Medtronic

Cardiac Rhythm Heart Failure

Product Performance Report

Important Patient Management Information for Physicians

2014

Second Edition – Issue 71

CRHF Product Performance Report

2014 Second Edition
Issue 71

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This report is available online at www.medtronic.com/CRDM ProductPerformance

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 CRHF 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 CRHF 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 Heart Failure Medtronic, Inc.

Contact Information

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

US Technical Services Department

Phone: 1 (800) 723-4636 (Tachy)
1 (800) 505-4636 (Brady)
Fax: 1 (800) 824-2362
www.medtronic.com/corporate/contact.jsp

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

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Europe (Heerlen NL) +31-45-566-8844
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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
CRHF 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, insertable cardiac monitors (ICMs), 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's PAN Registry. 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 Post Approval Network.

Introduction continued

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.

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, ICMs, and leads to Medtronic's Cardiac Rhythm and Heart Failure (CRFH) 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 CRFH 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.

Overview of Survival Analysis

Medtronic uses the Cutler-Ederer actuarial life table method for devices and Kaplan-Meier for leads to estimate the length of time over which they 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.

Introduction continued

For CRTs, 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 CRFH 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 and Method for Estimating Lead Performance.

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.

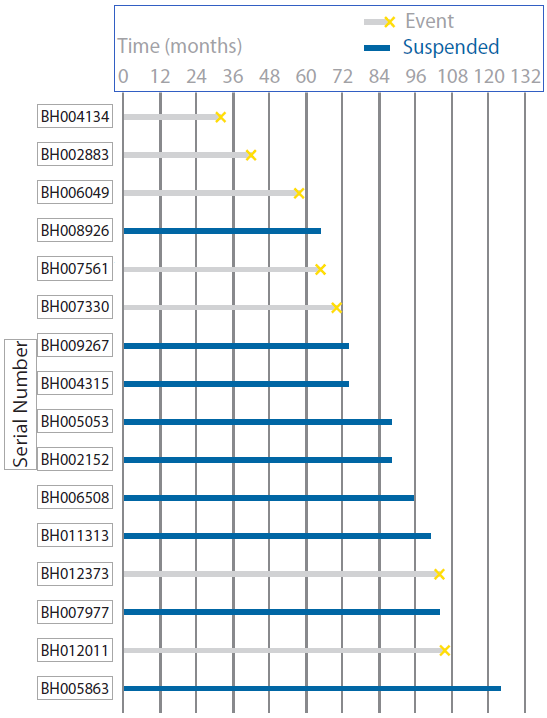


Figure 1 illustrates 16 patients who have implanted devices. The first patient's device (serial number BH004134) operated within performance limits for 32 months. At that time an event occurred. The fourth patient's device (serial number BH008926) did not have an event but is suspended, perhaps because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

Introduction continued

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.

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.

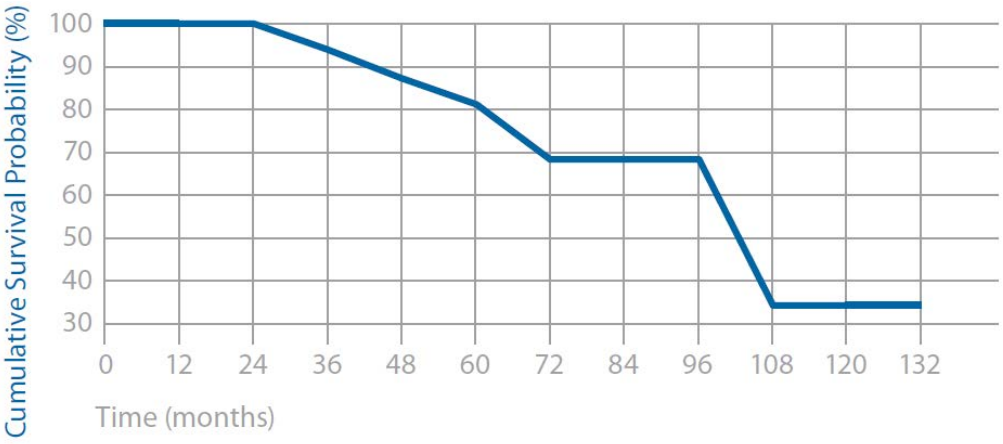
G
Cumulative Survival Probability

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.

Introduction continued

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.

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 device curves are actually computed and plotted using the Cutler-Ederer method and 1-month intervals (for CRT, ICD, and IPG devices) and leads curves are computed and plotted using Kaplan-Meier, which uses individual survival times.

A number of references are available for additional information on survival analysis using the Cutler-Ederer life table method[1] and for the Kaplan-Meier method.[2]

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

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

Method for Estimating CRT, ICD, and IPG Device Performance

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 without malfunction or battery depletion.

The survival estimates are determined from the analysis of Medtronic Cardiac Rhythm and Heart Failure (CRHF'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 CRHF and analyzed in the CRHF 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 CRHF 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 CRHF 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 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 CRHF 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. 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 CRHF maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Statistical Methods for Survival Analysis

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions assumed distributed evenly within the intervals (Cutler-Ederer Method), is used to determine survival estimates for CRT, IPG and ICD devices. 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%.

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 CRHF 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 comparing data in Medtronic's Device And Registrant Tracking (DART) system with data from Returned Product Analysis.

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.

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 devices 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.

Medtronic addresses this under reporting to ensure the number of devices in service is not overstated . Regular updates obtained from the Social Security Administration about deceased persons are 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. The correction factor for under reporting devices is also applied to account for devices that were removed and not reported or returned.

Cardiac Resynchronization Therapy

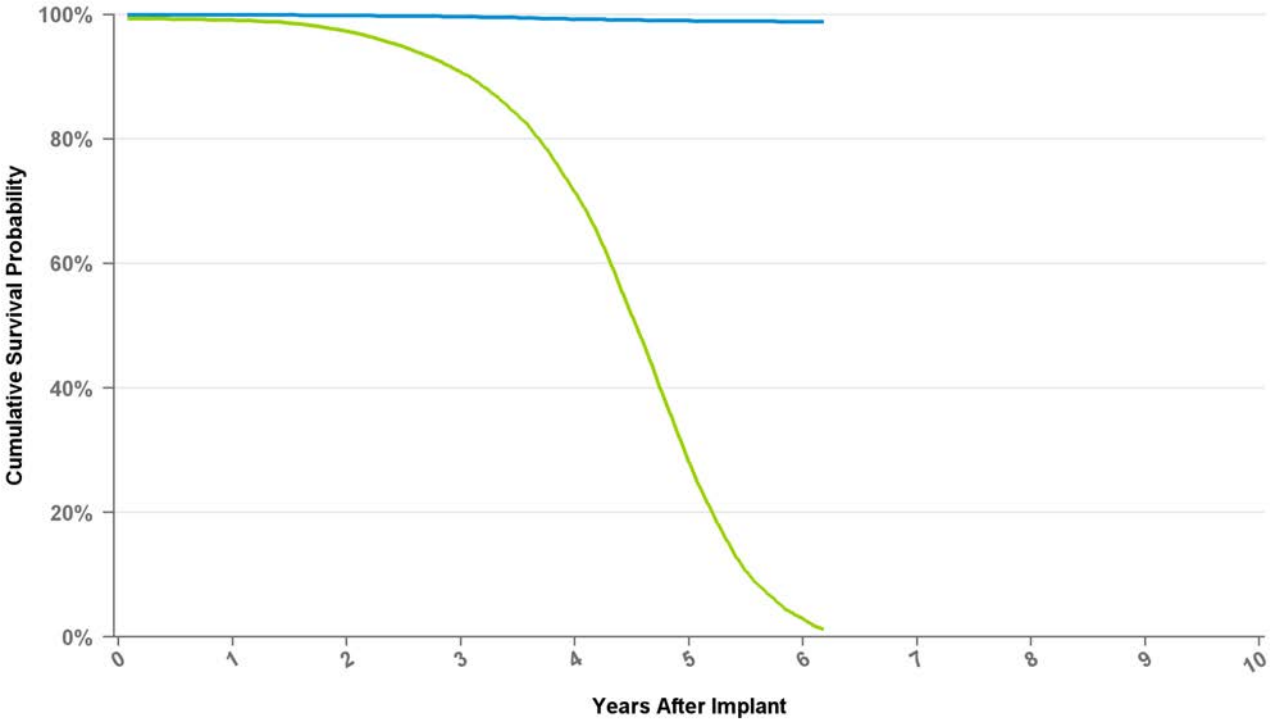
7299 InSync Sentry

US Market Release Date	4/8/2005
CE Market Approval Date	
Registered US Implants	31,184
Estimated Active US Implants	2,033
Normal Battery Depletions (US)	9,899

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 74 mo
Excluding NBD	100.0%	99.9%	99.7%	99.2%	99.0%	98.8%	98.8%
Including NBD	99.1%	97.3%	90.7%	71.5%	28.1%	2.9%	1.3%
Effective Sample Size	27077	23696	19199	12912	4471	299	120

Cardiac Resynchronization Therapy

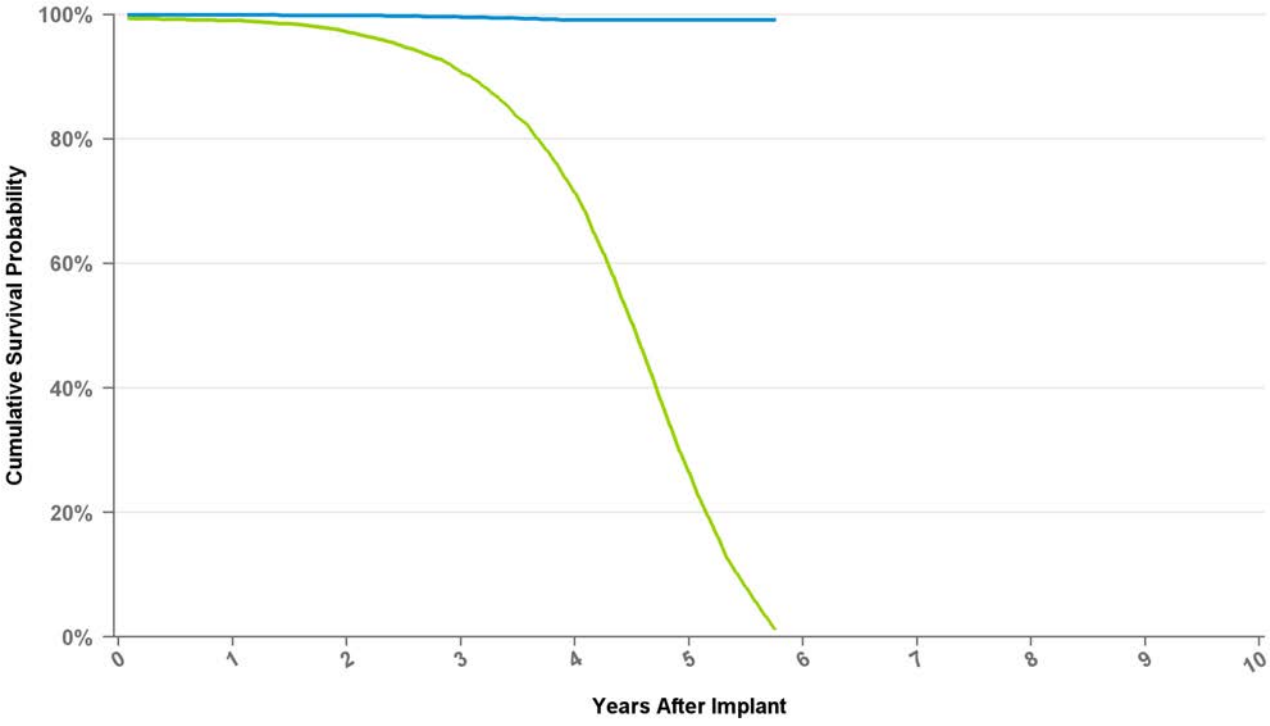
7304 InSync Maximo

US Market Release Date	4/8/2005
CE Market Approval Date	1/14/2005
Registered US Implants	18,984
Estimated Active US Implants	1,516
Normal Battery Depletions (US)	5,546

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	114
Therapy Not Compromised Malfunction	109
Battery Malfunction	1
Electrical Component	15
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	92
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 69 mo
Excluding NBD	100.0%	99.9%	99.6%	99.1%	99.1%	99.1%
Including NBD	99.0%	97.2%	90.7%	71.4%	26.5%	1.4%
Effective Sample Size	16801	14689	11942	8017	2397	141

Cardiac Resynchronization Therapy

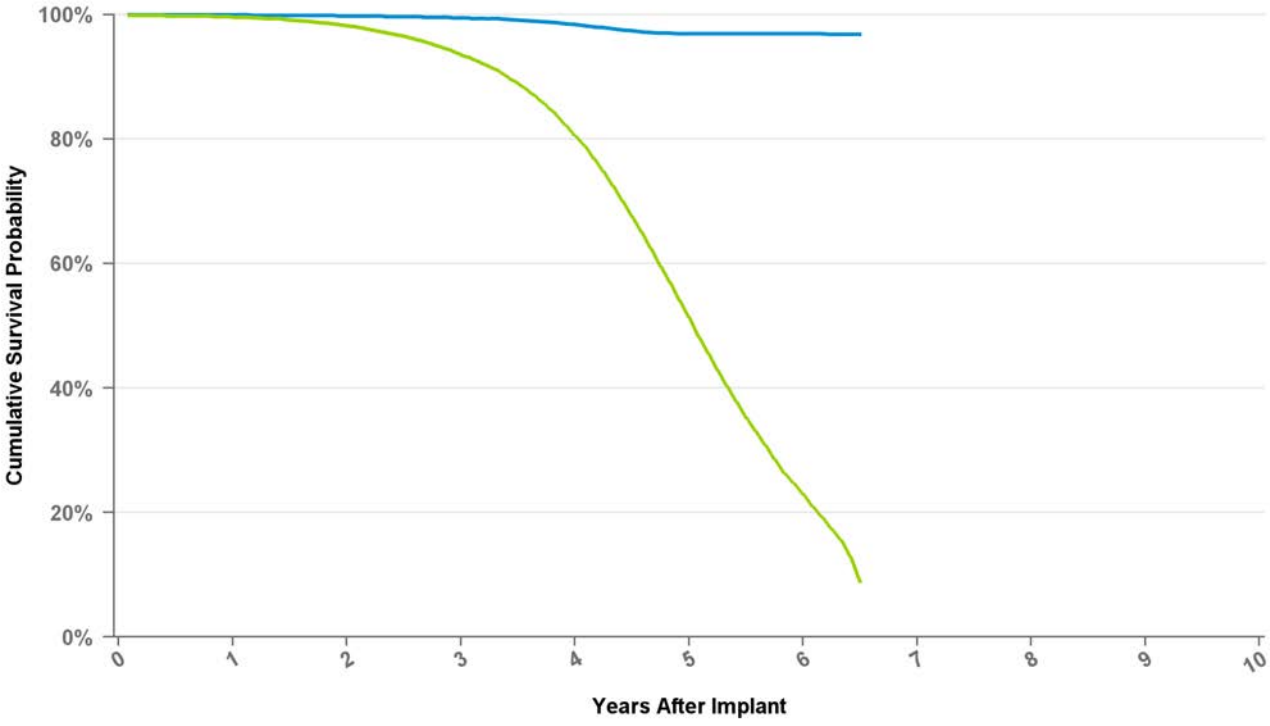
C154DWK Concerto CRT-D

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	81,300
Estimated Active US Implants	15,557
Normal Battery Depletions (US)	21,512

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,421
Therapy Not Compromised Malfunction	1,380
Battery Malfunction	0
Electrical Component	720
Electrical Interconnect	2
Other Malfunction	3
Poss Early Battery Depltn	651
Software Malfunction	4
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%	96.8%
Including NBD	99.6%	98.2%	93.5%	80.6%	51.4%	23.0%	8.9%
Effective Sample Size	72758	64309	54925	42817	23228	4916	484

Cardiac Resynchronization Therapy

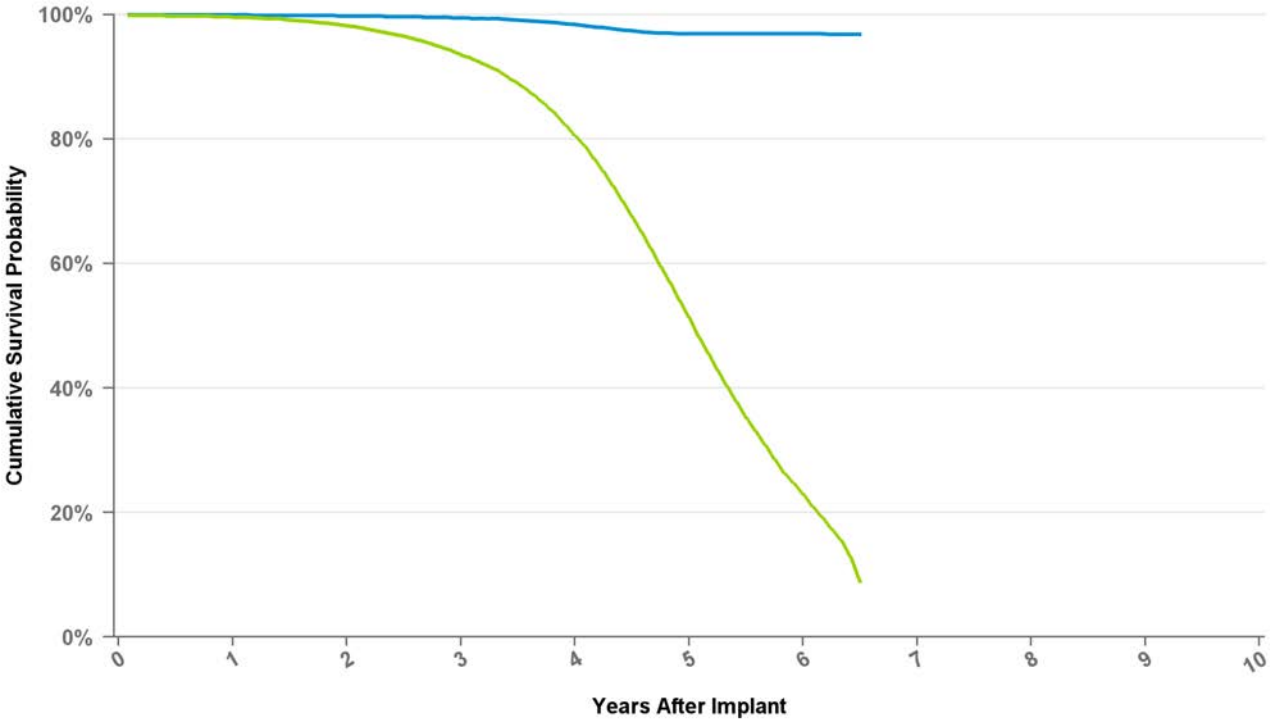
C164AWK Concerto CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%	96.8%
Including NBD	99.6%	98.2%	93.5%	80.6%	51.4%	23.0%	8.9%
Effective Sample Size	72758	64309	54925	42817	23228	4916	484

Cardiac Resynchronization Therapy

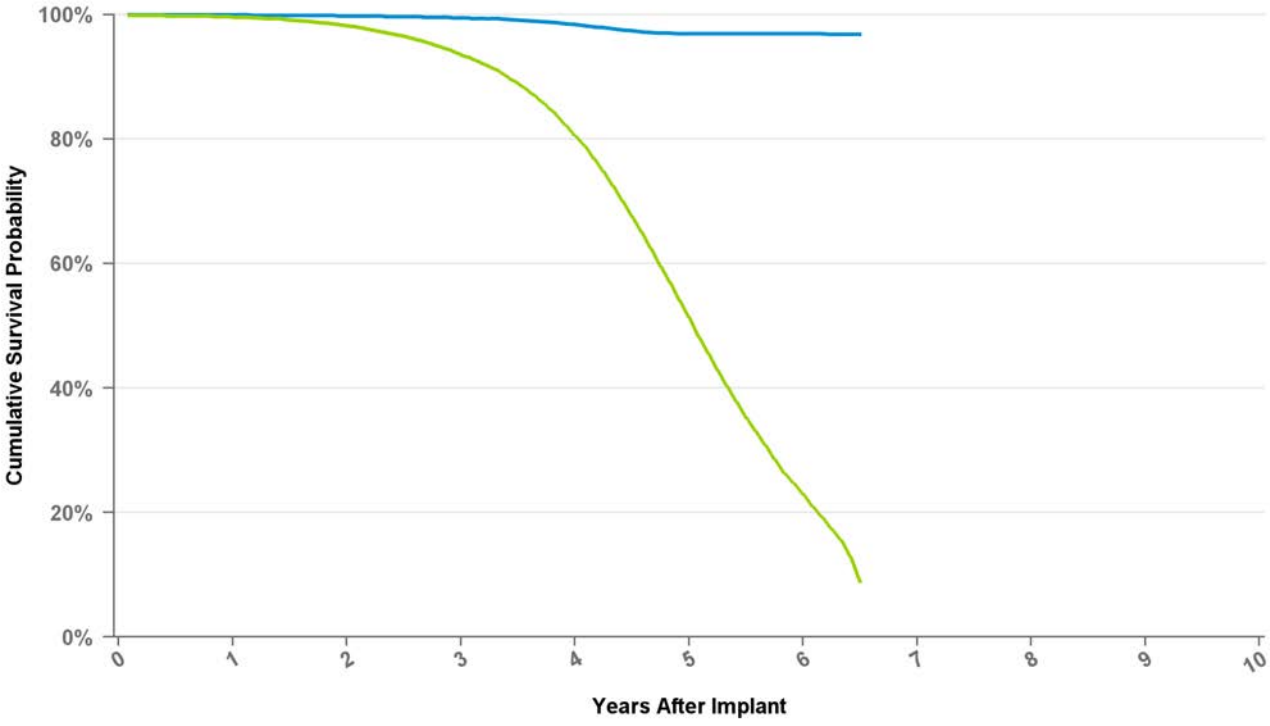
C174AWK Concerto CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 78 mo
Excluding NBD	100.0%	99.8%	99.5%	98.4%	96.9%	96.9%	96.8%
Including NBD	99.6%	98.2%	93.5%	80.6%	51.4%	23.0%	8.9%
Effective Sample Size	72758	64309	54925	42817	23228	4916	484

Cardiac Resynchronization Therapy

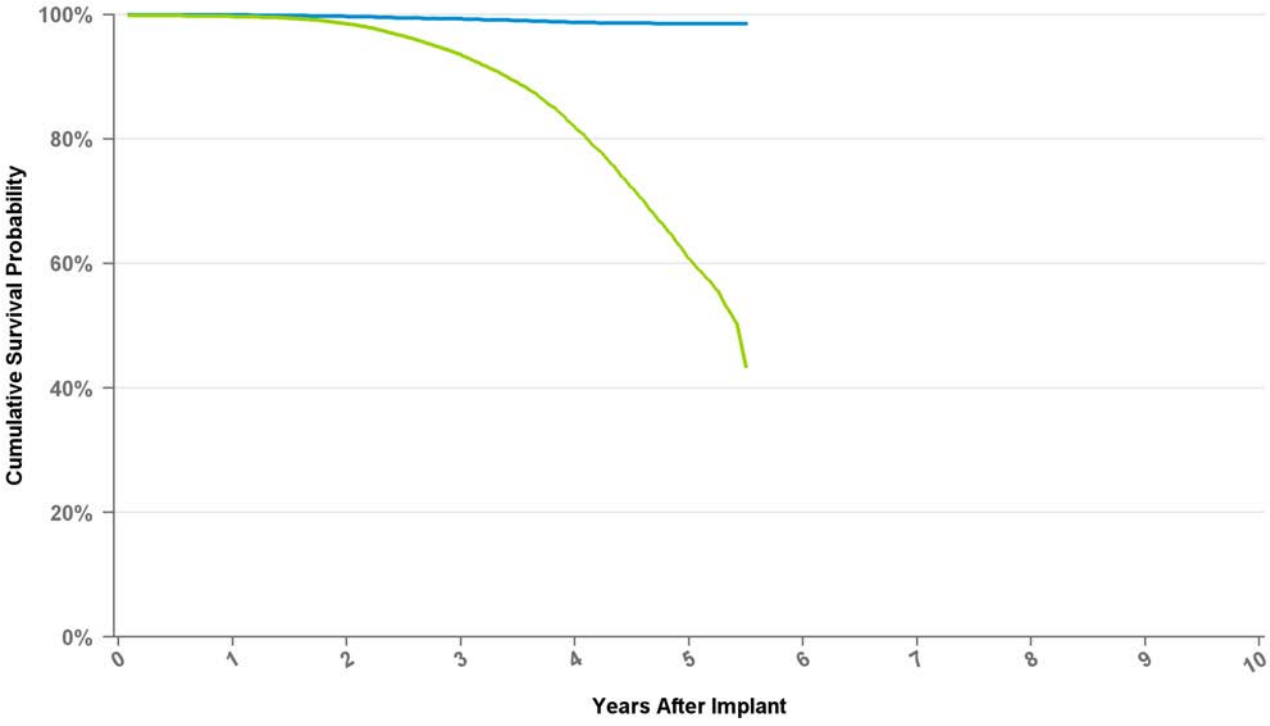
D204TRM Consulta CRT-D

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	2,074
Estimated Active US Implants	1,937
Normal Battery Depletions (US)	4

NBG Code	DDE-DDDR
Max Delivered Energy	35 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

CONSULTA, CRT, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.5%	98.5%
Including NBD	99.7%	98.5%	93.5%	81.8%	60.8%	43.4%
Effective Sample Size	61702	52258	40686	20487	4036	164

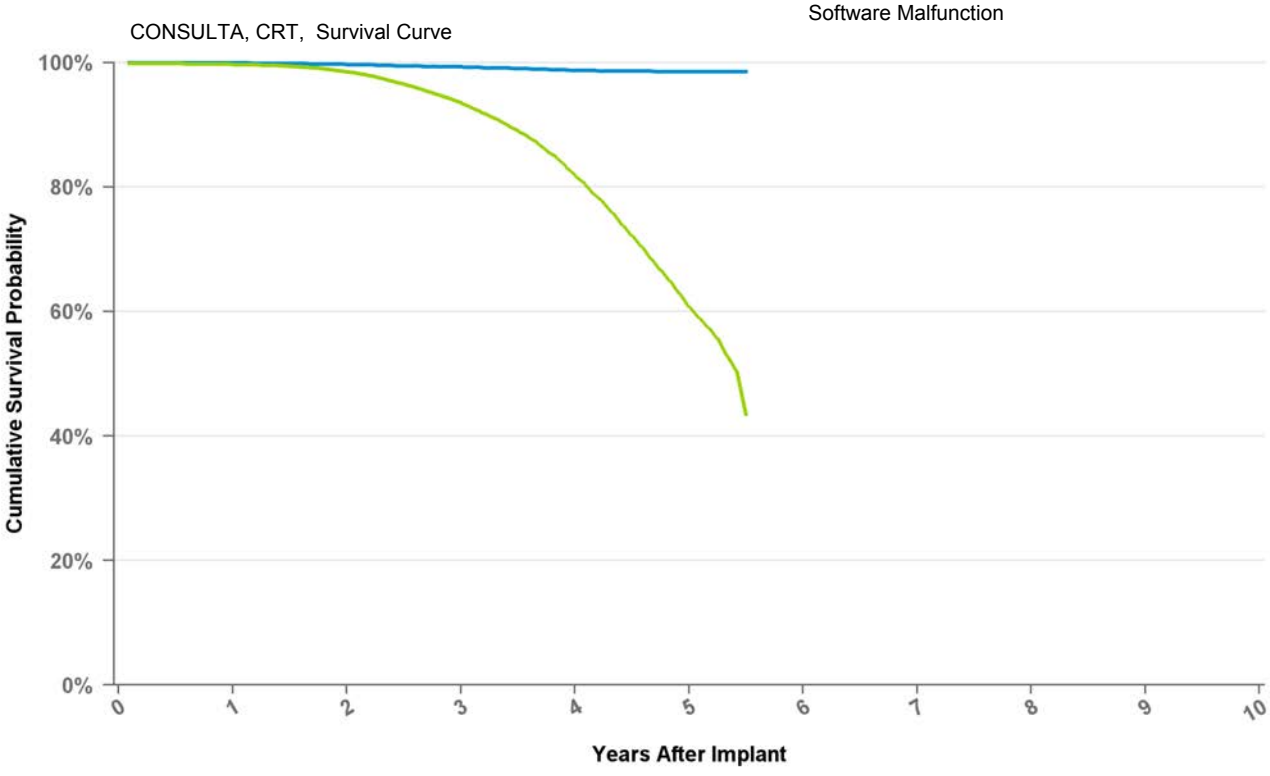
Cardiac Resynchronization Therapy

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



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.5%	98.5%
Including NBD	99.7%	98.5%	93.5%	81.8%	60.8%	43.4%
Effective Sample Size	61702	52258	40686	20487	4036	164

Cardiac Resynchronization Therapy

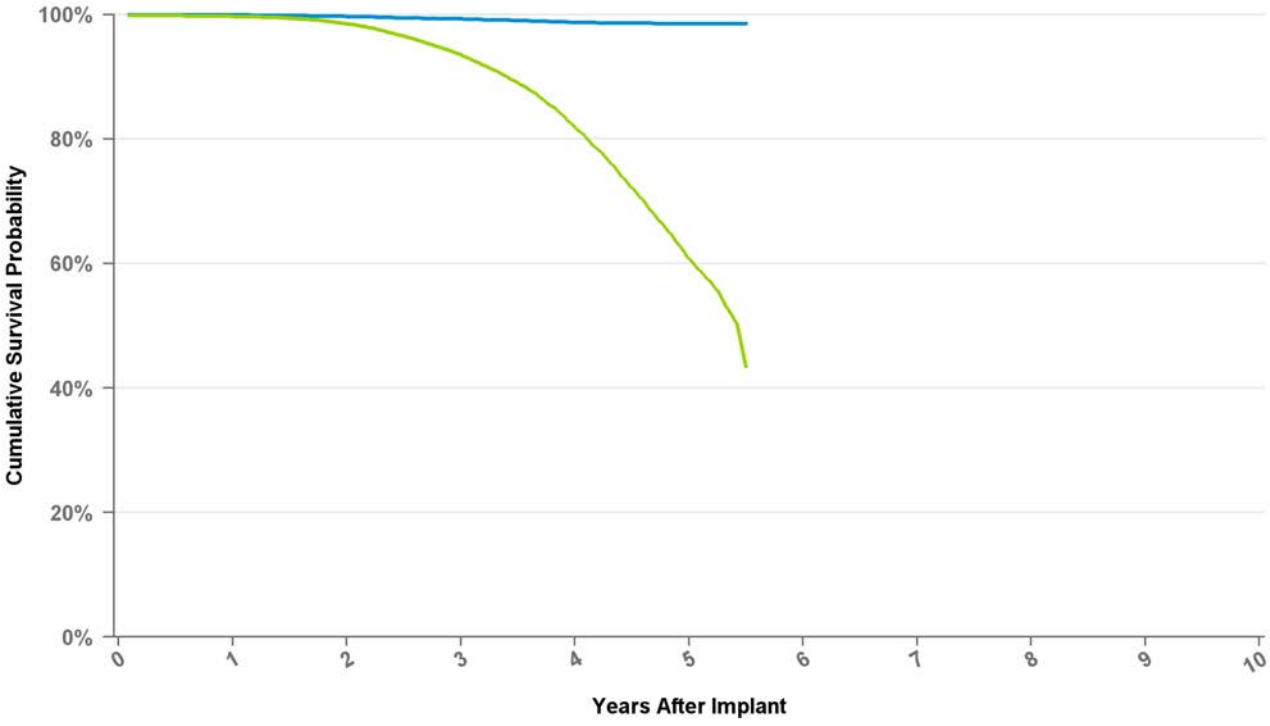
D224TRK Consulta CRT-D

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	65,722
Estimated Active US Implants	38,867
Normal Battery Depletions (US)	6,514

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	569
Therapy Not Compromised Malfunction	550
Battery Malfunction	1
Electrical Component	34
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	508
Software Malfunction	5
Therapy Compromised Malfunctions	19
Battery Malfunction	1
Electrical Component	18
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	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.5%	98.5%
Including NBD	99.7%	98.5%	93.5%	81.8%	60.8%	43.4%
Effective Sample Size	61702	52258	40686	20487	4036	164

Cardiac Resynchronization Therapy

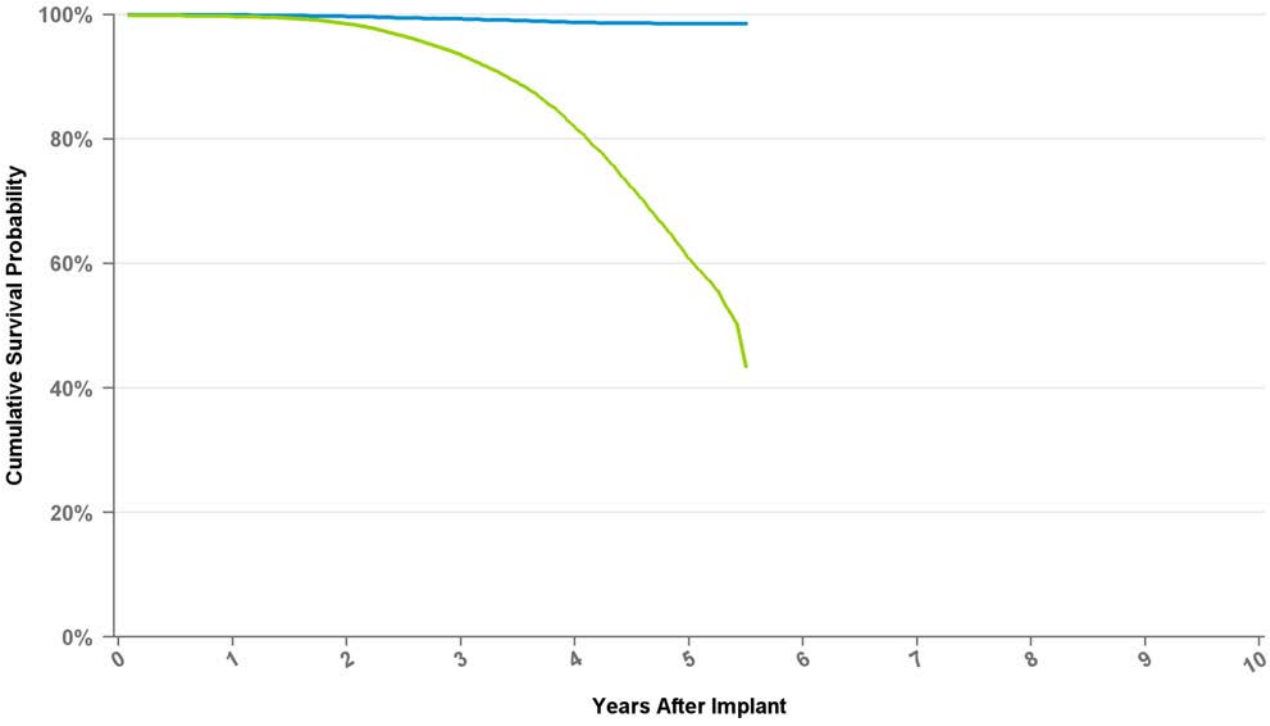
D234TRK Consulta CRT-D

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	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.7%	98.5%	98.5%
Including NBD	99.7%	98.5%	93.5%	81.8%	60.8%	43.4%
Effective Sample Size	61702	52258	40686	20487	4036	164

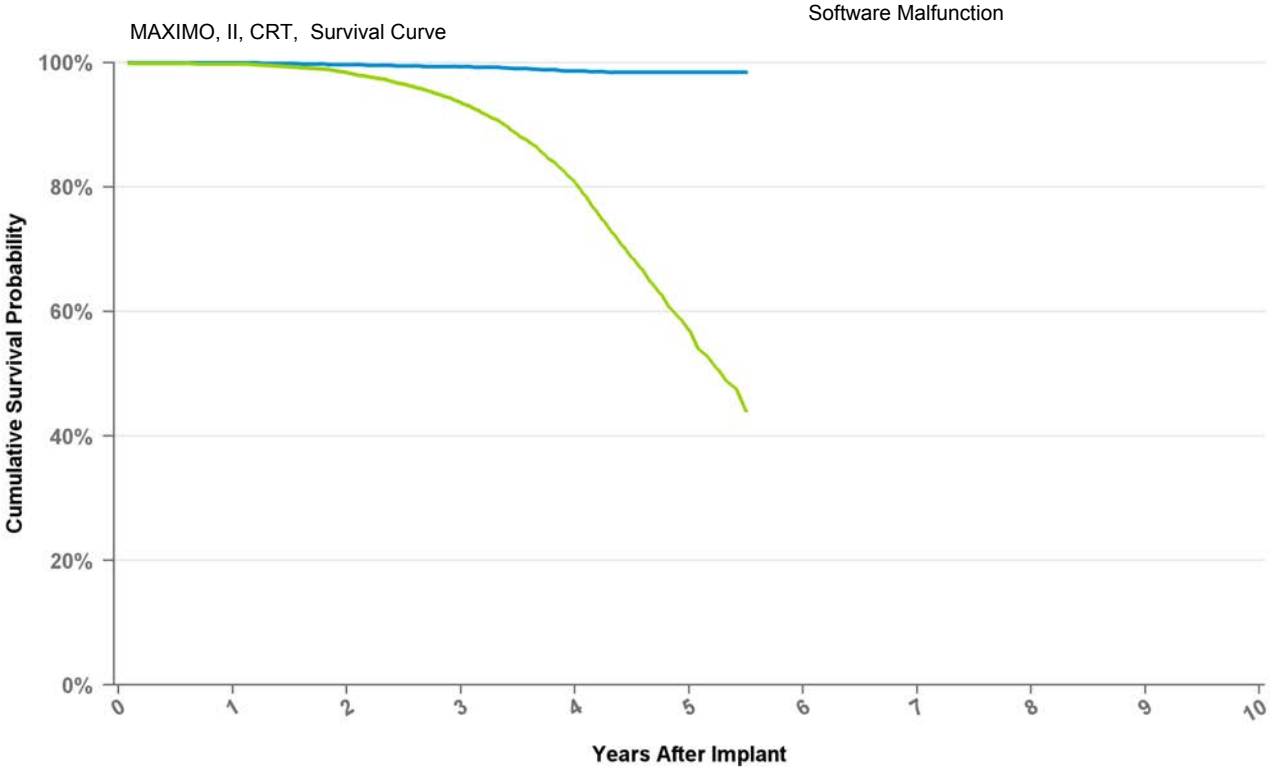
Cardiac Resynchronization Therapy

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



Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.4%	98.4%
Including NBD	99.8%	98.4%	93.5%	80.7%	57.1%	44.1%
Effective Sample Size	13929	11774	8869	4956	1164	116

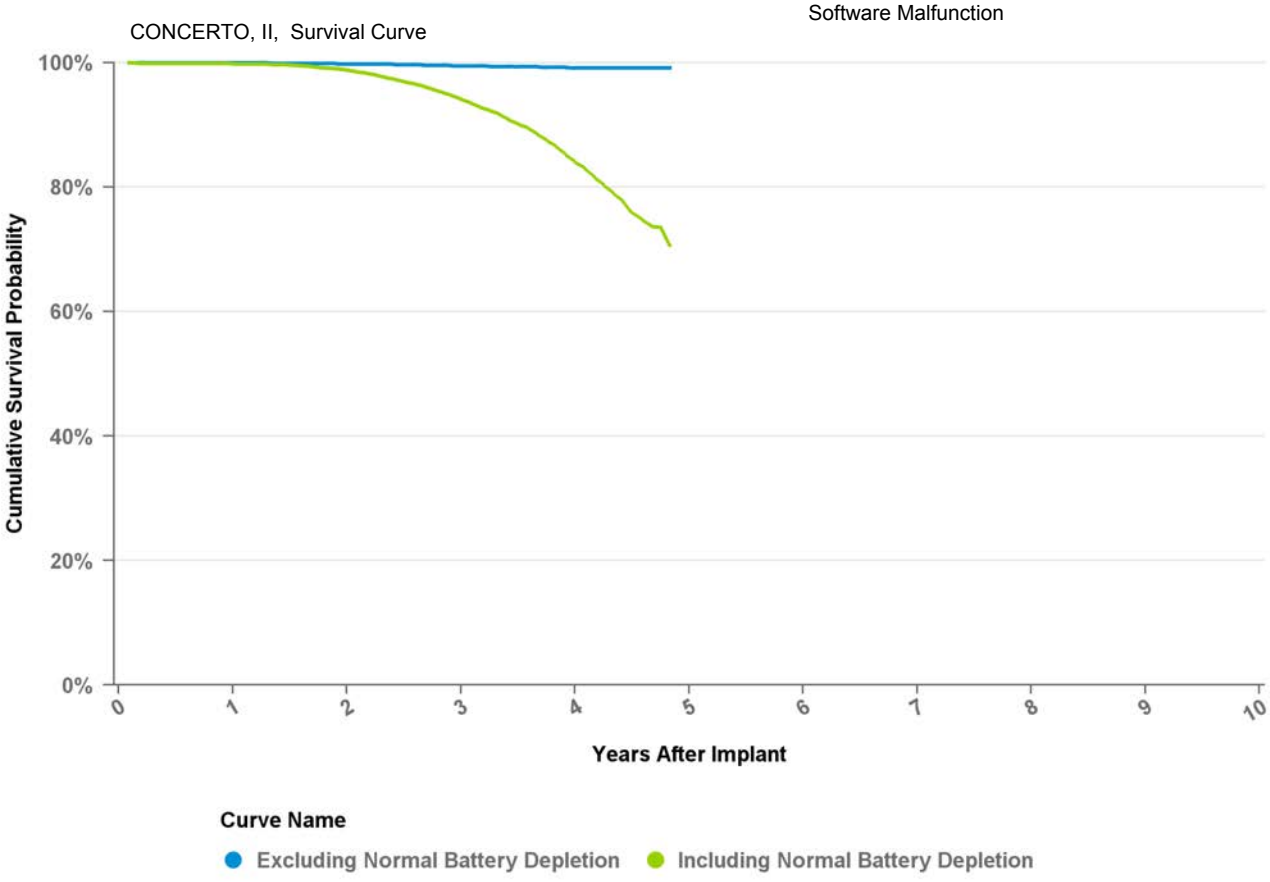
Cardiac Resynchronization Therapy

D274TRK Concerto II CRT-D

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	30,161
Estimated Active US Implants	19,354
Normal Battery Depletions (US)	2,252

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	176
Therapy Not Compromised Malfunction	173
Battery Malfunction	1
Electrical Component	13
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	158
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



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%
Including NBD	99.8%	98.8%	94.1%	84.0%	70.6%
Effective Sample Size	27408	25239	20759	8852	129

Cardiac Resynchronization Therapy

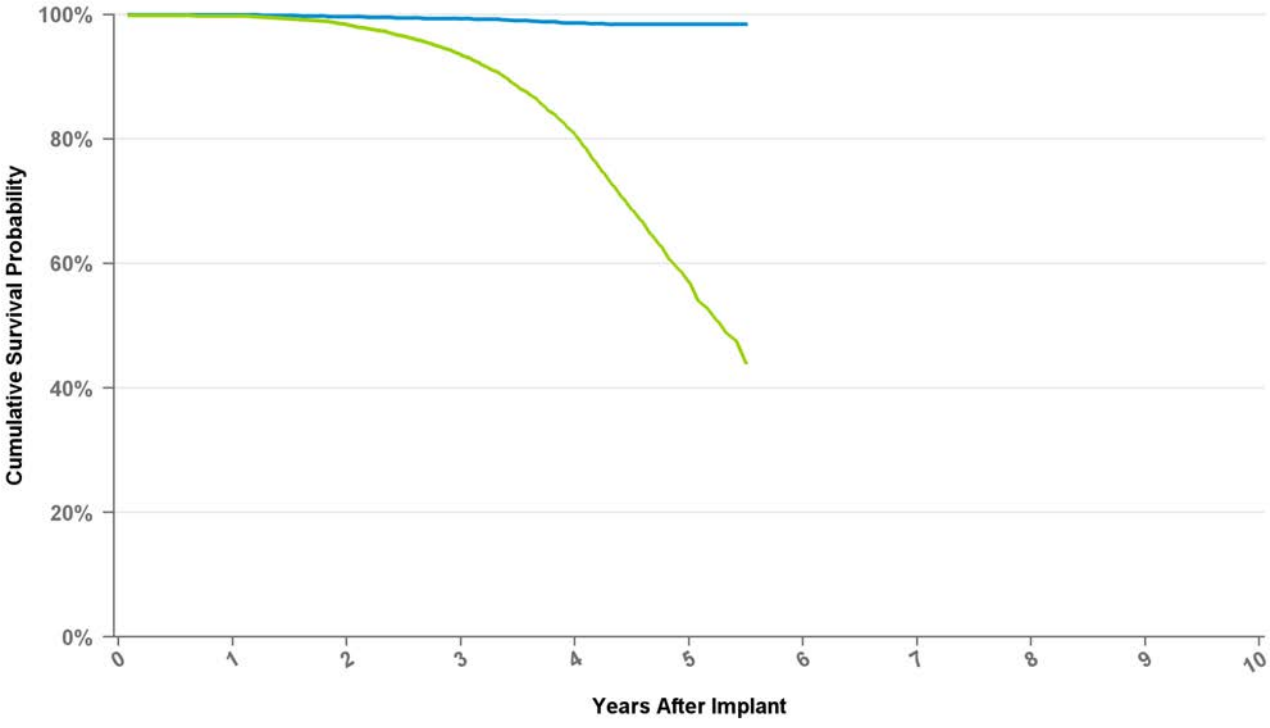
D284TRK Maximo II CRT-D

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	15,110
Estimated Active US Implants	8,564
Normal Battery Depletions (US)	1,713

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	134
Therapy Not Compromised Malfunction	131
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	126
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

MAXIMO, II, CRT, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 66 mo
Excluding NBD	100.0%	99.7%	99.3%	98.6%	98.4%	98.4%
Including NBD	99.8%	98.4%	93.5%	80.7%	57.1%	44.1%
Effective Sample Size	13929	11774	8869	4956	1164	116

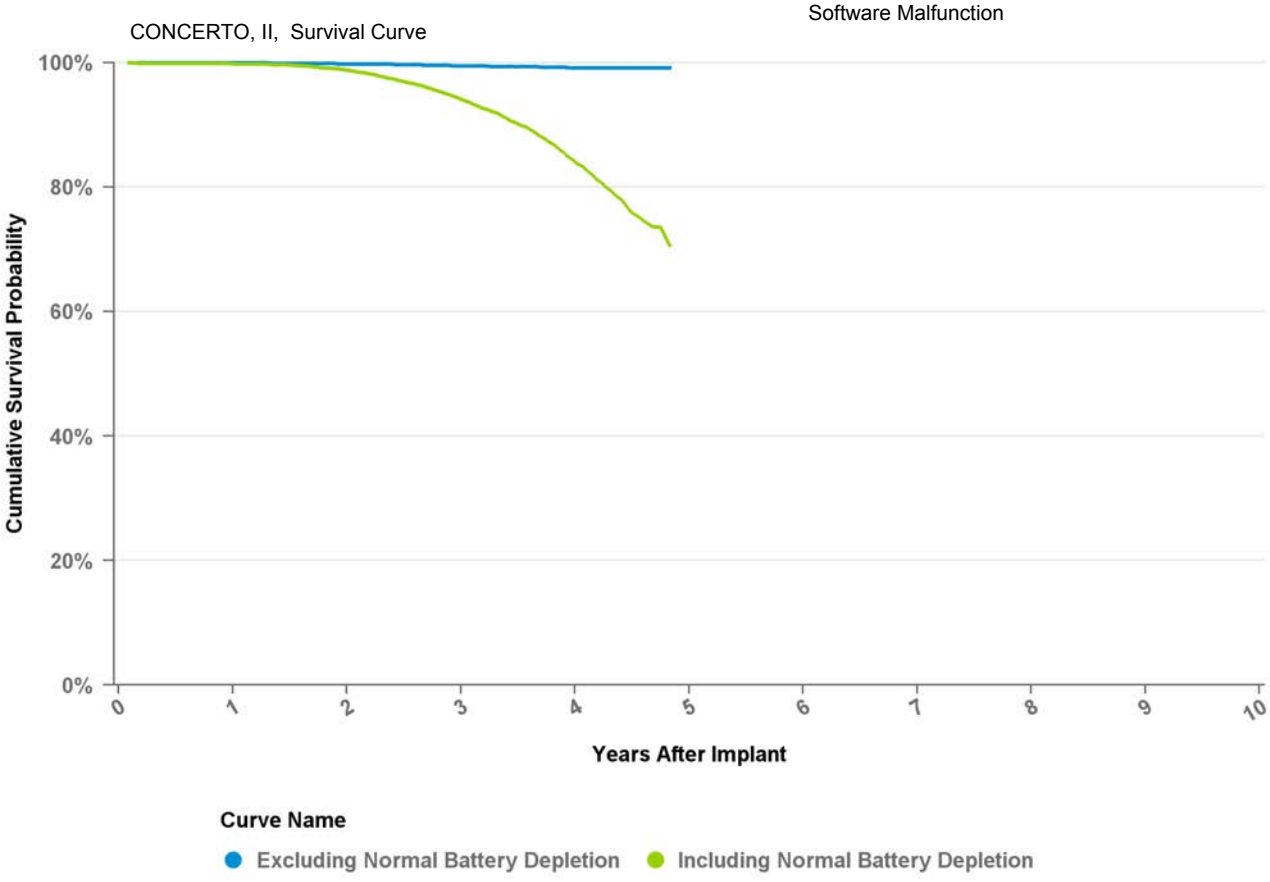
Cardiac Resynchronization Therapy

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



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	99.8%	99.5%	99.1%	99.1%
Including NBD	99.8%	98.8%	94.1%	84.0%	70.6%
Effective Sample Size	27408	25239	20759	8852	129

Cardiac Resynchronization Therapy

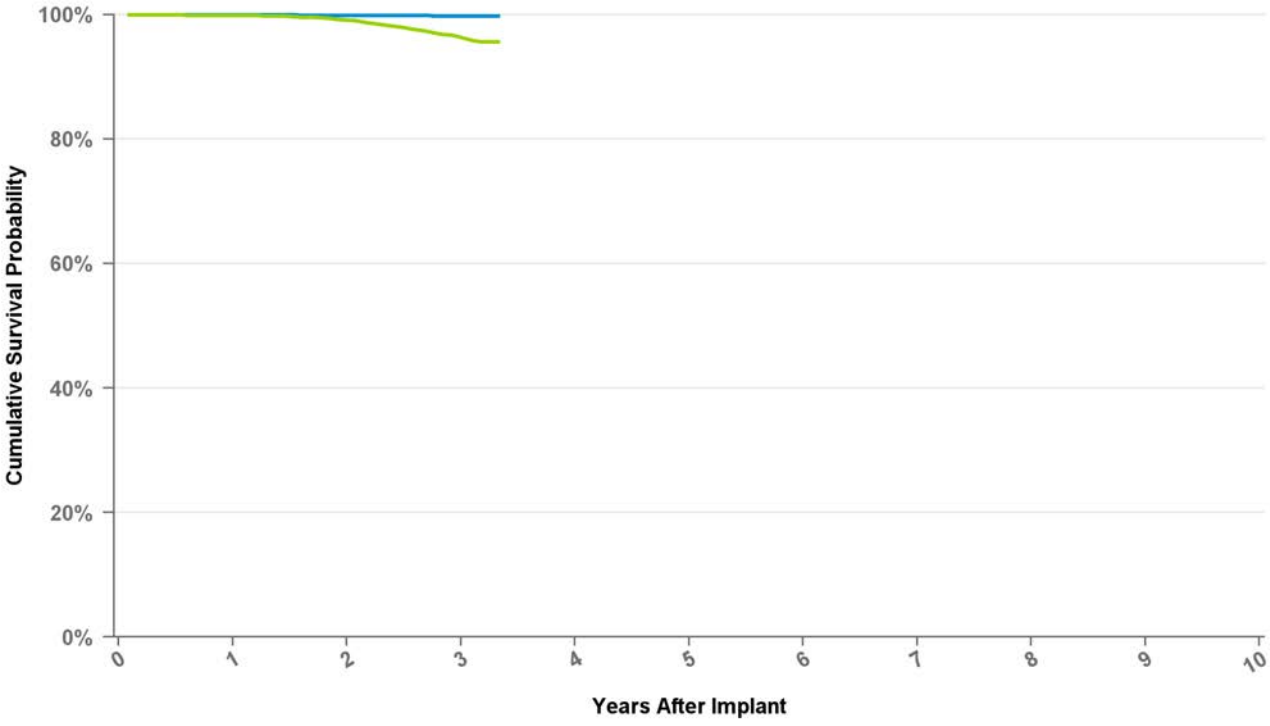
D314TRG Protecta XT CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	41,174
Estimated Active US Implants	36,535
Normal Battery Depletions (US)	400

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	39
Therapy Not Compromised Malfunction	37
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	27
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

D3xxTRx, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

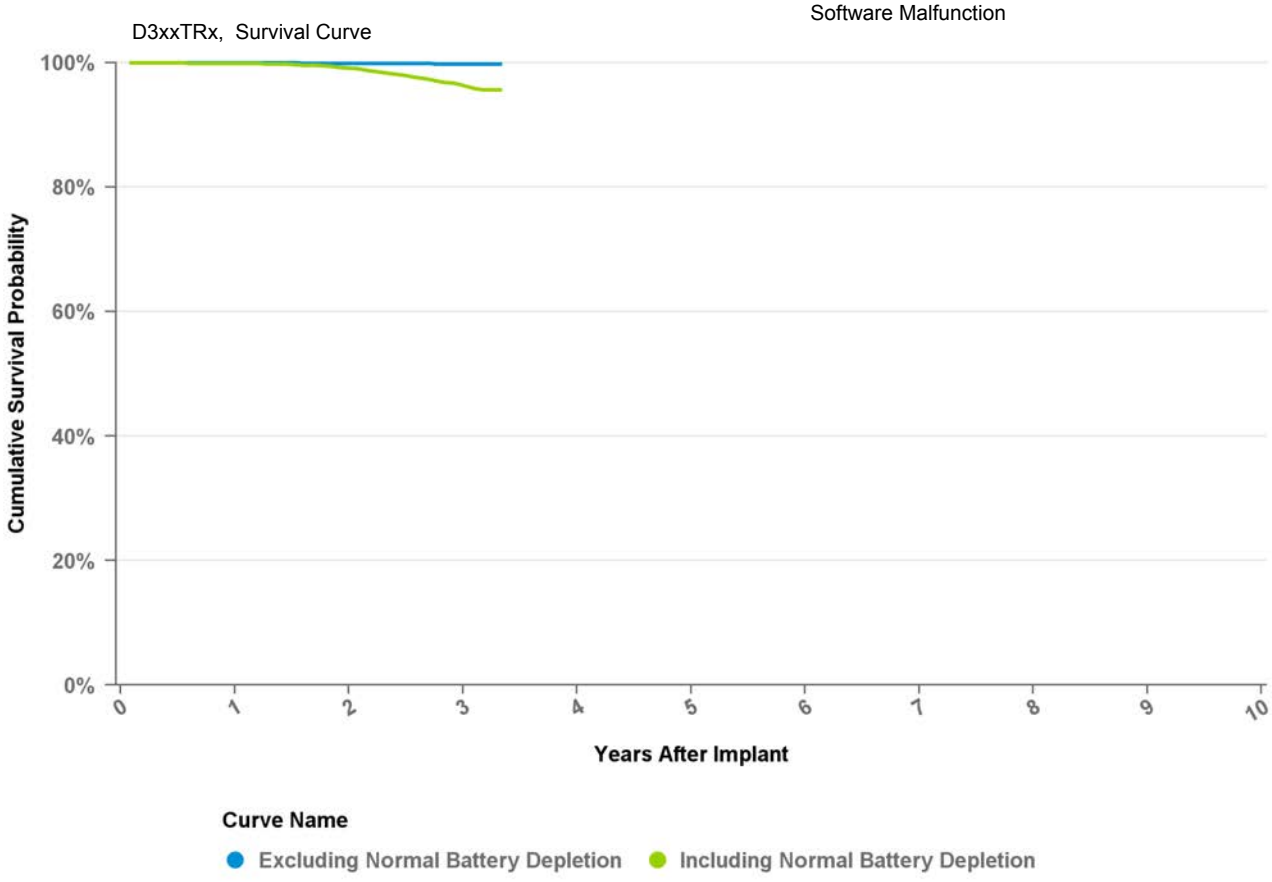
Cardiac Resynchronization Therapy

D314TRM Protecta XT CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	12,088
Estimated Active US Implants	11,401
Normal Battery Depletions (US)	26

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



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

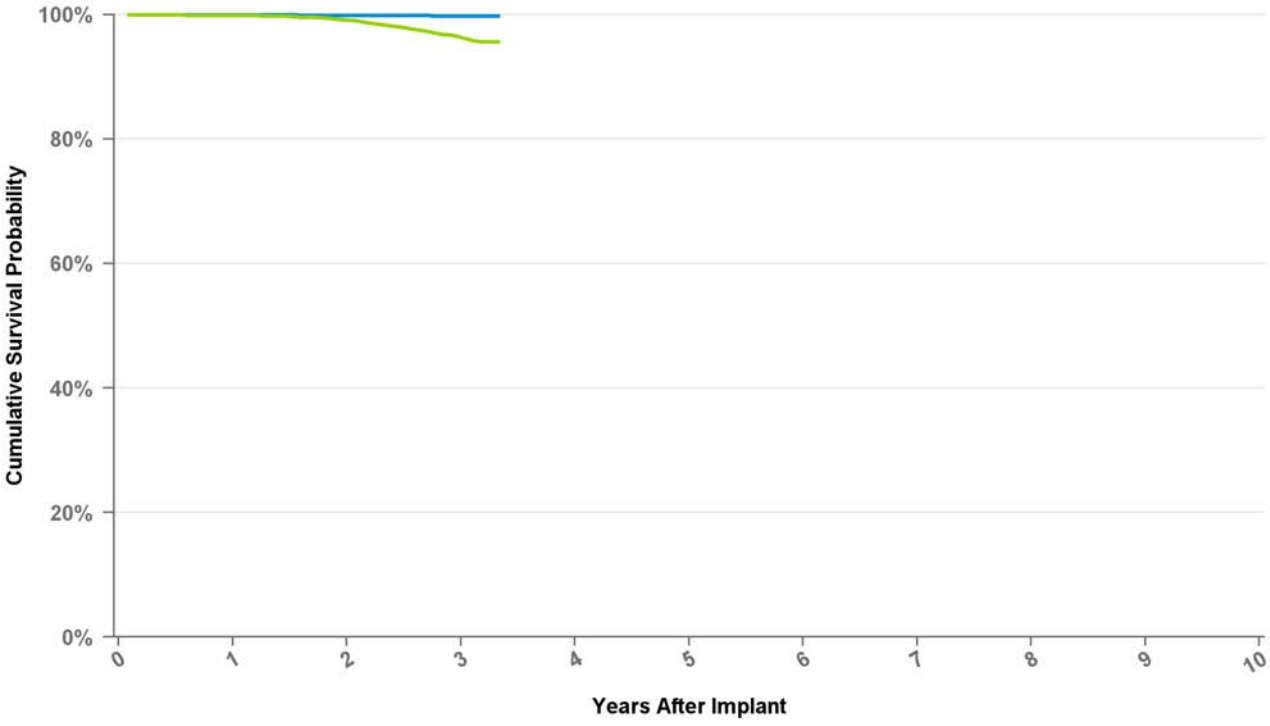
D334TRG Protecta CRT-D

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	7,588
Estimated Active US Implants	6,794
Normal Battery Depletions (US)	43

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

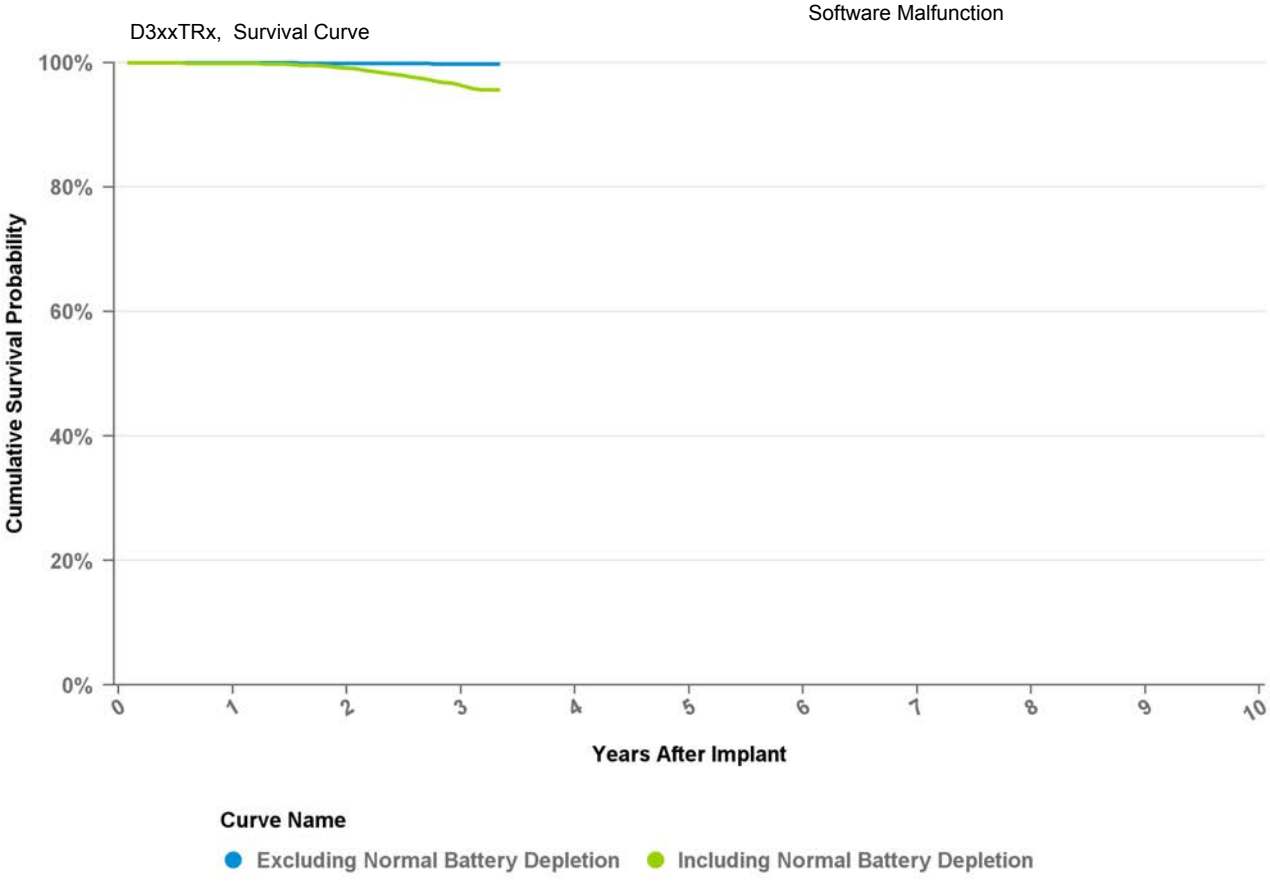
Cardiac Resynchronization Therapy

D334TRM Protecta CRT-D

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	1,675
Estimated Active US Implants	1,573
Normal Battery Depletions (US)	3

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1
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	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 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

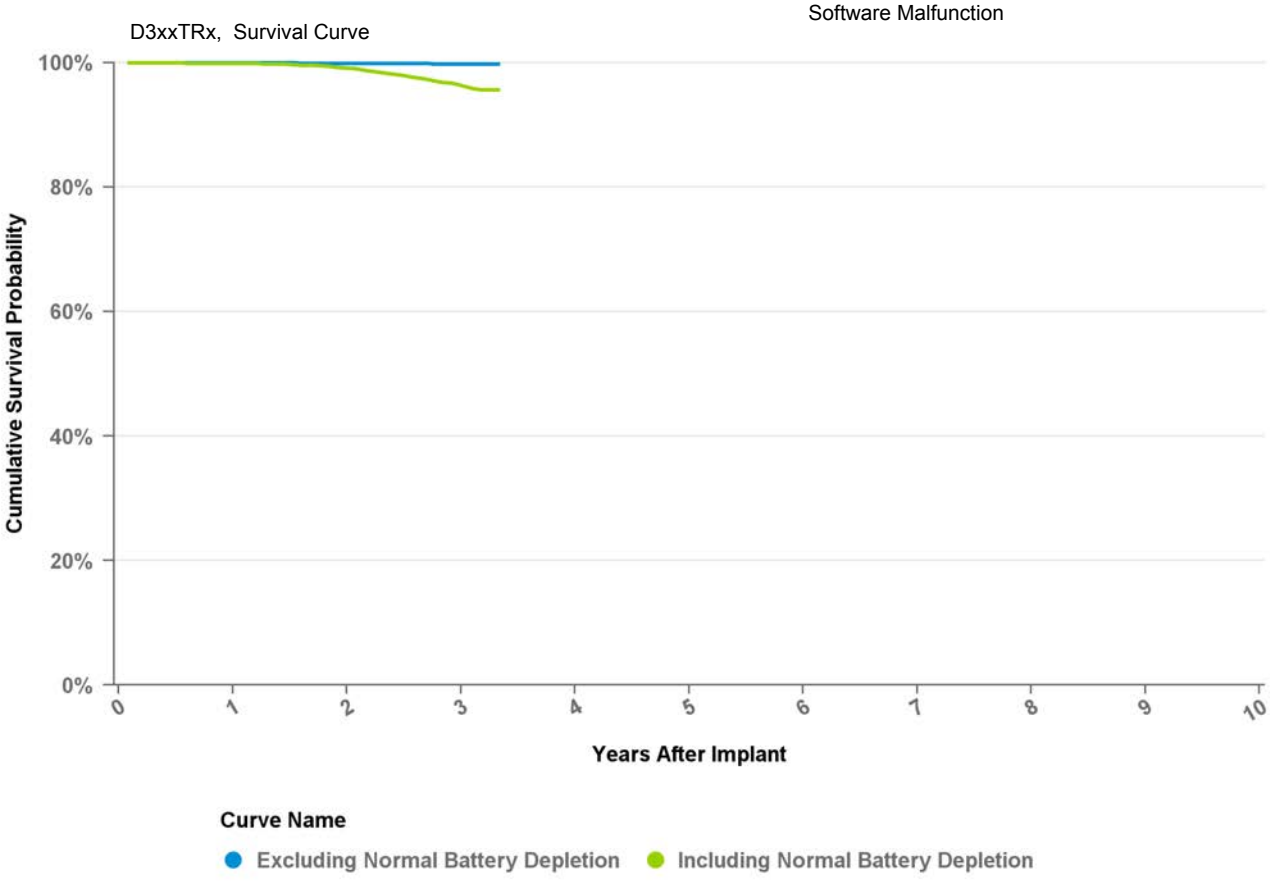
Cardiac Resynchronization Therapy

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



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

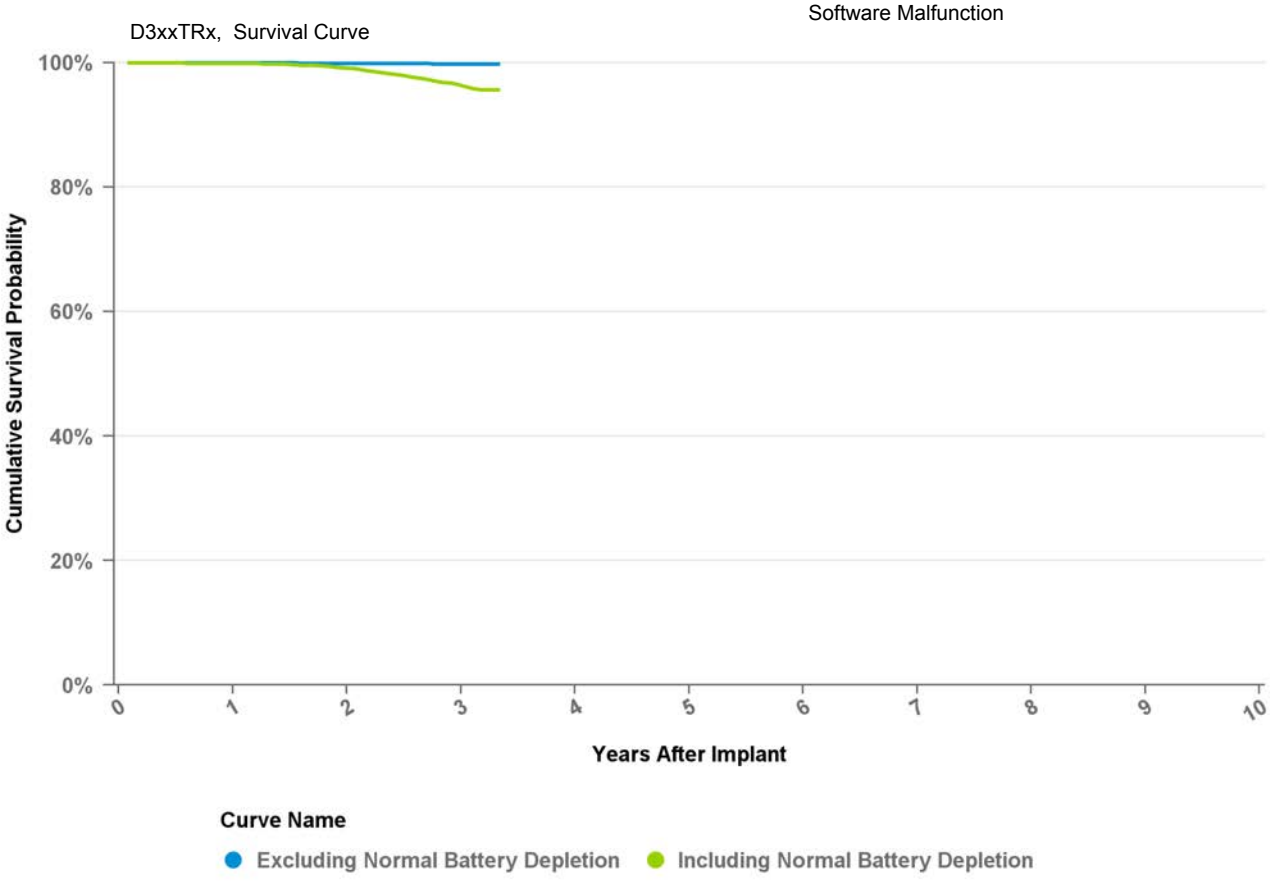
Cardiac Resynchronization Therapy

D354TRM Protecta XT CRT-D

US Market Release Date	
CE Market Approval Date	7/15/2010
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



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

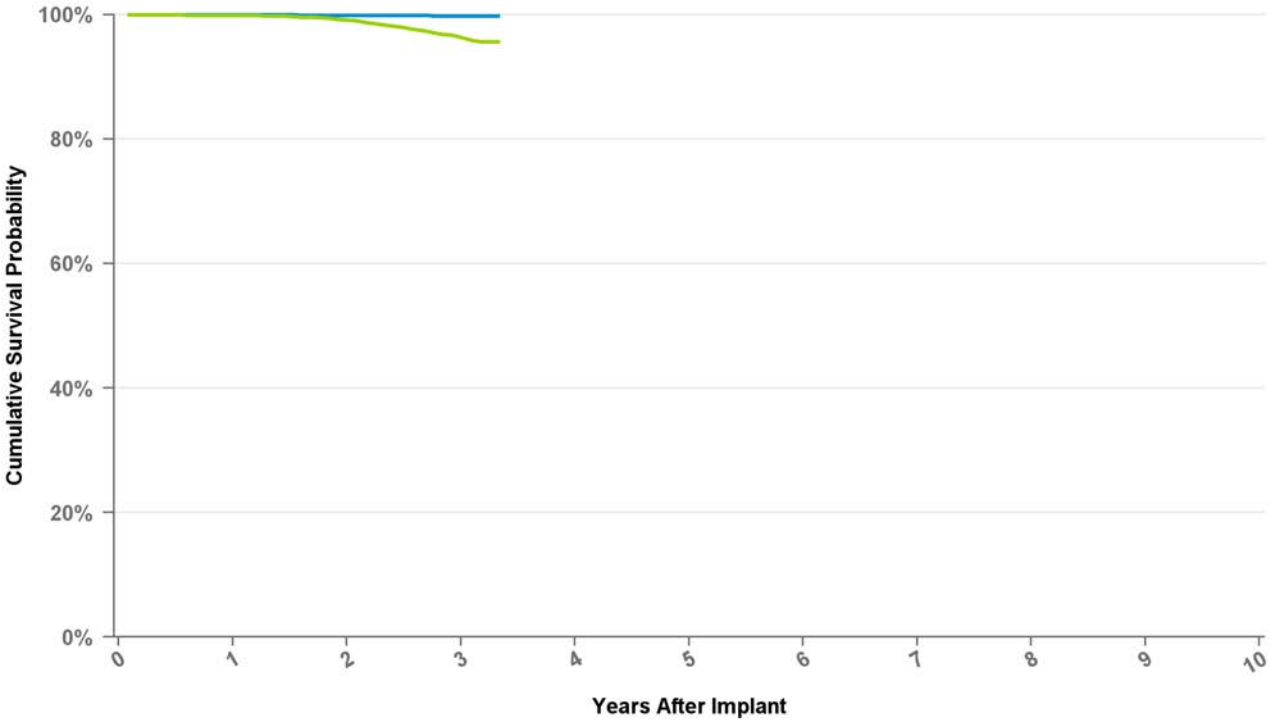
D364TRG Protecta CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

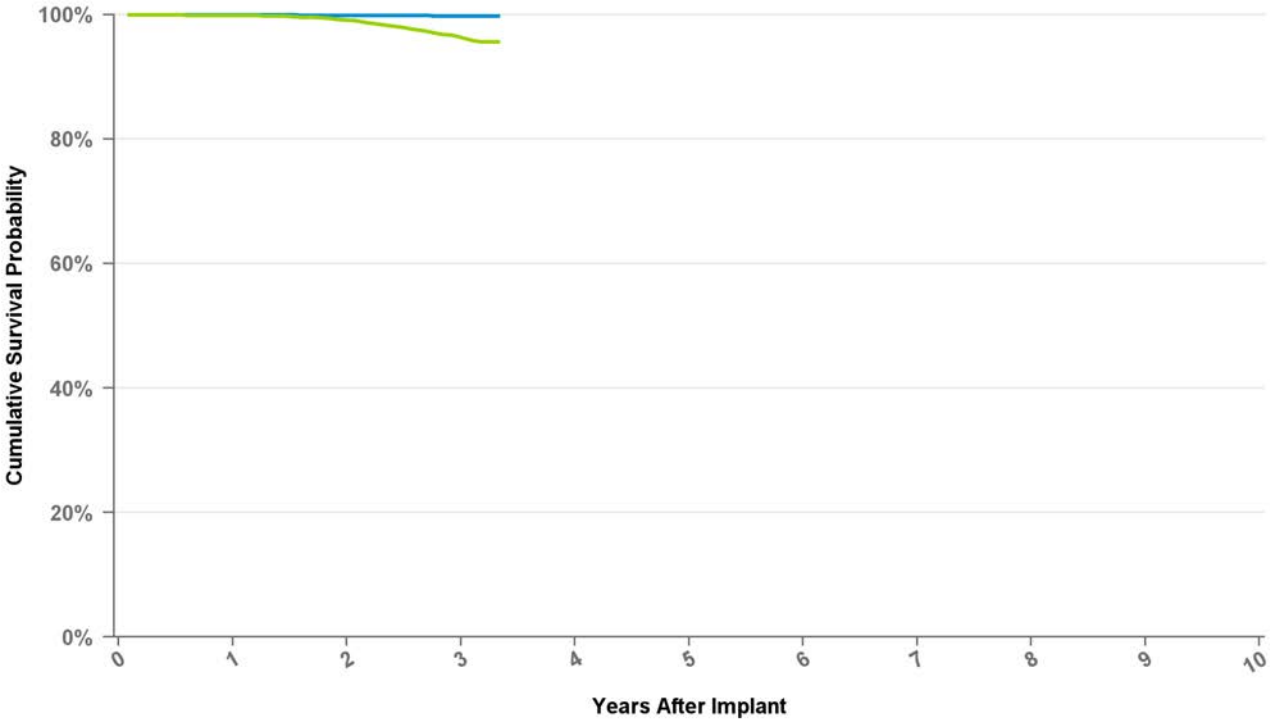
D364TRM Protecta CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

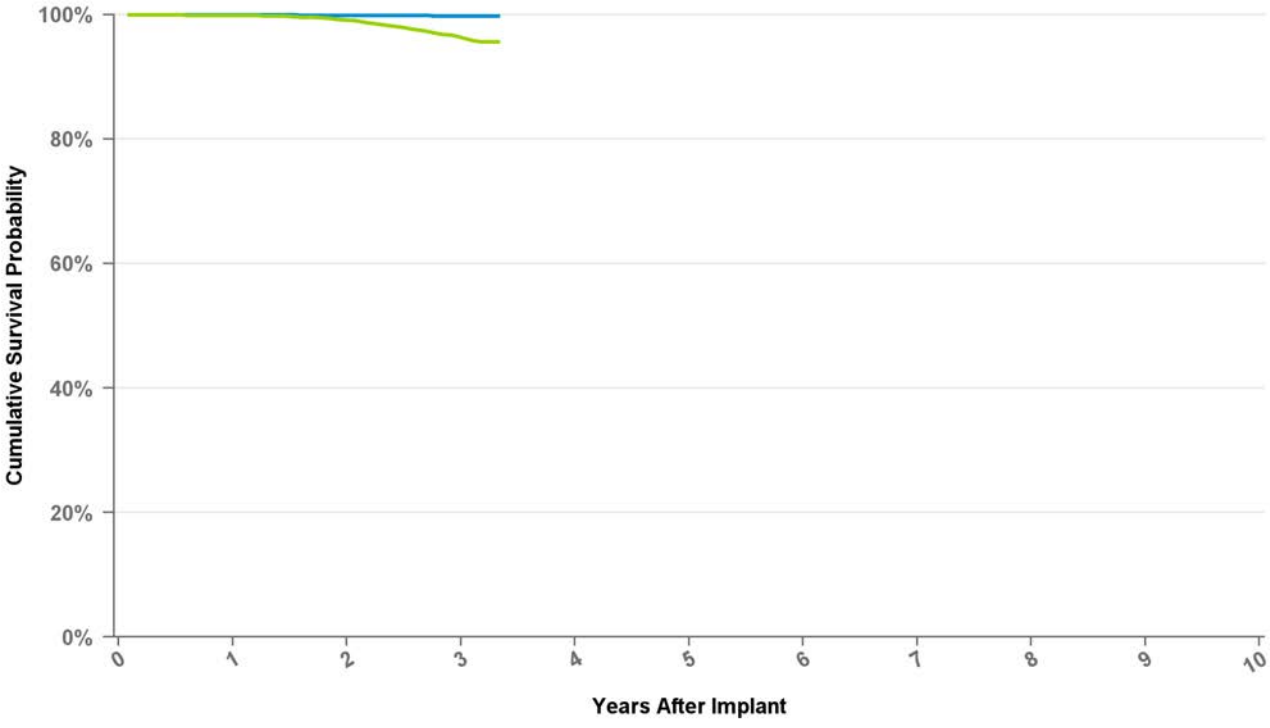
D384TRG Cardia CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

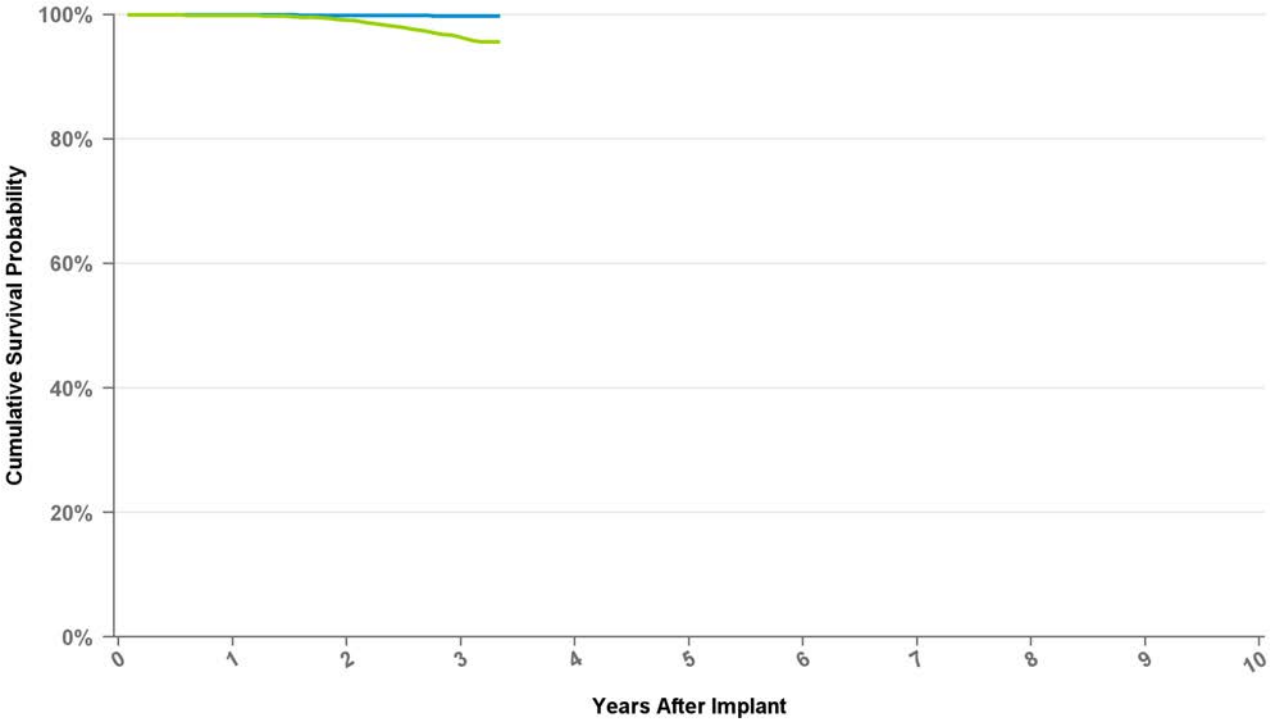
D394TRG Egida CRT-D

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	99.9%	99.8%	99.8%
Including NBD	99.9%	99.1%	96.3%	95.6%
Effective Sample Size	54707	27693	3717	342

Cardiac Resynchronization Therapy

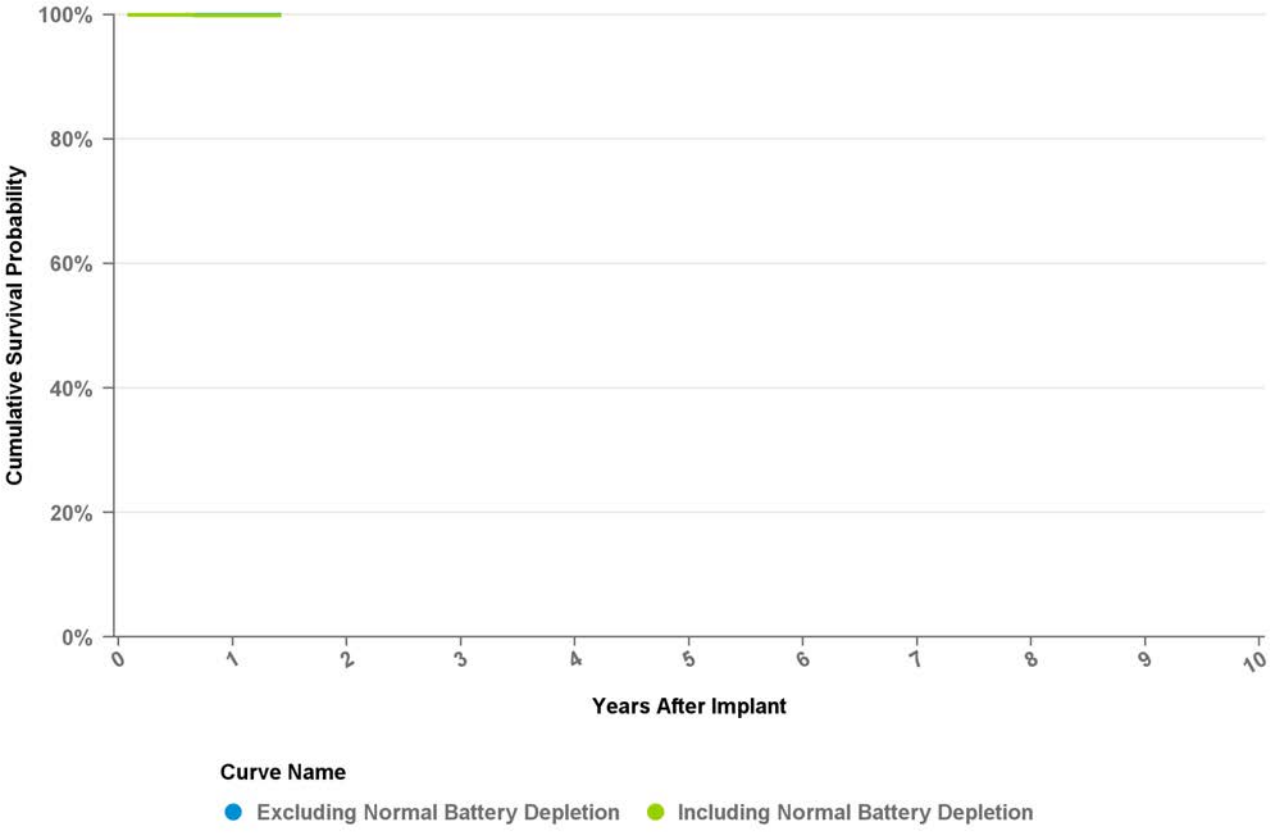
DTBA1D1 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	14,800
Estimated Active US Implants	14,509
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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

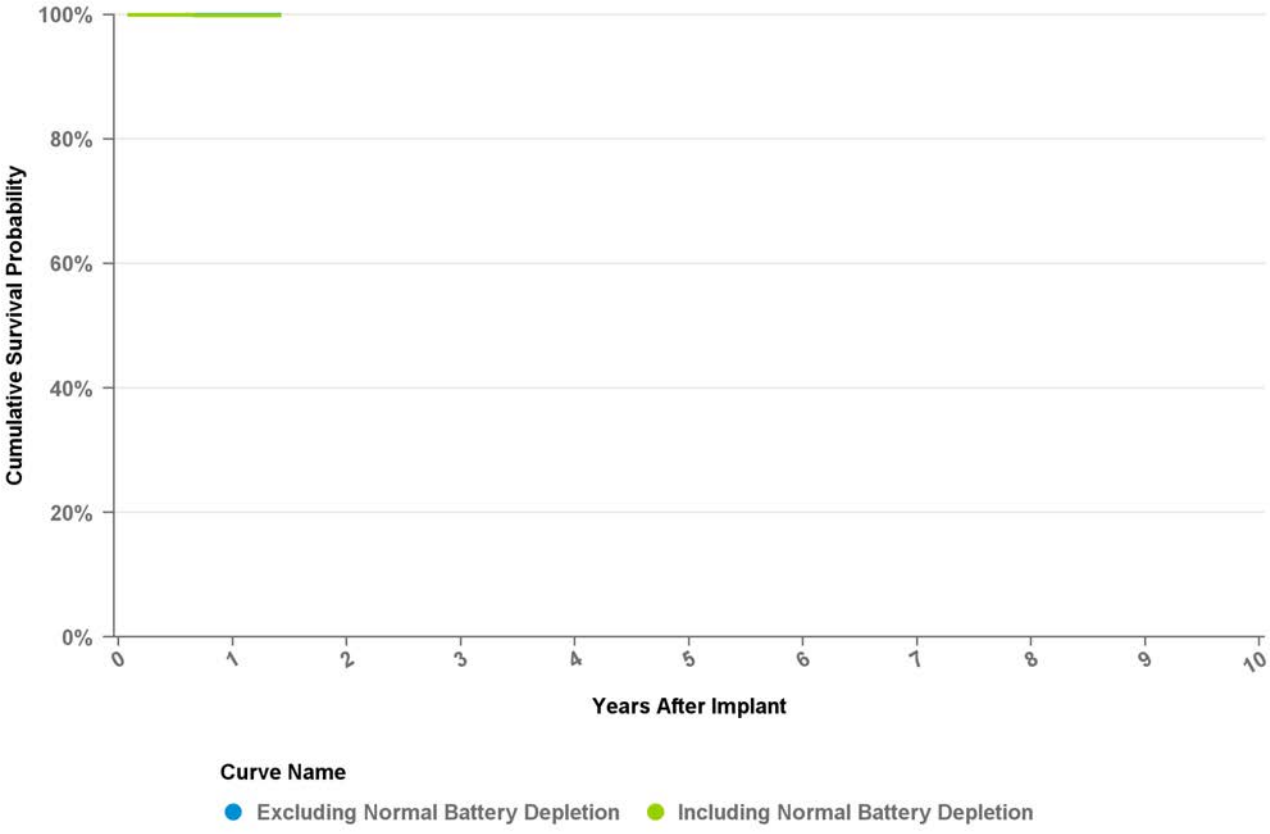
DTBA1D4 Viva XT

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	9,998
Estimated Active US Implants	9,828
Normal Battery Depletions (US)	0

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

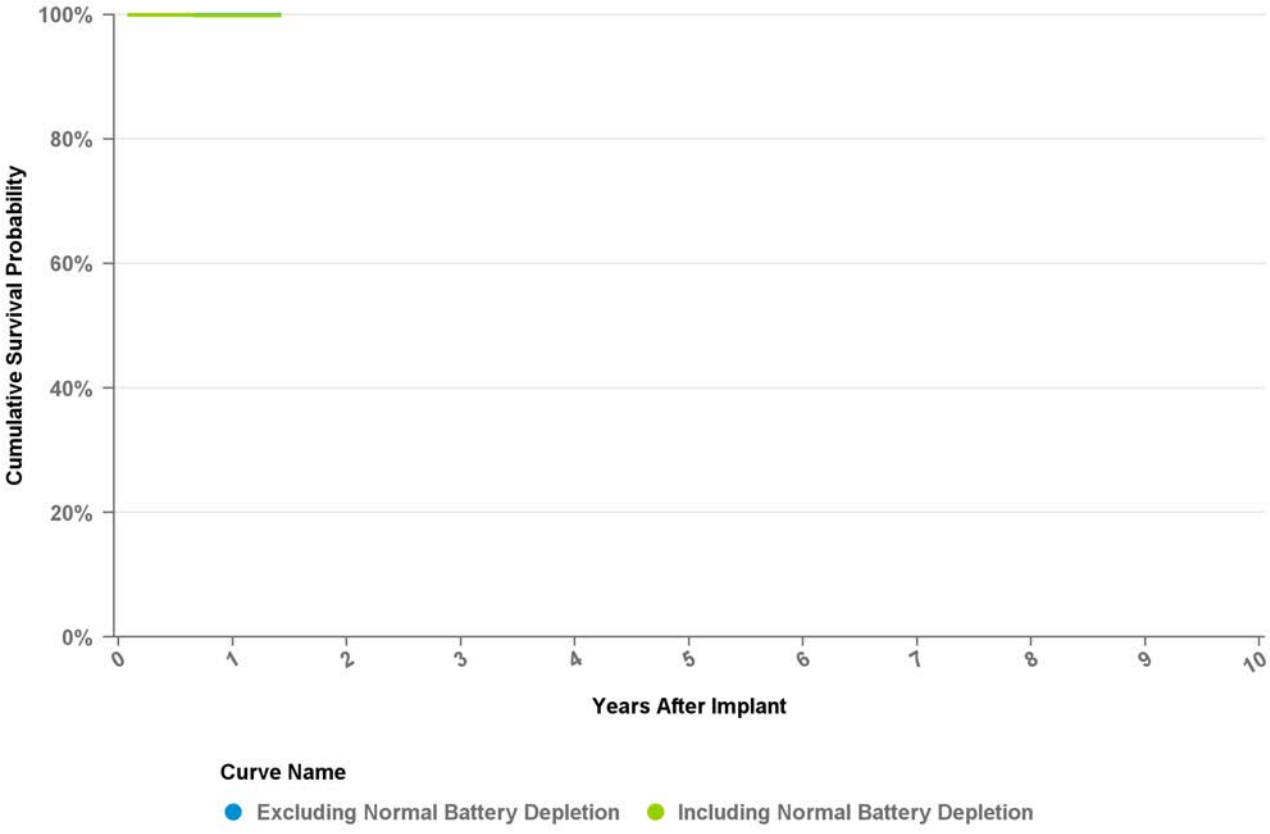
DTBA1Q1 Viva Quad XT

US Market Release Date	
CE Market Approval Date	
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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

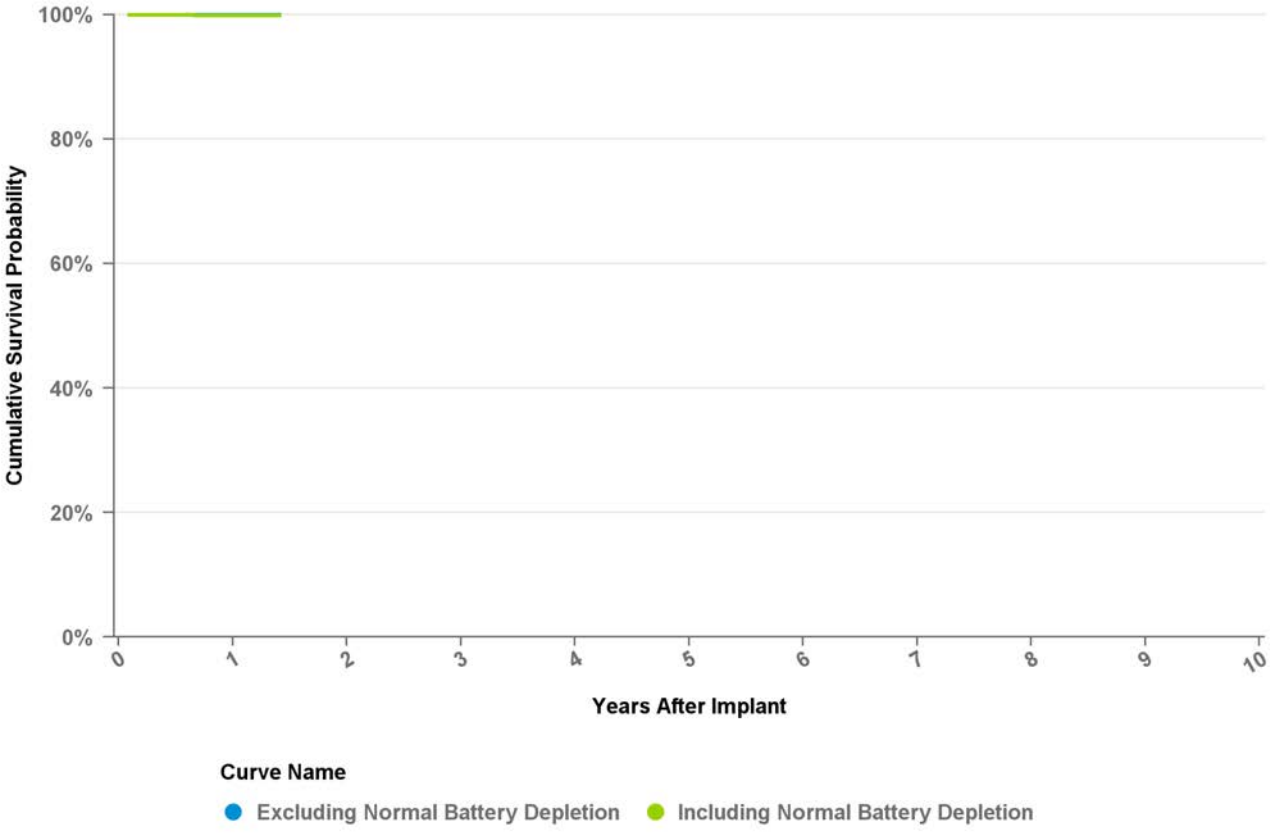
DTBA1QQ Viva Quad XT

US Market Release Date	
CE Market Approval Date	
Registered US Implants	102
Estimated Active US Implants	100
Normal Battery Depletions (US)	1

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

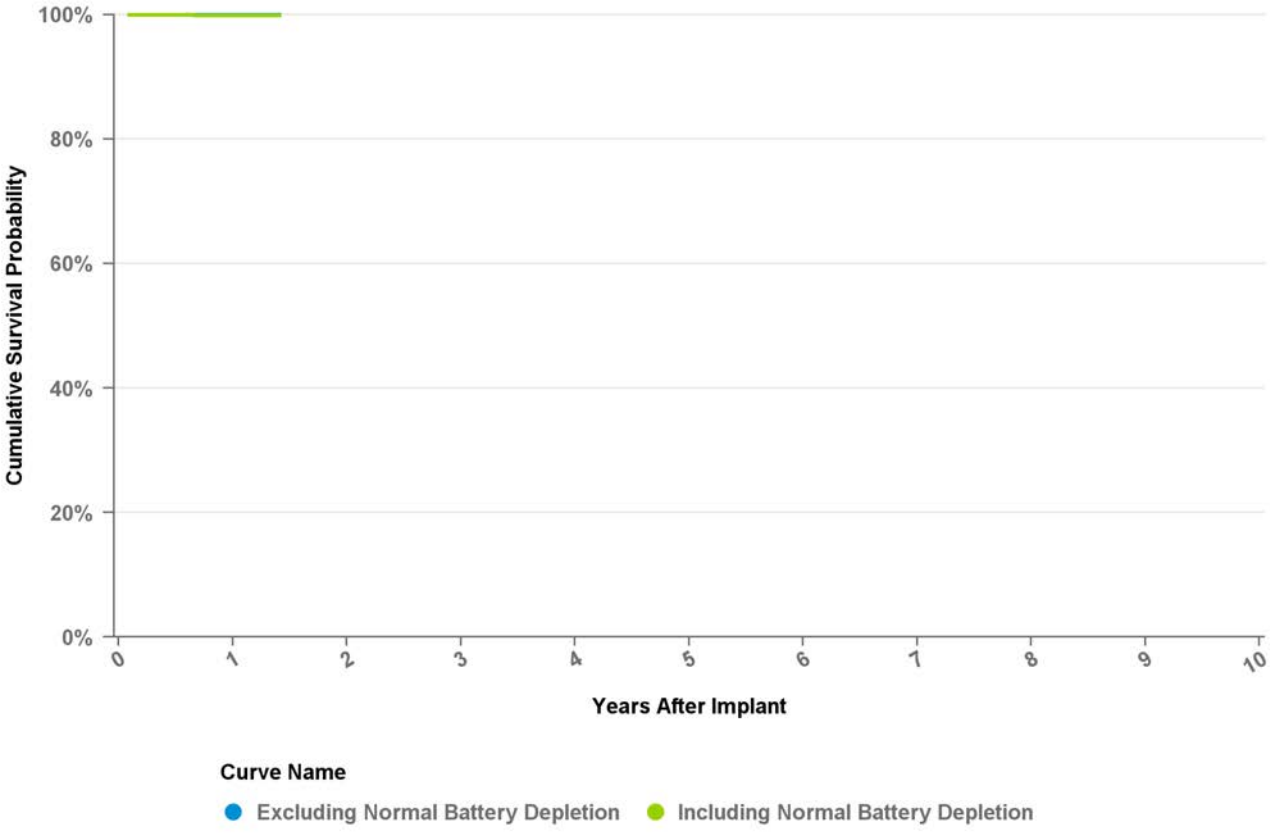
DTBA2D1 Viva XT

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

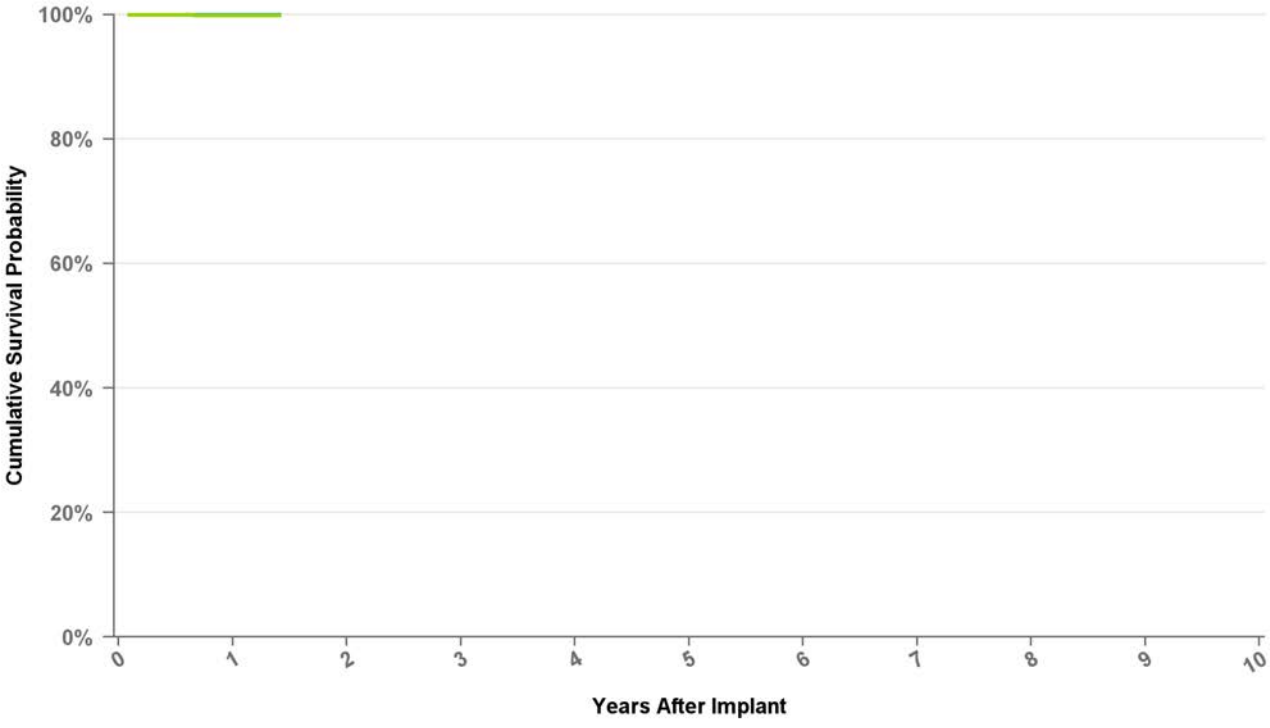
DTBA2D4 Viva XT

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

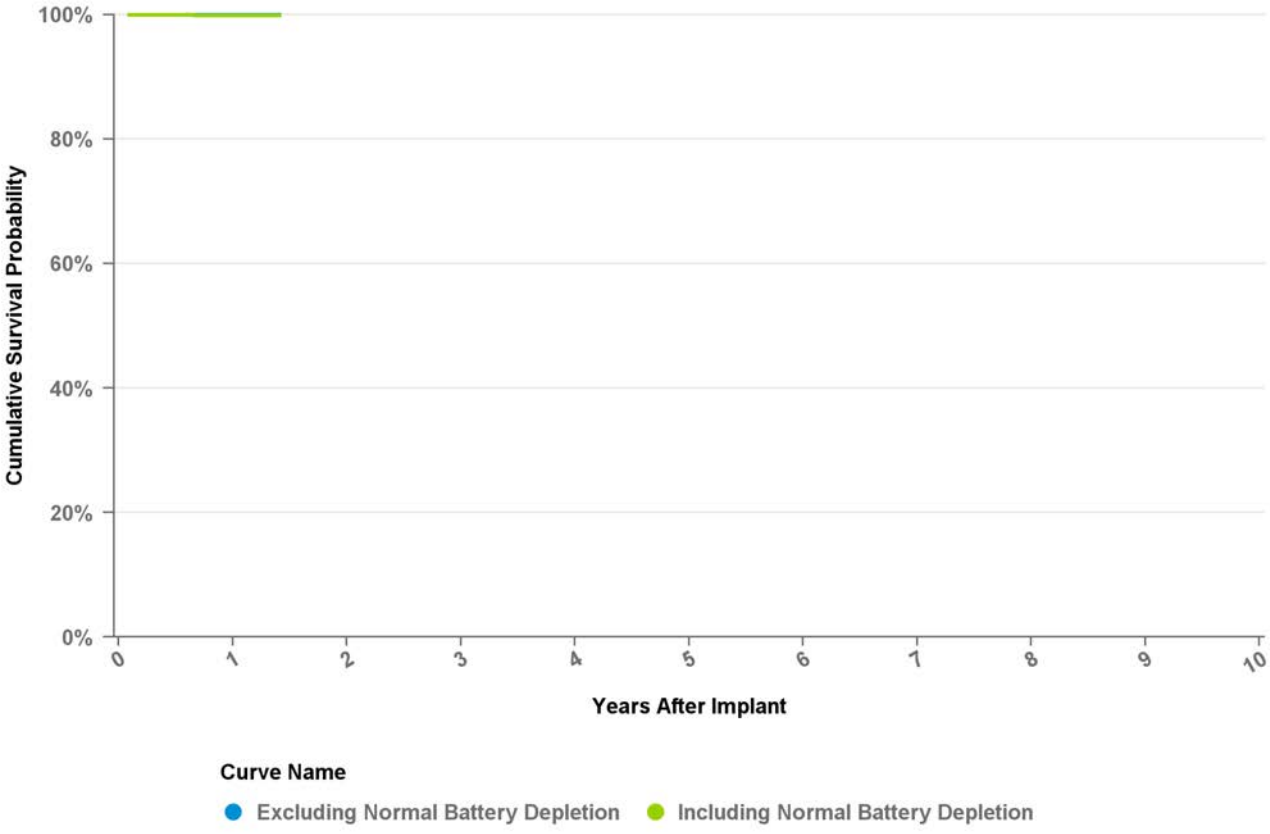
DTBA2Q1 Viva Quad XT

US Market Release Date	
CE Market Approval Date	9/13/2013
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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

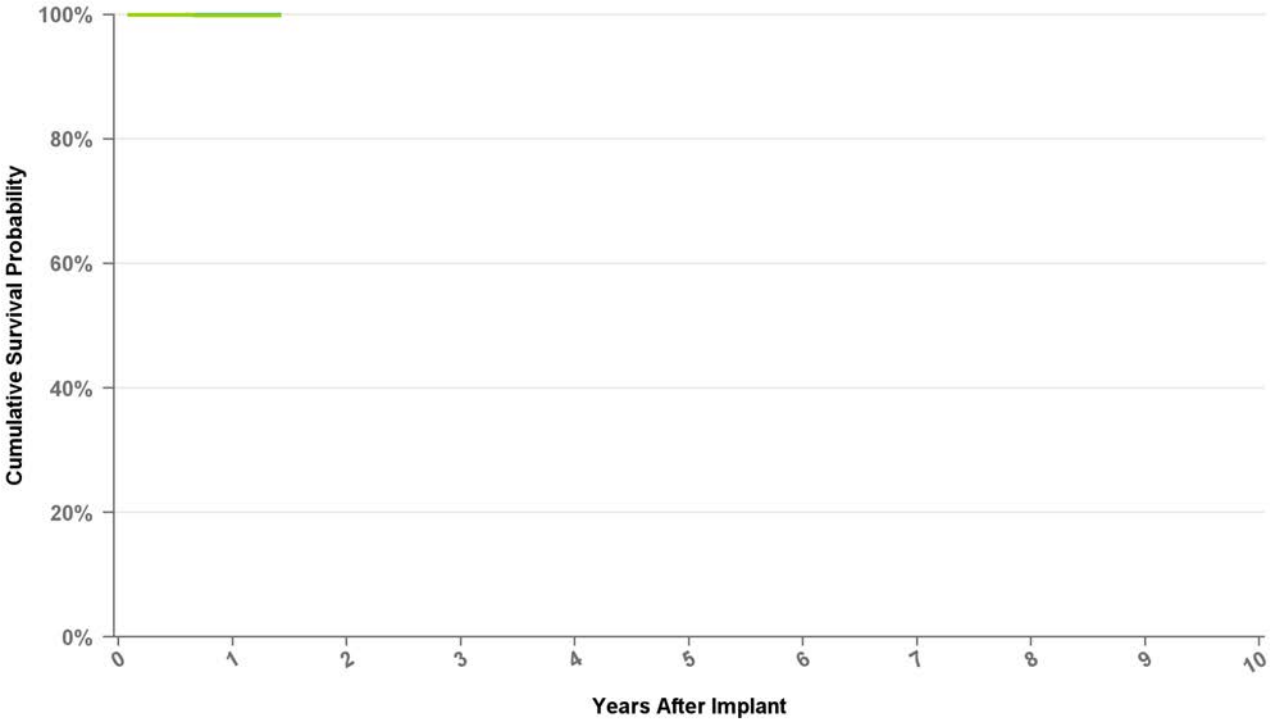
DTBA2QQ Viva Quad XT

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

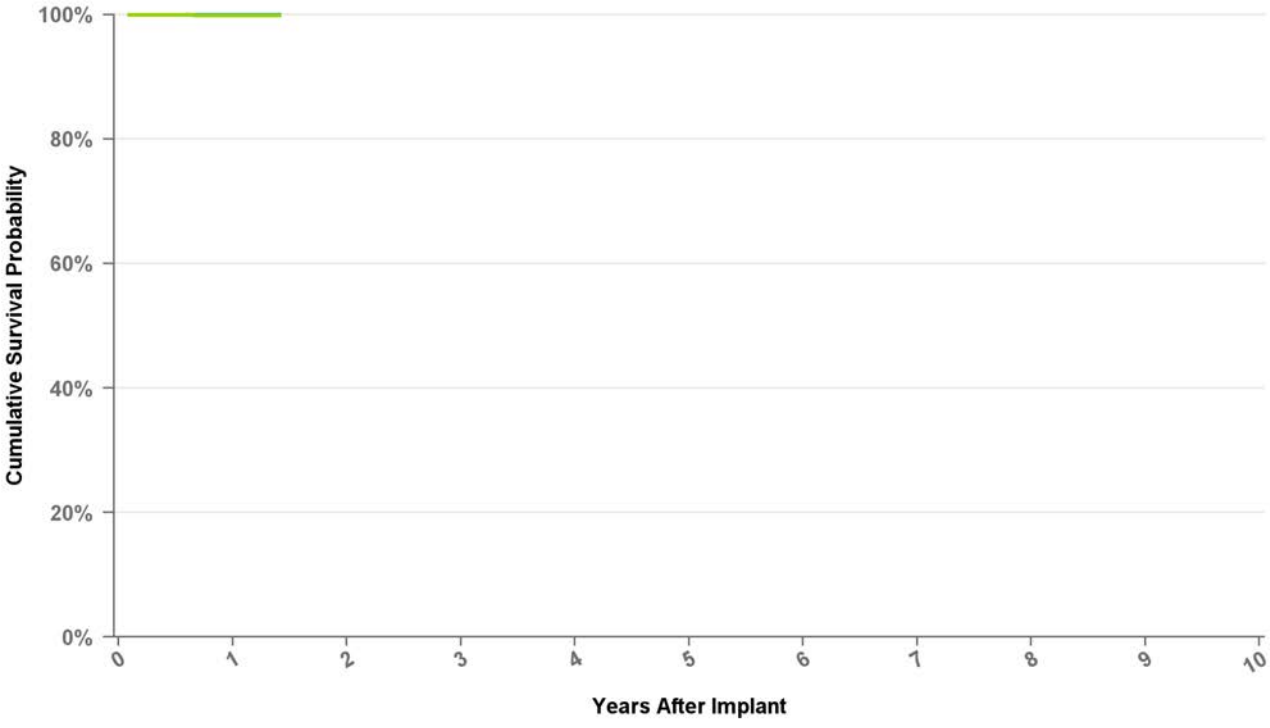
DTBB1D1 Viva S

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	4,620
Estimated Active US Implants	4,494
Normal Battery Depletions (US)	1

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

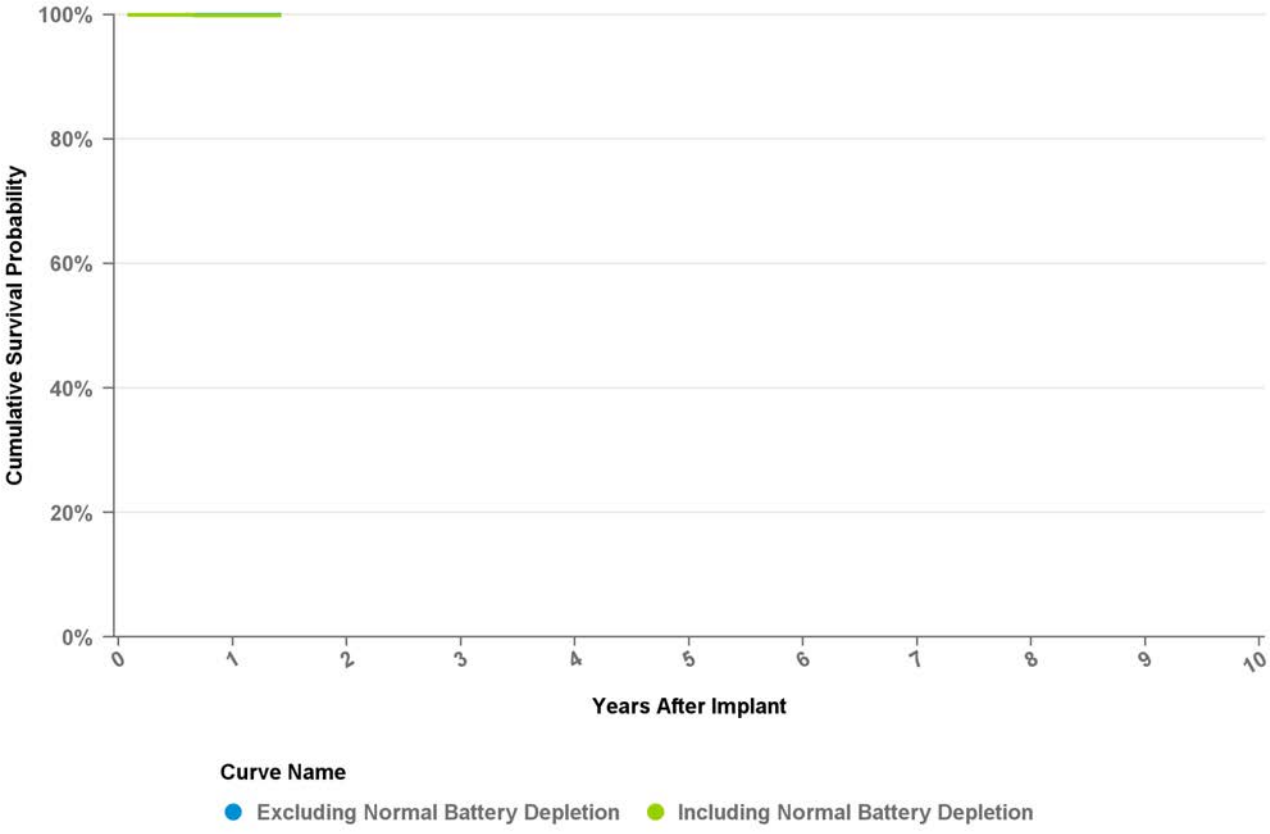
DTBB1D4 Viva S

US Market Release Date	1/29/2013
CE Market Approval Date	
Registered US Implants	2,406
Estimated Active US Implants	2,367
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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

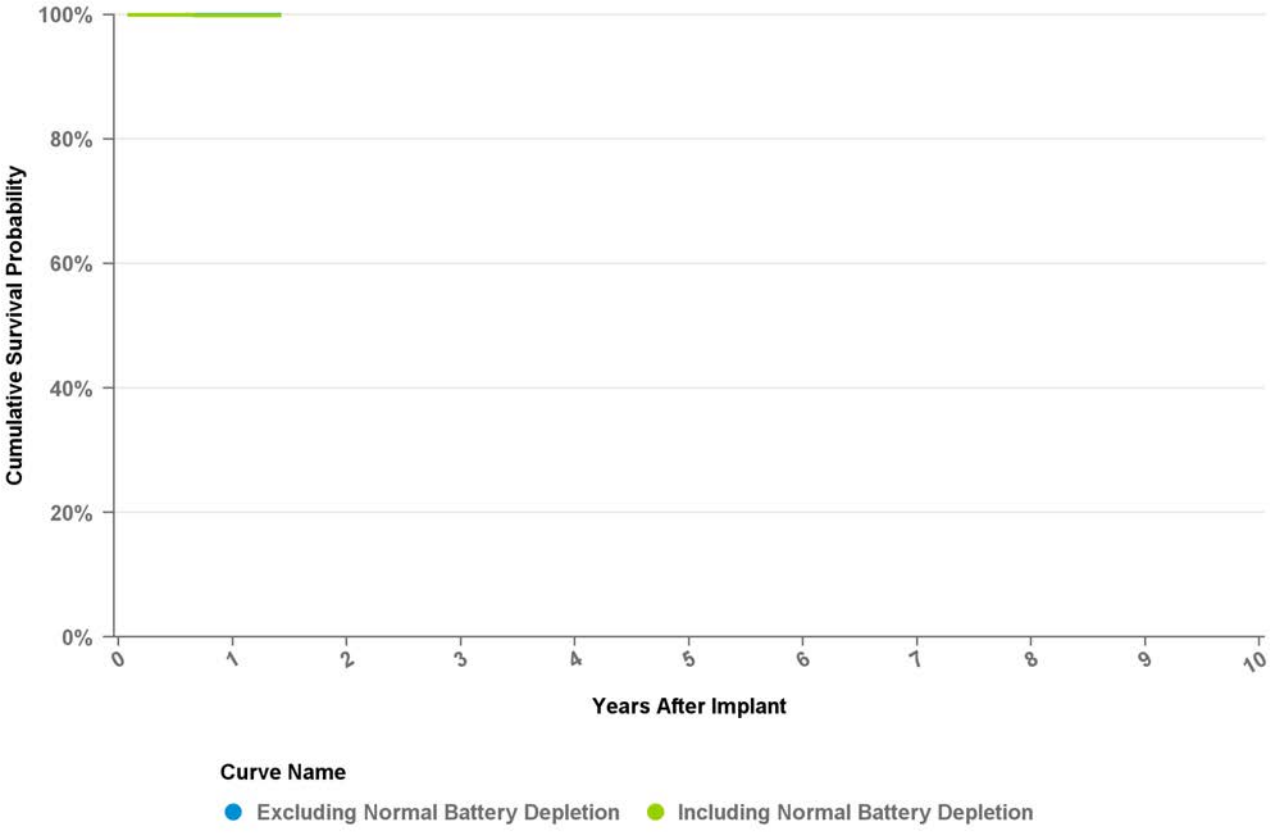
DTBB1Q1 Viva Quad S

US Market Release Date	
CE Market Approval Date	
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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

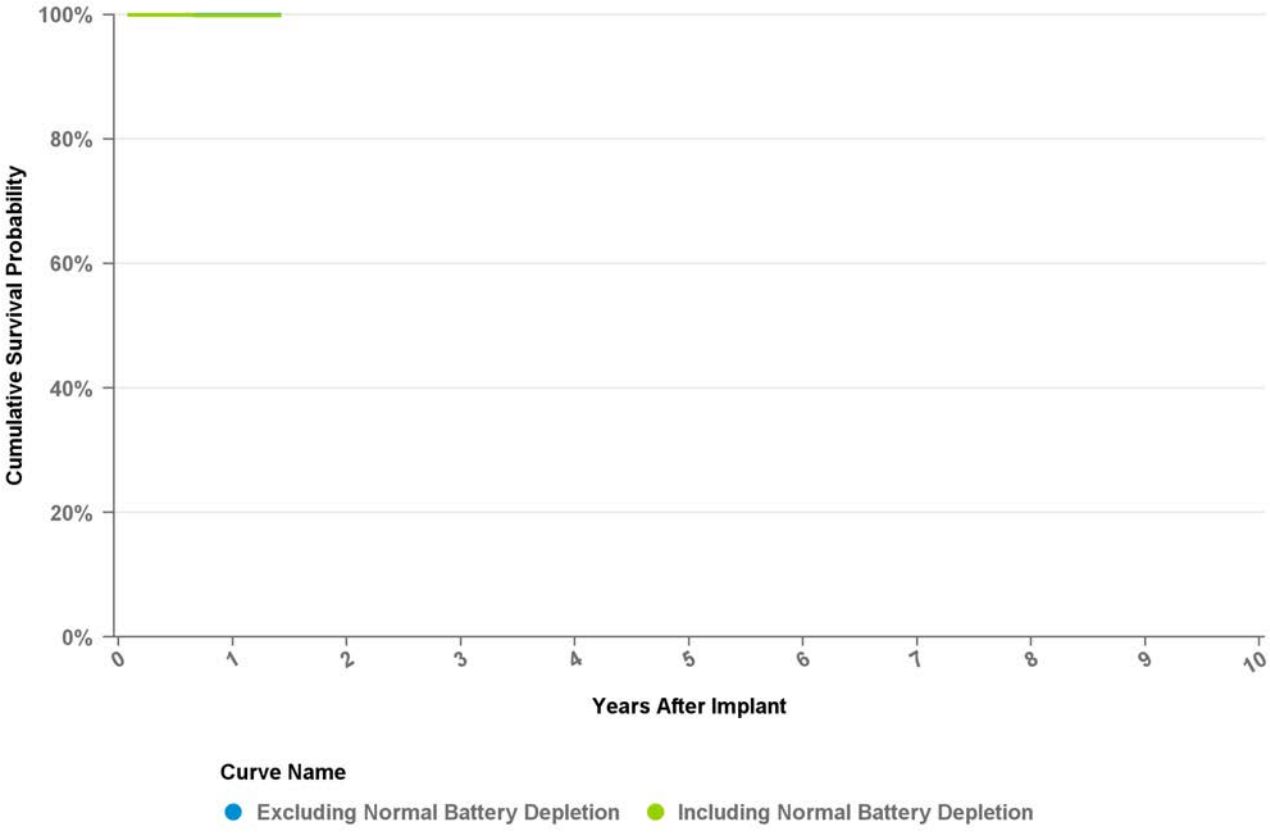
DTBB1QQ Viva Quad S

US Market Release Date	
CE Market Approval Date	
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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

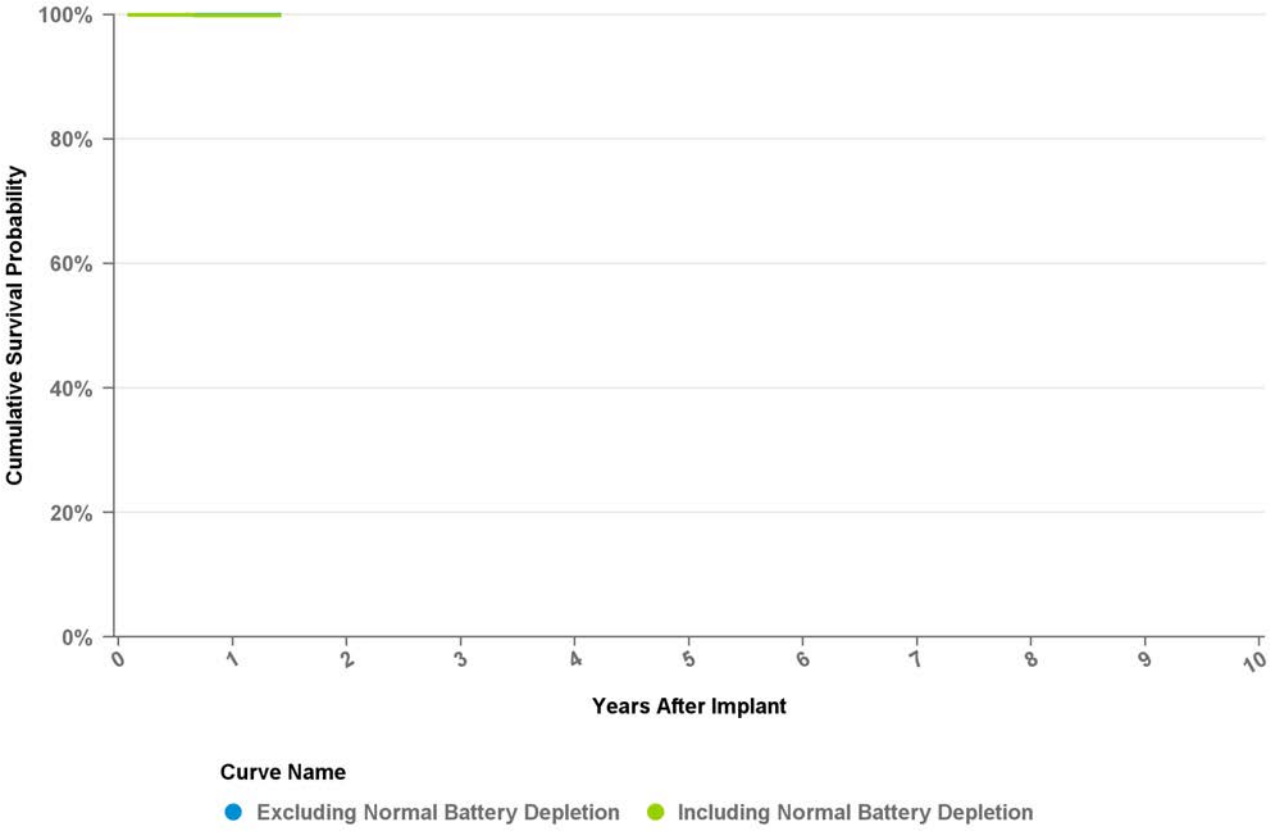
DTBB2D1 Viva S

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

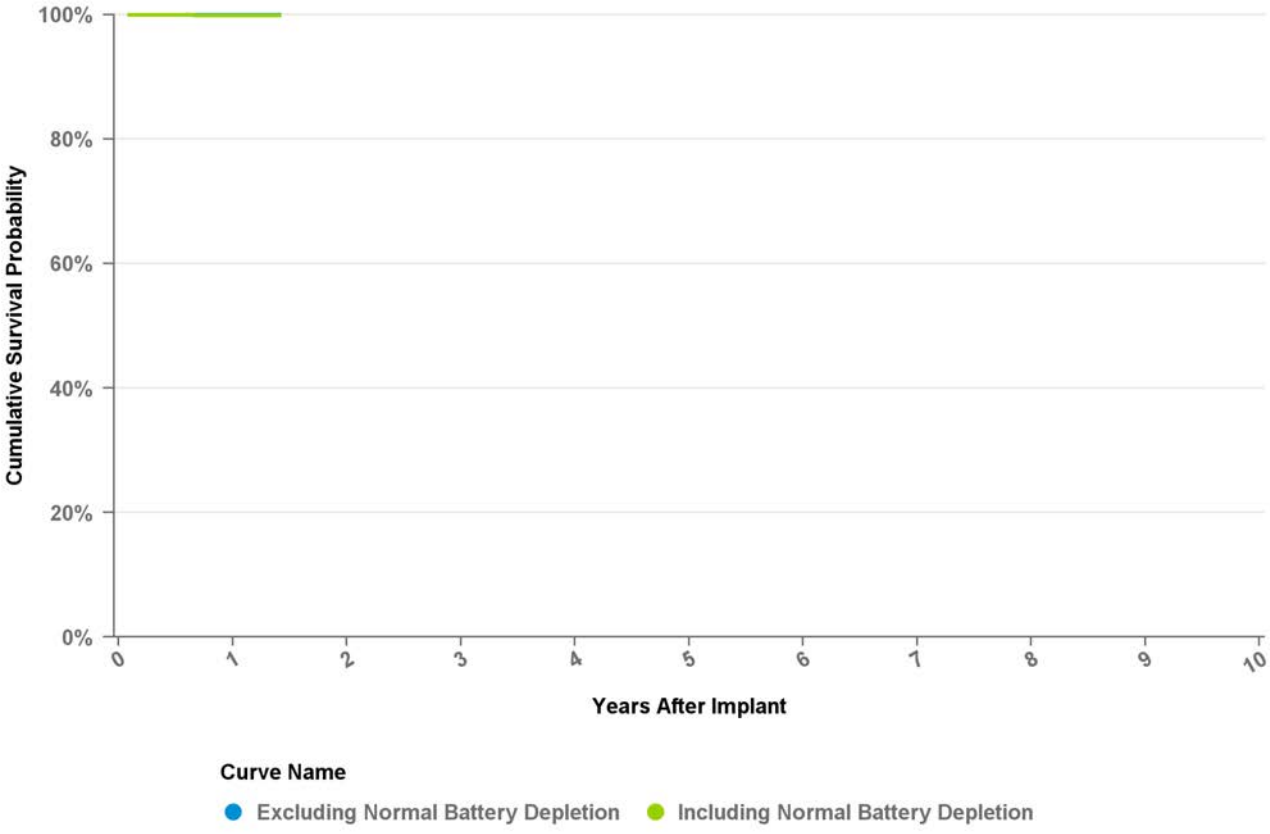
DTBB2D4 Viva S

US Market Release Date	
CE Market Approval Date	8/10/2012
Registered US Implants	1
Estimated Active US Implants	1
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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

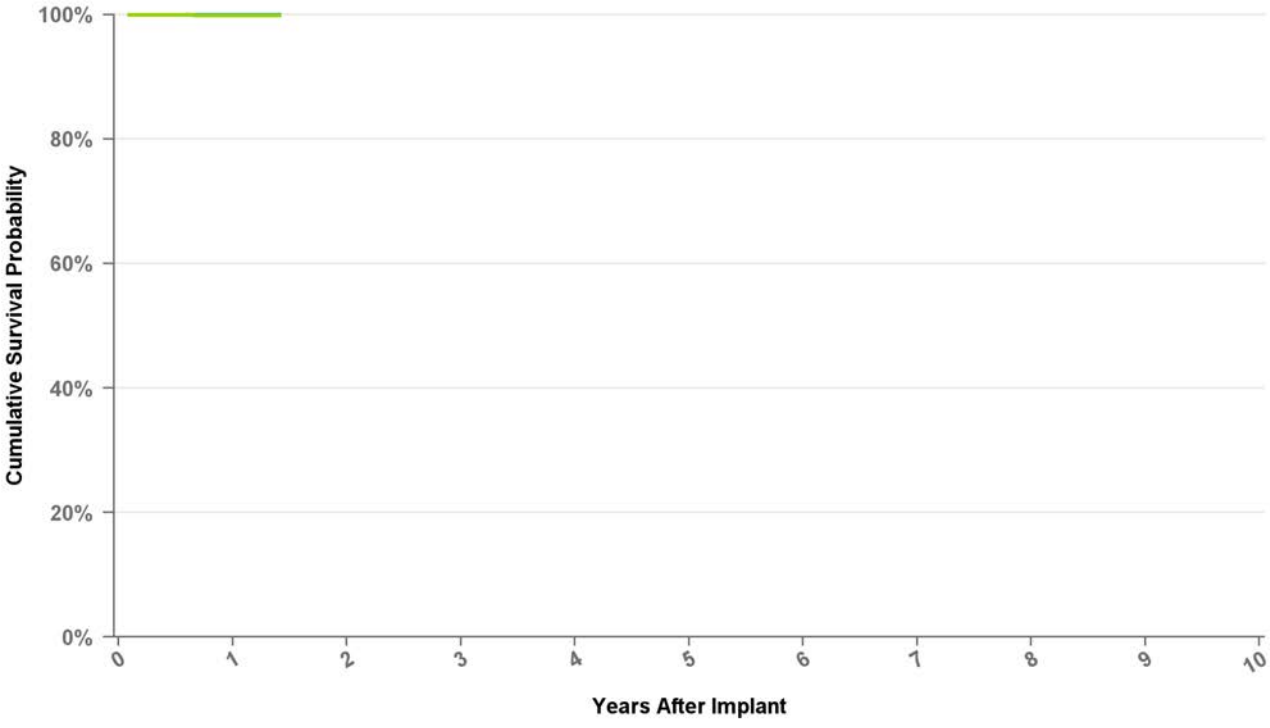
DTBB2QQ Viva Quad S

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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

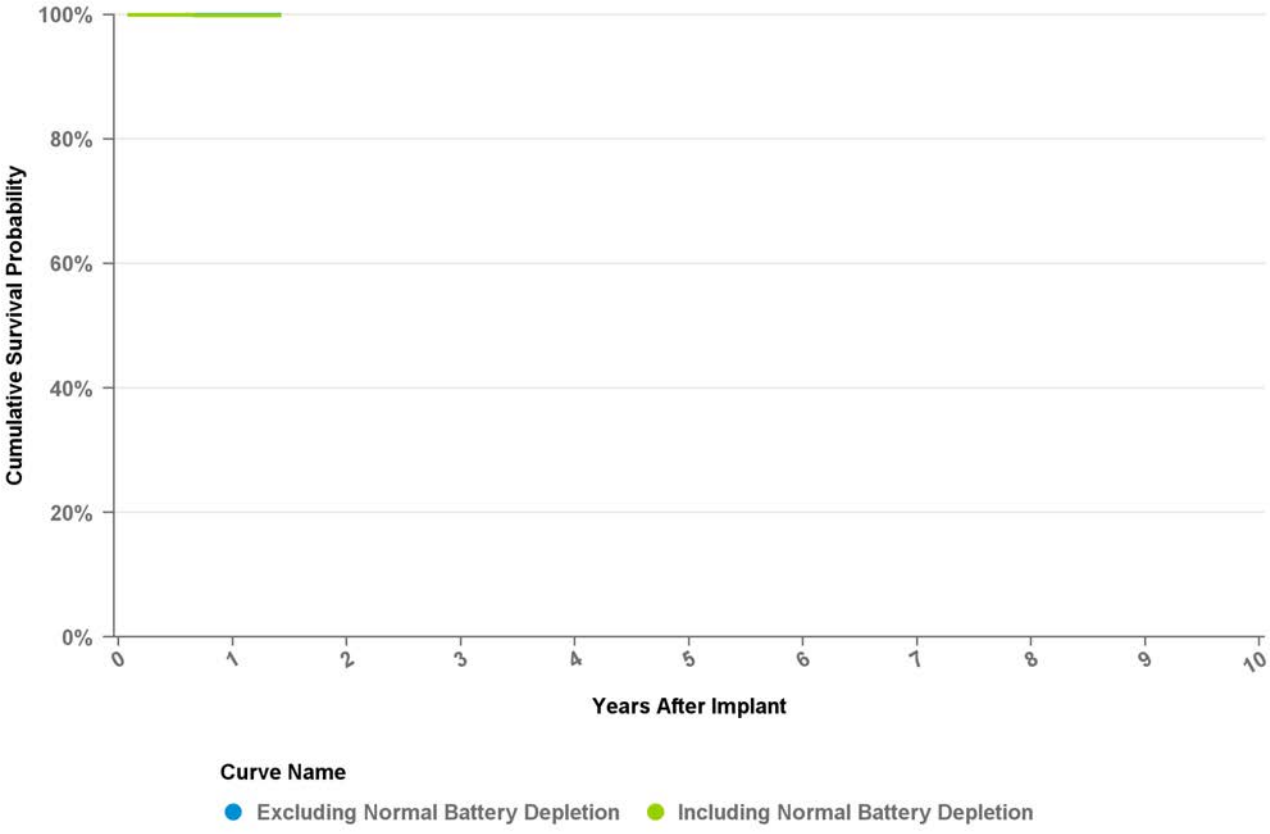
DTBC2D1 Brava

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	VVE-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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

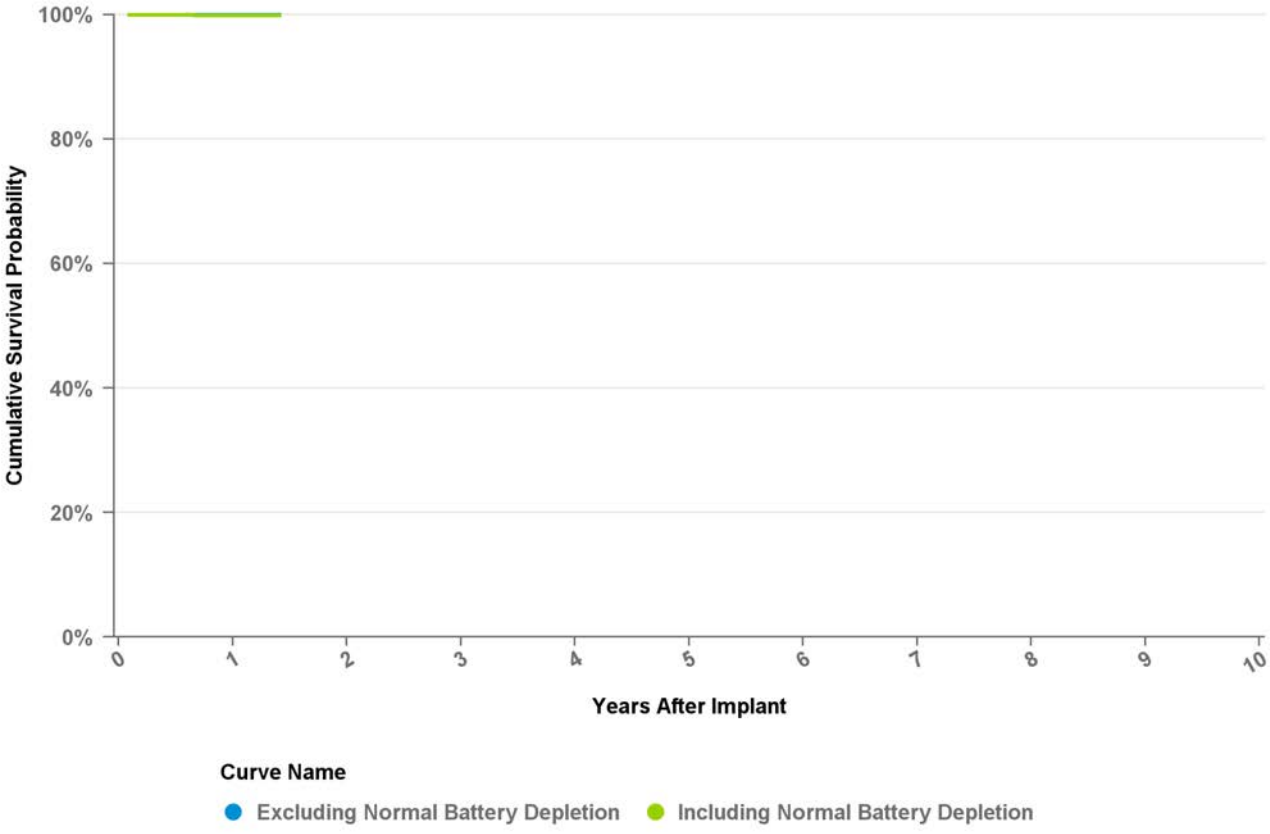
DTBC2D4 Brava

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	VVE-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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

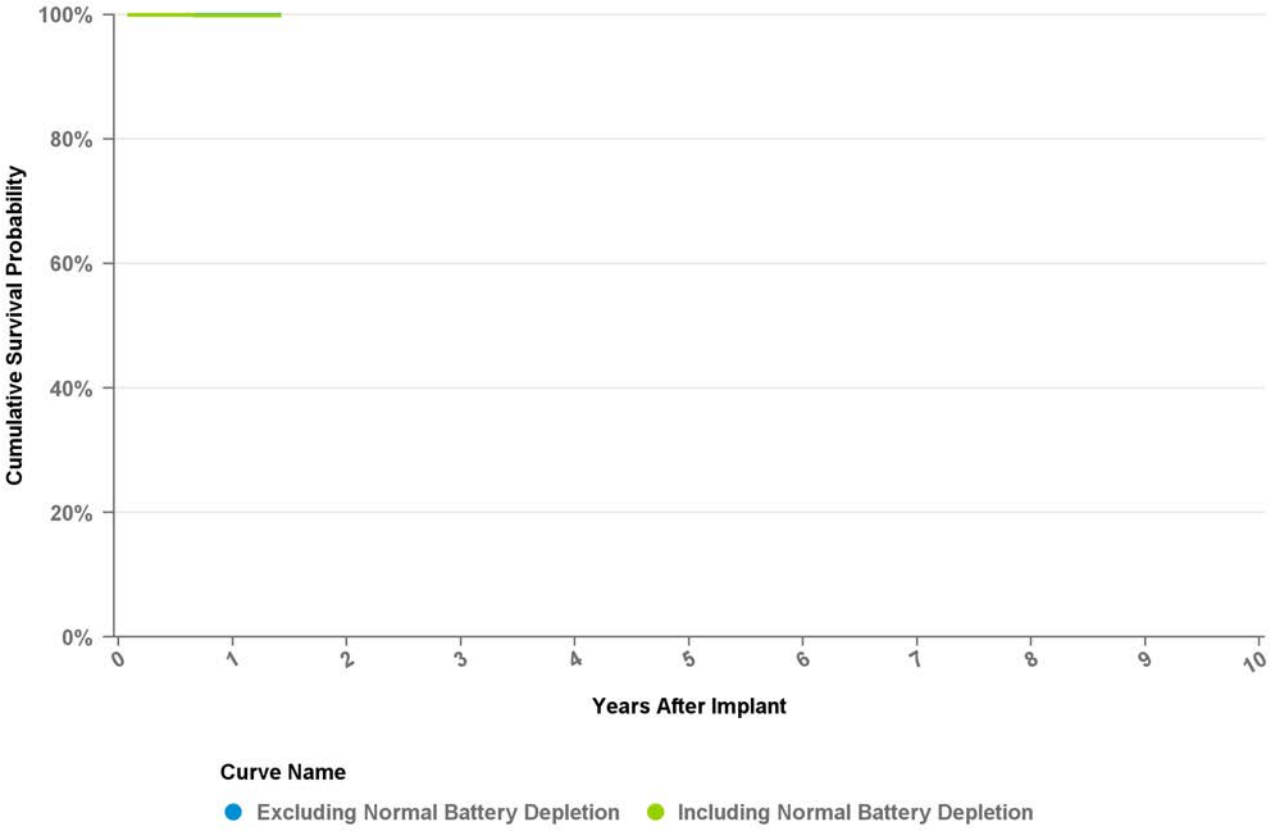
DTBC2Q1 Brava Quad

US Market Release Date	
CE Market Approval Date	9/13/2013
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	VVE-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

BLACKWELL, CRT-D, Survival Curve



Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Cardiac Resynchronization Therapy

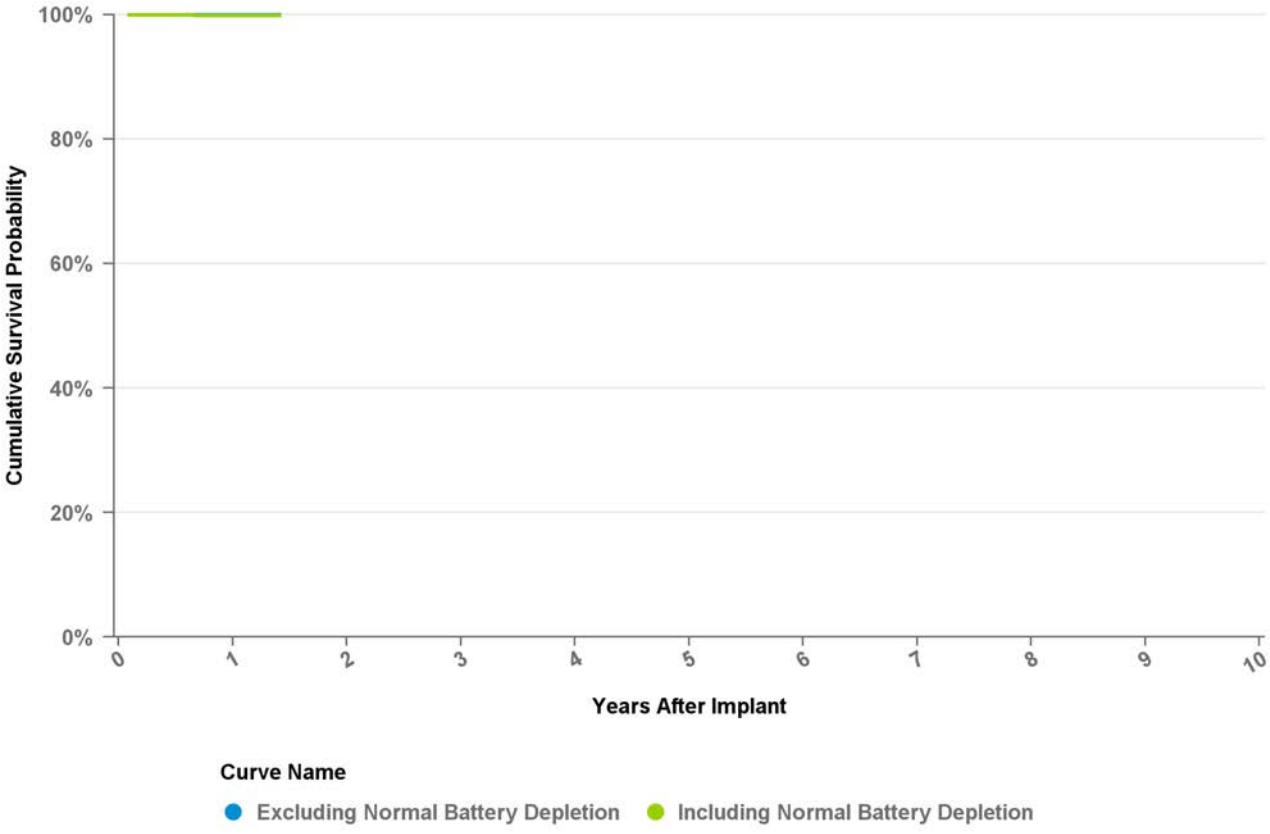
DTBC2QQ Brava Quad

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	VVE-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

BLACKWELL, CRT-D, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 17 mo
Excluding NBD	100.0%	100.0%
Including NBD	99.9%	99.9%
Effective Sample Size	4729	171

Implantable Cardioverter Defibrillator

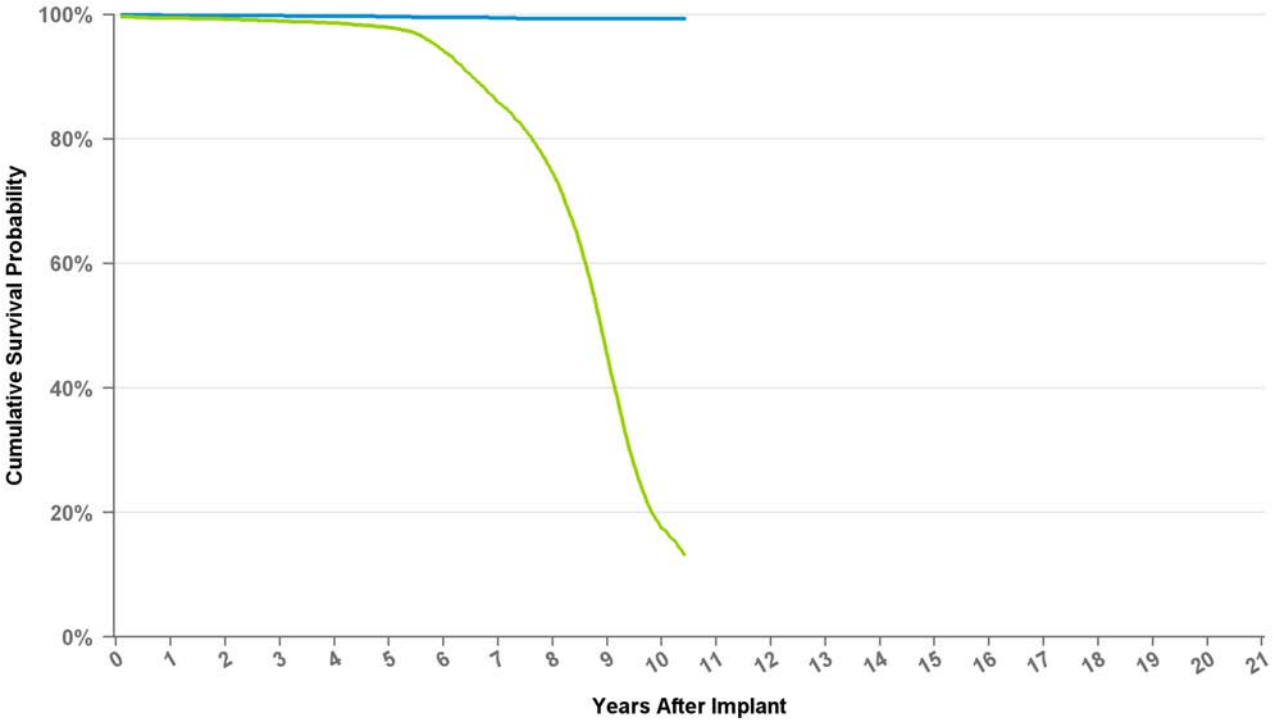
7230B Marquis VR

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)	25

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	10	at 125 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.9%	98.6%	97.9%	94.1%	85.9%	74.6%	45.3%	17.5%	13.3%
Effective Sample Size	17324	13568	11360	10203	9142	8028	6767	5458	3038	591	106

Implantable Cardioverter Defibrillator

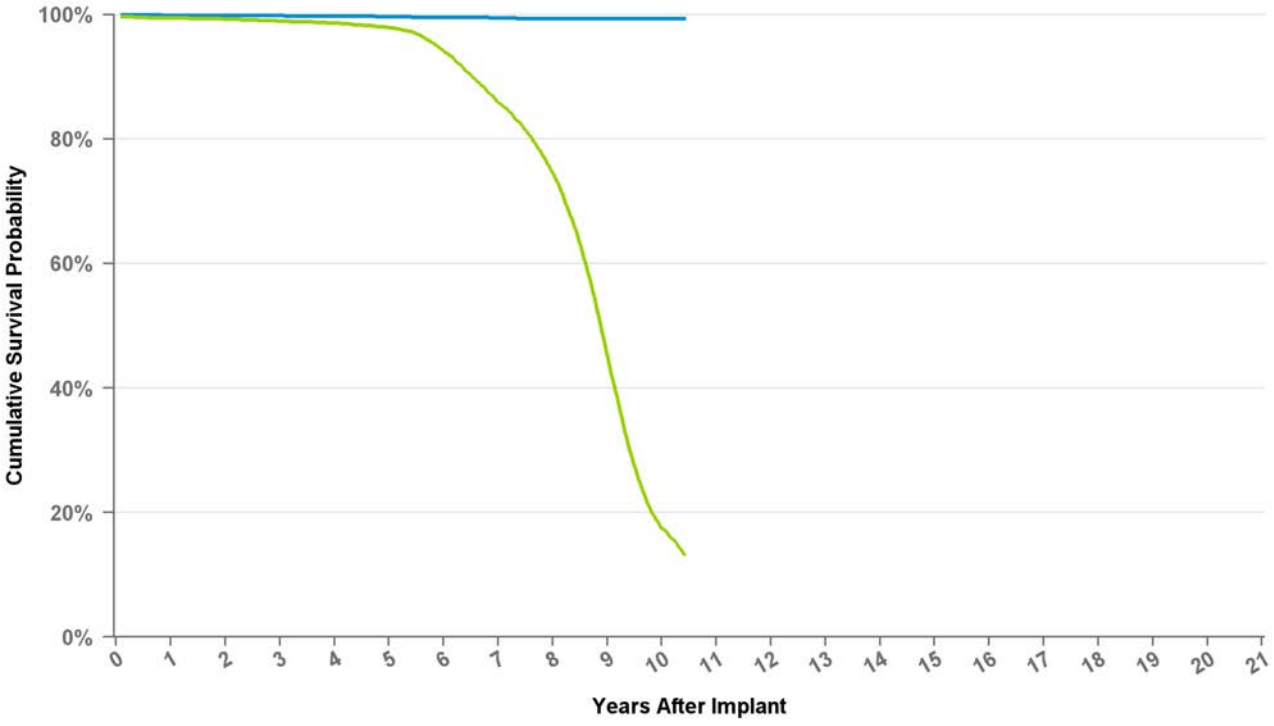
7230Cx Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	4/10/2002
Registered US Implants	18,564
Estimated Active US Implants	1,895
Normal Battery Depletions (US)	3,225

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.9%	98.6%	97.9%	94.1%	85.9%	74.6%	45.3%	17.5%	13.3%
Effective Sample Size	17324	13568	11360	10203	9142	8028	6767	5458	3038	591	106

Implantable Cardioverter Defibrillator

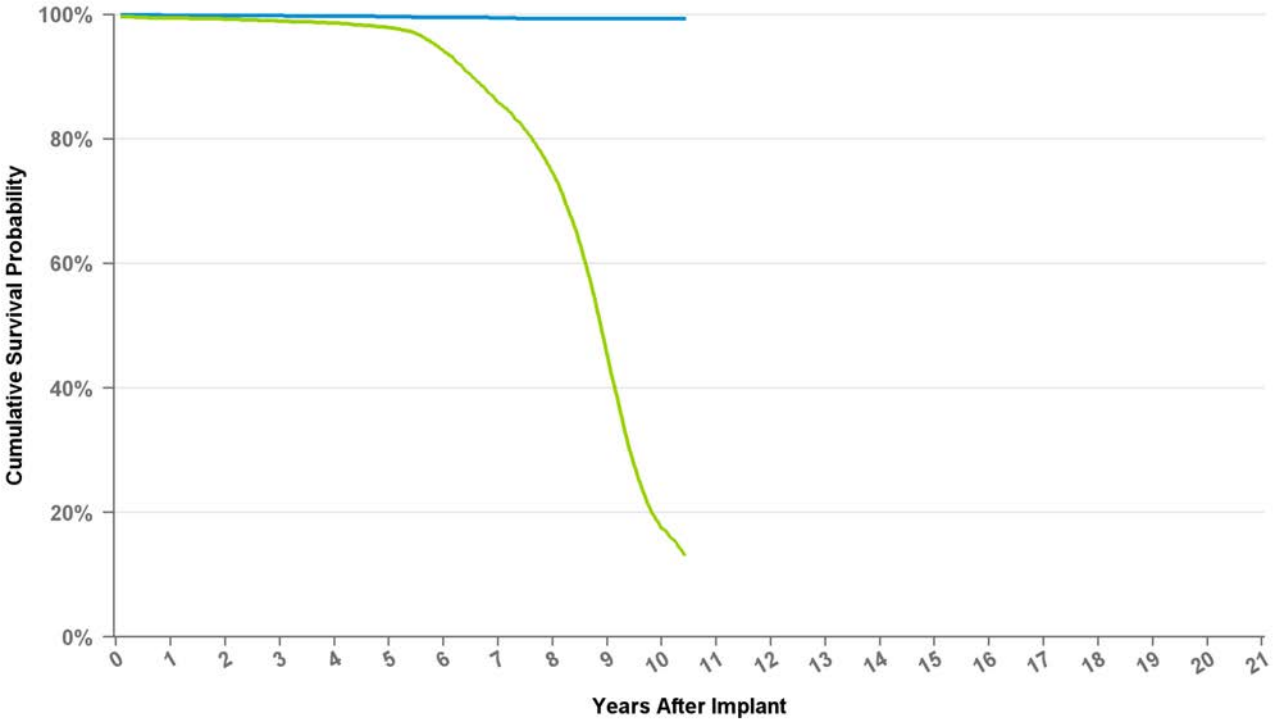
7230E Marquis VR

US Market Release Date	12/17/2002
CE Market Approval Date	8/21/2002
Registered US Implants	633
Estimated Active US Implants	63
Normal Battery Depletions (US)	76

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	99.9%	99.9%	99.9%	99.8%	99.7%	99.6%	99.5%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.5%	99.2%	98.9%	98.6%	97.9%	94.1%	85.9%	74.6%	45.3%	17.5%	13.3%
Effective Sample Size	17324	13568	11360	10203	9142	8028	6767	5458	3038	591	106

Implantable Cardioverter Defibrillator

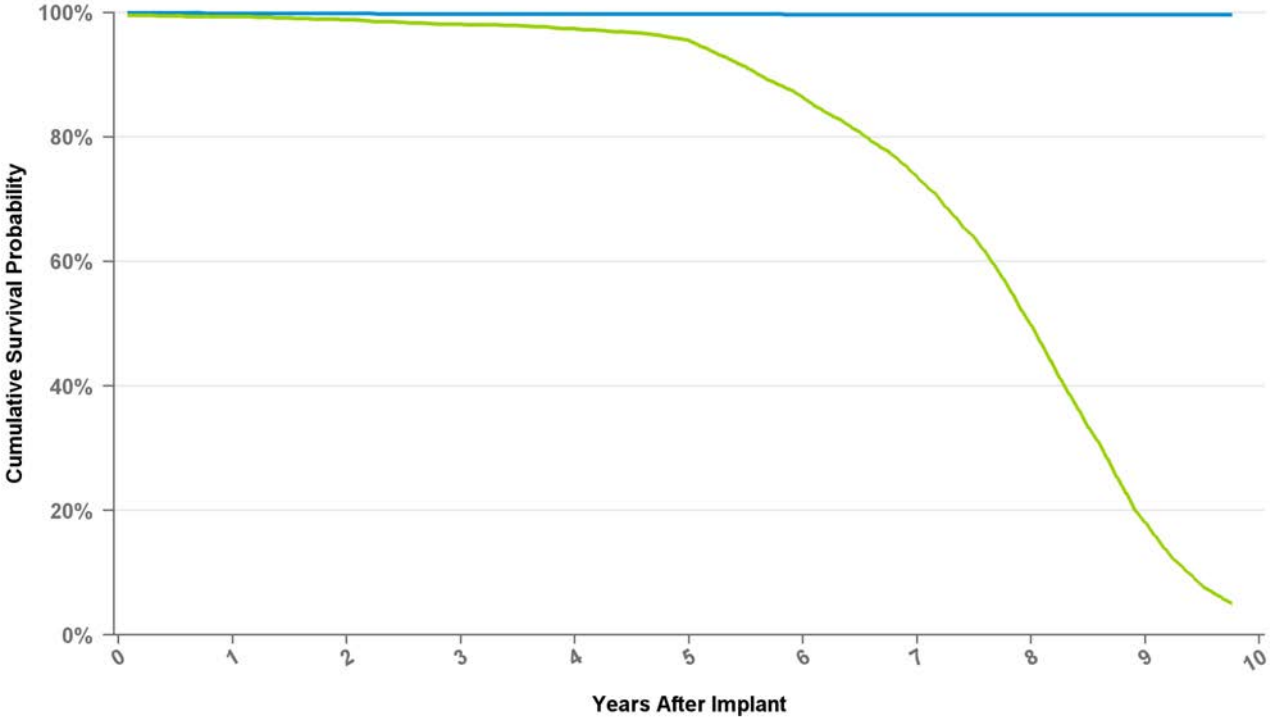
7231Cx GEM III VR

US Market Release Date	12/12/2000
CE Market Approval Date	12/8/2000
Registered US Implants	17,494
Estimated Active US Implants	1,577
Normal Battery Depletions (US)	3,862

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	9	at 117 mo
Excluding NBD	99.9%	99.9%	99.8%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.3%	98.8%	98.1%	97.4%	95.5%	86.3%	73.5%	49.8%	18.1%	5.1%
Effective Sample Size	15739	14053	12436	10941	9542	7891	6141	3699	1049	137

Implantable Cardioverter Defibrillator

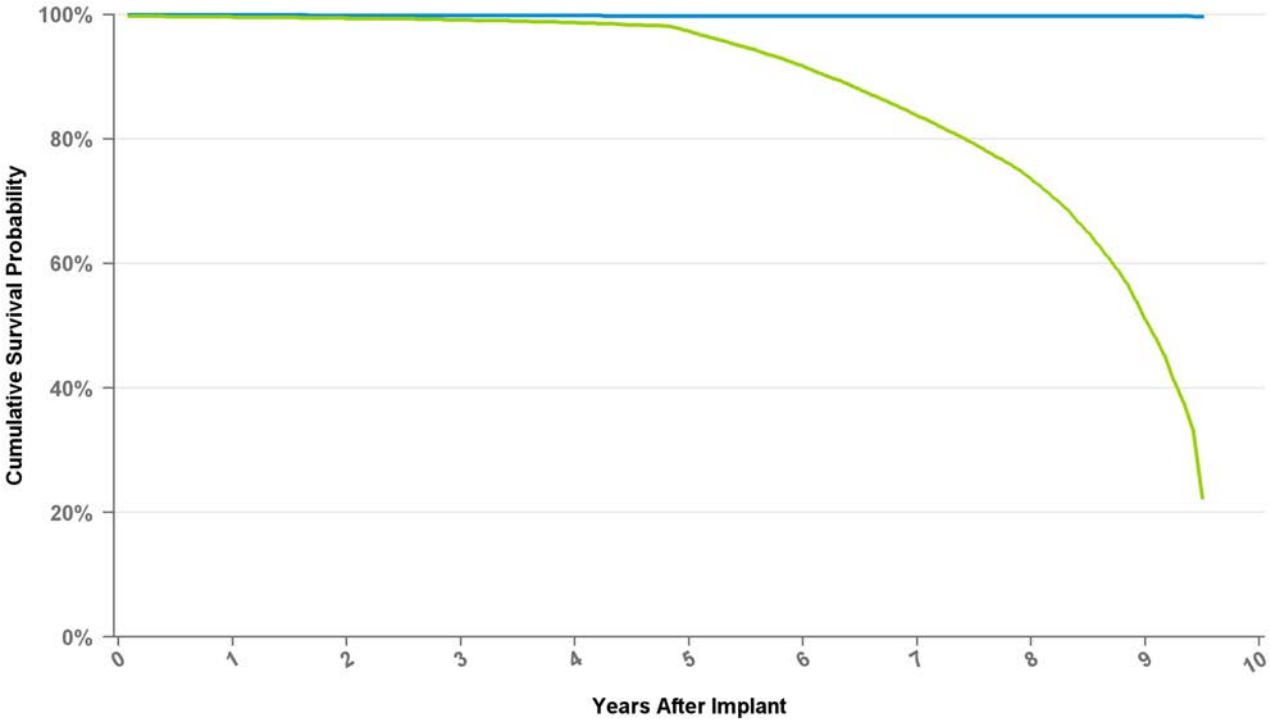
7232B Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	170
Estimated Active US Implants	68
Normal Battery Depletions (US)	14

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.6%	99.4%	99.1%	98.7%	97.3%	91.7%	83.7%	73.5%	51.0%	22.4%
Effective Sample Size	40684	36612	32842	29133	25728	21995	17549	12288	4365	205

Implantable Cardioverter Defibrillator

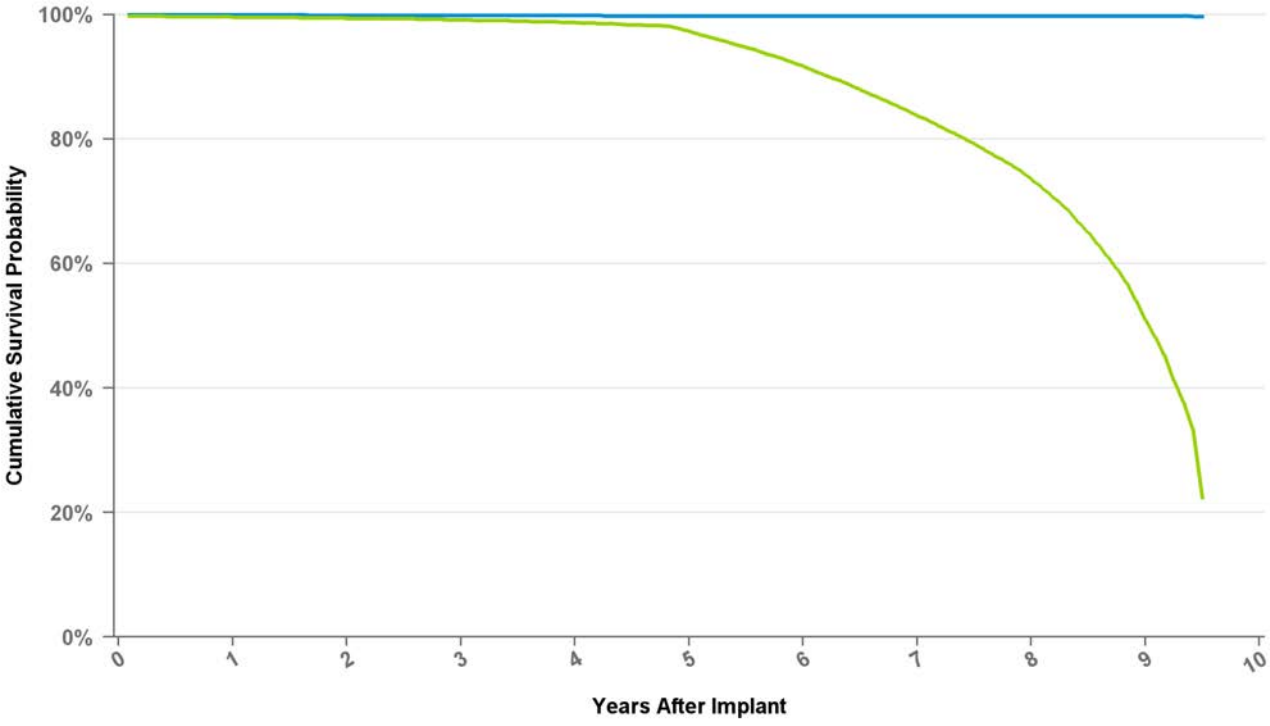
7232Cx Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	43,679
Estimated Active US Implants	13,333
Normal Battery Depletions (US)	6,061

NBG Code	VVE-VVIR
Max Delivered Energy	35J

Total Malfunctions (US)	76
Therapy Not Compromised Malfunction	61
Battery Malfunction	0
Electrical Component	28
Electrical Interconnect	0
Other Malfunction	6
Poss Early Battery Depltn	25
Software Malfunction	2
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.6%	99.4%	99.1%	98.7%	97.3%	91.7%	83.7%	73.5%	51.0%	22.4%
Effective Sample Size	40684	36612	32842	29133	25728	21995	17549	12288	4365	205

Implantable Cardioverter Defibrillator

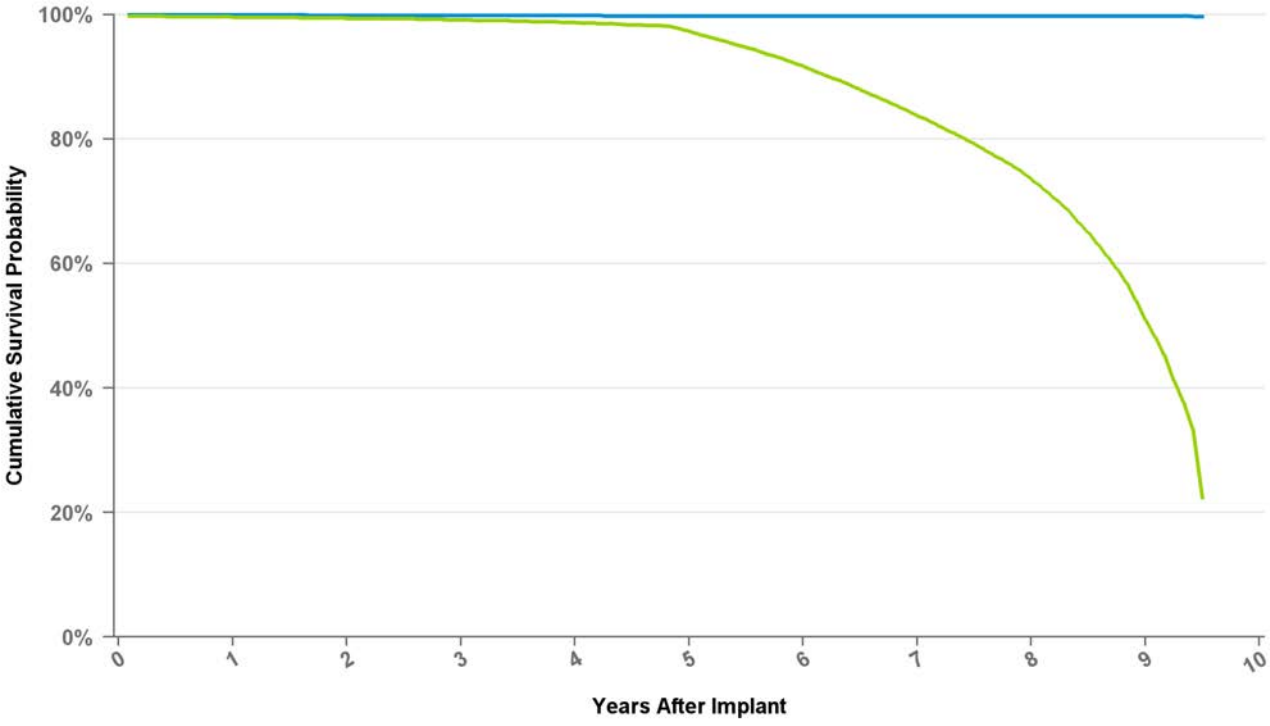
7232E Maximo VR

US Market Release Date	10/6/2003
CE Market Approval Date	10/22/2004
Registered US Implants	491
Estimated Active US Implants	176
Normal Battery Depletions (US)	28

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 114 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.8%	99.8%	99.8%	99.8%	99.8%	99.7%
Including NBD	99.6%	99.4%	99.1%	98.7%	97.3%	91.7%	83.7%	73.5%	51.0%	22.4%
Effective Sample Size	40684	36612	32842	29133	25728	21995	17549	12288	4365	205

Implantable Cardioverter Defibrillator

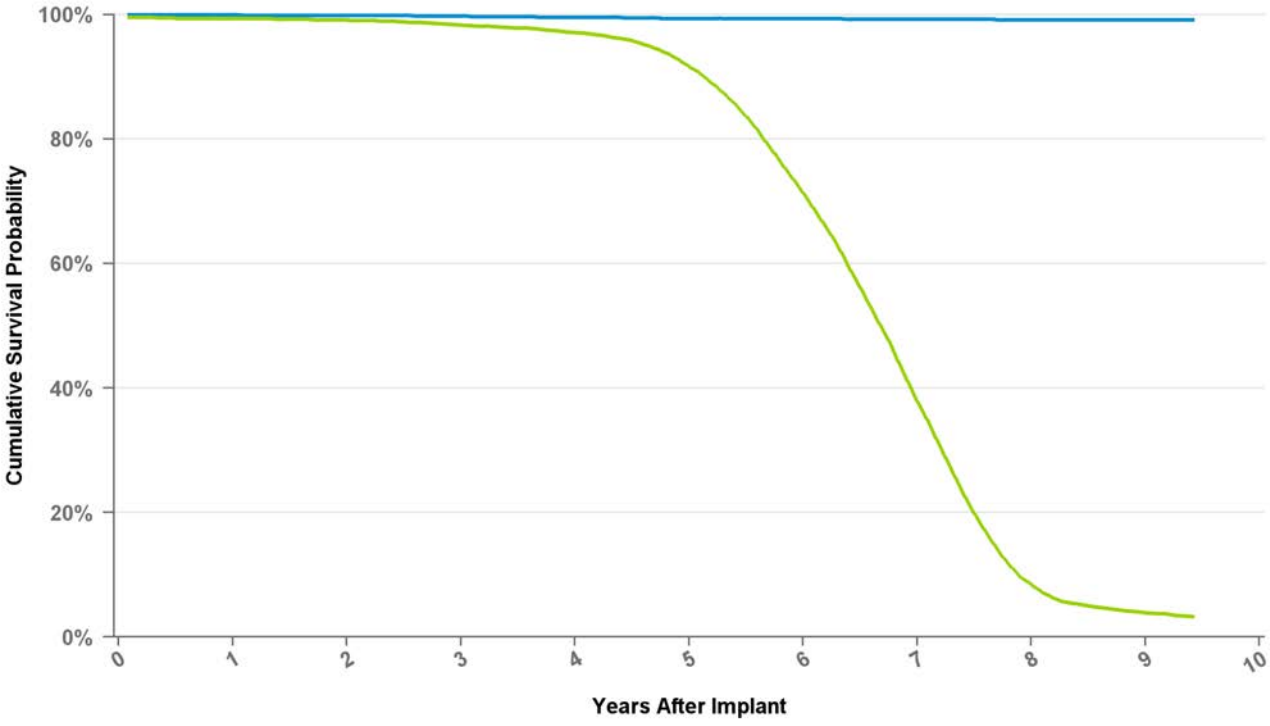
7274 Marquis DR

US Market Release Date	3/1/2002
CE Market Approval Date	2/25/2002
Registered US Implants	48,389
Estimated Active US Implants	2,689
Normal Battery Depletions (US)	9,058

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 113 mo
Excluding NBD	100.0%	99.9%	99.8%	99.6%	99.4%	99.3%	99.2%	99.1%	99.1%	99.1%
Including NBD	99.3%	99.1%	98.3%	97.1%	91.6%	71.4%	37.9%	8.4%	3.9%	3.3%
Effective Sample Size	42840	34502	26565	22608	18794	12952	6040	1010	268	140

Implantable Cardioverter Defibrillator

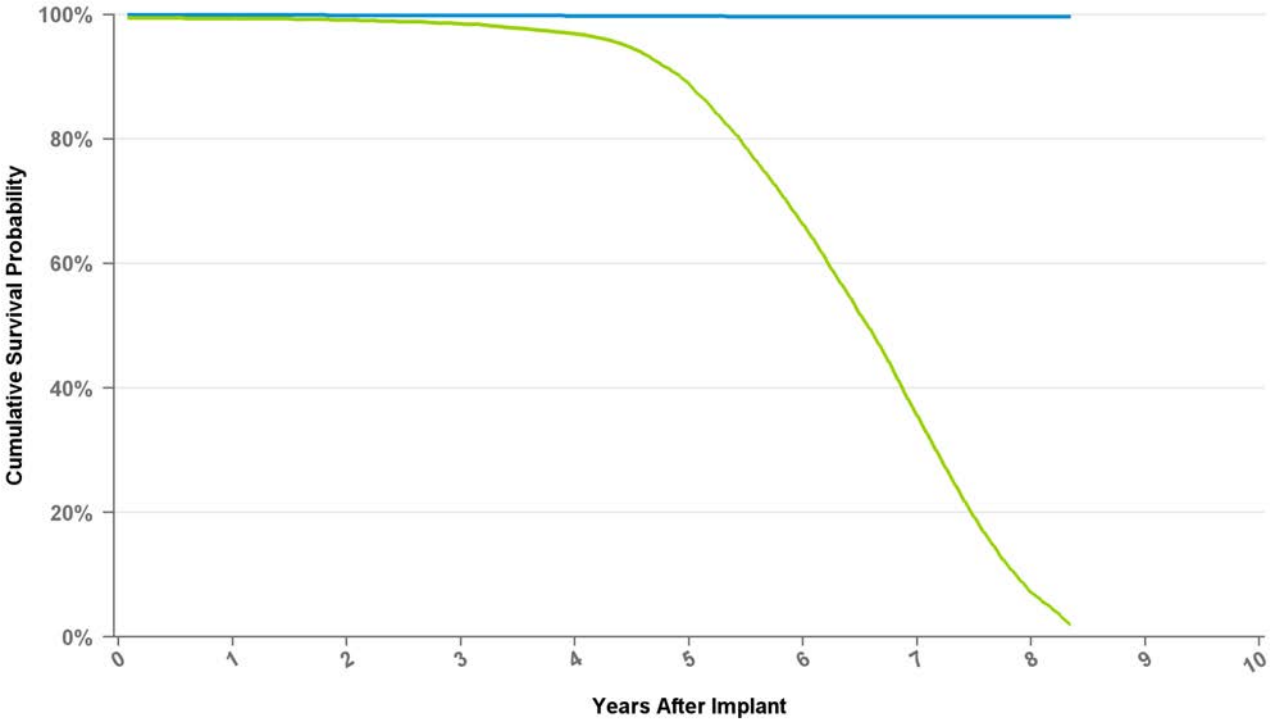
7278 Maximo DR

US Market Release Date	10/6/2003
CE Market Approval Date	10/28/2003
Registered US Implants	37,665
Estimated Active US Implants	4,438
Normal Battery Depletions (US)	10,297

NBG Code	VVE-DDDR
Max Delivered Energy	35J

Total Malfunctions (US)	72
Therapy Not Compromised Malfunction	62
Battery Malfunction	0
Electrical Component	24
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 100 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.4%	99.1%	98.5%	96.9%	88.8%	66.3%	35.6%	7.2%	2.0%
Effective Sample Size	33859	30305	27180	23928	19800	13111	5957	836	116

Implantable Cardioverter Defibrillator

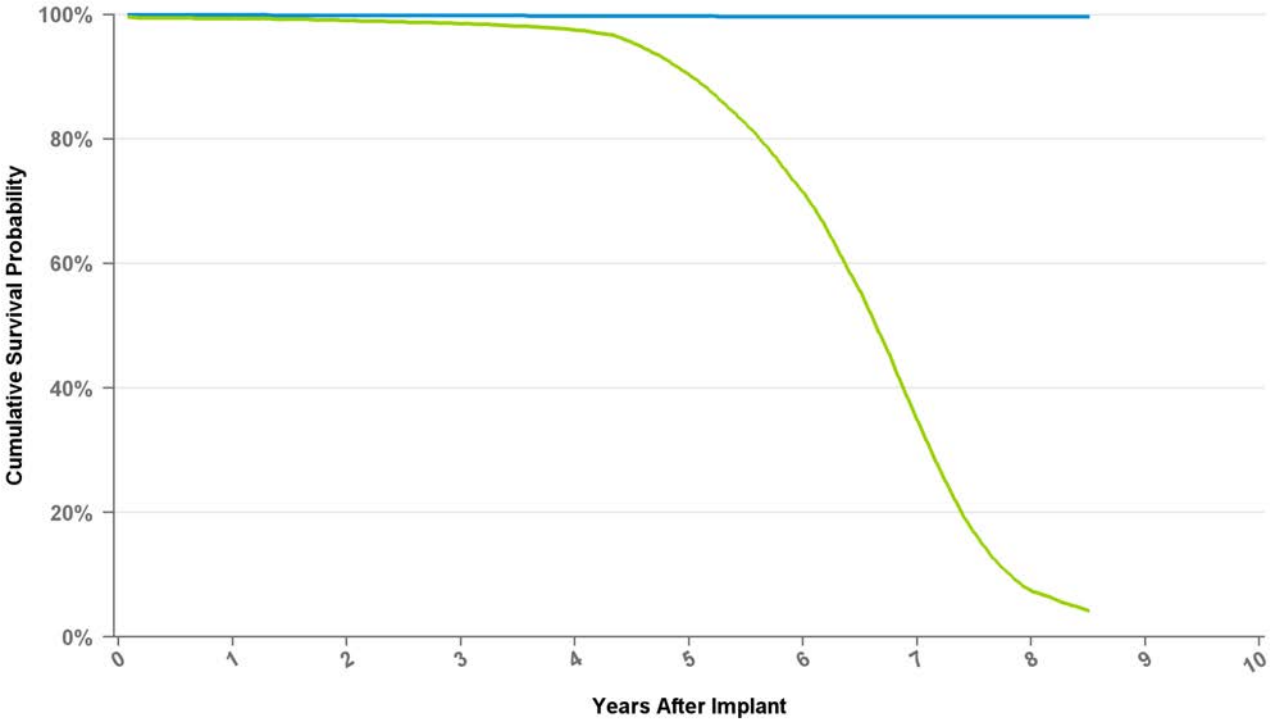
7288 Intrinsic

US Market Release Date	6/21/2004
CE Market Approval Date	5/4/2004
Registered US Implants	30,665
Estimated Active US Implants	2,993
Normal Battery Depletions (US)	9,964

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



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%	99.9%	99.9%	99.8%	99.8%	99.7%	99.7%	99.7%	99.7%
Including NBD	99.4%	99.0%	98.5%	97.5%	90.3%	71.5%	34.9%	7.4%	4.2%
Effective Sample Size	28598	26263	23688	20981	17799	12911	5809	799	118

Implantable Cardioverter Defibrillator

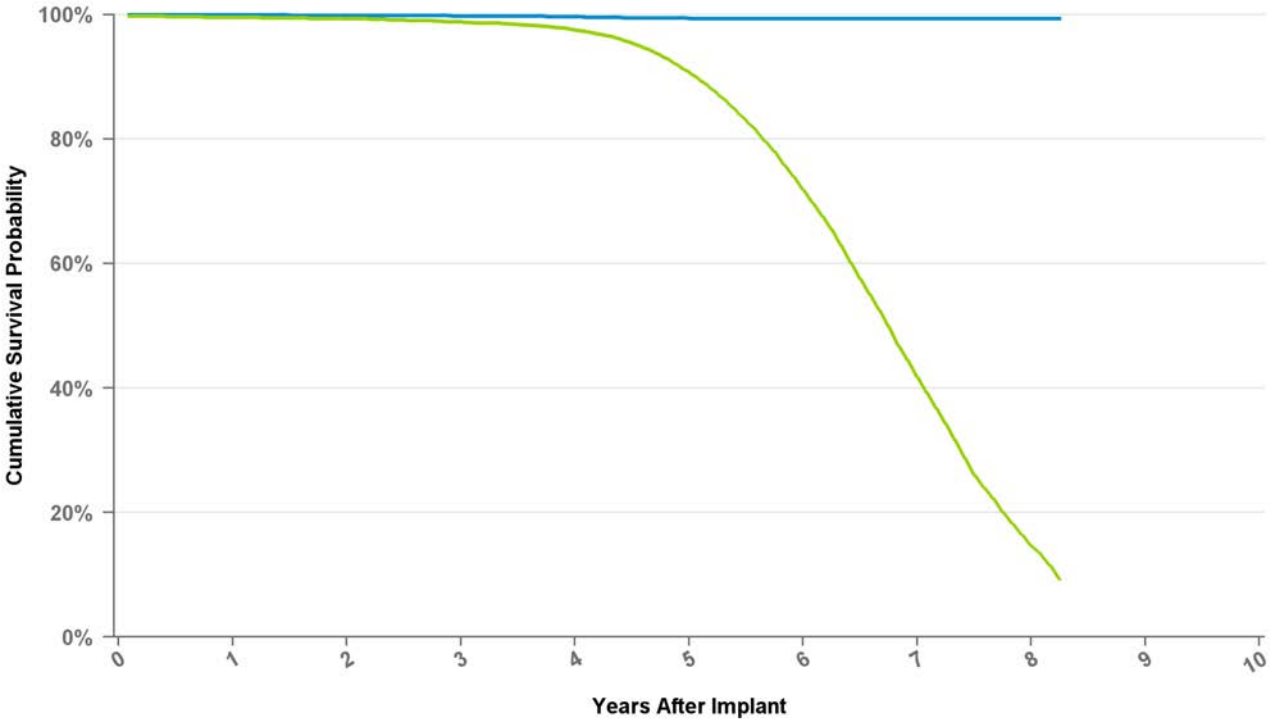
D144DRG Entrust Escudo

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.6%	99.3%	98.8%	97.5%	90.7%	71.9%	41.8%	14.7%	9.3%
Effective Sample Size	26272	24057	21681	19235	16117	11800	5804	1237	274

Implantable Cardioverter Defibrillator

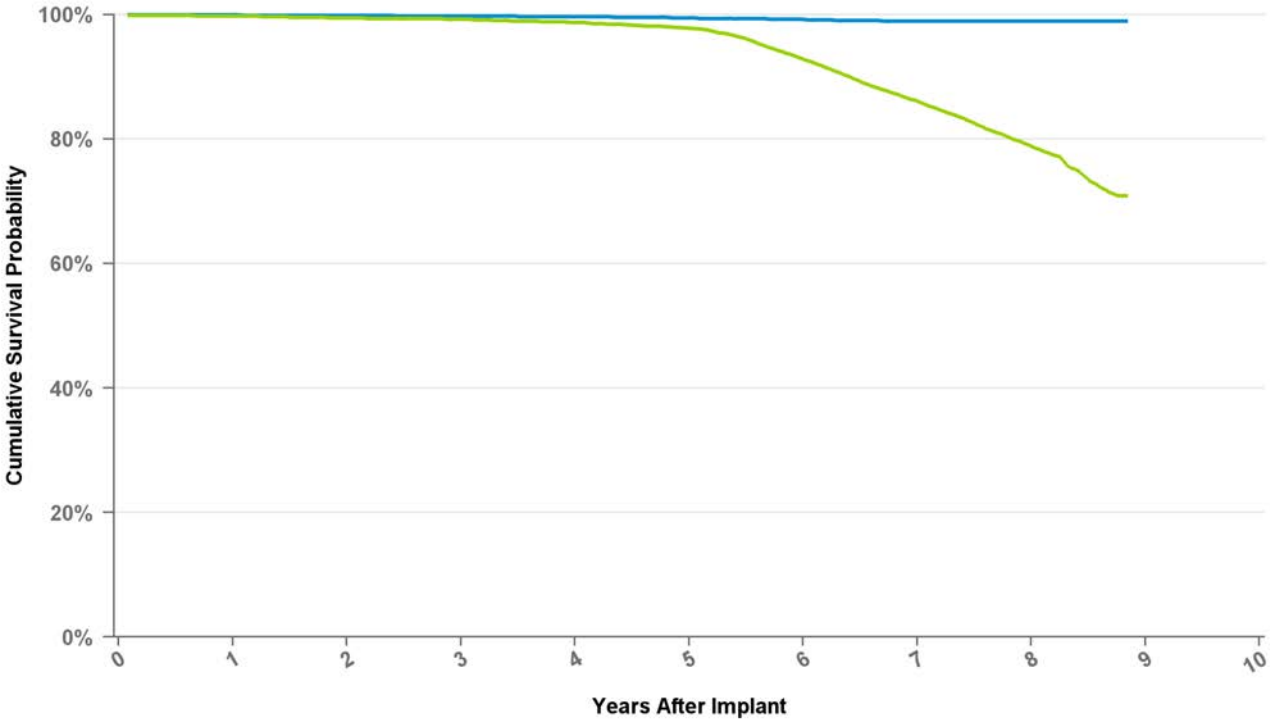
D144VRC Entrust Escudo

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.9%	98.9%
Including NBD	99.8%	99.5%	99.2%	98.7%	97.8%	92.8%	86.1%	78.8%	70.9%
Effective Sample Size	13630	12409	11155	9923	8835	7800	6136	3357	117

Implantable Cardioverter Defibrillator

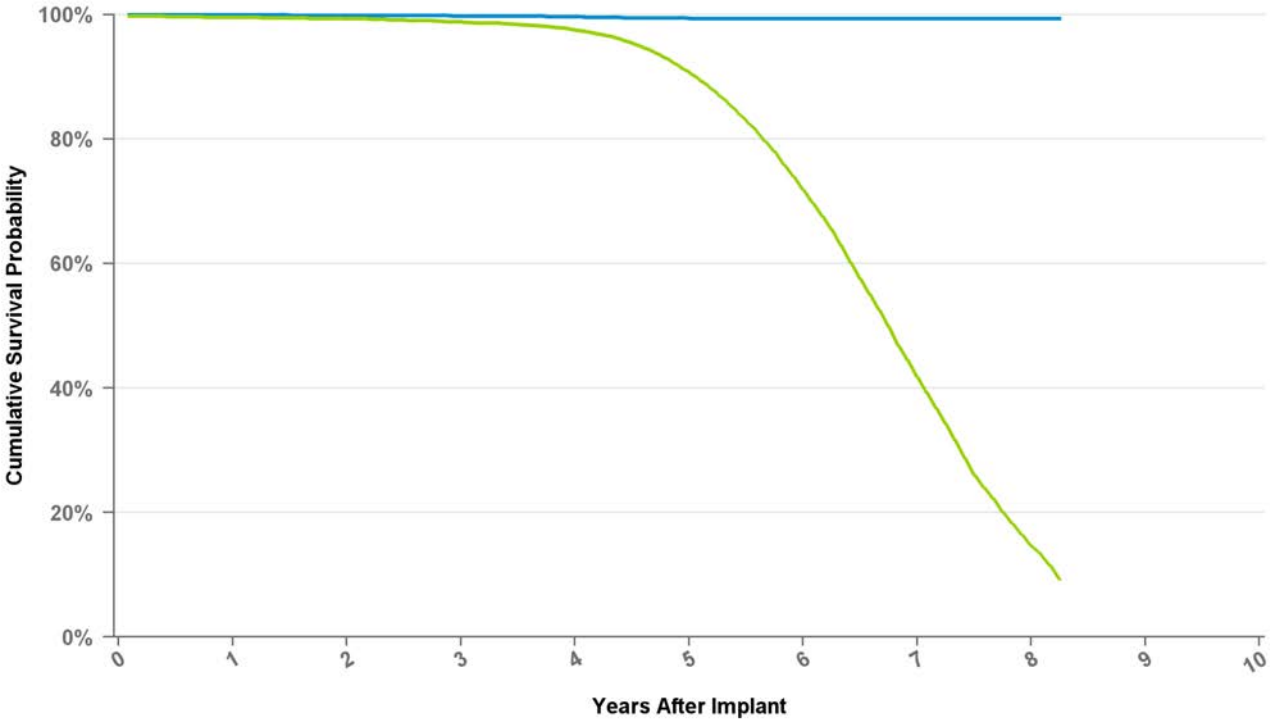
D154ATG Entrust AT

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	28,169
Estimated Active US Implants	4,242
Normal Battery Depletions (US)	8,160

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	124
Therapy Not Compromised Malfunction	110
Battery Malfunction	0
Electrical Component	30
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.6%	99.3%	98.8%	97.5%	90.7%	71.9%	41.8%	14.7%	9.3%
Effective Sample Size	26272	24057	21681	19235	16117	11800	5804	1237	274

Implantable Cardioverter Defibrillator

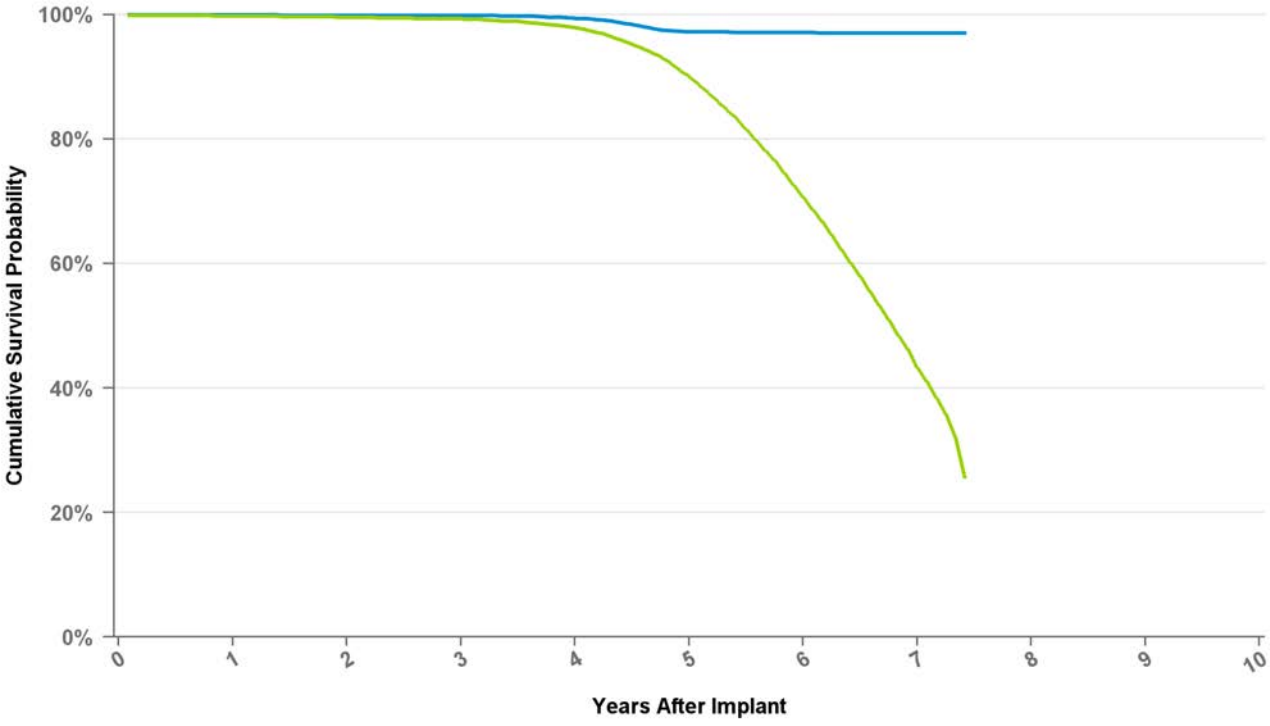
D154AWG Virtuoso DR

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	72,697
Estimated Active US Implants	29,932
Normal Battery Depletions (US)	11,190

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	1,444
Therapy Not Compromised Malfunction	1,415
Battery Malfunction	4
Electrical Component	1,270
Electrical Interconnect	2
Other Malfunction	4
Poss Early Battery Depltn	134
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 89 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.2%	97.1%	97.0%	97.0%
Including NBD	99.8%	99.6%	99.3%	97.9%	90.0%	70.7%	43.3%	25.7%
Effective Sample Size	67678	62378	57179	52045	42986	23836	4953	430

Implantable Cardioverter Defibrillator

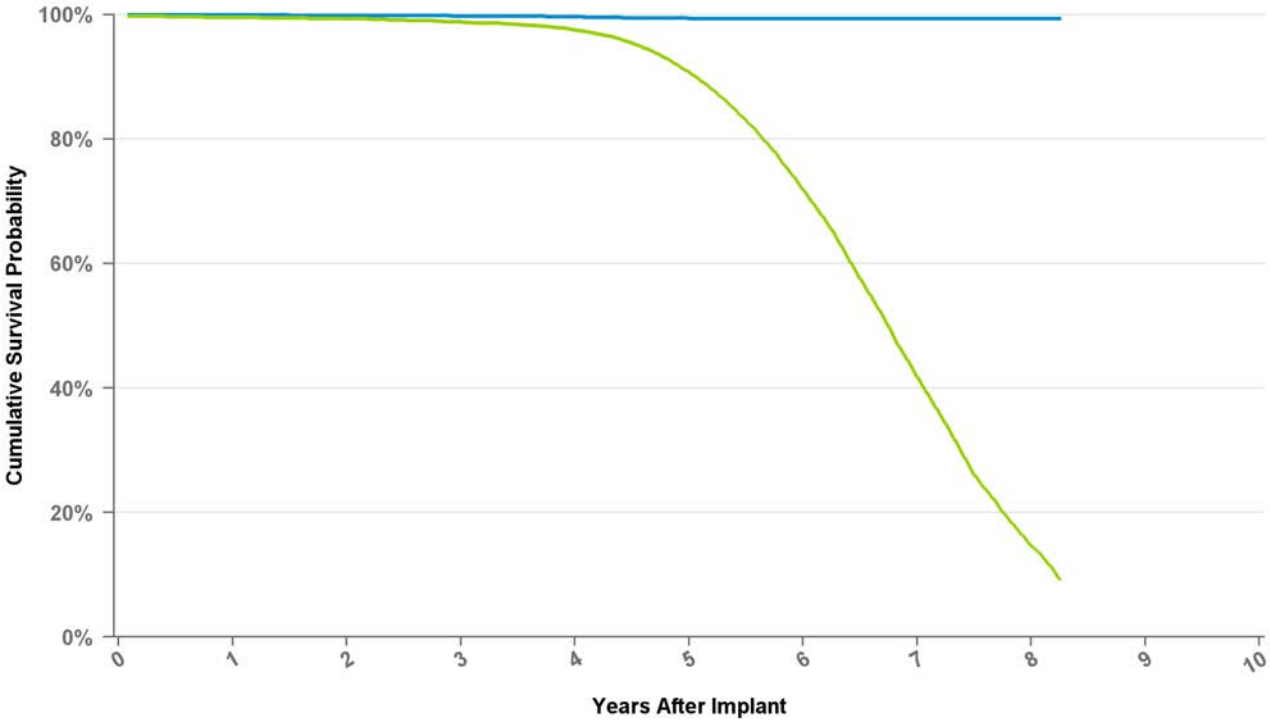
D154DRG Entrust DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 99 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.4%	99.4%	99.4%	99.4%	99.4%
Including NBD	99.6%	99.3%	98.8%	97.5%	90.7%	71.9%	41.8%	14.7%	9.3%
Effective Sample Size	26272	24057	21681	19235	16117	11800	5804	1237	274

Implantable Cardioverter Defibrillator

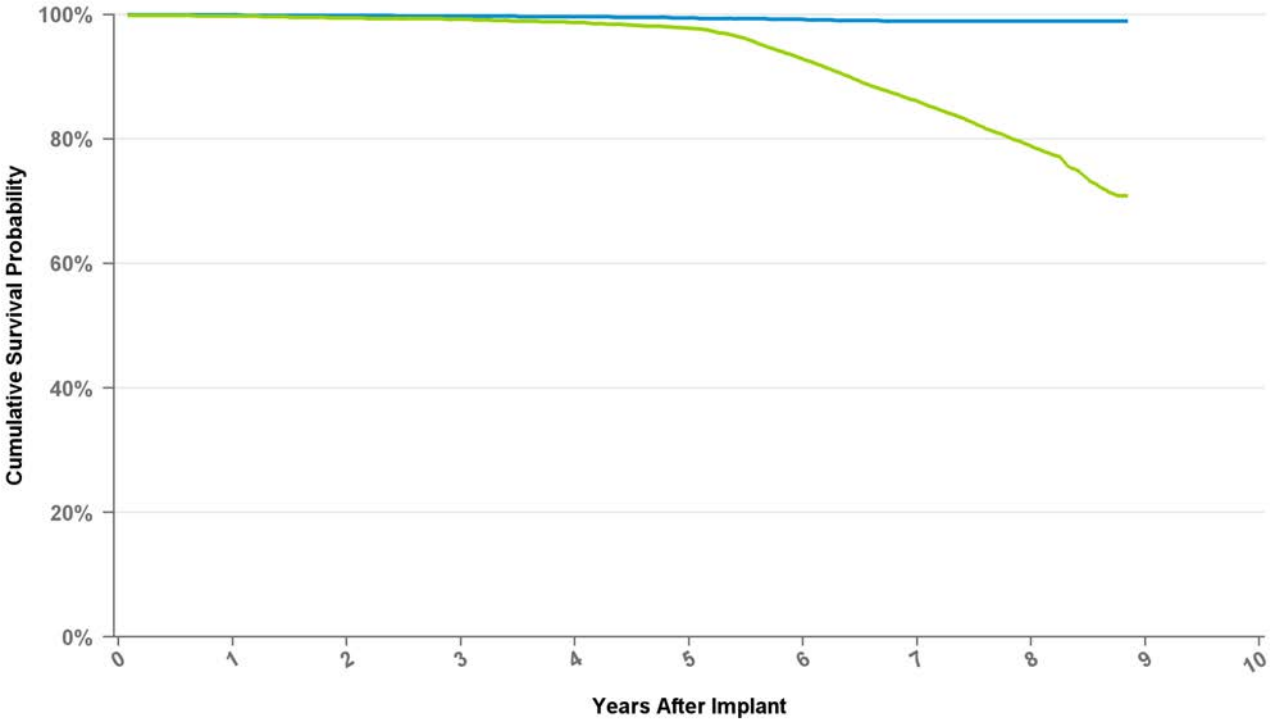
D154VRC Entrust VR

US Market Release Date	6/30/2005
CE Market Approval Date	2/4/2005
Registered US Implants	14,468
Estimated Active US Implants	6,201
Normal Battery Depletions (US)	1,095

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	104
Therapy Not Compromised Malfunction	85
Battery Malfunction	7
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 106 mo
Excluding NBD	100.0%	99.9%	99.8%	99.7%	99.5%	99.2%	98.9%	98.9%	98.9%
Including NBD	99.8%	99.5%	99.2%	98.7%	97.8%	92.8%	86.1%	78.8%	70.9%
Effective Sample Size	13630	12409	11155	9923	8835	7800	6136	3357	117

Implantable Cardioverter Defibrillator

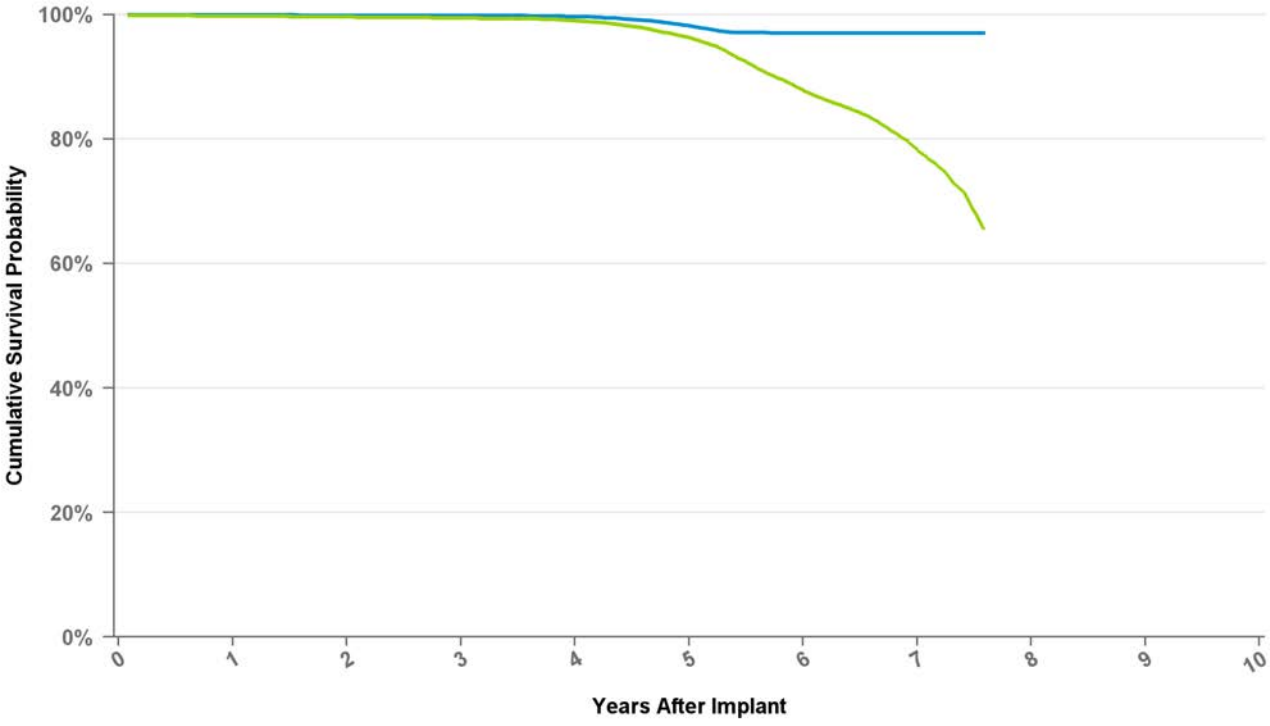
D154VWC Virtuoso VR

US Market Release Date	5/12/2006
CE Market Approval Date	
Registered US Implants	33,133
Estimated Active US Implants	18,058
Normal Battery Depletions (US)	1,705

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	647
Therapy Not Compromised Malfunction	632
Battery Malfunction	1
Electrical Component	611
Electrical Interconnect	1
Other Malfunction	4
Poss Early Battery Depltn	15
Software Malfunction	0
Therapy Compromised Malfunctions	15
Battery Malfunction	1
Electrical Component	14
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

D154VWC,D164VWC, Survival Curve



Curve Name

● Excluding Normal Battery Depletion ● Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 91 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.2%	97.0%	97.0%	97.0%
Including NBD	99.8%	99.7%	99.5%	99.0%	96.3%	87.8%	78.2%	65.6%
Effective Sample Size	30823	28276	25933	23771	20704	13464	4449	273

Implantable Cardioverter Defibrillator

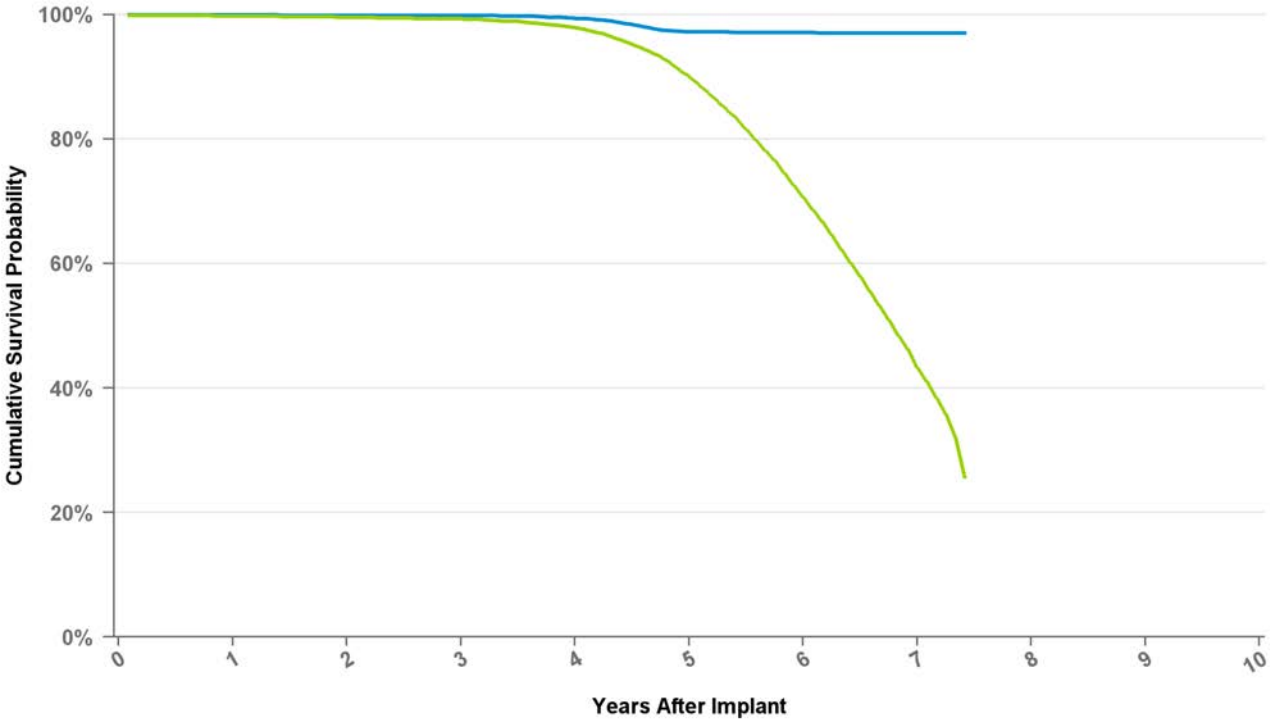
D164AWG Virtuoso DR

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	7	at 89 mo
Excluding NBD	100.0%	99.9%	99.9%	99.4%	97.2%	97.1%	97.0%	97.0%
Including NBD	99.8%	99.6%	99.3%	97.9%	90.0%	70.7%	43.3%	25.7%
Effective Sample Size	67678	62378	57179	52045	42986	23836	4953	430

Implantable Cardioverter Defibrillator

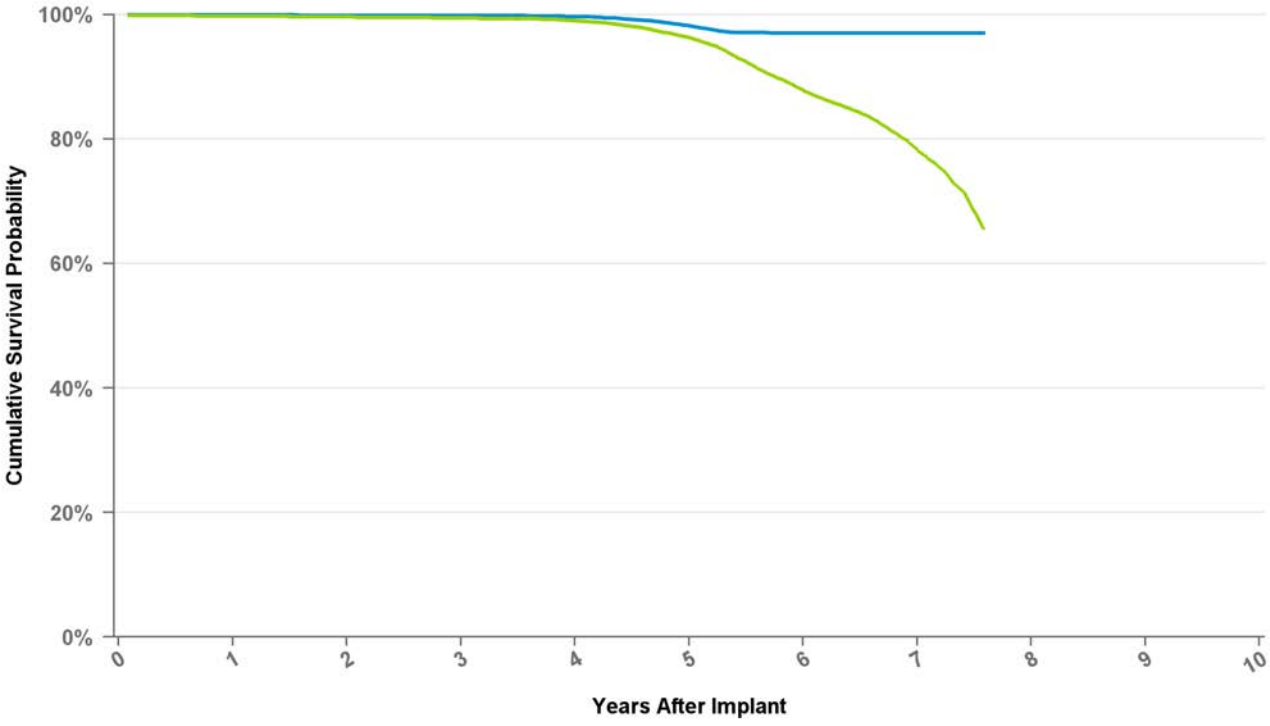
D164VWC Virtuoso VR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 91 mo
Excluding NBD	100.0%	99.9%	99.9%	99.7%	98.2%	97.0%	97.0%	97.0%
Including NBD	99.8%	99.7%	99.5%	99.0%	96.3%	87.8%	78.2%	65.6%
Effective Sample Size	30823	28276	25933	23771	20704	13464	4449	273

Implantable Cardioverter Defibrillator

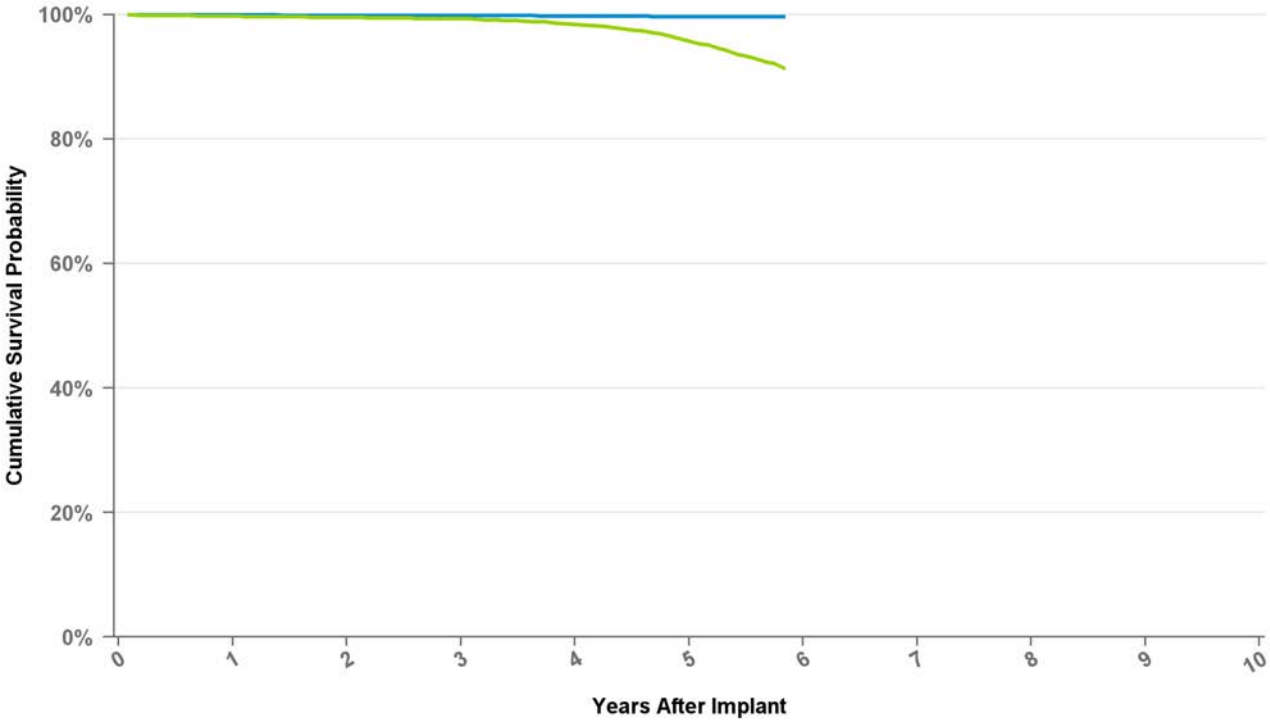
D204DRM Secura DR

US Market Release Date	1/9/2012
CE Market Approval Date	
Registered US Implants	1,852
Estimated Active US Implants	1,759
Normal Battery Depletions (US)	1

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.7%	91.3%
Effective Sample Size	48626	42739	36252	21633	7604	350

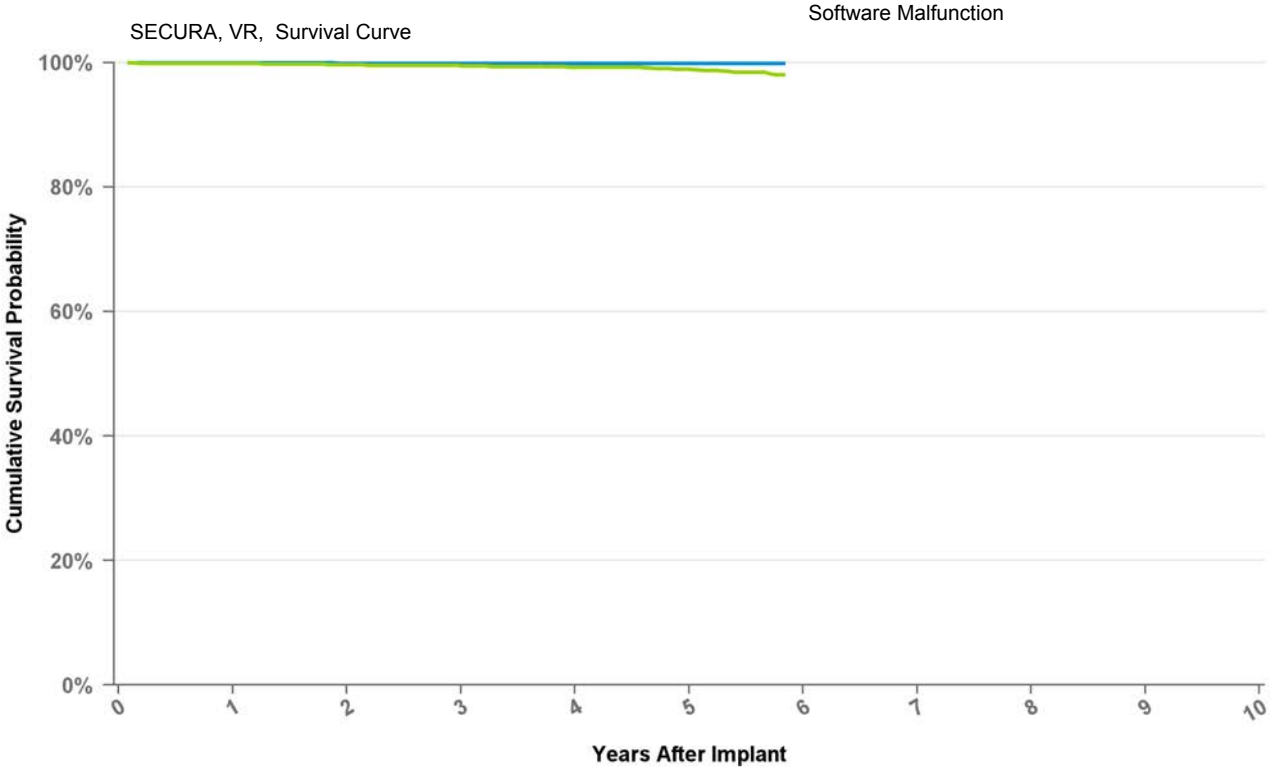
Implantable Cardioverter Defibrillator

D204VRM Secura VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	1,156
Estimated Active US Implants	1,113
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 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.9%	98.0%
Effective Sample Size	20066	17126	14069	8795	3424	240

Implantable Cardioverter Defibrillator

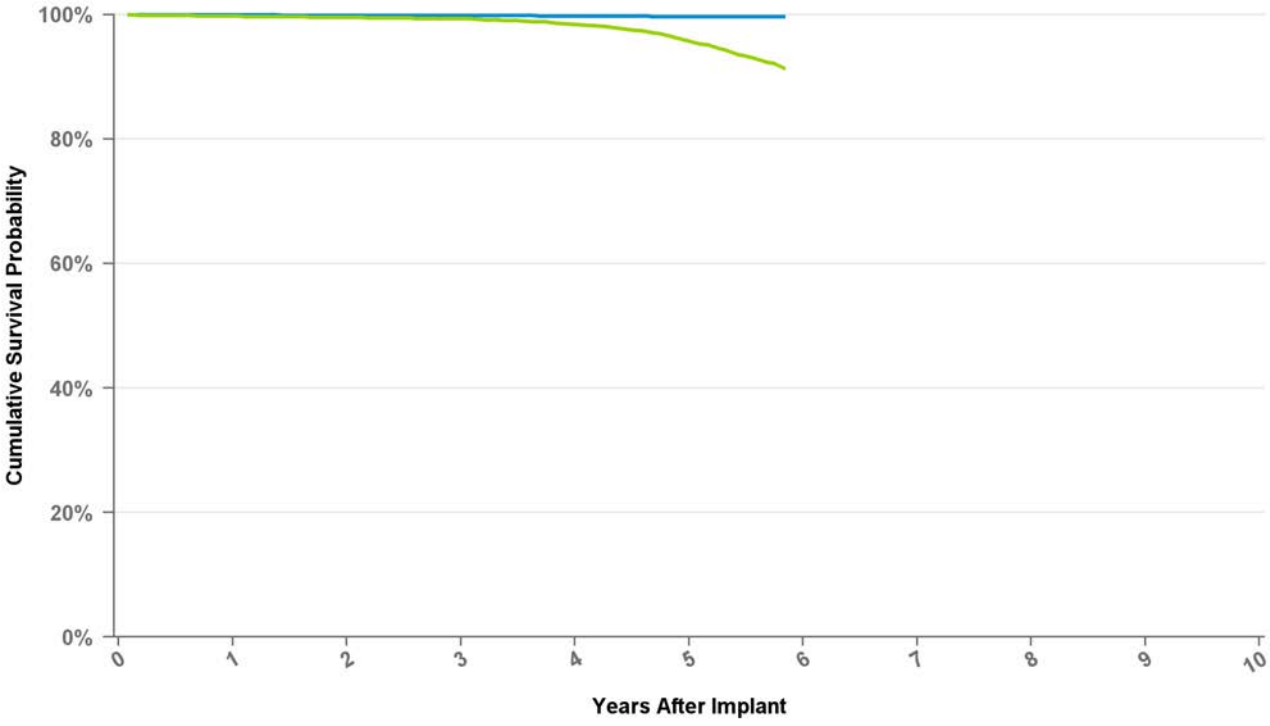
D214DRM Secura DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.7%	91.3%
Effective Sample Size	48626	42739	36252	21633	7604	350

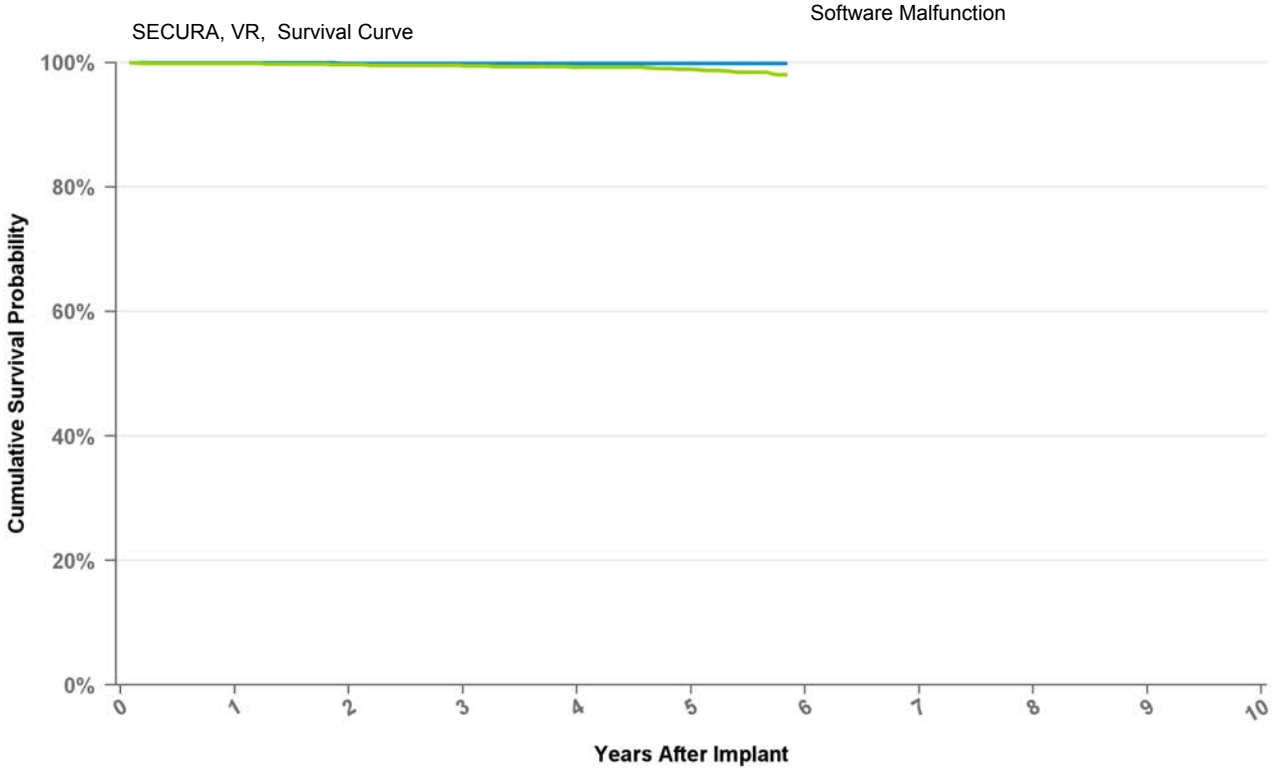
Implantable Cardioverter Defibrillator

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



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.9%	98.0%
Effective Sample Size	20066	17126	14069	8795	3424	240

Implantable Cardioverter Defibrillator

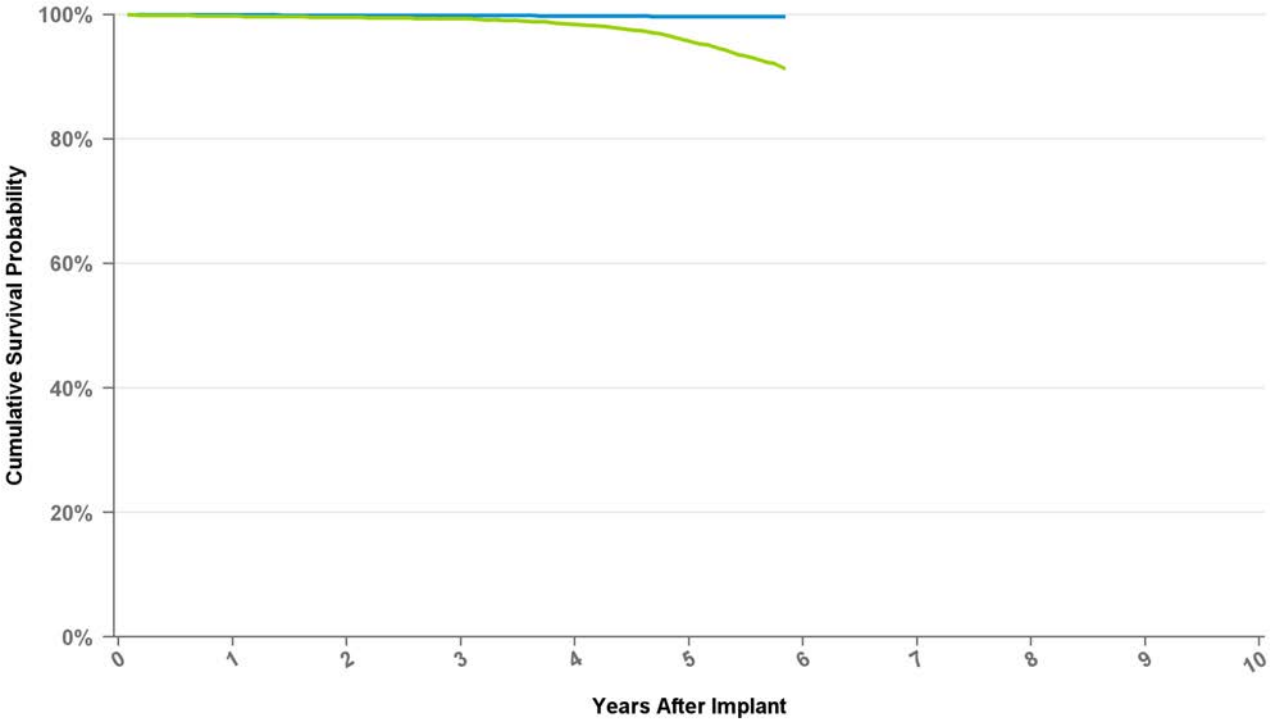
D224DRG Secura DR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	49,819
Estimated Active US Implants	39,166
Normal Battery Depletions (US)	587

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	88
Therapy Not Compromised Malfunction	76
Battery Malfunction	0
Electrical Component	21
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	45
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

SECURA, DR, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.7%	91.3%
Effective Sample Size	48626	42739	36252	21633	7604	350

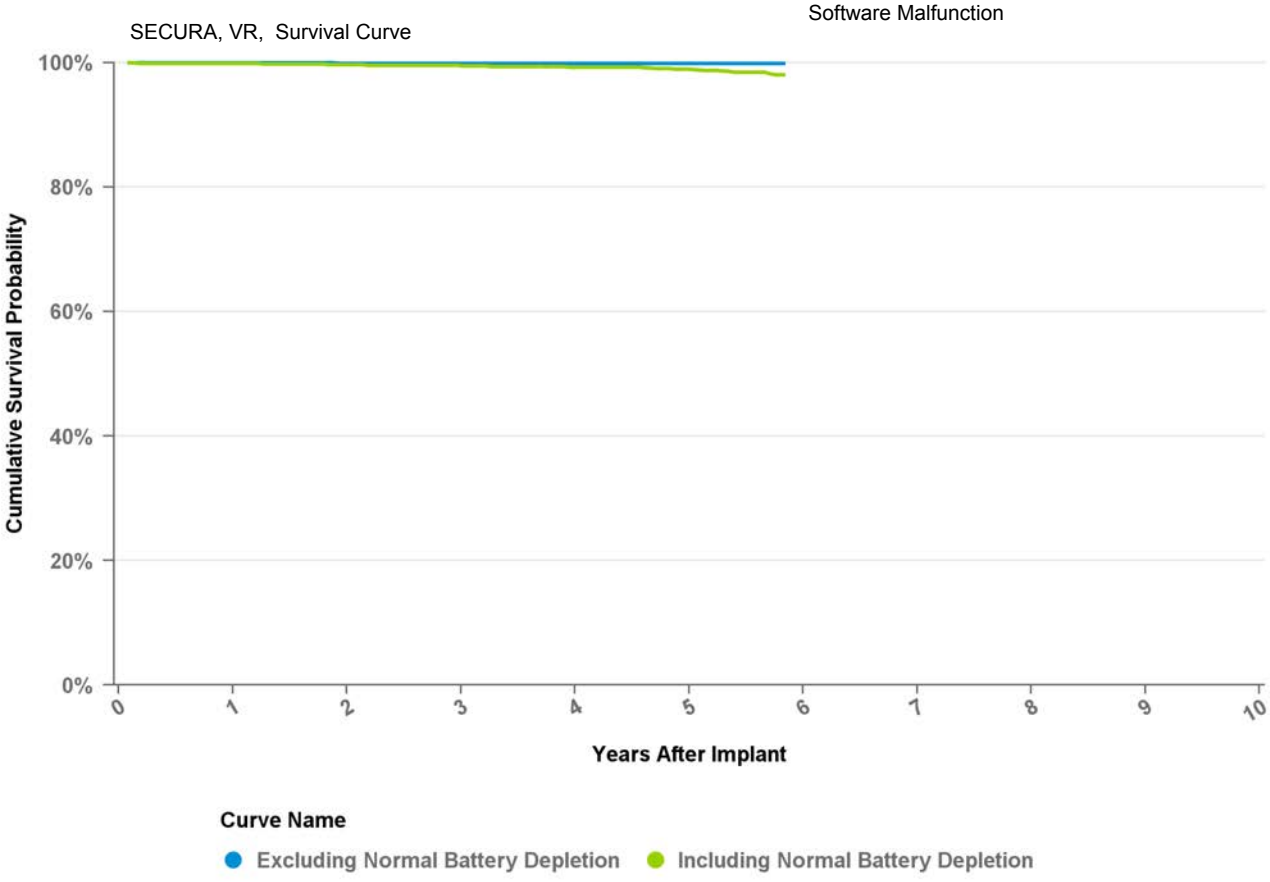
Implantable Cardioverter Defibrillator

D224VRC Secura VR

US Market Release Date	9/15/2008
CE Market Approval Date	
Registered US Implants	19,929
Estimated Active US Implants	15,988
Normal Battery Depletions (US)	71

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	20
Therapy Not Compromised Malfunction	14
Battery Malfunction	2
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	1
Poss Early Battery Depltn	6
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



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.9%	98.0%
Effective Sample Size	20066	17126	14069	8795	3424	240

Implantable Cardioverter Defibrillator

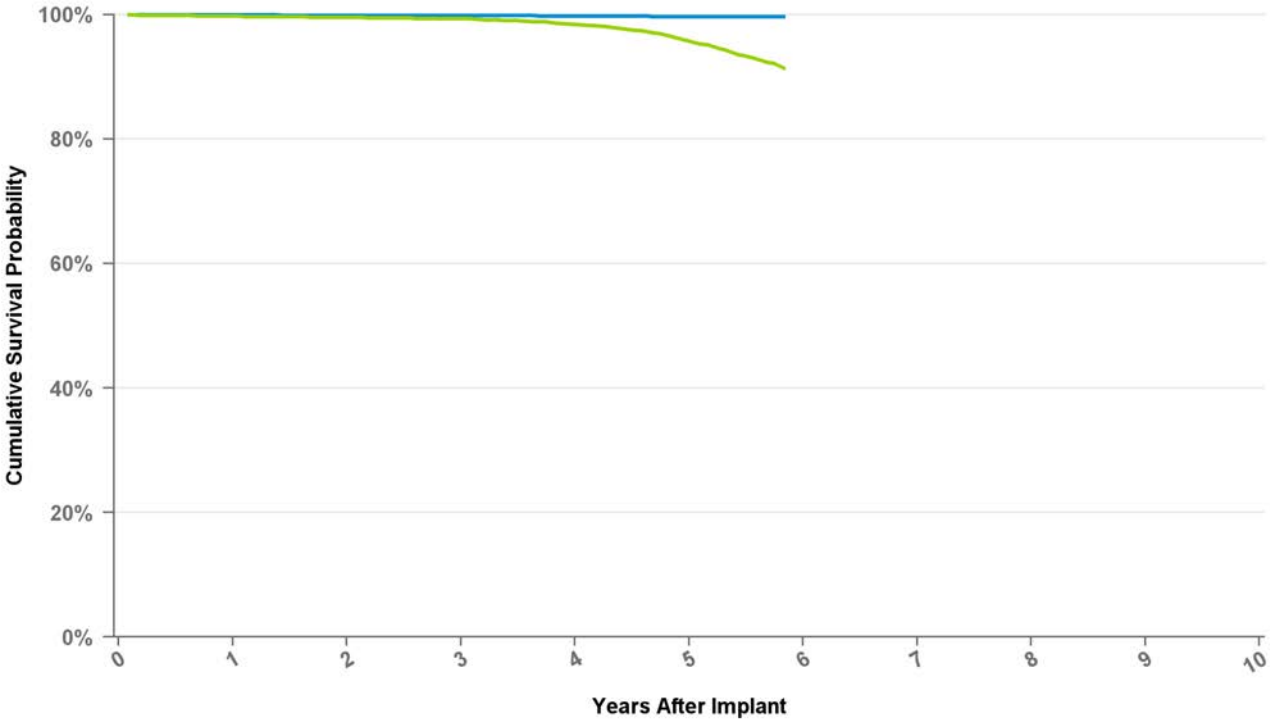
D234DRG Secura DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.8%	99.7%	99.7%
Including NBD	99.8%	99.6%	99.3%	98.4%	95.7%	91.3%
Effective Sample Size	48626	42739	36252	21633	7604	350

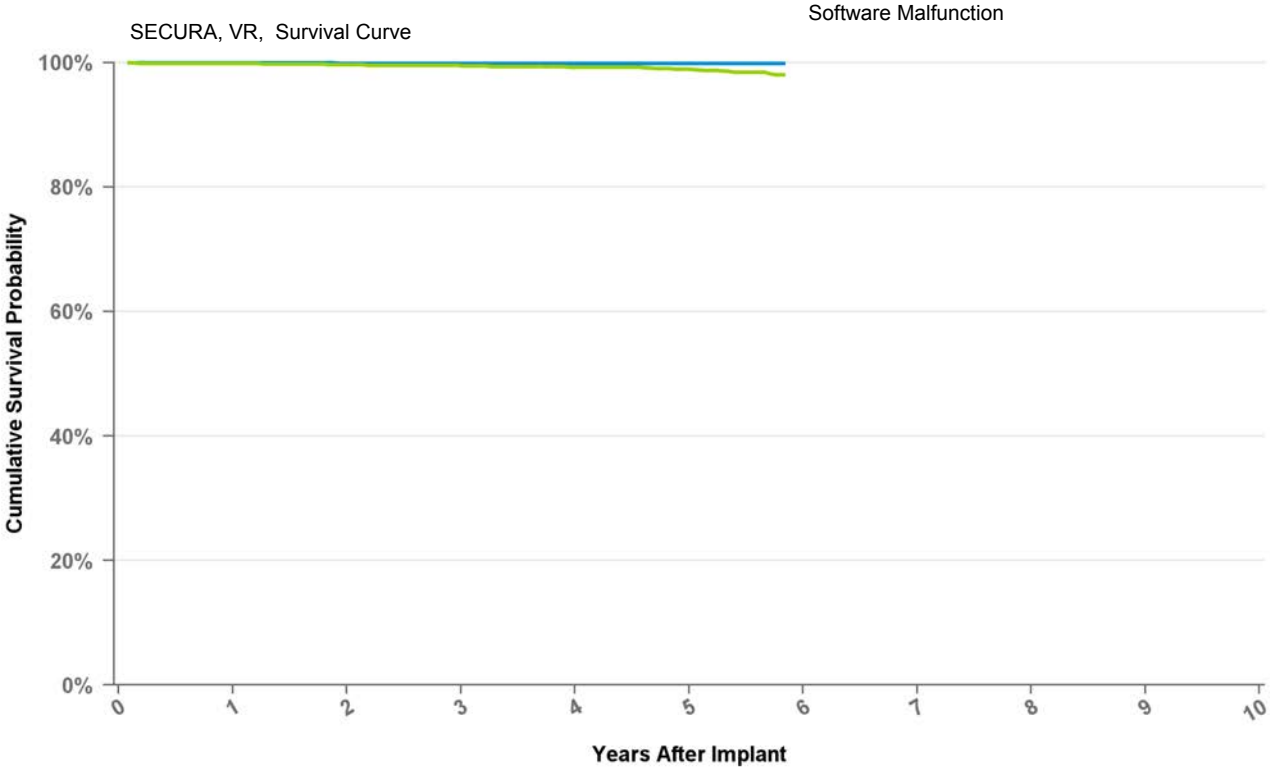
Implantable Cardioverter Defibrillator

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



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.2%	98.9%	98.0%
Effective Sample Size	20066	17126	14069	8795	3424	240

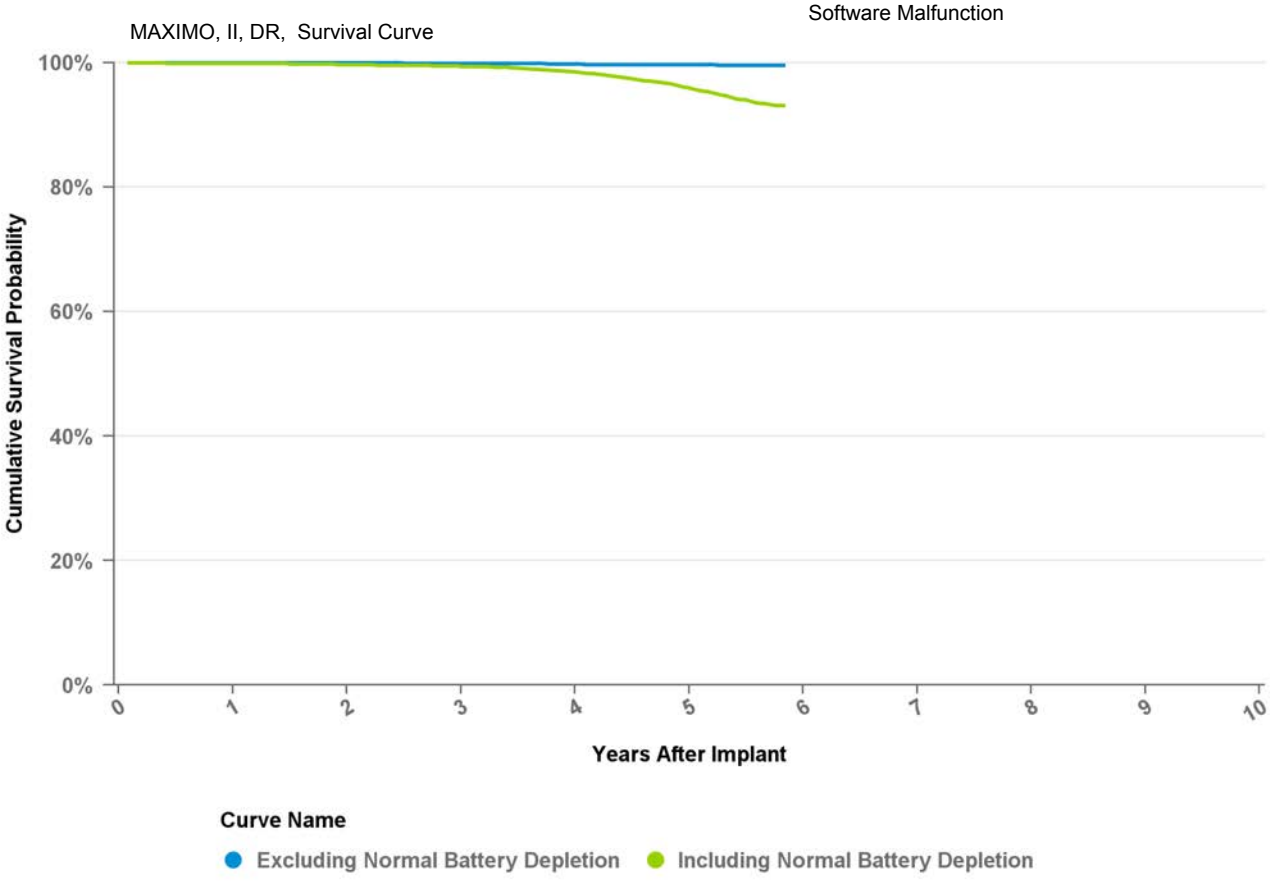
Implantable Cardioverter Defibrillator

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 70 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%
Including NBD	99.9%	99.7%	99.4%	98.5%	95.9%	93.1%
Effective Sample Size	19101	16682	13613	9074	3902	266

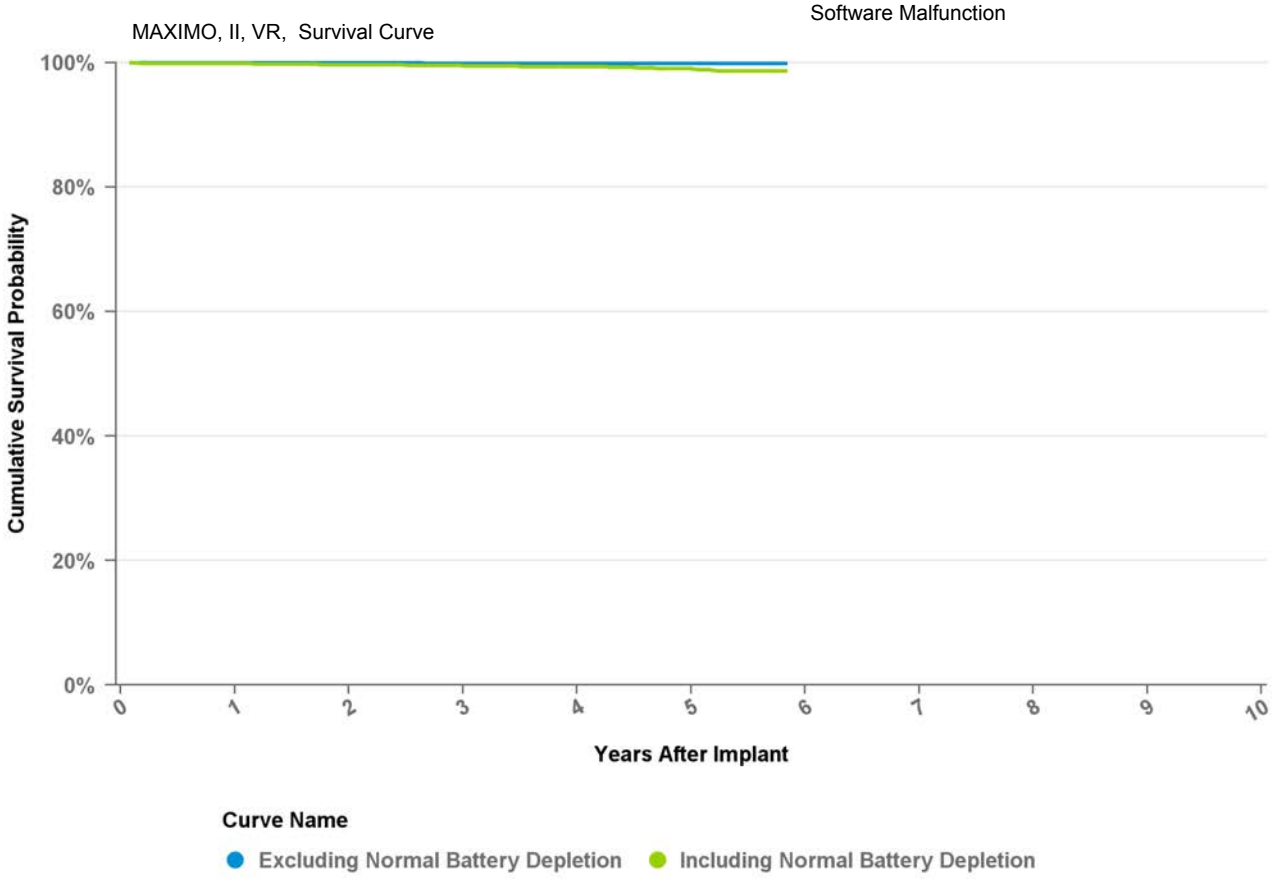
Implantable Cardioverter Defibrillator

D264VRM Maximo II VR

US Market Release Date	5/2/2012
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



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	98.6%
Effective Sample Size	12981	11357	9124	5922	2450	183

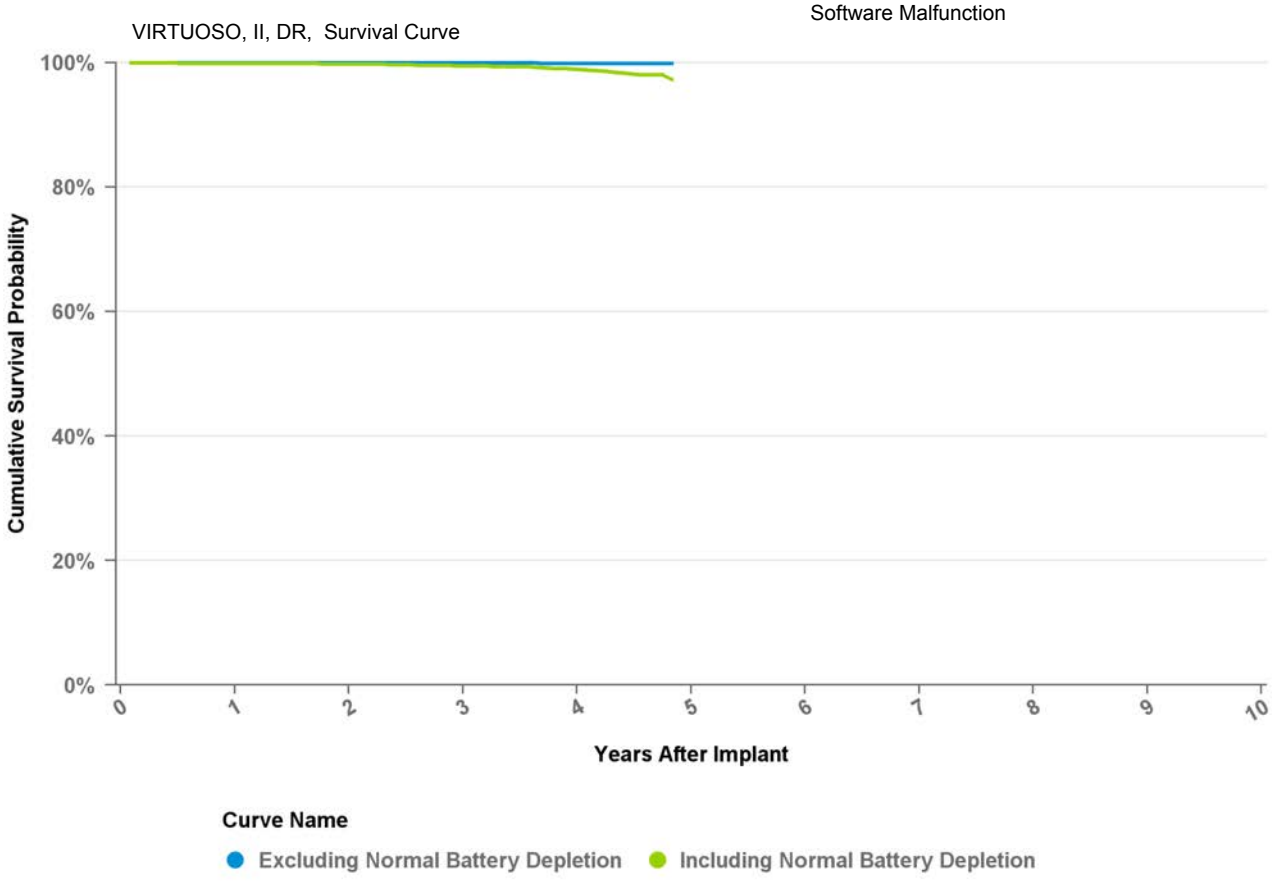
Implantable Cardioverter Defibrillator

D274DRG Virtuoso II DR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	22,218
Estimated Active US Implants	17,933
Normal Battery Depletions (US)	114

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	13
Therapy Not Compromised Malfunction	12
Battery Malfunction	2
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	6
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



Years	1	2	3	4	at 58 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	98.9%	97.2%
Effective Sample Size	20614	19208	16688	7954	251

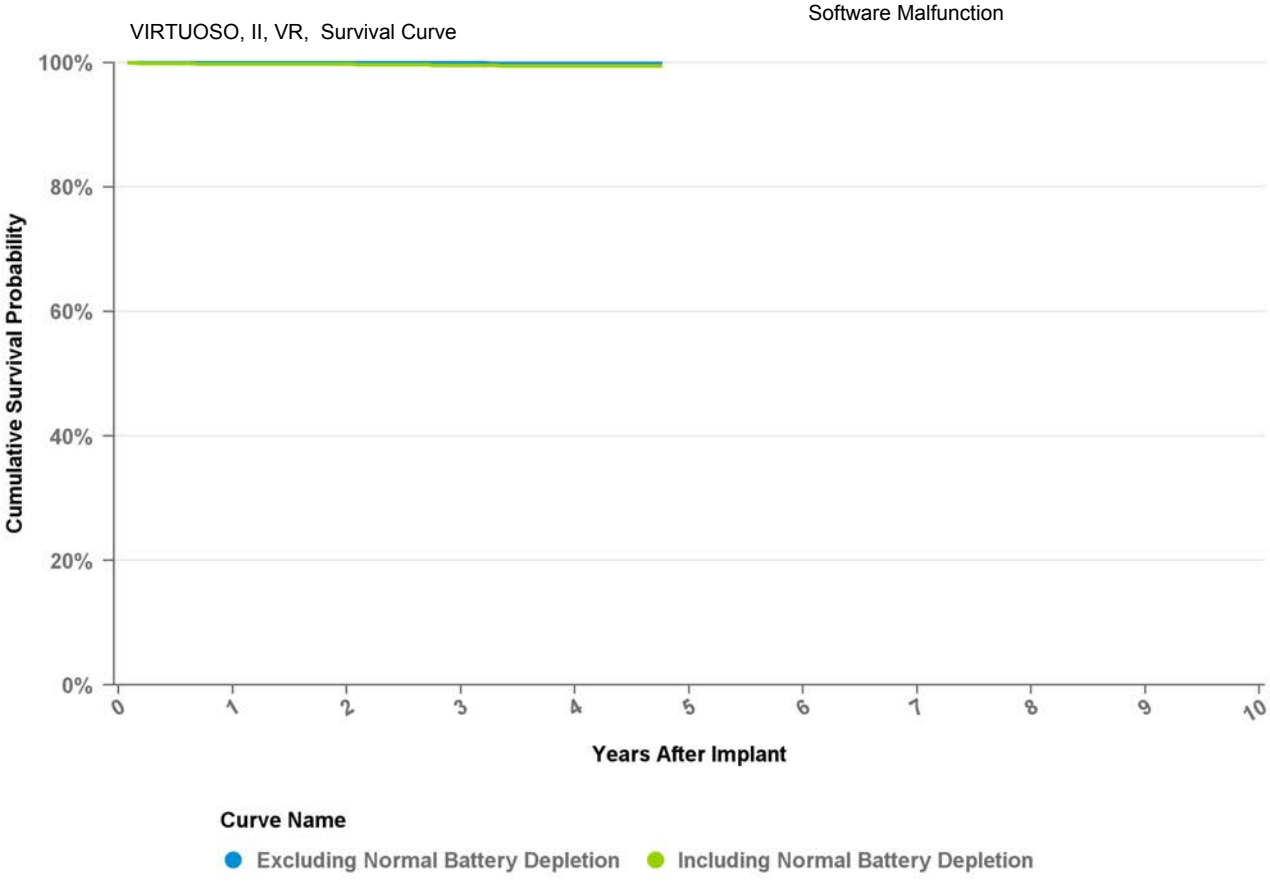
Implantable Cardioverter Defibrillator

D274VRC Virtuoso II VR

US Market Release Date	8/15/2009
CE Market Approval Date	
Registered US Implants	9,113
Estimated Active US Implants	7,535
Normal Battery Depletions (US)	18

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	1
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
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 57 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.8%	99.8%	99.6%	99.5%	99.5%
Effective Sample Size	8580	8007	6757	3088	225

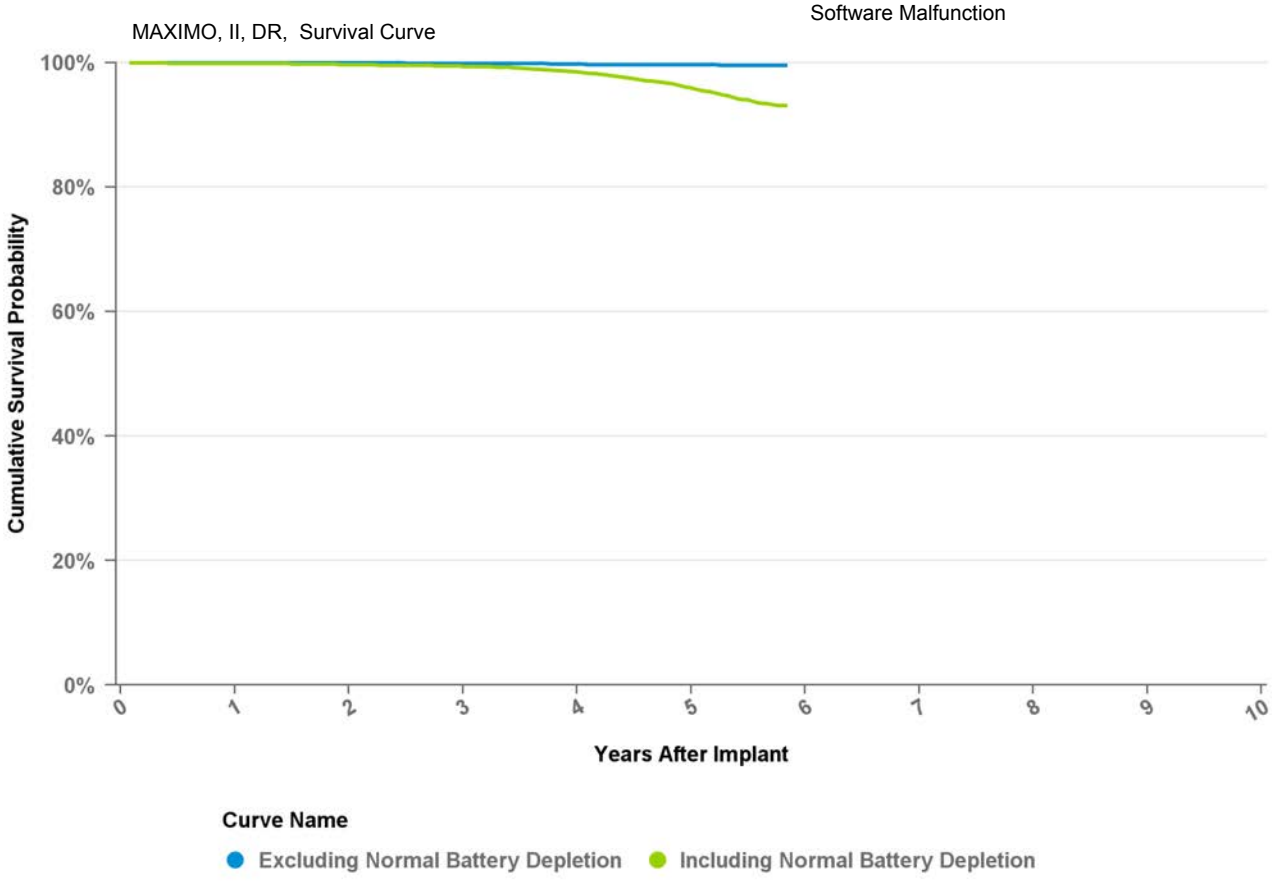
Implantable Cardioverter Defibrillator

D284DRG Maximo II DR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	20,037
Estimated Active US Implants	15,757
Normal Battery Depletions (US)	250

NBG Code	VVE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	40
Therapy Not Compromised Malfunction	34
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	30
Software Malfunction	0
Therapy Compromised Malfunctions	6
Battery Malfunction	0
Electrical Component	5
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%
Including NBD	99.9%	99.7%	99.4%	98.5%	95.9%	93.1%
Effective Sample Size	19101	16682	13613	9074	3902	266

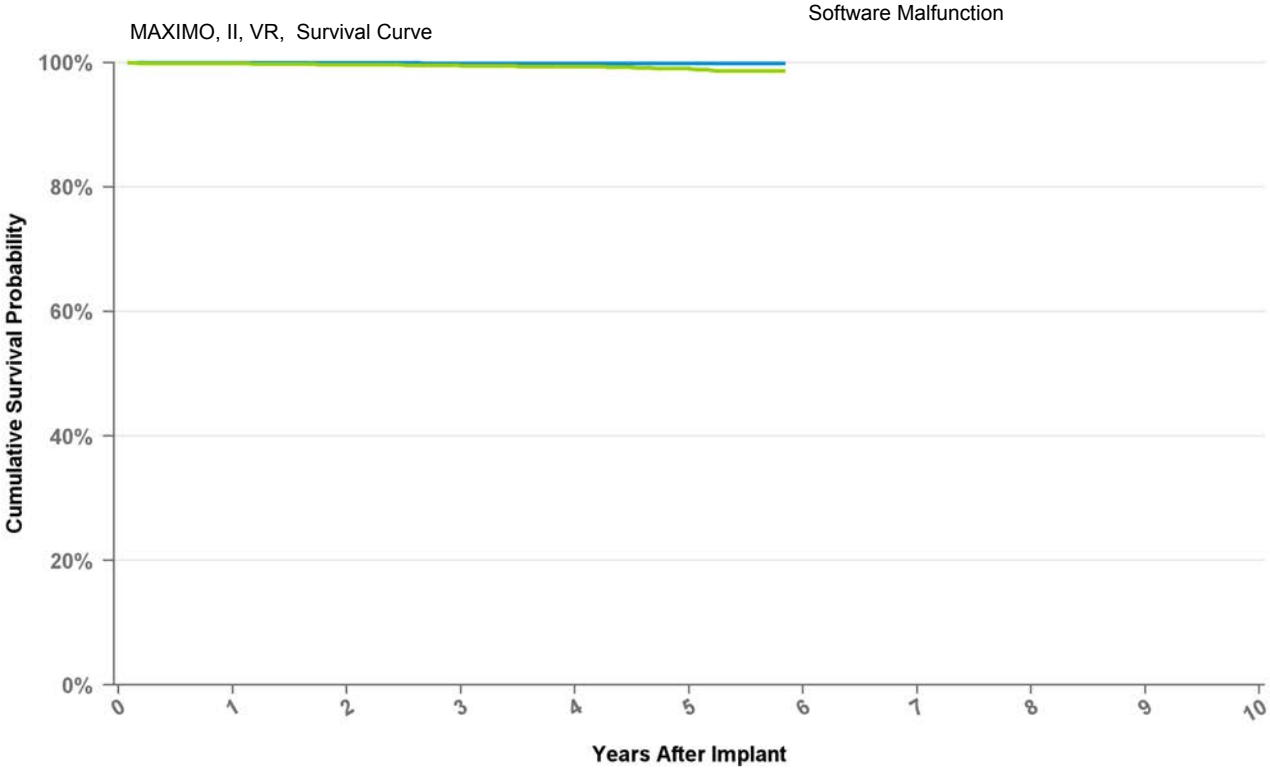
Implantable Cardioverter Defibrillator

D284VRC Maximo II VR

US Market Release Date	9/17/2008
CE Market Approval Date	3/14/2008
Registered US Implants	12,943
Estimated Active US Implants	10,526
Normal Battery Depletions (US)	49

NBG Code	VVE-VVIR
Max Delivered Energy	35 J

Total Malfunctions (US)	13
Therapy Not Compromised Malfunction	9
Battery Malfunction	0
Electrical Component	4
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	2
Software Malfunction	3
Therapy Compromised Malfunctions	4
Battery Malfunction	1
Electrical Component	2
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	1



Years	1	2	3	4	5	at 70 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.9%	99.7%	99.5%	99.3%	99.0%	98.6%
Effective Sample Size	12981	11357	9124	5922	2450	183

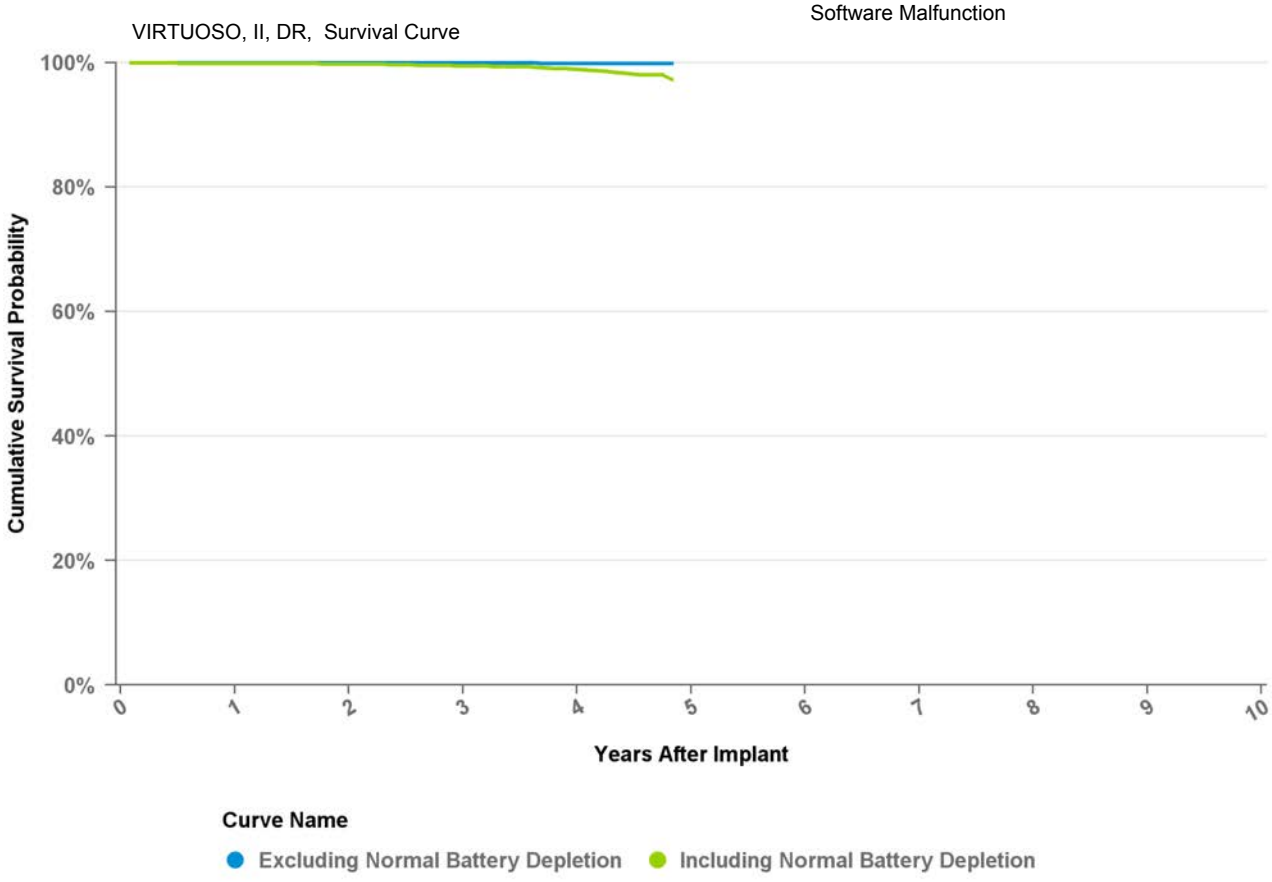
Implantable Cardioverter Defibrillator

D294DRG Virtuoso II DR

US Market Release Date	
CE Market Approval Date	8/20/2008
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	4	at 58 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.5%	98.9%	97.2%
Effective Sample Size	20614	19208	16688	7954	251

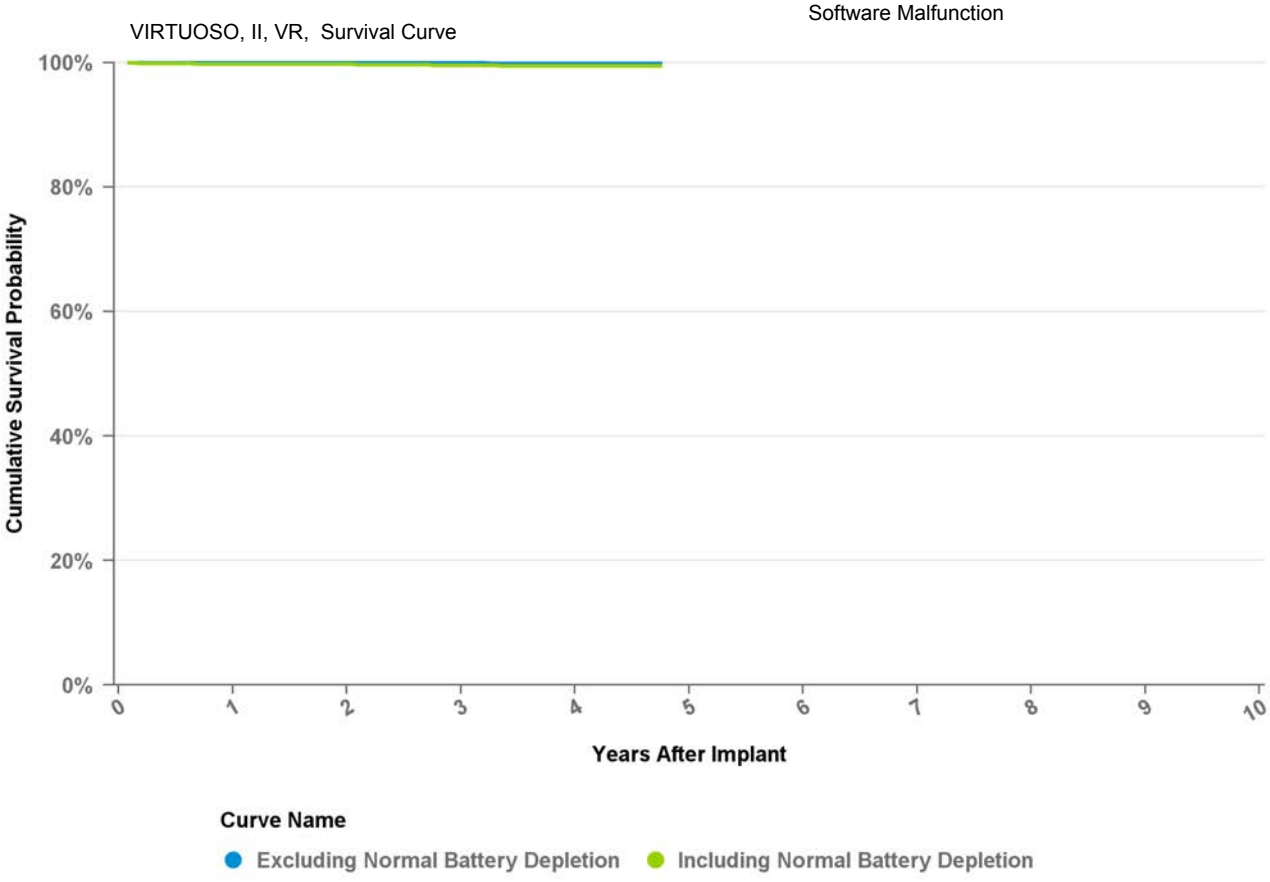
Implantable Cardioverter Defibrillator

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



Years	1	2	3	4	at 57 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Including NBD	99.8%	99.8%	99.6%	99.5%	99.5%
Effective Sample Size	8580	8007	6757	3088	225

Implantable Cardioverter Defibrillator

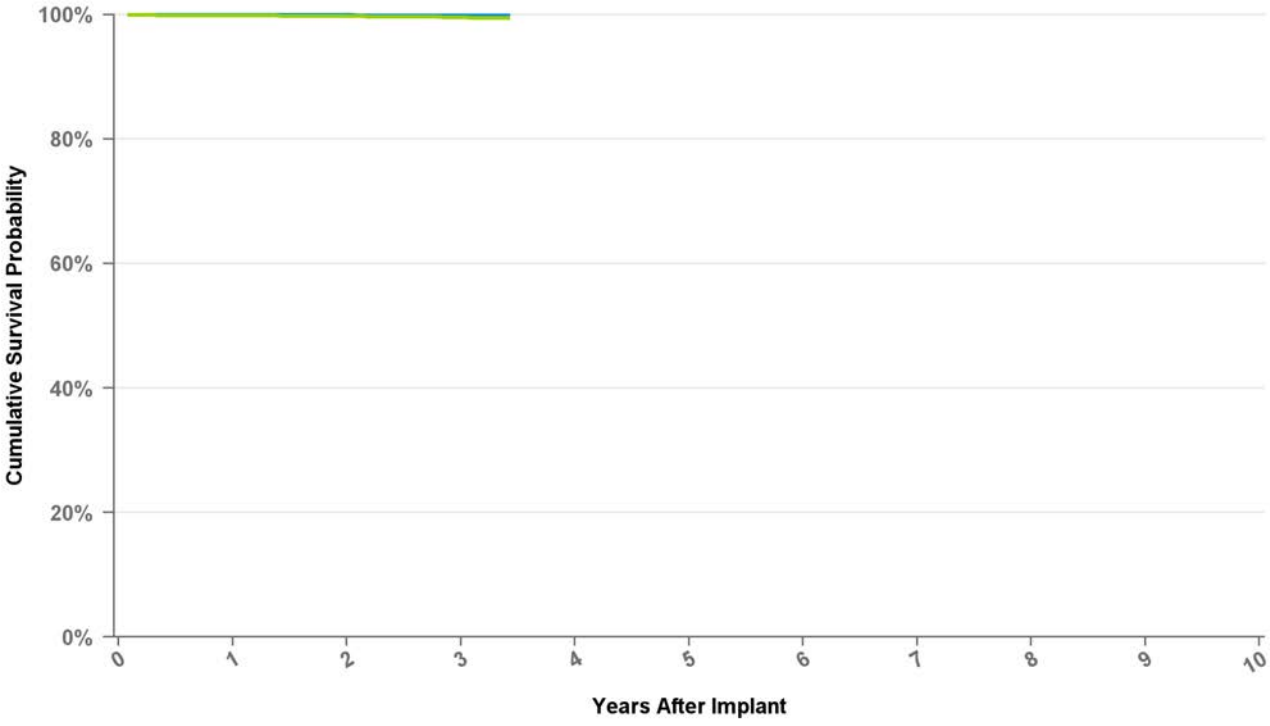
D314DRG Protecta XT DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	33,905
Estimated Active US Implants	31,103
Normal Battery Depletions (US)	39

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	16
Therapy Not Compromised Malfunction	12
Battery Malfunction	0
Electrical Component	12
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

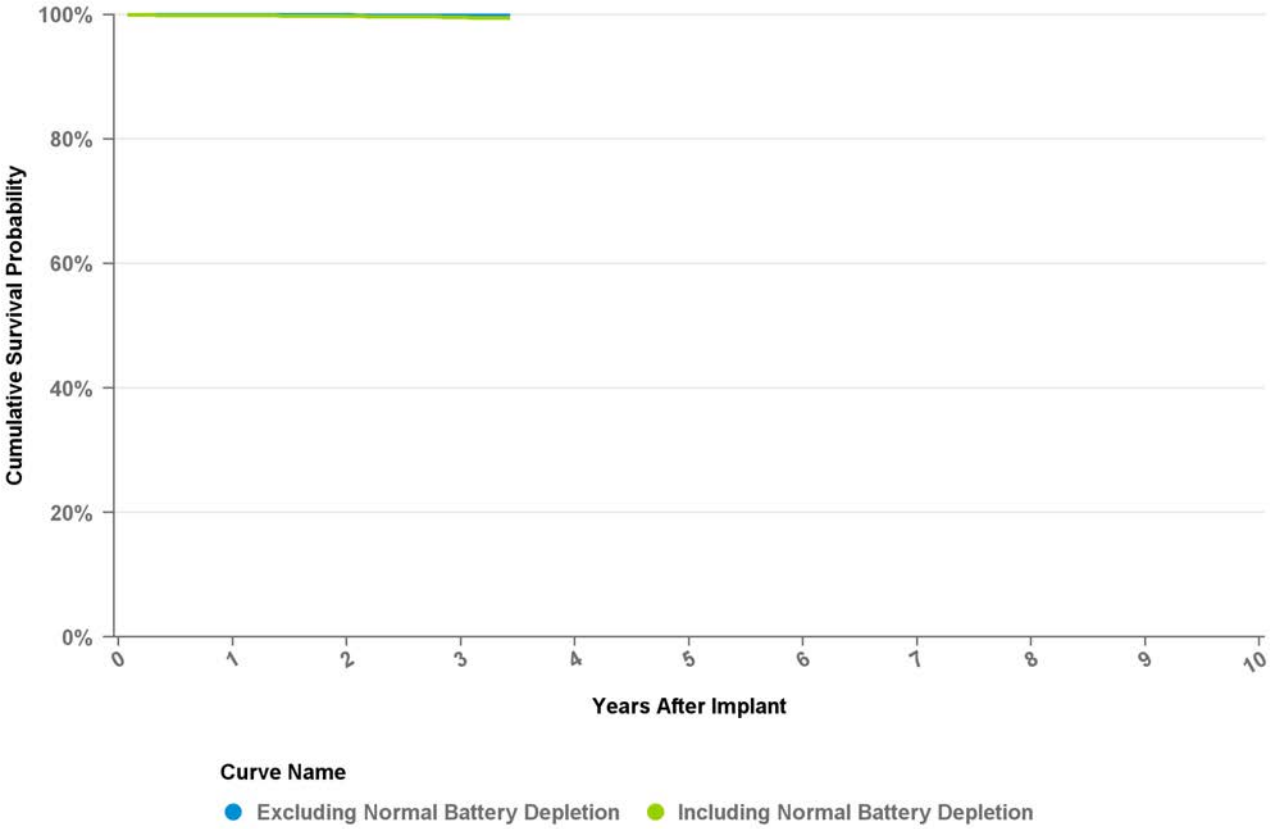
D314DRM Protecta XT DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	13,489
Estimated Active US Implants	12,784
Normal Battery Depletions (US)	8

NBG Code	DDE-DDDR
Max Delivered Energy	35 J

Total Malfunctions (US)	4
Therapy Not Compromised Malfunction	4
Battery Malfunction	0
Electrical Component	3
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

D3xxDRx, Survival Curve



Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

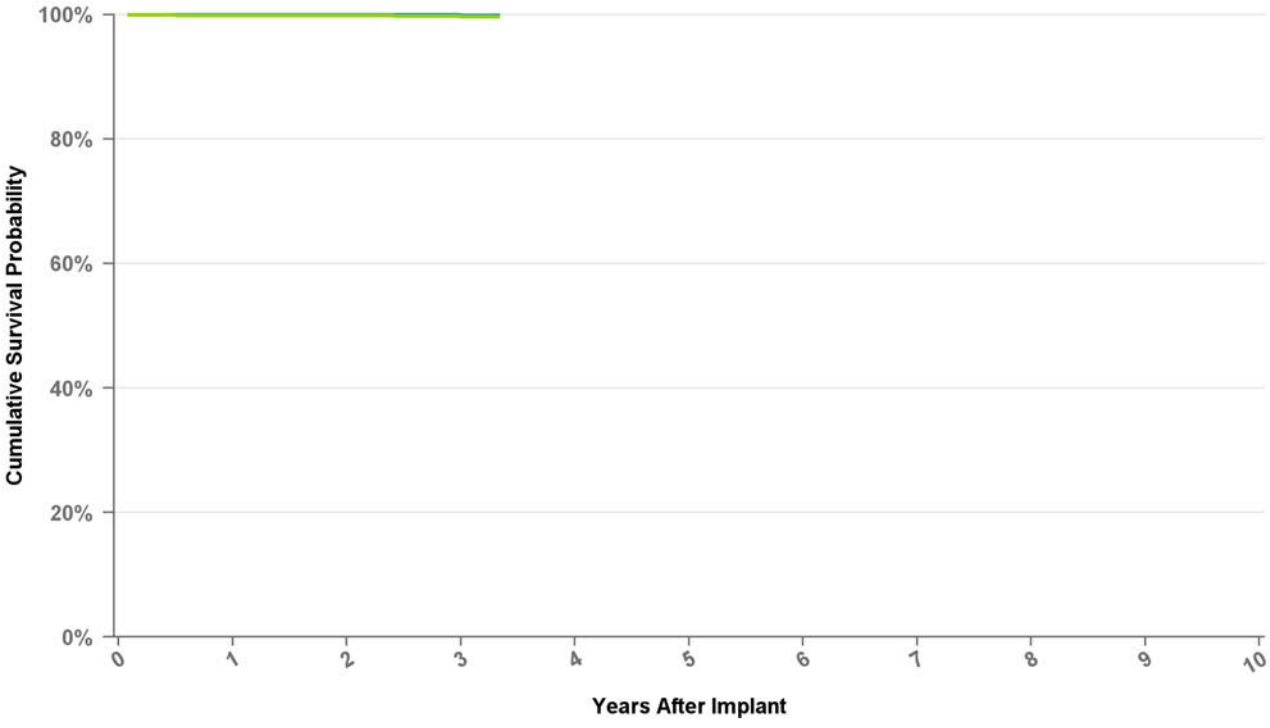
D314VRG Protecta XT VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	13,705
Estimated Active US Implants	12,634
Normal Battery Depletions (US)	12

NBG Code	VVE-VVIR
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	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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

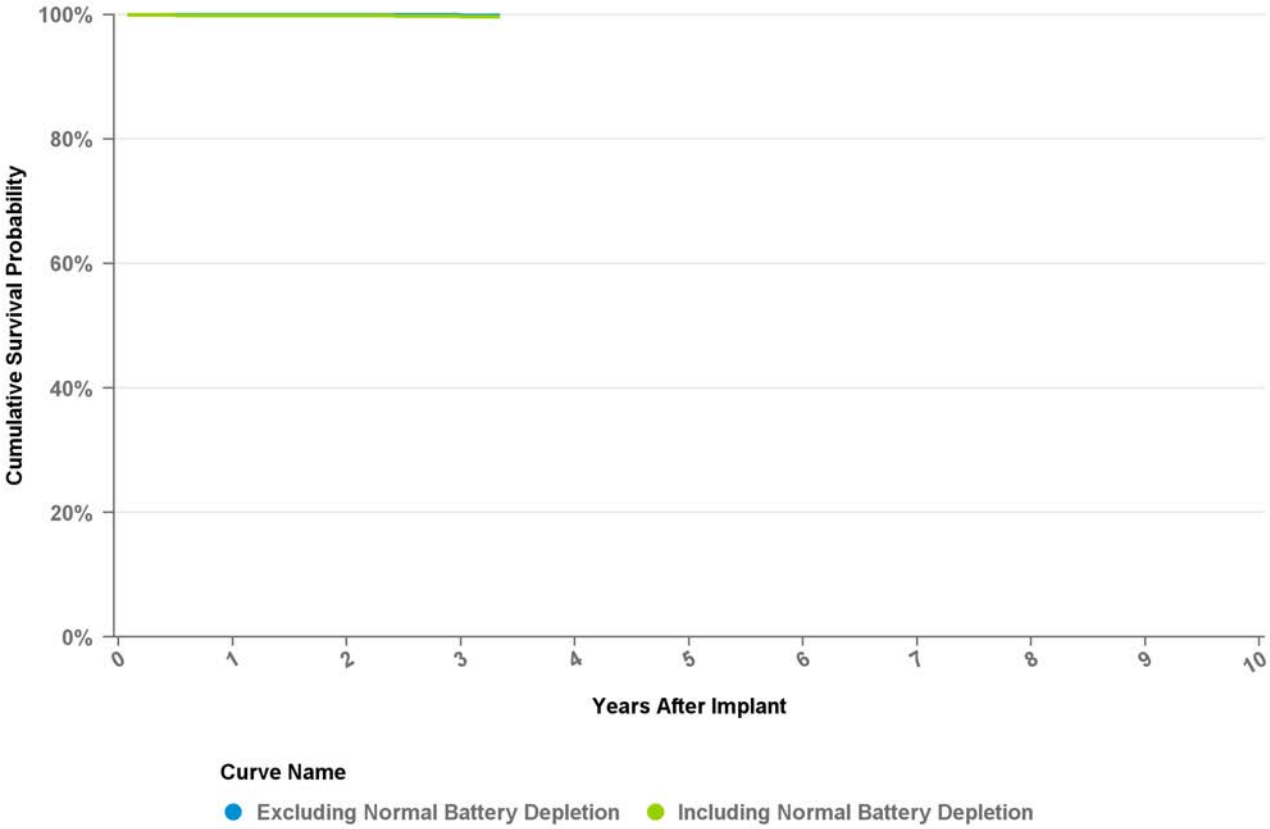
D314VRM Protecta XT VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	7,098
Estimated Active US Implants	6,757
Normal Battery Depletions (US)	1

NBG Code	VVE-VVIR
Max Delivered Energy	35 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

D3xxVRx, Survival Curve



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

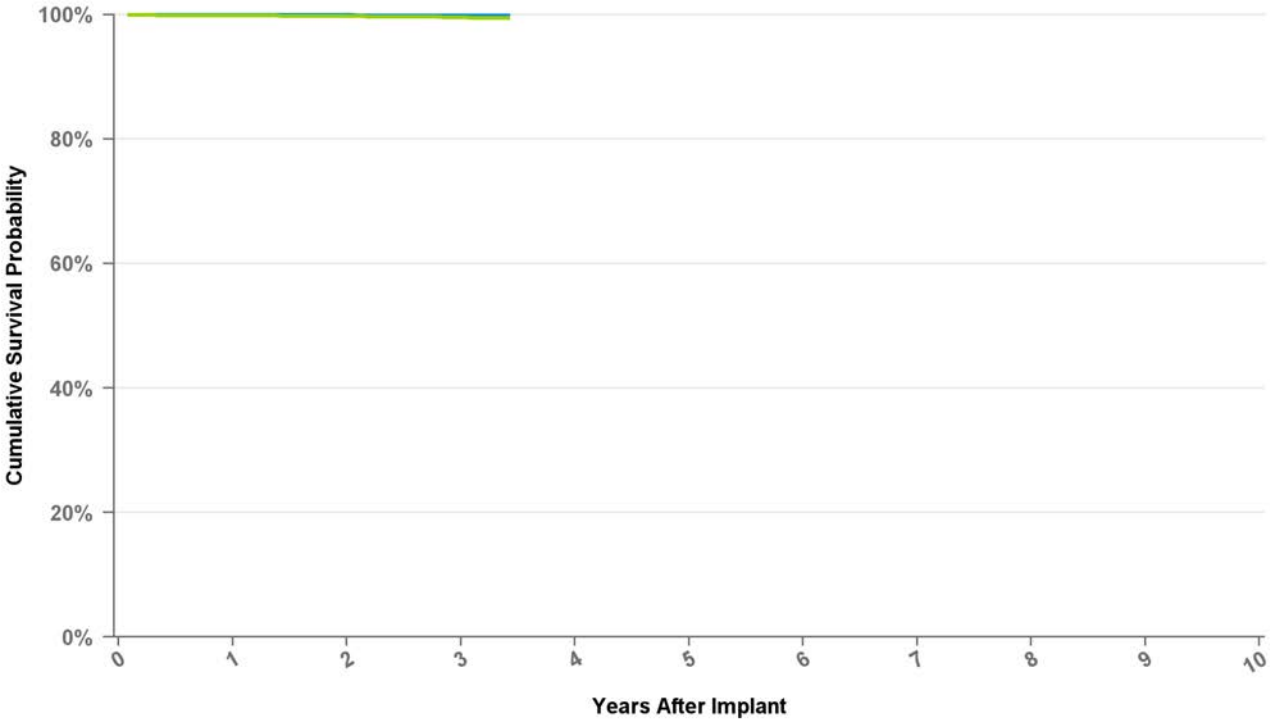
D334DRG Protecta DR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	10,170
Estimated Active US Implants	9,397
Normal Battery Depletions (US)	15

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

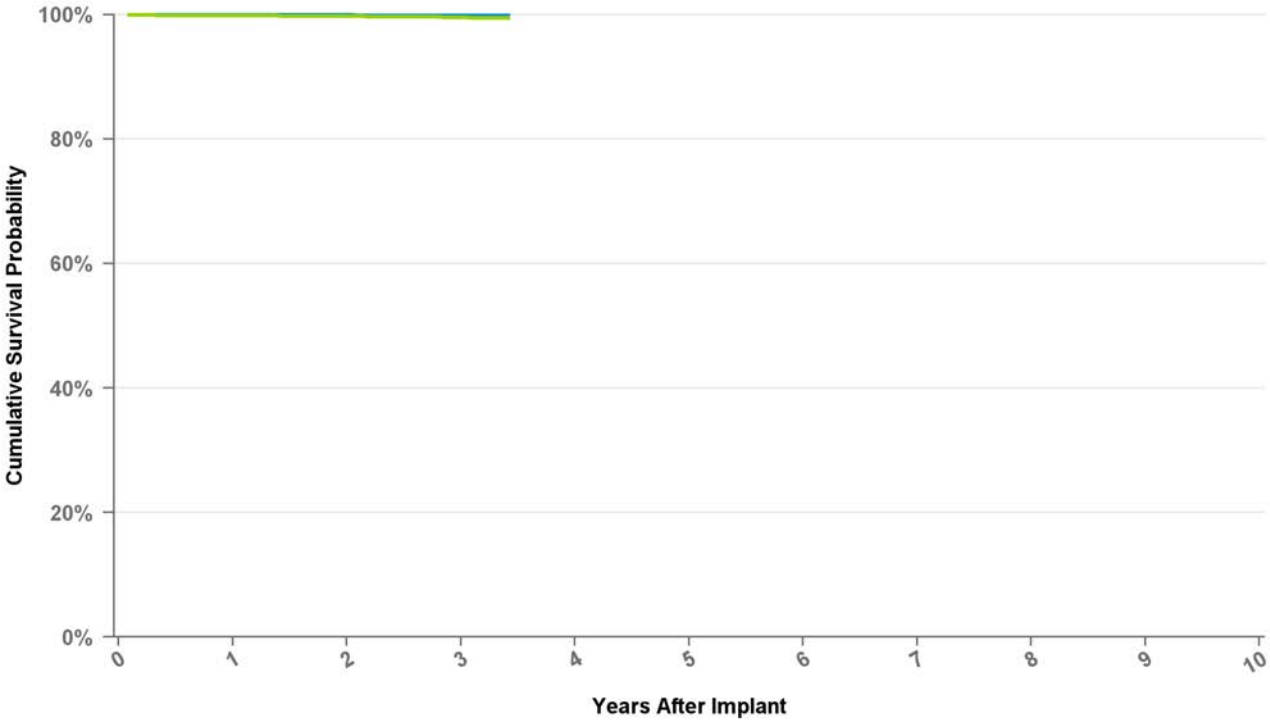
D334DRM Protecta DR

US Market Release Date	11/9/2011
CE Market Approval Date	
Registered US Implants	2,807
Estimated Active US Implants	2,676
Normal Battery Depletions (US)	4

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

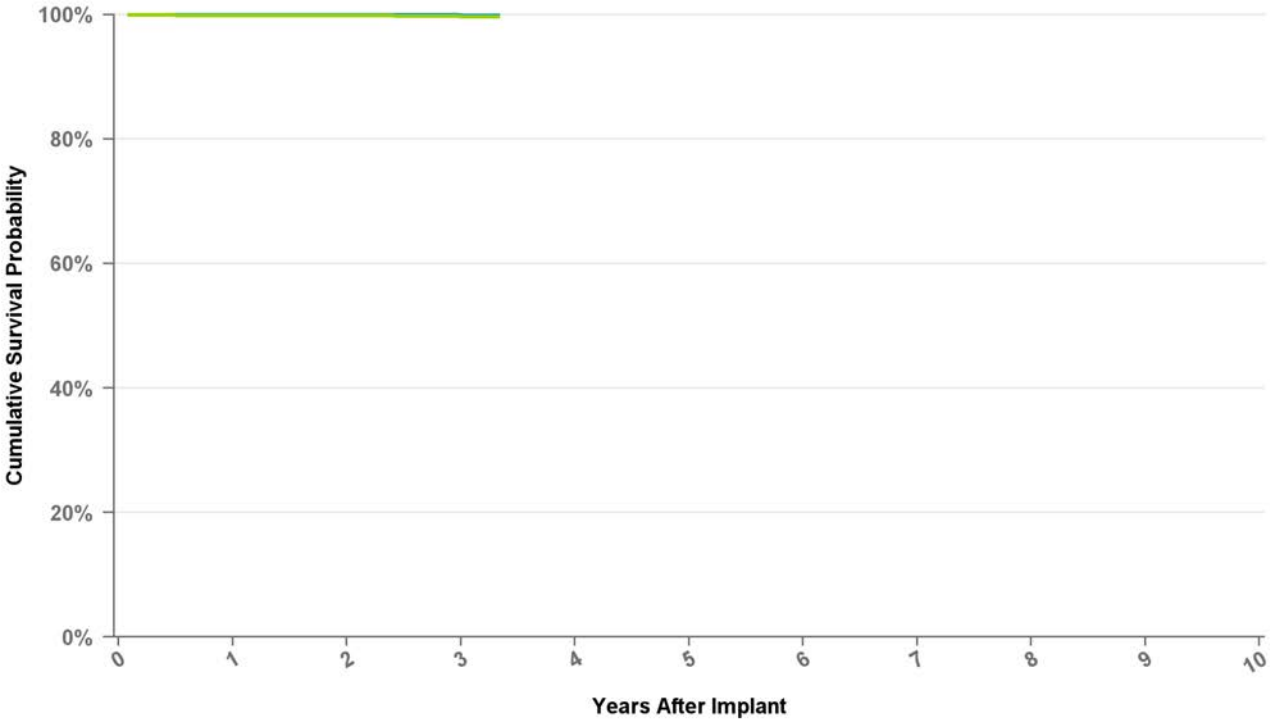
D334VRG Protecta VR

US Market Release Date	3/25/2011
CE Market Approval Date	
Registered US Implants	5,944
Estimated Active US Implants	5,505
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

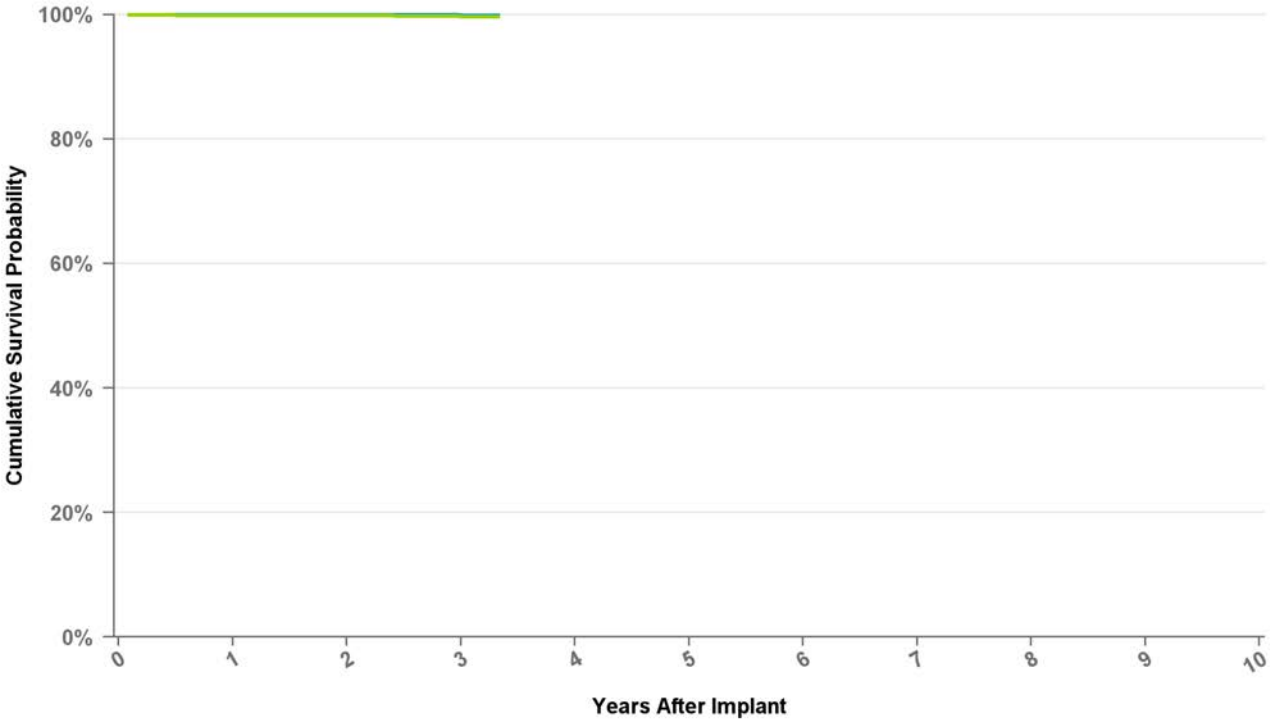
D334VRM Protecta VR

US Market Release Date	5/2/2012
CE Market Approval Date	
Registered US Implants	2,038
Estimated Active US Implants	1,952
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

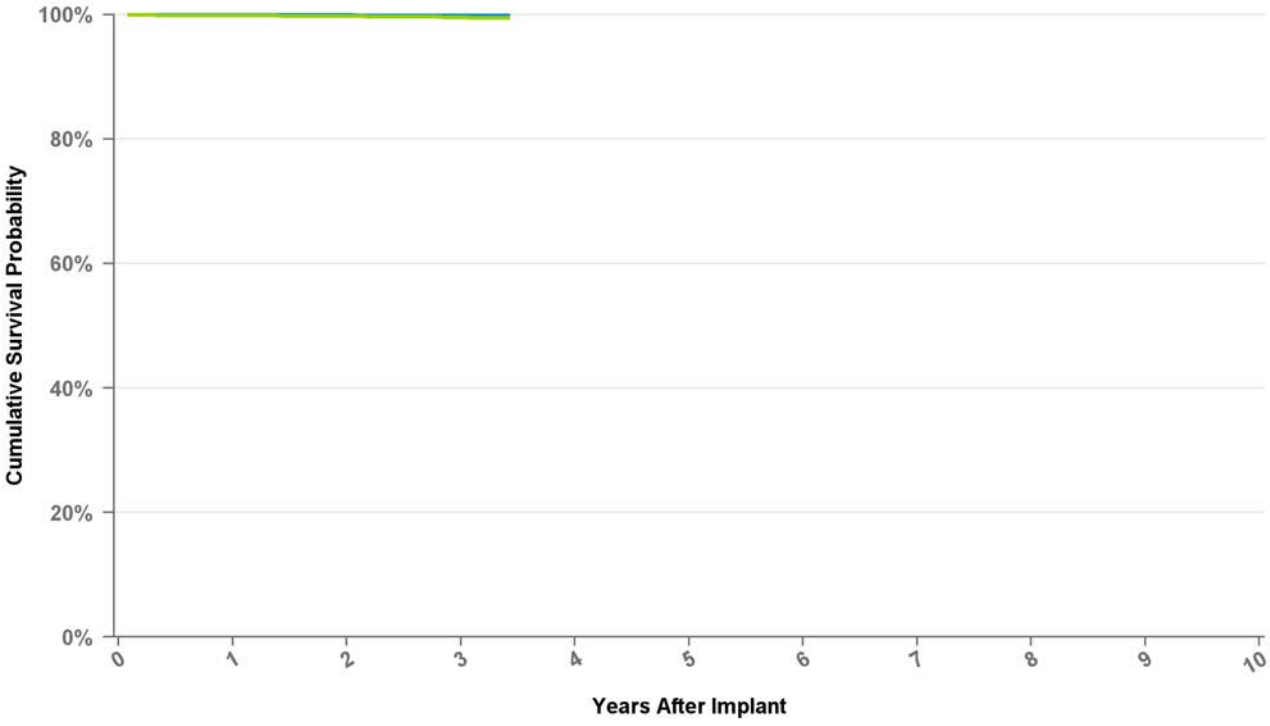
D354DRG Protecta XT DR

US Market Release Date	
CE Market Approval Date	3/25/2010
Registered US Implants	2
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

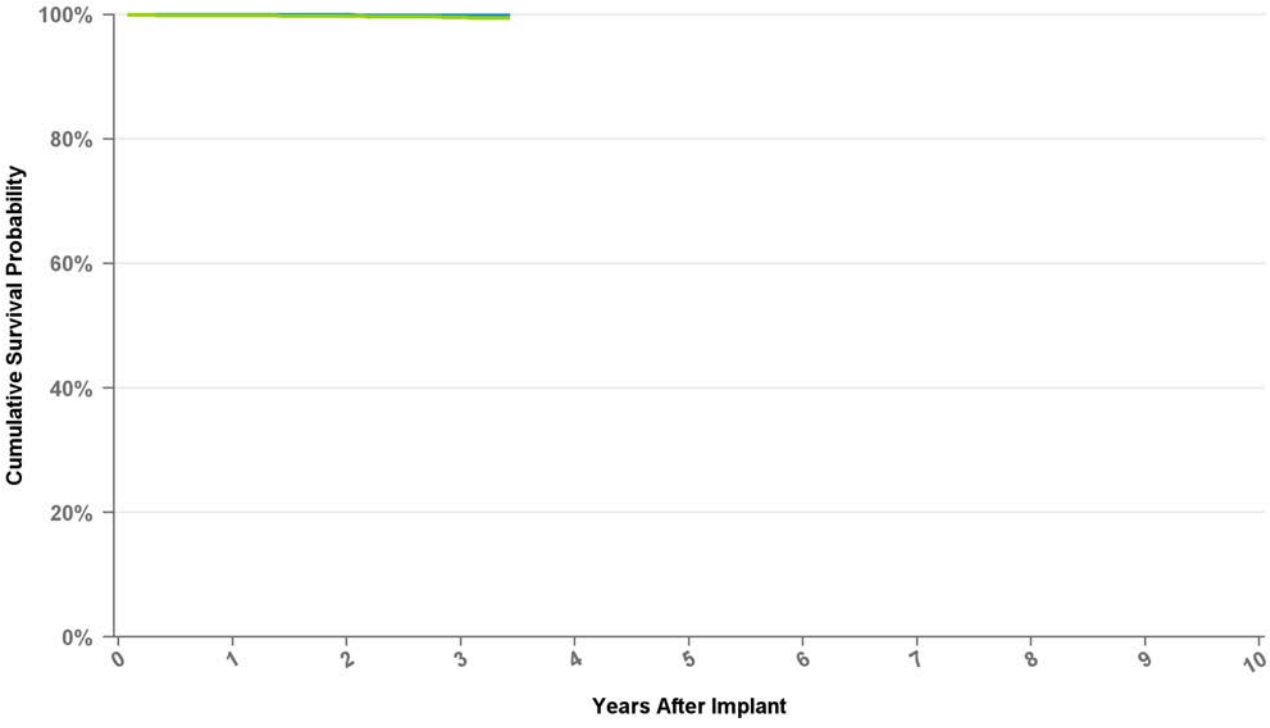
D354DRM Protecta XT DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

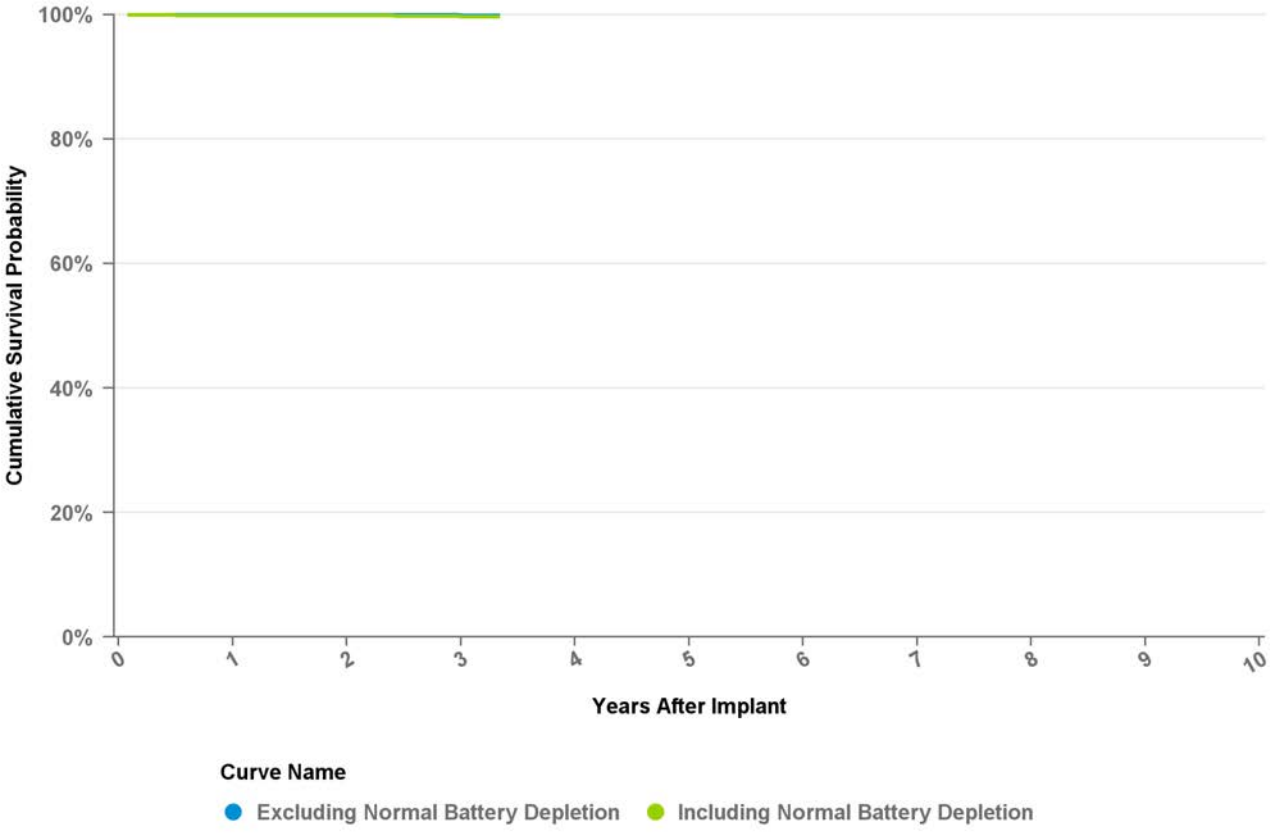
D354VRG Protecta XT VR

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

D3xxVRx, Survival Curve



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

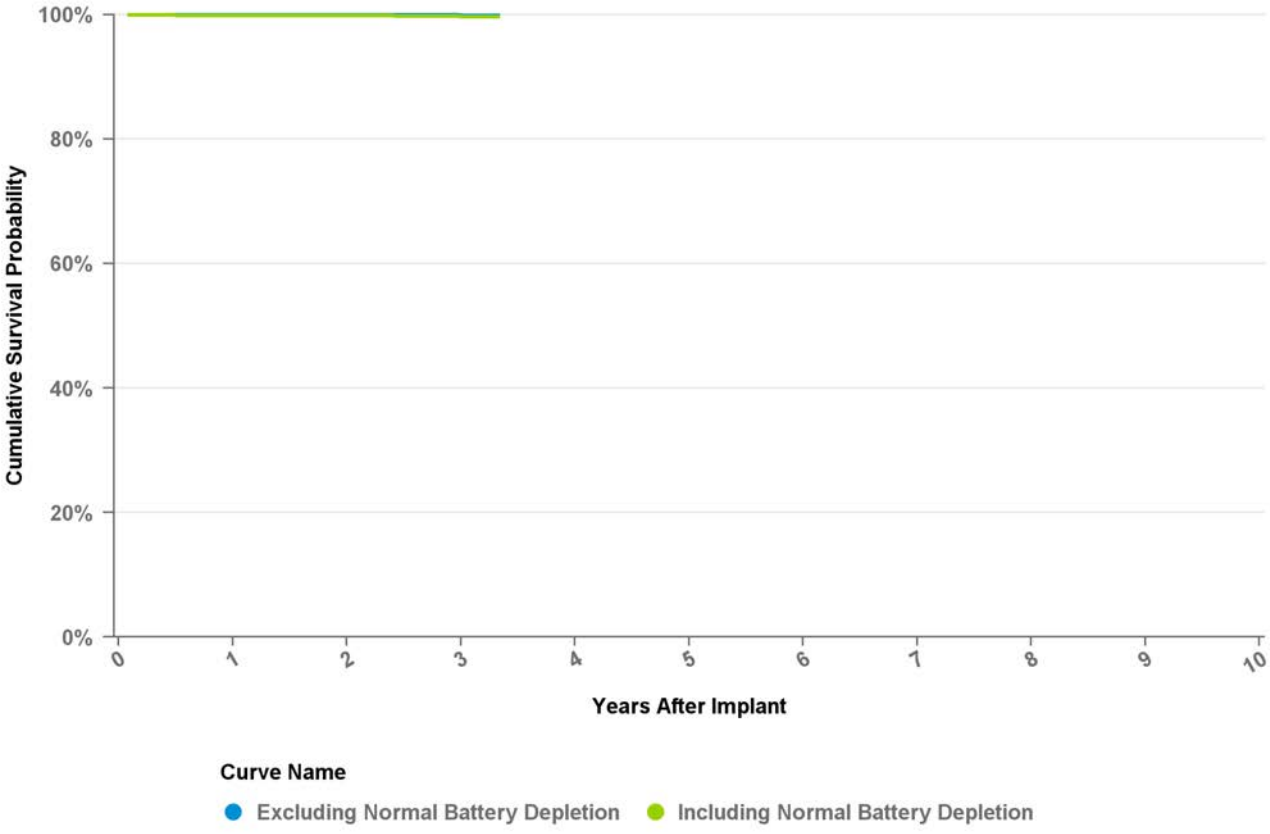
D354VRM Protecta XT VR

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	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

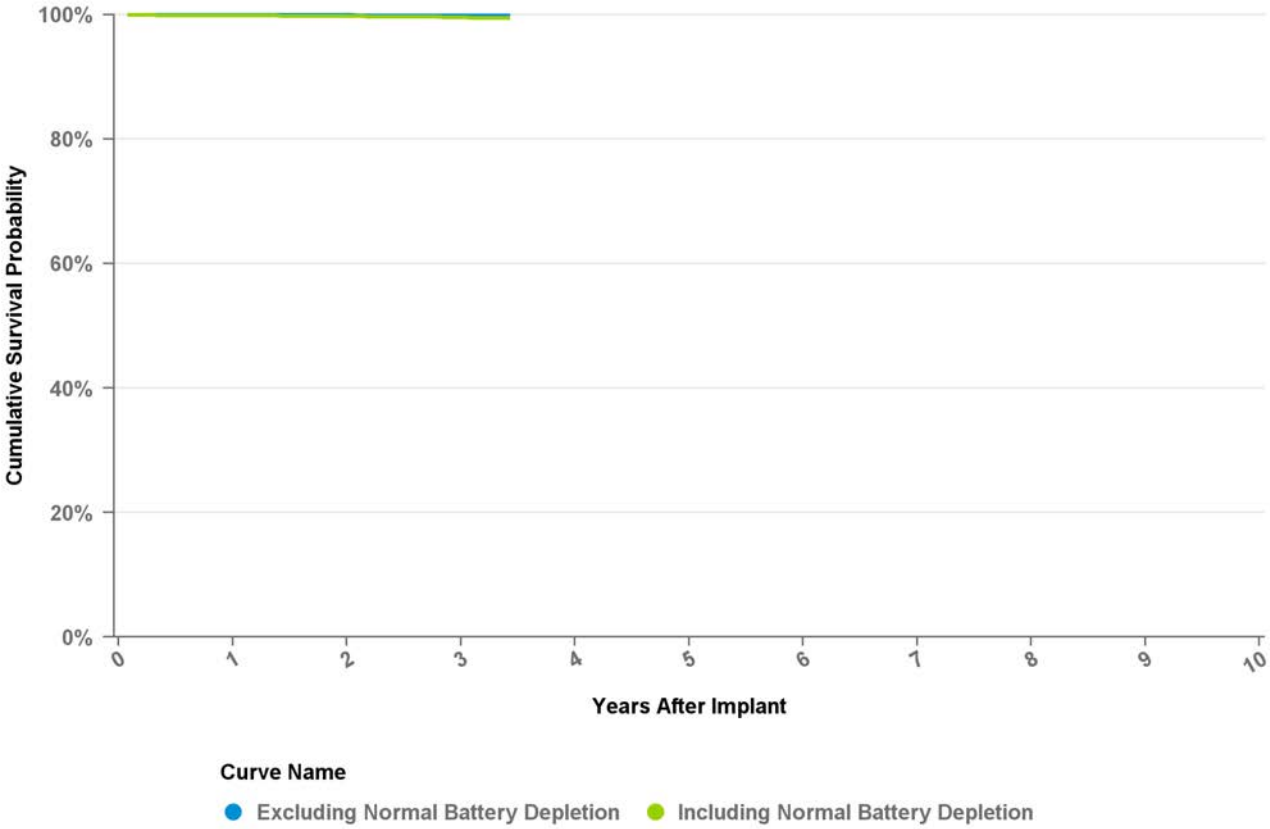
D364DRG Protecta DR

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

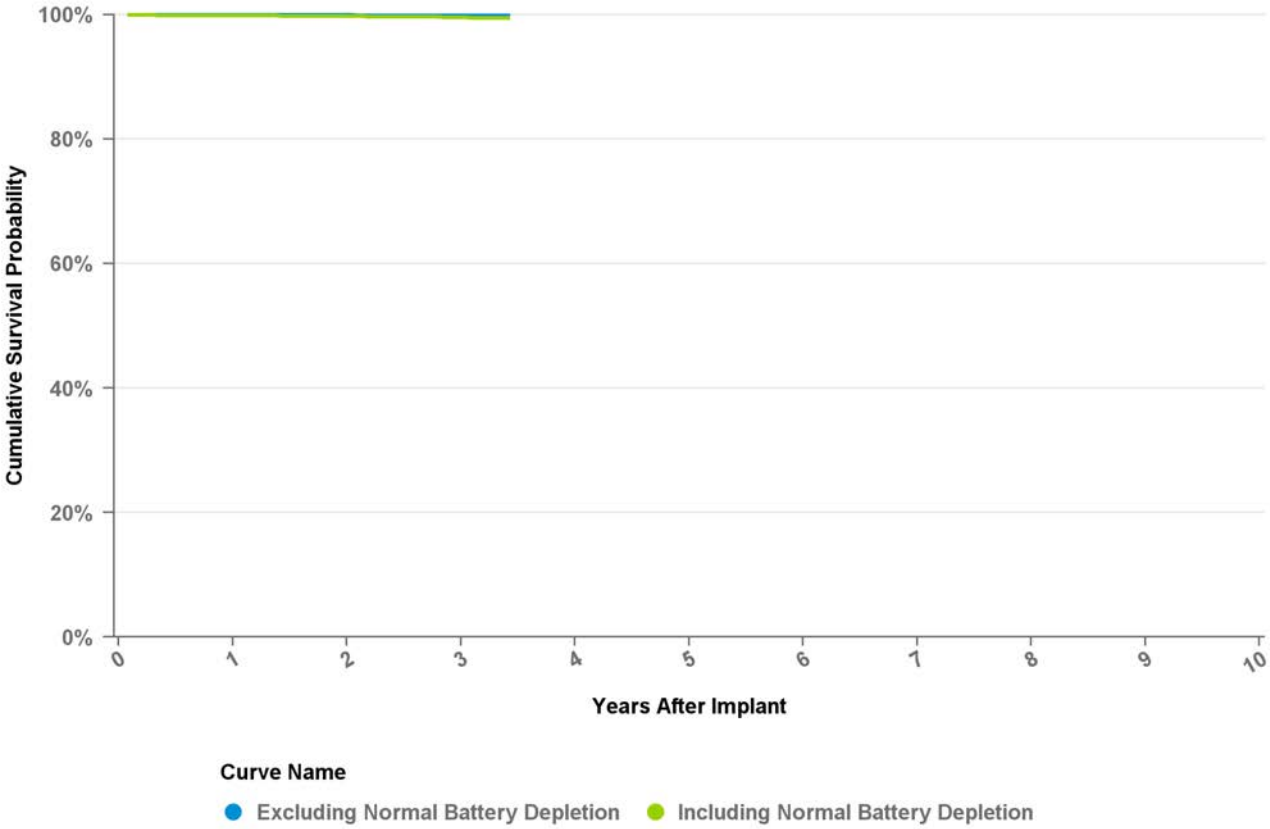
D364DRM Protecta DR

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

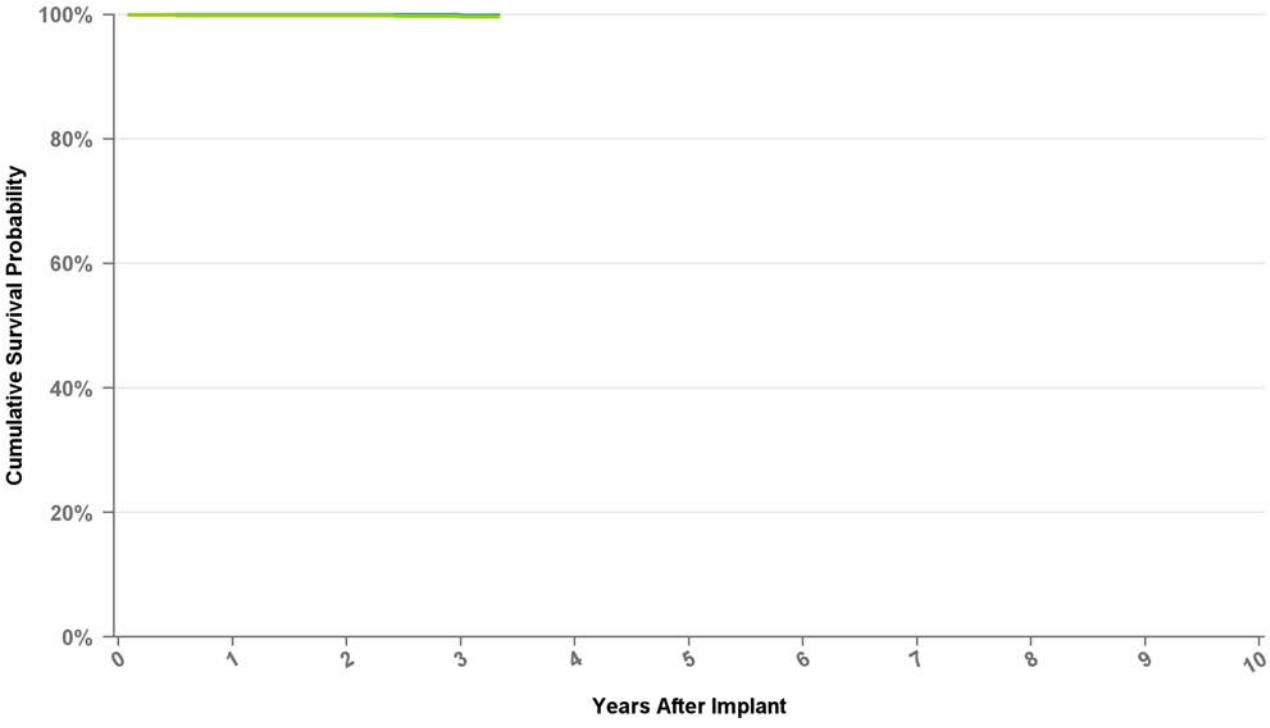
D364VRG Protecta VR

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

D3xxVRx, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

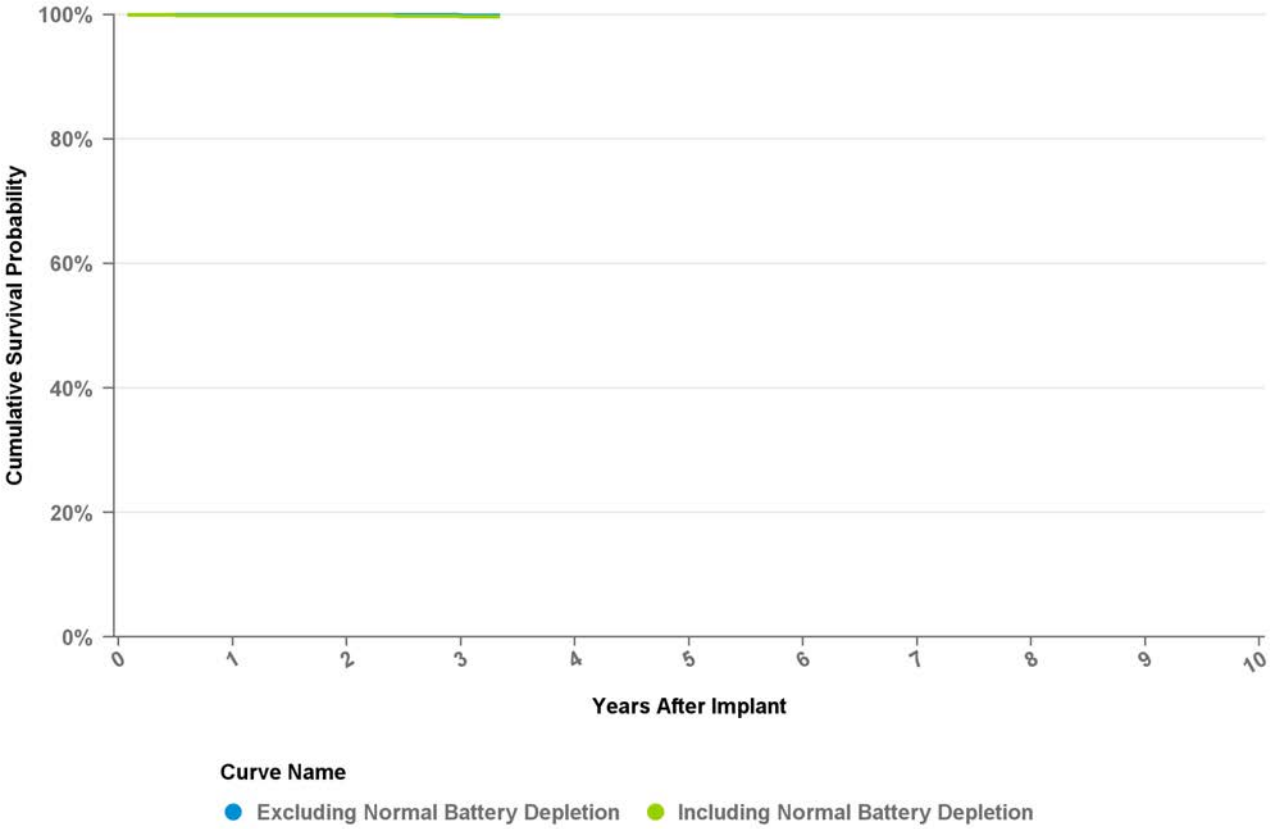
D364VRM Protecta VR

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

D3xxVRx, Survival Curve



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

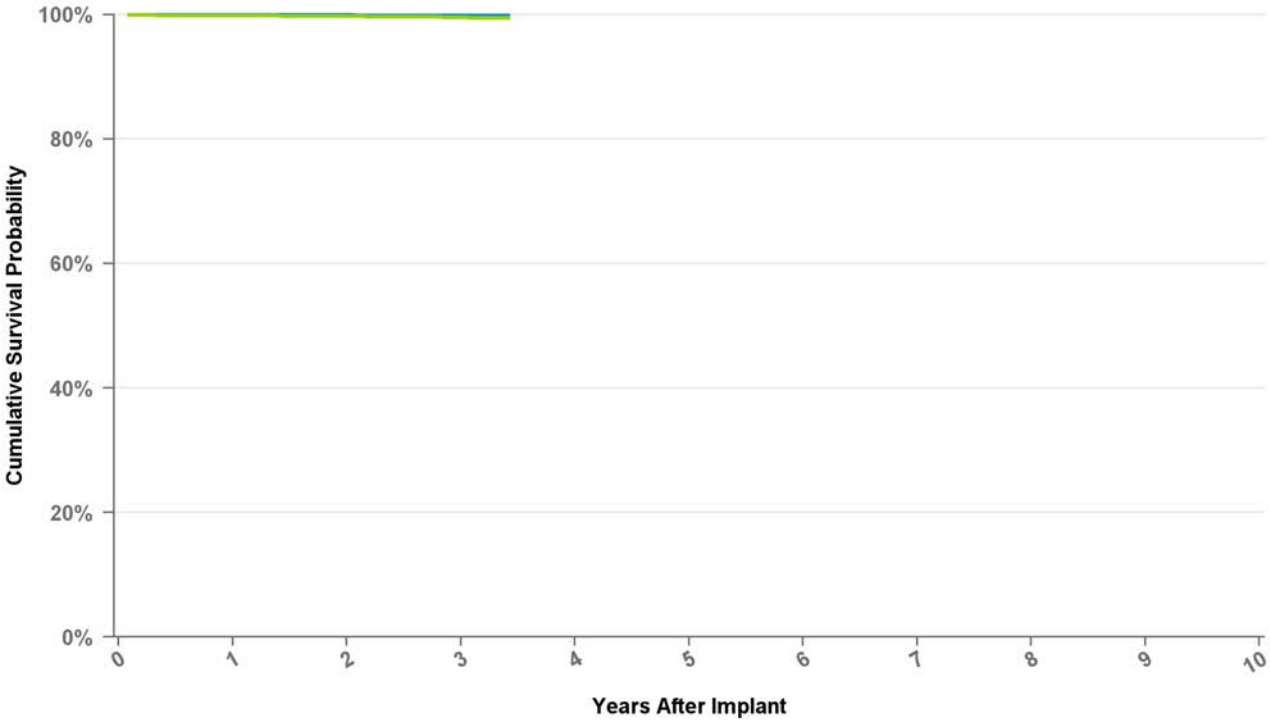
D384DRG Cardia DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

Implantable Cardioverter Defibrillator

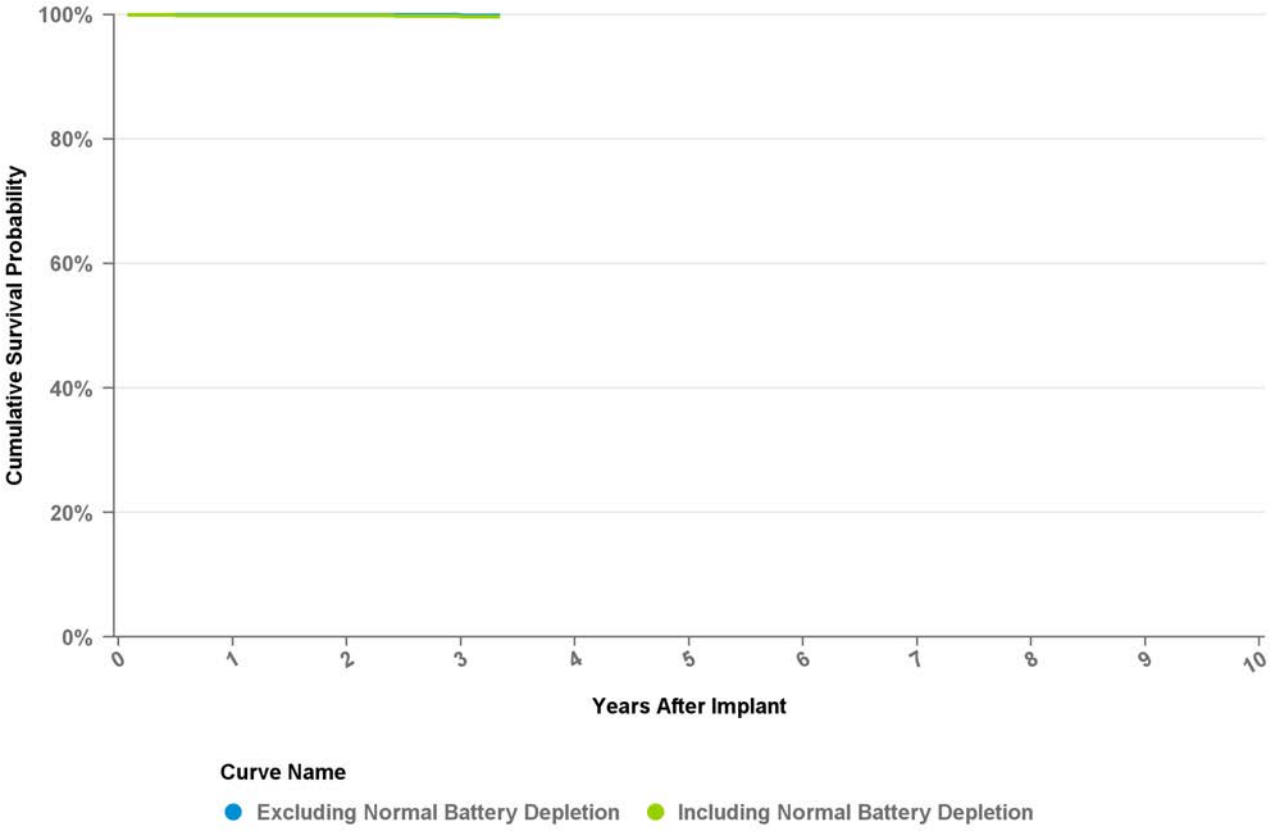
D384VRG Cardia VR

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	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

Implantable Cardioverter Defibrillator

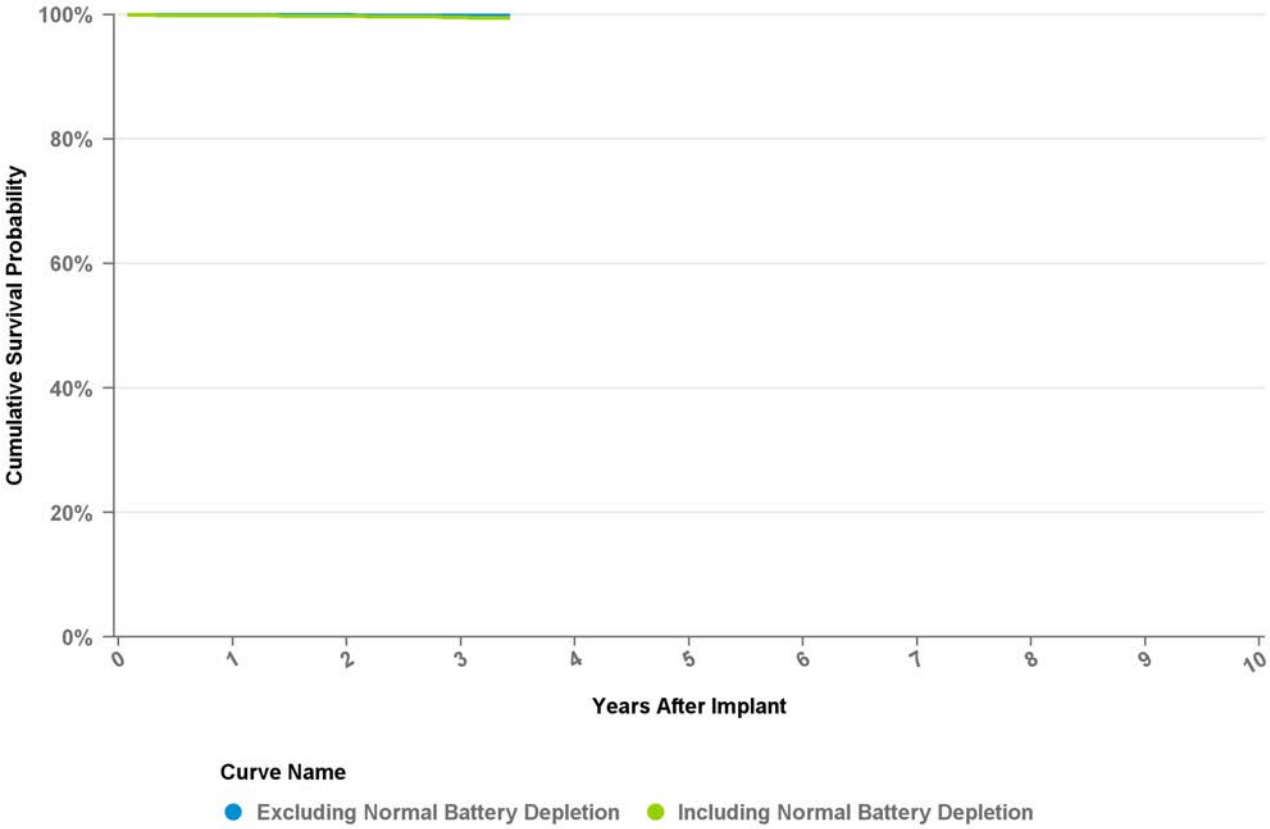
D394DRG Egida DR

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.8%	99.6%	99.5%
Effective Sample Size	54531	27697	4208	134

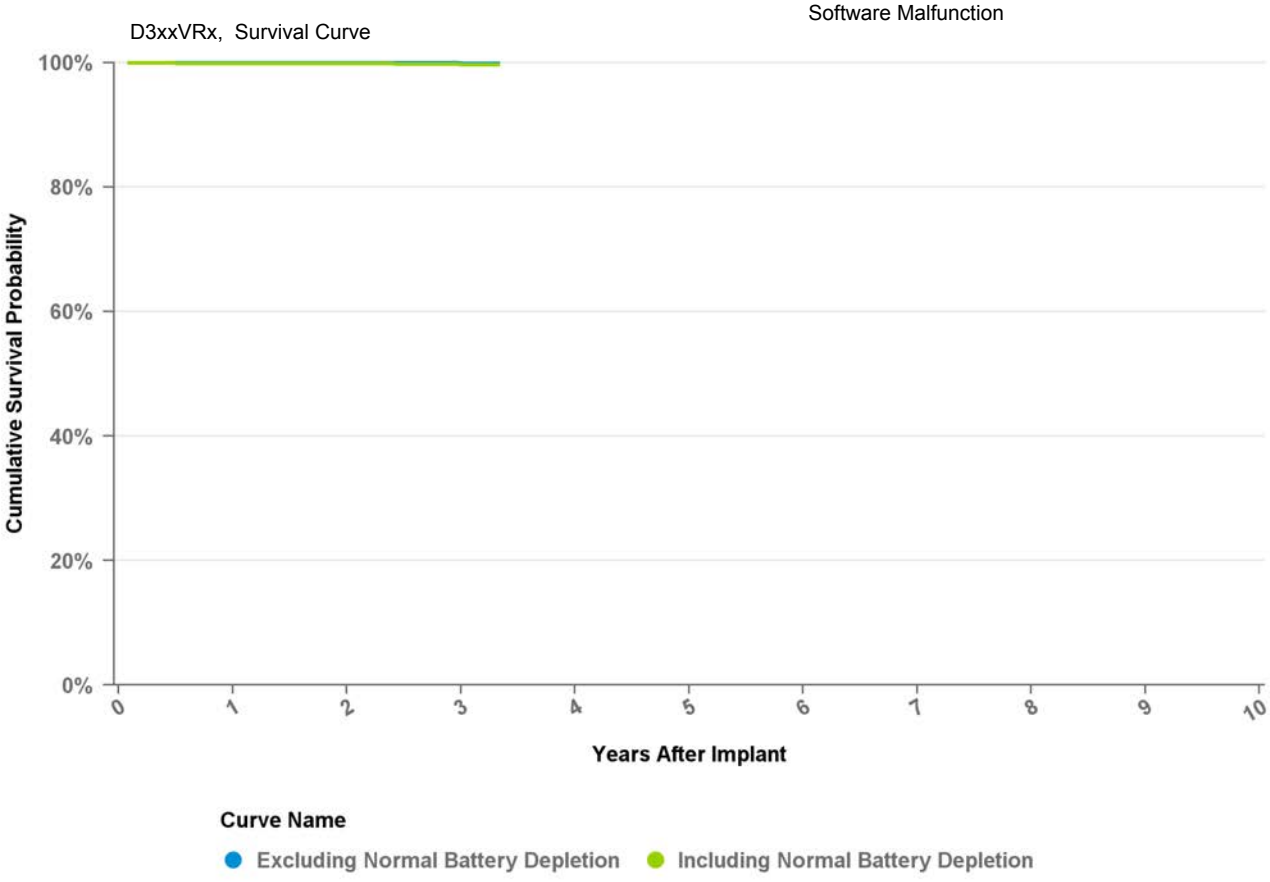
Implantable Cardioverter Defibrillator

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



Years	1	2	3	at 40 mo
Excluding NBD	100.0%	100.0%	99.9%	99.9%
Including NBD	99.9%	99.9%	99.7%	99.7%
Effective Sample Size	25285	11883	1699	218

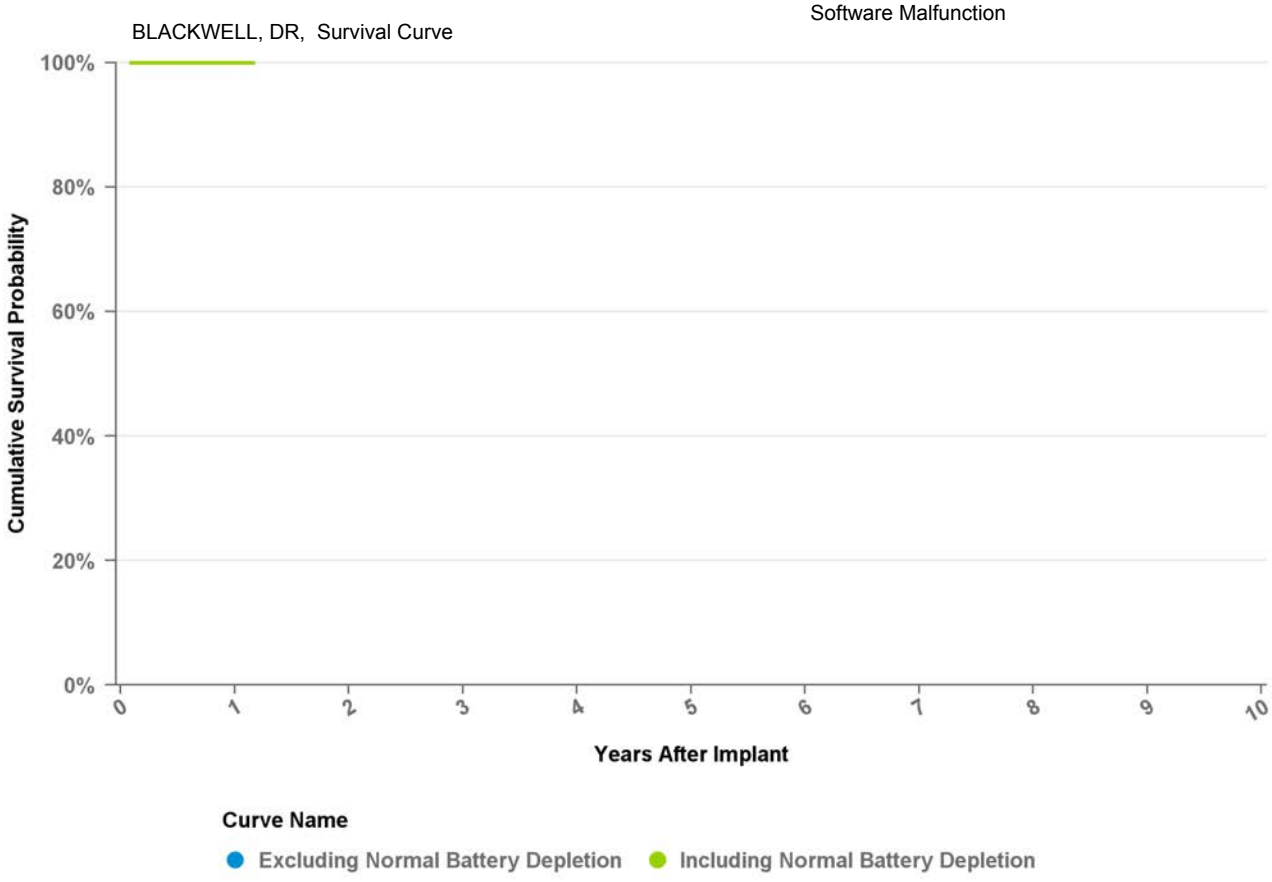
Implantable Cardioverter Defibrillator

DDBB1D1 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	10,489
Estimated Active US Implants	10,331
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

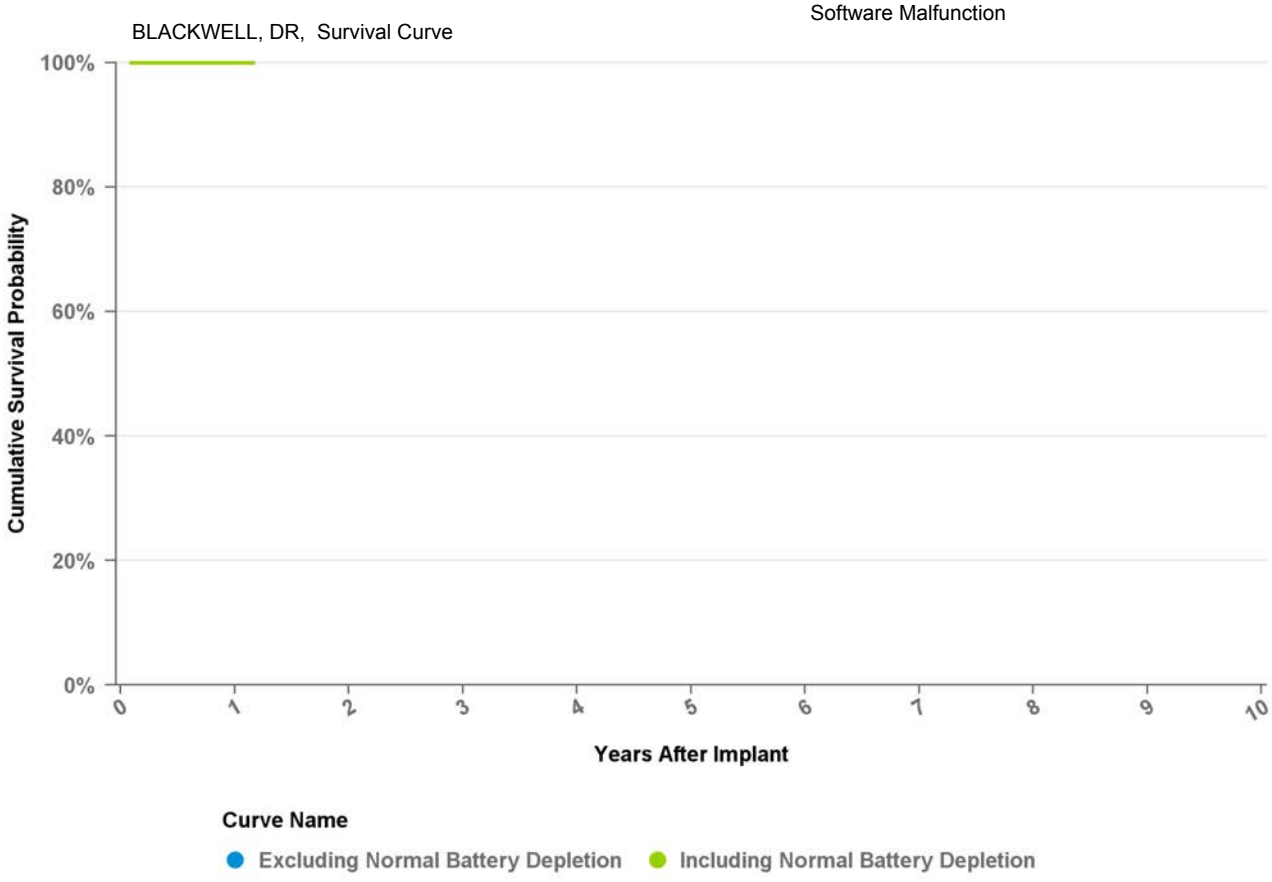
Implantable Cardioverter Defibrillator

DDBB1D4 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	10,350
Estimated Active US Implants	10,183
Normal Battery Depletions (US)	1

NBG Code	DDE-DDDR
Max Delivered Energy	36 J

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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

Implantable Cardioverter Defibrillator

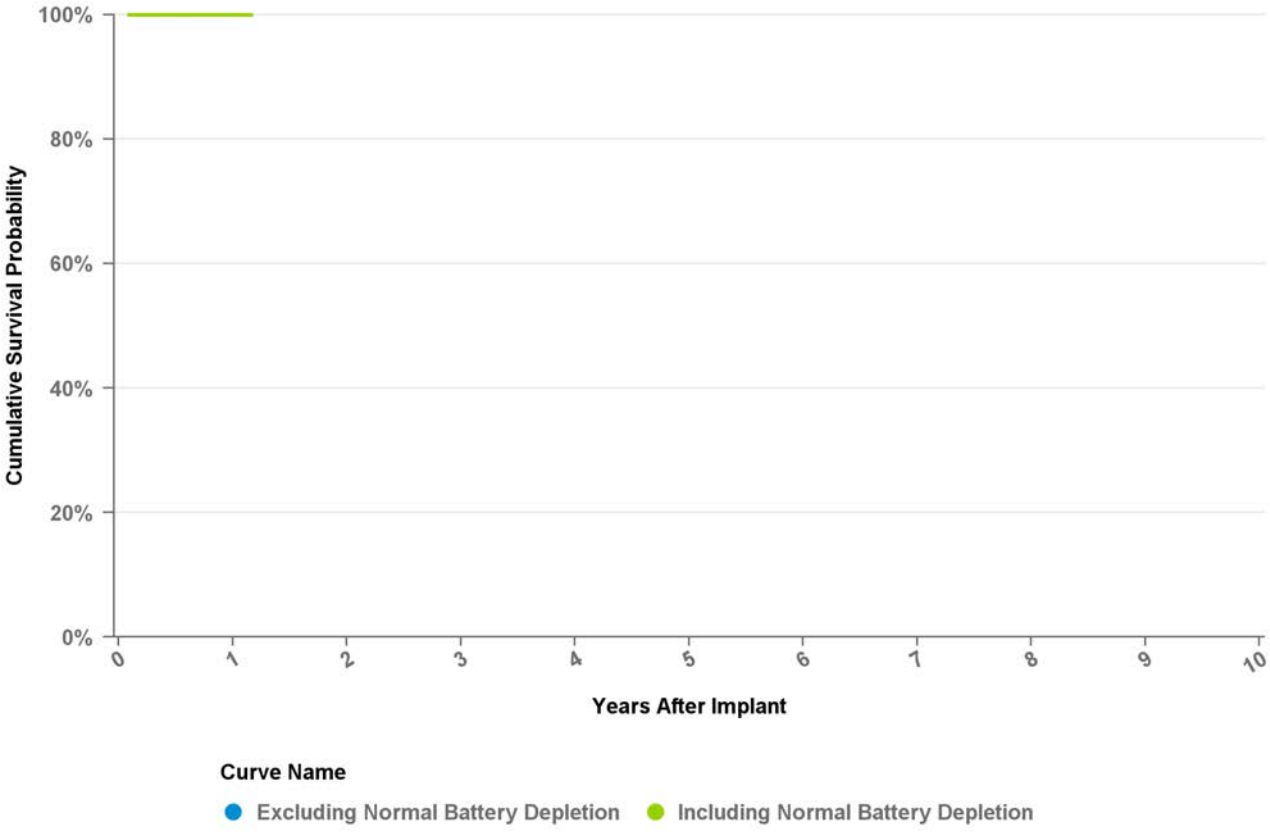
DDBB2D1 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
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

BLACKWELL, DR, Survival Curve



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

Implantable Cardioverter Defibrillator

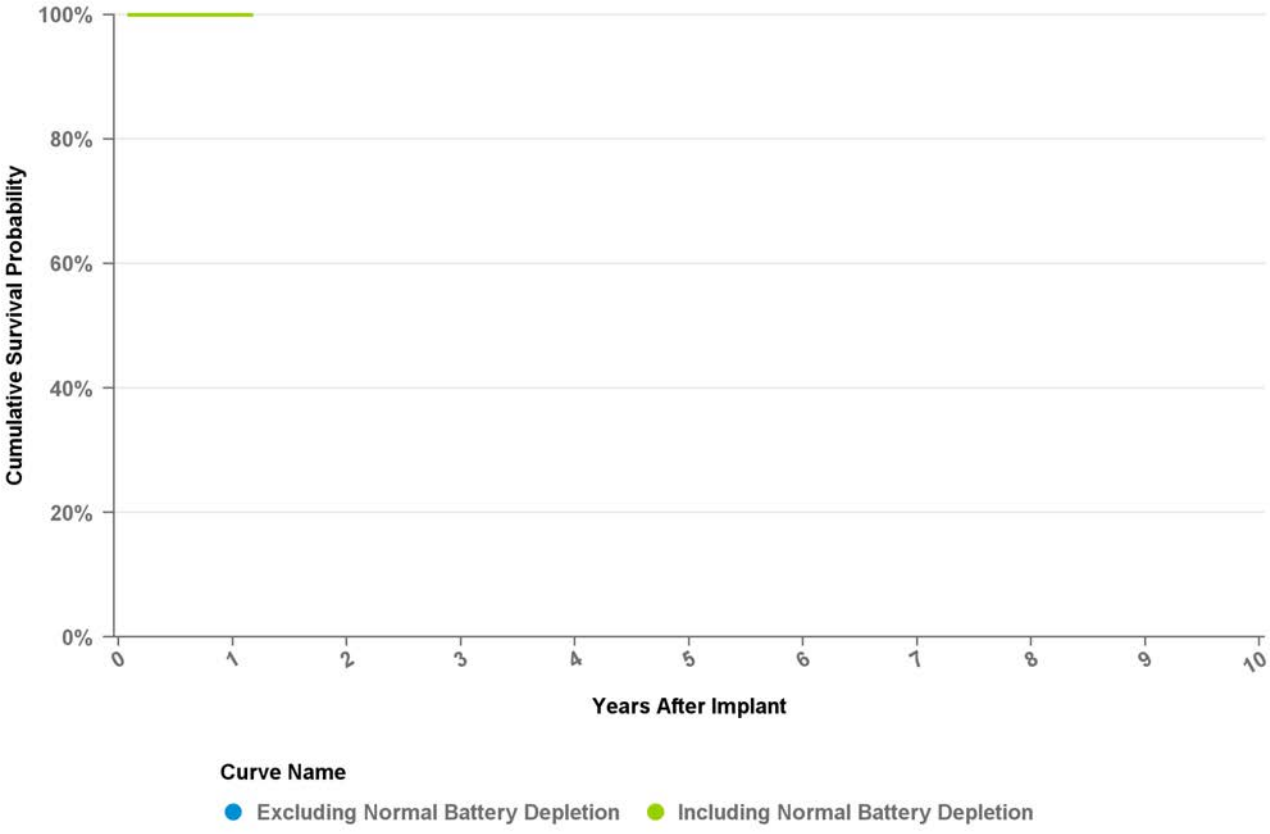
DDBB2D4 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
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

BLACKWELL, DR, Survival Curve



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

Implantable Cardioverter Defibrillator

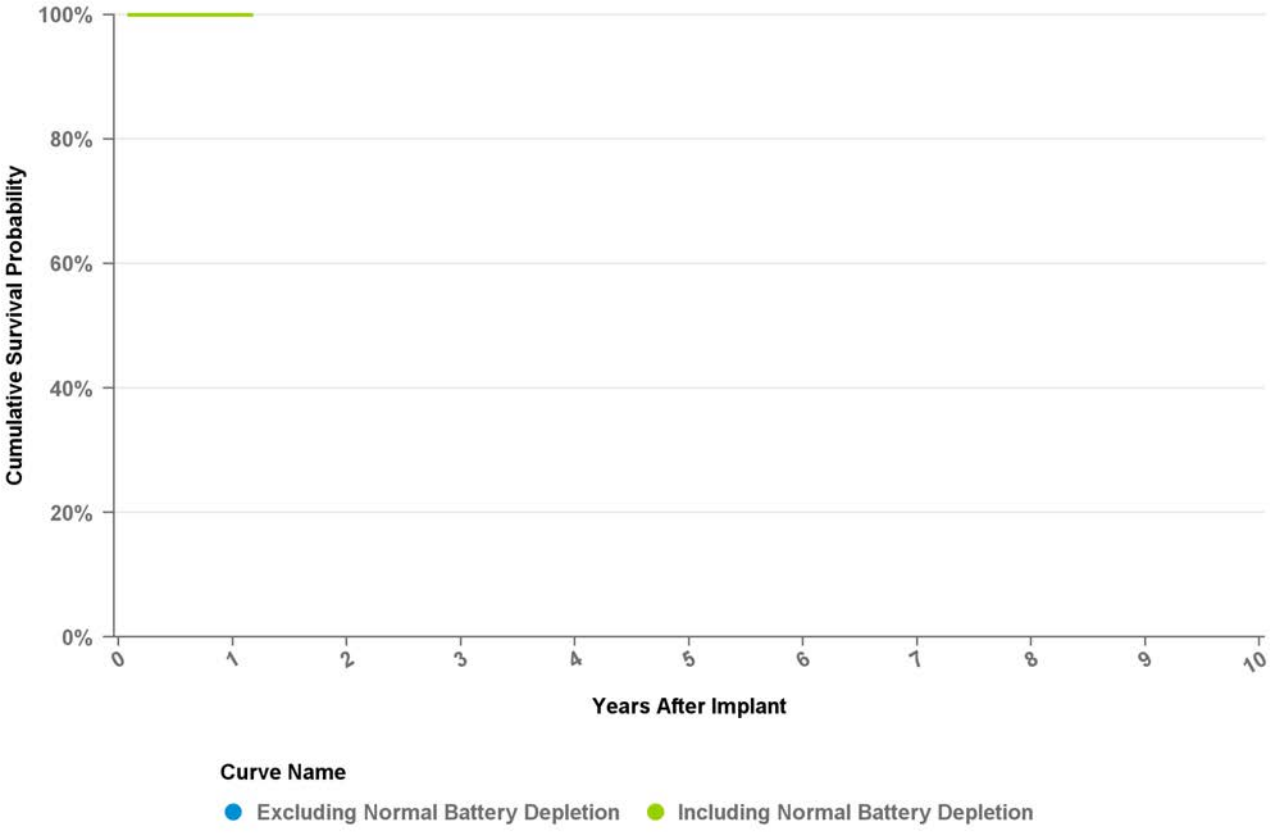
DDBC3D1 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	2,526
Estimated Active US Implants	2,488
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

BLACKWELL, DR, Survival Curve



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

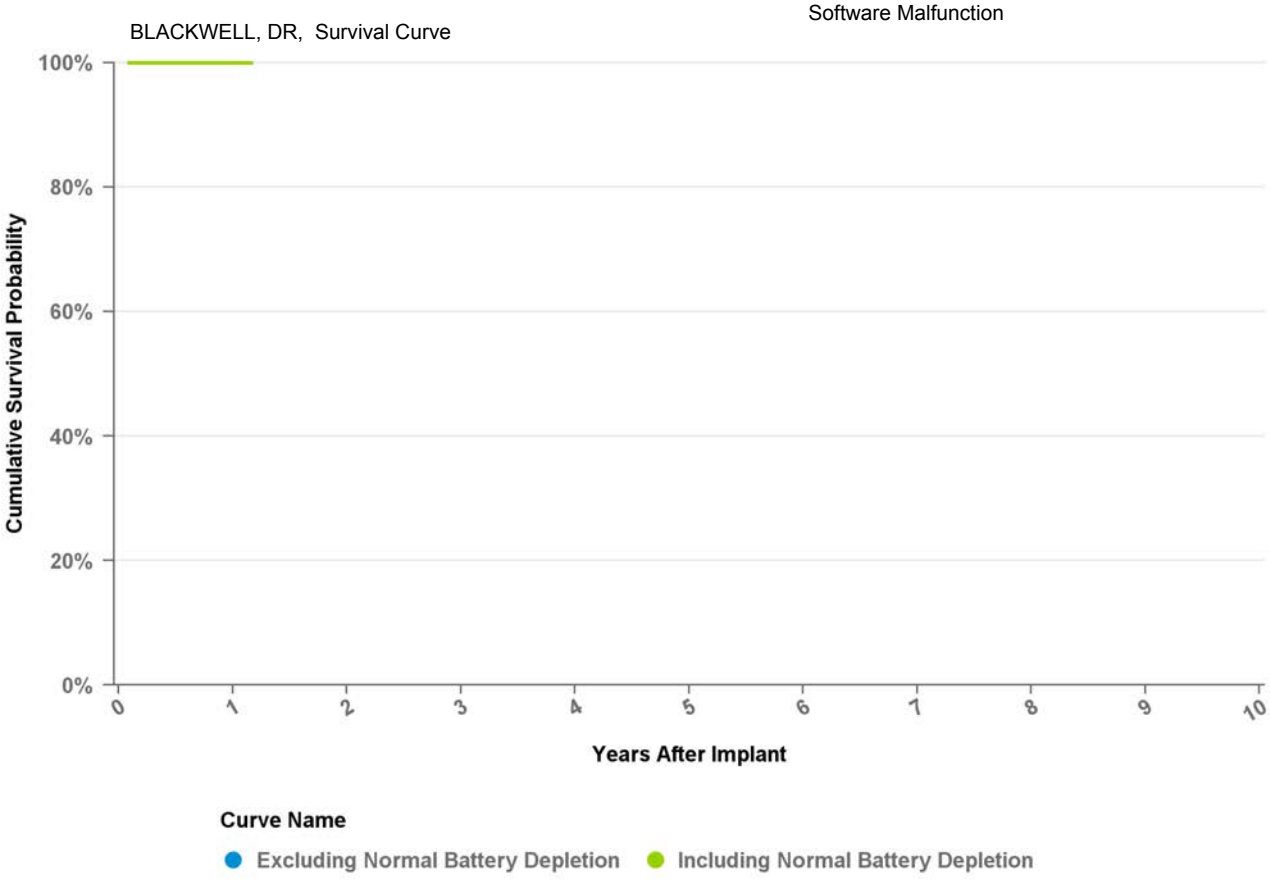
Implantable Cardioverter Defibrillator

DDBC3D4 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2013
Registered US Implants	2,241
Estimated Active US Implants	2,200
Normal Battery Depletions (US)	1

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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	3143	533

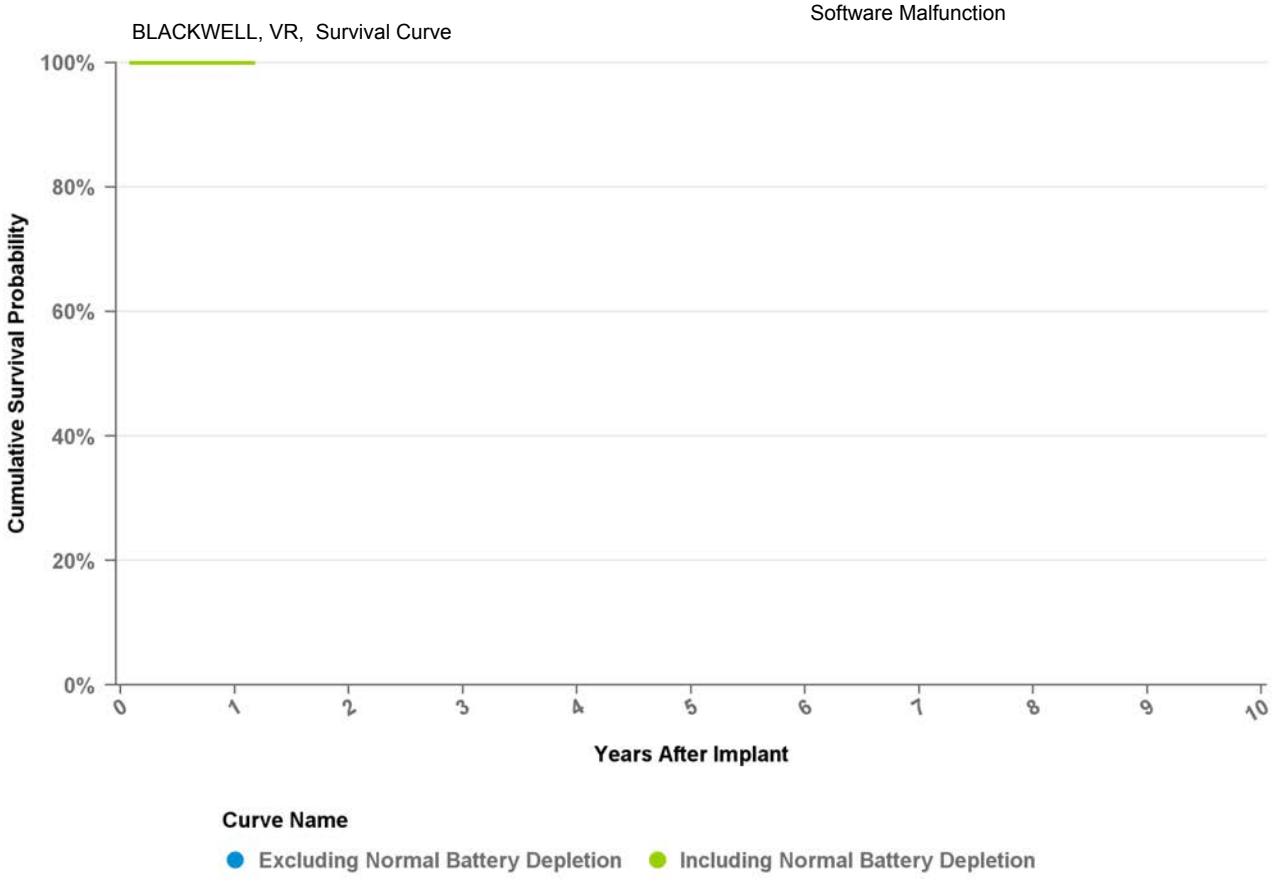
Implantable Cardioverter Defibrillator

DVBB1D1 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	4,409
Estimated Active US Implants	4,338
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

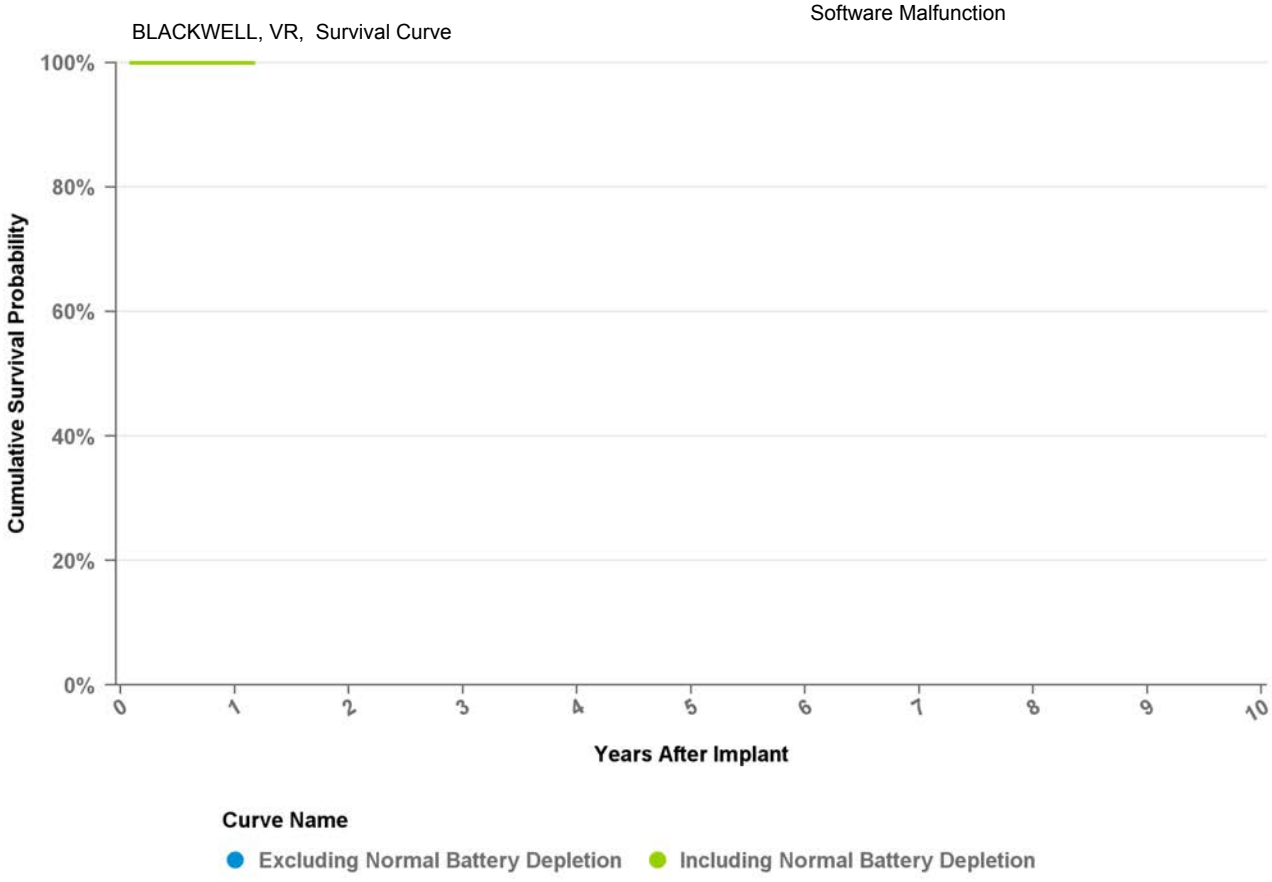
Implantable Cardioverter Defibrillator

DVBB1D4 Evera XT

US Market Release Date	4/3/2013
CE Market Approval Date	
Registered US Implants	8,003
Estimated Active US Implants	7,862
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

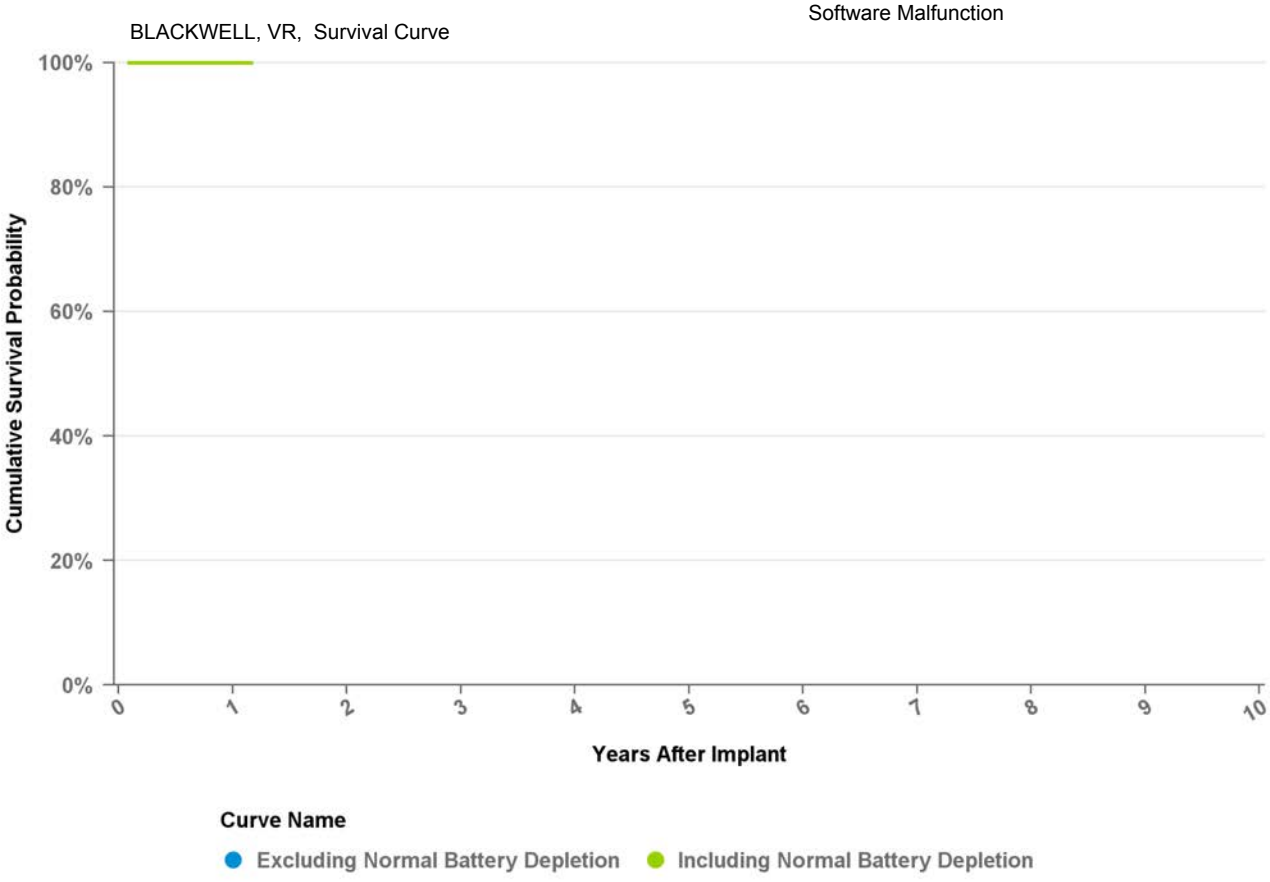
Implantable Cardioverter Defibrillator

DVBB2D1 Evera XT

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

NBG Code	VVE-VVIR
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

Implantable Cardioverter Defibrillator

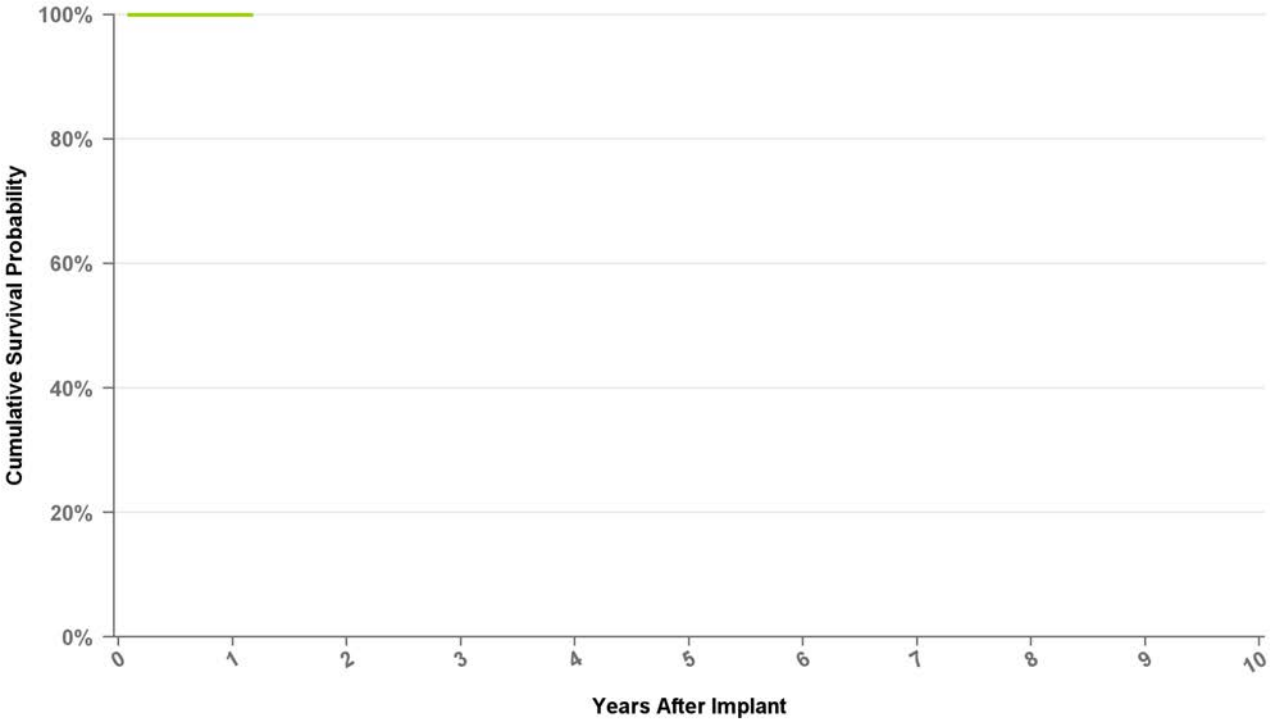
DVBB2D4 Evera XT

US Market Release Date	
CE Market Approval Date	12/17/2012
Registered US Implants	1
Estimated Active US Implants	1
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
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

BLACKWELL, VR, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

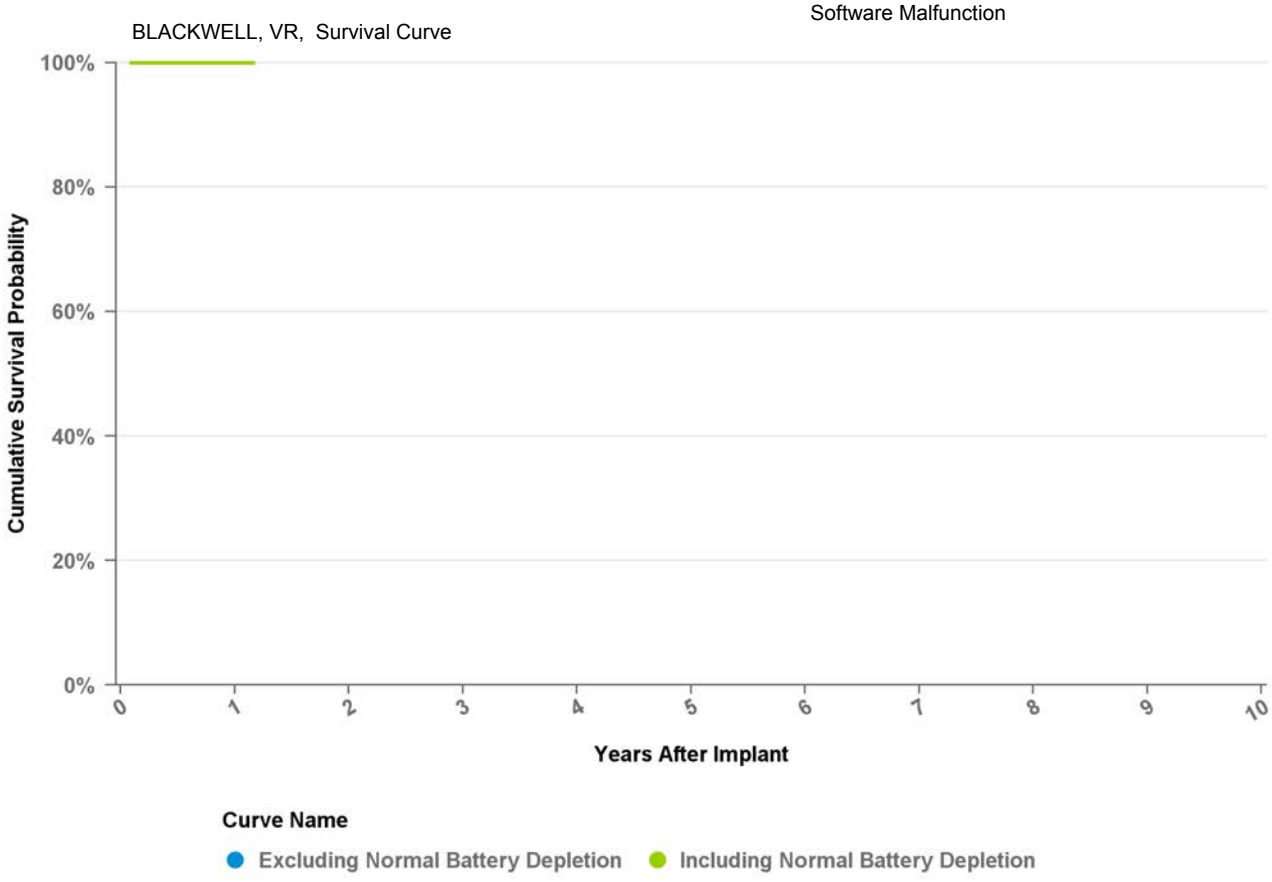
Implantable Cardioverter Defibrillator

DVBC3D1 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	1,122
Estimated Active US Implants	1,103
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

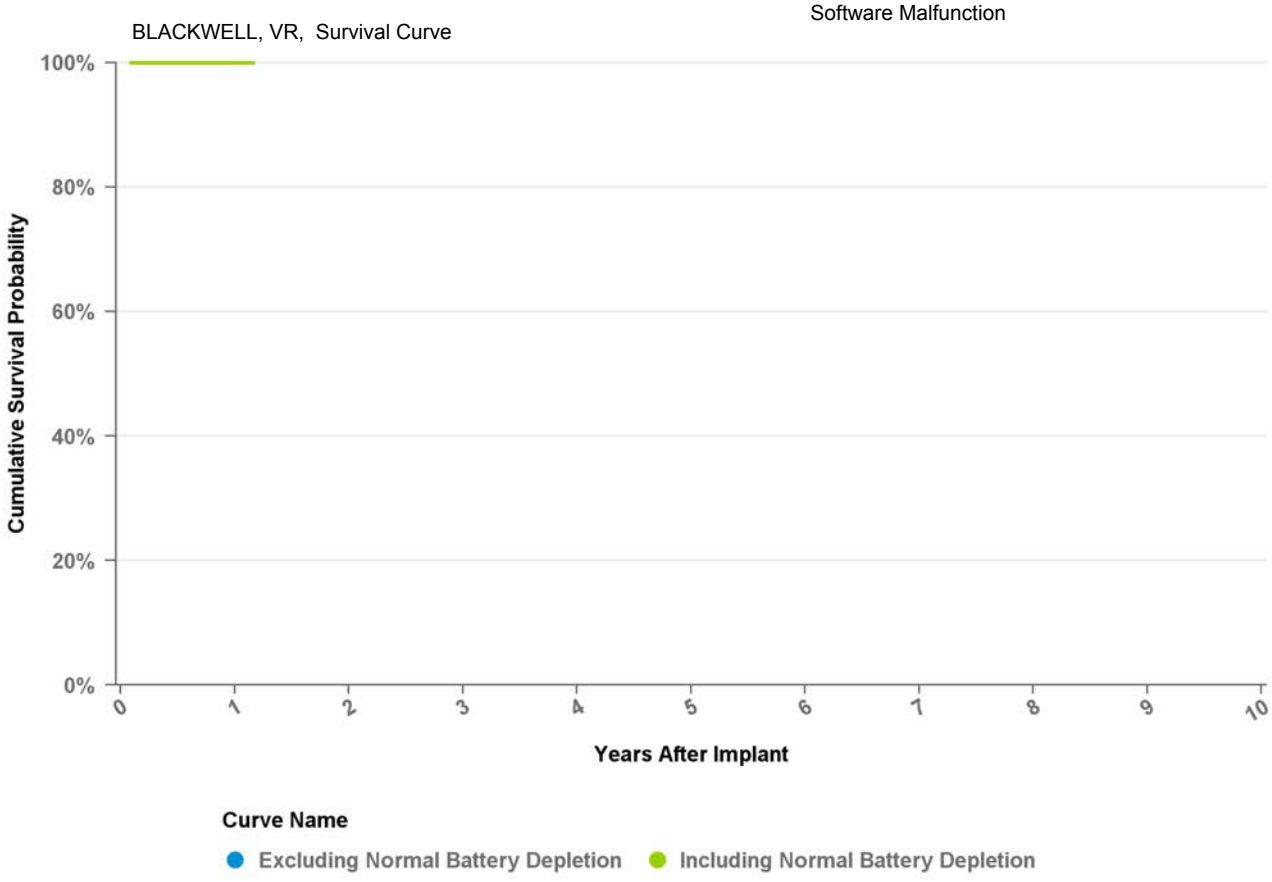
Implantable Cardioverter Defibrillator

DVBC3D4 Evera S

US Market Release Date	4/3/2013
CE Market Approval Date	12/17/2012
Registered US Implants	1,892
Estimated Active US Implants	1,859
Normal Battery Depletions (US)	0

NBG Code	VVE-VVIR
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



Years	1	at 14 mo
Excluding NBD	100.0%	100.0%
Including NBD	100.0%	100.0%
Effective Sample Size	1699	316

Cardiac Resynchronization Therapy

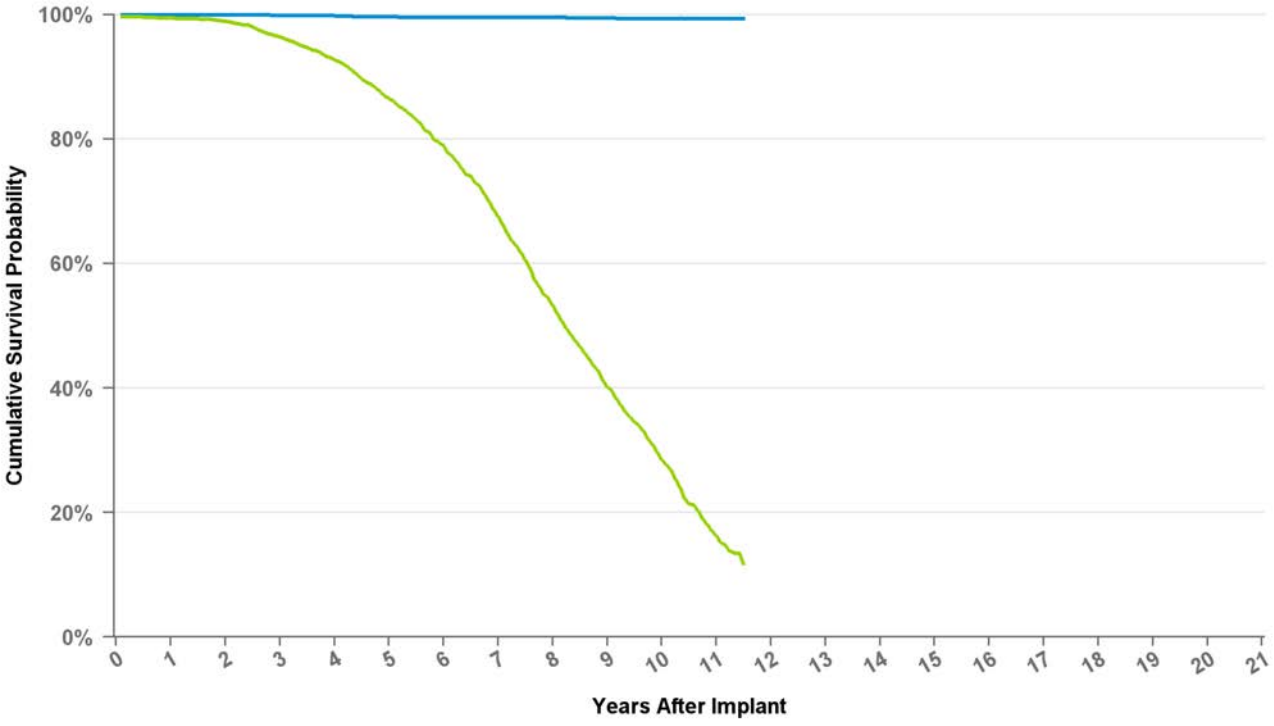
8040 InSync

US Market Release Date	8/28/2001
CE Market Approval Date	
Registered US Implants	15,332
Estimated Active US Implants	1,184
Normal Battery Depletions (US)	1,485

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	11	at 138 mo
Excluding NBD	100.0%	100.0%	99.9%	99.8%	99.7%	99.6%	99.6%	99.6%	99.5%	99.4%	99.3%	99.3%
Including NBD	99.5%	98.9%	96.4%	92.7%	86.5%	78.9%	67.6%	53.3%	40.2%	28.5%	16.3%	11.8%
Effective Sample Size	12231	10056	8027	6248	4848	3666	2618	1706	1080	636	284	161

Cardiac Resynchronization Therapy

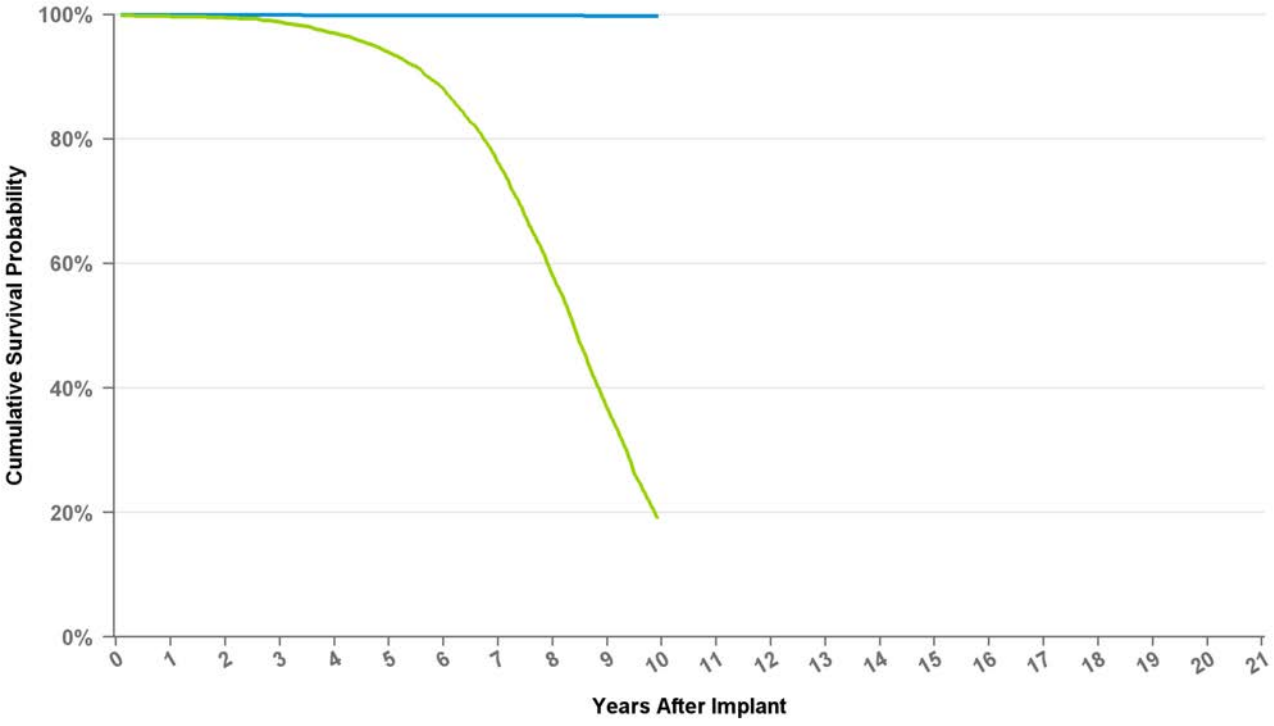
8042 InSync III

US Market Release Date	2/25/2003
CE Market Approval Date	2/7/2001
Registered US Implants	39,427
Estimated Active US Implants	12,605
Normal Battery Depletions (US)	2,976

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	25
Therapy Not Compromised Malfunction	15
Battery Malfunction	2
Electrical Component	2
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 119 mo
Excluding NBD	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.8%	99.8%
Including NBD	99.7%	99.5%	98.8%	97.0%	93.9%	88.0%	76.2%	58.1%	36.8%	19.2%
Effective Sample Size	34472	30092	26395	22017	15454	10286	6263	3163	1084	164

Cardiac Resynchronization Therapy

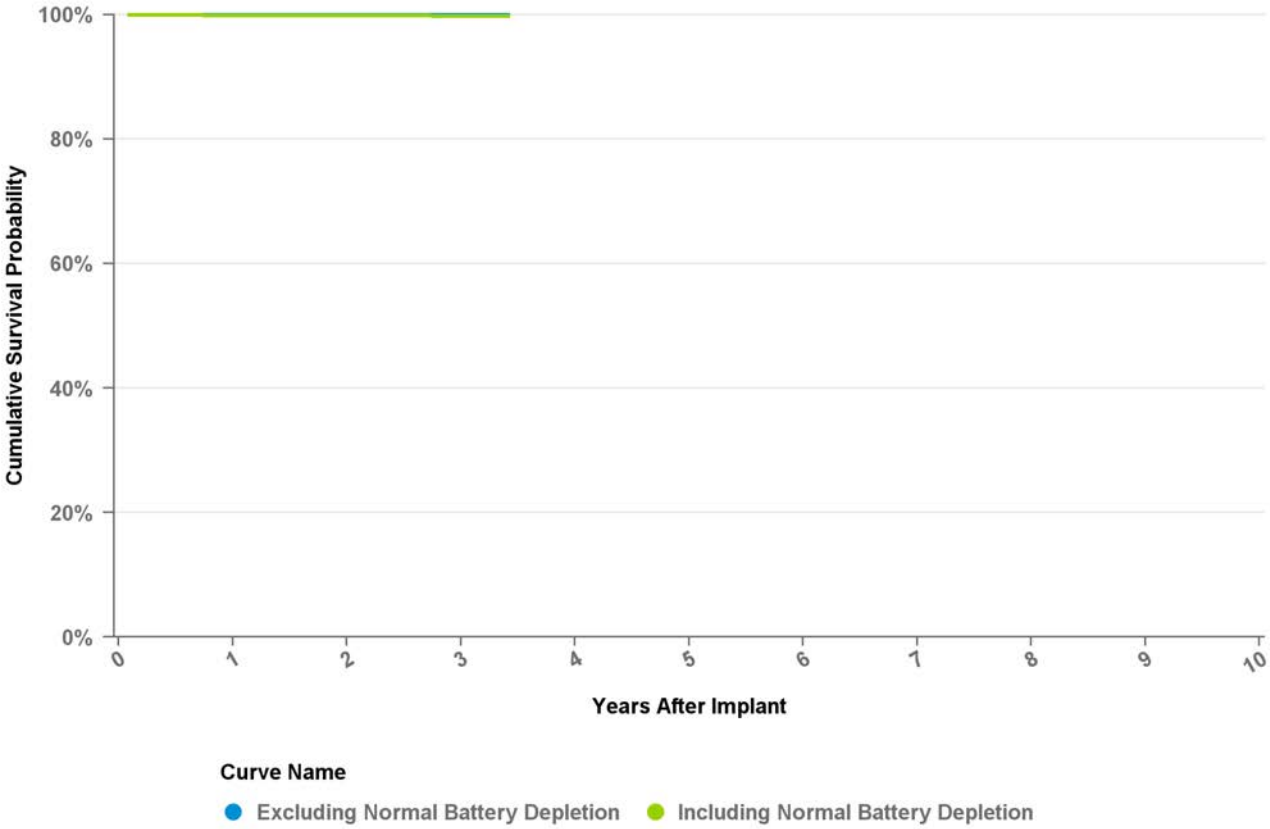
C2TR01 Syncra CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	5/11/2010
Registered US Implants	7,750
Estimated Active US Implants	6,837
Normal Battery Depletions (US)	5

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.8%
Effective Sample Size	15537	8560	2434	293

Cardiac Resynchronization Therapy

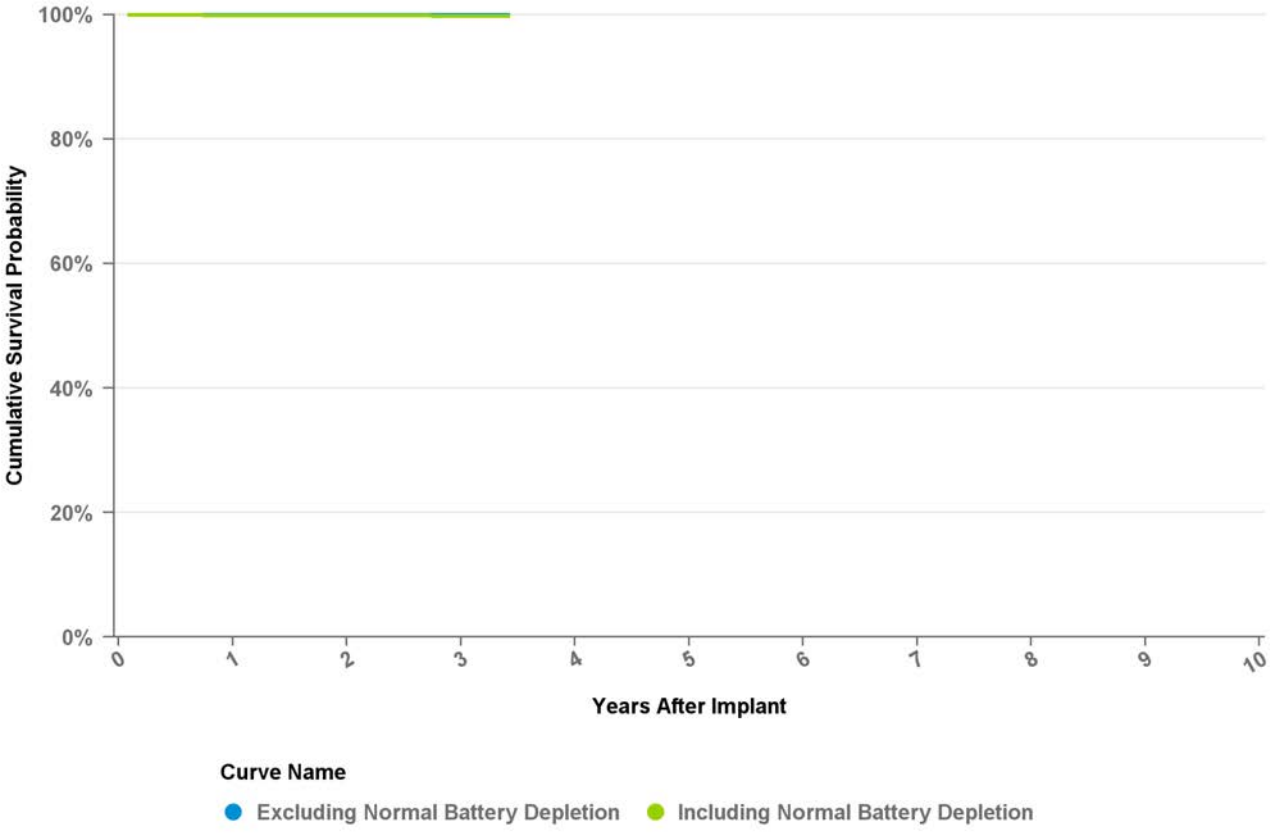
C3TR01 Consulta CRT-P

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.8%
Effective Sample Size	15537	8560	2434	293

Cardiac Resynchronization Therapy

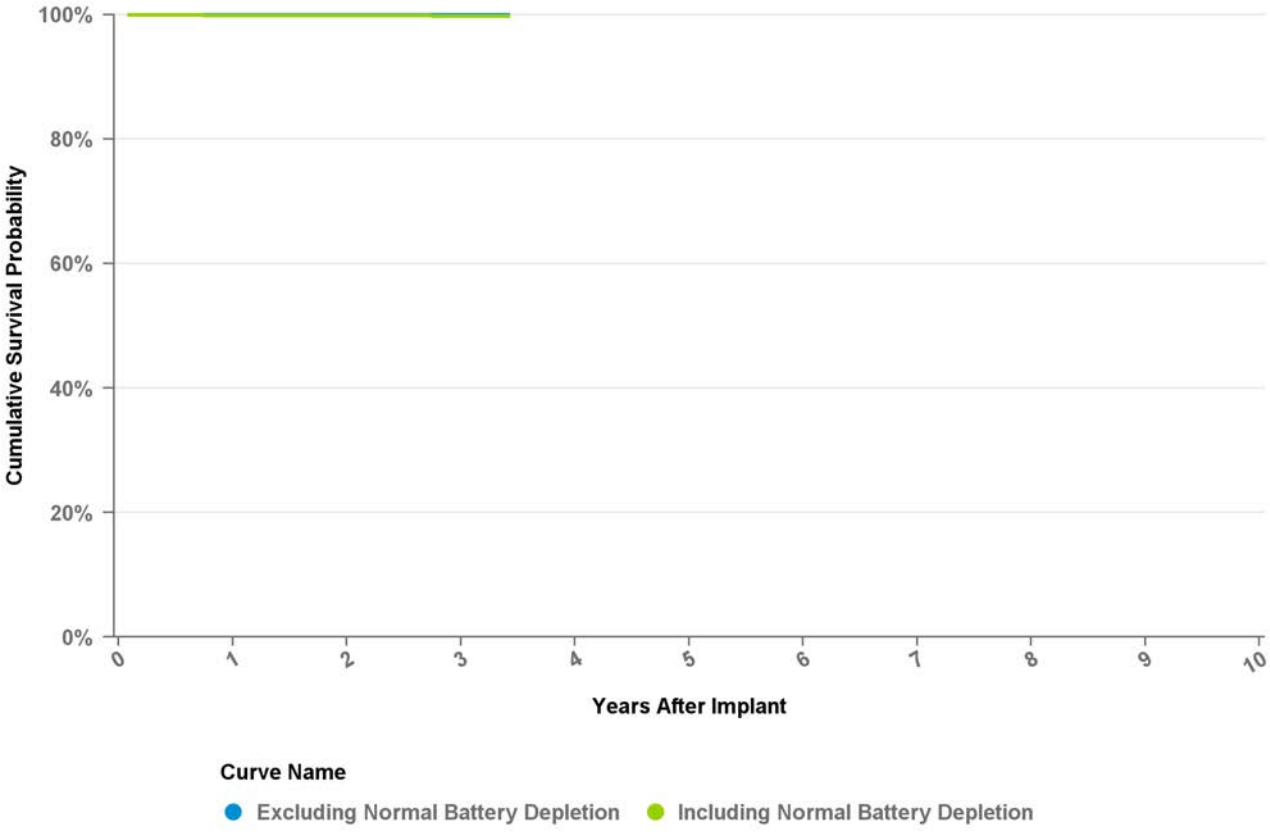
C4TR01 Consulta CRT-P

US Market Release Date	3/22/2011
CE Market Approval Date	
Registered US Implants	14,483
Estimated Active US Implants	13,321
Normal Battery Depletions (US)	8

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	3	at 41 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	99.9%	99.9%	99.8%	99.8%
Effective Sample Size	15537	8560	2434	293

Implantable Pulse Generator

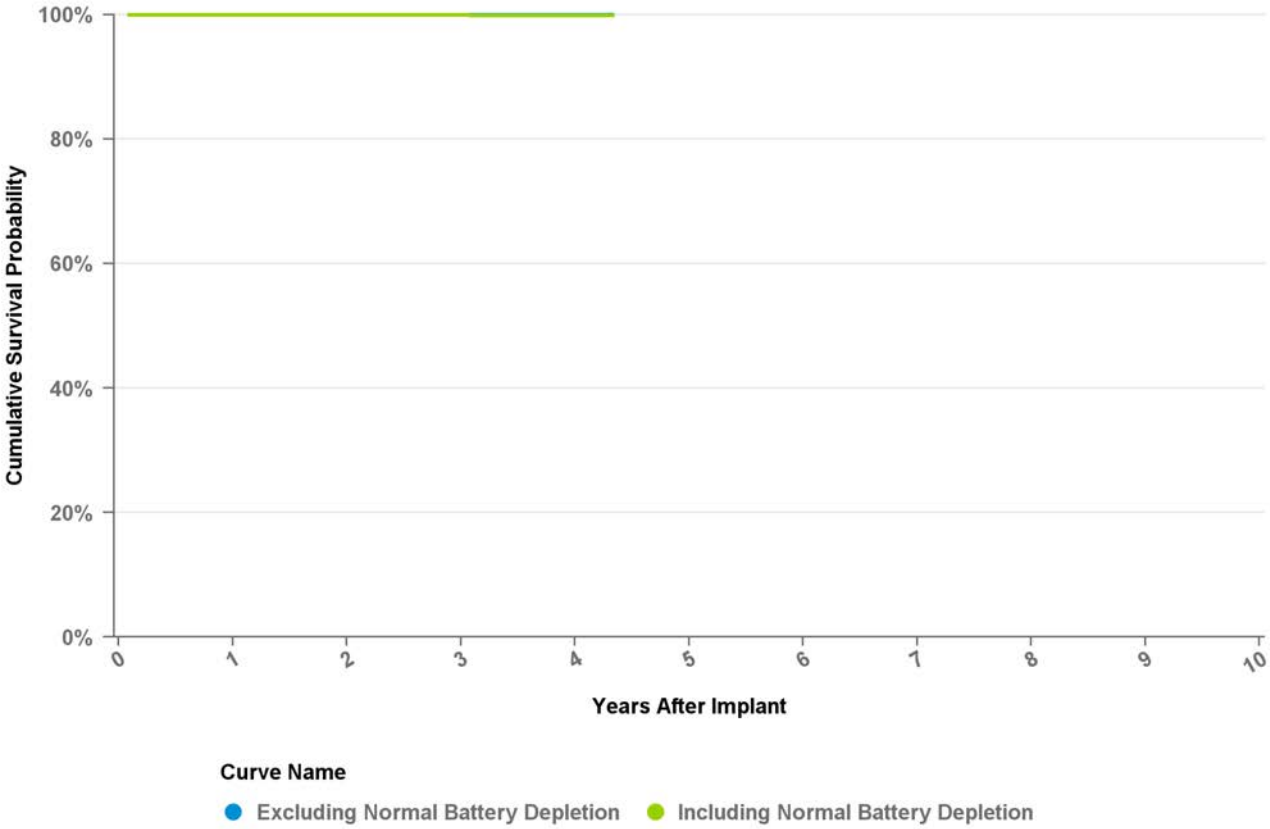
A2DR01 Advisa DR MRI

US Market Release Date	1/15/2013
CE Market Approval Date	
Registered US Implants	42,873
Estimated Active US Implants	42,208
Normal Battery Depletions (US)	1

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	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	23917	9397	4744	1227	219

Implantable Pulse Generator

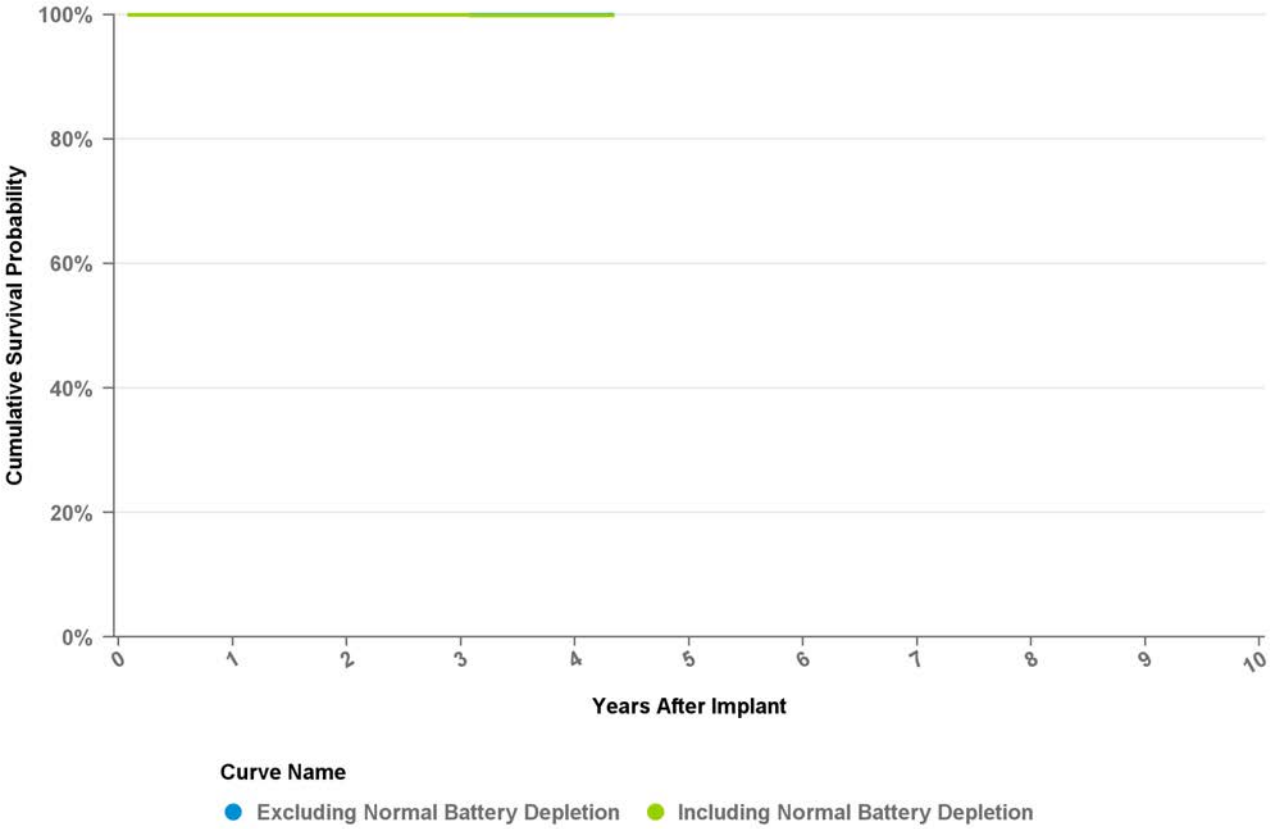
A3DR01 Advisa DR MRI

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	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	23917	9397	4744	1227	219

Implantable Pulse Generator

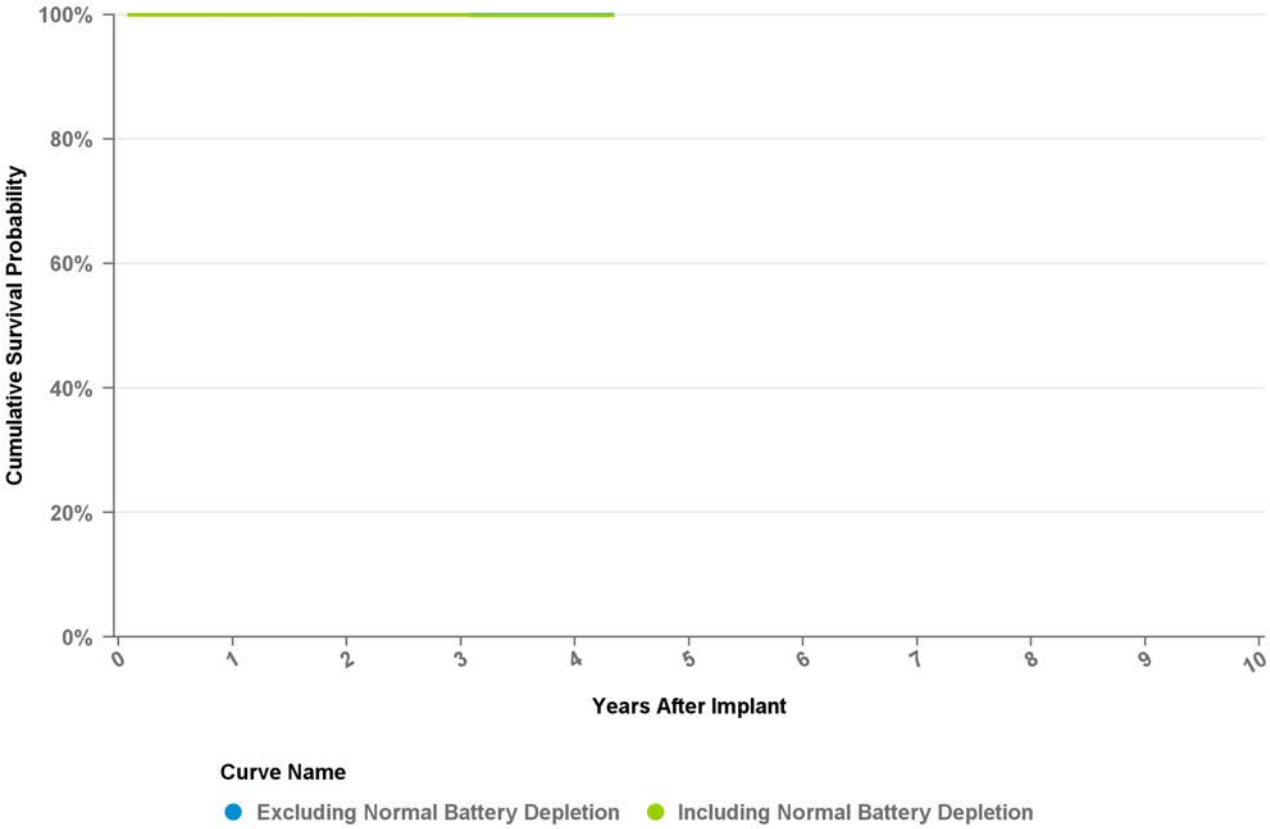
A4DR01 Advisa DR

US Market Release Date	4/4/2011
CE Market Approval Date	
Registered US Implants	1,532
Estimated Active US Implants	1,450
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	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	23917	9397	4744	1227	219

Implantable Pulse Generator

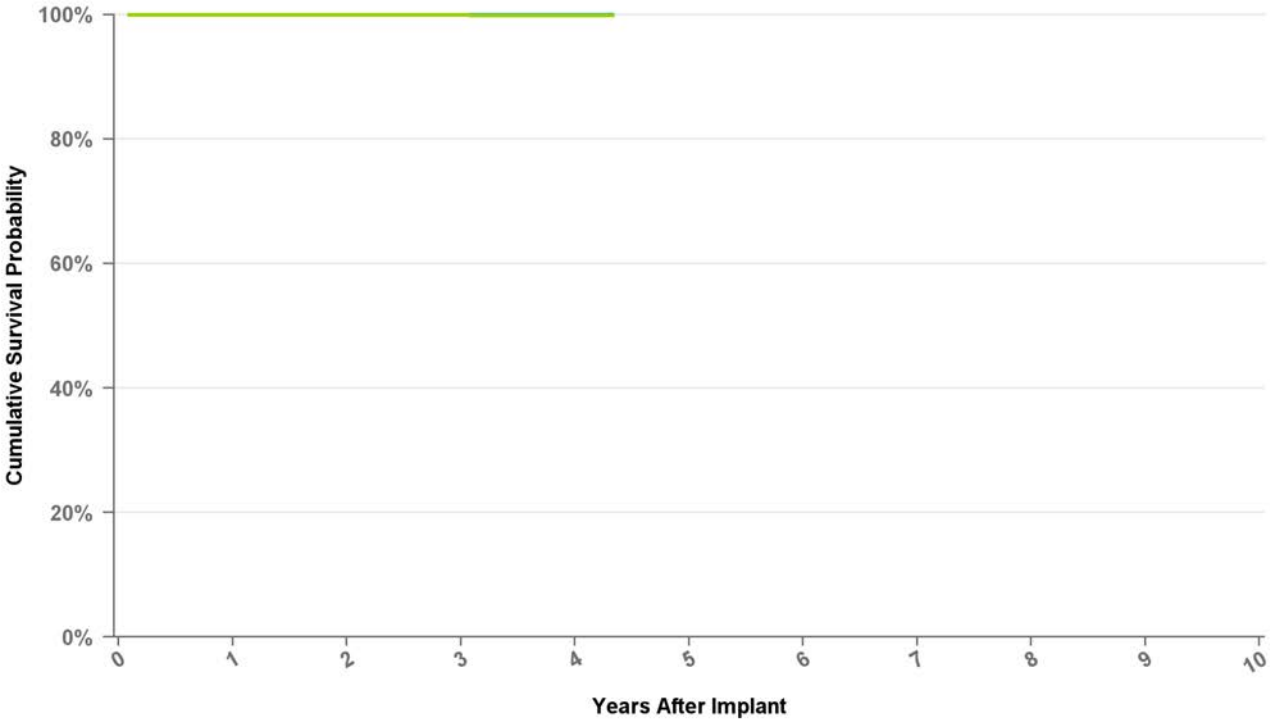
A5DR01 Advisa DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	23917	9397	4744	1227	219

Implantable Pulse Generator

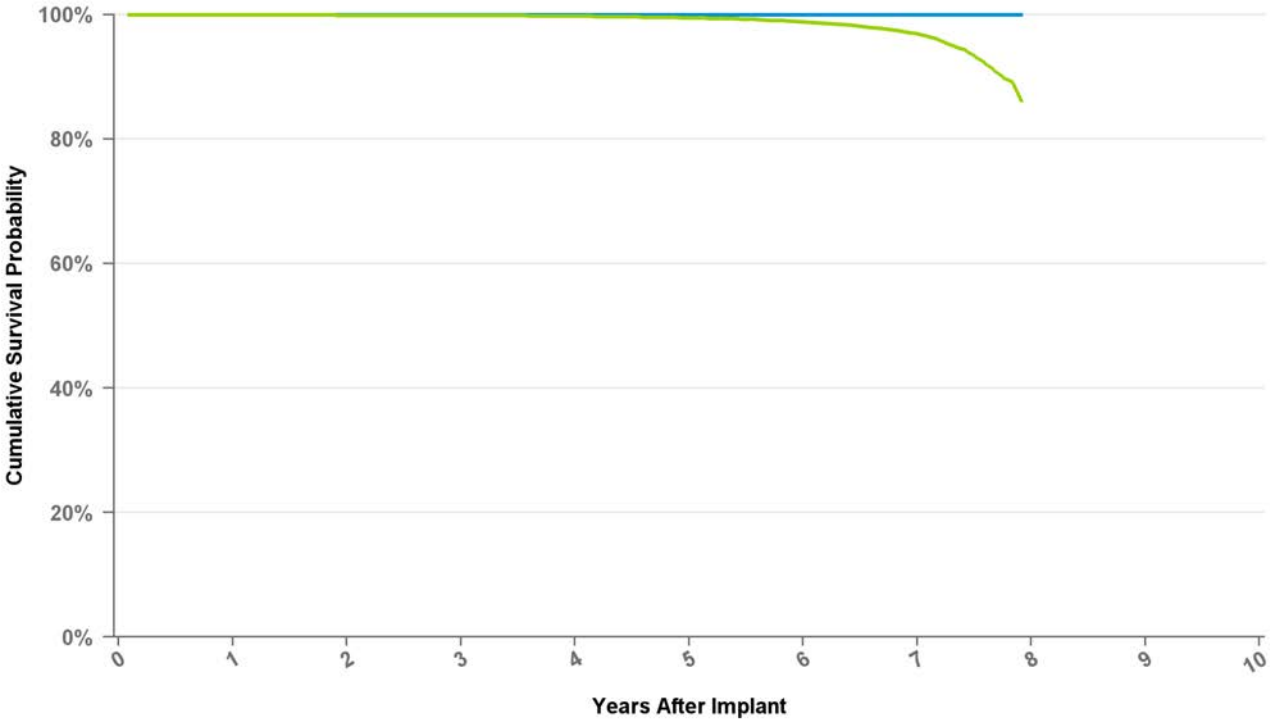
ADD01 Adapta D

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

ADDR01, ADDR03, ADDR06, ADD01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.8%	99.5%	98.8%	96.9%	86.1%
Effective Sample Size	351295	292468	234245	177021	122110	72049	29010	176

Implantable Pulse Generator

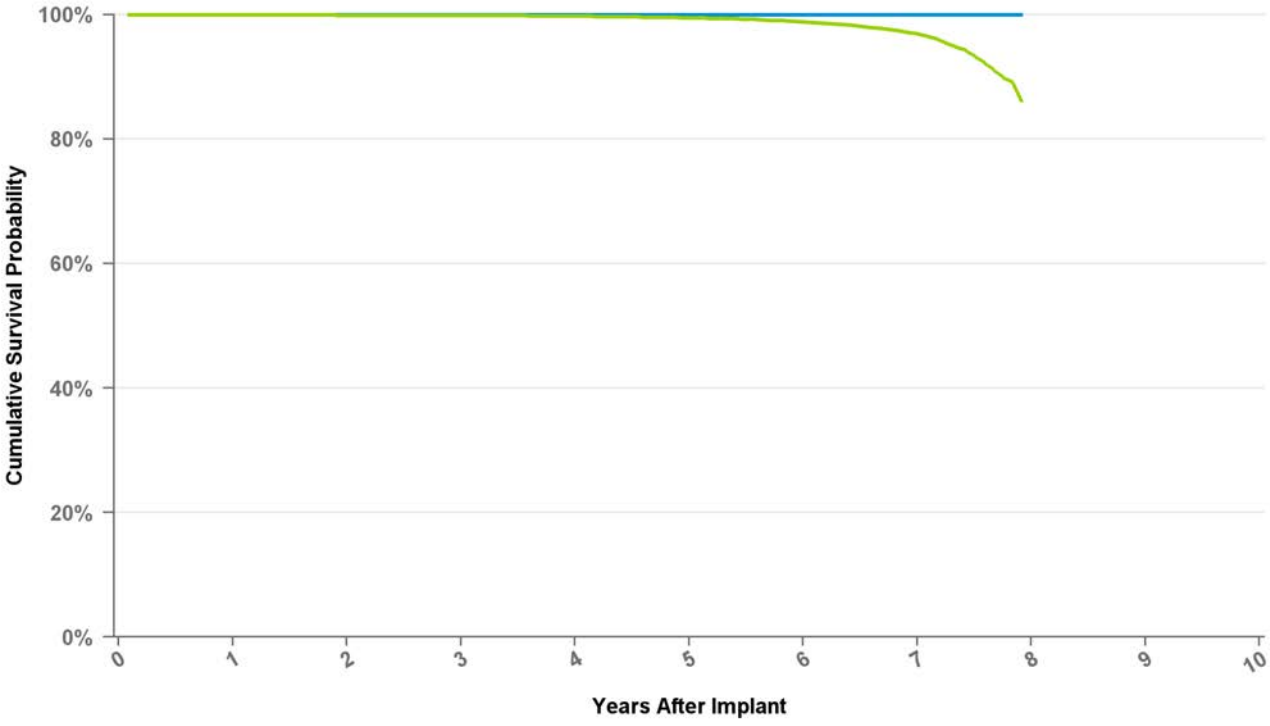
ADDR01 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	391,607
Estimated Active US Implants	317,827
Normal Battery Depletions (US)	1,606

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	68
Therapy Not Compromised Malfunction	45
Battery Malfunction	0
Electrical Component	43
Electrical Interconnect	1
Other Malfunction	1
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	23
Battery Malfunction	0
Electrical Component	19
Electrical Interconnect	2
Other Malfunction	2
Poss Early Battery Depltn	0
Software Malfunction	0

ADDR01, ADDR03, ADDR06, ADD01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.8%	99.5%	98.8%	96.9%	86.1%
Effective Sample Size	351295	292468	234245	177021	122110	72049	29010	176

Implantable Pulse Generator

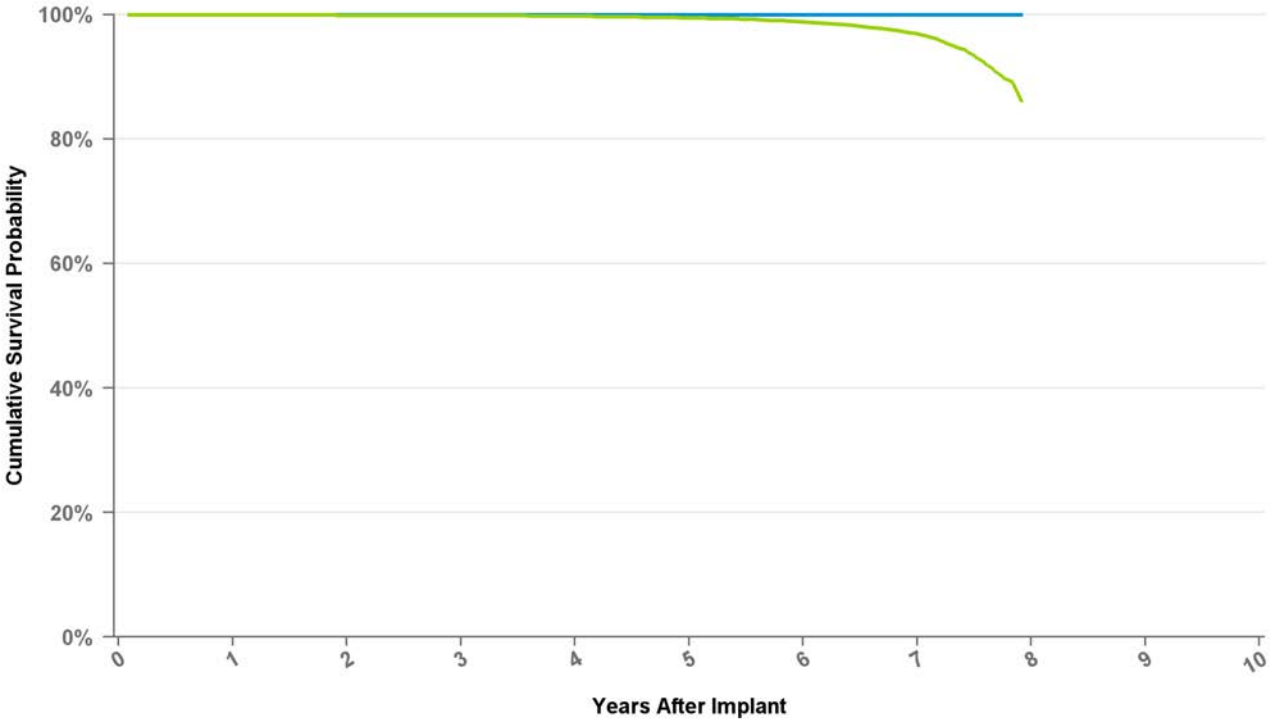
ADDR03 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	3,595
Estimated Active US Implants	2,734
Normal Battery Depletions (US)	43

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

ADDR01, ADDR03, ADDR06, ADD01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.8%	99.5%	98.8%	96.9%	86.1%
Effective Sample Size	351295	292468	234245	177021	122110	72049	29010	176

Implantable Pulse Generator

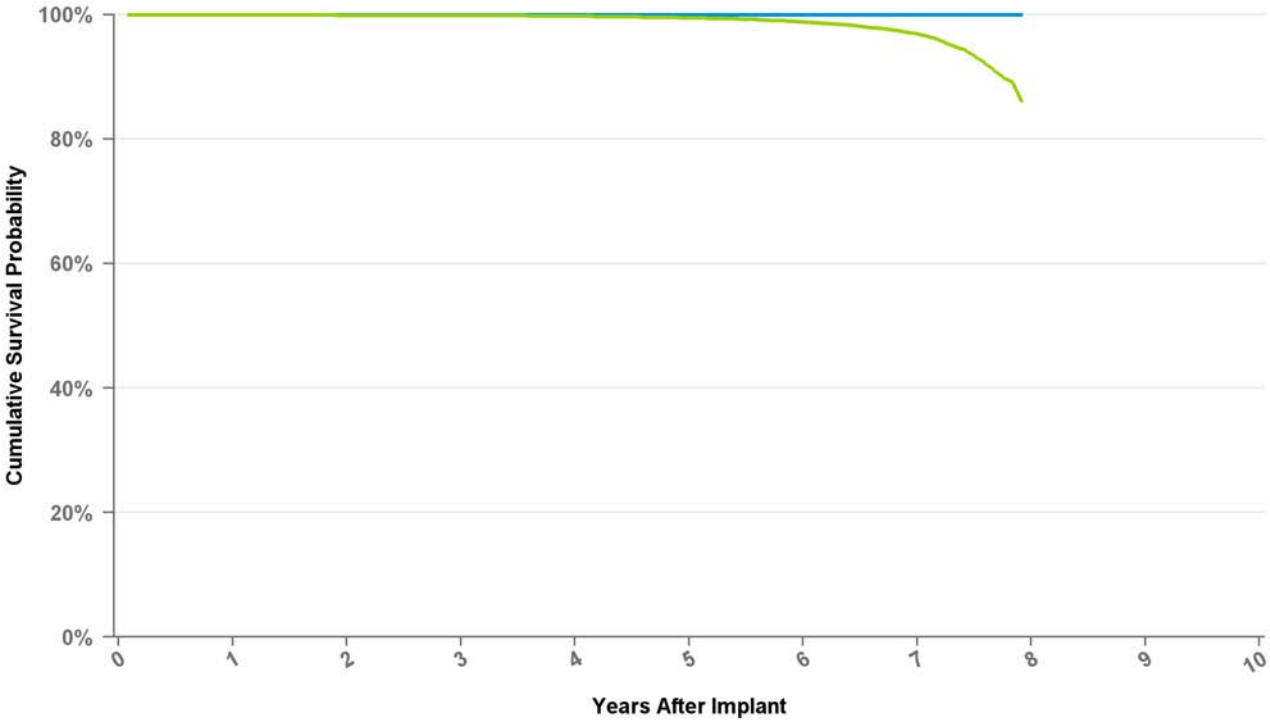
ADDR06 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2,836
Estimated Active US Implants	1,909
Normal Battery Depletions (US)	68

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

ADDR01, ADDR03, ADDR06, ADD01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.8%	99.5%	98.8%	96.9%	86.1%
Effective Sample Size	351295	292468	234245	177021	122110	72049	29010	176

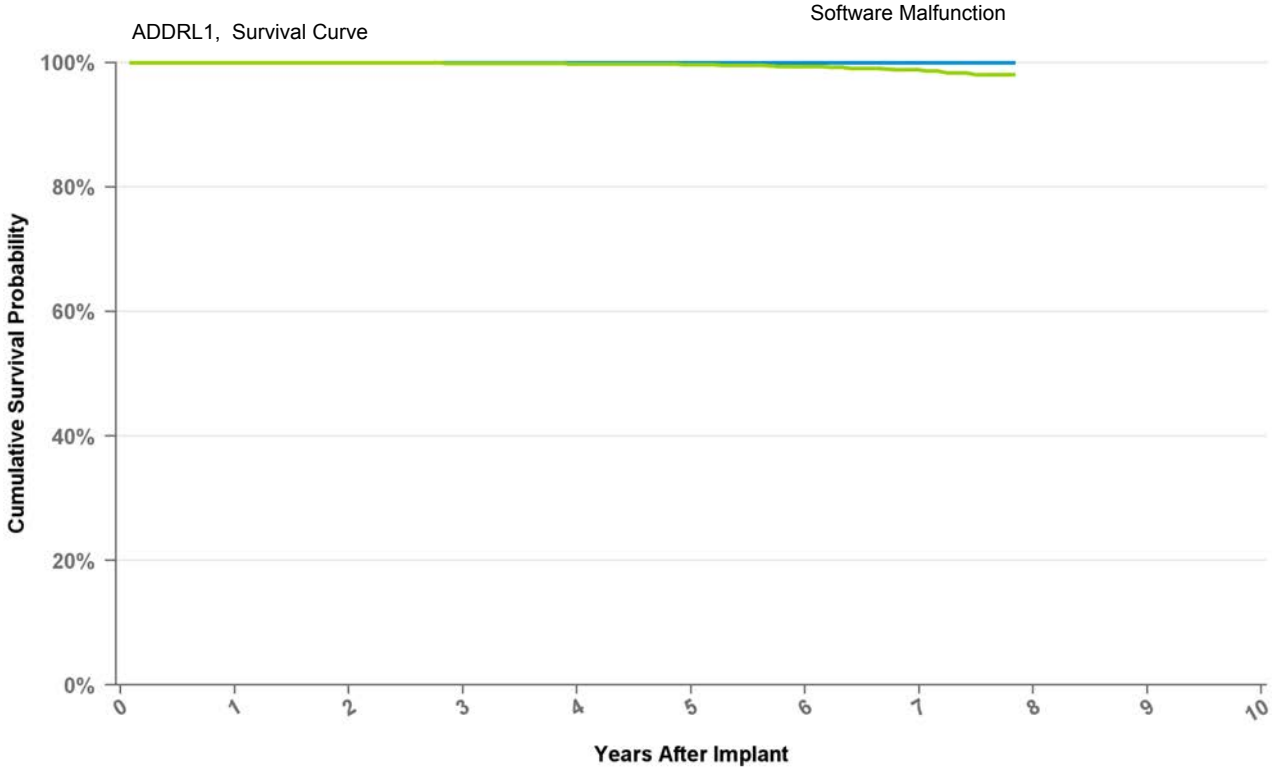
Implantable Pulse Generator

ADDRL1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	99,965
Estimated Active US Implants	89,605
Normal Battery Depletions (US)	91

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 94 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%	99.7%	99.3%	98.8%	98.0%
Effective Sample Size	83303	62731	44155	28875	16343	7636	2292	110

Implantable Pulse Generator

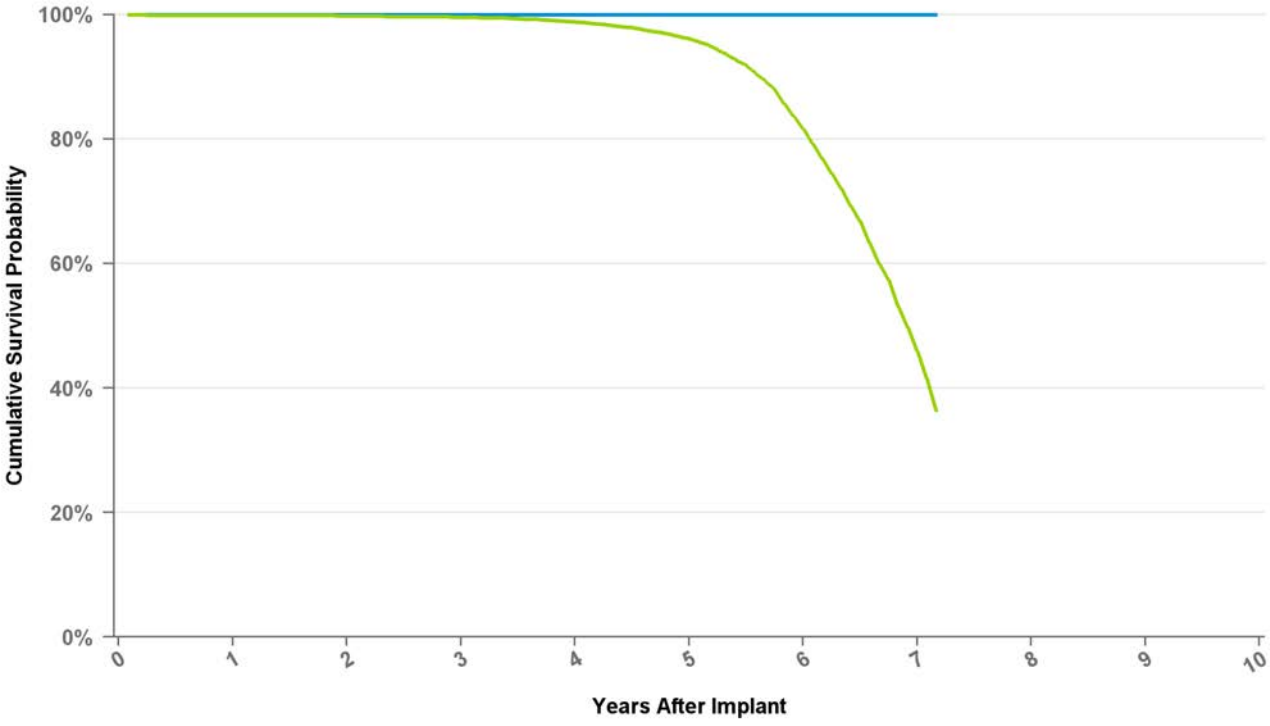
ADDRS1 Adapta DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	39,734
Estimated Active US Implants	28,506
Normal Battery Depletions (US)	1,284

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.9%	99.8%	99.6%	98.8%	96.1%	81.7%	46.0%	36.4%
Effective Sample Size	33295	26597	20257	14655	9237	4301	577	218

Implantable Pulse Generator

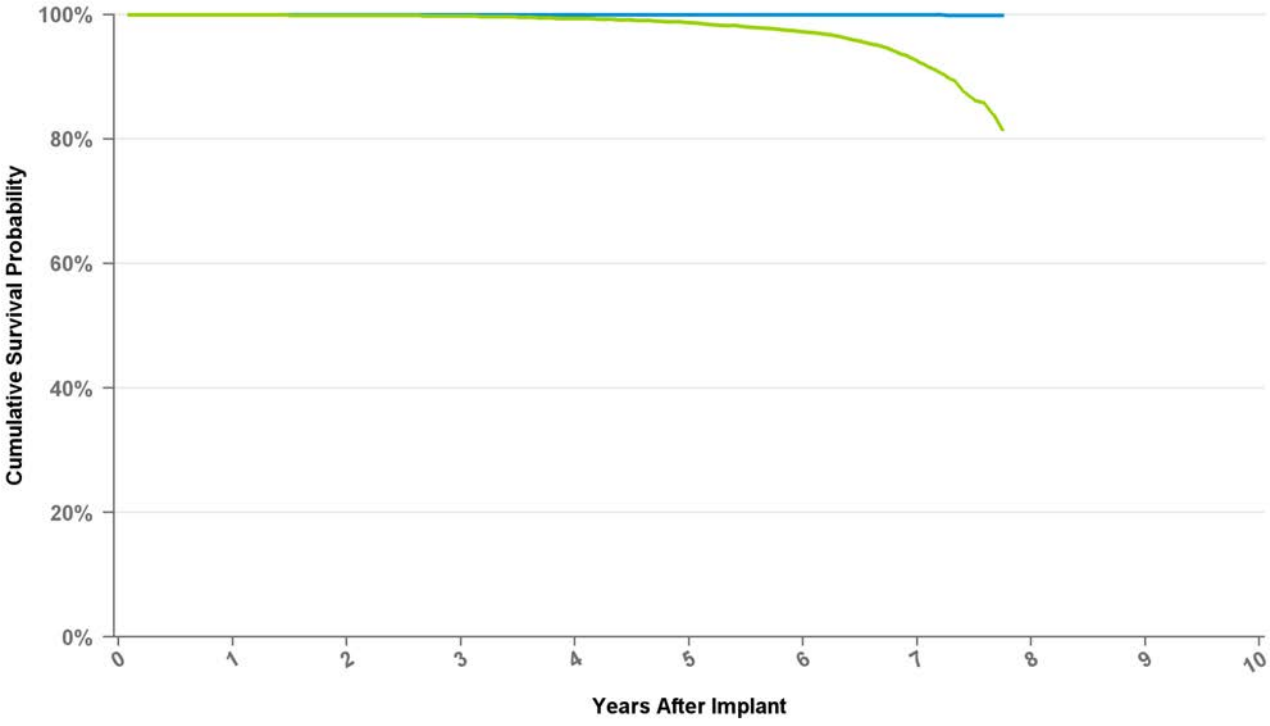
ADSR01 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	73,978
Estimated Active US Implants	52,488
Normal Battery Depletions (US)	476

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	10
Therapy Not Compromised Malfunction	6
Battery Malfunction	0
Electrical Component	4
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.7%	97.2%	92.5%	81.5%
Effective Sample Size	67340	52168	39196	28316	19119	10996	4137	309

Implantable Pulse Generator

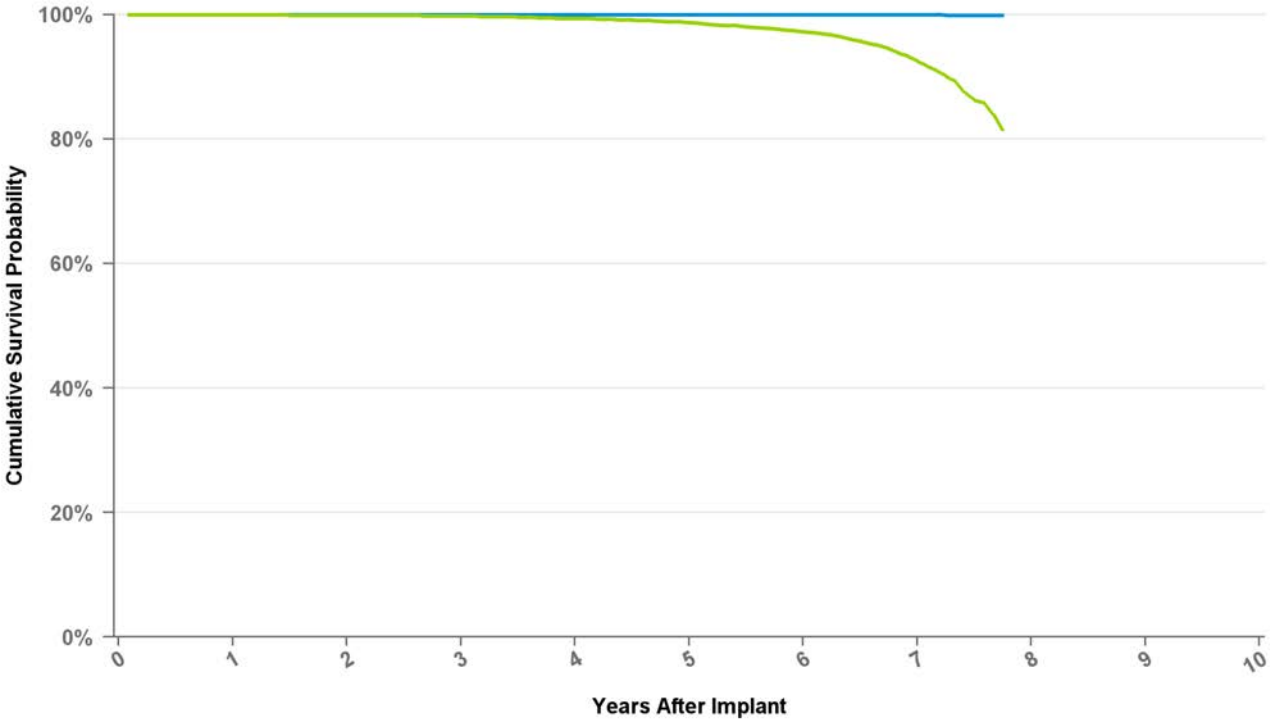
ADSR03 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1,757
Estimated Active US Implants	1,163
Normal Battery Depletions (US)	11

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.7%	97.2%	92.5%	81.5%
Effective Sample Size	67340	52168	39196	28316	19119	10996	4137	309

Implantable Pulse Generator

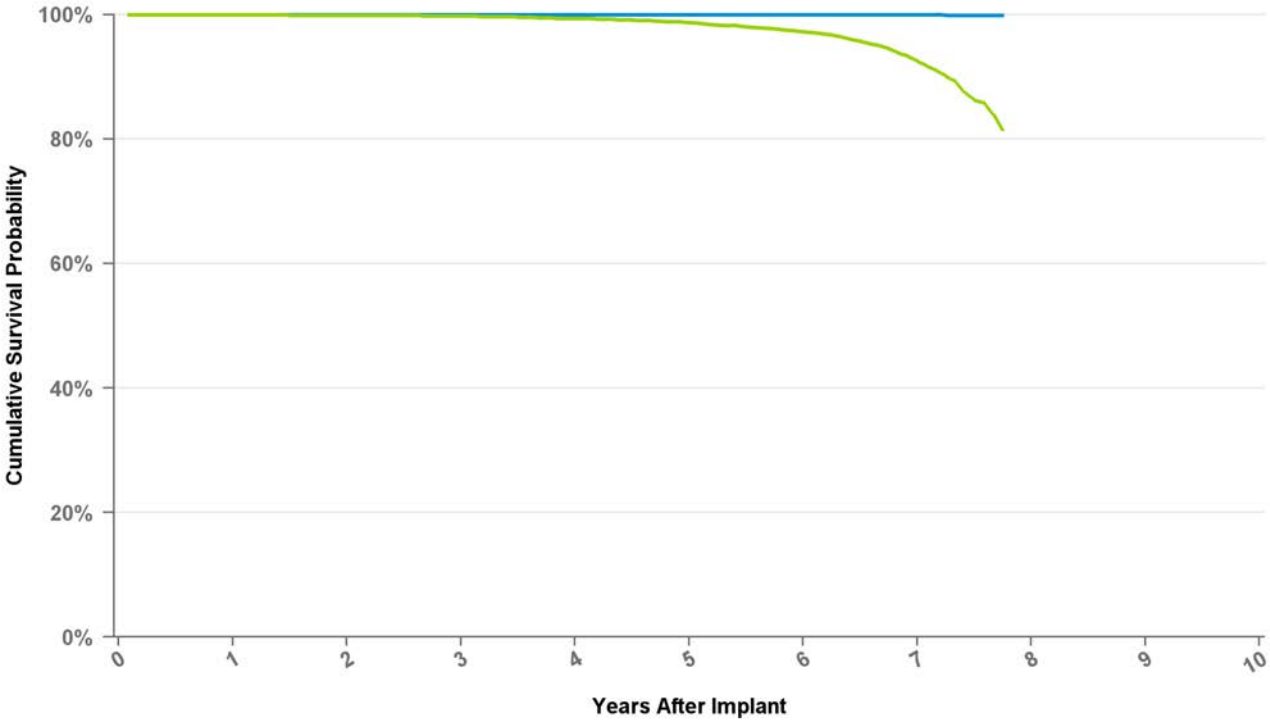
ADSR06 Adapta SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	2,398
Estimated Active US Implants	1,434
Normal Battery Depletions (US)	62

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 93 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%
Including NBD	100.0%	99.9%	99.8%	99.4%	98.7%	97.2%	92.5%	81.5%
Effective Sample Size	67340	52168	39196	28316	19119	10996	4137	309

Implantable Pulse Generator

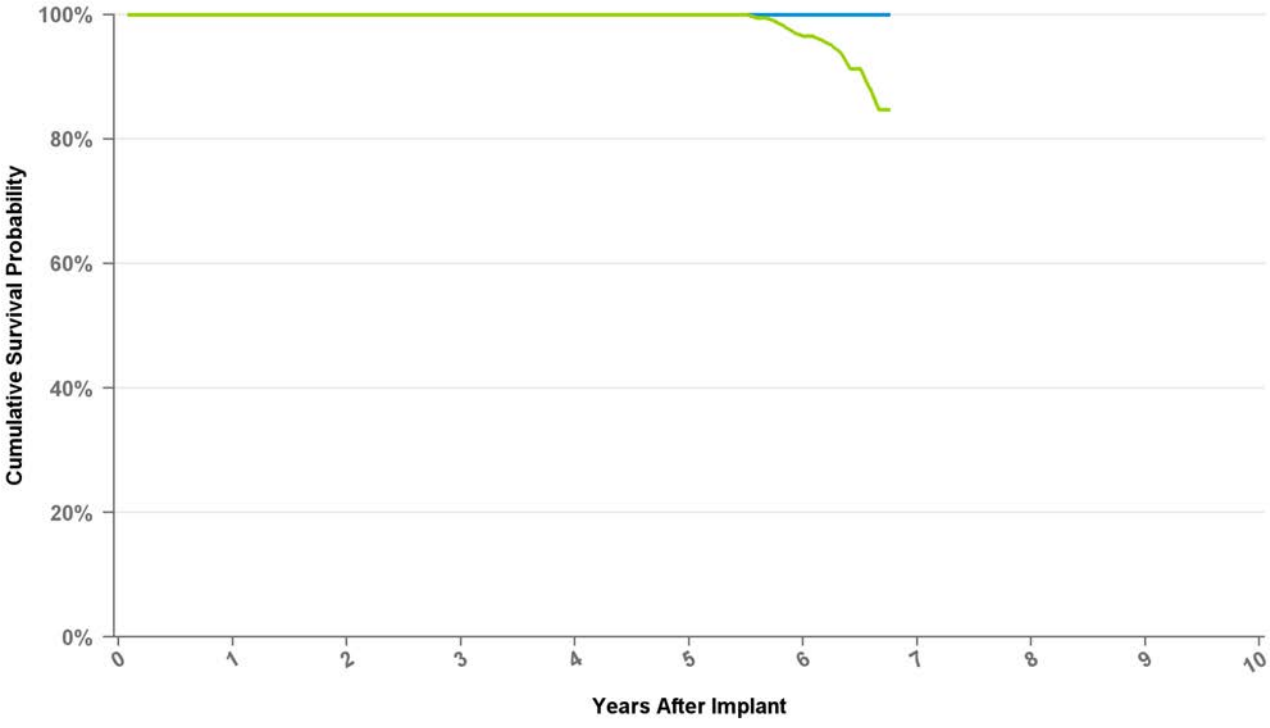
ADVDD01 Adapta VDD

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	994
Estimated Active US Implants	698
Normal Battery Depletions (US)	17

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 81 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%	96.5%	84.7%
Effective Sample Size	1315	1081	870	707	512	299	107

Implantable Pulse Generator

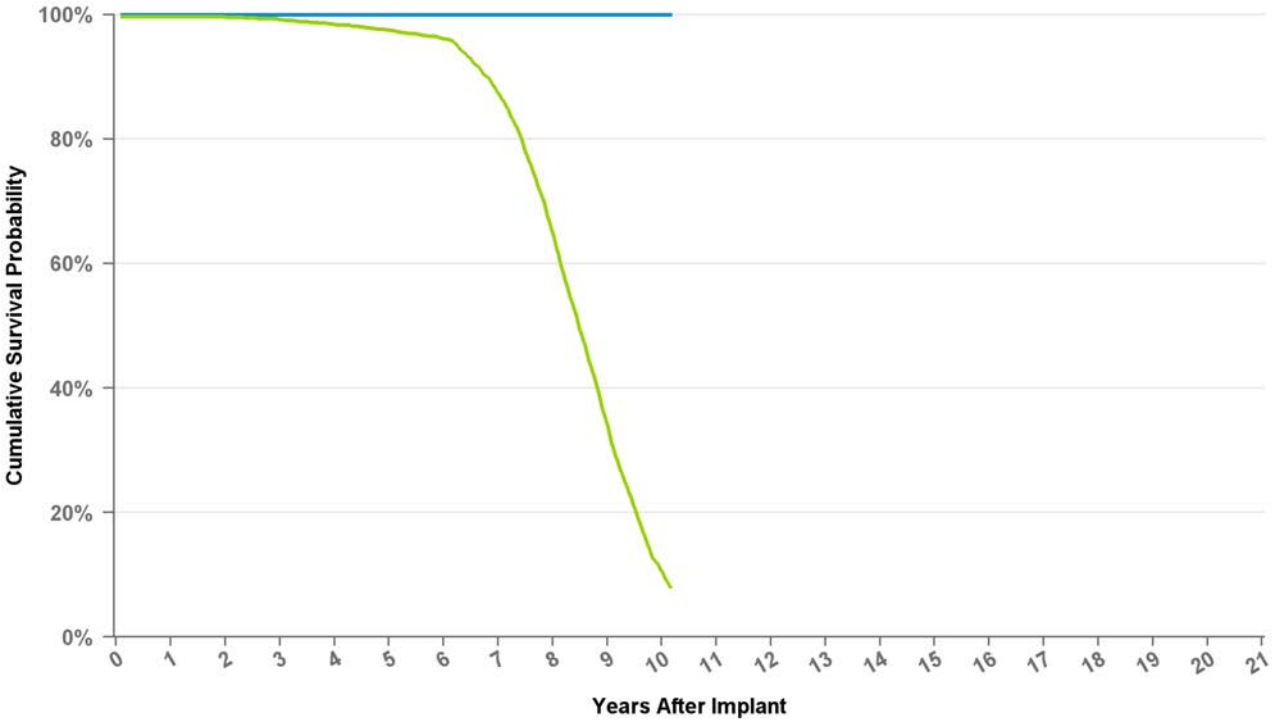
E1DR01 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	6,845
Estimated Active US Implants	808
Normal Battery Depletions (US)	1,640

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	10	at 122 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.6%	99.2%	98.4%	97.5%	96.1%	87.4%	65.0%	34.3%	10.6%	8.0%
Effective Sample Size	6212	5760	5312	4844	4415	3983	3314	2222	1025	223	138

Implantable Pulse Generator

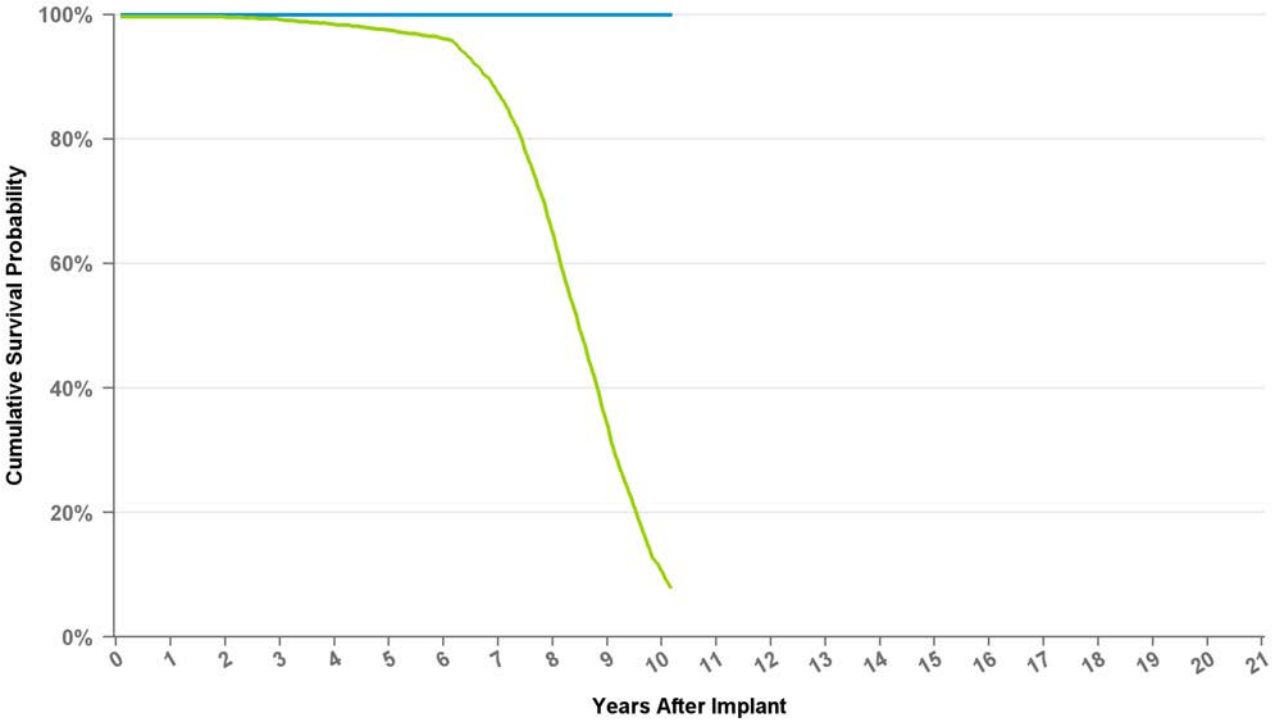
E1DR03 EnPulse DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 122 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.6%	99.2%	98.4%	97.5%	96.1%	87.4%	65.0%	34.3%	10.6%	8.0%
Effective Sample Size	6212	5760	5312	4844	4415	3983	3314	2222	1025	223	138

Implantable Pulse Generator

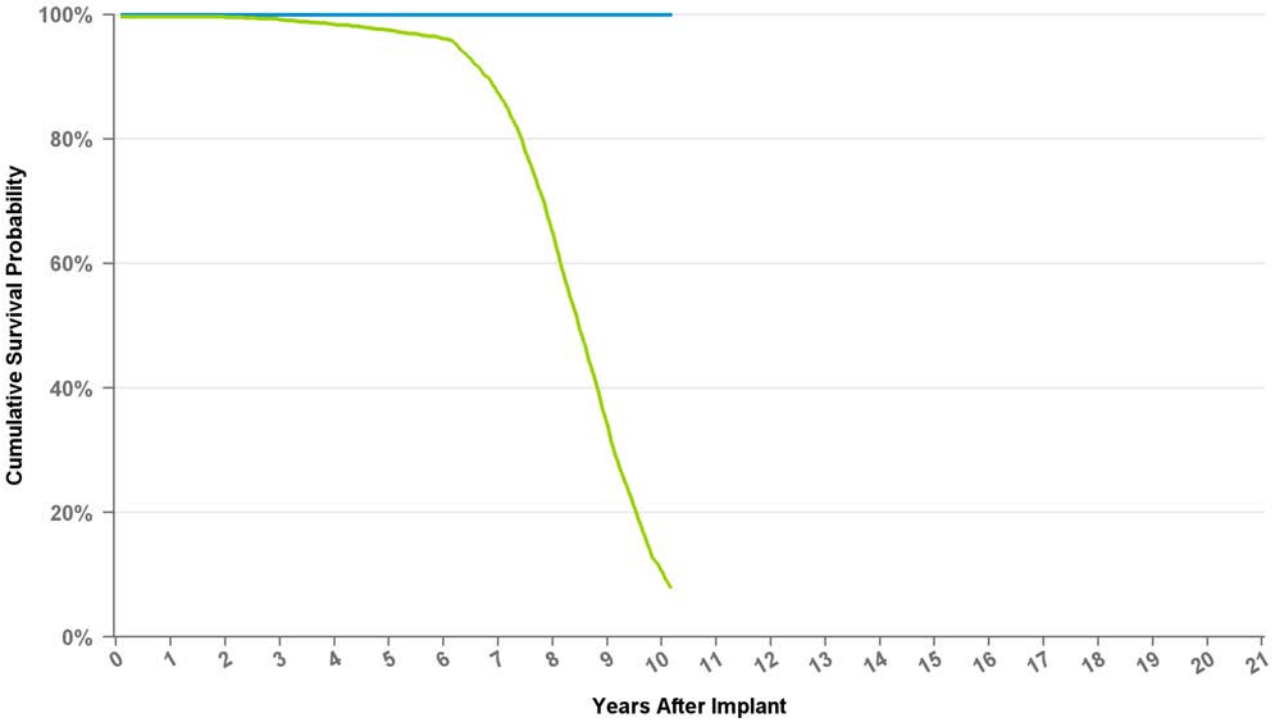
E1DR06 EnPulse DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 122 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.7%	99.6%	99.2%	98.4%	97.5%	96.1%	87.4%	65.0%	34.3%	10.6%	8.0%
Effective Sample Size	6212	5760	5312	4844	4415	3983	3314	2222	1025	223	138

Implantable Pulse Generator

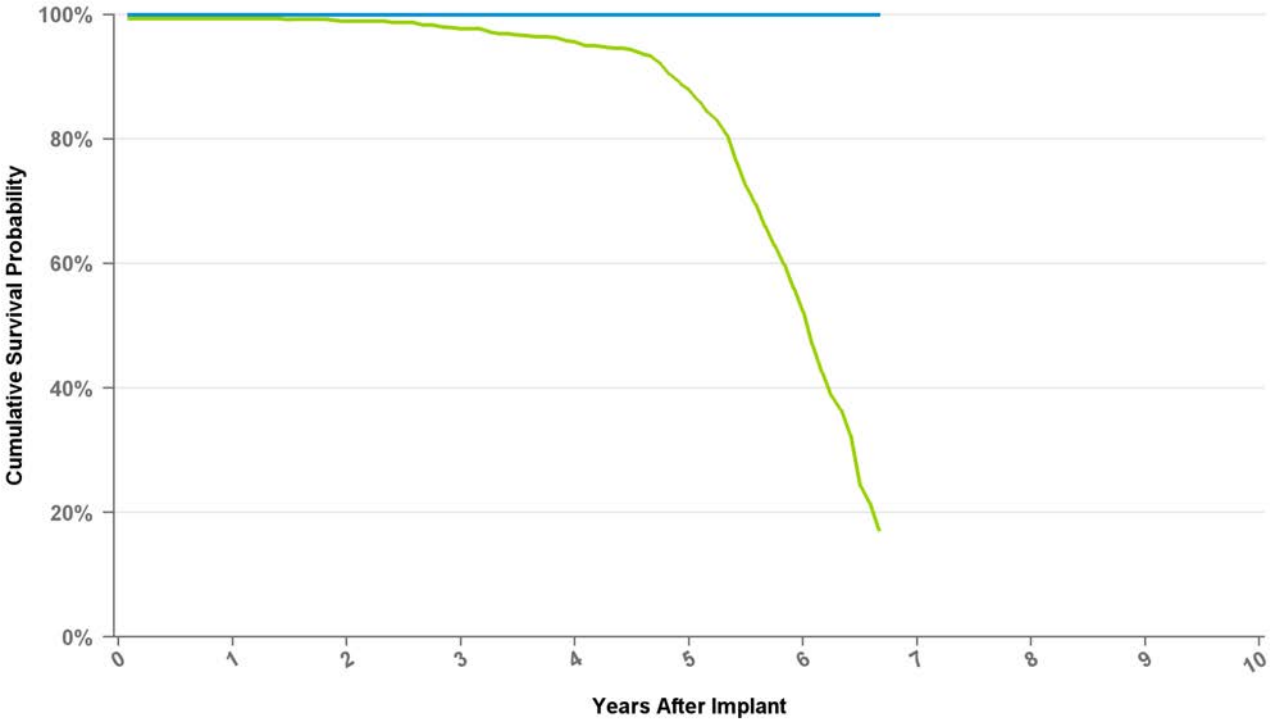
E1DR21 EnPulse DR

US Market Release Date	12/18/2003
CE Market Approval Date	
Registered US Implants	1,856
Estimated Active US Implants	144
Normal Battery Depletions (US)	376

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.3%	98.9%	97.7%	95.6%	87.8%	52.3%	17.2%
Effective Sample Size	1629	1477	1319	1157	947	451	119

Implantable Pulse Generator

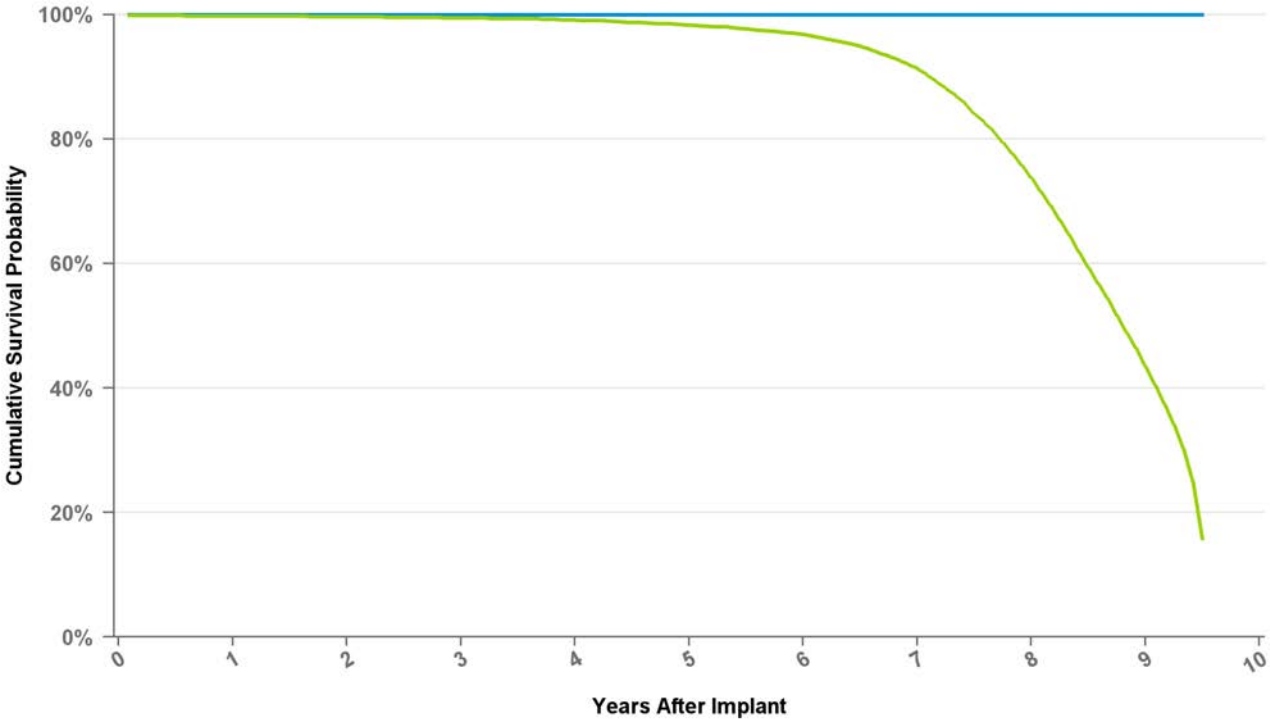
E2D01 EnPulse 2

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	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	99.8%	99.7%	99.5%	99.1%	98.3%	96.8%	91.3%	73.8%	43.5%	15.8%
Effective Sample Size	94823	87640	80591	73942	67438	61244	54093	37924	9306	573

Implantable Pulse Generator

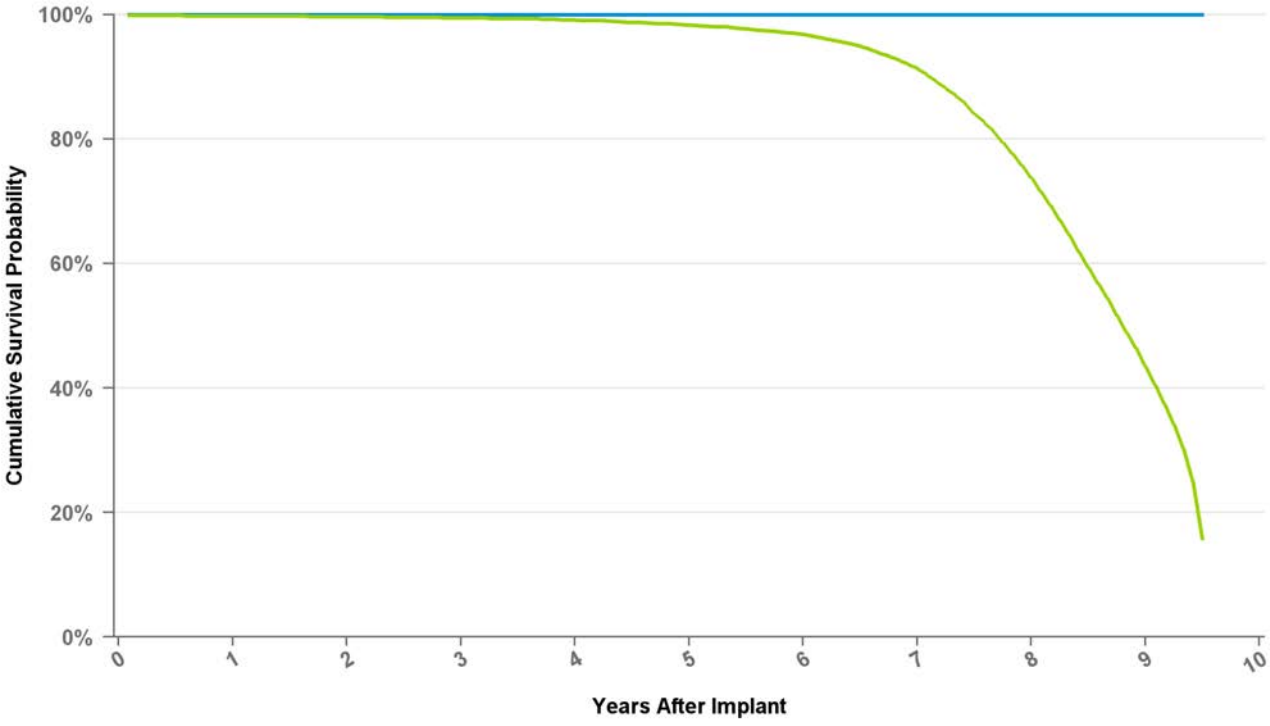
E2D03 EnPulse 2

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.8%	99.7%	99.5%	99.1%	98.3%	96.8%	91.3%	73.8%	43.5%	15.8%
Effective Sample Size	94823	87640	80591	73942	67438	61244	54093	37924	9306	573

Implantable Pulse Generator

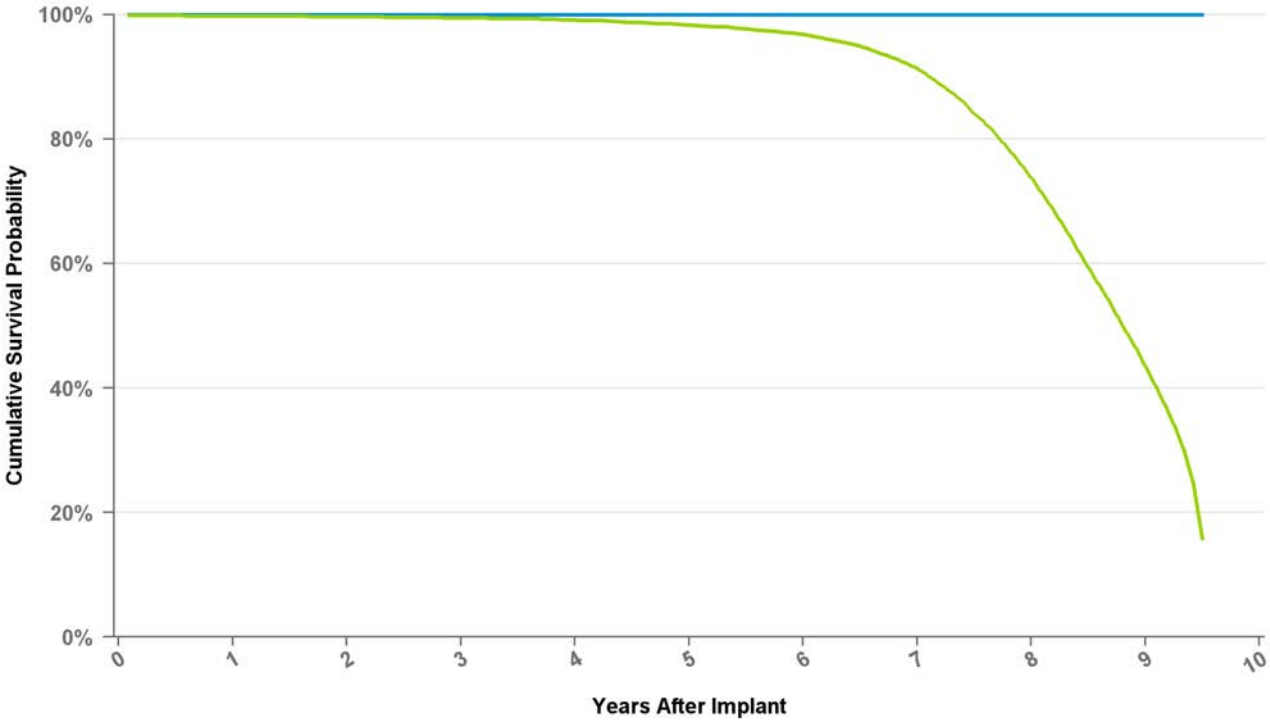
E2DR01 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	97,065
Estimated Active US Implants	27,556
Normal Battery Depletions (US)	14,617

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.8%	99.7%	99.5%	99.1%	98.3%	96.8%	91.3%	73.8%	43.5%	15.8%
Effective Sample Size	94823	87640	80591	73942	67438	61244	54093	37924	9306	573

Implantable Pulse Generator

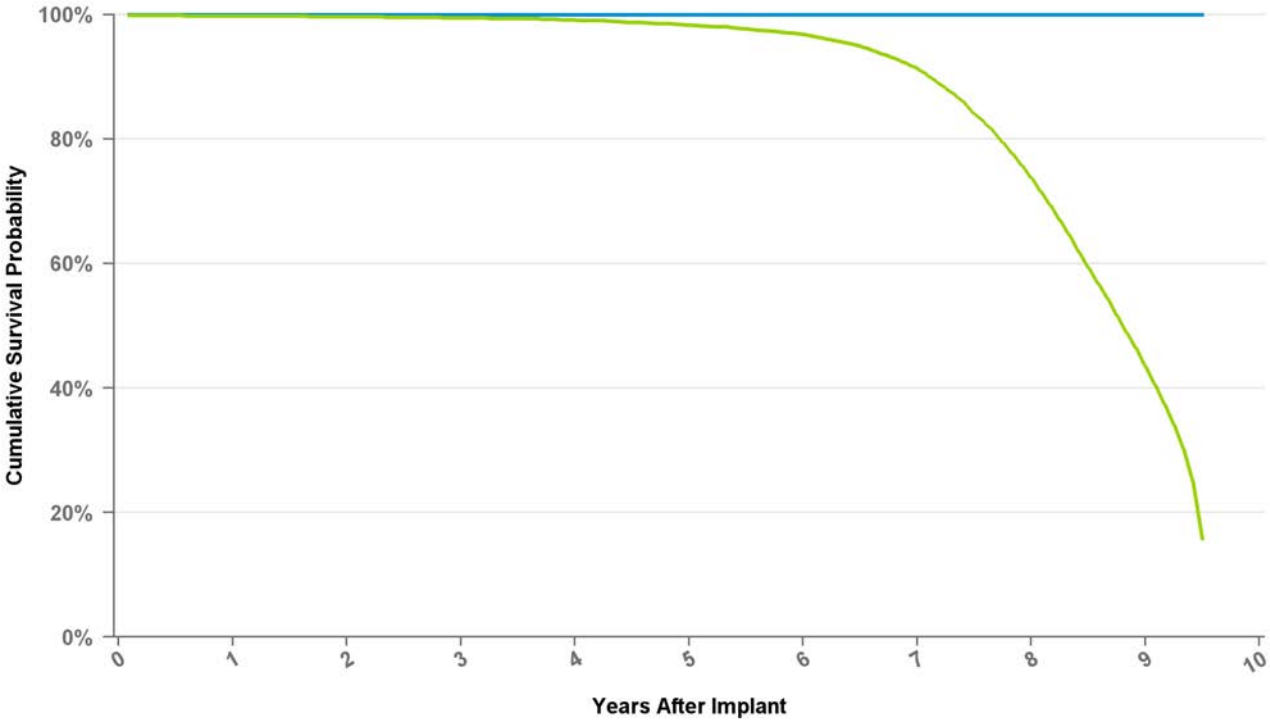
E2DR03 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	2,047
Estimated Active US Implants	619
Normal Battery Depletions (US)	304

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.8%	99.7%	99.5%	99.1%	98.3%	96.8%	91.3%	73.8%	43.5%	15.8%
Effective Sample Size	94823	87640	80591	73942	67438	61244	54093	37924	9306	573

Implantable Pulse Generator

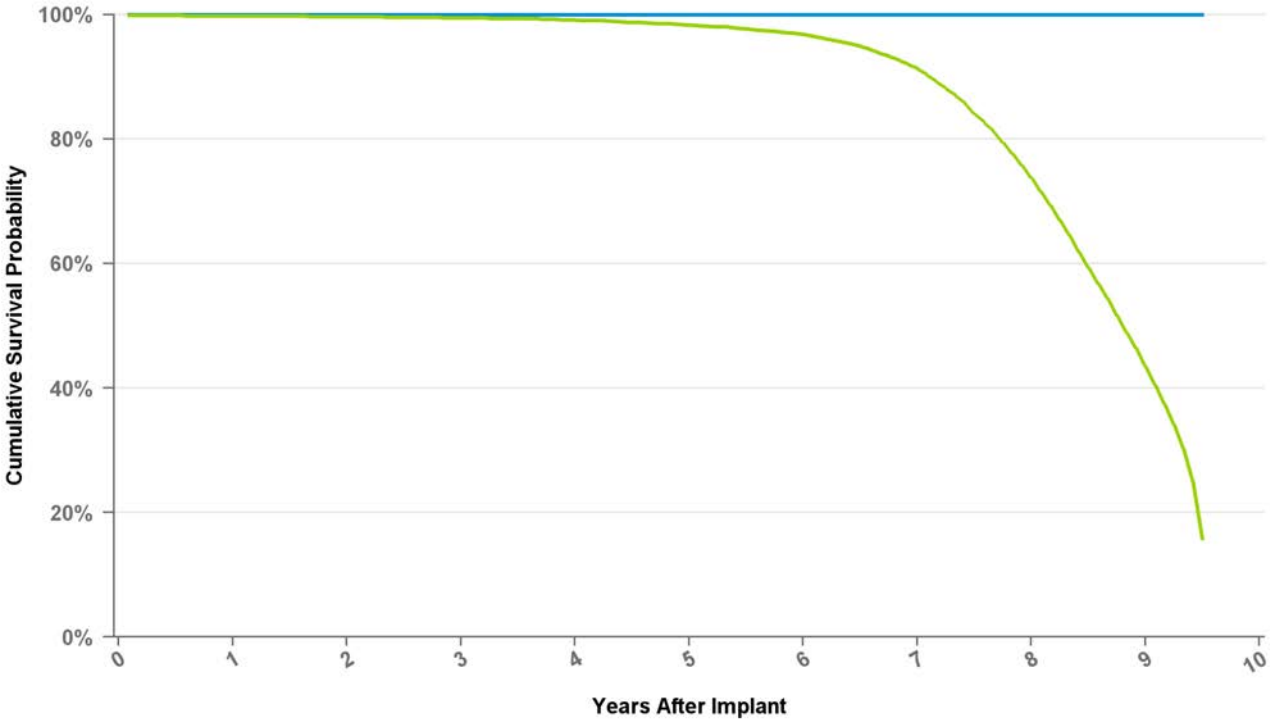
E2DR06 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	1,626
Estimated Active US Implants	350
Normal Battery Depletions (US)	244

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.8%	99.7%	99.5%	99.1%	98.3%	96.8%	91.3%	73.8%	43.5%	15.8%
Effective Sample Size	94823	87640	80591	73942	67438	61244	54093	37924	9306	573

Implantable Pulse Generator

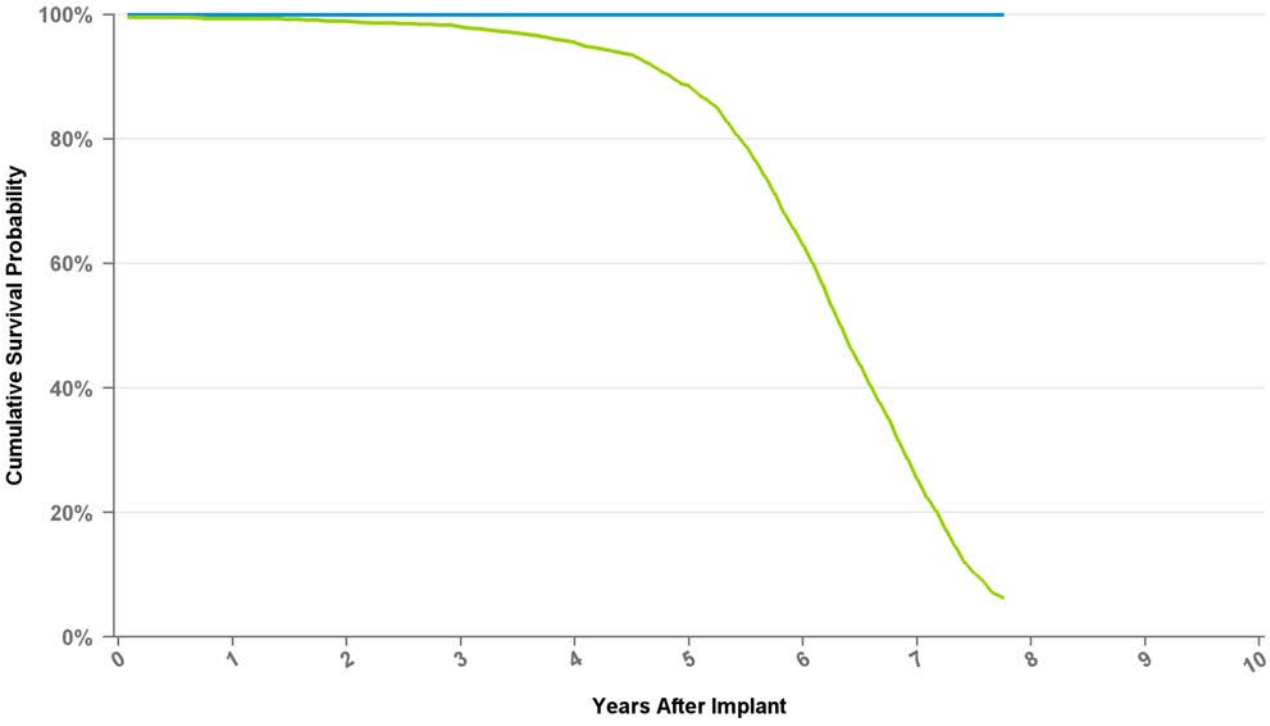
E2DR21 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	12,199
Estimated Active US Implants	1,594
Normal Battery Depletions (US)	2,263

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 93 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.4%	98.9%	98.0%	95.5%	88.5%	63.0%	25.4%	6.3%
Effective Sample Size	10836	9714	8726	7612	6296	3858	1184	136

Implantable Pulse Generator

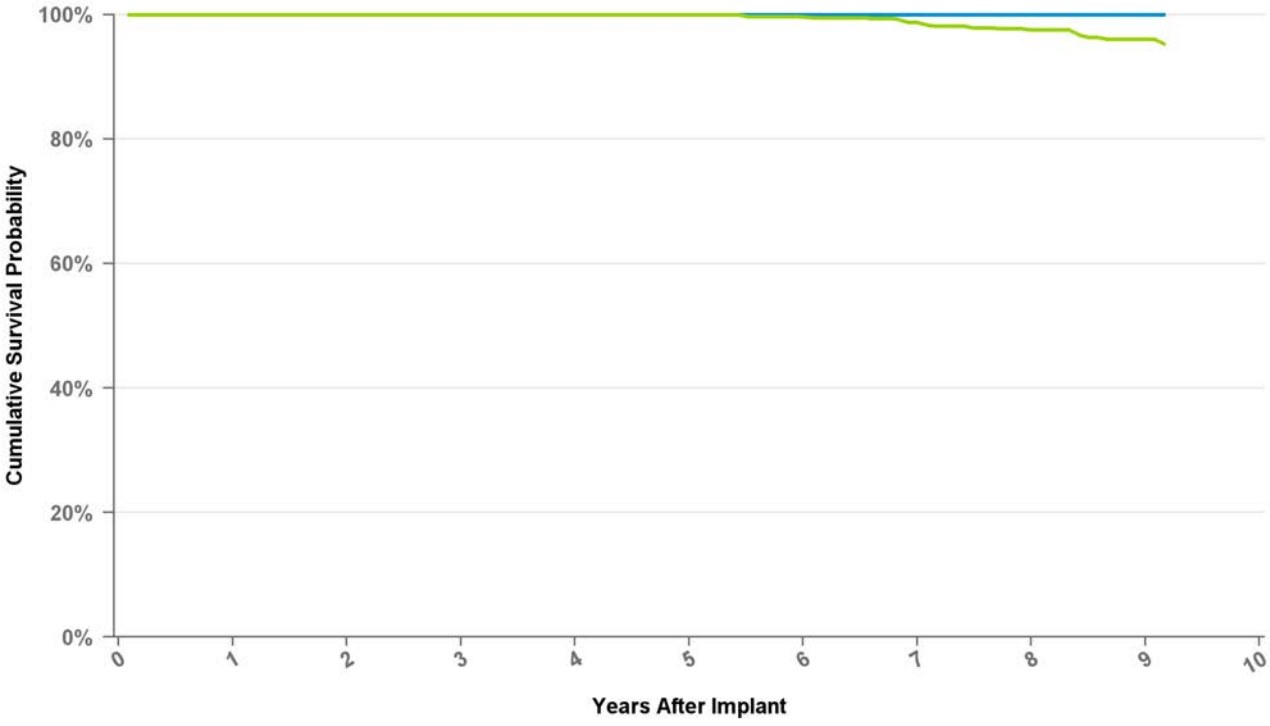
E2DR31 EnPulse 2 DR

US Market Release Date	2/20/2004
CE Market Approval Date	9/8/2003
Registered US Implants	587
Estimated Active US Implants	368
Normal Battery Depletions (US)	20

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.6%	98.7%	97.5%	96.0%	95.2%
Effective Sample Size	1354	1276	1203	1129	1059	973	897	744	218	123

Implantable Pulse Generator

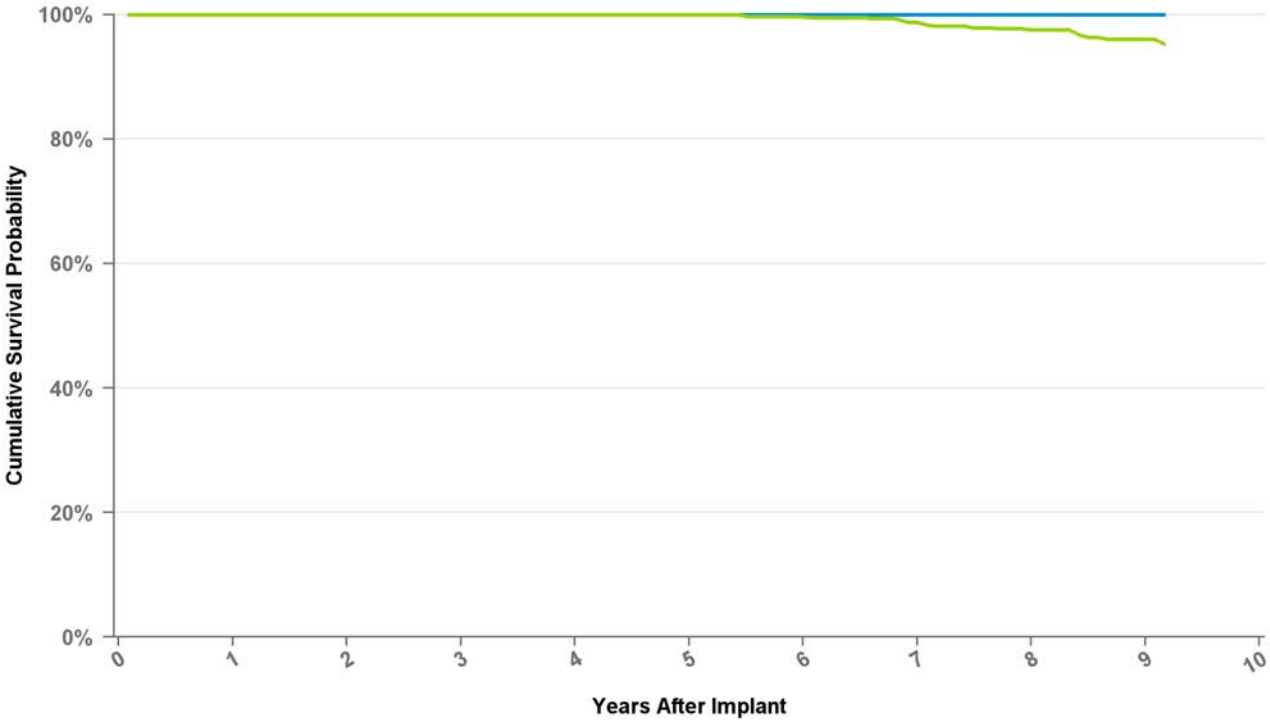
E2DR33 EnPulse 2 DR

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)	1

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.6%	98.7%	97.5%	96.0%	95.2%
Effective Sample Size	1354	1276	1203	1129	1059	973	897	744	218	123

Implantable Pulse Generator

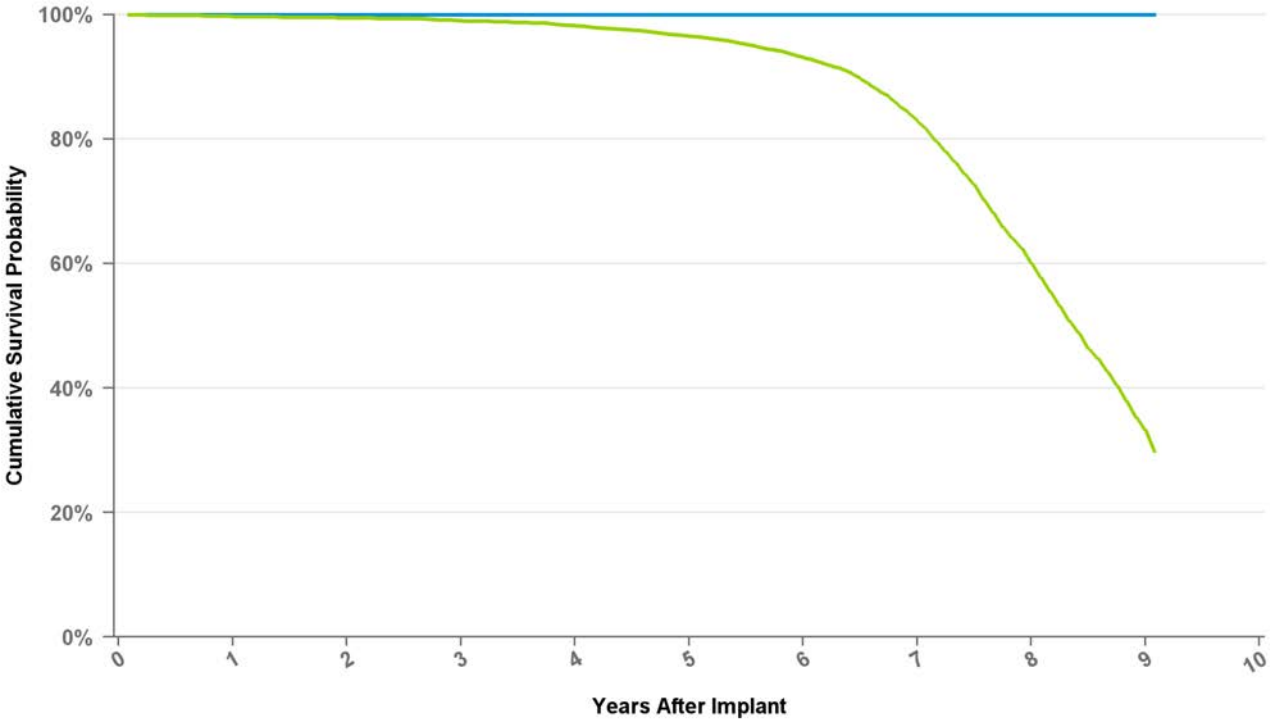
E2SR01 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	22,523
Estimated Active US Implants	4,114
Normal Battery Depletions (US)	2,392

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	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	99.7%	99.5%	99.0%	98.2%	96.5%	93.1%	82.9%	60.1%	33.3%	29.8%
Effective Sample Size	22598	19612	17119	14981	12867	11056	8954	5039	413	214

Implantable Pulse Generator

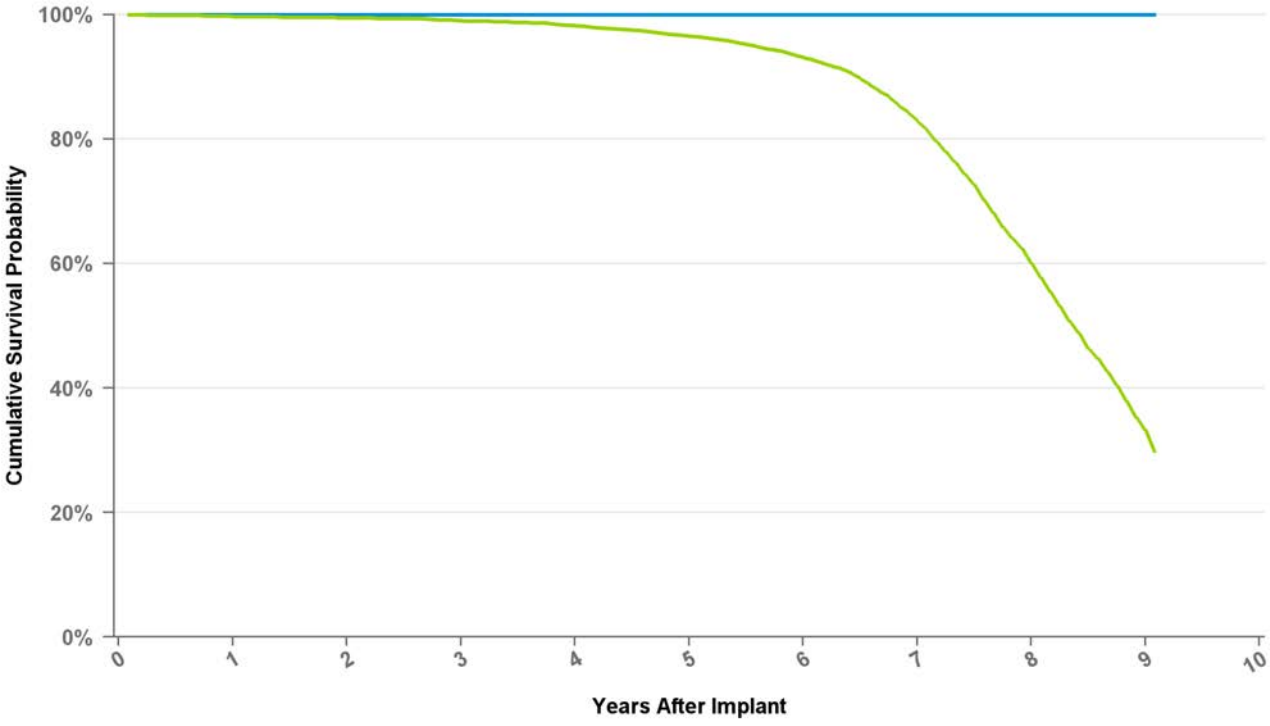
E2SR03 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,098
Estimated Active US Implants	215
Normal Battery Depletions (US)	110

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.7%	99.5%	99.0%	98.2%	96.5%	93.1%	82.9%	60.1%	33.3%	29.8%
Effective Sample Size	22598	19612	17119	14981	12867	11056	8954	5039	413	214

Implantable Pulse Generator

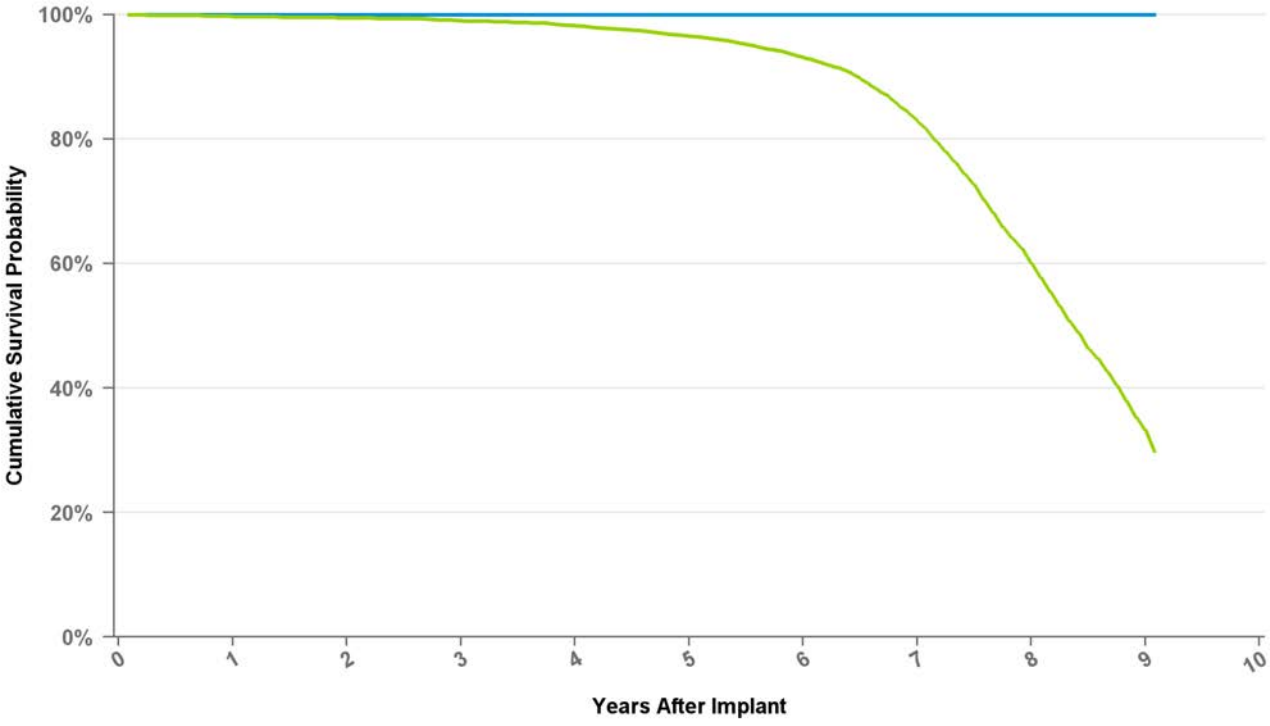
E2SR06 EnPulse 2 SR

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	1,749
Estimated Active US Implants	315
Normal Battery Depletions (US)	161

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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	99.7%	99.5%	99.0%	98.2%	96.5%	93.1%	82.9%	60.1%	33.3%	29.8%
Effective Sample Size	22598	19612	17119	14981	12867	11056	8954	5039	413	214

Implantable Pulse Generator

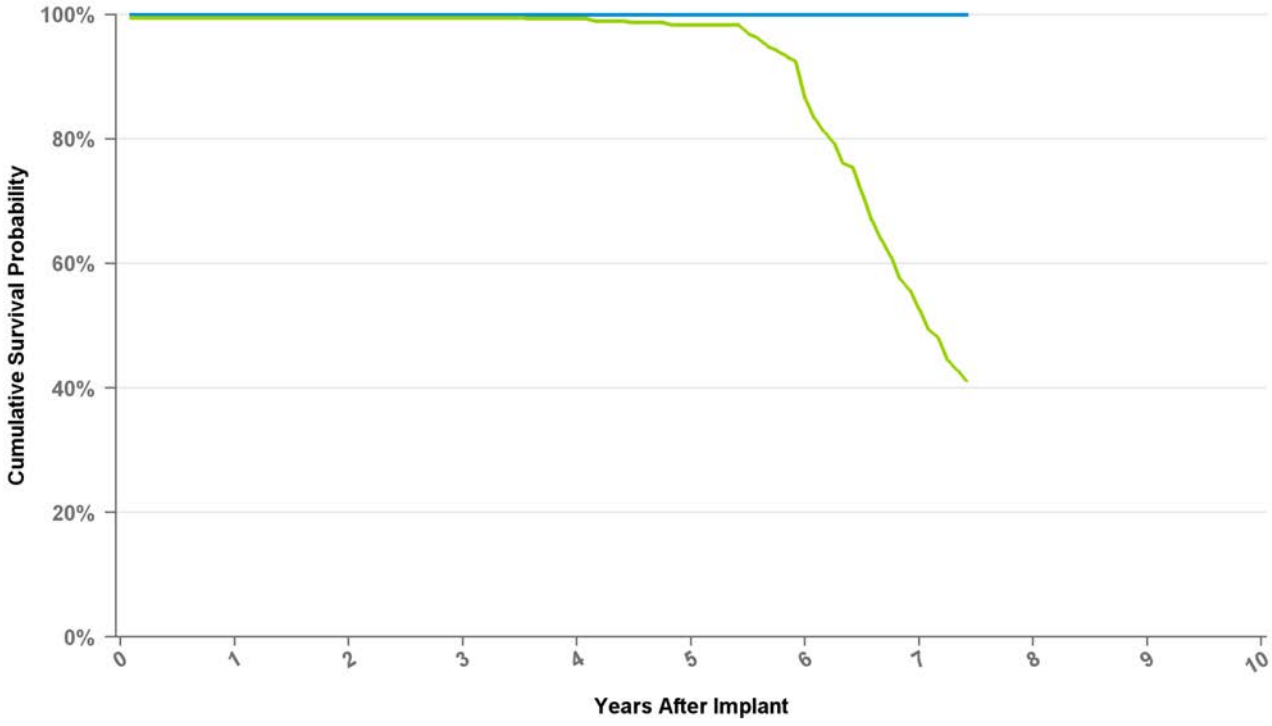
E2VDD01 EnPulse 2 VDD

US Market Release Date	12/18/2003
CE Market Approval Date	9/8/2003
Registered US Implants	556
Estimated Active US Implants	92
Normal Battery Depletions (US)	92

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 89 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.5%	99.5%	99.5%	99.3%	98.3%	86.5%	52.7%	41.2%
Effective Sample Size	705	649	595	543	489	406	179	100

Implantable Pulse Generator

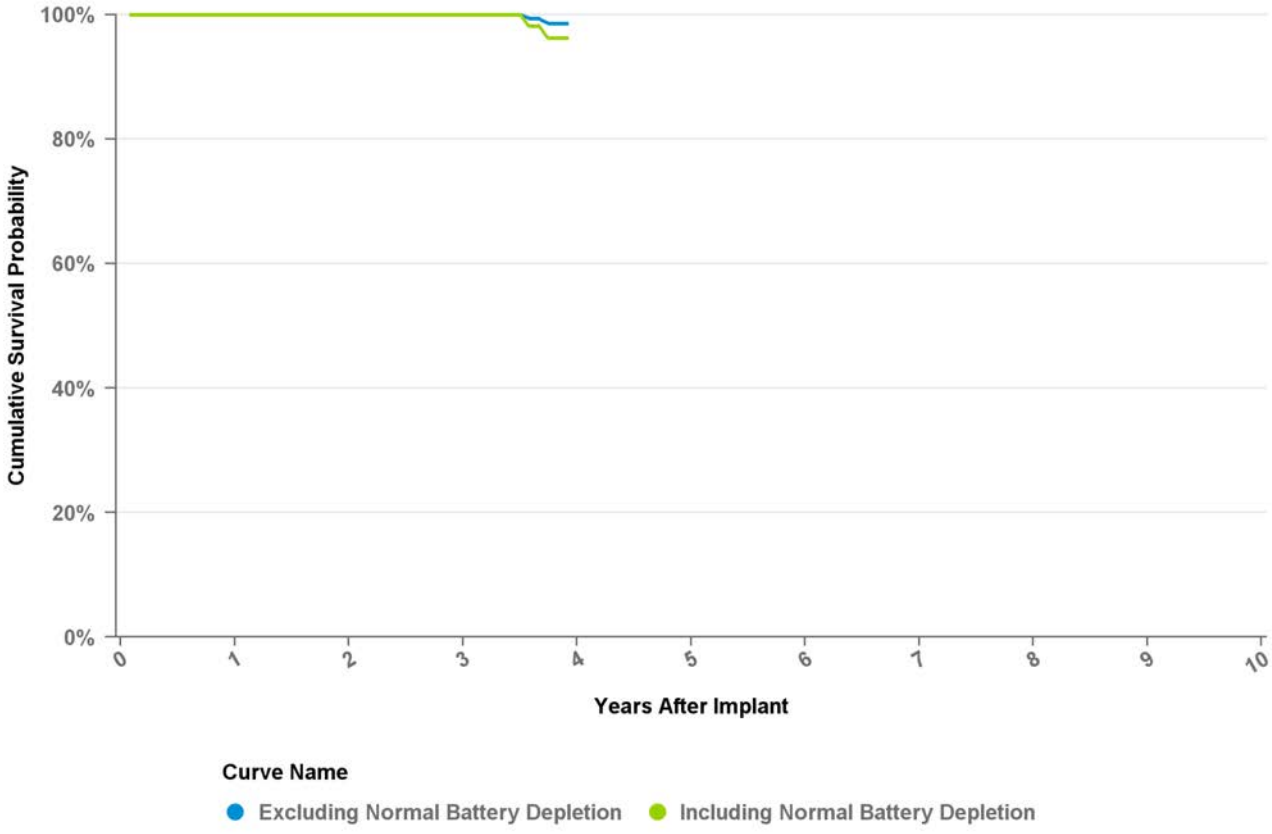
EMDR01 EnRhythm MRI

US Market Release Date	
CE Market Approval Date	9/30/2008
Registered US Implants	111
Estimated Active US Implants	64
Normal Battery Depletions (US)	3

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	14
Therapy Not Compromised Malfunction	14
Battery Malfunction	14
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	at 47 mo
Excluding NBD	100.0%	100.0%	100.0%	98.5%
Including NBD	100.0%	100.0%	100.0%	96.2%
Effective Sample Size	145	132	118	100

Implantable Pulse Generator

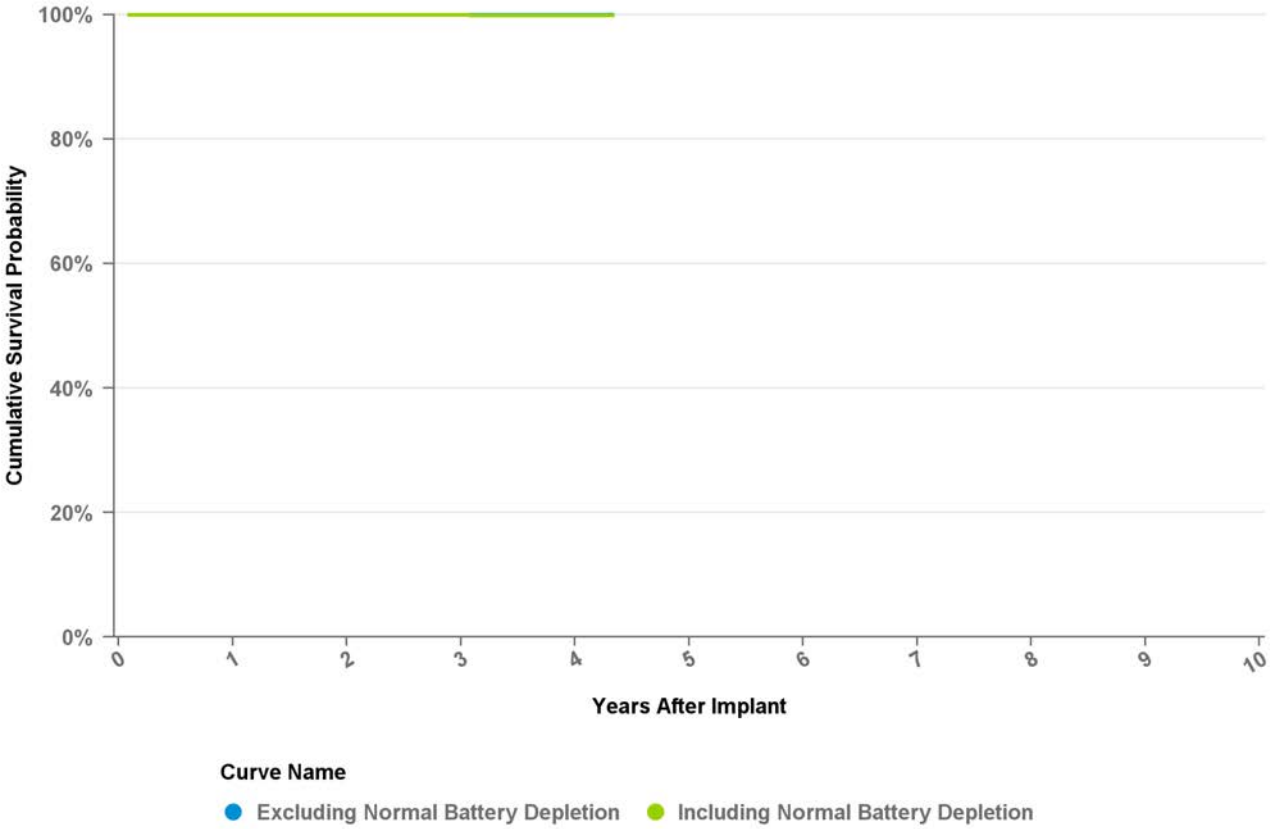
EN1DR01 Ensura MRI

US Market Release Date	
CE Market Approval Date	6/23/2010
Registered US Implants	3
Estimated Active US Implants	3
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	4	at 52 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	23917	9397	4744	1227	219

Implantable Pulse Generator

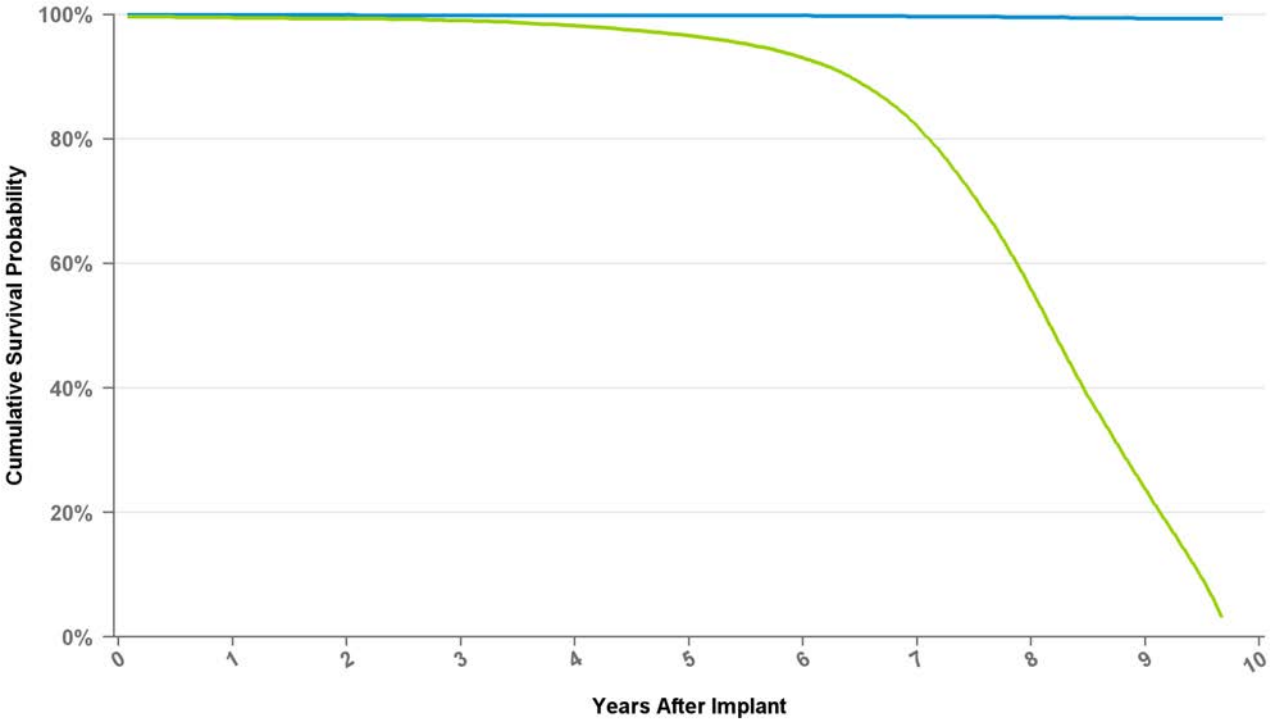
KD700 Kappa 700 DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 116 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	99.5%	99.4%	99.0%	98.2%	96.6%	93.0%	82.0%	55.8%	23.8%	3.4%
Effective Sample Size	180086	165059	150466	135831	121509	105917	83642	48032	14051	1419

Implantable Pulse Generator

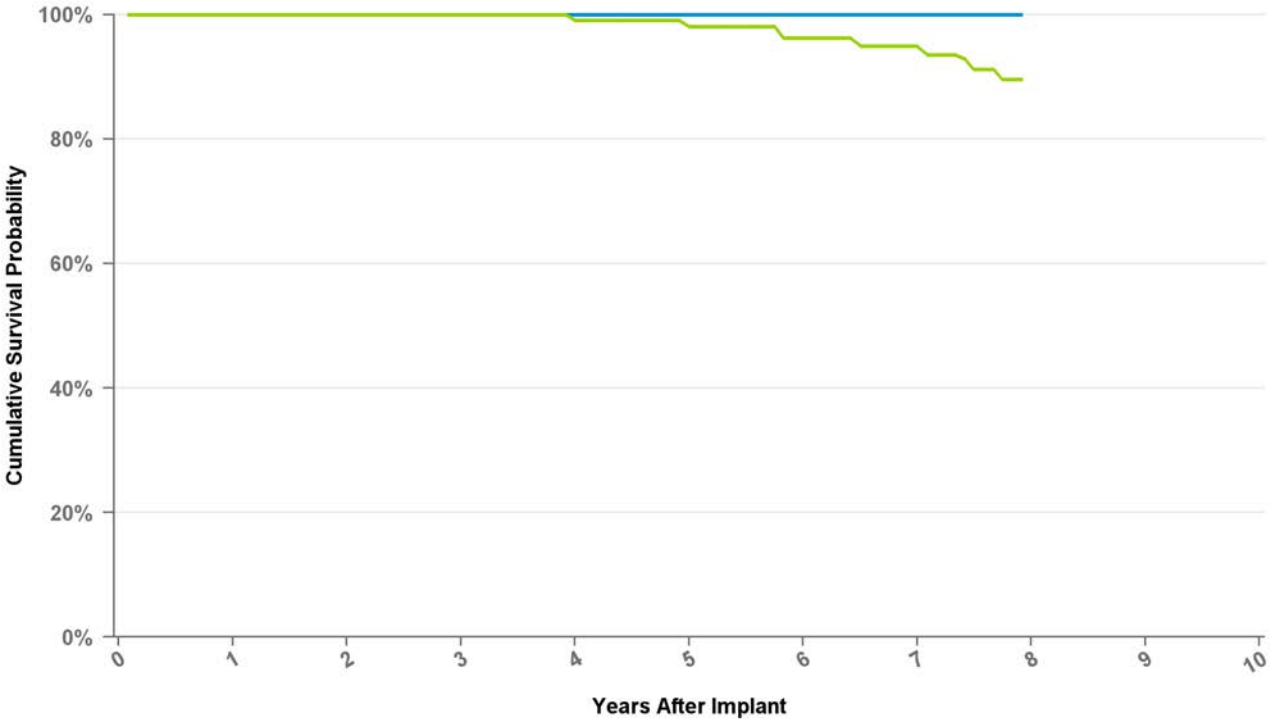
KD701 Kappa 700 DR

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	at 95 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%	99.0%	98.0%	96.2%	94.9%	89.6%
Effective Sample Size	289	260	229	206	186	161	136	100

Implantable Pulse Generator

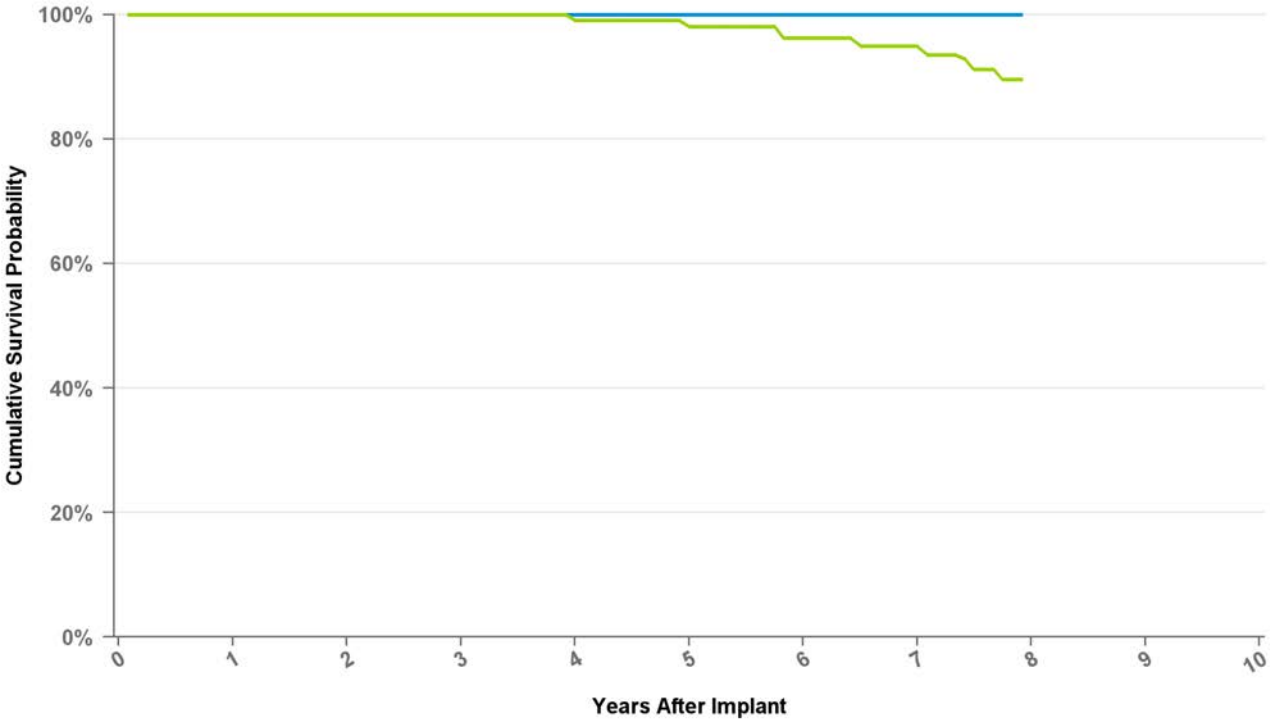
KD703 Kappa 700 DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.0%	98.0%	96.2%	94.9%	89.6%
Effective Sample Size	289	260	229	206	186	161	136	100

Implantable Pulse Generator

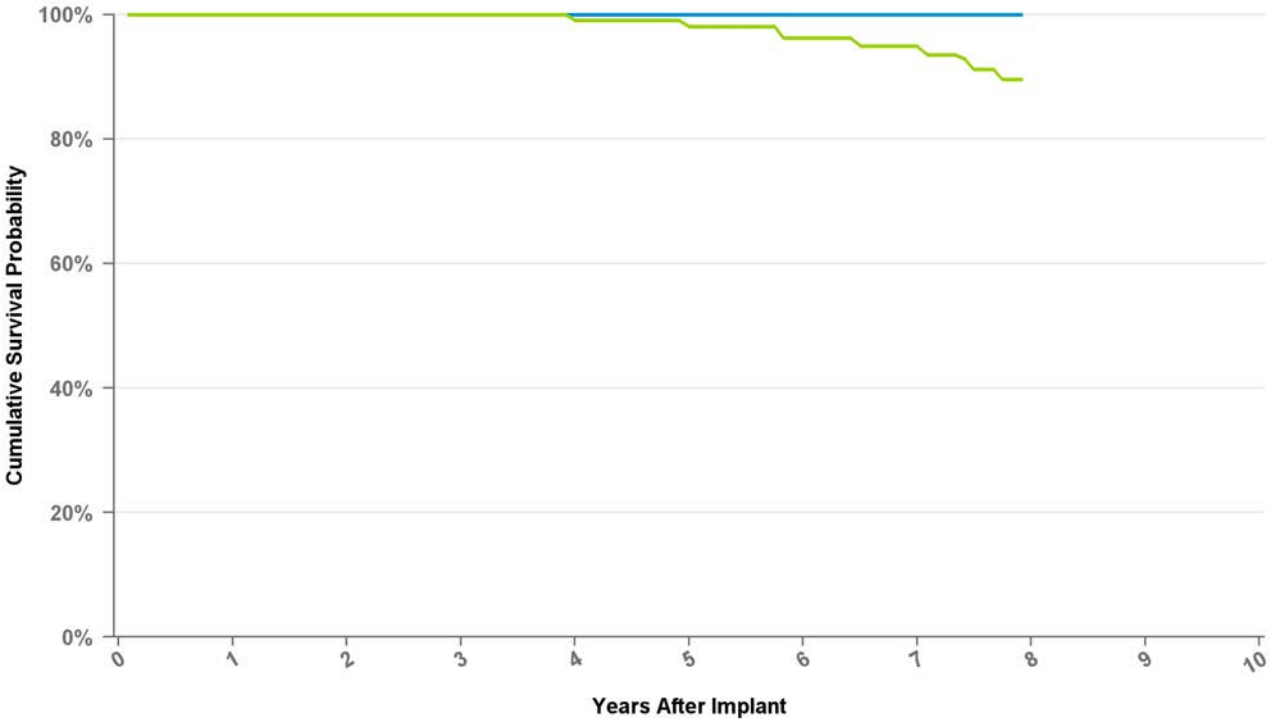
KD706 Kappa 700 DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 95 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%	99.0%	98.0%	96.2%	94.9%	89.6%
Effective Sample Size	289	260	229	206	186	161	136	100

Implantable Pulse Generator

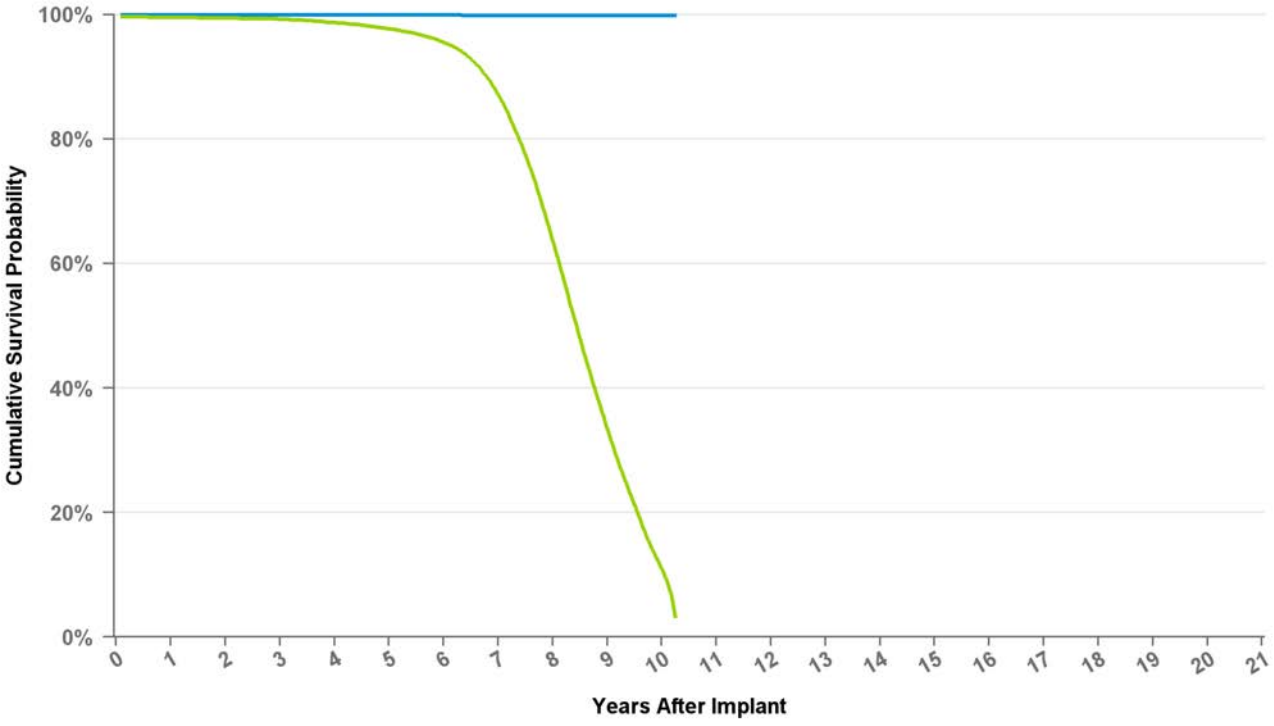
KD901 Kappa 900 D

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	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

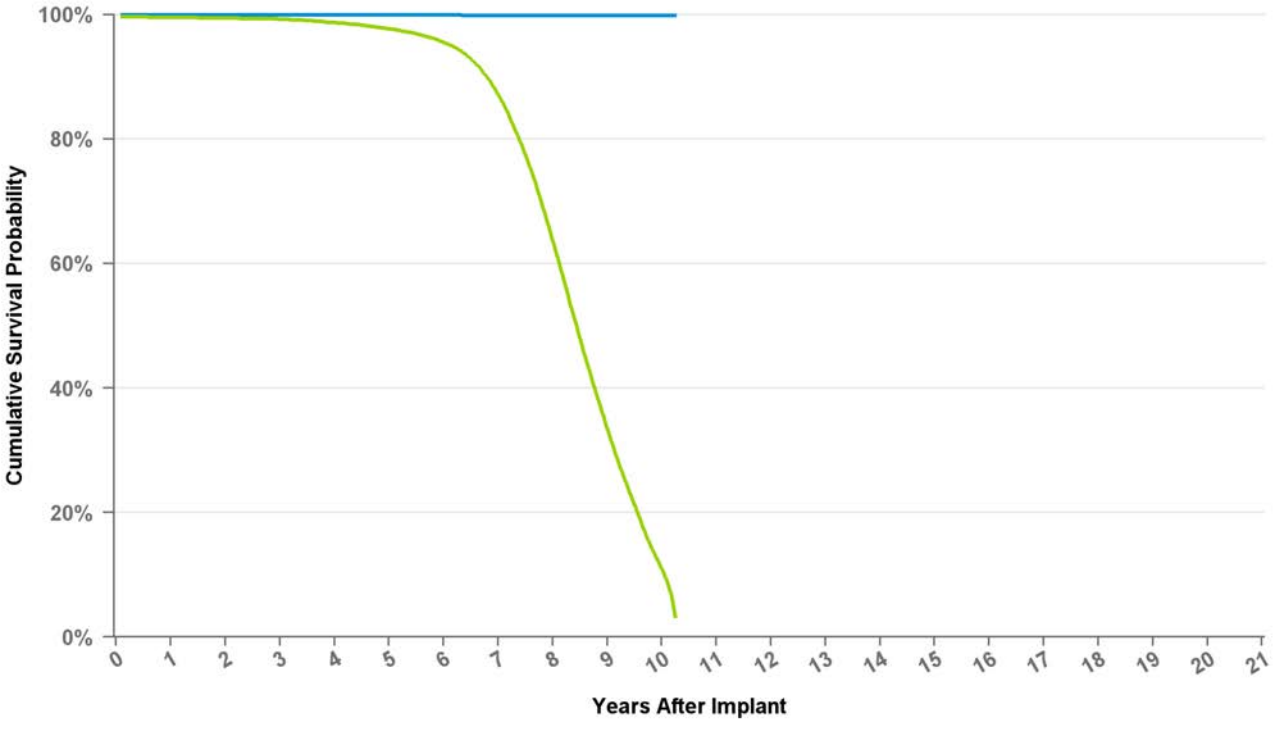
KD903 Kappa 900 D

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	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

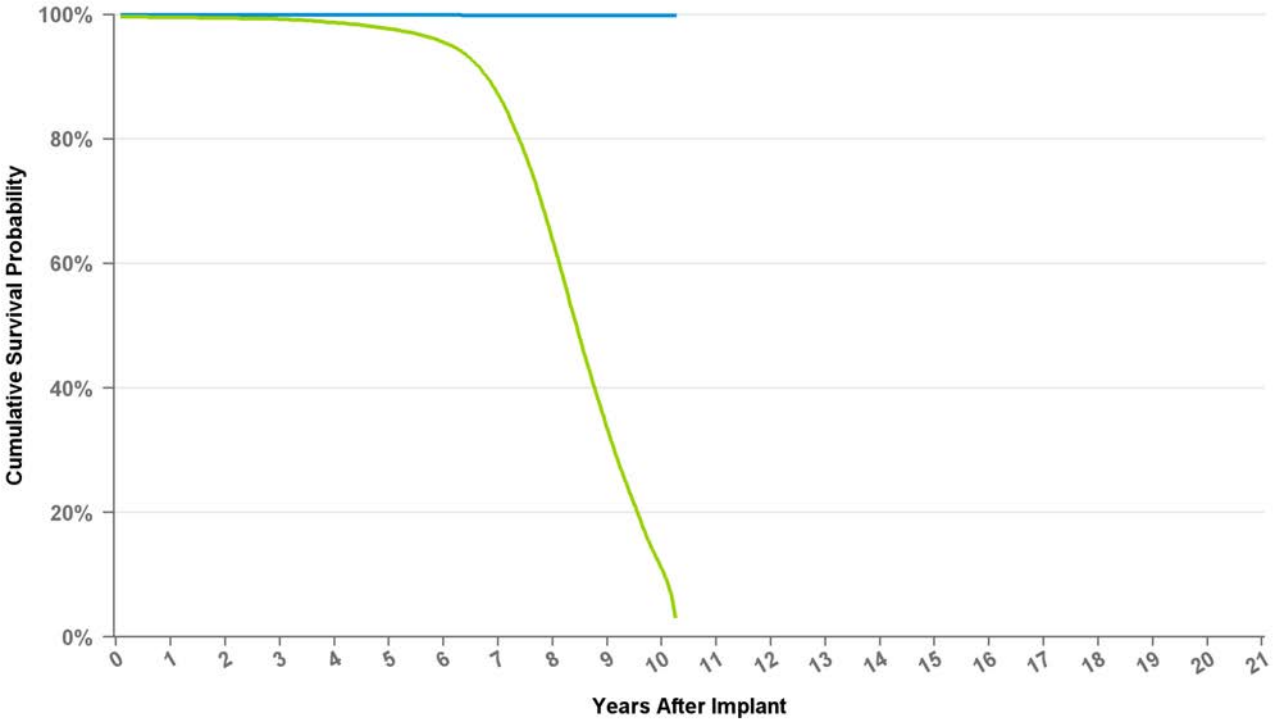
KD906 Kappa 900 D

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	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

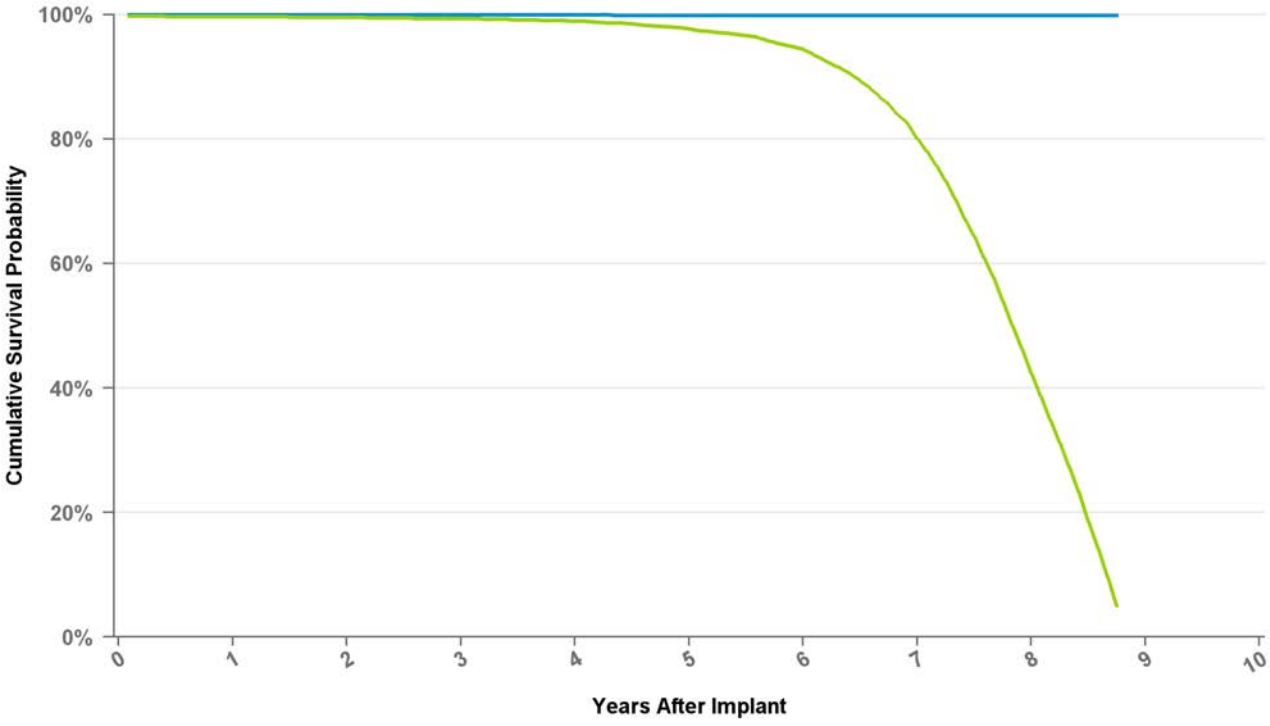
KDR401 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	39,405
Estimated Active US Implants	2,869
Normal Battery Depletions (US)	7,139

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.9%	97.7%	94.4%	80.1%	42.4%	5.0%
Effective Sample Size	44186	41057	37880	34811	31381	27397	20454	8390	820

Implantable Pulse Generator

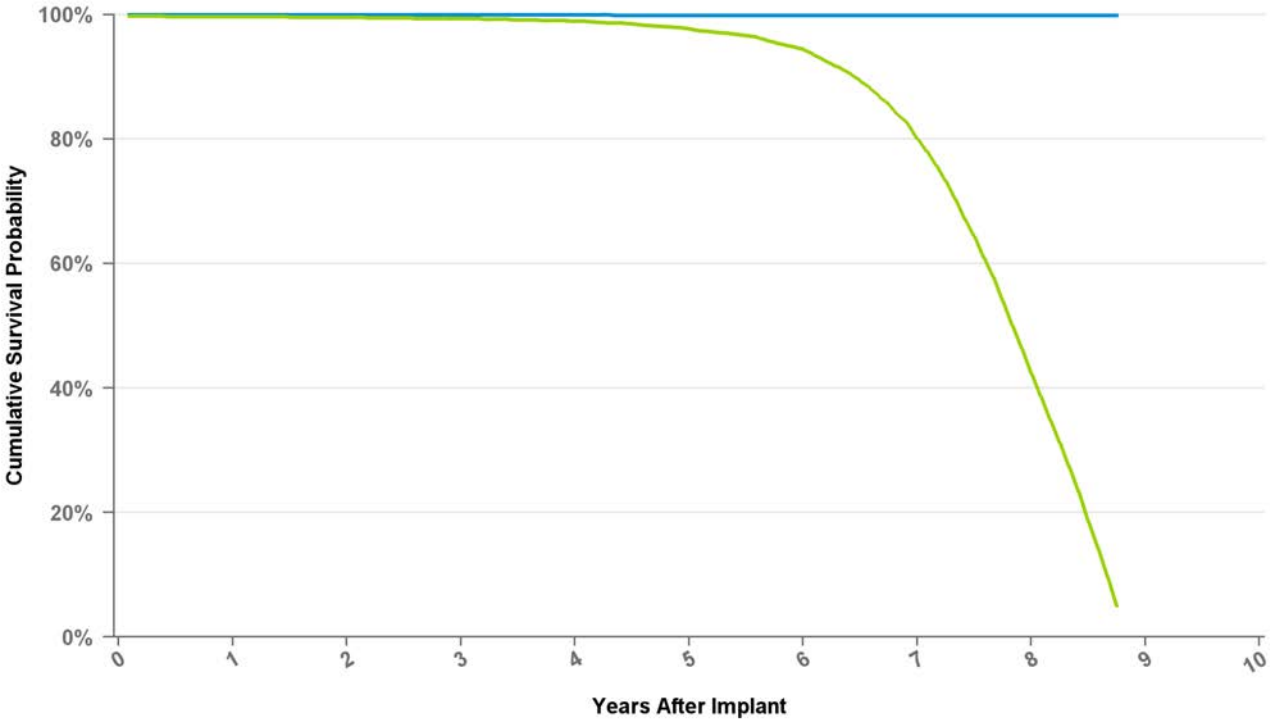
KDR403 Kappa 400 DR

US Market Release Date	1/30/1998
CE Market Approval Date	11/12/1996
Registered US Implants	7,310
Estimated Active US Implants	880
Normal Battery Depletions (US)	1,093

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 105 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.7%	99.6%	99.3%	98.9%	97.7%	94.4%	80.1%	42.4%	5.0%
Effective Sample Size	44186	41057	37880	34811	31381	27397	20454	8390	820

Implantable Pulse Generator

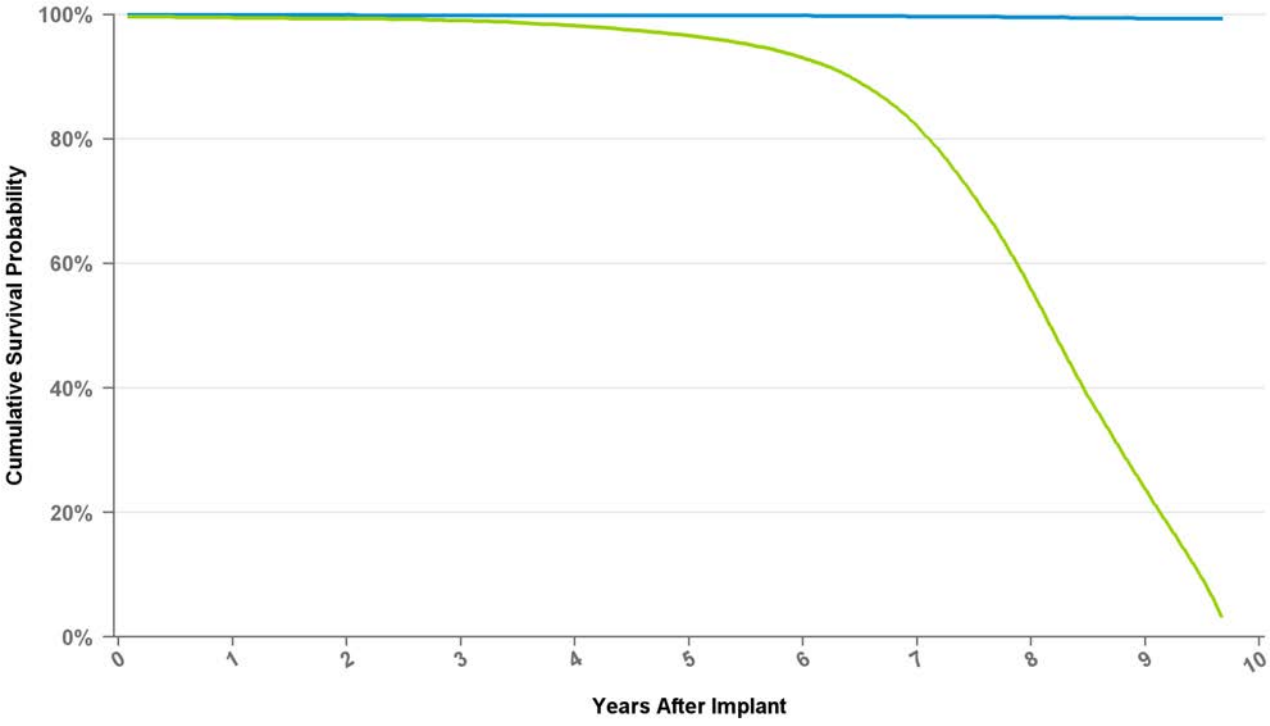
KDR700 Kappa 700 DR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 116 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	99.5%	99.4%	99.0%	98.2%	96.6%	93.0%	82.0%	55.8%	23.8%	3.4%
Effective Sample Size	180086	165059	150466	135831	121509	105917	83642	48032	14051	1419

Implantable Pulse Generator

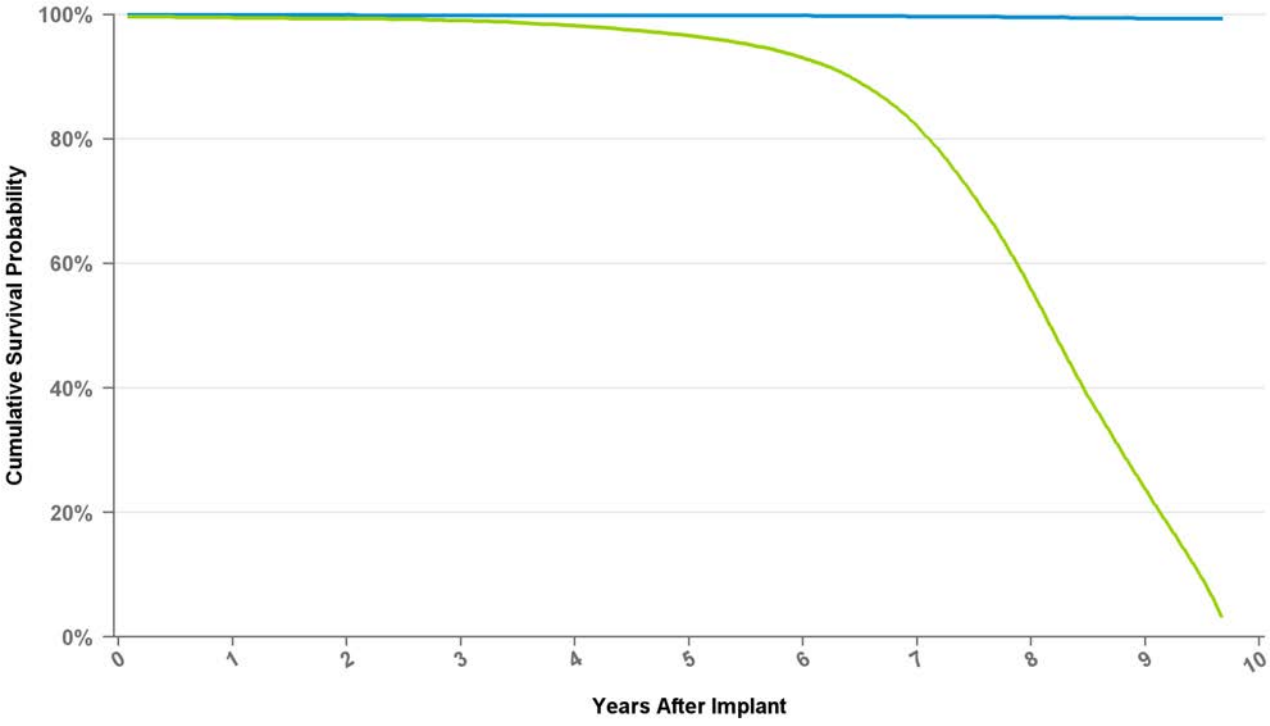
KDR701 Kappa 700 DR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	194,141
Estimated Active US Implants	18,425
Normal Battery Depletions (US)	35,822

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	702
Therapy Not Compromised Malfunction	48
Battery Malfunction	1
Electrical Component	23
Electrical Interconnect	18
Other Malfunction	3
Poss Early Battery Depltn	3
Software Malfunction	0
Therapy Compromised Malfunctions	654
Battery Malfunction	0
Electrical Component	16
Electrical Interconnect	637
Other Malfunction	0
Poss Early Battery Depltn	1
Software Malfunction	0

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 116 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	99.5%	99.4%	99.0%	98.2%	96.6%	93.0%	82.0%	55.8%	23.8%	3.4%
Effective Sample Size	180086	165059	150466	135831	121509	105917	83642	48032	14051	1419

Implantable Pulse Generator

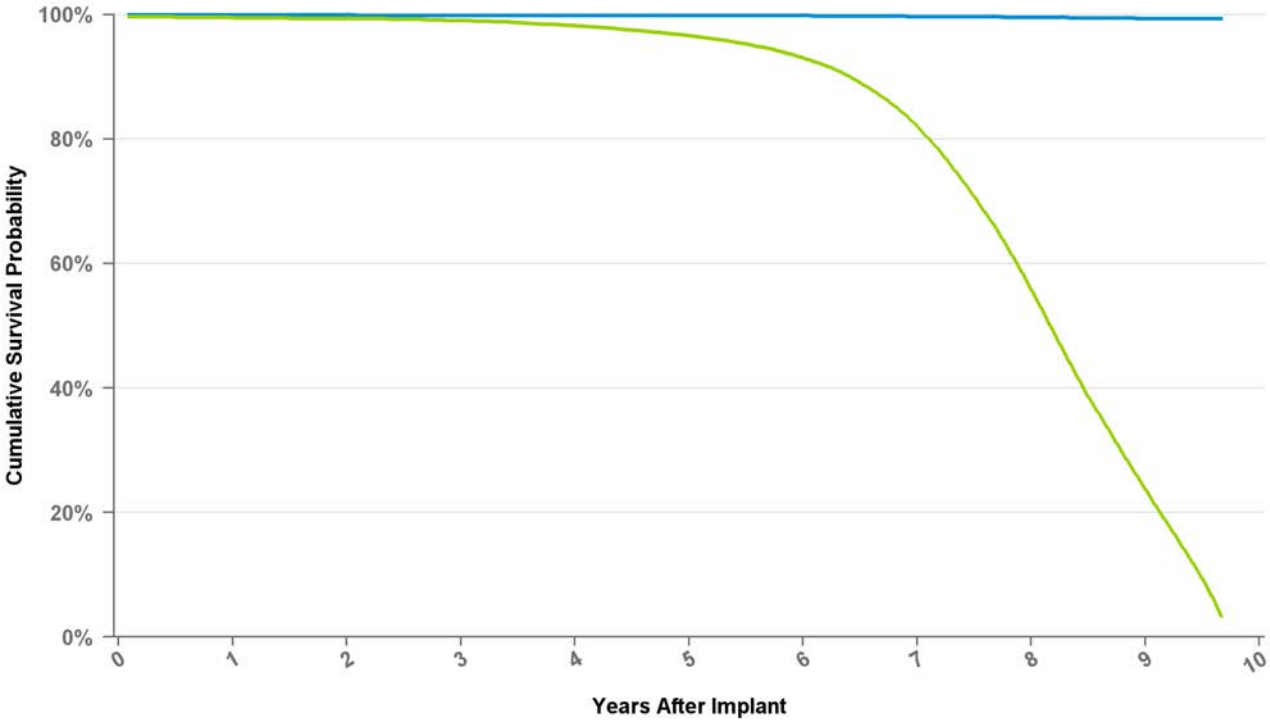
KDR703 Kappa 700 DR

US Market Release Date	2/5/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,226
Estimated Active US Implants	783
Normal Battery Depletions (US)	1,528

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 116 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	99.5%	99.4%	99.0%	98.2%	96.6%	93.0%	82.0%	55.8%	23.8%	3.4%
Effective Sample Size	180086	165059	150466	135831	121509	105917	83642	48032	14051	1419

Implantable Pulse Generator

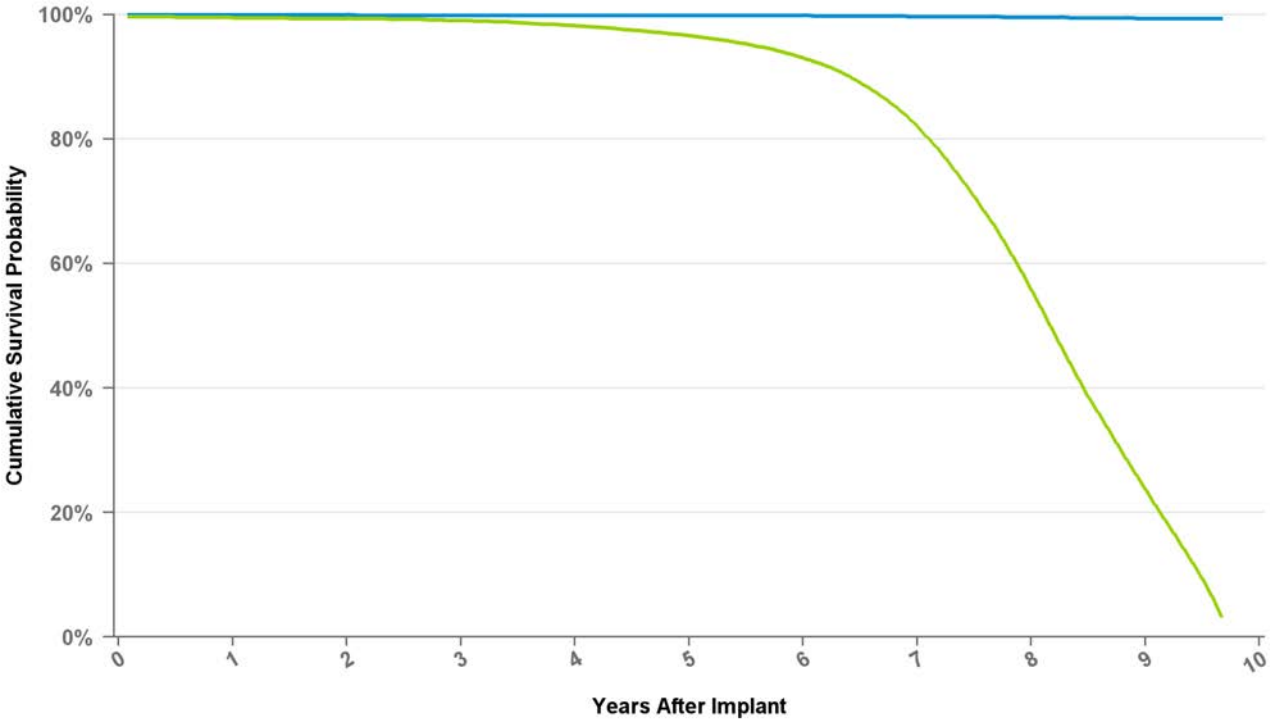
KDR706 Kappa 700 DR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,633
Estimated Active US Implants	181
Normal Battery Depletions (US)	402

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 116 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	99.5%	99.4%	99.0%	98.2%	96.6%	93.0%	82.0%	55.8%	23.8%	3.4%
Effective Sample Size	180086	165059	150466	135831	121509	105917	83642	48032	14051	1419

Implantable Pulse Generator

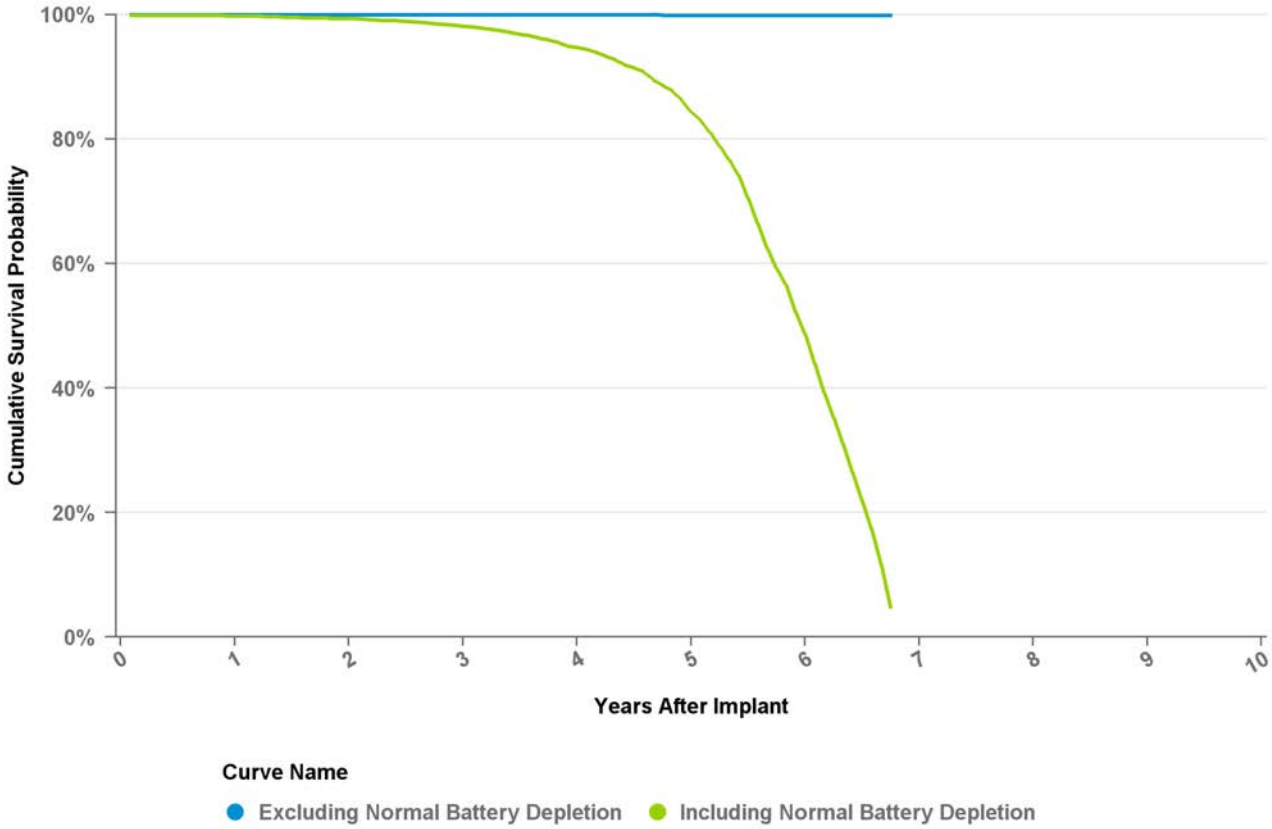
KDR721 Kappa 700 DR

US Market Release Date	2/11/1999
CE Market Approval Date	3/20/1998
Registered US Implants	9,838
Estimated Active US Implants	729
Normal Battery Depletions (US)	1,361

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	at 81 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%
Including NBD	99.8%	99.4%	98.1%	94.7%	84.4%	48.7%	4.8%
Effective Sample Size	8623	7613	6639	5600	4305	1785	171

Implantable Pulse Generator

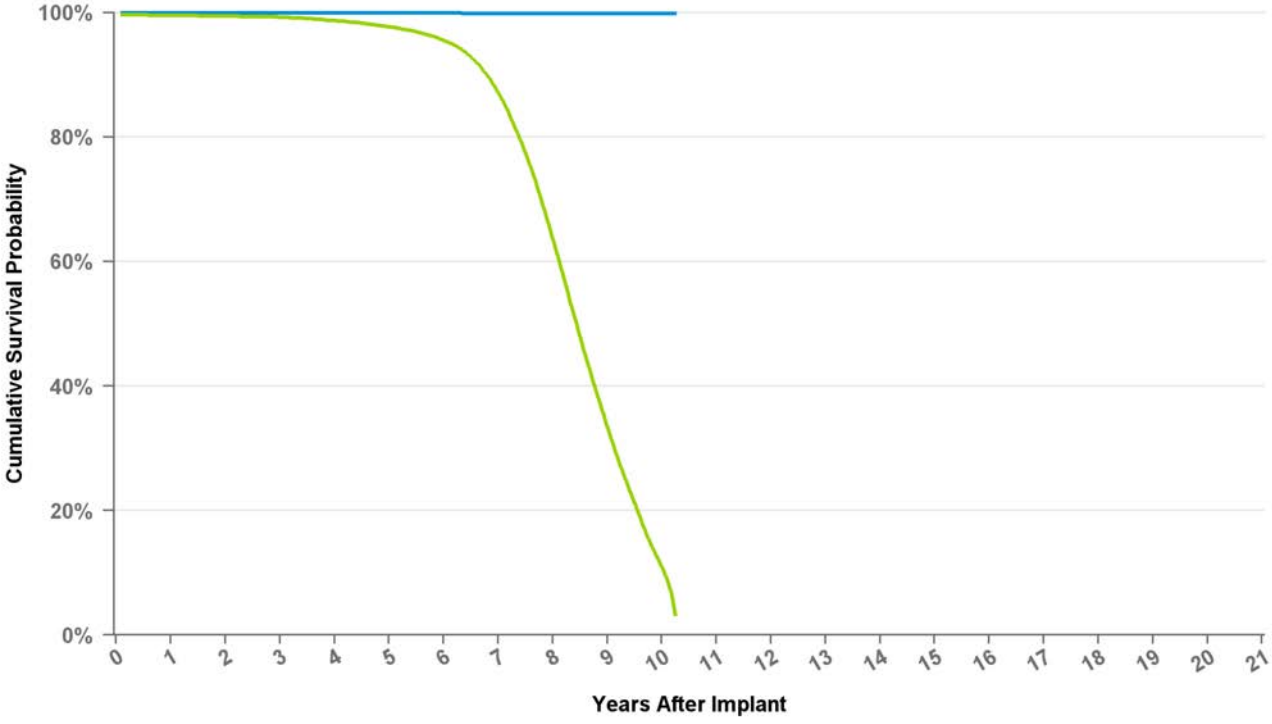
KDR901 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	120,683
Estimated Active US Implants	17,150
Normal Battery Depletions (US)	24,634

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

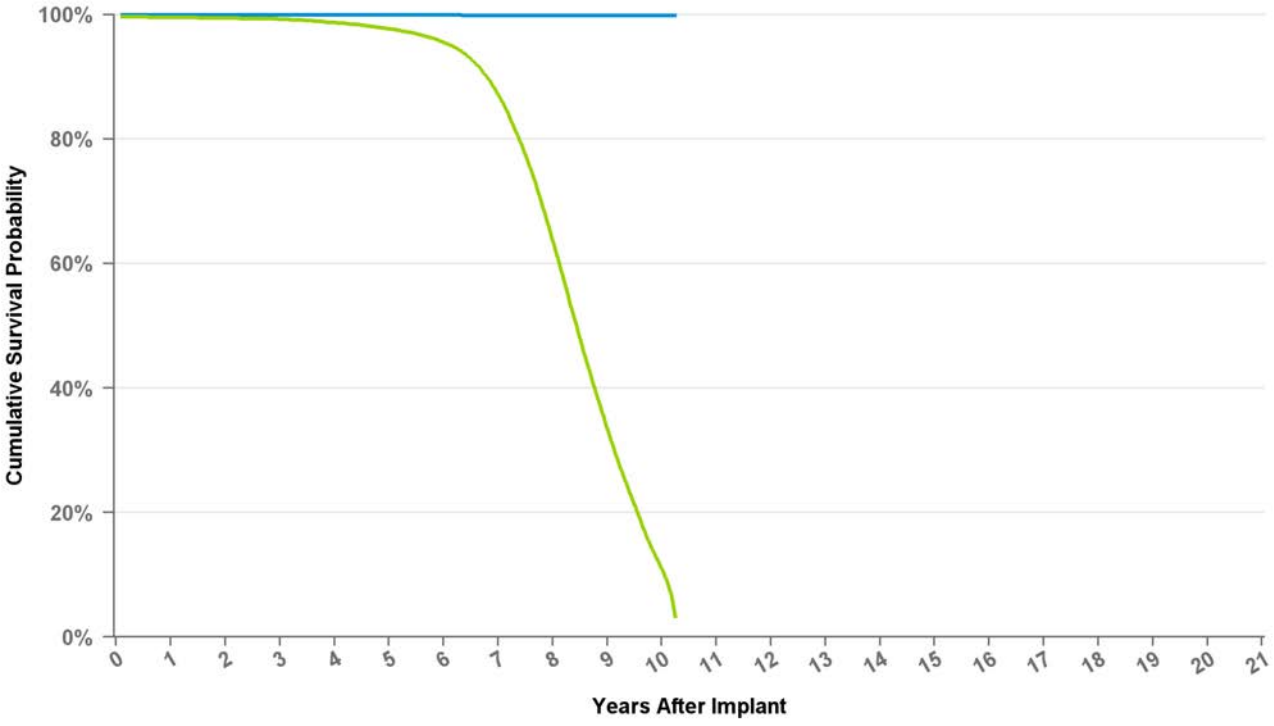
KDR903 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	3,168
Estimated Active US Implants	343
Normal Battery Depletions (US)	605

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

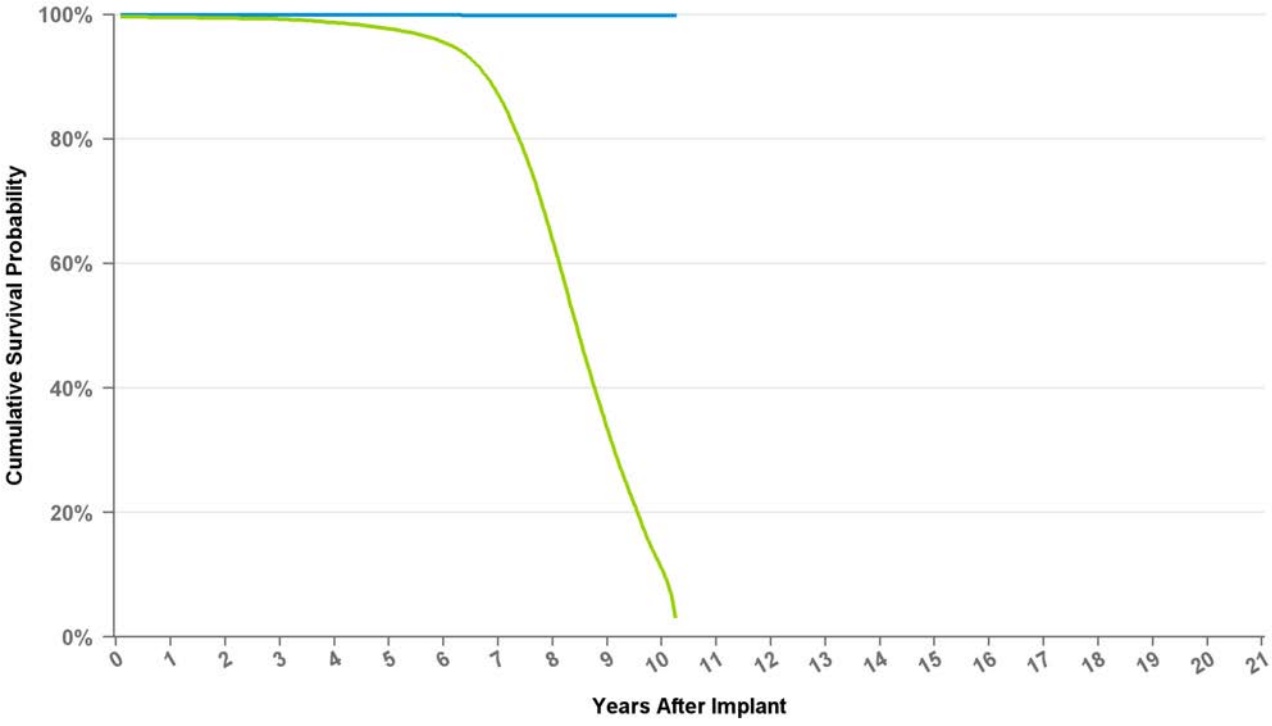
KDR906 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,509
Estimated Active US Implants	123
Normal Battery Depletions (US)	294

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 123 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.6%	99.5%	99.2%	98.7%	97.7%	95.5%	87.2%	63.7%	33.5%	11.0%	3.3%
Effective Sample Size	117156	107784	98674	89941	81393	72830	61162	39043	14324	2099	328

Implantable Pulse Generator

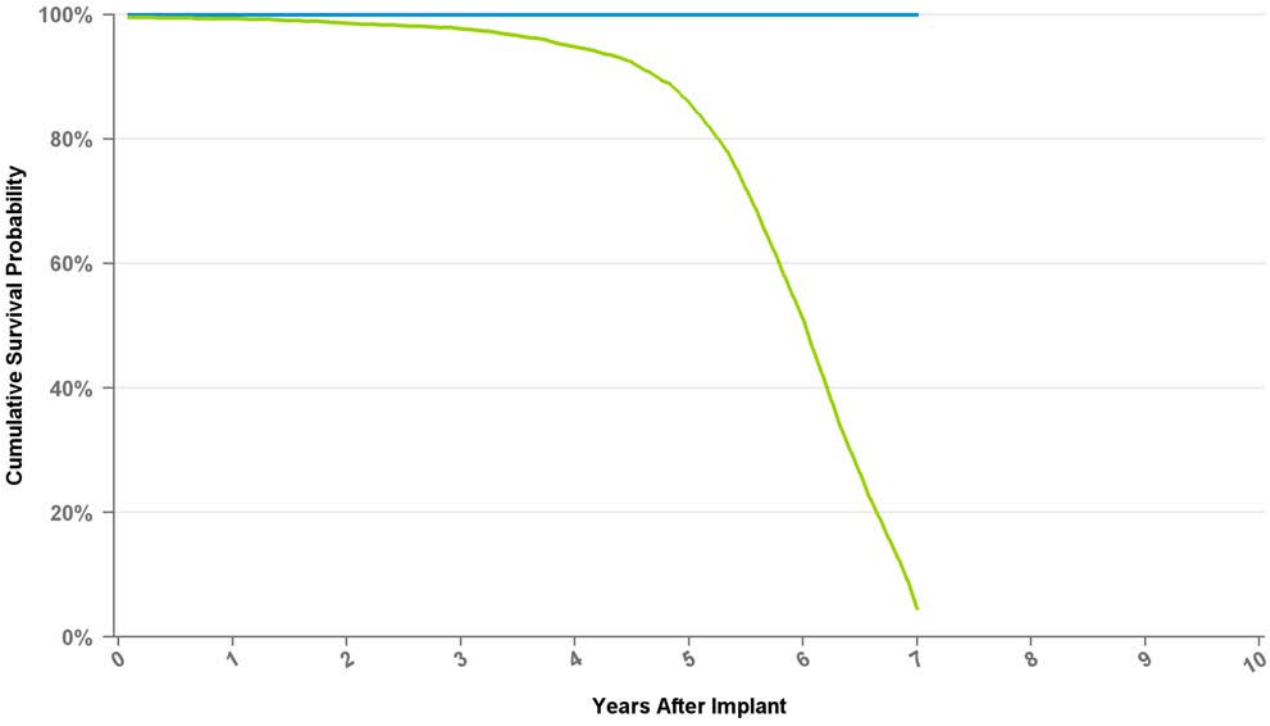
KDR921 Kappa 900 DR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	16,329
Estimated Active US Implants	1,356
Normal Battery Depletions (US)	2,872

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	99.3%	98.6%	97.7%	94.8%	85.8%	51.1%	4.6%
Effective Sample Size	14184	12616	11141	9602	7633	3542	244

Implantable Pulse Generator

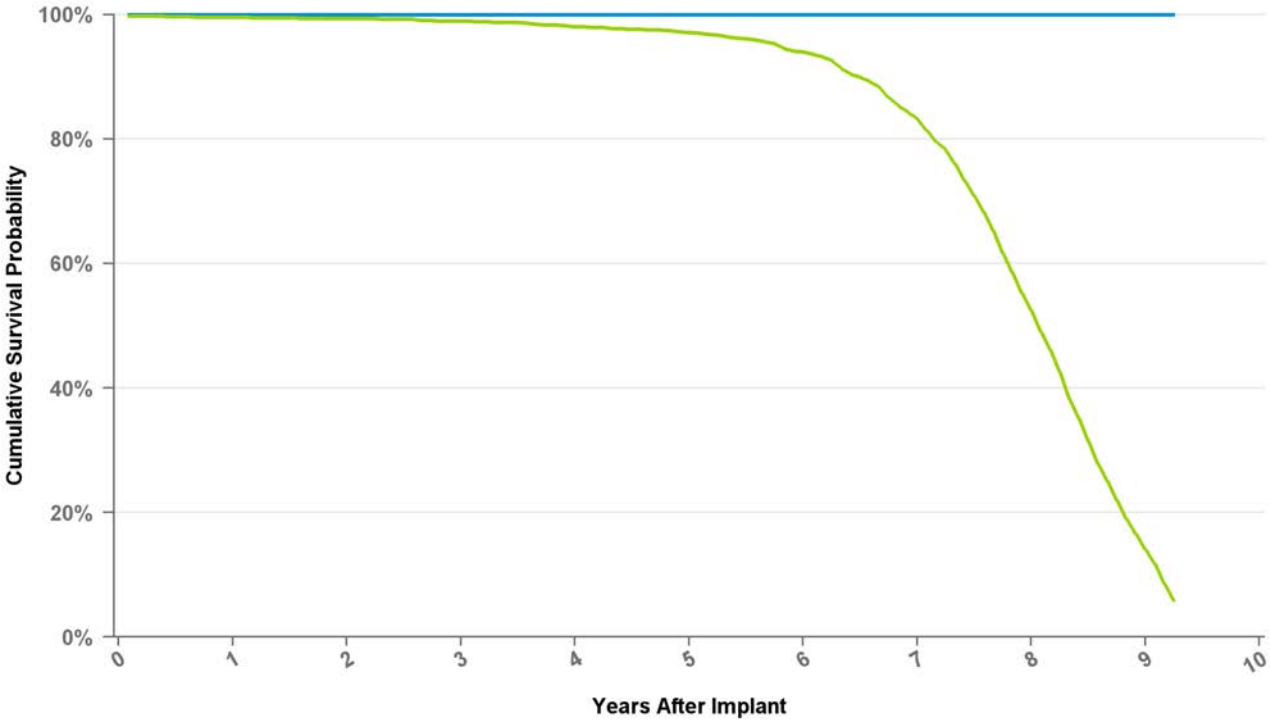
KSR401 Kappa 400 SR

US Market Release Date	2/18/1998
CE Market Approval Date	11/12/1996
Registered US Implants	11,788
Estimated Active US Implants	898
Normal Battery Depletions (US)	1,266

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 111 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	99.6%	99.3%	98.9%	98.0%	97.1%	94.0%	83.2%	52.5%	14.1%	5.9%
Effective Sample Size	13589	11932	10430	9150	7892	6618	5005	2423	357	126

Implantable Pulse Generator

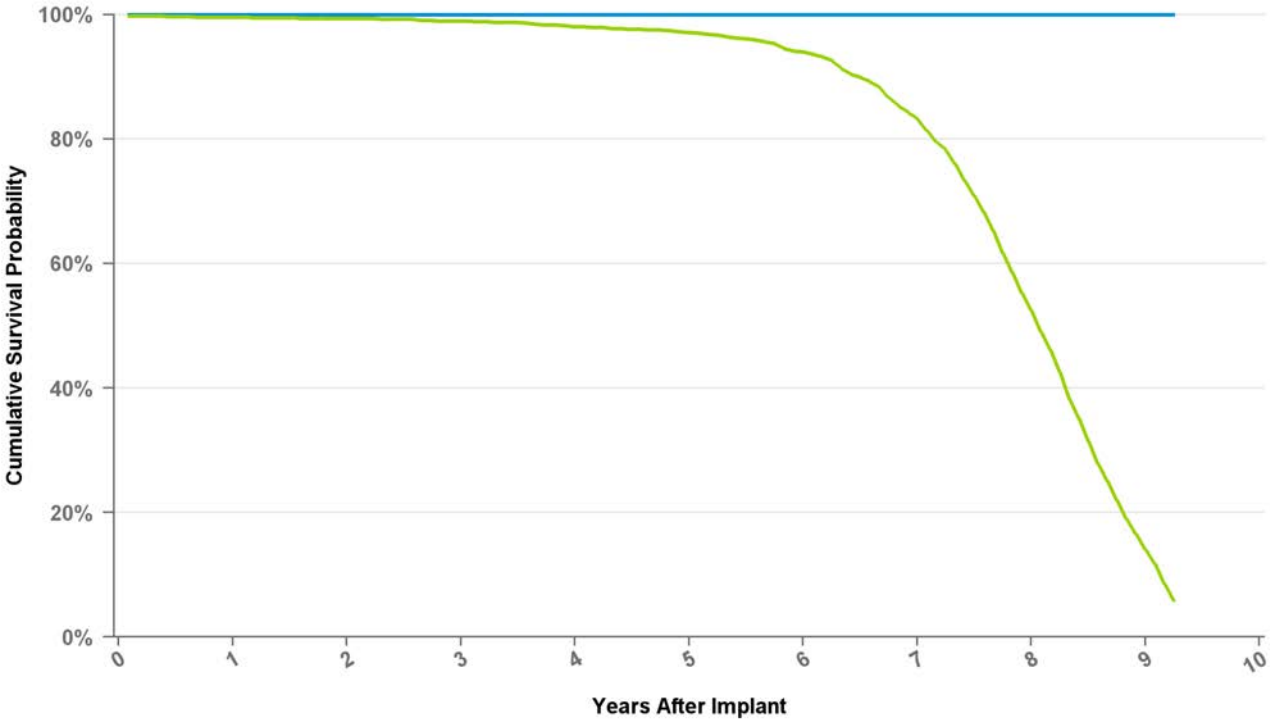
KSR403 Kappa 400 SR

US Market Release Date	2/24/1998
CE Market Approval Date	11/12/1996
Registered US Implants	3,620
Estimated Active US Implants	437
Normal Battery Depletions (US)	362

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	at 111 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	99.6%	99.3%	98.9%	98.0%	97.1%	94.0%	83.2%	52.5%	14.1%	5.9%
Effective Sample Size	13589	11932	10430	9150	7892	6618	5005	2423	357	126

Implantable Pulse Generator

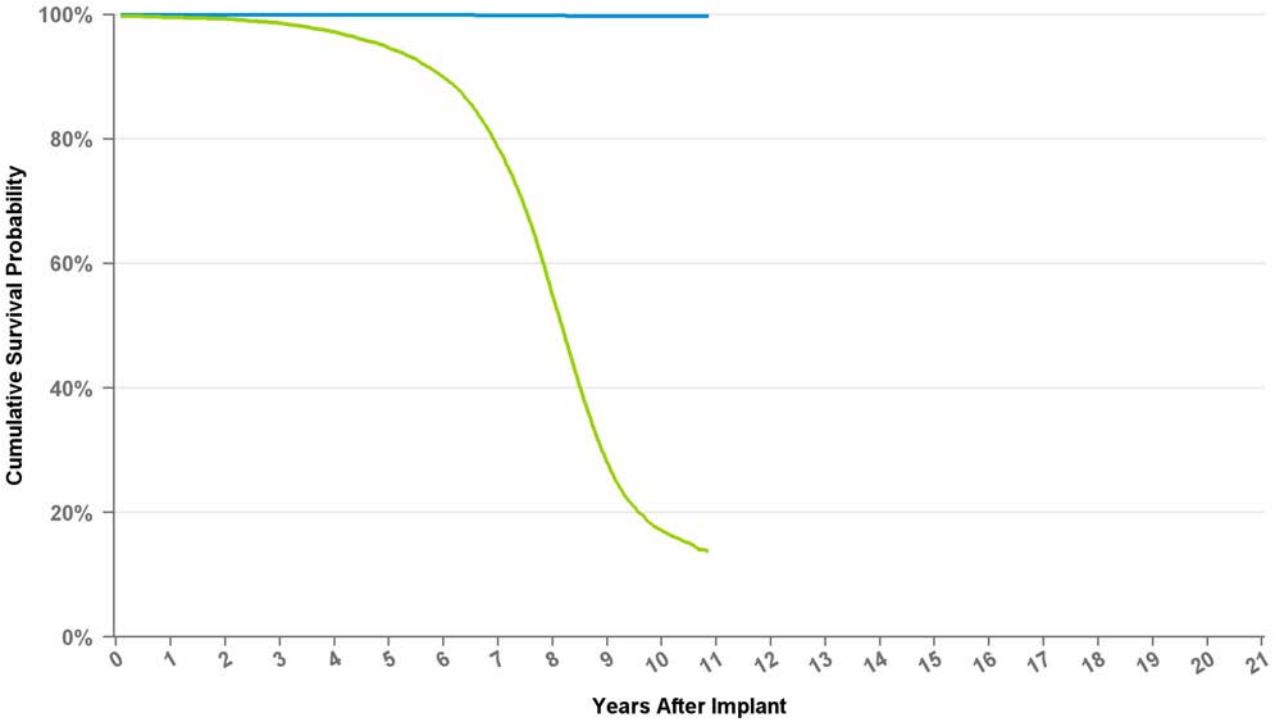
KSR700 Kappa 700 SR

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.6%	99.3%	98.6%	97.2%	94.6%	89.9%	78.6%	54.8%	28.1%	17.1%	13.8%
Effective Sample Size	48205	41530	35582	30380	25559	21008	15799	8834	2818	851	139

Implantable Pulse Generator

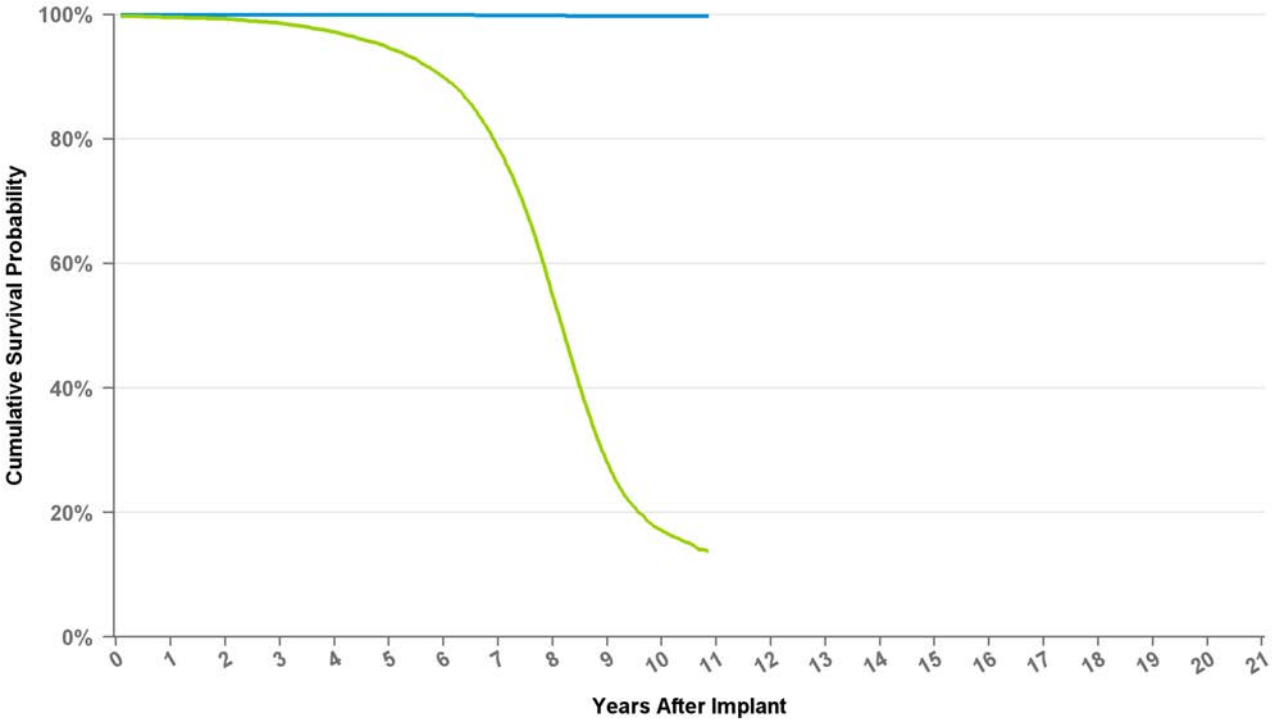
KSR701 Kappa 700 SR

US Market Release Date	1/29/1999
CE Market Approval Date	3/20/1998
Registered US Implants	48,465
Estimated Active US Implants	4,545
Normal Battery Depletions (US)	4,940

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.6%	99.3%	98.6%	97.2%	94.6%	89.9%	78.6%	54.8%	28.1%	17.1%	13.8%
Effective Sample Size	48205	41530	35582	30380	25559	21008	15799	8834	2818	851	139

Implantable Pulse Generator

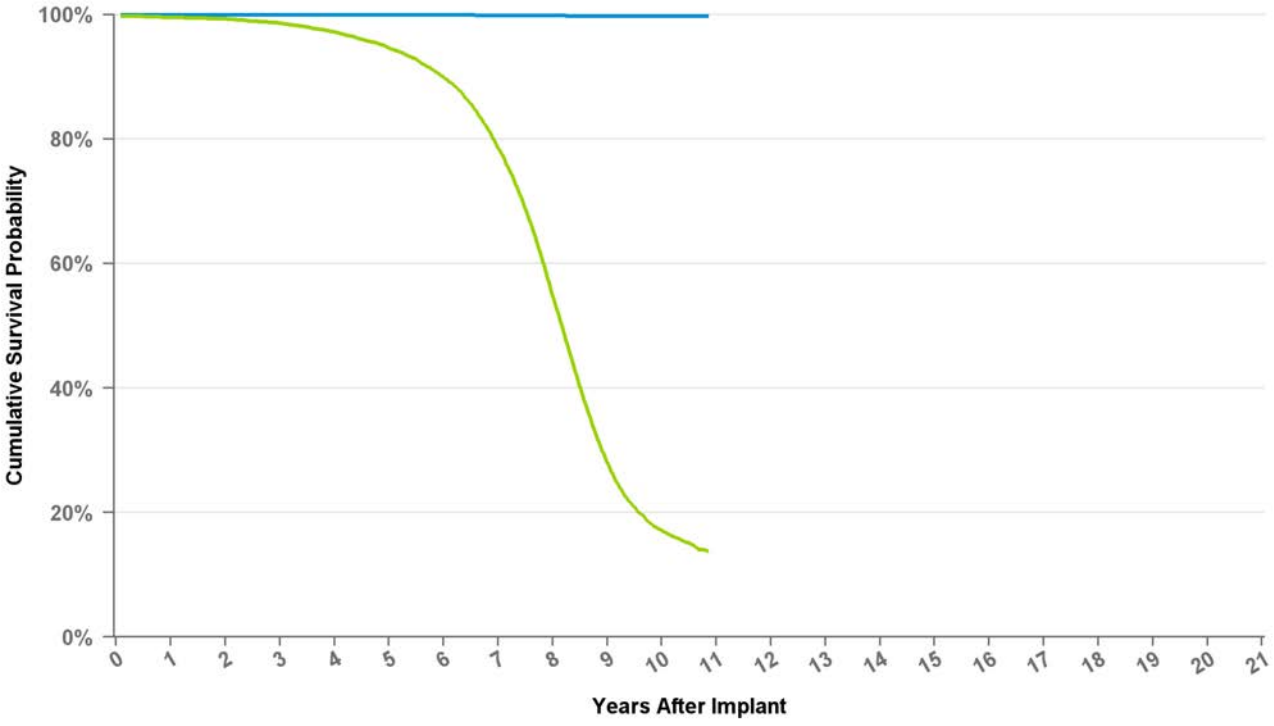
KSR703 Kappa 700 SR

US Market Release Date	2/8/1999
CE Market Approval Date	3/20/1998
Registered US Implants	3,607
Estimated Active US Implants	286
Normal Battery Depletions (US)	394

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.6%	99.3%	98.6%	97.2%	94.6%	89.9%	78.6%	54.8%	28.1%	17.1%	13.8%
Effective Sample Size	48205	41530	35582	30380	25559	21008	15799	8834	2818	851	139

Implantable Pulse Generator

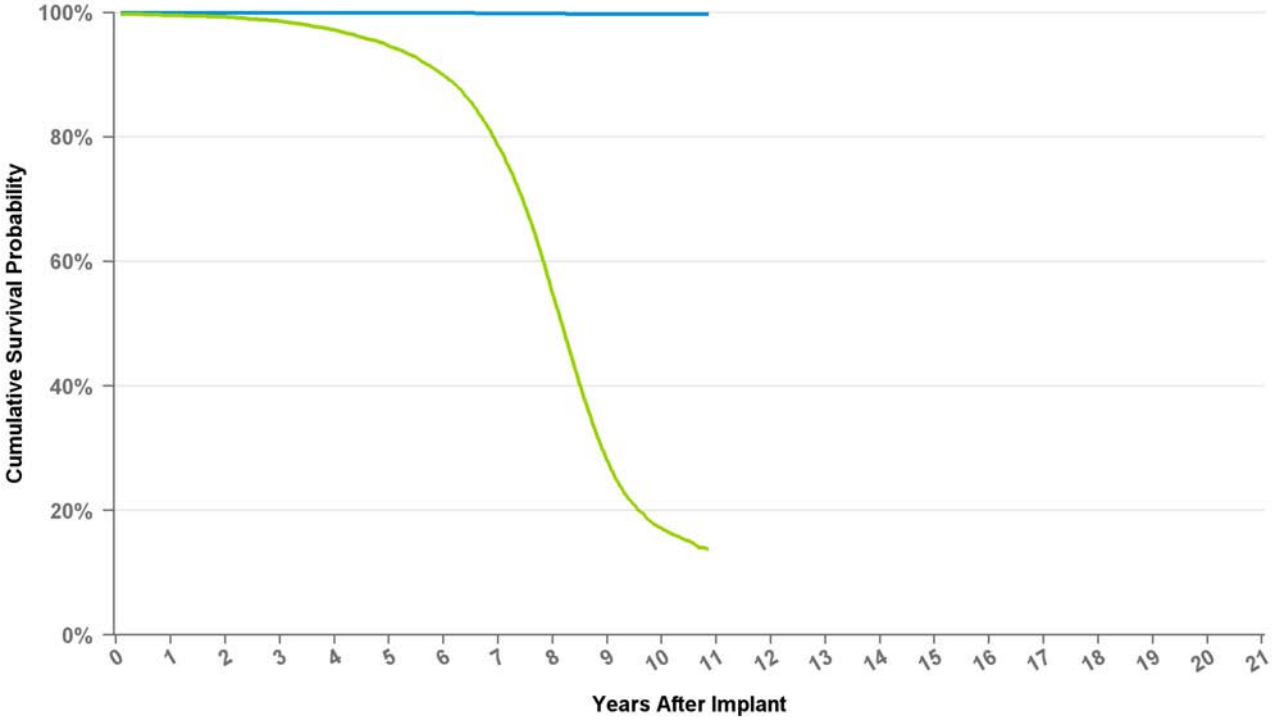
KSR706 Kappa 700 SR

US Market Release Date	2/9/1999
CE Market Approval Date	3/20/1998
Registered US Implants	2,920
Estimated Active US Implants	244
Normal Battery Depletions (US)	298

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

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%	99.9%	99.9%	99.8%	99.8%	99.8%
Including NBD	99.6%	99.3%	98.6%	97.2%	94.6%	89.9%	78.6%	54.8%	28.1%	17.1%	13.8%
Effective Sample Size	48205	41530	35582	30380	25559	21008	15799	8834	2818	851	139

Implantable Pulse Generator

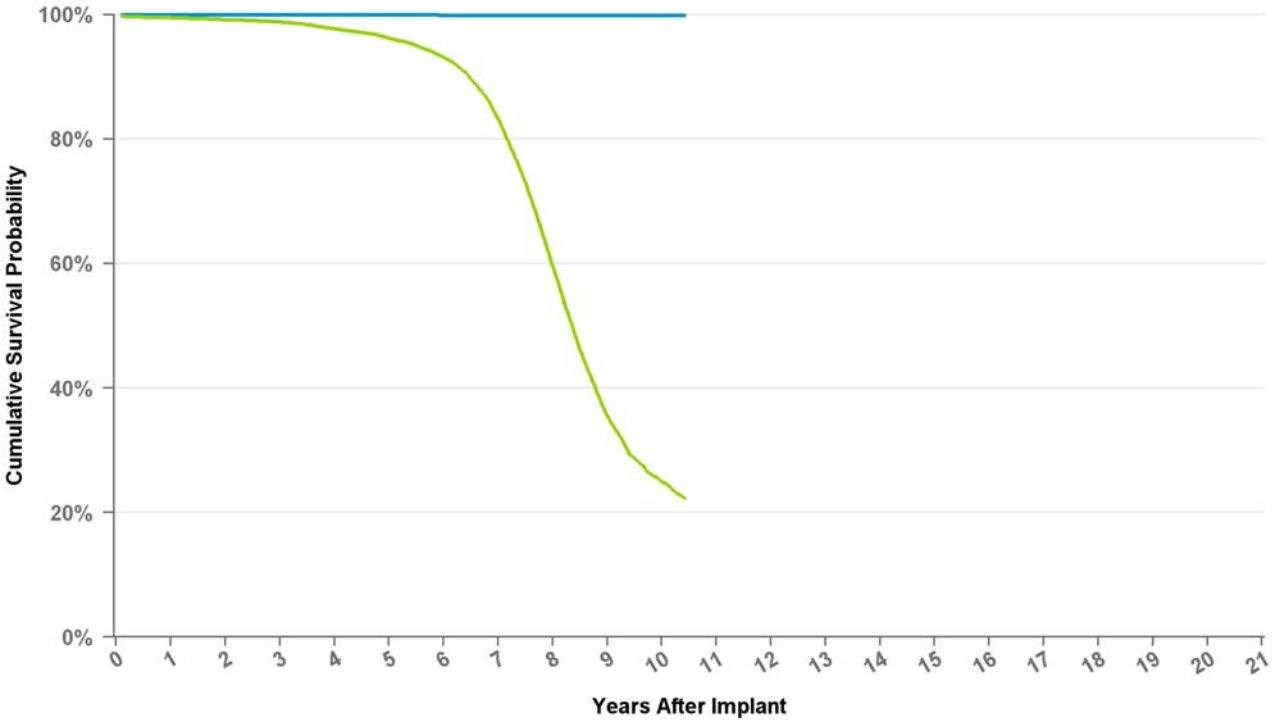
KSR901 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	34,127
Estimated Active US Implants	4,373
Normal Battery Depletions (US)	3,776

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	9	10	at 125 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.1%	98.8%	97.7%	96.2%	93.1%	83.3%	59.6%	35.6%	24.9%	22.3%
Effective Sample Size	31941	27500	23891	20574	17655	14978	11820	6910	2249	653	128

Implantable Pulse Generator

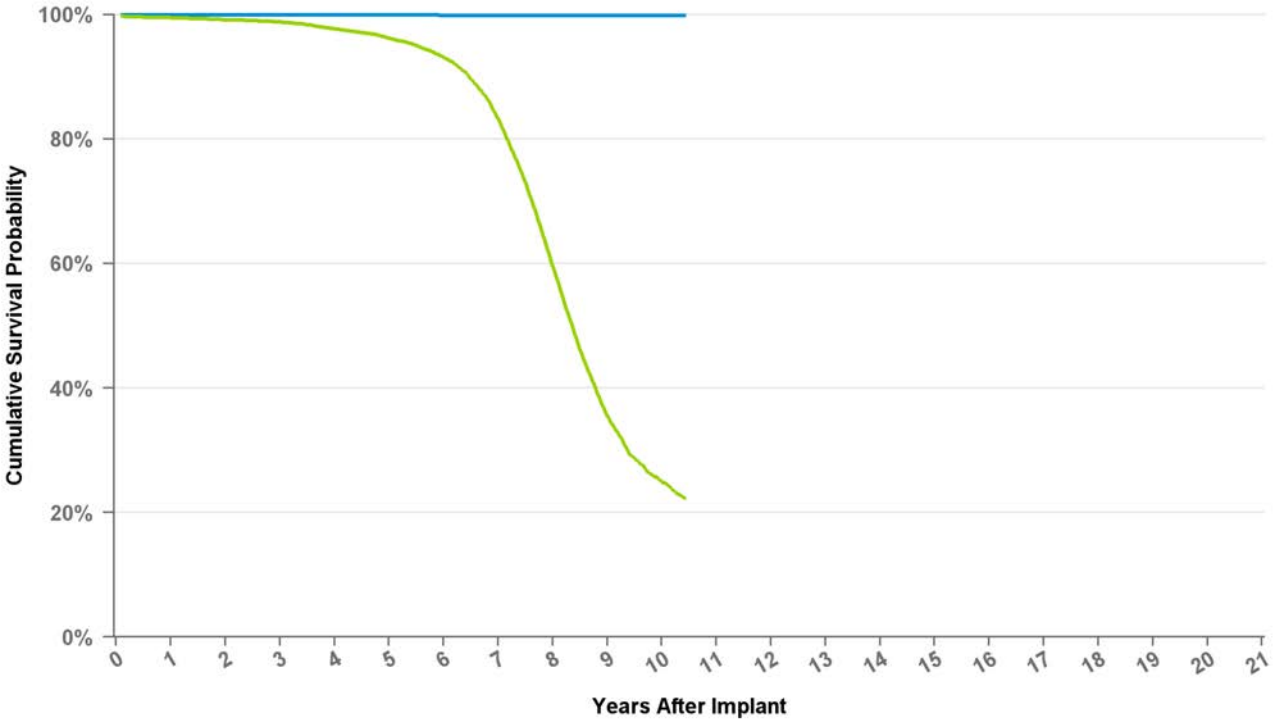
KSR903 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,372
Estimated Active US Implants	134
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



Years	1	2	3	4	5	6	7	8	9	10	at 125 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.1%	98.8%	97.7%	96.2%	93.1%	83.3%	59.6%	35.6%	24.9%	22.3%
Effective Sample Size	31941	27500	23891	20574	17655	14978	11820	6910	2249	653	128

Implantable Pulse Generator

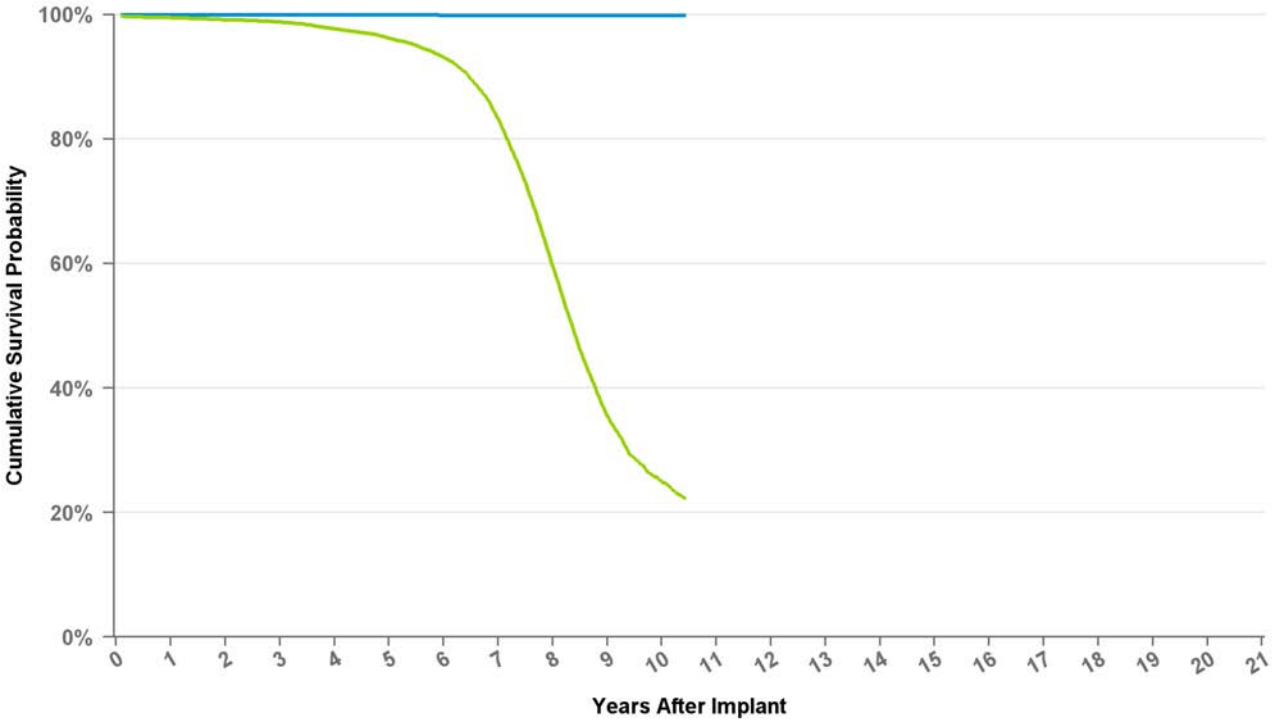
KSR906 Kappa 900 SR

US Market Release Date	1/9/2002
CE Market Approval Date	9/28/2001
Registered US Implants	1,322
Estimated Active US Implants	130
Normal Battery Depletions (US)	177

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	9	10	at 125 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Including NBD	99.5%	99.1%	98.8%	97.7%	96.2%	93.1%	83.3%	59.6%	35.6%	24.9%	22.3%
Effective Sample Size	31941	27500	23891	20574	17655	14978	11820	6910	2249	653	128

Implantable Pulse Generator

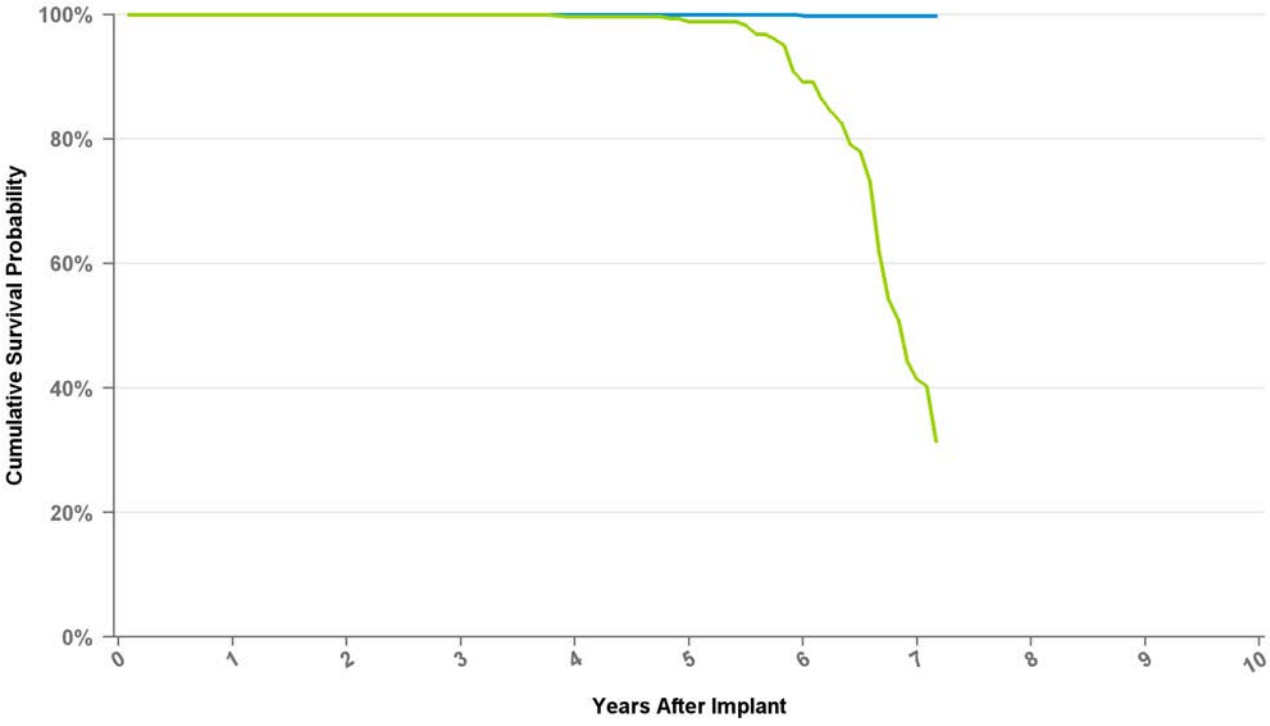
KVDD901 Kappa 900 VDD

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 86 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	99.8%	99.8%	99.8%
Including NBD	100.0%	100.0%	100.0%	99.7%	98.8%	89.2%	41.4%	31.4%
Effective Sample Size	763	705	649	592	542	433	151	128

Implantable Pulse Generator

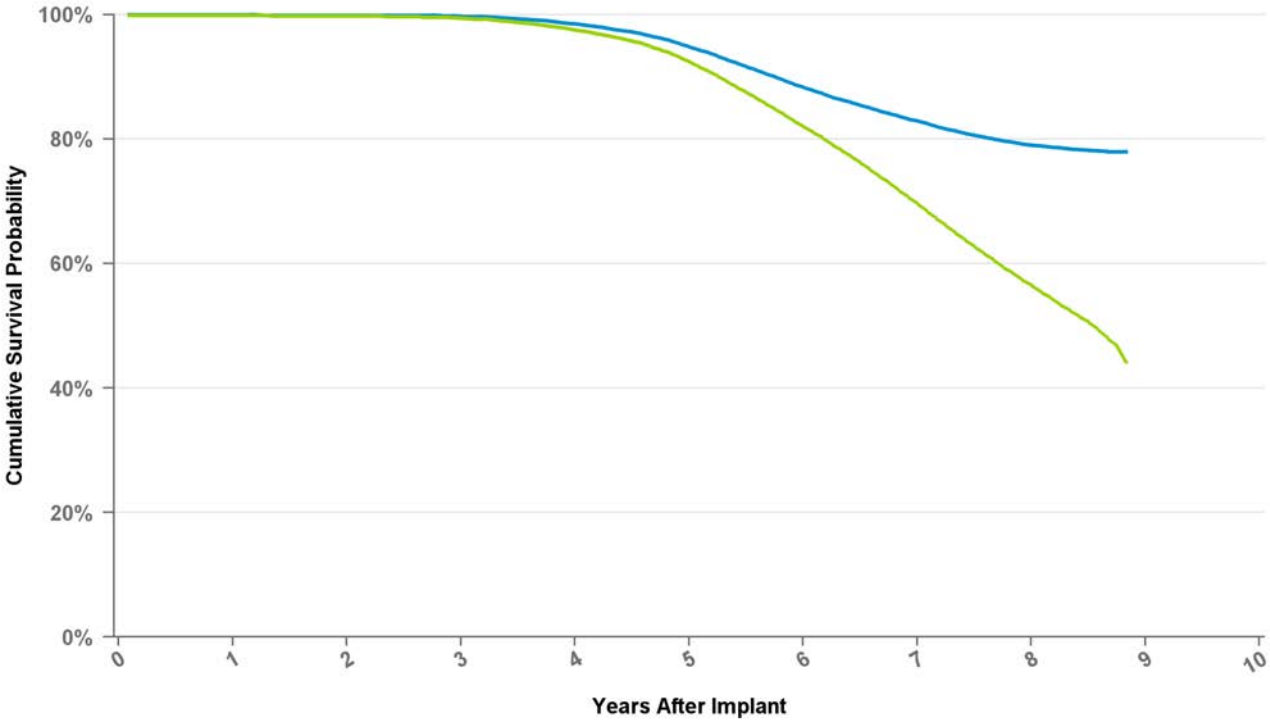
P1501DR EnRhythm DR

US Market Release Date	5/5/2005
CE Market Approval Date	8/13/2004
Registered US Implants	110,138
Estimated Active US Implants	53,837
Normal Battery Depletions (US)	3,917

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	10,589
Therapy Not Compromised Malfunction	10,536
Battery Malfunction	10,429
Electrical Component	49
Electrical Interconnect	2
Other Malfunction	2
Poss Early Battery Depltn	54
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	at 106 mo
Excluding NBD	100.0%	99.9%	99.7%	98.5%	94.8%	88.3%	82.9%	79.0%	78.0%
Including NBD	99.9%	99.8%	99.4%	97.5%	92.4%	82.0%	69.6%	56.5%	44.2%
Effective Sample Size	104107	97645	90655	76874	59539	41619	26521	12721	939

Implantable Pulse Generator

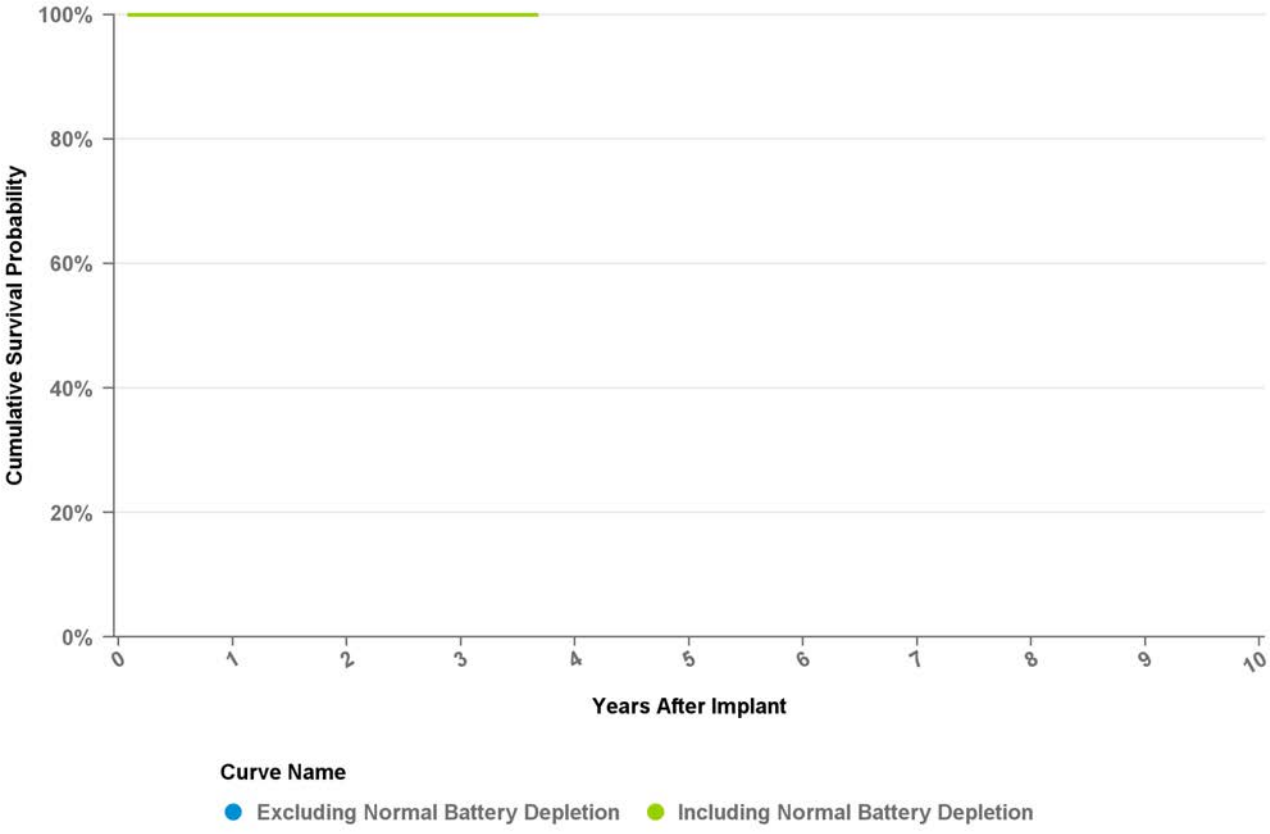
RED01 Relia D

US Market Release Date	
CE Market Approval Date	5/7/2008
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

REDR01, RED01, Survival Curve



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	268	216	151	101

Implantable Pulse Generator

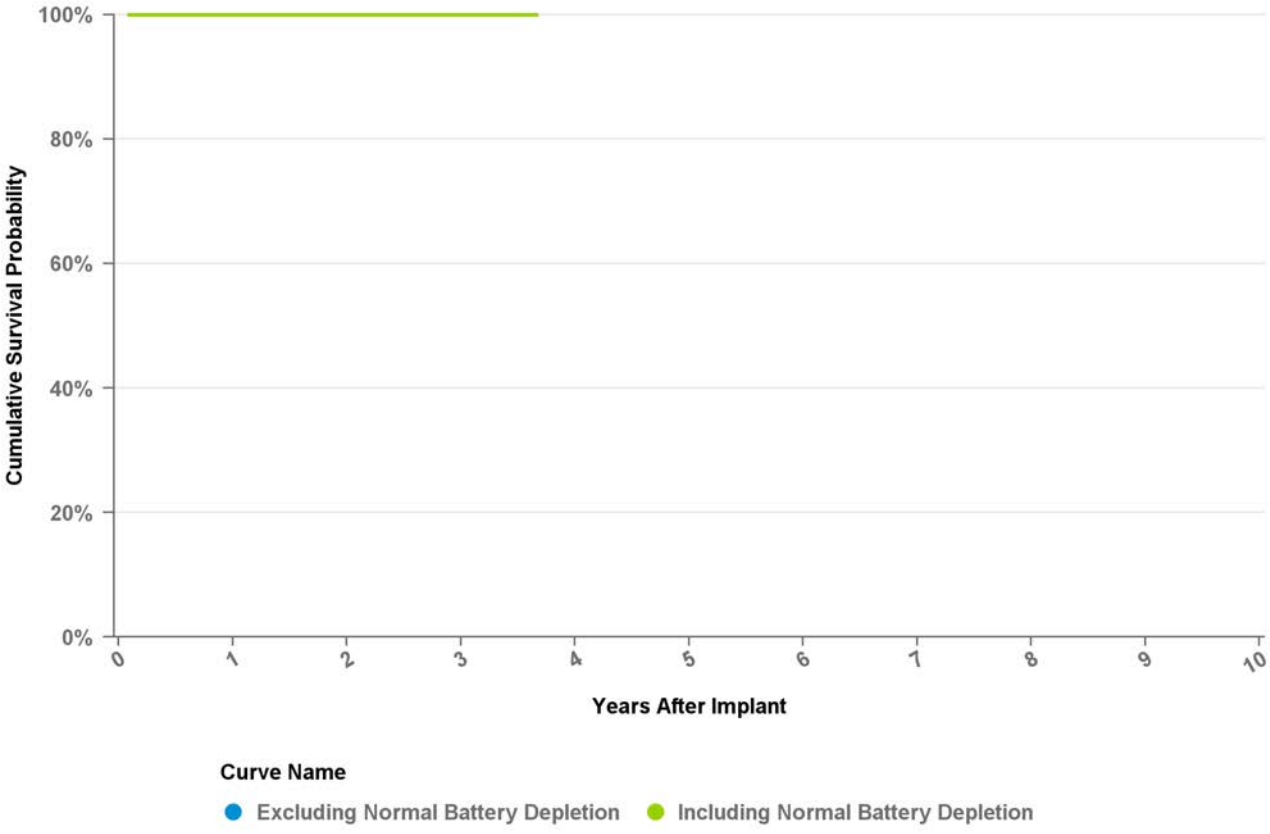
REDR01 Relia DR

US Market Release Date	
CE Market Approval Date	5/7/2008
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

REDR01, RED01, Survival Curve



Years	1	2	3	at 44 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	268	216	151	101

Implantable Pulse Generator

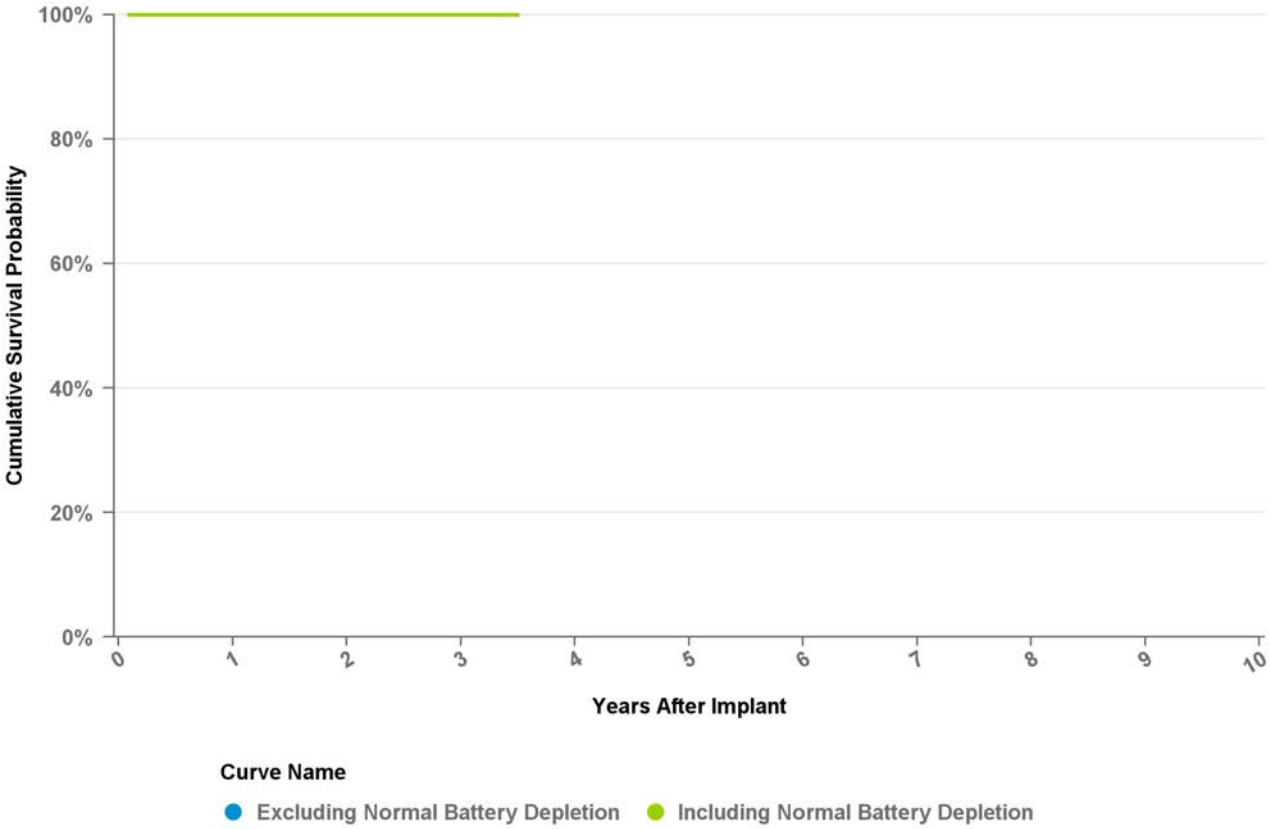
RES01 Relia S

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	1
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	AAI/VVI
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

RESR01, RES01, Survival Curve



Years	1	2	3	at 42 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	266	208	148	102

Implantable Pulse Generator

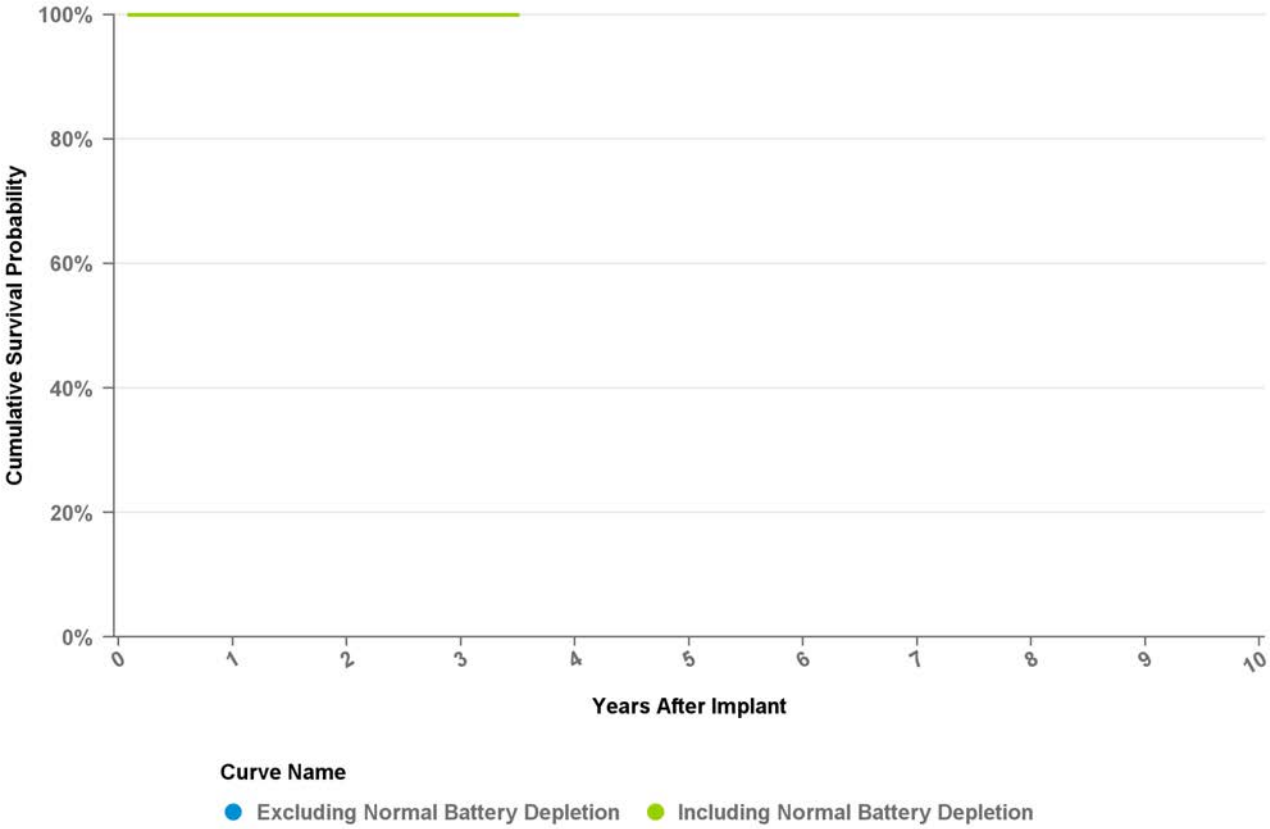
RESR01 Relia SR

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

NBG Code	AAIR/VVIR, AAI/VVI
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

RESR01, RES01, Survival Curve



Years	1	2	3	at 42 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	100.0%	100.0%
Effective Sample Size	266	208	148	102

Implantable Pulse Generator

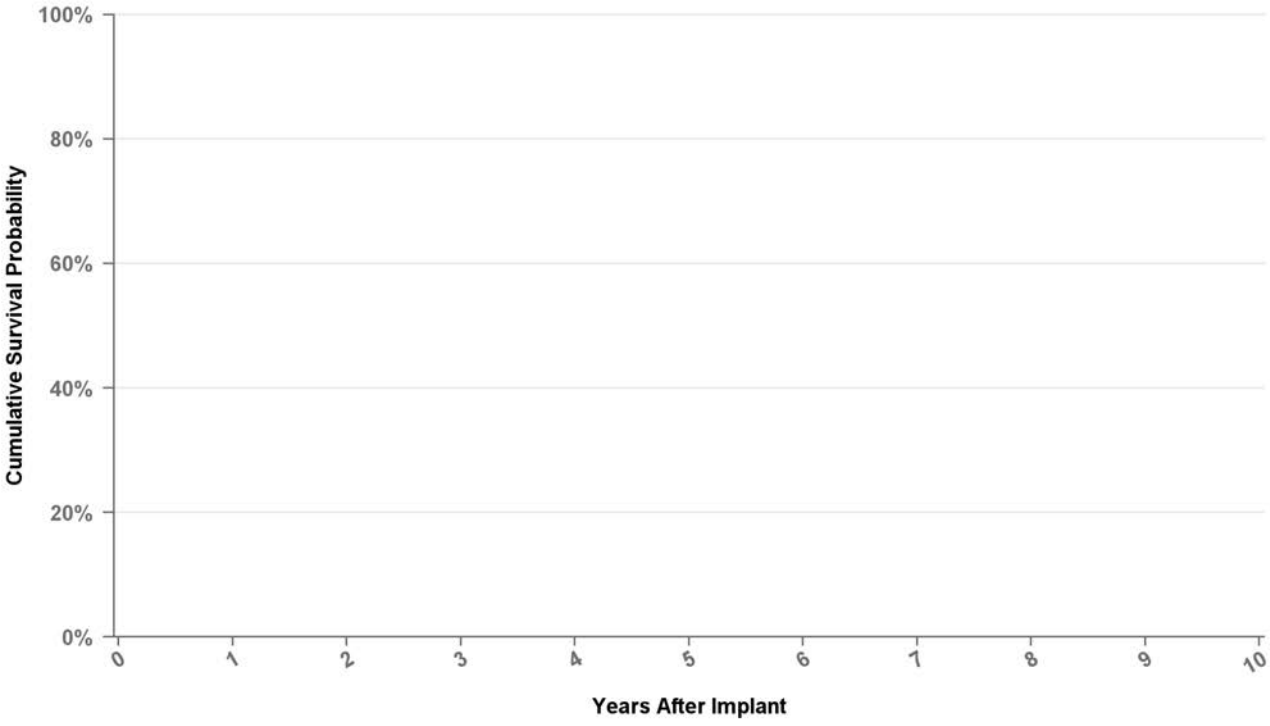
REVDD01 Relia VDD

US Market Release Date	
CE Market Approval Date	5/7/2008
Registered US Implants	0
Estimated Active US Implants	0
Normal Battery Depletions (US)	0

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

REVDD01, Survival Curve



Years

Excluding NBD

Including NBD

Effective Sample Size

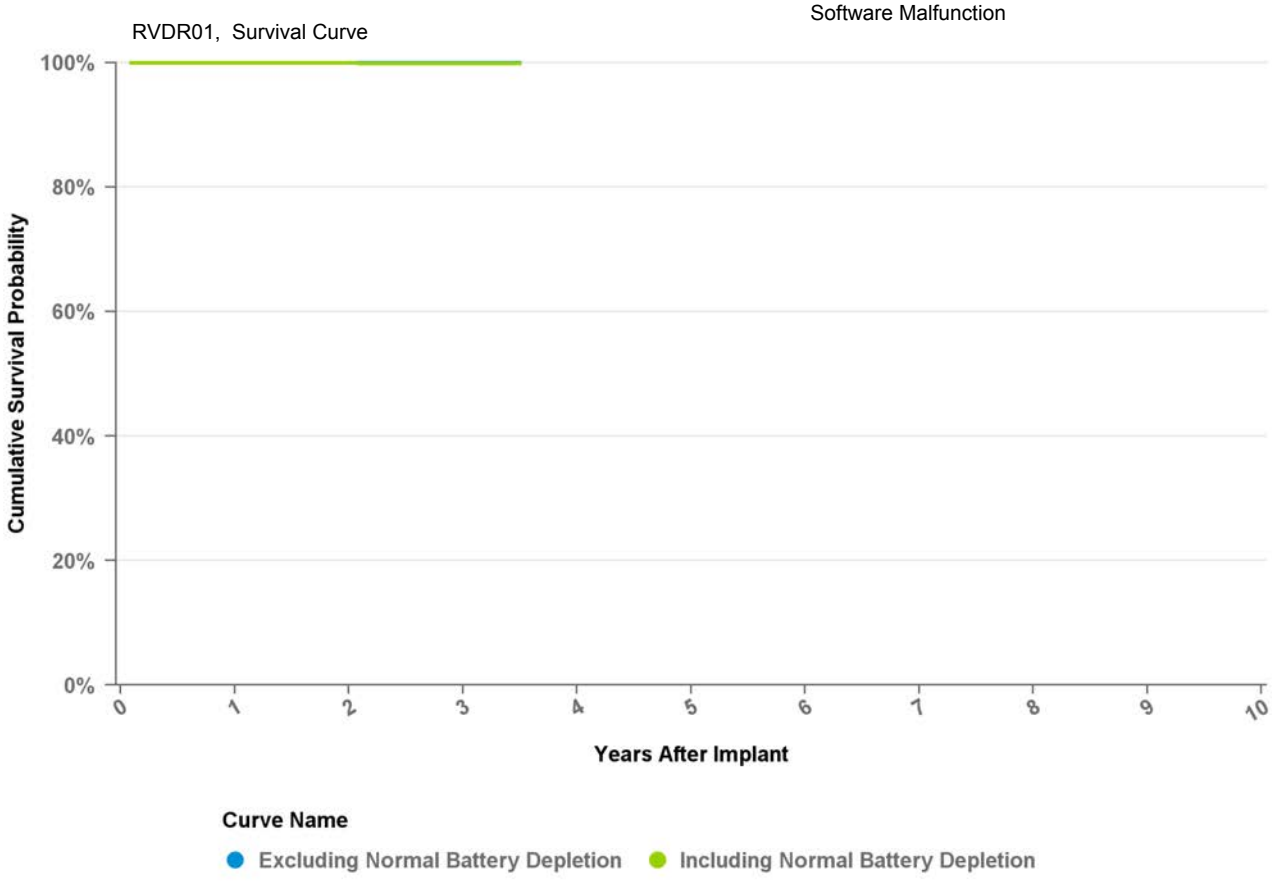
Implantable Pulse Generator

RVDR01 Revo MRI SureScan

US Market Release Date	2/8/2011
CE Market Approval Date	
Registered US Implants	63,354
Estimated Active US Implants	59,934
Normal Battery Depletions (US)	5

NBG Code	DDDRP
Max Delivered Energy	N/A

Total Malfunctions (US)	19
Therapy Not Compromised Malfunction	16
Battery Malfunction	1
Electrical Component	11
Electrical Interconnect	0
Other Malfunction	0
Poss Early Battery Depltn	3
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



Years	1	2	3	at 42 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.9%	99.9%
Effective Sample Size	57412	36726	10683	617

Implantable Pulse Generator

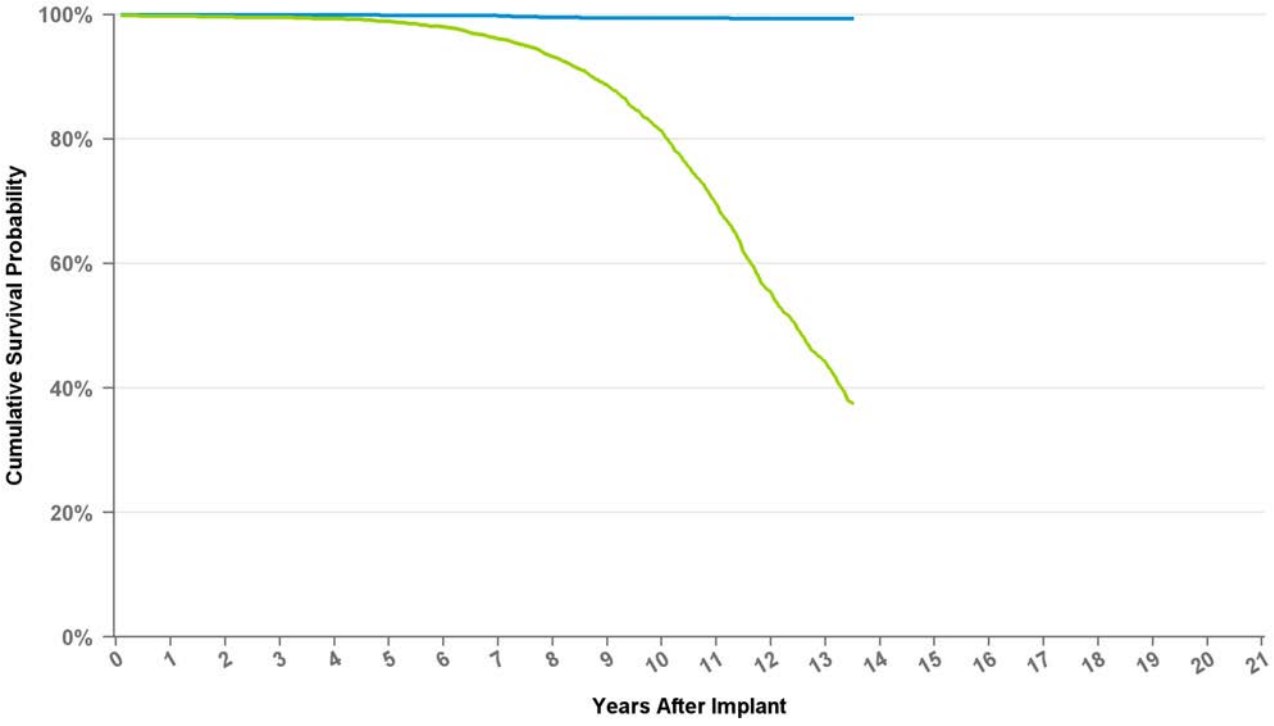
SD203 Sigma 200 D

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	225
Estimated Active US Implants	27
Normal Battery Depletions (US)	18

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	13	at 162 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%	99.3%	99.3%	99.3%
Including NBD	99.8%	99.7%	99.6%	99.3%	98.9%	98.0%	96.1%	93.2%	88.6%	81.2%	69.6%	55.3%	44.1%	37.5%
Effective Sample Size	14192	12719	11312	10127	8989	7951	6915	5991	5132	4047	2765	1498	547	134

Implantable Pulse Generator

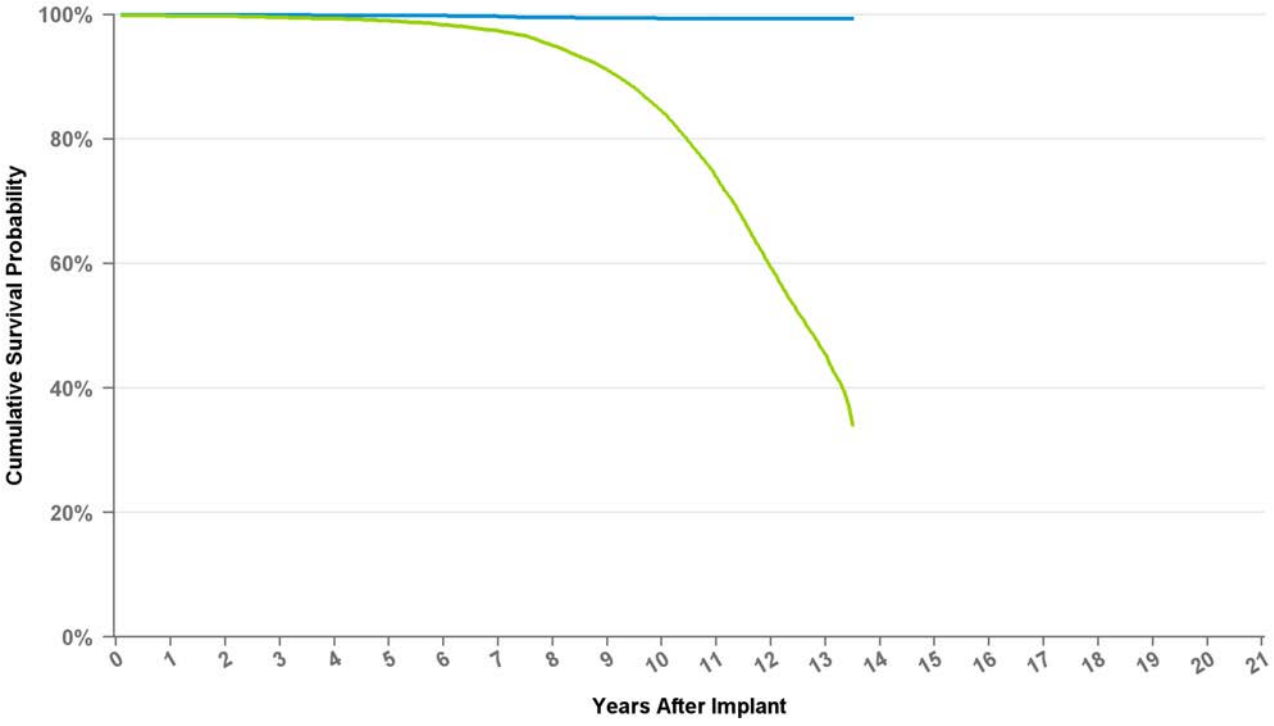
SD303 Sigma 300 D

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	122
Estimated Active US Implants	33
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	13	at 162 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%	99.3%
Including NBD	99.8%	99.8%	99.6%	99.3%	99.0%	98.3%	97.4%	95.0%	91.1%	84.4%	73.9%	59.4%	45.5%	34.1%
Effective Sample Size	96563	86479	77383	69000	61424	54715	47865	40195	31621	23085	14385	6951	2094	343

Implantable Pulse Generator

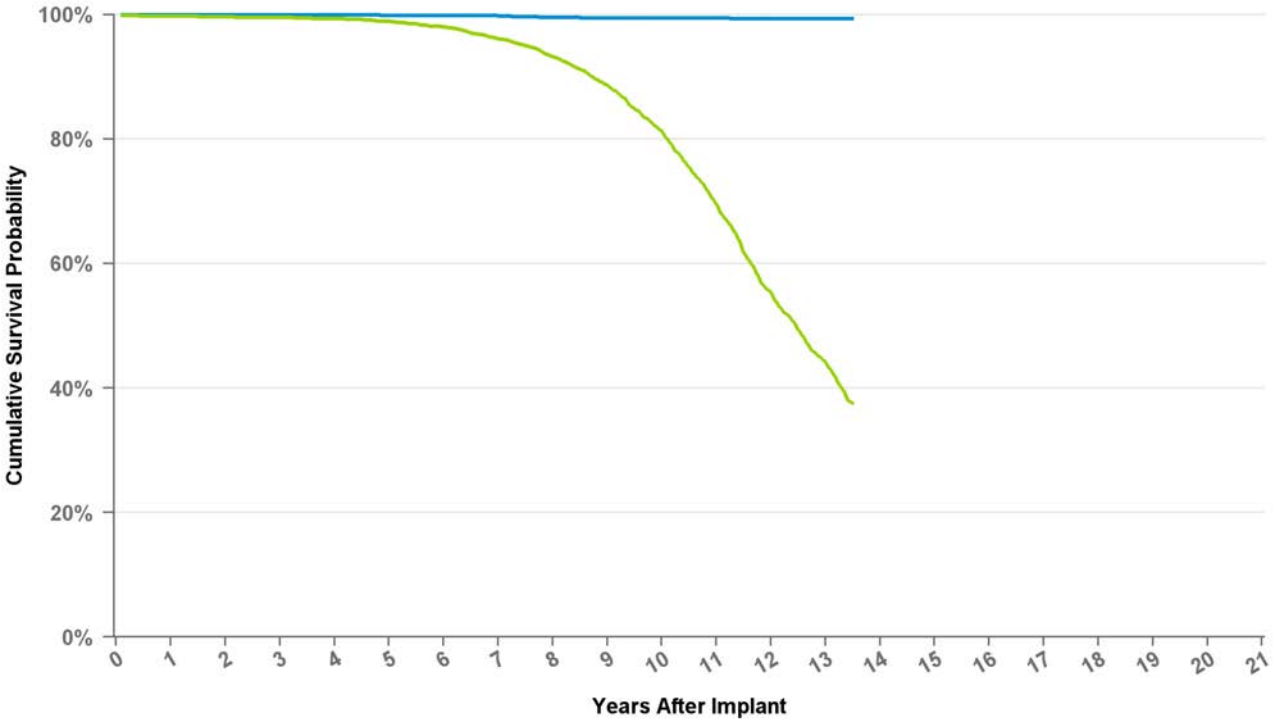
SDR203 Sigma 200 DR

US Market Release Date	8/31/1999
CE Market Approval Date	12/17/1998
Registered US Implants	15,643
Estimated Active US Implants	2,662
Normal Battery Depletions (US)	1,132

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	38
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	28
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	25
Other Malfunction	1
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	13	at 162 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%	99.3%	99.3%	99.3%
Including NBD	99.8%	99.7%	99.6%	99.3%	98.9%	98.0%	96.1%	93.2%	88.6%	81.2%	69.6%	55.3%	44.1%	37.5%
Effective Sample Size	14192	12719	11312	10127	8989	7951	6915	5991	5132	4047	2765	1498	547	134

Implantable Pulse Generator

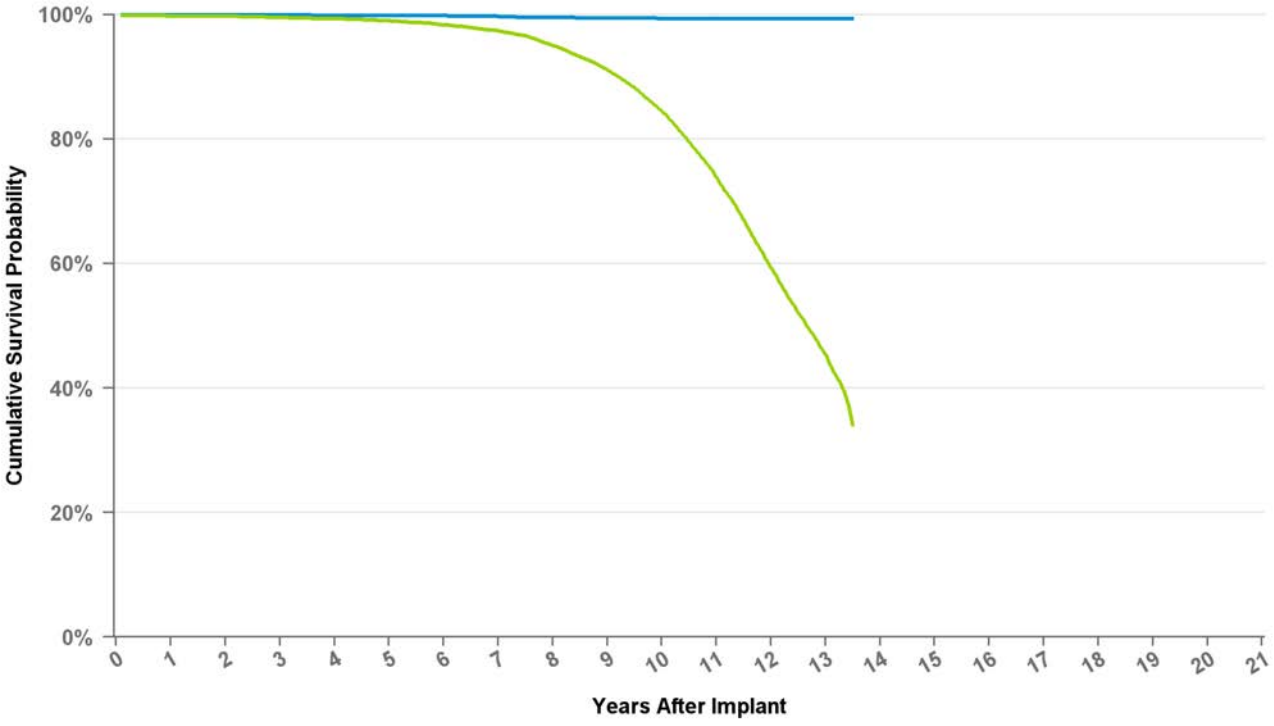
SDR303 Sigma 300 DR

US Market Release Date	8/26/1999
CE Market Approval Date	12/17/1998
Registered US Implants	105,564
Estimated Active US Implants	25,068
Normal Battery Depletions (US)	6,068

NBG Code	DDD/RO
Max Delivered Energy	N/A

Total Malfunctions (US)	273
Therapy Not Compromised Malfunction	60
Battery Malfunction	0
Electrical Component	9
Electrical Interconnect	49
Other Malfunction	1
Poss Early Battery Depltn	1
Software Malfunction	0
Therapy Compromised Malfunctions	213
Battery Malfunction	0
Electrical Component	7
Electrical Interconnect	205
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	13	at 162 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%	99.3%
Including NBD	99.8%	99.8%	99.6%	99.3%	99.0%	98.3%	97.4%	95.0%	91.1%	84.4%	73.9%	59.4%	45.5%	34.1%
Effective Sample Size	96563	86479	77383	69000	61424	54715	47865	40195	31621	23085	14385	6951	2094	343

Implantable Pulse Generator

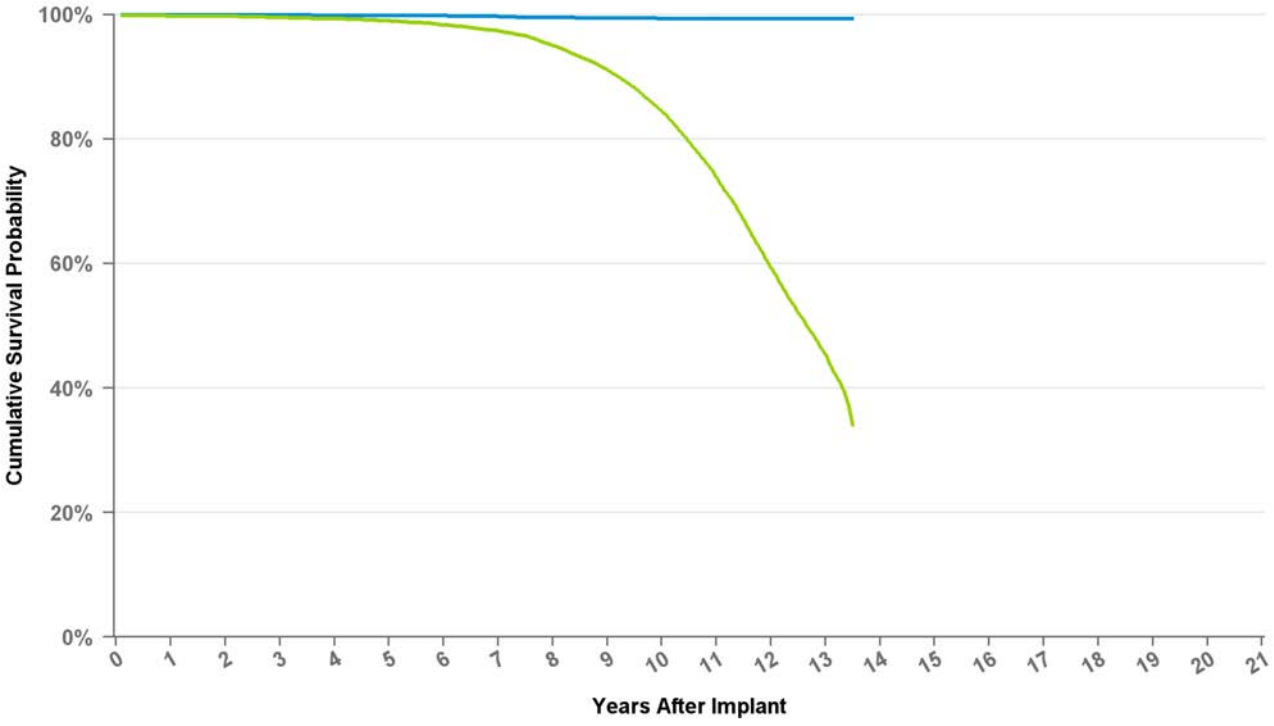
SDR306 Sigma 300 DR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	1,209
Estimated Active US Implants	163
Normal Battery Depletions (US)	139

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	13	at 162 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%	99.3%
Including NBD	99.8%	99.8%	99.6%	99.3%	99.0%	98.3%	97.4%	95.0%	91.1%	84.4%	73.9%	59.4%	45.5%	34.1%
Effective Sample Size	96563	86479	77383	69000	61424	54715	47865	40195	31621	23085	14385	6951	2094	343

Implantable Pulse Generator

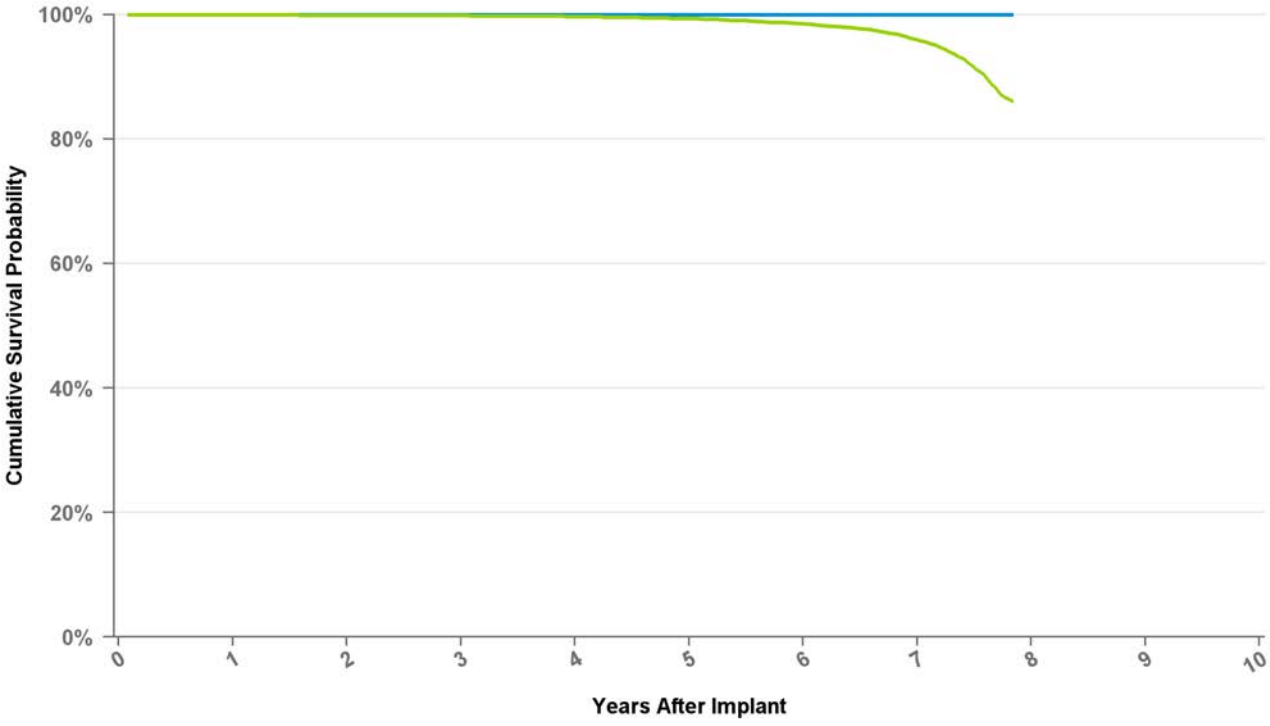
SED01 Sensia D

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	3
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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 94 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%	99.3%	98.5%	95.9%	86.0%
Effective Sample Size	117121	96637	76479	57066	38802	21389	7666	193

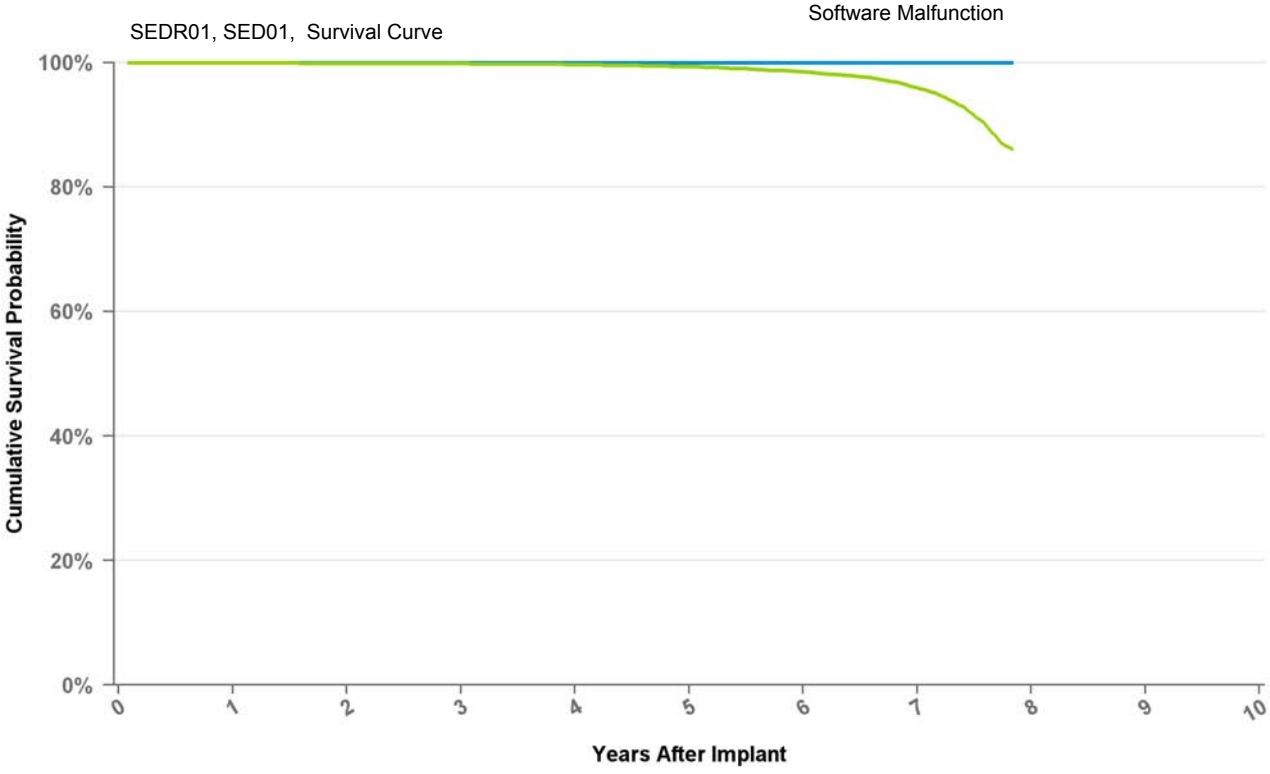
Implantable Pulse Generator

SEDR01 Sensia DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	135,852
Estimated Active US Implants	100,522
Normal Battery Depletions (US)	706

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	26
Therapy Not Compromised Malfunction	16
Battery Malfunction	0
Electrical Component	12
Electrical Interconnect	3
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



Years	1	2	3	4	5	6	7	at 94 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%	99.3%	98.5%	95.9%	86.0%
Effective Sample Size	117121	96637	76479	57066	38802	21389	7666	193

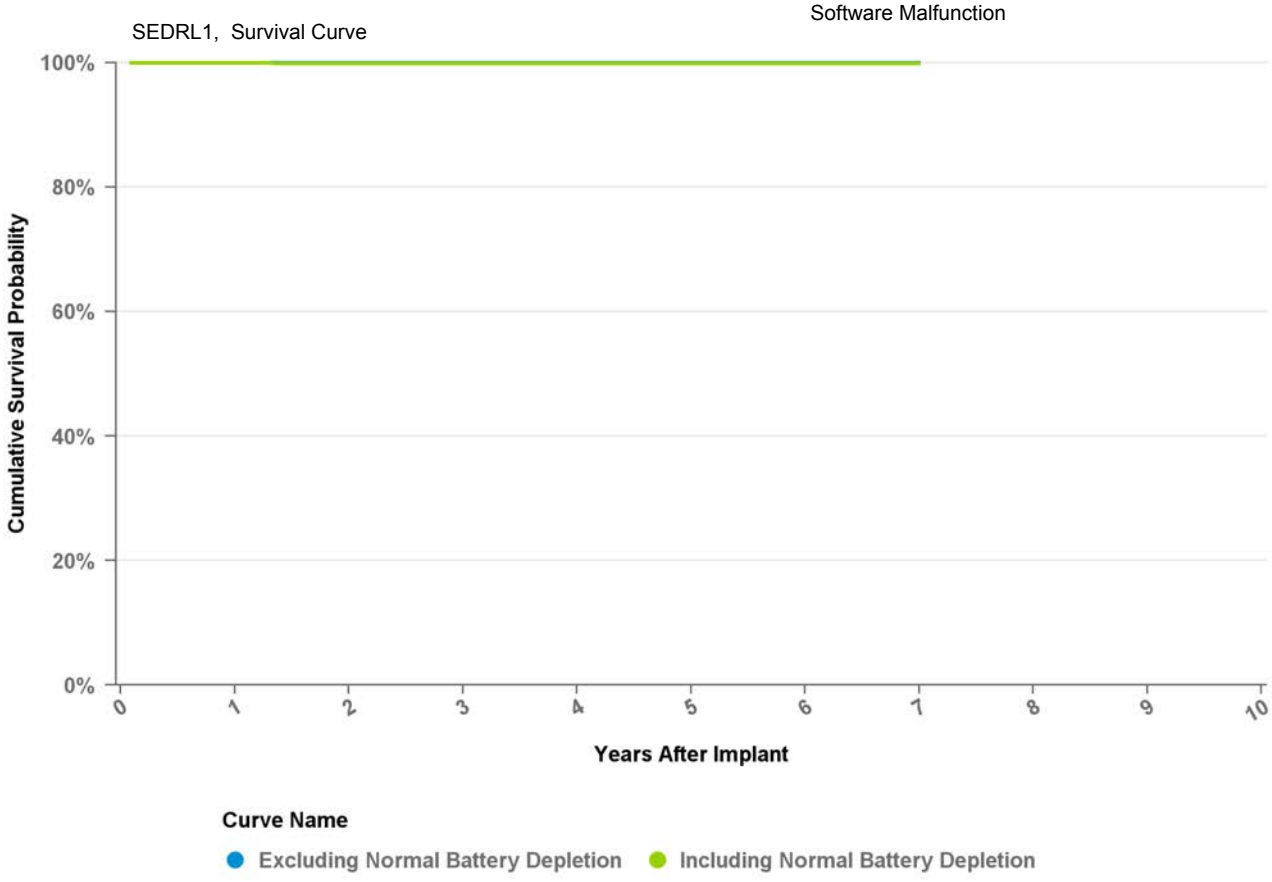
Implantable Pulse Generator

SEDRL1 Sensia DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	1
Estimated Active US Implants	1
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



Years	1	2	3	4	5	6	at 84 mo
Excluding NBD	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	99.9%	99.9%	99.9%	99.9%	99.9%	99.9%
Effective Sample Size	3486	2953	2349	1709	1032	523	122

Implantable Pulse Generator

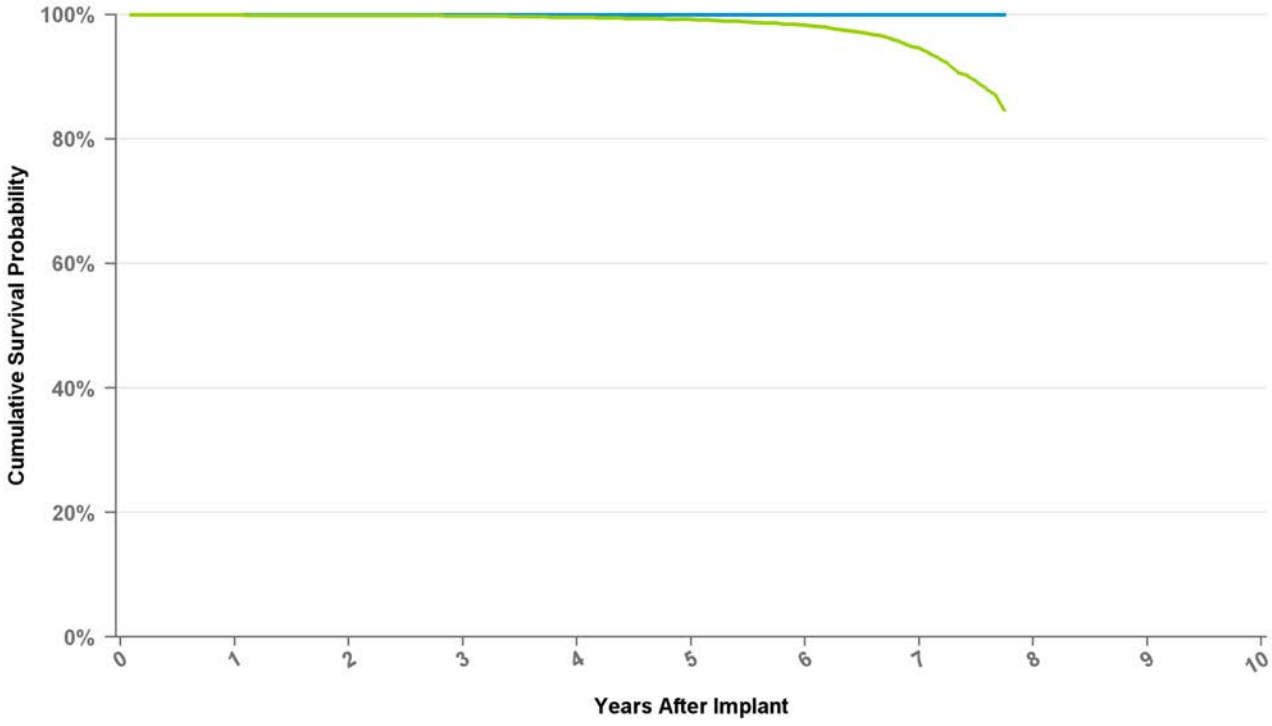
SES01 Sensia S

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 93 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%	99.2%	98.3%	94.6%	84.6%
Effective Sample Size	81984	64026	47496	33493	21512	11180	3812	179

Implantable Pulse Generator

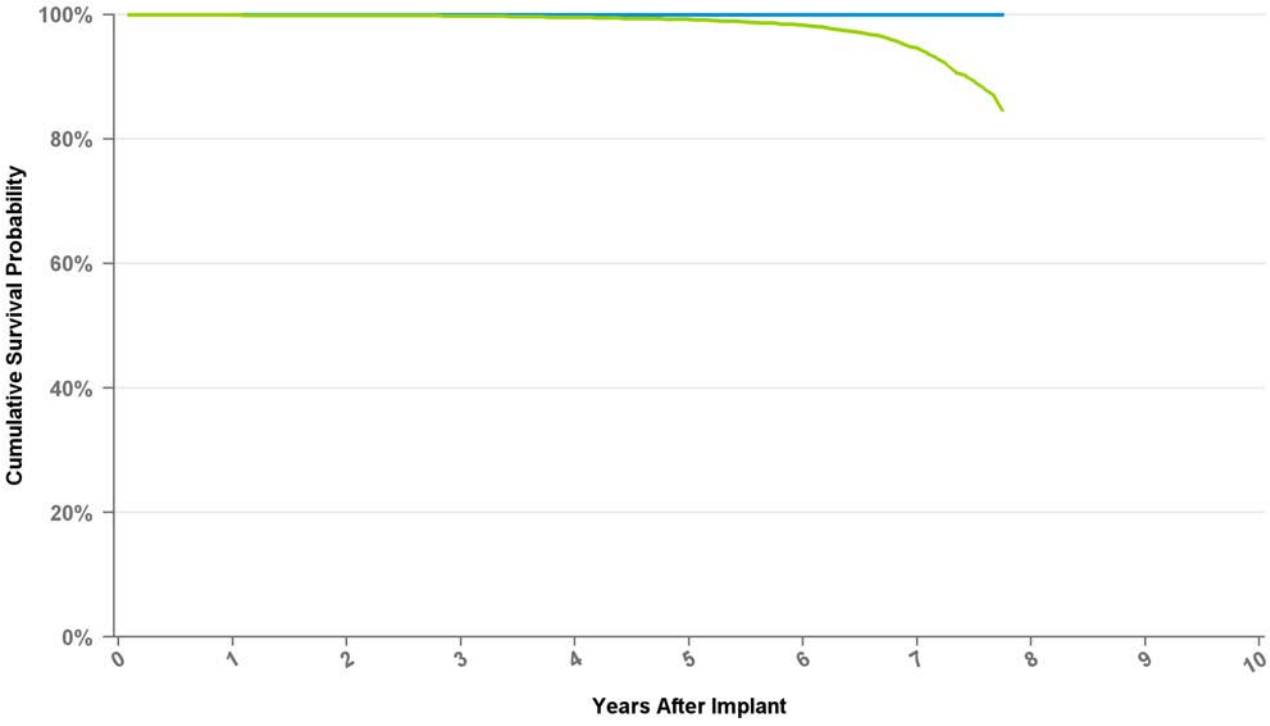
SESR01 Sensia SR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	98,308
Estimated Active US Implants	68,329
Normal Battery Depletions (US)	485

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	10
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	3
Battery Malfunction	0
Electrical Component	2
Electrical Interconnect	1
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0

SESR01, SES01, Survival Curve



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	at 93 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%	99.2%	98.3%	94.6%	84.6%
Effective Sample Size	81984	64026	47496	33493	21512	11180	3812	179

Implantable Pulse Generator

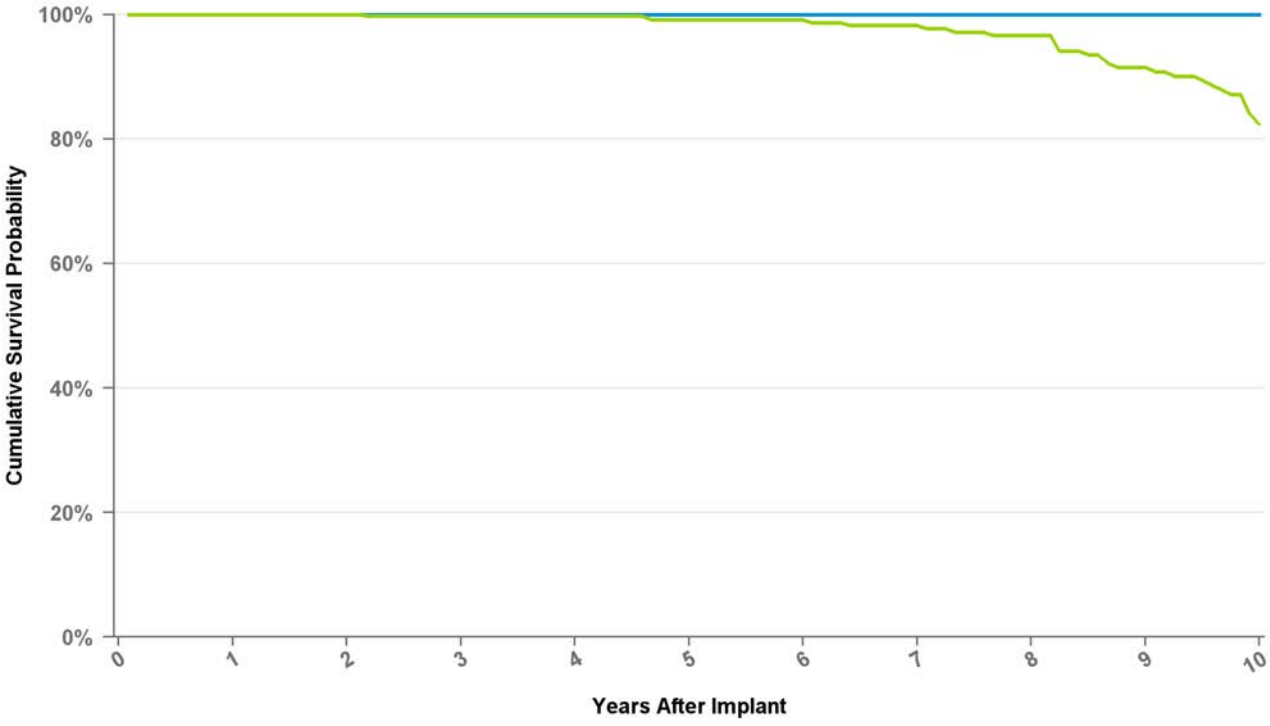
SS103 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	765
Estimated Active US Implants	98
Normal Battery Depletions (US)	23

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	10	at 124 mo
Excluding NBD	100.0%	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%	99.8%	99.8%	99.1%	99.1%	98.2%	96.6%	91.5%	82.4%	82.4%
Effective Sample Size	631	503	402	327	259	230	197	167	133	106	100

Implantable Pulse Generator

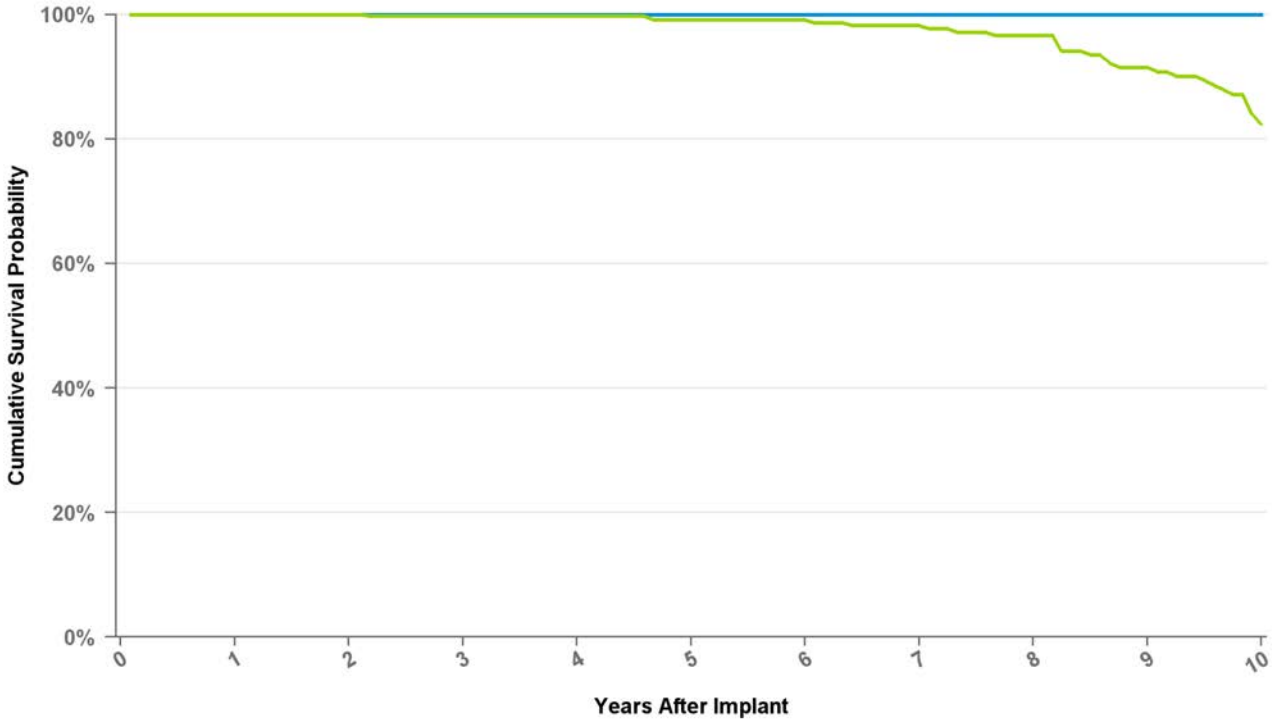
SS106 Sigma 100 S

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	68
Estimated Active US Implants	4
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



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%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Including NBD	100.0%	100.0%	99.8%	99.8%	99.1%	99.1%	98.2%	96.6%	91.5%	82.4%	82.4%
Effective Sample Size	631	503	402	327	259	230	197	167	133	106	100

Implantable Pulse Generator

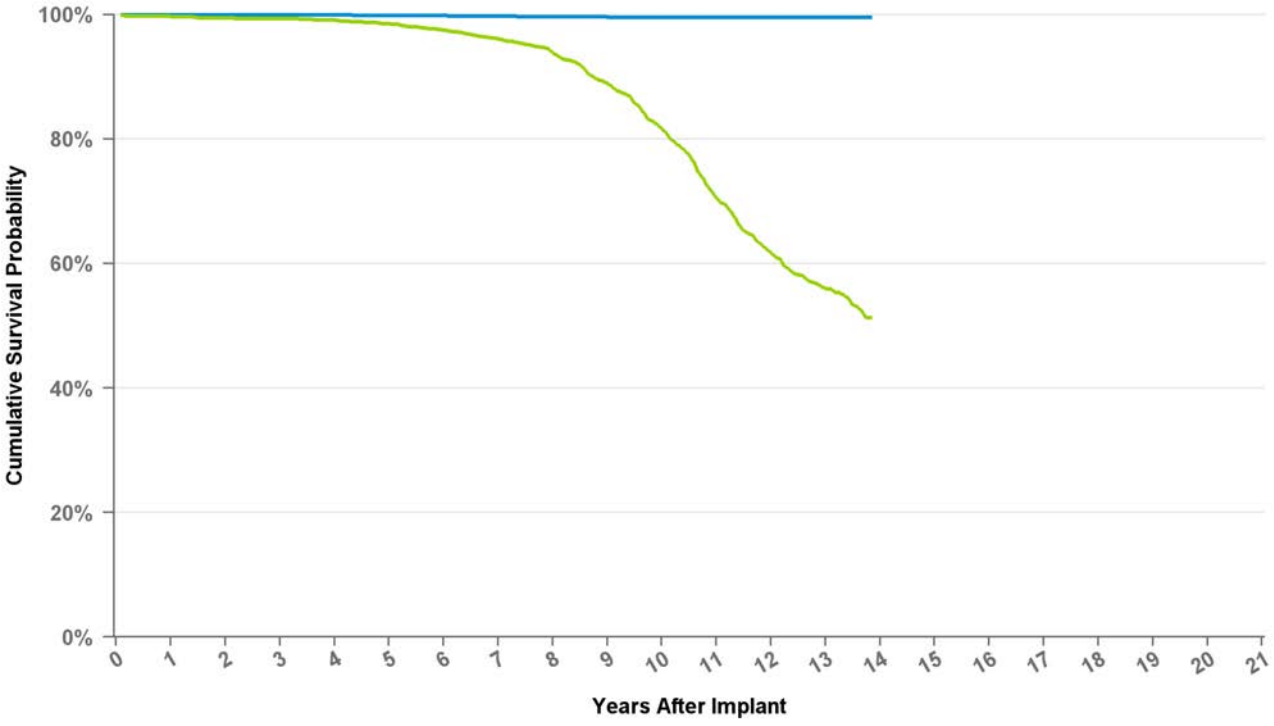
SS203 Sigma 200 S

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 166 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	99.7%	99.5%	99.3%	99.1%	98.5%	97.5%	96.1%	93.8%	88.9%	81.6%	70.6%	61.7%	56.0%	51.3%
Effective Sample Size	10339	8716	7406	6355	5455	4722	4044	3560	3042	2420	1727	1147	604	114

Implantable Pulse Generator

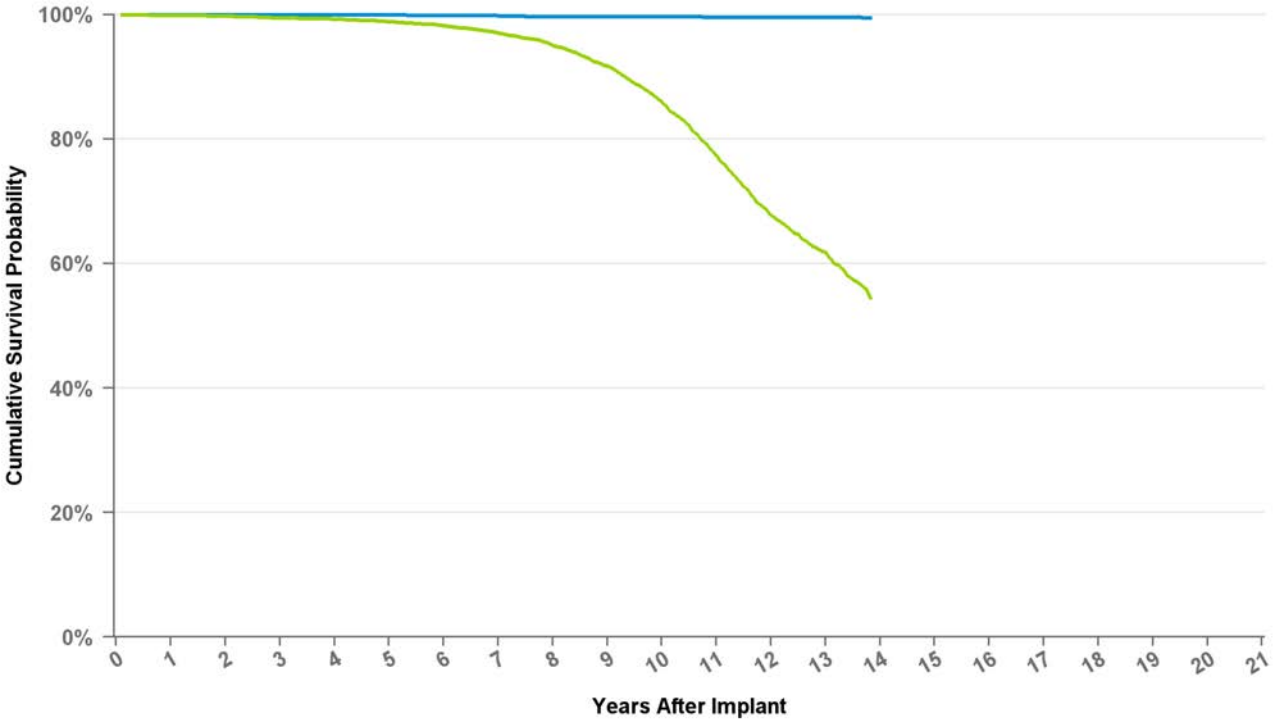
SS303 Sigma 300 S

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



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 166 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%	99.5%
Including NBD	99.9%	99.8%	99.5%	99.2%	98.8%	98.2%	97.0%	95.0%	91.7%	85.9%	77.4%	67.8%	61.8%	54.4%
Effective Sample Size	47119	39973	34121	29345	25385	22055	18846	15542	12409	9180	5880	3188	1441	118

Implantable Pulse Generator

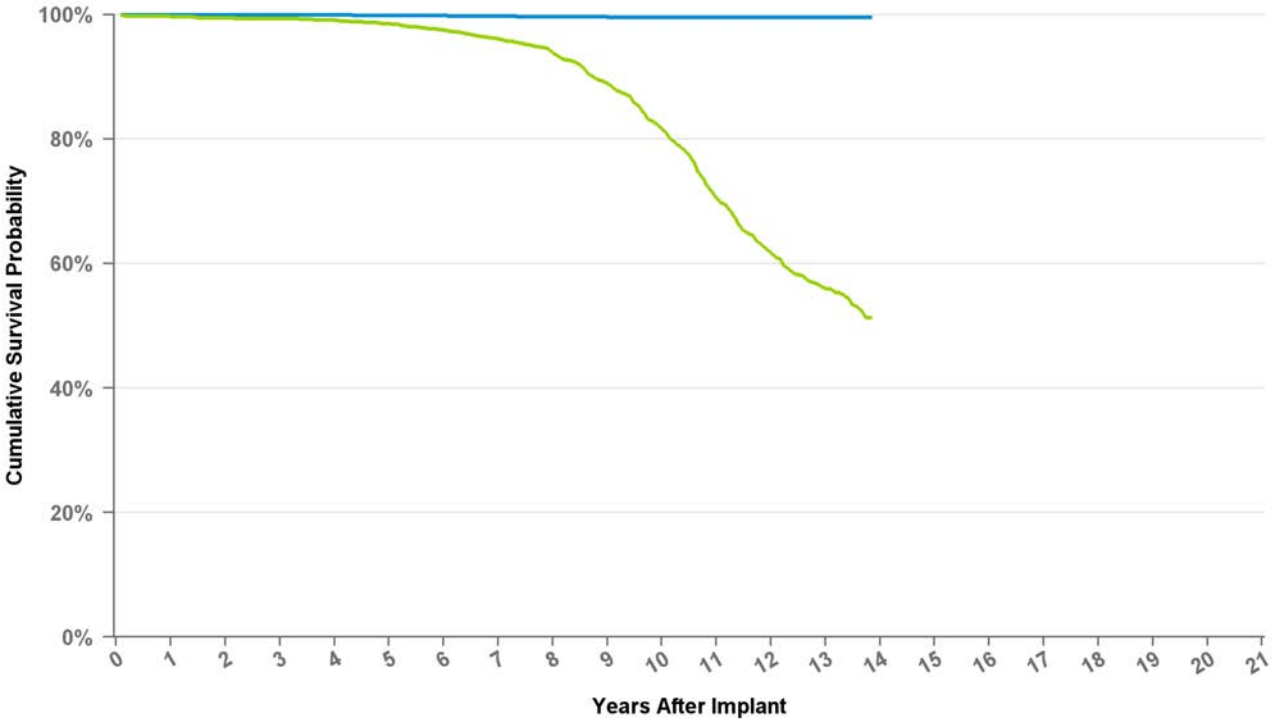
SSR203 Sigma 200 SR

US Market Release Date	9/2/1999
CE Market Approval Date	
Registered US Implants	12,123
Estimated Active US Implants	1,565
Normal Battery Depletions (US)	545

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 166 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	99.7%	99.5%	99.3%	99.1%	98.5%	97.5%	96.1%	93.8%	88.9%	81.6%	70.6%	61.7%	56.0%	51.3%
Effective Sample Size	10339	8716	7406	6355	5455	4722	4044	3560	3042	2420	1727	1147	604	114

Implantable Pulse Generator

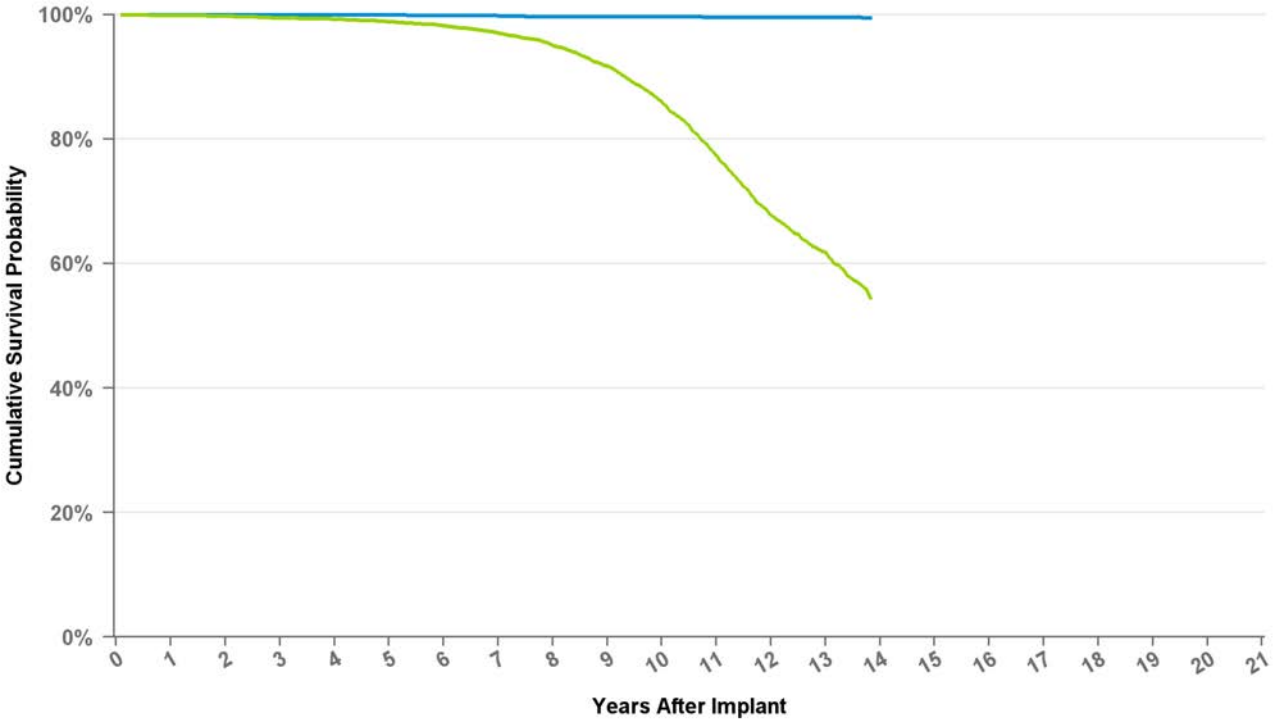
SSR303 Sigma 300 SR

US Market Release Date	8/30/1999
CE Market Approval Date	12/17/1998
Registered US Implants	51,697
Estimated Active US Implants	9,040
Normal Battery Depletions (US)	1,817

NBG Code	SSIR
Max Delivered Energy	N/A

Total Malfunctions (US)	57
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	43
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	40
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	13	at 166 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%	99.5%
Including NBD	99.9%	99.8%	99.5%	99.2%	98.8%	98.2%	97.0%	95.0%	91.7%	85.9%	77.4%	67.8%	61.8%	54.4%
Effective Sample Size	47119	39973	34121	29345	25385	22055	18846	15542	12409	9180	5880	3188	1441	118

Implantable Pulse Generator

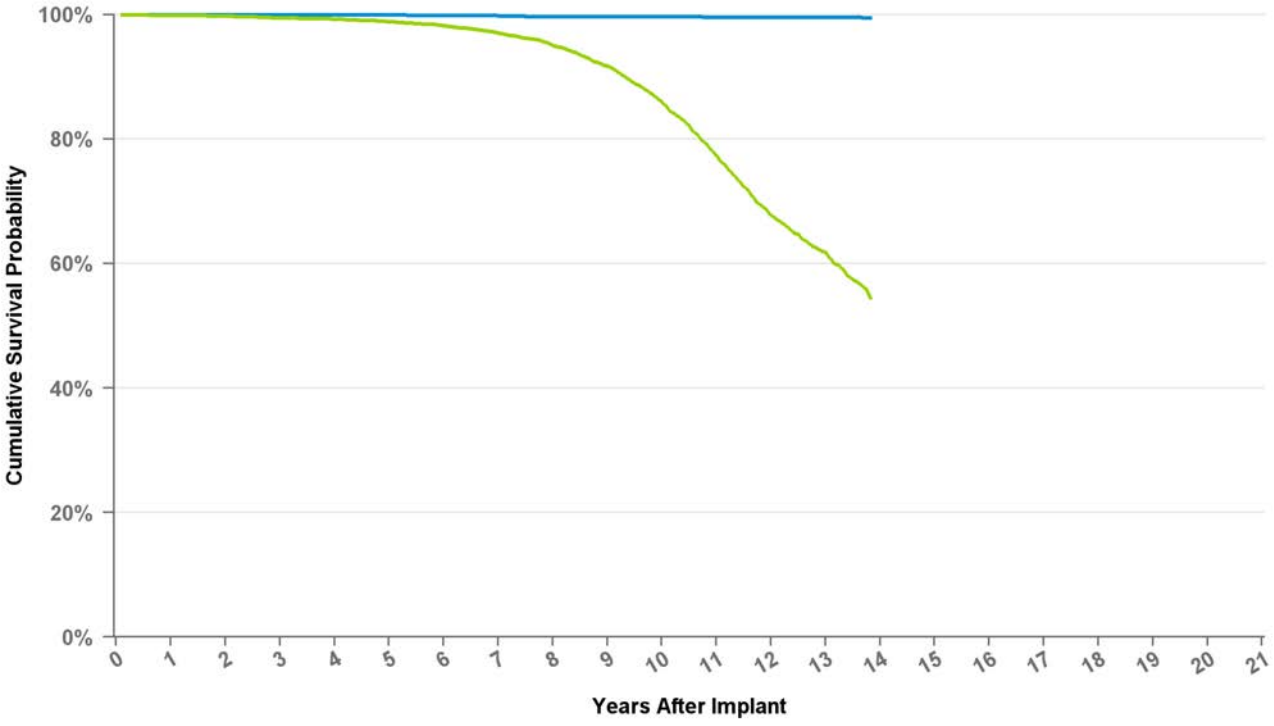
SSR306 Sigma 300 SR

US Market Release Date	9/7/1999
CE Market Approval Date	12/17/1998
Registered US Implants	2,218
Estimated Active US Implants	298
Normal Battery Depletions (US)	131

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	13	at 166 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%	99.5%
Including NBD	99.9%	99.8%	99.5%	99.2%	98.8%	98.2%	97.0%	95.0%	91.7%	85.9%	77.4%	67.8%	61.8%	54.4%
Effective Sample Size	47119	39973	34121	29345	25385	22055	18846	15542	12409	9180	5880	3188	1441	118

Implantable Pulse Generator

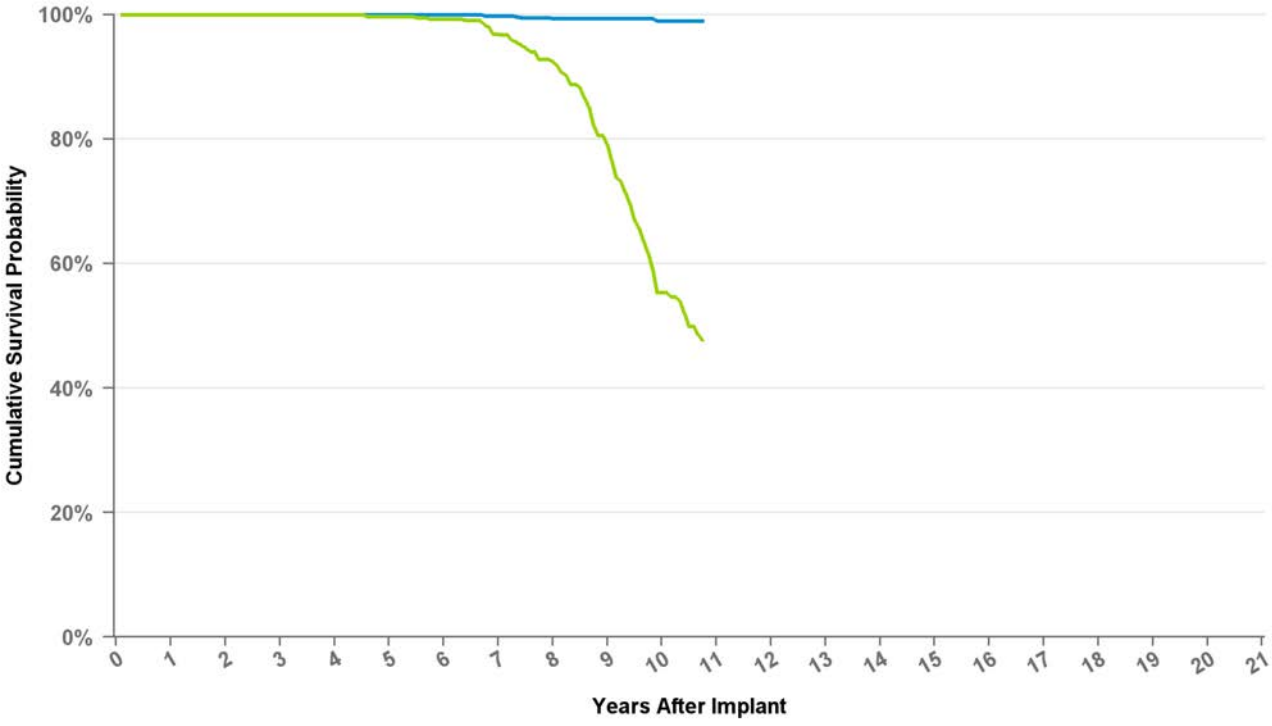
SVDD303 Sigma 300 VDD

US Market Release Date	9/15/1999
CE Market Approval Date	12/17/1998
Registered US Implants	650
Estimated Active US Implants	72
Normal Battery Depletions (US)	79

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



Curve Name

Excluding Normal Battery Depletion Including Normal Battery Depletion

Years	1	2	3	4	5	6	7	8	9	10	at 129 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%	100.0%	100.0%	100.0%	99.7%	99.2%	96.8%	92.4%	79.2%	55.3%	47.7%
Effective Sample Size	891	818	765	708	646	589	525	455	339	180	105

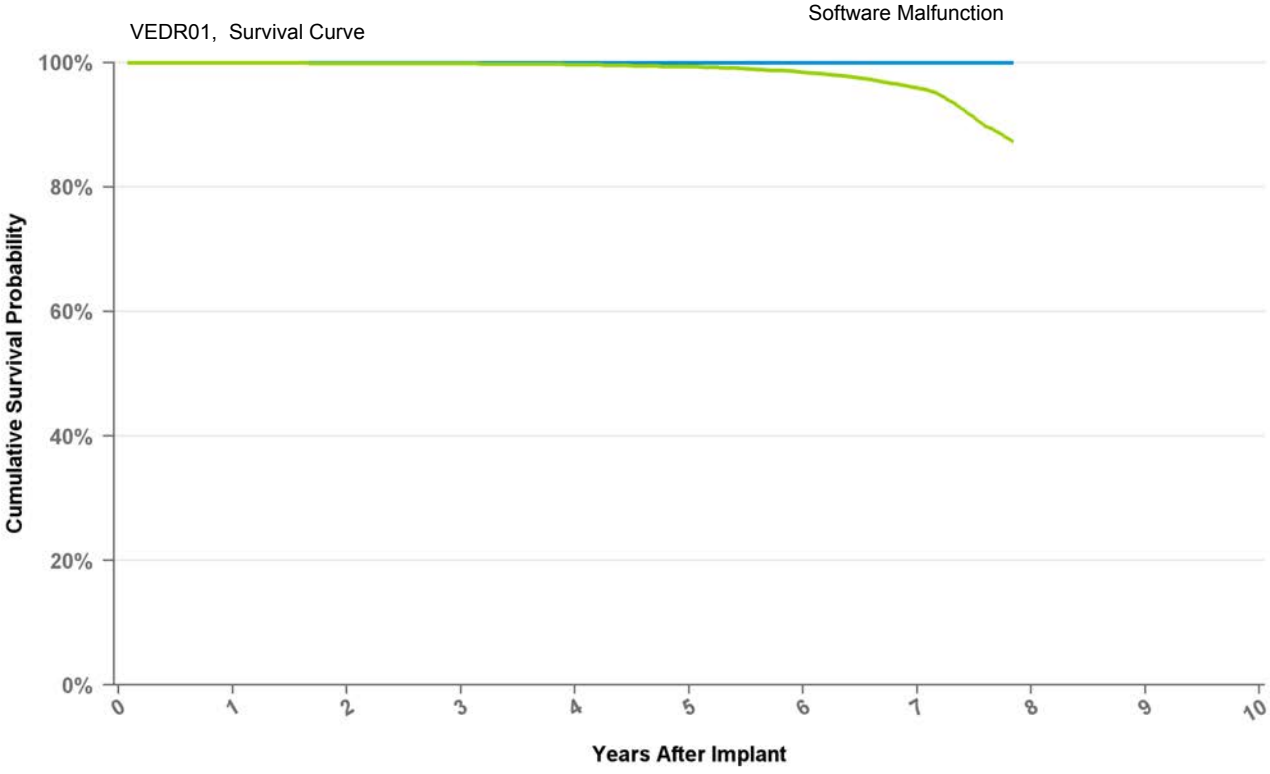
Implantable Pulse Generator

VEDR01 Versa DR

US Market Release Date	7/17/2006
CE Market Approval Date	9/20/2005
Registered US Implants	104,462
Estimated Active US Implants	77,602
Normal Battery Depletions (US)	719

NBG Code	DDDR
Max Delivered Energy	N/A

Total Malfunctions (US)	17
Therapy Not Compromised Malfunction	10
Battery Malfunction	0
Electrical Component	8
Electrical Interconnect	2
Other Malfunction	0
Poss Early Battery Depltn	0
Software Malfunction	0
Therapy Compromised Malfunctions	7
Battery Malfunction	0
Electrical Component	3
Electrical Interconnect	0
Other Malfunction	4
Poss Early Battery Depltn	0
Software Malfunction	0



Years	1	2	3	4	5	6	7	at 94 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%	99.3%	98.4%	95.9%	87.3%
Effective Sample Size	94281	80068	64908	50002	35463	21461	8956	287

Method for Estimating Lead Performance

Medtronic Cardiac Rhythm and Heart Failure (CRHF) 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 easily based on mechanical measurements, 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. Some leads are modified due to adverse device effect, however may not be explanted. 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 prospective 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 PAN Registry. The PAN Registry is a patient centric surveillance platform which follows patients implanted with Medtronic cardiac rhythm product(s). The Product Performance Report (PPR) tracks PAN Registry enrolled patients to monitor lead performance status in vivo. 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 clinical events that are classified as product performance events, and do not differentiate a lead hardware failure from other clinical events such as Failure to capture, perforation, dislodgement, or concurrent pulse generator failure.

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 product surveillance registry is a world-wide study that 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 rhythm 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. Patients are enrolled upon implantation of a Medtronic Cardiac rhythm product. 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. Number of enrollments is reviewed regularly to ensure adequate sample size is obtained for each individual product. 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 is require to inform Medtronic whenever a lead event has occurred, a lead is modified, or when a patient is no longer participating. Timely, accurate, and complete reporting and analysis of safety information for surveillance is crucial for the protection of patients, clinicians, and the sponsor Medtronic continually evaluates the quality and integrity of the data through a combination of on-site and centralized monitoring activities.

Lead Complications

Chronic lead performance is characterized 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.

Method for Estimating Lead Performance continued

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 of 30 days or less after the implant are considered procedure related and therefore are not included as product performance events.

- Product performance events includes, but not limited to: 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

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.

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. This phenomenon is called Left-truncation[2]. PPR lead survival analysis is estimated using the Kaplan-Meier method, a statistical method to incorporate data from these retrospectively enrolled devices, left-truncated data, was applied. The statistical technique 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 for each lead model. The survival estimates is the probability that a lead is free of a product performance event at a given time point. 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 sample size increases and performance experience accumulates, the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood’s formula is used to calculate the standard errors, and the log-log method is used to produce the 2-sided 95% confidence bounds.

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

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

Method for Estimating Lead Performance continued

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 CRHF 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 CRHF and found, through analysis, to actually have performed outside the performance limits established by Medtronic.

For leads designed for either ventricular or atrial use, the numbers listed in the Returned Product Analysis tables include both.

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

Method for Estimating Lead Performance continued

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.

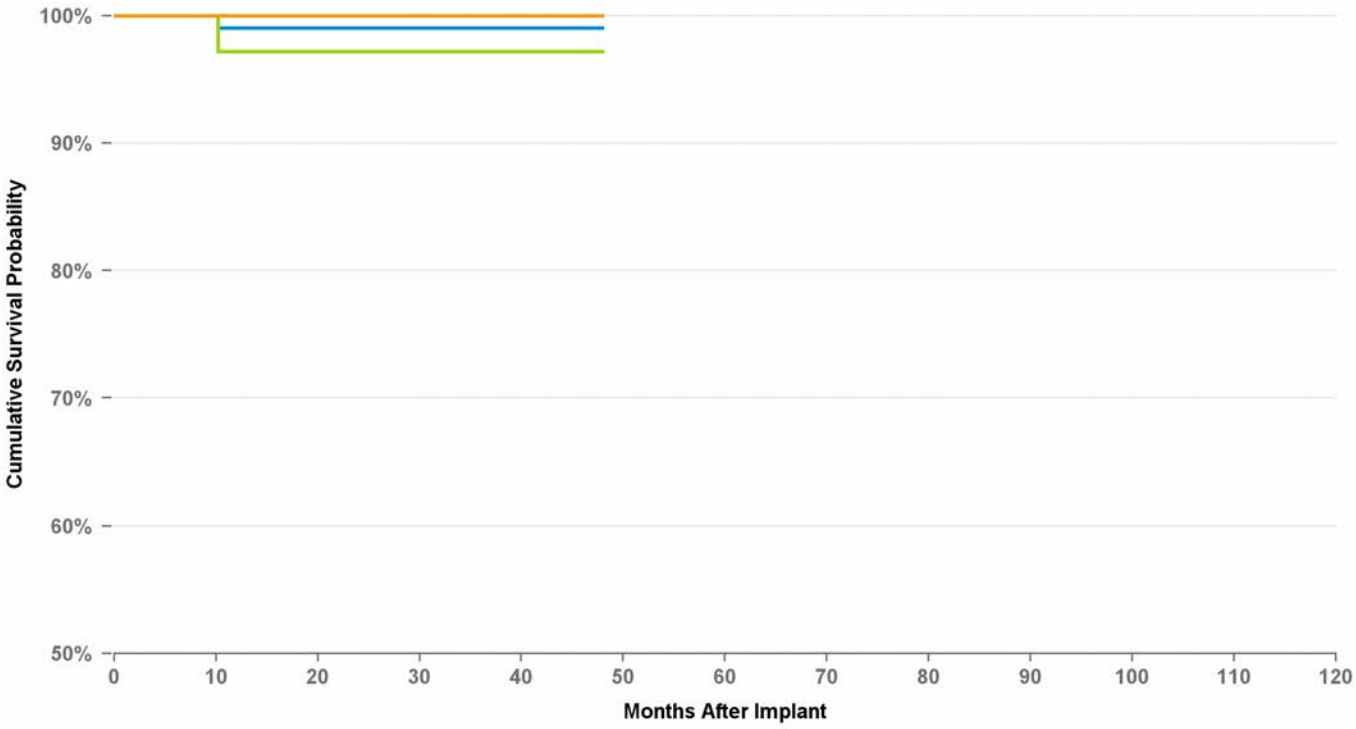
LEFT HEART PACING LEAD 2187

Distribution Data	
US Market Release	8/28/2001
CE Approval Date	
Registered US Implant	11,982
Estimated Active US	2,569
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	6,361
Number of Leads Active in Study	11

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

2187, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 48 mo
%	99.0%	99.0%	99.0%	99.0%
#	100	84	64	52

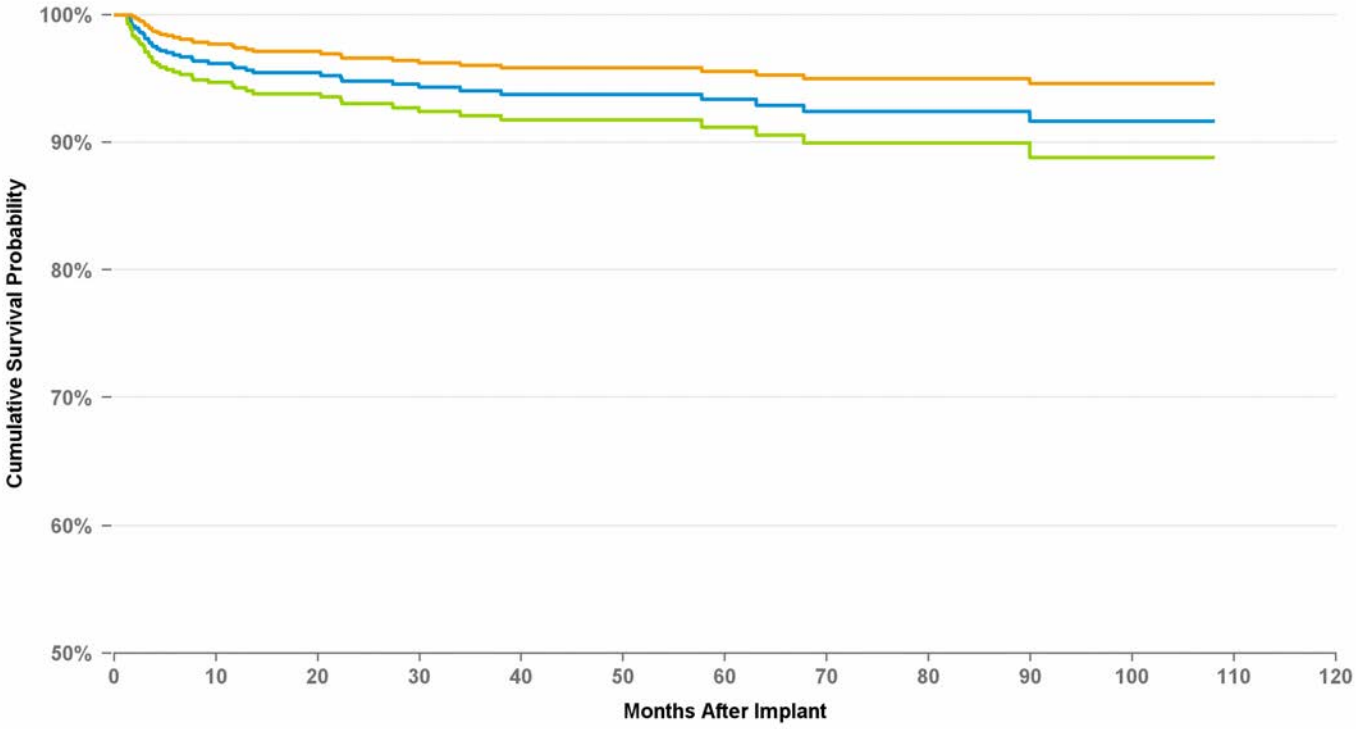
LEFT HEART PACING LEAD 4193

Distribution Data	
US Market Release	5/3/2002
CE Approval Date	12/22/2000
Registered US Implant	100,767
Estimated Active US	32,414
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	730
Cumulative Months of Follow-Up	31,719
Number of Leads Active in Study	115

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	17
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	58
Crimp Weld Bond	0
Insulation Breach	12
Other	48

4193, Survival Curve



Years	1	2	3	4	5	6	7	8	at 108 mo
%	95.8%	94.8%	94.0%	93.8%	93.4%	92.4%	92.4%	91.7%	91.7%
#	547	413	341	268	208	173	139	105	68

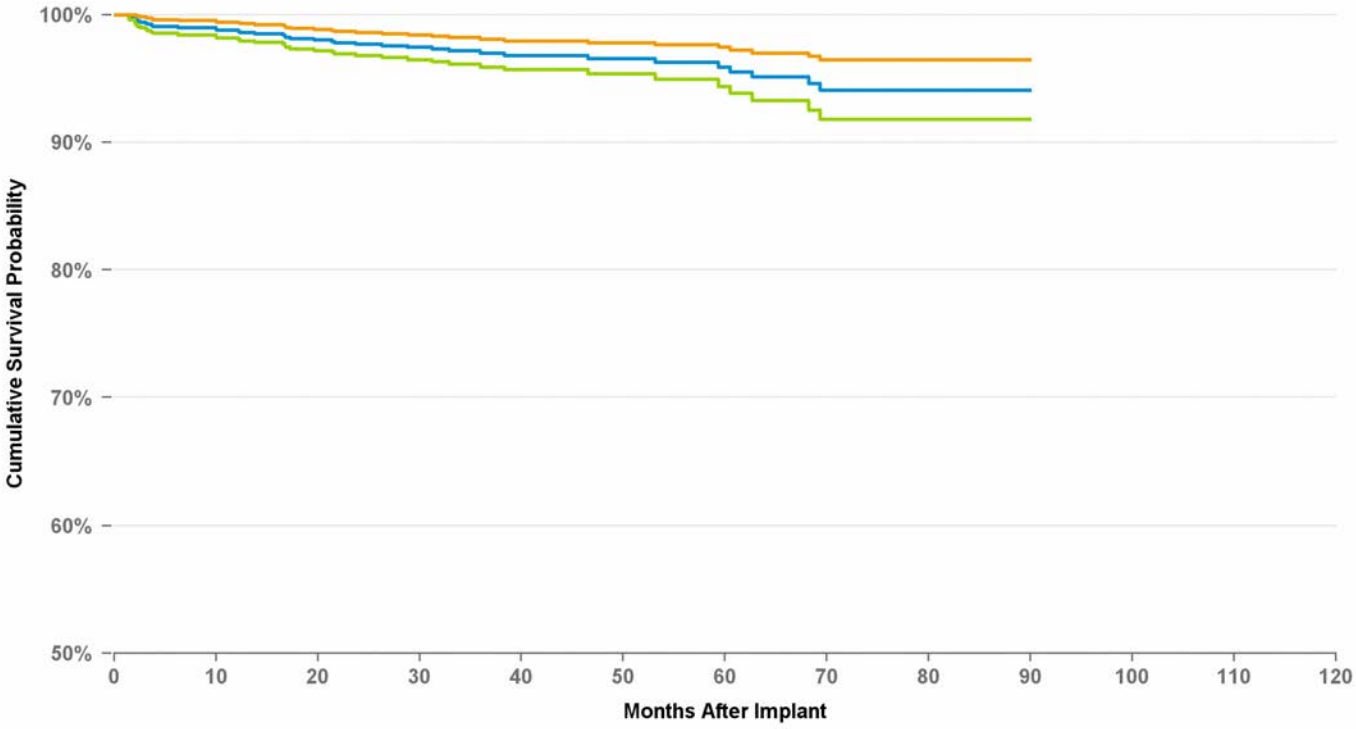
LEFT HEART PACING LEAD 4194

Distribution Data	
US Market Release	8/24/2004
CE Approval Date	7/14/2003
Registered US Implant	112,706
Estimated Active US	65,348
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	1,427
Cumulative Months of Follow-Up	48,621
Number of Leads Active in Study	713

Product Surveilance Registry Qualifying Complications	40
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	7
Failure To Capture	10
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	1
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	2
Lead Dislodgement	19
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	2
Extracardiac Stimulation	39
Failure To Capture	39
Failure To Sense	0
Impedance Abnormal	6
Insulation Breach	0
Lead Dislodgement	140
Oversensing	2
Unspecified	5
USA Returned Product Analysis	
Conductor Fracture	16
Crimp Weld Bond	0
Insulation Breach	67
Other	9

4194, Survival Curve



Years	1	2	3	4	5	6	7	at 90 mo
%	98.8%	97.7%	97.0%	96.6%	95.9%	94.1%	94.1%	94.1%
#	1,070	846	591	366	232	145	85	57

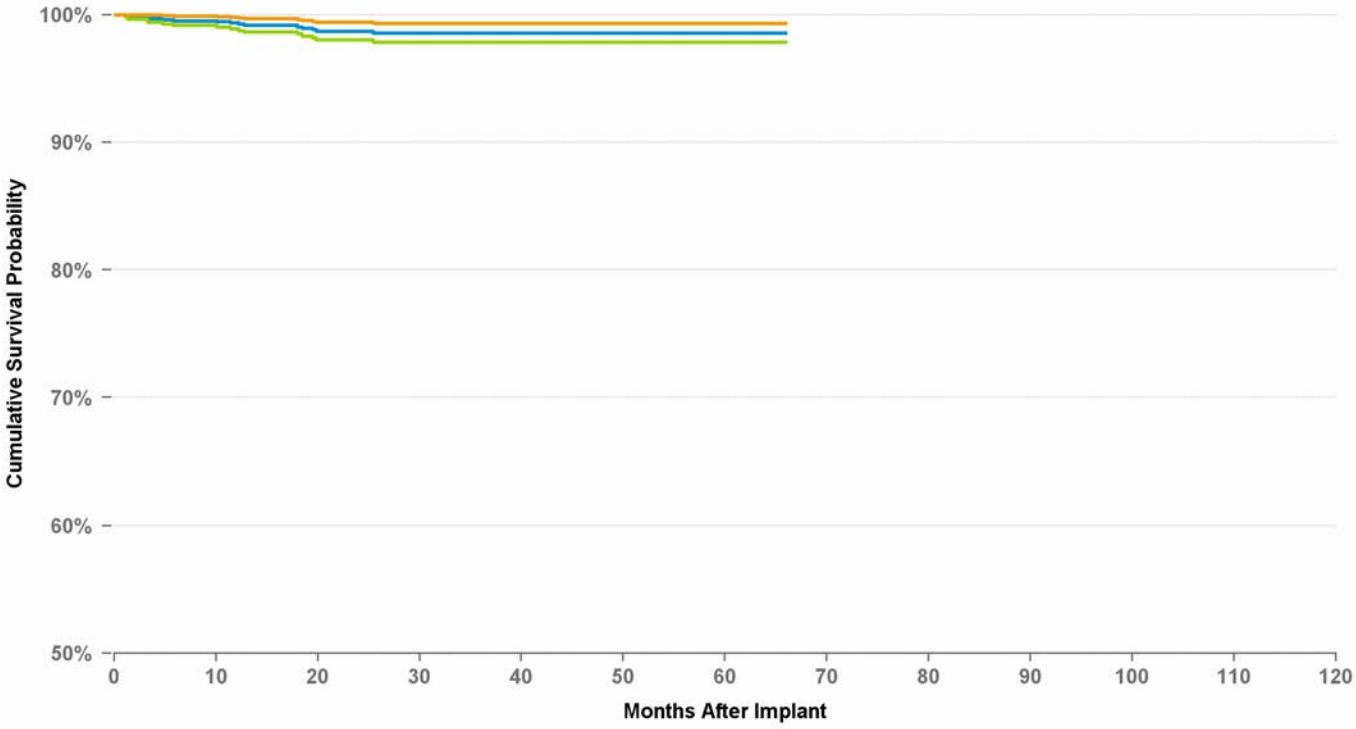
LEFT HEART PACING LEAD 4195

Distribution Data	
US Market Release	8/15/2008
CE Approval Date	5/13/2005
Registered US Implant	16,410
Estimated Active US	12,738
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	1,416
Cumulative Months of Follow-Up	39,099
Number of Leads Active in Study	893

Product Surveilance Registry Qualifying Complications	15
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	7
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	3
Medical Judgment	0
Other Complication	0
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	0
Extracardiac Stimulation	26
Failure To Capture	17
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	29
Oversensing	0
Unspecified	1
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	1
Other	4

4195, Survival Curve



Years	1	2	3	4	5	at 66 mo
%	99.3%	98.7%	98.6%	98.6%	98.6%	98.6%
#	1,081	753	451	177	62	50

LEFT HEART PACING LEAD 4196

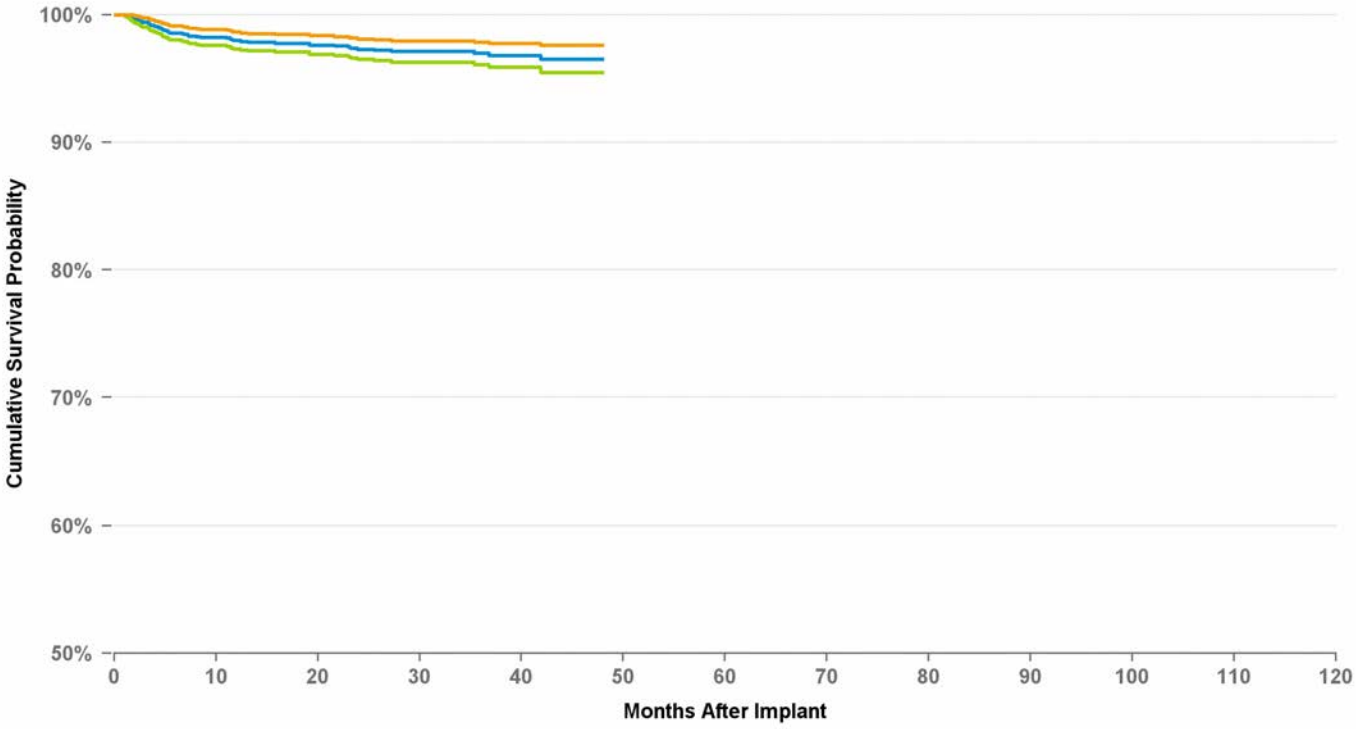
Distribution Data	
US Market Release	5/15/2009
CE Approval Date	7/24/2007
Registered US Implant	59,563
Estimated Active US	48,922
Product Characteristics	
Fixation Type	Double Curve
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,015
Cumulative Months of Follow-Up	53,327
Number of Leads Active in Study	1,000

Product Surveilance Registry Qualifying Complications	51
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	12
Failure To Capture	17
Failure To Sense	0
Impedance Abnormal	1
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	19
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	1
Conductor Fracture	2
Extracardiac Stimulation	73
Failure To Capture	44
Failure To Sense	1
Impedance Abnormal	7
Insulation Breach	1
Lead Dislodgement	159
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	0
Other	10

4196, Survival Curve



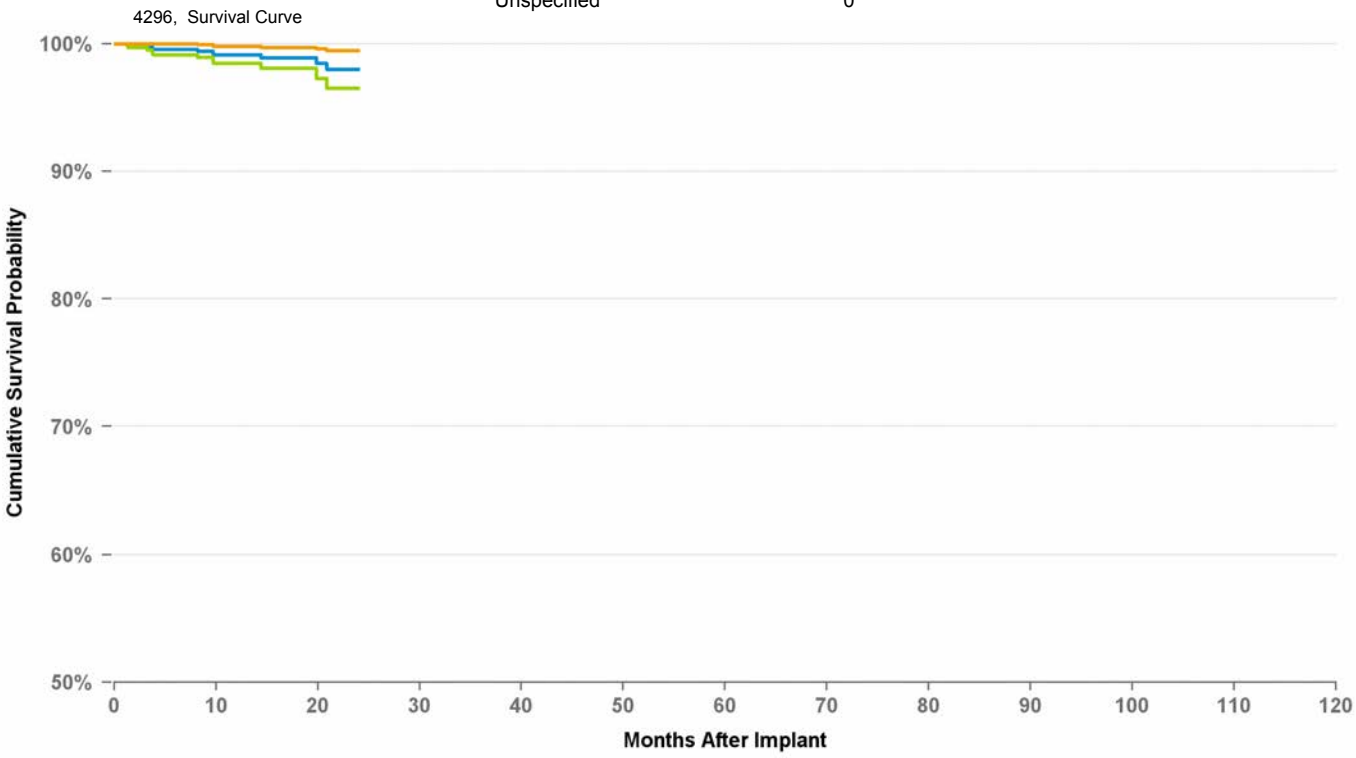
Years	1	2	3	at 48 mo
%	98.0%	97.3%	97.0%	96.5%
#	1,549	1,147	608	135

LEFT HEART PACING LEAD 4296

Distribution Data	
US Market Release	4/1/2011
CE Approval Date	12/18/2009
Registered US Implant	25,912
Estimated Active US	24,118
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	1,254
Cumulative Months of Follow-Up	13,332
Number of Leads Active in Study	966

Product Surveilance Registry Qualifying Complications	10
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	2
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	5
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	2
Conductor Fracture	0
Extracardiac Stimulation	32
Failure To Capture	12
Failure To Sense	0
Impedance Abnormal	8
Insulation Breach	2
Lead Dislodgement	82
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	2
Crimp Weld Bond	1
Insulation Breach	0
Other	2



Years	1	at 24 mo
%	99.1%	98.0%
#	523	100

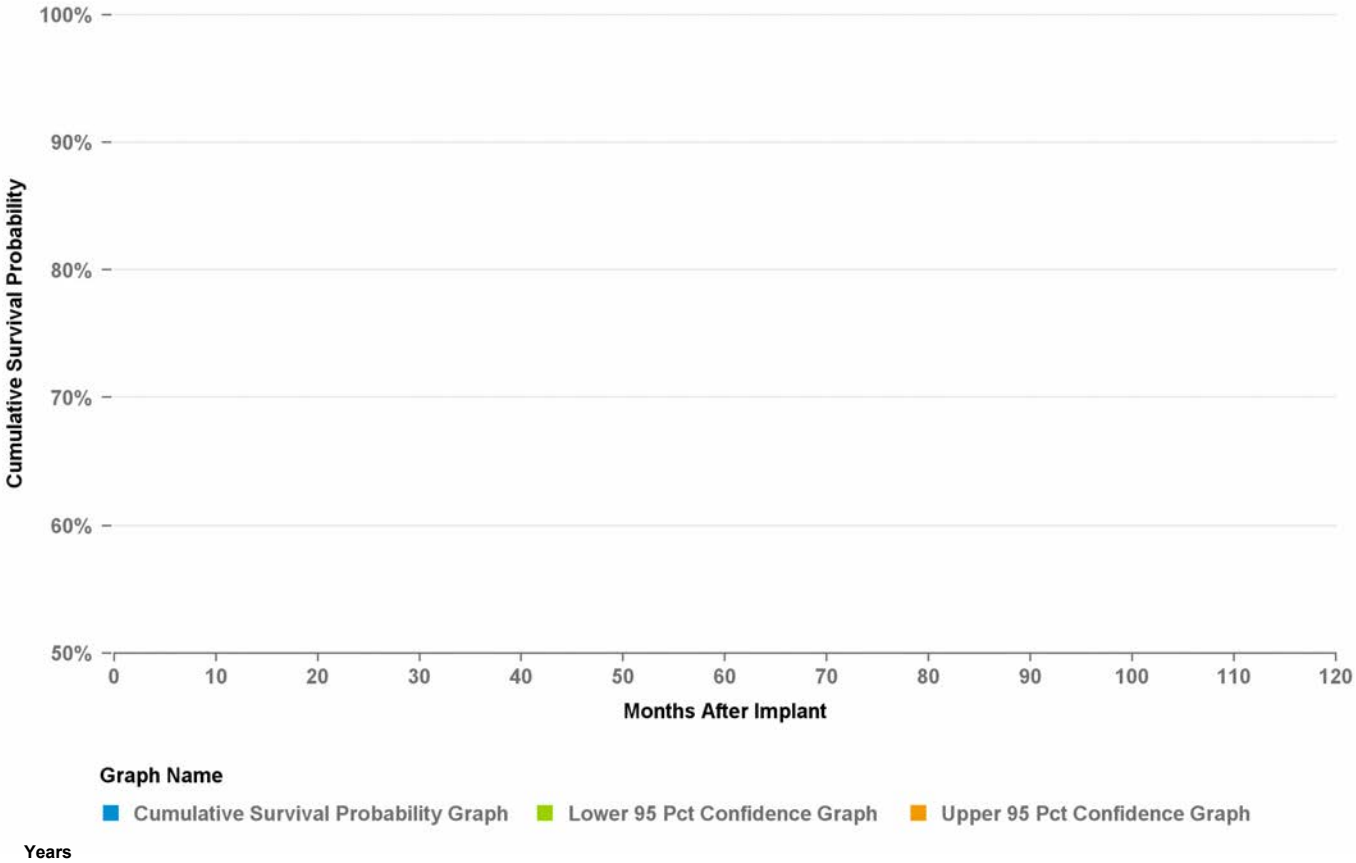
LEFT HEART PACING LEAD 4298

Distribution Data	
US Market Release	
CE Approval Date	1/1/2013
Registered US Implant	349
Estimated Active US	336
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	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

4298, Survival Curve



Years	
%	
#	

LEFT HEART PACING LEAD 4396

Distribution Data	
US Market Release	3/31/2011
CE Approval Date	12/18/2009
Registered US Implant	5,379
Estimated Active US	4,950

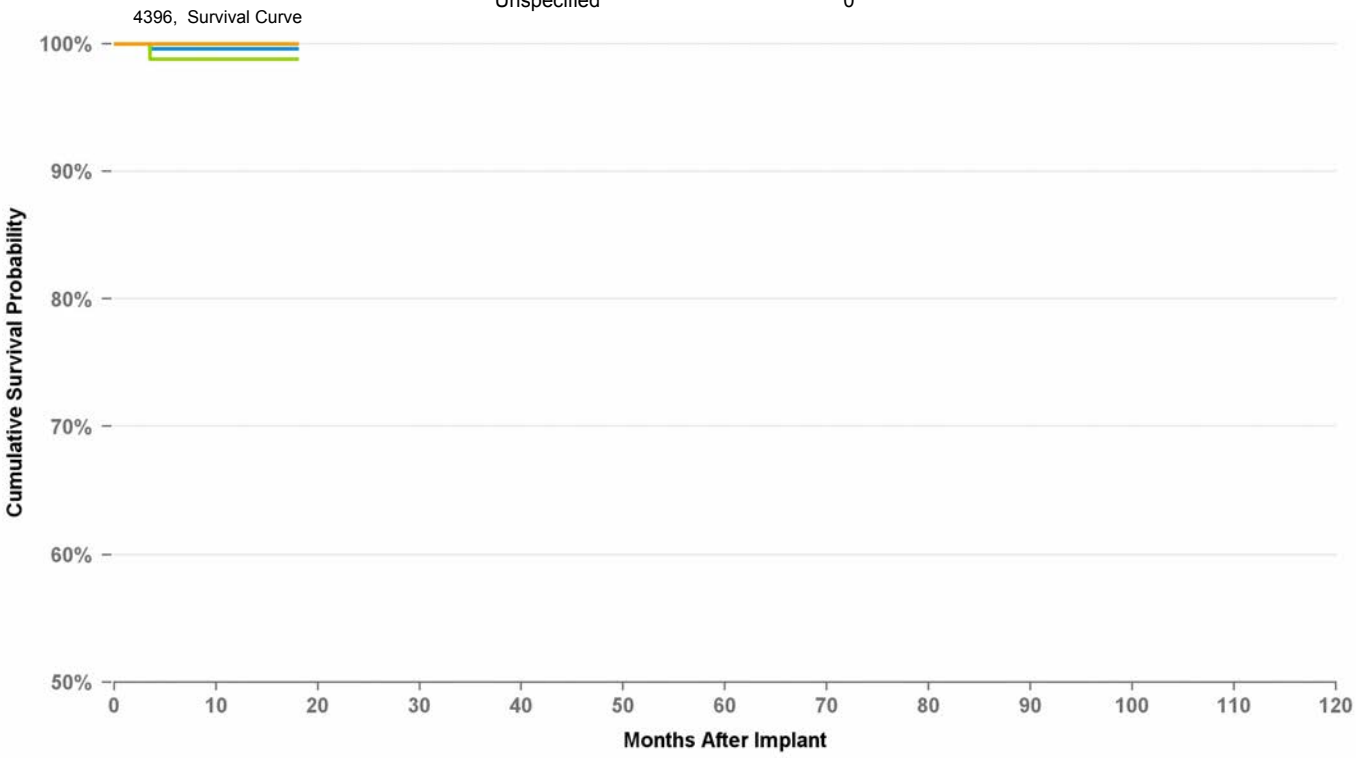
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	Dual Electrodes

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	329
Cumulative Months of Follow-Up	4,433
Number of Leads Active in Study	258

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	10
Failure To Capture	5
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	20
Oversensing	0
Unspecified	0

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



Years	1	at 18 mo
%	99.6%	99.6%
#	151	90

LEFT HEART PACING LEAD 4398

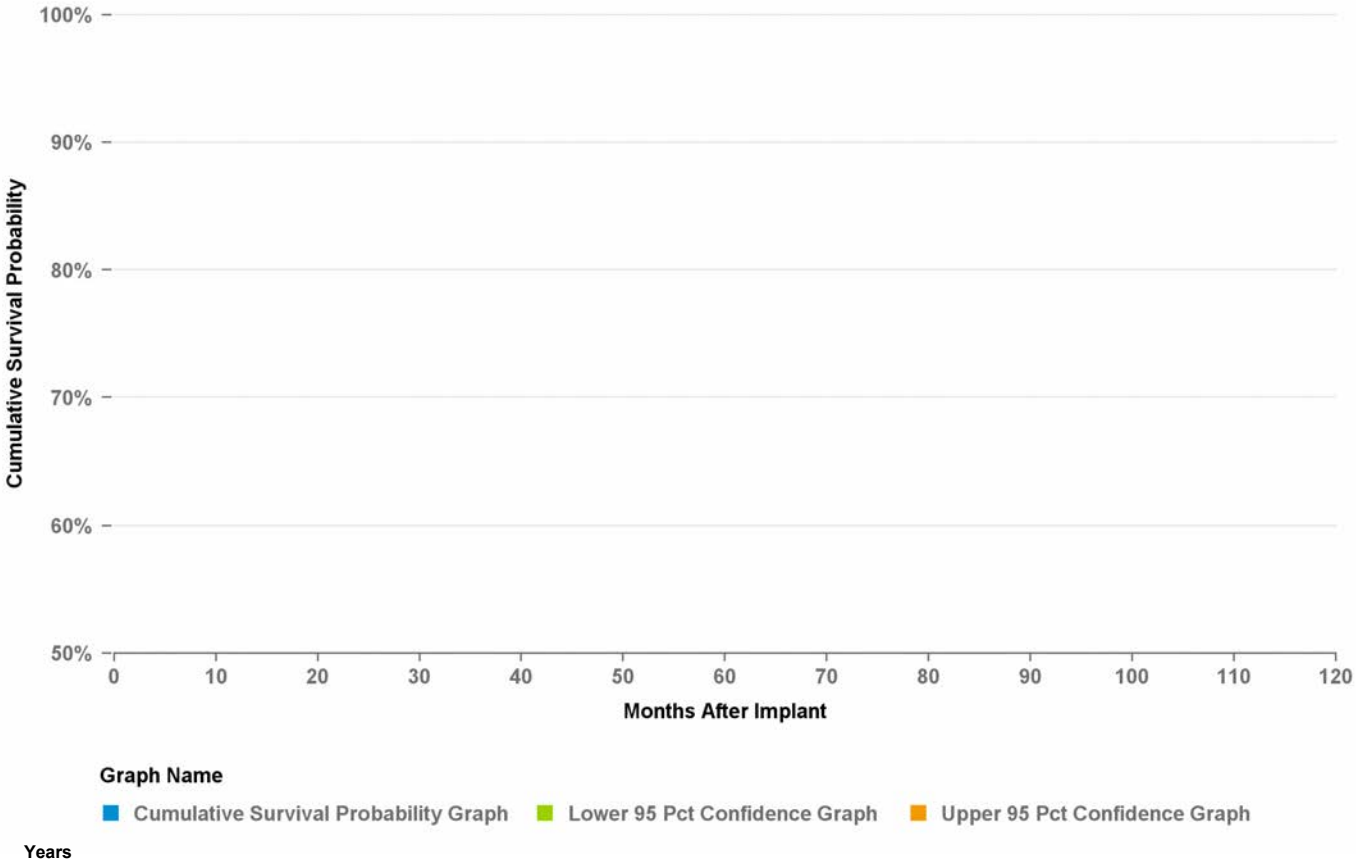
Distribution Data	
US Market Release	
CE Approval Date	1/1/2013
Registered US Implant	245
Estimated Active US	234
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Left Ventricular Cardiac Vein
Pace/Sense Polarit	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	2
Conductor Fracture	0
Extracardiac Stimulation	8
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

4398, Survival Curve



Years	
%	
#	

DEFIBRILLATION LEAD 6721

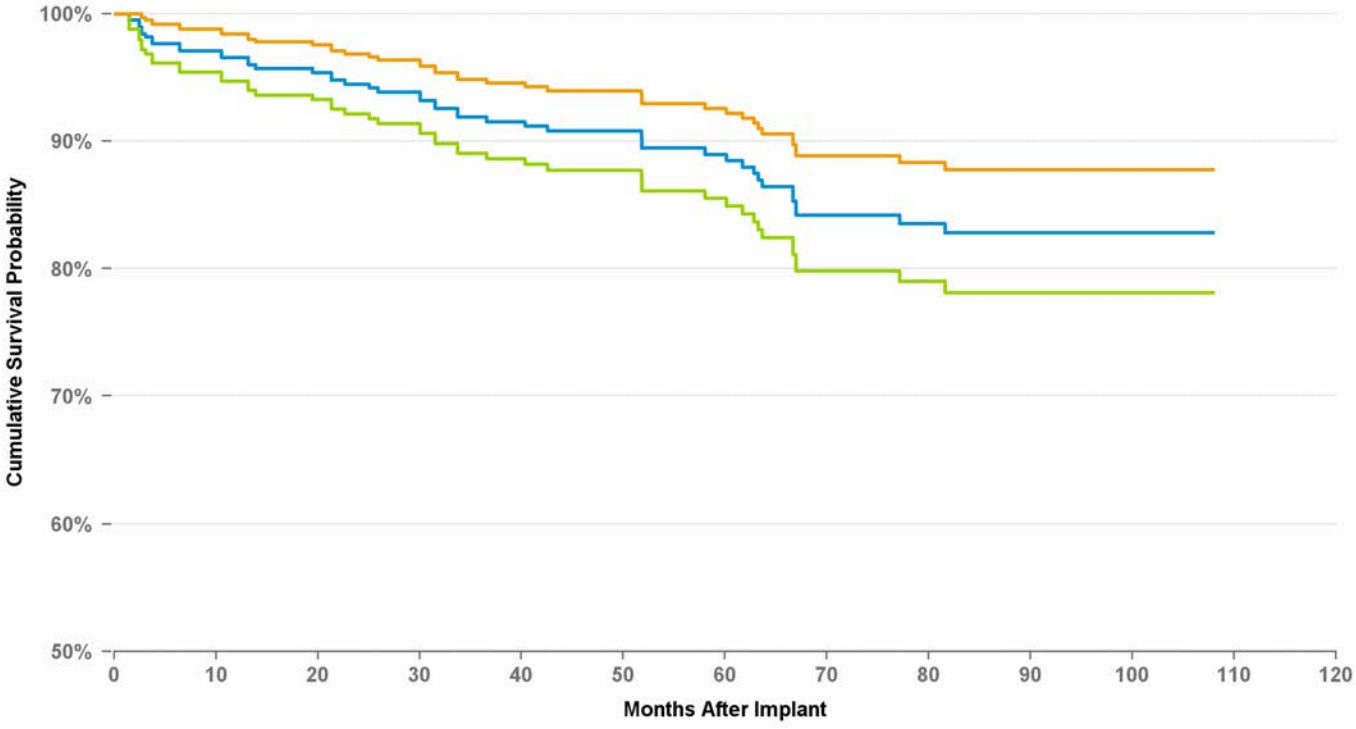
Distribution Data	
US Market Release	3/31/1994
CE Approval Date	1/1/1993
Registered US Implant	2,928
Estimated Active US	1,116
Product Characteristics	
Fixation Type	Suture
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Epi Patch
Lead Tip Location	Epicardial
Pace/Sense Polarit	n/a

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	408
Cumulative Months of Follow-Up	23,386
Number of Leads Active in Study	3

Product Surveillance 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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 108 mo
%	96.5%	94.5%	91.9%	90.8%	89.0%	84.2%	82.8%	82.8%	82.8%
#	339	310	265	213	182	131	98	63	55

DEFIBRILLATION LEAD 6930

Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implant	354
Estimated Active US	165

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

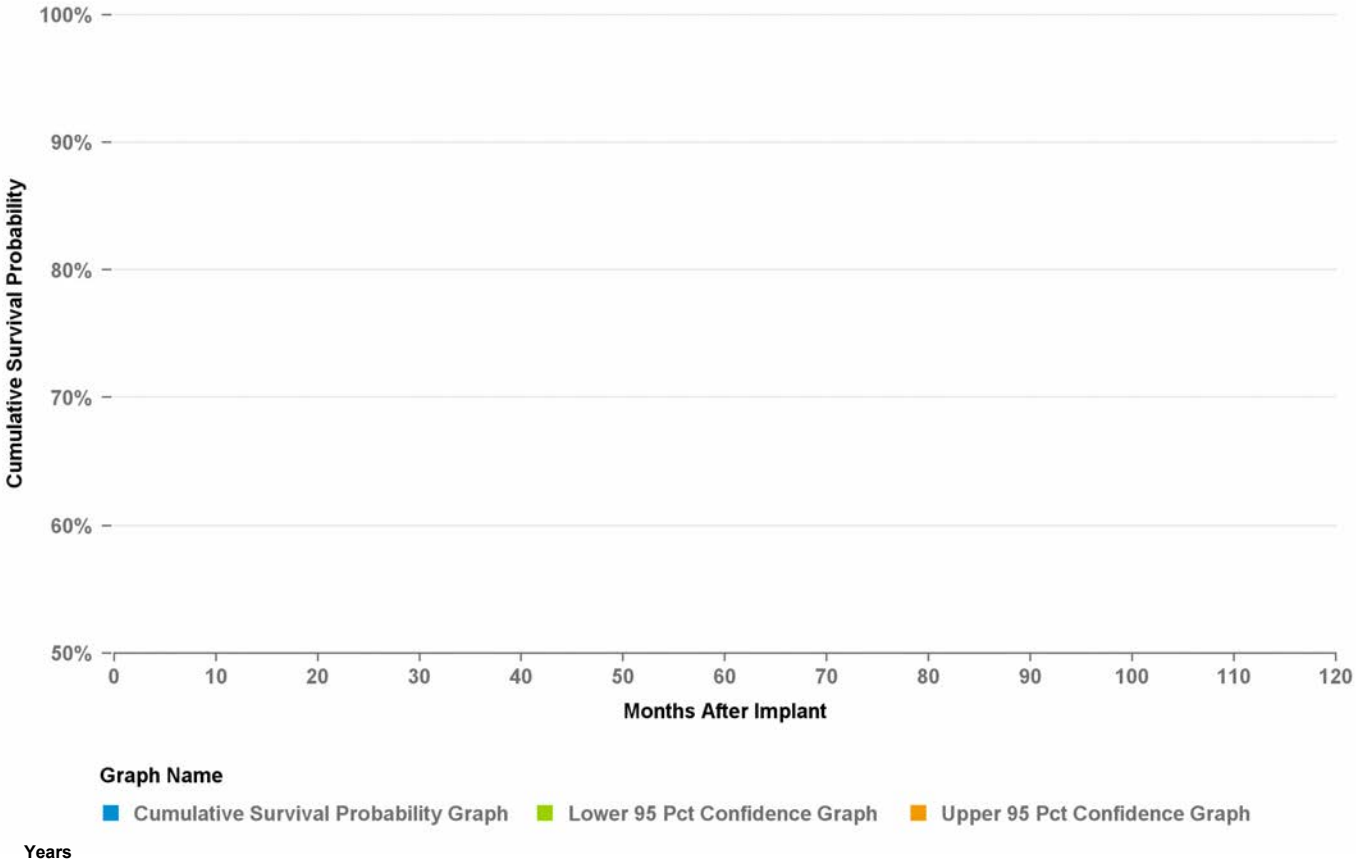
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	4
Cumulative Months of Follow-Up	203
Number of Leads Active in Study	2

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	4
Crimp Weld Bond	0
Insulation Breach	0
Other	0

6930, Survival Curve



Years	
%	
#	

DEFIBRILLATION LEAD 6931

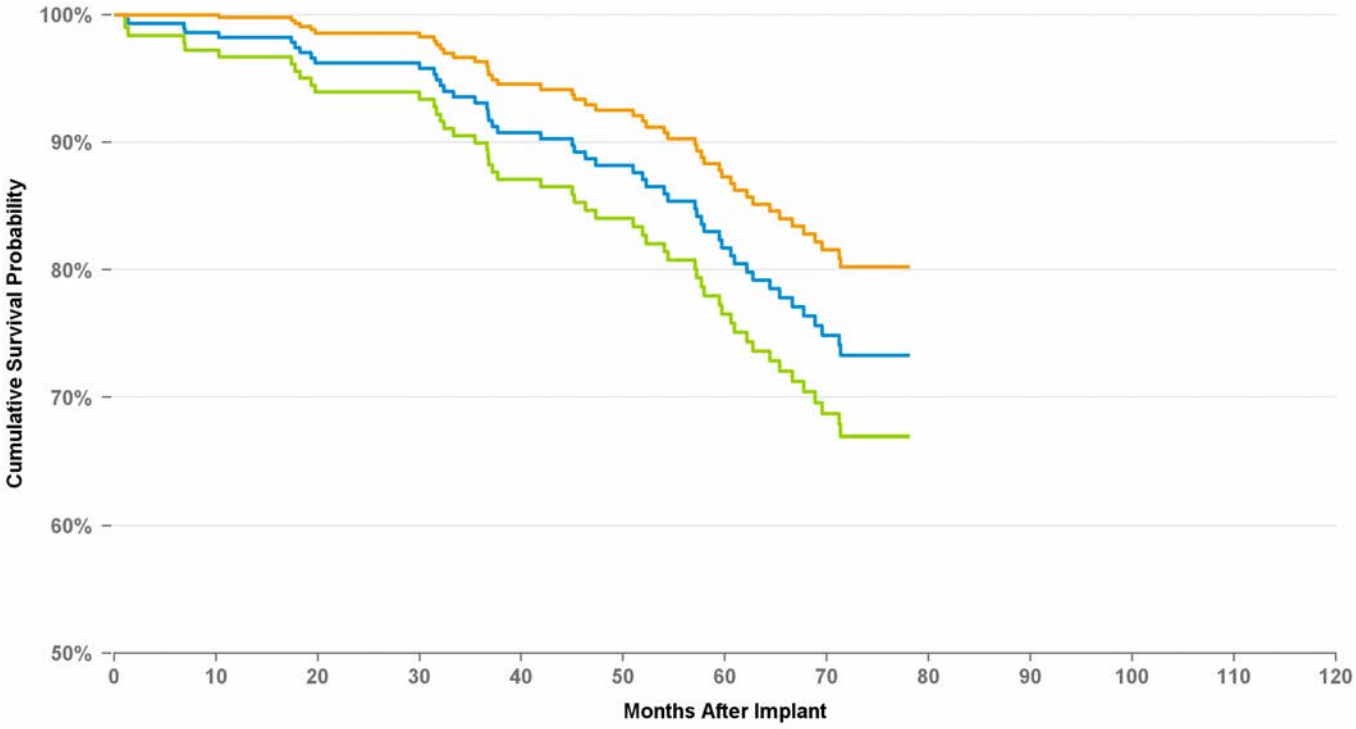
Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implant	8,080
Estimated Active US	3,120
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	296
Cumulative Months of Follow-Up	15,151
Number of Leads Active in Study	50

Product Surveilance Registry Qualifying Complications	54
Cardiac Perforation	0
Conductor Fracture	32
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
Failure To Sense	1
Impedance Abnormal	9
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	0
Lead Dislodgement	2
Medical Judgment	0
Other Complication	0
Oversensing	7
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	574
Crimp Weld Bond	0
Insulation Breach	1
Other	5

6931, Survival Curve



Years	1	2	3	4	5	6	at 78 mo
%	98.2%	96.2%	93.1%	88.2%	81.7%	73.3%	73.3%
#	262	231	201	160	130	93	67

DEFIBRILLATION LEAD 6932

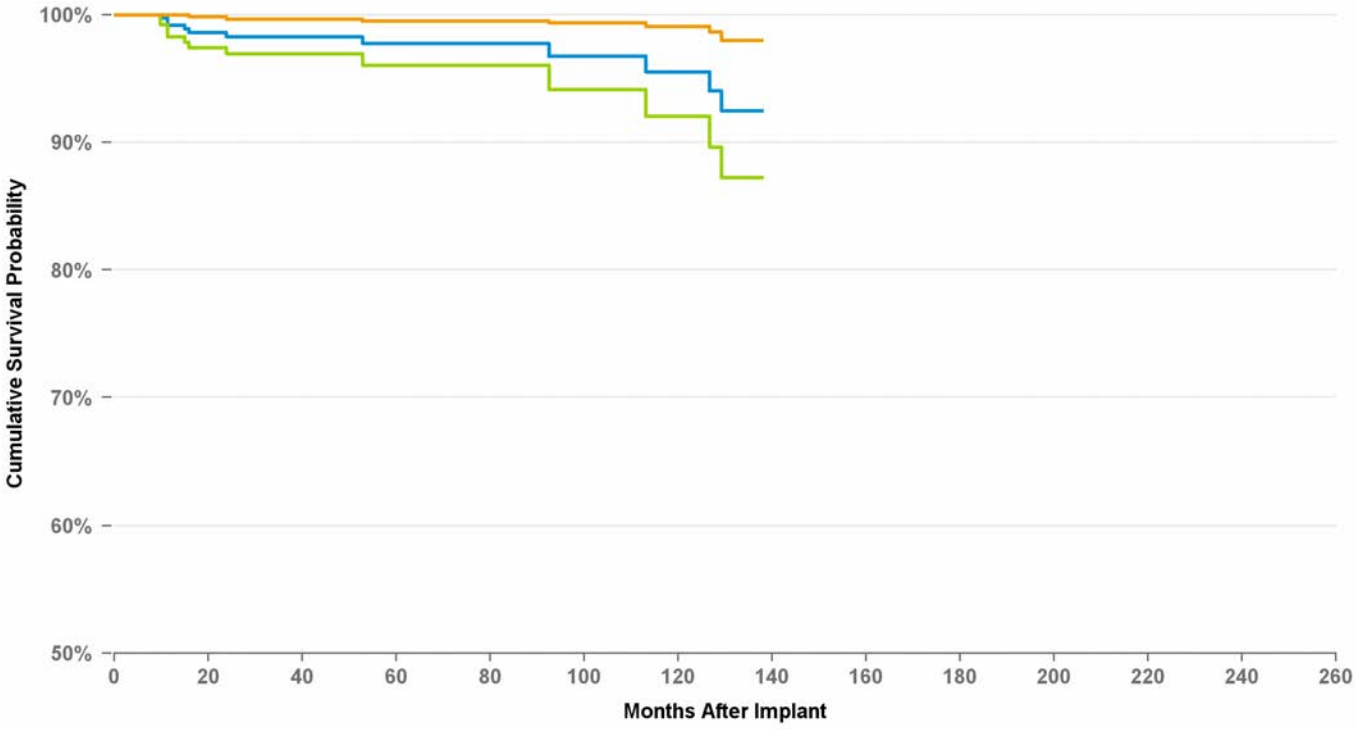
Distribution Data	
US Market Release	8/6/1996
CE Approval Date	
Registered US Implant	14,899
Estimated Active US	4,105
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	418
Cumulative Months of Follow-Up	25,540
Number of Leads Active in Study	35

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	23
Crimp Weld Bond	0
Insulation Breach	26
Other	2

6932, Survival Curve



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%	92.5%	92.5%
#	360	303	242	203	157	125	105	91	81	68	56	54

DEFIBRILLATION LEAD 6933

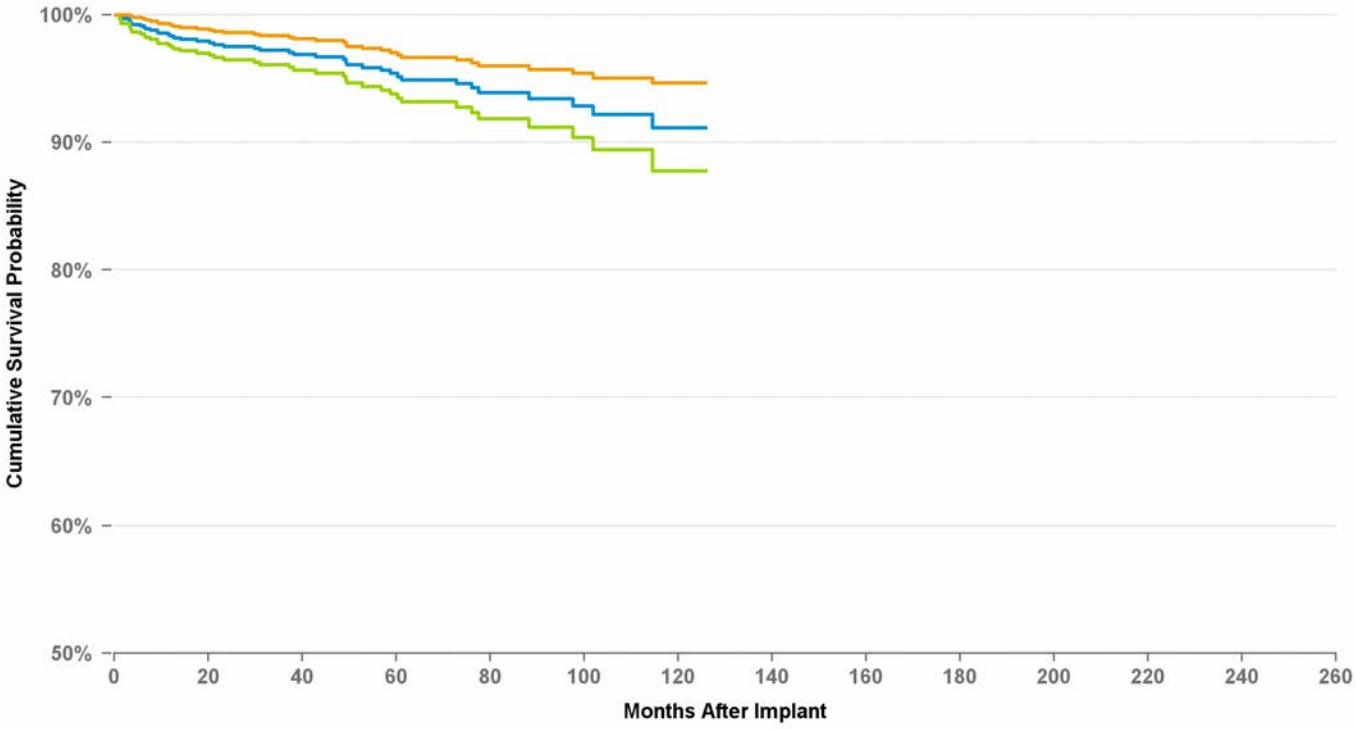
Distribution Data	
US Market Release	4/20/1994
CE Approval Date	
Registered US Implant	7,964
Estimated Active US	769
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,171
Number of Leads Active in Study	7

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	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	16
Other	0

6933, 6937, 6937A, 6963, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 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	72	57

DEFIBRILLATION LEAD 6935

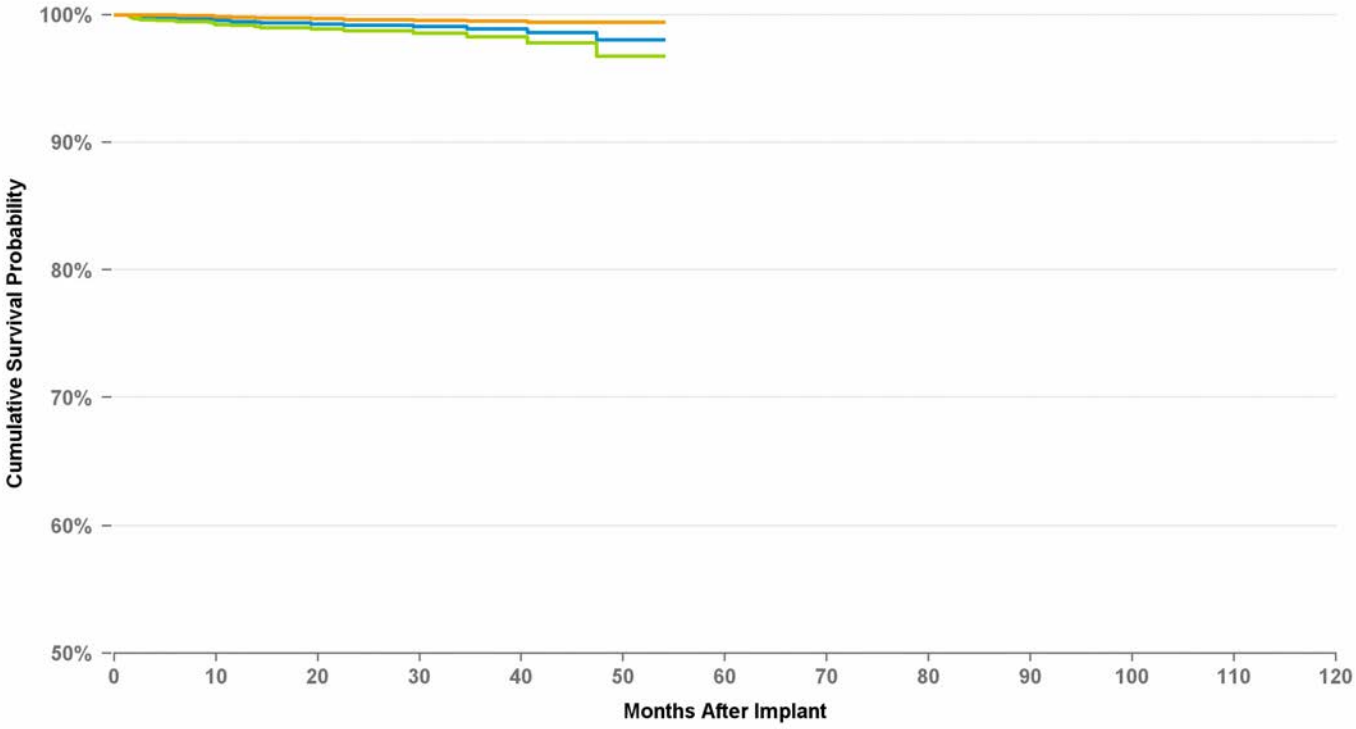
Distribution Data	
US Market Release	11/1/2008
CE Approval Date	3/31/2008
Registered US Implant	47,773
Estimated Active US	42,723
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	2,311
Cumulative Months of Follow-Up	52,846
Number of Leads Active in Study	1,590

Product Surveilance Registry Qualifying Complications	18
Cardiac Perforation	0
Conductor Fracture	6
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	5
Medical Judgment	0
Other Complication	1
Oversensing	3
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	13
Conductor Fracture	0
Extracardiac Stimulation	0
Failure To Capture	18
Failure To Sense	5
Impedance Abnormal	13
Insulation Breach	1
Lead Dislodgement	31
Oversensing	36
Unspecified	5
USA Returned Product Analysis	
Conductor Fracture	109
Crimp Weld Bond	0
Insulation Breach	4
Other	37

6935, Survival Curve



Years	1	2	3	4	at 54 mo
%	99.5%	99.2%	98.9%	98.1%	98.1%
#	1,689	980	479	151	53

DEFIBRILLATION LEAD 6935M

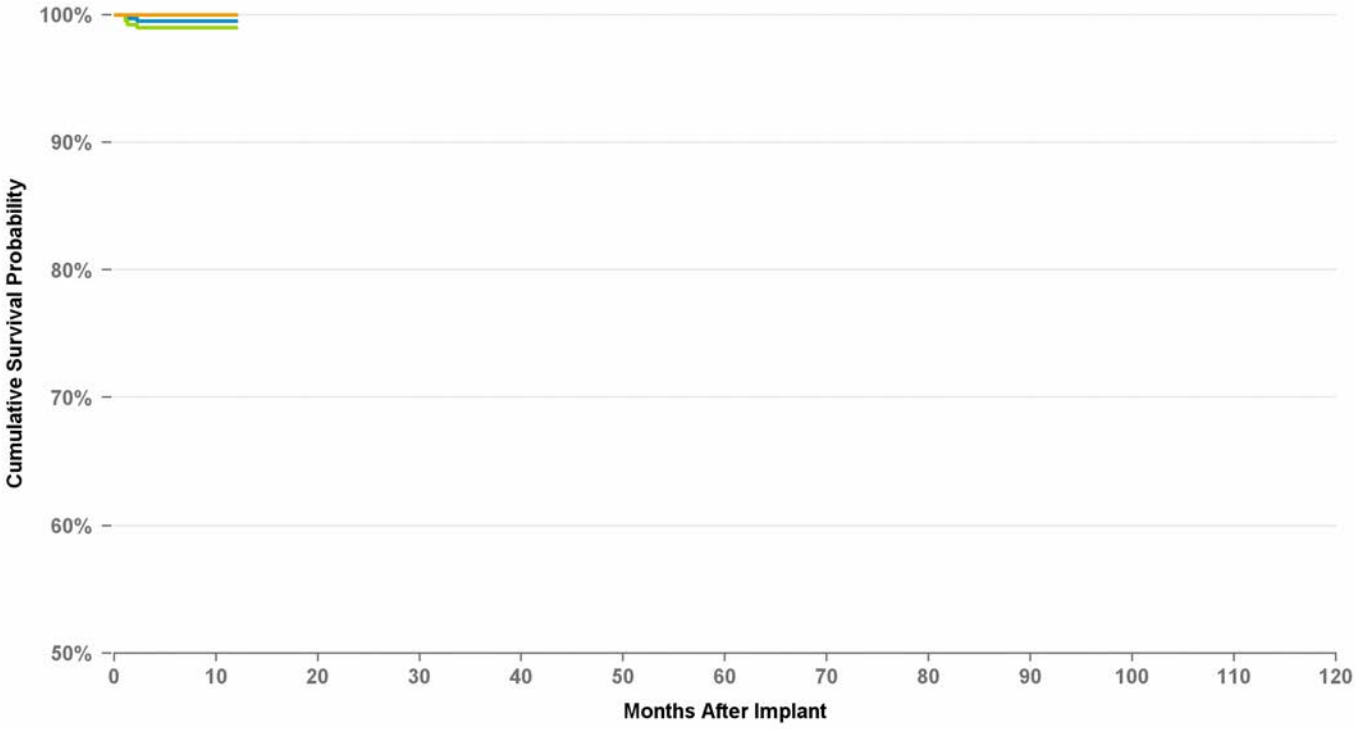
Distribution Data	
US Market Release	8/2/2012
CE Approval Date	7/12/2012
Registered US Implant	33,224
Estimated Active US	32,366
Product Characteristics	
Fixation Type	Active Screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,208
Cumulative Months of Follow-Up	5,177
Number of Leads Active in Study	1,121

Product Surveilance Registry Qualifying Complications	3
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	2
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	5
Conductor Fracture	0
Extracardiac Stimulation	3
Failure To Capture	28
Failure To Sense	5
Impedance Abnormal	7
Insulation Breach	1
Lead Dislodgement	41
Oversensing	26
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	5
Crimp Weld Bond	0
Insulation Breach	0
Other	2

6935M, Survival Curve



Years	at 12 mo
%	99.5%
#	140

DEFIBRILLATION LEAD 6937

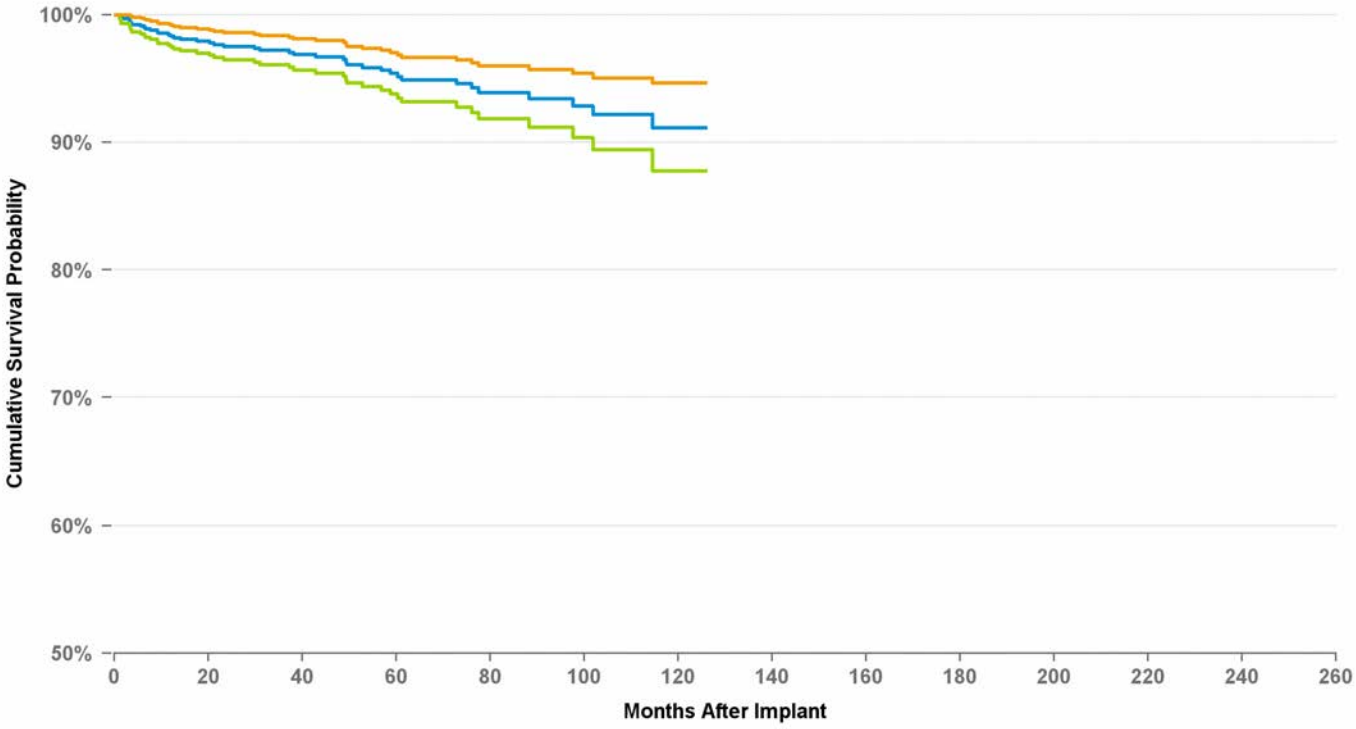
Distribution Data	
US Market Release	3/22/1996
CE Approval Date	4/19/1994
Registered US Implant	2,056
Estimated Active US	389
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,171
Number of Leads Active in Study	7

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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 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	72	57

DEFIBRILLATION LEAD 6937A

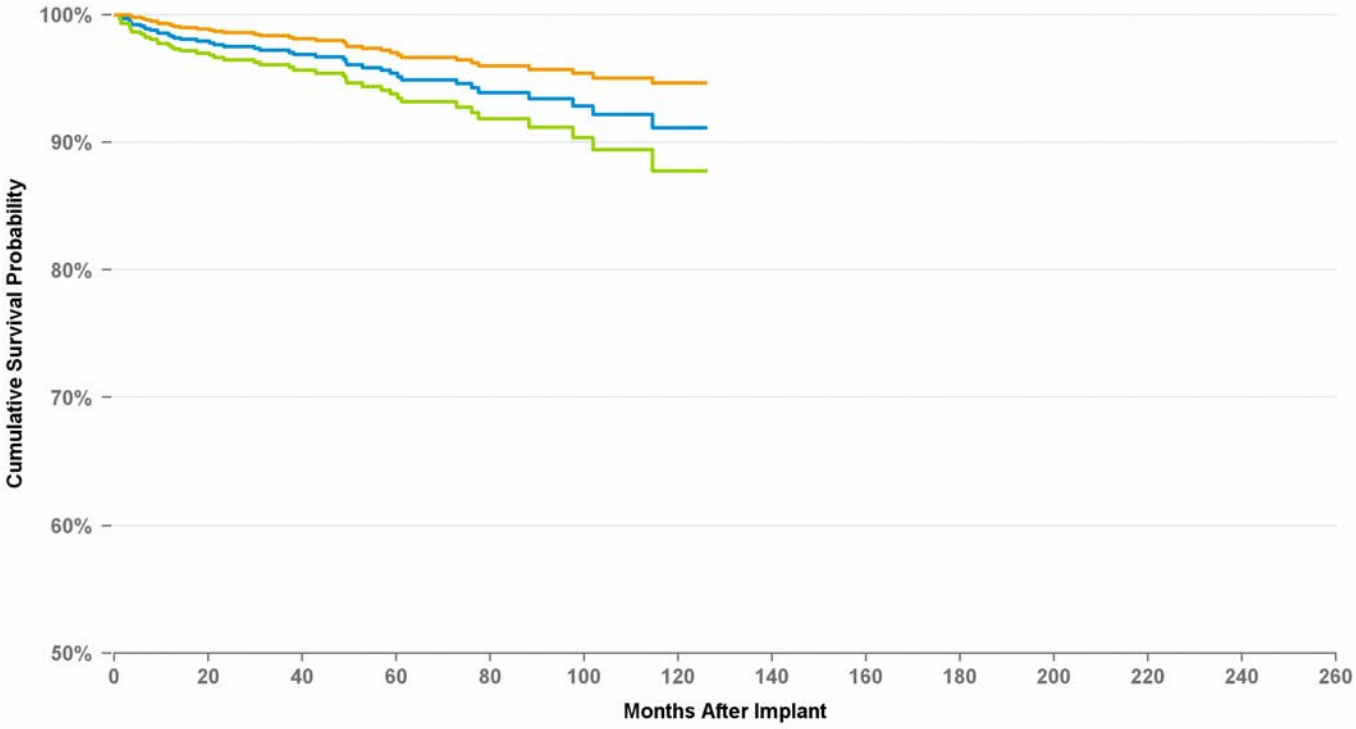
Distribution Data	
US Market Release	4/6/2001
CE Approval Date	
Registered US Implant	2,013
Estimated Active US	1,294
Product Characteristics	
Fixation Type	Passive
Lead Function	Defibrillation
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	SVC/CS
Pace/Sense Polarit	One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	966
Cumulative Months of Follow-Up	54,171
Number of Leads Active in Study	7

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	1
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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 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	72	57

DEFIBRILLATION LEAD 6942

Distribution Data	
US Market Release	7/18/1997
CE Approval Date	
Registered US Implant	17,684
Estimated Active US	5,123
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

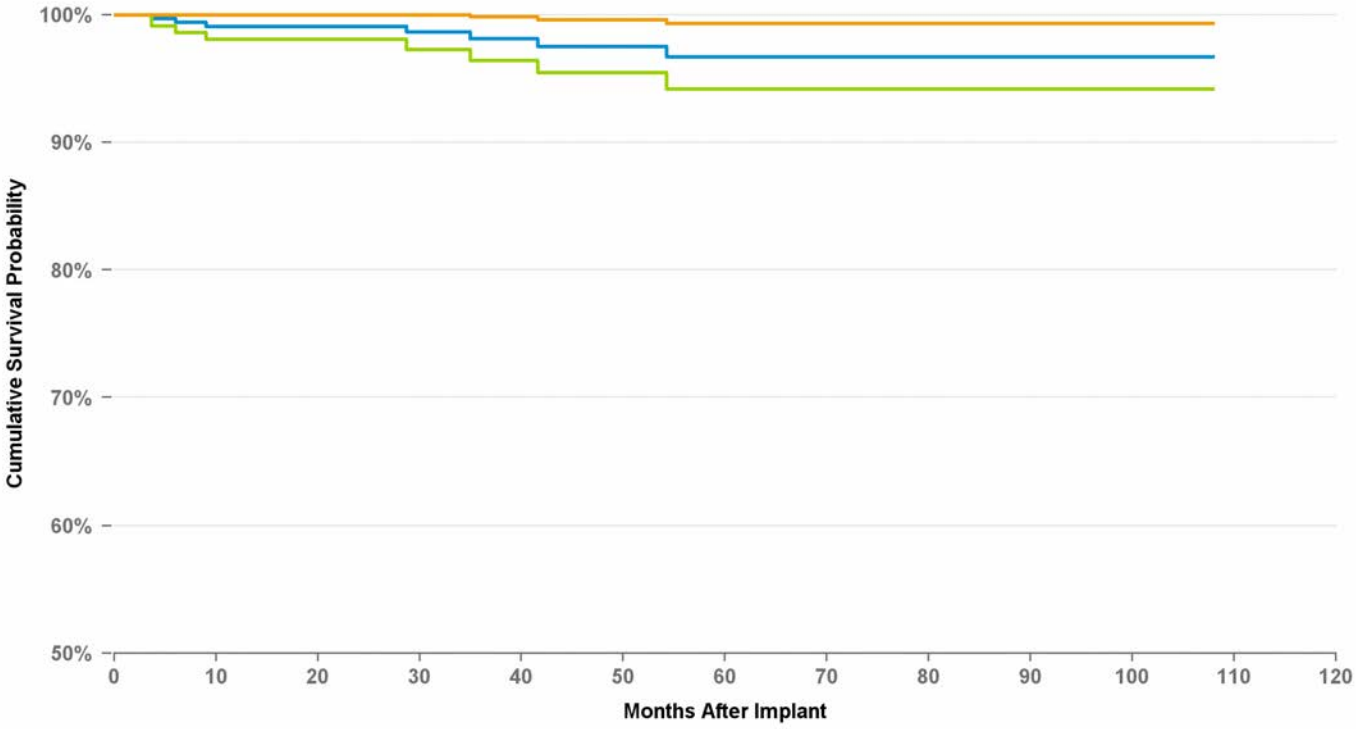
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	357
Cumulative Months of Follow-Up	19,213
Number of Leads Active in Study	13

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	2
Unspecified	1

USA Returned Product Analysis	
Conductor Fracture	15
Crimp Weld Bond	1
Insulation Breach	24
Other	4

6942, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

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%
#	303	235	179	139	113	96	75	64	53

DEFIBRILLATION LEAD 6943

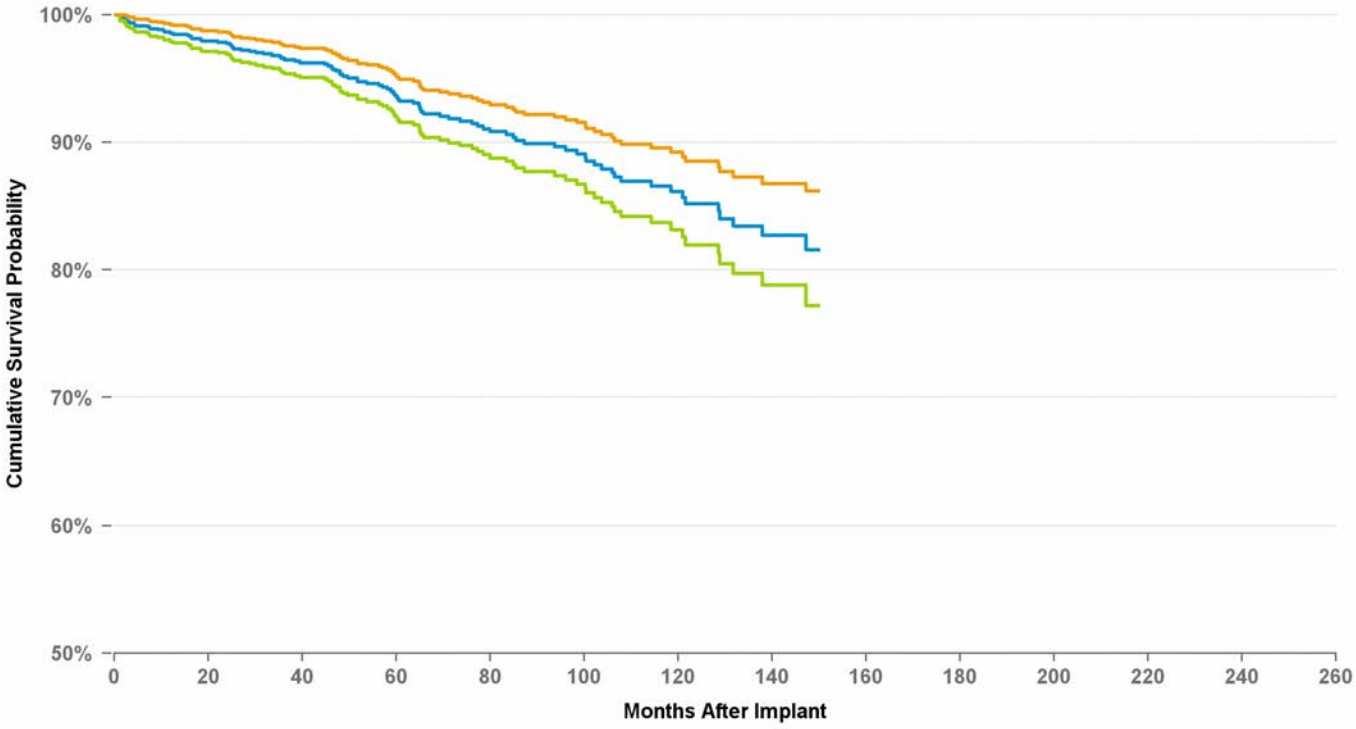
Distribution Data	
US Market Release	10/6/1997
CE Approval Date	
Registered US Implant	20,609
Estimated Active US	5,990
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/One Coil

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,326
Cumulative Months of Follow-Up	82,955
Number of Leads Active in Study	167

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	78
Crimp Weld Bond	1
Insulation Breach	31
Other	5

6943, Survival Curve



Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	98.6%	97.7%	96.6%	95.6%	93.5%	91.9%	90.6%	89.7%	87.0%	86.1%	83.4%	82.7%	81.6%
#	1,164	980	857	710	597	484	396	324	263	183	134	85	60

DEFIBRILLATION LEAD 6944

Distribution Data	
US Market Release	12/13/2000
CE Approval Date	11/5/1999
Registered US Implant	42,987
Estimated Active US	22,255
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

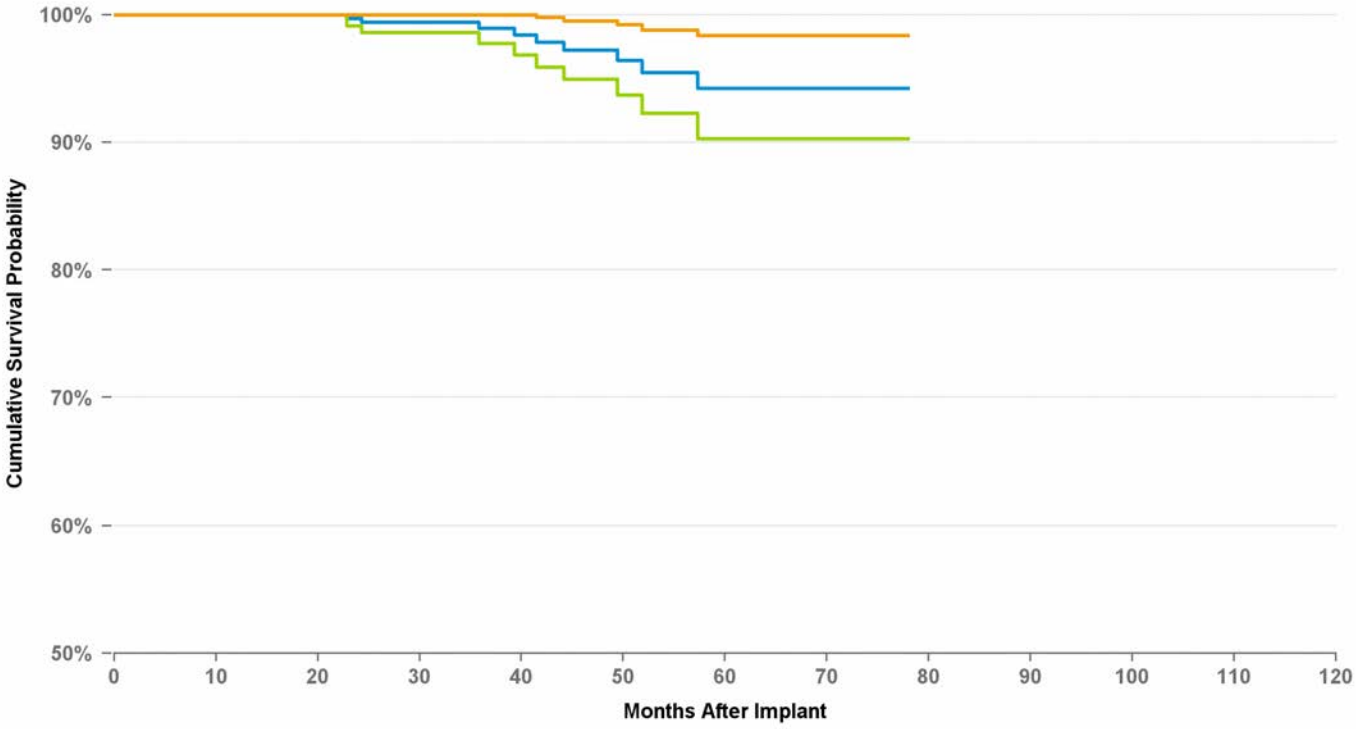
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	550
Cumulative Months of Follow-Up	20,595
Number of Leads Active in Study	262

Product Surveilance Registry Qualifying Complications	11
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	1
Oversensing	2
Unspecified	1

US Acute Lead Observations	
Cardiac Perforation	0
Conductor Fracture	2
Extracardiac Stimulation	0
Failure To Capture	12
Failure To Sense	3
Impedance Abnormal	9
Insulation Breach	0
Lead Dislodgement	18
Oversensing	11
Unspecified	6

USA Returned Product Analysis	
Conductor Fracture	136
Crimp Weld Bond	1
Insulation Breach	4
Other	5

6944, Survival Curve



Years	1	2	3	4	5	6	at 78 mo
%	100.0%	99.7%	98.9%	97.2%	94.2%	94.2%	94.2%
#	451	330	214	129	69	59	54

DEFIBRILLATION LEAD 6945

Distribution Data	
US Market Release	9/26/1997
CE Approval Date	
Registered US Implant	42,743
Estimated Active US	12,115
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

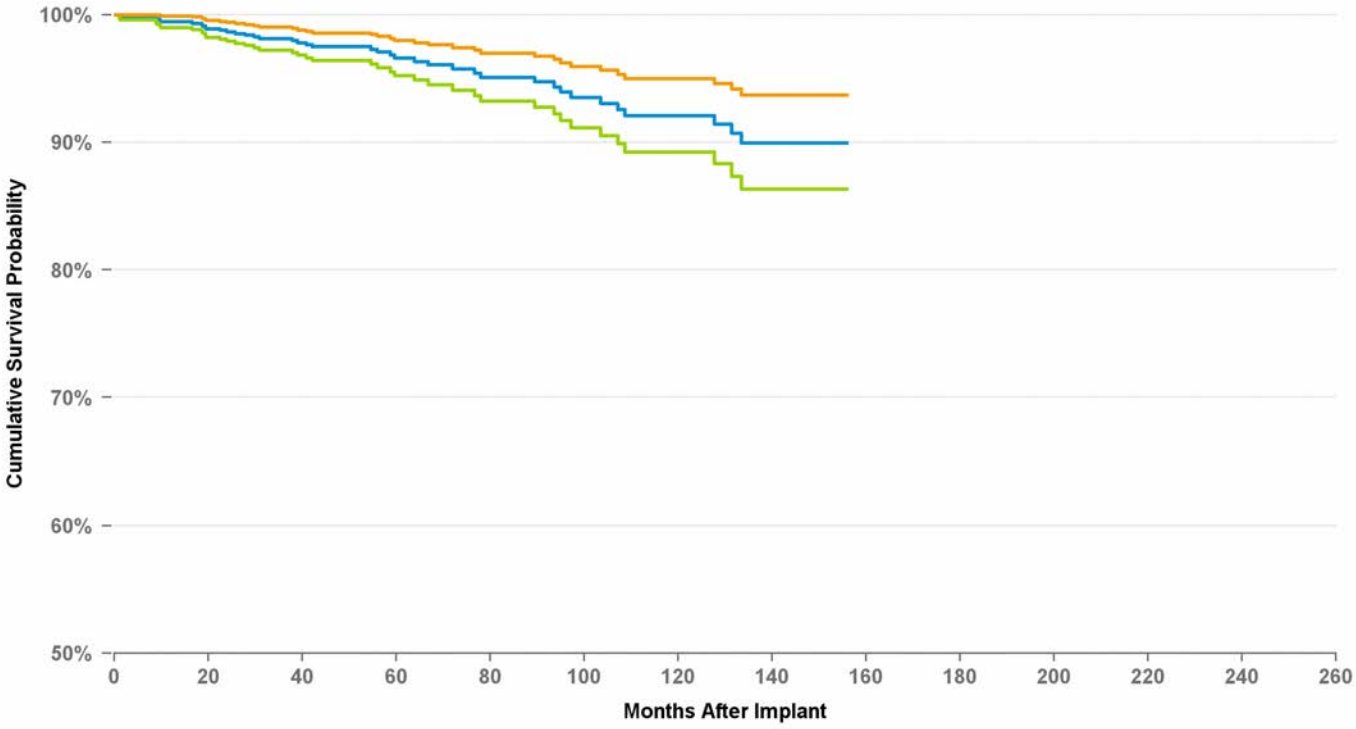
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,180
Cumulative Months of Follow-Up	65,395
Number of Leads Active in Study	116

Product Surveilance Registry Qualifying Complications	42
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	18
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	1
Insulation Breach	2
Lead Dislodgement	4
Oversensing	7
Unspecified	2

USA Returned Product Analysis	
Conductor Fracture	139
Crimp Weld Bond	1
Insulation Breach	41
Other	6

6945, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.4%	98.7%	98.1%	97.5%	96.6%	95.8%	95.1%	93.9%	92.6%	92.1%	90.7%	89.9%	89.9%
#	1,006	821	657	525	406	311	274	230	185	153	123	102	64

DEFIBRILLATION LEAD 6947

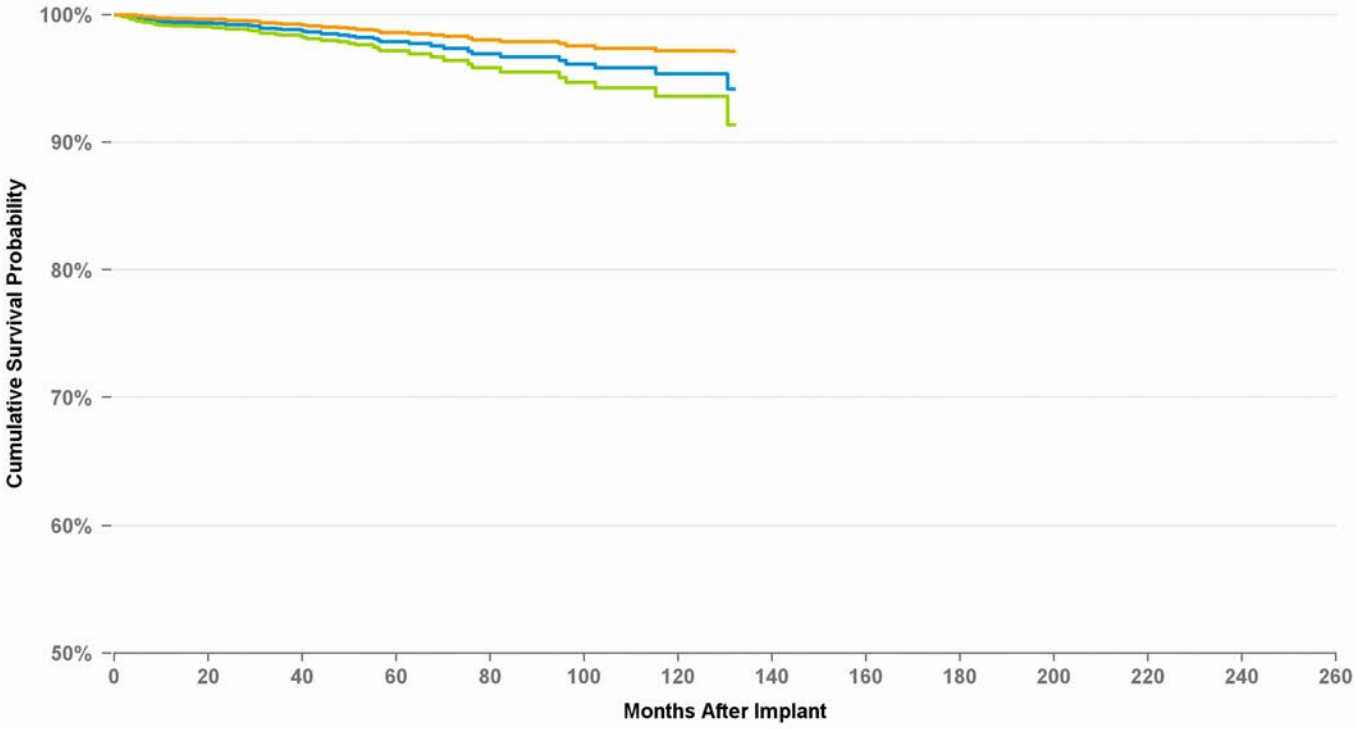
Distribution Data	
US Market Release	11/12/2001
CE Approval Date	10/4/2001
Registered US Implant	367,372
Estimated Active US	240,975
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	3,259
Cumulative Months of Follow-Up	134,902
Number of Leads Active in Study	1,308

Product Surveilance Registry Qualifying Complications	49
Cardiac Perforation	0
Conductor Fracture	13
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
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	2
Oversensing	14
Unspecified	2

US Acute Lead Observations	
Cardiac Perforation	26
Conductor Fracture	18
Extracardiac Stimulation	2
Failure To Capture	72
Failure To Sense	30
Impedance Abnormal	51
Insulation Breach	4
Lead Dislodgement	106
Oversensing	120
Unspecified	22
USA Returned Product Analysis	
Conductor Fracture	636
Crimp Weld Bond	4
Insulation Breach	56
Other	215

6947, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.4%	99.2%	98.8%	98.4%	97.9%	97.4%	96.7%	96.4%	95.8%	95.4%	94.2%
#	2,556	2,060	1,653	1,168	648	466	386	333	265	141	54

DEFIBRILLATION LEAD 6947M

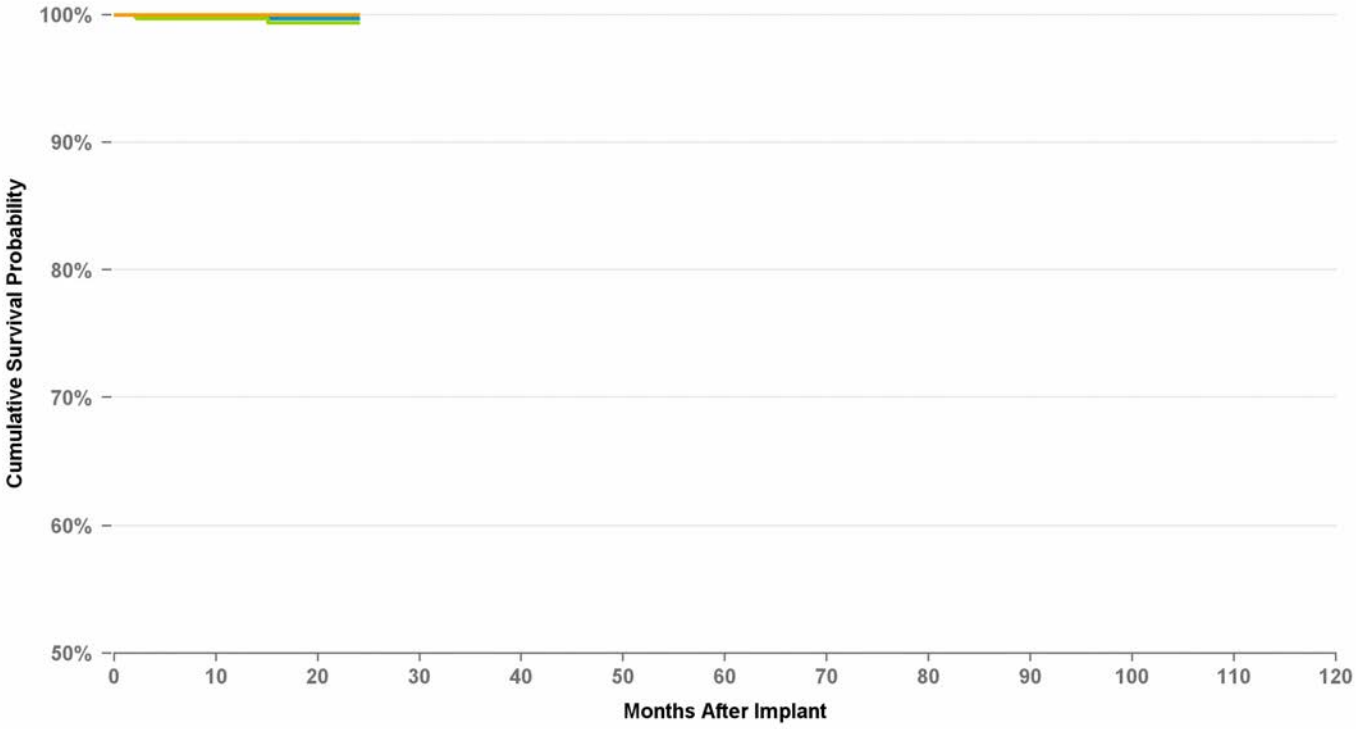
Distribution Data	
US Market Release	2/13/2012
CE Approval Date	3/12/2010
Registered US Implant	49,156
Estimated Active US	47,368
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,648
Cumulative Months of Follow-Up	20,116
Number of Leads Active in Study	1,373

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	6
Conductor Fracture	3
Extracardiac Stimulation	5
Failure To Capture	31
Failure To Sense	6
Impedance Abnormal	8
Insulation Breach	0
Lead Dislodgement	56
Oversensing	18
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	0
Insulation Breach	1
Other	6

6947M, Survival Curve



Years	1	at 24 mo
%	99.9%	99.7%
#	842	77

DEFIBRILLATION LEAD 6948

Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implant	10,378
Estimated Active US	4,399
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

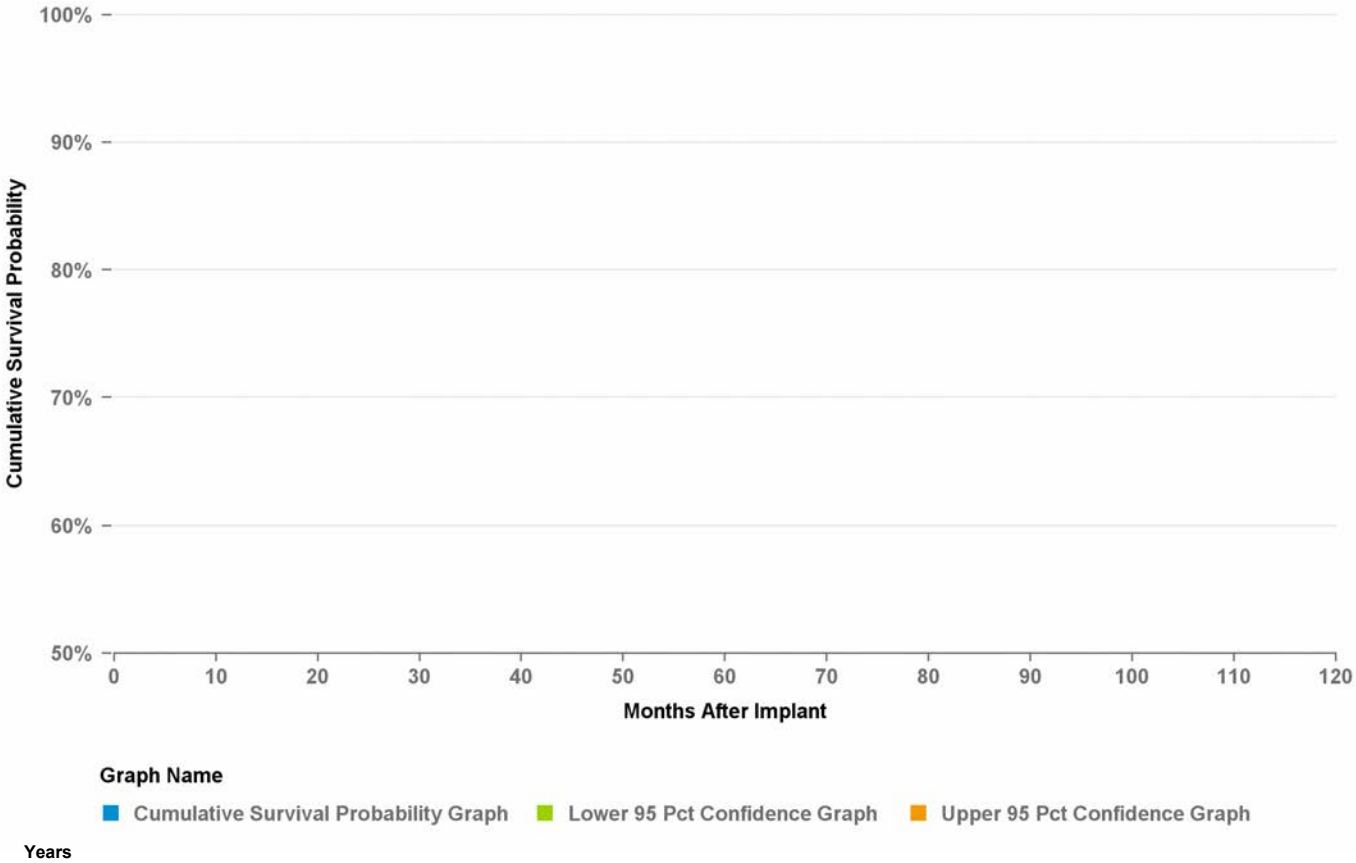
Product Surveilance Registry Results	
Number of Leads Enrolled in Study	37
Cumulative Months of Follow-Up	1,604
Number of Leads Active in Study	13

Product Surveilance Registry Qualifying Complications	4
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
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	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	172
Crimp Weld Bond	0
Insulation Breach	2
Other	2

6948, Survival Curve



Years	
%	
#	

DEFIBRILLATION LEAD 6949

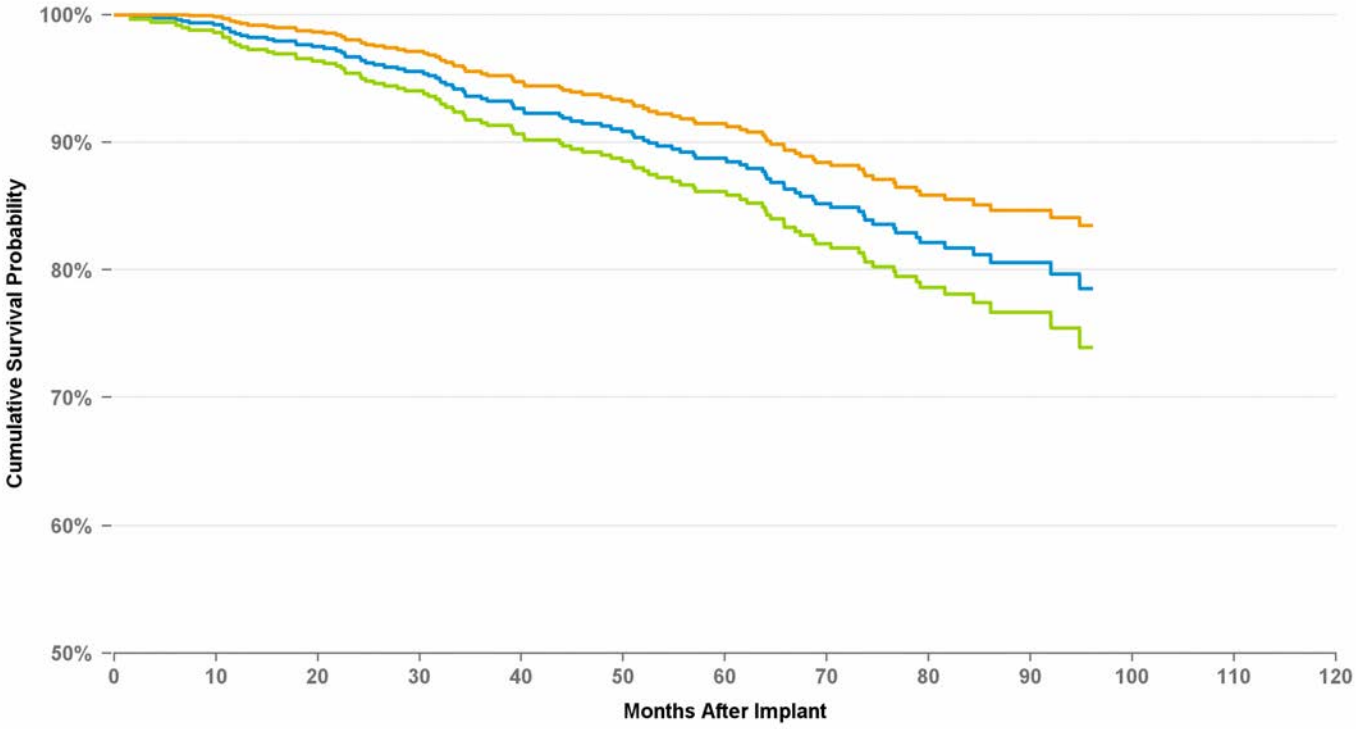
Distribution Data	
US Market Release	9/2/2004
CE Approval Date	
Registered US Implant	186,780
Estimated Active US	69,359
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	True Bipolar/Two Coils

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	893
Cumulative Months of Follow-Up	42,048
Number of Leads Active in Study	230

Product Surveilance Registry Qualifying Complications	91
Cardiac Perforation	0
Conductor Fracture	47
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	15
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	31
Unspecified	25
USA Returned Product Analysis	
Conductor Fracture	6,920
Crimp Weld Bond	3
Insulation Breach	31
Other	69

6949, Survival Curve



Years	1	2	3	4	5	6	7	at 96 mo
%	98.5%	96.7%	93.6%	91.3%	88.7%	84.9%	81.7%	78.5%
#	728	613	515	426	340	255	127	55

DEFIBRILLATION LEAD 6996

Distribution Data	
US Market Release	6/11/2001
CE Approval Date	12/19/1997
Registered US Implant	4,134
Estimated Active US	2,447

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

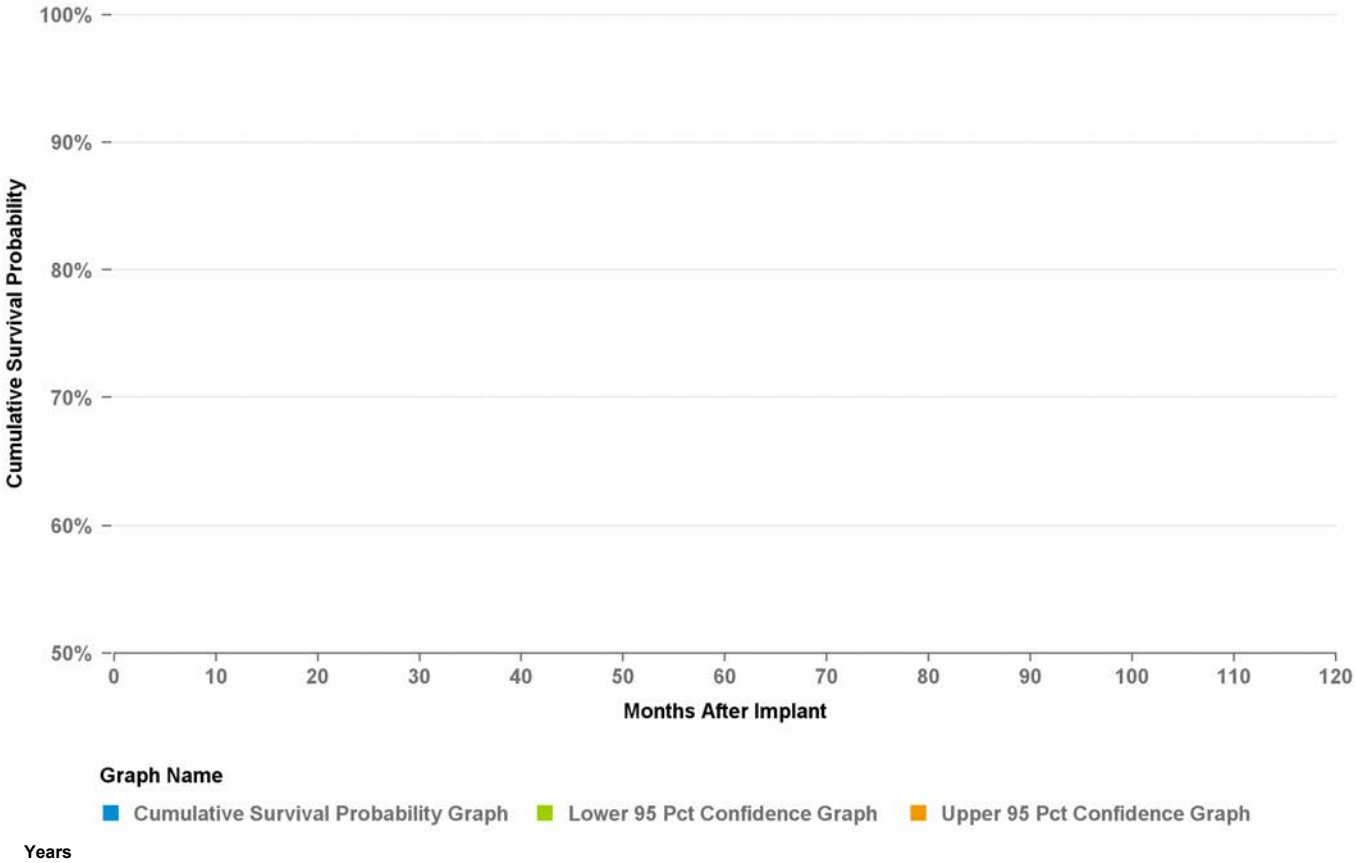
Product Surveillance Registry Results	
Number of Leads Enrolled in Study	44
Cumulative Months of Follow-Up	1,338
Number of Leads Active in Study	17

Product Surveillance 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



Years	
%	
#	

PACING LEAD

Distribution Data	
US Market Release	8/3/2005
CE Approval Date	1/31/2003
Registered US Implant	23,173
Estimated Active US	17,470
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	838
Cumulative Months of Follow-Up	28,952
Number of Leads Active in Study	502

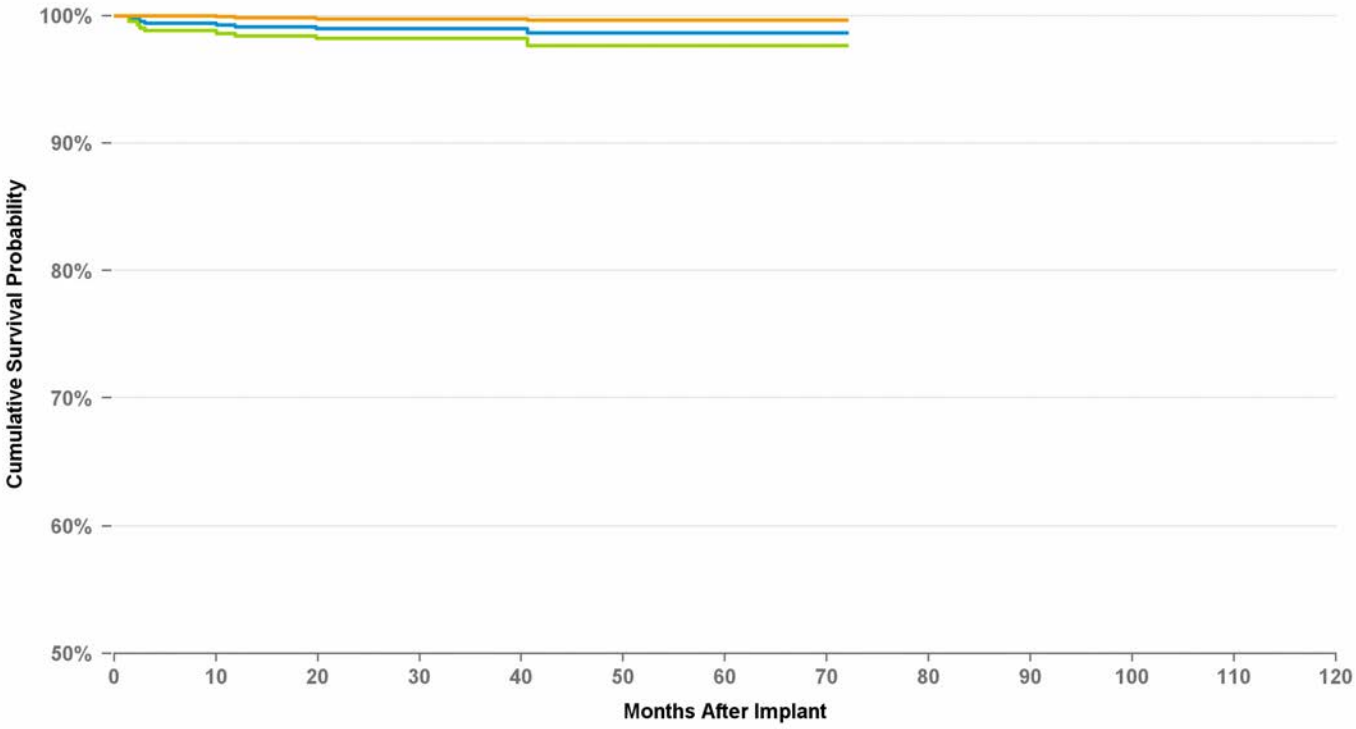
3830

Product Surveilance Registry Qualifying Complications	9
Cardiac Perforation	1
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	1
Failure To Sense	1
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	0
Oversensing	0
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	7
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	18
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	35
Oversensing	3
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	18
Other	3

3830, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	at 72 mo
%	99.1%	99.0%	99.0%	98.6%	98.6%	98.6%
#	701	578	374	151	76	54

PACING LEAD

3830

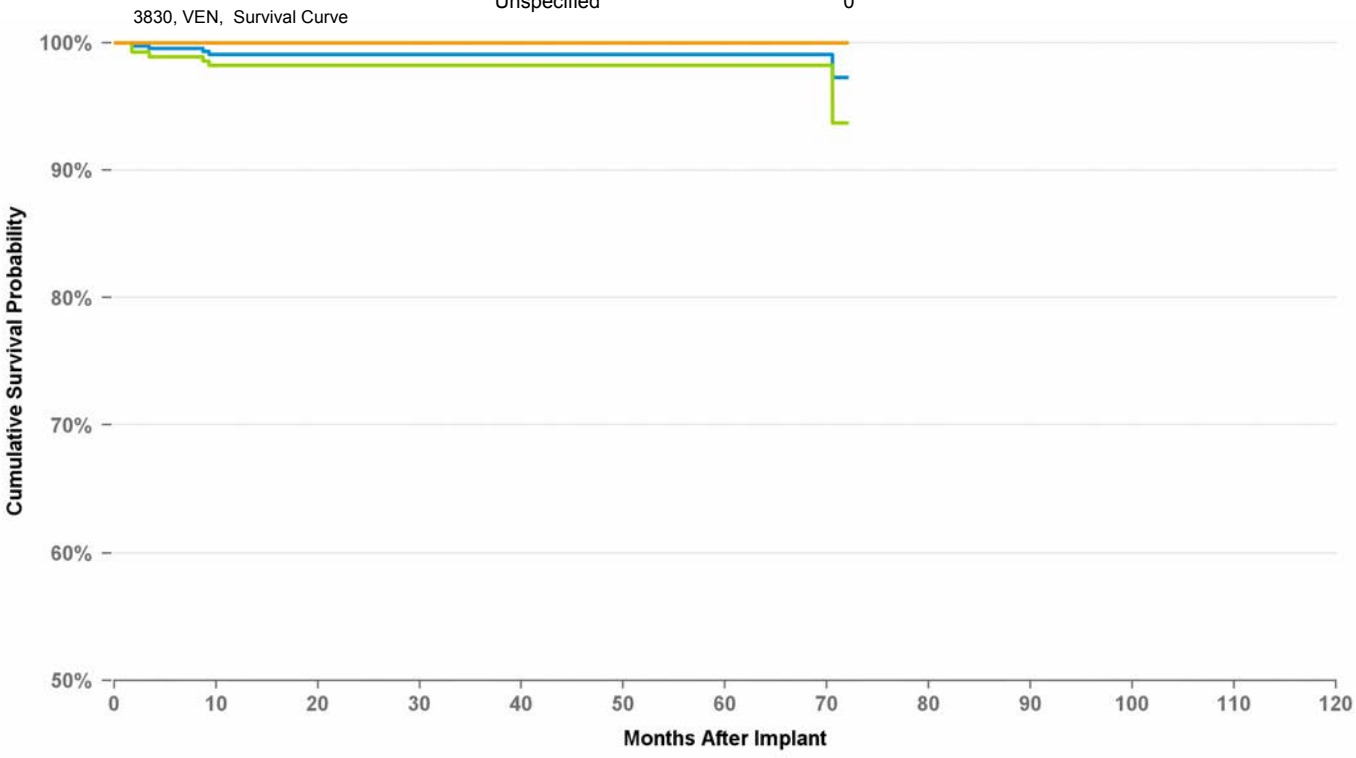
VENTRICULAR PLACEMENT

Distribution Data	
US Market Release	8/3/2005
CE Approval Date	1/31/2003
Registered US Implant	23,173
Estimated Active US	17,470
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	552
Cumulative Months of Follow-Up	19,367
Number of Leads Active in Study	324

Product Surveilance Registry Qualifying Complications	6
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	3
Medical Judgment	0
Other Complication	1
Oversensing	0
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	7
Conductor Fracture	1
Extracardiac Stimulation	0
Failure To Capture	18
Failure To Sense	1
Impedance Abnormal	0
Insulation Breach	1
Lead Dislodgement	35
Oversensing	3
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	18
Other	3



Years	1	2	3	4	5	at 72 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	97.3%
#	436	363	247	108	69	52

PACING LEAD

4024

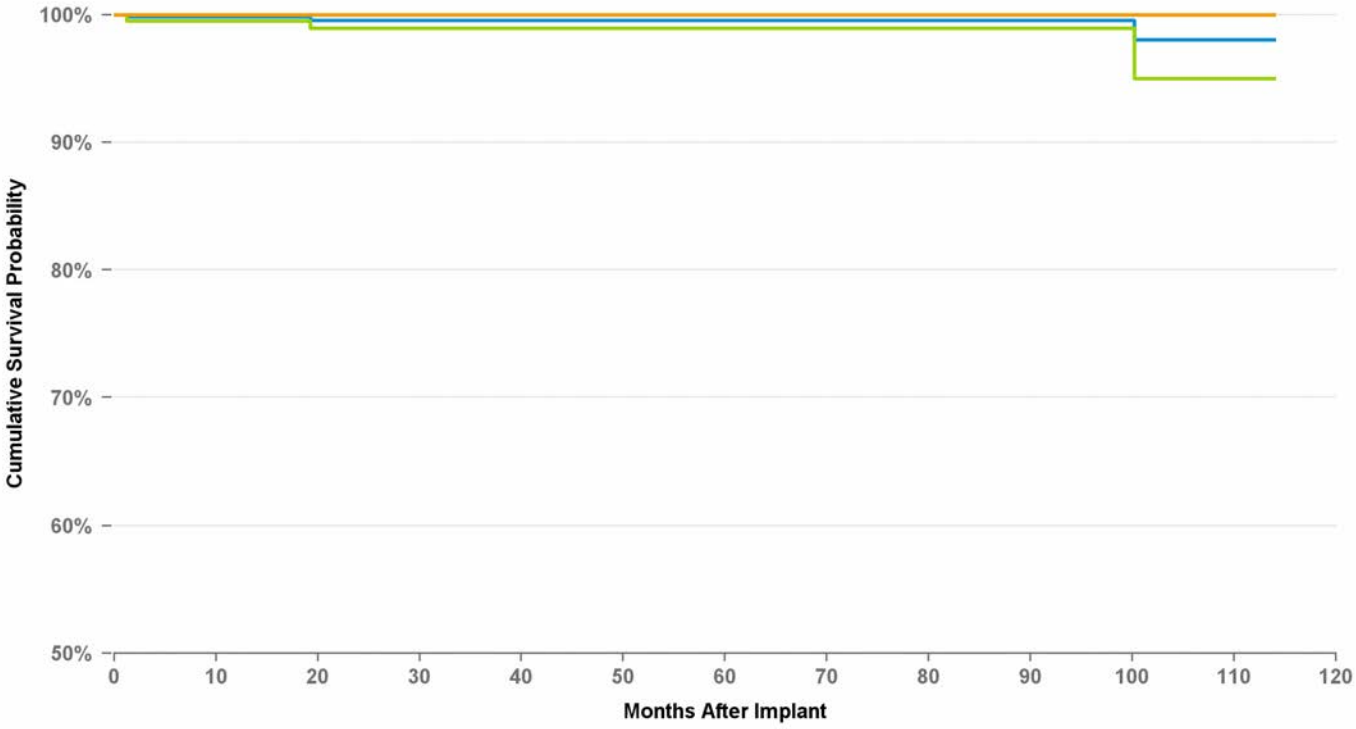
Distribution Data	
US Market Release	10/1/1991
CE Approval Date	
Registered US Implant	218,560
Estimated Active US	39,109
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,220
Cumulative Months of Follow-Up	25,219
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	200
Other	12

4024, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	99.6%	98.0%	98.0%
#	430	322	251	183	146	118	94	70	60	50

PACING LEAD

Distribution Data	
US Market Release	3/29/1996
CE Approval Date	
Registered US Implant	124,226
Estimated Active US	28,664
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	2,427
Cumulative Months of Follow-Up	123,366
Number of Leads Active in Study	187

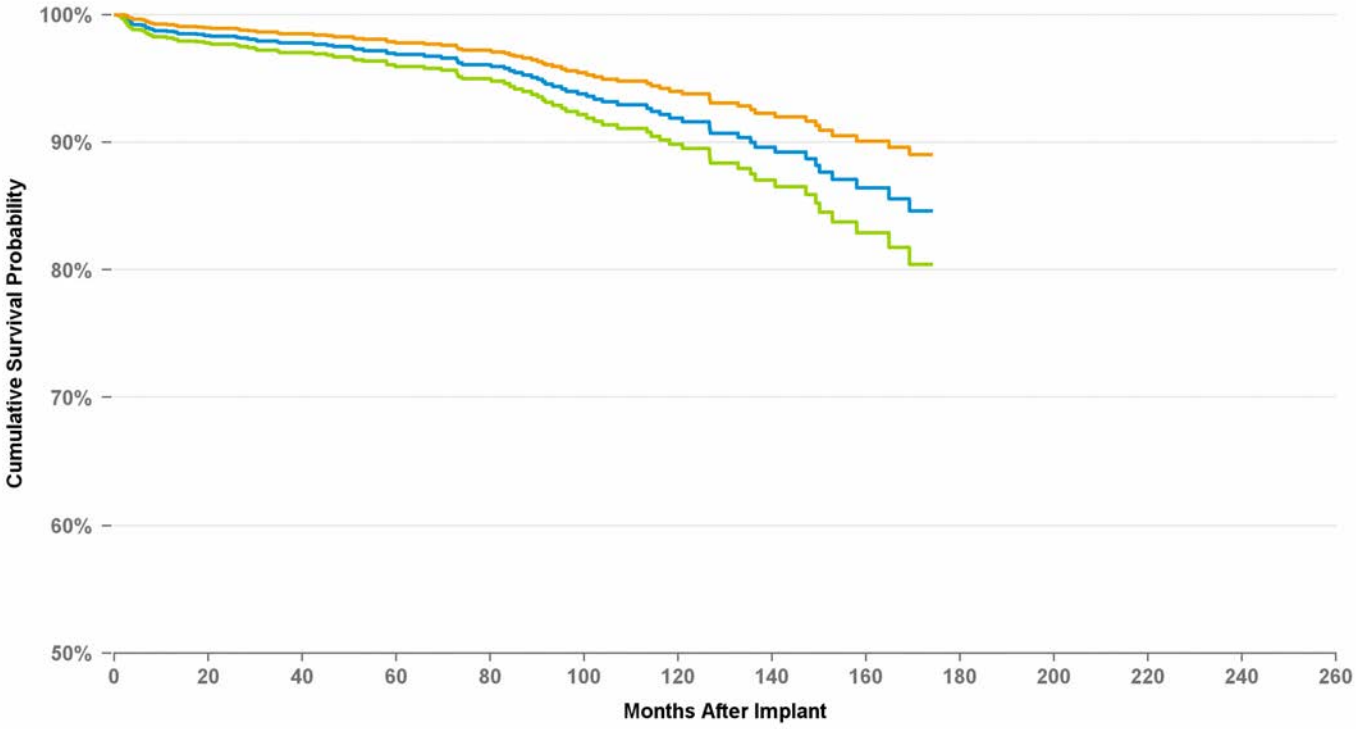
4068

Product Surveilance Registry Qualifying Complications	91
Cardiac Perforation	0
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	3
Failure To Capture	23
Failure To Sense	15
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	53
Crimp Weld Bond	0
Insulation Breach	194
Other	93

4068, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

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%	92.9%	91.9%	90.7%	89.2%	87.1%	85.6%	84.6%
#	1,601	1,394	1,195	1,016	873	737	586	484	399	334	269	191	134	91	66

PACING LEAD

4068

VENTRICULAR PLACEMENT

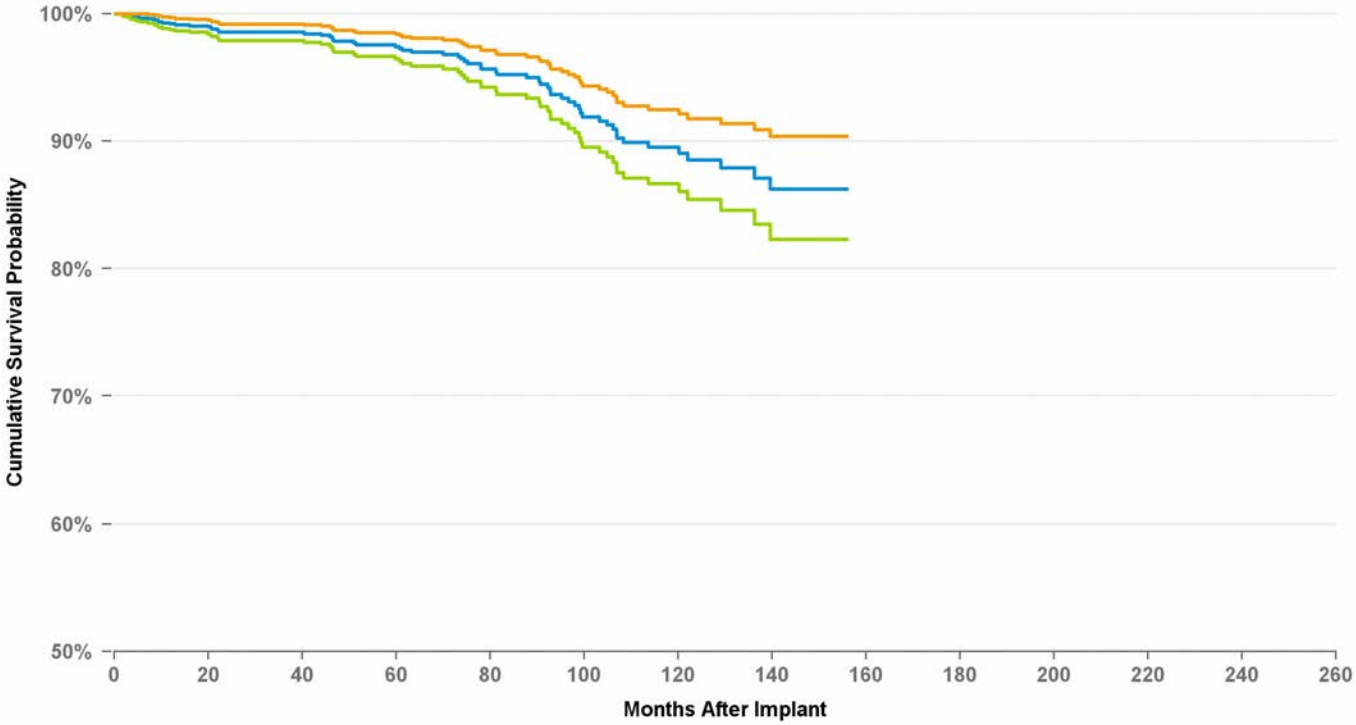
Distribution Data	
US Market Release	3/29/1996
CE Approval Date	
Registered US Implant	124,226
Estimated Active US	28,664
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,806
Cumulative Months of Follow-Up	91,135
Number of Leads Active in Study	99

Product Surveilance Registry Qualifying Complications	68
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	24
Failure To Sense	4
Impedance Abnormal	21
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	53
Crimp Weld Bond	0
Insulation Breach	194
Other	93

4068, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 156 mo
%	99.2%	98.5%	98.5%	97.8%	97.4%	96.8%	95.2%	93.4%	90.2%	89.5%	87.9%	86.2%	86.2%
#	1,288	1,110	964	802	666	532	420	330	260	191	124	78	52

PACING LEAD

Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implant	98,308
Estimated Active US	61,561
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	215
Cumulative Months of Follow-Up	16,773
Number of Leads Active in Study	118

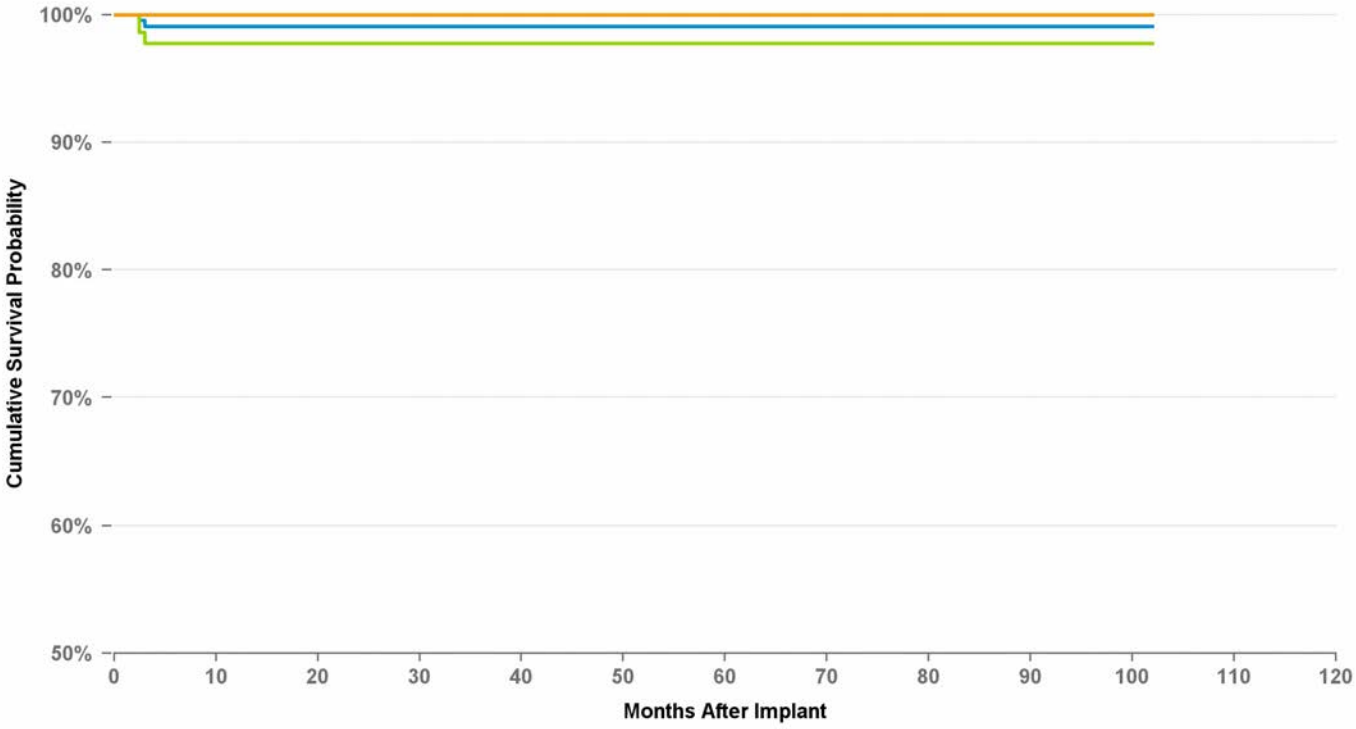
4074

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

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	13
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	36
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	39
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	26
Other	0

4074, ATR, Survival Curve



Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%
#	202	192	184	168	151	136	117	85	64

PACING LEAD

4074

VENTRICULAR PLACEMENT

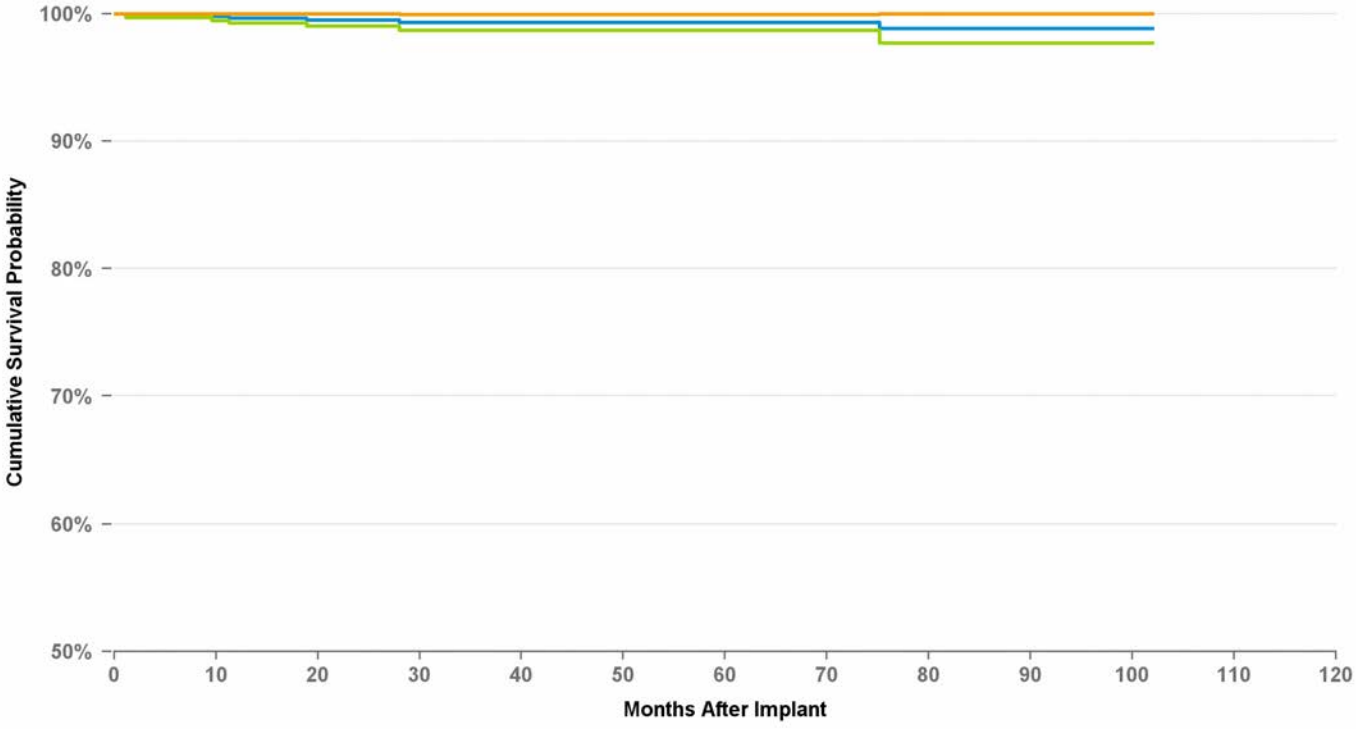
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implant	98,308
Estimated Active US	61,561
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,070
Cumulative Months of Follow-Up	39,876
Number of Leads Active in Study	635

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
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	13
Conductor Fracture	1
Extracardiac Stimulation	1
Failure To Capture	36
Failure To Sense	1
Impedance Abnormal	3
Insulation Breach	0
Lead Dislodgement	39
Oversensing	0
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	4
Crimp Weld Bond	0
Insulation Breach	26
Other	0

4074, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	at 102 mo
%	99.7%	99.5%	99.3%	99.3%	99.3%	99.3%	98.8%	98.8%	98.8%
#	791	574	389	299	261	214	155	87	60

PACING LEAD

Distribution Data	
US Market Release	2/25/2004
CE Approval Date	6/14/2004
Registered US Implant	491,687
Estimated Active US	377,938
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	2,185
Cumulative Months of Follow-Up	75,884
Number of Leads Active in Study	1,243

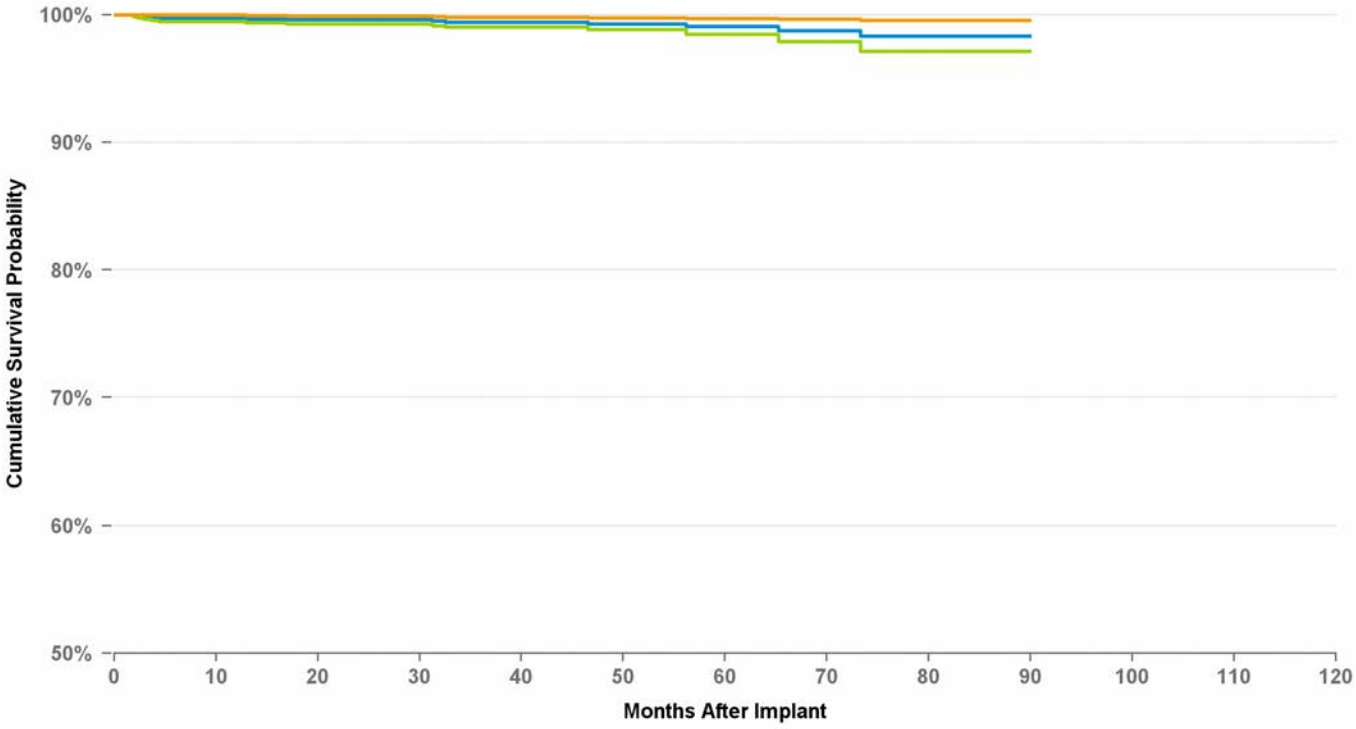
4076

Product Surveilance Registry Qualifying Complications	14
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	2
Failure To Sense	3
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)	1
Lead Dislodgement	6
Medical Judgment	0
Other Complication	0
Oversensing	1
Unspecified	0

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	64
Conductor Fracture	4
Extracardiac Stimulation	10
Failure To Capture	80
Failure To Sense	24
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	198
Oversensing	11
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	51
Crimp Weld Bond	1
Insulation Breach	52
Other	20

4076, ATR, Survival Curve



Years	1	2	3	4	5	6	7	at 90 mo
%	99.7%	99.6%	99.4%	99.3%	99.1%	98.8%	98.3%	98.3%
#	1,541	1,301	1,055	708	372	240	104	63

PACING LEAD

4076

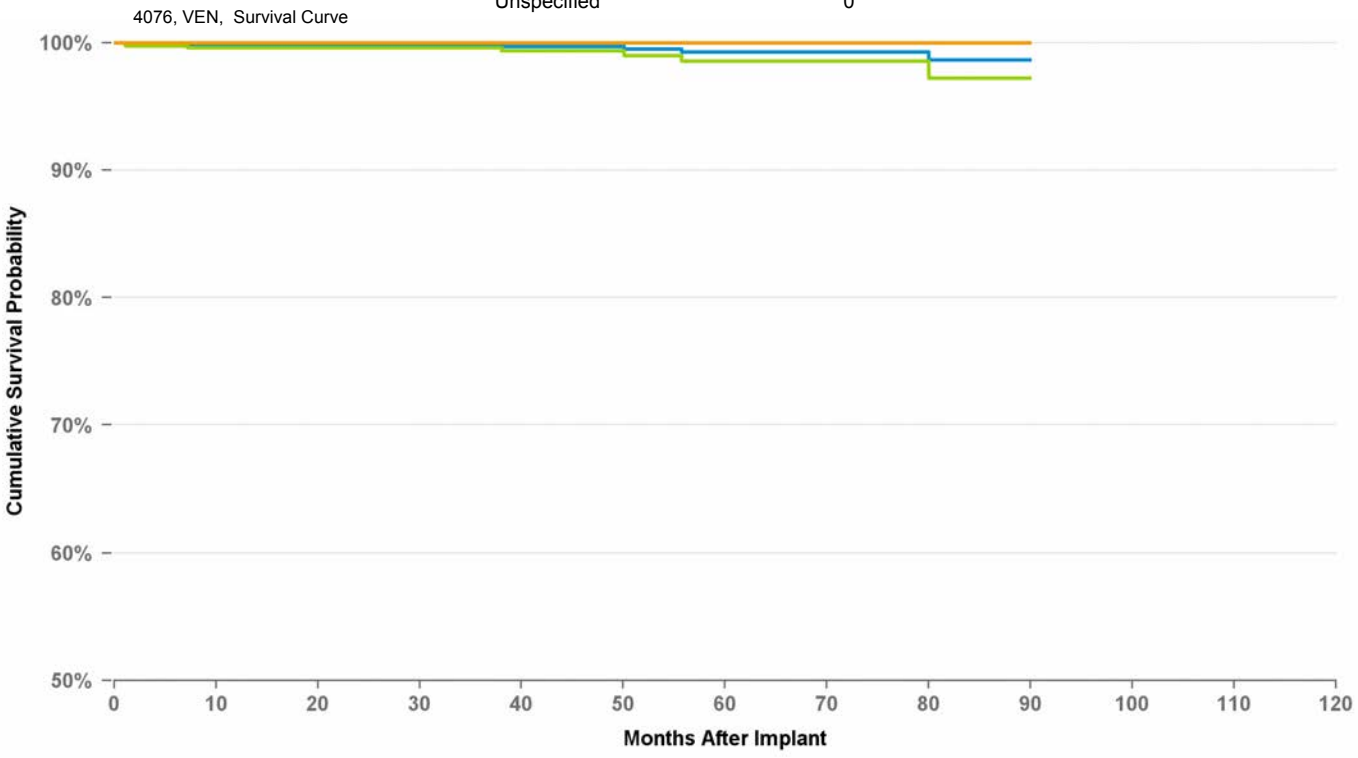
VENTRICULAR PLACEMENT

Distribution Data	
US Market Release	2/25/2004
CE Approval Date	6/14/2004
Registered US Implant	491,687
Estimated Active US	377,938
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	1,374
Cumulative Months of Follow-Up	57,152
Number of Leads Active in Study	682

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	3
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	64
Conductor Fracture	4
Extracardiac Stimulation	10
Failure To Capture	80
Failure To Sense	24
Impedance Abnormal	12
Insulation Breach	1
Lead Dislodgement	198
Oversensing	11
Unspecified	12
USA Returned Product Analysis	
Conductor Fracture	51
Crimp Weld Bond	1
Insulation Breach	52
Other	20



Years	1	2	3	4	5	6	7	at 90 mo
%	99.8%	99.8%	99.8%	99.7%	99.3%	99.3%	98.6%	98.6%
#	1,079	943	792	569	343	228	101	75

PACING LEAD

4092

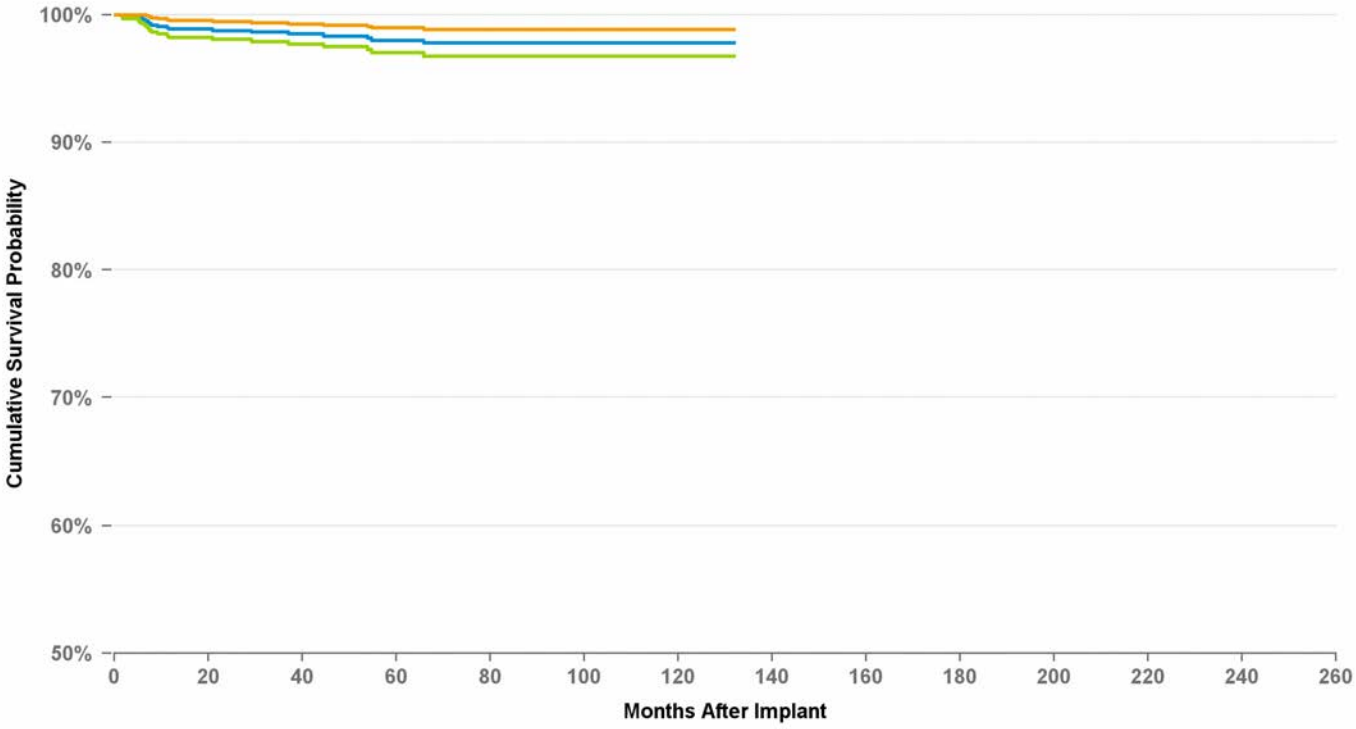
Distribution Data	
US Market Release	9/17/1998
CE Approval Date	4/15/1998
Registered US Implant	182,001
Estimated Active US	81,002
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,174
Cumulative Months of Follow-Up	66,037
Number of Leads Active in Study	278

Product Surveilance Registry Qualifying Complications	18
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	1
Failure To Capture	9
Failure To Sense	0
Impedance Abnormal	1
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	3
Conductor Fracture	4
Extracardiac Stimulation	1
Failure To Capture	31
Failure To Sense	0
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	26
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	56
Other	2

4092, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	98.9%	98.8%	98.6%	98.3%	98.0%	97.8%	97.8%	97.8%	97.8%	97.8%	97.8%
#	913	811	723	620	506	394	321	259	210	126	59

PACING LEAD

4524

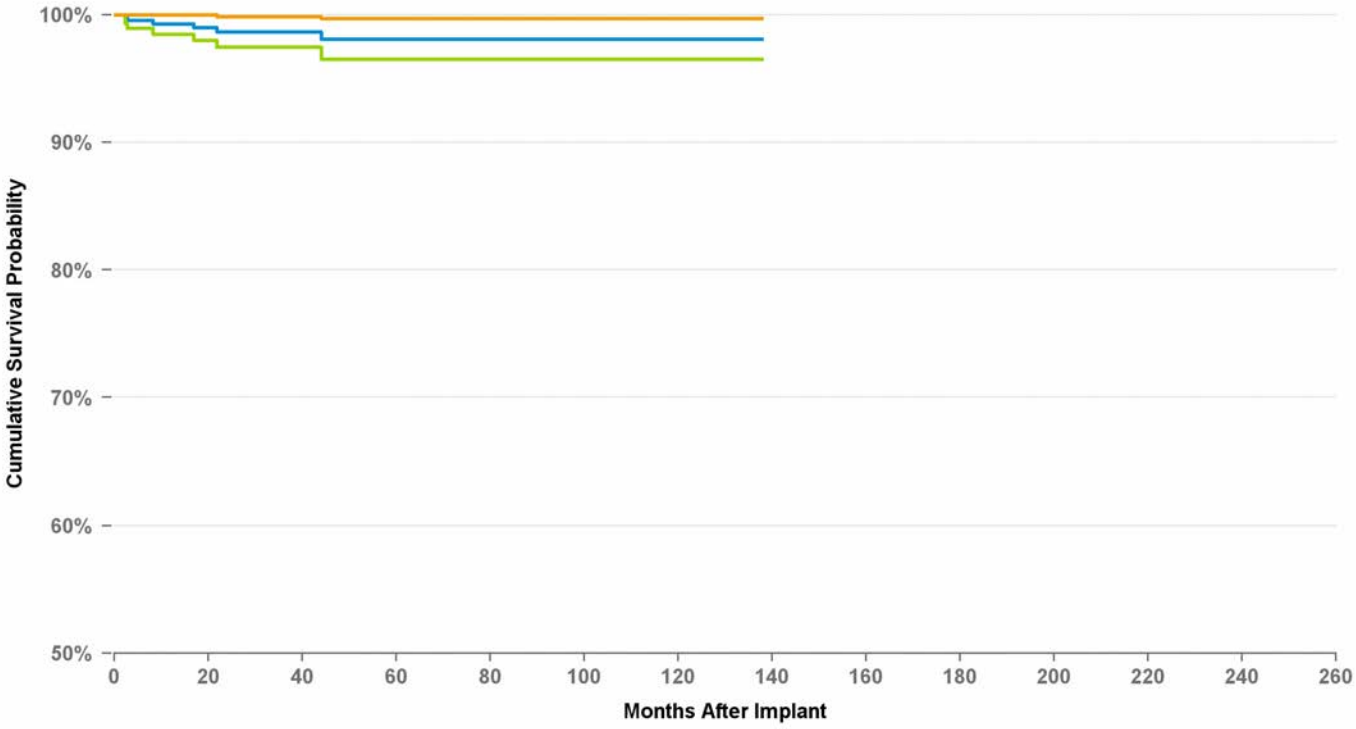
Distribution Data	
US Market Release	10/1/1991
CE Approval Date	
Registered US Implant	100,265
Estimated Active US	22,351
Product Characteristics	
Fixation Type	J-Shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	915
Cumulative Months of Follow-Up	23,210
Number of Leads Active in Study	27

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	3
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	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	77
Other	3

4524, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

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	86	75	66	55	53	52

PACING LEAD

4558M

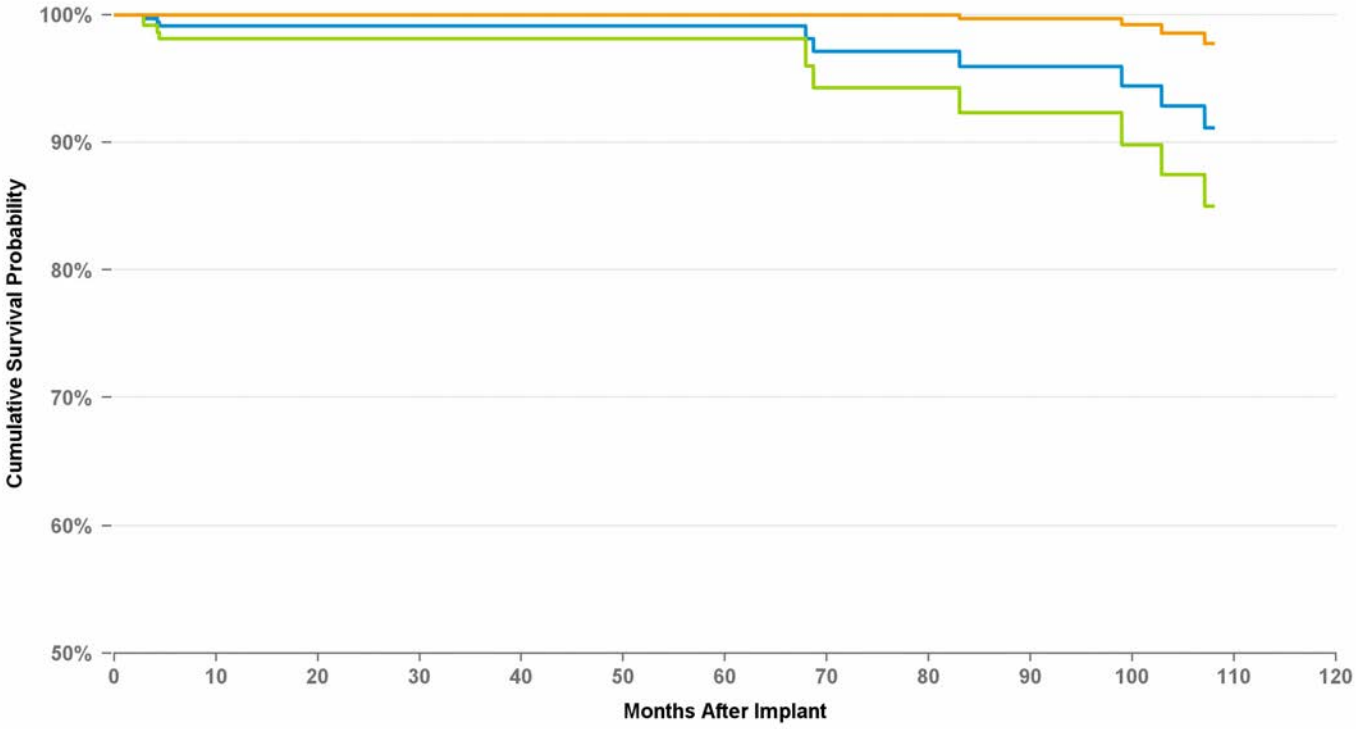
Distribution Data	
US Market Release	11/14/1994
CE Approval Date	
Registered US Implant	19,566
Estimated Active US	3,640
Product Characteristics	
Fixation Type	Active Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	540
Cumulative Months of Follow-Up	18,589
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	23
Other	20

4558M, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

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

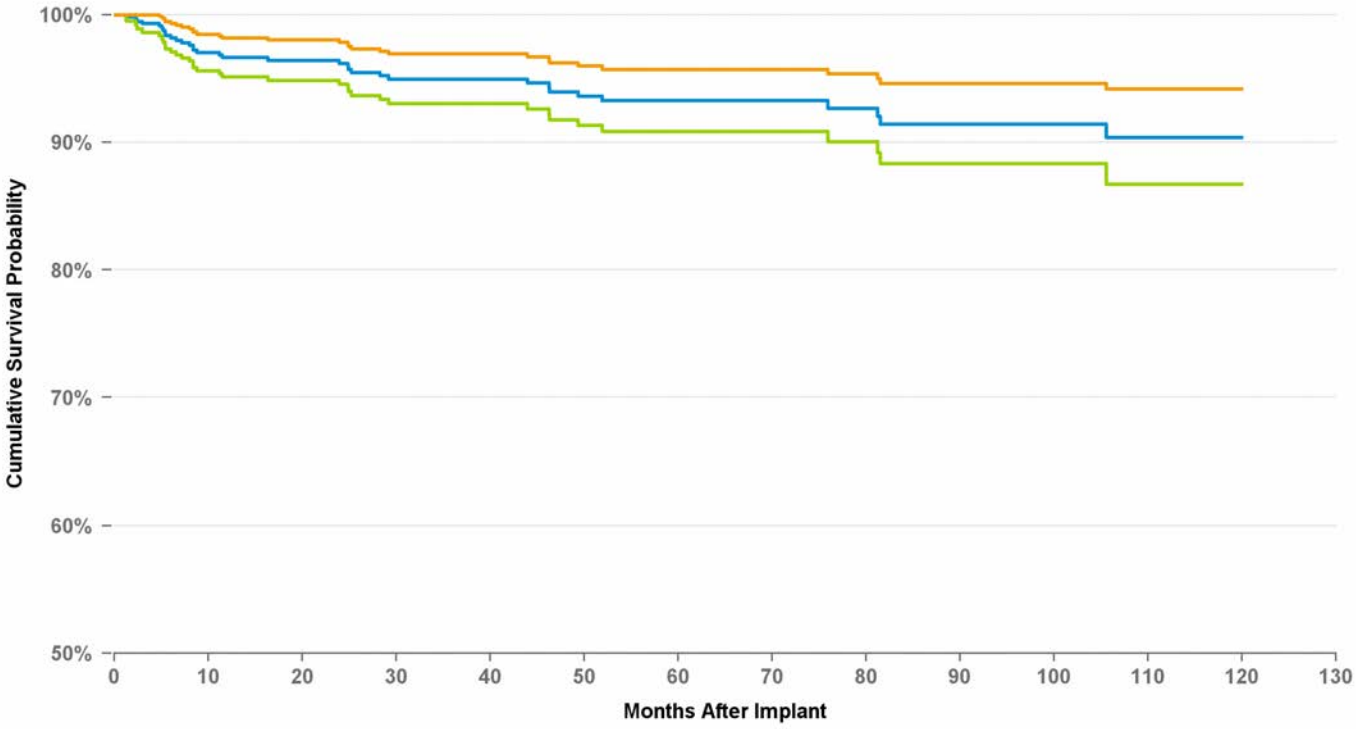
Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implant	69,205
Estimated Active US	20,015
Product Characteristics	
Fixation Type	J-shape, screw in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	665
Cumulative Months of Follow-Up	31,594
Number of Leads Active in Study	113

Product Surveilance Registry Qualifying Complications	36
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	19
Failure To Sense	3
Impedance Abnormal	3
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	7
Crimp Weld Bond	0
Insulation Breach	99
Other	52

4568, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	96.6%	96.2%	95.0%	94.0%	93.3%	93.3%	91.4%	91.4%	90.4%	90.4%
#	485	414	325	275	227	172	138	106	83	62

PACING LEAD

4574

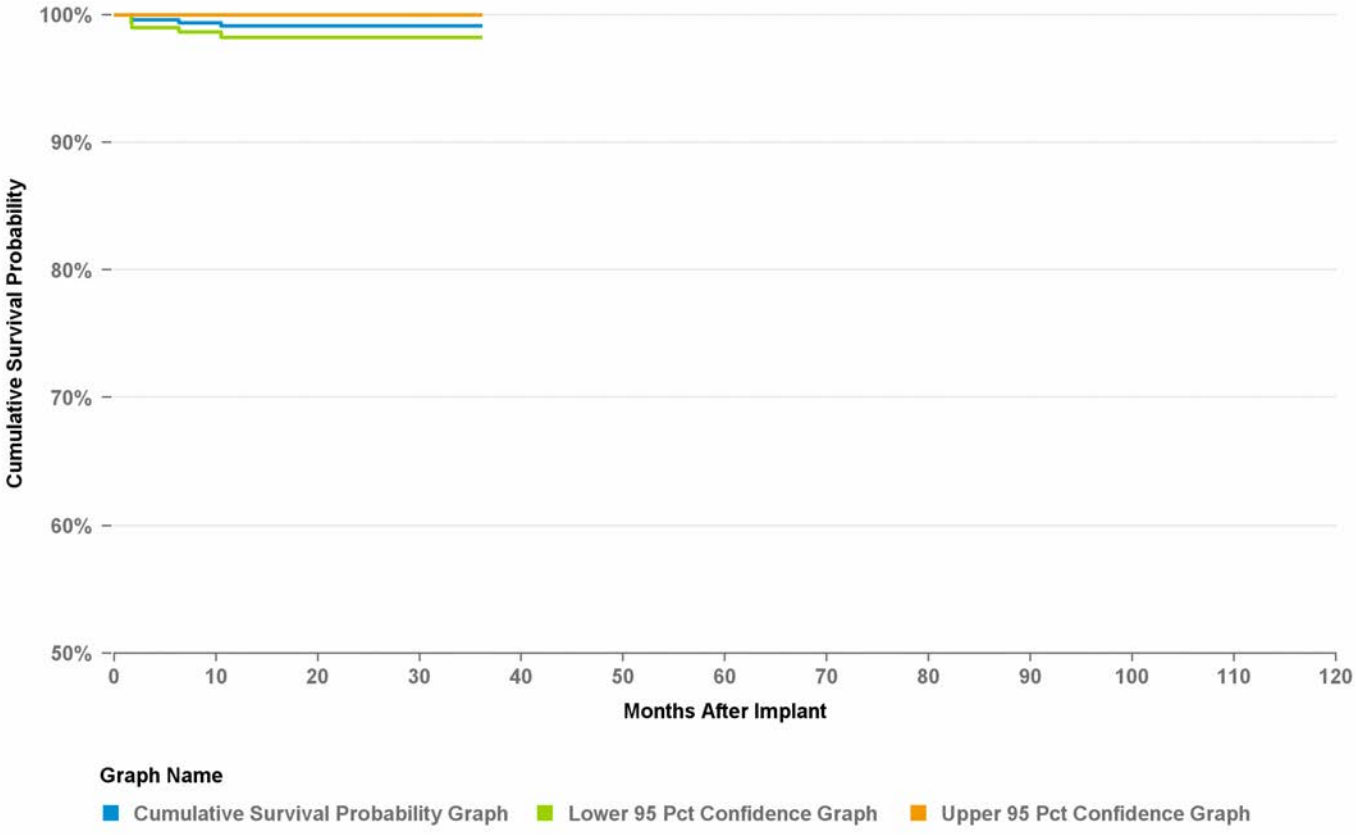
Distribution Data	
US Market Release	6/23/2002
CE Approval Date	2/1/2002
Registered US Implant	66,634
Estimated Active US	44,702
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	637
Cumulative Months of Follow-Up	11,229
Number of Leads Active in Study	462

Product Surveilance 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	1
Failure To Capture	19
Failure To Sense	8
Impedance Abnormal	0
Insulation Breach	0
Lead Dislodgement	47
Oversensing	1
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	10
Crimp Weld Bond	0
Insulation Breach	6
Other	0

4574, Survival Curve



Years	1	2	at 36 mo
%	99.1%	99.1%	99.1%
#	378	179	57

PACING LEAD

4592

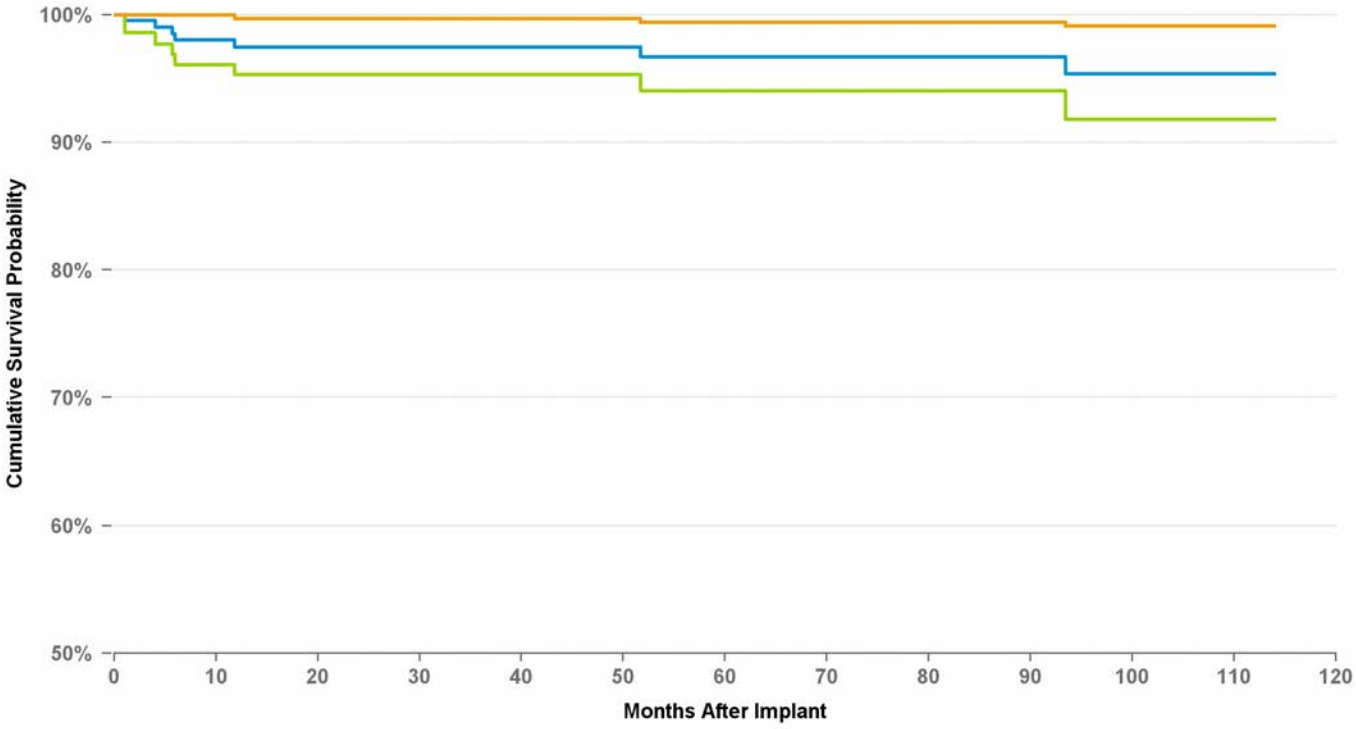
Distribution Data	
US Market Release	10/5/1998
CE Approval Date	4/15/1998
Registered US Implant	87,586
Estimated Active US	40,615
Product Characteristics	
Fixation Type	J-shape, tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium
Pace/Sense Polarit	Bipolar

Product Surveilance Registry 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	28
Oversensing	2
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	7
Crimp Weld Bond	0
Insulation Breach	21
Other	1

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	311
Cumulative Months of Follow-Up	15,367
Number of Leads Active in Study	71

4592, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 114 mo
%	97.5%	97.5%	97.5%	97.5%	96.7%	96.7%	96.7%	95.4%	95.4%	95.4%
#	189	166	148	134	110	100	79	71	59	51

PACING LEAD

5033

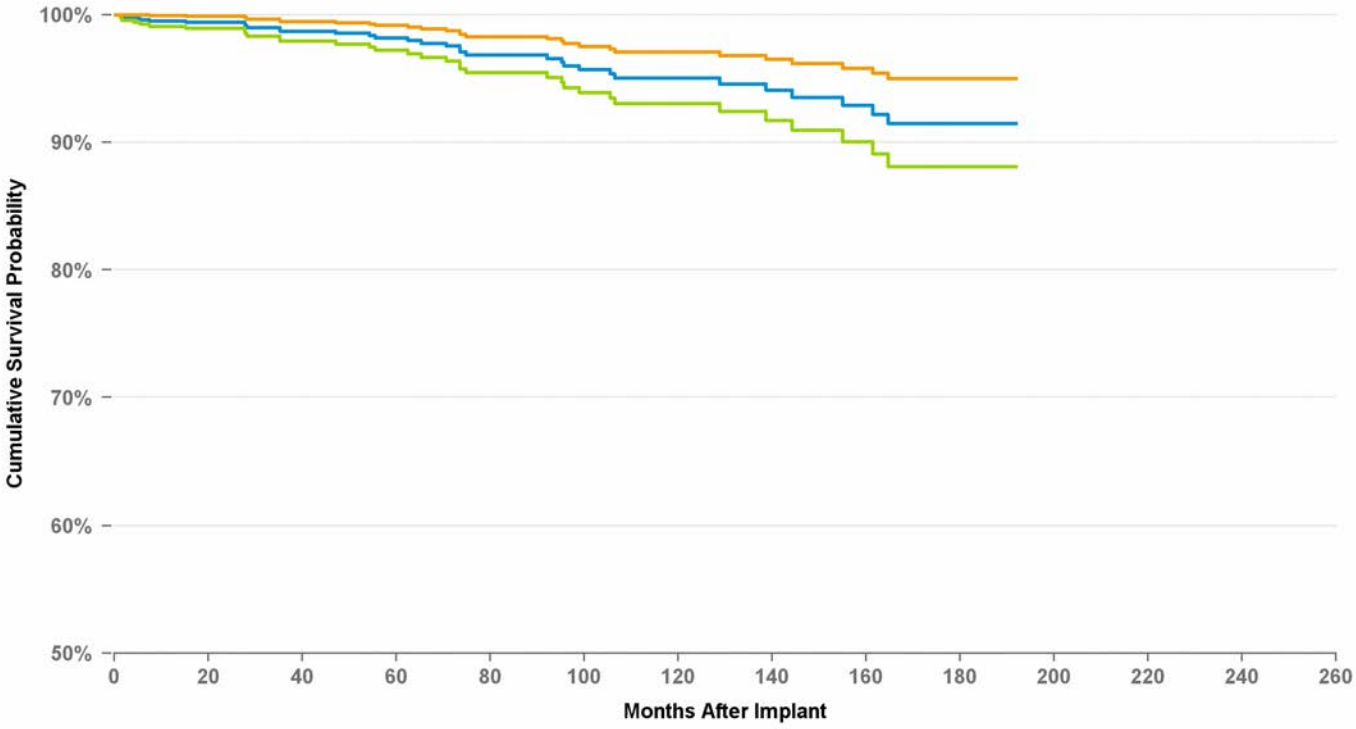
Distribution Data	
US Market Release	2/9/1996
CE Approval Date	
Registered US Implant	2,339
Estimated Active US	457
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,901
Cumulative Months of Follow-Up	77,216
Number of Leads Active in Study	30

Product Surveilance Registry Qualifying Complications	32
Cardiac Perforation	1
Conductor Fracture	8
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	16
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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	at 192 mo
%	99.5%	99.4%	98.7%	98.5%	98.2%	97.5%	96.9%	96.0%	95.0%	95.0%	94.6%	94.1%	92.9%	91.5%	91.5%	91.5%
#	902	761	672	584	510	436	379	326	276	236	197	169	146	118	100	62

PACING LEAD

5034

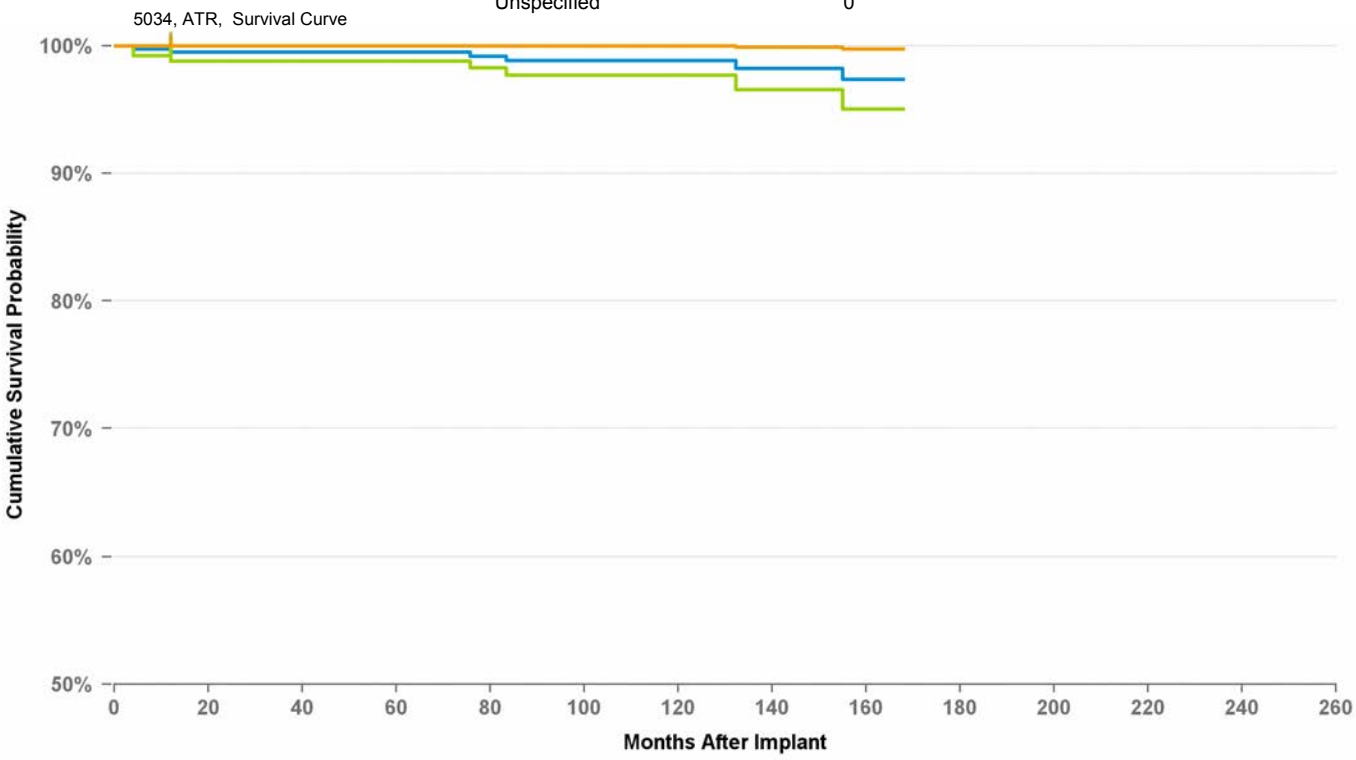
ATRIAL PLACEMENT

Distribution Data	
US Market Release	2/9/1996
CE Approval Date	
Registered US Implant	55,370
Estimated Active US	11,822
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 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	16
Crimp Weld Bond	0
Insulation Breach	15
Other	7

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	386
Cumulative Months of Follow-Up	46,516
Number of Leads Active in Study	83



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%	97.4%	97.4%
#	383	382	379	376	358	334	297	253	212	187	156	136	110	67

PACING LEAD

5034

VENTRICULAR PLACEMENT

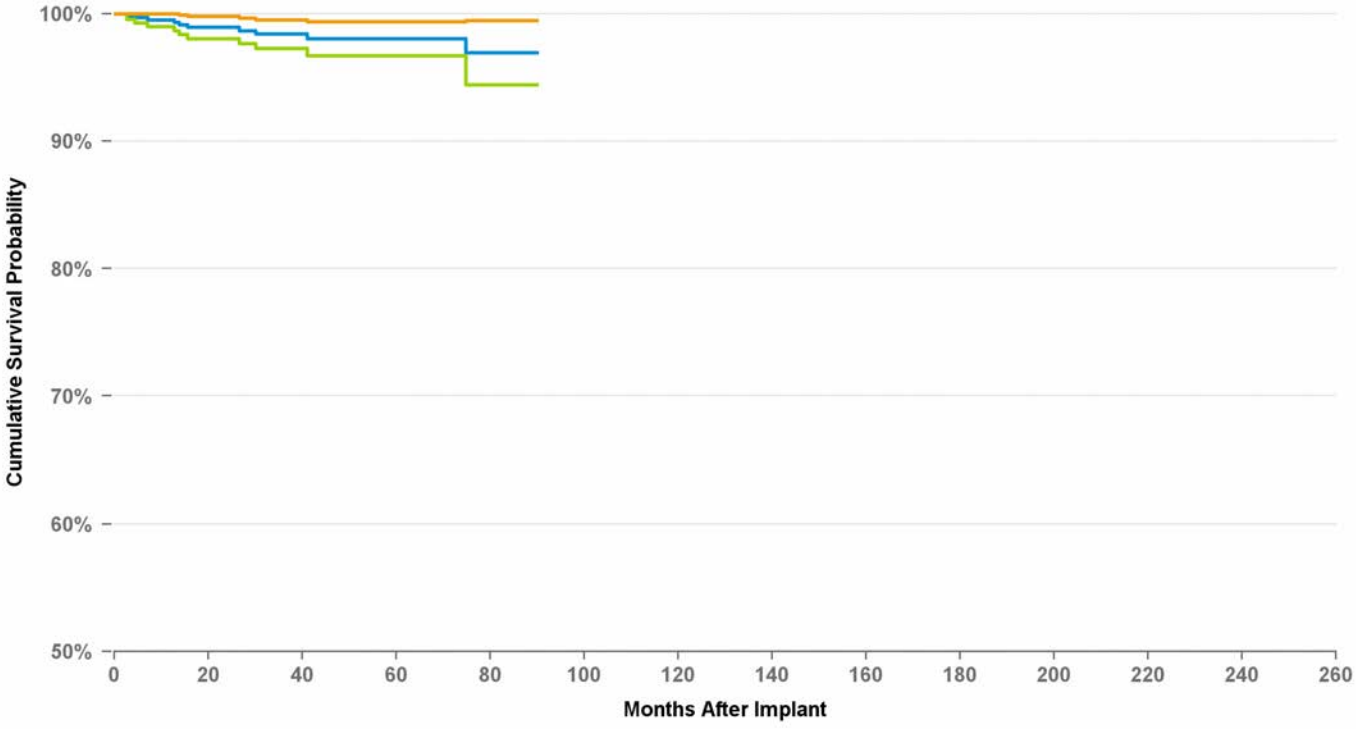
Distribution Data	
US Market Release	2/9/1996
CE Approval Date	
Registered US Implant	55,370
Estimated Active US	11,822
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,213
Cumulative Months of Follow-Up	28,012
Number of Leads Active in Study	9

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	16
Crimp Weld Bond	0
Insulation Breach	15
Other	7

5034, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph | Lower 95 Pct Confidence Graph | Upper 95 Pct Confidence Graph

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

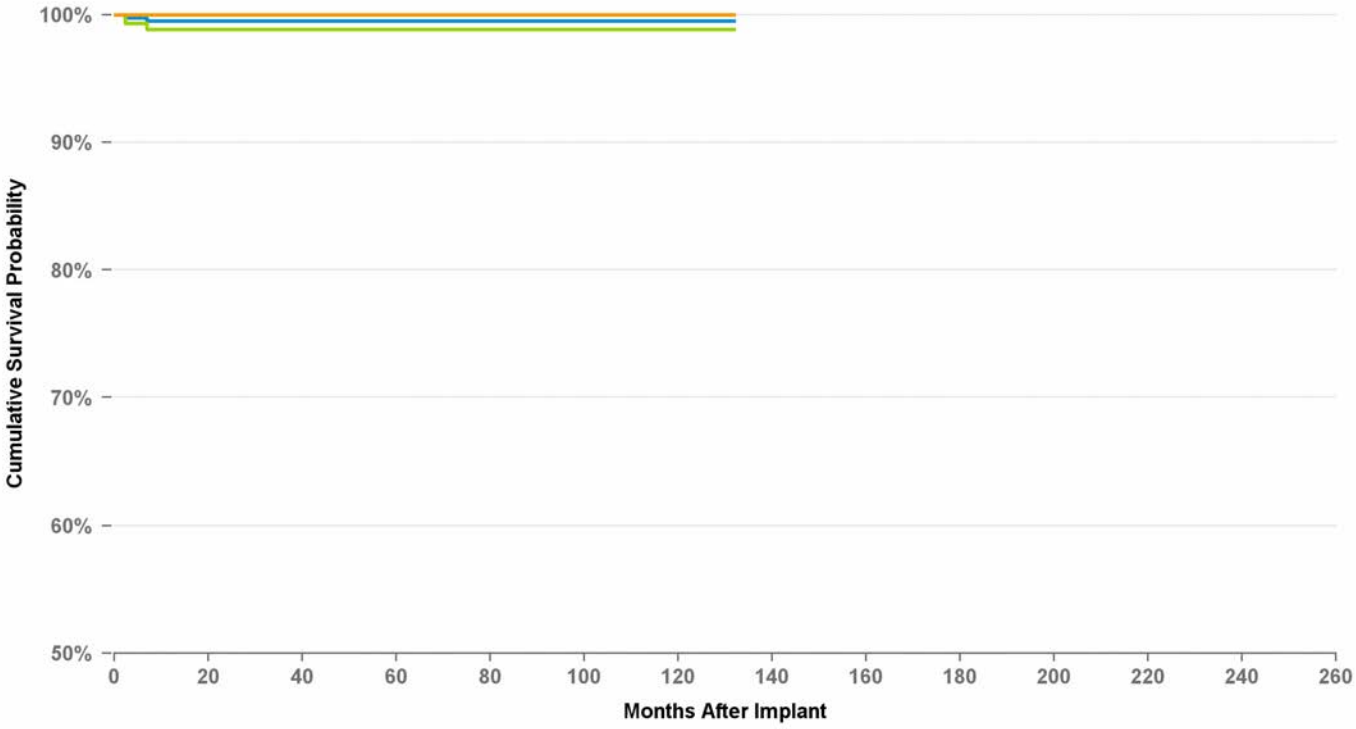
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implant	97,823
Estimated Active US	41,077
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	424
Cumulative Months of Follow-Up	35,546
Number of Leads Active in Study	95

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	26
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	1
Insulation Breach	30
Other	3

5054, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 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	147	96	66

PACING LEAD

5054

VENTRICULAR PLACEMENT

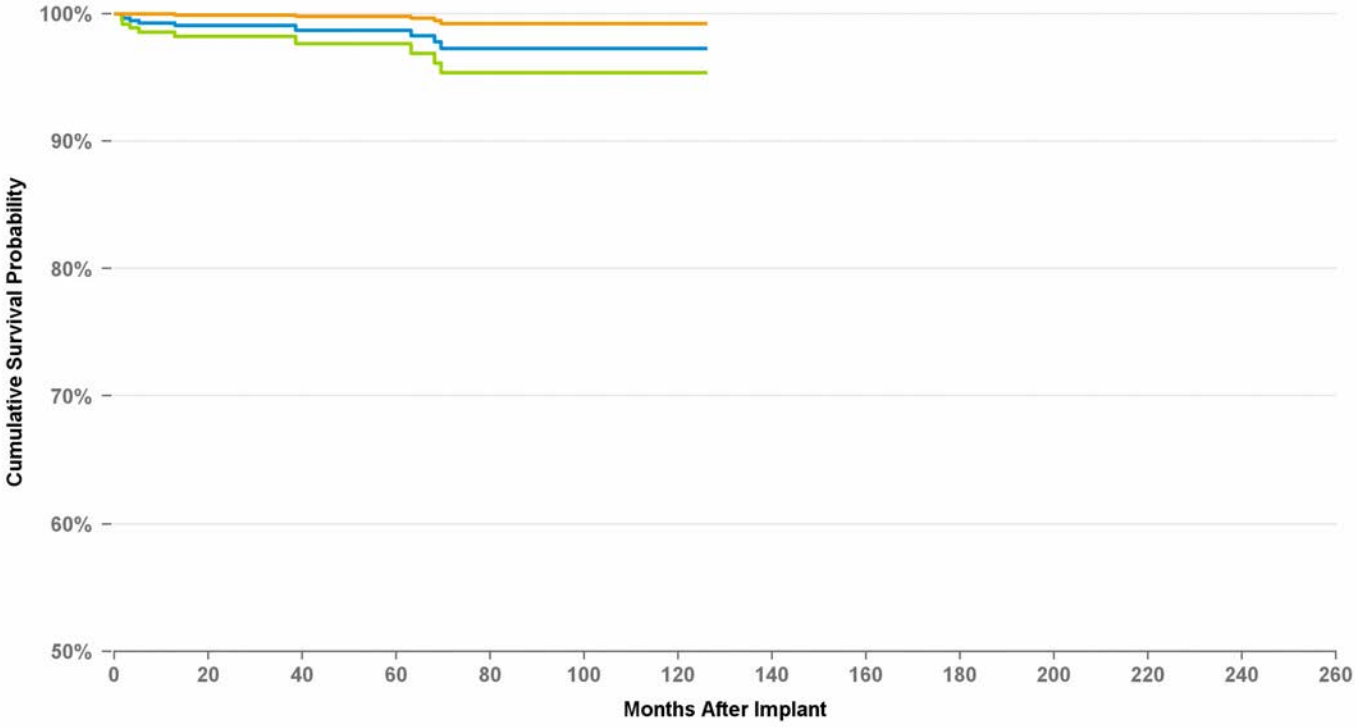
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implant	97,823
Estimated Active US	41,077
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	980
Cumulative Months of Follow-Up	31,386
Number of Leads Active in Study	87

Product Surveillance 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	26
Oversensing	0
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	12
Crimp Weld Bond	1
Insulation Breach	30
Other	3

5054, VEN, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 126 mo
%	99.3%	99.1%	99.1%	98.7%	98.7%	97.3%	97.3%	97.3%	97.3%	97.3%	97.3%
#	471	385	300	260	225	187	162	131	90	64	56

PACING LEAD

Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implant	102,401
Estimated Active US	27,882
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	977
Cumulative Months of Follow-Up	26,667
Number of Leads Active in Study	29

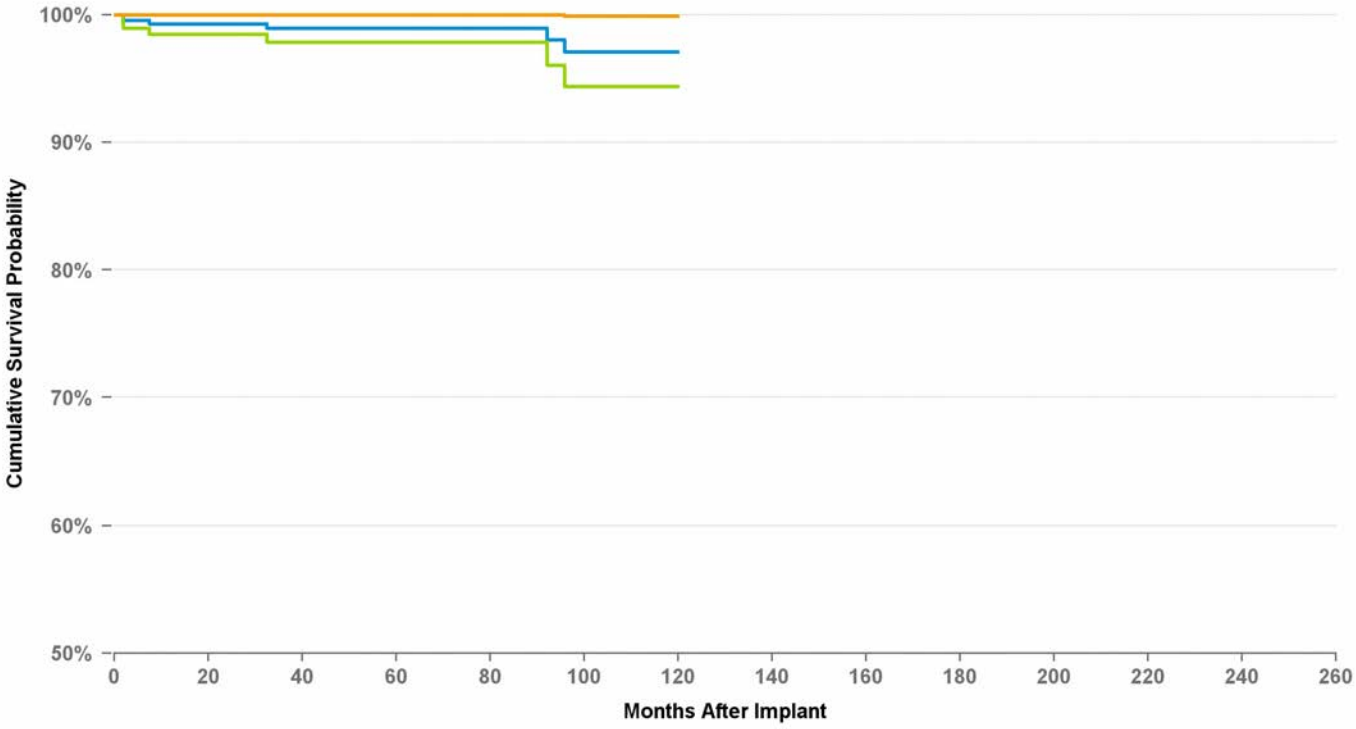
5068

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

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	18
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	58
Other	83

5068, ATR, Survival Curve



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%
#	349	302	257	225	193	155	128	100	68	57

PACING LEAD

5068

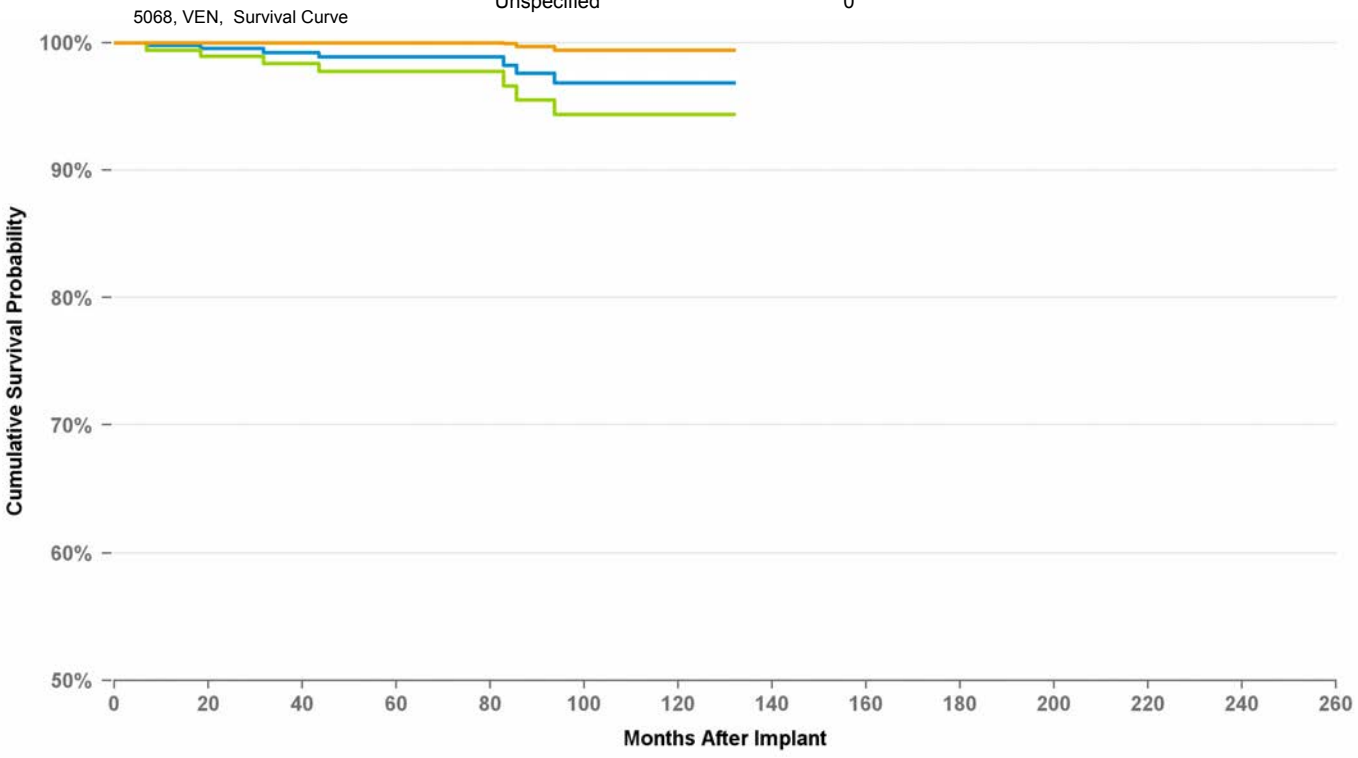
VENTRICULAR PLACEMENT

Distribution Data	
US Market Release	1/2/1997
CE Approval Date	
Registered US Implant	102,401
Estimated Active US	27,882
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	1,371
Cumulative Months of Follow-Up	31,404
Number of Leads Active in Study	54

Product Surveilance Registry Qualifying Complications	9
Cardiac Perforation	0
Conductor Fracture	1
Electrical Abandonment	0
Extracardiac Stimulation	1
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	18
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	58
Other	83



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%	96.9%	96.9%	96.9%	96.9%
#	448	359	291	246	223	189	151	125	102	80	58

PACING LEAD

5072

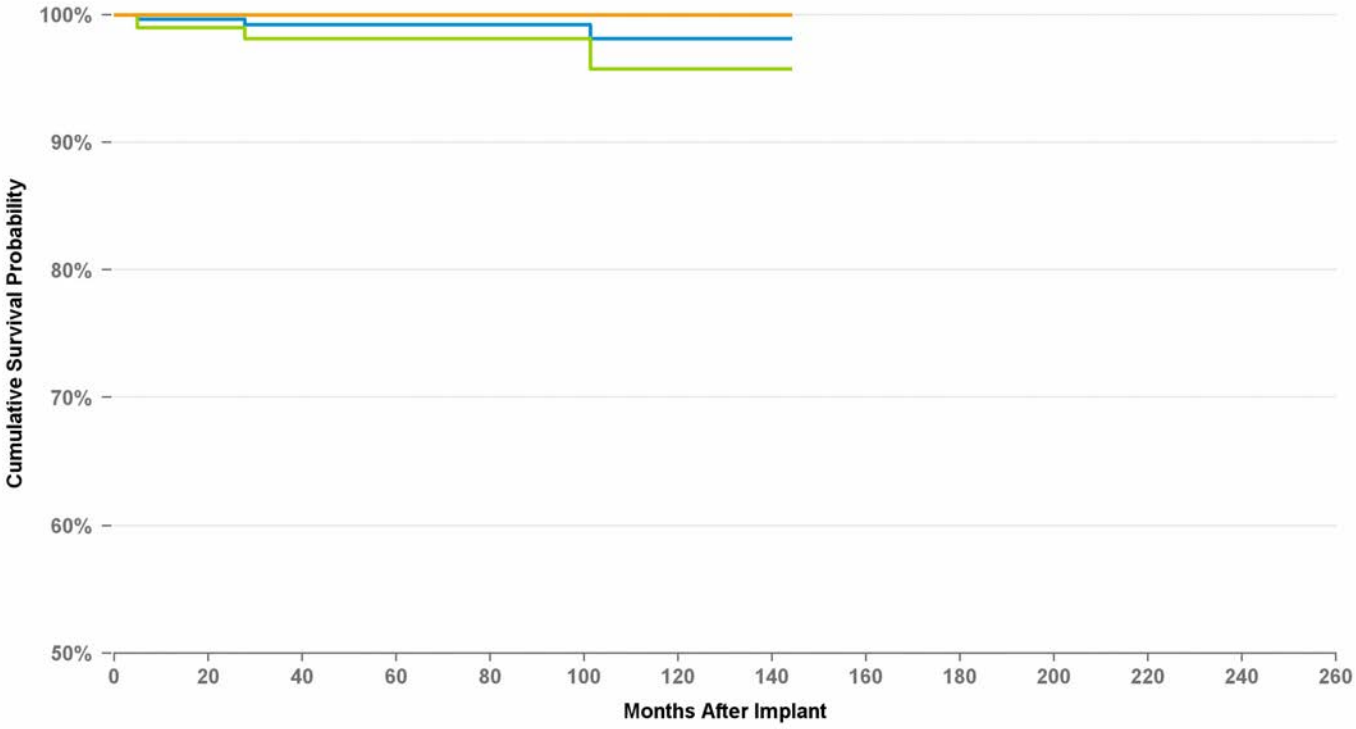
Distribution Data	
US Market Release	6/5/1998
CE Approval Date	9/25/1997
Registered US Implant	10,054
Estimated Active US	3,927
Product Characteristics	
Fixation Type	Fixed Screw
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	511
Cumulative Months of Follow-Up	22,783
Number of Leads Active in Study	12

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	9
Other	0

5072, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	at 144 mo
%	99.7%	99.7%	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%	98.1%	98.1%	98.1%	98.1%
#	258	231	216	191	157	136	109	93	83	73	63	51

PACING LEAD

5076

ATRIAL PLACEMENT

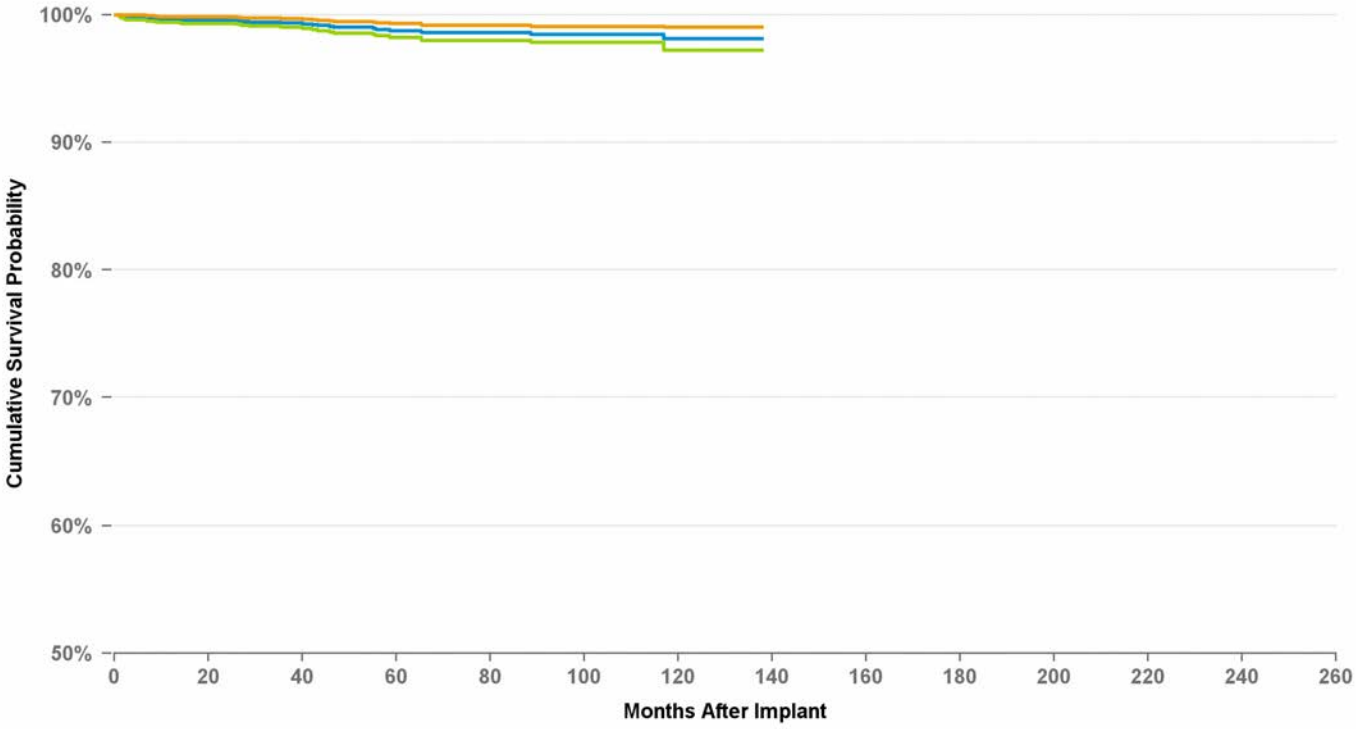
Distribution Data	
US Market Release	8/31/2000
CE Approval Date	8/12/1999
Registered US Implant	1,646,542
Estimated Active US	1,044,561
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	4,208
Cumulative Months of Follow-Up	155,504
Number of Leads Active in Study	1,801

Product Surveilance Registry Qualifying Complications	28
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	6
Medical Judgment	0
Other Complication	2
Oversensing	1
Unspecified	0

US Acute Lead Observations	
Cardiac Perforation	227
Conductor Fracture	15
Extracardiac Stimulation	18
Failure To Capture	278
Failure To Sense	45
Impedance Abnormal	18
Insulation Breach	8
Lead Dislodgement	681
Oversensing	42
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	535
Crimp Weld Bond	0
Insulation Breach	542
Other	193

5076, ATR, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	at 138 mo
%	99.6%	99.6%	99.4%	99.0%	98.8%	98.6%	98.6%	98.5%	98.5%	98.1%	98.1%	98.1%
#	2,351	1,861	1,592	1,324	1,119	951	800	599	388	227	120	85

PACING LEAD

5076

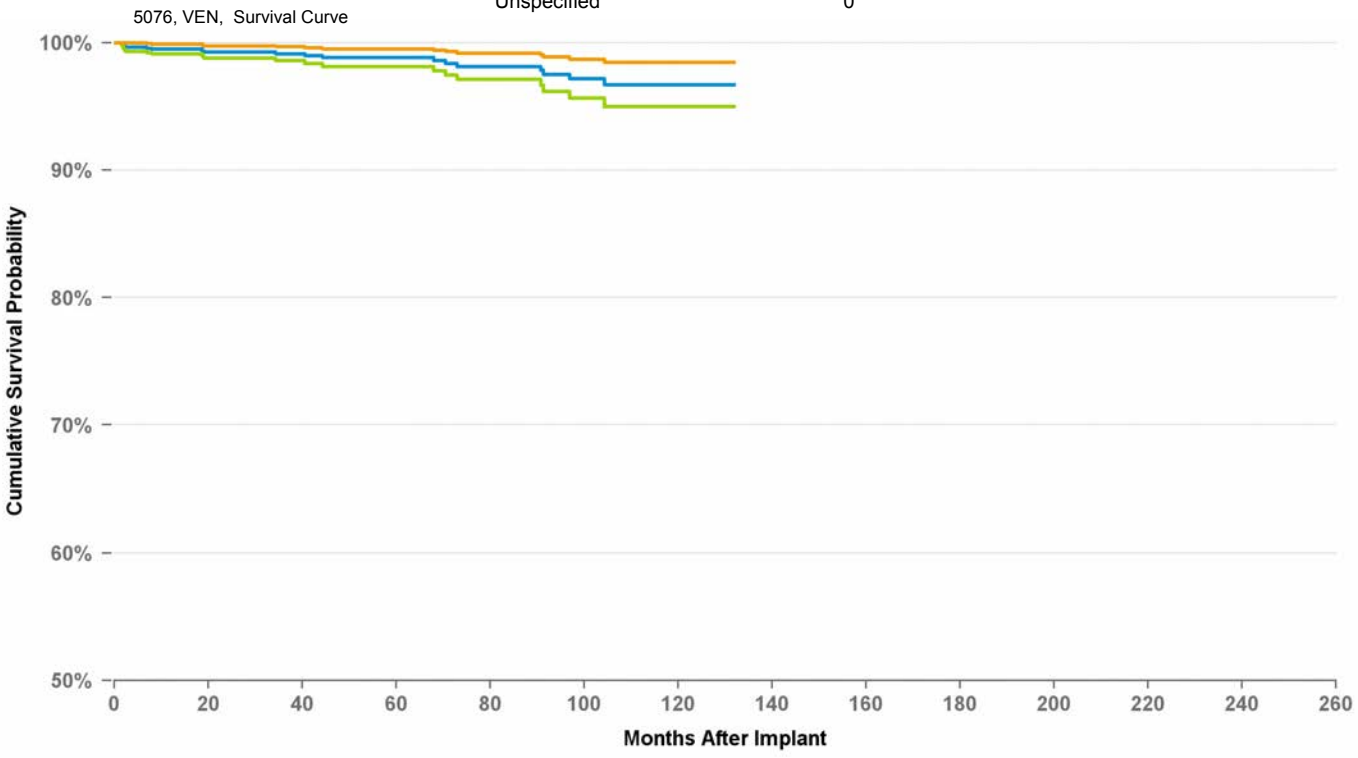
VENTRICULAR PLACEMENT

Distribution Data	
US Market Release	8/31/2000
CE Approval Date	8/12/1999
Registered US Implant	1,646,542
Estimated Active US	1,044,561
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	2,037
Cumulative Months of Follow-Up	70,879
Number of Leads Active in Study	656

Product Surveilance Registry Qualifying Complications	20
Cardiac Perforation	1
Conductor Fracture	4
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	7
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	227
Conductor Fracture	15
Extracardiac Stimulation	18
Failure To Capture	278
Failure To Sense	45
Impedance Abnormal	18
Insulation Breach	8
Lead Dislodgement	681
Oversensing	42
Unspecified	31
USA Returned Product Analysis	
Conductor Fracture	535
Crimp Weld Bond	0
Insulation Breach	542
Other	193



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	99.3%	99.1%	98.8%	98.8%	98.4%	98.1%	97.5%	96.7%	96.7%	96.7%
#	1,129	864	712	568	485	412	341	264	172	115	67

PACING LEAD

Distribution Data	
US Market Release	2/8/2011
CE Approval Date	1/21/2009
Registered US Implant	194,163
Estimated Active US	187,031
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	2,948
Cumulative Months of Follow-Up	47,602
Number of Leads Active in Study	2,378

5086MRI

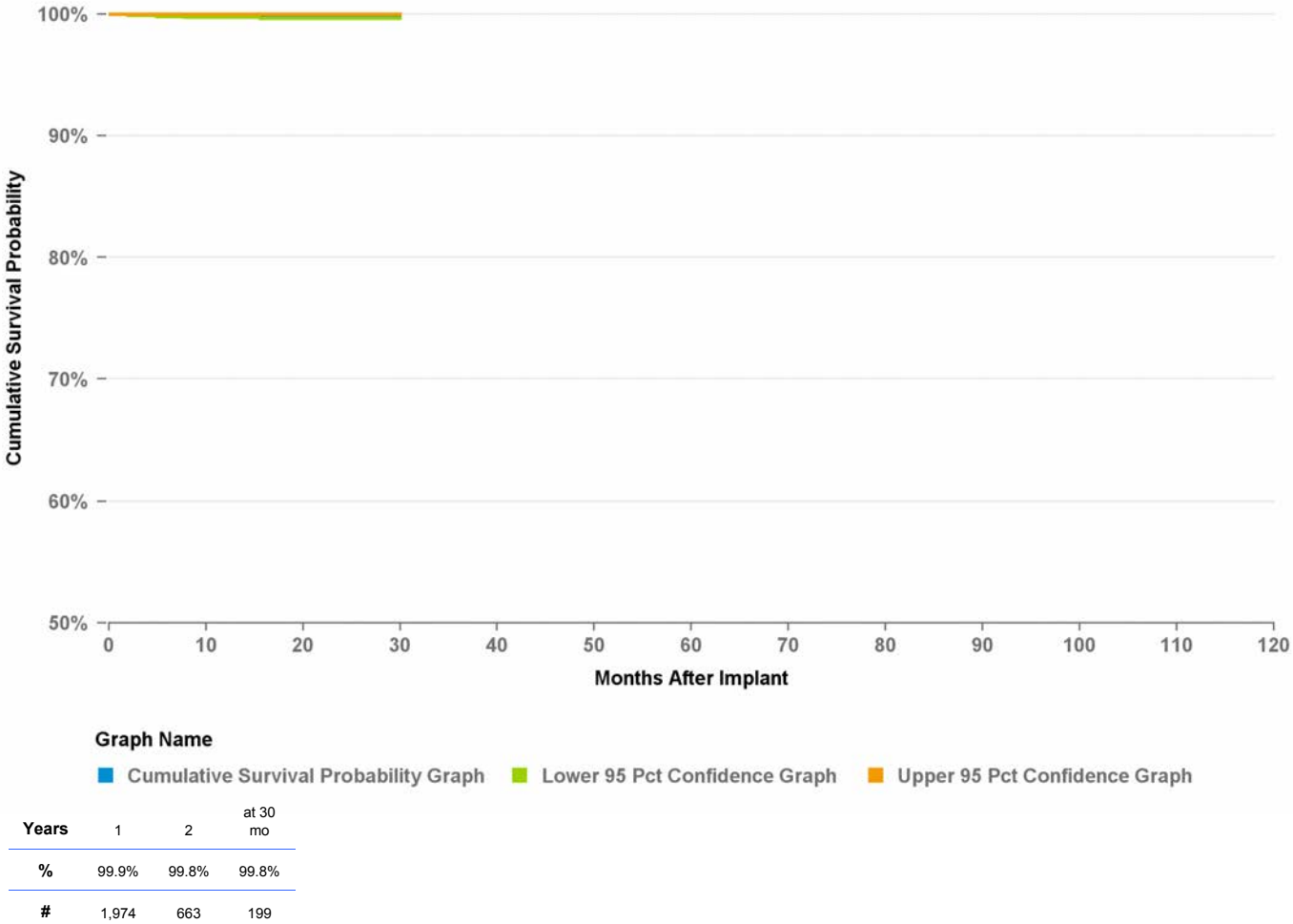
Product Surveilance Registry Qualifying Complications	4
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	0
Failure To Sense	0
Impedance Abnormal	0
Insulation Breach (ESC)	0
Insulation Breach (MIO)	0
Insulation Breach (not further defined)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

ATRIAL PLACEMENT

US Acute Lead Observations	
Cardiac Perforation	184
Conductor Fracture	2
Extracardiac Stimulation	14
Failure To Capture	114
Failure To Sense	25
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	264
Oversensing	27
Unspecified	0

USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	24
Other	10

5086MRI, ATR, Survival Curve



Years	1	2	at 30 mo
%	99.9%	99.8%	99.8%
#	1,974	663	199

PACING LEAD

Distribution Data	
US Market Release	2/8/2011
CE Approval Date	1/21/2009
Registered US Implant	194,163
Estimated Active US	187,031
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	2,937
Cumulative Months of Follow-Up	47,501
Number of Leads Active in Study	2,374

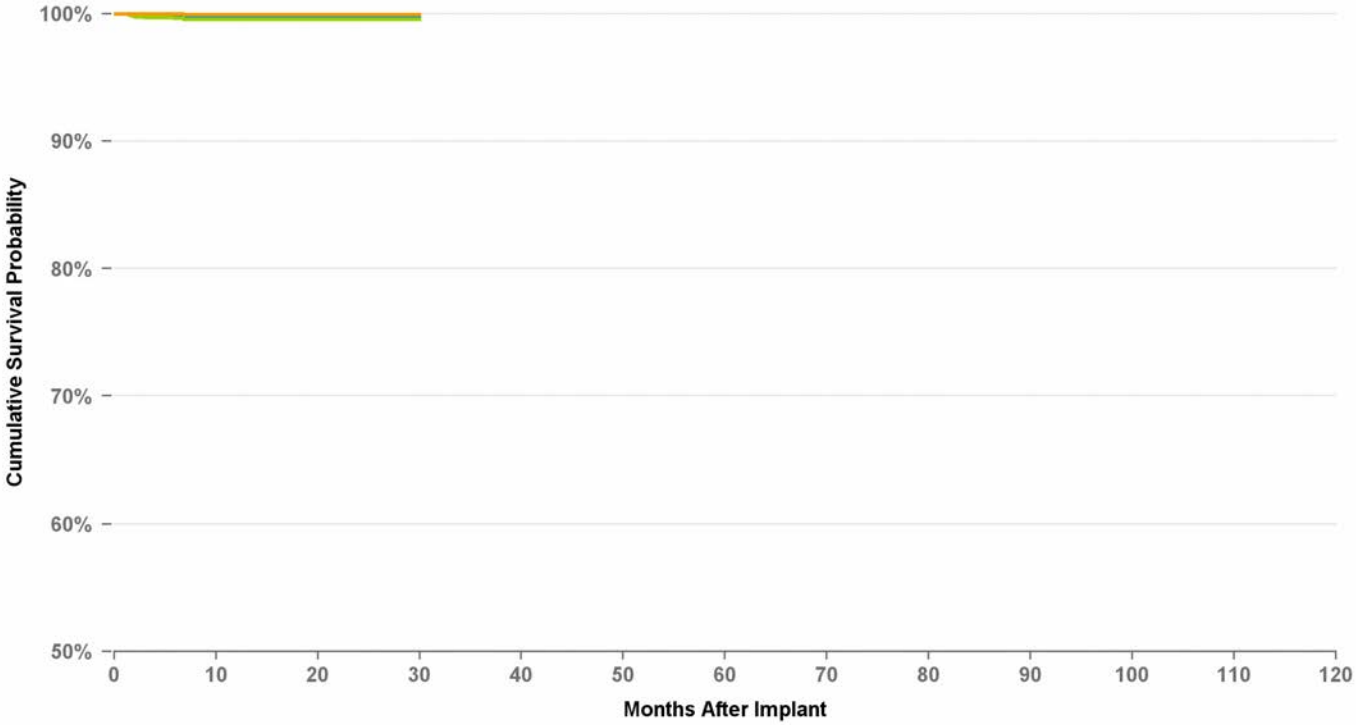
5086MRI

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	184
Conductor Fracture	2
Extracardiac Stimulation	14
Failure To Capture	114
Failure To Sense	25
Impedance Abnormal	9
Insulation Breach	1
Lead Dislodgement	264
Oversensing	27
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	24
Other	10

5086MRI, VEN, Survival Curve



Years	1	2	at 30 mo
%	99.8%	99.8%	99.8%
#	1,966	670	198

PACING LEAD

5092

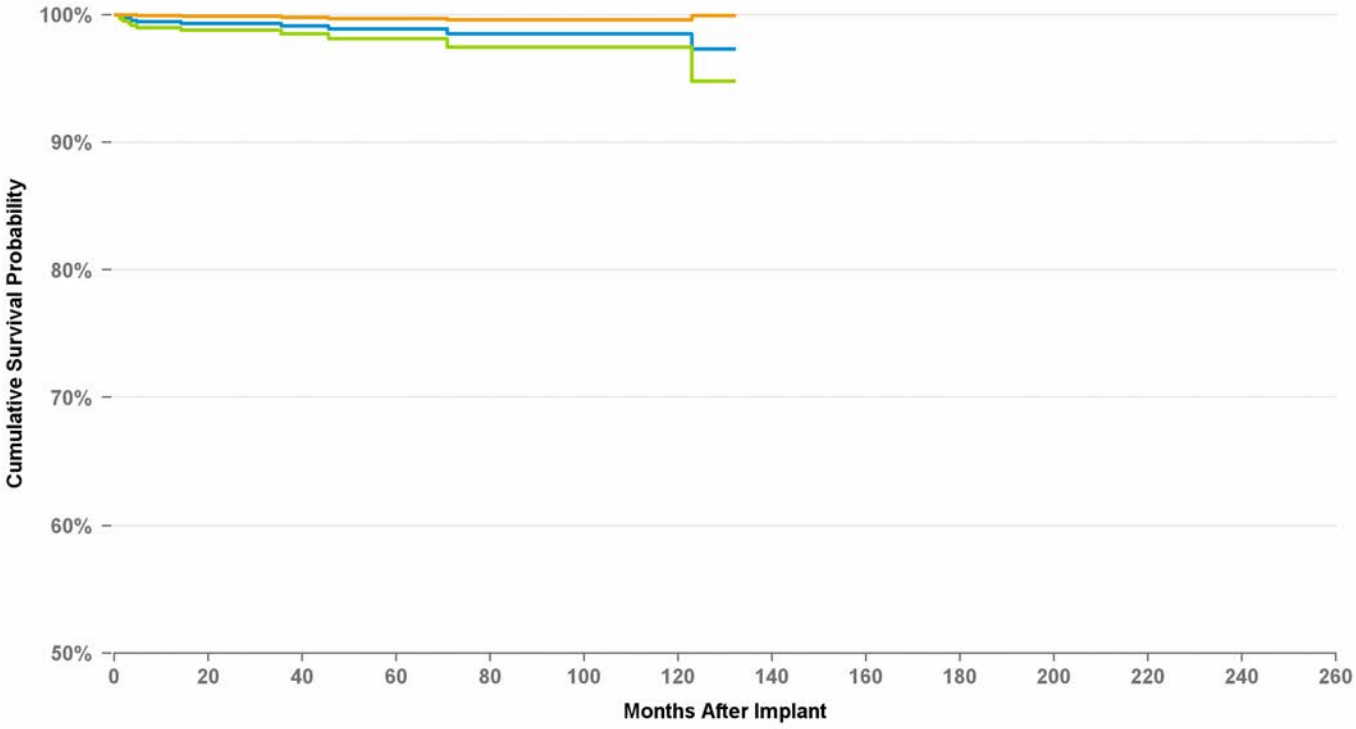
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	9/25/1997
Registered US Implant	137,275
Estimated Active US	62,038
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	1,189
Cumulative Months of Follow-Up	48,452
Number of Leads Active in Study	96

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	2
Extracardiac Stimulation	3
Failure To Capture	42
Failure To Sense	7
Impedance Abnormal	0
Insulation Breach	3
Lead Dislodgement	58
Oversensing	1
Unspecified	9
USA Returned Product Analysis	
Conductor Fracture	14
Crimp Weld Bond	0
Insulation Breach	41
Other	3

5092, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	99.3%	99.1%	98.9%	98.9%	98.5%	98.5%	98.5%	98.5%	98.5%	97.3%
#	803	637	501	404	319	249	201	150	114	89	58

PACING LEAD

5534

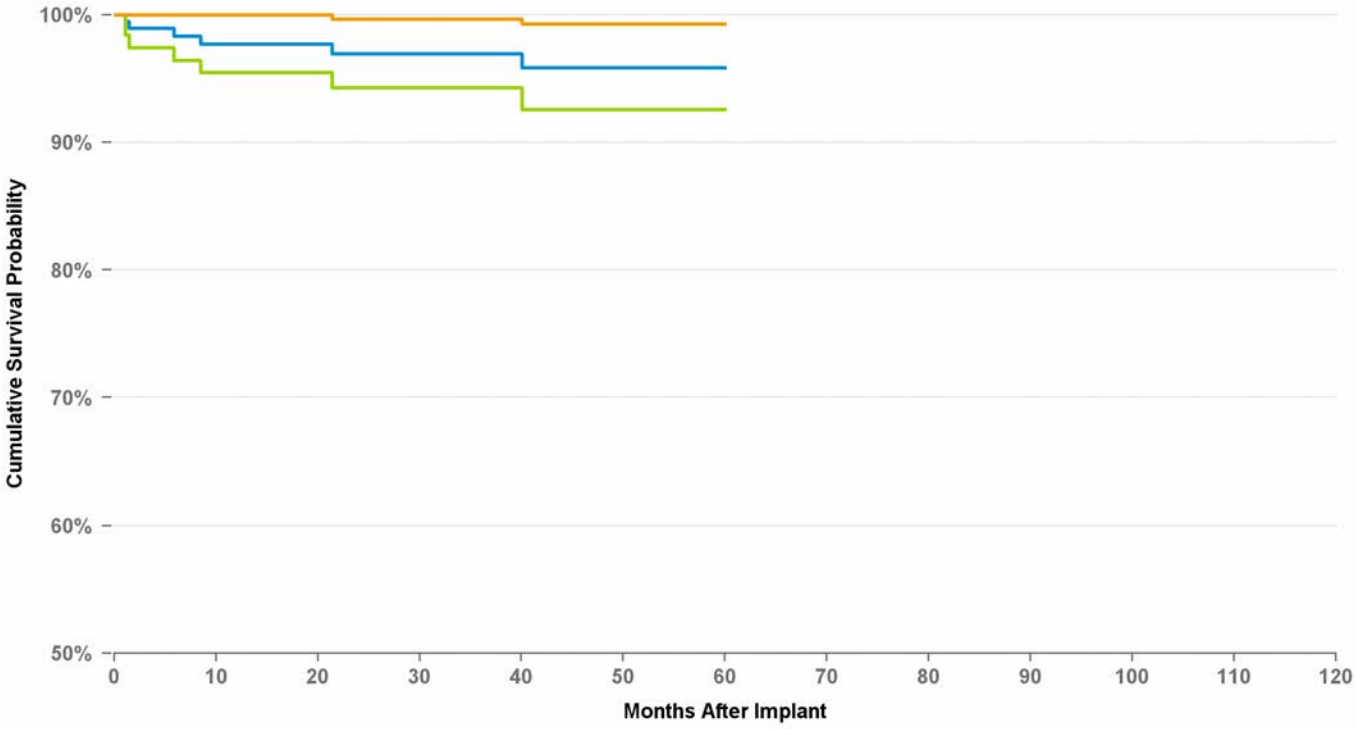
Distribution Data	
US Market Release	2/9/1996
CE Approval Date	
Registered US Implant	25,828
Estimated Active US	6,504
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	267
Cumulative Months of Follow-Up	9,578
Number of Leads Active in Study	4

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	5
Crimp Weld Bond	0
Insulation Breach	5
Other	4

5534, Survival Curve



Years	1	2	3	4	at 60 mo
%	97.7%	96.9%	96.9%	95.9%	95.9%
#	148	126	98	79	55

PACING LEAD

5554

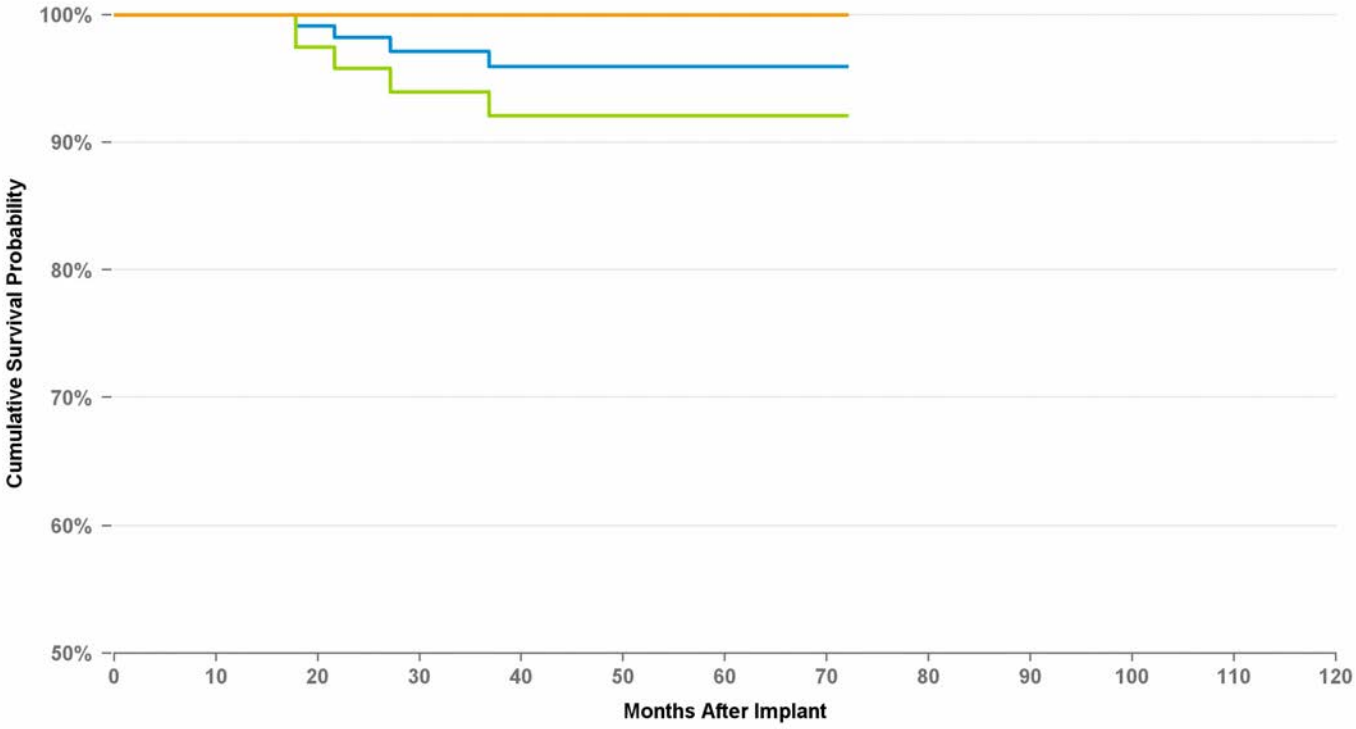
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	6/5/1997
Registered US Implant	63,288
Estimated Active US	28,941
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	352
Cumulative Months of Follow-Up	8,206
Number of Leads Active in Study	16

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	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	1
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	35
Oversensing	0
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	11
Crimp Weld Bond	0
Insulation Breach	24
Other	2

5554, Survival Curve



Years	1	2	3	4	5	at 72 mo
%	100.0%	98.2%	97.1%	95.9%	95.9%	95.9%
#	142	105	82	74	59	50

PACING LEAD

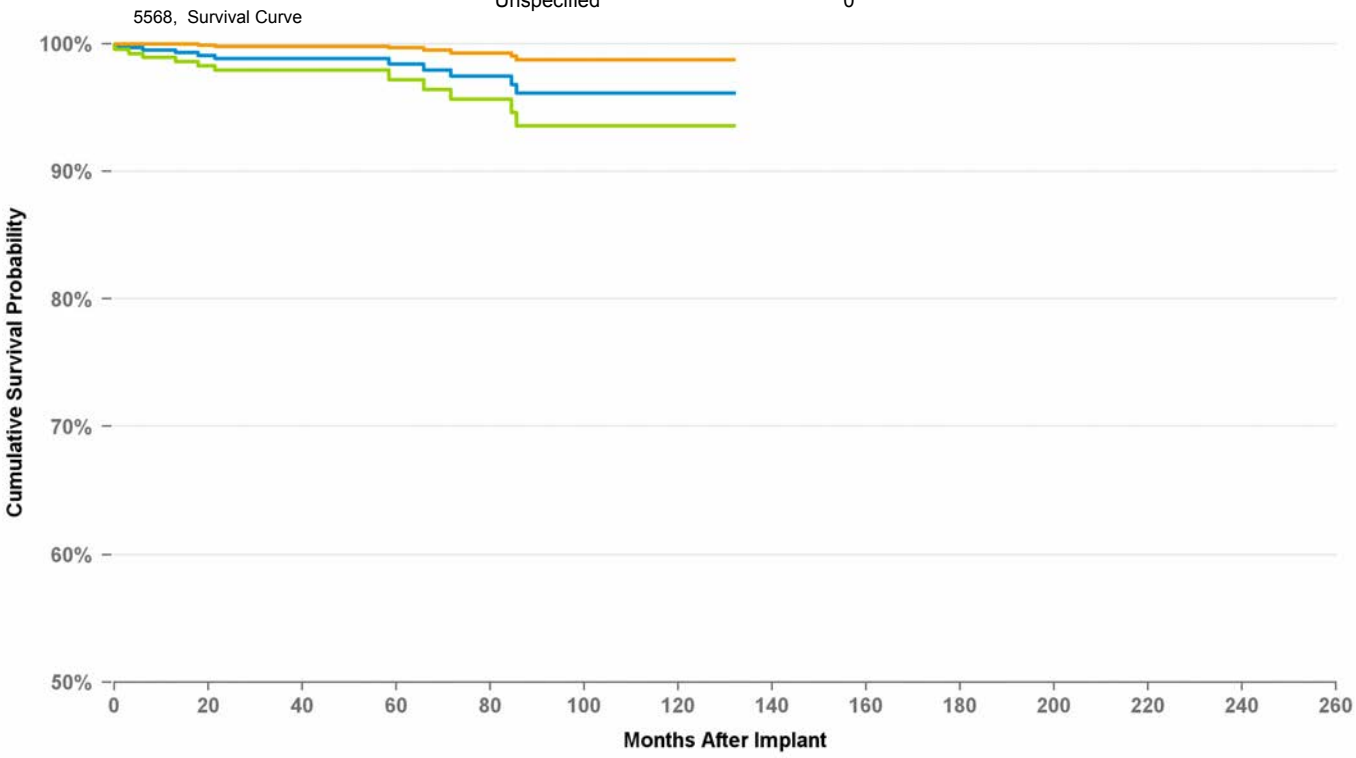
5568

Distribution Data	
US Market Release	1/2/1997
CE Approval Date	8/14/1996
Registered US Implant	94,516
Estimated Active US	51,515
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 Surveilance Registry Results	
Number of Leads Enrolled in Study	1,096
Cumulative Months of Follow-Up	33,971
Number of Leads Active in Study	115

Product Surveilance 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	11
Conductor Fracture	0
Extracardiac Stimulation	2
Failure To Capture	22
Failure To Sense	2
Impedance Abnormal	2
Insulation Breach	1
Lead Dislodgement	40
Oversensing	3
Unspecified	4
USA Returned Product Analysis	
Conductor Fracture	16
Crimp Weld Bond	0
Insulation Breach	38
Other	37



Years	1	2	3	4	5	6	7	8	9	10	at 132 mo
%	99.5%	98.8%	98.8%	98.8%	98.4%	97.5%	97.5%	96.1%	96.1%	96.1%	96.1%
#	503	411	346	278	228	186	145	121	102	79	59

PACING LEAD

5592

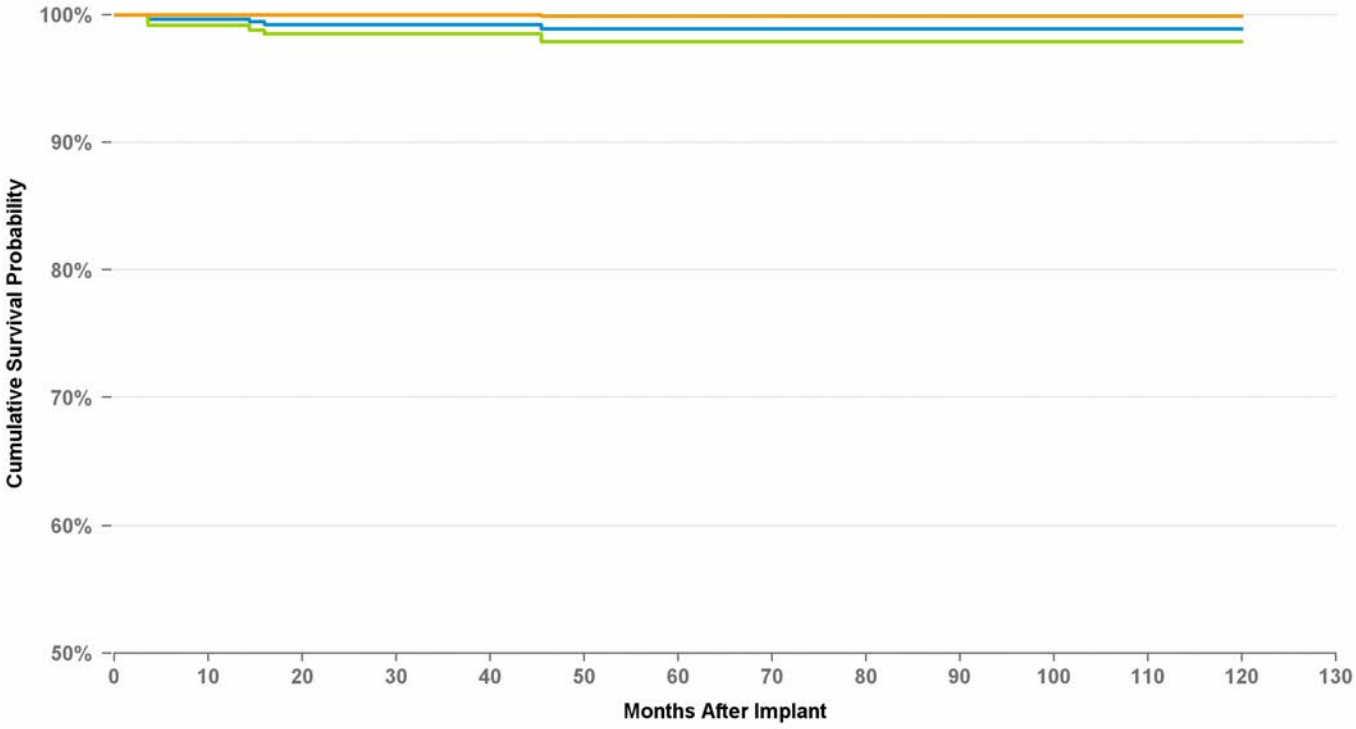
Distribution Data	
US Market Release	6/3/1998
CE Approval Date	9/25/1997
Registered US Implant	35,914
Estimated Active US	19,344
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	693
Cumulative Months of Follow-Up	31,746
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	32
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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.6%	99.2%	99.2%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%	98.9%
#	510	420	335	279	224	166	134	106	75	55

PACING LEAD

5594

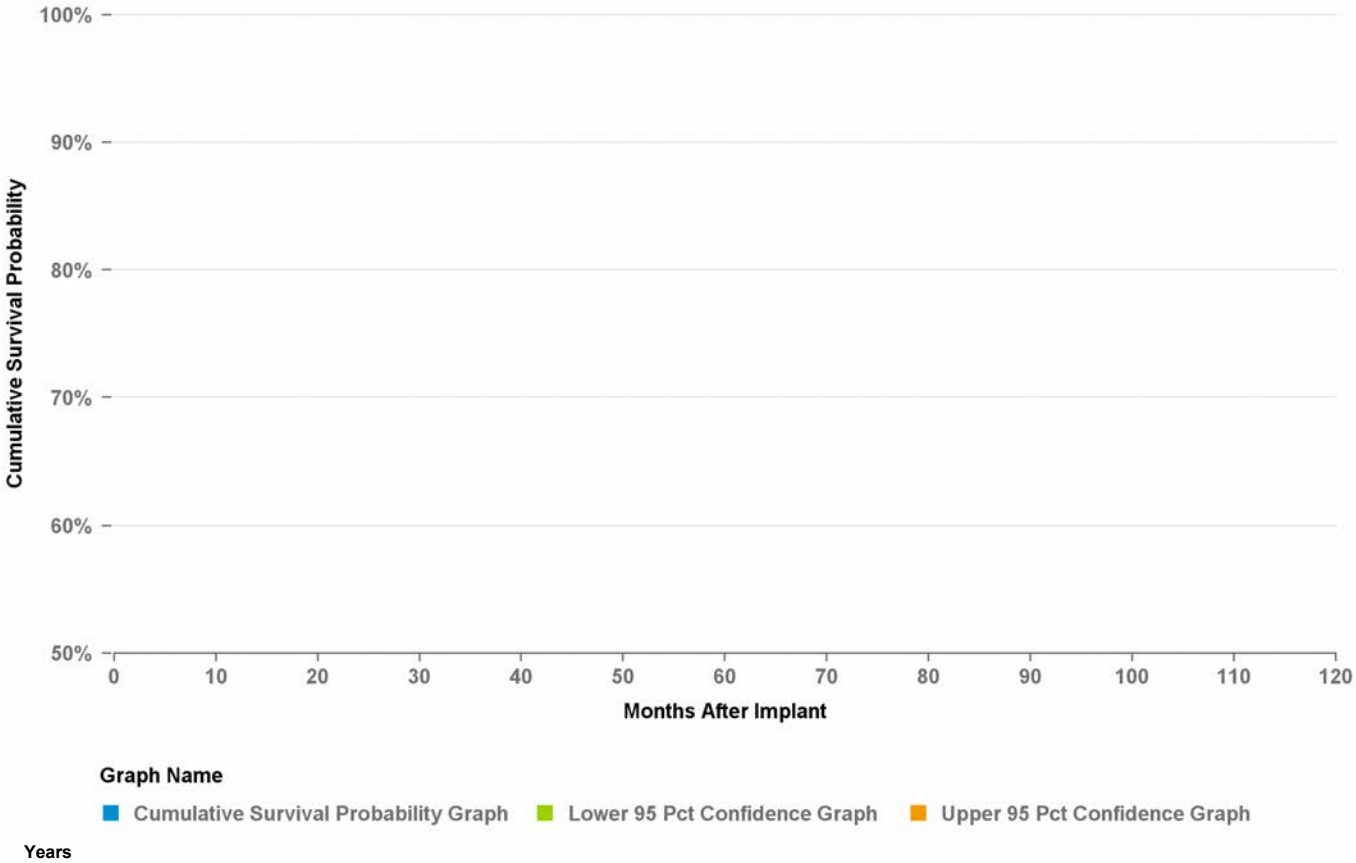
Distribution Data	
US Market Release	6/25/2001
CE Approval Date	3/23/2001
Registered US Implant	16,747
Estimated Active US	10,735
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	23
Cumulative Months of Follow-Up	1,609
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	10
Oversensing	0
Unspecified	2
USA Returned Product Analysis	
Conductor Fracture	9
Crimp Weld Bond	0
Insulation Breach	9
Other	1

5594, Survival Curve



Years	
%	
#	

PACING LEAD

6940

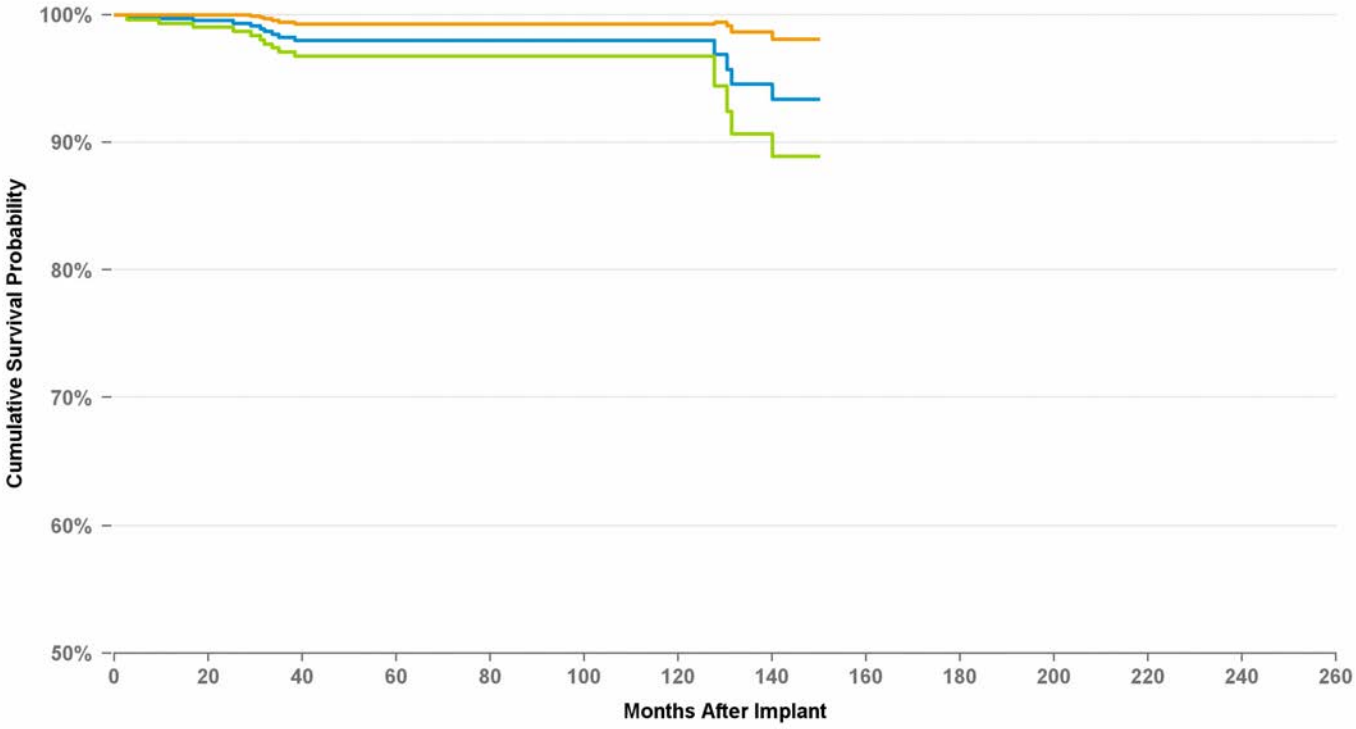
Distribution Data	
US Market Release	10/9/1998
CE Approval Date	
Registered US Implant	25,383
Estimated Active US	6,847
Product Characteristics	
Fixation Type	Active Screw-in
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Atrium - J
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	839
Cumulative Months of Follow-Up	42,597
Number of Leads Active in Study	64

Product Surveilance 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 Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	4	5	6	7	8	9	10	11	12	at 150 mo
%	99.7%	99.5%	98.2%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	98.0%	94.6%	93.4%	93.4%
#	627	508	419	345	278	218	189	153	126	96	79	68	57

EPI MYOCARDIAL LEAD 4965

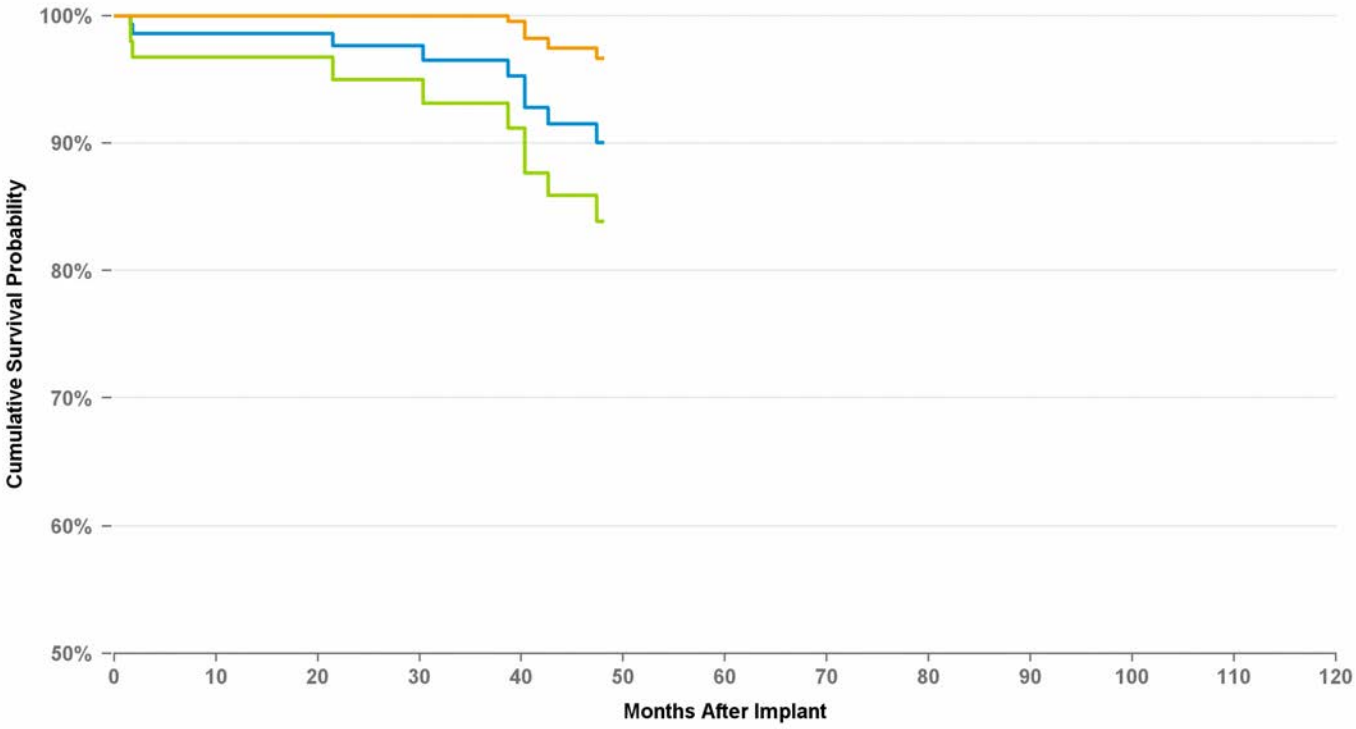
Distribution Data	
US Market Release	9/6/1996
CE Approval Date	1/1/1993
Registered US Implant	21,669
Estimated Active US	9,375
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveillance Registry Results	
Number of Leads Enrolled in Study	226
Cumulative Months of Follow-Up	6,616
Number of Leads Active in Study	12

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	6
Insulation Breach	0
Lead Dislodgement	0
Oversensing	1
Unspecified	3
USA Returned Product Analysis	
Conductor Fracture	188
Crimp Weld Bond	1
Insulation Breach	40
Other	0

4965, Survival Curve



Graph Name

Cumulative Survival Probability Graph Lower 95 Pct Confidence Graph Upper 95 Pct Confidence Graph

Years	1	2	3	at 48 mo
%	98.6%	97.6%	96.5%	90.0%
#	122	103	83	60

EPI MYOCARDIAL LEAD 4968

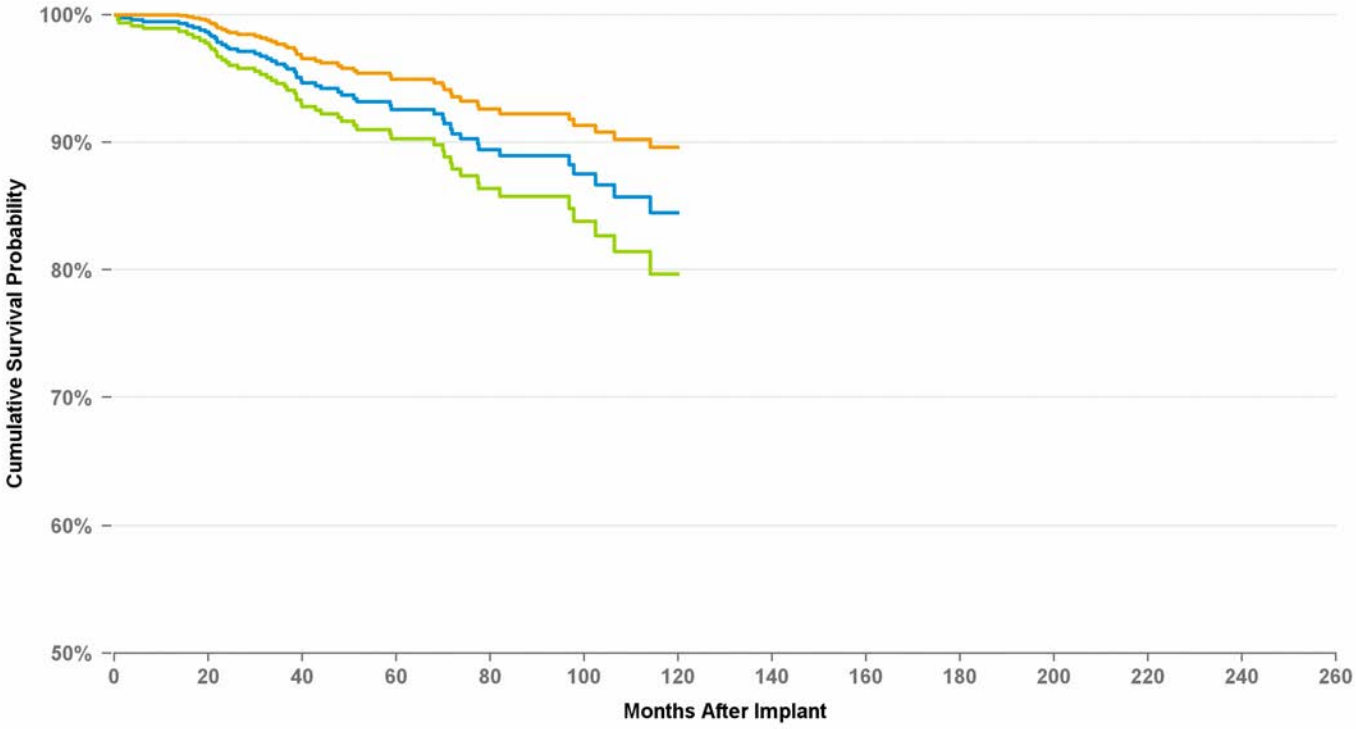
Distribution Data	
US Market Release	9/16/1999
CE Approval Date	4/21/1998
Registered US Implant	32,198
Estimated Active US	19,935
Product Characteristics	
Fixation Type	Suture
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Myocardial
Lead Tip Location	Atrium or Right Ventricle
Pace/Sense Polarit	Bipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	851
Cumulative Months of Follow-Up	42,305
Number of Leads Active in Study	302

Product Surveilance Registry Qualifying Complications	60
Cardiac Perforation	0
Conductor Fracture	14
Electrical Abandonment	0
Extracardiac Stimulation	2
Failure To Capture	20
Failure To Sense	3
Impedance Abnormal	4
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	2
Extracardiac Stimulation	1
Failure To Capture	22
Failure To Sense	0
Impedance Abnormal	3
Insulation Breach	1
Lead Dislodgement	3
Oversensing	3
Unspecified	0
USA Returned Product Analysis	
Conductor Fracture	41
Crimp Weld Bond	0
Insulation Breach	25
Other	1

4968, Survival Curve



Years	1	2	3	4	5	6	7	8	9	at 120 mo
%	99.5%	97.5%	96.2%	94.0%	92.6%	90.7%	88.9%	88.9%	85.7%	84.5%
#	661	569	475	366	299	225	170	123	80	57

EPI MYOCARDIAL LEAD 5071

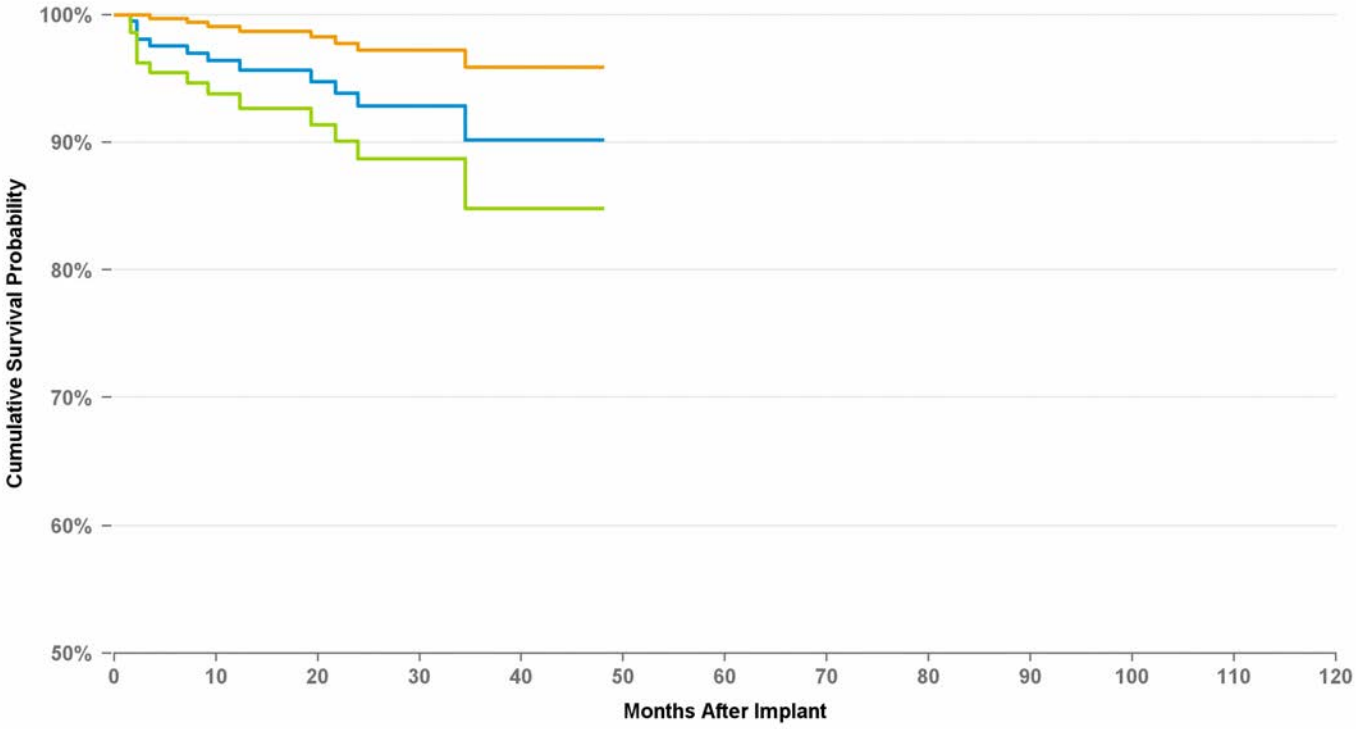
Distribution Data	
US Market Release	12/3/1992
CE Approval Date	1/1/1993
Registered US Implant	46,974
Estimated Active US	16,004
Product Characteristics	
Fixation Type	Fixed Screw In
Lead Function	Pacing/Sensing
Steroid Indicator	None
Lead Placement	Myocardial
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Unipolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	344
Cumulative Months of Follow-Up	7,249
Number of Leads Active in Study	85

Product Surveilance Registry Qualifying Complications	17
Cardiac Perforation	0
Conductor Fracture	0
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	14
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	4
Failure To Capture	42
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



Years	1	2	3	at 48 mo
%	96.4%	92.9%	90.2%	90.2%
#	136	93	66	52

VDD SINGLE PASS LEAD 5032

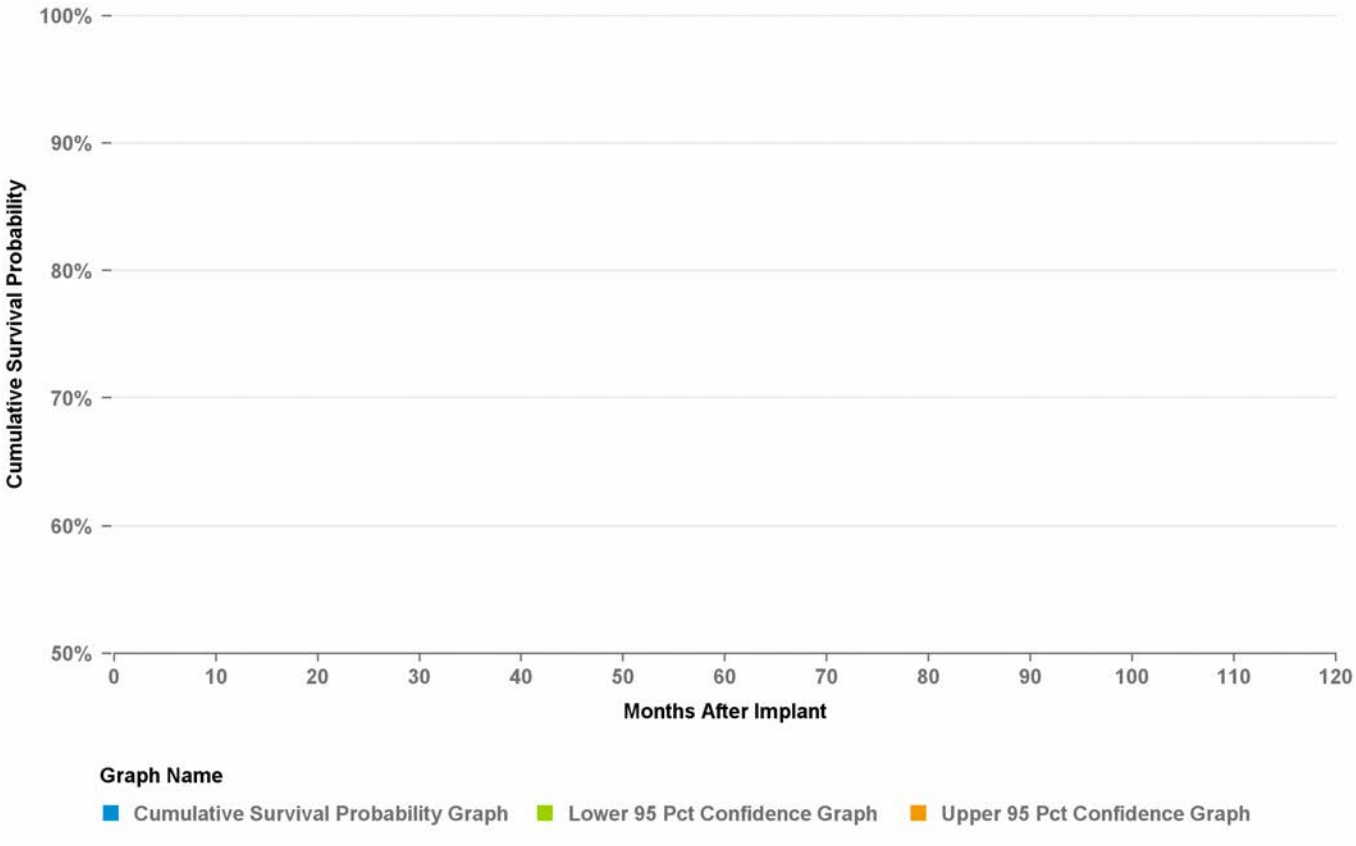
Distribution Data	
US Market Release	3/22/1996
CE Approval Date	
Registered US Implant	5,218
Estimated Active US	1,124
Product Characteristics	
Fixation Type	Tines
Lead Function	Pacing/Sensing
Steroid Indicator	Yes
Lead Placement	Transvenous
Lead Tip Location	Right Ventricle
Pace/Sense Polarit	Quadripolar

Product Surveilance Registry Results	
Number of Leads Enrolled in Study	38
Cumulative Months of Follow-Up	287
Number of Leads Active in Study	0

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	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

5032, Survival Curve



Years	
%	
#	

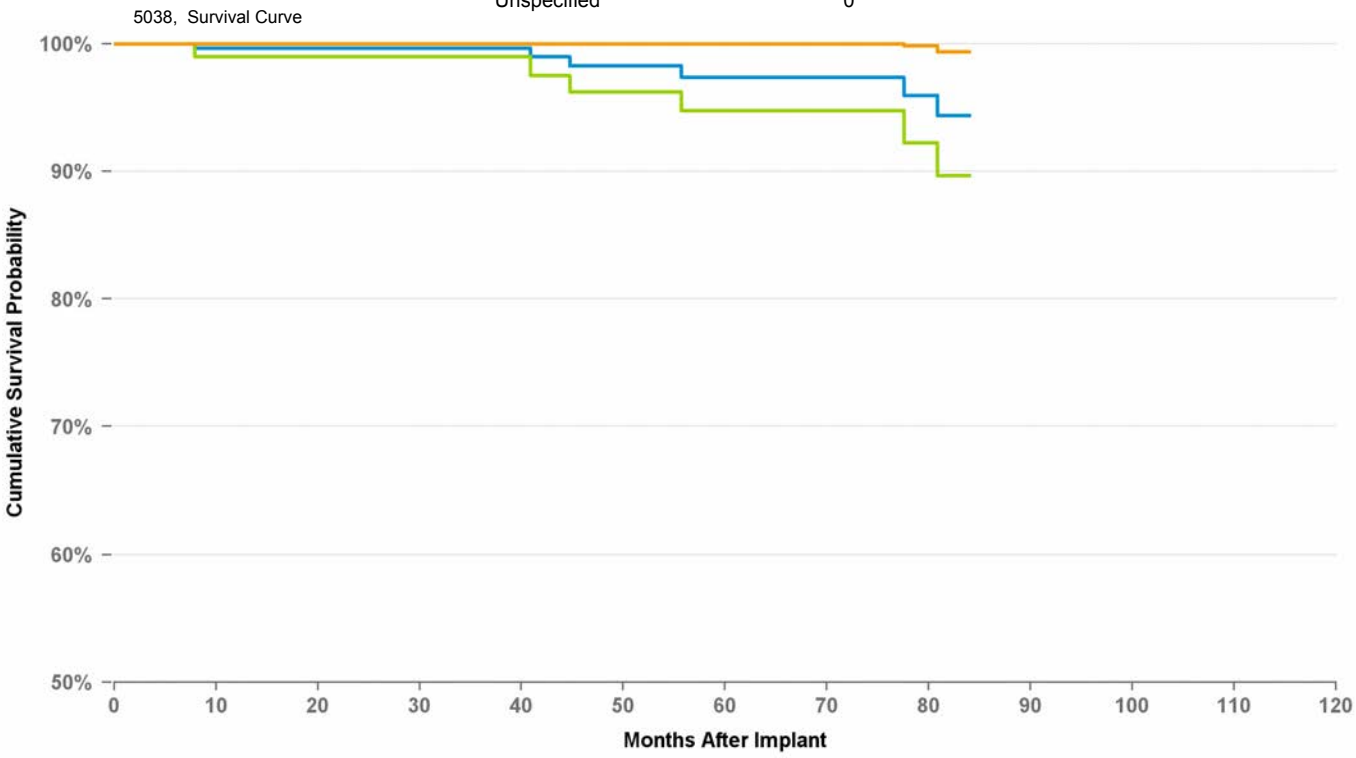
VDD SINGLE PASS LEAD 5038

Distribution Data	
US Market Release	9/10/1998
CE Approval Date	4/15/1997
Registered US Implant	9,075
Estimated Active US	3,480
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	566
Cumulative Months of Follow-Up	15,571
Number of Leads Active in Study	5

Product Surveilance Registry Qualifying Complications	6
Cardiac Perforation	0
Conductor Fracture	3
Electrical Abandonment	0
Extracardiac Stimulation	0
Failure To Capture	1
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



Years	1	2	3	4	5	6	at 84 mo
%	99.7%	99.7%	99.7%	98.2%	97.4%	97.4%	94.4%
#	288	218	160	130	106	77	55

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 CRHF 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.

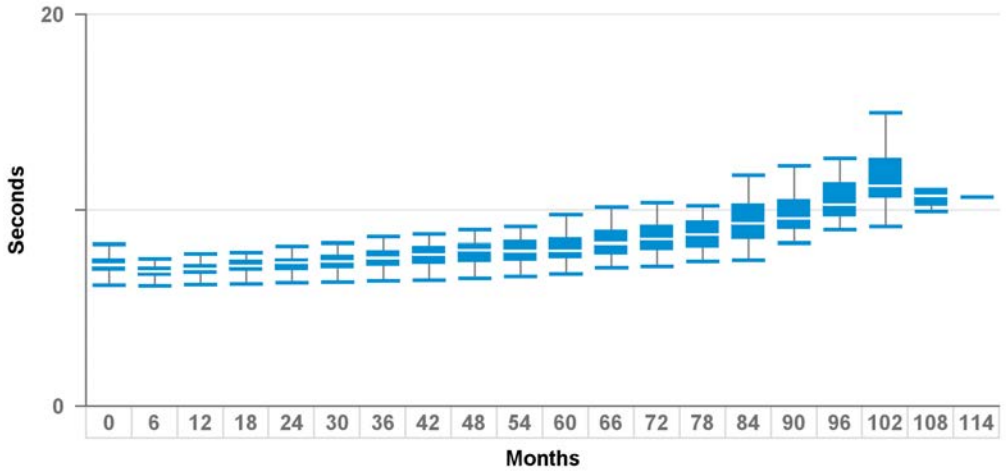
In our analysis performed for this report, only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. When more than one charge time is available 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.

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.

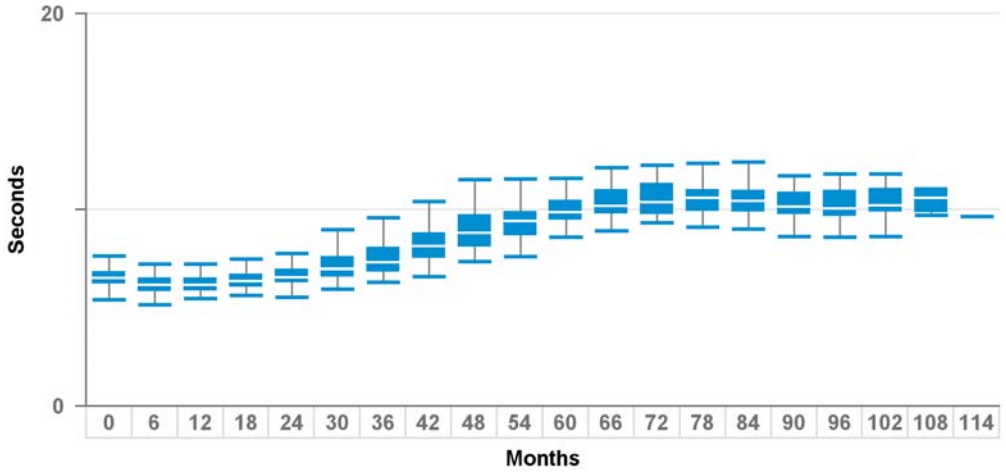
7230 Charge Time

Model Number	Brand
7230B	Marquis VR
7230Cx	Marquis VR
7230E	Marquis VR



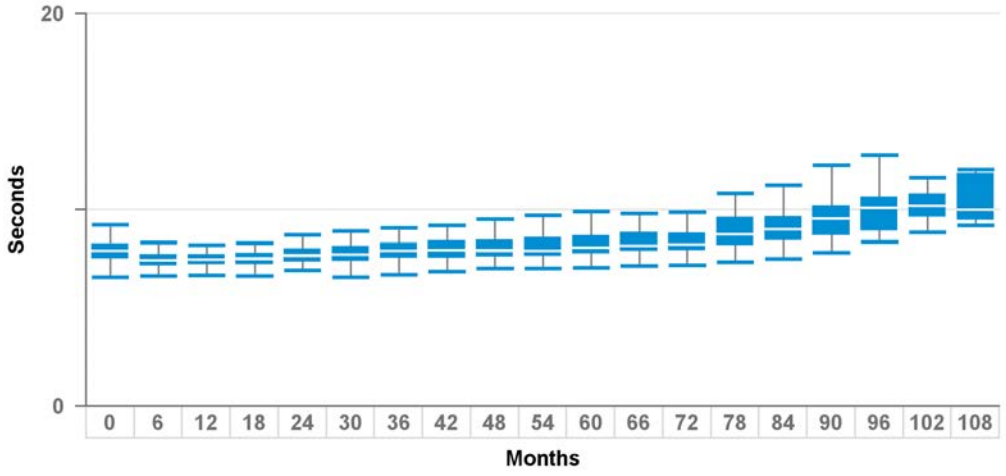
7231 Charge Time

Model Number	Brand
7231Cx	GEM III VR



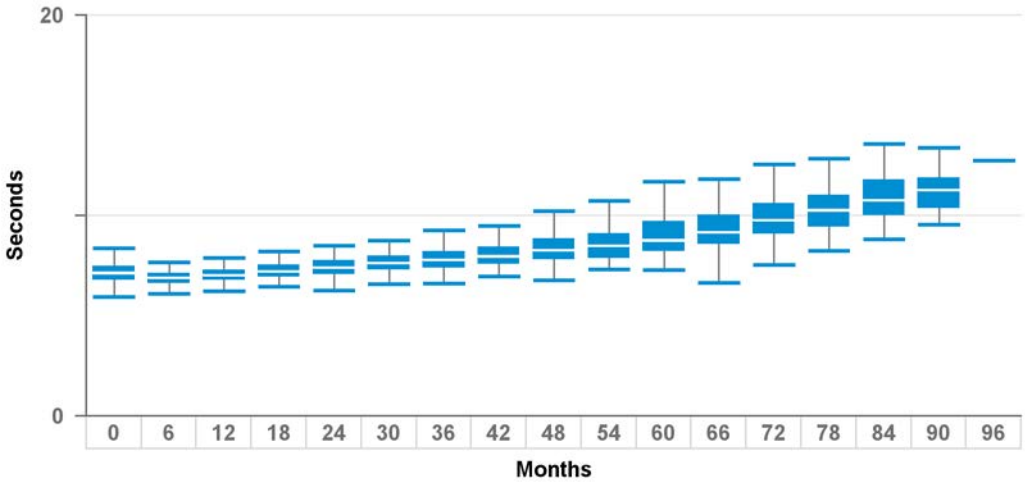
7232 Charge Time

Model Number	Brand
7232B	Maximo VR
7232Cx	Maximo VR
7232E	Maximo VR



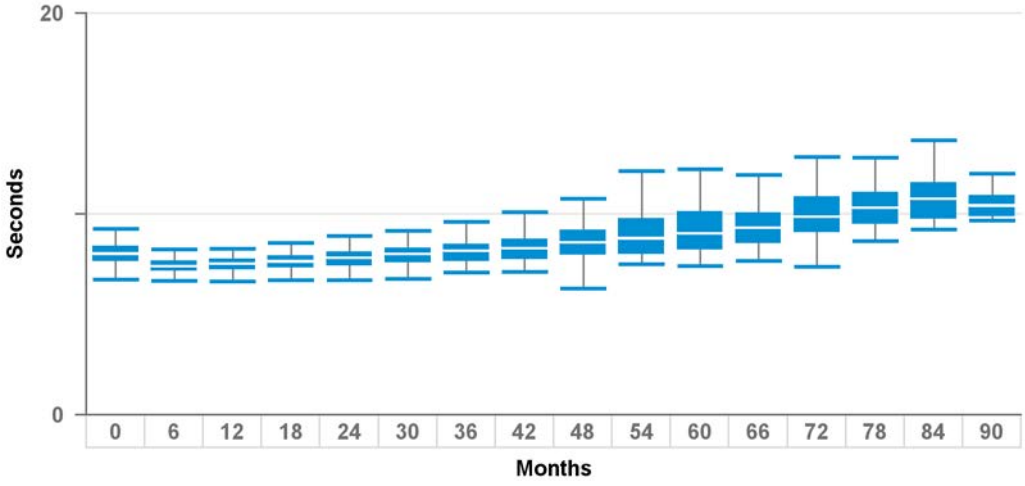
7274 Charge Time

Model Number	Brand
7274	Marquis DR



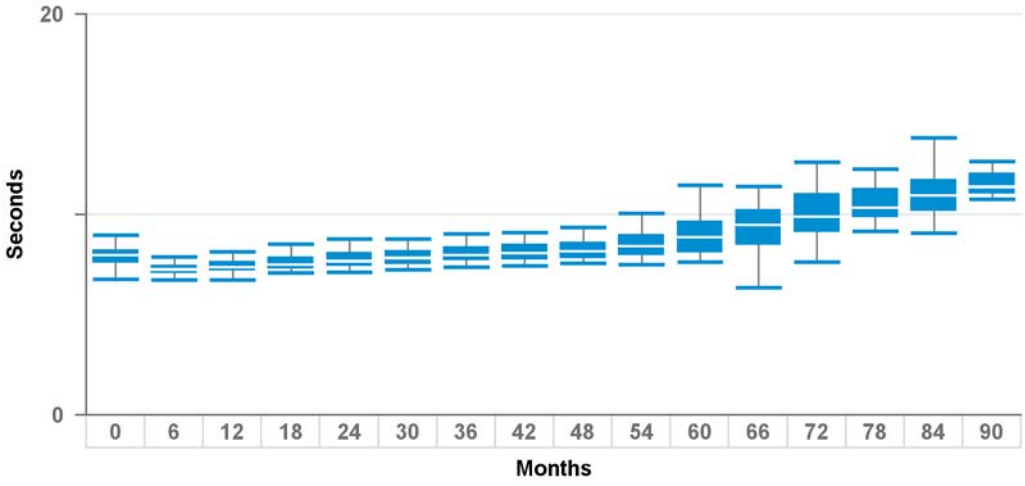
7278 Charge Time

Model Number	Brand
7278	Maximo DR



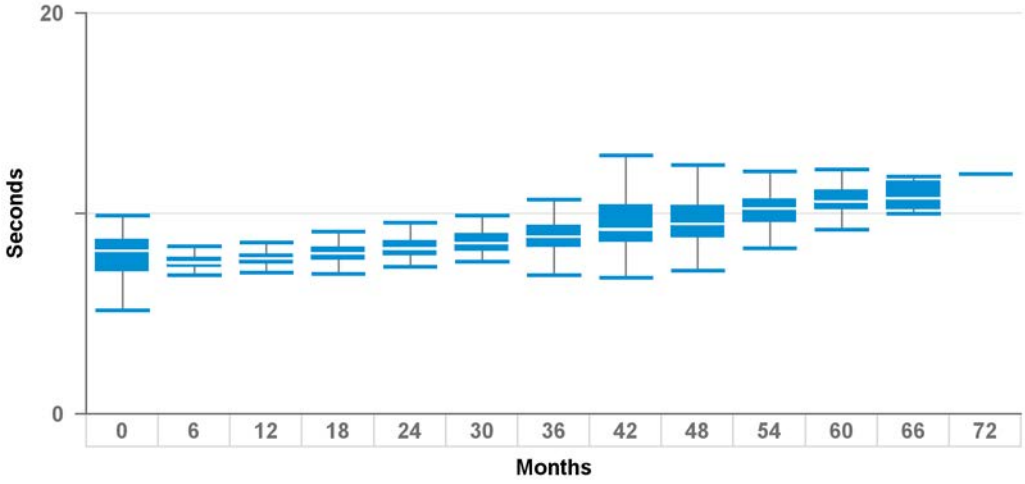
7288 Charge Time

Model Number	Brand
7288	Intrinsic



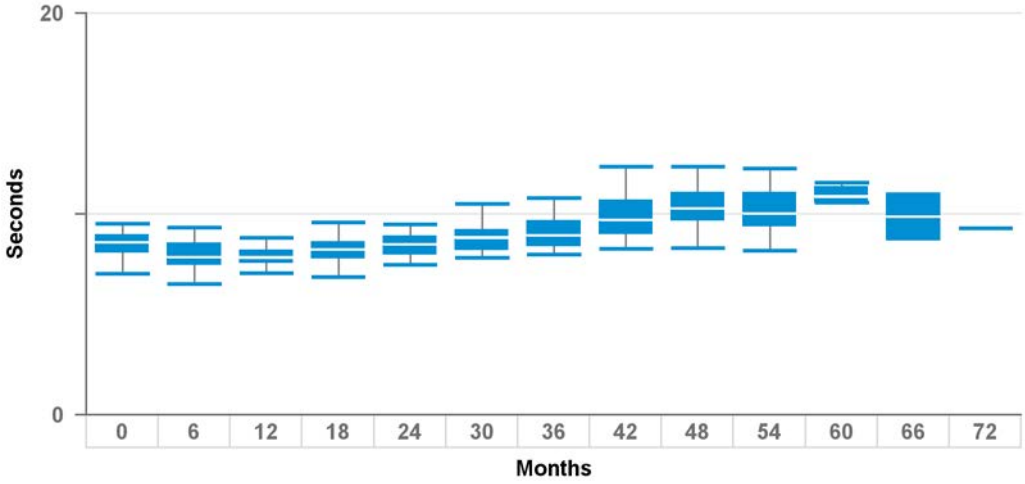
7299 Charge Time

Model Number	Brand
7299	InSync Sentry



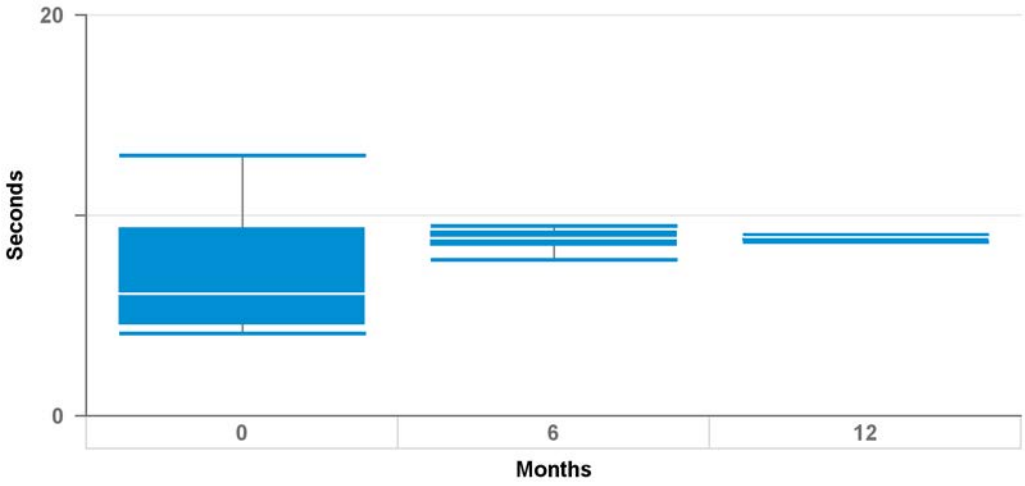
7304 Charge Time

Model Number	Brand
7304	InSync Maximo



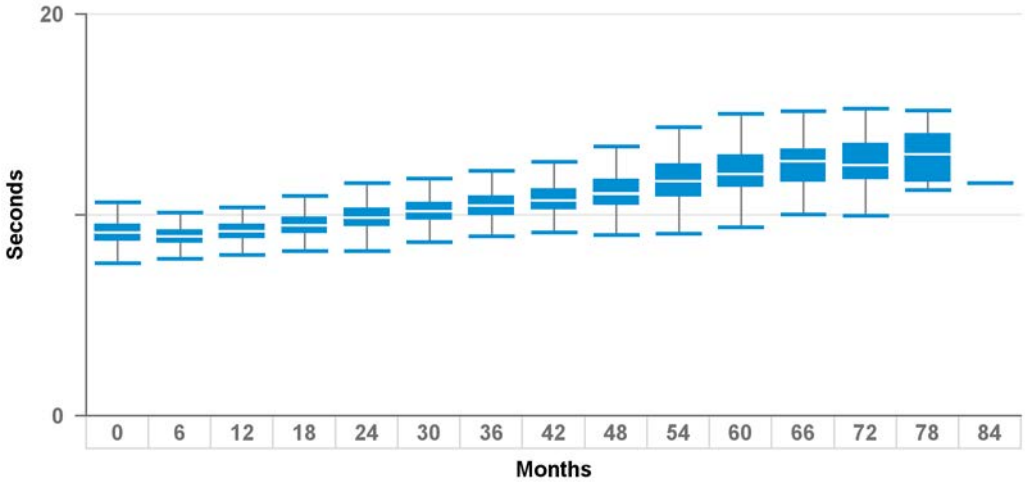
BLACKWELL, CRT-D Charge Time

Model Number	Brand
DTBA1D1	Viva XT
DTBA1D4	Viva XT
DTBA1Q1	Viva Quad XT
DTBA1QQ	Viva Quad XT
DTBA2D1	Viva XT
DTBA2D4	Viva XT
DTBA2Q1	Viva Quad XT
DTBA2QQ	Viva Quad XT
DTBB1D1	Viva S
DTBB1D4	Viva S
DTBB1Q1	Viva Quad S
DTBB1QQ	Viva Quad S
DTBB2D1	Viva S
DTBB2D4	Viva S
DTBB2QQ	Viva Quad S
DTBC2D1	Brava
DTBC2D4	Brava
DTBC2Q1	Brava Quad
DTBC2QQ	Brava Quad



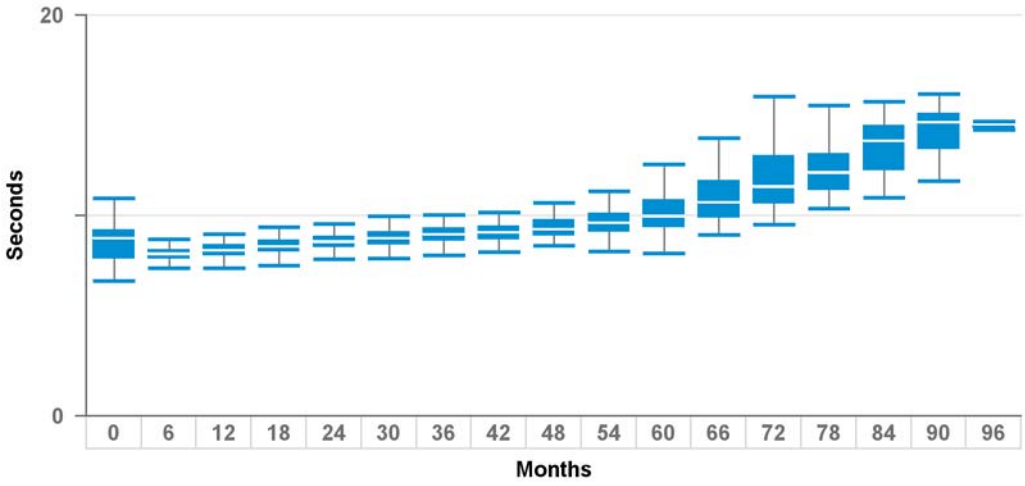
C154DWK, C164AWK, C174AWK Charge Time

Model Number	Brand
C154DWK	Concerto CRT-D
C164AWK	Concerto CRT-D
C174AWK	Concerto CRT-D



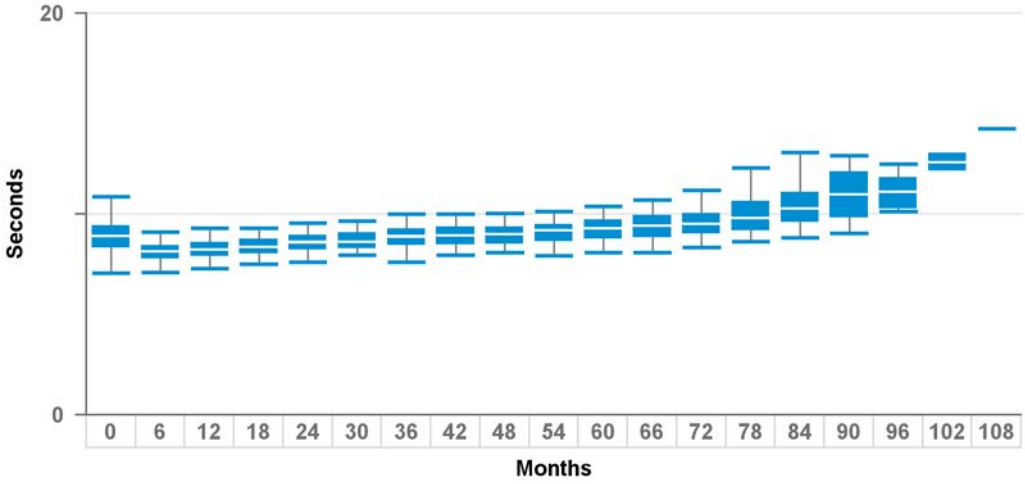
D144DRG, D154ATG, D154DRG Charge Time

Model Number	Brand
D144DRG	Entrust Escudo
D154ATG	Entrust AT
D154DRG	Entrust DR



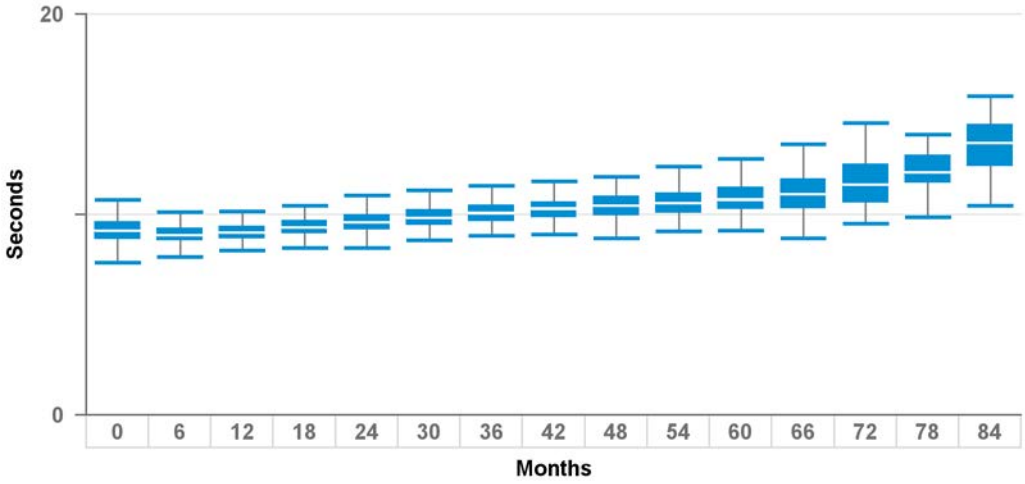
D144VRC, D154VRC Charge Time

Model Number	Brand
D144VRC	Entrust Escudo
D154VRC	Entrust VR



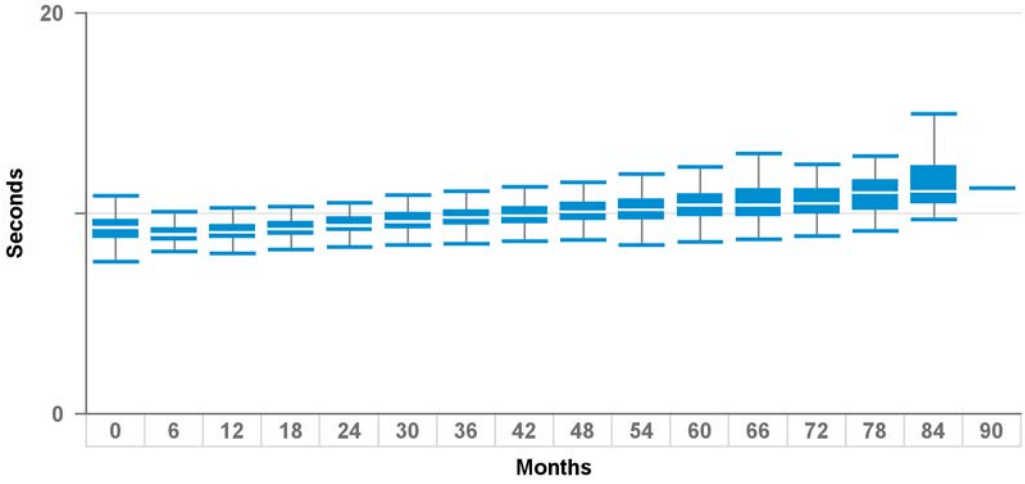
D154AWG, D164AWG Charge Time

Model Number	Brand
D154AWG	Virtuoso DR
D164AWG	Virtuoso DR



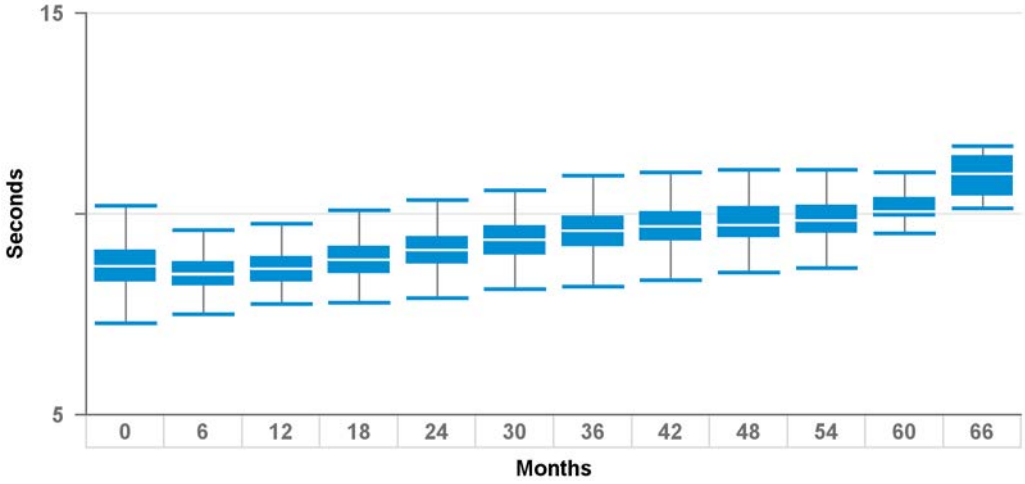
D154VWC, D164VWC Charge Time

Model Number	Brand
D154VWC	Virtuoso VR
D164VWC	Virtuoso VR



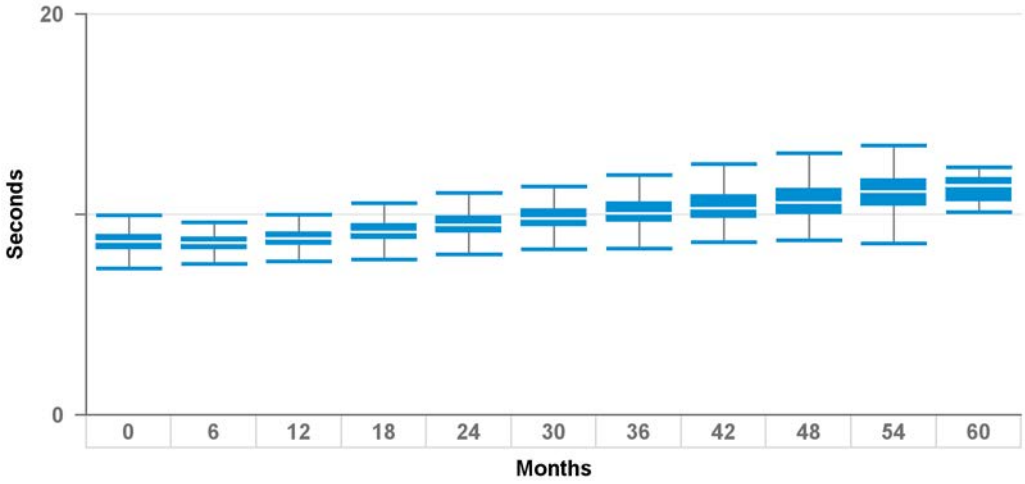
D204DRM, D214DRM, D224DRG, D234DRG Charge Time

Model Number	Brand
D204DRM	Secura DR
D214DRM	Secura DR
D224DRG	Secura DR
D234DRG	Secura DR



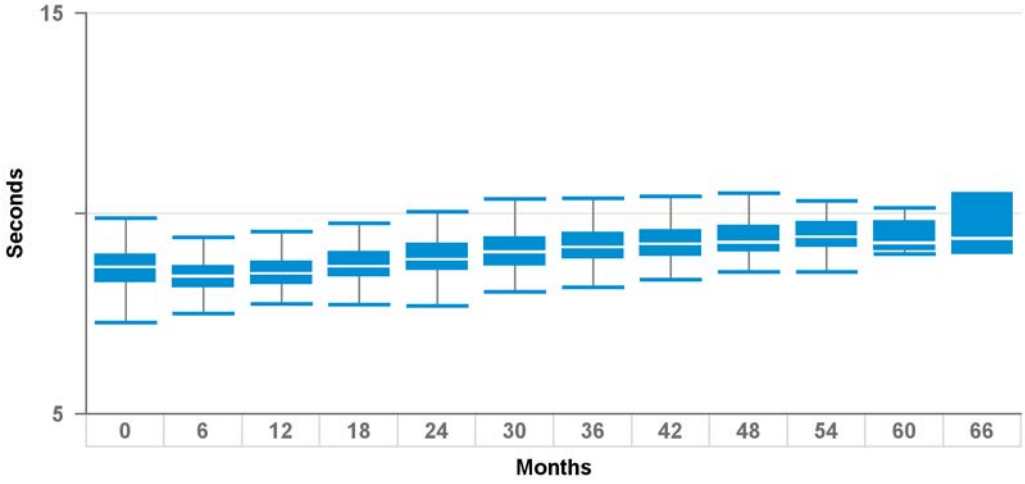
D204TRM, D214TRM, D224TRK, D234TRK Charge Time

Model Number	Brand
D204TRM	Consulta CRT-D
D214TRM	Consulta CRT-D
D224TRK	Consulta CRT-D
D234TRK	Consulta CRT-D



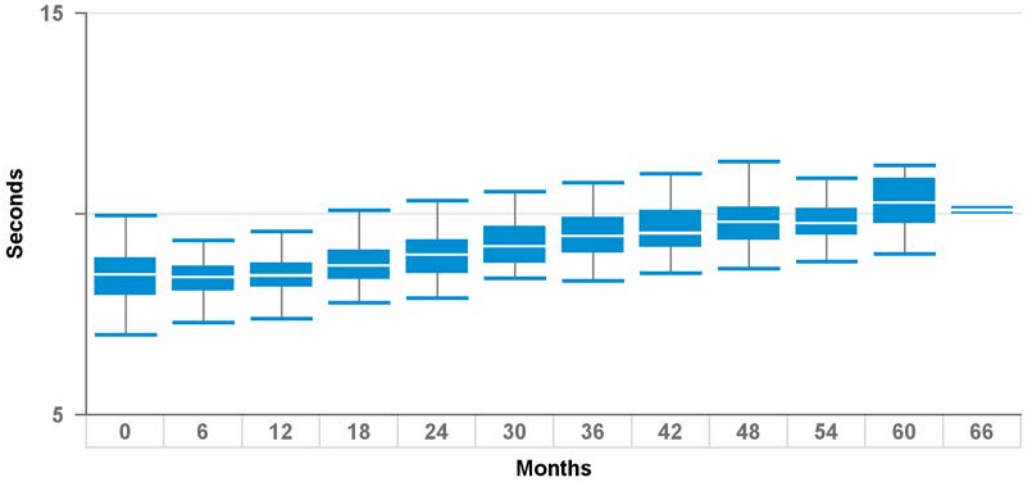
D204VRM, D214VRM, D224VRC, D234VRC Charge Time

Model Number	Brand
D204VRM	Secura VR
D214VRM	Secura VR
D224VRC	Secura VR
D234VRC	Secura VR



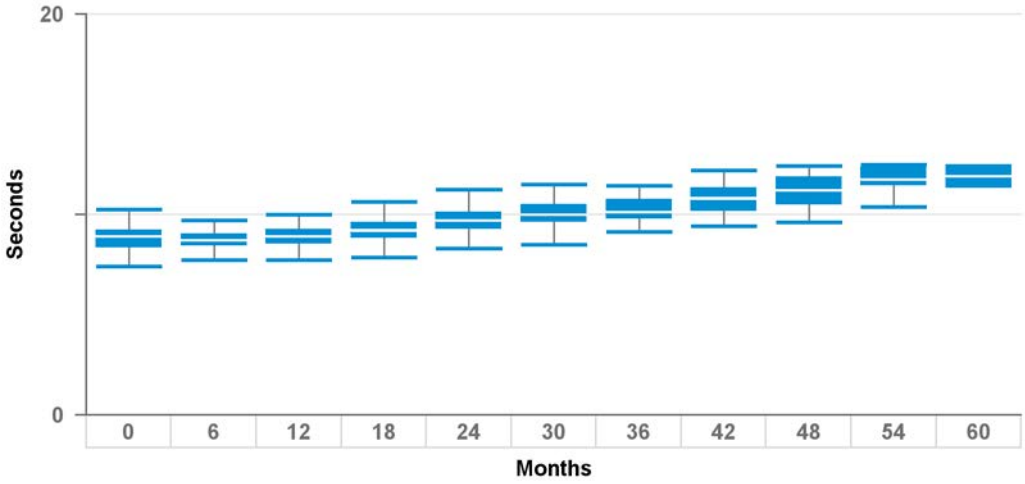
D264DRG, D284DRG, D384DRx, D394DRx Charge Time

Model Number	Brand
D264DRM	Maximo II DR
D284DRG	Maximo II DR
D384DRG	Cardia DR
D394DRG	Egida DR



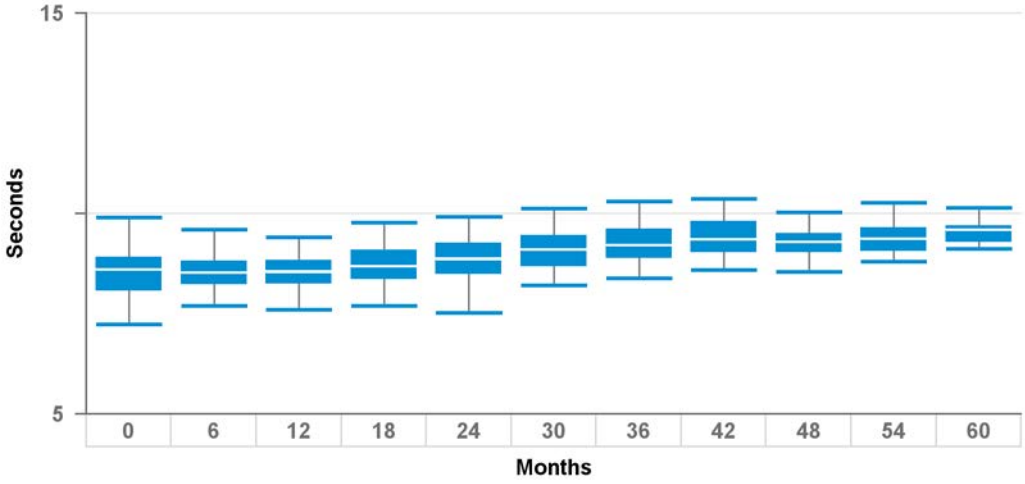
D264TRM, D284TRK, D384TRx, D394TRx Charge Time

Model Number	Brand
D264TRM	Maximo II CRT-D
D284TRK	Maximo II CRT-D
D384TRG	Cardia CRT-D
D394TRG	Egida CRT-D



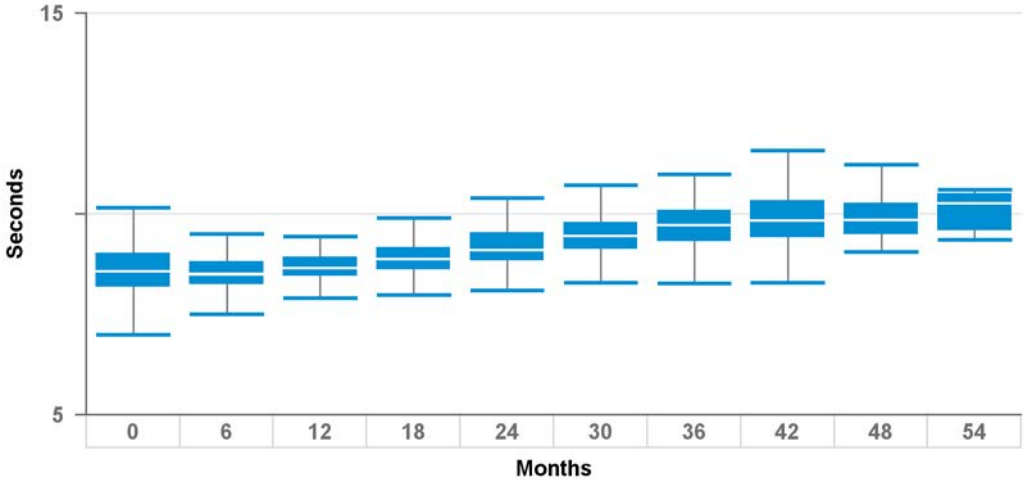
D264VRM, D284VRC, D384VRx, D394VRx Charge Time

Model Number	Brand
D264VRM	Maximo II VR
D284VRC	Maximo II VR
D384VRG	Cardia VR
D394VRG	Egida VR



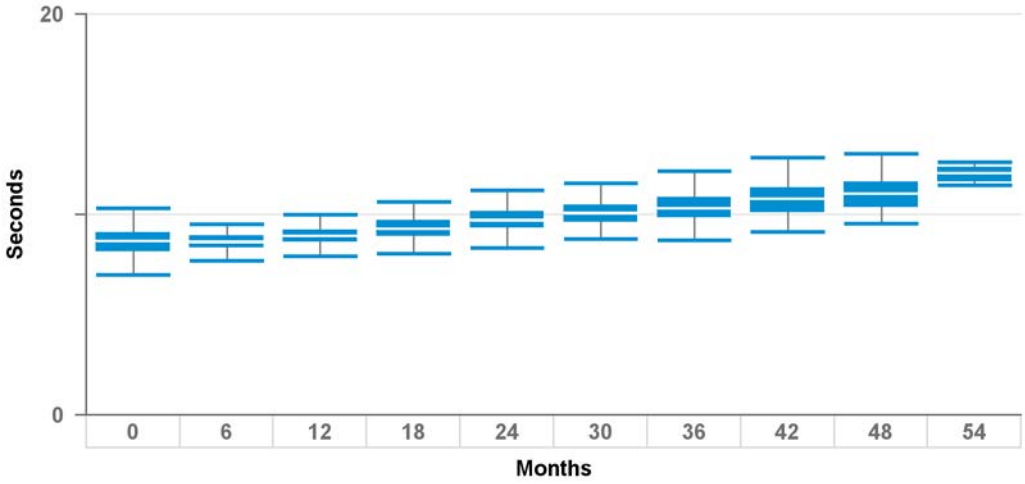
D274DRG, D294DRG Charge Time

Model Number	Brand
D274DRG	Virtuoso II DR
D294DRG	Virtuoso II DR



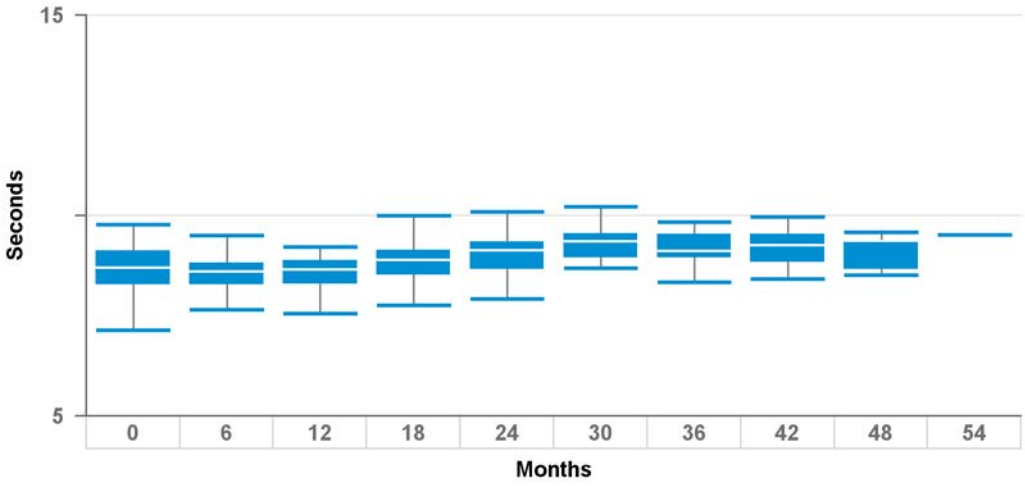
D274TRK, D294TRK Charge Time

Model Number	Brand
D274TRK	Concerto II CRT-D
D294TRK	Concerto II CRT-D



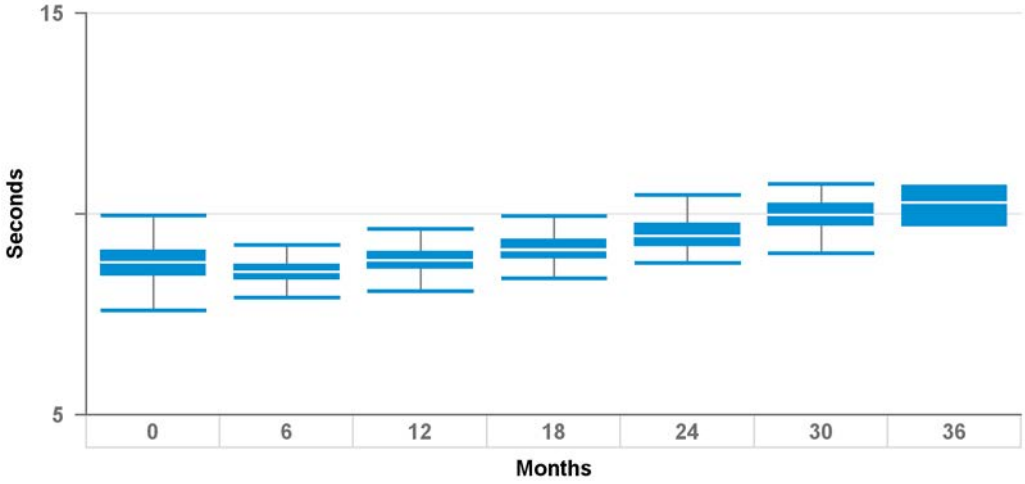
D274VRC, D294VRC Charge Time

Model Number	Brand
D274VRC	Virtuoso II VR
D294VRC	Virtuoso II VR



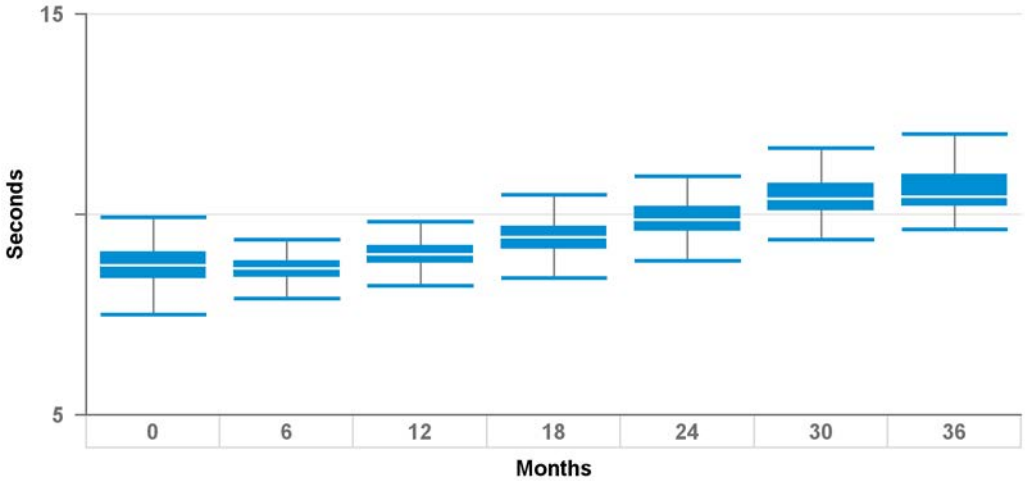
D314DRx Charge Time

Model Number	Brand
D314DRG	Protecta XT DR
D314DRM	Protecta XT DR



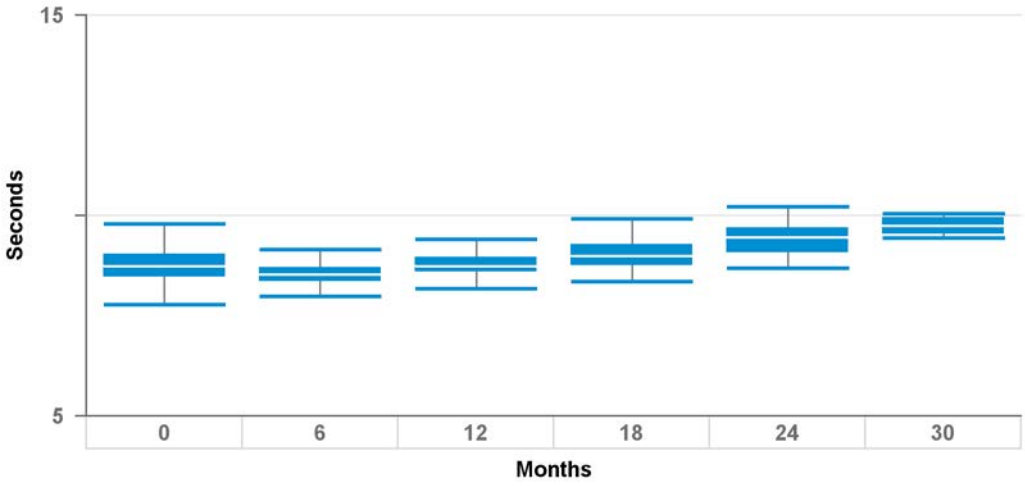
D314TRx Charge Time

Model Number	Brand
D314TRG	Protecta XT CRT-D
D314TRM	Protecta XT CRT-D



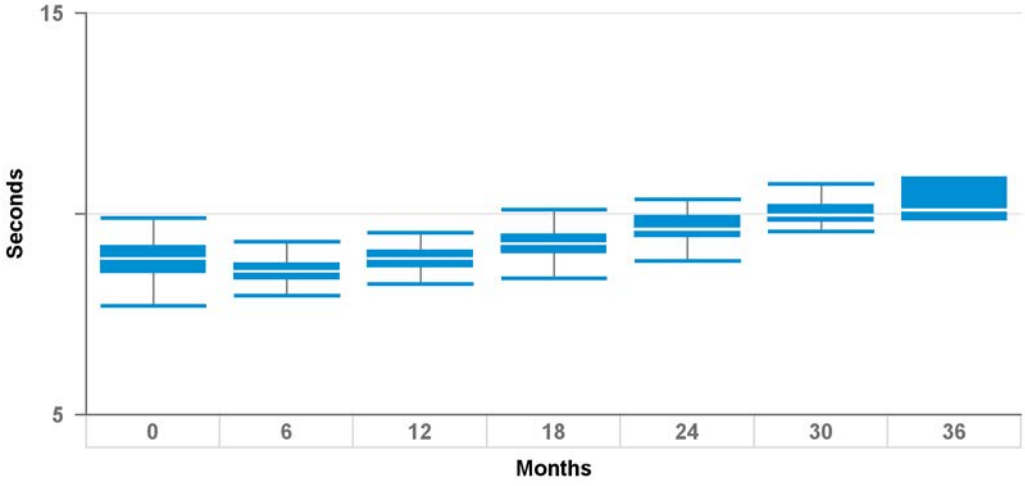
D314VRx Charge Time

Model Number	Brand
D314VRG	Protecta XT VR
D314VRM	Protecta XT VR



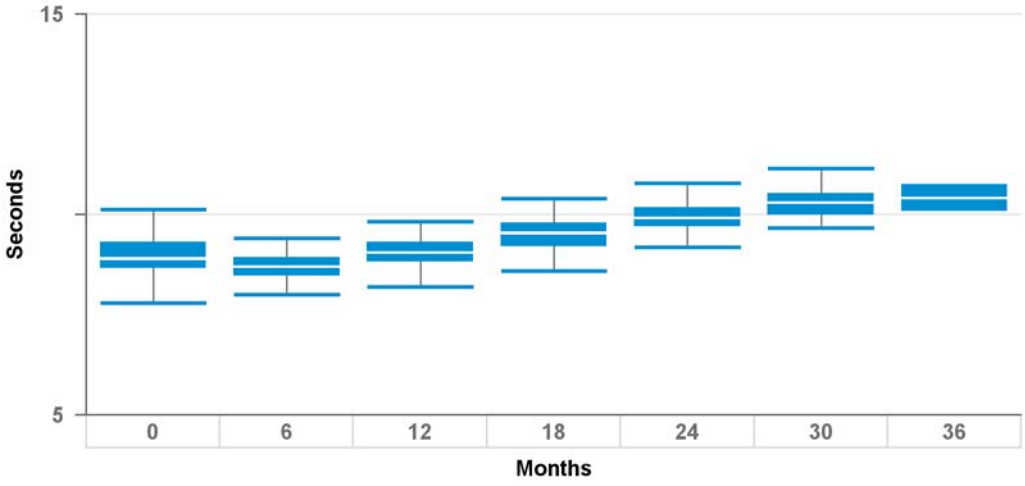
D334DRx, D364DRx Charge Time

Model Number	Brand
D334DRG	Protecta DR
D334DRM	Protecta DR
D364DRG	Protecta DR
D364DRM	Protecta DR



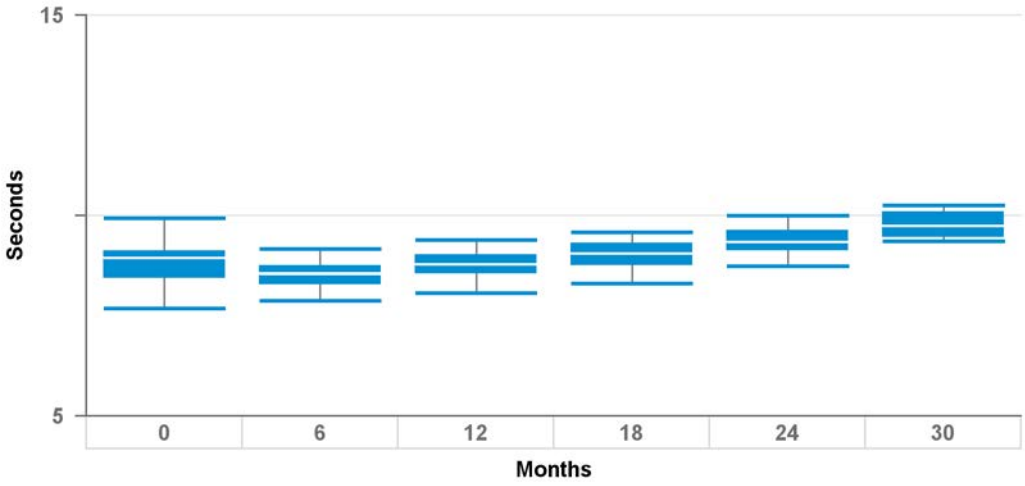
D334TRx, D364TRx Charge Time

Model Number	Brand
D334TRG	Protecta CRT-D
D334TRM	Protecta CRT-D
D364TRG	Protecta CRT-D
D364TRM	Protecta CRT-D



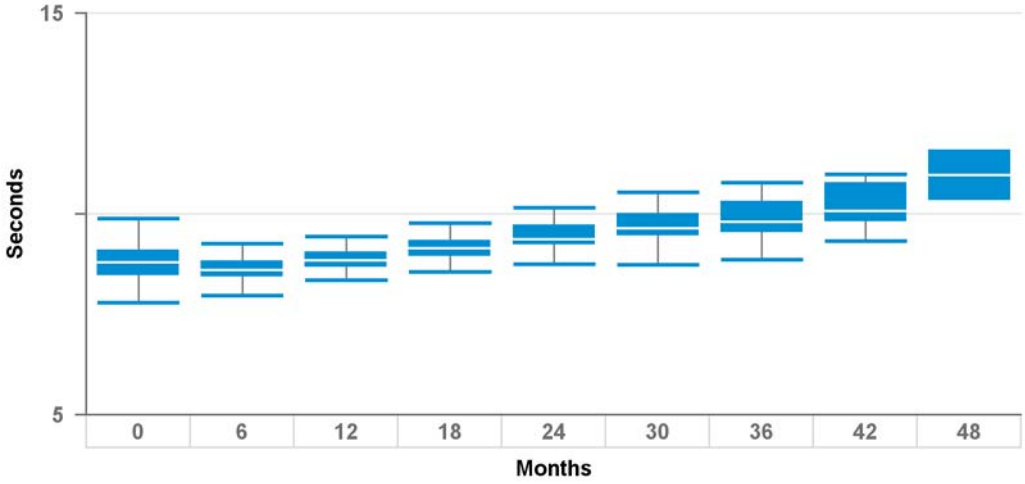
D334VRx, D364VRx Charge Time

Model Number	Brand
D334VRG	Protecta VR
D334VRM	Protecta VR
D364VRG	Protecta VR
D364VRM	Protecta VR



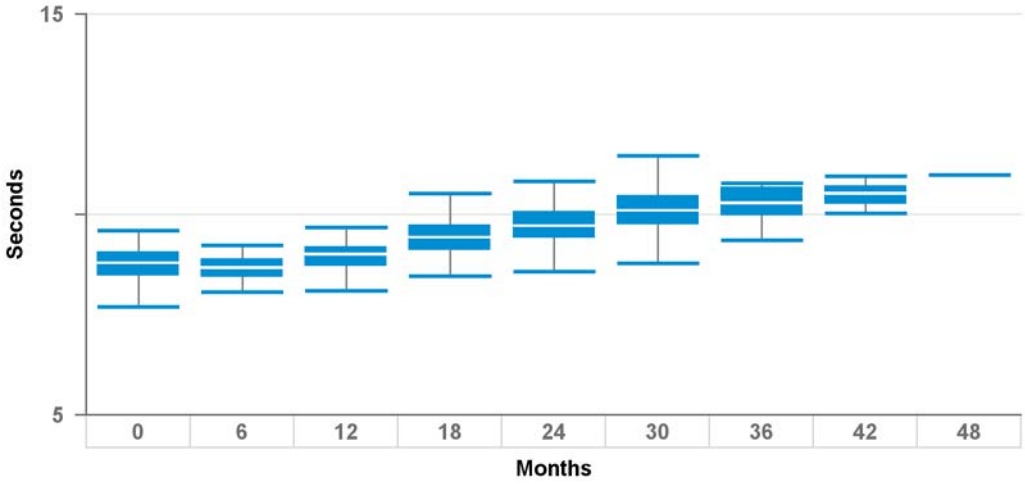
D354DRx Charge Time

Model Number	Brand
D354DRG	Protecta XT DR
D354DRM	Protecta XT DR



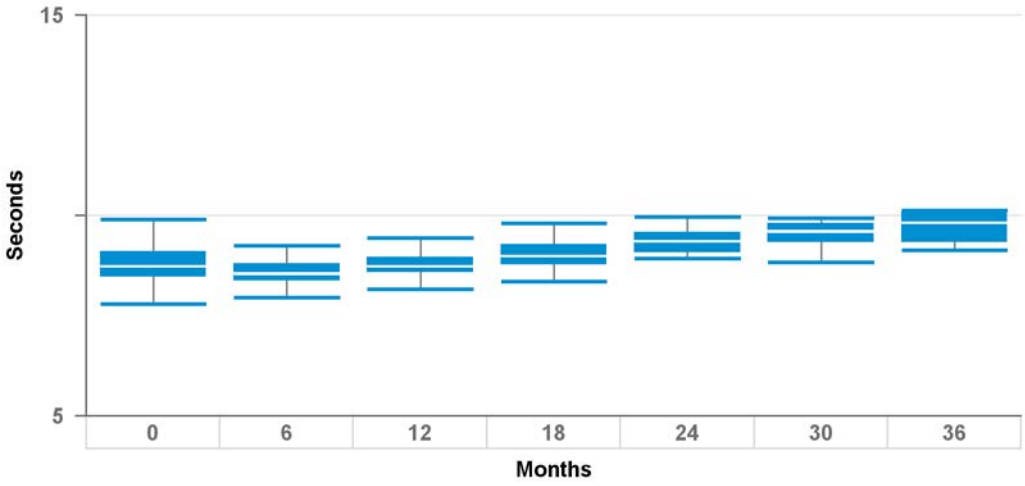
D354TRx Charge Time

Model Number	Brand
D354TRG	Protecta XT CRT-D
D354TRM	Protecta XT CRT-D



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. The Physician Letter is available at http://www.medtronic.com/for-healthcare-professionals/consulta-syncracrt-p/index.htm

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 July 31, 2014, 536 of the 779 devices have been returned from field inventory. Medtronic estimates the remaining 242 devices (44 in the U.S.) have been implanted. **There have been no reported or confirmed device failures or patient injuries.**

Initial Affected Population	Number of Confirmed Advisory Related Events	Estimated Remaining Active Population	Current Malfunction Rate (confirmed malfunctions over total population)
Up to 779 Worldwide (**44** United States)	**0** Worldwide (**0** United States)	**200** Worldwide (**39** United States)	**0%** Worldwide (**0%** United States)

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. The Physician Letter is available at http://www.medtronic.com/product-advisories/entrust/physician/index.htm

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 July 31, 2014, there have been 88 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)
69,200 Worldwide (**44,300** United States)	**88** Worldwide (**68** United States)	**17,500** Worldwide (**11,200** United States)	**0.13%** Worldwide (**0.15%** United States)

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. The Physician Letter is available at http://www.medtronic.com/enrhythm-advisory/physician.html

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 July 31, 2014, 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** Worldwide)	**12,224** Worldwide	**4,723**	**5.1%**	**0**	**72,700** 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	**72,700** 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.*

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. The Physician Letter is available at http://www.medtronic.com/kappasigma/physician.html

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 July 31, 2014, Medtronic has observed 459 Kappa devices and 306 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 (1.59%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 37 Kappa devices (0.06%) and 68 Sigma devices (0.45%) 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 100 Kappa devices remain implanted worldwide. Approximately 800 Sigma devices remain implanted worldwide. Of these, 200 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. We estimate that none of these devices remain active.

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 (**223** 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.	**<100** Worldwide (**<100** United States)	**0.79%** Worldwide (**1.40%** United States)	**1.1%**
Sigma Pacemakers				
14,900 Implanted Worldwide (est.) (**3,700** United States)	**238** Worldwide (**46** United States) with information indicating a clinical presentation. An additional **68** worldwide (**15** US) without information indicating a clinical presentation or with insufficent information to determine the state of the device at explant.	**800** Worldwide (**200** United States)	**2**% Worldwide (**1.6**% United States)	**4.8%**

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 78,300 remain implanted. According to Product Surveillance Registry results, lead survival is estimated to be 78.5% (+5/-4.6%) at 96 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)	**6,692** Worldwide**(4,729** United States)	**105,600** Worldwide(**78,300** 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.

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 July 31, 2014, 829 devices out of approximately 40,000 devices worldwide have been confirmed as having experienced interconnect wire separation.

Four hundred sixty-four(464) of the Sigma devices (1.4%) were returned with information indicating a problem with the patient's pacing system prior to explant. The remaining 365 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 4,300 remain implanted. Approximately 1,000 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)	**464** Worldwide (**79** United States) with information indicating a clinical presentation. An additional **365** Worldwide (**60** US) without information indicating a clinical presentation or with insufficient information to determine the state of the device at explant.	**4,300** Worldwide (**1,000** United States)	**2.0%** Worldwide (**1.4%** United States)	**3.9%**

Performance Notes

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

Purpose of this Information

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

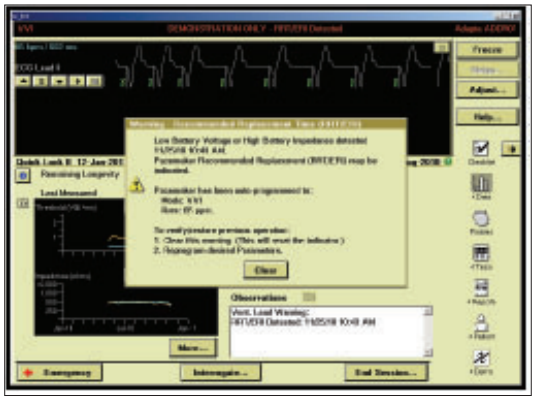
Background

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

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

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

Example 1 – Programmer Software Detects Measurement Lock-up ERI

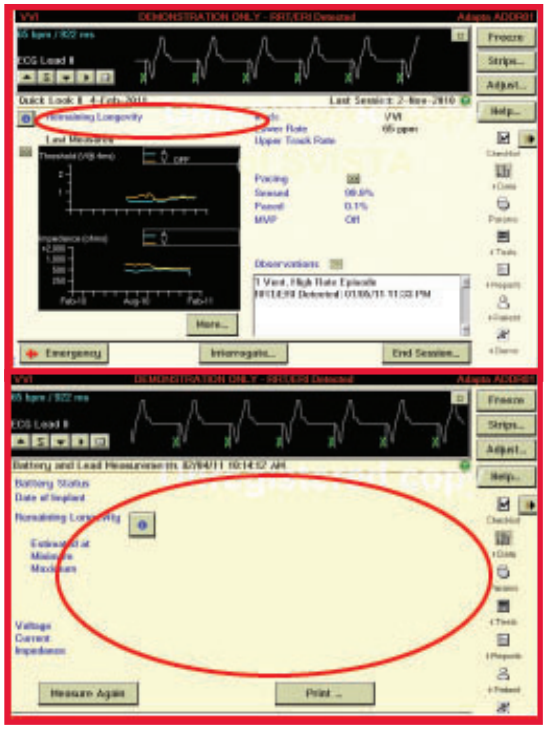


Reset Method for Kappa and EnPulse

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

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

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



Clinical Management of VCM near Elective Replacement

Background

Medtronic Technical Services has received reports of devices going to ERI or end of life (EOL) sooner than expected after a normal follow-up in which the device longevity was projected to be approximately 18 months. It has been noted that these cases typically involve Kappa 700 devices where Ventricular Capture Management set the ventricular lead to high output (5 V, 1 ms), which occurs by device design when a high threshold is measured. It is important for physicians and allied professionals to understand VCM behavior as it relates to longevity so that they can, in turn, understand how this affects management of the device and follow-up visits as VCM equipped IPGs near the end of their expected longevity.

Device Longevity and VCM Behavior

Ventricular Capture Management is a feature that uses evoked response sensing to determine the stimulation threshold needed to capture the ventricular chamber. Proper detection of the evoked response is crucial to the VCM algorithm determining an accurate capture threshold. There are rare conditions, however, during which the VCM algorithm will not be able to measure the evoked response accurately.[1] When this occurs, for safety reasons the VCM algorithm will reprogram the output to 5 V, 1 ms until the subsequent VCM measurement.

If the device has considerable remaining longevity, these occasional excursions to high output do not substantially affect remaining longevity. However, if the device has less than approximately 18 months remaining longevity, there is the possibility that the high output condition caused by the 5 V, 1 ms output will drain the battery and trigger ERI.

When ERI is declared by the device, VCM is disabled and the outputs are left at 5 V, 1 ms until the device is reprogrammed at an in-office follow-up. This increased current drain of a high output condition will speed depletion of the device, possibly resulting in the device getting to the EOL (battery voltage ≤ 2.15 V).

Please note that the following parameter changes occur when the device goes to ERI:

Table: IPG Therapy Parameter Changes at ERI

Parameter	Value
Pacing Mode	VVI
Lower Rate	65 bpm
Single Chamber Hysteresis	OFF
Sleep Function	OFF
Ventricular Capture Management	OFF
Atrial Sensing Assurance	OFF
Ventricular Sensing Assurance	OFF

Kappa 700 is Medtronic's first-generation VCM algorithm, which has a relatively higher incidence of evoked response undersensing compared to subsequent algorithms, resulting in more frequent high output conditions. Therefore, Kappa 700 products are the primary focus of this note. It should be noted that IPGs equipped with the second-generation VCM algorithm (Kappa 900, EnPulse, Adapta/Versa/Sensia, and Relia) have not been observed with evoked response undersensing in the general population, though the items listed in "Follow-Up Considerations" may also be used on these devices.

Follow-Up Considerations

- Estimated longevity in the event the device goes to high output can be determined by the following steps. This allows the clinician to determine follow-up frequency if he or she is concerned the device may go to ERI due to high output.
  - Program the ventricular channel to 5 V, 1 ms
  - Navigate to Data/Battery and Lead Measurements
  - When the message stating "Warning – Old Data" is displayed, select "Yes" to measure battery voltage and lead impedance at the new ventricular outputs
  - An updated remaining longevity estimate will be calculated on the elevated outputs. Note the "Minimum Remaining Longevity." Clinical decisions can be based on this value.
  - Program the Amplitude and Pulse Widths back to their original values before leaving the session
- If the capture trends and lead impedance trends are stable, VCM can be programmed to "Monitor Only" for the remaining device life. This should be considered only if remaining longevity is 18 months or less.
- Follow-up frequency can be increased for those patients who do not have stable capture or lead impedance trends. This can be done via a CareLink Home Monitor, or in-office.

[1] Medtronic, Inc. (2001). Medtronic Kappa 700/600 Series Pacemaker Reference Guide (Chapter 4, p. 27). Can be retrieved from http://manuals.medtronic.com.

Performance Notes

General Follow-Up and Replacement of ICD Leads

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

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. Unlike implantable cardioverter defibrillators (ICDs), a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. The determination that a lead may be approaching end of service life requires follow-up of the chronically implanted lead and thorough evaluation of lead integrity at ICD replacement.

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/clinic follow-up practice, and Medicare guidelines. In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity.

- Measure pacing and sensing threshold and compare to the chronic baseline. Significant increases or decreases may be indicative of lead failure, dislodgement, perforation, exit block, etc.
- Measure pacing impedance where possible and compare to the chronic baseline. Decreases of 30% or more or pacing impedances below 200-250 ohms may be indicative of insulation failure. Sudden and significant increases in pacing impedance may be indicative of conductor fracture.
- High voltage lead circuit impedance should be between 10-75 ohms at system implant. Chronic measurements below 10 and above 200 ohms may be indicative of high voltage lead circuit failure.
- Carefully review ECGs or the nonsustained detection log on Medtronic ICDs for indications of pacing and/or sensing abnormalities such as oversensing, undersensing, and loss of capture
- Elicit and investigate any patient complaints/symptoms that may be suggestive of potential lead failure

Where routine follow-up indicates, additional tools should be used to further evaluate performance. Tools include radiographic data, ICD electrograms, ICD Patient Alert and performance information from the Product Surveillance Registry (PSR).

The final decision on the functional integrity and continued use of an implanted lead must be a matter of medical judgment based on these factors as well as specific patient conditions.

General Criteria for Lead Replacement

The evaluation of a chronically implanted lead is an important part of the decision to continue to use the lead with a new ICD. However, these results alone do not necessarily predict the future integrity of that lead. With the expected longevity of today's ICDs varying between approximately 5 and 10 years, a physician replacing a device should consider a number of factors, including those listed below.

Factors that should be considered in a decision to replace or continue to use include:

- Pacing and sensing thresholds should be evaluated for the potential to maintain acceptable levels
- Pacing impedance should be measured. Bear in mind that pacing impedance below 250 ohms results in excessive battery current drain, which may seriously compromise ICD longevity, regardless of lead integrity.
- The physical appearance of the lead should be examined for insulation cracks, breaches, or other indications of lead wear or degradation
- Medtronic System Longevity Study data should be referenced. Actuarial survival of the lead and the observed lead failure mechanisms are specific factors to consider. Use of a new lead should be considered if failure mechanisms suggest an increased time dependency as suggested in the shape of performance curve for the specific lead model.
- Current publications may provide additional information on the clinical management of leads.[1-3] Ultimately, the decision to replace an implanted lead involves medical judgment.

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

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

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

Clinical Management of High-Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus, ICD systems attempt to dynamically adjust sensing of electrical events and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T and far-field P waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high-voltage therapies. This is due, in part, to the desire to err on the side of delivering lifesaving high voltage therapy rather than withholding it. Thus, an ICD system that is experiencing oversensing issues will continue to deliver therapeutic shocks as required, but may also subject the patient to unnecessary shocks.

Oversensing can be difficult to manage, in that the precipitating cause of the oversensing can be problematic to isolate. Oversensing can be caused by many factors, including myopotentials/far-field sensing, electromagnetic interference, T wave sensing, connector issues, incomplete or complete conductor fractures, and insulation breaches. While the individual physician must exercise medical judgment in determination of appropriate clinical management of ICD systems, the chart below may assist in the process of causal factor differentiation and possible intervention.

Phenomenon	Causal Factors	Characteristics	Management/Comments
Myopotentials/ Far-field sensing	Diaphragmatic muscle potentials in breathing, wide tip-to-ring (coil on integrated bipolar leads) spacing	Nonphysiological sensed event on EGM, which may confuse detection potentially resulting in false positive shocks	Check R waves for deterioration. Reprogram sensitivity. Try repositioning lead. Consider change-out to true bipolar lead, or if true bipolar lead in use, one with closer tip-to-ring spacing than current lead.
EMI (Electro-Magnetic Interference)	Arc welders, electrical generators, store walk-through security scanners, poorly insulated electrical equipment	Multiple and consecutive short intervals (< 140 ms) independent of underlying sinus beats. Associated with proximity to the EMI source.	Avoid EMI areas. True bipolar leads less susceptible.
T-wave sensing	Drugs, ischemic tissue, exercise, Long QT syndrome, electrolyte imbalance	Sense markers seen on EGM related to T wave. False positive detection.	Check for R wave deterioration and characteristics. If R wave > 3.0 mV, reprogram sensitivity. If R wave < 3.0 mV, reposition/replace lead. Address causal factor (e.g., drugs [if appropriate/medically viable]).
Connector problems	Loose setscrew, cross-threaded setscrew, incomplete lead insertion into header	This is an acute phenomenon seen within 6 months of implant (usually sooner)	Requires invasive check of connections. May be reproducible with pocket manipulation.
Incomplete conductor fracture	One or more filars of a multifilar conductor fracturing while leaving enough filars intact to provide a conduction circuit	Characterized by chaotic oversensing related to motion of the fracture site	Check EGMs and x-rays. Manipulate lead at suspected fracture site if possible as a provocative test. If confirmed, replace lead.
Lead insulation breach	Cuts, tears, metal ion oxidization, abrasion, cold flow, environmental stress cracking	Characterized by cyclical and/or erratic, intermittent, spontaneous oversensing; often post-pace or post-shock can cause false positives	Replace lead. If acute, usually secondary to implant damage/replacement damage. If late, material characteristic.
Oversensing during interrogation with programming head (not wireless telemetry) with complete lead fracture	Interrogation with a programming head in combination with complete lead fracture that creates an open circuit can induce noise on the sensing circuitry inside the ICD can	Nonphysiologic sensed event on EGM. If detection is enabled during interrogation, oversensing may result in inappropriate therapy.	Quickly remove the programming head. CANCEL the interrupted interrogation and manually load the software for the specific device model. Reposition the programmer head over the device and immediately select SUSPEND. Device will resume detection when programming head is removed, or when RESUME is selected. Replace lead.

Technical Services is available at all times to advise clinicians in the troubleshooting and management of Medtronic products. For assistance in the United States, please call 1 (800) 723-4636. In other countries, please contact your local Medtronic representative.

Performance Notes

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

Test/Observation	Possible Insulation Failure	Possible Conductor Failure	Possible Other System Failure	Effect on Test/ Observation
Pacing Impedance (Telemetered or Measured Invasively)	Sudden and Significant Decrease	Sudden and Significant Increase	Dislodgement Perforation Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Increase or Decrease Increase or Decrease Increase or Decrease
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase, Especially in Bipolar System	Sudden and Significant Increase	Dislodgement Exit Block Infarct at Electrode Site Perforation Improper IPG/Lead Connection	Increase Increase Increase Increase Increase
Electrograms (Telemetered or Measured Invasively)	Sudden and Significant Decrease in Amplitudes and/or Slew Rates for P and/or R Waves	Sudden and Significant Decrease or Disappearance of Amplitudes and/or Slew Rates for P and/or R Waves	Dislodgement Perforation Infarct at Electrode Site Electrolyte Imbalance Improper IPG/Lead Connection	Decrease Decrease Decrease Decrease Decrease
Waveform Analysis (Oscillographs of Pacer Artifact from ECG Electrodes)	Sudden Increase in Ratios of Leading-Edge Voltages to Trailing-Edge Voltages (i.e., over 25% increase)	Intermittent or No Pacer Artifacts (Even in Asynchronous Mode)	Improper IPG/Lead Connection	Intermittent or No Pacer Artifacts (Even in Asynchronous Mode)
Radiographs (Post-Implant, Recent, Current)	Not Discernible	Visual Observation of Conductor/Connector/ Electrode Fracture (Sometimes Discernible)	Dislodgement or Perforation. Improper IPG/Lead Connection.	Sometimes Discernible
Visual Inspection (Invasive)	Insulation Breach and/or Degradation, or Ligature Cut-Through	Not Easily Discernible	Connector Defect or Connector Pulled Apart. Improper IPG/ Lead Connection.	Sometimes Discernible
Pectoral Muscle Stimulation	Sudden Onset, Especially in Bipolar System		Connector Defect in Bipolar or Unipolar. Hypersensitivity to Unipolar Pulse Generator Can. Anti-Stim Coating or Protection Deficient.	
Phrenic Nerve/ Diaphragmatic Stimulation	Sudden Onset in Bipolar or Unipolar Systems		Perforation or Displacement of Atrial Lead (Phrenic Nerve)	
Pacemaker ECG Stimulus Artifact Size and Morphology Change (May Not Be Possible with Digital ECG)	Sudden Onset and Significant Change, Especially in Bipolar System (Increase in Size)	Sudden Changes, Usually a Decrease in Size	Perforation or Dislodgement. Connector Defect. Improper IPG/ Lead Connection.	Sometimes Discernible
Oversensing (Intermittent or Continuous)	Sudden Onset, Especially in Bipolar Systems		Physical Contact between the Electrode(s) on the Lead and that of Another Lead. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection.	Sometimes Discernible
Undersensing (Intermittent or Continuous)	Sudden Onset in Either Unipolar or Bipolar Systems	Sudden Onset in Either Unipolar or Bipolar Systems	Dislodgement or Perforation. Infarct at Electrode Site. Electrolyte Imbalance. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection.	Sometimes Discernible
Loss of Capture	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	

Mailer Kits Available for Returning Product

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

Mailer kits with prepaid US postage are available for use within the United States to send CRT, ICD, IPG, and leads to Medtronic's CRHF 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.

CRHF Returned Product Analysis Laboratory
Phone: 1 (800) 328-2518, ext. 44800
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