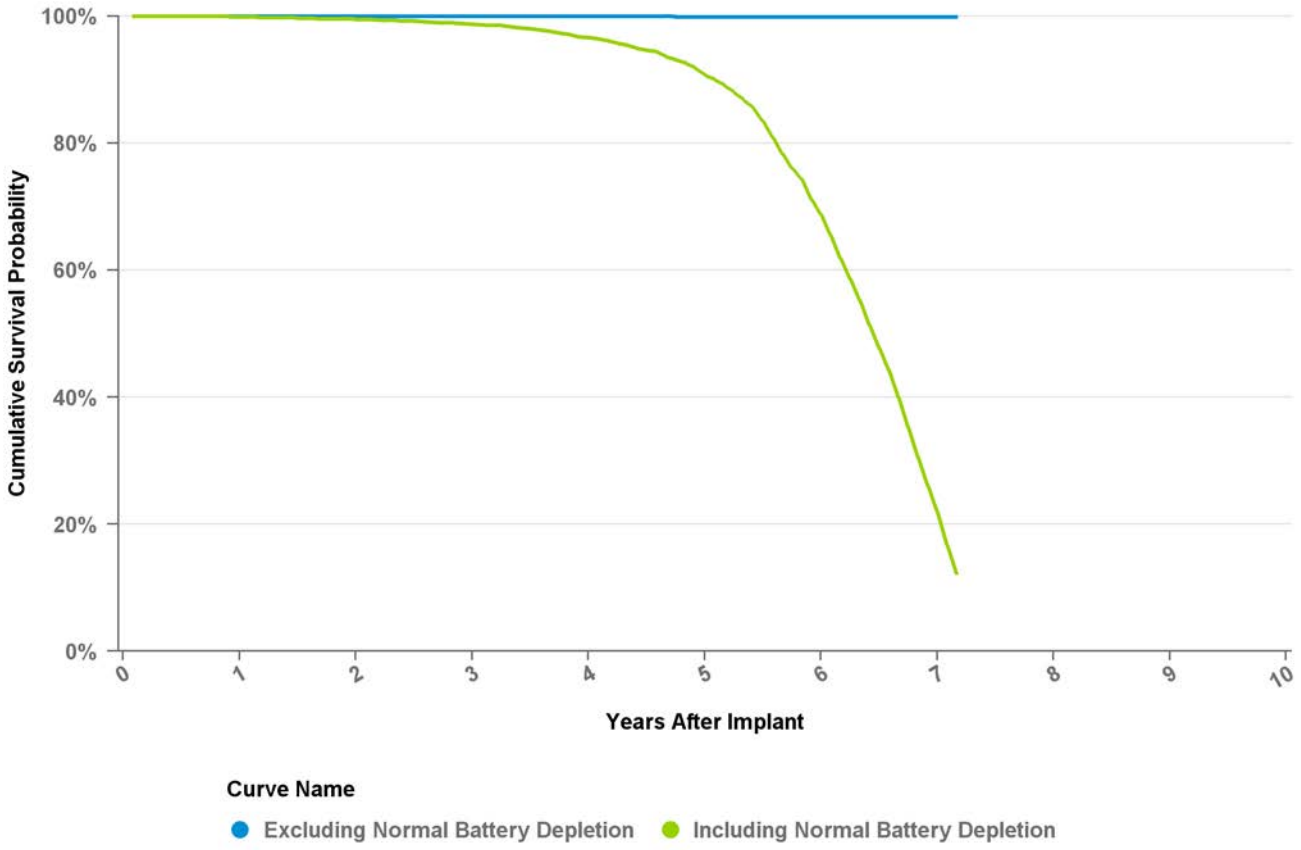
KDR721 Kappa 700 DR

US Market Release Date	2/11/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,838
Estimated Active US Implants	737
Normal Battery Depletions (US)	1,350

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	5
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	4
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KDR721, Survival Curve



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.5%	98.7%	96.6%	90.7%	68.8%	22.0%	12.3%
Effective Sample Size	8629	7619	6646	5641	4452	2256	316	126

Implantable Pulse Generator

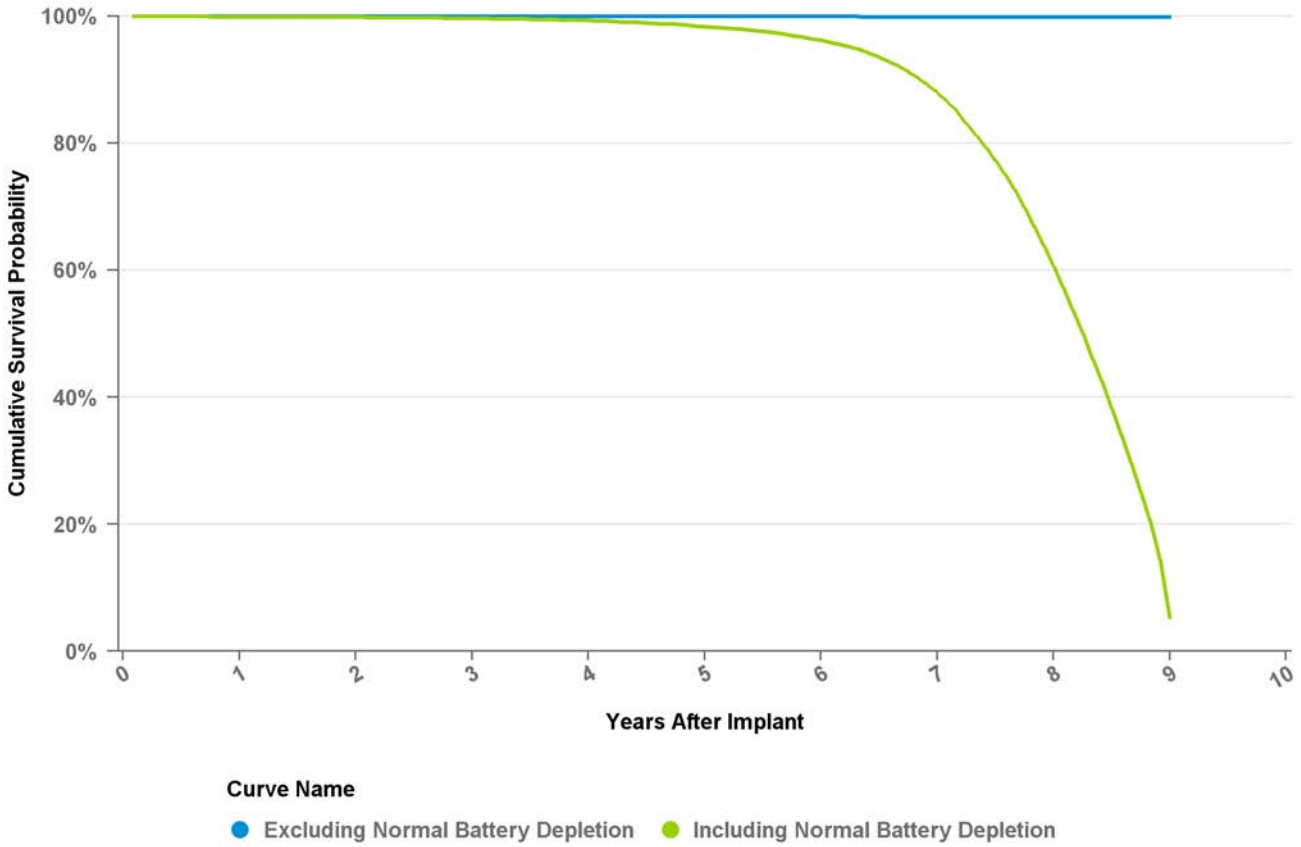
KDR901 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	120,692
Estimated Active US Implants	19,486
Normal Battery Depletions (US)	22,602

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	70
Therapy Not Compromised Malfunction	21
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	4
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	49
Battery Malfunction	0
Electrical Component	10
Electrical Interconnect	39
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

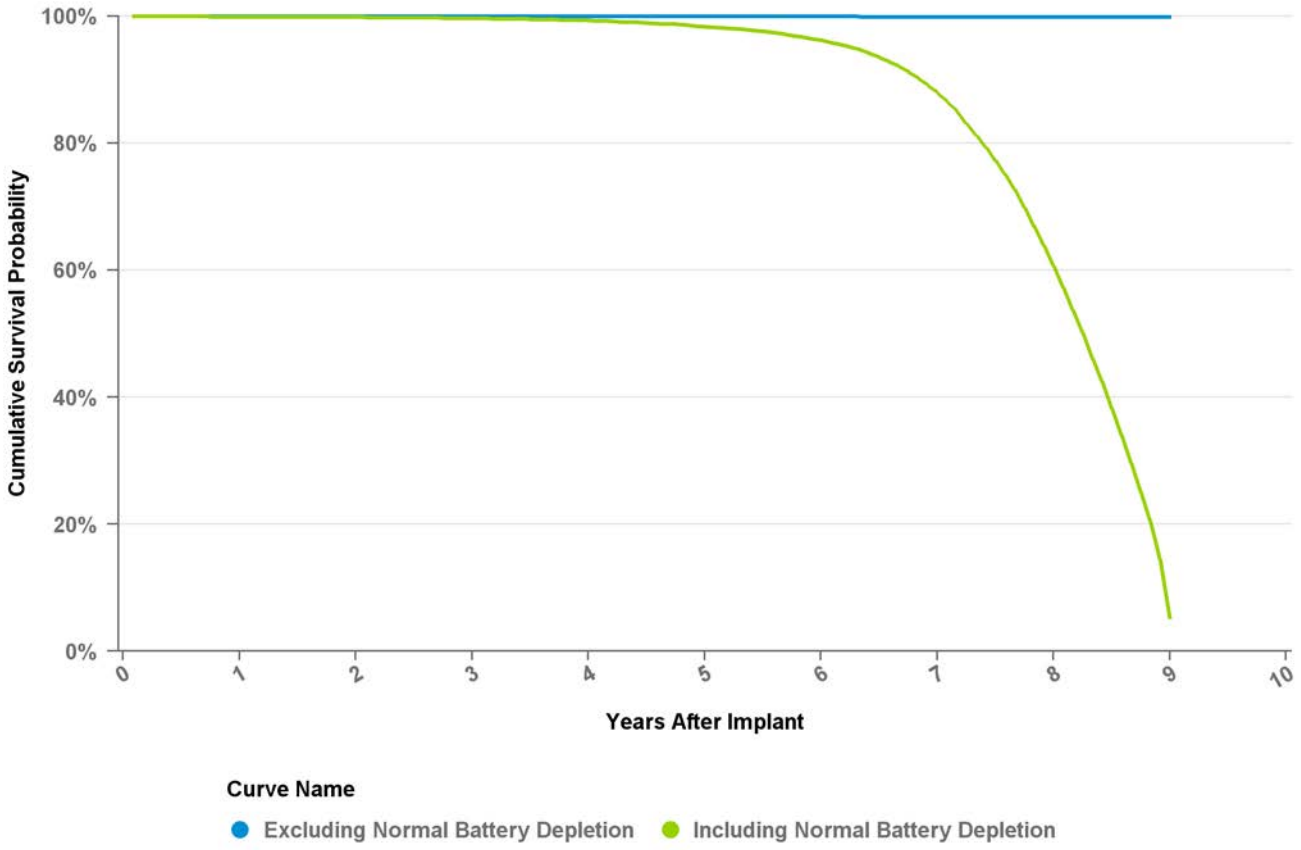
KDR903 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	3,168
Estimated Active US Implants	365
Normal Battery Depletions (US)	587

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	3
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

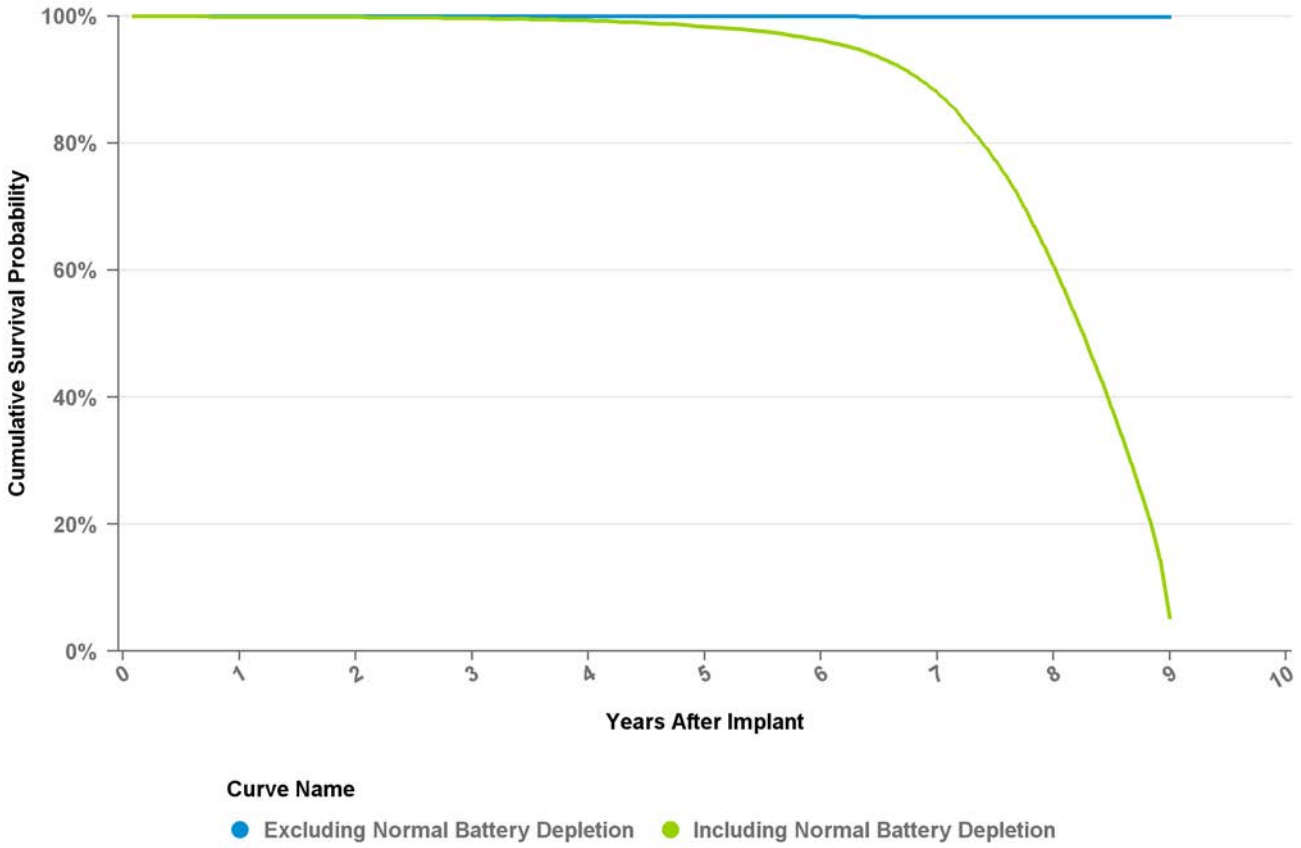
KDR906 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,509
Estimated Active US Implants	127
Normal Battery Depletions (US)	289

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KD901, KD903, KD906, KDR901, KDR903, KDR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.3%	98.3%	96.2%	87.9%	60.7%	5.3%
Effective Sample Size	117460	108101	98993	90246	81532	72563	59435	30260	1515

Implantable Pulse Generator

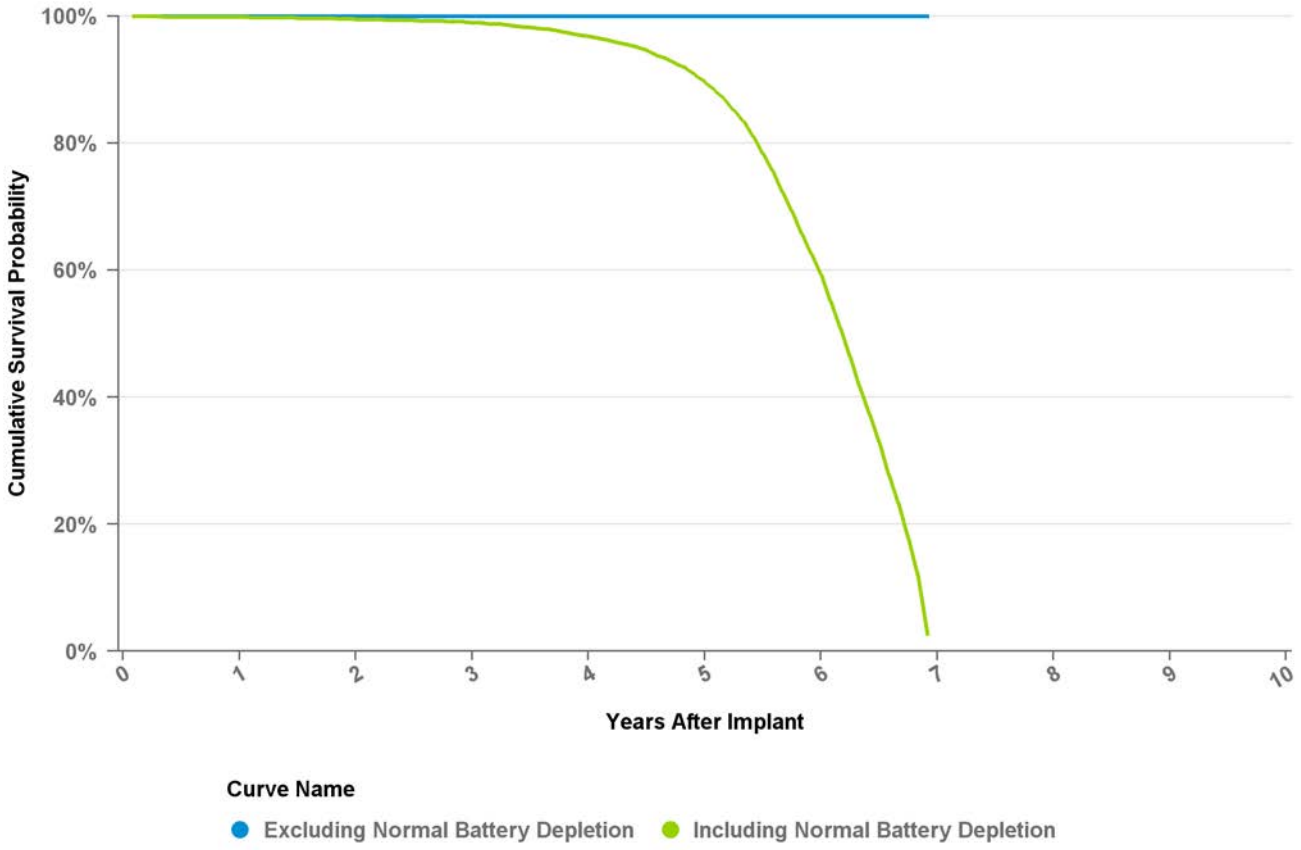
KDR921 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	16,329
Estimated Active US Implants	1,374
Normal Battery Depletions (US)	2,843

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	3
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KDR921, Survival Curve



Years	1	2	3	4	5	6	at 83 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.5%	98.9%	96.8%	89.6%	59.4%	2.7%
Effective Sample Size	14246	12704	11245	9713	7708	3511	145

Implantable Pulse Generator

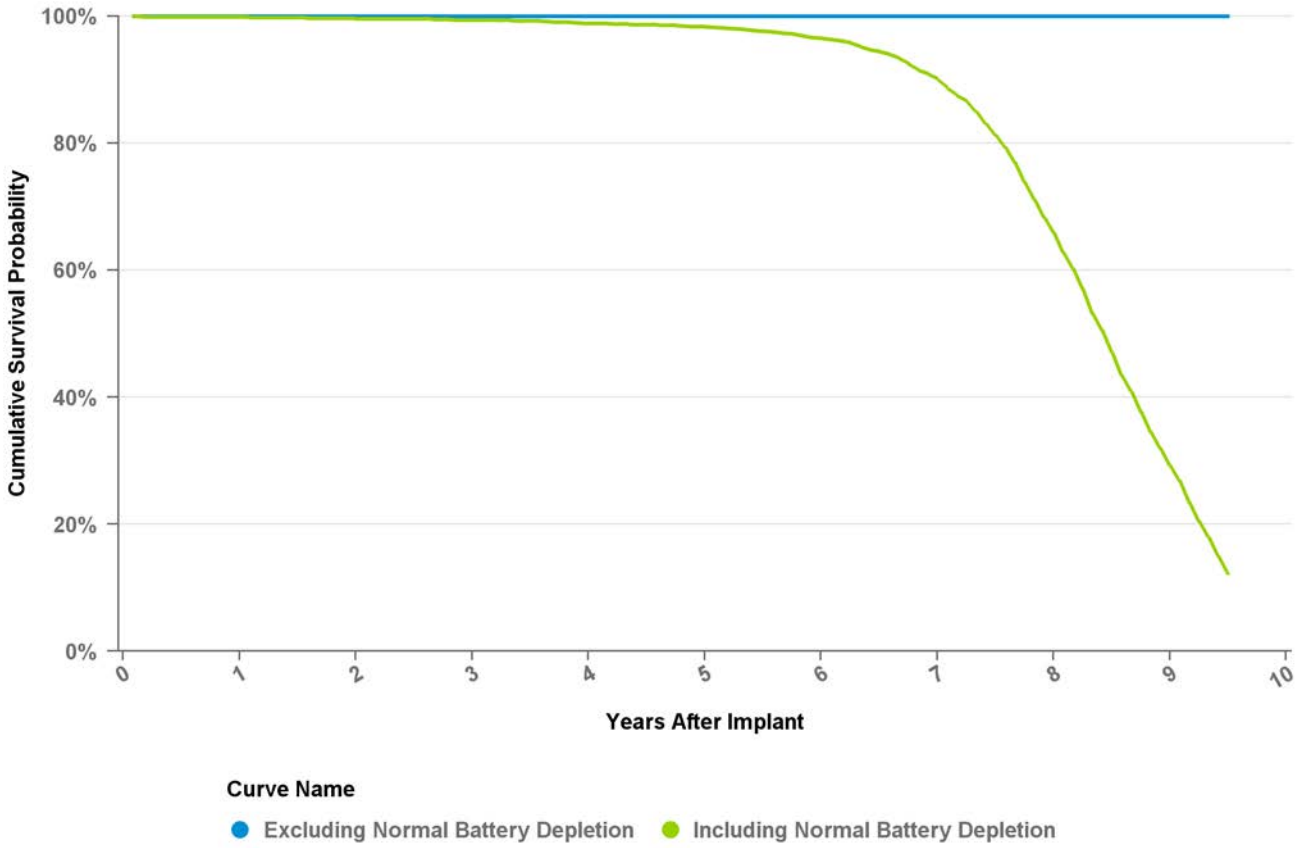
KSR401 Kappa 400 SR

US Market Release Date	2/18/1998
CE Market Approval Date	11/12/1996
Registered US Implants	11,788
Estimated Active US Implants	928
Normal Battery Depletions (US)	1,238

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR401, KSR403, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.6%	99.4%	98.8%	98.3%	96.5%	90.1%	66.0%	29.3%	12.3%
Effective Sample Size	13614	11961	10463	9177	7931	6710	5217	2656	574	121

Implantable Pulse Generator

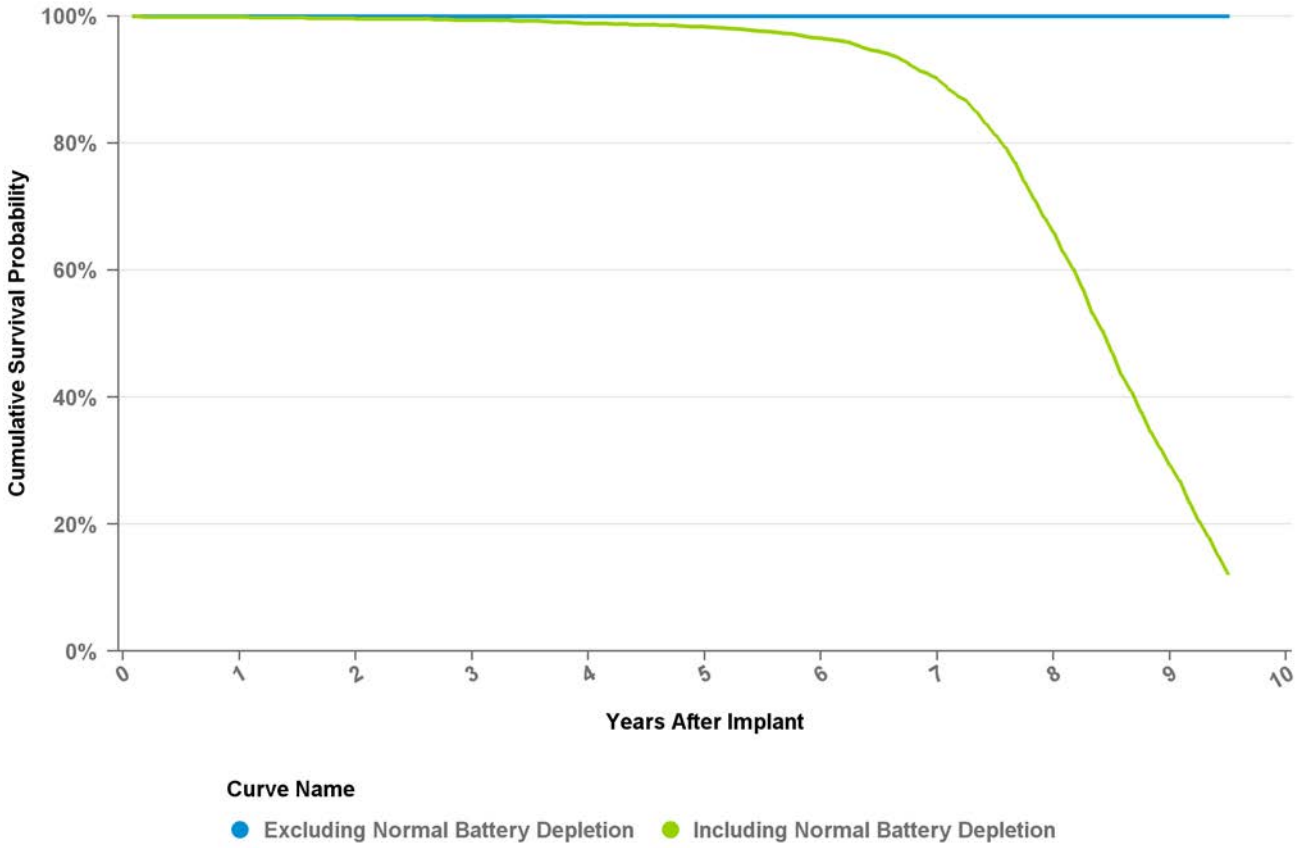
KSR403 Kappa 400 SR

US Market Release Date	2/24/1998
CE Market Approval Date	11/12/1996
Registered US Implants	3,620
Estimated Active US Implants	461
Normal Battery Depletions (US)	342

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR401, KSR403, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.6%	99.4%	98.8%	98.3%	96.5%	90.1%	66.0%	29.3%	12.3%
Effective Sample Size	13614	11961	10463	9177	7931	6710	5217	2656	574	121

Implantable Pulse Generator

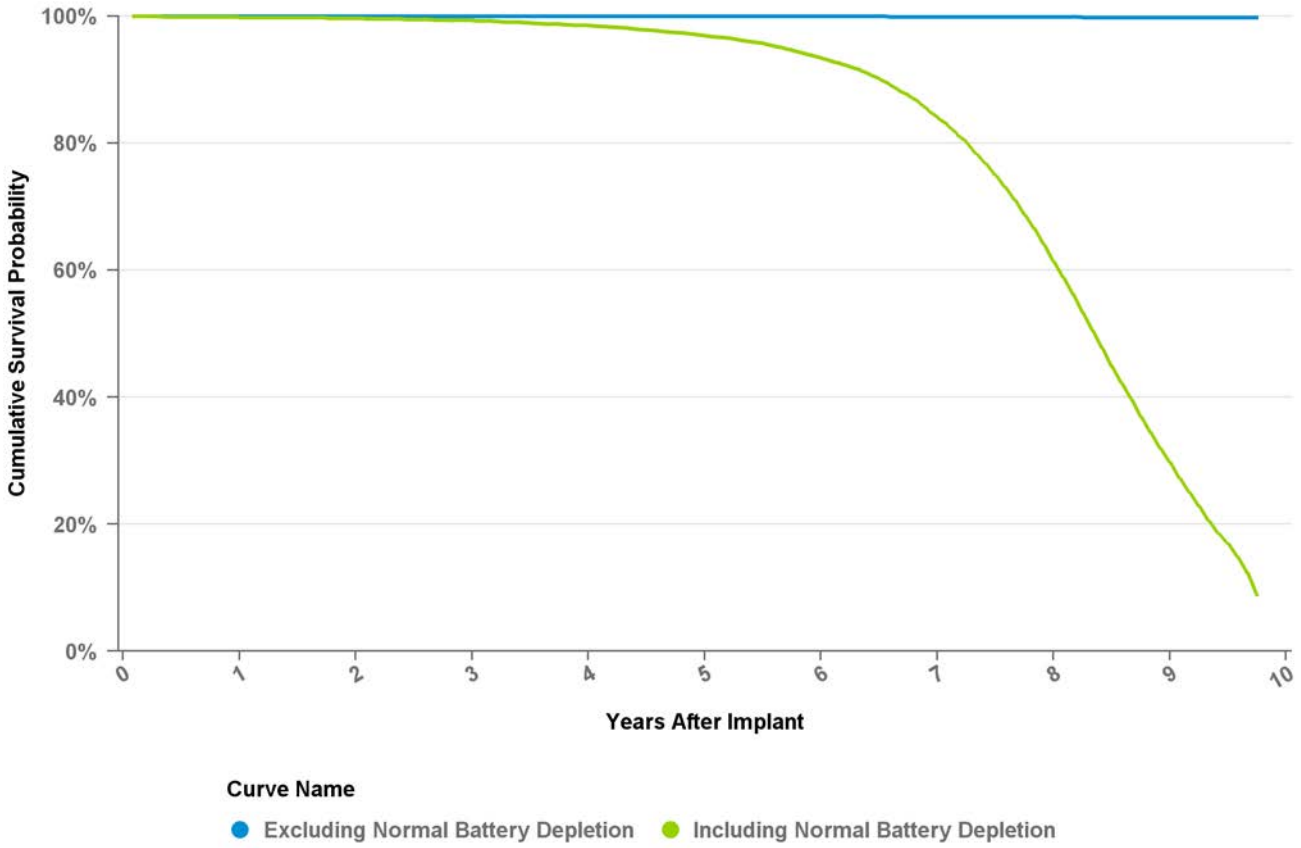
KSR700 Kappa 700 SR

US Market Release Date	
CE Market Approval Date	
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR700, KSR701, KSR703, KSR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.3%	98.5%	96.9%	93.4%	84.0%	61.4%	29.8%	8.9%
Effective Sample Size	48284	41647	35741	30631	25938	21432	16060	8258	1902	115

Implantable Pulse Generator

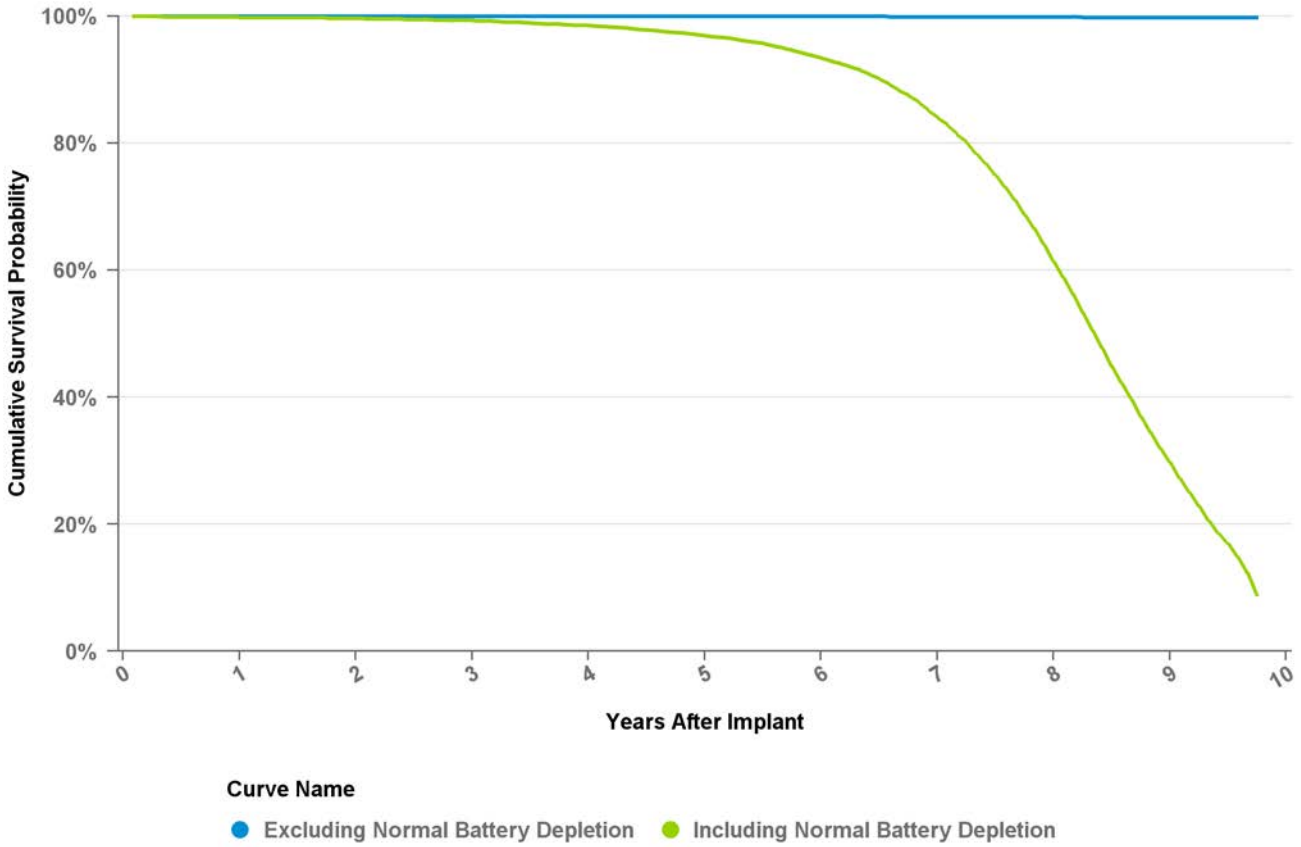
KSR701 Kappa 700 SR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	48,463
Estimated Active US Implants	4,779
Normal Battery Depletions (US)	4,744

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	22
Therapy Not Compromised Malfunction	3
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	19
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	17
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR700, KSR701, KSR703, KSR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.3%	98.5%	96.9%	93.4%	84.0%	61.4%	29.8%	8.9%
Effective Sample Size	48284	41647	35741	30631	25938	21432	16060	8258	1902	115

Implantable Pulse Generator

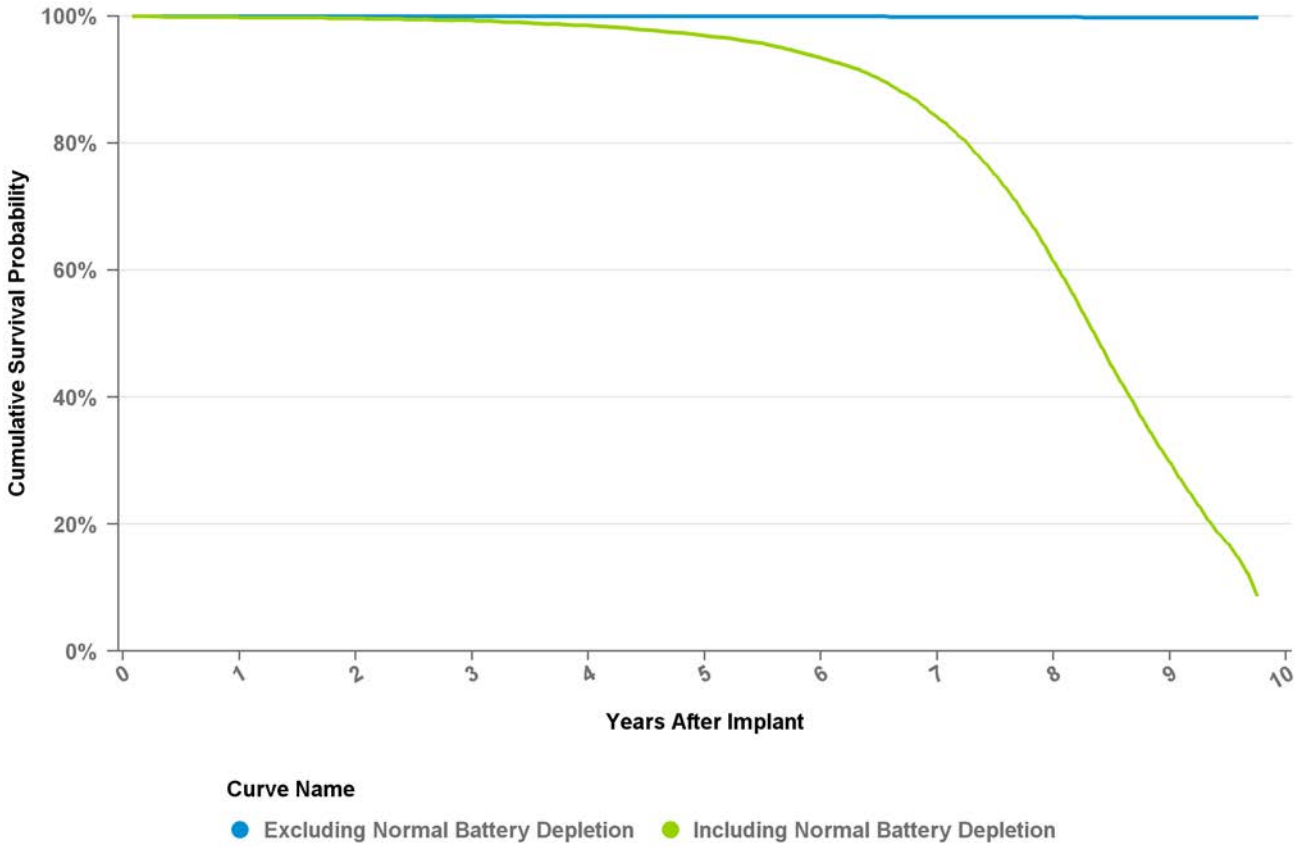
KSR703 Kappa 700 SR

US Market Release Date	2/8/1999
CE Market Approval Date	3/20/1998
Registered US Implants	3,607
Estimated Active US Implants	288
Normal Battery Depletions (US)	389

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	3
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR700, KSR701, KSR703, KSR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.3%	98.5%	96.9%	93.4%	84.0%	61.4%	29.8%	8.9%
Effective Sample Size	48284	41647	35741	30631	25938	21432	16060	8258	1902	115

Implantable Pulse Generator

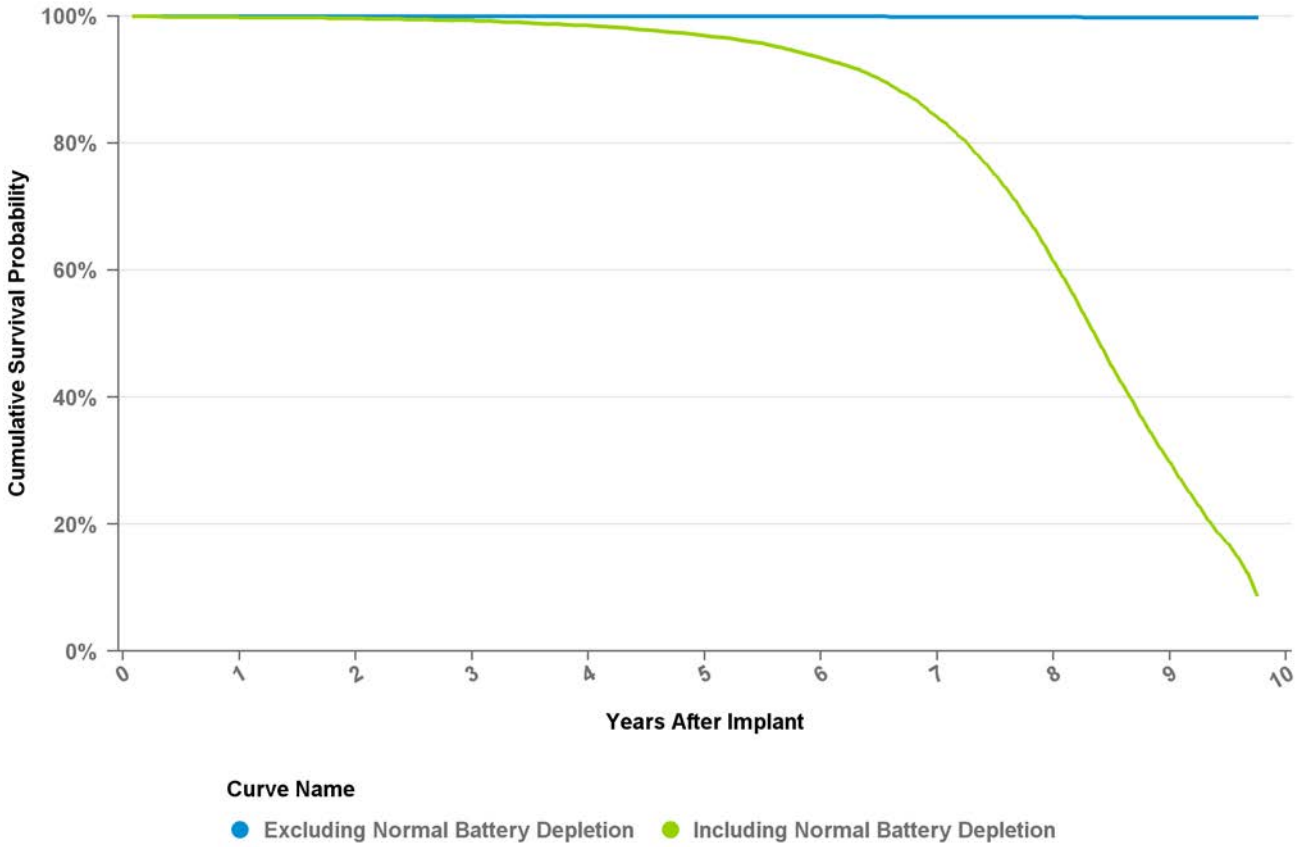
KSR706 Kappa 700 SR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,920
Estimated Active US Implants	246
Normal Battery Depletions (US)	296

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR700, KSR701, KSR703, KSR706, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.8%	99.7%	99.3%	98.5%	96.9%	93.4%	84.0%	61.4%	29.8%	8.9%
Effective Sample Size	48284	41647	35741	30631	25938	21432	16060	8258	1902	115

Implantable Pulse Generator

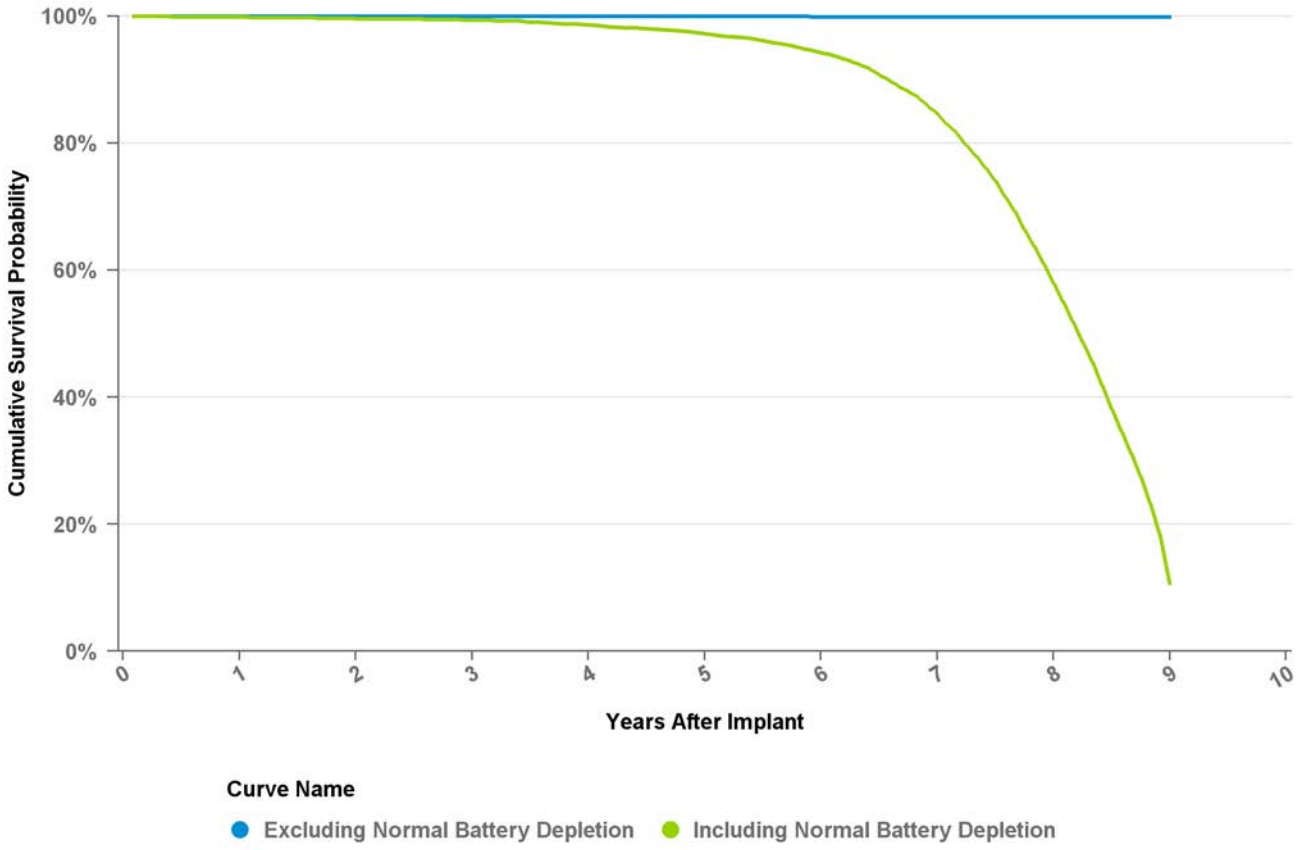
KSR901 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	34,128
Estimated Active US Implants	4,804
Normal Battery Depletions (US)	3,416

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	15
Therapy Not Compromised Malfunction	7
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	8
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	8
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR901, KSR903, KSR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.6%	99.4%	98.6%	97.2%	94.2%	84.6%	58.0%	10.6%
Effective Sample Size	32021	27602	23995	20672	17709	14928	11403	4904	187

Implantable Pulse Generator

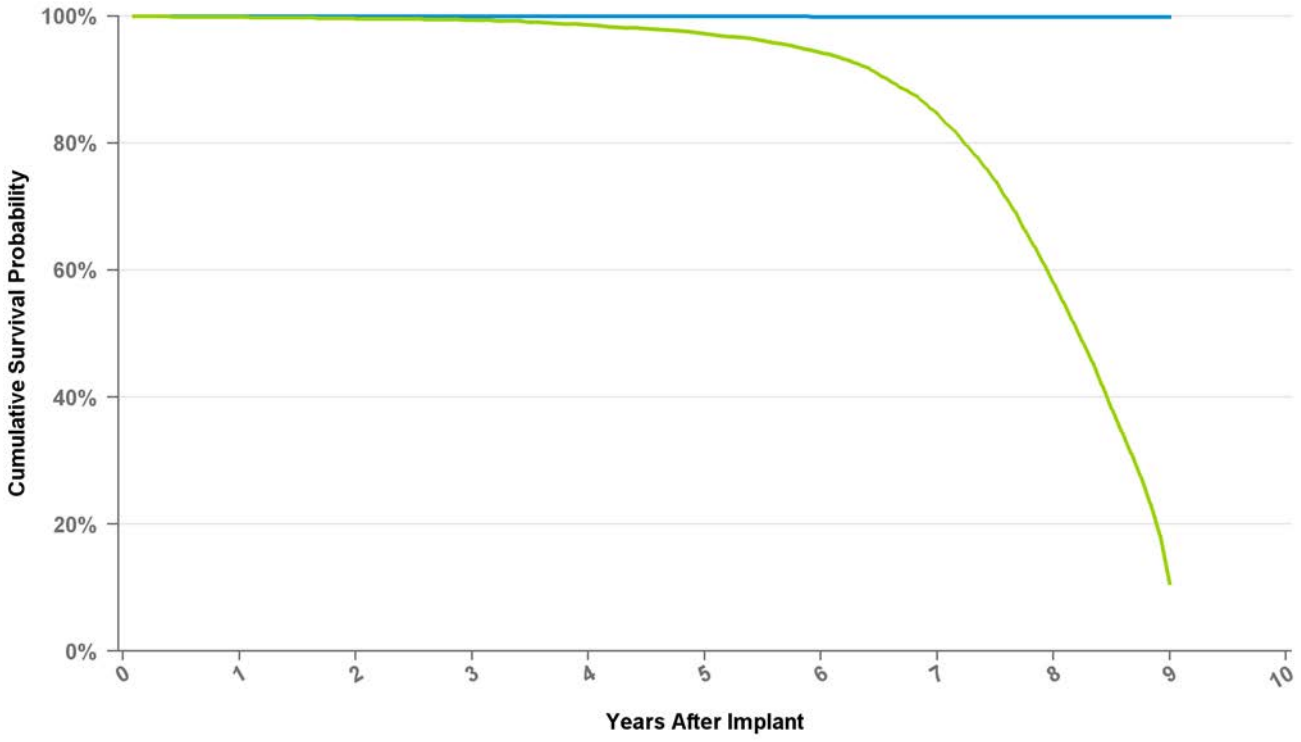
KSR903 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,372
Estimated Active US Implants	135
Normal Battery Depletions (US)	164

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR901, KSR903, KSR906, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.6%	99.4%	98.6%	97.2%	94.2%	84.6%	58.0%	10.6%
Effective Sample Size	32021	27602	23995	20672	17709	14928	11403	4904	187

Implantable Pulse Generator

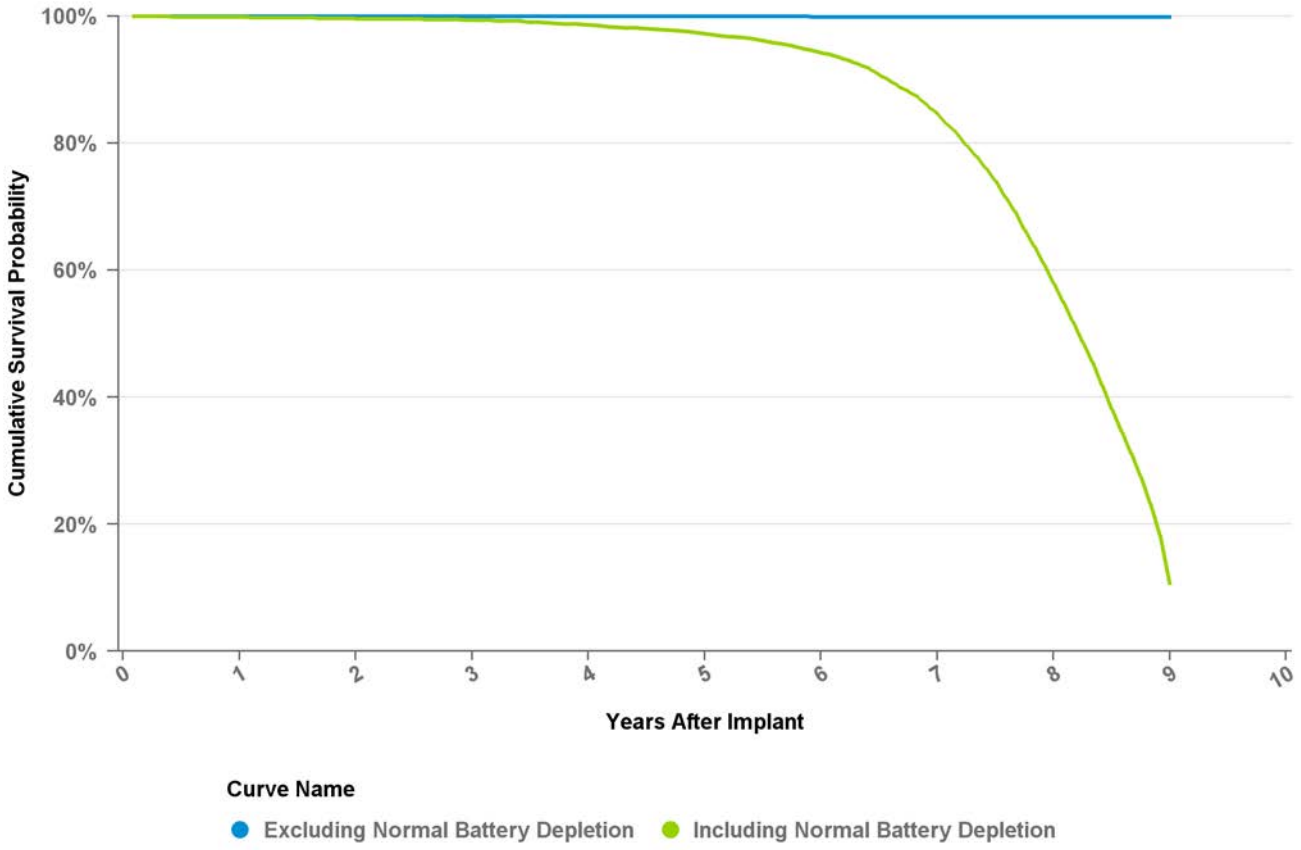
KSR906 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,322
Estimated Active US Implants	131
Normal Battery Depletions (US)	175

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KSR901, KSR903, KSR906, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.6%	99.4%	98.6%	97.2%	94.2%	84.6%	58.0%	10.6%
Effective Sample Size	32021	27602	23995	20672	17709	14928	11403	4904	187

Implantable Pulse Generator

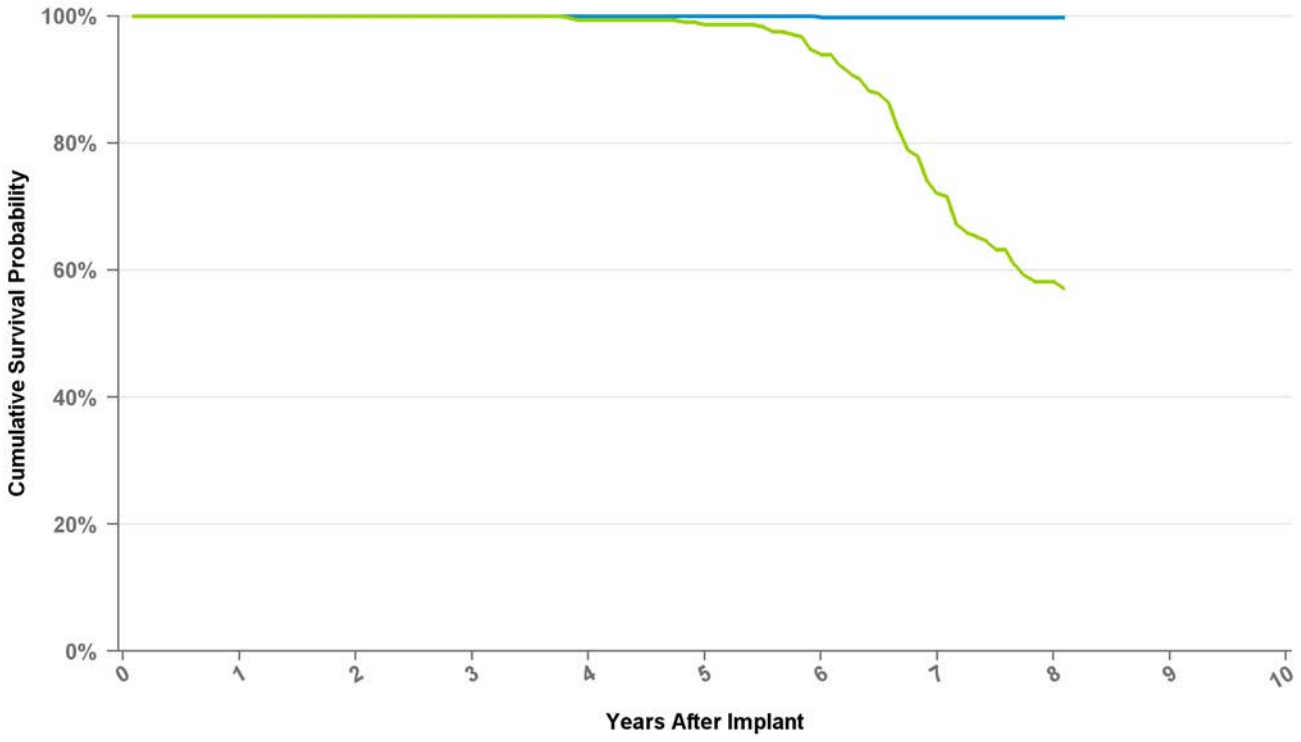
KVDD901 Kappa 900 VDD

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	566
Estimated Active US Implants	56
Normal Battery Depletions (US)	81

NBG Code	VDD
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

KVDD901, Survival Curve



Years	1	2	3	4	5	6	7	8	at 97 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.8%	99.8%	99.8%
Including NBD	100.0%	100.0%	100.0%	99.3%	98.6%	93.9%	72.1%	58.2%	57.1%
Effective Sample Size	765	712	660	603	557	464	253	112	105

Implantable Pulse Generator

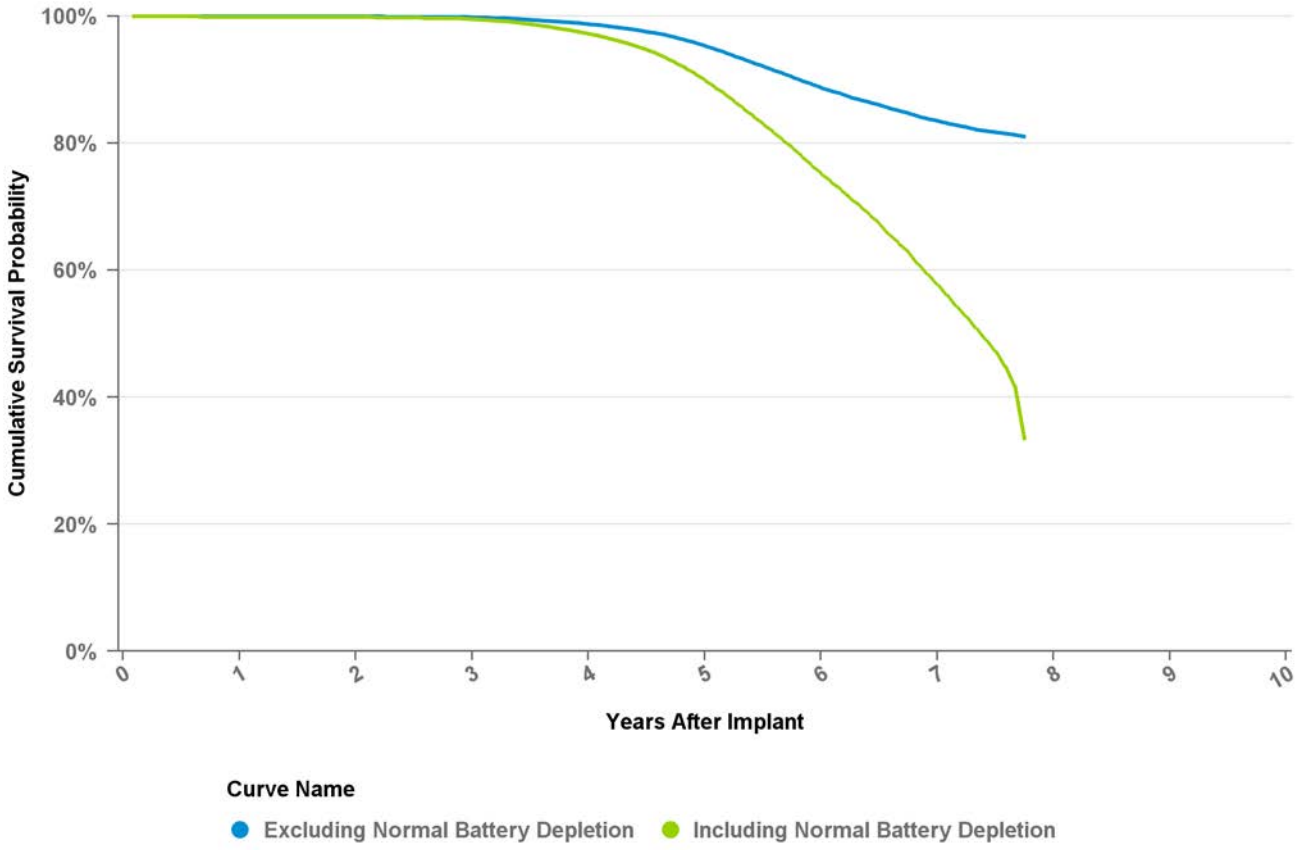
P1501DR EnRhythm DR

US Market Release Date	5/5/2005
CE Market Approval Date	8/13/2004
Registered US Implants	110,142
Estimated Active US Implants	58,897
Normal Battery Depletions (US)	2,341

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	8,783
Therapy Not Compromised Malfunction	8,730
Battery Malfunction	8,629
Electrical Component	44
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	55
Software Malfunction	0
Therapy Compromised Malfunctions	53
Battery Malfunction	5
Electrical Component	37
Electrical Interconnect	4
Other Malfunction	5
Poss Early Battery Depltn	2
Software Malfunction	0

P1501DR, Survival Curve



Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	100.0%	99.8%	98.7%	95.3%	88.7%	83.5%	81.0%
Including NBD	99.9%	99.9%	99.5%	97.2%	89.9%	75.2%	57.8%	33.5%
Effective Sample Size	104211	97444	87554	70829	51809	31660	14331	930

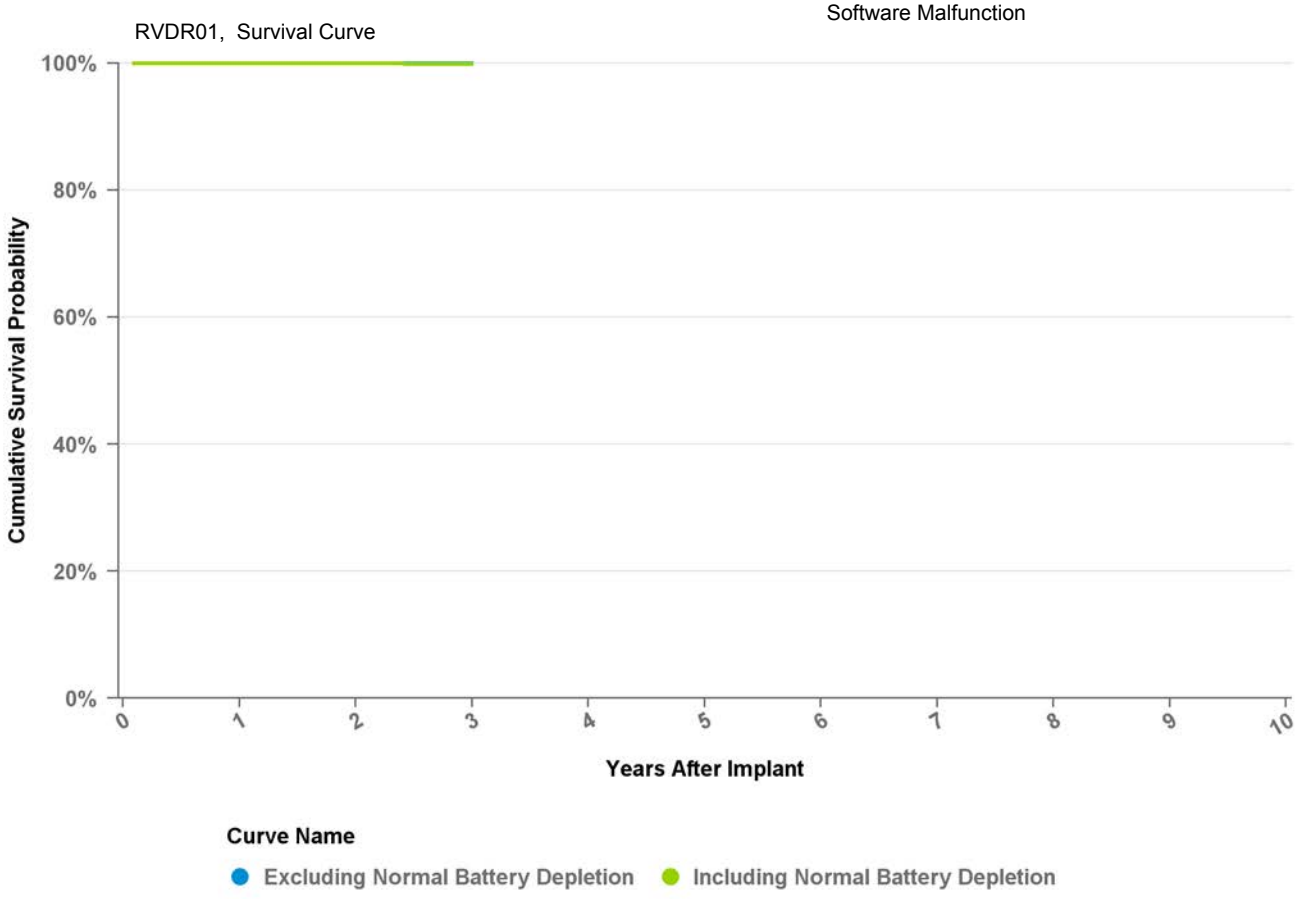
Implantable Pulse Generator

RVDR01 Revo MRI SureScan

US Market Release Date	2/8/2011
CE Market Approval Date	
Registered US Implants	61,700
Estimated Active US Implants	58,820
Normal Battery Depletions (US)	4

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	7
Therapy Not Compromised Malfunction	5
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	at 36 mo
Excluding NBD	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%
Effective Sample Size	49461	22345	305

Implantable Pulse Generator

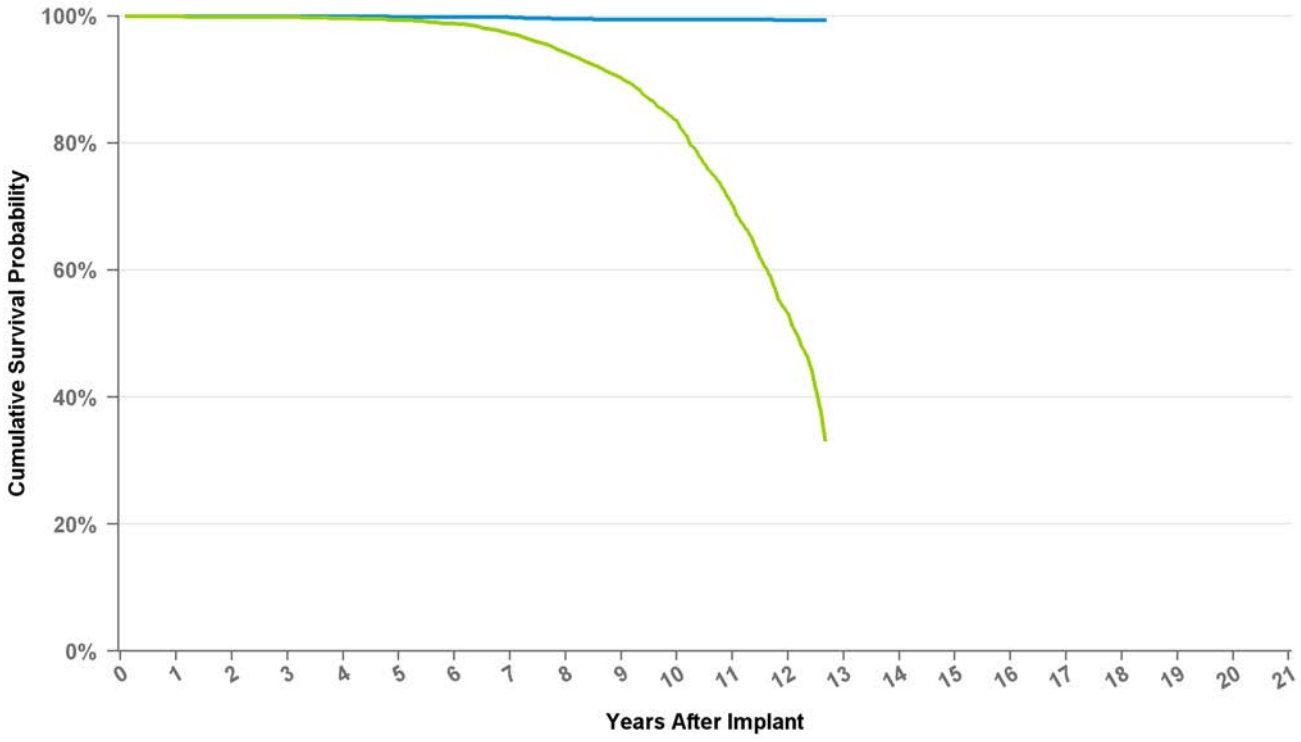
SD203 Sigma 200 D

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	225
Estimated Active US Implants	28
Normal Battery Depletions (US)	17

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SDR203, SD203, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 mo
Excluding NBD	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%
Including NBD	100.0%	83.4%	70.3%	53.2%	99.9%	99.9%	99.7%	99.4%	98.8%	97.2%	94.2%	90.2%	33.3%
Effective Sample Size	14205	3750	2240	859	12741	11334	10152	9017	7980	6944	5960	4986	115

Implantable Pulse Generator

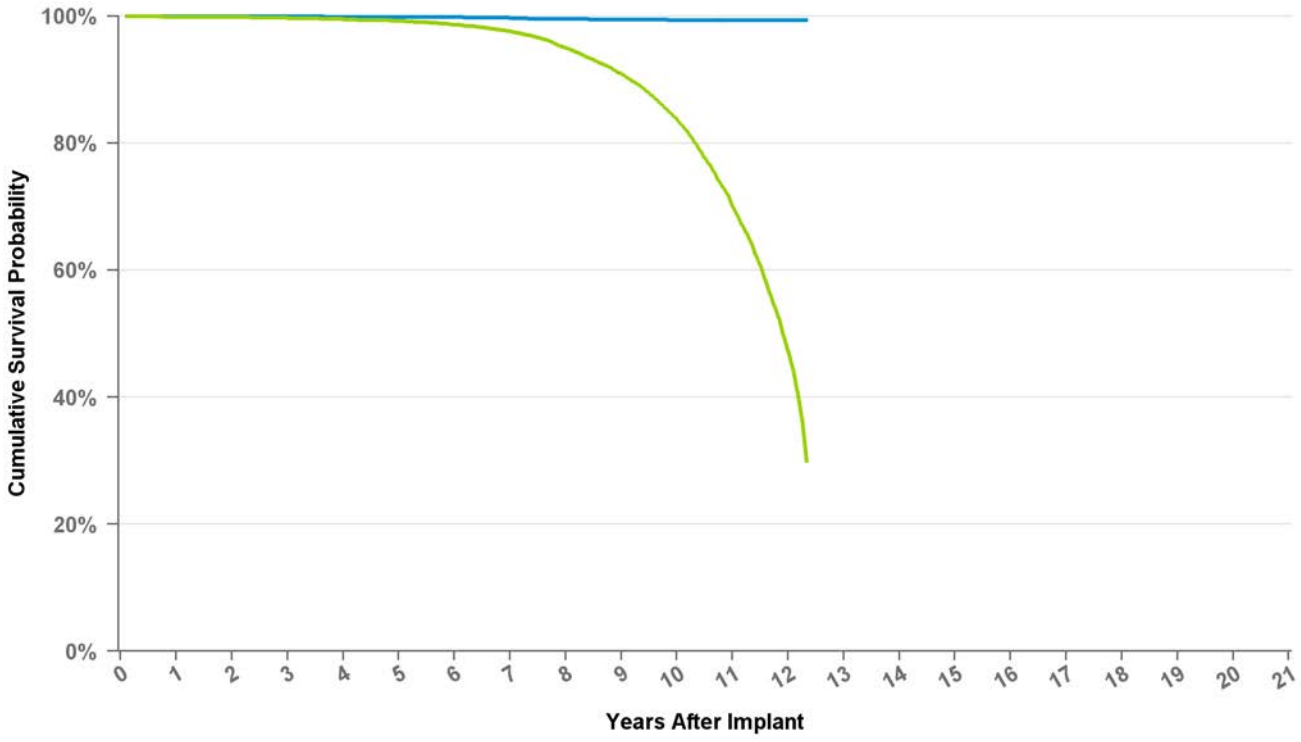
SD303 Sigma 300 D

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	122
Estimated Active US Implants	34
Normal Battery Depletions (US)	5

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SDR303, SDR306, SD303, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 148 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.9%	83.7%	70.1%	47.3%	99.9%	99.7%	99.5%	99.2%	98.6%	97.6%	95.0%	90.9%	29.9%
Effective Sample Size	96626	18936	9677	2386	86537	77452	69054	61422	54526	46445	37548	28374	515

Implantable Pulse Generator

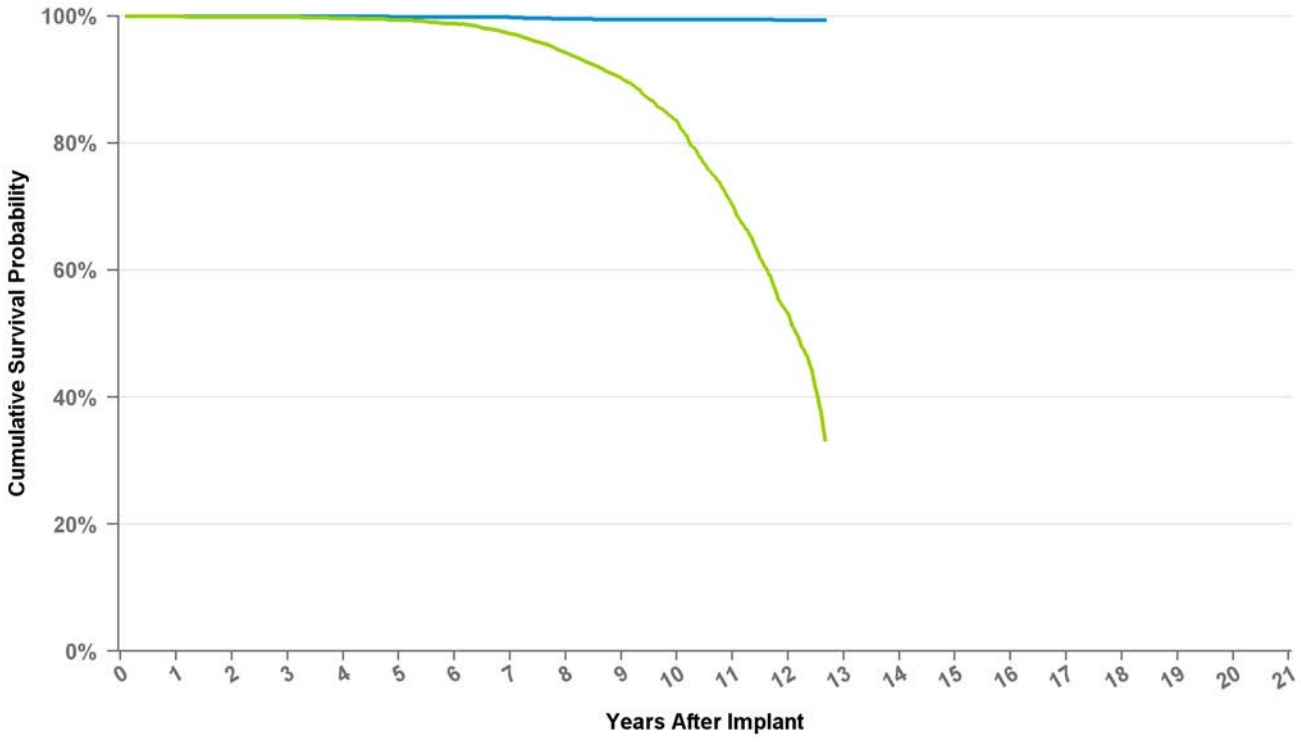
SDR203 Sigma 200 DR

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	15,642
Estimated Active US Implants	2,834
Normal Battery Depletions (US)	997

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	36
Therapy Not Compromised Malfunction	10
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	9
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	26
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	23
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0

SDR203, SD203, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 152 mo
Excluding NBD	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%
Including NBD	100.0%	83.4%	70.3%	53.2%	99.9%	99.9%	99.7%	99.4%	98.8%	97.2%	94.2%	90.2%	33.3%
Effective Sample Size	14205	3750	2240	859	12741	11334	10152	9017	7980	6944	5960	4986	115

Implantable Pulse Generator

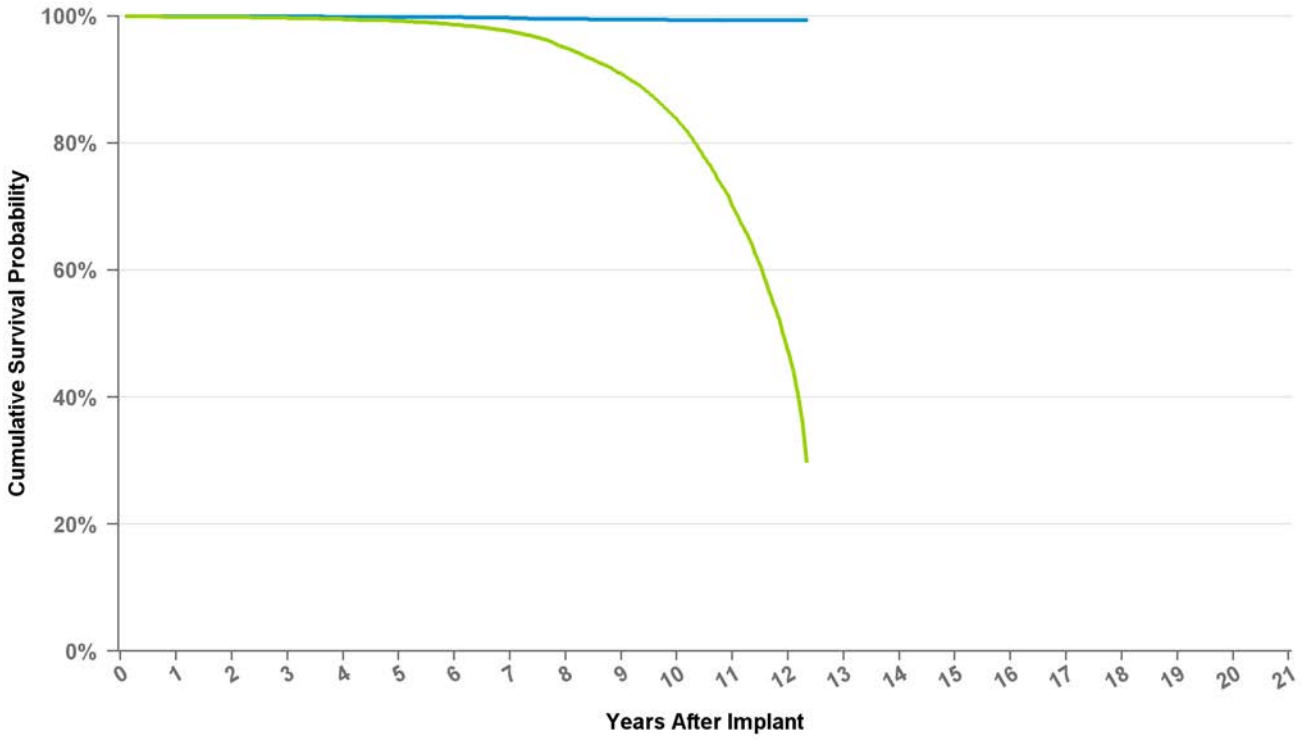
SDR303 Sigma 300 DR

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	105,558
Estimated Active US Implants	26,510
Normal Battery Depletions (US)	5,135

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	265
Therapy Not Compromised Malfunction	64
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	53
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	201
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	193
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0

SDR303, SDR306, SD303, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 148 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.9%	83.7%	70.1%	47.3%	99.9%	99.7%	99.5%	99.2%	98.6%	97.6%	95.0%	90.9%	29.9%
Effective Sample Size	96626	18936	9677	2386	86537	77452	69054	61422	54526	46445	37548	28374	515

Implantable Pulse Generator

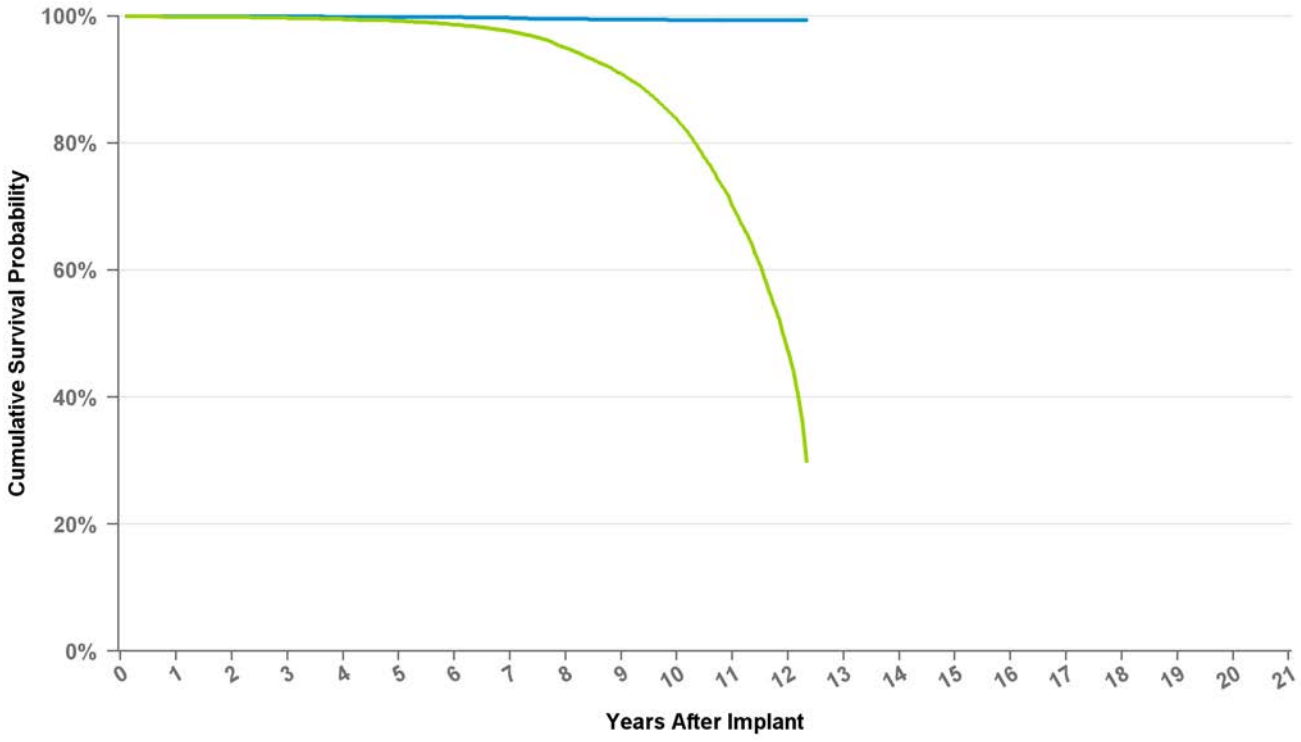
SDR306 Sigma 300 DR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	1,209
Estimated Active US Implants	176
Normal Battery Depletions (US)	127

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	5
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	5
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	5
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SDR303, SDR306, SD303, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 148 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.7%	99.6%	99.5%	99.4%	99.3%	99.3%	99.3%
Including NBD	99.9%	83.7%	70.1%	47.3%	99.9%	99.7%	99.5%	99.2%	98.6%	97.6%	95.0%	90.9%	29.9%
Effective Sample Size	96626	18936	9677	2386	86537	77452	69054	61422	54526	46445	37548	28374	515

Implantable Pulse Generator

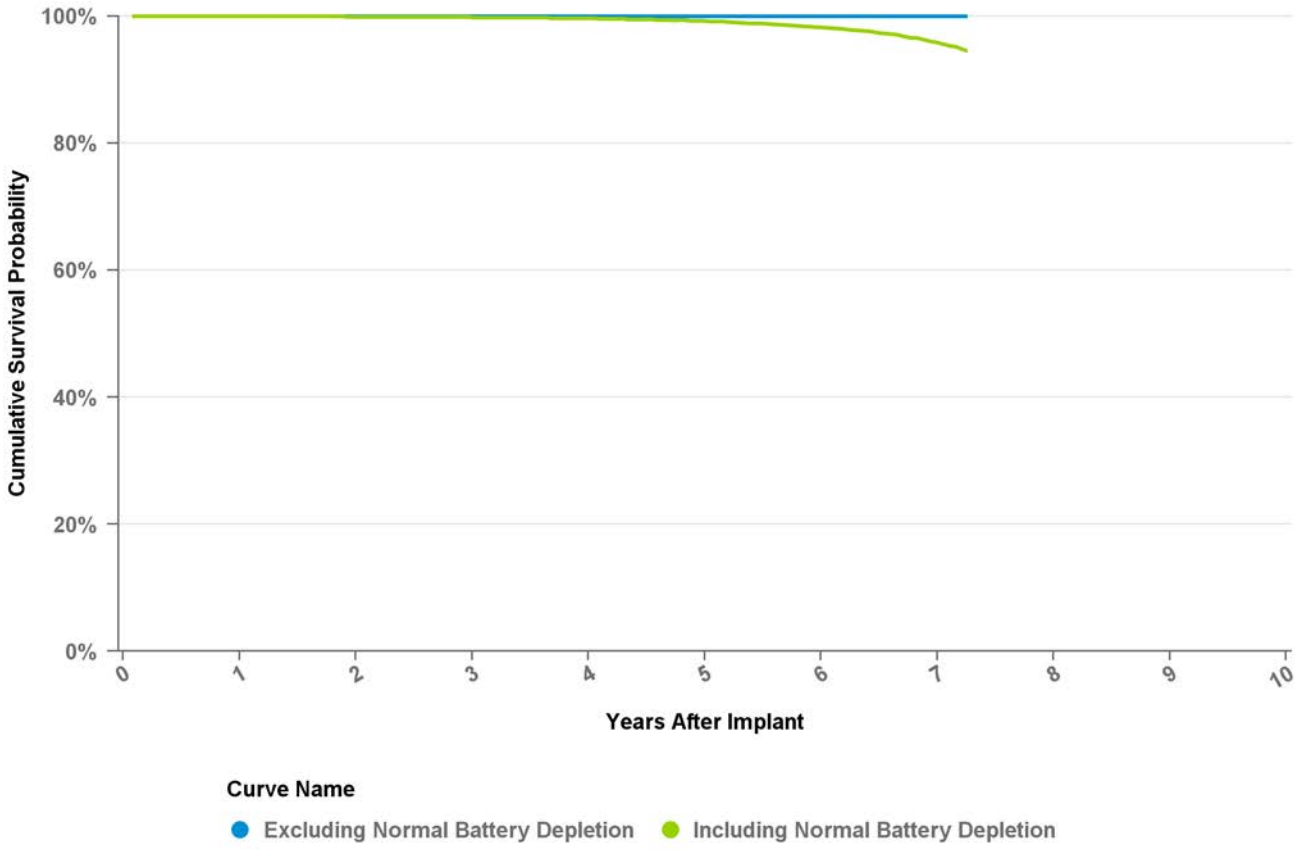
SED01 Sensia D

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2
Estimated Active US Implants	2
Normal Battery Depletions (US)	0

NBG Code	DDD
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SEDR01, SED01, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.2%	98.2%	95.8%	94.5%
Effective Sample Size	110400	89082	68302	48484	29690	13571	2073	311

Implantable Pulse Generator

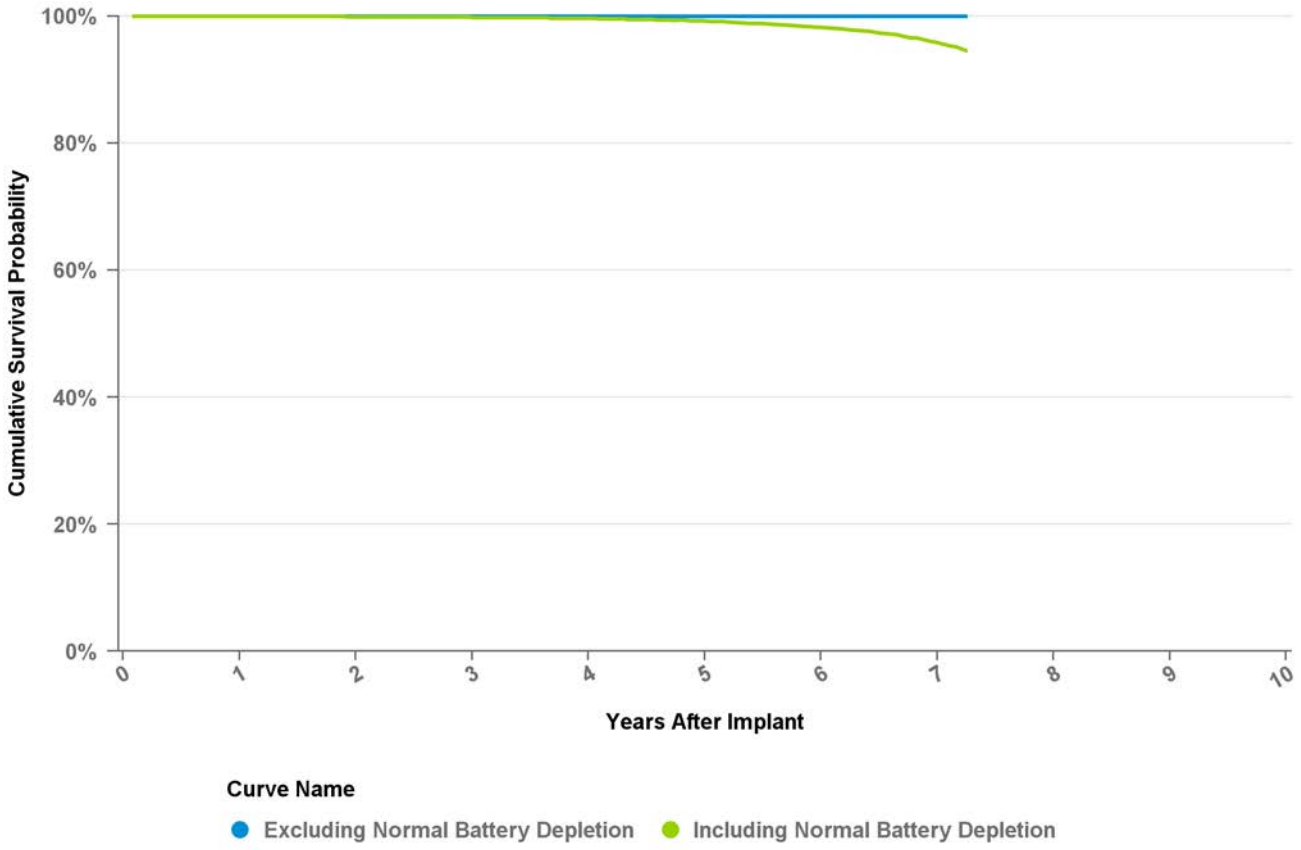
SEDR01 Sensia DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	130,145
Estimated Active US Implants	96,624
Normal Battery Depletions (US)	369

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	24
Therapy Not Compromised Malfunction	14
Battery Malfunction	0
Electrical Component	12
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	10
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	1
Other Malfunction	5
Poss Early Battery Depltn	0
Software Malfunction	0

SEDR01, SED01, Survival Curve



Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.7%	99.2%	98.2%	95.8%	94.5%
Effective Sample Size	110400	89082	68302	48484	29690	13571	2073	311

Implantable Pulse Generator

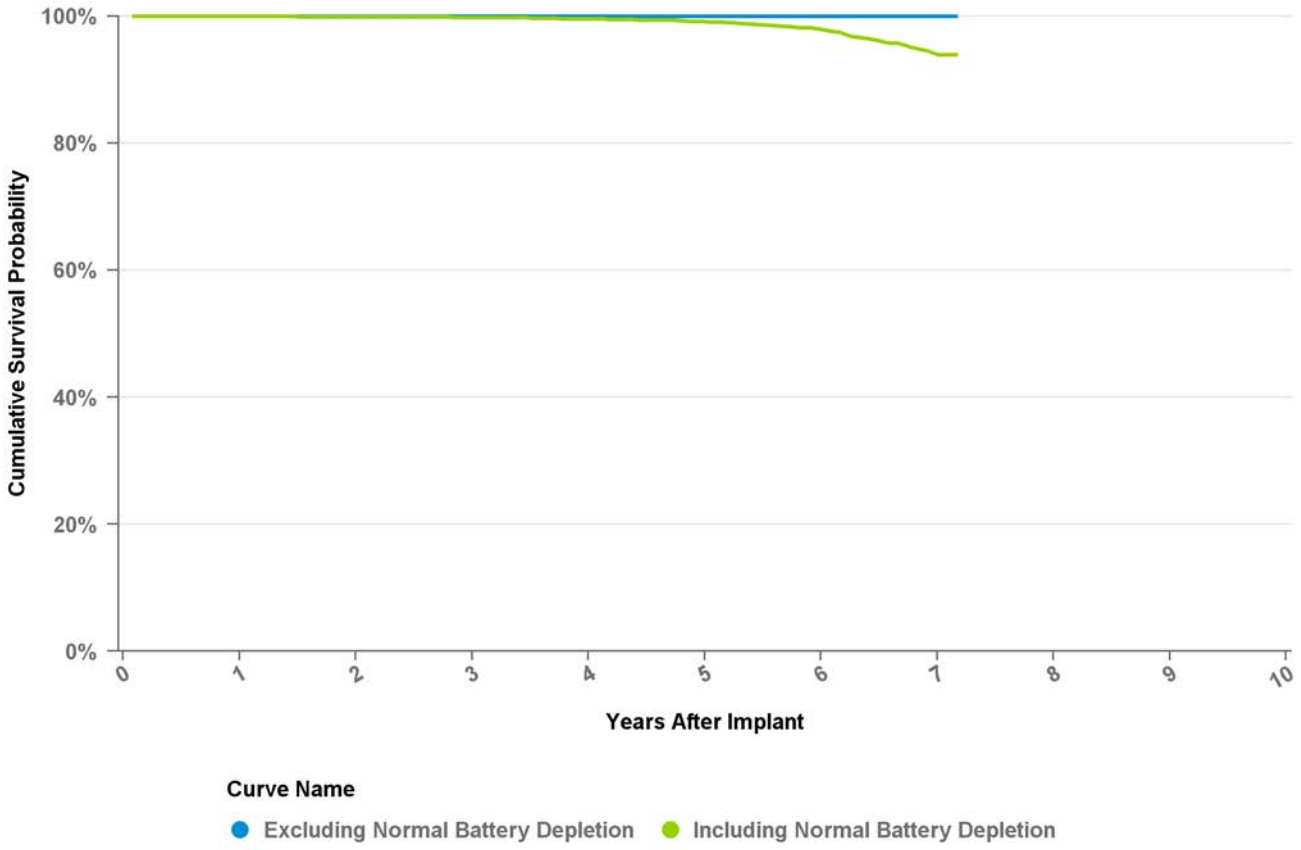
SES01 Sensia S

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	4
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	SSI
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SESR01, SES01, Survival Curve



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.1%	97.9%	93.9%	93.9%
Effective Sample Size	76016	57651	41526	27793	16035	6862	856	222

Implantable Pulse Generator

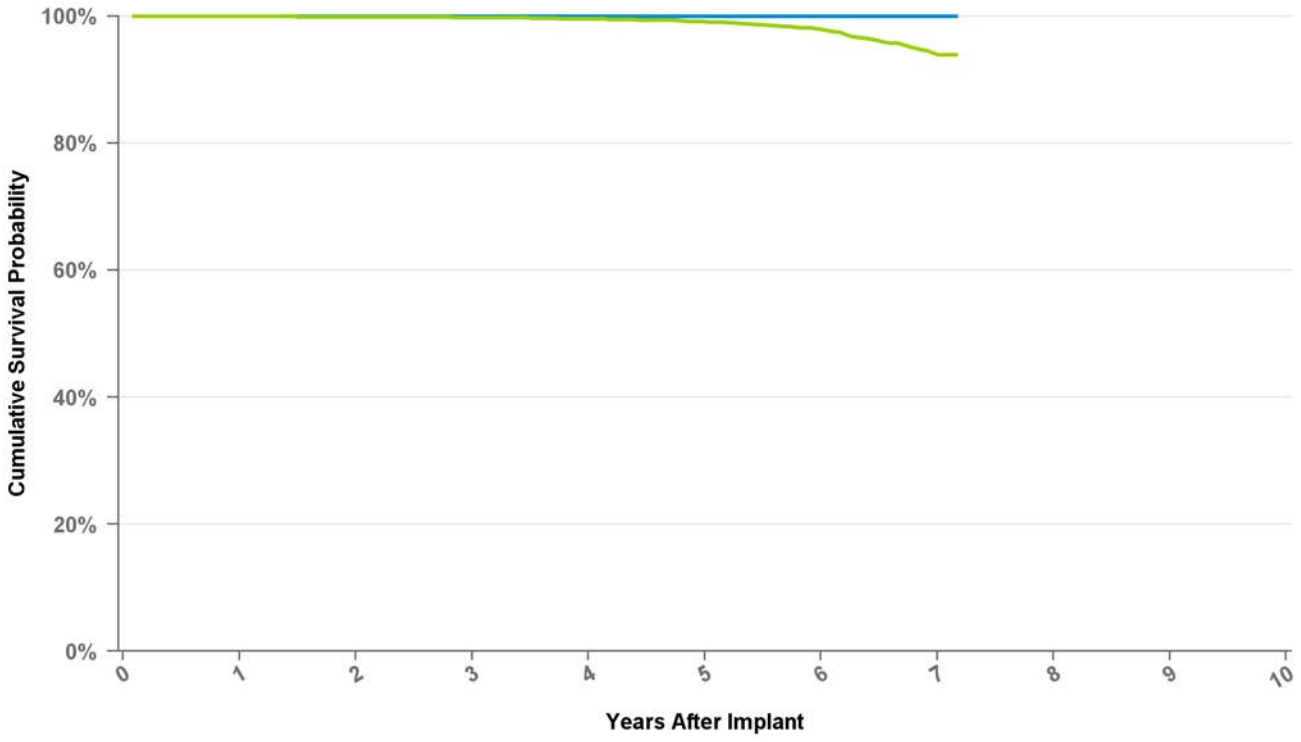
SESR01 Sensia SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	92,913
Estimated Active US Implants	64,227
Normal Battery Depletions (US)	271

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	9
Therapy Not Compromised Malfunction	7
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	2
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SESR01, SES01, Survival Curve



Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.8%	99.6%	99.1%	97.9%	93.9%	93.9%
Effective Sample Size	76016	57651	41526	27793	16035	6862	856	222

Implantable Pulse Generator

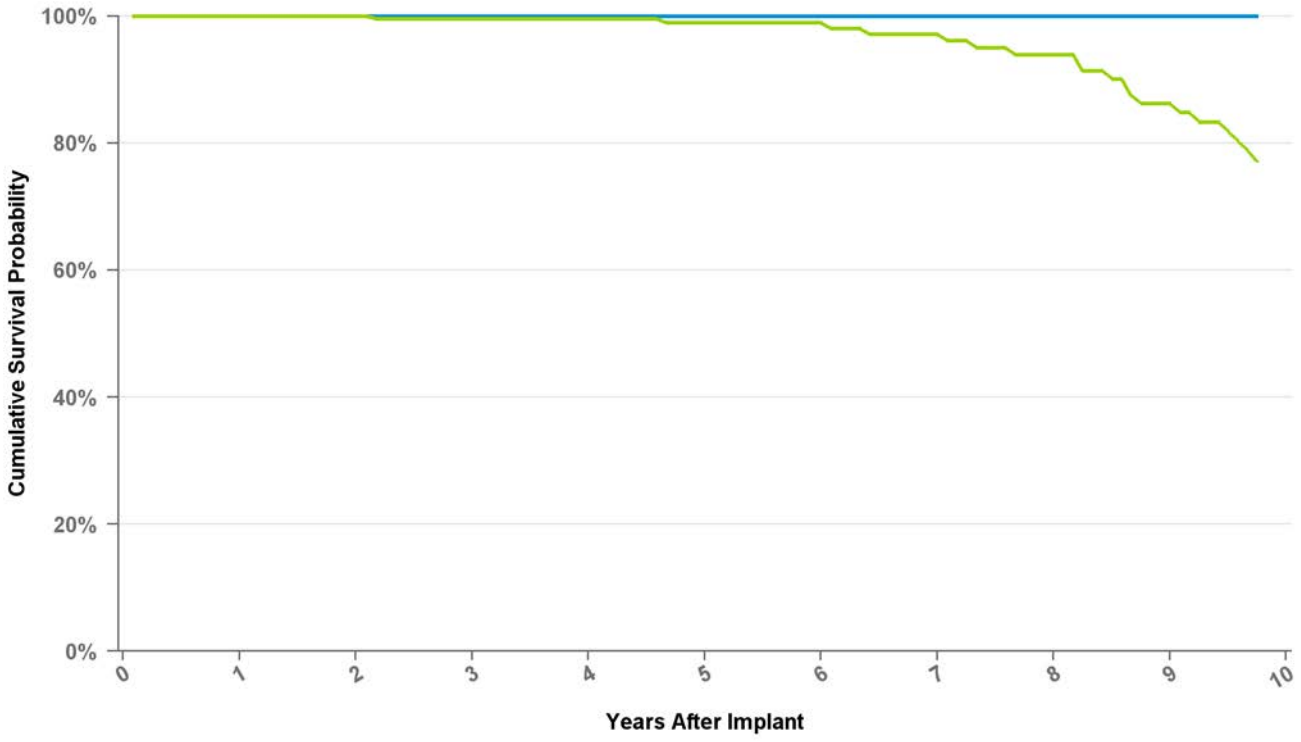
SS103 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	764
Estimated Active US Implants	98
Normal Battery Depletions (US)	22

NBG Code	SSI
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SS103, SS106, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.6%	99.6%	98.9%	98.9%	97.1%	93.9%	86.2%	77.2%
Effective Sample Size	630	502	400	325	257	228	194	163	123	102

Implantable Pulse Generator

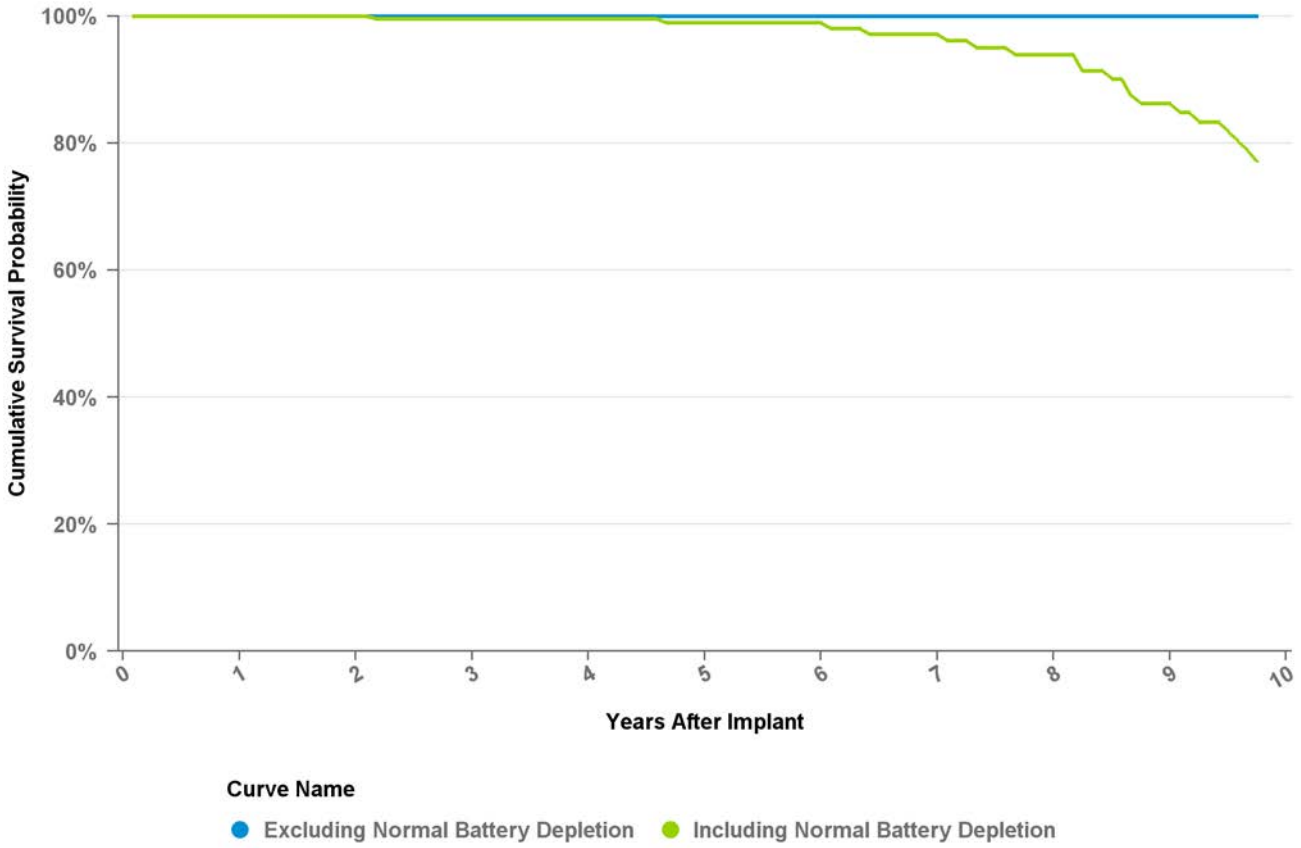
SS106 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	68
Estimated Active US Implants	5
Normal Battery Depletions (US)	7

NBG Code	SSI
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SS103, SS106, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 117 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.6%	99.6%	98.9%	98.9%	97.1%	93.9%	86.2%	77.2%
Effective Sample Size	630	502	400	325	257	228	194	163	123	102

Implantable Pulse Generator

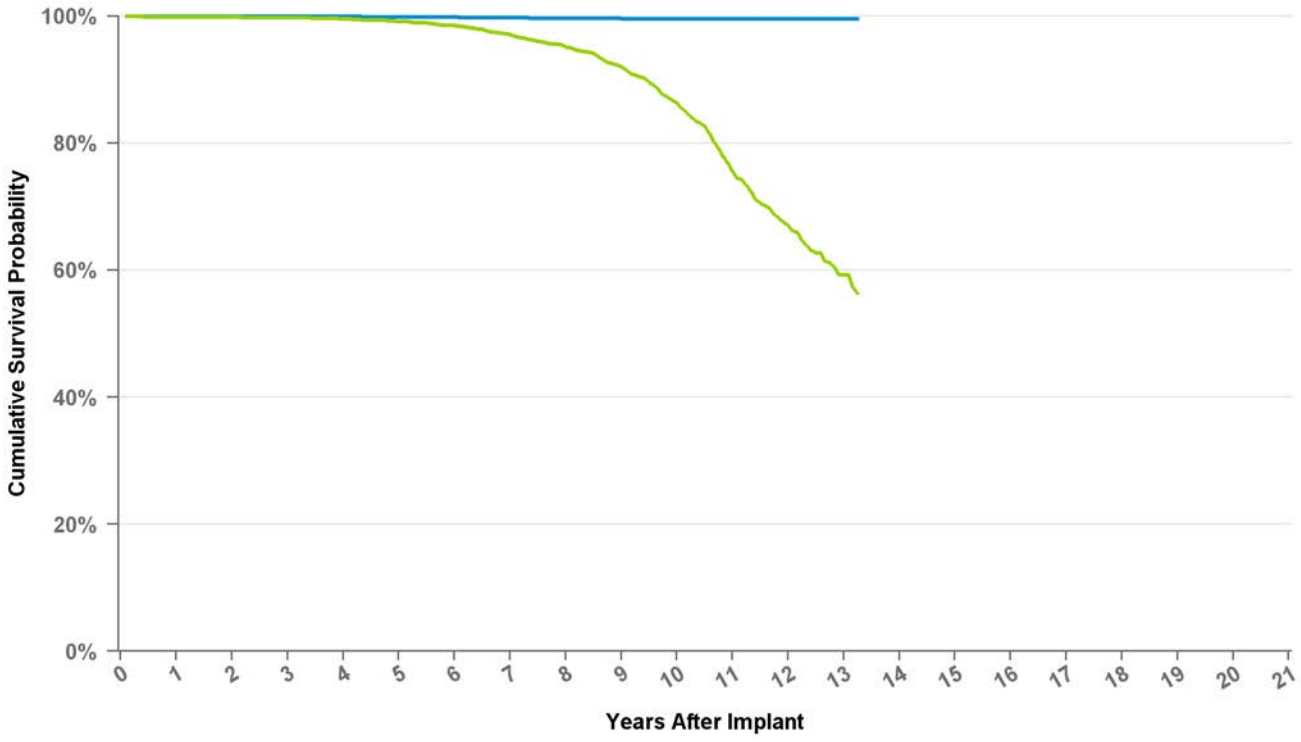
SS203 Sigma 200 S

US Market Release Date	8/30/1999
CE Market Approval Date	
Registered US Implants	4
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	SSI
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SSR203, SS203, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 159 mo
Excluding NBD	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%	99.6%
Including NBD	99.9%	86.3%	75.6%	67.0%	59.3%	99.9%	99.8%	99.6%	99.1%	98.5%	97.1%	95.1%	92.0%	56.4%
Effective Sample Size	10351	2332	1557	884	272	8738	7435	6385	5484	4753	4061	3559	3021	121

Implantable Pulse Generator

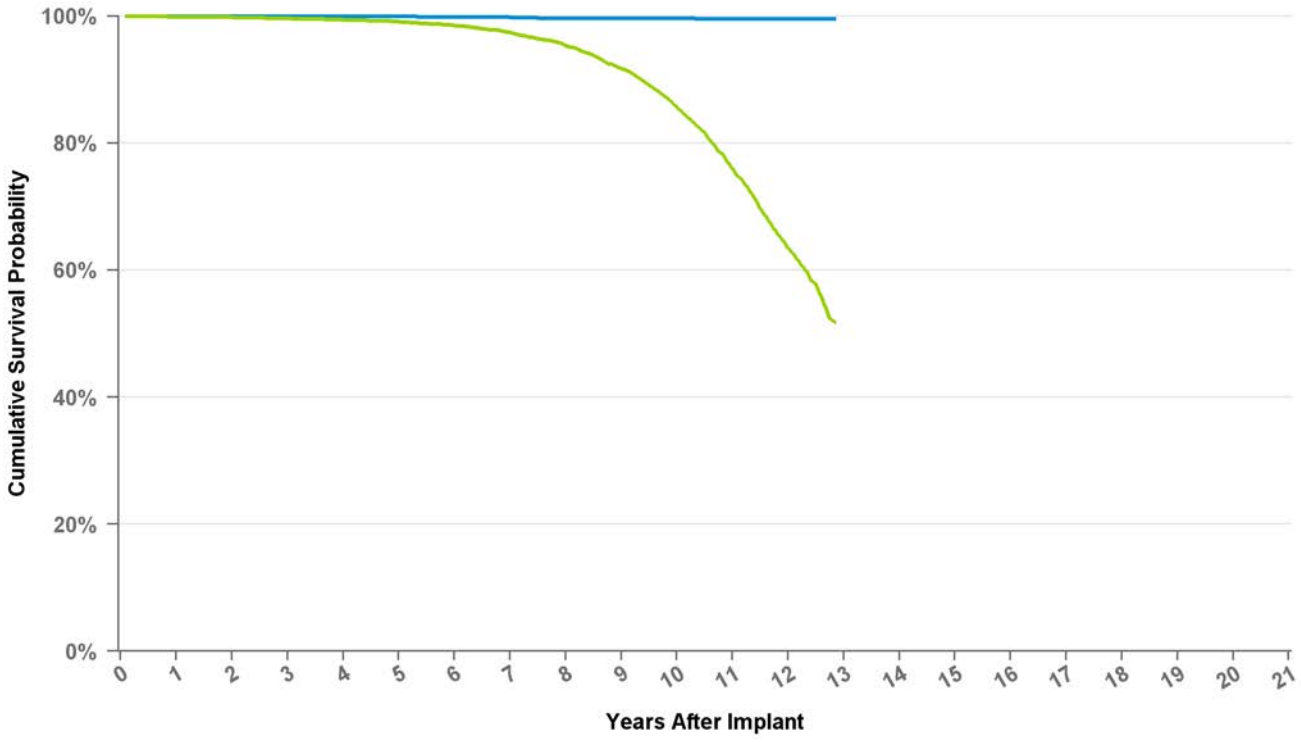
SS303 Sigma 300 S

US Market Release Date	9/15/1999
CE Market Approval Date	12/17/1998
Registered US Implants	221
Estimated Active US Implants	51
Normal Battery Depletions (US)	0

NBG Code	SSI
Max Delivered Energy	N/A

Total Malfunctions (US)	0
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SSR303, SSR306, SS303, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 154 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.9%	85.6%	76.0%	63.5%	99.8%	99.7%	99.4%	99.1%	98.5%	97.4%	95.3%	91.7%	51.8%
Effective Sample Size	47118	7604	4124	1686	39975	34129	29346	25364	21910	18165	14607	11076	160

Implantable Pulse Generator

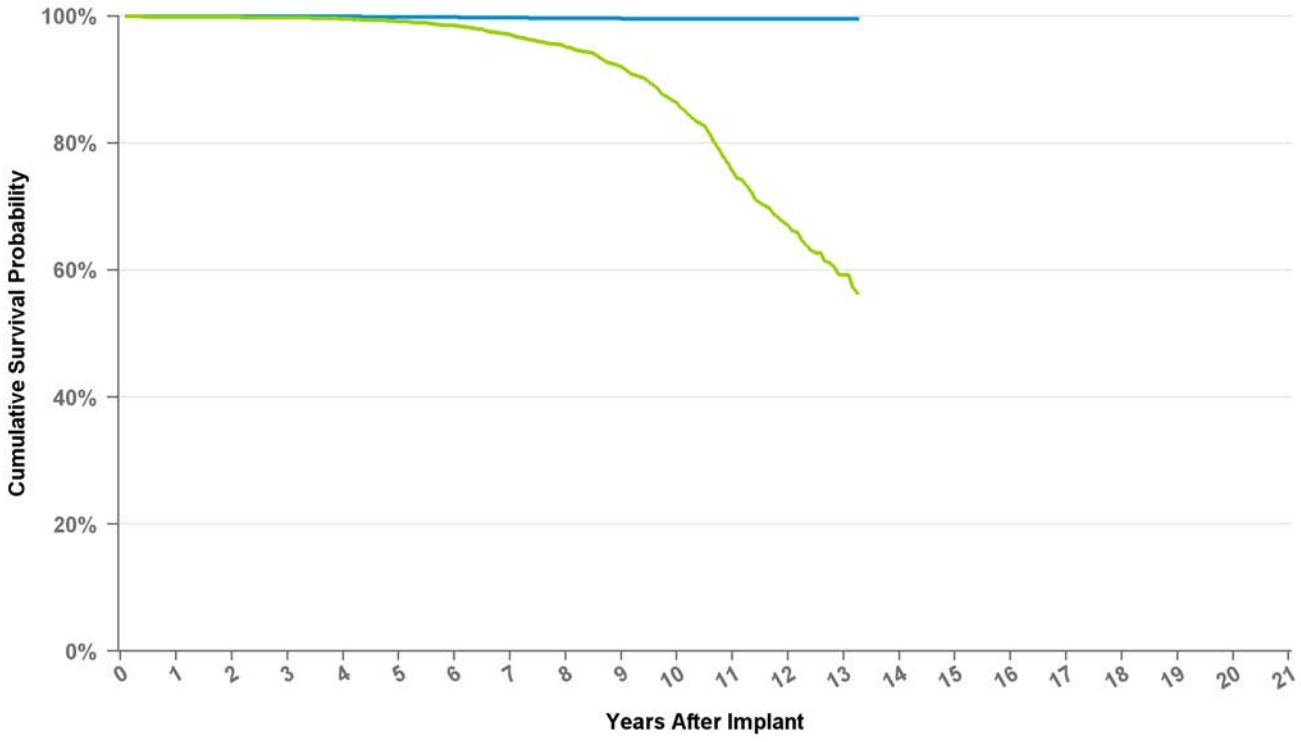
SSR203 Sigma 200 SR

US Market Release Date	9/2/1999
CE Market Approval Date	
Registered US Implants	12,123
Estimated Active US Implants	1,645
Normal Battery Depletions (US)	476

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	14
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	14
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	14
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SSR203, SS203, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 159 mo
Excluding NBD	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%	99.6%
Including NBD	99.9%	86.3%	75.6%	67.0%	59.3%	99.9%	99.8%	99.6%	99.1%	98.5%	97.1%	95.1%	92.0%	56.4%
Effective Sample Size	10351	2332	1557	884	272	8738	7435	6385	5484	4753	4061	3559	3021	121

Implantable Pulse Generator

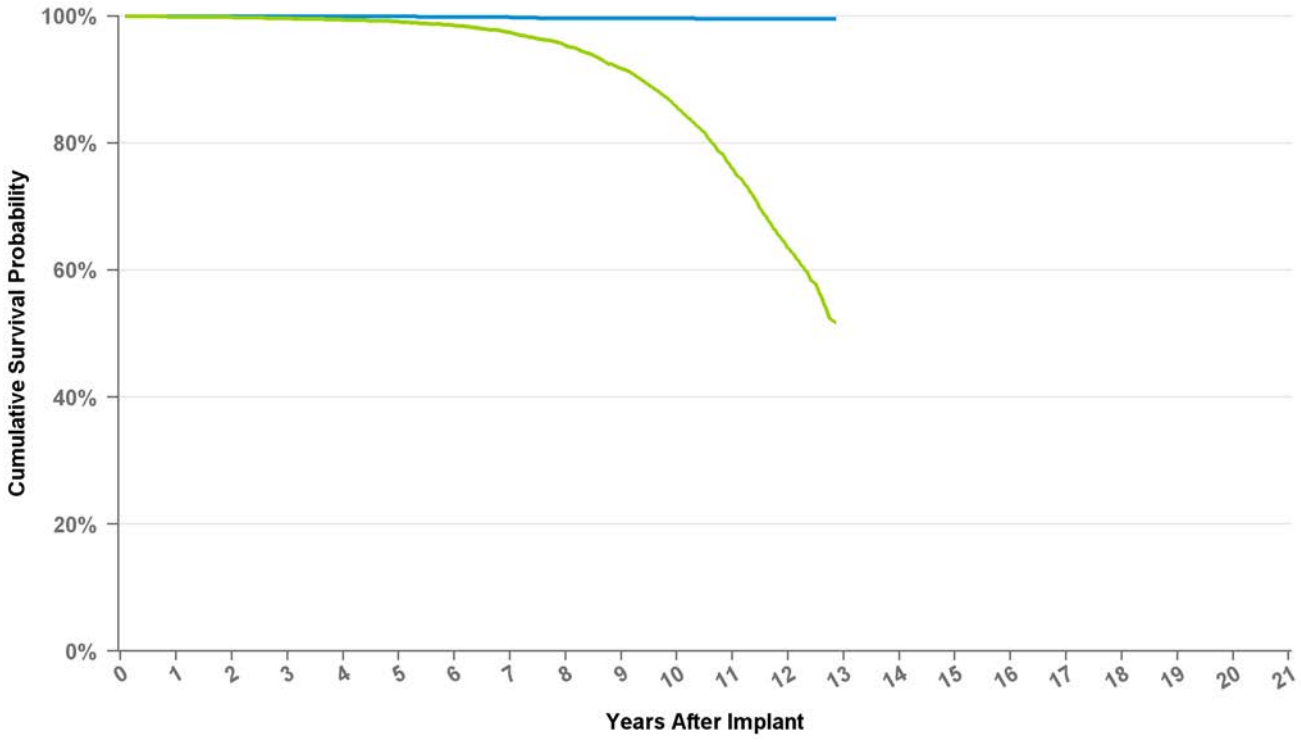
SSR303 Sigma 300 SR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	51,691
Estimated Active US Implants	9,448
Normal Battery Depletions (US)	1,537

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	56
Therapy Not Compromised Malfunction	14
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	12
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	42
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	39
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SSR303, SSR306, SS303, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 154 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.9%	85.6%	76.0%	63.5%	99.8%	99.7%	99.4%	99.1%	98.5%	97.4%	95.3%	91.7%	51.8%
Effective Sample Size	47118	7604	4124	1686	39975	34129	29346	25364	21910	18165	14607	11076	160

Implantable Pulse Generator

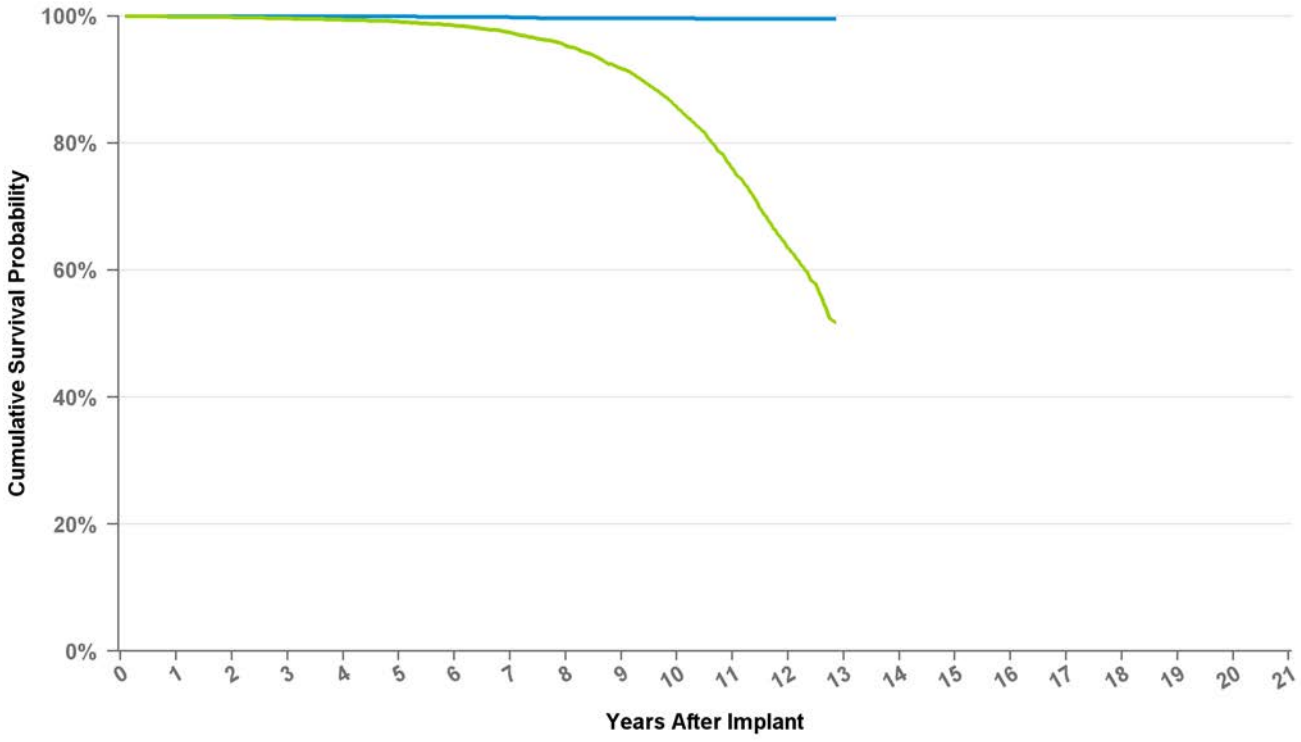
SSR306 Sigma 300 SR

US Market Release Date	9/7/1999
CE Market Approval Date	12/17/1998
Registered US Implants	2,218
Estimated Active US Implants	313
Normal Battery Depletions (US)	117

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	2
Therapy Not Compromised Malfunction	1
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SSR303, SSR306, SS303, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 154 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.8%	99.7%	99.7%	99.7%	99.6%	99.6%	99.6%
Including NBD	99.9%	85.6%	76.0%	63.5%	99.8%	99.7%	99.4%	99.1%	98.5%	97.4%	95.3%	91.7%	51.8%
Effective Sample Size	47118	7604	4124	1686	39975	34129	29346	25364	21910	18165	14607	11076	160

Implantable Pulse Generator

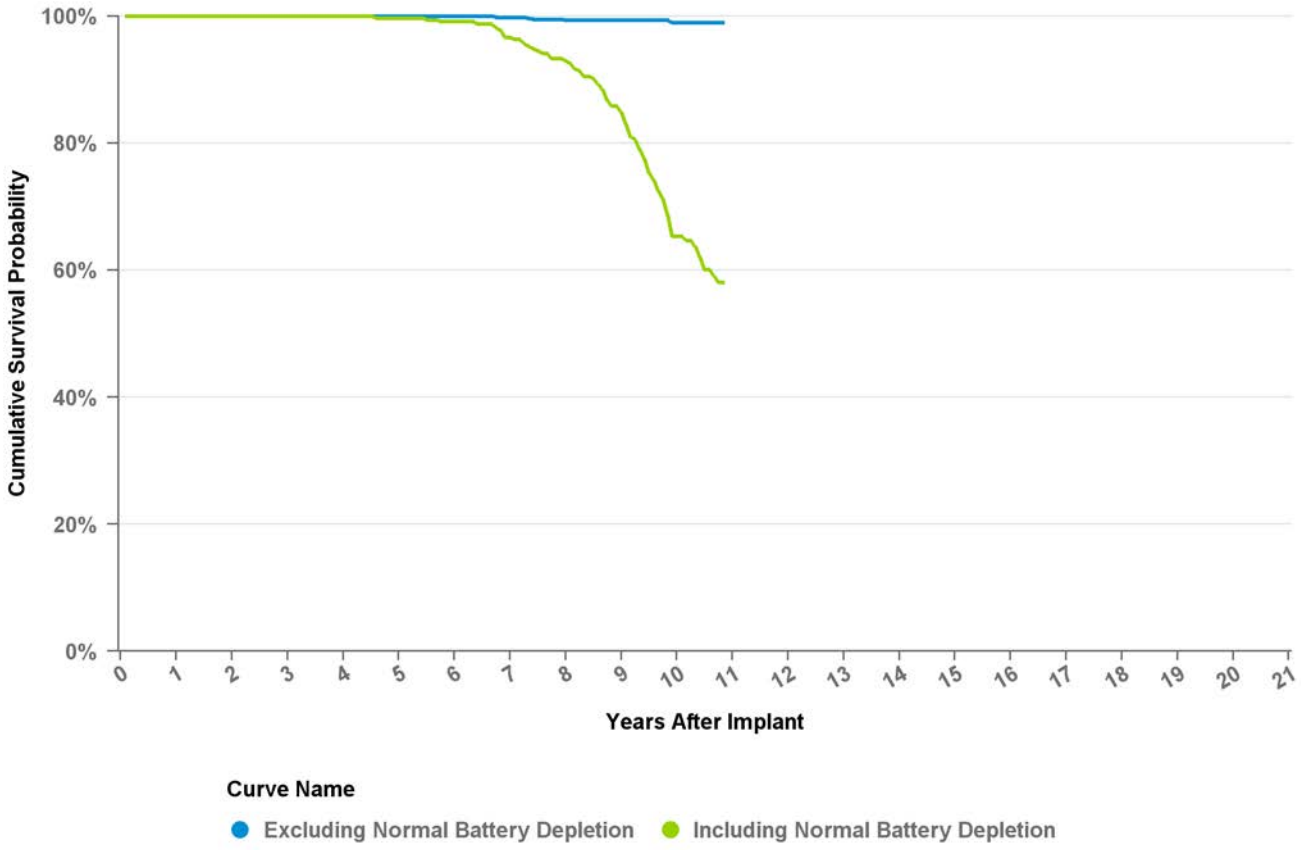
SVDD303 Sigma 300 VDD

US Market Release Date	9/15/1999
CE Market Approval Date	12/17/1998
Registered US Implants	650
Estimated Active US Implants	74
Normal Battery Depletions (US)	76

NBG Code	VDD
Max Delivered Energy	N/A

Total Malfunctions (US)	1
Therapy Not Compromised Malfunction	0
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	1
Battery Malfunction	0
Electrical Component	0
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SVDD303, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	at 130 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.3%	99.3%	98.9%	98.9%
Including NBD	100.0%	65.3%	100.0%	100.0%	100.0%	99.7%	99.1%	96.6%	92.9%	84.9%	58.1%
Effective Sample Size	893	182	822	772	719	664	612	547	479	368	105

Implantable Pulse Generator

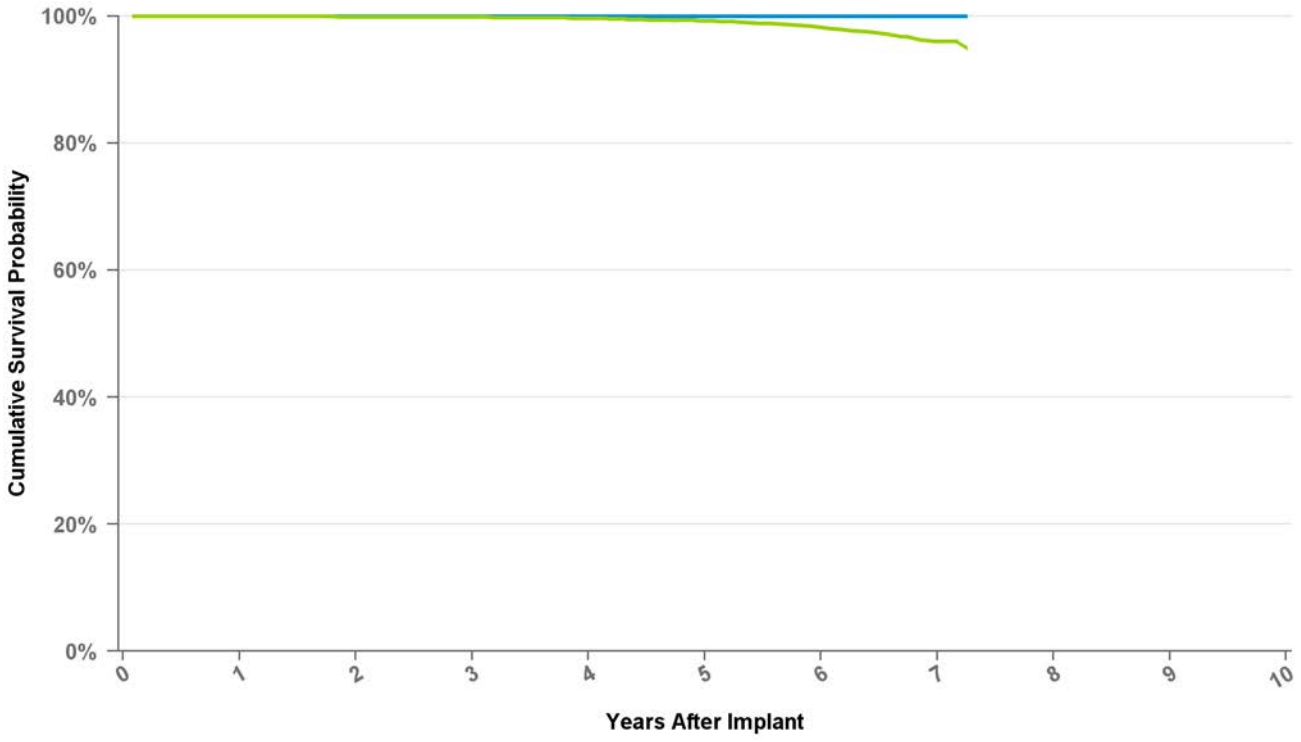
VEDR01 Versa DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	100,971
Estimated Active US Implants	75,554
Normal Battery Depletions (US)	354

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	14
Therapy Not Compromised Malfunction	8
Battery Malfunction	0
Electrical Component	6
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	0
Software Malfunction	0

VEDR01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 87 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.7%	99.2%	98.2%	96.0%	94.9%
Effective Sample Size	90046	74567	58988	43338	28473	14795	2764	517

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.

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 consolidated all cardiac rhythm surveillance registries into the Product Surveillance Registry (PSR), which is part of the PAN Registry platform. The PAN Registry is a patient centric surveillance platform which follows patients implanted with a Medtronic cardiac rhythm product. The Product Performance Report (PPR) tracks lead survival of PAN Registry enrolled patients. The PAN Registry is designed to record clinical observations representative of the total clinical experience. Lead survival estimates include both lead hardware failure and lead-related complications classified as product performance events, 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.

PAN Registry

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.

Method for Estimating Lead Performance continued

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 product survival probabilities. The data gathered may also be used to support the design and development of 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 and follow-up discontinued when sufficient duration and precision is achieved to effectively characterize product survivability.

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:

- Patient is intended to be implanted or is within 30 days post-implant of a Medtronic market-released cardiac lead connected to a market-released CRT, ICD, or IPG device, and the lead is used for a pacing, sensing, or defibrillation application, or
- Patient participated in a qualifying investigational study of a Medtronic cardiac rhythm 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 event has occurred, a lead is modified, 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, perforation, 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 event with at least one of the following classifications that is adjudicated by the committee as a complication and occurs more than 30 days after implant is considered a product performance event and will contribute to the survival analysis endpoint. Events with an onset date 30 days or less after the implant are considered procedure related and therefore are not included as lead-related complications.

Method for Estimating Lead Performance continued

Event Classifications

- Failure to capture
- Failure to sense/undersensing
- Oversensing
- Elevated pacing thresholds
- 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)
- Lead Insulation breach
- Lead Conductor fracture, confirmed electrically, visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement
- Structural Lead Failure

Note: Lead dislodgment with successful repositioning is not considered a product performance event and will not contribute to the survival analysis endpoint.

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.

The survival analysis for left truncated and right-censored data is conducted to estimate the long term product performance for each lead model periodically[2]. The survival functions are estimated using the Kaplan-Meier method. The calculated survival probability at a given time t is an estimator of survival probability beyond t, conditional on survival to the smallest of the entry time (post implant).The 2-sided point-wise confidence limit are calculated.

Active surveillance normally begins at the time of implant and continues until a product performance or censoring event occurs. In some cases in the PAN Registry, active surveillance of a device starts after the device was implanted. The survival probability of such device is conditional on survival to the time when the device enters the Registry. For the PPR analysis, a statistical method to incorporate data from these retrospectively enrolled devices was applied. This method is called left truncation[2]. Left truncation provides a statistical technique that uses data from existing devices while appropriately adjusting the device survival curves for the time the device was not actively followed in the registry. Thus, in some cases sample sizes may fluctuate from one time interval to the next interval.

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.

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.

Method for Estimating Lead Performance continued

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 received cut-off date (e.g. date of data entry at a study site). 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. 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.

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.

Method for Estimating Lead Performance continued

The numbers of malfunctions listed in the Returned Product Analysis tables are the actual numbers confirmed in the returned product analysis. The numbers of complications listed in the complications tables are the actual numbers observed in the 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 our reporting. 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."

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 reporting 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, we also provide 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.

Footnotes:

1: During the evolution of SLS, 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.

2: Klein, John P., Moeschberger, Melvin L. Survival Analysis Techniques for Censored and Truncated Data, New York: Springer-Verlag New York, Inc., 1997.

LEFT HEART PACING LEAD 2187

Distribution Data	
US Market Release	08/28/2001
CE Approval Date	
Registered US Implant	11,980
Estimated Active US	2,606

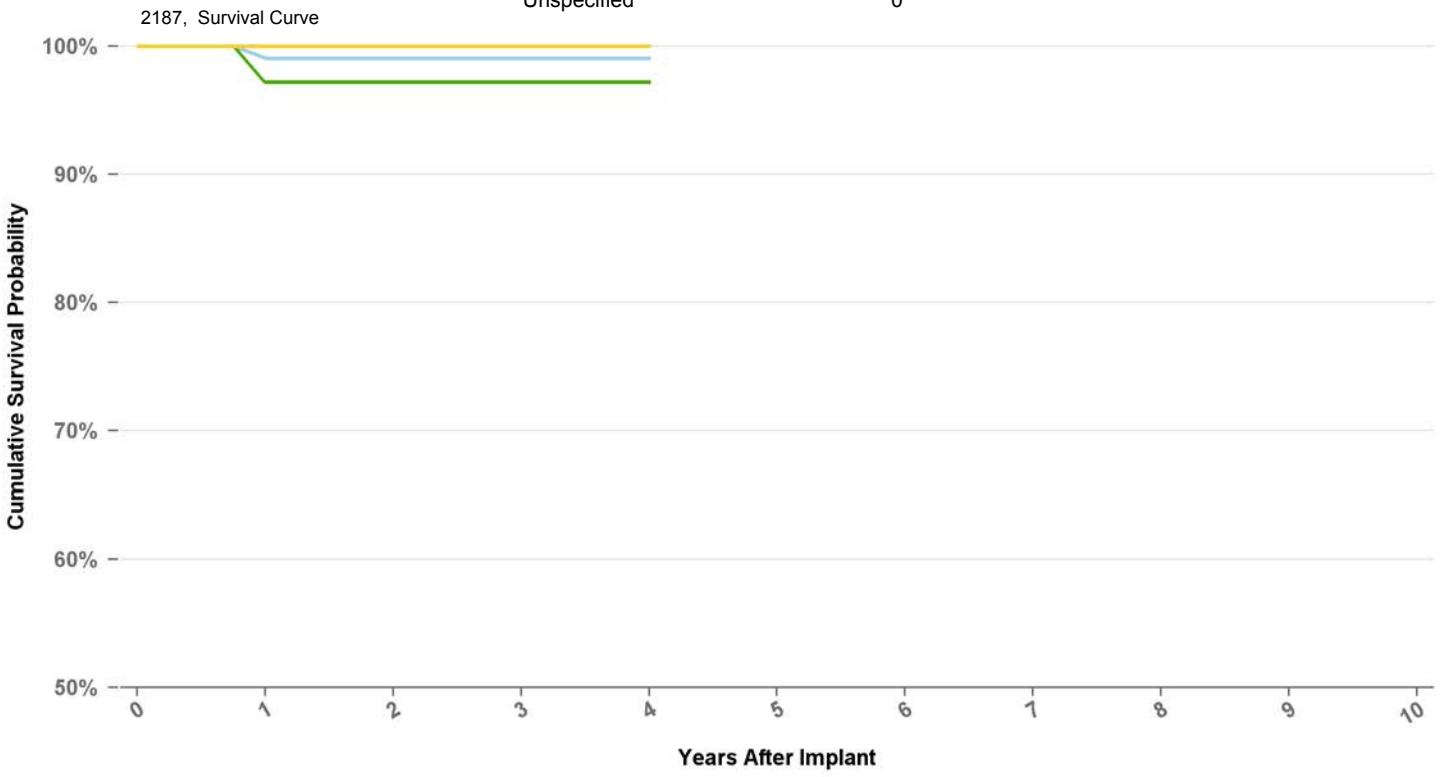
Product Characteristics	
Fixation Type	Distal Continous Curve
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Unipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	138
Cumulative Months of Follow-Up	6,321
Number of Leads Active in Study	13

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	9
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	0
Other	4



Years	1	2	3	at 48 mo
%	99.0%	99.0%	99.0%	99.0%
#	99	84	64	52

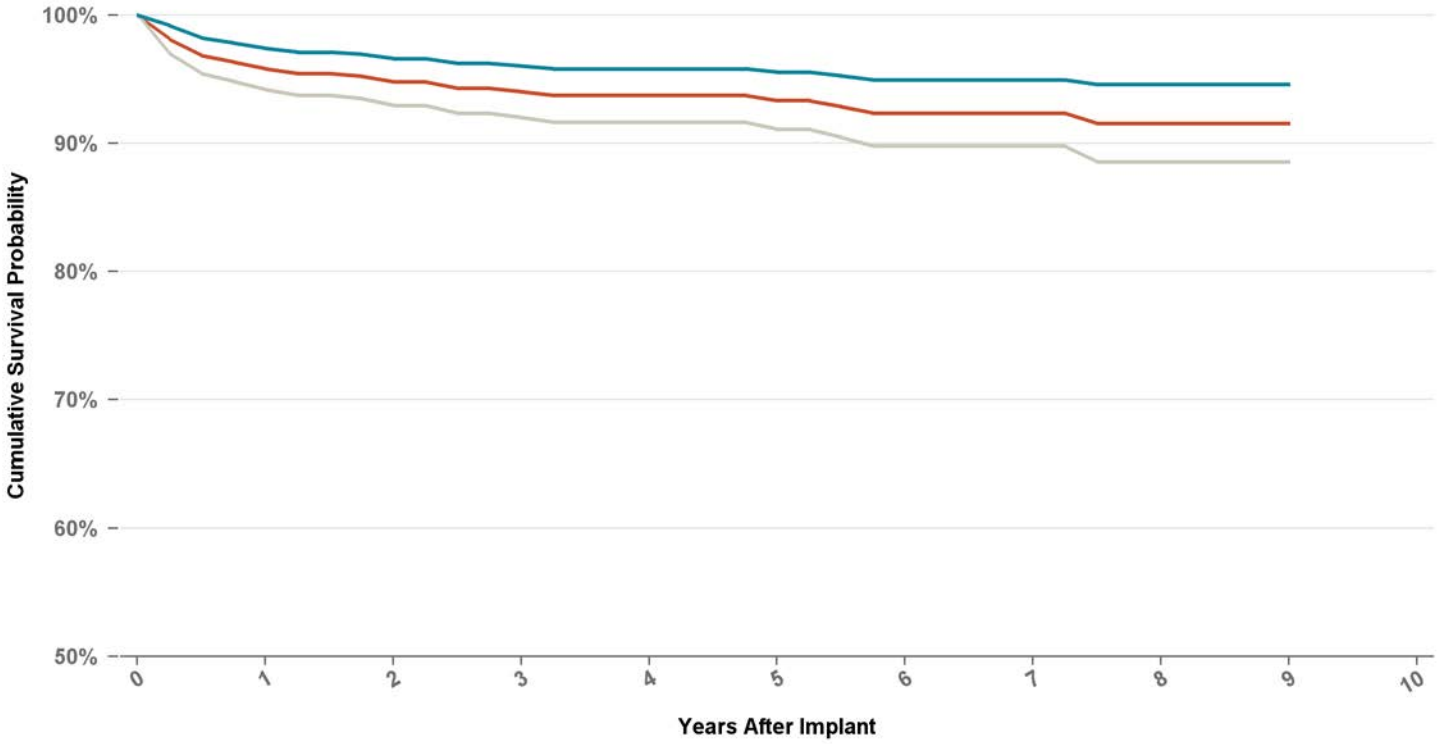
LEFT HEART PACING LEAD 4193

Distribution Data	
US Market Release	05/03/2002
CE Approval Date	12/22/2000
Registered US Implant	100,764
Estimated Active US	32,989
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Unipolar
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	715
Cumulative Months of Follow-Up	30,565
Number of Leads Active in Study	131

Product Surveilance Registry Qualifying Complications	41
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	9
Failure To Capture	13
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	14
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	3

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	16
Failure To Capture	11
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	45
Oversensing	1
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	55
Crimp Weld Bond	0
Insulation Breach	11
Other	48

4193, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4193_SURV

Lower 95 Pct Confidence Graph - 4193_SURV

Upper 95 Pct Confidence Graph - 4193_SURV

Years	1	2	3	4	5	6	7	8	at 108 mo
%	95.8%	94.8%	94.0%	93.7%	93.3%	92.3%	92.3%	91.5%	91.5%
#	533	407	336	264	206	169	128	95	56

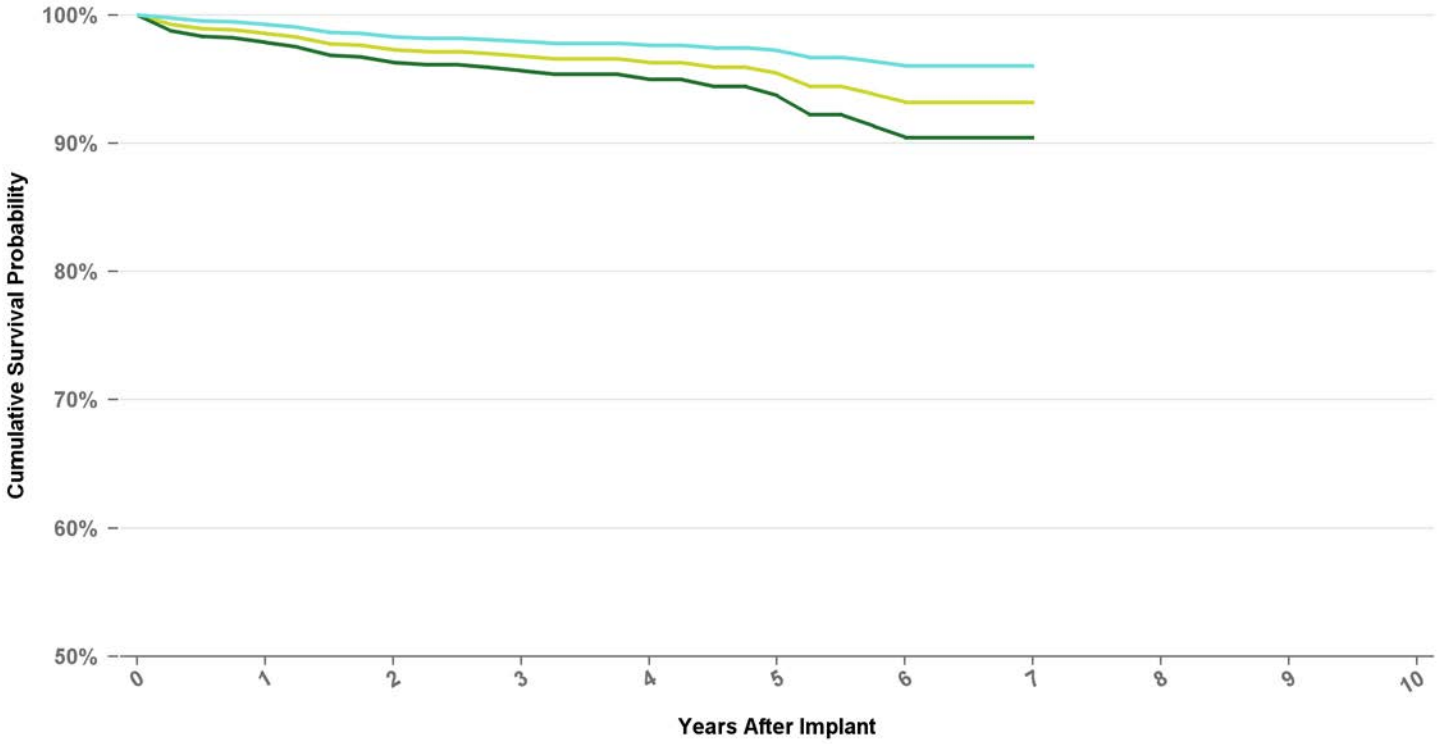
LEFT HEART PACING LEAD 4194

Distribution Data	
US Market Release	08/24/2004
CE Approval Date	07/14/2003
Registered US Implant	111,118
Estimated Active US	64,753
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Bipolar
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,387
Cumulative Months of Follow-Up	43,457
Number of Leads Active in Study	763

Product Surveilance Registry Qualifying Complications	40
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	8
Failure To Capture	12
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	1
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	17
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	32
Failure To Capture	36
Failure To Sense	0
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	130
Oversensing	2
Unspecified	5
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	59
Other	9

4194, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4194_SURV

Lower 95 Pct Confidence Graph - 4194_SURV

Upper 95 Pct Confidence Graph - 4194_SURV

Years	1	2	3	4	5	6	at 84 mo
%	98.6%	97.3%	96.8%	96.3%	95.5%	93.2%	93.2%
#	1,010	767	494	308	189	132	64

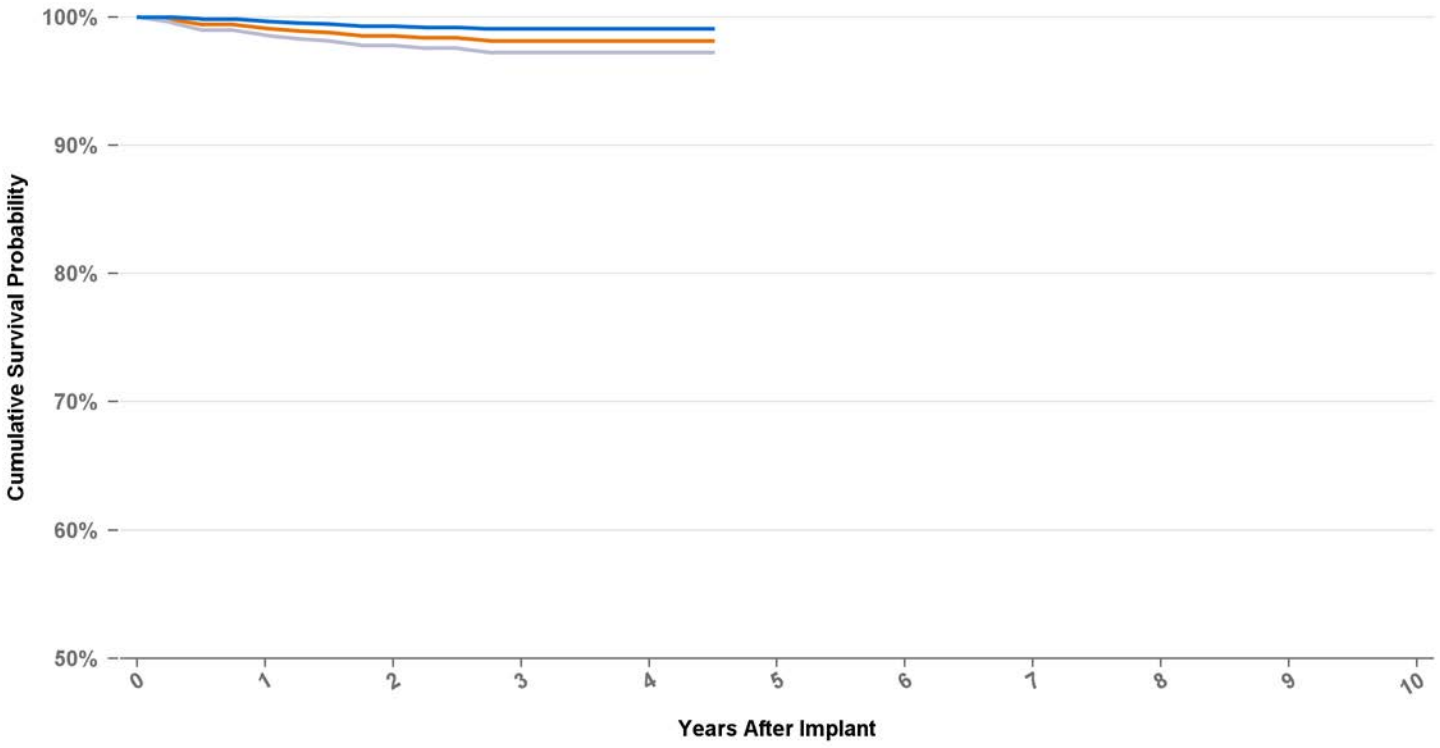
LEFT HEART PACING LEAD 4195

Distribution Data	
US Market Release	08/15/2008
CE Approval Date	05/13/2005
Registered US Implant	15,718
Estimated Active US	12,235
Product Characteristics	
Fixation Type	Deployable Lobe Fixation
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Unipolar
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,375
Cumulative Months of Follow-Up	33,402
Number of Leads Active in Study	918

Product Surveilance Registry Qualifying Complications	17
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	8
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	23
Failure To Capture	15
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	25
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	1
Other	3

4195, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4195_SURV

Lower 95 Pct Confidence Graph - 4195_SURV

Upper 95 Pct Confidence Graph - 4195_SURV

Years	1	2	3	4	at 54 mo
%	99.1%	98.5%	98.1%	98.1%	98.1%
#	981	628	349	106	58

LEFT HEART PACING LEAD 4196

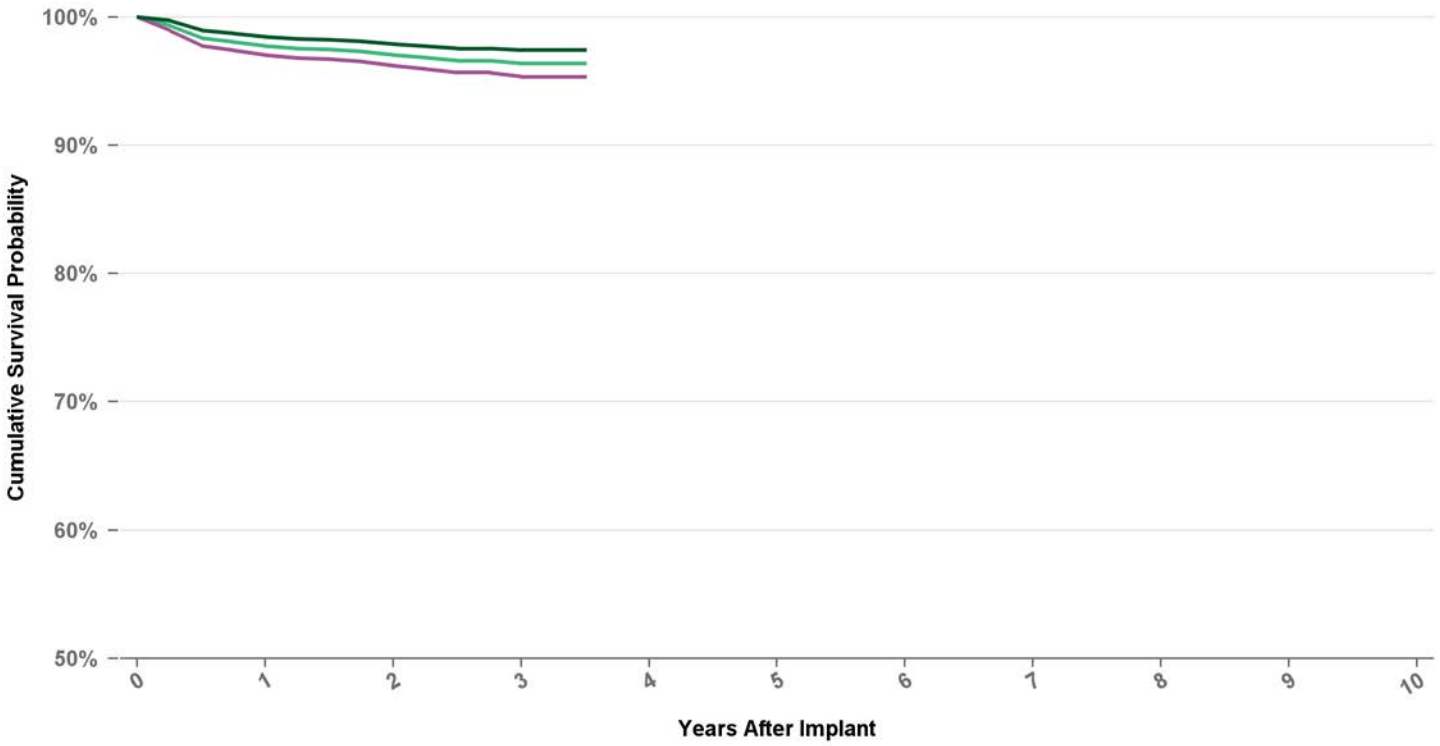
Distribution Data	
US Market Release	05/15/2009
CE Approval Date	07/24/2007
Registered US Implant	55,658
Estimated Active US	45,724
Product Characteristics	
Fixation Type	Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,969
Cumulative Months of Follow-Up	46,224
Number of Leads Active in Study	1,061

Product Surveilance Registry Qualifying Complications	52
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	13
Failure To Capture	18
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	18
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	69
Failure To Capture	37
Failure To Sense	1
Impedance Abnormal	6
Insulation Breach	1
Lead Dislodgement	137
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	0
Other	8

4196, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4196_SURV

Lower 95 Pct Confidence Graph - 4196_SURV

Upper 95 Pct Confidence Graph - 4196_SURV

Years	1	2	3	at 42 mo
%	97.7%	97.0%	96.4%	96.4%
#	1,492	996	385	165

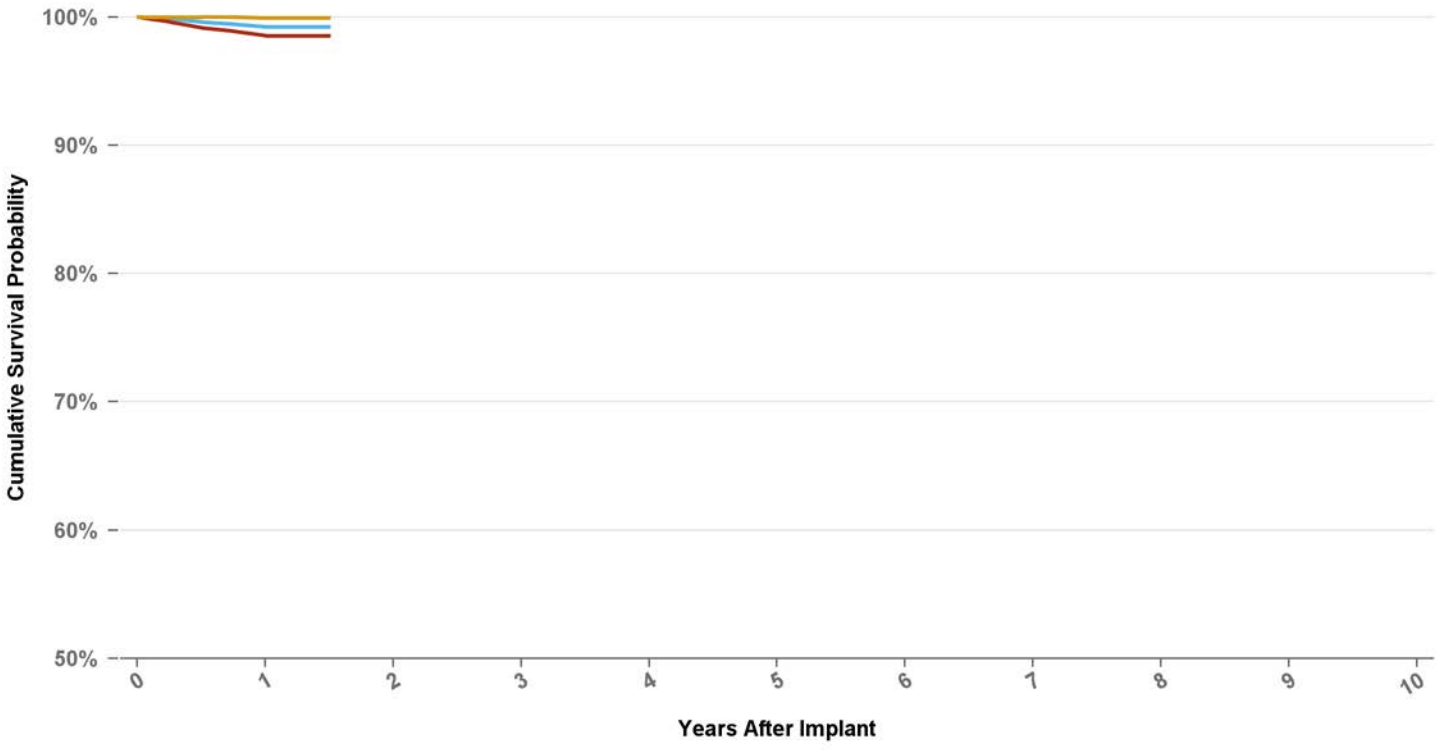
LEFT HEART PACING LEAD 4296

Distribution Data	
US Market Release	04/01/2011
CE Approval Date	12/18/2009
Registered US Implant	20,387
Estimated Active US	18,968
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Dual Electrodes
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,080
Cumulative Months of Follow-Up	9,104
Number of Leads Active in Study	865

Product Surveilance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	21
Failure To Capture	10
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	2
Lead Dislodgement	63
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	1
Insulation Breach	0
Other	2

4296, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4296_SURV

Lower 95 Pct Confidence Graph - 4296_SURV

Upper 95 Pct Confidence Graph - 4296_SURV

Years	1	at 18 mo
%	99.2%	99.2%
#	342	131

LEFT HEART PACING LEAD 4298

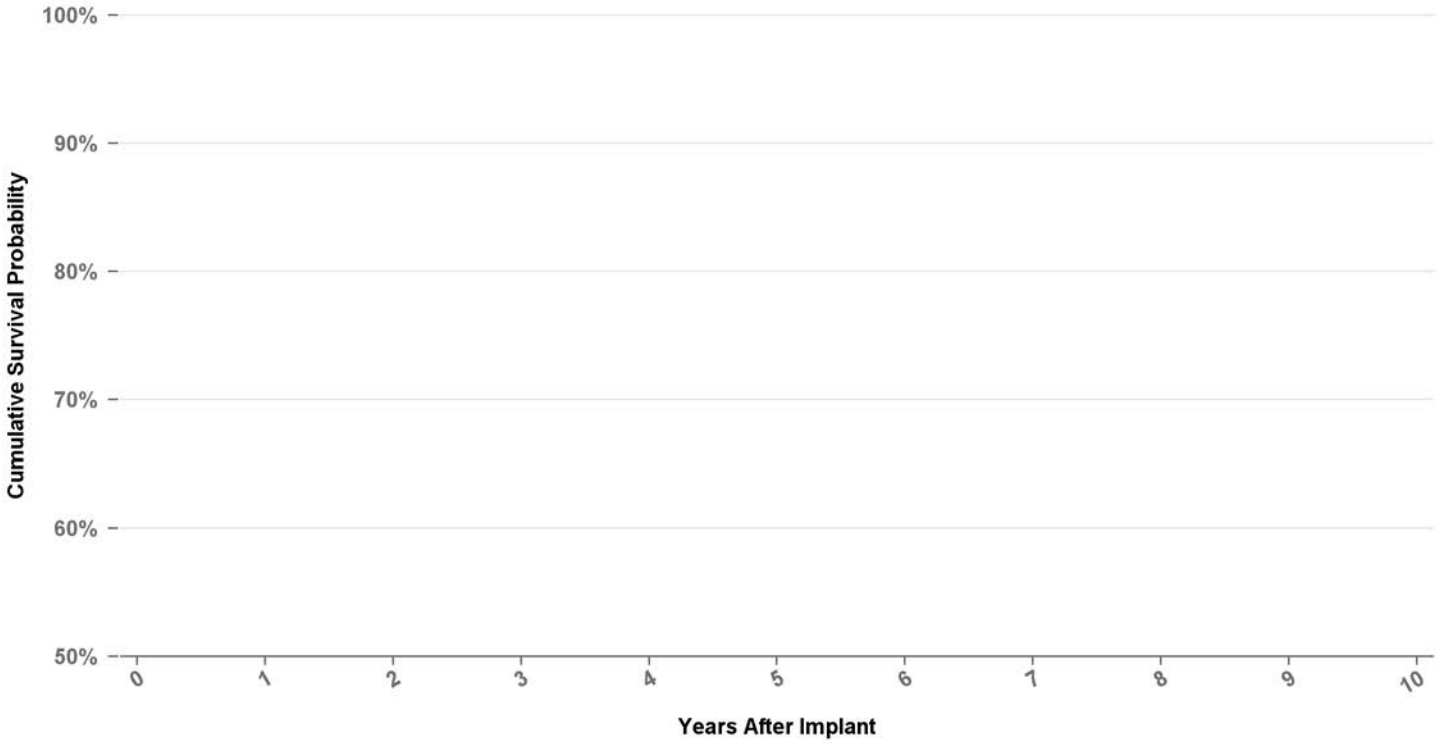
Distribution Data	
US Market Release	01/01/2013
CE Approval Date	01/01/2013
Registered US Implant	347
Estimated Active US	339
Product Characteristics	
Fixation Type	Distal Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0
Number of Leads Active in Study	0

Product Surveilance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	3
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	1



Graph Name

Cumulative Survival Probability Graph - 4298_SURV

Lower 95 Pct Confidence Graph - 4298_SURV

Upper 95 Pct Confidence Graph - 4298_SURV

Years	
%	
#	

LEFT HEART PACING LEAD 4396

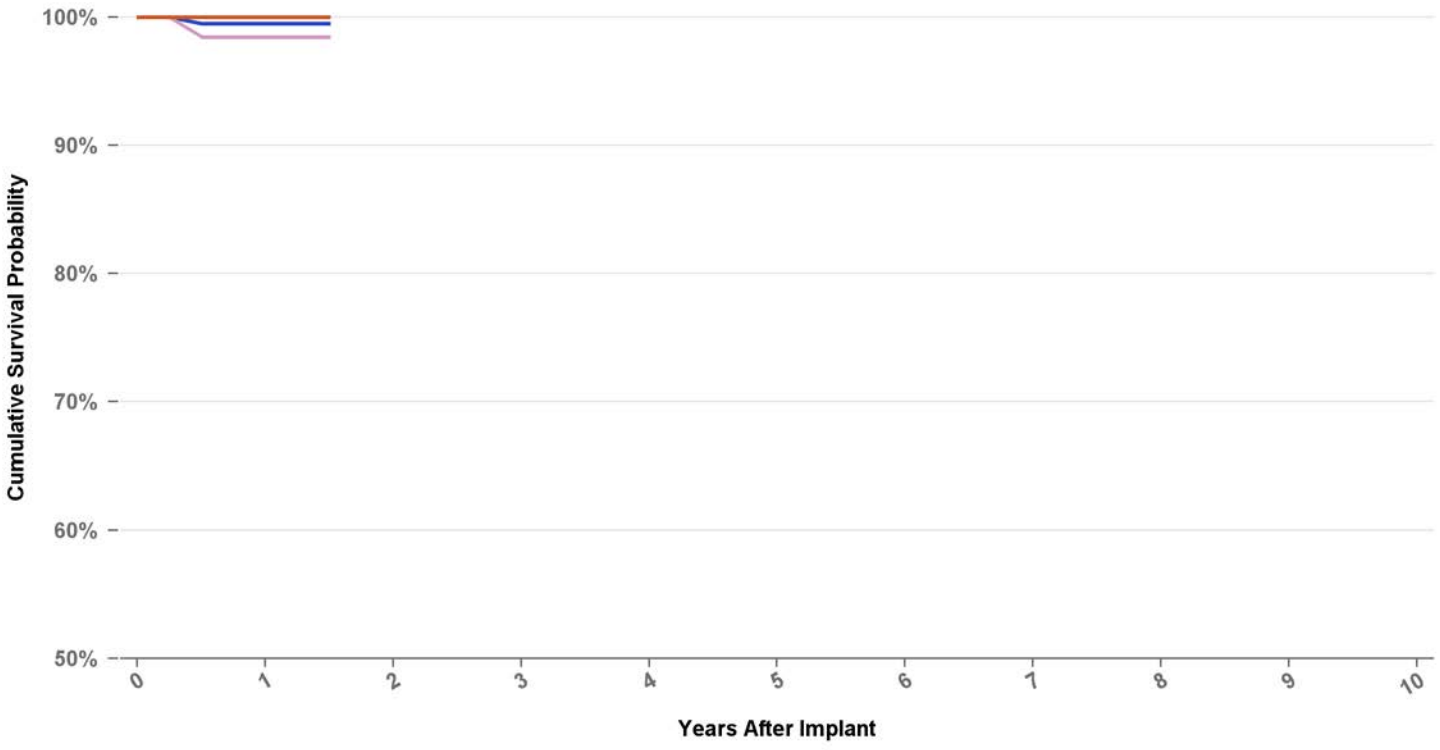
Distribution Data	
US Market Release	03/31/2011
CE Approval Date	12/18/2009
Registered US Implant	4,432
Estimated Active US	4,067
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Dual Electrodes

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	293
Cumulative Months of Follow-Up	3,079
Number of Leads Active in Study	232

Product Surveilance Registry Qualifying Complications	1
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	9
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	18
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	0

4396, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4396_SURV

Lower 95 Pct Confidence Graph - 4396_SURV

Upper 95 Pct Confidence Graph - 4396_SURV

Years	1	at 18 mo
%	99.5%	99.5%
#	109	60

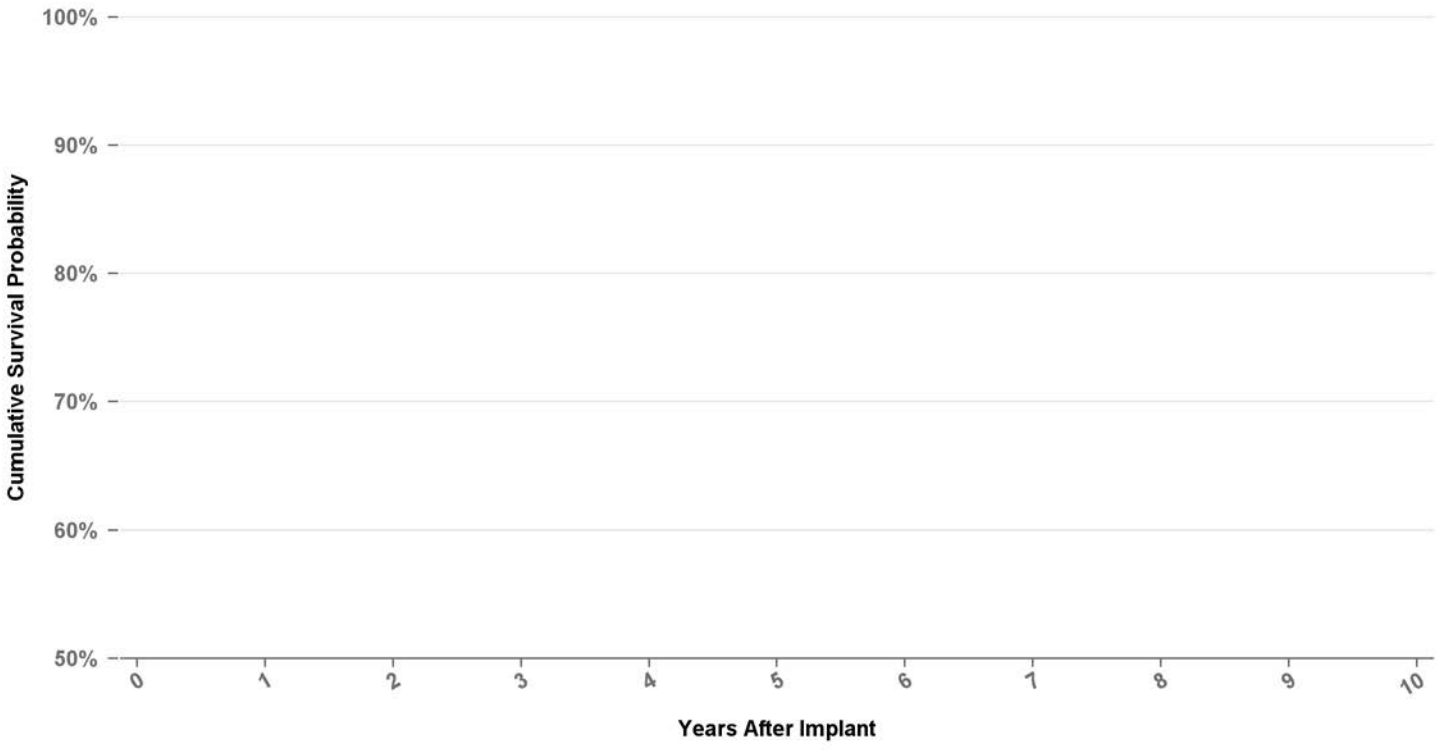
LEFT HEART PACING LEAD 4398

Distribution Data	
US Market Release	01/01/2013
CE Approval Date	01/01/2013
Registered US Implant	242
Estimated Active US	235
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	0
Cumulative Months of Follow-Up	0
Number of Leads Active in Study	0

Product Surveilance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	7
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	1



Years
%
#

DEFIBRILLATION LEAD 6721

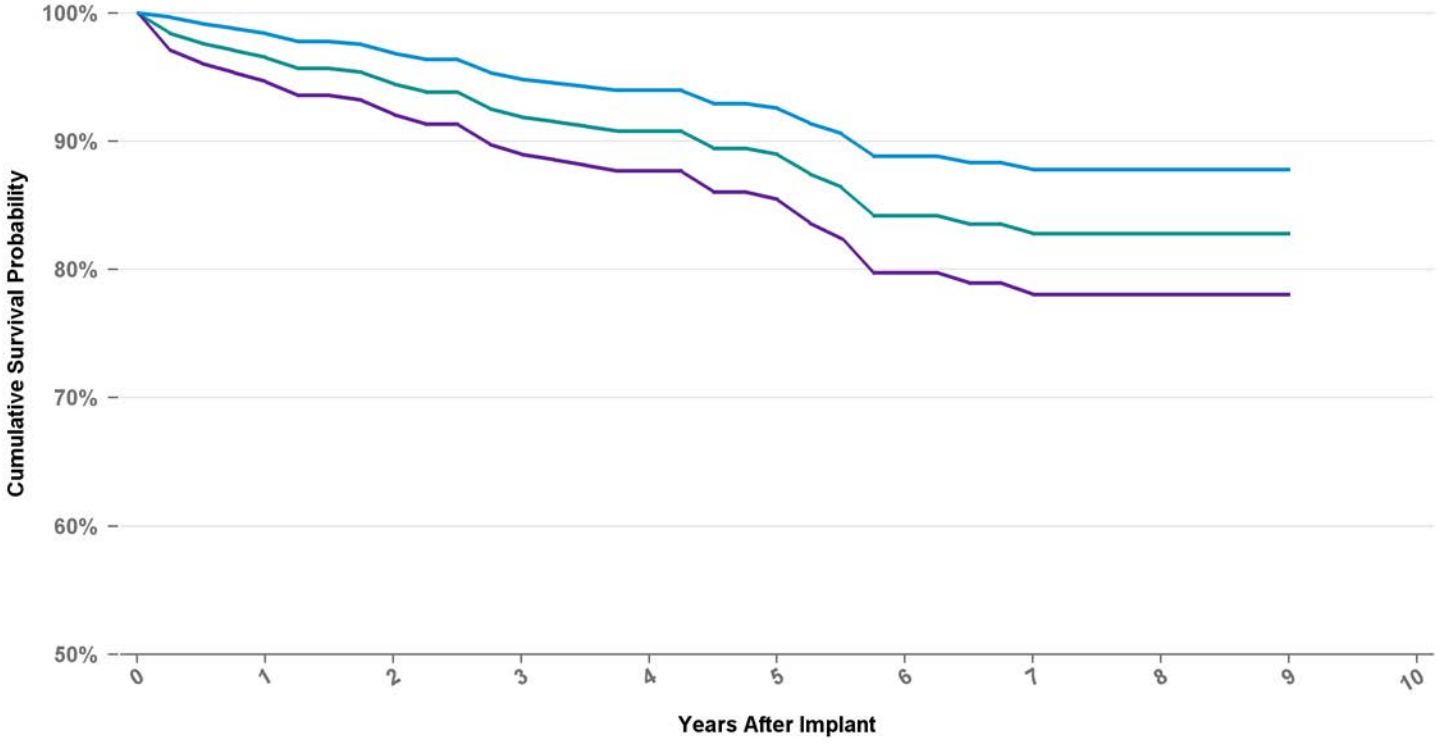
Distribution Data	
US Market Release	03/31/1994
CE Approval Date	01/01/1993
Registered US Implant	2,891
Estimated Active US	1,098
Product Characteristics	
Fixation Type	Suture
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Epi Patch
Lead Tip Location	Epicardial
Pace/Sense Polarit	n/a

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	408
Cumulative Months of Follow-Up	23,340
Number of Leads Active in Study	5

Product Surveilance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	21
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	8
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	12
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	1
Other	0

6721, 6921, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6721_6921_SURV

Lower 95 Pct Confidence Graph - 6721_6921_SURV

Upper 95 Pct Confidence Graph - 6721_6921_SURV

Years	1	2	3	4	5	6	7	8	at 108 mo
%	289.6%	283.4%	275.6%	272.3%	266.9%	252.6%	248.4%	248.4%	248.4%
#	339	310	265	213	182	131	98	63	55

DEFIBRILLATION LEAD 6930

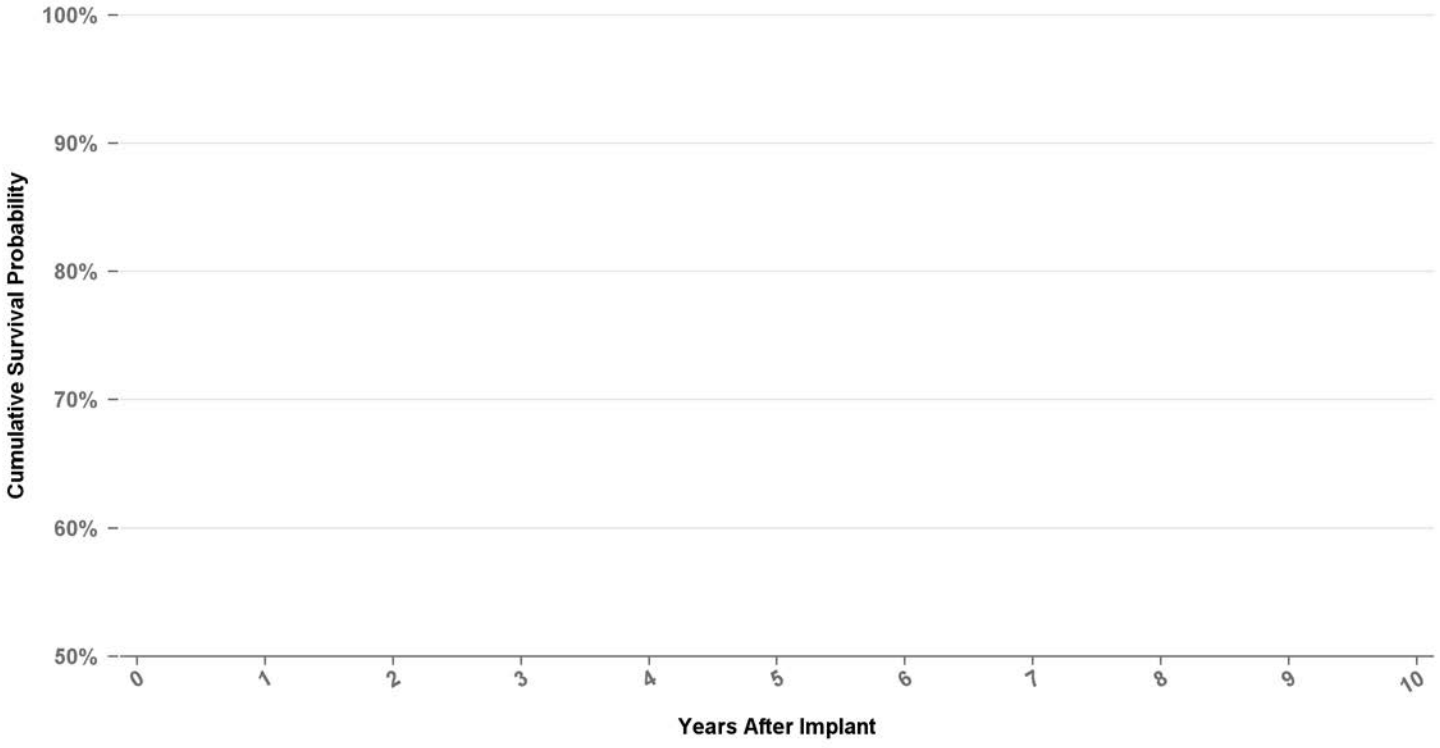
Distribution Data	
US Market Release	09/02/2004
CE Approval Date	
Registered US Implant	354
Estimated Active US	173
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	193
Number of Leads Active in Study	2

Product Surveilance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6930, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6930_SURV

Lower 95 Pct Confidence Graph - 6930_SURV

Upper 95 Pct Confidence Graph - 6930_SURV

Years	at 0 mo
%	100.0%
#	4

DEFIBRILLATION LEAD 6931

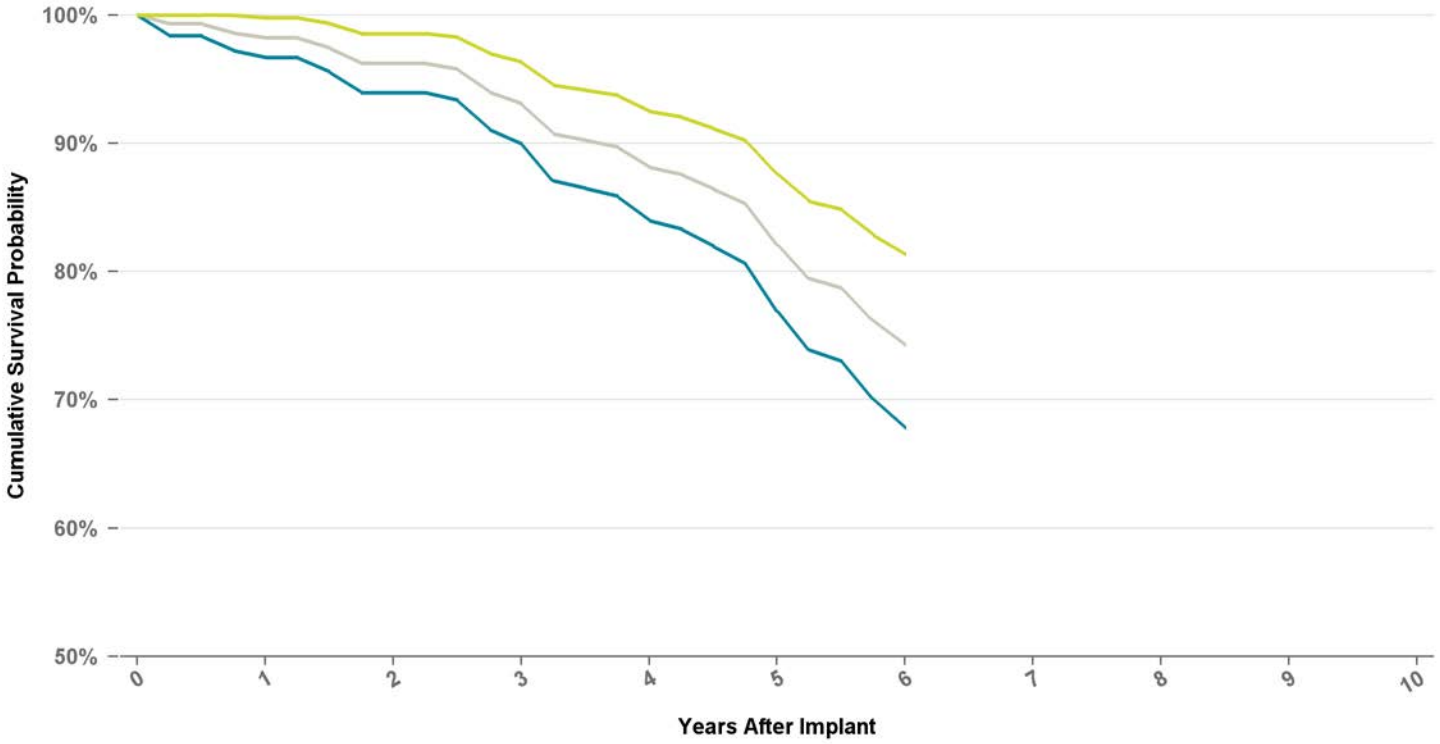
Distribution Data	
US Market Release	09/02/2004
CE Approval Date	
Registered US Implant	8,080
Estimated Active US	3,279
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	296
Cumulative Months of Follow-Up	14,349
Number of Leads Active in Study	94

Product Surveilance Registry Qualifying Complications	48
Cardiac Perforation	0
Conductor Fracture	28
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	8
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	6
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	3
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	552
Crimp Weld Bond	0
Insulation Breach	1
Other	5

6931, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6931_SURV

Lower 95 Pct Confidence Graph - 6931_SURV

Upper 95 Pct Confidence Graph - 6931_SURV

Years	1	2	3	4	5	at 72 mo
%	98.2%	96.2%	93.1%	88.1%	82.1%	74.2%
#	262	231	199	158	126	65

DEFIBRILLATION LEAD 6932

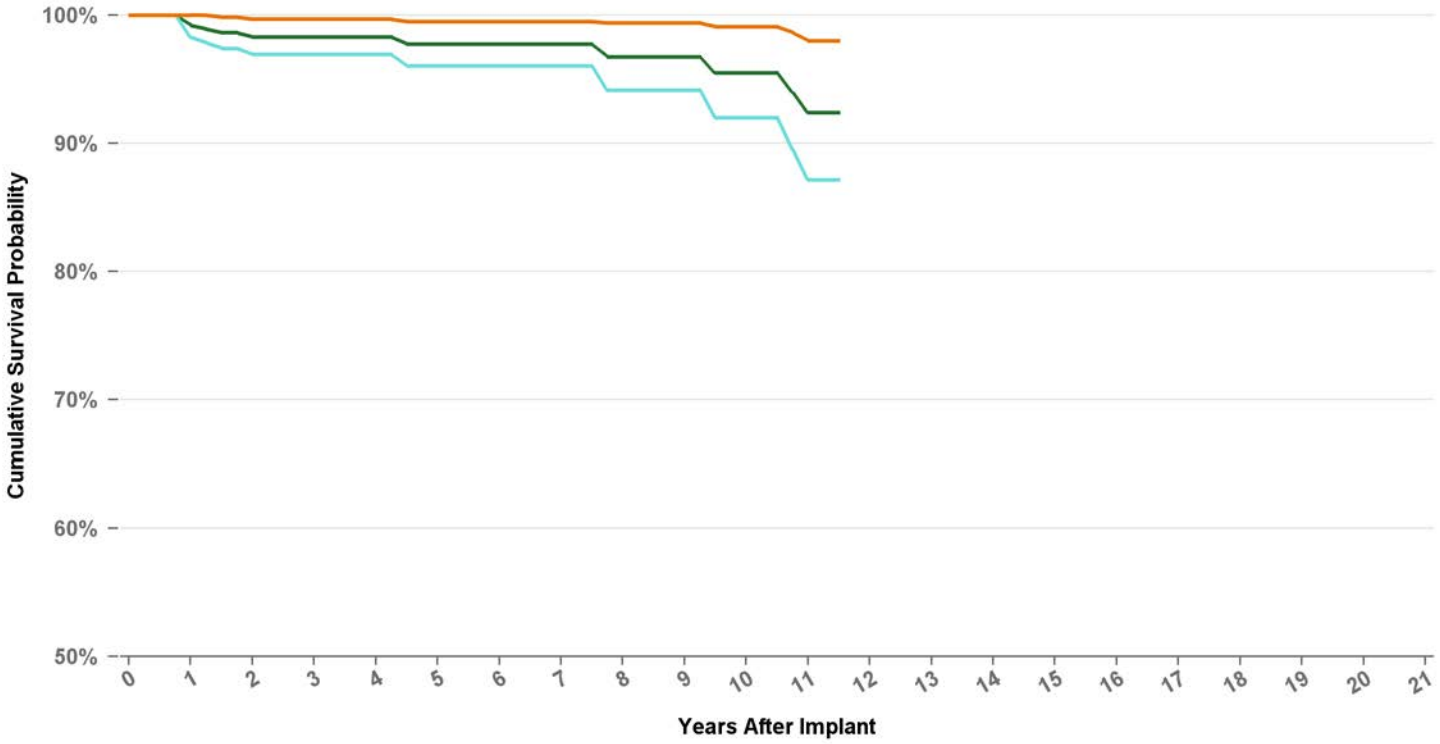
Distribution Data	
US Market Release	08/06/1996
CE Approval Date	
Registered US Implant	14,899
Estimated Active US	4,145
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	416
Cumulative Months of Follow-Up	25,332
Number of Leads Active in Study	37

Product Surveilance Registry Qualifying Complications	11
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	4
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	4
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	22
Crimp Weld Bond	0
Insulation Breach	25
Other	2

6932, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6932_SURV

Lower 95 Pct Confidence Graph - 6932_SURV

Upper 95 Pct Confidence Graph - 6932_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.2%	98.3%	98.3%	98.3%	97.7%	97.7%	97.7%	96.7%	96.7%	95.5%	92.4%	92.4%
#	359	302	241	202	157	125	105	91	80	67	55	52

DEFIBRILLATION LEAD 6933

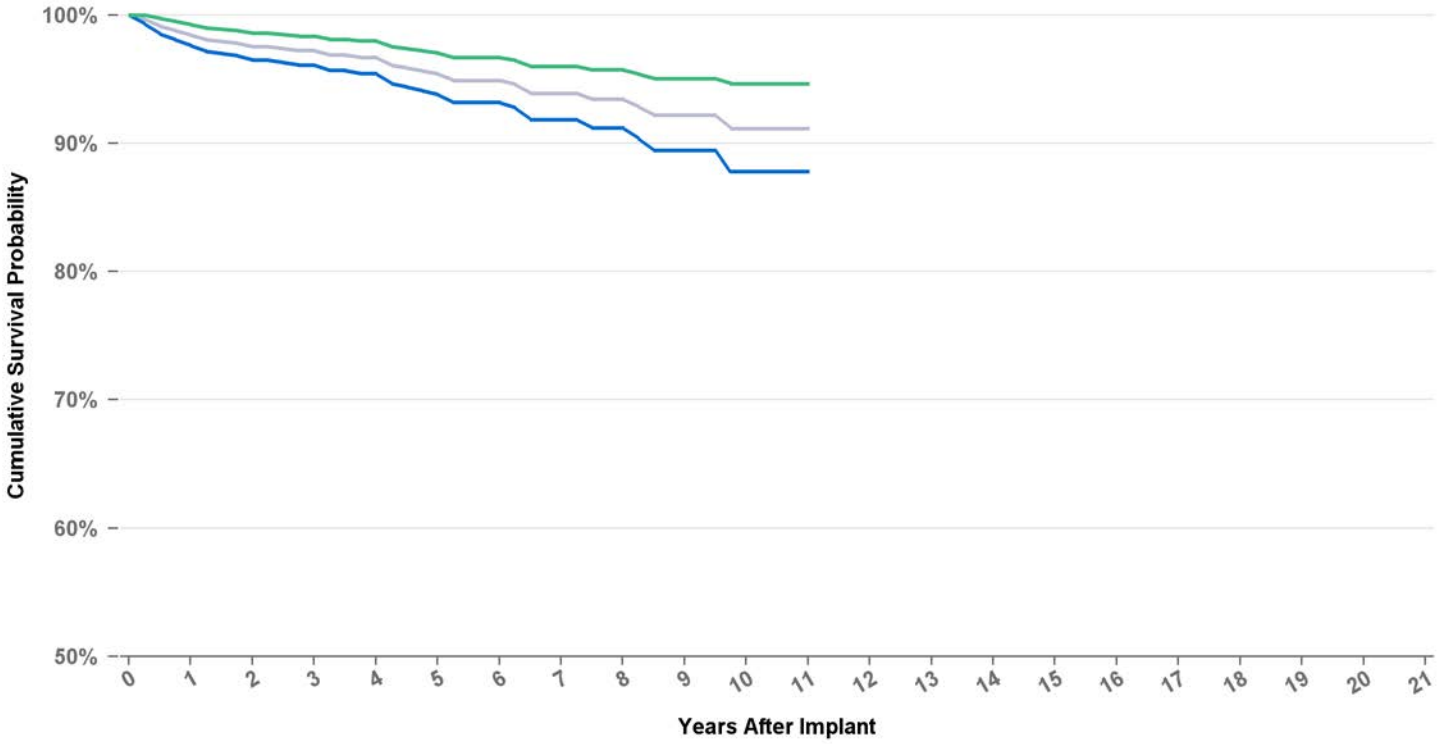
Distribution Data	
US Market Release	04/20/1994
CE Approval Date	
Registered US Implant	7,978
Estimated Active US	785
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,184
Number of Leads Active in Study	12

Product Surveillance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	16
Electrical Abandonment	0
Extracardiac Stimulation	4
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	10
Unspecified	4

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	105
Crimp Weld Bond	0
Insulation Breach	15
Other	0

6933, 6937, 6937A, 6963, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6933_6937_6937A_6963_SURV

Lower 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Upper 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	820	689	576	484	388	312	219	170	111	73	50

DEFIBRILLATION LEAD 6935

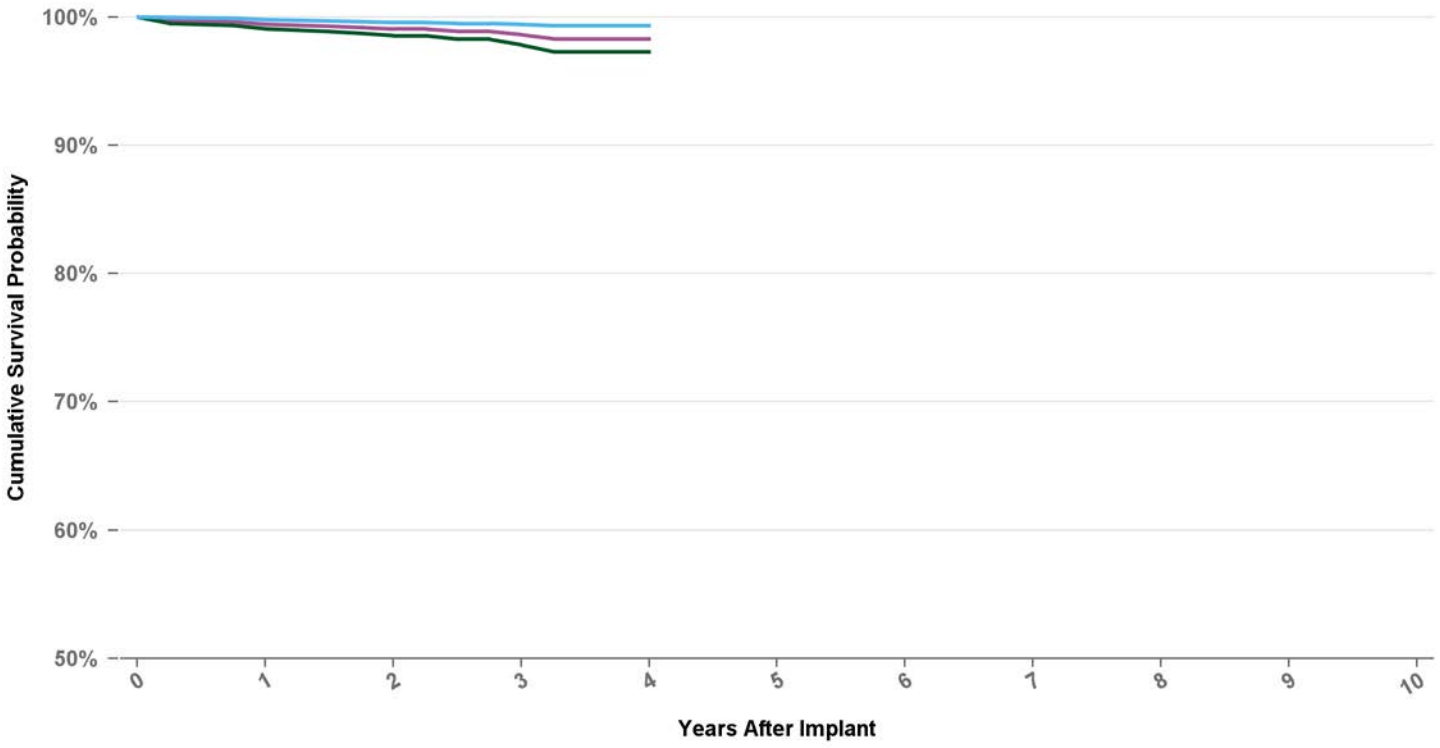
Distribution Data	
US Market Release	11/01/2008
CE Approval Date	03/31/2008
Registered US Implant	45,404
Estimated Active US	40,763
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,337
Cumulative Months of Follow-Up	42,517
Number of Leads Active in Study	1,744

Product Surveilance Registry Qualifying Complications	17
Cardiac Perforation	0
Conductor Fracture	5
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	4
Medical Judgment	0
Other Complication	1
Oversensing	4
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	12
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	17
Failure To Sense	5
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	29
Oversensing	30
Unspecified	5
USA Returned Product Analysis	
Conductor Fracture	83
Crimp Weld Bond	0
Insulation Breach	2
Other	37

6935, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6935_SURV

Lower 95 Pct Confidence Graph - 6935_SURV

Upper 95 Pct Confidence Graph - 6935_SURV

Years	1	2	3	at 48 mo
%	99.4%	99.1%	98.6%	98.3%
#	1,426	729	327	66

DEFIBRILLATION LEAD 6935M

Distribution Data	
US Market Release	08/02/2012
CE Approval Date	07/12/2012
Registered US Implant	21,777
Estimated Active US	21,212
Product Characteristics	
Fixation Type	Active Screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

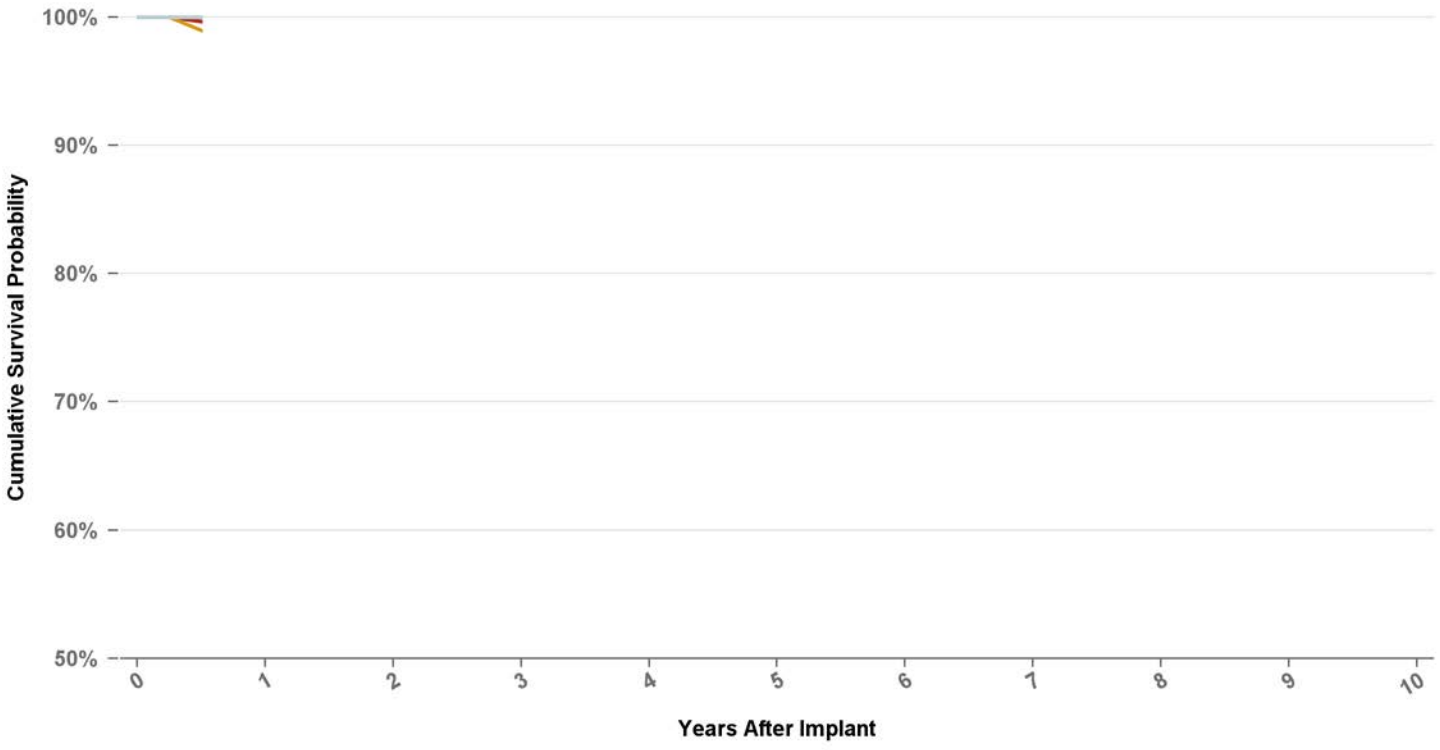
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	639
Cumulative Months of Follow-Up	1,845
Number of Leads Active in Study	589

Product Surveilance Registry Qualifying Complications	1
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	3
Failure To Capture	17
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	26
Oversensing	21
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	0
Crimp Weld Bond	0
Insulation Breach	0
Other	1

6935M, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6935M_SURV

Lower 95 Pct Confidence Graph - 6935M_SURV

Upper 95 Pct Confidence Graph - 6935M_SURV

Years	at 6 mo
%	99.6%
#	131

DEFIBRILLATION LEAD 6937

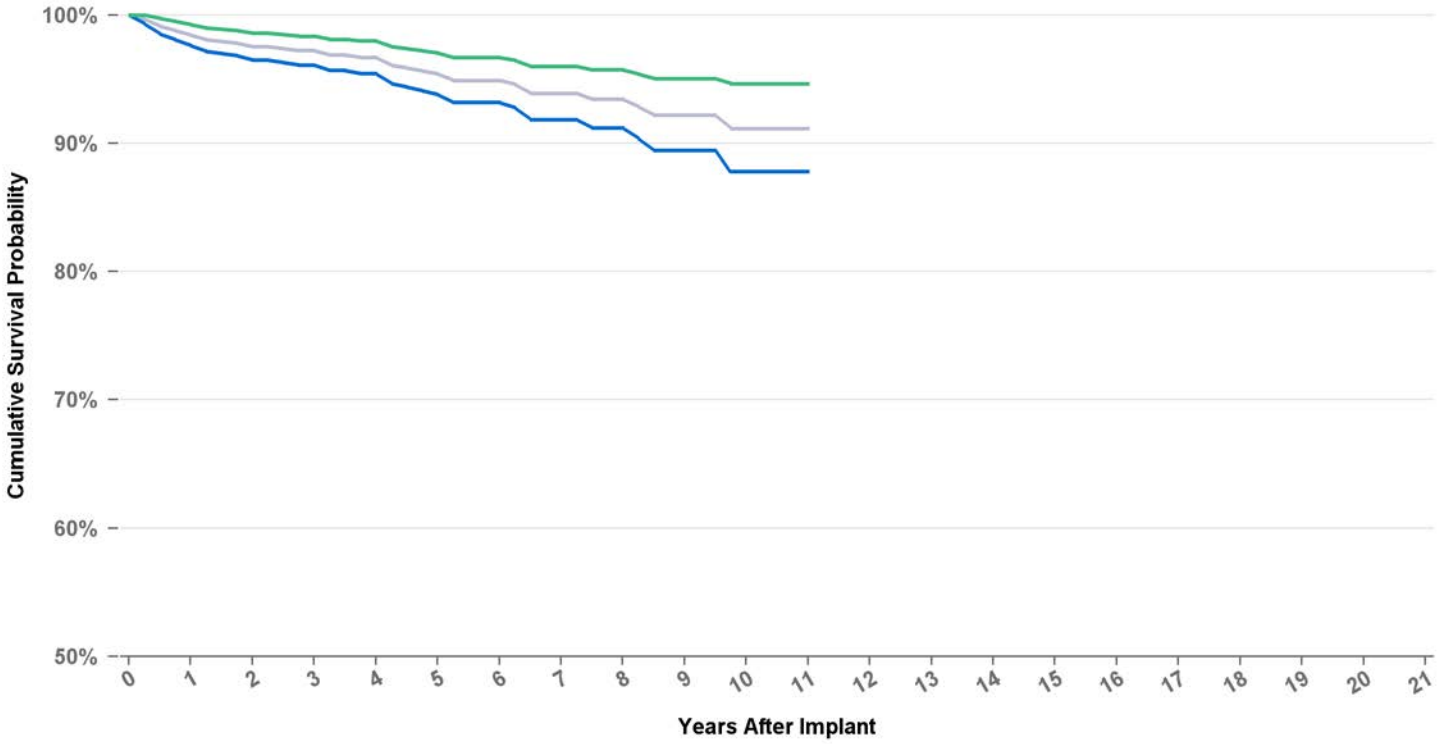
Distribution Data	
US Market Release	03/22/1996
CE Approval Date	04/19/1994
Registered US Implant	2,056
Estimated Active US	399
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,184
Number of Leads Active in Study	12

Product Surveilance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	16
Electrical Abandonment	0
Extracardiac Stimulation	4
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	10
Unspecified	4

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	18
Crimp Weld Bond	0
Insulation Breach	2
Other	1

6933, 6937, 6937A, 6963, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6933_6937_6937A_6963_SURV

Lower 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Upper 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	820	689	576	484	388	312	219	170	111	73	50

DEFIBRILLATION LEAD 6937A

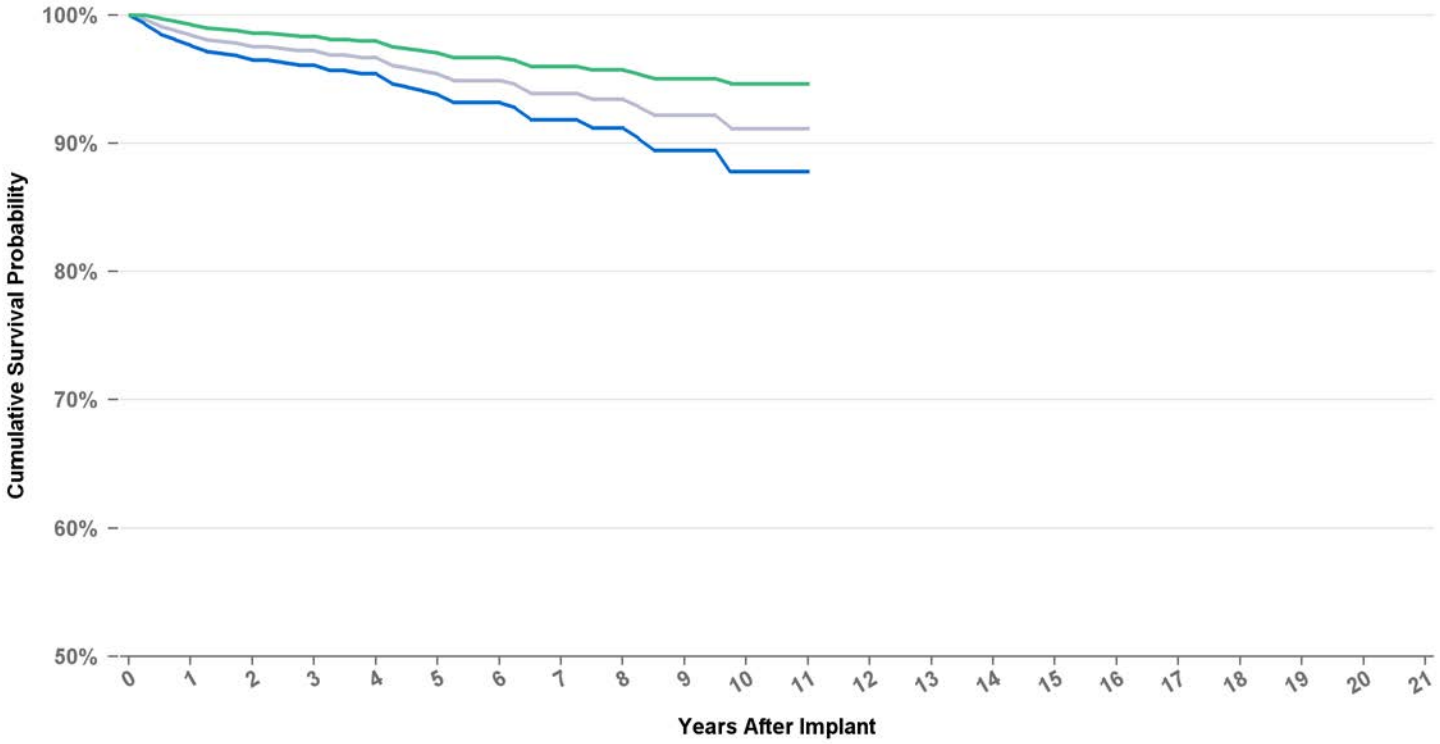
Distribution Data	
US Market Release	04/06/2001
CE Approval Date	
Registered US Implant	1,912
Estimated Active US	1,218
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,184
Number of Leads Active in Study	12

Product Surveillance Registry Qualifying Complications	47
Cardiac Perforation	0
Conductor Fracture	16
Electrical Abandonment	0
Extracardiac Stimulation	4
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	10
Unspecified	4

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6933, 6937, 6937A, 6963, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6933_6937_6937A_6963_SURV

Lower 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Upper 95 Pct Confidence Graph - 6933_6937_6937A_6963_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.4%	97.5%	97.2%	96.7%	95.4%	94.9%	93.9%	93.4%	92.2%	91.1%	91.1%
#	820	689	576	484	388	312	219	170	111	73	50

DEFIBRILLATION LEAD 6942

Distribution Data	
US Market Release	07/18/1997
CE Approval Date	
Registered US Implant	17,684
Estimated Active US	5,180
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Integrated Bipolar/ Two Coils

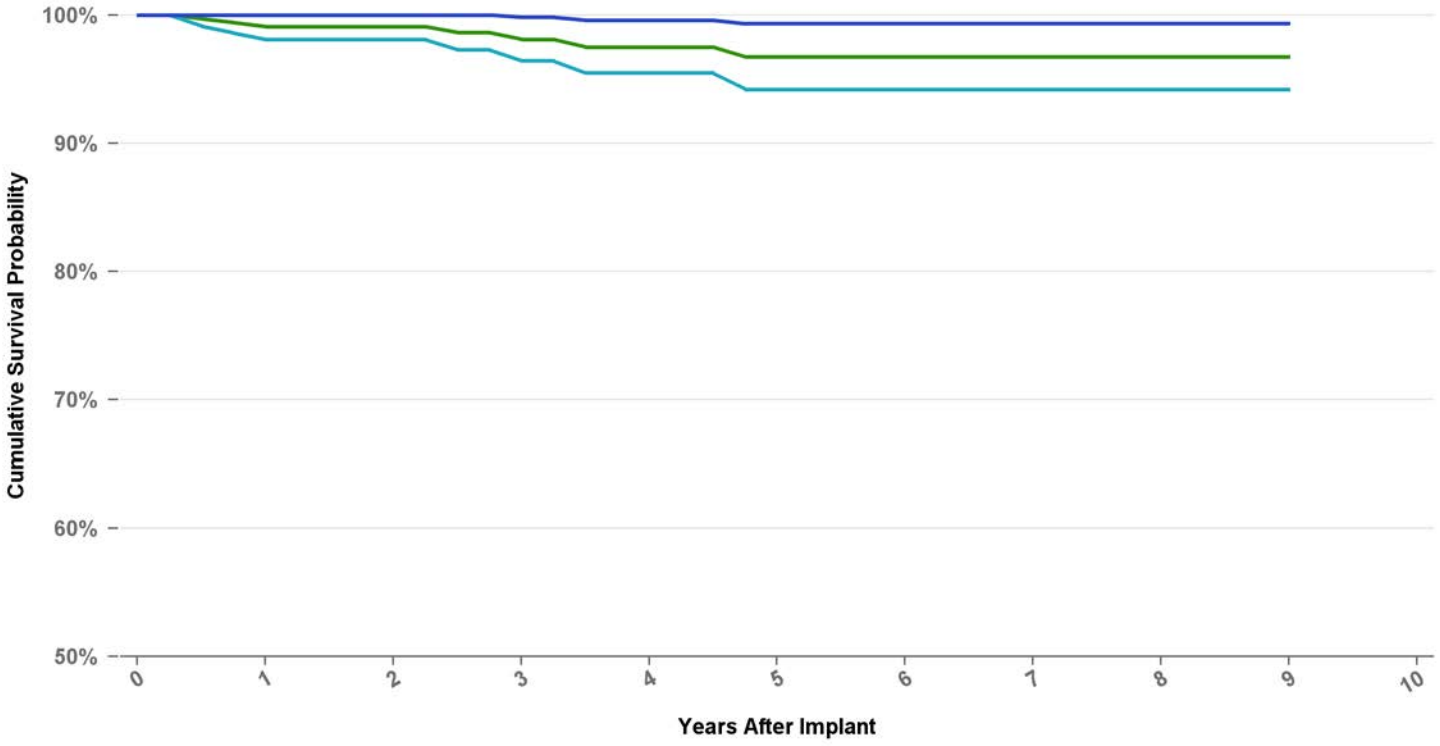
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	357
Cumulative Months of Follow-Up	18,886
Number of Leads Active in Study	30

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	3
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	1
Oversensing	1
Unspecified	1

USA Returned Product Analysis	
Conductor Fracture	15
Crimp Weld Bond	1
Insulation Breach	23
Other	4

6942, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6942_SURV

Lower 95 Pct Confidence Graph - 6942_SURV

Upper 95 Pct Confidence Graph - 6942_SURV

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.1%	99.1%	98.1%	97.5%	96.7%	96.7%	96.7%	96.7%	96.7%
#	301	235	179	139	113	96	74	63	51

DEFIBRILLATION LEAD 6943

Distribution Data	
US Market Release	10/06/1997
CE Approval Date	
Registered US Implant	20,609
Estimated Active US	6,081
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

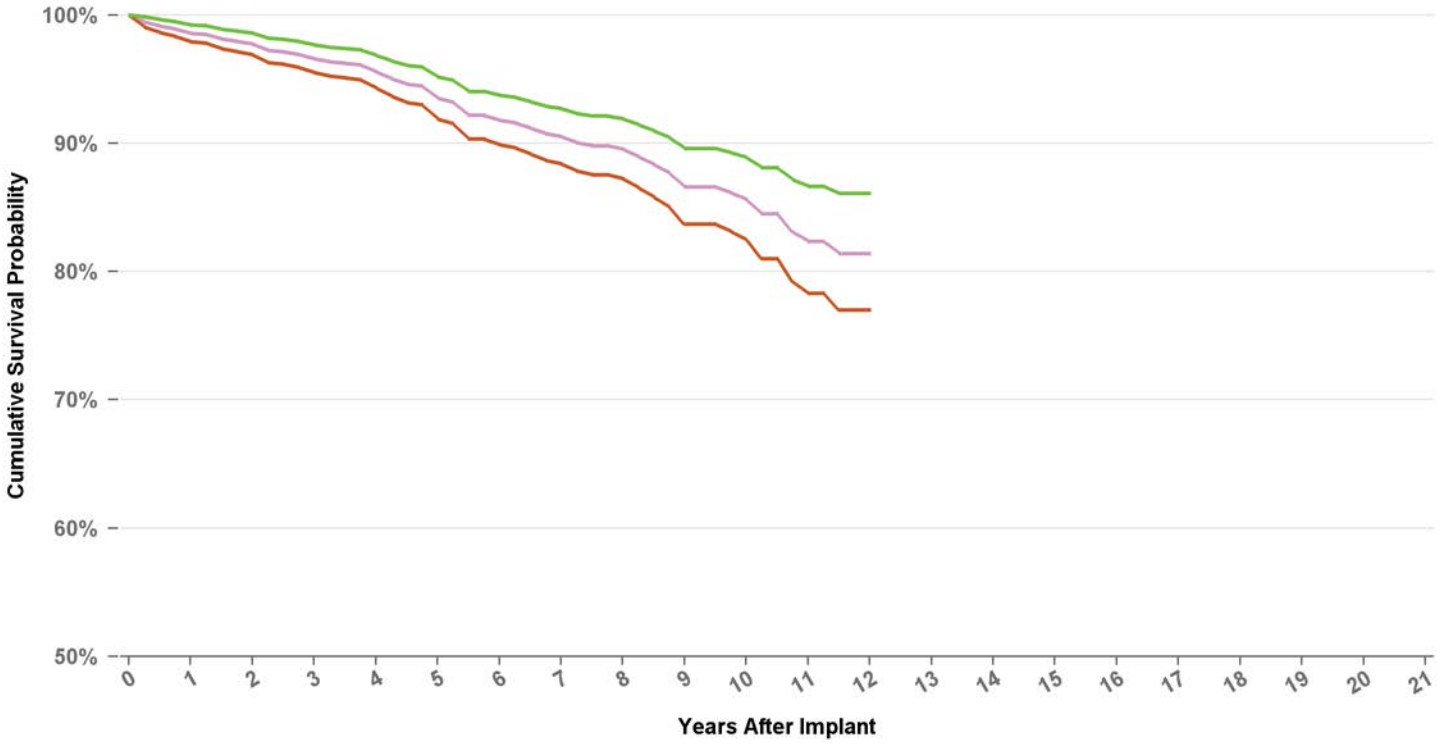
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,324
Cumulative Months of Follow-Up	80,571
Number of Leads Active in Study	188

Product Surveilance Registry Qualifying Complications	98
Cardiac Perforation	0
Conductor Fracture	27
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	8
Failure To Sense	7
Impedance Abnormal	8
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	2
Medical Judgment	0
Other Complication	1
Oversensing	41
Unspecified	3

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	0
Oversensing	1
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	74
Crimp Weld Bond	1
Insulation Breach	30
Other	5

6943, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6943_SURV

Lower 95 Pct Confidence Graph - 6943_SURV

Upper 95 Pct Confidence Graph - 6943_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	98.6%	97.7%	96.6%	95.6%	93.5%	91.8%	90.5%	89.5%	86.6%	85.6%	82.3%	81.4%
#	1,160	978	855	707	586	470	386	313	226	155	110	60

DEFIBRILLATION LEAD 6944

Distribution Data	
US Market Release	12/13/2000
CE Approval Date	11/05/1999
Registered US Implant	42,372
Estimated Active US	21,935
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

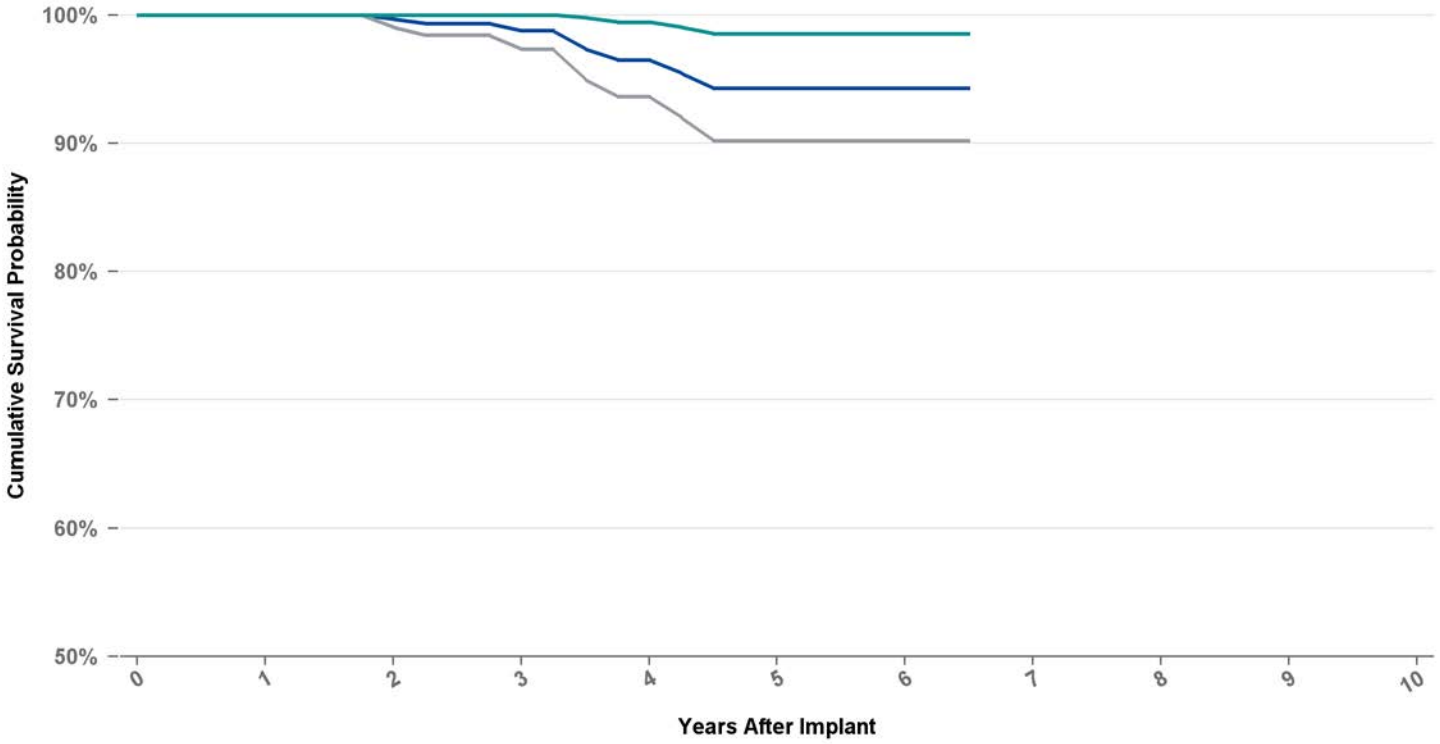
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	548
Cumulative Months of Follow-Up	18,656
Number of Leads Active in Study	287

Product Surveilance Registry Qualifying Complications	10
Cardiac Perforation	0
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	11
Failure To Sense	3
Impedance Abnormal	9
Insulation Breach	0
Lead Dislodgement	17
Oversensing	11
Unspecified	6

USA Returned Product Analysis	
Conductor Fracture	119
Crimp Weld Bond	1
Insulation Breach	4
Other	5

6944, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6944_SURV

Lower 95 Pct Confidence Graph - 6944_SURV

Upper 95 Pct Confidence Graph - 6944_SURV

Years	1	2	3	4	5	6	at 78 mo
%	100.0%	99.7%	98.8%	96.5%	94.3%	94.3%	94.3%
#	431	287	171	95	66	59	53

DEFIBRILLATION LEAD 6945

Distribution Data	
US Market Release	09/26/1997
CE Approval Date	
Registered US Implant	42,744
Estimated Active US	12,284
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Integrated Bipolar/ Two Coils

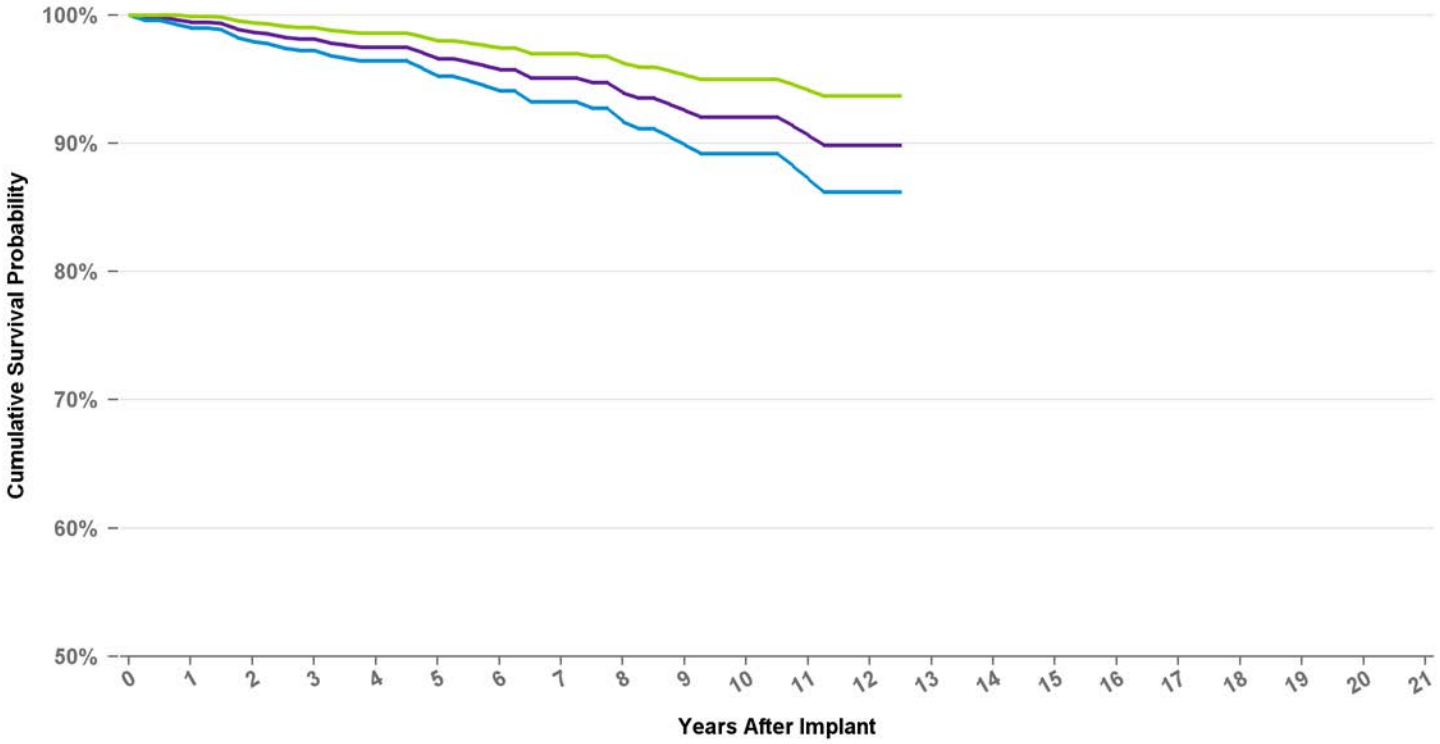
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,176
Cumulative Months of Follow-Up	64,536
Number of Leads Active in Study	122

Product Surveilance Registry Qualifying Complications	41
Cardiac Perforation	0
Conductor Fracture	10
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	4
Impedance Abnormal	5
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	17
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	2
Lead Dislodgement	4
Oversensing	7
Unspecified	2

USA Returned Product Analysis	
Conductor Fracture	134
Crimp Weld Bond	1
Insulation Breach	41
Other	6

6945, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6945_SURV

Lower 95 Pct Confidence Graph - 6945_SURV

Upper 95 Pct Confidence Graph - 6945_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.4%	98.7%	98.1%	97.5%	96.6%	95.7%	95.1%	93.9%	92.6%	92.0%	90.6%	89.8%	89.8%
#	1,003	820	656	525	406	308	273	230	184	149	120	84	66

DEFIBRILLATION LEAD 6947

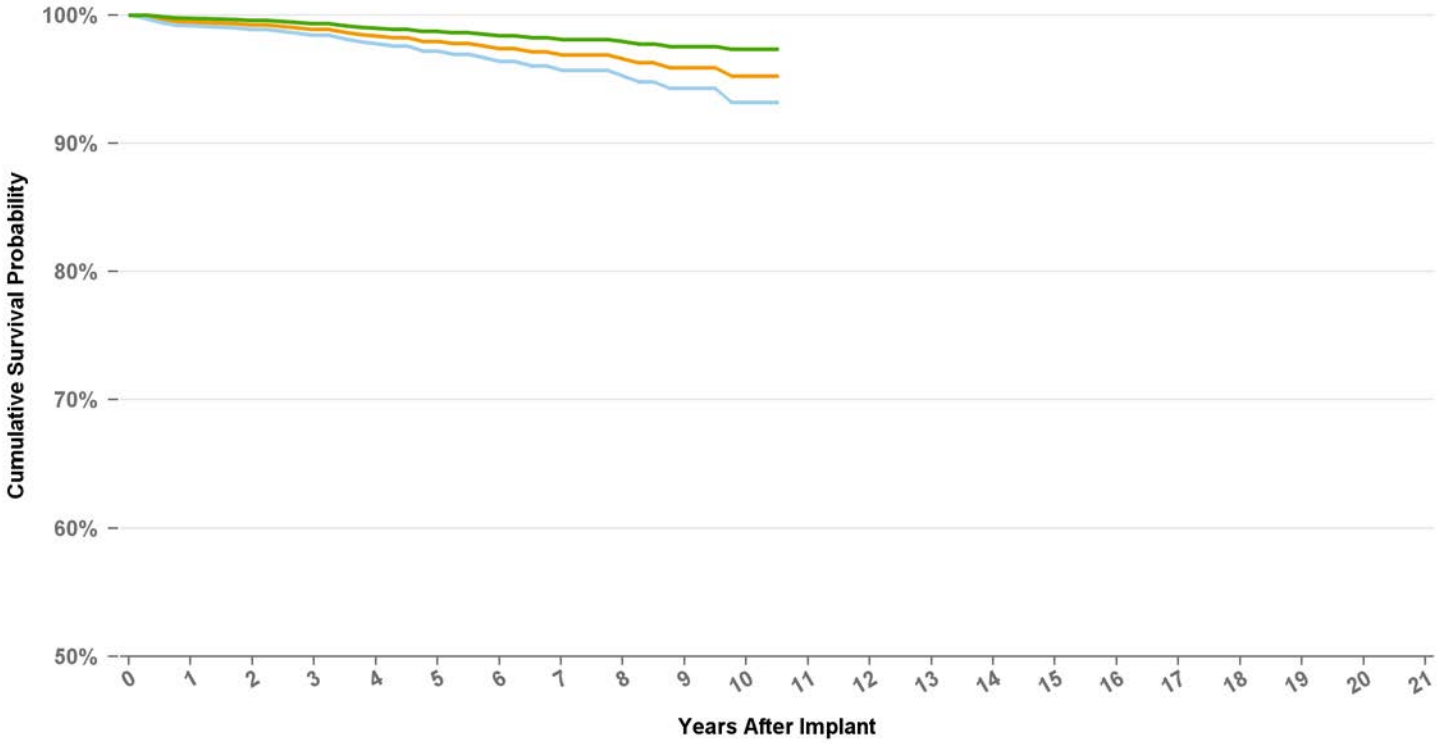
Distribution Data	
US Market Release	11/12/2001
CE Approval Date	10/04/2001
Registered US Implant	365,223
Estimated Active US	241,483
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	3,064
Cumulative Months of Follow-Up	121,574
Number of Leads Active in Study	1,299

Product Surveilance Registry Qualifying Complications	44
Cardiac Perforation	0
Conductor Fracture	10
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	2
Impedance Abnormal	7
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	3
Lead Dislodgement	4
Medical Judgment	0
Other Complication	1
Oversensing	14
Unspecified	2

US Acute Lead Observations	
Cardiac Perforation	26
Conductor Fracture	18
Extracardiac Stimulation	2
Failure To Capture	68
Failure To Sense	29
Impedance Abnormal	47
Insulation Breach	4
Lead Dislodgement	102
Oversensing	120
Unspecified	22
USA Returned Product Analysis	
Conductor Fracture	565
Crimp Weld Bond	4
Insulation Breach	47
Other	213

6947, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6947_SURV

Lower 95 Pct Confidence Graph - 6947_SURV

Upper 95 Pct Confidence Graph - 6947_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.4%	99.2%	98.9%	98.4%	97.9%	97.4%	96.9%	96.6%	95.9%	95.2%	95.2%
#	2,353	1,926	1,525	904	574	452	368	304	209	99	69

DEFIBRILLATION LEAD 6947M

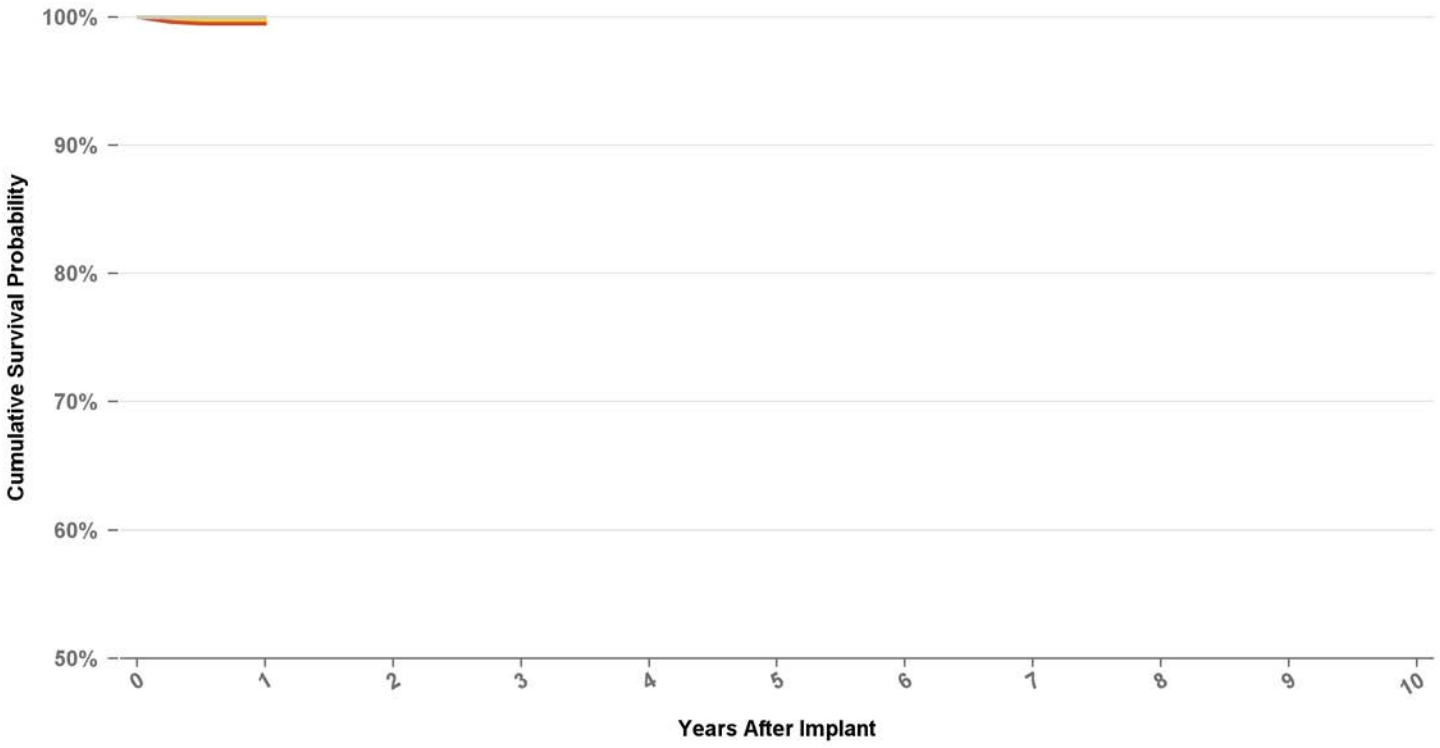
Distribution Data	
US Market Release	02/13/2012
CE Approval Date	03/12/2010
Registered US Implant	39,618
Estimated Active US	38,286
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,604
Cumulative Months of Follow-Up	11,921
Number of Leads Active in Study	1,449

Product Surveilance Registry Qualifying Complications	3
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	4
Conductor Fracture	1
Extracardiac Stimulation	4
Failure To Capture	25
Failure To Sense	5
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	38
Oversensing	14
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	1
Other	6

6947M, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6947M_SURV

Lower 95 Pct Confidence Graph - 6947M_SURV

Upper 95 Pct Confidence Graph - 6947M_SURV

Years	at 12 mo
%	99.8%
#	397

DEFIBRILLATION LEAD 6948

Distribution Data	
US Market Release	09/02/2004
CE Approval Date	
Registered US Implant	10,378
Estimated Active US	4,542
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

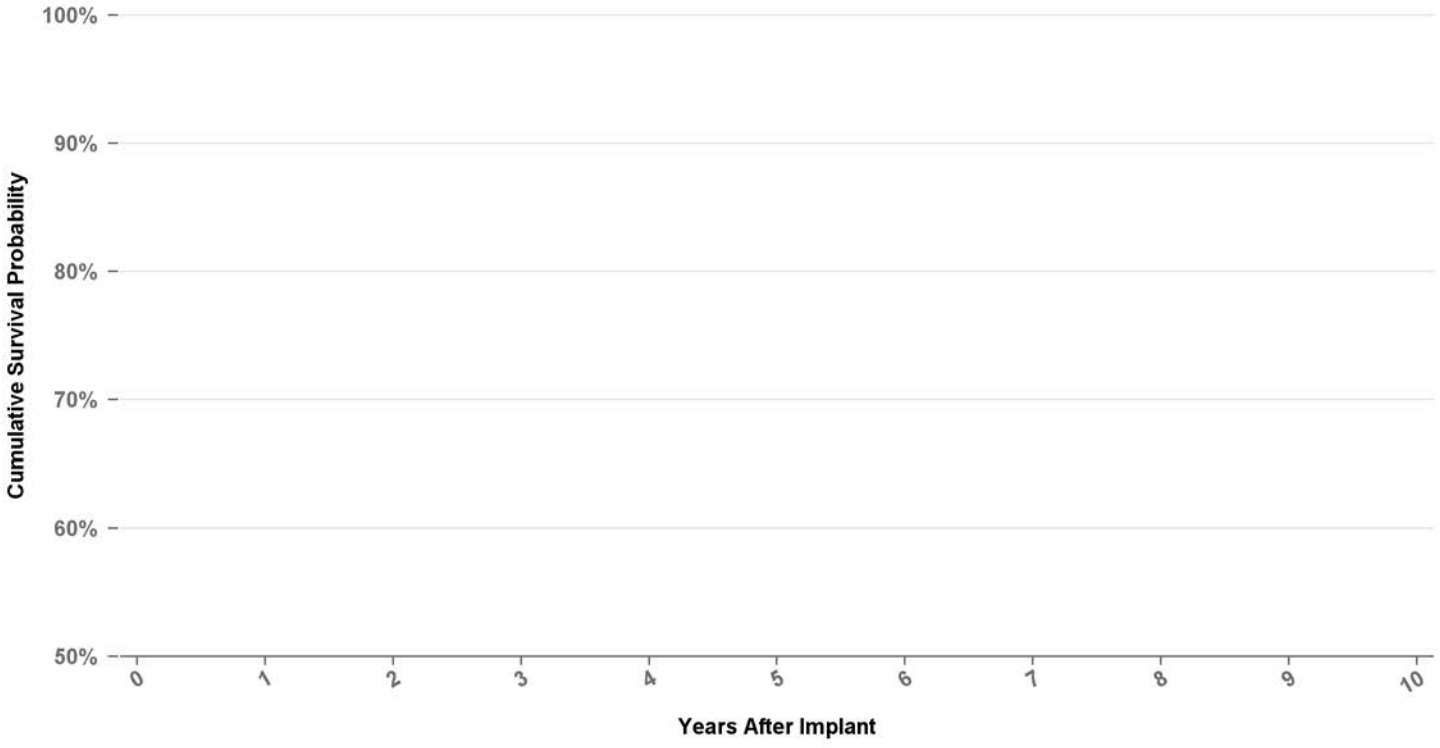
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	37
Cumulative Months of Follow-Up	1,498
Number of Leads Active in Study	16

Product Surveilance Registry Qualifying Complications	3
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	7
Oversensing	1
Unspecified	3

USA Returned Product Analysis	
Conductor Fracture	165
Crimp Weld Bond	0
Insulation Breach	2
Other	2

6948, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6948_SURV

Lower 95 Pct Confidence Graph - 6948_SURV

Upper 95 Pct Confidence Graph - 6948_SURV

Years	at 0 mo
%	100.0%
#	29.5

DEFIBRILLATION LEAD 6949

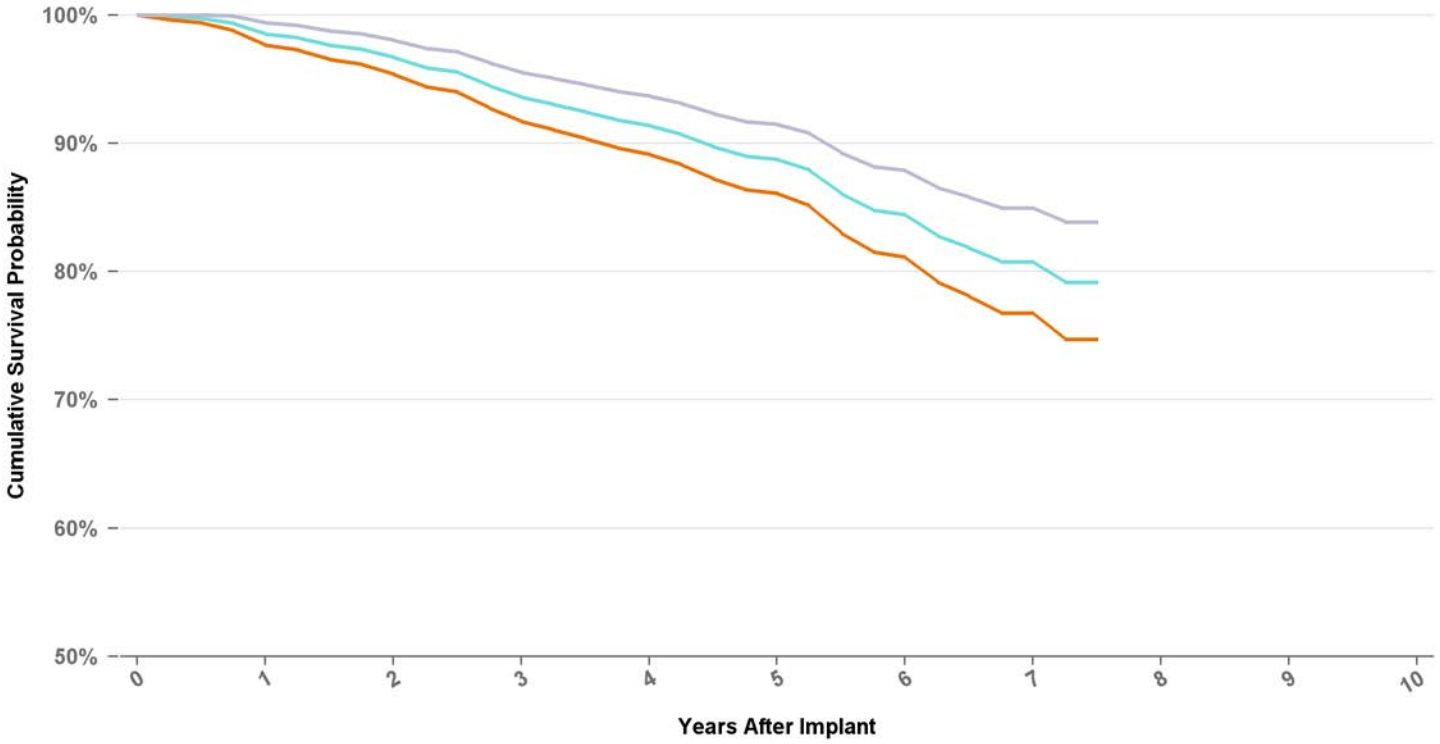
Distribution Data	
US Market Release	09/02/2004
CE Approval Date	
Registered US Implant	186,798
Estimated Active US	72,187
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	879
Cumulative Months of Follow-Up	39,661
Number of Leads Active in Study	282

Product Surveilance Registry Qualifying Complications	90
Cardiac Perforation	0
Conductor Fracture	45
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	5
Impedance Abnormal	16
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	2
Oversensing	16
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	10
Conductor Fracture	44
Extracardiac Stimulation	0
Failure To Capture	32
Failure To Sense	19
Impedance Abnormal	17
Insulation Breach	6
Lead Dislodgement	23
Oversensing	30
Unspecified	25
USA Returned Product Analysis	
Conductor Fracture	6,675
Crimp Weld Bond	3
Insulation Breach	29
Other	69

6949, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6949_SURV

Lower 95 Pct Confidence Graph - 6949_SURV

Upper 95 Pct Confidence Graph - 6949_SURV

Years	1	2	3	4	5	6	7	at 90 mo
%	98.5%	96.7%	93.6%	91.4%	88.7%	84.4%	80.7%	79.1%
#	699	604	504	410	326	216	97	58

DEFIBRILLATION LEAD 6996

Distribution Data	
US Market Release	06/11/2001
CE Approval Date	12/19/1997
Registered US Implant	4,001
Estimated Active US	2,348
Product Characteristics	
Fixation Type	Suture on Anchor Sleeve
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Subcutaneous
Lead Tip Location	Defibrillation
Pace/Sense Polarit	One Coil

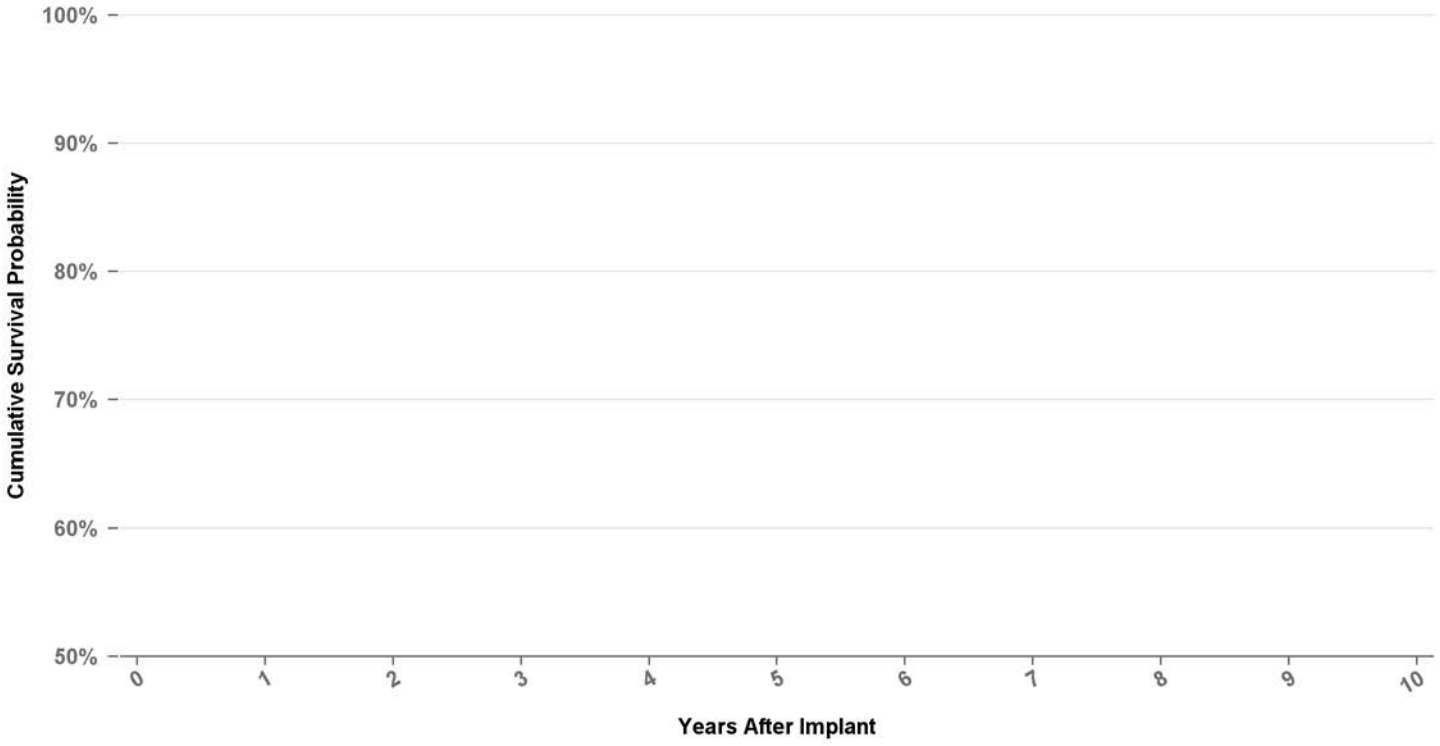
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	43
Cumulative Months of Follow-Up	1,255
Number of Leads Active in Study	18

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	5
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	24
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6996, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6996_SURV

Lower 95 Pct Confidence Graph - 6996_SURV

Upper 95 Pct Confidence Graph - 6996_SURV

Years	at 0 mo
%	100.0%
#	39

PACING LEAD

Distribution Data	
US Market Release	08/03/2005
CE Approval Date	01/31/2003
Registered US Implant	22,216
Estimated Active US	16,715
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	804
Cumulative Months of Follow-Up	24,884
Number of Leads Active in Study	500

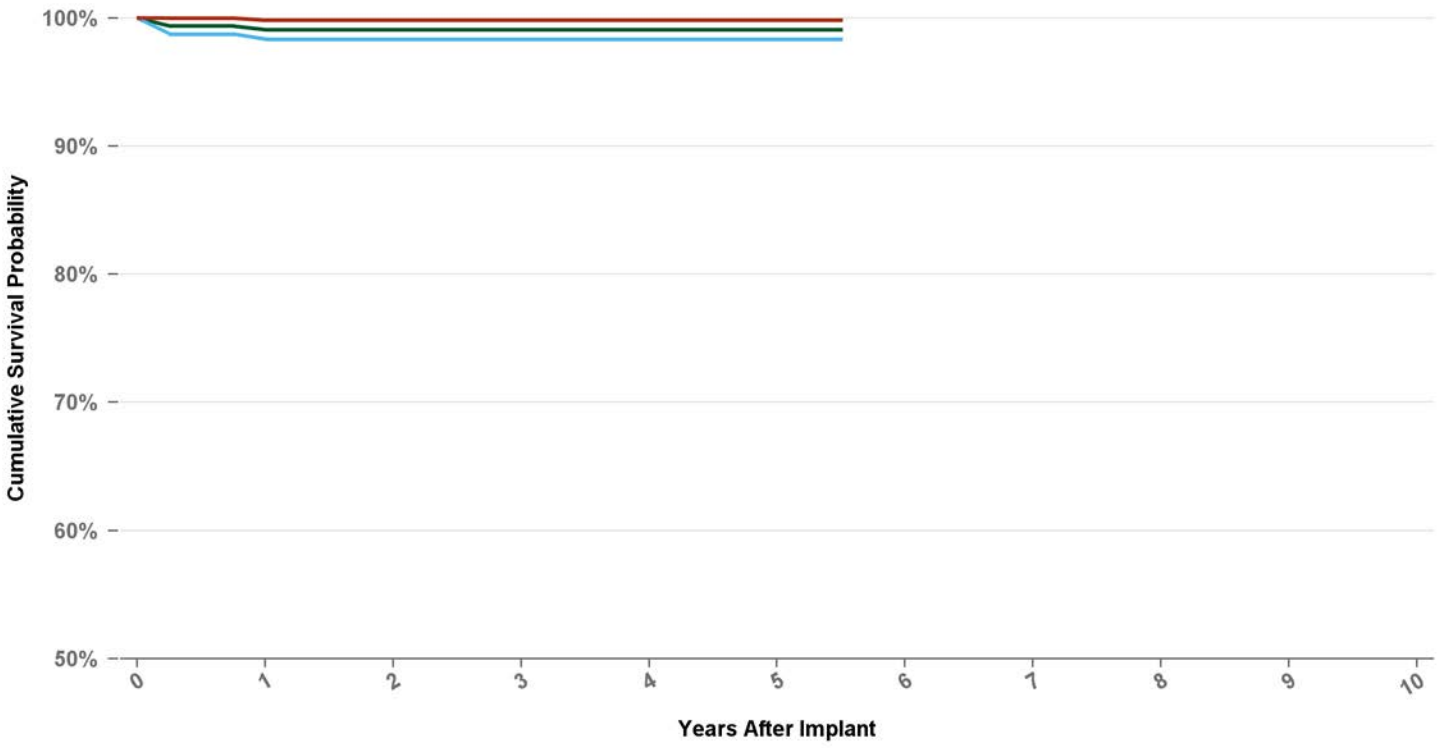
3830

Product Surveillance Registry Qualifying Complications	7
Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	6
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	15
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	32
Oversensing	3
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	15
Other	3

3830, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 3830_ATR_SURV

Lower 95 Pct Confidence Graph - 3830_ATR_SURV

Upper 95 Pct Confidence Graph - 3830_ATR_SURV

Years	1	2	3	4	5	at 66 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	672	490	250	118	68	56

PACING LEAD

3830

VENTRICULAR PLACEMENT

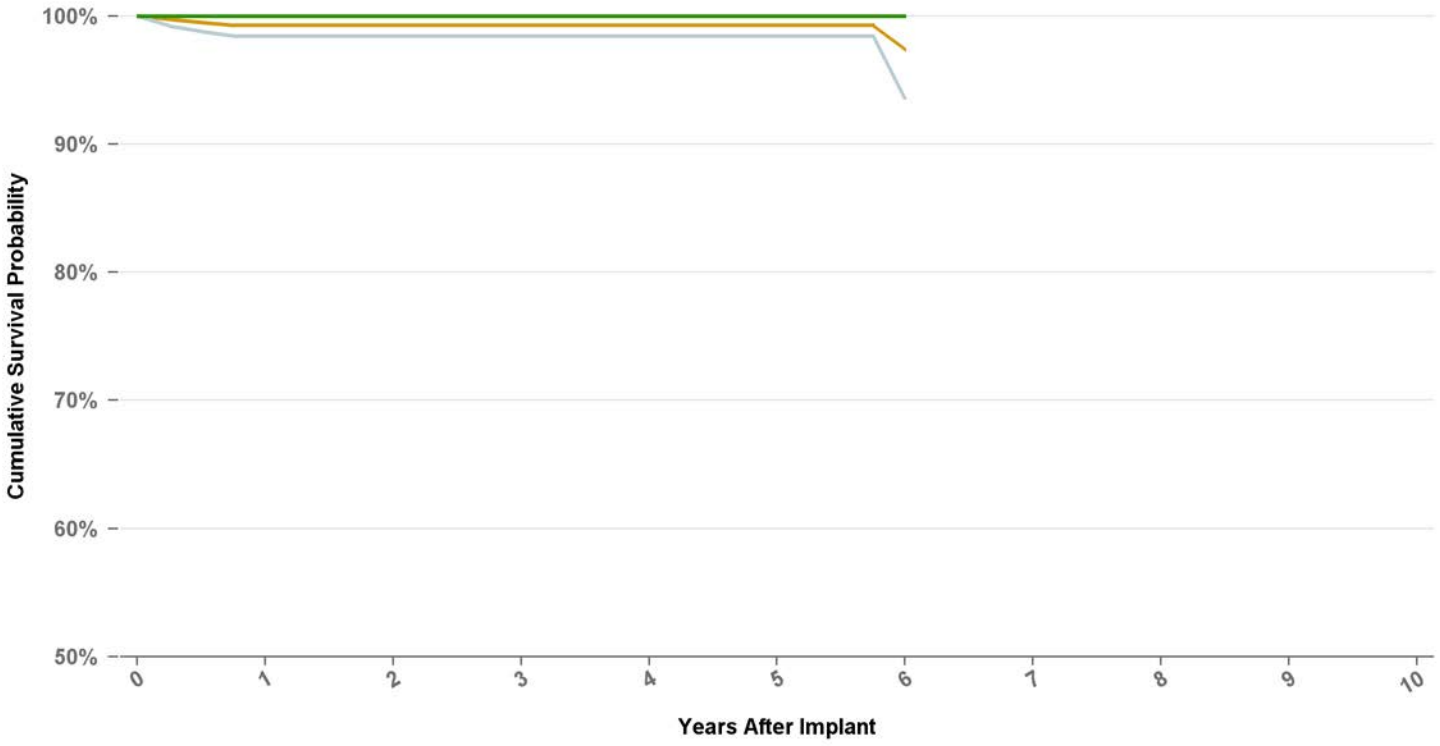
Distribution Data	
US Market Release	08/03/2005
CE Approval Date	01/31/2003
Registered US Implant	22,216
Estimated Active US	16,715
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	537
Cumulative Months of Follow-Up	16,381
Number of Leads Active in Study	329

Product Surveilance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	6
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	15
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	32
Oversensing	3
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	15
Other	3

3830, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 3830_VEN_SURV

Lower 95 Pct Confidence Graph - 3830_VEN_SURV

Upper 95 Pct Confidence Graph - 3830_VEN_SURV

Years	1	2	3	4	5	at 72 mo
%	99.3%	99.3%	99.3%	99.3%	99.3%	97.3%
#	411	296	157	92	63	50

PACING LEAD

4024

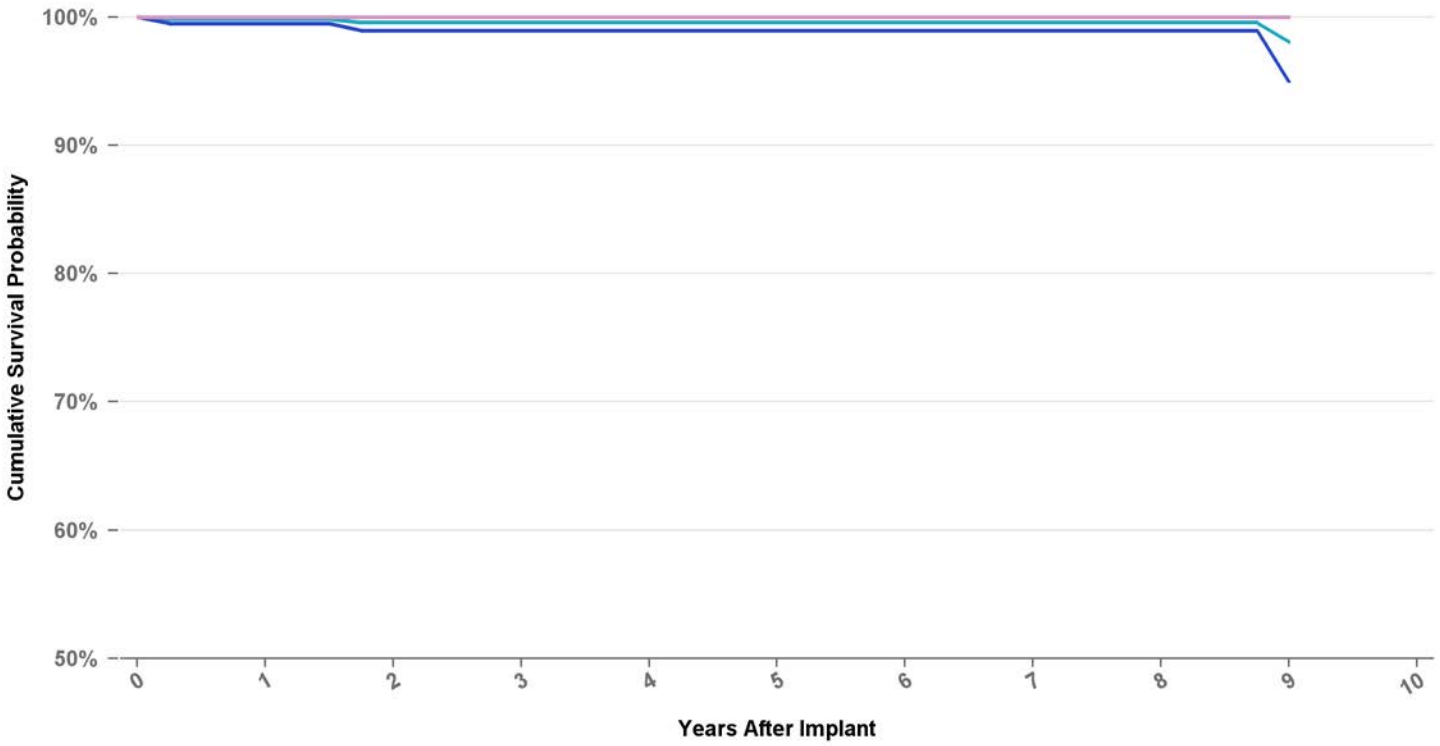
Distribution Data	
US Market Release	10/01/1991
CE Approval Date	
Registered US Implant	218,562
Estimated Active US	39,584
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,220
Cumulative Months of Follow-Up	25,107
Number of Leads Active in Study	10

Product Surveilance Registry Qualifying Complications	4
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	13
Conductor Fracture	10
Extracardiac Stimulation	2
Failure To Capture	103
Failure To Sense	16
Impedance Abnormal	8
Insulation Breach	1
Lead Dislodgement	49
Oversensing	2
Unspecified	20
USA Returned Product Analysis	
Conductor Fracture	28
Crimp Weld Bond	0
Insulation Breach	192
Other	12

4024, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4024_SURV

Lower 95 Pct Confidence Graph - 4024_SURV

Upper 95 Pct Confidence Graph - 4024_SURV

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	98.0%
#	430	322	251	183	146	118	94	70	60

PACING LEAD

Distribution Data	
US Market Release	03/29/1996
CE Approval Date	
Registered US Implant	124,258
Estimated Active US	29,093
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,425
Cumulative Months of Follow-Up	121,983
Number of Leads Active in Study	196

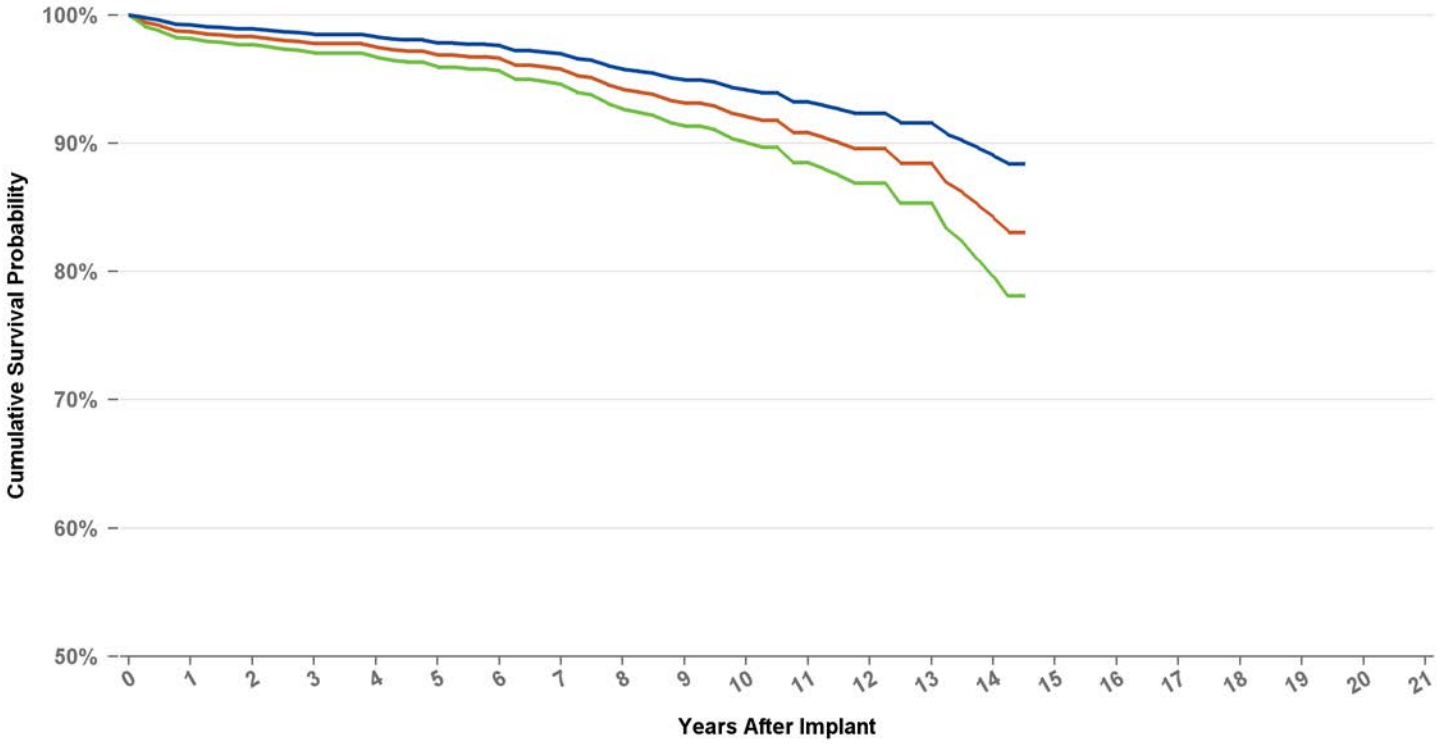
4068

Product Surveilance Registry Qualifying Complications	91
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	3
Failure To Capture	23
Failure To Sense	16
Impedance Abnormal	12
Insulation Breach (ESC)	2
Insulation Breach (MIO)	2
Insulation Breach (not further defined)	2
Lead Dislodgement	8
Medical Judgment	0
Other Complication	0
Oversensing	17
Unspecified	3

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	5
Conductor Fracture	3
Extracardiac Stimulation	1
Failure To Capture	23
Failure To Sense	5
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	31
Oversensing	0
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	51
Crimp Weld Bond	0
Insulation Breach	180
Other	93

4068, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4068_ATR_SURV

Lower 95 Pct Confidence Graph - 4068_ATR_SURV

Upper 95 Pct Confidence Graph - 4068_ATR_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	at 174 mo
%	98.7%	98.3%	97.8%	97.5%	96.9%	96.6%	95.8%	94.2%	93.1%	92.1%	90.8%	89.6%	88.4%	84.2%	83.1%
#	1,599	1,392	1,193	1,016	873	737	586	482	398	323	241	173	122	74	54

PACING LEAD

4068

VENTRICULAR PLACEMENT

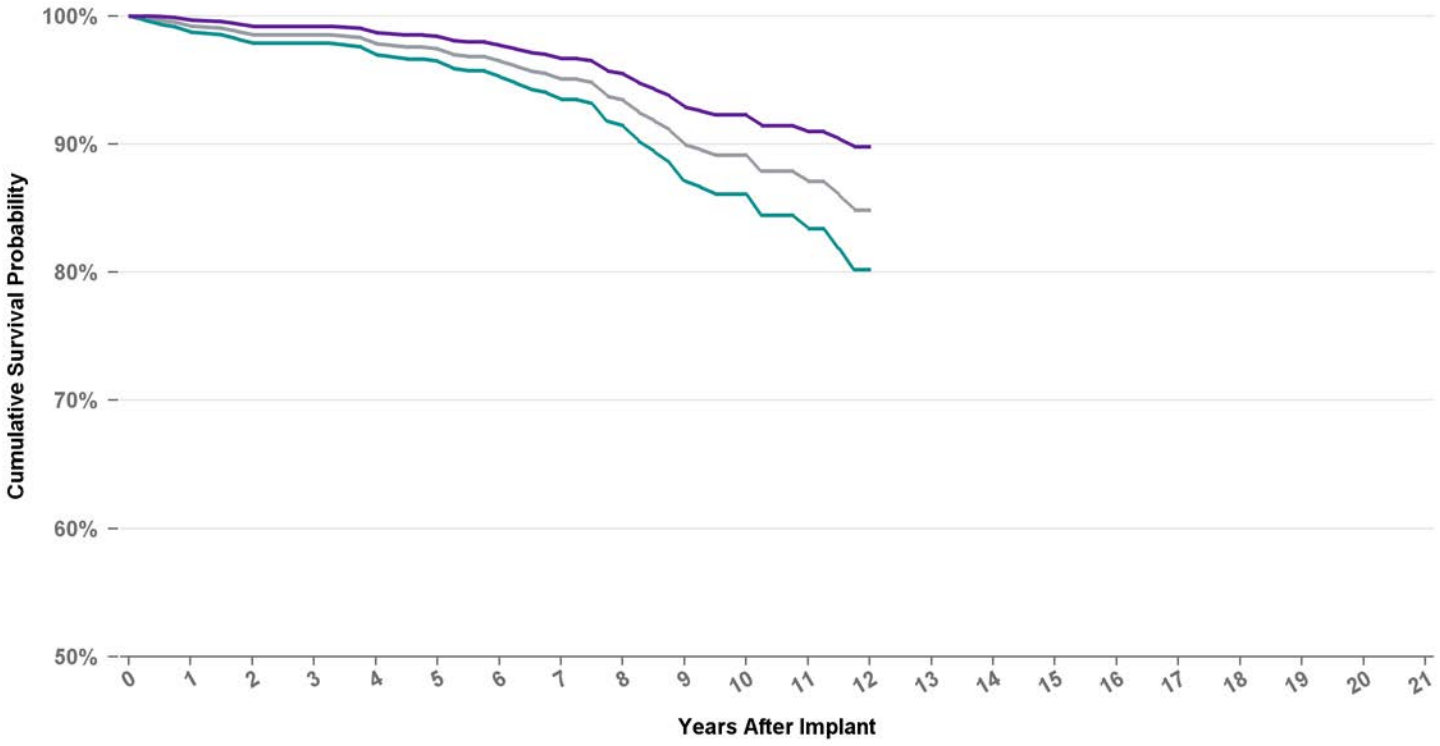
Distribution Data	
US Market Release	03/29/1996
CE Approval Date	
Registered US Implant	124,258
Estimated Active US	29,093
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,806
Cumulative Months of Follow-Up	88,693
Number of Leads Active in Study	107

Product Surveilance Registry Qualifying Complications	69
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	24
Failure To Sense	4
Impedance Abnormal	22
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	10
Unspecified	2

US Acute Lead Observations	
Cardiac Perforation	5
Conductor Fracture	3
Extracardiac Stimulation	1
Failure To Capture	23
Failure To Sense	5
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	31
Oversensing	0
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	51
Crimp Weld Bond	0
Insulation Breach	180
Other	93

4068, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4068_VEN_SURV

Lower 95 Pct Confidence Graph - 4068_VEN_SURV

Upper 95 Pct Confidence Graph - 4068_VEN_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.2%	98.5%	98.5%	97.8%	97.4%	96.5%	95.1%	93.4%	90.0%	89.1%	87.1%	84.9%
#	1,288	1,110	964	802	666	529	410	316	228	149	91	58

PACING LEAD

4074

ATRIAL PLACEMENT

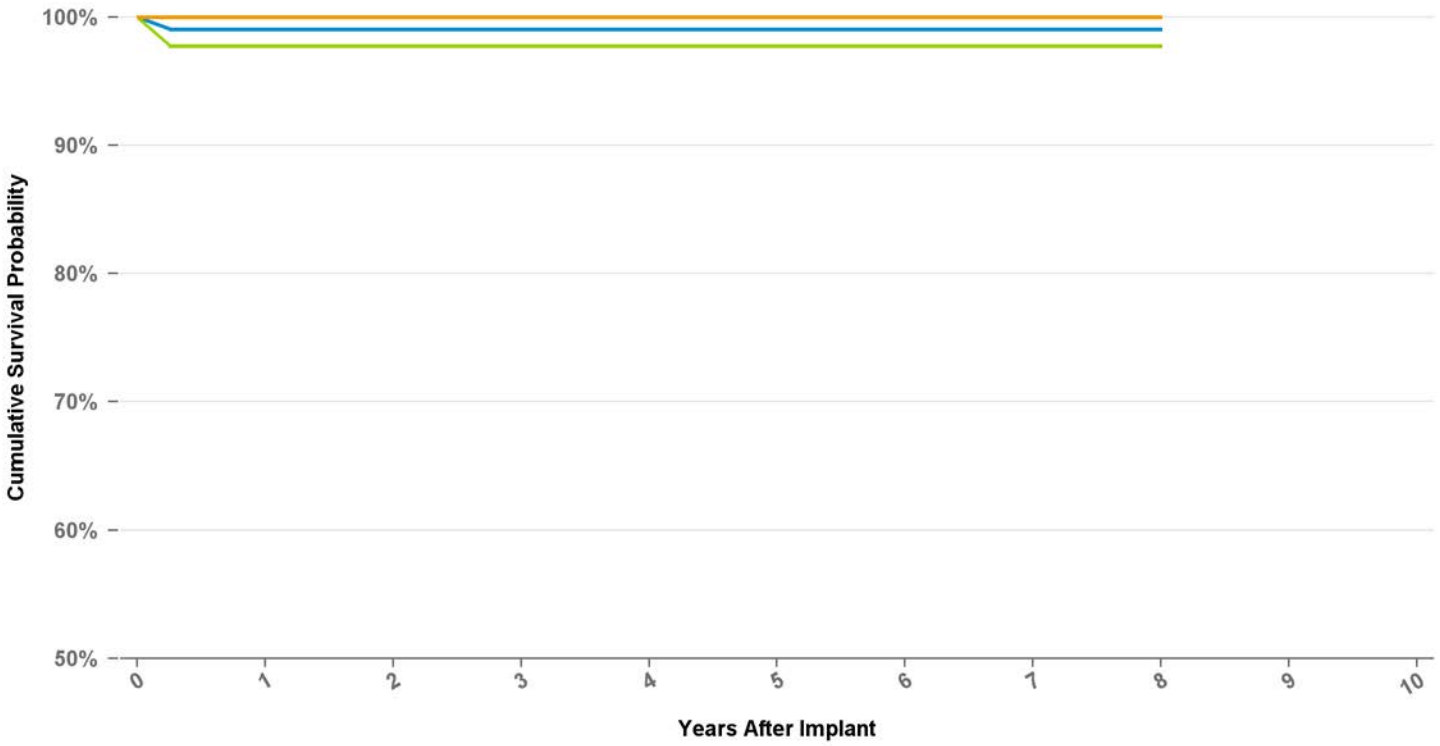
Distribution Data	
US Market Release	06/23/2002
CE Approval Date	02/01/2002
Registered US Implant	95,673
Estimated Active US	59,537
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	214
Cumulative Months of Follow-Up	15,498
Number of Leads Active in Study	132

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	11
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	35
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	36
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	21
Other	0

4074, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4074_ATR_SURV

Lower 95 Pct Confidence Graph - 4074_ATR_SURV

Upper 95 Pct Confidence Graph - 4074_ATR_SURV

Years	1	2	3	4	5	6	7	at 96 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	201	191	183	167	149	120	90	61

PACING LEAD

4074

VENTRICULAR PLACEMENT

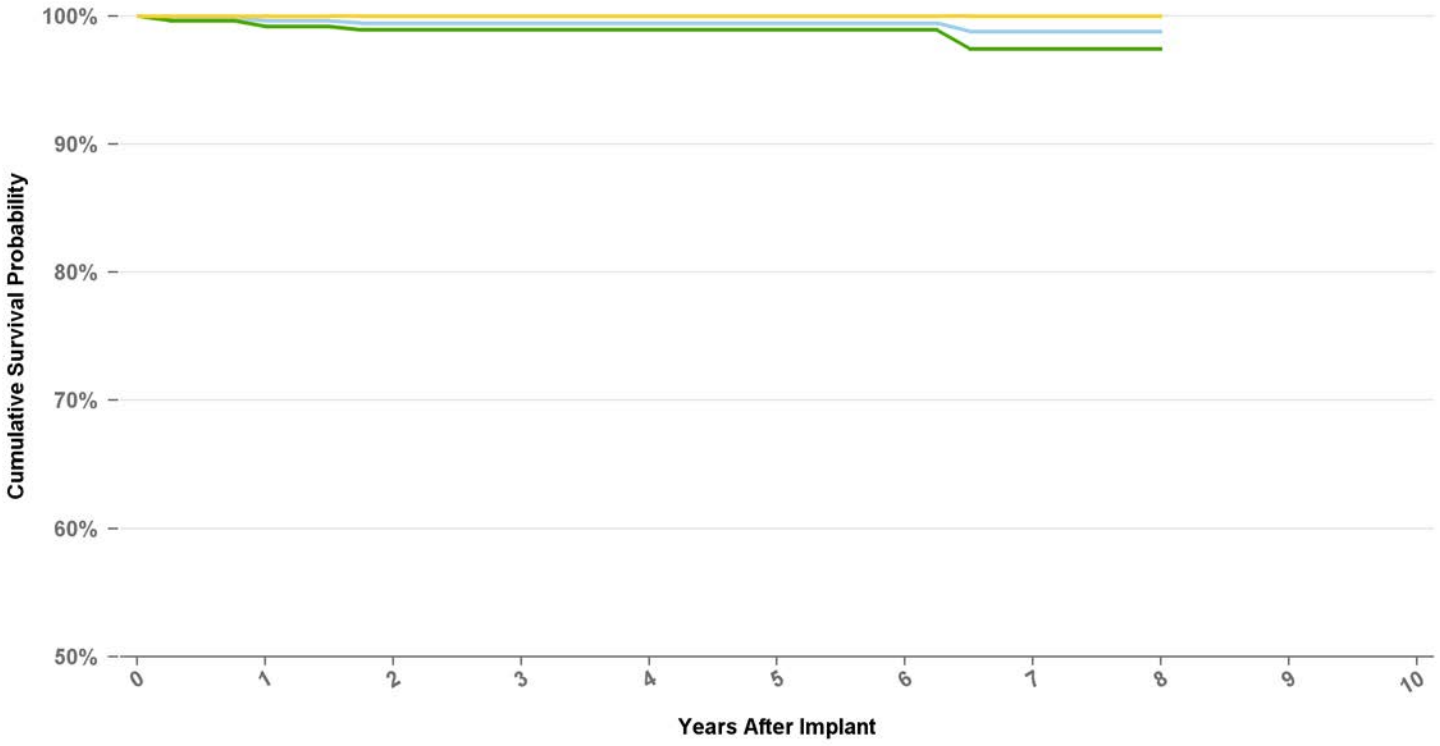
Distribution Data	
US Market Release	06/23/2002
CE Approval Date	02/01/2002
Registered US Implant	95,673
Estimated Active US	59,537
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,058
Cumulative Months of Follow-Up	34,835
Number of Leads Active in Study	664

Product Surveilance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	11
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	35
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	36
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	21
Other	0

4074, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4074_VEN_SURV

Lower 95 Pct Confidence Graph - 4074_VEN_SURV

Upper 95 Pct Confidence Graph - 4074_VEN_SURV

Years	1	2	3	4	5	6	7	at 96 mo
%	99.6%	99.4%	99.4%	99.4%	99.4%	99.4%	98.8%	98.8%
#	687	496	352	291	254	175	105	54

PACING LEAD

Distribution Data	
US Market Release	02/25/2004
CE Approval Date	06/14/2004
Registered US Implant	470,611
Estimated Active US	360,424
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,010
Cumulative Months of Follow-Up	68,409
Number of Leads Active in Study	1,148

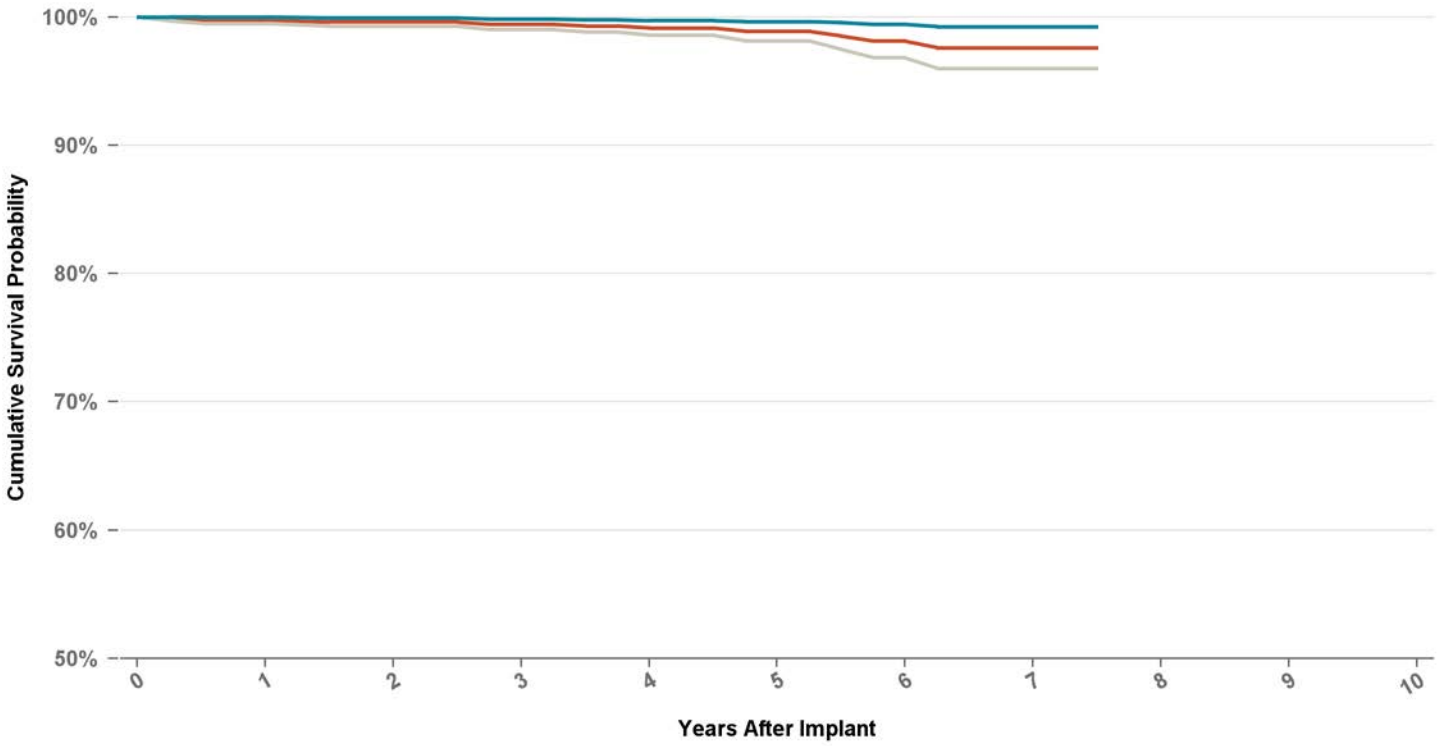
4076

Product Surveilance Registry Qualifying Complications	15
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	6
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	4
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	58
Conductor Fracture	4
Extracardiac Stimulation	10
Failure To Capture	78
Failure To Sense	21
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	152
Oversensing	7
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	44
Crimp Weld Bond	1
Insulation Breach	39
Other	21

4076, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4076_ATR_SURV

Lower 95 Pct Confidence Graph - 4076_ATR_SURV

Upper 95 Pct Confidence Graph - 4076_ATR_SURV

Years	1	2	3	4	5	6	7	at 90 mo
%	99.7%	99.6%	99.4%	99.1%	98.9%	98.1%	97.6%	97.6%
#	1,443	1,242	979	552	332	210	79	56

PACING LEAD

4076

VENTRICULAR PLACEMENT

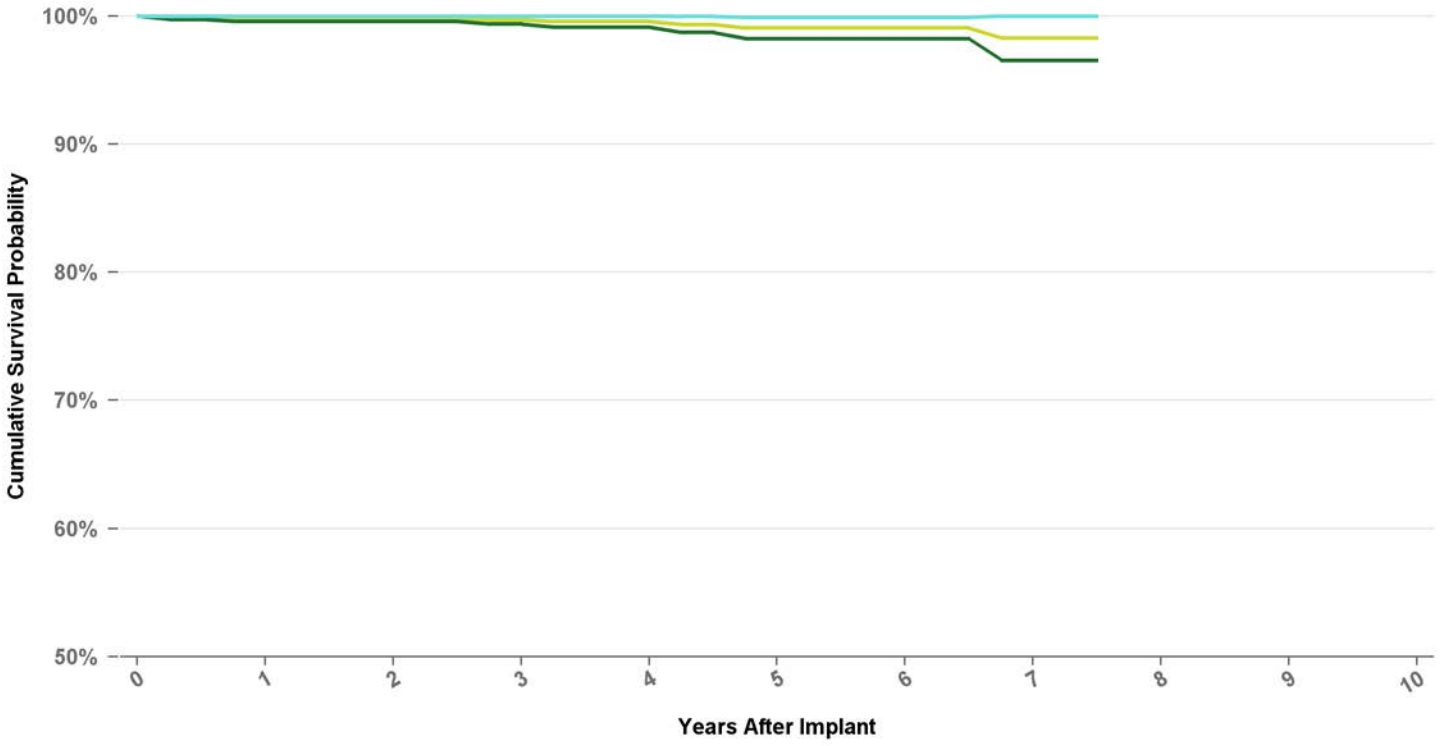
Distribution Data	
US Market Release	02/25/2004
CE Approval Date	06/14/2004
Registered US Implant	470,611
Estimated Active US	360,424
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,352
Cumulative Months of Follow-Up	53,549
Number of Leads Active in Study	705

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	4
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	58
Conductor Fracture	4
Extracardiac Stimulation	10
Failure To Capture	78
Failure To Sense	21
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	152
Oversensing	7
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	44
Crimp Weld Bond	1
Insulation Breach	39
Other	21

4076, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4076_VEN_SURV

Lower 95 Pct Confidence Graph - 4076_VEN_SURV

Upper 95 Pct Confidence Graph - 4076_VEN_SURV

Years	1	2	3	4	5	6	7	at 90 mo
%	99.8%	99.8%	99.7%	99.6%	99.1%	99.1%	98.3%	98.3%
#	1,062	930	747	470	314	203	83	65

PACING LEAD

4092

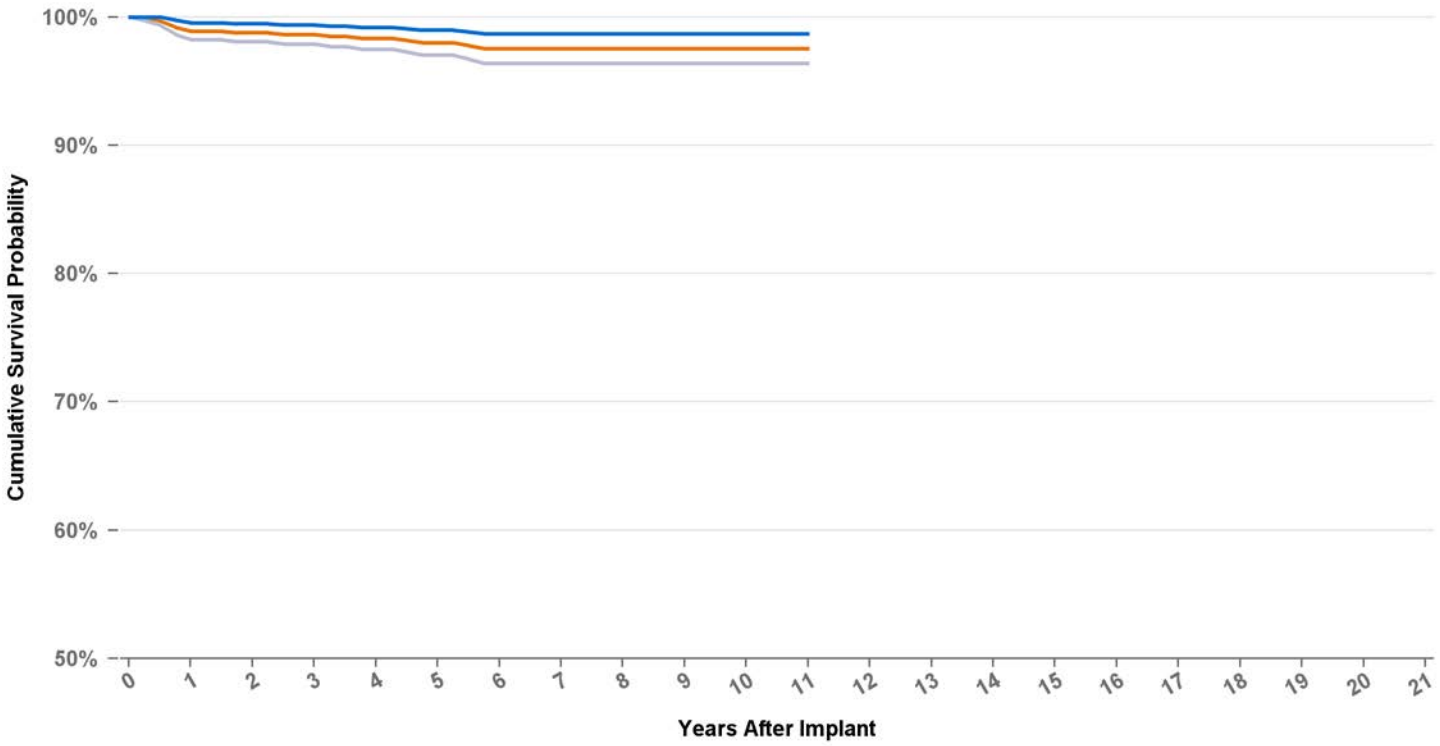
Distribution Data	
US Market Release	09/17/1998
CE Approval Date	04/15/1998
Registered US Implant	180,198
Estimated Active US	80,161
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,170
Cumulative Months of Follow-Up	62,896
Number of Leads Active in Study	276

Product Surveilance Registry Qualifying Complications	19
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	9
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	4
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	4
Extracardiac Stimulation	0
Failure To Capture	30
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	23
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	13
Crimp Weld Bond	0
Insulation Breach	56
Other	2

4092, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4092_SURV

Lower 95 Pct Confidence Graph - 4092_SURV

Upper 95 Pct Confidence Graph - 4092_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.9%	98.8%	98.6%	98.3%	98.0%	97.5%	97.5%	97.5%	97.5%	97.5%	97.5%
#	911	811	723	620	498	370	285	198	132	89	54

PACING LEAD 4524

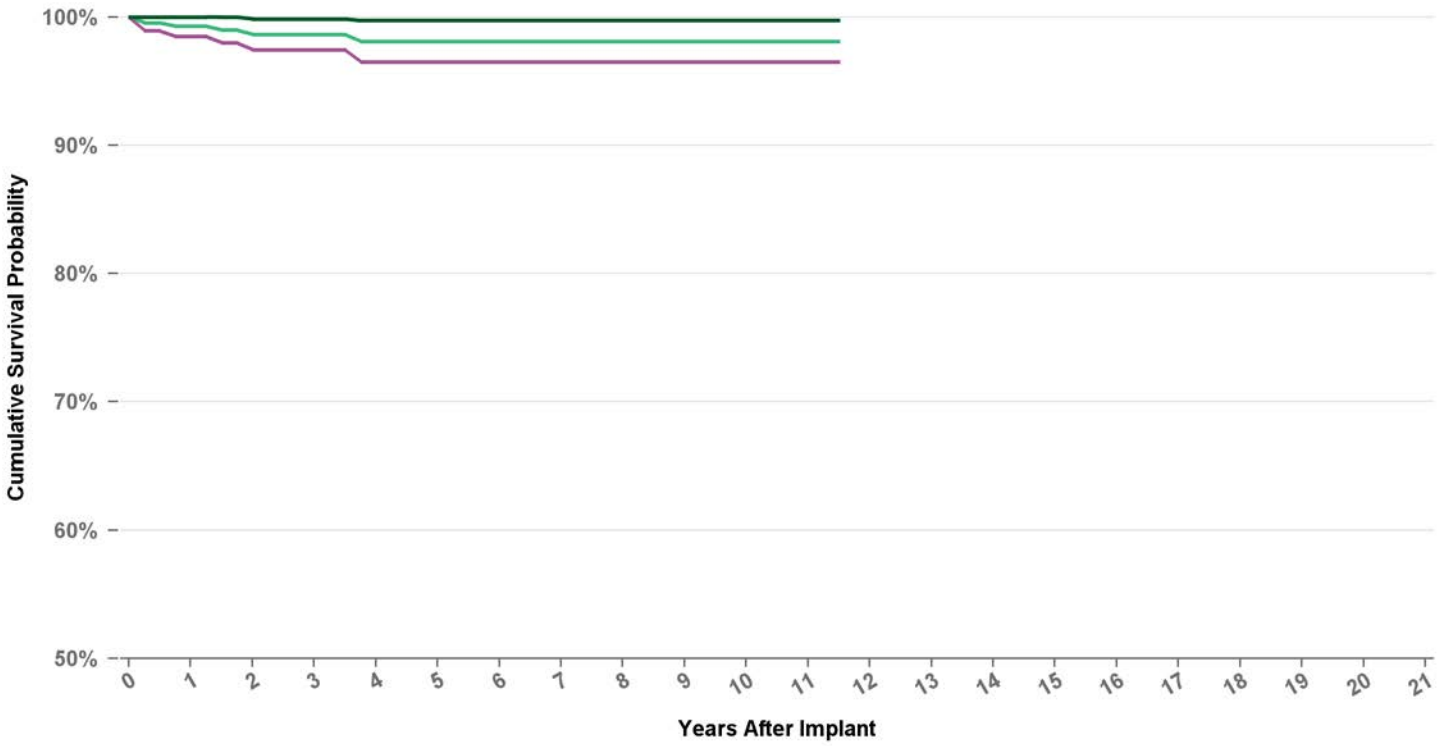
Distribution Data	
US Market Release	10/01/1991
CE Approval Date	
Registered US Implant	100,264
Estimated Active US	22,630
Product Characteristics	
Fixation Type	J-Shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	916
Cumulative Months of Follow-Up	23,020
Number of Leads Active in Study	28

Product Surveillance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	15
Failure To Sense	4
Impedance Abnormal	1
Insulation Breach	2
Lead Dislodgement	23
Oversensing	0
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	71
Other	3

4524, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4524_SURV

Lower 95 Pct Confidence Graph - 4524_SURV

Upper 95 Pct Confidence Graph - 4524_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.3%	98.6%	98.6%	98.1%	98.1%	98.1%	98.1%	98.1%	98.1%	98.1%	98.1%	98.1%
#	362	274	217	163	131	106	85	74	65	55	53	51

PACING LEAD

4558M

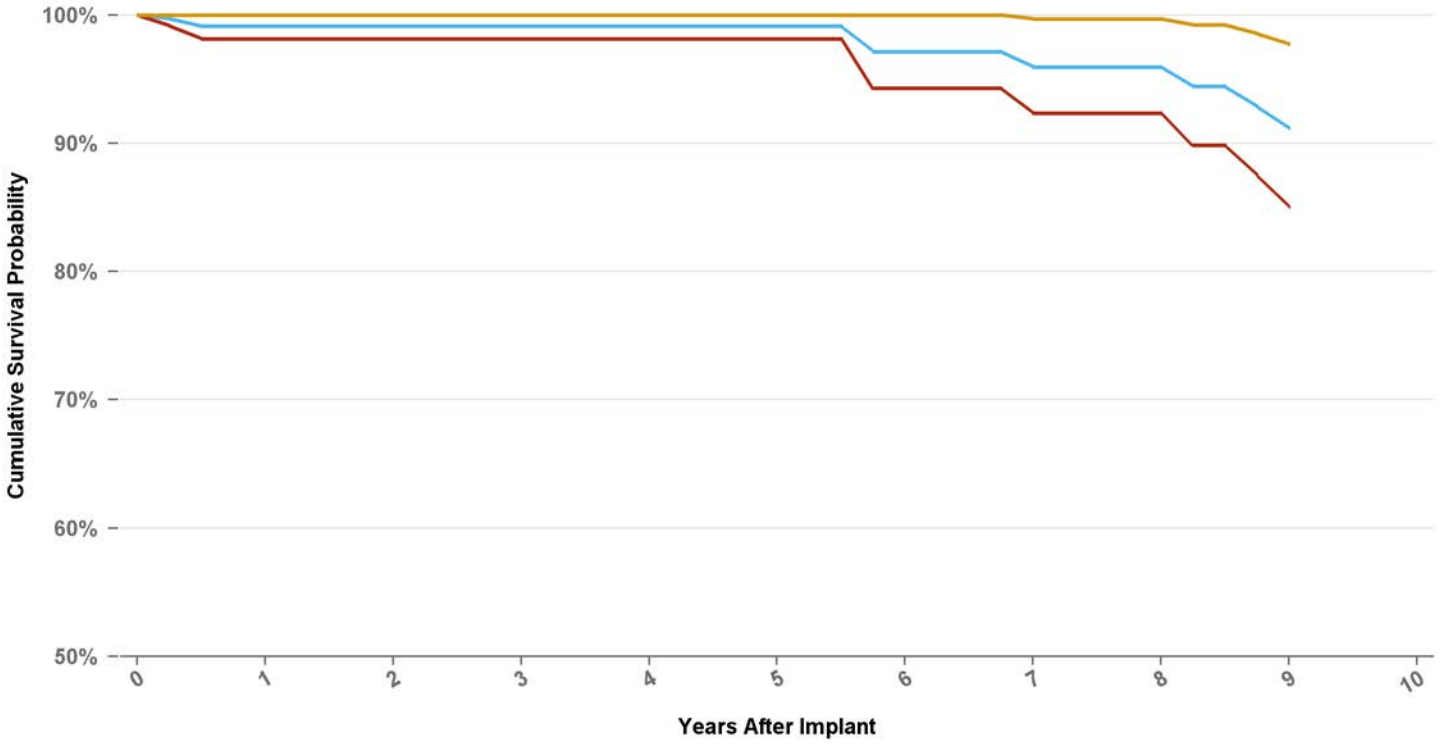
Distribution Data	
US Market Release	11/14/1994
CE Approval Date	
Registered US Implant	19,565
Estimated Active US	3,678
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	540
Cumulative Months of Follow-Up	18,129
Number of Leads Active in Study	5

Product Surveilance Registry Qualifying Complications	12
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	1
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	2
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	21
Other	20

4558M, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4558M_SURV

Lower 95 Pct Confidence Graph - 4558M_SURV

Upper 95 Pct Confidence Graph - 4558M_SURV

Years	1	2	3	4	5	6	7	8	at 108 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	97.1%	95.9%	95.9%	91.1%
#	278	225	180	140	115	88	80	64	53

PACING LEAD

4568

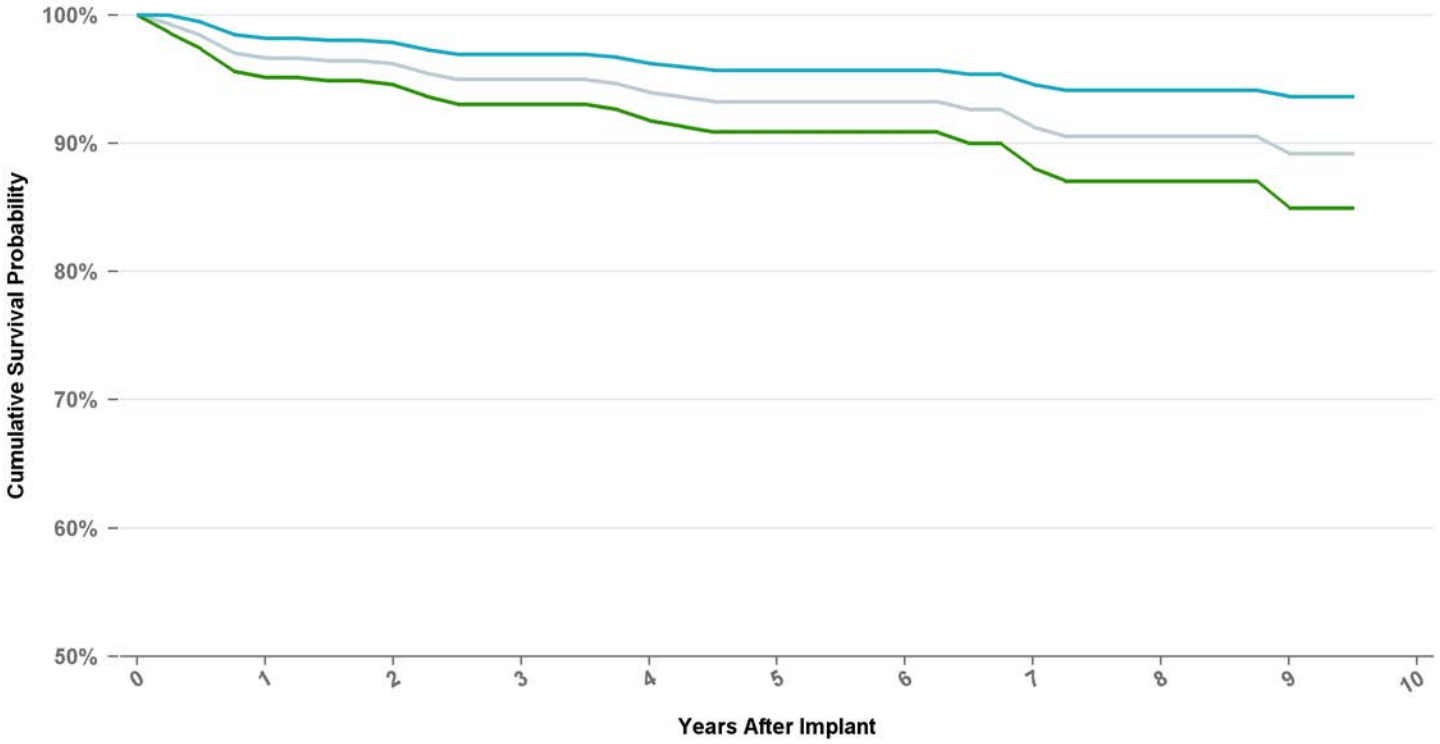
Distribution Data	
US Market Release	01/02/1997
CE Approval Date	
Registered US Implant	69,205
Estimated Active US	20,344
Product Characteristics	
Fixation Type	J-shape, screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	664
Cumulative Months of Follow-Up	30,244
Number of Leads Active in Study	111

Product Surveillance Registry Qualifying Complications	38
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	19
Failure To Sense	4
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	9
Medical Judgment	1
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	3
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	4
Oversensing	1
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	92
Other	52

4568, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4568_SURV

Lower 95 Pct Confidence Graph - 4568_SURV

Upper 95 Pct Confidence Graph - 4568_SURV

Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	96.6%	96.2%	95.0%	94.0%	93.3%	93.3%	91.3%	90.5%	89.2%	89.2%
#	483	413	324	275	223	164	125	87	64	56

PACING LEAD

4574

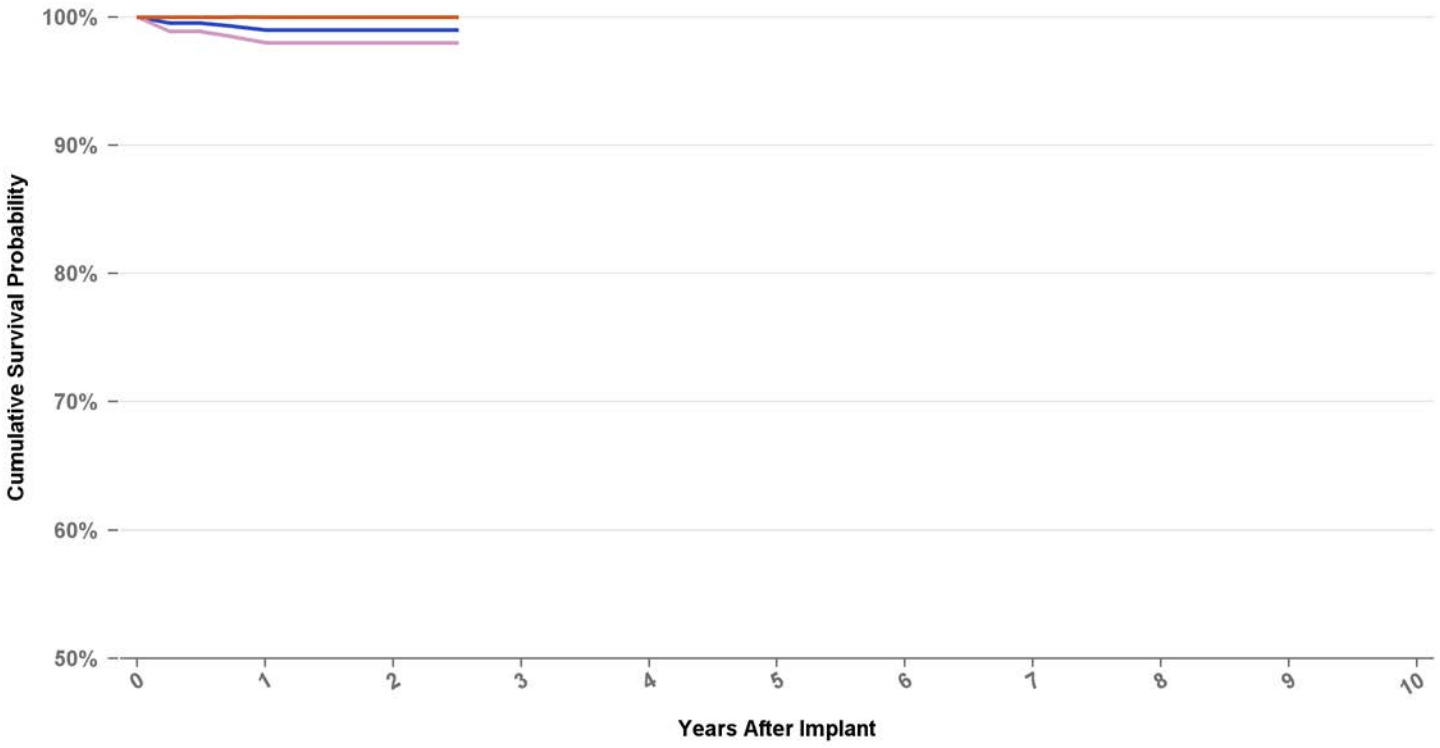
Distribution Data	
US Market Release	06/23/2002
CE Approval Date	02/01/2002
Registered US Implant	64,562
Estimated Active US	43,087
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	595
Cumulative Months of Follow-Up	8,472
Number of Leads Active in Study	440

Product Surveillance Registry Qualifying Complications	4
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	19
Failure To Sense	8
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	43
Oversensing	1
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	4
Other	0

4574, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4574_SURV

Lower 95 Pct Confidence Graph - 4574_SURV

Upper 95 Pct Confidence Graph - 4574_SURV

Years	1	2	at 30 mo
%	99.0%	99.0%	99.0%
#	295	101	63

PACING LEAD

4592

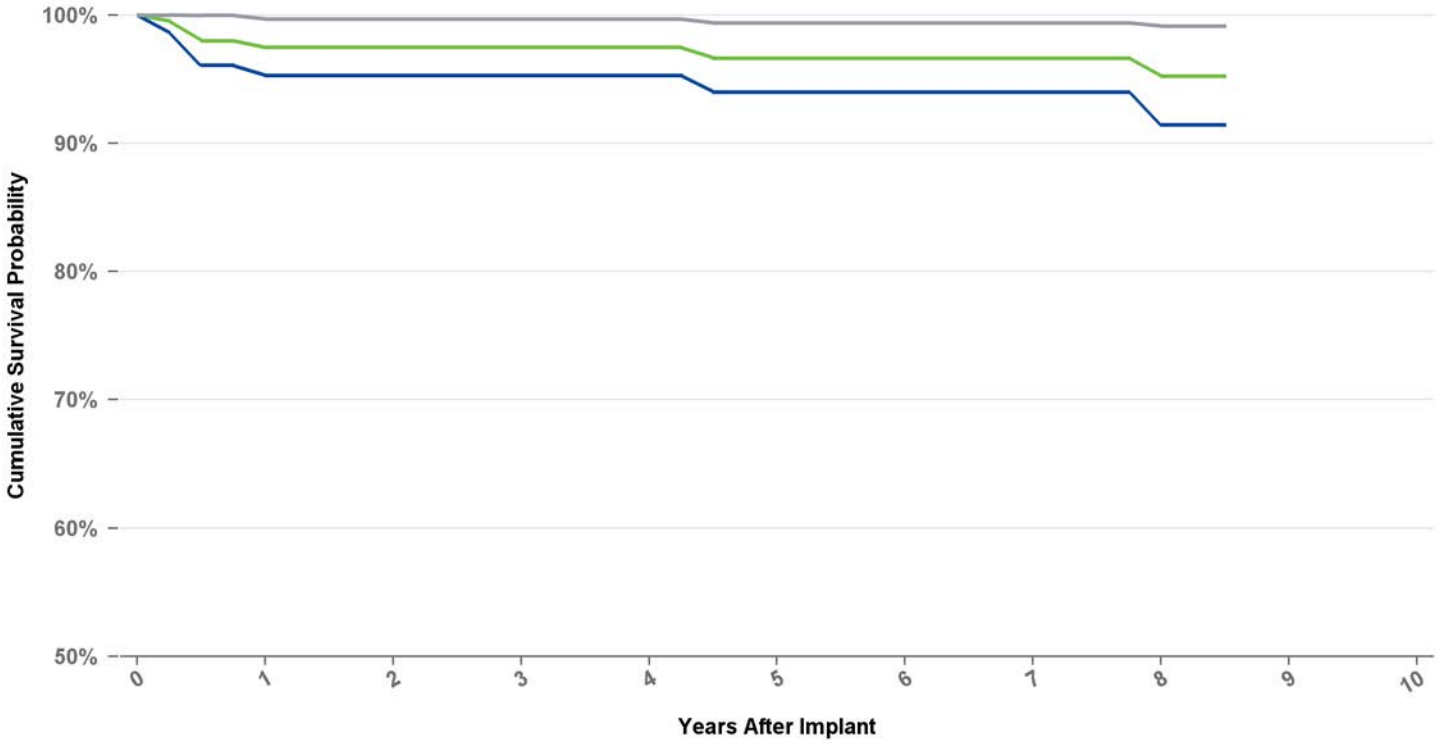
Distribution Data	
US Market Release	10/05/1998
CE Approval Date	04/15/1998
Registered US Implant	86,870
Estimated Active US	40,373
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	301
Cumulative Months of Follow-Up	14,614
Number of Leads Active in Study	66

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	8
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	26
Oversensing	1
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	19
Other	1

4592, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4592_SURV

Lower 95 Pct Confidence Graph - 4592_SURV

Upper 95 Pct Confidence Graph - 4592_SURV

Years	1	2	3	4	5	6	7	8	at 102 mo
%	97.5%	97.5%	97.5%	97.5%	96.6%	96.6%	96.6%	95.2%	95.2%
#	181	159	143	133	110	99	75	63	54

PACING LEAD

5033

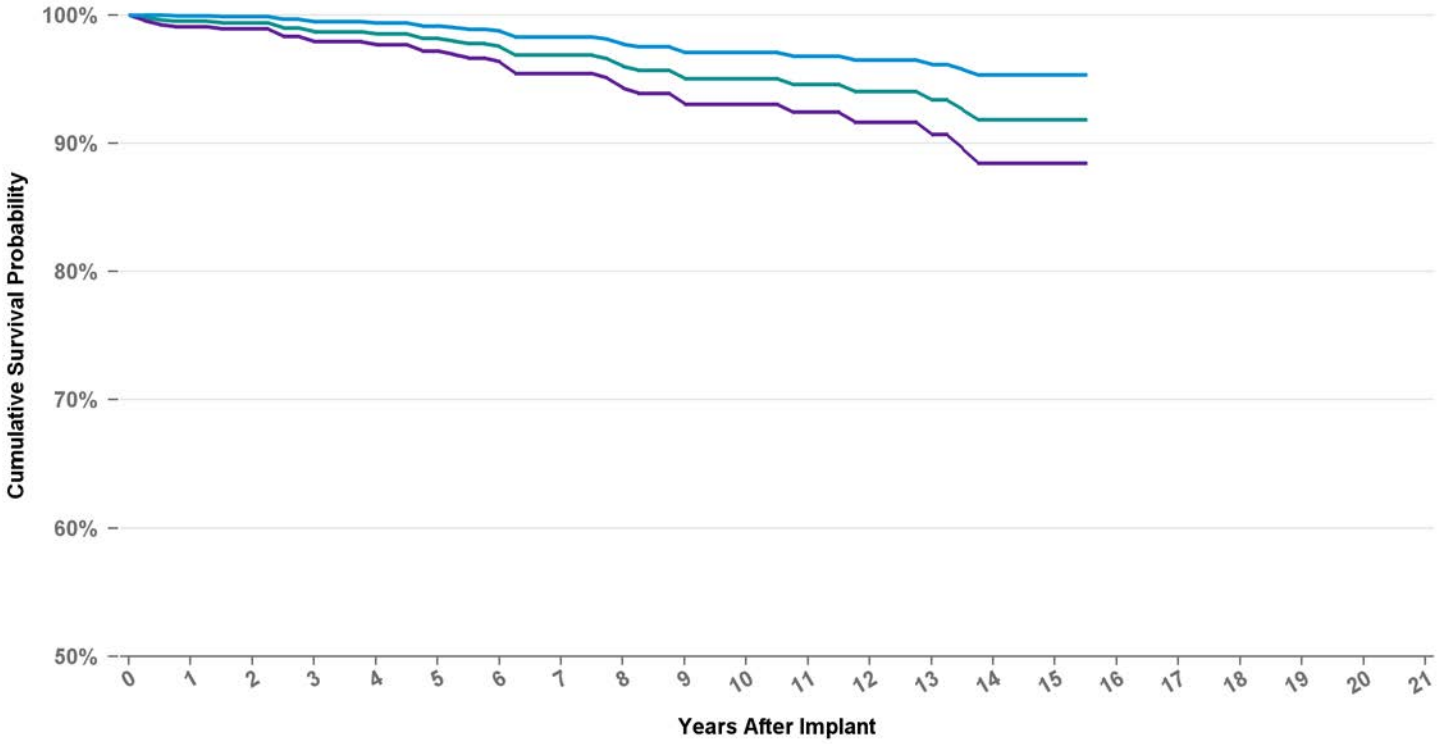
Distribution Data	
US Market Release	02/09/1996
CE Approval Date	
Registered US Implant	2,340
Estimated Active US	459
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,901
Cumulative Months of Follow-Up	75,796
Number of Leads Active in Study	131

Product Surveillance Registry Qualifying Complications	31
Cardiac Perforation	1
Conductor Fracture	8
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	15
Failure To Sense	0
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	1
Crimp Weld Bond	0
Insulation Breach	0
Other	3

5033, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5033_SURV

Lower 95 Pct Confidence Graph - 5033_SURV

Upper 95 Pct Confidence Graph - 5033_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 186 mo
%	99.5%	99.4%	98.7%	98.5%	98.2%	97.5%	96.9%	96.0%	95.0%	95.0%	94.6%	94.0%	93.4%	91.8%	91.8%	91.8%
#	902	761	672	584	510	436	379	326	276	233	194	159	136	104	75	58

PACING LEAD

5034

ATRIAL PLACEMENT

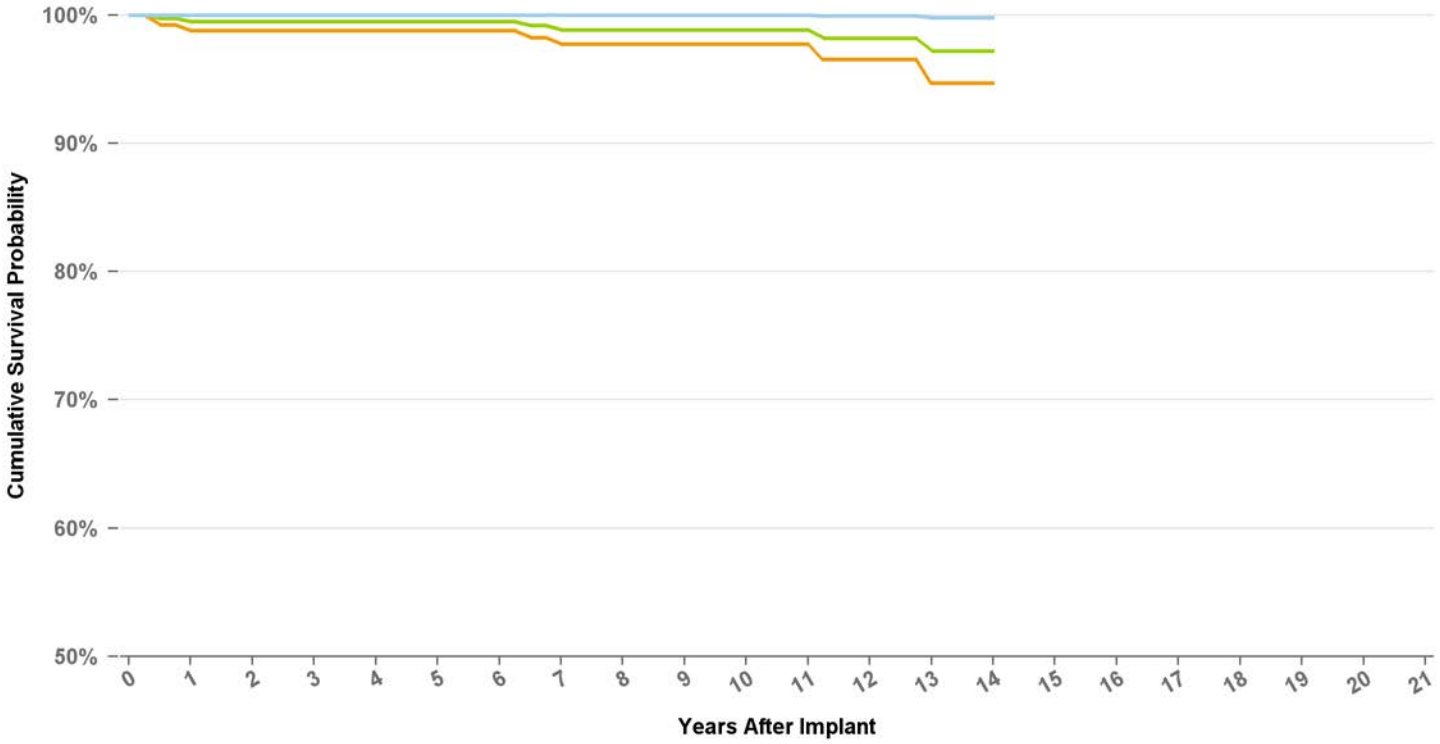
Distribution Data	
US Market Release	02/09/1996
CE Approval Date	
Registered US Implant	55,423
Estimated Active US	11,937
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	45,682
Number of Leads Active in Study	110

Product Surveillance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	28
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach	3
Lead Dislodgement	14
Oversensing	0
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	15
Other	7

5034, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5034_ATR_SURV

Lower 95 Pct Confidence Graph - 5034_ATR_SURV

Upper 95 Pct Confidence Graph - 5034_ATR_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	at 168 mo
%	99.5%	99.5%	99.5%	99.5%	99.5%	99.5%	98.8%	98.8%	98.8%	98.8%	98.8%	98.2%	97.2%	97.2%
#	383	382	379	376	358	334	297	253	212	187	154	124	92	53

PACING LEAD

5034

VENTRICULAR PLACEMENT

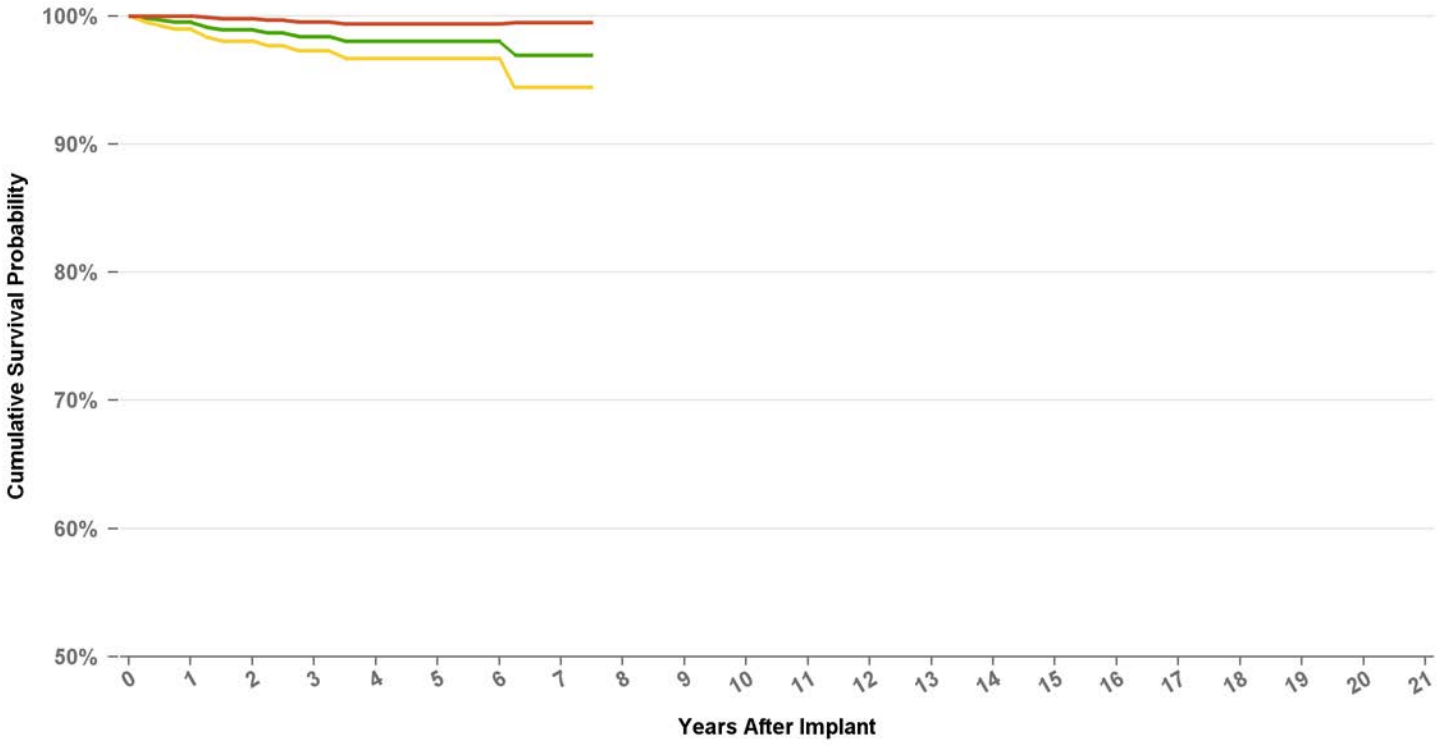
Distribution Data	
US Market Release	02/09/1996
CE Approval Date	
Registered US Implant	55,423
Estimated Active US	11,937
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,213
Cumulative Months of Follow-Up	27,981
Number of Leads Active in Study	12

Product Surveilance Registry Qualifying Complications	11
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	7
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	28
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach	3
Lead Dislodgement	14
Oversensing	0
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	15
Other	7

5034, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5034_VEN_SURV

Lower 95 Pct Confidence Graph - 5034_VEN_SURV

Upper 95 Pct Confidence Graph - 5034_VEN_SURV

Years	1	2	3	4	5	6	7	at 90 mo
%	99.5%	98.9%	98.4%	98.0%	98.0%	98.0%	96.9%	96.9%
#	517	415	307	221	155	96	61	57

PACING LEAD

5054

ATRIAL PLACEMENT

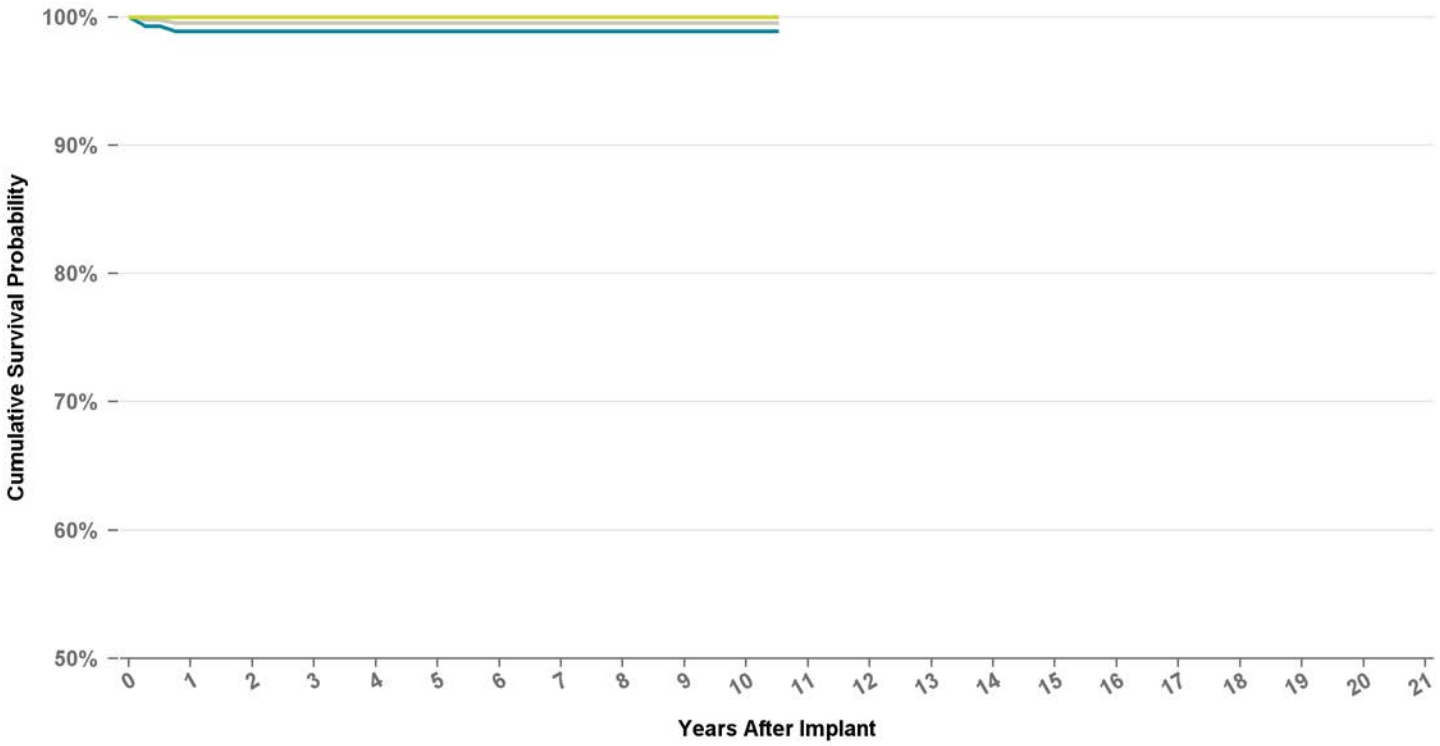
Distribution Data	
US Market Release	06/03/1998
CE Approval Date	06/05/1997
Registered US Implant	97,177
Estimated Active US	40,891
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	34,799
Number of Leads Active in Study	114

Product Surveilance Registry Qualifying Complications	2
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	22
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	23
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	1
Insulation Breach	28
Other	3

5054, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5054_ATR_SURV

Lower 95 Pct Confidence Graph - 5054_ATR_SURV

Upper 95 Pct Confidence Graph - 5054_ATR_SURV

Years	1	2	3	4	5	6	7	8	9	10	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%
#	410	390	357	321	288	251	218	184	135	83	69

PACING LEAD

5054

VENTRICULAR PLACEMENT

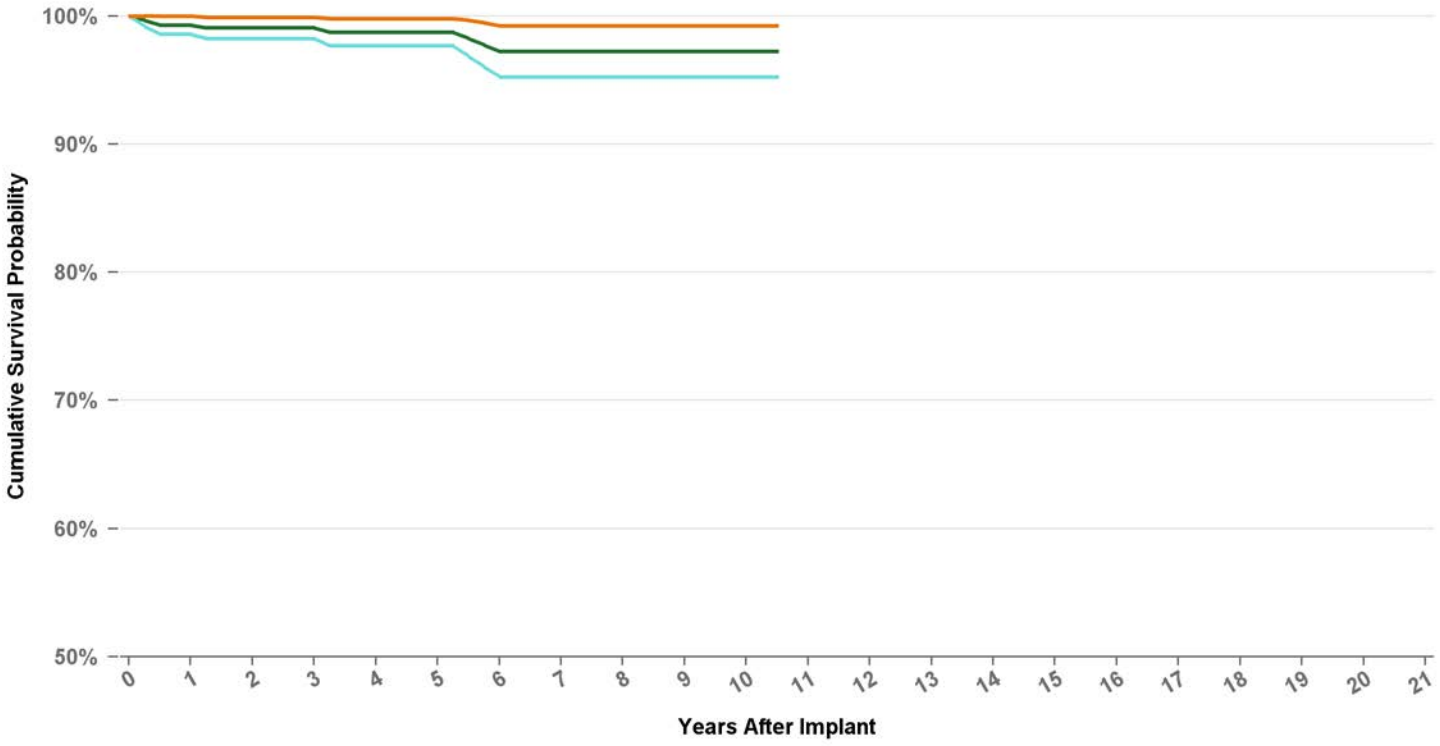
Distribution Data	
US Market Release	06/03/1998
CE Approval Date	06/05/1997
Registered US Implant	97,177
Estimated Active US	40,891
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	978
Cumulative Months of Follow-Up	30,556
Number of Leads Active in Study	88

Product Surveilance Registry Qualifying Complications	9
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	22
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	23
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	1
Insulation Breach	28
Other	3

5054, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5054_VEN_SURV

Lower 95 Pct Confidence Graph - 5054_VEN_SURV

Upper 95 Pct Confidence Graph - 5054_VEN_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.3%	99.1%	99.1%	98.7%	98.7%	97.2%	97.2%	97.2%	97.2%	97.2%	97.2%
#	470	385	300	259	219	180	154	114	82	61	53

PACING LEAD

5068

ATRIAL PLACEMENT

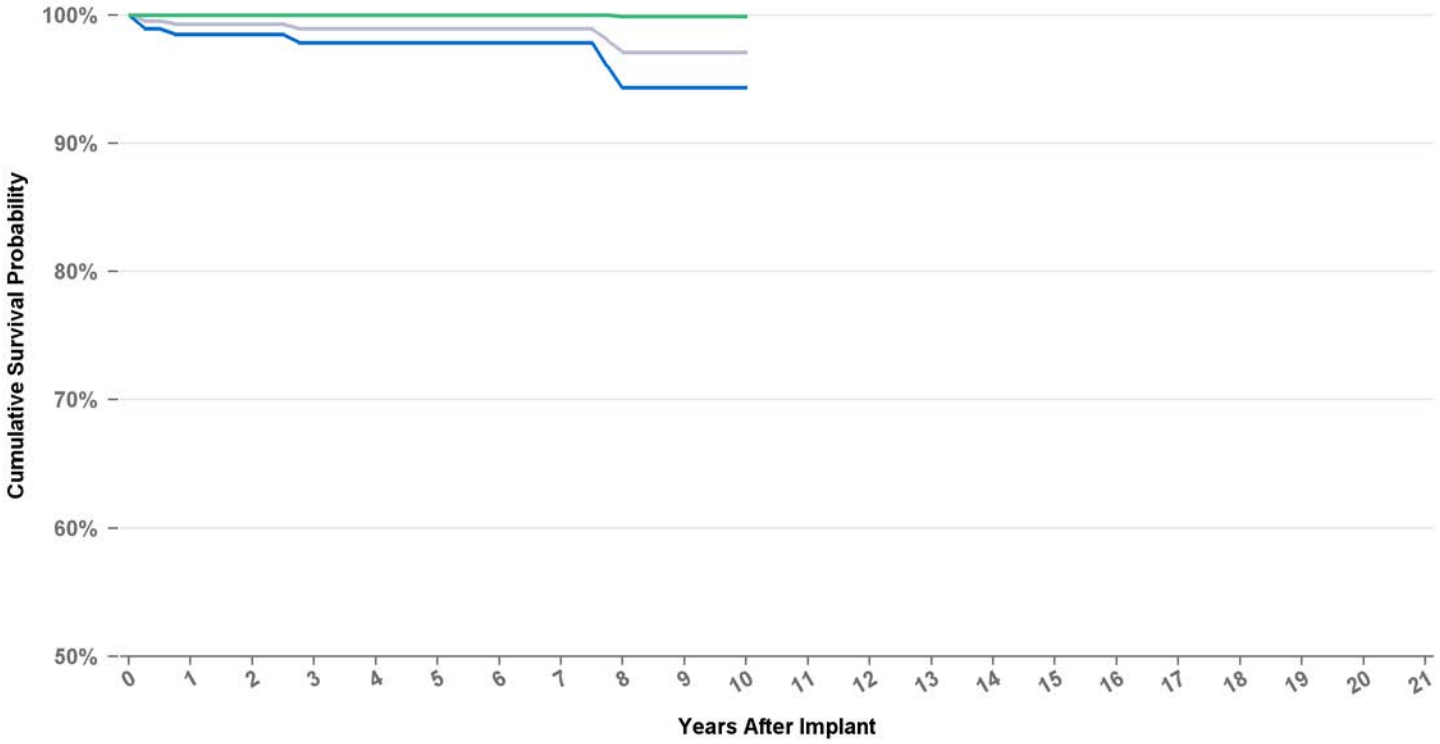
Distribution Data	
US Market Release	01/02/1997
CE Approval Date	
Registered US Implant	102,405
Estimated Active US	28,198
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	976
Cumulative Months of Follow-Up	26,313
Number of Leads Active in Study	36

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	16
Conductor Fracture	4
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	5
Impedance Abnormal	1
Insulation Breach	1
Lead Dislodgement	20
Oversensing	1
Unspecified	7
USA Returned Product Analysis	
Conductor Fracture	42
Crimp Weld Bond	2
Insulation Breach	57
Other	83

5068, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5068_ATR_SURV

Lower 95 Pct Confidence Graph - 5068_ATR_SURV

Upper 95 Pct Confidence Graph - 5068_ATR_SURV

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.3%	99.3%	98.9%	98.9%	98.9%	98.9%	98.9%	97.1%	97.1%	97.1%
#	348	301	256	224	192	154	127	99	67	56

PACING LEAD

5068

VENTRICULAR PLACEMENT

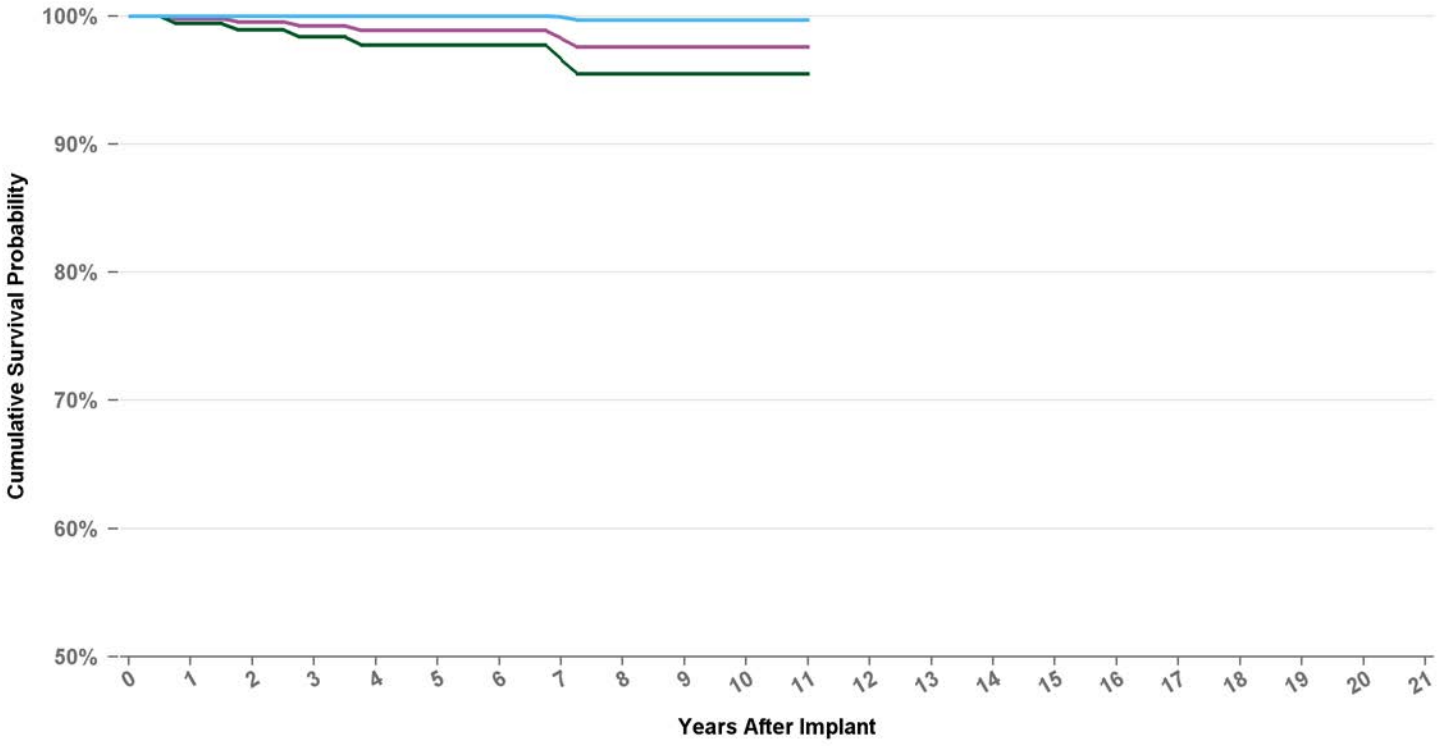
Distribution Data	
US Market Release	01/02/1997
CE Approval Date	
Registered US Implant	102,405
Estimated Active US	28,198
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,370
Cumulative Months of Follow-Up	31,202
Number of Leads Active in Study	57

Product Surveilance Registry Qualifying Complications	8
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	16
Conductor Fracture	4
Extracardiac Stimulation	0
Failure To Capture	31
Failure To Sense	5
Impedance Abnormal	1
Insulation Breach	1
Lead Dislodgement	20
Oversensing	1
Unspecified	7
USA Returned Product Analysis	
Conductor Fracture	42
Crimp Weld Bond	2
Insulation Breach	57
Other	83

5068, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5068_VEN_SURV

Lower 95 Pct Confidence Graph - 5068_VEN_SURV

Upper 95 Pct Confidence Graph - 5068_VEN_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.8%	99.6%	99.2%	98.9%	98.9%	98.9%	98.2%	97.6%	97.6%	97.6%	97.6%
#	448	359	291	245	222	188	150	125	102	79	55

PACING LEAD

5072

Distribution Data	
US Market Release	06/05/1998
CE Approval Date	09/25/1997
Registered US Implant	10,053
Estimated Active US	3,986
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

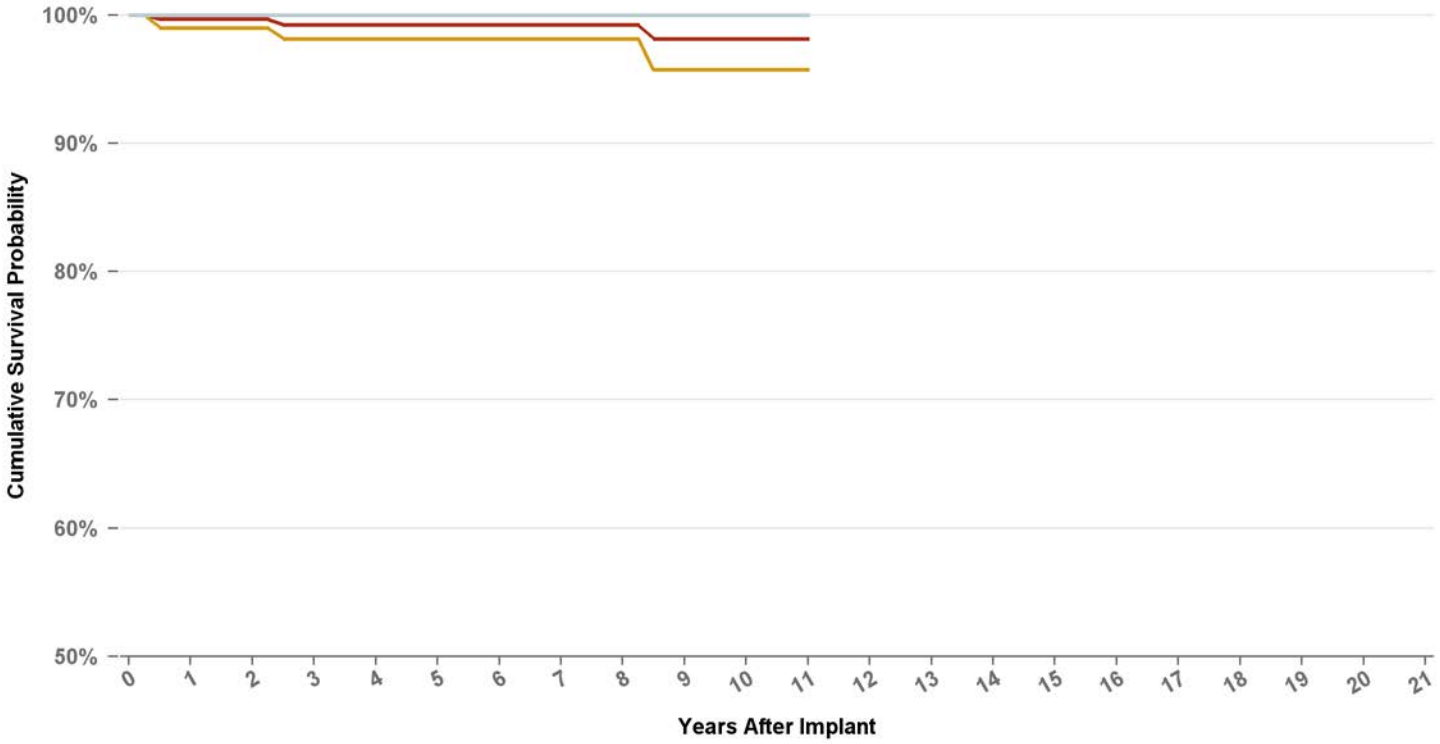
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	511
Cumulative Months of Follow-Up	22,165
Number of Leads Active in Study	51

Product Surveilance Registry Qualifying Complications	3
Cardiac Perforation	1
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	2
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	3
Crimp Weld Bond	0
Insulation Breach	7
Other	0

5072, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5072_SURV

Lower 95 Pct Confidence Graph - 5072_SURV

Upper 95 Pct Confidence Graph - 5072_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.7%	99.7%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.1%	98.1%	98.1%
#	258	231	216	191	157	136	109	93	83	73	63

PACING LEAD

Distribution Data	
US Market Release	08/31/2000
CE Approval Date	08/12/1999
Registered US Implant	1,595,428
Estimated Active US	1,004,937
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	3,733
Cumulative Months of Follow-Up	138,160
Number of Leads Active in Study	1,527

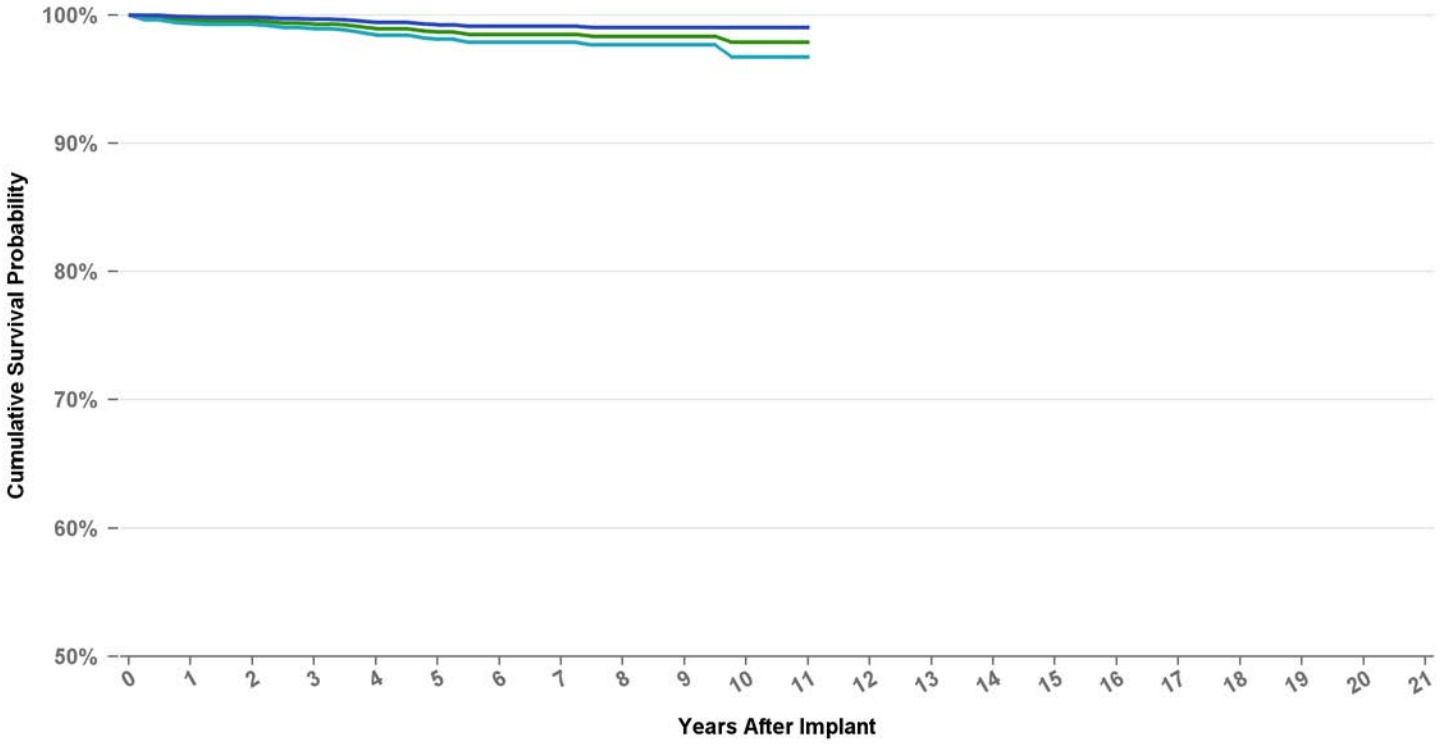
5076

Product Surveilance Registry Qualifying Complications	27
Cardiac Perforation	1
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	5
Medical Judgment	0
Other Complication	2
Oversensing	1
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	187
Conductor Fracture	13
Extracardiac Stimulation	14
Failure To Capture	253
Failure To Sense	41
Impedance Abnormal	15
Insulation Breach	8
Lead Dislodgement	584
Oversensing	32
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	483
Crimp Weld Bond	0
Insulation Breach	490
Other	190

5076, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5076_ATR_SURV

Lower 95 Pct Confidence Graph - 5076_ATR_SURV

Upper 95 Pct Confidence Graph - 5076_ATR_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.6%	99.5%	99.3%	98.9%	98.7%	98.5%	98.5%	98.3%	98.3%	97.9%	97.9%
#	1,962	1,697	1,481	1,266	1,094	925	757	512	310	177	71

PACING LEAD

5076

VENTRICULAR PLACEMENT

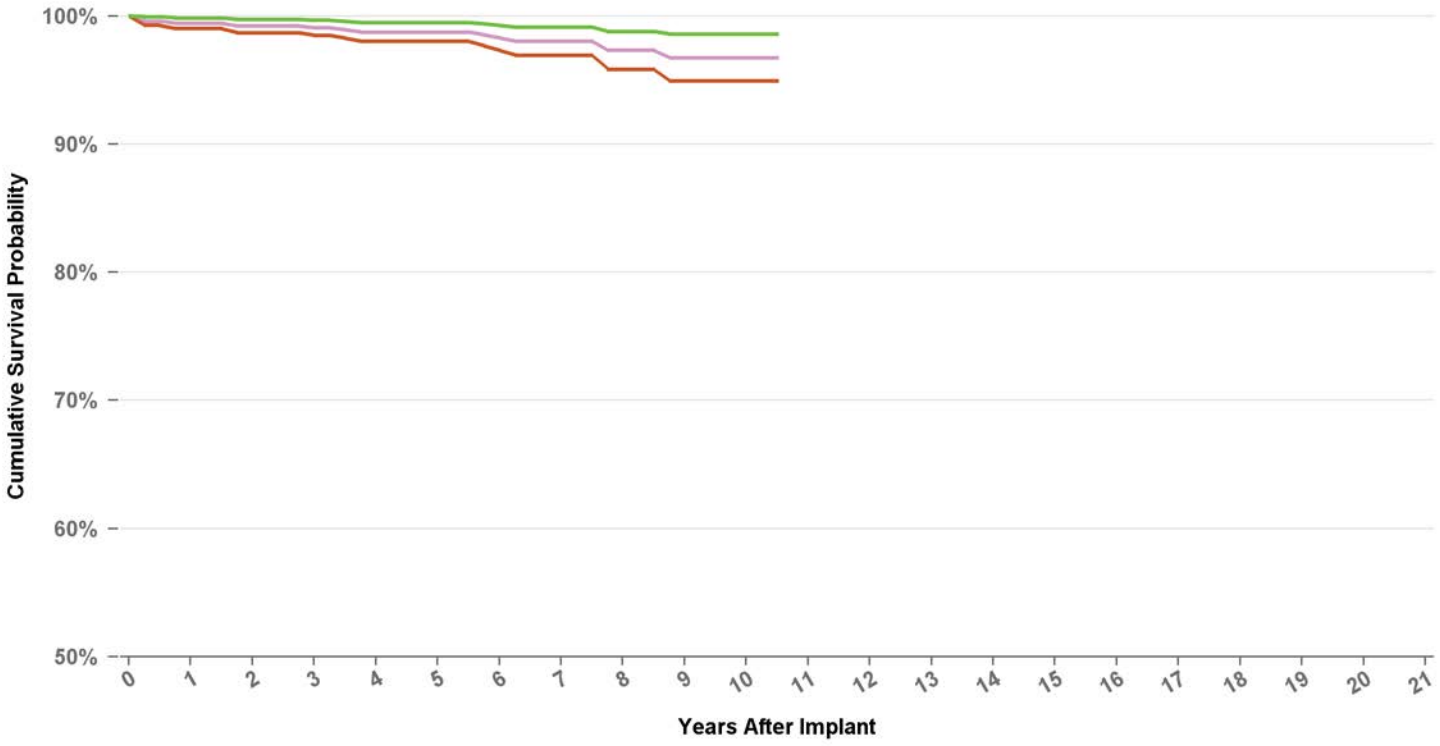
Distribution Data	
US Market Release	08/31/2000
CE Approval Date	08/12/1999
Registered US Implant	1,595,428
Estimated Active US	1,004,937
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,960
Cumulative Months of Follow-Up	65,783
Number of Leads Active in Study	639

Product Surveilance Registry Qualifying Complications	19
Cardiac Perforation	1
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	6
Failure To Sense	1
Impedance Abnormal	4
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	187
Conductor Fracture	13
Extracardiac Stimulation	14
Failure To Capture	253
Failure To Sense	41
Impedance Abnormal	15
Insulation Breach	8
Lead Dislodgement	584
Oversensing	32
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	483
Crimp Weld Bond	0
Insulation Breach	490
Other	190

5076, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5076_VEN_SURV

Lower 95 Pct Confidence Graph - 5076_VEN_SURV

Upper 95 Pct Confidence Graph - 5076_VEN_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.4%	99.2%	99.1%	98.8%	98.8%	98.3%	98.0%	97.3%	96.7%	96.7%	96.7%
#	1,026	840	694	561	480	399	322	238	144	92	71

PACING LEAD

Distribution Data	
US Market Release	02/08/2011
CE Approval Date	01/21/2009
Registered US Implant	159,331
Estimated Active US	153,559
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,800
Cumulative Months of Follow-Up	33,201
Number of Leads Active in Study	2,372

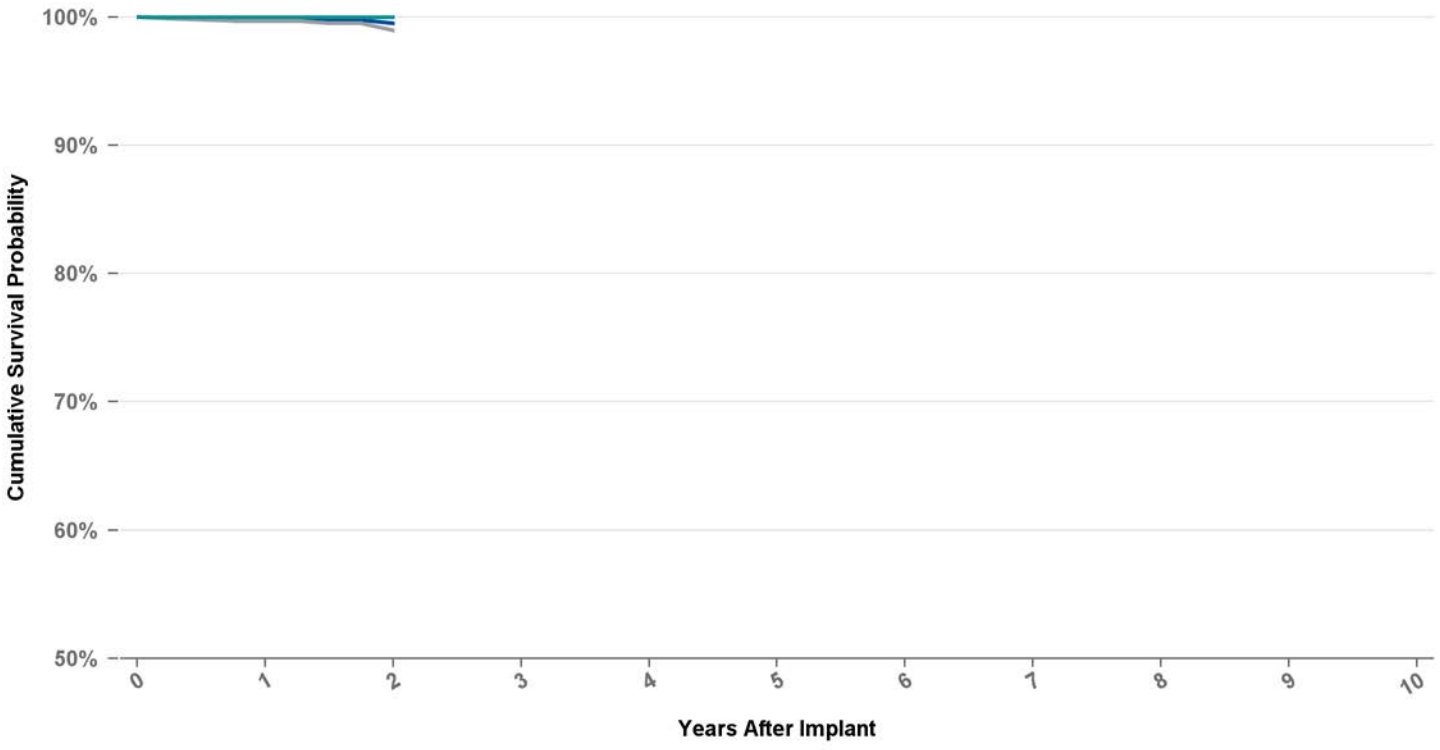
5086MRI

Product Surveilance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	4
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	148
Conductor Fracture	2
Extracardiac Stimulation	10
Failure To Capture	91
Failure To Sense	18
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	188
Oversensing	22
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	15
Other	8

5086MRI, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5086MRI_ATR_SURV

Lower 95 Pct Confidence Graph - 5086MRI_ATR_SURV

Upper 95 Pct Confidence Graph - 5086MRI_ATR_SURV

Years	1	at 24 mo
%	99.9%	99.5%
#	1,435	122

PACING LEAD

Distribution Data	
US Market Release	02/08/2011
CE Approval Date	01/21/2009
Registered US Implant	159,331
Estimated Active US	153,559
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,789
Cumulative Months of Follow-Up	33,141
Number of Leads Active in Study	2,362

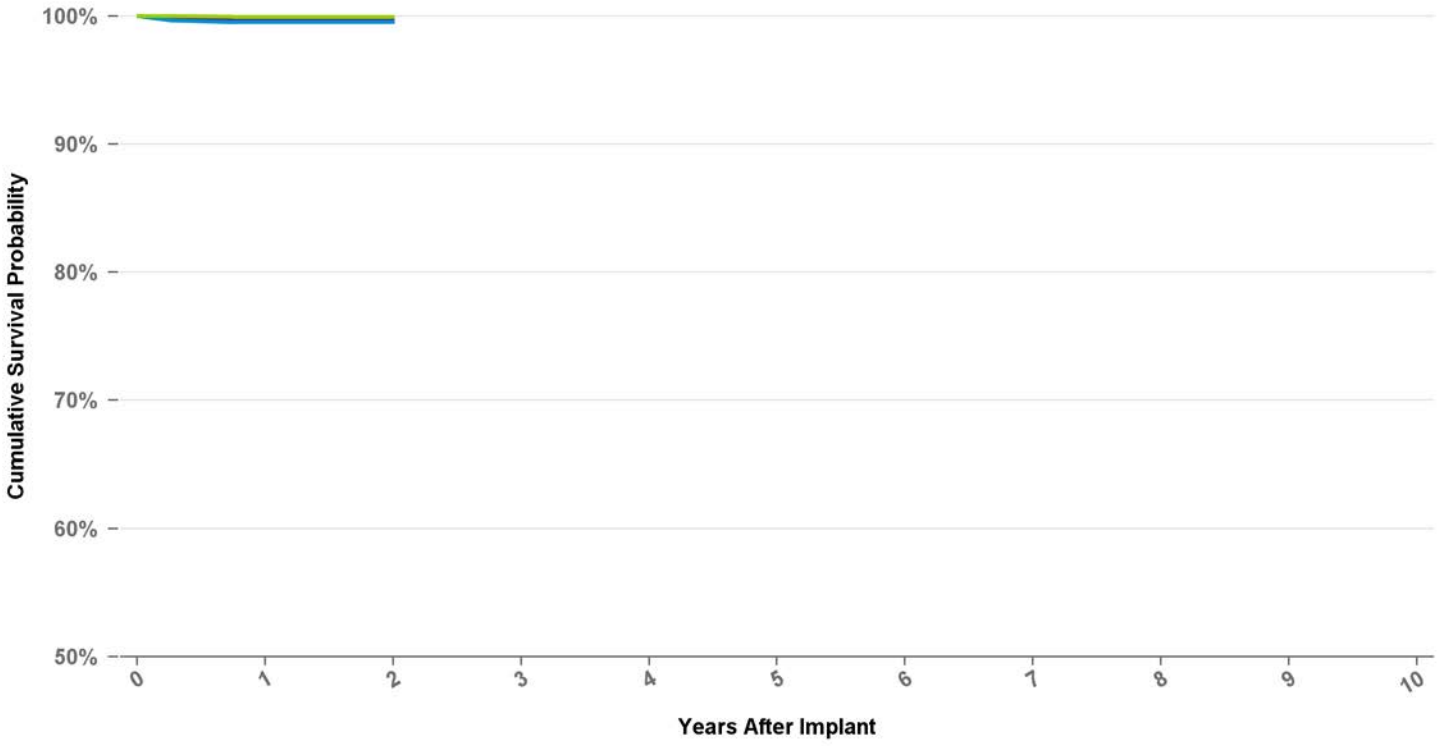
5086MRI

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

VENTRICULAR PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	148
Conductor Fracture	2
Extracardiac Stimulation	10
Failure To Capture	91
Failure To Sense	18
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	188
Oversensing	22
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	15
Other	8

5086MRI, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5086MRI_VEN_SURV

Lower 95 Pct Confidence Graph - 5086MRI_VEN_SURV

Upper 95 Pct Confidence Graph - 5086MRI_VEN_SURV

Years	1	at 24 mo
%	99.7%	99.7%
#	1,439	121

PACING LEAD

5092

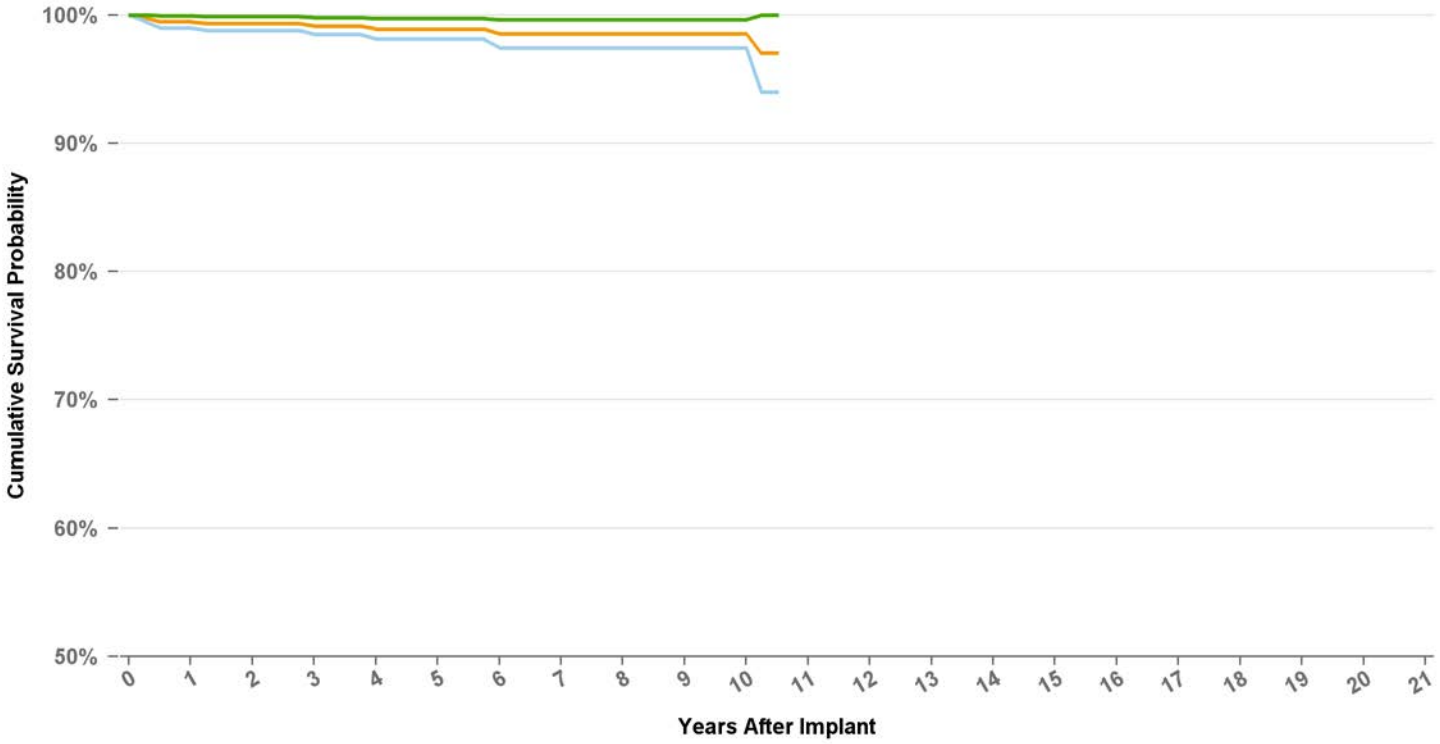
Distribution Data	
US Market Release	06/03/1998
CE Approval Date	09/25/1997
Registered US Implant	135,810
Estimated Active US	61,274
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,187
Cumulative Months of Follow-Up	47,405
Number of Leads Active in Study	128

Product Surveilance Registry Qualifying Complications	10
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	5
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	6
Conductor Fracture	1
Extracardiac Stimulation	3
Failure To Capture	38
Failure To Sense	6
Impedance Abnormal	0
Insulation Breach	3
Lead Dislodgement	54
Oversensing	1
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	40
Other	3

5092, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5092_SURV

Lower 95 Pct Confidence Graph - 5092_SURV

Upper 95 Pct Confidence Graph - 5092_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.0%
#	801	637	501	401	317	244	194	147	105	75	53

PACING LEAD

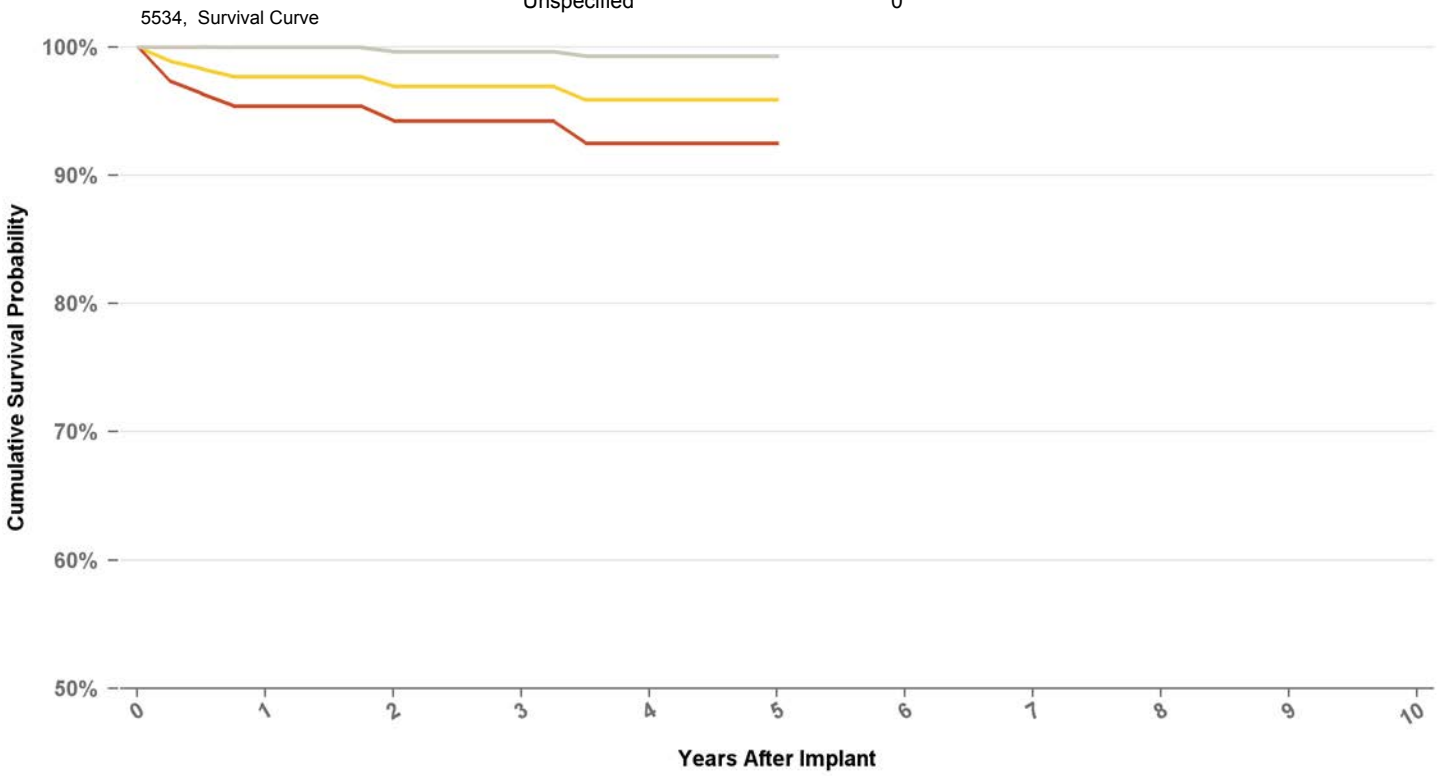
5534

Distribution Data	
US Market Release	02/09/1996
CE Approval Date	
Registered US Implant	25,846
Estimated Active US	6,569
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	5
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	4
Other	4

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	267
Cumulative Months of Follow-Up	9,462
Number of Leads Active in Study	8



Years	1	2	3	4	at 60 mo
%	97.7%	96.9%	96.9%	95.9%	95.9%
#	146	126	98	77	53

PACING LEAD

5554

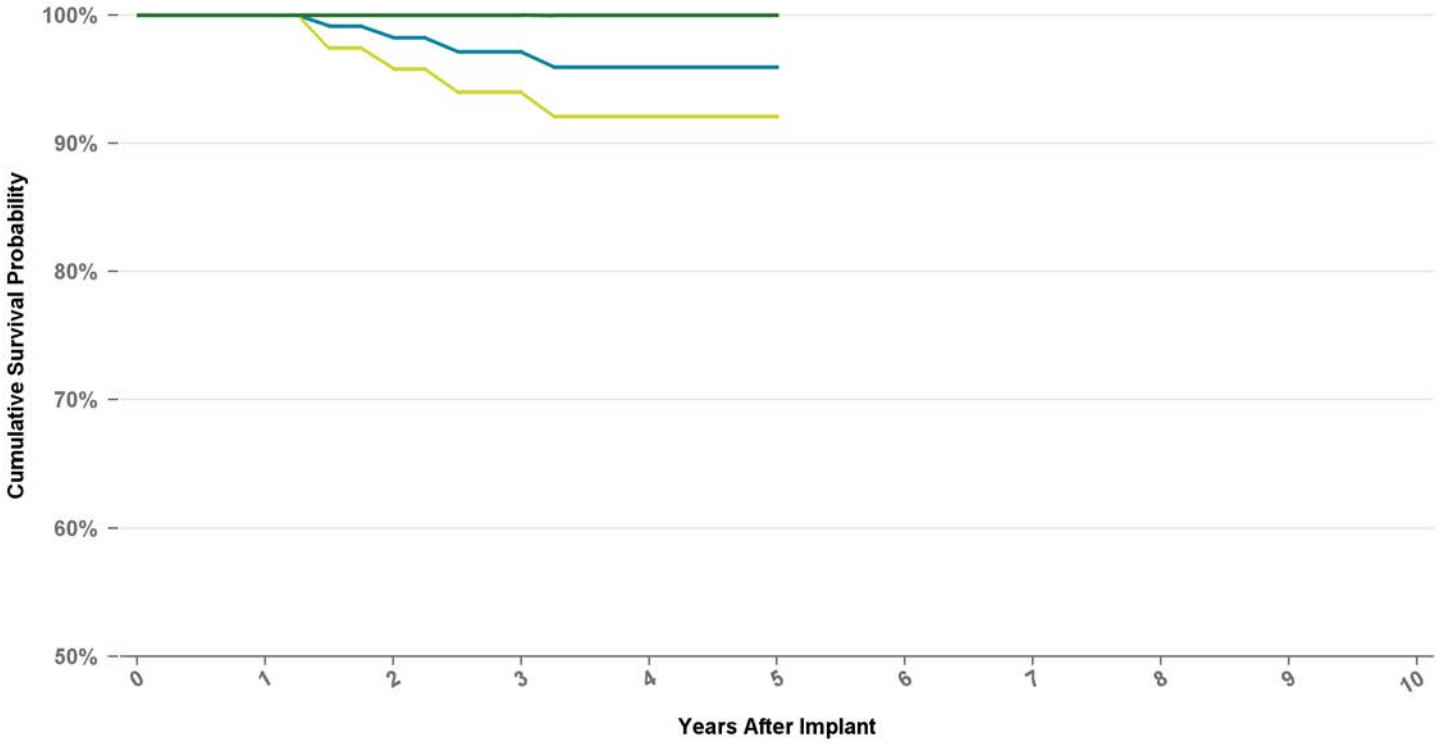
Distribution Data	
US Market Release	06/03/1998
CE Approval Date	06/05/1997
Registered US Implant	62,851
Estimated Active US	28,845
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	352
Cumulative Months of Follow-Up	7,717
Number of Leads Active in Study	38

Product Surveillance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	29
Failure To Sense	2
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	31
Oversensing	0
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	19
Other	2

5554, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5554_SURV

Lower 95 Pct Confidence Graph - 5554_SURV

Upper 95 Pct Confidence Graph - 5554_SURV

Years	1	2	3	4	at 60 mo
%	100.0%	98.2%	97.1%	95.9%	95.9%
#	141	105	82	72	59

PACING LEAD

5568

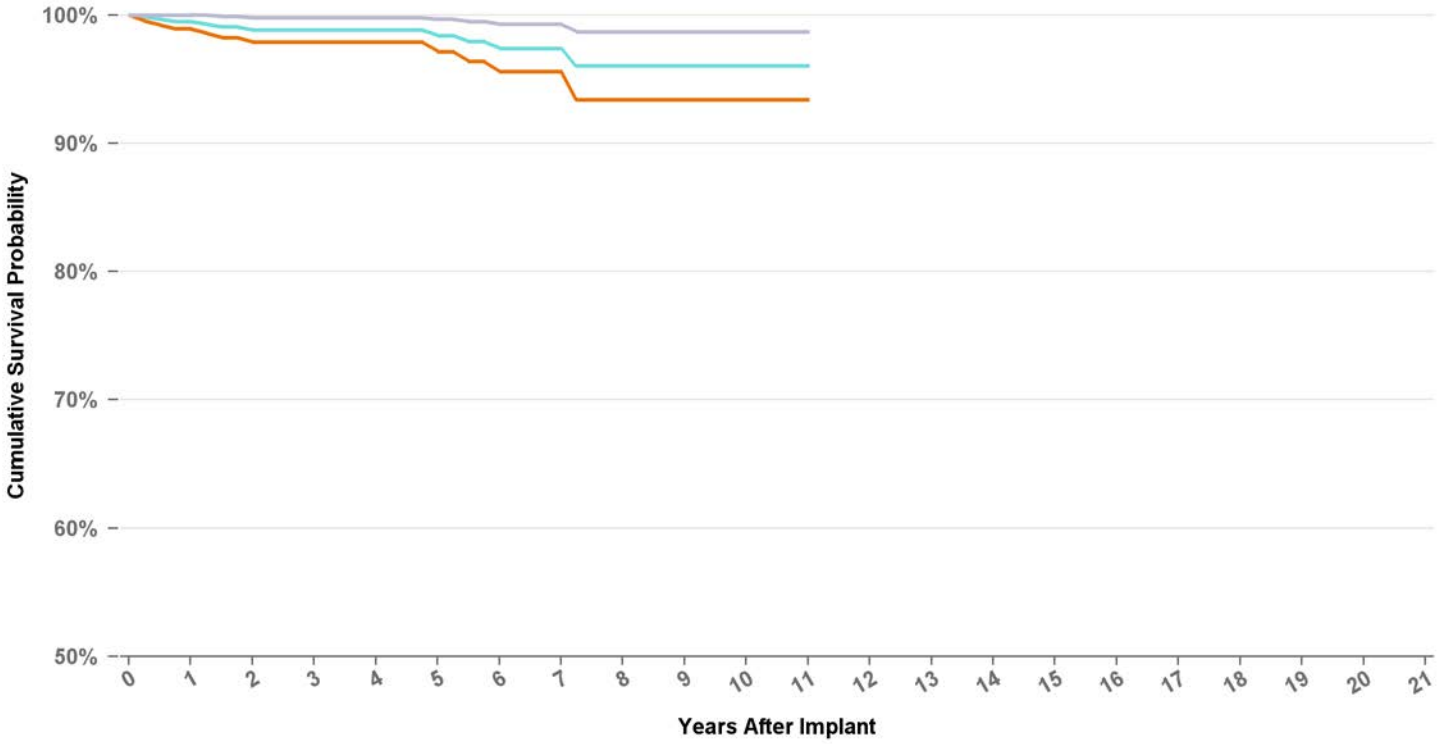
Distribution Data	
US Market Release	01/02/1997
CE Approval Date	08/14/1996
Registered US Implant	93,265
Estimated Active US	50,937
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	1,082
Cumulative Months of Follow-Up	33,206
Number of Leads Active in Study	108

Product Surveillance Registry Qualifying Complications	13
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	6
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	1
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	10
Conductor Fracture	0
Extracardiac Stimulation	2
Failure To Capture	21
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	35
Oversensing	2
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	30
Other	37

5568, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5568_SURV

Lower 95 Pct Confidence Graph - 5568_SURV

Upper 95 Pct Confidence Graph - 5568_SURV

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	98.8%	98.8%	98.8%	98.4%	97.4%	97.4%	96.0%	96.0%	96.0%	96.0%
#	489	404	339	272	227	184	141	121	102	78	57

PACING LEAD

5592

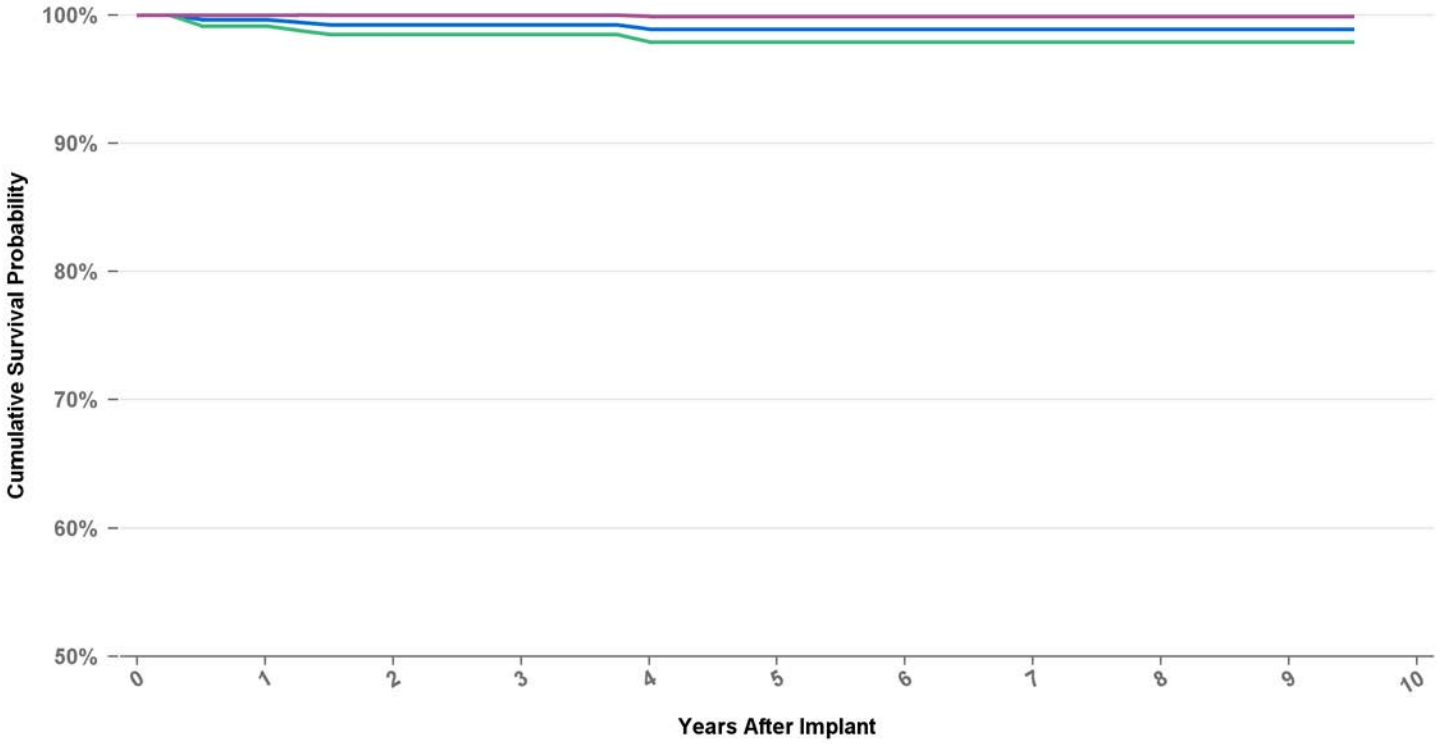
Distribution Data	
US Market Release	06/03/1998
CE Approval Date	09/25/1997
Registered US Implant	35,455
Estimated Active US	19,100
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	687
Cumulative Months of Follow-Up	31,066
Number of Leads Active in Study	116

Product Surveilance Registry Qualifying Complications	5
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	30
Oversensing	1
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	4
Other	0

5592, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5592_SURV

Lower 95 Pct Confidence Graph - 5592_SURV

Upper 95 Pct Confidence Graph - 5592_SURV

Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.6%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	507	418	333	277	223	162	129	104	70	52

PACING LEAD

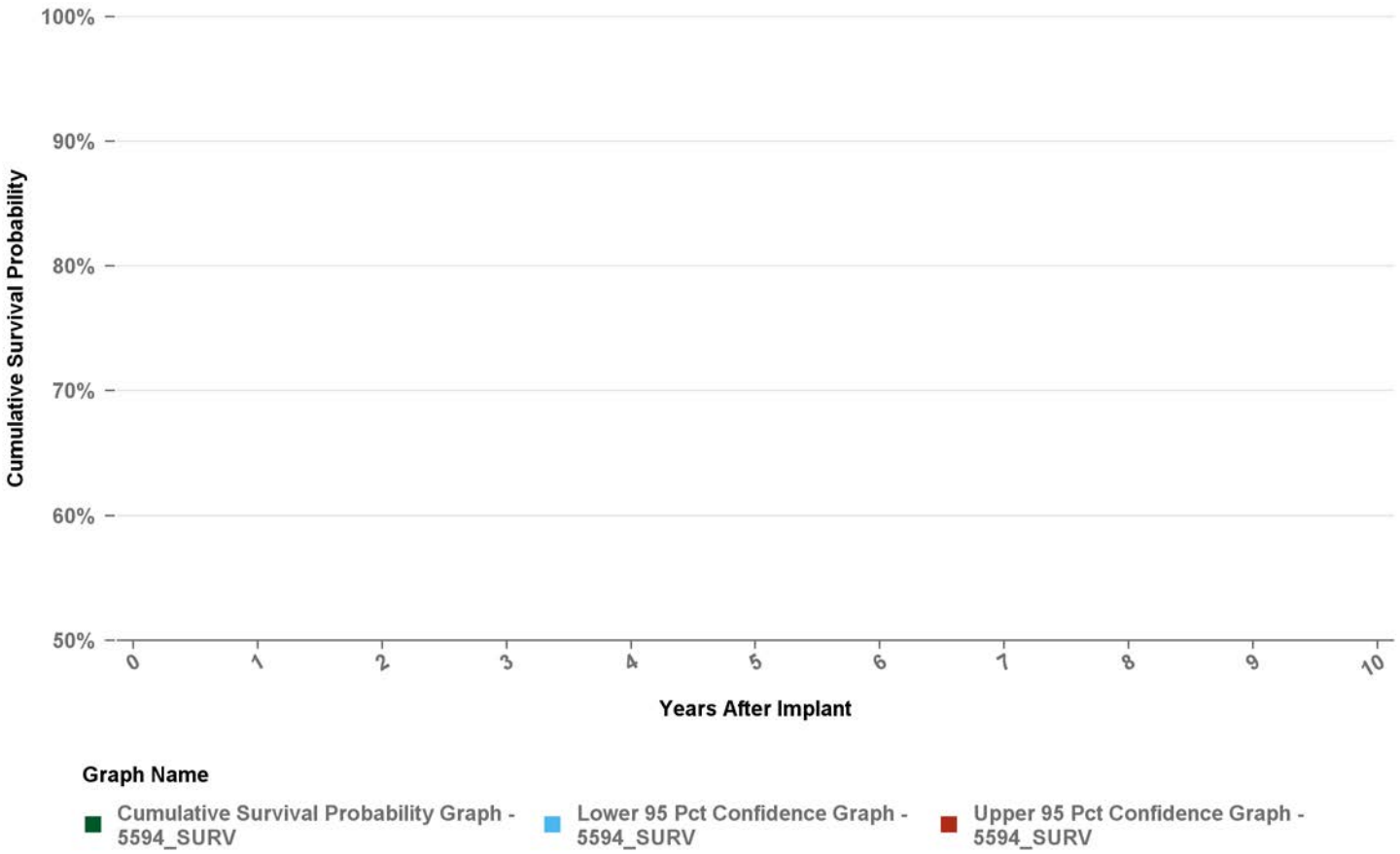
5594

Distribution Data	
US Market Release	06/25/2001
CE Approval Date	03/23/2001
Registered US Implant	16,436
Estimated Active US	10,542
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	23
Cumulative Months of Follow-Up	1,553
Number of Leads Active in Study	12

Product Surveilance Registry Qualifying Complications	0
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	9
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	8
Crimp Weld Bond	0
Insulation Breach	7
Other	1



Years
%
#

PACING LEAD

6940

Distribution Data	
US Market Release	10/09/1998
CE Approval Date	
Registered US Implant	25,385
Estimated Active US	6,934
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

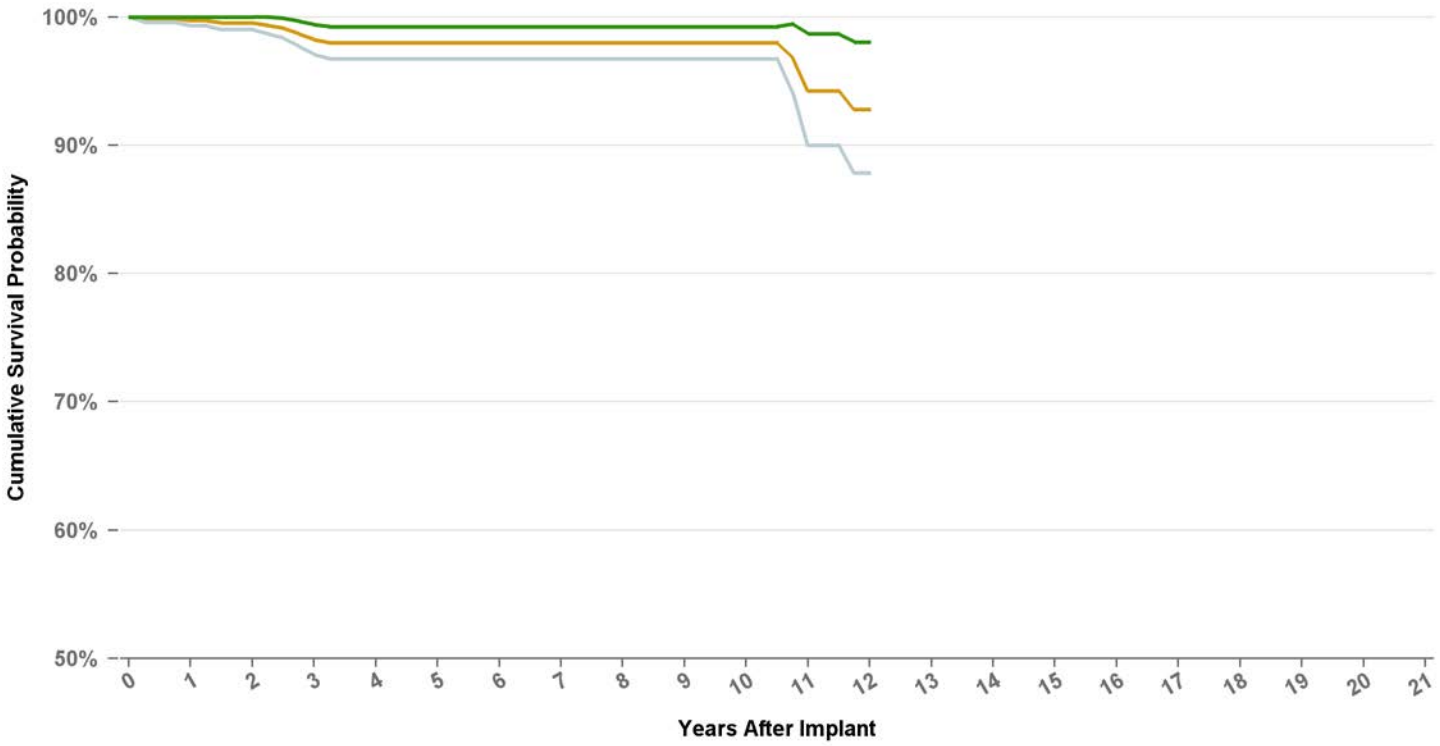
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	834
Cumulative Months of Follow-Up	41,556
Number of Leads Active in Study	77

Product Surveillance Registry Qualifying Complications	14
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	3
Medical Judgment	0
Other Complication	0
Oversensing	6
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach	0
Lead Dislodgement	6
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	18
Other	12

6940, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 6940_SURV

Lower 95 Pct Confidence Graph - 6940_SURV

Upper 95 Pct Confidence Graph - 6940_SURV

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.7%	99.5%	98.2%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	94.2%	92.8%
#	621	505	416	342	271	210	189	152	123	91	72	57

EPI MYOCARDIAL LEAD 4965

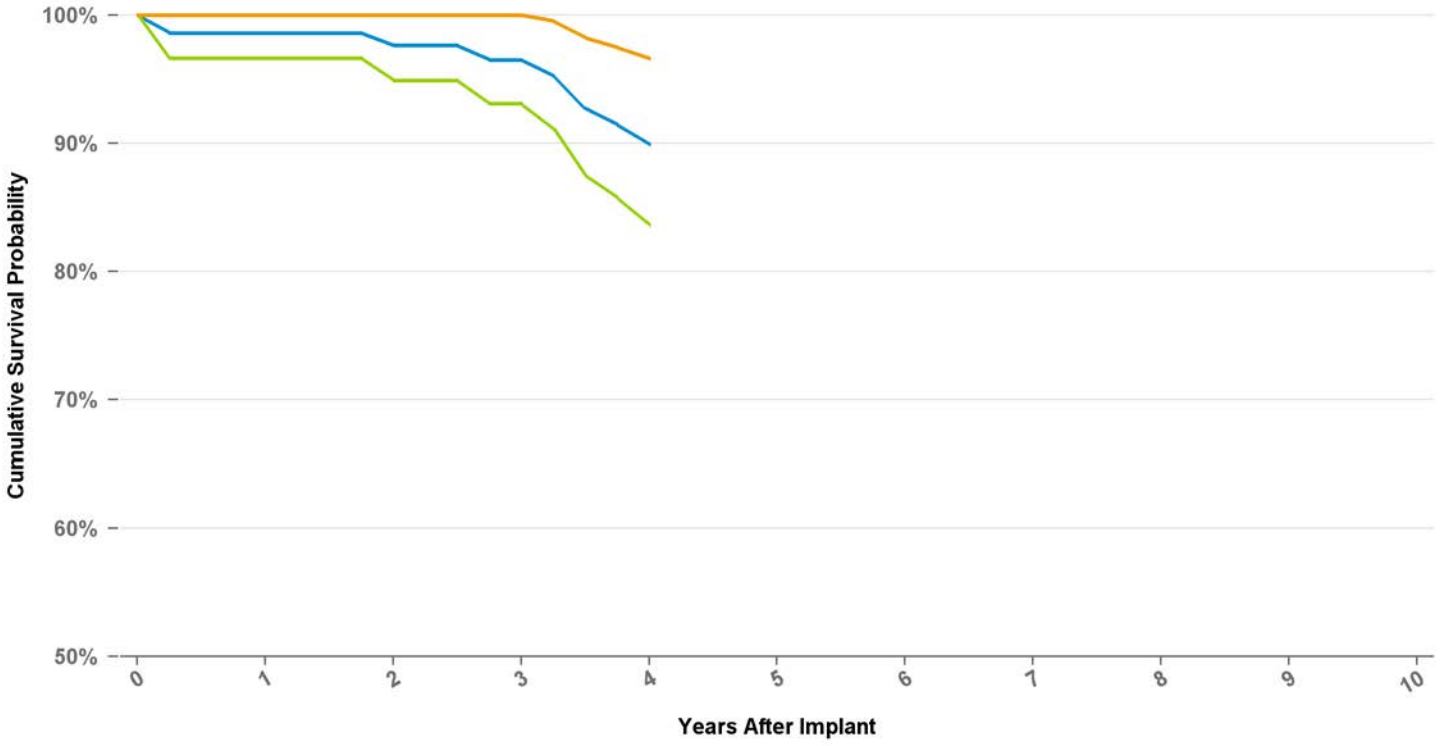
Distribution Data	
US Market Release	09/06/1996
CE Approval Date	01/01/1993
Registered US Implant	21,405
Estimated Active US	9,428
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	226
Cumulative Months of Follow-Up	6,388
Number of Leads Active in Study	29

Product Surveillance Registry Qualifying Complications	13
Cardiac Perforation	0
Conductor Fracture	6
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	4
Failure To Sense	5
Impedance Abnormal	5
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	180
Crimp Weld Bond	1
Insulation Breach	39
Other	0

4965, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4965_SURV

Lower 95 Pct Confidence Graph - 4965_SURV

Upper 95 Pct Confidence Graph - 4965_SURV

Years	1	2	3	at 48 mo
%	98.6%	97.6%	96.5%	89.9%
#	120	103	81	55

EPI MYOCARDIAL LEAD 4968

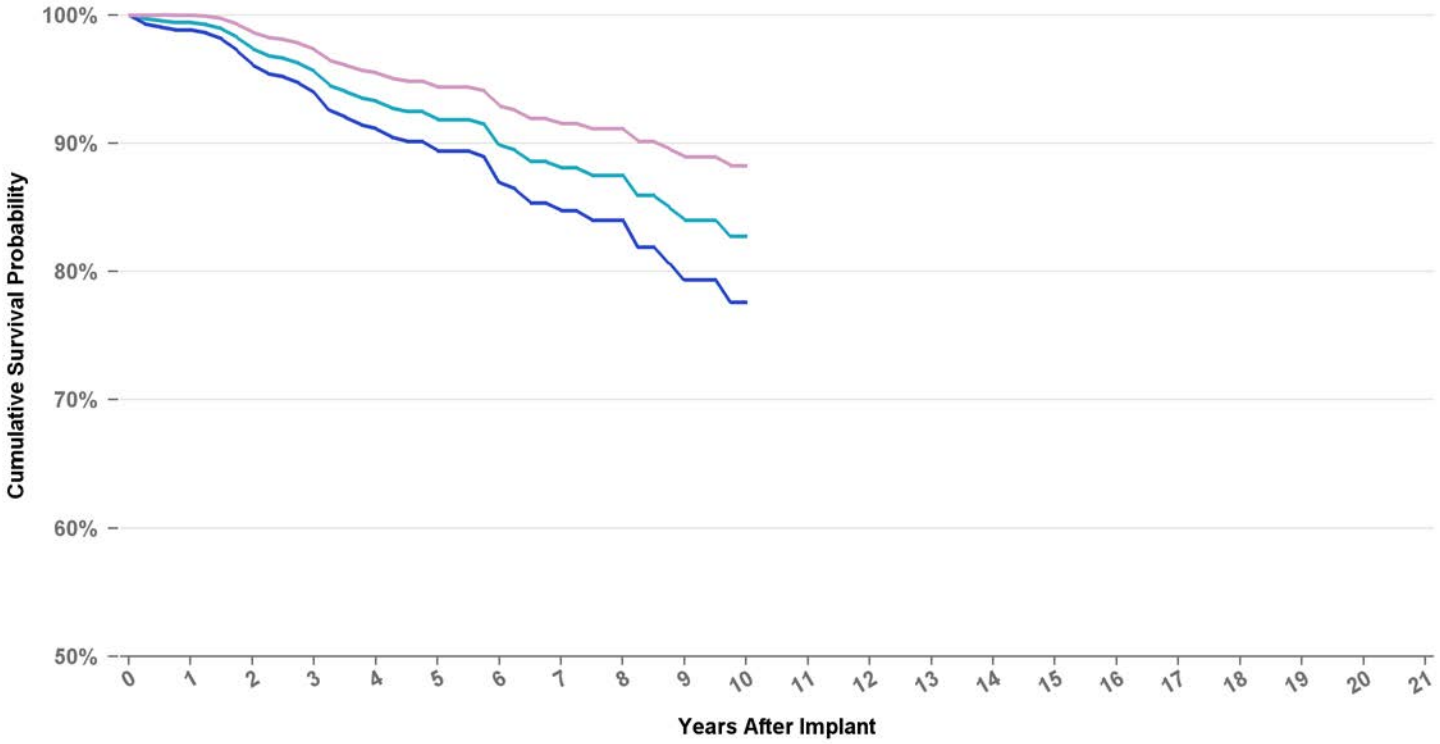
Distribution Data	
US Market Release	09/16/1999
CE Approval Date	04/21/1998
Registered US Implant	30,568
Estimated Active US	18,857
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	829
Cumulative Months of Follow-Up	40,201
Number of Leads Active in Study	303

Product Surveilance Registry Qualifying Complications	63
Cardiac Perforation	0
Conductor Fracture	14
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	22
Failure To Sense	3
Impedance Abnormal	5
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	3
Lead Dislodgement	0
Medical Judgment	0
Other Complication	1
Oversensing	13
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	18
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	3
Oversensing	4
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	38
Crimp Weld Bond	0
Insulation Breach	21
Other	1

4968, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 4968_SURV

Lower 95 Pct Confidence Graph - 4968_SURV

Upper 95 Pct Confidence Graph - 4968_SURV

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.4%	97.4%	95.6%	93.3%	91.9%	89.9%	88.1%	87.5%	84.0%	82.8%
#	630	542	450	345	286	213	159	112	73	54

EPI MYOCARDIAL LEAD 5071

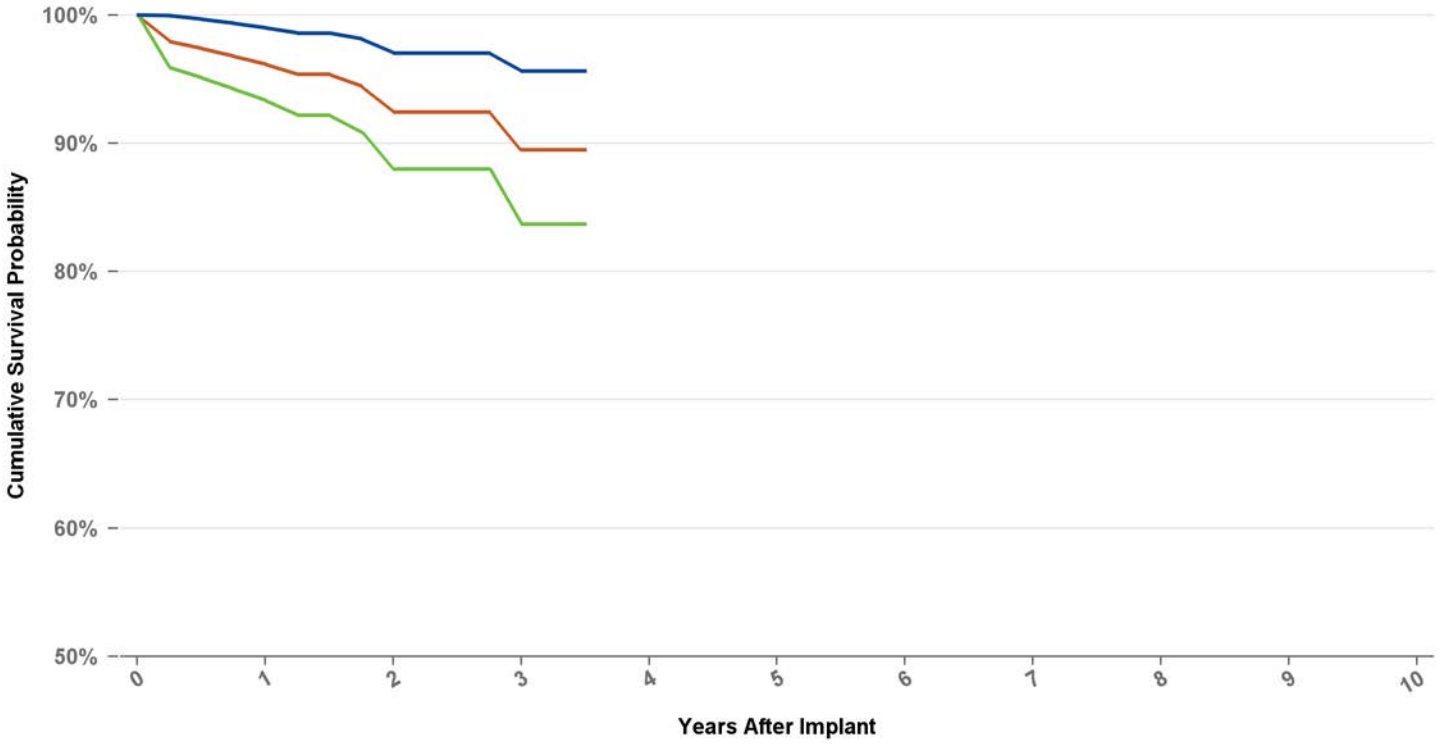
Distribution Data	
US Market Release	12/03/1992
CE Approval Date	01/01/1993
Registered US Implant	46,017
Estimated Active US	15,556
Product Characteristics	
Fixation Type	Fixed Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Myocardial
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	331
Cumulative Months of Follow-Up	6,671
Number of Leads Active in Study	84

Product Surveilance Registry Qualifying Complications	15
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	12
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	2
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	0
Extracardiac Stimulation	3
Failure To Capture	34
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach	0
Lead Dislodgement	0
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	2
Other	0

5071, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5071_SURV

Lower 95 Pct Confidence Graph - 5071_SURV

Upper 95 Pct Confidence Graph - 5071_SURV

Years	1	2	3	at 42 mo
%	96.2%	92.4%	89.5%	89.5%
#	124	86	58	55

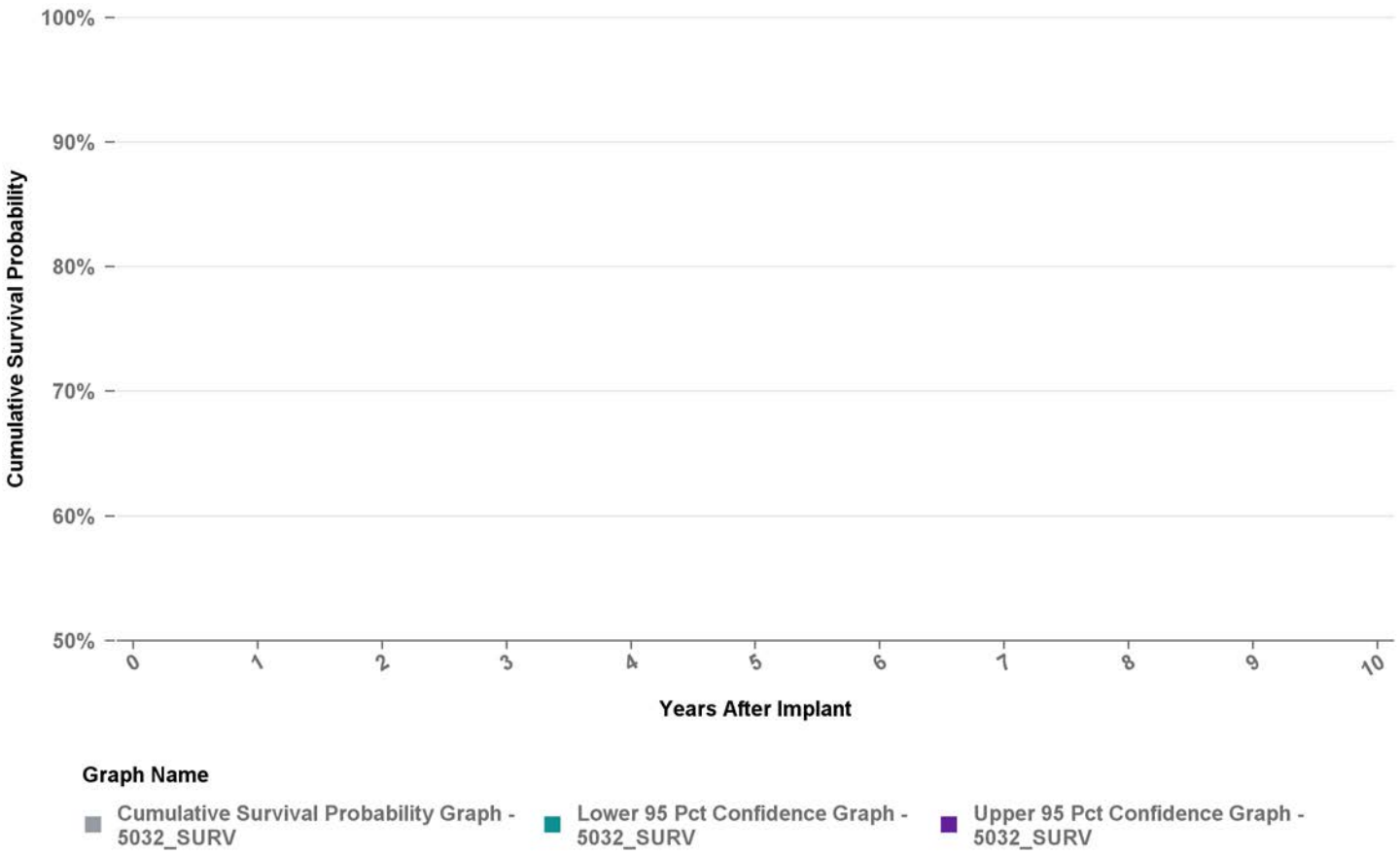
VDD SINGLE PASS LEAD 5032

Distribution Data	
US Market Release	03/22/1996
CE Approval Date	
Registered US Implant	5,218
Estimated Active US	1,129
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Quadripolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	287
Number of Leads Active in Study	0

Product Surveillance Registry Qualifying Complications	1
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	1
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	6
Other	0



Years	
%	
#	

VDD SINGLE PASS LEAD 5038

Distribution Data	
US Market Release	09/10/1998
CE Approval Date	04/15/1997
Registered US Implant	8,973
Estimated Active US	3,412
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Quadripolar

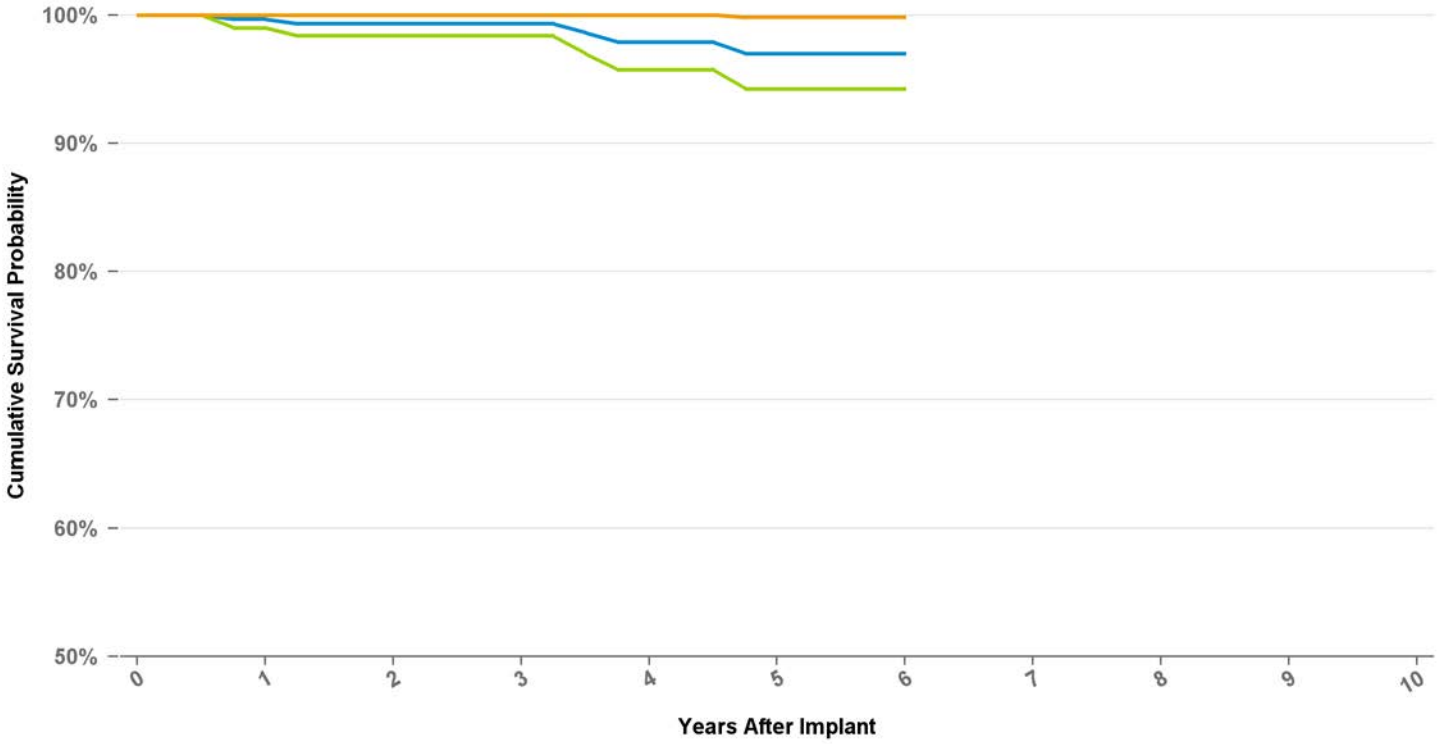
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	564
Cumulative Months of Follow-Up	14,215
Number of Leads Active in Study	42

Product Surveilance Registry Qualifying Complications	7
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	2
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	0
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	2
Oversensing	0
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	1
Other	0

5038, Survival Curve



Graph Name

Cumulative Survival Probability Graph - 5038_SURV

Lower 95 Pct Confidence Graph - 5038_SURV

Upper 95 Pct Confidence Graph - 5038_SURV

Years	1	2	3	4	5	at 72 mo
%	299.0%	297.9%	297.9%	293.7%	290.9%	290.9%
#	284	217	158	128	98	62

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.

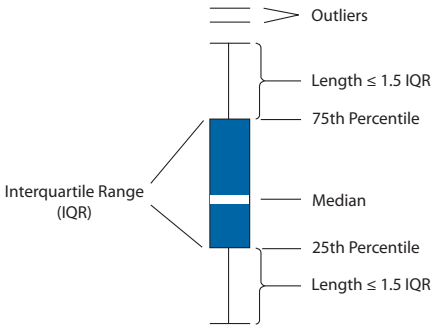
Data from over 20,000 devices contribute to the charge time data in this report. By tracking and reporting this charge time data, Medtronic is able to ascertain the actual performance of its charging circuitry. The insight gained through this information is applied to Medtronic's ongoing efforts to provide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

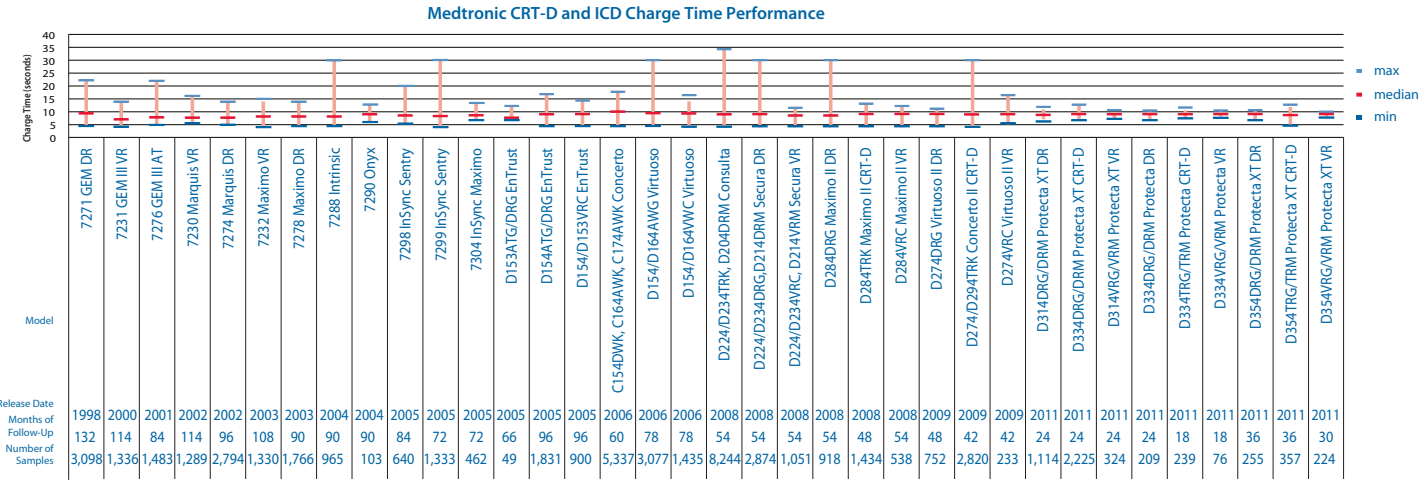
Data Presentation

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.

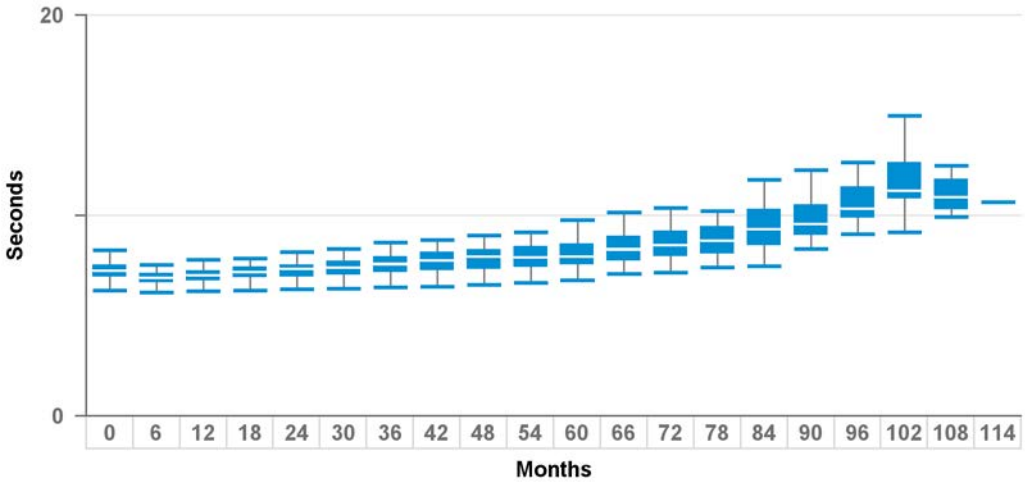




ICD and CRT-D Charge Time Performance

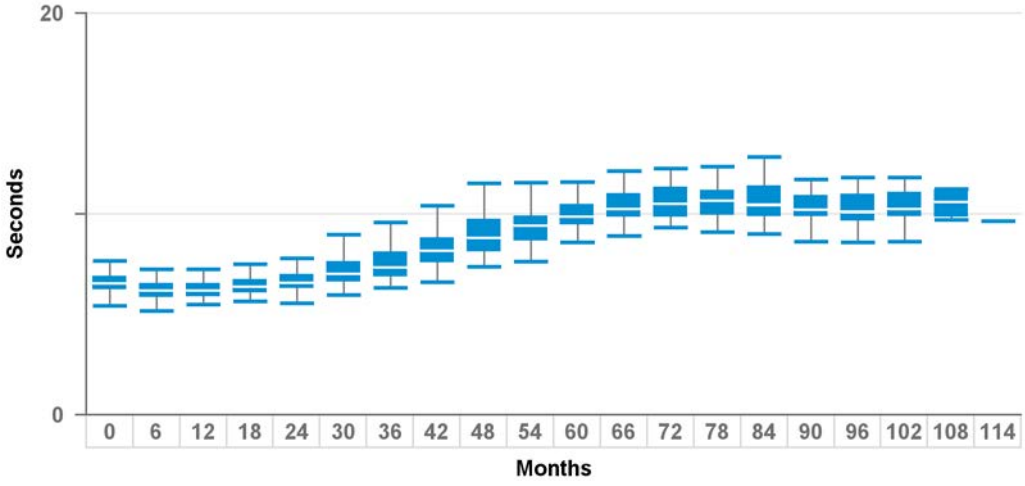
7230 Charge Time

Model Number	Brand
7230B	Marquis VR
7230Cx	Marquis VR
7230E	Marquis VR



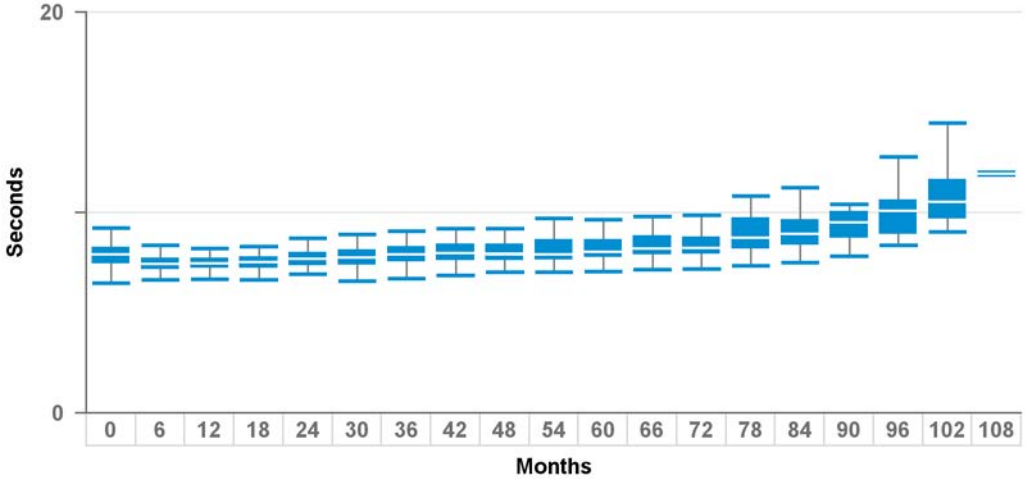
7231 Charge Time

Model Number	Brand
7231Cx	GEM III VR



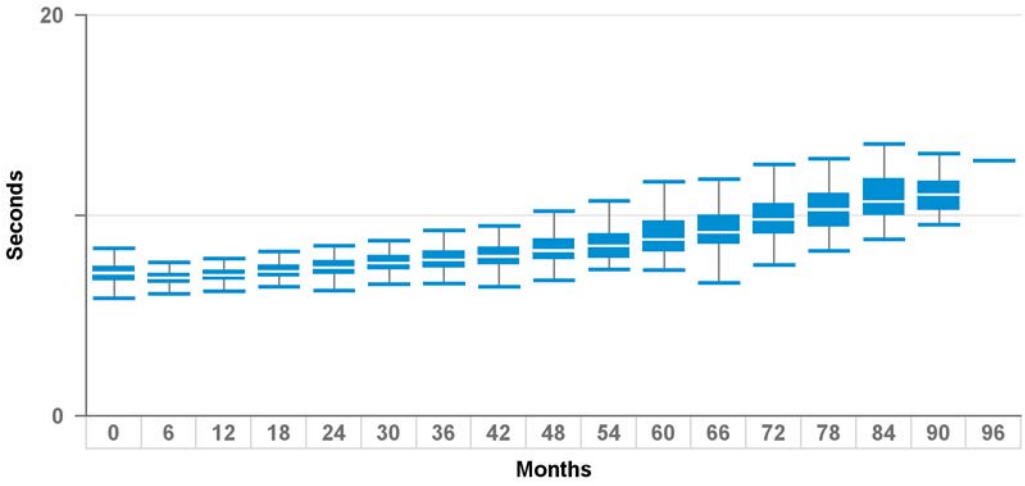
7232 Charge Time

Model Number	Brand
7232B	Maximo VR
7232Cx	Maximo VR
7232E	Maximo VR



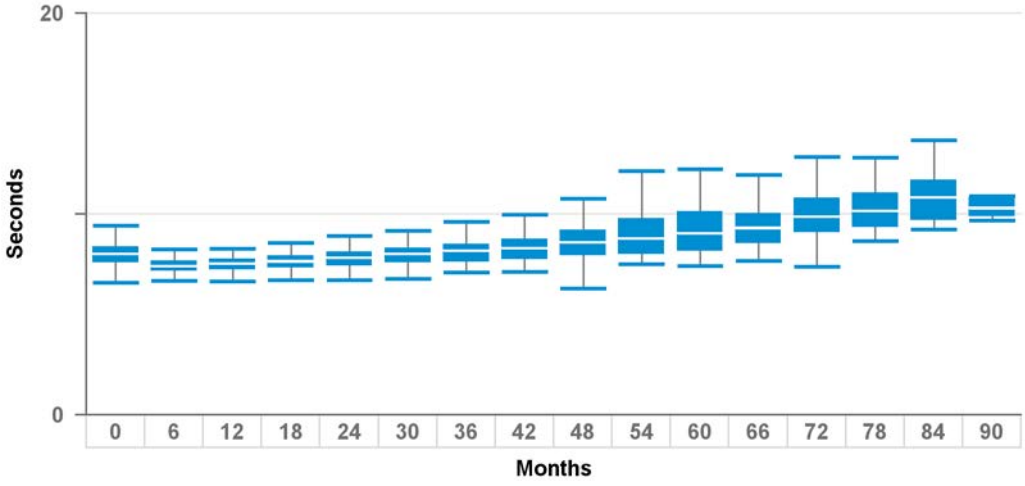
ICD and CRT-D Charge Time Performance
7274 Charge Time

Model Number	Brand
7274	Marquis DR



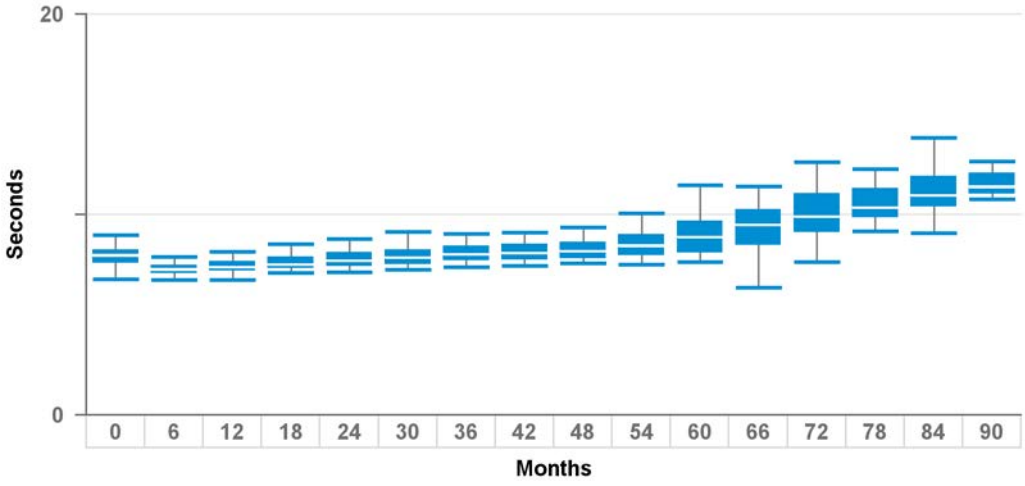
7278 Charge Time

Model Number	Brand
7278	Maximo DR



7288 Charge Time

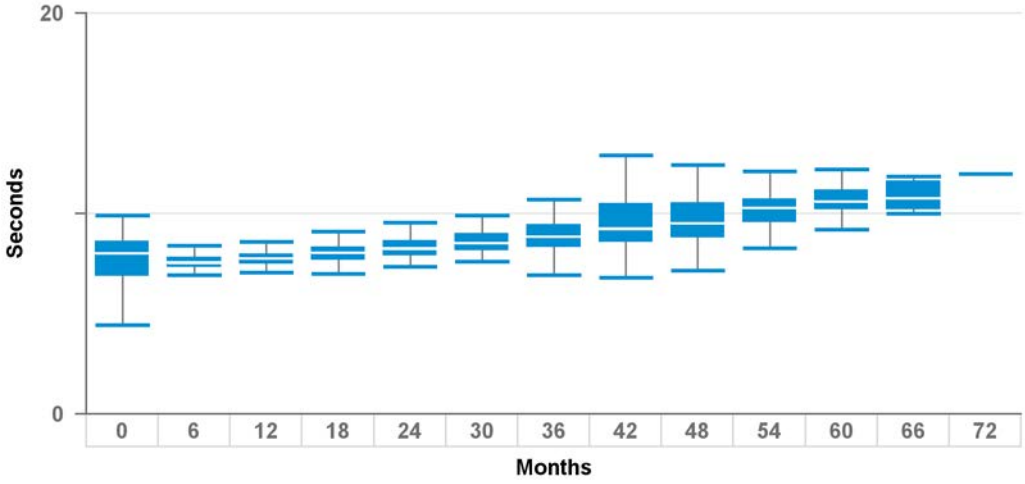
Model Number	Brand
7288	Intrinsic



ICD and CRT-D Charge Time Performance

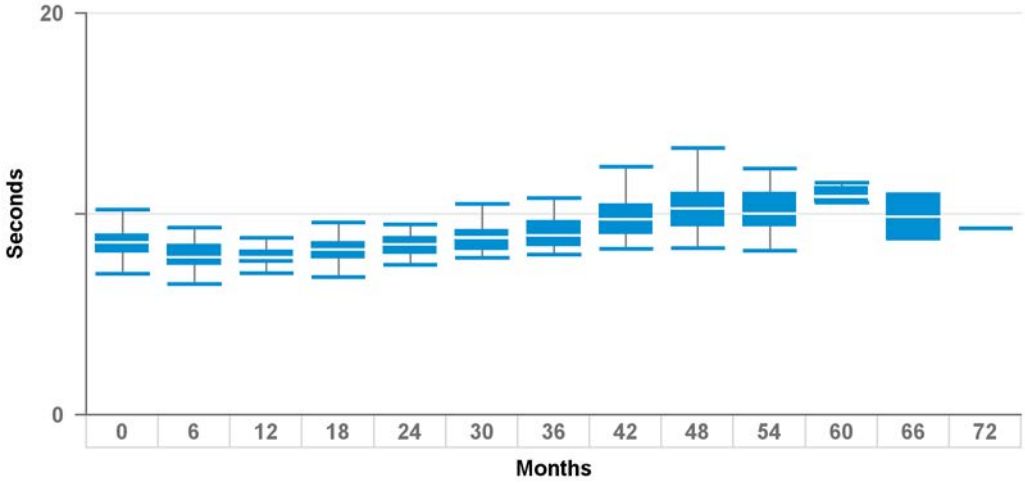
7299 Charge Time

Model Number	Brand
7299	InSync Sentry



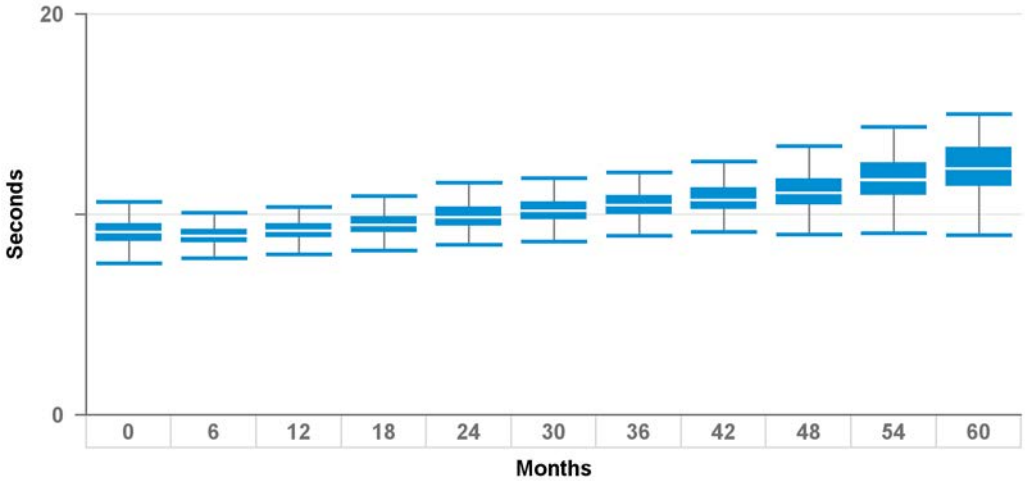
7304 Charge Time

Model Number	Brand
7304	InSync Maximo



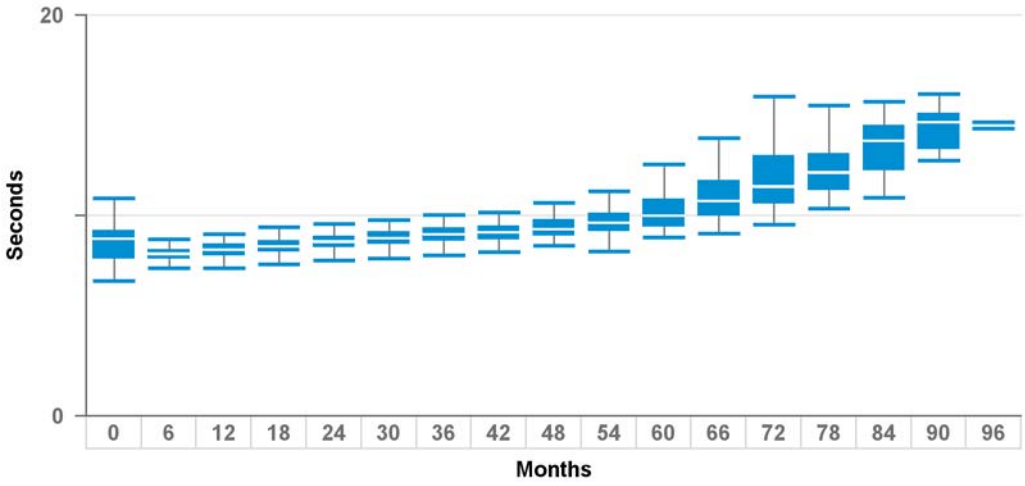
C154DWK, C164AWK, C174AWK Charge Time

Model Number	Brand
C154DWK	Concerto CRT-D DR
C164AWK	Concerto CRT-D DR AT
C174AWK	Concerto CRT-D DR AT



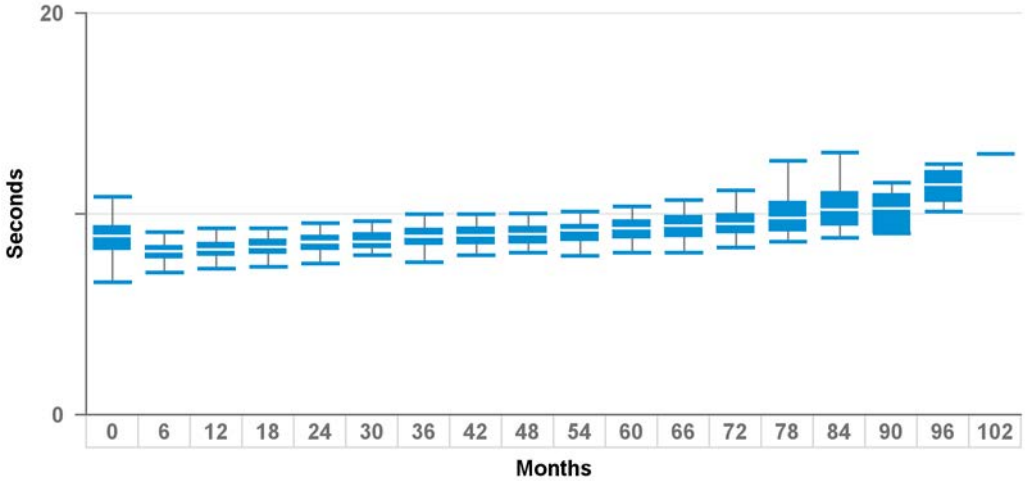
ICD and CRT-D Charge Time Performance
D144DRG, D154ATG, D154DRG Charge Time

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT
D154DRG	Entrust DR



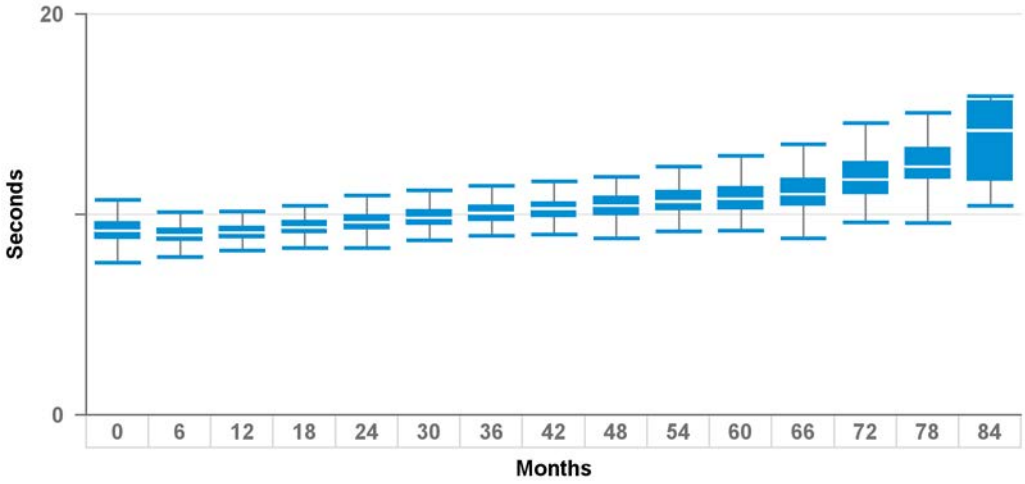
D144VRC, D154VRC Charge Time

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



D154AWG, D164AWG Charge Time

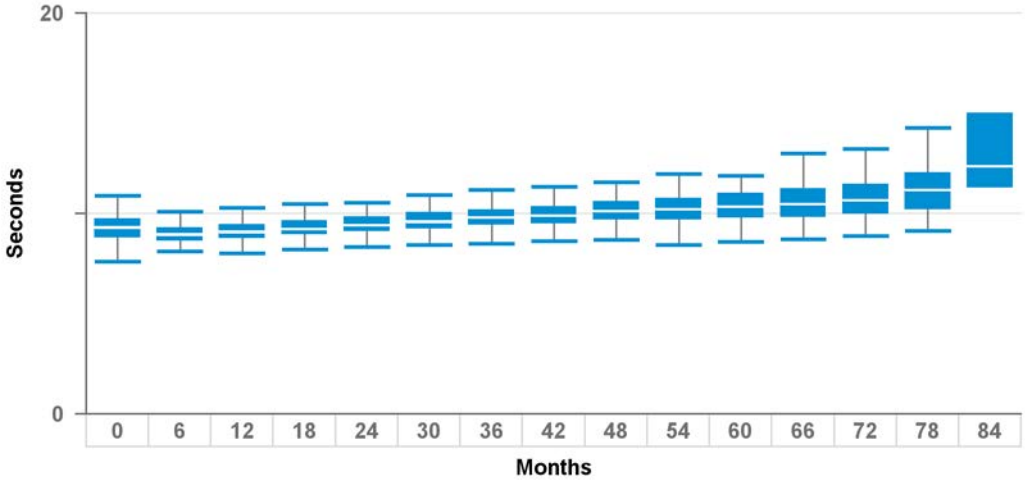
Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



ICD and CRT-D Charge Time Performance

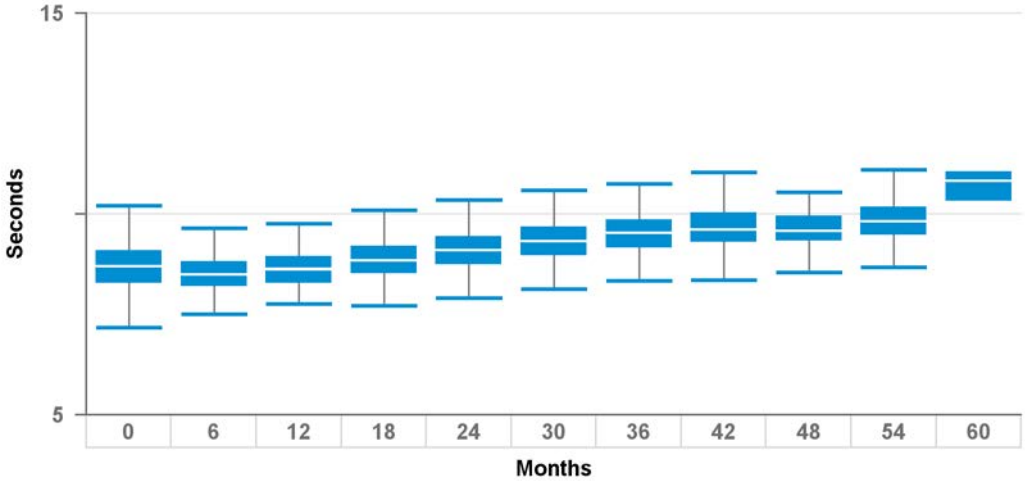
D154VWC, D164VWC Charge Time

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



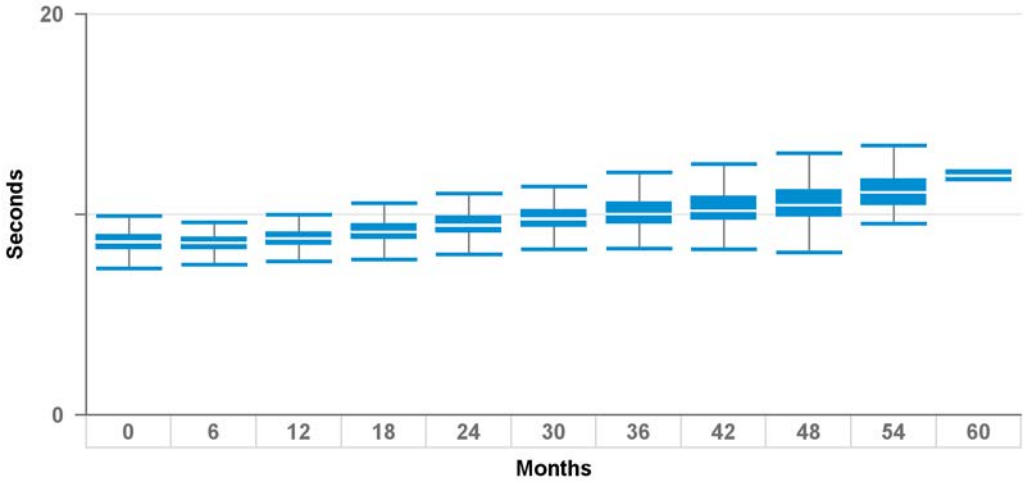
D204DRM, D214DRM, D224DRG, D234DRG Charge Time

Model Number	Brand
D204DRM	Secura DR
D214DRM	Secura DR
D224DRG	Secura DR
D234DRG	Secura DR



D204TRM, D214TRM, D224TRK, D234TRK Charge Time

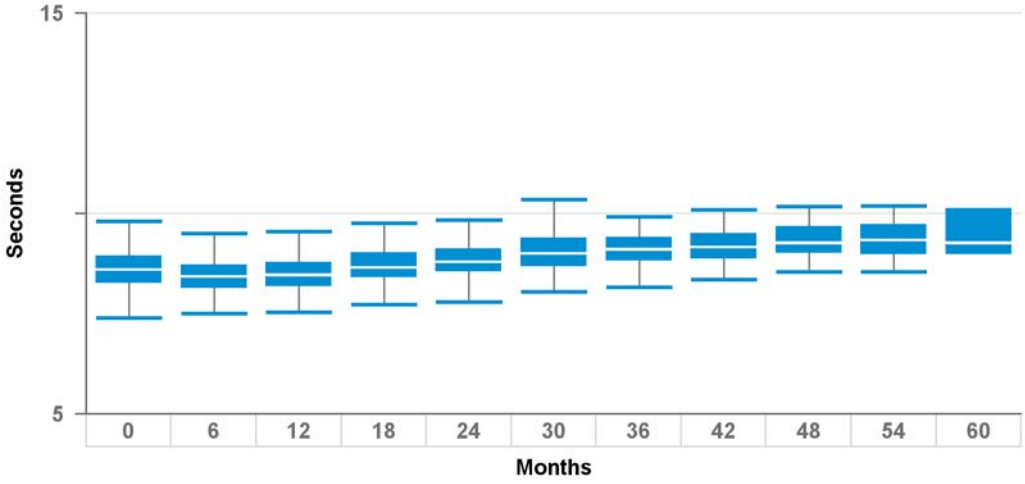
Model Number	Brand
D204TRM	Consulta CRT-D
D214TRM	Consulta CRT-D
D224TRK	Consulta CRT-D
D234TRK	Consulta CRT-D



ICD and CRT-D Charge Time Performance

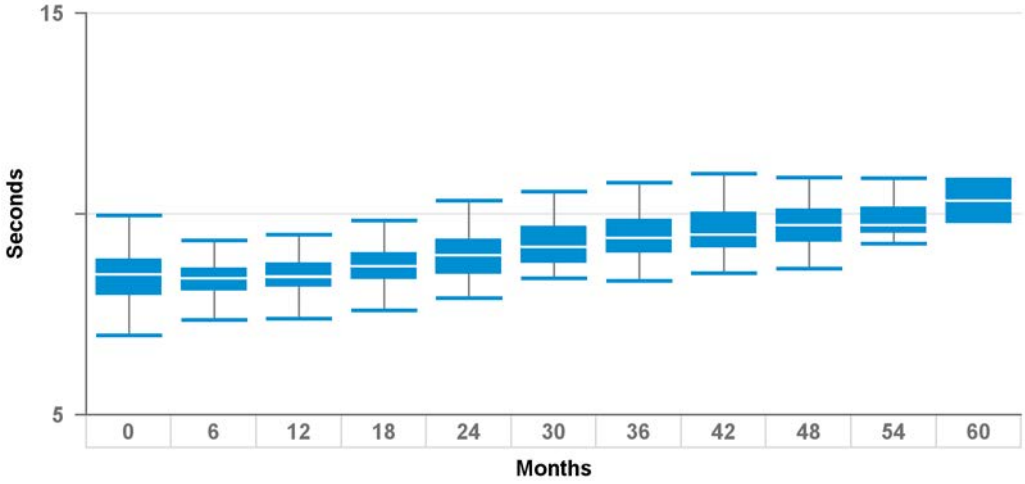
D204VRM, D214VRM, D224VRC, D234VRC Charge Time

Model Number	Brand
D204VRM	Secura VR
D214VRM	Secura VR
D224VRC	Secura VR
D234VRC	Secura VR



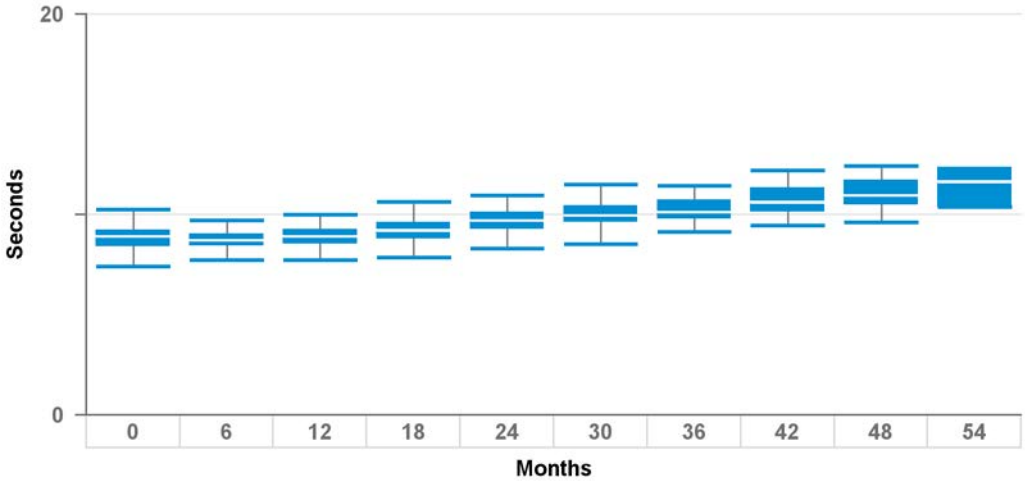
D264DRG, D284DRG, D384DRx, D394DRx Charge Time

Model Number	Brand
D264DRM	Maximo II DR
D284DRG	Maximo II DR
D384DRG	Cardia DR
D394DRG	Egida DR



D264TRM, D284TRK, D384TRx, D394TRx Charge Time

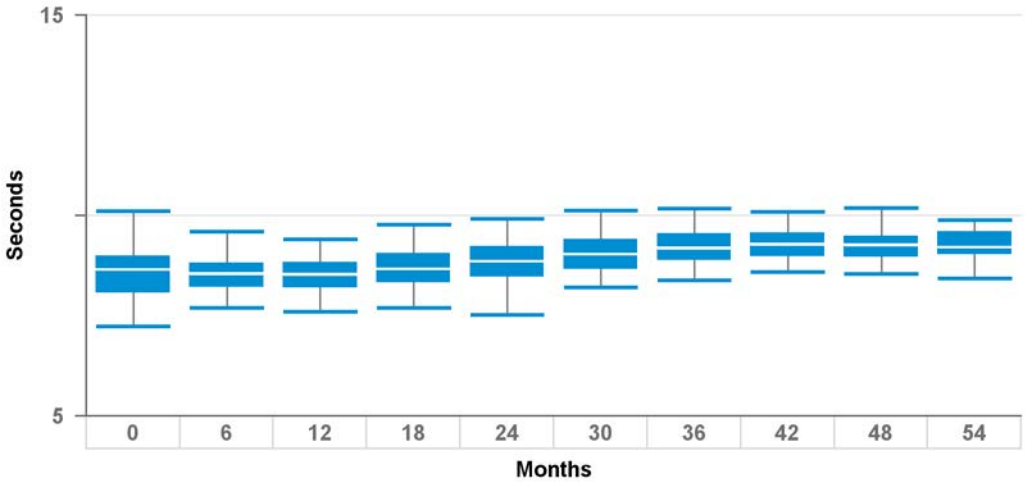
Model Number	Brand
D264TRM	Maximo II CRT-D
D284TRK	Maximo II CRT-D
D384TRG	Cardia CRT-D
D394TRG	Egida CRT-D



ICD and CRT-D Charge Time Performance

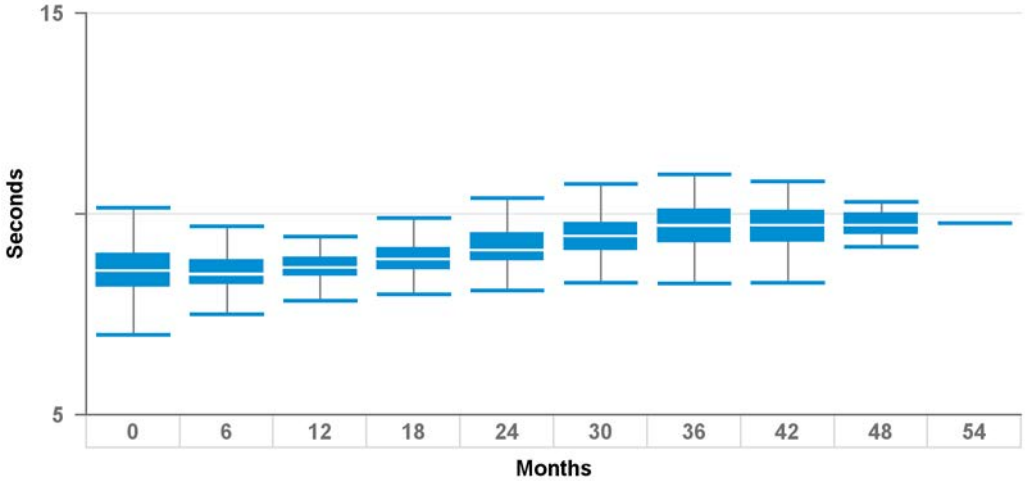
D264VRM, D284VRC, D384VRx, D394VRx Charge Time

Model Number	Brand
D264VRM	Maximo II VR
D284VRC	Maximo II VR
D384VRG	Cardia VR
D394VRG	Egida VR



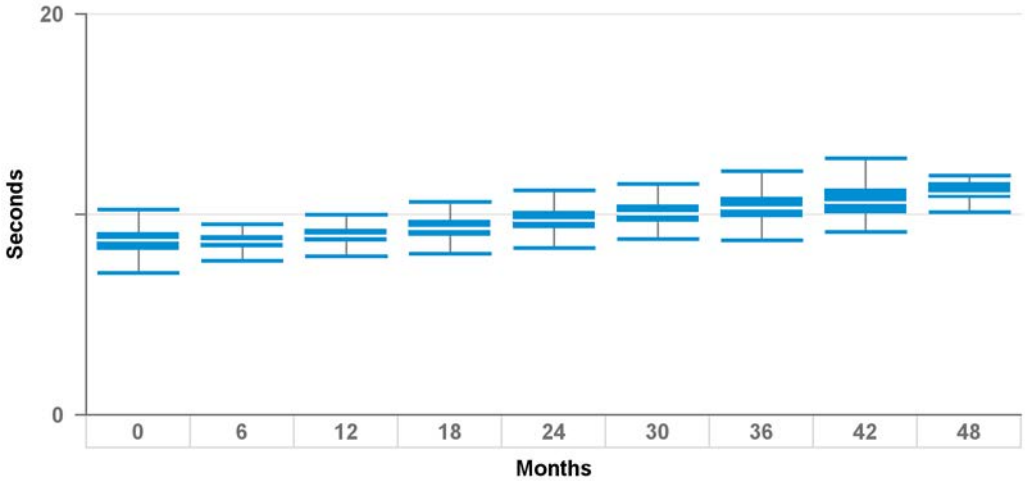
D274DRG, D294DRG Charge Time

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



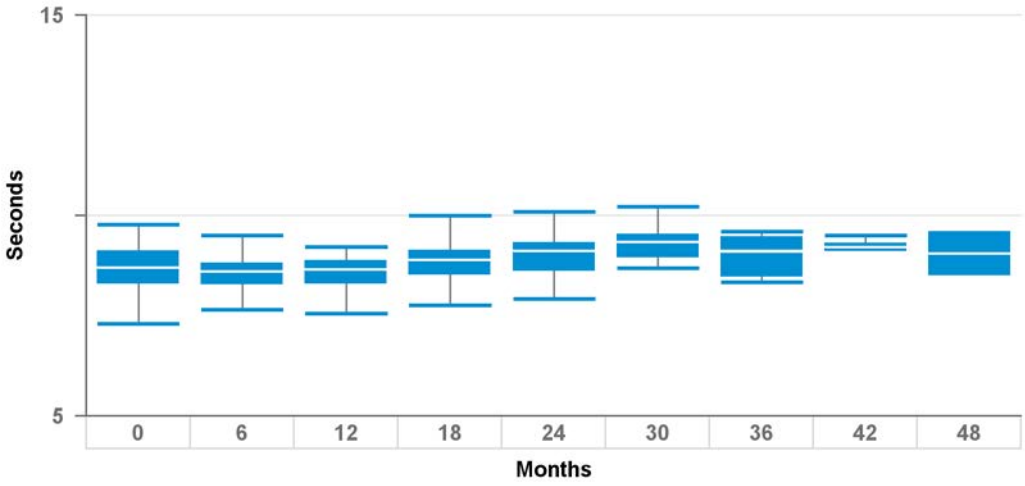
D274TRK, D294TRK Charge Time

Model Number	Brand
D274TRK	Concerto II CRT-D
D294TRK	Concerto II CRT-D



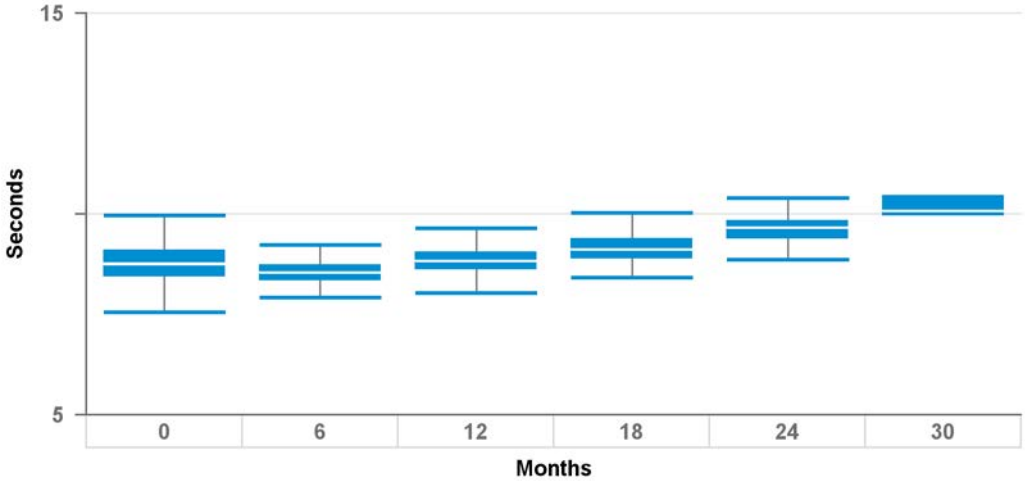
ICD and CRT-D Charge Time Performance
D274VRC, D294VRC Charge Time

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



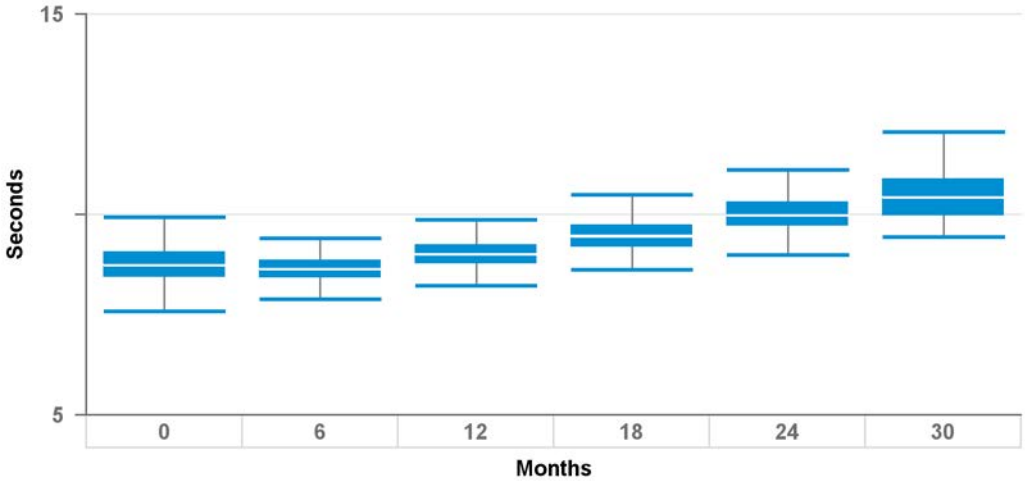
D314DRx Charge Time

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



D314TRx Charge Time

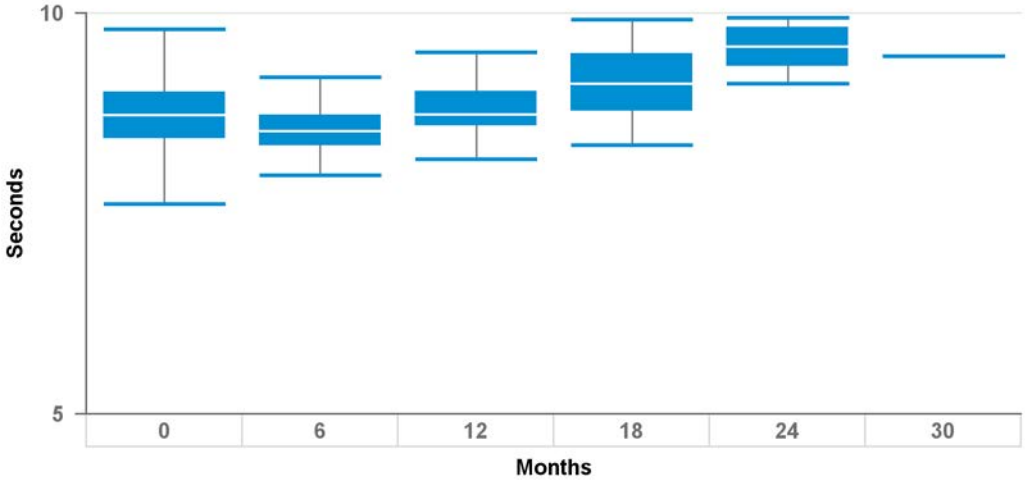
Model Number	Brand
D314TRG	Protecta XT CRT-D
D314TRM	Protecta XT CRT-D



ICD and CRT-D Charge Time Performance

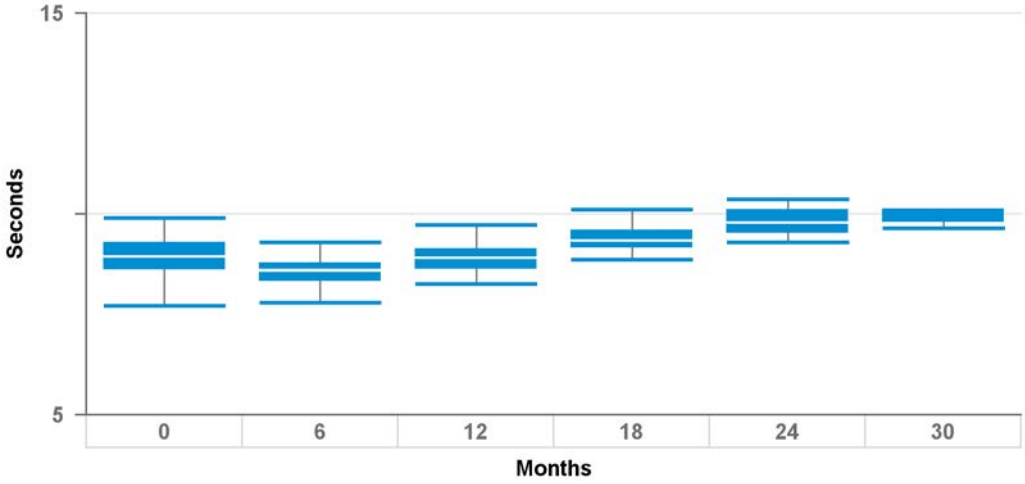
D314VRx Charge Time

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



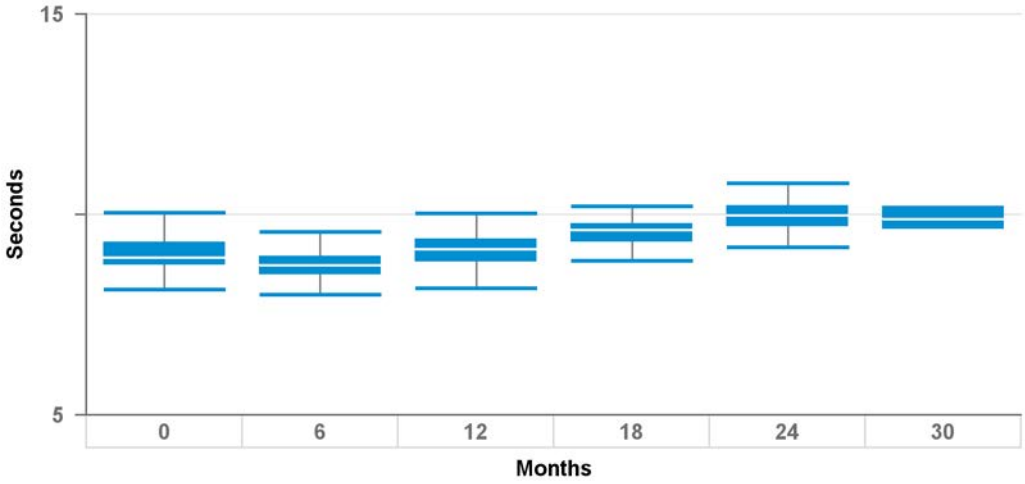
D334DRx, D364DRx Charge Time

Model Number	Brand
D334DRG	Protecta DR
D334DRM	Protecta DR
D364DRG	Protecta DR
D364DRM	Protecta DR



D334TRx, D364TRx Charge Time

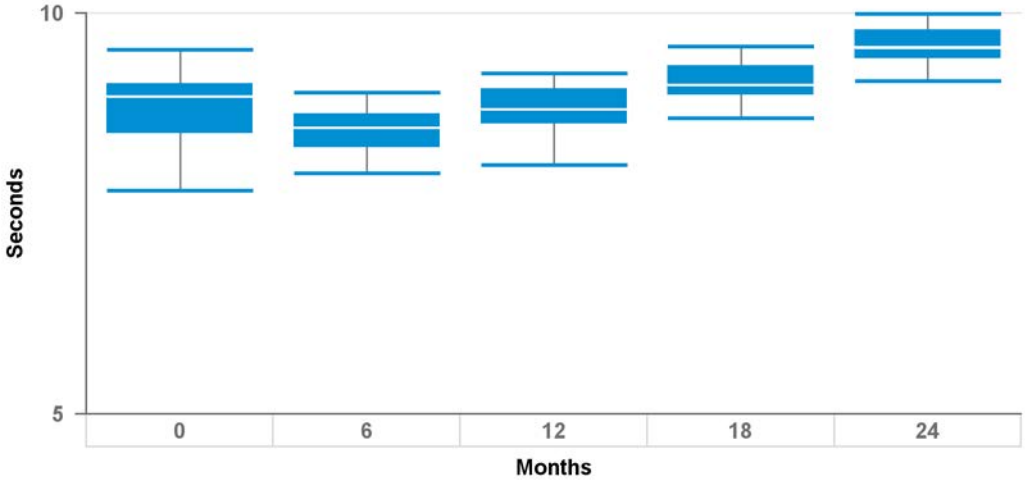
Model Number	Brand
D334TRG	Protecta CRT-D
D334TRM	Protecta CRT-D
D364TRG	Protecta CRT-D
D364TRM	Protecta CRT-D



ICD and CRT-D Charge Time Performance

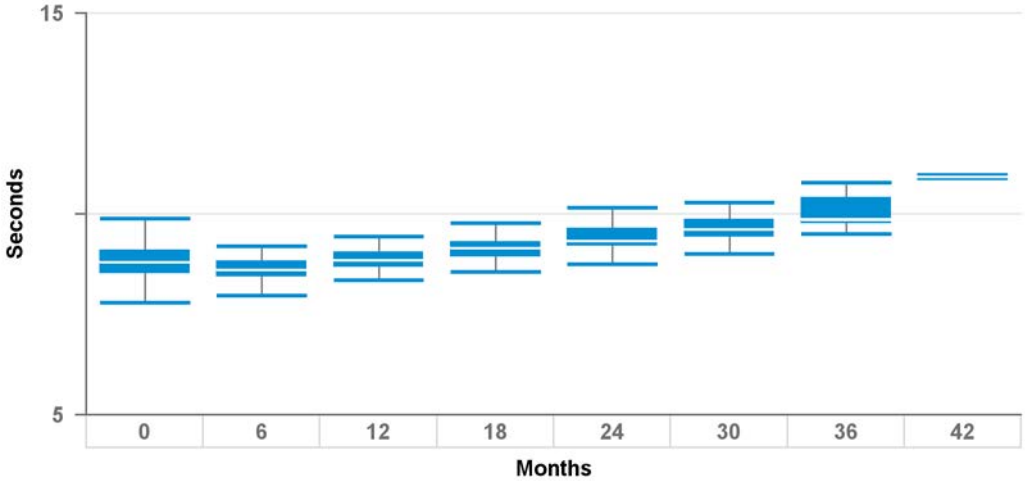
D334VRx, D364VRx Charge Time

Model Number	Brand
D334VRG	Protecta VR
D334VRM	Protecta VR
D364VRG	Protecta VR
D364VRM	Protecta VR



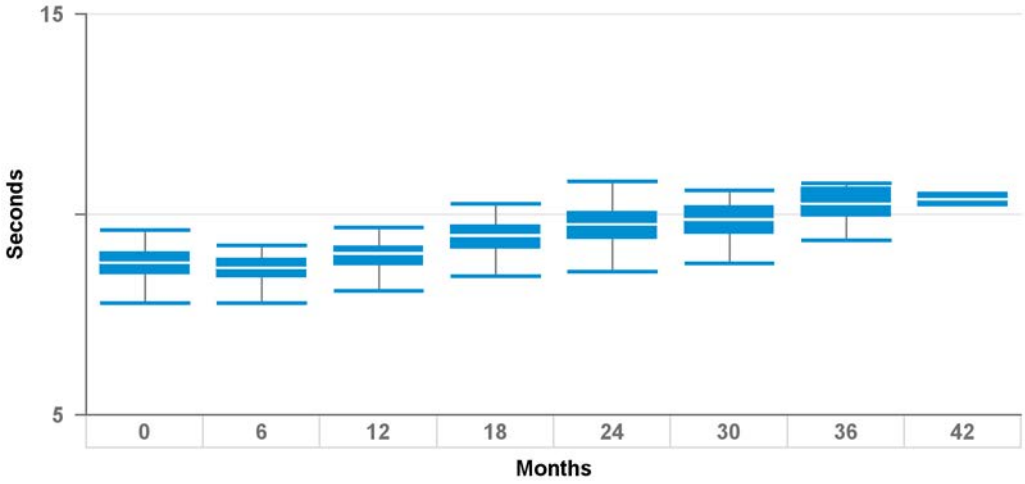
D354DRx Charge Time

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



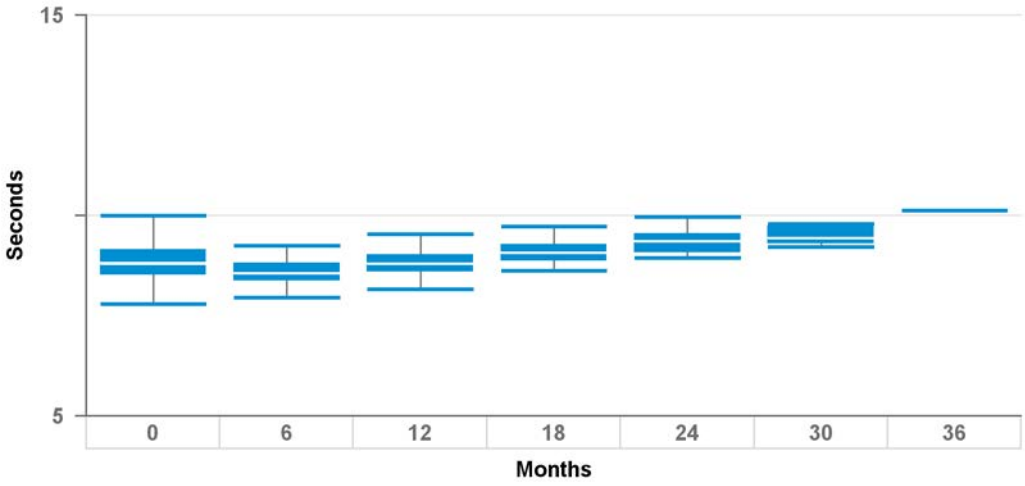
D354TRx Charge Time

Model Number	Brand
D354TRG	Protecta XT CRT-D
D354TRM	Protecta XT CRT-D



ICD and CRT-D Charge Time Performance
D354VRx Charge Time

Model Number	Brand
D354VRG	Protecta XT VR
D354VRM	Protecta XT VR



Potential Loss Of Device Hermeticity

Consulta® CRT-P and Syncra® CRT-P
Original Date of Advisory: June 2013

Product

Consulta® CRT-P and Syncra® CRT-P. Go to http://wwwp.medtronic.com/productperformance/ to determine if a specific device is affected.

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 January 31, 2014, 536 of the 779 devices have been returned from field inventory. Medtronic estimates the remaining 226 devices (41 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)	**226** Worldwide (**41** United States)	**0%** Worldwide (**0%** United States)

Specific Models This Applies To

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

Potential Rapid Battery Depletion

EnTrust® VR/DR/AT ICDs
Original Date of Advisory: March 2012

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 January 31, 2014, there have been 84 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)	**84** Worldwide (**64** United States)	**20,000** Worldwide (**12,900** United States)	**0.12%** Worldwide (**0.15%** United States)

Specific Models This Applies To

D144DRG Entrust Escudo
D144VRC Entrust Escudo
D153ATG Entrust AT
D153DRG Entrust DR
D153VRC Entrust VR
D154ATG Entrust AT
D154DRG Entrust DR
D154VRC Entrust VR

Low Battery Voltage Displayed at Device Interrogation

EnRhythm and EnRhythm MRI Pacemakers
Original Date of Advisory: February 2010

Product

All EnRhythm and EnRhythm MRI pacemakers.

Original Advisory Information (February 2010)

Two specific battery issues with EnRhythm pacemakers were identified. The risks to patients for both issue have been addressed by a Medtronic software update.

First Issue

In 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.

Medtronic's investigation found that none of these reports resulted in loss of therapy. Importantly, the original ERI notification, which uses the nightly battery voltage measurement, was unaffected and accurate. Medtronic identified the root cause as higher than expected battery impedance.

Medtronic's internal testing showed there was 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 obviates this risk.

Second Issue

Through internal accelerated testing, Medtronic identified a second issue that projects battery voltage could decrease sooner than expected due to a slightly increased rate of lithium depletion near end of device life. 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 eliminates 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 2.69V, whichever comes sooner.

Battery Issue	Software Update
Battery voltage could decrease sooner that expected due to a slightly increased rate of lithium depletion	Changed ERI battery voltage threshold from 2.59V to 2.81V 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 5000 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.
- 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.

Status Update

First Issue

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 September 10, 2013, percentage of devices that encountered ERI due to battery impedance has not exceeded the rate of 6-10% within 5 years of post-implant as communicated with our August 2011 Performance Update. Only devices using the updated software can trigger ERI due to impedance.

Initial Affected Population	Number of Confirmed ERIs due to impedance	Number of Confirmed ERIs due to impedance within 5 years post-implant	Estimated ERI rate due to impedance within 5 years post-implant[2]	Confirmed events of loss of therapy due to battery impedance	Estimated Remaining Active Population
All EnRhythm pacemakers (**146,500**	**10,081** Worldwide	**4,009**	**4.3%**	**0**	**79,100** Worldwide

Second Issue

Initial Affected Population	Number of Events of Loss of Therapy Due to Increased Rate of Lithium Depletion	Estimated Remaining Active Population
All EnRhythm pacemakers (**146,500** Worldwide)	**0** Worldwide	**79,100** Worldwide

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[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.*

[2]*Accounts for underreporting of impedance ERIs based on the fraction of replaced devices in the U.S. registration system that are subsequently returned.*

Specific Models This Applies To

EMDR01 EnRhythm MRI EMDR02 EnRhythm MRI P1501DR EnRhythm DR

Potential Reduced Device Longevity

Concerto CRT-D and Virtuoso ICD
Original Date of Advisory: September 2009

Product

A subset of Concerto CRT-D and Virtuoso ICD devices may not meet expected device longevity. You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ 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 January 31, 2014, 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 100 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 (**3,170** United States)	**<100** Worldwide (**<100** United States)	**42%** Worldwide (**45%** United States)

Specific Models This Applies To

C154DWK Concerto CRT-D DR
C164AWK Concerto CRT-D DR AT
C174AWK Concerto CRT-D DR AT
D154AWG Virtuoso DR
D154VWC Virtuoso VR
D164AWG Virtuoso DR
D164VWC Virtuoso VR

Potential Separation of Interconnect Wires (2009)

Kappa 600/700/900 and Sigma 100/200/300 Pacemakers
Original Date of Advisory: May 2009

Product

A specific subset of Kappa and Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ 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 January 31, 2014, Medtronic has observed 459 Kappa devices and 301 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-two (422) of the Kappa devices (0.72%) and 234 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. Approximately 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.

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
Kappa Pacemakers				
58,300 Implanted Worldwide (est.) (**17,600** United States)	**422** Worldwide (**222** United States) with information indicating a clinical presentation. An additional **37** worldwide (**25** US) without information indicating a clinical presentation or with insufficent 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)	**234** Worldwide (**50**United States) with information indicating a clinical presentation. An additional **67** worldwide (**17** US) without information indicating a clinical presentation or with insufficent information to determine the state of the device at explant.	**2,000** Worldwide (**500** United States)	**2**% Worldwide (**1.8**% United States)	**4.8%**

Specific Models This Applies To

KD701 Kappa 700 DR
KD703 Kappa 700 DR
KD706 Kappa 700 DR
KDR601 Kappa 600 DR
KDR603 Kappa 600 DR
KDR606 Kappa 600 DR
KDR651 Kappa 600 DR
KDR653 Kappa 600 DR
KDR701 Kappa 700 DR
KDR703 Kappa 700 DR
KDR706 Kappa 700 DR
KDR721 Kappa 700 DR
KDR921 Kappa 900 DR
KSR701 Kappa 700 SR
KSR703 Kappa 700 SR
KSR706 Kappa 700 SR
KSR901 Kappa 900 SR
KSR903 Kappa 900 SR
KSR906 Kappa 900 SR
KVDD701 Kappa 700 VDD
KVDD901 Kappa 900 VDD
SD203 Sigma 200 D
SD303 Sigma 300 D
SDR203 Sigma 200 DR
SDR303 Sigma 300 DR
SDR306 Sigma 300 DR
SR353 Sigma
SS103 Sigma 100 S
SS106 Sigma 100 S
SS203 Sigma 200 S
SS303 Sigma 300 S
SSR203 Sigma 200 SR
SSR303 Sigma 300 SR
SSR306 Sigma 300 SR
SVDD303 Sigma 300 VDD
SVVI103 Sigma 100 VVI

Potential Conductor Wire Fracture

6930, 6931, 6948, 6949 Sprint Fidelis Defibrillation Leads
Original Date of Advisory: October 2007

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 January 31, 2014, of the initial implant population of 205,600 in the United States, approximately 81,500 remain implanted. According to System Longevity Study results, lead survival is estimated to be 79.1% (+4.7/-4.5%) at 90 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.

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)	**6,514** Worldwide(**4,586** United States)	**104,000** Worldwide(**81,500** United States)	

Footnotes:

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

2: "Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management", Heart Rhythm, Vol 6, No 7, July 2009.

Specific Models This Applies To

6930 Sprint Fidelis
6931 Sprint Fidelis
6948 Sprint Fidelis
6949 Sprint Fidelis

Potential Separation of Interconnect Wires (2005)

Sigma Implantable Pulse Generators
Original Date of Advisory: November 2005

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ 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 January 31, 2014, 811 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred forty-seven(447) 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 5,600 remain implanted. Approximately 1,300 of these are in the United States.

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)	Predicted Malfunction Rate Over the Remaining Life of the Devices Still Implanted
40,000 Implanted Worldwide (est.) (**9,900** United States)	**447** Worldwide (**88** 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.	**5,600** Worldwide (**1,300** United States)	**2.0%** Worldwide (**1.5%** United States)	**3.9%**

Specific Models This Applies To

SD203 Sigma 200 D
SD303 Sigma 300 D
SDR203 Sigma 200 DR
SDR303 Sigma 300 DR
SDR306 Sigma 300 DR
SS103 Sigma 100 S
SS106 Sigma 100 S
SS203 Sigma 200 S
SS303 Sigma 300 S
SSR203 Sigma 200 SR
SSR303 Sigma 300 SR
SSR306 Sigma 300 SR
SVDD303 Sigma 300 VDD
SVVI103 Sigma 100 VVI

Advisories continued

Potential Premature Battery Depletion Due to Battery Short

Marquis 7274, 7230 Maximo 7278, 7232 InSync 7277, 7289, 7279, 7285 Original Date of Advisory: February 2005

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. You may use the "Search for Information by Serial Number" tool at http://wwwp.medtronic.com/productperformance/ 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 January 31, 2014, 192 Marquis Family devices have been confirmed as having this internal battery shorting mechanism. One hundred fifteen (116) of these devices were returned from the United States.

Out of the initial advisory population of 87,000 worldwide, approximately 2,200 remain implanted. Approximately 1,900 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
87,000 Worldwide (**76,000** United States)	**192** Worldwide (**116** United States)	**2,200** Worldwide (**1,900** United States)	**0.22%** Worldwide (**0.15%** United States)	Consistent with Medtronic projections, the observed rate of shorting may be between **0.2%** and **1.5%** over the second half of device life.

Specific Models This Applies To

7230B Marquis VR
7230Cx Marquis VR
7230E Marquis VR
7232B Maximo VR
7232Cx Maximo VR
7232E Maximo VR
7274 Marquis DR
7277 InSync Marquis
7278 Maximo DR
7279 InSync III Marquis
7285 InSync III Protect
7289 InSync II Marquis
7295 InSync II Protect
7299 InSync Sentry

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.

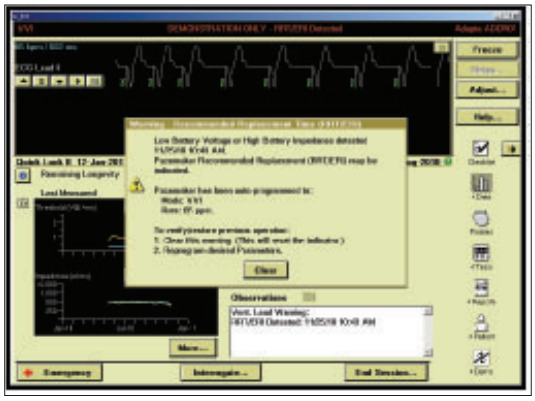
Background

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

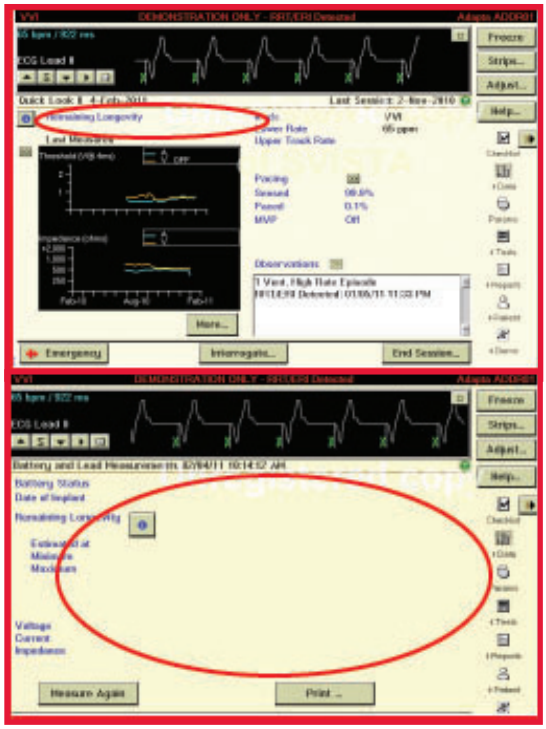


Reset Method for Kappa and EnPulse

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.

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 continued

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. . . . . Decrease Perforation. . . . . Increase or Decrease Electrolyte Imbalance. . . . . Increase or Decrease Improper IPG/Lead Connection. . . Increase or Decrease	
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase, Especially in Bipolar System	Sudden and Significant Increase	Dislodgement. . . . . Increase Exit Block. . . . . Increase Infarct at Electrode Site. . . . . Increase Perforation. . . . . Increase Improper IPG/Lead Connection. . . 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. . . . . Decrease Perforation . . . . . Decrease Infarct at Electrode Site. . . . . Decrease Electrolyte Imbalance. . . . . Decrease Improper IPG/Lead Connection. . . 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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